OPERATING MANUAL

MORE TARGETED. MORE GENTLE. MORE EFFECTIVE.

LiKAWAVE® VARIO vet

WITH INNOVATIVE

VARIO LOGIC TECHNOLOGY (VLT)

TABLE OF CONTENTS

1. SAFETY REGULATIONS

1.1 REQUIREMENTS FOR USE

Please observe the following directions closely:
The use of shockwaves requires medical knowledge and may only be used by medically trained specialist staff. Failure to use the device may cause in serious injury to the patient.

1.2 GENERAL INFORMATION

These directions must be read carefully and understood before activating the device.

LIKAWAVE VARIO VET is a sensitive medical device, whose production is subject to continuous quality control. Careful handling and regular maintenance must be ensured to guarantee safe operation of the device. The manufacturer recommends inspecting the device and the accessories after receipt and after each use, in order to guarantee safe operation of the device.

Devices which do not comply with the levels set under the standard, DIN EN 60601-1-2 may interfere with the function of the LIKAWAVE VARIO VET. It is recommended that electronic devices (e.g. mobile telephones) be switched off.

1.3 ACCESSORIES

LIKAWAVE VARIO VET may only be operated with the original accessories, which have been approved by the manufacturer for this device.

1.4 PACKAGING AND STORAGE OF THE DEVICE

If possible, keep the original packaging of the LIKAWAVE VARIO VET; this can be used for transport or for storage, if required.

The device contains no hazardous components. On disposal, please observe the country-specific disposal regulations.

1.5 TRANSPORT

The transport locks placed on the bottom of the device must be removed before using the device.

The transport locks must be reattached if the device is to be forwarded later on.

2. APPLICATION AND FUNCTION

2.1 APPLICATION AND GENERAL INFORMATION

2.1.1 ***Description of the Technology***

Shockwave therapy is a non-invasive procedure which is used on an out-patient basis for a large number of neuromuscular complaints.

LIKAWAVE VARIO VET generates the shockwave pneumatically. The intensity can be set to 1 of 25 levels. The frequency can be adjusted from 1 to 12 Hz.

2.1.2 ***Indications***

Thanks to intense research, new therapeutic options are expanding the list of indications. Currently, the main indications are:

- Achilles tendonitis – Achilles tendon pain
- calcified tendonitis – calcareous shoulder
- radial and ulnar humeral epicondylitis – golfer's elbow and tennis elbow
- patellar tendonitis – patellar apex syndrome
- plantar fasciitis – calcaneal spur
- chronic tendonopathies
- tibial stress syndrome
- trigger points
- necrosis of the femoral head
- pseudarthrosis

2.1.3 ***Contraindications***

⚠ Shockwave treatment must not be used in the following contraindications:

- for tumours
- in pregnancy
- for acute inflammation
- for thromboses and vascular inflammation
- while taking anticoagulant medications
- with the ongoing cortisone therapy

2.2 INFORMATION ON THE FUNCTION OF THE DEVICE

LIKAWAVE VARIO VET is a functional unit controlled by a microprocessor. The number of pulses (shockwave), the intensity and frequency are accurately controlled and monitored with the aid of a complex electronic control unit. The device has been developed on the basis of the most up to date technical and clinical insights.

3. SYSTEM PREPARATION

3.1 DELIVERY CONTENTS

- Device with touch display (10.4")
- Mains connection cable
- Handpiece with tubing connection
- Applicator S
- Applicator M
- Applicator L
- Contact gel
- Documentation
- Cleaning cloth and stylus for the touch display (not shown)

DEVICE WITH TOUCH DISPLAY (10,4")

