URGENT FIELD SAFETY NOTICE

Product Name: Analyst® MD Software – Versions 1.6.1 and 1.6.2. Component of API 3200MD™ LC/MS/MS System, 3200MD QTRAP® LC/MS/MS System, Triple Quad™ 4500MD LC/MS/MS System, and QTRAP® 4500MD LC/MS/MS System

Recall ID: 3258-0095

Field Safety Corrective Action: Software Update

Date: June 16, 2016
Dear Valued Customer,

On March 4, 2016, a letter was mailed to you advising of a field correction for the products listed above.

As per the original letter, the planned corrective action was to develop a software update to address the issue with the **Formula column feature in the Analyst MD software's Quantitation module**. The enclosed DVD package contains the software update to be installed on your instrument. Once installed, the temporary corrective actions outlined in the original letter to avoid the issue will no longer be necessary.

Please note that this correction only affects customers who are using the Formula column feature in the Analyst MD software's Quantitation module for the quantitative processing and reporting of results, and does not impact customers who are not using this software feature.

Reasons for the voluntary field correction

An issue has been identified with Analyst MD software where under certain conditions a user can be presented with incorrect quantitative results.

Conditions under which issue occurs:

1. Customer uses the Analyst MD software's Quantitation module for the quantitative processing and reporting of results.
2. In Analyst MD software's Quantitation module, customer uses the formula column feature in the results table.
3. If one or more sample entries are removed from the Results Table, the formula column in the table does not automatically refresh. This causes the content in the formula cell(s) to become out of sync with all sample entry rows that follow the deleted sample(s).
4. The incorrect data is presented in the Results table, which can be copied using the Ctrl-c function, exported to a text or pdf file, or printed.

This has been identified in both Analyst MD 1.6.1 and 1.6.2 software.

Affected Product Information

Software Name and Version Number	Instrument Model Name	Instrument Part Number (REF)
Analyst® MD Version 1.6.1 and 1.6.2	API 3200MD™ LC/MS/MS System	5024501
	3200MD QTRAP® LC/MS/MS System	5024500
	Triple Quad™ 4500MD LC/MS/MS System	5031257
	QTRAP® 4500MD LC/MS/MS System	5031231

Type of Action by the Company

A software update has been developed to address the issue with the Formula column feature in the Analyst MD software's Quantitation module. The enclosed DVD package contains the software update to be installed on your instrument. Once installed, the temporary corrective actions outlined in the original letter to avoid the issue will no longer be necessary.

Actions to be taken by the distributor/ customer

The enclosed software update should be installed in order to eliminate the potential for erroneous results when using the Formula column feature in the Analyst MD software's Quantitation module for the processing and reporting of results.

Follow your internal laboratory standard operating procedures for any validation activities that may be required after installation of the software update.

Instructions for Installing the HotFix 2

This HotFix is only applicable for computers configured with the Microsoft Windows 7-32 or -64 bit operating system. Do not install the HotFix on computers configured with the Windows XP operating system.

1. Deactivate the hardware profile and then close the Analyst® MD software.
2. On the DVD that comes with the software, navigate to the **Analyst MD 1.6.1 HotFix 2** or the **Analyst MD 1.6.2 HotFix 2** folder, double-click **Setup.exe**, and then follow the on-screen instructions.

When the HotFix is installed, a new entry is added to the Programs and Features list in Control Panel.

Additionally, a shortcut to the release notes is placed under **Start > All Programs > AB SCIEX > Analyst MD**

Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

Transmission of this Field Safety Notice (FSN)

Please communicate/ transfer this FSN to all those within your organization who need to be aware or any organization where the potentially affected device(s) has been transferred.

If applicable, direct accounts should in turn notify customers who received the product about the FSCA.

Contact reference person

If you have any questions regarding this notice please contact Michael Jarvis at michael.jarvis@sciex.com or +1 289 982 2894.

The undersigned confirms that the appropriate Regulatory Agency has been notified of this FSCA.

We sincerely apologize for the inconvenience this causes you. SCIEX aims to provide you with products of the highest quality.

Michael Jarvis, Product Manager
IVD Systems

2016/06/16

Enclosure: Response Form

RESPONSE FORM

Response is required

Device Name (check appropriate boxes):	Part Number
☐ API 3200MD™ LC/MS/MS System	5024501
☐ 3200MD QTRAP® LC/MS/MS System	5024500
☐ Triple Quad™ 4500MD LC/MS/MS System	5031257
☐ QTRAP® 4500MD LC/MS/MS System	5031231
Serial Numbers: <insert device serial number(s)>	

Check the appropriate box below:

I have read and understood the information within the accompanying SCIEX Notification dated June 16, 2016. All relevant personnel have been informed of its contents, any necessary actions taken and records retained as part of our Laboratory Quality System documentation, and:

☐ I have installed the Analyst MD 1.6.1 and 1.6.2 HotFix 2

or:

☐ I have decided not to install the Analyst MD 1.6.1 and 1.6.2 HotFix 2

or:

☐ We do not have any of the products identified above

Please sign the section below, indicating your acknowledgement of this communication.

Contact Person Name and Title (Please Print)

Company Name

Company Address (Street)

Company Address (City)

Company Address (Country, Zip Code)

Signature

Date

Telephone

Email

Please complete and return this form to:

AB Sciex
Attention: Regulatory Affairs Department

Email: regulatoryaffairs@sciex.com

OR

Fax: 905-660-2629