

HAIRMAX  
.com

*Lux 9, Professional 12*



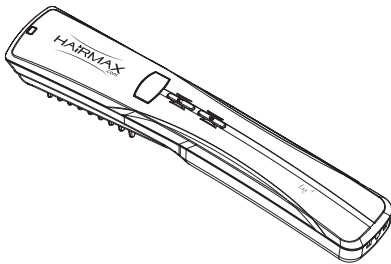
**USER MANUAL**

# HairMax Lux 9 & Professional 12

The HairMax LaserComb has helped hundreds of thousands of people combat their hair loss and grow beautiful hair. Now, Lexington is proud to introduce the next generation of the revolutionary HairMax LaserComb®.

## Introducing the New HairMax Lux 9 and Professional 12

Using advanced laser technology, the Lux 9 and Professional 12 provide safe and nourishing laser light energy to weakened hair follicles. The laser light energy stimulates the hair follicle, promoting new hair regrowth and producing healthier, more beautiful hair. The new Lux 9 and Professional 12 provide safe and effective at-home treatment as the original HairMax, but now are cordless. The new Lux 9 and Professional 12 feature a sleek ergonomic design with a rechargeable lithium ion battery to give you the freedom of movement as you treat your thinning hair.



The new HairMax Lux 9 and Professional 12 utilize the patented hair parting teeth mechanism. Remember, the laser treatments are only effective when the laser reaches the scalp. The teeth part the hair, moving it aside, to allow the maximum amount of laser energy to reach the scalp and energize the weakened hair follicles.

Like brushing your teeth to maintain healthy teeth & gums, regular HairMax usage is recommended. Use the HairMax three times a week on non-consecutive days for about 8 -11 minutes a session (eight minutes for Professional 12 and eleven minutes for Lux 9). Over the first few months, you may notice a gradual increase in the number of hairs in a specific location. Most users realize on-going improvements as they continue to use the HairMax. If you stop treating your scalp with the HairMax, your hair may regress back to its previous state.

## ABOUT LEXINGTON INTERNATIONAL



Lexington International, LLC is a leader in hair growth, hair care and hair science. The technology behind the HairMax LaserComb is a result of 20+ years in Research & Development in Sydney, Australia. Our primary objective is to help those suffering from Androgenetic Alopecia. The goal is to provide an effective treatment that is affordable, easy to use and provides noticeable results without adverse side effects. Lexington bases its success on the number of people whose lives are enriched. We truly care about conducting our business ethically and appropriately.

Because of this, Lexington complies with the FDA's Good Manufacturing Practices, is ISO 9001 & 13485 certified in quality standards and our products meet CE requirements for safety. Lexington's products are also Patented and Trademarked across the world.

## BENEFITS

The HairMax LaserComb is a home-use Low-Level Laser PhotoTherapy device to treat hair loss (Androgenetic Alopecia) and promote hair growth. Laser PhotoTherapy process bathes the hair and scalp in laser light to **energize weakened hair follicles**. In addition to **new hair growth** and reduction in shedding, many users also routinely report **normalization of scalp conditions, increased body, shine and manageability of their hair**.

Individual results may vary. Over time, most users continue to see an improvement of their hair and scalp conditions. If you stop using the HairMax your hair may regress back to its original state.

More reasons why HairMax users are satisfied with HairMax:

- Real Results within just weeks
- Thicker, Fuller, Healthier Hair
- Improved Hair Condition
- Convenient Home Treatment
- Certified, Completely Safe
- High User satisfaction

## **CLINICAL DATA**

The results of the key clinical study performed with the HairMax LaserComb led to US FDA Clearance to market in January 2007. This was considered a landmark event in the treatment of Androgenetic Alopecia. These clinical results were published in *Peer Reviewed Journal "HairMax LaserComb Phototherapy Device in the Treatment of Male Androgenetic Alopecia"*<sup>\*</sup>.

### **Study Objectives**

The study was conducted to support the FDA 510(k) submission and was subjected to an Investigational Review Board (IRB) approval and conducted in accordance with GCP (Good Clinical Practices). The objectives of the study were to assess the following:

- Promotion of hair growth through changes in hair density
- Cessation of hair loss
- Overall scalp health
- Safety

### **Study Design**

The study was designed as a multi-centered, double- blinded, randomized sham-device controlled trial conducted at four sites in the United States. Subjects were instructed to use the laser hair growth treatment device three times per week on non-consecutive days, for a total of 26 weeks. Hair density measurements were performed at baseline, immediately prior to randomization and again at 26 weeks.

### **Subject Population and Demographics**

The study population included males between the ages of 30 and 60 years with a diagnosis of Androgenetic Alopecia who had been experiencing active hair loss within the last 12 months. The inclusion criteria required a Norwood-Hamilton Classification of IIa to V and Fitzpatrick Skin Type Classification of I to IV.

### **Clinical Results**

Subjects in the HairMax LaserComb® laser hair treatment group had significantly greater increase in mean terminal hair density than subjects in the sham group ( $p < 0.0001$ ). Subjects in the HairMax LaserComb® group also had significantly better subjective assessments of overall hair growth than subjects in the sham group ( $p = 0.010$ ). No subject experienced a serious adverse event from the laser hair loss treatment and the adverse event profiles were similar between the two treatment groups.

<sup>\*</sup>Clin Drug Invest 2009; 29 (5): 283-292

## **⚠️ WARNINGS AND PRECAUTIONS**

**WARNING:** Only use the HairMax according to the instructions provided. Any other use is not recommended.

**WARNING:** Basic safety precautions should be observed when using this, or any other electrical device. Do not allow children to use or play with the HairMax. Keep out of reach of children. It is not a toy.

**WARNING:** Laser Light - Avoid Direct Eye Exposure. Do not point laser or allow laser light to be directed or reflected toward other people. Never use magnifying optical instruments with the HairMax. Do not stare directly at the laser light or its reflection off a mirror-like surface. Doing so can cause temporary irritation to your eyes. Prolonged direct exposure can harm your eyes.

**CAUTION:** If you are taking any photosensitizing medications or receiving any therapy that sensitizes the skin to light, use caution when using the HairMax. Please consult your physician if you have any other concerns.

**CAUTION:** Never use acetone or other solvents on any part of the HairMax. Use of solvents on the window can block the laser light from coming through.

**CAUTION:** Never use the HairMax if the cord or plug is damaged. Do not put strain on the cord. If any malfunction occurs, do not attempt to repair the HairMax yourself. This appliance has no user-serviceable parts and is not to be opened or modified by the user. Use the HairMax only for its intended use as described in this manual. Contact Lexington International LLC for repairs at 561.417.0200.

### **The following laser safety label can be found on this product:**



**Wavelength:** 655 nm  
visible red light

This Laser Product is designated as Class 3R during all procedures of operation.

**Note:** HairMax LaserComb has no user-serviceable parts.

**Location:** On the underside of the handle  
Model version varies

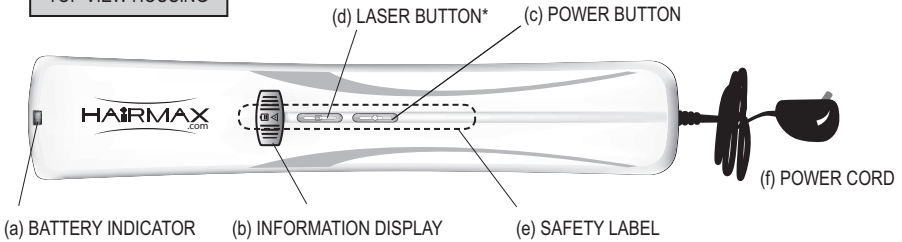
Accessible  
Laser  
Parameters

Wavelength 655 nm  
Laser Power for classification <5mW CW  
Beam Diameter <5 mm  
Divergence 57 mrad  
Number of lasers 9, 12

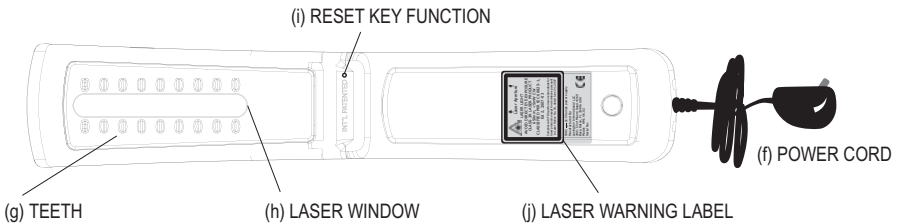
Please visit <http://www.internationalhairmax.com/QualitySafety>  
for more information or call 561.417.0200

# HAIRMAX Lux 9 & Professional 12 - PARTS

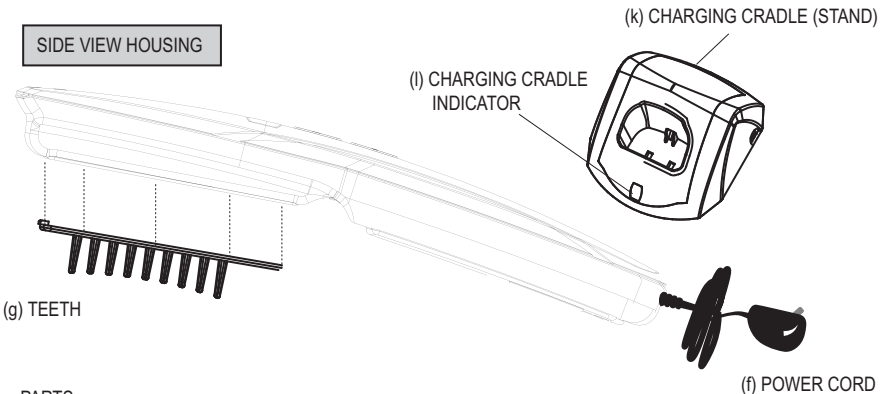
## TOP VIEW HOUSING



## BOTTOM VIEW HOUSING



## SIDE VIEW HOUSING



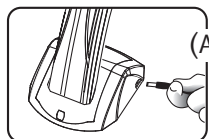
### PARTS:

- (a) BATTERY INDICATOR - Yellow during charging. Green is fully charged.
- (b) INFORMATION DISPLAY - Laser ON, Battery Level, Usage Time.
- (c) POWER BUTTON with GREEN light indicator - Turns on power.
- (d) LASER BUTTON with RED light indicator - Turns on laser (POWER button must be pressed first).  
\*Caution - Use only as directed. Any variation of controls, adjustments, performance or procedures, other than those specified, may result in hazardous exposure to laser light.
- (e) SAFETY LABEL (removable) - "PLEASE REFER TO OUR USER MANUAL BEFORE USING THIS PRODUCT."
- (f) POWER CORD - International. 110-240VAC.
- (g) TEETH - removable for cleaning
- (h) LASER WINDOW - Do not look into laser window when laser is turned on. See CAUTIONS
- (i) RESET KEY FUNCTION - to reset HairMax.
- (j) LASER WARNING LABEL - contains SERIAL NUMBER - not removable.
- (k) CHARGING CRADLE (STAND) - Stores and charges HairMax.
- (l) CHARGING CRADLE INDICATOR - RED during charging, GREEN is fully charged.

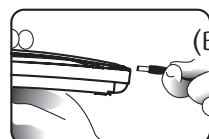
## METHODS OF CHARGING THE HAIRMAX

The HairMax is equipped with a built-in Lithium Ion Battery and once charged can be used without the attached power cord. The battery can be recharged thousands of times to provide years of continuous use.

Charging can be accomplished in the two following ways:



(A) **Method 1:** Charging the HairMax using the CHARGING CRADLE (stand) and power cord. See graphic (A).



(B) **Method 2:** Charging the HairMax by placing the POWER CORD directly into the handle end of the HairMax. See graphic (B).

## CHARGING INSTRUCTIONS

- 1) Read and understand all instructions prior to use.
- 2) Make sure to fully charge your HairMax prior to using it for the first time.
- 3) Remove the HairMax, CHARGING CRADLE and POWER CORD from the case.
- 4) Remove the SAFETY LABEL to gain access to the POWER and LASER BUTTONS.
- 5) Connect one end of the POWER CORD to the CHARGING CRADLE and insert the other end of POWER CORD to an indoor electrical wall outlet.
- 6) Place the HairMax in the CHARGING CRADLE. The charging process will begin. The CHARGING CRADLE Indicator will light up RED during charging. Within approximately 2-3 hours the CHARGING CRADLE Indicator will turn GREEN which means that the device is fully charged and ready for use.
- 7) As an option, the POWER CORD can be inserted directly to the end of HairMax and be charged in that manner. Plug the POWER CORD into the end of the HairMax as shown above (B). Plug the other end into an indoor electrical wall outlet. The BATTERY INDICATOR light on the HairMax will light up yellow during charging. When fully charged, the BATTERY INDICATOR light will change to GREEN. Your HairMax is now ready for use. It can be used with or without the POWER CORD.
- 8) When the Lithium Ion Battery requires charging, the BATTERY SYMBOL (within the INFORMATION DISPLAY) will begin to flash and the BATTERY INDICATOR light on the HairMax will begin flashing RED. Proceed with the steps 5 through 7 above to recharge your HairMax.

**Please Note:** If your device needs to be recharged during your treatment, simply insert the POWER CORD directly to the end of the device and other end into electrical wall outlet and continue with your treatment (see step 5 above). When finished, allow the device to fully charge.

## **PROPER USAGE**

The HairMax is a very effective product if used correctly. The HairMax is manufactured using precision components and should provide years of trouble-free service under normal usage. Please take time to read this entire instruction manual before operating the HairMax.

Use the HairMax 3 times per week on non-consecutive days. (For example, Monday, Wednesday, and Friday). The total time of each treatment should be 8-11 minutes (eight minutes for Professional 12 and eleven minutes for Lux 9). More frequent or longer usage will not increase results. Maximum results will not be seen if you do not follow the recommended treatment schedule.

Like brushing your teeth to maintain healthy teeth and gums, using the HairMax as recommended is needed to maintain healthy hair. If you stop using the HairMax, your hair may regress back to its original state.

Studies conducted during 20 years of development of the HairMax indicate that there is a maximum rate of return. Lexington has determined that using the HairMax for about 8-11 minutes (depending on the model) three times a week will provide the best results.

While there are no negative side effects from overuse, the best results are consistently obtained by using the HairMax according to directions. It is recommended that the HairMax be used on a clean scalp after washing. Your hair can be wet, towel dried or dry. If you do not shampoo every day, still use the HairMax as directed but check to make sure the laser window is clean. The HairMax should be used before applying any other topical treatments, gels, sprays or concealing products.



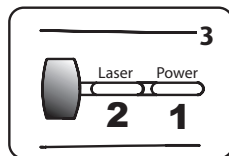
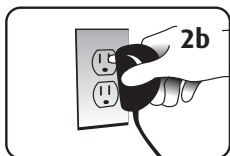
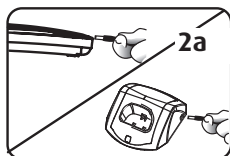
## INSTRUCTIONS FOR USE

***HairMax Lux 9 & Professional 12 can function by either using the power cord or cordless when properly charged (please refer to Methods of Charging on page 5.)***

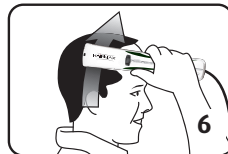
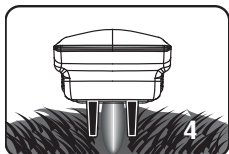
### GETTING STARTED

1. Read and follow all directions prior to use.
2. Charge your HairMax per Methods of Charging on page 5 or use optional power cord. (Illustr. 2a and 2b)
3. **Press and hold the POWER BUTTON (lower button) down for 2 – 3 seconds to turn on the device. The POWER BUTTON indicator will light up GREEN. Next, press the LASER BUTTON. The LASER BUTTON indicator will light up RED which means the laser is functioning. The INFORMATION DISPLAY will indicate the USAGE TIMER, BATTERY SYMBOL and the LASER SYMBOL.** You can clearly see the laser light when the HairMax is operating. (Avoid Direct Eye Exposure when the laser is illuminated.) The HairMax is now ready for use.

**Note:** The HairMax will automatically emit a beep tone and vibrate every four (4) seconds. This is an indication for the user to move the HairMax to the next portion of the scalp. For adjusting beep/vibration function please refer to page 7.

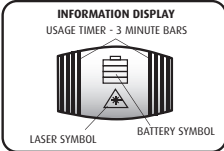


4. Place the HairMax flat on your scalp making sure that both rows of teeth are touching the scalp (illustration 4).
5. Start at your hairline. Move the HairMax slowly (in combing motion) by placing the device on a spot and leaving it there for 4 seconds. Once you hear the beep or feel the vibration (The HairMax features an audible beep tone every 4 seconds which can aid you in timing the movements), move the HairMax about 1/2 inch (1 cm) to the next spot without lifting the device off your head. You will make few complete passes over your scalp. For the first pass, move the HairMax against the direction of the hair growth - front to back (illustration 5) and side to side on the second pass (illustration 6). Repeat these passes within the recommended 8 or 11 minutes.



**IMPORTANT:** Do not lift the HairMax off of the head when moving every 4 seconds. The HairMax features a pair of comb teeth that part the hair so the light can more effectively penetrate to the scalp.

6. If you have long hair, use an ordinary comb or your hand to lift the long hair out of the way allowing the HairMax to deliver the laser light to the scalp.



During the treatment, the INFORMATION DISPLAY will provide the following information. LASER SYMBOL – the laser is turned on. USAGE TIMER – At the start of the treatment, all eight bars will be illuminated. A bar from each side will turn off in three minute intervals to time the treatment. There will be six bars after 3 minutes of use, four bars after 6 minutes, two bars after 9 minutes and finally all bars will turn off and the laser will turn off after 12 minutes of use. If further treatment time is needed, please restart the treatment process by pressing the LASER BUTTON. If treatment is complete, turn POWER BUTTON off. The BATTERY SYMBOL in the INFORMATION DISPLAY will flash to indicate the battery needs recharging. Please follow the Methods of Charging on page 5.

7. Turn off the HairMax by pressing and holding the POWER BUTTON (lower button) down for 2-3 seconds, remove the POWER CORD from wall electrical outlet and return the device and POWER CORD to the case for storage.

### **AUDIBLE BEEP TONE AND VIBRATION TIMER**

The HairMax is most effective when used correctly. In order to help time the movements, the HairMax will automatically vibrate and emit an audible tone every 4 seconds.

The audible beep and vibration can be turned off by pressing the top LASER BUTTON. Pressing it once turns on laser, beep and vibrate. Pressing it a second time turns off the beep/vibrate but the laser will remain on. To re-activate beep and vibration, simply press the LASER BUTTON again.

#### **Please Note:**

- Depending on the model, total time required for treatment with the HairMax should be **8-11 minutes (eight minutes for the Professional 12 and eleven minutes for the Lux 9)**.
- It is important to move the HairMax very slowly. Remember, you are bathing the scalp with laser light. If you move it too fast, the treatment will not be as effective.
- The HairMax is built with complex electronics to ensure optimum performance and proper delivery of laser treatments. If for some reason the HairMax will not turn off, it will be necessary to reset the device. Cover the laser window with a wash cloth or a small towel. Using a paper clip, press the RESET KEY located on the underside of the HairMax. See page 4 for location.

## MAINTENANCE INSTRUCTIONS

Always unplug the HairMax from the power electrical outlet before cleaning.

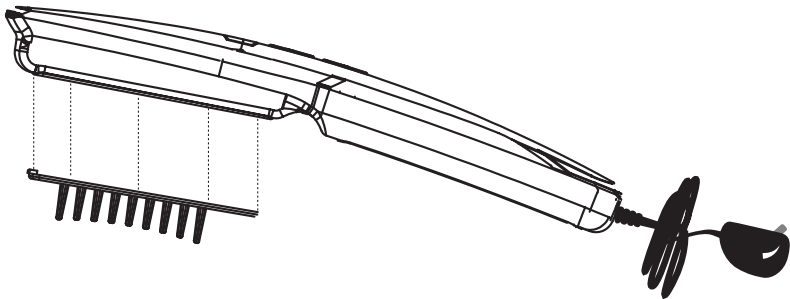
DO NOT use acetone or any other solvents on any part of the HairMax. Use of acetone or other solvents to clean the window can immediately block most of the laser light from coming through.

**To clean the LASER WINDOW** (from where the laser light shines through), unplug the device, turn power off and gently clean with a soft, slightly moistened cloth. Do not use any soaps or detergents – just warm water.

