Clinical Practice: QUADSCAN4000 Touch Screen

EVALUATE PATIENT'S NUTRITIONAL/HYDRATIONAL AND CELLULAR STATUS





MAKING DISEASE ASSE MORE ACCURATE

Complex changes occur in body composition during illness and monitoring these changes can provide an insight for early diagnosis and treatment.

As the need for non-invasive diagnostic systems increase and regular monitoring becomes even more important, clinicians see quick, simple solutions to monitor these changes.

Different effects of diseases that influence body composition or fluid states:

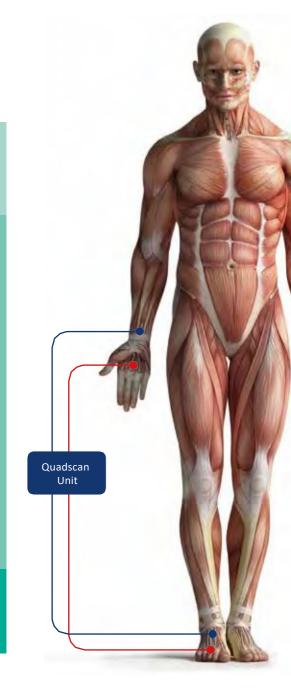
- + Increase in fat mass
- + Loss of fat-free mass
- + Excessive weight gain
- + Loss of body cell mass
- + Loss of bone mineral
- + Malnourishment
- + High blood density
- + Fluid imbalance
- + Oedema
- + Altered fluid status total body water, intracellular and extracellular fluid
- Increase in extracellular fluidsymptomatic of oedema
- + Decrease in intracellular fluid associated with body cell mass and potassium
- + Plasma volume increases and fluid accumulates in the peripheral tissue, lungs and abdominal organs
- + Higher bone mass and mineral density
- + Changes in mineral, water and protein contents
- + Muscle wasting in clinical patients.

TOTAL BODY COMPOSITION

Fat

Lean Soft Tissue

Bone Minerals



SSMENT

Intra Cellular Residual

Intra Cellular Water

Extra Cellular Water

Bone Minerals

Assessment of Body Fluid Composition could lead to:

- + Earlier diagnosis of illnesses
- + Earlier initiation of treatment
- + Early signs of cellular degradation
- + Early signs of shift in ECW/TBW ratio
- + More accurate prognosis
- + Patient outcome prediction with greater certainty
- + Reduction in hospitalization length of stay
- + Reduced costs through better patient management
- + Reduced patient anguish.

Bioelectrical Impedance Analysis (BIA) offers:

- + Non-invasive assessment of hydration and nutrition status
- + Assess nutritional status of patients on admission and pre-surgery
- + Monitor the Prediction Marker™during hospitalization, as a predictor of outcome
- **+** Monitorlean body mass, rather than total body weight to determine the patient's response to nutritional interventions
- + Determine if weight gain is due to an increase in lean / fat mass or fluid retention
- + Able to monitor hydration status
- + Test can be performed at the bedside, versus other more complicated and expensive methods, without the need to weigh the patient and irrespective of age, weight, or population group
- + Quick corrective action can be taken to improve the health of the patient
- + Ease of use allows for regular monitoring of status as frequently as required (minutes, hours, days, etc.)
- + Quick, reliable, cost-effective, reproducible results
- + Measurement parameters can be set up in the device to meet specific needs
- + QuadScan4000 Platinum Software Program included for detailed evaluation and tracking of change
- + Exact time of measurements recorded by internal real time clock.

INTRODUCTION

DEFINITIONS

ECW	Extracellular Water
ICW	Intracellular Water
TBW	Total Body Water
всм	Body Cell Mass
BMR	Basal Metabolic Rate
EAR	Estimated Average Requirement for Calories
ВМІ	Body Mass Index
BIA	Bioelectrical Impedance Analysis
FM	Fat Mass
FFM	Fat-Free Mass (Lean Weight)
FFMI	Fat-Free Mass Index
BFMI	Body Fat Mass Index
3SW	3rd Space Water
WHR	Waist/Hip Ratio

The QUADSCAN4000 units are battery-operated 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, conducts 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. Bodystat has developed its own algorithms to directly assess FFM & TBW.

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

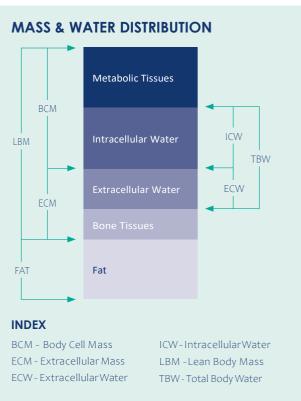
Furthermore, the measurement of TBW alone is only of limited value in the nutritional or functional assessment of the seriously ill patient. Patients with ongoing infections have been shown to retain fluid in response to nutritional support and weight gain is due to expansion of the extracellular water (ECW) space. It has been emphasized 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 extracellular and intracellular spaces may provide a useful index of the well-being or response to feeding of critically ill patients (Prediction Marker).

