Contents

1. Safety

Contents

Introduction

The Biolyte 2000 is designed for safety and convenience. For continuing safe operation, the instrument should be properly maintained by knowledgeable service personnel who are familiar with the safety warning in this manual.

Biological Safety

The waste bottle included in the reagent pack collects all blood, serum, plasma and urine samples aspirated through the instrument. Thus, ***reagent packs should be disposed of in a manner which will prevent possible spread of disease by waste.***

All Service Engineers should routinely use appropriate barrier precautions to prevent skin and mucous membrane exposure when in contact with blood fluids that are aspirated through the instrument.

Protective eyewear and face shields or mask should be worn during troubleshooting procedures that are likely to generate droplets of blood or other body fluids. This will prevent exposure of the mucous membranes of the mouth, nose, and eyes.

Gloves should be worn when handling any part of the external flow path that comes in contact with serum, plasma, whole blood and urine. Hands and other skin surfaces should be washed immediately and thoroughly if contaminated with blood or other body fluids.

Hands should also be washed immediately after gloves are removed. Engineers should take precautions to prevent injuries caused by sharp objects or devices used during troubleshooting when servicing and cleaning used instruments. Parts that have come in contact with any type of biological fluids and have been removed from an instrument should be flushed with bleach and distilled water. These parts should be sealed in a plastic bag or packaged in the original box and identified with appropriate labeling.

Electrical Safety

The instrument line voltage, fuse specifications, and frequency are specified on the serial number plate on the backside of the instrument near the power cord. The instrument should only be operated at the specified voltage and frequency. Line Voltage may be as high as 240 VAC. Caution should be observed when handling the capacitor banks, power supplies, and the LCD.

To remove the line voltage, unplug the line cord at the wall outlet. Do not attempt to remove the fuse without disconnecting the line cord.

Mechanical Safety

The sampler mechanism found on the instrument can exert extremely high pressure. Fingers and other objects should be kept away from the sampler mechanism whenever the system is performing a task. The sampler mechanisms are controlled by optical detectors. The analytical processor reads these switches and prevents computer controlled probe motion, which may cause injury to the operator or damage to the probe. These sensors should be checked periodically.

Chemical Safety

The chemicals provided with the instrument itself require no special handling, beyond that of normal laboratory reagents.

2. System Description

Contents

Introduction

The main modules of the Biolyte 2000 are as follows:

◎ Main Controller Module
◎ Driver PCB
◎ Power Supply
◎ Sampler Module
◎ AMP Module
◎ Pump Module
◎ Printer Module
◎ Keypad & Keypad PCB
◎ LCD Module

Main Controller Module

The Main Controller Module directs the input/output and process control functions of the system. It consists of four major circuit boards with different functions.

CPU PCB

A 16bit 80186 processor combined with the watch dog timer (W. D. T) function as the core of the CPU PCB. Through 因為 the execution 執行 of the program in the **Two 128K Byte ROM**, the CPU PCB performs various functions, such as sequence and input/output information.

Two 32K Byte RAM are used to store variables and perform operational functions. A real time clock provides the time and date for the system.

I/O PCB

The I/O PCB consists of two UARTs (Universal Asynchronous 非同步 Receiver

Transmitters 發射器) and one programmable input/output circuit.

One of the UART is a common RS-232 standard interface. The output connector, a 25pin D-sub female connector, is located at the backside of the Biolyte 2000.

The other UART is a 25pin D-sub male connector. It can be a barcode reader interface or a PUM (Program Update Module) interface.

The programmable input/output circuit controls the **printer module**. It detects the printer status, such as paper out and printer error. It also controls the printer module to print data.

ADC PCB

ADC PCB consists of one serial-to-parallel circuit, one **LCD/keypad control** interface, one programmable input/output circuit and one **RMS**.

The serial-to-parallel circuit receives the output serial signals from the AMP Module and converts them to 16bit parallel signals, which is then read off by the CPU PCB. It also provides four A/D channel select signals and various control signals to the AMP module.

The LCD/keypad control interface regulates 控製 the display of the LCD and receives the keypad inputs.

The programmable input/output circuit reads off standby signals and outputs various control signals that **regulates the sampler pump**, **optical position sensor**, **pump module**, **keypad, LCD, and AMP module A/D converter**.

The Biolyte 2000's RMS (Reagent Management System) verifies that a correct, unexpired fluid pack is being used. At the same time, it monitors the fluid volume in each fluid pack bottle and displays the volume of the least full bottle.

Base PCB

The Base PCB **provides the signal connections between the I/O PCB, CPU PCB, and ADC PCB**. There are four slots on the Base PCB: **I/O PCB slot, CPU PCB slot, ADC PCB slot, and a spare slot**. The Base PCB also provides the connectors for signals from printer module, driver module, and AMP module.

Cable Connections

The following cable connections are located on the Base PCB:

Name	Connect To
CON2	Printer Module
CON4	Power Supply
CON5	AMP Module
CON6	Driver PCB

The following cable connection is located on the ADC PCB:

Name	Connect To
J2	Keypad PCB

The following cable connections are located on the Driver Module:

Name	Connect To
CON1	Sampler Module
CON2	CON6 on the Base PCB
CON3	Sampler Location Detector on the Sampler Arm
CON4	Tilt Location Detector on the Sampler Arm
CON5	Power Supply

CON6	Pump Module
CON7	Pinch Valve

The following cable connections are located on the Keypad PCB:

Name	Connect To
J4	LCD Module
J6	J2 on the ADC PCB

Test Points

The following test points are located on the Base PCB:

Test Point	Function	Typical Range at 110VAC
CON4 pin1	-12V	-13V to -11V
CON4 pin2	+12V	13V to 11V
CON4 pin3	GND	–
CON4 pin4	+5V	4.75V to 5.25V

The following test points are located on the Driver PCB:

Test Point	Function	Typical Range at 110VAC
CON5 pin1	+5V	4.75V to 5.25V
CON5 pin2	+12V	13V to 11V
CON5 pin3	GND	–

The following test points are located on the Printer PCB:

Test Point	Function	Typical Range at 110VAC
CON4 pin1	+5V	4.75V to 5.25V
CON4 pin3	GND	–

RS232 Port

The RS232 interface port is a 25pin D-sub female connector, and is located at the backside of the Biolyte 2000. The RS232 port can be used to connect to PC.

The communication protocols are as follow:

Baud rates: 9600 bit/sec

Parity check: none

Start bit: 1 bit

Stop bit: 1 bit

Data bit: 8 bits

Pinouts are as follows:

Pin Number	Signal Name	Direction	Function
2	RxD	INPUT	Received Serial Data
3	TxD	OUTPUT	Transmitted Serial Data
4	CTS	INPUT	Clear To Send
5	RTS	OUTPUT	Request To Send
6	DTR	OUTPUT	Data Terminal Ready
7	GND	–	Signal Ground
20	DSR	INPUT	Data Set Ready

Driver PCB

The Driver PCB receives the control signals from ADC PCB and then regulates these signals to control the actions of the pump module and pinch valves. It drives the sampler module, pump module and pinch valves, and detects the sampler location and the tilt of the sampler arm.

Power Supply

The input specifications of the Power Supply are as follows:

Input Voltage Range : 85VAC ~ 264VAC

Input Frequency Range : 47HZ ~ 63 HZ

Maximum Input Current : 1A RMS (115VAC) or 0.6A RMS (230VAC)

The output specifications of the Power Supply are as follows:

Output Voltage	Max Load Current	Normal Voltage Range
+5V	3A	4.95V ~ 5.05V
+12V	2A	11.4V ~ 12.6V
-12V	0.3A	-12.6 ~ -11.4V

Sampler Module

The function of the Sampler Module is to vertically move the sampler arm and

probe to a specific position predetermined by the software. The Sampler Module consists of a stainless steel sample probe attached to an arm, driven by a stepping motor. Optical detectors are used to monitor both the home and probe positions.

The sampler tilts up for Manual Mode and down for Semi-Auto Mode. The driver PCB monitors two in position tilt sensors to verify correct positioning. The sampler has one optical position sensor which is interrupted by a flag on the sample arm. The position is used as an absolute position reference (HOME) and as a probe down signal. The probe down signal is linked by an interrupt to the driver PCB. Sampler motion is controlled by a step timer, step counter and a direction bit. All sampler positions are found by counting the number of steps from the home position.

The specifications of the Sampler Module are as follow:

Driver Type	:	Rack and Pinion
Motor Type	:	Stepper
Positioning	:	Number of steps from Home
Driver Voltage	:	+5V
Opto Voltage	:	+5V

AMP Module

The AMP Module measures the analyte voltages and sends the data to the Main Controller Module. It consists of one AMP PCB and two pinch valves (a Waste Valve and a Reference Valve).

AMP PCB

The AMP PCB contains the circuits for the following:

◎ Electrode Signal Circuit
◎ Air Detector
◎ A/D Converter

Electrode Signal Circuit

The voltages from the electrodes are measured with respect to a reference electrode. The electrode signal is fed from through a differential amplifier and sent to the analog multiplexer, which then selects the signal to be sent to the A/D converter.

Air Detector

The Air Detector detects the presence or the absence of fluid in the electrode train during analytical sequence. It does this by sensing changes in the photo diode 感光二極體 response between air and fluids, and, serum and whole blood. The light source is one red LED with one photo diode as the detector.

A/D Converter

The A/D Converter changes the analog input voltages to digital signals. It is a dual slope integrating converter with a four channel input muliplexer. The AMP PCB adapts a 16 bits A/D converter.

The specifications of the A/D Converter are as follows:

Conversion Type	:	Delta-sigma
Resolution	:	16 bits
Linearity Error	:	±0.0015%FS (Typical)
Operating Voltage	:	+5V
Conversion Rate	:	20 samples/sec
Operating Type	:	Bipolar
Input Voltage Range	:	±2.5V

Analog Channels are as follows:

Channel	**Function**	**Acceptable Range**
1	Electrode	-250 ~ 250mV
2	Electrode	-250 ~ 250mV
3	Electrode	-250 ~ 250mV
4	Photo Sensor	0 ~ 2 μ A
5	Future Expansion, Not Used	
6	Future Expansion, Not Used	

7	Future Expansion, Not Used
8	Future Expansion, Not Used

Waste Valve and Reference Valve

There are two pinch valves on the Biolyte 2000: Waste Valve and Reference Valve. They are driven by the Driver PCB. To conserve power, the voltage to the valves is reduced when they are closed and returned to normal voltage only when they are opened.

The valves control the flow of the fluids through the tubing, from the reagent pack into the electrode carrier. They are normally in the open position when fluid is being drawn to the electrode carrier. Once the fluid fills the electrode carrier completely and the slope readings are being taken, the valves will close to prevent back flow of fluids into the electrode carrier. After the reading are taken, the Waste Valve opens and the fluid is drawn out through the W-line.

Pump Module

The Pump Module controls the flow of the fluids through the W-line. The Pump consists of a rotating roller cage mounted directly on the shaft of a stepping motor. Tubing is stretched around the roller cage to accomplish aspiration. The Pump can be operated at different speeds and tested via the software. The specifications of the Pump are as follows:

Input Voltage : 12V
Input Current : 0.8A (maximum)
Control Signal : motor ON/OFF
motor direction
High/Low speed selection
Half/Full step selection

Printer Module

The Printer PCB directs the printer functions. It receives the signals from the ADC PCB and drives the printer to print, feed paper, and read off the printer status.

The Printer is a 32 column thermal printer with graphic and column print capability. The specifications of the Thermal Printer are as follow:

Paper width	:	58mm
Printing Columns	:	32
Printing Speed	:	46cps
Character Matrix	:	8-dot high*6-dot wide
Character Set	:	256
Operating Voltage	:	4.6~5.5V
Current Consumption	:	Standby 5.5mA max, Printing 4.0A max.

Keypad and Keypad PCB

The Keypad is located on the front panel of the instrument. The Keypad has 26 keys that are used to input all system functions.

There are many keys and key control circuits on the Keypad PCB. It connects with the ADC PCB through the J6 connector and with the LCD Module through the J4 connector.

LCD Module

The LCD (Liquid Crystal Display) Module is on the front panel of the Biolyte 2000. The electrical specifications of the LCD Module are as follows:

Item	SYN	Condition	Min.	Type	Max.	Unit
Supply Voltage for LCD	V_{DD}-V_O	T_a = 0℃	-----	4.8	-----	V
		T_a = 25℃	-----	4.5	-----	V
		T_a = 50℃	-----	4.2	-----	V

Input Voltage	V_I	-----	4.7	5.0	5.3	V
Input High Vol.	V_{IH}	-----	2.2	-----	V_{DD}	V
Input Low Vol.	V_H	-----	0	-----	0.6	V
Output High Vol.	V_{OH}	-----	2.4	-----	-----	V
Output Low Vol.	V_{OI}	-----	-----	-----	0.4	V
Supply Current	I_{DD}	V_{DD} =5V		4.0	10.0	mA

3. Replacement Procedures

Contents

Right and Left Side Panels Replacement

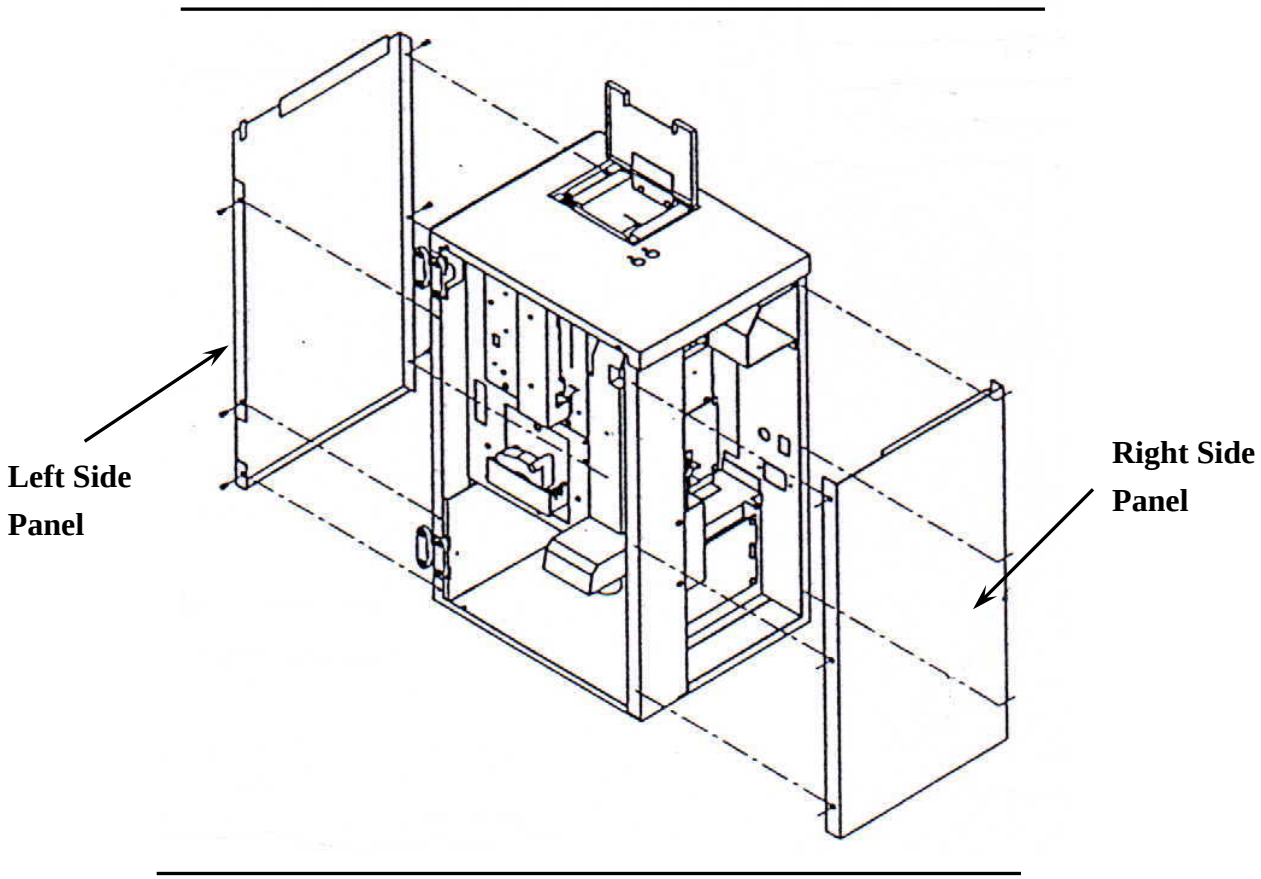


Figure 3-1. Right and Left Side Panels Replacement.

Right and Left Side Panels Removal

1. Power down the Biolyte 2000 by press the ON/OFF button at the backside of the Biolyte 2000 and removing the power cord.
2. Remove the six screws on the right or left side panel (Figure 3-1).
3. Remove the right or left side panel from the Biolyte 2000.

