Saalux®

User Manual

User manual

Saalux® UV comb

Version	UV-B Narrow band (311 nm), orange cap	UV-A1 (370 nm max.), grey cap
EU (230V/50Hz)	☐ No. 07-02-000-01	☐ No. 07-02-000-02
UK (240V/50Hz)	☐ No. 07-02-000-03	☐ No. 07-02-000-04
JP1 (100V/50Hz)	☐ No. 07-02-000-06	☐ No. 07-02-000-07
JP2 (100V/60Hz)	☐ No. 07-02-000-08	☐ No. 07-02-000-09
US (120V/60Hz)	☐ No. 07-02-000-10	☐ No. 07-02-000-11

Dear customer, we are delighted that you decided to purchase a Saalmann® therapy device. You made an excellent choice as the Saalux® UV comb sets new standards in terms of usability and design. The one-piece comb attachment comprises a disc filter which is integrated into the hair parter and protects the UV lamp from soiling. Moreover, the detachable comb attachment facilitates easy cleaning by rinsing and flushing out scales or hairs which usually soil the UV comb in the course of treatment.

The following directions for use familiarise you with the therapy device. Please review them carefully!

Content

1 Scope of Delivery

The set consists of the therapy device with UV lamp and comb attachment, UV protective goggles, count-down timer and a user manual.

2 Accessories and Spare Parts

Comb attachment	Item No. 07-02-005-01
User manual UK	Item No. 07-02-001-02
UV-protective goggles, red	Item No. 07-02-002-01
Count down timer	Item No. 07-02-003-01

3 Safety Information

„Caution“ safety information : this sign precedes important notices in the user manual.

The therapy device may only be used for the indications specified in this user manual.

The therapy device may only be used for the „intended use“ specified in this user manual. Any use beyond the defined scope is considered „not as intended“ and will immediately render the warranty void. The manufacturer accepts no responsibility for personal injury or damage to property resulting from „not as intended“ use.

The therapy device may only be used when in proper condition and with the original accessories.

The therapy device may only be operated in dry rooms and in the temperature range stated in this user manual.

Water and electricity are a dangerous combination! To avoid risk of electrocution:

– do not use this equipment in wet surroundings (e.g. in the bathroom or near a shower or swimming pool),
– do not let water run into the appliance.

The use of this device next to other equipment should be avoided, as it may result in improper operation. If use in the manner described above should nevertheless be necessary, this equipment and the other equipment should be checked for proper operation.

This device emits UV radiation through the transparent comb attachment, which can cause eye or skin irritation. Avoid the UV radiation of eyes and healthy skin. The UV radiation is not visible for the human eye and can lead to corneal inflammation (photokeratitis) and eye inflammation (photoconjunctivitis) within a short time.

It is imperative that during a therapy session, you wear the UV protective goggles included in the scope of delivery. Simply closing your eyes without protective goggles during a therapy session does not offer sufficient eye protection. Also, avoid looking into the UV lamp with unprotected eyes; immediately switch off the therapy device after treatment and also during short-term interruptions in the treatment session.

Never operate the device without comb attachment.

UV-radiation can cause the skin to get sun burnt within a short time. It is imperative that you pay attention to the therapy recommendations specified in the user manual.

To avoid erythema (sun burn), healthy skin (e.g. ears) must be protected with a high protection factor sun cream, which is to be applied to those areas in due time before the treatment session (see page 8)

The intensive use of the therapy device over years can promote the development of skin cancer. Avoid excessive sun exposure during the treatment cycle; also, adjust your leisure behaviour during this time. You should not visit tanning studios while using the device in a treatment cycle.

This device is not intended for use by persons 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 equipment to avoid the risk of fire or burns.

This device is not intended for independent use by children. The treatment of children is carried out exclusively by adults. Children should be supervised to ensure that they do not play with the equipment to avoid the risk of fire and burns.

Do not leave the device unattended when it is switched on to avoid the risk of fire or burns.

The device may not be altered.

Check if the voltage indicated on the device corresponds to the local mains voltage before you connect the equipment to avoid risk of electrocution or permanent damage to the device.
Make sure that you can unplug the power cord from the wall outlet at any time.

Always unplug the device after use and in case of a power failure to avoid risk of damage to the equipment.

