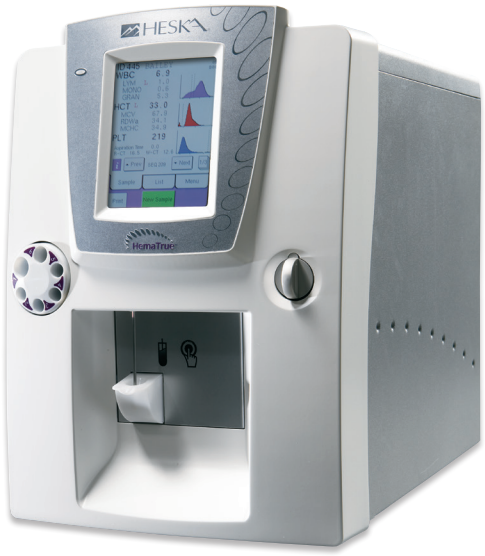
pm
product manual

HemaTrue

Veterinary Hematology Analyzer



HESKA

Analyzer Description

The HemaTrue® Veterinary Hematology Analyzer is a 17 parameter, 3-part leukocyte differential hematology analyzer produced by manufacturer for multi-species veterinary applications.

Serial Number

The serial number is located on the rear of the analyzer as indicated (Figure 1.1) and on the left side of the analyzer.

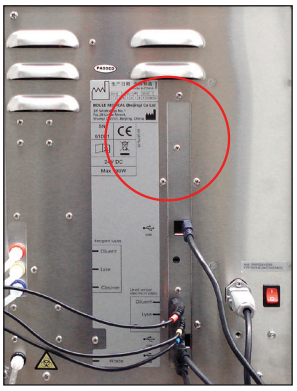


Figure 1.1

Software Version

The software version, along with serial number, is displayed on the screen when starting up the analyzer (Figure 1.2).

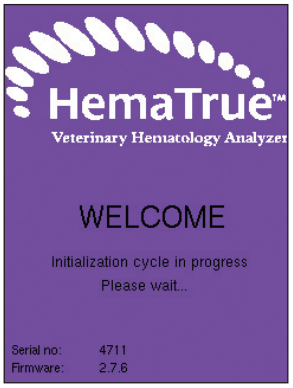


Figure 1.2

Additional Documentation

Additional documentation available from Heska Corporation includes:

- HemaTrue Veterinary Hematology Analyzer Installation Guide
- HemaTrue Veterinary Hematology Analyzer Quick Steps
- Sample Handling Procedures
- Guidelines for review and recommended follow-up of abnormal patient data
- Species specific application technical bulletins
- Analyzer performance data on animal populations

Optional Accessories and Consumables

Accessories and consumable lists are available from Heska Corporation.

Please call 800.464.3752.

International Standards

EN591:2001

EN61326:1997

EN61326/AI:1998

EMC 2004/108/EC

Standards harmonized with FDA

Technical Service and Support

If your HESKA® HemaTrue Veterinary Hematology Analyzer is not operating properly, contact Heska's Technical Support Services at 800.464.3752, option 3, for assistance. When calling, have the analyzer's model and serial number ready.

Repair Policy and Procedures

1. The HemaTrue Analyzer has a one (1) year exchange program. If a replacement HemaTrue Analyzer is shipped, the original analyzer will need to be returned to Heska.
2. A Return Goods Authorization (RGA) number is required to return any product to Heska. To obtain a return goods authorization number, please call 800.464.3752, option 3. If a UPS® or FedEx® shipping label has been provided, the RGA number will be on this label.

NOTE: Shipments received without an RGA number will become the property of Heska and Heska shall have no obligation to replace, repair or return such product. **Shipments not displaying a Return Authorization Number or shipments sent "freight collect" will be rejected.**

3. Heska shall bear the cost of all shipping, handling and transit insurance expenses incurred under the limited warranty. For non-warranty repairs, customer is responsible for all shipping, handling and transit insurance expenses.
4. Pack the device carefully in the original case to prevent shipping damage. See Cleaning, Maintenance and Transport section for details.
5. Write the RGA number on the outside of the shipping box or attach shipping label.
6. Mail the box to the address below, Attention: Service Department.
7. The customer must make all claims for damage or a lost shipment directly to the carrier.
8. See the Returned Goods Policy set forth in Heska's Terms and Conditions of Sale; for more details visit www.heska.com.

Heska Corporation
3760 Rocky Mountain Ave.
Loveland, CO 80538

Main: 970.493.7272 or 800.464.3752
Heska's Technical Support Services: 800.464.3752, option 3

Table of Contents

1.1 Intended Use

The HESKA® HemaTrue® Veterinary Hematology Analyzer is a veterinary-specific hematology cell counter using impedance technology to provide a Complete Blood Count (CBC), 3-part differential, and 3 histograms per patient sample. Results are provided in approximately 1 minute per sample with approximately 10 seconds of hands-on time. A minimum of 20 microliters of EDTA anticoagulated whole blood is required to perform a CBC consisting of WBC, RBC, PLT, HCT, HGB, MCV, MCH, MCHC, RDW, RDWa and MPV results. The report also includes a WBC differential reporting lymphocyte, monocyte and granulocyte absolute count and percentage. EDTA (purple top) tubes and EDTA-coated 20 microliter capillary tubes must be properly filled and mixed. Sample handling guidelines, including accepted lab procedures to check for the presence of micro clots and fibrin, must be followed.

The HemaTrue Veterinary Hematology Analyzer must be operated and maintained in accordance with procedures described in applicable product literature (*i.e.*, User Manual, package inserts, briefs or bulletins of any kind). If, under these prescribed conditions of operation and maintenance, an aberrant or abnormal result occurs, the user should first make certain that the analyzer is performing correctly and is being operated in accordance with the product labeling. If the analyzer is operating properly, and all quality control checks are within acceptable limits, the results may be reported to the veterinarian.

The HemaTrue Veterinary Hematology Analyzer is not intended to make diagnoses. The intended use of all Heska Corporation diagnostic products (analyzers, software and hardware) is to collect data reflecting the patient's status at a certain point in time. Such data should then be used in conjunction with other diagnostic information and the veterinarian's evaluation of the patient condition to arrive at a clinical diagnosis and appropriate course of treatment.

The hematology analyzer is a fully automatic hematology analyzer intended for in vitro diagnostic testing of blood specimens under laboratory conditions.

Operator Requirements

The following operator requirements must be fulfilled before operating the HemaTrue Veterinary Hematology Analyzer.

- Basic skills in a laboratory environment and awareness of good laboratory practice.
- Basic skills in hematology.
- It is highly recommended that the operator read and understand this manual.

1.2 Safety Instructions

Safety features are incorporated within the analyzer in order to protect the operator from injury, the analyzer from damage and the test results from inaccuracies.

Analyzer Restrictions

In order to insure the safety of the operator and analyzer, follow the instructions below:

- Do not use the analyzer outdoors.
- Do not modify the analyzer.
- Do not remove the cover unless requested by Heska's Technical Support Services.
- Do not use the analyzer for purposes other than described in this manual or by a Heska technical brief or product bulletin describing an application.
- Do not spill blood or other fluids on the analyzer in such a way that it can leak through the analyzer casing. (This may result in electrical malfunction and/or personal injury.)

Important

- **Unauthorized modification of the analyzer might result in erroneous results or risk for electrical shock.**
- **Spilling fluids into the analyzer might cause electrical malfunction and/or personal injury.**

Handling of Reagents

- If a reagent comes in contact with eyes, rinse with running water for several minutes. If irritation occurs, seek medical attention.
- If the reagent comes into contact with skin, wash affected area with water. If inflammation occurs, seek medical attention.
- If swallowed, rinse out mouth, and seek medical attention.

1.3 Biohazards

As there are no assurances of the absence of HIV, Hepatitis B or C viruses or other infectious agents in blood samples, blood controls, calibrators and waste, these products should be handled as potentially biohazardous.

Support Documentation

- Protection of Laboratory Workers From Infectious Disease Transmitted by occupationally acquired infections 2nd Edition, Approved Guidelines (2001) Document M29–T2 promulgated by the National Committee for Clinical Lab Standards in the U.S.A. (NCCLS).
- Follow local regulatory documentation.

Handling Biohazardous Material

- Standard laboratory practice recommends wearing protective gloves and laboratory glasses. Follow local regulations.
- Handle samples with great care. Report incidents according to local regulations.
- Do not touch the waste liquid when discarding waste.

MANDATORY ACTION

- **If blood comes in contact with eyes or open cut, wash affected area with plenty of water.**
- **If the waste liquid is inadvertently touched, wash affected area with disinfectant solution first and follow with soap**.

1.4 Emergency Procedure

In Case Of Emergency

If there are any obvious signs of malfunction such as smoke or liquid leaking out of the analyzer proceed as follows:

- Disconnect the main power supply immediately by pulling out the cord from the main supply.
- Contact Heska's Technical Support Services 800.464.3752, option 3.

1.5 Warning Signs in Manual

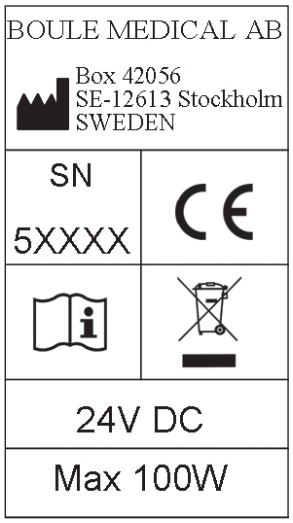
Warning Signs:

The following warning signs are used to identify possible hazards and to call the operator's attention to the hazardous condition.

Sign	Function
⚠	Warning: Indicates operation procedures that could result in personal injury or loss of life if not followed correctly.
⚠	Caution: Indicates operation procedures that could result in damage or destruction of equipment if not strictly observed.
ℹ	Important: Emphasizes operating procedures that must be followed to avoid erroneous results.
❗	Mandatory Action: Indicates that protective clothing, gloves or goggles must be used when performing described procedures.

1.6 Signs on Equipment

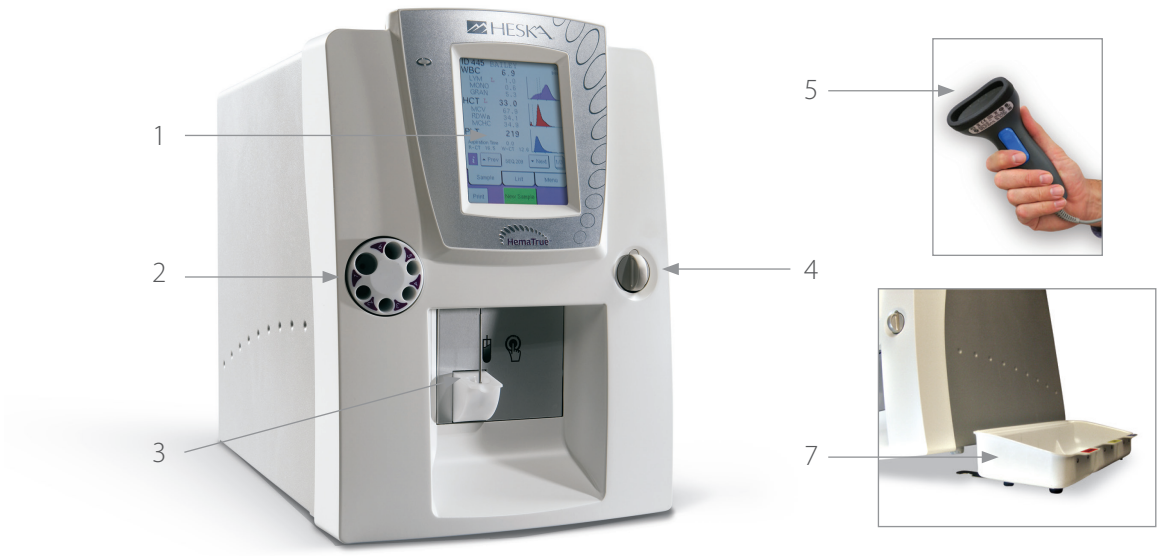
Signs placed on the analyzer define areas that need special attention or areas that contain danger. See IVD Symbol Table on the next page.



				
GB	Caution,consult instruction for use	Biological risk	Consult Instructions for Use-	Use by
DE	Achtung, Gebrauchsanweisung beachten	Biologissche Risiken	Gebrauchsanweisung beachten	Verwendbar bis
ES	Atención,ver instrucciones de uso	Riesgo biológico	Consulte las instrucciones de uso	Fecha de caducidad
IT	Attenzione, vedere le istruzioni per l'uso	Rischio biologico	Consultare le istruzioni per l'uso	Utilizzare entro
FR	Attention voir notice d'instructions	Risques biologiques	Consulter les instructions d'utilisation	Utiliser jusque
DK	Forsigtig se brugsanvisning	Biologisk fare	Se brugsanvisning	Holdbar til
GR	Προειδοποίησησυμβουλευτείτεταοδηγίεςχρήσης	Βιολογικοί κίνδυνοι	Συμβουλευτείτεςοδηγίεςχρήσης	Ημερομηνίαλήξης
SE	Varsamhet, se bruksanvisning	Biologisk risk	Se bruksanvisning	Använd före
PO	Atenção, ler as instruções de utilização	Risco biológico	Consultar as instruções de utilização	Data de validade
PL	Ostrzeżenie – skonsultować instrukcją obsługi	Ryzyko wystąpienia skażenia biologicznego	Skonsultować z instrukcją obsługi	Uzyc przed
NO	Forsiktig! Sjekk instruks nøye før bruk	Biologisk risiko	Sjekk instruks før bruk	Holdbarhet
EST	Hoiatus, vt. infot kasutusjuhendist	Bioloogiline risk	Tutvu kasutusjuhendiga	Kasutada enne
CZ	Upozornění, přečtěte si návod k použití	Biologické riziko	Přečtěte si návod k použití	Datum expirace
CN	注意，须参阅使用说明	生物危害	请参阅使用说明	有效期
	EC REP			LOT
GB	Authorized representative in the EC	Temperature limitation	Manufacturer	Lot number
DE	Bevollmächtigter in der Europäischen Gemeinschaft	Zulässiger Temperaturbereich	Hersteller	Chargenbezeichnung
ES	Representante autorizado en la Comunidad Europea	Limite de temperatura	Fabricante	Código de lote
IT	Mandatario nella Comunità Europea	Limiti di temperatura	Fabbricante	Codice del lotto
FR	Mandataire dans la Communauté européenne	Limites de température	Fabricant	Code du lot
DK	Repræsentant i det Europæiske Fællesskab	Temperaturbegrænsning	Producent	Lotnummer
GR	ΕξουσιοδοτημένοςαντιπρόσωποςτηνΕυρωπαϊκήΚοινότητα	Περιορισμοίθερμοκρασίας	Κατασκευαστής	ΑριθμόςΠαρτίδας
SE	Auktoriserad representant inom Europeiska Gemenskapen	Temperaturbegränsning	Tillverkare	Lotnummer
PO	Representante autorizado na Comunidade Europeia	Limites de temperatura	Fabricante	Número de lote
PL	Autoryzowany Przedstawiciel w Unii Europejskiej	Zakres temeratury przechowywania	Producent	Numer serii
NO	Autorisert representant i EC	Temperaturbegrensning	Produsent	Lot nummer
EST	Autoriseeritud esindaja EU-s	Temperatuuri piirang	Tootja	Lot number
CZ	Autorizovaný zástupce výrobce pro EU	Limitující teploty	Výrobce	Číslo šarže
CN	EC授权代表	温度限制	制造商	批号
	IVD	CONTROL H 16	CONT	CONTROL
GB	In Vitro Diagnostic Medical Device	High control, 16 parameters	Content	Control
DE	In Vitro Diagnostikum	Hoch Kontrolle, 16 Parameter	Inhalt	Kontrolle
ES	Producto sanitario para diagnóstico in vitro	Control alto, 16 parámetros	Contenido	Control
IT	Dispositivo medico-diagnostico in vitro	Controllo alto. 16 parametri	Contenudo	Controllo
FR	Dispositif médical de diagnostic in vitro	Contrôle haut, 16 paramètres	Contenu	Contrôle
DK	Medicinsk udstyr til in vitro-diagnostik	Høj Kontrol, 16 parametrer	Indhold	Kontrol
GR	In Vitro Διαγνωστικόιατροτεχνολογικόπροϊόν	ΠρότυποελέγχουΥψηλά, 16Παράμετρος	Περιεχόμενο	Πρότυποελέγχου
SE	In vitro diagnostik	Hög kontroll, 16 parametrar	Innehåll	Kontroll
PO	Dispositivo médico para diagnóstico in vitro	Controlo alto, 16 parâmetros	Conteúdo	Controlo
PL	Produkt medyczny do diagnostistyki in vitro	Poziomie wysokim kontrolny, 16-parametrowy	Zawartośćopalpwania	Materiał kontrolny
NO	In vitro bruk	Kontroll; 16 parametere, høy	Innehold	Kontroll
EST	In Vitro Diagnostika Meditsiini seade	Kõrge kontroll, 16 parameetrit	Sisu	Kontroll
CZ	Diagnostickézdinidlo In Vitro	Vysoká kontrola, 16 parametr	Obsah	Kontrola
CN	体外诊断产品	高值质控物，16参数	容量	质控物
	CONTROL N 16	CONTROL L 16	REF	CAL
GB	Normal control, 16 parameters	Low control, 16 parameters	Catalogue number	Calibrator
DE	Normal Kontrolle, 16 Parameter	Nierig Kontrolle, 16 Parameter	Bestellnummer	Kalibrator
ES	Control normal, 16 parámetros	Control bajo, 16 parámetros	Número de catálogo	Calibrador
IT	Controllo normale, 16 parametri	Controllo basso, 16 parametri	Numero di catalogo	Calibratore
FR	Contrôle normale, 16 paramètres	Contrôle bas, 16 paramètres	Référence du catalogue	Calibrateur
DK	Normal Kontrol, 16 parametrer	Lav Kontrol, 16 parametrer	Katalognummer	Kalibrator
GR	ΠρότυποελέγχουΚανονικά, 16Παράμετρος	ΠρότυποελέγχουΧαμηλά, 16Παράμετρος	ΑριθμόςκαταλόγουΚατάλογος	ΔιάλυμαΒαθμονόμησης
SE	Normal kontroll, 16 parametrar	Låg kontroll, 16 parametrar	Katalognummer	Kalibrator
PO	Controlo normal, 16 parâmetros	Controlo baixo, 16 parâmetros	Referência de catálogo	Calibrador
PL	Poziomie normalnym kontrolny, 16-parametrowy	Poziomie niskim kontrolny, 16-parametrowy	Numer Katalogowy	Kalibrator
NO	Kontroll; 16 parametere, normal	Kontroll; 16 parametere, lav	Katalog-/referansenr.	Kalibrator
EST	Normaalne kontroll, 16 parameetrit	Madal kontroll, 16 parameetrit	Kataloogi number	Kalibraator
CZ	Normální kontrola, 16 parametr	Nízká kontrola, 16 parametr	Katalogovéčíslo	Kalibrátor
CN	中值质控物，16参数	低值质控物，16参数	目录号	校准物

This section contains general information about the analyzer and optional accessories.

2.1 Analyzer Overview



1	Display	LCD color touch screen with incorporated keyboard and numerical pad.
2	Blood tube mixer	Uniformly mixes samples before analysis.
3	Whole blood sample probe	Aspirates whole blood for analysis.
4	MPA	Micropipettes adapter enables analysis using 20 µl of blood.
5	Barcode reader	Barcode reader enables user to quickly enter control, and reagent bottle identifications, and utilize the QC program.
6	Printer (not shown)	Prints sample results.
7	Reagent bottle tray	Attaches to analyzer to secure reagent bottles in place.

2.2 System Overview

The HemaTrue Analyzer is a fully automated multi-species hematology analyzer used for in vitro diagnostic testing of whole blood.

Complete blood counts (CBCs) are performed by simply entering a patient identification and selecting the appropriate species profile. Other functions, such as calibration and cleaning, are accessed via software menus.

Three external reagent reservoirs are used, one for isotonic diluent, one for a cyanide-free lysing solution, and one for enzymatic cleaning solution. Reagent volumes are monitored via liquid-sensing probes. When reagent levels become low, an appropriate message is displayed on the analyzer screen.

A sample memory is available that retains approximately 1,000 samples (Flash Memory ON). This memory is protected against main power failures. Sample search, selective printing and QC options are available from this menu.

Volume and Parameters:

The HemaTrue Analyzer measures up to 17 parameters using whole blood from an EDTA blood collection tube or a 20 µl capillary tube with True20™ Sampling. The following parameters are directly measured by the analyzer:

- Total Red Blood Cell Count (RBC)
- Total White Blood Cell Count (WBC)
- Total Platelet Count (PLT)
- Mean Cell Volume of RBCs (MCV)
- Mean Platelet Volume (MPV)
- Hemoglobin Concentration (HGB)

The following parameters are derived from the measured parameters:

- Size distribution histograms of PLT, RBC, WBC
- Hematocrit (HCT)
- Mean Cell Hemoglobin (MCH)
- Mean Cell Hemoglobin Concentration (MCHC)
- RBC Distribution Width (RDW)
- RBC Distribution Width (absolute) (RDWa)
- Lymphocyte concentration in absolute number and percentage (LYMF)
- Mid-sized cells (e.g., monocytes) in absolute number and percentage (MONO)
- Granulocyte concentration in absolute number and percentage (GRAN)

For cell counting and sizing, the HemaTrue Analyzer employs the electronic impedance method. A spectrophotometric technique is used to measure hemoglobin. A sophisticated microprocessor continually checks the test process for irregularities and after data is generated, finalizes the calculation of patient results. Numeric results, size distribution histograms and appropriate flags or messages are printed out at the end of the test.

For data output, the HemaTrue Analyzer comes equipped with USB outputs only. Different print formats are selected from several software options.

2.3 Specifications

This section describes the HemaTrue Analyzer and its parts in general.

User Environment:
The operator works with a menu from which the desired program is chosen (*e.g.*, discriminator settings).

Reagents:

Three external reagent reservoirs are used:

- Isotonic diluent (Diluent)
- Hemolyzing reagent (Lyse)
- Enzymatic cleaner (Cleaner)

Technology:

The HemaTrue Analyzer is a fully automatic hematology analyzer designed to measure 17 parameters using whole blood from an open inlet and/or 20 µl micropipettes.

3-Part WBC:

The analyzer performs a 3-part WBC differential by means of a cyanide free hemolyzing reagent.

Protected Sample Memory:

A sample memory is available and protected against main power failures. The sample memory also contains a search function with selective printing and QC options.

2.4 Short List of Specifications

Measuring principle RBC, WBC, PLT	Impedance
Measuring principle HGB	Photometer, cyanide free method 535 nm ± 5 nm
Programmable WBC discriminator	Yes
Sampling analyzer	Closed shear valve
Parameters reported	RBC, MCV, HCT, PLT, MPV, HGB, MCH, MCHC, WBC, RDW%, RDW abs, LYMPH abs, MONO abs, GRAN abs, LYMPH%, MONO%, GRAN%
Size distributions printed for:	RBC, PLT and WBC Diff
Aspirated blood volume (open tubes)	< 125 µl
Blood volume using the micropipette adapter (MPA)	20 µl
LCD	Graphical color touch screen, 240 columns x 320 rows
Keyboard	Virtual incorporated keyboard
Analysis time	< 1 minute
QC capabilities	Mean, SD, CV, Levey-Jennings
Control sample memory capacity	> 1,000 control samples (flash memory ON)
Sample memory capacity	> 1,000 samples (flash memory ON)
HGB correction on high WBC counts	Yes
Analyzer information messages on parameter abnormalities	Yes
Floating discriminator RBC/PLT	Yes (position printed)
Automatic HGB blank on each sample	Yes
Carry over	RBC, HGB, WBC ≤ 1%, PLT ≤ 2%
Barcode reader input	Yes
Serial output	Yes (conformed to standard EN 60950)
Power consumption (operational)	Max 100 VA
Power consumption (standby)	Max 20 VA
Mains frequency	50–60 HZ
Mains voltage	100–240 VHZ
Effective mains current	Max. 2 A
Certified external mains power supply	AML 150PS24 > 2556 or FDF1503–A–24–C14 (51441).
Built-in test/adjustment programs	Yes
Temperature	64–90°F (18–32°C)
Humidity (non-condensing)	Up to 80%
Dimensions	16.1 x 11.4 x 18.1 in (410 x 290 x 460 mm) (H x W x D)
Weight	≤18 kg (standard version) (≤ 40 lb)
Diluent consumption	Approximately 20 ml per analysis cycle
Lyse consumption	Approximately 5.0 ml per analysis cycle

2.5 Parameter Ranges

Measuring Range:

Parameter	Measuring Range
WBC	0–99.9 x 103/µl
RBC	0–25.0 x 106/µl
MCV	15–250 fl
PLT	0–1999 x 103/µl
HGB	0–99.9 g/dl

Correlation:

Correlation was performed, using a Bayer Advia® 120 as reference, resulting in the following correlation coefficients (R): WBC > 0.97, RBC > 0.98, MCV > 0.98, PLT > 0.95, and HGB > 0.98. Note that the range for each parameter was limited by the types of samples available for the study.

Reproducibility:

Reproducibility (Typical)		
Measured as an average of 10 measurements each on 3 different venous K2-EDTA collected normal samples, on three analyzers.		
Parameter X-mean (CGS units)		CV (%)
WBC	8.4	< 3.5
RBC	4.34	< 1.8
MCV	94.4	< 1.5
PLT	313	< 5.2
HGB	13.7	< 1.5

2.6 Reagents and Reagent Consumption

This section describes the reagent consumption for the HemaTrue Analyzer depending on a sample per day calculation.

Supported Reagents:
Use only Heska authorized reagents. Erroneous results and damage may occur if other reagents are used.

Diluent Consumption:
Approximately 20.0 ml per analysis cycle.

Lyse Consumption:
Approximately 5.0 ml per analysis cycle.

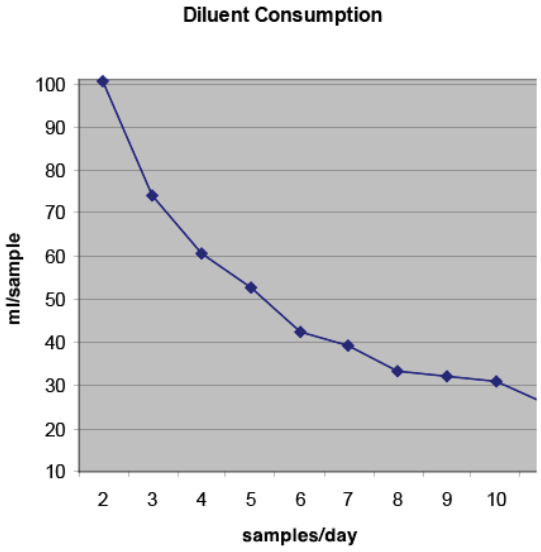
Cleaner Consumption:

The consumption of the Cleaner is variable depending on the usage per day. 32 ml per day can be estimated for the average user.

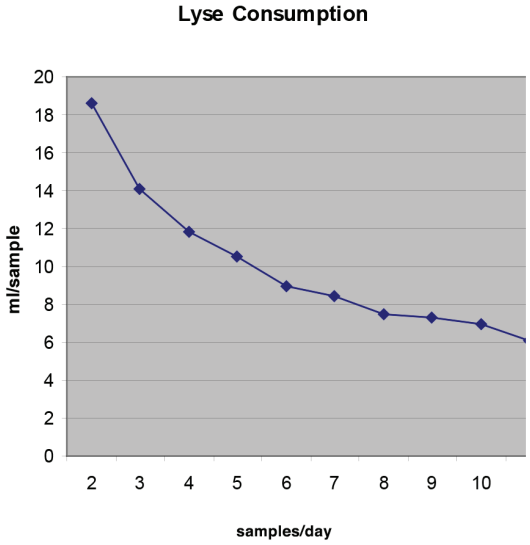
Consumption Calculation:

The consumption can be approximately calculated depending on the number of samples per day as shown on the graphs below. The figures, presented in the graphs, assume one background count, one control analysis, and one exit standby are performed per day. The consumption relation between the Diluent and the Lyse is approximately 5:1.

Diluent Consumption:



Lyse Consumption:



Abnormal test results, including both results with sample pathology messages and results outside the normal range, should be evaluated by microscopic examination of the blood film. The following are common examples:

- Anemia is further characterized by erythrocyte morphology seen on the blood film.
- Thrombocytopenia should be confirmed by ruling out platelet aggregation or clumping on the blood film and by examination of the blood tube for grossly visible clot(s).
- Abnormal WBC subpopulation concentrations should be checked for important morphologic abnormalities such as left shift, toxic change, and features of hematopoietic cell neoplasia.

In some instances, counts should be verified by an alternate procedure. The following are examples:

- Samples with RBC agglutination should have the HCT confirmed by microhematocrit centrifugation.
- Rare samples may have large numbers of unlysed RBCs, causing a falsely elevated WBC concentration.

The WBC count should be verified by an Unopette hemocytometer procedure.

The section below lists known limitations of automated blood cell counters. For detailed information regarding selected animal specimens, see *Hematologic Analysis of Veterinary Species* section.

3.1 WBC (White Blood Cells)

WBC counts that exceed the analyzer linearity limits (>100,000/µl) require dilution of the blood sample for an accurate WBC. A 50% dilution of whole blood with normal saline is assayed and the result is multiplied by 2 to arrive at the correct WBC value. Alternatively, the WBC may be reported as simply ">100,000/µl."

NRBCs. If present in very large numbers, nucleated red blood cells will be included in the WBC measurement. This is rare. In most cases, the concentration of NRBCs is sufficiently low that the effect on the WBC count is negligible, and the cells are detected only on the stained blood film. If NRBCs are present, the WBC count may be corrected by performing a manual differential, noting the number of NRBCs per 100 WBCs.

Unlysed RBCs. In rare instances, the RBCs in the sample may not be completely lysed and will subsequently be included in the total WBC count. Non-lysed RBCs may appear on the WBC histogram as an elevated baseline on the left side of the lymphocyte population. Incomplete RBC lysis may be observed in cattle or in kittens under 3 months of age. It is unlikely to be encountered in dogs or horses.

Heinz Bodies: Extreme Heinz body formation in cats may result in a false high WBC count and HGB measurement because of the persistence of the bodies in solution. This most often occurs when the RBCs contain a single, very large Heinz body.

WBC Agglutination. In rare instances, leukocyte agglutination may cause a false decrease in the WBC count when the agglutinated particles are counted as single cells. Agglutination of lymphocytes or neutrophils may occur. This is attributable to adherence of an immunoglobulin to the specific leukocyte that causes agglutination at temperatures below the body temperature. It may be observed on the stained blood film as clumps of the leukocyte type involved.

3.2 RBC (Red Blood Cells)

Agglutinated red blood cells. RBC agglutination causes a falsely decreased RBC count and a falsely increased MCV. Blood samples containing the agglutinated red blood cells may be identified by observing abnormal MCH and MCHC values, as well as by examination of the stained blood film. The HCT should be verified by microhematocrit centrifugation when agglutination is detected. Agglutination is usually associated with immune mediated hemolytic anemia and is due to a cold temperature dependent immunoglobulin adhered to the RBCs.

3.3 HGB (Hemoglobin)

Turbidity of the blood sample due to any number of physiologic and/or therapeutic factors may produce falsely elevated HGB results. Common causes include hyperlipidemia, marked Heinz body formation in cats, and extremely elevated WBC counts (>100,000). These conditions will cause a falsely elevated HGB measurement and can be detected by monitoring the MCHC.

3.4 HCT (Hematocrit)

Since HCT is calculated by multiplying MCV x RBC, any error in MCV and/or RBC measurement will produce an error in the HCT parameter. The magnitude of the error is unpredictable. Appreciable errors in the HCT may be detected by the MCHC value.

Red blood cell agglutination. RBC agglutination may produce a false low RBC value, creating a false low HCT. The MCV will also not be accurate. The HCT should be verified by microhematocrit centrifugation when agglutination is present.

3.5 RDW (RBC Distribution Width)

The red cell distribution width is a function of the RBC count and is derived from the RBC histogram. It is an index of RBC volume heterogeneity.

3.6 PLT (Platelets)

Platelet agglutination. Platelets may become agglutinated *in vitro* due to poor collection technique or platelet satellitosis caused by EDTA activation of immunoglobulins (rare in animals). This clumping may cause a decreased platelet count. The specimen may be recollected and reanalyzed. Alternatively, platelets may be evaluated for clumping and adequacy as judged from examination of the blood film.

Microcytes. If RBC/PLT separation is not accurate, very small RBCs may be included in the PLT count. On the HemaTrue Analyzer, the floating threshold accurately separates RBCs and platelets, so this type of interference is rare.

Giant platelets. Large platelets may fall outside the PLT measuring limits and be counted as RBCs. This exclusion of large platelets will falsely lower the total PLT count. The effect on RBC concentration is negligible.

3.7 MPV (Mean Platelet Volume)

Giant platelets. Large platelets may fall outside the PLT measuring limits and be counted as RBCs. This exclusion of large platelets will falsely lower the MPV.

Microcytes. If RBC/PLT separation is not accurate, very small RBCs may be included in the PLT count and affect the MPV. On the HemaTrue Analyzer, the floating threshold accurately separates RBCs and platelets, so this type of interference is rare.

3.8 LYMF (Lymphocytes)

The lymphocyte count is derived from the WBC histogram, where they form the left-most peak on the graph. The presence of nucleated red cells (NRBCs), numerous small platelet clumps, and erythrocytes that are resistant to lysis may also be included in this area.

3.9 MONO (Mid-sized Area)

The mid-sized area on the WBC histogram consists primarily of monocytes. Large lymphocytes, atypical lymphocytes or blast cells may also be included in this area.

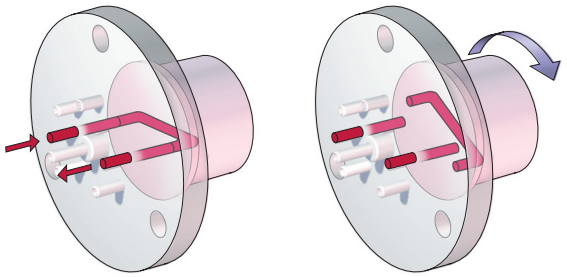
3.10 GRAN (Granulocytes)

The granulocyte cell count is derived from the WBC histogram, where they form the right-most peak on the graph. Granulocytes consist of neutrophils, eosinophils and basophils. Metamyelocytes, myelocytes, promyelocytes, blasts and plasma cells may also be included in this area. Likewise, some forms of lymphocytic leukemia with large blasts may extend into the granulocyte region.

