Instructions for Use

BVA-200®

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Part I. General Information – Understanding the Use of the Automated Analysis of Blood Samples Received by the Laboratory Following Administration of Radio-Iodinated ^{131}I Albumin Injection for Blood and Plasma Volume Determinations and Collaboration with the Clinical Site.[1]

1. General Information

1.1. INTENDED USE

The Daxor BVA-200® is an automated system that is used to measure/calculate the red cell mass (mL), plasma volume (mL) and total blood volume (mL), along with the related deviations from ideal values by amount (mL) and percentage (%) in adults. In addition, the Normalized Hematocrit (%) and Albumin Transudation Rate (%/min) are calculated. It is an in vitro medical device composed of a microprocessor, software, touchscreen, and gamma counter and accessory convenience kit.

The Daxor BVA-200 is intended to calculate human blood volumes by the method of tracer diffusion (Indicator dilution technique) with I-131 as the tracer after injection of I-131 Human Serum Albumin. The Daxor BVA-200 provides a Quantitative Assessment of total blood and plasma volumes using an automated system.

Data inputs to the software come from the measured characteristics of patient venous whole blood samples collected in K3EDTA vacutainer tubes (hematocrit and tracer concentration) and tracer calibration standards. The patient blood samples and the calibration standards are measured in a gamma counter, whose output is automatically input to this calculation program. The package also calculates the patient expected (or ideal) blood volume from physical parameters. Hyper- or hypovolemia, and associated red cell volumes are reported, with statistics showing the quality of the results.

For in vitro diagnostic use in a Clinical Laboratory setting and operated by laboratory technicians.

Rx use only.

1.2. PRINCIPLE OF THE TEST

The Daxor BVA-200 is designed to calculate human blood volume, using the method of tracer dilution, utilizing tagged serum albumin (I-131, resulting in "I-HSA"). Data inputs to the software come from the measured characteristics of patient blood samples, the patient's documented hematocrit, manufacturer's labeled tracer concentration, and tracer calibration standards. The software package also calculates the patient expected (or ideal) blood volume from physical parameters of height, weight, and sex that are provided to the laboratory in the labeling of the whole blood samples. Hyper- or hypovolemia, and associated red cell volumes, are reported, with statistics showing the quality of the results for evaluation by the clinician.

The patient blood samples and the calibration standards are measured in a gamma counter, whose output is automatically input to this calculation program.

[1] Refer to Approved Label for MEGATOPE (BLA 017837) for administration information.

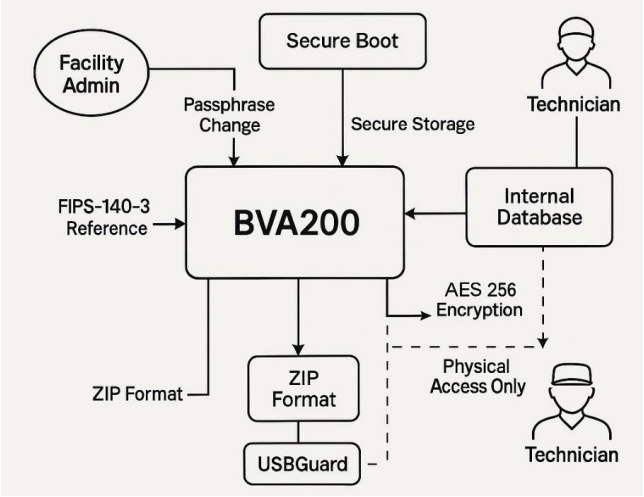
1.3. PRECAUTIONS

- Use the BVA-200 only for the purpose described in the instructions for use.
- Daxor recommends use of the accessories supplied to simplify and improve the accuracy of blood volume analyses.
- Suitable to be used in a medical laboratory environment.
- The radiation level in the blood samples measured is below 1 microcurie, which falls below the Nuclear Regulatory Commission's threshold of regulatory concern. This is considered an exempt amount under NRC guidelines, indicating no significant radiological safety concerns for handling or disposal.
- Specimens may be discarded, after their retention time, as standard medical waste in a biohazard container

1.4. CYBERSECURITY

- There is no network connection on the BVA-200 unit, and the wireless radios are disabled.
- The USB ports on the device are for transferring patient reports to a thumb drive or printer. Only Daxor approved thumb drives and printers may be used. The USB ports are configured to block any device not explicitly formatted for use with the BVA-200.
- The site administrator will be alerted when there are updates to the software. Updates will be performed by a Daxor Technician onsite, or the unit will be replaced with an updated unit.
- All test reports are saved on the device and are accessible in the Test Results Report List as described in Part III.
- Only Daxor Technicians have the capability to make changes to the device configuration.
- All user errors are logged on the device including failed login attempts.
- The BVA-200 does not track configuration changes internally. Records of updates are kept by Daxor.
- Failed login attempts per user are tracked. The device is not connected to any networks thus cannot send requests to unknown entities. The log is maintained in the database.
- The site administrator has permission to add users and change passwords. Users cannot be deleted from the unit to preserve the history logging of all users.
- Upon decommissioning of the unit, the user may request a complete history download of all information (including reports and user errors). The unit will be sanitized of sensitive, confidential, and proprietary data and software.

Diagram for Cybersecurity Control:



- There is no anti-malware enabled currently on the device. The firewall (ufw) isn't configurable by the user but the default policy is to deny all inbound traffic.
- SBOM is available upon request and housed on the daxor.com website.
- The timeline to develop and release patches is dependent on the risk level. Controlled risk vulnerabilities may take up to 3 months to complete and may be combined into one patch for ease of deployment. Uncontrolled risk vulnerabilities will be prioritized above controlled risk vulnerabilities and will be addressed and deployed as soon as possible.
- When a new version of the software is released, users are contacted via email informing them of the need for a software update. They have the option to return the product for updates or a Daxor Technician can perform the update at the user site. Patching capability is typically one week. Unusual circumstances (delay in shipping, Daxor Technician availability) may slightly increase this time.
- End of Support and End of Life for all software is checked at least once every 6 months. The verification date is updated in the SBOM Support documentation accordingly.
- SOUP issue trackers are checked at least once every 6 months. The verification date is updated in the SOUP list accordingly.
- CISA Known Exploited Vulnerabilities Catalog is checked at least once every 6 months.
- Security testing is run at least once every 6 months.

2. Patient Record Information to Accompany Blood Samples to Laboratory

Refer to the labeling of radio-iodinated ^{131}I albumin for drug administration information.

2.1. PATIENT SAMPLING RECORD

The laboratory receives a patient sample record generated at the patient site by the person(s) administering the radio-iodinated I-131 albumin.

The PATIENT SAMPLE RECORD includes the following information:

- Patient identification
- Patient weight
- Patient height
- Patient gender

- Patient hematocrit
- Healthcare provider to whom report is to be sent (Ordering Physician)
- Accession Number
- Sampling and Injection Date
- Injectate Dose
- Dose expiration date
- Dose Lot #
- Standard Lot #
- Presence of any amputation and amount (e.g., below knee, whole leg, etc.)
- Phlebotomist identification

The operator is responsible for ensuring that information is entered accurately. The software will flag values that are not acceptable (see below pages 17-19).

2.2. ANTICOAGULANT

The laboratory must ensure that all samples are drawn into purple top tubes (K3-EDTA) with a minimum of 2.5 mL of whole blood. Note that interference studies have demonstrated the measurement of the radiation emission is not affected by hemolysis. Thus, there is no need to check for hemolysis.

2.3. INDIVIDUAL PURPLE TOP TUBE LABELING

Each of the multiple blood timed samples must also be individually labeled with time of injection and time of sampling, including a baseline blood sample that is obtained prior to injection of radioisotope. Each such sample shall be labeled with:

- Patient identification number
- Sampling and Injection Date
- Time of injection (in 24-hour clock with minutes and seconds provided) or Dose Injection Timestamp, e.g., 12:06:30 for 6 minutes and 30 seconds after Noon.
- Timing of sample after baseline (in 24-hour clock with minutes and seconds provided).

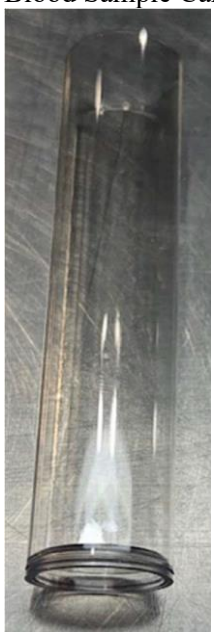
3. Convenience Materials Provided by Daxor

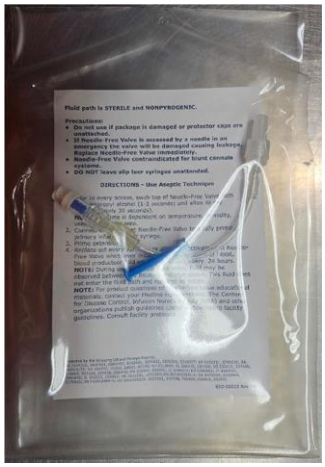
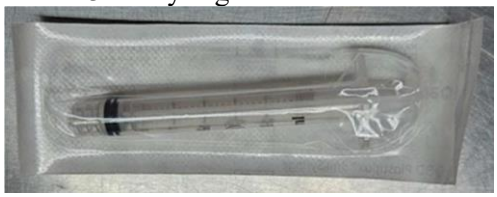
Daxor's Convenience Kit includes materials for safe transfer of whole blood at the laboratory into Whole Blood Collection Containers (WBCC) that facilitate safe and effective measurement of radiation emission in the BVA-200. The kit also includes materials for the use of the person(s) responsible for administering the drug product.

Daxor Equipment includes:

- The re-usable BVA-200 unit.

- The single use disposable Convenience Accessory Kit includes items for collection and processing of the blood samples and the purple top vacutainer. Other than the whole blood sample container and sleeve and cap, these are shown for convenience as this will be supplied to the clinical team:

Daxor Part Number	Part Name	Vendor(s)	Vendor Part Number
002-SCD2015	Blood Sample Cartridge	Daxor	002-SCD2015-B
002-SCD2165	Blood Sample Cartridge Sleeve 	ClearTec Packaging	SBT.012-.714
002-SCD2166	Blood Sample Cartridge Sleeve Cap	ClearTec Packaging	PRP.625RED
002-SCD2293	Cartridge Sleeve Sample Label	Daxor	002-SCD2293-A

Daxor Part Number	Part Name	Vendor(s)	Vendor Part Number
107623	20-Gauge x 1.16 inch Shielded IV Catheter	Becton Dickinson	382534
107622	6.5 inch IV Extension Set 	Medline	CIA2051260
002-SCD2163	3mL Vacutainer	Greiner	454217
002-SCD2164	Sterile 3mL Syringe 	Becton Dickinson	309657

Part II. Understanding the Clinical and Analytical Performance Characteristics of the BVA-200® and the Interpretation and Reporting of Results to the Healthcare Provider.

1. Performance Studies and Characteristics.

1.1. Clinical Comparison to BVA-100®

Performance of the BVA-200 was validated in a clinical comparison study with the predicate BVA-100 device, using blood derived from patients undergoing blood volume measurement with radio-iodinated I-131 albumin injection and measurement of subsequent samples with the BVA-100 as part of their clinical treatment or as part of a research study. A total of 319 unique, independent, comparable measurements were recorded. This study demonstrated robust and clinically meaningful substantial equivalence between measurements performed with the BVA-100 and -200. This study also demonstrated that the effects of matrix in whole blood (K3EDTA anticoagulant) are no different with the BVA-200 (used with whole blood) than with the BVA-100, which is cleared for marketing and analysis of blood volumes using the anticoagulated plasma fraction.

