



Blood Volume Analysis System

Blood Volume Analyzer BVA-100 and Volumex HSA I-131

Customer Site Requirements

The Daxor Blood Volume Analyzer BVA-100 System and Volumex HSA I-131 radiopharmaceutical with collection kit are designed to utilize the tracer dilution technique to provide a 98% accurate total blood volume, red cell volume, and plasma volume analysis within 90 minutes or less.

Daxor's FDA-approved, unique patented system requires minimum site preparation. However, there are federal and state regulations, as well as Daxor protocols, that must be followed when utilizing the Blood Volume Analysis System.

The following is a summary of the customer site requirements associated with conducting a blood volume analysis (BVA). Although regulations may vary slightly from state to state, a facility which performs a BVA typically requires the following:

1. Licensing, Handling, and Storage
 - a. NRC/RMA/Bureau of Radiological Health License
 - b. CLIA Laboratory License
 - c. A labeled and secured area/refrigerator to store Volumex radiopharmaceuticals

2. Patient and Analysis Area
 - a. Scale for height and weight
 - b. Reclining chair or stretcher
 - c. I.V. stand with I.V. normal saline fluid
 - d. Space for the BVA-100 System

Daxor provides its customers with (1) an on-site assessment to recommend compliance with all applicable federal and state regulations associated with conducting a BVA; (2) a full complement of manuals—*Quick Start Guide* and *Laboratory Operations Manual*; (3) installation; and (4) in-service training of personnel during installation of the BVA System.

Licensing, Handling, and Storage

Because the Blood Volume Analysis BVA-100 System requires (1) the transport, receipt, administration, and disposal of a radiopharmaceutical and (2) the collection, manipulation, and disposal of blood, various regulating agencies have become involved in regulating a blood volume analysis.

Radiopharmaceutical Transport, Receipt, Handling/Storage, Administration, and Disposal

Transport

Daxor's Volumex HSA I-131 kit is regulated by the Department of Transportation's Code of Federal Regulations (49 CFR) and the International Air Transportation Association (IATA) for ground and air shipments. Volumex radiopharmaceuticals are shipped in accordance with "Type A" and "Yellow 2" packaging and labeling requirements. In accordance with these regulations, the permitted level of radioactivity is less than 50 mR on the surface of the packaging and 1 mR at transport index. (Transport index is defined as 3 feet away from the package.) The maximum surface radioactivity reading of the Volumex kit is 4 mR and 0.2 mR at transport index, far below the permitted level of radioactivity. This allows Daxor to ship Volumex directly to a customer's licensed facility via any licensed common carrier.

Receipt

Because of its radioactivity, Daxor's Volumex kit is regulated by the Nuclear Regulatory Commission (NRC) and the Radioactive Materials Act (RMA), which is responsible for safe handling in order to insure the protection of both patients and personnel. State Departments of Health/Bureau of Radiological Health (DOH) also regulate the safe handling of radioactive materials. These governmental agencies provide facilities with the proper license/permit that allows Daxor to ship Volumex. Daxor can ship Volumex kits only to a facility that supplies Daxor with a copy of a valid RMA/NRC/Bureau of Radiological Health license that permits the receipt of radioactive materials with a radioactive level of 5 to 50 microcuries. The RMA/NRC/Bureau of Radiological Health license should also specify or be amended to reflect the receipt of Volumex HSA I-131 for blood volume analysis.

Handling/Storage

Volumex kits should be handled in accordance with the "as low as reasonably achievable" (ALARA) philosophy in the receipt and handling of radiopharmaceuticals, as regulated by federal, state and local regulations, and as directed by a facility's Radiation Safety Officer (RSO). Paragraph 20.1(c) of 10 CFR Part 20 states:

"...persons engaged in activities under licenses issued by the Nuclear Regulatory Commission pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974 should, in addition to complying with the requirements set forth in this part, make every reasonable effort to maintain radiation exposures, and releases of radioactive materials in effluents to unrestricted areas, as low as is reasonably achievable."

Each medical licensee must have a formal ALARA program (see 10 CFR 35.20). Volumex should be stored in a secure area, properly labeled as an area containing radioactive material, and within a "radioactive materials only" refrigerator. Typically, there is no requirement for lead shielding due to the low level of radioactivity.

