Dornier MedTech

To:

<< Name >>
<< Adresse >>

Name/name: Tom Peters
Abtlg./Dept. Qualitätsmanagement
Tel./phone: +49 8153 888-155
Email: mdro@dornier.com

Datum/date : Wessling, 2018-01-08

Urgent Safety Information:

Change to Software Configuration *Dornier Gemini*

Affected Devices: All installed devices of *Dornier Gemini* up to Serial Number 152, as well as Serial Numbers 158, 160 and 161.

Dear Customer,

the brand Dornier MedTech stands for highest quality and safety.
For this, we are sorry to inform you about a quality issue regarding our shock wave lithotripter Dornier Gemini.

Through customer feedback we received information that the level of intensity of the shock wave application has increased unintended during treatment. Our investigations did trace this back to an ergonomical issue of the touch panel, due to which the intensity can be increased by several light hits. It is possible to trigger this release unintended. The increase of intensity while applying shock waves is only possible in the mode "kV Change on the Fly".

The intensity is still limited to the maximal allowed intensity for treatment according to the operating manual, but unintended increase may also increase the occurrence rate of hematoma, damage of surrounding tissue and other known side effects.

It was therefore decided to deactivate the failure triggering mode „kV Change on the Fly" at your device to ensure patient safety. A service technician will conduct the necessary configurations during next service. An adjustment of the intensity level during shock wave application will not be possible from this point anymore.

We're currently working on a solution to make the mode safely available again.

What does the user have to do?

1. Until deactivation of the mode „kV Change on the Fly", adjustment of intensity during shock wave application is not allowed. This prevents the occurrence of above described problem.

2. We further on request you to please fill in the attached form immediately and send it back within 7 calendar days by FAX or e-Mail, to below mentioned contact.

Dornier MedTech

For any Questions, please contact the Dornier MedTech Italy Support at:

Tel.: +39 06 7235289
E-Mail: **pdilanzo@dornier.com**

We apologize empathically for any inconveniences caused by this action and hope for your understanding. Our highest priority is to assure that all harms for patients and users are ruled out at any time.

Thank you for your support.

Kind regards
Dornier MedTech GmbH

Tom Peters
Medical Device Reporting Officer

Dornier MedTech

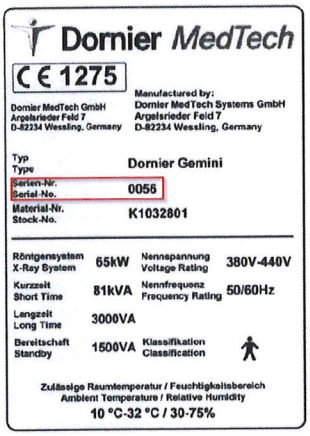
Klinik/Praxis Stempel - Clinic/Office Stamp

Urgent Safety Notice Dornier Gemini

Confirmation of receipt user

- ☐ We hereby confirm receipt and understanding of the Field Safety Notice
- ☐ We confirm that following product(s) is/are installed and used at our facility(please see the label on the devices back side):

Serial Number	Software version (shown in the start screen of the device)



- ☐ The above mentioned devices are under no valid service contract. (Dornier MedTech will approach you in this case to schedule the service.)

Contact Person (block capitals)

Date, Signature

Please send back the filled form at:

competence-center@dornier.com