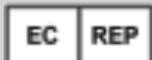


USER GUIDE

Model VS1500

VS
VSCULPT®

A Healthier You, Inside and Out™



Emergo Europe, Molenstraat 15
2513 BH The Hague, The Netherlands

Register your product at
www.vsculpt.com

To learn more about vSculpt treatments, accessories,
pelvic floor health, and precautions, visit uk.vsculpt.com.

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WELCOME TO VSCULPT

Congratulations on your purchase!

vSculpt is a handheld medical device intended for the purpose of toning, tightening and restoring weak pelvic floor muscles and vaginal tissues for the treatment of stress, mixed and mild to moderate urge incontinence in women. It is also indicated to improve sexual satisfaction in women who experience sexual dysfunction symptoms due to lack of lubrication and vaginal tissue laxity. For the treatment of pelvic muscle pain and increased healing and blood circulation.

To accelerate the healing properties of vSculpt, we recommend use with our Photonic Gel™ (sold separately).

It is important that you read and understand the instructions, warnings, precautions, and safety information in this booklet before using your vSculpt for the first time.

***Please charge your vSculpt 12 hours prior to first use to ensure proper operation and battery life.**

Register Your vSculpt

Register your vSculpt today at **www.vsculpt.com** to activate your one-year warranty and to gain access to exclusive vSculpt information, accessories, and product news.

BOX CONTENTS

- vSculpt Therapeutic Device
- USB Charging Cable
- Storage Sachet
- User Guide

PRECAUTIONS

Please read the following safeguards before using. Please use caution and good judgment when using vSculpt.



This Warning Symbol appears next to information about possible safety risks. Be sure to read and follow all the warnings and safety information.

- Use this product only for its intended use as described in these directions.
- This device is not intended for use by anyone under the age of 18, and close adult supervision is necessary if children under the age of 18 are near the device.

 **This device is not waterproof and should not be submerged. It can be cleaned with a damp cloth.**

 Only connect vSCULPT with the USB cable provided and to USB power adapters certified in compliance with IEC 60950-1 or IEC 60601-1 based national standards.

 No modification of this equipment is permitted.

 Do not disassemble this equipment.

 Do not attempt to charge device while using the device.

 Mobile RF communications equipment can affect medical electrical equipment.

- vSculpt is designed for individual use only. Please do not share.
- After each use, the device should be thoroughly cleaned.
- The device should not be used in the presence of an active sexually transmitted infection, as an active infection may have symptoms that are aggravated by use of the device.
- Do not use the device if you are using cancer-fighting drugs, medications, or topical creams that increase photosensitivity. These may cause an adverse reaction.
- This device is intended for vaginal insertion only.
- **Do not use silicone-based lubricants with the device.**
- Do not stare directly into the device lights.
- Do not use if you are pregnant or believe you may be pregnant.
- If you are experiencing abdominal pain, or have other medical issues

or health concerns, please consult your physician before using this device.

- If you experience numbness, skin irritation, dizziness, or feel pain, stop using this device immediately and consult your physician.
- Exercise caution when using near body piercings.
- If you are experiencing prolonged redness or sensitivity in the treatment area, discontinue use and consult your physician. In addition to speaking with your physician, please contact Joylux Customer Care at customercare@vsculpt.com.
- If any part of the device is cracked, broken, or damaged, or if there are signs of moisture or condensation on the inside of the device, discontinue use immediately.
- Do not use the device if the lights have been damaged in any way.
- If the device begins to overheat, turn off immediately.
- Do not use the device if you think the device has been immersed in water.
- Do not use or store the device near water, or where it can be dropped or pulled into water.

