bioMérieux

BIOMÉRIEUX

BacT/ALERT® 3D

B.25 UPDATE INFORMATION

For internal Use Only

bioMérieux , Inc
Box 15969
Durham, NC 27704-0969/USA
Tel. (1) 800-682-2666

Rev 1
18 May 2006
KC5-060414

TABLE OF CONTENTS

1. OVERVIEW

The BacT/ALERT® 3D B.25 software release is intended to be a mandatory upgrade to incorporate 21 CFR Part 11 compatibility features, Health Insurance Portability and Accountability Act (HIPAA) compatibility features, and high priority product extensions and improvements to the BacT/ALERT® 3D instrument line. It shall be available to all customers with existing installations and applied to new BacT/ALERT® 3D systems prior to distribution. The upgrade of current installation is intended to be performed by either the customer or by bioMérieux personnel. The update should take 30 to 45 minutes to complete. The BacT/ALERT® 3D instrument must be using software version B.12 for this update to be successful.

The purpose of this document is to provide bioMérieux subsidiaries and distributors with an awareness of design changes made in BacT/ALERT® 3D B.25 software. Changes that are involved in the day-to-day customer interaction with the BacT/ALERT® 3D have been detailed in the "New Features Guide for Software Version B.25". Please refer to this document for more details on these features. This document will discuss changes that involve support of the system by service or application specialists; it also presents technical information not generally given to customers. **This document is for internal use only and should not be given to customers.**

2. SETUP AND CONFIGURATION SCREEN

In software versions prior to BacT/ALERT® 3D B.25 software, changes to the instrument configuration and setting customer preferences were made in the INI files. This required exiting the software and accessing either the BTA3D.INI file or the EXTCOMP.INI file. There was no ability to track when changes were made or who made the changes to these initialization files. 21 CFR Part 11 compatibility requires the ability to track when these types of changes are made. To meet this requirement, the initialization (INI) files were eliminated and replaced with secure, application controlled configuration abilities. A new screen, Setup and Configuration screen, has been added to the Setup screen. This screen is accessed by pressing the new Setup and Configuration button, which is only available on the set up screen when logged on with the Service password (43432121 then touch the Key icon). The Setup and Configuration button has replaced the Configuration button. The Display Configuration screens are now accessed from the Setup and Configuration screen.

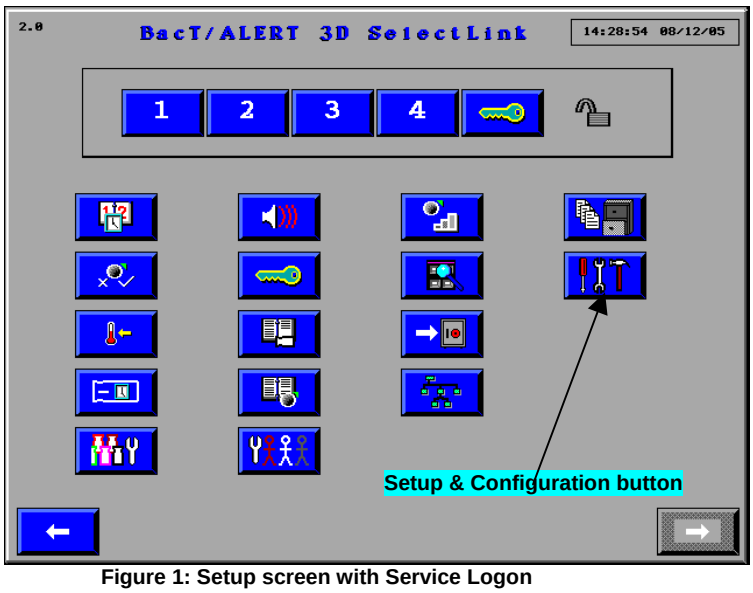

Figure 1: Setup screen with Service Logon

To access the Setup and Configuration Screen:

- Access the Setup screen
- Enter the Service password (43432121)
- Touch the Setup and Configuration button
- The Setup and Configuration screen will appear

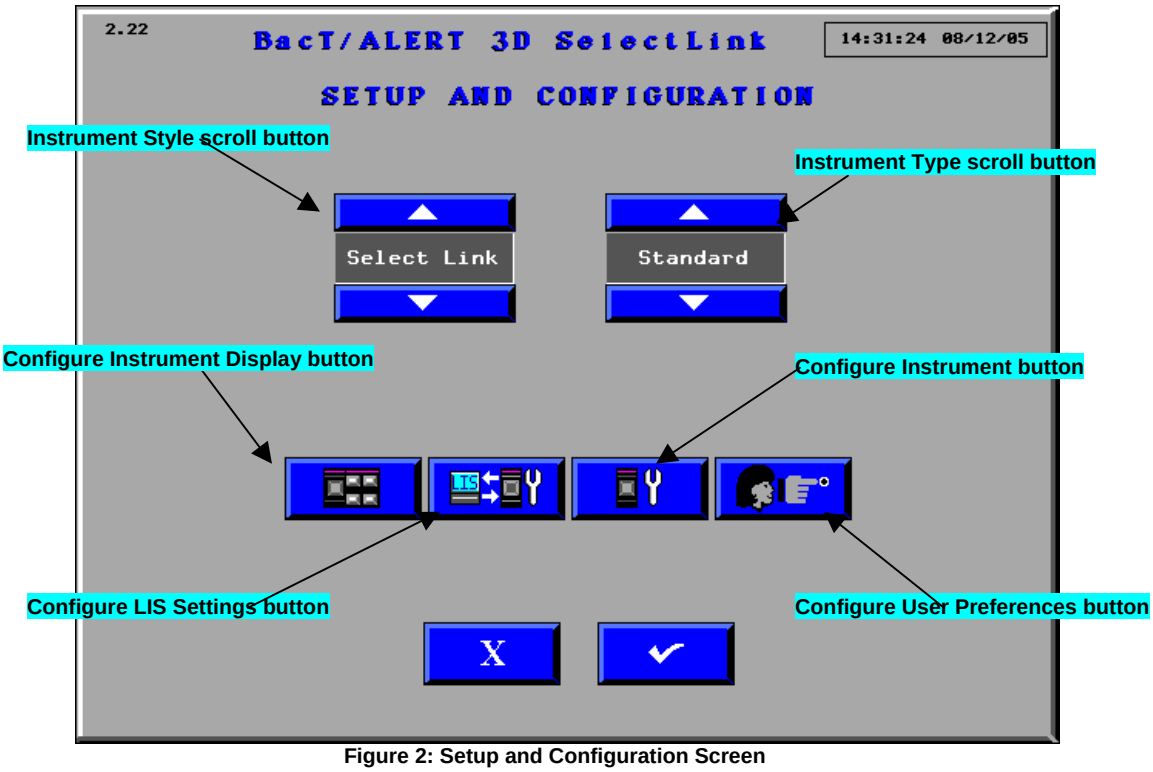

Figure 2: Setup and Configuration Screen

2.1 Instrument Style And Instrument Type Scroll Button

The Instrument Style scroll button allows service personnel to determine the style of the instrument. The options are Signature, Select, and Select Link. Press the up or down arrow to

scroll to the desired instrument style. The Instrument Type scroll button allows service personnel to determine the type of instrument. The options are Standard, Right Combo, Left Combo, Sixty. Press the up or down arrow to scroll to the desired instrument type. Pressing the check box will accept changes made to either of these settings. If changes are made and the check box is pressed, the instrument will automatically exit the software and go to the DOS prompt. When the system is restarted the new style and instrument type will be in effect.

2.2 Configure Instrument Display Screen

In previous versions of BacT/ALERT® 3D, this screen was accessed using the Configure Screen button available on the Setup screen when logged on with the Service password. It is used to configure the instrument display seen on the Main screen to match the physical set up of Controller Module and incubators currently installed. BacT/ALERT® 3D B.25 software made no changes to this screen or its functions.

2.3 Lis Configuration Screen

This screen allows service personnel to configure LIS settings.

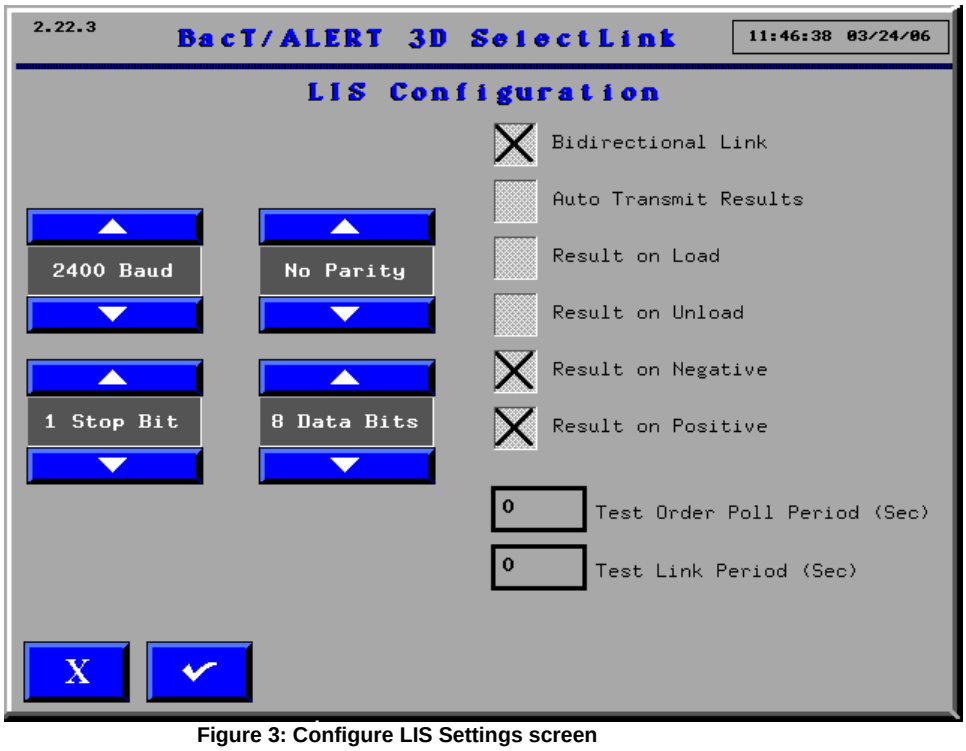

Figure 3: Configure LIS Settings screen

The scroll buttons are used to set the connectivity settings of BacT/LINK® to correspond with the settings of the user's LIS. The check boxes are used to set desired transmission options as follows:

- **Bidirectional Link**: If the box is not checked, data can only be transferred from the LIS to the BacT/ALERT® 3D. If the box is checked, data can be transferred in both directions.
- **Auto Transmit Results:** If the box is not checked the BacT/ALERT® 3D will only send results when polled by the LIS. If the box is checked, the BacT/ALERT® 3D will send results when they occur.
- **Result on Load:** If the box is check, the BacT/ALERT® 3D sets a flag so that bottle results of negative to date are sent to the LIS when the bottles are loaded. This feature is disabled if the box is not checked.
- **Result on Unload:** If the box is checked, the BacT/ALERT® 3D sets a flag so that bottle results are sent to the LIS when the bottles are unloaded. This feature is disabled if the box is not checked.
- **Result on Negative:** If the box is checked, the BacT/ALERT® 3D sets a flag so that results are sent to the LIS when the bottle goes from non-negative to negative or vice versa. This feature is disabled if the box is not checked.
- **Result on Positive:** If the box is checked, the BacT/ALERT® 3D sets a flag so that results are sent to the LIS when the bottle goes from non-positive to positive or vice versa. This feature is disabled if the box is not checked.
- **Test Order Poll Period (Sec):** If the setting is zero, the BacT/ALERT® 3D will not periodically poll the LIS for new test orders. A setting greater than zero indicates how often (in seconds) the BacT/ALERT® 3D will poll the LIS for new test orders.
- **Test Link Period (Sec):** If the setting is zero, the BacT/ALERT® 3D will not test the link with the LIS. A setting greater than zero indicates how often (in seconds) the link with the LIS will be tested.

2.4 Instrument Configuration Screen

This screen allows service personnel to configure settings related to the functionality of the instrument. Some of these settings set the boundaries for the appearance of error codes.

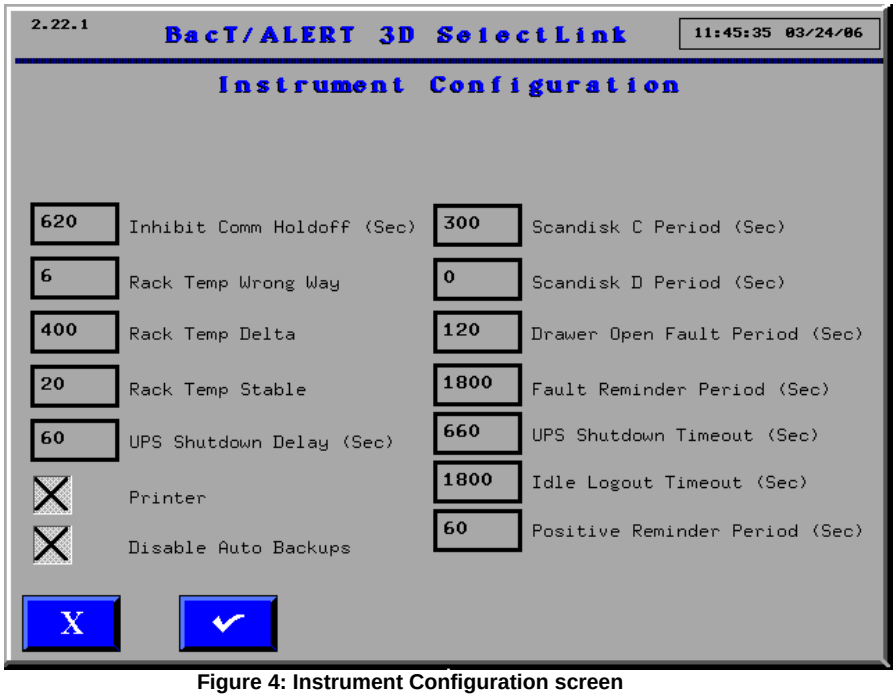

Figure 4: Instrument Configuration screen

- **INHIBIT COMM HOLDOFF (SEC):** Determine the time (in seconds) before the system will perform an Incubation Module power cycle following a communication problem between the Controller and Incubation Modules.
- **RACK TEMP WRONG WAY:** This setting determines how many times a rack temperature can move away from the set point before a fault is declared. **Note**: Changing this setting is not recommended.
- **RACK TEMP DELTA:** This setting determines the maximum temperature difference from the setpoint that will be tolerated before an error code is displayed. **Note**: the scale is Celsius x100. In the above example, 400 is equal to 4.00 Celsius degrees. **Note**: Changing this setting is not recommended.
- **RACK TEMP STABLE:** If the magnitude of the temperature change is less than this amount, the temperature is considered to be stable. **Note**: the scale is Celsius x100. In the above example, 20 is equal to 0.2 Celsius degrees. **Note**: Changing this setting is not recommended.
- **UPS SHUTDOWN DELAY (SEC):** This setting determines the delay in seconds between a power fault detection by the UPS and the time the BacT/ALERT® 3D sends a signal to the UPS to shutdown.
- **PRINTER:** A check in this box installs the printer icons for Select and SelectLink configurations. The software will need to be restarted before the printer connection is functional.
- **DISABLE AUTO BACKUPS:** A check in this box disables the automatic performance of a backup; only manual backups can be performed. If the box is not checked, the user can set a time for the performance of an automated backup by going to the Backup Management screen.
- **SCANDISK C PERIOD (SEC):** This setting sets the time period in seconds between the performance of a scandisk operation on the C drive. If this field is set at zero, no scandisk operations are performed on the C drive.

- **SCANDISK D PERIOD (SEC):** This setting sets the time period in seconds between the performance of a scandisk operation on the D drive. If this field is set at zero, no scandisk operations are performed on the D drive.
- **DRAWER OPEN FAULT PERIOD (SEC):** This setting determines the amount of time (in seconds) a drawer can be open before the Instrument Fault 20 ('Drawer Open Too Long') displays. If zero is entered in this box, the Instrument Fault 20 will not display regardless of how long the drawer has remained open.
- **FAULT REMINDER PERIOD:** This setting determines the time (in seconds) after which a silenced alarm and visual alarm will sound and display if the error condition has not been removed. If a zero is entered in this box, there will be no audio or visual reminder.
- **UPS SHUTDOWN TIMEOUT (SEC):** During a power failure, this setting determines the time allowed for a UPS to shutdown after the instrument has saved critical data. If the UPS does not shutdown within this time setting, the software will attempt to recover by automatically rebooting.
- **IDLE LOGOUT TIMEOUT (SEC):** This setting determines the time (in seconds) after which a timeout will occur unless a button is activated, a barcode is scanned or a bottle is loaded or unloaded. When a timeout occurs, any pending current function is cancelled. The inactivity timer does not trigger a timeout while a red operator error window is shown on the screen. If zero is entered in this box, no Idle Logout will occur.
- **POSITIVE REMINDER PERIOD (SEC):** This setting determines the time (in seconds) after which a silenced positive alarm will sound again if all positive bottles have not been unloaded. If zero is entered in this box, the alarm will only sound again when there is an increase in the number of positive bottles loaded.

2.5 User Preferences Screen

This screen is used by service personnel to set user preferences for entering Bottle ID, Accession Number, Hospital ID Number and Patient Name information. When in Signature mode, the Hospital ID and Patient Name settings are ignored.