The following table shows the results for Passing-Bablok and Deming Regressions for the Instrument vs Comparator (BVA-200 vs. BVA-100):

Measure	Regression	N	Slope (95% CI)	Intercept (95% CI)	Pearson correlation coefficient
TBV	Passing-Bablok	319	1.031 (1.014 to 1.049)	-138 (-235 to -59)	0.99
TBV	Deming	319	1.033 (1.017 to 1.050)	-153 (-241 to -69)	0.99
RCV	Passing-Bablok	319	1.016 (1.002 to 1.030)	-25 (-50 to 2)	0.99
RCV	Deming	319	1.024 (1.008 to 1.040)	-37 (-68 to -10)	0.99
PV	Passing-Bablok	319	1.033 (1.016 to 1.051)	-99 (-155 to -46)	0.99
PV	Deming	319	1.029 (1.014 to 1.046)	-83 (-138 to -32)	0.99
nHct	Passing-Bablok	319	1.007 (0.982 to 1.032)	-0.19 (-1.18 to 0.77)	0.98
nHct	Deming	319	1.022 (0.999 to 1.047)	-0.76 (-1.71 to 0.21)	0.98

This study confirmed the reference range of the ideal (patient normal) values for the calculated volumes (which are based on calculations detailed in reference 9):

Reference Status	Normal	Has Medical Condition
N	22	41
Age	36.7 ± 16.5	53.8 ± 16.8

Reference Status	Normal	Has Medical Condition
Sex	Female = 59% Male = 41%	Female = 24% Male = 76%
Inpatient / Outpatient	Outpatient Subject = 100%	Outpatient Subject = 54% Inpatient Subject = 46%
Hct	41.3 ± 3.1	39.5 ± 5.91
Deviation from Ideal Weight (%)	26.9% ± 33.7%	40.2% ± 30.5%
Ideal TBV	4860 ± 655	5430 ± 848
Ideal RCV	1850 ± 328	2150 ± 397
Ideal PV	3010 ± 352	3280 ± 466
BVA200_TBV	4950 ± 808	5770 ± 1420
BVA200_RCV	1850 ± 357	2030 ± 507
BVA200_PV	3110 ± 497	3730 ± 1070
BVA200_SD	0.0196 ± 0.0107	0.0154 ± 0.00641
BVA200_Slope (%/min)	0.205% ± 0.070%	0.197% ± 0.076%
BVA200_TBV Deviation from patient Ideal (%)	+1.75% ± 7.77%	+5.72% ± 15.8%
BVA200_RCV Deviation from patient Ideal (%)	-0.13% ± 8.29%	-5.40% ± 15.3%
BVA200_PV Deviation from patient Ideal (%)	+3.07% ± 10.5%	+13.1% ± 23.2%

The following table shows the results of the reference range study, along with the categories listed in the BVA report. The study confirmed that the reference range is accurate.

Value	Normal Range	Normal Females (N=13)	Normal Males (N=9)
TBV	-8 to +8	0.529 ± 0.09	3.52 ± 5.58
RCV	-10 to +10	0.95 ± 8.39	-1.69 ± 8.39
PV	-8 to +8	0.291 ± 11.9	7.07 ± 6.78
ATR	0 to 0.25	0.179 ± 0.0608	0.242 ± 0.0692
nHct	37 - 41 (females) 40 - 46 (males)	39.0 ± 4.53	44.2 ± 3.74

Value	Normal	Mild	Moderate	Severe	Extreme
TBV (absolute dev %)	0 to 8	>8 to 16	>16 to 24	>24 to 32	>32
RCV (absolute dev %)	0 to 10	>10 to 20	>20 to 30	>30 to 40	>40
PV (absolute dev %)	0 to 8	>8 to 16	>16 to 24	>24 to 32	>32

Value	Normal	Elevated	High	Very High

ATR (%/min)	0 to 0.25	0.25 to 0.40	0.40 to 0.50	> 0.50

1.2. PRECISION

Venous whole blood samples were obtained from male and female volunteers. Samples were spiked with various amounts of Volumex™ (radio-iodinated albumin I-131) to duplicate representative low volume (30 microCuries/mL radio-diluted in 2727mL of blood volume) and high volume (25 microCuries/mL diluted in 6250 mL of blood volume) ranges encountered by the BVA-100. Reference samples without Volumex™ were also prepared. A set of samples were diluted with plasma to reduce the hematocrit by 10% – thus a range of baseline hematocrits from approximately 40% to approximately 50% is expected plus a set with a range from 30% to 40%. While testing of radiation equipment is more typically done with check samples without blood contents, the addition of blood contents permitted a thorough performance evaluation. Testing was conducted to assess relative precision in gamma radiation, TBV, PV, RCV, and nHCT in both the BVA-100 and BVA-200. Comparison of measurements taken at different times, under different conditions, and by different operators where the same sample was run in different settings demonstrated no substantial effect of choice of device on results.

The following tables show the precision results for the BVA-200. All total precision percentage coefficient of variation results were below 3.6%.

BVA-200 TBV

Sample			Repeatability (Within-Run)		Between-Run		Between-Day		Between-Operator		Between-Instrument		Between-Calibrator		Reproducibility Total Precision	
	N	Mean Value	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample (HIGH_Vol_1000)	64	989	16.7	1.69	0.1	0.01	14.3	1.45	2.0	0.20	4.2	0.42	3.3	0.33	22.71	2.30
Sample (HIGH_Vol_15000)	64	14,322	379.6	2.65	14.2	0.10	186.6	1.30	42.7	0.30	93.7	0.65	101.2	0.71	447.17	3.12
Sample (HIGH_Vol_2500)	64	2,443	51.6	2.11	4.6	0.19	36.6	1.50	6.9	0.28	12.3	0.50	20.1	0.82	68.02	2.78
Sample (HIGH_Vol_5000)	64	4,967	120.6	2.43	6.6	0.13	101.1	2.04	42.4	0.85	40.0	0.81	10.5	0.21	168.28	3.39
Sample (HIGH_Vol_7500)	64	7,392	173.3	2.34	1.7	0.02	106.0	1.43	23.8	0.32	52.6	0.71	60.6	0.82	219.72	2.97
Sample (LOW_Vol_1000)	64	1,108	13.8	1.25	1.3	0.12	14.1	1.27	4.3	0.39	2.8	0.25	3.7	0.33	20.76	1.87
Sample (LOW_Vol_15000)	64	16,133	353.9	2.19	50.1	0.31	79.9	0.50	107.9	0.67	115.2	0.71	81.9	0.51	407.14	2.52
Sample (LOW_Vol_2500)	64	2,747	68.6	2.50	2.1	0.08	31.3	1.14	15.5	0.56	1.7	0.06	22.4	0.82	80.22	2.92
Sample (LOW_Vol_5000)	64	5,419	104.6	1.93	8.0	0.15	84.1	1.55	17.7	0.33	33.8	0.62	26.2	0.48	142.20	2.62

Sample	N	Mean Value	Repeatability (Within-Run)		Between-Run		Between-Day		Between-Operator		Between-Instrument		Between-Calibrator		Reproducibility Total Precision	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample (LOW_Vol_7500)	64	6,925	151.0	2.18	1.0	0.01	84.1	1.21	63.7	0.92	7.3	0.11	47.6	0.69	190.40	2.75

BVA-200 RCV

Sample	N	Mean Value	Repeatability (Within-Run)		Between-Run		Between-Day		Between-Operator		Between-Instrument		Between-Calibrator		Total Precision	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample (HIGH_Vol_1000)	64	536	9.0	1.68	0.0	0.00	7.8	1.46	1.1	0.21	2.3	0.43	1.9	0.35	12.33	2.30
Sample (HIGH_Vol_15000)	64	7,984	211.6	2.65	7.9	0.10	104.0	1.30	23.8	0.30	52.2	0.65	56.4	0.71	249.25	3.12
Sample (HIGH_Vol_2500)	64	1,343	28.4	2.11	2.6	0.19	20.1	1.50	3.8	0.28	6.7	0.50	11.2	0.83	37.44	2.79
Sample (HIGH_Vol_5000)	64	2,763	67.1	2.43	3.7	0.13	56.3	2.04	23.7	0.86	22.2	0.80	5.8	0.21	93.67	3.39
Sample (HIGH_Vol_7500)	64	4,121	96.6	2.34	0.9	0.02	59.1	1.43	13.2	0.32	29.3	0.71	33.8	0.82	122.48	2.97
Sample (LOW_Vol_1000)	64	186	2.3	1.24	0.2	0.11	2.4	1.29	0.7	0.38	0.4	0.22	0.6	0.32	3.48	1.87
Sample (LOW_Vol_15000)	64	2,834	62.2	2.19	8.8	0.31	14.0	0.49	19.0	0.67	20.2	0.71	14.5	0.51	71.57	2.53
Sample (LOW_Vol_2500)	64	464	11.6	2.50	0.3	0.06	5.3	1.14	2.6	0.56	0.3	0.06	3.8	0.82	13.57	2.92
Sample (LOW_Vol_5000)	64	928	17.9	1.93	1.4	0.15	14.4	1.55	3.0	0.32	5.8	0.62	4.4	0.47	24.33	2.62
Sample (LOW_Vol_7500)	64	1,146	25.0	2.18	0.2	0.02	13.9	1.21	10.5	0.92	1.2	0.10	7.9	0.69	31.50	2.75

BVA-200 PV

Sample	N	Mean Value	Repeatability (Within-Run)		Between-Run		Between-Day		Between-Operator		Between-Instrument		Between-Calibrator		Reproducibility Total Precision	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample (HIGH_Vol_1000)	64	453	7.6	1.68	0.0	0.00	6.6	1.46	0.9	0.20	1.9	0.42	1.5	0.33	10.39	2.29
Sample (HIGH_Vol_15000)	64	6,339	168.0	2.65	6.3	0.10	82.5	1.30	18.9	0.30	41.4	0.65	44.8	0.71	197.86	3.12
Sample (HIGH_Vol_2500)	64	1,101	23.2	2.11	2.0	0.18	16.5	1.50	3.1	0.28	5.5	0.50	9.1	0.83	30.61	2.78
Sample (HIGH_Vol_5000)	64	2,204	53.5	2.43	3.0	0.14	44.9	2.04	18.9	0.86	17.7	0.80	4.7	0.21	74.70	3.39
Sample (HIGH_Vol_7500)	64	3,271	76.7	2.34	0.8	0.02	47.0	1.44	10.5	0.32	23.3	0.71	26.8	0.82	97.28	2.97
Sample (LOW_Vol_1000)	64	922	11.5	1.25	1.1	0.12	11.7	1.27	3.6	0.39	2.3	0.25	3.0	0.33	17.25	1.87
Sample (LOW_Vol_15000)	64	13,299	291.7	2.19	41.3	0.31	65.8	0.49	89.0	0.67	95.0	0.71	67.6	0.51	335.62	2.52
Sample (LOW_Vol_2500)	64	2,283	57.1	2.50	1.7	0.07	26.0	1.14	12.8	0.56	1.4	0.06	18.6	0.81	66.72	2.92
Sample (LOW_Vol_5000)	64	4,492	86.6	1.93	6.7	0.15	69.7	1.55	14.7	0.33	28.1	0.63	21.6	0.48	117.79	2.62
Sample (LOW_Vol_7500)	64	5,778	126.0	2.18	0.8	0.01	70.2	1.21	53.2	0.92	6.1	0.11	39.8	0.69	158.92	2.75

BVA-200 nHct

Sample	N	Mean Value	Repeatability (Within-Run)		Between-Run		Between-Day		Between-Operator		Between-Instrument		Between-Calibrator		Reproducibility Total Precision	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample (HIGH_Vol_1000)	64	12	0.2	1.67	0.0	0.00	0.2	1.67	0.0	0.00	0.1	0.83	0.0	0.00	0.30	2.50
Sample (HIGH_Vol_15000)	64	175	4.7	2.69	0.2	0.11	2.3	1.31	0.5	0.29	1.2	0.69	1.2	0.69	5.53	3.16
Sample (HIGH_Vol_2500)	64	29	0.6	2.07	0.1	0.34	0.4	1.38	0.1	0.34	0.2	0.69	0.2	0.69	0.79	2.72

Sample			Repeatability (Within-Run)		Between-Run		Between-Day		Between-Operator		Between-Instrument		Between-Calibrator		Reproducibility Total Precision	
Sample (HIGH_Vol_5000)	64	61	1.5	2.46	0.1	0.16	1.2	1.97	0.5	0.82	0.5	0.82	0.1	0.16	2.05	3.36
Sample (HIGH_Vol_7500)	64	90	2.1	2.33	0.0	0.00	1.3	1.44	0.3	0.33	0.6	0.67	0.7	0.78	2.65	2.95
Sample (LOW_Vol_1000)	64	4	0.1	2.50	0.0	0.00	0.1	2.50	0.0	0.00	0.0	0.00	0.0	0.00	0.14	3.54
Sample (LOW_Vol_15000)	64	62	1.4	2.26	0.2	0.32	0.3	0.48	0.4	0.65	0.4	0.65	0.3	0.48	1.58	2.55
Sample (LOW_Vol_2500)	64	10	0.3	3.00	0.0	0.00	0.1	1.00	0.1	1.00	0.0	0.00	0.1	1.00	0.35	3.46
Sample (LOW_Vol_5000)	64	20	0.4	2.00	0.0	0.00	0.3	1.50	0.1	0.50	0.1	0.50	0.1	0.50	0.53	2.65
Sample (LOW_Vol_7500)	64	25	0.6	2.40	0.0	0.00	0.3	1.20	0.2	0.80	0.0	0.00	0.2	0.80	0.73	2.91

1.3. LINEARITY

Multiple samples were measured in both the BVA-100 and BVA-200 to assess both linearity and bias at the high and low measurements. The following results were obtained from the data in the method comparison study:

	N	Mean Expected	Mean Observed	SD	CV Percent	Global Slope	Mean Bias Percent	CI Lower	CI Upper
TBV	319	5323	5348	170	3.24	1.02	0.41	5088	5608
RCV	319	1905	1912	56	3.00	1.01	0.38	1828	1996
PV	319	3417	3433	105	3.11	1.02	0.37	3275	3590
nHCT	319	40.14	40.27	1.22	3.00	1.00	0.37	38.43	42.11

An additional study using contrived samples was performed to verify linearity and absence of bias at very high and low volume measurements (2000 mL to 18000 mL). The coefficient of variation (CV) for repeatability was ≤5% for all measured parameters across the tested concentration range. The maximum deviation from linearity was ≤8% for all measured parameters across the tested concentration range, as determined by comparison to a linear regression model. In conclusion, there is no clinically meaningful deviation from linearity.

