

LATEST GENERATION

Clinical Practice: MULTISCAN5000

THE FUTURE OF BIOELECTRICAL IMPEDANCE SPECTROSCOPY (BIS)



www.bodystat.com



INCORPORATING LATEST, STATE OF THE ART BIS TECHNOLOGY BASED ON DIRECT DIGITAL SYNTHESIS, DIGITAL SIGNAL PROCESSING & ACTIVE SHIELDING TECHNOLOGY

FEATURES & BENEFITS

The latest generation MultiScan5000 offers significant enhancements.

Precision, Accuracy & Reproducibility

- + Precise Cole-Cole model value parameters eliminating 'Hook Effect' & the need for time consuming clinician intervention
- + Elimination of stray capacitance ensuring precise, accurate & reproducible measurements
- + Precise and stable Impedance & Phase Angle values on multiple frequencies ensuring high quality BIS measurements
- + Phase Angle measures cellular health & the Prediction Marker tracks fluid status in multiple applications
- + New low capacitance & durable electrode lead wires with improved performance at high frequencies
- + Volume of fluid overload in litres (OHY)
- + BIVA vector analysis seen on display as well as in the Body Manager BIS software

Convenience

- + Lightweight & mobile enabling convenience and portability
- + Remote access for updates and system diagnosis
- + Innovative wireless charging providing convenience & safety

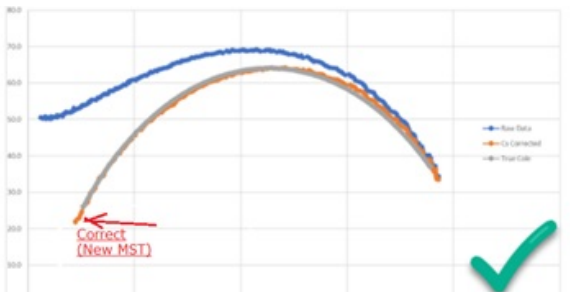
All Other Features

- + Totally non-invasive & just 6 seconds to receive the measurements, no waiting
- + Impedance quality control graph
- + Device stores 100 tests, therefore test recall is available on the device without having to download the measurements into the software.
- + USB interface to download into the Body Manager BIS software
- + Detailed trending reports visible in Body Manager BIS software
- + Reports for hydration, physiology, body composition, health, weight, loss and cardiovascular risk.
- + Personalised branding of reports (add logo to the report)
- + Client data can easily be transferred into EXCEL, XML or CSV .
- + Reports be saved on to any drive(C:/ or local server)
- + Reports can be emailed or saved as any format e.g. PDF.

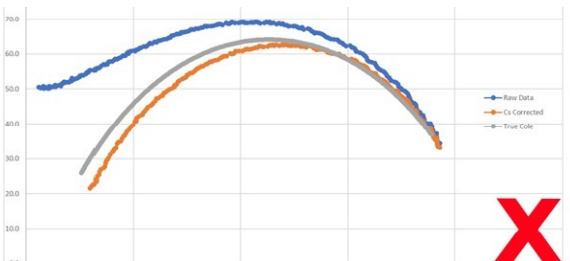


Precise Cole Model

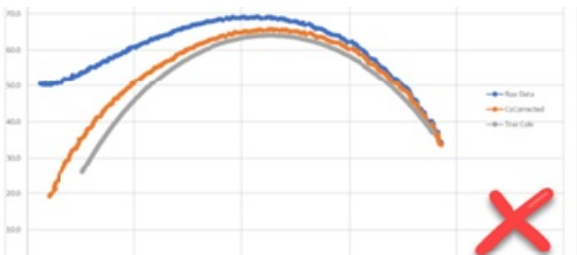
Legend: Raw Data, True Cole, Cs Corrected



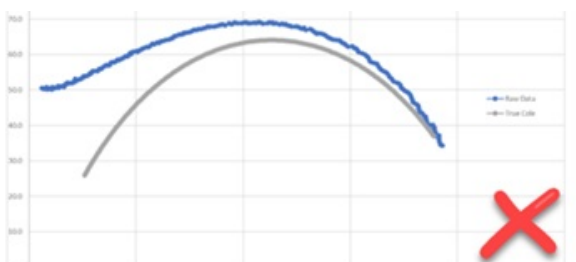
Automatically Adaptive Cs Compensation



Fixed Cs Compensation (case of over compensation)



Fixed Cs Compensation (case of under compensation)



No Cs Compensation

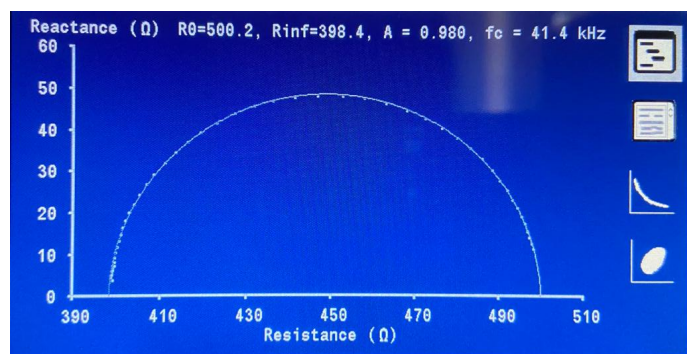
BIOELECTRICAL IMPEDANCE SPECTROSCOPY (BIS)

The **MULTISCAN5000** will measure at 50 frequencies ranging from 5 kHz to 1000 kHz and uses a method called Bioelectrical Impedance Spectroscopy (BIS).

BIS calculates body composition and hydration values using Cole-Cole analysis.

The 50 frequencies measured by the MultiScan5000 are used to produce the Cole-Cole plot. Cole-Cole Analysis is a mathematical model and the frequencies are plotted on the semi-circular Cole-Cole diagram. The diagram is then used to calculate the values for R_0 (resistance at zero kHz) and R_{inf} (resistance at infinite frequency).

Values for ECW, ICW, TBW and volume of over/ under-hydration are determined from the published scientific paper below.



RESEARCH

Moissl Ulrich M, et al. (2006). "Body fluid volume determination via body composition spectroscopy in health and disease." *Physiol. Meas.* **Vol 27**: 921-933

Chamney Paul W, et al. (2007). "A whole-body model to distinguish excess fluid from the hydration of major body tissues." *Am J Clin Nutr* **Vol 85**: 80-89.

Buendia Ruben. (2009). "Hook Effect on Electrical Bioimpedance Spectroscopy Measurements. Analysis, Compensation and Correction."

MULTISCAN5000

APPLICATION, RESULTS & ANALYSIS

MULTISCAN5000 APPLICATION

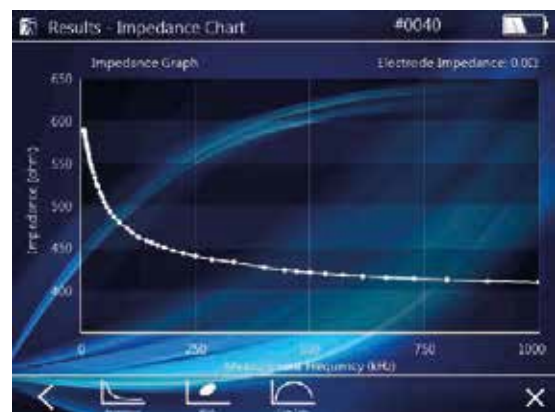
Diuretics, accurate fluid monitoring and the inevitable decrease of lean muscle mass are all concerns for patients, nurses and doctors alike. Bioelectrical impedance technology will meet all these needs non-invasively, giving accurate and reliable measurements for fluid, lean muscle mass, nutritional 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 **MULTISCAN5000** may be used to detect malnutrition in patients with normal or high body fat by an assessment of body cell mass. 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.

