URGENT FIELD SAFETY NOTICE

Product Name: MultiQuant MD software—Version 3.0, 3.0.1 and 3.0.2. Component of the API 3200MD™ LC/MS/MS system, 3200MD QTRAP® LC/MS/MS system, Triple Quad™ 4500MD LC/MS/MS system, and QTRAP® LC/MS/MS system.

Recall ID: 3558–0107

Field Safety Corrective Action: Software Update

Date: **June 16, 2016**

Dear Valued Customer,

AB SCIEX wishes to inform you a voluntary field safety corrective action on MultiQuant MD software—Version 3.0, 3.0.1 and 3.0.2. Component of the API 3200MD™ LC/MS/MS system, 3200MD QTRAP® LC/MS/MS system, Triple Quad™ 4500MD LC/MS/MS system, and QTRAP® LC/MS/MS system.

MultiQuant MD software may be used to perform quantitative analysis of data generated on the mass spectrometry systems listed above. This field action only affects customers who are using the **Sum Multiple Ions feature in MultiQuant MD software**. Customers who do not use the Sum Multiple Ions feature in MultiQuant MD software for quantitative processing and reporting of results are not impacted.

Affected Product Information

Software Name and Version Number	Instrument Model Name	Instrument Part Number (REF)
MultiQuant MD Version 3.0, 3.0.1 and 3.0.2	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 MultiQuant MD software where under certain conditions a user can be presented with incorrect quantitative results when using the Sum Multiple Ions feature.

The expectation is that the displayed "Sum Multiple Ions" chromatogram will be equal to the sum of the individual constituent chromatograms. In cases where the issue is observed, the incorrect data will present as a larger than expected chromatographic peak.

Conditions under which the issue occurs:

1. The user employs the Sum Multiple Ions feature in MultiQuant MD software to process data. This feature adds two or more chromatograms together.
2. The data to be processed includes unequally spaced data points, and the largest spacing between adjacent data points is at least two times the smallest spacing between adjacent data points.

The issue has been identified in MultiQuant MD 3.0, MultiQuant MD 3.0.1 and MultiQuant MD 3.0.2 software.

Actions to be taken by the distributor/ customer

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

- If acquiring data using a scan mode that generates unequal spacing between data points (Scheduled MRM, or IDA scans), avoid using the "Sum Multiple Ions" feature for data processing in MultiQuant MD software

If the device has been used for patient diagnosis using the "Sum Multiple Ions" feature for data processing in MultiQuant MD software, the following additional actions should also be taken:

- Create a results table, or open an existing results table, containing:
    - a "Sum Multiple Ions" chromatogram (e.g. Z, where Z=X+Y)
    - individual constituent chromatograms (e.g. X and Y)
- Compare the peak area of the summed ion chromatogram (Z) with the peak areas of the individual constituent chromatograms (X and Y). The peak area for the summed ion chromatogram should be similar to the sum of the peak areas of the individual constituent chromatograms.

- Based upon this review, your laboratory director may decide that a review of the patient results history is required.

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

Type of Action by the Company

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 12 weeks. Upon availability, AB 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.

Customer Notification Letter in additional languages will be provided to customer in 2 weeks since English letter issued.

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 SCIEX at +1 289 982 2712

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

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

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

X _____ 2016/06/16

Michael Jarvis
Product Manager, IVD Instruments

Enclosure: Response Form

RESPONSE FORM

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 AB 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.

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 AB Sciex?
Yes ☐ No ☐

Please fill in the attached table below with the information regarding the affected product you currently have at your site.

ON-SITE AFFECTED PRODUCT INFORMATION	
Lot/ Serial Number	Current Quantity in Customer's Inventory

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