



# RADIANCY

Facial Toning Device™



## USER MANUAL

October 2009, Revision 08



# RADIANCY

## Facial Toning Device™

### User Manual

Customer satisfaction is a Radiancy priority. To help us in providing you with the best possible product and support, please send us your comments and suggestions. Contact us at the addresses and telephone numbers below:

#### **US**

Radiancy Inc.  
40 Ramland Road South, Suite 200  
Orangeburg, NY 10962 USA

**Toll Free:** 888 661-2220

**Tel:** +1 845 398-1647

**Fax:** +1 845 398-1648

**E-mail:** [info@radiancy.com](mailto:info@radiancy.com)

#### **Israel**

Radiancy (Isreal) Ltd.  
5 Hanagar Street  
P.O. Box 7329

Hod Hasharon, 45240 Israel

**Tel:** +972 9 775-7500

**Fax:** +972 9 775-7511

**E-mail:** [sevice@radiancy.com](mailto:sevice@radiancy.com)



# List of Content

1. INTRODUCTION TO THE DEVICE .....	4
2. SAFETY INSTRUCTIONS .....	4
2.1. WARNING- To reduce the risk of burns, fire, electric shock, or injury .....	5
2.2. Cautions .....	5
2.3. Contraindications .....	6
3. DEVICE DESCRIPTION .....	7
3.1. Electrical Safety .....	8
3.2. Technical Specifications .....	9
4. TREATMENT PROTOCOLS .....	10
4.1. Client Records .....	10
4.2. General Guidelines .....	10
4.3. Understanding Energy Levels and Pulsing Sequences .....	11
4.4. Scheduling .....	13
4.5. Operating Instructions .....	13
4.6. Post Treatment .....	14
4.7. Labels .....	15
5. MAINTENANCE .....	18
5.1. Cleaning .....	18
5.2. LUA Replacement .....	18
5.3. Replacing the Fuse .....	19
6. TROUBLESHOOTING .....	20
7. SERVICE INFORMATION .....	21
8. WARRANTY .....	23



Before using Radiancy Facial Toning Device™ for the first time we strongly recommend reading through the user manual in its entirety. Pay particular attention to the sections on treatment protocols, operating procedures and post treatment protocols  
Introduction to the Device.



# 1. Introduction to the Device

Radiancy Facial Toning Device represents a breakthrough in the skin care market.

A micro phototherapy device for skin rejuvenation Radiancy Facial Toning Device can be used either as a stand alone treatment or packaged as part of a more comprehensive skin care program.

In clinical trials, skin histology showed an increase in the density of organized collagen fibers and the formation of new collagen after a course of treatment with the device. These improvements resulted in the rejuvenation of the skin's appearance and an improvement in overall skin texture and fine lines.

Radiancy Facial Toning Device is based on Radiancy's patented LHE® technology. LHE has been a mainstay in the professional phototherapy field since 2001 and has a solid reputation of safety and reliability.

## 2. Safety Instructions

As with any electrical device, certain precautions must be taken in order to ensure your safety and that of your client.

**READ ALL INSTRUCTIONS BEFORE USING  
ALL WARNINGS AND CAUTIONS SHOULD BE STRICTLY FOLLOWED**



## 2.1. WARNING - To reduce the risk of burns, fire, electric shock, or injury:

1. Use this device only for its intended use as described in this manual.
2. Always check the LUA for brown or darkened spots in the area inside the LUA opening before use. If any spots appear, do not use the LUA, instead return it to your distributor for replacement.
3. This device should never be left unattended when plugged in an outlet.
4. Never operate this device if it has a damaged cord or plug, if it is not working properly, if it has been damaged or dropped into water. Return the device to a service center for examination or repair.
5. Do not attempt to open the handpiece or base of this device.
6. Do not attempt to touch the hot area within the Light Unit Assembly (LUA).
7. Do not use an extension cord with this device. This device should be used only with the supplied AC cord.
8. Do not reach for an appliance that has fallen into water. Unplug immediately.
9. Do not place or store appliance where it can fall or be pulled into a tub or sink. Do not place in or drop into water or other liquid.
10. Always unplug this device from the electrical outlet immediately after using.
11. Unplug this device before cleaning.

