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: **2016/03/04**

Dear Valued Customer,

SCIEX wishes to inform you of a voluntary field safety corrective action on 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.

Analyst MD software is a component of the above listed mass spectrometers which is used for the control of the instrument and for quantitative analysis of results. This field action only affects customer who are using the **Formula column feature in the Analyst MD software's Quantitation module** for the quantitative processing and reporting of results. Customers who do not use the Formula column feature in Analyst MD and those who use MultiQuant MD or ChemoView MD Software for the processing and reporting of results are not impacted.

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

Reasons for the voluntary Field Safety Corrective Action (FSCA)

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

Actions to be taken by the customer

In order to eliminate the potential for erroneous results, implement the following temporary steps:

1. If using the Formula column feature in the Analyst MD software's Quantitation module for the processing and reporting of results, avoid deleting sample entries in the Results Tables.
2. If sample entries must be deleted from the Results Table, save, close, and reopen the results table prior to reporting values.

If the device has been used for patient diagnosis using the Formula column feature in the Analyst MD software's Quantitation module for the processing and reporting of results, the following additional actions should also be taken:

1. Open the original results table.
2. Compare the values in the Formula column to the original reported results

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

SCIEX

Type of Action by SCIEX

SCIEX is currently notifying customers to immediately implement this field correction, which is a temporary fix as outlined above.

Additionally, a software update is in development and is expected to be available in approximately 4 weeks. Upon availability, SCIEX will send a DVD with instructions on how to install the new software update. At that time, the above outlined temporary actions will no longer be necessary.

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.

Contact reference person

If you have any questions regarding this notice please contact SCIEX at+ 1 289 982 2531.

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

Please confirm receipt of this letter by signing and faxing back the attached Response Form within 1O days.

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

…… ….. 2016/03/04

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 **March, 04, 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.

or:

☐ We do not have this product.

Have there been adverse events associated with the affected product at your site?
Yes ☐ No ☐

If yes, please explain:

_____

_____

_____

Have these events already been reported to SCIEX?
Yes ☐ No ☐

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