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Quantum VII

Bioelectrical Impedance Analyzer (BIA)

Operators Manual

for the study of human body composition

by Clinicians and Healthcare Professionals


The New Quantum VII for 2023
QUANTUM VII
BIOELECTRICAL IMPEDANCE ANALYZER
Classical (RT) BIA
Res: 1004.6
Reac: 303.4
Phase: 16.8
Average N: 528
04/21/23 14:50:48
Bat: 89% Rec:17
RJL SYSTEMS
QUANTUM VII
BIOELECTRICAL IMPEDANCE ANALYZER
Classical (RT) BIA
Res: 1004.6
Reac: 303.4
Phase: 16.8
Average N: 605
04/21/23 14:51:22
Bat: 89% Rec:17
RJL SYSTEMS

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Manual last updated 04/22/2023

About the Quantum VII Real Time BIA

The new 2023 portable hand-held Quantum VII Biological Impedance Analyzer (BIA) continuously measures real time biological resistance and reactance electrical properties over time.

1. Accurate and repeatable resistance and reactance measurements taken every 1/2 second with 0.1 ohm stability from 0 to 1000 ohms resulting from RJL Systems patented subject isolation.
2. Accumulates and displays average, standard deviation (STD) and minimum - maximum values for each BIA sample.
3. Dual mode BIA includes Classical BIA and Scheduled BIA observations with automatic averaging.
4. Scheduled BIA sampling rate range is from 2 seconds to 24 hours and set with standard time (HH:MM:SS) including automatic shutdown to save power.
5. Industrial 8 GB memory card holds Classical and Scheduled BIA real time reports with time stamps.
6. Built-in communications includes Bluetooth Low Energy (BLE) and WiFi with website to access BIA records (see report samples).
7. 2.8 inch color display featuring glass capacitance touch screen for fast menu access.
8. Built-in accelerometer to measure subject 3D orientation (like an airplane) when carried or worn in clothing.
9. Rechargeable Li-Ion Polymer smart protected battery. More than 6 hours of continuous run time.

In Classical BIA mode the number of averages grows with time until the ON button is pressed. The average (mean), standard deviation (variance) and maximum – minimum BIA values are available on the display. The longer the subject is connected, the greater the number of average observations. A 10 second connection will result in approximately 20 average stable accurate readings. The average reading will not change when the subject is disconnected from the analyzer. Pressing the ON button again will save the BIA observations as a time stamped report record then shut the Quantum VII off.

In Scheduled BIA mode measurements are taken at specific intervals from 2 seconds to 24 hours. Any interval above 20 seconds will cause the Quantum VII to sleep until the next sample time arrives. The instrument will then wake up for 5 seconds to take a new measurement, average them and create a new report record. An experiment with a 1 hour sample rate could run for months on a single battery charge. Each time interval keeps the Quantum VII awake long enough to average six (6) resistance and reactance measurements.

BIA averaging stabilizes the effects of motion, respiration and circulation common in real time measurements. The standard deviation (variance) of the average resistance, reactance and phase angle are available to illustrate the magnitude of these events.

Graphic Display:

The LCD display is a 2.8 inch 320 X 240 pixel IPS bright display with vivid 24 bit colors and high viewing visibility and is true TFT (transflective). Behind the display is a non-removable 8 GB high endurance SD memory card with advanced ECC wear leveling. This SD card holds calibration and other important BIA information to maintain accuracy, stability and BIA event records.

BIA Engineering:

The BIA module is identical to all RJL analyzers. The subject is isolated from electrical components with transformers specially designed for a 50 Khz BIA instrument resulting in a true four electrode (tetrapolar) biological measurement. The resistance and reactance measurements are the same as the Quantum IV and Quantum V. The same calibration standards and acceptance tolerances are used with the Quantum VII, however, traditional BIA instruments do not have the averaging and scheduling feature of the Quantum VII.

Time Keeping:

Date and time are continuously maintained with a dual battery clock and calendar external to the micro-controller. When the main battery is replaced, a secondary back-up battery will keep the time accurately. The date and time are set manually from the main menu and can be corrected at any time. An Internet NTP time service (*time.nist.gov*) is also available as a menu item once the WiFi LAN is configured. This will precisely set the clock / calendar to 1 second accuracy.

Battery:

The Quantum VII uses a 7.4 Volt 850 mAh Lithium Ion battery with smart protection and is CE, RoHS MSDS Certified. It will last more than 6 hours of continuous operation and can be recharged without removal with the Quantum VII charger.

Scheduled BIA Observation (Real Time BIA Data Logging)

The timekeeping device has an alarm that can be programmed to interrupt the BIA loop and save the current time/date with BIA average values as a record on the 8 GB SD card. The alarm is programmed in standard time as HH:MM:SS with a minimum time of 2 seconds and a maximum of 24 hours (1 sec resolution). Each time an alarm (interrupt) is triggered a new alarm is set with the current time plus the alarm time. This standard feature records BIA values over time from 2 seconds to months on a single battery charge. Any programmed event time over 20 seconds will automatically turn the BIA off and wait for a new alarm to wake the BIA up again for 5 seconds to record the new average values. A one hour sample time (24 samples / day) experiment will last for months since there is more than 5 hours of battery life when continuously running.

The main menu has a SET SAMPLE TIME function. Any value other than 00:00:00 will activate the real time event logger (Scheduled BIA mode) and take the BIA out of its classical BIA mode. Returning the value to 00:00:00 will restore the Classical BIA mode. The top marque of the main screen indicates the current BIA mode. When in Time Interval mode the marque will display ***Event Time: 00:00:30,*** for example, and blink each time there is an interrupt to the BIA loop. The marque in BIA Classical mode is ***Real Time (RT) BIA***. In either mode real time averaging is done with a sample time of about 500 ms for complete resistance, reactance and current source with stable 0.1 ohm resolution.

In Classical BIA mode averaging is done until the ON button is pressed. In Time Interval mode sampling continues until the BIA loop is interrupted by the alarm or the BIA is shut down manually or automatically (sample time > 20 seconds).

Actual Scheduled BIA records:

The Quantum VII saves all BIA records as CSV (comma separated values) for reformatting by most spreadsheets including Excel and Libre Office. Headers are included in the CSV file as shown on the top line below. Graphs and statistics functions are built into these office tools. The time intervals are always precise to one second.

Rec No	Date-Time	Avg Res	STD Res	Avg Reac	STD Reac	Avg PA	STD PA	N Obs	Acc X	Acc Y	Acc Z
0	09/11/22 10:28:17	499.5	0	50.0	0	5.7	0	1	-0.971	0.023	-0.208
1	09/11/22 10:28:19	499.5	0	50.0	0	5.7	0	4	-0.966	0.009	-0.145
2	09/11/22 10:28:21	499.5	0	50.0	0	5.7	0	4	-0.973	0.014	-0.151
3	09/11/22 10:28:23	499.5	0	50.0	0	5.7	0	4	-0.966	0.011	-0.172

Average Resistance (Res), Reactance (Reac) and Phase Angle (PA) with their standard deviation (STD) are also saved with the number of averaging observations (N). The longer the sampling rate the greater is N (approximately 2/sec). Acc X, AccY and Acc Z is an instantaneous measurement of the Quantum VII 3D orientation to gravity (like an airplane). In this case the instrument is hand held straight up.

This real time event file has a sampling time of 2 seconds with 4 BIA averaging samples for every record except the first record (start time). Records are saved in structured binary format for improved storage and read-write speed. An event file can have 32,768 records and must be manually reset with the **CLEAR SUBJECT DATA** menu entry.

The only method to access any record is with the WiFi feature of the Quantum VII and its website. The Local Area Network (LAN) SSID and password will have to be set for the first time for the IP address of the website to work. See SET SSID WIFI.

The menu item **ORIENTATION (G)** is a good demonstration of how the accelerometer works. The blue line on the X and Y graph always points down independent of the instruments position.

Scheduled BIA is a measurement of biological structures that have electrical conductive properties over time. The resistance, reactance and phase angle of these measurements can change for many reasons that relate to plants, animal and humans. The Quantum VII presents an opportunity to study the Calculus of BIA of these structures and their applications.

Architecture:

The Quantum VII is built around a low power Arduino NANO 33 IOT (Internet of Things) with the following features:

Micro-controller	**Low power** Arm Cortex_MO+ 32 bit SAMD21
Radio Module	U-box NINA-W102 including **Wifi** and **Bluetooth Low Energy** (BLE) for communications
32 bit Memory	256K Flash and 32K RAM with 48 Mhz clock
Inertial Measurement Unit	Measures X Y Z acceleration and gyroscope (LSM6DS3).
Power when idle (off) Power when fully on	35 micro-amps (real time clock and support) 135 ma with 2.8 inch screen full brightness
Battery HiXon 9 V 850 mAh	Lithium Ion with smart protection and CE, RoHS MSDS certified.
Declaration of Conformity CE DoC (EU). Arduino Scarmagno, Italy,	*We declare under our sole responsibility that the NANO 33 IOT is in conformity with the essential requirements of the following EU Directives and therefore qualifies for free movement within markets comprising the European Union (EU) and European Economic Area (EEA).*

BIA Specifications:

Resistance (*Range Accuracy Resolution*)	0 to 1000 Ω ± 1/2 % 0.1 Ω resolution
Reactance (*Range Accuracy Resolution*)	0 to 500 Ω ± 1.0 % 0.1 Ω resolution
Constant Current (50 Khz)	200 micro-amps RMS ± 1% (displayed)
Sampling rate	500 milliseconds (R, Xc, CC with averaging)
50 Khz Sinusoidal Oscillator	Quartz crystal controlled. No harmonics.
Subject cable capacitance compensation	Yes
Weight	250 grams (8.8 oz)
Dimensions	length 165 mm (6.5in), width 82.5 mm (3.25 in), depth 28 mm (1.1 in)

Classical BIA Mode

Sampling Time = 00:00:00

Start : Press ON

Averages: Press ON again (STD, Min-Max)

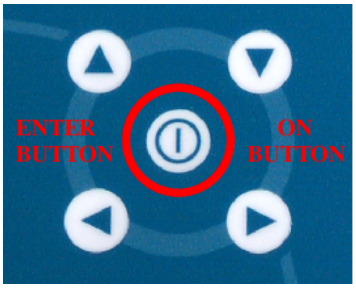
Turn OFF: Press ON again (BIA report saved)

Using the Quantum VII (Getting Started)

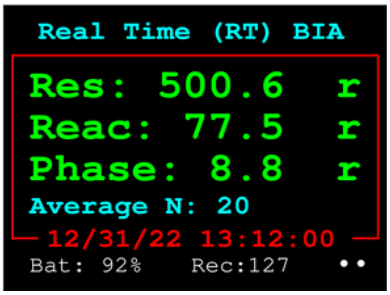
Before turning the analyzer on, prepare the subject (patient) as described in *Performing a BIA Test* page 24. Insert the subject cable into the top connector of the Quantum VII and start analyzer by pressing the middle ON button. In Classic BIA mode a splash screen will begin and take about three seconds then a green flash appears indicating there are no errors reading the calibration values. The marque starts with "**RJL SYSTEMS Q VII**" and changes to"**Real Time (RT) BIA**". The subject real time values are displayed with an increasing "Average N". Wait about 10 seconds and press the ON button again. The average N should stop counting and be about 20 meaning that BIA resistance and reactance samples have been taken and averaged along with the standard deviations (STD) and minimum maximum observations. The subject cable can now be disconnected without erasing these values. The STD and min/max values are available with the up/down buttons with marque labeling. Use the displayed average values for manual entry into the body composition program. Pressing the ON button again will save the average values as a time stamped record and shut the analyzer off.

There are many menu items that can be scrolled with the up/down buttons. To access the main menu just touch the display screen and use these buttons to select an item. See menu items and descriptions.

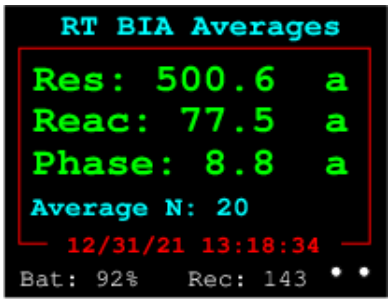
Classical BIA (Sampling Time 00:00:00) Screen Shots



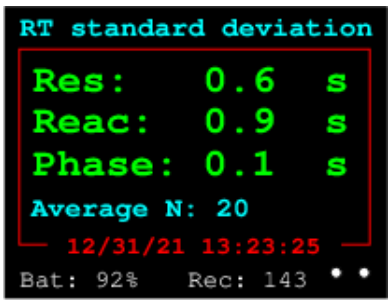
Real Time (RT) BIA



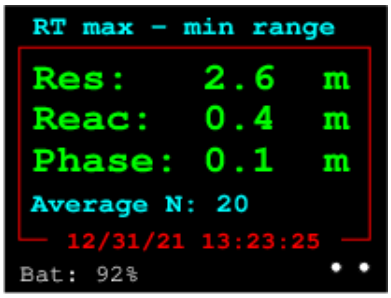
RT BIA Averages



RT standard deviation



RT max – min range



- Momentarily **pressing the ON button** starts the analyzer. The 7.4 volt Lithium Ion battery is now powering the instrument. A three second splash screen will appear, then the analyzer will display the real time resistance, reactance and phase angle of the connected subject. Notice there are small 0.1 ohm variations that are a result of breathing, circulation and motion.

- Each real time sample takes about 1/2 second. The number of actual samples are displayed below the measured BIA values (**Average N: XX)** and will continue to increase until the ON button is pressed. For example, a ten second interval will create about 20 average samples. The interval time can be any time from a few seconds to hours depending when the ON button is pushed.

- When **ON button is pressed** again the marque will change to **RT BIA Averages**. The average values of the measured resistance, reactance and phase angle are displayed along with the number of observations (N). The analyzer can now be disconnected from the subject with no change in these values. The averages are stable mean values of the subjects activities while supine.

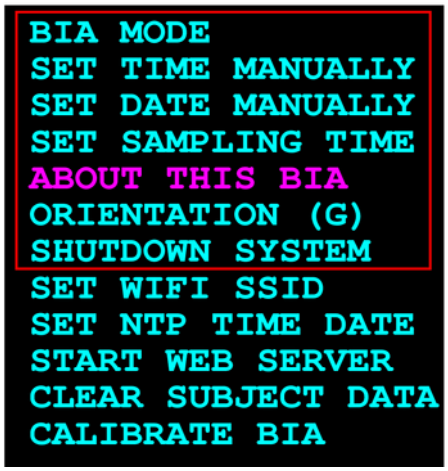
- Also available are the Standard Deviations (STD) or variance of the average observations. **Pressing the down Arrow** button will display the STD. The marque will display **RT standard deviations.** Note: The peak to peak STD are displayed (2 X ± STD). Pressing the up arrow key will toggle the average values back on the display. The applications of measuring BIA averages, standard deviations and min/max are many.

- The minimum and maximum values are also available by **pressing the down arrow again**. The marque will display **RT max – min range.** These values are maximum – minimum difference of a single maximum and minimum measurement of all the observed samples, or the extreme of the BIA observations.

- **Pressing the ON button again (second time)** will create a time stamped report with the average and standard deviation of the measured resistance, reactance and phase angle of N number of BIA observations. Then the the Quantum VII shutdown procedure starts and turns the instrument off in 2 seconds.

- The file containing the Classic BIA report records is available from the Quantum VII website.

The Main Menu



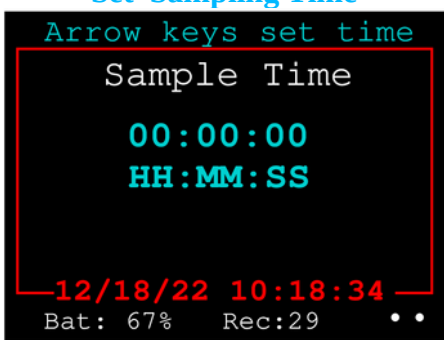
Touch the main display window and the Quantum VII menu is displayed. Use the UP/DOWN arrow keys to scroll the menu items. When the menu item color changes to magenta it can be selected by pressing the ON button and the display will change to the characteristics of the item. Touching the display window again will return the menu in most cases. When the Quantum VII is in any of its three communication modes the touch screen menu is disabled forcing the use of the ON/OFF button to turn the instrument off. This assures the BLE/WIFI radio is shutdown. The red box is the actual display window that scrolls to the other items.

There is a separate manual for the SET WIFI SSID menu item.

Set Time Manually

Set Date Manually

Set Sampling Time



Set Time Manually:

- Pressing the **left or right arrow** keys will navigate the change time line. Each number is highlighted magenta moving across the set/change time line in any direction (right - left).
- Pressing the **up or down arrow** keys will change the number up or down. The current number being edited is colored magenta. It is not required to edit all six time values. Only edit the time value that needs changing. If the time zone requires changing then just edit the hours value. Time is expressed as international time or a 24 hour clock, 1 PM is 13 hours.
- Pressing the **ON button** will save the new time in the analyzer real time clock non-volatile memory registers. A brief screen will be displayed "New Time Set" and the analyzer will shutdown.

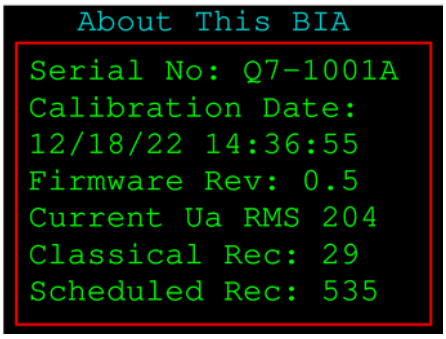
Set Date Manually:

- Pressing the **left or right arrow** keys will navigate the change date line. Each number is highlighted magenta moving across the set/change date line in any direction (right - left).
- Pressing the **up or down arrow** keys will change the number up or down. The current number being edited is colored magenta. It is not required to edit all six date values. Only edit the date value that needs changing. Pressing the **ON button** will save the new date in the analyzer real time clock non-volatile memory registers. A brief screen will be displayed "New Date Set" and the analyzer will shutdown.

Set Sampling Time:

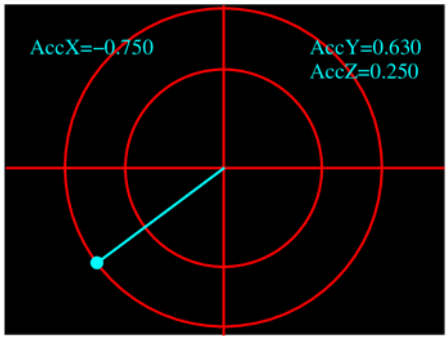
- See section **Scheduled BIA (Sampling time > 00:00:00)**

ABOUT THIS BIA



- Each Quantum VII has a unique serial number that should be referenced when calling RJL Systems for product service. Calibration values are kept on record for comparison to a new calibration procedure.
- The first firmware release of the Quantum VII is revision 0.050 dated 01/03/2023.
- The Current Ua RMS: is the actual real time 50 Khz constant current sourced to the subject (patient) and expressed in mico-amps RMS 204.
- Classical and Scheduled BIA record count is referenced and is an actual lookup of the records on the SD card that changes each time a record is deleted or appended.

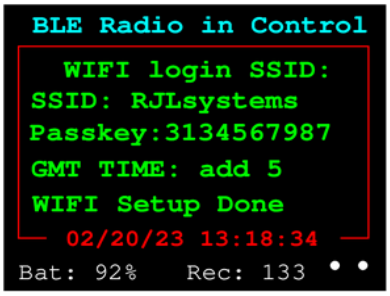
Orientation (G)



The Quantum VII is held at about 45 degrees tilted north east away from the user

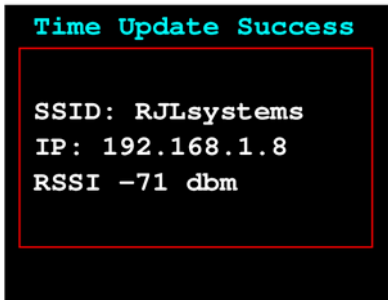
- **Orientation (G)** is the 3D position of the Quantum VII instrument with respect to gravity. The blue line and ball always points down independent of instrument position. This is a demonstration that helps define the meaning of AccX, AccY and Accz included in the Scheduled report.
- Scheduled BIA resistance and reactance observation on humans can be better understood by knowing if the subject is standing or supine by including these 3D variables.
- Orientation is also 3D position information during physical therapy by strapping the Quantum VII to an arm, leg or torso during exercise.

SET WIFI SSID



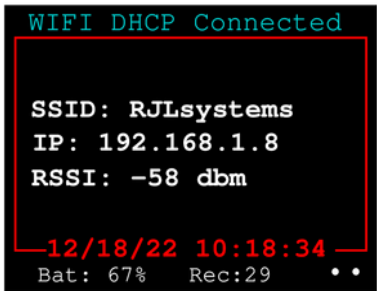
- **SET WIFI SSID** sets your local are network (LAN) WIFI DHCP IP address lookup with the BLE radio built into the Quantum VII.
- **See manual:**
  Setting up a Local Area Network WiFi connection on the Quantum VII using a Bluetooth Low Energy Terminal

SET NTP TIME DATE

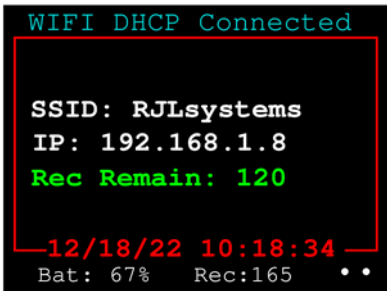


- **SET NTP TIME DATE** automatically retrieves internet time and date from *time.nist.gov* and sets the real time clock and calendar. The Dynamic Host Configuration Protocol (DHCP) address is automatically selected from the local area network to establish the connection. The time and date are GMT and corrected with the time zone info (New York add 5 EST). The SSID, LAN IP address and signal strength are displayed for a few seconds then changes to **Time Update Success** before displaying the new time and date and then shuts down.
  This is a good test to check the SSID and PASSKEY setup. “Connection failed” is displayed if there are problems with the setup.

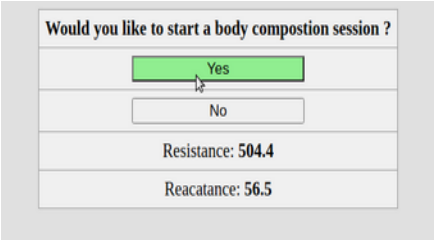
START WEB SERVER



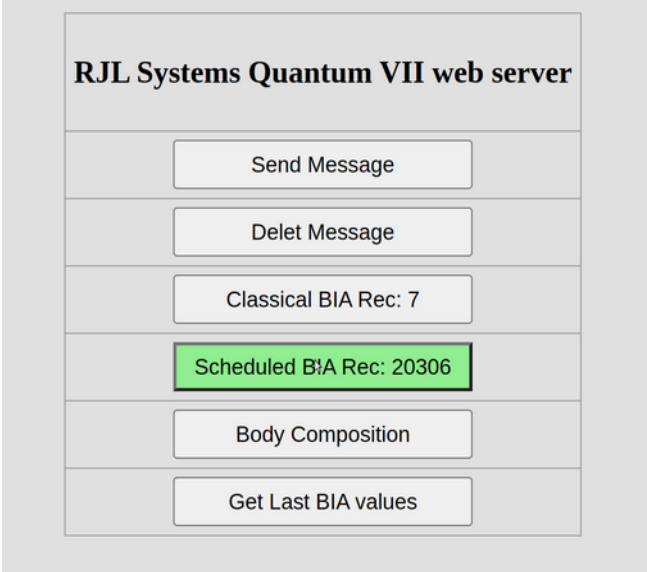
Records Remaining Counter



The records remaining counter are the number of records remaining to be downloaded to the web browser. The counter continuously decreases at a rate of about 10 records / second with an average WiFi connection.



- **START WEB SERVER** by using the assigned LAN IP address on the display. Using any browser that is connected to the same LAN displays a menu of services featured in the Quantum VII. On the top line of the browser enter http://192.268.1.8, for example. A menu with the following items will appear. Do not use the browser search tool.



- Send and Delete Message demonstrates that the internet connection is working. The message “Hello from client” will appear on the Quantum VII screen and be erased when the Delete Message button is pushed

- The Classical or Scheduled BIA records can be selected for viewing in CSV format on a new browser tab. These records are easily saved for analysis with any spreadsheet program. Note the Scheduled BIA records have 20,306 records. This will take about a few minutes to download depending on the WiFi connection. An example of Classical and Scheduled file records are in appendix A.

- Body Composition will link the Quantum VI to Interatctive BIA on the RJL Systems website. The last measured resistance and reactance values of the subject are displayed to help with the analysis.

Scheduled BIA Mode

Sampling Time > 00:00:00

More than 2000 saved records / battery charge

Start BIA logging : Press ON quickly

Management: Press ON for > 2 seconds

Averages : Press ON again (STD, min-max) last reading

Turn completely OFF: Press ON again

Scheduled BIA data logging:

The timekeeping device has an alarm that can be programmed to interrupt the BIA loop to store the current time and BIA values as a record on the 8 GB SD card. The alarm is programmed in standard time as HH:MM:SS with a minimum time of 2 seconds and a maximum of 23 hours (1 sec resolution). Each time an alarm (interrupt) is triggered and a new alarm time is set with the current time plus the alarm time. This standard feature records BIA values over time from 2 seconds to months on a single battery charge. Any programmed event time over 20 seconds will automatically turn the BIA off and wait for a new alarm to wake the BIA up again for 5 seconds to save a new record with updated average BIA values. A one hour (24 samples / day) will allow a BIA experiment to last for 3 months since there is over 6 hours of battery life when continuously running.

Starting and stopping the real time scheduler:

Starting:

When **SET SAMPLE TIME** is greater than zero the scheduler is active. It is always started by press the ON button momentarily when the Quantum VII is OFF. That gives the user a chance to set up an experiment (relocate the analyzer and connecting leads) before scheduling BIA observations. It is a good idea to start the scheduler at a time that is convenient, such as the second and minute hand on a watch, to know when it will turn back on.

Stopping:

The scheduler is stopped (interrupted) by pressing the ON button for two (2) second or greater. This will allow menu items to be selected such as starting the built in web server and downloading the saved records.

Notes:

- The main menu has a **SET SAMPLE TIME** function. Any value other than 00:00:00 will activate the real time event scheduler and take the BIA out of its classical mode.
- Returning the value to 00:00:00 will restore the classical BIA mode.
- The top marque of the main screen indicates the current BIA mode. When in scheduled mode the marque will display **Event Time: 00:00:30**, for example, and blink each time there is an interrupt to the BIA loop. In classical BIA mode the marque is **Classical RT BIA.**
- In both modes real time averaging is done with a sample time of about 500 ms for complete resistance, reactance, current source with 0.1 ohms of stable resolution.
- In classical BIA mode sampling and averaging is done until the ON button is pressed.
- In scheduled BIA mode sampling and averaging continues until the BIA loop is interrupted by the alarm (event) or is shut down manually.

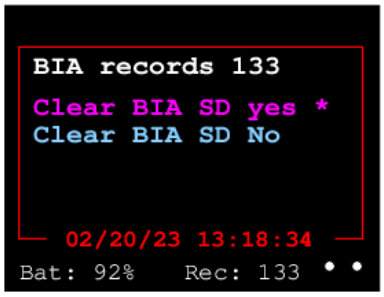
Two (2) Minute scheduler sampling time report.

RecNo	Date-Time	Avg Res	STD Res	Avg Reac	STD Reac	Avg PA	STD PA	N	Acc X	Acc Y	Acc Z	CCUa
0	04/15/23 18:54:27	1006.7	0.1	304.9	0	16.9	0	6	-0.1042	0.6238	0.7551	203.8
1	04/15/23 18:56:27	1006.7	0	304.7	0	16.8	0	6	0.0305	-0.0046	0.999	203.8
2	04/15/23 18:58:27	1006.7	0	304.7	0	16.8	0	6	0.0316	-0.0045	0.9976	203.8
3	04/15/23 19:00:27	1006.7	0	304.7	0	16.8	0	6	0.0303	-0.0048	0.9974	203.8
4	04/15/23 19:02:27	1006.8	0	304.7	0	16.8	0	6	0.0311	-0.0048	0.9998	203.8
5	04/15/23 19:04:27	1006.8	0	304.7	0	16.8	0	6	0.0304	-0.0046	0.9988	203.8
6	04/15/23 19:06:27	1006.8	0	304.7	0	16.8	0	6	0.0303	-0.0045	0.9983	203.8
7	04/15/23 19:08:27	1006.8	0	304.7	0	16.8	0	6	0.0293	-0.0048	0.9991	203.8
8	04/15/23 19:10:27	1006.7	0	304.7	0	16.8	0	6	0.0308	-0.0049	0.9988	203.8
9	04/15/23 19:12:27	1006.7	0	304.7	0	16.8	0	6	0.0302	-0.0049	0.9995	203.8

Acc X,Y and Z is an instantaneous measurement of the Quantum VII orientation to gravity (like an airplane). In this case the instrument is laying flat on a table (notice motion vibations). Average Resistance (Res), Reactance (Reac) and Phase Angle (PA) with their standard deviation (STD) are also saved with the number of averaging observations (N). The longer the sampling rate the greater is N (approximately 2/sec). A 1000 ohm resistor and a 5 % 0.01 capacitor are used as subjects, therefore, the standard deviation (STD) are 0. CCUa is the actual subject current in 50Khz microamps (Constant Current MicroAmps)

This scheduled BIA file has a sampling time of 2 minutes with 6 BIA averaging samples for every record. Records are saved in structured binary format for improved storage and read-write speed. An event file can have 32,768 records and must be manually reset.