## 2.2. Cautions

1. Do not apply the handpiece on birthmarks or pigmented lesions, like sun spots and age spots.
2. Birthmarks or pigmented lesions should be covered with a non-flammable white sticker prior to treatment.
3. Never look directly at the light coming from the Handpiece as this may cause eye injury.



4. Do not use this device on the eyelids or eye socket area.
5. Always provide protective eyewear whenever treating the face.
6. Never point the Handpiece so it emits a light pulse into free space. Make sure that during treatment the Handpiece is pointed at, and in full contact with, the skin.
7. Always remove the handpiece from the skin if the client indicates that it is too hot
8. Do not use flammable liquids such as alcohol or acetone to cleanse the skin prior to treatment.
9. Use of this product may cause temporary pigmentation changes.

## 2.3. Contraindications

Do not use this device on clients who:

1. are skin type VI.
2. are pregnant or lactating.
3. were exposed to strong sunlight or an artificial tanning machine in the past 21 days.
4. have a tattoo or permanent makeup in the treatment area.
5. have used medications, herbal preparations, lotions, or other chemicals that cause photosensitivity within past 6 weeks.
6. have abnormal skin conditions due to diabetes, for example, or to other diseases.
7. have been treated with Accutane within the past 6 months.
8. have been on a steroid regimen (i.e., asthma) for the last 3 months.
9. have a history of herpes outbreaks in the area of treatment, unless the client has consulted their physician and received prophylaxis treatment prior to Radiancy Facial Toning Device treatment
10. suffer from epilepsy.



11. have an active implant, such as a pacemaker, incontinence device, insulin pump, etc.
12. have diseases related to photosensitivity, such as Porphyria, Polymorphic Light Eruption, Solar Urticaria, Lupus.
13. have a history of skin cancer or areas of potential skin malignancies.
14. have received radiotherapy or chemotherapy treatments within the past 3 months.
15. have any other condition which in the practitioner's opinion would make it unsafe for them to be treated.

### 3. Device Description

Radiancy Facial Toning Device is a non-invasive Light and Heat based device that is designed to initiate collagen regeneration in the dermis, rejuvenating the skin's appearance and leading to the toning and tightening of the skin and the improvement of skin texture.

Radiancy Facial Toning Device is made up of three main components; the Base, on which is located the control panel and power switch (on/off), the Handpiece with the replaceable LUA and the power cord.



Figure 1 – Radiancy Facial Toning Device



The control panel contains indicator lights for power, ready, and charging. There is also a mute switch, and energy level settings for low, medium and high.

### 3.1. Electrical Safety:

Degree of protection against ingress water: ordinary

This device is not suitable for use in the presence of flammable anesthetic mixture with air or with Oxygen or Nitrous Oxide.

The design and technical specifications are subject to change without notice.



## 3.2. Technical Specifications

Light source:	LHE® (Light and Heat Energy)
Pulse duration:	2.2 msec
Fluence:	High 12 J/cm <sup>2</sup> in one working cycle (6.7 Sec.)
	Medium 9.6 J/cm <sup>2</sup> in one working cycle (5.3 Sec.)
	Low 6 J/cm <sup>2</sup> in one working cycle (3.3 Sec.)
Spot size:	14 x 27 mm
Wavelength:	400-1200 nm
Weight:	1.3Kg (2.8lbs)
Physical dimensions:	29.5 x 21 x 5.5cm (W x D x H) (11.6" x 8.3" x 2.2")

Mode of operation: Continuous

### Operation Conditions

Temperature:	5°C-30°C
Humidity:	30%-80% RH
Rating:	100/110VAC ±10% 25A 50-60 Hz 230VAC ±10% 16A 50-60 Hz

### Transport and Storage

Temperature:	-20°C to 80°C
Humidity:	0%-95% RH
Atmospheric pressure:	0.1-1.5 atm.



## 4. Treatment Protocols

### 4.1. Client Records

Keeping client records is very important both in treatment and post treatment client satisfaction. For your convenience we recommend using Client Profile forms. The forms will help you track: the number of visits, the energy level used during the last treatment and the number of passes as well as miscellaneous information such as physiological reaction to treatment and client responses to the treatment.

