

OPERATING INSTRUCTIONS

dermalight[®] 80 psoracomb

UV-B-311 nm – narrowband



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This document must be read carefully before using the dermalight80 product. Version 3.0

CE 0123

Thank you for choosing the **dermalight® 80** from www.beatpsoriasis.com The **dermalight® 80** 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® 80** 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. E.g. if you have purchased a product advertised at \$595 AMERICAN, then your credit card will have been charged for \$802 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 etc.

595.00 USD = **802.311 AUD**
United States Dollars Australia Dollars

1 USD = 1.34842 AUD

1 AUD = 0.741608 USD

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

2. ENVIRONMENTAL NOTICE

In the interest of saving our environment BEATPSORIASIS.COM may use recycled packaging and packaging materials where possible.

3. 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.

4. SAFETY INFORMATION

Read the operating instructions carefully before using the dermalight® 80 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® 80 emits intense UV radiation which can be dangerous - sunburn/skin burns, conjunctivitis, skin cancer and keratitis (retina damage) - if used improperly, especially when overdosed.

Never operate without UV safety goggles! You must wear the safety goggles at all times.

Never look directly into the light with your eyes open. If treating your face, keep eyes closed and goggles on at all times.

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

Never use the appliance in the bath tub!

Never use the appliance when housing or power cable are defect!

By using the appliance excessively (over months and years) the formation of skin cancer may be encouraged.

Do not carry out a UV-therapy after photosensitization of the skin by cosmetics or medicine.

Cover those parts of your body you don't want to treat.

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.

The safe handling and smooth operation of the dermalight® 80 presupposes familiarity with all the basic safety regulations.

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

The operating instructions, especially the safety information and safety regulations, must be observed by everyone working with this equipment.

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

The operator (doctor, clinic) must check at regular intervals that the equipment is being used by personnel in line with the safety regulations.

Additional safety instructions for doctors/clinics:

The operator (doctor/clinic) has to check the careful operation of the personnel handling the equipment in regular intervals.

Before commencing work, those people who are to work with the **dermalight® 80** have to:

- Observe the regulations governing safety and accident prevention.
- 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® 80** 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 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

The **dermalight® 80** is a UV radiation appliance for the treatment of skin diseases.

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

The operator may operate the equipment only if all the user information contained in these operating instructions is observed at all times. Failure to do so may render the manufacturer's warranty null and void and jeopardize the success of the therapy.

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 company Total Control Pty. Ltd. (Australia) H shall not be liable for any damage caused by the use or 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 accident-prevention regulations.

5. DESCRIPTION

5.1. GENERAL

dermalight® 80 is a medical radiation appliance designed for mobile use. The emission spectrum of its lamps lies in the UVB narrow band range.

Simple and universal use of the **dermalight® 80** is made possible by its low weight and handy shape. Treatment of the scalp - normally a difficult exercise - is easy to perform with the slip-on comb attachment.



Never start the dermalight® 80 without first putting on safety goggles. UVB radiation may harm your eyes!

5.2. SCOPE OF DELIVERY

The **dermalight® 80** is delivered with the following parts:

- **dermalight® 80** hand appliance with power-pack
- comb attachment
- UV-safety goggles with elastic headband
- operating instructions
- countdown timer

6. OPERATION

Plug the **dermalight® 80** into a mains outlet (110 V, 60 Hz or 240v, 50Hz; please ensure appropriate power supply for your location). Operate the **dermalight® 80** only from properly installed socket outlets. With the rocker switch on the top of the appliance you can switch the **dermalight® 80** on and off. After the appliance is switched on there may be an ignition delay of up to 30 seconds before the lamps emit a uniform light.

The **dermalight® 80** is ready for use immediately after lamp ignition, i.e. there is no warm-up period.

6.1. OPERATION WITH THE COMB ATTACHMENT

To use the **dermalight® 80** with the comb attachment (Order No. 1637), slip on the attachment from the front of the appliance until the two lugs on the comb snap into the recesses in the **dermalight® 80**. The attachment is correctly fitted when the four guide ribs of the comb are inside the guide slots of the **dermalight® 80**. The logo then lies at the front of the **dermalight® 80**.

6.2. OPERATING CONDITIONS

dermalight® 80 is designed for use in dry rooms with an ambient temperature never exceeding 45 °C.

Be sure to protect the appliance from chemical vapours and never use it in potentially explosive atmospheres.

The appliance can be used at any angle.

7. FIELDS OF APPLICATION AND THERAPY INFORMATION

7.1. FIELDS OF APPLICATION

By using the **dermalight® 80 UV-B-311 nm** it is possible to carry out UVB-therapy, depending on the indications.

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

- psoriasis
- vitiligo
- acne
- dermatitis
- **dermalight® 80** can be used for local irradiation of small circumscribed areas of skin all over the body, for wrinkles and for the scalp

Contra-indications: The following contra-indications are valid for all radiation units:

- hyperthyroidism
- lupus erythematosus
- tumorous skin changes
- diseased hyperphotosensitivity (e.g. xeroderma pigmentosa)
- porphyria disease
- floride tuberculosis or other floride processes
- accompanying medical treatment with potential skin damage or intensified photosensitivity
- pregnancy, because there is no experience

7.2. THERAPY INFORMATION

The optimum dose for all indications corresponds to the factor 0.7 - 0.9 MED (= minimal erythema dose). In order words, for treatment to be successful it is important to perform irradiation to a level just below the erythema limit (i.e. until a slight reddening of the skin becomes visible, which however does not become fully discernible until after around 6 to 12 hours).

The MED varies from patient to patient and depends on the skin type (see table 1). Your doctor will tell you in which class (1 - 6) you belong.

For the sake of simplicity we have based the following descriptions on skin type 2 (applies to the majority of Central Europeans).

For the therapy success it is essential to pre-treat your skin or scalp, i.e. to remove scale.

Guide values for skin type 2, **first** exposure :

approx. 60 seconds for each irradiated area of the body;

approx. 5-6 minutes for the **entire** hair-covered scalp.

The duration of the first exposure for hair-covered scalp depends on the extent of the hair covering and its thickness. The purpose of the comb is to part the hair and allow the UV radiation to get through to the scalp (see Chapter 4.3. THERAPY RECOMMENDATION).

The guide value for the percentage increase per exposure for skin type 2 is 25% to 30%.



In case of overdose (noticeable and visible sun burn or pronounced reddening of the skin), shorten the irradiation period or discontinue treatment.

Guide values for the maximum final exposure time (to complete the irradiation treatment) are:

approx. 3-4 minutes for each irradiated area or
approx. 2 times 20 minutes for the entire hair-covered scalp (f. ex. once in the morning and once in the evening).



UV safety goggles guaranteeing 100% UV protection must be worn during treatment. Suitable goggles are available as spare parts (see Chapter 6. SPARE PARTS AND ACCESSORIES).

Use sun lotion with a high sun block factor (≥ 15) on your forehead.

Radiation intensity decreases as the lamps grow older. This means that you must add an additional 10 - 20 % allowance to the exposure time after approx. 200 - 300 hours in operation. Remember to deduct this allowance again after replacing the old lamps with new ones.

For greater uniformity of irradiation we recommend combing your hair during exposure from left to right and then from the front to the back. Wear a glove on the hand holding the appliance to protect it from the UV radiation.

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

Table 1: Characteristics of the skin types

7.3. THERAPY RECOMMENDATION

Consult your doctor for a recommendation on your initial treatment time.

Example 1: Psoriasis of the hair-covered scalp

Therapy:	UV-B-311 nm therapy
Appliance:	dermalight® 80 with comb attachment
Patient's skin type:	2 (European average)
Irradiation distance:	2- 3 cm (is kept automatically by the comb attachment)
Duration of first exposure:	approx. 5-6 minutes for the entire scalp
Increase of exposure time per follow-up exposure:	approx. 20 - 30% of previous exposure time
Maximum exposure time:	2 times 20 minutes (entire scalp; e.g. one time in the morning and one time in the evening) per treatment
Duration of treatment:	4 - 6 weeks, longer for particularly serious cases
Frequency of irradiation:	4 - 7 times per week. Only ever once per day.
Max initial treatment	3 months

If skin irritations appear, decrease the treatment time of the following treatment by about 2 minutes. Only increase the time after two further treatments.

