HORIBA ABX SAS
Parc Euromédecine - Rue du Caducée
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Montpellier, July 12th 2018
Ref#: FSN_2018_07-12

URGENT: FIELD SAFETY NOTICE

Yumizen H2500 & H2500 SPS (version 1.1.0 or lower)

Dear HORIBA Medical Customer,

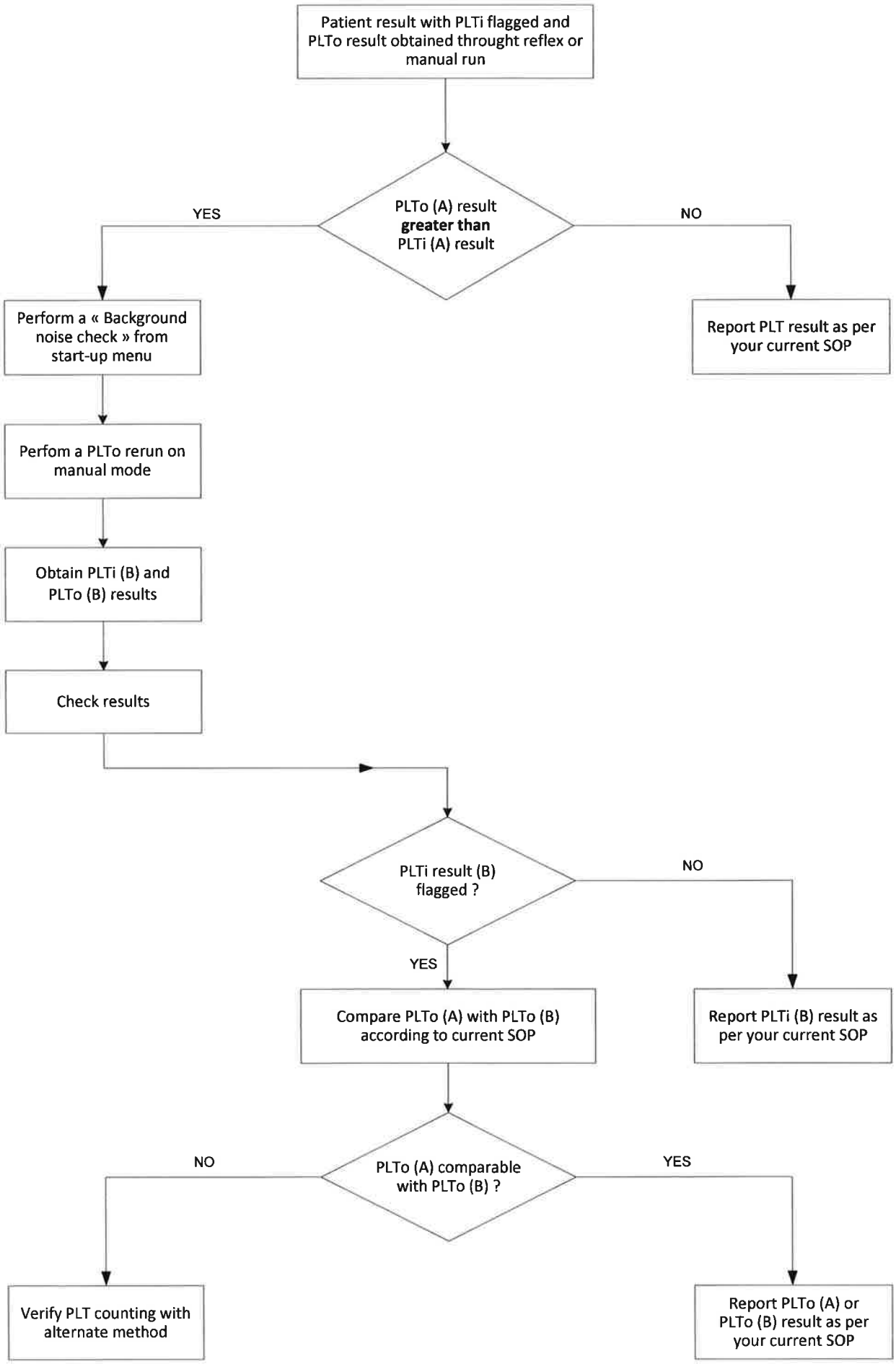
HORIBA Medical internal quality control process has confirmed an issue on the product model Yumizen H2500 and H2500 SPS.

ISSUE:
The Yumizen H2500 and Yumizen H2500 SPS provide Platelets analysis and counting by using impedance (PLTi) and optical (PLTo) measurement methods.
The PLTo analysis can be automatically triggered by the analysers through a reflex cycle based upon defined criteria linked with initial PLTi results.
It can also be selected as preferred analysis method when running the samples with the manual mode, in this case the analysers will provide Platelets analysis with both impedance and optical measurement methods.

HORIBA Medical has confirmed the possibility of overestimating PLTo results versus PLTi results.
The root cause is linked with insufficient cleaning of a hydraulic circuit, depending upon the combination of analyses performed prior to the PLTo analysis.

IMPACT:
The potential overestimation of the Platelets counting value could be critical for patient's cases with thrombocytopenia and notably with severe thrombocytopenia which could then not be detected as severe.
As far as we know, no such case occurred.

ACTION/RESOLUTION:
The corrective action will be implemented through a software upgrade that will be performed by your HORIBA Medical technical representative
In the meantime, Horiba Medical recommend to verify each PLTo result when they are greater than PLTi result, as indicated in the flowchart hereunder.


Patient result with PLTi flagged and PLTo result obtained throught reflex or manual run
PLTo (A) result greater than PLTi (A) result
YES
NO
Perform a « Background noise check » from start-up menu
Report PLT result as per your current SOP
Perfom a PLTo rerun on manual mode
Obtain PLTi (B) and PLTo (B) results
Check results
PLTi result (B) flagged ?
NO
YES
Compare PLTo (A) with PLTo (B) according to current SOP
Report PLTi (B) result as per your current SOP
PLTo (A) comparable with PLTo (B) ?
NO
YES
Verify PLT counting with alternate method
Report PLTo (A) or PLTo (B) result as per your current SOP

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.
As part of the official recall process we have informed our local authority (ANSM).
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,

Sylvain JACQUEMIN
Director of Quality & Regulatory Affairs

Montpellier, July 12th 2018
Ref#: FSN_2018_07-12

CUSTOMER ANSWER

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

HORIBA Medical

HORIBA ABX SAS
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34184 Montpellier Cedex 4, France
Fax : 04 67 14 18 75

URGENT : FIELD SERVICE NOTICE
Yumizen H2500 & H2500 SPS (version 1.1.0 or lower)

Could you please fill in the following sections:
Name of the Laboratory:

Address of the laboratory:

Telephone:

□ I have received the quality information *FSN_2018_07-12* concerning an issue on Yumizen H2500 and H2500 SPS Hematology analyzers.

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

Products concerned by the recall within your laboratory:

Serial number

Name: **Signature:**

Title:

Date: