

Urgent Field Safety Notice**Field safety corrective action****concerning**

the software of the floor stands FS 2-21, FS 2-25, FS 3-45
in combination with the
operating microscope HS Hi-R NEO 900 /A /A NIR

29.05.2019

Sender

MÖLLER-WEDEL GmbH & Co. KG
Rosengarten 10
22880 Wedel

Receiver

Doctors and clinic personal,
Distributors of MÖLLER-WEDEL GmbH & Co. KG

Dear Sir or Madam,

The MÖLLER-WEDEL GmbH & Co. KG has initiated a voluntary Field Safety Corrective Action concerning the software of floor stands listed below in combination with the operating microscope HS Hi-R NEO 900 / A / A NIR. Our records show that one or more of the floor stands listed below were supplied to you.

Identification of affected medical devices

Floor stands FS 2-21, FS 2-25, FS 3-45 with the software REF 615 586 in the versions 10.1.xx to 11.3.xx.:

Product	Reference no.	Serial no.
FS 2-21	615 510	101 to 360, SW-Version: 10.1.xx to 11.3.xx
FS 2-21	615 510	from 361
FS 2-25	615 550	101 to 376, SW Version: 10.1.xx to 11.3.xx
FS 2-25	615 550	from 377
FS 3-45	615 705	from 101
The Error only occurs in combination with the operating microscope HS Hi-R NEO 900 /A /A NIR		
HS Hi-R NEO 900	657 820	from 101
HS Hi-R NEO 900A	657 821	from 101
HS Hi-R NEO 900A NIR	657 822	from 101

Description of the problem

The XY coupling of the operating microscope can move in one direction as far as possible without responding to other commands for example to change the direction or stop the movement.

The error can only occur if the following commands are executed at the same time:

- quick multiple operation of the XY coupling via the footswitch (joystick)
- and simultaneous execution of other functions for example the change of the light intensity

Cause

A software error in the central control unit of the floor stand can cause the main control of the floor stand to stop responding and no further drive or stop commands of the XY coupling will be executed.

Possible risk

A possible patient hazard only exists if the optional microscope accessory EIBOS 2 is used. If the fundus observation module EIBOS 2 is in use, which has a distance of 4-7 mm from the patient's eye when pivoted in, a patient hazard may occur in the event of a fault. The same applies to the use of similar systems for fundus observation from third-party providers (e.g. Oculus Biom).

There are no reports of injuries. This security information is a preventive action in field in order to prevent a possible patient hazard.

What actions are to be taken?

Since the error only occurs with fast multiple operation of the XY coupling via the foot switch (joystick) and simultaneous execution of other functions for example the change of the light intensity of the microscope, we recommend the following actions to be taken:

1. Immediate action: Do not perform any other functions at the same time when operating the XY control, such as changes in the light intensity.
2. Perform a software update of the floor stand. You will receive the software version 11.4 through your local representative which will fix the bug.
3. Please send us the enclosed response form filled in as soon as possible

Transmission of the information

Please ensure that all users of the products mentioned are aware of and receive this urgent safety information. If you have passed the products to third parties, please forward a copy of this information and inform the below mentioned contact person.

Contact Details

The replacement of the component will be organized through your local distributor. He will contact the service personnel for updating the software. For questions concerning this procedure, please contact: J. Adler

Phone: +49 (0)4103 709 234, Fax: +49 (0)4103 709-355,

Email: vigilance@moeller-wedel.com

Please keep this information until the action has been closed accordingly.

The Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent Field Safety Notice".

We apologize for any inconvenience caused by this safety action and thank you in advance for your support in ensuring timely processing.

Yours Sincerely,

MÖLLER-WEDEL GmbH & Co. KG

Response / confirmation form
Urgent Field Safety Notice

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We hereby confirm that:

The software version 11.4 was installed on subsequent devices.

REF / Serial number of the Device: REF: _____ SN: _____

Name of facility: _____

Address: _____

Additions to address: _____

City: _____ ZIP Code: _____

Country: _____

Contact details: _____

Local Distributor: _____

Name of Employee: _____
(in printed letters)

Date and Signature: _____

Please return this form completed and signed via e-mail to:
vigilance@moeller-wedel.com or by fax to + 49 (0) 4103 709 355