SURVEY METHODS

Procedure: Bioimpedance Analysis (BIA)

1. Purpose

BIA is a method that is used to estimate body composition. BIA measures the electrical impedance of body tissues and has been used to assess fluid volumes, total body water, body cell mass and fat-free body mass. A small alternating electrical current is passed through surface electrodes placed on a hand and foot and the impedance to the current flow is measured by different electrodes placed adjacent to the injection electrodes. The voltage drop between electrodes provides a measure of impedance.

Impedance is the opposition to flow of an electric current. In human tissue, impedance is proportional to total body water. Impedance is high in fat tissue and low in lean tissue. Nonfat or lean tissue, where intracellular fluid and electrolytes are mainly found, is highly conductive and has limited resistance to alternating electrical current compared with fat tissue, which contains very little fluid and has high resistance to electrical current. The cell membrane consists of a nonconductive double layer of phospholipids between two layers of conductive protein molecules. The impedance of tissues is comprised of resistance and reactance. The resistive component is provided by the conductive characteristics of body fluids, whereas the cell membranes, acting as imperfect capacitors, provide the reactive component.

In human tissue, impedance is affected by the frequency of the flow of current. At low frequencies, there is minimal conduction through the cell membrane due to the high capacitance of the membrane. Mainly the extracellular water influences the impedance at low frequencies. At high frequencies, the capacitance of the membrane decreases and the current flows equally through both the extracellular water and the intracellular water. Impedance measures made over a range from low to high frequencies allow development of prediction equations relating impedance measures to extracellular fluid at low frequencies and to total body water at high frequencies. Lean body mass can be calculated based on an assumed hydration fraction for lean tissue and from this calculation, fat mass can also be calculated.

In SHOW, BIA is performed on all eligible and willing individuals 21 through 74 years. Women aged 21 through 59 years are asked to self-report their pregnancy status. Pregnant women will not be given BIA.

2. Responsibilities

SHOW surveyors have been trained to perform BIA. Operator/examiners must demonstrate proficiency by obtaining two consecutive measurements on a single, stable subject with result values within one percent.

3. Changes since last revision
None

4. Equipment Needed for this MOP

Exam Room

Each Survey Site will be equipped with an exam table suitable for the conduct of BIA. The tables should not be placed close to an electrical source heater. The exam table surfaces are non-
conductive and large enough for the subject to lie supine with their arms not touching their sides and legs not in contact with each other. Subjects may require assistance from the examiner to be correctly and safely positioned. For further information regarding survey site and exam room setup and selection please see the Survey Methods, Recruitment and Survey Administration Manual of Operations.

**Equipment and Supplies**

The Bioelectrical Impedance Analysis (BIA) equipment used in SHOW is the Quantum X (Figure 1) and Quantative IV, a standard for high-resolution whole body and regional bioelectrical resistance and reactance measurements. Accuracy and ease of use are the key features.

*Figure 1 - Quantum X resolution 0.1 ohm*

- The Stay-Fresh Pack (Figure 2) comes with 2 packages of adhesive electrodes (200 electrodes - 50 tests). The hard plastic storage box protects the electrodes from damage when being stored, and helps keep them from drying out once the packages have been opened. If electrodes become dried out, they are unreliable, and will prevent the patient from being accurately measured.
5. Related Documents
   BIA Instructional Manual
   SHOW Training Manual

6. Definitions

abducted: Drawn away from the body.

electrode: Electrical conductor used to make contact with the body to create conduction.

impedance: Measure of the opposition that a circuit presents in the body.

resistance: A measure of how difficult it is for electricity to flow through an object.

reactance: Measurement of capacitance (ability to store an electrical charge). The more capacitance the object has, or the faster the current changes direction, the less the object will “react” to the current.

7. Procedure

BIA MEASUREMENT

Preparation of Subject

Upon scheduling the Time 3 visit, the SP receives an instruction sheet for the Survey Center Visit (see Appendix). A major portion of this sheet highlights guidelines for avoiding certain activities that may affect the quality of test results, particularly the BIA. At the Survey Site the subject is asked to do the following in preparation for the BIA:

- the SP had urinated recently,
- the SP is in scrubs or appropriately loose clothing, and
- the SP has removed metal jewelry, eyeglasses, hair ornaments and other metal objects.
Safety Exclusions
The surveyor/examiner explains to the BIA procedure, what it involves (lying on their back for at least five minutes), and asks if they are willing to have the BIA test performed. If the subject is unable or unwilling to lie down, the test can be done while seated but is not optimal.

This is a brief explanation of the exam, not a standard script, and therefore the examiner may adjust the explanation to the SP’s level of understanding.

“This next exam will only take a few minutes and you will not feel anything during the measurement. I am going to wipe off your right hand and foot with an alcohol swab and attach these four electrodes (or patches). I will connect the electrodes to this machine and start the measurement. The machine will send a very small current through the electrodes but it is at such a low level that you will not be able to feel it. The measurement will take only a minute. The machine measures the amount of water in your body (the amount of water inside and outside of your cells). This helps scientists determine the amount of body fat.”

If the subject is willing to complete the test, the examiner asks if they have:
- A pacemaker
- an automatic defibrillator
- an artificial metal joint, a metal pin
- a metal plate
- other metal object in the body
- a coronary stent
- a metal suture material in their heart
- If they are currently pregnant

This information is recorded on the CAPI data form.

All safety exclusion questions are asked and documented even if the first one excludes the subject from the test.

