HEALTH HAZARD & RECALL EVALUATION FORM

PRODUCT INFORMATION

Name of product: **Analyst MD, component of 3200MD and 4500MD series**

Model/ Version number: **Software Version 1.6.1, 1.6.2**

Lot/ serial number: **N/A**

Marketing Status (US):

☐ 510k_____ x 510k exempt ☐ PMA_____ ☐ Pre-amendment

☐ Non-medical ☐ Other: _____

Non-US Marketing Status (Country and Classification; attach additional pages if required):

EU:

Products affected - 3200MD, 4500MD (General IVD)

Canada:

Products affected - 3200MD, 4500MD (Class I)

Singapore:

Products affected - 3200MD, 4500MD (Class I)

Korea:

Products affected - 3200MD, 4500MD (Class I)

China:

Product affected – API 3200MD (Class II)

India:

Products affected - 3200MD, 4500MD (non regulated)

Malaysia:

Products Affected – 3200MD, 4500MD (Class A)

Saudi Arabia:

Products Affected – 3200MD, 4500MD (Class I)

Product Description (including intended use):

Analyst™ MD 1.6.2 software is a component of the 3200MD and 4500MD. 3200MD and 4500MD are mass spectrometers intended to identify inorganic or organic compounds (e.g., lead, mercury, and drugs) in human specimens by ionizing the compound under investigation and separating the resulting ions by means of an electrical and magnetic field according to their mass. It is intended for in vitro diagnostic purposes. For in vitro diagnostic use.

PROBLEM DEFINITION, INVESTIGATION AND ANALYSIS

Source of Information:

x Customer Complaint	x Internal Identification ☐ Other, specify: _____
ID: Complaint 68582	ID: Issue 3258

Summary of Complaint/ Issue:

Issue first raised through a complaint from a non-medical device instrument customer (Complaint 68582) on Analyst 1.5.1.

Issue presents itself in Analyst Quantitation module, in Results Table view, when using formula columns. 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. This incorrect data is presented in the Results table, which can be copied via the Ctrl-c function, exported to a text file, exported to a pdf, or reported through Analyst Reporting.

During investigation, it was identified that this issue is also prevalent in Analyst MD 1.6.1 and 1.6.2 software.

Number of Similar Complaints/Issues Received / Over 2 years Time Period:

No similar complaints or issues received in last 2 years for Analyst MD.

Number of Resulting Injuries Reported:

U.S.: 0 Outside of U.S.: 0

Number of Resulting Deaths Reported:

U.S.: 0 Outside of U.S.: 0

Root Cause of Problem and/or Contributing Factors, if known:

The root cause of the issue was determined by the Analyst development team to be a defect in the code that removes samples from the results table. The defect causes the formula columns to not be updated automatically.

Ease of Product Failure Identification by Customer:

The issue may not be obvious if sample entries using the formula column are deleted from a batch. Ease of issue identification depends on specific application and method run by the customer. There is no indication of the issue given by the software.

Summary of Investigation Findings, if available (attach page if necessary):

See attached investigation report for detailed findings.

HEALTH RISKS

Health Risk Associated to Use of Product: Describe any risk to the health of the user or patient in association with product use. Include immediate and long term affects and any	**Wrong quantitative results displayed in a report from the device, which may potentially lead to an incorrect patient diagnosis.** **Clinical factors mitigating this risk: Per Product Safety Reference for the general use of 3200MD and 4500MD devices (Doc 0000015388), As a 'General-Use Medical Device', the product is not used as sole source of diagnostic data leading to a diagnostic decision, and is used in conjunction with other confirmatory tests and patient symptoms, supported by**

clinical factors that may mitigate the risk.	**corresponding general Instructions for Use (IFU) documentation.**
Population Segments at Greater Risk: Describe any populations that are at a greater risk of injury or death, if applicable.	**None – product is for general use, no specific population segments at greater risk**
Potential Public Health Risk: Describe any potential for injury or death going beyond the user or patient.	**None – product is for general use, no potential for risks beyond user or patient.**

RISK OF RE-OCCURENCE

Likelihood of Problem Re-occurrence with Product Use:

☐ Every time x Reasonable Probability ☐ Remote Probability ☐ Not Likely

Provide a Brief Explanation:

The likelihood of the hazardous situation to recur is considered probable, as documented in the Investigation report.

HEALTH HAZARD & RECALL EVALUATION

Based on the above information, the product hazard is assessed as:

☐ No Risk ☐ Low Risk x Moderate Risk ☐ High Risk

See Investigation Report for detailed analysis

x Yes, complete Remedial Action Items table below ☐ No

REMEDIAL ACTION ITEMS

Action items: Add more rows if required	Responsible Department(s): NA if not applicable	Date completed (yyyy/mm/dd)
☐ Labeling Revision Specify:	**NA**	**NA**
x Device Design Change Specify:	**Analyst Software team**	**Planned date of completion:**

