



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® 4500MD LC/MS/MS system.

Recall ID: 3558–0107

Field Safety Corrective Action: Software Update

Date: September 06, 2016

Dear Valued Customer,

On June 16, 2016, a letter was mailed to you advising of a field correction for the 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® 4500MD LC/MS/MS system.

As per the original letter, a software update has been developed to address the issue with the **Sum Multiple Ions feature in MultiQuant MD software**. The enclosed package contains the software update to be installed on your instrument. Upon installation of the software update, you may resume use of the Sum Multiple Ions feature.

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

The enclosed DVD package contains the following items:

- MultiQuant MD 3.0.2 disc
- MultiQuant MD 3.0.2 HotFix 1 disc

The MultiQuant MD 3.0.2 HotFix 1 should be installed in order to eliminate the potential for erroneous results when using the Sum Multiple Ions feature in the MultiQuant MD software.

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

1. Upgrading to MultiQuant MD 3.0.2 software, from MultiQuant MD 3.0/3.0.1 software

For customers using earlier versions of MultiQuant MD software (versions 3.0 or 3.0.1), MultiQuant MD 3.0.2 must be installed prior to installation of the HotFix.

MultiQuant MD 3.0.2 software is compatible with the Microsoft Windows XP operating system, with SP3, and the Windows 7 (32- or 64-bit) operating system, with SP1.

1. Log on to the computer as a user with Administrator privileges.



2. Double-click the **setup.exe** file on the MultiQuant MD 3.0.2 software DVD, and then follow the instructions on the screen.

2. Installation of MultiQuant MD 3.0.2 HotFix 1

This HotFix is compatible with the Microsoft Windows XP operating system, with SP3, and the Windows 7 (32- or 64-bit) operating system, with SP1. The MultiQuant MD 3.0.2 HotFix 1 folder includes installers for both the 32- and 64-bit operating system. Open the folder in the DVD and then use the appropriate installer.

1. Log on to the computer as a user with Administrator privileges.
2. Make sure that the MultiQuant MD 3.0.2 software is closed.
3. Double-click the **setup.exe** file in the appropriate folder and then follow the instructions on the screen.

System	Installer
Windows 32-bit system	setup.exe file found in the x86 folder
Windows 64-bit system	setup.exe file found in the x64 folder

Type of Action by the Company

A software update has been developed to address the issue with the Sum Multiple Ions feature in the MultiQuant MD software. The enclosed DVD package contains the software update to be installed on your instrument. Upon installation of the software update, you may resume use of the Sum Multiple Ions feature.

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. SCIEX aims to provide you with products of the highest quality.

X

Michael Jarvis
Product Manager, IVD Instruments

Enclosure: Response Form



RESPONSE FORM

Device Name (check appropriate boxes):	Part Number
<input type="checkbox"/> API 3200MD™ LC/MS/MS System	5024501
<input type="checkbox"/> 3200MD QTRAP® LC/MS/MS System	5024500
<input type="checkbox"/> Triple Quad™ 4500MD LC/MS/MS System	5031257
<input type="checkbox"/> QTRAP® 4500MD LC/MS/MS System	5031231
Serial Numbers: <insert device serial number(s)>	
My laboratory uses the following software for data processing:	
<input type="checkbox"/> Analyst MD software	
<input type="checkbox"/> MultiQuant MD software	
<input type="checkbox"/> Other (please specify):	
In my laboratory, the following version of Analyst software is currently installed:	
<input type="checkbox"/> Analyst MD 1.6.2 software	
<input type="checkbox"/> Analyst MD 1.6.1 software	
<input type="checkbox"/> Other (please specify):	
In my laboratory, the following version of MultiQuant software is currently installed (prior to receipt of the enclosed MultiQuant MD 3.0.2 software HotFix 1):	
<input type="checkbox"/> MultiQuant MD 3.0.2 software	
<input type="checkbox"/> MultiQuant MD 3.0.1 software	
<input type="checkbox"/> MultiQuant MD 3.0 software	
<input type="checkbox"/> Other (please specify):	
I intend to install the HotFix that has been provided for MultiQuant MD 3.0.2 software	
<input type="checkbox"/> Yes	
<input type="checkbox"/> No	Please specify your reason:
My laboratory uses, or has used, the Sum Multiple Ions feature in MultiQuant software:	
<input type="checkbox"/> Yes	
<input type="checkbox"/> No	
<input type="checkbox"/> Not sure	



Check the appropriate box below:

- ☐ I have read and understood the information within the accompanying SCIEX Notification dated September 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 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:

SCIEX

Attention: Regulatory Affairs Department

Email: regulatoryaffairs@sciex.com

OR

Fax: 905-660-2629