

BCM - Body Composition Monitor

Innovation for better outcome



Cardioprotective Haemodialysis

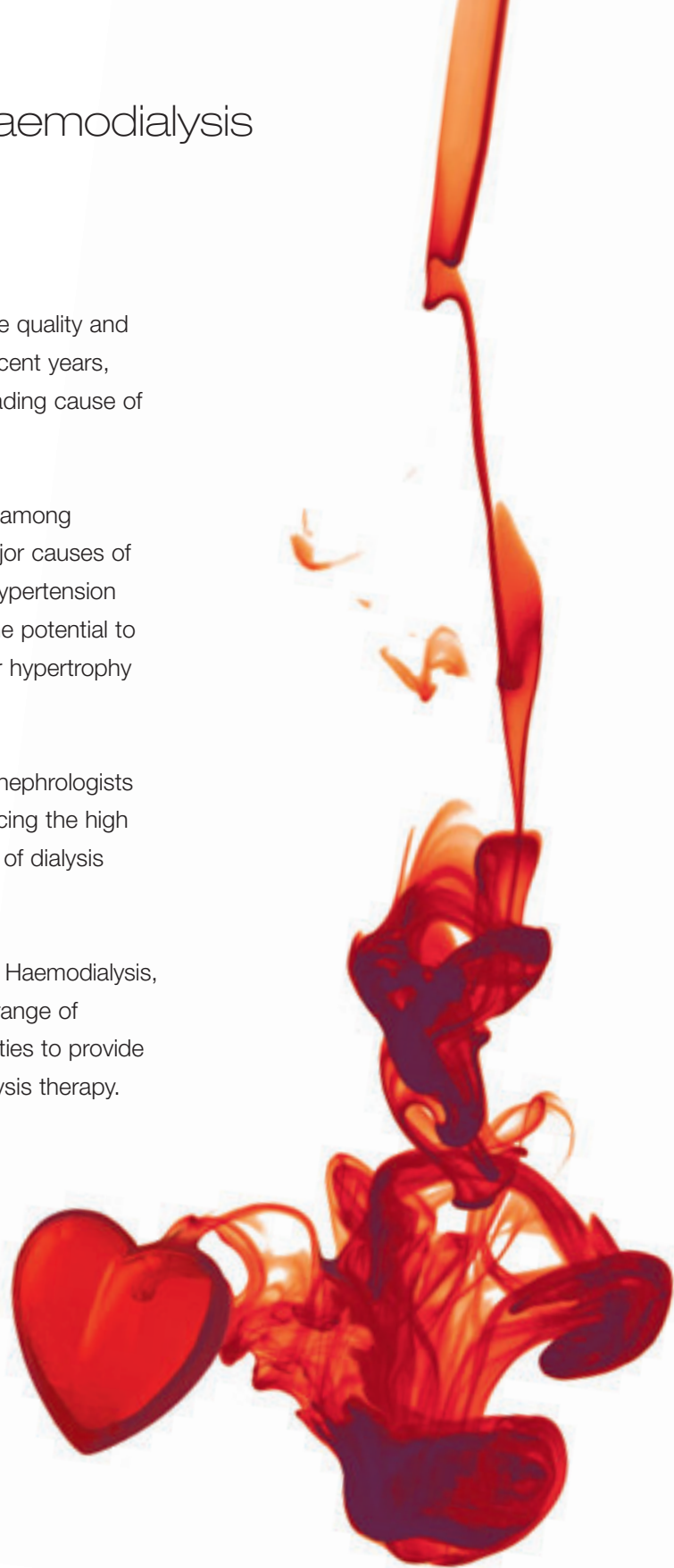
Despite significant improvements in the quality and efficacy of haemodialysis therapy in recent years, cardiovascular diseases remain the leading cause of death in dialysis patients.

Fluid overload is a common condition among patients on dialysis and one of the major causes of mortality. Improving the treatment of hypertension and correction of fluid balance have the potential to limit the development of left ventricular hypertrophy thus increasing life expectancy.¹

Fresenius Medical Care together with nephrologists world-wide is dedicated towards reducing the high cardiovascular morbidity and mortality of dialysis patients.