1.4. CARRYOVER

Analysis of the impact of a preceding high level spiked sample on the values of a following low level spiked sample were conducted for the BVA- 200 analyses of radiation emission. Sufficient high-level samples immediately followed by low-level samples by the same operator and with the same equipment were utilized to assess the potential for carryover. In conclusion, there is no carryover observed.

Be sure that blood is not spilled in the sample port. Clean as necessary. QC checks will demonstrate contamination if any.

1.5. SAMPLE STABILITY

The spiked venous whole blood stability, settling, FEDEX shipping study, and non-level positioning demonstrate that the gamma emission from a fixed amount of blood is impervious to temperature and humidity; that the decrease in radiation emission over time corresponds to the known decrease in radiation from the isotope in question (I-131); that the WBCC can withstand shipping; that the BVA-200 operates in a non-level position up to 15 degrees in any direction; and that settling does not affect gamma emissions read by the gamma counter scintillator inside the BVA-200.

Stability testing was performed on whole blood cartridges that were first measured, then allowed to settle in either refrigerated or room temperature conditions for a period up to four days. Samples were recounted at 18, 24, 48, and 120 hours in both agitated and settled states. Contrived samples were used that covered a wide range of possible Hct and volume values. No significant differences were observed, nor was there any significant drift of measurements observed. The study performed validates the measurement of cartridges up to 4 days of stability at refrigerated (4ºC/ 40ºF) and room temperature (22ºC/ 72ºF).

1.6. HANDLING TESTING/SHIPPING/DURABILITY OF THE DEVICE

A cartridge drop test was performed. The results validated that the cartridges still met all performance criteria after cartridges were dropped from a height of 48 inches onto a hard surface. None of the average measured parameters of the test differed from the pre-drop measurements by more than 2.7%. .

A simulated shipping & handling study was performed to assess resistance to breakage and radio-emission stability in a standardized shipping stress testing (Study ISTA-3A). This includes testing for temperature, humidity, vibration, and shock. As with the settling study, this study demonstrated that, once filled, the whole blood cartridge emission rate performs as expected for the volume and concentration of radioisotope. The testing validated sample integrity after shipping blood in a vacutainer tube, sample integrity after shipping blood in a cartridge, sample integrity after shipping a cartridge from a shipped vacutainer, and device integrity after shipping a device and a shipping cartridge. None of the average measured parameters of the test differed from the pre-ship measurements by more than 3.1%.

Tilt position – Testing established that the measurement of the analyte concentration (I-131 gamma emission) from the venous whole blood sample is stable notwithstanding non-level positioning at 15 degrees in any direction. None of the average measured parameters of the test differed from the pre-ship measurements by more than 3.1%.

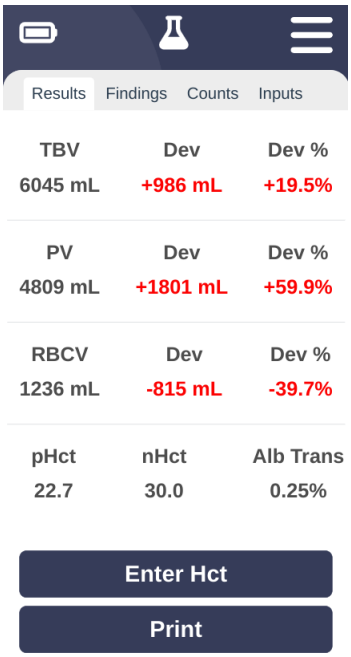
1.7. INTERFERENCE

A hemolysis interference study was performed. Hemolysis is a common interferant in medical diagnostic tests involving measuring analytes in blood. A study was performed with contrived samples to compare the BVA-200 reported parameters across three hemolysis levels. Baseline samples were verified to have

no hemolysis. Partial hemolysis was induced by subjecting blood samples to a partial freezing cycle at -20C. Complete hemolysis was induced by subjecting the partially hemolyzed blood samples to an additional complete freezing cycle (until completely frozen) at -20C. Level of hemolysis was verified by three independent methods (colorimetric matching, quantification of fluorescent absorption at 540 nm, and Hct measurement). Ten independent samples were used, with volume values measured after partial hemolysis and gross hemolysis compared to the baseline (no hemolysis). Results for all parameters were not affected by hemolysis: partial hemolysis values were - 0.72% ± 0.77% different from the baseline, and gross hemolysis values were - 0.14% ± 2.16% different from the baseline.

2. Sharing the Results

The operator can view the interactive screen and print out the report. The screenshot below from the BVA-200 touchscreen (which is also provided in the written printed report) shows an exemplary view of the BVA results.



The touchscreen permits the following operations as needed or provides displayed information as follows:

- Enter Hematocrit - This will open the Hematocrit Entry screen again if the operator needs to make a correction.
- Print - This will open the printer dialog and let the operator select a printer to print the test results.
- TBV - This is the patient's Total Blood Volume.
- Dev (on TBV row) - This is the amount (mL) that the patient's TBV deviates from the calculated ideal.
- Dev % (on TBV row) - This is the percentage that the patient's TBV deviates from the calculated ideal.
- PV - This is the patient's Plasma Volume.
- Dev (on PV row) - This is the amount (mL) that the patient's PV deviates from the calculated ideal.
- Dev % (on PV row) - This is the percentage that the patient's PV deviates

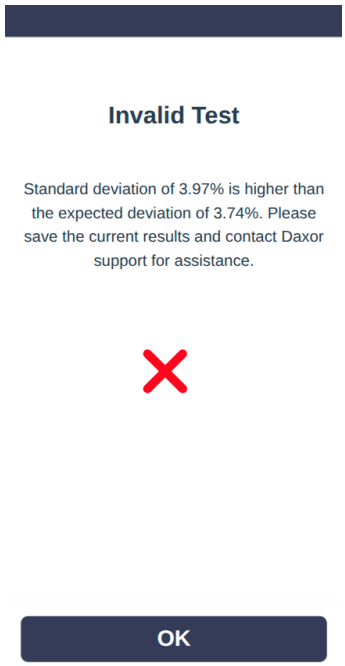
from the calculated ideal.

- RBCV - This is the patient's Red Blood Cell Volume.
- Dev (on RBCV row) - This is the amount (mL) that the patient's RBCV deviates from the calculated ideal.
- Dev % (on RBCV row) - This is the percentage that the patient's RBCV deviates from the calculated ideal.
- Items in RED are outside of normal range.
- pHct - This is the patient's peripheral hematocrit that the user entered in the Hematocrit Entry Screen.
- nHct - Normalized Hematocrit is the Hematocrit that would be observed if total blood volume were adjusted to normal by changing the plasma volume.
- Alb Trans - This is the patient's Albumin Transudation Rate
- Transudation Analysis - This shows where the patient's Albumin Transudation Rate falls when compared to ideal.

The table below shows software controls that affect the reporting range. Input values that exceed the "Warning Limits" prompt the user to confirm the value. Input values that exceed the "Warning Limits" are not validated by BVA-200. Output Values that exceed the warning limits result in a **warning indication on the report**. Output values that exceed the reporting limits are not reported numerically but will simply be reported as "Outside Range". In other words, for warnings, the user is informed that the output value is extreme (although still within reportable range) to draw attention to the possibility that there was some mistake in either the measurement or in the input values (for example, a gross error in the input value for patient weight).

		Warning Limits	
	Value	**Low**	**High**
Input Values	Height (inches)	48	84
	Weight (lbs)	1	400
	Hct	20	50
Output Values	TBV deviation	-40%	+50%
	RCV deviation	-40%	+50%
	PV deviation	-40%	+50%
	nHct	20	50
	Standard Deviation	0	3.74%

- The BVA-200 will identify the standard deviation of any multi-sample test as being "invalid" if the value is outside the acceptable error range; if so, the following user screen will be displayed:



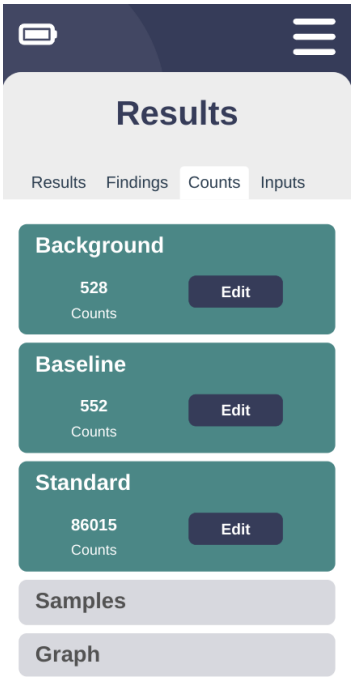
- Because the reporting range for the measurement is determined by deviations from ideal values, reportable ranges for TBV, RCV, and PV are patient-specific. The table below shows some examples of reportable ranges for a few sample patients with different characteristics.

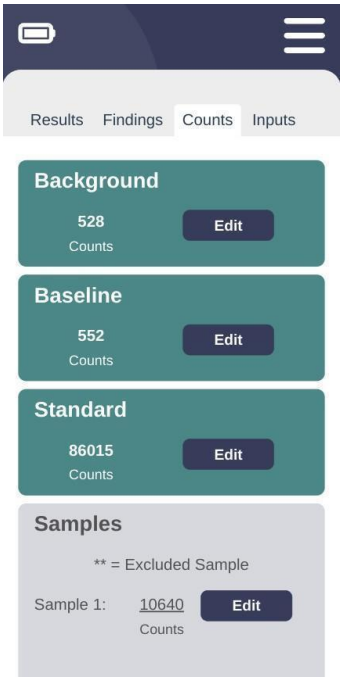
Reportable Ranges for TBV, RCV, and PV: examples

		short female			typical female			typical male			tall male		
	Height (in)	48	48	48	65	65	65	69	69	69	82	82	82
	Weight (lbs)	60	80	200	110	150	300	140	200	350	200	300	600
	Sex	F	F	F	F	F	F	M	M	M	M	M	M
TBV (mL)	**Ideal**	2194	2508	3991	3953	4233	6147	4846	5135	7269	7028	7845	11863
	Min (-60%)	878	1003	1596	1581	1693	2459	1938	2054	2908	2811	3138	4745
	Max (+150%)	5485	6270	9978	9883	10583	15368	12115	12838	18173	17570	19613	29658
RCV (mL)	**Ideal**	791	904	1438	1424	1525	2215	1965	2155	2947	2849	3180	4809
	Min (-60%)	316	362	575	570	610	886	786	862	1179	1140	1272	1924
	Max (+150%)	1978	2260	3595	3560	3813	5538	4913	5388	7368	7123	7950	12023
PV (mL)	**Ideal**	1404	1604	2552	2528	2708	3932	2882	3160	4322	4179	4665	7054
	Min (-60%)	562	642	1021	1011	1083	1573	1153	1264	1729	1672	1866	2822
	Max (+150%)	3510	4010	6380	6320	6770	9830	7205	7900	10805	10448	11663	17635

3. Counts

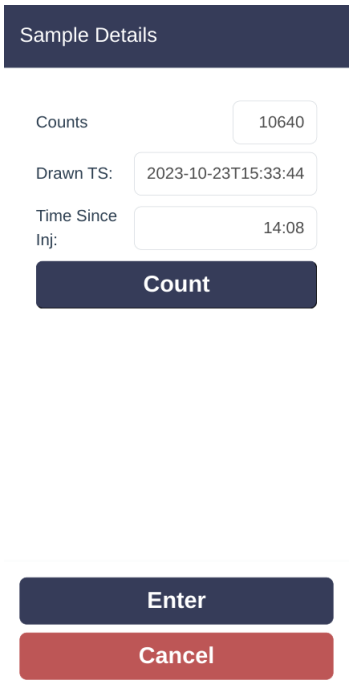
- This tab shows the counts for everything read by the system and includes the ability to modify the timestamps and re-count any given sample. The edit button beside each count will open the sample screen to allow any aspect of the samples to be modified. In addition, the bottom button will take the user to view a chart of the counts & unadjusted blood volumes.



