

URGENT SAFETY INFORMATION UV 7001

H. Waldmann GmbH & Co. KG, Postfach 5062, 78057 Villingen-Schwenningen

Responsible Jürgen Belzner
Phone +49 7720 601 483
Fax +49 7720 601 290
Email j.belzner@waldmann.com

Date 2018-10-22

USE OF THE UV THERAPY SYSTEM UV 7001 BY ENTERING THE IRRADIATION TIME

Dear customers,

According to our documentation, you are using at least one WALDMANN UV Therapy System UV 7001 for light therapy, with a serial number below number 71848.

A safe therapy with the UV 7001 device by entering the irradiation dose is based on the perfect function of the UV measurement technology and the associated dosimetry. In case of a defect of the sensor filter glasses, for example due to signs of aging, such as irreversible formation of a coating, the UV transmittance is reduced. This can lead to measurement errors and thus also to overdosing and ultimately to severe burns. Due to the age of your device, the sensors installed in your device may be affected by this problem. Since it is no longer possible to replace the sensors (there are no more spare parts available on the market) and it is not possible to estimate how quickly this sensor defect can occur, we can no longer guarantee proper operation of the device in combination with the sensor dosimetry.

USE BY ENTERING THE IRRADIATION TIME

Besides the operation by entering the desired irradiation dose (UVA/UVB dose in J/cm²) in combination with sensor dosimetry, the UV 7001 device is also designed for operation mode by entering the irradiation time (UVA/UVB time in min:sec), which functions without sensors. The basis for this operating mode is the actual intensity of the lamps as well as the desired irradiation dose, from which the irradiation time to be entered can be calculated manually.

We will contact you within the next few days to schedule an appointment with one of our service technicians free of charge. Our service technician will carry out an on-site measurement of the actual lamp intensity with a calibrated measuring device and will help to generate your individual conversion table(s) via our online conversion table (at www.waldmann-medical.com/conversion-table). These conversion tables serve you as a basis for the further use of the device by entering the irradiation time.

In order to ensure a safe operation of the device until the on-site measurement by our service technician, use the actual measured lamp intensity of the most recent maintenance (listed in our maintenance report under item 17) to calculate the irradiation time to be entered into the device for the treatments to be carried out until then. If the device has not been serviced regularly every 12 months, as prescribed by WALDMANN, or if a lamp replacement has been carried out after the last maintenance, please contact our service department (phone number +49 7720 601 253) to discuss the next steps.

For further information on using the device by entering the irradiation time, please refer to the instructions for use, part "3 Operation + Application", page 5. The online conversion table for calculating the irradiation time can be found at www.waldmann-medical.com/conversion-table.

Herbert Waldmann GmbH & Co. KG
Peter-Henlein-Straße 5
D-78056 Villingen-Schwenningen
Tel. +49 (0) 77 20 / 601-0
Fax +49 (0) 77 20 / 601-290
www.waldmann.com
USt.-IdNr. DE 217 355 961
WEEE-Reg-Nr. DE 77596560

Rechtsform Kommanditgesellschaft
Sitz Villingen-Schwenningen
Registergericht
Freiburg i. Br. HRA 602616
Komplementär Waldmann GmbH
Sitz Villingen-Schwenningen
Registergericht
Freiburg i. Br. HRB 602670
Geschäftsführer Gerhard Waldmann,
Markus Wiedmann

Bankverbindungen
Postbank Stuttgart
69450065
Sparkasse Schwarzwald-Baar
01301217
Volksbank Donau-Neckar eG
64390130
Volksbank eG Villingen
69490000
Deutsche Bank AG
69470039
Commerzbank AG
69440007
BW Bank
60050101
Dresdner Bank AG
69280035

BLZ
60010070
69450065
01301217
159390001
22760106
0431932
140252800
4800880
0821755500

Kto.Nr.
061601709
SOLADES1VSS
GENODES1TUT
GENODE61VS1
DEUTDE6F694
COBADEFFXXX
SOLADEST
DRESDEFF692

IBAN-Nr.
DE93600100700061601709
DE73694500650001301217
DE48643901300159390001
DE46694900000022760106
DE78694700390043193200
DE80694400070140252800
DE16600501010004800880
DE13692800350821755500

