

INSTRUCTIONS FOR USE

BODYSTAT® **QuadScan 4000**

This “Instructions for Use” contains information on
how to operate, storage and disposal
BODYSTAT® QuadScan 4000



**MULTI-FREQUENCY
BIA
TECHNOLOGY**



Bodystat®

BODY COMPOSITION TECHNOLOGY

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SECTION A

GENERAL

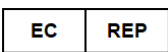
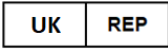
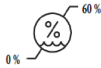
INFORMATION

YOUR HARDWARE UNIT

The BODYSTAT QuadScan 4000 system is supplied with the following:

- Multi-Frequency Impedance Measuring Unit
- **Red & Black** 1.2 metre Cable Leads (2)
- QuadScan User's Guide
- **Bodystat** Disposable Electrodes (300 qty - 3 packets)
- Duracell/Procell AA Batteries (6)
- **Bodystat** Calibrator
- **Bluetooth LE** module for use with the thermal printer and app
- **USB connection** fitted for data software
- Customised Padded Shoulder Bag
- **BIAS Platinum™** Software Program and User's Guide
- 12 Month Warranty on Return to Factory Basis (**excluding lead wires**).

DEFINITIONS AND SYMBOLS

	Symbol indicating the conformity to the Medical Devices Directive		Symbol indicating UK conformity assessed
	Date of manufacture (yyyy)		Manufacturers address
	Indication that the device is a Medical Device		This device is rated BF as per IEC60601-1
	European Union Authorised Representative		United Kingdom Responsible Person
	Keep dry		Humidity limitation
	Symbol advising those subjects with pace-makers or any implantable electronic device should not be tested		Represents a Warning or Caution message
	Temperature limitation		Consult instructions for use
	Symbol indicating how to dispose of your Bodystat device at the end of its life cycle.		Serial Number

DEFINITIONS

ECW	Extra-Cellular Water
ICW	Intra-Cellular Water
TBW	Total Body Water
BCM	Body Cell Mass
BMR	Basal Metabolic Rate
EAR	Estimated Average Requirement for Calories
BMI	Body Mass Index
BIA	Bio-Electrical Impedance Analysis
FFM	Fat –Free Mass (Lean Weight)
FFMI	Fat-Free Mass Index
BFMI	Body Fat Mass Index

TRANSLATIONS

If this **BODYSTAT® QuadScan 4000** User Guide is required in any of the following languages, please email info@bodystat.com:

Bulgarian	English	Hungarian	Russian
Czech	Finnish	Italian	Slovene
Chinese	French	Irish	Spanish
Danish	German	Polish	
Dutch	Greek	Portuguese	

Latest version of this document

If you want to check about any update or latest version or revision of this document, please email info@boystat.com indicating your model and serial number.

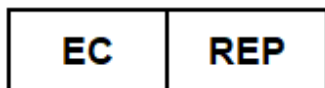
WARRANTY DISCLAIMER

Although all **BODYSTAT** hardware units and software programs are tested before release, no claim is made concerning the accuracy of the product. **BODYSTAT LTD**, as the manufacturers of the product and authors of the software, their distributors, and dealers, cannot assume liability or responsibility either implied or expressed for any loss or damage either real or consequential arising out of the use of this product.

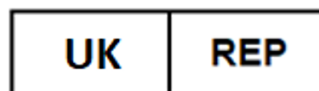
It is a condition of every sale and purchase of the product that the purchaser accepts all such risk, and acceptance thereof shall be deemed to have been given when purchase is made.

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NOTES, CAUTIONS AND WARNINGS FOR USERS



NOT recommended for Females in the early stages of pregnancy



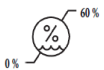
NOT recommended for subjects with pace-makers or any implantable electronic device.



If your **BODYSTAT® QuadScan 4000** unit arrives in cold weather, allow the system to warm up to room temperature before you switch on the unit.



Exposing a cold computerized system to a warm room causes condensation that could damage the system.



Wait at least 24 hours to allow for any possible condensation that may have formed inside the casing to dry before you operate the system.



Do **NOT** attempt to connect the **BODYSTAT® QuadScan 4000** hardware unit nor the Printer to a mains electricity supply.



This instrument is an internally powered, Type BF Applied Part device according to IEC 60601-1.



As with any other common electronic device, the **BODYSTAT® QuadScan 4000** unit of Bodystat Limited emits electromagnetic energy to perform its intended function. Nearby electronic equipment may be affected.



The device is not suitable for oxygen-enriched environments.



The device is not suitable for use with flammable gases, including environment with flammable anesthetics.

Cleaning guidelines: the hardware unit does not have to be sterilized but it is strongly recommended to perform periodic cleaning by wiping with a clean microfiber cloth and follow the recommendations from local health authorities about controlling the spread of infections.

Do not use in a sterile environment

SECTION B HOW TO USE

BODYSTAT®

QuadScan 4000

INTRODUCTION

As one of the world's leading developers of electrical bio-impedance (BIA) measuring units, **BODYSTAT®** is proud to announce the release of the **MULTI-FREQUENCY** bio-impedance analysis unit developed in the UK, the **BODYSTAT QuadScan 4000**.

Using the scientifically validated principle of *Bio-electrical Impedance Analysis*, a complete analysis of body composition and hydrational/nutritional information is displayed instantly on the touch screen liquid crystal display (LCD) of the unit.

The **QuadScan 4000** unit is battery-operated, lightweight and easy to use requiring no specialist skills. The unit has been electronically precision engineered to the highest quality standards offering the user a safe and efficient means of measurement.

The basic principle of the method is that lean tissue, which consists essentially of electrolyte-containing water, conduct the electrical current, whereas the fat acts as an insulator. The impedance of the body is therefore determined largely by the low-impedance lean tissues. Regression equations are then derived which relate impedance to **Fat Free Mass (FFM)** or **Total Body Water (TBW)** measured by independent techniques.

At **50 kHz** a proportion of the applied current is unable to penetrate the cell membranes and therefore passes only through the extra-cellular space. At this frequency **BIA** is only able to predict **TBW** and **FFM** in healthy subjects because of the close correlation between extra-cellular volume and **TBW** in these subjects.

Furthermore, the measurement of **TBW** alone is only of limited value in the nutritional or functional assessment of the seriously ill patient. Patients with ongoing infections have been shown to retain fluid in response to nutritional support and weight gain is due to expansion of the extra-cellular water (**ECW**) space. It has been emphasised that this weight gain cannot be viewed as an improvement in nutritional status as it does not reflect an improvement in protein store. There is also evidence that surgical patients who respond to nutritional support with an increase in **ECW** have increased postoperative complication rates compared with patients who lose water, and that they may benefit from longer courses of nutritional support.

Hence a measure of the distribution of **TBW** between **extra-cellular** and **intra-cellular** spaces may provide a useful index of the well-being or response to feeding of critically ill patients (*refer to the section PREDICTION MARKER*).

Similarly, it may be necessary to measure the extra- and intra-cellular fluid levels in competitive athletes in order to fully assess their hydrational status and measure performance levels at various levels of hydration intra-cellularly.

The **QuadScan unit** will measure at **5, 50, 100 and 200 kHz**. At the **50 kHz** frequency we are able to predict the value of **Total Body Water (TBW)** and **Fat-Free Mass**. However, at these low frequencies the current is unable to penetrate the cell membrane and at **5 kHz ECW** is predicted. At **200 kHz** the cell membrane is penetrated and both intra- and extra-cellular fluid spaces can be accessed to determine **TBW**. By deducting **ECW** from the **TBW** value at **200 kHz**, **ICW** is then calculated. Due to the higher frequency at **200 kHz**, a different **TBW** figure is predicted than that of the **50 kHz** figure. **The 3rd Space Water** is the difference between the two **TBW** figures.

The results displayed on the LCD display of the hardware unit are based on the **standard distal placement of electrodes** on the hand and foot. Total body weight is required by the predictive equations to display these results.

However, where body weight is not known, an **index** of **ECW/TBW** can still be displayed, known as the **PREDICTION MARKER**. This is the ratio of Impedance values at **200 kHz** divided by **5 kHz**.

In the accompanying software program, alternative predictive equations can be applied to the **body composition results** for **competitive athletes, children, COPD and geriatric**.

WHAT DOES THE QuadScan 4000 UNIT MEASURE?

The **QuadScan 4000** measures/estimates:

Options Displayed on the QuadScan unit	Explanation
Fat %* & Normal Range	Fat as a % of Total Body Weight
Fat Weight* & Normal Range	Est. FAT Weight determines Health Risk
Lean %* & Normal Range	Lean as a % of Total Body Weight
Lean Weight* & Normal Range	Est. Lean Muscle Mass includes Muscle, Bone & Water
Water %* & Normal Range	Total Body Water as a % of Total Body Weight
Total Body Water* & Normal Range	Total Body Water Volume in Litres
Dry Lean Weight*	Dry Lean Weight includes Muscle, Bone e.g. Lean minus Total Body Water
ECW %* & Normal Level	Extra-Cellular Water as a % of Total Body Weight
ECW Volume*	Extra-Cellular Water Volume in Litres
ICW %* & Normal Level	Intra-Cellular Water as a % of Total Body Weight
ICW Volume*	Intra-Cellular Water Volume in Litres (TBW minus ECW)
Body Cell Mass*	The total mass of cells in the body where oxygen is consumed, and carbon dioxide produced
3 rd Space Water*	Refer section Additional Information section for a full explanation.
Nutritional Index	ECW/TBW Nutrition Index
Basal Metabolic Rates*	Basal Metabolic Rate (Calories at rest)
BMR/Body Weight*	Basal Metabolic Rate per Kg/LB of Body Weight
Est. Average Requirement*	Estimated Average (Energy) Requirement based on the Activity Level selected
Body Mass Index (BMI) & Normal Range	Body Mass Index (Weight/Ht ² in metric)
BFMI (Body Fat Mass Index) & Normal Range	Body Fat Mass Index (Body Fat/Ht ² in metric) BFMI + FFMI = BMI
FFMI (Fat Free Mass Index) & Normal Range	Fat Free Mass Index (Lean/Ht ² in metric) BFMI + FFMI = BMI
Waist/Hip Ratio**	The ratio of the circumference of the waist to that of the hips
Prediction Marker	200/5 kHz Impedance Index
Impedance Values at 4 frequencies ranging from 5 kHz to 200 kHz	The Resistance to the Flow of the Current at 4 frequencies, 5, 50, 100 and 200 kHz
Resistance at 50 kHz	Resistance at 50 kHz
Reactance at 50 kHz	Reactance at 50 kHz
Phase Angle at 50 kHz	Phase Angle at 50 kHz

***estimated**

Grateful acknowledgement is made to:

WJ Hannan, SJ Cowan, CE Plester*, KCH Fearon and A Debeau of Medical Physics and Medical Engineering, Western General Hospital, Edinburgh, UK and *University Department of Surgery, Royal Infirmary, Edinburgh, UK

who have given us permission to use their equations for **ECF** and **TBW** (at 200 kHz) published in

Clinical Science (1995) **89**: 651 - 658 - **Comparison of bio-impedance spectroscopy and multi-frequency bio-impedance analysis for the assessment of extracellular and total body water in surgical patients.**

It should be noted that adjustments have been made to the equations to suit the electronic requirements of the **QuadScan 4000**.

IMPORTANT INFORMATION

FREQUENCIES USED TO PREDICT TBW

This is fully described in the Introduction section of this User's Guide.

The **QuadScan unit** will measure at **50 kHz** and **200 kHz** and at these frequencies, we are able to predict **Total Body Water (TBW)**. The **QuadScan 4000** unit will also allow you to decide on the information you would like displaying, for example, **Body Composition** information only or **Hydration/Nutrition** information only. (This is fully explained in the section **Customising Your Unit**). However, the frequency used to predict TBW is dependent on the option you have selected.

Body Composition Only uses **50 kHz** to predict TBW

Hydration/Nutrition Only uses **200 kHz** to predict TBW

Body Composition & Hydration/Nutrition uses **50 kHz** to predict TBW.

CAUTION MESSAGES OR SYMBOLS

CAUTION FAT/LEAN

When predicting TBW at 50 kHz and 200 kHz, a different value is obtained dependent on the frequency used. **Third Space Water** is the difference between the two frequencies. (Refer **Additional Information**).

If the value for 3rd Space Water is **above 2 litres**, it may be due to an excessive build up of fluid, e.g. patients with oedema, etc. This could also result in under-stating the Fat % figure and over-stating the Lean mass. Therefore, the following message will be displayed and the Fat & Lean values should be treated with caution.

If all the Body Composition results have not been selected for display, the above message will not be shown.

HYDRAT/NUTRIT RESULTS DISPLAYING A * SYMBOL

The unit contains a number of equations to estimate Hydration/Nutrition and Body Composition information. There is also an **additional equation** used in **QUADSCAN 4000** unit which is especially suited for the **age groups of 6 to 17 years**. This **equation only applies to the Body Composition results** and is automatically selected when the age of the subject is entered. The hydrational/nutritional information will still be displayed, however a * symbol next to the results of ECW, ICW, etc and will indicate that they may not be accurate and are to be treated with caution.

GUIDELINES FOR EQUIPMENT CARE

It is important to consider that the measurement of bio-impedance involves measuring highly sensitive values. Therefore, care should be exercised when handling the equipment, in particular the Cable Leads.

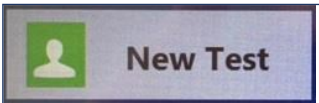
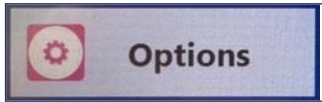
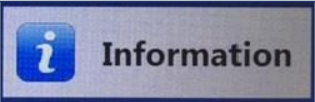
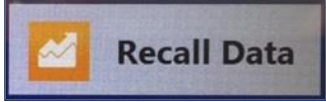


Detailed below are guidelines that we recommend should be followed:

- The QuadScan Unit is calibrated with the length of leads, for example, longer or shorter length leads will result in different impedance values especially at 200 kHz. Therefore, it is recommended that leads only supplied by Bodystat Limited are to be used.
- Despite the **cables and hardware unit being shielded** you should be aware that computers and other electrical equipment can cause interference which may adversely affect the impedance measurements, particularly at the higher frequency of 200 kHz.
- Regular calibration checks of the equipment are recommended and we also suggest that a log of calibration tests are maintained as a record in the **QuadScan 4000** software. Refer to the section of the User's Guide called **CALIBRATION**.
- Care should be taken at all times to avoid damaging the cables, i.e. they should not be tangled together and avoid tightly rolling them when not in use.
- It is recommended that the replacement of both sets of cables is made at least annually. However, replacement may be required more frequently if the cables are in constant use. Guidance can be given by the Bodystat Head Office.
- Cleaning Instructions: The hardware unit should periodically be wiped with a clean damp cloth.
- Disposal Instructions of Disposable Items:
 - Batteries** - these must be disposed of as per local regulations.
 - Electrodes** - these may be disposed of as normal waste.
- **Duracell® batteries only should be used - NOT re-chargeables**. Batteries should be clicked into place firmly to avoid excessive battery drainage.

SUMMARY OF OPERATIONAL FEATURES

The **QUADSCAN 4000** portable unit has been specifically designed to facilitate ease of use, speed of input and subsequent access to subject data. The following operational features are provided:

SELECTION	WHAT TO DO	BUTTON IMAGE
Turning the device ON/OFF	Press and hold briefly the Button at the top of the device	
Entering Subject Data and performing a measurement	Press the New Test button after switching the device on	
Installation/Options Mode Includes options for: • Language Options • Mid-Range Options • Imperial/Metric • Printer Pairing	Press the Options button after switching the device on.	
Serial Number/Year of Manufacture	Press the Information button after switching the device on.	
Recall Subject Data	Press the Recall Data button after switching the device on.	

Subject data may be entered, displayed, and recalled in imperial or metric measurements and may be altered at any time.

The **QUADSCAN 4000** unit is initially programmed to display **ALL** measurement data **except Lean %** which is not shown as a factory default option. The operator, however, can choose to display specific information only (refer **CUSTOMISING YOUR UNIT**).

The most recent 100 tests are always automatically stored in the memory of the **QUADSCAN 4000** unit and subject data may be recalled at any time. Data stored in memory is **not lost** after the unit is switched off (refer **RECALL SUBJECT DATA**).

If the unit has been switched on and no data has been entered for 60 seconds, an alarm signal sounds to warn the operator that the unit is still on and that battery power is being utilized.

The **QUADSCAN 4000** unit is fitted with a USB Port option to download the stored test data into a PC computer using the **BIAS Platinum Windows Software** program.

CONNECTING THE CABLE LEADS

Prior to connecting your cable leads we recommend that you read the section of the manual called **IMPORTANT GUIDELINES FOR EQUIPMENT CARE**.

The **QuadScan 4000** unit has two main cable leads. Each lead is to be inserted to the connectors at the rear of the unit. **The red dot on the lead wire should be lined up with the red dot on the device.**

DO NOT insert the leadwire into the device without aligning the red dots. Non-alignment will damage the socket mounted on the PCB. Such damage is not covered by our warranty.



The two main blue cable leads each contain a **RED** and **BLACK** crocodile clip. These can be attached to either the foot or the hand, they are therefore, interchangeable.

CUSTOMISING YOUR UNIT (OPTIONS)

The **QUADSCAN 4000** unit can be programmed by the operator to display specific information only. Subject data may be entered, displayed and recalled in imperial or metric measurements and may be altered at any time.

OPTIONS MODE

The **Installation Mode** comprises the following:

- **DISPLAY OPTIONS**
- **IMPERIAL / METRIC OPTIONS**
- **MID-RANGE OPTIONS**
- **LANGUAGE OPTIONS**

This facility allows the operator to choose:

1. **Information** required to be **entered**, e.g., Gender, Age, Height & Weight
2. **Information** required for **display**, e.g. Fat %, ECW %; ICW %, etc.
3. Units of measure in **metric** or **imperial**.
4. The **average expected input measurements** (or mid-range) of subjects to reduce the time of subject data entry.
5. **Data for Input/Display**, e.g., measure and display Impedance values only.
6. Select **language option**.

To access **Options Mode** select the icon from the main screen.

LANGUAGES

Press the <↓> key to switch between the language options. Press **PROCEED** to select.

After pressing the proceed button for language, the selection reverts to body composition and hydration/nutrition results options.

BODY COMPOSITION/HYDRATIONAL OPTIONS

The following screens allow the user to select **BODY COMPOSITION** results or **HYDRATIONAL/NUTRITIONAL** results only. This will increase Operational efficiency if the User requires specific results for Body Composition only and does not require the results of Hydration/Nutrition or vice versa.

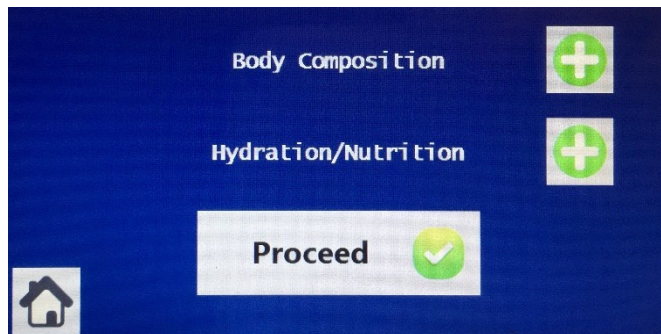


The green plus button confirms that the selection will be displayed in the results.

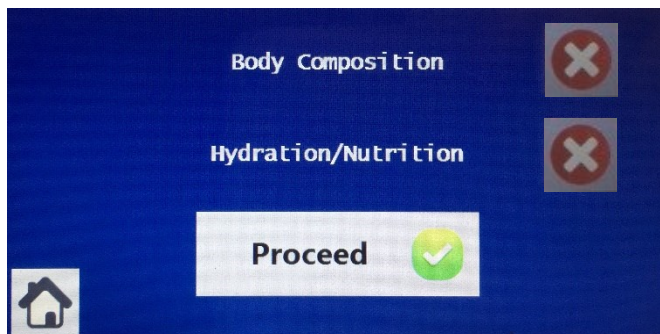


The red cross button hides the selection and the item chosen will not be displayed in the results.

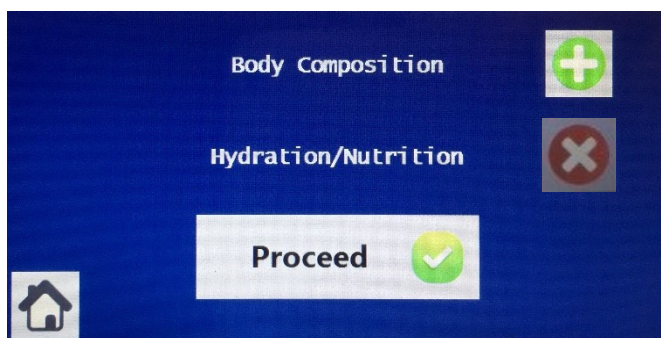
By selecting **red cross** in either of the screens below, then all of the results relating to that subject, e.g. Body Composition or Hydrational/Nutritional will not be displayed.



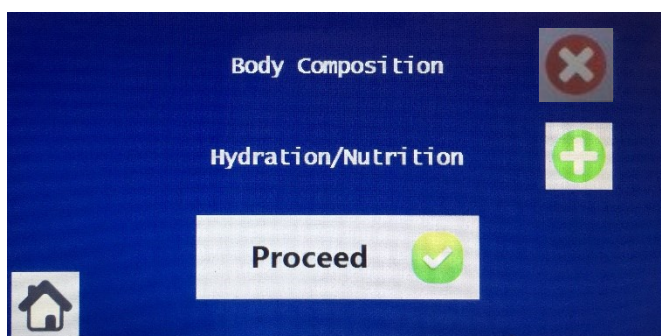
If **YES** is selected in **both** of the screens above, then all of the results for Body Composition and all of the results for Hydrational/Nutritional are displayed.