### Cleaning comb TEETH

To keep the TEETH of the combs clean, gently remove any hairs or dust with a slightly moistened towel.

For a more thorough cleaning, gently pull out comb TEETH from the center. TEETH can be washed using soap and water. Dry combs thoroughly and replace them by inserting the top of the TEETH first. Then, press the bottom of the TEETH with your thumb until they click into place. To order replacement combs, please order online at [www.hairmax.com](http://www.hairmax.com) or contact Lexington International at 561.417.0200.



If the POWER CORD becomes twisted, unplug and straighten it prior to use. Do not put strain on POWER CORD if you need to untangle or straighten it.

Only use directions, cleaning methods and operating procedures as specified in this manual.

## **WARRANTY**

The HairMax Lux 9 and Professional 12 are warranted by Lexington International LLC ("Manufacturer") against defects in materials or workmanship for 24 months from date of purchase. If this product is determined to be defective, Lexington will repair or replace it, at its option, at no charge during the warranty period.

After the warranty period, the user must pay for all parts and labor charges. If the product is repaired or replaced, either within or outside the warranty period, Lexington reserves the right to provide equivalent parts in different colors to your original product.

This warranty does not cover damages caused by acts of God, misuse, negligence, accident, modification of, or to any part of the product. This warranty does not cover damage due to improper operation or maintenance, connection to improper voltage supply, or attempted repair by anyone other than Lexington. This warranty is void if product is tampered with.

To obtain warranty service, you must deliver the product freight prepaid, in either its original packaging or packaging affording an equal degree of protection, together with your name and address, to:

**Lexington International LLC  
2901 Clint Moore Rd, Suite 260  
Boca Raton, FL 33496, USA**

**Limitation of Liability; Indemnity:** Except as expressly set forth above, Lexington International LLC shall not be liable for any special, indirect, or consequential damages that are directly or indirectly related to the use of, or the inability to use, the HairMax, even if Lexington International LLC has been advised of the possibility of such damages whether in an action of contract, negligence or other tortious action. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

**Governing Law:** The usage of the HairMax and the interpretation of its terms shall be governed by and construed in accordance with the laws of the State of Florida applicable to agreements negotiated, executed and performed wholly and solely within the State of Florida. The parties agree that the State of Florida's conflicts of laws rules shall not apply to this Agreement or any transaction performed by or under this Agreement.

**Jurisdiction and Venue:** The parties irrevocably submit and consent to the sole and exclusive jurisdiction and venue of the Florida state courts in and for Palm Beach County, Florida, U.S.A. and the Federal Courts in and for the Southern District of Florida, U.S.A. The parties agree not to raise the defense of forum non conveniens.

**Authorized Representative in Europe (Regulatory Affairs Only):** Emergo Europe, Molenstraat 15, 2513 BH The Hague, The Netherlands. Tel: (31) (0) 70 345-8570 Fax: (31) (0) 70-345-7299

**Congratulations on becoming a HairMax user!**

*To validate your warranty please register online at  
[www.internationalhairmax.com/warranty](http://www.internationalhairmax.com/warranty) or call 561.417.0200*

## **ELECTRICAL SAFETY**

To reduce the risk of hazard by electric shock:

- Always unplug the HairMax from the power outlet immediately after use.
- Do not use while near water or while bathing.
- Do not place or store the HairMax where it can fall or be pulled into a tub or sink.
- Do not expose the HairMax to running water, or drop into water or any other liquid. If the HairMax falls into water, unplug it immediately from the power outlet.
- Do NOT reach into or touch the water.
- If using the HairMax near water, the use of an electrical outlet protected by a Ground Fault Circuit Interrupter is recommended.
- Do not use the HairMax near heated surfaces. Contacting a heated surface with the cord or plug can cause the product to malfunction and produce an electrical shock.

### **RISKS**

**Harm to Eyes** - Do not shine the light from the HairMax directly into your eyes for extended periods of time. Prolonged direct exposure to your eyes may cause harm to your eyes.

**Scalp Itching** - If you experience more than mild itching during usage of the HairMax, please consult a physician.

**Tingling** - If you feel a more than a mild and temporary tingling lasting for a short period of time after applying HairMax, please consult a physician.