QUALITY CONTROL CHECK FOR MEASUREMENT ACCURACY

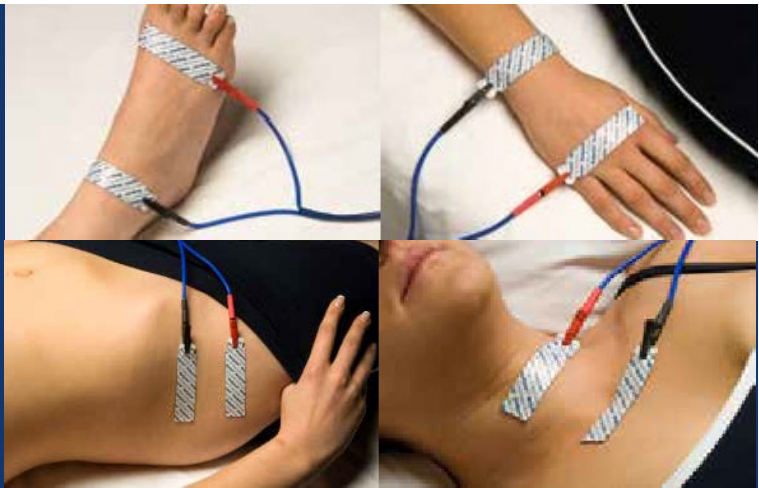
Immediately following a measurement, an impedance graph will be displayed. The impedance graph should be viewed to ensure that there are no bumps and that the measurement was successful. If the test has a bump and does not look smooth, then the test can be rejected by clicking the **Reject/Retest** option and repeating the measurement process again. If the test looks correct, click **Accept** to view the body composition and hydration results and pie charts.



DISPLAY RESULTS RESULTS TABLE

The summary page displays all the body composition and hydration measurements, each of which can be viewed as pie charts, Cole-Cole or BIVA, as well as viewing them as trends within the software.

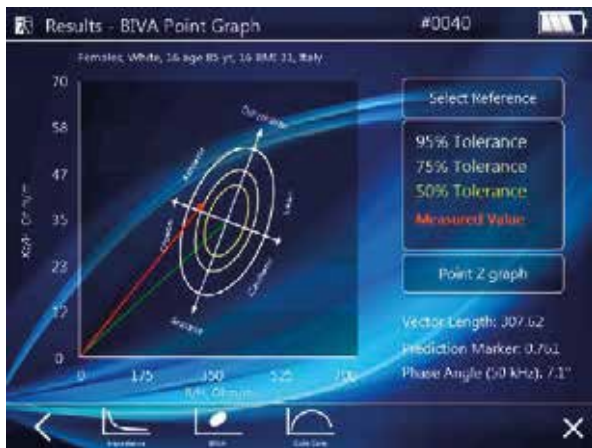
Result	Value	TBW (l)	Lean (kg)	Weight (kg)
ECW (l)	16.2	40.0 (35 - 41)	52.4 (50 - 55)	69.0 (66.0 - 72.0)
ICW (l)	24.8			
OCV (l)	-0.2			
Dry Lean (kg)	15.2			
Fat (kg)	16.6 (14 - 19)			
Result	Percentage	TBW (%)	Lean (%)	Normal Range
ECW (%)	23.4	59.3 (50 - 60)	76.0 (73 - 79)	20.0
ICW (%)	35.0			30.0
OCV (%)	-0.2			-
Fat (%)	24.0			(21 - 27)



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 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.



OVER-HYDRATION - DIALYSIS

The MULTISCAN5000 uses spectroscopy to calculate the volume of fluid overload in a patient about to undergo dialysis. This is of particular importance when assessing or monitoring dry or target weight for individual dialysis patients.



Please note: dehydration will show itself as a minus number, as per the image showing -0.4 OHY. For a dialysis unit, the hydration status provided by the Bodystat device provides an indication only for setting the target weight through the overhydration (OHY) value. However, a target weight cannot be set simply on the basis of the Bodystat data. Information on residual renal function, daily weight gains and symptoms on dialysis must also be considered in the course of normal clinical patient evaluation.

THE MULTISCAN5000 MEASURES:

OPTIONS DISPLAYED ON THE MULTISCAN UNIT	
Fat %* & Normal Range	BMR/Body Weight*
Fat Weight* & Normal Range	Est. Average Requirement*
Lean %* & Normal Range	Body Mass Index (BMI) & Normal Range
Lean Weight* & Normal Range	BFMI (Body Fat Mass Index) & Normal Range
Water %* & Normal Range	FFMI (Fat-Free Mass Index) & Normal Range
Total Body Water* & Normal Range	Waist/Hip Ratio
Dry Lean Weight* e.g. Lean minus Total Body Water	Prediction Marker
Skeletal Muscle Mass (SMM)*	Impedance Values at 50 frequencies ranging from 5 kHz to 1000 kHz
ECW %* & Normal Level	Resistance at 50 frequencies ranging from 5 kHz to 1000 kHz
ECW Volume*	Reactance at 50 frequencies ranging from 5 kHz to 1000 kHz
ICW %* & Normal Level	Phase Angle at 50 frequencies ranging from 5 kHz to 1000 kHz
ICW Volume*	BIVA Vector Graph including population reference selection*
Body Cell Mass*	Cole-Cole Diagram
Volume of Over-Hydration (OHY)*	Cell Membrane Capacitance*
Nutritional Index	Characteristic Frequency*
Basal Metabolic Rates*	

