Real time BIA manual



A Truly Portable Body Composition Analyzer





Complete Real Time Standalone BIA kit for body composition analysis and advanced scientific applications

RJL Systems presents the newest member of advanced body analyzers – Real Time BIA –

The past and present

The demand for accurate body composition assessments has increased steadily throughout the world. From outreach clinics in Guatemala, Africa and Asia to modern university teaching hospitals in the USA.

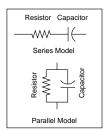
The common problem with virtually all body composition analyzers is that they require a PC or laptop computer to analyze BIA values and they can not save important patient records for future comparison. Printing a fast, detailed report in the field or office has also been a major problem.

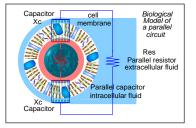
RJL Systems has the answer

The Real Time BIA Body Composition kit has all the components necessary to answer these problems.

- Infrared wireless keyboard
- Fast thermal printer (4 inch paper)
- The advanced PEA analyzer
- Accessories (electrodes, cables, etc.)
 - Rechargeable batteries
 - Rigid carrying case







- BIA range: 0 to 1000 ohms resistance and reactance
- BIA resolution: 0.1 ohms resistance and reactance
- Power: The PEA batteries operate as a true UPS with 2.5 hours of continuous life after power is off.
- Communications: Serial 38.4 kbps (RS-232)
- · Clock: Self powered internal clock and calendar

Physiological Event Analyzer (PEA)

The advanced PEA can incorporate up to four sensory modules that include BIA, ECG, IPG and GSR[1]. The PEA can store over 900 patient records for later export into Cyprus or any spreadsheet. In addition, the user can select Cryprus or Weight Manager body composition equations.

Application Paging

The PEA can have many different applications reside in its internal flash memory. Each application is selected with the front panel paging buttons or the keyboard page keys.

Page 0: Series (Res, Xc, Z and Phase angle)

Page 1: Parallel (Res, Xc, Cap and Z index)

Page 2: Real time BIA data logging (PC interactive)

Page 3: Body composition analysis (keyboard – printer)

Pages 4.5.6.7 future applications, pages 8.9 system info

Real time data logging

The PEA is also designed for the scientist who wants to capture physiological events in real time. These events originate from the sensory modules and are transferred back to a PC for analysis (sampling rate: 1 msec to days).

Cyprus body composition software

Body composition patient records can be transferred back to a Cyprus database for historical graphical/numerical comparisons.

[1] ECG, IPG and GSR will be available by fall 2003

Glossary:

BIA - Bioelectrical Impedance Analysis

ECG - Electrocardiography

IPG - Impedance Plethysmography

GSR - Galvanic Skin Response

Series Res - Measured BIA resistance (ohms)

Series Xc – Measured BIA reactance (ohms)

Z – Impedance – Vector sum of series Res & Xc (ohms)

Phase Angle – ArcTan of series Xc / series Res (dgrs)

Biological Model – The parallel model of Res and Xc

Parallel Res – The biological model of Res (ohms)

Parallel Xc – The biological model of Xc (ohms)

Cap – The capacitance of biological Xc (pico farads)

Features:

- Expansion: New sensory modules and features can be added by a field technician or at RJL Systems
- Equations: Includes Cyprus and Weight Manager body composition algorithms
- Includes: Cyprus and data logger on CD ROM
- Diagnostics: Internal monitoring, displayed on page 9

Note: Before installing any cables to the rear connectors make sure the PEA is OFF

Quad (4) use serial port

- 1. PEA thermal printer (RS-232 at 38.4Kb)
- 2. Subject record (info) 900 records max for download to Cyprus or any spread sheet.
- 3. Capture resistance and reactance values in Cyprus software on a PC or laptop
- 4. Real time data logging sampling rates from from 2 msec to days resistance and reactance (0.1 ohm resolution)

Subject lead set that connects to the hand and foot area of the patient.

See electrode card for more details.

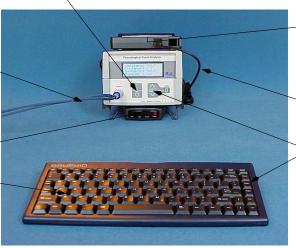
Infrared coupler — Infrared keyboard _

(contains two AAA batteries) Keyboard can be placed up to 8 feet from the PEA infrared coupler.

Setting up cables and connections



ON OFF buttons



PEA battery powered printer (rear view)

Not used (future applications)

Keyboard input connector to infrared mouse like coupler.

120 VAC fuse (.5 amp)

charges internal battery and powers the sensory electronics. Battery operates as true uninterruptible power supply (UPS 2.5 hrs).

— PEA thermal printer (contains 7.2 V 1100 mAh rechargeable Li–ion battery RJL part No. 70690)

Printer serial cable (RS-232 at 38.4 Kb)

> Keyboard paging keys (same as pressing the paging buttons on the PEA)

Application Paging

PEA applications are selected with the paging buttons



Use the ON buttons for setup on pages 8 and 9

Page 0: Series measurement

Resistance:	500.7
Reactance :	56.8
Impedance:	503.9
Phase DG :	6.47

Page 1: Parallel measurement

Cap	Reac (pF)	:	507.1 4471 712.3
Imp	Index	:	1273

Page 2: Real time logging

Real Time Data Logger Messages

Page 3: Body composition

First	Name:	
Last 1	Name:	

Page 8: Set time/date

10:38:40 AM
08/14/2003
Press 'ON' to
change date / time

Page 9: System info and setup

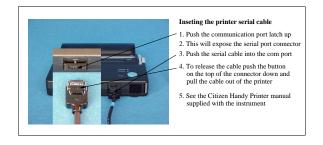
DIAGS	TEMP 85 F
DG +5V AN	+5V An -5V
5.00 5	.08 5.07
Press 'ON'	for SETUP

Pages 4, 5, 6, 7 are for future applications

What is the first thing to do?

Carefully unpack the keyboard, printer, PEA analyzer and the pouches in the cover from the carrying case. Open the left pouch and remove the black printer serial cable and the keyboard infrared coupler (looks like a keyboard mouse).

Make sure the PEA is turned off Plug the serial printer cable into the printer communications port by following the instructions on the right or referring to the *Citizen Handy Printer* user manual. Basically, push the communications port cover to the top and insert the cable. To release the cable, push the button on the top of the cable down and pull the cable out. The infrared port has been disabled.



The printer thermal paper has been installed before shipment and described in the *Citizen Handy Printer* user manual. Place the printer in any convenient place or on top of the PEA. Plug the 9 pin DB connector on the opposite end of the printer cable into the serial connector of the PEA (see drawing on page 3).

Located on the bottom front of the PEA are two tilt legs that should be pulled down, this will give the PEA a comfortable viewing angle. Place the keyboard infrared mouse between these two legs and connect the cable to the 9 pin keyboard connector on the back of the PEA. The keyboard has two AAA batteries installed. It maybe necessary to replace these batteries after 3 months of use. The batteries are only used when a key is pressed.

Turn the PEA on only when the keyboard and printer are connected

The LCD screen will light with a light gray background and a message will roll from left to right across the screen. This message will only appear when the PEA is turned on. The PEA will return to page 0 where series BIA results are displayed. Since a subject is not connected the LCD will display **Subject not connected**. The PEA is now ready for use.

RJL Systems Real Time Physiological Event Analyzer

Press the page up or page down keys on the far right of the keyboard. The LCD application page and the page number on the PEA should change accordingly. Page to page 9 for system information, the internal powder supply voltages and temperature will be displayed continuously.

Configuring the PEA

The user is able to configure the PEA to preferences that can vary from the time zone to the equations used to evaluate body composition and saving subject/patient records for future down load. See set-up description for application pages 8 and 9. All editing of any PEA field is done with the up/down arrow keys and the **Back Space** key. The current active field is always placed on the top line of the LCD display and will scroll up and down. The PEA user interface is highly intuitive and should be easy to use. Any questions can be answered by calling RJL Systems at 800 528-4513.

Application pages

Page 0: Series resistance and reactance

Resistance: 500.7 Reactance: 56.8 Impedance: 503.9 Phase DG: 6.47

The series model of resistance and reactance as measured directly for the BIA module with 0.1 ohms of resolution. Impedance and phase angle are calculated by the following equations.

Impedance or
$$Z = \sqrt{resistance^2 + reactance^2}$$
 Phase angle = arc-tan or atan $\frac{reactance}{resistance}$

Page 1: Parallel resistance and reactance

Par Res : 507.1 Par Reac : 4471 Cap (pF) : 712.3 Imp Index : 1273

The parallel model of resistance and reactance is a more accurate match to the true physiological or biological network of circuits. Res and Reac are the series values.

$$Parallel\ Res = Res + \frac{Reac^2}{Res} \qquad Parallel\ Reac = Reac + \frac{Res^2}{Reac} \qquad Cap\ (pf) = \frac{1\ X\ 10^{12}}{2 \bullet \Pi \bullet 50 K \bullet Par\ Reac}$$

Impedance Index (Imp Index) is proprietary to RJL Systems

Page 2: Real time data logging



Real time data logging is PC interactive and will display various messages relevant to the starting and ending of data logging. See the *RJL Systems PEA Data Logger* manual for further information.

Page 3: Body composition analysis



The body composition applications is a fully implemented analytical tool for assessing body composition. It makes use of the keyboard and printer including saving patient records for future download to Cyprus or any spreadsheet. Height and weight units can be metric or English and first/last name can be as long as 19 characters. In addition, each subject record is date and time stamped in military or English time/date standards (refer to page 9 set-up instructions).

Once a character is entered in the first or last name fields the paging feature of the PEA is disabled. All the subject/patient data must be entered to complete the record. Each field (name, height, weight, etc) will appear on the top line. Lines can be edited and scrolled with the arrow keys. The **Back Space** key is used to delete any character when editing a specific field. All numerical information is checked for validity and will not allow the user to move to the next field until the information is within an acceptable range. The resistance and reactance fields can be manually entered or be automatically read by the PEA by pressing the F1 function key on the top of the keyboard.

Once all the subject/patient information has been entered, the body composition results can be displayed on the LCD screen or printed. A subject record can only be saved when all information is successfully entered **and** the body composition option screen (display results, print results, etc) is entered. When printing a report make sure the printer is turned on (green light on top of the printer). It has an automatic shut-off feature to save battery power and can sometime turn off when not used in time. See page 9 **set-up** to set the equations (Cyprus or Weight Manager), units (English - metric) and the time/date format (English - international)

Page 4, 5, 6, 7: Future applications

These pages are intentionally left blank. Future applications will include special functions from users who want to expand the PEA beyond its current specifications and design. Accordingly, RJL Systems is willing to work with any customer who wants additional usefulness from the PEA on an instrumentation (hardware) and software basis.

Page 8: Set time and date

10:38:40 AM 08/14/2003 Press 'ON' to change date / time

Display the current time and date or change the time and date. Press the ON button (front panel) to change the time and date. Use the up/down arrow keys on the keyboard to select the time/date fi eld (i.e. day, minutes, seconds, etc) then use the **Back Space** key to delete character from fi eld. When complete press the ON key to exit (front panel). The time/date format (English - international) is selected on page 9 (set-up).

Page 9: System information and configure preferences

DIAGS TEMP 85 F DG +5V AN +5V An -5V 5.00 5.08 5.07 Press 'ON' for SETUP

Displayed on page 9 are internal parameters that include the operating temperature and the three main power supply voltages. These measurements are monitored continuously and reflect the real state of the PEA. Each PEA is temperature tested from -5 to 140 degrees Fahrenheit with less than 3 percent variation in power supply voltage and less than 1 percent variation in resistance and reactance.

The following preferences can be configured on page 9 when the ON button (front panel) is pressed.

Page 9 Set-up

	parameter	English - preference	metric - preference
•	Height	inch	centimeter
•	Weight	pounds	kilogram
•	Date Format	MM/DD/YYYY	YYYY/MM/DD
•	Time Format	AM/PM	24-hr
•	Equation set	Cyprus / FNA	Weight Manager
•	Save patient records	Yes	No

press ON (front panel) to exit the set-up mode.

Power supply, monitor and self diagnostics

The PEA can safely operate both from the power line (120/240 VAC) or its internal battery. This feature is implemented as a true **uninterruptible power supply (UPS)** with 2.5 hours of continuous battery life once the line voltage is in a "brown out" or "black out" condition. When the instrument is operated from the line, the battery is charged and the internal electronics are run independent of the battery. The battery is, therefore, charged at its maximum safe rate, without any leakage back to the internal electronics. Battery charging is part of a constant voltage (13.8 volts) current limited (170 Ma) power supply, keeping the battery from being over charged. When the battery is discharged to its minimum state the system will automatically turn off with an appropriate warning (blinking light C). This keeps the battery from being completely discharged thereby improving battery life (many years of trouble free operation). This power management feature allows events to be recorded in real time independent of power line conditions.



On the lower right hand corner there are four green LED's that continuously monitor the conditions of the power supply and battery.

Light A Indicates the instrument is powered from the 120/240 line.

Light B Indicates the battery if fully charged (trickle charging).

Light C Blinks when the battery is discharged to its minimum level,

then automatically turns the instrument off after 16 blinks.

Light D Indicates that all power supplies are within their specifications.

There are three internal switching power supplies powered from the battery or line. All digital components including the micro-controller are operated by a 5 volt digital supply, indicated on the third line below \mathbf{DG} +5V on LCD display (Page 9). The voltages of the \pm 5 volt analog supplies are indicated below \mathbf{AN} +5V and \mathbf{AN} -5V. ALL sensory modules (modalities) and the data acquisition sub-system require the analog supplies because of its low noise and temperature stability. The LCD display readings are continuous and reflect the instantaneous true power supply voltages.

```
DIAGS TEMP 85 F
DG +5V AN +5V An -5V
5.00 5.08 5.07
Press 'ON' for SETUP
```

Located on the upper right hand corner of the page 9 LCD display is the internal temperature of the PEA. The temperature is generally a few degrees higher than ambient and can be used to monitor the outside environment of the PEA. The temperature transducer is a National Semiconductor LM34 (± 1 degree Fahrenheit accuracy) and is located near the top cover of the PEA on the data acquisition board.

Power supply voltages and temperature are read with a 8 bit analog to digital converter. The resolution is limited to approximately 40 millivolts.

Bioelectrical Impedance Analysis (BIA) Certificate of Electrode Placement

Recommended Electrode Placement **RJL Systems** Detecting electrode must be adjacent to Detecting electrode ulner head an imaginary line must be adjacent to bisecting the inside an imaginary line ankle (medial mallealus). bisecting the ulner head of the wrist. Red clip Red clip Right hand Red leads Right foot Black leads Black clip Black clip Signal introduction electrodes are more distal No Has the patient consumed large amounts of alcohol in the last 24 hours. No Does patient have an implantable defibrillator, if yes stop BIA test. No Have the electrodes passed their expiration date, if yes discard. Yes Have you placed the four electrodes according to the above illustration. No Is the resistance value between 250 and 900 ohms. No Is the reactance value between 10 and 120 ohms. No Yes Yes Are resistance and reactance values stable. Technician: Health Care Provider: Comments:

Real time BIA manual

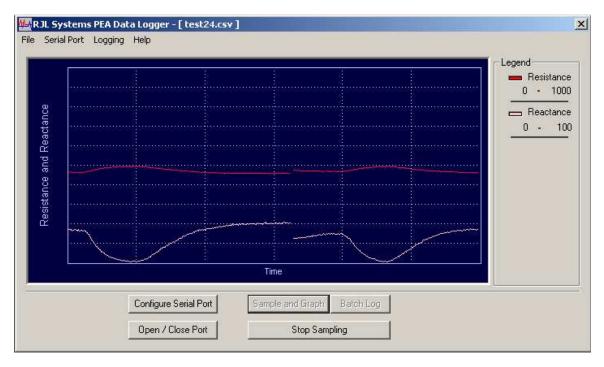


Real Time event logger user manual

Capturing (recording) resistance and reactance values with 0.1 ohm resolution from 2. 0 milliseconds to 45 days per sample (16 bits)

The applications described in this section of the manual are for investigational (research) purposes and have not been approved by the FDA for commercial use.

advanced scientific applications



- 1. **Minimum System Requirements** The RJL Systems Data Logger has the following minimum system requirements:
 - a. Windows NT 4.0, 2000, or XP (Windows 3.11, 95, 98, and Millennium Edition are not supported)
 - b. 64 MB of memory or greater
 - c. Display resolution of 800 x 600 pixels or greater 1024 X 768 recommended
 - d. Pentium-II 300 Mhz or greater (This is the minimum speed that will allow the graph to be updated every 2 ms)

If the computer does not meet or exceed these requirements, the setup program will not allow the Data Logger to be installed.

II. Installation of the RJL Systems Data Logger software.

The installation from the CD ROM is generally automatic by just inserting the disc. If the setup program does not automatically begin when the CD rom disk is inserted, select **Run** from the "Start Menu". In the box which opens, type "D:setup" to begin the setup process. (Substitute the letter of the appropriate CD- ROM drive for D, if necessary.) A box will appear with three buttons. Click the "Install DataLogger" button to begin the setup process.



The setup process consists of the following windows:

- A. Introduction
- B. License Agreement
- C. Select Destination Location
- D. Select Entry for Start Menu
- E. Verification of Installation Tasks
- F. Finish

Most users will simply accept the default options when installing.

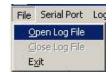
III. Program Operation

a. Start the Data Logger application by either double-clicking the icon on the desktop, or by selecting the shortcut from the **Start** menu.



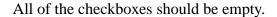


b. To open a log fi le, select "Open Log File" from the "File" menu. This will open a standard "fi le chooser" window. Type the name for the log fi le and select the folder in which to save it and click "Ok." The name of the log fi le will now appear in the title bar at the top of the Data Logger window. (see image on page 1)



c. Confi gure the serial port by either clicking the **Confi gure Serial Port** at the bottom of the window, or selecting "Confi gure Serial Port" from the "Serial Port" menu. Select which serial port to connect to the PEA with. (Usually either "COM1" or "COM2") For your PEA unit, the rest of the settings should be as follows:

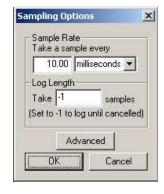
Baud Rate: 38.4k Data Bits: 8 Parity: None Stop Bits: 1



d. Set how often to take a sample in the "Sampling Options" window. This window is opened by selecting "Set Sample Rate and Duration" from the "Logging" menu. The minimum time period between samples is 1 millisecond, and the maximum is 45 days.

To take only a specific number of samples before closing the log file, specify the number of samples in the Log Length field. To take samples continuously until the "Stop Sampling" button is pressed, set the log length to '-1'

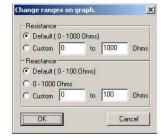




e. Clicking the "Advanced" button in the "Sampling Options" window opens the "Advanced Graphing Options" window. This window contains the following settings:



- 1. **Pixels per sample.** To spread the graph out a bit, and make details somewhat easier to read, raise this value. Its default value is 1.
- 2. **Sample skipping.** Computers with slower processors may not be able to keep up with faster sample rates. As a result, it may be desirable to log samples at a fast rate (for later processing) and only graph every other sample. The default is to plot every sample logged on the graph.
- f. **Graph Ranges.** The DataLogger defaults to a range of 0-1000 for Resistance, and 0-100 for Reactance. These ranges can be overridden by selecting "Graphing Options" from the "Logging" menu. Changing the range while logging is in progress will cause the graph to clear, but will not affect the readings going into the log fi le.



g. **Taking Samples.** Before logging can begin, the PEA must be turned on and connected to the serial port. Click the "Open / Close Port" button to initiate the conversation between the PEA and the Data Logger application. Once the data logger has successfully connected to the PEA, the "Sample and Graph" and "Batch Log" buttons will become active.



If the Data Logger can not open communications with the PEA, a warning message will appear. If this happens, make sure that the PEA is turned on, and that it is connected to your computer's serial port. Also, make sure that no other programs (like Palm Desktop's Hot-Sync Manager*) are attempting to use that same serial port. If the Data Logger still can not communicate with the PEA, go back to step "C" and verify that the port settings are correct. If all of the settings appear to be correct, it may be necessary to select a different COM Port.

Begin taking samples by clicking either the "Sample and Graph" or "Batch Log" button. When either of these buttons is clicked and no log file is presently open, a window will appear asking if the data is to be saved to a log file or not. Logging will begin immediately after this window is closed.

The "Sample and Graph" button retrieves (and graphs) data in real time. Therefore, the sample period must be greater than the amount of time required to transmit a sample. If the sample period is too small to accommodate data transmission, a window will appear with the minimum allowable sample rate for real-time data retrieval. If, while graphing, one of the channels should exceed the PEA's sensor range, (± 16384) that channel will disappear from the graph until it comes back into range. If the value is still within the sensor range, but outside the range on the graph, you may adjust the graph's range to bring it into view. (see above)

The "Batch Log" button, on the other hand, will store the log on the PEA itself, and retrieve the data only when logging is fi nished. By using the "Batch Log" button, sample rates of 1 ms. can be achieved, regardless of the time required to transmit a sample. When logging begins, the "Sample and Graph" and "Batch Log" buttons are disabled, and the "Stop

Sampling" button becomes active.

Logging will continue until one of three things happens:

- 1. The "Stop Sampling" button has been pressed.
- 2. The desired number of samples have been taken and saved to the log fi le (see part D.)
- 3. The application is closed.

In all cases, when logging has fi nished, the log fi le will be closed and marked with the date and time at which logging has fi nished.

IV. Log File Format

The log fi les generated by the data logger application are standard comma-separated fi les. (*.csv) The fi rst line in the fi le contains the timestamp of when the fi rst sample was taken. The second line specifi es what the sample period is. The last line contains the timestamp when the log fi le was closed. The remaining lines have the following format:

	A	В	С	D
1	Logging Beg	an: Thu Ma	r 13 16:55:0	02 2003
2	Taking a san	nple every:	2 seconds.	
3	1	497.7	0	
4	2	480.9	18.5	
5	3	475.5	23.6	
6	4	472.4	26.8	
7	5	472.4	26.8	
8	Logging Finis	shed: Thu N	1ar 13 16:5	5:08 20
a				

Column A: Sample ID #
Column B: Resistance Value
Column C: Reactance Value

Any values which the PEA has reported as being out of range (> 16384 or < -16384) will be listed as "N/A" in the log.

When logging has fi nished and the log fi le has been closed, it may be viewed with any text editor, (such as Microsoft Notepad*) spreadsheet, (such as Microsoft Excel* or Corel's Quattro Pro*) or any data-analysis software package (gnuplot - free, Matlab - \$\$, etc.).

V. Exiting From the Application

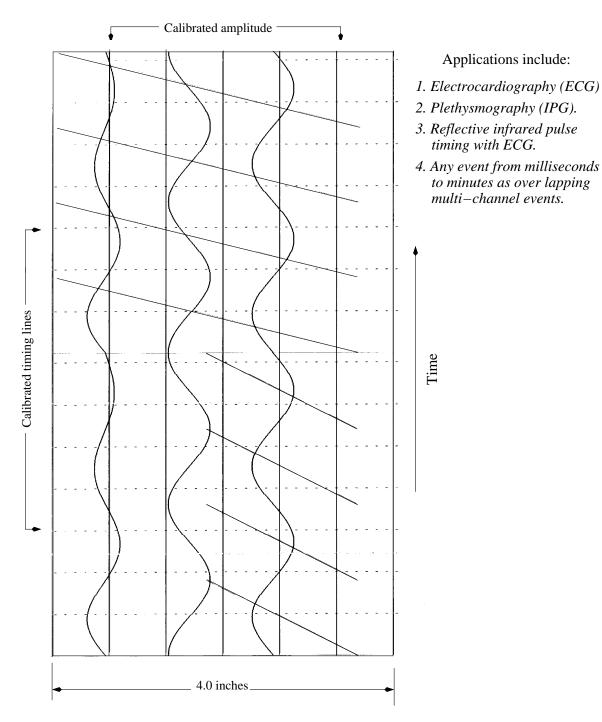
To exit from the data logger application, either click on the "X" button in the upper-right corner, or select "Exit" from the "File" menu. *

Notepad, Excel, and Quattro Pro are not RJL Systems products. They are each Copyrighted by their respective companies.

Palm Desktop and the Hot-Sync Manager are not products of RJL Systems. They are products of Palm, Inc. and Copyrighted by Palm Inc.

Transforming the PEA printer into a multichannel analog strip chart recorder

PEA Printer pixelizing 16 bit analog real time data



This image is an actual 4 channel recording from the PEA. The image is somewhat reduced in quality because it had to be scanned in by an image scanner then reduced in size (some touch up). There can be any number of channels with an arbitrary starting position and amplitude (signals can over lap).

Real time BIA manual



Technical description and applications

Electrical Cardiography (ECG)
Galvanic Skin Response (GSR)
Impedance Plethysmography (IPG)

The applications described in this section of the manual are for investigational (research) purposes and have not been approved by the FDA for commercial use.

advanced scientific applications

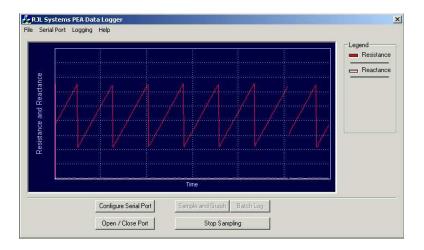
Physiological Event Analyzer (PEA) - Real Time BIA

The purpose of the PEA is to create a safe operating environment that displays and communicates with different self contained sensory modules which measure and monitor physiological events in real time including bioelectrical impedance analysis (BIA). The fundamental specification of the PEA is multi-channel fast high resolution (16 bits) data acquisition sub-systems. This coupled to a powerful 16 MHz micro-controller with a real time clock and calendar, creates an extremely versatile instrument.

The micro-controller unit (MC68HC812A4) is a 16-bit device composed of standard on-chip peripherals including external flash and Lithium battery powered RAM memory. The system is programmed entirely in the C programming language where run time objects are saved in 128KB of flash memory and user data is saved in non-volatile ram (body composition patient records).

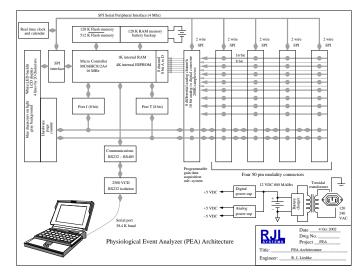
Sensory modules return analog signals with a full scale of \pm 2.000 volts with excellent stability and repeatability allowing full 16 bit conversion. The analog to digital conversion rate can exceed 100K samples/second. However, the serial communications rate is limited to 38.4 KBaud/sec that reduces the actual data transfer. At this rate two channels of 16 bit data has a maximum transfer rate of 2 milliseconds including saving samples to a local disc on a desk-top or lap-top. See manual on PEA Data Logger software which is shipped with all PEA instruments.

The data acquisition module also contains dual programmable gain instrumentation amplifiers to improve sensitivity and resolution.



The screen shot is the actual monitor of the Pea Data Logger API. Two channels are displayed with a sampling rate of 2 milliseconds (38.4 K baud/sec serial). The "saw tooth" wave is 5 Hz signal on channel 0. A constant voltage is on channel 1. The processor is a 700 MHz Pentium III with 33 percent of the CPU speed being used. Running the same application on a 2.5 GHz Pentium IV reduces the CPU usage to 10 percent.

There are four 50 pin connector slots for expansion of new sensory modules (modalities). Each modality slot is directly connected to any of eight analog differential lines of the data acquisition sub-system (16 bits at 100K samples/sec). Also, two 8 bit bi-directional micro-controller data registers are connected to these slots for further application development. This combination of a analog and digital bus structure makes development of new sensory modules simple and easy to implement. Modules currently in development are ECG (electrocardiography), galvanic skin response and GSR (impedance plethysmography).



Instrument design - safety and resolution

Isolation - safety:

A safe electrical isolation barrier between the subject/patient and earth ground must exist, eliminating the possibility of electrical shock. A leakage current across this barrier from a possible 120 VAC source should ideally be below 10 micro-amps, as defined by The Association for the Advancement of Medical Instrumentation (AAMI). Without this isolation, a medical device can not be connected to computers or a recording device that are connected to a 120 VAC source (plug). Safety (electrical isolation) of the PEA has been built into the entire instrument with 2500 volt isolation from the subject input to external computers and the actual 120/240 volt line connection. This exceeds UL-544 and most CE requirements. The main power supply operates from a step-down toroidal transformer with greater than 2500 volts of isolation.

In addition, the BIA sensory module is transformer-coupled at the subject interface and is tested with a high-resistance Hi-Pot instrument (Hewlett Packard 4329A). An applied voltage of 1000 VDC is placed between the subject and the analog ground for 2 minutes. The resistance recorded exceeds 10,000 Megohms at 1000 VDC, resulting in a leakage current of 0.1 micro-amps.

Resolution

The fundamental BIA specification is a direct linear measurement of resistance and reactance originating from zero at 50 KHz. In addition, the BIA modality has a high common mode rejection ratio at the operating frequency where background noise is rejected or attenuated to virtually zero (a true reading of living biological substances). A direct analog output of simultaneous resistance and reactance that can measure from 0 to 1000 ohms (\pm 1%) is available on channels 6 (resistance) and 7 (reactance).

The analog output signal must have an extremely high signal to noise ratio (SNR), or resolution, because of the small signal changes that are due to the series/parallel effect of the physiological event. The baseline resistance and reactance values may be 10,000 times larger than their respective changes. Designing the instrument as a pure analog device will achieve the highest possible resolution. The BIA modality is an analog circuit which can achieve a SNR of 10,000 to 1. With modest filtering, this ratio can be improved to 100,000 to 1 and maintain excellent frequency response of the event (segmental blood fbw).

LCD display

The display is back-lit with four ultra bright white light emitting diodes (LEDS). This creates a white-gray background that is contrasted with bright blue characters. Readability is excellent at any viewing angle or ambient light level. The display is updated at a viewing rate that is comfortable to read without any LCD flcker. The display can be reversed with a dark blue background and white characters, as an option.

LCD display - paging



The LCD display can be paged by pressing the page up or page down buttons. There are 10 LCD pages ranging from 0 to 9. Each page triggers a different response from the micro-controller (unique information). Since the LCD display is limited to 4 lines, paging allows the equivalent of 40 lines information to be displayed. See BIA modality LCD display. Paging also takes place with the keyboard scroll up and scroll down keys (optional).

The BIA modality LCD display

The BIA modality is electrically identical to the Quantum II and Quantum X instruments from RJL Systems. The difference is the analog outputs are filter with a 1 Hz second order active filter. This eliminates the cardiac circulatory effect caused by each heart beat. Without this fi lter the 0.1 resolution would be unstable and difficult to read. The filtered output is coupled directly to the 16 bit data acquisition sub-system for processing by the micro-controller then displayed on the LCD readout. All of the bioelectrical values are illustrated on two LCD pages. The BIA parameters are toggled by the front panel paging buttons. These values are not related to anthropometric measurements any including weight, height and age The series equivalent model of resistance and reactance is simultaneously read directly by the BIA modality, all other information is calculated from fundamental formulas of electrical engineering. All values except the Cap (Pf) (parallel capacitance - picofarads) and Imp Indx (impedance index) are expressed in Ohms.

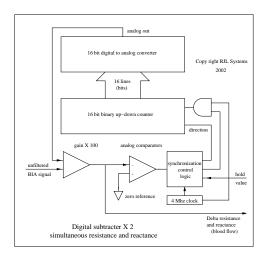
LCD page 0 (series model)

Resistance: 500.0
Reactance: 50.0
Impedance: 502.5
Phase DG: 5.7

LCD page 1 (parallel model)

Par Res : 505.0
Par Ract : 5050
Cap (pF) : 630.6
Imp Indx : 1152

Blood flow (Digital subtraction modality - optional)



The main BIA modality has optional blood fbw modality (second PC board) which increases the resolution from 0.1 Ohms to 0.01 Ohms, and decreases the subject maximum range to 200 Ohms full scale. The subject 50 Khz detection signal is multiplied by 10.0 with a 50 Khz resonant circuit, thereby, reducing background noise because of the narrow bandwidth of the tuned amplifier. When the tuned BIA modality is interfaced to a separate 16-bit digital-to-analog subtracter, the base line resistance and reactance signals are eliminated leaving only their calibrated changes with respect to time. The high signal-to-noise ratio of the tuned BIA detector and the digital subtracter will create a real time plethysmograph that can quantify resistance and reactance changes due to blood fbw.

Specifications: BIA modality

Isolation barrier Nominal: 10,000 Megohm at 1000 VDC

subject leads to analog ground

Constant current accuracy Nominal: 425 microamp at 50 Khz \pm 1 %

Regulation: better than 0.1 %

Range: 0 to 10,000 Ohms, resistive or capacitive

Resistance accuracy Nominal: 1.0 Ohm

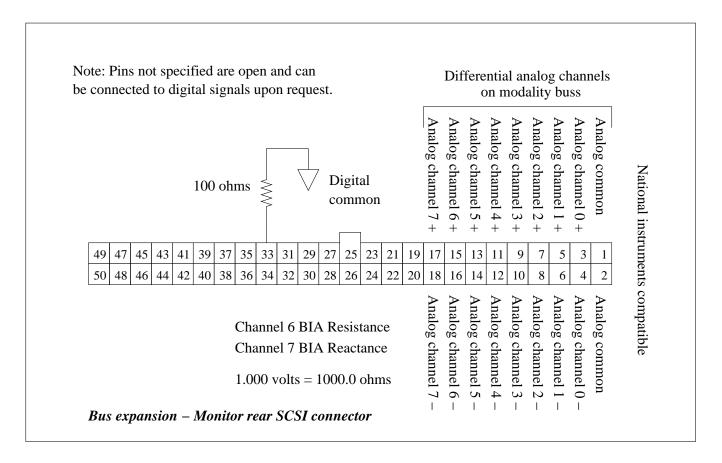
Range: 0 to 1000 Ohms (**Blood flow** 200 Ohms)
Resolution: 0.1 Ohm (**Blood flow** 0.01 Ohm)

Reactance accuracy Nominal: 1.0 Ohm

Range: 0 to 1000 Ohms (**Blood flow** 200 Ohms)
Resolution: 0.1 Ohm (**Blood flow** 0.01 Ohm)

Rear connector

Located on the back panel of the PEA is a 50 pin male SCSI connector. This connecter has all 8 differential analog channels and various digital registers available (optional). Therefore, the signals generated from the PEA modalities can be read by external data acquisition systems (pin compatible to the National Instruments PCMCIA data acquisition system). In addition external instruments which have analog outputs can be connected to any unused analog channels of the PEA. This creates a highly integrated instrumentation environment inclusive of PEA modalities. The micro controller digital I/O registers can be used for BIA electrode switching and scanning for impedance (resistance and reactance) tomography and multiple segmental observations when specially configured by an application request.



Serial communications

Located on the rear panel is a 9 pin RS-232 compatible serial connection to a local PC or workstation. Communication rates are at 38,400 bits/sec or higher. Programmed within the memory of the micro-controller is a "serial command interpreter" where specific simple requests are sent to the PEA for analysis. Once a request is sent, the PEA will immediately send the appropriate information back to the caller (PC or workstation). All internal PEA data are stored as signed 16 bit words. The data word is delivered back to the caller in a communication wrapper requiring three (3) bytes to complete the transfer of the 16 bit word. There are no control or escape characters transferred to the caller, therefore, most

software communication protocols (XON, XOFF) will work reliably. Considering a baud rate of 38.4 KBaud, a 16 bit word requires 781 micro seconds for a complete transfer. Real time data that requires faster sampling can be saved in the micro-controllers 128K (512K optional) battery backed RAM for later transfer to the caller as a special request.

Cyprus is fully compatible with this protocol allowing resistance and reactance values to be read directly into the Cyprus program to 0.1 ohms. In addition, data logging software is also available that can set sampling rates from milliseconds to days. The PEA is insensitive to its ambient temperature allowing it to be used in outdoor winter and summer outdoor conditions. Each PEA is tested (run) in an environment chamber with temperature extremes of -20 to 60 Celsius before shipment.

