

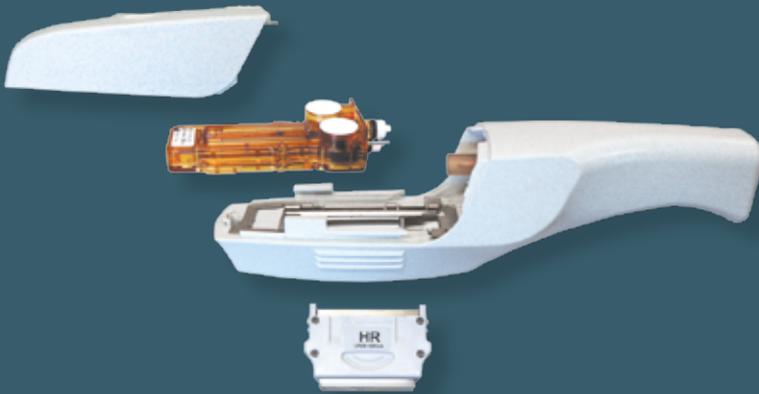
Dermeo®

 French designer and manufacturer

 ISO 9001  ISO 13485

Medical pulsed light device **MDFLASH4**

New technology for cosmetic
dermatology treatments



EASYLAMP®

Worldwide innovation: DERMEO has developed the first
water-cooled LAMP-CARTRIDGE interchangeable by the user

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0473


Numéro d'homologation
510(K) : K093168





Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

ORGANIZATION

Our research,
our innovations,
our expertise



The company

Set up in 2000, DERMEO became the only French IPL manufacturer offering medical devices combining the best technological features with the best results. At the top of an evolutionary innovation, DERMEO has technological and clinical expertise.

DERMEO is involved in designing, manufacturing, distributing, sales and after sales services of medical devices.



French product

The high quality of DERMEO's production tools complies with the French manufacturing protocols and enables total transparency and traceability from the designer to the patient. DERMEO only selects the best components from French or European origin.

The manufacturing steps are validated by us and by inspectors who check the conformity of the devices on the manufacturing line compared to the files.

The strategy of innovation and quality coupled with excellent knowledge of international regulations has allowed DERMEO to expand on all five continents.

Innovation
for
performance

Evolutionary technology

DERMEO is in constant development and recruits only the best engineers in mechanics, electronics, energy conversion, computer software development, optics and composite materials, who enabled DERMEO to be awarded several patents.

Quality

DERMEO provides you with the knowledge of an ISO 9001 and ISO 13485 certified expert. Compliance with these international and medical organizational standards is a guarantee of quality for both our customers and our suppliers. DERMEO has a medical devices vigilance cell which is registered by ANSM.

Medical research

Clinical research investments are made in partnership with groups of specialist doctors to assess the performance, security, and innocuousness of the devices that are on the market.

**DESIGNING, MANUFACTURING,
DISTRIBUTING, SALES, AND
AFTER SALES OF MEDICAL
AND AESTHETIC DEVICES.**

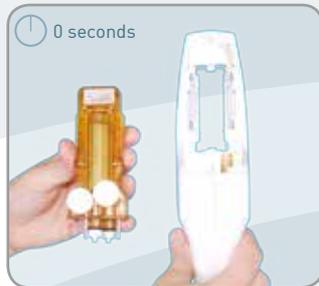


Easier,
faster,
more functional

Interchangeable EASYLAMP® LAMP CARTRIDGE

Worldwide innovation: DERMEO has developed the first water-cooled LAMP CARTRIDGE which is directly interchangeable by the user. When the lamp has to be changed, there is no need to send it back to the workshop or to contact a technician.

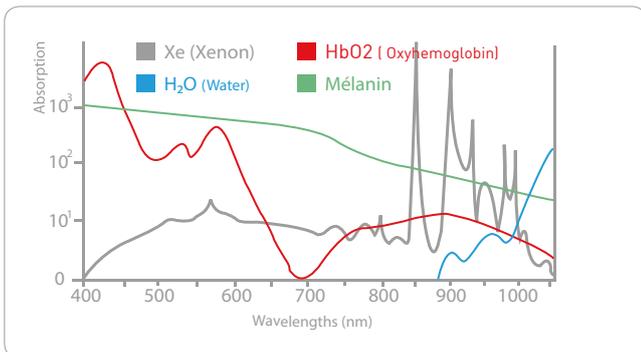
JUST 10 SECONDS ARE ENOUGH FOR THE OPERATOR TO CHANGE THE WATER-COOLED LAMP CARTRIDGE



Patent Filed

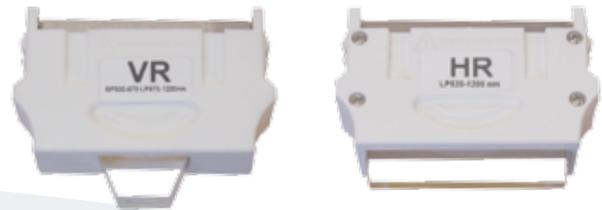
In a few seconds, the lamp can easily and safely be replaced. The replacement of the LAMP CARTRIDGE is simultaneously and without extra cost accompanied by the complete replacement of the cartridge containing the lamp, the optical cavity, reflectors, anti-UV filter and embedded electronics.

Absorption curve of chromophores by level of wavelength

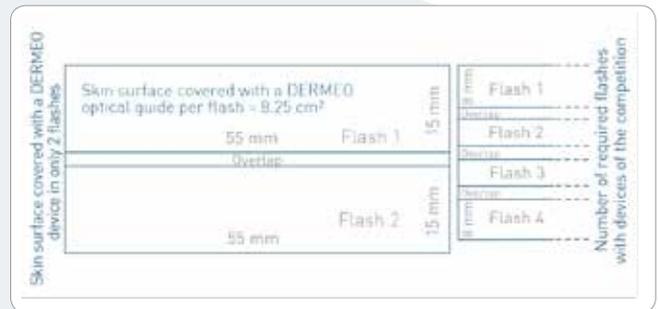


Interchangeable optical guides

To ensure optimal effectiveness of the treatments, DERMEO has created two different sizes for the optical guides, 2.25cm² and 8.25cm². This allows the operators to use up to 10 different filtrations.



The use of optical guides enables the operator to cover a large treatment area. The benefit obtained by the covered surface is materialized by a gain of flashes and time. Below it can be seen that two flashes are sufficient to treat an area of 28 mm, whereas with most competing devices, four flashes are required. Also, a large treatment area facilitates greater profitability.



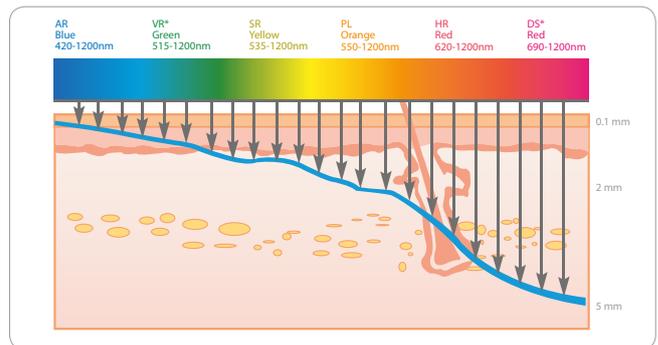
Benefits reflective filters

A filter is composed of several layers laid on a light guide made of quartz. The reflective filters allow multiband selective filtrations, and, therefore, the wavelengths are exactly adapted to the absorption peaks of the targeted chromophores.

The non sampled energy of the ray of light is reflected back into the lamp where the heat is dissipated by the water cooling system.

Results: No heating at the quartz and at the skin level.

Depth of the penetration of the light depending on the selected wavelength



In the United States of America the authorized claims by the F.D.A. for our device are: removal of unwanted hair from phototype skin I to V, treatment of benign cutaneous vascular lesions from phototype skin I to III, treatment of benign pigmented epidermal and cutaneous lesions from phototype skin I to III, treatment of inflammatory acne from phototype skin I to III.

CERTIFICATION & HOMOLOGATIONS

Our quality, Our certifications, your safety

The guarantee of a manufacturer that proposes a complete quality management system

DERMEO provides you with the knowledge of an ISO 9001 and ISO 13485 certified expert. Compliance with these standards is a guarantee of quality for both our customers and our suppliers.

RECOGNIZED QUALITY, VERIFIED SAFETY

Recognized quality, verified safety

MDFLASH4 medical devices are approved by many health Ministries around the world. Also, it has been cleared by the FDA (Food and Drug Administration) for the United States of America and the Ministry of Health for Australia.

The DERMEO devices comply with the North American self-extinguishability regulation, and has a medical device vigilance system which is registered at the ANSM.



International, medical approvals

International medical approvals

DERMEO has passed the inspections and audits of the Medical CE, as well as electromagnetic compatibility testing and electrical compliance.

MDFLASH 4 is approved by the Health Ministries of several countries including the United States of America, the Canada, Australia and is pending by the Health Ministries of Mexico, Kuwait and Saudi Arabia (updating in progress).

DERMEO MEDICAL DEVICES ARE COMPLIANT WITH INTERNATIONAL STANDARDS



TECHNIQUES

Comfortable, fast & efficient treatments thanks to the water cooling system

Water cooling for endurance and an exceptionally long life

Even at maximum power, the medical device can work for hours without overheating of the lamp or crystal. This is due to the continuous cooling of the lamp and filter, and the absorption of the infrared rays by the water. The stainless steel radiator facilitates a rapid and efficacious cooling of the lamp.

Optimal effectiveness through a power up to 80 J/cm² at cartridge level

To achieve optimal results, maximum power is needed for the treatment process: 80 J per cm², meaning more than 400 Joules per flash at lamp level. This leads to max 40 Joules per cm² at the level of the crystal.

Communicating powerful, efficient and effective systems

A balanced train of pulses for more security

To avoid risk of burning or discomfort caused by a single flash or a too long flash, all emitted flashes are cut into several pulses. Each pulse raises the target temperature, while the intervals between pulses allow the skin to dissipate the heat.



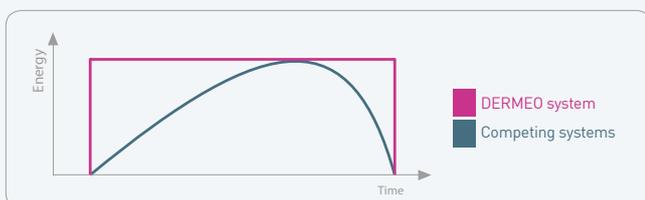
Balanced pulses for more comfort

Balance of pulses permits to get the same density of energy from the first until the last pulse by widening the duration of each pulse. This balance of train of pulse allows an efficient treatment of difficult skin conditions.

**TO ACHIEVE THE BEST RESULTS,
MAXIMUM POWER IS NEEDED**

A “simmer” for powerful and effective “square” pulses

The “simmer” enables the lamp to be powered up before the flash. The energy level needed is therefore reached more quickly and efficiently than with other pulsed light systems. With the simmer in use, the pulse comes in a “square” shape.



Connector for the hand piece

The new front connection facilitates simplified maintenance and easy replacement of the handpiece.



DI filter

With the deionization filter, the new generation of DERMEO pulsed light devices offers optimized water filtration, which significantly improves the quality of the water, and, therefore, the quality of the flash.



LCD color touch screen

MDFLASH 4 has a resistive 5.7 inches color touch screen, which provides the user with excellent legibility and comfort, even when wearing gloves. Featuring new, more ergonomic and intuitive software to facilitate comfortable daily use.



Evolutive software for easy updating

The software is embedded on an SD card, facilitating a quick and easy update of the medical systems via internet.



A user profile manager for a controlled delegation

The system can manage up to 5 different users. The administrator can, in detail, control the rights per user, meaning access to certain applications may be prohibited or restricted.

A logbook which allows access to complete information

At any time, access the number of flashes made per transaction, and view the date and time of carried out treatments.

Remote access

The user has the ability to remotely monitor the use of the system through optional networking software.



