

Daxor BVA-100®

Direct Intravascular Blood Volume Analysis



DAXOR
CORPORATION

Daxor BVA-100®: Introducing a New Standard for Blood Volume Measurement

Clinical research has proven that intravascular blood volume measurement represents a critical consideration for diagnosis and treatment of several acute and chronic conditions. Published studies from leading institutions such as the Cleveland Clinic, Yale University School of Medicine, and Columbia Presbyterian Medical Center have demonstrated that accurate blood volume analysis reveals information that can significantly improve medical outcomes. Yet, until recently, the difficulty of obtaining accurate and timely blood volume measurements has kept blood volume testing from becoming a standard of care. Physicians without the time and resources to perform complex and lengthy procedures have had to resort to surrogate methods that do not accurately measure blood volume.

With Daxor's Blood Volume Analyzer, BVA-100® and Volumex™ radiopharmaceutical, physicians now can directly measure blood volume rapidly and accurately. The BVA-100 measures intravascular blood volume with an accuracy of plus or minus 2.5% in 90 minutes or less, with preliminary results possible in 30 minutes for emergency cases. As the first FDA-approved instrument of its kind, the BVA-100 provides both rapid direct measurement of a patient's blood volume and ideal volume for a patient's body size. By delivering critical information on total blood, red blood cell and plasma volume, it enables more precise diagnosis and treatment. Clinical studies clearly show that direct blood volume measurement with the BVA-100 can result in improved outcomes and efficiencies in patient care.

The FDA-approved BVA-100 measures blood volume with an accuracy of plus or minus 2.5% in 90 minutes or less.



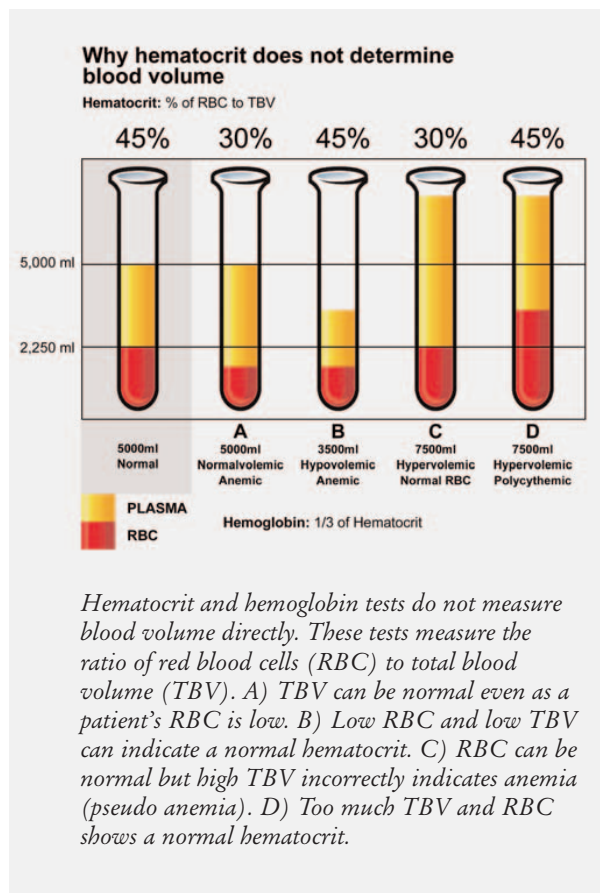
Rapid, Accurate, and Reliable Blood Volume Analysis

Many physicians today use a combination of clinical assessment and surrogate tests to determine blood volume. Clinical assessment relies on indirect indicators such as blood pressure, weight change, lung sounds, edema, and jugular venous distension. Surrogate tests such as hematocrit and hemoglobin only measure the ratio of red blood cells to total blood volume. Highly invasive tests like the pulmonary capillary wedge pressure measure pressures in the heart and lung. Although these tests offer useful clinical information, they do not measure blood volume directly. To measure blood volume accurately and directly, physicians formerly had no alternative to the dual isotope blood volume study, a complex and potentially error-prone test that takes up to six hours.

The Daxor BVA-100 system achieves the same accuracy as the dual isotope method* with several advantages that make it amenable to today's clinical environment. The easy to use BVA-100 system can be operated by a technologist in 90 minutes or less, and it automatically compares measured results to an individual's ideal blood volume. Daxor ensures reliability and quality control by providing precisely measured standards and Volumex injectate. In addition, a semi-automated process requiring duplicate measurements minimizes technologist error.

