

PREDICTION

PEACE OF MIND

WHAT IF YOU COULD PREDICT DISEASE OUTCOME MORE ACCURATELY?

ACCURACY

EXPERIENCE

MONITORING

RELIABILITY

REPRODUCIBILITY

PRECISION



Bodystat[®]
 CHANGING
 ATTITUDES TO HEALTH



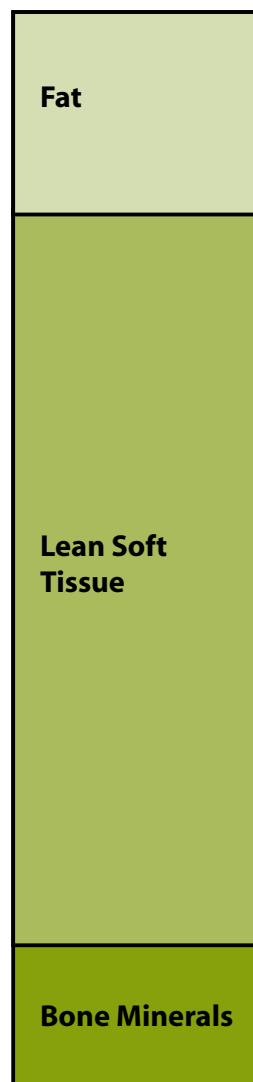
Making Disease Outcome Diagnosis More Accurate

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

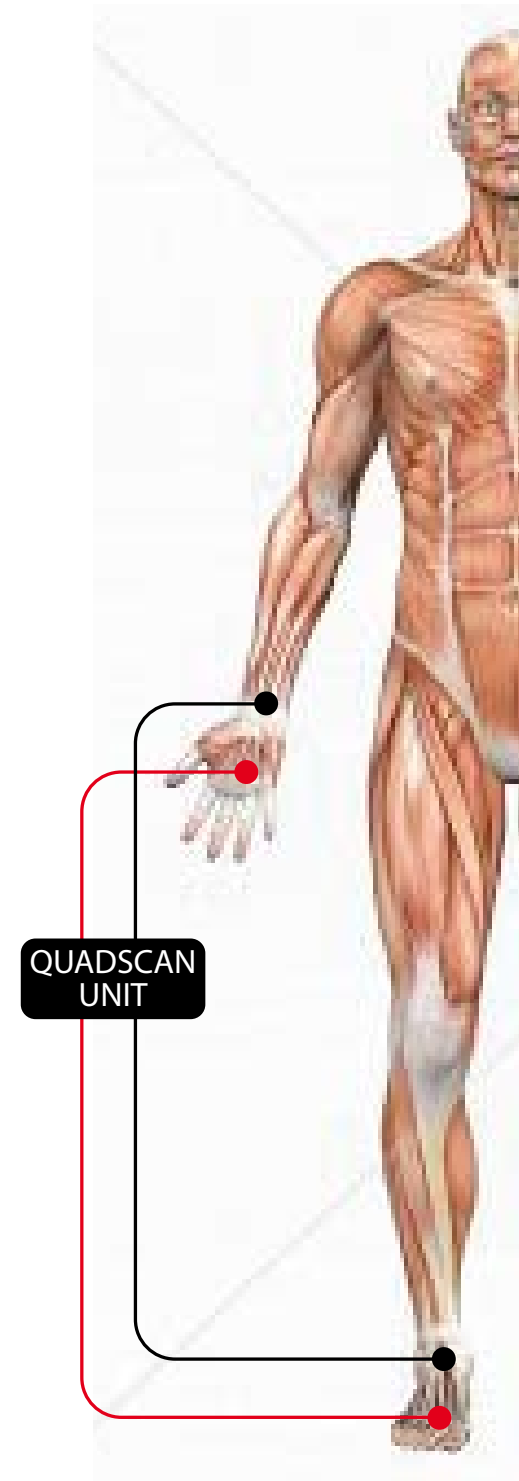
As the need for non-invasive, non-intrusive diagnostic systems increases and regular monitoring becomes even more important, clinicians seek quick, simple solutions to monitor these changes.