4.1 Principles of Measurement

General Measuring Principles:
The measuring principles of the HemaTrue Analyzer are based on impedance and spectrophotometry principles.

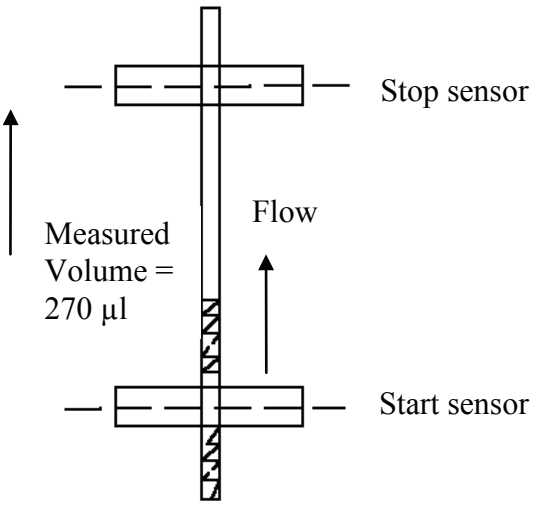
Whole Blood Dilution:
The RBC and WBC concentration values are determined by counting cells in whole blood dilutions of 1:40,000 for the RBC and 1:400 for the WBC.



Theoretical Principles (RBC Example):
If a sample contains 5 million red blood cells per µl, a dilution of 1:40,000 will give a final concentration of 5 million divided by 40,000 = 125 cells per µl. Each µl containing 125 cells, drawn through the aperture, will generate 125 pulses.

Measured Volumes (Example):
The measured volume drawn through the aperture is 270 µl (Manufacturer calibrated). Based on the assumption made above, the analyzer will count 270*125 = 33,750 pulses. The analyzer uses a fixed division factor of 67.5 calculated as 33,750/67.5 = 500 which is the correct value. (Based upon this calculation the analyzer would show RBC = 5.0 x 106 cells/µl.)

Theoretical Principles (WBC Example):
The calculation principle for white blood cells is the same but with a difference in dilution ratio and cell quantity.
An example of this could be as follows:
5,000 cells/µl diluted 1:400 =12.5 cells/µl.



Counting RBCs, WBCs and PLTs:

Detection and sizing of cells is accomplished using the electronic impedance principle and occurs in the orifice of the transducer.

The blood sample is first diluted to 1:400 (WBC and HGB) and 1:40,000 (RBC and PLT) through a precise shear valve analyzer. The shear valve "cuts" a very precise volume (22.5 µl) from the aspirated blood and dilutes it with an equally precise volume of diluent or lyse to achieve the final dilution ratios.

Two separate measuring chambers and transducers are used, one for RBCs and platelets and one for WBCs and hemoglobin analysis. After the appropriate reagent additions and dilutions are made, vacuum is applied to the diluted sample, which moves the solution through an 80 µm orifice (*i.e.*, aperture) in each chamber.

Platinum electrodes on each side of the orifice cause an electrical current to be constantly applied to the solution. When a cell is drawn into this constant current, the electrical conductivity of the environment changes. This generates an equivalent voltage pulse. The number of pulses corresponds to the number of cells detected, and the amplitude of each pulse is also directly proportional to the volume of the cell. Coincidence corrections (*i.e.*, multiple cells entering the counting area at the same time) are made within the software of the HemaTrue Analyzer.

In the RBC/PLT chamber, all cells are counted by the transducer. Platelet and RBC populations are separated based on their size by the floating threshold analyzer. WBCs are effectively excluded from the RBC measurement by an upper RBC threshold.

In the WBC/HGB chamber, a lysing reagent is added to the solution, lysing the RBCs and platelets. The remaining WBCs are then counted. Hemoglobin released from the lysed RBCs is measured spectrophotometrically to derive the HGB concentration.

All cell counts are measured on a precise aliquot of diluted sample. The amount measured is determined by the volume of a precisely calibrated glass column known as a metering tube. Two optical detectors are situated on the metering tubes for start and stop detection.

When analysis begins, two solutions are moved through different parts of the instrument at the same time. The diluted solution containing patient blood is moved through the counting apertures while an equal quantity of reagent is simultaneously moved toward the metering tubes. When the meniscus of the reagent column passes the optical path of the start detector, a voltage change is registered which activates the cell counting and sizing circuitry of the analyzer.

Cell counting and sizing continues until the reagent column reaches the stop detector. When the meniscus of the column reaches the detector, cell counting is stopped and the patient results and histograms are displayed (and automatically printed if so programmed by the user). By the use of metering tube technology, the HemaTrue Analyzer performs absolute counts related to fixed volumes rather than fixed analysis times as in other analyzers.

To exclude debris from platelet measurement, the HemaTrue Analyzer uses a lower discriminator and software calculations. A floating threshold then determines the separation between RBCs and platelets.

The instrument is programmed to use “floating” thresholds, RBCs are counted from the set-point of this variable discriminator and PLT are below the set point.

Sizing RBCs, WBCs and PLTs:

Cell sizing is done via a graphic matrix (*i.e.*, histogram) with cell volume on the horizontal (x-) axis and the relative number of cells on the vertical (y-) axis.

As stated above, RBCs and PLTs are counted and sized simultaneously in the same counting chamber, generating two curves. The software then searches for the "valley" between the two distributions and places a threshold at this location. This threshold is seen on the display and printout as a vertical dotted line. Cells with volumes between this threshold and a maximum upper limit are defined as "RBCs." The "PLT" distribution is defined by a fixed lower limit and the RBC/PLT threshold.

If the RBC count is very low, there may be slight differences in the shape of the curve from one count to another due to statistical sampling. The reproducibility of the curve is also dependent on the concentration of cells in the sample.

Sizing of WBC populations is done simultaneously using a second counting chamber and a second size distribution histogram. See WBC Differential Analysis in this section for details. As with the RBC/PLT sizing, the reproducibility of the curve is dependent upon the concentration of WBCs in the dilution.

Count Time for RBC and WBC Analysis:

"Count time" is defined as the time required for the sample to be drawn from the start detector to the stop detector in the metering tubes, equating to analysis of a fixed volume of fluid. See Counting RBCs, WBCs and PLTs in this section for details.

Count time is displayed on the results screen and printout.

NOTE: The "count time" is not related to the actual result. Atmospheric pressure variations, protein built-up within the orifice (aperture) and other secondary effects that might cause pressure changes will NOT influence RBC, PLT and WBC counts.

WBC Differential Analysis:

The 3-part differential technology is based on the reaction of the lyse reagent with each cell type. Lyse is added to the WBC/HGB analysis chamber, where membrane-active components lyse RBCs and platelets and shear cell membranes from leukocytes. The remaining nuclear particles are then sized. Lymphocyte nuclei form the smallest particle in the solution, mid-sized cells (mostly monocytes) form an intermediate sized particle, and granulocytes (neutrophils, eosinophils, and basophils) form the largest particles. When placed on the size distribution histogram, lymphocytes are the left-most population, granulocytes are the right-most population, and monocytes form an intermediate region.

Separation of WBCs into subpopulations varies among veterinary species. It is crucial that thresholds between the populations be correctly placed. Many analyzers use thresholds that are fixed in place on the histogram. This is often problematic, especially relative to samples that are not analyzed immediately. The lysing reagent reacts more strongly with old cells, causing the granulocyte population to collapse and finally blend into the lymphocyte population on the histogram.

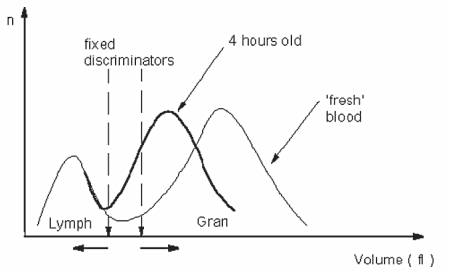


Figure 4.2

Refer to Figure 4.2 where the same sample is analyzed after approximately 4 hours. The vertical lines represent fixed thresholds separating lymphocyte and granulocyte populations. Note how the granulocyte peak shifts to the left, representing cellular collapse and decrease in size. The fixed discriminator technology is not to accurately separate the two peaks. This technology is clearly unreliable for analyzing blood greater than 4 hours old. This aging phenomenon applies to all methods of WBC analysis.

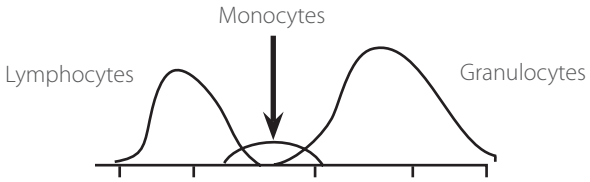


Figure 4.3

To overcome this problem, the HemaTrue Analyzer utilizes floating discriminator technology which utilizes mathematical algorithms in which the curves are analyzed independent of fixed discriminators. These algorithms then build distributions around the 3 main populations. Figure 4.3 shows the 3 curves created by the curve fitting algorithms.

MCV (Mean Cell Volume):

Mean Cell Volume is derived from the RBC histogram. MCV is calculated from the position of the RBC/PLT discriminator to a fixed upper limit. This discriminator may be "floating" or fixed by the user via the Discriminator Setup Program in the software.

In general, RBC counts lower than 0.60 (displayed value) do not give a MCV/HCT value due to insufficient cells for adequate analysis.

When MCV is calibrated, the entire RBC curve is recalculated and moved to reflect the new setting. The histogram therefore remains correct with respect to actual MCV values.

RDW (RBC Distribution Width):

RBC Distribution Width is calculated from the RBC distribution curve and represents the heterogeneity of the RBC population in the patient. RDW outside reference range indicates the presence of RBCs that are larger or smaller than normal. RDW is calculated using only a portion of the curve. This prevents inclusion of other populations that might interfere with accurate measurement.

HCT (Hematocrit):

HCT is defined as being the packed volume of red cells in whole blood and is calculated by multiplying MCV x RBC.

If MCV is not derived due to an insufficient number of RBCs, no HCT is calculated.

PLT (Platelet Count):

Platelets are counted in the same sample dilution as RBCs. The populations are separated by use of the RBC/PLT threshold, whether floating or fixed.

The reproducibility of the PLT count is directly dependent on the total number of cells entering the orifice. In the HemaTrue Analyzer, the CV will be less than 3.5% for samples with a normal platelet count. The CV will be lower for most samples, but on some samples it might be slightly higher. A "mean" CV of about 3.2% is expected for well-treated fresh EDTA whole blood samples within the range of 200–350 x 103/µl.

MPV (Mean Platelet Volume):

The mean platelet volume is determined from the PLT size distribution curve.

MPV is defined as being the mean value of the PLT size distribution curve from the lower discriminator to the position of the RBC/PLT threshold.

HGB (Hemoglobin Concentration):

Hemoglobin is measured from the same dilution as the WBC count. During this process, RBCs are lysed, releasing their intracellular hemoglobin into solution. A photometer then measures the increase in light absorbance due to the presence of these soluble molecules.

The photometer analyzer consists of a lamp, a cuvette and a filter at a wavelength of 535 nm.

For each sample a "blank" reading is taken on reagent alone. This is then used as a reference to eliminate any drift in absorbance by either the reagent, the cuvette, or the lamp.

The HGB readings are slightly corrected for turbidity in case of extreme WBC counts.

MCH (Mean Cell Hemoglobin):

MCH is a calculated value and is defined as HGB/RBC.

MCHC (Mean Cell Hemoglobin Concentration):

MCHC is a calculated value and is defined as HGB/HCT.

MCHC is calculated from 3 measured parameters (*i.e.*, HGB/HCT = HGB/(MCV x RBC) and therefore an excellent check of the integrity of the analyzer and the sample. MCHC may become elevated in the following conditions:

- Lipemia is present, causing turbidity in the sample and falsely elevating HGB.
- Heinz bodies are present in very high numbers, causing turbidity in the sample and falsely elevating HGB.
- RBC hemolysis has occurred, causing a false decrease in HCT.
- RBC agglutination is present, causing a false decrease in HCT.
- Extreme increases in MCHC may occur due to lack of reagent or instrument malfunction.

MCHC may be decreased in the following conditions:

- On rare occasions, low MCHC (*i.e.*, 30–32) may reflect a true deficiency of hemoglobin. In markedly regenerative anemias, with a very large population of reticulocytes, MCHC may truly be decreased because the reticulocytes have not manufactured their full complement of hemoglobin. MCHC may also be slightly decreased in cases of iron deficiency.
- MCHC < 30 typically indicates a problem in the analyzer.

As samples are analyzed, the analyzer software may produce three types of intelligent information. The information is designed to guide and aid the user in the practice of complete hematology. The three categories of information are:

- Low and High Abnormal Results—message of abnormal patient results or out-of-range control results with an L or H notation.
- Sample Pathology—messages for additional diagnostic or hematologic procedures involving the sample.
- Analyzer Information—messages for checking some functional aspect of the analyzer.

Information is indicated on the touch screen with the results and is printed on the patient report. For sample pathology and analyzer Information messages, the touch screen *i*-button becomes active when a message is present. The information is automatically included in the printed report. The user has the preference to access this information detail by either touching the *i*-button on the touch screen or reviewing the printed histogram report. Further detail and background information may also be obtained by referring to this section of the user manual. The three categories of intelligent information are outlined in detail in this chapter.

5.1 Low and High Abnormal Results Information

Reference ranges may be stored in the analyzer software for each species configuration. When a patient sample is analyzed, the analyzer software will compare each parameter value to its corresponding reference range stored in the analyzer software. Any value that is outside the reference range will result in display of an L for low or H for high next to the value. This information is included on the printed patient report. The printed report also shows the reference range for all values.

Estimation of Normalcy:

Reference ranges are inherently probabilistic estimates of normalcy in a given patient. The reference range is defined as the median 95% of values from a population of apparently healthy animals. Therefore, normally 5% of healthy animals may have values slightly H or L with 2.5% being distributed at each limit. Laboratory value normalcy for an individual is best determined by samples analyzed at the time of a routine adult health examination. Samples slightly out of range should prompt consideration of pathology while also considering that the value may be normal for that animal. Conclusive, meaningful pathology is not certain until values are considerably outside the normal range.

Unusual Species Reference Ranges:

Reference ranges are not required for proper sample analysis by the analyzer software. Therefore an unusual species not configured in the analyzer may be analyzed using a species configuration with a similar MCV range. An example is that a new world monkey could be analyzed as a dog. The values generated by the analyzer are reliable, but the results flagging against the dog reference ranges should be ignored. Differentials for unusual species should be verified by microscopy.

Control Assay Value Ranges:

The L and H messages are also applied to results of control samples compared with lot specific assay value ranges. The barcode reader enters assay value ranges into the analyzer memory for each lot of control material. The barcode reader is used to identify the control lot by scanning the tube each time a control is analyzed. The assay value ranges are designed to demonstrate that the analyzer is both calibrated to a reference standard and operating to specification. Control sample results are expected to be within these ranges 99% of the time. A sporadic value slightly outside the limits may occur normally. Troubleshooting action should be taken when control values are either consistently out of range or when values are markedly out of range.

5.2 Sample Pathology

The sample analysis software is capable of displaying intelligent information messages related to pathology that may be present in the sample.

Triggering Mechanisms:

The Sample Pathology information includes a short message defining the sample abnormality followed by recommendations for that sample. The information may be triggered by the following mechanisms:

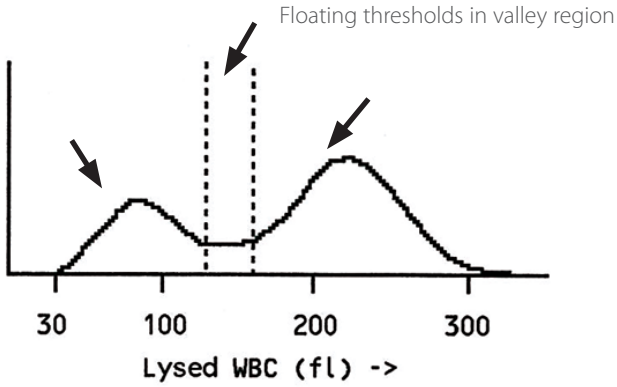
- Histogram shape abnormalities detected by analyzer software calculations.
- Selected values that exceed defined limits outside the reference range. These messages occur when selected values are moderately to markedly abnormal. Values slightly outside the reference range are typically treated as cautionary by the clinician, as described above.

Evaluating Sample Pathology:

This information brings attention to results that are likely to have additional pathology or clarifying findings that may be detected in either a blood film review or other procedures involving the sample. These are standard techniques used by laboratories in conjunction with all hematology analyzers. Recommendations for evaluating he sample for additional pathology may be accessed in the form of messages. The messages may be accessed either by touching the *i*-button on the touch screen or reviewing the printed report. These recommendations are patterned after procedures used in conjunction with analyzers by reference laboratories. The techniques and procedures are regarded as integral to the practice of complete hematology by any competent laboratory. Users are referred to standard textbooks of veterinary hematology for more in-depth information on hematologic procedures and pathology.

Understanding Various Sample Pathology Messages:

WBC Differential Distribution Abnormalities
Background on WBC histograms: The analyzer will provide information on pathologic distribution of the differential data. This is based on analysis of the WBC histogram shape and associated channel data. In most WBC distributions, the floating threshold software acts on the presence of two modes separated by a valley, as shown in the following WBC histogram.



