

## 1.1. Use of the Manual



### Warning

Use of controls or adjustments, or performance of procedures other than those specified herein, may be hazardous to subject, operator or system, and are not authorized by Venus Concept.

Personnel operating or maintaining the system are required to read this manual and to become thoroughly familiar with all its safety requirements and operating procedures before attempting to use or operate the system.

This manual has been prepared to aid medical and technical personnel to understand and operate the system. Do not operate the system before reading this manual and gaining a clear understanding of system operation. If any part of this manual is not clear, contact your Venus Concept representative for clarification.

This manual should always accompany the system, and all personnel operating the system must know its location.

## 1.2. Scope of the Manual

This User Manual includes:

- **Chapter 1: About this Manual**  
Provides information on the use and scope of the manual, document conventions, and a list of the used symbols.
- **Chapter 2: Safety and Regulatory Information**  
Provides general safety and regulatory information on the system, its intended use, possible hazards, and compliance with international standards, and shows the system's identification label.
- **Chapter 3: Installation**  
Provides information regarding the system installation, and its electrical and environmental requirements, equipment list, electrical connection and applicators' installation.
- **Chapter 4: System Description**  
Describes the system's main components and their descriptions.
- **Chapter 5: Operating Instructions**  
Provides detailed instructions on how to operate the system and describes its main interfaces.
- **Chapter 6: Advanced Features and Settings**  
Provides detailed information on the Tools screen and its features.

- **Chapter 7: Care and Maintenance**

Provides information on general user care and maintenance, including cleaning instructions.

- **Chapter 8: Troubleshooting**

Provides solutions to some problems that may arise while operating the system.

- **Chapter 9: Specifications**

Provides a detailed list of the system's technical information and specifications.

- **Appendix A: Clinical Guide for (MP)<sup>2</sup> Treatment with Diamondpolar Applicator**

Provides a clinical guide and detailed information on how to perform the skin treatment using the Diamondpolar applicators.

- **Appendix B: Clinical Guide for (MP)<sup>2</sup> Treatment with Octipolar Applicator**

Provides a clinical guide and detailed information on how to perform the skin treatment using the Octipolar applicators.

- **Appendix C: Clinical Guide for Fractional RF Treatment with Viva Applicator**

Provides a clinical guide and detailed information on how to perform the skin treatment using the Viva applicator.

- **Appendix D: Clinical Guide for SR515 and SR580 Applicators**

Provides a clinical guide and detailed information on how to perform the skin treatment using the SR applicators.

- **Appendix E: Clinical Guide for Hair Removal Using IPL HR Applicators**

Provides a clinical guide and detailed information on how to perform the hair removal treatment using the HR applicators.

- **Appendix F: Clinical Guide for the ACDUAL Applicator**

Provides a clinical guide and detailed information on how to perform the skin treatment using the ACDUAL applicator.

- **Appendix G: Manufacturer Warranty**

Provides the manufacturer warranty.

## 1.3. Document Conventions

The following messages in this manual prompt the reader to pay special attention to specific points:



### Warning

Warnings indicate precautions and instructions which, if not followed, may result in injury.



### Caution

Cautions indicate instructions, that if not followed may result in damage to the equipment or to the quality of treatment.

### Note

Notes provide information to aid in obtaining optimum equipment performance or procedure results.

## 1.4. Symbols

Table 1-1 describes the symbols that are used in this manual or on the product.

**Table 1-1. Glossary of Symbols Used in this Manual or on the Product**

Symbol	Description
	Waste of Electrical and Electronic Equipment (WEEE) Marking
	Type BF Equipment
	Manufacturer (accompanied by the name and address of the manufacturer)
	Date of Manufacture
	Symbol used with an HF isolated patient circuit
	Consult Instruction for Use
	System that includes RF transmitters or that applies RF electromagnetic energy for diagnosis or treatment

**Table 1-1. Glossary of Symbols Used in this Manual or on the Product**

	Authorised Representative in the European Community
	"Conformité Européenne" Symbol (CE Marking)
	Indication that the device has not been sterilized
	Do not re-use, single use, use only once
	<b>Warning:</b> A Warning alerts the user to the possibility of serious injury, death, or serious adverse reactions associated with the use or misuse of the system.
	<b>Caution:</b> A Caution alerts the user to the possibility of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or damage to the equipment.
	Indicates that Federal (USA) law restricts this device to sale by or on the order of a physician or licensed practitioner.

## Chapter 2

# Safety and Regulatory Information

### Chapter Contents:

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## 2.1. Introduction



### Warning

Read this chapter carefully to be familiar with all of safety requirements and procedures prior to operating the system.