MAINS CONNECTION CABLE

HANDPIECE WITH TUBING CONNECTION

HANDPIECE WITH MOUNTED APPLICATOR

APPLICATOR S

APPLICATOR M

APPLICATOR L

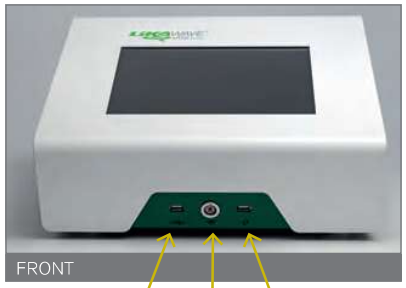
CONTACT GEL

3.2 DEVICE CONNECTIONS

Description of the device

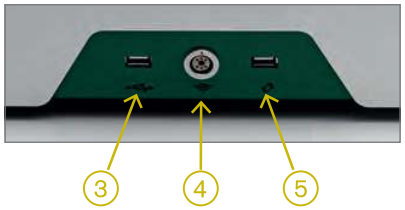
REAR

① Mains connection with ON / OFF switch and fuse holder
② Socket for foot switch



FRONT

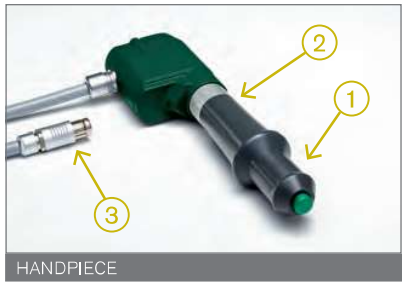
③ USB port
④ Socket for handpiece
⑤ Active-Sync interface (PC port)



3.3 LIKAWAVE VARIO VET HANDPIECE

HANDPIECE WITH TUBING CONNECTION

① Applicator
② Applicator socket
③ Jack for LIKAWAVE Shockwave device
④ ON / OFF button



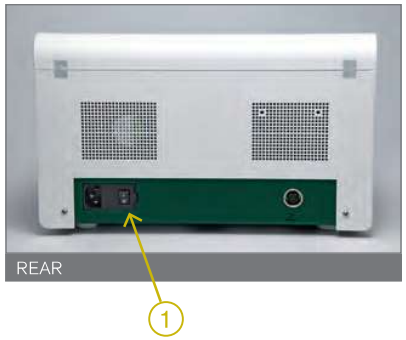
HANDPIECE

WARNING

For reasons of safety, the handpiece must never be connected to the device during maintenance. The device must also be disconnected from the mains supply.

4. INSTALLATION

4.1 MAINS CONNECTION



REAR

Connect the mains cable on the rear of the LIKAWAVE VARIO VET to an appropriate earthed power point. Switch the device on using the switch ①. The START MENU will appear on the user interface of the touch display after a short period.

① ON / OFF switch

4.2 CONNECTING THE HANDPIECE

The jack for the handpiece is inserted into the corresponding socket on the device, as shown. Ensure that the two red dots on the jack and the socket are aligned.


CONNECTING THE HANDPIECE

NOTE

For reasons of safety, the handpiece must never be connected while changing the applicator. Remove the connector.

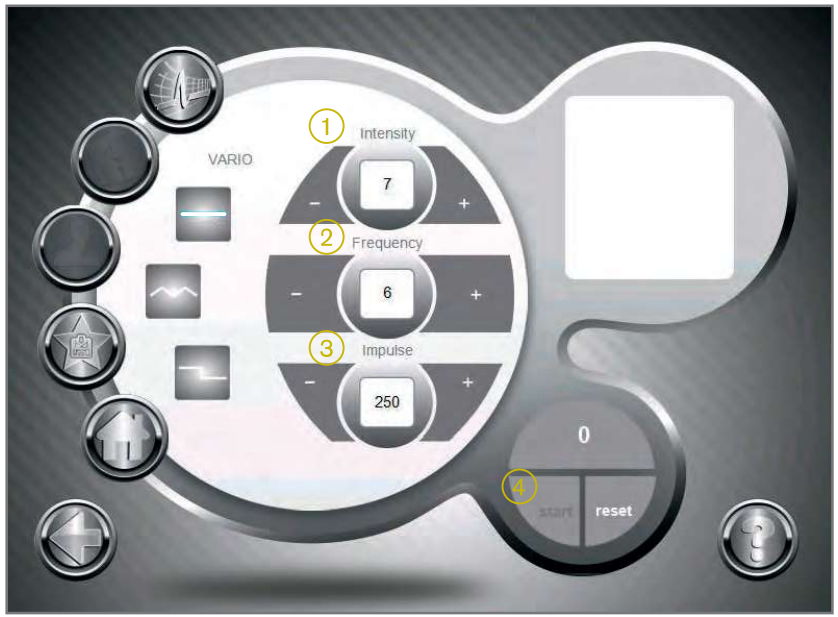
5. USING THE USER INTERFACE

5.1 START MENU

① Therapeutic mode
② Via the question mark: clarification of all menu items
③ Settings
④ Patient data base

5.2 THERAPEUTIC MODE

All settings can be changed and adjusted according to the indication and the patient's tolerance in the **»Treatment«** menu.



