HEALTH HAZARD & RECALL EVALUATION FORM

PRODUCT INFORMATION

Name of product: **4500MD Mass Spectrometer**

Model/ Version number: **QTRAP 4500MD (5031225) and Triple Quad 4500MD (5031227)**

Lot/ serial number: **See details in issue summary below.**

Marketing Status (US):

☐ 510k _____ × 510k exempt ☐ PMA _____ ☐ Pre-amendment

☐ Non-medical ☐ Other: _____

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

EU: General IVD

Canada: Class I

Singapore: Class I

Korea: Class I

India: non regulated

Malaysia: Class A

Saudi Arabia: Class I

Product Description (including intended use):

The 4500MD LC-MS/MS system is intended to identify inorganic or organic compounds (for example 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. For in vitro diagnostic use.

PROBLEM DEFINITION, INVESTIGATION AND ANALYSIS

Source of Information:

☐ Customer Complaint × Internal Identification ☐ Other, specify: _____

ID: _____ ID: Issue-3326

Summary of Complaint/ Issue:

A total of 11 units were released from Singapore manufacturing site with partial implementation of changes required under Engineering Change Order (ECO) 29905. Changes in ECO-29905 were implemented to improve compliance of the 4500MD with EMC requirements. Details provided below.

10 units of 4500MD LC-MS/MS systems were released from Singapore manufacturing site without replacing the Detector Assembly from 5030362 to 5043050 as required in ECO-29905. 6 units of 4500MD LC-MS/MS systems were released from Singapore manufacturing site without installing 4 extra screws (PN12916) on to top cover, a change required under ECO-29905. Details regarding the affected units are provided below:

Model	Serial Number	Components not implemented from ECO 29905	Consignee/ Location
Triple Quad 4500MD	BX21081601	Missing detector and screws	USA Distributor, McKesson Medical Surgical Sold to end user Highline Health LLC (NC, USA)
Triple Quad 4500MD	BX21101601	Missing detector and screws	USA Distributor, McKesson Medical Surgical Sold to end user Highline Health LLC (NC, USA)
Triple Quad 4500MD	BX21091601	Missing detector and screws	European Distribution Centre (Netherlands)
QTRAP 4500MD	BW20251601	Missing detector and screws	USA Distribution Centre (Dallas, USA)
QTRAP 4500MD	BW20241601	Missing screws only	USA Distribution Centre (Dallas, USA)
Triple Quad 4500MD	BX21111601	Missing detector and screws	Singapore Manufacturing Site
Triple Quad 4500MD	BX21121602	Missing detector only	Singapore Manufacturing Site
Triple Quad 4500MD	BX21131602	Missing detector only	Singapore Manufacturing Site
Triple Quad 4500MD	BX21141602	Missing detector only	Singapore Manufacturing Site
Triple Quad 4500MD	BX21151602	Missing detector only	Singapore Manufacturing Site
QTRAP 4500MD	BW20261602	Missing detector only	Singapore Manufacturing Site

Two of the affected units (BX21081601, BX21101601) are located and installed with customers. The remaining 9 affected units are located in Distribution Centre in Dallas (2 units), Distribution Centre in Netherlands, EU (1 unit) and Singapore Shipping area (6 units).

Number of Similar Complaints/Issues Received / Over 2 year Period:

0

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:

Root cause and/or contributing factors to be determined and documented in CAPA-0097.

Ease of Product Failure Identification by Customer:

9 of the 11 affected units have been quarantined at Singapore Manufacturing Site or Distribution Centers. These units are not in use.

2 of the affected units have been installed in USA at customer sites. Note that affected customers have not begun using instrument or validating any user developed methods.

The issue will not be obvious to the customer, as the missing components are internal. Ease of identification of erroneous results generated due to the issue depends on the specific application and method run by the customer.