Protect the device against unauthorized use:

- unplug the AC adapter from the socket immediately after use,
- store the device securely so that unauthorized persons cannot access the device (e.g. by locking it away).

Do not use it near children and never leave the device unattended (Danger of UV exposure and strangulation).

Do not subject the equipment to heavy shocks to avoid risk of damage to the lamp.

RF communications equipment (radios) and their accessories should not be used within 30 cm of the components and cables of the Saalux UV Comb. Observe the recommended EMC protective distances in Appendix 1. Failure to do so may lead to a reduction in the performance of the device.

4 Key to symbols

Symbols in the user manual and on the unit:

Caution:
Important note!

Caution:
Ultraviolet radiation!

Do not stare at light source!

Wear UV protective goggles!

Read the user manual!

Type BF applied part

Keep dry!

Medical Device

Manufacturer‘s CE-declaration with no. of Notified Body

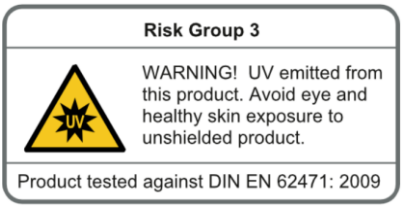
Manufacturer

Item No.

Batch Code

Class II equipment

Disposal instructions:
Do not dispose of the equipment with domestic waste!



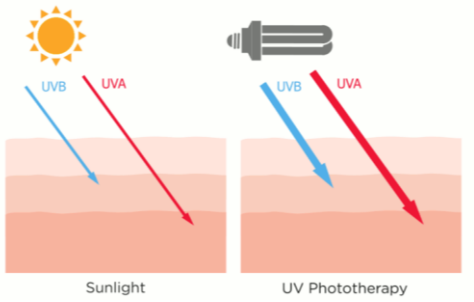
5 Intended Use

The unit is intended to be used in closed rooms. Allow the unit to reach room temperature before conducting a treatment. The device may only be used in a dry environment. The required minimum distance to shortwave microwave devices depends on their frequency and transmission power and is defined in the EMC tables (see attachment 1). For additional information, please refer to item 9 in the operating instructions.

At the start of the therapy, approx. 3 - 5 treatments per week are to be conducted. Exposure time depends on the patient's individual sensibility and skin type. Special care has to be taken never to reach the erythema threshold (development of sun burn). We refer to the specific instructions in this user manual. Due to the intermittent appearance of clinical symptoms, an according maintenance therapy in a domestic setting is indicated.

The treatment is conducted based on a doctor's recommendation and in accordance with the treatment guidelines laid down in the user manual. Any other use going beyond or deviating from the defined scope of usage is considered „improper use" and may lead to health impairment and injury.

6 Basic Information on UV Phototherapy



UV phototherapy is an established procedure, recognized for decades for the treatment of various skin diseases, particularly psoriasis, neurodermatitis and vitiligo. UV radiation affects the upper skin cells and, after repeated application, positively influences the immune system and the skin's regeneration behavior. Depending on the clinical picture, selected UV-spectral ranges (UV-B and UV-A) are applied, which in low strength are also present in natural sunlight.

7 Indications

According to version (UV-B narrowband, UV-A1) and recommendation by a medical professional, the Saalux® UV comb is used for the following indications:

- Psoriasis
- Vitiligo
- Neurodermatitis

8 Contraindications

The UV therapy must not applied in case of:

- Tumorous skin changes
- Abnormal sensitivity of the skin to light, e.g. Xeroderma Pigmentosum
- Porphyria disorders
- Florid Tuberculosis or other active processes
- Hyperthyroidism
- Lupus Erythematosus
- Accompanying medicinal treatment with potential skin damage
- Increased sensitivity to light

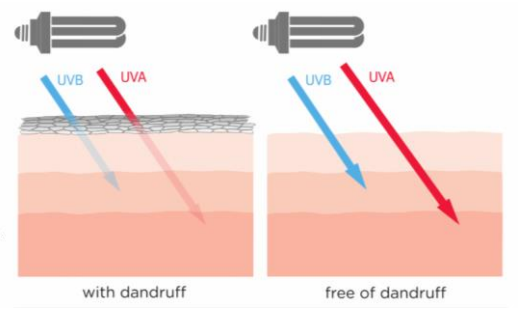
Following side effects may occur:

- Erythema (sunburn)
- Dry skin

9 Initial Operating Instructions

The device may only be used with a power supply that matches the supply voltage specified on the rating plate. To ensure safe operation of the unit, all its cables, plugs, control elements, and housing components must be in faultless condition. Prior to each use, check the device for possible damage; a defective unit may not be operated. Pay attention to the references on the unit and in the user manual. Please switch the unit off after you finished a treatment session.