Common pathologic leukocyte responses may often result in the presence of a predominant single leukocyte population. When the predominant population is greater than 90% of the cells, the histogram may have only one mode and inherently no valley. When this occurs, the analyzer software will utilize fixed thresholds placed on the histogram in average position for that species. The most common cause of a single mode is granulocyte predominance. This occurs in steroid responses, marked inflammatory responses, and the combination of these responses. Examples of granulocyte predominance with fixed thresholds are shown in the following WBC histograms.

- The histogram and data in Figure 5.2 are representative of a typical steroid response.
- The histogram and data in Figure 5.3 are representative of a chronic inflammatory response. In both cases the granulocytes make up greater than 90% of the WBC population. WBC analyses with single modes and fixed thresholds are placed into one of three categories. When this occurs, the *i*-button becomes active. Additional information may be obtained by either touching the *i*-button on the touch screen or reviewing the printed histogram report. Three categories of abnormal unimodal histogram are outlined below.

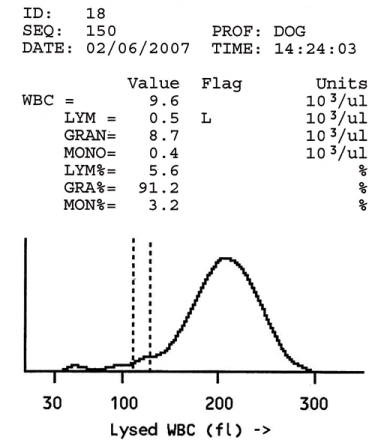


Figure 5.2

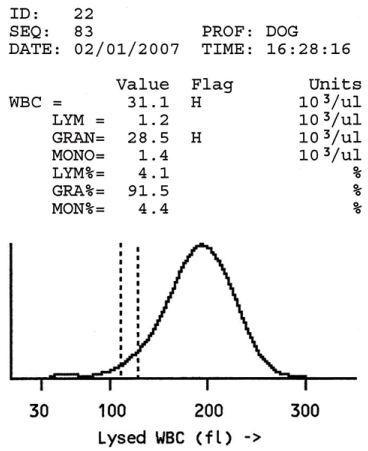


Figure 5.3

WBC Mode < 90 fl (Lymphocyte Predominance):
This pattern is usually due to either lymphocytosis or neutropenia. If it is due to neutropenia, the total WBC will be normal or decreased. If there is lymphocytosis, the total WBC will be increased. Lymphocytosis should be characterized by examination of the lymphocyte morphology on the stained blood film. Rarely, metarubricytosis may mimic lymphocytosis. An example of this type of histogram from a case of neutropenia is shown Figure 5.4.

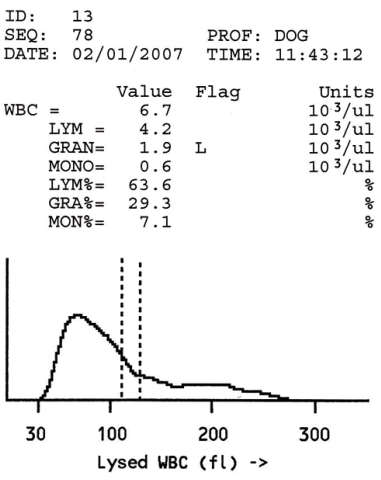


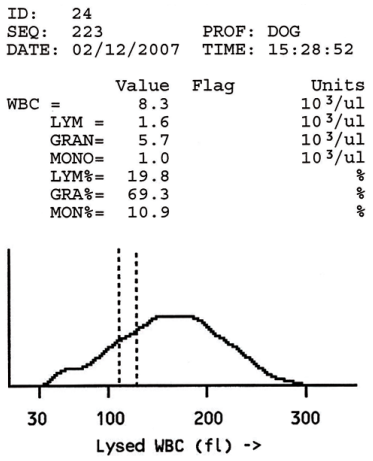
Figure 5.4

WBC Mode <170 fl (Abnormal WBC Distribution):

This is a relatively uncommon pathologic leukocyte response. Several highly abnormal WBC responses may cause this pattern. The pathology is best characterized by review of the blood film. An example of this type of histogram is shown in Figure 5.5 and possible causes are detailed under recommended actions.

WBC Mode >170 fl (Granulocyte Predominance):

Examples are shown in Figures 5.2 and 5.3 in WBC Differential Distribution Abnormalities. This is due to the most common pathologic leukocyte responses, steroid and/or inflammatory. When the granulocyte population has a mode of >190 fl, the differential analysis is highly reliable. Normal lymphocytes will not move into the granulocyte region. On rare occasions, blast cells in a leukemia may occur in the granulocyte region because they are highly unpredictable in all analytical analyzers.



Erythrocyte Sizing:

During the cell analysis interval, a very large number of erythrocytes are evaluated by individual cell analysis to determine the volume of each cell. Each cell volume value is assigned to a narrow, discrete volume bin on the x axis of a volume scale. The high number of cells analyzed results in construction of a highly reproducible erythrocyte volume distribution histogram. The shape and width of the histogram is very constant in the normal animal and these features are uniformly characteristic for each species. A typical histogram is shown in Figure 5.6.

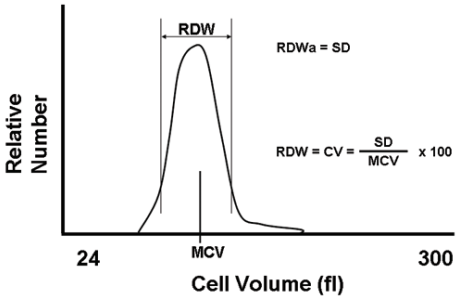


Figure 5.6

Erythrocyte Sizing Calculations:

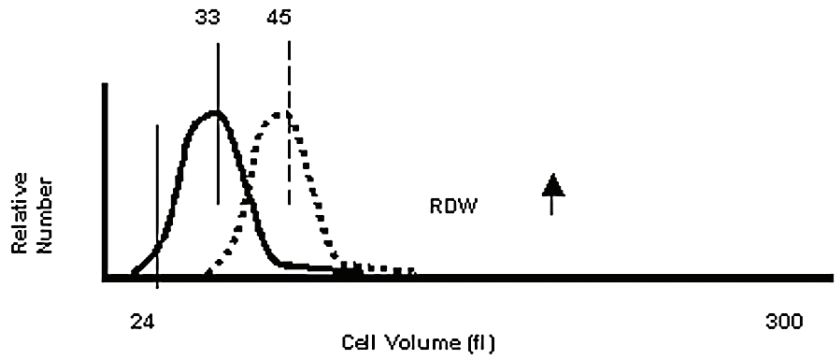
The mean cell volume, MCV, is calculated from the total number of erythrocyte volumes measured. The RDW value is a measure of erythrocyte volume dispersion or heterogeneity. After application of a technique to exclude the histogram tails, the RDW value is calculated by two methods. The RDWa is the standard deviation (SD) of erythrocyte volumes included in the calculation. The conventional RDW is more complex. It is calculated as a coefficient of variation (CV) by dividing the SD by the mean or MCV. For veterinary applications, the RDWa value is recommended.

An increased RDWa value indicates that there is a disturbance in the volume homogeneity of the erythrocyte population. Almost all disturbances are due to altered production by the marrow and other tissues with hemopoietic potential. These disturbances are associated with production of cells having abnormal volume and result in increased volume heterogeneity.

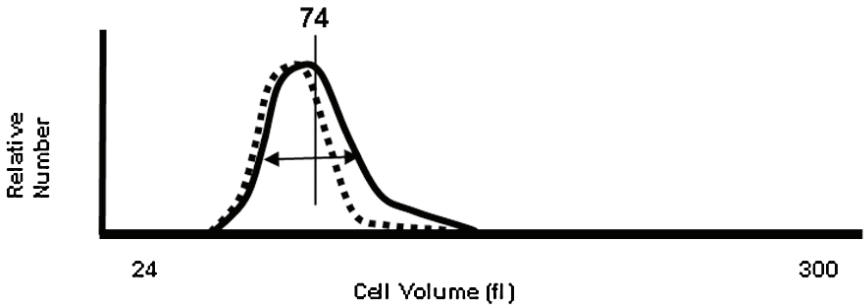
RDWa >10% Above Upper Limit:

Recommended actions for additional evaluation:

- First, examine the RBC histogram in conjunction with the MCV value to determine if the size disturbance is moving in either the microcytic or macrocytic direction.
- Examine the blood film for RBC morphologic defects associated with either microcytosis or macrocytosis. Some common pathology patterns are:
  - Increased RDWa as a result of production of microcytes is seen as widening of the RBC histogram on the left side. With time there is progressive reduction in MCV. Iron deficiency, indicating chronic external blood loss, is the cause. An example of a histogram with an increased RDWa and decreased MCV from a cat with iron deficiency is shown below. The dashed curve indicates a normal histogram, while the solid curve indicates the patient histogram.



  - Increased RDWa as a result of macrocyte production is seen as a widening of the RBC histogram on the right side. This is typical of regenerative anemia. This may also occur in myelodysplastic disease, especially in cats, in which



    there is a chronic poorly regenerative anemia. An example of an increased RDW due to macrocytic cell production in a dog with regenerative anemia is shown. The response has resulted in a mildly increased MCV. The dashed curve indicates a normal histogram, while the solid curve indicates the patient histogram.

    NOTE: There is no pathologic response that results in a decreased RDWa value.

MCHC:

The MCHC value has little clinical utility. Its value is regarded as a form of intra-sample quality control because of the constant relationship between HCT and HGB and their independent measurement in the analyzer. The MCHC value is calculated from the HCT and the hemoglobin concentration. HCT is derived from RBC concentration measurement and individual RBC sizing in one dilution and operational subanalyzer. The hemoglobin concentration is measured in a completely separate dilution and subanalyzer in which the RBCs are lysed liberating hemoglobin into the dilution.

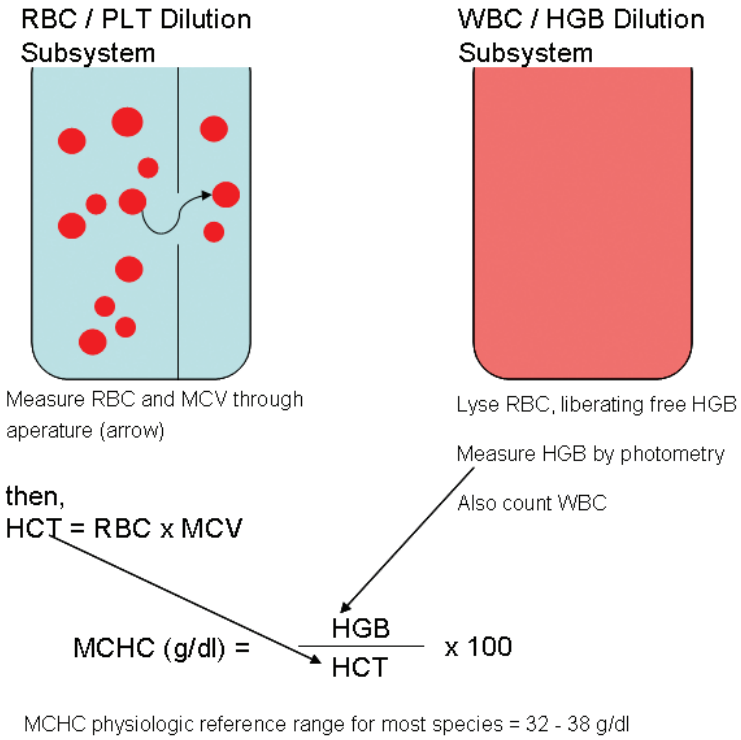
MCHC as a Physiologic Constant:

Within animal blood, the MCHC value is a physiologic constant that may be used to monitor the relationship between hemoglobin concentration and HCT. Therefore, for each sample, the HGB value corroborates the HCT value and vice versa.

An MCHC value that exceeds certain limits of either low or high indicate either a sample problem or an analysis problem in one of the measurement subanalyzers. This is a great tool for monitoring individual samples for such problems. If there is malfunction in one of the subanalyzers, then all values in that subanalyzer are suspect. For example, if there has been a dilution error in the hemoglobin subanalyzer, the total WBC value will be subject to the same dilution error.

Decrease in MCHC:

Values < 30 g/dl are not physiologic and values < 25 g/dl are nonsensical. Following are some scenarios and guidelines for reviewing samples with non-physiologic MCHC values.



MCHC physiologic reference range for most species = 32 - 38 g/dl

- Historically, iron deficiency was associated with MCHC values in the range of 26–32 g/dl range. However, this is exceedingly rare in results from automated hematology analyzers. In addition, iron deficiency should be accompanied by microcytosis (low MCV) and morphologic changes of hypochromia and fragmentation on the blood film.
- Extreme regeneration (typically reticulocytes > 25%) may be associated with mildly decreased MCHC (29–32 g/dl). This occurs because the immature erythrocytes are still synthesizing hemoglobin. Erythrocytes produced under conditions of maximal regeneration are macrocytic and may eventually result in an increased MCV.
- Hereditary stomatocytosis is a rare erythrocyte defect in selected breeds. This defect may be associated with very high MCV values (mid 90's) and MCHC values in the mid 20's as a result of pathologic cell swelling as the cell matures in the circulation. This situation is identified by stomatocytes on the blood film.
- Analysis of blood > 24 hours post collection may also slightly reduce the MCHC because of artifactual RBC swelling reflected in measurement of MCV and calculation of HCT. Values for MCHC in this situation are typically in the low 30's. More pronounced RBC swelling and decreases in MCHC may be seen in analysis of samples that have aged for 36 hours or longer.
- A decreased MCHC in the absence of any of the above findings or an MCHC value outside this limit indicates there is a mismatch in measurements on the analyzer from this specific cycle. That is, something has happened to one of the subanalyzer dilutions or subsequent measurements.

Increase in MCHC:

See *Sample Pathology Information Messages* table.

NOTE: Sample pathology information messages may be blocked by a serious analyzer information indicator, even if the parameter values may seem OK. It is recommended to always re-analyze the sample if the instrument reports any analyzer information indicator.

Sample Pathology Information Messages Table:

The following table summarizes all messages related to possible sample pathology. The criteria for triggering the messages are given. The respective message on the report and retrievable by the *i*-button are shown. Respective recommended follow-up actions for clarifying possible pathology are given.

Total WBC		
Criteria	Message	Recommended Action
< 3000	WBC: Leukopenia; slide review advised	The total WBC and differential are reliable. Pathology of WBC often associated with leukopenia may be detected on a slide review. Review the blood film for the presence of neutrophil toxic change and/or left shift. This is useful to differentiate severe inflammatory consumption from bone marrow injury.
> 15% above upper limit	WBC: Leukocytosis; slide review advised	The total WBC and differential are reliable unless there is pathology that may be detected as a distribution abnormality by histogram analysis. The slide should be examined with low power to confirm that the differential appears reasonable and that there are no surprises in the form of abnormal WBC types. See *WBC Differential Ddistribution Abnormalities* for additional detail.
WBC Differential		
Criteria	Message	Recommended Action
WBC Histogram Mode < 90 fl with single population present	WBC DIFF: Lymphocyte predominance; slide review advised	• Scan the blood film with low magnification to verify that the majority cell is lymphoid. • Use high magnification to determine if there is abnormal lymphocyte morphology when lymphocytosis is present. • Use high magnification to determine the presence of left shift and toxic change if the pattern is due to neutropenia. • An unusually high percentage of metarubricytes and rubricytes; typically > 50% NRBC. This is rare.
WBC Histogram Mode with < 170 with single population present	WBC DIFF: Abnormal WBC distribution; slide review advised	• Scan the blood film with low magnification to get a sense of the predominant cell population. Possibilities for this pattern include the following: – Unusually high percentage of monocytes; this may occur with a relatively low total WBC concentration in which monocytes are predominant. – Occasionally the granulocyte population may collapse into this middle region. This occurs occasionally in dogs for an unknown reason. – Predominance of blast cells that may occupy this middle region. – Inappropriate sample handling. Granulocyte collapse may occur if the sample has aged and is analyzed greater than 12 hours post collection. • Using criteria established for your laboratory, use high magnification to perform a microscopy differential to clarify the distribution of leukocytes present.

Sample Pathology Information Messages Table:

The following table summarizes all messages related to possible sample pathology. The criteria for triggering the messages are given. The respective message on the report and retrievable by the *i*-button are shown. Respective recommended follow-up actions for clarifying possible pathology are given.

