

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 2 of the BRC Standard Operating Procedure for using the ImpediMed SFB7 bioelectrical impedance machine. It was last reviewed in May 2014 and the next review date is set for May 16. The version number only changes if any amendments are made when the document is reviewed.

NIHR Southampton Biomedical Research Centre

Procedure for using the IMPEDIMED SFB7 BIOELECTRICAL IMPEDANCE MACHINE

BACKGROUND

This Standard Operating Procedure is to be used for measuring bioelectrical impedance (BI) using the ImpediMed SFB7 equipment. BI and Bioelectrical Impedance Spectroscopy (BIS) are methods designed for measuring body composition and are based on the observation that the body's lean compartment (which includes muscle, bone and water), conducts electricity far better than the body's fat compartment which is low in body water.

The ImpediMed SFB7 is a single channel – tetra polar device that scans 256 frequencies between 4 and 1000 kHz. Cole modelling with Hanai mixture theory are used to determine total body water (TBW), extracellular fluid (ECF) and intracellular fluid (ICF) from impedance data, and additional data can be generated both by the equipment directly and/or using the software supplied with the device.

PURPOSE

To ensure correct and uniform use of the ImpediMed SFB7 body composition monitoring unit for multi-frequency whole body electrical impedance.

SCOPE

This procedure applies to any study requiring measurements of bioelectrical impedance using the ImpediMed SFB7 body composition monitoring unit, within the BRC.

RESPONSIBILITIES

It is the responsibility of the measurer to use this procedure when measuring bioelectrical impedance using the ImpediMed SFB7 body composition monitoring unit. It is the responsibility of the principle investigator to ensure that staff members who are working on specific studies have adequate experience to do so.

PROCEDURE

Do not use this device on patients with active implanted medical devices, e.g cardiac pacemakers, defibrillators or patients connected to electronic life support devices. The ImpediMed SFB7 has yet to be clinically validated for use with pregnant patients; however, bioelectrical impedance technology has been shown to have no adverse affects.

Before testing

The operator should be mindful of the fact that certain situations are known to affect body water concentration:

- Just prior, during and just after menstruation.
- Use of diuretics.
- Renal or heart failure.
- Excessive exercise 2h prior to bioimpedance analysis.
- Consumption of excessive alcohol within 12h prior to analysis.

Preparing the volunteer

Prior to analysis the volunteer should:

1. Remove all jewellery (rings on fingers may be left on).
2. Remove stockings/tights/socks
3. Have an empty bladder
4. Be accurately measured for height (to the nearest 0.5 cm) and weight (to the nearest 0.1 kg).
5. Lie in the supine position for 5 minutes.
6. Ensure that their feet are not in contact with the bed frame (if present).
7. Extend their arms and legs making sure that they are not in contact with one another or touching/resting on any other part of the body.

Before using the ImpediMed SFB7:

8. Do not use the machine when it is plugged in to the mains. The measurements are meant to be made when the machine is operating on battery power.
9. Perform a calibration check on the machine (See "Calibration of the ImpediMed SFB7" section of this SOP). You will need to remove the alligator clips at the ends of the leads to do this.
10. Replace the alligator clips after performing the calibration test.

11. The manufacturers recommend the leads remain plugged in to the back of the device. Continual plugging and unplugging of the leads into the back of the machine is more likely to damage the leads over time.
12. Check the expiry date of the electrodes.
13. Remember to always use the stylus end (non-writing end) of the ImpediMed supplied pen to operate the touch screen. This pen is kept in the lid part of the ImpediMed carrying case.
14. Check the battery status in advance of seeing the patient. By selecting "setup" on the start screen you can check, by looking at the battery indicator, whether there is sufficient battery power to complete your series of measurements. To do this, select "setup" and look at the large battery symbol on the right side of the screen. To fully charge a depleted battery it will need to be plugged in for 6 hours (during which time the equipment may not be used). A fully charged battery supplies 4-8 hours worth of operating time before recharging is needed.
15. Wash your hands and explain the procedure to the volunteer.
16. Obtain accurate measurements of the volunteer's height (in cm, to the nearest 0.1 of a cm) and weight (in kg, to the nearest 0.1 of a kg) following appropriate SOPs.
17. Instruct the volunteer to remove their shoe and sock from their right foot, remove any watches or bracelets on the right wrist which may impede the correct placing of electrodes, and lie in the supine position for 5 minutes before taking the measurements.
18. Ensure that the legs and arms are spread out so they are not in contact with any other part of the body.
19. Thoroughly wipe (using sterettes) the area of the skin where the electrodes are to be attached (as products such as body moisturiser can affect the results).

Using the ImpediMed SFB7:

20. Turn on the SFB7 machine by pressing the on/off button on the front of the main unit (figure 1).

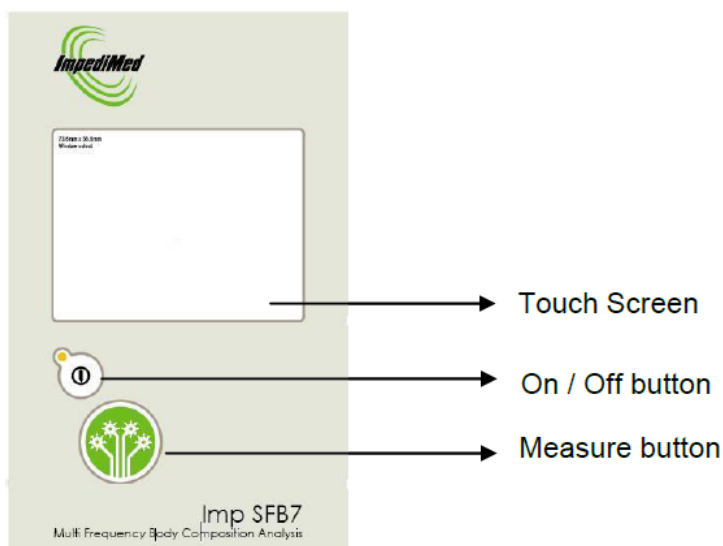


Figure 1. The front of the ImpediMed SFB7 unit.

21. To select whether you want the device to take measurements in BIS (bioimpedance spectroscopy) mode or in SFBI (selected frequencies) mode, tap "setup" (figure 2) on the start screen and then select "modules" (circled red, figure 3).

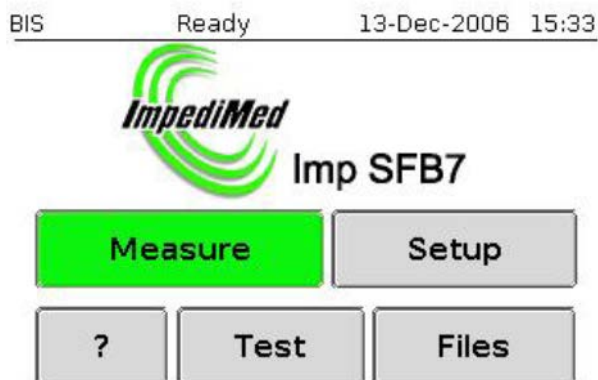


Figure 2. The start screen.

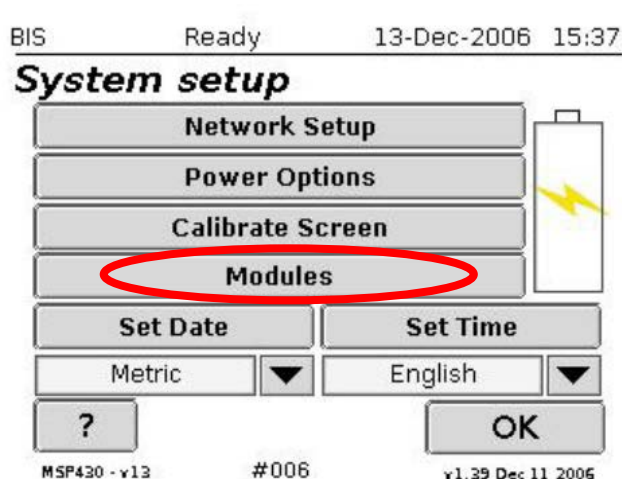


Figure 3. Setup screen

22. After tapping “modules”, choose either BIS or SFBI by tapping the screen. The one you have selected to use, from the “modules” screen will be marked with a cross. BIS will then be displayed on the upper left of the ImpediMed machine screen (circled red, figure 4).

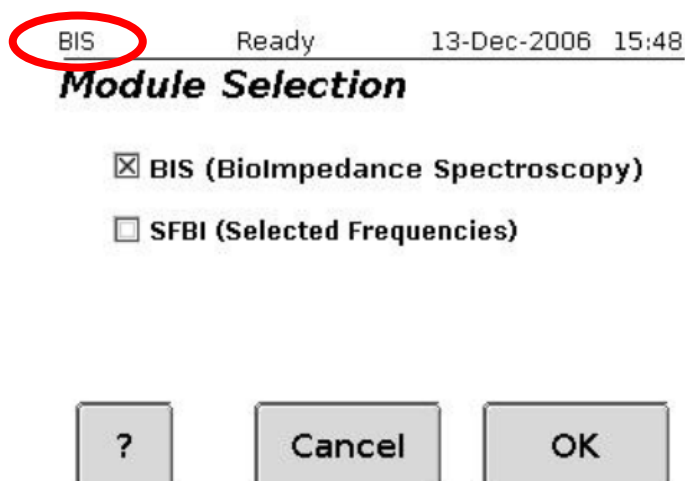


Figure 4. The module selection screen

23. Place two electrodes on both the right hand and the right foot with the tabs of the electrodes facing outwards (away from the volunteer) and connect the alligator clips on each lead to the appropriate electrode, following the instructions and diagrams below. There needs to be 5cm of free skin between the two electrodes. Use a ruler to measure this – there is one in the zip pocket of the ImpediMed machine case.
24. Note that the placement of the electrodes to which the red lead and the black lead are attached is further away from the knuckles and toes than that for the Bodystat QuadScan 4000 and the Bodystat 1500.

The yellow lead

The yellow lead end is attached to the electrode on the right hand, on the wrist next to the ulnar head (wrist joint, figure 5).

The red lead

The red lead is attached to the electrode on the dorsal surface of the right hand (figure 5).



Figure 5. Placement of electrodes on hand

The blue lead

The blue lead end is attached to the electrode on the dorsal surface of the right foot, on the ankle at the level of the medial and lateral malleoli (large protruding bones on the side of the ankle, figure 6).

The black lead

The black lead end is attached to the electrode on the dorsal surface of the right foot (figure 6).



Figure 6. Placement of electrodes on foot

Making measurements in BIS mode

25. Select BIS mode by following the instructions above (no. 2, figure 3 and 4)
26. Tap "measure" on the starting screen to take you to the BIS "measurement setup" (figure 7) screen and tap on the "file name" box. This will bring up a key pad where you can type in the file name and/or number of your choice. After choosing a name for your file tap "ok" (If at this stage, the machine switches itself off, please follow the instructions on the laminated letter from ImpediMed [in a pocket of the ImpediMed machine carry case], which describes how to avoid this).

BIS Ready 13-Dec-2006 16:20

Measurement setup

File Name
test07 -0005.mfu Reset

Measurements Patient Details
Single ▼ Edit...

Interval (seconds) Number
1 ← → 6 ← →

? Back Measure

Figure 7. Measurement setup screen for BIS

27. Tap "patient details" and select the volunteer's gender, height, weight and age (figure 8) and then tap "ok". If you tap on the area circled red in figure 8 (instead of changing the value using the arrows), you can enter a more accurate height and weight value using the numerical key pad on the screen.

BIS Ready 13-Dec-2006 16:29

Patient Details

Gender: Female ▼ Height: 175.0 cm ← →

Age (yrs): 35 ← → Weight: 70.0 kg ← →

? Cancel BCA Ok

Figure 8. Patient details screen for BIS

28. Tap the down arrow to the right of the “measurements” box and select “continuous” and “3” (figure 7 – showing “single”).
29. Check that all the alligator clips are correctly attached and that the volunteer is lying in the correct position and then press the measure button on the front of the device (large circular green button) or tap the “measure” box on the touch screen (figure 1 and 7).
30. Then tap “start” to begin.
31. Making measurements in SFBI mode – note: you do not need to enter details of weight, height, age and gender when using the SFBI mode only.
32. Select SFBI mode by following the instructions above (no. 2, figure 3 and 4)
33. Tap “measure” on the starting screen to take you to the SFBI “measurement setup” screen and tap on the “file name” box. This will bring up a key pad where you can type in the file name and/or number of your choice. After choosing a name for your file tap “ok” (If at this stage, the machine switches itself off, please follow the instructions on the laminated letter from ImpediMed [in a pocket of the ImpediMed machine carry case], which describes how to avoid this).
34. Tap the down arrow to the left of the “measurements” box and select “single” (figure 9).
35. Now the machine is set to SFBI, the box that said patient details in the BIS mode now says “Selected frequencies” and SFBI is displayed in the upper left of the screen (circled red, figure 9).

