

# eTwo / eMatrix

## *Sublative Rejuvenation and Wrinkle Treatment System Console User Manual*



**Syneron™**



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# 1. BEFORE YOU START

Read this manual to become familiar with all safety requirements and operating procedures before attempting to operate the system.

**Caution**

- Any radiofrequency (RF) device can cause injury if used improperly.
  - The eTwo/eMatrix system must be serviced only by Syneron Medical Ltd. qualified personnel.
- 

**Warning**

High voltage is present inside the system. Always be aware of the possible dangers and take proper safeguards as described in this manual.

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## Conventions Used in this Manual

1. The following conventions in the form of notes, cautions and warnings are used in this manual:

**Note**

The content of this **Note** offers general information that is important to keep in mind.

---

**Caution**

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 and/or patient, or damage to the equipment.

---

**Warning**

A **Warning** alerts the user to the possibility of injury, death, or serious adverse reactions associated with the use or misuse of the system.

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2. In many places throughout this manual you will see words or phrases in the text which are bolded in a sans-serif typeface, **such as this**. These are words and phrases that you will see on the LCD display of the control panel.
3. System Name: if you have ordered and received a system with **both** Sublative RF and Sublime applicators, the system will be named **eTwo**. If you have ordered and received a system with **only** the Sublative RF applicator, the system will be named **eMatrix**.

## Explanation of the Symbols Used in the System

<b>Symbol</b>	<b>Description</b>
	(on system) Attention: Consult Accompanying Document
	(on packages of high-density 144-pin tips) Caution: Use with Low Energy Settings!
	CE Compliance Symbol
	CSA Compliance Symbol
 10.08.2012	Discard Product After Expiration Date
	Product was Sterilized by Ethylene Oxide Process
	Waste of Electrical and Electronic Equipment (WEEE) compliance symbol
	RF Interference may occur in the vicinity of equipment with the following symbol
	Single Use Only
	Fuse
	Type BF Equipment
	Manufacturer
	Authorized Representative in the European Union

## 2. SAFETY

This chapter describes the safety issues regarding the use and maintenance of the eTwo/eMatrix system, with special emphasis on electrical safety.

### Introduction

The system is designed for safe and reliable treatment, when used in accordance with proper operation and maintenance procedures. Only trained practitioners are qualified to operate the system. The user and all other personnel operating or maintaining the system should be familiar with the safety information provided in this chapter. Syneron Medical Ltd. assumes no liability whatsoever for any damage or injury as a result of an application of a product which is not in strict accordance with the instructions provided with the product, or its operation by non-authorized personnel. The primary consideration should be to maximize safety for both treating attendant and the patient.



#### **Warning**

- Read this chapter to be familiar with all of its safety requirements and operating procedures prior to operating the system.
  - Any radiofrequency (RF) device can cause injury if used improperly.
  - High voltage is present inside the system.
  - Always be aware of the possible dangers and take proper safeguards as described in this manual.
  - Failure of the RF device could result in an unintended increase of output power.
  - **In the event of adverse effects or injury/illness, immediately contact:**
    - In North America: **Syneron, Inc.**
    - In Europe: **CEpartner4u B.V.**
    - Outside North America and Europe: **Syneron Medical Ltd.**
  - For complete contact information please refer to page 3 of this manual.
- 

### Patient Safety

Patient safety is primarily assured by a well-trained staff. A complete medical history of the patient should be completed and patient eligibility assessed, prior to scheduling treatment with the system. Patients should be fully informed of the treatment protocol, the likely results and any risks associated with the treatment.

The patient should wear Syneron-provided protective eyewear during the treatment.

For more detailed information please refer to the Clinical Guides in this manual.

## Treating Attendant

Personnel should not operate the system until they have been fully trained in its use.

## Cautions

- There are no user-serviceable parts inside the system.  
**ONLY SYNERON-AUTHORIZED PERSONNEL MAY SERVICE THE SYSTEM, ESPECIALLY INSIDE ITS CABINET.**
- Do not use the system if it has been dropped or if any other type of excessive force has been applied. The system must be examined by Syneron for safe operation after such an occurrence.
- Keep the bodies of the applicators clean; pay particular attention to the Sublime applicator tip's output lightguide and electrodes, as well as the RF electrodes of the Sublative RF applicator. Check the integrity of all components.
- Do not allow the applicators to come in contact with hard materials that could damage the tips.
- Make sure that all treatment personnel are familiar with the system's controls and know how to shut down the system instantly in case of an emergency.
- Patients with cochlear implants should not be treated on skin areas within a 1-centimeter (0.4") radius of the implant's location.
- Patients with cardiac pacemakers or other active implants should not be treated with the eTwo/eMatrix system; a possible hazard exists because of interference with the action of the pacemaker.
- Never use the system to treat on or in proximity to open/healing wounds.
- Never use the system in the presence of explosive or flammable gasses (such as flammable anesthetics, oxidizing gasses, etc.). If alcohol is used for cleaning and disinfecting, it must be allowed to dry thoroughly before the system is set to **Ready** mode.
- **When treating with the Sublime applicator:** always use a thin layer of clear coupling gel (recommended by Syneron) that has the appropriate optical transparency and electrical conductivity properties.

## Optical Safety

Refer to the **Sublime** applicator user's manual [PB7555(x)] for complete optical safety information concerning the Sublime applicator.

## RF Safety

For complete RF safety information concerning the Sublative RF and Sublime applicators, refer to:

- **Sublative RF** applicator user's manual
- **Sublime** applicator user's manual

## Electrical Safety Issues

- Keep all covers and panels of the system closed. Removing the covers creates a safety hazard.
- Always make sure the system is turned off before connecting/disconnecting the applicators to/from the system.
- Keep hands away from the applicators during system start-up.
- Do not allow contact between the patient and earthed metal components. If this cannot be achieved, use antistatic sheeting to protect the patient.
- Never use the system in the presence of explosive or flammable materials.
- Do not immerse any part of the system into liquids.
- Portable and mobile RF communications equipment can affect medical electrical equipment, interference may occur in the vicinity of the equipment.
- The use of accessories and cables other than those specified may result in increased emissions or decreased immunity of the device. It is forbidden to connect any third-party equipment to the system without written approval from Syneron Medical.



### **Warning**

- To avoid the risk of electric shock, this equipment must be connected only to an electrical supply outlet with protective earth.
  - Do not touch the tip connectors of the Sublative RF applicator while the system is turned on; this may cause electrical shocks.
  - Press the trigger to activate the applicator **only** when the applicator's tip is in full contact with the skin.
-

## Fire Hazards

- The absorption of energy raises the temperature of the absorbing material. Do not use the system in the presence of explosive or flammable materials.
- Keep drapes and towels moist to prevent them from igniting and burning.
- If alcohol is used for cleaning and disinfecting, it must be allowed to dry thoroughly before the system is set to **Ready** mode.

## System Safety Features

The system incorporates the following safety features. All personnel operating the system should be familiar with these features.

- The eTwo/eMatrix operating system is password-protected. Protect the password to avoid unauthorized use of the system. The password may be changed in the **Utilities** menu.
- The treatment mode cannot be activated unless an applicator has been connected to the system.
- An adjustable audible tone indicates system transition from **Standby** to **Ready** mode when a treatment pulse can be emitted.
- During startup, the system performs an internal self-test of its hardware and software.
- Hardware is tested while the system is idling (not emitting pulses), to ensure proper operation of its electrical circuitry. When a problem is detected, the system is disabled and an appropriate error message appears on the screen (refer to the **Troubleshooting** chapter).
- On-line monitoring of output energy prevents accidental energy emission to the patient.

## Equipment Classification

- Electric shock protection: Class I, Type BF
- Protection against ingress of liquids: Ordinary equipment
- Mode of operation: Continuous
- Not suitable for use in presence of flammable substance.
- The eTwo/eMatrix system and applicators comply with the U.S. Federal Regulations.
- The eTwo/eMatrix system is classified as a IIa device defined by the Medical Device Directive (93/42/EEC) for CE marking.

## System Nameplate

The system's ID nameplate is located on the bottom panel of the system, and it includes the system's identification, regulatory and electrical requirement information.

## Applicator Nameplates

The Sublative RF and Sublime applicator ID nameplate labels are adhered to the umbilical cable of each applicator near the connector, and they include the applicator's identification and electrical output information.

**Do not operate the eTwo/eMatrix system before verifying** that the following information is printed on the labels of the Sublative RF and/or Sublime applicators:

- Verify that the **Sublative RF** applicator's label has this printed on it:  
**Rated Voltage 275 V<sub>RMS</sub>**
- Verify that the **Sublime** applicator's label has this printed on it:  
**Rated Voltage 300 V<sub>RMS</sub>**



### 3. SYSTEM SETUP

The system is designed for operation in a clinical environment and it may be easily transported inside a protective carrying case. The eTwo/eMatrix 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 Sublative RF and/or Sublime applicators to the system platform.
4. Connect the power cable to the system cable connection port.
5. Plug the system's power cable into an appropriate electrical outlet.
6. Turn the system on.

#### Equipment List

**The following equipment is delivered in the shipping pack:**

- **eTwo** system console (if system ordered with Sublative RF **AND** Sublime applicators), ***or***:
- **eMatrix** system console (if system ordered **ONLY** with Sublative RF applicator)
- Sublative iD treatment tips (2 x 10-packs)
- User manual: eTwo/eMatrix system console
- User manual: Sublative RF applicator
- User manual: Sublime applicator \*
- Ultrasound gel (for Sublime treatment), ¼ liter bottle (x1) \*

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\* Delivered only with eTwo system for the Sublime applicator

## Electrical Requirements

The eTwo/eMatrix system incorporates a universal power supply module that allows it to be connected to standard electrical outlets anywhere. The system's electrical requirements are:

- 100 – 240 VAC  $\pm$ 10%; 3A; 50/60Hz; Single Phase

The electrical requirements are printed on the system's nameplate, located on the system's bottom panel.



### **Warning**

- For continued protection against fire, replace the fuse only with one of the same type and rating.
  - Proper grounding is essential for safe operation.
- 

## Environmental Requirements

- Corrosive materials can damage the system's elements; therefore the system should operate in a non-corrosive atmosphere.
- Metallic dust can damage electrical equipment.
- For optimal operation of the system, maintain room temperature between 15-30°C (59-86°F) and relative humidity of 10-80%.
- Due to the ablative nature of the treatment, always work in a well-ventilated room.

## Connect the Applicators



### Warning

Turn the system off and disconnect the power cable before connecting or disconnecting the applicators.

Refer to Figure 3-1:

- Connect the Sublative RF applicator to the connector on the **right** side of the system console.
- Connect the Sublime applicator to the connector on the **left** side of the system console.



### Note

To prevent mistakes when connecting the applicators, the system and the applicator umbilical cables have been marked with matching images (see Figure 3-1):

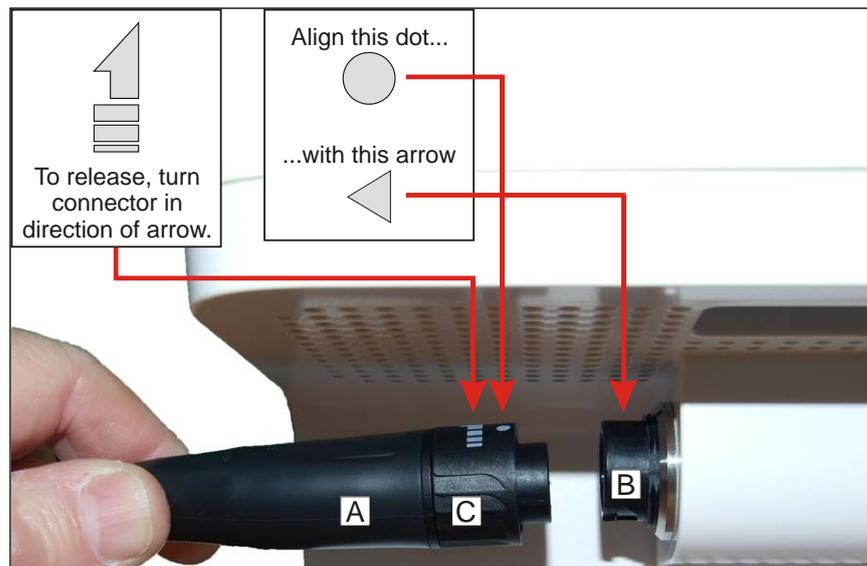
- The system's platform above the Sublative RF connector **and** the Sublative RF applicator's umbilical cable are marked with a single, grey-colored circle.
- The system's platform above the Sublime connector **and** the Sublime applicator's umbilical cable are marked with a double, grey-colored circle.



*Figure 3-1: Applicator Connection Ports*

Both the Sublative RF and Sublime applicators are connected in the same manner. Refer to Figure 3-2:

1. Connect the applicator's cable connector (**A**) to the system's connection port (**B**):
  - Align the white dot on the connector with the white arrow on the connection port.
  - Another way to properly insert the connector (**A**) is to align the single- or double-circle on the applicator umbilical cable with the single- or double-circle on printed on the console (see Figure 3-3).
  - Push the connector in until you feel it 'snap' into place.



*Figure 3-2: Connecting the Applicator*

2. To disconnect the applicator, turn the black ring (**C**) 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 3-3).



*Figure 3-3: Applicator in Cradle*

## 4. OPERATING INSTRUCTIONS

---



### **Warning**

- Ensure that the power cable is connected properly before turning the system on.
  - Dangerous voltage is present inside the system.
  - The applicators should always be connected and positioned in their respective cradles during system start-up.
  - Always turn the system off before connecting/disconnecting the applicators.
  - Never direct the applicator's tip at anything other than the treatment site.
- 

### **System Operation**

- I. Press the system's On/Off switch, shown by the red arrow in Figure 4-1.



*Figure 4-1: On/Off Switch*

- The system starts a self-test of controller memory while displaying a startup animation. When complete, the **Login** screen will be displayed.



*Figure 4-2: Login Screen*

- First-Time Operation:** press the **OK** button on the touch-screen – no password is required until one is set in the **Utilities** area of the program; the system will display the **Home** screen (see Figure 4-3).



**Note**

- Syneron strongly recommends setting a security password to protect the system from unauthorized use. Password configuration instructions are on page 4-12.
- Once the password is configured, it will be required by the **Login** screen (see Figure 4-2) every time the system is turned on.



*Figure 4-3: Home Screen*

4. From this screen you can advance to the following areas of the program by pressing the appropriate button on the screen:



- **Sublative RF** treatment mode



- **Sublime** treatment mode



- **Utilities** screen



5. Pressing the **Lock** button will return the system to the **Login** screen (see Figure 4-2); the system password will have to be keyed in again in order to continue operation.



6. Select the applicator you wish to use for the current treatment by pressing the appropriate button; the button will turn blue as an indicator that this applicator is now active:

- If you pressed the **Sublative RF** button, the **Treatment Program Selector** screen will appear (see Figure 4-4).
- When the **Sublime** button is pressed, no program selection is required; the system transitions directly into the **Sublime Treatment** screen (see Figure 4-7).

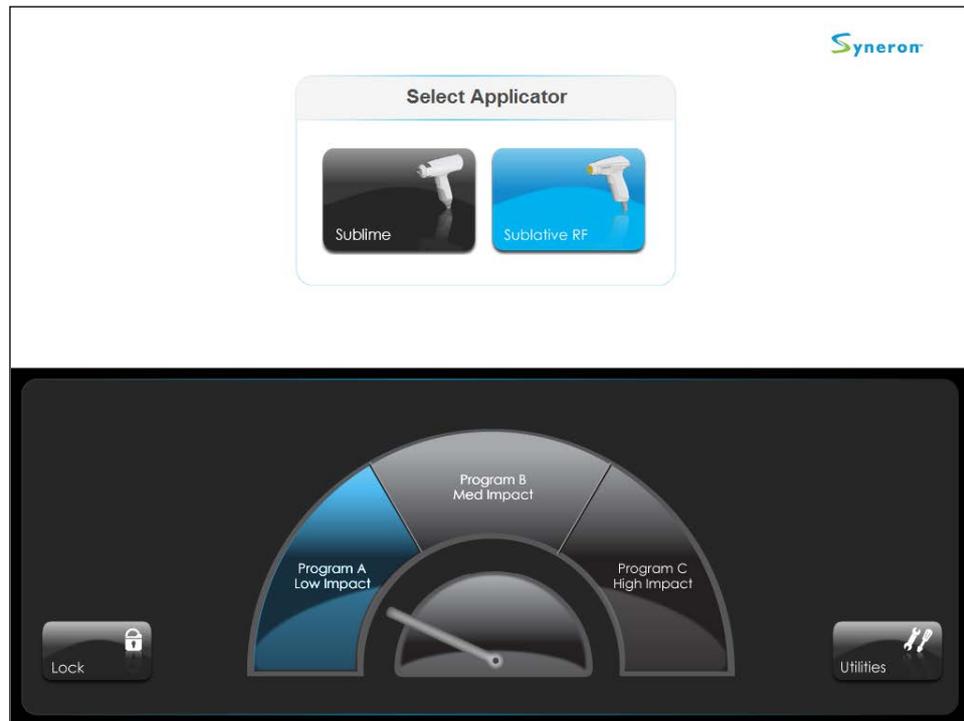


**Note**

If one or both of the applicators is not connected to the system when it is turned on, the applicator selection button(s) will not appear on the screen, indicating that the mode is disabled.

## Sublative RF Treatment Mode

Select a **Treatment Program**: there are three treatment programs to choose from, each offering different levels of ablation and resurfacing to the skin, at different intensities of impact. Select program **A** (Low Impact), **B** (Medium Impact) or **C** (High Impact); the **Treatment** screen will appear (see Figure 4-5).



*Figure 4-4: Treatment Program Selection Screen*

Figure 4-5 presents the main **Sublative RF Treatment** screen. The numbered tags in the illustration correspond to the following numbered explanations and definitions of the screens elements:

1. **Name and Illustration:** nametag and illustration of the currently active applicator.
2. **Description:** this tag describes the function of the currently active applicator.
3. **Standby and Ready Buttons:** press the **Ready** button to set the system to **Ready** mode; RF pulses will be emitted through the applicator tip when the trigger is pressed. Press the **Standby** button to set the system back to **Standby** mode. When the system is in **Ready** mode, pressing any other button will automatically return the system to **Standby** mode.



### Note

Wait until the green LED bar on the rear of the applicator illuminates, indicating that the system is charged and ready to emit a pulse.

