

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

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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:

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Return Response: (please provide additional information if applicable)

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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:	