The Daxor BVA-100 can be used to determine appropriate treatments and track efficacy, diagnose volume abnormalities associated with chronic illnesses or traumatic conditions, and assess risk before surgery. It is used in leading medical centers for diagnosing and treating patients with heart failure, kidney failure, syncope, and to aid in fluid and blood transfusion management in the critical care unit. It also has been used to aid in diagnosis and treatment of polycythemia, hypertension, anemia, chronic fatigue, and for pre-surgical evaluation.

* Dworkin, HJ, et al. Comparison of Red Cell and Whole Blood Volume as Performed Using both Chromium-51 Tagged Red Cells and Iodine-125 Tagged Albumin and Using I-131 Tagged Albumin and Extrapolated Red Cell Volume. *Am J Med Sci.* 2007;334(1):37-40.



Published Study Links Blood Volume Status to Outcome, Proves Value of Direct Blood Volume Measurement.

Articles in *Circulation* and the *American Journal of Cardiology* compared expert clinical assessment of blood volume to blood volume analysis using the Daxor BVA-100.* Expert cardiologists classified the blood volume status as hypervolemic (high blood volume) normovolemic (normal blood volume) or hypovolemic (low blood volume) in heart failure patients. The expert's assessments were incorrect 49% of the time. The failure of clinical assessment to identify blood volume proved especially significant in one study because the study demonstrated a strong correlation between blood volume status and patient outcomes. After two years, 55% of hypervolemic patients died or required urgent transplantation while 100% of normovolemic and slightly hypovolemic patients survived.

*Androne AS, et al. Relation of unrecognized hypervolemia in chronic heart failure to clinical status, hemodynamics, and patient outcomes. *Am J Cardiology.* 2004;93:1254-1259.

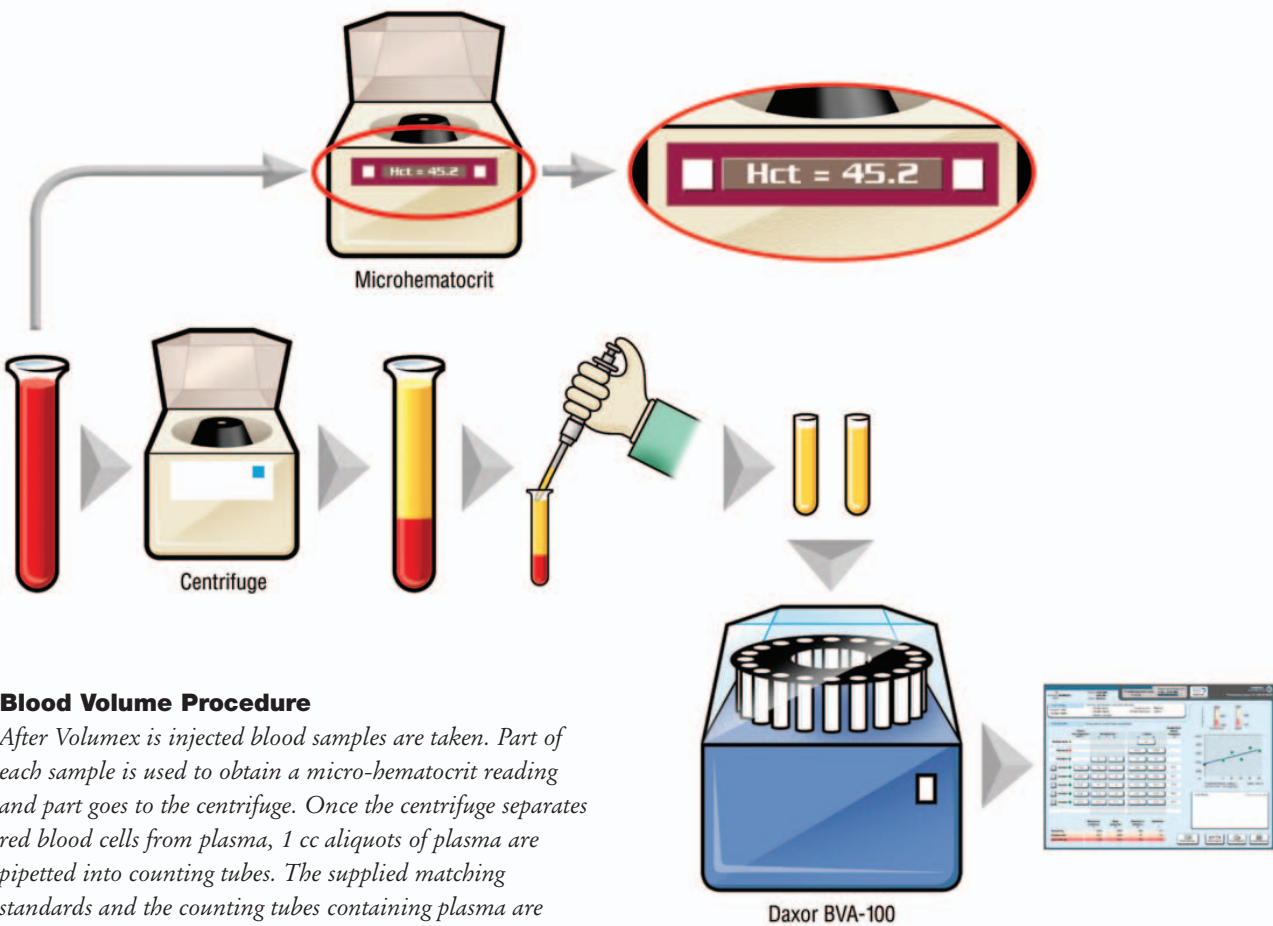
*Androne AS, et al. Hemodilution is common in patients with advanced heart failure. *Circulation.* 2003;107:226-229.

How the BVA-100 Works

Performing a Blood Volume Analysis Using Volumex Albumin I-131 radiopharmaceutical tracer*

The BVA-100 is a semi-automated system for intravascular blood volume analysis. It can be operated with minimal training by medical personnel trained to establish venous access as well as those licensed to inject a radiopharmaceutical. The FDA approved BVA-100 qualifies for Medicare and third party payer reimbursement.

A technologist measures the patient's height and weight and gains intravenous access. After obtaining a baseline blood sample, the technologist injects the Volumex radiopharmaceutical tracer into the patient and waits twelve minutes to allow for mixing. The technologist then draws five blood samples, one every six minutes. Microhematocrit measurements are performed for each sample.



Blood Volume Procedure

After Volumex is injected blood samples are taken. Part of each sample is used to obtain a micro-hematocrit reading and part goes to the centrifuge. Once the centrifuge separates red blood cells from plasma, 1 cc aliquots of plasma are pipetted into counting tubes. The supplied matching standards and the counting tubes containing plasma are placed into the carousel of the BVA-100.

The patient information and hematocrit values are entered into the BVA-100 which produces a complete report with total blood volume, plasma volume, red cell volume and rate of transudation. It also compares the measured results against the patient's ideal volume values.

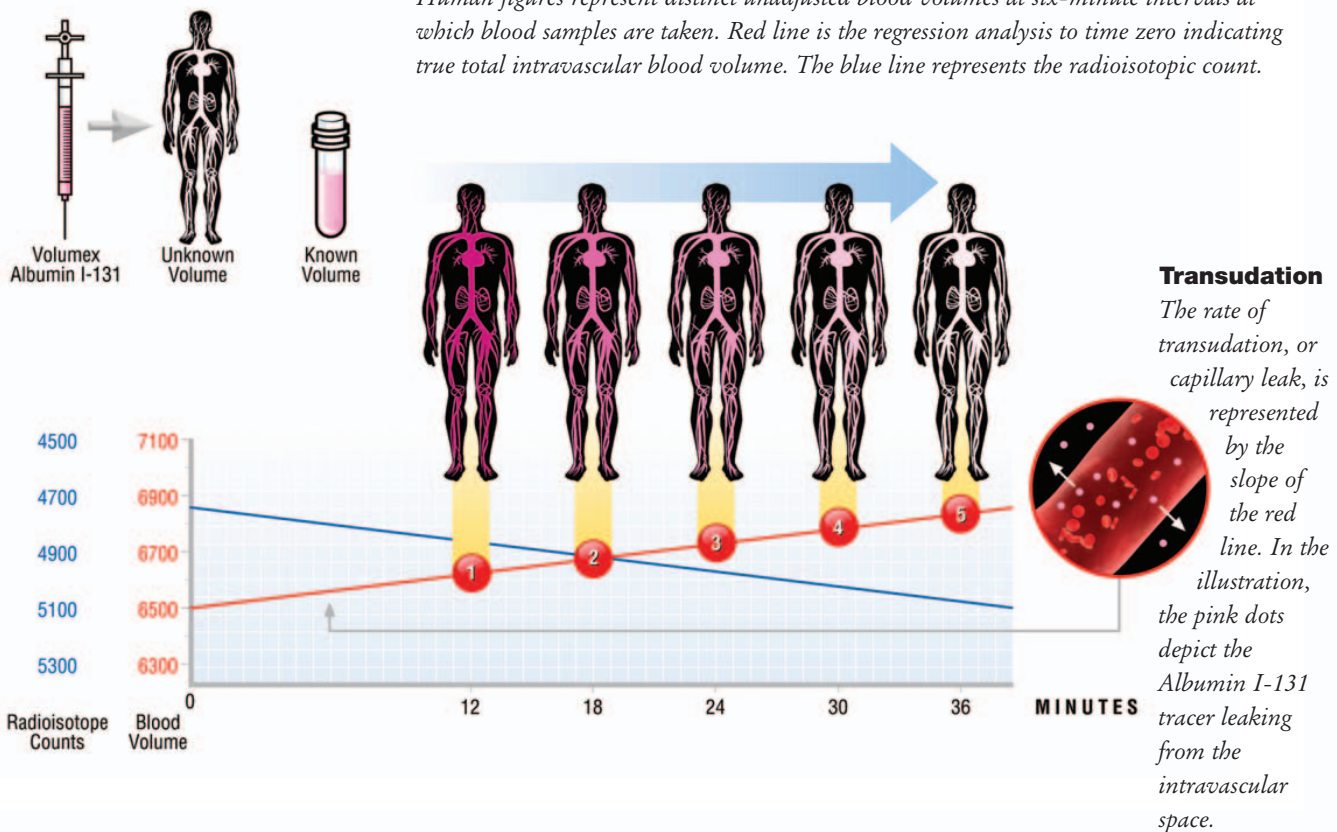
* Volumex (Iodinated I 131 Albumin Injection USP) is available in single unit dose volumetric flow-through chamber syringes containing an ultra low dose of 25 microcuries of activity in one milliliter on the date of calibration. Each volumetric flow-through chamber syringe is supplied with reference standards. Complete assay data for each single unit dose and reference standards are provided on their respective containers.

The Indicator Tracer Dilution Technique

The BVA-100 Blood Volume Analyzer calculates human blood volume using the indicator tracer dilution technique. A known quantity of radioisotopic tracer, Volumex Albumin I-131, is injected into a vein. Once the tracer has mixed thoroughly in the patient's bloodstream, blood samples are taken. The radioactivity of a small quantity of the patient's plasma is then compared with that of the same quantity of fluid with a known dilution, the standard. The larger the unknown volume, the more diluted the tracer becomes. The more diluted the sample the greater the total blood volume.



Human figures represent distinct unadjusted blood volumes at six-minute intervals at which blood samples are taken. Red line is the regression analysis to time zero indicating true total intravascular blood volume. The blue line represents the radioisotopic count.



Transudation
The rate of transudation, or capillary leak, is represented by the slope of the red line. In the illustration, the pink dots depict the Albumin I-131 tracer leaking from the intravascular space.

The BVA-100 Output

From the patient's height, weight, and gender the BVA-100 automatically calculates ideal blood volume.* The report for a blood volume analysis includes 3 basic parameters: Total Blood Volume (TBV), Red Cell Volume (RCV), and Plasma Volume (PV). Each parameter is expressed in milliliters and as a percentage deviation from the predicted normal value. The percentage deviation from normal is considered first, to determine whether the patient has a normal, depleted, or expanded volume. The absolute value in milliliters is important for quantifying the blood volume abnormality and making treatment decisions. For example, if a patient requires a transfusion, the blood volume deficit in milliliters can help determine how many units of blood are needed. In addition, the report provides the Standard Deviation (SD), and the normalized hematocrit.

