

# PERFORM Operating Document

## Use and Cleaning Procedures for Bodystat® QuadScan 4000

### PC-POD-CP-012-v01







#### Revision History

Version	Reason for Revision	Date
01	New POD	June 18, 2020

## I. Introduction

The content of this PERFORM Operating Document (POD) provides guidelines for use and the cleaning procedure for the Bodystat® QuadScan 4000 multi-frequency bio-impedance analysis unit. This unit assesses body composition measuring at 5, 50, 100, and 200 kHz. This POD applies to all users of the unit.

## 2. Device Components and Accessories

<p>a. Multi-Frequency Impedance Measuring Unit</p> 	<p>b. 2 Red and Black 1.2m Cable Leads with White Port</p> 
<p>c. 2 Red and Black 1.2m Cable Leads with Black Port</p> 	<p>d. Disposable Electrodes</p> 
<p>e. Calibrator</p> 	<p>f. Measuring Tape</p> 

## 3. Contraindications

This device cannot be used in participants with the following devices/conditions:

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

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## 4. Calibration

4.1 Prior to each test, check battery life by turning on the device (power switch on left side). Six black squares will appear on the LCD screen representing battery life. As power is consumed, fewer black squares will appear.

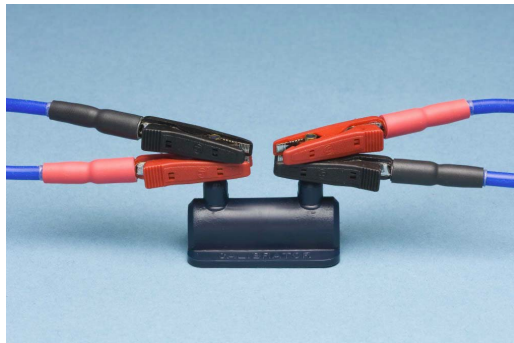
NOTE: Change all six batteries when only 1 square of battery life is shown. Turn off device before replacing with 6 non-rechargeable AA batteries (only Duracell or Procell recommended).

4.2 Connect “Red and Black 1.2m Cable Leads with White Port” to connector inputs at top of unit.



4.3 Attach a pair of red and black leads to any one terminal of calibration unit.

4.4 Attach other pair of red and black leads to other terminal of calibration unit.



4.5 Accept default settings

4.6 Press ←.

4.7 Using the ↓ arrow, scroll through calibration results. Select “impedance”.

4.8 Results at 5, 50, 100 and 200 kHz should reflect readings between 496 and 503.

4.9 If calibration results are outside of range:

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4.9.1 Check lead connections.

4.9.2 Replace all six batteries.

## 5. Setup

### 5.1 Equipment Setup

5.1.1 Press ← until “Press enter for new test” appears.

5.1.2 Press ← to see the following:

Test Number = 12
------------------

NOTE: QuadScan automatically allocates the next available test number. This number is used to identify the participant’s data during recall and should be noted on the data intake sheet.

5.1.3 Press ← .

NOTE: Device will signal an alarm sound to warn the user that unit is still on after a period of inactivity of 60 seconds.

### 5.2 Entering Participant Data

5.2.1 Using the ↑ and ↓ arrows, enter participant’s information.

NOTE: Enter physical activity level using following table.

Level of Activity	General	Activities
Very Low Movement Restricted	Generally inactive.	Laying at ease, sitting, writing, standing, driving.
Low/Medium Office/Light Work	Recreational activities for short duration and at low intensity.	Cycling (5.5 mph/9 kph), bowling, golf, hiking, tennis, walking (2.5 mph/4 kph).
Medium Weekend Recreation	Sporadic involvement in recreational activities for short duration and at moderate intensity.	Aerobics (low intensity), badminton, cycling (9 mph/14 kph), gymnastics (light), skiing (alpine), swimming, tennis (competitive), ballroom dancing.
Medium/High Moderate Exercise	Moderate job activity and moderate exercise 3 times per week.	Basketball, cycling (11-14 mph/18-22 kph), canoeing (vigorously), disco dancing, martial arts, handball, rope skipping (60-80 rpm), running

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		(5-6 mph/8-10 kph), walking (5-6 mph/8-10 kph).
Very High Vigorous Exercise at Competitive Level	Consistent job activity and vigorous exercise 4 times per week.	Aerobic (high-intensity), cycling (15-20 mph/24-32 kph), circuit weight training, calisthenics, field hockey, gymnastics (heavy), squash, ice hockey, handball, racquetball, rope skipping (120-140 rpm), soccer, running (7-9 mph/11-14 kph), cross-country skiing (7-9 mph/11-14 kph), swimming (55-70 yds/min / 46-64 metres/min).