Example 2: Psoriasis of a small circumscribed area of skin

Therapy:	UV-B-311 nm therapy
Appliance:	dermalight® 80 (without comb attachment)
Patient's skin type:	2 (European average)
Irradiation distance:	approx. 1 - 2 cm
Duration of first exposure:	approx. 45 - 60 seconds per irradiated area
Increase of exposure time per follow-up exposure:	approx. 20 - 30 % of previous exposure time
Maximum exposure time:	approx. 3 - 4 minutes per irradiated area.
Duration of treatment:	3 - 4 weeks, longer for particularly serious cases
Frequency of irradiation:	4 - 5 times a week, every day for severe cases. Only ever once per day.
Max initial treatment	3 months

If skin irritations appear, decrease the treatment time of the following treatment by about 20 seconds. Only increase the time after two further treatments.

Example 3: Treatment of Vitiligo or Acne

Distance: 3 cm, use the comb attachment as a distance holder. The comb attachment does not influence the treatment.

Frequency: 3 times a week

Maximum treatment time: 4 min 40 sec

If skin irritations appear, decrease the treatment time of the following treatment by about 20 seconds. Only increase the time after two further treatments.

You MUST cover the unaffected or normal skin with sun burn cream if treating vitiligo or other skin pigmentation conditions

8. MAINTENANCE INFORMATION

Daily: Check the filter glass for damage and dirt; check the housing for damage.

Every 300 operation hours :
Replace the lamps.

Every 2 years: Maintenance by our Customer Service or a technician authorized by us (applies only to commercial users but is compulsory to comply with the German Medical Products Act).

8.1. LAMP REPLACEMENT, REPAIRS

To ensure a high level of radiation intensity at all times we recommend replacing the lamps after approx. 300 operation hours.



Disconnect the appliance by unplugging the power-pack!

Use a suitable screwdriver to undo and remove the three screws from the housing, place the filter glass on a soft clean cloth where it cannot be scratched, and lift off the top half of the housing. With a turning action you can now take the lamps out of their holders and replace them with new ones. Re-close the housing, put the filter glass back in the opening, and screw the housing tight.

Safe operation of the dermalight[®] 80 is guaranteed only when an undamaged filter is fitted!

Only use original type UV-B-311 nm (Order No. 19174) as spare parts!

8.2. CLEANING THE HAND LAMP



Disconnect the appliance by unplugging the power-pack!

Never wipe the hand lamp or the filter glass with a dry cloth. To clean dusty or dirty surfaces, wipe with a damp soft cloth or sponge (add a little dishwashing liquid to warm water).

Anti-static plastic cleaners are also suitable.

Never clean with concentrated disinfectant or solvent such as Sagrotan, Lysoform, methyl alcohol or any other liquid containing alcohol.

8.3. CLEANING AND DISINFECTING THE COMB ATTACHMENT

The comb attachment (Order No. 1637) is skin-friendly and hygienic. Its poreless surface makes it difficult for dirt and bacteria to accumulate.

To clean and disinfect the comb, see Section 5.2.

- **At 25 °C the comb is resistant to the following chemicals:**

- Baktolan, up to 5 %
- Chinosol, up to 1 %
- Elmocid Gamma, up to 2 %
- Lugol's solution
- Mefarol, up to 1 %
- Merckojod, up to 1 %
- Merfen
- Perhydrol
- Perodin
- Sagrotan, up to 2 %
- Hydrogen peroxide, up to 40 %
- Zephirol, up to 5%

- **Under no circumstances are you to use:**

- Alcohol
- Baktolan, concentrated
- Gasoline mix
- Tincture of iodine, 5%
- Phenic acid
- Lysoform
- Perchloroethylene
- Sagrotan, over 2%
- Sidolin
- Spirit of wine
- Carbon tetrachloride
- Trichloroethylene

8.4. SPARE PARTS AND ACCESSORIES

- Lamp UV-B-311 nm (PL-S 9W/01) Order No. 19174
- Filter glass Order No. 1636
- Comb attachment Order No. 1637
- UV safety goggles with elastic headband Order No. 0029
- UV safety goggles "Profided" Order No. 0067
- Countdown timer Order No. 0466

Our current price list is available on request.

9. REPAIR AND SPARE PARTS SERVICE

For warranty claims, repairs and spare parts it is best to make use of our company's own facilities. If necessary, please contact:

PO Box 154, Ballajura, Western Australia, Australia 6066

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The power cable between the hand-held unit and the power-pack (series reactor) may be replaced only by an original power cable type HO5W-2x0.75 mm² with integrally moulded anti-kink sleeves which have to be bonded to the housing to prevent twisting.