The ① *intensity*, the ② *frequency* and the ③ *pulses* (number of shockwaves) and can be changed individually.

The device is activated for the treatment using ④ **»Start«** and the **ON / OFF** switch on the handpiece.

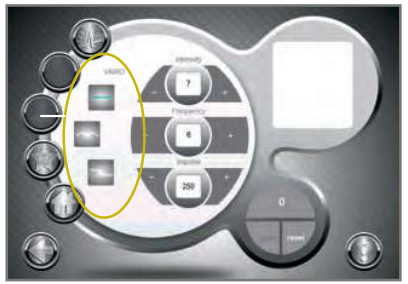
The settings can also be adjusted depending on the requirements during the treatment, using the respective » ▬ « and » ✚ « icons.

5.3 VARIO MODE

WITH INNOVATIVE

VARIO LOGIC
TECHNOLOGY (VLT)

Select from three different treatment modes

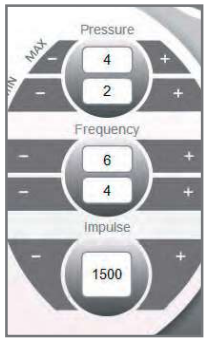


»Linear« – the intensity and the frequency remained constant.

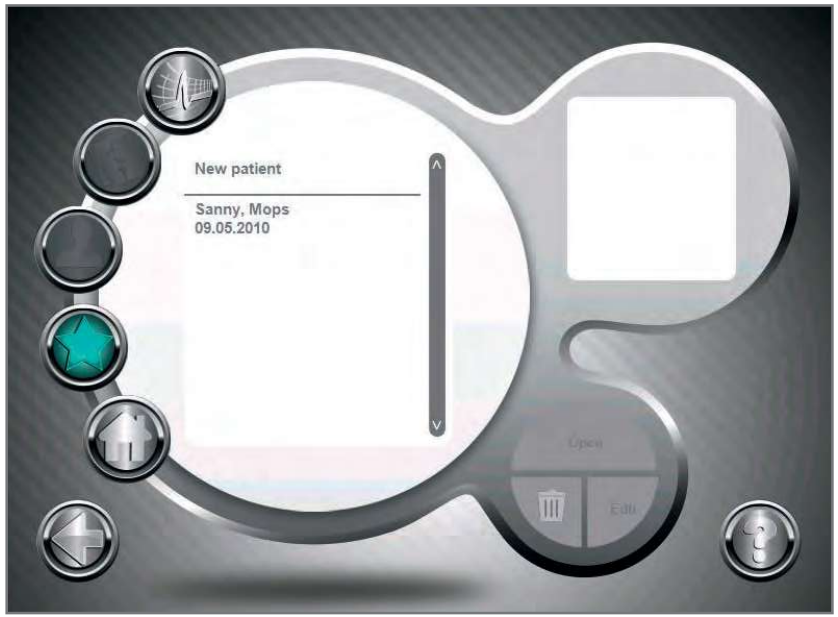
»Triangular form« – the maximum and minimum value of the intensity of the frequency can be set. For treatment with a continual, alternating change in the intensity and frequency.

»Pulse form« – the maximum and minimum value of the intensity of the frequency can be set. For treatment with a preset, stepped change in the intensity and frequency.

The intensity and frequency are preset (differences are 2 levels). The settings are dependent on the patient's sensivity to pain or tolerance. Corresponding manual changes in variation of the parameters can be made.



5.4 PATIENT DATA BASE



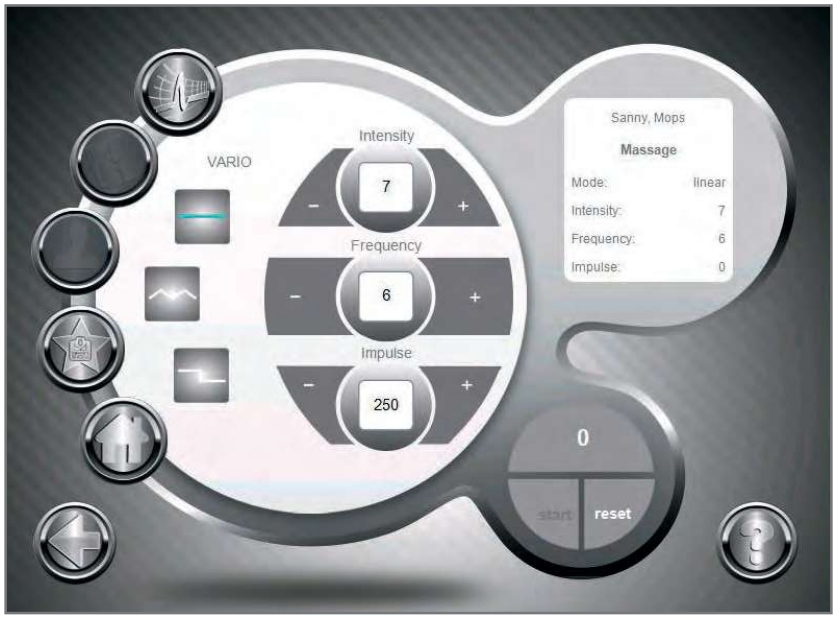
Here, patient data can be entered or saved with the corresponding treatment settings.

