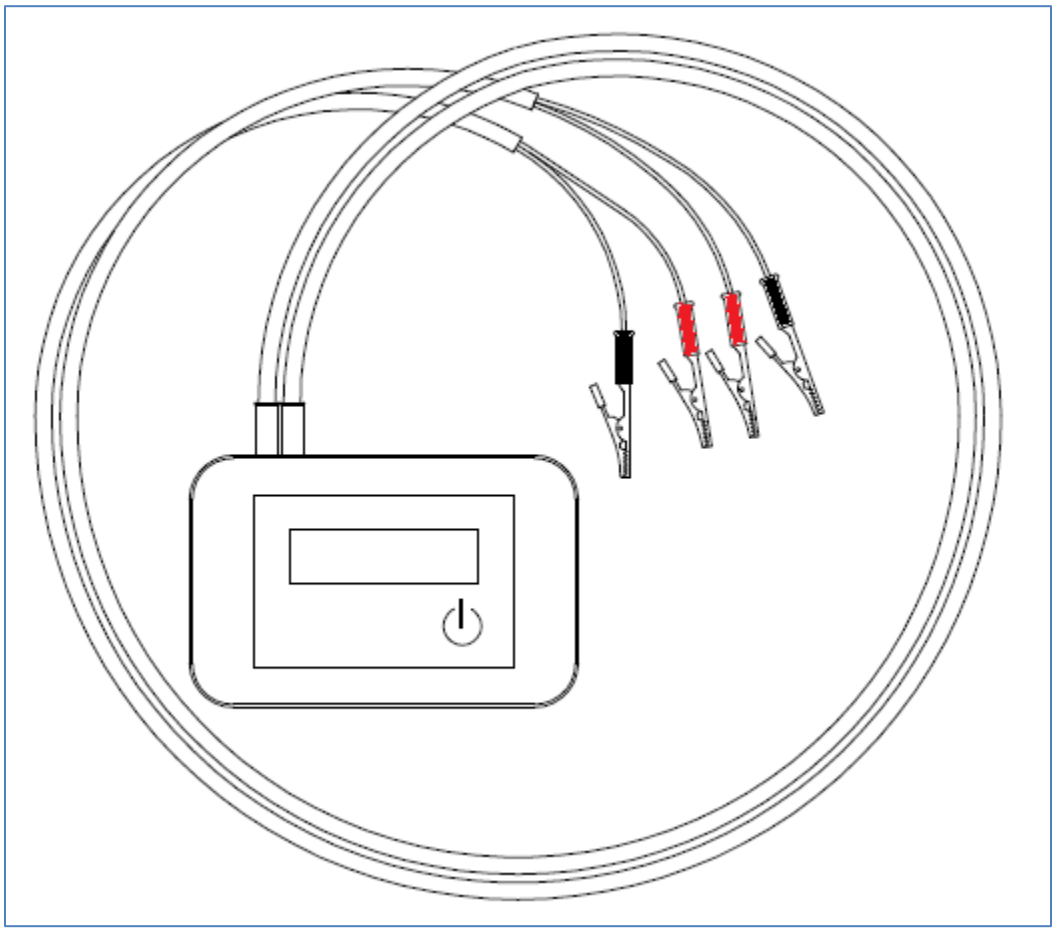
BIA/VITALITY ANALYZER™ USER MANUAL



NOTE: Vitality Analyzer™ & BIA Analyzer™ Devices are technically identical the labeling and logo are the only difference

IPGDx, LLC-POB 253-Harrisville, MI-48740-0253-(989)-724-5631 info@ipgdx.com

Table of Contents

Chapter One: Basic Overview

Statement of Intended Utilization of the BIA/Vitality Analyzer™

Indications for Use: The BIA/Vitality Analyzer™ is used to estimate the subject's body composition parameters of Fat Free Mass, Fat Mass, Total Body Water and Extra-Cellular Water; in "generally healthy" subjects of 18 to 87 years old.

Statement of Intended Use: The BIA/Vitality Analyzer™ is used to estimate a person's body composition parameters of Fat Free Mass, Fat Mass, Total Body Water and Extra-Cellular Water; in "generally healthy" subjects of 18 to 87 years old.

Warnings

This symbol requires your attention and compliance with the information and instructions associated with it such as;

1. This device should not be used on subjects that have a pacemaker or defibrillator implanted.
2. This device is not intended for use during pregnancy.
3. This device is not intended to diagnose, treat, cure or prevent any disease condition.

Contraindications

There are no known or reported contraindications to the use of this device. It should always and only be used as intended.

Precautions

1. Follow all instructions, directions and suggestions; contact the Company with any questions prior to using.
2. Treat the device with care and gentleness to extend its useful life, do not impact the device.
3. Do not immerse the device in liquids or get it wet in any way.
4. Use the device in a comfortable and controlled environment and not in extremes of temperature or humidity.
5. Do not bend, kink or otherwise compromise the subject cables.
6. Do not use the device if any component is broken.
7. Do not open the device case or modify any part of the device.

8. If you are not going to use the device for more than a month remove the batteries and replace them when you use the device again, use fresh batteries as needed.
9. For service on the device contact the Company.

Symbols, Abbreviations and Definitions

1. "Z" = impedance; the total opposition force of conduction measured in ohms.
2. "R" = resistance; one of the two vectors of phase sensitive impedance measured in ohms.
3. "X" = reactance; one of the two vectors of phase sensitive impedance measured in ohms.
4. "°" = phase angle, the arc-tangent of X and R expressed in degrees

Chapter Two: Specifications

Warranty

The device is warranted for a period of one-year (twelve-months) to be without defects in materials and/or workmanship from the delivery date specified in the invoice and the warranty covers parts and labor only.

Please note that you must register the warranty with the Company for it to be in effect and that registration must be made and the information received by the Company within thirty days of your receipt of the device.

The Company is responsible for repair or replacement at its discretion to cure any defects under the warranty.

A return merchandise authorization (RMA) must be issued by the company prior to returning the device to the company or receipt of a replacement device.

Contact the Company to agree on the delivery method and the documentation to be provided together with the instrument.

The Company declares that the content of this manual is accurate; however, we reserve the right to modify, change or revise this document. If the user thinks that there are some errors, they are recommended to contact the Company.

The Company does not provide any express or implicit guarantee for the misuse of the device.

The right of the user to ask for compensation due to fault or negligence of the Company is limited to the amount paid by the Customer for the purchase of the instrument.

This warranty does not cover and is void if the failure of your instrument is caused by defects, malfunctions, breaks or damages resulting from the non-observance of the use and maintenance instructions for the instrument.
The Company is not responsible for and the warranty will be revoked and cancelled if the user makes changes, improper use or misuse of the instrument.

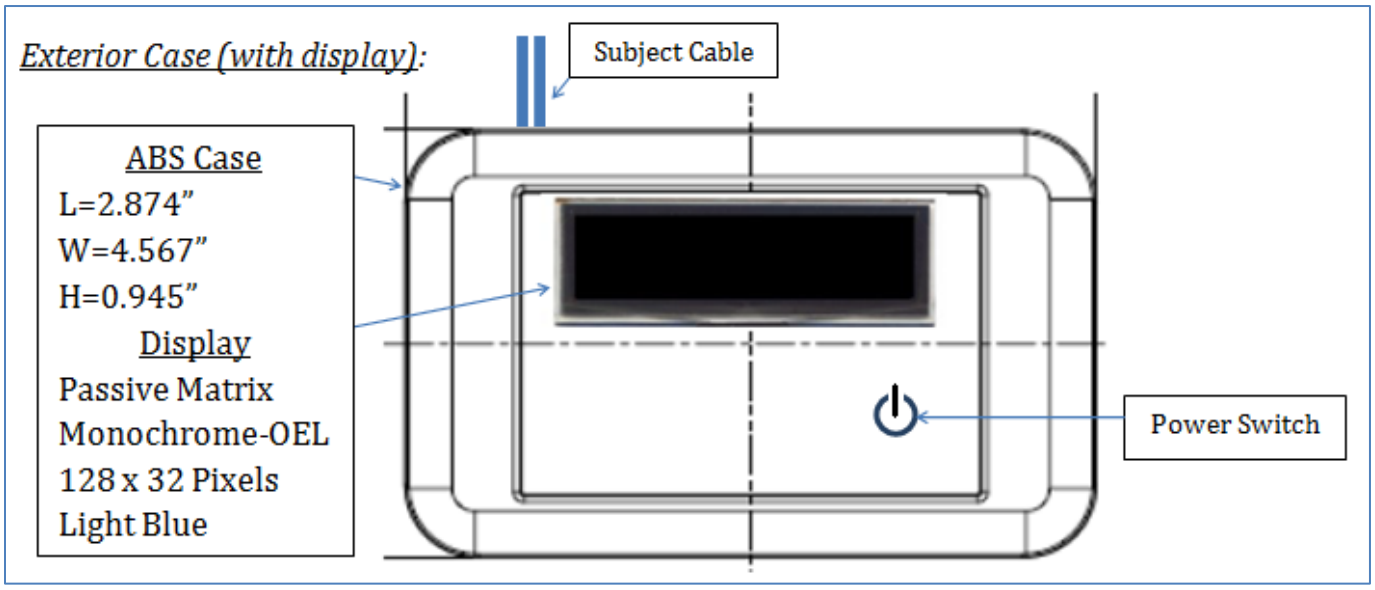
Description

The BIA/Vitality Analyzer™ is a generic bioimpedance analysis device intended only for the measurement of Impedance, Resistance, Reactance and Phase Angle in subject's aged eighteen to eighty seven years of age in the home or clinical environment of generally healthy men and women to estimate their body composition analysis; FFM, FM, TBW and ECW.

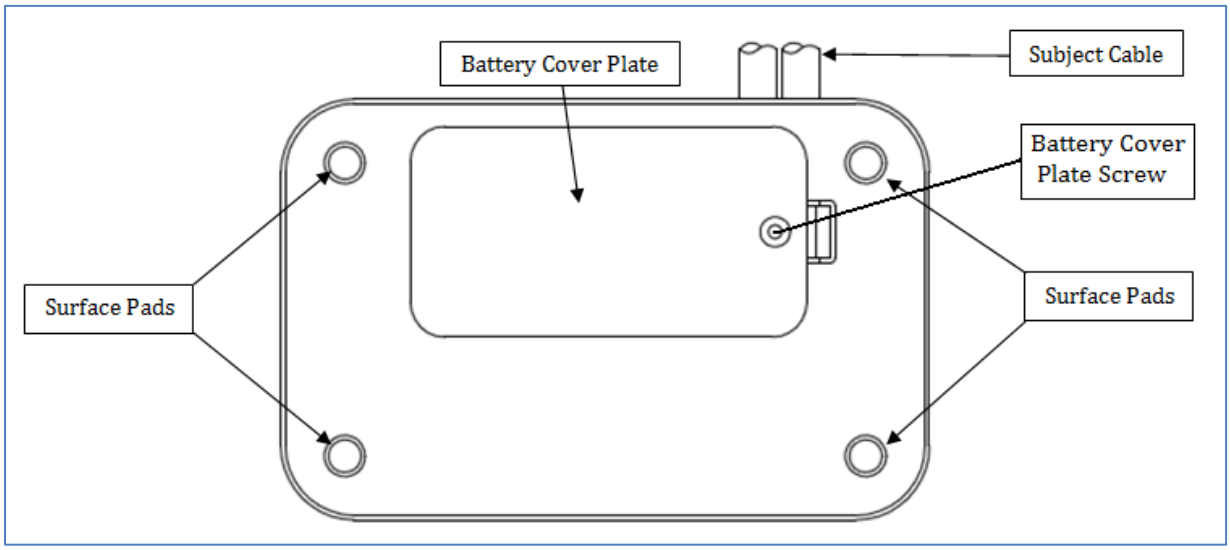
The BCA™ Custom Spreadsheet Application is included to estimate, track and record your test results. Made with MS Excel® it is included with your BIA/Vitality Analyzer™ system.

Use only 'GE' Mactrode electrocardiogram electrodes (FDA K060661) for testing.

Exterior Front

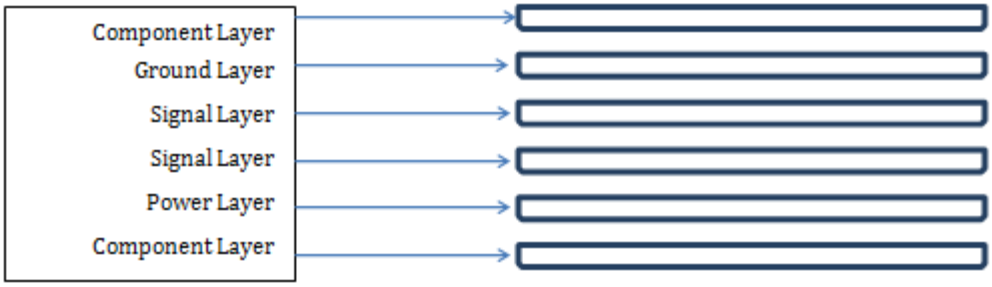


Exterior Back



Internal Electronic Systems

Six-Layer Custom Circuit Board:



Key Components:

- Impedance Analyzer Circuit
- Digital Signal Processor
- A/D and D/A
- Subject Cable
- Display
- Batteries (x2AA)

Features:

- Digital Signal Processor
- Eco-Power Management System (Disposable AA batteries)
  - Subject connected: automatic power off in 45 seconds
  - Subject disconnected: automatic power off in 8 seconds
- Measures Impedance, Resistance, Reactance and Phase Angle

Technical Operating Specifications

Power Supply

The device is powered by two disposable "AA" batteries housed on the back accessed via a removable plastic cover. Carefully remove the screw from the cover and replace the screw when done changing the batteries. Batteries should be removed from the device if it is not to be used for more than thirty days. A "LOW-BATTERY" signal is displayed when the batteries require replacement. Battery life with multiple tests and daily utilization is about three months.

Maintenance and Repair

The device has no parts subject to user maintenance and repair. All maintenance and repair must be performed by the Company. Contact the Company for maintenance and repair.

Subject Cables

The subject cables are permanently affixed to the device and should not be removed, twisted, kinked or otherwise mistreated. The color coded clip-tips on each cable can be removed for cleaning as necessary. We recommend using a disposable alcohol pad to cleanse them as necessary.

Cleaning the Device

We recommend that the device be wiped down after each use with a damp cloth. Do not use any solvents or cleaning agents on the device.

Storage and Transport

Store and transport the device in its original box container with the batteries removed in a dry, safe and room temperature environment of 15° to 35° (C), humidity 30% to 60% and atmospheric pressure 86-106 kPa.

Use

The device can be used as frequently as necessary with testing multiple times daily for months prior to battery power loss. Battery power loss is alerted on the display as noted above. You should not use the device in a wet environment or allow the device to be exposed to moisture. If the device is immersed contact the Company to arrange for repair at your expense. It is not possible to hurt a person with the device unless you hit them with it, we recommend not hitting anyone.

Calibration and Check

The device is self-validating and performs the validation routine internally each time it is energized.

Technical Specifications

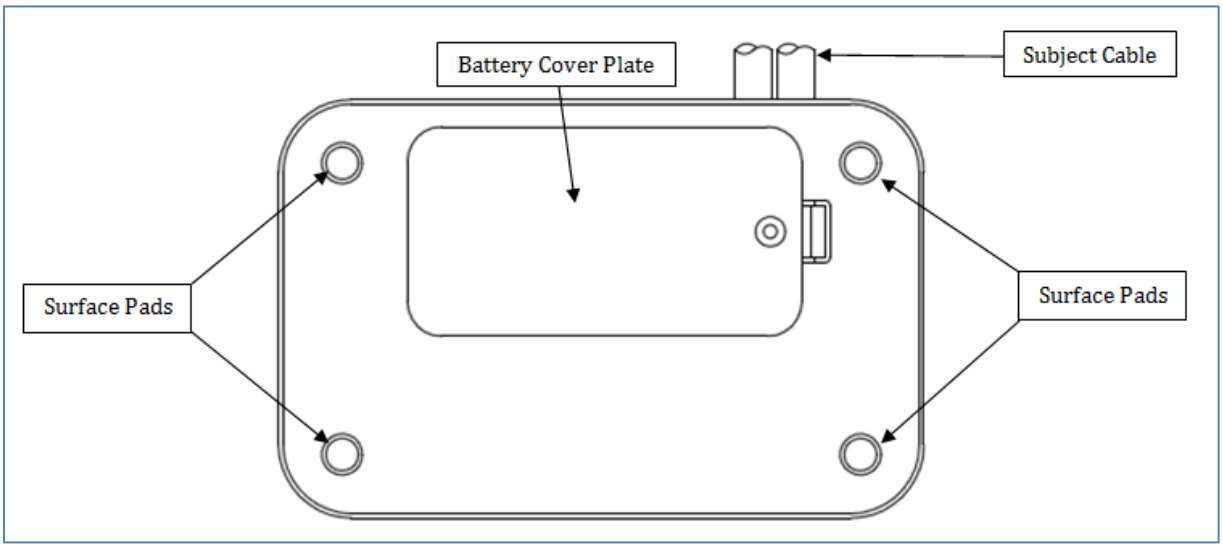
1. Device type: Fixed frequency, phase-sensitive, bioimpedance analyzer
2. Device name: BIA/Vitality Analyzer™
3. Measures: Impedance, Resistance, Reactance and Phase Angle
4. Output Signal: Nominal: 425 µA ±25 µA at 50 KHz crystal controlled, Sinusoidal wave form
    a. Range: 0 to 10,000 ohms, resistive or capacitive

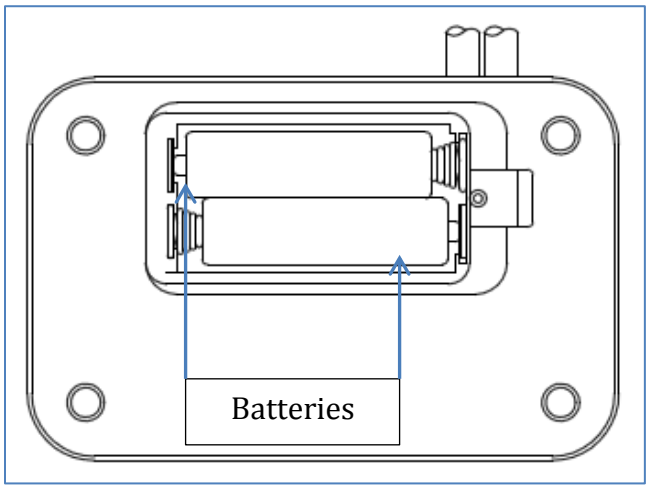
5. Measured Value Accuracy: Impedance-Resistance-Reactance: Nominal: ± 1.0 Ω, Range: 0 to 1000 Ω, Resolution: 1 Ω
    a. Phase Angle: Resolution: 0.1 degree, Range: 0 to 360°
6. Power Supply: two disposable "AA" batteries
7. Protection Class: Internal source medical device
8. Dimensions: L=2.874", W=4.567", H=0.945"
    a. Weight: 14.5 ounces (with batteries)
9. Operating Conditions: 45° to 85° (F) and between 30% and 80% humidity
10. Use only Electrodes: 'GE' Mactrode Electrocardiography (FDA: K060661)

Chapter Three: Operation and Testing

To Begin

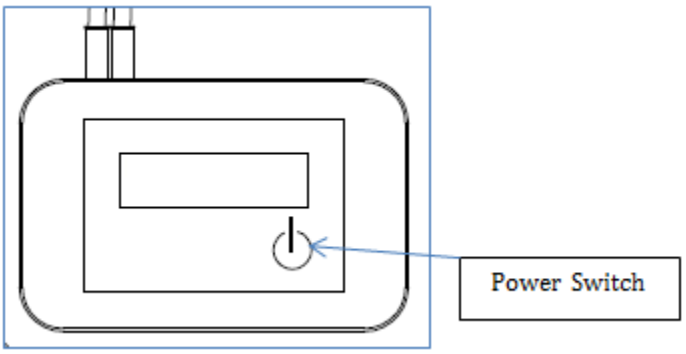
1. Once the device is removed from its shipping container;
    a. Remove the protective film from the display
    b. Place the two "AA" batteries in the device



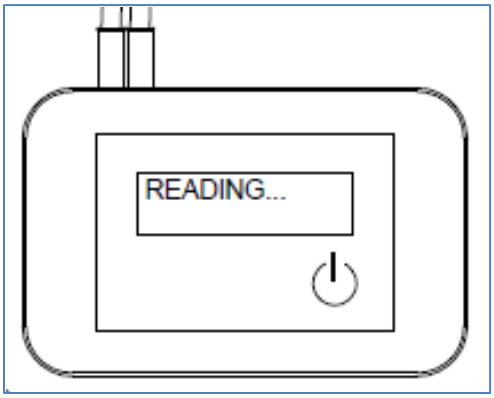


Device Power Management

1. Press and hold for two seconds the on-off switch on the right side of the front panel under the display area to energize the device and initiate the internal self-validation process.



2. The device will turn itself off.
3. Once the device is connected to a subject it will begin the reading after you energize it.



Performing a Test

Bioimpedance testing is the measurement of electrical values from a safe and highly controlled electrical circuit introduced into the test subject by two electrodes that introduce and set-up the circuit and two electrodes that make the measurement.

DO NOT TEST SUBJECTS WITH PACEMAKERS, IMPLANTED DEFIBRILLATORS OR ARE PREGNANT

It is important for the examiner to perform each test carefully and in the same manner so the data is accurate and subsequent measurements can be compared. The examiner should practice testing until they feel comfortable with the testing procedure. The examiner should be able to complete a test and a second test one after the other with the results of both tests being within one-percent of each other; this demonstrates proficiency of the examiner.

The person acting as the examiner should familiarize themselves with the testing materials, procedures and method and explain them to the subject being tested and answer any questions prior to testing. If you have any questions about the testing procedure you can call the Company to have them answered.

The subject should be prepared by not having;

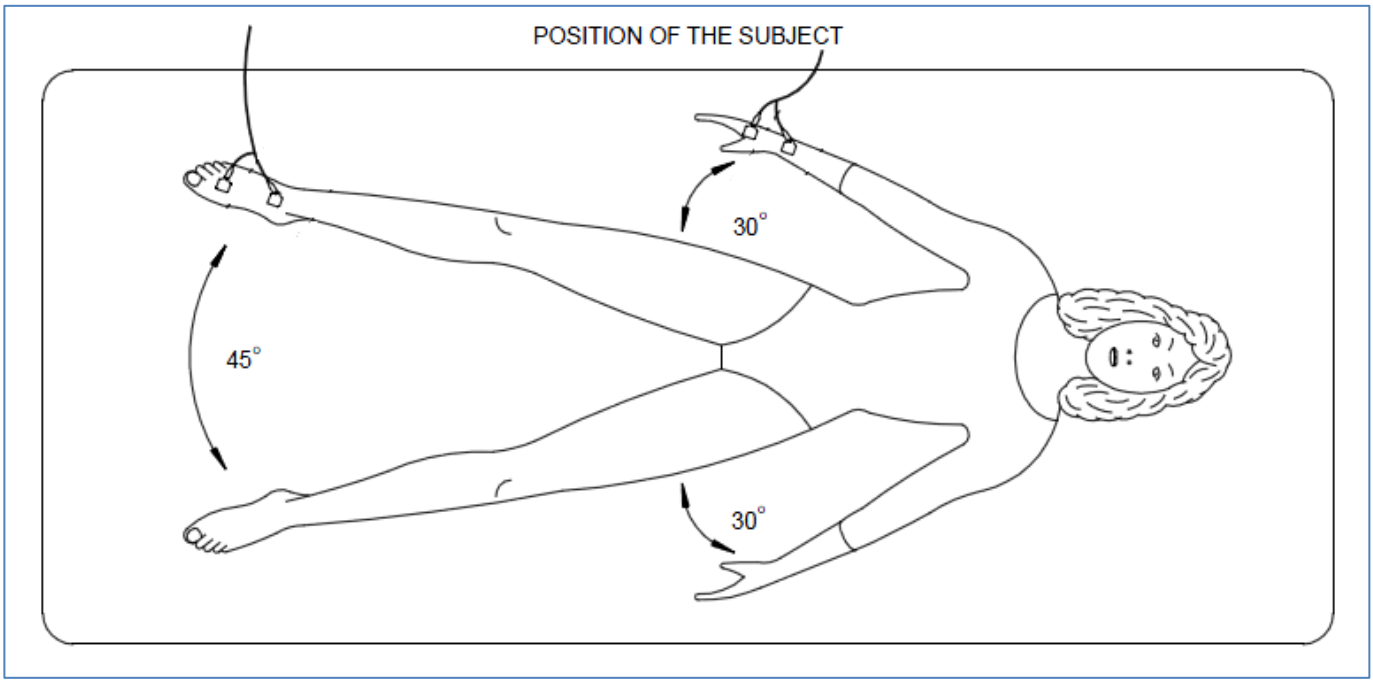
- Recently exercised
- Be sweaty, wet or damp skin
- A fever
- Physical trauma

The electrodes are placed on the subject in relation to anatomical landmarks on the wrist and ankle; generally the right side of the body is used. However the left side may also be used. It is important to use the same side for each test.

First gather the device, electrodes and writing materials to the testing area. The testing area should be comfortable, private and free of drafts, distractions or excessive noise. The testing area should have a firm, flat, and comfortable non-conductive surface (not a metal surface) large enough for the test subject to lie flat upon with their arms and legs separated out from their body.

Have the test subject remove any hanging or excessive jewelry they may be wearing. Then have the test subject remove their shoe and sock from the side being tested (generally the right side). Then have the test subject lie flat on the testing surface calmly and in a still, relaxed and comfortable manner; help the subject on and off the testing surface as needed.

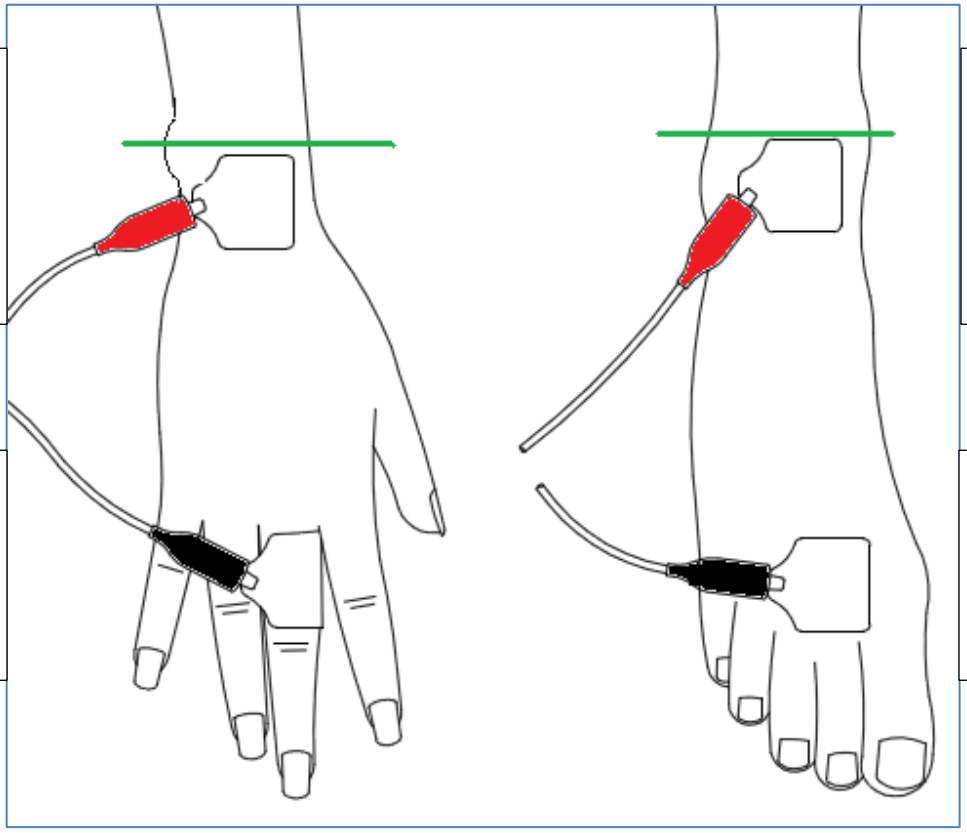
Then the examiner should make sure the test subject is positioned as illustrated, the electrodes are placed as illustrated and the clips of the subject cable are connected to the electrodes as illustrated;



"Place the electrodes with the tabs facing out towards device"

Electrode tabs out, top line cuts "bump" on little finger side of wrist in half, red clip

Electrode tabs out, top line cuts "bump" on big toe side of ankle in half, red clip

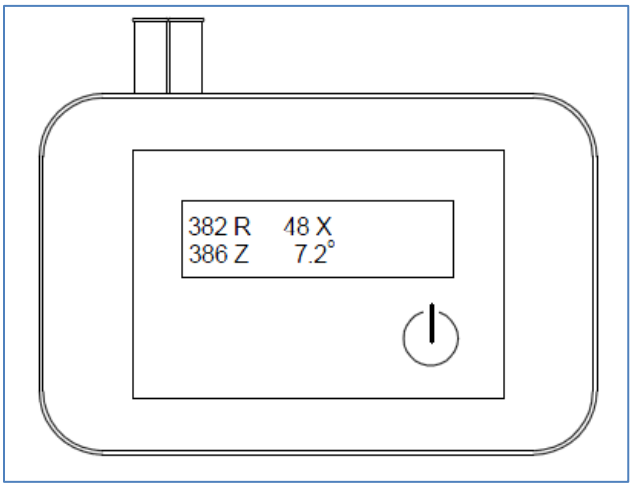


Electrode tabs out, electrode at base of middle finger, black clip

Electrode tabs out, electrode at base of second toe, black clip

"Remember Red above Black"

Next, the examiner should energize the device and then turn towards the test subject to ensure that they are calm, lying flat and not moving. Then the examiner should carefully and accurately record the measured values from the device.



Once the results are written down the examiner should disconnect the subject cable clips from the electrodes and set the device safely aside. Then the examiner should gently and carefully remove the electrodes ensuring that the test subject's skin is not traumatized and that the sticky-part of the

electrodes does not come into contact with the examiners hands. The electrodes can only be used for one test and should be disposed of.

The test subject's results are recorded and can be entered into the BCA™ Custom Spreadsheet Application, along with other data such as gender, age, height and weight to view the body composition estimates of Fat Free Mass, Fat Mass, Total Body Water and Extra-Cellular Water.

If you have any questions regarding the testing procedure please feel free to contact the Company; 989-724-5631, info@ipgdx.com.

Chapter Four: BCA™ Custom Spreadsheet Application

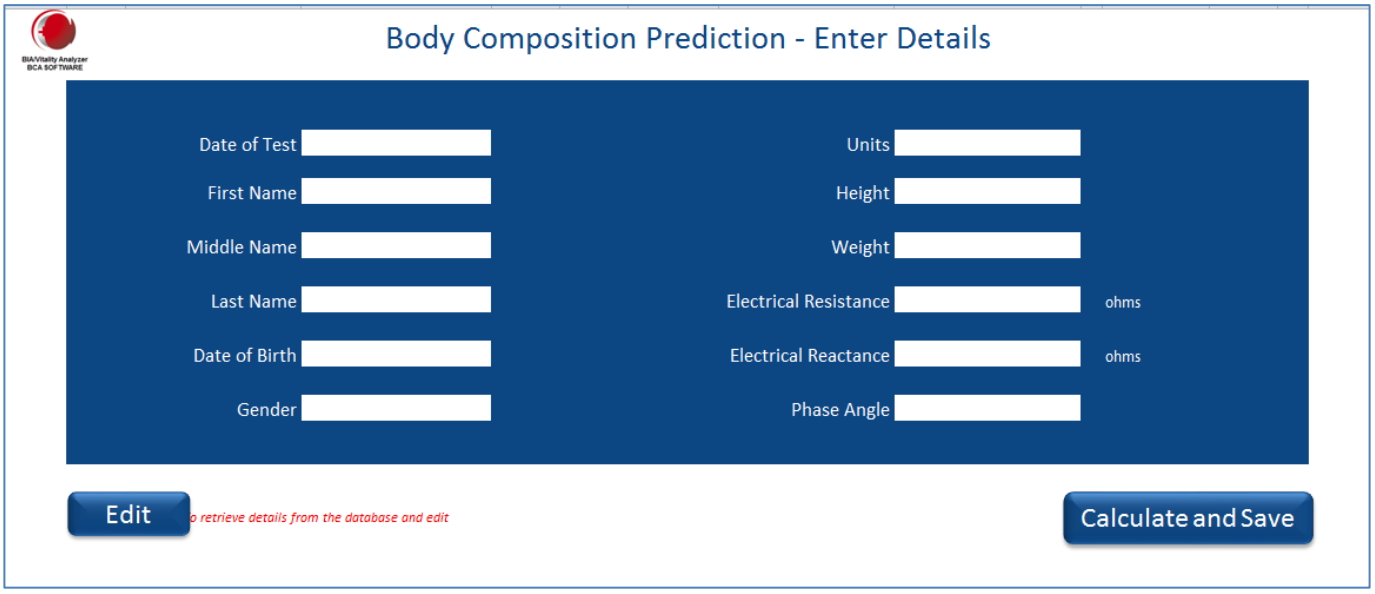
The BCA™ Custom Spreadsheet Application is designed for individual use to estimate record and track your body composition results.

Step One

Download the BCA™ Custom Spreadsheet Application from the download area of the BIA/Vitality Analyzer™ website onto the mobile, tablet or computer device of your choosing. Make a copy for each new subject and label the copy with the subject's name for future use.

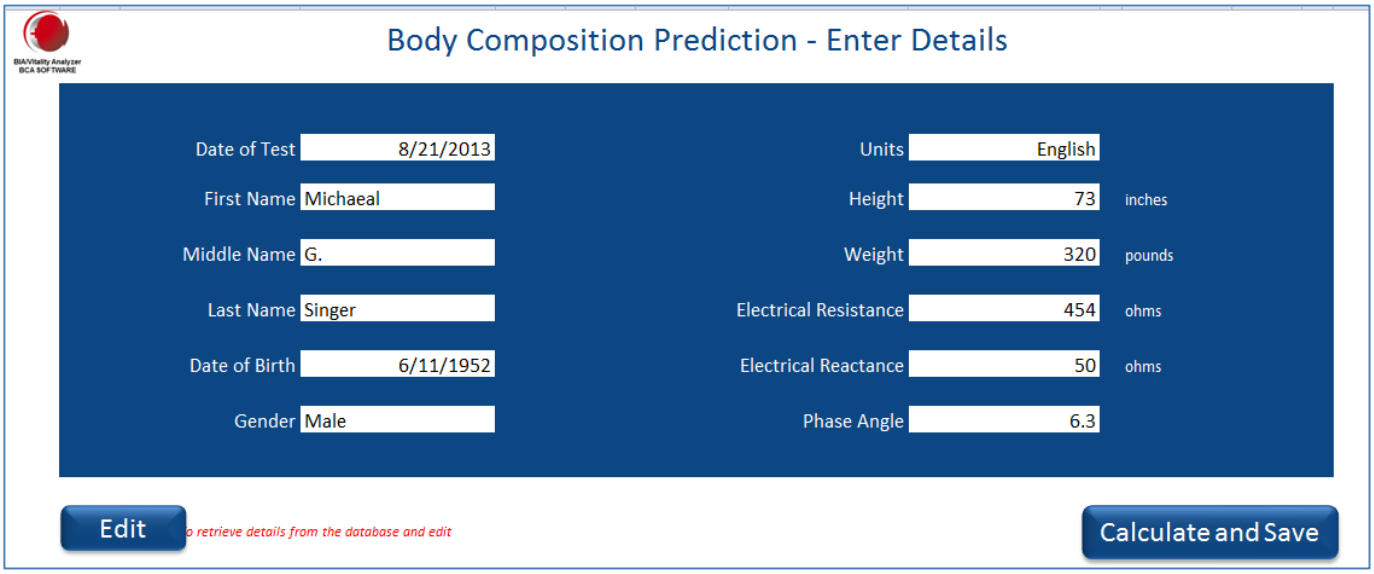
Step Two

With your test results in hand, open the BCA™ Custom Spreadsheet Application to the first worksheet, as seen below;

