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*Products For Health Care*

Date:22JAN2026

**Urgent Field Safety Notice**  
**Capillary Tube Kit, REF # 7303**

To the Attention of\*: Distributors who sold the Capillary Tube Kit, REF # 7303

Contact details of the Authorized Representative: *
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Emergo Europe B.V., Westervoortsedijk 60 6827 AT Amhem, The Netherlands
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**Urgent Field Safety Notice (FSN)**  
**Capillary Tube Kit, REF # 7303**

**Risk Evaluation:**

Elevated K<sup>+</sup> results may incorrectly indicate hyperkalemia or mask potential hypokalemia.

<b>1. Information on Affected Devices</b>	
1	1. Device Type(s)
·	Capillary Tube
1	2. Commercial name(s)
·	Capillary Tube Kit
1	3. Unique Device Identifier(s) (UDI-DI)
·	00840095607575, 00840095611626
1	4. Primary clinical purpose of device(s)
·	The capillary tube is an accessory to the analyzer for the purpose of collecting and presenting the blood samples.
1	5. Device Model/Catalog/Part Number(s)
·	REF 7303
1	6. Affected serial or lot number range
·	All unexpired capillary tube lot numbers; Lot number 22020 and greater
1	7. Associated devices
·	The EasyStat <sup>®</sup> analyzer

<b>2 Reason for Field Safety Corrective Action (FSCA)</b>	
2	1. Description of the product problem
·	Medica has identified that potassium (K <sup>+</sup> ) results obtained using the 7303 Capillary Tube Kit in capillary mode on the EasyStat analyzer may be falsely elevated. There is no effect on potassium testing performed using syringe/venous samples.
2	2. Hazard giving rise to the FSCA
·	A positive potassium bias (~20%) may lead to misclassification of patient results, including false identification of hyperkalemia or masking of true hypokalemia, which could result in inappropriate or delayed clinical management.
2	3. Probability of problem arising
·	All Potassium (K <sup>+</sup> ) results using the 7303 Capillary Tube Kit are affected
2	4. Predicted risk to patient/users
·	The condition has been classified as "Intolerable" (unacceptable).
	5. Background on Issue

2	A field complaint identified inconsistencies (positive bias) with the determination of K+ level in capillary samples using the Capillary Tube Kit on EasyStat analyzers. Preliminary testing by Medica has confirmed the complaint.
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<b>3. Type of Action to Mitigate the Risk</b>			
<b>3.</b>	<p><b>1. Action To Be Taken by the User</b></p> <p> <input type="checkbox"/> Identify Device    <input type="checkbox"/> Quarantine Device    <input type="checkbox"/> Return Device    <input type="checkbox"/> Destroy Device  <input type="checkbox"/> On-site device modification/inspection  <input type="checkbox"/> Follow patient management recommendations  <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU)  <input checked="" type="checkbox"/> Other                      <input type="checkbox"/> None         </p> <p>This information must be forwarded to end-users who received affected lots of the REF 7303 Capillary Tube Kits.</p> <p><b>Do not report potassium results obtained in capillary mode using affected lots of the 7303 Capillary Tube Kit on the EasyStat analyzer.</b></p>		
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 70%;">2. By when the action should be completed?</td> <td style="width: 30%;">Effective Immediately</td> </tr> </table>	2. By when the action should be completed?	Effective Immediately
2. By when the action should be completed?	Effective Immediately		
3.	<p>3. Particular considerations for:                      IVD</p> <p>Is follow-up of patients or review of patients' previous results recommended? Yes</p> <p>Review potassium (K+) capillary results performed using the REF 7303 Capillary Tube Kit on the EasyStat analyzer and any potential clinical decisions based on these results.</p>		
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 70%;">4. Is customer Reply Required? (If yes, form attached specifying deadline for return)</td> <td style="width: 30%;">No</td> </tr> </table>	4. Is customer Reply Required? (If yes, form attached specifying deadline for return)	No
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<b>3.</b>	<p><b>5. Action Being Taken by the Manufacturer</b></p> <p> <input type="checkbox"/> Product Removal                      <input type="checkbox"/> On-site device modification/inspection  <input type="checkbox"/> Software upgrade                      <input type="checkbox"/> IFU or labelling change  <input checked="" type="checkbox"/> Other    <input type="checkbox"/> None         </p> <p>Medica has quarantined all REF 7303 Capillary Tube Kits until investigation is complete.</p>		
3	<table border="1" style="width: 100%;"> <tr> <td style="width: 70%;">6. By when the action should be completed?</td> <td style="width: 30%;">Immediately</td> </tr> </table>	6. By when the action should be completed?	Immediately
6. By when the action should be completed?	Immediately		

FSN Ref: B2602

FSCA Ref: Not available at this time

3.	7. Is the FSN required to be communicated to the patient /lay user?	No
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<b>4. General Information</b>		
4.	1. FSN Type	New
4.	2. Further advice or information already expected in follow-up FSN?	Not planned yet
4	3. Anticipated timescale for follow-up FSN	To Be Determined
4.	4. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Medica Corporation
	b. Address	5 Oak Park Drive, Bedford MA, 01730, USA
	c. Website address	www.medicacorp.com
	d. SRN	US-MF-000037250
4.	5. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.  The Competent Authority has not yet been informed	
4.	6. List of attachments/appendices:	None
4.	7. Name/Signature	

<b>Transmission of this Field Safety Notice</b>	
	<p>This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.</p> <p>Please complete the "Customer reply Form" provided at the end of this Field Service Notice and email to Medica Corp. at <a href="mailto:technicalsupport@medicacorp.com">technicalsupport@medicacorp.com</a></p>

## Customer Reply Form

Medica requests that you provide the following information as part of the regulatory requirements regarding this Field Service Notification. Please email your response to [technicalsupport@medicacorp.com](mailto:technicalsupport@medicacorp.com)

<b>1. Field Safety Notice (FSN) information</b>	
FSN Reference number	26002
FSN Date	January 22, 2026
Product/ Device name	EasyStat Capillary Tubing Kit
Product Code(s)	REF 7303
Batch/Serial Number (s)	Lots 22020 and above

<b>2. Customer Details</b>	
Account Number with Medica	
Distributor Name	
Organisation Address	
Shipping address if different to above	
Contact Name	
Title or Function	
Email*	

<b>3. Customer action undertaken on behalf of Healthcare Organisation</b>		
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer Comments
<input type="checkbox"/>	I performed all actions requested by the FSN.	Customer Comments
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	Customer Comments