



To validate your warranty please register online at www.hairmax.com/warranty

To view our safety and usage videos, visit www.hairmax.com/videos.aspx

©Copyright 2010 Lexington International, LLC. All rights reserved.

TABLE OF CONTENTS

Glossary	4
Introduction	5
Contraindications	6
Warnings	6
Precautions	7
Electrical Safety	8
Indications	8
Risks	9
Benefits	9
Usage Recommendation	10
Summary of Clinical Data	10
Information on Condition	11
Norwood Hamilton Classification System	11
HairMax LaserComb and Parts	12
Methods of Charging the HairMax & Charging Instructions	13
Instructions for Use	14
Safety Label	16
Power Supply Specifications	16
Maintenance Instructions	17
Warranty	18
How to Monitor Device Activity	19
Device Failure Mode	19
Expected Life of the HairMax LaserComb	19
Troubleshooting	20
Warranty Card	.21-22

GLOSSARY

Crown - The top or highest part of the head.

Fitzpatrick Skin Type Classification Guide:

A system that classifies your skin type based on your complexion and responses to sun exposure:

- Type 1: Highly sensitive, always burns, never tans.
- Type 2: Very sun sensitive, burns easily, tans minimally.
- Type 3: Sun sensitive skin, sometimes burns, slowly tans to light brown.
- Type 4: Minimally sun sensitive, burns minimally, always tans to moderate brown.
- Type 5: Sun insensitive skin, rarely burns, tans well.
- Type 6: Sun insensitive, never burns, deeply pigmented.

Hair Density - The amount of hairs on the head. Generally, it is measured by counting the number of hairs found in one square centimeter of scalp.

LASER - Light Amplification by Stimulated Emission of Radiation is an optical source that emits photons in a coherent beam.

Low Level Laser - Also know as soft laser, cold laser or laser biostimulation. The HairMax LaserComb uses this type of laser.

Mean Terminal Hair Density - The average number of thick, pigmented hairs in the specific area.

Non-consecutive days - A day in between the treatment days.

Norwood Hamilton Scale - System that classifies the different ways in which baldness progresses in men.

Placebo Device - A device that looks and sounds like the HairMax LaserComb. The placebo device does not have a laser. This device was used in the study to test the effectiveness of the HairMax LaserComb.

Terminal hairs - thick, pigmented hairs

Vellus hair - fine, non-pigmented hair

HairMax LaserComb®

The HairMax LaserComb® is the First and Only home-use medical laser device that has been Clinically Proven and FDA Cleared (class II) for Marketing to Promote Hair Growth.^{*} The HairMax provides the convenience of treatment in your own home.

Our new HairMax Premium model provides the same safe and effective at-home treatment as the original HairMax, but now is cordless. This HairMax features a sleek ergonomic design with a rechargeable lithium ion battery to give you the freedom of movement as you treat your hair.



The HairMax LaserComb works directly on your scalp by parting your hair with two rows of teeth. The teeth are aligned with a row of laser beams. The teeth part your hair forming a clear path for the light to reach the scalp during use.

This path is a critical feature to the success of the treatment. Without the teeth your hair would block the laser beams from reaching the scalp. Parting the hair provides direct access to the scalp.

Like brushing your teeth to maintain healthy teeth & gums, regular HairMax LaserComb usage is required. Three times a week on non-consecutive days for 10 to 15 minutes a session is all that is needed to achieve results over time. Over the next few months, you may notice a gradual increase in the number of hairs in a specific location (Hair Density). Most users notice continued improvement as they continue to use the HairMax LaserComb. If you stop treating your scalp with the HairMax LaserComb after you see hair growth, this improvement may gradually disappear.

* Indication: FDA 510(k) Cleared for marketing to promote hair growth in males with Androgenetic Alopecia (male pattern hair loss) with Norwood IIa to V with Fitzpatrick skin types I to IV. No prescription needed.

CONTRAINDICATION

If you are taking any photosensitizing medications or receiving any therapy that sensitizes the skin to light, DO NOT use the HairMax LaserComb. Please consult your physician if you have any other concerns.

- **WARNING:** Do not allow children to use or play with the HairMax LaserComb. Keep out of reach of children. It is not a toy.
- **WARNING:** Avoid getting the HairMax LaserComb wet. Contact with water may result in an electrical shock.
- **WARNING:** Never use the HairMax LaserComb if the cord or plug is damaged. Such use can cause the HairMax LaserComb to malfunction and produce an electrical shock. If the HairMax LaserComb is not working properly or if it has been dropped, damaged or exposed to water, contact Lexington International, LLC at 561-417-0200.
- **WARNING:** Avoid using the HairMax LaserComb near heated surfaces. Contacting a heated surface with the cord or plug can cause the product to malfunction and produce an electrical shock.
- **WARNING:** Only use the HairMax LaserComb according to the instructions provided. Any other use is not recommended.
- **WARNING:** 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.

PRECAUTIONS

- **CAUTION:** Never leave the HairMax LaserComb unattended when plugged into a power outlet. An electrical malfunction can result in a fire.
- **CAUTION:** Do Not put strain on the cord when untangling or straightening it. Doing so can break the cord causing it not to work.
- **CAUTION:** Never use magnifying optical instruments with the HairMax LaserComb. Their use with this product can cause temporary irritation to the eyes.
- **CAUTION:** Never use acetone or other solvents on any part of the HairMax LaserComb. Use of solvents on the window can block the laser light from coming through.
- **CAUTION:** Not recommended for use by men with Norwood Hamilton Classification I, II, Va, VI, or VII (See drawings on page 12 of the User Manual) because they are not likely to experience hair growth from using the HairMax LaserComb.
- **CAUTION:** There is currently no validated scientific evidence supporting the effectiveness of the HairMax LaserComb on women.
- **CAUTION:** The safety or effectiveness of the HairMax LaserComb in men with Fitzpatrick Skin Types V and VI (see the description on these skin types on page 4 of the user manual) has not been evaluated.
- **CAUTION:** Use of controls or adjustments or performance of procedures other than those specified herein may result in harmful laser exposure.

NOTICE: If any malfunction occurs, do not attempt to repair it yourself. This appliance has no user-serviceable parts. Use the HairMax LaserComb only for its intended use as described in this manual. Contact Lexington International LLC for repairs at 561.417.0200.

ELECTRICAL SAFETY

Basic safety precautions should be observed when using this, or any other electrical device, especially when children are present.

DANGER: Keep away from water. Contact with water may result in an electrical shock.

To reduce the risk of hazard by electric shock:

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

INDICATIONS

The HairMax LaserComb is indicated to promote hair growth in males with androgenetic alopecia who have Norwood Hamilton Classifications of IIa to V and Fitzpatrick Skin Types I to IV.

Harm to Eyes – Do Not shine the light from the HairMax LaserComb directly into your eyes. **Prolonged** direct exposure to your eyes can cause harm to your eyes.

Scalp Itching – Less than 5% of the subjects in the clinical trial of the HairMax LaserComb reported mild scalp itch during the usage of the HairMax LaserComb. If you experience more than mild itching consult a physician.

Tingling – Less than 4% of the subjects in the clinical trial reported a mild and temporary tingling feeling. This lasted for a short period of time after applying the treatment. If the problem persists consult a physician.

Increased blood flow to the scalp – Less than 1% of the subjects in the clinical trial reported a mild increase in blood flow **(also known as vasodilatation)** to the scalp. This lasted for a short period of time after applying the treatment. If the problem persists consult a physician.

BENEFITS

The HairMax LaserComb is a home-use Low-Level Laser treatment to promote hair growth in men. The HairMax LaserComb uses laser light to treat and stimulate your scalp.

Individual results may vary. Your hair grows at a slow pace. Increases in the number of hairs in one specific location **(hair density)** are difficult to notice and are not immediately visible. A typical user will notice some increase in hair density within the first few weeks. Over time you will begin to re-grow hair.

Proper use according to the instructions leads to positive results. If you stop treating your scalp with the HairMax LaserComb after you see hair growth, this improvement may gradually disappear.

Use the HairMax LaserComb 3 times per week with at least a day between each treatment **(non-consecutive days).** (For example Monday, Wednesday, and Friday.) The total time of each treatment is 10-15 minutes. 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 ongoing HairMax LaserComb usage is needed to maintain healthy hair growth. If you stop using the HairMax LaserComb, any benefit may gradually disappear.

Summary of Clinical Data

A study was conducted at 4 different locations around the country. All participants in the study (ages 30-60) were males, diagnosed with hereditary hair loss, which is called **Androgenetic Alopecia**, and light to medium skin tones. A total of 123 men participated in the study. Subjects were divided into two groups. One group used the HairMax LaserComb. The second group used a **placebo device** that looked and sounded like the HairMax LaserComb but did not include a laser. The first group included 82 participants. The second group included 41 participants.

Subjects performed treatments 3 times per week on nonconsecutive days for 6 months. Hair growth was monitored during the study. The number of thick, pigmented (terminal) hairs in a specific area were compared from the beginning to the end of the study. 67 of 72 (93%) of men using the HairMax LaserComb who completed the study, had some increase in the number of terminal hairs in that area. The average number of terminal hairs per square centimeter **(mean terminal hair density)** measured in this study increased by 19 over a 6 month period. The area measured was roughly the size of a dime. No subjects experienced any serious or adverse events. The number and types of adverse events were similar in both groups.

Information on Condition

Androgenetic Alopecia (AGA) is a condition involving both genetic (inherited) and hormonal factors. AGA in men usually begins at the hairline. The hairline gradually recedes to form an "M" shape. The hair becomes finer and shorter. The hair at the top of your head (also called the **crown**) begins to thin. Over time, the top of the hairline meets the thinned crown, leaving a pattern of hair around the sides of your head. A system called the Norwood Hamilton classification system is used to determine the extent of hair loss. The following chart will assist in determining your stage of hair loss.

Norwood Hamilton classification system

The HairMax LaserComb is indicated for use in males with Norwood Hamilton Classification IIa through V. These classifications are shaded in the above diagram. Not recommended for remaining classifications: I, II, Va, VI and VII.

An estimated 50 million men in the United States experience AGA. A person's tendency to lose hair can be inherited from either side of a person's family or from both parents. Men of all races and ethnicities lose their hair. By age 40, nearly forty percent of men have visible signs of AGA. By age 50, fifty percent of men show signs of the condition.

HAIRMAX LASERCOMB AND PARTS



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 (A) 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 GREEN POWER INDICATOR on the HairMax will flash during charging (item "c" page 12). When fully charged, the GREEN POWER INDICATOR light will stop flashing and remain constant 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 laser will turn off and the RED LASER INDICATOR (item "d" page 12) will start to blink. 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). The Power Button Indicator will flash green during this charging process. When finished, allow the device to fully charge. Anytime your device is placed in the Charging Cradle, there won't be any illumination on the device. Charging status will be indicated by the Charging Cradle only.

HAIRMAX LASERCOMB INSTRUCTIONS FOR USE

New HairMax Premium can function by either using the power cord or cordless when properly charged (please refer to Methods of Charging on page 13.)

- **1.** Read and follow all directions prior to use.
- **2.** Charge your HairMax per Methods of Charging on page 13 or use an optional power cord (Illustr. 1a and 1b).
- 3. Press and hold the POWER BUTTON (right button) down for a couple of seconds to turn on the device. The GREEN POWER INDICATOR will light up. Next, press the LASER BUTTON. (Illustr. 2) The RED LASER INDICATOR will light up which means the laser is functioning. 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 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 function please refer to page 15.

- 4. Place the HairMax flat on your scalp making sure that both rows of teeth are touching the scalp (illustration 3).
- 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 (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 a couple of complete passes over your scalp. For the first pass, move the HairMax front to back (illustration 4) and side to side on the second pass (illustration 5). Repeat these passes within the recommended 10 to 15 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 (Illustr. 6)
- 7. Turn off the HairMax by pressing and holding the POWER BUTTON (right button) down for 2–3 seconds (Illustr. 7).Place your device to the CHARGING CRADLE for future usage or return the POWER CORD, the HairMax and CHARGING CRADLE to the case for storage.



AUDIBLE BEEP TONE TIMER

The HairMax is most effective when used correctly. In order to help time the movements, the HairMax will automatically emit an audible tone every 4 seconds. The audible beep can be turned off by pressing the LASER BUTTON. Pressing it once turns on laser and beep. Pressing it a second time turns off the beep but the laser will remain on. To re-activate the beep, simply press the LASER BUTTON again.

Please Note:

•Total time required for treatment with the HairMax should be **10 to 15 minutes.**

• 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 following laser safety label can be found on this product:



wavelength: 655 ± 5nm visible red light Class 3R

Note: HairMax LaserComb has no user-serviceable parts.

Location: On the underside of the handle. Please visit http://www.hairmax.com/QualitySafety.aspx for more information or call 561.417.0200

POWER SUPPLY SPECIFICATIONS

Output = 6VDC 1A. Plug: 9mm x 3.5mm, center positive.

The power supply for the HairMax LaserComb can be used in the United States and Internationally. This power supply will adapt to all power supplies from 110 volt/60 cycle (US) to 240 volt/50 cycle. If outlets in your country have different plugs than the power supply that comes with the HairMax LaserComb, use an inexpensive plug adapter, not supplied with the device.

MAINTENANCE INSTRUCTIONS

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

DO NOT use acetone or any other solvents on any part of the HairMax LaserComb. 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 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 LaserComb is 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 777 Yamato Road, Suite 105 Boca Raton, FL 33431, 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 LaserComb, even if Lexington International LLC has been advised of the possibility of such damages whether in an action of contract, negligence or other tortuous 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 LaserComb 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 LaserComb user! To validate your warranty please register online at www.hairmax.com/warranty or call 561.417.0200

How to Monitor Device Activity

Your HairMax LaserComb is inspected and tested during production. When working properly, both the green and the red lights above the buttons turn 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.

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

Device Failure Mode

The HairMax LaserComb is designed to last for 10-15 years of continuous use. 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 LaserComb

The HairMax LaserComb is a medical device manufactured under strict quality controls and validation through GMP (Good Manufacturing Practices). The HairMax LaserComb 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, the expected life of the HairMax LaserComb is 10-15 years of regular use. Please take time to read this entire instruction manual before operating the HairMax.

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 13.
- 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 13.
- 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 the POWER button for 5 seconds
- If using a power cord, unplug the HairMax and press the POWER button for 5 seconds

My HairMax beeps irregularly or doesn't beep

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

My HairMax beeps, but I do not see the laser

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

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. 561.417.0200 info@hairmax.com www.hairmax.com





Place Stamp Here

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

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.hairmax.com/warranty

Name:		
Serial Number:		
Date of Purchase:		
Address:		
	State:	
ZIP/Postal Code:	Country:	
Email:		
	his product (Reseller Name)?	
	our purchase of this product?	

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



To validate your warranty please return this completed warranty card or register online at: www.hairmax.com/warranty

To view our safety and usage videos, visit www.hairmax.com/videos.aspx

www.HairMax.com

Patented in the USA. Patent Pending in 104 countries. HairMax is a Registered Trademark of Lexington International.

©Copyright 2010 Lexington International, LLC. All rights reserved.

LEX12001-02 07/10