

Gilching, 31.07.2020

Safety information on dermalight®2000

Necessity to use the included short-term timer

Dear customer,

this letter is intended to inform you about a possible problem with the use of dermalight® 2000. With this safety notice we would like to explain to you,

- What exactly the problem is and under what circumstances it can occur
- Which activities should be taken by the user¹, to avoid endangering the patient
- What activities by Dr. Höhle Medizintechnik GmbH were made

This document contains important information, that will help you to continue using your device safely and properly.

Please make sure in your organisation that all users of the above mentioned product and other persons to be informed are aware of this safety information. If you have given the mentioned products to third parties, please forward them a copy of this important safety information or inform the contact person below.

For more information or assistance related to this problem, please contact:

Dr. Höhle Medizintechnik GmbH

Ms. Jessica Gessner (Managing director), Phone: +49 (0) 8105 730 29 0 / Email: jg@drhoenle.de

This safety notice has already been reported to the responsible authorities.

¹ For reasons of better readability the simultaneous use of male, female and diverse language forms are dispensed with. All personal names applies to all gender..



Dr. Höhle Medizintechnik GmbH

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Geschäftsführer(-in):
Prof. Dr. Karl Höhle
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Safety information on dermalight®2000

Affected products	dermalight® 2000 Article-no.: 70 05 00 – 76 10 20 Serial-no.: 120415J – 191528J
Description of the problem	<p>The use of the short-term timer is intended as a precautionary measure when using the dermalight® 2000, to indicate the need to switch of the device manually in the event of a possible failure of the automatic switch-off of the device.</p> <p>In practice, the use of the external timer is not always observed, despite the information in the instruction of use (Version: #705000/S1214d).</p>
Possible risk	<p>Failure of the automatic switch-off device and exceeding the permissible duration of the indicated UV-radiation treatment with risk of burns for patients.</p>
Necessary activities of the customer/user	<p>Make sure that all users of the above mentioned product and other persons to be informed are aware of this safety information.</p> <p>As a user, always set the time on the supplied external short-term timer in addition to the device timer.</p> <p>Please note the information in the instruction for use of the dermalight®2000, #705000/S0720d</p> <p>P. 3 _ Safety notice:</p> <p><i>„The short-term timer must be used for every treatment and started with the device at the same time. To do this, follow the procedure specified in „Setting the operating time“ p.6. The use of the device without the external short-term timer is prohibited.</i></p>



Dr. Hönle Medizintechnik GmbH

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Necessary activities of the customer/user	<p>P. 6 _ Setting the operating time _ point 6, 9 & 12</p> <p><i>„Set the time on the external short-term timer as well. This is used for additional monitoring of the device and must be worn on the users body during the ongoing treatment.“</i></p> <p><i>„Start the short-term timer at the same time. (The short-term timer is used to monitor the integrated timer and must always be started at the same time.“</i></p> <p><i>„After the expired time please check whether all bulbs are off. If not, switch off the device manually using the power switch, take the device out of operation and inform a service technician.“</i></p> <p>If you, as a user has relocated the external short-term timer or cannot find it, please contact:</p> <p>Dr. Hönle Medizintechnik GmbH Ms. Jessica Gessner (Managing director), Phone: +49 (0) 8105 730 29 0 Email: jg@drhoenle.de</p> <p>so that it can be delivered promptly</p> <p>The use of the device without the external short-term timer is prohibited.</p>
Activities taken by Dr. Hönle Medizintechnik GmbH	<p>Special emphasis on the need to use the short-term timer in the instruction for use in order to raise user awareness.</p>
Further information and support	<p>For more information or assistance related to this problem, please contact:</p> <p>Dr. Hönle Medizintechnik GmbH Ms. Jessica Gessner (Managing director), Phone: +49 (0) 8105 730 29 0 Email: jg@drhoenle.de</p>

Confirmation of receipt and understanding

Dear Sirs,

Please confirm the receipt of this safety information and send a signed version for our documentation back to us till **14.08.2020**:

Dr. Hönle Medizintechnik GmbH

Ms. Jessica Gessner (Managing Director)

Email: jg@drhoenle.de

Fax: 0049 8105 730 29 50

Address: Dornierstr. 4, 82205 Gilching, Deutschland

I hereby confirm the receipt and understanding of the previous safety information on the dermalight®2000:

Name (in block letters)

Date

Signature



Dr. Hönle Medizintechnik GmbH

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D-82205 Gilching, Germany

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