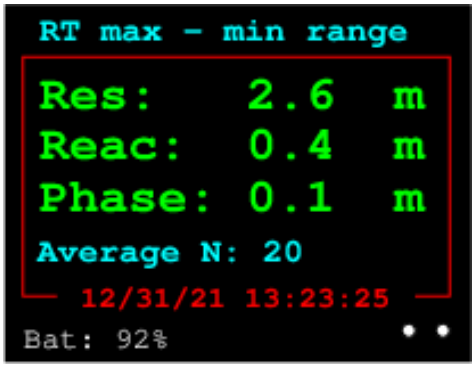
CLEAR SUBJECT DATA



- Two separate files are created for each Standard BIA and Scheduled BIA mode. These files contain all the samples for each mode and are located on the SD card. The only way to deleted these files are with the **CLEAR SUBJECT DATA** menu item.
- The Quantum VII must be in one of the two modes to clear the relevant file. If in the Classic BIA mode only these records are indicated and cleared. In Sheduled BIA mode only those files are cleared.

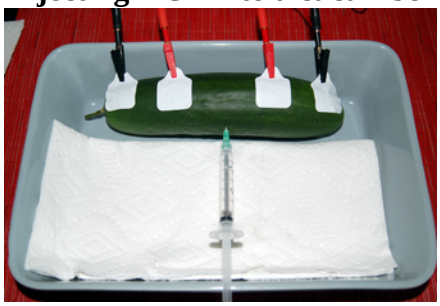
The only method to access any record is with the WiFi feature of the Quantum VII and its website. The Local Area Network (LAN) SSID and password will have to be set for the first time for the IP address of the website to work. See **SET SSID WIFI** as a seperate manual.

Marquee: RT max – min range

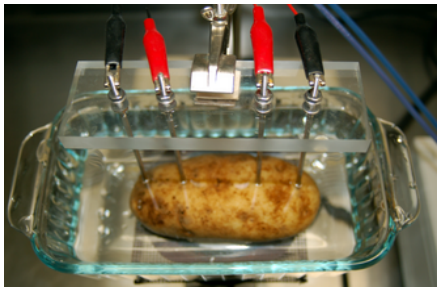


Typical BIA Measurement

Injecting KCL into a cucumber



Boiling a potato with BIA



- The range (maximum – minimum) of each BIA variable is available by **Pressing the Down Arrow** button again. The marque will display **RT max – min range**. Pressing the up arrow key will toggle the average values back. BIA range is not a statistical function like standard deviations are, but a measured maximum – minimum value during a period of time. Subject (patient) restlessness, motion, exercise and bad electrodes will greatly affect this value. Care should be taken to make sure the subject is quiet and comfortable to minimize the range of resistance and reactance during a BIA measurement period.
- The usefulness of the Quantum VII as a research tool in studying body composition changes due to digestion, exercise and forced motion are many. For example, a 15 minute study after eating a salty lunch would make a significant change in the standard deviation and max-min range values.

- Experiments with animals and plants are also possible with the Quantum VII since the BIA design is identical to all RJL Systems BIA analyzers.

BIA and Vegetables.

- A good demonstration of how BIA works can be illustrated with a cucumber. Using human electrodes where the distance between the detecting electrodes is 50 mm the amount of KCL solution injected can be recovered using historical BIA formulas. BIA resistance decreases proportionately (more volume) with each injection.

- Temperature has a large effect on vegetables. For example, a potato has a phase angle above 30 degrees at room temperature because of its cellular structure. However, when the potato is frozen or boiled all the cells are destroyed and phase angle is zero and will not recover when returned to room temperature.

- The Quantum VII is an ideal instrument for these experiments by observing the real time resistance, reactance and phase angle changes over time. The Quantum VII can be applied to almost anything living or dead.

RJL Systems
Standard Manual Entries

- **Care of the analyzer and cables**
- **Using the test resistor**
- **Subject preparation and test protocol**
- **Electrode Placement**
- **Trobleshooting Guide**
- **Standard Warranty**

Proper care of the analyzer and cables

RJL analyzers are built to last. Many RJL instruments built over 20 years ago are still being used today. The instruments we design and build are subjected to our rigorous quality assurance testing procedures. Like all sensitive electronic instruments, proper care and handling will minimize the risk of damage.

CLEANING & SANITIZING ANALYZER & CABLES

1 Make a solution of one part Hydrogen Peroxide to four parts water. Dampen a clean cloth with the solution and *gently* wipe the cables and the exterior of Analyzer's plastic casing as needed.

2 Never immerse cables or Analyzer into any liquid cleaning solution or use "spray on" cleaners

3 If an environmental hazardous material incident occurs, "Haz-Mat Protocol" at the site would determine exposure levels and if sterilizing all surfaces is mandated. There is no known method of adequately sterilizing the cables or Analyzer that would not cause damage to the units.

Disassembly of the analyzer – Never remove the protective plastic enclosure of the Analyzer. Doing so can damage the static-sensitive electronic components inside and **will cause calibration issues.**

Handling - Handle the Analyzer carefully. The Analyzer can be damaged by rough handling (i.e. shaking or being dropped). The cables can be damaged if stepped on, crushed, tied in knots, pulled on, etc. Always use caution when connecting and disconnecting them. Never try to "yank" the cables off the back of the Analyzer, always disconnect them by grasping and pulling on the connector that attaches the cables to the back of the unit. Do not use rubber bands to gather up the cables; keep them loosely coiled in the protective pouch provided.

Liquids - Keep liquids away from the Analyzer – spills or immersion in fluids can permanently damage the sensitive electronic components. Damage by immersion in liquids is NOT covered by warranty.

Storing - For optimum protection, store the equipment in the carrying case provided by RJL.

Temperature - If the Analyzer is exposed to cold temperature and brought into a warmer temperature, allow any condensation on the instrument to dry before testing. As a general rule, exposure to cold or hot temperatures does not cause damage or erratic test results - however, condensation can impair testing performance.

Testing the analyzer and cables - Test the equipment occasionally.

Transporting/shipping- The RJL carrying case was designed to protect the Analyzers and accessories while being transported or shipped. If the equipment is being shipped, pack the carrying case in an appropriate shipping container, mailing labels may not adhere well to the textured plastic surface of the case.

Subject cables information

Attaching and disconnecting the cables

Always grasp the plastic connector hood to connect AND disconnect cables from the Quantum VI to avoid damage to the cable's internal wires.

Why is testing subject cables important?

- Subject cables will last a long time if used and stored properly – testing assures they are in good condition.
- Damaged cables can cause erratic test results, resistance and reactance numbers that don't look "right" or are "jumping around".
- If the wires inside the cables are broken, they can not be fixed. The cables will need to be replaced.
- Test Resistors are supplied with every Analyzer - cables can be tested before BIA testing is done.
- RJL Systems will supply additional Test Resistors at no charge other than a shipping fee.
- Replacement cables can be purchased from RJL and shipped via "overnight" delivery if necessary. It is a good idea to purchase a spare set of subject cables and keep them in storage to prevent damaged cables from making the analyzer unusable.

How do I avoid damaging the cables?

- Handle cables gently! Don't fold them, use rubber bands around them, tie them in knots, step on them, roll over them with furniture, pull on them, etc.
- Store them loosely coiled in the protective zippered pouch provided in the Analyzer kit.
- Disconnect the cables from the analyzer by gently pulling on the connector that plugs into the analyzer. Do not pull on the cables themselves.
- Do not immerse the cables in liquids - if electrode residue or other grime accumulates on the cables or clips, clean them with a cloth moistened with rubbing alcohol. For general cleaning, we recommend a solution of (1) part hydrogen peroxide to (4) parts water. Dip a clean cloth into the solution and gently swipe the cables and clean the clips.

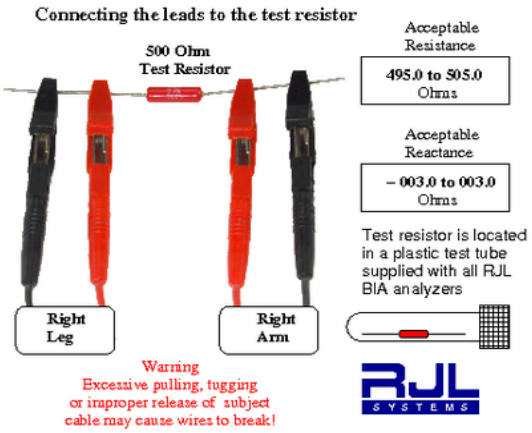
How often should cables be tested?

- If testing protocols do not dictate how often testing needs to be done in order to validate BIA data, testing intervals can depend on numerous factors. As a practical guideline, test the cables if they are were possibly subjected to improper handling, were stored away, or exterior damage to cable or clips is evident.
- If there is a heavy testing period scheduled, i.e. a health fair, research study or if instruments will be used while traveling, it's a good idea to test the cables in advance so if needed, new ones can be ordered and received in a timely manner.
- If different technicians use the same analyzer, it is a good idea to test them often.
- Testing does not damage the analyzer or cables, test the cables as often as needed.

Using the test resistor to check the analyzer and cables

1. CONNECT THE CABLES TO ANALYZER & TEST RESISTOR

1 Turn the analyzer "ON" and allow a few seconds for it to initialize. If the battery is low, a message will display and the analyzer will turn itself off after 10 seconds.
2 Attach the cables to the analyzer.
3 Remove the test resistor from its protective storage tube.
4 The test resistor looks like a capsule with a wire coming out of each end. Connect the two clips from cables tagged as "HAND" to one side of wire (doesn't matter which side) with red clip next to the resistor as shown on diagram below
5 Connect the two clips from cables tagged as "FOOT" to the wire on other side of the resistor, with red clip next to the resistor
6 Do NOT hold the test resistor during testing, lay it on flat surface or hold the leads and let the test resistor dangle, instead.



2. Test the Analyzer

Resistance measurement…… *acceptable* range is 495.0 to 505.0 ohms (500.0 is ideal)
Reactance measurement…… *acceptable* range is -003.0 to 003.0 ohms (0 Is ideal)
Readings within these ranges indicate the Analyzer is in good working order.

3. Test the Cables

Leave all clips attached to the test resistor and set the analyzer down. Flex the cables (almost any type of "flexing movement" of the cable will work) starting at one end of the cable, continuing along the entire length of the cable. While doing this, watch the **Resistance** value on the display.

No changes in the readings…….Cables are in good working order.
Slight changes: (within ± 2 ohms):……...Cables are acceptable for testing.
Major changes: (exceeding ± 2 ohms):…...Cables are indicating problems (broken wires, etc) and should be replaced. Contact RJL Systems to order a new set.

If either test fails, or you have questions about the results please call RJL Systems Technical Support. Note: Have your readings available or be prepared to run the test(s) again while an RJL technician is assisting you on the phone.

Preparation for subject testing

(WHAT TO DISCUSS WITH SUBJECT PRIOR TO TESTING)

Subjects who do not adhere to the pre-testing protocols
Failure to adhere to the pre-testing protocols described on the next page could alter the way the body interacts with the electrical signal of the BIA. This could alter the body's resistance and reactance, which would result in altered body composition estimates produced by the software. If an individual is unable to adhere to the pre-testing protocols, they should be as consistent as possible from test to test. If they always do the same things before being tested, they should have the same effects on the body's electrical properties. As a result, while all of the estimated results would be offset from their actual values, the amount of offset should be consistent. This means that you would still be able to track upward and downward trends in their body composition.

PREGNANCY
The FDA recommends against BIA testing on pregnant women because any possible effects on the fetus are still unknown by the FDA at this time. In addition, BIA testing would not be able to distinguish between the mother, fetus and amniotic fluids.

IMPLANTED ELECTRONIC DEVICES
Testing should be avoided on a subject with implanted electronic devices such as pacemakers or cardiac defibrillator (ICD's). BIA Analyzers introduce a small amount of alternating (AC) current into the body that may interfere with such devices.

METAL SURGICAL IMPLANTS
Test results may not be accurate on subjects with surgically implanted metals such as pins, rods, or joint replacements. If these metals are present on only one side of the body, use the other side when testing.

AMPUTATED LIMBS
BIA testing on subjects with amputated limbs may be performed if amputation is on one side of the body - use the other side for testing. The prediction equations used by the BC software assume that the person has not had either an arm or leg amputated. Expect the possibility the data cannot be accurately analyzed using BC software.

DIAGNOSTICS/TREATMENTS
BIA testing is not intended to diagnose a disease or treat a medical condition.

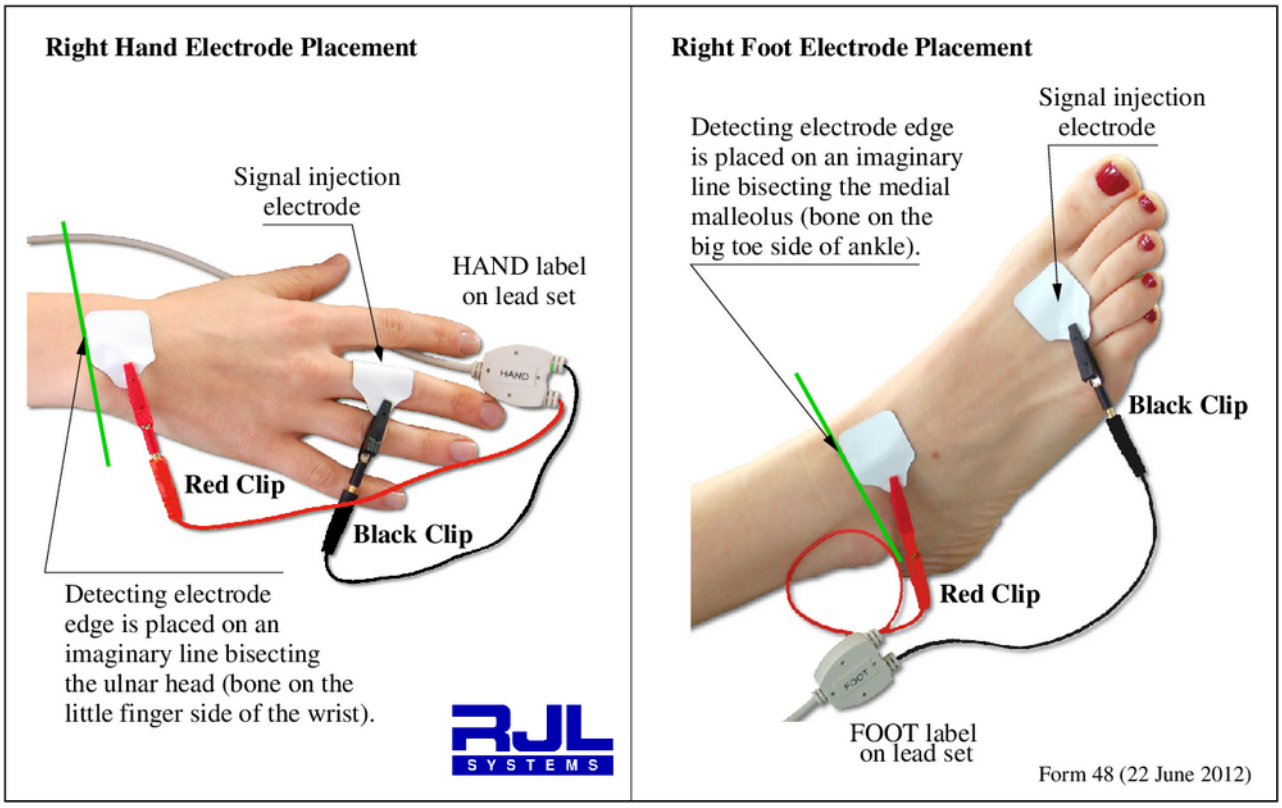
RISK OF ELECTRICAL SHOCK
Subject will <u>not</u> feel an "electrical shock" when tested, the amount of current is very small. RJL Analyzers have isolation transformers that prevent any harmful current from being exposed to the subject while being tested.

TESTING - HOW LONG IT TAKES
Depending on the proficiency of the technician, the actual test can take less than a minute. BIA analysis can be performed and results printed out afterwards if technician has access to computer and printer.

Pre-testing protocol for the subject

- Explain testing procedures to the subject and address any questions or concerns prior to testing.
- Name, gender, age, height, weight, and side of body being tested should be recorded. If exceptions to Testing Protocol are evident (i.e. subject tested sitting up due to wheelchair use) record the exception in the database record in the comment field, and test that individual in consistent manner every time.
- Testing area should be comfortable and free of drafts.
- The subject should, ideally, be tested laying down.
- The exam table surface must be non-conductive (not metal) and be large enough for the person to lay down flat, legs not in contact with each other, and the arms at approximately a 30 degree angle to the body.
- The legs should be separated and the arm being tested should be away from the body. The goal is to avoid skin-to-skin contact between the thighs and between the arm and the body. If this can not be achieved, use clean, dry towels or sheets to provide a non-conductive barrier.
- The subject should not be damp from sweating, have a fever, be in shock or feel cold/chilled.
- Wipe area where electrodes will be placed with an alcohol swab if lotion has been used, or subject has very dry/oily skin. Use of alcohol skin swabs is recommended at electrode sites for general hygiene purposes as well.
- The subject should avoid moving during testing.
- If testing is being done at regular intervals with the same subject, always ask subject if any changes have occurred, such as pregnancy or surgical implants, or if there have been any significant changes of their daily routine, especially compared to the date of the previous test.
- Strenuous exercise or saunas within 8 hours of testing is not recommended, as both activities can affect hydration levels.
- Refrain from drinking alcohol for 12 hours prior to testing (also a hydration issue).
- Jewelry on the arms, ankles, and body (i.e. bracelets, watches, dangling necklaces and chains) should be removed from side being tested. Earrings and rings are okay to leave on.
- Shoes, socks (or nylons) on the side used for testing should be removed.
- Eating food or drinking fluids prior to testing will *not* affect the test results if taken in moderate amounts.

Performing the BIA test



FOLLOW INSTRUCTIONS ON "PREPARATION FOR TESTING" BEFORE ANY TESTING IS DONE

1 Attach the electrodes as illustrated above – place the clips of the cables on the non-adhesive TAB of the electrode.
2 Ask subject being tested to remain quiet while testing is done.
3 Attach the subject cable to the top of the Quantum VI Analyzer.

HELPFUL HINT: THE RED CLIPS ARE ALWAYS PLACED "CLOSEST TO THE HEART"**.**

- **HAND leads** **black clip/ on finger** **red clip/ at wrist**
- **FOOT leads** **black clip/ by toe** **red clip/ at ankle**

1 Turn the Analyzer ON by pressing the (|) button.
2 The RJL Systems initial splash screen and a green flash will appear. After ten seconds the N count will start counting. The analyzer is now recording resistance, reactance and phase angle values. This will continue until the ON button is pushed. The run time could be from seconds to hours.
3 Pressing the ON button gently down will freeze the average, standard deviations, and range values. The **average** displayed resistance and reactance numbers are available for your body composition software. All values for each test are time stamped and saved internally.
4 Detach the clips, and gently remove the electrodes - being careful to not injure the skin .
5 Use BC software for analysis and printing reports.
6 Pressing the ON button again will turn the analyzer off.

Troubleshooting Guide

Possible causes of STRANGE TEST RESULTS OR ERRATIC RESISTANCE/REACTANCE DISPLAY:

- A malfunctioning analyzer or broken/damaged subject cables (see "Using the Test Resistor to Test Analyzer/Cables).
- Expired electrodes. RJL electrodes have an average shelf life of approximately 15 months. Check expiration date on the back of the packaging. If electrodes are gooey from heat exposure, dry, or smell "funny" do not use them! They can cause unusual readings if not adhering to skin properly.
- Cable clips placed on electrodes incorrectly or in reversed order see "Performing the BIA Test".
- Do not reuse electrodes. Discard the used electrodes after each test.

EQUIPMENT ISSUES:

- Analyzer keeps shutting itself off. Most likely, the battery is weak and needs re-charging. The analyzer will shut itself off after 10 seconds if battery is low. The analyzer will also turn itself off if the idle timeout is exceeded.

TESTING PROTOCOL:

- Subject is laying on a conductive (metal) table while testing see "Pre-Testing Protocols".
- Subject has very dry/oily skin or has used lotion where electrodes are placed. Use an alcohol swab to clean the area(s), let dry, and use fresh electrodes
- Technician did not get accurate pre-test information from the subject or neglected to ask about issues that may affect testing, like metal implants

SUBJECTS:

- Subject did not follow pre-testing protocol and/or subject did not provide accurate information to technician see "Pre-Testing Protocols
- Testing when the protocols have not been followed can cause inaccuracies in the estimated body composition results. However, if the deviations from the protocol are going to be consistent with every test, the impact of those deviations will be consistent as well.

DATA ENTRY ERRORS:

- Gender entered incorrectly – male vs. female
- Numbers transposed – 158 vs. 185
- Height entered as feet and inches, instead of actual inches – 5'6", listed as 56" instead of 66"
- Height or weight entered as "English" units when the software is set is for "Metric" – or vice versa
- Testing results for an individual entered in incorrect existing "similar name" patient record
- Cannot find prior test record for subject – check if record is in a different database if multiple databases are set up. Also check for misspellings of the subject's name.
- Wrong equation set used – i.e. pediatric equations used on an adult.

RJL Warranty information

RJL warrants its Bioelectrical Impedance Equipment against defects in materials and workmanship for a period of twelve (12) months from the date of shipment if the Equipment is in the possession of the original user and has been subject to normal operating conditions. RJL will, at its option, repair or replace FOB its factory in Clinton Township, Michigan, any Equipment which, upon its examination, is determined to be defective in workmanship or materials. RJL's determination shall be final. RJL assumes no responsibility for reimbursing Customer for repair or replacement costs incurred without RJL's prior authorization.

