

Chapter 37. Bioelectric Impedance Assessment (BIA)

37.1 Introduction

During the PVDOMICS study each participant will undergo Bioelectrical Impedance Assessment using the Tanita SC-240 Body Composition Analyzer. This device is intended to measure weight and impedance, estimation of body mass index (BMI), total body fat percent, and total body water percent for the purposes of this study. Please refer to the manual provided with the device in addition to this MOP prior to operating the device (See Appendix 37.1).

37.2 Preparations for Taking Measurements

- Tanita SC-240 Body Composition Analyzer (BIA machine)
- Identify a room (or space) for the Tanita SC-240 Body Composition Analyzer to sit on a flat surface (a carpeted floor is not ideal).
- Exam area should be comfortable and free of drafts.
- Device must be plugged directly into wall outlet. Do not use power strips.
- Perform daily device check prior to participant's arrival.
- Provide a chair for participants to place their bulky clothing, remove phones and other devices, coins, etc., and take off shoes and socks.
- Appropriate disinfectant to clean scale platform after each use.
- Wipes for bottom of feet, if needed.

37.3 Participant Exclusions and Preparation

- Explain the testing procedure to the participant.
- Participant should be asked whether he or she has an implantable defibrillator or pacemaker. Participants with an implantable defibrillator or pacemaker should not undergo the BIA procedure.
- Make sure that each participant has refrained from hard exercise (any physical activity where a participant breaks a sweat or becomes breathless) or taken a sauna within 12 hours prior to measurement. Test should be rescheduled if possible.
- Participants should wait 3 hours after waking or eating prior to have a measurement done. If a participant has experienced over-eating or over-drinking (i.e., greater than 8 oz.), has drank alcohol in the last 12 hours. Test should be rescheduled if possible.
- If a female participant is menstruating then the measurement should be rescheduled if possible, as test would be inaccurate.
- If participant is dehydrated, the measurement should be rescheduled.
- Participant should not have a fever or be in shock.
- Participant's height and weight should be accurately obtained; height using centimeters and weight using kilograms. The maximum weight for an accurate test is 440 pounds.
- If participant has a leg or arm that has been amputated, this must be recorded on the PVDOMICS BIA Form 132. If a double leg amputee, test cannot be done.
- Ask the participant to urinate prior to measuring.
- Ask the participant to use a wipe to clean off bottom of feet, if needed.

- Ask the participant to sit quietly before test and not use cell phones or other mobile devices.

37.4 Measuring Safely

- This device cannot be used in participants who have pacemakers or other mechanical implants of any kind. If a participant has such a device, this test will not be done. There is a weak electrical current that flows through the body during a measurement that could interfere with the medical device, resulting in serious injury or consequence. Also, avoid use of this device in any participant who is allergic to metals.
- When operating the device avoid using near any flammable gases or wet or oxygen rich areas, and make sure to use dry hands when plugging the device into the outlet.
- Please disinfect the scale platform prior to use and between participants.
- Do not touch participant during a measurement.
- Unplug the device from the wall outlet when not in use for long periods of time.

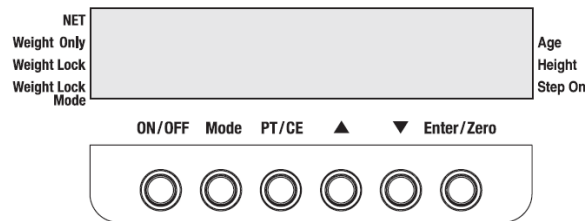
37.5 Initializing Device - Display Panel and Keys on Tanita SC-240

- On/Off key is located on the left hand of the display.
 - Mode selection key is next to the ON/OFF key on the left hand side of the display-you may choose the body composition analyzer or weight scale
 - PT/CE key is after the Mode selection key and used to clear input values or set preset.
-  The up key is next and is used to increase the numerical values
 The down key follows and is used to decrease numerical values
- Enter/Zero key is the last key and is used to enter the input value/reset the scale to zero/mode setting.

Please refer to the Tanita SC-240 Manual for Common Symbols and their meanings, common display messages and for proper insertion of batteries into the device and/or insertion of AC adapter.

Figure 1. See next page.

Names and Functions of Display Panel & Operation Keys



ON/OFF	ON / OFF key	: turn the power ON / OFF
Mode	Mode selection key	: Select Body composition analyzer / Weigh scale
PT/CE	PT / CE	: Set preset tare / Clear input values
▲	UP	: Increase numerical values
▼	DOWN	: Decrease numerical values
Enter/Zero	Enter / Zero reset	: Enter input value / Scale reset to zero / Mode setting
NET	: Indicates that the clothes weight is input	
Weight Only	: Indicates that the Weight Only (Scale) Mode	
Weight Lock	: Indicates that the Weight is locking	
Weight Lock Mode	: Indicates that the Weight Lock function is activated	
Age	: Indicates that the age is input	
Height	: Indicates that the height is input	
Step On	: Indicates that the measuring start	

37.6 Performing a BIA Measurement

- Bare feet must be used when taking a measurement and the feet must be over the electrode panels during measurements.
- The soles of the feet should be clean and free of dirt, and the participant should not be wet from sweat or urine.

Scale Mode

- Turn on Tanita SC-240 device, using the ON/OFF key.
- Use the MODE key and select the scale mode. Check that the weight only mode is selected. Input 1 kilogram for clothes weight. This is the standard weight for all clothes for each participant. So make sure all unnecessary clothing is removed and all shoes and socks are off. Use the up and down keys to input 1 kg. and then press the enter/zero key.
- Once the “Step on” is displayed and is flashing, have the participant step on the Tanita platform over the electrodes. Make sure the participant is not touching anything and that no one is touching the participant. The measurement will be displayed and the participant may step off of the platform (and seated until composition mode is accessed, if needed).
- Record the height in centimeters and weight in kilograms on PVDOMICS Form 132.

Body Composition Mode

- Press mode button on the device and choose body composition mode.
- Re-enter the clothes weight if needed (1 kg) and press 'enter/zero' key.
- Select the body type standard or athletic using the up and down keys. Press "Enter/Zero" key.
- Select the gender and use the "Enter/Zero" key.
- Input participant's age using the up and down keys and press "Enter/Zero" key.
- Input the height in centimeters using the up and down keys and press "Enter/Zero" key.
- Have the participant step on the platform again when the "Step On" is flashing. Make sure the participant is not touching anything, is standing still and that no one is touching the participant.
- Record the measured body fat percentage display, measured body mass index (BMI), total body water % and impedance on PVDOMICS Form 132.
- Participant is free to leave for other testing procedures.

Refer to the manual if any error messages display and attempt to re-perform the reading if needed.

37.7 Maintenance of Tanita SC-240 BIA Device

Prior to use and on a daily basis, make sure the device is on a stable and level surface, away from moisture and is in an environment with a stable temperature.

Each week, visually inspect the display, cables, electrodes, cords and connectors, to make sure there that they are free from damage, soiling and contamination. Do not use equipment that appears damaged.

37.8 Information about the Tanita SC-240 BIA Device

The URL for the Tanita website is: <http://www.tanita.com/es/tanita-health-ware/>

This website identifies that the Tanita BIA device works with Windows XP (32-bit and 64-bit English version) [Note: Windows XP is no longer supported by Microsoft], Vista (32-bit and 64-bit English version), Windows 7 (32-bit and 64-bit English version), Windows 8 (32-bit and 64-bit English version) and Windows 10(32-bit and 64-bit English version). Tanita 240 software is not compatible with Mac and not compatible with some netbooks. Cables are sold separately.

There 1 license per CD per computer. Additional licenses must be purchased separately if more than one computer will use the software. Local funds must be used by Clinical Center to purchase additional licenses and/or equipment.