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Field Safety Notice

September 7, 2017

- **Attention:** All countries where the MultiCare™ analyzer/Lumiratek C are placed on the market.
- **Commercial Name of the product:** MultiCare™ Analyzer/Lumiratek C
- **FSCA identifier:** September 7, 2017
  ** The software problems with our products are classified as reportable FSCA according to the section 4.6 of MEDDEV 2 12-1 rev.8. This FSN (Field Safety Notice) is issued to notify the user of the problem and to solve the problem to prevent the potential impact on the patient to the patient.*
- **Type of action:** Modification; software upgrades following the identification of a fault in the software version already in the fields. (This should be reported regardless of whether the software update is being implemented by customers, field service engineers or remote access)

- **Details on affected devices**

Type of device	Semi-automated I.A Systems
Model Name	MultiCare™ analyzer/Lumiratek C
Software Version	V006
LOT / Serial Number	LOT No.: MA0116001~007 / MA0117001~010
Device overview	The MultiCare™ system/LumiratechC is a reflectometry immunoassay instrument for the quantitative measurement in human blood, urine and other specimens. This system is for in vitro diagnostic use and professional use in hospital and clinic.

- **Description of the problem**

- Problem:
In case of the measurement of CRP and U-Albumin items using the MultiCare™ analyzer/Lumiratek C, the analyzer shows the result of "Lo" first correctly, However, the result is recorded "Hi" instead "Lo" in the memory. So, stored results are display incorrectly in review mode. However, there is no problem with the first displayed results that are displayed first, except for the results stored. We have conducted an activity to identify the cause of this problem and confirmed that it is caused by a software bug in the analyzer.

- Potential risk to patient:
The analyzer reads U-Albumin concentration between 5.0-300mg/L, CRP concentration between 3.0-150mg/L for capillary or venous whole blood sample and 3.0-120mg/L for plasma or serum sample. And if the test result is out of the measurement range, the analyzer displays 'Lo' message or 'Hi' message.
In CRP or U-Albumin measurements, if the patient's measurement result is indicated as 'Lo', which means that the concentration of the CRP or U-Albumin is low, at the same time the patient is normal. Furthermore, it is less likely that a person who is considered to be a patient is likely to display the results of the 'Lo' measurement. However, if the measurement result of 'Lo' is

displayed and you have confirmed it as the result stored in the review mode, incorrect diagnosis, prescription and treatment may be made. For example, antibiotics or kidney medicines may be prescribed to normal people. This can cause adverse drug reactions.

■ **Action to be taken by the manufacturer (SD Biosensor):**

- Identifying and quarantining the device:
All analyzer are identified and tracked by LOT number and SN number.

- Method of recovery, disposal or modification of device:
The analyzer software needs to be changed. You need to update your software to remove the bug. Because it requires a dedicated jig, our staff will go to each dealership for a business trip and update.

- Recommended patient follow up:
This problem only occurs when measuring CRP and U-ALB. It does not appear for other measurement items. Additionally, if the 'Lo' error does not occur, the other measurement results will not be affected by the bug. Otherwise, if a 'Lo' error occurs, the initial measurement result screen ordinarily displays 'Lo'. However, this result is displayed as 'Hi' when checking the data saved in the review mode. You do not refer to the stored data in the review mode. We assurance once again that even if you do not update the instrument's software, there is no effect on the results that are measured immediately. However, in order to eliminate any potential errors or risks that may arise, you should update your software as soon as possible.

- Timelines:

a. Date of the first problem occurred: 2017-08-22
b. Date of issue the FSN, FSCA: 2017-09-07
c. Date of follow corrective actions: 2017-09-30

- Confirmation form to be sent back to the manufacturer if an action is required:
Any form of your company does no matter. Please feel free to reply to any further action required.

■ **Transmission of this Field Safety Notice to all affected countries:**
UK, Italy, Slovenia, Germany, Belgium, Switzerland, Danmark, Sweden

■ **Contact reference person**

EEA	Distributor	Representative	Phone	E-mail address
UK	Lumira	Claire Alexander	+44-1241-439020	claire.alexander@lumiradx.com
ITALY	Iris Medical SRL	Francesco Mitolo	+393735416735	fmitolo@a-ps.it
SLOVENIA	Drasen Lab d.o.o	Robert Pal	+386 (0)68 66 53 14	info@drasenlab.com
GERMANY	Lumira	Uwe Klimpe	+491728123263	uwe.klimpe@lumiradx.com

■ **Transmission of this Field Safety Notice:**
This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please transfer this notice to other organizations on which this action has an impact. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

The undersign confirms that this notice has been notified the appropriate Regulatory Agency, Distributor or User.

Name / organisation, address, contact details.

Signature

■ **Please complete and return the customer's comment section in the below within 10days so we are assured you have received this important communication.**

Customer's comment:

We, SD BIOSENSOR, Inc., will continue our efforts to comply with high quality management standards and to maintain a consistently high quality management system to ensure customer's satisfaction and product safety. Sorry for this inconvenience and please don't hesitate to contact us if you need any help related with the issue.

Sincerely,

SD Biosensor, Inc

Geunkuk Song
Quality Management Representative
QA Division

Geunkuk Song
Quality Management Representative
SD Biosensor, Inc.