

DERMEO

Medical pulsed light devices

DERMEO THE PULSED LIGHT EXPERTS



Santé Health
Canada Canada

CE **FDA**
0473 Clearance number
510(k): K093168


licence number:
82603, 84973



The first watercooled **LAMP-CARTRIDGE DIRECTLY REPLACEABLE BY USER**
in only **10 seconds**


Dermeo
Paris



WORLDWIDE INNOVATION Patents Pending

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The products and treatments proposed in this brochure may be subject to specific regulations.
Users or purchasers are responsible for verifying the regulations applied in the country of use
as well as the specific conditions of use of this equipment with the correct countries and their
distributor. Skin Rejuvenation and Skin Type VI for hair removal claims have not been cleared by
the FDA and DERMEO makes no such effectiveness claims in the United States.



**DESIGNED
AND MADE
IN FRANCE**





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 a technological and clinical expertise.

We are involved in the design, manufacture, distribution, sales and after sales services of medical devices.

French product

The high quality of production tool DERMEO complies with the requirements of a French manufacture protocol and enables total transparency and traceability «from the designer to the patient». DERMEO chooses the best components that are made in France or Europe.

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.

Design, manufacture, distribution, sale, customer service of medical devices

The strategy of innovation and quality coupled with excellent knowledge of international regulations allows DERMEO to have an expansion on the five continents.



A research and constant evolution



Evolutionary technology

DERMEO is in a constant development using the best mechanical in electronics, energy conversion, computer, optics, mechanical and composite materials, leading to several patents.

Quality

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

Medical research

The clinical research investments are made in partnership with groups of specialist doctors to assess the performances, security and innocuity of the devices that are on the market.

EASYLAMP® CARTRIDGE LAMP replacement

Worldwide innovation: DERMEO has developed the first water-cooled LAMP-CARTRIDGE directly interchangeable by users. When the lamp has to be changed, there is no need to send it back to the workshop or to contact a technician. In a few seconds, the replacement of the lamp is easy and safe.

The replacement of the LAMP-CARTRIDGE accompanies simultaneously and without overcost the complete replacement of the cartridge containing the lamp, the optical cavity, reflectors, anti-UV filter and embedded electronics.



In 5 seconds, the user can change the indication

OPTICAL BLOCKS REPLACEMENT

A filter is composed of several layers laid on a light guide made in quartz.

The reflective filters allow multiband selective filtrations and therefore wavelengths exactly adapted to the absorption on the targeted chromophores areas of absorption.

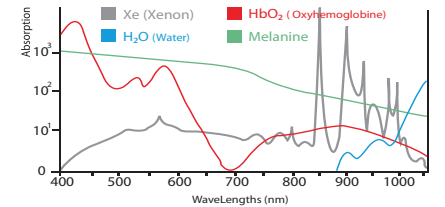


The dual band filter opening from 600 - 670 nm to 870 - 1200 nm spectral range targets the absorption peaks of the targeted chromophores.

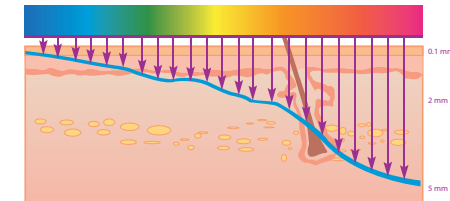
Reflective Filters

- Allow only the desired wavelengths and reflect the others
- The non sampled energy of the ray of light is reflected back to the lamp and dissipated in the water cooling system.

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



AR Blue 420-1200nm VR* Green 515-1200nm SR Yellow 535-1200nm PL Orange 550-1200nm HR Red 620-1200nm DS* 690-1200nm



*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.

Patent pending technology

With interchangeable optical units, 10 seconds only are sufficient to change the water cooled LAMP CARTRIDGE and 5 seconds are enough for the user to change the indication mode.



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

DERMEO provides you the knowledge of an expert certified ISO 9001 and ISO 13485. Compliance with these standards is a guarantee of quality for its customers and suppliers. DERMEO has a medical device vigilance system cell registered at the ANSM.



A recognized quality, a verified safety

MEDIFLASH 3 medical devices are approved by ANSM (French Ministry of Health), MEDIFLASH 3 and ESTHEFLASH 3 are approved by many health Ministries around the world and in particular by the FDA (Food and Drug Administration) for the United States of America and the Ministry of Health for Canada.

DERMEO medical devices are compliant with North American self extinguishing standards.



A guarantee of quality and safety



A cooling for exceptionally long life and endurance

Even at maximum power, the medical device can work for hours without overheating of the lamp or crystal. This is due to the continual cooling of the lamp and filter and the absorption of the infrared rays by the water.



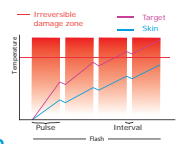
Optimal effectiveness through a power up to 80 J/cm² at the cartridge level

To achieve best results, maximum power is needed for the treatment process: 80 J per cm² whether more than 400 Joules. Which leads to 40 Joules per cm² max at crystal level.

The medical device can work for hours

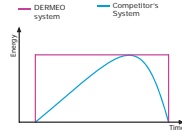
To achieve the best results, maximum power is needed

Balanced train of pulses for more security



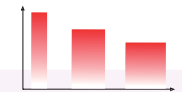
To avoid risk of burning or discomfort caused by a single flash or a too long flash, all system flashes are cut into several pulses. Each pulse raises the target temperature, while the intervals between pulses allow the skin to release heat.

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.

Balanced train of pulses for more security



Balance of pulses permits to get the same density of energy from the first until the last pulse by widening duration of each pulse. This balance of train of pulse allows you to treat difficult diseases with efficiency.

Evolutive software



The software is embedded on an SD card and is able to update easily and quickly DERMEO medical systems. With this innovation you can download from internet to your computer the last software version.

A fast and effective service



USB port provides the ability to transfer the historical events recorded on the system thus allowing traceability of treatments, or even put in a LAN or WAN.

A capacitive keyboard

From touch technology, capacitive keyboard is insensitive to mechanical wear and protects the screen against all forms of degradation associated with its use.

A user profil manager

The system can manage up to 5 different users. The administrator can control in detail the entitlements of users, access to certain applications that may be prohibited or restricted.

A colored TFT

With its 6 touch colored screen, 3rd generation of medical devices DERMEO allows users an easy and clear work.



International medical homologations



DERMEO medical devices are compliant with international standards

International medical approvals

Before the commercialisation of its devices, DERMEO was subjected to regulatory investigation from ANSM under the law of health watch and the Code of Public Health. DERMEO has succeeded the inspection and audit of Medical CE as well as electromagnetic compatibility testing and electrical compliance. DERMEO Medical devices have the free sale certificate attested by ANSM for ESTHEFLASH 3 and MEDIFLASH 3 are approved by the Health Ministries of several countries, including the United States of America and Canada.

MEDIFLASH 3

Indications:
Hair removal* and Skin Rejuvenation*, acne, pigmented and vascular lesions

MEDIFLASH 3, from 8 to 40 J/cm², depending on the filtration and the size of the quartz

- + 1 trolley + 2 quartz (your choice)
- + 1 EASYLAMP® LAMP-CARTRIDGE (lamp life: 30 000 flashes maximum)
- + accessories + marketing package
- + 2 years warranty full labour and parts



ESTHEFLASH 3

Indications:
Hair removal* and Skin Rejuvenation*.

ESTHEFLASH 3, from 8 to 20 J/cm², depending on the filtration and the size of the quartz

- + 1 trolley + 2 quartz (as you wish)
- + 1 EASYLAMP® LAMP-CARTRIDGE (lamp life: 60 000 flashes maximum)
- + accessories + marketing package
- + 2 years warranty full labour and parts

Clinical studies, scientific articles

A clinical report was officially established by the laboratory GREDECO to demonstrate the quality and effectiveness of DERMEO medical devices. This study was performed on volunteer patients recruited at the hospital of Pitié Salpêtrière in PARIS (FRANCE).



This study allowed us, in the real conditions of consultation, to assess the performance of the pulsed light device MEDIFLASH @ 3 on several subjects.

Regarding efficiency, we have got, in almost all configurations and on time, got very satisfactory results (Acne) or even excellent results (Rosacea, brown pigmented lesions, hair removal, rejuvenation).

The patients treated in this study had proven pathologies such inflammatory and retentional acne, rosacea, the telangiectasia, melasma and vitiligo.

Medical treatments showed satisfaction. As for aesthetic treatments such as rejuvenation, spots care and hair removal on light and dark skins care history demonstrates a high level of safety and efficacy.

Clinical references

- Dr. Sylvie Boisnic**
Dermatologist, Pathologist
Research Director GREDECO
Consultant at the Hospital de la Pitié-Salpêtrière - Paris
- Dr. Luc Benichou**
Consultant Medical Doctor GREDECO
- Dr. L. Ben Slama**
Stomatologist
- M. C. Branchet**
Bio-chemist
- Mme. Sophie Blondel**
Pharmacist Research Officer of GREDECO

Dermatological and aesthetic treatments with the device MEDIFLASH ® 3 from DERMEO present a high levels of efficiency and safety

Results approved over all indications

Vascular lesions treatment

The pulsed light is absorbed by oxyhaemoglobin, target of the vascular lesion treatments. The light is transformed into heat and photocoagulates to destroy the target vessels by rupturing the vessel wall. It does this without damaging the surrounding tissue. After treatment, the target vessel is eliminated by the body, without trace.

Good results on rosacea, telangiectasias, acne rosacea and injuries.

Care duration: 1 to 3 sessions are required at interval of 1 to 2 weeks
VR: 515-1200nm
RV Dual Band: 500-670 nm and 870-1200 nm

Hair removal

Pulsed light is absorbed by melanin (a coloured 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 "the selective photothermolysis" or "photodepilation".

Excellent results, 80% of hair removal 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
DS: 690 - 1200 nm for dark skin *

Acne treatment

The action of pulsed light on acne is based on the heating of the porphyrin produced by the bacteria *Propionibacterium acnes* on the skin. The result is the destruction of the cell membrane of the bacteria and the resulting aseptic skin. The treatment of acne scars and evolutionary acne by pulsed light can be preceded or accompanied by a nonphotosensitising antibiotic and/or hormone therapy (ethinylestradiol or cyproterone

acetate). Significant improvement providing to patients a significant aesthetic benefit.

