

## **Urgent Field Safety Notice**

### **pH Indicator Strips non-bleeding**

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**Date:** 02 May 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.

A letter was issued in May 2013 to customers which explained a new safety feature of the pH strips. This feature was intended to eliminate the risk of false positive readings from low buffered solutions when confirming tube placement. However, the stability testing of the product has indicated that the function of this additional safety feature may not be guaranteed over the shelf life of the product.

#### **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.

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**

Merck Serono Limited  
Bedfont Cross, Stanwell Road  
Feltham, Middlesex  
TW14 8NX  
United Kingdom

Phone + 44 (0)20 8818 7200  
Fax + 44 (0)20 8818 7267  
[www.merckserono.co.uk](http://www.merckserono.co.uk)

Registered in England Number 990823

We would like to inform users that the product functions correctly when the instructions are adhered to. This is supported by the stability data.

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 is implementing a revision to the Instructions For Use in order to strengthen the warning regarding use with low buffered solutions and has also committed to improving the design of the product



Dr Michael Thompson  
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 – I confirm receipt and I understand this Urgent Field Safety Notice and the required actions.</b>
	<b>No – I do not understand this Urgent Field Safety Notice. I would like Merck Serono to contact me.</b>

Customer Name  
(Please Print):

\_\_\_\_\_

Address:

\_\_\_\_\_

\_\_\_\_\_

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

Date: \_\_\_\_\_

\_\_\_\_\_  
**Customer Signature**