THE ORIGINAL
LASERCAP®

USER MANUAL

LaserCap SD
LaserCap HD
LaserCap HD+

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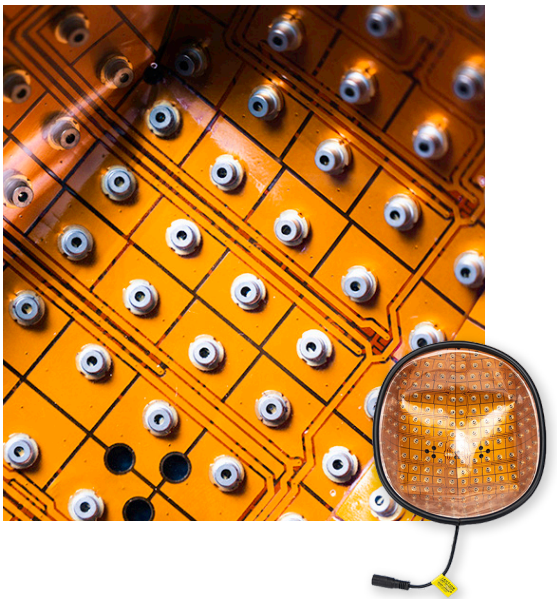


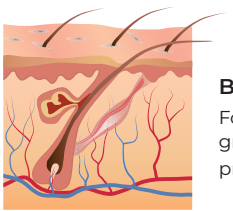
1. INTRODUCTION

Thank you for purchasing The Original LaserCap, and congratulations for taking the next step towards thicker, healthier hair!
Before you use your LaserCap, please carefully read and ensure you understand the content of this user manual.

How it works

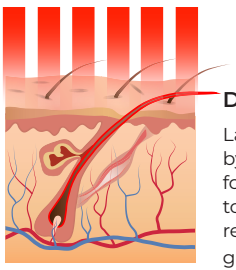
LaserCap is a FDA-cleared medical device that delivers a treatment called Low-Level-Laser-Therapy (LLLT), also known as Photobiomodulation Therapy (PBMT). LLLT is safe, natural, free from drugs or other chemicals, and is clinically proven to be an effective treatment for male and female pattern hair loss.

LLLT works by stimulating hair follicles with low intensity red laser light. When the cells of the hair follicle absorb this specific kind of light, they are able "work", that is, perform cellular respiration more efficiently, and consequently produce thicker, healthier hair.



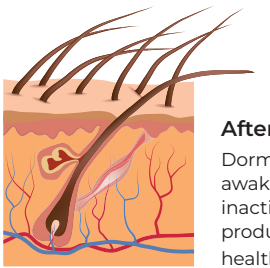
Before

Follicles are inactive, growing slowly and producing thin hair.



During

Laser light is absorbed by the cells of the hair follicle, providing energy to enhance cellular respiration and hair growth.



After

Dormant follicles are awakened from their inactive state and produce thicker, healthier, hair.

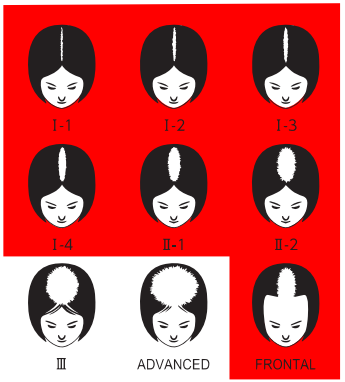
2.1 Indications for use

Degree of hair loss

LaserCap can be used by men and women with thinning hair due to hereditary pattern hair-loss, also known as Androgenetic Alopecia. Doctors use specific rating scales to describe the degree of hair loss (see image to the right). For men this is the Hamilton-Norwood scale, and for women this is the Ludwig-Savin scale. LaserCap is indicated to treat hair loss in men with Hamilton-Norwood classifications of IIa-V, and women with Ludwig-Savin classifications of I-II. These classifications are shaded in the diagram.

HAMILTON-NORWOOD SCALE FOR MEN

LUDWIG-SAVIN SCALE FOR WOMEN



2. IS LASERCAP RIGHT FOR YOU?

Skin Type

LaserCap is known to be effective in men and women with white to brown skin tones, specifically Fitzpatrick skin types 1-4 (see table below). The Fitzpatrick system is a way to classify skin type based on complexion and what happens when your skin is exposed to sunlight. This does not mean that LaserCap will not be effective for persons with darker skin types. Due to limitations of digital photography and hair counting software, the technology was not able to be tested for darker skin tones.

