

URGENT Field Safety Notification

regarding

VTRUST TD-4258 Ketone monitoring system

18 January 2019

FSCA-identifier: 14/ 01/ 2019

Type of action: Device modification

Sender:

TaiDoc Technology Corporation
B1-7F, No. 127, Wugong 2nd Rd, Wugu Dist., New Taipei city 24888, Taiwan

Receiver:

To all customers of VTRUST TD-4258 Ketone monitoring system

Details on affected devices:

VTRUST TD-4258 Ketone monitoring system (USB and WiFi connected meters)

Summary of Issue:

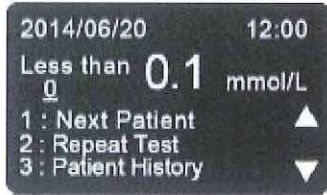
In software versions <1017, if the ketone level in the sample applied is less than 0.1 mmol/L the meter displays a 'Less than 0.1 mmol/L' message on-screen. This indicates that the reading is outside of the measuring range of the meter, 0.1 - 8.0 mmol/L. In rare cases, where the sample applied to the test strip is below the required 1.0 uL of whole blood, the meter may show the 'Less than 0.1 mmol/L' message.

Reason for Bulletin

The VTRUST meter will display an 'Error -011' message when an insufficient sample is applied to the test strip. In some cases, the 'Less than 0.1 mmol/L' message will be shown. Firmware versions >1017 show this message as an 'Error -007 Result below 0.1 mmol/L'. If an 'Error-007' message is shown on-screen, users must check to ensure the test strip is completely full. If the test strip is not completely full, as described in the Operator Manual and test strip insert, the user should remove the test strip and retest using a new strip. If the strip is full, the result can be recorded as 'Less than 0.1 mmol/L Below the measuring range of the meter'.

Introduced with SW version 1017:

- In rare cases, when the sample applied to the test strip is below the required 1.0 μ L of whole blood, the meter displays a 'Less than 0.1 mmol/L' message on-screen, which indicates that the reading is below the measurement range of the meter, 0.1 - 8.0 mmol/L).



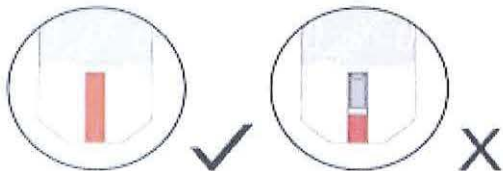
The result is below measurement limit,
0.1 mmol/L.

- With software 1017 the meter will display an on-screen error message 'Error-007 Result below 0.1 mmol/L' instead of the 'Less than 0.1 mmol/L' message currently shown.



Please note:

The test strip should be completely full before a result is accepted, as described in the VTRUST Operator Manual and test strip pack insert.



- The error message 'Error-011' will be displayed on both the VTRUST USB and WiFi connected meters, if the sample applied is not sufficient.

Action Required:

As patient safety is our first priority, we would therefore like to the software will be updated on-site.

Roche Diagnostics will contact you to upgrade your firmware to 1017 or above. This is a mandatory upgrade. New firmware is available now.

Please ensure that the VTRUST is used correctly and that the test strip is completely full when testing. Please only use VTRUST QC in 'QC Mode' on the meter.

Transmission of this Field Safety Notice:

Please bring this notice to the attention of all personnel in your hospital or Health Care facility who need to be aware of this issue.

Your national competent authority, users of the affected Ketone monitoring system, distributors have been informed about this field action.

If you have additional questions regarding this medical device correction (notification), please contact your Roche account.

There is no product safety impact and TaiDoc has not received any reports of Adverse Events related to this correction.

ATTACHMENTS:

Attachment 1: Acknowledgement Form



Jim Jan 2019. 1. 18.
Jim Jan
Management representative



Acknowledgement Form

Your timely response to this customer notification is requested. Please complete this form and fax or email it to burgesshill.techsupportdocs@roche.com **within 3 business days, even if you do not have product subject to this correction.**

Product Receipts – please check

I confirm to have received, read and understood the information in this Field Safety Notice for the above mentioned medical devices and intend to perform the requested actions.

Name (CAPITAL LETTERS):	
Position/Title of Person completing this Form:	
Company Name:	
Phone Number:	
E-mail:	
Address:	
Date (YYYY-MM-DD):	
Signature	