

FIELD SAFETY NOTICE

Biosensor on board stability

Date: 20 Jun, 2023

ID: FSN 2023_02

Affected products:

Cat. No.	Product name
REG00056	EC cartridge M
REG00057	EC cartridge L
REG00058	EC cartridge S
REG00061	EC cartridge S plus iCa
REG00062	EC cartridge M plus iCa
REG00063	EC cartridge L plus iCa
REG00064	EC Biosensor
REG00065	EC cartridge XS
REG00066	EC cartridge XS plus iCa

Dear Sir / Madam,

According to our internal records you have ordered and received one or several batches of EC Cartridge or EC Biosensor affected by this Field Safety Notice. See below the details of the defect that was detected in these batches.

List of affected lots:

List of affected lots of EC Cartridge – see attachment 1

List of affected lots of EC Biosensor – see attachment 2

Description:

EC cartridge is an IVD kit intended for calibration and quantification of sodium (Na⁺), potassium (K⁺), ionized calcium (iCa²⁺) and chloride (Cl⁻) on the EC 90 analyzer series. Product consists of EC Cartridge with calibration and reference solutions and 2 pcs of EC Biosensor. Product is intended only for IVD use by a professionally trained person. Product on board stability is guaranteed for 90 days after opening.

Long term evaluation of post market surveillance data we have received from market shown decreased on board stability of biosensor when guaranteed minimal on board time was not reached in about 1 – 2% of products sold globally.

Root cause investigation shown that material used for the isolation layer of EC Biosensor was identified as main factor with negative impact on product performance. Design change of EC Biosensor structure has been successfully validated with significant positive impact to on board stability.

Erba Lachema s.r.o., Karásek 2219/1d, 621 00 Brno, Czech Republic

Identification number: 269 18 846. Tax identification number: CZ26918846

Incorporated in the Commercial Register maintained by the Regional Court in Brno, Section C, insert 45458

Tel.: +420 517 077 111, e-mail: diagnostics@erba.com, www.erbalachema.com

Potential impact:

The on board stability of biosensor with previous design doesn't meet the specification at 100%. It might happen that biosensors do not pass calibration within specified on board lifetime of 90 days as declared in IFU. Nevertheless test results of biosensor accuracy and precision is guaranteed within specification once system calibration has successfully passed automatic calibration process.

Unplanned inoperable system can result from biosensor calibration failure which can cause diagnosis delay once replacement sensor or EC cartridge is not available at the moment.

Actions to be taken:

If you have any of the lots of EC Cartridge or EC Biosensor among those listed above, Erba will request you to:

- Identify, locate and block the affected pieces on your stock.
- Contact Erba as soon as possible in order to report number of blocked pieces on your stock.
- **Regarding EC Cartridge:** You will receive biosensors from fresh production to be replaced in affected batches of EC Cartridge on your stock. Please scrap biosensors provided in original packaging of EC Cartridge on your side. There is no issue with cartridge solutions performance therefore you can use product after biosensor replacement without any issue.
- **Regarding EC Biosensor (REG00064):** You will receive EC Biosensors from fresh production to replace affected batches of EC Biosensor on your stock. Discard affected pieces of EC Biosensor on your stock.
- Use other lots of EC Cartridge or EC Biosensor on your stock until the affected lots will be replaced.
- New lots of EC Cartridge and EC Biosensor are available and can be used without any risk.
- If you have already shipped the affected lots to any customer, please immediately inform them about this Field Safety Notice and instruct them to follow above described rules.
- Also forward this notice to all those who need to be aware within your organization.
- We ask customers outside the EU to handle necessary announcements to authorities in their countries.

Under current regulations, we are obliged to provide a complete chain of evidence of all corrective measures for our products. For this reason, we would like to ask you to fill in, sign the attached confirmation, and communicate this information to all concerned customers. Please send back filled confirmation to Erba Lachema by e-mail until **August 31, 2023**.

Please accept our sincere apologies for the inconvenience caused. In case you have any questions, please do not hesitate to contact us.

Erba Lachema s.r.o.



Best regards,

Erba Lachema, s.r.o.

Radim Herrmann
Quality Manager

A handwritten signature in blue ink, consisting of a series of fluid, connected strokes that form a stylized representation of the name "Radim Herrmann".