If **NO** is selected in **both** screens above, then the Impedance Values only will be displayed.



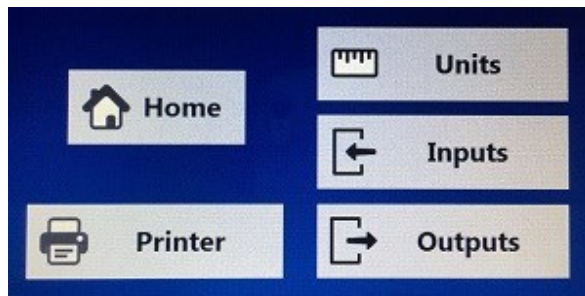
If **YES** is selected to **BODY COMPOSITION** and **NO** to **HYDRATION/NUTRIT**, the User can then view the results of **Body Composition only**, e.g. Fat, Lean, BMR, EAR, Waist to Hip, etc.



If **NO** is selected to **BODY COMPOSITION** and **YES** to **HYDRATION/NUTRIT**, the User can then view the results of **Hydration/Nutrition only**, e.g. ECW, ICW, etc.

Press **PROCEED** to select and to move to the next screen.

In the next screen, the user has the option to select Printer, Units, Inputs or Outputs. Alternatively, press the home button to revert back to the home screen.



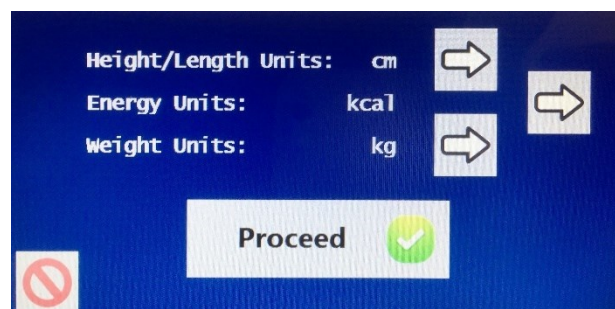
UNIT OPTIONS

The Unit option allows the user to select between the options below:

Height:
cm (centimetres) or **ft in** (feet & inches)

Calories:
kilocalories (kcal) or
kilojoules (kJ)

Weight:
kg (kilograms), **st/lb**
(stones/pounds) or **lb**
(pounds)



Press the <=> to change the appropriate unit selection and once complete, press the proceed button to confirm.

After pressing the proceed button, the selection reverts to the 4 options for Units, Inputs, Outputs or Printer. Further selections can be made or alternatively, press the home button to return to the main screen.

INPUT OPTIONS

The input options can be amended to reduce the time of subject data entry when performing a measurement. For example, if only female subjects are being measured or in the event of a particular age group being constantly measured.

By selecting the input option, the device will then display the standard default measurements required for input.

The first option available is for gender. Select the M for Male or F for Female.

Press the <↓> key to move down to the next input option.

Age, Height and Weight all have numerical selections and can be entered by choosing the appropriate numbers for that field. Once each option has been entered, press the <↓> key to move down to the next input option.

Once the weight option has been entered, the user can either select the next button to move to the next screen or the proceed button to save the recently entered options.

If the cursor is flashing on the weight option and the next button has been, the next screen showing waist/hip and activity level is displayed.

The first option is waist, followed by hip. Both options have numerical selections and can be entered by choosing the appropriate numbers for that field. Once each option has been entered, press the <↓> key to move down to the next input option.

For Activity Level select the appropriate option for the activity level required. Select one of five choices of average expected activity level of the subject being tested ranging from Very Low to Very High

Activity Level options:

On-screen	Description
V Low	Very Low
L/M	Low/Medium
Medium	
M/H	Medium/High
V High	Very High

The activity level has no effect on the body composition or hydrational/nutritional results. It is used only in the estimation of the Activity Energy Requirement.

	Range (Min/Max)
Age	1 to 99 years
Height	1' to 7'6" or metric equivalent of 30 cm to 229 cm.
Weight	2 lb to 660 lb or metric equivalent of 0.9 kg to 300 kg
Waist/Hip	5 cm to 648 cm or 2" or 255".

Once all options have been entered, press the proceed button to save the recently entered options.

Alternatively, press the red abort <❌> button to exit the screen without saving.

OUTPUT OPTIONS



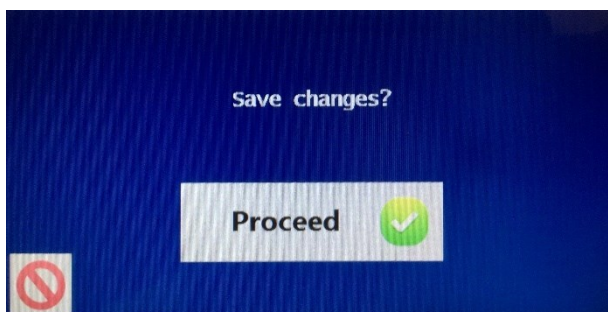
The green plus button confirms that the selection will be displayed in the results



The red cross button hides the selection and the item chosen will not be displayed in the results.

Press <↓> proceed. The Output options available are:

BODY COMPOSITION PIE CHART	
FAT %	
FAT WEIGHT	
LEAN %	
LEAN WEIGHT	
DRY LEAN WEIGHT	
TOTAL WEIGHT	
TBW %	
TBW	
WAIST/HIP RATIO	
ECW%	
ECW	
ICW%	
ICW	
3RD SPACE WATER	
BODY CELL MASS	
Nutrition Index	
BASAL. MET. RATE	
BMR/WEIGHT	
EST. AVERAGE REQ.	
BMI	
BFMI	
FFMI	
Impedance 5kHz	
Impedance 50kHz	
Impedance 100kHz	
Impedance 200kHz	



After the last output screen is displayed, a save changes screen is shown. To save changes to the output options, press the proceed button. To abort changes, press the red abort button to exit the screen without saving.

Once the options have been saved or aborted, the selection reverts back to the 4 options for Printer, Units, Inputs or Outputs. Further selections can be made or alternatively, press the home button to return to the main screen.

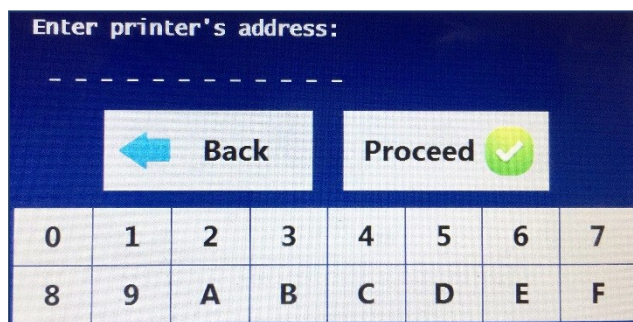
If the Waist Hip Ratio or EAR option is unselected from the output results, then the corresponding Waist Hip and Activity Level input measurements will also not be displayed when performing a test.

If all of the output display options have been removed except for the raw data impedance measurements, then the input screens for age, gender, height and weight, waist and hip will not be displayed. In this instance, the first screen that will appear when performing a test, will be the connect electrodes screen.

PRINTER OPTIONS

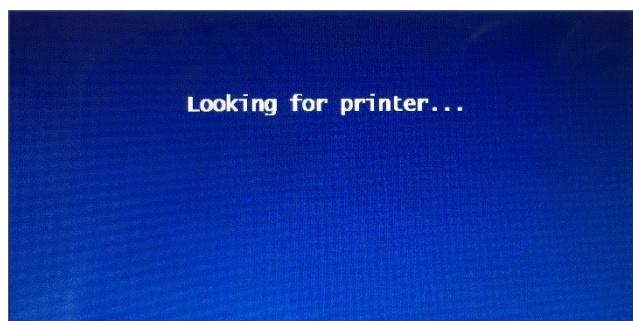
The **QuadScan 4000** device has the option of printing to a thermal printer. When using the printer for the first time, it is important that the printer is first paired with the **QuadScan 4000** device.

To pair the printer, press the printer button and the screen will ask for printer's address. Ensure that the printer is switched on at this stage.

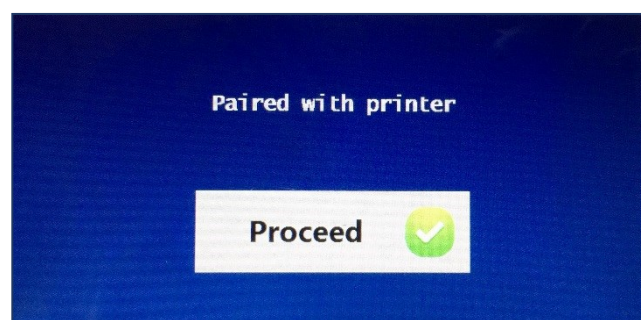


0	1	2	3	4	5	6	7
8	9	A	B	C	D	E	F

The printer's address can be found on the label on the reverse of the printer. The printer's address is a 12 digit code which must then be typed into the Bodystat device. Once the code has been typed into the device, press the proceed button.



The Bodystat device will then continue to search for the printer. If the device does not find the printer, ensure that the printer is switched on.



Once the device has been paired with the printer, a message will be displayed confirming the pairing has been completed. Press the proceed button to complete and the device will revert you back to the 3 options for Inputs, Outputs or Printer

PERFORMING A MEASUREMENT

MEASUREMENT ADVICE



NOT recommended for Females in the early stages of pregnancy



NOT recommended for subjects with pacemakers or any implantable electronic device.

For accurate and reproducible results on repeat tests, it is very **important that the subject is as normally hydrated as possible**. The following guidelines should ideally be followed wherever possible, particularly under research conditions:

- NO eating or drinking 4 to 5 hours prior to the test.
- NO exercise 12 hours prior to the test.
- NO alcohol or caffeine consumption 24 hours prior to the test.

***Proper hydration is essential for a healthy body status.
DO NOT therefore perform a test after strenuous exercise.***

The body would have lost excessive fluid through sweat and an abnormally low fluid level may increase the Impedance measurement resulting in an artificially lower **TBW** and higher **FAT %** than would normally be the case.

For best results with repeat tests on the same subject over a period of time, many users try to perform the test the same time of day (e.g. early morning, before lunch) wherever practicable.

Note that variations in body composition are likely to occur in subjects premenstrual, during menstruation, with renal failure, on some prescribed medications (particularly diuretics) and other conditions causing water retention or water loss.

PREPARING SUBJECT FOR MEASUREMENT

Height and weight must first be accurately determined if necessary. Note that these input factors are required to determine the **FAT, LEAN, ECW, TBW** etc, calculations which are displayed on the LCD screen of the **QuadScan 4000** hardware unit. However, where subject weight is not available, the **Prediction Marker**, resistance, reactance, phase angle and the four impedance values will still be displayed.

Ensure that the scale being used to measure weight has been accurately calibrated to measure to the nearest 0.1 kg or 0.2 lb.

For greater accuracy, it is preferable to measure height in metric, i.e. centimetres, as opposed to inches or half inches.

When repeat measurements are made on the same subject ensure that the **exact same** height as earlier measurements is used unless the subject has in the interim grown naturally in length.

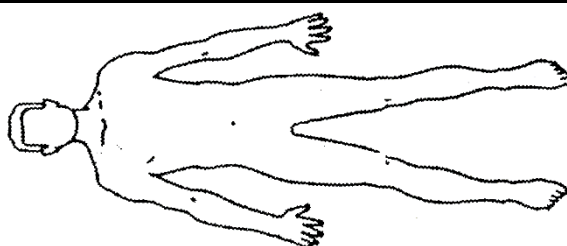
Then have the subject remove the right shoe and sock or stocking, and lie flat with the arms and legs spread slightly as shown in the diagram.



NO parts of the body should be touching one another.

In some overweight cases the inner thighs may touch in spite of the legs being spread slightly. Ensure that this does not happen by further spreading the legs. The subject should be in a comfortable relaxed position and then proceed to place the electrodes.

SUBJECT POSITION



PLACEMENT OF ELECTRODES AND LEADS

Distal Placement

The self-adhesive disposable electrodes are attached to the **RIGHT** hand and **RIGHT** foot, in order to avoid the battery current (low voltage) passing through the side of the body where the heart is situated.

The **BODYSTAT QuadScan 4000** unit has two main lead wires. *It does NOT matter which of the two sets of main leads are connected to the right hand or right foot.* They are therefore interchangeable.

However, it is important to ensure that the **RED** (injecting) leads are connected to the electrodes just behind the **finger** and **toe** as shown in the illustration.

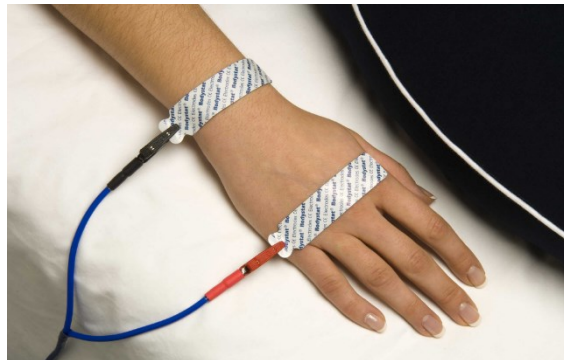
For convenience, the metal tab on the electrode should point in the direction from which the leadwire tension will occur as illustrated.

The **BLACK** (measuring) leads are then connected to the electrodes on the right **wrist** and right **ankle**.

Placement of the electrodes is as follows:

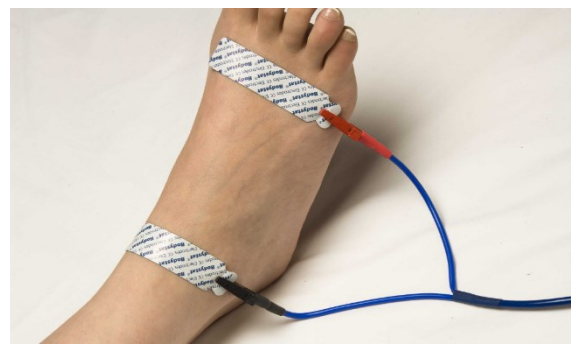
RIGHT HAND

- RED LEAD:** Behind the knuckle of the middle finger.
- BLACK LEAD:** On the wrist next to the ulna head.



RIGHT FOOT

- RED LEAD:** Behind the 2nd toe next to the big toe.
- BLACK LEAD:** On the ankle at the level of and between the medial and lateral malleoli (the large protruding bones on the sides of the ankle).



Once the subject is lying in the supine position, ensure that at least 3 to 4 minutes has elapsed before pressing the PROCEED button on the equipment.

This is to ensure that the fluid levels have stabilized in the body before a measurement is performed.

Segmental Measurements

Multi-frequency BIA technology has the advantage of performing measurements on specific sections of the body without the weight or other input data of the area being measured and still obtaining meaningful output data.

Only the accurate raw **Impedance** measurement data at **5 kHz** and **200 kHz** is used to calculate the **Prediction Marker** and applying its principles of interpretation. Some users may additionally use the **Reactance** and **Phase Angle** values to interpret the measurement results.

It may either be the health or nutritional status of the body cells or the ratio of ECW to TBW of the particular body segment that is being determined.

This may also depend on the medical condition and health status of the subject itself and the segmental area of measurement.

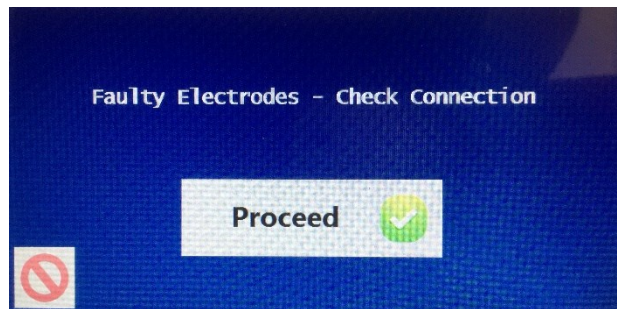
However, the **important point to remember** is that it is **CHANGE** in the marker that should be focused upon to determine the **TREND** over a period of time, either hours, days, weeks or months.

NOTE: The **Prediction Marker** concept is the area of intense and continuous investigation and interpretation. It is suggested that the **Bodystat** web page be reviewed from time to time to keep up to date with the most recent developments, research publications and practical applications of this technique.

It is **IMPORTANT** to always place the **BLACK LEAD**/electrode on a reproducible spot on the body to ensure accurate impedance values when monitoring **CHANGE**. The **BLACK** leads are placed on the **“INSIDE”** of the area of measurement and the **RED** leads on the **“OUTSIDE”** of the area. There should always be a minimum of **3cm (preferably 5cm)** between the placement of the **black** and **red** electrode to avoid electrical current and measurement problems.

HOW THE CURRENT IS APPLIED

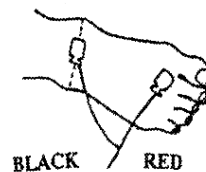
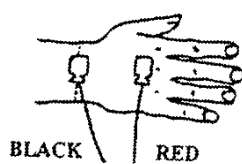
The **RED** leads are the source of **power** and sends the signal through the body - the injecting leads. The **BLACK** leads are the **sensing** or measuring leads. If the leads are not connected to the body correctly, the current cannot be transmitted effectively and therefore the impedance measurement will be inaccurate or the following message will be registered on the LCD screen.



The same message will be displayed if all four leads have not been connected to the electrodes attached to the body.

IMPORTANT POINTS REGARDING MEASUREMENT

- Subjects should be measured on a non-conductive surface.
- **Correct placement of the BLACK INNER electrode on the wrist and the ankle is critical.** The electrode placement behind the fingers and toes is not as critical.
- The electrode placement behind the fingers and toes is not as critical.



BLACK leads are placed on the **BACK** (rear) of the hand and foot

- There should always be a minimum of **3cm (preferably 5cm)** between the placement of the **black** and **red** electrode to avoid electrical current and measurement problems.
- Once the four electrode sites have been selected it may be necessary to apply a solvent to remove excess skin oil. In research conditions it might be considered necessary to shave the site of excess hair. This is to ensure that good contact is made between the skin and the electrode. Poor contact will result in higher Impedance values resulting in an under-determination of **TBW** and over-determination of **FAT Levels**.

- The skin should be at normal body temperature and not be sweating.
- Attach the crocodile (alligator) clips on the cable leads to the exposed tab, ensuring that metal contact is against the foil side of the electrode.
- For convenience, the metal tab on the electrode should point in the direction from which the cable lead tension will occur as illustrated.
- Once in place, press down on the electrodes to ensure good contact.
- The electrodes may be repositioned if necessary but should not be used on another subject since they may dry out thereby artificially increasing the Impedance values.
- Keep unused electrodes in the re-sealable plastic bag to ensure freshness.
- Always check that the electrodes are within their Expiry Date. This date can be found on the re-sealable plastic bag
- **DO NOT** cut the electrodes in half to increase their utilization. This will result in inaccurate measurements and poor reproducibility except in the case of tiny premature babies.
- Only the **best quality BODYSTAT Electrodes** as those supplied by **BODYSTAT LTD**, or their accredited distributors, should be used and **used only once**. This is to ensure accuracy of measurement and good reproducibility of tests.
- Pins in bones will not affect the measurements.

Quality Control Check of Measurement Accuracy

In order to ensure that your measurements are reliable, we strongly recommend reviewing the raw data impedance values. If an arm or leg moves, an electrode peels off, for example, during the few seconds of measuring time, it may invalidate that measurement. We also recommend that at least two sets of data should be collected at each time.

Two methods:

1. A quick check is to look at the Prediction Marker/Dehydration Index – the value **MUST** be lower than 1.00. However, this may not be conclusive evidence.
2. Review the four Impedance values immediately after measurement.

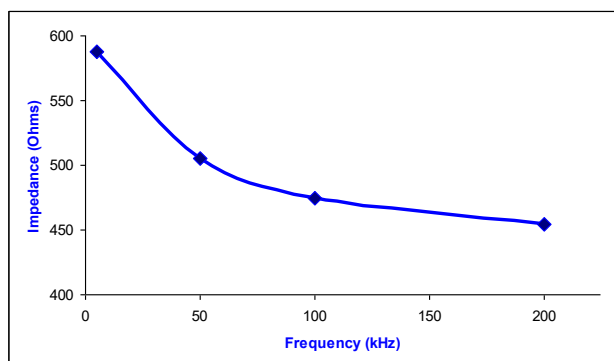
This means looking at the impedance values at each successive frequency. Each value **MUST** be lower than the previous impedance value.

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

If the four values are plotted on a graph, the curve should be smooth with minimal or no 'bumps'. The data points and curve should lie on or very close to each other. The table and graph illustrate this.

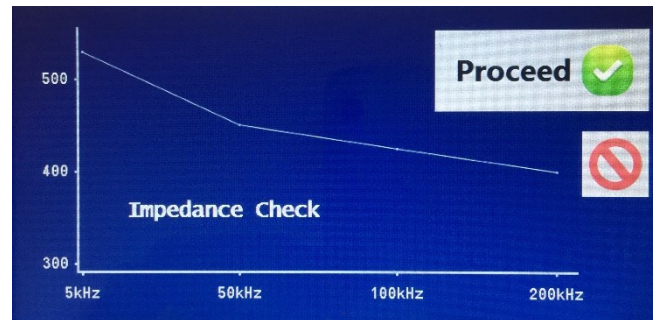
Graphic display of the raw data depicted above:

Healthy Female, Prediction Marker 0.772, Phase Angle 6.3°



Graph to show how as frequency **increases**, the impedance values must **decrease**.