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

- Loss or low body mass
- Increase in fat mass
- Loss of fat free mass
- Excessive weight gain
- Muscle wasting
- Loss of body cell mass
- Loss or low bone mineral
- Malnutrition
- High blood density
- Fluid imbalance
- Oedema
- Altered fluid status – Total body water, intra-cellular & extra-cellular fluid
- Increase in extra-cellular fluid – symptomatic of oedema
- Decrease in intra-cellular fluid – associated with body cell mass & 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 & protein contents
- Muscle wasting in clinical patients.



Total Body



Composition



**Intra-cellular
Residual**

**Intra-cellular
Water**

**Extra-cellular
Water**

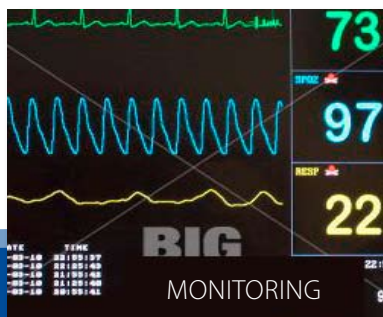
**Extra-cellular
Residual**

Assessment of Body Fluid Composition could lead to:

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

Bio-electrical Impedance Analysis (BIA) offers:

- Non-invasive assessment of hydration and nutrition status
- Assess nutritional status of patients on admission and pre-surgery
- Monitor the Illness Marker™ during hospitalization, as a predictor of outcome
- Monitor Lean 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, 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 system to meet specific needs
- QuadScan 4000 Software Program available for detailed evaluation & tracking of change
- Exact time of measurements recorded by internal Real Time Clock.



EVIDENCE-BASED CLINICAL APPLICATIONS



- **Burns** - Large changes in body fat mass during the treatment of major burns injuries.
(Sjöberg F et al.) Presented at the 10th European Burn Association.

- **Cancer** - Improving nutrition before surgery can decrease post-operative complications and length of stay.
Impact of a protein and energy dense nutritional supplement containing eicosapentaenoic acid on weight losing patients with head and neck cancer. Weed HG et al. Presented at the 2005 American Society of Clinical Oncology Annual Meeting.



- **Cardiovascular Disease** - Excessive fluid accumulation is associated with increased morbidity and prolonged convalescence after cardiopulmonary bypass.

Bioelectric impedance detects fluid retention in patients undergoing cardiopulmonary bypass.
Gonzalez J et al. J Thorac Cardiovasc Surg 1995 Jul; 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 systemic marker of disease severity in COPD staging.

Body composition and mortality in chronic obstructive pulmonary disease.
Annie MWJ Schols, et.al. Am J of Clinical Nutrition, Vol82, No 1, 53-59, July 2005

- **Critically Ill Patient** - Critically ill patients retain fluid, up to 30 litres and more.

The use of multi-frequency bio-impedance to assess fluid balance in critical illness.
Campbell IT et al. Proceedings of the Nutrition Society 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.

Assessing body composition of adults with diabetes.
Lisa M Stolarczyk et al. Diabetes Technology & Therapeutics. September 1, 1999, 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.

A Longitudinal Study of extra-cellular fluid in patients with kidney disease. Well LM. Jones CH. 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."

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.
Baker M et al. Cardiothoracic 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 extra-cellular fluid.

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



- **Elderly** - Improved estimation of body composition in elderly subjects by use of age-specific prediction equations.

Reilly JJ et al. The European Group for Research into Physical Activity for the Elderly. II International Conference, Sept 1994

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

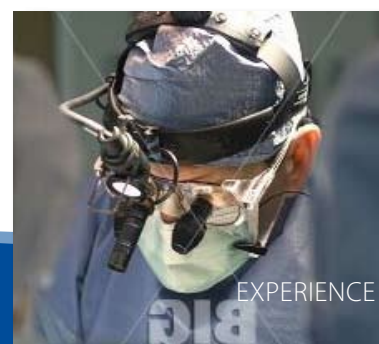
Loss of BCM (5% loss within 6 months) is a significant contributor to the morbidity and mortality associated with wasting diseases.
Body Composition Testing. M Cichock. American Heart Association, 2007

- **Hydration Status/Fluid Retention** - Measurement of extra-cellular and total body water provides useful information on the nutritional status of surgical patients and may be estimated from whole body bio-impedance measurements.

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



PREDICTION



EXPERIENCE

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

- **Malnutrition/Undernutrition/Nutrition** - Malnutrition results in a loss of body cell mass (BCM) accompanied by an expansion of the extra-cellular mass (ECM). *Body composition of patients with malnutrition and cancer.* Harry M. Shizgal, MD. Paper Presented at the Fourth Annual Nutrition Symposium on Current Concepts in Nutritional Management of the Patient With Cancer. Published Online: 29 Jun 2006

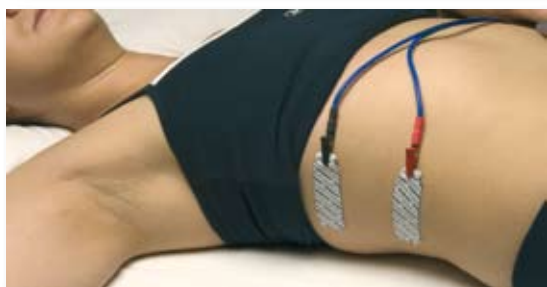


- **Neonates** – Bioelectrical impedance analysis is a simple, non-invasive method of estimating total body water in neonates receiving intensive care. It can be applied to both the assessment of changes

in body water and body composition.

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

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



- **Oedema** – The development of oedema after major abdominal surgery is associated with increased morbidity *Impact of oedema on recovery after major abdominal surgery and potential value of multifrequency bioimpedance measurements.* Itobi E et al. *Br J Surg.* 2006 March; 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.

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



- **Pulmonary Oedema** – Impedance measurement may be useful in estimating lung water associated with lung injury following cardiopulmonary bypass.

Anti-fibrinolytic agents & lung water in cardiac surgical patients. Diprose P et al. *Dept of Cardiac Anaesthesia, Southampton University Hospitals NHS Trust, Southampton, 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. *The Effects of Body Composition Changes to Observed Improvements in Cardiopulmonary Parameters After Exercise Training With Cardiac Rehabilitation.* Milani R V et al. *Chest* 1998; 113: 599-601

- **Segmental** - There is increased use of segmental impedance in the assessment of diseases that affect body fluid balance.

Human Body Composition. Steven Heymsfield. 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. *Impact of oedema on recovery after major abdominal surgery and potential value of multifrequency bioimpedance measurements.* Itobi E et al. *Br J Surg.* 2006 March; 93(3):354-61

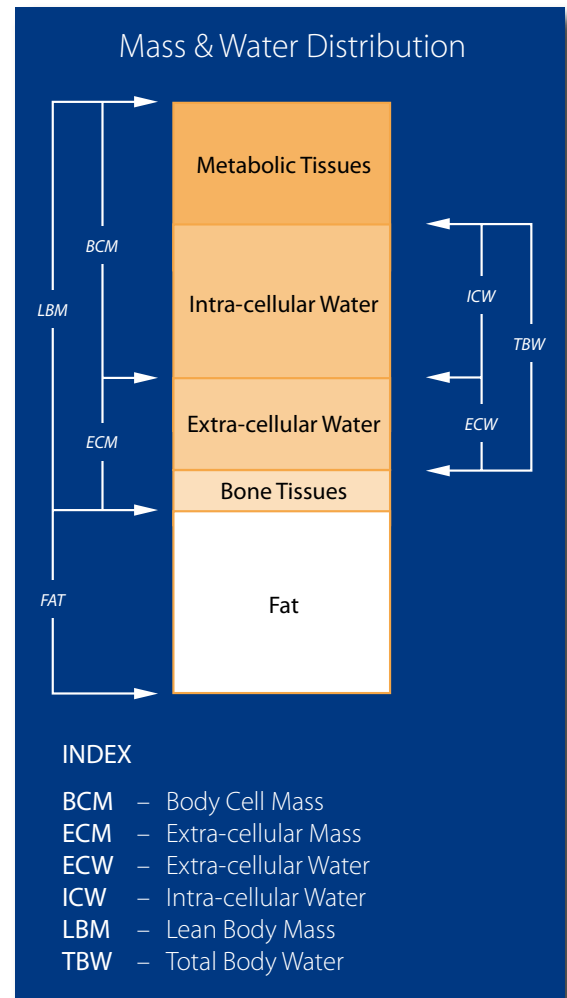


Bodystat® QuadScan 4000

Body Composition, Fluid & Illness/ Segmental Monitoring Unit



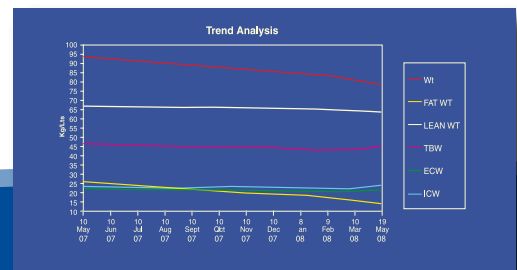
- Ease of use allows for regular monitoring of fluid body composition status and illness monitoring as required (eg minutes, hours, days, etc.).
- Illness Marker change in fluid volumes are still determined when total body weight is unknown.
- Full Body and Segmental Analysis.
- Quick corrective action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



THE QUADSCAN MEASURES:

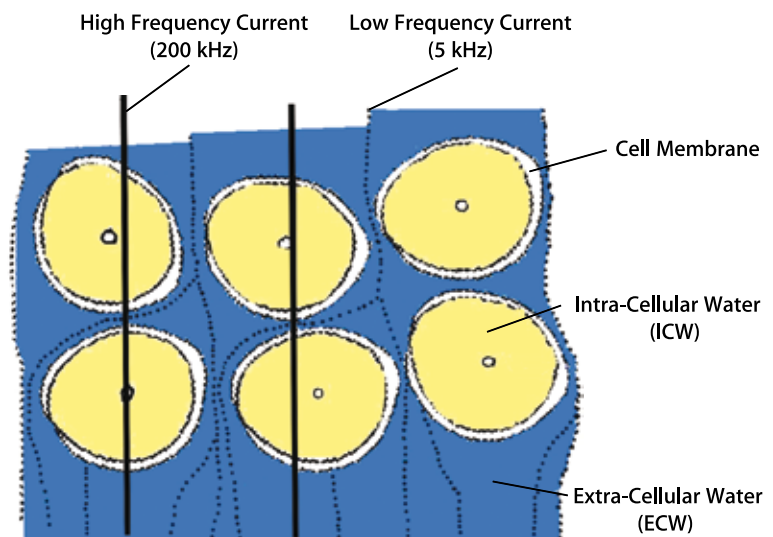
BODY COMPOSITION	HYDRATION STATUS	ILLNESS & SEGMENTAL MONITORING
Fat % and Mass*	Total Body Water – TBW*	Illness Marker™
Lean % and Mass*	Intra-cellular Water – ICW*	Phase Angle at 50 kHz
Dry Lean Mass*	Extra-cellular Water – ECW*	Resistance at 50 kHz
Body Mass Index - BMI	Third Space Water*	Reactance at 50 kHz
Fat Free Mass Index – FFMI*	Body Cell Mass*	Impedance Values at 5, 50, 100 and 200 kHz
Body Fat Mass Index- BFMI*		
	OTHER MEASUREMENTS	
Waist / Hip Ratio	Average Daily Calorie Requirement*	Basal Metabolic Rate*

*Estimated



Bio Electrical Properties

The **QuadScan 4000** 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 predominantly through the extra-cellular spaces while higher frequencies are able to penetrate the cellular membrane and pass through both intra-cellular and extra-cellular spaces. By applying Bodystat's own researched equations the system quickly determines values for body composition, hydration status and cellular health.



Bodystat Illness Marker™

It is well documented that in disease states, extra-cellular fluid plays a vital role in patient outcomes. Uniquely the **Quadscan 4000** can determine the expansion of the extra-cellular 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 extra-cellular water and total body water to determine each patients' unique **Illness Marker™**; an increase in this value shows further deterioration in health status while a decrease shows cellular improvement.

