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BACTEC® 9050 System Users Manual

BECTON DICKINSON AND COMPANY
BECTON DICKINSON MICROBIOLOGY SYSTEMS
7 Loveton Circle
Sparks, Maryland 21152 USA

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BRISTOL-MYERS SQUIBB-LAWRENCEVILLE
LABORATORY PROCEDURE

TITLE: Bactec 9050 Automated Blood Culture	DATED: 3/13/98
AUTHOR: Trisha Cohen	REVIEW DATE:

OVERVIEW:

The detection of microorganisms in a patient's blood has diagnostic and prognostic importance. Bacteria enter the blood from extravascular sites such as the genitourinary tract, respiratory tract, abscesses, surgical wound infections and other miscellaneous sites either directly or via the lymphatic vessels. When bacteria enter and/or multiply in the bloodstream at a rate that exceeds the capacity of the reticuloendothelial system to remove them, bacteremia results.

Blood cultures are essential in the diagnosis and treatment of the etiologic agents of sepsis. Bacterial sepsis constitutes one of the most serious infectious diseases and therefore the expeditious detection and identification of blood borne bacterial pathogens is an important function of the clinical diagnostic laboratory..

The Bactec 9050 instrument is designed for the rapid detection of microorganisms in clinical cultures of blood. The sample to be tested is inoculated into the vial which is entered into the Bactec 9050 for incubation and periodic reading. Each vial contains a sensor which detects increases in CO_2 produced by the growth of microorganisms. The sensor is monitored by the instrument every ten minutes for an increase in its fluorescence, which is proportional to the amount of CO_2 present. A positive reading indicates the presumptive presence of viable microorganisms in the vial.

MATERIALS LIST:

A. Media

1. Bactec Peds Plus/F Culture Vial
   Optimum blood volume for each vial is 1-5 mL.
   Each vial contains:
   a. 40mL Enriched Soybean-Casein digest broth.
   b. 0.02% SPS
   c. Resins
   d. CO_2
   e. O_2
   f. Sensor for CO_2 detection

2. Bactec Plus Anaerobic/F Culture Vial
   Optimum blood volume for each vial 8-10mL; 3-10 mL is acceptable
   Each vial contains:
   a. 25 mL pre-reduced enriched Soybean-Casein digest broth
   b. 0.05% SPS
   c. Resins
   d. CO_2 and N_2 (which support the growth of anaerobic microorganisms)
   e. Sensors for CO_2 detection

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PROCEDURE:

Specimen labeling:
Each vial should be labeled with the appropriate patient information:

- Patient Identification
- Laboratory Log Number
- Patient Location
- Date and Time of Collection
- Collector's Initials
- Site of Venipuncture

Entering new vials:

- Press the 'Vial Entry' key.
- Scan vial barcode by placing the vial in the alignment block in front of the scanner with the barcode facing the scanner. Rotate the vial slightly in front of the scanner. The system beeps once to indicate a successful scan.
  NOTE: If the vial barcode cannot be read, press the 'No Barcode' key. Select the vial media by using the Up/Down arrow keys. Press the 'Ok' key to confirm media type.
- Insert the vial into position indicated on the LCD display.
- If default protocol is acceptable, press 'Ok' key.
  NOTE: To modify the protocol length for a particular vial, select the 'Change Protocol' key. Select the desired protocol length using the Up/Down arrow keys. Press 'Ok' to confirm protocol length.
- Verify that all information is correct and that vial has been inserted into the indicated station. Press 'Ok' key to confirm.
- Repeat the above steps for each new vial. Then Press the 'Exit' key.

Positive Vials:
A. Notification of the presence of presumptive positive vials

- An audible alarm sounds if configured to a volume > 0.
- The New Positive Indicator on the front of the instrument flashes red.
- The 'Remove Positives' key appears in the LCD display when the door is open.
- On the main status display, that station with the positive vial is displayed as a filled circle with a plus sign in it, and the positive total in the summary region reflects the number of positives in the instrument.

B. Removal of positive vials

- Press the 'Silence Alarm' key to acknowledge the alarm.
- Open instrument door and press the 'Remove Positives' key.
- LCD display identifies the positive vial by position and the barcode number is also displayed.
- Remove vial from the station and scan the vial barcode. Repeat the above steps until all positives are removed (three beeps indicates all positives have been removed).
- Press the 'Exit" key.
  NOTE: A subculture and a Gram stain should be performed from each presumptive positive vial.

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Negative Vials:

A. Removal

- Open instrument door
- Press the 'Remove Negatives' key.
- LCD display identifies negative vials by position and the vial barcode number is also displayed.
- Remove the vial from the station and scan the vial barcode.
- Repeat the above steps until all negatives are removed (three beeps indicate the process is complete).
- Press the 'Exit' key and close door.

LIMITATIONS OF THE PROCEDURE:

Contamination

Care must be taken to prevent contamination of the sample during collection and inoculation into the Bactec vials. A contaminated sample will give you a positive reading, but this does not indicate a clinically significant result.

Recovery of SPS Sensitive and Fastidious Organisms from Blood Samples

Because blood can neutralize the toxicity of SPS toward organisms sensitive to SPS (such as some Neisseria species), the presence of optimum volumes of blood, based on media type, benefits the recovery of these organisms.

Some fastidious organisms, such as Haemophilus species, require growth factors, such as NAD, or factor V, which are provided by the blood specimen. If the blood specimen volume is 3.0 mL or less Bactec Peds Plus, an appropriate supplement may be required for recovery of these organisms. Bactec Brand FOS (catalog #4402153) or Horse serum and Defibrillated sheep blood may be used as nutritional supplements.

General Considerations

Optimum recovery of isolates will be achieved by adding the appropriate volume of blood for the type of vial inoculated. Use of lower or higher volumes may adversely affect recovery and/or detection time. Blood may contain antimicrobials or other inhibitors which may slow or prevent the growth of microorganisms. False negative readings may result when certain organisms do not produce enough CO_2 to be detected by the system or if significant growth has occurred before placing the vial into the system. False positivity may occur when the white blood cell count is high.

QUALITY CONTROL:

Each case of media has a certificate indicating that the media lot has been tested. However, the laboratory should also test each shipment of media through use of a positive and negative vial test. The positive vial should be inoculated with 1.0 ml of a 0.5 MacFarland standard of either Escherichia coli or Staphylococcus aureus. This vial and an uninoculated vial should be placed into the machine and tested. The inoculated vial should be detected as positive within 72 hours. The negative control vials should remain negative throughout the entire testing protocol.

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1

Introduction

1.1 BACTEC® 9050 Overview

The BACTEC® 9050 instrument is designed for the rapid detection of bacteria and fungi in clinical cultures of blood. Samples are drawn from patients and injected directly into BACTEC culture vials. Vials are then entered into the instrument as soon as possible to insure performance efficacy.

When microorganisms are present, they metabolize nutrients in the culture medium, releasing carbon dioxide into the medium. A dye in the sensor reacts with CO_2. This modulates the amount of light that is absorbed by a fluorescent material in the sensor. The instrument's photo detectors measure the level of fluorescence, which corresponds to the amount of CO_2 released by organisms. Then the measurement is interpreted by the system according to preprogrammed positivity parameters. (See Figure 1.)

At system start-up, the BACTEC® 9050 instrument performs self-diagnostics and loads its operating instructions. Then the instrument begins automated testing. A row of Light Emitting Diodes (LEDs) behind the vials illuminate, activating the vials' fluorescent sensors. The instrument's photo detectors then take the readings. A test cycle is completed every ten minutes. Positive cultures are immediately flagged by an indicator light on the front of the instrument, an optional audible alarm, and are displayed on the LCD screen.

When positive vials are identified, the lab technologist pulls them from the instrument for confirmation of results, and for isolation and identification of the organism.

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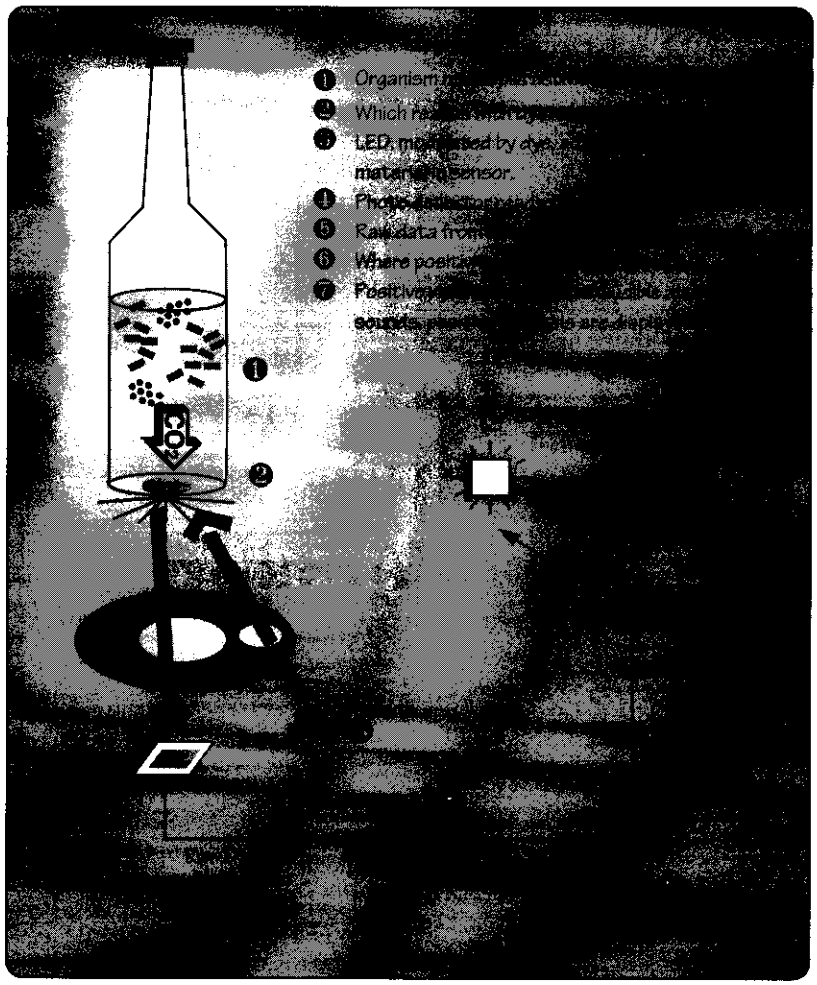


Figure 1 – BACTEC Fluorescent Test Technology

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An instrument is capable of monitoring a total of 50 BACTEC® culture vials. The practical capacity is 5 culture sets per day with a 5-day test protocol. The vials are arranged in 3 concentric rings designated A, B, and C. The vials are continuously incubated at 35° C, and are agitated for maximum recovery of organisms.

Major features of the BACTEC® 9050 instrument include:

- Automated, continuous, unattended testing of cultures through non-invasive fluorescent technology
- Minimum user interaction and handling
- Immediate notification of positives through an indicator lamp, indication on the LCD display, and an audible alarm
- Simple user interface, with picture icons to guide you through setup and routine operations
- Incubation and agitation for all cultures
- Proven BACTEC® culture media

1.2 Instrument Overview

The BACTEC® 9050 instrument (hardware) components are described in the following paragraphs and are shown in Figure 2. Controls and indicators for these modules are discussed in Section 3 – Controls and Indicators.

The major subsystems of the instrument include the following:

Rotor

The rotor contains 50 wells called "vial stations," into which vials are placed for incubation and testing. The rotor contains three rings of vial stations designated A, B, and C. Each station is numbered uniquely (1 – 50), but the system provides the ring letter designation (A, B, or C) to help you quickly identify where to place or remove vials. One row of stations (one station in each ring) contains the test LEDs that activate vial sensors and the photo detectors which take the actual readings.

The rotor is mounted at a 20° angle and rotates to provide agitation to culture vials. Agitation of cultures can improve both time to detection and recovery of organisms. The rotor's drive motor stops agitation when the cabinet door is opened.

The temperature inside the instrument is preset to maintain the internal temperature at 35° C ± 1.5° C. Over- and under-temperature alarm setpoints are preset at 35.5° C and 34.5° C, respectively.

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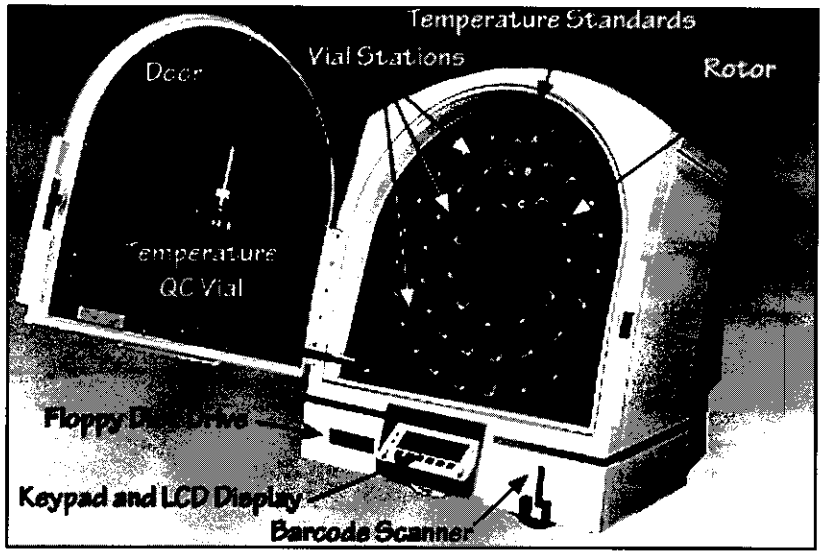


Figure 2 – BACTEC® 9050 Instrument

Keypad and LCD Display

The LCD Display is a 240 X 64 pixel Liquid Crystal Display that presents information about system status and function key definitions that enable you to perform system operations. Key definitions and status information are identified by picture icons that represent the type of information or operation that can be performed. A comprehensive list of system icons is presented in Section 5 – Reference.

The keypad enables you to perform operations such as entering and removing vials, adjusting setup parameters, etc. Four of the keys, marked with printed icons, perform fixed functions regardless of the current display or operation. Six other keys, teal in color, are software (soft) keys whose functions vary depending on the current active display. Each display shows icons representing the current Soft key assignments at the bottom of the screen. To perform the function represented by the icon, you press the corresponding Soft key below the icon.

Barcode Scanner

A barcode scanner is located on the front of the instrument to provide the ability to scan vial labels for specimen identification. The scanner turns on automatically whenever a barcode needs to be scanned.

Computer

The system computer stores all the system software, including the software which controls instrument operations and the user interface, which enables you to perform instrument operations, view vial statuses, print reports, etc.

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Floppy Disk Drive

A floppy disk drive is located on the front of the instrument to enable the installation of software updates and to copy important data files to floppy disk.

External Ports

Ports on the rear of the instrument allow the user to connect an optional Remote Alarm unit and an optional printer. Two other ports are for Field Service diagnostic use.

Instrument Calibration

Components of the BACTEC® 9050 instrument are selected and designed to maintain electrical and optical integrity throughout the product's life. All instruments are calibrated at the factory prior to shipment, and should not require recalibration during the usable life of the instrument, unless certain components are replaced. Calibration helps to insure that any fluorescent series medium vial in any station will have initial and final fluorescent values within a specified range.

1.3 Software Overview

The system software presents a simplified user interface on the LCD Display, with picture icons to represent all the functions, operations, setup parameters, and status conditions (see Section 5 – Reference for charts of all icons). Routine system operations are performed by pressing the teal soft key that corresponds to the definition shown on the screen.

There are three basic types of displays:

Main Status Screen – When the instrument door is closed, this screen appears. It shows the number of vials that are positive, negative, ongoing, available, and stations that are in error or anonymous. Also shown are the current date and time and the instrument temperature. Software keys allow you to configure the setup parameters, review system errors, or print the System Status Report. See Figure 3.

Configuration Screens – Accessible from the Main Status Screen, the Configuration Screens allow you to set the protocol length, the time and time format, the date and date format, the audible alarm volume, the instrument identification number, the DVE (Delayed Vial Entry) threshold (feature not available for use in the USA), to select the desired language for reports, to write data to a floppy disk, and to update system software.

Activity Screens – When the instrument door is opened, software key definitions appear that enable you to enter new vials, remove positive vials, remove negative vials, identify anonymous vials, and resolve station error conditions.

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Figure 3 – Main Status Screen

1.3.1 Built-in-Test (Patent Pending)

The system software is designed to continuously monitor the electrical and optical performance of all stations simultaneously. This functionality, called BIT (for Built-in-Test), automatically monitors each station every ten minutes for basic operational characteristics. These tests continually verify that signal output for each station is within design limits; this includes both empty stations and stations with ongoing vials.

Two different signal levels are used to verify operation of the station over the established signal range. Tests are performed on dark readings (the output from the station when its excitation LEDs are off) and on fluorescence unit readings (the output from the station when a vial is present and the excitation LEDs are on).

Dark readings are evaluated to be below a maximum established range. When they exceed that range, the software declares the station in error. High dark readings may indicate a light leak in the cabinet or an electrical failure within the instrument.

Fluorescence unit readings are evaluated to be within a specified maximum and minimum range which has been established for the instrument during calibration at the factory. Should an out of range reading occur, the software declares that station in error. This may occur due to an electrical or optical component failure.

Additionally, the fluorescence readings are evaluated for consistency while vials are in stations. If consecutive fluorescence unit readings vary by more than a predetermined amount, the station is declared in error. This feature determines the stability and the acceptability of a station for use during protocol.

These protection features verify that calibration has been maintained for all stations within the system, and insure that the user is alerted of electronic or optical changes or failures which may be significant enough to affect results.

The function of BIT can be demonstrated by entering a vial into the instrument, and then removing that vial from the station without scanning it out. The resulting error is the response of the BIT function. The user may resolve the error by using the resolve errors soft key.

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1.4 Manual Structure

This user's manual contains the following sections:

Section 1 – Introduction – provides an overview of the BACTEC® 9050 instrument and its uses in the microbiology laboratory, its major hardware and software components. An overview of this manual's structure and conventions is also included.

Section 2 – Installation – gives specifications for installing the BACTEC® 9050 instrument and instrument setup.

Section 3 – Controls and Indicators – explains the use and meaning of all controls and indicators of the system.

Section 4 – Operation – provides instructions for routine daily activities.

Section 5 – Reference – provides reference material on the user interface.

Section 6 – Maintenance – explains all system maintenance, including parts replacements. Depending on the serial number of your instrument, some parts replacements should be performed by service personnel only.

Section 7 – Troubleshooting – provides a convenient guide for identifying and correcting system malfunctions.

The **Glossary** explains several instrument and computer terms used in this manual, as well as abbreviations.

The **Appendices** contain warranty information, replacement parts list, a software update form, and a listing of Becton Dickinson international contacts.

The **Index** provides a listing of major topics and associated page numbers.

1.5 Use of this Manual

This user's manual is designed as a reference tool for technologists, supervisors, and other personnel who operate and maintain the BACTEC® 9050 instrument on a regular basis. Every attempt has been made to include all information which would be required during normal use and maintenance of the system. Should a question arise which is not answered in this manual, please contact the following parties (USA):

For assistance with mechanical, electrical, or software performance problems:

☎ Field Service 1–800–544–7434

For procedural or software operation questions:

☎ Technical Services 1–800–638–8656

International contacts are listed in Appendix D.

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Other documentation which may be of interest to the user includes:

BACTEC® 9050 Installation and Setup, MA–0102 – This document contains important information about preparing your laboratory for, and installing the BACTEC® 9050 instrument.

BACTEC® 9050 5–Minute Operator Training Guide, MA–0104 – This document presents instructions on how to perform routine operations on the BACTEC® 9050 instrument, in a step-by-step, interactive tutorial format.

BACTEC® Blood Collection Instructions, MA–0108 – This document presents information on collection of specimens for use with the BACTEC® fluorescent instrument series.

BACTEC Media Package Inserts – These documents contain important information on the use, storage, inoculation, performance, and limitations of each type of BACTEC medium. They are included with each carton of media, and are available upon request from the Technical Services Department.

1.6 Conventions

1.6.1 General

Keys

The four keys that have fixed functions are the UP ARROW (Increase) Key, the DOWN ARROW (Decrease) Key, the HOME ROTOR Key, and the SILENCE ALARM Key. These keys are marked with symbols representing their functions, and operate identically regardless of the active display or operation. Six other keys, the Software (Soft) Keys are teal in color, and have functions that vary depending on the active display. Each display shows icons representing the current Soft key assignments at the bottom of the screen. To perform the function represented by the icon, press the corresponding Soft key.

The four fixed function keys are always identified in your BACTEC® 9050 documentation by CAPITAL LETTERS (e.g., SILENCE ALARM key). The software keys are always identified by lowercase letters in quotes, and the words *soft key* (e.g., "vial entry" soft key).

End of Section

The end of each section of this manual is marked with an octagonal symbol. ●

1.6.2 Symbols Used on the Equipment

The following symbols appear on the BACTEC® 9050 instrument:

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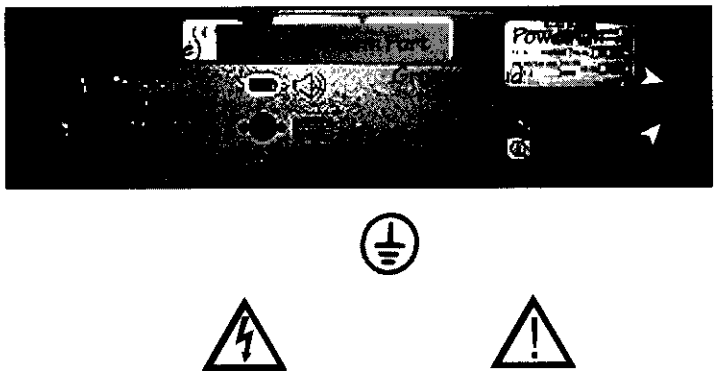


Figure 4 – Symbols Used on the BACTEC® 9050 Instrument

Top figure: Symbols for Serial Port, Remote Alarm Port, Printer Port, Keyboard Port, Power On and Off; Center figure: Symbol for electrical ground connection; Bottom figures: Left – Symbol for electrical hazard, Right – Symbol for "refer to accompanying documentation" for instructions (specifically, the Maintenance section of the user's manual)

1.6.3 Notes, Cautions, and Warnings

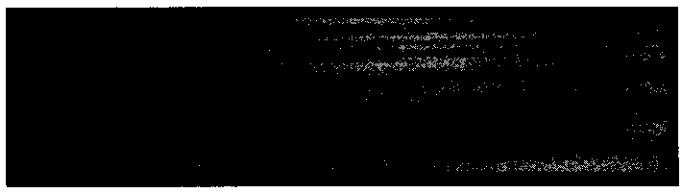
Throughout this manual, important information is presented in boxes offset from the regular text, and is labeled as either a NOTE, CAUTION, or WARNING. These messages are formatted as shown below and bear the following significance:

NOTE

Important information about system use worthy of special attention is presented as a NOTE.