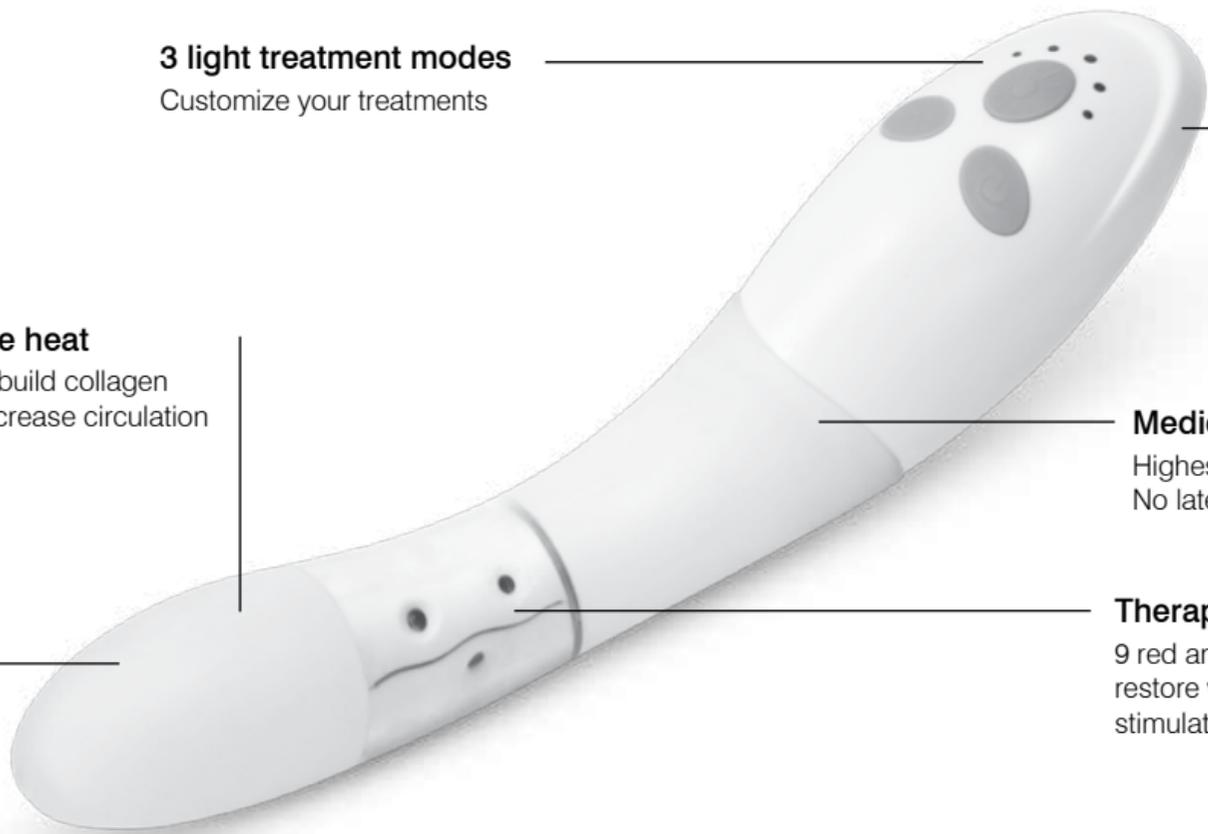
- Keep the USB charging cord away from children, as it poses a strangulation risk.
- Keep the charging cord away from heated surfaces.
- Do not operate the device or charging cord if either component has been damaged, dropped, or immersed in water, or if the cord is frayed or damaged.
- Do not disassemble. If the device is malfunctioning, contact Joylux Customer Care at customercare@vsculpt.com.

POTENTIAL RISKS

Please use vSculpt with caution. Inserting anything into the vagina (including vSculpt) without proper care could result in the following:

- Cramping
- Vaginal discharge
- Vaginal infection
- Vaginal irritation
- Vaginal sensitivity

SAY HELLO TO vSCULPT



3 light treatment modes

Customize your treatments

USB-rechargeable

Charging is easy and convenient

Gentle heat

Helps build collagen and increase circulation

Medical-grade materials

Highest grade for safety and comfort
No latex, phthalates, or BPA

Therapeutic lights

9 red and infrared LEDs to restore vaginal tissue and stimulate collagen production

Therapeutic vibration

Improves muscle tone
6 modes for customization

ACCESSORIES



We have designed complementary products to accelerate your results.

vSculpt Photonic Gel™

vSculpt Photonic Gel is specially formulated with hyaluronic acid and aloe. This premium water-based, ultra-concentrated gel provides lubrication and enhances photon energy transfer to maximize the therapeutic benefits of vSculpt.

DIRECTIONS

Apply desired amount of Photonic Gel to the tip of vSculpt or to the external genital area prior to use.

INGREDIENTS

Water/Aqua/Eau, Propylene Glycol, Hydroxyethylcellulose, PEG-45M, Sodium Hyaluronate, Aloe Barbadensis (Aloe Vera) Leaf Juice, Polyquaternium-5, Gluconolactone, Sodium Benzoate, Potassium Sorbate, Citric Acid

MEET VSCULPT

What to Expect

vSculpt offers a noninvasive method to help restore the muscle and tissue of your pelvic floor, improving your quality of life. To help you ease into using vSculpt, we recommend gradually increasing the treatment modes over the course of 3 weeks—start with the beginning treatment mode (6 minutes) during the first week, the intermediate treatment mode (8 minutes) during the second week, and then the advanced treatment mode (10 minutes) during the third week.

Upon first use, you may feel a warm tingling sensation within the vaginal canal. If at any time use becomes uncomfortable, please immediately discontinue use and wait a day before using again. Do not move on to the intermediate or advanced treatment modes until you can comfortably complete the prior treatment mode.

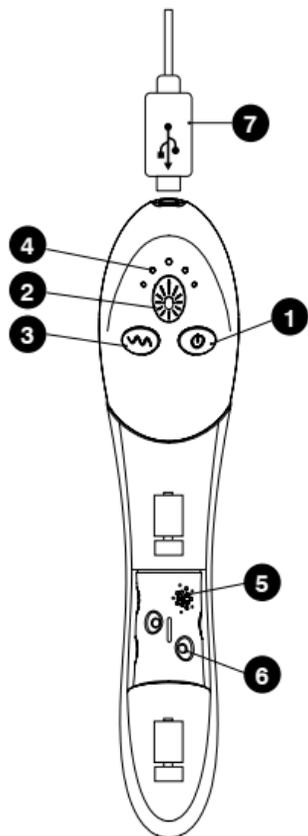
Results

For full results, we recommend you use your vSculpt every other day for 45 to 60 days. Upon completion of your initial therapy, use vSculpt once per week to maintain your results.

FEATURES

Legend

1. On/off button
2. Light therapy mode button
3. Sonic vibration mode button
4. Indicator lights
5. Infrared treatment lights
6. Red treatment lights
7. USB charger connection



Sonic Vibration Modes & Settings

SONIC VIBRATION MODES

1. Constant on – low intensity
2. Constant on – high intensity
3. Wave – low intensity
4. Wave – high intensity
5. Pulse – low intensity
6. Pulse – high intensity

LIGHT THERAPY MODES

1. Beginning Treatment (6 minutes)
2. Intermediate Treatment (8 minutes)
3. Advanced Treatment (10 minutes)

At any point during therapy, vibration can be adjusted or turned off.

At any point during therapy, treatment lights can be turned off.

PREPARATION FOR USE

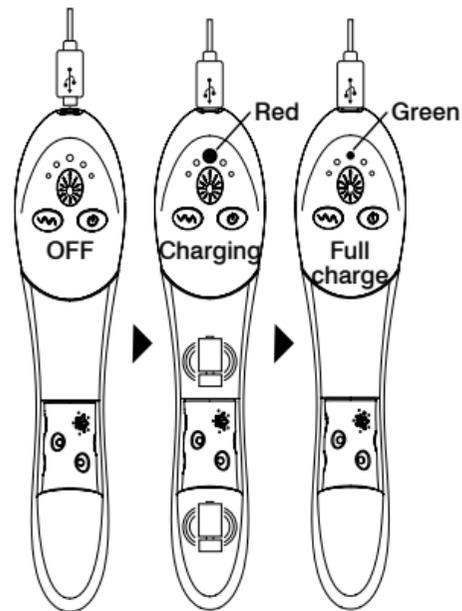
Consulting Your Physician

If you are under a doctor's care for any pelvic floor related conditions, please consult your physician before using vSculpt.

Charging

Charge your vSculpt 12 hours before first use and subsequently after each use ensuring the battery is fully charged.

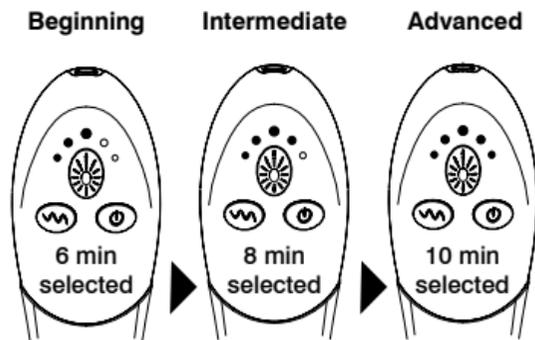
- Attach the provided USB charging cable to the vSculpt handle, plug into any universal USB-certified power source, and then plug into an electrical outlet.
- vSculpt will detect power and signal the motor to vibrate 2 times.
- The center red indicator light will illuminate, signifying that vSculpt is charging.
- Once the battery is fully charged, the red indicator light will turn to solid green, indicating the battery is fully charged.



GETTING STARTED

1. Apply desired amount of Photonic Gel to the tip of the device or externally prior to insertion.
2. Turn on vSculpt by pressing the power button
3. Choose your therapy mode of either 6, 8 or 10 minutes
4. Press the light therapy mode button to begin treatment
5. Lie back and relax – knowing you are improving your pelvic floor health

LIGHT THERAPY MODES



- Once a treatment mode has been selected, press and hold the light therapy mode button to activate the therapeutic treatment lights.



Using vSculpt

1. The therapeutic treatment lights will illuminate to solid red and the treatment timer is activated (the treatment program now cannot be changed).
2. Vibration will come on by default with constant low-intensity vibration, together with therapeutic lights. Sonic vibration mode is independent of the light treatment; you can change the vibration pattern and intensity at any time.
3. Insert vSculpt up to 4 inches into the vaginal canal or until the light window is entirely within the vagina.
4. vSculpt's internal timer is immediately activated and treatment time begins.
5. Once the treatment is completed, the therapeutic lights and vibration will automatically turn off.

USING vSCULPT (CONTINUED)

6. Sonic vibration modes are able to operate independently after light therapy treatment.
7. Temperature sensors monitor heat before, during, and after light treatment to ensure safety.
8. Though light treatments have default vibration, if you use a new sonic vibration mode for more than 1 minute, the next light treatment will adjust accordingly to include your preferred vibration mode.
9. After treatment time elapses, the treatment lights automatically turn off and are disabled for 2 hours 30 minutes to ensure your safety and treatment compliance.
10. You may continue to use vSculpt in vibration mode only while treatment lights are disabled.

Using vSculpt in sonic vibration mode only

- vSculpt has 6 sonic vibration modes:
 1. Constant on – low intensity
 2. Constant on – high intensity
 3. Wave – low intensity
 4. Wave – high intensity
 5. Pulse – low intensity
 6. Pulse – high intensity
- Scroll through the sonic vibration modes until desired vibration is reached. To turn off vibration, simply press and hold the sonic vibration mode button.
- Preferred sonic vibration mode: If your selected sonic vibration mode was used for more than 1 minute, vSculpt will store this mode in memory. The next time vSculpt is turned on, your preferred sonic vibration mode will be initiated.

