SIEMENS

Urgent Field Safety Notice

BR-00114

November 2013

BFT* II Analyzer (Catalog No. OVKF03 / SMN 10458677)
Incorrect SHP Predilution in Reference Guide for all Endogenous Coagulation Factors

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Dear valued customer,

Our records indicate that you are using a BFT* II® Analyzer.

Siemens Healthcare Diagnostics is conducting a field safety corrective action due to a misprint in the BFT* II Analyzer Reference Guide Versions 3.00, 3.01 and 3.02; in the application sheets of all endogenous coagulation factors. The misprint might lead to a risk of L result reporting for all endogenous coagulation factors. If you are not testing the endogenous coagulation factors on a BFT II Analyzer please disregard this communication.

Reason for Field Action
It has been confirmed that Standard Human Plasma (SHP, REF ORKL) pre-dilution ratios given in the Reference Guides of the BFT* II Analyzer do not correspond to the standard dilution procedure for endogenous coagulation factor determination. The incorrect dilution ratio stated in the Reference Guides is limited to the lowest calibration point.

Preparation of calibration curve (level 6) for Factor VIII :

30 µl of Prediluted SHP	incorrect: 1:25	correct: 1:20

Preparation of calibration curve (level 6) for Factor IX, XI, XII:

30 µl of Prediluted SHP	incorrect: 1:25	correct: 1:10

Risk to Health
In regard to factor VIII determination, the false predilution of SHP does not have a clinical impact.

Factor XII deficiency is not associated with bleeding symptoms; the clinical role of factor XII deficiency in unclear and minor increase will not affect patient's health.

The described issue may cause erroneous results that could lead to an incorrect classification of hemophilia B. Erroneously increased values for coagulation factors IX and XI determinations may increase the risk of bleeding in patients that are not appropriately managed.

Look back is not recommended in hemophilia patients, because these patients are regularly monitored.

Siemens Healthcare Diagnostics Products GmbH

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35041 Marburg, Germany

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Actions to be taken by Customer
Please be advised to discontinue the use of the affected application sheets for determination of endogenous coagulation factors from the BFT* II Reference Guide Versions 3.00, 3.01 and 3.02. Please contact your local Siemens representative in order to receive the revised BFT* II Reference Guide.

Please distribute this information to all appropriate personnel in your laboratory, retain a copy in your files and forward this information to all parties that may use this product.

We apologize for any inconvenience that this situation has caused. Thank you for your continued support.

Sincerely yours,

Original signature is on file

.....……
Dr. Norbert Dedner
Director
Quality Systems & Compliance

Original signature is on file

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Burcin Seza Guney
Senior Product Manager
Global Marketing Hemostasis

EFFECTIVENESS CHECK

Incorrect SHP Predilution in Reference Guide of BFT* II Analyzer for all Endogenous Coagulation Factors

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated November 2013 regarding incorrect SHP predilution in the BFT* II Analyzer Reference Guide Versions 3.00, 3.01 and 3.02 for all endogenous coagulation factors.

Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number indicated at the bottom of this page.

I have read, understood and implemented the information provided in the November 2013 letter # BR-00114. Yes ☐ No ☐

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number(s):

Street:

City: State: Phone:

Customer Sold to #: Customer Ship to #

PLEASE FAX THIS COMPLETED FORM TO your local Siemens representative.