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



- + Ease of use allows for regular monitoring of fluid body composition status and illness monitoring as required (e.g. minutes, hours, days, etc.)
- + Prediction Marker change in fluid volumes is still determined when total body weight is unknown
- + Full body and segmental analysis
- + Quick corrective action can be taken to improve the health of the patient
- + Hospital efficiency can be improved, with bed occupancy time reduced.



THE QUADSCAN MEASURES:				
Body Composition	Hydration Status	Segmental Monitoring		
Fat % and Mass*	Total Body Water - TBW*	Prediction Marker™		
Lean % and Mass*	Intracellular Water - ICW*	Phase Angle at 50 kHz		
Dry Lean Mass*	Extracellular Water - ICW*	Resistance at 50 kHz		
Body Mass Index - BMI	Third Space Water*	Reactance at 50 kHz		
Fat-Free Mass Index - FFMI* Body Fat Mass Index - BFMI*	Body Cell Mass*	Impedance Values at 5, 50, 100 and 200 kHz		
OTHERMEASUREMENTS				
Waist / Hip Ratio	Average Daily Calorie Requirement*	Basal Metabolic Rate*		

APPLICATIONS & MEASUR OUTPUTS

The QUADSCAN4000 Touch measures at four different frequencies: 5, 50, 100 and 200 kHz.

APPLICATIONS

Diuretics, accurate fluid monitoring and the inevitable decrease of lean muscle mass are all concerns for patients, nurses and doctors alike.

Bioelectrical Impedance Technology will meet all these needs non-invasively, giving accurate and reliable measurements for fluid, lean muscle mass, nutritional status and overall cellular health.

Bioelectrical Impedance Technology has been used successfully in dialysis wards to measure the volume

of fluid over-hydration to help determine dry weight, as well as in IC wards to assess nutritional status, recovery rate and hydration levels.

In addition, the QuadScan4000 may be used to detect malnutrition in patients with normal or high body fat. Body cell mass can easily be obscured by an expansion of extracellular fluid which will not be detected by looking at an overall increase in total body weight.



A decrease of body cell mass can be obscured by an expansion of extracellular water

EMENT



WHAT DOES THE QUADSCAN TOUCH MEASURE?

OPTIONS DISPLAYED ON THE QUADSCAN UNIT	EXPLANATION
Fat %* & Normal Range	Fat as a % of Total Body Weight
Fat Weight* & Normal Range	FAT Weight determines Health Risk
Lean %* & Normal Range	Lean as a % of Total Body Weight
Lean Weight* & Normal Range	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
Skeletal Muscle*	Skeletal Muscle Mass (SMM)*
ECW %* & Normal Level	Extracellular Water as a % of Total Body Weight
ECW Volume*	Extracellular Water Volume in Litres
ICW %* & Normal Level	Intracellular Water as a % of Total Body Weight
ICW Volume*	Intracellular 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
3rd Space Water*	Refer to additional information in users guide for a full explanation.
Nutritional Index	ECW/TBW Nutrition Index
Basal Metabolic Rates*	Basal Metabolic Rate (Kcalories 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/Ht² in metric)
BFMI (Body Fat Mass Index) & Normal Range	Body Fat Mass Index (Body Fat/Ht²in metric) BFMI + FFMI = BMI
FFMI (Fat-Free Mass Index) & Normal Range	Fat-Free Mass Index (Lean/Ht² 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 ranging from 5 kHz to 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
BIVA Vector Graph including population reference selection	Bio-Impedance Vector Analysis Graph plotted against the selected population group.

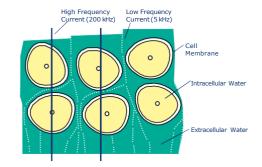
estimated*

QUADSCAN4000 TOU

EXTRA FEATURES

The QUADSCAN4000 non-invasively measures the flow of current through the body at four different frequencies: 5, 50, 100 & 200 kHz. Low frequencies have difficulty penetrating the cell wall and pass predominately through the extracellular spaces, while higher frequencies are able to penetrate the cellular membrane and pass through both intracellular and extracellular spaces. By applying Bodystat's own unique researched equations, the system quickly determines values for body composition, hydration status and cellular health.

BIOELECTRICAL PROPERTIES



BODYSTAT PREDICTION MARKERTM (IMPEDANCE RATIO)

It is well documented that in disease states, extracellular fluid plays a vital role in patient outcomes. Uniquely, the QUADSCAN4000 can determine the expansion of the extracellular fluid space which is a proven indicator to improving or declining cellular status. Bodystat uses the multi-frequency bio-impedance raw data measurement values it obtains for extracellular water and total body water to determine each patient's unique Prediction Marker; an increase in this value shows further deterioration in health status while a decrease shows cellular improvement.

Potential opportunity for use:

- Predictor of Outcome before surgery
- + Identify potential high risk surgery patients and track the effect of surgery
- + Raise awareness of potential complicated clinical courses of patients during hospitalization
- + Effectiveness of rehabilitation recovery after surgery
- + Assessment of cellular health & hydration status.

No subject weight, age, height or gender is required

- + Often a problem in areas such as ICU
- + Suitable for WHOLE BODY and SEGMENTAL analysis.

Applies to ANY:

- + Disease state or physical health state
- + Age and population group
- + Uses only the latest in Multi-Frequency BIA technology
- + Quick to perform the test requiring little or no skills
- + Inexpensive, non-invasive and cost effective.

Healthy Male 51 yrs			
Frequency	Impedance in Ohms	"Prediction Marker"	
5 kHz	573		
50 kHz	480		
loo kHz	450		
200 kHz	433	0.756	
Variance between 5 and 200 kHz	140		

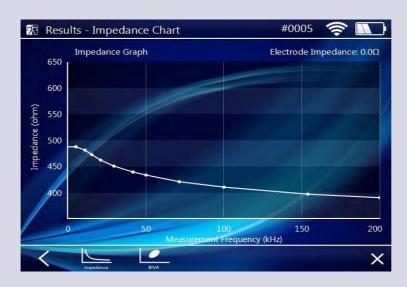
'Dying' Male 51 yrs			
Frequency	Impedance in Ohms	"Prediction Marker"	
5 kHz	568		
50 kHz	530		
loo kHz	515		
200 kHz	504	0.887	
Variance between 5 and 200 kHz	64		

Itobi, E el al., (March 2006) "Impact of oedema on recovery after major abdominal surgery and potential value of multifrequency bioimpedance measurements" British Journal of Surgery **Vol93** (3): 354-61



QUALITY CONTROL CHECK OF MEASUREMENT ACCURACY

Immediately following the 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, you have the option to reject the test and repeat the measurement immediately with no inconvenience to the patient.



PROGNOSTIC OR NUTRITIONAL MARKERS

"Phase Angle, BIVA and the Prediction Marker TM are obtained directly from resistance, reactance or impedance, and evidence in the literature indicated that they could be used as prognostic or nutritional markers."

ESPEN, "Blue" Book, *Basics in Clinical Nutrition* Fourth Edition Page 20 (2011)

Rinniella, E et al (April 2018) "Phase Angle & Impedance Ratio : Two Specular ways to analyze Body Composition". Annals of Clinical Nutrition, 2018, 1:1003



SEGMENTALANALYSIS

The **QUADSCAN4000** units are battery-operated 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.

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 yet is still able to obtain meaningful output data.

If requiring only the left leg, right leg, right arm or left arm to be measured, connect the electrodes according to the principal of equipotentials.

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.

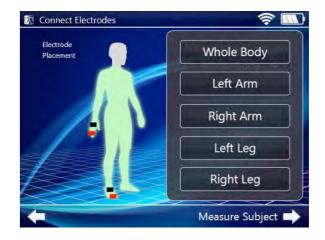
Some users may additionally use the Reactance and Phase Angle values to interpret the measurement results.

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 it is CHANGE in the biomarker that should be focused upon to determine the TREND over a period of time, hours, days, weeks or months.





BODY MANAGER PLATINUM SOFTWARE & BIVA

BODY MANAGER PLATINUM SOFTWARE

The included Body Manager Platinum software is ideal for use when subsequent repeat tests are performed in order to track an individual's progress. The software includes four main features:

- Body Composition Providing detailed analysis of the whole body. These reports comprise of the Body Composition Professional and Simplified Reports:
- **Trends** This tracks the results over a period of time to assess change and progress.
- Health Report Based on the Framingham Study, this gives a general health report including smoking, diabetes, blood pressure and Cholesterol.
- Weight Loss Report –enables a selection of varying intensity exercises and their duration, calculating the calories burned and the number of weeks required to achieve target weight.

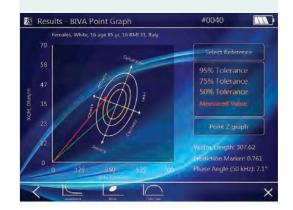
In addition, the software includes:

- Hydration Reports a 1 page report of an individual's hydration results. Allowing the user to track Water, ECW, ICW, etc over a period of time.
- BIVA analysis To provide a detailed overview of an individual's hydration and nutritional
- Physiology report a detailed physiology report
 where the user can track trends for heart rate,
 blood pressure, cholesterol, waist-hip, VO2 Max,
 flexibility, grip strength, glucose and lung function.

BIVA – BIOELECTRICAL IMPEDANCE VECTOR ANALYSIS

BIVA represents a quick pictorial method of showing hydration and nutritional status of a subject in comparison to their population group. It can also be referred to as the "RXc graph". Developed by Professor Antonio Piccoli in 1994, BIVA simply uses Resistance(R) and Reactance(Xc) at 50 kHz, measured to the subject's height (not requiring the subject's weight).

The subject's results are shown in the form of a dot on the vector graph. The positioning of the dot reflects the subject's health status in comparison to their relevant population group.

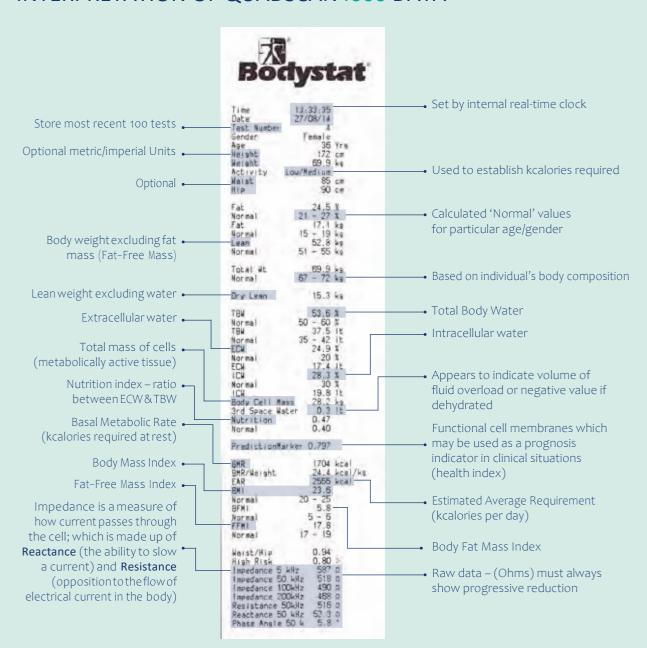


QUADSCAN4000 SPEC

BODY COMPOSITION, FLUID & SEGMENTAL MONITO

BODY COMPOSITION ANALYSIS:

INTERPRETATION OF QUADSCAN4000 DATA



RING UNIT

QUADSCAN4000

Body Composition, Fluid & Segmental Monitoring Unit





- Portable thermal printer fitted with bluetooth offering clear, immediate print out of results at point of measurement.
- Battery operated and light weight.
- + Multi-frequency for the measurement of extracellular and total body water assessment
- + Unique Prediction Marker[™] (whole body and segmental) based on raw impedance data only, without the need for actual body weight
- + Assesses fluid ratio between ECW and TBW and cellular health status in healthy people and in the critically ill
- + Applies to all age groups from neonates to the very elderly and irrespective of population group
- + Includes comprehensive body composition and fluid analysis software with alternative predictive equations.