TYPE 1	Clinically tested to be effective for these skin types	Very white or freckled skin, always burns with sun exposure.
TYPE 2		White skin, usually burns with sun exposure.
TYPE 3		White or olive skin tone, sometimes burns with sun exposure.
TYPE 4		Brown skin, rarely burns with sun exposure.
TYPE 5	Not clinically tested to be effective	Dark brown skin, very rarely burns with sun exposure.
TYPE 6		Black skin, rarely burns with sun exposure.

Not a candidate?

If your hair loss is advanced, caused by something other than androgenetic alopecia, or if you have a very dark skin tone, LaserCap may still likely be beneficial for you, on its own, or in combination with other treatments. In these cases you should consult with a medical professional to see if you should use LaserCap.

2.2 Contraindications for use

If any of the following apply to you, consult with a physician before using LaserCap.

- You are taking medications or have a medical condition that makes your skin sensitive to sun or light.
- You are allergic to red or near infrared light (645-660nm).
- You have a history of skin cancer of the scalp, head or neck.
- You are suffering from severe diseases such as cancer, hematological diseases, severe diabetes, or heart disease.
- You are suffering from scalp injury.
- You are under 18 years of age.

3. SIDE EFFECTS, WARNINGS & PRECAUTIONS

3.1 Warnings & Precautions

- Do not stare directly at the red laser lights or their reflection, as it can temporarily irritate your eyes. If you stare at the light for too long, it could harm your eyes. Never use optical instruments like magnifiers or microscopes when using LaserCap.
- Laser light - avoid direct eye exposure.
- Keep out of the reach of children.
- Discontinue use if scalp itching or tingling occurs and lasts more than one hour after completion of a treatment session. If the problem continues for more than one hour after treatment, discontinue usage and consult with a physician.
- Do not get the LaserCap device or power pack wet. This may result in electrical shock.
- Do not drop in water because you may get an electrical shock. If damaged by water, contact customer service promptly.
- Never use in the bathtub, shower or swimming pool. This could result in serious danger resulting in an electrical shock, injury, and even death.
- Do not use when your hair is wet from showering, swimming or bathing. Towel dry your hair before use.
- Do not use near any heated surfaces as this could cause malfunction or electrical shock.
- Do not operate if the LaserCap device, power pack, wall charger, or any cords are damaged. If you notice damage to any of the above, contact customer service promptly.
- Always unplug the LaserCap from power prior to cleaning the device. Failure to do so may result in an electrical hazard and may cause harm or injury.
- Do not modify this equipment without authorization from the manufacturer.
- Do not dispose of the power pack or burn the power pack; please recycle the power pack at the end of its useful life.
- The LaserCap device should never be connected directly to the wall charger and should only be powered by the power pack.
- The power pack should only be charged with the provided wall charger.
- Power pack contains lithium battery. Do not attempt to replace or otherwise modify battery, as doing so can result in a hazard such as excessive temperature, fire, or explosion. Discontinue use of the power pack and device if the power pack shows signs of damage such as unusual odor, excessive heat, popping sounds, or swelling.
- Safety of non-thermal lasers for use during pregnancy has not been established.

3.2 Non-Serious Side Effects

A small portion of users may experience the following non-serious side effects during treatment with LaserCap:

- Pruritus (itchiness) and/or paresthesia (tingling) of the scalp skin.
- Mild headache.

If these side effects occur, they will normally be very mild and transient, occurring only during treatment. If these side effects are not tolerable or persist for more than an hour after treatment, discontinue use of LaserCap and consult with a physician before using LaserCap again.

4.1 Component Identification

Before using your LaserCap, please unpack and ensure you have all of the following components:

1. LaserCap Device
2. Power Pack
3. Wall Charger for Power Pack
4. Belt Clip for Power Pack
5. Baseball Hat

1.

2.

3.

4.

5.

4.2 Warranty Registration

Please register your device as soon as possible so that we can provide you warranty service if necessary. To register your device, please go to lasercap.com/warranty-registration, or call us at 1-855-424-7774.

5.1 Charging the Power Pack

The power pack should be fully charged before using LaserCap. To test the charge, turn the power pack switch to the on (I) position, and look at the charge indicator lights. The power pack is fully charged when all four (4) charge indicator lights are illuminated. Charge the power pack when it is not at full charge. To do so, follow these steps:

1. Turn the power pack to the off (O) position.

2. Plug the wall charger into a wall outlet.

3. Plug the wall charger cord into the black port of the power pack labeled “CHG”. **If the power pack beeps continuously, make sure it is switched to the off (O) position.**

4. Check the wall charger indicator light. When the power pack is charging, the light will be red. When the power pack is fully charged the light will turn green.

5. Unplug the power pack when it is fully charged.

The power pack is fully charged when all four charge indicator lights are illuminated.

Turn the power pack to the off (O) position and plug the wall charger cord into the black CHG port.

The wall charger indicator light will be red when the power pack is charging, and green when the power pack is fully charged.

5.2 Operating the LaserCap

*Use LaserCap for 30 minutes every-other-day, or as directed by your medical provider.
*The laser lights will blink (pulse) rapidly during use. This is normal and an important feature of the technology.

1. Place the LaserCap device in the included baseball hat, or other hat of your choosing. Make sure the LaserCap device power cord sticks out freely from the back or bottom of the hat. You may also use LaserCap without a hat.

2. Make sure the power pack is in the off (O) position. Then plug the power pack cord into the LaserCap device power cord.

3. Place the LaserCap device on your head.

4. To start treatment, turn the power pack switch to the on (I) position. The power pack will beep one time.

5. Wear the LaserCap for 30 minutes until the power pack beeps four times and shuts off. Then turn the power pack to the off (O) position and remove the LaserCap device from your head.

***If the power pack is at low charge, it will shut off and will beep continuously in series of three. In this case, turn the power pack to the off (O) position and charge the power pack.**

With the power pack in the off (O) position, plug the power pack cord into the LaserCap device power cord.

5.3 Maintenance and Storage

- Charge the power pack after every use. The battery should be fully charged prior to using the LaserCap.

- **Cleaning**
  - You may clean the interior clear plastic liner of the device with a slightly damp cloth or alcohol wipe after each use.
  - Disconnect the power pack before cleaning.
  - Do not use acetone or solvents for cleaning.
  - NEVER submerge the device or any of its components in water.

- **Storage**
  - To avoid breakage or missing parts, neatly store the device and components after each use. It is recommended to use the included carrying case for storage.
  - Store the device and components in a cool, dry place. Avoid exposure to excessive heat, cold, or moisture.

6. RESULTS AND EXPECTATIONS

6.1 Compliance Requirements

If you are not compliant with your treatment protocol, you will not see any positive results from LaserCap. Make sure you use LaserCap for 30 minutes every other day, or as directed by your medical provider.

6.2 Timeline of Results

If you are compliant with your treatment protocol, you should start to see positive results from LaserCap within 4-6 months. Over the next 1-2 years you may see continued improvement, after which you should continue to use LaserCap to maintain your results.

*You may see increased hair shedding for the first 1-2 months using LaserCap. This is a normal part of the regrowth process and should not be a cause for concern.

6.3 Quality of Results

LLLT is an evidenced-based treatment for hair loss, proven to be effective in numerous high quality clinical trials. LaserCap is furthermore cleared by the FDA as an effective treatment for male and female pattern hair loss.

Nevertheless, it is important to understand that results from LLLT can be subtle. Results will also vary from person-to-person based on degree of hair loss when starting treatment, genetics, environmental conditions, and other factors inherent to each individual. In some cases LLLT will produce hair regrowth and thickening, while in other cases results will be limited to stabilization or slowing of the rate of hair loss.

Better results may be achieved by combining LaserCap with other evidence-based hair loss treatments. These include but are not limited to, medications such as minoxidil (Rogaine) and finasteride (Propecia), and hair transplant surgery.

In any case, if you are not satisfied with your results from LaserCap, please contact us so we can better understand your concerns and provide you with additional recommendations.

7. TROUBLESHOOTING

If you are experiencing technical difficulties with your LaserCap device, please refer to the following guidelines:

LaserCap device will not turn on or is turning off during use:

Make sure you are charging the battery and operating the device correctly (refer to sections 5.1 and 5.2). If the problem persists, contact customer service.

Some of the LaserCap lights are not lighting up:

Contact customer service.

There is damage to the surfaces or wires of the LaserCap:

Discontinue using LaserCap, and contact customer service.

LaserCap device feels too hot:

Some amount of warmth is to be expected during treatment. If LaserCap feels uncomfortably warm, make sure you are not using it near external heat sources, in direct sunlight, inside an insulated or thick hat, or for longer than the recommended treatment period.
If you are continuing to experience and uncomfortable level of warmth during treatment, discontinue use of LaserCap and contact customer service.

8. WARRANTY, REPLACEMENT PARTS, RETURNS

8.1 Warranty

The LaserCap Lifetime Limited Warranty Policy covers against defects in materials or workmanship from date of purchase with proof of purchase. If a LaserCap device is determined to be defective within five (5) years from date of purchase, LaserCap Company will repair, or replace with a like model, free of charge. After five (5) years from date of purchase, LaserCap Company will repair or replace a device for a charge depending on the scope of repair or replacement. LaserCap Company reserves the right to decide whether a repair or replacement will be offered for a defective device.