10 Therapy Recommendation



Removing dandruff:
Plaques and scales absorb the UV radiation and prevent the UV radiation from penetrating into the diseased skin layers. In case of extensive infestations, thoroughly remove plaques and scales before starting the UV therapy (e.g. with the Saalux dandruff solution, see back page).

UV protection
Prior to starting the treatment, all healthy skin areas (the ears, amongst others) should be covered or creamed with an according light protection screen in due time (please consider application time!).

Prior to or during a therapy session, the skin must be free of topical applications like, e.g. ointments; do not use sun protection on the skin that is to be treated. Certain pharmaceuticals increase the skin‘s UV-sensitivity, a fact you might want to discuss with your physician! Since scales on the scalp can impact treatment success, a thorough cleaning prior to the treatment session is imperative. Moreover, moist skin has a better UV-absorption which means that the treatment of moist skin (possibly after washing) can accelerate the therapeutic success.

Moisty skin
Moisty skin is more receptive for UV radiation. Therefore the application on moisty skin (e.g. after washing the scalp) may accelerate the therapy success.

Operation of Timer
At the onset of the treatment session, please make sure that the count-down timer is functioning properly (e.g. battery o.k.?)

Prior to starting a treatment session, plug the device into a suitable outlet, put on the protective goggles and keep the device switched on for approx. 5 min in order to achieve a stable UV-output.

Please set the provided count-down timer by pressing the according buttons „MIN“ for minutes and „SEC“ for seconds to the desired treatment time. Pressing the „Stop/Start“-button starts or interrupts the countdown for treatment time. By simultaneously pressing both „MIN“ and „SEC“ push buttons, the count-down timer resets to „00:00“.

Finding the right dose and treatment duration:

It is common nowadays to use the classification made by the American dermatologist Thomas Fitzpatrick in 1975 to define various skin types. Dark skin types (type 5 and 6) are very rare at our latitude and thus are not taken into account here.

The following applies:

Persons of skin type 1: (pale white skin; blond or red hair - always burns, never tans) are not suitable for UV-therapy!

Skin type 2: fair; blond hair - usually burns, tans minimally (fair European type).

Skin type 3: fair, light-brown or brown hair, tans uniformly after repeated sun exposure (dark European type T).

Skin type 4: brown or black hair - rarely burns, always tans well (Mediterranean type)

The following dosage is recommended for patients of skin type 2, 3, and 4. **Please note that these doses refer to the treatment of the entire scalp and never just to one spot** which would result in an overdosage in the form of an erythema (sun burn)! Special attention should be paid to the inner surfaces of the outer ears. They should not be treated for an extended period since they are extremely sensitive to UV light (light protection screen see above).

The treatment times indicated are mere guide values; please consult with your dermatologist to determine your individual numbers. Upon reaching the highest dosage indicated for the according skin type, it is not sensible to increase further the dosage arrived at is to be maintained. Keep in mind, however, that excessive doses can lead to an acute aggravation of your skin condition (the so-called Köbner phenomenon) and too low doses result in an unnecessarily increased „lifetime dose“ without the desired therapeutic success.

Dosage recommendations for Psoriasis with UV-B narrowband
Treatment duration for the entire scalp (for smaller surfaces, the treatment time must be reduced accordingly):

Skin type II	**Session**	**Time (min:sec)**	**Dosage (mJ/cm²)**
	1	3:00	630
	2	3:00	630
	3	3:30	735
	4	4:00	840
	5	4:00	840
	6	4:30	945
	No further increase	5:00	1050
Skin type III	**Session**	**Time (min:sec)**	**Dosage (mJ//cm**
	1	3:30	735
	2	3:30	735
	3	4:00	840
	4	4:30	945
	5	4:30	945
	6	5:00	1050
	No further increase	6:00	1260
Skin type IV	**Session**	**Time (min:sec)**	**Dosage (mJ/cm²)**
	1	4:00	840
	2	4:00	840
	3	4:30	945
	4	5:00	1050
	5	5:00	1050
	6	5:30	1155
	No further increase	7:00	1470

Dosage recommendations for Vitiligo with UV-B narrowband
Treatment duration per body region:

Session	Time (min:sec)	Dosage (mJ/cm^2)
1	0:20	70
2	0:40	140
3	1:00	210
4	1:20	280
5	1:50	385
6	2:20	490
7	2:50	595
8	3:20	700
9	3:50	910
10	4:20	1050
No further increase		

Dosage recommendations for Neurodermatitis with UV-A1
Treatment duration per body region:

Session	Time (min:sec)	Dosage (J/cm^2)
1	1:00	0.5
2	2:00	1.0
3	3:00	1.5
4	4:00	2.0
5	5:00	2.5
6	6:00	3.0
7	8:00	4.0
8	10:00	5.0
9	12:00	6.0

Conducting the Therapy

Only use the device in a dry environment. Always use the UV protective goggles provided and never look into the UV lamp with unprotected eyes! While you conduct the treatment, there should not be any additional persons close by (exposure to scatter radiation).

Always protect your eyes with the UV protective goggles!

According to skin type, start the therapy of the entire scalp with 3 (skin type 2), 3.5 (skin type 3) or 4 (skin type 4) minutes. Please position the count-down timer where it is easily visible and acoustically perceivable for you; after counting down to zero, an acoustic signal will sound for approx. 30 seconds. You can turn it off by pressing any button. After pressing the Start/Stop button, the previously set or lapsed time will appear in the display again.

The treatment is to take place slowly, distributed uniformly over the head and against the direction of hair growth with parallel alignment of the radiation source to the skin. The hair parter or comb attachment facilitates reaching the hairy scalp skin and ensures the required treatment distance.

Other skin lesions (besides those on the scalp) are treated in an identical way but always with mounted comb attachment.

The treatment should be conducted **three to five times weekly**. The duration of the treatments depends on the severity of the skin disease. Generally, 20 - 25 sessions should be sufficient for the skin conditions to subside. A prolonged maintenance treatment is not recommended.

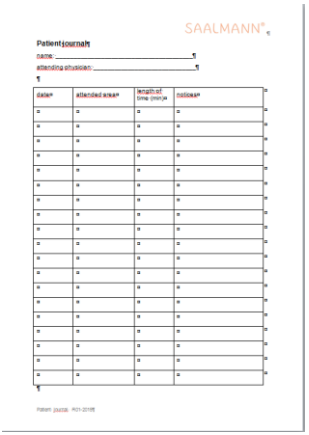
Therapy monitoring:

Following every treatment session, monitor the treated skin areas for therapeutic success as well as for possible side effects:

Should you discern side effects like a sun burn or painful change in the **diseased skin**, you have to reduce the dose for the next treatment by 40% and you may only continue with the treatment after the side effects have abated. If in doubt, consult your attending physician.

Should you discern side effects like a sun burn or painful change in the **healthy skin**, make sure to provide better protection for the next treatment like using sunscreen with a high protection factor or more carefully cover these areas with textiles..

Should you **not experience any successful therapy outcome** at all, gradually increase the dose as described in the tables. If you have reached the maximum dose according to your skin type and still do not notice any therapeutic effect, the service life of the UV lamp may be expired (see chapter 14). If in doubt, consult your attending physician.


SAALMANN

Patient journal

name: _____

attending physician: _____

date	attended area	length of time (min)	notices

Patient journal - ROY-20195

After every individual treatment, document your therapy outcome and success in the patient diary provided and discuss your therapy results regularly with your attending physician.

End of a treatment series:

To maintain the positive treatment outcome, it is recommended to „phase out“ the therapy after the lesions have disappeared. This can be done by e.g. decreasing daily treatment for the next 3 weeks to 3 times weekly, for 3 weeks to 2 times weekly and for 3 weeks to once a week.

11 Cleaning and Disinfection

Prior to cleaning and disinfecting, switch off the device and pull the plug from the outlet. Let the device cool off before you begin cleaning. You achieve better cleaning results if you pull the comb attachment from the unit and clean it separately.

Wipe the comb housing with a moist cloth. If needed, the comb attachment can be detached from the housing and cleaned on the inside and outside under running water with a mild soap or dish detergent. Avoid wiping either device or comb attachment with a dry cloth which can scratch the surface.

Do not use aggressive or solvent-based cleaners. These affect the surfaces of the device. Avoid any penetration of liquids during cleaning.

When using the device by several patients, the comb attachment must be cleaned and disinfected before any patient change, in order to prevent infections between patients. The following disinfectants can be used for this purpose:

- Descosept Spezial (wiping disinfection)
- Microzid sensitive liquid (wiping disinfection)
- Sani Cloth Active (wiping disinfection)

For a sufficient disinfecting effect, the application instructions of the respective manufacturers must be observed. If other disinfectants are used, only products suitable for acrylic glass are to be selected.

12 Transport and Storage

Protect the UV comb during transportation from undesirable shocks; the UV lamp may be damaged (glass breakage). Store the therapy device in dry rooms and do not expose it to high temperatures.

13 Errors and Troubleshooting

UV lamp does not light	-	Check the outlet or use another outlet. Verify that the UV lamp is tightly inserted into the socket. First switch off the device and unplug the power cord.

If this did not fix the problem, contact the address specified in the manual.

14 Life cycle and service life

The service life of the UV comb is essentially dependent on the frequency of use. The average service life of the UV lamp is 500 hours. After this runtime, UV-radiation decreases. This also becomes evident by a decreasing therapy result. A defective or poor UV lamp may only be replaced by the manufacturer or professionals trained and authorized by the manufacturer. The use of a wrong UV lamp can cause burns. After replacing the UV lamp, the treatment duration has to be determined again (see chapter 10).

15 Maintenance and Repair

For commercial use the manufacturer recommends to carry out maintenance at the latest every 2 years, which is generally also recommended for private use. The commercial user is responsible for complying with all applicable national regulations and inspections (e.g. occupational safety).

For maintenance or repair ship in the original packaging if possible. Please make sure that the device is protected against shocks and that packaging is suitable for the method of shipment selected.

Please don’t forget to clean the device and accessories prior to shipping it!

16 Warranty

The UV comb has been manufactured and tested with the greatest care. Should, however, a malfunction occur, we grant you a manufacturer warranty for all defects caused by material deficiency or manufacturing error. The manufacturer warranty extends over 4 years for final customers/consumers and 2 years for commercial customers (applicable are the provisions of the manufacturer‘s general terms and conditions in the version in force at the date of purchase).

Any intervention on the therapy device by buyer or third parties renders the warranty claim void. Any defects or errors which are or might be caused by

improper handling or disregard for the „intended use“ or the user manual, result in the immediate loss of warranty claims against the manufacturer.

Categorically excluded from all warranty claims are wear parts or glass breakage (e.g. the UV lamp). Also excluded from the warranty is the UV-intensity of the UV lamp.

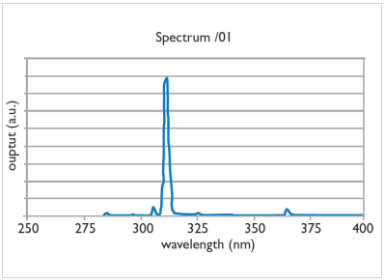
Should you have any reason for a claim, please get in touch with us. The contact information is specified in the user manual.

17 Electromagnetic compatibility

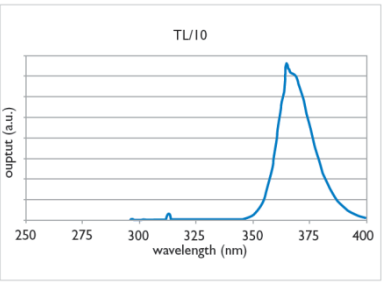
Medical-electrical devices are subject to special precautions regarding EMC. Please refer to appendix 1 for information on specific requirements for the electromagnetic environment.

18 Spectral Distribution of the Flow of Radiation

UV-B narrowband



UV-A1 (370 nm max.)