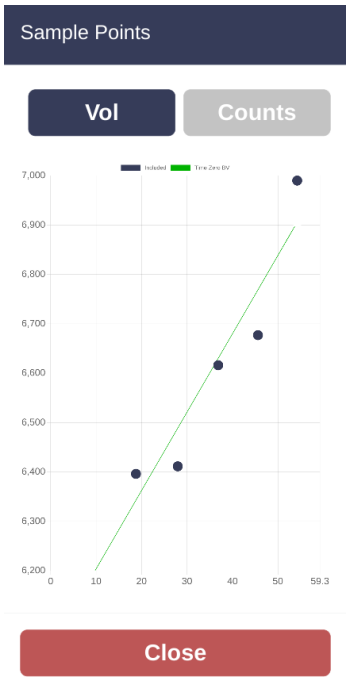


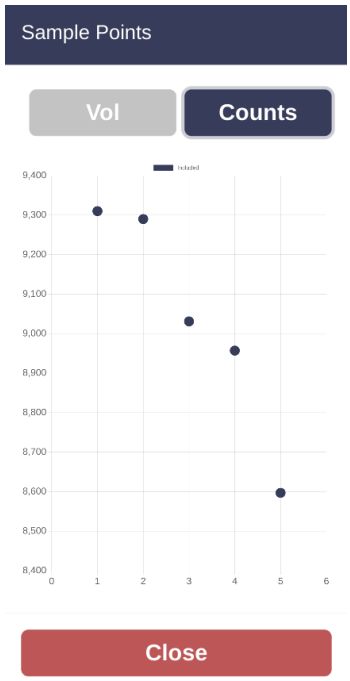
4. Sample Details

- This screen lets the user edit the timestamp or recount the sample.
- If a recount is done at a later time, the software algorithm adjusts the counts to accommodate for the decay of the Volumex.

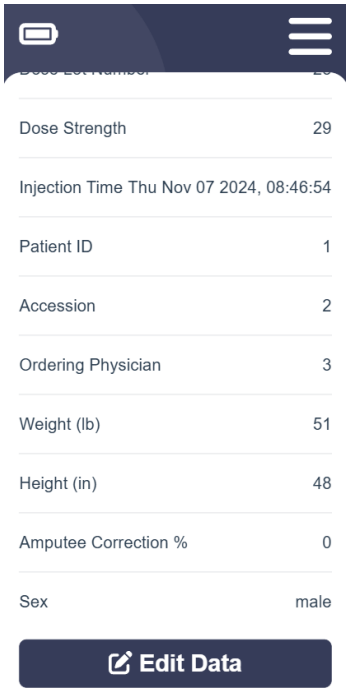


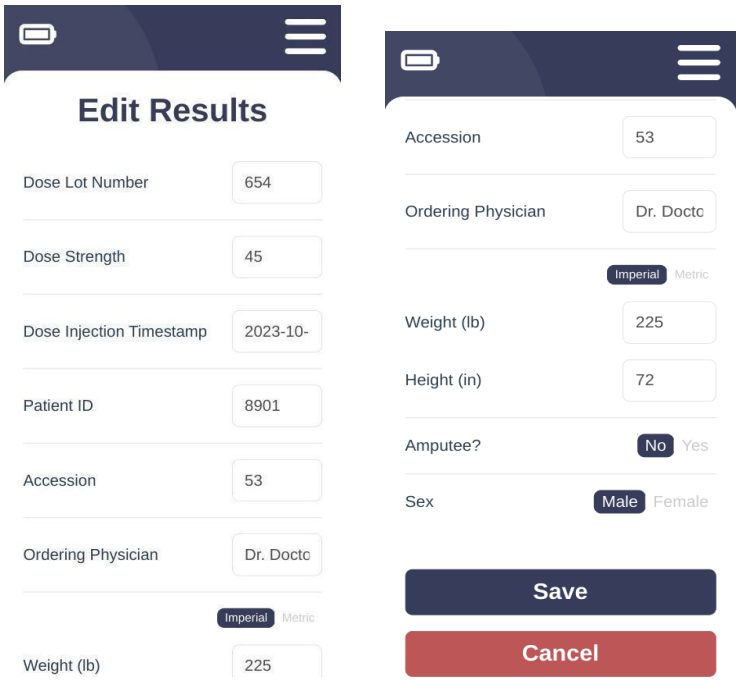
- Counts - This reflects the counts read by the detector.
- Drawn TS - This is the precise timestamp the sample was drawn.
- Time Since Inj - This is an easier way to adjust the Drawn TS in that the user may input minutes and seconds since injection and the system will then calculate the precise timestamp of the draw. Must be in format MM:SS.
- Count - This will start reading from the detector and generate the number of counts. The assumption is that the sample in question is in the well and should be used only during testing or to check stored samples.
- Enter - This simply saves the details of the sample.
- Cancel - This will leave the screen and discard any changes made.
- Note: for background, baseline, and standard samples, there will be no Drawn TS nor Time Since Inj for the user to enter since the timestamps for those are irrelevant.
- Graph - This shows a chart of the unadjusted blood volumes and counts at specific time intervals used to produce the Time Zero Blood Volume (Patient's TBV).





- Vol - This button will change the chart to show the unadjusted volumes.
- Counts - This button will change the chart to show the counts.
- Close - This will return the user to the previous screen.
- Inputs - This shows the patient data and injectate dose data entered during the test as well as a button to edit the data.





- Save - This will save any modifications made.
- Cancel - This will return the user to the prior screen discarding any modifications.
- Note: For details about each individual field, please refer to the test pages.

Part III. Information for Laboratory Operators – Step-by-Step Instructions from Receipt of Whole Blood to Preparing and Sharing Results.

1. Precautions

- Daxor recommends use of the accessories supplied to simplify and improve the accuracy of blood volume analyses.
- Do not use the BVA-200 if it is not working properly or if it has suffered any damage. Examples include (a) damage to the flexible supply cord or its plug, (b) damage caused by dropping the equipment, and (c) damage caused by splashing liquid onto it.
- Do not let the BVA-200 or any of its flexible cords come into contact with surfaces which are too hot to touch.
- Do not place anything on top of the BVA-200.
- Suitable to be used in a medical laboratory environment.
- BVA-200 Device is in compliance in environments with Conducted Emissions from 150 kHz to 30 MHz and Radiated Emissions from 30 MHz to 1 GHz.
- The device was tested and passed Radiated Immunity from 80 Mhz to 6 GHz and Fast Transient/Burst Immunity to severity levels of 1 kV.
- Surge Immunity was tested and passed with 5 positive discharges and 5 negative discharges at levels of 0.5kV Line to Line and 1kV Line to PE at every 90° phase angle starting at the 0° phase angle. Signal lines were tested with 5 positive discharges and 5 negative discharges of 1kV at asynchronous phase angles.
- Move BVA-200 away at least 3 meters from any devices that pose potential harmful interference such as Metal detectors, electronic article surveillance systems (EAS), diathermy, electrocautery, electrosurgical, and MRI equipment.
- “Harmful interference” is defined in 47 CFR § 2.122 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.
- The BVA-200 analyzer is used to test whole blood containing I-131-HSA (<1 microcuries) in an enclosed source (vacutainer tube or cartridge with sleeve to limit biohazard) intended for the clinical laboratory and handled by laboratory operators for storing, filling cartridges and disposing of samples. The radiation level in the blood samples is below 1 microcurie, which is not distinguishable from background, and thus falls below the Nuclear Regulatory Commissioner’s threshold for concern. This level of exposure is exempt from occupational monitoring under NRC guidelines (10 CFR 31.11, 10 CFR Part 32, and 10 CFR Part 31) indicating no significant radiological safety concerns for handling or disposal. Specimens may be discarded after retention time, as standard medical waste in a biohazard container.
- Specimens may be discarded, after their retention time, as standard medical waste in a biohazard container

2. Acceptance of Whole Blood Samples – Patient Record Information, Anti-Coagulation, and Labeling of Samples of Whole Blood

2.1. PATIENT SAMPLE RECORD

The laboratory receives a patient sample record generated at the patient site by the person(s) administering the radio-iodinated I-131 albumin. The PATIENT SAMPLE RECORD includes the following information:

- Patient identification
- Patient weight
- Patient height
- Patient gender
- Patient hematocrit
- Healthcare provider to whom report is to be sent (Ordering Physician)
- Accession Number
- Sampling and Injection Date
- Injectate Dose
- Dose expiration date
- Dose Lot #
- Standard Lot #
- Presence of any amputation and amount (e.g., below knee, whole leg, etc.)
- Phlebotomist identification

2.2. ANTICOAGULANT

The laboratory must ensure that all samples are present in purple top tubes (K3-EDTA) with a minimum of 2.5 mL of whole blood. Note that interference studies have demonstrated the measurement of the radiation emission is not affected by hemolysis. Thus, there is no need to check for hemolysis.

2.3. INDIVIDUAL PURPLE TOP TUBE LABELING

Each of the multiple blood timed samples must also be individually labeled. Each such sample shall be labeled (on the tube, and/or on the patient sample record) with:

- Patient identification number
- Sample Time:
  - Time of injection (in 24-hour clock with minutes and seconds provided) or Dose Injection Timestamp, e.g., 12:06:30 for 6 minutes and 30 seconds after Noon.
  - Timing of sample after baseline (in 24-hour clock with minutes and seconds provided).

2.4. SAMPLE STABILITY

Sample stability studies have shown that the measurement of cartridges can be conducted up to 4 days after filling when stored either at refrigerated (40°F / 4°C) or room temperature (72°F / 22°C) conditions. After filling whole blood containers (below), specimens can be stored in a tube rack so that they stand upright for up to 4 days at refrigerated (40°F / 4°C) or room temperature (72°F / 22°C).

2.5. ADDITIONAL ACCEPTANCE CHECKS / SPECIMEN HANDLING

- The laboratory operator is responsible for assuring that the clinical samples were properly labeled before beginning unit preparation and measurement.
  - The dose lot # and sample lot #’s must match.
  - The dose expiration date should not have yet occurred.
- After filling from purple top tubes (below), inspect the cartridges to ensure there are no large air bubbles or leakage.

- Radioactivity levels in the specimens are very low. It is recommended that the samples can be kept for up to 7 days for resolution of clerical errors or patient identification errors. However, there is no guarantee that radioactivity can be measured accurately beyond the expiration date of the original ^{131}I injectate. It is recommended that the tubes be kept separated according to date.
- Specimens may be discarded, after their retention time, as standard medical waste in a biohazard container.
- Sample photographs are shown below:

- The cartridges should be placed with an appropriate sleeve, e.g., “baseline,” “sample 1,” etc., as shown below.

2.6. STANDARD

The standard is pre-prepared by Daxor and provides the exact concentration of analyte (radiation emission level) that is to be found in a dilution of the original injectate to a volume of 1000 mL. The standard is used by the operator only as shown below.

3. Initial Set-up After Sample Acceptance – Filling Whole Blood Cartridges Preparatory to Analysis.

i. Safety:

1. Biohazard - Observe universal precautions applicable to blood and body fluids for handling the samples.
2. If leakage from the Standards container is noted, perform radiation safety procedures in accordance with site SOP.
3. If leakage is noted from the blood samples, do not use and report to clinical team.

3.1. BASELINE SAMPLE – LABELED AS OBTAINED BEFORE DRUG ADMINISTRATION

- Using the clear sleeve labeled “Baseline”, remove the red cap from the sleeve and remove the cartridge from the sleeve. Set the open sleeve in the vial rack. Keep the cap and cartridge close by. (See Single Use Convenience Kit Components at Part I, Section 3).

- Using the filled purple top blood sample labeled as a baseline blood sample fill a provided WBCC ensuring that the WBCC is completely filled to the membrane. Filling is complete when resistance to further filling is provided by the air-permeable membrane on the opposite side of the cartridge.

- Inspect the cartridge to ensure there are no large air bubbles. If large bubbles are present, gently flick the cartridge while applying gentle pressure on the syringe plunger until bubbles disappear. Once the syringe is removed, the cartridge self-seals and will not leak.

- Place the used syringe in the appropriate disposal container.
- Place the filled cartridge back into the sleeve labeled “Baseline” **with the small Luer lock side facing up** as shown on the label.

3.2. FILLING WBCC FROM PROPERLY LABELED POST-INJECTION BLOOD SAMPLES

Using the blood samples labeled as Sample 1, Sample 2, etc., follow the same procedure below to fill each corresponding Whole Blood Cartridge Container. For instance, using the clear sleeve labeled "Sample 1", remove the red cap from the sleeve and remove the cartridge from the sleeve. Set the open sleeve in the vial rack. Keep the cap and cartridge close by.

- Transfer blood from vacutainer into a 3-mL syringe using a female vacutainer access device.
- Transfer blood from the 3-mL syringe to fill the sample cartridge.
- Inspect the cartridge to ensure there are no large air bubbles. If large bubbles are present, gently flick the cartridge while applying gentle pressure on the syringe plunger until bubbles disappear. Once the syringe is removed, the cartridge self-seals and will not leak.

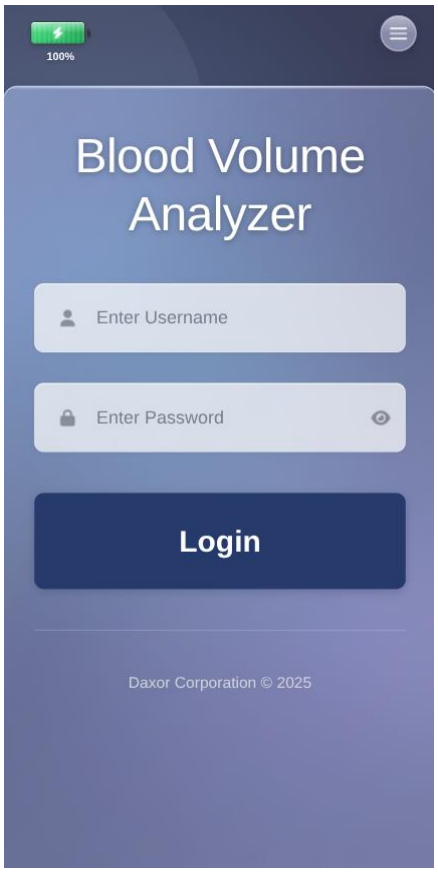
- Place the used syringe in the appropriate disposal container.
- Place the filled cartridge back into the sleeve labeled “Sample 1” with the small luer lock side facing up as shown on the label.

- Repeat with subsequent samples. The ordering physician will have specified the number of samples to use (up to 5 samples).

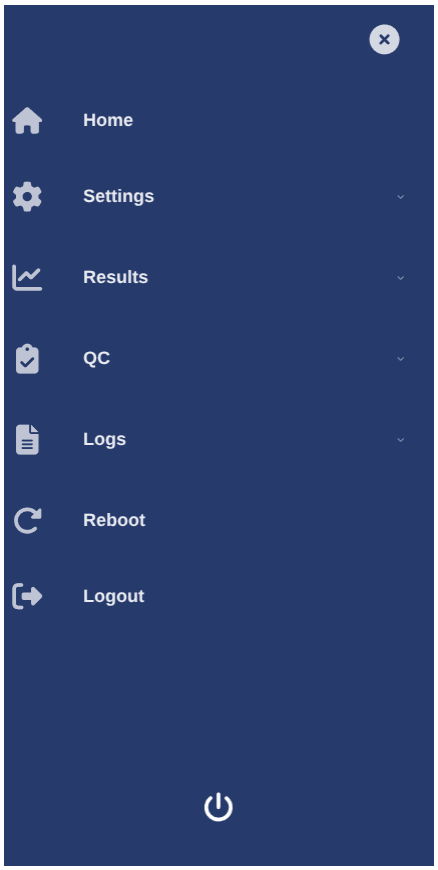
4. BVA-200 Unit Preparation and Setting Up for Sample Analysis

- Place the BVA-200 unit on a surface that is:
    - Level (no more than 15° tilt is permissible)
    - Free of vibration and sudden jolts
    - Free of hair, dust, and other contaminants
    - Free of interfering equipment with enough space to operate (at least 3 feet from any other electronic equipment)
    - Located in an ambient operating temperature of 60°F / 16°C / 16°C to 85°F / 29°C.
- Plug the power supply into the unit, then plug the detachable power supply cord into the power adapter and into a grounded electrical outlet. The power cord is specific to Daxor's BVA-200, please call Daxor Technical Service if cord is lost or misplaced. Do not permit the power cord to contact any hot surface.

- Press the power button to turn on the unit.
- The display then shows the following



- The operator will be given a username and password by the site or laboratory administrator. The site administrator will have a username and password that will allow them to add usernames and passwords for each person who will be using the BVA-200. Passwords must be eight characters minimum with at least one upper case letter and one number.
- Access the system menu by clicking the standard hamburger menu icon (three parallel horizontal lines) in the upper right-hand corner.

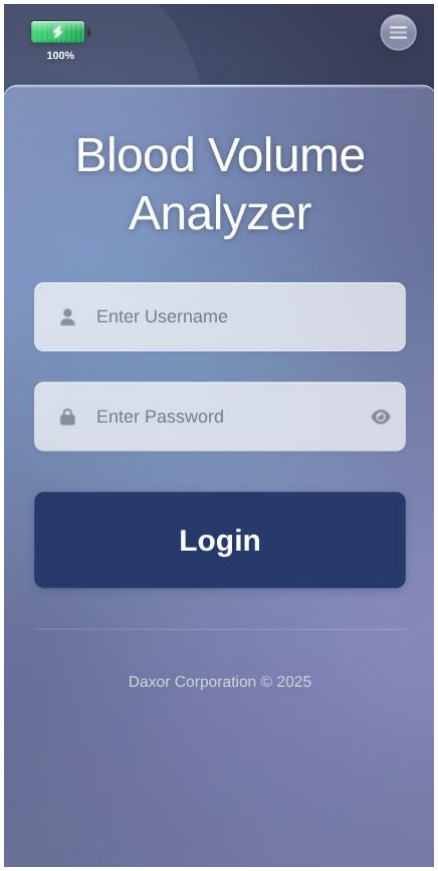


- The hamburger allows the user to access the following functions (each page is more fully detailed in subsequent sections of the Operator's Manual):
    - Home - Returns the user to the landing screen. It will stop any use of the detector.
    - System Settings – Allows the user to adjust screen and volume settings.
    - Test Results - This will take the user to the list of all test results including incomplete ones that are waiting for more information (such as the hematocrit) before the BVA calculations can occur. The user will have the ability to export test result(s) as either a PDF or Microsoft Excel document within a password protected and encrypted ZIP file to a USB flash drive. In addition, the user may load individual test results to modify. Lastly, the user may print any test result.
    - QC Logs - Similar to Test Results, this will take the user to the list of all QC logs recorded with the ability to export as PDF or Microsoft Excel within a password and encrypted ZIP file to a USB flash drive. The user may also print.
    - QC - This will take the user to the QC landing page which displays an indicator if any given QC test is still valid or needs to be performed.
    - Reboot - Reboots the system. It takes about 5 minutes.
    - Shutdown - Shuts down the system. Useful to preserve the battery charge prior to shipping.
    - Logout - Logs the current user out of the system. Useful to prevent unauthorized access.

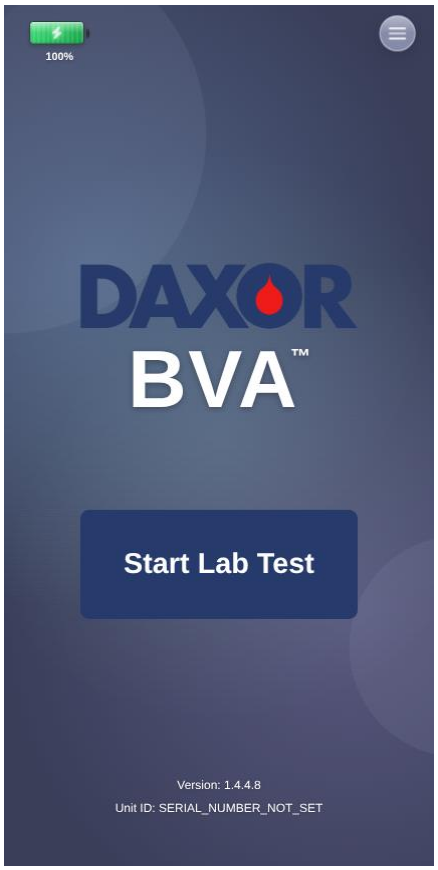
5. Running the Test

5.1. RUNNING THE TEST

- Current Hematocrit - The clinical team provides a hematocrit value of the patient as part of the Patient Sample Record.
- Power on the BVA-200 Unit and log in with your assigned username and password.

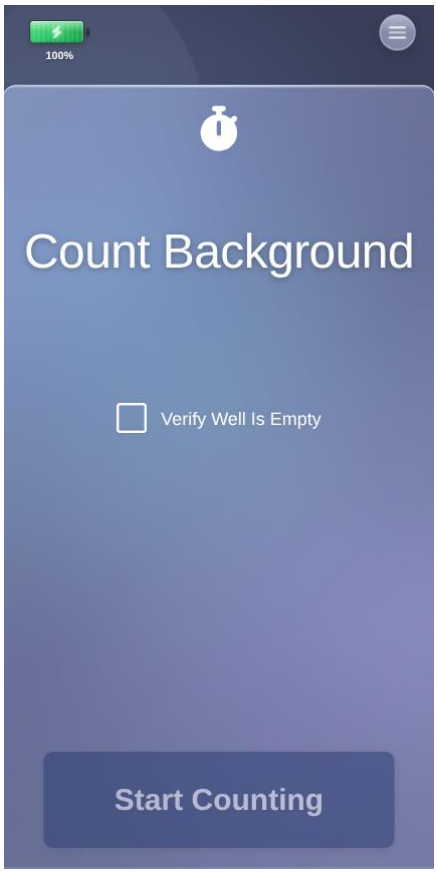


- This will take you to the Home Screen. Press “Start Lab Test”.



- If the appropriate required QC tests need to be performed, the user will be redirected to the QC page to perform the necessary procedures. If / after all necessary QC tests are run, the user will be redirected to the first page of the guided BVA test. A background count is taken for 1 minute to detect any potential radioactivity in the surrounding area that may affect the results.
- There will be 3 checkboxes. These are “Dose Not Expired”, “Dose & Standard Lot #’s Match”, and “Current Hematocrit”.
- Dose Not Expired - The operator should check the expiration date on the sample labeling to ensure it has not expired. Upon confirmation, the operator should click this checkbox. The operator cannot continue with the test if this box isn’t checked.
- Dose & Standard Lot #’s Match - The operator should make sure the dose lot # injected and the standard lot # are identical. Upon confirmation, the operator should click this checkbox. The operator cannot continue with the test if this box is not checked.
- Current Hematocrit – The operator has previously checked that a hematocrit was provided on the Patient Sample Record by the clinical team.
- Next - Once the operator has completed the tasks and checked each corresponding checkbox, the Next button will become enabled and the operator can click it to proceed to the next step.
- The BVA-200 will then automatically conduct a background count for 1 minute to detect any potential radioactivity in the surrounding area that may affect the results. If there is a unacceptable level of background radiation in the laboratory, an error will be reported and the testing cannot proceed. The operator should check with the laboratory director to identify if there is a source of background radiation.

- This page is to let the user know the system is ready to start counting the background.

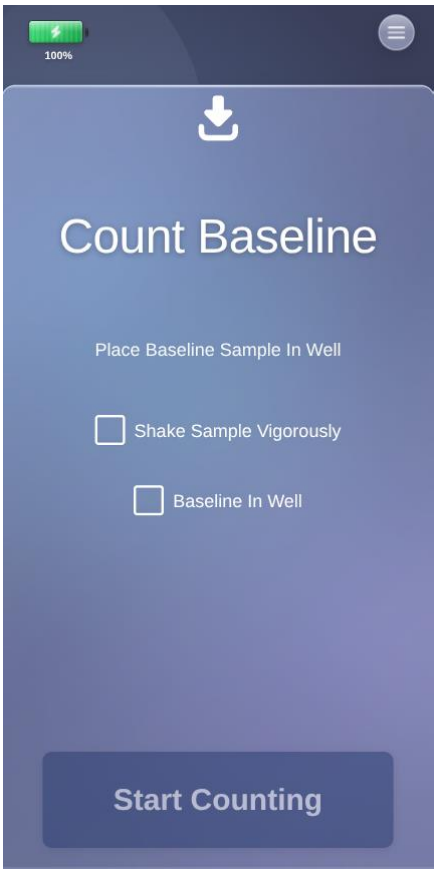


- Verify that there is nothing in the well, check the box and hit the “Start Counting” button. While the background is counting, it will bring you to the dose injection timestamp screen.

- You will need to refer to the “Patient Sample Record” form for the rest of the next steps (see Part III, Section 2.1)
- Enter the assayed dose strength (enter value at Part III, Section 2.1, Injectate Dose)
- Click in the “Dose injection timestamp” box. Enter the date and time the dose was injected.
- Select “Next.”
- Wait for the background to finish counting.

5.2. COUNT BASELINE SAMPLE

- When the background is finished counting, the user will automatically be taken to the Count Baseline screen.

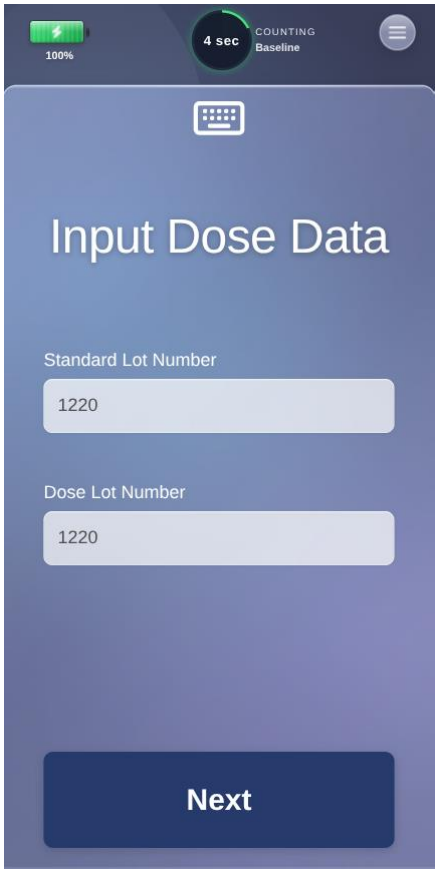


- Follow the prompts on the screen to count the labeled **Baseline Sample**.
  - Shake baseline sample vigorously: Place fingers on top of cap and on bottom of sleeve to ensure cap does not come off. Shake vigorously for 30 seconds.
  - Baseline In Well – The user should place the Baseline Sample in the well so that the bottom of the Baseline label is flush with the top of the well. Check the box to indicate that it is ready to be counted. Once checked, the Start Counting button will become enabled.

- Start Counting - This button will only be enabled if the user has confirmed that the baseline sample is in the well and ready to be counted. Clicking the button will activate the detector and start counting the baseline sample.

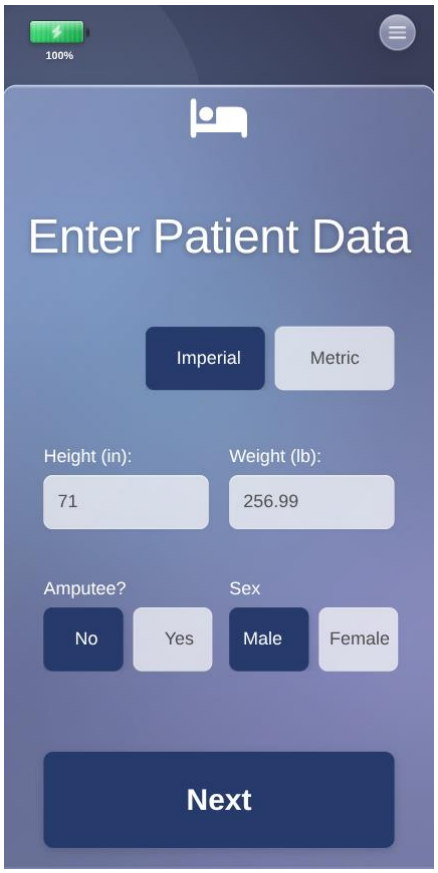
5.3. INPUT DOSE AND PATIENT DATA FROM PATIENT SAMPLE RECORD (PART III, SECTION 2.1.)

- Input Injectate Dose Data: This screen is where the user will input data about the injectate dose.



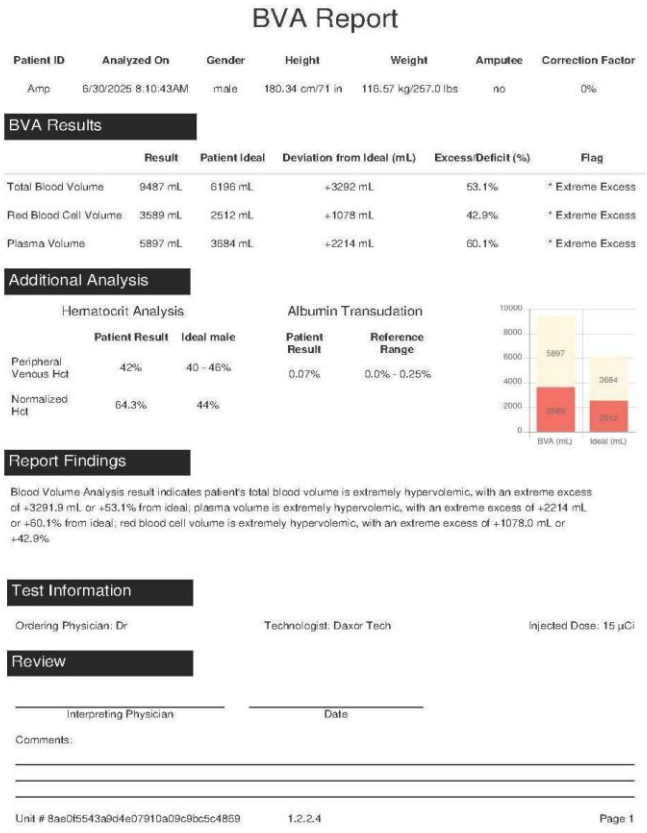
- Enter the Standard and Dose lot numbers from the Patient Sample Record. [Note: as previously, these numbers must match.]
- Next - The button will only allow the user to proceed if the input from the user in the above fields has passed validation, i.e., entered information matches acceptable values.

- Enter Patient Data: This screen is where the operator will input the values from the Patient Sample Record: Patient's height, weight, amputee status, and sex.



- Imperial / Metric - This button toggles the input values to reflect if the user is inputting the weight / height in Imperial or Metric units of measurement. All values stored in the database and used in the calculations will be metric so if the user enters the data in Imperial units, it will be converted.
- Height - This is how tall the patient is reported to be.
- Weight - This is how much the patient is reported to weigh.
- Amputee? - This is used to select if the patient has any amputated or otherwise missing limbs. Clicking on Yes will open the Amputee Selection screen.
- Sex - Allows the user to enter if the patient is reported to be a Male or Female.

- Using the information regarding any patient amputations provided on the Patient Sample Record, select the corresponding limbs on the screen. Each time a limb is toggled, the system will produce a correction percentage.
- Note that the final report (sample shown below) will indicate whether an amputee correction factor (and how much) was included in calculating patient normals. For example, a report with no correction factor will look like the report on the left. Note that the report on the right identifies that an amputation factor has been added. Thus, the report should confirm both that the Patient Sample Data on amputation was provided and that these data were entered by the operator.



BVA Report

Patient ID	Analyzed On	Gender	Height	Weight	Amputee	Correction Factor
Amp	6/30/2025 8:10:43AM	male	180.34 cm/71 in	116.57 kg/257.0 lbs	no	0%

BVA Results

	Result	Patient Ideal	Deviation from Ideal (mL)	Excess/Deficit (%)	Flag
Total Blood Volume	9487 mL	6196 mL	+3292 mL	53.1%	* Extreme Excess
Red Blood Cell Volume	3589 mL	2512 mL	+1078 mL	42.9%	* Extreme Excess
Plasma Volume	5897 mL	3684 mL	+2214 mL	60.1%	* Extreme Excess

Additional Analysis

Hematocrit Analysis

	Patient Result	Ideal male
Peripheral Venous Hct	42%	40 - 46%
Normalized Hct	64.3%	44%

Albumin Transudation

Patient Result	Reference Range
0.07%	0.0% - 0.25%

Report Findings

Blood Volume Analysis result indicates patient's total blood volume is extremely hypervolemic, with an extreme excess of +3291.9 mL or +53.1% from ideal; plasma volume is extremely hypervolemic, with an extreme excess of +2214 mL or +60.1% from ideal; red blood cell volume is extremely hypervolemic, with an extreme excess of +1078.0 mL or +42.9%

Test Information

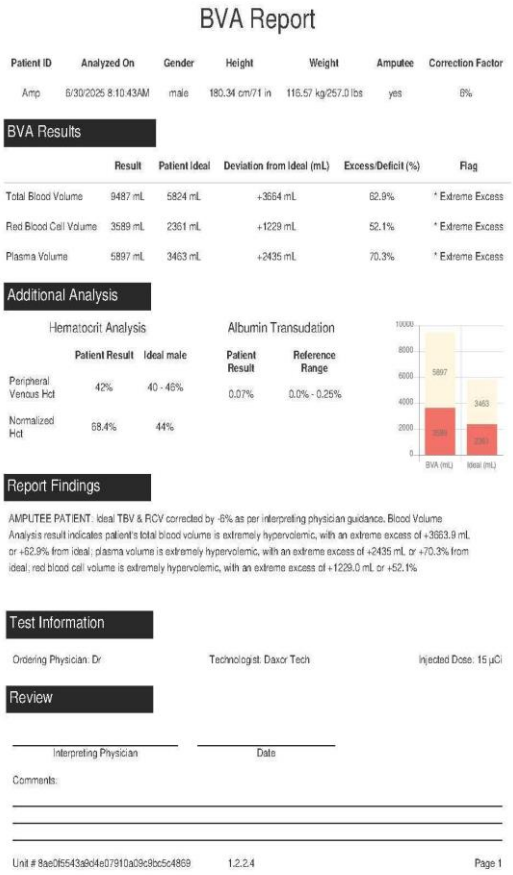
Ordering Physician: Dr | Technologist: Daxor Tech | Injected Dose: 15 µCi

Review

Interpreting Physician _____ Date _____

Comments:

Unit # 8ae0f5543a9d4e07910a09c9bc5c4869 1.2.2.4 Page 1



BVA Report

Patient ID	Analyzed On	Gender	Height	Weight	Amputee	Correction Factor
Amp	6/30/2025 8:10:43AM	male	180.34 cm/71 in	116.57 kg/257.0 lbs	yes	6%

BVA Results

	Result	Patient Ideal	Deviation from Ideal (mL)	Excess/Deficit (%)	Flag
Total Blood Volume	9487 mL	5824 mL	+3664 mL	62.9%	* Extreme Excess
Red Blood Cell Volume	3589 mL	2361 mL	+1229 mL	52.1%	* Extreme Excess
Plasma Volume	5897 mL	3463 mL	+2435 mL	70.3%	* Extreme Excess

Additional Analysis

Hematocrit Analysis

	Patient Result	Ideal male
Peripheral Venous Hct	42%	40 - 46%
Normalized Hct	68.4%	44%

Albumin Transudation

Patient Result	Reference Range
0.07%	0.0% - 0.25%

Report Findings

AMPUTEE PATIENT. Ideal TBV & RCV corrected by -6% as per interpreting physician guidance. Blood Volume Analysis result indicates patient's total blood volume is extremely hypervolemic, with an extreme excess of +3663.9 mL or +62.9% from ideal; plasma volume is extremely hypervolemic, with an extreme excess of +2435 mL or +70.3% from ideal; red blood cell volume is extremely hypervolemic, with an extreme excess of +1229.0 mL or +52.1%

Test Information

Ordering Physician: Dr | Technologist: Daxor Tech | Injected Dose: 15 µCi

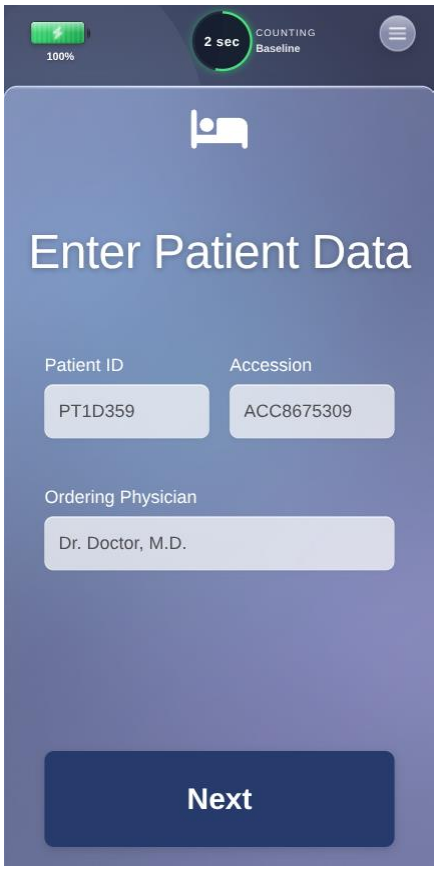
Review

Interpreting Physician _____ Date _____

Comments:

Unit # 8ae0f5543a9d4e07910a09c9bc5c4869 1.2.2.4 Page 1

- Next - Will take the user to the next screen of the test.
  - Enter Patient Data (continued): This screen is where the user will input the Patient ID, Accession, and the Ordering Physician.



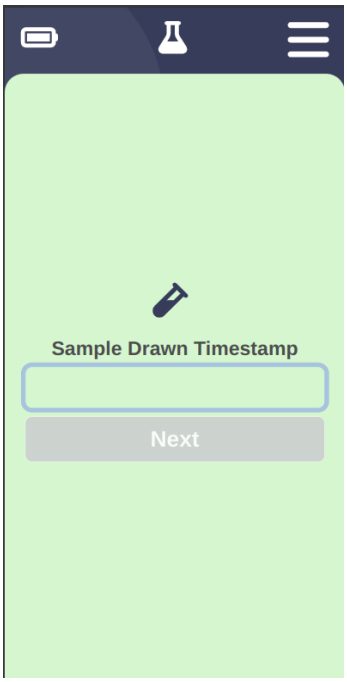
- Patient ID - Enter the identifier assigned to the patient. The identifier can be numbers, letters, or a combination of them. Typical identifiers include, for example, a Medical Record number, or a customer-defined identifier specific to blood volume tests and analysis.
- Accession - Enter the patient's Accession number. Other identifiers are possible here, depending upon the preferences expressed at installation.
- Ordering Physician - This is simply the name of the provider that ordered the BVA test.
- Next - This button will not let the user proceed until at a minimum the Patient ID and Ordering Physician have been entered.
- The system must complete counting the baseline sample before proceeding to step 4.4.

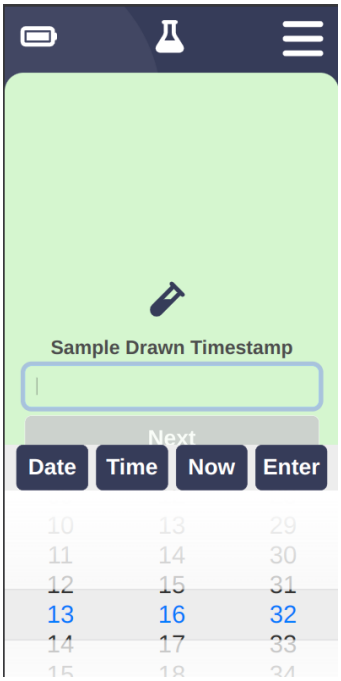
5.4. COUNT STANDARD

- At this point, the system should be finished counting the baseline sample and is ready to start counting the standard. Remove the baseline sample from the well and set it aside.
- Standard In Well - The user should gently place the standard sample in the well and check this box to indicate that it is ready to be counted. Once checked, the Start Counting button will become enabled.
- Start Counting - This button will only be enabled if the user has confirmed that the standard is in the well and ready to be counted. Clicking the button will activate the detector and start counting the standard sample.
- At this point, the standard is being counted and the user must wait until the system finishes counting.

- Counting Standard - The system will also prevent the user from proceeding to the next screen until the system has completed counting the standard sample.
- The system will automatically navigate the user to the “Sample Drawn Timestamp” screen when counting is complete. Remove the standard sample from the well and set it aside.

5.5. COUNTING SAMPLES



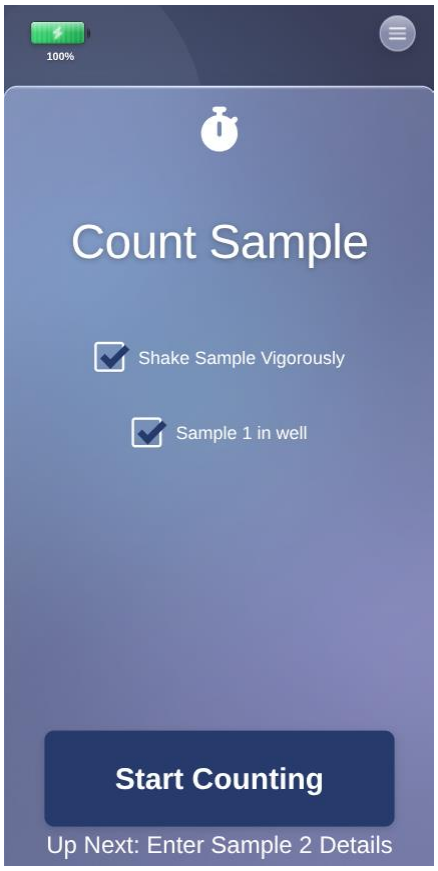


- Sample Drawn Timestamp – Enter data provided by clinical team. This is to indicate the exact time the sample was drawn from the patient. This timestamp will be used by the BVA-200 in the internal calculations to determine the patient's blood volume.
- Click the box to initiate time & date selection.
- Enter date & time. Accurate notation of the sample's post-injection withdrawal time is important. Withdrawal times should have been recorded by the clinical team for each sample to within ± 6 seconds.
- Enter- This button records the date & timestamp.
- Next - This button will take the operator to the next step.

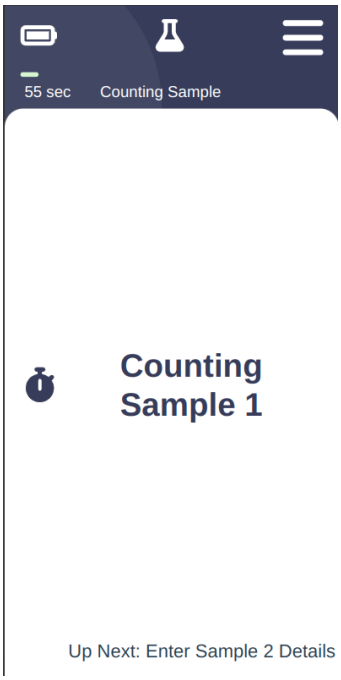
- Follow the prompts to count the sample.
    - Shake sample vigorously: Place fingers on top of cap and on bottom of sleeve. Shake

vigorously for 30 seconds.

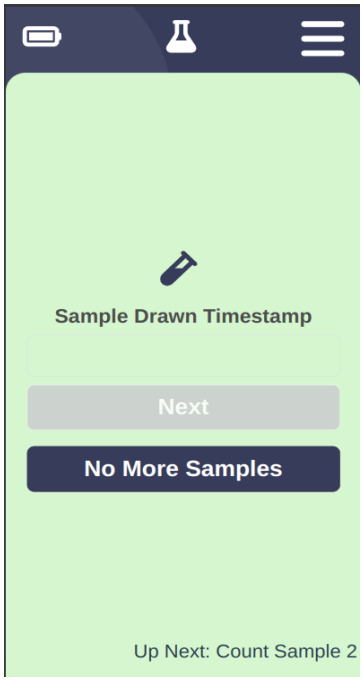
- Sample 1 in well- the operator should place Sample 1 in the well so that the bottom of the Sample 1 label is flush with the top of the well. Check the box to indicate that it is ready to be counted. Once checked, the “Start Counting” button will become enabled.



- Start Counting - This button will only be enabled if the user has confirmed that Sample 1 is in the well and ready to be counted. Clicking the button will activate the detector and start counting Sample 1.



- The operator cannot proceed from this screen until the system has finished counting the sample. The operator will be automatically taken to the next step once counting is complete.



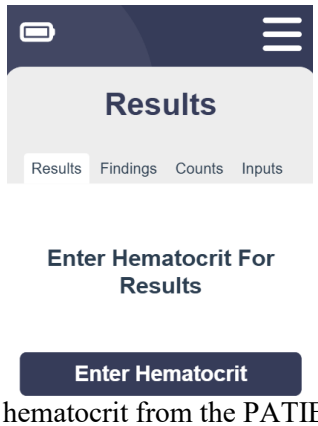
- When the operator reaches this screen, the system has finished counting the current patient sample. The operator may count another sample or finish the test. The test is saved incrementally after each patient sample has been counted.
- Multiple post-injection blood samples can be collected to perform the blood volume analysis. If you have more than one blood sample, repeat Section 4.5 for each sample.

- No More Samples - Clicking this button tells the system that the user has all the samples needed and is ready to view / print the test results.
- Go To Results - This is for the operator to confirm that all the samples are counted.

6. Preparing and Printing the Report

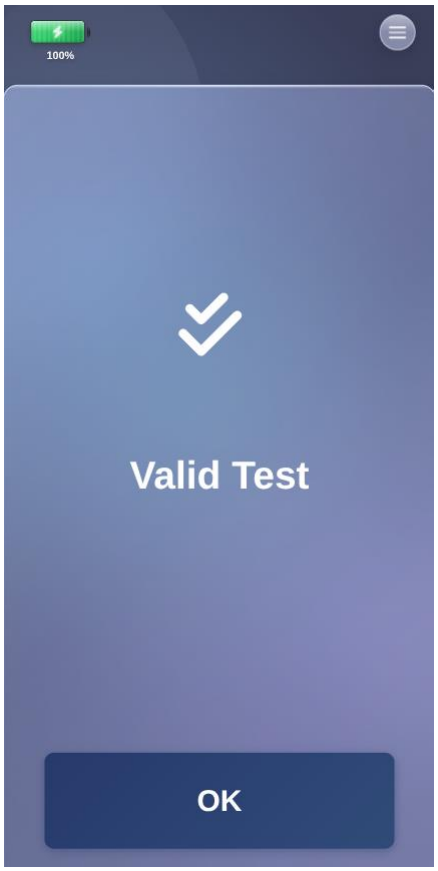
6.1. ENTER HEMATOCRIT

- The patient's hematocrit (from Patient Sample Record) must be entered before results can be calculated.



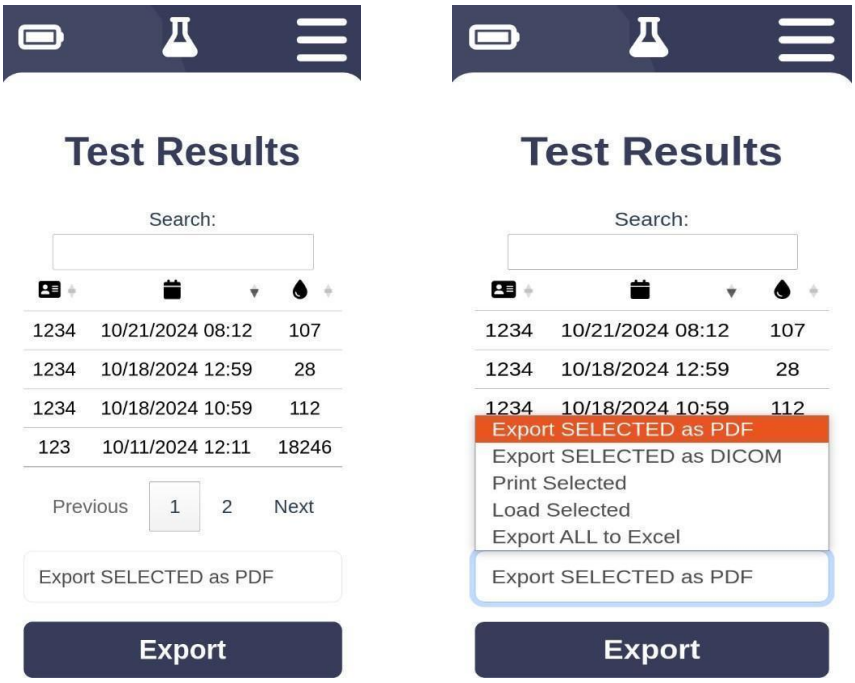
- Enter Hematocrit (obtain the hematocrit from the PATIENT SAMPLE REPORT). This will open the Hematocrit Entry screen. The operator can type in the patient's hematocrit value here and press Enter.

- Enter - The operator should click this to enter the hematocrit into the calculations.
- Cancel - The operator can click this to return to the prior screen.
- VALID TEST - This is to let the operator know if the Blood Volume Analysis test results were within specific criteria to be considered a valid test. If the test results are invalid, the screen will show an “X” and “Invalid Test”. Please call Daxor technical support for further assistance.
- Clicking the OK button simply dismisses this screen and returns the user to the Results screen.



7. Test Results Report

- From the BVA-200 Landing Screen, the operator can display/share the Test Results Report List with the healthcare provider by clicking on the hamburger menu or a report can be printed by the laboratory operator for inclusion in the patient record or other transmission to the healthcare provider.
- This page lists all the tests performed (both complete and incomplete) in a grid with the ability to filter, search, and sort and various options of ways to interact with them.



- Search - The user may type any value in the search box including date & time of test, patient ID, etc. to narrow down the list of results.
- Previous, X, Next - These buttons allow the user to switch between pages of results. The system only loads a few results at a time.
- Export SELECTED as PDF - This option will generate 1 PDF stored in a password protected & encrypted ZIP file on a plugged in USB flash drive for the selected test result.
- Export SELECTED as DICOM – This option will generate a Dicom structured report.
- Print Selected - This will open the printer dialog and let the user select which printer they wish to print the selected test result to.
- Load Selected - This will load the test and open the Test Results screen.
- Export ALL to Excel - This option will generate 1 single Excel file with all the test results on this unit and will be saved in a password protected & encrypted ZIP file on a plugged in USB flash drive.

Please also refer to Part II which details methods to share results using the interactive screen.