Total WBC		
Criteria	Message	Recommended Action
< 3000	WBC: Leukopenia; slide review advised	The total WBC and differential are reliable. Pathology of WBC often associated with leukopenia may be detected on a slide review. Review the blood film for the presence of neutrophil toxic change and/or left shift. This is useful to differentiate severe inflammatory consumption from bone marrow injury.
> 15% above upper limit	WBC: Leukocytosis; slide review advised	The total WBC and differential are reliable unless there is pathology that may be detected as a distribution abnormality by histogram analysis. The slide should be examined with low power to confirm that the differential appears reasonable and that there are no surprises in the form of abnormal WBC types. See *WBC Differential Ddistribution Abnormalities* for additional detail.
WBC Differential		
Criteria	Message	Recommended Action
WBC Histogram Mode < 90 fl with single population present	WBC DIFF: Lymphocyte predominance; slide review advised	• Scan the blood film with low magnification to verify that the majority cell is lymphoid. • Use high magnification to determine if there is abnormal lymphocyte morphology when lymphocytosis is present. • Use high magnification to determine the presence of left shift and toxic change if the pattern is due to neutropenia. • An unusually high percentage of metarubricytes and rubricytes; typically > 50% NRBC. This is rare.
WBC Histogram Mode with < 170 with single population present	WBC DIFF: Abnormal WBC distribution; slide review advised	• Scan the blood film with low magnification to get a sense of the predominant cell population. Possibilities for this pattern include the following: – Unusually high percentage of monocytes; this may occur with a relatively low total WBC concentration in which monocytes are predominant. – Occasionally the granulocyte population may collapse into this middle region. This occurs occasionally in dogs for an unknown reason. – Predominance of blast cells that may occupy this middle region. – Inappropriate sample handling. Granulocyte collapse may occur if the sample has aged and is analyzed greater than 12 hours post collection. • Using criteria established for your laboratory, use high magnification to perform a microscopy differential to clarify the distribution of leukocytes present.
WBC Differential		
Criteria	Message	Recommended Action
Grans ≥ 90% and WBC Histogram Mode > 170 fl	WBC DIFF: Granulocyte predominance; slide review advised	• Scan the blood film with low magnification to verify that there are no surprises such as: – Blast cells that may mimic granulocytes – An unusual percentage of eosinophils • Examine the granulocytes at higher magnification to determine if there is additional pathology. This includes left shift cells (bands and metamyelocytes) and neutrophil toxic change. • Using criteria established for your laboratory, perform a microscopy differential if any of the above abnormalities are present. This is typically done in laboratories when any of the above abnormalities are prominent on scanning.

RDWa		
Criteria	Message	Recommended Action
> 10% above upper limit	RDW: Evaluate histogram and RBC morphology on slide	See description of RDW in this section.
MCV		
Criteria	Message	Recommended Action
> 10% below lower limit	MCV: Evaluate histogram and RBC morphology on slide	As described for RDWa, a low MCV will be associated with an RBC histogram that has widened to the left. Evaluate the blood film for RBC features of iron deficiency.
> 10% above upper limit	MCV: Evaluate histogram and RBC morphology on slide	As described for RDWa, a high MCV will be associated with an RBC histogram that has widened to the right. Evaluate the blood film for RBC features of regeneration or dysplastic production (cats) and other morphologic features that may be related to a specific cause of anemia.
HCT		
Criteria	Message	Recommended Action
> 10% below lower limit	HCT: Anemia; evaluate RBC on slide	Recommended actions for additional evaluation: • Determine if the anemia is non-regenerative or regenerative by evaluating the following. Examine the RBC size information. This includes the RDW, RBC histogram, and MCV. – When a regenerative response occurs due to acute blood loss or hemolysis, there is accumulation of macrocytic erythrocytes in blood. This will result in progressive changes in the form of increased RDW and widening of the RBC histogram on the right side. After a number of days of prominent regeneration, the MCV may become increased above the upper limit of the reference range. – With non-regenerative anemia the RDW, MCV, and RBC histogram remain normal. – Iron deficiency is associated with the production of microcytic erythrocytes. This is seen as widening of the RBC histogram on the left side, increased RDW, and low normal or decreased MCV. In very chronic situations, homogeneously microcytic cells replace the whole RBC normocyte population. This results in a markedly low MCV and RBC histogram that is moved to the left. • Examine the RBC's in the blood film monolayer to determine either absence or evidence of erythrocyte regeneration. This is indicated by increased polychromatophilic erythrocytes on the Wright's stained slide. The most reliable method for quantifation of the regenerative response is to evaluate a stained slide for reticulocytes using new methylene blue or brilliant cresyl blue. The presence of regeneration indicates that the anemia is due to either hemorrhage or hemolysis. The absence of regeneration present for several days or longer indicates the anemia is due to one of several causes of bone marrow suppression of erythrocyte production. • Examine the blood film for RBC morphologic defects that provide additional clues to the cause of the anemia. – For hemolytic disease this includes specific RBC changes such as spherocytes and hemotropic parasites. In most cases hemolytic disease will have a normal to high normal total protein concentration whereas with hemorrhage the total protein is expected to be low normal or decreased. – For chronic external blood loss leading to iron deficiency changes may include hypochromic erythrocytes (increased zone of central pallor), keratocyte injury, and fragments. – Non-regenerative anemia is typically associated with normal RBC morphology. – If there is prominent agglutination present, as in many cases of immune mediated hemolytic anemia, the hematocrit should be verified by microhematocrit centrifugation. A false low HCT in this situation is also suggested by an abnormally high MCHC value (see next page).
> 10% above upper limit	HCT: Evaluate patient for causes of polycythemia	• Evaluate physical hydration status and serum or plasma protein concentration and other laboratory values for signs of hemoconcentration. • If hemoconcentration is ruled out, check for signs of a cardiopulmonary blood oxygenation problem or primary polycythemia.

MCHC		
Criteria	Message	Recommended Action
> 10% below lower limit	MCHC: In the following order: • Evaluate for extreme RBC regeneration • Run Control	• Examine the data and blood film for any features that may explain a mildly decreased MCHC value. • If erythrocyte abnormalities on the blood film are ruled out, analyze the sample a second time. • If the results are consistent on re-analysis, check the analyzer with a blood control sample. If the control exhibits the same result, contact Technical Support.
> 10% above upper limit	MCHC: In the following order: • Evaluate for turbidity, lipemia, and extreme hemolysis • Heinz bodies—cat • Evaluate for agglutination/spin crit • Oxyglobin treatment • Run Control	• This value is not physiologic. It is usually due to interference with the hemoglobin measurement because of sample turbidity or sample hemolysis. Check the sample for the known sample-related causes of a disproportionately high hemoglobin or false low HCT. Potential causes of sample-related high hemoglobin relative to HCT include: – Lipemia—the most common cause. – Marked sample hemolysis. – Marked agglutination in immune-mediated hemolytic anemia. In this instance the hemoglobin measurement is accurate, but the HCT is falsely low because large aggregates of RBC are not included in the derivation of HCT. Agglutination may be seen on the slide or in a saline wet mount of a small amount of blood. – Marked Heinz body formation in cats – this may be seen on the slide. • If sample-related causes are ruled out, re-analyze the sample. If the results of re-analysis are consistent, check the analyzer with a blood control. If the control exhibits the same problem, contact Heska's Technical Support Services.
PLT		
Criteria	Message	Recommended Action
> 25% below lower limit	PLT: Evaluate platelets on slide	• The stained blood film should be examined to verify the decreased platelets. – Platelet clumping is the most common cause of a decreased platelet concentration measurement, especially in cats. This examination should start with low power examination of the feathered edge for platelet clumping. Large platelet clumps will be observed on the feathered edge, while numerous small platelet clumps may be evenly distributed on the slide. If prominent platelet clumping is present, it may be assumed that the platelets are likely adequate. If there is further concern, the sample should be recollected with a clean venipuncture and analyzed again. – If clumping is ruled out, the platelet density should be examined by high magnification in the monolayer or counting area of the slide. Using criteria established for your microscope, verify that the decreased measurement corresponds to a decrease in platelet density in the counting area. Prominently decreased platelets to a degree associated with bleeding is associated with nearly a complete absence of platelets on the slide.
> 50% above upper limit	PLT: Evaluate histogram for extreme RBC microcytosis	• High platelet concentration is not very important for clinical interpretation or diagnostic purposes. Thrombocytosis has been associated with iron deficiency anemia, but may also occur uncommonly in association with a variety of inflammatory states. This is presumably resulting in cytokine responses that enhance platelet production. The following two steps are used to confirm the marked thrombocytosis. – Evaluate PLT/RBC histogram to make sure that extreme RBC microcytosis has not contributed to the PLT measurement by exceeding the floating threshold limits. – Scan a blood film to confirm that platelets are prominently increased in the counting area or monolayer.

The analyzer software monitors a number of analytical and analyzer functions and will display information that requires the possible attention of the operator. This information will alert the operator to check the analyzer or institute selected troubleshooting procedures. This information is presented on the touch screen as a code next to one or more parameters. Additional detail and recommendations may be accessed by either pressing the *i*-button on the touch screen or reviewing the printed report.

Analyzer Information Indicators:

Aspiration Indicators (Sample Probe)			
Indicator	Message	Description	Action
AF	Aspiration failed: Check sample	Possible reasons for AF flag include sample of inadequate volume, clogging or air bubbles in sample tube. **NOTE:** This flag is also displayed when running a background count (blank) without selecting the background analysis profile.	Check profile type is correct and then re-analyze sample.
HGB Indicators (HGB)			
HF	HGB measuring problem: run prime cycle	The instrument detected a problem during the filling of liquid in the WBC counting chamber during HGB blank.	Run a "prime cycle" before re-analyzing the sample.
HH	HGB measuring problem: run prime cycle	The HGB blank or sample readings reported a light level that was too high.	
HL	HGB measuring problem: run prime cycle	The HGB blank or sample readings reported a light level that was too low.	
HN	HGB measuring problem: Wait one minute then re-analyze	The HGB sample reading reported more light than the blank reading. This gives a negative HGB value.	Wait one minute and then re-analyze the sample.
HO	HGB measuring problem: Restart analyzer	The HGB dark (offset) reading reported a light level that was too high or too low.	Switch off the analyzer and switch it back on after 3 seconds, and then re-analyze the sample.
HS	HGB measuring problem: Run prime cycle	Individual HGB readings vary too much.	Run a "prime cycle" before re-analyzing the sample.

NOTE: If various HF, HH, HL or HN indicators repeatedly appear, the High Altitude Compensation mode may need to be changed to moderate or maximum compensation in higher elevations.

Measuring Chamber Indicators (RBC, PLT, WBC)			
OR	Measurement warning: Re-analyze	The cell pulses arrived faster than the analyzer could process them. Possible reasons might be air bubbles, electrical disturbances or incomplete lysing. **NOTE:** Filtered away cell pulses might raise the OR flag, so it might not be possible to see them in the histograms or the result parameters. This is a hard limit determined by the software.	Re-analyze sample.
SE	Measurement statistics warning: Re-analyze	The rate of cell pulses per time unit varies too much. Possible reasons might be clogging, air bubbles, electrical disturbances or difficult to lyse cells. **NOTE:** Filtered away cells might raise the SE flag, so it might not be possible to see them in the histograms or the result parameters.	Re-analyze sample.

Mixing Beaker Indicators (RBC, PLT, WBC)			
TE	Liquid analyzer problem: Run prime cycle	The analyzer detected an abnormality during the emptying of the first dilution from the mixing beaker. Reasons for flagging might be a time-out, or too short of a transfer time.	Run a "prime cycle" before re-analyzing the sample.
Reagent and Control Indicators (RBC, PLT, WBC, LYM/MONO/GRAN)			
EC	Expired control	A control blood was used past its expiration date.	Use a fresh blood control.
ER	Expired reagent	The reagent was used past its expiration date. Change to a non-expired lot of reagent.	Use a new lot of reagents.
NR	Not enough reagent left: Check reagent levels	The analyzer's capacity counter has gone below zero and no reagent is detected. Reason for no reagent may include empty reagent bottle or reagent tube assembly not inserted correctly into reagent bottle.	Check reagent levels. Check reagent wand placement.
Reagent Pipette Indicators (RBC, PLT, WBC)			
DF	Diluent analyzer problem: Run prime cycle	The analyzer detected an abnormality during one of the fill cycles of the diluent pipette. Reasons for flagging might be timeout, short time or bubbles at the upper detector.	Verify analyzer is filled, run a "prime cycle" and then re-analyze sample.
DP	Diluent analyzer problem: Run prime cycle	The analyzer detected an abnormality during one of the empty cycles of the diluent pipette. Reasons for flagging might be timeout, short time or liquid not detected at the lower detector.	
LF	Lyse analyzer problem: Run prime cycle	The analyzer detected an abnormality during the fill cycle of the lyse pipette. Reasons for flagging might be timeout, short time or bubbles at the upper detector.	
LP	Lyse analyzer problem: Run prime cycle	The analyzer detected an abnormality during the empty cycle of the lyse pipette. Reasons for flagging might be timeout, short time or liquid not detected at the lower detector.	
ST	Air bubbles: Run prime cycle	The time for the liquid meniscus to pass from the lower to the upper detector is unreasonably short.	Run a "prime cycle" before re-analyzing the sample.
TB	Air bubbles: Run prime cycle	Air bubbles were detected by the start detector in the diluent column.	
TL	Possible orifice blockage: Run prime cycle and then re-analyze	The liquid meniscus in the measuring tube never passed the lower detector.	
TU	Possible orifice blockage: Run prime cycle and then re-analyze	The liquid meniscus in the measuring tube passed the lower detector but never passed the upper one.	
#####		The count is too high or too low for the analyzer to measure. If it is suspected that the flag is due to an extremely high result, you may dilute the sample with saline. This flag can also be generated if electrical interference is present.	

6.1 Installation

Unpack Materials:

Unpack, identify, and lay out the following components shipped with the analyzer:

- HemaTrue Veterinary Hematology Analyzer User Manual (CAT 5610)
- HemaTrue Veterinary Hematology Analyzer Quick Steps (CAT 5609)
- Waste tube
- Reagent tube assembly for the Diluent (Red)
- Reagent tube assembly for the Lyse (Yellow)
- Reagent tube assembly for the Cleaner (Blue)
- Reagent bottle tray
- Line conditioner (CAT 4062)
- Power adapter and cord
- Installation form
- Barcode reader
- USB cable for data transfer or printer

Make sure reagents, controls and printer are available for use during installation.

Place the Analyzer in the Intended Work Space Within the Facility:

The analyzer should be placed in a laboratory environment according to the guidelines below:

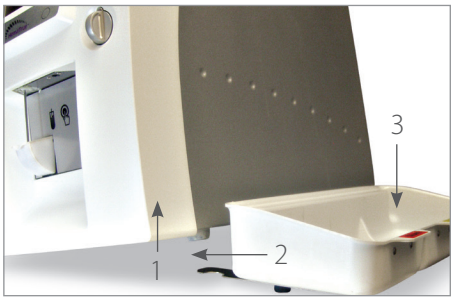
- Place the analyzer on a clean horizontal surface.
- Avoid direct sunlight exposure.
- Ensure the analyzer has access to proper ventilation. The analyzer should have at least 2 inches (5 cm) of free space above it, and at least 4 inches (10 cm) in the rear.
- Avoid placing analyzer in close proximity to devices which may produce electrical interference.
- The fluid Waste container or drain must be at or below the level of the analyzer.
- Avoid lifting the analyzer from the front cover; lift from sides.

Connect Reagent Tray:

Perform the following steps in order:

Install the Reagent Bottle Tray

1. Carefully lift up right-hand side of analyzer about 1 inch off of the counter top.
2. Slide plate of reagent bottle tray underneath the analyzer so the analyzer's right-hand feet align with corresponding holes in the plate.
3. The Diluent position (red label) should be towards the front of the analyzer.



Connect Reagent Tubing:

The tubing connections are located on the rear of the analyzer, to the left of the interface cable panel.

The connections use secure Luer-Lok fittings. Twist clockwise to tighten.

Perform the following steps in order:

1. Connect the waste tube to the analyzer and plumb to Waste container or drain (#1).
2. Connect the Diluent reagent tube assembly (red) to the analyzer (#2).
3. Connect the Lyse reagent tube assembly (yellow) to the analyzer (#3).
4. Connect the Cleaner reagent tube assembly (blue) to the analyzer (#4).
5. Plug the Diluent, Lyse and Cleaner reagent level sensor plugs into the respective level sensor electrical inlets (#5).

NOTE: The cap and probe end of the reagent tubes may be set beside the reagent tray for use when the reagents are installed. Remove the protective plastic film from each reagent tube assembly before placing assemblies into the reagent containers.

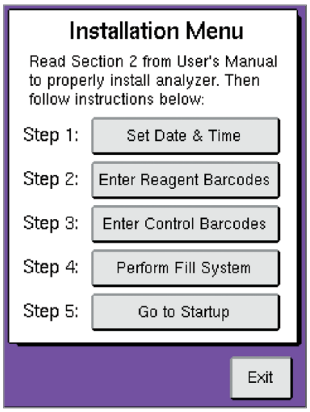
Connect Electrical and Cable Connections:

1. Connect the barcode reader cable (#1).
2. Connect a PC USB cable, if applicable (#2).
3. Connect the printer USB cable, if applicable (#3).
   - Epson C88+ protocol or OkiData protocol compatible through the USB cable (supplied by Heska as an accessory).
   - Supported printers: Epson C88+ or OkiData B411dn.
   - It is recommended to use the printer supplied by Heska.
4. Connect the power cord to the back of the analyzer #4, but do not plug it into an electrical socket. Make sure power switch is OFF ("O") (#5).
5. Plug the analyzer into the CVT (line conditioner) provided with analyzer. Plug the CVT into a grounded electrical socket.
6. Turn ON the power switch (#5). After analyzer initialization, an INSTALLATION MENU will appear.

Configure the HemaTrue Analyzer:

Perform the following steps in order:

1. Press **SET DATE & TIME**. Enter the date and time and press **EXIT** to return to the INSTALLATION MENU.

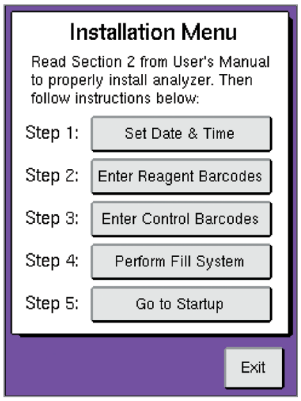


2. Press **ENTER REAGENT BARCODES.** Scan Barcode 1 and then Barcode 2 on the Diluent container. Press and hold **ON** button each time a barcode is scanned.
   a. Press **ENTER ANOTHER BARCODE** and scan Barcode 1 and then Barcode 2 on the Lyse container.
   b. Press **ENTER ANOTHER BARCODE** and scan Barcode 1 and then Barcode 2 on the Cleaner container.
   c. Place the Diluent, Lyse, and Cleaner bottles in the appropriate color-coded locations of the reagent bottle tray with handles facing outward.

   d. Remove the bottle caps and packaging seals. Place the respective color-coded reagent tube assembly into each reagent container. The reagent containers and reagent tube assemblies will have the appearance as shown to the right.

   e. Press **EXIT** to go back to the INSTALLATION MENU.

3. Press **ENTER CONTROL BARCODES** to enter the control assay value ranges. Using the control barcode insert sheet that is supplied with the control samples, scan Barcodes 1–9 in order. Press and hold **ON** on the scanner for each of the 9 barcodes to be scanned. When accepted, press **EXIT** to return to the INSTALLATION MENU.
4. Press **PERFORM FILL ANALYZER** to fill the analyzer with reagents. This step will last about 3 minutes.



5. Press **GO TO STARTUP** after the analyzer has finished the fill cycle. The analyzer will enter the daily startup menus.

NOTE: After initial setup, it is recommended to print all analyzer settings and keep for personal records. Select [Advanced] from MAIN MENU ▶ [Setup] ▶ [Print All Settings]. This can only be done if printer is connected directly to the HemaTrue Analyzer.

Follow Daily Startup Sequence

After pressing **GO TO STARTUP** in Step 5 above, refer to *Getting Started and Running a Sample* sections of the *HemaTrue Veterinary Hematology Analyzer Quick Steps Guide* (CAT 5609) for daily startup procedures and sample analysis.

Set Altitude Compensation, if Necessary

The default setting "0" is for installation at an altitude of less than 3,250 ft (1,000 m) above sea level.

Skip this step if installation is at an altitude of less than 3,250 ft.

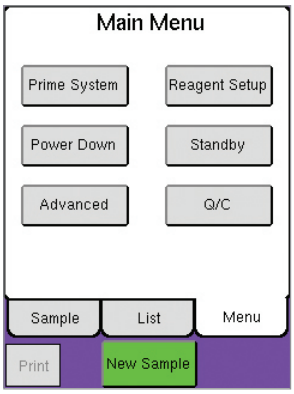
For installation at an altitude greater than 3,250 ft, select [Advanced] from MAIN MENU ▶ [Setup] ▶ [Setup Menu 2] ▶ [Setup Menu 3] > [High Alt Setting].

Press the button containing **0**. Enter operator ID and Authorization Code (2576) and press **OK**. Press **1** on the screen keypad. Press **OK**. The setting will be 1= Moderate Compensation. Press **EXIT** five times to navigate out to the MAIN MENU.

7.1 Menu Selection

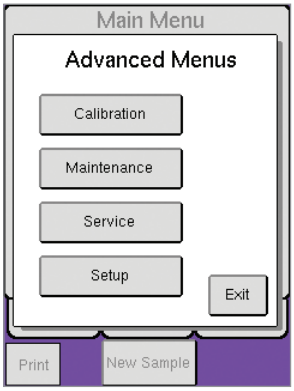
Main Menu Upon Initialization:

- From the Main Menu screen, all other menus can be accessed for setup.



List and Analyzer Menu:

- By pressing ADVANCED, the Advanced Menus will be displayed.



7.2 Initial Setup

Initial setup of the analyzer, except date and time, has been factory set to default values for veterinary users. However, other user definable formats may be preferred. Details are provided below.

Setting Up Date/Time:

The date/time function is shown on all samples and printouts and should always be setup correctly. To set date/time follow the instructions below:

1. Start by selecting [Advanced] from the MENU tab.
2. Select [Setup], then select [Setup Menu 2].
3. Select [Date/Time Setup] to enter the set date/time menu.
4. Select [Date Format] to select date specific setting.
   1 = DD/MM/YY; 2 = YY/MM/DD, 3 = YY/DD/MM, 4 = MM/DD/YY
5. Press on the item that you want to change and enter the changes on the numerical pad.

Setting Up Language:

Change of display language is performed by following the instructions below:

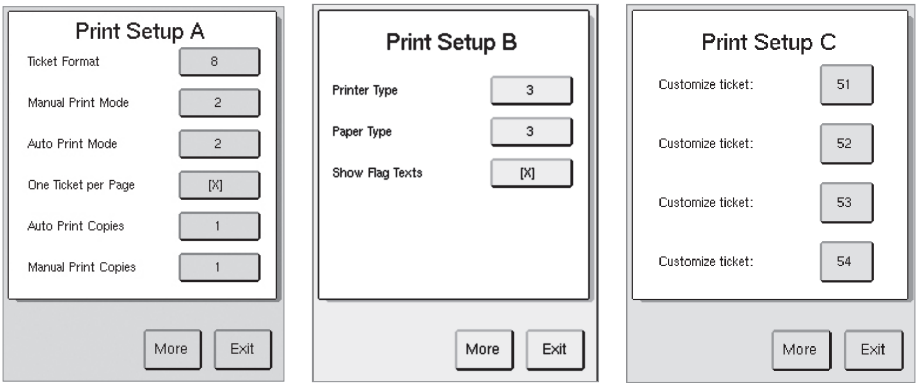
1. Start by selecting Advanced from the MENU tab.
2. Select [Setup], then select [Setup Menu 2].
3. Select [Regional Setup]; a list of local settings will be displayed.
4. Press **MORE** until language button is displayed.
5. Press **LANGUAGE** to enter language screen.
6. Choose the number that corresponds with the language desired and press **OK** to save.

7.3 Advanced Setup

Initial advanced setup of the analyzer has been factory set to default values for veterinary users. However, other user definable formats may be preferred. Details on how to configure the analyzer for barcode readers, printers, data communication, *etc.,* are provided below.

Printer Setup Menus:

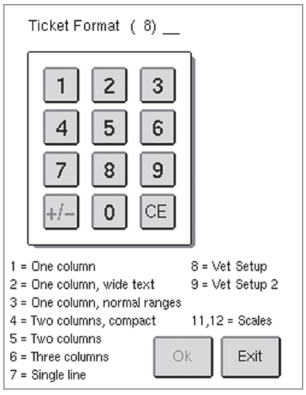
To change printer and printout formats select [Advanced] from the MAIN MENU, then [Setup], and then [Print Setup]. There are three PRINT SETUP MENUS to choose from. Press **MORE** to access the three different screens (A, B, C).



Print Setup A:

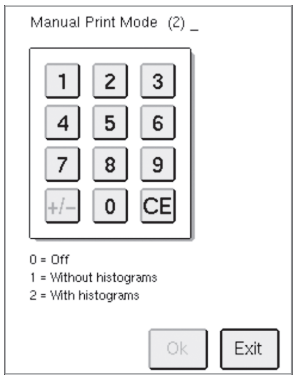
Ticket Format

This function allows the user to change the column layout of the printout. To change the format, choose the corresponding number from the list below and press **OK**. To use the Heska ticket format, enter 8.



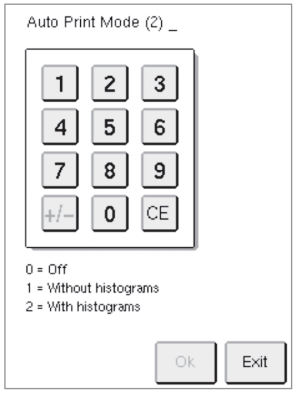
Manual Print Mode

This function allows the user to printout a result using the **PRINT** button. To turn this function off, select [0]. If a printout is preferred, select either [1] or [2] to choose if printout will contain a histogram along with the numerical values. Press **OK** once a number has been selected.



Auto Print Mode

This function allows the user to select whether a printout is automatically printed after each sample, background, or control analysis. If no automatic printout is preferred, select [0]. If a printout is preferred, select either [1] or [2] to choose if printout will contain a histogram along with the numerical values.



One Ticket Per Page

This function allows the user to print more than one analysis per page. Default is set to one analysis per page (activated). Select [Inactivate] if user wants to print more than one analysis per page. The allowable number of analyses per page is dependent on print format setup. See Figure 7.9 to activate or inactivate the ability to print more than one analysis per page.

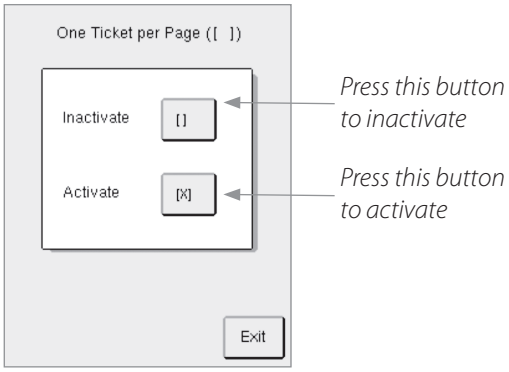


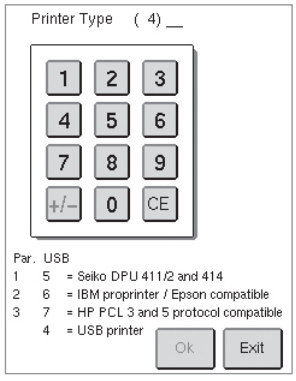
Figure 7.9

Print Setup B:

Printer Type

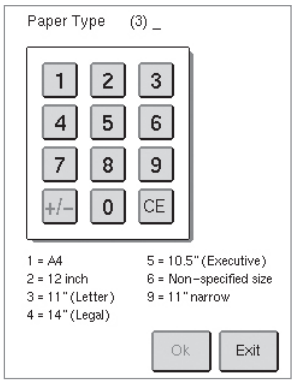
The analyzer has been automatically set to the USB printer, which is compatible with the printer provided by Heska. (Printer type 4.) Contact local distributor for current list of available USB printers. If using USB printer other than that specified by distributor, the printer must be HP PCL 5 compatible.

To connect the instrument to a printer, follow the instructions in *Section 6: Installation*. Once connected via USB cable, instruct the printer to interface with the instrument by verifying the printer type is set to.



Paper Type:

This function allows the user to choose the type (size) of paper used for the printout. Paper types are printer dependent. Select from the following list:



1. Seiko DPU 411/2 and 414 (not applicable, uses paper rolls)
2. IBM Proprinter/Epson compatible
   - 1 = A4
   - 2 = 12"
   - 3 = 11" (Letter)
   - 4 = 14" (Legal)
   - 5 = 10.5" (Executive)
   - 6 = Non-specified size
3. HP PCL 3 and 5 protocol compatible
   - 1 = A4
   - 3 = 11" (Letter)
   - 4 = 14" (Legal)
   - 5 = 10.5 " (Executive)
   - 6 = Non-specified size

Show Flag Texts:

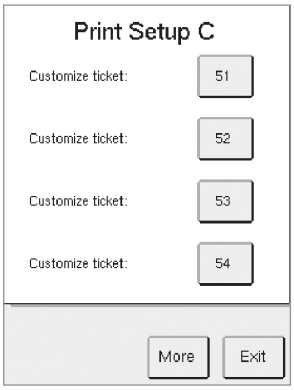
This function allows the user to choose whether flag text is printed. Default is set to display flag text (activated). Select [Inactivate] if user does not want to display flag text on printout.

NOTE: If an option is not available, the number will not be accepted when operator presses **OK**.

Print Setup C:

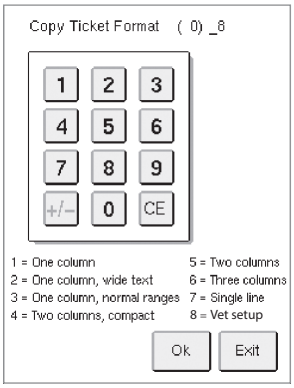
Customized Print Formats

The Customized Print Format allows the user to copy a ticket format, enter their own Header and Footer text, margins, paper length, histogram format, and parameter order for the results on the printout.



Step 1: Select [Advanced] from the MAIN MENU ▶ [Setup] ▶ [Print Setup]. Press **MORE** twice to enter Print Setup C and select one of the Customize ticket buttons 51–54.

Step 2: Choose a Ticket Format, by copying a pre-established Ticket Format (Heska Default format = 8) and press **OK** to accept and then **MORE** to continue to next Step).



NOTE: Parameter Order and Histogram format are not changeable in Ticket Format 8.

Step 3: To change the format of the histograms choose [Histogram Format]. Select one of the formats from the list below, then press **OK** to save:

0 = Default for the ticket format and printer selected.

1 = 3 double width histograms placed vertically (same as Printer Type 1 Format).

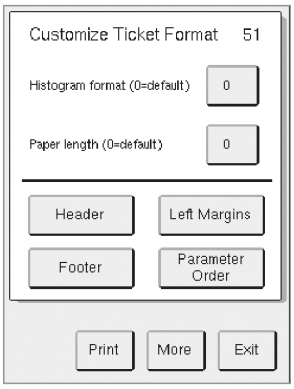
2 = 3 single width histograms placed horizontally (same as Printer Type 2 Format 4).

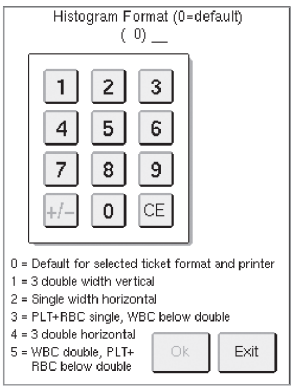
3 = PLT and RBC single width histograms side by side and WBC double width histogram in next row.

4 = 3 double width histograms placed horizontally (very wide, set left margin to 0).

5 = WBC double width histogram and PLT and RBC single width histograms side by side in next row (same as Heska Format 8).

NOTE: By selecting [Print] the user can printout and view the last sample with the new format changes.



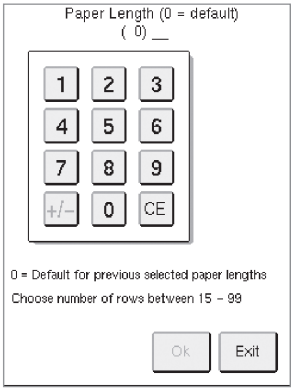


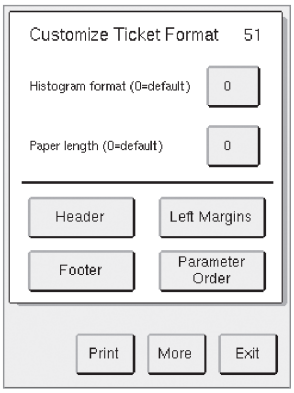
Step 4: To change the format of the paper length select [Paper Length], then select one of the formats from the list below.

This selection is only used in case the connected printer is not conforming to the current standard, and allows the user to override the current selections regarding form feed and print form lengths as shown in *Paper Type* section. Press **OK** to save:

0 = Default for the ticket format and printer selected

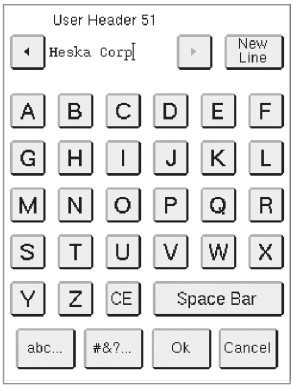
15–99 = Choose the number of rows to adjust the paper length

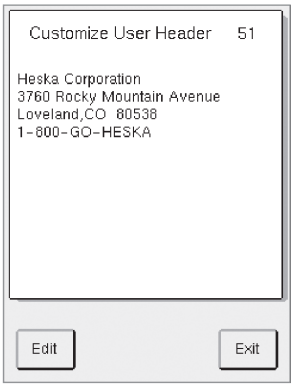




Step 5: Select [Header] and then [Edit]. The Header text is positioned above the parameters and ID on the printout. Begin by typing in the desired Header text. This text will be displayed between the two arrows on the top of the page.

- To add another line of text, select [New Line] and an enter symbol will appear to show where the next line begins. (Put one new line at end of the header text entry).
- To delete a word or letter, use the arrow buttons to place the cursor before the word or letter to be deleted and then press CE until deleted.
- To enter a space press Space Bar.



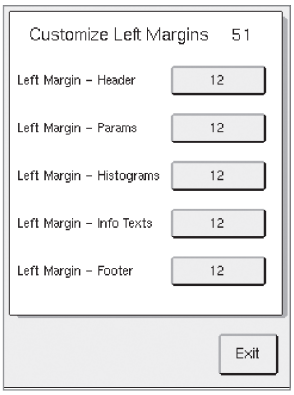


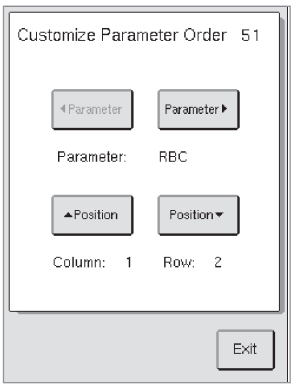
Step 6: When the Header is complete press **OK** and the Header will appear on the display page to view. If no further edits are necessary select **EXIT**. If not entering a footer, customizing margins, or parameter order, go to Step 10.

