

December 20, 2010

Ref#: FSN_2010_10-22

URGENT: FIELD SAFETY NOTICE

ABX MICROS 60 Haematology Analyzer MICROS ABC Vet Haematology Analyzer for veterinary purpose SCIL ABC Vet Haematology Analyzer for veterinary purpose

Dear Horiba Medical Customer,

Horiba Medical internal quality control process has confirmed an issue on specific (as of 1st of June 2010) ABX Micros 60, Micros ABC Vet & SCIL Vet ABC haematology analyzers.

ISSUE:

Unwanted/erroneous characters and/or values may appear on the LCD screen only, when returning to screen results after the following events:

- A technical alarm of the system (see user manual: section 5. "Maintenance & Troubleshooting", chapter 2.5. "Troubleshooting Specific ERROR Messages")
- An access to the contrast adjustment function (see user manual: section 5. "Maintenance & Troubleshooting", chapter 1.3.7.2. "LCD Contrast Adjustment")

At the time the result is displayed on the screen, if an event such as the ones above mentioned occurs, the information linked with the event will be displayed on the LCD screen in place of the results (For instance: "printer error").

When returning to the result display, the data might have been modified by unwanted/unexpected characters, result values might be erroneous as well.

When the result is displayed right after the run, values are correct.

IMPACT:

Erroneous values may be reported if directly used/copied from the LCD screen. No erroneous result are transmitted to the LIS nor printed.

In addition, in the case the instrument has the option of using a memory card, no erroneous results are recorded within the memory card thus any result display, print or transmission from the memory is correct.

ACTION/RESOLUTION:

We currently request the customer not to use the screen display to report results. Only use printout or transmission through LIS system. If you experience any of the above mentioned issues, contact your Horiba Medical representative immediately.

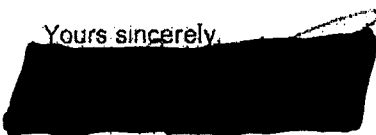
COMPLETE AND RETURN THE ENCLOSED RESPONSE FORM WITHIN 10 DAYS SO WE MAY MAINTAIN OUR RECORDS.

Please share this information with your laboratory staff, and retain this notification as part of your Quality System documentation.

If you have any questions regarding this Product Corrective Action, please contact your local Horiba Medical representative.

We sincerely apologize for any inconvenience that this may have caused to your laboratory.
Thank you for your continued support of Horiba Medical products.

Yours sincerely,


Director of Quality & Regulatory Affairs

December 20, 2010

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FAX ANSWER

Could you please return this document filled in and signed to:

HORIBA
Medical

HORIBA ABX SAS
Parc Euromédecine - Rue du Caducée
BP 7290
34184 Montpellier Cedex 4, France
Fax : 04 67 14 18 75

ABX MICROS 60 Haematology Analyzer
MICROS ABC Vet Haematology Analyzer for veterinary purpose
SCIL ABC Vet Haematology Analyzer for veterinary purpose

Display issue on specific (as of 1st of June 2010) ABX Micros 60, Micros ABC Vet & SCIL Vet ABC haematology analyzers.

Could you please fill in the following sections:

Impacted analyzer(s) within your laboratory:

Type of analyzer	Serial number

Name of the laboratory:

I have received the quality information FSN_2010_10-22 concerning a display issue on specific (as of 1st of June 2010) ABX Micros 60, Micros ABC Vet & SCIL Vet ABC haematology analyzers.

I have understood the recommendations of Horiba Medical to prevent the issue on my analyzer(s).

Name:

Signature:

Title:

Date: