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 using the Seca medical Body Composition Analyser validation test kit. It was approved in December 2014 and the next review date is set for December 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 mBCA VALIDATION TEST KIT

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.

In order to be confident that the Seca mBCA machine is working correctly it must undergo monthly validation checks. A record of which is kept in the Seca mBCA validation folder in the Bod Pod and Body Comp room (WC205A) in the NIHR Wellcome Trust Clinical Research Facility (CRF).

PURPOSE

To ensure the correct validation procedure for the Seca mBCA machine, within the BRC.

SCOPE

This procedure applies to any individual performing the monthly validation checks on the Seca mBCA machine, within the BRC

RESPONSIBILITIES

It is the responsibility of the individual to use this procedure when performing monthly validation checks on the Seca mBCA machine and they will be responsible for reporting and recording the outcome of the validation test in the validation test folder held in the Bod Pod and Body Comp room (WC205A).

PROCEDURE

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. Position the components of the Test kit on the equipment in the following order.

    a. Position one small cylindrical test weight on each foot electrode (figure 1). It does not matter which one goes on which electrode but the end with the hole in the centre needs to be face-up.
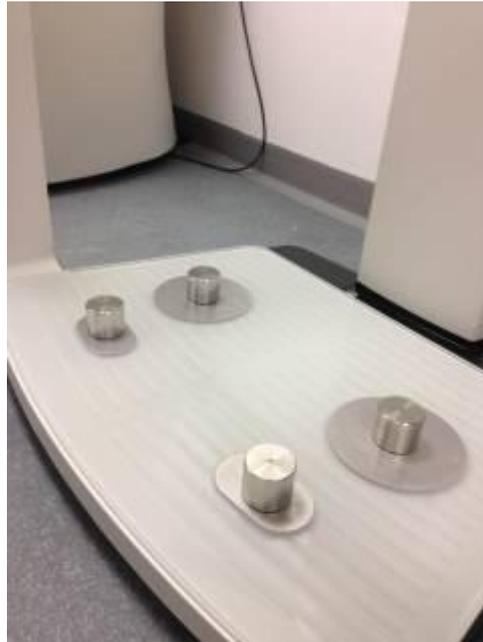
Figure 1.

b. Clip the red and black clips to contact the hand electrodes on each side of the machine, in the positions shown in figure 2. Make sure the red clips are at the front (figure 2).

Figure 2.

c. Connect red leads in the "hand leads" bag to the red clips and black leads in the "hand leads" bag to the black clips over the hand electrodes (figure 3). The attachment side of the clips needs to face outwards and the larger pin end of the leads must be pushed through the hole and the screw mechanism used to tighten the lead in place. Leave the other end of the leads to dangle for the moment.
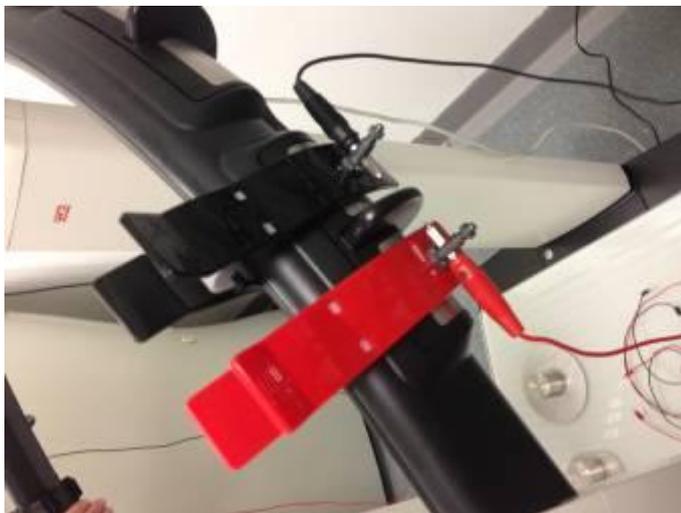

Figure 3.

d. Make sure the sets of red and black leads and the Reference Unit are out of the case and then place the case on its end on to the machine (figure 4). Double check you are using the Reference Unit do NOT use the Test Unit. Leave all the other components in the box.

Figure 4.

e. Now use the other set of red and black leads.
f. Take two red leads from the "foot leads" bag and connect one to each of the cylindrical weights on the ball of the foot electrodes (figure 5).

g. Take two black from the "foot leads" bag and connect one to each of the cylindrical weights on the heel of the foot electrodes (figure 5).
h. Place the Reference Unit on top of the case and connect the other end of the two red and two black leads plugged into the weights, into the corresponding coloured positions at the person's foot-end of the image on the Reference Unit (figure 5).
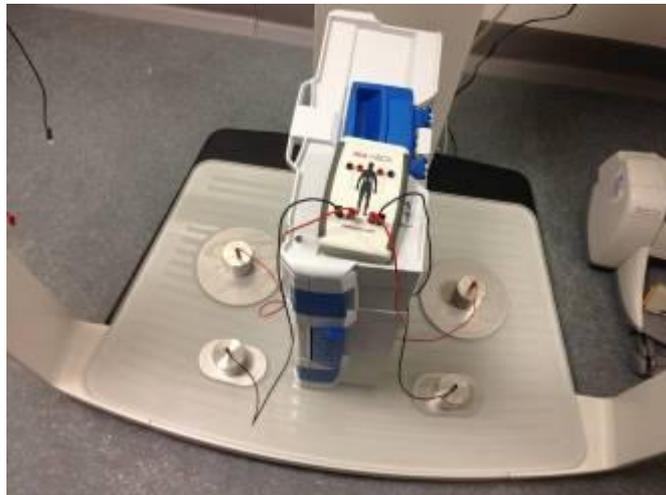

Figure 5.

i. Now take the dangling opposite end of the red leads for the hands that you previously connected to the red clips and connect the dangling free end to the corresponding coloured positions at the person's head-end of the image on the Reference Unit (figure 6).
j. Do the same for the black leads (figure 6).

Figure 6.

11. Set-up of the test kit is now complete. Check that your set up matches that shown in figure 6.
12. Work with the machine now as if you are measuring a participant
13. The weight should read the weight of the test kit (5.8kg). Press hold to fix the weight.
14. Enter a height value of 1 meter and then press the BIA button on the right of the display panel.
15. Carry out the measurement by performing the long (75 second) test. This requires you to make sure that all the boxes are ticked (**including the "raw data for impedance"** box) when you are viewing the screen shown in figure 7. Do not touch the machine whilst the measurement is in progress.
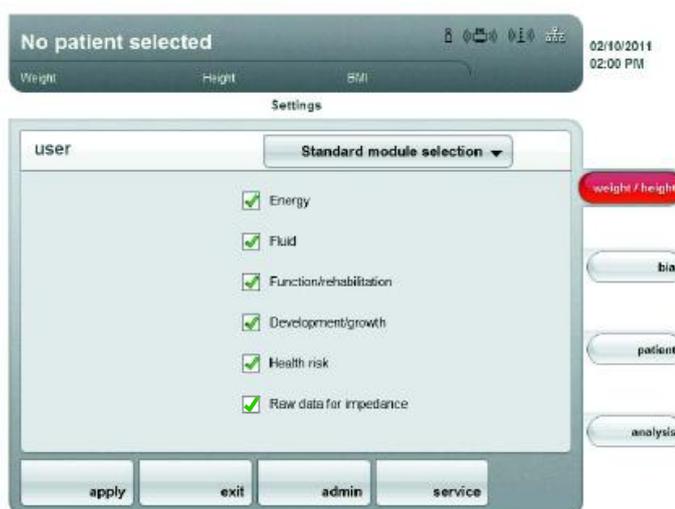

Figure 7.

16. When the measurement is complete, press "continue".
17. When asked to enter "Activity Level" enter the value **1.5** and then press "confirm".
18. On the screen that requests the patient details:

    For First Name, enter "**3**" and for Surname enter "**VALIDATION**"

19. When this has been entered press "search".
20. Enter user PIN when requested.
21. Wait until the machine has completed the patient search and when VALIDATION 3 has been found, press "confirm".
22. Press "save".
23. Open the file on the laptop and obtain navigate to the "Raw Data for Impedance" section. Select "Right Half of Body" and check the results at 5 and 50kHz fit within the required limits.

Raw Data Measurements	Target Value
Z_{re} (50kHz)	524.9Ω (+/-1Ω)
Φ_{re} (50kHz)	0.0° (+/-0.1°)
R_{re} (50kHz)	524.9Ω (+/-1Ω)
Xc_{re} (50kHz)	0.0Ω (+/-1Ω)
Z_{re} (5kHz)	524.9Ω (+/-1Ω)
Φ_{re} (5kHz)	0.0° (+/-0.1°)
R_{re} (5kHz)	524.9Ω (+/-1Ω)
Xc_{re} (5kHz)	0.0Ω (+/-1Ω)

24. Record the results on the Seca mBCA Validation Record Form in the blue folder labelled Seca mBCA Validations in the Bod Pod and Body Comp room in the CRF (WC205A)
25. If there are any problems and the results are not within the specified limits repeat the test twice more. If the problem persists, please report the problem to the SCBR Operations Manager and clearly mark the machine "Do not use" so that it is not used again before repair/recalibration.
26. Shut down the laptop and the mBCA machine.
27. Completely dismantle the validation kit set-up and return all the components to the box.