Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

Device Details	
Device Name	ELECTROLYTE ANALYZER W/O STARTERKIT 9180
Device Model	03157334001
Manufacturer	Roche Diagnostics
Country of Origin	Germany
Reference	Attached
Reason of Alert	The Analyzer may produce incorrect sodium (Na^+) results due to an issue linked to the new DD reference electrode and instructs them to stop using Na^+ results and switch to the appropriate alternative system. The issue can lead to falsely high or low sodium (Na^+) results that may influence clinical decisions and potentially cause adverse health consequences.
Action should be taken	Please refer to "Actions to be taken by Customer/ User" in the attached FSN And for more information please contact the authorized representative General Medical W.L.L at registration.medics@intercol.com & meher.medics@intercol.com.

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

For more information please contact Medical_Devices@nhra.bh

Urgent Field Safety Notice

SBN-RDS-NPC-2025-003

RDS / Near Patient Care
Version 2
November 2025

EA 9180 Na discrepant results

Product Name	ELECTROLYTE ANALYZER W/O STARTERKIT 9180
GMMI / Part No **Device Identifier (UDI)**	ELECTROLYTE ANALYZER W/O STARTERKIT 9180 / GMMI: 03157334001 / UDI: 04015630031832 Diamond Diagnostics (manufacturer): Reference Electrode 9180 / GMMI: 09969772001 / UDI: 07613336230893 Reference Electrode Housing 9180 / GMMI: 09969764001 / UDI 00811403010424
Production Identifier (Lot No./Serial No.)	n/a
SW Version	n/a
Type of Action	Field Safety Corrective Action (FSCA)
Document History **Version 1** **Version 2**	 Initial Release Update of recommendation to switch to alternative system

Dear Valued Customer,

Description of Situation

An increasing number of global complaints have been identified related to both falsely high and low sodium (Na+) results from the 9180 Electrolyte Analyzer. These discrepant measurements affect the entire measurement range, with deviations reported between -60 to +40 mmol/L compared to reference values.

Measurement results for other parameters (K+, Cl-, Ca^{2}+, Li+) are not affected.

The detectability and medical risk attributable to incorrect sodium test results depends significantly on the constellation of diagnostic and clinical parameters as erroneous results are not flagged by the instrument and

standard calibration and QC procedures do not reliably identify the issue. Together, in specific clinical scenarios, it is possible that clinical care could be influenced by incorrect (even though still believable) sodium test results, potentially causing adverse health consequences for patients.
The issue is sporadic and is linked to the introduction of the RoHS-compliant, CE-marked Reference Electrode 09969772001 (manufactured by Diamond Diagnostics, hereafter "DD Ref Electrode"), which was introduced to replace the former mercury-based Roche Reference Electrode 03112306180.

There are no reports of patient harm linked to this issue.

Actions taken by Roche

A Corrective and Preventive Action (CAPA) investigation has been initiated, and root cause investigation continues. Once the root cause analysis is complete, appropriate corrective and preventive measures will be defined and communicated, as needed.

Actions to be taken by the customer/user

[For countries that can use the Roche Reference Electrode and the DD Ref Electrode is in use/available:
Please immediately stop using sodium (Na+) results from your 9180 analyzer with the DD Ref Electrode and switch back to the mercury-based Roche Reference Electrode (03112306180) and Reference Electrode Housing (03112284180).
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[For countries that cannot use the Roche Reference Electrode and the DD Ref Electrode is in use:
Please immediately stop using sodium (Na+) results from your 9180 analyzer with the DD Ref Electrode and switch to an alternative testing system (e.g. **cobas** b 221, **cobas** b 123, **cobas** Integra 400 (only in ISE-D mode, and only for Serum and/or Plasma samples)) to obtain sodium (Na+) results. Please ensure that sodium (Na+) results from your 9180 analyzer with the DD Ref Electrode are not used for any clinical decision making.
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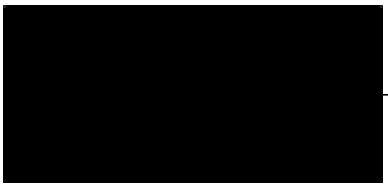
In this case, no general recommendations with respect to the review of previous results can be given using the DD Ref Electrode. Please follow your standard laboratory operating procedures. Any specific questions raised should be addressed individually, considering all relevant clinical information.

SBN-RDS-NPC-2025-003
EA 9180 Na discrepant results

Yours sincerely,

For on behalf of
Roche Diagnostics Middle East FZCO

Subchapter Lead Quality



Regional Quality & Product Safety Lead, Middle East