(Source: Medical Treatment Phototherapy, Philips)

19 Technical Data

UV-Output (comb attachment level)	UV-B narrowband (311 nm): approx. 3.5 mW/cm² UV-A1 (370 nm max.): approx. 8 mW/cm², each for continuous operation and +/- 20%
Voltage/Frequency (see page 1)	EU version - 230V/50 Hz UK version - 240V/50Hz JP1 version - 100V/50Hz JP2 version - 100V/60Hz US version - 120V/60Hz
Power input	40 VA

Weight handheld unit	165 g
Weight base unit	450 g
Protection class II	double insulated 
Device classification	BF 
Photobiological classification (according to EN 62471:2009)	UV-B narrow band (311 nm): risk group 3 UV-A1 (370 nm max.): free group

Requirements for:	**Operation**	**Transport and storage**
Temperature	+10°C to +30°C	-20°C to +70°C
Relative humidity	30 % to 70 %	< 90 %, non-condensing
Air pressure	700 hPa – 1060 hPa	700 hPa – 1060 hPa

20 Disposal instructions

The device may not be disposed of as domestic waste. Dispose of the device in a waste facility that accepts electronics/electrical appliances.

21 Manufacturer contact information

If necessary, contact the manufacturer for assistance with regard to the use or maintenance of the Saalux device or to report unexpected operations or incidents.

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Appendix 1 – Electromagnetic compatibility

Electromagnetic emissions

The Saalux device is designed for operation in the electromagnetic environment specified below. The user should ensure that the device is used in such an environment.

interference emission	**Compliance**	**Electromagnetic surrounding - Guidance**
RF emission according CISPR 11	Group 1	The Saalux device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission according CISPR 11	Class B	The Saalux device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emission according IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Electromagnetic immunity

The Saalux device is designed for operation in the electromagnetic environment specified below. The user should ensure that the device is used in such an environment.

Immunity test	**IEC 60601-test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	**± 8 kV** contact discharge **max. ± 15 kV** air discharge	**± 8 kV** max. **± 15 kV**	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical transients / bursts IEC 61000-4-4	**± 2 kV** for power supplies	**± 2 kV**	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	**± 1 kV** for line(s) to line(s)	**± 1 kV**	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	**0 %** U_T for 0.5 cycle **0 %** U_T for 1 cycle **70 %** for 25 cycles **0 %** U_T for 250/300 cycles	**0 %** U_T for 0.5 cycle **0 %** U_T for 1 cycle **70 %** for 25 cycles **0 %** U_T for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Saalux device requires continued operation during power mains interruptions, it is recommended that the Saalux device is powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field	**30 A/m**	**30 A/m**	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

IEC 61000-4-8			
NOTE: U_T is the a. c. mains voltage prior to application of the test level.			

Electromagnetic Immunity The Saalux device is designed for operation in the electromagnetic environment specified below. The user should ensure that the device is used in such an environment.			
Immunity test	**IEC 60601-test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Saalux device, including cables, than the recommended separation distance (d in meter) calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	**3 V rms** 150 kHz to 80 MHz **6 V rms** 150 kHz to 80 MHz within ISM bands and amateur radio bands	**3 V rms** **6 V rms**	
Radiated RF IEC 61000-4-3	**10 V/m** 80 MHz to 2700 MHz	**10 V/m**	
Radiated RF according IEC 61000-4-3 in close proximity to wireless communication devices	according to IEC 60601-1-2:2014 Table 9	**passed**	(corresponds to a recommended safety distance of 0.3 m to the devices of the corresponding radio services)
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol 
NOTE: These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.			

Appendix 2 – Patient diary

Name: _____

Physician: _____

Date	**Treated area:**	**Duration** (min)	**Notes:** - therapeutic effect - side effects

Date	**Treated area:**	**Duration** (min)	**Notes:** - therapeutic effect - side effects

Date	**Treated area:**	**Duration** (min)	**Notes:** - therapeutic effect - side effects

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Date	**Treated area:**	**Duration** (min)	**Notes:** - therapeutic effect - side effects

Accessories und add-on products for the Saalux® UV comb:

UV-protective goggles – large version
For professional staff and wearer of glasses
Art. No. 07-01-023-01

Saalux® dandruff solution
Gentle removal of dandruff before starting the therapy:

- Faster therapy success
- Protection of healthy skin
- Clinically used recipe
- Vegetable base, without salicylic acid
- Easy to wash out

75 ml bottle with handy soft tip applicator and 200 ml refill bottle.

More information on: www.saalmann-medical.de
or order directly on: www.saalmann-medical-shop.de

A product of

SAALMANN®