For safety reasons, parts are to be repaired or replaced only the original supplier or an authorized dealer.

10. TECHNICAL DATA

Type	dermalight® 80 UV-B-311 nm
Order No.	19233 110v / 19158 240v
Power supply #1, 110v	110 V ~ / 60 Hz (mainly USA)
Power supply #2, 240v	240 V ~ / 50 Hz (European)
Power consumption	20 VA
Lamp	1 x UV-B-311 nm (PL-S 9W/01)
Dimensions (L x W x H)	325 x 82 x 40 mm
Weight (without power cable)	300 g
Radiation outlet	110 x 40 mm
Operating temperature	5 - 45 °C
MPG class	IIa
Protection class	II, totally insulated
Hand-held unit	drip-proof ◆ IPX1
Marking	CE 0123

All technical specifications are subject to technical alterations.

UV intensity at a distance of 3 cm:	UVB radiation intensity:
E(UV-B-311 nm)	3.5 mW/cm ²

Symbols:



device of protection class II



Attention, see operating instruction



part of application: type B



not ionised radiation

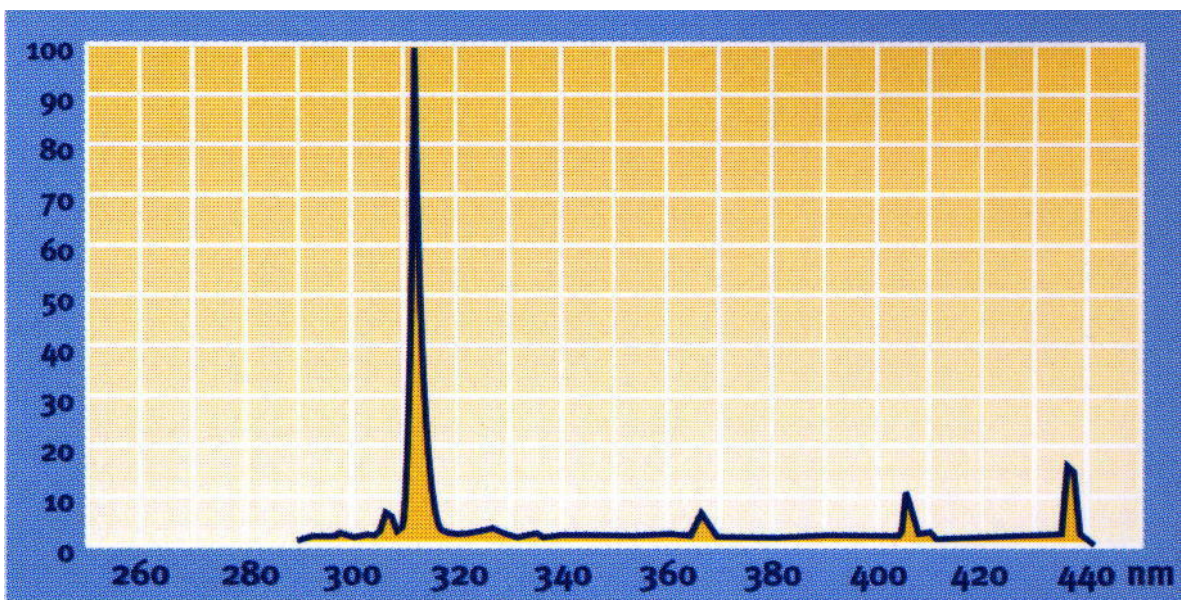


drip proof IPX1

(Subject to technical alteration!)

Therapy spectrum:

Relative spectral radiation distribution (%)



Wave length [nm]

11. WARRANTY AND LIABILITY

In principle, the general terms of sale and delivery of Beat Psoriasis shall apply. These shall be submitted to the operator upon the signing of contract at the very latest. 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® 80** 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® 80**
- operation of the **dermalight® 80** with defective and/or malfunctioned safety and protective equipment
- unauthorized structural modifications of the **dermalight® 80**
- inadequate checking of wear parts
- repairs performed by persons who are not authorized
- catastrophes caused by foreign bodies or acts of God

12. ENVIRONMENTAL PROTECTION

According to care and careful use, the lifetime of the appliance is between 5-10 years. When the maximum life time is reached, please return the lamps or complete appliances to us. We will ensure that they are disposed of in an environmentally acceptable manner.

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