OPERATING INSTRUCTIONS

dermalight® 800

UV-B-311 nm - narrowband



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Before putting the unit into operation and starting the treatment, read these operating instructions carefully.



Thank you for choosing the **dermalight**® **800** from <u>www.beatpsoriasis.com</u> The **dermalight**® **800** is the original and most technically advanced phototherapy device available. It is both convenient and economical and been proven highly effective by various clinical trials for the treatment of many skin diseases. While several imitation products exist, rest assured that you are using the latest product available. In order to achieve the best possible results, please follow these instructions exactly. In most cases, improvements in psoriasis can be seen in as little as 4 weeks and sometimes only several days, but very noticeable improvements often take 2 months or more. We suggest a minimum of 3 months is required to gauge if you respond well to this treatment. We hope that you will be satisfied with the **dermalight**® **800** and look forward to hearing from you again soon. Please do not hesitate to contact us if you require additional information or advice on using the product. Please read all the attached information thoroughly before using your new product.

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1. PRICING NOTICE FOR ALL CLIENTS

Please note that all invoices and credit cards are charged in AUSTRALIAN dollars, or \$AUD. Export orders are charged at the appropriate advertised AMERICAN dollar rates, converted to AUSTRALIAN using the daily international money exchange rate as published at www.xe.com Therefore, prices quoted in American are close approximations only due to exchange rate fluctuations, and possibly credit card and bank charges.

For example, if you have purchased a product advertised at \$2795 AMERICAN, then your credit card will have been charged for \$3819 AUSTRALIAN using the exchange rate below. Exchange rates change on a daily basis and some banks use a different rate and may also charge their customer's a conversion fee or other bank fees for international transactions. If your bank has over charged your credit card due to fees or an unfair exchange rate, please raise this issue with your bank or credit card provider.

2,795.00 USD
United States
Dollars

3,819.35 AUD
Australia Dollars

1 USD = 1.36649 AUD

1 AUD = 0.731800 USD

Australian customers are also charged the 10% GST. All other clients are exempt from Australian taxes.

2. Business Opportunity

We trust that you will find our phototherapy devices an extremely successful treatment for your skin condition. Phototherapy treatment is becoming increasingly popular as patients are moving away from dangerous drugs and their side effects. Phototherapy has been in use for many decades, and with recent advances in UV globe technology is now the safest form of treatment for many skin conditions. Subsequently, BEATPSORIASIS is seeking motivated people to join our worldwide distribution network. If you are interested in marketing and selling Dermalight products in your area, please do not hesitate to contact us. There is no requirement to carry stock and no up front expenses.



3. SAFETY INSTRUCTIONS

Read the operating instructions carefully before using the dermalight $^{\circ}$ 800 for the first time.



All important safety information is marked with this symbol. Please follow these instructions carefully to prevent health risks and damage to property.



dermalight® 800 emits intense UV radiation which can be dangerous - sunburn/skin burns, conjunctivitis and keratitis - if used improperly, especially when overdosed.

Never operate without UV safety goggles!

Perform irradiation only as described in the operating instructions or as prescribed by a doctor.

By use as agreed skin reactions and skin irritations are not excluded at every time. The result of long time treatment are side effects, like erythema, bubbles and erosions, pigmentation and itching.

Please note any side reactions in your patient diary and consult your doctor for eventual changes of the therapy plan.

The irradiation must not be carried out after photosensitizing of the skin by cosmetics or medicaments (possibility of higher photo-sensibility of your skin – ask your doctor). Please do not use any perfumes, lotions, aftershafe lotions or cosmetics before the therapy.

The safe handling and smooth operation of the **dermalight**® **800** presupposes familiarity with all the basic safety regulations.

The operating instructions contain important information on how to operate the equipment safely.

The operating instructions, especially the safety information and safety regulations, must be observed by all those who work with this equipment.

The accident-prevention rules and regulations prevailing at the place of use must also be observed.



Additional safety instructions for doctors and clinics

The operator must check at regular intervals that the equipment is being used in line with the safety regulations.

Before commencing work, those people who are to work with the **dermalight**® **800** undertake:

- To observe the regulations governing safety and accident prevention.
- To read the chapter on safety and the warnings contained in these operating instructions and to observe these at all times during operation.

Hazards when using the equipment

The **dermalight**® **800** was built according to the state of the art and in compliance with recognized safety standards. The equipment must be used

- · only for that purpose for which it was intended,
- only when in perfect working order.

Improper use can endanger the health of the user and/or third parties (including serious damage to the skin and eyes) as well as impairing the equipment or other items of property.