SAVING THE PATIENT DATA

The patient data can be saved in the patient file in accordance with three options:

1. **Saving the current therapeutic data for a new patient**
2. **Saving under the therapeutic mode**

5.4.1 *Saving the current therapeutic data for a new patient*



Following the current treatment, touch the ① **»Save«** icon and select **»New Patient«**.

Using the keyboard, a new patient can now be entered with name and date of birth.

PLEASE NOTE: To find the numerical keyboard, you must be in ① lowercase mode. The numerals 0 – 9 can be found using the ② special characters key. In the uppercase mode, there are only special characters, but no numerals.

Patients are listed in alphabetical order.

5.4.2 ***Saving under the therapeutic mode – adjusting the treatment as desired***

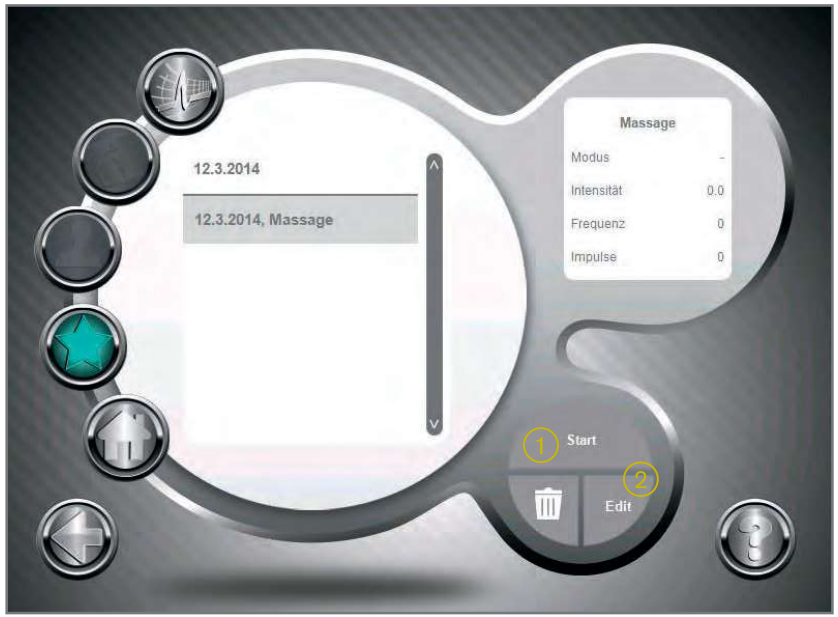
Using the **»Save«** icon, you can now select an available patient:

For example, „Sanny, Mops".

Select **»Start«** and commence the treatment. The preset data have been automatically saved.

For „Sanny, Mops" next treatment, go to the patient data menu and select „Sanny, Mops". Confirm your selection with **»Open«** and the date of the last treatment(s) will appear.

Select the desired treatment and, when you would like to start the treatment, confirm with ① **»Start«**.



The following options can be selected:

① **»Start«** the treatment with the adjusted data.

If you change the treatment parameters here manually and touch the star symbol again, the new data are saved under the current date.

Brief additions in text form or new indications can be entered for the corresponding date via ② **»Edit«**.

The text entry is deleted by touching the 🗑 icon (see page 19).

SUMMARY OF MEMORY OPTIONS

Using the Treatment mode:

Treatment mode > Therapeutic settings > Start > Save > New patient
Treatment mode > Therapeutic settings > Save > New patient > Start
Treatment mode > Therapeutic settings > Save > New patient > Back
Treatment mode > Therapeutic settings > Save > New patient

Once you touch the **»Save«** icon, the data is saved under the respective name with the current date. Depending on whether you select an indication recommendation or not, an indication is already ended here. Otherwise, you can enter additions or new indications via **»Edit«**.