PEA modalities under development

The following list is just a sample of the information which can be collected by the PEA with the proper modality boards installed:

- Real time bioelectrical impedance analysis (Impedance Plethysmography). Quantitative blood fbw on virtually any segment of the human or animal body.
- Electrical Impedance Tomography (resistance and reactance)
- Electro-cardiograph (ECG)
- Galvanic Skin response (GSR)
- Infrared peripheral blood fbw (skin and wound blood fbw)
- Blood pressure and volume monitoring from inflated cuffs

Regulatory

The applications described in this manuscript are for investigational (research) purposes and have not been approved by the FDA for commercial use. The RJL Systems Quantum series of instruments have been approved for use as body composition analyzers only. However, they may be used for other applications as investigational devices. RJL Systems welcomes the mutual collaboration of commercial and/or academic organizations to further the advancement of BIA sciences that may lead to patents and FDA approval of new specific applications using real-time BIA. The Quantum and PEA series of instruments have been submitted to US and world patent offices.

PEA Communication Protocol Implementation 1.1

Page Assignments (applications)

The PEA has ten screen pages, which can be selected via the "page up" and "page down" buttons on the front panel. At present, the pages are arranged as follows:

Page	Purpose
0	Serial Resistance, Serial Reactance, Impedance, and Phase Angle
1	Parallel Resistance, Parallel Reactance, Capacitance, and Impedance Index
2	Real time data logger message display
3	Body Composition Analysis
4 - 7	Currently Unused
8	Display and set current time and Date.
9	Unit Health. This page displays the voltages of the three main power supplies and the internal temperature (F). Also, modify configuration options.

Analog Channels 8 - bit (Unsigned. Values range from 0 - 255)

Channel	Value	Scale
0	Voltage on the -5V	approx 0.0385 V / Division
	Analog Power supply	
1	Voltage on the +5V	approx 0.0385 V / Division
	Digital Power supply	
2	Voltage on the +5V	approx 0.0385 V / Division
	Analog Power supply	
3	Temperature (Fahrenheit)	approx 0.65 Degrees / Division
4	Subject Connected detection	Subject connected if value > 50
5 - 7	Currently unused	

16 - bit (Signed. Values range from -32768 to 32767)

Channel	Value	Scale
0 - 5	Currently Unused	
6	Resistance	0.1 Ohm / Division
7	Reactance	0.1 Ohm / Division

Serial Settings

Version 1.1 of the PEA requires the following settings on the host serial port:

38400 bps

8 data bits

NO parity

1 stop bit

NO fbw control *

*The PEA does understand XON and XOFF (software fbw control) characters and does not send them. A host computer may communicate with the PEA using a specially designed software, such as the RJL Systems Data Logger, or, for testing purposes, any terminal program, such as Kermit or Hyper Terminal.

Number Transmission

PEA - to - Host : Integer Encoding (3-byte code)

Ideally, in the interest of rapid communication, the PEA would transmit raw, binary data to the host computer. However, doing so would bring the possibility of sending XON and XOFF characters as part of the data. Therefore, the data must go through a form of encoding before transmission.

In this encoding scheme, a 16 bit value to be transmitted is broken into three segments - the low 5 bits, the middle 6 bits, and the high 5 bits. (On the PEA, integers are 16 bits long, and the PEA's processor is a big-endian device.) Decimal 32 (a space character) is added to each of these segments, and they are transmitted in that order (low, middle, high)

For example, the integer 15763 (00111 101100 10011 in binary) would be transmitted as [3L']

An 8 bit value is normally treated as a 16 bit value where the top 8 bits are 0.

Note that SHRT_MAX (32767 - 01111 111111 11111 in binary) is a special value intended, under normal circumstances, to represent a value "OUT OF RANGE"

Host - to - PEA : ASCII Strings

For simplicity sake, since the vast majority of traffic will be from the PEA to the host computer, any numbers transmitted to the PEA by the host will be sent as ASCII strings.

Conversation

Any message that consists of just a single character will be enclosed in single quotes. ('')

If the message is a multi-byte string, it will be enclosed in double quotes. (" ")

For the remainder of this document, the following conventions will be used to represent certain special characters:

Escaped	Character	Character Code
	decimal (hex)	Name
\t	9 (0x09)	Tab
\r	13 (0x0D)	Carriage Return

Protocol Detection

Message	Meaning
"V\r"	Protocol version detection.
"v\r"	When the PEA receives either of these strings, it responds with a string identifying the version of the protocol implemented. For version 1.1 of the PEA protocol, this response string will be "PEA11\r".

Front Panel Management

Message	Meaning					
">0\r" ">9\r"	Go to the specified page. The LED page indicator is updated, and the information associated with that page number is displayed on the LCD. No data is returned to the host.					
" <text\r"< th=""><th>Go to page 2 and display the message text (everything between '<' and '\r') on the LCD. For easy formatting, it is recommended that the message text be 40 characters or less. No data is returned to the host.</th></text\r"<>	Go to page 2 and display the message text (everything between '<' and '\r') on the LCD. For easy formatting, it is recommended that the message text be 40 characters or less. No data is returned to the host.					
'{'	Lock the front panel. This command changes to page 2, displays a "Please Wait" message, and locks the page up and page down buttons. This is especially useful in higher data rate logging applications, to prevent updating the LCD from taking valuable time away from data logging and processing. No data is returned to the host.					
'}'	Unlock the front panel. This command changes to page 2, displays a "Logging Finished" message, and unlocks the page up and page down buttons. If the PEA is still in the process of taking samples, this command also stops logging. No data is returned to the host.					

Instantaneous Value Detection

These commands return the current value detected on the specified Analog channel. No storing or logging of the data is performed. Upon receiving one of these commands, the PEA will return a 3-byte encoded integer. (See above.) To determine the actual value, decode the integer, and multiply by the appropriate scale factor. (See Analog Channels tables.)

Message	Meaning	Message	Meaning
'a'	Get value from 8-bit channel 0	'A'	Get value from 16-bit channel 0
'b'	Get value from 8-bit channel 1	'B'	Get value from 16-bit channel 1
'c'	Get value from 8-bit channel 2	'C'	Get value from 16-bit channel 2
'd'	Get value from 8-bit channel 3	'D'	Get value from 16-bit channel 3
'e'	Get value from 8-bit channel 4	'E'	Get value from 16-bit channel 4
'f'	Get value from 8-bit channel 5	'F'	Get value from 16-bit channel 5
'g'	Get value from 8-bit channel 6	'G'	Get value from 16-bit channel 6
'n'	Get value from 8-bit channel 7	'H'	Get value from 16-bit channel 7

Log Management

The PEA uses an 8-bit mask to determine which channels are to be logged when it comes time to take a sample. The default log mask is 192, (binary 00000000 11000000) which instructs the PEA to log Resistance and Reactance values only.