Release software fix with software code correction		**2016/03/16**
x Stop Shipment Details: **Stop shipment shall be placed on 3200MD and 4500MD until controls are implemented to ensure customer notification letter accompanies the product.**	**Quality Assurance**	**2016/02/24**
☐ Device Inspection/ Settings Adjustment/ Repair on Site Details:	**NA**	**NA**
x Customer Notification Letter Details: **Issue communication to customers to provide details of issue and information for countermeasures. Advise customers of upcoming software fix availability.** **Letter to be translated into required languages**	**Primary Market Manager to draft communication.** **Technical, Quality Assurance, Regulatory Affairs, Legal to provide input.** **Regulatory Affairs to send communication to existing customers.**	**Planned date of completion:** **English letter: 2016/02/26** **Translated letters: 2016/03/04**
☐ Device Retrieval (product removal from site for repair, modification, adjustment, relabeling, destruction, or inspection) Details:	**NA**	**NA**
x Other Details: **New risk items to be added to "Risk Analysis Work Sheet for Analyst® MD Software" (Doc# 0000011450) to capture this issue and planned design mitigations.** **Refer to recall strategy form for detailed actions for recall conduct.**	**Analyst Software team (Bryan Gittens)**	**2016/03/16**

REGULATORY AUTHORITY REPORTING	
For a medical device, based on the remedial actions being taken,	x Yes

do any health regulatory authorities require notification? Refer to the appendices of QP-087 Recalls for reportable recall criteria	☐ No ☐ NA, not a medical device

If Yes, which health authorities will be notified? (check all that apply)	x FDA x Health Canada x EU Competent Authorities, specify: MHRA x Other, specify: _____ CFDA, Malaysia MDA, Saudi FDA, Korea FDA

Do non-health regulatory authorities require notification of the event/ issue/ recall?	☐ Yes x No

If Yes, which authorities will be notified?	☐ Canadian Standards Association ☐ Electrical Safety Authority ☐ Other, specify: _____

The attached, completed Health Hazard and Recall Evaluation has been reviewed and approved by the following personnel (additional lines may be added as needed),

2016/02/24

X Abhi Kannan

Abhi Kannan
Regulatory Affairs Manager
Signed by: Kannan, Abhi

X M Elizabeth Culotta 24 Feb 2016

Beth Culotta
Director of Quality

2016/02/24

X John Gibbons

John Gibbons
Sr. Applications Scientist
Signed by: Gibbons, John

2016/02/24

X Bryan Gittens

Bryan Gittens
Software Team lead, Analyst MD
Signed by: Gittens, Bryan

2/24/2016

X Tamara Smith

Tamara Smith
Sr Clinical Global Market Manager
Signed by: Smith, Tamara

Document Revision History

Rev	Date *(yyyy/mm/dd)*	Author *(full name)*	Description of Change
A	2015/02/24	Abhi Kannan/ Echo Yu	First release

Template Revision History

Rev	Date *(yyyy/mm/dd)*	Author *(full name)*	DCR #	Description of Change
A	2012/05/01	Rizwana Choudry	C00085	Initial Release
B	2012/07/18	Rizwana Choudry	C00207	Updated template to incorporate all products distributed by AB SCIEX
C	2012/12/19	Rizwana Choudry	C00323	- Updated to include documentation of recall decision - Updated to include remedial action items listing and regulatory authority reporting
D	2013/07/08	Rizwana Choudry	C00496	Updated document reference in footer

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 10 days.

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

Scott Cundy, VP Regulatory Affairs and Quality Assurance

2016/03/04

Tamara B. Smith, Director Clinical Diagnostics

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

إفادة تأكيد عدم تأثر المملكة العربية السعودية بإشعار إنذار السلامة

Date: 07/03/2016

التاريخ: يوم/ شهر / سنة

Statement Confirming KSA is Not Affected By FSN

Saudi Food and Drug Authority
Medical Devices Sector
National Center for Medical Devices Reporting (NCMDR) –Surveillance Dept.

الهيئة العامة للغذاء والدواء
قطاع الأجهزة والمنتجات الطبية
المركز الوطني لبلاغات الأجهزة الطبية – إدارة الرقابة

Dear NCMDR Follow up team ,

We AB Sciex Pte. Ltd. confirms that **none** of the affected medical devices included in the below Field Safety Notice –FSN were supplied to and/ or shipped to and/ or /installed in the KSA , **therefore, Kingdom of Saudi Arabia is not affected by this FSN.**

السلام عليكم ورحمة الله وبركاته،،،

السادة فريق قسم المتابعة بالمركز الوطني لبلاغات الأجهزة والمنتجات الطبية،

نحن (اسم الممثل القانوني أو اسم الجهة الصانعة) نؤكد بأنه لم يتم توريد و/أو شحن و/أو تركيب أي من الأجهزة والمنتجات الطبية المتأثرة والواردة في إشعار إنذار السلامة أدناه إلى المملكة العربية السعودية، **لذا نود إفادتكم بأن المملكة العربية السعودية لم تتأثر بإشعار إنذار السلامة المذكور.**

Medical Devices Name	NCMDR reference number / ECRI reference number / Confirmation Code
API 3200MD™ LC/MS/MS System	
3200MD QTRAP® LC/MS/MS System	
AB SCIEX Triple Quad™ 4500MD	
AB SCIEX QTRAP® 4500MD	

Abhi Kannan, Regulatory Affairs Manager
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