Optionally, patients can also be saved before starting the treatment:

For this, select **»New patient«**, enter the name and date of birth and save by touching the **»Disc«** icon. If the patient is called up later on, no treatment has yet been entered. In this case, you must first start a treatment and then save the data under the respective patient, as described in 5.4.1.

Deleting datas:

Datas can be deleted using the 🗑 icon. In order to avoid the accidental deletion of datas, the icon must be pressed for a longer period. 3 warning tones will sound in order to preclude an operating error.

5.5 SETTINGS

The current device data can be found under **»Settings«**, in the **»System«** submenu:
- shockwaves applied by the device and handpiece
- version number of firmware and software

① **»System«**: see above
② **»Languages«**:
select device language
③ **»Import / Export«**:
data input / output
④ **»Sound«**: change the volume
⑤ **»Service«**:
service directions / input
⑥ **»Date / Time«**:
make corrections

5.6 OPERATION: STARTING AND STOPPING THE TREATMENT

After starting the treatment via the touch display, the device can be stopped and re-started at any time via the handpiece (ON / OFF button). The application stops automatically once the preset number of pulses (shockwaves) has been reached.

5.7 CHANGING APPLICATORS

⚠ Switch the device off and remove the handpiece pressure hose from the device before each change.

Screw the applicator to be removed from the socket in a downwards direction and screw in the desired applicator.


ASSEMBLY / DISASSEMBLY

NOTE

Ensure that the small O-ring on the applicator is present and functional (replace O-ring if required).

BEFORE ASSEMBLY

AFTER ASSEMBLY

5.8 RISKS IN USAGE

WARNING

The device must not be applied to sensitive areas of the body or to areas where internal organs may be affected.

Ensure that the louvres on the device are not covered.

The device must not be in operation while changing the applicator and the handpiece must be disconnected from the device.

Be mindful of the patient's pain feedback.

When changing the revision kit, the handpiece connection should be removed from the device. The device must also be switched off an disconnected from the mains supply.

6. TECHNICAL DATA

OPERATING CONDITIONS	
Transport locks	Remove from the bottom of the device prior to activation
Ambient temperature	+ 10 °C to + 40 °C
Relative humidity	30 % to 75 %
Air pressure	700 hPa to 1060 hPa
Position	Horizontal in a trolley or as a table-top device

TRANSPORT AND STORAGE CONDITIONS	
Ambient temperature	- 10 °C to + 55 °C
Relative humidity	25 % to 85 %
Air pressure	650 hPa to 1100 hPa
Additional conditions	Transport only in the original packaging

POWER CONNECTION	
Maximum power input	200 VA
Voltage	108 V~ to 240 V~
Frequency	50 / 60 Hz
Replaceable fuses	2 x 2 AT

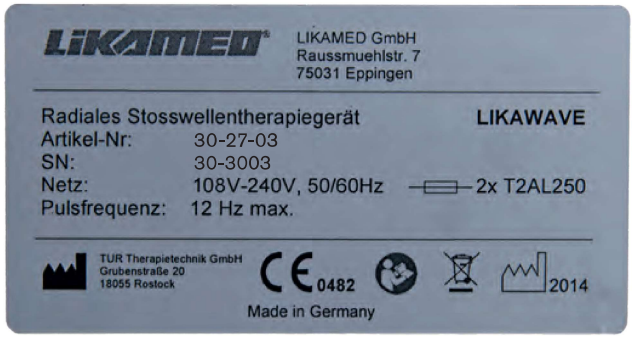
DIMENSIONS	
Dimensions (L x W x H)	340 x 300 x 200 mm
Screen dimensions (diagonal)	10,4“ = 26,3 cm

CLASSIFICATION	
Application class in accordance with MDD 93/42/EEC	II a
Application part	type BF
IP protection	IP 20

VARIABLES	
Pulse (shockwave) intensity	Intensity levels: 1 - 25
Pulse (shockwave) frequency	12 Hz maximum
Number of pulses (shockwaves)	from 250 to 5,000

6.1 IDENTIFICATION PLATE

On the bottom of the device.