Right and Left Side Panels Installation

1. Install the right or left side panel onto the Biolyte 2000.
2. Fasten the six screws on the right or left side panel (Figure 3-1).

LCD Module Replacement

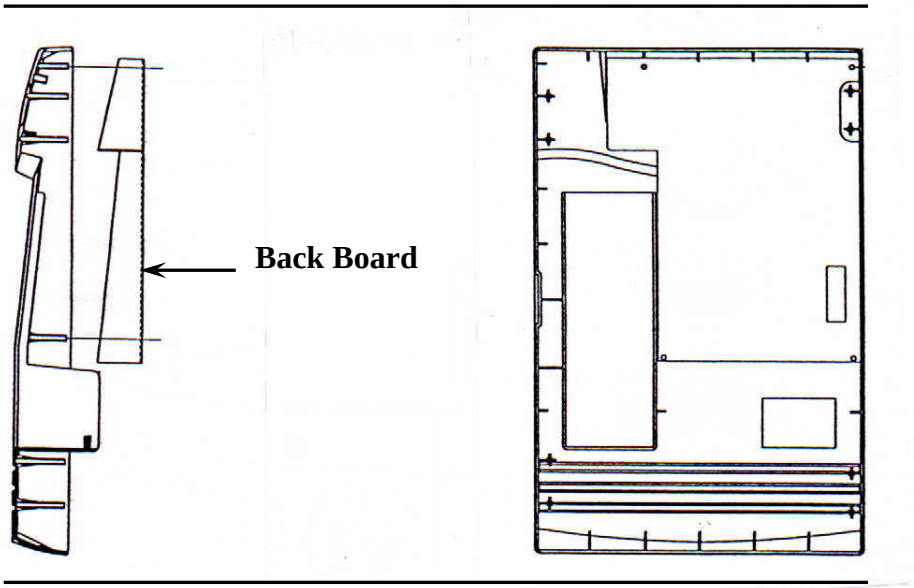


Figure 3-2. LCD Module Replacement 1.

LCD Module Removal

1. Power down the Biolyte 2000 by press the ON/OFF button at the backside of the Biolyte 2000 and removing the power cord.
2. Remove the four screws on the front panel back board (Figure 3-2).
3. Remove the front panel back board.
4. Disconnect the Keypad flat cable from the Keypad PCB.
5. Disconnect the LCD flat cable from the LCD module.
6. Remove the four screws on the LCD module (Figure 3-3).
7. Remove the LCD module from the Biolyte 2000.

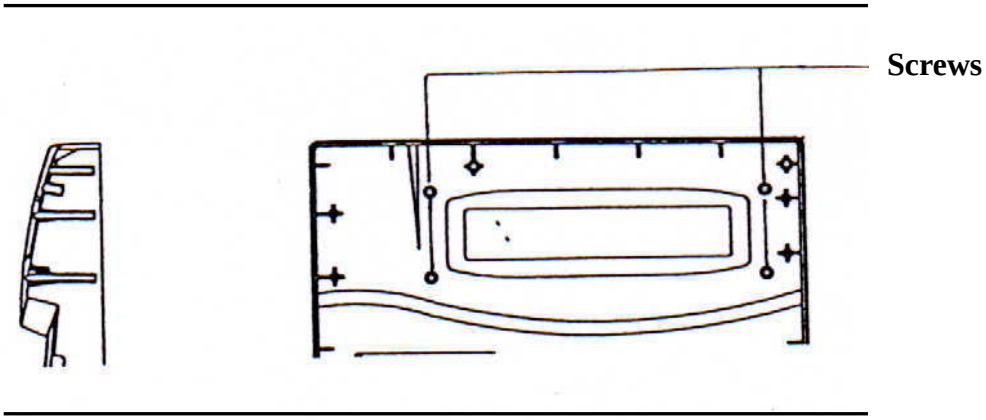


Figure 3-3. LCD Module Replacement 2.

LCD Module Installation

1. Orient the LCD module so **the low profile header is on the right side.**
2. Install the LCD module into the Biolyte 2000.
3. Install the four screws on the LCD module (Figure 3-3).
4. Reconnect the LCD flat cable to the LCD module.
5. Reconnect the Keypad flat cable to the Keypad PCB.
6. Fasten the four screws on the front panel back board (Figure 3-2).

Keypad PCB Replacement

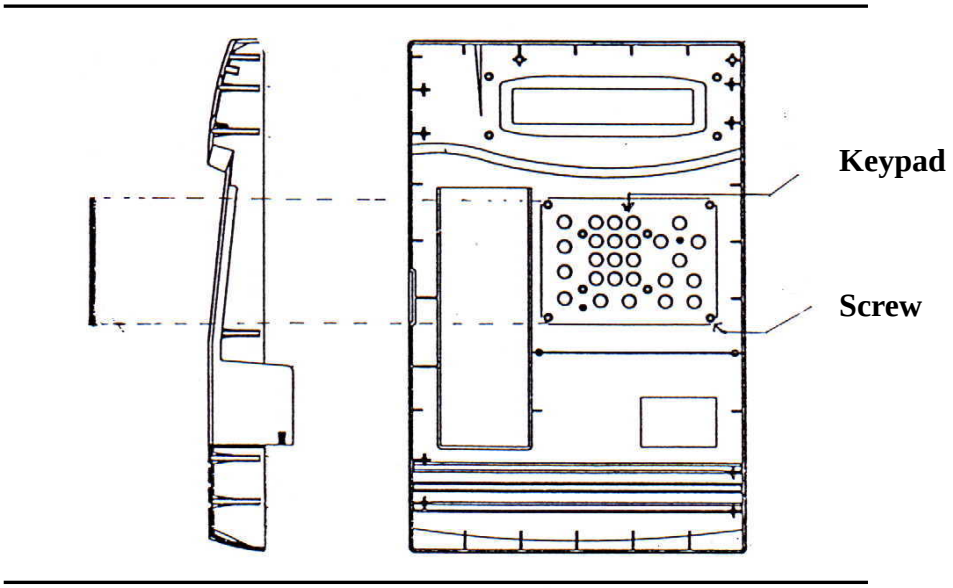


Figure 3-4. Keypad PCB Replacement.

Keypad PCB Removal

1. Power down the Biolyte 2000 by press the ON/OFF button at the backside of the Biolyte 2000 and removing the power cord.
2. Remove the front panel back board (Figure 3-2).
3. Disconnect the connectors from the J1 and J3 on the keypad PCB.
4. Remove the eight screws on the keypad PCB (Figure 3-4).
5. Remove the keypad PCB from the Biolyte 2000.

Keypad PCB Installation

1. Orient the keypad PCB so the low profile headers are on the right side.
2. Install the keypad PCB into the Biolyte 2000.
3. Fasten the eight screws on the keypad PCB (Figure 3-4).
4. Reconnect the connectors to the J1 and J3 on the keypad PCB.
5. Fasten the four screws on the front panel back board (Figure 3-2).

I/O PCB, CPU PCB and ADC PCB Replacement

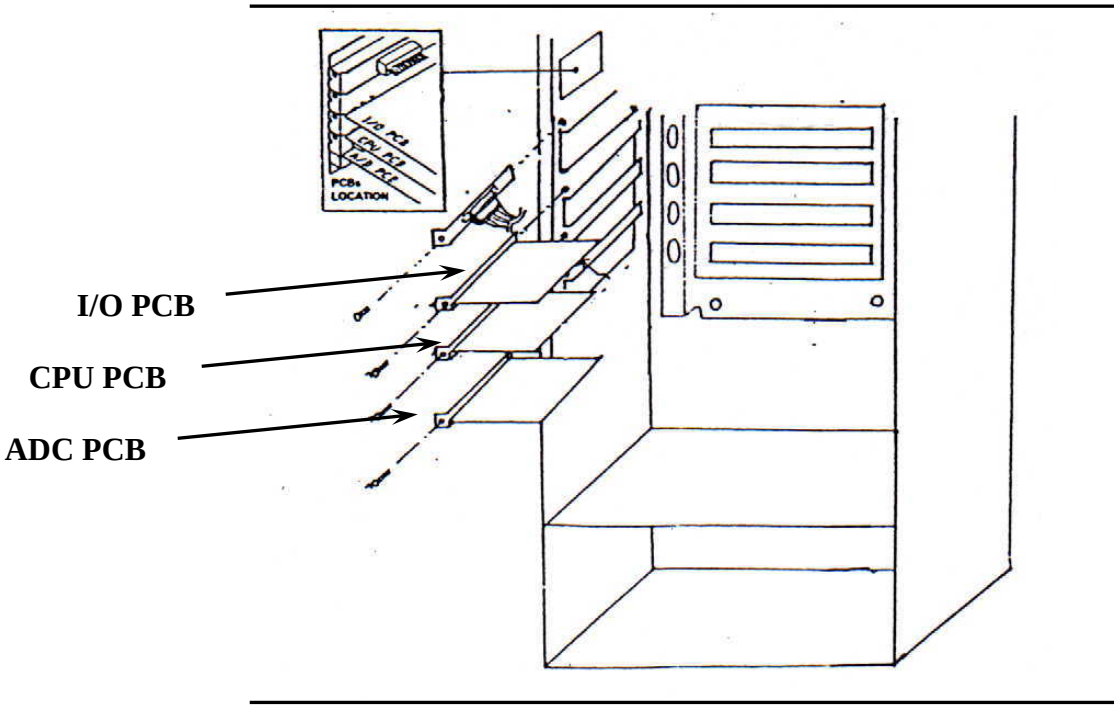


Figure 3-5. I/O PCB, CPU PCB and ADC PCB Replacement.

I/O PCB, CPU PCB and ADC PCB Removal

1. Power down the Biolyte 2000 by press the ON/OFF button at the backside of the Biolyte 2000 and removing the power cord.
2. The locations of the I/O PCB, CPU PCB and ADC PCB are shown in Figure 3-5.
3. Remove the left side panel (Figure 3-1).
4. To remove the I/O PCB,
    a. Disconnect the connector from the J1 of the I/O PCB.
    b. Remove the screw on the left side of the I/O PCB.
    c. Remove the I/O PCB from the Biolyte 2000.
5. To remove the CPU PCB,
    a. Remove the screw on the left side of the CPU PCB.
    b. Remove the CPU PCB from the Biolyte 2000.
6. To remove the ADC PCB,
    a. Disconnect the connectors from the J1 and J2 of the I/O PCB.
    b. Remove the screw on the left side of the ADC PCB.
    c. Remove the ADC PCB from the Biolyte 2000.

I/O PCB, CPU PCB and ADC PCB Installation

1. To install the I/O PCB,
    a. Install the I/O PCB into the Biolyte 2000.
    b. Fasten the screw on the left side of the I/O PCB.
    c. Reconnect the connector to the J1 of the I/O PCB.
2. To install the CPU PCB,
    a. Install the CPU PCB into the Biolyte 2000.
    b. Fasten the screw on the left side of the CPU PCB.
3. To install the ADC PCB,
    a. Install the ADC PCB into the Biolyte 2000.
    b. Fasten the screw on the left side of the ADC PCB.
    c. Reconnect the connectors to the J1 and J2 of the ADC PCB.
4. Reinstall the left side panel (Figure 3-1).

Base PCB Replacement

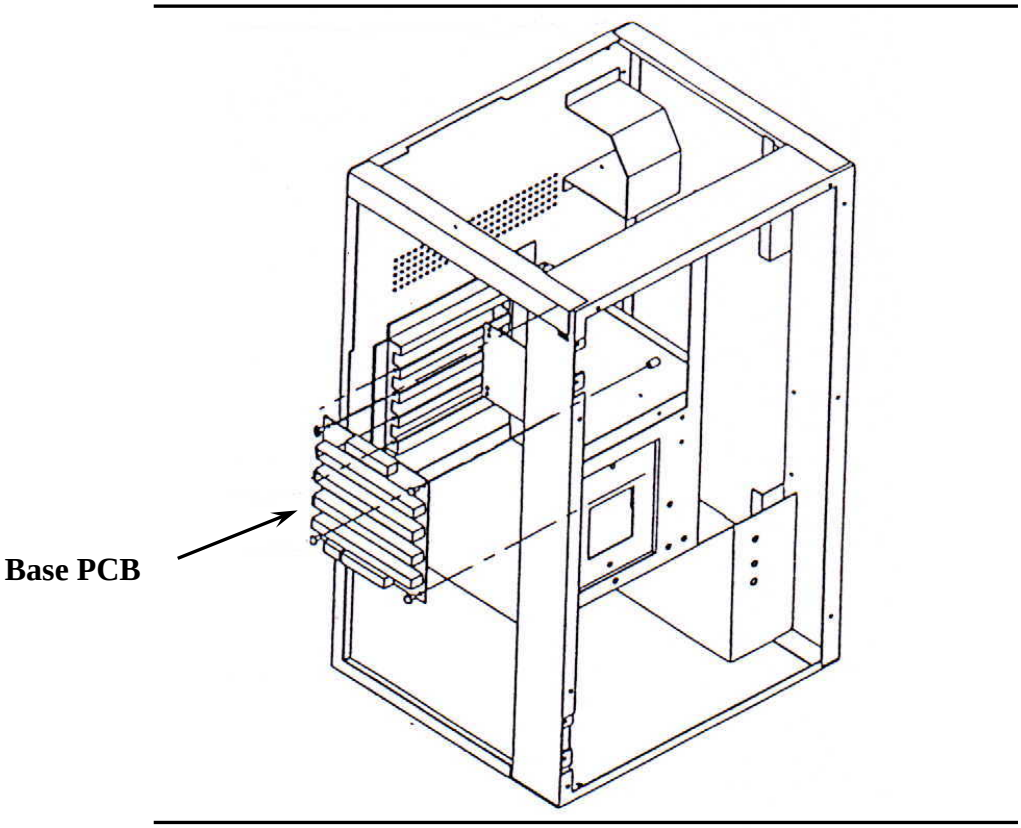


Figure 3-6. Base PCB Replacement.

Base PCB Removal

1. Power down the Biolyte 2000 by press the ON/OFF button at the backside of the Biolyte 2000 and removing the power cord.
2. Remove the Pump Module (Figure 3-9).
3. Remove the left side panel (Figure 3-1).
4. Remove the I/O PCB, CPU PCB and ADC PCB (Figure 3-5).
5. Disconnect the connectors from the CON1, CON4, CON5, and CON6 of the Base PCB.
6. Remove the four screws on the Base PCB (Figure 3-6).
7. Remove the Base PCB from the Biolyte 2000.

Base PCB Installation

1. Install the Pump (Figure 3-9).
2. Install the Base PCB into the Biolyte 2000.
3. Fasten the four screws on the Base PCB (Figure 3-6).

4. Reconnect the connectors to the CON1, CON4, CON5, and CON6 of the Base PCB.
5. Install the I/O PCB, CPU PCB and ADC PCB (Figure 3-5).
6. Install the left side panel (Figure 3-1).

Driver PCB Replacement

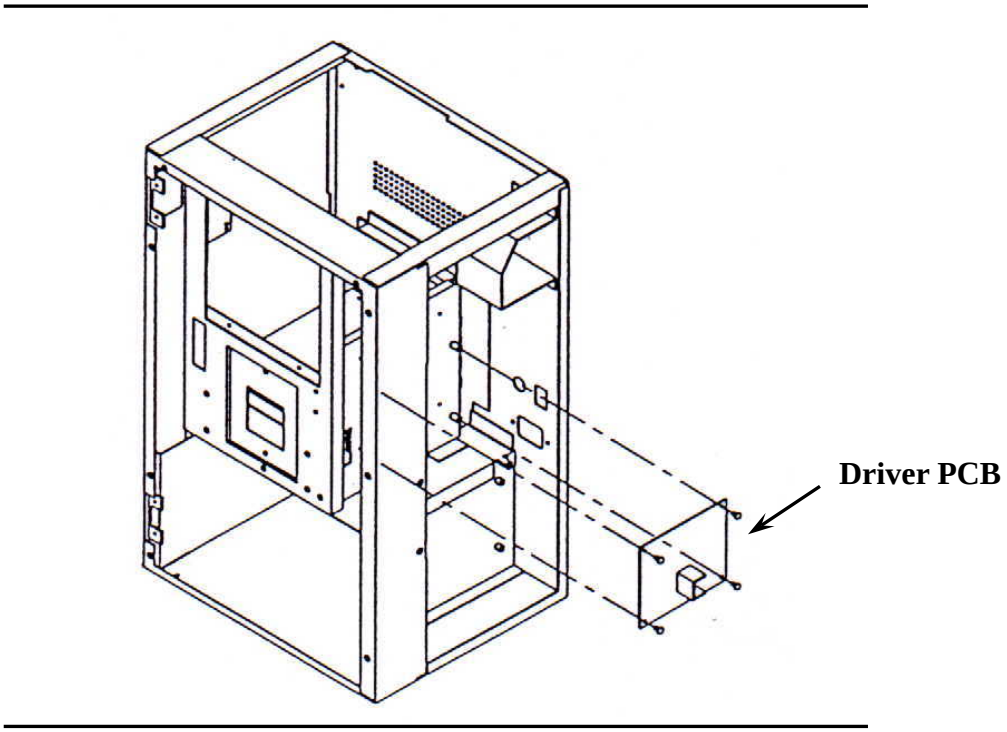


Figure 3-7. Driver PCB Replacement.

Driver PCB Removal

1. Power down the Biolyte 2000 by press the ON/OFF button at the backside of the Biolyte 2000 and removing the power cord.
2. Remove the right side panel (Figure 3-1).
3. Disconnect the connectors from the CON1, CON2, CON3, CON4, CON5, CON6 and CON7 of the driver PCB.
4. Remove the four screws on the driver PCB (Figure 3-7).
5. Remove the driver PCB from the Biolyte 2000.

Driver PCB Installation

1. Install the driver PCB from the Biolyte 2000.
2. Fasten the four screws on the driver PCB (Figure 3-7).
3. Reconnect the connectors to the CON1, CON2, CON3, CON4, CON5, CON6 and CON7 of the driver PCB.
4. Install the right side panel (Figure 3-1).

Power Supply Replacement

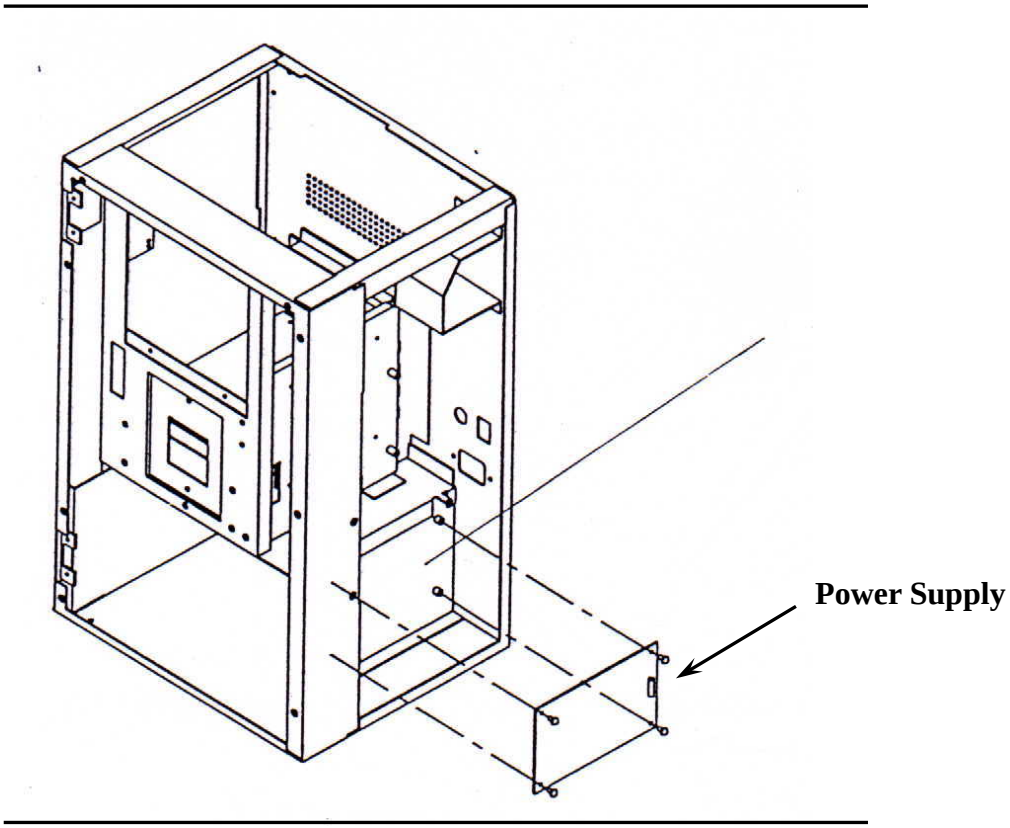


Figure 3-8. Power Supply Replacement.

Power Supply Removal

1. Power down the Biolyte 2000 by press the ON/OFF button at the backside of the Biolyte 2000 and removing the power cord.
2. Remove the right side panel (Figure 3-1).
3. Disconnect the connectors from the TB1 and TB2 of the power supply.
4. Remove the four screws on the power supply (Figure 3-8).
5. Remove the power supply from the Biolyte 2000.

Power Supply Installation

1. Install the power supply from the Biolyte 2000.
2. Fasten the four screws on the power supply (Figure 3-8).
3. Reconnect the connectors to the TB1 and TB2 of the power supply.
4. Install the right side panel (Figure 3-1).

Pump Module Replacement

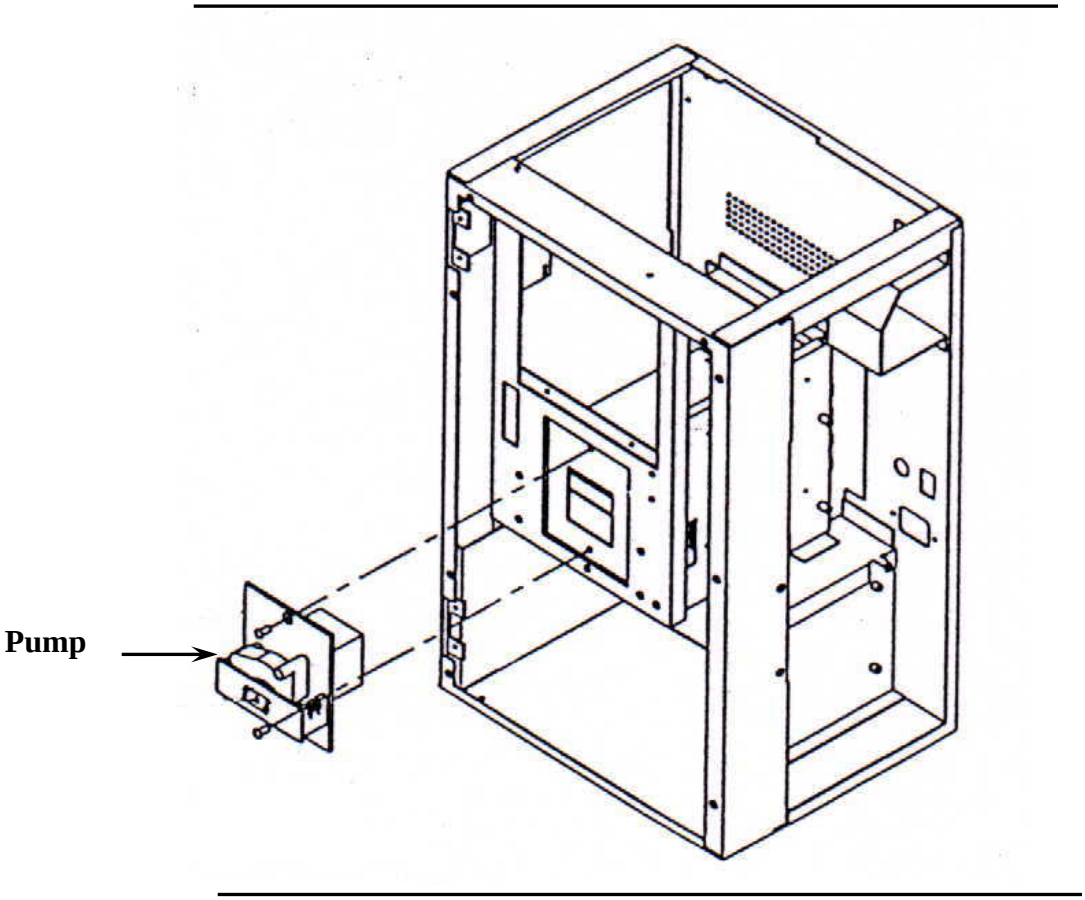


Figure 3-9. Pump Module Replacement.

Pump Module Removal

1. Purge the system of all fluids.
2. Remove the W-line from the pump.
3. Power down the Biolyte 2000 by press the ON/OFF button at the backside of the Biolyte 2000 and removing the power cord.
4. Remove the right and left side panels (Figure 3-1).
5. Disconnect the connector from the CON6 of the Driver PCB.
6. Remove the two screws on the pump (Figure 3-9).
7. Remove the pump out of the Biolyte 2000.

Pump Module Installation

1. Install the pump into the Biolyte 2000.
2. Fasten the two screws on the pump (Figure 3-9).

3. Reconnect the connector to the CON6 of the Driver PCB.
4. Reinstall the right and left side panels (Figure 3-1).

Note: If it is difficult to install the Pump Module, remove the I/O PCB, CPU PCB, and ADC PCB first. Connect the connector to the CON6 of the Driver PCB, then reinstall the I/O PCB, CPU PCB, and ADC PCB back to their slots.

AMP Module Replacement

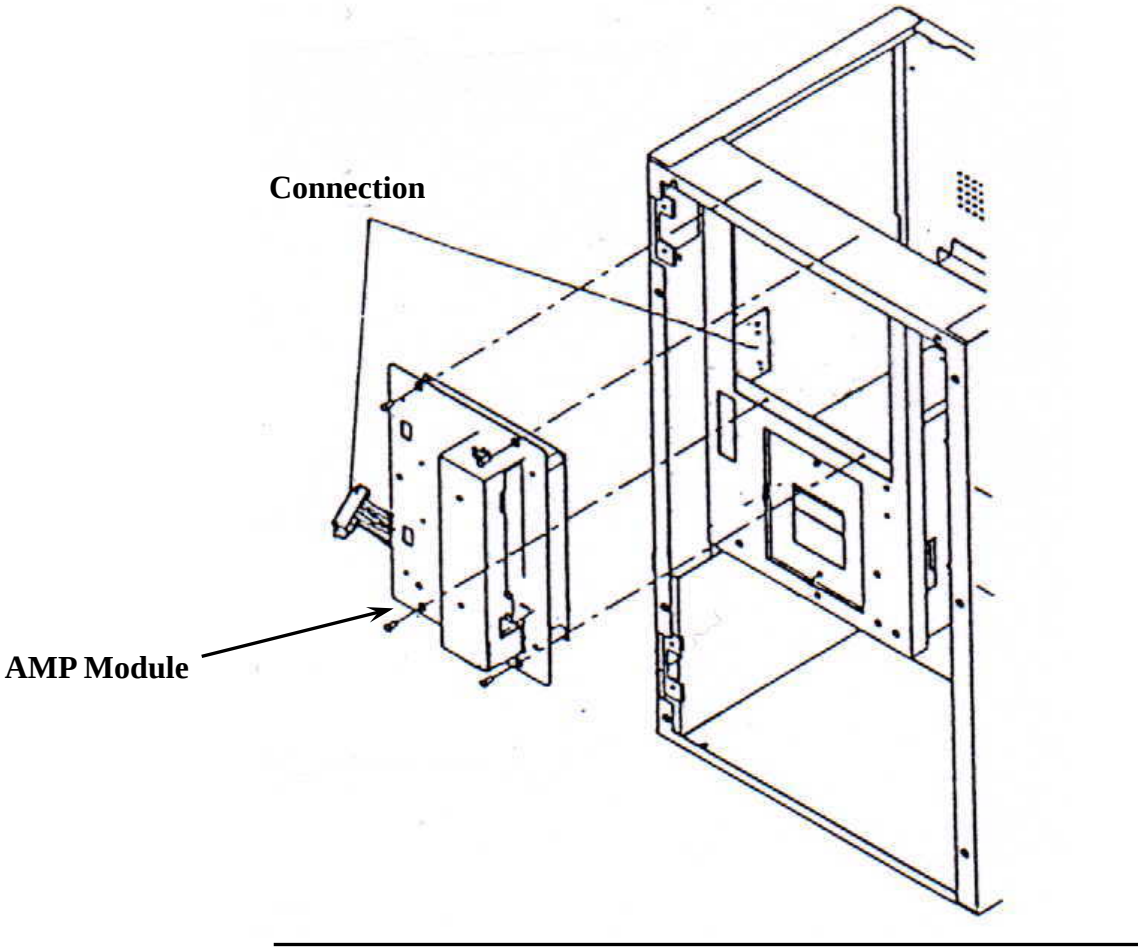


Figure 3-10. AMP Module Replacement.

AMP Module Removal

1. Purge the system of all fluids.
2. Power down the Biolyte 2000 by pressing the ON/OFF button at the back of the Biolyte 2000 and removing the power cord.
3. Remove all tubing from the electrode carrier, waste valve, and reference valve.
4. Remove the electrode carrier.
5. Remove the four screws on the AMP module (Figure 3-10).
6. Remove the left side panel (Figure 3-1).
7. Disconnect the connector from the location indicated in Figure 3-10.
8. Remove the AMP module from the Biolyte 2000.

AMP Module Installation

1. Reconnect the connector to the location indicated in Figure 3-10.
2. Install the AMP module from the Biolyte 2000.
3. Fasten the four screws on the AMP module (Figure 3-10).
4. Install the left side panel (Figure 3-1).
5. Install the electrode carrier and all tubing.

Sampler Module Replacement

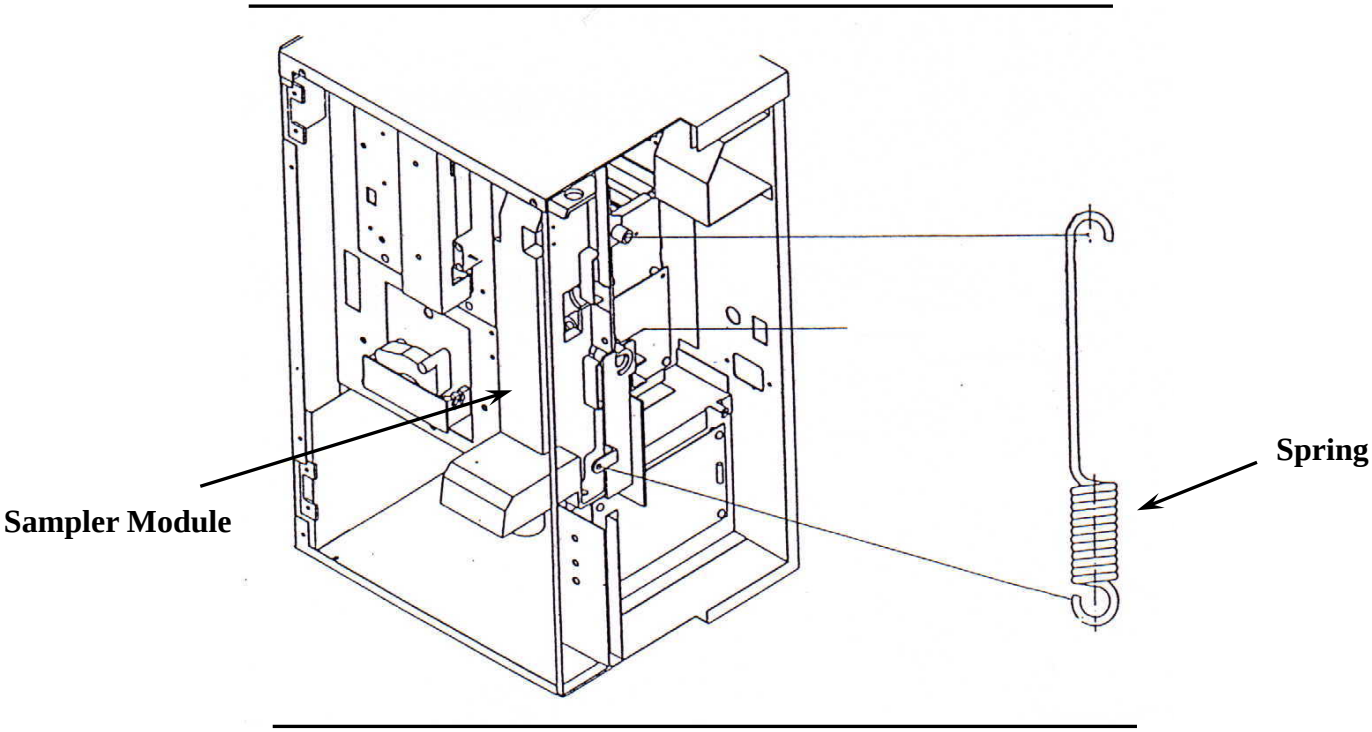


Figure 3-13. Sampler Module Replacement.

Sampler Module Removal

1. Purge the system of all fluids.
2. Power down the Biolyte 2000 by pressing the ON/OFF button at the backside of the Biolyte 2000 and removing the power cord.
3. Remove the S-line from the probe, and remove the septum from the sampler module.
4. Remove the right side panel (Figure 3-1).
5. Remove the top end of the sampler spring from the sampler module (Figure 3-13).
6. Disconnect the connectors from the CON1 and CON3 of the driver PCB.
7. Remove the screw on the backside of the sampler module.
8. Remove the sampler module from the Biolyte 2000.

Sampler Module Installation

1. Install the sampler module into the Biolyte 2000.
2. Install the screw on the backside of the sampler module.
3. Reconnect the connectors from the CON1 and CON3 of the driver PCB.
4. Install the top end of the sampler spring from the sampler module (Figure 3-13).

5. Install the right side panel (Figure 3-1).
6. Install the S-line to the probe, and install the septum to the sampler module.

Printer Module Replacement

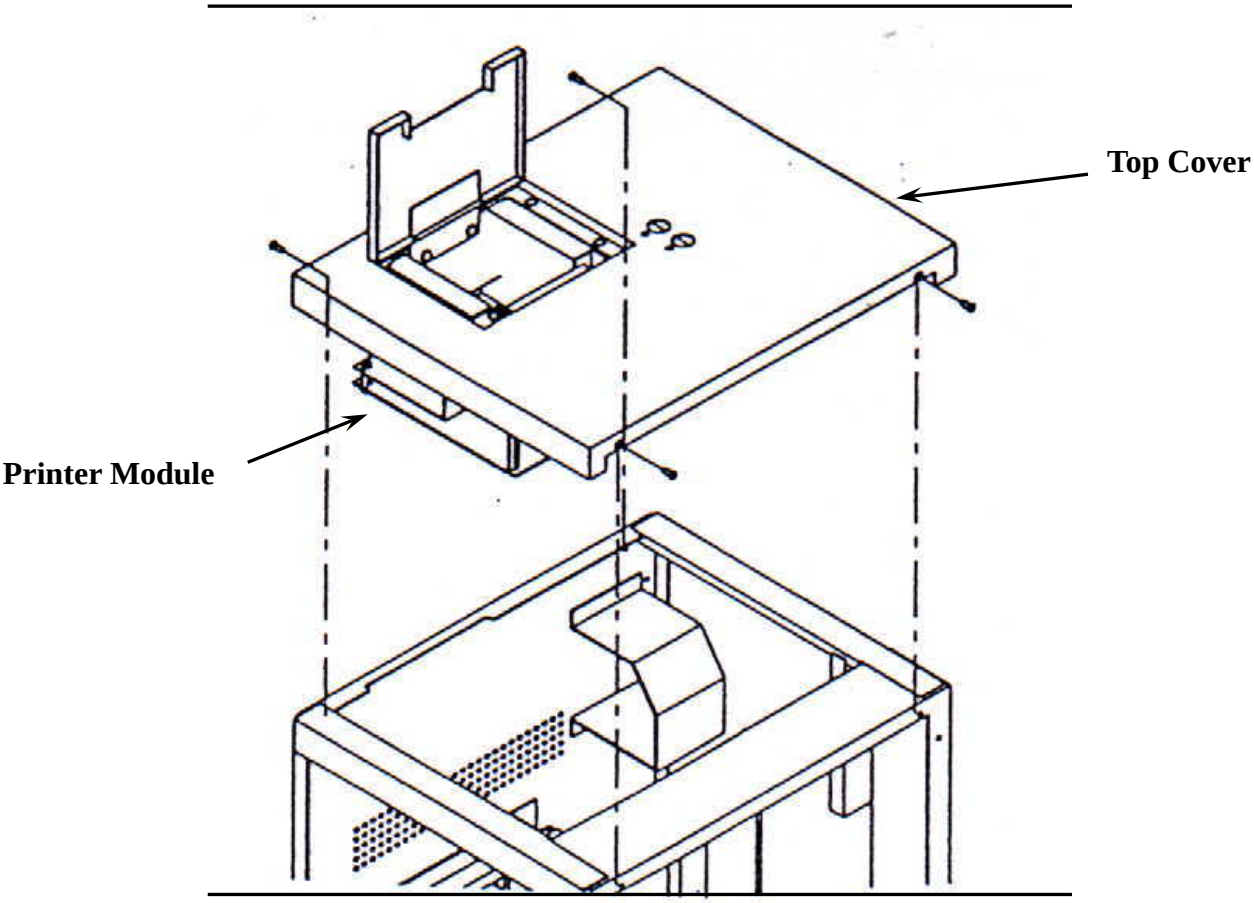


Figure 3-11. Printer Module Replacement 1.

Printer Module Removal

1. Power down the Biolyte 2000 by press the ON/OFF button at the backside of the Biolyte 2000 and removing the power cord.
2. Remove the thermal printer paper.
3. Remove the right side panel (Figure 3-1).
4. Disconnect the connectors from the CN2 and CN3 of the printer PCB.
5. Remove the four screws on the top cover (Figure 3-11).
6. Leave up the top cover with the printer module.
7. Open the printer cover.
8. Remove the four screws on the top of the printer chamber (Figure 3-12, lower).
9. Remove the top cover from the printer module.
10. To remove the thermal printer head,
    a. Disconnect the flexible printed circuit from the CN2 of the printer extended PCB.

b. Remove the four screws on the thermal printer head.
c. Remove the thermal printer head from the printer module.

11. To remove the printer PCB/printer extended PCB,
    a. Disconnect the connector from the CN2 of the printer extended PCB.
    b. Disconnect the connector from the CN3 of the printer PCB.
    c. Remove the four screws on the backside of the printer PCB (Figure 3-12, medium).
    d. Remove the printer PCB/printer extended PCB from the printer module.
12. To remove the printer control PCB,
    a. Remove the four screws on the printer control PCB (Figure 3-12, upper).
    b. Disconnect the connector from the J1 of the printer control PCB.
    c. Remove the printer control PCB from the printer module.

Printer Module Installation

1. To install the thermal printer head,
    a. Install the thermal printer head into the printer module.
    b. Fasten the four screws on the thermal printer head.
    c. Reconnect the flexible printed circuit to the CN2 of the printer extended PCB **(Note: Make sure that the contact area can not be seen for proper connection.)**
2. To install the printer PCB/printer extended PCB,
    a. Install the printer PCB/printer extended PCB to the printer module.
    b. Fasten the four screws on the backside of the printer PCB (Figure 3-12, medium).
    c. Reconnect the connector to the CN3 of the printer PCB.
    d. Reconnect the connector to the CN2 of the printer extended PCB.
3. To install the printer control PCB,
    a. Install the printer control PCB into the printer module.
    b. Reconnect the connector to the J1 of the printer control PCB.
    c. Fasten the four screws on the printer control PCB (Figure 3-12, upper).
4. Install the top cover to the printer module.
5. Fasten the four screws on the top of the printer chamber (Figure 3-12, lower).
6. Install printer module to the top cover.
7. Fasten the four screws on the top cover (Figure 3-11).
8. Install the top cover into the Biolyte 2000.
9. Reconnect the connectors from the CN2 and CN3 of the printer PCB.
10. Install the right side panel (Figure 3-1).
11. Install the thermal printer paper.

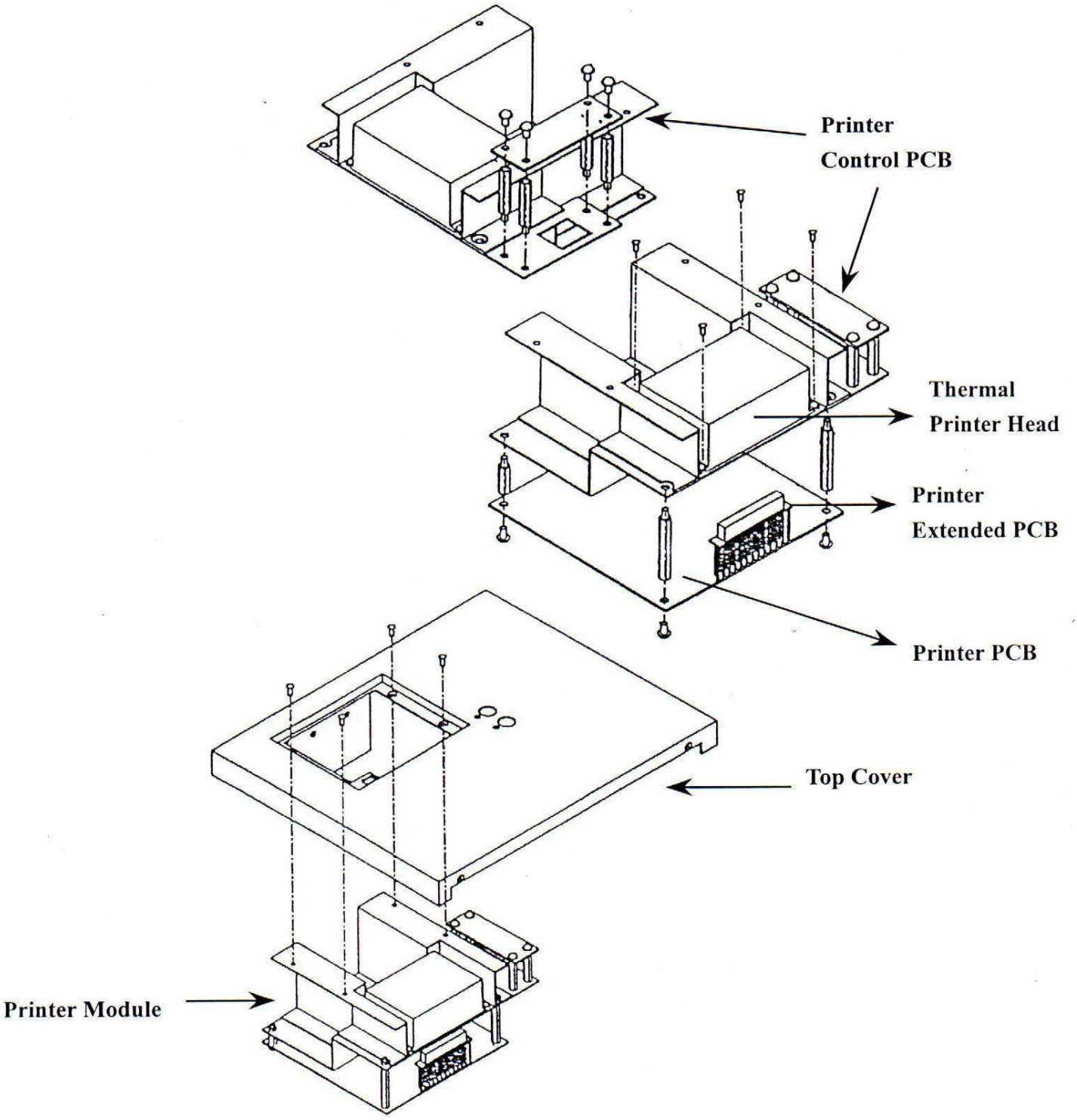


Figure 3-12. Printer Module Replacement 2.

4. Troubleshooting

Contents

First Initiate

Power on. Press the Enter key twice before the screen finishes showing the System Initial Screen (Figure 4-1). Then, screen will switch to the First Initiate Warning Screen (Figure 4-2).

Figure 4-1. System Initial Screen.

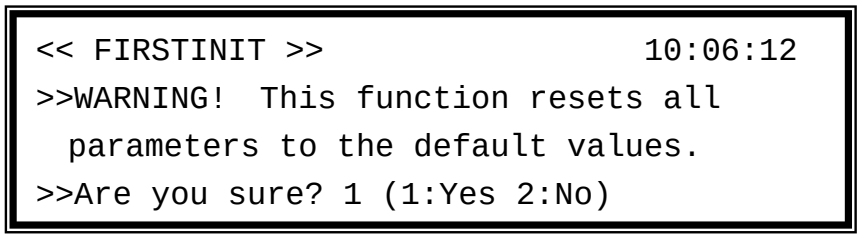


Figure 4-2. First Initiate Warning Screen.

Input 1 or 2, then press the Enter key to initiate system or not. If yes, system will reset all parameters to the default values (see Appendix II).

At the end of the first initiate procedure, system will printout the following:

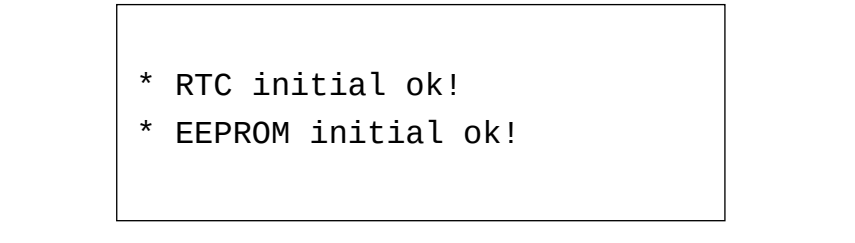


Figure 4-3. First Initiate Printout.

Note: Always initiate the system after replacing any parts.

Instability Error Codes

0001 Na+ Instability STD-A
0002 Na+ Instability STD-B
0101 K+ Instability STD-A
0102 K+ Instability STD-B
0201 Cl- Instability STD-A
0202 Cl- Instability STD-B
0301 LI+ Instability STD-A
0302 Li+ Instability STD-B
1001 Na+ Instability STD-A
1002 Na+ Instability STD-B
1008 Na+ Instability Sample
1101 K+ Instability STD-A
1102 K+ Instability STD-B
1108 K+ Instability Sample
1201 Cl- Instability STD-A
1202 Cl- Instability STD-B
1208 Cl- Instability Sample
1301 LI+ Instability STD-A
1302 Li+ Instability STD-B
1308 Li+ Instability Sample

Instabilities are detected when the electrode's response curve fails to reach a steady state plateau prior to the electrode millivolt reading.

Suggested solutions are as follows:

1. Verify that the problem occurs on multiple samples. If not suspect the presence of a sample interferant or a sample handling problem.
2. If the instability error is accompanied by a flow or slope error, resolve these error codes first and the instability error should be resolved.
3. Remove the electrode carrier and check to see if all sealing gaskets are present and there is no leakage.
4. Check the delivery of the reference solution.
5. Flush the reference electrode and the appropriate electrode giving the instability error.
6. If the error persists on an electrolyte channel, replace the individual electrode and then the reference electrode.
7. Clean the electrode pins with alcohol and reinstall the electrode carrier.
8. Check the reagent pack and replace the pack, if applicable.
9. Check the tubing harness at the septum manifold, look for leaks at the septum assembly, or pinched tubing.
10. If all channels are giving instability errors, reposition the electrode carrier in the train.
11. Verify the flow of all the standards, and that there are no leaks in the tubing harness.
12. Transfer the data in the Biolyte 2000 to PC, then initiate the system.
13. Replace the AMP Module.

Overload Error Codes

0003 Na+ Overload STD-A
0004 Na+ Overload STD-B
0103 K+ Overload STD-A
0104 K+ Overload STD-B
0203 Cl- Overload STD-A
0204 Cl- Overload STD-B
0303 LI+ Overload STD-A
0304 Li+ Overload STD-B
1003 Na+ Overload STD-A
1004 Na+ Overload STD-B
1009 Na+ Overload Sample
1103 K+ Overload STD-A
1104 K+ Overload STD-B
1109 K+ Overload Sample
1203 Cl- Overload STD-A
1204 Cl- Overload STD-B
1209 Cl- Overload Sample
1303 LI+ Overload STD-A
1304 Li+ Overload STD-B
1309 Li+ Overload Sample

An electrode overload error occurs when the millivolt readings for a standard of the sample exceeds the operational limits of the electrode.

Suggested solutions are as follows:

1. Verify the problem occurs on multiple samples.
2. Solve all flow error codes first.
3. If a potassium problem, the reference solution has probably been pumped backwards into the reagent pack as a result of a flow problem, replace the reagent pack.
4. Reseat the electrode carrier on the instrument.
5. Inspect all sealing washers for damage.
6. Check the delivery of the reference solution.
7. Clean the pins on the back of the electrodes with alcohol.
8. Replace the individual electrode.
9. Replace the reference electrode.
10. Transfer the data in the Biolyte 2000 to PC, then initiate the system.
11. Replace the AMP Module.

Drift Error Codes

1007 Na+ E-0 Drift **1107 K+ E-0 Drift**
1207 Cl- E-0 Drift **1307 Li+ E-0 Drift**

An E-Zero Drift error code is generated when the millvolt reading for the one point calibration has drifted, beyond a preset software limit, from the reading of the past two point calibration.

Suggested solutions are as follows:

1. Recalibrate the system.
2. Repeat the sample analysis, if volume permits.
3. Check for the presence of air bubbles in the standard lines.
4. Verify that the pinch valves are performing properly.
5. Check the tubing harness for fluid or air leaks.
6. Flush the flowpath with deionized water to remove any fibrin clots.
7. Replace the septum Assembly, it may have a leak.
8. Condition the electrode, if this is applicable.
9. Flush or clean the reference electrode to remove any protein build up in the electrode.
10. Clean the pins on the back of the electrodes with alcohol.
11. Replace the individual electrode, if required.
12. For electrodes with flowcells, verify that no fluid has leaked into the chamber.
13. Verify proper delivery of the reference solution, if applicable.

