Dornier MedTech

To whom it may concern:

Cc: Chairman Medical Board

Relevant Head of Departments

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 unintendedly during treatment. Our investigations traced 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 unintendedly. 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 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.

Dornier MedTech Asia Pte Ltd
Co. Regn No.: 199403836G

2 Venture Drive
#23-18 Vision Exchange
Singapore 608526

Telephone: (65) 6572 6068
Fax: (65) 6572 6093
Email: infoasia@dornier.com

www.dornier.com

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

What does the user have to do?

1. After 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.

For any Questions, please contact your Distributor or the Dornier MedTech Asia Support Hotline at:

Tel.: +65 6572 6056/+65 9748 5064

E-Mail: **asiaregulatory@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
Hejie Wang
Quality Management and Regulatory Affairs Manager
Dornier MedTech Asia Pte Ltd

[redacted]

Signature

13 Feb 2018

Date