URGENT FIELD SAFETY NOTICE
IMMEDIATE ACTION REQUIRED

Ref No:	PFSN 9180 Electrolyte Analyzer - wrong arrow direction for Calcium results on system display SBN-CPS-2020-014
Date:	18/12/20
Type of Action:	Field Safety Corrective Action (FSCA)
System Affected:	9180 Electrolyte Analyzer
Software Version:	N/A

Product No	Material No	Lot No
9180 Electrolyte Analyzer	03157334001	N/A

Summary of Issue

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

Reason for Notice

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

Roche Diagnostics
Charles Avenue
Burgess Hill
West Sussex
RH15 9RY

√	Immediate Action Required
	Action Required
	Information Only

Registered No 571546

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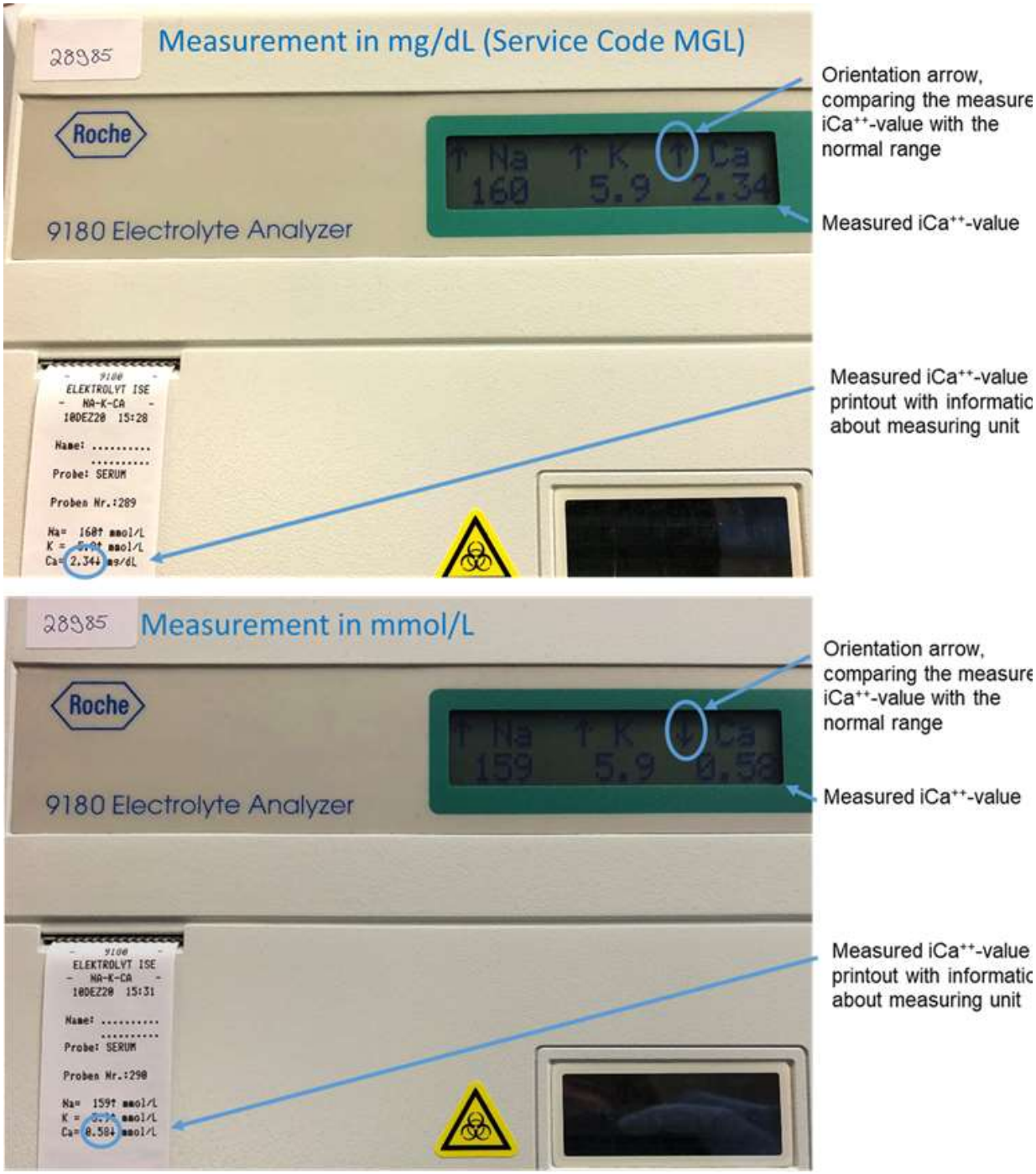

Due to the residual medical risk associated with this issue, customers using the affected products must be informed using the FSN-CPS-2020-014.