Any faults which might impair the safety of the equipment must be remedied immediately.

Proper use of the equipment

The dermalight® 800 is a UV-radiation cabin for the treatment of skin diseases.

Any other use of the equipment going beyond this shall be deemed improper and hazardous.

The operator may operate the equipment only if all the user information contained in these operating instructions is observed at all times.

The operator undertakes to observe the prescribed schedule for inspection and maintenance work and the replacement of wear parts (e.g. lamps) this work entails.

The firm of www.beatpsoriasis.com shall not be liable for damage caused by the improper use of the equipment.

Proper use also entails:

- adherence to all the information contained in the operating instructions.
- adherence to the schedule for inspection and maintenance work
- adherence to the general and specific safety information and safety regulations contained in these operating instructions as well as the prevailing accidentprevention regulations

4. DESCRIPTION AND PICTURE

The **dermalight**[®] **800** is a modern UV-therapy unit. The emission spectrum is UVB 311nm. It contains a small, innocuous part of visible radiation.



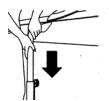
Never use dermalight® 800 without UV protective goggles, because the UV-irradiation can evoque damages on the eyes.

dermalight® **800** is delivered with a mobile tripod. The unit is therefore easy to handle and can be moved to any place where the therapy is carried out. The irradiation unit is swivelling. This enables a treatment in standing, lying or sitting position.

Height regulation:



Open the height regulation knob with some rotary motions anticlockwise, in order to move the telescope rod (a pneumatic spring keeps the rod in the desired position).



The height can be adjusted by moving the rod upwards or downwards. Attention! Do not move the telescope rod too high. Maximum 4 snap-in holes may be visible.

After having knob clockwise, in



chosen the correct height, fix the height adjustment order to fix the telescope rod.

Treatment in standing position:

Move the irradiation unit in vertical position and – if necessary – adjust the height. Take care to keep the correct distance.

Treatment in sitting position:

Put a chair in front of the **dermalight**[®] **800**. Move the irradiation unit, until it has the optimum position. If necessary, adjust the height.

Treatment in lying position:

Put the **dermalight**[®] **800** besides a bed or a daybed. Move the irradiation unit to a horizontal position and move the unit above the bed. Adjust the correct height of the unit. If the distance between the lamps and the body shall be 60 cm, the distance between lamps and daybed must be minimum 80 cm. Take care that the lamps are directly above you.



Picture 1: Therapy unit dermalight® 800





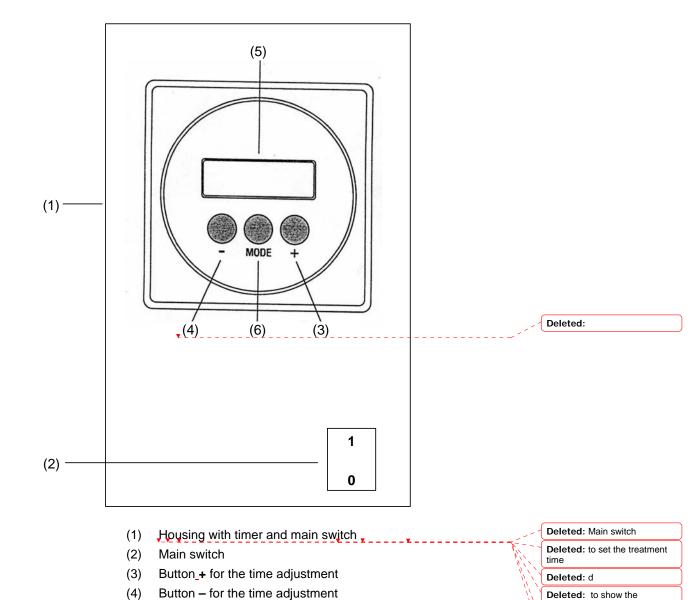


Adjustment of the therapy time:

The therapy is controlled by the integrated automatic timer. Please use the timer in the following way: (see also picture 2, page 8):

- · Connect the mains plug with the properly installed socket outlet.
- Switch on the mains plug switch lights green.
- Adjust the treatment time with the buttons + (3) or (4).
 - (By pressing the +-button the time is increased, by pressing the --button the time is decreased. By pressing the buttons + or longer, the time is counting up or down faster.
- The adjusted time is displayed (5) in minutes and seconds. For safety reasons the maximum time is limited to 10 min. If you want to treat longer, adjust 10 minutes and after that adjust the remaining therapy time.
- · For safety reasons, adjust the time also on the external timer.
- Don't look in the lamps without protection; wear the UV-protective googles!
- Pess the MODE button (6) to start the treatment, the UV lamps will be switched on and the treatment time counts down.
- Start the external timer at the same time (the external timer is necessary for additional control of the integrated timer and should always be started at the same time).
- By pressing the **MODE** button (start-stop) (6) during the treatment, the treatment is interrupted, the remaining time is stored and indicated at the display. By pressing the **MODE** button (6) again, the treatment can be continued.
- The end of the treatment is indicated by a signal, the UV lamps are switched off automatically.
- If you want to carry out another treatment, f. ex. on another part of the body with the same treatment time, it is possible to adjust the same time again by pressing the MODE button (6) again; the treatment starts as described above.
- · Switch off the unit on the main switch at the end of the treatment.
- Disconnect the mains plug from the socket outlet.

Picture 2: Electronic timer



treatment time

Deleted: to start and stop the

Deleted: O

radiation

Display: indicates the treatment time

MODE-button to start and stop the treatment

(5)

(6)



4.1. SYMBOLS

The following table shows all symbols indicated on the unit and their definition:

Unit of protection class I



Attention: please see operating instructions!



Part of application type B



Not ionised radiation

~

Alternating current

4.2. SCOPE OF DELIVERY

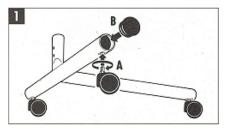
- UV-irradiation device dermalight® 800
- UV-goggles with elastic headband
- Operating instructions

5. **OPERATION**

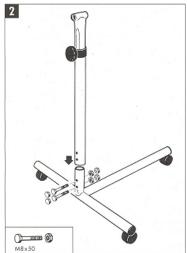
5.1. INSTALLATION

2 persons are necessary for the mounting of the unit.

Don't take the unit out of the package for the mounting.



Mount the three rolls (A) and the plug (B) on the tripod foot.

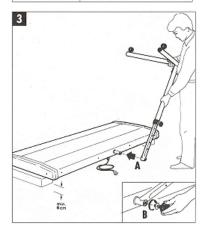


Put the tripod foot on an even surface.

Put the telescope rod on the connection part of the tripod foot. Take care, that the drilled holes are upon each other (see picture).

Connect both parts with the attached screws and nuts (M8 x 50).

Put the caps (M8) on the nuts and screw heads.



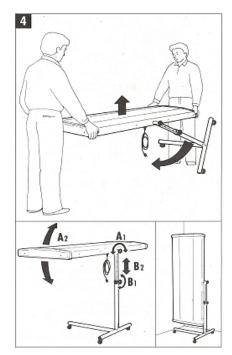
Put the irradiation unit (with the polystyrene packing on the grinding faces) on the floor.

Put the telescope rod on the connection part of the irradiation unit.

Connect both parts with the twist-grip screw (M10 \times 23).

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treatment and relief without drugs



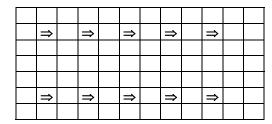
Put the unit on the tripod, with the help of a second person.

Take off the polystyrene packing.

Attention: The protection plate for the lamps is lying loose on the unit. Hold it during the removement of the packing, otherwise it will fall down!

Adjust the angle of inclination of the irradiation unit:

- Loosen the twist-grip screw a little bit.
- Adjust the desired angle of inclination
- Attention! In order to put the irradiation unit in a vertical position, the telescope rod has to be drawn out as much as possible (maximum 4 snap-in holes may be visible!)
- Fix the twist-grip screw again.



Fix the distance pieces, as shown on the sketch, on the protection grid of the unit.

Connect the mains plug of the **dermalight**[®] **800** to the socket outlet (230 V / 50 Hz). Only use the **dermalight**[®] **800** on properly installed socket outlets.

Operation conditions: dermalight® 800 must not be used in damp rooms, like bathrooms

After each use switch off the device and disconnect the mains plug from the socket outlet.

5.2. AREAS OF APPLICATION

With the **dermalight**® **800** it is possible to carry out UVB 311nm-therapy, depending on the indications.

Indications: Given the latest findings in photodermatology, this means that the following indications can be treated with promise of success:

- Psoriasis
- Vitiligo

Contra-indications: Because there are no experiences in the case of pregnancy, you should carry out a UV-therapy only after consulting your doctor in charge. The following contra-indications are valid for all irradiation units:

- Hyperthyroidism
- · Lupus erythematosus
- Tumorous skin changes
- Diseased hyperphotosensitivity (e.g. Xeroderma pigmentosa)
- Porphyrin disease
- · Floride tuberculosis or other floride processes
- Accompanying medical treatment with potential skin damage or intensified photosensitivity

5.3. THERAPY RECOMMENDATION



Never operate dermalight 800 without UV protective goggles. This goggles must have a UV protection of 100 %.