Within the concept of Cardioprotective Haemodialysis, Fresenius Medical Care offers a wide range of monitoring tools and treatment modalities to provide your patients with state-of-the-art dialysis therapy.

With the introduction of the BCM - Body Composition Monitor Fresenius Medical Care further facilitates the realization of Cardioprotective Haemodialysis.



¹ Left ventricular hypertrophy is present in 70% of the dialysis population (Levin, A et al., Prevalent left ventricular hypertrophy in the predialysis population: identifying opportunities for intervention, Am J Kidney Dis 1996; 27(3):347-54)

BCM - Body Composition Monitor

Achieving optimal fluid balance remains a major clinical challenge especially when a number of comorbid complications is present. Assessment of fluid status based on subjective indicators has been a limiting factor in the control of fluid balance.

Increasing patient numbers and constraints on physicians' time have further reduced the scope for quality assessment.

The BCM - Body Composition Monitor is the first device that determines individual fluid status and body composition in an easy and objective way. The Body Composition Monitor assists the physician in the convenient assessment of clinically relevant parameters:

- Quantification of fluid status:
 - Overhydration
 - Total body water (V)
- Assessment of body composition:
 - Lean tissue mass
 - Adipose tissue mass

Furthermore, the BCM - Body Composition Monitor helps to investigate the link between fluid status and blood pressure, therefore allowing a more appropriate prescription of ultrafiltration and antihypertensive agents.

The measurement is based on a non-invasive and accurate method that is easy to apply and results are obtained within just two minutes.

The BCM - Body Composition Monitor can be applied for the vast majority of chronic kidney disease patients with or without renal replacement therapy.



BCM - Body Composition Monitor

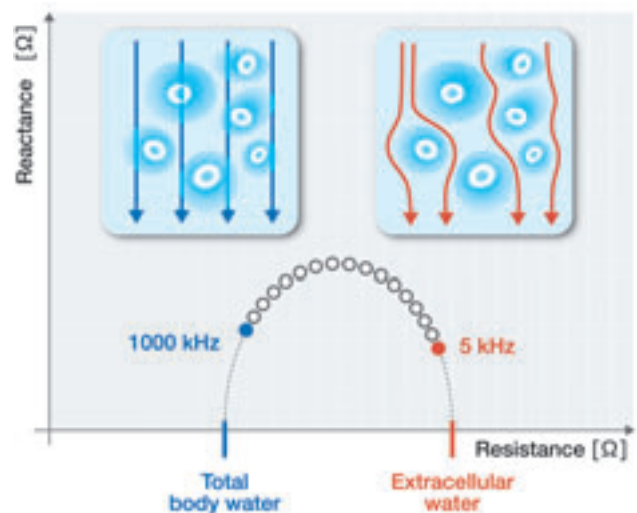
From technology to therapy

The BCM - Body Composition Monitor employs the latest bioimpedance spectroscopy techniques. It measures at 50 frequencies over a range from 5 to 1000 kHz to determine the electrical resistances of the total body water (TBW) and the extracellular water (ECW).

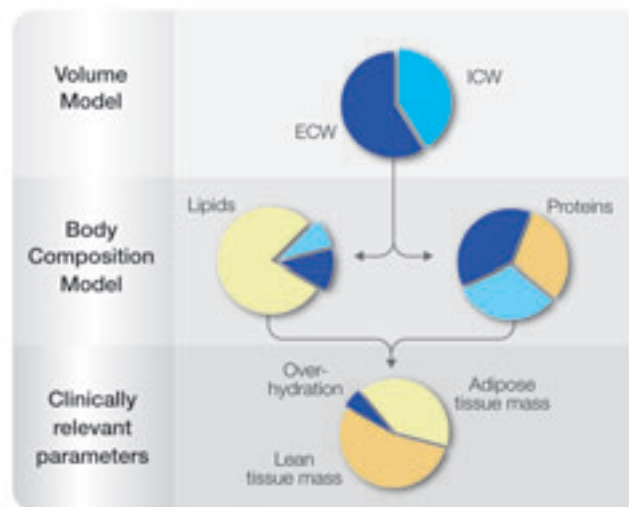
While high-frequency current passes through the total body water, low-frequency current cannot penetrate cell membranes and thus flows exclusively through the extracellular water.

