Urgent Field Safety Notice

ProTime® 3 Cuvettes
Product Codes: PRO3-25 and PRO3-50
Reference Number IVD12.099 RAF 12-009
Return of Medical Device to the Supplier

Date

Attention:
ProTime3 Cuvette Home User

Details on affected devices:
Please refer to the attached list of affected ProTime3 cuvette lot numbers.

Description of the problem:
ITC is conducting a voluntary medical device field safety corrective action of some of its ProTime3 Cuvettes which you use. This action does not involve the ProTime instrument or the ProTime5 cuvette. We apologize for this inconvenience and we assure you that we are addressing this matter.

ITC is requesting the return of some ProTime3 disposable cuvettes because INR test results may be lower than expected, or lower than a laboratory analyzer's result. Test results that are too low may contribute to administering an improper dose of Coumadin or warfarin medicine and increased the risk of bleeding. Four adverse event reports have been received by ITC; the events occurred in the US and no permanent injuries or deaths were associated with these reports.

ITC recommends that you contact your physician and make them aware of the situation. Your PT/INR record should be reviewed and INR trends evaluated to determine if a repeat test is warranted. The repeat test, if required, should be conducted using a ProTime5 cuvette or a reference laboratory. The ProTime5 cuvettes are available and can be used on your ProTime instrument for PT/INR testing. Please refer to the enclosed information for more information about the ProTime5 cuvettes.

ITC requests that you contact your Dealer or ITC Technical Support (Telephone 1-732-548-5700 extension 4707 or Email ProTime@itcmed.com) immediately to report any patient injury that may have resulted from use of ProTime3 Cuvettes.

Please take the following actions:

1. Check your cuvettes to determine if you have any of the affected lots listed in the attached table.
2. If you have any affected lots, stop using them.
3. Fill out the attached Patient Self Tester Tracking Form and return it to your Dealer.
4. Your Dealer will contact you to arrange for return of any affected cuvettes you have to them. They will also arrange to provide you with replacement product for unused, unopened cuvettes.

Please contact your Dealer or ITC Technical Support (Telephone 1-732-548-5700 Extension 4707 or email ProTime@itcmed.com) immediately if you become aware of an adverse event due to the use of affected ProTime3 cuvettes.

ITC has notified the relevant National Competent Authorities of this FSCA. The Authorized Representative is MDSS GmbH (Telephone: +49 511 6262 8630) or email info@MDSS.com.

We apologize for any inconvenience that this matter may cause.

Please call your Dealer if you have any questions or need additional information.

20 Corporate Place South
Piscataway, NJ 08854 USA
Telephone +1-732-548-5700

RAF 12-009
ProTime3 Cuvettes
List of Affected Lots PRO3-25 or PRO3-50

Cuvette Pouch Lot Number	Outer Package Lot Number	Item Number	Expiration Date (m/dd/year)

Patient Self Tester Response Form

ProTime3 Cuvettes Product Code: PRO3-25 or PRO3-50

IVD12.099 RAF# 12-009

Please complete and return this form:

Name _____

Address _____
Street

_____
City Country Postal Code

Telephone Number _____

E-Mail Address _____

Please select all that apply:

☐ I have read and understand the attached letter.

☐ I do not have any of the affected lots of cuvettes.

☐ I have the following cuvettes that were listed on the attached table and have stopped using them:

What is the ProTime3 Cuvette Lot Number?	How many unused cuvettes do you have?

☐ I was not able to complete the actions provided in the letter because (please describe below):

_____

_____ _____
Signature Date

_____
Name (Print)

Return this form to your Distributor

PATIENT INFORMATION – ProTime® Cuvette Comparison

For Patients previously using the ProTime 3 Cuvette

The kit you are receiving contains the ***ProTime5*** Cuvette. The **ProTime5** Cuvette in this kit is intended for patient self testers and can be used on your existing ProTime Microcoagulation System.

Please note the following:
The sample volume required by the ProTime 5 is slightly larger. To accommodate the increased sample volume, the ProTime 5 is packaged with a Tenderlett that has a larger collection cup.

Please follow these steps to ensure a good sample:
- After incising the finger, wipe away the first drop of blood.
- Make sure to gently massage from the base of the finger to force blood to the tip so that a large drop of blood forms.
- Touch the large drop of blood to the collection cup. Keep adding blood until the blood level fills the cup above the line.

NOTE: Please do not interchange the Tenderlett® packaged with the ProTime3 and the Tenderlett packaged with the ProTime5.

	ProTime 3	ProTime 5
Description	▪ Blue color coded for ID ▪ 1 channel for PT ▪ 2 channels for controls ▪ Requires 27 µl of blood (approximately 1 large drop)	▪ Black color coded for ID ▪ 3 channels for PT ▪ 2 channels for controls ▪ Requires 65 µl of blood (approximately 3 drops)
Image		
Product Codes	**PRO3-4** The kit contains the following: ▪ 4 PRO3 Cuvettes ▪ 4 Tenderlett Plus LV ▪ 4 Antiseptic wipes ▪ 4 Gauze pads	**PRO5-4** The kit contains the following: ▪ 4 PRO5 Cuvettes ▪ 4 Tenderlett Plus ▪ 4 Antiseptic wipes ▪ 4 Gauze pads
Incision Device	Tenderlett Plus LV	Tenderlett Plus