The NIHR Southampton Biomedical Research Centre (BRC) has a tight quality assurance system for the writing, reviewing and updating of Standard Operating Procedures. As such, version-controlled and QA authorised Standard Operating Procedures are internal to the BRC.

The Standard Operating Procedure from which information in this document has been extracted, is a version controlled document, managed within a Quality Management System. However, extracts that document the technical aspects can be made more widely available. Standard Operating Procedures are more than a set of detailed instructions; they also provide a necessary record of their origination, amendment and usage within the setting in which they are used. They are an important component of any Quality Assurance Framework, but in themselves are insufficient and need to be used and interpreted with care.

Alongside the extracts from our Standard Operating Procedures, we have also made available here an example Standard Operating Procedure and a word version of a Standard Operating Procedure template. Using the example and the Standard Operating Procedure template, institutions can generate their own Standard Operating Procedures and customise them, in line with their own institutions.

Simply offering a list of instructions to follow does not assure that the user is able to generate a value that is either accurate or precise so here in the BRC we require that Standard Operating Procedures are accompanied by face-to-face training. This is provided by someone with a qualification in the area or by someone with extensive experience in making the measurements. Training is followed by a short competency assessment and performance is monitored and maintained using annual refresher sessions. If you require any extra information, clarification or are interested in attending a training session, please contact Dr Kesta Durkin (k.l.durkin@soton.ac.uk).

This document has been prepared from Version 1 of the BRC Standard Operating Procedure for bioelectrical impedance using the Seca medical Body Composition Analyser. The document was written in January 2014, authorised in June 2014 and the next review date is set for June 2016. The version number only changes if any amendments are made when the document is reviewed.

NIHR Southampton Biomedical Research Centre

Procedure for USING THE SECA MEDICAL BODY COMPOSITION ANALYSER (mBCA)

BACKGROUND

The Seca mBCA (medical Body Composition Analyser) analyses body composition using the Bioelectrical Impedance methodology. Bioelectrical Impedance is a method used to obtain impedance values generated by different components of the body in response to a small electric current. Cells that have the highest proportion of fat (consisting of only 10-20% water) are the most efficient at blocking/reducing the small electric current (giving higher impedance values). Lean tissue cells (found in Fat Free Mass (FFM) [organs, muscle and bone]) which consists mostly of water (70-75%) allow the electric current to pass much more easily (giving lower impedance values). Based on the impedance results obtained which are a measure of how much the electric current is blocked or reduced by components of the body, equations can be used to calculate Total Body Water (TBW) which in turn is itself used to calculate additional information. At lower frequencies the applied current can not pass through cell membranes; it passes around the cells in the extra-cellular space and hence works out the amount of Extra-Cellular Water (ECW) only. Higher frequency currents can penetrate cell membranes thus permitting the calculation of TBW (that which passes around the cells + the water inside the cells). Using the values for TBW and ECW, the Intra-Cellular Water (ICW) can then be calculated (TBW - ECW = ICW). This is why using machines that make measurements at more than one frequency can provide more information to the user.

PURPOSE

To ensure correct and uniform use of the Seca mBCA within the BRC.

SCOPE

This procedure applies to any study that requires measuring bioelectrical impedance using the Seca mBCA within the BRC.

RESPONSIBILITIES

It is the responsibility of the measurer to use this procedure when measuring bioelectrical impedance using the Seca mBCA. It is the responsibility of the Principal Investigator to ensure that staff members who are working on specific studies have adequate experience to do so.

PROCEDURE

Setting up

1. Switch the laptop, printer and Seca mBCA machine on at the wall sockets.
2. Get the SECA Wireless Dongle (figure 1) out of the box file and plug into a USB port on the laptop. The box file is on the bottom on the workstation desk next to the printer and is labelled "Seca mBCA".

Figure 1. Seca wireless dongle

3. Turn on the Seca mBCA machine by pressing the on/off button on the bottom left corner of the display panel.
4. Do not touch any part of the equipment during this process as you will interfere with internal set-up calibrations.
5. Wait until the start screen is displayed. It should say 0.00 in centre of the screen as it will not be registering any weight.
6. Switch on the laptop and log in with your UHS login details.
7. Click the "SECA medical software" icon on the computer desktop to open the Seca mBCA software program.
8. It will ask for a username and password. This will be supplied to you after training. During the training session the trainer will use their log in details.
9. Enter the user name and password that has been assigned to you.
10. Press login.
11. Check that the Seca mBCA machine and the computer are communicating with each other by searching for a patient through the Seca mBCA machine.
12. On the Seca mBCA display screen press the "patient" button on the right side of the screen.
13. Tap the "ID" box.

