

URGENT RECALL/CORRECTION/FIELD SAFETY NOTICE

PN# CR170028

Commercial name of the affected product: LABScreen® Multi

FSCA-identifier: CR170028

Type of action: Review Product Insert

19 April 2017

Attention: Distributors and Users

The purpose of this letter is to advise you that One Lambda, Inc., A Thermo Fisher Scientific brand, is conducting a recall/correction of the LABScreen® Multi product documentation.

Reason for the Voluntary Recall (Description of the problem):

The Product Insert (LM-MUTR-PI Rev 8, released on April 20, 2016) incorrectly states, in the *Instrument Requirement* section, the capability to use the LABScan 3D (Luminex FM3D) instrument in conjunction with the LABScreen Multi product. The product functions as indicated, this is a documentation error only.

Risk to Health: There is no risk to the patient or end user as a result of this problem. Acquisition of the product using LABScan 3D is not likely, as no LSMUTR acquisition protocols were created for the LABScan3D.

Product and Distribution Information:

Catalog ID: LSMUTR

Lot: 007

Batch: 0000091458

0000099706

0000145845

Expiration Date: 2/28/2018

5/31/2018

11/13/2018

Action to be taken by the user or distributor: Please download LABScreen Multi Instruction for Use revision 9 (LM-MUTR-PI Rev 9) from the One Lambda website and discontinue the use of any LABScreen Multi Instruction for Use with revision 8 (LM-MUTR-PI Rev 8). If the product was analyzed using the LABScan 3D instrument (Luminex FM3D), re-analyze the results using the LABScan 100 (Luminex 100/200) to ensure accuracy.

End User: Please complete the attached **Acknowledgement Form** and return to One Lambda, Inc.

Distributors – our records indicate that you may have purchased products for re-sale. Please complete the **Acknowledgement Form** in regards to inventory you have received and/or is still in stock. In addition, please contact your affected customers, advise them of the situation and provide them with a copy of this letter. Please insert your information onto the **Acknowledgement Form** and have your end users return the **Acknowledgement Form** back to you.

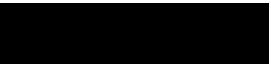
Type of Action by the Manufacturer: Update to LABScreen Multi Instruction for Use (LM-MUTR-PI) to remove the statement for use on the LABScan 3D (Luminex FM3D).

Transmission of this Field Safety Notice: This notice needs to be passed on to all who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Contact reference person: If you have additional questions or concerns regarding this matter, you may contact One Lambda's Customer Support team for assistance at Email: techsupport@onelambda.com or Phone: +1 (818) 702-0042. You may also contact our authorized representative in Germany: MDSS GmbH, Tel.: +49 511 62628630, vigilance@mdss.com

We appreciate your immediate attention to this field correction. We apologize for any inconvenience this may have caused and appreciate your understanding as we take action to ensure customer safety and satisfaction.

The undersigned confirms the appropriate Regulatory Agencies have been advised of this Field Safety Notice.


Angela Estany
Regulatory Affairs and Quality Director

**Field Safety Notice Return Response
ACKNOWLEDGEMENT FORM**

PN# CR170028

Customer Information (Please Complete)

Name:

Address:

Product: LABScreen® Multi

Catalog ID: LSMUTR

Lot: 007

Batch: 0000091458

0000099706

0000145845

Expiration Date: 2/28/2018

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I have read and understand the attached Field Safety Notice and instructions and have taken appropriate actions:

_____ (initial)

Any patient death or injury associated with the recalled product? ____ Yes ____ No

If yes please explain:

Return Response: (please provide additional information if applicable)

DISTRIBUTORS:

I have identified and notified my customers that were shipped or may have been shipped product affected by this letter: ____ Yes ____ No

Please sign and date below indicating that all transmission actions have been taken and that this information has been disseminated to all required individuals. Return to One Lambda via fax +1 818-702-6956 or email Vanessa.Powell@thermofisher.com or 1lambda-regulatory@thermofisher.com.

Signature of Receipt by End User/Distributor:

Signature

Date

Print: (please complete)

Name/Title:	
Telephone:	
Email Address:	

ADDENDUM

With reference to the latest information from HSA on the circulation of FSN, please be informed that the Chairman Medical Board and relevant Head of Departments of the facilities need to be aware of the issues pertaining the medical device used in the facility. Kindly circulate the email to the mentioned parties.

From : HSA_MD_Info@hsa.gov.sg
To : <Undisclosed recipients:>
Reply to : "HSA MD Info (HSA)" <HSA_MD_Info@hsa.gov.sg>
Subject : Field Safety Notices
Date : Mon, 27 Feb 2017 16:19:06 +0800

Dear Industry Stakeholders,

With effect from **8 March 2017**, all Field Safety Notices (FSNs) are required to be copied (i.e. include in cc) to the Chairman Medical Board and relevant Head of Departments of the affected local hospitals. This is to ensure that all relevant personnel involved in the management of the hospitals are aware of the issues pertaining to the medical devices used in their facility. This is also to facilitate timely implementation of any recommended follow-up measures and corrective actions by the end-users in the healthcare facilities (e.g. revised instructions for use, updated maintenance requirements etc.).

FSN is a communication sent out by a product owner or its representative to the device users in relation to a Field Safety Corrective Action (FSCA). It is disseminated when the FSCA is initiated for any medical device that has been supplied locally. Currently the FSNs are disseminated by local companies to the appropriate end-users of their medical device. The dissemination of FSN may proceed at the earliest to the users once the FSCA has been reported to HSA.

For more information on FSCA, click [here](#) to download the guidance.

Thank you.

Yours Sincerely

MEDICAL DEVICES BRANCH
HEALTH PRODUCTS REGULATION GROUP
HEALTH SCIENCES AUTHORITY