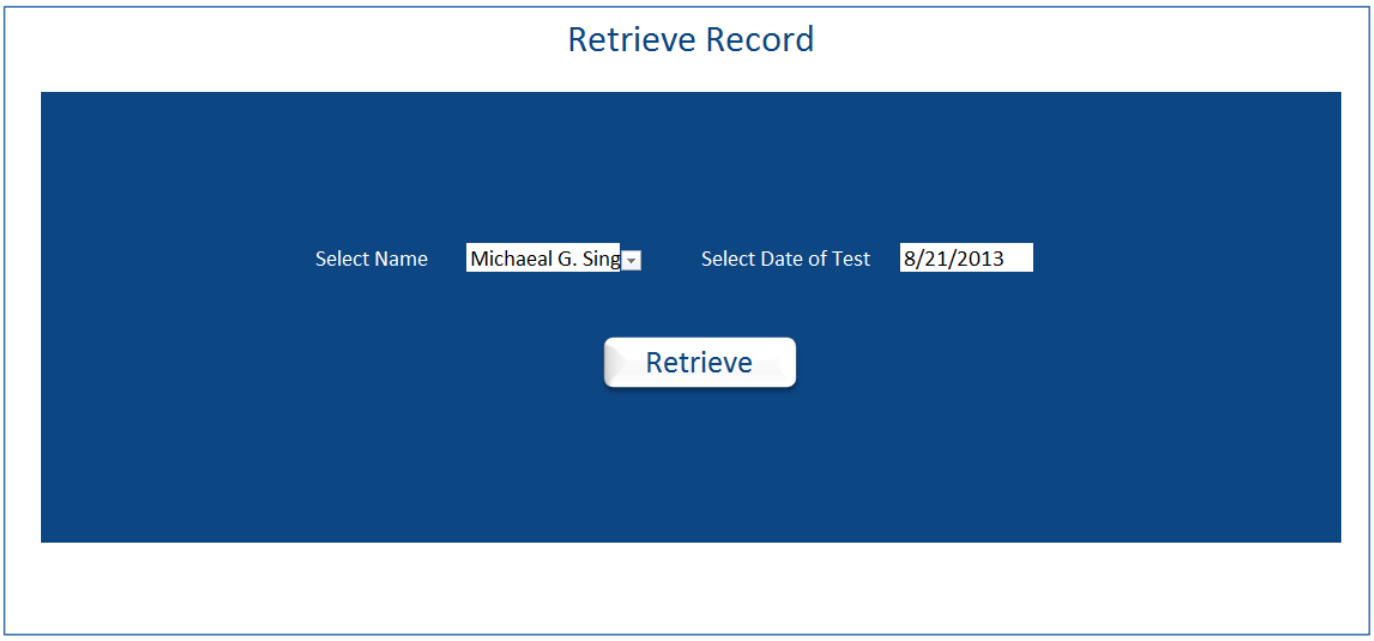


If this is your first test;

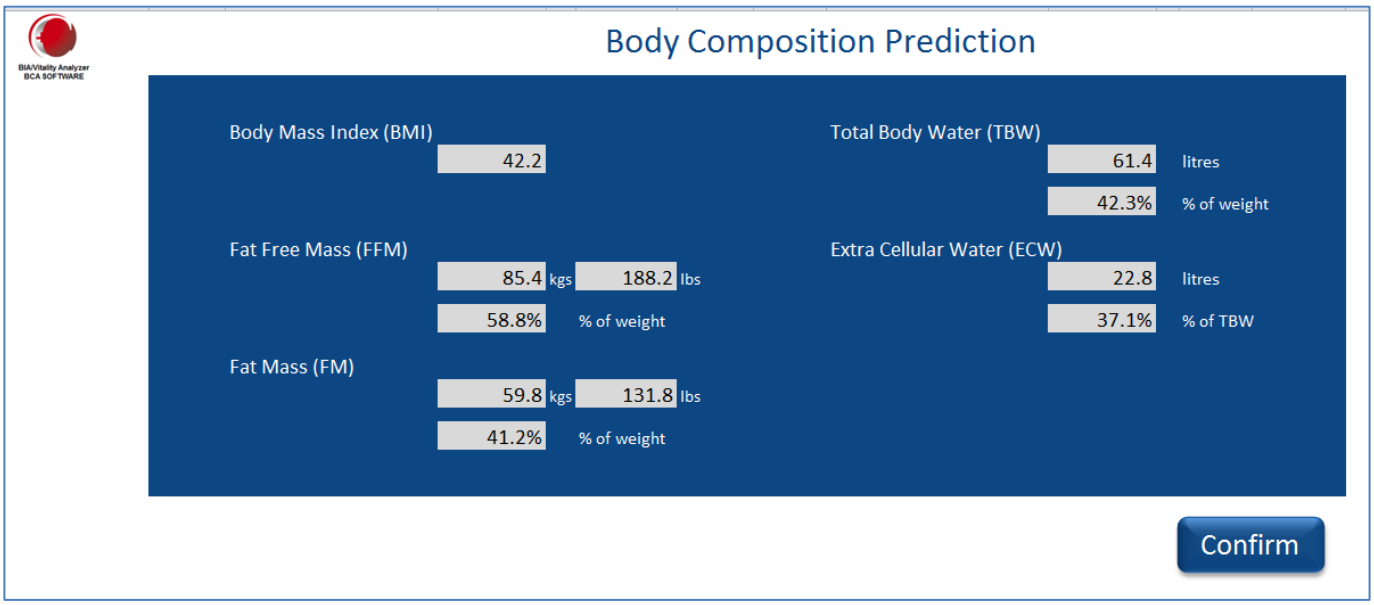
Beginning with the Date of Test; select and enter the twelve items displayed moving to each item with the tab key, Units (English or Metric), First Name, Height (inches or centimeters), Middle Name, Weight (pounds or kilograms), Last Name, Electrical Resistance value (in ohms), Select your Date of Birth, Electrical Reactance value (in ohms), Gender (select male or female), Phase Angle. Then activate the "Calculate and Save" button.



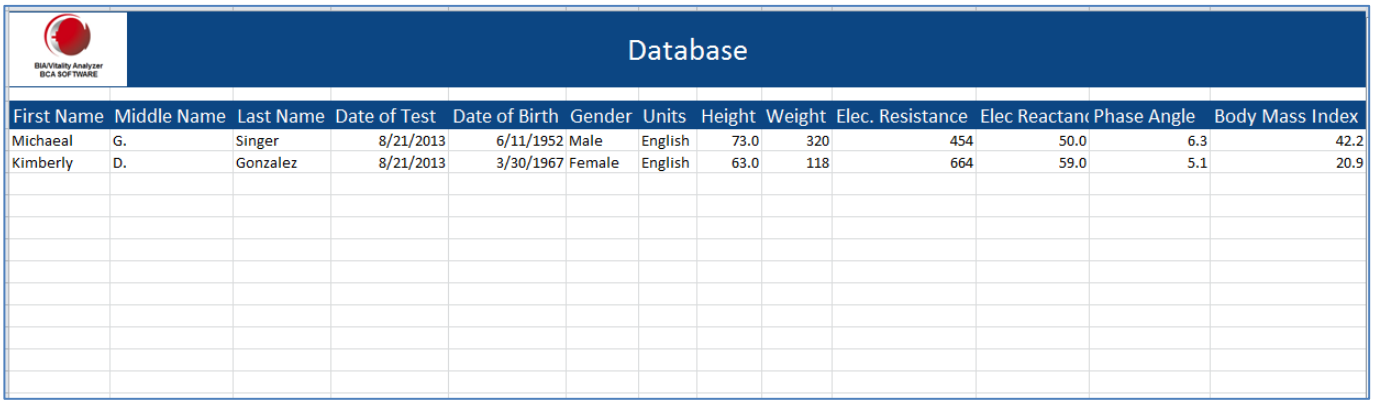
If your record is already in the BCA™ Custom Spreadsheet Application activate the "Edit" button to view the following screen and select your name;



