

Urgent Field Safety Notice



SBN-CPS-2020-014

CPS / Point of Care/BGE

Version 1

December 2020

9180 Electrolyte Analyzer - wrong arrow direction for Calcium results on system display

Product Name	9180 Electrolyte Analyzer
System	9180 Electrolyte Analyzer
GMMI / Part No	9180 Electrolyte Analyzer / 03157334001
Device Identifier	
Production Identifier (Product name/Product code)	03157334001
SW Version	All versions
Type of Action	Field Safety Corrective Action

Dear Valued Customer,

Description of Situation

During internal verification studies the following possible scenario was observed: if the unit for iCa⁺⁺ is set to mg/dL (Service Code MGL configured) and a measured iCa⁺⁺-value is lower than the normal range, an upward arrow is shown on the display instead of a downward arrow independent of serial number or software version.

The displayed numeric result is correct and on the printout result and arrow direction are shown correctly.

To date, no customer complaints have been received by Roche regarding this issue since the launch of the product.

Only iCa⁺⁺ is affected.

iCa⁺⁺ - normal ranges (blood, serum, plasma): 1.15 - 1.33 mmol/L

4.6 - 5.32 mg/dL

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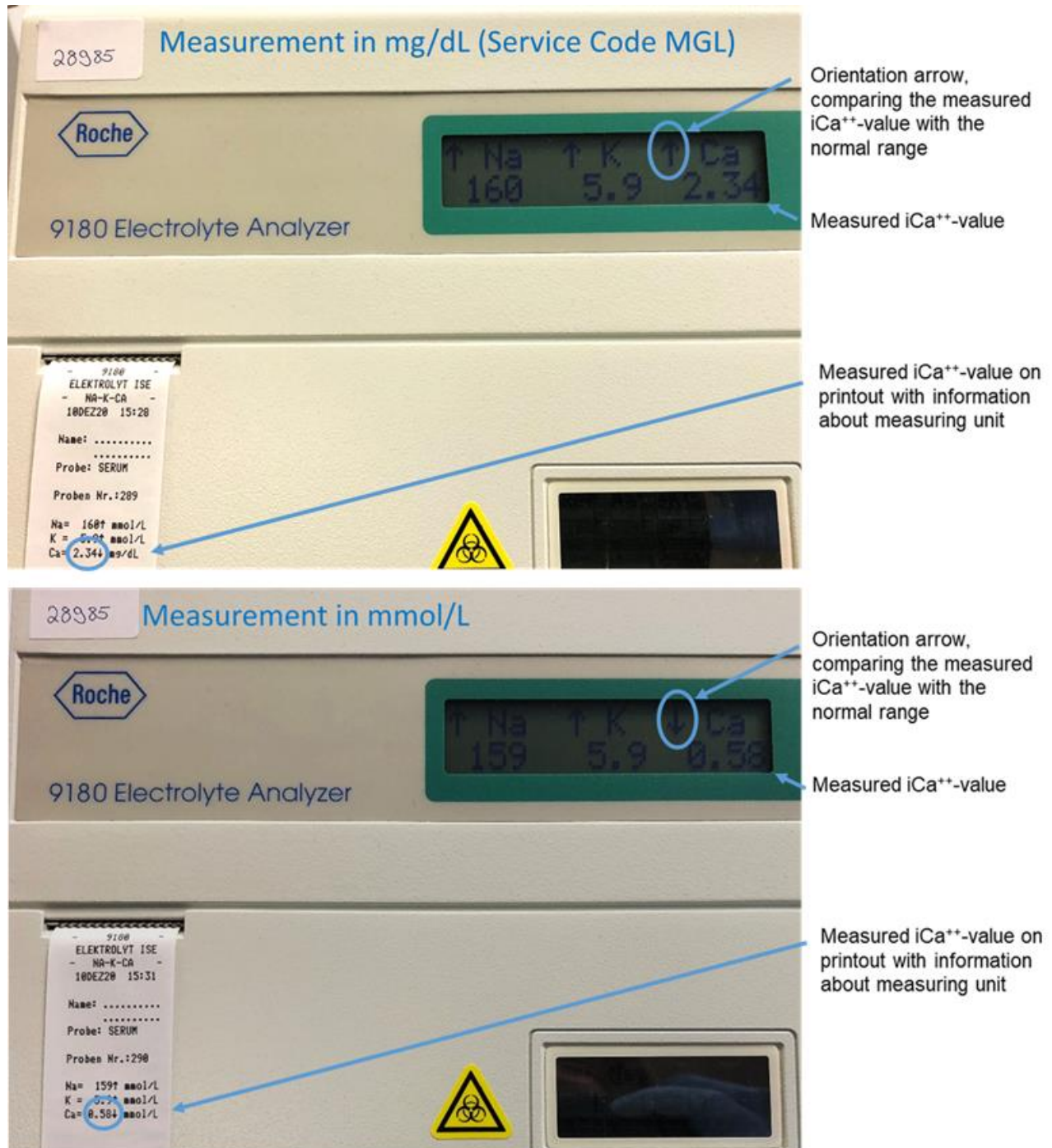


