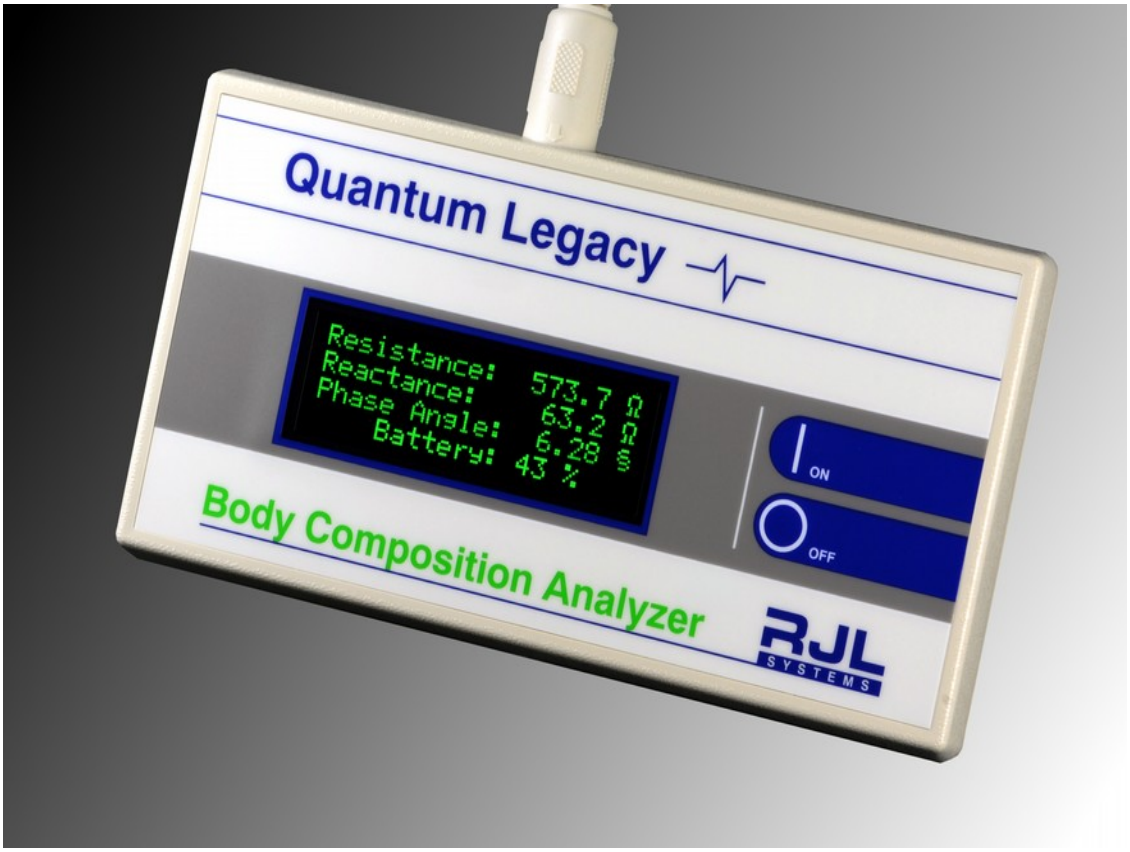
RJL Systems introduces the Quantum Legacy

QUANTUM LEGACY

Bioelectrical Impedance Analyzer

USER'S MANUAL



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Manual Last Revised
July 12 2019

About Us – RJL Systems

RJL SYSTEMS WAS THE FIRST COMPANY TO DEVELOP THE USE OF BIOELECTRICAL IMPEDANCE ANALYSIS (BIA) TO ASSESS HUMAN BODY COMPOSITION BY ENGINEERING THE “GOLD STANDARD” OF BIA INSTRUMENTS IN 1981. RJL ANALYZERS PROVIDE BIA MEASUREMENTS FOR USERS AROUND THE WORLD – THEY ARE RECOGNIZED AS “RESEARCH QUALITY” BECAUSE OF THEIR REPUTATION FOR ACCURACY AND RELIABILITY.

RJL has registered patents on our instruments, trademarks, and copyrights on our software and papers. Customers are buying products directly from the company that develops, engineers, and manufactures the analyzers – NOT a third party vendor or distributor.

RJL’s Quantum Analyzers have FDA clearance as a Class II medical device for safe use on the human body to collect BIA data. RJL is registered with the FDA as a Medical Device Manufacturer (Registration No. 1831675). The Quantum Legacy BIA System and accompanying software are marketed under the following FDA clearances: K830292C, K862383, and K070999.

RJL Systems is registered as an ISO-13485 2016 compliant company.

