PERFORM Operating Document

Use and Cleaning of ImpediMed SFB7

PC-POD-CP-010-v01

Revision History

<table>
<thead>
<tr>
<th>Version</th>
<th>Reason for Revision</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>New POD</td>
<td>November 26, 2015</td>
</tr>
</tbody>
</table>

Summary

The content of this PERFORM Operating Document (POD) provides guidelines for the safe use and cleaning of the ImpediMed SFB7 as identified in the equipment inventory at the PERFORM Center, Concordia University.
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APPENDIX I: POD TRAINING RECORD FORM
1 Definition of Terms

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Operating Procedure (SOP)</td>
<td>SOP’s at PERFORM are any operating document that require a full review process and approval by the SD.</td>
</tr>
<tr>
<td>PERFORM operating document (POD)</td>
<td>Operating documents that are specific to an instrument or technique that require approval by area managers.</td>
</tr>
<tr>
<td>Protocol</td>
<td>Methods that are developed by users on specific instruments/equipment</td>
</tr>
<tr>
<td>Users</td>
<td>Person using space or equipment at the PERFORM Centre that has received adequate technical and safety training.</td>
</tr>
<tr>
<td>Supervisor</td>
<td>Knowledgeable person regarding all or an aspect of a project or program and is familiar with PERFORM’s best practices, that is responsible for ensuring that users conduct their activities in a safe manner and within scope of the project.</td>
</tr>
<tr>
<td>PERFORM Employees</td>
<td>Concordia employee that has been assigned to PERFORM.</td>
</tr>
</tbody>
</table>

2 Relevant Documents

This POD is governed by the following Concordia University policies, SOPs, and PODs:
- PC-SOP-GA-007 “General Access to PERFORM Centre”.
- PC-SOP-GA-009 “Emergency Response Procedures at the PERFORM Centre”.
- PC-SOP-CP-001 “Cardio-Pulmonary Suite – Access, Use, and Training of Personnel”.
- PC-POD-GA-001 “PERFORM Centre Booking System for Facilities and Equipment”.

3 Introduction

3.1 Background

Body composition can be assessed using various techniques from field to more clinical tests. The ImpediMed SFB7 is a portable battery powered device that offers a rapid, reliable, non-invasive, and cost effective means of measuring body composition (i.e. fat-
body fat can be estimated. This technique is known as bioelectrical impedance analysis.

3.2 Purpose
The objectives of the current POD are to 1) outline the procedure for using ImpediMed SFB7; 2) provide a set of standard practices for safe operation and a training guide for new users of the systems at the PERFORM Centre, Concordia University; and 3) outline the procedure of cleaning/disinfecting of auxiliary items used for this device.

3.3 Scope
This POD applies to all users and supervisors using the ImpediMed SFB7 at the PERFORM Centre, Concordia University. Any other document other than this POD is out of scope for this operating procedure.

3.4 Responsibility
It is the responsibility of all users and supervisors to ensure that this POD is followed.

4 Device Components

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>BIA electrodes</td>
</tr>
<tr>
<td>2</td>
<td>Lead set</td>
</tr>
<tr>
<td>3</td>
<td>Alligator clips (4)</td>
</tr>
<tr>
<td>4</td>
<td>Test cell for calibration check</td>
</tr>
<tr>
<td>5</td>
<td>Power module for recharging the battery</td>
</tr>
<tr>
<td>6</td>
<td>Main power cable</td>
</tr>
<tr>
<td>7</td>
<td>Crossover network cable</td>
</tr>
<tr>
<td>8</td>
<td>CD-ROM</td>
</tr>
<tr>
<td>9</td>
<td>Stylus pen</td>
</tr>
<tr>
<td>10</td>
<td>Microfiber cloth</td>
</tr>
</tbody>
</table>
5 Device Calibration

5.1 Plug power cable into outlet and back of device to be sure it is charged. **Battery Status Indicator**

The LED indicator on the Imp SFB7 indicates the status of the internally installed rechargeable Lithium-ion. The colour of the LED behaviour is defined as below:

<table>
<thead>
<tr>
<th>LED Colour</th>
<th>LED behaviour</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>Off</td>
<td>- Unit is turned off</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- No external power is present</td>
</tr>
<tr>
<td>Green</td>
<td>Off, flicking on at 1 second intervals.</td>
<td>- Unit is turned off</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- External power is present</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Batteries are charging</td>
</tr>
<tr>
<td>Green</td>
<td>On</td>
<td>- Unit is operational</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- External Power is present</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Batteries are fully charged</td>
</tr>
<tr>
<td>Green</td>
<td>On, flicking off at 1 second intervals.</td>
<td>- Unit is operational</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- External Power is present</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Batteries are charging</td>
</tr>
<tr>
<td>Green</td>
<td>1 second on, 1 second off</td>
<td>- Unit is operational</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- No external power is present</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Unit is running off batteries</td>
</tr>
<tr>
<td>Orange</td>
<td>On</td>
<td>- Unit is operational</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Batteries are flat</td>
</tr>
<tr>
<td>Red</td>
<td>Off, flicking on at 1 second intervals.</td>
<td>- Unit is operational</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Batteries are flat</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Unit will shut down after four seconds.</td>
</tr>
<tr>
<td>Red, Orange</td>
<td>Off, flicking on twice at 1 second intervals.</td>
<td>Battery Charger Fault</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Battery Voltage Detection Fault</td>
</tr>
</tbody>
</table>

5.2 Turn device on by pressing the On/Off button on the front panel of the unit. After a couple of seconds the device will display the ImpediMed logo and will go to the main menu.

5.3 Connect each colored lead to corresponding color on back of device. Make sure the arrow on lead is in line with notch on device.

5.4 Remove alligator clips from lead wires.

5.5 Connect leads to the test cell according to color coding.
5.6 Press “Test” on screen using stylus pen.

NOTE: Stylus should always be used when making selections on touch screen.

5.7 Press “Start”. Screen will display “Calculating”.
5.8 Should it read “pass”, device is ready to use

NOTE: Should it read “fail”, contact area supervisor.

5.9 Click “More” and when the graph is displayed click “More” again. “Rzero” and “Rinf” should read “Rzero: 604 (± 7 ohms)” and “Rinf: 403 (± 5 ohms)”.  
5.10 Press “Back” 4 times.
5.11 Disconnect the leads from test cell and replace the alligator clips.

NOTE: Failing to adhere to the above conditions may affect your results.

6 Modes & Predetermined Measurement Settings

The ImpediMed SFB7 offers two modes of functions: bioimpedance spectroscopy (BIS), and selected frequencies (SFBI).

6.1 BIS Mode

This mode measures BI parameters over a frequency range of 4-1000 kHz with 256 data points defining the BIS mode as a true BI spectroscopy. 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.

6.2 SFBI Mode

This mode measures BI 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.

6.3 Predetermined Measurements Settings

Touching 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 commenced immediately after the previous measurement has been completed. In interval mode, another sequential measurement is made after the interval of time selected (in seconds).

For Interval measurement setting, the interval between measurements can be selected by touching the arrow buttons next to the “Interval” edit box or by using the keypad (see Start up Screen section) that is selected by touching the “Interval” edit box.

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 using the keypad (see Start up screen section) that is selected by touching the “Number” edit box.

7 Contraindications for Use

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

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

8 Preliminary Instructions

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

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

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

8.1.3 Also, the following situations affect body water concentration:
   i. just prior, during, just after menstruation
   ii. use of diuretics
   iii. renal or heart failure

9 Preparation Prior to Test

9.1 Evaluator must plug device at least 15 minutes in advance to ensure battery is charged for evaluation.

9.2 Check that participant has followed preliminary test instructions.

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

10 Test Procedure

10.1 Ask participant to turn off mobile phone.

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

10.3 Remove all jewelry, stockings, pantyhose, and/or socks.

10.4 Lie participant on their back on table feet shoulder width apart. 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.

10.5 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).

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

10.7 Clean the sites with an alcohol swab.  
10.8 Allow sites to dry for 30 seconds before placing electrodes.  
10.9 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.  
10.10 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.  

10.11 Click “Measure” in main menu.  
10.12 Click on the box under “File Name” and enter participant ID and press “Ok”.  
10.13 Click on “Edit” under “Patient Details”.  
10.14 Enter information and click “Ok”.

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

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

10.16 Click “Measure”.
10.17 Click “Start”. Once measurements are completed (based on predetermined settings) the device will say “Ready” at the top. Data is automatically saved.
10.18 Press “Exit”, then “Back” 2 times to go back to the main menu.

## 11 Data Retrieval

### 11.1 Reading data from device

11.1.1 Press “Files” from the main menu.
11.1.2 Use the arrow buttons to navigate the file list.
11.1.3 The selected file can be viewed by touching “View File”.
11.1.4 Press “More…” button will display a Cole-Cole plot.
11.1.5 Files can be sorted by name or date and time. Touch either the “Name Sort” or “Date Sort” button.

### 11.2 Exporting data from device

NOTE: When the file storage memory on the device is full, the device 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 Biolmp Body Composition Analysis software or delete the files which are not required.

11.2.1 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 computer’s 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 computers CD-Rom drive.
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 Biolmp 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 “Biolmp” 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 SFB7 device to your PC:
1. Turn off your SFB7 and shutdown your PC.
2. Attach the RED Ethernet crossover cable from your device to your PC.
3. Turn on your PC and once the PC is booted turn on your Imp SFB7 device.
4. Your PC will now detect the new network connection and you are ready to upload files from the SFB7 to your software or computer.

NOTE: BIS and SFBI measurement data is stored on board, 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.
12 Safety and Cleaning

12.1 Safety

12.1.1 Only use the power adaptor (Amtex 9940) that is supplied with this device. The use of any other power adaptor may expose the patient to the risk of electrocution.

12.1.2 Do not connect the Imp SFB7 device to:

12.1.2.1 Patients with active implanted medical devices, e.g cardiac pacemakers, defibrillators or patients connected to electronic life support devices.

12.1.2.2 Patients undergoing external defibrillation.

12.1.3 Do not plug SFB7 leads to any mains power outlet/point.

12.1.4 Do not use or operate device in the presence of strong electromagnetic fields.

12.1.5 The ImpediMed SFB7 should be unplugged from the recharging unit before use to avoid possible noise contamination of the measurement.

12.1.6 The ImpediMed SFB7 has yet to be clinically validated for use on pregnant patients.

12.1.7 Only use ImpediMed electrodes.

12.1.8 Avoid placing an electrode on an irritated skin site.

12.1.9 If skin irritation occurs seek professional advice.

12.1.10 Allow skin to dry thoroughly before placing electrodes on skin.

12.1.11 Do not connect alligator clips to patient’s skin.

12.1.12 Do not mix single use and reusable or different brands of electrodes.

12.1.13 Do not cut the electrode, use whole electrode only.

12.1.14 Do not use extra gel with solid gel electrodes.

12.1.15 Do not leave the electrodes attached to the skin for longer than 1 hour.

12.1.16 Use only the cable leads supplied by ImpediMed Limited with the Imp SFB7. The use of non ImpediMed leads can cause damage to the device or give an incorrect reading.

NOTE: There are no user adjustable parts in the device, do not disassemble unit.
12.2 Care and Maintenance

12.2.1 Care of the product:
   12.2.1.1 When in use always keep the SFB7 in the carry case.
   12.2.1.2 Clean the SFB7 with a dry, clean cloth only.
   12.2.1.3 Avoid exposure to water, impact and excessive heat or direct exposure to sunlight.

12.2.2 Care of the leads:
   12.2.2.1 Clean leads with a damp cloth if required.
   12.2.2.2 Wherever possible leads should remain connected to the device.
   12.2.2.3 Unnecessary removal of the leads from the device may reduce lead life.
   12.2.2.4 Ensure that the lid of the case does not close on the leads.
   12.2.2.5 Do not wind the leads tightly, crinkle, or twist the leads, as this may cause the fine wires inside to break.
   12.2.2.6 If the leads appear to be damaged, contact ImpediMed or a licensed distributor for replacements.

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

12.2.4 Care of the touch screen:
12.2.4.1 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.

12.2.4.2 If necessary clean the touch screen with a soft damp cloth, and do not use any liquids directly.

# 13 Troubleshooting

If the user encounters any problems, prior, or during testing, they can refer to the table below.

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Cause</th>
<th>Solution</th>
</tr>
</thead>
</table>
| 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 securely 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." |
APPENDIX I

POD Training Record Form
**POD Title**

Use and Cleaning of ImpediMed SFB7

**SOP Code**

<table>
<thead>
<tr>
<th>Ownership</th>
<th>Document type</th>
<th>Area</th>
<th>SOP Number</th>
<th>Version</th>
</tr>
</thead>
<tbody>
<tr>
<td>PC</td>
<td>POD</td>
<td>CP</td>
<td>010</td>
<td>V01</td>
</tr>
</tbody>
</table>

**Training Record**

<table>
<thead>
<tr>
<th>Full Name</th>
<th>Institution</th>
<th>Contact (email or phone number)</th>
</tr>
</thead>
</table>

**Signature**

Sign here: ___________________________  Date: _____________