Slope Error Codes

0005 Na+ Slope Too Low	**0006 Na+ Slope Too High**
0105 K+ Slope Too Low	**0106 K+ Slope Too High**
0205 Cl- Slope Too Low	**0206 Cl- Slope Too High**
0305 Li+ Slope Too Low	**0306 Li+ Slope Too High**

A Slope error is generated when the difference between the electrode millivolts for the calibration standards during the two point calibration is either above or below the predefined software limits. Slope values can be obtained from Status Screen

Suggested solutions are as follows:

1. Check the reagent pack, replace if reagents are low.
2. If a potassium problem, the reference solution has probably been pumped backwards into the reagent pack as a result of a flow problem, replace the reagent pack.
3. If a sodium problem, perform a Na Conditioning Cycle.
4. Condition the flowpath with serum.
5. Replace the electrode.
6. Check the flow of the reference into the reference electrode.
7. The electrical ground on the electrode carrier may be defective, replace the electrode carrier.
8. Replace the reference electrode.
9. Ensure that reagent pack is installed correctly.
10. The reagent pack may have become contaminated or frozen, replace the reagent pack.

Flow Error Codes

0400 Air Detector Uncalibrated
0401 No STD-A
0402 No STD-B
0403 No Sample
0404 Flow Rate Too Short
0405 Flow Rate Too Long
1400 Can't Tell Air from Fluid
1401 No STD-A
1402 No STD-B
1403 No Sample
1404 Flow Rate Too Short
1405 Flow Rate Too Long
2400 Air Detector Uncalibrated
2401 No STD-A
2402 No STD-B
2403 No Sample

Flow problems can be subtle and generate error codes such as Flow Time Too Long even though Fluid flow is visible throughout the flowpath. Flow problems can also be the result of complete blockages in the flowpath that result in air detector related error codes of No Standard when required error codes.

A "No Standard" error code is generated when the Air Detector detected the presence of air in the flowpath, at a point in time when a calibration or analysis standard should be on the flowpath.

A "No Sample" error code is generated at the beginning of the analysis sequence, when the sample under aspiration does not react the air detector with a specified time limit.

Suggested solutions are as follows:

1. If an insufficient sample or no sample when required error code is generated verify the presence of sample, and repeat the analysis.
2. Check the tubing harness for possible air leaks or crimps. Replace the tubing harness, if required.
3. Verify that the reagent pack is not empty.
4. Verify that the probe is positioned in the center of the septum chambers.
5. Verify proper pinch valve performance, if required.
6. Flush the entire flowpath with deionized water to remove any fibrin clots. Ensure that the probe, S-line, electrodes, spacer and W-line are blockage free.
7. Check the positioning of the W-line under the Waste Valve. Ensure that the tubing is installed correctly. Flow will be backwards, if pinched.

8. Replace the septum assembly.
9. Verify that the reagent pack is installed correctly.
10. Verify that the tubing harness has been installed correctly, if it has just been replaced.
11. Verify that all dummy tubing segments if necessary.
12. Replace the pump tubing segment if necessary.
13. Replace the S-line.
14. Replace the probe.
15. Replace the Air Detector.
16. Replace the reagent pack.

Sampler Error Codes

0407 Sampler Error
1407 Sampler Error
2000 Illegal Probe Position
2100 Sampler Error
0409 Probe Position Error
1409 Probe Position Error
2001 Illegal Probe Speed

Sampler errors may be the result of a sampler of optical position sensor failure. Sampler errors may also be due to system voltage problems therefore, all voltages and cable connections should be tested/reseated. Sampler Tilt and Illegal Sampler Position errors result from having the Sampler Module in the wrong position when trying to perform certain functions.

Suggested solutions are as follows:

1. Adjust the probe position from the “Probe Adjustment” option in the “Maintenance” function.
2. Verify all system voltages at the Main Controller Board test points.
3. Reseat all cables/connectors on the sampler.
4. Replace the septum assembly, if the error is a sampler movement error.
5. Replace the probe, if the error is a sampler movement error.
6. Transfer the data in the Biolyte 2000 to PC, then initiate the system.
7. Replace the Sampler Module.
8. Replace the PCBs according to the following orders:
   (1) Driver PCB
   (2) ADC PCB
   (3) CPU PCB
   (4) Base PCB

Pump Error Codes

2002 Illegal Pump Speed

Pump error may be the result of a pump or optical position sensor failure. If a Pump was just replaced on a system and errors are occurring, verify that the correct Pump has been installed. Pump errors may also be due to system voltage problems there, all voltages and cable connections should be tested/reseated.

Suggested solutions are as follows:

1. Verify that the Pump Module is installed correctly.
2. Verify all system voltages at the Main Controller Board test points.
3. Reseat all cables/connectors on the Pump Module.
4. Replace the Pump Module.
5. Transfer the data in the Biolyte 2000 to PC, then initiate the system.
6. Replace the Main Controller Board.
7. Replace the PCBs according to the following orders:
   (1) Driver PCB
   (2) ADC PCB
   (3) CPU PCB
   (4) Base PCB

Printer Error Codes

2101 Printer Time Out **2102 Printer Out of Paper**
2103 Printer Error **2104 Printer Off-Line**

Printer Error Codes are generated when an error condition occurs during the printing process due to a paper jam, software communication breakdown or a hardware failure.

Suggested solutions are as follows:

1. Verify that the printer contains paper and that the paper has not jammed.
2. If the printer is not printing but paper is advancing, the paper may be in upside down. Turn the paper over.
3. Perform a Printer Test from the Device Tests menu.
4. If the error persists, power down the system for 30 seconds.
5. Verify and reseat all cable connections on the Printer Module.
6. Transfer the data in the Biolyte 2000 to PC, then initiate the system.
7. Replace the Printer Module.
8. Replace the PCBs according to the following orders:
   (1) ADC PCB
   (2) CPU PCB
   (3) Base PCB
9. Replace the Printer Cables.

Math Error Codes

0408 Math Error **1408 Math Error**

Math errors are the result of a software error that is detected during calibration or analysis. When the software problem is detected the cause could be due to a transient spike on the power line and may not reoccur of could be the result of a hardware problem within the system. When this error code occurs all calibrations of analysis fail for that particular sequence. Unless the problem reoccurs, no intervention is required on the part of the operator.

Suggested solutions are as follows:

1. Power down the system for 30 seconds.
2. Plug the system into a different power source.
3. Transfer the data in the Biolyte 2000 to PC, then initiate the system.
4. Replace the CPU PCB.

Software Error Codes

2003 Illegal Command
2004 Illegal Parameter
2005 Illegal Error Code
2200 EEP Erase Error
2201 EEP Write Error
2202 Memory Write Error
2203 Memory Clear Error

Software errors are the result of a minor software problem that is detected during a sequence. When the software problem is detected, the cause could be due to a transient spike on the hardware problem within the system. When these error codes occur, all calibrations of analysis fail for that particular sequence. Unless the problem reoccurs, no intervention is required on the part of the operator.

Suggested solutions are as follows:

1. Power down the system for 30 seconds.
2. Plug the system into a different power source.
3. Transfer the data in the Biolyte 2000 to PC, then initiate the system.
4. Replace the CPU PCB.

Analog to Digital Converter Error Codes

0406 ADC Not Ready **1406 ADC Not Ready**
2106 ADC Error

A/D Converter errors are due to a variety of reasons. Overloads may be due to a hardware problem. Other A/D errors are usually the direct result of a software or hardware error condition.

Suggested solutions are as follows:

1. Verify that the male electrode pins are not bent or broken.
2. Power down the system for 30 seconds.
3. Verify and reseat all cable connections between the AMP Module and the Main Controller Board.
4. Transfer the data in the Biolyte 2000 to PC, then initiate the system.
5. Replace the AMP Module.
6. Replace the PCBs according to the following orders:
   (1) ADC PCB
   (2) CPU PCB

Westgard Rule Violation Error Codes

2300 Westgard Rule 1-2s
2301 Westgard Rule 1-3s
2302 Westgard Rule 2-2s
2303 Westgard Rule 4-1s
2304 Westgard Rule 10x
2305 Control Outside Range

A Westgard Rule error is generated when results for one or more parameters on the laboratory quality control material have violated one or more of the Westgard rules that have been enabled.

Westgard Rules are set up to alert the operator to various trends within the quality control data. Depending upon the laboratories quality control requirements, possibly all of the Westgard Rules may be active on a system. The Westgard Rules and a general interpretation of each violation are noted below. Corrective actions to be taken by the laboratory will vary depending upon the individual laboratories Quality Control practices:

For information regarding troubleshooting Quality Control related problems, reference the results related troubleshooting potion within this section.

QC Westgard Rule Violation 1-2s
This error code means that a single QC result for at least one analyte is greater than two standard deviations from the mean.

QC Westgard Rule Violation 1-3s
This error code means that a single QC result for at least one analyte is greater than three standard deviations from the mean.

QC Westgard Rule Violation 2-2s
This error code means that two consecutive QC results for at least one analyte are greater than two standard deviations from the mean on the same side of the mean.

QC Westgard Rule Violation 4-1s
This error code means that four consecutive QC results for at least one analyte are greater than one standard deviation from the mean on the same side of the mean.

QC Westgard Rule Violation 10x

This error code means that ten consecuiive QC results for at least one analyte are on the same side of the mean.

Out of Range Error Codes

1005 Na+ Conc. Too Low	**1006 Na+ Conc. Too High**
1105 K+ Conc. Too Low	**1106 K+ Conc. Too High**
1205 Cl- Conc. Too Low	**1206 Cl- Conc. Too High**
1305 Li+ Conc. Too Low	**1306 Li+ Conc. Too High**

Out of Range Error occur during an analysis sequence only. The error is generated when the measured result exceeds the measurement range of the individual electrode. The result is displayed with a Greater than (>) or Less Than (<) sign. No action is required on the operators part. The sample should be repeated on another instrument within the laboratory that may have a greater measurement range.

Sodium Results

The sodium electrode is a high impedance electrode. Result variations can be attributed to static electricity, flow, and grounding problem. The electrode warranty is nine months, therefore, if the electrode is beyond the warranty, replace the electrode, otherwise reference the solutions below.

The following is a recommended series of steps to solve sodium result problems.

1. If control problems, verify programmed Q.C. ranges and expiration date.
2. Verify that the electrode carrier is seated properly.
3. Verify that flow times are acceptable (preferably mid range), if not, troubleshoot the flow problem.
4. Condition the electrode with Na Conditioning Solution.
5. Clean the flowpath.
6. Clean and flush the reference electrode.
7. Replace the septum assembly.
8. Replace the pump tube segments.
9. Replace the sodium electrode.
10. Replace the reference electrode.
11. Replace the reagent harness.

Potassium Results

The potassium electrode is an organic membrane exchanger electrode. Result variations can be attributed to static electricity, sample hemolysis, and plasma/serum difference. The electrode warranty is six months, therefore, if the electrode is beyond the warranty, replace the electrode, otherwise reference the solutions below.

The following is a recommended series of steps to solve potassium result problems.

1. If control problems, verify programmed Q.C. ranges and expiration date.
2. Verify that the electrode carrier is seated properly.
3. Verify that flow times are acceptable (preferably mid range), if not, troubleshoot the flow problem.
4. Condition the electrode with serum.
5. Clean the flowpath.
6. Clean and flush the reference electrode.
7. Replace the septum assembly.
8. Replace the pump tube segments.
9. Replace the potassium electrode.
10. Replace the reference electrode.
11. Replace the reagent harness.

Chloride Results

The chloride electrode is an organic membrane exchanger electrode. The electrode warranty is one month, therefore, if the electrode is beyond the warranty, replace the electrode, otherwise reference the solutions below.

The following is a recommended series of steps to solve chloride result problems.

1. If control problems, verify programmed Q.C. ranges and expiration date.
2. Verify that the electrode carrier is seated properly.
3. Verify that flow times are acceptable (preferably mid range), if not, troubleshoot the flow problem.
4. Condition the electrode with serum.
5. Clean the flowpath.
6. Clean and flush the reference electrode.
7. Replace the septum assembly.
8. Replace the pump tube segments.
9. Replace the chloride electrode.
10. Replace the reference electrode.
11. Replace the reagent harness.

Lithium Results

The lithium electrode is an organic membrane exchanger electrode. The electrode warranty is one month, therefore, if the electrode is beyond the warranty, replace the electrode, otherwise reference the solutions below.

The following is a recommended series of steps to solve lithium result problems.

1. If control problems, verify programmed Q.C. ranges and expiration date.
2. Verify that the electrode carrier is seated properly.
3. Verify that flow times are acceptable (preferably mid range), if not, troubleshoot the flow problem.
4. Condition the electrode with serum.
5. Clean the flowpath.
6. Clean and flush the reference electrode.
7. Replace the septum assembly.
8. Replace the pump tube segments.
9. Replace the lithium electrode.
10. Replace the reagent pack.
11. Replace the reference electrode.
12. Replace the reagent harness.

Urine Result Problems

The urine sample is placed in the cup and a dilution of the sample is made with the Biolyte 2000 Urine Diluent. In addition to the suggestions outlined under the results related problems portion of this section, the following is a recommended series of steps to solve urine result problems.

1. Verify that the urine diluent is fresh.
2. Verify that the Chem Set A Level 6 is fresh.
3. Verify that the correct urine diluent is being used depending upon the model of the Biolyte 2000.
4. Verify that there are no air bubbles trapped at the bottom of the sample cup. An air bubble at the bottom of the sample cup will result in less sample being drawn and thus an over-dilution of the sample occurring.
5. Replace the W-line.
6. Replace the tubing harness.

Instrument Correlation

Correlation between the Biolyte 2000 and other instrumentation may be biased due to differences in measurement technologies, for example, direct versus indirect measurement. Performance of the Biolyte 2000 should be based upon the followings:

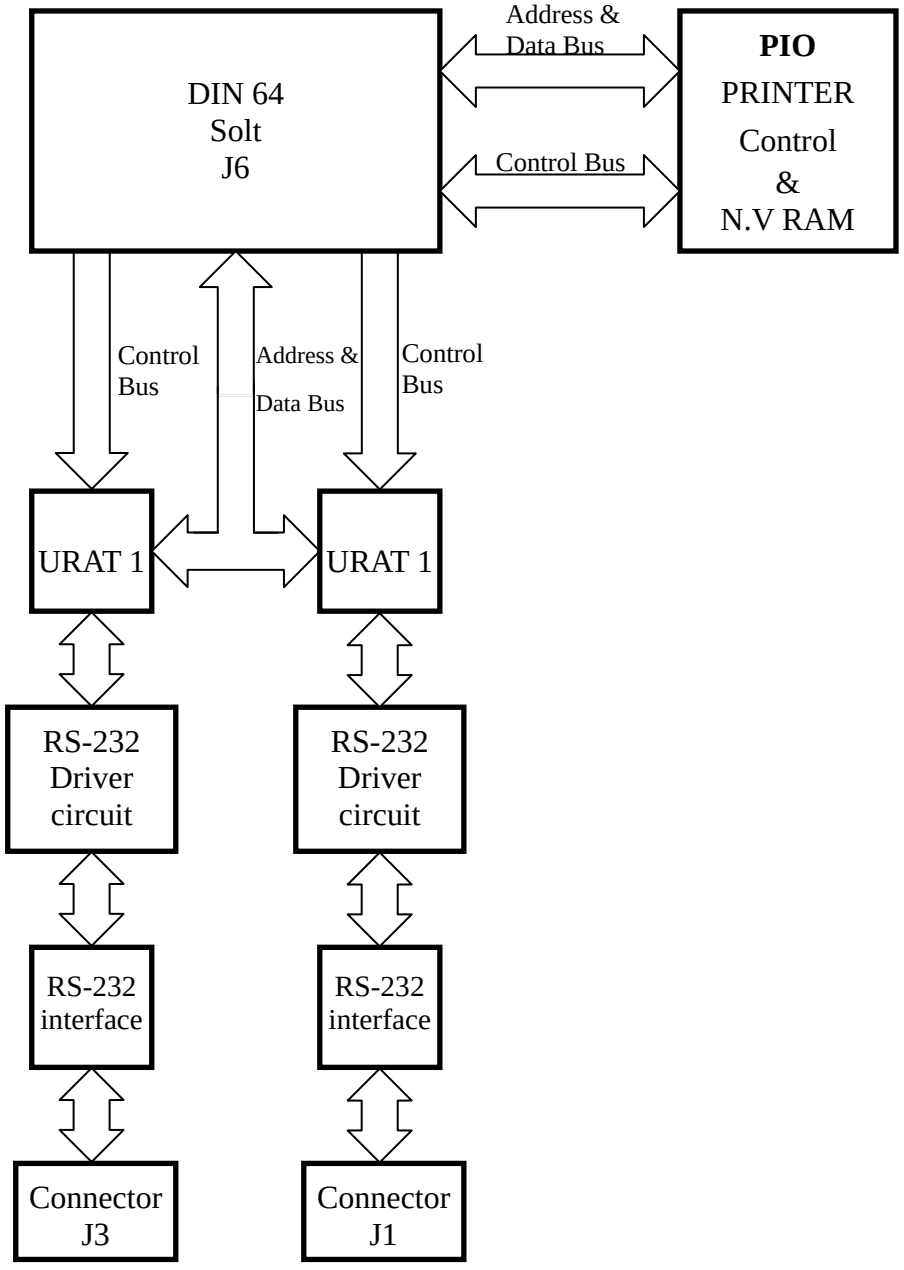
1. The instrument ability to recover the assayed control values on the Biolyte 2000 Biomedical Stat Control material.
2. The instruments ability to meet Biolyte 2000 Biomedical's stated specifications for with-in run and day to day precision.
3. The laboratory's own historical correction data between the Biolyte 2000 and the other instrument.

