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August 10, 2012
Ref. FSN_2012_12-17

URGENT: FIELD SAFETY NOTICE (CORRECTION)
ABX PENTRA ML (Validation system)
Versions V8.0.x and below
Versions V9.0.1 and V9.0.2

Dear HORIBA Medical Customer,

HORIBA Medical internal quality control process has confirmed an issue on HORIBA Medical data management and validation system ABX PENTRA ML.

HISTORY OF THE ISSUE (observed in V9.0.1):

During the sample processing, the auto-validation of a patient sample was blocked by the ABX PENTRA ML, asking for a slide review.

Once the manual run for the slide entry was entered by the user, the first discipline (DIFF report) was correctly uploaded to the LIS (Laboratory Information System).

At that step, the user created a second manual run to enter a new WBC value. After validating this manual run, the first discipline (DIFF) was again correctly uploaded to the LIS

Then, the user manually validated the second discipline (CBC) coming from the instrument run.

The ABX PENTRA ML uploaded the full report (CBC + DIFF) to the LIS.

The data received at that stage by the LIS were not those just validated for that patient and displayed on the screen, but those of a previous run from the same patient history.

ANALYSIS:

After checking the database and the files exchanged by the ABX PENTRA ML and the LIS, it was identified that a "ghost run" had been created by the ABX PENTRA ML between the last manual run and the report of the concerned patient.
The reason of this "ghost run" creation is still under investigation.
Its presence, associated with a manual run, may provoke an erroneous upload of data to the LIS.

The following conditions of occurrence where confirmed.
2 cases must be considered, depending of the software version of ABX PENTRA ML, according to the fact that the discipline feature is available or not:

- Case of Software version V8.0.x and below:
  The "Discipline" feature is not available. In consequence, only the complete report can be automatically uploaded to the LIS by the ABX PENTRA ML.

  Sequence of events inducing the issue in this case:
  1. A complete report for the current patient has been manually validated through a manual run and correctly uploaded to the LIS.
     AND
  2. A ghost run has been created by the ABX PENTRA ML.
     AND
  3. At least one history result (anteriority exists in the patient file) must exist for that given patient.
     AND
  4. A reflex slide must be have been requested.
     AND
  5. A manual run associated with the slide entry must have been created.
     AND

6. The data entry for this manual run must have been done on the ABX PENTRA ML server (The one hosting the database).
   AND
7. The report is manually re-uploaded to the LIS using the manual upload function key: 

If the above chronology of event exists, then the latest report uploaded to the LIS is incorrect and corresponds to a history result of the same patient.

- Case of Software versions V9.0.1 and V9.0.2:
  The "Discipline" feature is available and activated. (It is not active by default).
  The principle of the "Discipline" function is that, as soon as all results of a given discipline are validated, they enter the final patient report and are automatically uploaded to the LIS by the ABX PENTRA ML.

  Sequence of events inducing the issue in this case:
  1. A first complete discipline for the current patient, manually validated through a manual run, is available in the patient report on the station ABX Pentra ML and is correctly uploaded to the LIS.
     AND
  2. A "ghost run" has been created by the ABX PENTRA ML.
     AND
  3. At least one history result (anteriority exists in the patient file) must exist for that given patient.
     AND
  4. A reflex slide must be have been requested.
     AND
  5. A manual run associated with the slide entry must have been created.
     AND
  6. The data entry for this manual run must have been done on the ABX PENTRA ML server (The one hosting the database).
     AND
  7. A second complete discipline is validated and automatically uploaded to the LIS by the ABX PENTRA ML.

  If the above chronology of events exists, then the latest report uploaded to the LIS is incorrect and corresponds to a history result of the same patient.

In both cases, the results of the current run are correctly displayed on the analyser and on the ABX PENTRA ML.
When printed, runs or reports from the analyser or from the ABX PENTRA ML are correct.
The database of ABX PENTRA ML is not affected, history files remain correct in any case.

LEVEL OF OCCURRENCE:

The analysis described above lead us to consider the level of occurrence as very exceptional.
We have no knowledge of any other similar case from the several hundred active ABX PENTRA ML products over the past 10 years.

The common condition of occurrence is the appearance of a "ghost run" created by the ABX PENTRA ML associated with multiple manual actions (manual entry of data, results or comment).

However, since software versions V9.0.1 and V9.0.2 provide more automatic features such as disciplines and thus less visible cases than software version V8.0.x and below, the corrective actions shall be differentiated.

ACTION/RESOLUTION:

A software update without the default is developed and will be installed as soon as possible on all systems.

In the meantime, the following recommendations must be taken into account when you use the ABX PENTRA ML:

- Software versions V8.0.x and below:
  The coherence of all results being manually re-uploaded to the LIS must be systematically checked.

- Software versions V9.0.1 and V9.0.2:
  In the case where the “Discipline” feature is used, after an entry of results in a manual run, the coherence of all data uploaded to the LIS must be checked for the patient file.

  In the case where the “Discipline” feature is not used, the coherence of all results being manually re-uploaded to the LIS must be systematically checked.

Please share this information with your laboratory staff, and retain this notification as part of your Quality System documentation. It is mandatory for you to complete and return the enclosed response form within 10 days so we may maintain our records.

In application of the official recall procedure, the French authority ANSM has been informed of this action.

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 trust in HORIBA Medical products.

Yours sincerely,

Thierry AUTHIER

Information and Post-Analytical Range Product Manager

Arnaud PRADEL

Quality and Regulatory Affairs Director

August 10, 2012
Ref. FSN_2012_12-17

FAX ANSWER

Could you please return this document properly filled in and signed to your local Horiba Medical representative.

HORIBA ABX SAS
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URGENT: FIELD SAFETY NOTICE FOR CORRECTION
ABX PENTRA ML ()
Versions V8.0.x and below
Versions V9.0.1 and 9.0.2

Could you please fill in the following sections:

Name of the Laboratory:

Address of the laboratory:

Telephone:

□ I have received the quality information concerning PENTRA ML expert validation system for use with HORIBA Medical instruments.

□ I have well understood the recommendations given by HORIBA Medical for my device(s):

Please fill in below with the software version of your PENTRA ML product:

ABX PENTRA ML software version:

Name: **Signature:**

Title:

Date: