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PERFORM Operating Document

Use and Cleaning of ImpediMed SFB7

PC-POD-CP-010-v02

Revision History

Version	Reason for Revision	Date
02	Created a more consolidated version	May 7, 2020

1. Introduction

The content of this PERFORM Operating Document (POD) provides guidelines for use and the cleaning procedure for the ImpediMed SFB7 bio-impedance analysis unit. This unit assesses body composition (i.e. fat-free mass, fat mass, intra-/extracellular fluid) of participants. This POD applies to all users of the unit.

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2. Unit Components

1= BIA electrodes
2= Lead set
3= Alligator clips (4)
4= Test cell for calibration check
5= Power module for recharging the battery
6= Main power cable
7= Crossover network cable
8= CD-ROM
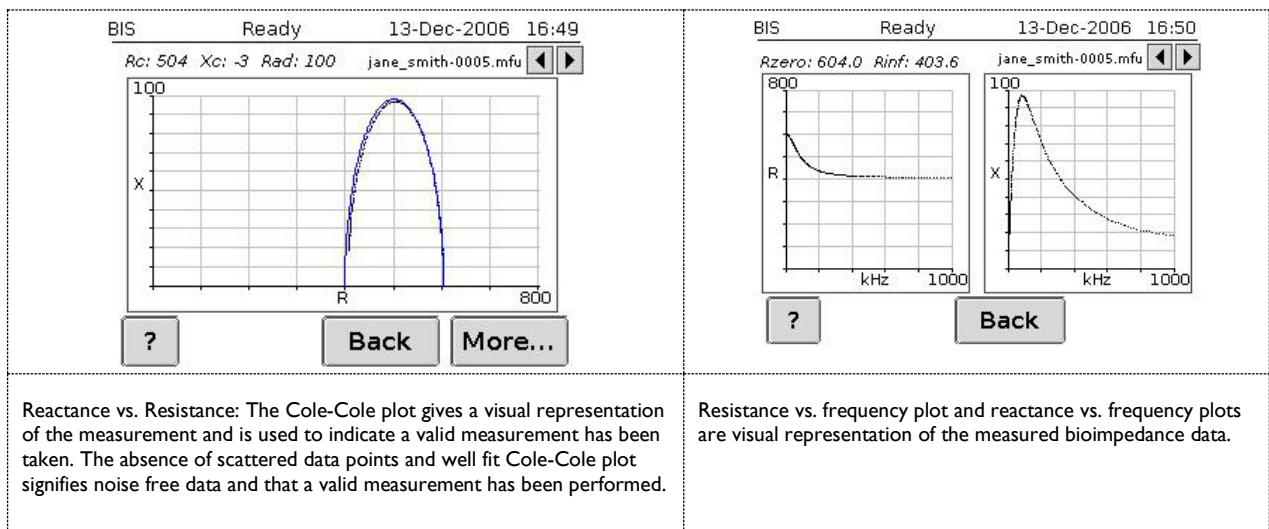9= Stylus pen
10= Microfiber cloth

3. Unit Calibration

Please see user manual for calibration instructions.

4. Modes & Predetermined Measurement Settings

This unit offers two modes of functions: bioimpedance spectroscopy (BIS), and selected frequencies (SFBI).

a. BIS Mode

Reactance vs. Resistance: The Cole-Cole plot gives a visual representation of the measurement and is used to indicate a valid measurement has been taken. The absence of scattered data points and well fit Cole-Cole plot signifies noise free data and that a valid measurement has been performed.

Resistance vs. frequency plot and reactance vs. frequency plots are visual representation of the measured bioimpedance data.

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This mode measures bioimpedance parameters over a frequency range of 4-1000 kHz with 256 data points defining the BIS mode as a true BIS. On-screen graphs display the measured data in the form a cole-cole plot. In addition, the characteristic frequency for the subject is determined as well as total cell membrane capacitance. These estimates are then used in algorithms to give body water and fat-free mass. This mode is what is most commonly used in community programs at PERFORM.

b. SFBI Mode

This mode measures bioimpedance parameters over a frequency range of 4-1000 kHz. There are 8 selectable frequencies of which 5 are fixed and 3 are user definable. The 5 fixed frequencies are: 5, 10, 50, 100, 500 kHz, and the 3 user definable frequencies may be any in the range of available frequencies. A user may also specify the number of measurements to be taken, with a specified measurement interval.

The SFBI function is included to allow a user to compute and present estimates of body composition using published algorithms.

c. Predetermined Measurements Settings

Tapping (with stylus) the arrow button next to the "Measurements" selection box allows the selection of single or continuous measurements, or several measurements made spaced at a selected interval of time. In continuous mode, another measurement is taken immediately after the previous measurement has been completed. In interval mode, another sequential measurement is made after the interval of time selected (in seconds). This is done by tapping the arrow buttons next to the "Interval" edit box or by tapping inside the "Interval" edit box which will make the keypad option available.

For Interval and Continuous measurement settings, the number of measurements can be selected by touching the arrow buttons next to the "Number" edit box or by tapping inside the "Number" edit box which will make the keypad option available.

5. Contraindications for Use

This unit must not be used on participants with the following devices/conditions:

a. Active implanted medical devices (e.g. cardiac pacemaker, defibrillators, or participants connected to electronic life support devices)
b. Undergoing external defibrillation
c. Pregnant

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6. Preliminary Instructions

Participant should respect the following instructions in order to minimize changes in the body's hydration status (as this can over or underestimate values):

    a. Excessive exercise should be avoided 2 hours prior to measurement to avoid changes in vascular perfusion, temperature, cutaneous blood flow, vasodilation, and fluid losses.

    b. Refrain from drinking excessive alcohol within 12 hours prior to BIA.

The following situations will also affect body water concentration:

    a. just prior, during, just after menstruation

    b. use of diuretics

    c. renal or heart failure

7. Preparation Prior to Test

    a. Evaluator must charge unit at least 15 minutes in advance to ensure battery is charged for evaluation.

    b. Check that participant has followed preliminary test instructions.

NOTE: Unit will automatically shut-off after a period of inactivity.

8. Test Procedure

    a. Turn on the unit with by pressing the power button directly below the screen.

    b. Ask participant to turn off mobile phone.

    c. Have participant remove all jewelry, stockings, pantyhose, and/or socks.

    d. Ask participant if they want to go to the washroom. Measure height (nearest 0.5 cm) and weight (nearest 0.1 kg).

    e. Lie participant on their back on table with feet shoulder width apart. Extend their arms by their side with palms down, legs slightly apart (if necessary, place towel between participant's legs or arms and torso in order to prevent skin-to-skin contact and reduced impedance).

    f. Measurement should be taken within 10 minutes of the participant lying down. There is evidence that impedance values rise sharply within the first 10 minutes after the participant assumes the supine position and then continue to rise more gradually for up to 4 hours.

    g. Using the anatomical locations shown below shave the sites, if necessary.

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NOTE: Measurements can be done on either the right or left side, but do not mix sides. Consistent measurement practices and electrode placement are important to obtain accurate results.

Yellow (Sense lead)

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

Red (Current source lead)

The **red** lead end is attached to the electrode on the dorsal surface of the right hand

Blue (Sense 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 medial and lateral malleoli (large protruding bones on the side of the ankle)

Black (Current sink lead)

The **black** lead end is attached to the electrode on the dorsal surface of the right foot

5 cm

h. Clean the sites with an alcohol swab.
i. Allow sites to dry for 30 seconds before placing electrodes.
j. Place electrodes, with tabs pointing away from body, ensuring that they are 5 cm apart measured from the center to center (a 1-cm displacement of electrodes can result in a 2-percent change in resistance). Do not press down on the electrodes too firmly.
k. Attach lead wires to electrode tabs.

NOTE: Ensure that the metallic part of clip is in direct contact with the conductor side (underside) of the electrode tab and that the clips are aligned to the centers of the electrode tabs. The ImpediMed SFB7 should be unplugged from the recharging unit before use to avoid possible noise contamination of the measurement.

l. Click "Measure" in main menu.
m. Click on the box under "File Name" and enter participant ID and press "Ok".
n. Click on "Edit" under "Patient Details".
o. Enter information and click "Ok".

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p. Predetermined measurement settings (e.g. number of measures to be taken and at what interval) may be set to the following, but can be modified at this stage:

> **Measurement: interval**
> **Interval(s): 10**
> **Number: 3**

q. Click "Measure".
r. Click "Start". Once measurements are completed (based on predetermined settings) the unit will say "Ready" at the top. Data is automatically saved.
s. Press "Exit", then "Back" 2 times to go back to the main menu.

9. Data Retrieval

a. *Reading data from unit*

   i.   Press "Files" from the main menu.
   ii. Use the arrow buttons to navigate the file list.
   iii. The selected file can be viewed by touching "View File".
   iv. Press "More…" button will display a Cole-Cole plot.
   v.   Files can be sorted by name or date and time. Touch either the "Name Sort" or "Date Sort" button.

b. *Exporting data from unit*

NOTE: When the file storage memory on the unit is full, the unit stops taking measurements and displays the "File system full remove files to make space" screen. In order to continue taking measurements, transfer files on to a PC loaded with BioImp Body Composition Analysis software or delete the files, which are not required.

   i.   To transfer data to the Analysis Software you need to do these three steps first:

Step 1: Installing the AMD-Tek or Swann USB-Ethernet adapter. Safety, Care and Maintenance:
   1. Insert the supplied AMD-Tek or Swann USB-Ethernet adapter into a spare USB slot on your computer.
   2. Your computers operating system will automatically detect and install the drivers for the adapter.
   3. Restart your computer to allow the adapter to be fully installed.
   4. Once your computer has restarted insert your ImpediMed software CD-Rom into your computer's CD-Rom drive.

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5. Select your language.
6. Click the Set up the USB Ethernet adapter button.
7. This window will display all USB-Ethernet adapters that have been installed on your computer. Click the USB to fast Ethernet converter inside the network adapters found window and click the Next button to start auto-configuring your USB-Ethernet converter.
8. Click the Finish button to continue the auto-configuration.
9. Click the OK button and restart your computer when the above prompt window appears to finalize the USB-Ethernet adapter setup.