To obtain the clinically relevant output parameters, two advanced physiological models are used in the BCM - Body Composition Monitor:

- A volume model describing electrical conductance in a cell suspension enabling the total body water and extracellular water as well as the intracellular water (ICW) to be calculated².
- A body composition model calculating the three principal body compartments overhydration, lean tissue and adipose tissue from ECW and TBW information³.



The Cole-Cole plot displays the raw data of the measurement separating ECW from TBW.



The BCM - Body Composition Monitoring device takes three steps to display the final output parameters: overhydration, adipose tissue mass and lean tissue mass.

2 Moissl, U et al., Body fluid volume determination via body composition spectroscopy in health and disease. *Physiol. Meas* 2006; 27: 921-933.

3 Chamney, P et al., A whole-body model to distinguish excess fluid from the hydration of major body tissues. *Am J Clin Nutr* 2007; 85: 80-89.

A precise “V” for dialysis dose assessment

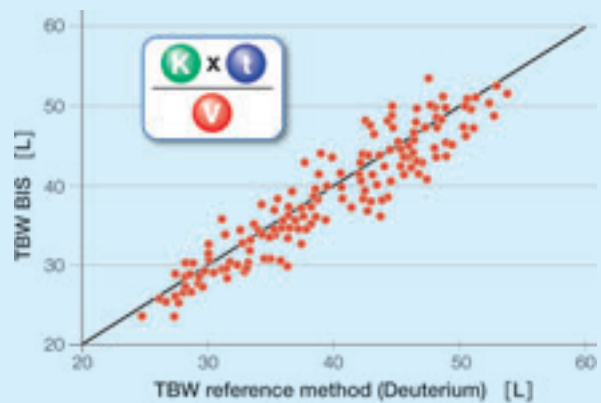
The BCM - Body Composition Monitor provides an accurate determination of total body water (TBW) which has been validated against gold standard dilution methods.

As TBW is equivalent to the urea distribution volume (V), there is no need for time consuming kinetic urea modelling or anthropometric equations which can produce erroneous results in extremes of body composition.

European Best Practice Guidelines recommend a target dialysis dose of urea $eKt/V \geq 1.2$ per session for a thrice-weekly schedule.⁴

Thus BCM - Body Composition Monitor can be used for

- Dialysis dose prescription
- “V” input for the Fresenius Medical Care OCM[®] option.



The Body Composition Monitor assessment of total body water is validated against gold standard reference methods.

How is the BCM – Body Composition Monitor validated?

All output parameters have been validated against the gold standard reference methods in various studies involving more than 500 patients and healthy controls.

These reference methods include:

- Extracellular water – bromide dilution
- Intracellular water – total body potassium (TBK)
- Total Body Water – deuterium dilution
- Lean Tissue Mass – Dual Energy X-ray Absorptiometry (DEXA)
- Adipose Tissue Mass – 4-compartment modelling, DEXA, air displacement plethysmography and under water weighing
- Body Cell Mass – magnet resonance tomography, TBK
- Overhydration – by expert clinical assessment

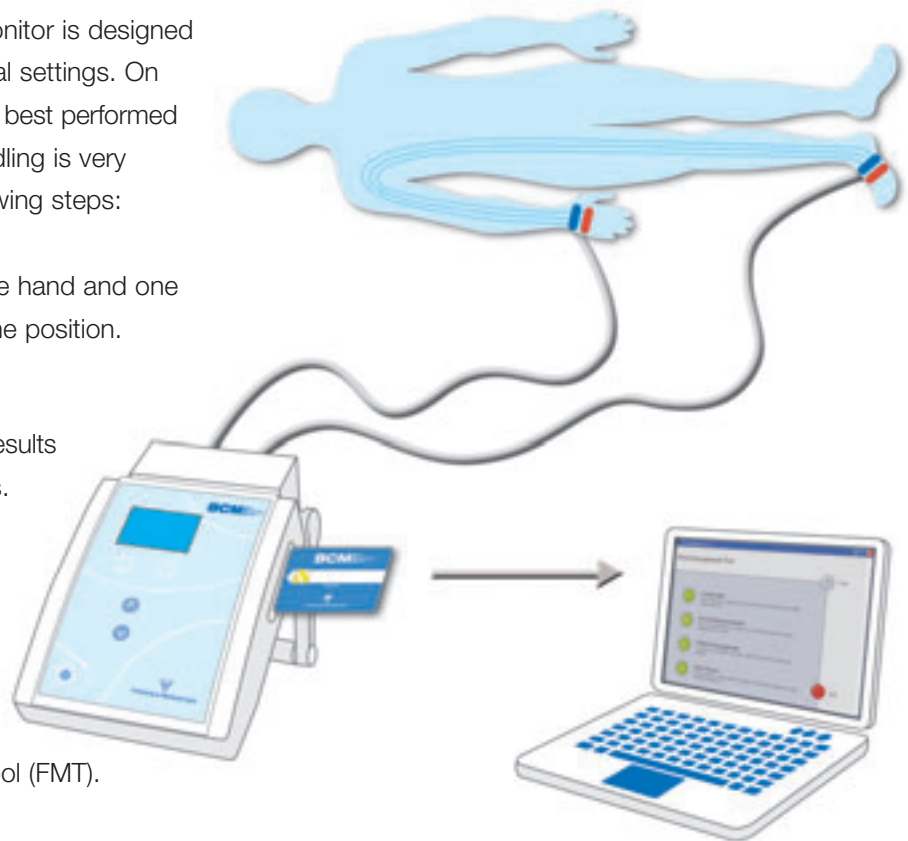
⁴ European Best Practice Guidelines for Haemodialysis. Nephrol Dial Transplant 2002; 17 Suppl. 7

BCM - Body Composition Monitor

Handling

The BCM – Body Composition Monitor is designed for application in a variety of clinical settings. On treatment days, measurements are best performed before the start of treatment. Handling is very straight forward involving the following steps:

- Electrodes are attached to one hand and one foot with the patient in a supine position.
- Patient cable is connected.
- Measurement is initiated and results are displayed within 2 minutes.
- Results are stored on the PatientCard.
- Data can be transferred via PatientCard to a personal computer for further analysis with the Fluid Management Tool (FMT).



Patient analysis & management

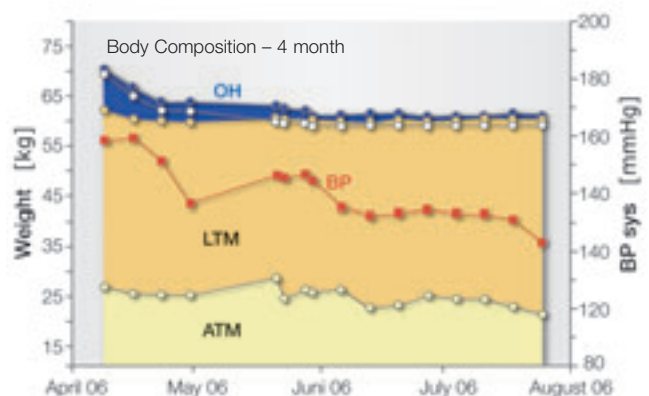
The Fluid Management Tool (FMT) operates in conjunction with the BCM – Body Composition Monitor and can be easily installed on a personal computer.

This software provides a quick overview of the fluid status and body composition of the patient - including reference ranges for dialysis patients and the healthy population.

Body Composition Plot

The FMT displays the development of the three primary compartments adipose tissue mass (ATM), lean tissue mass (LTM) and overhydration (OH) over time.

In addition, the systolic blood pressure (BP sys) is displayed which allows the influence of overhydration on blood pressure to be identified. Consequently, it is easy to observe changes in body composition and how these impact overhydration.



Body composition and blood pressure variation over time.