SPECIFICATION

MEASUREMENT	
Technology	Bioelectrical Impedance Spectroscopy (BIS) Lock-In Signal Conversion Technology
Impedance Measuring Range	20 - 1300 ohms
Accuracy	Impedance 2-3 Ω Resistance: +/- 2 Ω Reactance: +/- 1 Ω Phase Angle: +/- 0.2 $^\circ$
Test Current	620 Micro-Amps R.M.S. (Root Mean Square)
Frequency	50 frequencies ranging from 5 kHz to 1000 kHz (KiloHertz)
Calibration	A calibrator is supplied for independent verification from time to time.
Configuration	2 lead wires (removable)
Computation Time	6 seconds
PC Communication	USB interface
GENERAL	
Operating Temperature	+ 5 $^\circ\text{C}$ to + 40 $^\circ\text{C}$
Storage Temperature	0 $^\circ\text{C}$ to + 60 $^\circ\text{C}$
Relative Humidity	70% less up to +60 $^\circ\text{C}$ 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	EEMB 3.7V Lithium Polymer ion Battery
Battery Charger	Qi-Certified Charger
Dimensions	222mm L x 140mm W x 20mm H (8.7'L x 5.5'W x 0.8'H)
Weight	Unit weight - 470 grams
Service	There are no servicable parts
Quality Standards	Manufactured to strict ISO 13485-2016 quality standards. Fully accredited by the Medical Devices Directive (MDD) with its CE1639 marking and for EN60601, also FDA cleared.

EVIDENCE-BASED CLINICAL APPLICATIONS



+ 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

+ BIVA Vector Analysis – Fluid overload on admission evaluated by BIVA was significantly related to mortality in patients admitted to the ED. Kammar-García et al., "Mortality in adult patients with fluid overload evaluated by BIVA upon admission to the emergency department." *Postgrad Med J* 2018;0:1–6.

+ Different types of fluid status distinguished by BIVA combined with serum NT-pro BNP measurements corresponded to different clinical conditions and treatment outcomes, which implies a value of this method for evaluation of fluid status among patients receiving CRRT. Chen H et al., "Fluid overload at start of continuous renal replacement therapy is associated with poorer clinical condition and outcome: a prospective observational study on the combined use of bioimpedance vector analysis and serum N-terminal pro-B-type natriuretic peptide measurement" *Critical Care* (2015) 19:135

+ 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*

+ 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-impedance 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*

+ Our data show a strong inverse correlation between PhA and IR in all patients: the lower is PhA, the higher is IR. Further studies are needed to correlate IR to clinical outcomes.

Rinninella E et al. "Phase angle and impedance ratio: Two specular ways to analyse body composition". *Ann Clin Nutr.* 2018; 1: 1003

+ **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.

Heymisfield, 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)



CLASS-LEADING TECHNOLOGY

THE BODYSTAT STORY

For 31 years, we have been producing medical devices and software that utilise bioimpedance technology in the measurement of core cellular health to the critical acclaim of clinical physicians and international research institutions. But for us, this success is only one part of our story.

At the heart of the Bodystat story is a driving ambition and passion to make a difference to the general health and well-being of all nations, large and small. Our fundamental belief is that with more accurate and earlier detection of cellular changes, clinicians around the world can make earlier diagnosis and thereby improve patients' chances of a faster recovery.

Of course, without our partners in the medical and research fields, none of this would have been possible. For over quarter of a century we have developed deep and long-lasting relationships which have helped evolve our thinking, and the development of bioelectrical impedance technology and analysis for the betterment of all. To all our friends and partners, thank you. Together, we are making the world a better place.



MULTISCAN 5000



QUADSCAN 4000



BODYSTAT 1500MDD



BODYSTAT 500/1500

CE1639

ABOUT BODYSTAT

Bodystat Ltd, based on the Isle of Man (British Isles), has been established since 1990 and is a registered ISO 13485:2003 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 Europe, 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.

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version 01/21

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