If a LaserCap power pack or power pack charger is determined to be defective within one (1) year from date of purchase, it will be replaced free of charge. After one (1) year from date of purchase, a new power pack or power pack charger must be purchased by the user. Other accessories are not covered by warranty and must be purchased by the user.

Note that failure to use and care for the LaserCap as instructed will void the product warranty.

Customers must register their LaserCap device after purchase to be eligible for warranty service. To register your device please go to: lasercap.com/warranty-registration-form/

To initiate a warranty claim please call +1 855-424-7774, or email info@lasercap.com.

8.2 Replacement parts

Replacement parts that are not covered under warranty can be purchased at the lasercap.com website

9. OTHER INFORMATION

9.1 Technical Specifications

Product Name: LaserCap SD, LaserCap HD, LaserCap HD+
Trade Mark: The Original LaserCap®
Model: LaserCap SD, LaserCap HD, LaserCap HD+
Wavelength: 650nm
Type of Light: Low Level Laser Therapy (LLLT)
Laser Power for Classification: <5mW, Laser Class 3R
Number of Laser Diodes (5mW): 80, 224, 300
Power Adapter: Input: AC100-240V, 50/60Hz, Output: DC12.6V 1A
Battery: Lithium Ion Rechargeable Battery, Model: YB1202600, Input: DC12.6V 3A, Output: DC9-12.6V 3A 50% Duty Cycle 6 Hz, Capacity: 11.1V 2600mAh 28.86Wh
Input: 12.6v 3A
Operating Environment Temperature: 10°C-30°C (50°F-86°F)
Operating Environment Humidity: 20%-80%
Operating Environment Pressure: 70kPa-106kPa
Storage & Transportation Temperature: -10°C-60°C (14°F-140°F)
Storage & Transportation Humidity: 20%-80%
Electrical Safety Classification: Class II, Type BF, IP22
Life Time: 5 Years

9.2 Disposal

DO NOT throw away this device with normal household waste at the end of its life. Due to the battery and laser components of the LaserCap this device must be taken to an official collection point for these materials. Contact your municipality for recycling information. By doing this, you help to preserve the environment.

9.3 Disclaimer

LaserCap Company is not responsible for any consequences caused by improper use of LaserCap products. By purchasing this product, customer assumes full responsibility of proper and safe use as outlined in this manual. For further guidance, please visit www.fda.gov.

9.4 Relevant Symbols and Explanations

Symbol	Explanation	Symbol	Explanation
YYY-MM	Manufacturer Year and month of manufacture		Laser Safety Symbol
	Type BF applied part	IP22	IP Classification
	Follow instructions for use		Dispose of the device in accordance with the relative WEEE (Waste Electrical and Electronic Equipment)
	Storage and transportation humidity		Storage and transportation temperature

Labels on package and device are in compliance with IEC60825-1 Standard:

Laser Warning Label

10. EMC Statements

The following table describes the relevant labeling in the User Instruction Manual for the section contained in the IEC 60601-1-11 standard.

Clause	Requirement	IFU Reference
4.2.1	Environmental conditions of transport and storage between uses	Section 9
4.2.2	Environmental operating conditions	Section 9
7.1	Usability of identifications, marking, and accompanying documents intended for lay operator or lay responsible organization evaluated by an operator whose profile included eight years of education	See User Manual
7.2	The enclosure is marked with the IP classification required by 8.3.1	Section 9
7.3.1	Assistance in setting up, using, or maintaining the ME Equipment or ME System when needed or to report unexpected operation or events. Accompanying documents include a postal address and either a phone number or web address for the lay operator or lay responsible organization to contact the manufacturer or manufacture's representative	Section 7 Back Cover
7.3.2	Accompanying documents include necessary details for healthcare professional to brief the lay operator or lay responsible organization on any known contraindication(s) to the use of ME Equipment or ME System and any precautions to be taken including the following: Precautions to be taken in the event of changes in the performance of ME Equipment or ME System / Precautions to be taken regarding the exposure of the ME Equipment or ME System to reasonably foreseeable environmental conditions.	Section 2 Section 3
7.4.1	Additional requirements for warning and safety notices (strangulation, small part hazard, allergic reaction to accessible materials and contact injury) Also: Use of accessories / interconnection with other equipment/ modification of equipment / use outside carrying case if carrying case vital to meeting requirements	Section 3
7.4.2	Additional requirements for an electrical power source: the typical operation time or number of procedures; the typical service life; and for a rechargeable internal electrical power source, the behavior of the ME Equipment while the rechargeable internal electrical power source is charging.	Section 5
7.4.3	The instructions for use shall include easily understood diagrams illustrations, or photographs of the fully assembled and ready-to-operate ME Equipment including all controls, visual information signals, and indicators provided with the ME Equipment (see 7.1)	See User Manual
7.4.4	The instructions for use shall include: easily understood diagrams, illustrations, or photographs showing proper connection of the patient to the ME Equipment, accessories and other equipment (see 7.1); and the time for switching "on" until the ME Equipment is ready for normal use, if that time exceeds 15 s (see 15.4. of the general standard).	See User Manual
7.4.5	The instructions for use shall include a description of generally known conditions that can unacceptably affect the equipment and the steps that can be taken by the lay operator to identify and resolve these conditions, and shall include, where applicable, at least the following issues; the effects of lint, dust, light etc. / a list of known devices or other sources that can potentially cause interference problems / the effects of degraded sensors and electrodes, or loosened electrodes, that can degrade performance or cause other problems / the effects caused by pets, pests or children / The instructions for use shall explain the meaning of the IP classification marked on the ME Equipment and, if applicable, on any carrying case provided with the ME Equipment.	Section 3 Section 7 Section 9 Section 10
7.4.7	Additional requirements for cleaning disinfection and sterilization: frequency of cleaning / if intended for multiple patients, state cleaning needed between patients / where professional hygienic maintenance is required, provided details for source of these services	Section 5

10. EMC STATEMENTS

LaserCap requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in these accompanying documents. Portable and mobile RF communications equipment can affect medical electrical equipment.

WARNING: A risk of increased emissions or decreased immunity may result if any additional cables are attached. The LaserCap should not be used adjacent to or stacked with other equipment.

WARNING: observe to verify normal operations if it is necessary to use adjacent to or stacked with other equipment.

1	Guidance and manufacturer's declaration - electromagnetic emissions		
2	The LaserCap is intended for use in the electromagnetic environment specified below. The customer or the user of the Trans Dermal Inc. LaserCap should assure that it is such an environment.		
3	Emissions Test	Compliance	Electromagnetic environment - guidance
4	RF emissions CISPR 11	Group 2	The LaserCap must emit electromagnetic energy in order to perform its intended function. Nearby equipment may be affected
6	RF emissions CISPR 11	Class B	The LaserCap is suitable for use in all establishments, including domestic establishments, including domestic establishments and those directly connected to the public low - voltage power supply network that supplies buildings used for domestic purposes.
7	Harmonic emissions IEC 61000-3-2	Class A	
8	Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The Trans Dermal Inc. LaserCap is intended for use in the electromagnetic environment specified below. The customer or the user of the Trans Dermal Inc. LaserCap should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic
Electrostatic discharge (ESD) IEC 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/ burst IEC 610004-4	± 2kV for power supply lines	± 2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	± 1kV line(s) to lines (2) ± 2kV line(s) to earth	± 1kV line(s) to lines (2) ± 2kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% Ut (>95%dip in Ut) for 0,5 cycle 50% Ut (60% sip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut for 5 s	<5% Ut (>95%dip in Ut) for 0,5 cycle 50% Ut (60% sip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Trans Dermal Inc. LaserCap requires continued operation during power mains interruptions, it is recommended that the Trans Dermal Inc. LaserCap be powered from an interruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be a levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: Ut is the A.C mains voltage prior to application of the test level.			

10. EMC STATEMENTS

Guidance and manufacturer's declaration - electromagnetic immunity			
The LaserCap is intended for use in the electromagnetic environment specified below. The customer or the user of the Trans Dermal Inc. LaserCap should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the LaserCap, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = [3.5/3] √P d = [3.5/3] √P 80 MHz to 800 MHz d = [7/3] √P 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	
NOTE at 80 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey shoule be considered. If the measured field strength in the location in which the Trans Dermal Inc. LaserCap is used exceeds the applicable RF compliance level above, the Trans Dermal Inc. LaserCap should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Trans Dermal Inc. LaserCap.			

Recommended separation distances between portable and mobile RF communications equipment and the LasserCap			
The LaserCap is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Trans Dermal Inc. LaserCap can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LaserCap as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	150 kHz to 80 MHz d = [3.5/3]√P	80 MHz to 800 MHz d = [3.5/3]√P	800 MHz to 2.5 GHz d=[7/3] √P 800 MHz to 2.5 GHz
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.689	3.689	7.379
100	11.667	11.667	23.333
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 800 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

11. CONTACT INFORMATION

Corporate Office - Customer Service - Warranty Repairs

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