The distance between the lamps and your body should be 30 or 60 cm. Take care to have the correct distance.

Cover parts of you body you don't want to treat with towels or other UV-impermeable material.

For your additional safety please use always the external timer together with the integrated timer.

The therapy examples in chapter 3.4 contain standard values for treatment times dependent on the treatment distance and the skin type.

The classification of your skin type is made by your doctor. Table1 shows specifications for a rough classification of the skin types.

Skin type	Specifications
1	light skin, red- or fair-haired, blue or green eyes, freckles always quick sunburn; scarcely or no browning even after repeated treatments (Celtic type)
2	fair-haired, blue, grey or green eyes almost always sunburn; moderate browning after repeated treatments (fair European type)
3	light brown or brown hair, brown eyes moderate often sunburn; progressive browning after repeated treatments (dark-skinned European type)
4	dark brown or black hair, brown eyes rare sunburn; quickly beginning and clear browning (Mediterranean type)

Table 1: Characteristics of the skin types



The patient is standing, sitting or lying at a distance of 30 cm or 60 cm in front of the **dermalight**® **800** (please see also chapter 2. DESCRIPTION AND PICTURE)

The treatment frequency is approx. 4-5 times a week. The treatment period is approx. 4-5 weeks



In case of overdose (noticeable and visible sunburn or pronounced reddening of the skin) the treatment time has to be decreased or the treatment has to be discontinued.



5.4. THERAPY EXAMPLES

Example 1: Therapy of psoriasis

(Standard values for treatment times per side of the body, dependant on the skin type.)

Treatment distance: 60 cm

Treatment frequency: ca. 4 - 5 times per week (for a period of 3-5 weeks)

Pre-treatment of the skin: For the treatment of psoriasis it is absolutely necessary to pre-treat the skin, i. e. you have to remove the plaques from the skin in order to achieve good therapy results.

	Skin type 1 - 2		Skin type 3 - 4		
Session	Dose	Time	Dose	Time	
	[mJ/cm ²]	[min:sec]	[mJ/cm ²]	[min:sec]	
1	200	01 : 02	300	01 : 34	
2	300	01 : 34	400	02 : 05	
3	400	02 : 05	500	02 : 36	
4	500	02 : 36	600	03 : 08	
5	600	03:08	700	03 : 39	
6	700	03 : 39	800	04 : 10	
7	800	04 : 10	900	04 : 41	
8	900	04 : 41	1000	05 : 12	
9	1000	05 : 12	1100	05 : 43	
10	1000	05 : 12	1200	06 : 14	
11	1000	05 : 12	1300	06 : 46	
12	1000	05 : 12	1400	07 : 17	
13	1000	05 : 12	1500	07 : 48	
14	1000	05 : 12	1600	08 : 20	
15	1000	05 : 12	1700	08 : 51	
16	1000	05 : 12	1800	09 : 22	
17	1000	05 : 12	1900	09 : 53	
18	1000	05 : 12	2000	10 : 24	
19	1000	05 : 12	2100	10 : 55	
20	1000	05 : 12	2200	11 : 26	



In case of overdose (noticeable and visible sunburn or pronounce reddening of the skin), decrease the irradiation time of the following treatment about 1-2 minutes. Only increase the time after two further treatments.



Example 2: Therapy of Vitiligo or Acne

(Standard values for treatment times per side of the body, for all skin types)

Therapy distance: 60 cm

Therapy frequency: 3 times per week

Session	Dose Time	
	[mJ/cm ²]	[min:sec]
1	65	00 : 20
2	130	00 : 41
3	195	01 : 01
4	260	01 : 21
5	325	01 : 42
6	390	02 : 02
7	455	02 : 22
8	520	02 : 43
9	585	03:03
10	650	03 : 23
11	715	03 : 43
12	780	04 : 04
13	845	04 : 24
14	910	04 : 44
15	975	05 : 05
16	1000	05 : 12

Maximum treatment time: 5 minutes, 12 seconds



In case of skin irritations, reduce the treatment time for the next treatment by 15 to 60 seconds and increase the time only after 2 further treatments.