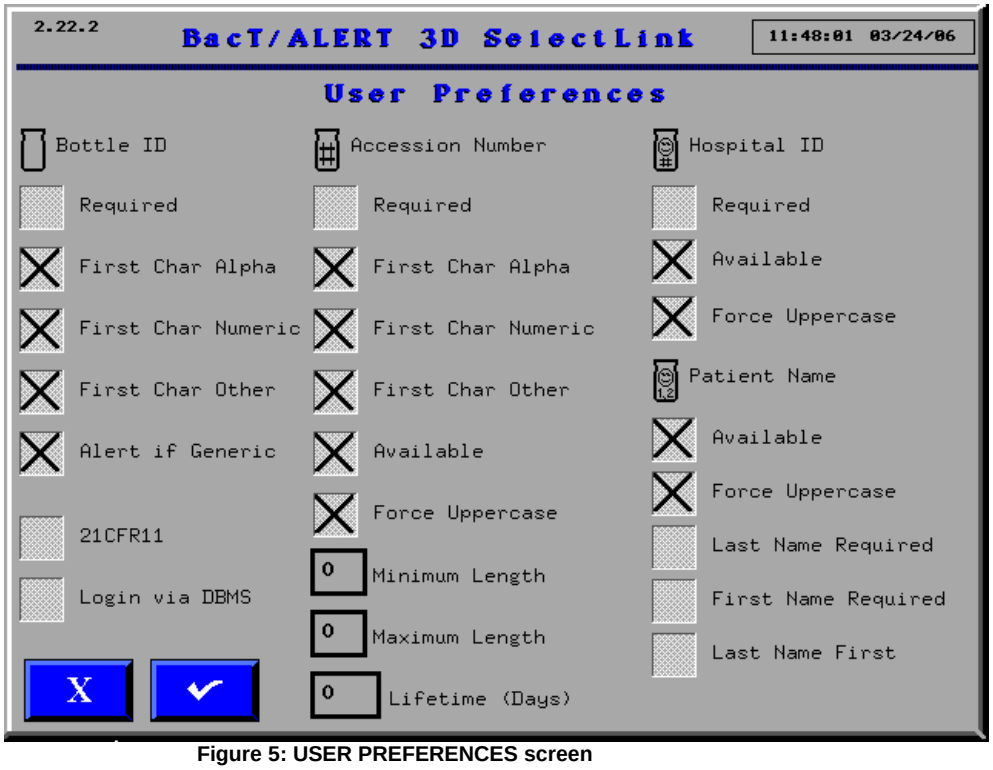

Figure 5: USER PREFERENCES screen

BOTTLE ID

- **REQUIRED:** If this box is checked, then this field must contain an entry before a bottle can be loaded; a 902 error will occur if a bottle ID is not entered. Checking this box will disable the ability to load bottles anonymously. If this box is not checked, then bottles can be loaded either as identified (a Bottle ID has been entered into this field) or anonymously.
- **FIRST CHARACTER ALPHA:** If this box is checked then the first character of the Bottle ID can be an alpha character ('A-Z' or 'a-z'). If the box is not checked, a 923 error will occur if the first character of the Bottle ID is an alpha character.
- **FIRST CHARACTER NUMERIC:** If this box is checked then the first character of the Bottle ID can be a numeric character. If the box is not checked, a 923 error will occur if the first character of the Bottle ID is a numeric character.
- **FIRST CHARACTER OTHER:** If this box is checked then the first character of the Bottle ID can be a character other than a letter or a number. If the box is not checked, a 923 error will occur if the first character of the Bottle ID is a character other than a letter or a number.

21 CFR11

- If this box is checked then the 21 CFR Part 11 mode is enabled (refer to the **New Features Guide for Software Version B.25** document for specific details regarding the 21 CFR Part 11 mode).

LOGIN VIA DBMS

- A check in this box only applies to instruments which are in 21 CFR Part 11 mode and requires a data management system capable of sending a login signal to the BacT/ALERT® 3D. This feature will not be available with the OBSERVA® data management system until a future version of OBSERVA®. **This box should not be checked until the system is connected to an OBSERVA® software version that can send a login signal to the BacT/ALERT® 3D.** If this box is checked on a system in 21 CFR Part 11 mode which is connected to a OBSERVA® data management system that is not capable of sending a login signal, the user will be unable to log on to the BacT/ALERT® 3D and access to functions will be severely decreased. Log on with the service name and password is possible if LOGIN VIA DBMS is checked and connected to a DBMS which cannot send a login signal. **Note**: This box should never be checked in a Signature system with BacT/VIEW® as the data management system.

ACCESSION NUMBER

- **REQUIRED:** If this box is checked, then this field must contain an entry before a bottle can be loaded; a 902 error will occur if an accession number is not entered.. If this box is not checked, then entry of an accession number in this field is not required before a bottle can be loaded.
- **FIRST CHARACTER ALPHA:** If this box is checked then the first character of the Accession Number can be an alpha character ('A-Z' or 'a-z'). If the box is not checked, a 923 error will occur if the first character of the Accession Number is an alpha character.
- **FIRST CHARACTER NUMERIC:** If this box is checked then the first character of the Bottle ID can be a numeric character. If the box is not checked, a 923 error will occur if the first character of the Bottle ID is a numeric character.
- **FIRST CHARACTER OTHER:** If this box is checked then the first character of the Accession Number can be a character other than a letter or a number. If the box is not checked, a 923 error will occur if the first character of the Accession Number is a character other than a letter or a number.
- **AVAILABLE:** If this box is checked then the field is enabled. If this box is not checked, the field is displayed, but it is disabled.
- **FORCE UPPER CASE:** If this box is checked, an entry in this field will be forced to upper case regardless of how it is entered. If this box is not checked then entry will appear exactly as entered.