6.2 DESCRIPTION OF THE ICONS

~	Alternating current
	Fuse
CE 0482	In conformity with Medical Device Guidelines (93/42/EEC) with reference to the notified body.
	Application part: Classification BF
	Note and observe accompanying document
	Disposal in compliance with the disposal provisions for electrical devices
	Manufacturer
	Date of manufacture (year)
	Active-Sync connection
	Handpiece connection
	USB connection
	Footswitch connection
	Note and observe Operating Manual

7. CLEANING

7.1 DEVICE, SCREEN AND HANDPIECE

Switch off the device and unplug from the mains supply before cleaning and disinfection. The exterior of the device and of the handpiece can be wiped down using warm water and a damp cloth, if required, with a mild detergent additive containing alcohol. Ensure that fluid does not get into the device through the slits in the housing. Please use the enclosed cleaning cloth to clean the touch display. Wipe dry using a gentle pressure.

Essentially, for users in the Federal Republic of Germany, the use of disinfectants which are entered on the respectively current DGHM (German Association for Hygiene and Microbiology) list is recommended for routine work.
For officially prescribed measures (e.g. decontamination), however, the RKI (Robert Koch Institute) list applies. Jack connectors which have become moist through cleaning and disinfection should be dried thoroughly prior to further use. Daily cleaning and disinfection are recommended.

7.2 APPLICATORS

Switch off the device and unplug from the mains supply before cleaning and disinfection. Remove the handpiece pressure hose from the device. Remove the applicator (see 5.9) and carefully cleaned and each individual part. Where there is heavy soiling, disassemble the applicator into its component parts. Disinfection should always be performed in conformity with the nationally applicable regulations. We recommend detergents and disinfectants which are entered on the respectively current DGHM (German Association for Hygiene and Microbiology) list. Avoid contact with and handling of sharp objects.

The correct component (seals) order must be observed during assembly.

An O-ring must always be present on the applicator pin; otherwise, the functionality of the device cannot be guaranteed (see Note under 5.7).

8. MAINTENANCE AND MONITORING

8.1 GENERAL

The device must be disconnected from the electricity supply prior to every inspection / service. The device or the handpiece must never be opened by an unauthorised person. All regular services and repairs must only be performed by a specialist authorised by LiKAMED. For further enquiries, please refer to your LiKAMED authorised specialist retailer or directly to LiKAMED.

Regular services must be performed in order to guarantee the safety, both of the patient and of the user. These are also required to maintain the safety and functional characteristics of the system. We recommend our yearly service by a LIKAWAVE authorised specialist.

The user is obligated to verify the regular servicing, i. e. regular servicing must be documented for each device. This record must be kept at least until the next regular service. The first inspection record must be kept for the entire service life of the device. The contents and guidelines for the regular services should be implemented in accordance with the LIKAWAVE service order.

WARNING

The patient is placed at risk and the guarantee shall expire if:

- the device is not connected to the mains supply with an earth wire / earth connection (VDE 0107)
- the device is not used in accordance with this operating manual
- extensions and/or accessories not approved by the manufacturer are used or unauthorised modifications are undertaken
- services have not been performed regularly within the given respective period

8.2 SERVICING INTERVALS

The recommended intervals for regular inspection for the LIKAWAVE VARIO VET are:

PART	INTERVAL	TASK	PERSON
Seals (O-rings) Relative humidity	With every change of applicator	Check that O-ring is present; check for damage	User
Applicator	Approximately 3,000,000 pulses	Exchange applicator	User
Revision kit (acceleration tubing with projectile) in the handpiece	Approximately 1,500,000 pulses	See servicing directions	LiKAMED authorised specialist
Device	Recommended yearly; at least every 2nd year	See servicing directions	LiKAMED authorised specialist

8.3 FAULTS

8.3.1 ***The device cannot be switched on or does not start***

- Check the mains connection cable for damage and exchange if necessary
- Check the fuses on the device mains connection
- Contact your specialist dealer or LiKAMED

8.3.2 ***The handpiece does not function properly***

- Check whether the seal (O-ring) is on the applicator (see Note, under 5.7)
- Exchange the applicator (see 5.7)
- Check handpiece and connection tubing for damage
- Order required maintenance / servicing (see 8.1)

9. END OF SERVICE LIFE (DISPOSAL)

LiKAMED will maintain the supply of spare parts for a minimum of 10 years. Should the operation of the control unit, contrary to expectations, no longer be possible, this should be sent to the available refuse collection or disposal systems at the end of its service life, allowing for the separation of materials. National as well as local provisions for disposal must be observed.

10. ELECTROMAGNETIC COMPATIBILITY

ELECTROMAGNETIC EMISSION

Guidelines and Manufacturer's Declaration: Electromagnetic Emissions

This shockwave device is intended for operation in an environment as described below. The customer or user of the product should ensure that it is operated in a similar environment.

ELECTROMAGNETIC INTERFERENCE	CONFORMITY	ELECTROMAGNETIC ENVIRONMENT GUIDELINES
HF emissions in accordance with CISPR11	Group 1	This shockwave device uses conducted HF energy, which is required for the internal function of the device, which is intentionally generated. Hence, its HF emission is very slight, and it is unlikely that adjacent electronic devices that will be interfered with.
HF emissions in accordance with CISPR11	Class B	This shockwave device is suitable for use in all establishments, including those in living areas and similar, which are immediately connected to a public mains service which also supplies buildings.
Harmonic emissions in accordance with IEC 61000-3-2	PASS	
Voltage fluctuation emissions / flicker in accordance with IEC 61000-3-3	PASS	

ELECTROMAGNETIC INTERFERENCE WITH OTHER DEVICES

Guidelines for avoiding, recognising and correcting electromagnetic interference from other devices

Other electrical / electronic devices should not be operated in the immediate vicinity of the shockwave treatment device and should not be stacked with the device. If such an arrangement is unavoidable, the respective devices should be monitored and their proper function should be verified. Due to the range of functions of the device, these effects may be very different and may be difficult to recognise, to an extent.

DEVICE	INTERFERENCE	CORRECTIVE ACTION
Radio, TV appliances	▪ Static / crackling in the sound ▪ Horizontal lines in the picture	▪ Increase the clearance ▪ Change the arrangement ▪ Change the alignment ▪ Change the reception channel
Monitoring systems, e.g. baby monitor	▪ Static / crackling in the sound	
Cordless telephone		
Radio thermometer, radio weather stations	▪ Disrupted data transfer ▪ No or incorrect display	
General electronic devices	Malfunction, e.g. stopping or changing the intended operating mode	

ELECTROMAGNETIC STABILITY

Guidelines and Manufacturer's Declaration: Electromagnetic Stability

This shockwave device is intended for operation in an electromagnetic environment as described below. The customer or user of the product should ensure that it is operated in a similar environment.

ELECTROMAGNETIC STABILITY INSPECTION	IEC 60601 TEST LEVEL			COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT GUIDELINES
Static electricity discharge (ESD) in accordance with IEC 61000-4-2	Display, cable	D, L	± 2 kV	PASS	Floors should be made from wood or concrete or covered in ceramic tiles. If the floor is covered in synthetic material, the relative humidity must be at least 30%.
		D, L	± 4 kV		
		D, L	± 8 kV		
	Coupling plate	I, H, V	± 2 kV	PASS	
		I, H, V	± 4 kV		
	Housing (all sides), connecting plugs (handpiece)	D, K	± 2 kV	PASS	
		D, K	± 4 kV		
Rapid transient electrical disturbances / bursts in accordance with IEC 61000-4-4	± 0,5 kV for power cable			PASS	The quality of the mains supply voltage should be consistent with a typical business or hospital environment.
Surges in accordance with IEC 61000-4-5	L + N network | ± 0,5 kV capacitive coupling, symmetrical			PASS	The quality of the mains supply voltage should be consistent with a typical business or hospital environment.
	L + N network | ± 1 kV capacitive coupling, symmetrical			PASS	
	L + PE, N + PE network | ± 0,5 kV capacitive coupling, asymmetrical			PASS	
	L + PE, N + PE network | ± 1 kV capacitive coupling, asymmetrical			PASS	
	L + PE, N + PE network | ± 2 kV capacitive coupling, asymmetrical			PASS	
Voltage drops, short interruptions and supply voltage fluctuations in accordance with IEC 61000-4-11	20 ms | UT - 100%			PASS	The quality of the mains supply voltage should be consistent with a typical business or hospital environment. If the user of the shockwave therapy device also requires a continuous function, even where interruptions to the energy supply occur, we recommend powering the shockwave therapy device using an uninterruptible power supply or a battery.
	100 ms | UT - 60%			PASS	
	500 ms | UT - 30%			PASS	
	5000 ms | UT - 100%			PASS	
Magnetic field at the supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	3 A / m			PASS	Magnetic fields in the mains frequency should comply with the typical values as found in a business or hospital environment.