OFFER

Profitability,
flexibility,
efficiency

MDFLASH4[®]

MDIFLASH 4, from 8 to 40 J/cm², depending on the filtration and the size of the optical guide.

INDICATIONS :

- Light Skin Hair removal*
- Dark Skin Hair removal*
- Skin Rejuvenation*
- Acne treatment *
- Treatment of Pigmented Lesions*
- Treatment of Vascular lesions*
- 1 EASYLAMP[®] LAMP-CARTRIDGE
- Accessories
- Marketing package
- 2 years full warranty on labor & parts



Marketing, sales,
legal

Sales arguments

DERMEO provides its users with relevant marketing material, such as a list with unique selling points and a list containing frequently asked questions with appropriate answers, which can be used when interacting with patients that are interested in treatments by DERMEO's devices.

Training

The training program is supported by 2 volumes of training manuals. One is theoretically and technically oriented, whereas the other volume focuses on the practical and commercial aspects.

Media exposure

DERMEO's products and treatments receive a strong national and international exposure in on and offline media.

Clinical and legal

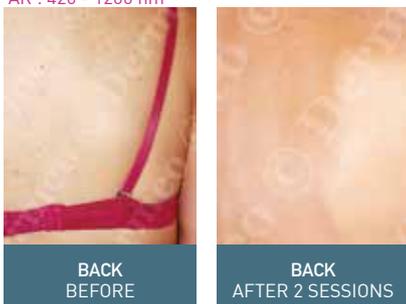
To provide better information to patients and better protection to practitioners, models of quote / informed consent / medical history forms, which have been validated and approved by doctors and lawyers, are available for the users.

Clinical studies, scientific articles

Acne treatment

The application of pulsed light on acne is based on the heating of the porphyrin which is produced by the Propionibacterium Acnes bacteria. The result is the destruction of the bacteria's cellular membrane, resulting in aseptic skin. Significant improvement of the skin provides patients with the desired aesthetic effect.

Care duration: depending on severity. 1-2 week interval between two sessions
AR : 420 - 1200 nm



BACK
BEFORE

BACK
AFTER 2 SESSIONS

Vascular lesions treatment

The pulsed light is absorbed by oxyhemoglobin, the target of the vascular lesion treatments. The light is transformed into heat and photocoagulates the blood in order to destroy the target vessels by rupturing the vessel wall. It does this without damaging the surrounding tissue. After the treatment the target vessel is naturally eliminated by the body, without leaving any trace. Good results on rosacea, telangiectasies, acne rosacea and injuries

Care duration: 1 to 3 sessions are required at interval of 1 to 2 weeks
VR Dual Band: 500-670 nm and 870-1200 nm



NOSE
BEFORE

NOSE
AFTER 2 SESSIONS

Rejuvenation

Flashes of pulsed light reduce the effects of ageing skin. The treatment stimulates collagen production, modifies connective tissue, tightens dilated pores, improves skin elasticity and reduces fine lines. The skin tone improves, pores are tightened and color increases. The tolerance for this treatment has proven to be excellent.

Care duration : 3 à 5 sessions are necessary at interval of 1 to 2 weeks.
SR : 535 - 1200 nm



CHEEKBONE
BEFORE

CHEEKBONE
AFTER 1 SESSION

Results approved over all indications

Clinical studies, scientific articles

To demonstrate the quality and effectiveness of DERMEO's medical devices, a clinical report was officially established by the GREDECO laboratory. This study was performed on volunteer patients which were recruited at the hospital of Pitié-Salpêtrière in Paris (FRANCE).



This study allowed us to assess the performance of the pulsed light device on several subjects in the real conditions of consultation.

Regarding efficiency, we have obtained, in almost all configurations and on time, very satisfactory results (acne) or even excellent results (rosacea, brown pigmented lesions, hair removal, and rejuvenation). The patients treated in this study had proven pathologies such inflammatory and retentional acne, rosacea, telangiectasia, melasma and vitiligo.

Medical treatments showed satisfaction. As for aesthetic treatments such as rejuvenation, spots care and hair removal on light and dark skin, a high level of safety and efficacy has been demonstrated.

DERMATOLOGICAL AND AESTHETIC TREATMENTS WITH DERMEO DEVICES PRESENT HIGH LEVELS OF SAFETY AND EFFICIENCY

Pigmented lesions treatment

During the sessions, the pulsed light energy is absorbed by melanin, causing an accumulation of heat and destruction of the pigment. After the session, the destroyed particles are eliminated by phagocytosis. The pigment and the melanocytes leave no trace.

Excellent results from the first session.

Care duration: 1 to 3 sessions are necessary at interval of 1 to 2 weeks.
PL : 550 – 1200 nm



Hair Removal Light Skin

Pulsed light is absorbed by melanin (a colored pigment) present in hair during the growth stage (anagen phase), and is then conducted down to the root of the hair. This light is turned into heat, and it is the heat that destroys the follicle and the root, without side effects. This is called "selective photothermolysis" or "photodepilation."

Excellent results, 80% of hair removed after the third session.

Care duration: 8 to 12 sessions are required at interval of approximately six weeks.
HR: 620 - 1200 nm for light skin



Clinical references

Dr. Sylvie Boinsic
Dermatologist, Pathologist Research Director
GREDECO
Consultant at the Hospital de la Pitié-Salpêtrière

Dr. Luc Benichou
Consultant Medical Doctor GREDECO

Dr. L. Ben Slama
Stomatologist

M. C. Branchet
Bio-chemist

Mrs. Sophie Blondel
Pharmacist Research Officer of GREDECO

Hair Removal Dark Skin

The use of a specific filter (DS 690 nm) makes it possible to safely perform treatments on dark skin. The specific filtration for dark skin promotes the absorption of the pulsed light by the melanin, and thus a high level of efficiency.

The obtained results are very satisfactory.

Care duration: 8 to 12 sessions are required at interval of approximately six weeks.
DS: 690 - 1200 nm for dark skin



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Light at the service of innovation

Designer and manufacturer of new technologies
for medical and aesthetic treatments.

Covered spectrum	420 à 1200 nm
Fluence in J/cm ² at optical guide level	Until 40 J/cm ²
Possible filtrations	LP 420-1200 nm, LP 500-670 & LP870-1200 nm, LP 535-1200 nm, LP 550-1200 nm, LP 620-1200 nm, LP 690-1200 nm Other filtrations upon request
Treatment surfaces	55x15 mm = 8.25 cm ² / 15x15 mm = 2.25 cm ²
Repetition frequency	1 to 0.3 Hz
Mode of emission	Multi-pulsed
Number of pulses per flash	4 to 6 par flash
Duration of pulses	2 to 6 ms
Inter-pulse interval	15 to 50 ms
Maximum number of flashes (pulses) per lamp cartridge	60.000 (360.000)
Setting mode	Automatic
Networking possibilities	USB, SD, RJ45 optional
Control panel	LCD TFT capacitive touch screen, emergency stop button, key
Lamp cooling system	Internal water cooling
Internal water circuit	Deionized water
Treatment of internal water	Interchangeable DI filter

Dimensions (H x W x D) in mm	334 x 339 x 497 (device) 1100 x 480 x 497 (device with trolley)
Weight	30 Kg
Electric current	120-230V-10-5A
Electric frequency	50/60Hz
Electrical protection	T16A-250VAC
Average consumption at maximum power	960W
Protection category	1, type BF
Protection index	IP30
Warranty	2 years warranty on parts and labor
Certifications of the manufacturer	ISO 9001, ISO 13485, ISO 13485 : CMDCAS
Conformities of the device	Test reports and CB certificate according to edition 3: IEC 60601-1 : 2012, EC 60601-1-2:2007, IEC 60601-1-6 : 2010, IEC 62366:2007, IEC 60601-2-57 : 2011, IEC 62471:2006
Markings and homologations	Europe USA Australia Canada Saudi Arabia Singapore, Mexico
	CE 0473 classe IIb 510(K) K093168 DV-2013-MC-20543-1 82603 Approval pending Ongoing

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