

**URGENT FIELD SAFETY NOTICE****Use of 5% Hypochlorite for Cleaning on ORTHO AutoVue® *Innova/Ultra*,
ORTHO VISION® and ORTHO VISION® Max Analyzers**

Dear Customer,

As part of a Field Safety Corrective Action, the purpose of this notification is to inform you that 5% Hypochlorite must not be used on ORTHO AutoVue *Innova/Ultra*, ORTHO VISION or ORTHO VISION Max Analyzers.

Issue Description

In 2018, Ortho made available to some customers a communication indicating that if they notice contamination despite weekly maintenance of their systems, they may decontaminate with commercially available 5% hypochlorite. This information was incorrect. Use of 5% hypochlorite is not validated for use on ORTHO AutoVue *Innova/Ultra*, ORTHO VISION or ORTHO VISION Max Analyzers and can corrode stainless steel probes over time.

Impact to Results

If 5% hypochlorite comes into contact with stainless steel probes, pitting corrosion can occur and potentially lead to carryover and false positive results.

Low concentrations of sodium hypochlorite are also known in literature to destroy the S-antigen on intact red blood cells (RBCs). Therefore, test results relying on the presence of the S-antigen could potentially be affected.

If your laboratory performed S-antigen typing or antibody testing after using 5% hypochlorite for decontamination, please discuss the need to review previously reported patient results with your medical director. This is particularly important for blood donors and women who are pregnant.

REQUIRED ACTIONS**For ORTHO VISION and ORTHO VISION Max Analyzers:**

As stated in the ORTHO VISION ORTHO BioVue Cassettes Reference Guide (Pub No. J55655) and ORTHO VISION Max ORTHO BioVue Cassettes Reference Guide (Pub No. J55657):

- For the LIQUID SYSTEM Decontamination only, the solutions listed below can be used:
 - 70% isopropyl alcohol
 - 70% ethanol
 - 0.1M NaOH
- Use only a mild detergent or a 70% isopropyl alcohol solution when cleaning system components or surfaces. To prevent corrosion of system parts and possible erroneous results, do not use any other cleaning solutions or solvents on the system unless specifically directed in a maintenance wizard or procedure.

REQUIRED ACTIONS, continued

For ORTHO AutoVue *Innova* and ORTHO AutoVue *Ultra* Analyzers:

As stated in the ORTHO AutoVue® *Innova/Ultra* Training and Reference Guide (Pub. No. J23848, Version 2.01):

AutoVue provides four different ways to flush the instrument and fluidic system.

- Saline
- Water

Fluidic decontamination

- NaOH* and water
- NaOH* and Saline

*0.1N

For all Customers:

- Complete the enclosed Confirmation of Receipt form *and please specify if the 5% Hypochlorite cleaning regime was implemented at your facility* no later than MM/DD/YY

Contact Information

If you have further questions, please contact Ortho Care™ Technical Solutions Center at *insert appropriate number* / *insert signatory if required*

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Use of 5% Hypochlorite for Cleaning on ORTHO AutoVue® Innova/Ultra, ORTHO VISION® and ORTHO VISION® Max Analyzers

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

DD-JUN-2019

Send to: Name

e-Mail Address: email address

Fax: Fax 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 Product Correction Notification instructing that 5% Hypochlorite must not be used on ORTHO AutoVue Innova/Ultra, ORTHO VISION or ORTHO VISION Max Analyzers.

Please choose from below (more than one selection may be appropriate):

- My laboratory received a letter that incorrectly recommended use of 5% Hypochlorite for decontamination on our ORTHO AutoVue Innova/Ultra or ORTHO VISION/ORTHO VISION Max Analyzer(s).
My laboratory implemented use of 5% Hypochlorite for decontamination on our ORTHO AutoVue Innova/Ultra or ORTHO VISION/ORTHO VISION Max Analyzer(s)
My laboratory did not use 5% Hypochlorite on our ORTHO AutoVue Innova/Ultra or ORTHO VISION/ORTHO VISION Max Analyzer(s).

Print Name:

Phone Number: Date:

Your Comments:

Signature:

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

that 5% Hypochlorite must not be used on ORTHO AutoVue, ORTHO VISION or ORTHO VISION Max Analyzers