14. Search for "TEST1" by typing this into the ID box.
15. Press the enter button (↵).
16. Press "Search" again.
17. You will be asked to enter your PIN. This will be given to you after you have been trained and deemed competent to use the Seca mBCA machine.
18. Enter the PIN.
19. Press the enter button
20. If the machine finds "TEST1" then you have confirmed the connection between the laptop and the Seca mBCA machine. If there is no connection the machine's display panel will read "unable to establish connection with database".
21. Set up is now complete and you can return to the main display screen by pressing the "weight/height" button on the display panel.

Making the measurements and saving the results

1. Wash your hands and explain the procedure to the participant.
2. Ask them to remove any outer clothing, empty pockets and remove chunky jewellery.
3. Ask them to remove both shoes and socks/tights.
4. Ask them to stand on the Seca mBCA machine such that their heels and balls of each foot are touching the metal electrodes on the base of the machine (figure 2).

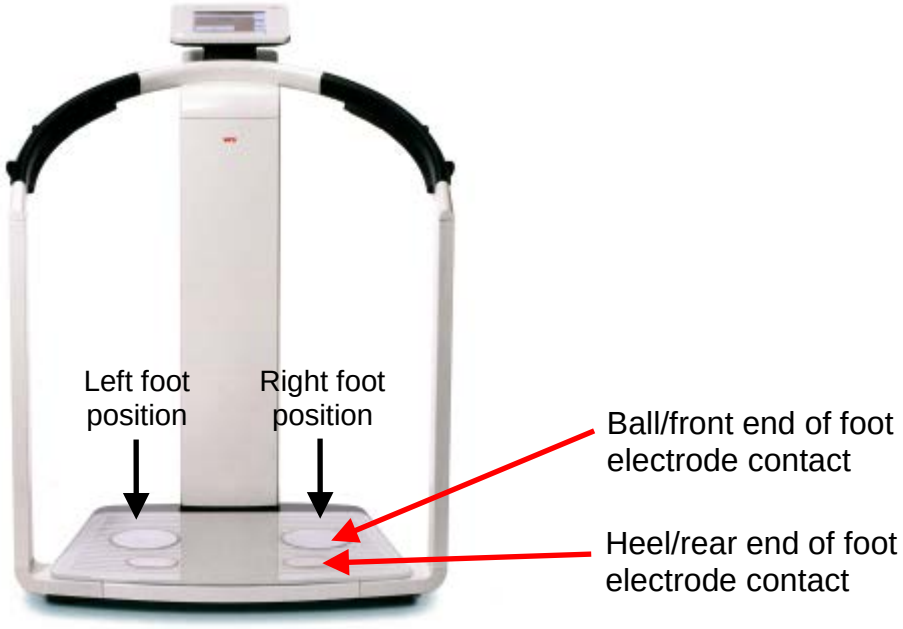

Figure 2. Foot placement on the Seca mBCA machine

5. Ask the participant to keep still and look straight ahead whilst the Seca mBCA machine takes a measurement of their weight.
6. You can tell when this is completed as the weight displayed in the weight box in the bottom left of the screen will stop flashing and displays the word "hold" and the machine makes a beep sound.
7. Ask the participant to remain in position.
8. Now press the height box which is to the right of the weight box and enter the person' height measurement value, determined by following the appropriate SOP and then press the enter button.
9. Press the second button down on the right hand side of the display panel "BIA".
10. Ensure that every box is ticked before proceeding.
11. Press "continue".
12. Accept or decline the safety information box. Press no if the participant is not included in the following groups of individuals:
    a. Electronic implants (such as cardiac pacemakers)
    b. Prostheses
    c. Electronic life-support systems connected (such as artificial heart/lung)
    d. Portable electronic medical device connected (such as ECG)
13. The next screen is a diagram of a person with 4 red boxes pointing to:

    Hand, left

    Hand, right

    Foot, left

    Foot, right

The person's arms should be extended, but not under tension. Their legs should be relaxed with knees slightly bent and not under tension (figure 3). The participant must remain in the same position with their hands on the rail and their feet and fingers making contact with the electrodes until point number 23.

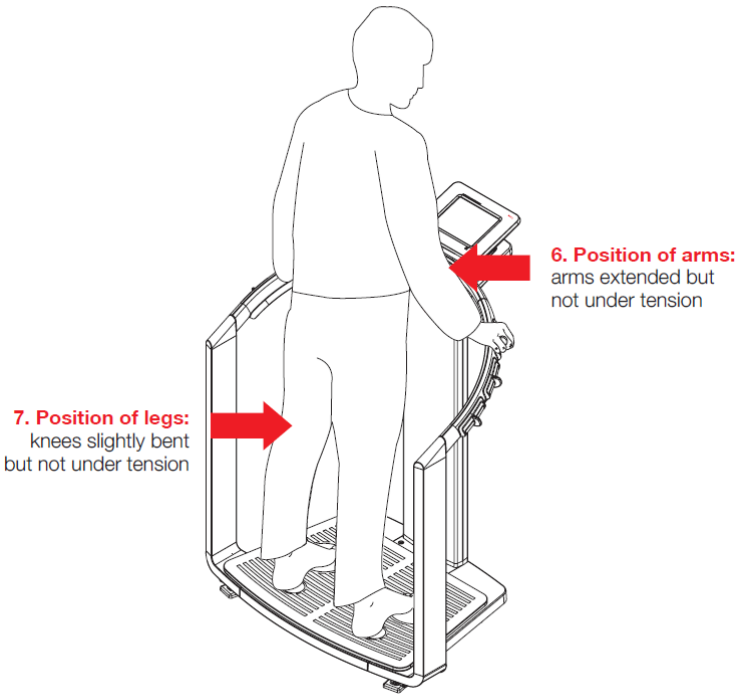

Figure 3. Positioning of the participant on the Seca mBCA machine

14. Ask the participant to position their hands on the sides of the machine in a very specific way. Four fingers on each hand must make contact with the electrodes and the fingers on each hand must be separated by a finger spacer – with two fingers making contact on each side of the spacer (figure 4). There are three positions (A, B and C) to accommodate individual heights/arm lengths.

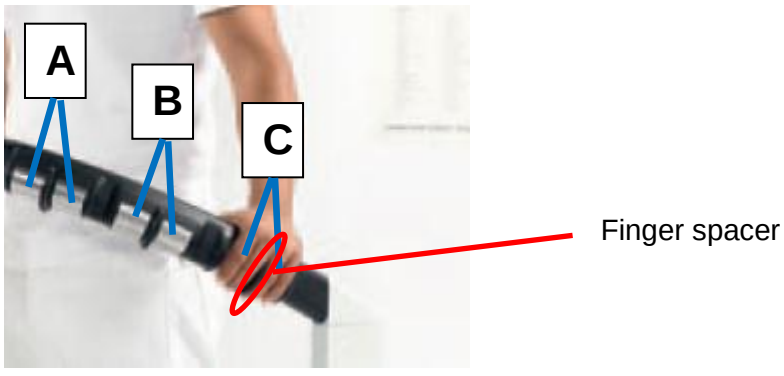

Figure 4. Positioning of hands for electrode contact on the Seca mBCA machine

15. When the machine can detect sufficient contact with all 4 electrodes the red boxes will display green tick symbols and the measurement will begin.

16. The measurement will take 75 seconds, during which time the participant must remain in the same position with their hands on the rail and their feet and fingers making contact with the electrodes.
17. At the end of the measurement the screen will display "End of measurement. Measurement completed successfully".
18. Press continue on the bottom left of the display panel.
19. The participant may now release their grip on the hand electrodes.
20. You will be asked to enter a value for activity level (figure 5).

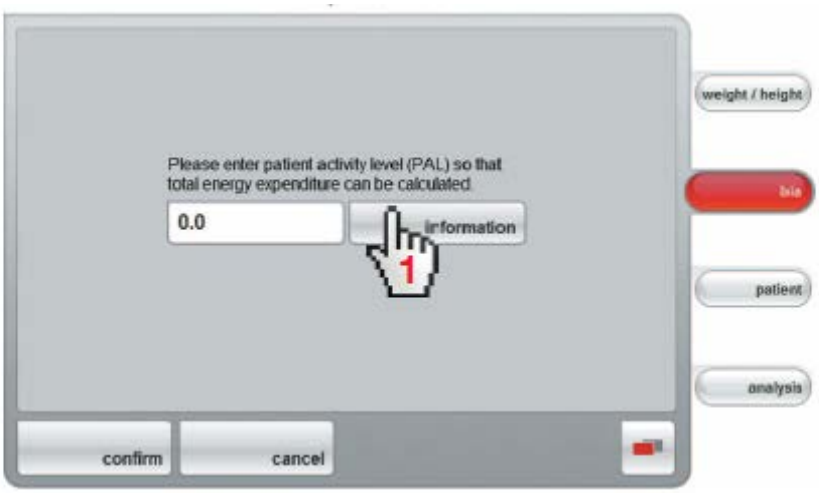

Figure 5. Activity level options.