To Select	8-bit channel						16-bit channel									
	7	6	5	4	3	2	1	0	7	6	5	4	3	2	1	0
Set bit #	15	14	13	12	11	10	9	8	7	6	5	4	3	2	1	0
Default mask	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0
Bytes trans	2	2	2	2	2	2	2	2	3	3	3	3	3	3	3	3

To determine the total number of bytes required to transmit a complete sample, add the number of bytes required to transmit each individual channel selected, plus one. The one extra byte is to accommodate the delimiting '\r', which begins each sample.

When a logged sample is transmitted to the host computer, the delimiter '\r' is sent first, then each selected channel in ascending order. For example, a total of seven bytes, one for the beginning delimiter, then three for Resistance, and fi nally, three for Reactance, are required to transmit the default sample.

Notice the difference in the number of bytes required to transmit an 8-bit channel versus a 16-bit one. Because log samples are most commonly transmitted while the logging is in progress so they can be plotted on a graph in real time, the high byte (which will always be ' ') is eliminated in the interest of reducing transmission time.

Message	Meaning
"^number\r"	Set the log mask on the PEA to the specified number. No data is returned to the host.
' &'	Retrieve the current log mask. The value is returned to the host in 3-byte code.
'#'	Clear the log from memory. Before beginning to take samples, send this command to clear the old log from the PEA and start a new one.
"~number\r"	Set the logging interval to number x 1.024 milliseconds. The PEA will then calculate the amount of time required to transmit a complete sample. If the logging interval is greater than the amount of time required to transmit the coded sample, the string "number\r" is returned to the host. If, on the other hand, the interval is shorter than the amount of time required to transmit, the minimum value to support real-time transmission of values is returned instead of the actual logging interval. Note that since the PEA does not measure time in exact milliseconds, you may wish to divide your desired sample interval by 1.024 before sending it to the PEA (round to the nearest integer) Valid values for number range from 1 to 4294967295. (50.9 days)
"!number\r"	Begin logging, and "batch" the samples. Samples are stored on the PEA for later retrieval by the host. By "batching" the log in this manner, it is possible to take samples faster than they can be transmitted. Once number samples have been taken or the PEA's storage memory has been filled, the PEA stops logging data, and transmits the string "\t\t\t\t\" to the host as a signal that it is done. Setting number to -1 indicates that the PEA is to take samples forever, or until the PEA's memory is full, or logging has been ended by the host. Valid values for number range from -1 to 2147783647.
"!0\r"	Stop logging. This is actually a special case of the above command, and can be interpreted as "Take zero more samples, and then stop." The PEA sends the string "\t\t\t\t" to the host in acknowledgment.
".number\r"	Begin logging, and "stream" the samples. Take number samples, and transmit them to the host as they are taken. The data is not stored locally on the PEA. When the PEA receives this command, the specified logging interval is compared against the amount of time required to transmit a sample at the current communications rate. If the logging interval is less than the amount of time required to transmit a sample, it is automatically increased to the minimum value required to accommodate real-time transmission of the data. Samples are then transmitted to the host as they are taken. Stop logging by sending the string "!0\r" to the PEA. Valid values for number range from -1 to 2147783647.
'@'	Go to the beginning of the log. If a log has been "batched" on the PEA, when you are ready to begin reading the sampled data from the unit, send this character. No data is returned to the host.
' \$'	Get next sample. The next sample in the log is transmitted to the host. If there are no more samples left in the log (at the end) the string "\t\t\t" is sent to the host.
'%'	Retransmit previous sample. In the event of a communications error or a serial timeout, send this command to retransmit the previous sample.

Time Management

The PEA contains an RTC (Real Time Clock and calendar) chip. This section details the commands for setting and retrieving values from the RTC. A command to retrieve a value will begin with a lowercase 't'. A command to set a value will begin with an uppercase 'T'. Values are identified as follows:

Identifi er	Value	Range	Command to Retrieve	Command to Set
h	Hour	0-23	"th"	"Thnumber\r"
m	Minute	0-59	"tm"	"Tmnumber\r"
S	Second	0-59	"ts"	"Tsnumber\r"
M	Month	1-12	"tM"	"TMnumber\r"
D	Day	1-31	"tD"	"TDnumber\r"
Y	Year	0-9999	"tY"	"TYnumber\r"

To retrieve a value, the entire command message will be two (2) characters long - the command 't', and the identifier to retrieve. ("tm" will retrieve the present Minute)

The command to set a value must be terminated by a carriage return. ('\r') The message will begin with the command 'T', next will be the identifier to set, followed by the value in plain ASCII, and the carriage return. ("Tm53\r" will set the value for Minute to 53)

Patient Record Manipulation

In addition to serving as a data-logging device, the PEA can also be used as a stand-alone body-composition analyzer. Entered patient records are stored in battery-backed RAM for output to a host computer at a later date. Because they are retained after shutdown, patient records take precedence over batched data samples. However, since data samples are stored at the beginning of the RAM, while Patient records go at the end, this situation should arise only if large numbers of batched samples are stored AND a large number of patient records are stored.

Message	Meaning	Record Information
'Z'	Transmit current (most recent) patient record. This causes the most recent record to be transmitted in plain ASCII, with carriage returns ('\r') separating the individual fields. Fields will be ordered as in the adjacent table. In the event that this command is received when there are no remaining stored records in memory, an empty record is transmitted. (11 consecutive carriage-returns)	First Name Last Name Subject ID Flags (Bitfi eld) bit 0 - 0 = in 1 = cm bit 1 - 0 = lb 1 = kg Gender (0 = Male / 1 = Female) Age Resistance Reactance Height Weight
'X'	Remove current (most recent) record from memory. The most recent record is deleted from memory, making the previous record the most recent.	Desired Weight