

URGENT PRODUCT CORRECTION NOTIFICATION**Potential Incorrect Wire Configuration on
VITROS® 5600 Integrated Systems****Date Issued** February 18, 2016**Affected
Products**

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

**Issue
Explanation**

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 **March 4, 2016**.

**Contact
Information**

If you have any questions, contact our Technical Solutions Center at 1-800-421-3311.

Sincerely,

Doria Jordanou

Doria Jordanou
Sr. Regulatory Quality & Compliance Associate

Enclosure:

- Confirmation of Receipt Form