

Urgent Field Safety Notice

POC 16-020.A.OUS

July 2016

Xprecia Stride™ Coagulation Analyzer

Data Management Software CD V1.0 Included with Some Analyzers

Our records indicate that your facility may have received the following product:

Table 1. Affected Product

Analyzer	Siemens Material Number (SMN)	Data Management Software CD inside Analyzer Kit
Xprecia Stride Coagulation Analyzer	10714595	V1.0

Reason for this Urgent Field Safety Notice

Siemens Healthcare Diagnostics has confirmed that version (V1.0) of the Data Management Software (DMS) CD was packaged with some Xprecia Stride Coagulation Analyzers. The version of the DMS CD should have been V1.1 as this will match the version of firmware pre-loaded on the analyzer. These two versions must match in order to provide full functionality to the analyzer.

Risk to Health

There is no impact to patient results or to the safety of the operator.

Actions to be Taken by the Customer

- If a V1.0 DMS CD was included with your analyzer, please discard it and complete the attached form to request a V1.1 DMS software CD.
- If you loaded firmware onto your analyzer with a V1.0 DMS software CD, you will need to reload the firmware onto your analyzer with a V1.1 DMS software CD.
- If a V1.1 DMS software CD was included with your analyzer, then no action is needed.

Please retain this letter with your laboratory records, and forward this letter to those who may have received this product.

We apologize for the inconvenience this situation may have caused. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

Xprecia Stride is a trademark of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK

Data Management Software CD V1.0 Included with Some Analyzers

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice POC 16-020.A.OUS dated July 2016 regarding Data Management Software CD V1.0 Included with Some Analyzers. Please read each question and indicate the appropriate answer.

Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

- 1. I have read and understood the instructions provided in this letter. Yes No

- 2. Do you have a V1.0 DMS software CD? Please check inventories before answering. Yes No

If the answer to question #2 above is yes, please complete the table below and indicate the quantity of V1.1 DMS CDs required.

Product Description	Quantity of V1.0 DMS Software CDs Discarded	Quantity of V1.1 DMS Software CDs Required
V1.0 DMS Software CD (SMN # 10714617)		

Name of person completing questionnaire: _____

Title: _____

Institution: _____ Instrument Serial Number: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

To fax this completed form please send it to the Customer Care Center at (###) ###-####. If you have any questions, contact your local Siemens technical support representative.

Signature	
Company Stamp	

2 Edgewater Drive
Norwood, MA 02062

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DQSP-00003-T1V2.0 Effective: June 28, 2016
Related Procedure: DQSP-00003 Field Action