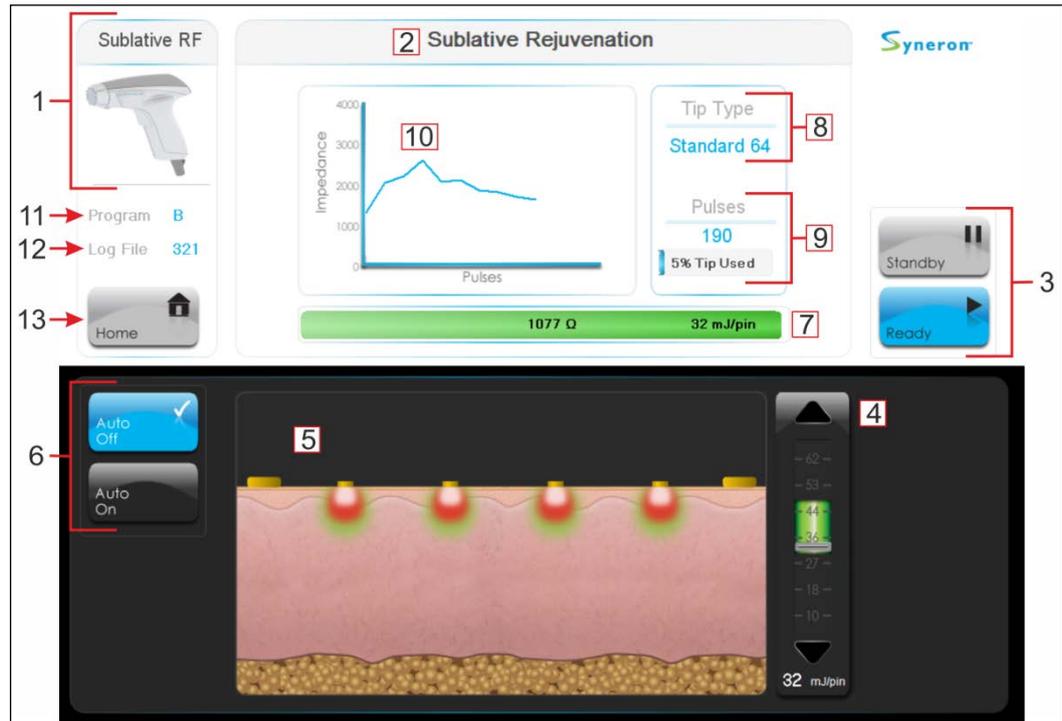


Figure 4-5: Sublative RF Treatment Screen Elements

- Requested Energy Selection Bar:** press anywhere inside the bar, or on the ▲ or ▼ buttons to increase or decrease the RF energy (mJ/pin) within program A, B or C.



**Note**

Pressing the ▲ or ▼ buttons after reaching the extreme end or beginning of the treatment program's energy range will transition the system to the next higher or lower treatment program, as exhibited by the **Program** tag shown by arrow # 11 in Figure 4-5.

- Tissue Effect Illustration:** displays effect of the RF energy penetration into the skin. The illustration changes intuitively as the levels of requested RF energy (mJ/pin) are adjusted.
- Auto Off and Auto On:** toggle the **Auto Repeat** mode that enables continuous pulsing at a fixed repetition rate of **1 pulse per second (Hz)** by pressing the **Auto On** button.
- Skin Feedback Bar:** after a pulse is emitted, this bar exhibits four indications: the skin's impedance (Ohms), the RF energy delivered (mJ/pin), corrective action (on Orange or Red) and the type of pulse delivered. The pulse type is displayed by the following color bars:
  - Green Bar** – optimal delivery of energy, this pulse is accompanied by a single 'click' sound. This pulse will be counted by the **Pulses** counter.



- **Orange Bar** – non-optimal delivery of energy; accompanied by a corrective action message (**Dry the skin**) and a single 'click' sound. The pulse delivered energy to the treatment spot, yet it may need to be repeated.

**This pulse will NOT be counted by the Pulses counter.**



If the **Training Sound** mode is turned on (refer to **Utility Screen Elements** starting on page 4-8), a single tone will sound.

- **Red Bar (High Impedance)** – a high impedance red bar means that the pulse was cut before energy was delivered to the treatment site due to debris on the tip or incomplete contact with the skin; this pulse is accompanied by a corrective action message (**Clean Tip/Check Contact**) and a double tone.

**This pulse will NOT be counted by the Pulses counter.**



#### Note

If the **Clean Tip/Check Contact** message appears on the skin feedback bar, set the system to **Standby** mode and clean the tip's matrix according to instructions starting on page 5-1.

8. **Tip Type Indicator:** indicates the type of Sublative iD tip currently connected to the applicator: **Standard 64** or **High Density 144**.
9. **Pulses Counter:** when a new tip is connected the bar starts at 0%, and progresses up to 100% as the tip is used until completion.
  - When a tip reaches the end of its pulse life, a message will be displayed warning that the tip has expired and needs to be replaced. The pulse life indicator will reset to zero when the tip is replaced with a new one.
  - If no tip is connected to the applicator and you attempt to set the system to **Ready** mode, the system will display a message (**No Tip Detected**) requiring a tip to be connected before proceeding.
10. **Impedance/Pulses Graph:** displays a forward-moving average of the impedance measured by the pulses. Each point in the graph on the Y-axis represents the average impedance of the previous five pulses; the next point of the graph will show the average impedance of the previous five pulses.



#### Note

- During the first four pulses of the treatment session – before a 5-pulse average can be established – each point on the graph represents the measured impedance of only that pulse. The moving average begins at the fifth pulse emitted.
- The measured impedance of **each** pulse is displayed on the skin feedback bar (in Ohms).

- 11. Selected Program Indicator:** displays which Sublative RF treatment program was selected for use: **A** (Low Impact), **B** (Medium Impact) or **C** (High Impact).
- 12. Log File:** denotes the name of the currently open system log file. These log files may be downloaded to a flash drive (disk on key) and then emailed to Syneron for troubleshooting purposes. Refer to the **Utilities Screen Elements** section starting on page 4-12.
- 13. Home:** pressing the **Home** button will transition the system to the **Home** screen (see Figure 4-3 on page 4-2).

## System Sound Effect Definitions

The following table defines the various sound effects emitted by the eTwo/eMatrix system and to which actions they relate.

If you are reading a PDF copy of this manual, click the speaker icons in the table to hear the sound effect sample for each of the actions.

<i>Description</i>	<i>Definitions</i>	<i>Demonstration</i>
Click	<ol style="list-style-type: none"> <li>1. On-screen parameter changes.</li> <li>2. Treatment pulse that generates a <u>Green</u> skin feedback bar or (if Training Sound is turned off) an <u>Orange</u> skin feedback bar (will be accompanied by a <b>Dry the skin</b> message).</li> </ol>	
Single Tone	Treatment pulse that generates an <u>Orange</u> skin feedback bar when the Training Sound feature is toggled on. This will be accompanied by a <b>Dry the skin</b> message.	
Double Tone	Treatment pulse that generates a <u>Red</u> skin feedback bar. This will be accompanied by a <b>Clean Tip/Check Contact</b> message.	
Down-Scaled Whistle	Tip cleaning is required; the system will transition to <b>Standby</b> mode. This will be accompanied by a <b>Clean Tip/Check Contact</b> message.	
Bell	<u>Warning!</u> This sound is generated when the system detects an error situation. An appropriate error message is displayed on the screen.	
Down-Scaled Chime	This sound is generated when the system transitions to <b>Standby</b> mode.	
Up-Scaled Chime	This sound is generated when the system transitions to <b>Ready</b> mode.	
Voice Message	The system delivers several instructions or selection indications in the form of a voice message; click the icon to hear a sample.	

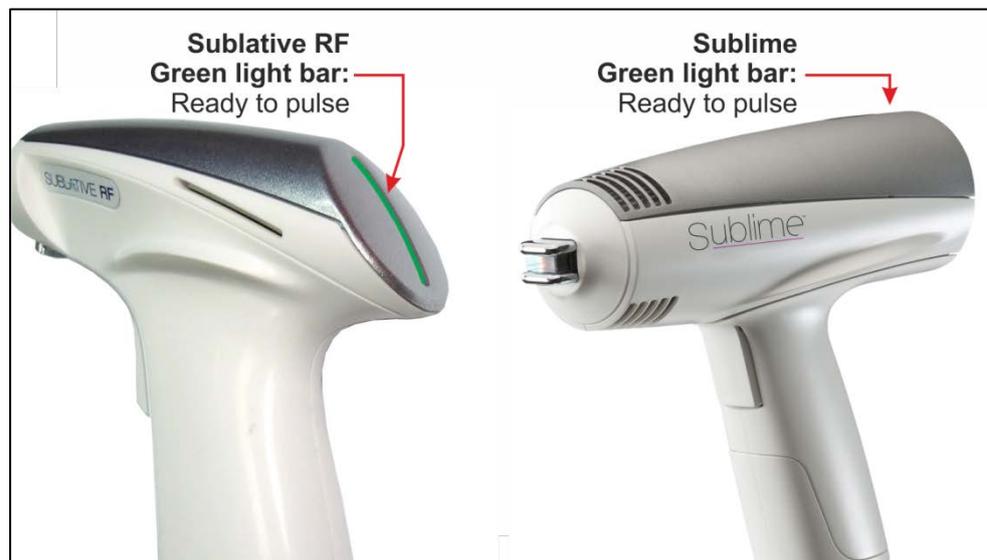
## Charging and Emitting a Pulse

The eTwo/eMatrix applicators emit a radiofrequency pulse when charged and the applicator's trigger is pressed.

The green RF indication light bar on the applicator illuminates when the applicator is sufficiently charged and ready to emit the pulse (see Figure 4-6).

The indication light bar goes off during pulse discharge, and remains off until the applicator is recharged and ready for the next pulse.

If a pulse was not delivered, or delivery of energy was not optimal, the indication light bar will flash amber light until the applicator is properly charged for the next pulse (green light bar).



*Figure 4-6: Charge Indication Light Bar*

## Sublime Treatment Mode

Figure 4-7 presents the main **Sublime Treatment** screen. The numbered tags in the illustration correspond to the following numbered explanations and definitions of the screens elements:

1. **Name and Illustration:** nametag and illustration of the currently active applicator.
2. **Description:** this tag describes the function of the currently active applicator.
3. **Standby and Ready Buttons:** press the **Ready** button to set the system to **Ready** mode; light pulses and RF energy will be emitted through the applicator tip when the trigger is pressed. Press the **Standby** button to set the system back to **Standby** mode. When the system is in **Ready** mode, pressing any other button will automatically return the system to **Standby** mode.
4. **Requested RF Energy Selection Bar:** select the desired RF energy to be delivered to the treatment site by pressing anywhere inside the bar, or on the ▲ or ▼ buttons to increase or decrease the RF energy anywhere from a minimum of 40 J/cm<sup>3</sup> up to a maximum of 100 J/cm<sup>3</sup> in increments of 10 J/cm<sup>3</sup>.

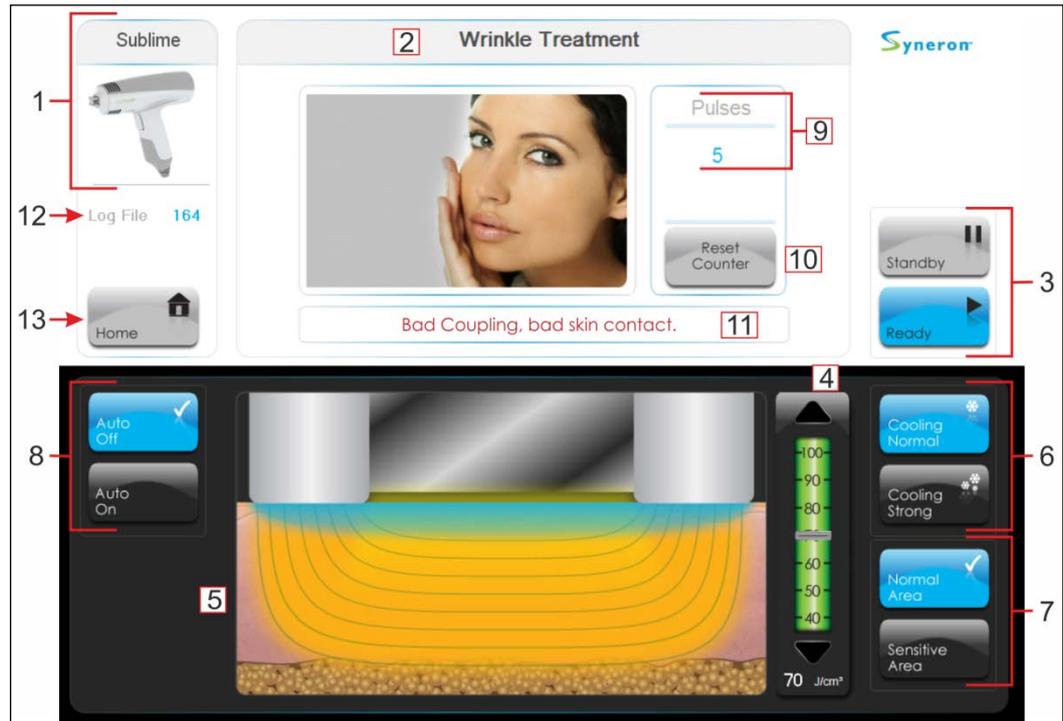


### Note

The optical energy is automatically set without user input.

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5. **Tissue Light & RF Effect Illustration:** displays the relative depth penetration into the skin of the light and RF energies. The illustration changes intuitively as the level of applied RF energy is adjusted.
6. Select the desired mode for the level of tip cooling in the Sublime applicator's tip:
  - **Cooling Normal** temperature (default selection): 15°C / 59°F
  - **Cooling Strong** temperature: 10°C / 50°F
7. **Normal Area** and **Sensitive Area Modes:** determine if the treatment area is to be considered **Normal** or **Sensitive**, and select the appropriate mode:
  - The **Sensitive Area** mode should be employed when treating bony areas such as the forehead, around the eyes or other bony or thin-skinned areas known to be sensitive. Otherwise use the **Normal Area** mode.
  - **Sensitive Area** mode will reduce the selected RF energy level by 30%. **Normal Area** will increase the RF energy level back to the selected level.



*Figure 4-7: Sublime Treatment Screen Elements*

8. **Auto Off** and **Auto On**: toggle the **Auto Repeat** mode that enables continuous pulsing at a fixed repetition rate of **1 pulse per second (Hz)** by pressing the **Auto On** button.
9. **Pulses**: represents the accumulated number of pulses in the current treatment.
10. **Reset Counter**: press this button to reset the **Pulses** counter back to **0** (zero).
11. **Message Area**: informative, cautionary or error messages generated by the system are displayed in this box.
12. **Log File**: denotes the name of the currently open eTwo/eMatrix system log file. These log files may be downloaded to a flash drive (disk on key) and then emailed to Syneron for troubleshooting purposes. Refer to the **Utilities Screen Elements** section starting on page 4-12.
13. **Home**: pressing the **Home** button will transition the system to the **Home** screen (see Figure 4-3).

## Utilities Screen Elements

Figure 4-8 presents the **Utilities** screen. The numbered tags in the illustration correspond to the following numbered explanations and definitions of the screens elements:

### System Information Box:

1. **Software Version:** displays the version of the software package currently installed in your eTwo/eMatrix system.
2. **Sublative RF Applicator Pulses:** this open-ended counter displays the accumulated number of pulses emitted by the Sublative RF applicator. This count value will be displayed only when the applicator is connected to the system.
3. **Sublime Applicator Pulses:** this open-ended counter displays the accumulated number of pulses emitted by the Sublime applicator. This count value will be displayed only when the applicator is connected to the system.



Figure 4-8: Utilities Screen Elements

### Maintenance Box:

4. **Change Password:** press this button; a virtual keypad screen (similar to the **Login** screen) will appear. Follow the on-screen instructions above the keypad to change the password:
  - Enter the old (current) password and press **OK** (✓).
  - Enter the new password and press **OK** (✓).
  - Enter the new password again for confirmation and press **OK** (✓).

**Note**

Press the **Cancel (X)** button to exit without changing the password.

5. **Copy Data to USB:** the system's save log files may be downloaded to a flash drive (disk on key) and then emailed to Syneron for troubleshooting purposes:
  - Press this button; a pop-up window will appear.
  - Follow the on-screen instructions.
6. **Update Software:** refer to the **Software Update Procedure** section, beginning on page 5-3.
7. **Home:** pressing this button will transition the system to the **Home** screen (see Figure 4-3 on page 4-2).

**Audio Settings Box:**

8. **Audio Level:** adjust the volume level of the voice messages and action tones emitted by the system.
9. **Voice On/Off:** the system emits messages and instructions in a human voice. This feature may be turned off (X) or back on (✓) by toggling this button.
10. **Training Sound** (Sublative RF only): when set to **On**, every emitted pulse that generates an **orange** skin feedback bar will also sound this single tone, instead of the normal 'click' sound. This feature may be turned **On** (✓) or back **Off** (X) by toggling this button.

**Display Settings Box:**

11. **Brightness:** adjust the brightness level of the LCD screen.
12. **Display Log Name:** when active, the name of the log file (\*.csv) will be displayed on the **Treatment** screen, directly under the icon of the active applicator. This feature is useful when performing clinical trials with the eTwo/eMatrix system, or for troubleshooting purposes. This feature may be turned on (✓) or back off (X) by toggling this button.



## 5. MAINTENANCE

### Cleaning the System

Clean the system at least once a week. Turn the system off and wipe all surfaces with a soft, damp, non-abrasive cloth. Be careful not to spill any liquids on or into the system.

The LCD screen should be cleaned with a dedicated LCD cleaning solution; this can be obtained from any office supply store.

### Cleaning the Applicator

Wipe the body of the applicator with alcohol/chloride/acetone-free disinfectant after each treatment session.

Pay special attention to the tip of the Sublime applicator (light guide and electrode rails).

### Cleaning the Sublative iD Tip

Ablated debris may accumulate on the tip's pin matrix during treatment.

The system will switch to **Standby** mode and display a message requiring cleaning of the tip at specific intervals, dependent on the energy level used.

The higher the energy level – the more often the system will stop for tip cleaning.

After cleaning the tip as instructed, press **Ready** to continue treatment.

### How to Clean the Tip

- Clean the tip's matrix with a gauze pad slightly moistened with 70% alcohol.
- Use a dry gauze pad to absorb all the alcohol. Make sure the tip is completely dry before beginning to treat again.
- When finished, reset the system to **Ready** mode and continue the treatment.



#### **Caution**

- Ensure clean tips; accumulated debris or non-dry skin may lead to pain!
  - Discard used Sublative iD tips as bio-hazardous waste.
-

## Fuse Replacement

### To replace burnt fuses:

1. Turn off the system and disconnect the power cable from the outlet.
2. Unplug the power cable from the cable's connection port on the service panel.
3. Remove the fuse housing as shown in Figure 5-1.
4. Remove the burnt fuses from the housing and replace them with new ones.
5. Make sure that the fuses fit snugly within the fuse housing.
6. Insert the fuse housing into its receptacle and push it in until it snaps into place.
7. Connect the power cable to the system and to the power outlet.
8. Turn on the system and verify that it is functioning properly.



### Caution

- Make sure that the type and rating of the new and the replaced fuses match.
- Always replace both fuses at the same time.



*Figure 5-1: Fuses Replacement*

## Software Update Procedure

The **Software Update** feature in the **Utilities** screen (see Figure 4-8) allows you to easily update the eTwo/eMatrix system's software application package after receiving a new version from Syneron.

The new software package will be delivered to you by one of the following methods:

- A USB flash drive (disk on key) with loaded software will be mailed to you, or:
- The software package will be emailed to you; unzip the package directly onto your own blank disk on key.

To update the software, access the **Utilities** screen and press the **Update Software** button; a pop-up window will appear with complete instructions on how to install the new software. Follow the on-screen instructions until the installation is complete.



### **Caution**

It is very important that during the update process the system does not lose power, or be interrupted in any way.

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## System Integrity

Inspect the eTwo/eMatrix system on a regular basis and at least once a month for damage to the applicators, umbilical cables and system base. If any evidence of broken, cut or otherwise damaged parts are detected, contact the Syneron Service Center to correct this. Using the system when it is damaged may cause unexpected results.



## 6. TROUBLESHOOTING

The eTwo/eMatrix system is equipped with a self-testing software routine that continuously monitors system operation. If a system malfunction is detected, an error message will appear on the LCD screen.

The following troubleshooting tables do not attempt to list all possible system failures. Any fault not listed should be referred to Syneron's Service Center.

### Sublative iD Tip Related Messages

Table 6-1 provides a list of Sublative iD tip related pop-up messages that will appear on the LCD screen during the normal course of patient treatment; follow the actions required by the pop-up message and resume normal operation. If the corrective action does not clear the pop-up message, restart the system and try again. If the problem persists, contact Syneron's Service Center.

*Table 6-1: Sublative iD Tip Related Messages*

<i>Message</i>	<i>Required Action</i>
<b>New Tip Detected</b>	The system has detected that a new tip is connected to the applicator during transition to <b>Ready</b> mode; press <b>OK</b> , observe <b>Tip Type</b> display at the top-right corner of the treatment screen, and proceed with normal operation.
<b>No Tip Detected</b>	During transition to <b>Ready</b> mode the system has detected that <u>no tip</u> is connected to the applicator; ensure that a valid tip is connected, press <b>OK</b> and proceed with normal operation.
<b>Used Tip Detected</b>	During transition to <b>Ready</b> mode the system has detected that you have connected an expired tip to the applicator; discard the expired tip, connect a new tip, press <b>OK</b> and proceed with normal operation.
<b>Please clean tip and press Ready to continue</b>	This message will pop up during treatment after specific intervals or events; clean the tip per instructions, resume <b>Ready</b> mode and proceed with normal operation.
<b>Tip Is Disconnected</b>	This message will pop up if the tip is inadvertently disconnected during operation; reconnect the tip, press <b>Cancel</b> and proceed with normal operation. If the problem persists replace the tip with a new one.
<b>Tip has expired</b>	This message will pop up when the connected tip reaches the end of its pulse life; discard the used tip, connect a new tip, press <b>Cancel</b> and proceed with normal operation.
<b>Incorrect tip connected. Replace with correct tip type.</b>	The system has detected that an old-style tip is connected to the applicator. The old tips are no longer supported by the system; discard all old-style tips from your stock and use only the new tips.

## Sublime Related Messages

Table 6-2 provides a list of Sublime applicator related pop-up messages that may appear on the LCD screen during the normal course of patient treatment; follow the actions required by the pop-up message and resume normal operation. If the corrective action does not clear the pop-up message, restart the system and try again. If the problem persists, contact Syneron's Service Center.

*Table 6-2: Sublime Related Messages*

<b>Message</b>	<b>Required Action</b>
<b>Bad coupling, bad skin contact</b>	The system has detected that light/RF energy transfer to the skin is less than optimal, probably because there is not full contact or not enough coupling gel applied to the treatment area. Ensure full contact or apply more coupling gel to the treatment area and proceed with normal operation.
<b>Applicator is cooling down</b>	The internal temperature of the Sublime applicator has risen above its design limit and the system has disabled operation until it cools down; wait several minutes and proceed with normal operation.
<b>Replace Sublime IR lamp</b>	The system has detected that the Sublime IR lamp is not functioning correctly and must be replaced. Contact your local Syneron representative.

## System Warning Messages

Table 6-3 provides the list of system warning messages that may appear on the LCD screen during operation. A system warning will disable further use of the system until the problem is resolved. If the corrective action does not resolve the problem, contact Syneron's Service Center.

*Table 6-3: System Warning Messages*

<b>System Warning Message</b>	<b>Probable Cause</b>	<b>Corrective Action</b>
<b>Sublative RF applicator disconnected</b>	The applicator has been disconnected while the system is in <b>Standby</b> or <b>Ready</b> mode.	Connect the applicator to the system and proceed with normal operation.
<b>Sublime applicator disconnected</b>		
<b>Preventive maintenance of Sublime applicator required</b>	The Sublime applicator will require service in the near future.	Contact Syneron Service Center to schedule service.
<b>Preventive maintenance of Sublime applicator required prior to use</b>	The Sublime applicator requires service before it can be used.	Contact Syneron Service Center to schedule immediate service.
<b>Incorrect Sublative RF applicator connected</b>	The wrong Sublative RF applicator is connected to the system.	Connect and use only the Sublative RF delivered with this system [FG7054(x)]

## System Error Messages and Malfunctions

Table 6-4 provides the list of system error messages that may appear on the LCD screen during operation. A system error will disable further use of the system until the problem is resolved. If the corrective action does not resolve the problem, contact Syneron's Service Center.

*Table 6-4: System Error Messages*

<b>System Error Message</b>	<b>Probable Cause</b>	<b>Corrective Action</b>
<b>No Applicators connected</b>	Applicators are not connected properly or are disconnected.	Turn the system off, check applicator connection and turn system on.
<b>Missing Start-Up Values</b>	Software malfunction.	Restart the system. If problem persists, contact Syneron Service Center.
<b>Temperature Fault</b>	Cooling system malfunction.	Turn the system off, allow to cool for several minutes and restart. If problem persists, contact Syneron Service Center.
<b>Missing Calibration Data</b>	Software malfunction.	Restart the system. If problem persists, contact Syneron Service Center.

## Symptoms without Messages

Table 6-5 lists several possible symptoms indicating malfunctions that do not appear on the LCD panel. If the corrective action listed in the table does not solve the problem, contact Syneron Service Center.

*Table 6-5: System Malfunctions Troubleshooting Guide*

<b>Symptom</b>	<b>Probable Cause</b>	<b>Corrective Action</b>
System does not start.	Power cable disconnected.	<ul style="list-style-type: none"> <li>• Check power cable</li> <li>• Plug cable into wall</li> </ul>
	Blown fuse(s).	Replace fuses (refer to Maintenance section)
No display on the LCD.	LCD malfunction.	Call Syneron Service.
Sublative iD tip ceases to function.	<ul style="list-style-type: none"> <li>• Tip disconnected.</li> <li>• System is restarted.</li> <li>• System was shut down as a result of a power failure.</li> </ul>	Replace the tip with a new one.
No light emitted from the Sublime applicator's IR lamp.	IR lamp malfunction.	Check for IR lamp operation by pressing the trigger in Ready mode with the tip pressed against the skin; call Syneron Service if not functioning.



