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HAIRMAX.COM | 1-866-LASERCOMB (1-866-527-3726)



HairMax LaserComb®

Premium Model

USER MANUAL

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To view videos about usage, quality and safety, visit: www.hairmax.com/videos www.hairmax.com/QualitySafety

#### Introduction of HairMax LaserComb<sup>®</sup>

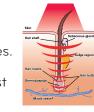
The HairMax LaserComb is a home-use laser device that has been Clinically Proven to treat heredity hair loss in men and women. The LaserComb is an over-the-counter (OTC) device that can be sold directly to the public. The LaserComb features a cordless design that can be used with or without the included power cord.

### Indications

The LaserComb is indicated to treat Androgenetic Alopecia (hereditary hair loss), and promote hair growth in females who have Ludwig (Savin) I-4, II-1, II-2, or frontal patterns of hair loss and in males who have Norwood Hamilton Classifications of Ila to V and who both have Fitzpatrick Skin Types I to IV.

# How the LaserComb works

The LaserComb works by providing laser energy to stimulate hair follicles. For optimal results, the laser must not be blocked by the hair and must have an unobstructed path to the



scalp. The LaserComb has teeth that part the hair and allow the maximum amount of laser energy to reach the scalp.

### Treatment with HairMax LaserComb

The LaserComb should be used for 11 minutes per treatment, 3 times per week, spaced out every other day. For example, Monday, Wednesday, Friday. The LaserComb should not be used more than the recommended treatment time per day. Clinical studies demonstrate that most users see benefits in as little as 16 weeks.

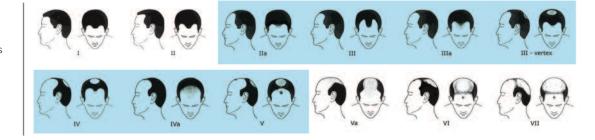
## HairMax LaserComb Benefits

A clinical study was conducted in men and women over a six month time period. The study showed that 93% of the men and women had an increase in the number of hairs (based on a minimum of 32 new hairs per square inch being observed at follow up).

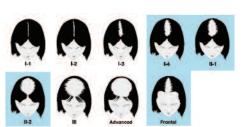
See pages 7-8 for detailed results of the study.

The LaserComb can be used by men and women with thinning hair or pattern baldness caused by a hereditary condition. Doctors use a system known as the **Norwood Hamilton Classification (men)** and the **Ludwig-Savin Classification (women)** to describe the degree of hair loss. Below are the pictures of the scales. The shaded areas show the type of hair loss that can be treated with the LaserComb.

Norwood Hamilton Classification - Males



Ludwig-Savin Classification - Females



The HairMax LaserComb has not been clinically tested for hair loss outside of the shaded areas.

The LaserComb was only studied in light to medium skin tones (Types 1,2,3,4) as described in the Fitzpatrick Scale below. If your hair loss and skin tone fall into these categories, the LaserComb should work for you.

**Fitzpatrick Skin Type Classification Guide:** A way to describe your skin type based on your complexion and what happens to your skin in sunlight.

Type 1	d to or es	Very white or freckled skin, always burns with sun exposure (very fair; often in people with red or blond hair and blue eyes)
Type 2	Testec ctive fo	White skin, usually burns with sun exposure (fair; often in people with red or blond hair and blue, green, or hazel eyes)
Type 3	iically Te e effectivesse skin	White or olive skin tone, sometimes burns with sun exposure (fair; seen in people with any hair or eye color)
Type 4	Clin	Brown skin, rarely burns with sun exposure (common in people of Mediterranean descent)
Type 5	inically ed for skin	Dark brown skin, very rarely burns with sun exposure (common in people of Middle-Eastern descent)
Type 6	Not Clinical Tested for these skin types	Black skin, never burns with sun exposure

A Do not stare directly at the red laser light or its reflection in a mirror because it can temporarily irritate your eyes. If you stare at the light for too long, it could harm your eyes. Also, never use a magnifying glass when using the LaserComb because it can cause temporary irritation to your eyes.