Documentation of Quality Parameters

If there are no exclusions, a series of questions are asked that may affect the accuracy or comparability of the BIA test. These questions document:
- amputations
- atrophy of limbs
- presence of hearing aids
- use of diuretics
- recent exercise
- heavy physical activity
- sauna use
- recent use of alcohol
- recent meal
- hydration status
- presence of metallic fibers in clothing
- sweating
- wet skin
- any involuntary body movement
Selection of Site

BIA is done using the right arm and right leg unless this is contraindicated. Reasons for using the left limbs are documented in the data collection system.

Positioning of the Subject

The examiner instructs the SP to do the following. Ideally the subject will have changed out of their own clothing into disposable scrubs and socks.

- Remove the right shoe, sock, nylons or other material covering their ankle or wrist
- Remove bracelets, necklaces and belts and clothing that contain metal.
- Remove jewelry on the electrode side, such as rings, watches, earrings.
- Lie on their back on the exam table face upward, arms comfortably abducted from the body 30 degrees and legs comfortably separated so that thighs are not touching (see Figure 4). Those who cannot tolerate this position should not do the BIA.

![Figure 3 - Body position](image)

- The examiner confirms the correct position of the SP on the exam table. If the SP is unable to keep arms from touching the side of the body, a piece of thin acrylic fabric can be slipped between the arm and the side of the body. Thighs should not touch skin nor should arms contact trunk.

Electrode Placement for BIA

The examiner follows the sequence below in placing the electrodes for BIA IV and X:

- Clean the electrode sites with alcohol, particularly if the skin is dry or covered with lotion.
- Ensure that the black ‘current-injection’ and red ‘voltage-detector’ electrodes are at least 7.5 cm. apart, respectively.
- Ensure that the device cables are not touching the ground, the SP or any metal objects, and are not routed near high voltage equipment (e.g., computer monitor). Check that the cables are not intertwined.
- Attach the electrodes and patient cables as shown in Figure 5.
Figure 4 – Electrode placement on hand and foot.
<table>
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<th>Step</th>
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| 1    | **Preparation:**  
SP will be wearing scrubs and peds, or informs interviewer that SP will remain in own clothes. If SP wears own clothes, make sure SP can breathe freely. |
| 2    | Place the black current-injection electrode (I) on the dorsal surface of the right hand proximal to the metacarpal-phalangeal joint (Figure 5), specifically on the first joint of the middle finger. |
| 3    | Place the red current-injection electrode (I) on the dorsal surface of the right foot proximal to the metatarsal-phalangeal joint (Figure 5), specifically at the base of the second toe. |
| 4    | Place the center of a voltage-detector electrode (V) on the mid-line between the prominent ends of the right radius and ulna of the wrist (Figure 5). |
| 5    | Place the center of a voltage-detector electrode (V) on the mid-line between the prominent ends of the right radius and ulna of the wrist (Figure 5). |
| 6    | Place the center of a voltage-detector electrode (V) on the mid-line between the prominent ends of the right radius and ulna of the wrist (Figure 5). |
| 7    | Place the center of a voltage-detector electrode (V) on the mid-line between the prominent ends of the medial and lateral malleoli of the right ankle (Figure 5 BIA X). |
| 8    | Connect the black current-injection (I) lead alligator clips to the electrodes placed on the right hand and foot (BIA X). |
| 9    | Connect the leads labeled hand to the right hand of the SP then gently place the red alligator clip first then the black alligator clip second. (BIA IV)  
Connect the leads labeled foot to the right foot of the SP then gently place the red alligator clip first then the black alligator clip second (BIA IV). |
| 10   | Connect the red voltage-detector (V) lead alligator clips to the electrodes placed on the right wrist and ankle. |
| 11   | Confirm the default settings on the analyzer (once this has been checked at the beginning of the day, it does not have to be repeated before every test). |
| 12   | Attach the BIA electrodes and alert the SP to the start of the BIA test. |
| 13   | When the electrodes are placed,  
- The SP is asked to lie quietly and not move.  
The examiner presses the ‘Capture’ button and turns the analyzer on.  
- When the measurements have stabilized, the examiner records the displayed Resistance (R) and Reactance (Xc) values on the data form. |

### 8. Post Procedure Processing

Results of Bioimpedance Analysis are reported to subjects a few weeks after the Survey Center Visit. The results are included in the SHOW Findings Report (see Appendix D). The result is listed as percentage of body fat. The American Council on Exercise recommended values for men and women are listed on the report to assist subjects in interpreting their result. No recommendations are given related to the reported percentage. The Findings Report carries a...
statement saying that if abnormal results have been noted, SHOW recommends that they discuss their results with a health care provider.

**QUALITY CONTROL AND ASSURANCE**

- All of the field team surveyors are trained in the BIA examination procedure when they begin their field training. Proficiency is achieved with two consecutive measurements made on a single, stable subject that must result in resistance values within one percent of each other.
- Field team are given a re-certification training each year and must test-out annually on this device.
- Exam components are tape recorded for random monitoring by managers to assure adherence to protocol and accurate documentation of responses.
- Time to complete this exam component is analyzed across the field team and consistent outlying times for any particular examiner will be monitored and retraining done if necessary.
- The instrument completes a self test at the start of each use.
- Calibration is completed at the start of each exam week.
- Electrodes are stored in air-tight containers to retain moisture. Dried electrodes are discarded
- Data entry includes noting most recent calibration time for instrument.

Daily and weekly checks for the BIA device are listed in the following sections.

9. **Records**

An electronic copy of this and related documents are stored on the SHOW S Drive.