5.2.2 Screen will display:



**5.3 Participant Setup**

NOTE: The following situations affect body water concentration:

- Just prior, during, just after menstruation.
- Use of diuretics.
- Renal or heart failure.

*5.3.1 Participant preparation prior to appointment:*

- No eating or drinking 4 to 5 hours.
- Exercise should be avoided for 12 hours.
- Refrain from drinking alcohol or caffeine within 24 hours.

*5.3.2 Upon participant arrival*

5.3.2.1 Ensure participant followed pre-test instructions.

5.3.2.2 Measure participant height and weight.

5.3.2.3 Ask participant to turn off mobile phone and remove all jewelry, stocking/pantyhose and/or socks.

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- 5.3.2.4 Lie participant on their back on table, for 3-4 minutes before measurement, with feet shoulder width apart.
- 5.3.2.5 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).
- 5.3.3 Identify electrode placement on right side of body.
- 5.3.3.1 Upper body: behind knuckles and on wrist next to ulna head, must be minimum 3 cm apart.
- 5.3.3.2 Lower body: Behind toes and on the ankle between the medial and lateral malleoli, must be minimum 3 cm apart.
- 5.3.4 Shave electrode sites, if necessary.
- 5.3.5 Clean the sites with an alcohol swab.
- 5.3.6 Allow sites to dry for 30 seconds before placing electrodes.
- 5.3.7 Place electrodes, with metal tabs pointing away from body. Do not press down on electrodes too firmly.
- 5.3.8 Attach lead electrodes at electrode tabs with alligator clips.
- 5.3.8.1 **Red** leads are connected to the electrodes behind knuckles and behind toes.
- 5.3.8.2 **Black** leads are then connected to the electrodes on wrist next to ulna head and on the ankle between the medial and lateral malleoli. As shown below.



NOTE: Attach the crocodile (alligator) clips on cable leads to the exposed tab, ensuring that metal contact is against the foil side of the electrode.

## 6. Measurement

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- 6.1 Once connected, Press ←. Measuring will display on screen.
- 6.2 An audible signal will indicate completion of measurements.
- 6.3 Disconnect alligator clips from electrodes.
- 6.4 Remove electrodes and switch unit OFF.

## 7. Quality Control Check of Measurement Accuracy

Review raw data impedance values to ensure reliability. There are two methods:

- 7.1 Illness Marker/Dehydration Index must be lower than 1.00.
- 7.2 Review the four Impedance values at each successive frequency immediately after measurement. Each value must be lower than previous value. See example ?

Frequency Khz	5	50	100	200
Impedance Values (Ohms)	588	505	475	454

## 8. Understanding Results

- 8.1 Body Composition only uses 50 kHz to predict Total Body Water (TBW)
- 8.2 Hydration/Nutrition only uses 200 kHz to predict TBW
- 8.3 Body Composition & Hydration/Nutrition uses 50kHz to predict TBW
- 8.4 Hydration/Nutrition Results Displaying a ■ symbol will indicate that the results may not be accurate
- 8.5 The QuadScan 4000 utilizes the following Regressions Equations, however further equations can be found in the software program such as children's equation for age groups 6 to 17 years old.
- 8.6 Hydration/Nutritional:
  - 8.6.1 Regression Equation 1, Full Participant Data
  - 8.6.2 Regression Equation 2, No Participant Data
- 8.7 Body Composition:
  - 8.7.1 Regression Equation 1, Full Participant Data

## 9. Display Results

FAT (%)	Fat as % of total body weight	
FAT (kg)	Estimated fat weight	Determines Health Risk
LEAN (%)	Lean muscle mass as % of total body weight	Includes muscle, bone & water
LEAN (kg)	Estimated lean muscle mass	
TOTAL	Total actual body weight	
DRY LEAN WEIGHT	Estimated dry lean weight	Includes muscle & bone (ex. Lean minus TBW)
TBW (%)	Estimated total body water	
TBW (lt)	Total body water volume	
ECW (%)	Estimated extra-cellular water	
ECW (lt)	Estimated extra-cellular water volume in litres	
ICW (%)	Estimated intra-cellular water	
ICW (lt)	Estimated intra-cellular water volume	TBW minus ECW
BODY CELL MASS	Total mass of cells in the body where oxygen is consumed and carbon dioxide is produced.	
3rd SPACE WATER	Estimated transcellular space water volume	
NUTRITION	ECW/TBW Nutrition Index	
Illness Marker	200/5 kHz impedance Index	
BASAL MET. RATE	Estimated basal metabolic rate	
BMR/Body Weight	Basal metabolic rate per kg or lb of body weight	
EST. AVERAGE REQ.	Estimated average energy requirement	
BMI	Body mass index	Weight/height <sup>2</sup> in metric
BFMI	Body fat mass index	Body fat/height <sup>2</sup> in metric
FFMI	Fat free mass index	Lean/ height <sup>2</sup> in metric (BFMI+FFMI=BMI)



