

Heidelberg Engineering GmbH · Max-Jarecki-Str. 8 · 69115 Heidelberg · Germany

2026-07-13

Dr. Frank Müller

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Urgent Field Safety Notice for SPECTRALIS® Users

For attention of: Representatives for medical device safety; ophthalmic technicians and physicians practicing in the field of ophthalmology

Affected devices: SPECTRALIS® with Flex Module

SPECTRALIS® is a multimodal imaging platform optimized for the posterior segment of the eye. The Flex Module provides SPECTRALIS® with a degree of flexibility that goes far beyond conventional ophthalmic imaging, extending all multimodal diagnostic functionality to various positions and acquisition environments. The Flex Module allows imaging patients in the supine position.

Reference ID: TFID-10785

Dear Customer,

This is an important notice regarding your SPECTRALIS® with Flex Module, manufactured by Heidelberg Engineering.

There is a possibility that the castor wheels of the Flex stand are not properly attached. The wheels may come loose when the Flex Module is being pulled or pushed during movement or transportation, affecting the stability of the stand. As a result, the Flex stand may tip over if not correctly handled or supported by the operator. A falling Flex Module stand may cause impact or crushing injuries, particularly to the feet, legs, hands or arms of the operator or nearby persons.

When does the failure occur?

The failure may occur when the device is being pulled or pushed during transportation. Moving the Flex stand over thresholds, gaps or uneven surfaces may result in uplift, impact or lateral loading. This may lead to the risk of castor detachment, potentially resulting in loss of support and tipping of the stand.

What steps should I take to operate my device safely?

Ensure that all castor wheels are properly aligned. Each wheel should stand upright and be in a straight position.

- If a wheel is **upright and straight**, it is correctly positioned (see Figure 1) .
- If a wheel is **tilted or leaning**, it is not correctly positioned (see Figure 2)



Figure 2 Tightened wheel

Correctly positioned

Move the device only when necessary



Figure 2 Loose wheel
⚠ Do not move stand.

Incorrectly positioned

⚠ If the wheels are tilted or leaning, do not move the stand anymore until the problem has been corrected!

In any case, please schedule a service appointment with your Heidelberg Engineering service partner as soon as possible so that the castor fastenings can be inspected and, if necessary, corrected.

What else should I do now?

Please distribute this notice to all involved persons in your organization and outside your organization who would benefit from the information including where the potentially affected devices have been transferred to.

Please maintain awareness on this notice and resulting action for an appropriate period of time to ensure effectiveness of the corrective action. Ensure to keep this field safety notice until the field safety corrective action has been completed.

Please report all device-related incidents, including incidents related to the potential failure described in this notice, to Heidelberg Engineering or your local Heidelberg Engineering partner.

Please provide your contact details by completing the confirmation form and returning it to:

Heidelberg Engineering GmbH
Attn. Dr. Frank Müller
Max-Jarecki-Straße 8
69115 Heidelberg
Germany

FSCA@HeidelbergEngineering.com

The national competent authority is receiving a copy of this field safety notice.

If you need technical assistance, please contact your local Heidelberg Engineering partner.

We apologize for any inconvenience caused as a result of this issue. Please do not hesitate to contact us at FSCA@HeidelbergEngineering.com if you have any further questions or concerns. We thank you in advance for your cooperation.

Yours faithfully,

Dr. Frank Müller
Head of Product Safety
Heidelberg Engineering GmbH

CONFIRMATION FORM

Our documents show that you have received an affected device. Please fill out this form and return it to:

Heidelberg Engineering GmbH
Attn. Dr. Frank Müller
Max-Jarecki-Straße 8
69115 Heidelberg
GERMANY

E-Mail: FSCA@HeidelbergEngineering.com

Fax: +49 6221 6463 62

Device: SPECTRALIS with Flex module
Version: All
Reference ID: TFID-10785
Document Date: 2026-07-13
Type of action: Recommended action

Contact Name : Job title :

Organization : Department :

Phone : Fax :

E-mail : Device S/N :

Address :

- ☐ I have received and taken note of the field safety notice concerning SPECTRALIS and I understand its content.
- ☐ I have performed all actions requested by the field safety notice.
- ☐ I have informed all concerned persons within and outside my organization about the recommended actions.
- ☐ *I do not have affected devices.*

Comments:

Place, Date

Name, Signature

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