Figure 1

Due to the residual medical risk associated with this issue, customers using the affected products must be informed using the FSN-CPS-2020-014.

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Actions to be taken by Roche Diagnostics


The User manual of the 9180 Electrolyte Analyzer will be updated and following content will be included in **Chapter 4 Calcium Electrode**:

Make sure that iCa⁺⁺ values are reported in mmol/L instead of mg/dL or contact your Roche Services representative. The guiding arrow on the display can be wrong if the unit for iCa⁺⁺ is set to mg/dL (Service Code MGL configured) and if a measured iCa⁺⁺-value is lower than the normal range.

If you use the unit mg/dl for iCa⁺⁺, always use arrow information from the printout and not from the display.

In addition, a violator will be added into the leaflet of iCa⁺⁺ electrode as follows:

Make sure O-ring is installed / O-Ring muss vorhanden sein. / Vérifiez la présence du joint d'étanchéité. / Assicurarsi che l' O-ring sia installato. / Asegúrese de que la junta tórica está instalada. / Confirmar a presença do O-ring. / Let er op, dat de O-ring is geïnstalleerd. / O-ringen måste vara installerad. / Kontrollér at O-ringen er på plads. / Βεβαιωθείτε ότι το O-ring έχει τοποθετηθεί / O-링이 정확하게装着されているかを確認してください。 / 确保O环已安装好了



Make sure that iCa⁺⁺ values are reported in mmol/L instead of mg/dL or contact your Roche contact person.

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AVL is a trademark of AVL List GmbH.

Roche Diagnostics GmbH
Sandhofer Strasse 116
D-68305 Mannheim, Germany
www.roche.com

Distribution in USA by:
Roche Diagnostics
Indianapolis, IN
Made in Switzerland


Calcium Electrode (maintenance free)

9180, AVL 918x

REF 03110354180

GTIN 04015630028696


CONTENT 1

i **IVD** **CE**  15–30 °C

For USA: Rx only

Ca²⁺

cobas[®]



This disclaimer will be included into the leaflet of all future iCa⁺⁺ electrode lots. Update leaflets are expected to be available from Q2 2021.

Actions to be taken by the customer/user

Only customers using configuration mg/dL are affected.

Customers are advised to always make sure that iCa⁺⁺ values are reported in mmol/L instead of mg/dL or contact the responsible Roche contact person.

It is recommended to always use the printout as the printout shows the correct arrows and units.

Make sure that all users are aware of the issue.

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Communication of this Field Safety Notice (if appropriate)

This notice must be passed on to all those who need to be aware within your organization where the devices have been distributed/supplied (if appropriate).

Please transfer this notice to other organizations/individuals on which this action has an impact.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action.

The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the World:

Include if applicable: The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

We apologize for any inconvenience this may cause and hope for your understanding and your support.

<closing salutations>,

Contact Details

To be completed locally:

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com