URGENT SAFETY INFORMATION UV 7001



RISK OF USE BY ENTERING THE IRRADIATION DOSE

For safety reasons, the device may no longer be used by directly entering the desired irradiation dose due to the sensor issue. A UV overdose may be administered, which can lead to severe burns of the patients. **Therefore, this operating mode is no longer a proper use of the device. Please only use the dosage by entering the irradiation time in the future.**

PASSING ON THE INFORMATION DESCRIBED HERE

Please ensure in your organisation that all users of the above device and other persons to be informed are aware of this urgent safety information. If you have handed over the products to third parties, please forward a copy of this information to them or contact the person listed below.

Please keep this information at least until the measure has been completed.

This letter is accompanied by a confirmation letter that you have received this urgent safety information and that you will only operate the affected device in accordance within the provided specifications. Please sign and return the confirmation letter to Waldmann at the address below or hand it over to our service technician during the on-site appointment.

If the affected device is no longer in operation in the meantime, please inform us as soon as possible.

Your contact at Herbert Waldmann GmbH & Co. KG:

Quality Manager Medical Devices/Health and Safety Officer, Mr. Jürgen Belzner

Phone: +49 7720 601 483

Email: j.belzner@waldmann.com

Availability: Mon.-Thu. 8 am – 4 pm; Fri. 8 am – 12 pm

Villingen-Schwenningen, 2018-10-22

Jürgen Belzner

Herbert Waldmann GmbH & Co. KG
Peter-Henlein-Straße 5
D-78056 Villingen-Schwenningen
Tel. +49 (0) 77 20 / 601-0
Fax +49 (0) 77 20 / 601-290
www.waldmann.com
USt.-IdNr. DE 217 355 961
WEEE-Reg-Nr. DE 77596560

Rechtsform Kommanditgesellschaft
Sitz Villingen-Schwenningen
Registergericht
Freiburg i. Br. HRA 602616
Komplementär Waldmann GmbH
Sitz Villingen-Schwenningen
Registergericht
Freiburg i. Br. HRB 602670
Geschäftsführer Gerhard Waldmann,
Markus Wiedmann

Bankverbindungen
Postbank Stuttgart
Sparkasse Schwarzwald-Baar
Volksbank Donau-Neckar eG
Volksbank eG Villingen
Deutsche Bank AG
Commerzbank AG
BW Bank
Dresdner Bank AG

| BLZ | Kto.Nr. |
|----------|------------|
| 60010070 | 061601709 |
| 69450065 | 01301217 |
| 64390130 | 159390001 |
| 69490000 | 22760106 |
| 69470039 | 0431932 |
| 69440007 | 140252800 |
| 60050101 | 4800880 |
| 69280035 | 0821755500 |

| BIC-Code |
|-------------|
| PBNKDEFF |
| SOLADES1VSS |
| GENODES1TUT |
| GENODE61VS1 |
| DEUTDE6F694 |
| COBADEFFXXX |
| SOLADEST |
| DRESDEFF692 |

| IBAN-Nr. |
|------------------------|
| DE93600100700061601709 |
| DE73694500650001301217 |
| DE48643901300159390001 |
| DE46694900000022760106 |
| DE78694700390043193200 |
| DE80694400070140252800 |
| DE16600501010004800880 |
| DE13692800350821755500 |

URGENT SAFETY INFORMATION UV 7001



Herbert Waldmann GmbH & Co. KG

Mr. Jürgen Belzner
Peter-Henlein-Straße 5
D-78056 Villingen-Schwenningen
Germany

CONFIRMATION LETTER

I hereby confirm that the urgent safety information concerning the UV therapy system UV 7001 (FSCA reference number BfArM: 12175/18), dated October 1st, 2018, has been received and acknowledged. Future treatments with the affected device will only be carried out by entering the irradiation time.
All affected users (operating personnel) and, if applicable, other third parties have been informed and instructed.

Serial number/s:

Place, Date:

Address:

Name / Signature / Stamp Physician: