



NEW DIMENSIONS IN DIAGNOSIS™

URGENT: MEDICAL DEVICE RECALL

Dear Triage® MeterPro™ Customer:

We have identified an issue in **Triage MeterPro (part numbers 55070/55071, all serial numbers), software version 5.02**. Enclosed is a software upgrade (version 5.02.028) that will immediately resolve the matter. We ask that you take the time today to install this upgrade by following the attached Software Installation Instructions and then complete and return the Certificate of Installation that is also enclosed herein. Please note that there is no need to return your meter and/or any Triage products - **this software upgrade will fulfill the recall requirement**. This recall extends to the user level.

The issue has two possible manifestations:

- Corruption of the reagent lot memory which prompts the user to REINSTALL reagent and QC Device code chips
- Potential failure of the QC Sample Lockout feature to identify a failed external QC result. This does not apply when the QC Sample Frequency is set to "NONE"

The potential health hazard associated with this issue is the extremely remote possibility of an incorrect result, either higher or lower, meaning a potential false positive or false negative. **The likelihood of an incorrect result is extremely remote, requiring a confluence of five specific meter conditions combined with operator actions unlikely to all be met. However, in order to eliminate any possibility of an incorrect result, we encourage you to install this upgrade today.**

BIOSITE

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INSTRUCTIONS TO CUSTOMERS:

You can determine whether or not the issue has occurred in your meter by navigating as follows:

- Navigate to the "RECALL RESULTS" menu;
- Select QC RESULTS;
- Select REAGENTS LOTS – QC

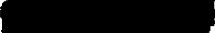
The meter will then display a list of all Reagent Lots in the meter memory. If any of the Panel names are listed as "invalid" then the issue has occurred. If all of the names are properly displayed, then the issue is not active. We recommend checking the Reagent Lots – QC list for the word "Invalid" after every reagent lot code chip is installed.

UNTIL SOFTWARE VERSION 5.02.028 IS INSTALLED, THE ISSUE COULD BECOME ACTIVE. PLEASE REFER TO THE ATTACHED SOFTWARE INSTALLATION INSTRUCTIONS.

Should you have any questions about the information contained in this recall notice or would like additional information on the use of the Triage MeterPro, please contact Biosite Technical Support at (888)-BIOSITE (246-7483), option 1.

Sincerely,




Sr. Manager, Regulatory Compliance
Biosite Incorporated

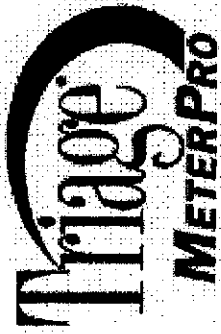
Enclosures



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SOFTWARE INSTALLATION INSTRUCTIONS

1. Turn the meter on and allow it to run self-test	
2. At the main menu, select	INSTALL NEW CODE CHIP
3. Press Enter	
4. Screen will display:	INSERT CODE CHIP
5. Insert Supervisor Code Chip® Module into Code Chip Module port	
6. Press Enter	
7. Meter briefly displays message:	PLEASE WAIT READING CODE CHIP
8. Then displays:	SUPERVISOR CODE CHIP IN PORT TO LOAD PROGRAM REMOVE IT AND INSERT PROGRAM CODE CHIP
9. Remove Supervisor Code Chip Module	
10. Insert Software Upgrade Code Chip Module	
11. Press Enter	
12. Meter displays message:	PLEASE WAIT LOADING PROGRAM
13. The software loads into the meter. This may take up to 3 minutes.	SOFTWARE UPGRADE SUCCESSFUL
<i>(If you receive the message "Software Upgrade Unsuccessful", pull the chip out , reinsert it and try again.)</i>	
14. Press Enter.	
15. The meter performs a System Test. During this test it will display the software version in lower left-hand corner and returns to main menu. Verify this number is 5.02.028.	
16. Remove Software Upgrade Code Chip Module	
17. Run the QC Device.	
18. Federal regulations require Biosite to maintain customer records for this software upgrade. We have included a software upgrade certificate in this packet that after faxing to Biosite, you may add to your instrument records. You may also complete a certificate of installation online at www.biosite.com .	
After upgrading all meters in your institution, the Software Upgrade Code Chip Module may be discarded. In the interest of environmental impact, we have provided a self-addressed stamped envelope for you to return the Software Upgrade Code Chip Module to Biosite.	



CERTIFICATE OF INSTALLATION

Triage[®] MeterPro Software

Site Name _____ Software Version _____

Address _____ Comments _____

City, State, Zip _____

Meter(s) Serial # _____

Date of Install _____

Installation Performed by _____ Name / Title _____

Signature _____

Installation Successful? _____ Yes / No

Meter Turned Off/On and System Test Completed Successfully? _____ Yes / No

QC Device Run Successful? _____ Yes / No

Please complete the Certificate of Installation online at www.biosite.com or return this form by fax to (858) 404-0796.