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Medical Device Recall – Type III
Follow-up Customer Communication

CompoLab TM and CompoLab TM Cuvettes

September 23, 2022

Dear Healthcare Provider,

Subject: Incorrect version of Instructions For Use (IFU) supplied with the CompoLab TM Cuvette and Operator's Manual (OM) for the CompoLab TM device.

Affected Devices: CompoLab TM device, Product Code 9034000 and CompoLab TM Cuvettes Product Code 9034050

Fresenius Kabi Canada issued a customer communication on May 19, 2022 to notify customers of a **Type III recall** initiated for CompoLab TM hemoglobinometer (product code 9034000) and for CompoLab TM Cuvettes (product code 9034050). This product notification detailed the below issue and the required steps for customers to perform.

This follow-up communication is to advise customers that in order to prevent product disruptions, product currently shipped from Fresenius Kabi Canada will exhibit the same issue listed below. Please continue to follow the instructions herein to ensure correct IFU and OM are used. All sites receiving affected product are to be notified of the issue and instructed to follow directions as listed below.

Issue:
Fresenius Kabi Canada has identified that the OM for the CompoLab TM and the IFU for the CompoLab TM Cuvettes currently included in the box are not the most current versions as approved by Health Canada.

The versions of the IFU and OM in the box do not reflect the updated instructions for capillary sampling, limitations or cleaning of the devices.

Potential Risk:
There is no risk associated with this event. Customers affected by this notification are in possession of the current versions of the IFU and OM documents. Fresenius Kabi Canada has initiated this Type III recall out of an abundance of caution.

Required Actions for Users:

1) Please disregard the IFU/OM in the box of the product and refer to the correct IFU/OM using the URL link as stated below:

	CompoLab TM	CompoLab TM Cuvette
English	https://www.fresenius-kabi.com/en-ca/documents/CompoLabTM_OP_08_10_20_EN-CAN.PDF	https://www.fresenius-kabi.com/en-ca/documents/CompoLab-TM-Cuvette-Insert-EN-CAN-V2.pdf
French	https://www.fresenius-kabi.com/fr-ca/documents/CompoLabTM_OP_08_10_20_FR-CAN.PDF	https://www.fresenius-kabi.com/fr-ca/documents/CompoLab-TM-Cuvette-Insert-FR-CAN-V2.pdf

2) Please ensure within your organization that every user of the concerned products and all other relevant persons or entities where the concerned products have been transferred are informed about this customer communication and the actions as described herein.

3) No return of product is required

4) Complete the attached reply form and submit to Canada_Product_Complaints@fresenius-kabi.com as soon as possible.

Fresenius Kabi Canada is committed to providing you with the highest level of service, product quality and reliability. We apologize for any inconvenience this has caused and we appreciate your attention to this matter.

Please fill out the Customer Reply Form attached to this letter to acknowledge receipt of this notification and return it to Fresenius Kabi Canada via the fax number or email address stated on the form. If you have any questions or require additional information, please contact Fresenius Kabi Canada at 1-877-821-7724.

Sincerely,

Anabela Costa
Sr. Director, Quality and Vigilance
Fresenius Kabi Canada