## 7. SYSTEM SPECIFICATIONS

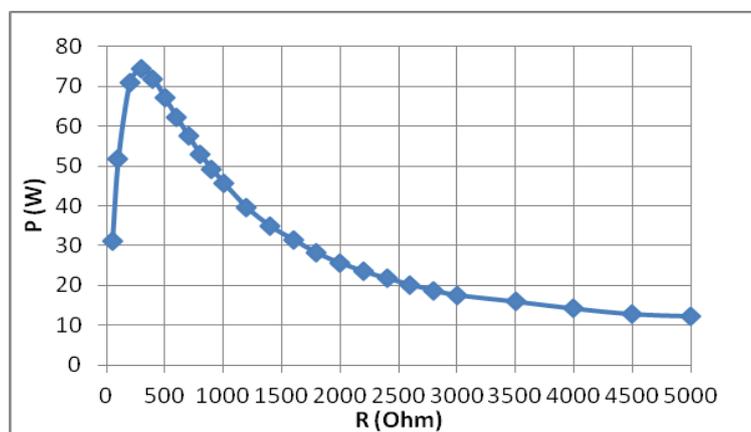
### Sublative RF Output Parameters

- Total RF energy: Up to 62 milliJoules per pin (mJ/pin)
- Programs' RF energy:
  - ⇒ Program A: 10 – 30 mJ/pin, in 5 mJ increments
  - ⇒ Program B: 32 – 48 mJ/pin, in 4 mJ increments
  - ⇒ Program C: 50 – 62 mJ/pin, in 3 mJ increments
- Power range: 20 – 75 W (Impedance: 200 – 2,500 Ohms)
- Max. Voltage output (applicator electrodes):  
275 V<sub>RMS</sub> (without load)
- Electrodes: Two active and bi-polar applicator electrodes (no neutral electrode)

### Sublative RF Power Characteristics

***IEC 60601-2-2:2006 Cl. 6.8.3 bb-1: Output Power versus Load impedance at Half and Full Output Control***

The power curve of the Sublative RF applicator with 144-pins tip is shown in Figure 7-1 below (Half and Full output control diagrams are identical).



***Figure 7-1: Power versus Load Impedance, Sublative RF 144-Pins***

***IEC 60601-2-2:2006 Cl. 6.8.3 bb-2: Output Power versus Output Control at a Specified Load***

Output power of the Sublative RF applicator with 144-pins tip at 500Ω (as a typical load) is 70W for the whole range of output control.

***IEC 60601-2-2:2006 Cl. 6.8.3 cc: Peak Output Voltage versus Output Control***

Peak output voltage of the Sublative RF applicator with 144-pins tip is 275V for the whole range of output control.

## Sublative iD Treatment Tips

- Sublative iD **Standard** tip: 64 electrode pins  
     ⇒ Tip footprint: 12 x 12 mm
- Sublative iD **High Density** tip: 144 electrode pins  
     ⇒ Tip footprint: 12 x 12 mm

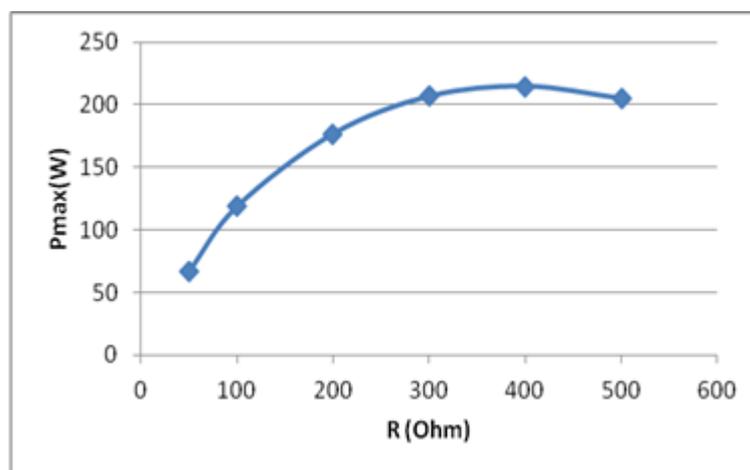
## Sublime Output Parameters

- RF energy density: 40 – 100 J/cm<sup>3</sup>
- Optical fluence: 6 W/cm<sup>2</sup> ± 20%
- Wavelength: 700 – 2000 nm
- Power range: 70 – 200 W (Impedance: 50 – 500 Ohms)
- Pulse repetition rate: 1 Hz
- Tip footprint: 8 x 12 mm
- Max. Voltage output (applicator electrodes):  
     300 V<sub>RMS</sub> (without load)
- Electrodes: Two active and bi-polar applicator electrodes (no neutral electrode)

## Sublime Power Characteristics

### *IEC 60601-2-2:2006 Cl. 6.8.3 bb-1: Output Power versus Load Impedance at Half and Full Output Control*

The Power curve of the Sublime applicator is shown in Figure 7-2 below (Half and Full output control diagrams are identical).



*Figure 7-2: Sublime Power versus Load Impedance*

***IEC 60601-2-2:2006 Cl. 6.8.3 bb-2: Output Power versus Output Control at a Specified Load***

Output power of the Sublime applicator at 200Ω (a typical tissue load) is 175W for the whole range of output control.

***IEC 60601-2-2:2006 Cl. 6.8.3 cc: Peak Output Voltage versus Output Control***

Peak output voltage of the Sublime applicator is 300V for the whole range of output control.

**Electrical Requirements**

- 100 – 240 VAC ±10%; 3A; 50/60Hz; Single Phase

**Environmental Requirements****Treatment Room**

- Temperature: 15° – 30°C [59° – 86°F];
- Relative humidity: 10% – 80%
- Air pressure range: 700 – 1060 hPa [0.70 – 1.06 Bars]

**Storage/Transportation**

- Temperature: 10° – 55°C [50° – 131°F];
- Relative humidity: 10% – 80%
- Air pressure range: 700 – 1060 hPa [0.70 – 1.06 Bars]

**System Display**

- High-resolution color, 15" LCD screen with touch-screen technology

**System Dimensions**

- Closed system [W x D x H]: 53 x 30 x 23 cm / 21.8 x 11.8 x 9.1"
- Open system [W x D x H]: 53 x 30 x 40 cm / 21.8 x 11.8 x 15.7"
- Sublative RF applicator [W x H]: 15 x 16 cm / 5.9 x 6.3"
- Sublime applicator [W x H]: 20 x 20 cm / 7.8 x 7.8"
- Applicator umbilical cable: 190 cm / 74.8"

## **System Weight**

- eTwo/eMatrix system: 8.5 kg. / 18.7 lbs.
- Ablative RF applicator: 0.5 kg. / 1.1 lbs.
- Sublime applicator: 1.0 kg. / 2.2 lbs.