A Keep the LaserComb out of the reach of children.

- ⚠ Do not drop the LaserComb in water because you may get an electrical shock. If the LaserComb gets damaged by water, contact Customer Service toll-free at 1-866-527-3726
- A If the cord is damaged on the LaserComb do not use the device because you could get an electrical shock. If the cord gets damaged, contact Customer Service toll-free at 1-866-527-3726.
- A Do not use the LaserComb near any heated surfaces because this could cause the device not to work properly and may cause an electrical shock. Contact Customer Service toll-free at 1-866-527-3726.
- A Laser light avoid direct eye exposure.

#### CAUTIONS

A If you are taking any medications or products that make you sensitive to light, you should test the LaserComb to make sure you do not have a reaction. Some of the things that can cause increased sensitivity to the LaserComb could be medicines for colds, allergies, pain medicine and drugs to treat infections. To test the LaserComb for sensitivity, turn the device on, hold the device on one spot, shining the light on your forearm. After two minutes, turn the device off and set aside. Look at the spot where you held the laser light over the next five minutes. If you see any reaction such as redness or rash, do not use the LaserComb and contact our Customer Service toll-free at 1-866-527-3726 to return your product and get a refund.

A Only use the LaserComb as directed. Do not try to change the way the LaserComb operates. Changes may result in harmful laser exposure. Contact Customer Service toll-free at 1-866-527-3726 for repairs.

A Never use acetone or other solvents on any part of the LaserComb. Use of solvents on the window can block the laser light from coming through.

NOTICE: If any malfunction occurs, do not attempt to repair the LaserComb yourself. This appliance has no user-serviceable parts Use the LaserComb only for its intended use as described in this manual. Contact Customer Service toll-free at 1-866-527-3726.

### Risks

HairMax LaserComb has been clinically tested on both men and women. In the clinical study for men, 5% of the men said they had itching or tingling from using the LaserComb. None of the women in the clinical study reported any of these side effects from using the LaserComb. If you have itching, tingling or any other side effect that bothers you, stop using the LaserComb and contact Lexington's Customer Service toll-free at 1-866-527-3726.

## Testing the LaserComb for sensitivity

Before beginning treatment, be sure to test the HairMax LaserComb for sensitivity. Turn the device on, hold the LaserComb on one spot, shining the light on your forearm. After two minutes, turn the device off and set aside. Look at the spot where you held the laser light over the next five minutes. If you see any reaction such as redness or rash, do not use the HairMax LaserComb and contact Customer Service toll-free at 1-866-527-3726 to return your product and get a refund. If you don't experience any reaction, proceed with the treatment instructions on page 12.

Your HairMax LaserComb is inspected and tested during production. When working properly, both the green and the red light indicators above the power and laser 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 onto the palm of your hand to see if the red laser light appears. You will also hear a beep tone.

If one or both of the light indicators is not lit, the laser light does not appear, or there is no beep tone, contact Customer Service toll-free at 1-866-527-3726 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, the red laser light will no longer shine out of the device.

## Expected Life of the HairMax LaserComb

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

Clinical studies were conducted at multiple locations in the United States. Participants in the study were males diagnosed with hereditary hair loss, which is called Androgenetic Alopecia, and had light to medium skin tones. Subjects were divided into two groups, LaserComb Group and a Control Group. The Control Device looked and sounded like the LaserComb device but did not include a laser light. The Clinical studies adhered to all GCP (Good Clinical Practice) guidelines, were approved by an IRB (Institutional Review Board) and listed on www.clinicaltrials.gov.

During the 6 month clinical study, subjects treated their hair once per day, 3 times per week on non-consecutive days. The number of thick, normal healthy hairs in the target zone were counted at week 1, week 16 and week 26.

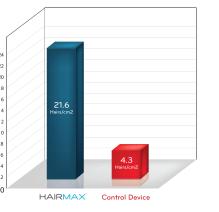
Results at the 26 week visit showed that over 93% of the men saw an increase in hair counts (based on a minimum of 32 new hairs per square inch being observed at the follow up visit).

No subjects in the study experienced any serious adverse events. In fact, the number and types of adverse events were similar in the LaserComb and Control Groups.

## Hair Count Change

In the clinical study, after 26 weeks of treatment with the LaserComb devices versus the Control Device, the following increases in hair count were found.

## Mean Terminal Hair Count Changes From Baseline in MALES 26 Weeks, Observed Hair Count



A clinical study was conducted at multiple locations in the United States. All participants in the study were females, diagnosed with hereditary hair loss, which is called Androgenetic Alopecia, and had light to medium skin tones. Subjects were divided into two groups. One group used the LaserComb and the other group used a Control Device. The Control Device looked and sounded like the LaserComb, but did not include a laser light. The Clinical studies adhered to all GCP (Good Clinical Practice) guidelines, were approved by an IRB (Institutional Review Board) and listed on www.clinicaltrials.gov.

During the 6 month study, subjects treated their hair once per day, 3 times per week, on non-consecutive days. The number of thick, normal, healthy hairs in the target area were counted at Week 1, Week 16 and Week 26.

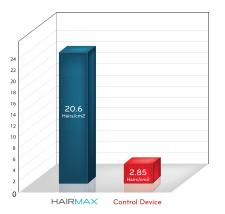
Results at 26 weeks showed that over 90% of the women saw some increases in hair counts (based on a minimum of 32 new hairs per square inch being observed at the follow up visit).

No subjects in the study experienced any serious adverse events. In fact, the number and types of adverse events were similar in the HairMax LaserComb and control groups.

## Hair Count Change

In the clinical study, after 26 weeks of treatment with the LaserComb and a Control Device, the following increases in hair count were found.

### Mean Terminal Hair Count Changes From Baseline in FEMALES 26 Weeks, Observed Hair Count







Use the LaserComb 11 minutes per treatment, three treatments per week. The treatments should be spaced every other day, for

example Monday, Wednesday, Friday. Do not use the LaserComb more than 11 minutes per treatment day. Most users see benefits in as little as 16 weeks (based on clinical studies).

When you receive the LaserComb take all the parts out of the case. Remove the safety label located between the laser button and power button. You must charge your LaserComb before using.

## Charging Methods

METHOD 1: Charging the LaserComb using the charging cradle (stand) and power cord. Plug the power cord into the cradle and the other end into an electrical wall outlet. While the device is charging you will see a red light on the charging cradle. After

about 2-3 hours the light on the charging cradle will turn green which means that the LaserComb is fully charged and ready to use. During this charging method the light on the device will not light up.



METHOD 2: Charging the LaserComb by placing the power cord directly into the handle end of the Laser-Comb and the other end into an electrical wall outlet.



When the LaserComb requires charging, the laser will turn off anf the red laser indicator (Item "B" on

page 9) will start to blink. You will have to charge your LaserComb with one of the charging methods as described on page 10.



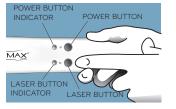
#### Please Note:

If your device needs to be recharged during your treatment, simply insert the power cord directly into the end of the device and other end into an electrical wall outlet and continue with your treatment. When finished, allow the device to fully charge.

## Proper Use

The LaserComb should be used for 11 minutes. Use a watch or clock to time your treatment.

First, press the power button and hold it down for 3 seconds and the power button light will light up green.



Second, press the laser button which will light up red. That means the LaserComb is ready to be used. Shine the LaserComb onto the palm of your hand and you will see that the laser light is on (do not look at the laser light directly). Do not use the LaserComb if the device is damaged or defective, instead call Customer Service toll-free at 1-866-527-3726.

(Figure B). Move the

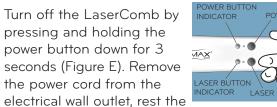
on one spot for 4 seconds.

