



Date: May 26, 2021

Field Notice

QPlus® Cartridges
HemoSonic KT-0010
Lot3000000028

Dear HemoSonic International:

The purpose of this notification is to inform you that HemoSonic, LLC has identified a potential issue with this specific lot of QPlus Cartridges which may be observed when whole blood samples are analyzed on the Quantra® Hemostasis Analyzer (Quantra).

An internal user reported unusual results from 3 whole blood samples. Specifically, the Clot Stiffness (CS) and Fibrinogen contribution to Clot Stiffness (FCS) values were similar, with the Platelet Contribution to Clot Stiffness (PCS) results < 2 hPa, or not calculable.

HemoSonic has initiated an investigation of the cartridge filling process for Lot 3000000028 to explain the similar CS and FCS results.

- The investigation revealed a discrepancy among the reagent beads that could potentially impact up to 3% of this cartridge lot.
- It is noteworthy that whole blood testing of a sample of cartridges from quarantined kits of QPlus lot 3000000028 performed at HemoSonic did not replicate the reported issue.
- In order to reduce the potential for a recurrent issue in the future additional quality control (QC) steps will be implemented in the process of filling cartridges.

Risks to Health:

Although HemoSonic did not replicate the reported issue, there is a potential for a false high FCS result in combination with a false low PCS result which could lead to an incorrect diagnosis of the coagulation status of the patient and a delay in the administration of needed blood products.

Results obtained with the Quantra QPlus Cartridge should not be the sole basis for a patient's diagnosis. The Quantra QPlus test results should always be considered within the clinical context of the individual patient. In the event of inconsistencies with the patient's clinical status, samples should be supplemented with additional clinical information and/or testing.

Actions to be Taken:

- Forward this communication to any customers who may have received this specific product lot from you, and members of your organization who need to be aware.



2. Destroy any remaining QPlus Cartridges Lot# 3000000028 inventory you may have in stock and recommend the same to your customers that have received this specific lot. There is no need to destroy other KT-0010 lots.
3. Complete the attached Customer Response F01m and return via email to HemoSonic Regulatory Affairs at regulatory@hemosonics.com so that HemoSonic may acknowledge receipt of this notification and actions requested.

Contact Information:

If you require any further assistance, please contact:

HemoSonic Technical Support at (001) 800.280.5589

We appreciate your immediate attention to this matter and apologize for any inconvenience this may have caused.

xxx

HemoSonic, LLC

Customer Response Form and Field Notice
ATTENTION: Regulatory Affairs
 Regulatory Field Action
 HemoSonics KT-0010: QPlus® Cartridges
 Lot 3000000028

Return acknowledgement to HemoSonics
 Email this form to **regulatory@hemosonics.com**
 Deadline for returning the Distributor form is June 3, 2021

Distributor Details	
Company Name	HemoSonics International
Account Number	C000017
Address	3 Allee Theresa ES 10009 92665 Asnieres Sm Seine Cedex FR
Shipping Address (if different from above)	Z1 Des Bethunes 14-16 Avenue Des Bethunes 95310 Saint Ouen L'Aumone FR
Contact name	Catherine Pedrosa
Title or Function	Marketing Manager
Telephone Number	+33 (0)1 46 88 22 37
Email	catherine.pedrosa@stago.com

Please check actions completed:

<input type="checkbox"/>	I confirm receipt and have read and understand the Field Notice.
<input type="checkbox"/>	I have informed applicable customers of this Field Notice Date of Communication:
<input type="checkbox"/>	I have received confirmation of reply from all applicable customers.
<input type="checkbox"/>	I confirm that _ kits of QPlus Lot 3000000028 in inventory have been destroyed.
<input type="checkbox"/>	Neither I nor any of my customers has any kits of QPlus Lot 3000000028 in inventory.

Signature: _____

Signature:

Date: _____