CAUTION

Information on an activity which potentially could cause damage to the instrument or system is presented as a CAUTION.



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1.7 Summary of Warnings and Cautions

Special messages presented in this manual which relate to operator and instrument safety, and which appear as CAUTION and WARNING boxes in the manual, are summarized below. Please read this section completely before you begin to operate your BACTEC® 9050 instrument.

For all instruments with serial numbers from 1000 – 1695, parts replacements should be performed by service personnel only. Instrument power should be turned off, and the power cord should be disconnected, before beginning any module replacement procedure.

The intake filters on the sides of the instrument must remain unobstructed at all times. Restricted air flow may cause excessive temperatures in the instrument, which can affect organism recovery and possibly cause hardware malfunctions.

Because of its size and weight, two persons should lift the BACTEC® 9050 instrument.

It is mandatory that all system users become thoroughly familiar with all controls and indicators before attempting to operate the instrument.

The door sensor helps protect you from possible injury from the movement of the rotor. Do not tamper with the door sensor in any way, or attempt to defeat its function.

Never attempt to insert or remove vials when the rotor is in motion.

"Universal Precautions"[1] should be followed in handling all items contaminated with blood or other body fluids.

[1] Recommendations for Prevention of HIV Transmission in Health Care Settings. MMWR 1987; 36 (Supplement #2S): (Inclusive Page Numbers).

Vials should be handled with extreme care at all times, and should not be forced into or out of stations. Vial necks are susceptible to breakage if they are struck against another object.

When the system notifies you of alerts and errors, you should immediately respond to the condition.

All maintenance and repair other than the procedures described in Section 6 – Maintenance, must be performed by qualified service personnel. For all instruments with serial numbers from 1000 – 1695, parts replacements should be performed by service personnel only.

All portions of the body that could possibly come in contact with the affected instrument surfaces must be completely covered before beginning the decontamination process.

After the rotor is removed, DO NOT lay it down on either the front or back sides. (On the rear, the tabs can snap off.) Stand the rotor upright and wedge both sides so it does not roll.

If any error sub-codes other than those listed here appear, contact Field Service for assistance.

- If the recommended corrective actions do not solve the problem, contact Becton Dickinson at the numbers provided in Appendix D.

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WARNINGS/CAUTIONS relating to the use of BACTEC MYCO/F LYTIC culture vials with the BACTEC 9050 instrument:

Biosafety Level 2 practice, containment equipment, and facilities are recommended for preparing acid-fast stains and for culturing clinical specimens. For activities involving the propagation and manipulation of *Mycobacterium tuberculosis* or *Mycobacterium* species grown in culture, Biosafety Level 3 practice, containment equipment, and facilities are required as recommended by CDC.

Because an inoculated leaking or broken vial may produce an aerosol of mycobacteria, including *M. tuberculosis* or other bacteria, appropriate handling should be observed.

If an inoculated vial is found to be leaking or is accidentally broken during collection or transport, use the established procedure in your facility for dealing with mycobacterial spills. As a minimum, "Universal Precautions" should be employed. Vial should be discarded in an appropriate manner. In the rare instance where a vial is found to have leaked contents into the instrument proper, or if a vial is accidently broken, turn off the instrument immediately. Vacate the affected area. Contact your facility's Safety or Infection Control Officer(s). Determine the necessity of turning off or modifying the settings of the air handling units serving the affected area. Do not return to the area until any potential aerosols have settled or have been removed by appropriate ventilation. Becton Dickinson Microbiology Systems should be notified by calling 1-800-544-7434 in the U.S.A. or the appropriate Becton Dickinson representative in your area. Guidelines for proper handling of accidental mycobacterial contamination due to breakage of culture tubes or broth suspensions have been issued by the CDC.[6]

If recovery of mycobacteria is intended, CDC-NIH guidelines strongly recommend that the test instrument be placed in the mycobacteriology laboratory where the additional safety issues that the recovery of mycobacteria present can be addressed.

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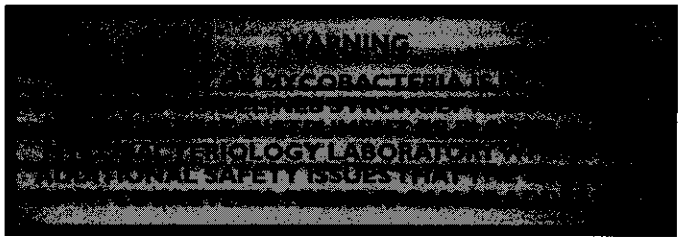
2

Installation and Setup

2.1 General Requirements

The BACTEC® 9050 instrument should be installed in an area that is free from undue vibration, direct sunlight, high humidity, dust, temperature extremes, and corrosive or explosive vapors or gases. The system will operate within specifications in room temperatures between 18.3° – 32.0° C (65° – 89.6° F). Relative humidity should be between 10% and 90% (non-condensing). Clearances on all sides should be at least 12 inches. Environments which exceed these limits could adversely effect the performance of the system components.

The incubator should maintain its temperature to within plus or minus 1.5° C of the temperature setting (35° C). This accuracy can be assured only if the room temperature meets the requirements given above.



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2.2 Instrument Specifications

Physical Dimensions	
Height	28.5 in (72.4 cm)
Width	24 in (61 cm)
Depth	25.5 in (64.8 cm)
Weight (no vials)	103 lb (46.7 kg)
(with vials)	118.5 lb (53.8 kg)

Clearance Requirements	
Left side	12 in (30.5 cm)
Right side	12 in (30.5 cm)
Back	12 in (30.5 cm)
Top	12 in (30.5 cm)
Optimum bench height	30 - 36 in (77 – 92 cm)

Electrical Requirements	
Input Voltage	100 – 117 Volts AC (± 10%) or 220 240 Volts AC (± 10%)
Input Current	3 Amp maximum
Input Line Frequency	50 or 60 Hz
Heat	1200 Btu/hr

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Environmental Requirements	
Non-Operating Storage	
Temperature	–4° F to 140° F (–20° C to 60° C)
Humidity	10% to90% non-condensing
Operating Conditions	
Temperature	65° F to 89.6° F (18.3° C to 32° C)
Humidity	10% to 90% non-condensing
Locations	Level surface, No direct sunlight, No direct heat
Altitude	0 to 10,000 ft (3,048 M) above sea level
Use of earthquake anchoring is strongly recommended in locations susceptible to earthquake activity.	
Installation Category II and Pollution Degree 2 as per IEC 664.	

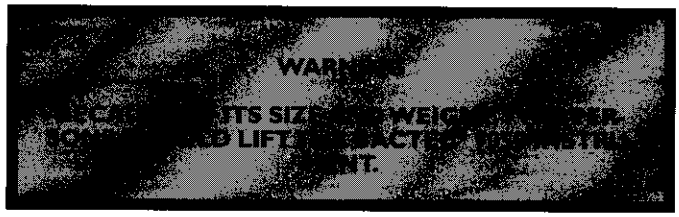
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2.3 Installation

Complete instructions on unpacking and installation of the BACTEC® 9050 instrument are provided in the separate document titled *BACTEC® 9050 Installation and Setup*, MA–0102.

CAUTION

The intake filters on the sides of the instrument must remain unobstructed at all times. Restricted air flow may cause excessive temperatures in the instrument, which can affect organism recovery and possibly cause hardware malfunctions.



2.4 Instrument Setup

2.4.1 General

The BACTEC® 9050 instrument ships with all setup parameters preset to factory default values. Before using the instrument for blood culture testing, you should review the instrument setup parameters to see if they are suitable for your laboratory. These parameters are described in Section 2.4.2– Setup Parameters, and include:

- Test Protocol Duration
- Time Format and Time
- Date Format and Date
- Audible Alarm Volume
- Instrument Number
- DVE (Delayed Vial Entry) Media Thresholds (feature not available for use in the USA)
- Language (for System Status Report)

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After reviewing and adjusting the setup parameters, you should carefully review the material in the *BACTEC® 9050 5-Minute Operator Training Guide*, MA–0104. This one-page guide will familiarize you with routine use of the BACTEC® 9050 instrument.

When you are familiar with system operation, you may proceed with automated BACTEC® culture testing.

2.4.2 Setup Parameters

To review and/or adjust the instrument setup parameters, first make sure the instrument door is closed. When the door is closed, a display like the one shown below appears (note that printer and system alert icons may not be shown):



Figure 5 – Main Status Screen

Any changes to configuration parameters are in effect from the time of the change forward. Changes do not affect vials that are currently being tested (Ongoing vials). Also note that any changes you make cannot be "cancelled" per se – you must manually change the new value back to its previous value.

To enter configuration mode, press the soft key corresponding to the icon shown below (the "configuration" soft key). (For a complete listing of system icons, see Section 5 – Reference.)



When you enter configuration mode, the first of nine setup displays (Test Protocol Duration) appears.

Test Protocol Duration (1/9)



There are three test protocol duration settings: General media, Mycosis/IC–F* medium, and Myco/F Lytic medium. When this display is first accessed, the test protocol for general media (all media types other than Mycosis/IC–F* and Myco/F Lytic) is highlighted. The default setting is 5 days. To increase or decrease the number of days for general media, use the UP ARROW or DOWN ARROW key. You can choose from 4 to 7 days.

* Not available for use in USA (more)

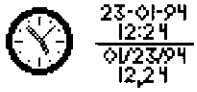
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To adjust the test protocol duration for Mycosis/IC–F medium (not available for use in the USA) press the "move to other field" soft key to highlight that field. Use the UP ARROW or DOWN ARROW key to increase or decrease the displayed value. You can choose from 5 to 42 days. The default value is 14 days.

To adjust the test protocol duration for Myco/F Lytic medium, press the "move to other field" soft key to highlight that field. Use the UP ARROW or DOWN ARROW key to increase or decrease the displayed value. You can choose from 5 to 42 days. The initial default value is 42 days. The recommended testing protocol for the following organisms are: 7 days for yeast, 30 days for fungi, and 42 days for mycobacteria.

Press the "configuration" soft key to advance to the next setup display, or press the "exit" soft key to exit configuration mode.

Time and Time Format (2/9)



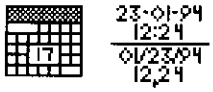
When this display is first accessed, the minutes value is highlighted. To adjust the minutes, use the UP ARROW or DOWN ARROW key to increase or decrease the displayed value.

To adjust the hours value, press the "move to other field" soft key to highlight the hours field. Use the UP ARROW or DOWN ARROW key to increase or decrease the displayed value.

To adjust the time format, press the "format" soft key (shown above). The default time format (colon separated) is shown. Continue to press the "format" soft key to rotate among the format choices until the desired selection is shown. You can choose among period (.) or comma (,) or colon (:) separators.

Press the "configuration" soft key to advance to the next setup display, or press the "exit" soft key to exit configuration mode.

Date and Date Format (3/9)



When this display is first accessed, the year value (at default, the right field) is highlighted. To adjust the year, use the UP ARROW or DOWN ARROW key to increase or decrease the displayed value.

To adjust the day value (at default, the middle field), press the "move to other field" soft key to highlight the day field. Use the UP ARROW or DOWN ARROW key to increase or decrease the displayed value.

To adjust the month value (at default, the left field), press the "move to other field" soft key to highlight the month field. Use the UP ARROW or DOWN ARROW key to increase or decrease the displayed value.

To adjust the date format, press the "format" soft key (shown above). The default date format (MM/DD/YY) is shown. Continue to press the "format" soft key to rotate among the format choices until the desired selection is shown. You can choose from the following:

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Slash separators (/)	MM/DD/YY or MM/DD/YYYY	DD/MM/YY or DD/MM/YYYY	YY/MM/DD or YYYY/MM/DD
Hyphen separators (–)	MM–DD–YY or MM–DD–YYYY	DD–MM–YY or DD–MM–YYYY	YY–MM–DD or YYYY–MM–DD
Period separators (.)	MM.DD.YY or MM.DD.YYYY	DD.MM.YY or DD.MM.YYYY	YY.MM.DD or YYYY.MM.DD

Press the "configuration" soft key to advance to the next setup display, or press the "exit" soft key to exit configuration mode.

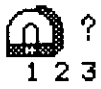
Audible Alarm Volume (4/9)



Select the volume of the instrument's audible alarm. The default setting is 5, which is at the center of the volume range. To increase or decrease the volume, use the UP ARROW or DOWN ARROW key (a sample volume tone sounds each time you adjust the setting). You can choose from 0 (audible alarm off) to 10 (loudest).

Press the "configuration" soft key to advance to the next setup display, or press the "exit" soft key to exit configuration mode.

Instrument Number (5/9)



Select the instrument identification number. The default setting is 1. To increase or decrease the instrument number, use the UP ARROW or DOWN ARROW key. You can choose a number from 1 to 99. If there is only one instrument at your location, you should leave this value set at 1.

Press the "configuration" soft key to advance to the next setup display, or press the "exit" soft key to exit configuration mode.

DVE Media Thresholds (6/9)



This feature is not available for use in the USA. For information on use internationally, refer to the *BACTEC® 9050 Delayed Vial Entry Instructions*, MA–0113.

Language (7/9)



Select the language in which you want the System Status Report to print. The default setting is English. To scroll through the available selections, use the UP ARROW or DOWN ARROW key. You can choose from the following language selections:

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English
Spanish
French
German
Italian
Chinese
Japanese
Polish

Press the "configuration" soft key to return to the first setup display, or press the "exit" soft key to exit configuration mode.

Save Data to Disk (8/9)



Under certain circumstances, Becton Dickinson will advise you to save system data to a floppy disk. These circumstances include some error conditions and system malfunctions. To use the function, insert a blank, formatted, write-enabled floppy disk in the disk drive. Then press the "perform action" soft key.

Update Software (9/9)



From time to time, updated versions of the system software may be provided to you. New software should be installed as soon as it is received, and logged on the form in Appendix C of this User's Manual. Updated program software is furnished on 3-1/2 inch floppy disk(s), labeled "BACTEC® 9050 System Software, Version y.yyz" (where "y.yy" is the software version number, and "z" is the revision). The associated catalog number is also printed on the label.

To install a software update, insert the floppy disk containing the new software into the disk drive, then press the "perform action" soft key to initiate the update. The system reboots and then immediately begins to update the system software (provided the disk is formatted, is not write-protected*, and contains either the same or a later version of system software). The names of any files being updated appear on the LCD Display, as well as a progress indication. When the update is complete, the user interface loads and you may proceed with normal system operation.

* Note that write-protection does not have to be disabled with version 1.1 or later of system software

2.5 System Start-up

Whenever power is applied to the instrument, the system is initialized, performs self-diagnostics, and reports any problems to the error file. If any files are missing or corrupted which would prevent proper operation of the system, the start-up process is aborted. If not, the computer loads the operating instructions and begins culture testing.

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3

Controls and Indicators

3.1 General

This section describes the meaning and use of the controls and indicators of the BACTEC® 9050 instrument. The overall layout of the instrument cabinet is shown in Figure 6. Individual components are illustrated in figures accompanying the related text.



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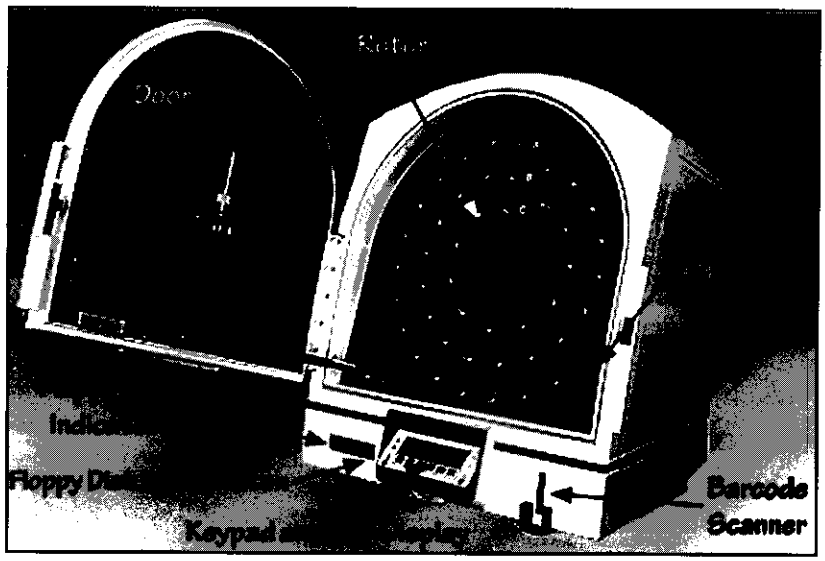


Figure 6 – BACTEC® 9050 Instrument Layout

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3.2 On/Off Switch

The system power (On/Off) rocker switch is on the rear of the instrument at the bottom right (see Figure 7). When in the "O" (Off) position, power is removed from the instrument. When in the "|" (On) position, power is applied to the instrument. Power must be turned on for the incubator, agitator, and culture testing modules to work. For normal operation, the power should remain On at all times (except during some maintenance procedures).

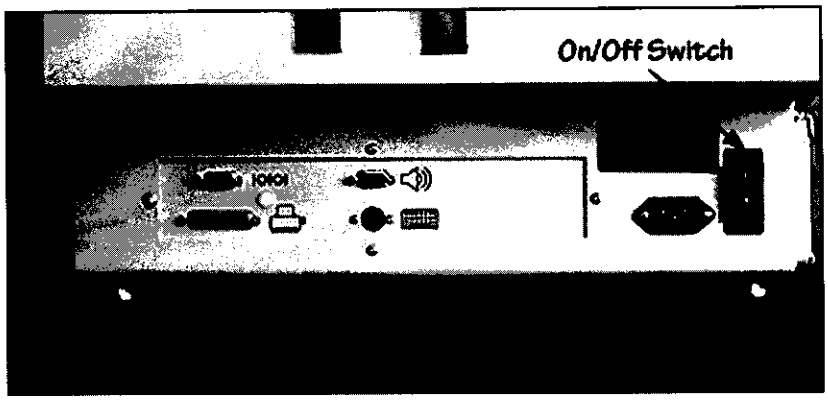


Figure 7 – On/Off Switch

3.3 Keypad and LCD Display

The keypad and LCD display are located on the front of the BACTEC® 9050 instrument, at the bottom center. The keypad is used to enter information and issue commands to the instrument. The LCD display presents setup and status information. See Figure 8.

The controls and indicators of the keypad and LCD display are presented in clockwise order from the top right of the module.

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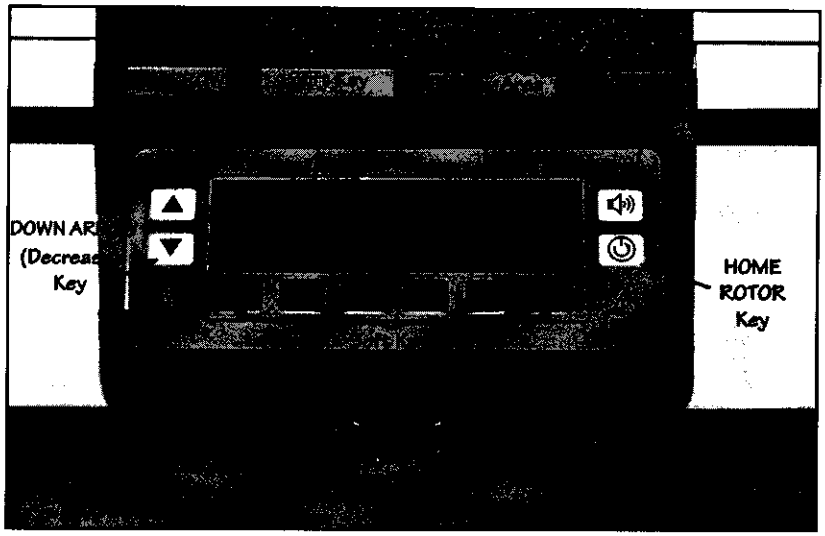


Figure 8 – Keypad and LCD Display

3.3.1 SILENCE ALARM Key

The SILENCE ALARM key is located at the top right of the Keypad/LCD Display module. When pressed, it turns off the audible alarm for the current "alert" alarm. It does not silence "door open" type audible alarms. (See Section 3.7– Audible Tones and Alerts, for an explanation of alarm types and tones.)

3.3.2 HOME ROTOR Key

The HOME ROTOR key is located on the right side of the Keypad/LCD Display module, below the SILENCE ALARM key. When pressed, it causes the rotor in the instrument to return to the "home" position, with the temperature standard bottles in the 12:00 position. The HOME ROTOR key is active only when the instrument door is closed and the rotor is in motion.

It is not necessary to home the rotor prior to opening the door. However, you may find it easier to locate vial stations when the rotor is homed, since the rotor's position then corresponds to the representation in the display.

Note that if vial testing is in progress when the HOME ROTOR key is pressed, those test results are discarded.

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3.3.3 Alarm Indicator

The Alarm Indicator is located on the right side of the Keypad/LCD Display, at the bottom. This light flashes yellow whenever the system encounters an error condition that requires operator attention. The indicator continues to flash until the condition is corrected.

When an alarm occurs, an icon (resembling the one above the Alarm Indicator) appears in the soft key assignments area of the Main Status Screen. Press the soft key corresponding to the System Alert icon. The first error code is shown on the display. Correct any error conditions as soon as possible by following the directions on the door placard and in Section 7 – Troubleshooting.

If there is an audible alarm sounding, you can silence it by pressing the SILENCE ALARM Key.

3.3.4 Brightness Dial

The Brightness Dial is located below the Keypad/LCD Display, at the center. It is a knurled rotary dial. Rotate the dial clockwise to increase the overall brightness of the LCD Display screen. Rotate counterclockwise to reduce the brightness. It is not uncommon to have to change the brightness setting if you change your viewing angle.

