

February 17, 2016

URGENT PRODUCT CORRECTION NOTIFICATION

Potential Incorrect Wire Configuration on VITROS® 5600 Integrated Systems

Please distribute this information to the appropriate personnel at your facility

Dear Valued Customer,

VITROS® Product	Product Codes	Software Version	Unique Device Identifier No.
VITROS® 5600 Integrated System	6802413	Version 3.2.1	10758750002740
	6802915		10758750007110

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 Result

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 preventive measures within our manufacturing process to help prevent this issue from re-occurring.

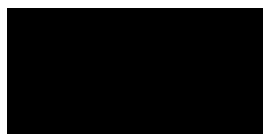
Actions Required from You

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.

1. Store this notification with your user documentation until the wires within your system(s) are inspected.
2. Please complete and return the **Customer Acknowledgement** Form within **(2) two business days** to indicate that you have been informed of this anomaly.

If you have any questions, please contact Customer Technical Services at **1800 5646 766**.

Yours sincerely,



Lee, Ching Hwee
Senior Regulatory Affairs Specialist