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

Pigmented lesions treatment

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

Excellent results from the first session

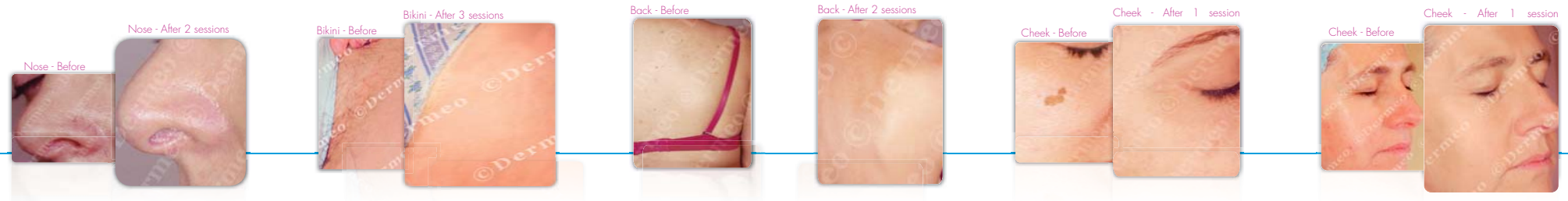
Care duration: 1 to 3 sessions are necessary at interval of 1 to 2 weeks.
PL: 550 - 1200 nm

Rejuvenation*

Flashes of pulsed light reduce the effects of skin ageing. This treatment stimulates collagen production, modifies connective tissue, tightens dilated pores, improves skin elasticity and reduces fine lines.

The skin tone has improved, pores are tightened and increased color was observed. Tolerance has always been very good

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



DERMEO gives access to its technology and democratizing treatments to better meet the request of the patient

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The follow up of the cares demonstrates a high level of safety and efficiency

Promotion of the technology

DERMEO brand is known all around the world and is recognized by its commitments on the quality of its equipment and cares. In France, DERMEO connects you with customer interest by our cares.



Sales arguments

DERMEO provides to its users a guide to selling points as a list containing the most common questions asked by patients who are interested in treatments with answers. The user is thus immediately trained to sale our cares.



Training

The training session of devices is supported by 2 volumes of training manual, one with a theoretical and technical part and the other with business and practical part.



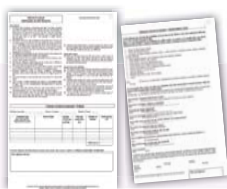
Media exposure

DERMEO products and cares receive a strong national and International exposure.



Clinical and legal

To provide better information to patients and better protection to practitioners, models of quote / informed consent / medical history forms are available for the users.



Technical specifications:

Spectrum covered	420 to 1200 nm	
Fluence in joules/cm ² at quartz level	up to 40 J/cm ²	
Lamp type	Xenon	
Repetition frequency	1 to 0.3 Hz	
Emission mode	Multi pulsed	
Number of micro-pulses	4 to 6 per flash	
Pulse duration	2 to 6 ms	
Interval	15 to 50 ms	
Configurations	Automatic	
Communication ports	USB, SD Card	
Control panel	Touchpad keyboard, LCD color screen, emergency stop button and ignition key	
Lamp cooling method	Internal water-cooling	
Hand piece cooling method	Progressive system air	
Internal Water-Cooling	0.5 litres (Deionized water only)	
Dimensions (H x W x D)	376 x 330 x 485 (without trolley)	
	1145 x 458 x 518 mm (with trolley)	
Weight	28 kg (without water and trolley)	
Network voltage	120 VAC	110 to 127 VAC
	230 VAC	208 to 253 VAC
Electric current	120 VAC	10 A
	230 VAC	16 A
Electric frequency	47-63 Hz	
Electrical protection	Fuse T16 A - 250 VAC	
Average consumption at maximum power	960 Watts	

Protection category	1, type BF
Protection index	IP30
Warranty	2 years full labour & parts
Manufacturer certification	ISO 9001, ISO 13485 and CMDCAS
Conformities:	
Europe : MEDIFLASH 3 KINEFLASH 3	Medical CE 0473 Directive 93/42/CEE Annexe 2 / classe IIB
Europe : ESTHERFLASH 3 KINEFLASH 3	Directive 2006/95/CE Directive 2004/108/CE NF EN 60601-1, NF EN 60601-1-2
USA : ESTHERFLASH 3 MEDIFLASH 3	Homologation 510(k) : 093168 Certification cEListus UL 60601-1:2009 I84.06, FCC part 18
Canada : ESTHERFLASH 3 MEDIFLASH 3	licence IN/NIH : 82603, 84973 Certification cEListus CAN/CSA-C22.2 No 601.1-M90 CAN/CSA-CE/IEC CISPR 11-04
Other countries	CB report, IEC 60601-1 (enpending)
Environmental standards	WEEE / DEEE - RoHS / LSD

YOUR RETAILER



Dermeo
Paris