Depending on the customer application it may be easier/harder to identify an erroneous result, since the expected range of measured analyte concentrations will vary from one application to another, and therefore it is possible that an erroneous result may nevertheless be believable. In the case of a believable but erroneous result, a review by the end user of the raw data used to generate the result, and/or review of the results in conjunction with other confirmatory tests and patient information, according to the user's internal operating procedures, may help to identify this product failure. The ability of the user to identify an abnormality in the raw data will depend upon the severity, and the duration, of the interference caused by the product failure.

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

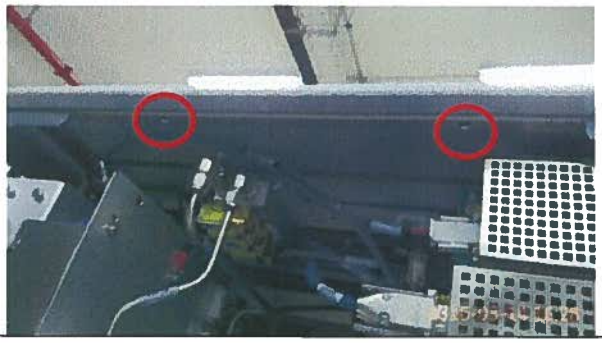
Total of 11 units were released from Singapore manufacturing site without implementing two of the changes (additional 4 screws on mass spectrometer top cover, and updated flange assembly component) required under Engineering Change Order (ECO) 29905.

After ECO-29905 was implemented, 6 x 4500MD LC-MS/MS units were released from Singapore manufacturing site without installing 4 extra screws (PN12916) on to top cover which was implemented as part of ECO-29905.

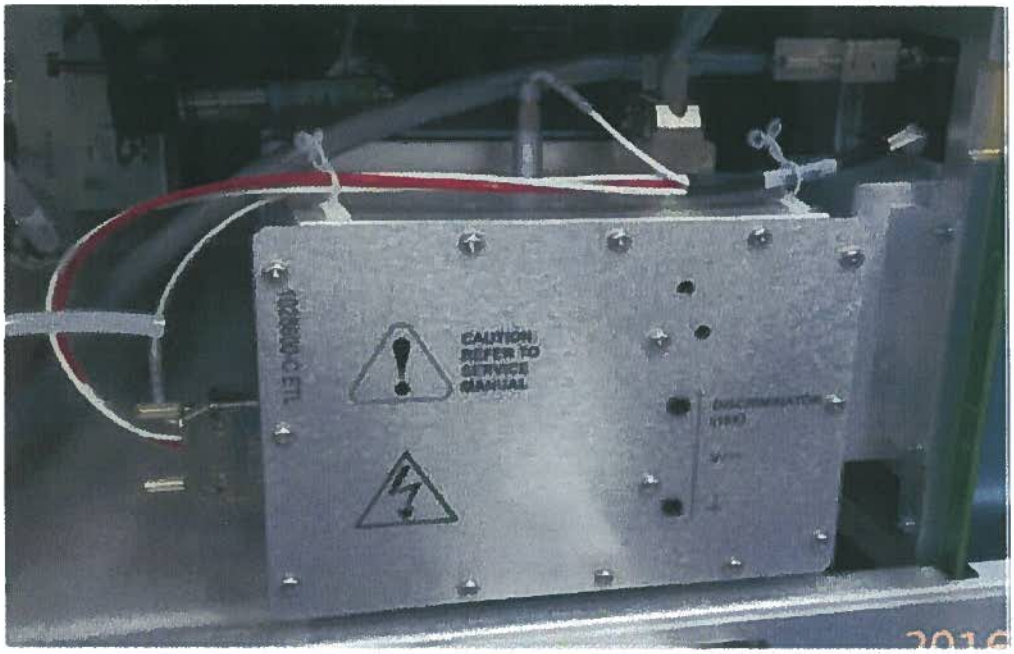
10 x 4500MD LC-MS/MS units were released from Singapore manufacturing site without replacing Detector Assembly from PN 5030362 to PN 5043050 as required per ECO 29905.

Root cause investigation is ongoing and to be documented in CAPA-0097.

The below illustrates the location of the missing screws on the right and left sides of the top panel of the instrument.