SPECIFICATION

MEASUREMENT Technology Bio-Impedance Analysis (BIA) Impedance Measuring Range 20 - I300 Ω ohms Accuracy Impedance (5 kHz): +/- 2 Ω Impedance (50 kHz): +/- 2 Ω Resistance (50 kHz): +/- 2 Ω Resistance (50 kHz): +/- 3 Ω Impedance (100 kHz): +/- 3 Ω Impedance (100 kHz): +/- 3 Ω Impedance (100 kHz): +/- 3 Ω Impedance (200 kHz): +/- 3 Ω Test Current 620 Micro-Amps R.M.S. (Root Mean Square) Frequency 5/50/Ioo/200 kHz (KiloHertz) Calibration A calibratoris supplied for independent verification from time to time. Configuration 2 LEMO lead wires (removable) Computation Time 3 seconds PC Communication USB interface GENERAL Operating Temperature Operating Temperature + 5 °C to + 40 °C Storage Temperature 0 °C to + 60 °C Relative Humidity 70%Iess up to +60 °C non-condensing. It should not be used in anarea where condensation could form on the inside of the unit housing. Atmospheric Pressure 860 hPa to 1060 hPa Internal Power Source Duracell MN1500 alkaline batteries, 6xAA(LR6) 1.5y non-rechargable Dimensions 240mm L x 155mm W x 30mm H (5" Colour Touch Display) Weight Unit Weight – 410 grams		
Impedance Measuring Range Accuracy Impedance (5 kHz): +/- 2 Ω Impedance (50 kHz): +/- 2 Ω Resistance (50 kHz): +/- 3 Ω Resistance (50 kHz): +/- 3 Ω Resistance (50 kHz): +/- 3 Ω Impedance (100 kHz): -/- 3 Ω Impedance (100 kHz): -/- 3 Ω Impedance (200 kHz): -/- 2 Ω Impedance	MEASUREMENT	
Range Ran	Technology	Bio-Impedance Analysis (BIA)
Impedance (50 kHz): +/- 2Ω Resistance (50 kHz): +/- 2Ω Resistance (50 kHz): +/- 2Ω Reactance (50 kHz): +/- 2Ω Reactance (50 kHz): +/- 3Ω Impedance (100 kHz): +/- 3Ω Impedance (100 kHz): +/- 3Ω Impedance (100 kHz): +/- 3Ω Impedance (200 kHz): +/- 3Ω Impeda	=	20 - I300 Ω ohms
Frequency 5/50/loo/200 kHz (KiloHertz) Calibration A calibratoris supplied for independent verification from time to time. Configuration 2 LEMO lead wires (removable) Computation Time 3 seconds PC Communication USB interface GENERAL Operating Temperature + 5 °C to + 40 °C Storage Temperature 0 °C to + 60 °C Relative Humidity 70% less up to +60 °C non-condensing. It should not be used in an area where condensation could form on the inside of the unit housing. Atmospheric Pressure 860 hPa to 1060 hPa Internal Power Source Duracell MN1500 alkaline batteries, 6x AA (LR6) 1.5v non-rechargable Dimensions 240mm L x 155mm W x 30mm H (5" Colour Touch Display) Weight Unit Weight – 410 grams Low Battery A battery power bar can be seen in the top right comer of the display. If the unit has been switched ON and no data has been entered for 2 minutes, an alarm signal sounds to warn that the unit is still on and the battery is in use. Automatic shut off if left unattended for 3 minutes. Service There are no servicable parts other than the need for periodic battery replacement. Quality Standards Manufactured to strict ISO I3485-2016 quality standards. Fully accredited by the Medical Devices Directive (MDD) with its CE1639	Accuracy	Impedance (50 kHz): +/- 2 Ω Resistance (50 kHz): +/- 1 Ω Reactance (50 kHz): +/- 1 Ω Phase Angle (50 kHz): +/- 0.2° Impedance (100 kHz): +/- 3 Ω
Calibration A calibratoris supplied for independent verification from time to time. Configuration 2 LEMO lead wires (removable) Computation Time 3 seconds PC Communication USB interface GENERAL Operating Temperature + 5 °C to + 40 °C Storage Temperature 0 °C to + 60 °C Relative Humidity 70% less up to +60 °C non-condensing. It should not be used in an area where condensation could form on the inside of the unit housing. Atmospheric Pressure 860 hPa to 1060 hPa Internal Power Source Duracell MN1500 alkaline batteries, 6x AA (LR6) 1.5v non-rechargable Dimensions 240mm L x 155mm W x 30mm H (5" Colour Touch Display) Weight Unit Weight — 410 grams Low Battery A battery power bar can be seen in the top right corner of the display. If the unit has been switched ON and no data has been entered for 2 minutes, an alarm signal sounds to warn that the unit is still on and the battery is in use. Automatic shut off if left unattended for 3 minutes. Service There are no servicable parts other than the need for periodic battery replacement. Quality Standards Manufactured to strict ISO 13485-2016 quality standards. Fully accredited by the Medical Devices Directive (MDD) with its CE1639	Test Current	620 Micro-Amps R.M.S. (Root Mean Square)
Configuration 2 LEMO lead wires (removable) Computation Time 3 seconds PC Communication USB interface GENERAL Operating Temperature +5 °C to + 40 °C Storage Temperature 0 °C to + 60 °C Relative Humidity 70% less up to +60 °C non-condensing. It should not be used in an area where condensation could form on the inside of the unit housing. Atmospheric Pressure 860 hPa to 1060 hPa Internal Power Source Duracell MN1500 alkaline batteries, 6xAA(LR6) 1.5v non-rechargable Dimensions 240mm L x 155mm W x 30mm H (5" Colour Touch Display) Weight Unit Weight - 410 grams Low Battery Abattery power bar can be seen in the top right comer of the display. If the unit has been switched ON and no data has been entered for 2 minutes, an alarm signal sounds to warm that the unit is still on and the battery is in use. Automatic shut off if left unattended for 3 minutes. Service There are no servicable parts other than the need for periodic battery replacement. Quality Standards Manufactured to strict ISO 13485-2016 quality standards. Fully accredited by the Medical Devices Directive (MDD) with its CE1639	Frequency	5/50/100/200 kHz (KiloHertz)
Computation Time 3 seconds PC Communication USB interface GENERAL Operating Temperature +5 °C to + 40 °C Storage Temperature o °C to + 60 °C Relative Humidity 70% less up to +60 °C non-condensing. It should not be used in an area where condensation could form on the inside of the unit housing. Atmospheric Pressure 860 hPa to 1060 hPa Internal Power Source Duracell MN1500 alkaline batteries, 6xAA (LR6) 1.5v non-rechargable Dimensions 240mm L x 155mm W x 30mm H (5" Colour Touch Display) Weight Unit Weight – 410 grams Low Battery Abattery power bar can be seen in the top right corner of the display. If the unit has been switched ON and no data has been entered for 2 minutes, an alarm signal sounds to warn that the unit is still on and the battery is in use. Automatic shut off if left unattended for 3 minutes. Service There are no servicable parts other than the need for periodic battery replacement. Quality Standards Manufactured to strict ISO I3485-2016 quality standards. Fully accredited by the Medical Devices Directive (MDD) with its CE1639	Calibration	A calibrator is supplied for independent verification from time to time.