Erba Lachema s.r.o.
Karásek 2219/1d, 621 00 Brno
DIČ: CZ26918846 -7-

<mailto:r.herrmann@erba.com>

Confirmation of receipt

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

ID: FSN 2023_02

Name: Biosensor on board stability

Affected products:

Cat. No.	Product name
REG00056	EC cartridge M
REG00057	EC cartridge L
REG00058	EC cartridge S
REG00061	EC cartridge S plus iCa
REG00062	EC cartridge M plus iCa
REG00063	EC cartridge L plus iCa
REG00064	EC Biosensor
REG00065	EC cartridge XS
REG00066	EC cartridge XS plus iCa

Herewith I confirm that we have received above mentioned customer notification and that all required actions have been implemented and all concerned parties have been informed about this Field Safety Notice. The use and further distribution of the affected products has been stopped until replacement by fresh Biosensors.

Number of unused pieces of EC Cartridge (all types) on your stock: boxes

Number of unused pieces of EC Biosensor (REG00064) on your stock: pcs

Customer name:

Confirmed by:
(name and position)

Date and sign:

Please complete this form and send it back via email until **August 31, 2023**.

Thank you for your efforts.

Erba Lachema, s.r.o.

Radim Herrmann

Quality Manager

<mailto:r.herrmann@erba.com>

Catalogue number	Product name	Batch number	QTY shipped	Manufacturing date (release date)	Expiration date	Biosensor lot
REG00057	EC cartridge L	2201086	13	03.02.2022	31.07.2023	100030+100031
REG00058	EC cartridge S	2201087	100	03.02.2022	31.07.2023	100031
REG00062	EC cartridge M plus iCa	2201088	100	03.02.2022	31.07.2023	100030+100031
REG00061	EC cartridge S plus iCa	2201089	77	03.02.2022	31.07.2023	100031
REG00058	EC cartridge S	2201150	150	03.02.2022	31.07.2023	100031
REG00062	EC cartridge M plus iCa	2201151	100	03.02.2022	31.07.2023	100031
REG00061	EC cartridge S plus iCa	2201152	50	03.02.2022	31.07.2023	100031
REG00061	EC cartridge S plus iCa	2201217	46	17.02.2022	31.07.2023	100032
REG00062	EC cartridge M plus iCa	2202041	35	17.02.2022	31.08.2023	100031+100032
REG00058	EC cartridge S	2205130	199	15.06.2022	30.11.2023	100033
REG00056	EC cartridge M	2206059	33	13.06.2022	31.12.2023	100033
REG00062	EC cartridge M plus iCa	2206060	50	13.06.2022	31.12.2023	100033
REG00061	EC cartridge S plus iCa	2206061	20	13.06.2022	31.12.2023	100033
REG00058	EC cartridge S	2206160	222	13.07.2022	31.12.2023	100035
REG00061	EC cartridge S plus iCa	2207031	51	12.07.2022	31.01.2024	100037
REG00063	EC cartridge L plus iCa	2207032	2	12.07.2022	31.01.2024	100037
REG00065	EC cartridge XS	2207034	21	15.07.2022	31.01.2024	100037
REG00066	EC cartridge XS plus iCa	2207035	25	15.07.2022	31.01.2024	100037
REG00062	EC cartridge M plus iCa	2207044	22	19.07.2022	31.01.2024	100037
REG00058	EC cartridge S	2207056	122	02.08.2022	31.01.2024	100037
REG00062	EC cartridge M plus iCa	2207057	20	03.08.2022	31.01.2024	100038
REG00061	EC cartridge S plus iCa	2207058	56	02.08.2022	31.01.2024	100038
REG00057	EC cartridge L	2207059	10	29.07.2022	31.01.2024	100037
REG00058	EC cartridge S	2207072/1	50	03.08.2022	31.01.2024	100038
REG00058	EC cartridge S	2208048	149	05.09.2022	31.01.2024	100038
REG00061	EC cartridge S plus iCa	2208049	70	12.09.2022	31.01.2024	100038
REG00065	EC cartridge XS	2208050	50	22.08.2022	29.02.2024	100040
REG00062	EC cartridge M plus iCa	2208051	82	23.08.2022	29.02.2024	100040
REG00058	EC cartridge S	2208103/1	73	23.08.2022	29.02.2024	100040
REG00058	EC cartridge S	2208104/1	27	24.08.2022	31.01.2024	100038
REG00065	EC cartridge XS	2208122	39	01.09.2022	31.01.2024	100038
