



VENUS VIVA



User Manual International

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Before You Start

Glossary of Symbols Used in this Manual

The following are symbols that you will find throughout this operating manual and their meanings:

	WARNING sign: The information stated where you will see this symbol is <u>extremely important</u> and must be noted!
 Note	Provides general information that is important to keep in mind.
	Waste of Electrical and Electronic Equipment (WEEE) Marking.
	Fuse.
	Type BF Equipment.
M	Manufacturer.
P	Authorized Representative in the European Community.
	Manufacturer (accompanied by the name and address of the manufacturer).
	Date of Manufacture.
	Symbol used with a HF isolated patient circuit.

	<p>Consult Instruction for Use.</p>
	<p>System that includes RF transmitters or that applies RF electromagnetic energy for diagnosis or treatment.</p>

S/N Label

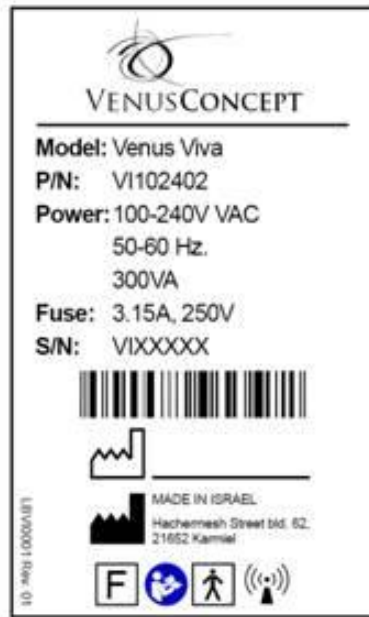


Figure 1-1, Venus Viva
Serial Number Label



WARNING

The User Manual is for clinical use only. Please read the User Manual instructions carefully before installing or using the System to become familiar with all safety requirements and operating procedures thereby prevent accidents, injury and reduce the risk of damaging the machine.

The Venus VIVA 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. Introduction

View of Venus Viva System

a



b



c



d



e



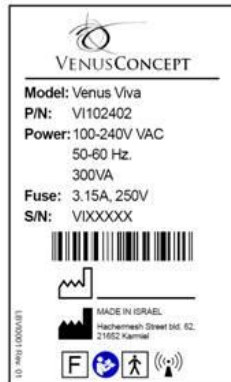
f



g



h



i



j



- a. Diamondpolar Applicator. (detachable accessory)
- b. Firm FX Applicator. (detachable accessory)
- c. Diamondpolar Holder.
- d. Firm FX Holder.
- e. Diamondpolar Applicator Socket.
- f. Firm FX Applicator Socket.
- g. Touch Screen.
- h. Serial Number Label.
- i. On/Off Button.
- j. Power Socket.

System Description

The Venus VIVA is a non invasive medical aesthetic device intended for use in dermatologic and general surgical procedures requiring:

- Ablation and resurfacing of the skin, using Firm FX applicator
- Treatment of moderate to severe facial wrinkles and rhytides in Fitzpatrick skin types I- IV, using Diamondpolar applicator

Skin Rejuvenation with Venus Viva is a unique procedure which uses radio frequency energy to deliver an effective but controlled ablative treatment.

The energies supplement each other to provide optimal treatment results with minimal risk of side effects.

The system offers 2 main applicators for face area:

- Diamondpolar Applicator. (detachable accessory)
- Firm FX Applicator. (detachable accessory)

Intended user and environment:

- The device is intended to be used by professional practitioners in the medical aesthetic field.
- The operator should stand near the client.
- The operator is not allowed to leave a client during the entire treatment.

3. Safety

This chapter describes safety issues regarding the use and maintenance of the System, with special emphasis on electrical safety.



Please carefully read this chapter and be familiar with all of its safety requirements and operating procedures prior to operating the System.

Introduction

The System is designed for a safe and reliable treatment when used in accordance to proper operating and maintenance procedures as outlined in this operating manual. Only trained and qualified personnel, 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 client and the treatment operator.



The Operator

- All operators **MUST** be familiar with the system controls and know how to shut down the system in case of trouble.
- Always be aware of the possible dangers of using the System and take proper precautions as described in this manual.
- 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 will void all service agreements.
- RF used in this (MP)² technology can cause injury if used improperly.
- High voltage is present inside the System, do not attempt to open the casing.

- Disconnect the System from the power supply before servicing (pull out the plug).
- 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.
- Venus Viva System should be kept out of the reach of Children.
- Do not allow the Applicators to come in contact with metal elements this could damage the (MP)² electrodes.
- A patient history should be completed prior to treatment to ensure no complications could arise. It is important to verify client does not fall under the exclusion criteria.
- 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). The use of antistatic sheeting is recommended for this purpose.
- The cables to the Applicators should be positioned in such a way that contact with the PATIENT or other leads is avoided.
- The product should not be in contact with other equipment.
- Failure of the System could result in an unintended increase of output power.
- Interference produced by the operation of HF SURGICAL EQUIPEMENT may adversely influence the operation of other electronic EQUIPEMENT.
- For PATIENT 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 then be fully informed of the treatment protocol, expected results and should sign informed consent form prior to beginning treatments.
- Only authorized person is allowed to stand near the system during the treatment.
- Stop the treatment in case of unexpected changes in client's condition.

- Do not drop the Applicators. In case the Applicators were dropped, turn off the system immediately. Don't use the broken applicator and call to local service support.
- There are no user-serviceable parts inside the system. ONLY Venus-AUTHORIZED PERSONNEL MAY SERVICE THE SYSTEM, ESPECIALLY INSIDE ITS CABINET.
- Keep the bodies of the applicators clean; pay particular attention to the RF electrodes of the Firm FX applicator. Check the integrity of all components.
Tip of the Firm FX applicator should be used per patient only
- Do not allow the applicators to come in contact with hard materials that could damage the tips.



Electrical and Mechanical Safety

- Keep all covers and panels of the System closed. Removing the covers creates a safety hazard.
- Keep your hands away from the applicators during the System start-up.
- Perform maintenance procedures when the System is shut down and disconnected from power.
- Move the System slowly and carefully. The System weighs approximately 8kg (~17pounds) 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.



Fire Hazards

- 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.

4. System Installation

The system is designed for operation in a clinical environment and it may be easily transported inside a protective carrying case. The Venus VIVA system is set up by doing the following:

1. Unpack the system.
2. Check the integrity of the system and all components.
3. Connect the Firm FX applicator to the system platform
4. Connect the Diamondpolar applicator to the system platform.
5. Connect the power cable to the system cable connection port.
6. Plug the system's power cable into an appropriate electrical outlet.
7. Turn the system on.

Equipment List

The System includes the following:

- System platform (Console Venus VIVA).
- Diamondpolar Applicator. (detachable accessory)
- Firm FX Applicator. (detachable accessory)
- Power cord.
- User Manual.
- Quick reference guide (only for non-English speakers' countries).
- Ultrasonic Bath
- Tips
- Brush

Electrical Requirements

The System can automatically accommodate the most of the local mains voltage. Specifically, the System can be energized of the mains voltage as follow:

Single phase 100/120/240V ~, 350W(MAX), 50/60Hz



For continued protection against fire, only fuses that are defined on the System label can be insulated in the System. Only power cord which is suitable to be connected to the System and approved for the local mains, must be used.

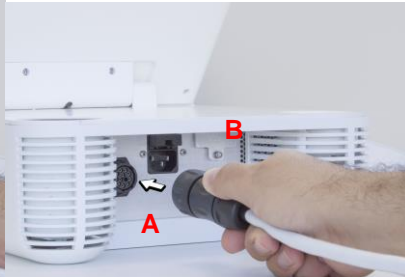
Environmental Requirements

- Corrosive materials can damage electronic parts, ensure that the environment is free from corrosive material.
- Metallic dust can damage electrical equipment.
- For optimal operation, the System should be placed in a room with temperature between 10°- 35°C (50°-95°F) with a relative humidity of less than 80% and altitude up to 3000m.
- For optimal storage, system should be stored in a place with temperature between -20 to 55°C (-13 to 131°F) with a relative humidity of 0-90 % @ 55°C non-condensing. For Optimal transportation system should be transport under the temperature range between -10°- 60°C (14°-140°F) with a relative humidity of less than 80% and altitude up to 15000m.