Administration

Daxor's Volumex HSA I-131 is approved by the FDA for intravenous use and is indicated for blood volume determinations and protein turn-over (capillary leak) studies (Volumex Package Insert). The Volumex kit consists of a diagnostic radiopharmaceutical injectate provided as a prepackaged unit dose of 1 mL of I-131 iodinated human serum albumin, with a corresponding matched standard. There is no mixing, diluting, or preparation required for the HSA I-131 or the matched standard. Volumex is shipped ready to use. The Volumex radiopharmaceutical is administered intravenously through an access port of an established I.V. line. There are no known contraindications or adverse reactions. Safety and effectiveness in children have not been established. Volumex should be administered to a pregnant woman only if clearly needed, and formula feedings should be substituted for nursing mothers. Following administration of Volumex, collection and manipulation of blood specimens and the quality control and quality assurance of the

BVA-100 system are regulated by the Clinical Laboratory Improvement Amendments (CLIA). A laboratory is defined to be a facility that performs certain testing on human specimens in order to obtain information that can be used for the diagnosis, prevention, or treatment of any disease or impairment of a human being; or the assessment of the health of a human being; or procedures to determine, measure or otherwise describe the presence or absence of various substances or organisms in a human body (42 CFR 493.2). Tests are categorized as waived, moderate or high complexity. Daxor’s BVA-100 System consists of three waived tests (microhematocrit, centrifuge, fixed quantity pipetting), and an automated gamma counter, making the BVA-100 system a moderate complexity test.

Disposal

Dispose of all radioactive materials in accordance with regulatory standards. Infectious radioactive materials (i.e., syringes, needles, patient blood sample containers, glass tubes, etc.) will generally be held for as long as it takes for the radioactive material to decay to be no greater than background. Typically, the radioactivity of the used Volumex injectate, matched standards, and patient blood samples is no greater than background and can be disposed of as infectious waste within a sharps container upon completion of a blood volume study.

Patient and Analysis Area

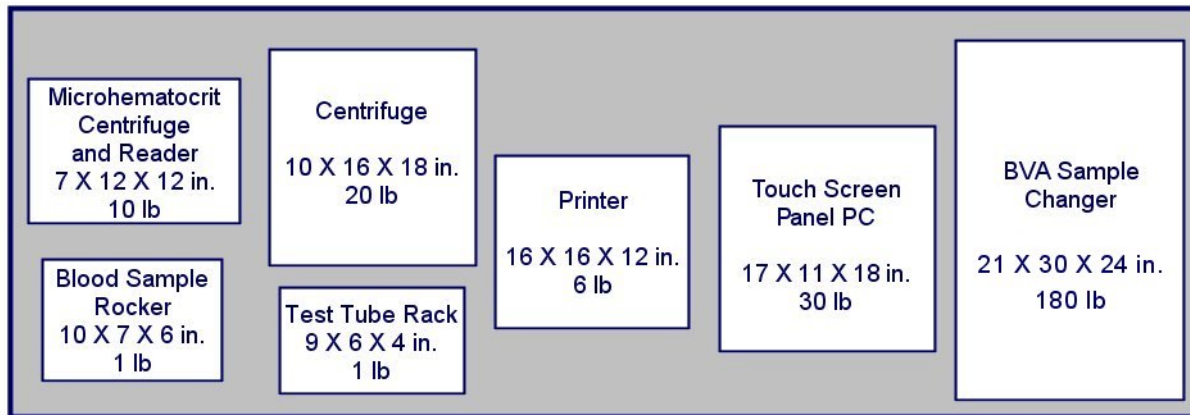
Patient and Analysis Area—The BVA System includes all the specialized equipment necessary to perform a blood volume analysis.

- BVA 100 Blood Volume Analyzer, touch screen panel PC, printer
- Microhematocrit centrifuge and reader
- Centrifuge
- Fixed volume pipet
- Patient blood sample rocker
- Test tube rack
- Calibrated timer
- Patient sample collection kit
- 15-amp, grounded, multi-plug power strip to accommodate 10 components

The following additional equipment is required to facilitate a BVA. (1) an accurate scale to measure patient height and weight, (2) a recumbent chair or stretcher, and (3) an IV stand with IV normal saline fluid.

The BVA-100 requires a controlled operating temperature range between 65 and 85 °F.

The following approximate space is required to support the BVA-100 system. A minimum of 5 feet wide by 3 feet deep is recommended. Components can be separated to accommodate space restrictions.



Approximate Space Requirements (not to scale) for BVA-100 Components