UVee Full Body UV Therapy Systems Model: T9000

Operating Instructions

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Tel: +32-475606433

Fax: +32-70419404

www.uvee.be

UVee by

UV Therapy Systems DESIGN, DEVELOPMENT, AND PRODUCTION OF PROFESSIONAL MEDICAL UV THERAPY SYSTEMS INNOVATIVE EXCELLENCE, MADE IN EUROPE

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General Information

1.1 Usage

The UVee Full Body UV Therapy System (UVee FB) is mainly used for total radiation of the body and is designed and built to keep the patient's safety optimal.

The device is composed of 24 UV-A and 24 UV-B lamps to provide a therapy of UV-A or UV-B radiation.

The radiation spectrum values of the lamps are:

- for UV-A lamps: between 315 and 400 nm with a peak at 365 nm
- for UV-B lamps: a peak at 311 nm

The safety of the patient has been the primordial point during the development of this device. The electric and electronic circuits assure a constant and automated control. Several UVlight sensors permanently measure the power of the UV-A radiation, while another set of sensors measure the power of the UV-B radiation to which the patient is exposed. These values are then transferred to the microprocessor to calculate the duration of the treatment.

A clearly readable full color display is visible inside the device for the patient's safety. The patient can follow the remaining time as well as the remaining dose of the radation session on the display. Note that eye protection needs to be worn by the patient at all times when the device is in operation.

A countdown of the radiation time, the actual dose the patient is still to receive and the instantaneous power of the radiation are constantly displayed on the iPad control panel. In case of interruption of the treatment by pushing the stop button or opening the door, the remaining dose remains on the displays.

By pushing the "stop" button inside the cabin or on the control panel, by opening the door, when a fault is detected, or simply at the end of the treatment session, the lamps switch off immediately.

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1.2 Important Safety Notices

A number of regulations must be followed strictly in order to maintain the correct functioning of the device and to guarantee the save use of the device and the safety of the patient, operator, and maintenance person.

- The device may only be operated by a dermatologist trained in phototherapy. It is the dermatologist's final responsibility to set the correct dose and radiation type, and verify the dose setting on the control panel and inside of the device before letting a patient start the treatment session. The dose must be continuously monitored during the treatment.
- Safety goggles (UV eye protection) for the patient are obligatory. Closing the eyes is not sufficient and can damage the patient's eyesight!
- Only use the UVee certified safety goggles for the patient. If required, you can order additional safety goggles at UVee or via your distributor.
- The Plexiglas in front of the lamps needs to be kept clean at all times. Attention!
 - o Turn off the power before cleaning.
 - o Unplug the mains cable before cleaning.
 - While cleaning, make sure no liquids enter the device.
 - Use only a slightly moist cloth.
 - Do not spray directly on the device!
 - Be sparse with cleaning products, alcohol and water.
- The Plexiglas may only be removed by a trained UVee technician. There are no user serviceable parts inside or outside of the device.
- Ensure that the device is disconnected completely from the electricity network before a technician performs maintenance or repair tasks.
- The lamps must be inspected regularly by a trained UVee technician (after 500 hours of radiation time or every year, whichever comes first).
- The operator should never be in the room where the device is located during a radiation session unless he/she wears UV eye protection.
- Only use the UVee certified UV glasses for the operator. If required, you can order additional UV glasses at UVee or via your distributor.
- The room where the device is located must be sufficiently ventilated or airconditioned to ensure proper operation of the device. The device must be kept within its safe operating temperature range and environmental parameters.
- If any discrepancy or anomaly is observed during operation or outside of the operation of the device, it is required to unplug the device from mains immediately (provided you can safely do so), stop using the device and contact the Manufacturer (UVee bv) and the distributor immediately.
- Do not use the device in an oxygen rich environment.

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- Do not use the device near inflammable products.
- Only connect the power cable to a separately fused 16A wall plug
- Before plugging in the power cable, check that the cable is clean and undamaged. Using a damaged power cable my cause death or serious injury.
- Only use the UVee certified power cable for the device. If required, you can order a new cable at UVee or via your distributor.
- Do not use the device is there is any visible indication of dew condensation. Also, do not use the device for at least 1 hour after it has been moved from a cold to a warmer environment or if the room where the device is installed has warmed up quickly.
- Leave a space of at least 30cm around the device clear to ensure proper ventilation.

