Ortho Clinical Diagnostics	**URGENT FIELD SAFETY NOTICE** **Potential Incorrect Wire Configuration on VITROS® 5600 Integrated Systems**

Date Issued February xx, 2016

Affected Products

VITROS® Product	Product Code	Unique Device Identifier No.
VITROS® 5600 Integrated System	6802413 6802915	10758750002740 10758750007110

Issue Explanation

As part of a Field Safety Corrective Action, this notification provides information regarding the potential for four wires connected to the power supply to have been misconfigured within your VITROS® 5600 System(s) during manufacturing.

> *The electrical wires are located in an area that is intended to be accessed only by an Ortho-trained service representative. Normal use, maintenance and troubleshooting on your VITROS® 5600 System will not expose an operator to electrical hazards as a result of this issue.*

If a system has the incorrect wire configuration, it is possible that if the power to an individual module is intended to be shut off, it will remain on. However, there is no risk to Ortho-trained service personnel if they follow normal procedures and power off the appropriate module or the VITROS® 5600 System as a whole prior to working on a component.

NOTE: Ortho has had no customer complaints or any reports that operators or Ortho-trained service representatives have experienced an adverse event related to this issue.

Impact to Results

There is no impact to the results generated with an affected system.

Resolution

As a precaution, your Ortho-trained service representative will contact you to schedule an inspection of the wiring within the VITROS® 5600 Systems at your facility. Following the inspection, reconfiguration of the wiring on your system will be performed if appropriate.

We have implemented corrective and preventative measures within our manufacturing process to help prevent this issue from re-occurring.

Required Actions

- An Ortho-trained service representative will contact you to schedule the inspection of the wiring configuring within the VITROS® 5600 System(s) at your facility. If appropriate, the wiring will be reconfigured.
- Store this notification with your user documentation until the wires within your system(s) are inspected.
- In accordance with regulatory requirements, complete the Confirmation of Receipt form to indicate that you have been informed of this anomaly. Please return your form by **February xx, 2016.**

Contact Information

If you have any questions, contact our Technical Solutions Center at insert number.

Enclosure: Confirmation of Receipt Form

Confirmation of Receipt – Response Required

URGENT FIELD SAFETY NOTICE

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*Please return completed form by **fax** or **scan to PDF** and email so that we can complete our records no later than*: **DD-MM-YYYY**

Send to: Name e-Mail Address: email address Fax: Fax Number

Please Confirm

I received the Urgent Field Safety Notice (Ref. CL2016-048_EU) regarding the potential for a misconfiguration of four wires within my VITROS® 5600 System. I understand that an Ortho trained service representative will contact me to perform an inspection and reconfigure the wiring on my system, if appropriate.

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

Your Name: _____ Signature: _____

Phone Number: _____ Date: _____ Required if sent by fax or a scanned PDF

Your Comments: _____

Your Name and Address

Verify your name and mailing address:

Please complete this section if any of this information has changed

Institution/
Contact Name: _____
Address: _____
City: _____ State/Prov: _____ Zip/Postal Code: _____
Phone: _____ Fax: _____
e-Mail: _____