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29.03.2018

Urgent safety information

Corrective action: Replacement of FRIWO power supply plugs

Dear Customer,

According to our records, you work with an APOLLOblue laser system from our company.

LAP GmbH Laser Applikationen has received feedback from the market that the power supply plug type FW7660M/24 of the GPP10 series from the manufacturer FRIWO Gerätebau GmbH used in the above-mentioned product APOLLOblue could have safety-relevant defects, and we now need to inform you about these.

Description of the situation:

We were informed by a customer that the power supply plug, type FW7660M/24 of the GPP10 series manufactured by FRIWO Gerätebau GmbH belonging to the medical product APOLLOblue was being pulled out of the socket when the housing cover of the lower part of the power supply unit detached itself. This exposed potentially live parts inside the power supply plug, which can lead to a risk of electric shock. No personal injury was reported.

Analyses by FRIWO have shown that the screw domes of the housing can break in an unknown small number of power supply plugs of type FW7660M/24 of the GPP10 series, which were produced between calendar week 50/2013 and calendar week 23/2014. This can therefore lead to the hazardous situation as described above.

The risk is caused solely by the power supply plug used by FRIWO Gerätebau GmbH and not by the APOLLOblue laser system from LAP GmbH Laser Applikationen.

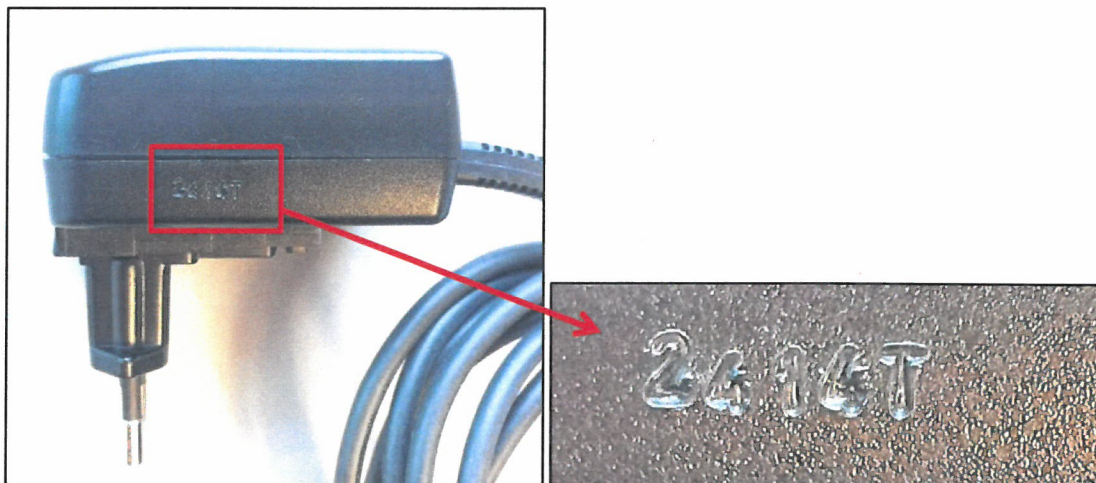
Affected systems:

APOLLOblue laser systems delivered with a FW7660M/24 power supply plug of the series GPP10 by FRIWO Gerätebau GmbH manufactured from calendar week 50/2013 to calendar week 23/2014.

Potentially affected batch numbers:

45130, 46130, 47130, 48130, 51130, 52130, 01140, 02140, 03140, 04140, 05140, 06140, 07140, 08140, 09140, 10140, 11140, 12140, 13140, 14140, 15140, 16140, 17140, 18140, 19140, 20140, 21140, 22140, 23140

You will find these batch numbers punched into the side of the black plastic housing, as shown in the following figure as an example:



(Example: 2414T = week 24 from the year 2014)

The manufacturer FRIWO confirms that the described error does not occur with any other batch numbers.

Measures to be performed by the user:

In principle, you can continue working with the LAP laser system if the relevant power supply plug is not touched or unplugged from the socket.

To check the power supply plug, disconnect the power socket into which the power supply plug to be checked is plugged.

If the power supply comes from one of the affected batches listed above, please follow the instructions below:

- Check the affected power supply plug for external damage that may occur when it is unplugged from the socket. Only use the power supply plug if the housing is externally intact.
- The device must not be used if it is damaged or if it is suspected of being damaged. Damage to the equipment may result in contact with live parts, which may result in the risk of electric shock.



- In the event of damage to the device, contact the LAP contact provided below immediately to request a replacement device.

Never replace the power supply plug used with an unauthorised power supply plug and do not attempt to repair the defective power supply plug yourself.

Disclosure of the information described here:

Please ensure that all users of the above product and other relevant persons in your organisation are aware of this urgent safety information.

If you have given the products to third parties, please forward a copy of this information or inform the contact person provided below.

Please retain this information at least until the action has been completed.

The Medicines & Healthcare Products Regulatory Agency (MHRA) in the United Kingdom and the Federal Institute for Drugs and Medical Devices (BfArM) in Germany have received a copy of this safety information.

Contact:

If you have any further questions, please contact our Service Centre.

Telephone: +49 (0) 4131 9511339

E-mail: service.healthcare@lap-laser.com

Fax: +49 (0) 41319511396

You can reach our Service Centre from Monday to Friday from 8:00 – 16:00 (CEST).

We apologise for any inconvenience caused and thank you for your understanding.

With kind regards,

A handwritten signature in blue ink that reads 'Torsten Hartmann'.

Torsten Hartmann
Safety Officer for Medical Devices
LAP GmbH Laser Applikationen



Please complete the confirmation form and return it by post, e-mail or fax to:

LAP GmbH Laser Applikationen
BU Healthcare Technical Service
Zeppelinstraße 23
21337 Lüneburg
Germany

E-mail: service.healthcare@lap-laser.com
Fax: +49 (0) 41319511396

Confirmation form

- We hereby confirm that we have received and understood the information on the corrective measure "Replacement of FRIWO power supply plugs".
- The FRIWO power supply plugs of the type FW7660M/24 of the series GPP10 from one of the affected batches were replaced by spare devices provided by LAP GmbH Laser Applikationen.

Name: _____

Organisation: _____

Address: _____

Contact no.: _____

Date, signature