

WaveLight AG · Am Wolfsmantel 5 · 91058 Erlangen, Germany

**WaveLight AG**  
Am Wolfsmantel 5  
91058 Erlangen, Germany  
Tel. +49/9131/6186-0  
Fax +49/9131/6186-111  
info@wavelight.com  
www.wavelight.com

Dear customer,

Please, take notice of the following information!

Urgent Safety Information :  
Modification concerning Lifting Table Diagnostic 1171

2009-01-23

**Sender:**

Manufacturer of the Lifting Table according to 93/42/EWG:  
Ergo-Tec GmbH  
Gewerbestraße 2  
91489 Wilhelmsdorf  
Germany

**Recipient:**

All users of the Lifting Table Diagnostic 1171

**Identification of affected medical devices:**

Lifting Table Diagnostic 1171, used as optional accessory for the WaveLight diagnostic systems ALLEGRO Analyzer, ALLEGRO Topolyzer und ALLEGRO Oculyzer.  
Serial numbers 0001 to 0306.

**Description of the problem, including the identified root cause:**

During a re-evaluation of the design of the lifting table by a third party testing laboratory various deviations in relation to the standard EN SIO 60601-1 were detected, although the lifting table was labelled as conform to EN ISO 60601-1.

The manufacturer of the Lifting Table, Ergo-Tec GmbH, has evaluated the risks resulting from the deviations from the standard EN ISO 60601-1. According to this risk evaluation none of the deviations pose an immediate hazard for health, safety or effectiveness of the table, or influence the effectiveness of the Lifting Table or the mounted WaveLight diagnostic devices

Most of the deviations concern the user comfort or the labelling of the table, and were evaluated as low risk. Some of the deviations represent a potentially increased risk.

In these cases there is no immediate hazard for the user, a risk could only arise as a consequence of an already present defect of the table (e.g. a damaged cable insulation). A modification of the tables during the next service visit was deemed as sufficient.

**Which measures must be taken by the recipient?**

The recipient must not take any measures. The WaveLight diagnostic devices and the corresponding Lifting Table can be used without restrictions according to the user manual.

Your service partner for the Lifting Table Diagnostic will perform the required corrections of the Lifting Table Diagnostic 1171 during the next regular service visit.

**Forwarding of this information:**

Please make sure in your organization that all users of the above mentioned medical devices or other individuals are made aware of this **urgent safety information**. In case you have transferred the devices to a third party, please forward a copy of this information, or inform the contact person listed below. Please keep this information at least for the time until the corrective measures have been taken. The German authorities for pharmaceuticals and medical devices (BfArM) has received a copy of this "urgent safety information".

**Contact person:**

In case you should have any questions in the meantime to this letter, please don't hesitate to contact us at any time:

WaveLight AG  
Customer Support  
Am Wolfsmantel 5  
91058 Erlangen  
Germany  
Hotline: + 49 1805 / 52 62 62

Best Regards

WaveLight AG



Xaver Auer  
Vice President Customer Support



Ralph Sättele  
Director Quality Management and Legal Affairs