- **MINIMUM LENGTH:** This setting determines the minimum numbers of characters allowed in an accession number when the accession number is entered manually via the keyboard at the time of Bottle load. If an accession number is entered by scanning a barcode, this setting does not apply.
- **MAXIMUM LENGTH:** This setting determines the maximum numbers of characters allowed in an accession number when the accession number is entered manually via the keyboard at the time of Bottle load. If an accession number is entered by scanning a barcode, this setting does not apply. If the number is zero, then the accession number is limited to 16 characters.
- **LIFETIME (DAYS):** This setting determines the length of time (in days) after which an accession number may be reused. If the number is zero then the accession number will always be considered to be unique (i.e. the lab does not reuse accession numbers). If the number is greater than zero, then the Hospital ID setting is enabled regardless of the Hospital ID setting in User Preferences. If this is a Signature system (i.e. data management system connected) then this setting is ignored.

HOSPITAL ID NUMBER

- **REQUIRED:** If this box is checked, then this field must contain an entry before a bottle can be loaded; a 902 error will occur if a hospital ID is not entered.. If this box is not checked, then entry of an accession number in this field is not required before a bottle can be loaded.
- **AVAILABLE:** If this box is checked then the field is displayed and enabled. If this box is not checked, the field is not displayed.
- **FORCE UPPER CASE:** If this box is checked, an entry in this field will be forced to upper case regardless of how it is entered. If this box is not checked then entry will appear exactly as entered.

PATIENT NAME

- **AVAILABLE:** If this box is checked then the field is displayed and enabled. If this box is not checked, the field is not displayed.
- **FORCE UPPER CASE:** If this box is checked, an entry in this field will be forced to upper case regardless of how it is entered. If this box is not checked then entry will appear exactly as entered.
- **LAST NAME REQUIRED:** If this box is checked, then this field must contain an entry before a bottle can be loaded; a 902 error will occur if a last name is not entered.. If this box is not checked, then entry of a last name in this field is not required before a bottle can be loaded.
- **FIRST NAME REQUIRED:** If this box is checked, then this field must contain an entry before a bottle can be loaded; a 902 error will occur if a first name is not entered.. If this box is not checked, then entry of a first name in this field is not required before a bottle can be loaded.
- **LAST NAME FIRST:** If this box is checked then the first field after the Hospital ID field will be the Last Name field. If this box is not checked then the first field after the Hospital ID field will be the First Name field.

3. 21 CFR Part 11

BacT/ALERT® 3D version B.25 software provides various security and auditing capabilities for industry users in compliance with U.S. regulations. Code of Federal Regulations Title 21, Part 11 (21CFR Part 11) is a rule established by the Federal Drug Administration (FDA) that covers the management of electronic signatures. Its purpose is to ensure regulatory compliance so that all documents, records and knowledge are controlled and managed in compliance with governmental regulations. These capabilities are only functional if the 21 CFR Part 11 mode is enabled. Enabling 21 CFR Part 11 mode can only be performed by bioMérieux personnel. The

21 CFR Part 11 mode can be enabled by bioMérieux service personnel by going to the Setup screen, logging on with the Service password, and accessing the Setup and Configuration screen (see section 2 and 2.5 of this document for details).

3.1 Logging On

When the 21 CFR Part 11 Mode is enabled, the system will require a user to log on with both user name and password to perform most functions. While not logged on, the user can load or unload bottles anonymously, view error status, view the bottle count table status, hear and clear audible alarms and view screen color changes that occur when an instrument error happens or when a bottle status changes to positive. Service personnel will be required to log on to gain full access to the system. BacT/ALERT® 3D software has a 21 CFR Part 11 Service user name and password hardcoded into the system. The Service user name is **service** and the password is **biomerieux3d**. This password should never be given to the customer. Figure 6 shows the Main screen with 21 CFR Part 11 mode enabled; this system is in the logged off status.

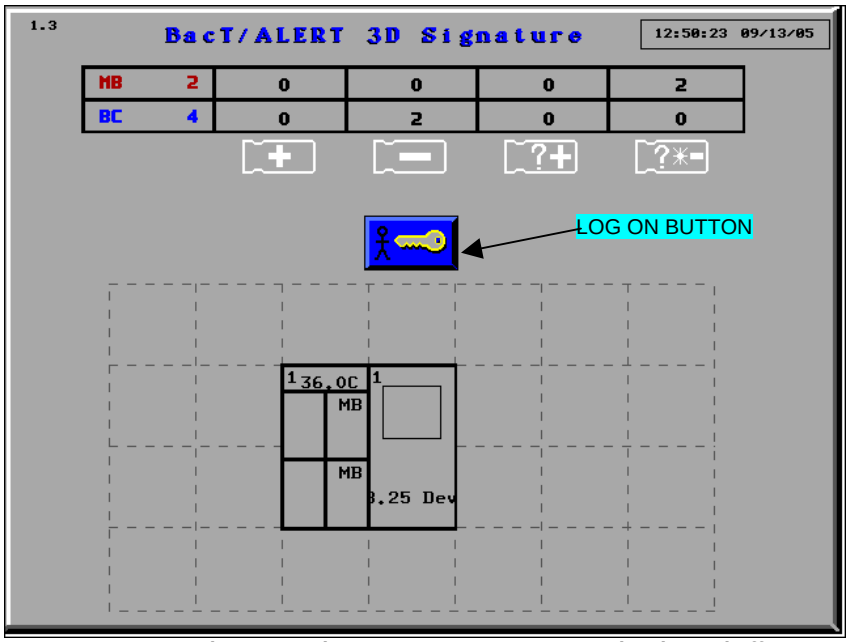

Figure 6: Main screen:21 CFR Part 11 mode – logged off status

Non-service users also must log onto the system. Each user should have a User name and a password. User names must be a minimum of one character with a maximum length of 24 characters. Passwords must be a minimum of six characters with a maximum length of 24 characters. **Note:** both User Name and Password are case sensitive. To log on touch the Log on Button on the Main screen to access the Log in screen. The Log In screen will appear (see Figure 7).