Another important factor in ensuring optimal client satisfaction is the use of a photographic diary which should be incorporated into the Client Profile. Collagen renewal can take up to several months to become noticeable. Since the changes are subtle and occur over time it is important to have a photographic diary that will graphically document the improvement.

Always have the client sign an 'Informed Consent Form' before commencing treatment.

### 4.2. General Guidelines

Radiance Facial Toning Device can be used as a stand alone treatment, or may be combined with skin supplements.

While you should rely on your experience and expertise in this area we offer the following suggestions as to the best way to incorporate Radiance Facial Toning Device into a comprehensive skin care program.



- Cleansing
- Drying the face
- 2 passes with Radiancy Facial Toning Device
- Cooling hydrating mask
- Massage (non-oily lotion)
- Application of toners
- Application of moisturizers
- Application of sun screen

### 4.3. Understanding Energy Levels and Pulsing Sequences

**Note:** Energy levels should always be set according to your client's comfort level. Since some clients may find the Radiancy Facial Toning Device treatment uncomfortably hot on their skin it is very important to be cautious as you proceed with treatment.

1. There are three energy level options; low, medium and high. Each energy level setting represents the number of pulses being delivered during the pulse sequence. The more pulses delivered during the sequence, the higher the total level of energy ultimately delivered to the treatment area. It is therefore important to deliver the maximum total light energy possible during treatment without causing excessive redness or pain.
2. It is also important to explain to your client that the more light energy delivered to the skin the better will be the effectiveness of treatment.
3. Differences in skin type, biology and comfort levels usually dictate that a client must initially be treated at the lower energy level settings. After the first 1-2 treatment sessions, however, the skin generally becomes less sensitive, which will allow you to gradually increase the energy level during subsequent treatments.



4. **Note:** Since, as mentioned earlier, the goal is to deliver the highest number of pulses, it is recommended to use a higher setting even if it means that you need to remove (due to client discomfort) the Handpiece before the sequence is completed.

Whatever level you treat at it is very important that the client's comfort level be your guide to energy level setting. The device uses trains of pulses, which you can stop at any point by lifting your finger off the pulse switch and lifting the Handpiece off the skin. Set an agreed sign with the client to mark her/his point of tolerance.

#### **Cautions:**

Skin Types IV & V should only be treated on the Low Energy setting.  
Skin Type VI should not be treated with Radiancy Facial Toning Device.

Evaluate your skin type according to the Fitzpatrick Skin Type Classification below.

#### **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

#### **ENERGY LEVEL SETTINGS**

Skin Type	Beginning Energy Level
I-III	Low-Medium
IV-V	Low

**Note:** Darker skin may be more sensitive to the energy emitted from the LUA and may therefore require a lower energy level setting.



## 4.4. Scheduling

For optimal results, Radiancy Facial Toning Device treatments should be performed twice a week for 4 to 5 weeks.

## 4.5. Operating Instructions

**The skin must be clean and completely dry before**

1. Before you plug in the device, verify that the Light Unit Assembly is locked correctly into the Handpiece. A spring mechanism allows the Light Unit Assembly to retract when pressed to the skin.
2. Attach the power cord to the device.
3. Plug the cord into an electrical outlet.
4. Apply a new hygienic ring. Never reuse hygienic rings between patients.
5. Press the power switch to turn on the device. Once the Ready Indicator turns on you can start treatment.
6. Using light pressure, apply the Handpiece opening to the skin. Make sure to stretch the skin where you apply the Handpiece. Once the Handpiece opening is applied correctly to the skin an audio signal is heard. Always make sure the LUA is in full contact with the skin before pushing the Pulse Switch.
7. Press and hold the pulse switch to trigger a sequence of therapeutic light pulses. This sequence takes a few seconds, depending on the energy level setting (see specifications).

**If during the pulse sequence the client complains that the Light Unit Assembly feels too hot on the skin, remove it and wait until the Ready Indicator turns on again.**

8. After emitting a pulse sequence, remove the Handpiece from the skin for about 10 seconds to allow the Light Unit Assembly to cool down. Apply the next sequence **only** when the Ready Indicator turns on.



9. Placing the handpiece on the skin before the “Ready” indicator turns on may result in unwanted side effects due to pre-heating of the skin.
10. **Note:** if at any point the device goes into “Charging” mode for longer periods, this is due to an internal safety mechanism that monitors the LUA temperature and is designed to avoid over-heating. Wait until the Ready indicator light turns on again, and only then replace the Handpiece on the skin.
11. Administer pulses on the treatment area sequentially from right to left, in a horizontal pattern. Stacking/overlapping can cause crusting or blisters which might result in transient pigmentation changes.
12. After covering the entire area, wait one to two minutes to allow the skin to cool down, and repeat the procedure making sure to begin at the initial starting point with the handpiece held vertically.
13. Record the treatment in your LUA log.

**When treatment is completed turn the device off by pressing the power switch. Stop treatment if you see full redness of the skin, blistering, or burns.**

14. **Note:** Make sure to wait 5 minutes between two consecutive clients.

## 4.6. Post Treatment

Instruct patients to avoid sun exposure or protect their skin with sunscreen throughout the treatment process and at least for 3 weeks following the last treatment.

Advise the client that in any case it is preferable to avoid sun exposure, because this is a critical factor in skin aging.

Some clients may experience hyperpigmentation resulting from the treatment. These effects, when they occur, are generally mild and transient and may be treated with a bleaching agent. Also recommend that your client stay out of the sun until the condition resolves.






## 4.7. Labels

This section describes the labels affixed to the FTD. It is recommended that users review the meaning of these labels for everyday usage, 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 FTD main unit and its external package.

## STANDARD INTERNATIONAL SYMBOLS ON FTD

Symbol	Meaning	Comments
	Attention! Consult accompanying documents	
	Degree of protection against electric shock: Type BF applied part.	
	The CE mark represents the compliance to the European Low Voltage Directive 2006/95/EC and the Electromagnetic Compatibility Directive 2004/108/EC.	Appears on 230V devices only.
230V~	Voltage sticker, appearing on outer package	On 100V & 110V systems, sticker will say "100-110VAC"



## STANDARD INTERNATIONAL SYMBOLS ON FSD

Symbol	Meaning	Comments
	On/Off sign	
	Class II equipment – double insulation	
	The C-Tick mark represents compliance to Australian EMC Regulations.	
	Protect the environment by not disposing of this product with household waste (2002/96/E). Check your local authority for recycling advice and facilities (Europe only).	
	The symbol on the label affixed to this device means "Attention, consult accompanying documents".	



In addition, other stickers are found on the main unit and the LUAs. These include serial numbers of system parts and some usage warnings. See table below.

### ADDITIONAL LABELS

Label	Location and Comments
<p><b>RADIANCY™</b>        Model: Radiancy Facial Toning Device™        P/N: 3004170        Rating: 100-115V ~ 1.4A        50-60Hz        SN FTDYYMMXXXXX</p> <p>U.S. Patent 6,187,001 and other pending patents</p>	<p>Located at the bottom of the system this label includes manufacturer details, voltage information, and the system's serial number. (100V systems and 230V systems, respectively. There is also a sticker for 110V systems).</p>
<p><b>FUSE</b>  <b>T1.4AL250V</b>        P/N: 2004810</p>	<p>On rear panel, above power inlet.</p>
<p><b>Warning</b>        Do not look directly at the emitted light</p>	<p>This warning appears next to the opening on all LUAs</p>
<p>S022101</p>	<p>On LUA – Serial Number</p>



## 5. Maintenance

### 5.1. Cleaning

Always unplug the device prior to cleaning it. Only use a specially formulated cleaner for electronic equipment. Never immerse the unit or any of its parts in water.

### 5.2. LUA Replacement

The LUA has a life of 80,000 pulses or approximately 200 full facials. Although the lamp may continue to flash after that, the pulses will be weak and ineffectual. To ensure effectiveness always replace the LUA after 200 full facials.

To replace the Light Unit Assembly:

1. Turn the device off and unplug the cord from the electrical outlet.
2. Grasp the LUA by both ends and pull it out of the socket, as shown in Figure 2.
3. Line up the holes in the socket with the metal and plastic posts in the LUA and push it gently into place, as shown in Figure 3.
4. If correctly installed, the LUA will spring back when pushed.