If the Biolyte 2000's performance meets the first two criteria and a bias stall exists, the bias can be eliminated by calculation and implementation of slope and intercept correction factors.

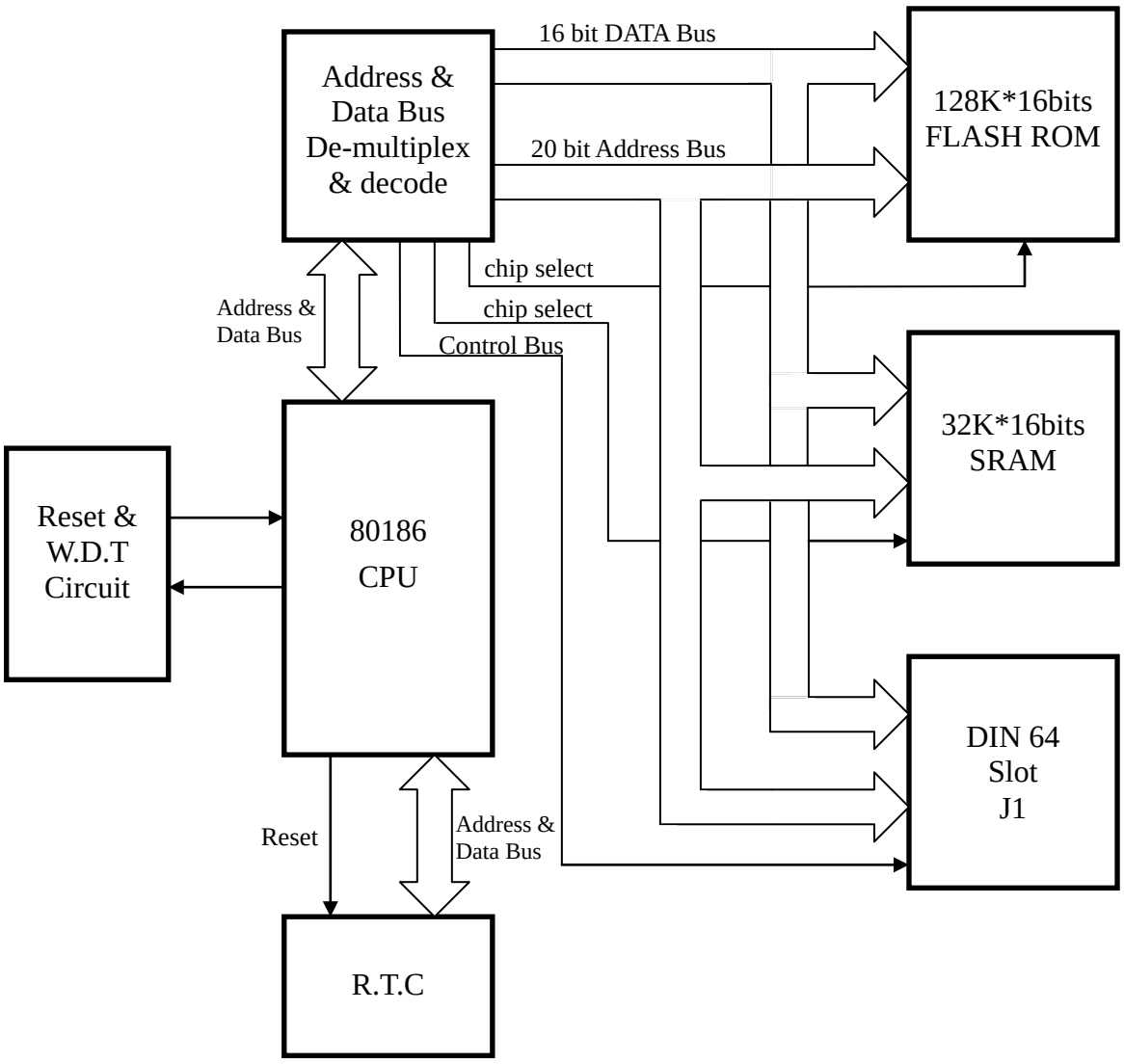
5. Circuit Diagrams

Contents

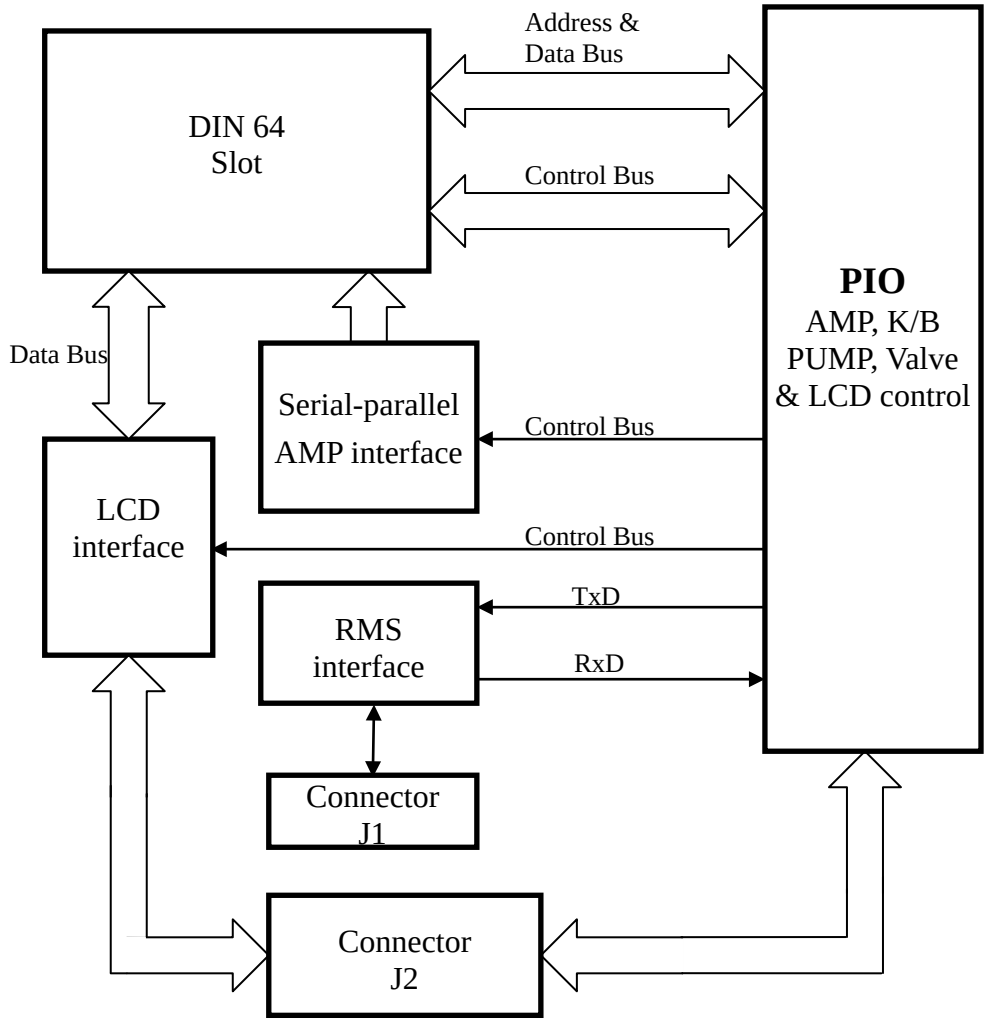
I/O PCB Block Diagram



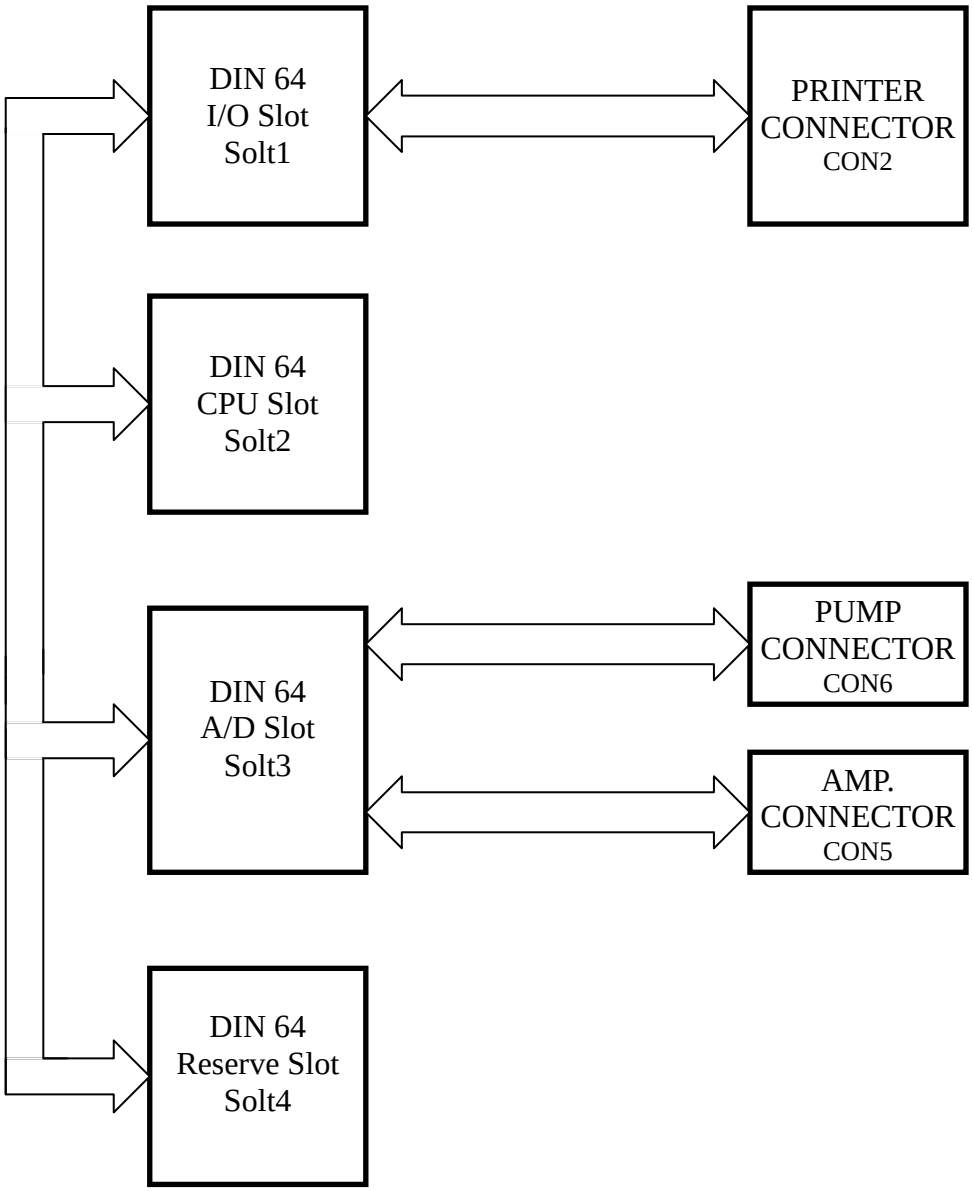
CPU PCB Block Diagram



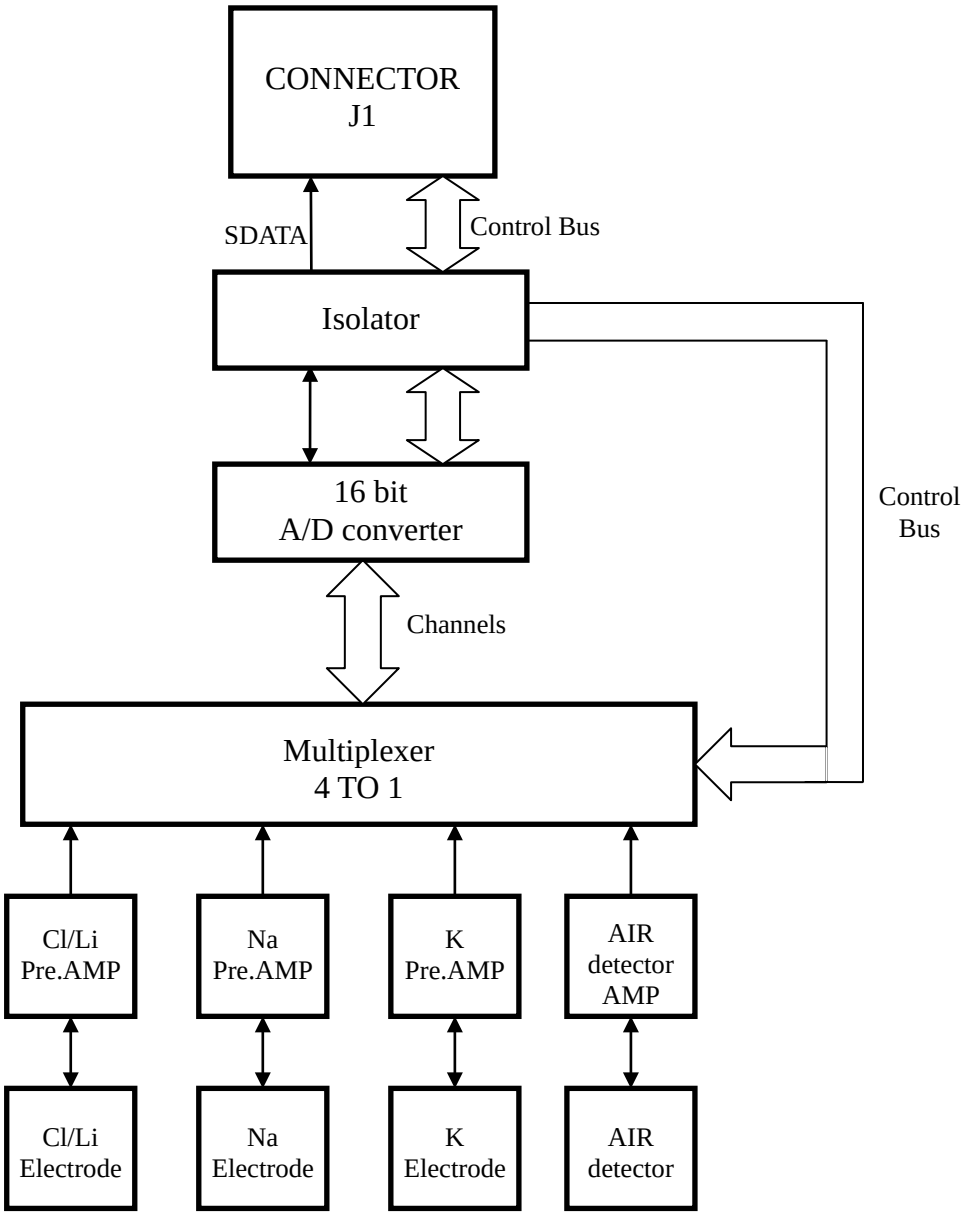
ADC PCB Block Diagram



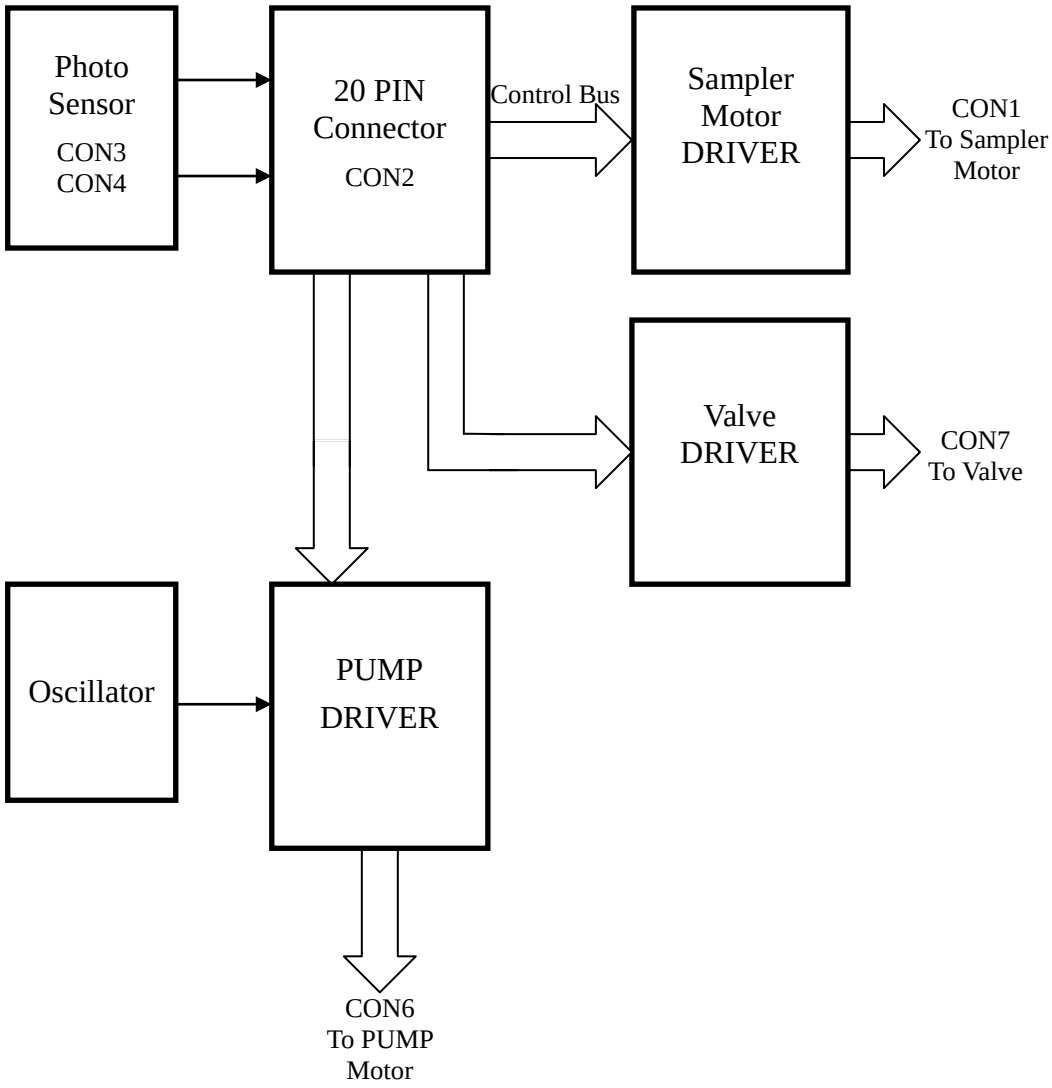
Base PCB Block Diagram



AMP PCB Block Diagram



Driver PCB Block Diagram



6. Appendix

Contents

Appendix I: Software Structure

Power ON	Function Key	Sub-Function 1	Sub-Function 2	Sub-Function 3
Main	Start/Standby			
	Sample Type			
	Calibrate			
	Analyze			
	Status			
	Flowpath			
	Menu	1. Setup	1. Test select	
			2. Units setting	
			3. Resolution set	
			4. 2-Pt cal setup	
			5. Date/Time set	
			6. Results settings	1. Reference Set
				2. Panic Set
				3. Offsets
		2. Operation		
		3. Data	1. Recall	
			2. Transfer	
			3. Clear	
		4. Software version		
		5. Diagnostic	1. Device exercise	1. Valve exercise
				2. Pump exercise
				3. Probe exercise
			2. Device test	1. Speaker
				2. Printer
				3. LCD
				4. Keypad
				5. Sampler sensor
				6. Serial port
			3. Air detector test	
			4. Error log	1. View error log
				2. Print error log
				3. Clear error log
			5. System test	1. Probe position
				2. Pump movement
				3. Valves set
			6. Sensor mV data	
		6. Maintenance	1. Condition Na	1. Condition Na
				2. Condition f-path
			2. Clean flow path	
			3. Reagent info	
			4. Prime	
			5. Probe adjustment	
			6. Cal. pump frequency	
	QC	1. Analyze control		
		2. QC setup		
		3. Print W-R viol'n		
		4. Statistics	1. Browse QC data	
			2. Print QC data	
			3. Print L-J chart	
			4. Brows statistics	
			5. Print statistics	
		5. Clear QC Data		

Appendix II: Initial Data Value

1. Save in RTC:
   - Date/Time: auto-count
   - Tests set: ON(Na+, K+, Cl-), OFF(Li+)
   - Unit set: mmol/L (for 4 sensors)
   - Resolution set: 123(Na+, Cl-), 12.3(K+), 1.23(Li+)
   - Operator set: ON(3, 5, 6), OFF(1, 2, 4)
   - Pump speed: LO
   - Dilute ratio: 3
   - Print more: OFF

2. Save in EEPROM:
   - Reference limit: [mmol/L]

	Na+	K+	Cl-	Li+
Blood	136-146	3.5-5.0	96-106	1.75-1.20
Urine	27-287	25-120	170-250	-
CSF	-	-	120-130	-

   - Panic limit:[mmol/L]

	Cl-	Na+	K+	Li+
Range	60-200	60-200	1.0-10.0	0.10-5.00

   - Slope of last calibration: NC
   - STD-A Volt. of last calibration: 0 (for 4 sensors) [mV]
   - Control sample expiration date: 1998/01/01 (for 7 levels)
   - Control sample lot number: 0 (for 7 level)
   - Control sample concentration range: 0 (for 7 levels & 4 sensors) [mmol/L]
   - Flow time of calibration & analysis procedure: [sec.]

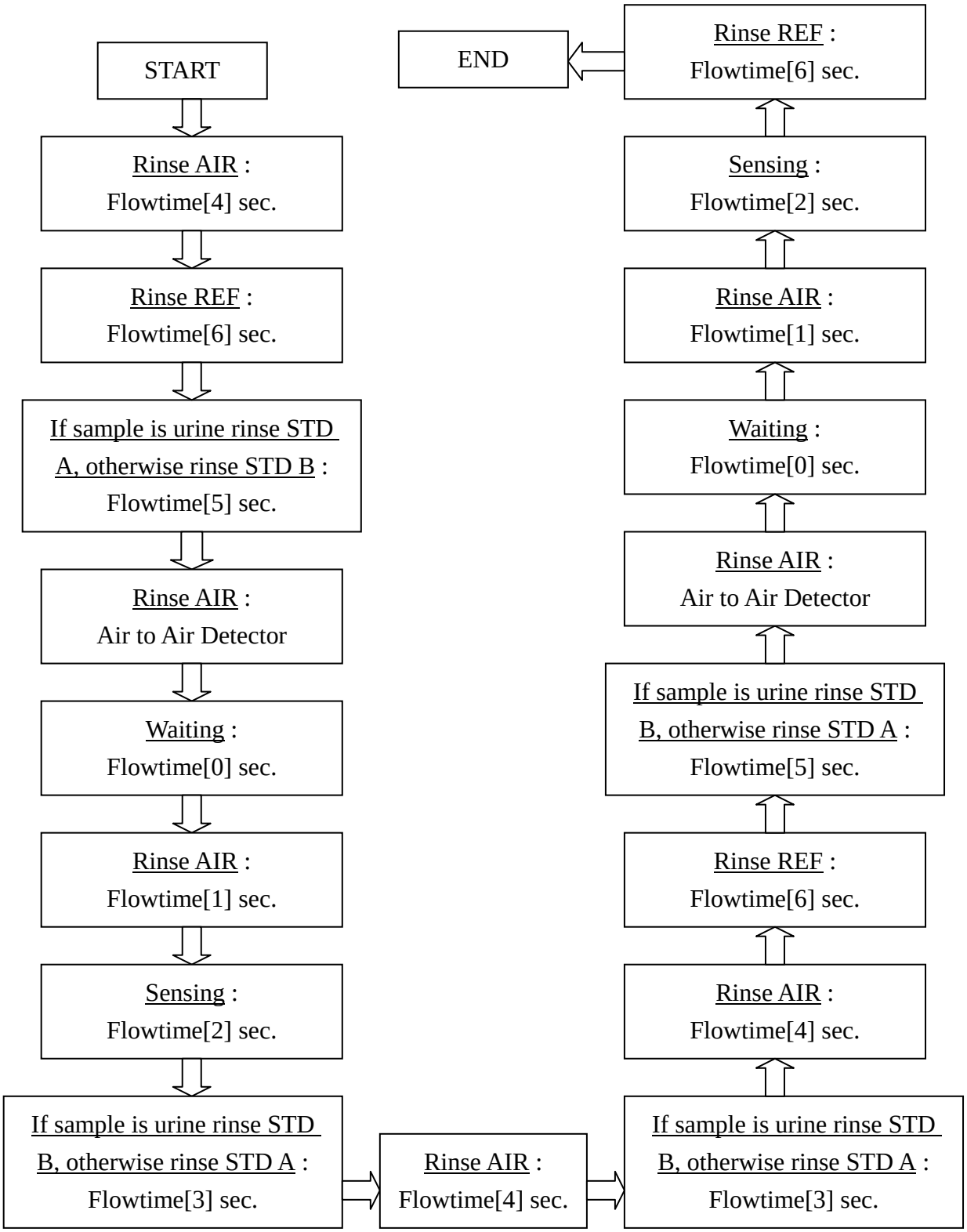
Flowtime	0	1	2	3	4	5	6	7
Serum/Plasma	0	0	7	0.5	0.5	5	1	0
Whole Blood	0	0	10	1	1	8	1	0
Urine	0	0	10	0.5	0.5	5	1	0
CSF	0	0	7	0.5	0.5	5	1	0

   - Probe speed: 1500
   - Air sensor range: 65 [mV]
   - Air limit: 200 [mV]
   - Analysis test number: 0
   - Correction factor: slope=1.00, intercept=0.00
   - Error code of 50 error log: 0
   - Probe position: AIR=500, STD-A=380, STD-B=260, REF=620, Sample (IN)=1420, Sample (OUT)=1900, AIR (OUT)=750
   - QC: Control Mean=0, Control SD=AUTO, Control W-R=OFF

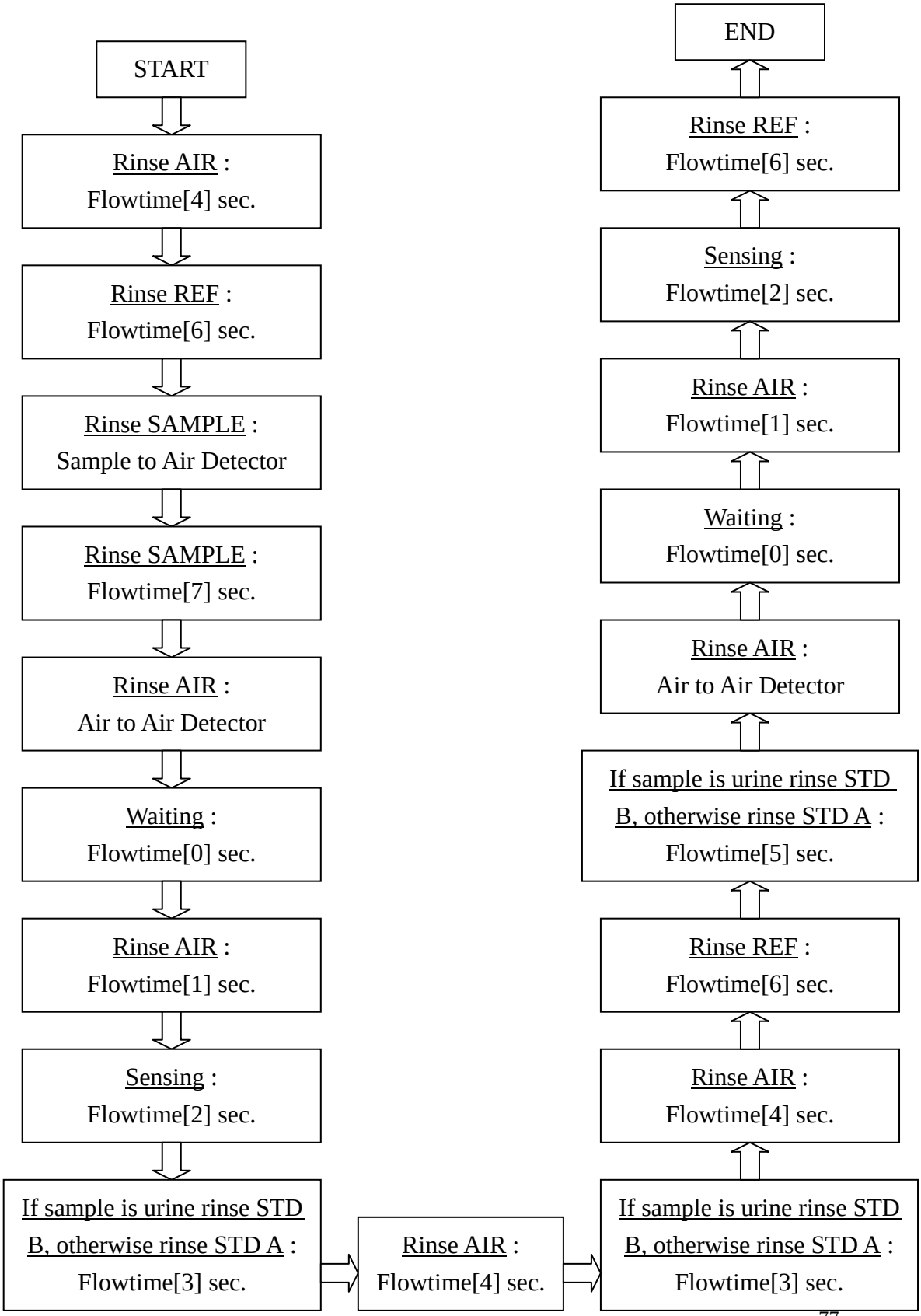
3. Initial after power on:
   - Calibration interval: 2 hour
   - Flow rate of calibration: 2.0 sec
   - Flow rate of analysis: 2.0 sec

- Analysis result: * SAMPLE ID: “ “
  * Access #: 0
  * Name: “ “
  * Sequence #: 0
  * Analyze Date: 2000/00/00
  * Analyze Time: 00:00:00
  * Sample type: Serum/Plasma
  * Concentration: 0 (for 4 sensors)
- Control sample result: * Level: 0
  * Analysis Date: 20000/00/00
  * Analysis Time: 00:00:00
  * Concentration: 0 (for 4 sensors)

Appendix III: Flow Chart of Calibration



Appendix IV: Flow Chart of Analysis



Appendix V: Program Download Procedure

1. Power off the Biolyte 2000.

2. Plug the PUM (Program Update Module) onto the barcode reader port of the Biolyte 2000.

3. Power on. Press the Flowpath key while and the screen finishes displaying the Power On Screen (Figure 8-1). Once the Flowpath key is pressed, the system will display the Select Test Item Screen (Figure 8-2).

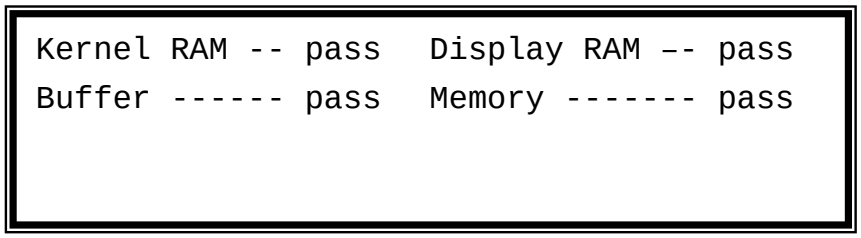


Figure 8-1. Power On Screen.

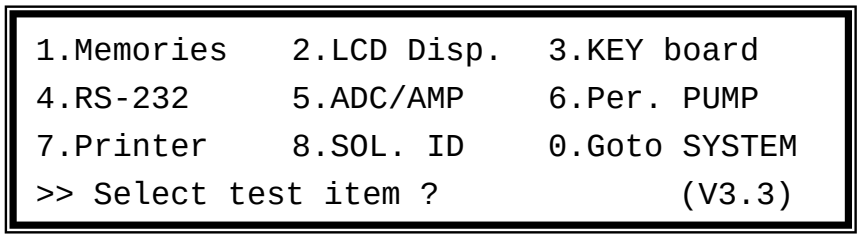


Figure 8-2. Select Test Item Screen.

4. Press ← key to download program. At this time, screen will show the Download Program Screen (Figure 8-3).

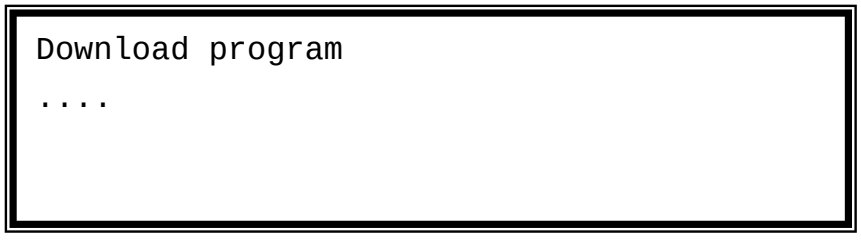


Figure 8-3. Download Program Screen.