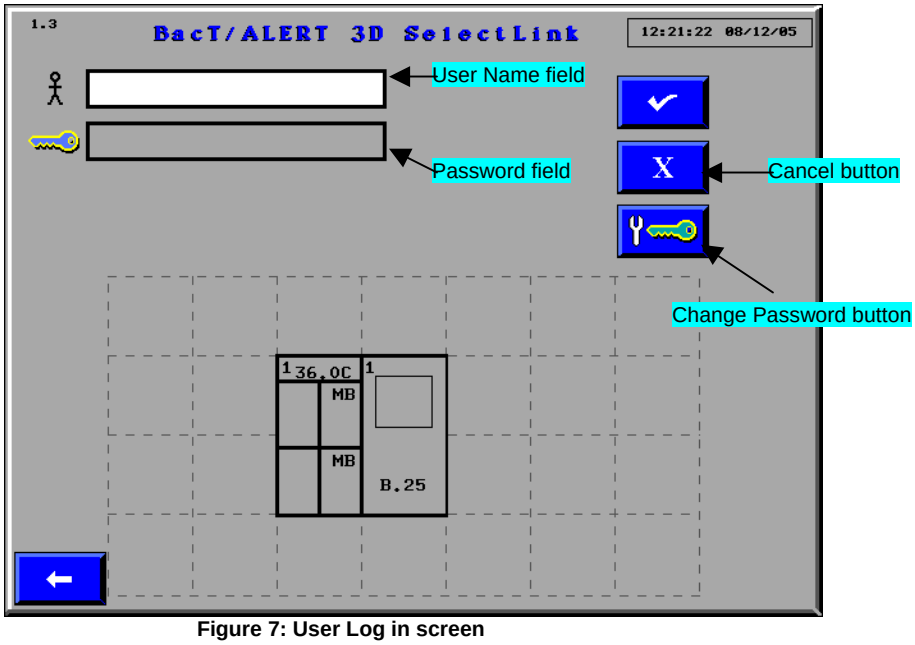

Figure 7: User Log in screen

The user must type their valid user name in the User Name field and press the Tab key or the Enter key on the keyboard to move the focus to the Password field. The user must type in their password; pressing the Check button on the screen or pressing the Enter key on the keyboard will log the user in. Pressing the Cancel button will clear both the User Name and Password fields. Press the left arrow to return to the Main screen.

Each user determines their own password. When a new user is created, the first time this user logs on they should enter their user name and press the check mark or press the Enter key on the keyboard. This will bring up the User Log In Change Password screen.

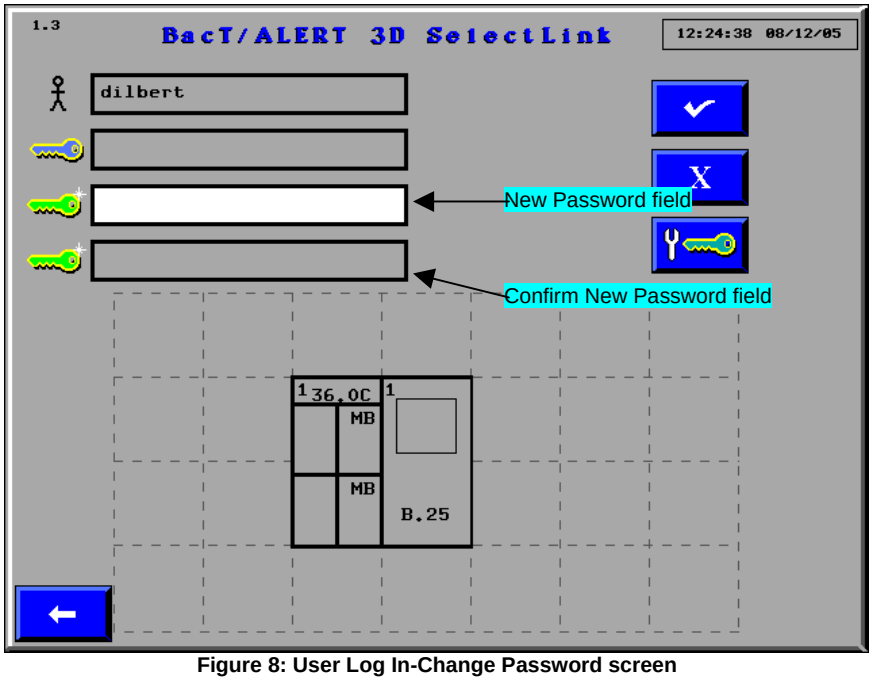

Figure 8: User Log In-Change Password screen

When a system is first upgraded to BacT/ALERT® 3D version B.25 or first installed at a customer site, there will be no user names added to the system. Logging on can be accomplished by entering the User Name of '**setup**' with a password of '**setup**'. This will provide access to the system to allow the user to create new users. Once at least one user has been created this special 'SETUP' user name and password will no longer be valid.

3.2 Logging Off

When any user (including service personnel) has completed their activity with the BacT/ALERT® 3D, they should log off of the system to assure that access by unauthorized individuals is not possible. To log off go to the main screen and click on the Log Off icon, which is located in the lower left corner of the Main screen. When this button is pressed the user will be logged off and the screen will revert to the Main screen with the Log On button displaying (see figure 6)