Part IV. Miscellaneous Information.

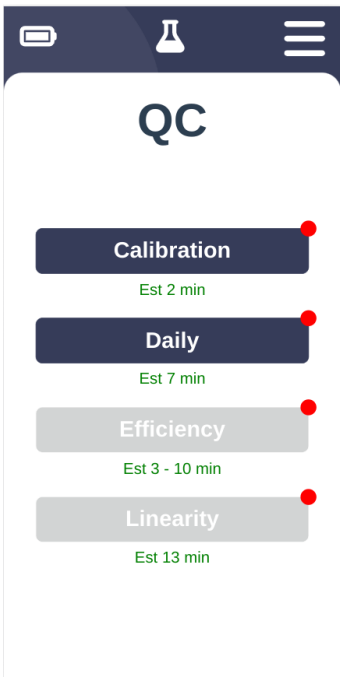
1. Calibration and Quality Control

CALIBRATION

- Calibration of the gamma counter is an automatic function in the BVA-200. The calibration is automatically checked, and if necessary adjusted, at the beginning of each Daily QC test as well as at the beginning of each patient test.

QUALITY CONTROL

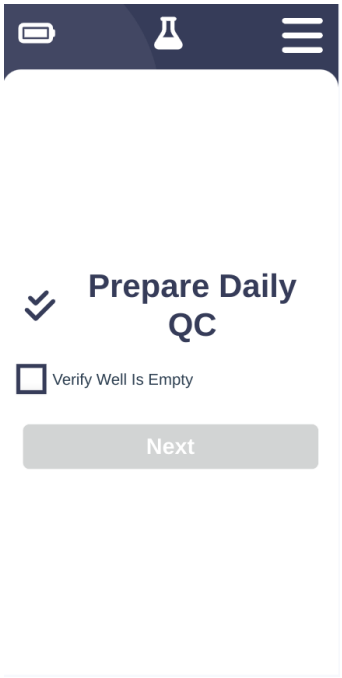
- Quality control features of the BVA-200 are used to verify the functionality of the gamma counter and to check for well contamination. The machine will not proceed until QC has succeeded on the various specified schedules. From the Main Menu dropdown, access previous QC test results by pressing the QC Logs button. To verify that QC is current and perform overdue QC, access the Quality Control screen from the Main Menu dropdown by pressing the QC button. The Quality Control screen will appear.



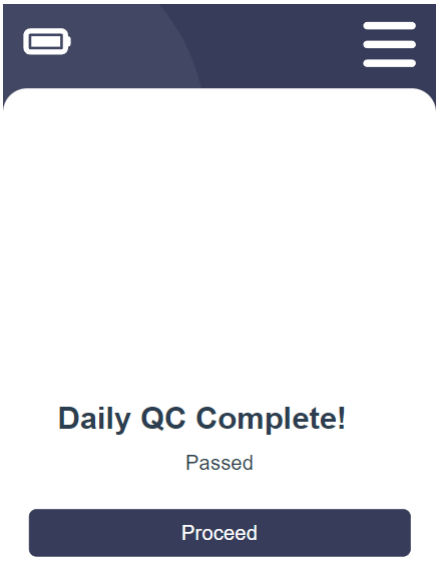
- This section provides an overview of the three types of QC tests. From the Quality Control screen, a new test can be performed. Before beginning a QC test, ensure that no unexpected radioactive sources are close to the gamma counter during the respective test. A red dot indicates a test needs to be performed.
- The three types of QC tests available are Daily QC and two forms of quarterly QC – efficiency and linearity. The latter (linearity) is the responsibility of Daxor Technical Staff but is detailed below.

DAILY QC

- Prerequisites for Daily QC are that an I-131 source is present and over the strength of 5 nCi.
- Daily QC checks (a) background, (b) potential contamination of well, (c) the Volumex Standard, and (d) calibration, detector resolution, and constancy of the gamma counter. This test should be performed each day that patient samples are measured.



- The screen shown appears when the user presses the Daily QC button. The user currently signed in will be recorded as the Analyst. The screen will prompt the user to ensure the well is empty. Pressing Next will initiate the counting of the background so that it can be verified and removed from the following counts. After 1 minute has passed, the screen will prompt the user to place a I-131 source into the well and click count. The test proceeds automatically, and a pass or fail determination will be reached for each measured parameter. During the test, the user has the option of aborting it by choosing the drop-down menu on the upper right and choosing home.
- When Daily QC is complete, the following screen appears:



- If a Daily QC test results in a FAIL, the user should ensure no other radioactive sources (*e.g.,* other samples or doses) are located near the unit. If the test continues to FAIL, contact Daxor Technical Support.
- When the test is completed, the user can print the report or electronically export a PDF version of the report to an available user-selected location.

Daily QC Report

Performed By	Performed On
admin	11/09/2023 13:32

Background

	CPM	Acceptance Criteria	Pass
Background Data	109	< 200	PASS

Calibration

	Centroid	Fine Gain	Acceptance Criteria
Calibration Data	363	2575	360 - 368

Constancy

	Measured	Expected	Time
Minute One	5910	5910	11/09/2023 13:28
Minute Two	6000	5910	11/09/2023 13:29
Minute Three	5974	5910	11/09/2023 13:30
Minute Four	5936	5910	11/09/2023 13:31
Minute Five	5895	5910	11/09/2023 13:32

	Ratio	Acceptance Criteria	Pass
Result	0.7%	< 10%	PASS

Review

Reviewed By: _____ Date _____

Comments:

QUARTERLY QC

- Efficiency — compares the brightness of the detector by counting a sample based on its strength to verify that the received counts are within an acceptable range for the sample strength.
  - This test should be conducted quarterly.
  - Prerequisite for Efficiency is that an I-131 source is present and over the strength of 5 nCi.
  - The device automatically walks through efficiency testing.

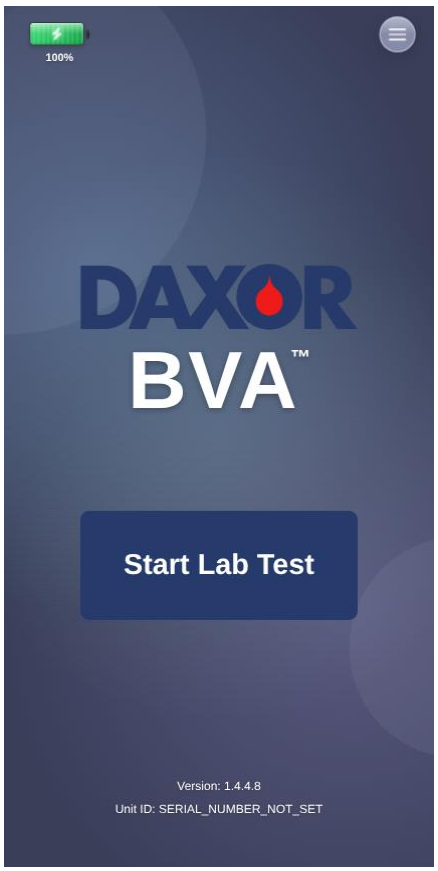
- Linearity —measures energy calibration, detector resolution, and linearity of the gamma counter. The QC calibration radiation sources are provided by Daxor and span the measurement range of the gamma counter
    - This test should be conducted quarterly by the Daxor Technical Staff in cooperation with local personnel.

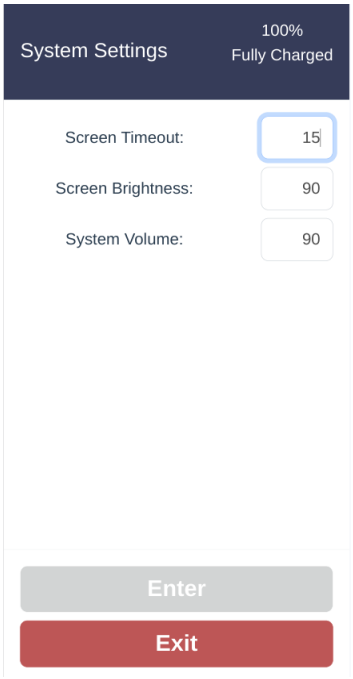
When a Full Three-part QC test has been passed, the QC buttons change to green, and blood volume tests can be performed. Blood volume tests cannot be performed if the system is in a failed QC state. Blood volume tests can be performed if the Daily QC status has passed and the quarterly QC statuses are expired, so long as the last quarterly test was not a failure; however, those tests are not considered valid and should not be used for the purpose of reporting results.

If a QC test results in a FAIL, the user should ensure no other radioactive sources (e.g., other samples or doses) are located near the unit and verify I-131 source is at least 5 nCi. If the test continues to FAIL, contact Daxor Support.

2. System Settings

- From the BVA-200 Home Screen, modify system settings by clicking on the hamburger menu.





- This allows the operator to change the following settings:
    - Screen Timeout - The time in minutes before the screen will turn off to preserve energy.
    - Screen Brightness - An integer value between 1 and 100 which reflects the intensity of the backlight.
    - System Volume - An integer value between 1 and 100 which reflects the loudness of the system speakers.

3. Maintenance

3.1. Equipment Cleaning

- Regular maintenance of the BVA-200 will help assure reliable operation, depending on the environment.
- Caution: Daxor recommends only the cleaning methods described in this section. If another method is needed, contact Daxor Technical Support beforehand to verify that the proposed method will not damage the unit. Daxor is not responsible for damage caused by non-recommended cleaning methods.
- Clean the BVA-200 unit at least weekly or whenever visibly soiled. Standard precautions should be taken whenever working with blood or blood products. Disconnect the power supply from the electrical connection before proceeding. Inspect the cartridge well during cleaning to ensure it is free of damage or cracks.
- Clean the unit enclosure (not including the screen) and the cartridge well with a soft cloth dampened with a mild, non-abrasive detergent, a 30% isopropyl alcohol solution, or a 10% bleach solution. An EPA registered disinfectant detergent or germicide that is approved for healthcare setting may also be used. Pre-soaked towelettes may be used as an alternate. Do not spray or pour any detergents, solutions or other liquids directly onto the analyzer, instead dampen a cloth.
- Clean the unit's screen using a soft, lint-free cloth dampened with a glass-cleaning fluid, window cleaner, or a 10% bleach solution. An EPA registered disinfectant detergent or germicide that is

approved for healthcare setting may also be used. Apply the solution to a lint-free cloth, then wipe the screen. Pre-soaked towelettes may be used as an alternate. Do not use alcohol on the screen. Do not spray cleaner directly onto the display, instead dampen a cloth.

- The power cord and adaptor can be cleaned and disinfected in the same way as the unit enclosure.
- Allow all surfaces to remain wet for 3 minutes. Then wipe with gauze until dry.
- Inspect all surfaces. If necessary, repeat until all visible soil is removed.

4. Backup of BVA-200 Records

- The BVA-200 software automatically retains all tests.
- All patient data and the files associated with blood volume tests can be backed up to storage media for safe storage, record-keeping, DAXOR-assisted instrument evaluations, or data restoration in the event of inadvertent data loss. Backups generated by the BVA- 200 software are encrypted and password-protected to address security & regulatory needs. See your facility's procedures and policies.

5. Limitations

- Limitation: If either the background sample cartridge or the test sample collection cartridges cannot be completely filled either due to an insufficient amount of blood collected, or an obstruction such as extreme clotting, then the sample may not be included in the test. The test may not be performed with insufficiently filled cartridges.
- If the test result is invalid as flagged by the software, there may be delays in reporting results to physicians and patients due to the need to consult with Daxor Technical Support, or to repeat the test, including recounting of samples or repeat administration of entire test.

6. Questions and Answers

- The power cord is specific to Daxor's BVA-200, please call Daxor Technical Service if the cord is lost or misplaced.
- If the test results are invalid, the screen will show an "X" and "Invalid Test". Please call Daxor Technical Support for further assistance.
- If a QC test results in a FAIL, the user should check the well surroundings for radioactivity and verify I-131 source is above 5 nCi. If the test continues to FAIL, contact Daxor Technical Support.

7. Automated Notifications

- The BVA-200 system advises operator intervention in four specific, objectively defined circumstances. The following table details these, and describes operator actions.

BVA-200 Automated Notifications Specifying Further Actions	Sample Screen	Action
QC Needed		Perform Quality Control
Background Too High		There is background radiation either in the laboratory or the sample well. Check that the sample well is empty and clean; clean if necessary.
Invalid Test Result		Contact Daxor Technical Support

BVA-200 Automated Notifications Specifying Further Actions	Sample Screen	Action
Invalid Patient Data		Correct invalid data entry (e.g., invalid height, weight)

8. Symbol Index

in-vitro diagnostic medical device

Lot number

Use-by date

Temperature limit

Caution

Consult instructions for use, or consult electronic instructions for use

Control

Indicates potential biological risks

Manufacturer

9. References

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