

May xx, 2013

URGENT FIELD SAFETY NOTICE

Inspection of the Slide Alignment Guide Assembly on VITROS® Systems

Dear Customer,

As part of a Field Safety Corrective Action, this notification provides information regarding the slide alignment guide assembly used in the VITROS® Systems listed below:

- VITROS® 4600 Chemistry Systems (Product Code 6802445)
- VITROS® 5600 Integrated Systems (Product Code 6802413)
- VITROS® 5,1 FS Chemistry Systems (Product Code 6801375, 6801890)

Slide alignment guides are designed to properly position MicroSlides during processing.

Investigation Summary & Impact to Results

Ortho-Clinical Diagnostics, Inc. (OCD) determined that extension springs on some VITROS® Systems may be out of our manufacturing specifications. An extension spring is part of the slide alignment guide assembly.

During an internal evaluation in our manufacturing facility, it was discovered that some extension springs had insufficient force. If the extension spring does not provide sufficient force, MicroSlides may not be properly positioned within the MicroSlide incubator, which has the *potential* to cause imprecise results. Our evaluation determined that it is unlikely that an out of specification extension spring alone will adversely affect results. We have had no customer complaints related to this issue. As a safeguard, there are two slide alignment guides per system to help ensure proper slide positioning.

Resolution

As a *precaution*, your OCD trained service personnel will perform an assessment and/or proactively replace the extension springs (Part No. J21694) on your VITROS® System(s). Alternately, the slide alignment guides (Part No. J26083) may also be assessed and/or replaced. After service is performed, a record of service will be provided that summarizes the results of our assessment and indicates if replacement of these parts occurred.

IMPORTANT TO NOTE: *The assessment may already have been performed on some systems. All customers must complete the Confirmation of Receipt form in order for OCD to comply with regulatory requirements.*

Required Actions

- | |
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| <ul style="list-style-type: none">➤ Complete and return the attached Confirmation of Receipt Form no later than May xx, 2013. For our records, we require the Form even if your system has already been assessed.➤ Store this notification and record of service (<i>when provided</i>) with your user documentation. |
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We apologize for the inconvenience this may cause your laboratory. If you have any additional questions, please contact Customer Technical Services at **insert appropriate number**.

Sincerely,

insert appropriate name
insert appropriate title

Confirmation of Receipt - Important Response Required

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So that we can complete our records, please return this form to us no later than **May xx, 2013.**

FAX TO: *insert appropriate name*

FAX: *insert appropriate number*

Section I: Confirmation

I received the Urgent Field Safety Notice (Ref. CL13-013_EU) and understand that an assessment and/or replacement of the extension springs on the VITROS® System(s) in my facility is required.

Please choose from the following options:

- The assessment and/or replacement of the extension springs has been completed on my VITROS® System(s).
- I understand that OCD trained service personnel will contact me to schedule the assessment and/or replacement of the extension springs on my VITROS® System(s).

**Your signature provides confirmation that you have received and understood this notification.*

Your Name: _____ Job Title (optional): _____

Signed*: _____ Date: _____

Fax Number: _____ Telephone Number: _____

J Number: _____ Institution: _____

Your comments are always welcome:

Section II – Verification of your Name and Address

Verify your name and mailing address:

Please complete this section if your name and/or mailing address have changed:

Institution / Contact Name: _____

Address: _____

City: _____ State/Province: _____ Zip/Postal Code: _____

Telephone: _____ FAX: _____