

# Spa Touch **elite**

## User Manual



Smart Skin Solutions  **RADIANCY™**

January 2011, Revision 02



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## **GLOSSARY OF TERMS**

**Efficacy:** The ability to produce a desired effect;

**Erythema:** A reddening of the skin.

**Hyperpigmentation:** A skin condition in which there is excessive pigmentation, often seen as dark spots on the skin.

**Hypopigmentation:** A skin condition in which there is a lack of pigmentation. The skin appears paler than normal.

**Keloids/Hypertrophic scarring:** Smooth, pink, raised, firm, fibrous growths on the skin that form secondary to injury.

**Photosensitivity:** Extreme sensitivity to the sun leaving the patient prone to sunburn. Some medicines have this side effect.

**Pigmentation:** The amount of melanin (molecules containing color) in the skin, hair, & eyes.

**Vellus (facial) hair:** Fine baby peach-fuzz hair that is not easily visible to the naked eye.

## 1. INTRODUCTION TO THE SYSTEM

SpaTouch Elite is a Light & Heat Energy (LHE<sup>®</sup>) based device for the treatment of Hair Removal (HR). It is based on the principle of selective photothermolysis, utilizing specific wavelength range and pulse duration to selectively coagulate the hair follicles with minimal effect to the surrounding skin tissue.

SpaTouch Elite consists of a console, a footswitch and one handpiece. The handpiece contains a pulse switch, a ready indicator light and one treatment lamp. The handpiece is held by the operator and placed directly upon the treatment area. The operator then simultaneously presses the footswitch and the pulse button to emit the therapeutic pulse. In this manual, the term operator applies to all qualified personnel trained to operate the SpaTouch Elite system.

**Important Note** – The SpaTouch Elite user manual is meant as a starting point for treatment, a reference guide of general recommendations. As you gain more experience with the device, you may use your personal expertise to better individualize treatment parameters.

## 2. SYSTEM DESCRIPTION

This chapter provides a detailed description of the SpaTouch Elite system, its main components, controls, and technical specifications. Please review this material to familiarize yourself with controls, ports and connectors, as well as the consumable items used during treatment.

### 2.1. System Components and Controls

The SpaTouch Elite system consists of the following main components (Figure 1):

- System console (main unit)
- Handpiece
- Footswitch



**Figure 1: SpaTouch Elite Main System**



### 2.1.1. Main Unit (System Console)

The main unit controls the operation of the entire system.

It includes the following major parts:

#### Front View:

- Operation Panel, Display Screen, On Switch, Handpiece Cradle



Figure 2: Front View of Console & Panel

#### Right Side View:

- Handpiece power and air connections



Figure 3: Handpiece Connections

## SYSTEM DESCRIPTION

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### Back View:

- Power Cord Inlet, Main Power Switch, Fuse Drawer, Footswitch Port, System Fan Outlet, Air Exhaust Port



**Figure 4: Back Panel**

### 2.1.2. Handpiece

The handpiece connects to the main unit by a spiral cable containing electrical wiring and an air suction hose. The Handpiece consists of an LHE lamp, pulse switch and pulse counter. When not in use, the handpiece should be stored in its niche on the front of the main unit.

**Warning:** Do not drop the handpiece. This may damage the lamp/handpiece.



**Figure 5: Handpiece**

### 2.1.3. Footswitch

The footswitch arrives connected to the main unit. The system will emit a pulse only if the footswitch and handpiece buttons are pressed simultaneously.



**Figure 6: Footswitch**

## 2.2. Technical Information

**Table 1: Technical Specifications**

<b>Technical Specifications</b>	
<b>Light Source</b>	Light & Heat Energy (LHE)
<b>Wavelength Range</b>	
HR	400-1200 nm
HR V-VI (optional)	550-1200 nm
<b>Fluence</b>	4-11 J/cm <sup>2</sup>
<b>Spot Size</b>	
Standard	25 x 50 mm
Adaptor Sizes	13 x 50 mm; 13 x 35 mm; 13 x 12 mm
XL (optional)	35 x 50 mm
<b>Pulse Generation Method</b>	Capacitor bank electrical discharge switch
<b>Physical Dimensions</b>	43 cm x 43 x 22 cm / 16.93 x 16.93 x 8.66 in. (w/d/h)
<b>Weight</b>	7 kg.; 15.43 lbs .
<b>Electrical Requirements</b>	Single phase 100-240VAC, 50/60Hz, 6.3A, 50-60 Hz
<b>Operation Conditions</b>	
Temperature	5°-30° C
Humidity	30%-80% RH
<b>Transport &amp; Storage</b>	
Temperature	-20°- 80° C
Humidity	0%-95% RH; 0.1-1.5 atm.

### 2.3. Safety Features

Many features were built in to the SpaTouch Elite to help insure the safety of the user and client. The following are a few examples:

- Pressing the “**Start/Stop**” button when the confirmation screen appears ensures the operator has selected the correct treatment mode and/or protocols.
- The “Ready” indicator light on the handpiece advises the user when the system is charging (unlit) or ready to emit a pulse (lit).
- The Footswitch prevents accidental pulses.
- An internal and independent safety electronic circuit shuts down pulse flashing ability in the event of a disabled blower.

### 2.4. Major Precautions & Warnings

#### 2.4.1. Precautions

- Verify that SpaTouch Elite's nominal voltage (see label at the bottom of the system console) conforms to the electrical voltage of your electrical outlet. Make sure that the electrical outlet has proper grounding.
- Do not open SpaTouch Elite's outer case, as dangerous voltages are present inside the system.
- Only Radiancy certified personnel are authorized to perform service within the protective covers of SpaTouch Elite.
- This system may not be operated or played with by children. Children must be supervised when they are around or near the system.

- Persons with reduced physical, sensory or mental capabilities, or lack of experience and knowledge, may not operate the system unless they have been given instruction and are under supervision.
- To perform routine maintenance always shut down the system. Disconnect power and wait a minimum of 5 minutes.
- Performing maintenance procedures while the system is connected, or less than 5 minutes from disconnection may be hazardous to the operator and destructive to the system.
- Never use any flammable substance such as acetone or alcohol on the skin prior to treatment.
- Never use flammable substances or harsh chemicals to clean or disinfect any part of the SpaTouch Elite system.
- Always make sure to completely lift the Handpiece off the client's skin between pulses in order to avoid excessive heating of the handpiece or skin.
- When the Handpiece is replaced, repeat testing procedures for each client during the first 500 pulses.

### **2.4.2. Warnings**

- Verify that all safety measures are working properly.
- Delivering excessive energy to the treatment site may cause thermal damage to the skin, resulting in burns, crusting, or abnormal pigmentation.
- As a safety precaution, always have a first aid kit equipped to treat burns at your disposal.
- Although SpaTouch Elite is considered an "eye-safe" device when operated according to instructions, supplying clients

with protective eyewear during facial treatment will provide extra protection against discomfort from light exposure.

- Never look directly at the light coming from the handpiece as this may cause temporary eye discomfort.
- Look away during the flash to further prevent discomfort.
- Never allow the handpiece to emit a pulse into 'free space'. Always make sure that the Handpiece is pointed at and in full contact with the skin during pulse application.
- Even when the Energy level on the screen is set at "0", the system can still trigger a pulse. Therefore be aware of the position of the Handpiece at all times to avoid accidental flashing.
- Always remain in visual contact with the screen to ensure that the established energy is the correct "working energy".
- Pigmented moles and beauty spots and any suspicious (abnormal) pigmented lesion should be covered with a non-flammable white sticker.

### **2.5. Contraindications**

The SpaTouch Elite should not be used on clients who:

- Used any method of epilation other than shaving in the treatment area within the past 30 days.
- Have inflammatory skin conditions or open sores.
- Are pregnant or lactating.
- Have tanned by sun or artificial tanning machine within the last 21 days.
- Have a tattoo or permanent makeup in the treatment area.
- Have abnormal skin conditions due to different diseases, conditions (e.g. diabetes) or medicinal intake.

- Have a history of skin disorders such as vitiligo or psoriasis in the treatment area.
- Have a history of local skin infections.
- Have been treated with isotretinoin (Accutane) within the past 6 months.
- Have used any medications, herbal preparations or chemicals within the past 6 weeks that cause photosensitivity. These include but are not limited to gold therapy, tetracycline or sulfa drugs, and certain psychiatric medications.

In case of uncertainty regarding photosensitizing side-effects, have the client consult their physician.








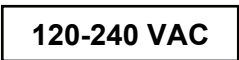

- Suffer from epilepsy.
- Have diseases related to photosensitivity, such as Porphyria, Polymorphic Light Eruption, Solar Urticaria, Lupus and other autoimmune diseases.
- Have a history of herpes outbreaks in the treatment area, unless the client has consulted their physician and received prophylaxis treatment prior to treatment.
- Have a history of skin cancer or clients who have areas of potential skin malignancies.
- Have received chemotherapy or radiotherapy treatments within the past 5 years should not be treated without their acting physician's consent.
- Have been on a steroid regimen (i.e., asthma) over the last 3 months.
- Have an active implant, such as a pacemaker, incontinence device, insulin pump, etc.
- Have any other condition which in the practitioner's opinion would make it unsafe for them to be treated.

## 2.6. Labels

This section describes the labels affixed to SpaTouch Elite. It is recommended that users review the meaning of these labels for everyday use and in case any details are needed for service.

The table below briefly reviews a number of the internationally recognized symbols that are found on the SpaTouch Elite main unit and its external package.

**Table 2: International Standards Labels**

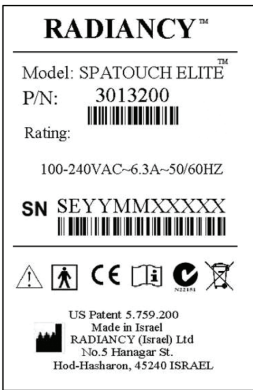


Symbol	Meaning
	Attention, consult accompanying documents before use
	Attention, consult accompanying documents before use
	Manufacturer
	Authorized representative in the European community
	Degree of protection against electric shock: Type BF applied part
	Protect the environment by not disposing of this product with household waste (2002/96/EC). Check your local authority for recycling advice and facilities (Europe only).
	The CE mark represents the compliance to the European Low Voltage Directive 2006/95/EC and the Electromagnetic Compatibility Directive 2004/108/EC.
	Voltage label - appears on the outer package.
	The C-Tick mark represents compliance to Australian EMC Regulations.



## CHAPTER 2

Additional stickers found on the main unit and the handpieces include serial numbers of system parts and usage warnings.

**Table 3: Additional Labels**

Label	Location and Comments
	<p>Located on the back of the system this label includes manufacturer details, voltage information, and the system's serial number.</p>
	<p>Handpiece label located on the SpaTouch Elite handpiece.</p>
<div style="display: flex; justify-content: space-around;"> <div data-bbox="244 981 433 1068" style="border: 1px solid black; padding: 5px; text-align: center;"> <b>100-240VAC</b>  <b>50/60HZ</b> </div> <div data-bbox="454 981 628 1068" style="border: 1px solid black; padding: 5px; text-align: center;"> <b>Fuse 5x20T</b>  <b>250V 6.3A</b> </div> </div>	<p>On rear panel.</p>
<div style="display: flex; justify-content: space-around;"> <div data-bbox="227 1112 417 1232" style="border: 1px solid black; padding: 5px;"> <p style="text-align: center;"><b>DANGER</b></p> <p style="font-size: 8px;">NEVER TRIGGER A PULSE UNLESS THE HANDPIECE OPENING IS IN FULL CONTACT WITH THE TREATED AREA OR THE ABSORBING PAD.</p> <p style="font-size: 8px;">VISIBLE TO NEAR INFRARED LIGHT</p> </div> <div data-bbox="444 1112 646 1232" style="border: 1px solid black; padding: 5px;"> <p style="text-align: center;"><b>DANGER</b></p> <p style="text-align: center;"><b>HIGH VOLTAGE</b></p> <p style="text-align: center;"><b>KEEP OUT</b></p> </div> </div>	<p>On rear panel.</p>
	<p>This warning appears on all handpieces, next to opening.</p>

## **2.7. Compliance with International Standards**

The SpaTouch Elite complies with the following international standards and directives:

EMC Standards:

EN 55014-1, EN 55014-2,  
EN 61000-3-2, EN 61000-3-3

Harmonized Standards:

EN 60335-1; EN 60335-2-27 -  
Household and similar electrical appliances – Part 1:

EU Directives:

- Low Voltage Directive 2006/95/EC  
- Electromagnetic Compatibility Directive  
2004/108/EC

The CE mark represents the compliance to the European Low Voltage Directive 2006/95/EC and the Electromagnetic Compatibility Directive 2004/108/EC.

### **3. INITIAL SET UP**

#### **3.1. Unpacking SpaTouch Elite**

The SpaTouch Elite system is supplied with the following components:

- Main Unit (console)
- 1 Standard Handpiece
  - Optional Handpieces:
    - XL Handpiece
    - Handpiece for sensitive skin (V-VI\*)
- Client Safety Goggles
- 3 Small Area Adaptors
  - Not compatible or available with the XL handpiece
- 1 pack of 10 hygienic rings
- Footswitch
- Power Cable
- User Manual
- 2 Fuses
- Treatment Coat

\*The V-VI handpiece addresses the comfort, safety and efficacy issues of treating clients with skin types V and VI.

#### **3.2. Electrical Requirements**

Before unpacking SpaTouch Elite, make sure the work site meets the following electrical requirements. SpaTouch Elite requires a separate single phase supply line with nominal voltage (according to the local line voltage):

- Single phase 100-240 VAC, 50-60 Hz, 6.3A,

SpaTouch Elite is grounded via the grounding conductor in the power cable that is plugged into the wall power outlet. Good grounding is essential for safe operation of the device.

It is recommended that the system's power cable not be placed on the same circuit as devices with heavy variable loads, such as air conditioning units.

The fuses located within the unit are rated 5x20T, 250V 6.3A for 100-240VAC.

Be sure to use the appropriate fuse for your region's electrical requirements. When a fault in the system occurs, the fuse will burn out and the system will not run.

### 3.3. Installation

SpaTouch Elite is designed for easy installation and does not require any on-site preparation. Installation is carried out as follows:

- Unpack the system and place it in a designated location. It should be placed on a flat, stable surface, such as table, counter or sturdy cart.
- Verify that the system is intact and that all its components are present.
- Verify that the nominal voltage, recorded on the underside of the unit, conforms to the electrical voltage of your country (100-120V/220-240V).

#### 3.3.1. Handpiece Connection

Connect the Handpiece according to the following instructions (Figure 7):

- a. Align the Handpiece power and air connectors with its power outlet and air suction inlet. Use the metal prongs as a guide.
- b. Snap into place.

Power and air connections.



Connected handpiece



**Figure 7: Handpiece Connection**

## INITIAL SET UP

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Note: Turn the system off and unplug it from the electrical outlet before replacing or exchanging handpieces

To remove the handpiece:

- a. Push button on back of connector
- b. Gently pull and pop out connection.

After the handpiece/s are connected:

- Plug the system into a designated electrical outlet.
- Test the system for proper operation.

When not in use, always make sure the handpiece is in its cradle. Do not drop the handpiece. This may cause damage to the lamp and handpiece.

#### 4. GENERAL GUIDELINES FOR THE OPERATION OF SPATOUCH ELITE

The general guidelines below are relevant for all SpaTouch Elite applications. To insure client safety, attain optimal clinical results and protect device performance, operators should adhere to the following protocols.

- **Activate** – Turn on the system
- **Set Energy Levels** – Always use the test energy levels defined in Table 4 as a starting point.
- **Position Handpiece**– Always position the Handpiece in full contact with the skin with 15-20% overlapping. After the pulse is administered, immediately and completely remove the handpiece from the skin.
- **Apply Pulse** – Press the footswitch. With the footswitch pressed, simultaneously push the handpiece pulse switch.
- **Rest Between Pulses** – Remove the handpiece completely away from the skin to prevent preheating the skin.
- **Apply Additional Pulses** – To trigger the next pulse, wait until the “Ready” indicators are lit and the audible signal is heard. Place the Handpiece on the next treatment spot and repeat.

<p><b>WARNING:</b> To avoid eye discomfort, never look directly at the light emitted from the Handpiece.</p>
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- **Overlapping** – Overlap pulses between 15-20%. Stacking (placing one pulse on top of the other) and/or excessive overlapping can cause crusting or blisters which can lead to temporary pigmentary changes.
- **Area Adaptors** – The Area Adapters should be used when treating small or narrow areas. No energy level adjustments are necessary when using the small area adaptors.
- **Hygienic Rings** – Use a new hygienic ring for each client. You may reuse the same hygienic ring for the same client. Remember to clean it after each use.

- **New Handpiece Retest** – Each time an old Handpiece is replaced with a new one, the testing procedure for all existing clients should be repeated for the first 500 pulses.
- **Excessive Energy Level** – Stop treatment if overall redness of the treated area is observed. Full redness of the area may indicate use of an excessive energy level. It is recommended to treat with caution, especially during the initial treatments.
- **Post Treatment** – Mild redness and regional pain may be noticed in the treatment area and can last from a few hours up to a few days. Most clients will feel some discomfort for up to an hour or two after treatment. A post treatment preparation (e.g., Biafine or Aloe) can be used to help soothe the area but should not be used on skin with open wounds. Cold packs alternately applied for 10-15 minutes on the affected area are another post treatment option. If blistering or burns occur, apply first aid for burns and direct your client to seek medical consultation and treatment if necessary.  
If skin crusting occurs, do not continue treatment until the crusting has resolved and completely healed.
- **Sun Exposure** – The client should be advised to avoid sun exposure and/or artificial tanning devices for a minimum of 21 days before and after treatment. If hypo or hyper pigmentation occurs, the client should continue to be diligent about sun or light exposure until it resolves. Pigmentary changes generally resolve within a few months and may be treated with daily application of sunscreen and bleaching creams.
- **Early Termination:** Hair Removal treatment results should be evaluated after 4-7 treatments, depending on the case. If you do not observe at least 30% reduction of hair after 4-5 treatments, you and your client should consider the possibility of early termination.
- **Vellus Facial Hair:** Do not attempt to remove vellus facial hair as induced hair growth may result.

- **Facial Hair:** Before treating clients with excessive facial hair growth, see section 7.6.
- **Photo History:** Radiancy highly recommends that base line pictures be taken before the first treatment and periodically throughout the treatment course. This photo history may be presented as part of the consent form.
- **Fine Hair** – If the chosen energy level provides expected results on most treated areas, but is not sufficiently effective on fine hair, energy may be increased to reach required results on those treatment areas.
- **When to Retreat:** Schedule treatments an average of 21-28 days apart. There should be at least 30% regrowth.
- **Reevaluating Energy Levels:** Energy levels should be reevaluated during each treatment and for each treatment area.
- **Raising the Energy Level:** As treatment progresses, the remaining hair will turn lighter in color and texture. Raise the energy levels accordingly, keeping in mind your client's comfort and safety.
- **Hair and Skin Color:** In all cases, hair must be darker than the skin (even slightly) for successful treatment.
- **Maintenance:** Perform maintenance treatments as needed.



## 5. OPERATION

### 5.1. Turning on the System

1. Turn on the main power switch

Main Power Switch



Figure 8: Main Power Switch Location

2. Press and release the on (⏻) button.

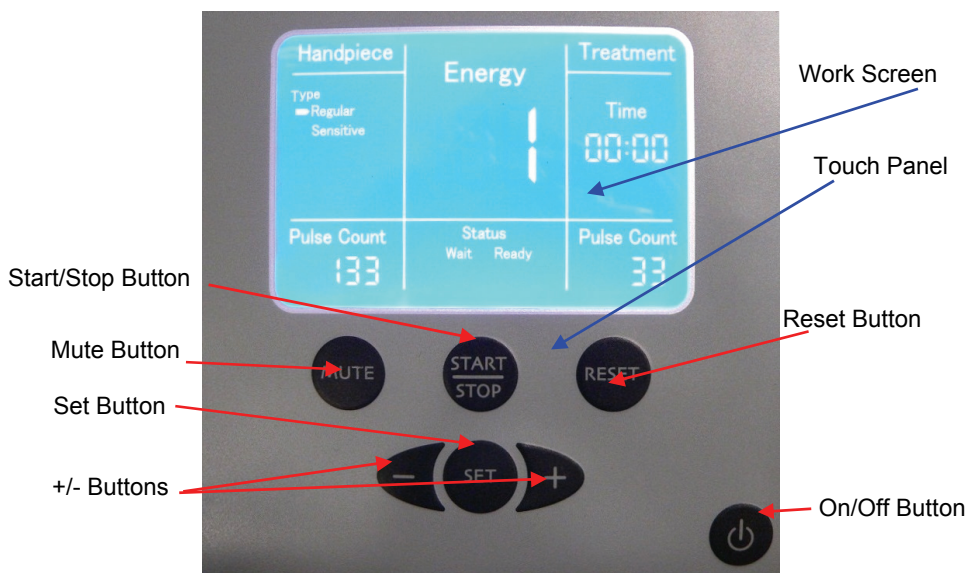
On/Off Button (⏻)



Figure 9: Location of On/Off Button/Switch

### 5.2. Working with the Touch Panel & Screen

SpaTouch Elite's intuitive touch panel is designed to guide you through the entire treatment process. It is recommended to read this section carefully and to become completely familiar with the user-interface before beginning treatment.



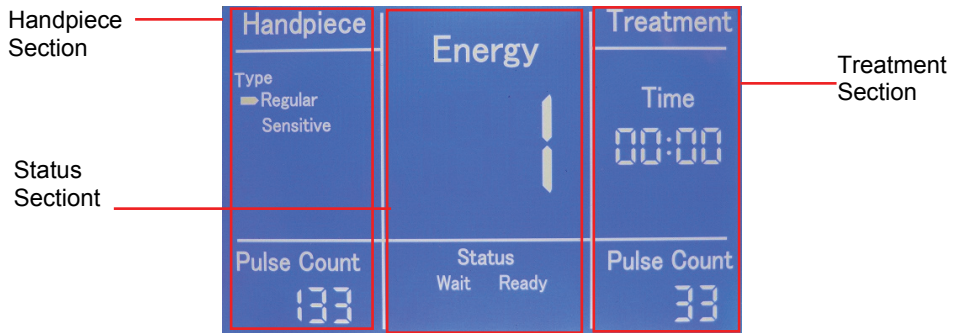
**Figure 10: Touch Panel and Work Screen**

To activate the buttons, firmly, yet gently press the button for the desired function. Refer to Figure 10 for the location and function of each button.

- **On/Off (⏻) Button** – turns the system off and on.
- **Start/Stop Button** – switches between "Ready" and "Wait" modes.
- **Set Button** – sets energy level after adjusting it with **+/-** buttons.
- **+/- Button** – increases (+) or decreases (-) the energy level.
- **Reset button** – resets both the "Time" and "Pulse Count".
- **Mute button** – turns on/off the sound feedback after a pulse emission.

When the system is in mute mode, the icon is lit.

After turning on SpaTouch Elite, the Work Screen (Figure 11) will appear above the control panel.



**Figure 11: Work Screen**

The screen is divided into 3 sections (Figure 11):

- **Left – Handpiece Section.**

This section displays:

- The type of handpiece attached to the unit.
- The total number of pulses emitted by that handpiece.
- An alert when that handpiece approaches its pulse limit.

- **Center – Status Section.**

This section displays:

- The energy level, from 1-100
- The device's readiness to emit a pulse: "Wait" or "Ready"

- **Right – Treatment Section.**

This section tracks pulses and time for each treatment. It displays:

- the elapsed time of current treatment
- the number of emitted pulses for the current treatment
- The fields in this section may be reset by pressing the "**Reset**" button located on the touch panel (Figure 10).

### 5.3. Emitting a Pulse

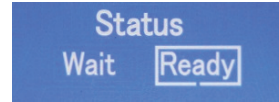
To emit a pulse:

1. Turn on the system (see section 4.2). A blinking square will appear around "Wait" (Figure 12: System Readiness; Wait).
2. Adjust the energy level using the **-/+** buttons.

3. Press the **Set** button to confirm your energy level selection. A blinking square will appear around "**Ready**" (Figure 13).
4. Press the **Start/Stop** button to switch into "Ready" mode. A permanent square will appear around "Ready" when the system is ready to emit a pulse.



**Figure 12: System Readiness; Wait**



**Figure 13: System Readiness; Ready**

5. Emit a pulse
  - Place the handpiece over the targeted treatment area.
  - Simultaneously press the foot and the HP pulse switches.

#### **5.4. Adjusting Energy Level**

- Adjust energy level using the -/+ buttons.
- Press the **Set** button to confirm energy level selection
- Press the **Start/Stop** button to enter "Ready" mode.

#### **5.5. About Ready Mode**

SpaTouch Elite will only emit pulses during the Ready Mode.

The Ready Mode is indicated by two methods.

- An audible signal.
- A permanent square will outline "Ready" (Figure 13) on the Work Screen.

If you wish to exit Ready Mode during treatment, press the **Start/Stop** button once. The permanent square outlining "Ready" will fade, a permanent square outline around "Wait" icon will appear and the system will temporarily go into Rest Mode.

To reenter Ready mode, press the **Start/Stop** button once more.

#### **5.6. System Shut Down**

Press and hold the On/Off button (🔌) for 2 seconds to turn system off.

### 5.7. Alerts

- **Approaching HP Pulse Limit** – When the word "**Approaching**" appears on the Handpiece section of the Work Screen, 1,000 or less pulses remain on the handpiece (Figure 14).
- **HP Pulse Limit Exceeded** – When the Handpiece exceeds its pulse limit, the word "**Exceeded**" will appear on the Handpiece Section of the Work Screen (Figure 15).

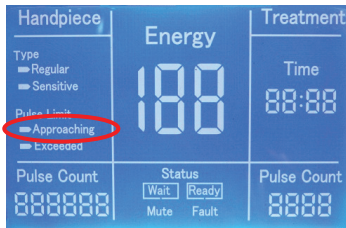


Figure 14: Approaching Pulse Limit

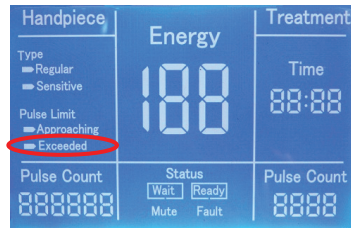


Figure 15: Pulse Limit Exceeded

- **IMPORTANT NOTE:** SpaTouch Elite will NOT operate once the pulse limit is exceeded.

### 5.8. Mute

- Press the **Mute** Button to turn off the sound (Figure 10).
- When the system is in mute mode, the word **Mute** will appear on the Status Section of the Work Screen (Figure 16). System Fault
- Press the **Mute** Button again to return sound. The word **Mute** will no longer appear in the Status Section of the Work Panel (Figure 17).

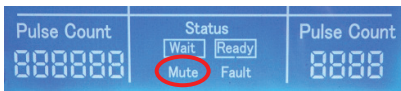


Figure 16: Mute Activated

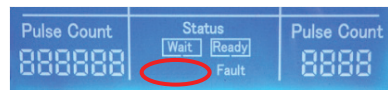


Figure 17: Mute Deactivated

### 5.9. System Fault

When the word **Fault** appears on the Status Section of the Work Screen (Figure 18), shut down the system using the main power switch on the back of the system. Wait 5 minutes, and then turn the system on again using the same switch. If the problem persists, contact an authorized Radiance or a Radiance technician for service.

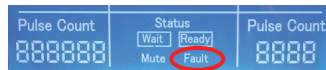


Figure 18: Fault Indicator

## **6. PRE-TREATMENT**

### **6.1. Client History**

- During the first visit, examine the areas intended for treatment and take your client's history.
  - A complete client history includes any and all information regarding previous hair removal methods and treatments and your client's reaction to them. ,i.e: is your client easily irritated by shaving, has had any reactions to waxing or if their skin is generally sensitive to creams and lotions.
- Find out if the client has a history of keloids or hypertrophic scarring. Clients with a history of these conditions should be treated less aggressively.
- Determine your client's skin's type

### **6.2. Side Effects**

- Thoroughly explain to the client the treatment procedure, expected results, possibility of side effects, and the importance of completing a full treatment course. Advise the client that there may be some discomfort, redness or swelling associated with the treatment. There is a minimal risk of more severe side effects such as blistering, changes in texture, and hypo or hyperpigmentation. These side effects are usually transient and should resolve themselves within a few months.
- In case any serious side effects occur, refer to the Adverse Effects Report (Chapter 12). If the effects match any of the criteria found there, copy then fill out the form and send it by FAX or email to your Radiancy Distributor and to Radiancy Ltd. within 48 hours of noticing the effects.

### **6.3. Informed Consent Form**

- Have the client sign an Informed Consent Form (ICF) indicating that they consent and agree to the treatment and that they understand and agree to the procedure and its potential side effects.
- Keep on a hard copy file all client records, including pre-treatment photographs.

### **6.4. Anesthesia**

- Topical or general anesthesia is not required. Should the client feel discomfort, however, it may be recommended. Ice packs may be used or if a topical anesthesia is applied, carefully follow the manufacturer's instructions.

### **6.5. Pre-Treatment Preparations**

#### **6.5.1. Determining the Client's Skin Type**

- To evaluate client's skin type, use the Fitzpatrick Skin Type Classification scale:

##### **FITZPATRICK SKIN TYPE CLASSIFICATION**

- I Always burns, never tans
  - II Always burns, tans less than average
  - III Sometimes burns, tans average
  - IV Rarely burns, tans with ease
  - V Moderately pigmented, always tans
  - VI Deeply pigmented, never burns
- Take into consideration whether or not the client heals darker in the area of an injury or scratch or have a history of keloids or hypertrophic scarring. This can reveal a potential for pigmentary changes after burns.
  - Keep in mind that the client's skin tone may appear darker during the summer when there is greater sun exposure.

- If there is any doubt regarding actual skin photo type, always start treating the client according to the higher option (e.g. a client is skin Type III or IV treat him as a skin Type IV)

**Caution:** As some clients may have a delayed reaction to the light flash, do not perform more than 3 test pulses during the first test session. Wait at least 24 hours before administering the first treatment. For clients with Fitzpatrick Skin Types IV-VI, we recommend waiting at least 48 hours to evaluate the test results.

### **6.5.2. Prior to Treatment:**

- It is highly recommended to take photos of the treated area before, during and at the end of the treatment.
- Thoroughly clean the area to degrease the skin and remove any remains of cream, makeup, or topical anesthesia. Do not use any flammable solutions, such as alcohol or acetone to clean the treatment area.
- Ensure that the skin surface is completely dry.
- Cover moles and pigmented spots with non-flammable white sticker or styptic pencil.
- When treating the face:
  1. Draw back the hair and cover it.
  2. Provide protective eyewear for client.

### **WARNING**

Pigmented moles and beauty spots should be covered with a white sticker. Do not use flammable material.



### **6.5.3. Pre-Treatment Test**

- The purpose of testing is to get to know your client's skin characteristics, understand its sensitivities and to establish the pulse energy level for your client's first complete session.
- Optimal energy level settings differ between clients, skin types, treatment areas and applications.
- The energy levels in the test tables are intentionally conservative and are meant as a starting point. From this starting point, you should be able to pin-point the highest and safest energy level for your client.
- Stay in constant verbal contact with your clients to learn exactly how the treatment is affecting them, what they are feeling and if they are comfortable. This will help you decide whether or not to use a higher energy level.

### **6.6. Post Treatment Care**

- In addition to post treatment care described in Chapter 4, advise the client to avoid bathing in hot water, facial peeling creams or preparations that may irritate the skin for 24 hours following treatment.
- Advise your client to avoid sun exposure during treatment as well as 21 days before and following treatment.
- Advise your client to use sunscreen to protect the skin.

## 7. TREATMENT PROTOCOLS

**IMPORTANT:** When treating skin types V-VI, you must use the optional V-VI handpiece. Do not use the standard handpiece.

### 7.1. Indications

The SpaTouch Elite treatment is indicated for clients in good general health, 18 years of age or older with Skin Types I-VI according to Fitzpatrick Skin Type Classification.

### 7.2. Pre-Treatment

- **Trimming:** Prior to testing or treatment, the hair should be trimmed to a length of 1-2 mm or shaved 3-6 days before treatment and left to re-grow to the desired length of 1-2 mm.
- **Skin Preparation:** Clean, dry and cover spots. Be sure there are no unattached hairs left on the skin surface before beginning treatment.

### 7.3. Pre-Treatment Test

- Set the energy level for the first pulse according to the table below.

**Table 4: Energy Level Setting**

	<b>I</b>	<b>II</b>	<b>III</b>	<b>IV</b>	<b>V</b>	<b>VI</b>
1 <sup>st</sup> Pulse	45	40	35	30	10	0
2 <sup>nd</sup> Pulse	50	45	40	35	15	2
3 <sup>rd</sup> Pulse	55	50	45	40	20	5

- For example, if the client has skin Type III, the energy level for the first test pulse should be set at 35.
- Pulses should be applied on adjacent test spots, include test spots on the intended treatment area.

### 7.3.1. Required Reaction:

- **Darkening/burning of the hair**
- **Skin redness around the hair** (Perifollicular erythema) - immediately or within 10-15 minutes after pulsing.

• **Note for advanced users:** The optimal result is achieved when the hair in the majority of the pulse area has completely disintegrated. If the energy level you're using provides good results but still not optimal, you may attempt to raise the energy level in increments of 2-5 with each pulse until most of the hair in the pulse zone is disintegrated.

- If the required reaction in the target area is observed, this is the appropriate energy level to begin treatment. If the required results do not appear, increase the energy level according to Table 4 until the required results are observed.
- Wait a minimum of 30 seconds between test pulses to determine the skin's reaction.
- If the required result is not observed immediately following or within 24 hours after the test, you have not yet reached the optimum level for the treatment area.
- As you begin treatment, continue to raise the energy level by increments of 5 until the required results are observed. This often means raising the level above those recommended in the table.
- If a side effect occurs at any point, lower the energy level to the last used energy level that did not cause a side effect. Resume treatment only after the skin has completely healed.

### 7.3.2. The Treatment Course

Refer to the Table 5 for treatment course recommendations:

**Note:** Since it is strongly recommended that clients do not use any other method of hair removal while undergoing LHE treatments, the

initial frequency of each treatment course takes into consideration the clients desire to be hair-free, previous methods of removal and hair growth cycles.

### **7.4. Work Protocol**

- 6-10 sessions, with 4-8 weeks between each session.
- Set the initial energy level according to test results.
- According to your judgment, apply ice (non-humid), such as an ice pack, to the site of the next pulse before applying the pulse to increase client comfort.
- Perform one complete pass of the treatment site during each session.

### **7.5. Post-Treatment Care**

- Mild redness in the treatment area is normal and can last anywhere from a few hours to a few days.
- Although some hairs remain intact, most bleached and/or burned hairs usually fall out within two weeks of treatment.
- On the night following treatment, clients should avoid bathing in hot water, or applying any harsh topical that might irritate the skin, such as skin peels.
- Clients should be instructed to cleanse skin with lukewarm water and gentle soap, and hydrate it with a suitable moisturizer.
- Advise your client to avoid sun exposure during treatment as well as 21 days before and following treatment.
- Clients may shave from 2-3 days after treatment until 1 week before the next treatment.
- Advise your client to use sunscreen to protect the skin.
- Perform maintenance every 6 months as necessary.

### **7.6. Considerations for Feminine Facial Hair**

Facial hair is generally obstinate and one of the hardest conditions to treat for successful long term removal. Often caused by chronic or life stage hormonal

## TREATMENT PROTOCOLS

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imbalances, it is important to understand that light-based treatments do not treat the underlying causes of these imbalances and can, at best, offer temporary cosmetic relief. Please note that in some cases, this treatment may stimulate excessive hair growth.

When treating unwanted facial hair it is crucial to correctly set the client's expectations and be very clear about anticipated outcomes. The patient should be informed that the number of treatments needed for acceptable hair removal cannot be pre defined, and additional maintenance treatments may be required. Keep in mind that in most cases, the underlying cause is unclear. This hair removal treatment is cosmetic only and not a permanent solution.

**Table 5: Treatment Course Recommendations**

<b>Method Used Before LHE Treatment</b>	<b>LHE Treatment Course</b>
Waxed once in 3 weeks	Every 3-4 weeks, then gradually lengthen the interval as needed (after 30% regrowth occurs)
Tweezed every week	Every 1-2 weeks for the first 1-2 months, then gradually lengthen the interval to 3-4 weeks and longer as needed (after 30% regrowth occurs)
Tweezed every day	1-2 times per week for the first 1-2 months and , then gradually lengthen the interval to 2-3 weeks and longer as needed (after 30% regrowth occurs)

1. **Maintenance** – Performed every 6 months as necessary.
2. **Early Termination** – Interim treatment results should be evaluated after 4-7 treatments, depending on the case. If the practitioner does not observe at least 30% reduction of hair they should consider, together with the patient, the possibility of early termination.

## 8. MAINTENANCE

### 8.1. Cleaning Instructions

#### Caution:

- Before cleaning the handpiece and main unit, always turn the unit off, disconnect it from energy and wait a minimum of 5 minutes.
- Do not use cleaning solutions that contain ingredients that may harm plastic, such as ammonia, acetone, hydrochloric acid (HCl), chlorine bleach etc.

#### 8.1.1. Lamp & Reflector

During treatment, debris accumulates on the lamp. This may affect performance and the life of the lamp. Use the supplied cleaning tool to clean the lamp after each treatment (Figure 19).

##### Tip A

Use this end to clean between the lamps and reflector.



##### Tip B

Use this end to clean between the lamps

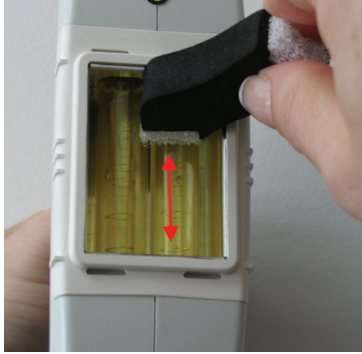
**Figure 19: Handpiece Cleaning Tool**

1. Put 2 drops of alcohol on the sponge part of the cleaning tool (Figure 20)



**Figure 20: Applying Alcohol to the Cleaning Tool**

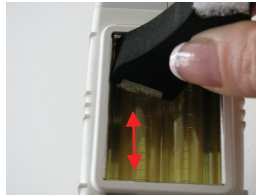
2. Use Tip B to gently rub along the length of the lamps **between the two lamps** until the debris is removed (Figure 21).



**Figure 21: Cleaning the Lamps**

3. Use Tip A to gently rub along the length of the lamps **between the lamp and reflector** until the debris is removed (Figure 22)

**IMPORTANT:** Do not let the sponge part of the cleaning tool touch the reflector. The black part will automatically clean the reflector as you clean the lamp (Figure 22).



**Figure 22: Cleaning the Reflector**

4. Gently remove the remaining debris with a clean, damp lint-free cloth or a cleaning wipe.
5. Make sure the lamp and reflector are completely dry before the next treatment.

### **8.1.2. Main Unit**

- Cleaning of the main unit (system console) should be done with a soft nonabrasive cloth, moistened with mild detergent or soap suitable for external cleaning of electrical equipment.
- Avoid getting cleaning solution into the machine. Spray the solution directly onto the cloth and not onto the unit itself.

## 8.2. Parts & Attachments

### 8.2.1. Handpiece Replacement

- The handpiece must be replaced every 20,000 pulses.
- Remove the handpiece from the system and return it to your Radiancy representative for a replacement.
- Remove the handpiece by pressing down on the top button and pulling straight out. Attach new handpiece according to directions found in section 3.3.1.

### 8.2.2. Area Adaptors

- The Area Adaptors are used when treating different size and shape areas.
- For hygienic reasons, clean the area adaptor between each client with a soft, damp cloth, as you would the handpiece.



**Figure 23: Area Adaptor**

#### **To install the Area Adaptor:**

- Hold the adaptor in one hand and the handpiece in the other. Place the adaptor on the handpiece as shown in Figure 1.
- Align the two tabs with the openings on the small ends of light unit.
- Gently press until you hear a clicking sound signaling that the adaptor is firmly in place.

#### **To remove the Area Adaptor:**

- Hold the adaptor in one hand and the handpiece in the other
- Gently pull off the adaptor

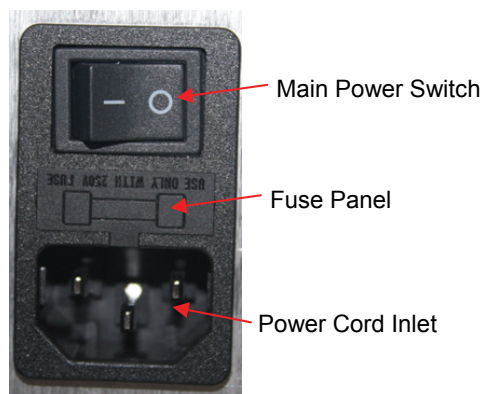


### 8.2.3. Hygienic Rings

Use a new hygienic ring for each client. Simply place the hygienic ring over the lamp opening and push gently into place.

### 8.2.4. Fuse Replacement

- Turn off the unit and disconnect the system from the electrical outlet. Wait 5 minutes.
- Pull out the fuse drawer located in the back panel.
- Replace the fuse and push the drawer back into position.



**Figure 24: Fuse Location**

## 9. TROUBLESHOOTING

Situation/Symptom	Possible Cause	Solution
The system does not turn on (Numbers are not shown on the display and the lights are off)	The "On/Off" switch on the back panel of the system is in the Off position	Toggle the "On/Off" switch to the On position.
	Power cable is disconnected	Toggle the "On/Off" switch to the Off position. Check that the power cable is plugged into the electrical outlet and connected to the main unit power inlet.
	Blown fuse	Check the fuse inside the fuse drawer. Replace fuse if blown.
The "Ready" signal is not heard when the system is ready	The "Mute" switch is on	Press the "Mute" button to turn it to off
A pulse is not triggered when pressing on the Handpiece pulse switch	The Footswitch was not pressed	Simultaneously press the Footswitch and Handpiece pulse switch
	The main unit has not completed the recharging cycle	Wait for the steady Square Ready indicator to be lit on the panel
	The Handpiece pulse switch was pressed before pressing the Footswitch	Release the pulse switch on the Handpiece. Then simultaneously press and hold the Footswitch and the Handpiece pulse switch
	The handpiece is worn out	Check the number of pulses that were performed with the handpiece. Replace If over 20,000 pulses.
	Improper locking of lamp into Handpiece caused darkening of contact points	Stop system operation. Call Radiancy service immediately
The cooling air-flow is weak	Rupture in the Handpiece spiral tube	Replace the Handpiece

## 10. SYSTEM ERRORS:

If a system error occurs, one of the following appears on the work screen: **E1, E2, E3, E4, E5, E6, E7, E8, E9, F1, F2, F3, F4, F5, F6 or F7.**

In all instances, begin by turning off the system using the main power switch located on the back.

Wait 5 minutes and then turn on the system. If the error persists, follow the steps mentioned below. Do not remove the cover to open the system and attempt to fix the problem yourself. This will void your warranty and/or aggravate the problem.

**Table 6: List of System Errors**

<b>Error</b>	<b>Fault</b>	<b>Solution</b>
E1	Blower fault	Shut down the system using the power switch on the back of the system. Contact Radiancy or a Radiancy authorized technician.
E2	Fan fault	Make sure nothing is physically blocking the fan. Shut down the system using the power switch on the back of the system. Wait 5 minutes, and then restart the machine. If nothing is blocking the fan and the problem persists, shut down the system and contact Radiancy or a Radiancy authorized technician.
E3	Handpiece is not properly connected	Shut down the system using the power switch on the back of the system and wait 5 minutes. Detach the handpiece and then reattach it, making sure it is properly connected. Turn the system on once again using the main power switch. If the problem persists, shut down the system and contact Radiancy or a Radiancy authorized technician.
E4	Charging fault	Shut down the system using the power switch on the back of the system. Contact Radiancy or a Radiancy authorized technician.
E5	Unrecognized handpiece Fault	<ul style="list-style-type: none"> <li>• Make sure you are using the SpaTouch Elite handpiece (and not a Mistral or Kona handpiece)</li> <li>• If the problem persists, follow the steps for solution indicated for E3</li> </ul>

		<ul style="list-style-type: none"> <li>If the problem persists, shut down the system using the power switch on the back of the system. Contact Radiancy or a Radiancy authorized technician.</li> </ul>
E6	Handpiece CHECKSUM fault	Shut down the system using the power switch on the back of the system. Contact Radiancy or a Radiancy authorized technician.
E7	300V fault	Shut down the system using the power switch on the back of the system. Contact Radiancy or a Radiancy authorized technician.
E8	600V fault	Shut down the system using the power switch on the back of the system. Contact Radiancy or a Radiancy authorized technician.
E9	Discharge fault	Shut down the system using the power switch on the back of the system. Contact Radiancy or a Radiancy authorized technician.
F1	MUX Fault	Shut down the system using the power switch on the back of the system. Contact Radiancy or a Radiancy authorized technician.
F2	Blower communication fault	Shut down the system using the power switch on the back of the system. Contact Radiancy or a Radiancy authorized technician.
F3	Handpiece communication fault	Shut down the system using the power switch on the back of the system. Contact Radiancy or a Radiancy authorized technician.
F4	Digital POT communication fault	Shut down the system using the power switch on the back of the system. Contact Radiancy or a Radiancy authorized technician.
F5	A2D communication fault	Shut down the system using the power switch on the back of the system. Contact Radiancy or a Radiancy authorized technician.
F6	Handpiece has exceeded its pulse limit.	Shut down the system using the power switch on the back of the system. Wait 5 minutes and replace the handpiece before restarting the system.
F7	Charging over voltage fault	Shut down the system using the power switch on the back of the system. Contact Radiancy or a Radiancy authorized technician.

## 11. SPATOUCH ELITE SERVICE

Radiancy Israel	<b>Radiancy (Israel) Ltd.</b> 5 Hanagar St., P.O. Box 7329 Hod Hasharon, 45240, ISRAEL	Tel: 972-9-775-7500 Fax: 972-9-775-7511 service@radiancy.com
Radiancy North America	<b>Radiancy Inc.</b> 40 Ramland Road South, Suite 200 Orangeburg, NY 10962, USA	Toll Free number: 888-661-2220 Tel: 1-845-398-1647 Fax: 1-845-398-1648 info@radiancy.com

## 12. ADVERSE EVENTS REPORT FORM

Date of Report \_\_\_\_\_

In the case of any of the adverse events listed below, please complete this form and send a copy to your distributor and Radiancy Ltd. no longer than 24-48 hours after you learn of the occurrence. Retain a copy for your own records.

**Radiancy (Israel) Ltd.**  
**5 Hanagar St., P.O. Box 7329**  
**Hod Hasharon, 45240**  
**Israel**  
**FAX: 972-9-775-7511**  
**info@radiancy.com**

**Adverse Event** - Any unwanted medical occurrence in a subject whether or not it is device related.

### **Outcomes attributed to the adverse event :**

- Hospitalization (mm/dd/yy) \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_
- Required intervention to prevent permanent impairment/damage
- Disability or permanent damage
- Death (mm/dd/yy) \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_
- Other serious (important medical events)

**Submission of a report does not constitute an admission of fault or that the medical personnel, facility, importer, manufacturer or product caused or contributed to the event**

### **Client Information :**

First Name: \_\_\_\_\_

Last Name: \_\_\_\_\_

Age: \_\_\_\_\_

Gender : Female  Male

### **Treatment Administration :**

Date of event: (mm/dd/yy) \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

Please specify device used:

Device Name: \_\_\_\_\_

Company: \_\_\_\_\_

Serial Number: \_\_\_\_\_

Where was the treatment done?

Name of Facility: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Who performed the treatment?

Full Name: \_\_\_\_\_

Title: \_\_\_\_\_

Who is preparing and submitting this report?

Full Name: \_\_\_\_\_

Title: \_\_\_\_\_

What sort of treatment was performed ? \_\_\_\_\_

What was the treatment area: \_\_\_\_\_

First time the adverse effect was observed: (mm/dd/yy) \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Date the adverse effect resolved: (mm/dd/yy) \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Please describe in detail the event or problem. If there is not enough room, continue on other paper and attach to report.

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Treatment discontinued?     Yes  No

If yes, provide an explanation for discontinuation:

\_\_\_\_\_

\_\_\_\_\_

---

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Please attach and list all relevant documentation (client file ,discharge report etc.):

---

---

Please include any other relevant client history , including any preexisting medical condition(s):

---

---

Relation to the Treatment:

- Probable
- Possible
- Probably not
- Not related

Event Outcome:

- Resolved
- Improved
- Unchanged
- Worsened



### 13. WARRANTY

After receiving SpaTouch Elite and operating it for the first time, please fill out this Warranty Card and send to:

**Radiancy (Israel) Ltd.**  
**5 Hanagar St., P.O. Box 7329**  
**Hod Hasharon, 45240**  
**Israel**

SpaTouch Elite™ Warranty Card:

#### User Information:

Name: \_\_\_\_\_  
Street: \_\_\_\_\_  
City: \_\_\_\_\_  
State: \_\_\_\_\_  
Zip Code: \_\_\_\_\_  
Tel: \_\_\_\_\_  
Fax: \_\_\_\_\_  
Mobile: \_\_\_\_\_  
E-mail: \_\_\_\_\_

#### System Details:

Serial Number: \_\_\_\_\_  
Purchase Date: \_\_\_\_\_  
Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Was the system received without visible external damage?

Yes  
 No. Please describe: \_\_\_\_\_

Did the system operate properly immediately after installation?

Yes  
 No. Please describe: \_\_\_\_\_





# RADIANCY™

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