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Waist/Hip	Waist/Hip ratio	
IMPEDANCE 5 kHz	The resistance to the flow of the current at 5 kHz	
IMPEDANCE 50 kHz	The resistance to the flow of the current at 50 kHz	
IMPEDANCE 100 kHz	The resistance to the flow of the current at 100 kHz	
IMPEDANCE 200 kHz	The resistance to the flow of the current at 200 kHz	
RESISTANCE 50 kHz		These values are required by certain types of BIA users for subject assessment
REACTANCE 50 kHz		
PHASE ANGLE 50 kHz		

## 10. Data Retrieval

### 10.1 Reading data from device

- 10.1.1 After successful measurements, results are displayed as selected by user.
- 10.1.2 Top line displays Estimated Measure Results.
- 10.1.3 Bottom line displays Recommended or Normal Level for participant measured. See image below.



- 10.1.4 Use buttons ← or ↓ to display next screen.
- 10.1.5 Use ↑ to scroll back to previous screen.

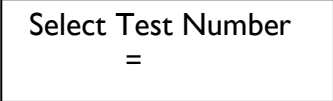
### 10.2 Recall Participant Data

NOTE: Data is not lost after the unit is switched off or during battery replacement.

- 10.2.1 Hold down ← key while switching unit ON.

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10.2.2 Recall Data will appear on screen, release button.

10.2.3  Press ← to select test number.

10.2.4 Input data is displayed first, followed by output data.

10.2.5 To exit from this program, switch unit OFF.

### 10.3 *Exporting data from device*

10.3.1 Switch Quadscan ON. The LCD screen should read Test Number = X.

10.3.2 On laptop 2, open “Quadscan” software.

NOTE: If prompted, enter password “12345” and communications port “7”.

10.3.3 On top menu bar, click “blue screen with red down arrow” symbol to download data.

10.3.4 Participant files will appear; select data to be viewed.

10.3.5 Click “Print Preview” to access a drop-down menu.

10.3.6 Click “Summary” to access client’s “Summary Results”.

## 11. Safety, Care and Maintenance

### 11.1 *Safety*

11.1.1 Do not connect QuadScan device to participants with active implanted medical devices, i.e. cardiac pacemakers, defibrillators or patients connected to electronic life support devices.

11.1.2 Do not connect QuadScan device to participants undergoing external defibrillation.

11.1.3 Do not use or operate device near strong electromagnetic fields or water.

11.1.4 Computers and other electrical equipment can cause interference.

11.1.5 Only use QuadScan Electrodes.

11.1.6 Avoid placing an electrode on an irritated skin site.

11.1.7 Do not cut electrode.

11.1.8 Do not use extra gel with solid gel electrodes.

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

11.1.10 Use only cable leads supplied by QuadScan.

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

11.1.12 Do not disassemble unit.

### 11.2 *Care*

11.2.1 Care of the product:

11.2.1.1 Unit should be periodically wiped with a clean damp cloth.

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11.2.1.2 Avoid exposure to water, impact and excessive heat or direct exposure to sunlight.

11.2.2 Care of the leads:

11.2.2.1 Clean leads with a damp cloth if required.

11.2.2.2 Cables should not be wrapped around the unit, tangled or tightly rolled when not in use.

## 12. Troubleshooting

Problem	Possible Cause	Solution
Results Out Of Range	Device is not correctly set-up	<ol style="list-style-type: none"> <li>1. Recheck input data</li> <li>2. Medications that result in unnaturally high fluid levels.</li> </ol>
Faulty Electrode Check Connection	Cable leads have not been properly attached to the electrodes	<ol style="list-style-type: none"> <li>1. Ensure participant is in correct position</li> <li>2. Recheck the electrodes.</li> <li>3. Ensure leads are inserted properly</li> <li>4. Ensure leads are not tangled</li> <li>5. Ensure alligator clips are attached securely</li> <li>6. Perform calibration</li> </ol>
LCD screen display is blank	Battery power is dead	<ol style="list-style-type: none"> <li>1. Check to see if batteries are inserted properly</li> <li>2. Replace with new Duracell batteries</li> </ol>
ECW% Fat Readings are always incorrect	Malfunction of the electronic memory micro processor	<ol style="list-style-type: none"> <li>1. Perform calibration</li> <li>2. Change batteries</li> <li>3. Check cables</li> <li>4. Return unit to dealer</li> </ol>
Strange characters on LCD screen	Malfunction of the liquid crystal display	<ol style="list-style-type: none"> <li>1. LCD screen should be replaced</li> </ol>