Step 2: Installing your BioImp software:
1. Once your computer has restarted re-insert your ImpediMed software CD-Rom into your computers CD-Rom drive.
2. Select your language.
3. Click the Install "BioImp" button.
4. Click the "Next" button to continue or "Cancel" to exit the software setup.
5. Click the "Yes" button to accept the software license agreement and continue with installation and follow the onscreen instructions to finish installation of your software.

Step 3: Connecting your unit to your PC:
1. Turn off your unit and shutdown your PC.
2. Attach the RED Ethernet crossover cable from your unit to your PC.
3. Turn on your PC and once the PC is booted turn on your unit.
4. Your PC will now detect the new network connection and you are ready to upload files from the unit to your software or computer.

NOTE: BIS and SFBI measurement data is stored on the unit, but only BIS measurement data is retrievable via Ethernet.

NOTE: Uploaded files are automatically deleted from the Imp SFB7. Sophisticated file transfer ensures that each file is transferred, confirmed as received, before deletion.

10. Safety and Cleaning

a. Safety

i. Only use the power adaptor (Amtex 9940) supplied with the unit. The use of any other power adaptor may expose the patient to the risk of electrocution.
ii. Do not connect the uniy to:

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1. Patients with active implanted medical devices, e.g cardiac pacemakers, defibrillators or patients connected to electronic life support devices.
2. Patients undergoing external defibrillation.

iii. Do not plug the unit leads to any mains power outlet/point.
iv. Do not use or operate unit in the presence of strong electromagnetic fields.
v. The ImpediMed SFB7 has yet to be clinically validated for use on pregnant patients.
vi. Only use ImpediMed electrodes.
vii. Avoid placing an electrode on an irritated skin site.
viii. If skin irritation occurs, ask participant to seek professional advice.
ix. Allow skin to dry thoroughly before placing electrodes on skin.
x. Do not connect alligator clips to patient's skin.
xi. Do not mix single use and reusable or different brands of electrodes.
xii. Do not cut the electrode, use whole electrode only.
xiii. Do not use extra gel with solid gel electrodes.
xiv. Do not leave the electrodes attached to the skin for longer than 1 hour.
xv. Use only the cable leads supplied by ImpediMed Limited with the Imp SFB7. The use of non ImpediMed leads can cause damage to the unit or give an incorrect reading.

NOTE: There are no user adjustable parts in the unit, do not disassemble the unit.

b. *Care and Maintenance*

i. Care of the product:
1. When not in use always keep the unit in the carry case.
2. Clean the unit with a dry, clean cloth only.
3. Avoid exposure to water, impact and excessive heat or direct exposure to sunlight.

ii. Care of the leads:
1. Clean leads with a damp cloth if required.
2. Wherever possible leads should remain connected to the unit.

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3. Unnecessary removal of the leads from the unit may reduce lead life.
4. Ensure that the lid of the case does not close on the leads.
5. Do not wind the leads tightly, crinkle, or twist the leads, as this may cause the fine wires inside to break.
6. If the leads appear damaged, contact ImpediMed or a licensed distributor for replacements. See website information https://www.impedimed.com/products/sfb7/.

iii. Care of the electrodes:
1. The electrodes are for single use. Please discard after use.
2. Reseal the electrode pouch after use.
3. Unused electrodes should remain in the supplied pouch and in a cool dry place to prevent electrode gel from dehydrating.
4. Use by expiry date.
5. Do not use an electrode if the conductive adhesive is dry and no longer pliable or sticky. This may result in inaccurate measurements.

iv. Care of the touch screen:
1. Always use the stylus pen provided to operate the touch screen. Use the rubber end of the stylus pen to operate Imp SFB7 touch screen.
2. If necessary clean the touch screen with a soft damp cloth, and do not use any liquids directly.

11. Troubleshooting

If the user encounters any problems, prior, or during testing, they can refer to the table below in addition to the user manual located in the unit carrying case.

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Problem	Possible Cause	Solution
No display when SFB7 is switched ON.	1. Battery power is low. 2.No external power.	1. Attach external power pack and try again. 2. If external power pack is attached, check that power pack is plugged in and switched on.
The message "Out of Range Check Leads and Electrodes" is displayed on the screen. Or The reading is obviously incorrect.	The device is not correctly set up.	1. Ensure the leads have been correctly fitted according to the colour coding. 2. Ensure the leads are inserted properly into the lead sockets. 3. Ensure the leads are not damaged or tangled. 4. Ensure the lead are properly inserted into the alligator clips. 5. Ensure the alligator clips are securly attached to the electrodes. 6. Ensure the electrodes are fresh. 7. Perform the calibration check to determine if the device is faulty. 8. If performing the calibration check, ensure the colour coding is correct and the leads are pushed snugly into the test cell.
The device stops responding to touch screen commands.	Internal software fault.	1. Power the device off. Power the device on. 2. Report the fault to ImpediMed.
Power light is blinking. Or Power light is red. Or Power light is orange.	Normal behaviour.	Refer to section "Battery Status Indicator."