



To : Whom it may concern  
From : [local affiliate]  
Subject : Ambix Nova (ECMD202215)

Telephone : [local affiliate]  
Telefax : [local affiliate]  
Date : 21-Oct-2022

**Field Safety Notice affects the following products:**

Article name	Article number	Serial number
Ambix Nova	N0445xx	To be entered locally

Dear Sir or Madam,

Fresenius Kabi initiates this precautionary, voluntary field safety corrective action to inform about a potential risk of not meeting the  $\pm 5\%$  accuracy in flowrate.

Fresenius Kabi has received information from customers, which have pointed to an early finish of a programmed infusion volume of parenteral nutrition. Investigations identified, that due to a deviation during the calibration process, the affected Ambix Nova pumps may infuse faster than expected and may result in an over-delivery of between 5-15%.

Fresenius Kabi has not received any reports of patient harm related to this pattern.

Based on this information, Fresenius Kabi decided to recall all affected pumps for a check, which will be executed by Fresenius Kabi Field Services.

Therefore you are asked to check any stocks of the above-mentioned products in your facility and not to continue using them. Fresenius Kabi will approach you to organize the needed check of the affected products.

**In addition, we ask you to note the following information:**

1. Final User: If the respective product is stored in your facility, please stop usage of the product and further internal distribution.
2. Distributor: Please immediately stop selling the concerned product to your customers. If quantities of pumps have already been shipped from your inventory, please immediately inform your customers about this product recall and ask them to return the products.
3. PLEASE COMPLETE THE ENCLOSED "URGENT FSCA RESPONSE FORM" AND SEND IT BACK TO US IMMEDIATELY AT:  
E-mail: <local affiliate>  
Fax: <local affiliate>

Please ensure within your organization that every user as well as all relevant persons are informed about this product recall.

After successful control and/or recalibration the product will be ready for use again.

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 letter and the actions as described herein.

Fresenius Kabi is committed to providing you with the highest level of service, product quality and reliability. We apologize for any inconvenience.

If you have any further questions concerning the FSCA please contact: **local product manager**.

Sincerely,

Signature

**<name local affiliate>**  
**<function>**

**URGENT FSCA response form**

**Ambix Nova**  
**Article number:** N0445xx  
**Serial number:** xxx

We kindly ask you to fill out this form completely and tick the appropriate boxes.

Please send the completed form to Fresenius Kabi at: [xxx@fresenius-kabi.com](mailto:xxx@fresenius-kabi.com)

Please do not return any goods to us unsolicited.

Name of the hospital / institution / client:	
Customer number: Delivery note number:	
Address of the hospital / institution / client:	
Contact person: Function:	
Phone number:	

I have read the information dated 21 October 2022 and have informed all relevant persons about the FSCA and the described procedure.

**Date:** .....

**Signature:** .....