Next, the Body Composition Prediction worksheet comes up;

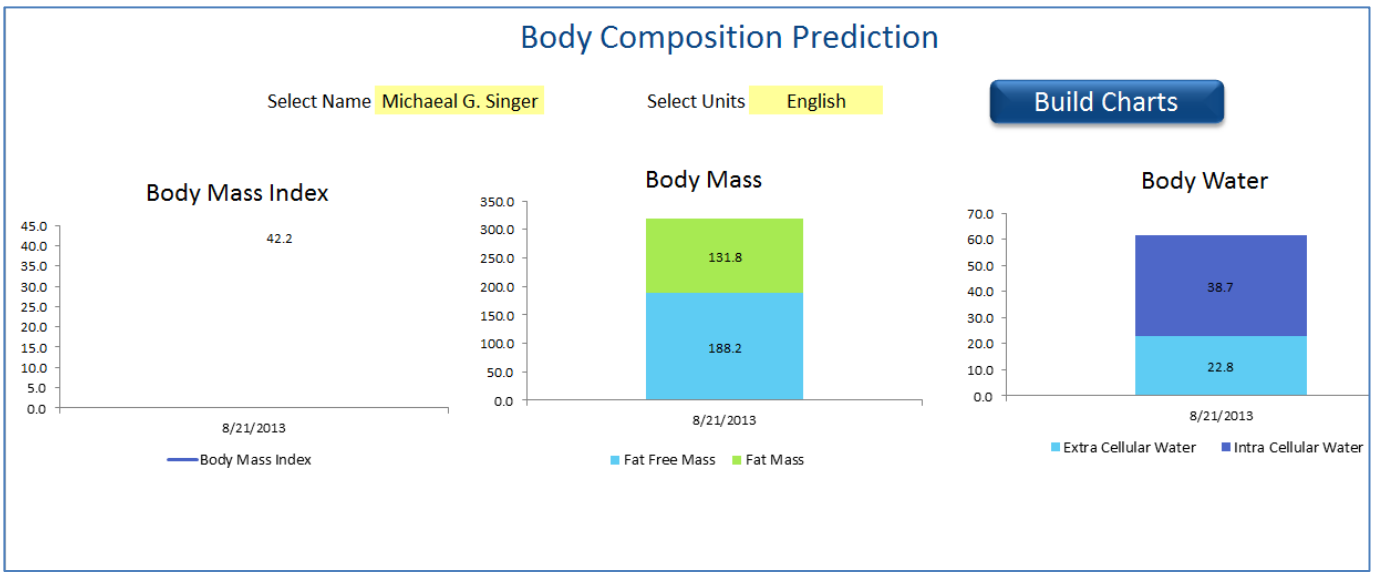


If you like you can select print and print the results. Once done viewing select and engage the "Confirm" button to save the record to the "Database" worksheet (see below);



First Name	Middle Name	Last Name	Date of Test	Date of Birth	Gender	Units	Height	Weight	Elec. Resistance	Elec Reactanc	Phase Angle	Body Mass Index
Michaeal	G.	Singer	8/21/2013	6/11/1952	Male	English	73.0	320	454	50.0	6.3	42.2
Kimberly	D.	Gonzalez	8/21/2013	3/30/1967	Female	English	63.0	118	664	59.0	5.1	20.9

Next you can visit the "Charts" worksheet and view a graphical representation of your results which you may print if you like, (see below);



There is a sixth and final worksheet in the BCA™ Custom Spreadsheet Application labeled "Settings" which is solely for the management and actions of the spreadsheet and must not be changed, (see below);

Please do not edit or delete this sheet

Inputs	Cell
First name	D7
Middle Name	D9
Last Name	D11
Date of Birth	D13
Gender	D15
Height	I7
Weight	I9
Electrical Resistance	I11
Electrical Reactance	I13
Phase Angle	I15
Units	I5
Date of Test	D5

Calculations	Cell
Body Mass Index	D6
Fat Free Mass	D11
Fat Free Mass %	D13
Fat Mass	D16
Fat Mass %	D18
Total Body Water	J6
TBW %	J8
Extra Cellular Water	J11
ECW %	J13
Intra Cellular Water	J16
ICW %	J18
Fat Free Mass in lbs	F11
Fat Mass in lbs	F16

When you are done with this session save your work until the next session use.

Please feel free to contact the company at (989) 724-5631 or via email; info@ipgdx.com with any questions.

Chapter Five: Service

Step One

Always communicate with the Company first regarding any problems with the device. There is no service that you can perform on the device other than changing the batteries.

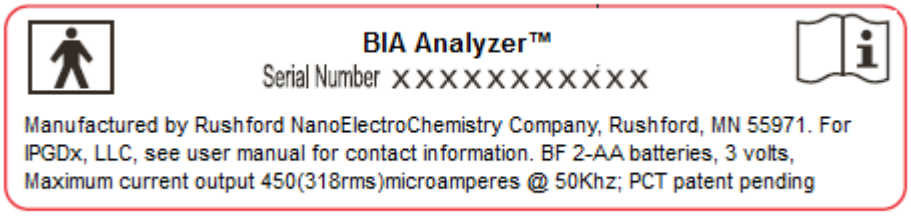
Step Two

If necessary the Company may ask you to return the device for repair or replacement, if so you will be issued a Return Merchandise Authorization (RMA) number, package the device professionally and send it to the Company.

Device photos

NOTE: Vitality Analyzer™ & BIA Analyzer™ Devices are technically identical the labeling and logo are the only difference

Device Labeling



 This symbol designates the device as International Electro-Technical Commission category designation "BF" denoting energy transfer to the subject with a non-permanent contact under IEC60601 standards.

 This symbol indicates referring the reader to the device user manual (this document).

Company contact information

IPGDx, LLC
POB 253
705 South Lake Huron Shore Road
Harrisville, MI 48740-0253
989-724-5631(USA/ES(D)T)
info@ipgdx.com

Included in your purchase is:

BIA/Vitality Analyzer™
Two AA disposable batteries
Two sets subject cable clips
BCA™ Custom Spreadsheet Application
One package of 'GE' Mactrode Electrodes (#100) (Use only these electrodes for testing)
One year return to factory warranty

