Erba Lachema s.r.o.

FIELD SAFETY NOTICE

RGT Cooling Assembly – Replacement of not approved Peltier Modules

Date: October 8th, 2026

ID: FSN 2026_02

Affected product: XL 640 (installed in 2022)

Affected LOT: SN 645843

Dear Madam / Sir,

The ERBA XL 640 is an automatic analyser with an additional ISE module intended for *in vitro* photometric quantification of clinical chemistry parameters and ion-selective quantification of specific electrolytes, such as Na+, K+, Li+ and Cl-, in serum, plasma and urine, with a capacity of 640/800 tests per hour. The results of the tested clinical chemistry parameters can be used for screening, monitoring and diagnosis. The specific intended use depends on the individual parameter and is described in the IFU of each reagent kit provided by ERBA. The analyser is intended for professional use in clinical laboratories only.

During the investigation of a fire incident involving an ERBA XL 640 analyser, it was identified that the fire originated in the **RGT cooling assembly**.
During the technical investigation, the cooling system and Peltier devices were suspected. It was identified that locally sourced Peltiers modules were used to replace the defective peltier in the cooling unit.
The ERBA-supplied Peltier devices have integrated thermal pads, which forms part of the assembly and results in different overall change in the dimensions. The locally sourced Peltiers were not dimensionally compatible with the original cooling module configuration.

Due to this difference, replacement of an individual Peltier was not possible while maintaining the required mechanical fit and contacts. Consequently, three Peltiers which were purchased from local market were used.

Potential impact:

Incorrect or non-approved Peltier components, dimensional incompatibility, inadequate thermal paste, formation of air pockets may result in abnormal heating of the cooling module.
In the event of excessive heating or an electrical/thermal failure, this may lead to damage to the cooling system and surrounding components and, in severe circumstances, may present a potential fire or electrical safety hazard.
If the instrument is operated following such an abnormal condition without appropriate technical inspection and verification, there is also a potential risk of further instrument damage and interruption of laboratory operation.

The potential risk described above applies to analysers on which the RGT cooling assembly has been serviced using Peltier modules that are not specified and/or validated by Erba or using unauthorized/non-approved service methods.

Actions to be taken:

Erba recommends that:

- Only ERBA supplied spare parts should be used for replacement. Individual peltiers should not be replaced.
- The cooling fan, airflow, connectors, wiring and associated cooling components should be inspected following any abnormal heating or cooling-system failure.
- Check the cleanliness of the hot fins as it should be dust free.
- In case of reagent temperature failures due to peltiers then the complete cooling unit should be replaced.
- Instruments showing signs of burning, overheating, smoke or abnormal temperature should be removed from service and technically inspected before further operation.
- Service engineers should be informed of the above requirements and the applicable service instructions.

The completed confirmation of receipt should be returned to Erba to maintain the required evidence of communication and implementation of corrective actions.

Please complete and return the Confirmation of Receipt below.

Best regards,



Jitka Augustinová
Quality Manager
mailto: j.augustinova@erba.com

Erba Lachema s.r.o.

Confirmation of receipt

Please, confirm that the customer information below has been received by your facility.

Date: 08.10.2026
ID: FSN 2026_02
Affected product: XL 640

Affected LOT:

We hereby confirm that we have received the **Field Safety Notice concerning ERBA XL 640– RGT cooling assembly** and that the information has been communicated to the relevant personnel within our organization.

Number of ERBA XL 640 analysers at this facility on which the RGT cooling assembly and other spares described above has previously been serviced/repaired: _____

Number of analysers identified with Peltier modules & other spares described above different from those specified and/or validated by Erba: _____

Customer name: .....

Confirmed by: .....
(name and position)

Date and signature: .....

Please complete this form and send it back via email until November 30th, 2026.

Thank you for your effort!

Erba Lachema, s.r.o.

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