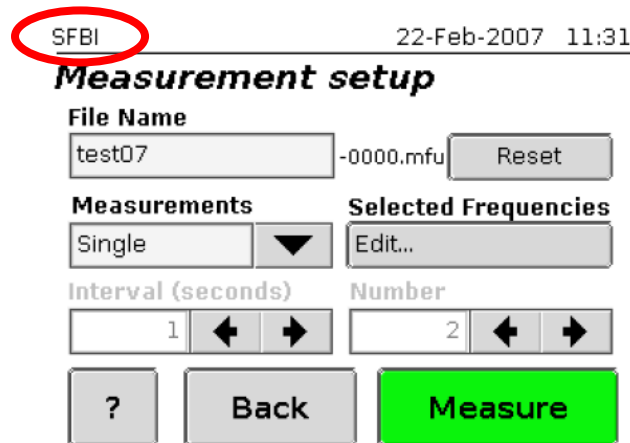


Figure 9. Measurement setup screen for SFBI

36. Tapping on the “selected frequencies” box will take you to the “frequency selection” screen where you may then select which frequencies you would like the machine to use for the measurements (figure 10). Tap on the boxes to put a cross in the frequencies you want to use. This section also gives you the opportunity to select frequencies of your own choice.

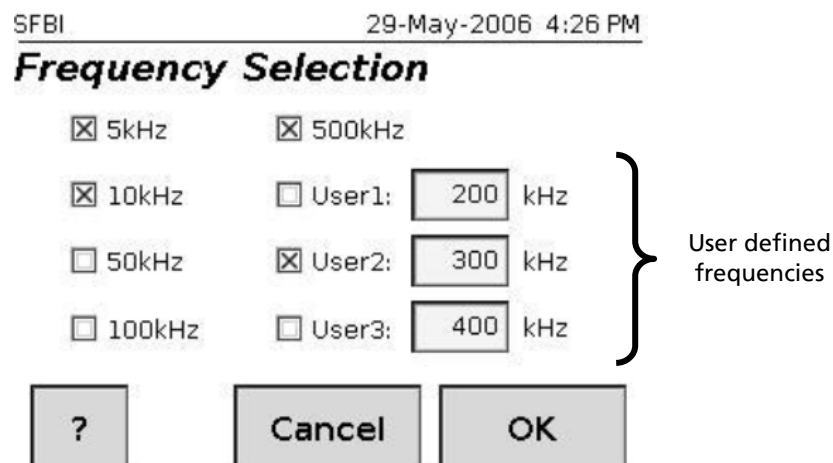


Figure 10. Frequency selection screen for SFBI

37. To make measurements at user-defined frequencies, tap on the box containing the numerical values, adjacent to the User1, User2 and User3 boxes. By doing so, you will be taken to the number keypad where you can enter the kHz value of your choice. Ensure that the boxes next to User1, User2 and User3 are marked with crosses or the machine will not make the measurements at your chosen frequencies.
38. Check that all the alligator clips are correctly attached and that the volunteer is lying in the correct position and then press the measure button on the front of the device (large circular green button) or tap the “measure” box on the touch screen (figure 1 and 7).

Calibration of the ImpediMed SFB7

ImpediMed recommends that calibration checks be performed at the start of each day of use. This is done using the RRC Test Cell, supplied with the machine.

39. Switch on the machine and set it to BIS mode, by following the instructions above (no. 2, figure 3 and 4).
40. Remove the alligator clips from the ends of the leads.
41. Plug the leads into the appropriate sockets of the test cell (figure 11).



Figure 11. The leads connected to the calibration Test Cell

42. From the starting screen, tap "test"
43. Then tap "start".
44. The screen will display "Calculating".
45. Followed by "passed" in green text or "failed" in red text.
46. If the test fails, an error code will be shown. In this instance, contact ImpediMed, your distributor or an authorised service centre, quoting the error code to arrange for service or repair.
47. By tapping "more" you can view graphs.

The R_{zero} value should be 604 ohms (± 5) and the R_{inf} value should be 403 (± 5)