Used parts and lamps must be recycled. You can bring them to your local recycling center or have your distributor handle the replaced parts/lamps for recycling.

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2 Operating the Device

2.1 Introduction

The next section in this manual explains the different use cases of operating the device. To operate the device you need:

- 1. An operator with access to the UVee iPad Control Panel
- 2. A patient who is aware of and has understood the patient operating instructions and the safety regulations of using the device, as instructed by the operator.

2.2 Switching the device ON/OFF

To power ON the device, follow these steps:

- 1. Plug in the mains cable
- 2. Toggle the power switch at the top rear of the device to ON

To turn the device completely OFF, follow these steps:

- 1. Toggle the power switch at the top rear of the device to OFF
- 2. Disconnect the mains cable from the wall socket
- 3. Unplug the mains cable from the top rear power socket in the device

Always power OFF The device:

- before doing maintenance,
- · before cleaning the device, or
- if a fault or other anomaly occurs.

2.3 Operating Instructions for the Patient

Make sure that the patient is knowledgeable in using the device before each treatment session. The patient must be made aware of the following:

- 1. Always use the device fully naked, to avoid get skin burn on upcoming sessions.
- 2. After the dermatologist has set the dose, verify the following:
 - a. The patient's name is displayed on the display inside the device.
 - b. The radiation type (UV-A or UV-B) corresponds to the radiation type that the dermatologist has told the patient.
 - c. The dose display corresponds to the dose that the dermatologist has told the patient.
- 3. The patient can then enter the device and close the door.
- 4. The patient can press the "Start/Stop"-button in the device whenever he/she is ready to start the session.
- The patient should stand so that all required parts of the body get an even amount of radiation (the patient can hold on to the vertical handle bars for a more comfortable position).

Important Information for whenever the patient:

- · feels as if the session lasts too long, or
- · starts to feel nausea or uncomfort, or
- needs to take a break.

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The patient can ALWAYS open the door and step out of the device. Opening the door will immediately pause the treatment session.

Alternatively, the patient can press the "Start/Stop"-button at any time to pause the treatment session. Note that pressing the "Start"-button again will continue the session, provided that the door is closed.

A session cannot be started as long as the door is not closed.

2.4 Detailed Operating Instructions for the Device Operator

These instructions are laid out over the next pages.

Main Screen of the iPad PUVA Control app 2.4.1

This shows all the components of the main screen of the iPad control panel. Each component is numbered and will be referenced to on the next pages.



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Prepare a Manually Controlled Session

Prepare a Manually Controlled session

To manually control the UV Therapy System, follow these steps:

- 1. Press Manual Control (1.20)
- 2. Select UVA or UVB with (1.1)
- 3. Set dose with (1.3)
- 4. Press the Set button (1.6)

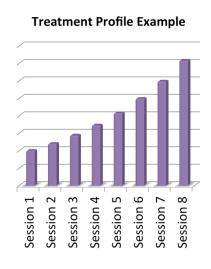
The dose and the selected UV-Type will appear on the display in the cabin. The system is now ready for the session to be started.

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What is a Treatment Profile

What is a Treatment Profile? (1)

A treatment profile determines the doses that a patient will receive over multiple sessions (called a "treatment"). Each session advances the treatment profile automatically to the next dose.



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What is a Treatment Profile? (2)

A treatment profile has the following parameters:

- UV Type (A or B)
- Start dose value (in Joule) If not specified, starts at zero.
- End dose value (in Joule) 3. If not specified, ends at max (20 J uvA or 5 J uvB)
- Increment each session with a fixed amount of Joule or with a 4. percentage of the previous dose
- 5. Whether each dose has to be given twice before incrementing it
- How many extra sessions (if any) need to be given when the end dose is

The operator can ALWAYS override the calculated dose and UV type using (1.1) and (1.3).

The dose for the next session is always calculated based on the previous dose, if it was overriden by the operator.

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2.4.4 Prepare a Patient's Session Without a Treatment Profile

Prepare a Patient's Session without a Treatment Profile

To start a session for a patient without a treatment profile, follow these steps:

- 1. Select a patient without a Treatment Profile from the patient list (1.19)
- 2. Select UVA or UVB with (1.1)
- 3. Set dose with (1.3)
- 4. Press the Set button (1.6)

The name of the patient, the dose and the selected UV-Type will appear on the display in the cabin. The system is now ready for the session to be started.

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2.4.5 Prepare a Patient's Session With a Treatment Profile

Prepare a Patient's Session with a Treatment Profile

To start a session for a patient who has a treatment profile, follow these steps:

- 1. Select a patient with a Treatment Profile from the patient list (1.19)
- 2. The UV type and the automatically calculated dose value are shown in (1.1) and (1.3)
- 3. Optionally, the operator can override the calculated dose using (1.3) (in that case, the dose for the next session will be recalculated automatically)
- 4. Press the Set button (1.6)

The name of the patient, the dose and the selected UV-Type will appear on the display in the cabin. The system is now ready for the session to be started.

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2.4.6 Start a Session

Start a Session

Once a session is prepared, the Start button (1.7) becomes active.

- 1. The patient enters the cabin and puts on appropriate eye protection
- 2. The door is closed (the session cannot be started otherwise)
- 3. A) the patient presses the physical red Start/Stop switch in the cabin, or
- B) the operator presses the Start button (1.7) on the iPad The lamps will now turn on.

As an emergency stop, the patient can simply push open the door of the cabin. The lamps will turn off immediately.

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2.4.7 Pause a Session

Pause a Session

When a session is started (i.e. lamps are on), it is possible to temporarily stop (pause) the session in three different ways:

- A) the patient or operator opens the door, or
- B) the patient presses the physical red Start/ Stop switch in the cabin, or
- C) the operator presses the Pause button (1.7) In either of these cases, the lamps will switch off immediately. The session can be restarted by following the instructions of "Start a Session".

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2.4.8 **Abort a Session**

Abort a Session

When a session is in progress, the system is locked until the session ends (reaches value 0.00) or until the session is aborted. To interrupt a running session you need to abort it to regain control of the control panel:

1. Press the Abort button (1.8) The Abort button is only active when a session is in progress.

If the lamps were on, they will switch off immediately.

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Lock / Unlock the Screen

Lock / Unlock the Screen

To prevent an unauthorized person to operate the system, the operator can lock the screen. The Start/ Pause button (1.7) and the Abort button (1.8) are operational whether the screen is locked or not, due to security reasons.

To lock the screen:

1. Press the Lock button (1.4)

To unlock the screen:

1. Press and hold the Lock button (1.4) for 2 seconds

Note: in an upcoming version, the press and hold will be replaced by a code lock keypad.

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2.4.10 Treatment Profile Presets



Define/Edit Treatment Profile Presets

There are 12 Treatment Profile Presets which can be defined by the doctor. 6 are for UVA and 6 for UVB. To define a preset, follow these steps (all steps are optional):

- Select the Preset which you want to edit (2.2) 1.
- 2. Set a Start and End dose for the treatment using (2.3) and (2.4)
- Choose whether you want to increment the dose in each session in percentage or with a fixed Joule value (2.5)
- Set the increment amount using (2.6), based on (2.5) 4.
- Turn (2.7) on if you want each session twice with the same dose
- Choose the amount of extra session you want the patient to have when the end dose has been reached (2.8)

You can change multiple presets by selecting a different preset using (2.2). When done with all modifiations, press the Done button (2.1).

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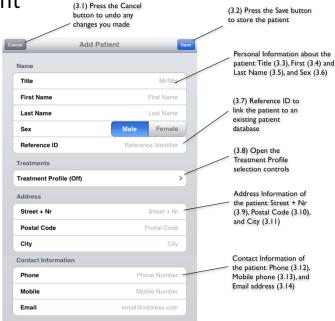
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2.4.11 Add/Modify a Patient

Add/Modify **Patient**



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Add a Patient

To add a new patient to the patient database, follow these steps:

- Press the +-sign (1.21) to open the Add Patient control
- Fill in the Add Patient form (scroll down to see all the fields (3.3) until (3.14)) – All fields are optional.
- Note that pressing the Treatment Profile button (3.8) opens the Treatment Profile selection control
- 4. Press the Save button (3.2) to store the patient in the database

If you do not want to save the patient, simply press the Cancel button (3.1) instead.

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Modify a Patient

To modify an existing patient, follow these steps:

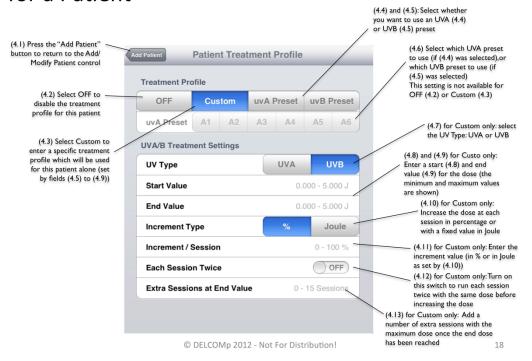
- Find the patient in the Patient List (1.19)
- Press the blue arrow next to the patient's name (1.17)
- Modify any of the fields as you see fit (scroll down to see all the fields (3.3) until (3.14))
- Note that pressing the Treatment Profile button (3.8) opens the Treatment Profile selection control
- 5. Press the Save button (3.2) to store the changes in the database

If you do not want to save the changes, simply press the Cancel button (3.1) instead.

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2.4.12 Treatment Profile Selection for a Patient

Treatment Profile Selection for a Patient



2.4.13 Add a Custom Treatment Profile to a Patient

Add a Custom Treatment Profile to a **Patient**

If you have a patient who requires a specific treatment profile (i.e. not one the presets), you can add a custom treatment profile to that patient.

- Follow the first steps in "Add"- or "Modify a Patient" and press the Treatment Profile button (3.8)
- 2. Select Custom (4.3)
- Choose the UV Type UVA or UVB (4.7)
- 4. Set a Start and End dose for the treatment using (4.8) and (4.9)
- Choose whether you want to increment the dose in each session in 5. percentage or with a fixed Joule value (4.10)
- Set the increment amount using (4.11), based on (4.10) 6.
- 7. Turn (4.12) on if you want each session twice with the same dose
- Choose the amount of extra session you want the patient to have when 8. the end dose has been reached (4.13)
- 9. Press Add Patient (4.1)
- 10. Continue with the last step(s) of "Add"- or "Modify a Patient" to Save the settings

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2.4.14 Attach a Preset Treatment Profile to a Patient

Attach a Preset Treatment Profile to a Patient

To make sure that a patient uses one of your predefined Treatment Profile Presets, you can easily select a preset for that patient:

- 1. Follow the first steps in "Add"- or "Modify a Patient" and press the Treatment Profile button (3.8)
- 2. Select UVA Preset (4.4) or UVB Preset (4.5)
- 3. Choose the Preset number A1 to A6 (for UVA) or B1 to B6 (for UVB) in (4.6)
- 4. The fields (4.7) to (4.13) will show the settings for the selected preset. However, you cannot modify the preset here.
- 5. Press Add Patient (4.1)
- 6. Continue with the last step(s) of "Add"- or "Modify a Patient" to Save the settings

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2.4.15 Print a Patient Card

Print a Patient Card

Note: To be able to print using the iPad, an Apple AirPrint compatible printer has to be attached to the same (Wireless) network as the iPad

- 1. Select the patient from the patient list (1.19)
- 2. Press the Print button (1.13) (note: if no printer is found, this button is not visible!)
- Select the printer (and optionally change the printer settings)
- 4. Press Print

A print out with the details of the patient and the treatment history will be produced.

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2.4.16 Print the List of Patients

Print the List of Patients

Note: To be able to print using the iPad, an Apple AirPrint compatible printer has to be attached to the same (Wireless) network as the iPad

- 1. Press (1.11) to open the Settings control
- 2. Scroll down to the bottom of the control and press the Print Patient List button
- 3. Select the printer (and optionally change the printer settings)
- 4. Press Print

A print out with a list of the patient database and a summary of the patients' treatments will be produced.

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Maintenance

3.1 Lamps and Plexiglas

The UV-lamps have an approximate lifetime of 500 hours. After this time or when you notice a significant loss in radiation power, the lamps must be replaced. It is strongly advised to replace the lamps at least once a year, even if the lamps have not been used yet for 500 hours.

When a single lamp fails, all 24 lamps of the same type (UVA or UVB) need to be replaced. Failing to do so will compromise the correct operation of the device and will invalidate the warranty.

Every 2 years, the Plexiglas lamp covers need to be replaced to keep optimal UV translucency. (This roughly corresponds with every other time the lamps are replaced.)

3.2 Yearly Maintenance

The device must be inspected every year by a trained UVee technician. Skipping the yearly inspection invalidates the warranty.

3.3 Cleaning the Device

Unplug before cleaning!

Ensure that the power is switched off and the device is disconnected from the electricity network, with the mains cable unplugged, before cleaning.

When you use cleaning products make sure that they do not affect the materials. A slightly moist cloth, lightly dipped in lukewarm water with a little bit of soap is sufficient for regular maintenance.

Attention! While cleaning, no liquids may enter the device. Only use a slightly moist cloth and be sparse with cleaning products, alcohol and/or water.

3.4 Device Lifetime

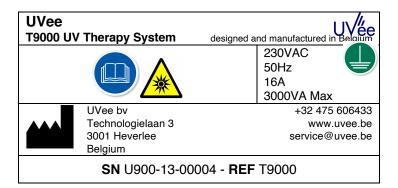
With proper maintenance as specified above and by following the instructions specified in this manual, the device lifetime is estimated to be 10 years.

The lifetime may be severely reduced if the instructions are ignored, if maintenance is skipped, or if any potential issue is not immediately reported to UVee.

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Technical Information

4.1 Identification Label



4.1.1 **Explanation of Symbols**



This symbol indicates that you need to consult the instructions for use. (L0458)



Warning Label – Hazard Symbol. (Figure 201.102 in EN 60601-2-57:2011) This symbol indicates that the device provides hazardous (UV) radiation.

Note: It is important that only patients who are aware of the security risks and who wear the required UV-radiation blocking safety goggles use the device.



This symbol indicates the manufacturer of the device. (Symbol 5.2 of EN 980:2003)

Next to this symbol you can find the address and contact information of the manufacturer.



Symbol ISO 7010, LB 0459.

This symbol indicates the electric insulation class of the device, according to EIC 61140. Insulation class I: chassis connected to electrical earth.

SN

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This symbol indicates the manufacturer's serial number. (Symbol 4.5 of EN 980:2003)

Format: SN U900-YY-SSSSS

U900 indicates the device type. YY is the production year of the device. SSSSS is the production sequence number of the device.

Example: **SN** U900-13-00004

means device type U900, build in 2013 with production sequence number 4.

REF

This symbol indicates the catalogue number of the device. (Symbol 4.9 of EN 980:2003)

Example: REF T9000

T9000 is the catalogue number of the device.



This symbol indicates that is required to wear UV protection goggles when the device is in operation.

4.2 Other Labels

RISK GROUP 3

WARNING UV emitted from this device may be hazardous. Avoid eye or skin exposure.



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4.3 Technical Data

4.3.1 **Features and Dimensions**

Dimensions						
Outer	Approx. 101 x 101 x 205 cm					
• Inner	Approx. 75 x 75 x 194 cm					
• Step	< 11 cm					
Weight	Approx. 400 kg (including packaging)					
Lamps and Sensors						
• UVA	24 Philips Medical UVA 100W					
• UVB	24 Philips Medical UVB 100W (TL-01 narrowband)					
Electronic start	yes					
Electronic run	yes					
UV Sensors	4					
Mains						
 Connection 	16 A / 230 V AC / 50 Hz					
Power Usage	Max. 3000 VA					
 Cos Φ 	0,99 (electronic lamp control)					
 Power Surge at lamps on 	None					
Software						
 On-board Firmware 	Remote upgradable (using iPad Control					
 Apple iPad Control Panel 	Remote upgradable (via Apple AppStore)					
Interfaces						
 WiFi Network Connection (WLAN) 	yes					
 Apple iPad Control Panel 	yes					
 Easy to read patient display in the cabin 	yes, full color					
Door open/closed detection	yes, with automatic start/ stop					
Built-in Clock	yes					
Audible Alarms	yes					
iPad Control Panel						
 Operate and Monitor Cabin Status 	local and remote					
Patient Database	unlimited number of patients					
Therapy Plans	yes, with history					
Monitor progress and error codes	yes, with audible and visual indicators					
Print patient cards and lists	yes					
Upgrade software using internet	yes (internet connection required)					
Backup all data	yes					

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4.3.2 **Operational Parameters**

Operational Environmental Requirements						
Relative Humidity	10% - 70% (non-condensing)					
Atmospheric Pressure	Below 2000 m above sea level.					
Temperature	15°C-30°C					
Oxygen Rich Environment	Not suited for use in Oxygen Rich					
Near Inflamable Products	Not suited for use near Inflamable Products					
Transport Environmental Requirements						
Relative Humidity	10% - 70% (non-condensing)					
Atmospheric Pressure	Not Applicable					
Temperature	-15°C - 50°C					

4.3.3 **Classifications**

Classifications	
Electric Insulation Class	Class I
IP Classification	IP2X
EN 60601-2.57 Classification	Risk Group 3
Directive 93/42/EEC Classification	Class IIa

Belgium

UV Therapy Systems

DESIGN, DEVELOPMENT, AND PRODUCTION OF PROFESSIONAL MEDICAL UV THERAPY SYSTEMS INNOVATIVE EXCELLENCE, MADE IN EUROPE

5 Photo Therapy

- Warning -

Giving the wrong dose or the wrong type of radiation to a patient can result in serious burns:

- The dose must be set by a dermatologist trained in phototherapy.
- The dose must be continuously monitored during the treatment.

5.1 Therapeutic Advise

It is not possible to treat all patients in the same way.

Patients who are very sensitive at the beginning of their treatment may endure higher doses at the end of the treatment than patients who endured higher doses at the beginning. For some of the patients it is even impossible to exceed small doses. In some cases the dose must even be reduced.

The therapy must be adapted to the reactions of the patient. Before every treatment you should check to see how the patient has reacted to the previous treatment.

If a patient reacts negatively to the radiation you should take next points into consideration.

- Exposure to sun during a treatment
- Taking photosensitizing medication.
- Stopping the use of protection cream, which may have been used before.
- Perfumed cosmetics, bath foam and some laxative tea may contain photosensitizing materials.

Sometimes it is necessary to protect the face since the facial skin is more sensitive.

UV radiation causes dehydration of the skin; it will be necessary to use neutral cream or oil baths after the treatment.

The application of a rich cream before the treatment increases the penetration of the UV radiation and increases the efficiency of the treatment. The cream may not be too rich since in that case it will reflect the radiation.

The patient must be naked during the whole treatment, to avoid covered body parts getting burned at a later stage of the treatment.

5.2 Eye Protection (Safety Goggles and UV Glasses)

All patients must wear special protective UV goggles. Closing the eyes is absolutely insufficient and may damage the eyesight.

When the operator is in the same room as the device, he/she should wear protective UV glasses.

UVee bv Technologielaan 3 B-3001 Leuven Belgium email: service@uvee.be

B-3001 Leuven Belgium

5.3 Treatment Duration

Inform the patient that it might take 15 to 20 sessions before the symptoms disappear (ex: psoriasis). An irregular treatment can influence the result. The more you repeat the treatment the higher the dose becomes and the faster you obtain healing.

5.4 Indicative Doses for UVB Therapy (Psoriasis) TL01

An example:

SESSION	1 st	2 nd	3 rd	4 th	5 th	6 th	7 th	8 th	9 th	10 th	Maximum
PHOTO TYPE											Dose J/cm²
II	0.10	0.15	0.20	0.30	0.40	0.55	0.70	0.90	1.10	1.40	1.40
III	0.20	0.30	0.40	0.55	0.70	0.90	1.10	1.40	1.70	2.10	2.10
IV	0.30	0.40	0.55	0.70	0.90	1.10	1.40	1.70	2.10	2.50	2.50
V	0.40	0.55	0.70	0.90	1.10	1.40	1.70	2.10	2.50	3.00	3.00

IMPORTANT: The dose values entered on the device must always be set by and verified by a dermatologist trained in phototherapy. The table above is merely provided as an example.

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