The below illustrates the photograph of the detector assembly (PN 5043050).



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 clinical factors that may mitigate the risk.	**This issue poses risk of incorrect quantitative results, 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 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 specific population segments at greater risk

RISK OF RE-OCCURENCE

Likelihood of Problem Re-occurrence with Product Use:

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

Provide a Brief Explanation:

The likelihood of a hazardous situation to occur is considered remote, as documented and rationalized in the Risk review 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 Risk review report for details

Based on the Health Hazard Evaluation, are remedial actions required?

× 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
☐ Device Design Change Specify:	NA	NA
☐ Stop Shipment Details:	NA	NA
x Device Inspection/ Settings Adjustment/	Singapore QA (Indran Thandavarian) to	Planned date of completion: March 25,

Repair on Site Details: **Affected instruments at customer's site shall be reworked by Field Service Engineer with parts and instructions provided by Singapore manufacturing site.**	**ship/provide required parts and instructions for field correction.** **Service (Ali Nibakht) to coordinate FSE site visit and correction. Correction to be carried out per service repair procedures for detector FRU.**	**2016** **Planned date of completion: March 28, 2016**
x Customer Notification Letter Details: **1 affected customer in USA to be notified of issue, immediate actions, and site visit for rework.**	**Product Manager (Michael Jarvis) to prepare communication.** **Technical SME, Quality Assurance, Regulatory Affairs, Legal to review and provide input.** **Local sales rep (Ray Giska) to deliver customer communication once it is available.**	**Planned date of completion: March 21, 2016** **Planned date of completion: March 25, 2016** **Planned date of completion: March 25, 2016**
x Device Retrieval (product removal from site for repair, modification, adjustment, relabeling, destruction, or inspection) Details: **Affected units in US Distribution Center and European Distribution Center have been quarantined and are to be shipped to Singapore manufacturing site for re-work. All affected units targeted to be reworked and retested by April 8th 2016.**	**Singapore QA (Indran Thandavarian)**	**Planned date for completion of rework: April 8 2016**
☐ Other Details:	**NA**	**NA**

REGULATORY AUTHORITY REPORTING	
For a medical device, based on the remedial actions being taken, do any health regulatory authorities require notification?	x Yes ☐ No

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HEALTH HAZARD & RECALL EVALUATION FORM

Refer to the appendices of QP-087 Recalls for reportable recall criteria	☐ 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: _____ **Malaysia MDA, Saudi FDA, Singapore HSA**
Do non-health regulatory authorities require notification of the event/ issue/ recall?	x Yes ☐ No
If Yes, which authorities will be notified?	x 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),

2016/03/22

X [signature]
Beth Culotta
Director of Quality

X Abhi Kannan
Abhi Kannan
Regulatory Affairs Manager
Signed by: Kannan, Abhi

X – See attached –
Indran Thandavarian
Senior Engineer II, QA/RA
2016/03/23

X – See attached –
Michael Jarvis
Product Manager, IVD Instruments
2016/03/23

Refer to the appendices of QP-087 Recalls for reportable recall criteria	☐ NA, not a medical device
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Do non-health regulatory authorities require notification of the event/ issue/ recall?	x Yes ☐ No
If Yes, which authorities will be notified?	x 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),

2016/03/22

X Beth Culotta

Beth Culotta
Director of Quality
Signed by: DefaultImage

2016/03/22

X Abhi Kannan

Abhi Kannan
Regulatory Affairs Manager
Signed by: Kannan, Abhi

X 2016/03/23

Indran Thandavarian
Senior Engineer II, QA/RA

X - See attached 2016/03/23

Michael Jarvis
Product Manager, IVD Instruments

HEALTH HAZARD & RECALL EVALUATION FORM

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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: _____ Malaysia MDA, Saudi FDA, Singapore HSA
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Beth Culotta
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2016/03/23

X Abhi Kannan

Abhi Kannan
Regulatory Affairs Manager
Signed by: Kannan, Abhi

2016/03/22

X - See attached -

Indran Thandavarian
Senior Engineer II, QA/RA
2016/03/23

X

Michael Jarvis
Product Manager, IVD Instruments

2016/03/22

X Dave Moase

Dave Moase
Team Lead, Regulatory Compliance Engineering
Signed by: Moase, Dave

2016/03/22

X Ali Nikbakht

Ali Nibakht
Manager, MS Service Product Management
Signed by: Nikbakht, Ali

Document Revision History

Rev	Date *(yyyy/mm/dd)*	Author *(full name)*	Description of Change
A	2016/03/21	Echo Yu/ Abhi Kannan	Initial release
B	2016/03/22	Echo Yu	Corrected the device model description under section "Summary of Complaint/ Issue", to reflect the naming rule: for QTRAP 4500MD, S/N starts with BW; for Triple Quad 4500MD, S/N starts with BX.

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

March 25, 2016

URGENT: MEDICAL DEVICE CORRECTION

4500MD LC/MS/MS System

Dear Valued SCIEX Customer,

SCIEX is initiating a field action for the product listed above. This letter contains important information that needs your immediate attention.

These products are mass spectrometers for clinical use. They are intended to identify inorganic or organic compounds 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. They are intended for *in vitro* diagnostic use.

Reasons for the voluntary field correction

An issue has been identified with a small number of 4500MD LC/MS/MS Systems where under certain conditions, there is the possibility that a user will be presented with incorrect quantitative results.

The issue can occur if the system is exposed to electromagnetic interference which generates false ion counts on the detector, leading to incorrect quantitative results.

It may be possible to identify an erroneous result caused by this issue, by review of the result or by review of the raw data:

- An erroneous result may be outside of the expected concentration range of normal results, thereby rendering the result unbelievable
- The raw data may display irregularities in signal intensity or signal stability

Risk to Health:

If the aforementioned conditions are met, the software will display the incorrect quantitative results without indication to the user, which could result in incorrect reporting of patient results.

How to recognize if the issue has occurred:

It may be difficult to identify if incorrect data has been reported. SCIEX recommends that the below actions are taken to eliminate the potential for erroneous results and to review initial files and verify the results.

Actions to be taken by the Customer/User:

In order to eliminate the potential for erroneous results, do not use the affected systems to generate results until the issue has been addressed by this field corrective action to be carried out by a Sciex Field Service Employee (FSE).

Product information

Provided below are the details of the affected products at your site:

Instrument Model Name	Instrument Part Number (REF)	Serial Numbers
Triple Quad ™ 4500MD LC/MS/MS System	5031231	BX21081601 BX21101601

There are a limited number of affected products in the field. No other affected units have been distributed to customers.

Type of action by the Company

A Sciex Field Service Employee (FSE) will be sent to customer sites to perform the field corrective action on the affected systems. The approximate date of the corrective field action at your site is March 28th, 2016.

Other information

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected product(s) listed above to another laboratory, please provide them a copy of this letter.

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

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

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

Sincerely,

2016/03/24

X Michael Jarvis

Michael Jarvis
IVD Systems Product Manager
Signed by: Michael.Jarvis

Michael Jarvis
IVD Systems Product Manager
2016/03/25

Enclosure: Response Form

RESPONSE FORM

Device Name (check appropriate boxes):	Part Number
☐ Triple Quad™4500MD LC/MS/MS System	5031257
Serial Numbers: BX21081601, BX21101601	

Check the appropriate box below:

☐ I have read and understood the information within the accompanying SCIEX Notification dated March 25, 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

AB SCIEX

إفادة تأكيد عدم تأثر المملكة العربية السعودية بإشعار إنذار السلامة

Date: 22/04/2016

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
AB SCIEX Triple Quad™ 4500MD	3326-0097
AB SCIEX QTRAP® 4500MD	3326-0097

Abhi Kannan, Regulatory Affairs Manager
AB Sciex Pte. Ltd.,
Blk 33, Marsiling, Industrial Estate Road 3, #04-06,
Woodlands Central EST
739256 Singapore