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

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 Venus Versa is used exceeds the applicable RF compliance level above, the Venus Versa should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Venus Versa. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Table 2-4. Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the ME Equipment or ME System that is not Life-Supporting

Recommended separation distances between portable and mobile RF communications equipment and the Venus Versa

The Venus Versa is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Venus Versa can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Venus Versa as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$	800 MHz to 2.5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for 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.

2.13. System Labels

Figure 2-2 and Figure 2-3 show the labels that are affixed on the rear side of the system console.

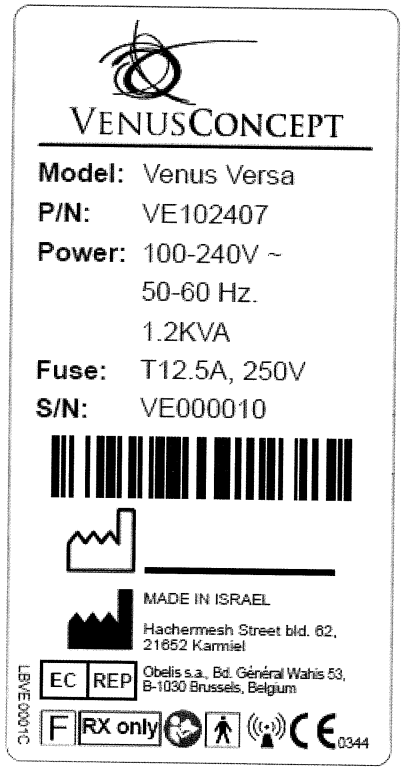

Figure 2-2. System Identification Label

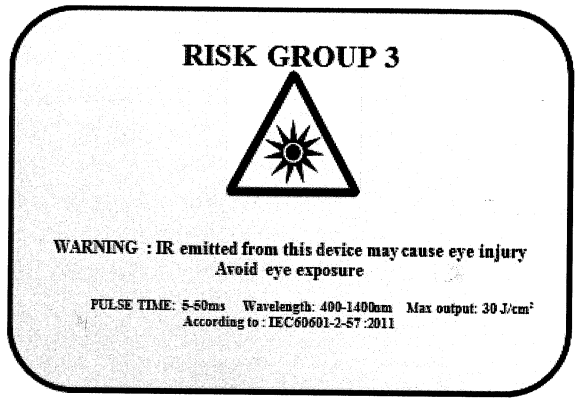

Figure 2-3. Light Emission Warning Label

2.14. Contact Information

USA: Venus Concept USA Inc.
4556 N. Hiatus Road, Sunrise, FL 33351
United States

Tel.: 1.416.907.0115
Fax: 954.572.5680

Canada: 255 Consumers Rd. Suite 100,
Toronto, Ontario. M2J 1R4, Canada

Europe: EC REP Obelis S.A. - Bd. Général Wahis 53
B-1030 Brussels, Belgium.

International: Hachermesh Street Bld. 62,
Karmiel 21652, Israel

For Latin America and the Caribbean, call 1-888-907-0115.

For all other inquires, contact:

Venus Concept
3 HaBarzel St.
Tel Aviv 69710, Israel

Tel.: +972 3 647 1882

General Inquiries: info@venusconcept.com

Service Inquiries: service@venusconcept.com

Clinical Inquiries: clinicalsupport@venusconcept.com

Website: www.venusconcept.com

Chapter 3

Installation

Chapter Contents:

3.1. Installing the System

The system must be installed only by a qualified Venus Concept technician.

3.2. Electrical Requirements

The system should be connected to a mains power supply with the following output:

- Single phase
- 100-240 VAC
- 1.2 kW (Max.)
- 50-60 Hz

As long as the electrical outlet meets the above requirements, the system automatically adjusts itself to the local mains voltage.

> ⚠ ***Warning***
>
> - For continued protection against fire, only fuses that are indicated on the system label can be installed in the system.
> - Only use a compatible power cord which is approved for the local mains electricity.

3.3. Environmental Requirements

- Corrosive materials can damage the electronic parts. Ensure that the environment is free from corrosive material.
- Metallic dust can damage the electrical equipment. Ensure that the environment is free from metallic dust.
- For optimal operation, the system should be placed in a room with an ambient temperature of 15°-30°C (59°-86°F), a relative humidity of less than 80% @ 35°C, and an altitude of up to 3000m.
- For optimal storage, system should be stored (with water removed) in a room with an ambient temperature of -20°C to 55°C (-4°F to 131°F) and a relative humidity of 0-90% @ 55°C non-condensing.
- For optimal transportation, the system should be transported (with water removed) at a temperature range of -20°C to 55°C (-4°F to 131°F), at a relative humidity of less than 80% @ 60°C, and an altitude of up to 15000m.

3.4. Equipment List

The system includes the following:

- System console
- SR515 Applicator (optional detachable accessory)
- SR580 Applicator (optional detachable accessory)
- HR650 Applicator (optional detachable accessory)
- HR690 Applicator (optional detachable accessory)
- HR650XL Applicator (optional detachable accessory)
- HR690XL Applicator (optional detachable accessory)
- ACDUAL IPL Applicator (optional detachable accessory)
- Diamondpolar Applicator (optional detachable accessory)
- Octipolar Applicator (optional detachable accessory)
- Viva Applicator (optional detachable accessory)
- Goggles
- Patient eye protectors
- Ultrasonic gel
- Power cord
- User Manual

3.5. Connecting the System to the Mains Power

To connect the system to electricity:

1. Connect the power cable to the power connection port, as shown in Figure 3-1.

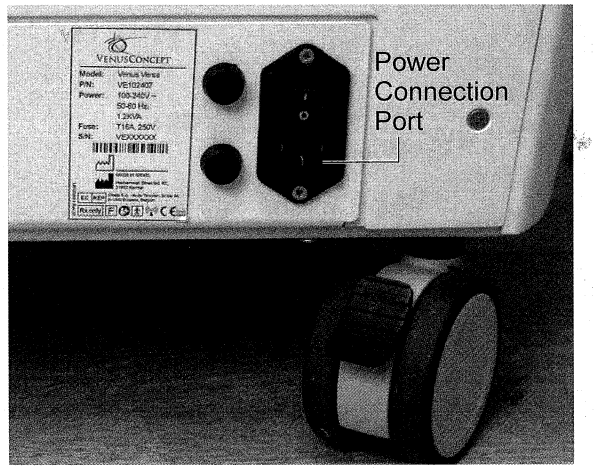

Figure 3-1. Power Connection Port on the System's Rear Side

2. Plug the other end of the power cable to the mains power supply.

3.6. Connecting the Applicators

3.6.1. Connecting the IPL Applicator

To connect an IPL applicator:

. Insert the applicator's cable connector to its receptacle on the system console, as shown in Figure 3-2.

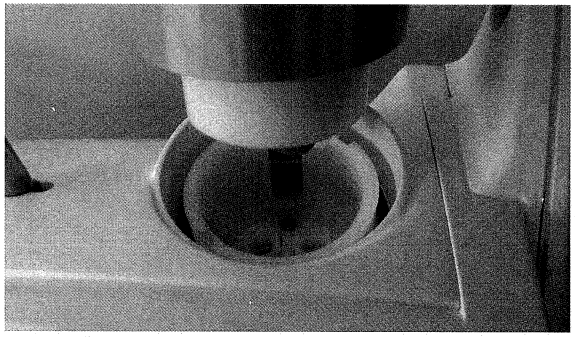

Figure 3-2. Connecting the IPL Applicator's Cable Connector

. Rotate the cable connector clockwise to lock it in place.

. Place the applicator in its cradle.

To disconnect an IPL applicator:

. Rotate the applicator's cable connector counter-clockwise to unlock it.

. Pull the cable connector out of its receptacle

3.6.2. Connecting the RF Applicators

To connect an RF applicator:

1. Insert the applicator's RF cable connector to its receptacle on the system console.

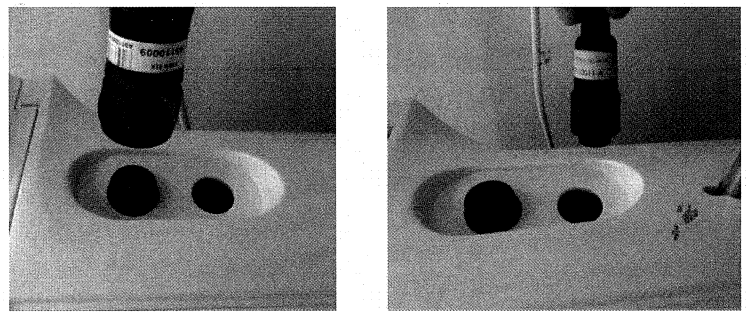

Figure 3-3. Connecting the RF Applicator's Cable Connector

2. Rotate the cable connector clockwise to lock it in place.
3. Place the applicator in its cradle.

To disconnect an RF applicator:

1. Rotate the applicator's cable connector counter-clockwise to unlock it.
2. Pull the cable connector out of its receptacle.

3.6.3. Connecting the Viva Applicator Tip

To connect a tip to the Viva applicator:

1. Hold the tip with its printed lot number facing bottom-right.
2. Align the tip with the applicator, as shown in Figure 3-4.

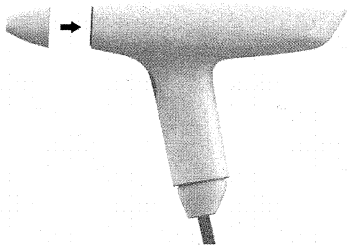

Figure 3-4. Connecting a Tip to the Viva Applicator

3. Push the tip into the applicator's tip connection port until it clicks in.

To disconnect the tip from the Viva applicator:

1. From under the applicator's tip connection port press the release button to disengage the tip.
2. Remove the tip.

Chapter 4

System Description

Chapter Contents:

4.1. General Description

The Venus Versa system is a non-invasive IPL and RF skin treatment device intended for use in dermatological procedures *(see Appendices A, B, C, D, E and F)*.

4.2. System Components

Figure 4-1 shows the Venus Versa system components.

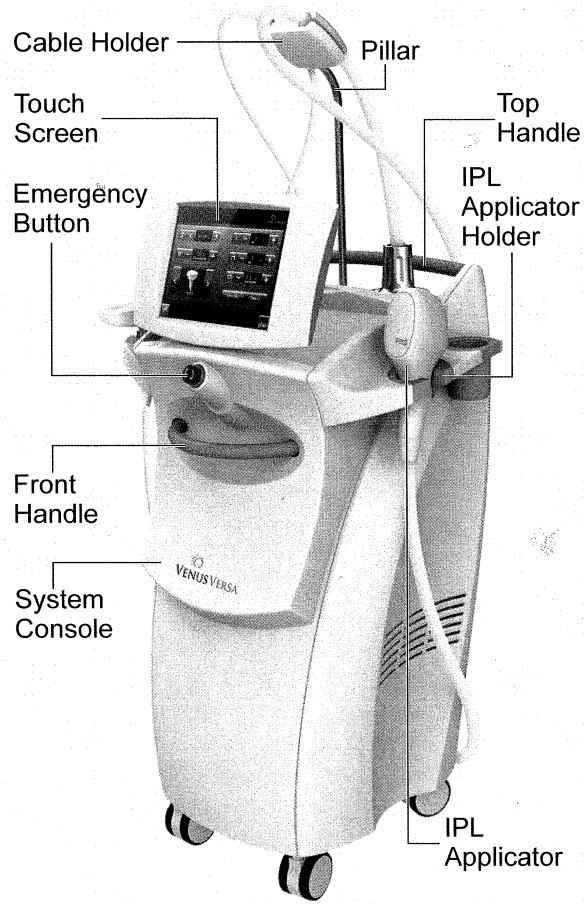

Figure 4-1. System Components

4.2.1. System Console

The system console is the main enclosure that holds and contains all external and internal system components.

4.2.2. Touch Screen

The touch screen is the primary means of communication between the user and the system.

The on-screen graphical user interface keeps the user informed of the system status and operating parameters at all times.

Via the touch screen, the user controls and monitors the system operation, using the touch-sensitive buttons and indicators.

4.2.3. Emergency Button

Figure 4-2 shows the emergency button, which is located on the front side of the system console.

Figure 4-2. Emergency Button

Pressing the emergency button shuts down the system immediately.

To resume the system operation, turn the emergency button clockwise, to release it (the button pops out), and then restart the system.

4.2.4. IPL Applicator Connection Receptacle

Figure 4-3 shows the IPL applicator connection receptacle, which is located on top of the system console.

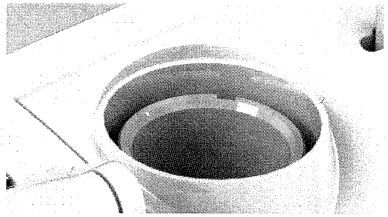

Figure 4-3. IPL Applicator Connection Receptacle

The IPL applicator connection receptacle is the port that connects the IPL applicator to the system.

4.2.5. RF Applicator Connection Receptacles

Figure 4-4 shows the RF applicator connection receptacles, which is located on top of the system console.

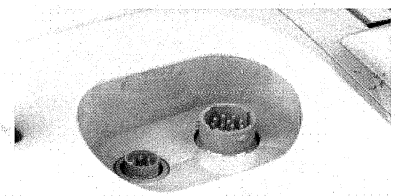

Figure 4-4. RF Applicator Connection Receptacles

The RF applicator connection receptacles are the ports that connect the RF applicators to the system.