Step 7: The Footer text is positioned below the parameters and histograms on the printout. Repeat Steps 5–6 to customize the footer, except choose [Footer] at Step 5.

Step 8: Left Margins allows the user to edit the left margins for the header, parameters, histograms, information text, and footer for a selected ticket format.

- Select [Left Margins]. Choose which margin to change, and select the margin by the number of spaces from the left side of the printout page. (Example: Choosing 12 for the header will move the header text 12 spaces from the left side of the page.)
- Select [Ok] to save margin spacing. Choose next margin to be changed, and when complete press EXIT to save.





Step 9: Parameter Order allows the user to edit how the order of parameters appears on the printout. The number of columns and rows is dependent on the copy of the ticket format selected. Select [Parameter Order].

- By pressing the ▲ POSITION and POSITION ▼ buttons the user scrolls through the Rows and Columns. If there is more than one column, the second column can be viewed by pressing POSITION ▼ one more time after the last row of the previous column is displayed.
- By scrolling through the positions, the current parameter that is in that position is viewed under the Parameter buttons.
- To change a parameter in a certain position, scroll to the position first and then use the ▼ PARAMETER and ▲ PARAMETER buttons to select the new parameter for that position.
- The user can change one or multiple parameters at a time. If many parameters will be changed, continue with position and parameter selections until complete, and then press EXIT.
- Parameter order and position can be viewed the same as the Header and Footer by selecting [Print].

NOTE: 'Skip' means that nothing is printed at the selected row and 'Blank' means that an empty field (line) will be printed in that position.

NOTE: If Format 4 is chosen, WBC parameters in the second column are fixed and cannot be edited.

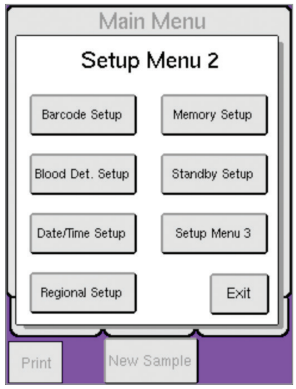
Step 10: To choose the new Customized Print formats as printout default, select [Exit] and then [More] to enter Print Setup A. Enter your customized ticket number (Example: 51) into [Ticket Format] and press OK to save.

Setup Menu 2:

Barcode Setup

To setup the barcode reader follow the instructions below. (Note that the default barcode setting is 9600N81). See barcode reader insert to determine types of barcodes that can be scanned if using barcodes for patient IDs.

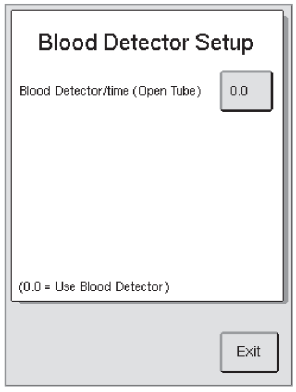
1. Start by selecting [Advanced] from the MENU tab.
2. Select [Setup], then [Setup Menu 2].
3. Select [Barcode Setup] to enter the BARCODE SETUP MENU.
4. Touch box next to set USB barcode reader and connect barcode reader to an available USB port on the back of the instrument.



Blood Detector Setup

This function allows the user to enable and disable the blood detector.

- Setting this function to "0" enables the blood detector function. When enabled, aspiration stops when blood is detected by the blood detector sensor.
- A fixed aspiration time can also be selected (from 0.1–10 seconds) if needed. (Setting blood detector to any value except "0" disables the blood detector).



Memory Setup:

Storing Raw Data

- The default for Storing Raw Data is 'Inactive', as this function takes up a larger amount of memory when activated and will decrease the number of samples stored in memory.
- The main purpose for activating this function is for research studies and service use. (A special program is needed when transferring this data to a computer. Contact Heska's Technical Support Services for more details.)
- Choose [Activate] if function is needed.

Activate Flash Memory

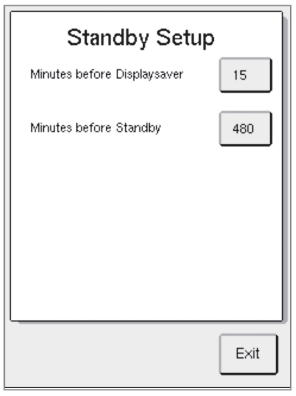
The default for Flash Memory Mode is 'Inactive'. Contact Heska's Technical Support Service for more details on activating this mode.

Standby Setup:

These functions allow the standby timeouts to be changed.

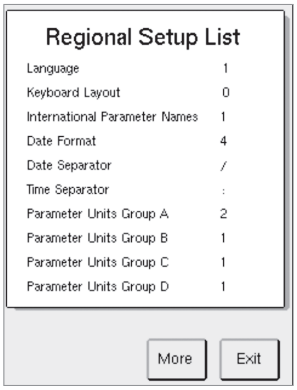
- Minutes before Display saver can be set from 2–120 minutes. The default is 15 minutes.
- Minutes before Standby can be set from 10–720 minutes. The default is 480 minutes.

NOTE: It is recommended that 480 minutes not be exceeded.



Regional Setup A:

This function allows the user to select the language, keyboard layout, and international parameter names.

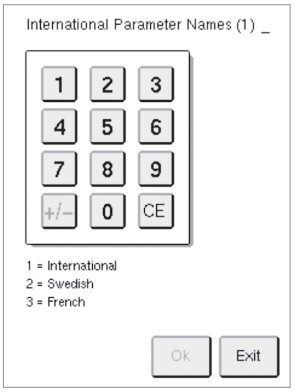


International Parameter Names

- Many countries have different names and acronyms for hematology parameters.
- This functional allows the user to set language dependent parameter names. (Example: France vs. Switzerland, both use the French language but they use different parameter names.)
  1 = International

  2 = Swedish

  3 = French



Regional Setup B:

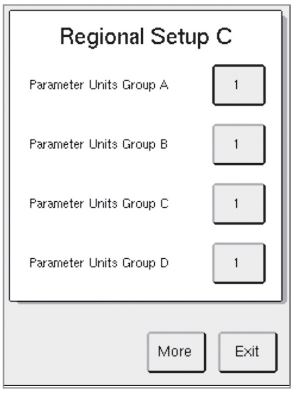
This function allows the user to set the date format, the date separator, and the time separator.

Regional Setup C:

Parameter Unit Selection

This section describes how to set the parameter units for the HemaTrue Analyzer. The parameter units are in groups.

- Select Parameter Units Group A, B, C, or D, then enter selection number to choose the desired parameter unit group, and then press **OK** to select new group. The table below lists the parameter unit groupings.



Parameter Units Group A		
Selection 1	Selection 2	Selection 3
RBC 10^12/l	RBC 10^6/ul	RBC 10^6/mm^3
WBC 10^9/l	WBC 10^3/ul	WBC 10^3/mm^3
PLT 10^9/l	PLT 10^3/ul	PLT 10^3/mm^3
DIFF 10^9/l	DIFF 10^3/ul	DIFF 10^3/mm^3

Parameter Units Group B	
Selection 1	Selection 2
MCV fl	MCV um^3
MPV fl	MPV um^3
RDW(a) fl	RDW(a) um^3
PDW fl	PDW um^3

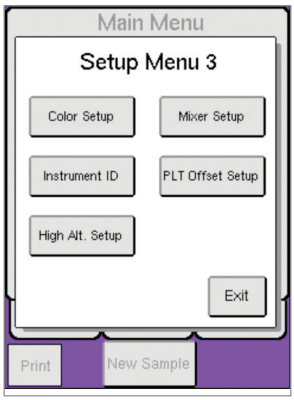
Parameter Units Group C		
Selection 1	Selection 2	Selection 3
HGB g/dl	HGB g/l	HGB mmol/l
MCH pg	MCH pg	MCH fmol
MCHC g/dl	MCHC g/l	MCHC mmol/l

Parameter Units Group D	
Selection 1	Selection 2
HCT %	HCT l/l

Setup Menu 3:

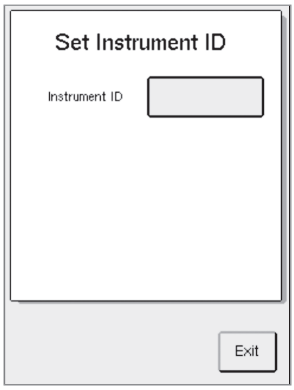
Color Setup

This function allows the user to choose a black and white display instead of a color display. Choose [Activate] to change to black and white display.



Instrument ID Setup

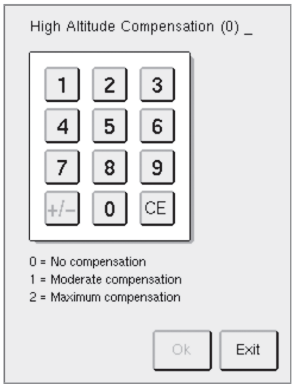
If multiple instruments are used in the same laboratory, a specific ID name or number can be entered here for ease of identification.



High Altitude Setup

- The default setting for this function is "0", no compensation for installation at an altitude of less than 3,250 feet (1,000 meters) above sea level.
- This function only needs to be activated if various HF, HH, HL, or HN Indicators repeatedly appear. If so, then the mode may need to be changed to Moderate or Maximum compensation in higher elevations.

- By choosing 1 or 2, the software incorporates some minor timing sequences for the wash cycles. No other functions are affected.



Mixer Setup

To change mixer setup follow the instructions below:

1. Start by selecting [Advanced] from the MENU tab.
2. Select [Setup] and then [Setup Menu 2].
3. Select [Setup Menu 3], then [Mixer Setup].
4. If the mixer is activated the button will have brackets [X]. To deactivate press button and select ([ ]).

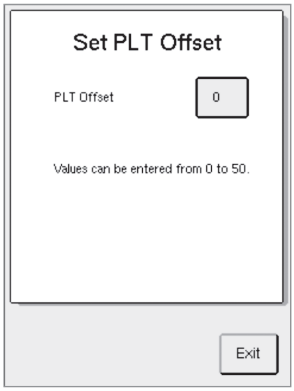
NOTE: Upon sample aspiration the mixer will discontinue rotation until sample analysis is complete.

IMPORTANT

Prior to analysis, the tube should be placed in the mixer for a minimum of one minute.

PLT Offset Setup

- The function of the Platelet (PLT) Offset is to set a background count value for PLT. It is recommended to keep PLT Offset value at "0."
- The PLT Offset can be set from 0–50, if necessary. (This function should not be used for the purpose of forcing QC background count acceptance).



Data Communication

The analyzer is equipped with USB outputs for connection to a computer.

To connect to a PC computer using a USB connector, simply plug in USB cable to the type B USB port on the analyzer (bottom most port) and a type A USB port on the computer.

Serial Output Setup A:

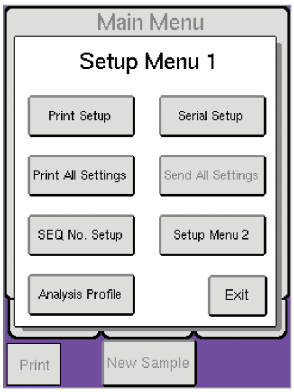
To select options for sending results:

1. Start by selecting [Advanced] from the MENU tab.
2. Select [Setup] and then [Serial Setup] to enter the SERIAL SETUP MENU.
3. To set Manual Send Mode function select from the following:
   0 = None (default), 1 = Without Histograms, or 2 = With Histograms.
4. To select Auto Send Mode function select from the following:
   0 = None (default), 1 = Without Histograms, or 2 = With Histograms.

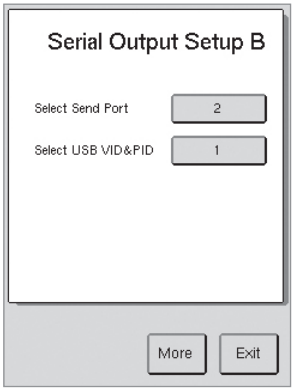
Serial Output Setup B:

Plug in cable between analyzer and computer, and follow the instructions below:

1. Start by selecting [Advanced] from the MENU tab.
2. Select [Setup], then [Serial Setup] and the [More].



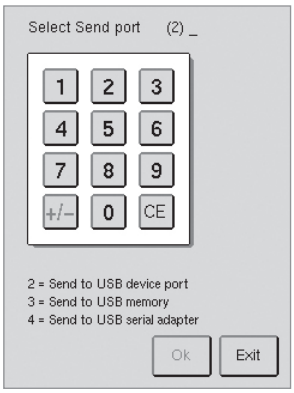
3. To activate the USB connection to a PC computer, select [Select Send Port], press **2** and then **OK** to save.



4. To activate the USB connection to a memory stick, select [Select Send Port], then press **3** and then **OK** to save.

NOTE: For Select Send Port activation to function correctly user must have a PC application that can receive and process reports.

5. To activate the USB to serial adapter connection to a PC computer, select [Select Send Port], then press **4** and then **OK** to save.



7.3 Reagent Setup

This section describes the functions of the REAGENT SETUP MENU and how to access reagent statistics.

Entering New Reagents

The HemaTrue Analyzer is interlocked with Heska specified reagents for optimal performance. The reagent bottles must be identified by the analyzer before analysis of samples can begin. To identify reagents scan in or manually enter the barcodes on the reagent bottles by selecting [Reagent Setup] from the MAIN MENU and then [Enter New Reagent]. Barcodes can be scanned or lot numbers from reagent bottles can be manually entered.

View Reagent:

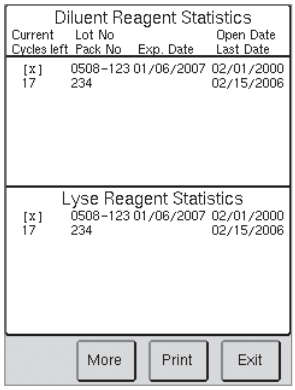
The analyzer monitors reagent consumption and computes remaining cycles. This information may be viewed at any time, in one of two ways:

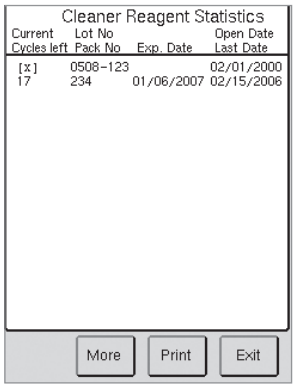
Method 1

1. Start by selecting [Reagent Setup] from the MENU tab.
2. On the lower left-hand side of the Reagent Setup Menu, the remaining cycles for Diluent and Lyse are displayed. (It is important to remember that cycles include sample analyses, wash cycles, background counts, primes, exit standbys, *etc*.)

Method 2

1. The second method of viewing reagent statistics is by selecting [View Reagents] from the Reagent Setup Menu. There are two screens that are divided into the last four Diluent Reagent Statistics, the last four Lyse Reagent Statistics, and the last four Cleaner Statistics. For each, the operator can view the following:
    - [X] indicates which reagent is currently activated.
    - The number of cycles left for specific reagent bottle.
    - The Lot and Pack Numbers.
    - The Expiration Date of the specific reagent bottle.
    - The Open Date, when the reagent bottle was first used on the analyzer.
    - The Last Date, when the last time the reagent bottle was used to run a cycle.





Inactivate Reagent:

It is possible for the operator to inactivate the current reagent bottle by selecting [Inactive Reagent] on the Reagent Setup Menu and then pressing **YES**. Once deactivated the operator must scan in or manually enter another reagent bottle before analysis of samples can begin. An inactive reagent can be reactivated by simply scanning the barcode on the reagent bottle again.

Reagent Indicators:

The interlocked reagent analyzer displays indicator and warning messages to alert the operator when reagents are running low and need to be changed. See *Sections 12.2* and *12.3*.

7.5 User Interface

This section describes the functions of available menus in the analyzer that have not been described in any other section of this manual.

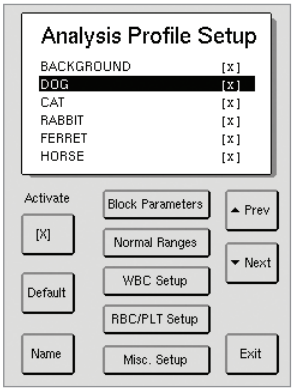
NOTE: The operator will be prompted to enter a 4-digit Operator ID (Operator ID is recommended for in-house records, but is not required) and Authorization Code (REQUIRED) before a change or update to an analysis profile can be made. To update or change analysis profiles input the Authorization Code [2576].

Analysis Profile:

It shall be possible for authorized operators to customize analysis profiles. Six animal/species analysis profiles have been pre-defined in the HemaTrue Analyzer. Each analysis profile has many different formatting options, including profile name, default settings, normal ranges, analysis constants, blocking parameters, *etc*. To add or change analysis profile settings see the following menu options:

1. Start by selecting [Advanced] from the MENU tab.
2. Select [Setup], then [Analysis Profile] to enter the ANALYSIS PROFILE SETUP MENU.

3. To set profile name press **NAME**.
   - Press PREV or NEXT to choose an open profile on list (e.g., AP8, AP9, etc.).
   - Press NAME ON DISPLAY to enter new profile name and press OK when complete.
   - Press NAME ON PRINTOUT to enter new profile name to be displayed on printout and press OK when complete.

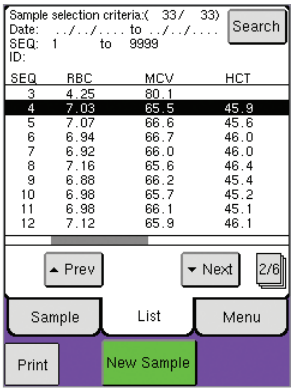


NOTE: Remember to [Activate] the new profile in order to view it as a selection for sample analysis.