3.3.5 Soft Keys

The six software (soft) keys are located near the bottom of the Keypad/LCD Display, at the center. These keys are teal colored. None of the keys has a fixed function – the functions of the keys vary depending on the current active display. Each display shows icons representing the current soft key assignments at the bottom of the screen. To perform the function represented by the icon, press the corresponding soft key.

A complete icon legend is provided in Section 5 – Reference.

3.3.6 New Positive Indicator

The New Positive Indicator is located on the left side of the Keypad/LCD Display, at the bottom. This light flashes red whenever a new positive culture is detected. The indicator continues flashing until all positive vials are removed from the instrument. Refer to Section 4.5 for information on removing positive vials.

If there is an audible alarm sounding, you can silence it by pressing the SILENCE ALARM Key.

3.3.7 DOWN /UP ARROW Keys

The DOWN and UP ARROW keys are located on the left side of the Keypad/LCD Display. The DOWN ARROW key, represented by a down arrowhead, is used to decrease a displayed value, or to scroll downward in a list. The UP ARROW key, represented by an up arrowhead, is used to increase a displayed value, or to scroll upward in a list.

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3.3.8 Display Area

The Display area is located at the center of the Keypad/LCD Display. It is used to present information to you, and to show the soft key definitions that allow you to perform routine operations.

The LCD Display is programmed to automatically dim after 5 minutes of inactivity. To return the brightness to normal, press one of the unassigned keys (such as the rightmost soft key).

More information on displays is presented in Section 5 – Reference.

3.4 Door Interlock Switch

When the door of the instrument is opened, a door switch senses the condition (see Figure 6). This switch tells the system to immediately stop the rotor drive motor, start the door open timer, and discard the results of any tests in progress.



Because vial test results of tests in progress are discarded when the door is opened, door openings should be minimized if possible.

3.5 Floppy Disk Drive

The floppy disk drive is located on the front of the instrument, at bottom left. Its primary purposes are to enable you to save data to floppy disk, and to perform software updates when they are released. See Figure 9.

3.5.1 Floppy Disk Indicator

The Floppy Disk Drive Indicator light is on the left side of the drive below the insertion slot. When off it indicates that no activity is occurring in the drive. When on or flashing, it indicates that the disk drive is accessing a floppy disk. **Do not attempt to eject a floppy disk while this indicator is lit.**

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3.5.2 Floppy Disk Eject Button

The floppy disk drive eject button is located to the lower right of the insertion slot. When a floppy disk is inserted fully into the slot, this button extends itself. To remove a disk, fully depress the eject button. **Do not attempt to eject a floppy disk while the floppy disk indicator is lit.**

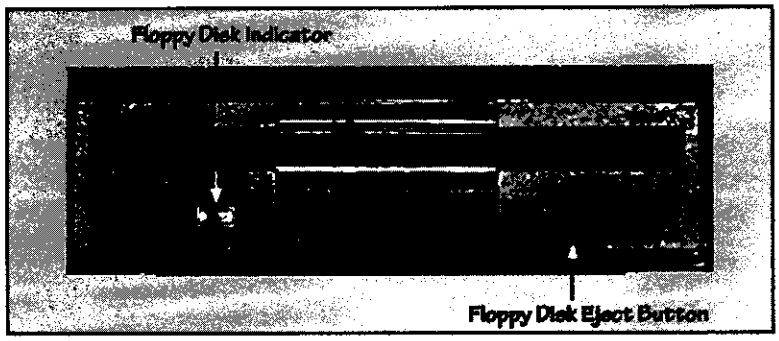


Figure 9 – Floppy Disk Drive Controls and Indicators

3.6 Barcode Scanner

The barcode scanner is located to the right of the Keypad/LCD Display module. When the door is opened and an activity is initiated (e.g., entering new vials, removing positive vials, etc.), the scanner turns on and is ready to read a vial barcode.

To scan a vial barcode, place the vial in the alignment block in front of the scanner. If necessary, rotate the vial slightly until the acknowledgment beep sounds (indicating that the barcode was scanned successfully).

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3.7 Audible Tones and Alarms

Eight different types of sounds are generated by the BACTEC® 9050 instrument as you perform operations. Each of the sounds is unique. These tones are designed to keep you informed about various operational states of the instrument.

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4

Operation

4.1 General

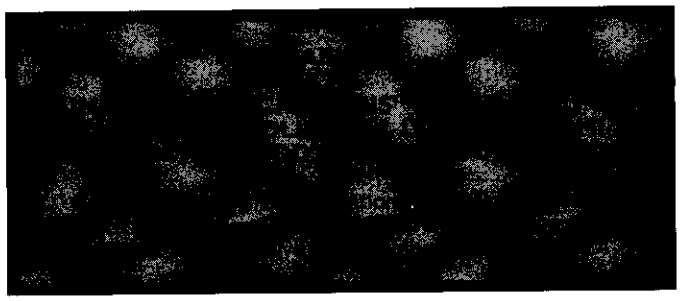
This section describes routine operation of the BACTEC® 9050 instrument. The following major topics are discussed:

- Preparing Specimens
- Daily Checks
- Entering New Vials
- Positive and Negative Specimens
- Printing System Status Reports
- Resolving Station Errors
- Identifying Anonymous Vials

These topics are offered in a general logical order which might fit the workflow of the average laboratory. Some of the operations, such as daily checks, may be done at your convenience. Other operations, like monitoring the system for new positives and alarm conditions, should be ongoing throughout the day.

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4.2 Preparing Specimens



Collection

Specimens should be collected aseptically from the patient and inoculated into the vials. Refer to the appropriate *Media Package Insert* for specific recommendations on specimen collection. Vials should be labeled and sent to the laboratory at once. Additional information is also provided in the *BACTEC® Blood Collection Instructions*, MA–0108.

Preparation

At least one aerobic culture vial and one anaerobic culture vial should be prepared. To prepare a vial, remove the plastic flip cap and clean the exposed rubber septum with 70% isopropyl alcohol. Use a separate swab for each vial. Inoculate the vial with the appropriate volume of sample (refer to the *Media Package Insert* for specific information on vial inoculation).

4.2.1 Media Quality Control

Refer to the specific culture media package insert for Quality Control recommendations.

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4.3 Daily Checks

Each day several simple system checks should be done.

The following checks should be made:

- Check the temperature readout on the instrument's LCD display. Verify that the temperature is currently at 35° C ±1.5° C. Also check the reading on the temperature QC vial. If the readings are not 35° C ±1.5° C, refer to the instructions in Section 7 – Troubleshooting.
- If you have an optional printer, check its paper supply. If the paper supply is low or exhausted, replace the paper.

4.4 Entering New Vials

After specimens have been prepared, they should be scanned and placed in the instrument as soon as possible. However, all BACTEC® fluorescent series instruments (9240, 9120, 9050) have delayed vial positivity criteria that provide for routine delays caused by vial transport, overnight lab closures, etc. The system accommodates the following delay conditions:

For Plus Aerobic/F, Plus Anaerobic/F, PEDS Plus/F, and Lytic/10 Anaerobic/F Media Types:

- Up to 20 hours if vials are incubated prior to entry in the instrument, or
- Up to 48 hours if vials are not incubated (i.e., held at room temperature)

For Standard Aerobic/F and Standard Anaerobic/F Media Types:

- Up to 12 hours if vials are incubated prior to entry in the instrument, or
- Up to 48 hours if vials are not incubated (i.e., held at room temperature)

Before placing vials into the instrument, you should always scan their barcodes and place them in their assigned stations through the vial entry activity. Certain media types use different positivity criteria, and the system can only apply these criteria if the vial label – in which the media type is encoded – is scanned (or the media type is entered manually). In addition, if the vials are not assigned to their stations prior to placement in the instrument, they become anonymous vials, and must be identified before other states (such as positive, negative, etc.) can be displayed. Anonymous vial identification involves the removal and reinsertion of vials, which can result in an increase of false positive rates. Therefore anonymous vial loading into the instrument should be minimized.

There are two ways to enter new vials into the instrument:

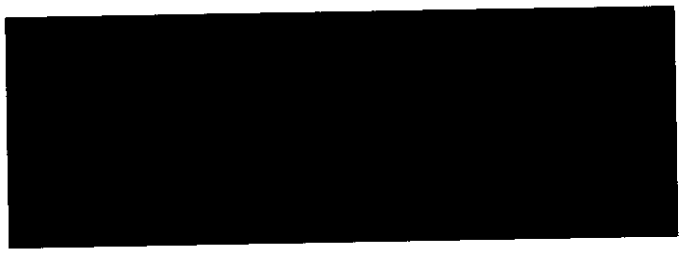
- By scanning the vial barcode when the "barcode scanner ready" icon appears
- By manually selecting the medium type if the vial barcode cannot be scanned by pressing the "no barcode" soft key

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Both methods are explained in Figure 10.

Prior to placing vials into stations, visually inspect all vials for positives. Evidence of microbial growth includes hemolysis, turbidity, and excess gas pressure (causing the vial septum to bulge outward). All such vials should be treated as positives; they should be stained and subcultured.

To enter new vials in the instrument:



Take the new cultures to the instrument. Open the instrument door. Follow the procedure shown in Figure 10.

NOTES

When scanning vial barcodes, place the vial in the alignment block in front of the scanner with the barcode label facing the scanner. If necessary, rotate the vial slightly so the scanner can read the label. The system beeps once to indicate a good scan.

Station assignments are calculated by the system software to balance the rotor. In order to maintain rotor balance, you should always enter vials into the instrument as described in Figure 10, and place the vials where the system indicates.

When inserting vials into stations, carefully push the vial into the station. Press against the shoulders to insure that the vial is fully seated in the station.

Once the vials are placed in stations, they should not be twisted or turned. Vials should not be removed except in the following conditions:

- Removal of positive
- Removal of negative
- Reassign if station becomes bad
- Identification of anonymous vials

Any vial reassigned to a new station should be subcultured immediately.

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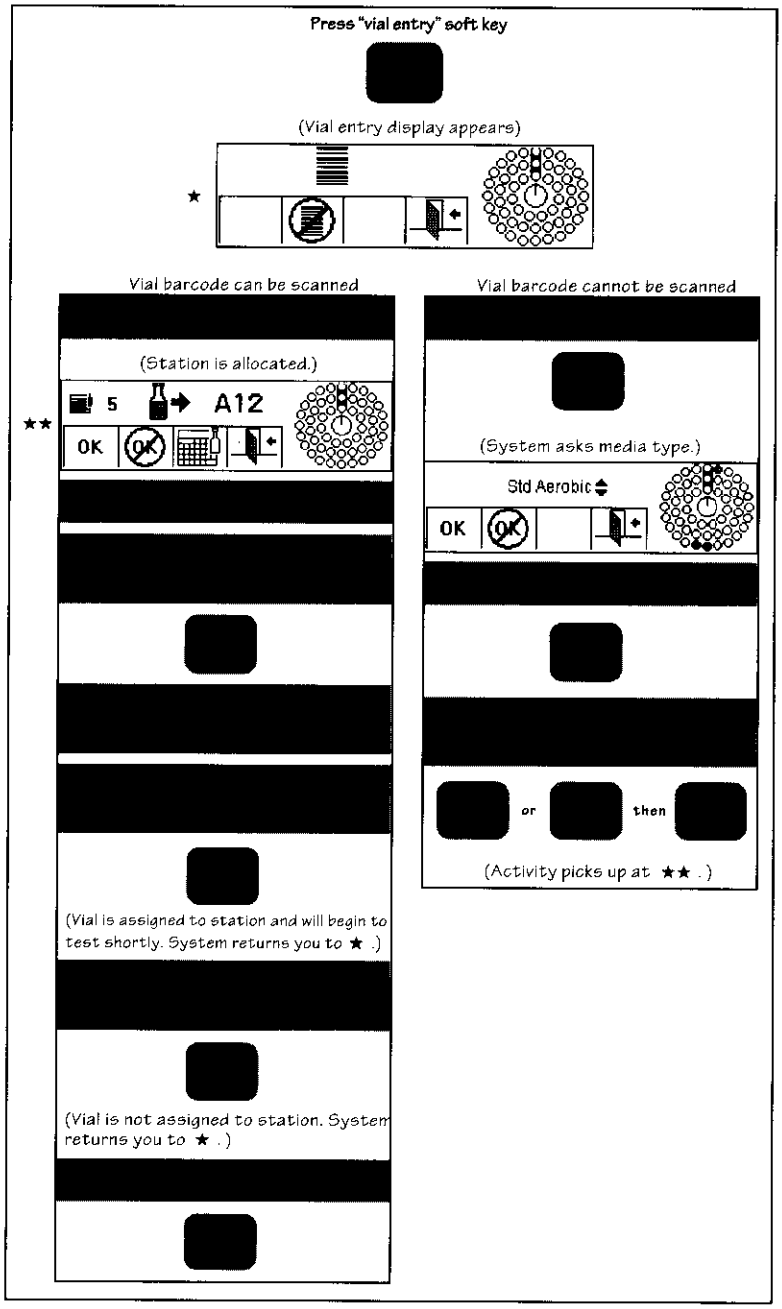


Figure 10 – Entering New Vials

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4.5 Positive and Negative Specimens

4.5.1 General

Many positive cultures will be detected in the first 24 hours after inoculation, but ongoing negative vials must still be kept for several days to assure maximum recovery. With the BACTEC® 9050 instrument, vials are typically held for 5 – 7 days before they are discarded as negative. Each laboratory should set the protocol length based on its own policies and conditions. Your protocol length can be from 4 – 7 days.

A subculture and a Gram stain should be performed from each positive vial. In most cases, organisms will be seen and a preliminary report can be made to the physician. Preliminary antimicrobial susceptibility and identification procedures may also be set up from fluid in the culture vials. The results from these preliminary tests should be confirmed by using standardized laboratory procedures.

The system allows re-entry of instrument-positive vials for up to 3 hours after their removal (subject to the conditions described in Section 4.5.3). The re-entry feature resets positivity routines, retains previous test readings, and continues to test the vial as an ongoing culture.

For a maximum yield of isolates, negative cultures may be stained and/or subcultured during the test period or immediately prior to their disposal.

4.5.2 Notification of Positive and Negative Vials

The system notifies you of new positive cultures in several ways:

- New Positive indicator lamp on the front of the instrument flashes.
- On the Main Status display, the station is displayed as a filled circle with a plus sign (+) in it, and the positives total in the Summary reflects the number of positives in the instrument.
- When the door is opened, the "remove positives" soft key appears in the soft key assignment area of the LCD Display.
- Until silenced, the audible alarm sounds (if enabled).

Negative cultures may exist as ongoing negatives (in protocol) and out-of-protocol negatives. You are notified of these conditions as follows:

- Ongoing Negatives – On the Main Status display, the station is displayed as a filled circle.
- Out-of-Protocol Negatives – On the Main Status display, the station is displayed as a filled circle with a minus sign (–) in it. Also, the negatives count in the Summary reflects the number of final negatives in the instrument. No audible alarm sounds for notification. When the door is opened, the "remove negatives" soft key appears in the soft key assignment area of the LCD Display.

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4.5.3 Removing Positive Vials

Press the SILENCE ALARM key to silence the audible alarm. Open the instrument door. Follow the procedure shown in Figure 11.

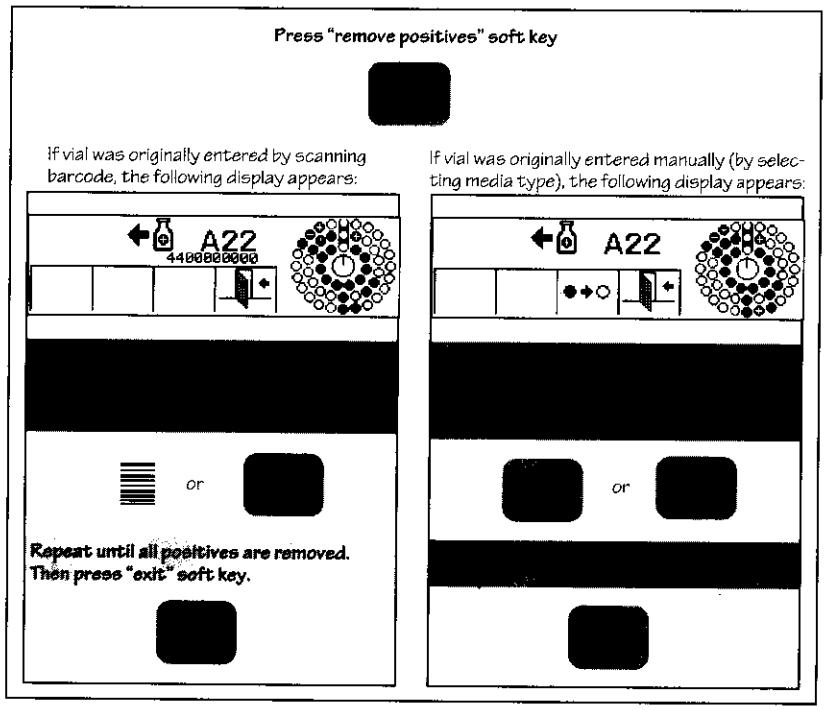


Figure 11 – Removing Positive Vials

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NOTE

The New Positive indicator remains lit until all new positive vials are removed through the Remove Positives operation.

Instrument positive vials can be returned to the instrument for additional testing subject to the conditions described below.

Returning Positive Vials to the Instrument for Further Testing

The system allows you to return a pulled positive vial – if the vial was originally scanned into the instrument – for up to 3 hours after removal (or until the vial goes out of protocol, whichever is earlier). The re-entry feature resets positivity routines, retains previous test readings, and continues to test the vial as an ongoing culture. If the vial is not returned within the 3-hour re-entry window, previous test results are discarded. If the vial was manually entered (by selecting media type), the system treats it as a new vial if it is removed and subsequently re-entered.

The following precautions should be observed when using the vial re-entry feature. Instrument-positive vials should be subcultured and Gram stained upon removal from the instrument. Even though a 3-hour re-entry window exists for the return of a vial to an ongoing status, the vial should be returned to the instrument as soon as possible. Vials should remain at room temperature while they are out of the instrument.

To return a pulled positive vial to the instrument for further testing, open the door. Press the "vial entry" soft key. Next scan the vial's barcode label. Place the vial in the indicated station (this may differ from the original station). Previous test results are retained only in the following circumstances:

- You originally scanned the vial barcode when entering it in the instrument.
- You return the vial within the required time frame.
- You scan the vial label to re-enter the vial.
- You return the vial to the same instrument from which it was removed.

If you do not use the vial entry activity to re-enter the vial, it becomes Anonymous at the next test cycle, and the previous test results are removed from the database if it is not identified within the 3-hour period.

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4.5.4 Removing Negative Vials

Open the instrument door. Follow the procedure shown in Figure 12.

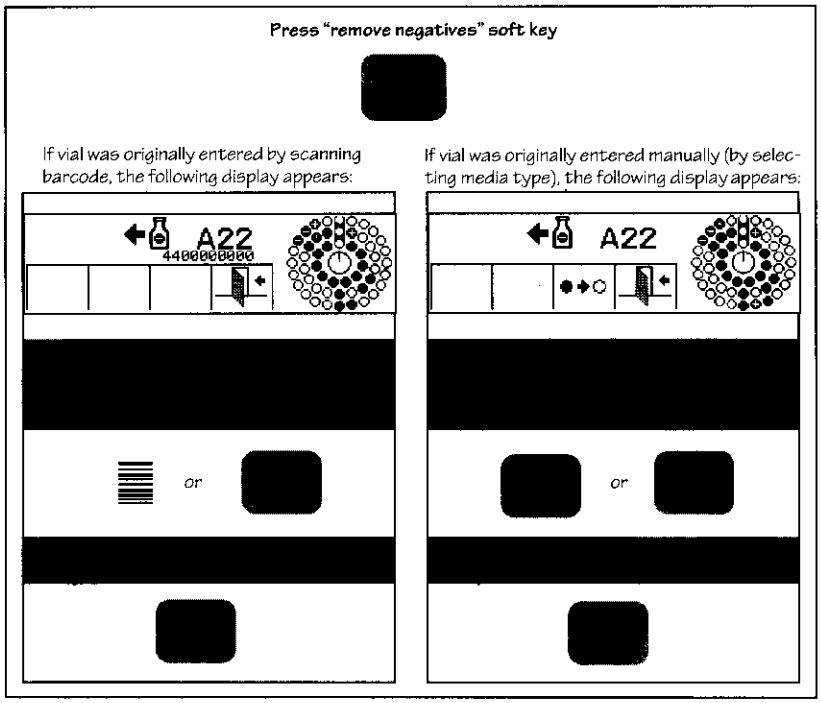


Figure 12 – Removing Negative Vials

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4.6 Printing System Status Reports

If your system is configured with an optional printer, you can print a System Status Report that provides information about current and recently removed culture vials. The report is divided into three main sections: the top section contains information about the instrument, the middle section contains information on vials currently in the instrument, and the bottom section contains information on vials removed in the past 24 hours.

The top section presents the following system/instrument information:

- Report Name
- Product Name
- Date and time that the report was requested
- Instrument number
- Incubator temperature
- System software version
- Ring status (≡ indicates good, X indicates bad , and ? indicates an unknown state)

The middle section (Current Vials) presents the following information on vials currently in the instrument:

- Station Number (the sort order of the report)
- Vial Barcode Sequence Number (if vial was entered manually by selecting media type, the last 8 digits are indicated with hyphens; digits 3 and 4 indicate the selected or scanned media type)
- Vial Status (+ indicates positive, = indicates ongoing, _ indicates negative, ? indicates anonymous [Sequence Number appears blank], and ! indicates error)
- Start of Protocol Date and Time
- Protocol Length
- End Date and Time (for positives, the Date and Time that system flagged positive; for negatives, the end of protocol Date and Time; for ongoing, error, and anonymous, blank)
- Time to Detection in hours and hundredths of hours for positive vials

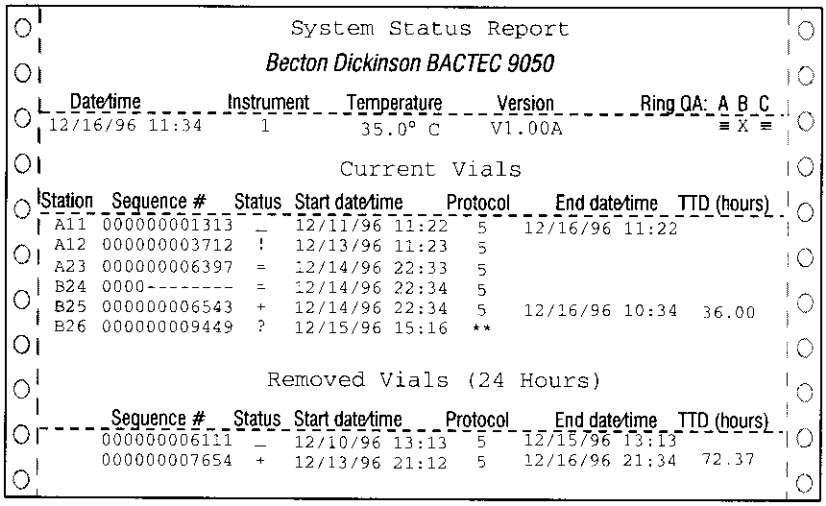
The bottom section (Removed Vials) presents all of the fields named directly above except Station Number. Vials that have been removed from the instrument in the 24 hours *preceding the report request time* are included in this section.

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In order for the report to print correctly, you must set your printer to skip printing across the perforation. Consult your printer operating manual for instructions on how to set this feature in the printer.

To Print the System Status Report

From the Main Status Screen, press the "print report" soft key. The icon appears on the display only if a printer is attached to the system, is turned on, and is online.



System Status Report

Becton Dickinson BACTEC 9050

Date/time	Instrument	Temperature	Version	Ring QA: A B C
12/16/96 11:34	1	35.0° C	V1.00A	≡ X ≡

Current Vials

Station	Sequence #	Status	Start date/time	Protocol	End date/time	TTD (hours)
A11	000000001313	_	12/11/96 11:22	5	12/16/96 11:22	
A12	000000003712	!	12/13/96 11:23	5		
A23	000000006397	=	12/14/96 22:33	5		
B24	0000--------	=	12/14/96 22:34	5		
B25	000000006543	+	12/14/96 22:34	5	12/16/96 10:34	36.00
B26	000000009449	?	12/15/96 15:16	**		

Removed Vials (24 Hours)

Sequence #	Status	Start date/time	Protocol	End date/time	TTD (hours)
000000006111	_	12/10/96 13:13	5	12/15/96 13:13	
000000007654	+	12/13/96 21:12	5	12/16/96 21:34	72.37

Figure 13 – System Status Report

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4.7 Resolving Station Errors

As you perform activities at the BACTEC® 9050 instrument, and as vial testing progresses, system alerts and errors may occur. Different types of alerts and errors are flagged by either "E" error codes, audible tones, the System Alert icon appearing, or the System Alert indicator flashing (or a combination of these). Generally, the more serious the condition, the more ways the system notifies you of the problem.

CAUTION

When the system notifies you of alerts and errors, you should immediately respond to the condition.

System alerts, which comprise all "E" type error codes except those in the 30's, are reported in the system alert log. These errors cause the system alert icon to appear on the Main Status screen, and can be reviewed by pressing the "system alert" soft key. The errors must be reviewed to clear the system alert condition.

Activity errors (such as scanning an unexpected barcode) cause the activity error icon to appear on the activity screen (e.g., remove positives, remove negatives, etc.). They do not put the system into an alert condition, and can frequently be cleared by simply performing the activity correctly (such as scanning the correct barcode).

Station errors (type E12) can occur from a number of causes. These errors are reported in the system alert log, and are also flagged by the appearance of the resolve errors icon on the Main Activity screen. The general operation of resolving error stations is shown in Figure 14. Specific suggestions for resolving error stations are provided in Section 7.2 – Error Messages, under error code E12.

All the "E" type error codes are discussed in detail in Section 7.2 – Error Messages. The audible tones are discussed in Section 3.7 – Audible Tones and Alerts.

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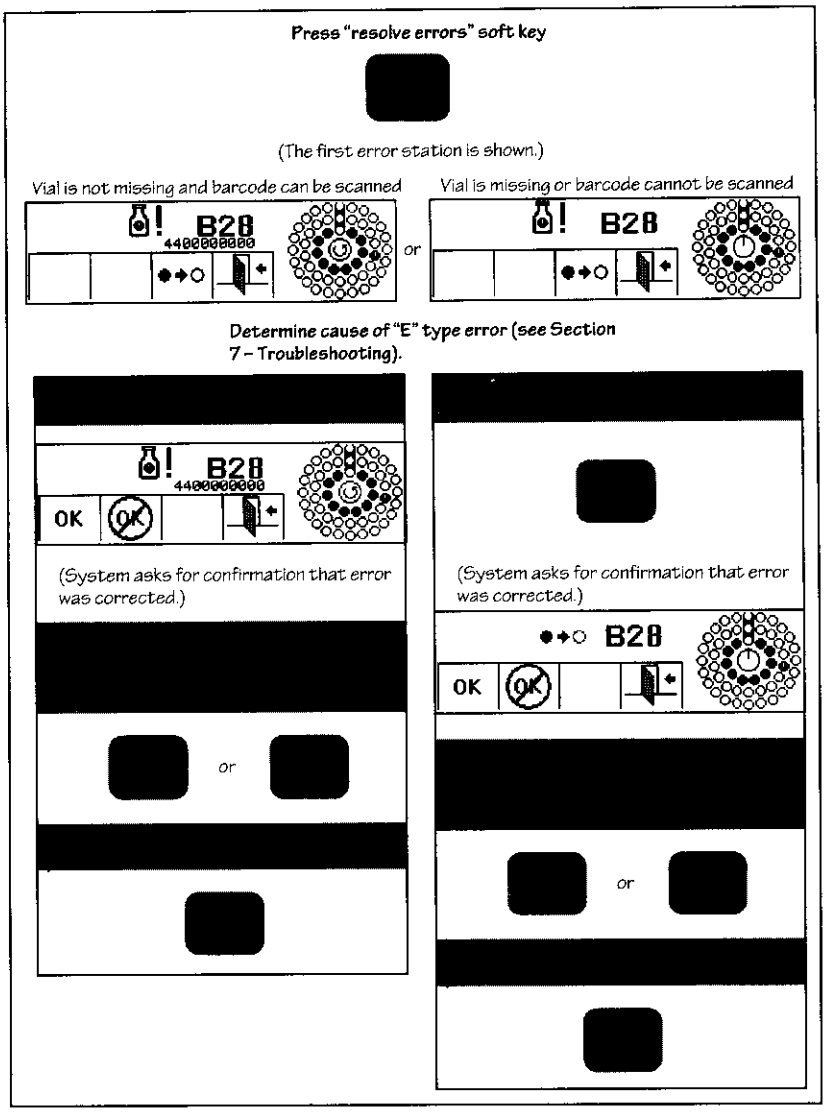


Figure 14 – Resolving Station Errors

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4.8 Identifying Anonymous Vials

An anonymous vial is one which is physically in a station but has not been assigned to that station through the Vial Entry activity. It is very important that when the system notifies you of anonymous vials (anonymous count in Summary window increments and Identify Anonymous icon appears when door is opened), you identify them as soon as possible. The anonymous state supersedes all others, which means that vials that are anonymous may in fact also be positive, out-of-protocol, in error, etc. However, before any other status can be displayed, the anonymous vial must be identified to the system.

The Identify Anonymous function enables you to locate anonymous vials in the instrument and assign them to stations.

To Identify Anonymous Vials

Open the instrument door.

Follow the steps in Figure 15.

Note that because the removal and reinsertion of vials can result in an increase of false positive rates, anonymous vial loading into the instrument should be minimized.

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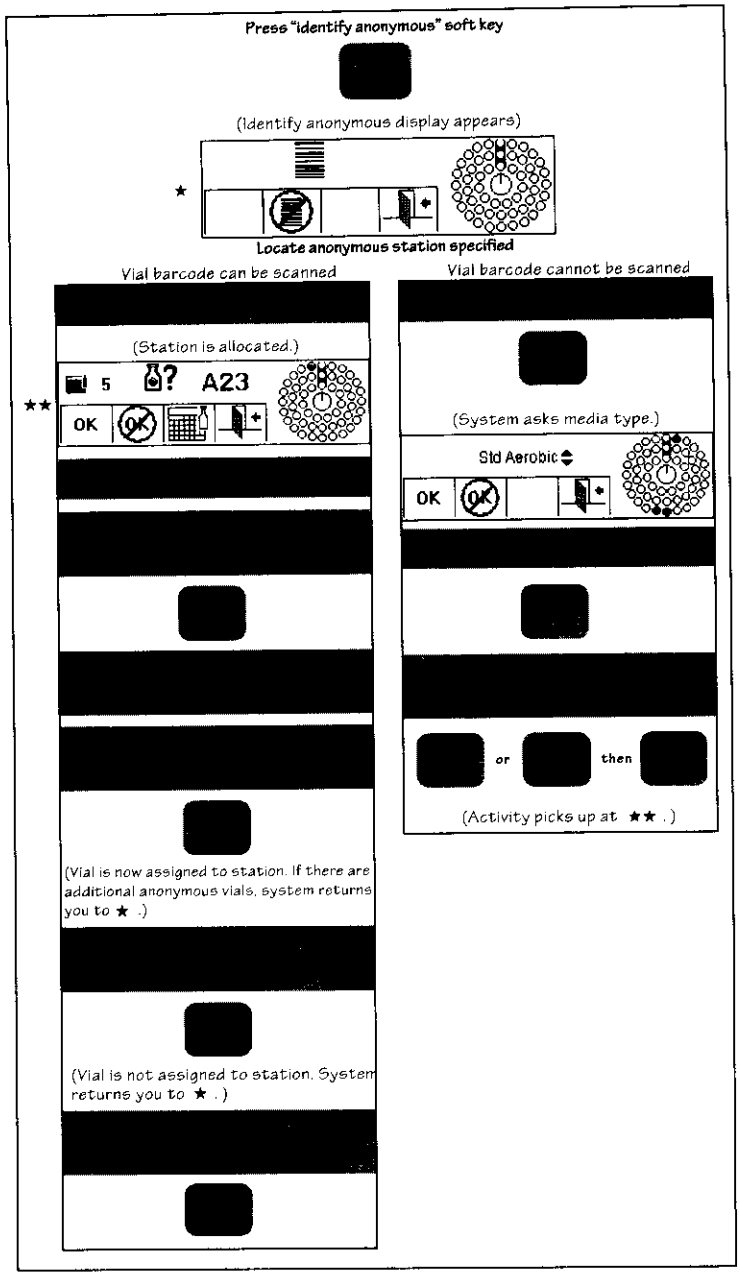


Figure 15 – Identifying Anonymous Vials

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4.9 Power Failures and Manual Operation

The information in the system is stored in memory until a power failure occurs. When a power failure occurs, the data is transferred into non-volatile RAM. Data in NVRAM is maintained by a long-life battery. After the data is transferred, the system is completely shut down. No vial testing occurs until power is restored.

When power is restored, the times that power was lost and restored are noted in the system alert list and can be viewed on the display (note that if multiple power failures occur, only the latest is retained in the alert list). Culture vial testing resumes when power is restored.

For the period of time that power is out, the system misses one test reading for each ten minutes of power outage. Although unlikely, missed readings can result in detection failures. Therefore if testing is interrupted for longer than forty minutes, to ensure maximum recovery it is recommended that you perform a subculture on ongoing culture vials.

You may, at your option, connect the system to an Uninterruptible Power Supply (UPS). Use of a UPS may help prevent interruptions to testing, or – if the UPS is connected to an emergency power line – the necessity of subculturing vials in the event of a sustained power failure.

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5 Reference

5.1 General

This section presents reference material on the BACTEC® 9050 user interface. The following information is presented:

- Software menu tree
- Display types and regions
- Icon Charts

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5.2 Software Menu Tree

The following is a hierarchical list of all displays/functions in the system. The sections where these activities are discussed in detail are noted in parentheses.

Main Status Screen (Door Closed)

- Configuration
  - Set Test Protocol Duration (Section 2.4.2)
  - Set Time Format and/or Time (Section 2.4.2)
  - Set Date Format and/or Date (Section 2.4.2)
  - Set Audible Alarm Volume (Section 2.4.2)
  - Set Instrument Number (Section 2.4.2)
  - Set DVE (Delayed Vial Entry) Media Threshold (feature not available for use in the USA; international users refer to MA–0113, *BACTEC® 9050 Delayed Vial Entry Instructions*)
  - Set Language for Report (Section 2.4.2)
  - Write Data to Disk (Section 2.4.2)
  - Update Software (Section 2.4.2)
- Print Report (Section 4.6)
- Review System Alert List (Section 4.7, 7.2)

Main Activity Screen (Door Open)

- Vial Entry (Section 4.4)
- Remove Positives (Section 4.5.3)
- Remove Negatives (Section 4.5.4)
- Identify Anonymous (Section 4.8)
- Resolve Station Errors (Section 4.7, 7.2)

5.3 Display Types

There are two main types of display screens. When the instrument door is closed, the Main Status screen (Section 5.3.1) is displayed. When the door is open, the Main Activity screen (Section 5.3.2) is displayed.

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5.3.1 Main Status Screen

The Main Status screen (Figure 16) is displayed when the instrument door is closed. This screen presents up to three icons representing soft key definitions that allow you to perform system level activities. These icons are as follows:

- The "configuration" icon, where you can access seven setup parameters, the write data to disk function, and the update software function.
- The "print report" icon. This icon appears only if you have an optional printer, it is attached, turned on, and online.
- The "review system alert" icon, which allows you to review any system alerts that may have occurred or that may still exist.

In addition, system and station status information is always in view. The following information is presented:

- Current date
- Current time
- Current instrument temperature in degrees and tenths of degrees Celsius
- Summary region, showing number of vials that are positive, negative, ongoing, available, and stations that are in error, anonymous, or blocked (note that summary counters may total greater than 50 because vials can have multiple statuses)
- Rotor representation, showing the locations of the various vial statuses when the rotor is in the "home" position (with the temperature standards at the 12:00 position)

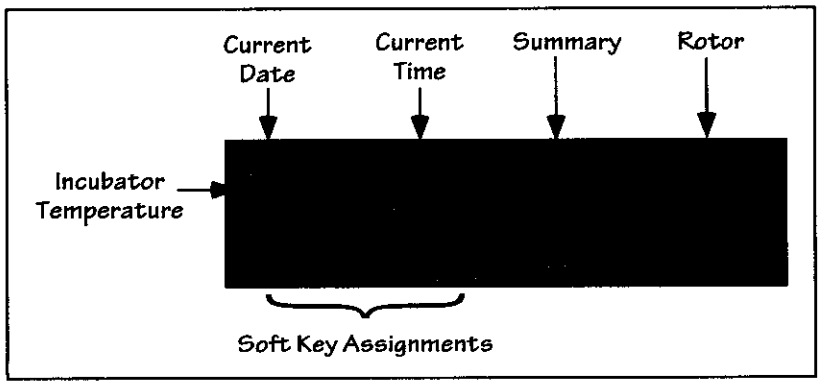


Figure 16 – Main Status Screen

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5.3.2 Main Activity Screen

The Main Activity screen (Figure 17) is displayed when the instrument door is open. This screen presents up to four icons at a time representing soft key definitions that allow you to perform vial- and station-related activities. These icons are as follows:

- The "vial entry" icon, which allows you to enter new culture vials for testing.
- The "remove positives" icon. This icon appears only if there are positive vials in the instrument. It allows you to remove these positive vials.
- The "remove negatives" icon. This icon appears only if there are final (out-of-protocol) negative vials in the instrument. It allows you to remove these negative vials.
- The "identify anonymous vials" icon. This icon appears only if there are anonymous vials in the instrument. It allows you to identify these anonymous vials so that the system can apply the correct positivity criteria and display any underlying statuses.
- The "resolve station errors" icon. This icon appears only if there are error stations in the instrument *and* there are no anonymous vials. It allows you to resolve the error stations.

In addition, system and station status information is always in view. The following information is presented:

- Current date
- Current time
- Current instrument temperature in degrees and tenths of degrees Celsius
- Summary region, showing number of vials that are positive, negative, ongoing, available, and stations that are in error, anonymous, or blocked (note that summary counters may total greater than 50 because vials can have multiple statuses)

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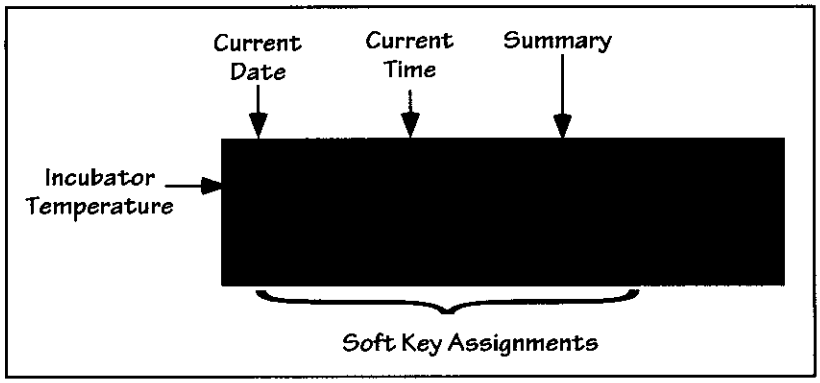


Figure 17 – Main Activity Screen

5.4 Icon Charts

The following charts show all the icons that appear in the system. The icons are arranged in groups of where during system operation they appear.

Station Status Icons

Icon	Meaning	Icon	Meaning
⊖	Negative station	⊕	Positive station
●	Ongoing station	○	Empty (available) station
◐	Error station	◒	Anonymous station
⊗	Blocked station		

Main Status Screen Icons

Icon	Meaning	Icon	Meaning
	Temperature readout		Configuration/Utility Setups
	Print report		Review System Alerts

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Rotor Status Icons

Icon	Meaning	Icon	Meaning
	Temperature standards		Rotor is in intermediate position
	Rotor is at home position		Rotor is rotating

Alert/Error Notification Icons

Icon	Meaning	Icon	Meaning
	Activity error or instrument full		System alert
	Problem with disk inserted or no disk is inserted		Power was removed at this time
			Power was restored at this time

Activity Icons

Icon	Meaning	Icon	Meaning
	Vial entry		Set individual vial protocol
	Remove positives		Remove negatives
	Resolve station errors		Identify anonymous
	No barcode to scan – enter vial medium type manually		Barcode Scanner is ready

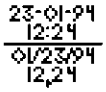
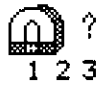
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Media Type Icons (for manual vial entry)	
Icon	Meaning
25mL Plus Aerobic	BACTEC Plus Aerobic/F medium (25 ml)
25mL Plus Anaerobic	BACTEC Plus Anaerobic/F medium (25 ml)
40mL Plus Aerobic	BACTEC Plus Aerobic/F medium (40 ml)
40mL Plus Anaerobic	BACTEC Plus Anaerobic/F medium (40 ml)
PEDS	PEDS Plus/F medium
Lytic	Lytic/10 Anaerobic/F medium
Mycosis-IC/F	Mycosis IC/F medium (not available for use in USA)
MYCO/F LYTIC	Myco/F Lytic medium
Std Aerobic	BACTEC Standard/10 Aerobic/F medium
Std Anaerobic	BACTEC Standard Anaerobic/F medium

Miscellaneous Actions Icons			
Icon	Meaning	Icon	Meaning
OK	Confirm your selection/operation	OK	Cancel your selection/operation
	Scroll down or decrease value		Scroll up or increase value
	Perform the desired action		Move to other field (left)
	Move to other field (right)		Value can be adjusted up/down
	Force station available		Exit the current operation

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Configuration Icons

Icon	Meaning	Icon	Meaning
	Set Protocol duration		Set time or date format
	Set date		Set time
	Set speaker volume		Set instrument number
	Set report language	English	English language
Español	Spanish language		Chinese language
Italiano	Italian language	Deutsch	German language
日本語	Japanese language	Français	French language
Polski	Polish language		Set DVE threshold
AEROBIC	Aerobic threshold	ANAEROBIC	Anaerobic threshold
	Copy data to disk		Update software
	Writing data to disk		

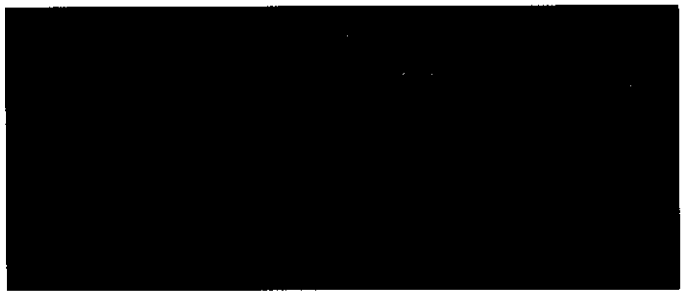
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6

Maintenance

6.1 General

The BACTEC® 9050 instrument requires minimal maintenance from the user to provide reliable performance. Daily verifications include: checking the incubator temperature and printer paper supply (if configured). Routine preventive maintenance consists only of a monthly changing or cleaning of the cabinet air filters. All other procedures are on an "as needed" basis. Any maintenance or repair not described in this section should be performed by Becton Dickinson personnel only.



Note that if testing is interrupted for longer than forty minutes in performing any maintenance procedure, to ensure maximum recovery it is recommended that you perform a subculture on ongoing culture vials.

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6.1.1 Instrument Symbols



Left: Symbol for electrical ground connection; Center: Symbol for electrical hazard, Right: Symbol for "refer to accompanying documentation" for instructions (specifically, the Maintenance section of the user's manual)

6.2 Routine Maintenance

Each day the following checks should be made:

- Check the temperature readout on the instrument's LCD display. Verify that the temperature is currently at 35° C ±1.5° C. Also check the reading on the temperature QC vial. If the readings are not 35° C ±1.5° C, refer to the instructions in Section 7 – Troubleshooting.
- If you have an optional printer, check its paper supply. If the paper supply is low or exhausted, replace the paper.

6.2.1 Air Filter Replacement

Change or clean the air filters on both sides of the instrument monthly. If the instrument's environment is especially dusty, check the filter more frequently. These filters must remain clean and unobstructed; restricted air flow may cause the vials to reach excessive temperatures, which can affect organism recovery and possibly cause hardware malfunctions or failures. The filters can be cleaned and reused. See Figure 18.

Required Materials

New or clean air filters

To Replace the Air Filters

1. The air filters are located on the sides of the instrument near the bottom. To remove a filter, lift it up slightly, then pivot the bottom outward. Lower the filter out of the filter housing.
2. Wash the filter in a solution of warm, soapy water. Dry it thoroughly and place it on a paper towel (if you are going to reuse it immediately).
3. Replace the filter by sliding the top up into the filter housing. Pivot the bottom in toward the instrument, and lower the filter into place.

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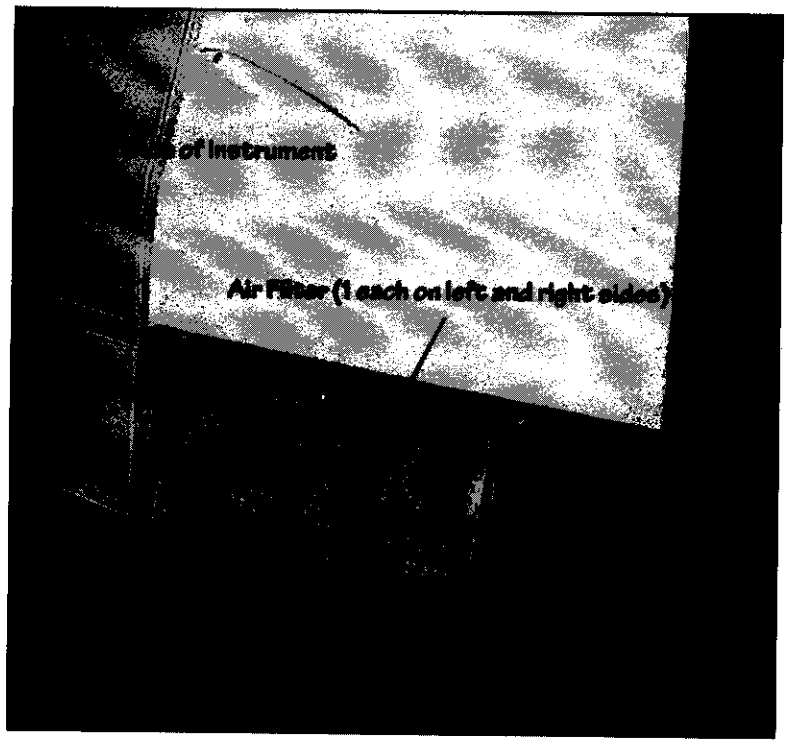


Figure 18 – Air Filter Replacement

6.2.2 Temperature Verification (QC)

A thermometer and special vial are provided for temperature verification (QC) of instrument incubation. It is recommended that the accuracy of the thermometer be verified against a calibrated lab thermometer to insure the validity of the temperature verification.

The temperature control circuitry is designed to maintain the cabinet temperature at 35° C ±1.5° C. If your manual reading is within 1.5° C of the setpoint (35° C), the controller and heaters are operating within their specifications.

The temperature vial is mounted in a bracket on the inside of the instrument door (see Figure 2).

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6.2.3 Barcode Scanner Window

There are no user-serviceable parts in the barcode scanner. The only required periodic maintenance is to clean the scanner's window. To clean the window, use a damp, lint-free, non-abrasive cloth. Dry the window with a dry lint-free non-abrasive cloth.

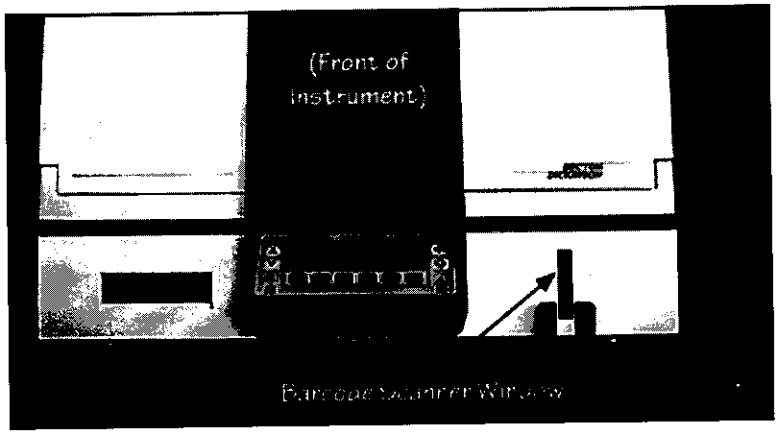


Figure 19 – Barcode Scanner Window

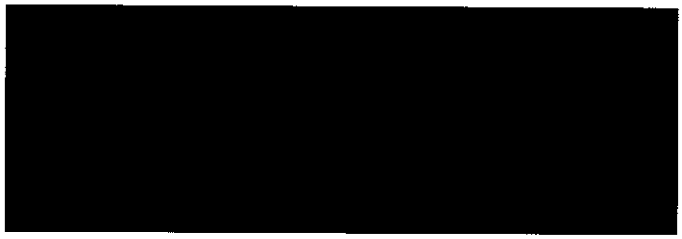
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6.2.4 Decontamination

A situation requiring biological decontamination of one or more stations can occur at any time. The priority in this situation is to first limit the extent of the contamination and then to decontaminate the station or replace the rotor if complete decontamination cannot be accomplished. If there any doubts that the affected station(s) cannot be completely decontaminated, the rotor should be replaced.

To Decontaminate a Station or Rotor

The solution recommended to clean the affected surface should be at least a 10 per cent household bleach solution. All surfaces must be thoroughly washed with the freshly prepared bleach solution so the surfaces are "glistening wet." If you are not sure of the extent of the contamination, thoroughly wash the entire exterior of the Rotor with the freshly prepared bleach solution. Proceed in the following manner to decontaminate a station or Rotor if a vial should break in a station.



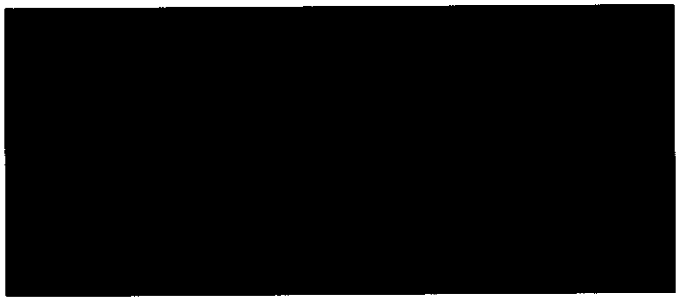
1. Wear gloves and a gown, completely covering any body surfaces that could possibly come in contact with the affected instrument surfaces.
2. Carefully remove broken glass with forceps, one piece at a time.
3. Completely absorb the contaminated spill (gauze pads are most effective).
4. Apply the bleach solution to the affected surfaces so the surfaces are "glistening wet."
5. Absorb the applied solution with gauze pads or paper towels.
6. Thoroughly dry all wet surfaces.
7. Discard ALL cleanup materials with biohazardous waste.

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6.3 Module Replacement

The BACTEC® 9050 instrument has been designed and tested for troublefree performance. However, in the event of a malfunction, most of the major system components can be replaced. Procedures for removing and replacing components are provided in the sections that follow.

Replacement modules may be swapped for failed modules which are then returned to Becton Dickinson. Credit is then applied towards the replacement module. Only replacement parts supplied by Becton Dickinson should be used in the procedures described in this section.



Module replacement instructions are organized in the following groups:

Front Cabinet Components (Damper Cylinder, Door Sensor Switch, Rotor, RTD [temperature sensor]) – Section 6.3.1

Front Panel Components (Barcode Scanner, Floppy Disk Drive, Keypad/LCD Display) – Section 6.3.2

Rear Cabinet Components (AC and DC Power Distribution Boards, Blower, Computer Board, Detector Board, Fan, Heater, I/O Board, Main Transformer, On/Off Switch, +5V/±15V and 40V Power Supply Boards) – Section 6.3.3

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6.3.1 Front Cabinet Components

Front cabinet components include the door damper cylinder, the door sensor switch, the rotor, and the RTD.

6.3.1.1 Damper Cylinder

To replace the damper cylinder, follow the steps below and refer to Figure 20.

Required Materials

Small Flathead Screwdriver

To Remove the Damper Cylinder

1. Begin the removal at the end of the damper cylinder near the bottom center of the door interior. Pry the metal clip off with a small flathead screwdriver.
2. Pull the clip out of the hole.
3. Snap the cylinder's cap off the ball.
4. Repeat these steps for the other end (near the instrument interior) and remove the damper cylinder.
5. Reverse the steps to replace the damper cylinder. When snapping the cap over the ball, be sure to reinforce ball from the bottom.

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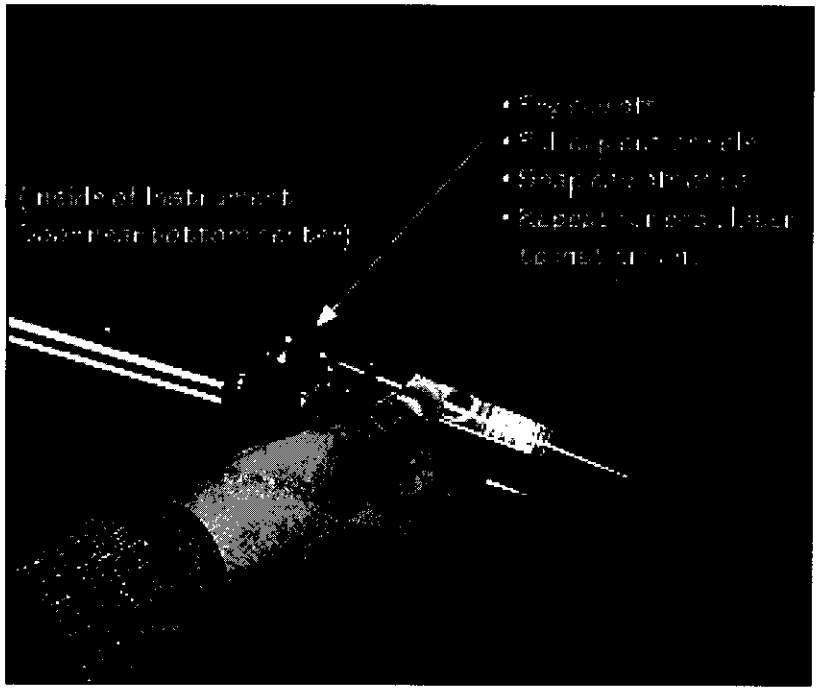


Figure 20 – Damper Cylinder Removal

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6.3.1.2 Door Sensor Switch Replacement

To replace the door sensor switch, follow the steps below. Refer to Figure 21.

Required Materials

Medium Phillips Screwdriver

To Replace the Door Sensor Switch

1 Remove the front panel (Section 6.3.2.1).

2 Reach up inside the interior of the instrument through Keypad/LCD Display hole to find the Door Sensor Switch. (Some people may find it easier to remove the barcode scanner [see Section 6.3.2.2] and reach up through that hole).

3 Squeeze the tabs on each side of the switch together and push the switch forward.

4 Disconnect the wires and remove the switch.

5 When replacing the switch, reconnect either wire to either **inside** terminal – do not plug the wires onto the outer two terminals on the switch.



Figure 21 – Door Sensor Switch Removal

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6.3.1.3 Rotor

The rotor may need to be removed in order to replace the RTD (temperature sensor) module, to clean up if a culture vial breaks, etc. See Figures 22 and 23.

Required Materials

No tools required

NOTES

Removing and replacing the rotor requires two people.

If the rotor is replaced, all vials should be subcultured.

To Remove the Rotor

1. Remove the rear cabinet shell (see Section 6.3.3.1).
2. Open the instrument door.
3. Remove the magnetic disk covering the hub.
4. Unscrew the hubcap (turn counterclockwise).
5. Grasp the rotor by placing your fingers in empty vial stations (try to distribute your grasp evenly among the wells).
6. When you are ready to remove the rotor, the second person should push the driver motor down (see Figure 23).
7. Wiggle the rotor out of the instrument.

CAUTION

After the rotor is removed, DO NOT lay it down on either the front or back sides. (On the rear, the tabs can snap off.) Stand the rotor upright and wedge both sides so it does not roll.

8. When you are ready to replace the rotor, the second person should again push the driver motor down.
9. Wiggle the rotor back into the instrument. Note that the magnetic disk covering the hub fits in one orientation only – a small notch in the disk must be placed surrounding a metal tab on the rotor.

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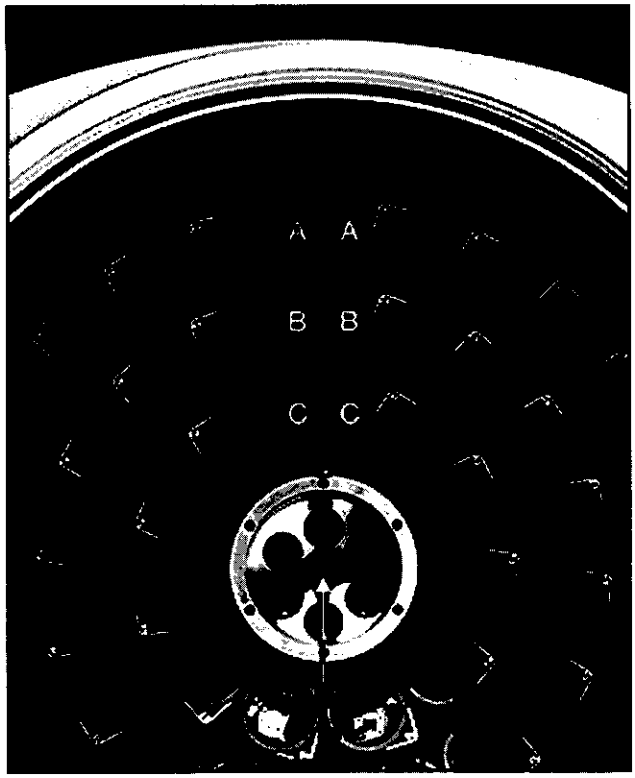


Figure 22 – Rotor Removal

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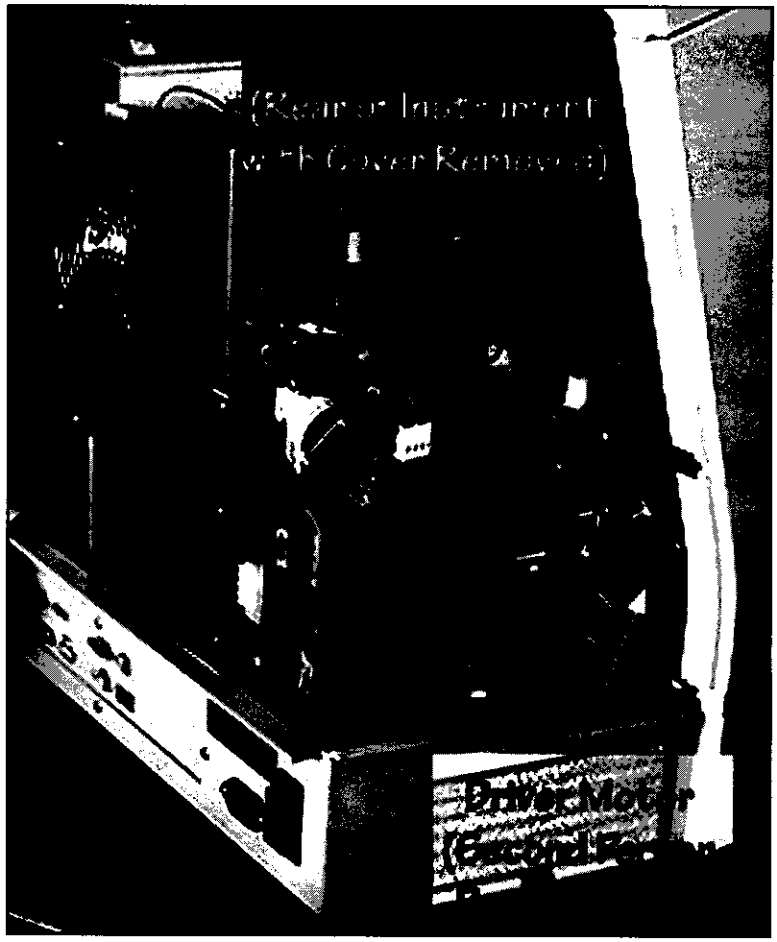


Figure 23 – Rotor Removal – Pushing Down Driver Motor

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6.3.1.4 RTD

The RTD (resistance temperature device, or temperature sensor) is located behind the rotor on the right side (facing the front). To remove the RTD, follow the steps below and refer to Figures 24, 25, and 26.

Required Materials

Small Phillips Screwdriver

To Remove the RTD

1. Remove the rotor (Section 6.3.1.3) and rear cabinet shell (Section 6.3.3.1).
2. Unscrew the small phillips screw on the black mounting clip.
3. Push the rubber grommet in the through-hole through to the front of the instrument.
4. Unplug the maroon 3-wire connector from the I/O Board (located near the front end of the I/O Board).
5. Feed the RTD cable through the through-hole to the front of the instrument and remove the RTD.
6. Replace the RTD by reversing the above steps. Be sure to replace the rubber grommet in the through-hole.

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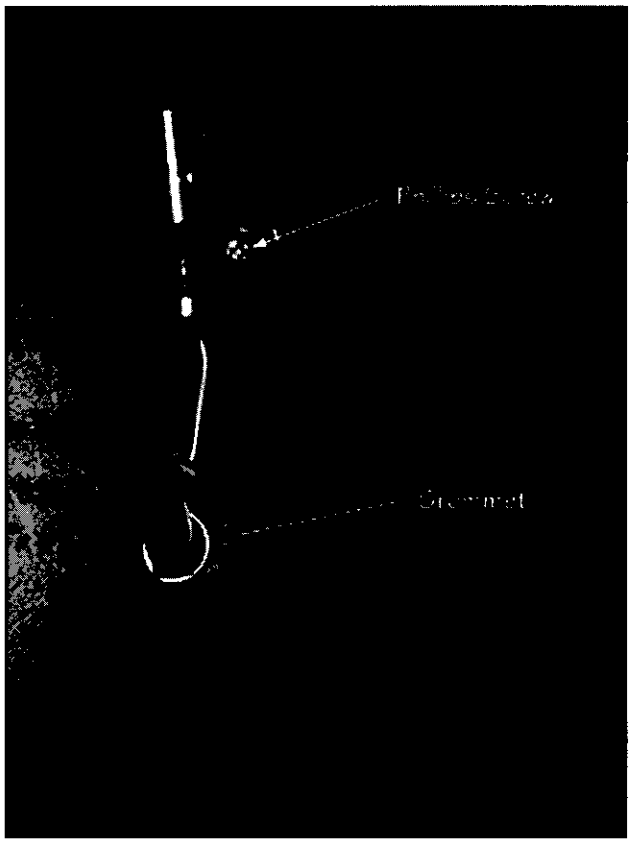


Figure 24 – RTD Removal (A)

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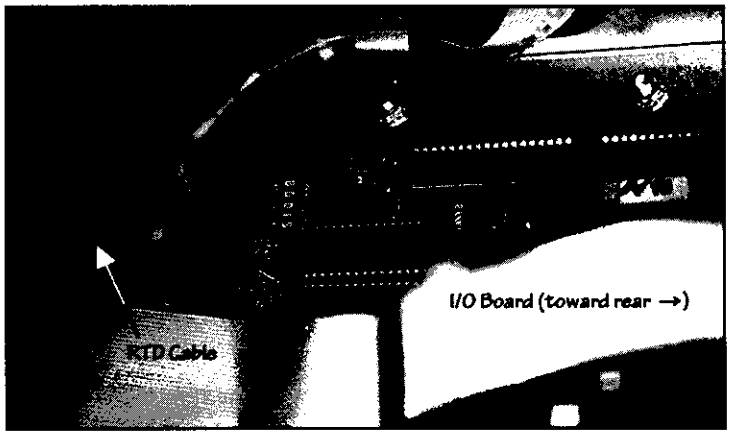


Figure 25 - RTD Removal (B)

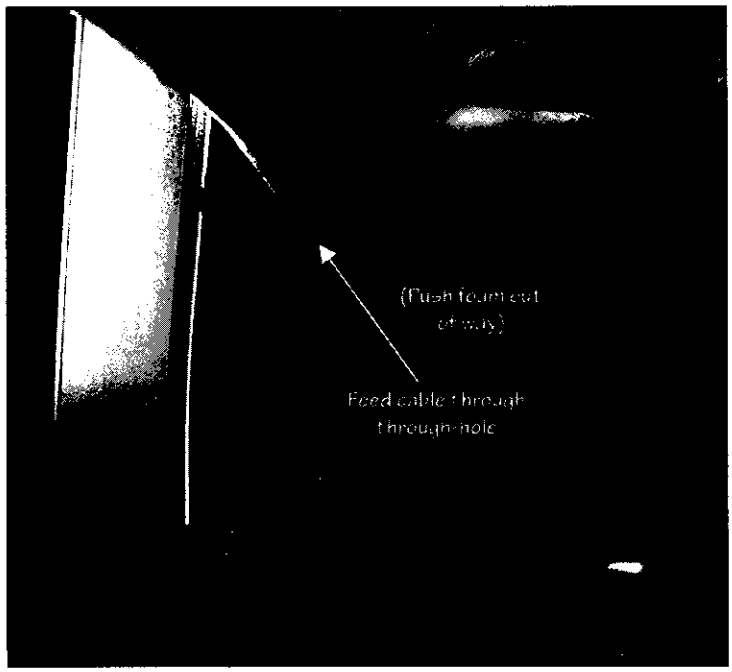


Figure 26 - RTD Removal (C)

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6.3.2 Front Panel Components

6.3.2.1 Front Panel Removal

The front panel, which is located at the bottom of the instrument, must be removed to replace the Barcode Scanner, Floppy Disk Drive, or Keypad/LCD Display. Refer to Figures 27 and 28.

Required Materials

Medium Phillips Screwdriver

Small Flathead Screwdriver

To Remove the Front Panel

1 Unscrew the two phillips screws under the Keypad/LCD Display.

2 Disconnect the wide flat ribbon cable by pulling outward on the tabs at the connector's end.

3 Disconnect the d-shaped connector (use the small flathead screwdriver to loosen the screw locks).

4 Disconnect the barcode scanner and remove the panel assembly.

5 Replace the front panel by reversing the above steps. Be sure to reattach all cables when replacing the front panel.

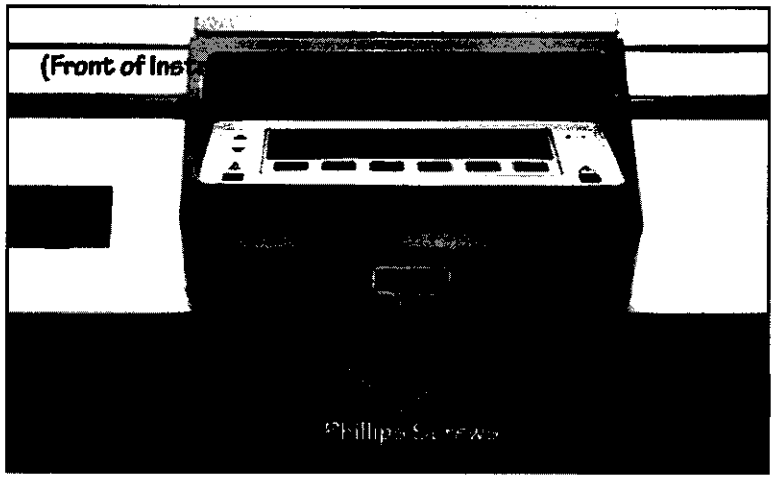


Figure 27 – Front Panel Removal (A)

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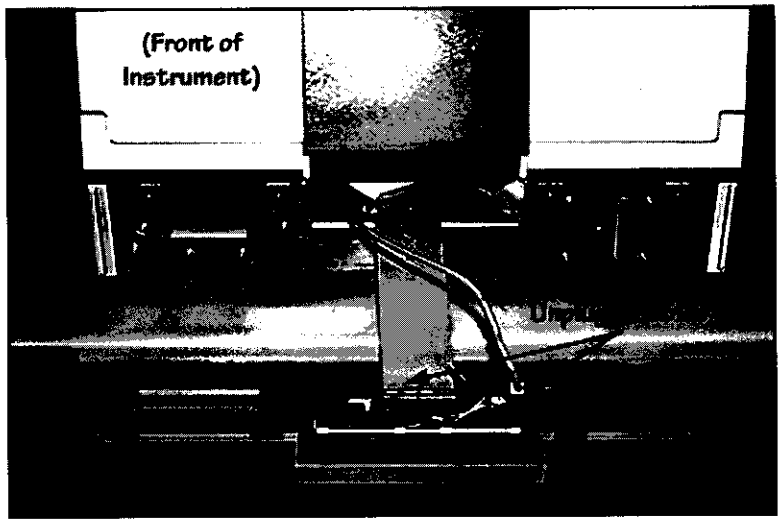


Figure 28 – Front Panel Removal (B)

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6.3.2.2 Barcode Scanner Replacement

To replace the barcode scanner, follow the steps below. Refer to Figure 29.

Required Materials

Phillips Screwdriver (some instruments require Flathead Screwdriver instead)

To Replace the Barcode Scanner

1. Remove the front panel (Section 6.3.2.1).
2. Remove the four phillips screws. (Some instruments have captive fasteners that are designed to be loosened by hand or with a flathead screwdriver.
3. Remove the whole scanner/bracket assembly.
4. Replace the assembly by reversing the above steps.

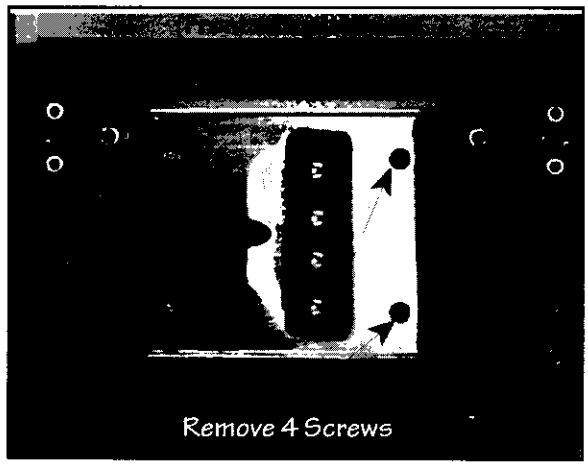


Figure 29 – Barcode Scanner Removal

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6.3.2.3 Floppy Disk Drive Replacement

To replace the floppy disk drive, follow the steps below. Refer to Figures 30 and 31.

Required Materials

Phillips Screwdriver (some instruments require Flathead Screwdriver instead)

To Replace the Floppy Disk Drive

1. Remove the front panel (Section 6.3.2.1).
2. Remove the four phillips screws. (Some instruments have captive fasteners that are designed to be loosened by hand or with a flathead screwdriver.
3. Remove the whole floppy disk drive/bracket assembly.
4. Unplug the small red/black cable.
5. Unplug the flat ribbon cable and remove the drive assembly.
6. To replace the drive, reattach the small red/black cable to the new drive.

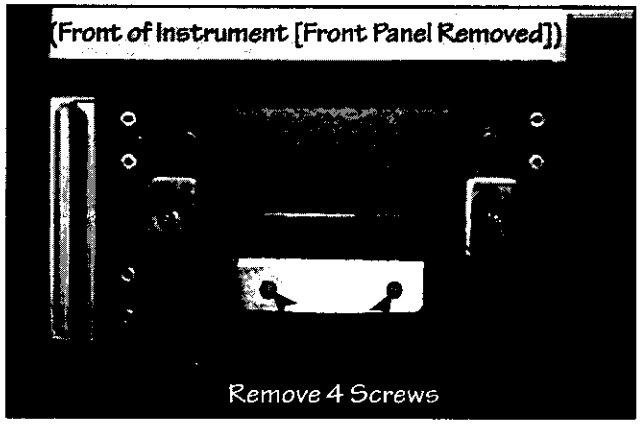


Figure 30 – Floppy Disk Drive Removal

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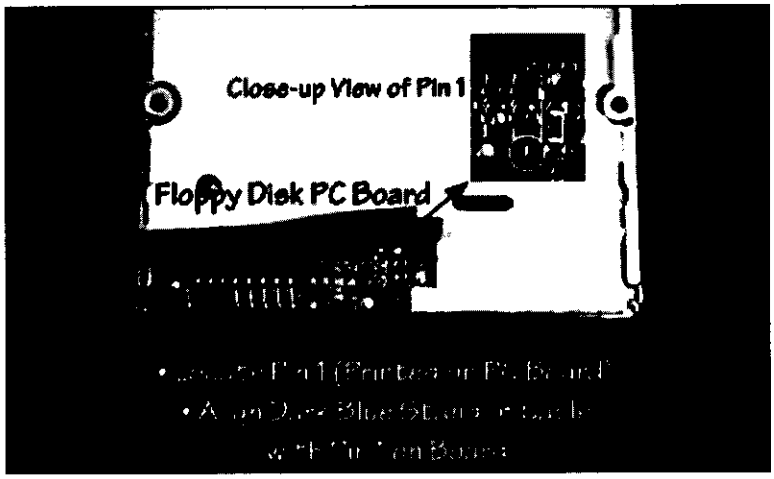


Figure 31 – Floppy Disk Drive Pin 1 Identification (typical)

7 Before attaching the flat ribbon cable, you must identify Pin 1 on the disk drive. Locate the cable socket on the drive assembly. Locate the pins on the printed circuit board that correspond to the pins of the cable socket. Locate the Pin 1 designation (marked by white number "1") on the printed circuit board (not the connector). Align the dark blue strand of the flat ribbon cable with Pin 1 of the printed circuit board, and plug in the cable.

Note that in most cases, the dark blue strand will be oriented at the center of the board. However , this orientation can vary among different disk drive manufacturers. It is important to verify the location of Pin 1 on the drive's pc board. If necessary, you can peel the plastic shield away from the disk drive (as shown in Figure 31) to see better.

8 Insert the new drive/bracket and tighten the fasteners.

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6.3.2.4 Keypad/LCD Display Replacement

The Keypad/LCD Display is part of the front panel assembly. The entire assembly must be replaced. Refer to Figures 32 and 33.

Required Materials

Medium Phillips Screwdriver

Small Flathead Screwdriver

To Remove the Front Panel

1. Unscrew the two phillips screws under the Keypad/LCD Display.
2. Disconnect the wide flat ribbon cable.
3. Disconnect the d-shaped connector (use the small flathead screwdriver to loosen the screw locks).
4. Disconnect the barcode scanner and remove the panel assembly.
5. Replace the front panel by reversing the above steps. Be sure to reattach all cables when replacing the front panel.

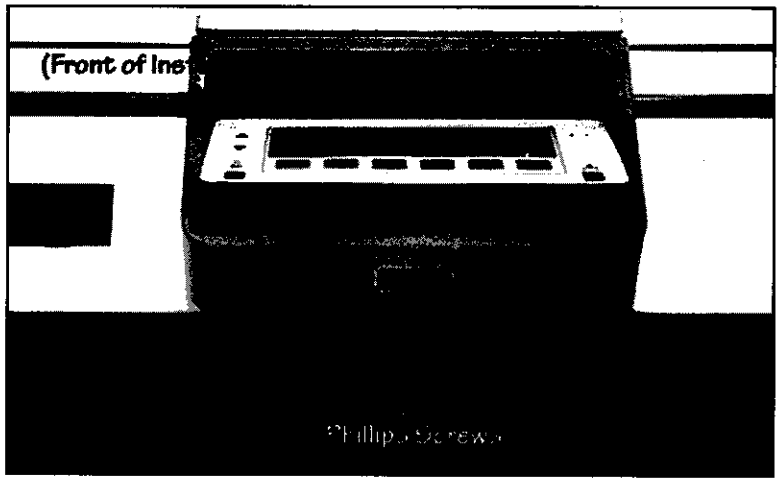


Figure 32 – Keypad/LCD Display Removal (A)

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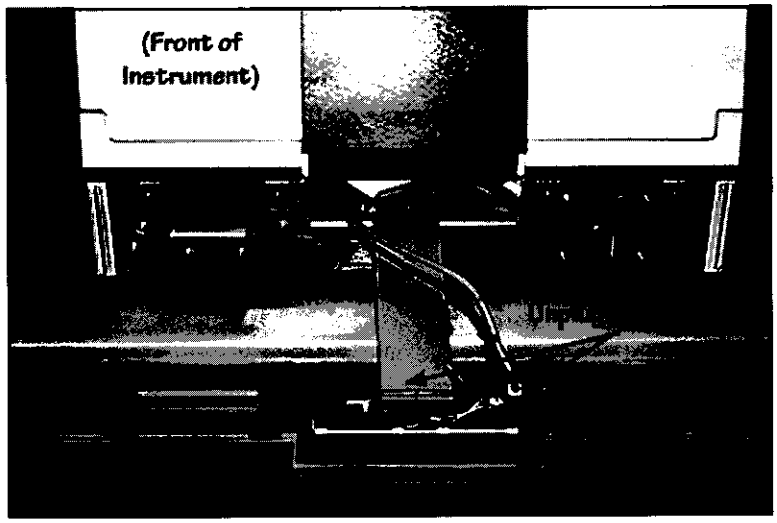


Figure 33 – Keypad/LCD Display Removal (B)

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6.3.3 Rear Cabinet Components

6.3.3.1 Rear Cabinet Shell

The rear cabinet shell must be removed to gain access to the following internal components: AC and DC Power Distribution Boards, Blower, Computer Board, Detector Board, Fan, Heater, I/O Board, Main Transformer, On/Off Switch, +5V/ ±15V and 40V Power Supply Boards, RTD. See Figures 34 and 35.

Required Materials

Medium Phillips Screwdriver

To Remove the Rear Cabinet Shell

1. The rear cabinet shell is held to the instrument frame by 5 phillips screws with flat washers.
2. There is one screw on each side of the instrument toward the bottom rear. Remove these two screws and flat washers.
3. The other three screws are on the rear of instrument. One is at the top center of the rear panel. There is also one screw on the far right of the rear panel and one on the far left, approximately halfway down. Remove these three screws and flat washers.
4. Lift the rear cabinet shell off the frame.

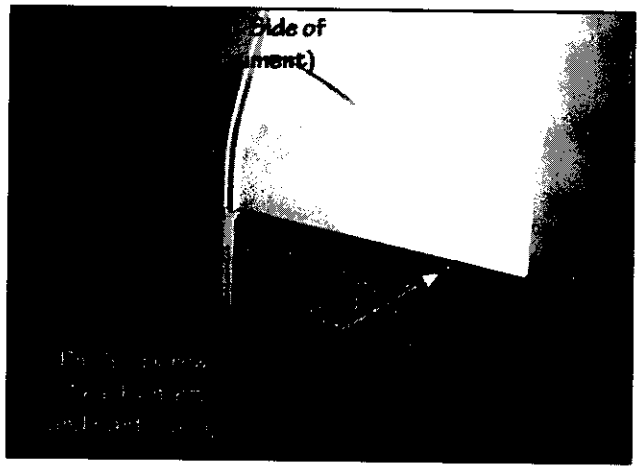


Figure 34 - Rear Cabinet Shell Removal (A)

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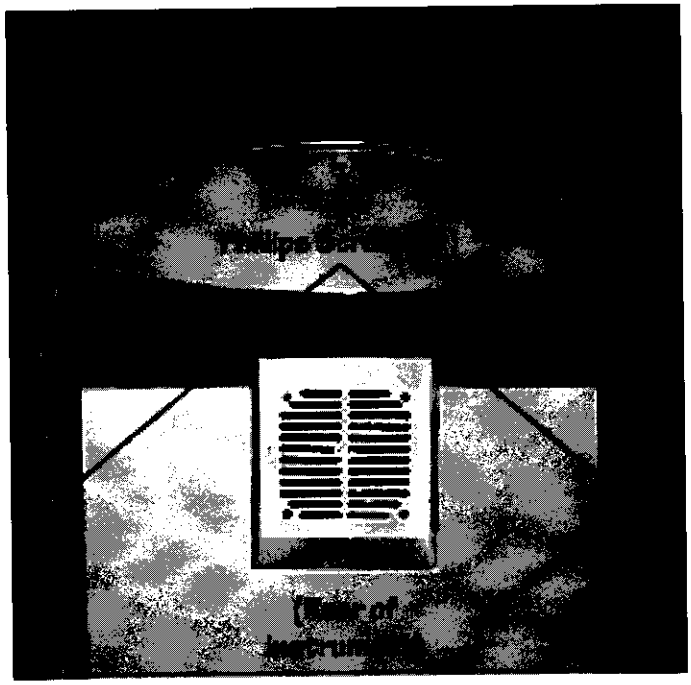


Figure 35 – Rear Cabinet Shell Removal (B)

5 Replace the cabinet shell by reversing the above steps. When replacing the shell, be sure the metal clips (there is one at each screw location) are in place around the screw hole.

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6.3.3.2 Electrical Guard

The electrical guard must be removed to access the Power Supply Boards, the AC and DC Distribution Boards, and the Main Transformer. To remove the guard, follow the steps below and refer to Figure 36.

Required Materials

Small Phillips Screwdriver

To Remove the Electrical Guard

1. Remove the 2 small phillips screws from the top edge of the guard.
2. Remove the small phillips screw from the lower rear edge of the guard.
3. Lift the guard up as far as possible, then move it rearward away from the instrument.
4. Replace the guard by reversing the above steps. DO NOT OVERTIGHTEN THE SCREWS WHEN REPLACING THE GUARD.

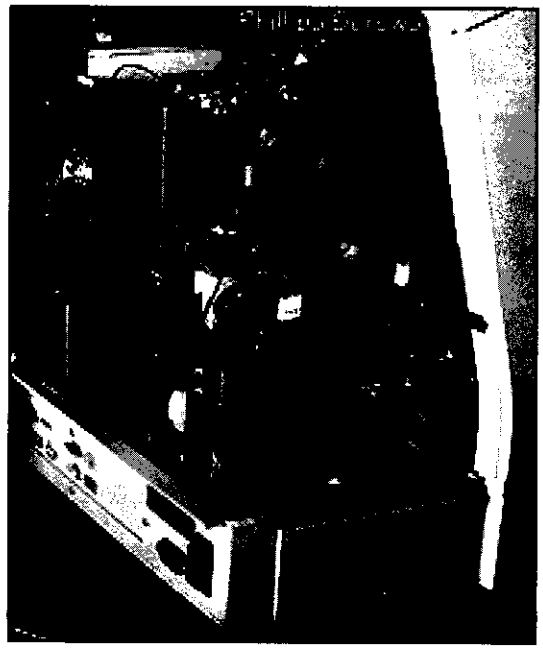


Figure 36 – Electrical Guard Removal

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6.3.3.3 AC Power Distribution Board

The AC Power Distribution Board is located in the right electronics compartment (facing the rear). It is mounted vertically, and contains four large relays and two large transformers. To remove the board, follow the steps below and refer to Figure 37. Fuses F1 and F2 are Type T (slow blow) rated 100 mA, 250 VAC.

Required Materials

$^{5}/_{16}$" Hex Nut Driver

To Replace the AC Power Distribution Board

1. Remove the rear cabinet shell as described in Section 6.3.3.1.
2. Remove the Electrical Guard as described in Section 6.3.3.2.
3. Rock out the two cable connectors at the bottom right of the board.
4. Squeeze the tabs and rock out the cable connector at the bottom left of the board and the cable connector at the far left of the board.
5. Disconnect the cable at the top right of the board by pulling outward on the tabs to loosen it, then pull the cable free of the connector.
6. Remove the six nuts that hold the board to the chassis upright and remove the board.
7. Replace the board by reversing the steps above.

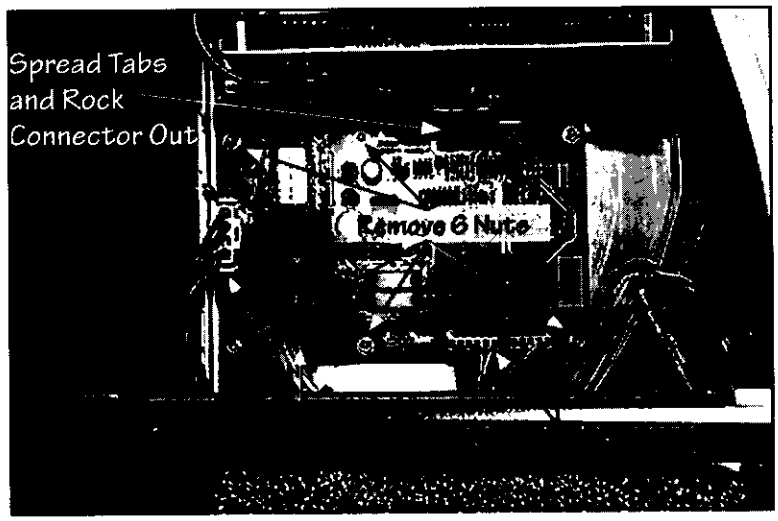


Figure 37 – AC Distribution Board Removal

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6.3.3.4 Blower

The blower is located to the left of center facing the rear of the instrument. It is a large cylindrical black module. To remove the blower, follow the steps below and refer to Figure 38.

Required Materials

Small Phillips Screwdriver

To Replace the Blower

1. Remove the rear cabinet shell as described in Section 6.3.3.1.
2. Unplug the large black cable from the bulkhead fitting.
3. Remove the four small phillips screws that hold the blower assembly in place and remove the blower.
4. To replace the blower, reverse the above steps.

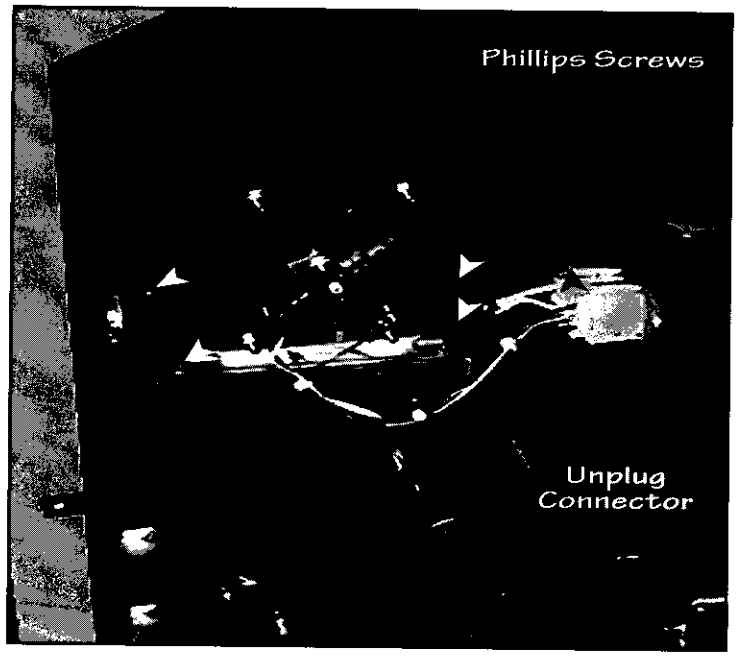


Figure 38 – Blower Removal

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6.3.3.5 Computer Board

The computer board is a small piggyback board mounted at the rear of the larger I/O Board on the bottom of the left electronics compartment. To remove the computer board, follow the steps below and refer to Figure 39.

Required Materials

No tools required

To Replace the Computer Board

1. Remove the rear cabinet shell as described in Section 6.3.3.1.
2. You can remove the computer board without removing the I/O board, but it is easier and safer to replace the computer board with the I/O board out of the instrument. See Section 6.3.3.10 for instructions on removing the I/O board.
3. Disconnect the three ribbon cables on the front side of the board by rocking them off.
4. Disconnect the ribbon cable on rear side of board.
5. Lift the computer board up off the I/O board.
6. Replace the computer board by reversing the above steps. When replacing the computer board, note that it fits on the I/O board in one orientation only. Be sure to carefully align the computer board's pins with the sockets on the I/O board.

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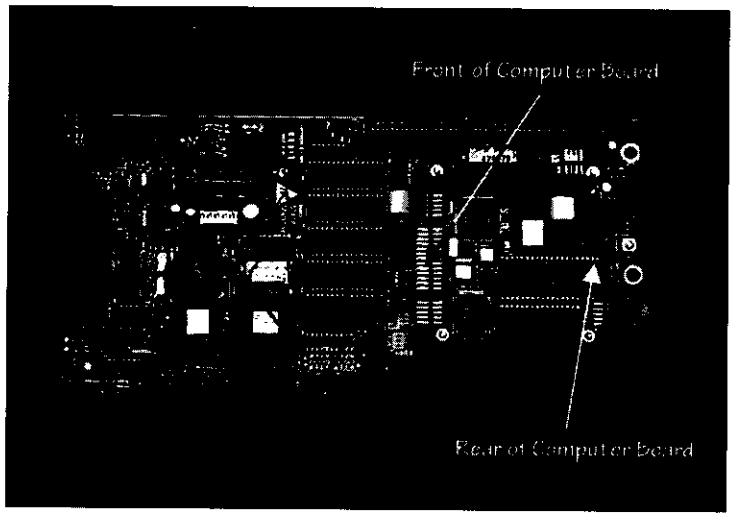


Figure 39 – Computer Board Removal

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6.3.3.6 DC Power Distribution Board

The DC Power Distribution Board is mounted on a bracket horizontally beneath the two power supply boards. To remove the board, follow the steps below and refer to Figure 40.

Required Materials

$^{5}/_{16}$" Hex Nut Driver

To Replace the DC Power Distribution Board

1. Remove the rear cabinet shell as described in Section 6.3.3.1.
2. Remove the Electrical Guard as described in Section 6.3.3.2.
3. Remove the cables and wire harnesses from the retaining clips below the board/mounting bracket assembly.
4. Unplug the 2 connectors at the front of the board by rocking them out.
5. Unplug the 2 connectors at the rear of the board by rocking them out.
6. For the ribbon cable on the rear of the board, push the tabs outward and rock out the connector.
7. Remove the three nuts on vertical mounting bracket. One nut is at the top center and the other two are at the extreme left and right sides. Be sure you remove the correct nuts. Remove the board. Note that the board remains attached to the mounting bracket.
8. Replace the board by reversing the above steps. Note that the connector labeled "TEST" is not used.

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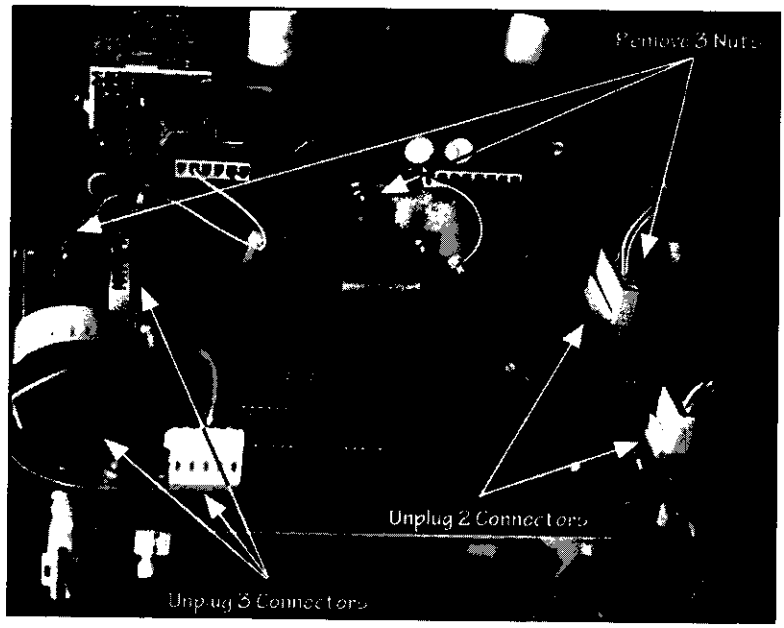


Figure 40 – DC Power Distribution Board Removal

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6.3.3.7 Detector Board

The detector board sits behind the rotor but is designed to be removed from the rear of the instrument. To remove the detector board, follow the steps below and refer to Figure 41.

Required Materials

Medium Phillips Screwdriver

Flashlight (optional)

Medium Flathead Screwdriver (optional)

To Remove the Detector Board

1. Remove the rear cabinet shell as described in Section 6.3.3.1.
2. Reach through the area in the center of the instrument (beneath the fan) to where the detector board is mounted. (You can use the flashlight to illuminate the area.)
3. Disconnect the ribbon cable connector (left side when facing the board from the rear) on the board by flipping the tabs outward and rocking the connector out.
4. Loosen the four black knurled captive fasteners (there is one on each corner) and remove the board. You should be able to turn by the fasteners by hand, but you can use a flathead screwdriver if you prefer.
5. Replace the board by reversing the steps above. Be sure to fit the board over the two guide pins.

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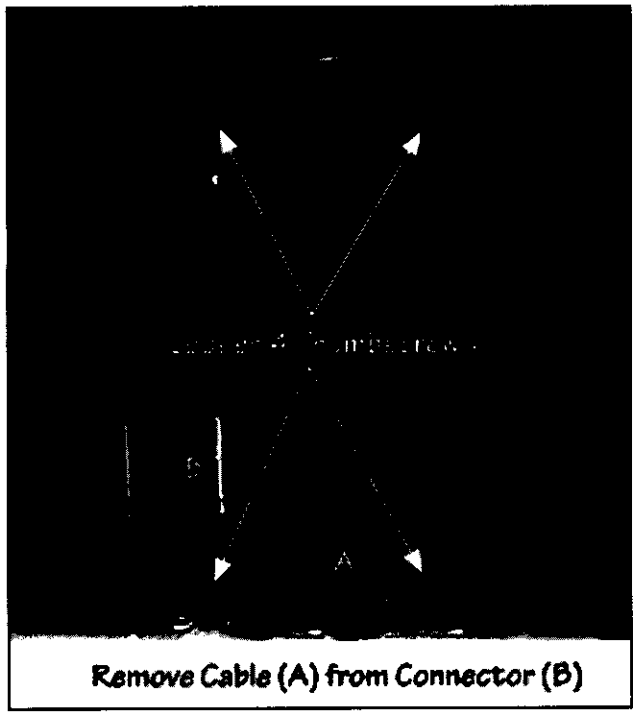


Figure 41 – Detector Board Removal

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6.3.3.8 Fan

To replace the fan, follow the steps below and refer to Figure 42.

Required Materials

Small Phillips Screwdriver

To Replace the Fan

1. Remove the rear cabinet shell as described in Section 6.3.3.1.
2. Unplug the two quick disconnect wires on the right side of the fan assembly. Note that the gray wire is attached to the rear terminal, and the blue wire is attached to the front terminal.
3. Disconnect the ground wire on the top of the fan assembly. Unscrew the small phillips screw, and remove it and the flat washer. The ring terminal is attached to the ground wire, and beneath it is an external star washer. Save this mounting hardware for reattaching the ground wire later.
4. Remove the four small phillips screws that hold the fan to the chassis and remove the fan.
5. Replace the fan by reversing the above steps. Be sure you place one finger guard on each side of the fan itself. Also be sure to replace the hardware and wires in the following order: the external star washer, the ground wire ring lug, the flat washer, and the phillips screw.

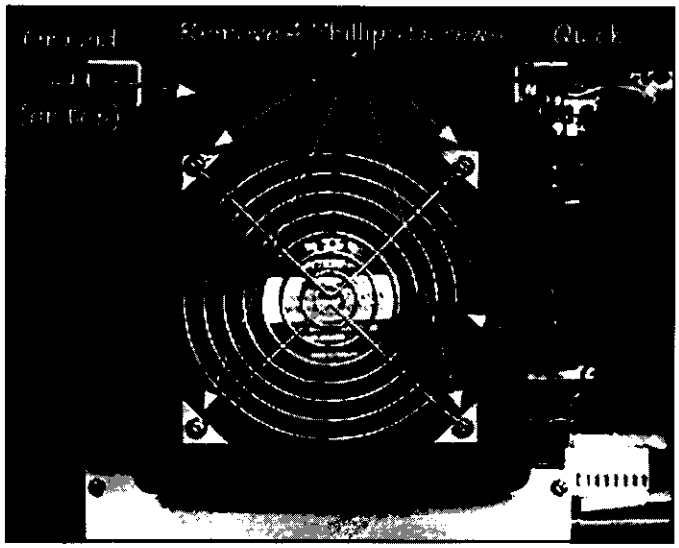


Figure 42 – Fan Removal

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6.3.3.9 Heater

The heater is located in the left electronics compartment near the top of the instrument. To replace the heater, follow the steps below and refer to Figure 43. The thermal over-temperature switch is a manual reset type. This switch should only operate in an abnormal condition. It is rated for 10 cycles of operation.

Required Materials

$^{5}/_{16}$" Nut Driver

To Replace the Heater

1. Remove the rear cabinet shell as described in Section 6.3.3.1.
2. Disconnect the heater cable from its connection on the chassis upright.
3. Remove the four $^{5}/_{16}$" nuts that hold the assembly to the blower duct work.
4. When removing the heater assembly, be sure the insulation clears the top sheet metal.
5. Transfer the cable from the old assembly to the new heater, one connection at a time. Note that the black wire is an internal connection and does not have to be disconnected. Be sure you connect the yellow wire to the lower left terminal, the orange wire to the terminal on the reset button, and the green/yellow (ground) wire to the bottom right stud. Note that the extra hardware attaching the ground wire should be placed, from front to rear: external star washer, the ground wire's ring lug, the flat washer, and the lock washer.
6. To replace the heater, insert in with the widest part downward. Replace the four nuts. Plug the cable back into the chassis upright connector.

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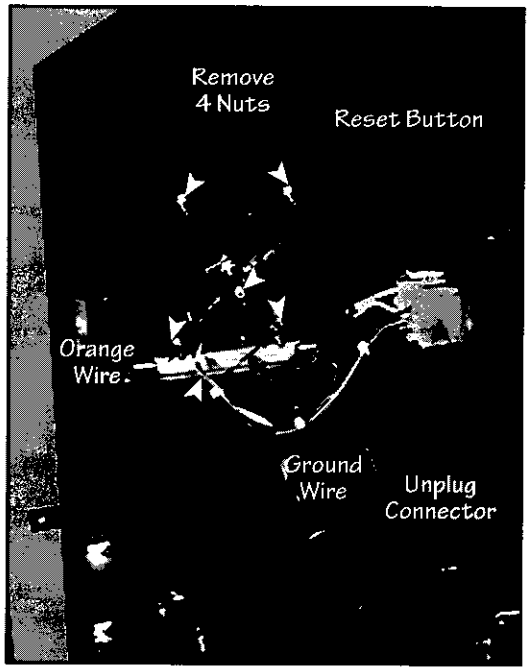


Figure 43 – Heater Removal

6.3.3.10 I/O Board

The I/O board is a large board located at the bottom of the left electronics compartment. To remove the I/O board, follow the steps below and refer to Figure 44.

NOTE

If the I/O Board is replaced, all vials should be subcultured.

Required Materials

Medium Phillips Screwdriver

To Replace the I/O Board

1 Remove the rear cabinet shell as described in Section 6.3.3.1.

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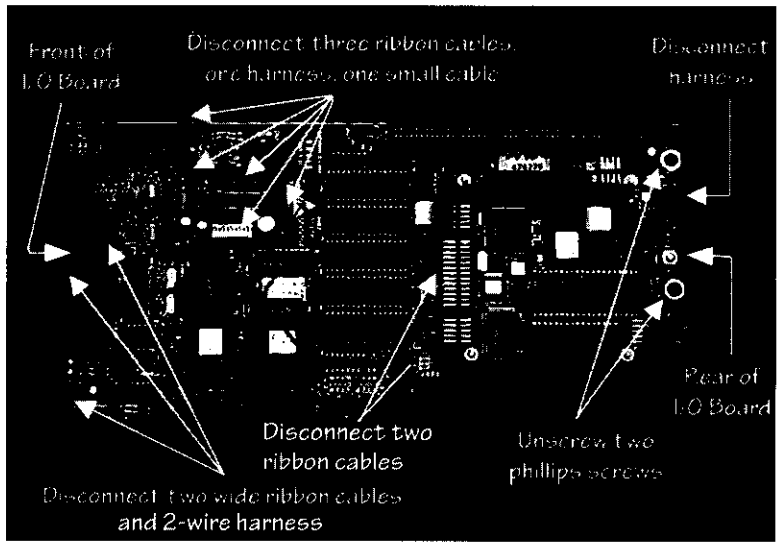


Figure 44 – I/O Board Removal

2 Unplug the two wide flat ribbon cables at the front of the board, and the 2-wire harness at the front left.

3 Unplug the five cables on right side of the board (three are ribbon cables, one is a harness style cable, and the fifth is a small cable).

4 Disconnect the cable harness at the rear of the board (toward the right).

5 Remove the two phillips screws/flat washers holding down the rear of the board. Wiggle the board up and out.

6 Disconnect the 2 ribbon cables (originating at the rear panel) from the front of the computer board. Remove the computer board and place it on the new I/O board as described in Section 6.3.3.5.

7 Replace the board by reversing the above steps. Note that the front of the board has two keyhole cutouts. Place the wide part of the hole over the studs, then slide the board to the narrow part of the cutouts. Be sure you reconnect all the cables.

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6.3.3.11 Main Transformer

The main power transformer is mounted to the bottom chassis in the right electronics compartment. To replace the main transformer, follow the steps below and refer to Figures 45, 46, and 47.

Required Materials

$^{7}/_{16}$" wrench

To Replace the Main Transformer

1. Remove the rear cabinet shell as described in Section 6.3.3.1.
2. Remove the Electrical Guard as described in Section 6.3.3.2.
3. Remove the cable harness from the tie-ups that secure it to the chassis upright. Unplug the cable harness. Be careful not to bend the varistor (red disk) on the AC Distribution Board when unplugging the connector.
4. For instrument serial numbers 1000 – 1695 only, disconnect the ground wire that is attached to the chassis bottom (see Figure 45).

   For instrument serial numbers 1696 and above, remove the bolt that holds the transformer to the chassis and lift the transformer out of the cabinet (see Figure 46).
5. Replace the transformer by reversing the above steps. Note that when replacing the transformer, components should be placed in the following order (from bottom to top): rubber insulating pad, transformer, rubber insulating pad, metal disk.

   For instrument serial numbers 1000 – 1695 only, when reattaching the ground wire, from the bottom you should place: (all other ground wires undisturbed), the ground lug, the flat washer, the lock washer, the nut.



Figure 45 – Main Transformer Removal (A)
For Instrument Serial Nos. 1000 – 1695 Only

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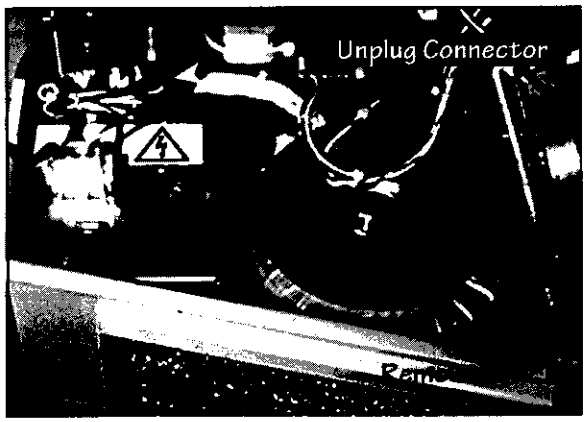


Figure 46 – Main Transformer Removal (B)
For Instrument Serial Nos. 1696 and above

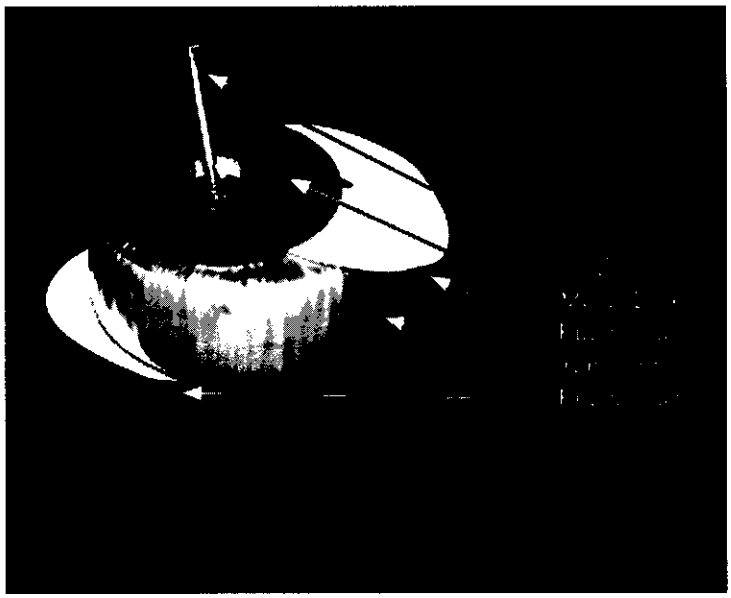


Figure 47 – Main Transformer Removal (C)
For All Instrument Serial Nos.

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6.3.3.12 On/Off Switch, Line Filter, and Interlock Switch



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6.3.3.13 Power Supply (5V / +15V / –15V) Board

The 5V/±15V Power Supply is located at the top of the right electronics compartment, toward the front of the instrument. (The 40V Power Supply is right next to this board, toward the rear of the instrument.) To replace the 5V/±15V Power Supply, follow the steps below and refer to Figure 48.

Required Materials

$^{5}/_{16}$" Hex Nut Driver

To Replace the Power Supply Board

1. Remove the rear cabinet shell as described in Section 6.3.3.1.
2. Remove the Electrical Guard as described in Section 6.3.3.2.
3. Unplug the white connector on the top of the board.
4. Unplug the connector on the bottom of the board.
5. There is one nut on each of the board's four corners. Remove these nuts and remove the board.
6. Replace the board by reversing the above steps.

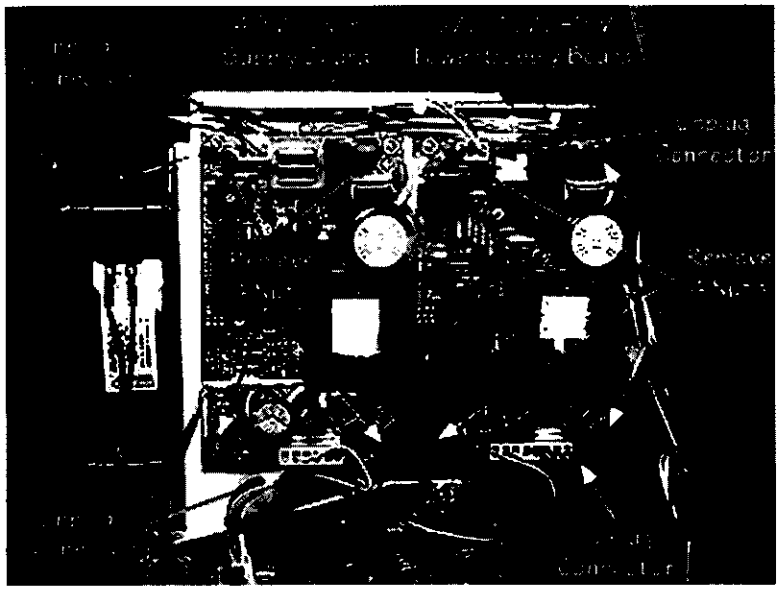


Figure 48 – Power Supply (5V/±15V) Removal

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6.3.3.14 Power Supply (40V) Board

The 40V Power Supply is located at the top of the right electronics compartment, toward the rear of the instrument. (The 5V/±15V Power Supply is right next to this board, toward the front of the instrument.) To replace the 40V Power Supply, follow the steps below and refer to Figure 49.

Required Materials

$^{5}/_{16}$" Hex Nut Driver

To Replace the Power Supply Board

1. Remove the rear cabinet shell as described in Section 6.3.3.1.
2. Remove the Electrical Guard as described in Section 6.3.3.2.
3. Unplug the white connector on the top of the board.
4. Unplug the connector on the bottom of the board.
5. There is one nut on each of the board's four corners. Remove these nuts and remove the board.
6. Replace the board by reversing the above steps.

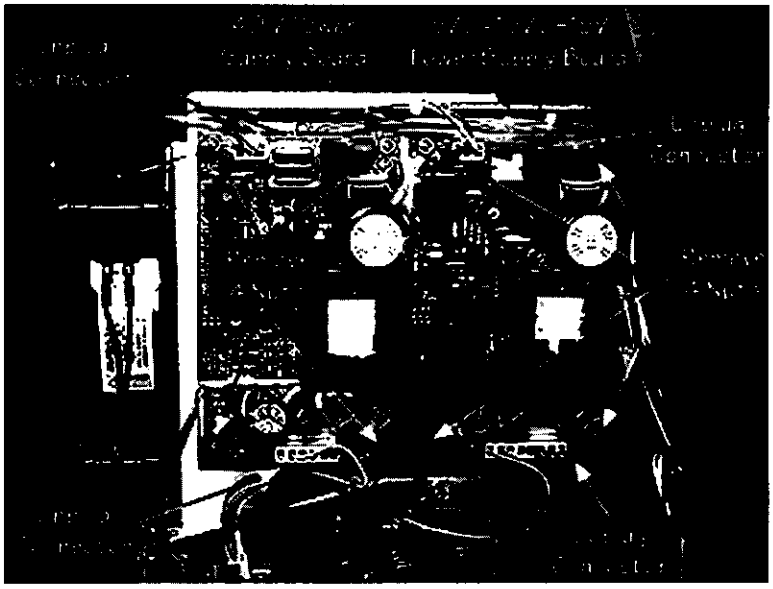


Figure 49 – Power Supply (40V) Removal

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7

Troubleshooting

7.1 General

7.1.1 Instrument Service

If your BACTEC® 9050 instrument malfunctions or operates unusually in any way, you may initially attempt to solve the problem by following the procedures in this section. All other servicing attempts will terminate the responsibility of the manufacturer under the terms of the warranty.

If you cannot repair a system malfunction, contact your local Becton Dickinson representative (contact numbers are listed in Appendix D).

This section discusses error messages, which appear when the system has encountered a known problem. These messages are listed in numerical order, along with possible causes of the message and corrective actions.

7.1.2 Instrument Symbols



Left: Symbol for electrical ground connection; Center: Symbol for electrical hazard, Right: Symbol for "refer to accompanying documentation" for instructions (specifically, the Maintenance section of the user's manual)

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7.2 Error/Alert Messages

CAUTION

When the system notifies you of alerts and errors, you should immediately respond to the condition.

When the system encounters an alert or error condition, the error code is either displayed on the screen or written into the System Alert list. The error code is an abbreviation for the conditions described in the listing below.

Codes in the E30 series (E30, E31, etc.) are not written into the System Alert list, but are displayed on the screen when they occur. (They also cause the Activity Error tone to sound [sequence of short high beep and short low beep repeated four times].) These are activity (or "workflow") types of errors. In most cases, this means that some action you have performed was not what the system expected, but you can usually perform the correct action, as recommended below, without exiting the current operation. These activity errors are flagged by the Activity Error icon:



System alerts, which comprise all error codes except those in the E30 series, are reported in the System Alert list. These errors cause the Alert tone (medium beep on for one second, off for 3 seconds, repeating) to sound (if it is enabled). Also the System Alert icon appears on the Main Status Screen. The errors must be reviewed to clear the system alert condition. The System Alert list can be viewed from the Main Status Screen by pressing the "system alert" soft key:



The error messages are listed in numerical order. Error sub-codes are shown in the system alert list, and indicate specific conditions detected. Many sub-codes are listed in the "Possible Causes" and "Corrective Actions" sections below.

CAUTION

If any error sub-codes other than those listed here appear, note the sub-code and contact Becton Dickinson for assistance.

If the recommended corrective actions do not solve the problem, contact Becton Dickinson.

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E01 Temperature alarm

POSSIBLE CAUSE(S)

Incubator temperature is too high (00000001) or too low (00000002).

- Door was kept open too long.
- Room temperature is not within recommended range.
- Air filters are dirty, restricting fresh air intake.
- RTD, heater, fan, or blower is defective.

CORRECTIVE ACTION(S)

- ❒ Check current incubator temperature on LCD Display to see if temperature is still too high or too low.
- ❒ Minimize number and duration of door openings.
- ❒ Make sure room temperature is within range specified in Section 2 – Installation and Setup.
- ❒ Clean or replace air filters.
- ❒ Check thermometer vial to see if manual reading agrees with displayed reading.
- ❒ Reset manual thermostat (see Figure 43 for location of Reset button).
- ❒ 00000001 – At temperatures in excess of 38° C, viability of many organisms may have been lost. Recollection of specimens should be considered.
- ❒ 00000002 – At temperatures below 32° C, detection of some organisms may be missed or delayed. Subculture of vials should be considered.

E02 Rotor RPM out of spec

POSSIBLE CAUSE(S)

Rotor speed is too fast, too slow (00000002), or stopped (00000004).

- Something is impeding or jamming movement of rotor.
- A vial is not seated in the station.

CORRECTIVE ACTION(S)

- ❒ Check for and remove anything that may be impeding or jamming the movement of the rotor.
- ❒ Make sure all vials are seated in stations.
- ❒ All vials should be subcultured.

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E05 Temperature standardization error

The temperature standards are out of tolerance.

POSSIBLE CAUSE(S)

- Temperature standards are not seated.
- Cover over temperature standards is not in place.
- Debris, spilled media, or blood inside instrument is affecting temperature standard readings

CORRECTIVE ACTION(S)

- ❒ Check/reseat temperature standards.
- ❒ Check/adjust cover over temperature standards.
- ❒ Check that there is no debris, spilled media, or blood inside instrument. Clean if necessary.

E06 Rotor configuration error

POSSIBLE CAUSE(S)

- Rotor is not mounted correctly.
- Hold-down nut (hubcap) is not tight.

CORRECTIVE ACTION(S)

- ❒ Check rotor mounting – correct if necessary.
- ❒ Check hubcap and tighten if necessary.

E07 Power supplies high/low

POSSIBLE CAUSE(S)

- Temporary electrical anomaly.

CORRECTIVE ACTION(S)

- ❒ Reboot instrument.

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E09 No tests in over 40 minutes

POSSIBLE CAUSE(S)

- Instrument has been off or door has been opened for longer than 40 minutes.
- Four consecutive test cycles were missed (e.g., due to door openings).
- System clock was set more than 40 minutes ahead.

CORRECTIVE ACTION(S)

❒ If instrument has been off, four consecutive readings were missed, or door has been open for longer than 40 minutes, **all vials should be subcultured**. If system clock was set more than 40 minutes ahead, subculture not required. If this error occurs and none of the above events happened, write data to disk and contact Becton Dickinson.

E10 Database corruption

POSSIBLE CAUSE(S)

- Database checksum test failed.

CORRECTIVE ACTION(S)

❒ Write data to disk and call Becton Dickinson.

❒ 00000002, 00000008 – All vials should be subcultured.

E11 Printer error

POSSIBLE CAUSE(S)

- Printer paper is jammed or exhausted.
- Printer cable is disconnected during printing.
- Printer power is turned off during printing.
- Printer was taken offline during printing.

CORRECTIVE ACTION(S)

❒ Check paper and clear jam or add paper if necessary.

❒ Check printer cables (power and communications), reattach if necessary.

❒ Turn printer power on.

❒ Place printer online.

❒ Request report again. It will not resume printing automatically when error condition is corrected.

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E12 Error vial or error station

NOTE

The E12 message is the corresponding System Alert to the Resolving Station Errors activity discussed in Section 4.7.

POSSIBLE CAUSE(S)

00000001, 00000002, 00000004, 00000008

- System cannot detect a vial in a station where one should be. The vial may not be seated in the station completely, or may have been pulled out of the instrument without being scanned out.

CORRECTIVE ACTION(S)

- ❒ If vial is in station, or was removed but you have now located it, use the resolve station errors activity to scan the vial label. If the station was in a "hardware" error condition (such as with errors E05 and E06), the current station will be blocked from use and the vial will be relocated to a new station (if one is available). If the station was in a "software" error condition (error E12 with any of the sub-codes listed above), the error condition is cleared after you scan the label and confirm the error resolution.

- ❒ If the vial cannot be located, press the "force station available" soft key. This **forces the vial's protocol to be terminated** and clears the error condition. Vials that are cleared in this manner are reported as follows on the System Status Report: vials with a status of positive are reported as positives; vials with a status of negative are reported as negatives; vials with a status of ongoing are reported as errors.

- ❒ Always be sure to press against the vial shoulders when placing vials into stations, to insure that they are fully seated.

- ❒ To avoid station errors, always use one of the remove vial activities (such as remove positives or remove negatives) to scan the vial out of the station prior to physically removing it.

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E13 Power Failure

POSSIBLE CAUSE(S)

- Power was removed from instrument.

CORRECTIVE ACTION(S)

❒ Message is informational. If multiple power failures have occurred, only the latest one is reported in the alert list. Note the power failure and restore times in your instrument log.

E30 Unexpected vial was scanned

POSSIBLE CAUSE(S)

- During the remove positives, remove negatives, or resolve station errors activities, the vial barcode you scanned is not the one the system expected for the station. Either you pulled a vial from a different station than the one specified; or more than one vial has been placed in the wrong station.

CORRECTIVE ACTION(S)

❒ If the station is still displayed on the activity screen, verify that you pulled the vial from the specified station. If you did not (you will know because a vial is still in that station), press the "exit" soft key, then press the "vial entry" soft key. Scan the vial label and place the vial where the system indicates. **If there is a vial in the indicated station, do not remove that vial to "swap" locations.** Go to belo w.

❒ If you pulled the vial from the specified station, you must try to determine how many vials are misplaced, and where they are located. It may be helpful to print a System Status Report (if you have an optional printer), add a column labeled "actual station," and relabel the existing station column as "assigned station." If you do not have a printer, you can draw a chart, with one column labeled "vial sequence number," a second column labeled "assigned station," and a third column labeled "actual station."

Write down the current vial sequence number. Write the station specified on the activity screen in the "actual station" column.

Press the "exit" soft key, then press the "vial entry" soft key. Scan the vial label, and write the station in the "assigned station" column of your chart. There will be a vial in this station.

Place the first misplaced vial aside – it must be subcultured, because vial test results cannot be transferred reliably among multi-station misplacements.

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Remove the vial from the station currently displayed on the vial entry screen. Write this vial sequence number on the chart, as well as the actual station. Now scan the current vial label. Write the station now displayed in the "assigned station" column. Place this vial aside for subculturing.

Go to the station now displayed. If there is a vial in this station, repeat the steps in the previous paragraph. Continue to do so until the actual station matches the assigned station, or until there is no vial in the assigned station. When one of these conditions occurs, you have probably reached the end of the vial misplacements.

- ❒ All vials involved in misplacement scenarios must be subcultured.
- ❒ When the next test cycle or rotor scan occurs, any stations from which vials were removed will go into error. Resolve all the station errors as described above under error E12 and in Section 4.7 after the misplaced vials have been subcultured.

E31 Diskette error

POSSIBLE CAUSE(S)

- Floppy disk is not inserted.
- Floppy disk is not formatted.
- Floppy disk is write-protected.
- Floppy disk is full.

CORRECTIVE ACTION(S)

- ❒ Insert formatted floppy disk.
- ❒ Move write-protect tab toward center of floppy disk.
- ❒ Use a new floppy disk.

E32 Instrument full

POSSIBLE CAUSE(S)

- During Vial Entry or Resolve Station Errors, the system tried to allocate a station but found that none are available.

CORRECTIVE ACTION(S)

- ❒ Remove final negative vials if any exist. If not, vial should be tested manually.

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E33 Moved vial with no error

POSSIBLE CAUSE(S)

- The system has detected a vial in a station that does not have a vial assigned to it (i.e., an anonymous vial). When you are identifying anonymous vials, the system does **not** expect a known barcode to be scanned (if it knows the barcode, that means the vial was previously scanned in and assigned to a *different* station). Scanning a known barcode during the identify anonymous activity causes this error to occur. The two main causes of the error are: 1) you pulled a vial from a different station than the one specified in the identify anonymous screen; or 2) more than one vial has been placed in the wrong station.

CORRECTIVE ACTION(S)

❒ To correct the error condition, you have to determine: 1) whether you pulled the wrong vial or vials have been misplaced; 2) if vials are misplaced, where does the instrument think vials should be; and 3) where vials are actually located.

❒ If the station is still displayed on the identify anonymous screen, verify that you pulled the vial from the specified station. If you did not (you will know because a vial is still in that station), press the "exit" soft key, then press the "vial entry" soft key. Scan the vial label and place the vial where the system indicates. **If there is a vial in the indicated station, do not remove that vial to "swap" locations.** Go to below.

❒ If you pulled the vial from the specified station, you must try to determine how many vials are misplaced, and where they are located. It may be helpful to print a System Status Report (if you have an optional printer), add a column labeled "actual station," and relabel the existing station column as "assigned station." If you do not have a printer, you can draw a chart, with one column labeled "vial sequence number," a second column labeled "assigned station," and a third column labeled "actual station."

Write down the current vial sequence number. Write the station specified on the identify anonymous screen in the "actual station" column.

Press the "exit" soft key, then press the "vial entry" soft key. Scan the vial label, and write the station in the "assigned station" column of your chart. There will be a vial in this station.

Place the first misplaced anonymous vial aside – it must be subcultured, because vial test results cannot be transferred reliably among multi-station misplacements.

(more)

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Remove the vial from the station currently displayed on the vial entry screen. Write this vial sequence number on the chart, as well as the actual station. Now scan the current vial label. Write the station now displayed in the "assigned station" column. Place this vial aside for subculturing.

Go to the station now displayed. If there is a vial in this station, repeat the steps in the previous paragraph. Continue to do so until the actual station matches the assigned station, or until there is no vial in the assigned station. When one of these conditions occurs, you have probably reached the end of the vial misplacements.

- ❒ All vials involved in misplacement scenarios must be subcultured.
- ❒ When the next test cycle or rotor scan occurs, any stations from which vials were removed will go into error. In addition, the anonymous station that began the problem is still anonymous. Go to the identify anonymous activity, and recall the anonymous vial that originally generated this error. Select any media type, then press the "OK" soft key. Press the "OK" soft key again at the confirmation prompt. Allow this station to go into error too, then resolve all the station errors as described above under error E12 and in Section 4.7 after the misplaced vials have been subcultured.

E34 Update error

POSSIBLE CAUSE(S)

- During a software update, an error occurred.

CORRECTIVE ACTION(S)

- ❒ Return to the "update software" operation and repeat the software update.

E50 Internal software error

POSSIBLE CAUSE(S)

- System encountered a software error.

CORRECTIVE ACTION(S)

- ❒ Write data to disk and call Becton Dickinson.

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Limited Warranty

This warranty gives you specific legal rights. Additionally, you may have other rights that vary from region to region.

The BACTEC® 9050 is warranted to be free from defects in material and workmanship. Full responsibility is assumed by the manufacturer for servicing any instrument or its components (except for expendable supplies such as filters) which under normal operating conditions, prove to be defective within one year of delivery.

Becton Dickinson Microbiology Systems will furnish new or remanufactured components upon its option. All replacements shall meet new part specifications. Defective components become the property of Becton Dickinson.

It is understood that the equipment covered by this Agreement has been installed in accordance with the recommendations and instructions in the BACTEC 9050 System User's Manual and the BACTEC® 9050 Installation and Setup guide.

Any damage to a BACTEC® 9050 resulting from the insertion or removal of cables that connect this instrument to systems other than those approved or supplied by Becton Dickinson or the negligence of the owner to maintain reasonable care and precautions in the operation and maintenance of the system will void this warranty and terminate the obligations of the manufacturer as stated herein.

This warranty is in lieu of all other warranties, whether express or implied, including but not limited to, warranties of merchantability, or fitness for a particular use. In no event will Becton Dickinson Microbiology Systems be liable for indirect or consequential damages.

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B

Replacement Parts

The following items may be ordered by calling your local Becton Dickinson representative (see Appendix D).

Item	Catalog Number
Barcode Scanner Assembly	4405812
Blower	4405807
Computer Board	4405820
Front Panel Assembly	4405811
Damper Cylinder w/ Mounting Brackets	4405801
DC Distribution Board	4405827
Detector Board	4405817
Door Sensor Switch	4405816

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Item	Catalog Number
Fan	4405814
Fan Guards	4405815
Filters, Air (2)	4405810
Floppy Disks	4405847
Floppy Disk Drive	4405813
Heater	4405808
I/O Board	4405818
Knob	4405803
Main Transformer	4405824
Manual, BACTEC® 9050 System User's (ea.)	4405845
On/Off Switch/Circuit Breaker	4405822
Placard, Instrument (ea.)	4405846
Power Control/AC Distribution Board	4405823
Power Supply +5V, +/– 15V	4405825
Power Supply +40V	4405826
Rotor	4405802
RTD Assembly	4405809
Temperature Standard	4405652
Thermometer, Temperature QC (ea.)	4405844

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Software Update Log

ORIGINAL = 1.21B

Date Received	Software Version	Date Installed	Installed By	Notes
1/27/00	1.30A	1/27/00	DSP	

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D

International Contacts

Becton Dickinson
Mexico, S.A. de C.V.
Monte Pelvoux 111 • 9th Floor
Col. Lomas de Chapultepec
11000 Mexico D.F.
Voice: 52 5 237 1200 • Fax: 52 5 237 1287

Becton Dickinson
Asia Pacific Division
30 Tuas Avenue 2
SIngapore 639461
Voice: (65) 8610633 • Fax: (65) 8601590

Nippon Becton Dickinson Co., Ltd.
Akasaka DS Building
5–26 Akasaka 8-chome
Minato-ku, Tokyo 107
Japan
Voice: (81) 3 54138181 • Fax (81) 3 54138133

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Becton Dickinson
Latin America Diagnostics Division
Rua Alexandre Dumas 1976
04717-004 Sao Paulo, S.P. Brazil
Voice: (55) 11 5459833 • Fax: (55) 11 2478644

Becton Dickinson
Becton Dickinson and Company
6200 Dixie Road, Unit #2
Mississauga, Ontario
Canada L5T 2E1
Voice: (905) 564-0260 • Fax: (905) 564-0262

Becton Dickinson
European Divisions
5 Chemin des Sources • BP 37
38241 Meylan CEDEX France
Voice: 33 76 416464 • Fax: 33 76 418560

Becton Dickinson
Microbiology Systems
7 Loveton Circle
Sparks, Maryland 21152
USA
Voice: (410) 316-4000 • Fax: (410) 316-4826
Toll-Free: Technical Services: ~~1-800-638-8656~~ → 1-800-638-8663 OPTION # 3
Field Service: 1-800-544-7434

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E

Supplemental Forms

On the following pages are two forms that are provided for your optional use. The first form is a specimen log sheet for manual tracking of patient demographic information relating to culture vials. The second form is a Maintenance/ Quality Control log that can be used to track the instrument temperature.

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Specimen Log Sheet

Date	Specimen Access No.	Vial Sequence No.	Patient Name	Patient ID No.	Gram Stain	Organism ID	Comment	Final Status

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Quality Control Log Sheet

Date	LCD Temp. Readout (35°C ± 1.5°C)	Temperature QC Vial (35°C ± 1.5°C)	Initials	Comment	Action

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Glossary and Abbreviations

Below are some terms used within this manual which may be unfamiliar to the casual computer user. Most terms are described within the context of the BACTEC 9050 system, rather than in the strictly technical sense.

anonymous vial

Anonymous vials are those which have been placed in the instrument without being assigned their location through Vial Entry (have not been "scanned" into the instrument).

bit

An abbreviation for "binary digit," which is the elemental unit of information in a computer. The value of a bit can be either 1 or 0. All data used by the computer is in the form of bytes, made up of bit combinations.

blocked station

A station in the instrument which encounters an out-of-range reading. The instrument assumes the hardware has failed in the station and blocks the station from use if there is no vial assigned to it, otherwise the station reports an error status.

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boot

To start a computer or instrument. May refer to physically turning on the power, in addition to the Operating System starting itself (or "boot-strapping").

buffer

A short-term storage region. A buffer can exist in the computer's memory, in the database, etc.

byte

A unit of data consisting of eight bits of information. A byte is often used as the unit of measure of computer memory or disk storage capacity. Common compound forms of the term include kilobyte (1,024 bytes) and megabyte (1,048,576 bytes).

database

A file or files containing specific pieces of like information to which a program refers.

date

Dates format can be customized by the user in the Configuration function. You can select the order of day, month, and year values, and select among several separators for those values.

DD

Designation for the day of the month (1 to 31).

default

A default is a predefined field response which can usually be changed. Sometimes the default entry represents the "safe" condition. Sometimes, the manufacturer anticipates a "most common response."

disabled

Not active or not communicating.

diskette

Synonym for "floppy disk." A floppy disk, or diskette, is a medium on which computer information is magnetically encoded. For this reason, floppy disks should always be stored away from any sources of magnetic interference, such as computer monitors, power supplies, etc.

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dot matrix

Used to describe a type of printer technology. A dot matrix printer possesses a print head consisting of a rectangular matrix of retracting pins. Characters are formed by an array of these pins striking a print ribbon adjacent to the paper.

download

Transmission of information from a higher-level component to a lower-level one.

DVE

Delayed Vial Entry. A set of positivity criteria which compensate for the delay of entry of vials into the instrument for testing.

enabled

Active or communicating.

field

An area on a display containing a discrete piece of information. The collective of responses to fields is a file, or record.

file

A file is a discrete, unified collection of information. Some of the many different types of files include: configuration records, program files, error logs, etc.

floppy disk

Synonym for "diskette." A floppy disk, or diskette, is a medium on which computer information is magnetically encoded. For this reason, floppy disks should always be stored away from any sources of magnetic interference, such as computer monitors, power supplies, etc.

format

For floppy disks, formatting erases any existing information on the disk and prepares the disk to receive data from the type of computer system on which it is being used (e.g., IBM-PC®, Apple Macintosh®, etc.).

hardware

The physical components of a system. The LCD Display, floppy disk drive, cables, interface boards, etc. represent the system hardware. Compare to "software."

HH

Designation for the hour of the day in 24-hour military (or international) format.

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initialize

To start up and provide fundamental instructions. When a system is initialized, generally its memory is checked and cleared, its "state of health" is verified, and it is prepared for routine activities. Similarly, when a disk (floppy or hard) is initialized, its information is cleared (erased), and it is formatted (i.e. given its fundamental instructions on where to store information).

interface

A go-between. The user interface for the BACTEC 9050 system is the displays, icons, and soft keys through which you view information and perform activities.

kilobyte

1,024 bytes. Abbreviated "kb" or sometimes "k." See also "byte."

LCD

Liquid Crystal Display. A type of display technology with characters composed of black dots against a gray background.

LED

Light Emitting Diode. A type of indicator light.

megabyte

1,048,576 bytes. Usually abbreviated "MB." See also "byte."

MM

Designation for the month of the year in numeric form (1 to 12), or for the minutes of the hour (01 to 59).

positive

A vial is deemed positive if, during its test, it meets the predefined criteria of the system software. These criteria relate to the measurement of fluorescence in the vial sensor over one or more test readings.

program

A software utility.

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Pulled Positive

If it was originally scanned into the instrument, any positive vial which has been removed through the Remove Positives operation can be placed back in the instrument for further testing for up to 3 hours after removal (or until it goes out of protocol, whichever comes first). During this re-entry window of time, the vial is referred to in the system and this manual as a "Pulled Positive."

reboot

To restart a device. Rebooting may sometimes be recommended to clear the computer's memory, to unfreeze a system which will not respond to keypad input, etc.

RTD

Resistance Temperature Device, a type of temperature sensor.

software

The instructions and information used by a computer to function. Software is the "mind" and hardware is the "body" of a computer.

soft keys

The six teal keys on the Keypad/LCD display whose functions vary with each display. The functions are defined by the software, thus the name.

station

An individual well in the rotor that holds a vial.

subsystem

A part of the whole system. The I/O Board is an example of a subsystem of the BACTEC 9050 instrument.

time

Time is entered and displayed in 24-hour military (or international) format (e.g., 8:00 p.m. is indicated by 20:00).

upload

Transmission of data from a lower-level component to a higher-level one.

VAC

Volts Alternating Current.

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wand, wanding

The process of reading a barcode label with a barcode scanner. Synonymous with "scanning."

YY or YYYY

Designation for the year.

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