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EXHIBITS

This service manual contains the following sections:

Section I - **Introduction** - provides an overview of the BACTEC® 9050 instrument and its major hardware and software components. An overview of this manual's structure is also included.

Section II - **Installation and Setup** - gives specifications for installing the BACTEC® 9050 instrument and instrument setup.

Section III - **Controls and Indicators** - explains the use and meaning of all controls and indicators of the system.

Section IV - **Operation** - provides information and reference material on system operation.

Section V - **Maintenance** - explains all system maintenance and decontamination.

Section VI - **Module Replacement** - provides instructions for module replacement.

Section VII - **Troubleshooting** - provides a guide for identifying and correcting system malfunctions.

Section VIII **- Critical Adjustments and Special keys -** provides reference material on system critical adjustments and special key functions.

Reference - contains reference material listing and description.

This service manual is designed as reference tool for service personnel who repair and maintain the BACTEC® 9050 on a regular basis. Should a question arise which is not answered in this manual, please contact:

Product Support **Voice: 800.544.7434**
BDB **410.316.4000**
7Loveton Circle
Sparks, MD 21152 **Fax: 410.316.4008**

I INTRODUCTION

1.1 BACTEC® 9050 OVERVIEW

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

When microorganisms are present, they metabolize nutrients in the culture medium, releasing carbon dioxide (CO_2) into the medium (for the O_2 sensor principle of operation, refer to Myco/F Lytic media package insert). 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 photodetectors measure the level of fluorescence, which corresponds to the amount of the CO_2 released by organisms. Then the measurement is interpreted by the system according to preprogrammed positivity parameters (Figure 1).

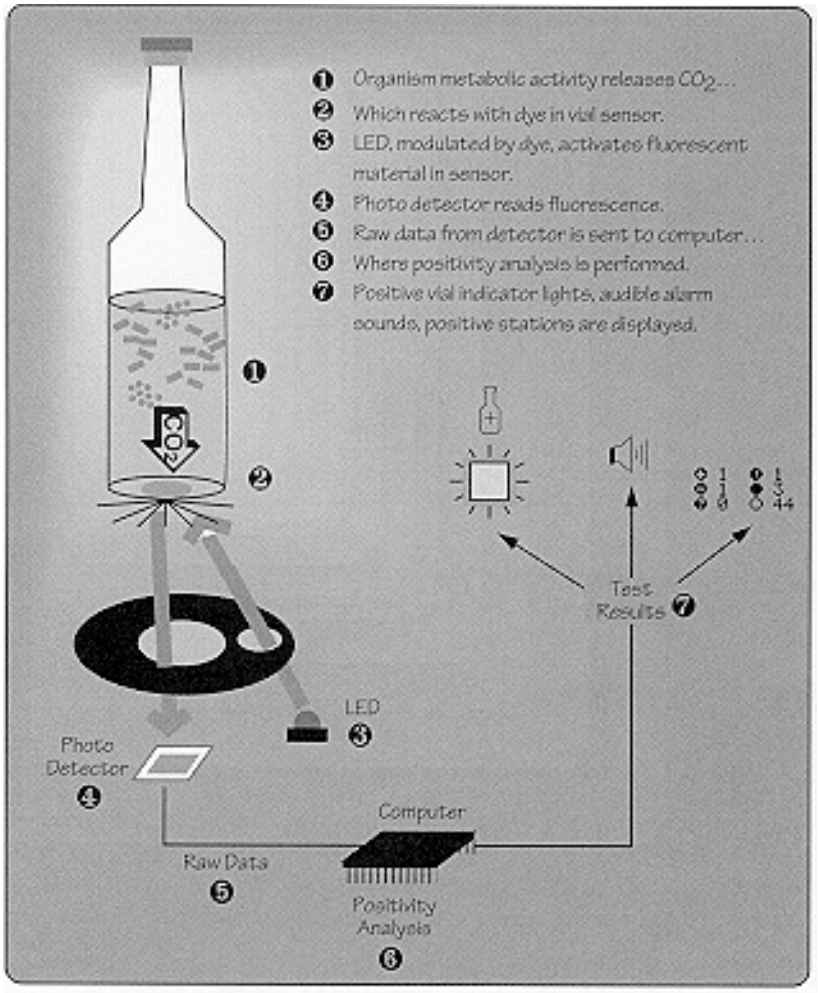


Figure 1 - BACTEC Fluorescent Test Technology

At the system startup, the BACTEC® 9050 instrument performs self-diagnostics and loads its operating instructions. Then the instrument begins automated testing. A row of Light Emitting Diodes (LED's) behind the vials illuminates, 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 any organisms.

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 three concentric rings designated A, B, and C. The instrument is continuously incubated at 35ºC, and vials 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 AND MODULE DESCRIPTIONS

The BACTEC® 9050 instrument (hardware) components are described in the following paragraphs and are shown in Figure 2.

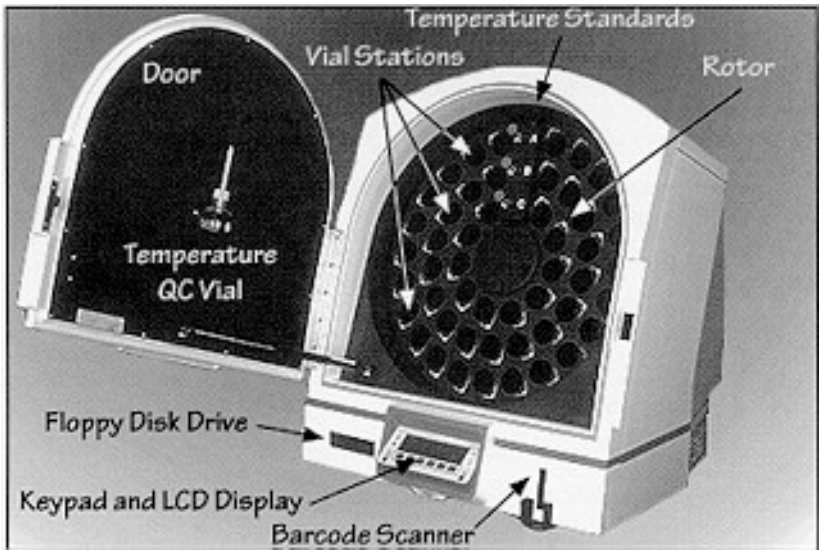


Figure 2 - BACTEC® 9050 Instrument

The major subsystems of the instrument include the following modules:

1.2.1 Rotor

The rotor contains 50 wells called "vial stations" into which vials are placed for testing. The rotor contains three rings of vials stations designated A, B, and C. While each station is numbered uniquely (1-50), it also has a letter designation for ring A, B, and C. This helps the user quickly identify where to place or remove vials. Each ring contains one “temperature standard” vial that is used during the built-in-test (BIT) to assure proper temperature operating range for the instrument.

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 (TTD) and recovery of organisms. The rotor's drive motor stop agitation when the cabinet door is opened or when the “Home Rotor” key is pressed.

The temperature inside the instrument is preset to maintain the internal temperature at 35° C ±1.5° C. Above and below temperature alarm setpoints are preset at 36.5° C and 33.5° C, respectively.

1.2.2 Keypad and LCD Display

The LCD display is a 240 x 64 pixel Liquid Crystal Display (LCD) 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.

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.

Overview

The User Interface (I/F) Board provides interface between the physical hardware and the instrument operator. A single 50 pin ribbon cable back to the I/O Accessory Board provides power and control to the following devices through the User I/F Board: the keypad, the LCD display, the positive and error indicator LED's, and the barcode scanner.

Interface to I/O Board - J5:

A single 50 pin latch eject header J5 provides the connection to the 50 ribbon cable back to the I/O board. All power, data, and control signals pass through this connector.

Keypad Interface - J6

The interface to the membrane keypad is through an 11pin header, J6. There is one common signal trace that goes to one side of each of the 10 keys. It is connected to ground.

LCD Display Interface - J1, J7:

Control Interface:
There are two 20 pin connectors on this board for the LCD, although, at this time only J7 is used. The reason for the second connector is to allow some flexibility for a LCD from an alternative manufacturer that does not have the same dimensions between mounting holes and the 20 pin connector. Most of the

signals that get to the LCD via this 20 pin connector are simply routed through the User I/F board from the I/O board. The front accessible thumb wheel is mounted to a 10K, 1 turn pot that varies the negative voltage required for the biasing. Depending on the value of this voltage, which should range somewhere between - 15V and -7V (approximately), the level of contrast will be different.

Backlight interface:
Depending on whether the backlight in use is an LED or CFL (cold cathode fluorescence) type, the drive circuit and connector used will vary. Currently, only the CFL type is used. Because the CFL bulb on the LCD module has a limited lifetime (10,000 - 20, 000 hours), the backlight will be turn off when not in use (acts like a screen saver).

Positive and Error Indicators

The positive and error indicators are made up of four LED's in the package. They are turned ON and OFF by a single control line for each.

Barcode Wand Connection - J2:

The barcode gun connects to a DB9 connector J2. Power (5V) and ground as well as the serial transmit and receive signals go through this connector. The serial signals are routed through this board from the I/O board. They actually originate on the PC/104 board (COM2).

1.2.3 Barcode Scanner

A barcode scanner is located on the front of the instrument to provide the ability to scan vial labels for vial identification. The scanner turns ON automatically whenever the door is opened and the vial entry or vial removal soft key is pressed.

Two barcode scanner types are used in the BACTEC® 9050, one made by the ZEBEX America, Inc (Alpha-10 series) and the other one by the Opticon, Inc (MR-1100 series).

1.2.4 PC/104 CPU Module

The PC/104 CPU Module stores all the system software, including the application software which controls instrument operations and the user interface, which enables you to view results, perform instrument operations, print reports, etc. The BACTEC® 9050 utilizes the AMPRO CoreModule miniaturized modular device that incorporates the major elements of a 25 MHz 386SX PC/AT compatible computer. It includes standard PC/AT compatible elements including:

- Low-power 80386SX-25 CPU
- BIOS ROM, in FLASH EPROM
- DRAM, 2M, 4M, 8M or 16M bytes
- Two RS232C serial ports
- Keyboard interface
- Speaker interface
- Standard timers
- Real-time clock
- Bi-directional parallel ports

In addition, the CoreModule/386 includes the following enhancements:

- Solid State Disk (SSD) capability with the battery backup option
- Watchdog timer option
- Low power, typically under 3.4 watts

For more information about the CoreModule/386, refer to the CoreModule/386 technical manual that can be ordered from AMPRO Computers, Inc. Phone (408) 522-2100, FAX (408) 720-1305.

1.2.5 +5VDC/±15VDC Power Supply

The 5VDC/±15VDC Power Supply is used to provide outputs of +5.0 VDC and ±15VDC to the DC Distribution/Ramp Generator Board.

The power supply outputs must meet the following specifications:

+5 VDC = 4.95 VDC to 5.05 VDC	Adjustable (refer to procedure TI-0283)
+15 VDC = 14.25 VDC to 15.75 VDC	Non-adjustable
-15 VDC = -14.25 VDC to -15.75 VDC	Non-adjustable

Voltages can be measured at the P1 connector removed from the DC Distribution/Ramp Generator Board.

1.2.6 +40VDC Power Supply

The +40 VDC Power Supply is used to provide output of +40 VDC to the DC Distribution/Ramp Generator board. +40 VDC is used to operate the stepping motor that drives the instrument rotor.

The power supply output must meet the following specifications:

+40 VDC supply = 39.0 to 41.0 VDC	Adjustable (for instructions refer to procedure TI-0283)

Voltage can be measured at the P1 connector removed from the Ramp Generator Board/Stepping Motor Board.

1.2.7 AC Power Control and Distribution Board

The AC Power Control and Distribution Board is used to monitor the AC line voltage, detect two voltage ranges (90-130 and 180-260), supply pulses when the AC line crosses zero for a line frequency test 50/60 Hz, and detect when the AC power line is failing, generating a signal for software to allow data transfer to non-volatile memory. Signals from the computer will activate two solid state relays, one for the blower, one for the incubation heater. This board also provides part of the AC power distribution.

General Description

The autoselect detector uses a power supply monitoring circuit, U1 to activate the proper solid state relay. When the AC line is below 130 VAC, SSE3 is selected and the AC line is connected to the 120 VAC taps on the main power transformer. Since there is no lower threshold to these circuit line voltages below 90 volts AC and up to 130 volts, AC will be passed to the main power transformer. When the AC line exceeds approximately 132 volts the detector will de-activate the SSR3 and no AC line voltage will be passed to the main transformer. When the AC line exceeds approximately 180 VAC solid state relay SSR1 will be activated connecting the AC line to the 240 volt tap on the main transformer. LED indicator D3 has been placed across SSR3 and D1 has been placed across SSR1 in the primary circuit. A separate + 5 volt power supply, U5, is required to operate the line voltage detection system and the solid-state relays.
A double LED optocoupler, U4, has been used to generate duty cycle pulses. These signals will be used by the computer to determine the power line frequency, 50/60 Hz. T1, a low power transformer has two secondaries, one secondary operates the +5 volt supply and the duty cycle generator, the other is used to operate the AC line voltage monitor.

The secondary of the main power transformer supplies 120 VAC to the two commercial power supplies, the incubator blower, the cooling fan, and 120 VAC the incubator heater. The computer controls two solid-state relays, SSR2-4. One is in series with the heater, and the other is in series with the blower. LED indicators D2-4 are used to indicate signal from the computer.

Connector Descriptions

J2 Main power connector, AC voltage from circuit breaker and RFI filter. Nominal voltage 90-130 volts 50/60 Hz. AC for domestic power lines. Nominal voltages 180-260 volts 50/60 Hz. AC for international power lines.

J3 Main power transformer connector, both primary and secondary are connected via this 9-pin connector.

J4 2 pins of this connector are for the instrument-cooling fan. Nominal voltage is a secondary voltage of the main power transformer.

J4 2 pins of this connector are for the incubator heater. The 120 volt secondary delivers power to the heater through SSR2. The computer controls SSR2. D2, a green indicator indicates when the computer calls for heat.

J4 2 pins of this connector are for the incubator blower. The nominal 120 volt secondary delivers power to the blower through SSR4. The computer controls SSR4. D4, a yellow indicator is ON when the computer wants the blower to run. The blower will run continuously except when the door is opened.

J5 5 pin connector, supplies nominal 120 volts power from secondary of the main power transformer to the two commercial power supplies.

J1 10 pin ribbon cable IDC connector.