Figure 2



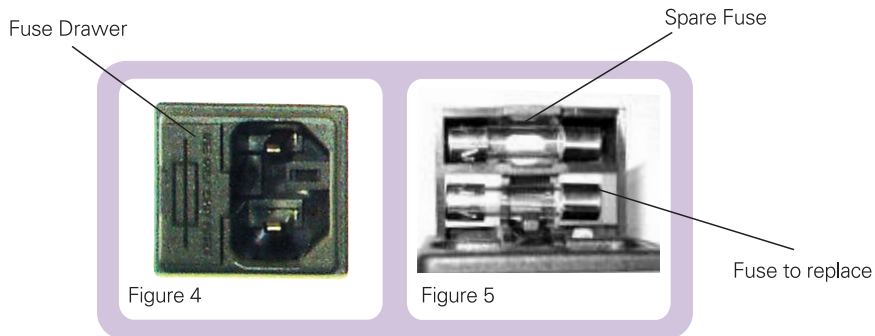
Figure 3



### 5.3. Replacing the Fuse

Should the device turn off unexpectedly or fail to operate when you have plugged it in and pushed the on/off switch, it is possible that you may have a blown fuse. To check this:

1. Turn the device off and unplug the cord from the wall electrical outlet.
2. Pull out the fuse drawer located at the rear part of the base (Figure 4). Remove the inner fuse (Figure 5). Check the filament if it is severed the fuse needs to be replaced.
3. Replace the fuse with the spare (located in the outer bay of the fuse drawer) and push the drawer back into place.





## 6. Troubleshooting

1. If the device does not start:
  - a. Make sure that the power cord is connected into the wall electrical outlet.
  - b. Check the fuse inside the fuse drawer. Replace fuse if blown. (see 5.3 for instructions on replacing the fuse)
2. If a pulse sequence is not released when pressing the Pulse Switch:
  - a. Gently press the Handpiece opening onto the skin and listen for the audio signal. If there is no audio signal contact the Radiancy Facial Toning Device service center.
  - b. The device might be overheated. Turn off the device for 30 minutes to allow it to cool down.
3. If the rate of pulses within a sequence slows down or if the Charging and Ready Indicators turn on and off repeatedly:
  - a. The device may be overheated. Turn off the device for 30 minutes to allow it to cool down.

If the problem persists, contact the local Radiancy Facial Toning Device service center.



## 7. Service Information

### US

Radiancy Inc.  
40 Ramland Road South, Suite 200  
Orangeburg, NY 10962 USA

**Toll Free:** 888 661-2220

**Tel:** +1 845 398-1647

**Fax:** +1 845 398-1648

**E-mail:** info@radiancy.com

### Israel

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

**Tel:** +972 9 775-7500

**Fax:** +972 9 775-7511

**E-mail:** sevice@radiancy.com



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The Quality Management System of Radiancy complies with the Quality Management Standard ISO 13485-2003.



**Manufacturer:** Radiancy (Israel) Ltd., 5 Hanagar St., P.O. Box 7329, Hod Hasharon, 45240, Israel, Tel: 972-9-775-7500, Fax: 972-9-775-7511



**European Representative:** Obelis S.A., Av. de Tervuren 34 Bte .44, B-1040 Brussels, Belgium: Tel: 32 (0) 2 732 5954, Fax: 32 (0) 2 732 6003, GSM 07545 4660, e-mail: [mail@obelis.net](mailto:mail@obelis.net)



## 8. Warranty

After receiving Radiancy Facial Toning Device and operating it for the first time, please fill out this Warranty Card, photocopy and send to:

**Radiancy (Isreal) Ltd.**  
**5 Hanagar Street**  
**P.O. Box 7329**  
**Hod Hasharon, 45240 Israel**  
**Fax: +972 9 775-7511**

### RADIANCY FACIAL TONING DEVICE™ WARRANTY CARD:

#### User Information:

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

Street: \_\_\_\_\_

City: \_\_\_\_\_

State / Province: \_\_\_\_\_

Country: \_\_\_\_\_

Zip Code: \_\_\_\_\_

#### System Details:

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

Purchase  
Date: \_\_\_\_\_

Comments: \_\_\_\_\_

Tel / Fax / Mobile: \_\_\_\_\_

E-mail: \_\_\_\_\_

Was the system received without visible external damage? No ☐ Yes ☐

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

Did the system operate properly immediately after installation? No ☐ Yes ☐

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



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