RJL warrants that its Software will confirm to its Software description applicable at the time of order for a period of twelve months from the date of shipment, if the Software is in the possession of the original user and has been subject to normal operating conditions. RJL will, at its option, confirm or replace FOB its factory in Clinton Township, Michigan, the Software that, upon its examination, is determined to be defective. RJL's determination shall be final. In the event RJL shall give written notice to Customer of any updated or revised software material and Customer fails to forthwith use the same, RJL shall be released from any and all liability related to or resulting from Customer's disregard of such notice.

THE WARRANTIES STATED HEREIN ARE EXCLUSIVE AND COMPRISE RJL'S SOLE AND ENTIRE WARRANTY OBLIGATIONS AND LIABILITITES IN CONNECTION WITH THE EQUIPMENT AND SOFTWARE SOLD AND LICENSED HEREUNDER, AND ARE IN LIEU OF AND EXCULDE ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, ARISING BY OPERATION OF LAW OR OTHERWISE, INCLUDING, BUT NOT LIMTED TO, WARRANTIES OR MERCHANT ABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

LIMITATION OF LIABILITY

RJL SHALL NOT BE LIABLE FOR ANY SPECIAL, INDIRECT, INCIDENTAL, ECONOMIC OR CONSEQUENTIAL DAMAGES ARISING OUT OF ANY BREACH OR WARRANTY, EXPRESSED OR IMPLIED. CUSTOMER'S SOLE REMEDY FOR ANY SUCH BREACH OF WARRANTY SHALL BE THE REPAIR OR REPLACEMENT OF THE EQUIPMENT OR SOFTWARE.

HOW TO MAKE A WARRANTY CLAIM:

The customer should notify RJL of a warranty claim at (800) 528-4513. Please provide the model and serial numbers of the unit, date of purchase, warranty period, and description of the defect. If RJL requests, the Customer will, at its own expense, deliver the equipment in appropriately protective packing to RJL Systems. RJL Systems will pay for the return shipping expense

WHAT IS NOT COVERED:

Accessories are not covered under this warranty. Warranty terms do not apply if repairs/replacement are needed due to customer using the device improperly, physical damage caused by neglect/abuse, or if instrument is disassembled by the customer.

For Analyzers not purchased directly from RJL Systems, contact your service provider for further information.

If the Analyzer is not working properly, please contact RJL Systems Service Department for assistance before shipping the unit back for diagnostic evaluation.

If problem cannot be resolved over the phone, a Return Merchandise Authorization (RMA) number will be issued.

IF REPAIR IS NEEDED:

RJL Systems requires that an RMA # be issued prior to shipping a unit to us for diagnostic evaluation. RJL Systems cannot assume any responsibility for instruments sent without prior authorization.

Customer is responsible for all shipping costs – including insurance if desired - both to and from RJL Systems.

If the Analyzer is a discontinued model, RJL Systems will advise if repair parts for the unit can still be obtained and at what cost

After RJL Systems receives and performs a diagnostic evaluation on the unit, we will contact the customer with a repair estimate (labor and parts) before proceeding with service. The customer must agree to these costs before any work begins

Cost of the repair service must be paid in full before the unit is shipped back to the customer

If repairing the Analyzer is not cost-effective, RJL Systems will provide assistance with selecting a new unit if customer wishes to purchase a replacement

RJL Systems' Service policy guarantees the repair for up to one year.

SHIPPING INSTRUCTIONS

Write the RMA number on the outside of the shipping box

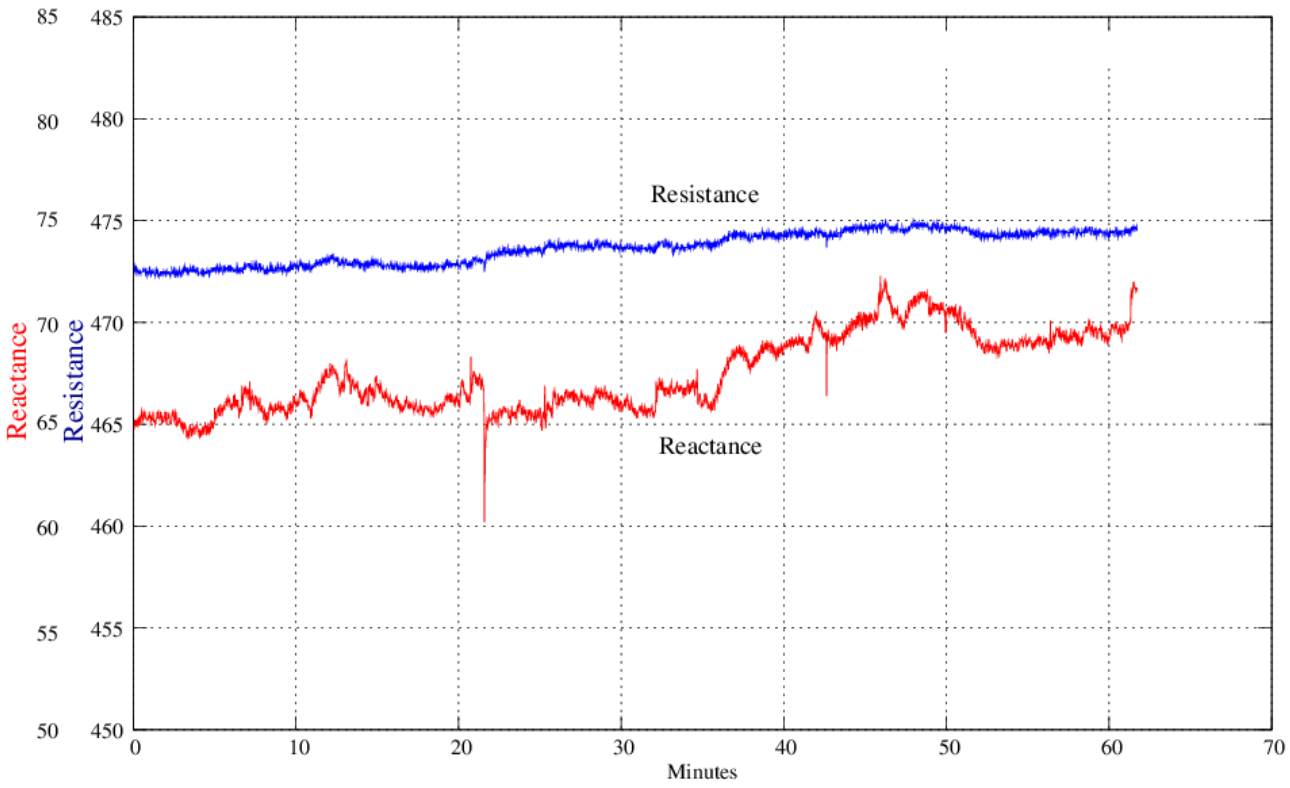
ALWAYS include the subject cables with the shipment so entire system can be evaluated.
Place the Analyzer in its protective carrying case, and then pack it into a shipping container. Shipping labels may not adhere well to the textured plastic surface of the carrying case

We suggest placing identifying papers (letterhead, business card etc) inside the case with the instrument. This will ensure that the shipper can trace the origin of the package in the rare instance that damage to the container or it's shipping label occurs

Appendix A

Scheduled Quantum VII sampling of whole body

with no liquids of food consumed



One hour real time monitoring of a whole body BIA

32 year, 222 lb, 77 inch male measured in the morning before showering or any daily activity