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Actions to be taken by Roche Diagnostics

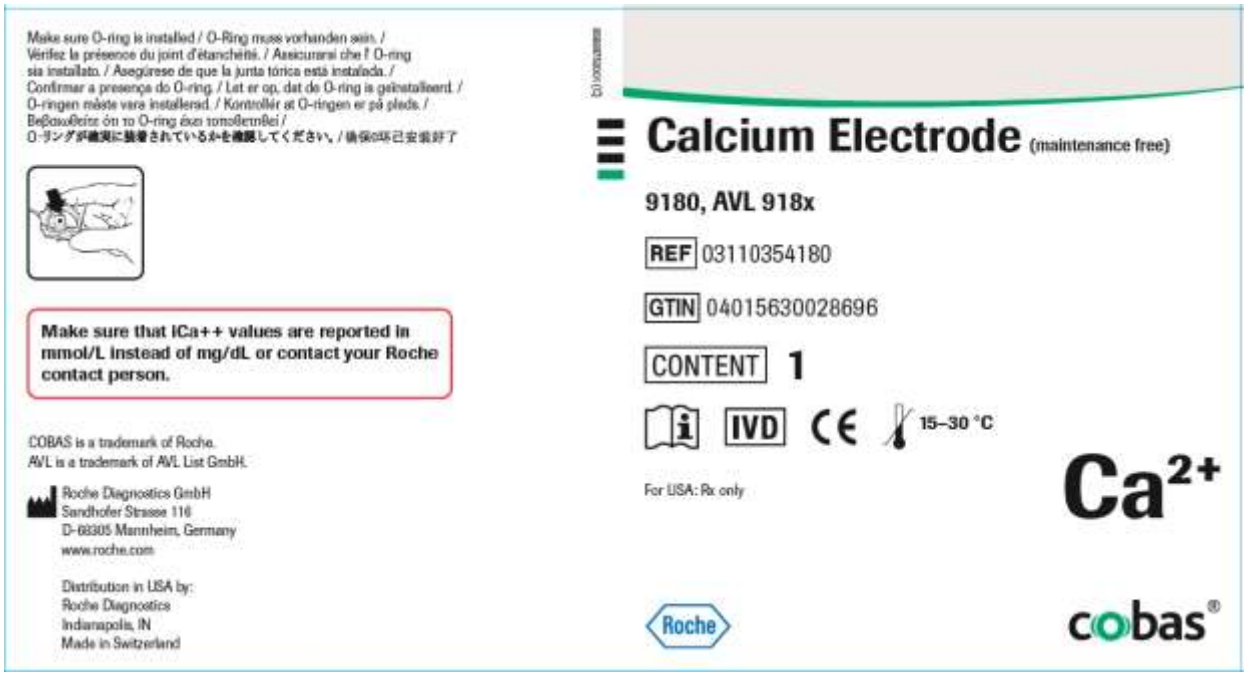
The User manual of the 9180 Electrolyte Analyzer will be updated and following content will be included in Chapter 4 Calcium Electrode:

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:



This disclaimer will be included into the leaflet of all future iCa++ electrode lots.

Update leaflets are expected to be available from Q2 2021.

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Action Required

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.

Please complete and return the Acknowledgement Form which accompanies this Field Safety Notice by 1st January 2021.

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

If you have forwarded the affected product(s) listed above to another laboratory, please provide a copy of this notice to them.

Attachments PFSN 9180 Electrolyte Analyzer - wrong arrow direction for Calcium results on system display SBN-CPS-2020-014 Acknowledgement Form

This action is being conducted with the knowledge of the Medicines and Healthcare Products Regulatory Agency (MHRA), the Health Products Regulatory Authority (HPRA), and other International Regulatory Agencies.

Roche Diagnostics operates a vigilance system that complies with the IVD Directive 98/79 EC

A copy of this notice can also be found on the Roche Dialog Portal

If you require any further information please contact our

Technical Support Hotline

UK: 0808 100 19 20

Ireland: 1800 40 95 64

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ACKNOWLEDGEMENT

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Field Safety Notice Ref No: PFSN 9180 Electrolyte Analyzer - wrong arrow direction for Calcium results on system display SBN-CPS-2020-014 Acknowledgement Form
Date: 18/12/20
Type of Action: Field Safety Corrective Action (FSCA)

Kindly complete and return this form to the e mail address shown on the footer before Friday 1st January 2021.

Product Catalogue No: 9180 Electrolyte Analyzer 03157334001

System:

Customer Name & Dept:

Address:

Are the above contact details correct? (Please circle) Yes No (If no please insert correct details below)

Contact Name:

Department:

Telephone:

If you require an electronic copy of this field safety notice in addition to the hard copy please print your e-mail address below:

Email:

Please acknowledge receipt of information and awareness of any required actions described within the accompanying Field Safety Notice.

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

If you have forwarded the affected product(s) listed above to another laboratory, please provide a copy of this notice to them.

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email to burgesshill.techsupportdocs@roche.com

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Date: 18/12/20
Type of Action: Field Safety Corrective Action (FSCA)

I acknowledge receipt of this Field Safety Notice and have read, understood and implemented its content.

Name:

Signed:

Date:

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