Pin 1 + 5 volt from main power supply.
Pin 2 Incubator heater control line from computer, TTL high activates the heater, TTL low de-activates the heater.
Pin 3 Incubator Blower control line from computer, TTL high activates the blower, TTL low de-activates the blower.
Pin 4 Digital ground
Pin 5 Power fail detects signal. When the instrument is operating normally, this line will be at least 5 volts or TTL high. When the power line fails, this line will go TTL low. Pin 6 Power line frequency system 50/60 Hz detect. Positive pulse, 5 volt, TTL compatible, width will vary with input voltage changes. The nominal variations may be 47-53 Hz.
Pin 7 This pin is used to monitor REFV1.
Pin 8 This pin is used to monitor the 50/60 Hz output.
Pin 9 This pin is used to monitor REFV2.
Pin 10 This pin is used to monitor REFV3.

1.2.8 DC Power Distribution /Ramp Generator Board

This board operates the stepping motor that drives the main rotor. This board also serves as the DC distribution network for all power supply voltages. Using up-down counters connected to a DAC, a linear ramp is created. A V and F converter reads the linear ramp voltage and converts to a variable frequency signal. This pulse train creates the steps required to operate the stepping drive motor. This board also distributes the DC power for the entire instrument.

General description

Two up/down counters U8 and U13 and oscillator U16 are used to generate an 8-bit word. Zero count and full count latch systems U14, U9, U10, U7 inhibit overflow in either direction. The frequency of oscillator U16 determines the ramp up and ramp down rate. The ramp up/down rate is approximately 1 second. This rate is adjustable using R39. The 8-bit word is converted into a linear ramp with U5, a DAC. The DAC 0-10 volt output drives U6, a V to F converter. U6 generates the pulse train that drives the stepping motor. The pulse train is amplified and sequenced using U4 and U1; they also provide adequate current driving capabilities. D1-2 and D4-9 are used as catch diodes to protect the drive transistors. This PC board is also used to distribute DC power. J1 is connected directly to the +5, ±15 volts power supply. Connection to the accessory board is via a 5-conductor wire harness from J6. Connection to the floppy drive is via a conductor wire harness from J5. The door switch is also connected via J5 with a 2-conductor cable. The door switch must be closed before the stepping motor will run. A 14-pin connector and ribbon cable allow control signal and data from/to the computer via J4. A "Manual run" switch is provided to override all control inputs and allow manual operation of the stepping motor.

Inputs

1. Start - J4 - Pin 2

A positive-going TTL level change from the computer will start the ramp generator. The ramp will go from 0 to 10 volts when this line is held positive. With 10 volts applied to the V to F converter 2000 pulses will be generated per second. These pulses will drive the stepper motor at the 30 rpm rate.

2. Stop - J4 - Pin 2

When this signal returns low, the ramp will go from 10 volts to 0 volts. The stepper motor will slow down and stop. The green LED, DS2 will be illuminated.

3. Door Switch - J5 - Pin 3&4

When the door is open the switch contacts will be open and a stop signal is sent to the ramp generator. The rotor will stop in any angular position. The red LED, DS3 will be illuminated when the door is open.

4. Release brake -J4 -Pin 8

This positive going TTL signal must be present to release the brake if the computer generates the stepping motor pulses. This line must remain positive for entire sequence.

Output Signals

1. Drive J4 - Pin 12

TTL level pulse train from the V to F converter to the L297 L298 output driver. The normal frequency is approximately 2000 per second when the stepping motor is running.

2. Door Open J4 - 10

A TTL level signal, high when the door is open, low when the door is closed.

3. 40 volt monitor J4 - Pin 14

A 4-volt DC level is available to monitor the +40 volt supply. A 10/1 resistive divider is used to create this voltage using resistors R12 and R23.

4. -15 volt monitor J4 - Pin 4

U2, R3, and R4 are used to generate a positive 3 volts when the negative power supply equals -15 volts.

Power Supply Inputs:

1. + 5 volts @ 0.2 amps	J1 - 5	CURRENTS FOR
2. Return	J1 - 6	
3. +15 volts & 0.1 amps	J1 - 1	RAMP GENERATOR
4. Return	J1 - 2	
5. -15 volts & 0.01 amps	J1 - 3	BOARD ONLY
6. Return	J1 - 4	
7. +40 volts & 0.750 amps	J1 - 8	
8. Return	J1 - 9	

Power Supply Distribution Outputs:

A. To accessory Board	B. to Floppy Drive
J6 - Pin 1: +15 volts	J5 - Pin 1: + 5 volts
J6 - Pin 2: Analog Ground	J5 - Pin 2: Digital Ground
J6 - Pin 4: +5 volts	
J6 - Pin 5: Digital Ground	

1.2.9 I/O BOARD

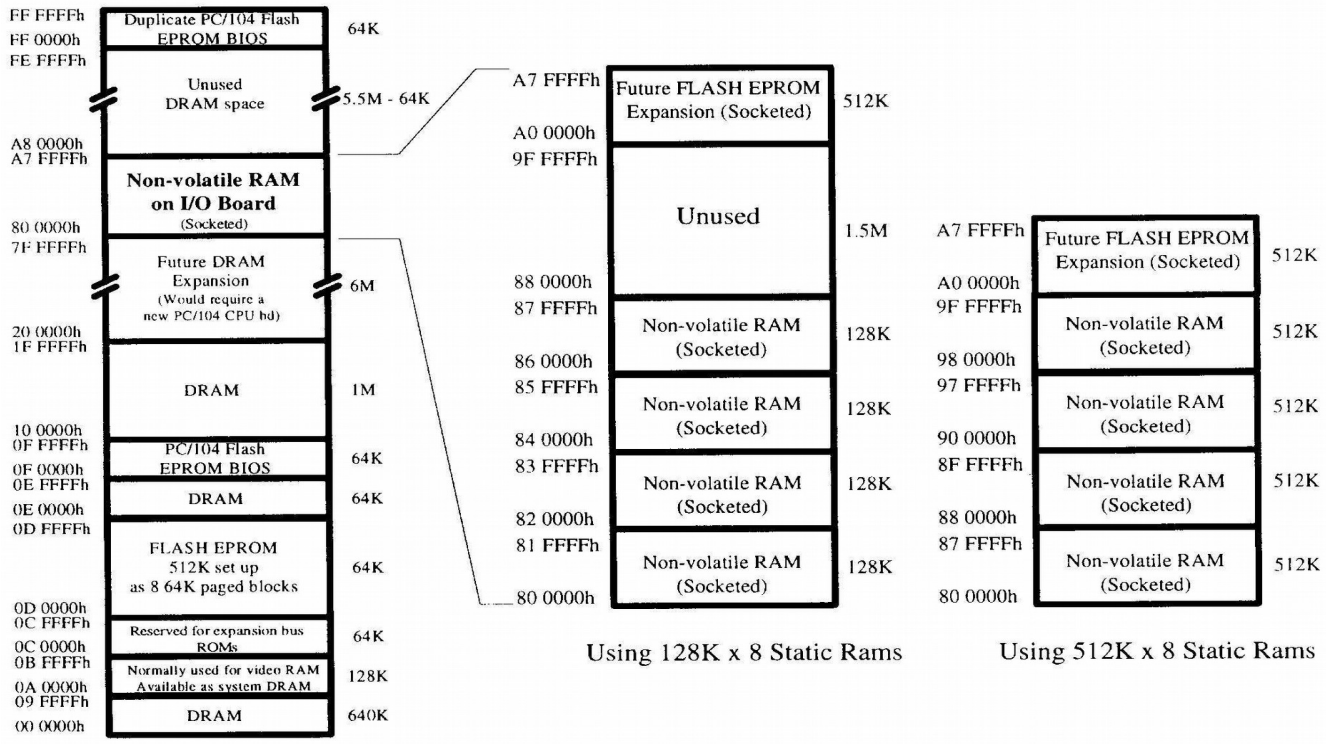
Overview:

The purpose of the I/O Board is to provide an interface between the PC/104 core module CPU board and the rest of the BACTEC® 9050 instrument. While the executable software resides and runs on the 386/486SX module, the I/O board provides a physical mounting and electronic link for this module. This connection gives the I/O board full access to the ISA bus which allows it to act as an extension of the PC/104 CPU as well as interface to the unique hardware requirements of the BACTEC® 9050.
The I/O board provides all the hardware required to interface with the User Interface Board, the Source Detector Board, the AC Power Control & Distribution Board, the Ramp Generator/Stepper Driver Board, and the Floppy Disk Drive. The following sections provide details of this hardware and its functionality.

Memory Map

The memory map for the system is shown in Table 1. This map shows the first 16 megabytes of physical address space. Currently, the CPU board is purchased with 2 MB of DRAM (00 0000h-1F FFFFh). The next 6 MB of address space (20 0000h - 7F FFFFh) is left open, and could be used for future DRAM expansion. The PC/104 board has 32 pin socket which is populated with a 512Kb flash EPROM (set up as eight 64Kb paged blocks). Executable code resides here. The next 2.5 MB of address space (80 00000h - A7 FFFFh) is allocated to non-volatile memory residing on the I/O board.

Memory map Table



Data Storage (80 000h- 9F FFFFh)

There are four 32 pin sockets for battery backed SRAMs. By changing a jumper configuration, these sockets can be set up to accept either 1Mbit (128Kx8) or 4 Mbit (512Kx8) chips. Depending on the amount of data to be backed up, this allows for any of the following non-volatile RAM sizes: 128 KB, 256kB, 384kB, 512Kb, 1Mb, 1.5Mb or 2Mb. The map shows the address locations of each chip.

Additional Program Storage (A0 0000h - A7 FFFFh)

Above the battery backed SRAM location, another socket is provided for 512Kb of additional flash EPROM. This flash provides room for code expansion (if the 512Kb of flash on the PC/104 is not enough).

I/O Map

With exception of the floppy drive controller, all of the BACTEC® 9050 custom hardware can be accessed through I/O ports 300h - 30 Fh. Table 2 gives a brief description of these ports. Details about each device and port will be given in the I/O Devices Description section.

Port Address (Hex)	Device/Function	Description
300 301 302 303	PIA 1	Output port - User I/F Board Output port - Source/Detector Board Output port - A/D Converter setup PIA 1 control port
304 305 306 307	PIA 2	Output port - motor, blower heater, etc. Input port - detector flags, door, etc. Input port - Board configuration PIA 2 control port
308 309	Keypad	Input port - Keys K1 to K4 Input port - Keys K5 to K10
30A 30B	LCD	Input/Output command port Input/Output data port
30C 30D	A/D Converter	Input - low byte/Output - start conversion Input - high nibble
30E	Speaker Volume	Output - increment value
30F	Test port	Input/output - readback latch

Table 2 - I/O Map

Interrupt Structure

The hardware has been designed to make use of the normal PC interrupt architecture so the appropriate inputs of different devices create interrupts to alert the CPU of any changes in state of the input. While polling can still be accomplished by reading the ports, it is not necessary to detect a state change. Inputs have been grouped together so that any of several inputs can create an interrupt. Once that interrupt occurs, software will read a port to determine which input was responsible for generating the interrupt. Table 3 below shows the conventional use as well as our use for the standard 16 PC interrupts. As can be seen from the table, there are six IRQ's available: IRQ9, 10, 11, 12, 15, and 5. The I/O board uses four: IRAQ9, 10, 11, and 12. IRQ5 was saved intentionally because it is one of the interrupt options available to network boards. IRQ15 is also not used. An explanation of each interrupts follows:

On ISA Bus?	Interrupt	Conventional Use	BACTEC Use
Y	NMI	Memory parity error or I/O channel check	Power Fail Warning
	IRQ 0	Clock tick - timer 0	SAME
	IRQ 1	Keyboard interrupt	SAME (no keyboard in system under normal use, but possible for debug)
	IRQ 2	Cascaded for IRQ 8-15	SAME
	IRQ 8	Real Time Clock	SAME
Y	IRQ 9	Available (re-directed from IRQ 2)	Keypad inputs
Y	IRQ 10	Available	Flags, Home and Door sensors
Y	IRQ 11	Available	A/D Conversion done
Y	IRQ 12	Available	50/60 Hz Zero Crossing and Motor Steps inputs
	IRQ 13	Co-processor	SAME

Y	**IRQ 14**	**Hard Disk Controller**	**See IRQ 1 note**
Y	**IRQ 15**	**Available**	**Available (not used)**
	IRQ 3	**Serial port (COM2)**	**SAME**
Y	**IRQ 4**	**Serial port (COM1)**	**SAME**
Y	**IRQ 5**	**Parallel port (LPT2)**	**Save for possible future network board (not used)**
Y	**IRQ 6**	**Floppy Disk Controller**	**SAME**
Y	**IRQ 7**	**Parallel port (LPT1)**	**Printer**

Table 3 - Interrupt Assignments

NMI- Power Fail

The NMI (non-maskable interrupt which actually is maskable via I/O port 70h) is used on the I/O board to alert the CPU of a power failure. This interrupt can occur for one of two reasons, either a DRAM parity error on the PC/104 board has occurred, or a signal called I/O Channel Check on the ISA bus connector has gone low. The I/O board feeds a power fail signal into this pin on the ISA connector. Therefore, if a NMI occurs, the software should read port 305h and determine if it occurred due to a power failure. If so, the CPU has around 20 milliseconds of valid power to do an orderly shutdown.

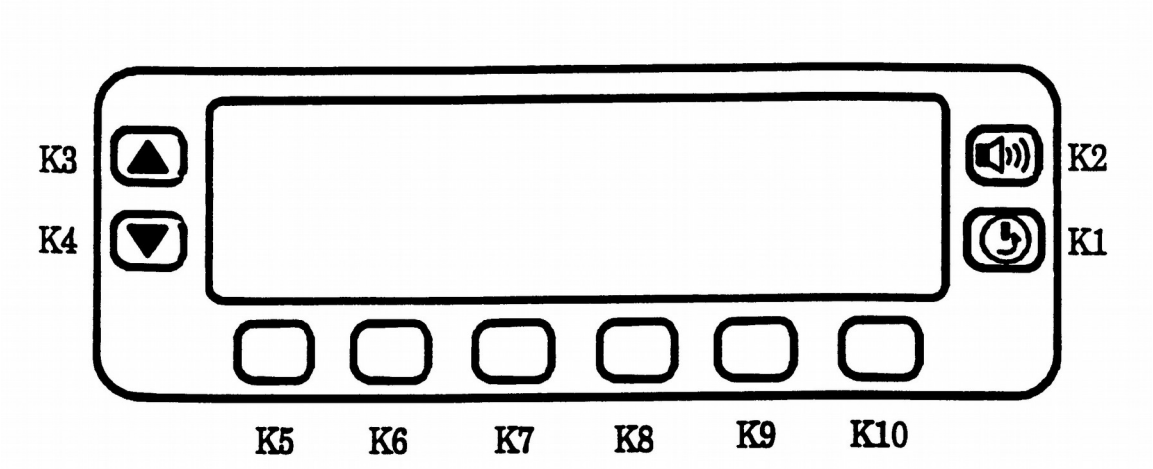
IRQ9 - Keypad Inputs

The IRQ9 interrupt is generated by a pressing a key on the keypad. Table 4 shows the key number definitions. Any key K1-K10 that is pressed will cause an interrupt. If a second key is pressed while the first is held down, no additional interrupt will occur with the exception of the K2 key. The K2 key is treated like a shift key. If it is held down, and a second key (K1 or K3-K10) is pressed, then an interrupt will occur for that second key press. After an interrupt, software should read ports 308h and 309h to determine which key caused the interrupt.

