

## Urgent Field Safety Notice pH Indicator Strips non-bleeding

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**Date:** 05 November 2014

**Attention:** Risk/Safety Managers, Clinicians, Nursing, NICU, PICU, SCBU, ICU and other users of these devices

### Details on affected devices:

Merck Serono pH Indicator Strips non-bleeding 0 - 6.0 (090120604)

Batch numbers: HC360449, HC360899, HC365489, HC366938, HC368071, HC371552, HC374106\*

Merck Serono pH Indicator Strips non-bleeding 2.0 - 9.0 (090120603)

Batch numbers: HC360448, HC360898, HC363740, HC365490, HC366937, HC369701, HC371551\*

\*Also to include any subsequent batches until such time that the improved design of the product as discussed in the final paragraph of this Urgent Field Safety Notice has been completed and communicated to end users.

### Description of the problem:

Merck Serono supplies pH Indicator Strips for the semi-quantitative, visual determination of the pH in gastric tube aspirate of human origin for assessment of correct tube placement, as described in the Instructions For Use.

Following the Field Safety Notice that was issued in May 2014, Merck Serono has updated the Instructions For Use for pH Indicator Strips non-bleeding 0 - 6.0 and pH Indicator Strips non-bleeding 2.0 - 9.0. *“Do not dilute the sample material with any type of water (e. g. distilled, sterilized, potable, bottled or tap water) or any other diluents as this can lead to the test sample having too low a buffering capacity to give an accurate reading. We recommend that tubes are not flushed before initial confirmation of correct tube placement. If tubes are subsequently flushed ensure that the flush solution is fully removed before taking gastric samples for pH measurement.”*

Merck Serono legal entity – UK

[www.merckserono.com](http://www.merckserono.com)

Merck Serono is a division of Merck.

#### Registered Office and Principal Place of Business

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Registered in England Number 990823

**Advise on action to be taken by the user:**

We would like to remind users that the product is not intended for the determination of the pH using any type of low buffered solution (e.g. distilled, sterilized, potable, bottled or tap water, feed/food and/or medication) as sample material. We advise to only use fresh gastric tube aspirate.

We would like to inform users that the product functions correctly when the instructions are adhered to. This is supported by the stability data.  
Please amend your protocol to introduce this warning in your current practice.

pH Indicator Strips should be stored as described in the Instruction For Use.

Action

Please complete and return the attached Confirmation Form (Attachment 1) by Fax to +44 (0) 208 818 7263 or by email to [medinfo.uk@merckgroup.com](mailto:medinfo.uk@merckgroup.com)

**Transmission of this Field Safety Notice:**

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected pH strips have been transferred.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

**Contact reference person:**

If there are any queries about the notice please contact our Medical Information department on:

Phone: +44 (0) 208 818 7373

Email: [medinfo.uk@merckgroup.com](mailto:medinfo.uk@merckgroup.com)

Merck Serono has implemented a revision to the Instructions For Use in order to strengthen the warning regarding use with low buffered solutions. Merck Serono has committed to improving the design of the product.

Dr Lisa Moore-Ramdin  
Associate Medical Director UK and Ireland

Attachment 1

**URGENT FIELD SAFETY NOTICE**

**Merck Serono pH Indicator Strips non-bleeding 0 - 6.0 (090120604)**  
**Merck Serono pH Indicator Strips non-bleeding 2.0 - 9.0 (090120603)**

**Safety Feature - Stability**

Upon completing the following information, **please fax this sheet to Merck Serono Ltd, Medical Information Department at +44 (0) 208 818 7263 or return via email to [medinfo.uk@merckgroup.com](mailto:medinfo.uk@merckgroup.com)** or by post at the following address below:

**Medical Information Department  
Merck Serono Ltd  
Bedfont Cross  
Stanwell Road  
Feltham  
Middlesex  
TW14 8NX**

Please check one of the statements below and complete the contact details:

Check One Box ✓	
	<b>Yes</b> – I confirm receipt and I understand this Urgent Field Safety Notice and the required actions.
	<b>No</b> – I do not understand this Urgent Field Safety Notice. I would like Merck Serono to contact me.

Customer Name  
(Please Print): \_\_\_\_\_

Address: \_\_\_\_\_  
\_\_\_\_\_

Phone Number: \_\_\_\_\_

\_\_\_\_\_  
**Customer Signature** Date: \_\_\_\_\_