



URGENT: Field Safety Corrective Action- FSCA# 01-12

Commercial name of affected products	Galileo Echo Blood Bank Analyzer Cat No.: 0087000
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2012-03-09

Dear Blood Bank or Laboratory Manager:

Detail of affected devices: **Galileo Echo** Blood Bank Analyzer
Cat No.: 0087000

Detail of the problem

Our investigation into a customer complaint regarding a failed temperature sensor on the Echo revealed that the communication process to alert the user of an out of range temperature is not functioning as intended. Review of the service history for the Echo elevated temperature incubator indicates an infrequent rate of temperature failure; therefore, the likelihood of adverse assay impact is rare.

The elevated temperature incubator is set to maintain a temperature of 38.5 (± 0.4)°C. The expected operation is that the system flags results if temperatures go outside this range. The Echo does monitor for these conditions, but will not generate errors to alert users and will not flag results generated if the temperature is out of specification.

This issue affects only those assays processed by the elevated temperature incubator. Assays incubated in the ambient temperature incubator are not impacted.

The affected assays include Screen, Ready ID, Extend I, Extend II, Crossmatch and Weak D. Incubation of these assays below 38.1°C may lead to weak or unexpected negative reactions.

Through limited testing of Capture assays during our initial investigation, tests incubated up to 50°C demonstrates comparable reactivity to control tests performed within the established range

Advise on action to be taken by the user

We recommend you implement a daily temperature check of the elevated temperature incubator. This can be achieved by reviewing the Instrument Status Report, or by using the mouse to point to Incubators on the Echo instrument map as described in the Echo Operator Manual (pg 3-19)

You can view and print the instrument status report using the following steps:

- Click on the Reports selection at the top of the main screen
- Click on Instrument Status under Reports

A copy of a revised Echo Daily Maintenance record with temperature check is included with this communication.

We are currently developing a correction for this communication process which will be provided in a future software upgrade available in Q4 2012. Until this time, we recommend you implement a daily temperature check of the elevated temperature incubator.



Any technical concerns should be addressed to Technical Support at tech.support.eu@immucor.com or at the phone number+49 (0) 6074 8420-50

We apologize for any inconvenience that this action causes you.

Please verify your receipt of this notification by completing the attached response form and returning it to us by facsimile+49 (0) 6074 8420-99, or by mail to

IMMUCOR Medizinische Diagnostik GmbH
Adam-Opel-Straße 26A
D-63322 Rödermark, Germany

Sincerely,

Dr. Alfred Wörsching
RA/QA Manager Immucor Germany

Response form to:

Faxnumber: +49 (0) 6074 8420 99

IMMUCOR Medizinische Diagnostik GmbH
Dr. Alfred Wörsching
Adam-Opel-Str. 26 A

D-63322 Rödermark

VIGILANCE RESPONSE FORM

I verify that our facility is aware of the field correction FSCA# 01-12 of Galileo Echo Blood Bank Analyzer
Name:
Position:
Facility/Institution
City/State
Telephone
Fax number