IRQ10 - Flag, Home & Door Sensor Inputs

This interrupt will occur whenever one of the cup flags passes through the optical switch, or when the rotor passes the home position, or when the door changes state. In order for the cup flags to cause an interrupt, one (and only one) of the three optical switches must be enabled by software control (see I/O Devices Description section). The door switch will cause an interrupt on either an opening or closing condition. After an interrupt occurs, software should read port 305h to determine which input caused the interrupt.

KEY PAD ASSIGNMENT TABLE



IRQ11 - A/D Conversion Finished

This interrupt will occur at the end of each A/D conversion.

IRQ12 - 50/60 HZ Zero Crossing & Motor Step Inputs

This interrupt will occur for each zero crossing or stepper motor pulse. After a power up, as part of initialization, this interrupt can be used to determine whether the system is using 50 or 60 Hz power. This interrupt is used in this mode when the stepper motor is not running so that only zero crossing pulses cause interrupts. By counting the number of pulses for a given time period, the 50/60 Hz determination can be made. There are two zero crossing pulses for each cycle (100/sec-50Hz, 120/sec - 60Hz). Once this has been determined, the zero crossing pulses can be disabled as an input to IRQ12 so that the interrupt will occur for each motor step pulse.

1.2.10 Source/Detector Board

Overview

The Source Detector Board is responsible for acquiring the fluorescence signals from the bottles. Power, control, and measurement data all flow on a single 20-pin ribbon cable that is connected to the I/O board. The source detector consists of three detectors and source holders (DASH) that house the source LED's, photodiodes, and filters. Also on this board are three optical interrupter switches that indicate when a bottle is over the DASH, one Hall-effect sensor used for homing, and a secondary temperature sensor.

Interface to I/O Board - J1:

A single 20 pin latch eject connector J1 provides the connection to the 20 pin ribbon cable back to the I/O board. All power, control, and measurement signals pass through this connector.

Source LED's:

There are four green source LED's housed in each DASH station. The four LED's are connected in series and have a regulated current passing through them. Adjusting R24 and measuring the voltage between test points TP35 and TP36 sets the current. It is set in test to .500V (from a range of 0 to .6V) which correlates to 25.0mA. The LED current can be calculated by dividing the voltage between the test points by 20 (TP36-TP35)/20. Each string of LEDS can be turned ON and OFF by a control signal. This allows dark measurements to be taken.

Optical switches and Hall Effect Sensor:

Each DASH has an optical switch located next to it. The purpose of this optical switch is to provide a signal when a cup flag passes through it that can be used by the computer to determine when to take A/D readings of the selected detector signal. Each optical switch sends back an active high signal to the I/O board. These optical switches can be turned ON and OFF by an individual control signal. When an optical switch is turned on, it emits a small spectrum of light, mostly in the infrared range. Because of the high sensitivity of our photodiode/transimpedance circuit, some of this light is converted to a photo current that is superimposed on the fluorescent signal photo current. The unwanted photocurrent can be removed by turning the optical switch off while each reading is being taken..

The Hall effect sensor creates an active low signal for each pass of the magnet located on the rotor. This signal (called HOME) is used to determine if the rotor is spinning, to determine when to issue a stop signal to the rotor motor to position it at home, and to determine when the temperature standard vials will pass in front of the detector stations.

Backup Temperature Sensor:

The backup temperature sensor is located on the Source Detector board. Its purpose is to provide software with the ability to check the RTD to see that it is working correctly. The accuracy of the backup temperature sensor (located in U11-REF02H) is +/- 3.0° C. The RTD is much more accurate than the backup sensor, and because they are not located right next to each other and have different response times, it is not unusual for them to be several degrees apart. If the RTD were to open, then software would flag an error when the two temperature signals differed by more than 5.0° C. The scale for the backup temperature sensor is 100mv/° C from 0 - 500° C. For example, a voltage reading of 3.55 from the backup temperature sensor would be equivalent to 35.5° C.

1.2.11 Incubator Heater

Incubator heater is rated at 144 watts ±5% at 120V. The following high limit thermostat types are used:

1. Manual reset P/N T501-807M-L131 (opens at 53° C)
2. Automatic reset P/N 36T21L60-1 (opens at 60° C)

1.2.12 Blower

Blower is rated at 115VAC, 50/60 Hz, .64A, .015HP, 3,000 RPM.

1.2.13 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 (not used).

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. Pressing the teal Soft key that corresponds to the definition shown on the screen performs system operations.

The 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 errors, or print the system Status Report.

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, select the desired language, Save data to disk, and upgrade the 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.

1.3.1 Built-in-Test (BIT)

The system software is designed to continuously monitor the electrical and optical performance of all stations simultaneously. This functionality, called BIT (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 established signal range. Tests are performed on dark readings (the output from the station when its excitation LED's are OFF) and on fluorescent unit readings (the output from the station when a vial is present and excitation LED's is 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 electrical failure within the instrument.
Fluorescence unit readings are evaluated to be within a specified maximum and minimum range that 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 electrical or optical component failure.

Additionally, the fluorescence readings are evaluated for consistency while vials are in stations. If consecutive fluorescence unit readings vary more than a predetermined amount, the station is declared in error. This feature determines the stability and 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 that 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 error soft key.

II 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 and gases. The system will operate within specifications in room temperature 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 that 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.

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 220-234 Volts AC (+/- 10%)
Input Current	3.0 Amp maximum
Input Line Frequency	50 or 60 Hz

Environmental Requirements

Non-Operating Storage

Temperature	-4º F to 140º F (-20º C to 60º C)
Humidity	10% to 90% non-condensing

Operating Conditions

Temperature	65º F to 89.6º F (18.3º C to 32º C)
Humidity	10% to 90% non-condensing
Locations	Level surface. No direct sunlight, no direct heat.
Altitude	0 to 10,000 ft (3,048 meters) above sea level

Use of earthquake anchoring is strongly recommended in locations susceptible to earthquake activity.

2.3 Installation and Instrument Setup

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*.

III 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 3. Individual components are illustrated in figures accompanying the related text.

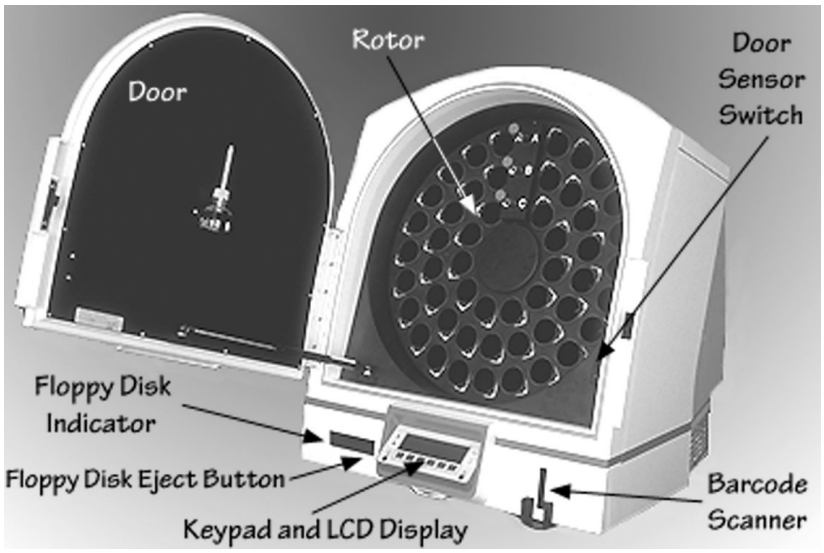


Figure 3 - BACTEC® 9050 Instrument Layout

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 4).

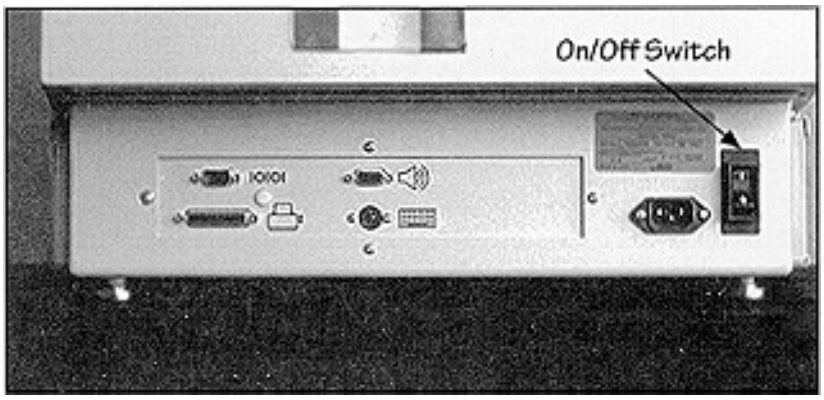


Figure 4 - On/Off Switch

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 5).

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

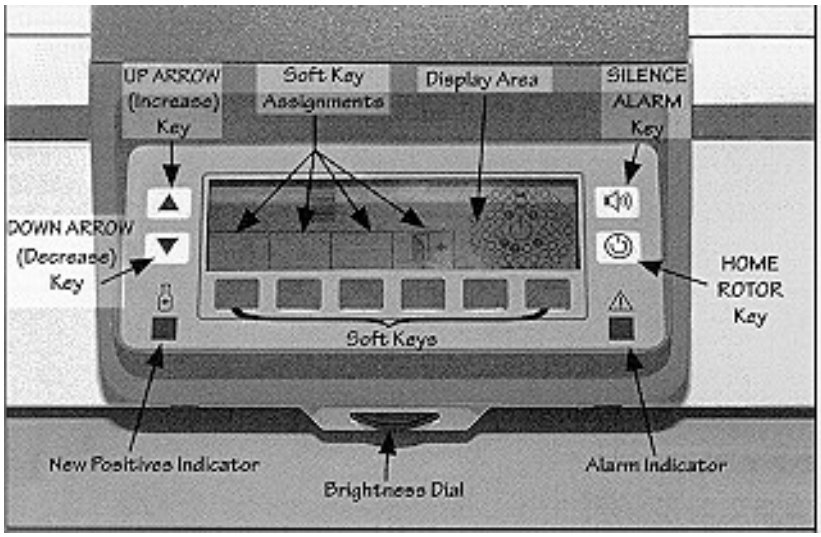


Figure 5 - Keypad and LCD Display

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.

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.

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 assignment area of the Main Status Screen. Press the Soft key corresponding to the System Alert icon. The first error code is shown on display. Correct any error conditions as soon as possible by following the directions on the door placard and in troubleshooting section.

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 counter-clockwise 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 of the BACTEC® 9050 System User's Manual.

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 illuminates 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 of the BACTEC® 9050 System User's Manual for information on removing positives 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.

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 any of the unassigned keys (such as the right most Soft key).

3.4 Door Interlock Switch

When the door of the instrument is opened, a door switch senses the condition (see Figure 3). 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.

3.5 Floppy Disk Drive

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

3.6 Audible Alarms

The BACTEC® 9050 instrument generates eight different types of sounds 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.

Type	Examples	Sound
Acknowledge	Scanning a barcode	Single short high beep
Sample audible alarm	In Configuration mode, the audible alarm volume was adjusted	Three tones progressing from high to low ("Figaro")
Activity complete	All positives are removed	Three short fast high beeps

Door closed	Door was closed	Two short fast high beeps
Rotor home	Rotor homed after HOME ROTOR key was pressed	Five tones progressing from low to high (“arpeggio”)
Activity error	Unexpected barcode scanned	Short high beep then short low beep-sequence repeated four times
Alert	New positives vial	Single medium beep - one second on, three seconds off, repeating
Door open alarm	Door has remained open for longer than 5 minutes	Loud shrill trill

Table 5 - Audible Tones and Alarms Descriptions

IV OPERATION

For complete instructions on operation of the BACTEC® 9050 instrument, refer to *BACTEC® 9050 System User’s Manual MA-0103*.

4.1 Power Failures and Emergency Operation

The data is kept in memory until a powerfail occurs, then it is written into NVRAM. When a powerfail condition occurs, the internal power supply guarantees 30 milliseconds before total failure. At this time, the system is completely shut down. No testing is done until power restored. Although, an external UPS connected to the instrument will provide no difference in instrument behavior, the user may consider connecting an UPS to instrument. The instrument will only view this UPS as a power source, meaning the instrument will retain power as long as the UPS maintains power. If the UPS should lose power, the instrument will perform powerfail activities as it would if no UPS were connected. When power resumes, testing continues normally if the interruption was less than 40 minutes. If longer than 40 minutes, ongoing cultures should be subcultured. When power resumes, power out and power resumption times are listed on the display and optional printer. 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 40 minutes, to ensure maximum recovery it is recommended that you perform a subculture on vials that have experienced instrument shutdown due to power failure. To avoid the burden of manually subculturing vials in a power outage, Becton Dickinson strongly recommends that the BACTEC® Fluorescent Series Instrument system be connected to an emergency power line.

V MAINTENANCE

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. Routine preventive maintenance consists only of a monthly changing and cleaning of the cabinet air filters. All other procedures are on an "as needed" basis.

5.1 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 you have an optional printer, check its paper supply. If the paper supply is low or exhausted, replace the paper.

5.1.1 Air Filter Replacement

Change or clean the air filters on both sides of the instrument weekly. If the instrument's environment is especially dusty, check the filter more frequently. These filters must remain clean and unobstructed; restricted airflow may cause the vials to reach excessive temperatures, which can affect organisms' recovery and possibly cause hardware malfunction or failures. The filters can be cleaned and reused. (See Figure 6).

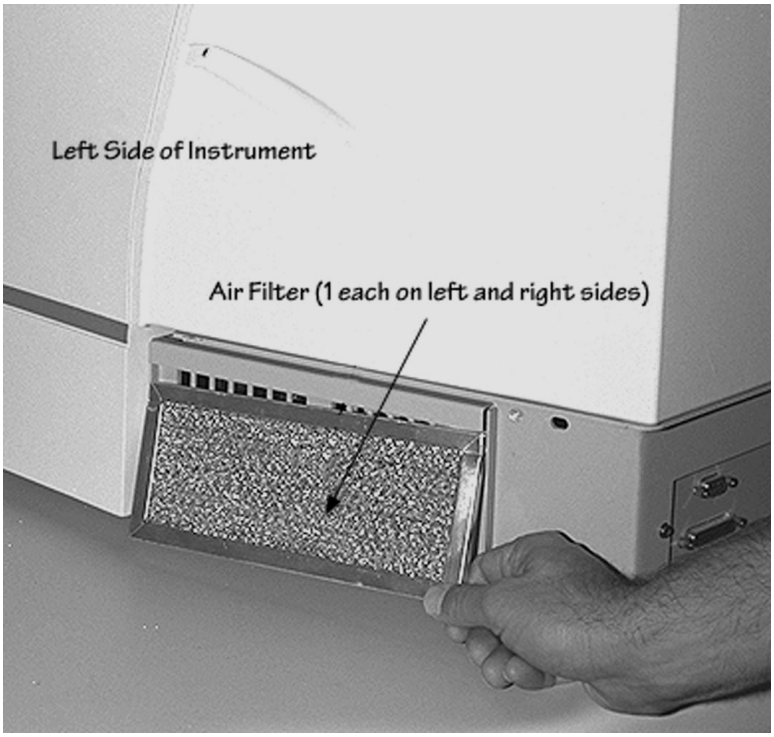


Figure 6 - Air Filter Replacement

Required Materials

New or clean Filters

To replace the Air Filter

1. The air filters are located on the sides of the instrument near the bottom. To remove a filter, lift it up slightly, and 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.

5.1.2 Temperature Verification (QC)

A thermometer and special vial are provided for temperature verification (QC) of the 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 the 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).

5.1.3 Barcode Scanner

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 (see Figure 7).

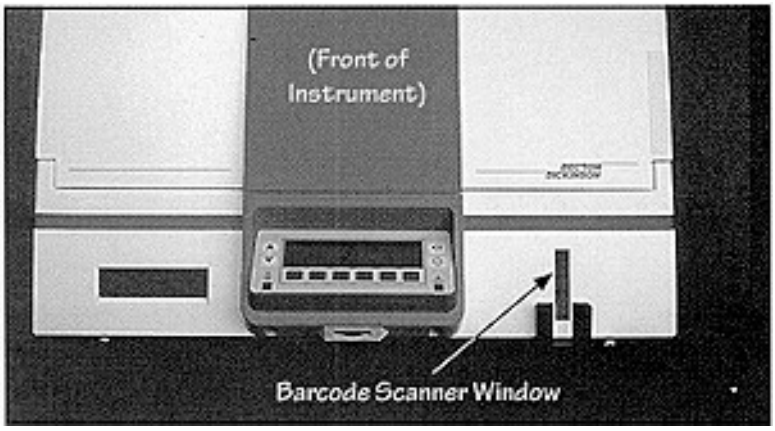


Figure 7 - Barcode Scanner Window

5.2 Decontamination

5.2.1 General

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 station or replace the rotor if complete decontamination cannot be accomplished. If there are any doubts that the affected station (s) cannot be completely decontaminated, the Rotor should be replaced.

5.2.2 Decontaminating a Station or Rotor

The solution recommended to clean the affected surface should be at least a 0.5 % bleach solution (1/4 cup of household bleach to a gallon of water). 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.

Warning

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

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, and discard in an appropriate Sharps container.

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.

Warning

INSTRUMENT POWER SHOULD BE TURNED OFF AND THE POWER CORD SHOULD BE DISCONNECTED BEFORE BEGINNING ANY MODULE REPLACEMENT PROCEDURE

VI MODULE REPLACEMENT

The BACTEC® 9050 instrument has been designed and tested for trouble-free 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.

Module replacement instructions are organized in the following groups:

Front Cabinet Components (Damper Cylinder, Door Sensor Switch, Rotor, RTD.

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

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

6.1 Front Cabinet Components

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

6.1.1 Damper Cylinder

To replace the damper cylinder, follow the steps below and refer to Figure 8.

Required Materials

Small Flathead Screwdriver

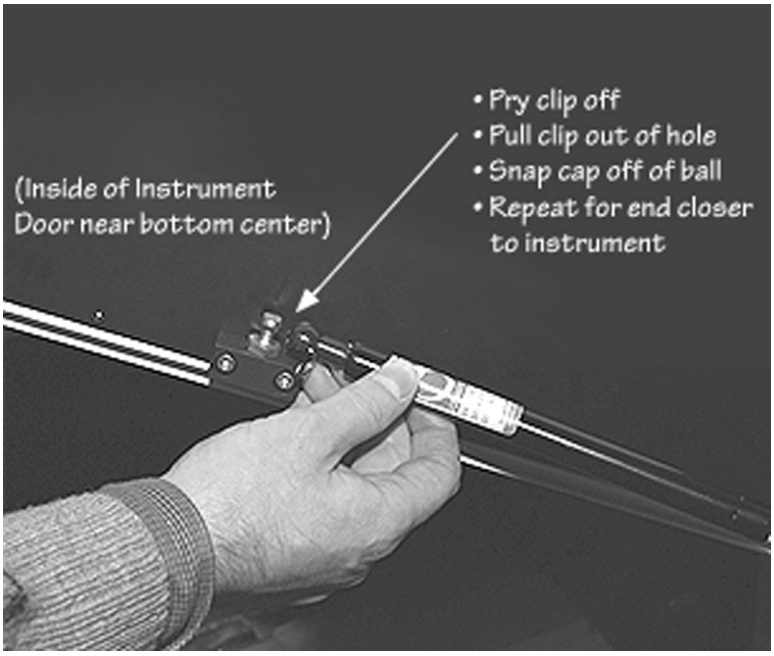


Figure 8 - Damper Cylinder Removal

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.

6.1.2 Door Sensor Switch Replacement

To replace the door sensor switch, follow the steps below. Refer to Figure 9.

Required Materials

Medium Phillips Screwdriver

To Replace the Door Sensor Switch

1. Remove the front panel (see Section 6.2.1)

2. Reach up inside the interior of the instrument through Keypad/LCD Display hole to find the Door Sensor Switch (it may be easier to remove the barcode scanner [see Section 6.2.2] 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. CAUTION: When replacing the switch, reconnect either wire to either inside terminal - do not plug the wires onto the outer two terminals on the switch.

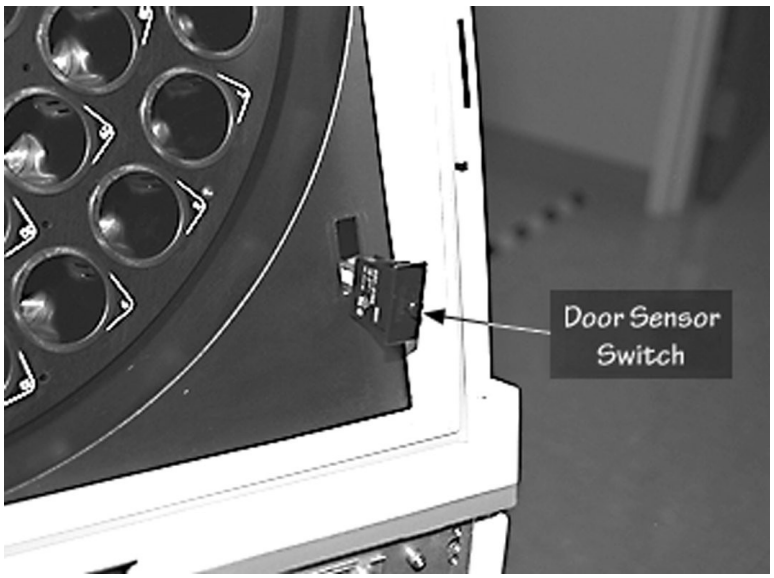


Figure 9 - Door Sensor Switch Removal

6.1.3 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. Refer to Figure 10.

Required materials

No tools required

To remove the Rotor

1. Remove the rear cabinet shell (see Section 6.3.1).
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. Wiggle the rotor out of instrument

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

7. Wiggle the rotor back into the instrument.

Figure 10 - Rotor Removal

6.1.4 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 11,12, and 13.

Required Materials

Small Phillips Screwdriver

To Remove the RTD

1. Remove the rotor (see Section 6.1.3) and rear cabinet shell (see Section 6.3.1).
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.

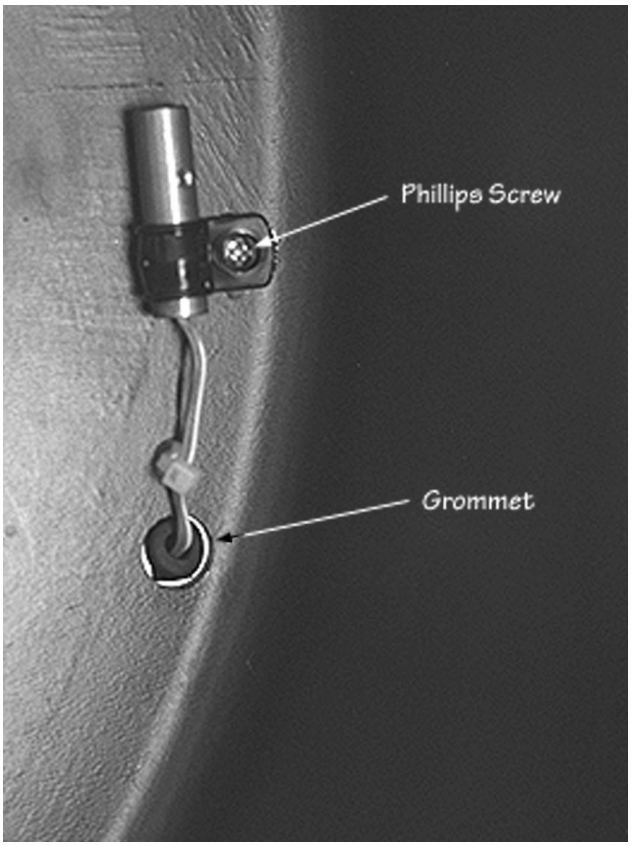


Figure 11 - RTD Removal (A)

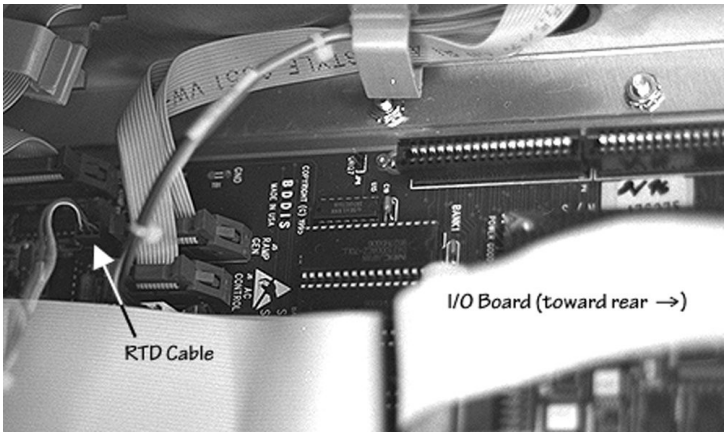


Figure 12 - RTD Removal (B)

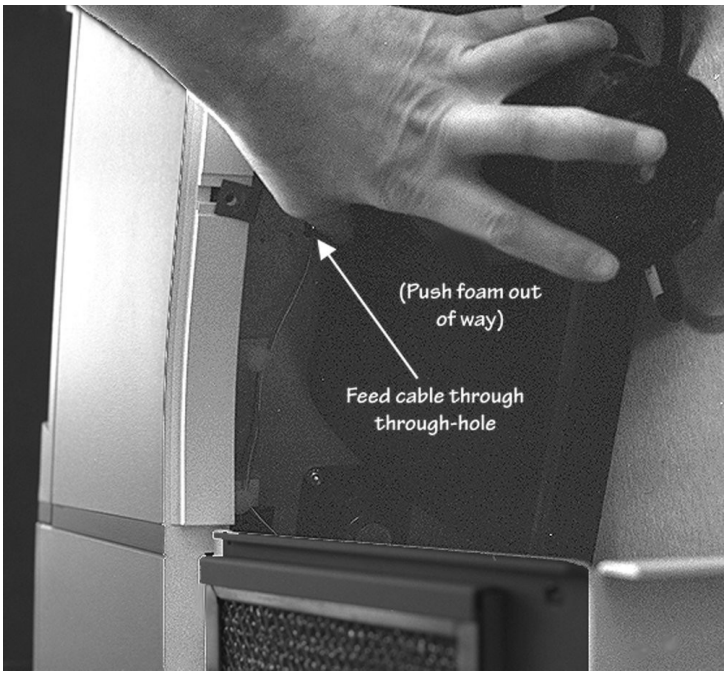


Figure 13 - RTD Removal (C)

6.2 Front Panel Components

6.2.1 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 14 and 15.

Required Materials

Medium Phillips Screwdriver
Small Flathead Screwdriver

To Remove 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 end 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.

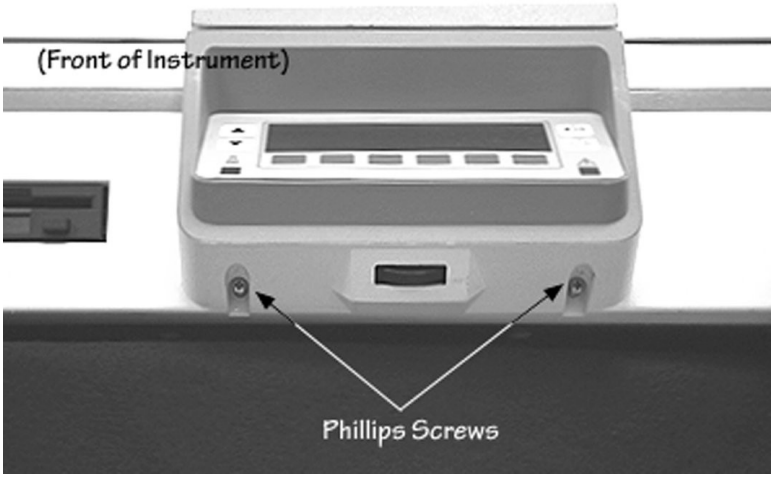


Figure 14 - Front Panel Removal (A)

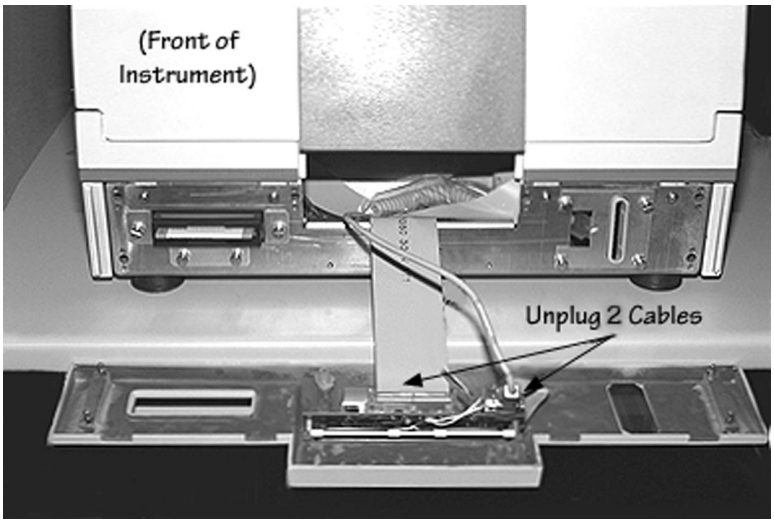


Figure 15 - Front Panel Removal (B)

6.2.2 Barcode Scanner Replacement

To replace the barcode scanner, the follow the steps below. Refer to Figure 16.

Required Materials

Phillips Screwdriver (some instruments require Flathead Screwdriver instead)

To Replace the Barcode Scanner

1. Remove the front panel (see Section 6.2.1).
2. Loosen 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.

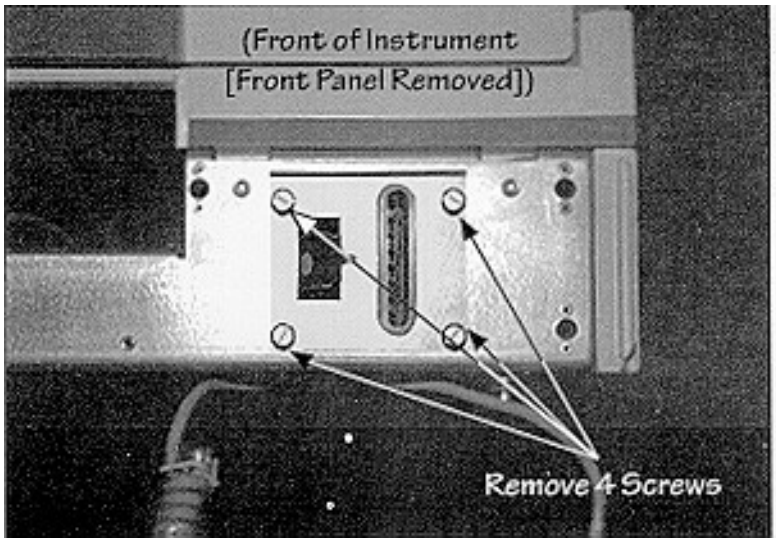


Figure 16 - Barcode Scanner Removal

6.2.3 Floppy Disk Drive Replacement

To replace the floppy disk drive, follow the steps below. Refer to Figures 17 and 18.

Required materials

Phillips Screwdriver (some instruments require Flathead Screwdriver instead)

To Replace the Floppy Disk Drive

1. Remove the front panel (see Section 6.2.1)
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.
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 corresponds to the pins of the cable socket. Locate the Pin 1 designation (marked by white number "1") on the printer 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 location of Pin 1 on the drive's PC board. If necessary, you can peel the plastic shield away from the disk drive to identify Pin 1.
8. Insert the new drive/bracket and tighten the fasteners.

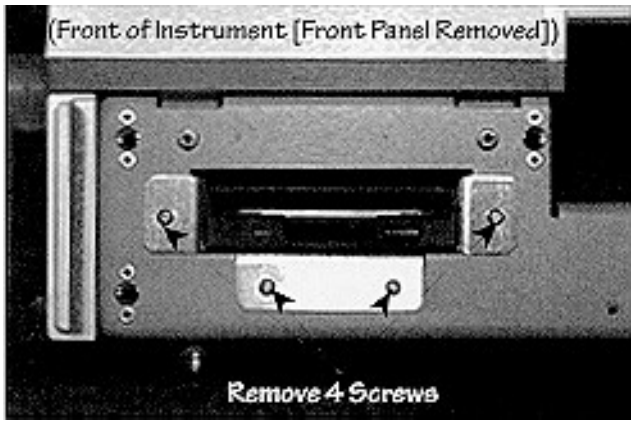


Figure 17 - Floppy Disk Drive Removal

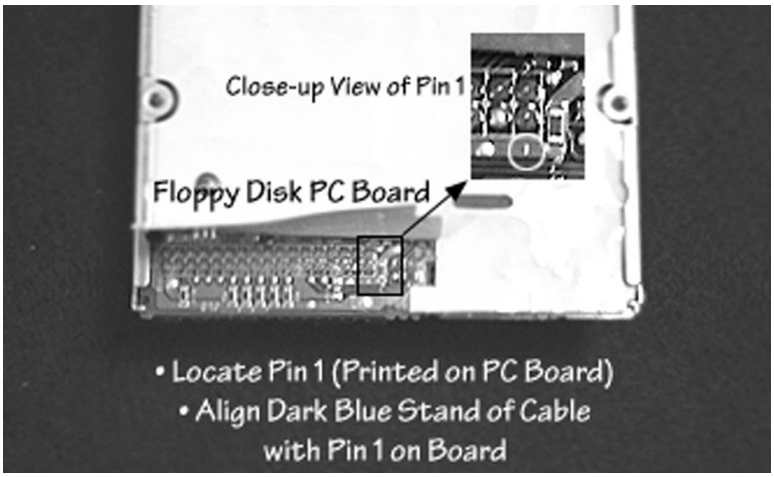


Figure 18 - Floppy Drive Pin 1 Identification (typical)

6.2.4 Keypad/LCD Display Replacement

The Keypad/LCD Display is part of the front panel assembly. The entire assembly must be replaced. Refer to Figures 19 and 20.

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.

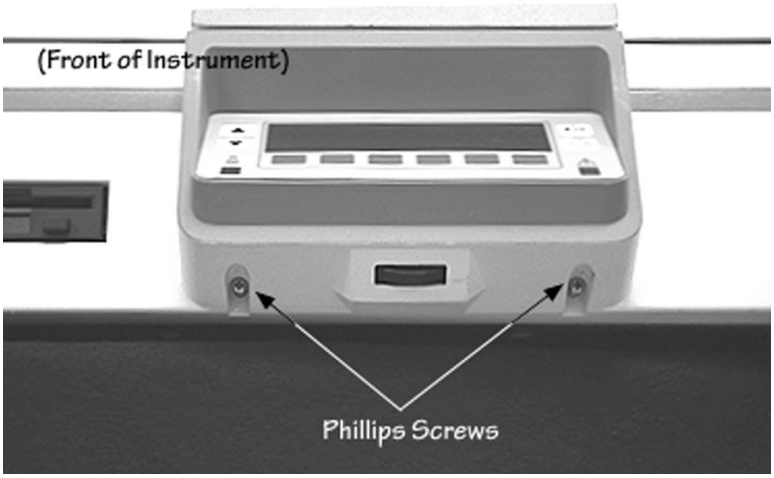


Figure 19 - Keypad/LCD Display Removal (A)

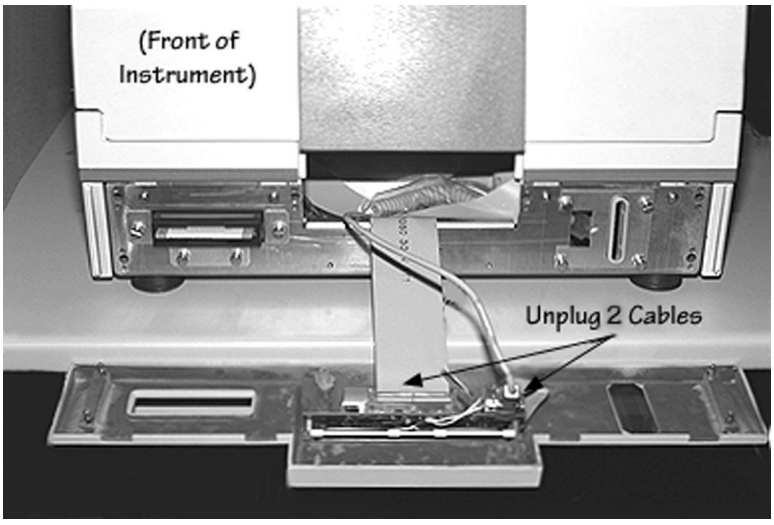


Figure 20 - Keypad/LCD Display Removal (B)

6.3 Rear Cabinet Components

The rear cabinet shell must be removed to gain access to the following internal components: AC and DC Power Distribution Boards, Motor, Blower, Computer Board, Source/Detector Board, Fan, Heater, I/O Board, Main Transformer, On/Off Switch, +5V/±15V, 40V Power Supply Boards, RTD. Refer to Figures 21 and 22.

Required Materials

Medium Phillips Screwdriver

6.3.1 To Remove Rear Cabinet Shell

1. The rear cabinet shell is held to the cabinet frame by 5 Philips 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 the 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 off the frame.
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.

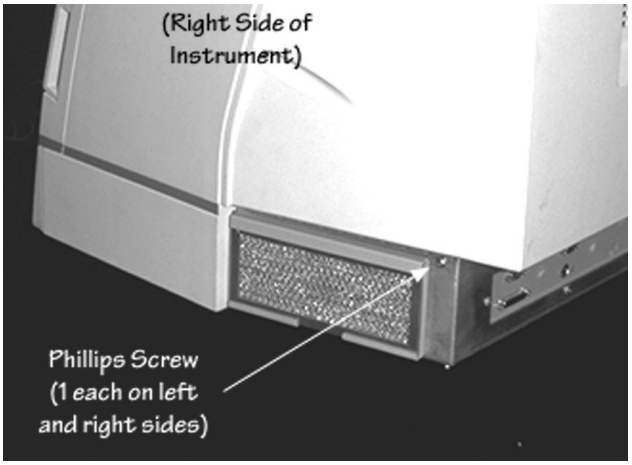


Figure 21 - Rear Cabinet Shell Removal (A)

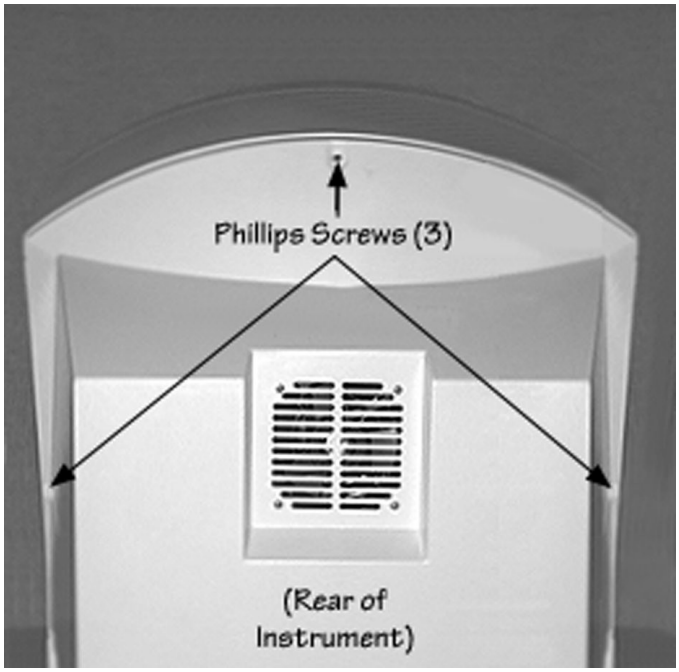


Figure 22 - Rear Cabinet Removal (B)

6.3.2 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 23.

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 23 - Electrical Guard Removal

6.3.3 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. Fuses F1 and F2 are Type T (slow blow) rated 100 ma, 250VAC.

To remove the board, follow the steps below and refer to Figure 24.

Required Materials

5/16'' Hex Nut Driver

To Replace the AC Distribution Board

1. Remove the rear cabinet shell (see Section 6.3.1).
2. Remove the Electrical Guard (see Section 6.3.2)

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.

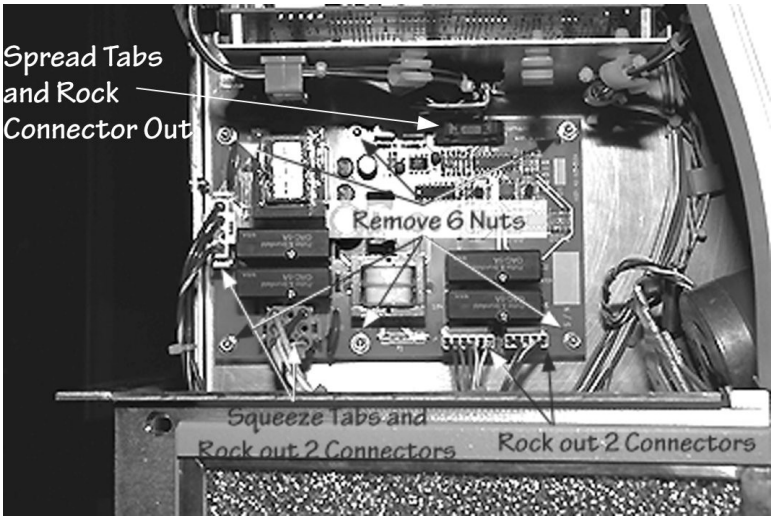


Figure 24 - AC Distribution Board Removal

6.3.4 Blower

The blower is located to the left of center facing the rear of the instrument. To remove the blower, follow the steps below and refer to Figure 25.

Required Materials

Small Phillips Screwdriver

To Replace the Blower

1. Remove the rear cabinet shell (see Section 6.3.1).
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.

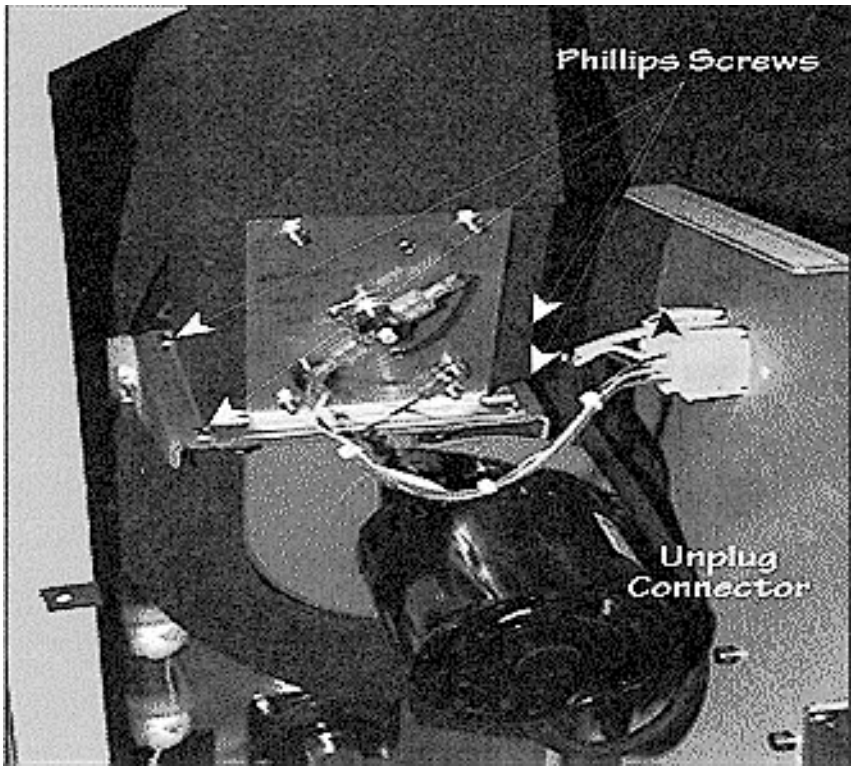


Figure 25 - Blower Removal

6.3.5 PC/104 CPU Module

The PC/104 CPU Module is mounted at the rear of the I/O Board on the bottom of the left electronics compartment. To remove the PC/104 CPU Module, follow the steps below and refer to Figure 26.

Required materials

No Tools Required

To Replace the PC/104 CPU Module Board

1. Remove the rear cabinet shell (see Section 6.3.1).
2. The board can be removed 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 6.3.10 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 the rear side of the 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.

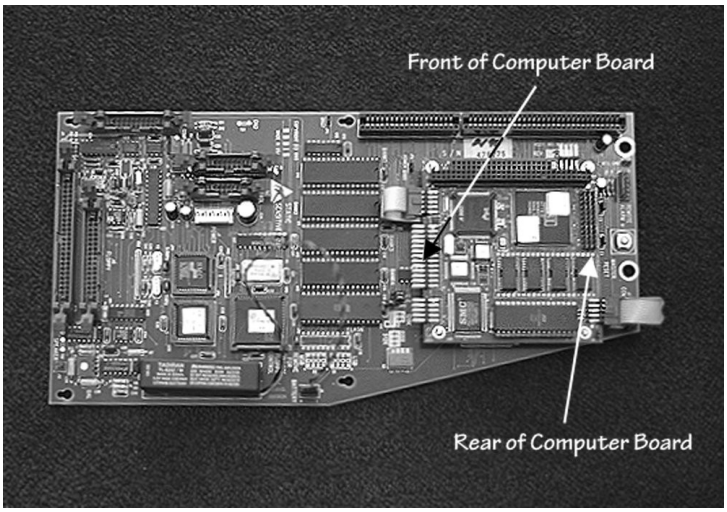


Figure 26 - PC/104 CPU Module Removal

6.3.6 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 27.

Required Materials

5/16" Hex Nut Driver

To Replace the DC Power Distribution Board

1. Remove the rear cabinet shell (see Section 6.3.1).
2. Remove the Electrical Guard (see Section 6.3.2)
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 the 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.

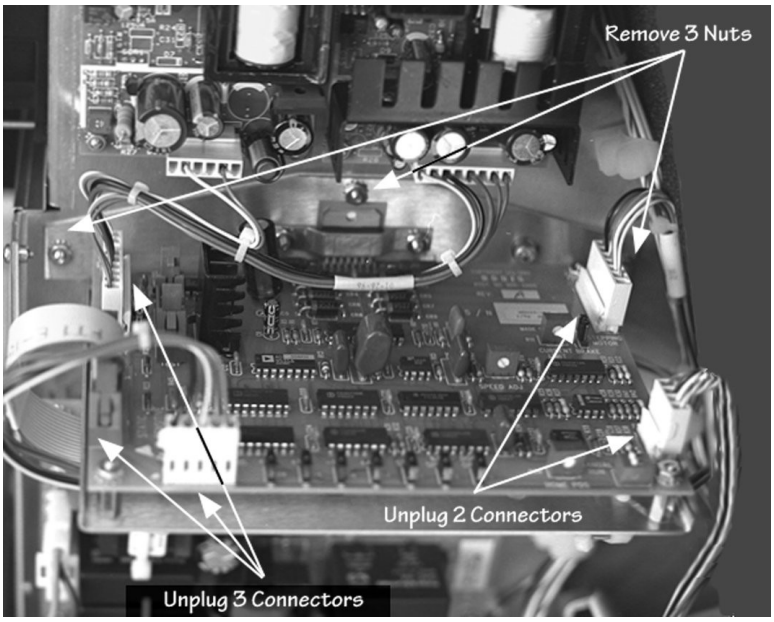


Figure 27 - DC Power Distribution Board Removal

6.3.7 Source/Detector Board

The Source/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 28.

NOTE: If the Source/Detector board is replaced, all vials must be subcultured.

Required materials

Medium Phillips Screwdriver
Flashlight (optional)
Medium Flathead Screwdriver

To Remove the Detector Board

1. Remove the rear cabinet shell (see Section 6.3.1).
2. Reach through the area in the center of the instrument (beneath the fan) to where the detector board is mounted (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. The fasteners should be turned by hand, but a Flathead screwdriver can be used if preferred.
5. Replace the board by reversing the steps above. Be sure to fit the board over the two guide pins.

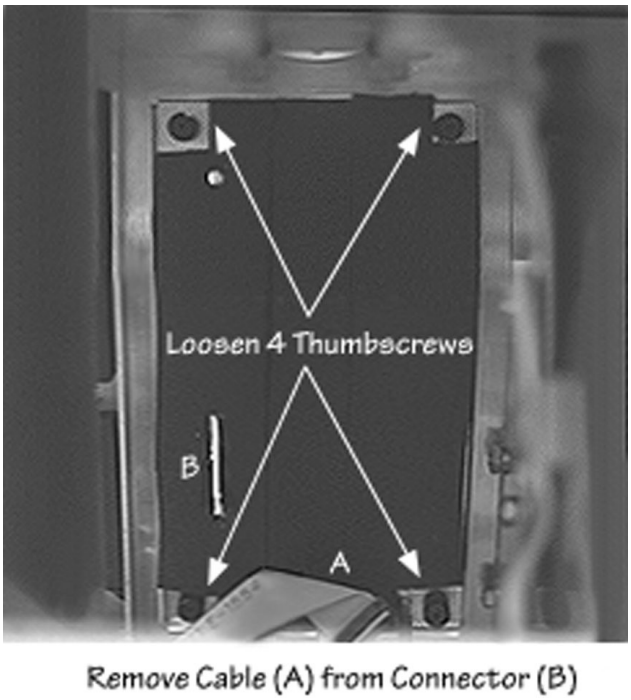


Figure 28 - Source/Detector Board Removal

6.3.8 FAN

To replace the fan, follow the steps below and refer to Figure 29.

Required materials

Small Phillips Screwdriver

To Replace the Fan

1. Remove the rear cabinet shell (see Section 6.3.1).
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 to 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.

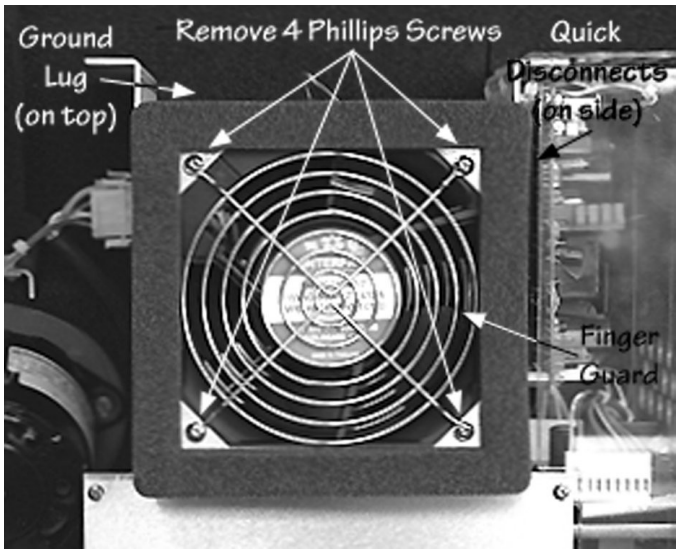


Figure 29 - Fan Removal

6.3.9 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 30.

Required materials

5/16" Nut Driver

To Replace the Heater

1. Remove the rear cabinet shell (see Section 6.3.1).
2. Disconnect the heater cable from its connection to chassis upright.
3. Remove the four 5/16" nuts that hold the assembly to the blower ductwork.
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 to 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.

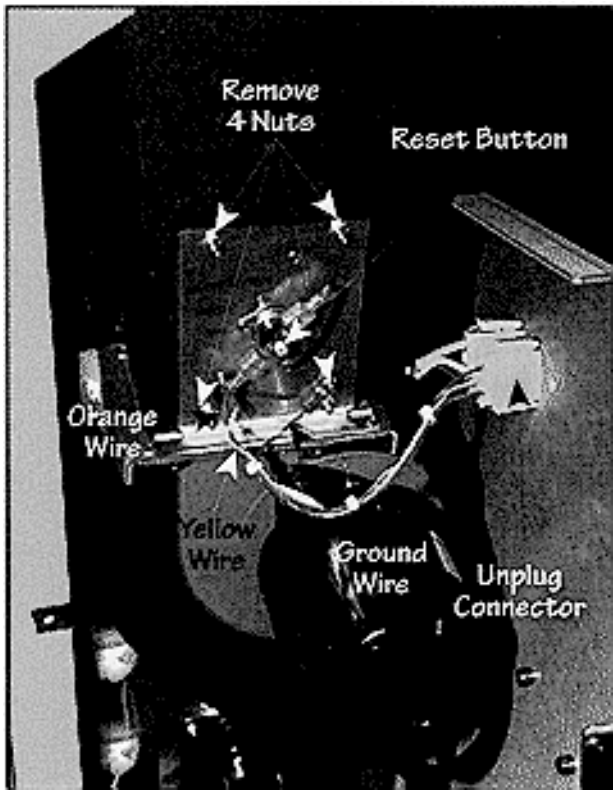


Figure 30 - Heater Removal

6.3.10 I/O Board

The I/O Board is located at the bottom of the left electronics compartment. To remove the I/O Board, follow the steps below and refer to Figure 31.

NOTE: If the I/O board is replaced, all vials must be subcultured.

Required Materials

Medium Phillips Screwdriver

To Replace the I/O Board

1. Remove the rear cabinet shell (see Section 6.3.1).
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 the 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 6.3.5.
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, and then slide the board to the narrow part of the cutouts. Be sure to reconnect all cables.

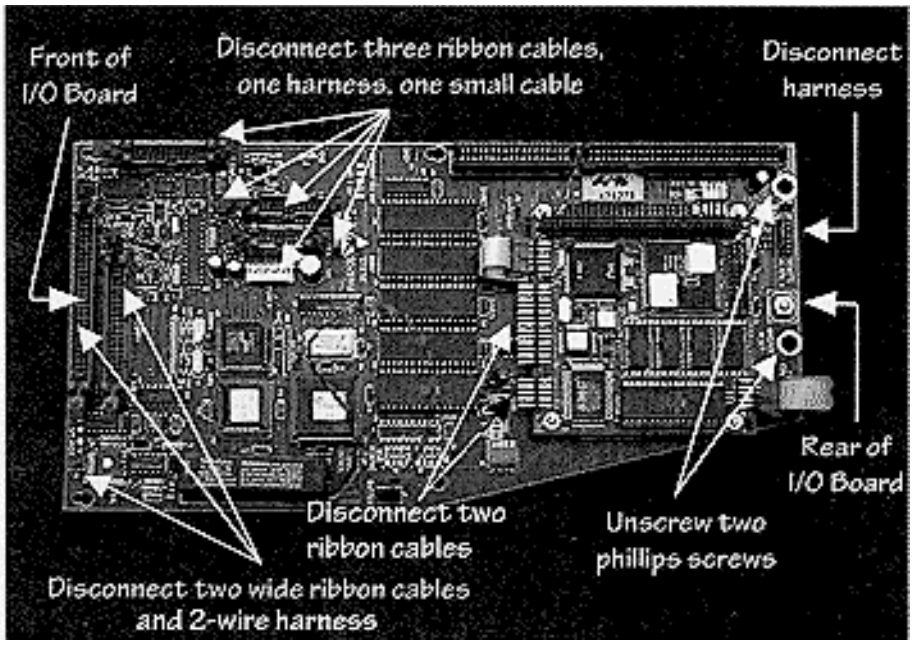


Figure 31 - I/O Board Removal

6.3.11 Motor Replacement

Required materials

3/8" wrench

To replace motor

1. Remove power from the instrument.
2. Remove the rear cover (see Section 6.3.1).
3. Remove the electrical guard (see Section 6.3.2).
4. Disconnect the motor power cord from the DC Power Distribution board (see Section 6.3.6).
5. Remove the wire from the cable clamp located beneath the board. Additional wires may also be removed as necessary by releasing them from their retainers (see Section 6.3.6).
6. Loosen the four nuts found inside the right side of the tunnel beneath the fan (Figure 32)
7. Holding the motor with the right hand remove the nuts completely.
8. Pull the assembly straight out toward the side of the cabinet. As the screws free the holes rotate the motor upward and toward the rear of the cabinet to remove.
9. Replace motor by reversing the above steps.

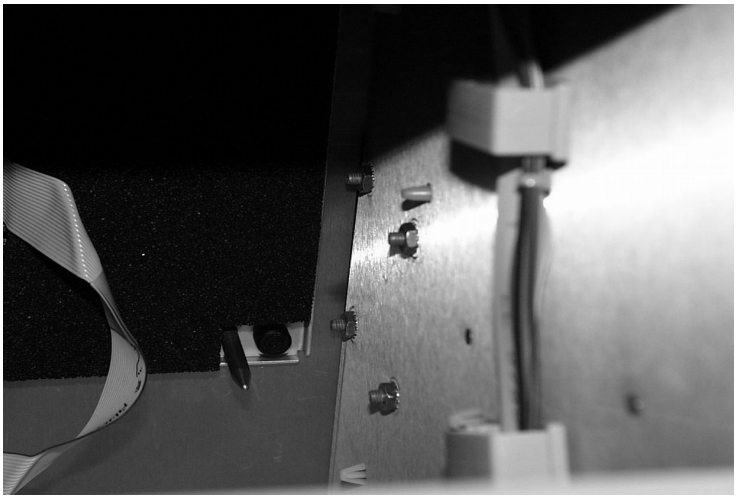


Figure 32 - Motor Removal

6.3.12 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 32, 33, and 34.

Required materials

7/16" wrench

To Replace the Main Transformer

1. Remove the rear cabinet shell (see Section 6.3.1).
2. Remove the Electrical Guard (see Section 6.3.2).
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 on the AC Power 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.
   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.
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 number 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, and the nut.

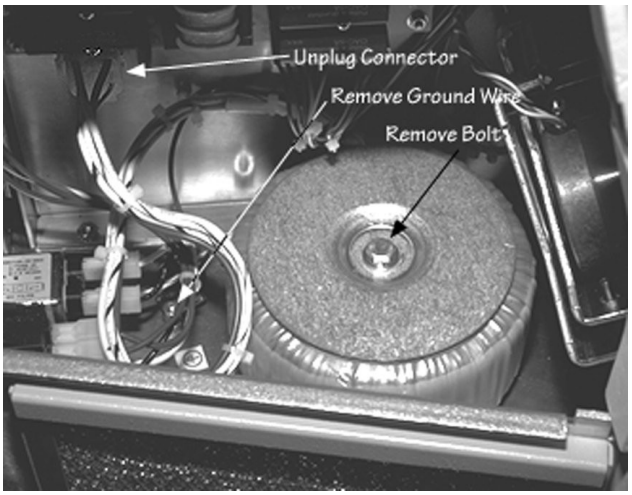


Figure 33 - Main Transformer Removal (A)

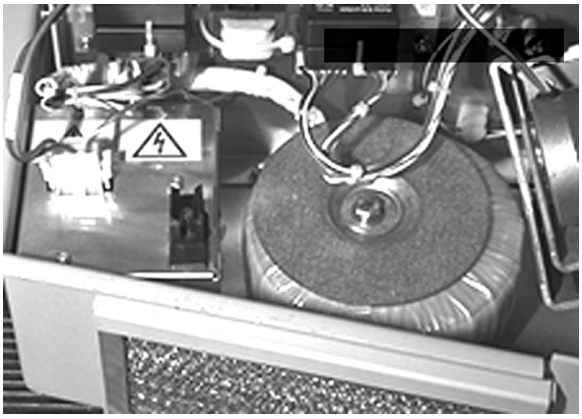


Figure 34 - Main Transformer Removal (B)

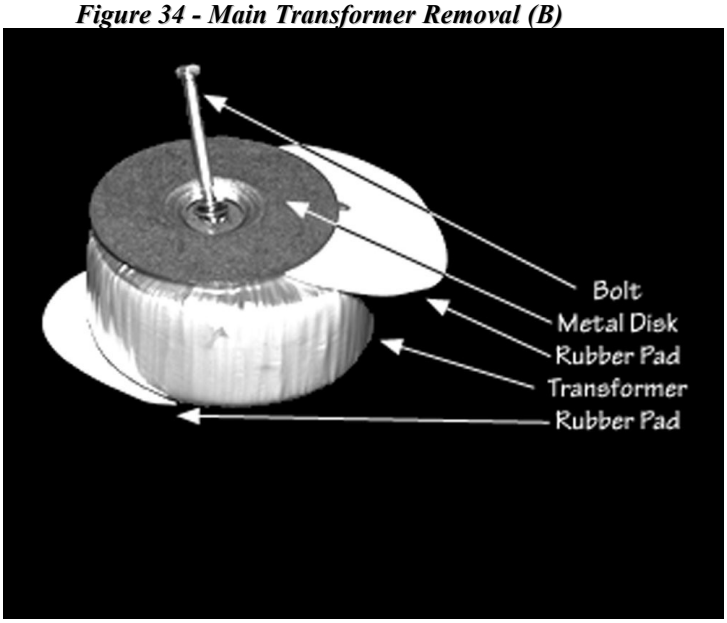


Figure 35 - Main Transformer Removal (C)

6.3.13 On/Off Switch

The On/Off switch is located on the right side of the instrument (facing the rear). To replace the On/Off switch, follow the steps below.

Required materials

No Tools Required

To Replace the On/Off Switch

1. Remove the rear cabinet shell (see Section 6.3.1)
2. The switch is removed by pushing it rearward out of the chassis while depressing tabs on the top and bottom. Press the top two taps simultaneously and push the switch outward from the instrument. Now push the bottom two tabs simultaneously and push outward. Continue this process while rocking the switch out of the chassis.
3. Disconnect the wires and attach them to the new switch one at a time, in the same locations (as mounted in the instrument, the blue wire at the top left, brown wire top right, black wire lower left, and white wire lower right). Be sure to hold the connector itself and pull it away from the switch.
4. After the wires are connected to the new switch, rock the switch back into the chassis.

6.3.14 Power Supply (5VDC / ±15VDC) Board

The 5VDC/±15VDC Power Supply is located at the top right electronics compartment, toward the front of the instrument (the 40VDC Power Supply is right next to this board, toward the rear of the instrument). To replace the 5VDC/±15VDC Power Supply, follow the steps below and refer to Figure 35.

Required materials

5/16" Hex Nut Driver

To Replace the Power Supply Board

1. Remove the rear cabinet shell (see Section 6.3.1).
2. Remove the Electrical Guard (see Section 6.3.2).
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.

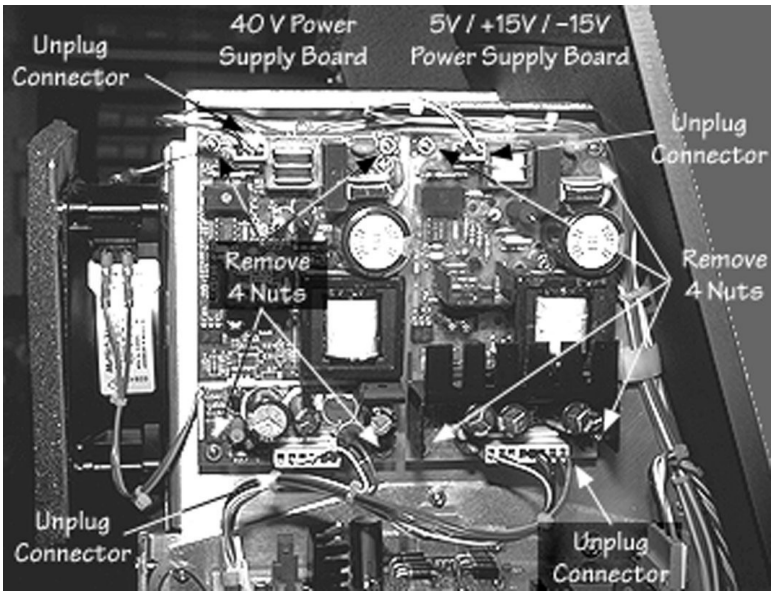


Figure 36 - Power Supply (5 VDC / ±15VDC) Board

6.3.15 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 5VDC/±15VDC is right next to this board, toward the front of this instrument.) To replace the 40V Power Supply, follow the steps below and refer to Figure 36.

Required Materials

5/16" Hex Nut Driver

To Replace the Power Supply Board

1. Remove the rear cabinet shell (see Section 6.3.1.)
2. Remove the Electrical Guard (see Section 6.3.2).
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.

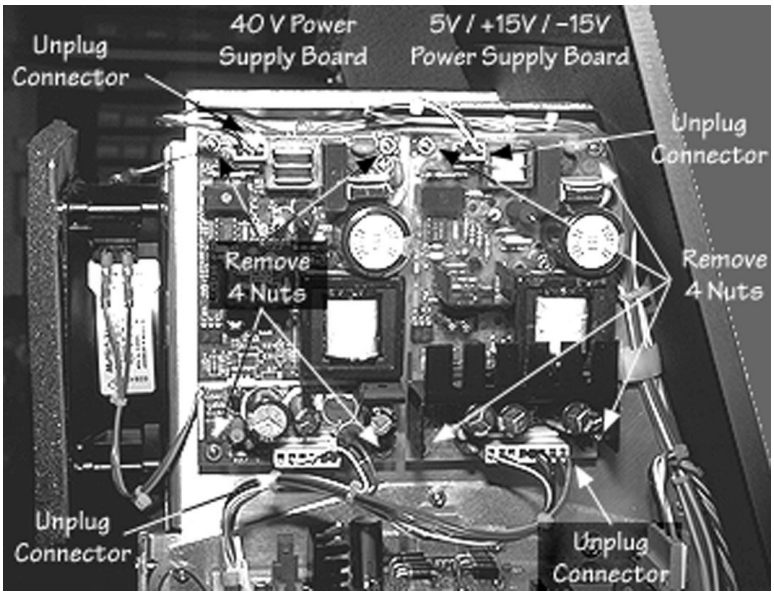


Figure 37 - Power Supply (40V) Removal

VII TROUBLESHOOTING

7.1 Diagnostic software

The BACTEC® 9050 Hardware Diagnostic Utility is utilized to perform system diagnostics by using the instrument keypad. To access the utility menu selections, load the Diagnostic Utility floppy diskette into the floppy drive and reboot the instrument. Follow the instructions on the instrument keypad display to exercise desired diagnostics options.

The BACTEC® 9050 Software Diagnostic Utility is utilized to perform the instrument data analysis and troubleshooting. When a "Save Data to Disk" is performed from the Configuration menu, the following files are written to the floppy disk:

- EVENTLOG.DAT
- SYSPARMS.DAT
- DATABASE.DAT
- NORMDATA.DAT

The EVENTLOG.DAT file is a binary log of the events that have occurred in the BACTEC® 9050 system.
This binary file contains information such as:

- Vials (and barcodes) that are entered via Vial Entry and Identify Anonymous activities
- Vials (and barcodes) that are removed via Remove Positives and Remove Negatives activities
- Vials in error that are resolved via Resolve Station Errors
- All alerts that are reported, detected and cleared
- All door open and close events
- Logging of a System Status Report request
- Configuration modifications
- All instances of when a Save Data is performed
- Software version being executed when the system is booted
- Time logged when the system detects a positive

- Instances and reasons why a test cycle is aborted
- Instances of a power failure and boot codes to determine what caused the reboot
- Assert and General Protection information
- Updated power failure reporting to indicate the time of the power failure and the time of power recovery
- Indication of the line frequency

The SYSPARMS.DAT binary file contains the instrument configuration settings.

The DATABASE.DAT file contains the BACTEC® 9050 database. The database contains two sections: the active portion and the history portion. The active portion contains the 50 stations in the instrument. The history portion contains the last 50 vials that were removed.

The NORMDATA.DAT file contains the normalization values for each station in the BACTEC® 9050 instrument. Starting with the system software version V1.10L, the NORMDATA.DAT file is resident in both NVRAM and FLASH memory once the instrument has been calibrated. If a "Clear NVRAM" (with the Diagnostic mode switch enabled) is performed or the NVRAM battery is removed, the NORMDATA.DAT file will be written from FLASH into NVRAM during reboot process.

The BACTEC® 9050 Software Diagnostic Utility contains 3 executable files:

- LISTLOG.EXE
- DB_DUMP.EXE
- SYSREAD.EXE

Note: None of the BACTEC® 9050 Software Diagnostic utilities are case sensitive. All data files can be viewed by using text editor applications.

7.1.1 LISTLOG.EXE

The LISTLOG.EXE is utilized to dump the EVENTLOG.DAT file into a readable format. The LISTLOG.EXE utility can dump the entire EVENTLOG.DAT file or can be given a start time and end time to dump a portion of the EVENTLOG.DAT file (see Exhibit 1).

```
1997Jan20 07:51:38 Error vial: at C49
1997Jan20 07:52:38 Workflow: (41)View events START
1997Jan20 07:52:55 Door: OPEN
1997Jan20 07:54:28 Workflow: (41)View events END
1997Jan20 07:56:42 Error resolve: 449104734920 at C44
1997Jan20 07:57:09 Error resolve:        CLEAR at C49
1997Jan20 07:57:15 Door: CLOSE
1997Jan20 08:02:18 Door: OPEN
1997Jan20 08:02:19 Door: CLOSE
1997Jan20 08:02:20 Door: OPEN
1997Jan20 08:02:28 Misc: Test aborted - Door open during test.
1997Jan20 08:03:27 Vial Protocol: 446500760004 set for 5 days
1997Jan20 08:03:31 Door: CLOSE
1997Jan20 08:13:22 Anonymous vial: at B39
1997Jan20 08:28:33 Door: OPEN
1997Jan20 08:28:37 Door: CLOSE
1997Jan20 08:34:25 Misc: Rotor HOME
1997Jan20 08:47:05 S/W Version: V1.10L Inst: 1
1997Jan20 08:47:05 Misc: PF byte 07
1997Jan20 08:47:05 Event Auto: (E10)Corrupt database, (00000008)Normalization table
   00 00 00 00 00 00 00 00
1997Jan20 08:47:12 Misc: Zero crossing = 241 in 2 seconds.
1997Jan20 08:47:12 Fault: (3)Powerfail at 1997Jan20 08:34:33
1997Jan20 08:47:12 Event Auto: (E13)Power failure, (20000000)
   19 2E E3 32 08 31 E3 32
1997Jan20 08:47:12 Misc: Watchdog time:  1
1997Jan20 08:47:17 Misc: Watchdog time:  5
1997Jan20 08:47:21 Workflow: (41)View events START
1997Jan20 08:47:34 Workflow: (41)View events END
1997Jan20 08:47:38 Workflow: (41)View events START
1997Jan20 08:47:56 Workflow: (41)View events END
1997Jan20 08:48:30 Door: OPEN
1997Jan20 08:48:51 Anonymous ident: 449206864556 at B39 for 5 days
1997Jan20 08:49:01 Door: CLOSE
1997Jan20 08:49:08 Door: OPEN
1997Jan20 08:49:28 Remove positive: 449100002860 from A11
1997Jan20 08:49:33 Remove positive: 449100035038 from A12
1997Jan20 08:49:44 Remove positive: 449100002717 from C47
1997Jan20 08:49:45 Event Clear: (E00)Positive vial, (20000000)
   00 00 00 00 00 00 00 00
1997Jan20 08:49:54 Door: CLOSE
1997Jan20 08:50:35 Door: OPEN
1997Jan20 08:50:39 Door: CLOSE
1997Jan20 08:50:39 Misc: Test aborted - Door open during test.
1997Jan20 08:56:09 Door: OPEN
1997Jan20 08:56:26 Entered vial: 449100002860 at A12 for 5 days
1997Jan20 08:56:37 Entered vial: 446500760004 at A11 for 5 days
1997Jan20 08:56:40 Door: CLOSE
1997Jan20 09:03:04 Event Set: (E06)Station flag error, (00000001)Ring A
```

Exhibit 1

LISTLOG with no Time Constraints

To exercise, type: “LISTLOG EVENTLOG.DAT>LOG”

- >LOG pipes the entire EVENTLOG.DAT output to a file called LOG

LISTLOG with Time Constraints

To exercise, type "LISTLOG EVENTLOG.DAT -a1996/03/11 00:00:00 -b1996/03/20 00:00:00>LOG"

- This would dump the EVENTLOG.DAT from the time denoted by -a (March 11, 1996 at midnight) up to the time denoted by -b (until March 19, 1996 at midnight), inclusive

LISTLOG by Message Type

To exercise, type: "LISTLOG EVENTLOG.DAT -X<type>-I<type> >LOG"

-I would include the following messages where <type> is the numeric value
-X would exclude the following messages where <type> is the numeric value

The following types of messages are available:

1 Anonymous identification	13 Fault
2 Assert	14 Remove Negative
3 Barcode	15 Remove Positive
4 Barcode error	16 Negative Vial
5 Door	17 Positive Vial
6 Entered vial	18 S/W Version
7 Error Resolve	19 Exception
8 Event	20 Anonymous vial
9 Exception	21 Error Vial
10 Keystroke	22 Code Error
11 Misc	23 Workflow
12 Move Vial	24 Vial Protocol

Note: Typing the -X parameter with no numbers will exclude all messages. You must then use the -I parameter designation for each message type that you would want to see. Also, using the –I parameter without the -X parameter is useless.

For example:

LISTLOG EVENTLOG.DAT -X-I12-I20>LOG

would only dump the messages with the type of Move Vial and Anonymous vial

LISTLOG with Time Constraint by Message Type

The EVENTLOG.DAT file can also be dumped using both the inclusion/exclusion parameters in combination with the time parameters using the following format:
LISTLOG EVENTLOG.DAT -a<date/time>-b<date/time>-x<type>-i<type> >LOG

7.1.2 SYSREAD.EXE

The SYSREAD.EXE is utilized to dump the SYSPARMS.DAT file into a readable format (see Exhibit 2).

BDMS 9050 SysParms Utility V1.10J (C) 1996

```
SYSREAD   Date: Thu Mar 06 14:22:51 1997

System parameters listing for file: sysparms.dat

Sysparms version number    2
Temperature setpoint       35
Instrument number          1
Date format value          0
  Date ordering      mdy
  Date delimiter     /
  Date year length   2
Time format value          0
  Time delimiter     :
Protocol length            7
Fungal protocol length     14
MycoB protocol length      5
Alarm volume               5
Aerobic DVE threshold      20
Anaerobic DVE threshold    20
Selected language          1
Detected line frequency    60HZ
Power fail time value      1057
  Power fail time     Fri Feb 28 16:13:21 1997
Power restore time value   48115
  Power restore time  Thu Mar 06 12:43:31 1997
Power fault time value     1057
  Power fault time    Fri Feb 28 16:13:21 1997
Software version last run  V1.10L
Checksum value             D789
Checksum is valid.
```

Exhibit 2

The command line to execute this utility is:

SYSREAD SYSPARMS.DAT>SYS

- >SYS pipes the output to a file called SYS

7.1.3 DB_DUMP.EXE

The DB_DUMP.EXE is utilized to dump the DATABASE.DAT file into the a readable format (see Exhibit 3)

```
]BDMS 9050 DB Dump Utility V1.10J (C) 1996

Database version: 1
Station C50  Flags 2:
----------------------
            Status: AVAILABLE
             Flags:
```

```
          Barcode:
        Accession:
       Entry time: <none>
   Protocol length: 7
 Current Time Stamp: Fri Mar 07 15:33:21 1997
Positive Time Stamp: <none>
        Raw value: 0038
  Normalized value: 0030
 Compensated value: 0030
    Smoothed value: 20c9
       Dark value: 0004
     Total Samples: 0
       Algorithms: 0000
    Old Algorithms: 0000
     Reentry Count: 0
Data Buffer new-old: 0000 0000 0000 0000 0000 0000 0000 0000 0000 0000

Old record index 02 archived on Fri Mar 07 15:22:57 1997:
------------------------------------------------------------
           Status: POSITIVE
            Flags:
          Barcode: 449100002717
        Accession:
       Entry time: Wed Mar 05 17:23:22 1997
   Protocol length: 7
 Current Time Stamp: Fri Mar 07 15:13:22 1997
Positive Time Stamp: Wed Mar 05 17:43:22 1997
        Raw value: 0e18
  Normalized value: 0d32
 Compensated value: 0d32
    Smoothed value: 0d33
       Dark value: 0006
     Total Samples: 276
       Algorithms: 8000
    Old Algorithms: 0000
     Reentry Count: 0
Data Buffer new-old: 0d32 0d33 0d32 0d35 0d32 0d33 0d30 0d35 0d34 0d34
```

Exhibit 3

The command line to execute this utility is:

DB_DUMP DATABASE.DAT>DB

- >DB pipes the output to a file called DB

7.2 Instrument Service

Two general types of problems are described in this section:

Error Messages - which appear when system has encountered a known problem. These messages are listed alphabetically, along with possible causes of the message and corrective actions.

Other malfunctions - organized by symptom, and providing possible causes and corrective actions.

7.3 Error/Alert Messages

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. The Activity Error icon flags these activities errors.

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.

7.3.1

E01 Temperature Alarm

Subcode 00000001 Incubator temperature is too high

Subcode 00000002 Incubator temperature is too low

Subcode 00000004 Bad main temperature sensor (RTD)

Subcode 00000008 Bad backup temperature sensor (located on the Source/Detector Board)

Possible Cause(s)

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

Corrective Action(s) for Subcodes 00000001 and 00000002

- 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 2.2 - Instrument Specifications.
- Clean or replace air filters.
- Check temperature vial to see if manual reading agrees with displayed reading.
- Reset manual thermostat (see Figure 30 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.

Corrective action (s) for Subcodes 00000004 and 00000008

- Check RTD for Open/Short states.
- Check RTD connection to I/O Board
- Replace RTD
- Check connector between Source/Detector Board and I/O Board
- Verify and adjust if necessary temperature setting on the I/O board per procedure TI-0283.
- Replace Source/Detector Board

7.3.2

E02 Rotor RPM out of Spec (Normal speed is 30 RPM)

Subcode 00000001 Rotor speed is too fast

Possible Cause(s)

- Speed adjustment is not correct

Corrective Action(s)

- Determine rotor speed with the BACTEC® 9050 Diagnostic software V1.00
  Adjust (per procedure TI-0283) the Ramp Generator/DC Distribution board to obtain 30 RPM ±0.5 RPM rotor speed

Subcode 00000002 Rotor speed is too slow

Possible Cause(s)

- 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.
- Adjust (per procedure TI-0283) the Ramp Generator/DC Distribution board to obtain 30 RPM ±0.5 RPM rotor speed.

Subcode 00000004 Rotor stopped

- Rotor is not rotating

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.
- Check stepper motor and Urethane belt for visual defects
- Verify voltage (40V) DC Power Distribution/Ramp Generator Board. Adjust if necessary per procedure TI-0283.
- Replace Motor or Ramp Generator/DC Distribution board

- Home Sensor has failed. Replace Rotor.

7.3.3

E05 Temperature Standardization Error

The temperature standards are out of tolerance.

Subcode 00000001 Ring A Temperature Standardization Error OR
Subcode 00000002 Ring B Temperature Standardization Error OR
Subcode 00000004 Ring C Temperature Standardization Error

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/replace temperature standards.
- Check/adjust cover on temperature standards.
- Check that there is no debris, spilled media, or blood inside instrument. Clean if necessary.
- Check RTD and its connection to I/O board. Replace if defective.

7.3.4

E06 Rotor Configuration Error

Subcode 00000001 Ring A Rotor Configuration Error OR
Subcode 00000002 Ring B Rotor Configuration Error OR
Subcode 00000004 Ring C Rotor Configuration Error

Possible Cause(s)

- Rotor is not mounted correctly.
- Hold down nut (hubcap) is not tight.
- Bottle Cup Flags are broken or blocked.
- Source/Detector board optical sensors are blocked or non-functional.

Corrective Action(s)

- Check for visual defects.
- Check rotor mounting - correct if necessary.
- Check hubcap and tighten if necessary.
  Run diagnostics to verify that all bottle cup flags are read correctly
  (Ring A - 24; Ring B - 18; Ring C - 11). If not, inspect for visual damage or blockage.
- Replace bottle cups if necessary.
- Replace Source/Detector board if necessary.

7.3.5

E07 Power Supplies High/Low

Subcode 00000001 +5 VDC is too high

Possible Cause(s)
- +5 VDC is out of acceptable range (>5.25 VDC)

Corrective Action(s)

- Run Diagnostics to check +5 VDC. Adjust +5, ±15 VDC Power Supply if necessary per procedure TI-0283.
- Replace +5, ±15 VDC Power Supply if necessary.

Subcode 00000002 -5 VDC is too low

Possible Cause(s)

- -5 VDC is out of acceptable range (<4.75 VDC)

Corrective Action(s)

- Run Diagnostics to check -5 VDC. Adjust +5, ±15 VDC Power Supply if necessary per procedure TI-0283.
- Replace Power Supply if necessary.

Subcode 00000004 +15 VDC is too high

Possible Cause (s)

- +15 VDC is out of acceptable range (>15.75 VDC)

Corrective Action(s)

- Replace Power Supply

Subcode 00000008 +5 VDC is too low

Possible Cause (s)

- +15 VDC is out of acceptable range (<14.25 VDC)

Corrective Action (s)

- Replace Power Supply

Subcode 000000010 -15 VDC is too high

Possible Cause (s)

- -15 VDC is out acceptable range (>15.75 VDC)

Corrective Action (s)

- Replace Power Supply

Subcode 000000020 -15 VDC is too low

Possible Cause (s)

- -15 VDC is out of acceptable range (<14.25 VDC)

Corrective Action (s)

- Replace Power Supply

Subcode 000000040 +40 VDC is too high

Possible Cause (s)

- +40 VDC is out of acceptable range (>42 VDC)

Corrective Action (s)

- Run Diagnostics to check +40 VDC. Adjust +40 VDC Power Supply if necessary per procedure TI-0283.
- Replace Power Supply if necessary.

Subcode 000000080 +40 VDC is too low

Possible Cause (s)

- +40 VDC is out of acceptable range (<38 VDC)

Corrective Action (s)

- Run Diagnostics to check +40 VDC. Adjust +40 VDC Power Supply if necessary per TI-0283.
- Replace Power Supply if necessary.

7.3.6

E09 No Tests in Over 40 Minutes

Possible Causes(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 opened for longer that 40 minutes, **all vials should be subcultured**. If system clock was set more than 40 minutes ahead, subculturing is not required. If this error occurs and none of the above events happened, write data to disk and contact Becton Dickinson.
- Check door interlock switch. Replace if necessary

7.3.7

E10 Database Corruption

Possible Cause(s)

- Database checksum test failed.

Corrective Action(s)

- Write data to disk (backup) and send it to Becton Dickinson.
- 00000002, 00000008 - All vials should be subcultured.

7.3.8

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 off-line during printing.

Corrective Action(s)

- Check paper and clear jam or add paper if necessary.
- Check printer cables (power and communication), reattach if necessary.
- Turn printer power on.
- Place printer on-line.
- Request report again. It will not resume printing automatically when error condition is corrected.
- Replace printer if necessary.

7.3.9

E12 Error Vial or Error Station

Note

The E12 message is the corresponding System Alert to the Resolving Station Errors activity discussed in Section 4.7.7 of the BACTEC ® 9050 System User's Manual

Possible Cause(s)

Subcodes 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 the vial is in the station, or was removed but you have now located it, use the "resolve station errors" activity to scan the vial label.
- 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.
- 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 immediately after removing it.

7.3.10

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.
- Clear the error. Check power connection to instrument.
- If external power is present, remove the back cover and defeat safety interlock switch to check AC Power Distribution Board performance. Replace if necessary.

7.3.11

E30 Unexpected Vial Was Scanned

Possible Cause(s)

- During the remove positives, remove negatives, or resolve station error activities, the vial barcode scanned is not the one the system expected for the station. Either a vial was pulled from a different station other 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 the vial was pulled from the specified station. If not (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 the vial is pulled from the specified station, try to determine how many vials are misplaced, and where they are located. It may be helpful to print a System Status Report (if an optional printer is being used), add a column labeled "actual station," and relabel the existing station column as "assigned station." If a printer is not available, 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 the chart. There may 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.

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, the end of the vial misplacements has probably been reached.

- 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 of the BACTEC ® 9050 System User's Manual after the misplaced vials have been subcultured.

7.3.12

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.
- Replace floppy drive if necessary,

7.3.13

E32 Instrument Full

Possible Cause(s)

- During Vial Entry or Resolve Station Errors, the station 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.

7.3.14

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 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) a vial was pulled 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, determine: 1) whether the wrong vial was pulled 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 the vial was pulled from the specified station. If not (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 the vial was pulled from the specified station, try to determine how many vials are misplaced, and where they are located. It may be helpful to print a System Status Report (if an optional printer is being used), add a column labeled "actual station," and relabel the existing station column as "assigned station." If a printer is not available, 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 the chart. There may be a vial in this station.

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

  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, the end of the vial misplacements has probably been reached.

- 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, and 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 of the BACTEC ® 9050 System User's Manual after the misplaced vials have been subcultured.

7.3.15

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. Check for "Write/Protect".
- Try another software update diskette.

7.3.16

E50 Internal Software Error

Possible Cause(s)

- System encountered a software error.

Corrective Action(s)

- Write data to disk (backup) and send it to Becton Dickinson.

VIII CRITICAL ADJUSTMENTS AND SPECIAL KEY FUNCTIONS

8.1 Homing Rotor

The rotor "Home" position is defined as the location of the temperature standard bottles at the 12:00 o'clock position. The user may find it easier to locate vial stations when the rotor is homed, since the rotor's position then corresponds to its representation on the display. Refer to the procedure TI-0283 for the "Home" position verification and adjustment instructions.

8.2 Temperature verification and adjustment

The primary (RTD) temperature can be verified by viewing the main status screen or by using the BACTEC® 9050 Hardware Diagnostic Utility. Refer to the procedure TI-0283 for the temperature verification and adjustment instructions.

8.3 Rotor Speed verification and adjustment

The Rotor speed can be verified by using the BACTEC® 9050 Hardware Diagnostic Utility. Refer to the procedure TI-0283 for the Rotor speed verification and adjustment instructions.

8.4 Instrument Calibration (Normalization)

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. Calibration helps to insure that any fluorescent series medium vial in any station will have initial and final fluorescent values within a specified range. Refer to the procedure TI-0283 for the instrument calibration (normalization) instructions.

8.5 Clearing database

Refer to the procedure TI-0283 for instructions.

REFERENCES

Schematics

905-8000	System Schematic
905-8001	Source Detector PCB
905-8002	User Interface PCB
905-8003	I/O Accessory PCB
905-8004	AC Power Control and Distribution PCB
905-8005	Ramp Generator/Stepping Driver PCB

Procedure

TI-0283	System Test for BACTEC® 9050 instruments

Starter Group Documents

MA-0102-A	BACTEC® 9050 Installation and Setup
MA-0103	BACTEC® 9050 System User's Manual
MA-0104	BACTEC® 9050 5 Minute Operator Training Guide

Software

System Software Diskette (Catalog # 4405856)
Software Diagnostic Diskette (Catalog #4405855)
Hardware Diagnostic Diskette (for Becton Dickinson Service Personnel use only)

All reference materials available upon request