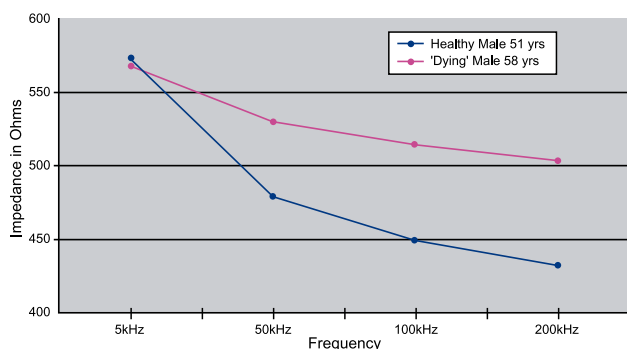
- **Potential opportunity for use:**
 - Predictor of Outcome before surgery
 - Identify potential high risk surgery patients and track the effect of surgery
 - Raise awareness of potential complicated clinical courses of patients during hospitalization
 - Effectiveness of Rehabilitation recovery after 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, Cost effective.

Healthy Male 51 yrs

Frequency	Impedance in Ohms	"Illness Marker"
5 kHz	573	
50 kHz	480	
100 kHz	450	
200 kHz	433	
Variance between 5 and 200 kHz	140	0.756

'Dying' Male 58 yrs

Frequency	Impedance in Ohms	"Illness Marker"
5 kHz	568	
50 kHz	530	
100 kHz	515	
200 kHz	504	
Variance between 5 and 200 kHz	64	0.887



The greater the variance between the two values at 5 and 200 kHz, the healthier the body cell.

Reference: Impact of oedema on recovery after major abdominal surgery and potential value of multifrequency bioimpedance measurements
Itobi E et al., *British Journal of Surgery*, 2006 March; 93(3):354-61



QUADSCAN 4000

Body Composition, Fluid & Illness Segmental Monitoring Unit

- **Multi-frequency** for the measurement of Extra-Cellular and Total Body Water assessment.
- Unique **Illness Marker™** (whole body & segmental) based on raw Impedance data only, without the need for actual body weight.
- Assesses fluid ratio between **ECW** & **TBW** and cellular health status in healthy people and in the critical ill.
- Applies to all age groups from neonates to the very elderly and irrespective of population group.
- Includes comprehensive **Body Composition & Fluid Analysis** software with alternative predictive equations.



OPTIONAL EXTRA

BODYSTAT® PRINTER

- Portable Thermal Printer fitted with Bluetooth offering immediate off-site print out of results.
- Battery operated and light weight.

SPECIFICATIONS

MEASUREMENT

Technology

Bio-Impedance Analysis (BIA) Lock-in Signal Conversion Technology

Impedance Measuring Range

20 - 1300 ohms

Accuracy

Impedance: 2-3 Ω
Reactance (50 kHz): +/- 1Ω
Phase Angle (50 kHz): +/- 0.2°

Test Current

200 Micro-Amps R.M.S.
(Root Mean Square)

Frequency

5/50/100/200 kHz (KiloHertz)

Calibration

Automatic internal calibration check each time a measurement is taken. A calibrator is supplied for independent verification from time to time.

Configuration

2 Lead Wires (removable)

Computation Time

11 seconds

PC Communication

Bluetooth wireless interface



GENERAL

Operating Temperature

+ 5 °C to + 45 °C

Storage Temperature

0 °C to + 60 °C

Relative Humidity

70% or 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,
6 x AA (LR6) 1.5v Non-rechargeable.

Dimensions

310mm x 180mm x 55mm,
12.20" L x 7.09" W x 2.17" H

Weight

Unit weight - 883 grams

Low Battery

Displays a warning when the battery power is low and needs replacement.

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

Service

There are no serviceable parts other than the need for periodic battery replacement.

Quality Standards

Manufactured to strict ISO 13485-2003 quality standards. Fully accredited by the Medical Devices Directive (MDD) with it's CE 0120 marking and for EN60601.



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