

**IMPORTANT SAFETY ALERT - BacT/ALERT® BacT/VIEW® Users**

December 16, 2005

Dear Blood Bank and Laboratory Services Supervisor,

We are sending this letter to inform you of a database corruption situation that may lead to a failure to report positive cultures or cause a delay in appropriate patient therapy when using the BacT/VIEW® data management feature of our BacT/ALERT® system. Database corruptions can interrupt communication between the BacT/VIEW computer and a site's laboratory information management system/laboratory information system (LIMS/LIS). While this type of corruption will not impact the accuracy of your bottle results, it can cause a delay in the transmission of these results to your site's LIMS/LIS system. Awareness and understanding of this issue is important for laboratories who:

- 1) Provide patient testing and blood component bacterial testing services to blood banks and/or hospital blood transfusion services and,
- 2) Rely solely upon their LIMS/LIS system for notification of positive bottle results.

It is important that the information below be communicated appropriately within your laboratory to increase awareness of:

- 1) What happens when a PC database corruption occurs,
- 2) Where to find instructions within the User's Manual that will allow you to troubleshoot the issue,
- 3) Actions that may be taken in order to reduce the likelihood that a PC database corruption will occur, and
- 4) Actions that may be taken in order to reduce the impact of a database corruption on your laboratory's ability to get current results from your LIMS/LIS system.

The attachments provide additional information to help you address this issue. We hope you will find this information useful. Please complete the attached acknowledgement form and fax it back to Nathan Hardesty at 314-731-8689 upon receipt of this letter. If you have any questions please contact your local customer service department.

Regards,

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*Sandra L. Perreand*  
*Director, Regulatory Affairs*  
*bioMerieux, Inc*

## Background:

The BacT/VIEW<sup>®</sup> computer uses a conventional Intel based PC platform. As with all PC's, users will occasionally experience software or hardware failures that prevent a PC from communicating or functioning as intended. In the case of BacT/VIEW software, a database corruption<sup>1</sup> will trigger the appearance of the "OpenInsight<sup>®</sup> Debugger" screen, a message indicating "String space format error", or other error messages. When these messages appear, you should contact bioMerieux Service immediately for assistance, as described in the Troubleshooting section of your BacT/VIEW Users Manual.

It is important to realize that when a computer failure occurs, the BacT/VIEW may not be able to communicate with a site's LIMS/LIS system. In this case, new bottle culture results will not be transmitted to the site's LIMS/LIS system until the error situation is resolved. Depending upon how your LIS interface is programmed, if a BacT/VIEW error message goes undetected by the site, notification of positive results can be delayed. Health care providers may not be provided up to date results.

Electrical storms or other heavy equipment on the same AC circuit can create power fluctuations that may cause database corruptions in PC's, including the BacT/VIEW. In order to limit the impact of such occurrences, we recommend that a dedicated power circuit be used for the system.

There are steps that can be taken to minimize the occurrence of database corruption errors. These steps include:

1. Do not reboot the computer without first properly exiting the BacT/VIEW software,
2. Do not abruptly turn off the computer or remove its power supply,
3. Run the BacT/VIEW system using a protected power source either from an Uninterruptible Power Supply (UPS) or through a conditioned power line.

There are also workflow practices a laboratory can utilize that can minimize the impact of a data base corruption or other computer failure. These include:

1. It is imperative that you validate your LIMS/LIS connection and its subsequent functionality upon interfacing with our BacT/VIEW software. This applies whether your site is using an "off the shelf" LIMS/LIS system or a site developed LIMS/LIS systems.
2. Do not turn off the audible alarms on the BacT/ALERT<sup>®</sup> system or on your LIMS/LIS system.
3. We recommend that laboratory personnel check the status of the your BacT/ALERT system at least once per shift to ensure that there are no error messages on the screen of the BacT/VIEW<sup>®</sup> computer and check for any positive bottles on the BacT/ALERT<sup>®</sup> control module screen.
4. Your LIMS/LIS should be designed to raise an alarm or provide some other notification to staff when the BacT/VIEW computer stops communicating with LIMS/LIS system.

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<sup>1</sup> A database corruption, as defined here, is an error in the organization of data stored on the computer's hard drive. This corruption does not modify test results in the database or the instrument, but prevents the BacT/VIEW software from accessing its stored data successfully.

5. We recommend programming your LIMS/LIS to periodically query BacT/VIEW for new test results if you are relying solely on your LIMS/LIS system instead of the BacT/VIEW or the BacT/ALERT 3D control module for notification of test results.
  - a. If BacT/VIEW does not provide a response to the query within 15 minutes, then test results in the LIMS/LIS cannot be trusted until BacT/VIEW is responsive again. In this case, the LIMS/LIS should raise an alarm or provide some other notification to staff that results are not up to date.
  - b. You should note that BacT/VIEW can be non-responsive for up to an hour while it performs a routine system backup. The time of day when a backup is made is controlled by your site's setup of BacT/VIEW and it may be beneficial if all laboratory personnel are informed of the scheduled backup time.
  - c. Laboratory personnel should be trained on how to detect and respond to a loss of communication between the BacT/VIEW computer and LIMS/LIS the system.
6. If the bottle result field on your LIMS/LIS system is blank and the test time elapsed has exceeded the minimum incubation period required by your laboratory's testing protocol, you may be having a data transmission problem. The BacT/VIEW sends results with the date/time the bottle was loaded and the date/time results were transmitted.

**SAFETY ALERT - BacT/ALERT® BacT/VIEW®**

**Customer Information:**

Customer Number: \_\_\_\_\_ Facility Name: \_\_\_\_\_

Address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Contact Name: \_\_\_\_\_  
Contact Title: \_\_\_\_\_

Phone Number: \_\_\_\_\_  
Fax Number: \_\_\_\_\_

Date of Acknowledgement: \_\_\_\_\_

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**It is imperative that you complete this Response Form and return it by fax to the number indicated below. This form is used for tracking purposes in compliance with FDA regulations.**

Please fax this form to (314) 731-8689 or (919) 620-6350, attention Nathan Hardesty.

If you have any questions please contact your local bioMérieux representative.