

An:

<< Name >>
<< Adress >>

Name/name: [REDACTED]
Abtlg./Dept. Qualitätsmanagement
Tel./phone: ++49-8153-888-[REDACTED]
Fax/fax: ++49-8153-888-[REDACTED]
Email: [REDACTED]@dornier.com

Datum/date : Wessling, 2014-10-27

Safety notice / corrective measure for medical device:

Dornier Medilas D12, Medilas D Opal

Dear Customer,

the name Dornier MedTech stands for the highest standards of quality and safety. We therefore are very sorry to have to inform you of a quality-related defect in the diode laser devices Medilas D12 (Medilas D Opal). During a re-validation of the software, it became apparent that the predecessor version of this software has a low probability that the laser may emit too much power. If the laser is used under visual control, the user can recognise this error and respond appropriately. In applications without visual control, though, excessive power may be emitted without noticing.

This applies to the following lasers, which have software version 1.3.1 or 1.3.2 installed:

Medilas D Opal, Artikel-Nr. K2012700, K2012701, K2012703, K2012704, K2012705

What do you, as a user, have to do?

1. In order to ensure the maximal levels of quality and safety, please return your laser no later than **31.12.2014** to **Dornier MedTech Laser GmbH**. The **Dornier MedTech Laser** Team will perform a software update on your unit and remedy the problem.
2. For regulatory reasons, please complete the appended response form at your earliest convenience and return it by email to the contact address given
1. If you have appointments scheduled already, you can continue to use the product, albeit with special care, until you ship it back to **Dornier MedTech Laser**. The likelihood of this defect actually occurring is very low. To date, there have been no user complaints related to an event of this kind.

If you have any other questions, please contact your dealer and/or the **Dornier MedTech Laser Laser Quality Support Hotline** at:

Tel.: +49-(0)175-7212091
E-Mail an dmtlaser.service@dornier.com

Dornier MedTech GmbH

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Sitz der Gesellschaft:
Wessling
Amtsgericht München
HRB 113816
Ust-Id Nr. DE 183642248
Steuer-Nr. 117/115/20564

Vorsitzender des Aufsichtsrats:
Prof. Tan Ser Kiat

Geschäftsführung:
Abel Boon Thong Ang
Ng Siok Eng Catherine

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Dornier MedTech GmbH Postfach 1251 D-82231 Wessling

We apologise for any inconvenience resulting from this action and appreciate your understanding. It is our top priority to make sure, at all times, that any hazards for patient and user are excluded to the extent possible.

Thank you for your support.

Yours sincerely,
Dornier MedTech GmbH


Safety Officer