DID YOU KNOW?

Infrared light is not visible to the naked eye. vSculpt has 6 red and 3 infrared LED-emitters. When activated, only the 6 red LED-emitters will be visible, but all 9 LED-emitters are activated.

TREATMENT PLANS

Your therapeutic regimen requires use of vSculpt every other day for 45 to 60 days.

We recommend a gradual introduction of vSculpt therapy by increasing your treatment duration over two weeks. This allows you time to become familiar and comfortable with vSculpt and its many modes and settings.

WEEK 1

Beginning Treatment (6 minutes), 3 times weekly with 1 day between treatments.

WEEK 2

Intermediate Treatment (8 minutes), 3 times weekly with 1 day between treatments.

WEEKS 3-8

Advanced Treatment (10 minutes), 3-4 times weekly with 1 day between treatments.

Each of us is unique. Take the time you need to adjust to the 10 minute treatment time. Your ramp up time may be slower or faster- both of which are ok. To achieve optimal results, the goal is to reach 23-30 sessions of 10 minutes each.

Maintenance Plan

After you have completed your treatment plan for 45 days, we recommend using your vSculpt 1-2 times weekly for 10 minutes. This will help maintain your results.

vSculpt with Kegel Exercises

Kegel exercises are one way to help strengthen your pelvic floor muscles. While vSculpt helps more than just pelvic floor muscles, when combined with Kegels, it can amplify your results. Please see the step-by-step guide below.

1. Begin using vSculpt as directed.
2. When vSculpt is inserted into the vagina, identify the muscles you use to stop urinating.
3. While holding the vSculpt, squeeze these muscles for up to 10 seconds, then relax for up to 10 seconds. Your stomach and thigh muscles should not tighten when you do this.
4. Repeat as often as you can during the vSculpt light treatment. Ideally, you should be able to do this Kegel exercise 10 to 15 times.

IMPORTANT INFORMATION

Care, Cleaning, & Storage

vSculpt is made with body-safe, medical-grade silicone and is easy to clean. We recommend that you gently clean vSculpt with water and antibacterial soap prior to first use and after each subsequent use to kill bacteria and ensure freshness.

- Make sure vSculpt is turned off.
- Do not immerse vSculpt into water, run under water, or place in a dishwasher, sterilizer, or autoclave.
- Use a soft nonabrasive cloth and gentle antibacterial soap to wipe clean.
- Soaps may cause irritation, and any residue should be wiped off.
- Be careful to avoid the electronic controls and charging port.
- After you clean vSculpt, let it air dry.
- Store vSculpt in a cool, dry location, protected from dirt, dust, and impurities.
- Use of other cleaning solutions and appliances may damage vSculpt and its electronics.
- With proper care, the vSculpt device will perform for a minimum of two years.

SUPPORT

Warranty and Product Registration

One-year warranty against manufacturer defect-related problems resulting from normal use of the product. Register your vSculpt today at www.vsculpt.com to activate your warranty. Sign up for vSculpt email and gain exclusive access to vSculpt treatments, accessories, pelvic floor health and wellness information, and new product introductions.

Warranty Exclusions

Not covered under the one-year warranty: damage caused by misuse, abuse, neglect, alterations, or unauthorized repair; normal wear and tear, including chips, scratches, abrasions, discoloration, or fading

Troubleshooting Guide

PROBLEM: vSculpt won't turn on. Try one or more of the following:

- Make sure your vSculpt is charged. See "Charging" section of user guide.
- Make sure you are pressing and holding the On/Off button.
- If it still doesn't turn on, contact customer care at Joylux Customer Care at customer care@vsculpt.com.

PROBLEM: The treatment lights won't turn on. Try one or more of the following:

- Make sure your vSculpt is charged. See "Charging."
- Make sure your vSculpt is on. See above or "Get Started."
- Make sure a treatment program has been selected. See "Get Started."
- Press the Light Therapy Mode Button.
- If the lights still do not turn on, contact Joylux Customer Care.

PROBLEM: The vibration won't turn on. Try one or more of the following:

- Make sure your vSculpt is charged. See "Charging."
- Make sure your vSculpt is ON. See above or "Get Started."

SUPPORT (CONTINUED)

- If using in Light Therapy Mode, make sure a treatment program has been selected. See “Get Started.”
- If using in Sonic Vibration Mode only, press and hold the Sonic Vibration Mode Button.
- If the vibration does not turn on, contact Joylux Customer Care.

If you continue to experience problems, please contact customer care at customercare@vsulpt.com.

Do not attempt to disassemble vSculpt as this may cause damage, malfunction, electrical shock, fire, or personal injury. There are no user-serviceable parts inside the unit. If vSculpt is malfunctioning, contact customer care.

Never operate vSculpt if the USB charging cable is damaged. If vSculpt is not working properly, or if it has been dropped, damaged, or submerged in water, contact customer care.

Contact Information

customercare@vsulpt.com
www.vsuplt.com
1126 34th Avenue
Suite 309
Seattle, WA 98122
USA

About Joylux, Inc.

Joylux, Inc. is a global health technology company creating innovative light-based medical devices to transform women's pelvic floor health and empower women to live their best lives. For more information, please visit us at www.joyluxinc.com or www.vsuplt.com.

Waste Electrical and Electronic Equipment Directive (WEEE)

Joylux, Inc complies with Directive 2012/19/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 January 2003 on waste electrical and electronic equipment (WEEE).

vSculpt contains a lithium-ion battery. This product has required the extraction and use of natural resources for its production. It may contain hazardous substances that could impact health and the environment if not properly disposed of. In order to avoid the dissemination of those substances in our environment and to diminish the pressure on natural resources, we encourage you to use the appropriate take-back systems for product disposal. Those systems will reuse or recycle in a sound way most of the materials of the product you are disposing of.

The crossed-out wheeled bin symbol informs you that the product should not be disposed of along with municipal waste and invites you to use the appropriate separate take-back systems for product disposal.

If you need more information on the collection, reuse, and recycling systems, please contact your local or regional waste administration.

You may also contact your retail store, supplier, or local government for more information on the environmental performances of this product.

For instructions on how to dispose of this device, please visit www.vsculpt.com.

RoHS Compliant

The European Union has established requirements for Restriction of Hazardous Substances (RoHS) in all Electrical and Electronics Equipment (EEE). Please see Directive 2011/65/EU that entered into force 21 July 2011 becoming effective 2 January 2013.

CE Mark

vSculpt is approved in Europe as a medical device and has received the CE mark indicating compliance with all appropriate regulations.

Federal Communications Commission Power Input (FCC)

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

ELECTROMAGNETIC CAUTIONS

Guidance and manufacturer's declaration – electromagnetic emissions

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

Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions (CSFPR 11)	Group 1, Class [B]	<p>The vSculpt 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.</p> <p>The vSculpt 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.</p>
Harmonic emissions (IEC 61000-3-2)	Complies (1)	
Voltage fluctuations/flicker emissions (IEC 61000-3-3)	Complies (2)	
Notes:	<p>(1) The EUT utilizes less than 75W. No limits are specified for equipment with less than 75 W input rating.</p> <p>(2) The EUT is unlikely to produce significant voltage fluctuations or flicker. No testing required.</p>	

Guidance and manufacturer's declaration-electromagnetic immunity- For all ME equipment and ME systems

The vSculpt is intended for use in the electromagnetic environment specified below.

The customer or the user of the vSculpt should assure that it is used in such an environment

Immunity Test	Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) (IEC 61000-4-2)	± 6kV contact ± 8 kV air	± 6kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic fast transient/burst (IEC 61000-4-4)	± 2 kV power supply lines ± 1 kV for input/output lines	± 2 kV power supply lines N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge (IEC 61000-4-5)	± 1 kV differential mode ± 2 kV common mode	N/A ± 2 kV common 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) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the vSculpt requires continued operation during power mains interruptions, it is recommended that the vSculpt be powered from an uninterruptible power supply or a battery. NOTE: UT is the a.c. mains voltage prior to application of the test level.
Power frequency (50/60 Hz) magnetic field (IEC 61000-4-8)	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of atypical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity – for ME equipment and ME systems that are not Life-Supporting

The vSculpt is intended for use in the electromagnetic environment specified below.

The customer or the user of the vSculpt should assure that it is used in such an environment.

Immunity Test	Test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the vSculpt including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF (IEC 61000-4-6)	3 Vrms 150 kHz to 80 MHz outside ISM bands	6 V 150 kHz to 80 MHz	$d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$
Radiated RF (IEC 61000-4-3)	3 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 2.7 GHz	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ 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 metres (m)^(b)

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^(c) should be less than the compliance level in each frequency range^(d)

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

(See notes on following page)

Notes: 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.

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

^(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

TECHNICAL SPECIFICATIONS

Model: VS1500

Main Power: Lithium-ion rechargeable battery, 2,200 mAh capacity

Electrical Class: Internally Powered

Electrical Type: TYPE BF - silicone

LED Type: Diode

Wavelengths: 662 nm, 855 nm

Light Energy (Fluence):

6 minutes = 13.0 J/cm² +/- 20%

8 minutes = 17.4 J/cm² +/- 20%

10 minutes = 21.7 J/cm² +/- 20%

Operational Frequencies: 32 MHz; 83 kHz; 50 MHz.

USB Input Power: 5VDC, 450mA

Treatment Cycle: 6, 8, 10 minutes

Operating Modes: Three modes: light only, vibration only, light and vibration

Ingress Protection: IP34

Protected from solid foreign objects greater than 2.5 mm diameter. Protected from water splashing against the enclosure from any direction shall have not harmful effect.

Cooling: Passive

Weight: 0.35 kg +/- 0.03kg (0.77 lbs +/- 0.07 lbs)

Dimensions: Length 24 cm (9.4 in), Width 3.7 cm (1.5 in), Depth 3.7 cm (1.5 in)

Power Requirement: Internally powered 5VDC

Temperature:

Operating: 5°C (41°F) - 40°C (104°F)

Storage: -25°C (-13°F) - 70°C (158°F)

Atmospheric Pressure Range: 700 hPa to 1,060 hPa.

Relative Humidity:

Operating: 15% to 93%, Non-Condensing

Storage: 15% to 93%, Non-Condensing

Light Source Risk Group: Exempt

Safety Certifications:

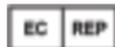
UL/IEC/EN 60601-1; IEC/EN 60601-1-2; IEC/EN 60601-1-11; IEC 60825-1; IEC EN 62471; EN 60601-2-57 CAN/CSA-C22.2 No. 601.1-M90

Average Service Life: 2 years – may vary depending upon usage patterns

GLOSSARY OF SYMBOLS



Accompanying User Guide



Emergo Europe, Molenstraat 15
2513 BH The Hague, The Netherlands

Authorized Representative in
the European Community



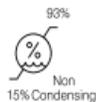
CE Mark with Notified Body Number



Device Model Number,
Catalog Number



General Warning Symbol



Humidity Limits



Keep Dry



Light Therapy Mode Button



Manufacturer



ON/OFF (Push Button)



Restriction of Hazardous Substances



Serial Number



Sonic Vibration Mode Button

70°C (158°F)



-25°C (-13°F)

Temperature Limits



Type BF Applied Parts



Waste Electrical and Electronic Equipment
(WEEE) compliant

