



Date: March 15, 2021

Field Notice
QStat® Cartridges
HemoSonics KT-0022
Lot 3000000029

Dear Keller Medical GmbH:

The purpose of this notification is to advise you that HemoSonics, LLC has identified potential issues with this specific lot of QStat Cartridges that may be observed when certain hypocoagulable whole blood samples are analyzed on the Quantra® Hemostasis Analyzer (Quantra).

Internal testing of whole blood containing therapeutic doses of direct oral anticoagulants (Xarelto [rivaroxaban] and Eliquis [apixaban]) with this lot of QStat Cartridges revealed poor precision for the Clot Stiffness (CS) parameter (CV>15%) and a higher than expected rate of Test Errors for the CS and Clot Stability to Lysis (CSL) parameters. This was confirmed using native and contrived whole blood samples. Testing of normal donor whole blood without direct oral anti-coagulants performed as expected and met all requirements for Quality Systems approval of this Cartridge lot.

Risks to Health:

There is the potential that an inaccurate CS test result may be obtained when a sample from a patient taking a direct oral anticoagulant is analyzed on this QStat Cartridge lot. Results obtained with the Quantra QStat Cartridge should not be the sole basis for a patient's diagnosis. The Quantra QStat test results should always be considered with 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:

1. 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 QStat Cartridges Lot# 3000000029 inventory you may have in stock and recommend the same to your customers that received this specific lot. There is no need to destroy other KT-0022 lots.
3. Complete the attached Customer Response Form and return via email to HemoSonics Regulatory Affairs at regulatory@hemosonics.com so that HemoSonics may acknowledge receipt of this notification and actions requested.

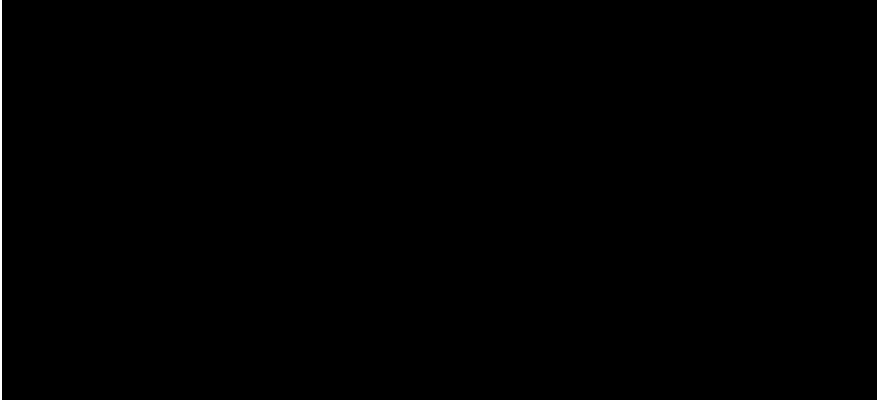


Contact Information:

If you require any further assistance, please contact:

HemoSonics Technical Support at (001) 800.280.5589

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





Customer Response Form and Field Notice
ATTENTION: Regulatory Affairs
Regulatory Field Action
HemoSonics KT-0022: QStat® Cartridges
Lot 3000000029

Return acknowledgement to HemoSonics

Email this form to **regulatory@hemosonics.com**

Deadline for returning the Distributor form is March 19, 2021

Distributor Details	
Company Name	Keller Medical GmbH
Account Number	C000002
Address	Wiesbadener Weg 2A, 65812 Bad Soden 66812 Germany
Shipping Address (if different from above)	
Contact name	Andreas Freund
Title or Function	Business Process Manager
Telephone Number	+49 6196 56163-17
Email	Andreas.Freund@keller-medical.de

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 QStat Lot 3000000029 in inventory have been destroyed.
<input type="checkbox"/>	Neither I nor any of my customers has any kits of Lot 3000000029 in inventory.

Print Name:
Signature:
Date: