



## VIGTIG PRODUKT INFORMATION

Dear Valued bioMérieux Customer,

Our records indicate that you have received one of the following products.

**Product Description:** BacT/ALERT® 3D B.40.xx firmware

### Description of issue:

BacT/ALERT® instrument software architecture is linearly designed to scan, process and load one bottle at a time. bioMérieux recently launched the new BacT/ALERT® 3D B.40.xx firmware that contains additional features such as bottle recalculation and bottle authentication. As a result of the additional features, customers with Control Modules containing LBC-586 CPUs, distributed from 1997 through November 2007, and running B.40 firmware may exhibit a slightly slower instrument interface issue that may result in bottles being improperly loaded into the instrument.

To aid the user when loading bottles, the instrument provides auditory feedback to indicate when bottles have been properly scanned. The BacT/ALERT User Manual does not clearly define the functionality of the audible beeps or the consequence if the proper loading sequence is not followed. The proper auditory sequence is two beeps after scanning the Bottle ID barcode and three beeps after scanning the Accession ID barcode. An improper load occurs when the user performs another action (such as loading a bottle or scanning another barcode) before the reply beep(s) have been issued. An improper load results in the first bottle not being recognized as being loaded in the instrument and the second bottle's readings being incorrectly reported in association with the first bottle. Improper loads of two bottles can occur multiple times when loading batches of bottles.

### Impact to the Patient:

BacT/ALERT® Culture Bottles are used with the BacT/ALERT® Microbial Detection System in qualitative procedures for the recovery and detection of microorganisms (bacteria and yeast) from specimens including: blood and other normally sterile body fluids and processed or aseptically prepared products.

Customers who improperly load bottles may experience one or more of the following incorrect results from the instrument:

- No results for bottles not being recognized as being loaded in the instrument
- False negative or false positive results due to improper algorithm assignment
- Positive results reported on the wrong patient
- Negative results for a patient who may have a true positive result

**Required actions:**

We have modified our instructions for use to clarify how to properly load bottles and to provide appropriate cautions and warnings concerning bottle loading, especially in regards to the audible beep indicators. Pending introduction of new labeling, please review and implement the enclosed correction to the BacT/ALERT User Manual (Attachment B) when using the BacT/ALERT B.40 firmware.

We request you take the following actions at this time:

1. Ensure this letter and guidance in Attachment B on how to properly scan and load bottles into the BacT/ALERT 3D instrument is distributed, and training is provided to all appropriate personnel within your organization.
2. To check for lost bottles in your system:
  - a) Identify all anonymous bottles following the Handling Anonymous Bottles procedures in the BacT/ALERT 3D User Manual.
  - b) Ensure there are no anonymous bottles currently loaded in the instrument.
  - c) Reboot the system following the Reboot/Shutdown procedure in your BacT/ALERT 3D User Manual.
  - d) If anonymous bottles are detected as a result of the instrument reboot, remove the bottles from the instrument, immediately subculture the bottles, and call your bioMérieux representative to report the incident.
3. Fill out and return the Acknowledgement Form in Attachment A by Fax to confirm receipt of this notice.

bioMérieux is committed to providing our customers with the highest quality products. We sincerely apologize for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please contact your local bioMérieux Customer Service representative.

Thank you for your continued use of bioMérieux products,

**Tina Alsing**  
**Application Specialist**  
**bioMérieux Nordic**



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**Attachments**

Attachment A – Customer Acknowledgement Form

Attachment B – Supplementary Instructions For Use – Bottle Loading