PC Communication GENERAL Operating Temperature	Configuration	2 LEMO lead wires (removable)
GENERAL Operating Temperature	Computation Time	3 seconds
Operating Temperature	PC Communication	USB interface
Storage Temperature 0 °C to + 60 °C Relative Humidity 70% less up to +60 °C non-condensing. It should not be used in an area where condensation could form on the inside of the unit housing. Atmospheric Pressure 860 hPa to 1060 hPa Internal Power Source Duracell MN1500 alkaline batteries, 6xAA(LR6) 1.5v non-rechargable Dimensions 240mm L x 155mm W x 30mm H (5" Colour Touch Display) Weight Unit Weight – 410 grams Low Battery A battery power bar can be seen in the top right comer of the display. If the unit has been switched ON and no data has been entered for 2 minutes, an alarm signal sounds to warn that the unit is still on and the battery is in use. Automatic shut off if left unattended for 3 minutes. Service There are no servicable parts other than the need for periodic battery replacement. Quality Standards Manufactured to strict ISO I3485-2016 quality standards. Fully accredited by the Medical Devices Directive (MDD) with its CE1639	GENERAL	
Relative Humidity 70% less up to +60 °C non-condensing. It should not be used in an area where condensation could form on the inside of the unit housing. Atmospheric Pressure 860 hPa to 1060 hPa Internal Power Source Duracell MN1500 alkaline batteries, 6xAA(LR6)1.5v non-rechargable Dimensions 240mm L x 155mm W x 30mm H (5" Colour Touch Display) Weight Unit Weight — 410 grams A battery power bar can be seen in the top right comer of the display. If the unit has been switched ON and no data has been entered for 2 minutes, an alarm signal sounds to warm that the unit is still on and the battery is in use. Automatic shut off if left unattended for 3 minutes. Service There are no servicable parts other than the need for periodic battery replacement. Quality Standards Manufactured to strict ISO I3485-2016 quality standards. Fully accredited by the Medical Devices Directive (MDD) with its CE1639	Operating Temperature	+5°C to + 40 °C
an area where condensation could form on the inside of the unit housing. Atmospheric Pressure 860 hPa to 1060 hPa Internal Power Source Duracell MN1500 alkaline batteries, 6xAA(LR6) 1.5v non-rechargable Dimensions 240mm L x 155mm W x 30mm H (5" Colour Touch Display) Weight Unit Weight – 410 grams Low Battery Abattery power bar can be seen in the top right comer of the display. If the unit has been switched ON and no data has been entered for 2 minutes, an alarm signal sounds to warn that the unit is still on and the battery is in use. Automatic shut off if left unattended for 3 minutes. Service There are no servicable parts other than the need for periodic battery replacement. Quality Standards Manufactured to strict ISO I3485-2016 quality standards. Fully accredited by the Medical Devices Directive (MDD) with its CE1639	Storage Temperature	o °C to + 60 °C
Internal Power Source Duracell MN1500 alkaline batteries, 6x AA(LR6) 1.5v non-rechargable Dimensions 240mm L x 155mm W x 30mm H (5" Colour Touch Display) Weight Unit Weight – 410 grams Low Battery A battery power bar can be seen in the top right corner of the display. If the unit has been switched ON and no data has been entered for 2 minutes, an alarm signal sounds to warm that the unit is still on and the battery is in use. Automatic shut off if left unattended for 3 minutes. Service There are no servicable parts other than the need for periodic battery replacement. Quality Standards Manufactured to strict ISO I3485-2016 quality standards. Fully accredited by the Medical Devices Directive (MDD) with its CE1639	Relative Humidity	an area where condensation could form on the inside of the unit
Dimensions 240mm L x 155mm W x 30mm H (5" Colour Touch Display) Weight Unit Weight – 410 grams A battery power bar can be seen in the top right comer of the display. If the unit has been switched ON and no data has been entered for 2 minutes, an alarm signal sounds to warn that the unit is still on and the battery is in use. Automatic shut off if left unattended for 3 minutes. Service There are no servicable parts other than the need for periodic battery replacement. Quality Standards Manufactured to strict ISO I3485-2016 quality standards. Fully accredited by the Medical Devices Directive (MDD) with its CE1639	Atmospheric Pressure	860 hPa to 1060 hPa
Weight Unit Weight – 410 grams A battery power bar can be seen in the top right comer of the display. If the unit has been switched ON and no data has been entered for 2 minutes, an alarm signal sounds to warn that the unit is still on and the battery is in use. Automatic shut off if left unattended for 3 minutes. Service There are no servicable parts other than the need for periodic battery replacement. Quality Standards Manufactured to strict ISO I3485-2016 quality standards. Fully accredited by the Medical Devices Directive (MDD) with its CE1639	Internal Power Source	Duracell MN1500 alkaline batteries, 6x AA (LR6) 1.5v non-rechargable
A battery power bar can be seen in the top right comer of the display. If the unit has been switched ON and no data has been entered for 2 minutes, an alarm signal sounds to warn that the unit is still on and the battery is in use. Automatic shut off if left unattended for 3 minutes. Service There are no servicable parts other than the need for periodic battery replacement. Manufactured to strict ISO I3485-2016 quality standards. Fully accredited by the Medical Devices Directive (MDD) with its CE1639	Dimensions	240mm L x 155mm W x 30mm H (5" Colour Touch Display)
display. If the unit has been switched ON and no data has been entered for 2 minutes, an alarm signal sounds to warn that the unit is still on and the battery is in use. Automatic shut off if left unattended for 3 minutes. Service There are no servicable parts other than the need for periodic battery replacement. Quality Standards Manufactured to strict ISO I3485-2016 quality standards. Fully accredited by the Medical Devices Directive (MDD) with its CE1639	Weight	Unit Weight – 410 grams
Dattery replacement. Quality Standards Manufactured to strict ISO I3485-2016 quality standards. Fully accredited by the Medical Devices Directive (MDD) with its CE1639	Low Battery	display. If the unit has been switched ON and no data has been entered for 2 minutes, an alarm signal sounds to warn that the unit is still on and the battery is in use. Automatic shut off if left
accredited by the Medical Devices Directive (MDD) with its CE1639	Service	battery replacement.
	Quality Standards	accredited by the Medical Devices Directive (MDD) with its CE1639

EVIDENCE-BASED CLINICAL APPLICATI



- + BURNS Large changes in body fat mass during the treatment of major burns injuries. Sjoberg F et al. Presented at the 10th European Burn Association.
- + CANCER Improving nutrition before surgery can decrease post-operative complications and length of stay. Weed HG et al. (2005) "Impact of a protein and energy dense nutritional supplement containing eicosapentaenoic acid on weight losing patients with head and neck cancer" Presented at the American Society of Clinical Oncology Annual Meeting.



+ CARDIOVASCULAR DISEASE – Excessive fluid accumulation is associated with increased morbidity and prolonged convalescence after cardiopulmonary bypass.

Gonzalez J et al. (July 1995) "Bioelectric impedance

detects fluid retention in patients undergoing cardiopulmonary bypass" *J Thorac Cardiovasc Surg*; **Vol 110 (1):** 111-8

+ COPD – Fat-free mass is an independent predictor of mortality irrespective of fat mass... supports the inclusion of body composition assessment as a systematic marker of disease severity in COPD staging.

Schols Annie MWJ, et al., (July 2005) "Body composition and mortality in chronic obstructive pulmonary disease" Am J of Clinical Nutrition **Vol 82:** No 1, 53-59

+ CRITICALLY ILL PATIENT – Critically ill patients retain fluid, up to 30 litres and more.

Campbell IT et al. (1998) "The use of multi-frequency bio-impedance to assess fluid balance in critical illness" *Proceedings* of the Nutrition Society **Vol 53:** 62A

- + DIABETICS Overweight and obesity are associated with the development of type 2 diabetes. Thus, it is important for clinicians to accurately measure and monitor the body composition of at-risk individuals and patients with diabetes. Stolarczyk Lisa M et al., (September 1st 1999) "Assessing body composition of adults with diabetes" Diabetes Technology & Therapeutics. Vol 1 (30): 289-296)
- **+ DIALYSIS/NEPHROLOGY** As renal function declines salt & water retention worsens resulting in an increase in body weight due to an increase in water content.

 Well LM. Jones CH. "A longitudinal Study of extra-cellular fluid in patients with kidney disease" *Renal Unit, York Hospital, UK*

- + DRUG DOSING "... the calculation of lean body mass (LBM) might be an important factor when determining drug doses as opposed to total body weight. This may avoid giving overweight patients a relative overdose of heparin."

 Baker M et al. (2008) "Calculation of Lean Body Mass using Bio-impedance analysis could be used to accurately determine Heparin/Protamine dosage for obese patients undergoing cardiac surgery and cardiopulmonary bypass" Cardiothoraric Unit, Nottingham City Hospital Trust, UK.
- **+ EATING DISORDERS** Bulimic patients with a past had lower percentage of body fat, lower muscle mass and higher percentage of extracellular fluid.

Vaz, Francisco J et al., (2003) "History of anorexia nervosa in bulimic patients: Influence on body composition" *Int J of Eating Disorders* **Vol 34:** 148-155



+ ELDERLY – Improved estimation of body composition in elderly subjects by use of age-specific prediction equations.

Reilly JJ et al. (September 1994) The European Group for Research into Physical Activity for the Elderly.

II International Conference

+HIV/AIDS – Body composition testing can be used to monitor lipodystrophy and wasting, two problems associated with HIV.

Cichock, M. (2007) "Loss of BCM (5% loss within 6 months) is a significant contributor to the morbidity and mortality associated with wasting diseases" Body Composition Testing. American Heart Association

+ HYDRATION STATUS/FLUID RETENTION – Measurement of extracellular and total body water provides useful information on the nutritional status of surgical patients and may be estimated from whole body bio-impendence measurements.

Hannah WJ et al. (December 1995) "Comparison of bio-impedance spectroscopy and multi-frequency impedance analysis for the assessment of extracellular and total body water in surgical patients" Clin Sci (Lond) Vol 89(6): 655-8

+ LYMPHEDEMA – Early intervention will reduce the long term consequences of Lymphedema post breast cancer. Ward L C. (March 1st 2006) "Bioelectrical impedance Analysis: Proven utility in Lymphedema risk assessment and therapeutic monitoring" Lymphatic Research and Biology Vol 4 (1): 51-56

{~

ONS



+ MALNUTRITION/UNDERNUTRITION/NUTRITION -

Malnutrition results in a loss of body cell mass (BCM) accompanied by an expansion of the extracellular mass (ECM).

Shizgal, Harry M. MD. (29th June 2006) "Body composition of patients with malnutrition and cancer" Paper presented at the Fourth Annual Nutrition Symposium on Current Concepts in Nutritional Management of the Patient with Cancer. Published Online



+ NEONATES – Bioelectrical impedance analysis is a simple, non-invasive method of estimating total body water in neonates receiving intensive care. It can be applied to both the assessment of changes inbody

water and body composition.

Wing Tang et al. (September 1997) Arch Dis Child Fetal Neonatal Ed **77:** F123-F126

+ OBESITY – Severe obesity is accompanied by large increases in fat mass and alterations in the composition of fat free mass, in particular total body water and its extracellular compartment.

Das SK. (2005) Current Opinion in Clinical Nutrition and Metabolic Care, **Vol.8** (No.6) 602-606

+ OEDEMA – The development of oedema after major abdominal surgery is associated with increased morbidity Itobi E et al. (March 2006) "Impact of oedema on recovery after major abdominal surgery and potential value of multifrequency bioimpedance measurements" *Br J Surg.* **Vol 93** (3): 354-61



+ PAEDIATRICS – Body composition in children is of increasing interest within the contexts of childhood obesity, clinical management of patients and nutritional programming as a pathway to adult disease.

Wells LC. (Mat 2003) "Body composition in childhood: effects of normal growth and disease" Proc. Nutr. Soc. **Vol 62**(2): 5210-8



+ PULMONARY OEDEMA – Impedance measurement may be useful in estimating lung water associated with lung injury following cardiopulmonary bypass.

Diprose P et al. "Anti-fibrinolytic agents & lung water in cardiac surgical patients" Abstract and poster presented in Miami at the Society of Cardiovascular Anesthesiologists meeting end April 2003. Southampton University Hospitals, UK

+ REHABILITATION – Changes in body composition, as a consequence of dietary and exercise modification, contributed to the ''observed" improvement noted in weight-adjusted peak aerobic capacity following cardiac rehabilitation and exercise training.

Milani R V et al. (1998) "The Effects of Body Composition Changes to Observed Improvements in Cardiopulmonary Parameters After Exercise Training with Cardiac Rehabilitation" Chest **Vol 113**: 599-601

+ SEGMENTAL – There is increased use of segmental impedance in the assessment of diseases that affect body fluid balance.

Heymsfield, Steven. Human Body Composition published in 2005. Page 87

- + SURGERY The development of oedema after major abdominal surgery is associated with increased morbidity. Age and the reduced ability to excrete administered fluid load are significant aetiological factors and bioimpedance analysis can potentially identify patients at risk. Itobi E et al. (March 2006) "Impact of Oedema on recovery after major abdominal surgery and potential value of multifrequency bioimpedance measurements" Br J Surg. Vol 93 (3): 354-61
- **"Phase Angle, BIVA** and the **Prediction Marker** are obtained directly from resistance, reactance or impedance, and evidence in the literature indicated that they could be used as prognostic or nutritional markers." ESPEN, "Blue" Book, Basics in Clinical Nutrition Fourth Edition Page 20 (2011)



(£ 1639

ABOUT BODYSTAT

Bodystat Ltd, based on the Isle of Man (British Isles), has been established since 1990 and is a registered ISO 13485:2016 company. We specialise solely in BIA Technology and are dedicated to expanding the knowledge of this to improve health and well-being. We have an extensive range of research papers (available on our website) dedicated solely as non-commercial, free materials for educators.

Our devices are manufactured in the U.K. made to the highest specifications and use only the best electrical components. The high quality of our devices ensures accurate results that are both reproducible and reliable.

Bodystat Limited

3allakaap • Ballafletcher Road Cronkbourne • Douglas sle of Man • IM4 4QJ • British Isles Tel: +44 (0) I624 62957I
Fax: +44 (0) I624 6II544
Email: info@bodystat.com
Web: www.bodystat.com