## **How to Monitor Device Activity**

Your HairMax is inspected and tested during production. When working properly, both the Information Display and the Laser/Power Indicators will be turned on. A red laser light shines through the window at the bottom of the device. DO NOT look directly at the laser light.

Shine the laser light at the palm of your hand to see red laser light “speckles” appear. You will also hear a beep tone and feel a vibration.

Do not operate the laser if the unit is defective or damaged. If one or both of the indicator lights is not lit, the laser light does not appear, or there is no beep tone or vibrate, contact Lexington International LLC for repair or replacement.

## **Device Failure Mode**

The laser light does not fade or diminish over time. At the end of the laser’s life or if it fails for any other reason no red light will shine out of the device. Do not look directly at the laser light. Direct the laser light at the palm of your hand to see red laser light “speckles” appear. If no light appears, contact Lexington International LLC for repair or replacement.

## **Expected Life of the HairMax**

The HairMax is a Low-Level Laser Therapy device manufactured under strict quality controls and validation through GMP (Good Manufacturing Practices). The HairMax contains a high quality laser diode designed to last at least 15,000 hours. Based on that rating and the durability of the components being used, all models of the HairMax will provide you with many years of reliable service.

## TROUBLESHOOTING

**Before sending your HairMax in for repair, please try these helpful items. If these do not resolve your problem, please contact Lexington's warranty department.**

### **My HairMax will not turn on**

- Make sure your HairMax is fully charged. Please refer to Methods of Charging on page 5.
- Insert power cord into the HairMax. Press the POWER button then the LASER button.
- Try another wall electrical outlet.

### **My HairMax is turning off during use**

- Make sure your HairMax is fully charged. Please refer to Methods of Charging on page 5.
- Insert power cord into the HairMax. Press the POWER button then the LASER button.
- Try another wall electrical outlet.

### **My HairMax will not turn off.**

- Press and hold POWER button for 5 seconds
- If using power cord, unplug HairMax and press POWER button for 5 seconds
- If unsuccessful, utilize the RESET KEY (page 7)

### **My HairMax beeps/vibrates irregularly or doesn't beep/vibrate**

- If using power cord, unplug HairMax. Plug in power cord again and press the POWER button then the LASER button.

### **My HairMax beeps and vibrates, but I do not see the laser**

- If using power cord, unplug HairMax. Plug in power cord again and press the POWER button then the LASER button.

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If these helpful tips did not resolve your problem, please contact Lexington Intl. LLC for repair or replacement:

### **Lexington International, LLC**

777 Yamato Road, Suite 105

Boca Raton, FL 33431

Tel. 561.314.2430

info@hairmax.com

www.internationalhairmax.com

# Warranty Card

The HairMax has a 2 year warranty against defects in materials or workmanship from Lexington International, LLC. Items that are damaged or abused are not covered under the warranty and will be charged at their regular repair rates. Lexington may extend this warranty period under certain product failures. Please refer to the User Manual for complete warranty terms. We guarantee your satisfaction.

**To validate your warranty please return this completed warranty card or register online at:  
[www.internationalhairmax.com/warranty](http://www.internationalhairmax.com/warranty)**

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

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

**Date of Purchase:** \_\_\_\_\_

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

**City:** \_\_\_\_\_ **State:** \_\_\_\_\_

**ZIP/Postal Code:** \_\_\_\_\_ **Country:** \_\_\_\_\_

**Email:** \_\_\_\_\_

**Where did you purchase this product (Reseller Name)?**

\_\_\_\_\_

**What factors influenced your purchase of this product?**

\_\_\_\_\_

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\_\_\_\_\_

\*Please fill out this form, fold it, staple or tape it at the designated area, place postage stamp and mail it back to us.



tape  
or staple



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**Place  
Stamp  
Here**

**Lexington International, LLC  
2901 Clint Moore Rd., #260  
Boca Raton, FL 33496  
USA**



To validate your warranty please return this completed  
warranty card or register online at:

**[www.internationalhairmax.com/warranty](http://www.internationalhairmax.com/warranty)**

**[www.InternationalHairMax.com](http://www.InternationalHairMax.com)**

Patented in the USA. Patent Pending in 104 countries.  
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