



October xx, 2018

**URGENT FIELD SAFETY NOTICE**

**Incorrect Determination of On-Analyzer Stability Time  
on VITROS® XT 7600 Integrated Systems**

Dear Customer,

As part of a Field Safety Corrective Action, Ortho Clinical Diagnostics initiated this Urgent Field Safety Notice to inform you of a software anomaly. Under specific conditions, the VITROS® XT 7600 Integrated System may incorrectly extend the on-analyzer stability time for a loaded VITROS Reagent\*.

VITROS System	Affected Software	Product Code	Unique Device Identifier No.
VITROS® XT 7600 Integrated Chemistry System	Version 3.4	6844461	1075870031658

\*VITROS Reagents are defined as individual MicroWell packs, MicroSlide cartridges and/or Diluent packs, all MicroTip packs, including MicroTip Partnership Assays (MPAs) and User Defined Assays (UDAs)

**Background Information**

When VITROS Reagents are loaded, the VITROS XT 7600 System is designed to automatically determine:

- If a reagent pack or cartridge is full or partially used.
- If the Shelf Expiration Date for the reagent is included on the ADD loaded on your system.
- The on-analyzer stability time, which is the amount of time the reagent may remain on the analyzer to ensure optimal reagent performance.

**Description of Anomaly and Impact to Results**

Our investigation confirmed that under a specific scenario, a software anomaly will occur causing the VITROS XT 7600 System to incorrectly determine the reagent’s on-analyzer stability time. The identified scenario is outlined in the Question and Answer Section on Page 2.

When the anomaly occurs, the system could use reagents past their on-analyzer stability time without alerting the user with a condition code or flagging the associated results with an RE (Reagent Expired) code.

In the event reagents are used beyond their specific on-analyzer stability times, the associated test results may be affected.

**Rate of Occurrence**

Based on condition code data obtained via e-Connectivity®, approximately 96% of all cartridges/packs are depleted *before* their expected on-analyzer expiration time, therefore the results would not be affected by this anomaly. The specific scenario related to the VITROS XT 7600 System involves loading a used cartridge with only one slide left, without specifying the date opened. The actual rate of this scenario cannot be determined through e-Connectivity, but is considered improbable.

Ortho has received no customer complaints related to this anomaly on VITROS XT 7600 Systems.

**Detection**

Any occurrence of this anomaly is not easily identifiable. However, performing daily quality control testing will help to assess if reagents are performing within expectations.

## Resolution

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The resolution to this anomaly will be included in the next version of software that is expected to be released in December 2018. In the interim, to prevent occurrence of the anomaly, please follow the instructions below.

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## REQUIRED ACTIONS

**To prevent the occurrence of this anomaly until the new software version is installed:**

- Newly opened reagents should be loaded normally using the Load/Unload process.
- To load partially used reagents, or full reagents that have been previously loaded on another system, do not use the Load/Unload process button. You must use Manual Load process following the V-docs Manual Load instructions for your system. Ensure that all information on the Manually Load Cart dialog screen is complete and accurate for each cartridge loaded.

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## ADDITIONAL REQUIRED ACTIONS

- Complete and return the Confirmation of Receipt form no later than **October xx, 2018**.
- Post this notification by each VITROS 7600 System in your facility or with your user documentation.
- Please forward this notification if the product was distributed outside of your facility.

## Contact Information

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In the event reagents are used beyond their specific on-analyzer stability times (OAS), the associated test results may be affected. The potential impact to test results that may be observed is obtainable from Ortho Care Technical Solutions Center.

We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact Ortho Care™ Technical Solutions Center at *insert appropriate number* / *insert signatory if required*

## Questions and Answers

### 1. What is "on-analyzer stability time"?

VITROS Reagents all have a specific "on analyzer stability time," which is the amount of time the reagent may remain on the analyzer to ensure optimal reagent performance. This varies by reagent and is different from the shelf expiration date.

### 2. How is the analyzer supposed to work with regard to on-analyzer stability time?

The analyzer is intended to keep track of on-analyzer stability time regardless of whether a reagent is full or partially used and loaded using the Load/Unload or Manual Load process.

### 3. What scenario can cause the anomaly to occur?

Ortho has discovered the scenario below where the open expiration of a reagent may be incorrectly set. The scenario that can cause the anomaly is listed below.

**IMPORTANT to NOTE:** The instructions provided under Required Actions will prevent your system from using reagents incorrectly beyond the on-analyzer stability time indicated in the Instructions for Use.

### Scenario that can cause the anomaly

The open expiration date for a partially used reagent loaded without specifying the date opened will be incorrectly assigned as if the reagent was full and will be given full on-analyzer stability time. This occurs when a MicroSlide cartridge containing a single slide is loaded without specifying the date opened.

# Confirmation of Receipt – Response Required

Communication ID: 2018-194

Date of Issue: 2018-10-xx

## URGENT FIELD SAFETY NOTICE

### Incorrect Determination of On-Analyzer Stability Time on VITROS® XT 7600 Integrated Systems

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

**xx-OCT-2018**

Send to: **Insert name**

e-Mail Address: **insert email address**

Fax: **Insert number**

### 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: \_\_\_\_\_

### Please Confirm

I received the Urgent Field Safety Notice with information that under specific circumstances, VITROS XT 7600 Systems may incorrectly determine the on-analyzer stability time for VITROS Reagents (MicroWell packs, MicroTip packs, MicroSlide cartridges and/or Diluents).

I understand the information provided in the customer letter and will follow the instructions to evaluate current status on our VITROS System(s) and help mitigate a potential occurrence of the anomaly until new software is installed.

**Please choose from the following:**

- My laboratory has identified "at risk" packs/cartridges, removed them from our system, and requests credit for the unused tests in open reagents (only) listed below.
- My laboratory has not identified or removed any "at risk" packs/cartridges from our system and does not require credit for unused tests.

**Please enter the product name/Product Code (REF number) and Lot Number for each partially used product as well as the remaining quantities of tests in each partially used pack/cartridge.**

Product Name/Product Code/LOT	Quantity of Unused Tests in Open Reagents (only)
VITROS / /	
VITROS / /	
VITROS / /	
VITROS / /	
VITROS / /	
VITROS / /	

Print Name: \_\_\_\_\_

Phone Number: \_\_\_\_\_ Date: \_\_\_\_\_

Your Comments: \_\_\_\_\_

Signature: \_\_\_\_\_

Required  
Your signature confirms  
that you have received  
and understand this  
communication.

If you are responding for more than one location, please list below all locations and Customer Numbers (UCNs) that your signature represents:

Locations you Represent: \_\_\_\_\_

**For Customers Who Order from a Distributor**

**Distributor Name**

If you order from a Distributor, please provide the name of your distributor