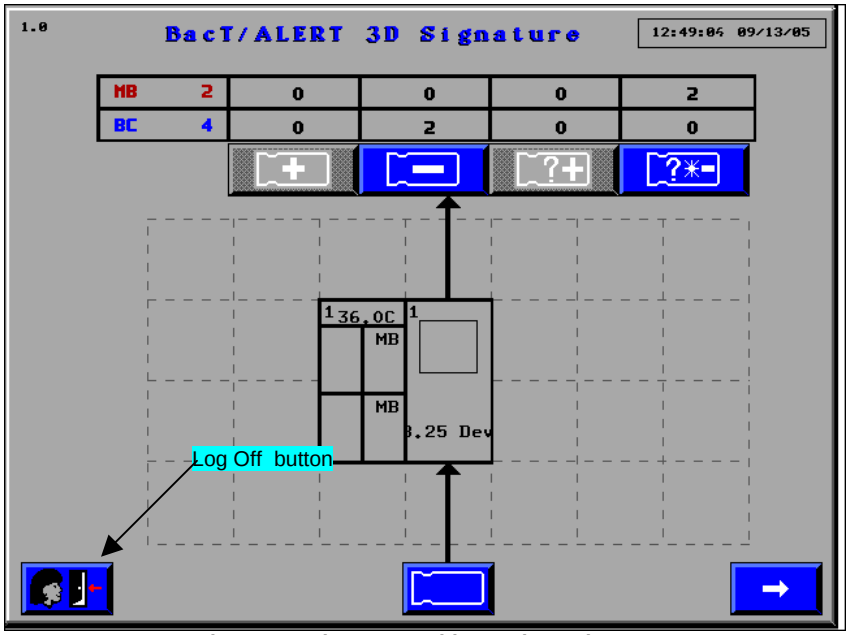

Figure 9: Main screen with user logged on

For information regarding the creation of new users, refer to the User Manual for Version B.25 or the **New Features Guide for Software Version B.25** document.

4. AUDIT TRAIL LOG

One of the requirements for 21 CFR Part 11 compatibility is an audit trail which records activities and other related information. This new feature was considered to be of value to both Clinical and Industry users regardless of the 21 CFR Part 11 mode status. If the 21 CFR Part 11 mode is activated, accessing the audit trail requires a user log on. Once the user is logged on, pressing <Ctrl + D> on the keyboard will bring up screen 2.6 Instrument Cntrl/software screen; pressing the numeric key 7 on the keyboard will display the Audit Trail. For instruments that are not in the 21 CFR Part 11 mode, access to the audit trail can be accessed once a successful log on to the Set Up screen has been achieved. After logging on at the Set Up screen, pressing <Ctrl + D> on the key board will bring up screen 2.6; pressing the numeric 7 key will display the audit trail. Refer to the User Manual for Version B.25 or the **New Features Guide for Software Version B.25** document for specific details regarding the Audit Trail. Included in the Audit trail is a log of the date and time whenever the firmware is upgraded. The Audit Trail is only in English and it is not editable.

5. EVENT LOG REDESIGN

In BacT/ALERT® 3D software, the event log has been re-designed to correct a problem, which interrupted communication with the DBMS and to increase the size to be able to log the Audit Trail events. The new design of the Event log includes separate files for high and low priority event logs. The size of the high priority event log will contain enough room for a six-incubator system to store events for at least 72 hours. The size of the low priority event log will contain enough room to store events for at least 12 hours. The rack and module temperature readings are now stored in the low priority event log. Prior to BacT/ALERT® 3D version B.25 software, bottle readings were the only events stored in the low priority event log. The high and low priority event logs are stored in separate files on the flash drive and new event data is written to these files every two minutes. When reading the event log, corrupted events can be ignored and deleted without losing all of the information in the entire log.

6. IMPROVEMENT TO SYNCHRONIZATION WITH DBMS

In previous versions of BacT/ALERT® 3D software, if the DBMS and the instrument lost synchronization the DBMS requested the instrument to resend every event from the beginning of the instrument's event log queues. This process could take a long time to reach completion. To reduce the time needed to achieve synchronization with the DBMS, the instrument will no longer send data from the earliest point of the log. It will search 72 hours from the time of the request for data and begin sending events from that point.

When BacT/ALERT® 3D software was connected to OBSERVA® as the DBMS, the two systems at times lost synchronization if the OBSERVA® computer was rebooted while the BacT/ALERT® 3D software was still running. This was triggered by extra characters, which transmitted from OBSERVA® to the instrument when OBSERVA® was rebooted. To avoid the synchronization problem a specific reboot procedure had to be followed. With BacT/ALERT® 3D software, the instrument will ignore these characters. There is no longer a need to follow the reboot procedure, which was sent out in KC5-GCS MAR 2004-09.

7. READING GAP DETECTION

It is extremely important for all service personnel to understand the new feature of gap detection. When servicing an instrument, if the software has been at the DOS level or powered off for more than 60 minutes, an Error Code 80 will display for all cells with bottle loaded. According to current BioMérieux recommendations, bottles displaying an error cord 80 must be subcultured.

The BacT/ALERT® 3D takes bottle readings every 10 minutes. If bottle readings are missed during a critical point in the algorithm a false negative status may result. It has been determined that if more than six readings are missing (time span of one hour) there is an increased risk of a false negative result. BioMérieux recommends that bottles that have missed more than 6 consecutive readings require subculture to avoid missing a positive culture.

Gaps in readings may occur if some or all of the hardware is not powered or is non-operational. Gaps may also occur if a bottle with a Negative to Date status is removed from the instrument for a time period in excess of one hour. Previous versions of BacT/ALERT® 3D software did not provide the user with the ability to determine the time-span of missing readings. BacT/ALERT® 3D version B.25 software alerts the users to bottles, which have more than one hour's missed readings.

For any bottle, if there is more that 60 minutes between two consecutive bottle readings, the instrument will display a Error Code 80 on the Cell Status screen and an audible alarm will sound

if activated. This error code will appear only for bottles with a status of 'Negative to Date' when the gap occurs. These bottles will have a 'How Determined' code of 205 on the Edit Bottle Detail screen. A 'How Determined' code of 205 means "Missed Readings". Bottles that have a status of positive or negative at the time of the gap detection will not display an Error Code 80.
NOTE: the instrument will continue to take readings on bottles displaying an error 80 code.

When a bottle displays an Error Code 80, bioMérieux recommends that the bottle should be unloaded, subcultured and then reloaded. This will clear the Error Code 80 and the 'How Determined' code will revert back to 6, which means 'Test in Progress'. To assist in unloading Negative to Date bottles that have an Error Code 80, BacT/ALERT® 3D version B.25 software has a new keyboard function; if Ctrl + F3 is pressed on the keyboard (press both keys simultaneously) the instrument will go into an unload mode for any bottle in which a gap in bottle readings has been detected. The green drawer indicator will light for drawers containing cells with an Error Code 80, the green cell indicator will light for all of the cells with an Error Code 80 and the Main Screen changes to the unload mode.

If a report is viewed or printed while any bottle has an Error Code 80, the report will show a special indicator of '!' next to the test result field. Below is an example of a load report with bottles with Error Code 80

1st Load Time	Accession	Bottle ID	Cell ID	Test Result
1st Load Time = 09/21/05				
09/21/05			1A57	*!
1st Load Time = 09/01/05				
09/01/05		SNBCN739	1A33	*!
09/01/05		SNBCN73F	1A31	*!
09/01/05		SABB477W	1A32	-!
09/01/05		SABB4783	1A34	+

If a bottle that has an Error Code 80 changes status to a positive status, the 'How Determined' code of 205 (Missed readings) will be overridden by the new positive status. If a bottle that has an Error Code 80 reaches maximum test time it will retain its 'How Determined' status of 205 (Missed readings) and will require subculture.

BacT/ALERT® 3D version B.25 software also provides a means to clear all cells with Error Code 80 with a password protected keyboard function. **If a user enters a valid password on the Setup screen and presses Alt+F5 on the keyboard (press both keys simultaneously) all bottles for which a reading gap has been detected will revert back to negative to date and all Error Code 80 faults will be removed from the screen.** The clearing of Error Code 80 with the keyboard function is logged in the Audit Trail. If Error Code 80 is cleared using the keyboard function bioMérieux recommends printing an unload report before clearing the Error Code 80. This list can be used to identify bottles that had a gap in the bottle readings so that they can be subcultured at the user's convenience.

8. BPA/BPN BOTTLE TYPES ADDED

Prior to BacT/ALERT® 3D version B.25 software the BacT/ALERT® BPA and BPN bottle types had to be added by Manufacturing or were added by the customer by using the Bottle Customization screen. Software version B.25 has hard coded the bottle type parameters for both the BacT/ALERT® BPA and BPN bottle. The parameters that have been added for these bottle types do not differ from the parameters which would be added by scanning in the barcodes.

9. CORRECTION OF ALGORITHM FOR PF BOTTLES

In 2005, an error was discovered in the algorithm used to analyze BacT/ALERT PF® bottles (refer to KC5-FCA 2005-05). The short term corrective action for this error was to scan in the correct algorithm using the Bottle Customization screen. The Field Corrective Action indicated that the permanent corrective action would be achieved with the release of BacT/ALERT® B.25 software. With B.25 software, the correct algorithm for the BacT/ALERT® PF bottles has now been hardcoded into the software. This algorithm cannot be removed by replacing the flashcard. It is no longer necessary to perform the PF algorithm update after replacing the flashcard nor is it necessary to verify that the update has been done. All systems shipped with software version B.25 have the correct algorithm for the BacT/ALERT® PF bottles hardcoded into the system.

10. CORRECTION OF MB RESULT CHANGE ON UNLOAD EVENT

When loaded, a Mycobacteria bottle will run the standard blood culture algorithm (H2) for the first four days to look for contamination. After this time, the Mycobacteria algorithm (G3) is solely used to monitor the bottle. In previous version of BacT/ALERT® 3D software, only the result from the G3 algorithm was sent once the bottle was unloaded. The consequence of this was that if a bottle was determined to be positive by the H2 algorithm, once the bottle was unloaded the result of negative to date as determined by the G3 algorithm was sent to the DBMS and the LIS. With BacT/ALERT® 3D version B.25 software, if either algorithm is positive, then the bottle result is set to positive when an unload event occurs.

11. CORRECTION TO LIS CONCERNS

BacT/ALERT® 3D version B.25 software corrects the LIS concerns that were found to exist in previous version of the software. The concerns that are corrected in version B.25 are:

11.1 Results sent based upon Accession Number

In previous versions of the software, when a bottle result changed, the results of all bottles associated with a Patient ID were sent. This caused difficulties with some LIS. In BacT/ALERT® 3D version B.25, the sending of results will conform to the guidelines detailed in the **"BacT/LINK® Interfacing Software for bioMérieux's BacT/ALERT® Microbial Detection Systems" document**. In BacT/ALERT® 3D version B.25 software, when a bottle changes status, the system will send to the LIS the results of all bottles associated with the accession.

11.2 Correction of 'Final Negative' status

In previous versions of the software, negative results were sent to the LIS with a 'preliminary' bottle status. This has been corrected to conform to the BacT/LINK Interfacing document. Negative bottles will have a preliminary bottle status until the bottle is unloaded. Upon unload, the bottle status of the negative bottle will change to final. This status will be sent to the LIS.

11.3 Correction of accession's test status

With BacT/ALERT® 3D B.25 software the accession status will be set as follows;

- Final is all bottles in the accession have a final result status (negative and unloaded)
- Preliminary if at least one bottle in the accession has a positive test result
- Incomplete if all bottles are still negative to date or negative and not unloaded

11.4 Ability to tolerate trailing spaces sent by LIS

Previous versions of BacT/ALERT® 3D software would report a software exception (error 19) if the LIS sent trailing spaces in a field. Version B.25 software, in conformance with ASTM standards will tolerate trailing spaces within a field that is sent by the LIS .

11.5 Correction of incorrect sequence number

In previous versions of BacT/ALERT® 3D software, the sequence number was not always being reset properly. This resulted in rejections of data by the LIS. Version B.25 software has corrected this defect.

12. REMOVAL OF PRINT REPORT BUTTONS FROM MAIN SCREEN

In order to be HIPAA compatible, the Print Report buttons, which were formerly located on the main screen in Select and Select LINK are only available from the Report Selection screen which is accessed from the Set Up screen. These reports are now password protected as a result of this change.

13. SOFTWARE UPGRADES LOGGED

The date and time whenever the software is upgraded is now logged on the audit trail.

For a description of the new features the BacT/ALERT 3D customers will experience, please read the **New Features Guide for Version B.25**. For more detailed information regarding new features refer to the **BacT/ALERT® 3D User Manual version B.25.**