6. MAINTENANCE

Acc. to the Medical Device Directive (MDD) and the regulations for operators the safety of the unit has to be checked every 2 years by our Customer Service or by a technician authorized by the company Www.beatpsoriasis.com. This applies only to commercial users. Nevertheless we generally recommend the same procedure also for private users.

6.1. LAMP REPLACEMENT

Please see also chapter 5. REPAIR AND SPARE PARTS SERVICE. After approx. 400 operating hours, the UV-lamps should be exchanged completely with the starters. This is necessary to have always a high irradiation intensity.

All lamps of the **dermalight**® **800** are exchanged at the same time. If you replace only one lamp, this can lead to different intensities on different parts of the body.

6.2. CLEANING



Disconnect the mains plug from the socket outlet.

Let the device cool down!

Clean the device with a humid cloth, only if necessary.

Take care, that no water can trickle inside the housing.

Do not use scouring powder and solvent like alcohol, acetone or petrol.

6.3. SPARE PARTS AND ACCESSORIES

•	UVB 311nm-lamps	ArtNo	19025
•	Starter	ArtNo.:	0568
•	UV-protective googles "doctor"	ArtNo.	0067
•	UV-protective googles "patient"	ArtNo.	0029
•	External timer	ArtNo.	0466

Our current price list is available upon request.

7. REPAIR AND SPARE PARS SERVICE

Please contact our company for warranty claims, repairs and spare parts:

PO Box 154, Ballajura, Western Australia, Australia 6066 Tel: (+61) 08.9302.4587 Fax: (+61) 08.9302.3579

www.beatpsoriasis.com info@beatpsoriasis.com

For safety reasons the replacement of parts or the repair of the unit may only be carried out by www.beatpsoriasis.com or by an authorized dealer.

8. TECHNICAL DATA

Type dermalight® 800 uvb 311nm narrowband

Art.No. 19801

Power supply 230 VAC / 50 Hz Fuse protection F= 2 x 6,3 A/T

Capacity 800 Watt

Dimensions (W x D x H) 80 cm x 80 cm x 190 cm

Weight (with tripod) ca. 50 kg

UV-Lamps 7 medical UVB 311nm-lamps à 100 Watt

Operation temperature $5 - 45 \, ^{\circ}\text{C}$

MDD-class IIa
Protection class I

CE-mark **(6**0123

Manufacturer A.L.T. Lichttherapietechnik GmbH

Thura Mark 10

D- 06780 Zörbig bei Leipzig



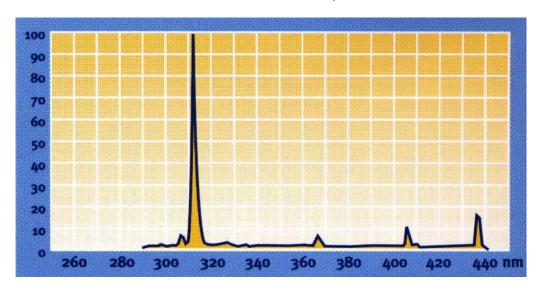
(Subject to technical alterations)



THERAPY SPECTRUM 8.1.

Main emission: 310 nm - 315 nm

Relative irradiation distribution spectrum



Wave length (nm)

9. ENVIRONMENTAL PROTECTION

The UV-lamps contain substances, which can harm the environment. Please take care, that the lamps are not disposed with the household rubbish, after having reached their maximum service life. Please take them to official collection points, in order to grant an environmentally suitable disposal.

The dermalight® 800 has been constructed for a long-time reliable operation. If you don't want to use dermalight® 800 any more, please take care, that the electronic parts must not be disposed with the household rubbish. Please take the unit to official collection points, in order to grant an environmentally suitable disposal.

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WARRANTY AND LIABILITY 10.

In principle, the General Terms of Sales and Delivery of www.beatpsoriasis.com shall apply. These shall be submitted to the operator upon the signing of contract at the very



latest. The warranty for the unit is 12 months (not for lamps). There shall be no warranty or liability claims in the event of personal injury or damage to property if these are attributable to one or more of the following causes:

- the use of the dermalight[®] 800 for a purpose other than that for which it was intended
- failure to observe the information on the assembly, commissioning, operation and maintenance of the unit contained in the operating instructions
- improper assembly, commissioning, operation and maintenance of the dermalight[®] 800
- operation of the dermalight[®] 800 with defective and/or malfunctioned safety and protective equipment
- unauthorized structural modifications of the dermalight[®] 800
- inadequate checking of wear parts
- repairs performed by persons who are not authorized by the manufacturer
- · catastrophes caused by foreign bodies or acts of God