



Customer Notification
DC-22-03.A.OUS
October 2022

Dimension® Clinical Chemistry System

Dimension® QuikLYTE® Integrated Multisensor
Sodium Calibration Failure Due to Low Sodium Slope

Our records indicate that your facility may have received the following product:

Table 1. Dimension® Affected Product

Product	Siemens Material Number (SMN)/REF (Catalog Number)	Unique Device Identification (UDI)	Lot Number	Expiration Date (YYYY-MM-DD)	1 st Distribution Date (YYYY-MM-DD)
QuikLYTE Integrated Multisensor	10445058 (S600)	008427680142912AD88722073010445058840	2AD887	2022-07-30	2022-03-02
		008427680142912BD88822080610445058840	2BD888	2022-08-06	2022-03-03
		008427680142912BD89022082710445058840	2BD890	2022-08-27	2022-05-02
		008427680142912CD89122091010445058840	2CD891	2022-09-10	2022-04-25
		008427680142912CD89222092410445058840	2CD892	2022-09-24	2022-05-11
		008427680142912DD89422101510445058840	2DD894	2022-10-15	2022-06-14
		008427680142912DD89522102210445058840	2DD895	2022-10-22	2022-06-21
		008427680142912ED89622102910445058840	2ED896	2022-10-29	2022-06-27

Reason for Customer Notification

Siemens Healthineers has received reports of sodium calibration failures (Error code 384 - IMT failed to calibrate) with the Dimension QuikLYTE Integrated Multisensor lots listed in Table 1 due to a low sodium slope exceeding the acceptable slope limit. Siemens internal investigation has confirmed a calibration failure due to a low slope is not observed with all sensors within these lots. The frequency of sodium calibration failures due to a low sodium slope is low, impacting less than 2% of the sensors in Table 1. Sodium Quality Control and patient results are not impacted when the sensor is calibrated successfully. The failed sodium calibration can occur when the sensor is initially loaded on the system or during subsequent auto-calibration. Potassium and Chloride slopes are not impacted by this issue.

Actions to be Taken by the Customer

For the products listed in Table 1, please perform the following steps:

- If you observe a “Sodium Calibration Failure (Error Code 384 – IMT failed to calibrate) during calibration with a QuikLYTE sensor lot listed in Table 1, remove and discard the sensor then load a new sensor from the same or an alternate lot to calibrate.
- If you have experienced this issue, you may request no-charge replacement product from your local Siemens Healthineers or distributor office. Please review your inventory of these products and assess your laboratory’s replacement needs.
- Complete and return the Product Replacement Form for your laboratory’s no charge replacement needs for currently or previously observed sodium calibration failures due to a low sodium slope for the lots listed in Table 1.

Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers Technical Support Representative.

Dimension® and QuikLYTE® are trademarks of Siemens Healthineers.

PRODUCT REPLACEMENT FORM
Dimension® QuikLYTE® Integrated Multisensor
Sodium Calibration Failure Due to Low Sodium Slope

This response form is to request no-charge product replacement and confirm receipt of the enclosed Siemens Healthineers Customer Notification DC-22-03.A.OUS dated October 2022, regarding Sodium Calibration Failure Due to Low Sodium Slope with QuikLYTE lots 2AD887, 2BD888, 2BD890, 2CD891, 2CD892, 2DD894, 2DD895, and 2ED896. Please read each question and indicate the appropriate answer.

Return this completed form to Siemens Healthineers as per the instructions provided at the bottom of this page.

1. Have you read and understood the Customer Notification instructions provided in this letter. Yes No

2. Have you experienced sodium calibration failures due to a low sodium slope with any of the lots listed in Table 1? Yes No

If the answer to question 2 above is yes, please complete the table below to indicate the quantity of affected sensors in your laboratory and replacement quantity required.

Product Description REF #/SMN #/Lot #	Quantity of Sensors Discarded/ Replacement Quantity Required
Dimension QuikLYTE SMN 10445058 – lots 2AD887, 2BD888, 2BD890, 2CD891, 2CD892, 2DD894, 2DD895 & 2ED896	

Name of person completing questionnaire: _____

Title: _____

Institution: _____ Instrument Serial Number: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

Please send a scanned copy of the completed form via email to fscareportingunit.my@siemens-healthineers.com

If you have any questions, contact your local Siemens Healthineers technical support representative.