REG00058	EC cartridge S	2208132/1	52	24.08.2022	31.12.2023	100036
REG00058	EC cartridge S	2208148/1	97	07.09.2022	31.12.2023	100036
REG00062	EC cartridge M plus iCa	2208157	39	06.09.2022	31.12.2023	100035
REG00062	EC cartridge M plus iCa	2208166	34	07.09.2022	31.12.2023	100035
REG00058	EC cartridge S	2208178	150	07.09.2022	30.09.2023	100032
REG00061	EC cartridge S plus iCa	2209056	82	16.09.2022	30.09.2023	100032
REG00063	EC cartridge L plus iCa	2209073	50	20.09.2022	30.11.2023	100034
REG00058	EC cartridge S	2209082/1	118	20.09.2022	30.11.2023	100034
REG00058	EC cartridge S	2209099/1	29	20.09.2022	31.12.2023	100035
REG00058	EC cartridge S	2209164/1	53	26.09.2022	31.12.2023	100035
REG00066	EC cartridge XS plus iCa	2209179	97	23.09.2022	30.11.2023	100033
REG00065	EC cartridge XS	2209189	106	30.09.2022	31.12.2023	100036
REG00063	EC cartridge L plus iCa	2209207	7	03.10.2022	30.11.2023	100033
REG00062	EC cartridge M plus iCa	2209214	134	05.10.2022	31.12.2023	100036
REG00062	EC cartridge M plus iCa	2209226	30	04.10.2022	30.11.2023	100033
REG00058	EC cartridge S	2209228/1	55	31.10.2022	31.01.2024	100037
REG00058	EC cartridge S	2210054/1	87	21.10.2022	31.01.2024	100037
REG00058	EC cartridge S	2210055/1	83	21.10.2022	31.01.2024	100039
REG00061	EC cartridge S plus iCa	2210117	85	19.10.2022	31.01.2024	100039
REG00065	EC cartridge XS	2210127	52	20.10.2022	31.01.2024	100039
REG00065	EC cartridge XS	2210128	201	21.10.2022	31.01.2024	100039
REG00065	EC cartridge XS	2210155	82	31.10.2022	31.01.2024	100039
REG00058	EC cartridge S	2210188	100	04.10.2022	31.03.2024	100043
REG00058	EC cartridge S	2210201	97	07.11.2022	31.03.2024	100043
REG00065	EC cartridge XS	2211079	13	07.11.2022	31.03.2024	100043
REG00065	EC cartridge XS	2211086	63	08.11.2022	31.03.2024	100043
REG00065	EC cartridge XS	2211090	195	14.11.2022	30.04.2024	100046
REG00061	EC cartridge S plus iCa	2211118	91	15.11.2022	30.04.2024	100046
REG00058	EC cartridge S	2211157	79	22.11.2022	30.04.2024	100046
REG00063	EC cartridge L plus iCa	2211163	12	25.11.2022	30.04.2024	100046
REG00056	EC cartridge M	2211202	40	25.11.2022	30.04.2024	100046
REG00058	EC cartridge S	2211208	136	29.11.2022	31.03.2024	100044
REG00058	EC cartridge S	2211214	6	01.12.2022	31.03.2024	100044
REG00061	EC cartridge S plus iCa	2212163	120	05.01.2023	31.03.2024	100044
REG00066	EC cartridge XS plus iCa	2212164	23	05.01.2023	31.03.2024	100044
REG00062	EC cartridge M plus iCa	2212184	189	05.01.2023	31.03.2024	100045
REG00061	EC cartridge S plus iCa	2301011	78	05.01.2023	31.03.2024	100044
REG00066	EC cartridge XS plus iCa	2301175	48	26.01.2023	31.03.2024	100045
REG00061	EC cartridge S plus iCa	2303123	82	14.03.2023	31.03.2024	100045
REG00057	EC cartridge L	2303126	40	17.01.2023	31.03.2024	100045
REG00058	EC cartridge S	2303127	59	17.03.2023	31.03.2024	100045
REG00056	EC cartridge M	2303132	115	20.03.2023	29.02.2024	100040
REG00062	EC cartridge M plus iCa	2303133	86	20.03.2023	29.02.2024	100040
REG00061	EC cartridge S plus iCa	2303184	75	27.03.2023	31.03.2024	100044
		TOTAL	5534			

Catalogue number	Product name	Batch number	QTY shipped	Manufacturing date (release date)	Expiration date	Lot of Biosensors
REG00064	EC Biosensor	2206141	189	30.06.2022	30.09.2023	100032
REG00064	EC Biosensor	2206142	95	30.06.2022	30.11.2023	100034
REG00064	EC Biosensor	2207050	200	18.07.2022	30.11.2023	100040
REG00064	EC Biosensor	2210171	10	24.10.2022	31.01.2024	100038
REG00064	EC Biosensor	2210176	348	31.10.2022	31.03.2024	100043
TOTAL			842			