5. The screen will display " **. . . .** " when the new software is being downloaded.

6. Once downloading is completed, system will beep and automatically restart.

7. If the program fails to be downloaded, system will beep three times.
   Repeat step 1 to 4 (re-download) again.

8. Remove the PUM from the barcode port of the Biolyte 2000.

9. Initiate the system.

10. Enter the Menu Screen and input *4* to access the Software Version Screen to check whether the software version has been updated.

Appendix VI: Data Transfer Protocol

1. Object

This document describes how the Biolyte 2000 transmits data to an external computer.

2. Low-level Protocol (Transfer Link)

This protocol used by Biolyte 2000 is designed according to ASTM E1381-91. There are three distinct phases in transferring information between the instrument and a computer system. The three phases are establishment, transfer, and termination

Note: Biolyte 2000 is always the sender; it cannot be the receiver.

2.1 Establishment phase

- Biolyte 2000 transmits the <ENQ> transmission control character to the intended receiver.
- The receiver has 15 seconds to reply with an <ACK> (if ready) or <NAK> (if not ready) after receiving an <ENQ> character.
- If the receiver responds with an <ACK> character, Biolyte 2000 will proceed to transfer phase.
- If the receiver responds with an <NAK> or any other character (except <ACK>), Biolyte 2000 will proceed to Termination phase.
- If the receiver does not respond within 15 seconds period, Biolyte 2000 will send another <ENQ> character.
- If the receiver does not respond within 15 seconds period again, Biolyte 2000 will proceed to Termination phase.

2.2 Transfer phase

- Biolyte 2000 has 30 seconds to transmit the first frame. If no frame or <EOT> is received within 30 seconds, the receiver will proceed to the Termination phase.
- The receiver has 15 seconds to respond with an acknowledgment control character (<ACK> or <NAK>).
- If the receiver responds with an <ACK> character, Biolyte 2000 will transmit next frame within 30 seconds.
- If the receiver responds with an <NAK> character, Biolyte 2000 will transmit the same frame again within 30 seconds period. If Biolyte 2000 has transmit the same frame 6 times, it will proceed to Termination

phase.

- After all frames have been send, Biolyte 2000 will proceed to Termination phase.

2.3 Termination phase

- Biolyte 2000 transmits an <EOT> character and then regards the data link to be in a neutral state. Upon receiving <EOT>, the receiver also regards the data link to be in the neutral state.

For more details in time and data link between two systems please refer to ASTM E1381-91.

3. High-level Protocol (Transfer Information)

This protocol used by Biolyte 2000 is designed according to ASTM E1394-91. This protocol is intended to apply to the structure of messages exchanged between clinical instruments and computer systems.

The structure of records is described in Table I. The column "ASTM REF" lists the sections of the ASTM E1394-91. The column " ASTM NAME" lists the field names that is defined in ASTM E1394-91. The column "IMPLEMENTATION" lists the data formats of the field.

The frame structure is illustrated as follows:

<STX> FN test <ETX> C1 C2 <CR> <LF>

where:	<STX>	- Start of Text transmission control character
	FN	- single digit Frame Number 0 to 7
	text	- Data Content of Message
	<ETX>	- End of Text transmission control character
	C1	- most significant character of checksum 0 to 9 and A to F
	C2	- least significant character of checksum 0 to 9 and A to F
	<CR>	- Carriage Return ASCII character
	<LF>	- Line Feed ASCII character

Checksum: The checksum is initialized to zero with the <STX> character. The first character used in computing the checksum is the frame number and the last character is <EXT> character.

4. Reference

4.1 ASTM E1381-91 "Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems"

4.2 ASTM E1394-91 "Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems"

Header Record		
ASTM REF	**ASTM NAME**	**IMPLEMENTATION**
7.1.1	Record Type ID	Single character: “H”
7.1.2	Delimiter Definition	Standard delimiters: |\^&
7.1.3	Message Control ID	Not used
7.1.4	Access Password	Not used
7.1.5	Sender Name or ID	BioCare^Biolyte^mm..mm^dd..dd “mm..mm” – version of software “dd..dd” – analyzer serial No.
7.1.6	Sender Street Address	Not used
7.1.7	Reserved Field	Not used
7.1.8	Sender Telephone Number	Not used
7.1.9	Characteristics of Sender	Not used
7.1.10	Receiver ID	Not used
7.1.11	Comment or Special Instruction	Not used
7.1.12	Processing ID	Not used
7.1.13	Version No.	This value identifies the version level of the ASTM specification. Single character : “1”
7.1.14	Data and Time of Message	Date and time at which message was transmitted. (This is not the time of the analysis.)

Patient Information Record		
ASTM REF	**ASTM NAME**	**IMPLEMENTATION**
8.1.1	Record Type ID	Single character: “P”
8.1.2	Sequence Number	Single character: “1” (This will always be “1” because there will be only one patient record per message.)
8.1.3	Practice assigned patient ID	Not used
8.1.4	Laboratory Assigned Patient ID	Patient ID if a available; otherwise, blank.
8.1.5	Patient ID No. 3	Not used
8.1.6	Patient Name	Not used
8.1.7	Mother’s Maiden Name	Not used
8.1.8	Birthday	Not used
8.1.9	Patient Sex	Not used
8.1.10	Patient Race-Ethnic	Not used
8.1.11	Patient Address	Not used
8.1.12	Reserved Field	Not used
8.1.13	Patient Telephone Number	Not used
8.1.14	Attending Physician ID	Not used
8.1.15	Special Field 1	Not used
8.1.16	Special Field 2	Not used

8.1.17	Patient Height	Not used
8.1.18	Patient Weight	Not used
8.1.19	Patient's Known or Suspected Diagnosis	Not used
8.1.20	Patient Active Medications	Not used
8.1.21	Patient's Diet	Not used
8.1.22	Practice Field No. 1	Not used
8.1.23	Practice Field No. 2	Not used
8.1.24	Admission and Discharge Dates	Not used
8.1.25	Admission Status	Not used
8.1.26	Location	Not used
8.1.27	Nature of Alternative Diagnostic Code and Classifiers	Not used
8.1.28	Alternative Diagnostic Code and Classification	Not used
8.1.29	Patient Religion	Not used
8.1.30	Marital Status	Not used
8.1.31	Isolation Status	Not used
8.1.32	Language	Not used
8.1.33	Hospital Service	Not used
8.1.34	Hospital Institution	Not used
8.1.35	Dosage Category	Not used

Test Order Record		
ASTM REF	**ASTM NAME**	**IMPLEMENTATION**
9.4.1	Record Type ID	Single character: "O"
9.4.2	Sequence Number	Single character: "1" (This will always be "1" because there will be only one order per message.)
9.4.3	Specimen ID	Not used
9.4.4	Instrument Specimen ID	Sample serial No.
9.4.5	Universal Test ID	Not used
9.4.6	Priority	Not used
9.4.7	Requested/Ordered Date and Time	Not used
9.4.8	Specimen Collection Date and Time	Not used
9.4.9	Collection End Time	Not used
9.4.10	Collection Volume	Not used
9.4.11	Collection ID	Not used
9.4.12	Action Code	Not used
9.4.13	Danger Code	Not used
9.4.14	Relevant Clinical Information	Not used
9.4.15	Date /Time Specimen	Not used

	Received	
9.4.16	Specimen Descriptor	“Serum/Plasma”, “Whole Blood”, Urine”
9.4.17	Ordering Physician	Not used
9.4.18	Physician’s telephone Number	Not used
9.4.19	User Field No. 1	Not used
9.4.20	User Field No. 2	Not used
9.4.21	Laboratory Field No. 1	Not used
9.4.22	Laboratory Field No. 2	Not used
9.4.23	Date/Time Results Reported or Last Modified	Not used
9.4.24	Instrument Charge to Computer System	Not used
9.4.25	Instrument Section ID	Not used
9.4.26	Report Types	“P” – preliminary results(Results require remote review)
9.4.27	Reserved Field	Not used
9.4.28	Location or Ward of Specimen Collection	Not used
9.4.29	Nosocomial Infection Flag	Not used
9.4.30	Specimen Service	Not used
9.4.31	Specimen Institution	Not used

Result Record		
ASTM REF	**ASTM NAME**	**IMPLEMENTATION**
10.1.1	Record Type ID	Single character: “R”
10.1.2	Sequence Number	Counts the items sent for this order; ‘1’ for the first items, ‘2’ for the second, etc.
10.1.3	Universal Test ID	Five parts The first three parts are not used (see sections 6.6.1.1-6.6.1.3 of ASTM E1394-91). The fourth part is item name assigned by BioCare. Which are defined below: “Cl-” - chloride concentration “Na+” - sodium concentration “K+” - potassium concentration “Li+” - lithium concentration The fourth part is item type; it will be one of the following: M – measured C - Calculated
10.1.4	Data or Measurement Value	Value of the parameter as an ASCII string. “±###.##” – if too many digits
10.1.5	Units	Concentration unit “mmol/L” “mEq/L”

10.1.6	Reference Ranges	Not used
10.1.7	Result Abnormal Flags	Not used
10.1.8	Nature of Abnormality Testing	Not used
10.1.9	Result Status	Not used
10.1.10	Date of Change of Instrument Normative Values or Units	Not used
10.1.11	Operator Identification	Not used
10.1.12	Date/Time Test Started	Date and time at which the analysis started. (This field will be used only in the first result record.)
10.1.13	Date/Time Test Completed	Not used
10.1.14	Instrument Identification	Not used

Message Terminator Record		
ASTM REF	**ASTM NAME**	**IMPLEMENTATION**
13.1.1	Record Type ID	Single character: “L”
13.1.2	Sequence Number	For this record type this is always “1”.
13.1.3	Termination Code	“N” - normal termination “T” - sender aborted

Example

This example includes both low-level and high-level protocol.

The responses from computer are shown as <ACK>.

Example data:

- Instrument: Biolyte
- Software version: 2.1.1.1
- Analyzer serial No.: 5
- Patient ID: 123456789
- Sample type: Serum/Plasma
- Sample serial No.: 12
- Date and time analyzed: Oct 29, 1999 08:50:59
- Date and time transmitted: Oct 29, 1999 10:36:31
- Item result:

  Na+ : 167 mmol/L

  K+ : 7.2 mmol/L

  Cl- : 151 mmol/L

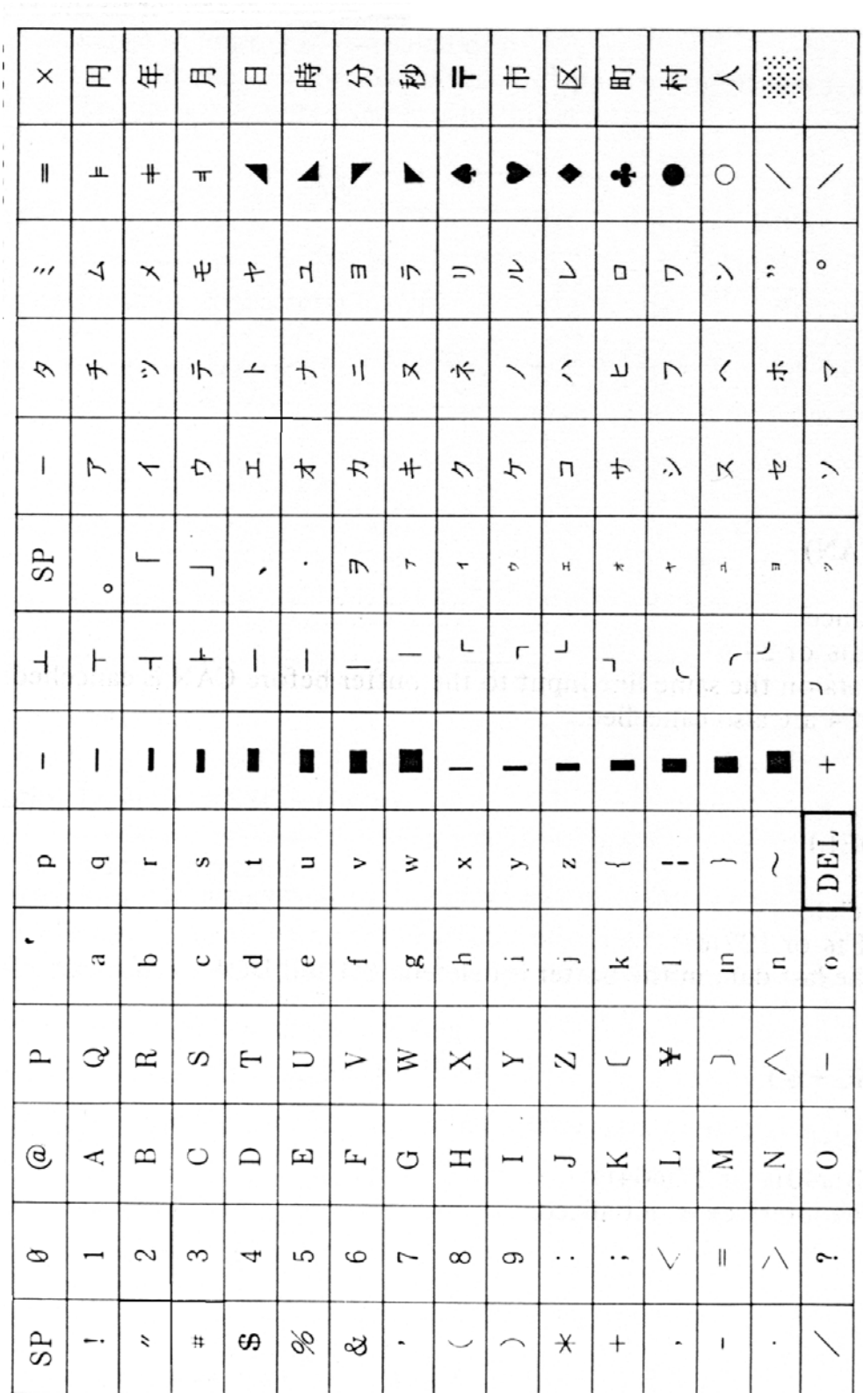
Transmit format:

<ENQ>

<ACK>

<STX>1H|\^&|||BioCare^Biolyte^1.2.1.1^5|||||||1|19991029103631<CR><ETX>c3
<CR><LF>
<ACK>
<STX>2P|1||123456789 <CR><ETX>34<CR><LF>
<ACK>
<STX>3O|1||12||||||||||Serum/Plasma|||||||||P<CR><ETX>2b<CR><LF>
<ACK>
<STX>4R|1|^^^Na+^M| 167
|mmol/L|||||||19991029085059<CR><ETX>ea<CR><LF>
<ACK>
<STX>5R|2|^^^K+^M| 7.2 |mmol/L<CR><ETX>30<CR><LF>
<ACK>
<STX>6R|3|^^^Cl-^M| 151 |mmol/L<CR><ETX>21<CR><LF>
<ACK>
<STX>7L|1|N<CR><ETX>09<CR><LF>
<ACK>
<EOT>

Appendix VII: All Characters of Printer



SP	0	@	P	'	p	—	⊥	SP	—	タ	ミ	=	×
!	1	A	Q	a	q	—	⊤	。	ア	チ	ム	ㅏ	円
"	2	B	R	b	r	—	ㅓ	「	イ	ツ	メ	ㅐ	年
#	3	C	S	c	s	—	ㅏ	」	ウ	テ	モ	ㅔ	月
$	4	D	T	d	t	—	—	、	エ	ト	ヤ	◢	日
%	5	E	U	e	u	—	—	・	オ	ナ	ユ	◢	時
&	6	F	V	f	v	—	ㅣ	ヲ	カ	ニ	ヨ	◤	分
'	7	G	W	g	w	—	ㅣ	ァ	キ	ヌ	ラ	◤	秒
(	8	H	X	h	x	—	⌐	ィ	ク	ネ	リ	♠	干
)	9	I	Y	i	y	—	ㄱ	ゥ	ケ	ノ	ル	♥	市
*	:	J	Z	j	z	—	ㄴ	ェ	コ	ハ	レ	◆	区
+	;	K	[	k	{	—	ㄴ	ォ	サ	ヒ	ロ	♣	町
,	<	L	¥	l	¦	—	⌐	ャ	シ	フ	ワ	●	村
-	=	M	]	m	}	—	ㄱ	ュ	ス	ヘ	ン	○	人
.	>	N	^	n	~	—	ㄴ	ョ	セ	ホ	゛	／	▒
/	?	O	_	o	DEL	+	ㄴ	ッ	ソ	マ	°	＼	

Appendix VIII: LCD Characters