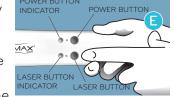






Next move the LaserComb against the way your hair grows from front to back. Now move the LaserComb side to side (Figure C). Repeat these passes within the required treatment of 11 minutes. If you have long hair, use your fingers to lift your hair out of the way allowing the LaserComb to deliver the laser light to the scalp (Figure D).





device in the charging cradle or return the device and power cord to the case for storage.



per week

### Please Note:

- It is important to move the LaserComb very slowly. Remember, you are bathing the scalp with laser light. If you move it too fast, the treatment will will not achieve the optimal results to promote hair growth.
- Total time required for treatment is 11 minutes.

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

## What is included:



## **Troubleshooting**

The LaserComb has advanced electronics to ensure that the device is working like it is supposed to and that the proper amount of laser energy is being delivered. If for some reason you are experiencing difficulties with your device, please try one of the tips below if:

### Your LaserComb will not turn on

- Make sure your LaserComb is fully charged.
- Insert power cord into the LaserComb then press the power button for 4 seconds and then the laser button.
- Try another electrical wall outlet.

# Your LaserComb is turning off during use

- Make sure your LaserComb is fully charged.
- Insert power cord into the LaserComb then press the power button for 4 seconds and then the laser button.

• Try another electrical wall outlet.

#### Your LaserComb will not turn off

- Press and hold power button for 5 seconds.
- If using power cord, unplug the LaserComb and press power button for 5 seconds.

## Your LaserComb beeps irregularly or doesn't beep

• If using power cord, unplug the LaserComb. Plug in power cord again and press the power button then the laser button.

## Your LaserComb beeps, but you do not see the laser

• If using power cord, unplug the LaserComb. Plug in power cord again and press the power button then the laser button.

# You have trouble understanding any of these instructions

 Contact Customer Service toll-free at 1-866-527-3726.

SAFETY LABEL   LASER PARAMETERS					
Wavelength:	655nm <sup>+</sup> /- 10nm visible red light				
Laser Power for classification <5mW CW					
Divergence	57 mrad				
Number of lasers	9				
This Laser Product is designated as Class 3R during all procedures of operation.					
Note:	LaserComb Advanced 7 has no user-serviceable parts.				
Location:	On the underside of the handle   Model version varies				



## **Power Supply Specifications**

Output = 6VDC 1.0A. 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).

## Cleaning your HairMax LaserComb

- Keep your LaserComb clean.
- Turn off the LaserComb by pressing the power button.
- Unplug the power cord from the device and from the electrical wall outlet.
- Clean the laser window with a soft, slightly moistened cloth.
- To clean the comb teeth, gently remove any hairs or dust with a slightly moistened towel.
- Don't use any acetone, soap or detergents, only warm water.
- To clean the teeth more thoroughly, gently pull out the comb teeth from the center. Then you can separately wash them using soap and warm water.

 After you dry the comb teeth, put them back on the device by inserting the top tabs into place and then press the bottom of the



at hairmax.com or call Customer Service toll-free at 1-866-527-3726.

## Electrical Safety

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



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

#### 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

To validate your warranty please register online at www.hairmax.com/warranty or call Customer Service toll-free at 1-866-527-3726

#### WARRANTY CARD

The HairMax LaserComb 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 Intl. 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 card register online at www.hairmax.com/warranty

or complete and mail this warranty card

Name:		Serial Number:						
Date of Purchase:		located on yellow safety label, on the bottom of the device						
Address:								
City:	State:	ZIP/Posta	al Code:					
Country:	Email:							
Where did you purchase this product (Reseller Name)?								
What factors influenced your purchase of this product?								



<sup>\*</sup>Please fill out this form, detach it, place it in the envelope or fold out and mail it directly back to us with a postage stamp.

Lexington International, LLC

2901 Clint Moore Boca Raton, FL 3



## HairMax Customer Service:

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To view videos about usage, quality and safety, visit: www.hairmax.com/videos www.hairmax.com/QualitySafety

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