21. Press the "information" button to help you in determining the value to enter for an individual's activity level, for example, if from the list of choices below you and the participant agree that your lifestyle leads you to chose 1.6 (mainly sitting down, occasionally standing), then you can press 1.6 (figure 6). If you feel as though you are in between 1.6 and 1.8 (mainly standing or walking) then you can either: a) when you are faced with the screen shown in figure 5, press the white box where it is displaying 0.0 and it will allow you to enter 1.7. Or b) if you are faced with the screen shown in figure 6 you can select one from the list by pressing it, but if you want to enter a value in between as described above, press "cancel" to take you back to the screen shown in figure 5.

Figure 6. Options for physical activity level.

22. When you have entered your chosen value for activity level, press the enter button, then "confirm".
23. The participant may now step off the machine and replace outer clothing, shoes, socks/tights and jewellery that they might have removed.
24. The "patient" button (third button down on the right of the screen) will be highlighted red now and you will be required to enter patient details: Enter an ID for the participant. The designated patient number/ID of that participant will be helpful here. Enter date of birth, surname and first name and then press "create".
25. Select "male" or "female" and then select the participant's ethnicity.
26. Press "continue" on the bottom left of the screen.
27. Then press "confirm" on the bottom left of the screen.
28. Check all the details you have entered are correct.
29. If they are, press "confirm" again on the bottom right of the screen.
30. If not, press "cancel" and amend.
31. You will then be taken to the analysis section and the fourth button down on the right of the screen will be highlighted red.
32. Press "save".
33. Return to the laptop and check that the participant you have measured has been saved to the database. The new participant/measurement should be there in the list (figure 7).

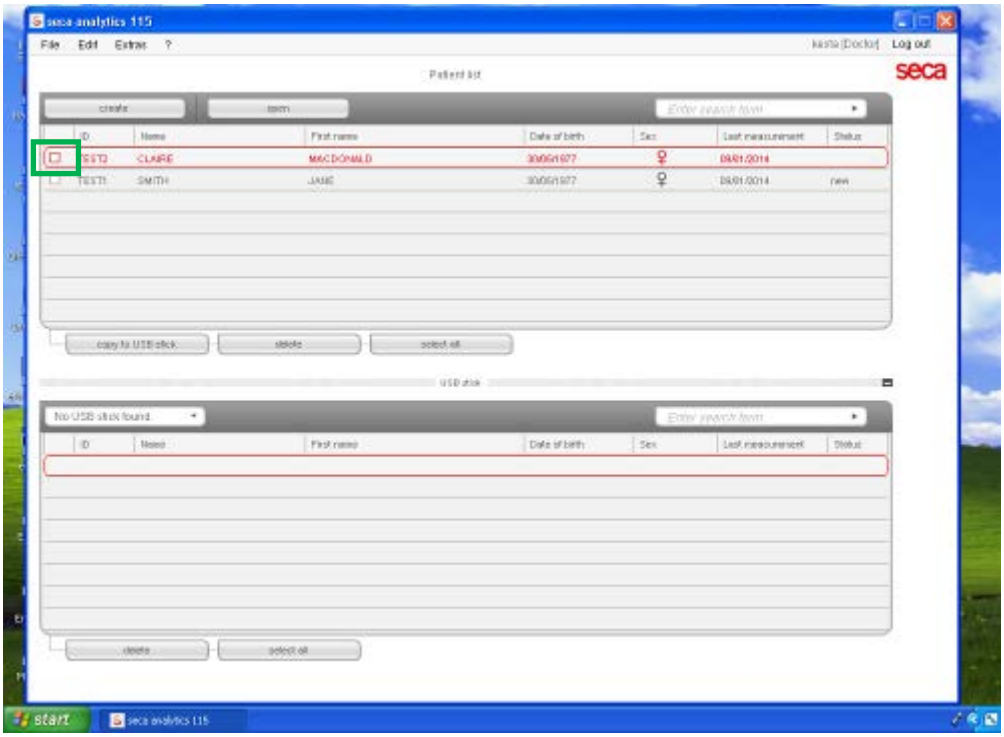

Figure 7. List of results shown in the Seca mBCA software on the linked laptop.

34. To open one of the test results double click anywhere on the row to bring up a results window (figure 8).

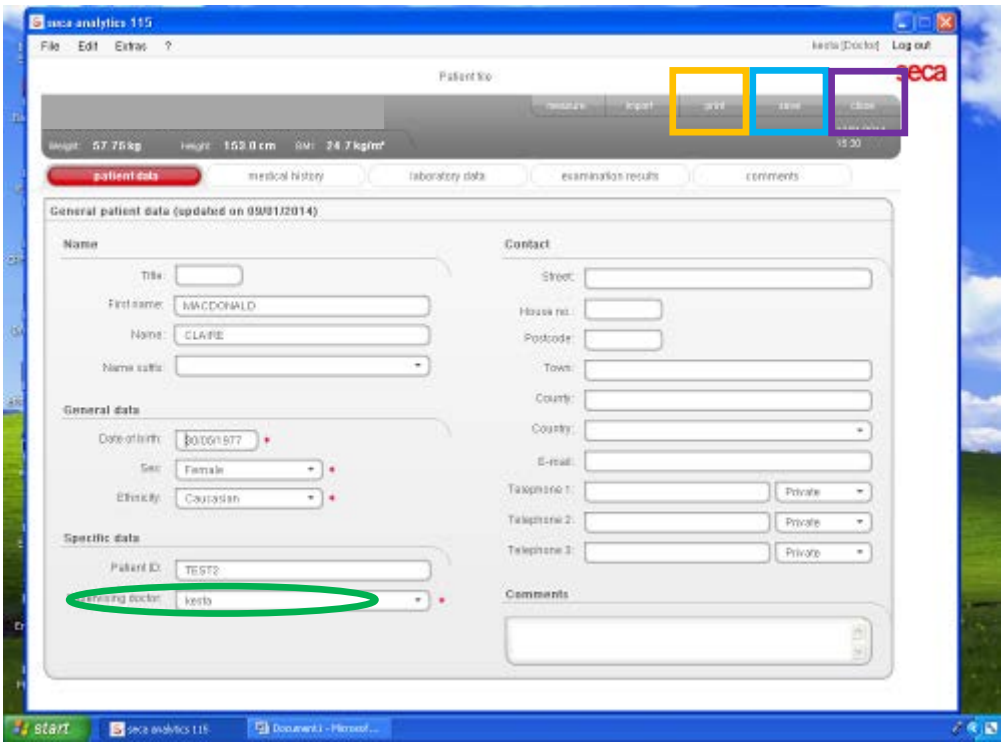

Figure 8. Participant test results

35. Assign a "supervising doctor". You must do this in order to view the results. To do so, use the dropdown menu (outlined in green, figure 8) and select the name you have been told to use when saving your data, during your training session. If one is already assigned, move on to point number 36.
36. After this, press "save" (outlined in blue, figure 8). A box appears saying the data has been saved. Press "ok" on the small window that appears.
37. **Always save and close any open participant data files before opening another.**
38. If you want to print or save a pdf. version of the results press "print" (outlined in yellow, figure 8).
39. Put a cross in all the relevant boxes (cardiometabolic risk is not always available to tick); there is no need to select "patient printout" and "therapy plan".
40. Select "create pdf".
41. The software will them produce and automatically open a pdf version of the results.
42. Save to where you have arranged to store your data by selecting "file", "save a copy", give the document an easily identifiable filename (i.e. participant ID and visit number) and then "save".
43. If you want to print the document go to "file", "print" and select printer *hp deskjet 990c* from the drop-down printer list, then press "print". The document will be printed from the printer in the room on the bottom shelf of the work station.
44. Close the pdf results file.
45. To get back to the main patient list press the "close" button (outlined in purple, figure 8).
46. To export and save the data to .csv format (recommended) select which patient you want to export data for by putting a cross in the box (outlined in green, figure 7).
47. Next go to "file" then "export".
48. From the window that appears, select which parameters you want to export (select all) and then press "ok".
49. Select the folder you want to save the data to and then press "ok".
50. Then press "save".

Shutting down

1. Log out of the computer software program by pressing "log out" on the top right of the software screen.
2. Press the X to close the software window completely.
3. Shut down the computer.

4. Turn off the Seca mBCA machine by pressing and holding the on/off button until the light goes out and screen goes blank.
5. Unplug the dongle (figure 1) and replace in the Seca mBCA labelled box file.
6. Switch off laptop, printer and Seca mBCA machine at the wall sockets.