RJL instruments go through a rigorous testing, calibration and inspection process that complies with ISO standards. Conformity of products and services to International Standards provides assurance about overall product quality, safety, reliability and accuracy

Any questions or technical support needed regarding our products will be handled by the professionals who designed and built the analyzers, and the related software

The Company’s 30+ years of engineering expertise and knowledge in BIA science make it uniquely qualified to provide custom-made instruments of any size or scope

If you sign up for the e-mail newsletter (via website), you will receive information on interesting new developments in the field of BIA science and/or RJL products

All RJL products come with a warranty and continued technical and product support.

Quantum Legacy System Kit Contents

- Quantum Legacy Analyzer
- Subject cables with protective pouch
- Test resistor in protective plastic tube and laminated “How To” cable testing card
- Two (2) Stay Fresh Packs of electrodes (400 total electrodes)
- Quantum Legacy User’s Manual and video (thumb drive)
- BC (Body Composition) Software and User's Manual (thumb drive)
- Carrying Case

Overview of the Quantum Legacy

- The Quantum Legacy is extremely accurate and easy to use with an enclosure that has a comfortable ergonomic design. It operates from a single 9 volt alkaline battery and can perform hundreds BIA tests on single battery.

- The Quantum Legacy precisely measures and displays resistance, reactance and phase angle at 50 Khz with 0.1 ohms of resolution. It has the same accuracy and repeatability as the Quantum IV.

- BC software is included with the Quantum Legacy. Resistance and reactance data from the instrument is manually entered into BC.

Features of the Quantum Legacy

ON/OFF buttons

Pressing the on button:

- Turns the analyzer "ON". The replaceable 9 volt alkaline battery is now powering the instrument.
- Holding the ON button for three (3) seconds will enable the language selection menu where English, Spanish, French or Italian can be selected as the operating language throughout the instrument.

Pressing the off button:

- Disconnects the 9 volt battery from the instrument.
- If cables are disconnected from the electrodes on the subject or the test resistor, the analyzer will also automatically turn itself off with a 10 second count down.

9 Volt Alkaline Battery

The Quantum Legacy uses a single common 9 Volt alkaline battery. Battery life is over two hours with continuous use. This means 100's of BIA tests can be performed with a single battery.

Percent battery remaining is continuously display on the LCD display. It is safe to operate the Quantum Legacy with 1 percent of battery life remaining. Once a low battery is detected, the instrument will automatically shut off with a 10 second count down.

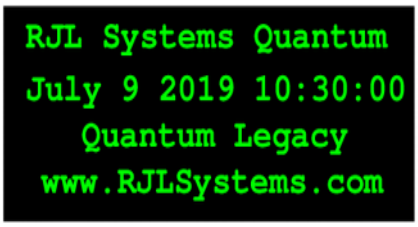
Environment temperature

The Quantum Legacy is designed to greatly reduce the effects of hot and cold environment temperatures on the test measurements. There is less than a one percent change of full-scale resistance and reactance from -20 to 60 degrees centigrade. Therefore, the instrument can be used in desert, arctic, and high altitude studies without concern of degrading accuracy and reliability.

Understanding the display screen

When the Quantum Legacy is turned ON this is what happens:

About: After the Quantum Legacy has initialized, this screen will appear. This screen displays the name of the analyzer and the version of the firmware program running on it. If you ever have to call for support, you will be asked for this information.



This screen is displayed only for a few seconds before displaying the BIA readings. You may press ON to go to the main menu, instead.

BIA Readings:

After a few seconds, the analyzer will switch to the BIA Readings screen. If the subject cables are connected to both the Quantum Legacy and the test subject, the actual measured electrical properties will be displayed.

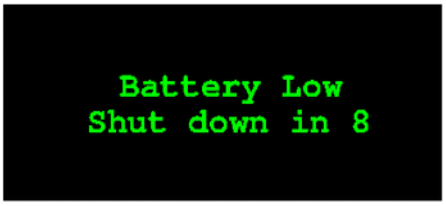
Press ON to go to the main menu.

If this message displays instead of the BIA readings, either the subject cables are not attached to the analyzer, or one or more clips is disconnected from the subject. The Quantum Legacy will automatically turn itself off sooner if it is left on with this message displayed than any other screen.

Press ON to go to the main menu.

Please Note: If the analyzer's battery power is low:

When the batteries' charge is low enough to possibly affect the accuracy of the resistance and reactance readings, this message is displayed. The Quantum Legacy will not respond to any button presses (except OFF) and will not display any readings until the battery has been charged.



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.

Batteries

1) If battery is low, the analyzer will display a message for 10 seconds and turn itself off.

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 Legacy 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.

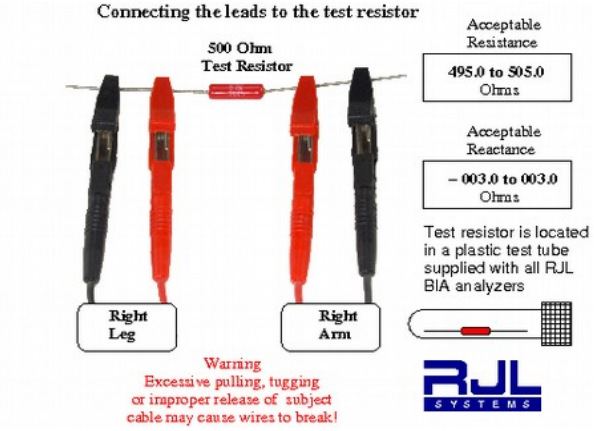
How often should cables be tested?

- 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.

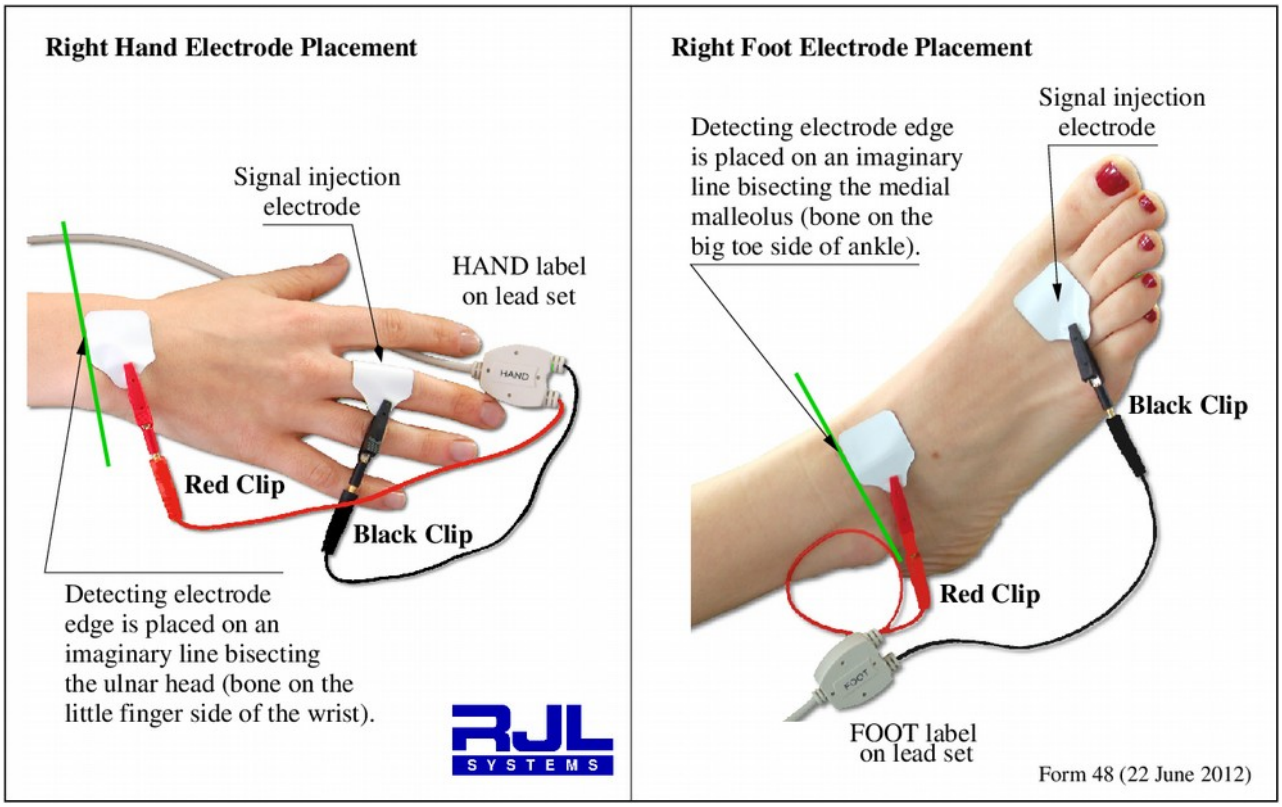
Risk of electrical shock
Subject will <u>not</u> feel an "electrical shock" when tested, the amount of current is very small. RJL Analyzers have isolation transformers that prevent any harmful current from being exposed to the subject while being tested.

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



IMPORTANT:

Follow instructions on "preparation for testing" before any testing is done

1. Attach the subject cable to the back of Analyzer.
2. Attach the electrodes as illustrated above – place the clips of the cables on the non-adhesive TAB of the electrode.

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. Ask subject being tested to remain motionless while testing is done.
2. Turn the Analyzer "ON".
3. Once the values have stabilized, record the resistance and reactance numbers if analyzer is not connected to a PC via the USB port cable.
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.

Please note: If test results seem unusual or inaccurate, refer to Troublshooting Guide or call RJL Systems Technical Support for assistance.

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