Immediately following a measurement, an impedance graph will be displayed. The impedance graph should be viewed to ensure that there are no bumps and that the measurement was successful. If the test has a bump and does not look smooth, then the test can be rejected by clicking the red close option and repeating the measurement process again. If the test looks correct, click the Proceed button to view the body composition and hydrational results.



Here are some examples of typical valid measurement values

Healthy Female, (during menstrual cycle) Prediction Marker 0.816 Phase Angle 5.1°

Frequency (kHz)	5	50	100	200
Impedance Values (Ohms)	733	656	624	598

Healthy Male, Prediction Marker 0.769 Phase Angle 6.6°

Frequency (kHz)	5	50	100	200
Impedance Values (Ohms)	562	478	450	432

Critically Ill Male in ICU, Oedematous (survived) Prediction Marker 0.874 Phase Angle 3.3°

Frequency (kHz)	5	50	100	200
Impedance Values (Ohms)	333	312	301	291

Critically Ill Male in ICU, Significant fluid overload (died) Prediction Marker 0.957 Phase Angle 0.7° ***

Frequency (kHz)	5	50	100	200
Impedance Values (Ohms)	233	227	225	223

*** There is thought that PA cannot be measured accurately in a state of significant fluid overload. The Prediction Marker value, however, is accurate.

These are actual examples of inaccurate measurements

Prediction Marker 0.077 *(impossible to have such a value)*

Frequency (kHz)	5	50	100	200
Impedance Values (Ohms)	1978	276	175	152

Prediction Marker 9.080 *(cannot be >1.00)*

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

Prediction Marker 0.772
(even though IM “looks” OK, one measurement is suspect)

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

ENTERING SUBJECT DATA INTO THE HARDWARE UNIT

Switch the **QUADSCAN 4000** unit **ON**. No message will be displayed on the touch screen LCD if the batteries are flat, in which case replace **ALL** the batteries **ONLY** with new Duracell/Procell Batteries.

Select the New Test button on the screen to perform a Bodystat measurement.

Once the new test option has been selected, the following screen will be displayed:

Test Number: 61		↑		Next ↓	
Gender: Female		⊘		Proceed ✓	
Age: 30 Yrs					
Height: 165 cm					
Weight: 65.5 kg					
-	M	-	F	-	
-	-	-	-	-	

The **QUADSCAN 4000** unit automatically allocates the next available number. The test number is used to identify the subjects' data if tests are to be recalled for viewing. It is, therefore, recommended that a manual record of the test numbers should be maintained against the respective subjects.

The first option available is for gender. Select the M for Male or F for Female. Press the **<↓>** key to move down to the next input option.

Test Number: 61		↑		Next ↓	
Gender: Female		⊘		Proceed ✓	
Age: 30 Yrs					
Height: 165 cm					
Weight: 65.5 kg					
1	2	3	4	5	
6	7	8	9	0	

Age, Height and Weight all have numerical selections and can be entered by choosing the appropriate numbers for that field. Once each option has been entered, press the **<↓>** key to move down to the next input option.

Height and weight may be displayed either in imperial or metric (refer **CUSTOMISING YOUR UNIT**).

Once the weight option has been entered, the user can either select the next button to move to the next screen or the proceed button to move to the

measurement screen (without entering waist/hip or activity levels). If the waist/hip and activity screen is skipped at this stage, then the device will use the defaulted option for those results (unless the Waist Hip Ratio has been omitted in the options menu).

If the cursor is flashing on the weight option and the next button has been, the next screen showing waist/hip and activity level is displayed.

Test Number: 61
 Waist: 65 cm
 Hip: 90 cm
 Activity: Very Low

Navigation buttons: Up arrow, Next (Down arrow), Proceed (Green checkmark)

1	2	3	4	5
6	7	8	9	0

The first option is waist, followed by hip. Both options have numerical selections and can be entered by choosing the appropriate numbers for that field. Once each option has been entered, press the $\updownarrow$ key to move down to the next input option.

Test Number: 61
 Waist: 65 cm
 Hip: 90 cm
 Activity: Very Low

Navigation buttons: Up arrow, Next (Down arrow), Proceed (Green checkmark)

V Low	L/M	Med	M/H	V High
-	-	-	-	-

For Activity Level select the appropriate option for the activity level required. Select one of five choices of average expected activity level of the subject being tested ranging from Very Low to Very High.

The activity level has no effect on the body composition or hydrational/nutritional results. It is used only in the estimation of the Activity Energy Requirement

See the [Input options](#) section ([page 18](#)) for details about choices available for the activity level

If the Waist Hip Ratio or EAR option is unselected from the output results, then the corresponding Waist Hip and Activity Level input measurements will also not be displayed when performing a test.

Notes about activity levels:

NOTE 1: *Very Low* - for a person with light energy expenditure at work and who has non-active leisure pursuits.

NOTE 2: *Very High* - for a person in energy-demanding work whose leisure time pursuits are also energy-demanding.

Refer ***METABOLIC RATES*** for detailed description for each of the five Activity Levels.

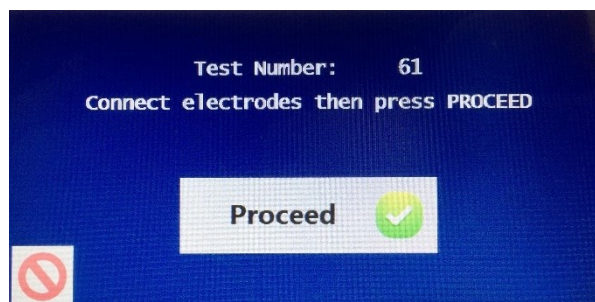
Once all options have been entered, press the proceed button to move to the measurement screen.

Alternatively, press the red abort <> button to exit the screen without measuring.

The next screen displayed is for connecting the electrodes. The unit has already been connected to the four surface electrodes as fully explained in the ***PERFORMING A MEASUREMENT*** section of this manual and the required subject data has now been entered.

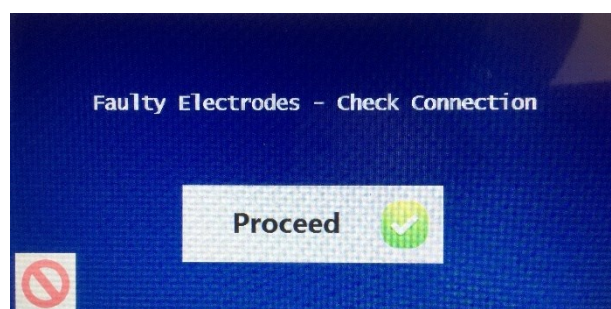
Ensure that the unit has been switched on for *at least one minute* before taking the electronic measurement and that the subject has been lying down for approx. 3 to 4 minutes for greatest accuracy of measurement and reproducibility of results.

Check the subject to ensure that all the electrodes and leads are firmly connected and that the subject is still lying flat in the correct position.

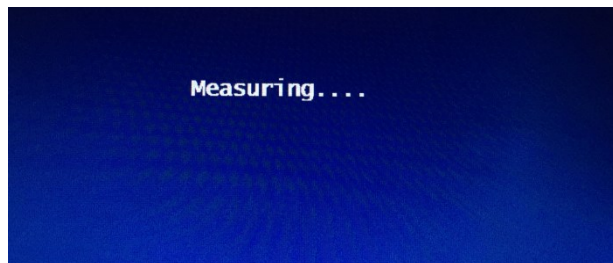


Press the <Proceed> key.

If the leads have not been properly attached to the electrodes, a message will be displayed:



Re-check the electrode and lead connections. Ensure that the subject is still in the correct position and press the **<Proceed>** key as before.



Wait a few seconds for the results to be displayed on the LCD screen.

The data has now automatically been saved and stored enabling both input and output subject data to be recalled later.

The electrodes and leads may at this stage be removed.

The next screen that is automatically displayed is dependent on how the operator has set up the user selectable **DISPLAY OPTIONS** (refer **CUSTOMISING YOUR UNIT**, page 16) as defined in that section.

REPEATING A MEASUREMENT

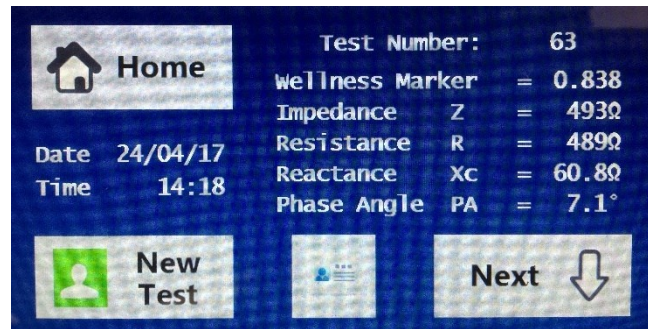
In the event that you wish to repeat a measurement, **provided the unit is not switched off** it will hold the previous input data in its memory. This will allow a quick re-test or simple amendment to an incorrectly keyed-in parameter. Once the unit is switched off, it will revert to the default settings.

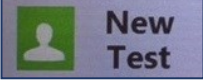
The user can select to change the default settings, refer to **CUSTOMISING YOUR UNIT**. This facility is useful if the same subject is being constantly measured over a period of time. This will allow the testing to be performed quickly, saving time for maximum operational efficiency.

DISPLAY RESULTS

After successful measurement and processing of the subject data, the results are displayed as selected by the operator.

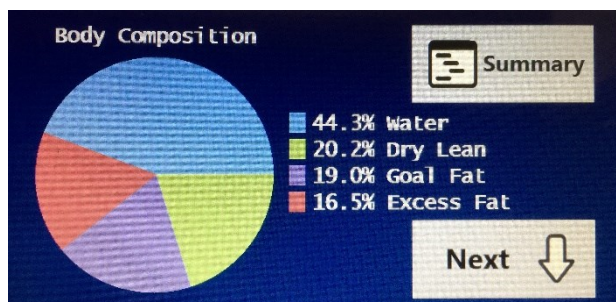
The first screen displayed is the test summary screen which shows the Wellness Marker, Impedance, Resistance, Reactance and Phase Angle at 50 kHz.



	Once the summary screen has been displayed, a new test can now be performed by selecting the new test button.
	Alternatively, the results for that particular test can be viewed by selecting the results icon.
	To print the results to the paired thermal printer, select the print icon.

RESULTS ICON

If the results icon has been pressed, then the first screen displayed is the input data that was entered for that particular test. By pressing the next button the result output data is now displayed. If the next arrow was pressed from the summary screen, then the first screen displayed is the actual results for that subject.



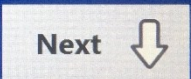
The first result screen displayed is the body composition pie chart for that particular test. Each pie chart shows the Fat, Water and Dry Lean.

Each result displays the **Estimated Measured Result**. Underneath the result displays the **Recommended** or **Normal Level** (where appropriate) for the subject measured.

Select the Next button to move to the next results screen or alternatively press the summary button to move back to the summary page.

The display results are automatically stored in memory and the operator can safely scroll forwards through the data by using the <↓> key.

The results displayed below are in the order as they would appear on the LCD screen of the QuadScan 4000 unit if both the **Body Composition** and the **Hydration/Nutrition** results were set to be displayed in the Installation Mode. (Refer *Customising Your Unit*).

Fat %	14.1 %	 Summary
Normal	14 - 20 %	
Fat	9.6 kg	
Normal	10 kg - 14 kg	
Lean %	85.9 %	
Normal	80 - 86 %	
Lean	58.4 kg	
Normal	56 kg - 61 kg	
Dry Lean	14.0 kg	

Fat as a % of Total Body

Fat Weight

Lean Weight (muscle, bone & water)

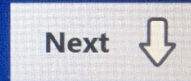
Dry Lean Weight (muscle, bone)

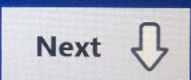
Total Weight

Total Body Water %

Total Body Water Volume

Waist/Hip*

Total Weight	68.0 kg	 Summary
Normal	68 kg - 73 kg	
TBW %	65.3 %	
Normal	55 - 65 %	
TBW	44.4 lt	
Normal	37 - 44 lt	
Waist/Hip	0.89	
High Risk	1.00	

ECW %	27.0 %	 Summary
Normal	26 %	
ECW	18.3 lt	
ICW %	36.4 %	
Normal	34 %	
ICW	24.8 lt	
3rd Space Water	1.3 lt	

Extra-Cellular Water %

Extra-Cellular Water Volume

Intra-Cellular Water %

Intra-Cellular Water Volume

3rd Space Water

Body Cell Mass	35.4 kg	 Summary
Nutrition Index	0.43	
Normal	0.43	
Basal Metabolic Rate	1722 kcal	
BMR/Body Weight	25.3 kcal/kg	
Est. Average Req.	2755 kcal	 Next

Body Cell Mass

Nutrition Index

Basal Metabolic Rate

BMR/Body Weight

Est. Average Requirement

Body Mass Index

Body Fat Mass Index

Fat Free Mass Index

BMI	22.2	 Summary
Normal	20 - 25	
BFMI	3.1	
Normal	3 - 5	
FFMI	19.1	
Normal	18 - 20	 Next

 Home	Impedance 5kHz	543Ω
 Summary	Impedance 50kHz	462Ω
	Impedance 100kHz	434Ω
	Impedance 200kHz	411Ω
 New Test		

Impedance Values at 5, 50, 100 and 200 kHz

RECALL SUBJECT DATA

This feature allows an operator to recall, at a later stage, both the input and output test data for manual recording purposes or entry into computer software programs such as spreadsheets, etc. However, it would be more efficient to download the data into the **QuadScan 4000** software program supplied with the **QuadScan 4000** unit and then in turn to easily save the subject data in **Excel, XML or CSV files**.

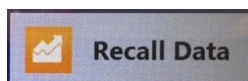
At the time of subject data entry, a test number is automatically allocated by the **QUADSCAN 4000** unit. It is advisable to manually record the name of the subject being tested against that number. This will enable an operator to subsequently recall data of the correct subject number.

A maximum of 100 tests will be stored in the memory of the **QUADSCAN 4000** unit at any one time. When the memory reaches its maximum capacity **FOR THE FIRST TIME**, and a further test (number 101) is performed, **the oldest number, i.e. test number 1, is automatically dropped from the memory**.

At all times thereafter, the most recent 100 tests will always be stored but successive tests will be numbered in ascending order, i.e., 101, 102, 103, etc to a maximum number of 99,999. Thereafter, the numerical series will automatically revert back to number 1. Thus, each test will maintain its own unique allocated number for subsequent recall purposes.

NOTE: Tests are automatically stored in memory after subject data has been entered and the **QUADSCAN 4000** unit has successfully performed a measurement.

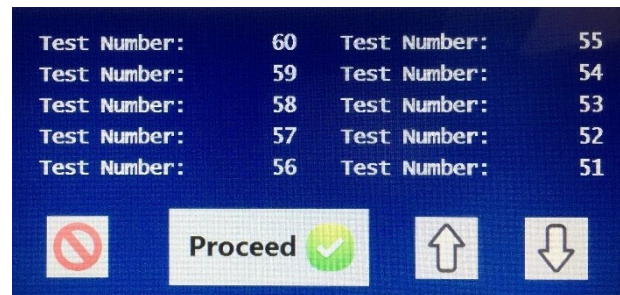
Data is not lost after the unit is switched off or during battery replacement.



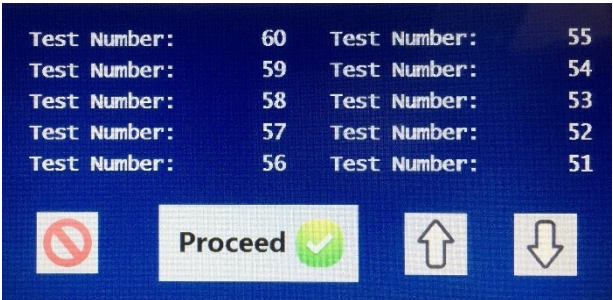
To access this recall option, select the recall data button from the home screen.

The screen on the right is displayed on the LCD screen:

The number that will be displayed at the top shall be the most recent test that was tested and saved immediately prior to selecting this option. Ten tests are displayed per page, and it may be necessary to use the up and down arrow keys at the bottom to scroll through the pages.

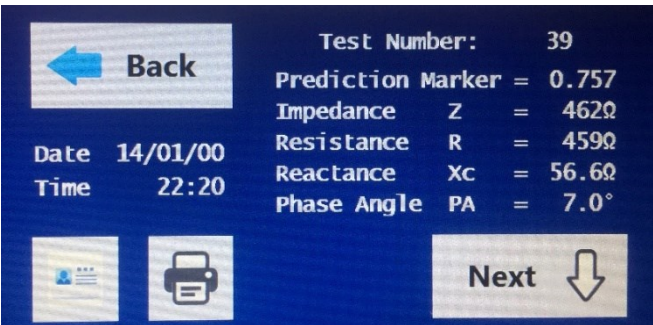


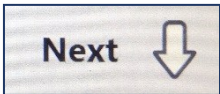
The number that will be displayed at the top shall be the most recent test that was tested and saved immediately prior to selecting this option. Ten tests are displayed per page, and it may be necessary to use the up and down arrow keys at the bottom to scroll through the pages.



Select the test to display and press the proceed button to view the Input details and Results information.

The first screen displayed is the test summary screen which shows the Impedance at 50 kHz, Resistance, Reactance and Phase Angle.



	The results for that particular test can be viewed by selecting the results icon.
	To view the results for that particular test without viewing the input data, select the next button.
	To print the results to the paired thermal printer, select the print icon.

Press the home button to return to the main screen.

The first screen displayed is the input data that was entered for that test. By pressing the next button, the result output data is then displayed.

Once all the results have been reviewed, the user has the option of selecting the back arrow or alternatively going back to summary screen. The back arrow allows the user to go back to the recall screen to select a further test.

NOTE:

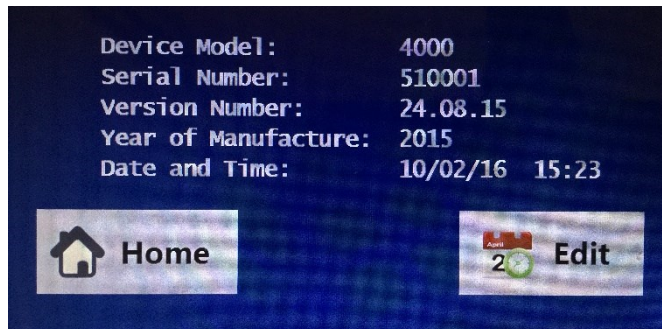
- The **OUTPUT** data displayed will depend on what has last been saved in **DISPLAY OPTIONS** (refer **INSTALLATION MODE**) of the program. If the operator wishes to display, for example, only **FAT %**, the **DISPLAY OPTIONS** must first be amended.
- Test data originally stored in **kg** weights may be recalled in **lb** or **st/lb** and vice versa. Similarly, height may be entered in **ft/ins** and recalled in **cm**. In each case, simply change the options in **INSTALLATION MODE**.

INFORMATION ABOUT THE DEVICE

Access to the **QUADSCAN 4000** unit serial number may be necessary from time to time. This will be required for warranty purposes, etc.

The serial number may be accessed as follows:

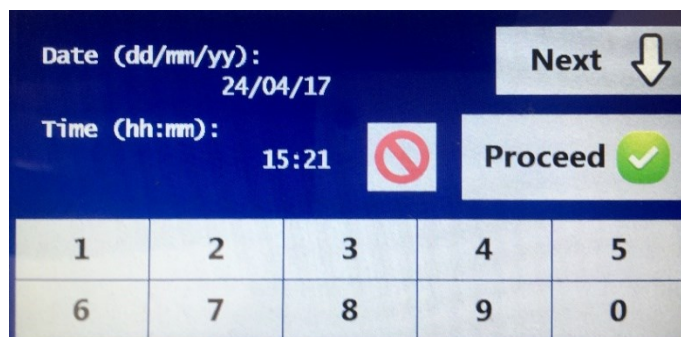
While switching the unit **ON** and then select the information button from the home screen.



Press the home button to return to the main screen.

EDIT DATE AND TIME

To edit the time, select the edit button at the bottom of the screen. The cursor will flash over the number in question and use the numerical keypad at the bottom of the screen to enter the date. Press the next key to move down the time option and the numerical keypad can be used to change the time option.



To exit the screen without entering a date or time, press the red abort <  > button.

Once complete select the proceed button and the information screen will again be displayed.

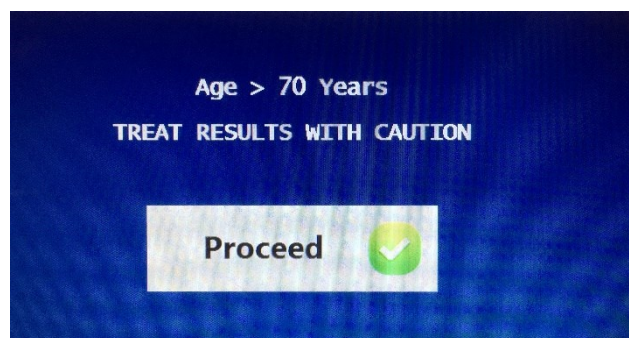
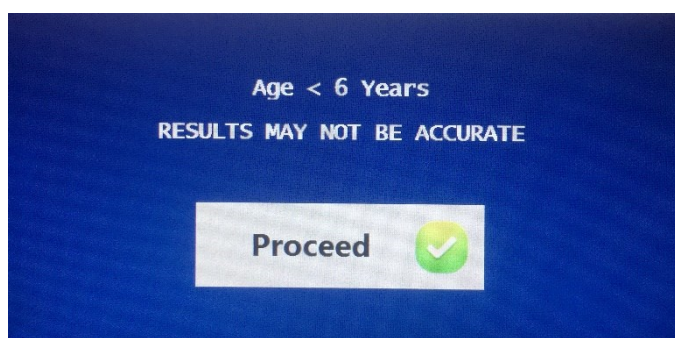
ADDITIONAL INFORMATION

CHILDREN'S EQUATION

There are two regression equations or formulae used in the program of the **QUADSCAN 4000** unit for the determination of body composition. One is suited for the **age groups 18 to 70 years** as found in our popular **BODYSTAT®1500** unit. There is also an additional equation used in **QUADSCAN 4000** unit which is especially suited for the **age groups 6 to 17 years**. This equation **only applies to the results of Body Composition** and is automatically selected when the age of the subject is entered. The hydrational/nutritional information will still be displayed, however, a * symbol next to the results of ECW, ICW, etc will indicate that they may not be accurate and are to be treated with caution.

Age groups outside of this range may of course still be measured (for example, for regular monitoring of changes in body composition or fluid monitoring) but the results, in particular the recommended or optimal results, may have to be treated with caution.

If the age of the subject being measured is **under 6 years or older than 70 years**, the following message will be displayed:



The body composition & hydrational results of the subject will still be displayed along with accurately measured Impedance values.

After performing a measurement on a subject of 17 years and under, then the appropriate regression equation for the Body Composition results must be selected after downloading the data into the QuadScan Software.

Grateful acknowledgement is made to the following people in determining the body composition measurements for children ages 6 to 17 years of age:

Linda B. Houtkooper published in J.Appl.Physiol. 72(1):366-373, 1992. Bioelectrical impedance estimation of fat-free body mass in children and youth: a cross validation study

Kushner, R.F., et al published in American Journal of Clinical Nutrition, 56, 835-839, 1992. Is the Impedance index (ht²/R) significant in predicting total body water?

Lohman, T.G. published in Pediatric Exercise Science, 1, p.21, 1989. Assessment of Body Composition in Children.

3rd SPACE WATER

As explained in the Introduction Section of the User's Guide, the **50 kHz** frequency is used to predict the value of Total Body Water (**TBW**) and Fat-Free Mass. However, at this frequency the current is unable to penetrate the cell membrane fully and at **5 kHz** only **ECW** is predicted. At **200 kHz** the cell membrane is penetrated and both intra- and extra-cellular fluid spaces can be accessed to determine **TBW**. Due to the higher frequency at 200 kHz, a different TBW figure is predicted than that of the 50 kHz figure. The 3rd Space Water is the difference between the two TBW figures.

The value for 3rd Space Water can therefore, be positive or negative. If the value is positive then the TBW at 50 kHz is higher than the TBW at 200 kHz. If the value is negative, then the TBW at 50 kHz is lower than the TBW at 200 kHz.

On the odd occasion, the **value for 3rd Space Water could exceed 2 litres**. This may be due to an excessive build-up of fluid, e.g. patients with oedema, etc. This could also result in under-stating the Fat % figure and over-stating the Lean mass. Therefore, the following message will be displayed, and the Fat & Lean values should be treated with caution.

CAUTION MESSAGE FAT/LEAN

If all of the Body Composition results have not been selected for display, the above message will not be shown.

IMPORTANCE OF TRACKING CHANGES

It may be important to note, even if the absolute percentage Fat/ECW figures, for example, are suspect for a particular subject, that accurate measurements can still nevertheless be made on a regular basis to **monitor the changes in body or fluid composition** over a period of time.

Since the **QUADSCAN 4000** unit measures the Impedance values very accurately it has excellent reproducible qualities. This enables an operator to track whether FAT, LEAN, ECW or TBW (for example) on the same subject is on the increase or decline. Thus even if there is some doubt as to the accuracy of the absolute figures, **tracking the changes of body or fluid composition can help to determine whether any clinical or nutritional program, for example, is having the desired effect**.

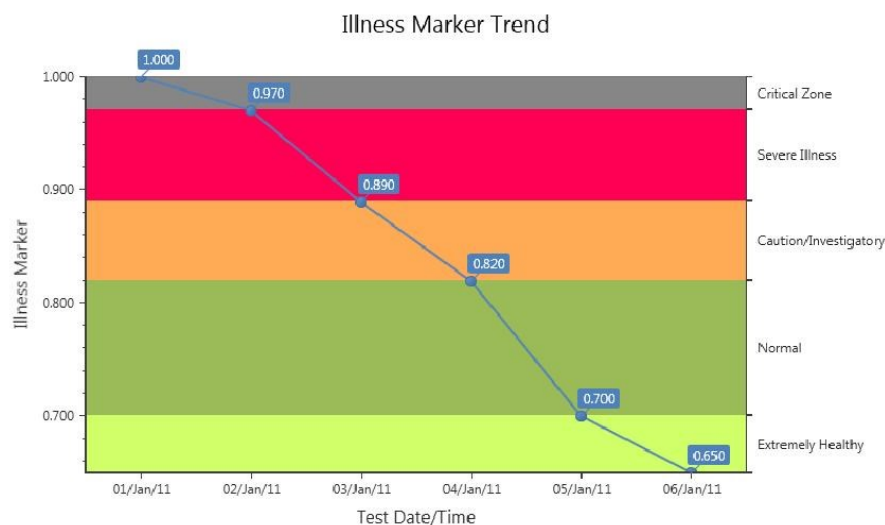
The **Impedance values** on its own may also give the first signs of **changes in the nutritional status of a patient**. If the Impedance values increase over consecutive measurements (in terms of hours, days, weeks or months, etc) it may indicate that the body is losing fluid. This is because the electronic resistance to the flow of the current in the body when the measurement is taken has increased. Water is a good conductor of electricity and the less fluid in the body the higher therefore the resistance factor in the body. This results in a higher Impedance value being registered by the **QUADSCAN 4000** unit and hence higher fat % figures and lower body fluid volumes.

It should be noted, however, that many other factors will affect the impedance values, such as the electrolytic concentration of the fluid.

PREDICTION MARKER

This index is calculated using **only** the **Impedance** value at **200 kHz** divided by the **Impedance** at **5 kHz** and applying its principles of interpretation. The answer is therefore always **less than 1.00**. In the section **Display Results**, the Prediction Marker is calculated to be **0.783 (553 / 706)**.

The table below shows the normal range for the **PREDICTION MARKER** as experienced by Bodystat.



However, the “healthier” the body cells the lower the value appears to be; for example, between 0.65 to 0.75. In the case of critically ill hospitalised patients, this ratio could significantly show higher values, upwards of 0.89, for example. Some published research papers (refer **Research section** on www.bodystat.com) have instead calculated the Index as **Impedance** value at **5 kHz** divided by the **Impedance** at **200 kHz**. In this case the value would be shown as **1.277**.

The principle remains the same; the closer to 1.00 the “less healthy” the body cells or the higher the ratio between ECW and TBW.

Since it uses only accurate raw measurement data, it benefits from the fact that no subject input data is required and no regression equation is applied.

It is therefore a quick and easy measurement to make. To setup the hardware device to display only the raw data measurements, select **NO** to **BODY COMPOSITION and HYDRATIONAL/NUTRITIONAL** in the section **options menu**.

The method can be *applied to any age* group including premature new-born babies and segmental measurements of the body (refer section on *Performing a Measurement*).

At the time of this writing, our limited opinion on the interpretation of the significance of the Prediction Marker, depends on the medical condition and health status of the subject itself.

It may either be the health or nutritional status of the body cells or the ratio of ECW to TBW of the whole body or particular body segment that is being determined.

Some users may additionally use the **Reactance** and **Phase Angle** values to interpret the same measurement results.

However, the **key point to remember** is that it is **CHANGE** in the marker that should be focused upon to determine the **TREND** over a period of time, either hours, days, weeks or months.

NOTE

The **Prediction Marker** concept is an area of intense and continuous investigation and interpretation on an international basis.

For a fuller understanding and to keep up to date with the most recent developments, research publications and practical applications of this technique; refer to the **Bodystat** web page from time to time.

SECTION C

TECHNICAL

INFORMATION

METABOLIC RATES - BASAL (At Rest) and ACTIVITY LEVELS

ESTIMATED AVERAGE (Energy) REQUIREMENT (E.A.R.)

To estimate the total daily energy expenditure level of a person, an assessment of the average activity level during a 24-hour period should be made when entering the data in the **QuadScan 4000** unit. This can only be a subjective assessment, but the following table may help:

ACTIVITY LEVEL

Level of Activity	General	Activities
Very Low <i>Movement Restricted</i>	Generally inactive.	Laying at ease, sitting, writing, standing, driving.
Low/Medium <i>Office/Light Work</i>	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 <i>Weekend Recreation</i>	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 <i>Moderate Exercise</i>	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 (5-6 mph/8-10kph), walking (5-6 mph/8-10kph).
Very High <i>Vigorous Exercise at Competitive Level</i>	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)

CALIBRATION

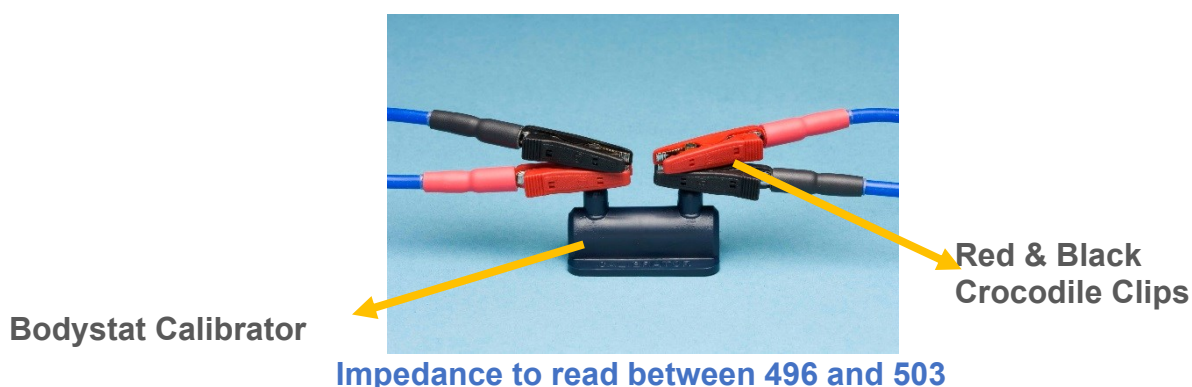
A separate **BODYSTAT** calibrator is supplied with each **QuadScan 4000** unit to enable the operator to independently verify that the unit remains in calibration at all times. This should be done from time to time perhaps weekly depending on frequency of use. However, this is only an independent check and an operator will not be able to physically re-calibrate the unit.

It is also recommended that the operator use their own body as another independent check. This should be performed on a subject whose body composition does not fluctuate greatly and remains fairly constant.

PROCEDURE

1. Attach one **pair** of red and black leads to any one terminal of the calibration unit. Then attach the other **pair** of red and black leads to the other terminal of the calibration unit.
2. Switch the unit **ON** and enter any subject data or accept the default displays on the LCD screen.
3. Provided that the leads have been correctly attached to the calibrator and after "**MEASURING**" is displayed, scroll through the results until the Impedance values are reached. The results at all four impedance values should reflect readings of between **496** to **503**, approximately a 0.5% variance on either side of the high precision 500-ohm resistor in the **BODYSTAT** calibrator.
4. If the readings are outside of this range, the following should be checked: Are the leads correctly attached as per the procedure above?
5. If the results are still incorrect, first replace **ALL** batteries with new **Duracell** or **Procell** batteries (refer **BATTERY REPLACEMENT** section).
6. If the unit remains outside of the calibration range, contact **BODYSTAT LTD** or your dealer.

NOTE: The IMPEDANCE values must first be selected as a **DISPLAY OPTION** if not already done so (refer **INSTALLATION MODE**).



BATTERY REPLACEMENT

Due to its unique electronic design, **BODYSTAT LIMITED** estimates an approximate **40-to-50-hour** battery life from the batteries supplied with the **QuadScan 4000** unit.

The exact specification for batteries is:

AA Type (LR6) batteries : 6 units

Alkaline 1.5V (NON-rechargeable)

ONLY Duracell® (Model MN1500) or Procell® batteries are recommended



Do not use Type R6 Carbon zinc batteries.



When the device is switched **ON**, a battery symbol is displayed in the top right-hand corner of the screen. The battery indicator will show as full with a new set of batteries. As power is consumed fewer black squares will fill the battery indicator. When the battery indicator is empty or on one square it may become necessary for replacement of **ALL** of the batteries.

If the unit has been switched **ON** and no data has been entered for 60 seconds, an **alarm signal** sounds to warn the operator that the unit is still on and that battery power is being utilized.

It is highly recommended that the batteries should be removed from the Bodystat unit should the unit not be used for some time.

Keep battery contact surfaces and battery compartment contacts clean by rubbing them with a clean pencil eraser or a rough cloth each time you replace batteries.



Ensure the unit is switched OFF when replacing the batteries.



Batteries should be clicked into place to avoid excessive battery drainage.

SUPPORT

Useful information and links can be found on our website at www.bodystat.com. Some of these have been listed below along with contact details:

TECHNICAL SUPPORT:

Technical Support including trouble shooting guides and frequently asked questions (FAQ) can be found on our website under the support tab.

RESEARCH & VALIDATION:

Refer to the BODYSTAT web page for the principles of [Bioelectrical Impedance Analysis \(BIA\)](#), validation of the accuracy of the **BODYSTAT** technology, the most recent updated **BODYSTAT** research papers and its use in a variety of applications.

CONTACTS:

For Sales Enquiries – sales@bodystat.com

For Research Enquiries – research@bodystat.com

For Hardware/Software Support Enquiries – support@bodystat.com

For Account Enquiries – accounts@bodystat.com

SPECIFICATIONS

MEASUREMENT:	
Measuring Principle	Bioelectrical Impedance Analysis (BIA) Lock-in Signal Conversion Technology
Impedance Measuring Range	20 - 1300 Ω (ohms)
Accuracy	
5 kHz Impedance	$\pm 2 \Omega$ (ohm)
50 kHz Impedance	$\pm 2 \Omega$
50 kHz Resistance	$\pm 2 \Omega$
50 kHz Reactance	$\pm 1 \Omega$
50 kHz Phase Angle	$\pm 0.2^\circ$
100 kHz Impedance	$\pm 3 \Omega$
200 kHz Impedance	$\pm 3 \Omega$
Resolution	$\pm 1 \Omega$
TEST CURRENT	620 Micro-Amps R.M.S.(Root Mean Square)
WAVEFORM	Sinusoidal
PC COMMUNICATION	Bluetooth Wireless Interface, USB
FREQUENCY	5, 50, 100, 200 kHz (KiloHertz)
INTERNAL POWER SOURCE	<u>Battery powered:</u> 6 x AA (LR6) <u>Type:</u> Alkaline <u>Battery preference:</u> Duracell® model MN1500  Do not use type R6 Carbon zinc batteries. DO NOT CONNECT AN EXTERNAL POWER SUPPLY
OPERATING TEMPERATURE	+5°C to +40°C
STORAGE TEMPERATURE	0°C to +60°C
HUMIDITY	Less than 70% R.H. (relative humidity) up to +60°C - non-condensing
ATMOSPHERIC PRESSURE	860 hPa to 1060 hPa

There are no serviceable components

Environmental Responsibility

Disposal of Bodystat devices at the end of its life cycle



For devices located within the European Union

Refer to your local Environmental Agency taking into consideration the ***Directive 2002/96/EC on waste electrical and electronic equipment (WEEE)*** and, if the case, any other relevant Community legislation in that regard.

For devices located within the UK

Refer to your relevant regulator: Environment Agency (England) / Natural Resources Wales (Wales) / Northern Ireland Environment Agency (Northern Ireland) / Scottish Environmental Protection Agency (Scotland)

Further details can be found in the following statutory instrument: ***The waste Electrical and Electronic Equipment Regulations 2013***

For all other countries/regions

- Dispose of Bodystat devices properly at the end of its life cycle.
- Observe current regulations in force in your country for the disposal of electronic devices.

Other considerations:

All Bodysat devices (including Printed Circuit Boards -PCBs- and polymeric enclosures) meet RoHS compliance (please refer to our website for details)

Cardboard packaging and another packing/storage material should be recycled where possible.

At the end of the life cycle of your **Bodystat** device, it is important that all batteries are removed & recycled according to the battery manufacturer's instructions.

Please refer to the local authorities for the disposal of batteries.

It is important not to dispose of large amounts of alkaline batteries in a group. Used batteries are often not completely “dead”. Grouping used batteries together can bring these “live” batteries into contact with one another, creating safety risks. Never dispose of batteries in a fire because of the risk of explosion.

For updated information about Bodystat's environmental policy please refer to the following link: www.bodystat.com/support/

EMC – ELECTROMAGNETIC COMPATIBILITY

Table 1 - Guidance and manufacturers declaration – electromagnetic immunity		
The QuadScan 4000 is intended for use in the electromagnetic environment specified below. The customer or the user of the QuadScan 4000 should assure that it is used in such an environment.		
Emissions test	Compliance	
RF Emissions CISPR 11 EN 55011: 2016 + A11: 2020	Group 1	The QuadScan 4000 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected The QuadScan 4000 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF Emissions CISPR 11 EN 55011: 2016 + A11: 2020	Class A	
Harmonic emissions IEC 61000-3-2 EN 61000-3-2: 2019	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3 EN 61000-3-3: 2013 +A1:2019	Not applicable	

Table 2 - Guidance and manufacturers declaration – electromagnetic immunity			
The QuadScan 4000 is intended for use in the electromagnetic environment specified below. The customer or the user of the QuadScan 4000 should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic environment - guidance
Electrostatic Discharge (ESD)	± 6 kV contact	$\pm 2, 4$ & 6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
IEC 61000-4-2 EN 61000-4-2: 2009	± 8 kV air	$\pm 2, 4$, & 8 kV air	
Electrical fast transient/burst	± 2 kV for power supply lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-4	± 1 kV for input/output lines		
Surge	± 1 kV lines(s) to lines(s)	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-5	± 2 kV lines(s) to earth		
Voltage dips, short interruptions and voltage variations on power supply input lines	$<5\% U_T$ ($>95\%$ dip in U_T for 0,5 cycle $40\% U_T$ (60 % dip in U_T for 5 cycles $70\% U_T$ (30 % dip in U_T for 25 cycles $5\% U_T$ ($>95\%$ dip in U_T for 5 s	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the QuadScan 4000 requires continued operation during power mains interruptions, it is recommended that the QuadScan 4000 be powered from an uninterruptible power supply or battery.
IEC 61000-4-11			
Power Frequency (50/60 Hz) magnetic field	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
IEC 61000-4-8			
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table 3 - Guidance and manufacturers declaration – electromagnetic immunity

The QuadScan 4000 is intended for use in the electromagnetic environment specified below. The customer or the user of the QuadScan 4000 should assure that it is used in such an environment			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	$d = [1.17]\sqrt{P}$ 80 MHz to 800 MHz $d = [2.33]\sqrt{P}$ 800 MHz to 2,5 GHz Where P is maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF	3 V/m	3 V/m	
IEC 61000-4-3 EN 61000-4-3: 2020	80 MHz to 2,7 GHz	80 MHz to 2,7 GHz	
	27 V/m, 18 Hz PM 385 MHz	27 V/m, 18 Hz PM 385 MHz	
	28 V/m, 50 %18 Hz PM 450 MHz	28 V/m, 50 %18 Hz PM 450 MHz	
	9 V/m, 217 Hz PM 710 MHz	9 V/m, 217 Hz PM 710 MHz	
	9 V/m, 217 Hz PM 745 MHz	9 V/m, 217 Hz PM 745 MHz	
	9 V/m, 217 Hz PM 780 MHz	9 V/m, 217 Hz PM 780 MHz	
	28V/m, 18 Hz PM 810 MHz	28V/m, 18 Hz PM 810 MHz	
	28 V/m, 18 Hz PM 870 MHz	28 V/m, 18 Hz PM 870 MHz	
	28 V/m, 18 Hz PM 930 MHz	28 V/m, 18 Hz PM 930 MHz	
	28V/m, 217 Hz PM 1720 MHz	28V/m, 217 Hz PM 1720 MHz	
	28 V/m, 217 Hz PM 1845 MHz	28 V/m, 217 Hz PM 1845 MHz	
	28 V/m, 217 Hz PM 1970 MHz	28 V/m, 217 Hz PM 1970 MHz	
	27 V/m, 217 Hz PM	27 V/m, 217 Hz PM	

	2450 MHz	2450 MHz	
	9V/m, 217 Hz PM 5240 MHz	9V/m, 217 Hz PM 5240 MHz	
	9 V/m, 217 Hz PM 5500 MHz	9 V/m, 217 Hz PM 5500 MHz	
	9 V/m, 217 Hz PM 5785 MHz	9 V/m, 217 Hz PM 5785 MHz	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PB840 Ventilator is used exceeds the applicable RF compliance level above, the QuadScan 4000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the QuadScan 4000

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_1]$ V/m.