Hospital
Department Address
Department Phone Number
Department
Department Director

Blood Volume Analysis
Final Report
Physician

Patient Demographics

Patient Name: John Smith ID #: 0000000 Accession: 0000000 Referring MD: Dr. Jones CC: -	DOB: 9/27/1945 Gender: Male Height: 70.3 inches Weight: 205.0 lb Deviation from Ideal Weight: +25.9%	Analyzed On: 1/1/2007 2:44 PM Age: 61 Analyst: CRH Injectate Lot: V52502-144 Location: Nuclear Medicine
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Comments:

Blood Volume Analysis Results

	BVA Result	Patient Ideal	Deviation from Ideal	Excess/Deficit %
Total Blood Volume	6308 mL	5480 mL	+828 mL	+15.1% Mild Excess
Red Blood Cell Volume	2344 mL	2222 mL	+122 mL	+5.5% Normal Excess
Plasma Volume	3964 mL	3258 mL	+706 mL	+21.7% Moderate Excess

Category	Value (mL)
BVA (Total)	6308
Red Blood Cell Volume (RBCV)	2344
Plasma Volume (PV)	3964
Ideal (Total)	5480
Red Cell Volume (RCV)	2222
Plasma Volume (PV)	3258

Blood Volume Interpretation Guideline

	Normal	Mild	Moderate	Severe	Extreme
BV, PV Deviation (±%):	0 to 8	>8 to 16	>16 to 24	>24 to 32	>32
RCV Deviation (±%):	0 to 10	>10 to 20	>20 to 30	>30 to 40	>40

Additional Analysis

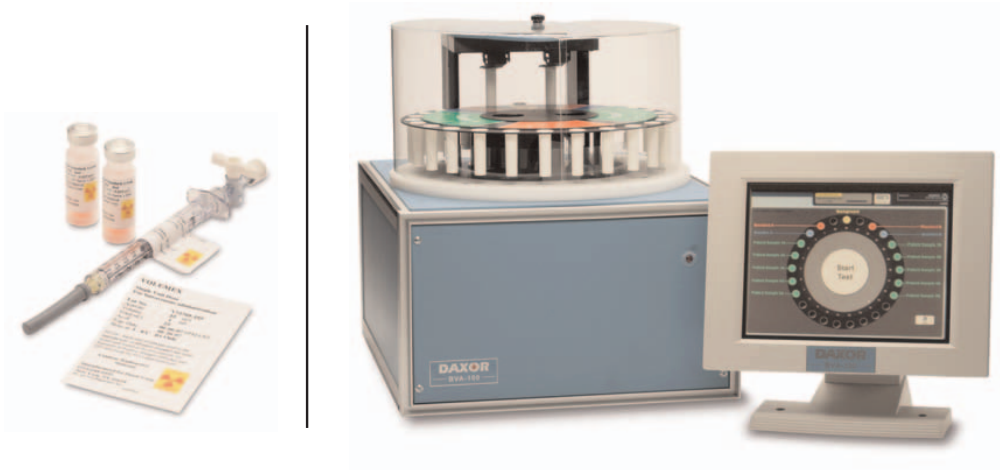
Hematocrit Analysis			ml/kg Analysis			Albumin Transudation Analysis/Slope (%/min)	
	Patient Result	Normal (Male)		Patient Result	Patient Ideal	Patient Result	Reference Range
Peripheral Venous Hct	41%	38% - 45%	Total Volume	67.8	58.9	0.30%	Normal: 0 to 0.4%
Normalized Hct (nHct)	47%	38% - 45%	Plasma Volume	42.6	35.0		High: 0.4 to 0.5%
			RBC Volume	25.2	23.9		Unusually High: >0.5%

Report Findings

Blood Volume Analysis result indicates patient's total blood volume is mild hypervolemic, with mild excess of +828 mL or +15.1% from ideal; plasma volume is moderate hypervolemic, with moderate excess of +706 mL or +21.7% from ideal; red blood cell volume is normal volemic, with normal excess of +122 mL or +5.5%.

*Feldschuh J, Enson, Y. Prediction of the Normal Blood Volume. Relation of Blood Volume to Body Habitus. Circulation. 1977;56:605-612.

*Feldschuh J, Katz S. The importance of Correct Norms in Blood Volume Measurement. Am J Med Sci. 2007;334(1):41-46.



Daxor BVA-100®
A Diagnostic Tool to Guide Blood Volume Management Therapy



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