The system is designed for a safe and reliable treatment when used in accordance with proper operating and maintenance procedures as outlined in this manual. Only qualified personnel, trained by an authorized trainer, can use the system and perform the treatments. The operator and all other personnel operating or maintaining the system should be familiar with all of the safety information provided in this manual.

The primary objective should always be in maximizing the safety of both the patient and the treatment operator.

You should carefully read the User Manual instructions before installing or using the system to become familiar with all safety requirements and operating procedures, and thereby prevent accidents, injury and reduce the risk of damaging the machine.

The Venus Versa is designed for professional use only. The manufacturer cannot be held responsible for damage or injury caused by improper use or for uses other than those for which this machine is intended.

## 2.2. Intended Use

The Venus Versa system is a multi-application device intended to be used in aesthetic and cosmetic procedures.

For information on the system's intended use, see the Indications and Contraindications sections in Appendices A, B, C, D, E and F of this User Manual.

## 2.3. Intended User and Environment



### Warning

The device is intended to be used by professional practitioners in the aesthetic field, such as physicians, nurses and other trained practitioners.

- The operator should stand near the patient during system operation.
- The operator is not allowed to leave a patient during the entire treatment.

## 2.4. Safety Information



### Warning

- Use of controls or adjustments, or performance of procedures other than those specified herein, may result in hazardous radiation exposure and are not authorized by Venus Concept.
- Personnel operating or maintaining the system are required to read this manual and to become thoroughly familiar with all its safety requirements and operating procedures before attempting to use or operate the system.
- The system should be protected against unauthorized use. Make sure that only authorized users have access to the system's Login code.
- High voltage is present inside the system. Do not attempt to open its casing.
- Always be aware of the possible dangers of using the system and take proper precautions as described in this manual.
- The system must be serviced by Venus Concept authorized service personnel only.
- Failure of the system could result in an unintended increase of output power.
- Any radiofrequency (RF) device can cause injury if used improperly.

- All operators must be familiar with the system controls and know how to shut down the system in case of a problem.
- Do not touch the inner parts of the system. The system services and repairs must be performed by qualified personnel only. Failure to do so may result in injury and will void all service agreements.
- Disconnect the system from the mains power supply before servicing (pull out the plug from the electricity socket).
- Do not use the system unless all enclosure panels are properly in place.
- Do not tamper with the controls or attempt to open up the system.
- Do not abuse, sit or lean on the system.
- The system should be kept out of the reach of children.
- A patient history should be completed prior to treatment to ensure that no complications could arise. It is important to verify that the patient does not fall under the exclusion criteria.
- The product should not be in contact with other equipment.
- For patients with cardiac pacemakers or other active implants, a possible hazard exists because interference with the action of the pacemakers may occur, or the pacemaker may be damaged. In case of doubt, approved qualification advice should be obtained.
- This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating.
- Portable and mobile RF communications equipment can affect the system.

- The patient should be fully informed of the treatment protocol and the expected results, and should sign the informed consent form prior to beginning of the treatments.
- Only authorized persons are allowed to stand near the system during the treatment.
- Stop the treatment in case of unexpected changes in the patient's condition.
- Do not drop the applicators. If an applicator is dropped, turn off the system immediately. Do not use a broken applicator and call the local service support.
- There are no user-serviceable parts inside the system. ONLY VENUS-AUTHORIZED PERSONNEL MAY SERVICE THE SYSTEM, ESPECIALLY INSIDE ITS CABINET.
- Do not allow the applicators to come in contact with hard materials that could damage their tips.
- The tip of the Viva applicator is for single use only.

## 2.5. Electrical and Mechanical Safety

- Keep all covers and panels of the system closed. Removing the covers creates a safety hazard.
- Perform maintenance procedures only when the system is shut down and disconnected from the mains power. Any maintenance procedure must be performed only by authorized personnel.
- Move the system slowly and carefully. The system weighs approximately 50 kg (110 lbs) and may cause injury if proper care is not taken when moving it.
- The system is grounded through the grounding conductor in the power cord. This protective grounding is essential for safe operation.

## 2.6. Fire Safety



### Warning

There is risk of fire if the system is used in the presence of flammable materials, solutions or gases, or in an oxygen enriched environment. Some materials, e.g. darkly colored clothing or cotton wool, when saturated with oxygen, may be ignited by the high temperatures produced in normal use of the equipment.

- Do not use the system in the presence of explosive or flammable materials.
- Do not use flammable substances when preparing the skin for treatment.
- If germicide swipes is used for cleaning and disinfecting the system, it must be allowed to fully dry before the system can be used again.

## 2.7. Protective Eyewear

- Exposure to intense pulsed light requires eye protection. Make sure to wear eye goggles during the IPL treatment.
- The patient has to wear eye cover during the IPL treatment.

## 2.8. Optical Safety during the IPL Treatment

- Do not direct the light from the treatment head at anything other than the targeted area.
- Do not allow reflective objects such as jewelry, watches, surgical instruments or mirrors to reflect the pulsed light.
- Do not expose any part of the skin, except for the test patch and the treatment area to the light pulse.
- Do not look directly into the IPL aperture of the treatment head, even if you are wearing safety glasses.
- The IPL treatment room should be clearly identified with a caution sign, as shown in Figure 2-1.



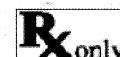
**Figure 2-1. IPL Treatment Room Caution Sign**

## 2.9. RF Treatment Safety Precautions


**Warning**

- RF used in this device can cause injury if used improperly.
- Applicator tip is for single use and has to be disinfected prior to use.
  
- Do not allow the applicators to come in contact with metal elements, as this could damage the (MP)<sup>2</sup> electrodes.
- The patient should not come into contact with metal parts which are earthed or which have an appreciable capacitance to earth (for example operating table supports, etc.). Use of antistatic sheeting is recommended for this purpose.
- Applicators' cables should be positioned in such a way that they do not come in contact with the patient or with other leads.
- Interference produced by the operation of HF surgical equipment may adversely influence the operation of other electronic equipment.
- Keep the bodies of the applicators clean. Pay particular attention to the applicator's RF electrodes. Check the integrity of all components.
- The applicator tip should be changed for each patient.
- The applicator tip must be cleaned before using it for the first time. Make sure that the applicator tip is clean before each treatment.
- Keep your hands away from the applicators during the system start-up.

## 2.10. Compliance with International Standards


**Warning**


- Federal (USA) law restricts this device to sale by or on the order of a physician or licensed practitioner.
- Prior the first treatment, the patient has to fill the Health Declaration Form. If there are one or more positive answers, treatment is not allowed.

The Venus Versa system complies with the following standards:

- EN 60601-1: Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for safety Collateral Standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-2-57 Medical Electrical Equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
- IEC 60601-2-2 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

## 2.11. System Safety Features

- The system is password-protected and does not allow the user to enter the Treatment screen without entering the correct Login code.
- Emission of treatment pulses is disabled unless the user presses the **Ready** button to place the system in the Ready state. When the system is in the Ready state, pressing any button on the screen will set the system back to the Standby state in which pulse emission is disabled.
- The system is equipped with an Emergency button which shuts down the system immediately in an emergency situation.

## 2.12. Electromagnetic Compatibility

**Table 2-1. Manufacturer's declaration – Electromagnetic Emissions**

Guidance and manufacturer's declaration – electromagnetic emissions		
The Venus Versa is intended for use in the electromagnetic environment specified below. The customer or the user of Venus Versa should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 2	The Venus Versa must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	The Venus Versa 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.
RF emissions CISPR 14-1	Complies	The Venus Versa is not suitable for interconnection with other equipment.
RF emissions CISPR 15	Complies	The Venus Versa is not suitable for interconnection with other equipment.

**Table 2-2. Manufacturer's Declaration – Electromagnetic Immunity**

Guidance and manufacturer's declaration – electromagnetic immunity			
The Venus Versa is intended for use in the electromagnetic environment specified below. The customer or the user of the Venus Versa should assure that it is used in such an environment.			
Emissions Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8 kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines; ±1kV for I/O lines	±2kV for power supply lines; Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV line(s) to line(s); ±2kV line(s) to earth	±1kV line to line; ±2kV line(s) to earth	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 5s	<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 5s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ME equipment or ME system requires continued operation during power mains interruptions, it is recommended that the ME equipment or ME system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m, 50 Hz @ 230 VAC mains; 60 Hz @ 120 VAC mains	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the AC mains voltage prior to application of the test level.			

**Table 2-3. Manufacturer's Declaration – Electromagnetic Immunity that is not Life-Supporting**

Guidance and manufacturer's declaration – electromagnetic immunity			
The Venus Versa is intended for use in the electromagnetic environment specified below. The customer or the user of Venus Versa should assure that it is used in such an environment.			
Emissions Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	V1 = 3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the ME equipment or ME system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[ \frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[ \frac{3,5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[ \frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	E1 = 3 V/m 80 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>a</sup> , should be less than the compliance level in each frequency range. <sup>b</sup> Interference may occur in the vicinity of equipment marked with the following symbol: 