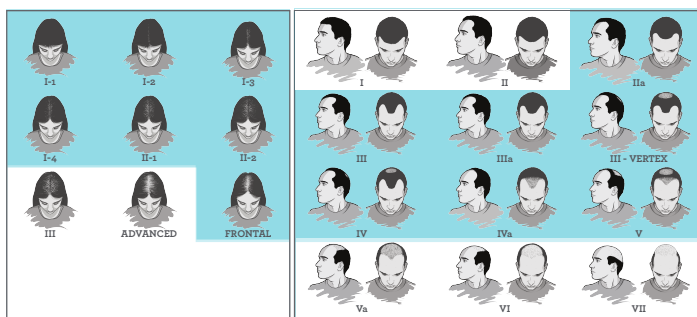




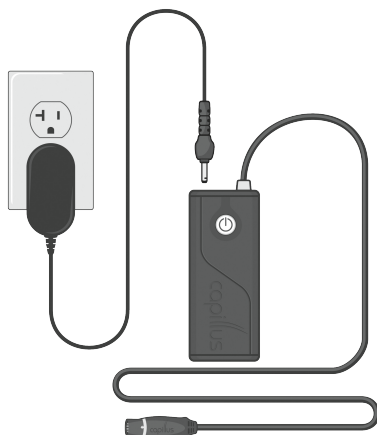
User Instruction Manual

capillus

A



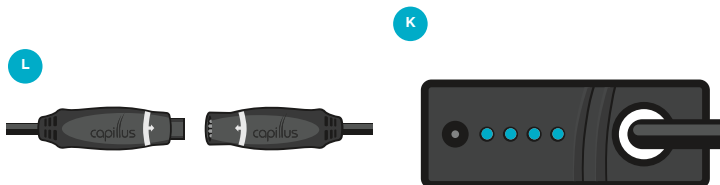
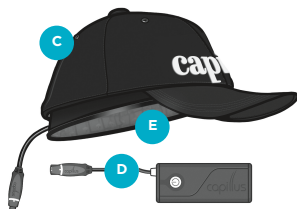
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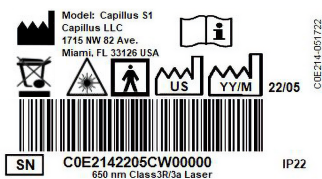
M



**Capillus sports cap
available only for select
models.**



**Additional accessories
available for purchase**





IMPORTANT SAFETY INSTRUCTIONS

When using this device, basic safety precautions should always be followed, including the following:

SAVE THESE INSTRUCTIONS. PLEASE READ ALL INSTRUCTIONS BEFORE USING

Please read all instructions before using your Capillus® device. Please keep this user manual for future reference and be sure to follow all warning and safety information included herein. If you have any questions regarding operation, please contact Capillus Customer Service toll-free at 1-888-470-2710 or via email at support@capillus.com.

1. **DO NOT STARE DIRECTLY AT LASER LIGHT OR ITS REFLECTION FOR EXTENDED PERIODS. PROLONGED EYE EXPOSURE CAN CAUSE EYE DAMAGE.**
2. Use this device only for its intended use and according to the instructions provided. Any other use may result in injury.
3. To protect against the risk of electric shock, do not immerse the appliance in water or other liquids. Do not place or store the unit where it can fall or be pulled into a tub or sink.
4. If the unit accidentally falls into water or other liquid, unplug it from the electrical outlet immediately. **DO NOT REACH INTO OR TOUCH THE WATER.**
5. Always connect the plug into outlet first, then attach the power supply to the unit. Always unplug the power adapter from the power outlet immediately following charge. The Battery Pack should always be turned off when connecting/disconnecting from power supply.
6. Do not operate the device when it or any of its components are damaged, or if the Battery Pack or power supply have been dropped or damaged. To avoid the risk of electric shock, do not disassemble any part of the appliance or its accessories. Contact Capillus Customer Service for examination and repair.
7. This device is not intended for use by persons (including children) with reduced physical, sensory, or mental capabilities, or lack of experience and knowledge, unless they have been given supervision or instruction concerning use of the device by a person responsible for their safety.
8. Children should be supervised to ensure that they do not play with the device or its accessories and components. Do not leave the device unattended while connected to Battery Pack.
9. Conditions that will void warranty: a) Commercial use, b) inappropriate use, c) failure to comply with the instructions, d) connecting your Battery Pack to the device incorrectly, as this may cause irreparable damage.
10. If the power supply is damaged, contact Capillus for replacement to avoid electrical hazard or damage.
11. Do not adjust or modify the device as this may result in hazardous radiation exposure. Do not use any power adapters or other sources of power, other than that provided with the device. Use only the power supply provided with the device.

SAVE THESE INSTRUCTIONS FOR FUTURE REFERENCE.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help

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CORPORATE INFORMATION



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 Email: support@capillus.com
 Website: www.capillus.com

Capillus and the Capillus logo are trademarks of Curallux, LLC registered in the USA and other countries. Patent number US10099065 B2. Capillus laser devices are made in the USA from foreign-sourced raw materials. All product information and articles are intended to be for informational purposes only.

REGULATORY COMPLIANCE

Curallux, LLC lasers comply with 21 CFR 1040 for Class 3R Laser Products as administered by the Center for Device and Radiological Health of the US Food and Drug Administration and standard IEC60825 of the International Electrotechnical Commission.

Capillus's Quality System for medical device design and manufacturing is registered by Intertek and is compliant with the following:

ISO13485:2016

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

ABOUT THE CAPILLUS® DEVICE

The Capillus® laser therapy cap is a portable home-use Low-Level Laser Therapy (LLLT) device. The device features a laser device embedded with laser diodes (<5mW) on its interior surface, and is powered by a certified rechargeable Battery Pack that connects to the device. The laser device is either worn under the sports cap included with the device or any other hat of your choosing. The Battery Pack can be clipped onto your waistband or belt, or slipped into your pocket. The Capillus® laser therapy cap provides low-level laser therapy to the scalp and hair follicles to stimulate cellular activity and promote the flow of blood. There is no need for constant user effort. The hands-free design makes it easy and comfortable to use while performing daily activities.

INDICATIONS FOR USE

The Capillus® laser therapy cap is intended to treat androgenetic alopecia and promote hair growth in males who have Norwood Hamilton Classifications of IIa-V patterns of hair loss, and to treat androgenetic alopecia and promote hair growth in females who have Ludwig (Savin) scale Classifications I-1 to I-4, II-1, II-2, or frontal patterns of hair loss; both with Fitzpatrick Skin Types I to IV.

IS CAPILLUS LASER THERAPY RIGHT FOR YOU?

If your hair loss is due to heredity, Capillus laser therapy may be a great treatment option for you. Hair loss is a serious issue that affects millions of men and women around the world. The most common type of hair loss is a result of your genes: androgenetic alopecia (pattern baldness). It's a progressive condition (worsens over time) and constitutes 98% of hair loss. If you begin treatment during the earlier stages of progression, the Capillus® laser therapy cap may stop further progression and regrow your thinning hair.

Capillus is intended for treatment of adults with hair loss represented within the shaded areas indicated on Fig. A shown on page 1.

Low-Level Laser Therapy has only been tested on following Fitzpatrick skin types: **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. Low-Level Laser Therapy has NOT been clinically tested on following Fitzpatrick skin types: **TYPE 5:** Sun-insensitive skin, rarely burns, tans well. **TYPE 6:** Sun insensitive, never burns, deeply pigmented.

INTENDED USAGE

The Capillus® device should be used only for the purpose described in this manual. The Capillus® device is intended for use on the human scalp only. Any other use is not recommended.

FREQUENCY OF USE

The Capillus® laser therapy cap should be used every day. The total time of each session is 6 minutes. Exceeding the recommended times or frequency will not increase the effect of the device; and may in fact cause a negative effect. Do not exceed recommended usage.

DURATION OF USE

Although you should see significant results within 4 months, the Capillus® device may be used indefinitely according to the instructions above. Cessation of use may result in loss of new hair growth.

WHAT'S INCLUDED

FIGURES B-I: CAPILLUS LASER THERAPY CAP COMPONENTS

Refer to Page 1 to see referenced figures. Inside the box, the following components can be found: the Capillus laser device [Fig. E], which is fitted into a premium quality sports cap (Capillus sports cap available only for select models which can be switched out with your favorite cap) [Fig. C]; a rechargeable lithium-ion Battery Pack [Fig. D] for operating the device; and the corresponding Universal AC Adapter [Fig. G]. Additional accessories are available for purchase, including: 4 interchangeable plug adapters for use in international markets [Shown in Fig. G]; a lightweight carrying case [Fig. B] which can be used to store the device and protect it from dust and moisture, as well as for traveling. A detachable shoulder strap [Fig. H] is included with the carrying case for long travels.

INSTRUCTIONS FOR CHARGING BATTERY PACK

Before initial use, please charge the Battery Pack overnight as per the following instructions for optimal battery life. Only charge the Battery Pack with the provided AC adapter.

STEP 1

Fig. **J**: Insert provided AC adapter into power outlet and then connect Battery Pack to AC adapter. Make sure access to AC adapter is unobstructed, for safety. The indicator lights on the top of the Battery Pack will indicate charge level.

STEP 2

Fig. **K**: Once all four indicator lights are turned on and static (no blinking), the Battery Pack is ready for use. Disconnect Battery Pack from AC adapter for use. Disconnect AC adapter from power outlet. We recommend storing all parts of your device in the Carrying Case, Fig. **B** when not in use.

INSTRUCTIONS FOR USE

The figures in this section refer to the items illustrated on Page 1.

STEP 1

Unpack the components and make sure all the parts are present according to Page 2. If there are parts missing, contact customer service at 1-888-470-2710 or support@capillus.com.

STEP 2

Refer to Fig. **K**: For optimal battery life, Battery Pack, Fig. **D** should be charged overnight before first use until all 4 indicator lights on top of Battery Pack, Fig. **D** are on and static. Battery, Fig. **D** should also be disconnected from laser device, Fig. **E** between uses for optimal battery life and performance. After initial charge, please charge Battery Pack, Fig. **D** only when one indicator light is left.

STEP 3

Refer to Fig. **L**: Connect the laser device, Fig. **E** to the Battery Pack, Fig. **D** by matching up the small white indicator arrows on the cables to each component. Important: The arrows must be aligned for the cables to make a proper connection. Once the arrows are aligned, push cables together and secure.

STEP 4








Refer to Fig. **M**: Place laser device, Fig. **E** on your head as shown and press and hold for 1 second the power button on front of Battery Pack, Fig. **D** to begin treatment. Battery level indicators on top of Battery Pack, Fig. **D** will light. The emission indicator light on top of the Battery Pack will glow red to indicate that treatment has begun and lasers are operational. Please note that there is a sensor on the inside of the device that only allows light to be emitted when the cap is on the head. Should you hear continuous beeping during treatment it may be an indication that treatment has been disrupted. If treatment is interrupted for 10 minutes or longer, the treatment session will be reinitiated upon start. NOTE: The Capillus® laser device will not operate if the Battery Pack, Fig. **D** is connected to the AC adapter, Fig. **G**.

STEP 5

When the automatically programmed treatment session is finished (6 minutes), you will hear three longer successive beeps to indicate the treatment period is over, the lasers will automatically shut off, and the emission indicator light on the Battery Pack, Fig. **D** will turn off. When treatment is over after 6 minutes, the Battery Pack, Fig. **D** will turn off automatically. Disconnect Battery Pack, Fig. **D** from laser cap and store until next use.

SAFETY LABELS

Refer to Fig. **N**: The laser safety label can be found on the cable of the laser device, Fig. **E**.
Refer to Fig. **O**: Label can be found on the exterior of the laser device, Fig. **E**. Actual image may differ.

LEGEND	
SYMBOL	EXPLANATION
	INDICATES MANUFACTURING COMPANY.
	INDICATES LASER LIGHT RADIATION AS DESCRIBED ON LABEL (FIG. 0).
	INDICATES TYPE BF APPLIED PART (60335); B=BODY, F=FLOATING APPLIED PART. NO CONDUCTIVE CONTACT TO USER.
	INDICATES COUNTRY OF MANUFACTURE.
	INDICATES DATE OF MANUFACTURE, IN YEAR-MONTH FORMAT. DATE IS ADJACENT TO THE SYMBOL.
	READ ACCOMPANYING DOCUMENTS.
	INDICATES THE UNIQUE DEVICE IDENTIFIER.
IP22	INDICATES MINIMUM PROTECTION AGAINST DUST AND MOISTURE. PLEASE USE THE CARRYING CASE FOR PROTECTION BETWEEN USES.

The Capillus® laser therapy cap gives off no heat or harmful radiation, causes no pain, and does not require the use of drugs or topical applications.

EYE SAFETY CAUTION: Class 3R 5 MilliWatts, 650 Nanometers Red Laser Diodes. DO NOT STARE DIRECTLY INTO THE LASER LIGHT FOR EXTENDED PERIODS.

CONTRAINDICATIONS

- Laser therapy should not be used in conjunction with medications or products that are photosensitizing.
- Consult with your physician before using the Capillus® laser therapy cap if you have cancer of the scalp, or you are sensitive to light of 650 nm in wavelength.

MAINTENANCE INSTRUCTIONS

If it is necessary to clean the surfaces of your Capillus® laser therapy cap, please follow these instructions. Note: the Capillus® laser therapy cap has no parts that can be serviced by the user. If service is required, contact Capillus, LLC.

- DISCONNECT ALL CABLES ON THE CAPILLUS® LASER THERAPY CAP BEFORE CLEANING
- To clean the Capillus® laser therapy cap, gently wipe the inner surface of the laser device with an alcohol wipe or a water-moistened cloth. Do not use excessive pressure or force as this may damage the unit.
- DO NOT use acetone or any other solvents on any part of the device. Acetone and other solvents will damage the unit and void the warranty.

OPERATING INFORMATION

The Capillus® laser therapy cap is designed to work in ambient temperature between -4° and 140° F (-20° and 60° C).




		
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STORAGE & TRANSPORT INFORMATION

Use carrying case, Fig. B provided to store and protect your device from dust and moisture between uses. The Capillus® laser therapy cap is designed to be shipped or stored in temperatures between -13° and 158° F (-25° and 70° C). Battery life may be shortened if stored outside of these temperature ranges. After transport or storage in extreme temperatures, it is recommended to keep the device in normal room temperature for at least 3 hours before charging or using.

 -25° C 70° C	 93% RH 15% RH	 1060 hPascals 700 hPascals
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LEGEND

SYMBOL	EXPLANATION
	INDICATES TEMPERATURE RANGE.
	INDICATES RELATIVE HUMIDITY RANGE.
	INDICATES ATMOSPHERIC PRESSURE RANGE.

LIMITED WARRANTY

Please refer to limited warranty details below for your Capillus laser therapy cap model.

CAPILLUS ONE CAPILLUS ONE S CAPILLUS ULTRA	CAPILLUS PLUS CAPILLUS PLUS S1 CAPILLUS X+	CAPILLUS PRO CAPILLUS PRO S1 CAPILLUS PRO S2 CAPILLUS SPECTRUM	CAPILLUS RX CAPILLUS MD MD DUO RX DUO
LASER DEVICE WARRANTY PERIOD			
1 Year	2 Years	3 Years	5 Years
BATTERY PACK & AC ADAPTER WARRANTY PERIOD			
1 Year			

Capillus warrants the device against defects in materials or workmanship for a period indicated above from the date of purchase from a Capillus authorized center. To activate your warranty, register your device within 30 days of purchase at www.capillus.com/activatewarranty. If a defect in material or workmanship exists, Capillus will repair or replace the necessary parts with new or reworked parts at no charge. Any replacement part will be covered under the original limited warranty. This Warranty is not transferable and does not cover damages caused by acts of God, misuse, negligence, accident, or modification of any part of the unit as determined by our service department. This Warranty does not cover damage due to improper operation or maintenance, connection to improper voltage supply, or attempted repair by anyone other than the company. Failure to use and maintain the device in accordance with the instructions in this manual will void the product warranty.

Batteries will need to be replaced over time through Capillus. Please contact Capillus customer service should you need to get warranty service or order replacement parts such as Battery Packs or AC adapter.

Do not disassemble any part of the Capillus® laser therapy cap and don't attempt to repair the device by yourself. Disassembling the device may damage it or may cause injury to you. If the Capillus® device is damaged, malfunctions, or comes in contact with liquid, contact Capillus. The lithium-ion battery should be replaced only by Capillus.

ELECTROMAGNETIC INTERFERENCE - EMC/EMF

This appliance complies with all applicable standards regarding electromagnetic fields (EMF). If handled properly and according to the instructions in this user manual, the appliance is safe to use based on scientific evidence currently available.

MATERIALS

This product is compliant with the current Restriction of Hazardous Substances (RoHS) regulation; there are no materials used with known allergens or adverse health effects.

TROUBLESHOOTING

For any problems operating the Capillus® laser therapy cap, please contact Capillus Customer Service at 1-888-470-2710 or support@capillus.com. If you experience any discomfort during or after use, please discontinue use immediately and contact your physician.

NOTICE: Do not attempt to repair any portion of the Capillus® laser therapy cap. If a malfunction occurs, disconnect the Capillus® laser therapy cap from the electrical source and contact Capillus Customer Service toll-free at 1-888-470-2710 or email at support@capillus.com.

DEVICE SPECIFICATIONS

Please refer to specifications below for your Capillus® laser therapy cap model.

CAPILLUS ULTRA		CAPILLUS ONE	CAPILLUS ONE S	CAPILLUS PLUS	CAPILLUS PLUS S1
NO. OF DIODES	82	112	128	202	214
TOTAL OUTPUT	410 mW	560 mW	640 mW	1010 mW	1070 mW
CAPILLUS X+		CAPILLUS PRO	CAPILLUS PRO S1	CAPILLUS PRO S2	CAPILLUS RX
NO. OF DIODES	244	272	304	308	312
TOTAL OUTPUT	1220 mW	1360 mW	1520 mW	1540 mW	1560 mW
CAPILLUS SPECTRUM		CAPILLUS MD	MD DUO	RX DUO	
NO. OF DIODES	312	320	320	330 1650 mW	
TOTAL OUTPUT	1560 mW	1600 mW	1600 mW		
LASER DEVICE			BATTERY PACK		
TYPE		5 mW	TYPE		Lithium-Ion
WAVELENGTH		650 nm +/- 5	INPUT		DC5V/1.5A
WAVELENGTH / SPECTRUM		650 nm +/- 5 / 808 nm +/- 5			
OUTPUT MODE		Continuous Wave	OUTPUT		DC5V/5A
AC ADAPTER			CAPACITY		3500mAh/3.6V
			SERVICE LIFE EXPECTANCY*		
INPUT		AC100-240V, 50/60Hz, 0.6A		3 Years	
OUTPUT		DC5V, 3A		5 Years Physician models	

The power supply for the Capillus® laser therapy cap has been designed for use in the United States and some international regions with power inputs as per above. We also include 3 alternate plugs for use in other countries. If the power outlets in your country use plugs different than the type supplied, it will be necessary to obtain an appropriate country-specific plug adapter.

*In the case that a device needs repair, this indicates how long a particular model can be serviced after purchase, due to the availability of parts in inventory.

AMBIENT OPERATING CONDITIONS

- Operating Temperature: -20° Celsius (-4° Fahrenheit) to 60° Celsius (140° Fahrenheit)
- Humidity: 15% to 90% RH
- Atmospheric Pressure: 700 hPascals to 1060 hPascals

CLASSIFICATIONS

IEC 60825 Classification: Class 3R Laser Product; output power <5mW
 FDA Medical Device Class: Class II

EYE SAFETY

UNLESS WEARING SUITABLE LASER SAFETY EYE-WEAR PROTECTION, DO NOT STARE AT THE LASER LIGHT FOR LONG PERIODS AS IT CAN DAMAGE YOUR EYES.

capillus

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