Connect the Applicators



*Figure 4-1,
Firm FX Applicator Socket*



*Figure 4-2,
Diamondpolar Applicator Socket*

1. Connect the applicator's cable connector (A) to the system's connection port
2. To disconnect the applicator, turn the black ring (B) counter-clockwise (in the direction of the arrow) until it releases and then pull the connector out.
3. Seat the applicator in its cradle (see Figure 4-3).



*Figure 4-3
Applicators in its cradle*

Connect/Disconnecting a Tip to Firm FX Applicator

Refer to Figure 4-4: to connect a tip to the applicator, hold it in the correct orientation – with the embossed "T" facing the top of the applicator and aligned with the top of the applicator – and push it onto the applicator's connection port (A) until you feel it click.

To remove the tip from the applicator, press the release button under the tip's connection port (B); the tip will pop off.

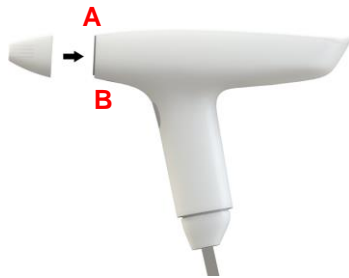


Figure 4-4
Connecting a tip to Firm FX applicator

5. Operating the System

Turning the System On/Off

Before turning the System “ON”, verify that the power cord is connected to the inlet located on the rear panel of the system and to the main power outlet.

Switch on the system by turning the main power switch located in the rear panel of the system to its “ON” position, and by turning on the “ON/OFF” button located underneath the screen. The ON/OFF button will be illuminated in green and within 50 seconds the Login Screen (See Figure 5-1) will be displayed on the system’s touch screen.

Login Screen

Once Login screen is displayed, enter the 8 character code provided with the installation documents and press the *Confirm* button (see Figure 5-1, marked A).

It is recommended to change initial Login code, using Set Login Code option in Tools Menu. Once the correct code has been entered, the default Treatment screen will be displayed.

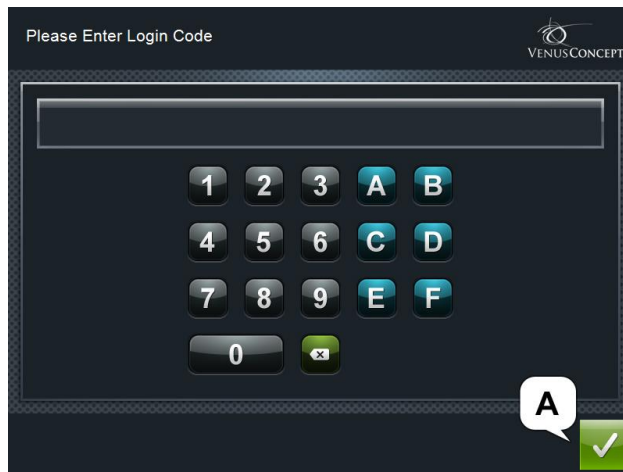


Figure 5-1: Login screen

Treatment Screen

The **Treatment** Screen is the system main screen (see Figure 5-2). Operator can control treatment parameters, start and stop a treatment, and access *Tools* screen from this screen.

In order to perform a treatment, operator should follow these steps:

1. Select the desired Applicator according to required treatment mode and area
2. Adjust treatment parameters
3. Initiate treatment

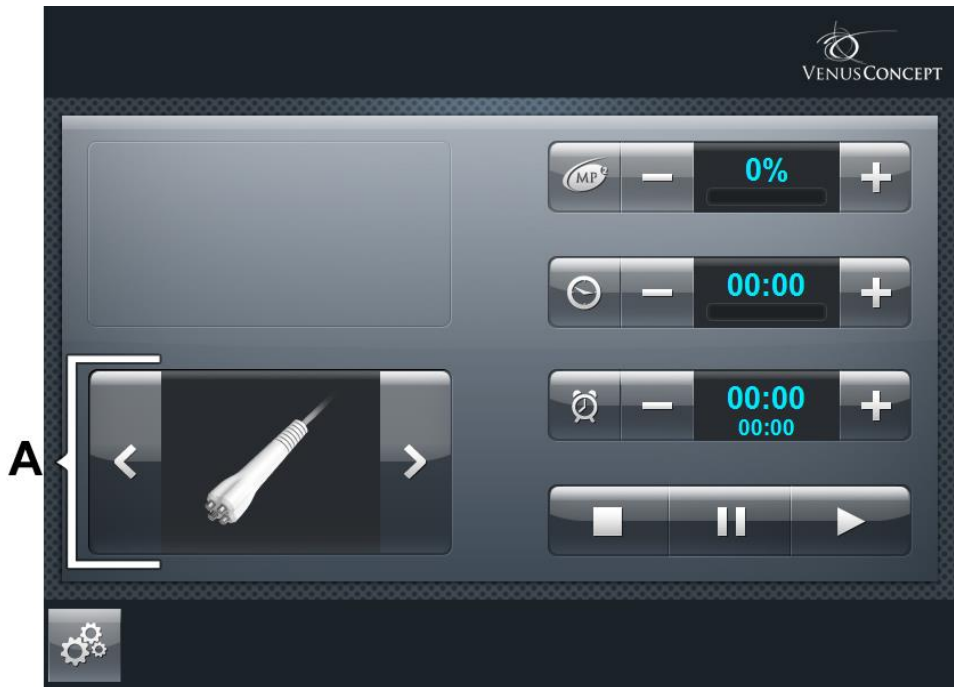


Figure 5-2: Default Treatment screen

Selecting Desired Applicator

Before initiating the treatment, operator should select the desired applicator, according to the required treatment modality and the size of the treatment area.

- Firm FX Applicator is intended for fractional RF treatment
- Diamondpolar applicator is intended for (MP)² treatments for face area

Selecting the desired applicator is done by pressing on the left and right arrows on the *Applicator Selection* button (see Figure 5-2, marked A). Each applicator is associated with certain treatment parameters which will be displayed on the screen upon selection of applicator. The system default applicator is the Diamondpolar applicator.

Fractional RF Treatment Mode

Figure 5-3 presents the treatment parameters associated with Firm FX applicator. The numbered tags correspond to the following numbered elements of the screen:

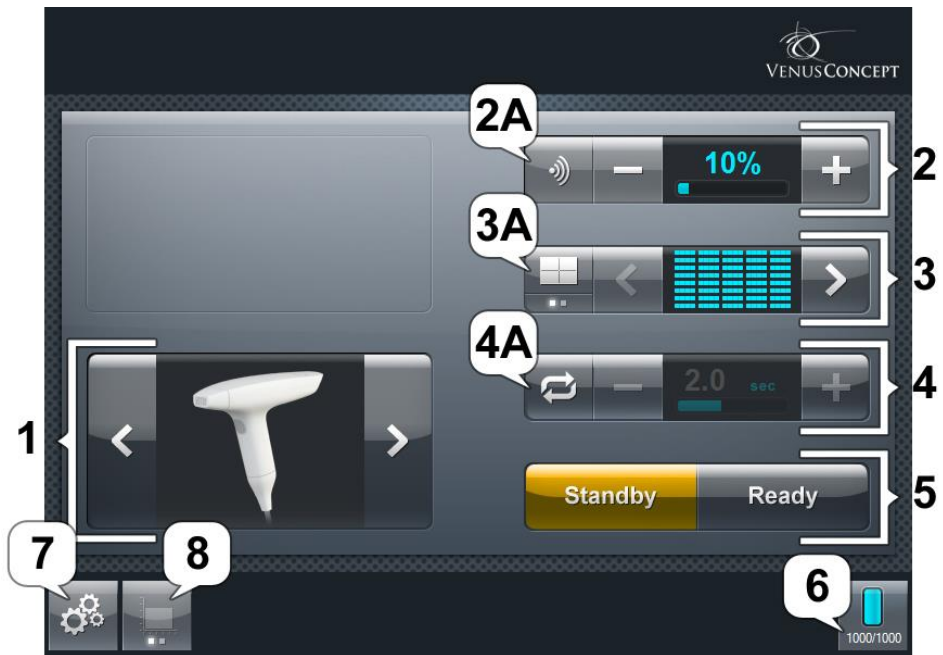


Figure 5-3: Firm FX Treatment screen

1. **Applicator Selector Button:** This button allows the operator to switch to a different applicator.
Pressing the left and right arrows will enable the operator to browse through the various applicators.
2. **Energy Indicator Adjustment Button:** This button allows the operator to determine the RF output of the Firm FX applicator once a pulse is fired.
Energy is measured in percent of maximum power, and confined to 11%-100%. Energy is adjusted by pressing the "+" and "-" buttons located on the screen next to the Energy icon (marked 2A) and is done in one percent increments.
Pressing on the "+" and "-" buttons continuously will adjust the energy in ten percent increments.
3. **Pattern Selector Button:** This button allows the operator to determine the footprint of the tip as well as which pins will be active once a pulse is fired by Firm FX applicator.
Patterns are grouped into two groups. Operator can toggle between the two groups by pressing on the rectangle icon (marked 3A). Once a pattern group has been selected, operator can browse through the various patterns by pressing on the left and right arrows adjacent to the rectangle icon.
4. **Automatic Operating Mode Button:** This button enables repetitive pulsing of the Firm FX applicator at a rate determined by the operator.
Operator can turn on the Automatic Operating Mode by pressing on the arrow icon (marked 4A), and adjust the time interval between every 2 pulses by pressing the "-" and "+" buttons adjacent to the arrow icon. Time interval between pulses is defined in seconds and adjustment is done in 0.1 sec increments.
5. **Standby and Ready Buttons:** Standby mode is the default mode of the system and enables the operator to adjust treatment parameters. When the system is in Standby mode, the Firm FX is inactive and the Standby button is illuminated in yellow. Operator can switch to Ready mode by pressing on the Ready button. When the system is in Ready mode, the Ready button will illuminate in green, the Standby button will change to grey and the Firm FX applicator will be active. When system is in Ready mode, pressing any button on the screen will set the system back to Standby mode.
6. **Pulse Counter Indicator:** This indicator displays the remaining number of pulses out of the total number of pulses of the connected tip. Once the tip is consumed, a message will be displayed warning that the tip is consumed and needs to be replaced.
7. **Tools Button:** This button allows the operator to access the Tools screen.

8. **Advanced Settings Button:** This button allows qualified operators to control additional parameters related to the pulse fired by Firm FX applicator. Once this button is pressed, Advanced Treatment screen will be displayed with additional elements as described in Figure 5-4.

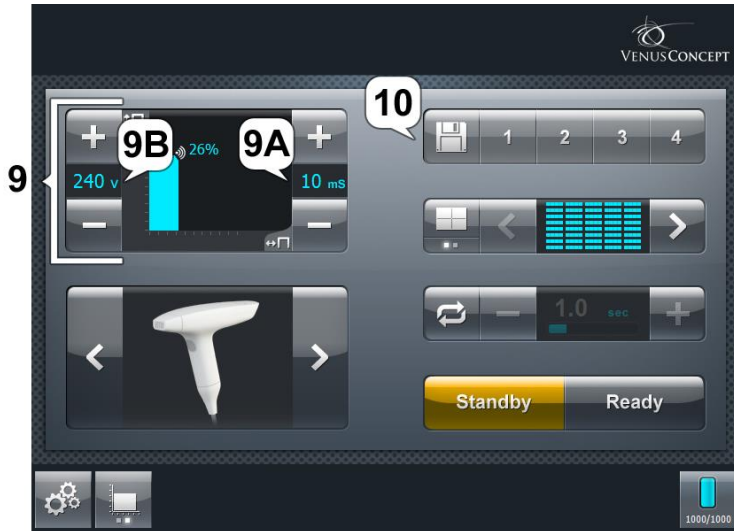


Figure 5-4: Advanced Treatment screen

9. **Pulse Profile Graph:** This element displays and controls specific parameters of the pulse fired by Firm FX applicator. A pulse is defined by its duration (X axis) and amplitude (Y axis), and their values determine the RF energy output of the applicator.

Pulse duration can be adjusted by pressing the "+" and "-" buttons adjacent to the *Pulse Duration* indicator (marked 9A). Pulse duration is measured in milliseconds (mSec) and adjustment is made in one mSec increments. Pulse amplitude can be adjusted by pressing the "+" and "-" buttons adjacent to the *Pulse Amplitude* indicator (marked 9B). Pulse amplitude is measured in Volts and adjustment is made in one Volt increments. The graph will display the resultant RF energy output in percent of maximum RF energy output.

10. **Save Profile Buttons:** These buttons allow operator to save the pulse profile as determined by pulse duration and pulse amplitude, for easy access in future treatments.

Saving profile settings is done by pressing the desired button (marked 10) for 3 seconds. Any profile previously saved to the selected button, will be over-ridden by the newly saved one.

Operator can access the saved profile by pressing on the desired button.

Operating the Firm FX Applicator

The Firm FX applicator (see Figure 5-5) emits a radiofrequency pulse when the system is in Ready mode, a tip is connected and the trigger is pulled. The applicator is equipped with a light bar that indicates when the applicator is ready to emit a pulse. Pull the trigger (marked A) to emit a pulse.



Figure 5-5: Firm FX applicator

(MP)² Treatment Mode

Figure 5-6 presents the treatment parameters associated with Diamonpolar applicator.

The numbered tags correspond to the following numbered elements of the screen:

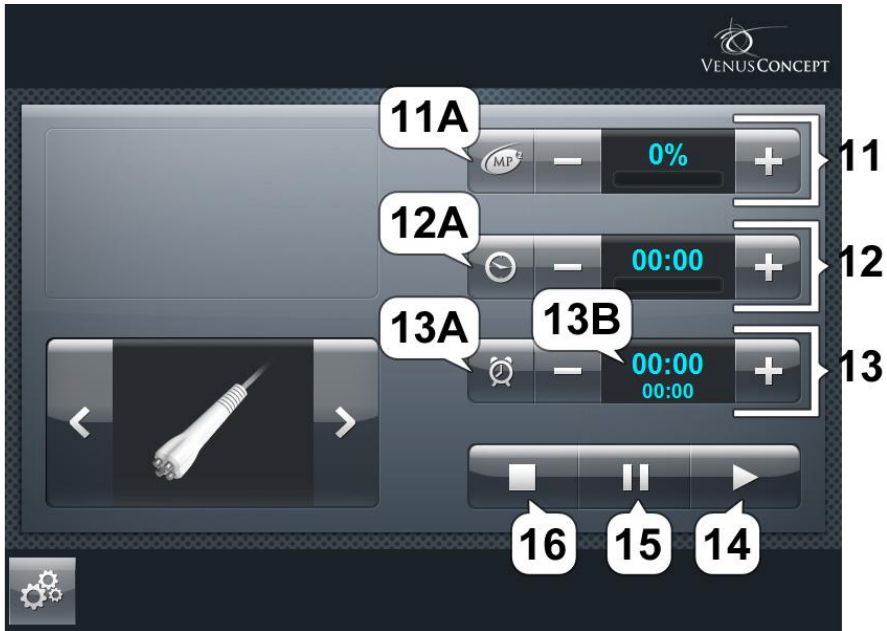


Figure 5-6: (MP)² Treatment screen

- 11. Energy Indicator Adjustment Button:** This button allows the operator to determine the RF output of the Diamonpolar applicator once treatment is initiated. Energy is measured in percent of maximum (MP)² power output (120W), and confined to 0-100%. Energy is adjusted by pressing the "+" and "-" buttons located adjacent to the Energy icon (marked 11A) and is made in one percent increments. Pressing on the "+" and "-" buttons continuously will adjust the energy in ten percent increments.

- 12. Treatment Time Adjustment Button:** This button allows the operator to determine the treatment time, in minutes, by pressing the "+" and "-" buttons located adjacent to the clock icon (marked 12A). Adjustment is done in one minute increments and is confined to 0-30 minutes. Treatment time can be adjusted before and during treatment. Pressing the clock icon will set treatment time to zero.
- 13. Interval Timer:** The Interval Timer allows the operator to divide the treatment time into time segments. This feature can be used at operator's discretion, and is convenient when a large treatment area is divided into smaller areas which are then treated individually.
- The *Interval Timer* begins countdown when treatment is initiated and beeps when timer is zeroed. It then begins countdown again. This process repeats itself as long as treatment is undergoing.
- Interval Timer is set between 0-30 minutes, and adjusted by pressing the "+" and "-" buttons located on the screen adjacent to the Interval Timer button (marked 13A). Adjustments are done in 15 seconds increments.
- The **Countdown Timer** (marked 13B) begins countdown when treatment is initiated and beeps when timer is zeroed.
- Pressing the Interval Timer button will synchronize the Countdown Timer with the Interval Timer.
- 14. Start Button:** This button allows the operator to initiate treatment once treatment parameters have been set.
- Once the Start button has been pressed, it will illuminate in green, the system will emit (MP)² energy through the selected applicator, and Treatment Time will initiate countdown.
- 15. Pause Button:** This button allows the operator to pause the treatment without changing the selected treatment settings.
- Once the Pause button has been pressed, it will illuminate in red, the system will stop emitting (MP)² energy and treatment time countdown will temporarily stop. Pressing the Start button will resume the treatment.
- 16. Stop Button:** This button allows the operator to end the treatment while treatment is in progress or paused.
- Pressing the Stop button will end the treatment. An "End of Treatment" message will appear, and treatment parameters will be reset to zero.

Tools Screen

Accessing **Tools Screen** is done by pressing the **Tools** button (see Figure 5-3, marked 7) on any **Treatment screen**.

Tools screen will appear (see Figure 5-7), enabling operator to personalize the system, and allowing a qualified Venus Concept technician to update the system software, calibrate the screen and control various settings.

Figure 5-7 presents the Tools screen. The numbered tags correspond to the following numbered elements of the screen:



Figure 5-7: Tools screen

Confirm Button: This button saves any changes made to the system settings, and confirms and selections made (e.g. language selection). Any changes or selections made will not be stored if the *Confirm* button is not pressed following the change/selection.

1. **Return Button:** This button allows the operator to return to the Treatment screen.

2. **Language Button:** This button allows the operator to select the language of the system software from a number of languages offered. Selecting a language is done by toggling to the desired language and pressing the *Confirm* button.
3. **Set Volume Button:** This button allows the operator to set the volume of the system speakers.
Pressing the Volume button will display a new window (see Figure 5.8) which controls the volume level. Adjusting the volume level is done by pressing on the "+" and "-" buttons adjacent to the loudspeaker icon (marked 4A). Volume level is defined in percent of maximum volume and adjustment is made in one percent increments.
Changes made to the volume level are saved by pressing the *Confirm* button (marked 4B), or aborted by pressing the *Exit* button (marked 4C).

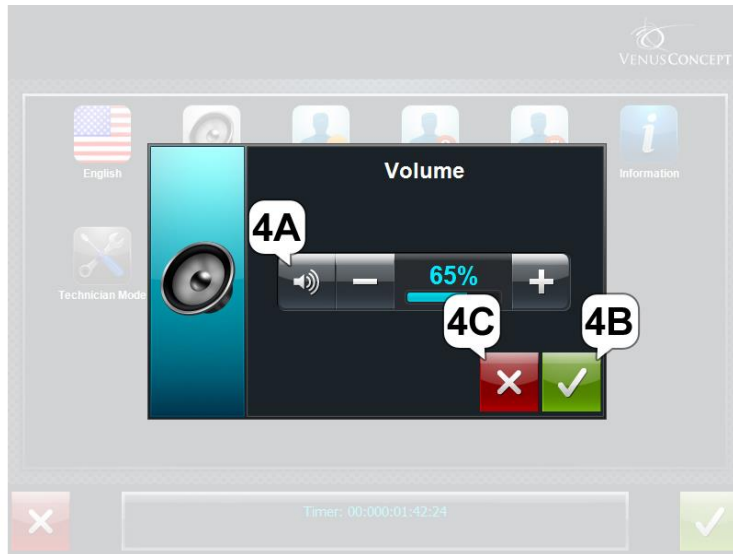


Figure 5-8: Set Volume screen

4. **Set Login Code Button:** This button allows the operator to change the login code required to access the treatment screen. Pressing the *Set Login Code* button will display a new window (see Figure 5.9) and guide the operator through the 3 steps required to change the code:
 - i. Enter current login code, then press the *Confirm* button (marked 5A)
 - ii. Enter a new 8-character login code, then press the *Confirm* button
 - iii. Re-enter the new login code, then press the *Confirm* button

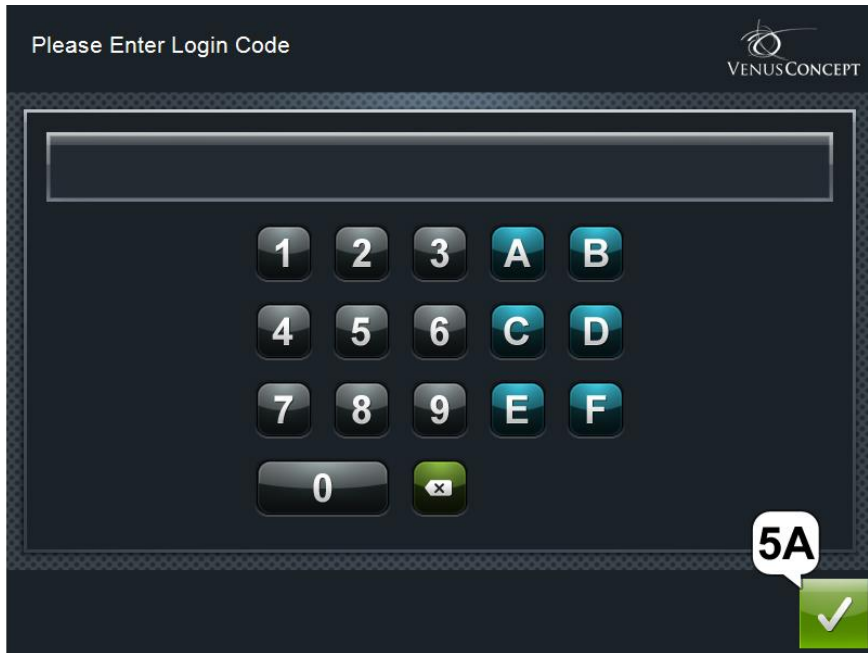


Figure 5-9: Set Login Code screen

5. **Logout Button:** This button allows the operator to log out of the treatment screen and lock the system. Once the Logout button is pressed, the login screen will be displayed and the login code will need to be entered in order to access the treatment screen.

6. **Set Auto Logout Time Button:** This button allows the operator to define the time period, after which the system will automatically logout if not in use. Pressing the *Set Auto Logout Time* button will display a new window (see Figure 5-10) which controls the Auto Logout Time. Adjusting the time is done by pressing on the "+" and "-" buttons adjacent to the padlock icon (marked 7A). Auto Logout Time is defined between 15 minutes 4 hours and adjustment is made in one minute increments. Changes made to the volume level are saved by pressing the *Confirm* button (marked 7B), or aborted by pressing the *Exit* button (marked 7C).

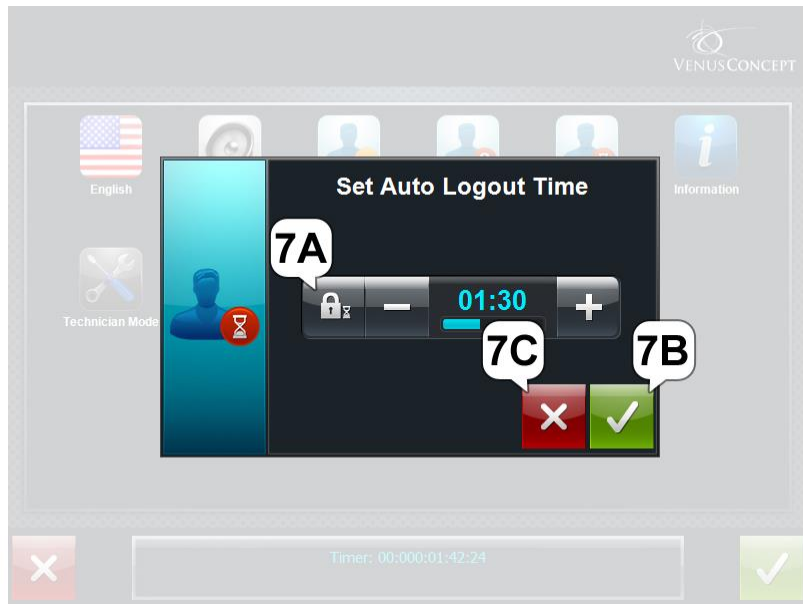


Figure 5-10: Set Auto Logout Time screen



System will automatically Logout if Screen has not been activated for 30 minutes.

7. **System Information Button:** This button allows the operator to view information regarding the system software and hardware. Pressing the System Information button will display a new window (see figure 5-11) showing the system Software version, and the serial number of the device. Pressing the Confirm button (marked 8A) will close the System Information screen.



Figure 5-11: System Information screen

8. **Technician Mode Button:** This button is password protected, to be used by qualified Venus Concept technicians only.

- 9. Activation Code Button:** This button allows the operator to extend the use of the device, in case it has been restricted by **Expiration Date** or **Operation Time** (see details below). This button also allows the operator to change the configuration of the device in case new applicators are added to the system and need to be activated.

The use of the system may be restricted to either a specific date (referred to as **Expiration Date**) or a limited time of operation (referred to as **Operation Time**). If the use is restricted, the appropriate information will be displayed at the bottom of the Tools screen. If no such information is displayed, the use of the system is unrestricted.

- i. If use of system is restricted to a **specific date**, the effective **Expiration Date** will be displayed. One week before Expiration Date, a message will appear on the screen indicating: "Your Activation Period is About to Expire. Please contact your area CSA to receive your new activation code. (Expiration Date: MMM-DD-YYYY)".
If Expiration Date has passed and without extending it, a message will appear on the screen indicating: "Activation Period Has Expired. Expiration Date: MMM-DD-YYYY. Please Enter New Activation Code".
- ii. If use of system is restricted to a **limited operation time**, the **remaining Operation Time**, in hours, will be displayed. If remaining operation time is less than 10 hours, a message will appear at the bottom of the Treatment screen indicating: "Remaining Operation Time: XX:YY hours". The text of this message will turn red if remaining operation time is less than one hour. If there is no remaining operating time, a message will be displayed indicating: "Your Activation Period Has Expired. Please Enter New Activation Code".
- iii. If use of system is restricted to both **specific date and a limited operation time**, both **effective Expiration Date and remaining Operation Time** will be displayed and the messages mentioned above will be displayed accordingly.

To extend the use of the system when it is restricted by date or time, operator should follow these steps:

- i. Press the *Activation Code* button. A new window will be displayed (see Figure 5-12), displaying a 4-character Key number (marked 10A).
- ii. Contact your local representative and mention the Key number displayed on the screen. The representative will provide a new 16-character activation code.

- iii. Enter the new activation code on the screen and press the *Confirm* button (marked 10B). Press the *Exit* button (marked 10C) to exit without Entering an activation code.

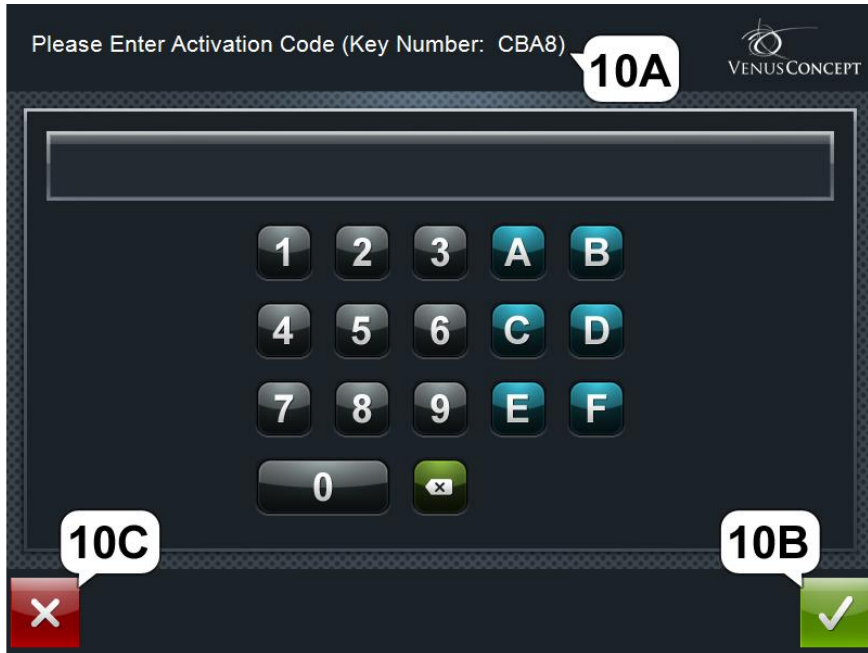


Figure 5-12: Activation Code screen

6. Treatment Procedures

Fractional RF Treatment Mode Using Firm FX Applicator

The Venus Viva system, using the Firm FX applicator, is designed for use in dermatological procedures requiring ablation and resurfacing of the skin.

Through an array of small electrodes organized on a tip, Radiofrequency energy is transmitted into the tissue, producing an injury in a certain pattern to the skin. The unaffected areas promote faster healing and the result is an improvement in the tone and texture of the skin.

Exclusion Criteria

- Pacemaker or internal defibrillator, or any other active electrical implant anywhere in the body
- Permanent implant in the treated area such as metal plates and screws, or an injected chemical substance
- Current or history of any kind of cancer, or current condition of any other type of cancer, or pre-malignant moles.
- Severe concurrent conditions, such as cardiac disorders.
- Pregnancy and nursing.
- Impaired immune system due to immunosuppressive diseases such as AIDS and HIV, or use of immunosuppressive medications. *
- Patients with history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area, may be treated only following a prophylactic regime.
- Poorly controlled endocrine disorders, such as diabetes.
- Any active condition in the treatment area, such as sores, psoriasis, eczema, and rash.
- History of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin.
- History of bleeding coagulopathies, or use of anticoagulants.
- Face lift or eyelid surgery (if periorbital treatment is performed) within a year prior to treatment.

- Facial dermabrasion, facial resurfacing, or deep chemical peeling within the last three months, if face is treated.
- Neurotoxin/collagen/fat injections or other methods of augmentation with injected bio-material in the treated area within 6 months prior to treatment.
- Use of Isotretinoin (Accutane®) within 6 months prior to treatment.
- Use of non-steroidal anti-inflammatory drugs (NSAIDS, e.g., ibuprofen-containing agents) one week before and after each treatment session.
- Any surgical procedure in the treatment area within the last 6 months or before complete healing.
- Treating over tattoo or permanent makeup.
- Excessively tanned skin from sun, tanning beds or tanning creams within the last two weeks.
- As per the practitioner's discretion, refrain from treating any condition which might make it unsafe for the patient.

() Indicated conditions may be treated at the discretion of – and under the full responsibility of the medical director/physician, although treatment is not recommended. In such cases, a small area should be treated and assessed a few days later to determine if the patient will tolerate the treatment without developing short-term adverse effects. Test spots cannot indicate long-term adverse events.*



In case of uncertainty regarding potential side effects, have the patient consult his/her primary care physician and bring a written consent for treatment.

Possible Side Effects

Improper use of the system could result in side effects. Although these effects are rare and expected to be transient, any adverse reaction should be immediately reported to the physician. Side effects may include any of those conditions listed below. Side effects may appear either at the time of treatment or after.

The side effects may include:

- Discomfort or significant pain post-treatment
- Excessive skin redness (erythema) and/or swelling (edema)
- In-grown hairs
- Damage to natural skin texture (crust, blister, burn)
- Change of pigmentation (hyper- and hypo-pigmentation)
- Scarring

Treatment of male patients in hair-bearing areas may result in some damage to the follicles and subsequent loss of hair. Avoid the beard area and other hair- growing zones if the patient does not wish to experience hair growth reduction.

Pre-treatment

- Complete or update the patient's medical and physical history.
- Exclude from treatment patients presenting any contraindications for treatment.
- Determine why the patient is seeking treatment and what the expectations are.
- Inform the patient about the treatment protocol, typical treatment results and possible adverse effects and discomfort.
- Instruct the patient about safety aspects he/she should observe.
- Advise the patient to avoid skin irritation or intentional skin tanning. Sun-screen is advisable when outdoors during daylight hours.
- The patient should discontinue any irritant topical agents for 2-3 days prior to treatment.
- The patient should arrive for treatment with clean skin. There should be no lotion, make-up, perfume, powder or bath/shower oil present on the skin in the area to be treated. Shave any hair in the treatment area.
- No lotion, gel or coupling medium should be used during treatment.
- Areas of dental crowns, caps, braces, or other metal dental implants may be more sensitive to treatment and the clinician may use dental rolls, gauze or a tongue depressor to isolate the area and make the treatment more comfortable.

- Applicator cleaning: before each treatment clean the entire applicator surface with a medical disinfectant that does not contain alcohol. Ensure that it is dry before beginning the treatment.
- Connect the tip to the distal port of the applicator and ensure that the tip is secured in place (see page 4-4).
- Check the integrity of the tip's electrode-pins; ensure that none are missing. Do not use if any pins are missing.
- Each tip has to be per patient, prior to each treatment the tip has to be cleaned according instructions on page 7-2

Test Treatment

When beginning a new treatment, perform a small test spot in a non-conspicuous area of the treatment site, prior to the first complete session. Test spots are performed to establish the following requirements:

1. Confirm the patient's suitability for treatment: for skin types I – III wait 24-48 hours before assessing the skin response, and for skin types IV-VI wait 5-7 days.
2. Establish and confirm treatment parameters: if the desired end-point of erythema and edema – in a tip-shaped pattern – has not been achieved within 10-15 minutes, increase the RF indicator level. If the response is excessive, decrease the parameters.

Test spot results will indicate if the patient can tolerate the treatment without developing adverse effects. According to patient tolerance to the test spot, you may determine treatment parameters and whether anesthesia is needed. In addition, it is advisable to perform a test spot whenever changing parameters.



Asian patients – after spot testing enforce a "waiting period" for one skin type level higher than apparent skin type.

Treatment Procedure

- Shave any hair in the treatment area.
- Ensure skin is completely dry during the entire treatment. If skin moistens during treatment (i.e., perspiration, etc.) re-wipe the skin with an alcohol pad and ensure that the skin is completely dry before continuing treatment.
- When treating full-face, after completing the first half of the face, make sure to dry the untreated half before commencing treatment.
- Set the treatment parameters (see **Firm FX Treatment Screen Elements** starting on page 5-3). Set the desired energy level according to the skin type, severity of the treated condition, treatment area, bone proximity, etc. Set conservative parameters for a test spot for the first treatment, and then gradually increase during treatment or in subsequent treatments according to desired impact and test spot results.
- Select the desired tip pattern, and enable automatic operation mode, if you wish.
- Treatment consists of a single pass over the treatment area. Adjust treatment parameters according to the test spot response. To perform treatment, place the tip on the target zone; perpendicular to the skin surface and with full contact with it.
- Emit a pulse by pressing the applicator's trigger; this will create a tip-shaped pattern on the patient's skin that will appear 1-2 minutes later. Move the applicator to an adjacent spot on the skin, emit another pulse. There should be no untreated gaps between the pulses, be careful not to overlap the treated zones.
- Examine the treated area. The immediate responses, indicative of the desired effect, are erythema and edema in the immediate area of the tip-shaped pattern and possibly also around it. The edema usually appears 1–2 minutes after pulsing and reaches its peak (of up to moderate edema) within 30 minutes. It should be noted that erythema is not easily noticeable – if at all – in darker skin types, so the edema will be more prominent in these patients.
- Untreated patches of skin: after completing a full pass on the entire treatment area, if untreated patches of skin are apparent, re-treat these patches with the following procedure:
 - Wipe the untreated patch of skin with a dry gauze pad.
 - Wipe the tip with a dry gauze pad.
 - Treat the untreated patches of skin as normally.

- Fine-tuning of the parameters should be done before proceeding to treatment of the entire facial sub-area with the selected parameters.
- Treatment consists of a single pass over the designated area. The applicator tip should be placed on the skin, a pulse emitted, then lifted and moved to an adjacent spot of the skin. The emitted pulses should create tip-shaped patterns, and leaving no untreated gaps between them, while also being careful not to overlap the affected zones.
- The parameters can be modified during subsequent visits, as per the practitioner's discretion.
- During treatment, check that the electrode-pins are free of cellular debris (may appear as black material). If there is debris, clean the tip before continuing to treat. Complete cleaning instructions may be found in the Maintenance chapter of this manual (see page 7-2).



- **The system must be in Standby mode when cleaning the tip.**
- **Always check the integrity of the electrode-pins on the tip – ensure that no pins are missing. If any pins are missing, do not use the tip.**
- **During treatment inspect the tip for cleanliness, and if necessary clean more often than specified on page 7-2 (especially when using high parameters; there may be more debris buildup).**



- **Always perform a test spot and wait as needed to evaluate results before treatment and before setting or changing presets.**
- **Use lower RF energy levels when treating in close proximity to bone.**
- **Ensure that the skin is completely dry during treatment.**
- **Ensure clean tips; accumulated debris or non-dry skin may lead to pain!**

Treatment Protocol

The number of treatment sessions depends on the individual patient and typically varies between 3-4 sessions, every 4-6 weeks.

One touch-up session may be needed every ~6 months, according to individual response.

Treatment Parameters

Selecting the appropriate RF Energy level is essential for successful treatment.

Always start with a low energy level and observe the skin's reaction before increasing the energy.

When applying energy to tissue, there are different effects achieved in the tissue: at a relatively low increase of temperature there may be activation of cellular components of the skin; further temperature increase may lead to cellular destruction (necrosis/coagulation) and an even further temperature increase leads to ablation.



The choice of treatment parameters should take into consideration the diffusion and depth of the lesion, as well as its specific anatomical location such as proximity to bone. In addition, patient's skin type and tolerance should always be considered.

Post Treatment Care

- Post-treatment emollient cream should be applied to the treatment area.
- Post-treatment cooling is not necessary. In the event of post-treatment discomfort, it is recommended to cool the treated area immediately with air cooling. Cold (not frozen) packs may also be used. Blistered or ulcerated skin can be treated with a prescribed cream.
- Tiny scabs of less than 1 mm diameter will usually form 24-72 hours post-treatment and may remain for several days. The scabs should not be touched or scratched even if they itch, and should be allowed to shed off naturally.
- Blistered or ulcerated skin can be treated with a prescribed antibiotic ointment or burn treatment cream as per physician's discretion.
- During the first two days following treatment, care should be taken to prevent trauma to the treated site: avoid hot baths, massage, etc. The skin should be kept clean to avoid contamination or infection; any mechanical or thermal damage to the area must be avoided.
- Moisturizer may be applied only several hours (~½ a day) after each treatment and then should be applied regularly throughout the course of the treatment. Make-up may be applied only 12 hours after each treatment if desired, unless an unwanted reaction occurs in the area. Generally 24 hours after treatment, patients may use regular soaps, but not scrub soaps or exfoliants.
- The patient should use a high-factor sunscreen (at least 30 SPF) and protect the treated area from sunlight for at least one month after the treatment.

Tanning of any sort (sun exposure, tanning beds, and artificial sunless tanning lotions) is not allowed in the treated areas during the entire course of the treatment. Tanning after treatment may cause hyperpigmentation.

Follow-Up

The following are recommendations for post-treatment follow-up. The most suitable regimen for each patient should be determined after reading this section.

- The patient should return 2-3 days after treatment to ensure that no adverse events have occurred.
- The patient should return several weeks (4-6) after the last treatment for evaluation of the treatment area.
- Update the patient's medical history before each session while being mindful of sun tanning, new medications, etc. If the patient has not violated the contraindications, treatment may be performed.
- Prior to treatment, perform a test spot in order to choose the adequate treatment parameters.
- If no results are observed and adverse events are noticed, treatment should be discontinued.

Treatment Conclusion

Treatment should be concluded when the results are satisfactory to the patient or according to the physician's discretion. Generally 3-4 sessions within 4-6 weeks are needed. Do not perform more than five consecutive sessions.

(MP)2 Treatment Mode Using Diamondpolar Applicator

The Venus Viva system, using the diamondpolar applicator, is designed for use in dermatological procedures requiring treatment of moderate to severe facial wrinkles and rhytides in Fitzpatrick skin types I- IV.

Contraindications

Treatment with the device is contraindicated for patients with any of the following conditions:

- Implantable defibrillators, cardiac pacemakers, and other metal implants
- Subjects with any implantable metal device in the treatment area.

Exclusion Criteria

- Actinic Keratozis
- Cancer, Melanoma
- Demyelinating Diseases
- Defibrillator/Pacemaker
- Disorder of the Thyroid Gland
- Epilepsy
- Fever
- Infection in the treated area
- Multiple Sclerosis
- Mental Diseases
- Metal implants near treated area excluding dental implants
- Moles at the treated area
- Ongoing use of Isotretinoin (e.g. Roaccutane)
- Pregnancy or IVF procedure
- Specific skin's Autoimmune Diseases

Pre-Treatment

Recommended Accessories - Prior to treatment, it is advised to ensure that you have the following:

- Glycerin in gel or liquid formulation
- Camera & Tripod (Tracking tools to follow the client's progress)

Clinical Data Management

- Establish a detailed patient medical history, including previous treatment modalities. This would include, and not be limited to, a questionnaire to ensure that the client does not fall under any of the exclusion criteria.
- Review with patient the informed consent form to ensure that they are well informed of the treatment protocol and possible side-effects.
- Determine why the patient is seeking this treatment, in order to understand and manage their expectations to ensure a satisfactory outcome.

Expected Clinical Effects

- Mild discomfort associated with the treatment.
- Heat sensation will be felt both during and following the treatment.
- Erythema could be present in the treated area for up to 2 hours post procedure.
- Adverse Effect: Skin burn - might occur if the operator does not follow instructions, i.e. staying too long with the Applicators on the same spot. If such a burn occurs, it should be treated conventionally.

Documentation

- It is strongly recommended that photographs of the treatment area are taken before and upon completion of the treatment series, to document clinical results and ensure a positive outcome. Consistency in photography conditions is imperative and efforts should be made to keep it.
- Treatment documents should be kept with patient chart.

Preparing for the treatment

- All Jewelry and/or metal items should be removed from the treatment area,
- Treated area should be clean and free of lotions, creams and make-up.
- Ensure that the patient is relaxed, comfortable and lying down on the treatment bed with the treated area exposed.
- Glycerin should then be applied thoroughly to the treatment area.

General Treatment Information

- The recommended treatment duration is between 15 to 30 minutes depending on the treatment area.
- Acceptable results will likely require a number of treatments performed over a period of time, all determined by the area and procedure being performed.
- In the initial treatment it is important to adjust the treatment time and required energy level to best suit the patient's tolerance to the treatment. Tolerance will increase as the patient gets more familiar with the treatments.
- The aim of the procedure is to heat the surface of the skin on the treatment area and raise the temperature at least to the therapeutic temperature = End Point, and maintain it for the remaining time of the treatment.
- End Point temperature should be at least 40°C but should not exceed 45°C.
- For optimal results, it is recommended to maintain the highest temperature tolerated by the patient, as long as it does not exceed 45°C.
- If large areas are treated, it is recommended to divide it into smaller areas, and divide the total treatment time accordingly.
- During the procedure, ensure that you are gently pressing the electrodes of the applicators against the skin, making sure all electrodes are in contact with the skin as much as possible.
- Applicator strokes should be long and continuous, and performed in form of “8” figure, circles, elliptical or waves. Applicator must always be in motion while there is contact with the skin surface.
- If measured skin surface temperature (when measured by the digital thermometer) at endpoint is less than 40°C, treatment is not optimal and the desired results will not be accomplished.
- Achieved skin temperature depends on applicator movement speed and energy level. The lower the energy the slower the movement should be and vice-versa.
- In the event that the patient experiences discomfort or pain during the treatment, either decrease the energy %, or apply more glycerin, or perform bigger and quicker movements or stop the treatment.
- Typically, optimal results will be achieved within 6-10 sessions performed once a week. The actual number of sessions needed depends on the initial condition of the patient and their compliance.

7. Maintenance

This chapter describes the routine maintenance procedures users should perform: cleaning the various Apparatus.

All other service/maintenance procedures are to be performed by the company's authorized service personnel ONLY!

For continued protection against fire, replace the fuse ONLY with one of the same type and rating as recommended in this user manual in chapter 8.

Cleaning the System

- All of the System's external parts should be cleaned / wiped down at least once a week.
- Turn off the system before wiping down any of the surfaces to ensure safety.
- The Applicators have to be cleaned after each treatment by using Germicide wipes or alternative means. Please ensure that the Applicators are fully dried before performing the next treatment.
- Avoid using detergents that can damage or destroy external plastic such as ammonia, acetone, hydrochloric acid, chlorine bleach, etc.

Cleaning the applicators



Do not immerse the treatment applicator in any liquid.

- Use a soft cloth, moistened with enzymatic detergent solution such as 0.5% ANIOSYME DD1, to clean the applicator until it is visually clean. Use the enzymatic detergent according to manufacturer instructions.
- Use a soft cloth, moistened with water to remove detergent residuals.

Disinfection the applicators

- Use germicide swipes to disinfect the applicator for at least 1 minute.
- Dry the applicator with a clean cloth.



- Assure that the applicator is dried from any inflammable substance.
- Always perform the cleaning procedure prior to disinfection.

Cleaning the tip

- Clean for one minute the tip's pins with soft-nylon bristled brush soaked in 70% Ethanol alcohol
- Put down the tip into ultrasonic cleaner (bath) with 70% Ethanol for 15 minutes
- Ensure the tip is down in ultrasonic cleaner filled by Ethanol to about 50% of the tip height
- Use a dry gauze pad to absorb all the alcohol. Make sure the tip is completely dry before beginning to treat again.
- If the tip requires cleaning during treatment, ensure that the system is in Standby mode before cleaning.
- When finished, reset the system to Ready mode and continue the treatment.

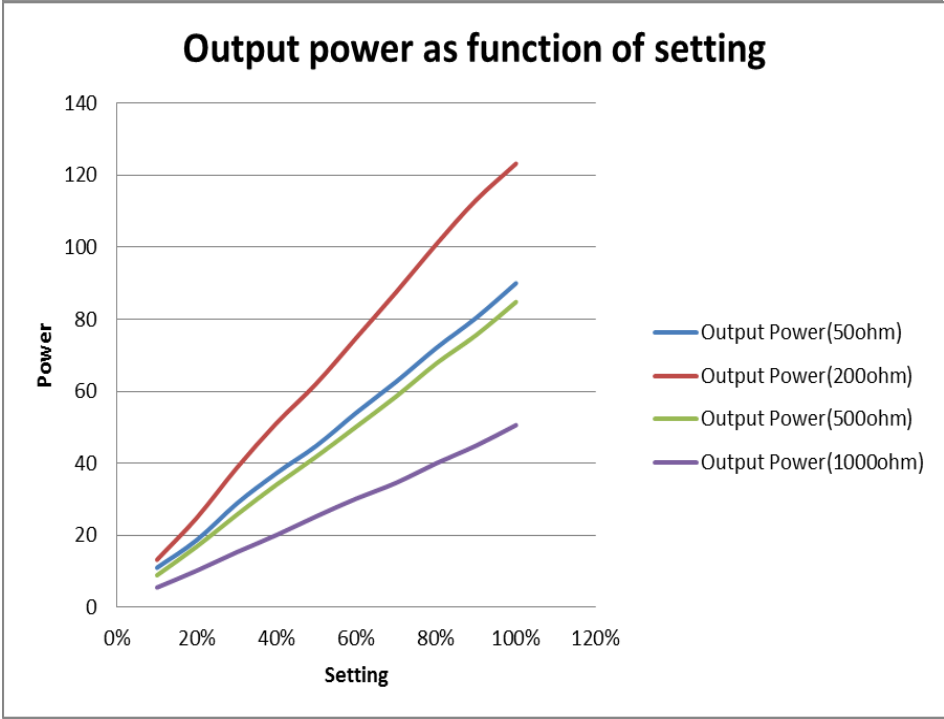
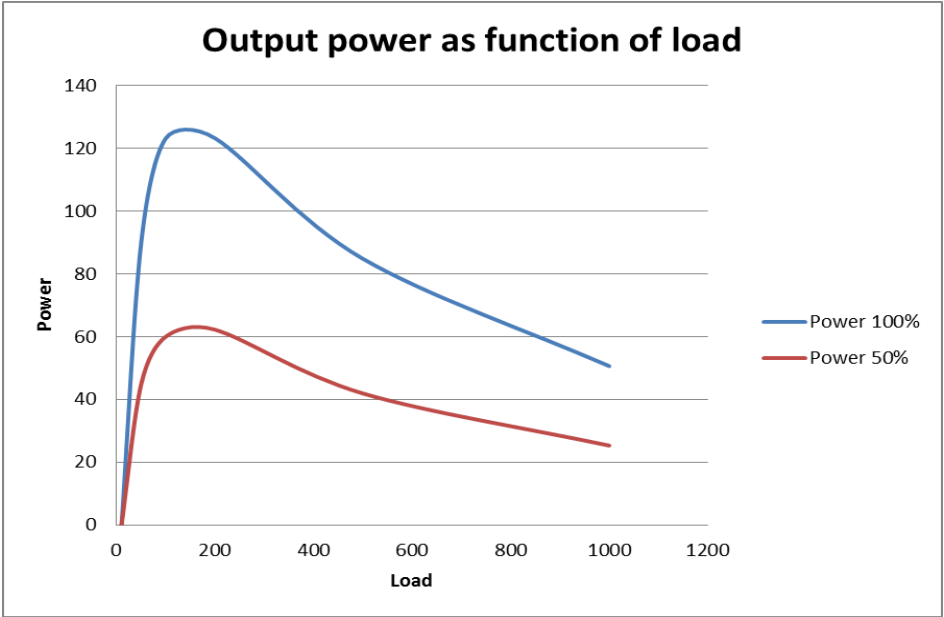
8. Troubleshooting

Failure	Correction
No Power	<ul style="list-style-type: none"> ➤ Check the power cable. Make sure that the Plug cable is inserted into both the wall socket and the System inlet. ➤ Make sure that main front switch is in "on" position. If the cable is connected properly and still there is no power, contact your local distributor.
No Display	<ul style="list-style-type: none"> ➤ Turn the system to its "ON" position on the front panel. ➤ Check the power cable. Make sure that the Plug cable is inserted into both the wall socket and the System inlet. ➤ Restart System (turn System off for 2 minutes and then turn System on). ➤ If still there is no display, contact your local distributor.
Touch Screen Does Not Respond	<ul style="list-style-type: none"> ➤ Restart system (turn system off for 2 minutes and then turn System on). ➤ If the screen still does not respond, contact your local distributor.
No Energy in Applicators	<ul style="list-style-type: none"> ➤ Make sure Applicators are connected properly. ➤ If the Applicators are connected properly and still there is no energy in Applicators, contact your local distributor.
Fuse is blown In the event that you switch "ON" the system and nothing appears on the screen, it is most likely that the main fuse burnt.	<ul style="list-style-type: none"> ➤ Make sure to disconnect system from wall electricity ➤ On the rear panel, you will find the inlet with a fuse box. ➤ Pull the fuse drawer out using a flat screwdriver. ➤ Remove the two fuses and check if they are burnt. ➤ Replace fuses if necessary as shown on figure below.
The message: " Error - Can't Read Configuration File"	<ul style="list-style-type: none"> ➤ Restart system (turn system off for 2 minutes and then turn System on). ➤ If the message still appears, contact your local distributor.

appears on the screen	
The message: " Error - Can't Read Configuration File" appears on the screen	<ul style="list-style-type: none"> ➤ Restart system (turn system off for 2 minutes and then turn System on). ➤ If the message still appears, contact your local distributor.
The message: " Error - Can't Read Language File" appears on the screen	<ul style="list-style-type: none"> ➤ Restart system (turn system off for 2 minutes and then turn System on). ➤ If the message still appears, contact your local distributor.
The message: "The Machine is Locked - Please Contact Your" appears on the screen	<ul style="list-style-type: none"> ➤ Restart system (turn system off for 2 minutes and then turn System on). ➤ If the message still appears, contact your local distributor.
The message: "End of Treatment - Press Confirm to Continue" appears on the screen	<ul style="list-style-type: none"> ➤ Set treatment time and then press the start button to start treatment.
The message: "Set New Login Code Failed - Please Try Again" appears on the screen	<ul style="list-style-type: none"> ➤ In order to set new login code, the operator has to enter the new login code twice. If the new login code is not identical in both times - the login code is not replaced. ➤ Try to set login code again.
The message: "Invalid Activation Code - Please Enter New Activation Code" appears on the screen	<ul style="list-style-type: none"> ➤ Try to enter the activation code again ➤ If the message still appears, contact your local distributor.

9. Technical Specifications

Technical Specification & Configurations	
Input Voltage	100/120/240V ~, 350W(MAX), 50/60Hz.
Output RF Frequency	1MHz ,460KHz
Fuse	3.15A, 250V
Max RF Output Power (Diamonpolar applicator)	Up to 120W
Max Output Energy (Firm FX applicator)	62mJ/pin
Magnetic Pulse Frequency	15Hz.
Magnetic Field	15 Gauss
Dimensions	W x L x H : 380mmx400mmx280mm
Weight	8 Kg





10. Manufacturer Warranty

The Company warrants that the product shall be free from defects in materials and workmanship for a period of 1 (one) year from the date of shipment by the Distributor to the purchaser, provided however that in no event shall any warranty extend more than 15 months from the date it was delivered to the local distributor. The liability of the Company under this warranty is limited to the repair or replacement (at Company's sole decision) of any allegedly defective part or parts under warranty at its expense.

The warranty contained herein does not extend to any product that is modified or altered, is not maintained to the Company's maintenance recommendation, is operated, handled or stored in a manner other than that specified by the Company, has its serial number removed or altered, or is treated with abuse, negligence or other improper treatment (including without limitations, use outside the recommended working environment).

The Company makes no warranty in respect to accessories and other parts made by other manufacturers, whether or not warranted by such manufacturers, which have been attached or connected to the product after installation, unless such accessory and other parts have been supplied by the Company.

Please fill in your details, scan and e-mail to service@venus-concept.com

Business Name: _____

Contact: _____

Address: _____

Telephone Number: _____

Email Address: _____

Date Purchased: _____

S/N: _____