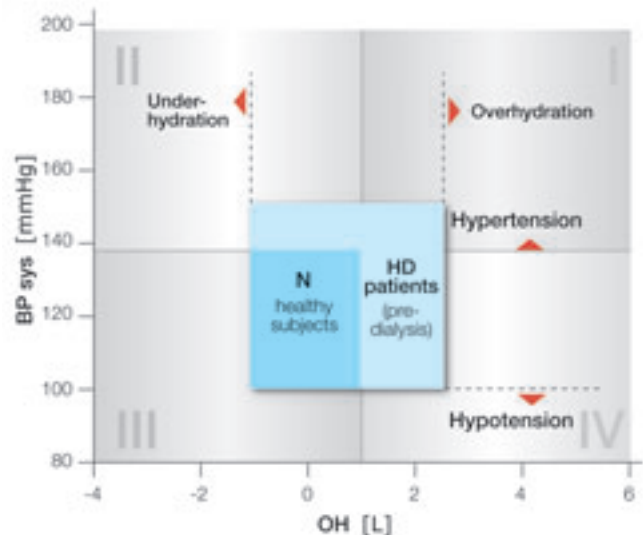
Hydration Reference Plot

It is known that overhydration often leads to hypertension. However, in many patients this relationship can be heavily influenced by underlying comorbidities⁵. For example, in some patients, hypertension may be dependent on vascular disorders⁶ while on the other hand, there are patients who exhibit apparently normal or low blood pressure despite gross overhydration⁷.

The hydration reference plot depicts the association between overhydration status and systolic blood pressure on one graph.

The easiest way to identify abnormal conditions is to compare patient results with a reference population.

The reference region N has been defined from measurements in healthy subjects allowing direct comparison of patient parameters. A second reference region indicates the typical range of well managed patients measured pre-dialysis and with a maximum weight gain of 2.5 L. Both reference ranges are adjusted for age and sex. The position of the patient in the plot allows a first interpretation of the patient's condition at the time of the measurement and aids the physician to possible actions the patient might benefit from.



Overhydration (OH) and systolic blood pressure (BP sys) are combined in one graph – the Hydration Reference Plot (HRP).

The BCM – Body Composition Monitor ...

- ... is the first device that measures the individual overhydration
- ... improves management of hypertension and fluid status
- ... provides a basis for nutritional assessment
- ... determines "V" for dialysis dose prescription
- ... measures non-invasively, fast and easy

5 Jones CH et al., The relationship between serum albumin and hydration status in hemodialysis patients, J Ren Nutr. 2002; 12(4):209-12

6 Levin NW et al., What clinical insights from the early days of dialysis are being overlooked today? Semin Dial. 2005; 18(1):13-21.

7 Cannella G et al., Inadequate diagnosis and therapy of arterial hypertension as causes of left ventricular hypertrophy in uremic dialysis patients. Kidney Int. 2000; 58(1):260-8.

Technical data	
Key parameters	Unit
Overhydration (OH) (pre-/postdialytic)	[L]
Lean tissue index (LTI)	[kg/m ²]
Fat tissue index (FTI)	[kg/m ²]
Total body water (TBW) (Urea distribution volume V)	[L]
Extracellular water (ECW)	[L]
Intracellular water (ICW)	[L]
ECW / ICW	-
Lean tissue mass	[kg] and [%]
Fat mass	[kg]
Adipose tissue mass	[kg] and [%]
Body Cell Mass	[kg]

Ordering information	
BCM - Body Composition Monitor System	Art. No.
BCM - Body Composition Monitor device, 10 PatientCards, 10 electrode sets, Fluid Management Tool software CD-ROM (single user license), patient cable, External USB 2.0 Card Reader, AC adapter, Test box	H02 201 1
Fluid Management Tool	Art. No.
Additional single user license	M35 140 1
PatientCards	Art. No.
10 pieces	M34 860 1
BCM - Body Composition Monitor Electrodes	Art. No.
40 disposable electrodes (10x4)	M35 143 1

Technical changes reserved!

Technical Information	
Measurement time	approx. 2 min
Data output	LC-Display; integrated SmartCard writer
Measuring frequency range	50 discrete frequencies in the range from 5 – 1000 kHz
Battery	Lithium-Ion battery, capacity 5 hours
AC adapter	100 – 240 V AC; 50 – 60 Hz
Operating conditions	0° – 35°C, 30 – 70% humidity
Dimensions	16.9 x 11.2 x 27.2 cm (W x H x D), 2 kg (weight)
Languages	English, German
Medical product class	Ila



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