Note: UT is the mains AC voltage prior to the usage of the test levels. | **Key:** **D** direct discharge to the test device | **L** air discharge | **I** indirect discharge to the test device | **H** horizontal coupling plate under the test device | **K** contact discharge | **V** vertical coupling plate

Guidelines and Manufacturer's Declaration: Electromagnetic Stability, Non-life-supporting Devices

This shockwave device is intended for operation in an electromagnetic environment as described below. The customer or user of the product should ensure that it is operated in a similar environment.

STABILITY TEST	IEC 60601 TEST LEVEL	CONFORMITY LEVEL	ELECTROMAGNETIC ENVIRONMENT GUIDELINES
Conducted HF disturbance variables in accordance with IEC 61000-4-6	3 V_{eff} 150 kHz – 80 MHz	PASS	Portable and mobile radio devices should not be used in closer proximity to the product, including the cables, than the recommended protective distance calculated in accordance with the equation applicable to the transmission frequency. **Recommended protective distance:** $D = 1{,}2\sqrt{P}$ (for 150 kHz – 80 MHz) $D = 4\sqrt{P}$ (for 80 MHz – 800 MHz) $D = 8\sqrt{P}$ (for 800 MHz – 2,5 GHz) where P is the power rating of the transmitter in watts (W) according to the information of the transmitter manufacturer and d is the recommended protective distance in metres (m) The field strength of stationary radio transmitters for all frequencies corresponding to an investigation site (see a) should be less than the conformity level (see b). Interference may occur in the environment of devices carrying the following symbol. 
Radiated HF disturbance variables in accordance with IEC 61000-4-3	3 V/min 80 MHz – 2,5 GHz	PASS	

Note 1: *80 MHz and 800 MHz are High Frequency.*

Note 2*: These guidelines may not be applicable in all cases. The diffusion of electromagnetic variables is affected by the absorption and reflection of buildings, objects and people.*

a) *The field strength of stationary transmitters such as base stations for radio telephones and mobile agricultural radio devices, amateur radio stations, AM and FM radio and television transmitters cannot be theoretically predetermined. In order to determine the electromagnetic environment with respect to the stationary transmitters, a study of the site should be considered, so that the intended function can be verified by reference to the field strength measured at the site.*

b) *The field strength should be less than 3 V/m above frequencies of 150 kHz to 80 MHz.*

RECOMMENDED PROTECTIVE DISTANCES

Recommended protective distances between portable and mobile HF telecommunication devices and the product

This shockwave therapy device is intended for operation in an electromagnetic environment in which the HF disturbance variables are controlled. The customer or user of the product can help tool for it electromagnetic interference by maintaining the minimum distance between portable and mobile HF telecommunication devices (transmitters) and the product - depending on the output rating of the communication device, as given in the table on the right.

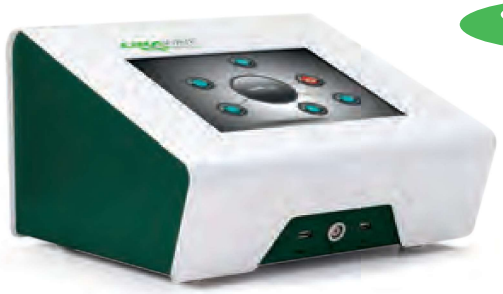
	PROTECTIVE DISTANCE IN METRES, DEPENDING ON THE TRANSMITTER FREQUENCY		
RATED TRANSMITTER OUTPUT IN WATTS	**150 kHz – 80 MHz** **D = 1,2 √P**	**80 MHz – 800 MHz** **D = 4 √P**	**800 MHz – 2,5 GHz** **D = 8 √P**
0.01	0.12	0.4	0.8
0.10	0.38	1.24	2.53
1.00	1.20	4.00	8.00
10.00	3.80	12.65	25.30
100.00	12.00	40.00	80.00

*For transmitters whose maximum rated output is not given in the table above, the recommended protective distance **D** in metres (m) can be determined using the formula given in each column, where **P** is the maximum rated output of the transmitter in watts (W) in accordance with the information of the manufacturer of the transmitter.*

Note 1: *80 MHz and 800 MHz are High Frequency.*

Note 2*: These guidelines may not be applicable in all cases. The diffusion of electromagnetic variables is affected by the absorption and reflection of buildings, objects and people.*

LiKAWAVE® VARIO vet



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