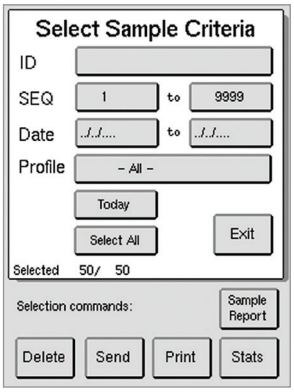
4. To set new profile as default press **DEFAULT** and select [X].
5. To block certain parameters select [Block Parameters] to see list and then [More] to view specific parameters. Press any parameter and select [X] to block parameter.
6. To change RBC/PLT discriminators select [RBC/PLT Setup] to see list and then [More] to view specific discriminators. Press specific discriminator button to change value and then **OK** to save.
7. To change WBC discriminators press **WBC SETUP** to see list and then [More] to view specific discriminators. Press specific discriminator button to change value and then **OK** to save.
8. To change normal ranges select [Normal Ranges] to see list and then [More] to view specific parameter range. Press **SPECIFIC PARAMETER RANGE** to change value and then **OK** to save.

Sample Memory:

The following procedures explain how to search for previous sample analyses and statistics, and print, send, and delete sample results that are stored in memory.



1. To view recent previous analyses present in a sequential list, press **PREV** or **NEXT** to scroll through samples in either SAMPLE or LIST MENUS.



2. To view a specific sample or a group of samples press **SEARCH** in LIST MENU. In this menu samples can be selected by Sample ID, SEQ, DATE, and Sample Profile. Press corresponding button to select, and then **EXIT** to return to LIST MENU and view newly selected samples.

NOTE: To return to previous selection criteria press **SEARCH**, then **SELECT ALL**, and then **EXIT**.

3. To view Sample Statistics, select sample or group of samples to view, and press **STATS** to enter the STATISTICAL RESULTS MENU.
4. To print or send selected sample or sample statistics press **PRINT** or **SEND**.
5. To delete a selected sample or group of samples press **DELETE**. The analyzer will display a prompt to verify deletions, press **YES**.
6. To print a summary report of every sample run press **SAMPLE REPORT** and then **PRINT ALL SUMMARY REPORT**.
7. To print a summary report of a selected group of samples, select desired criteria (See #2 above), then press **SAMPLE REPORT** and then **PRINT PATIENT SUMMARY REPORT**.

NOTE: These summary reports will print on a horizontal sheet of paper. To print summary reports you can only use HP PCL 3 and 5 protocol compatible and USB printers.

All Settings:

From Menu tab press **ADVANCED** and then **SETUP** to enter SETUP MENU.

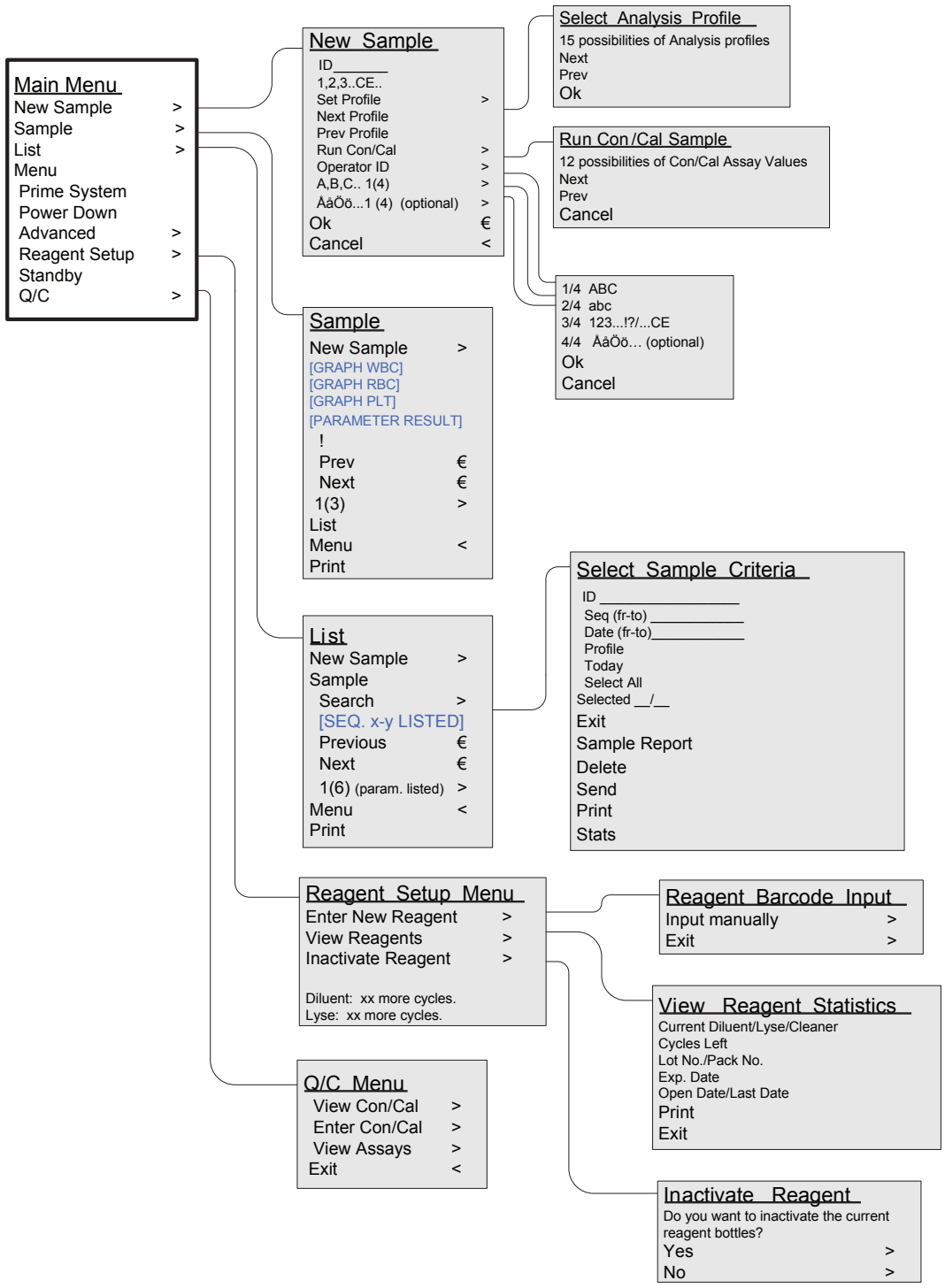
- To print all analyzer settings, verify analyzer is connected to a printer and press PRINT ALL SETTINGS.
- To send all analyzer settings, verify analyzer is connected to a computer and press SEND ALL SETTINGS.

Change Sequence Number:

From MENU tab press **ADVANCED** and then **SETUP** to enter SETUP MENU. To change sequence number press **SEQ NUMBER SETUP**, press **NEXT SEQ NUMBER,** enter in new sequence number and press **OK** to save.

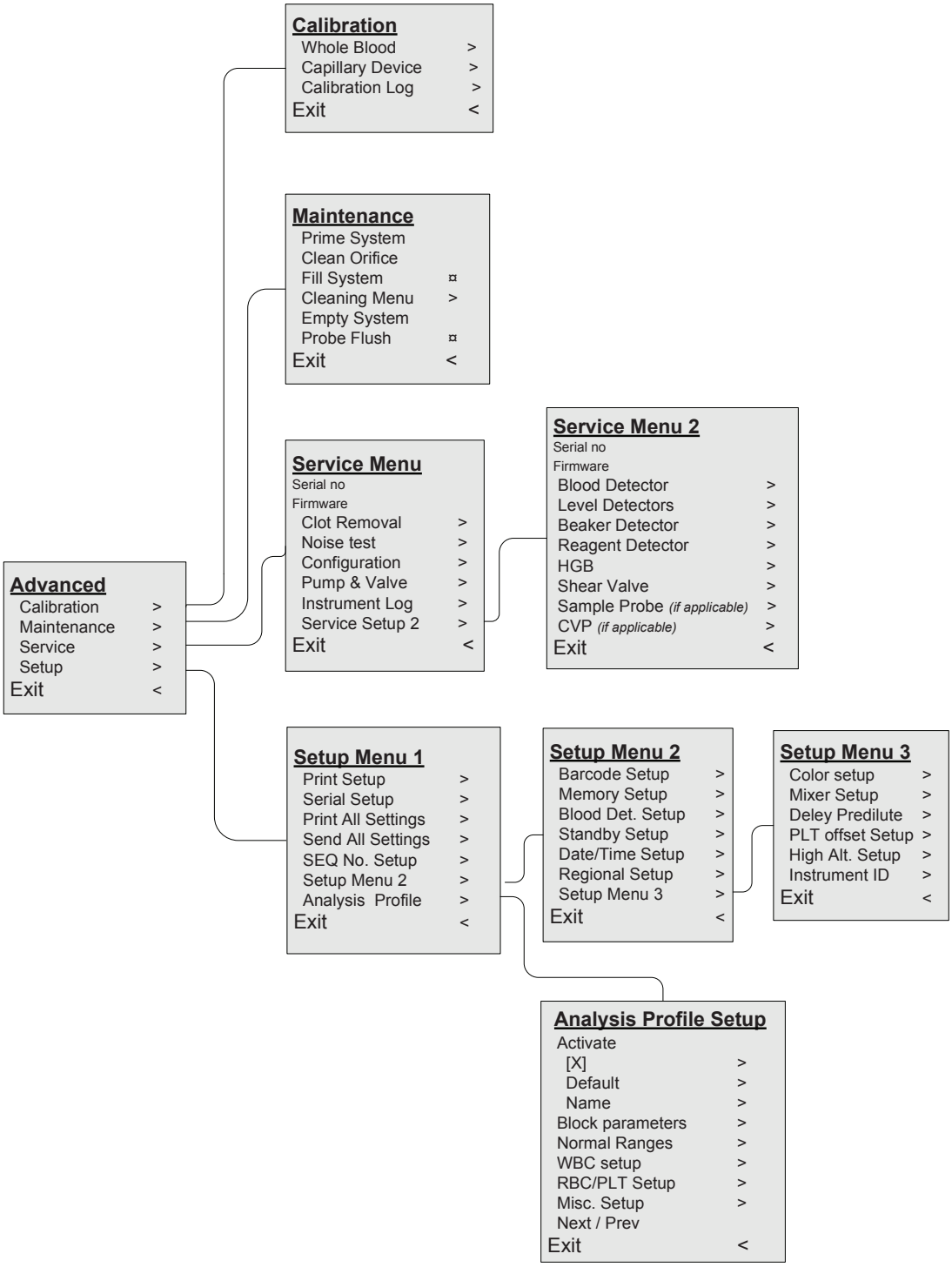
7.6 Main Menu Structure Flowchart

Main Menu Structure:

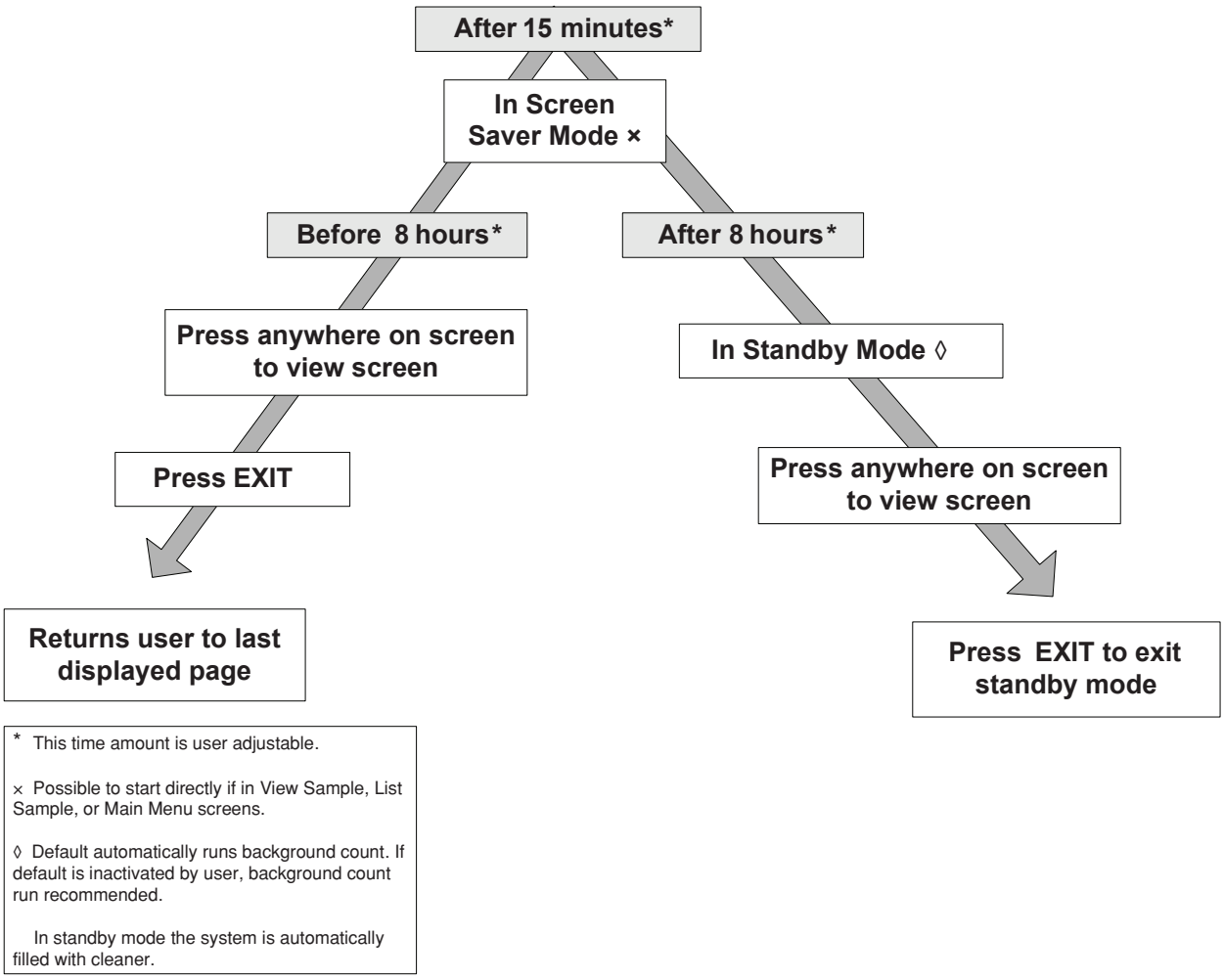


7.7 Advanced Menu Structure Flowchart

Advanced Menu Structure:



Analyzer Standby and Cleaning Cycles:



* This time amount is user adjustable.

× Possible to start directly if in View Sample, List Sample, or Main Menu screens.

◊ Default automatically runs background count. If default is inactivated by user, background count run recommended.

In standby mode the system is automatically filled with cleaner.

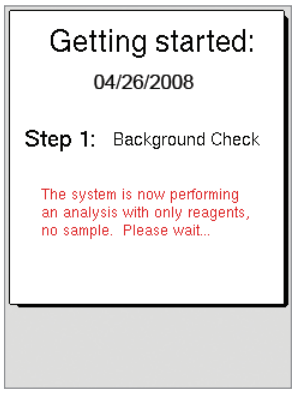
8.1 Startup Sequence

The following sequence walks the operator through the beginning of the daily startup routine for the analyzer. There are 2 steps which take the user through a background and control analysis sequence with detailed guidance at each step.

Default setup:

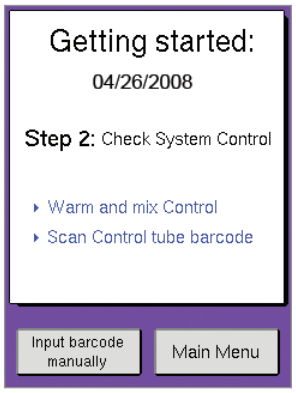
The startup sequence is set as a default in the HemaTrue Analyzer but can be bypassed if a different startup routine is desired. It is recommended by Heska to use this guided startup sequence.

1. Touch display or switch on power to the analyzer.
2. Press **EXIT STANDBY** or **PWRUP**, depending on how the analyzer was shutdown previously, to "wake up" the analyzer.
3. Press **START PLATE** to begin a Background Check, the first step of the startup sequence.



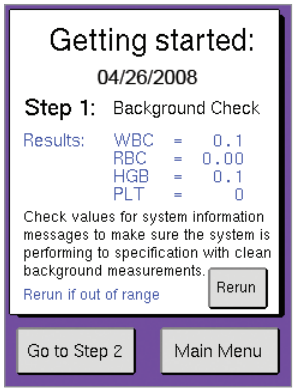
4. When complete, the background count results are displayed. If the results are acceptable, scan in the barcode on the control vial and follow directions on the display to begin the second step of the startup sequence.

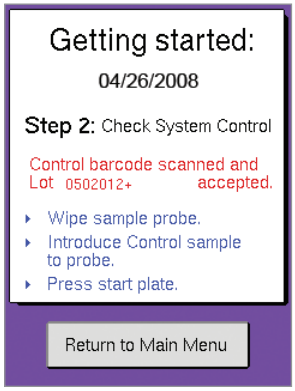
NOTE: If the background count results have a H (high) indicator, press **RERUN** to analyze background count again.



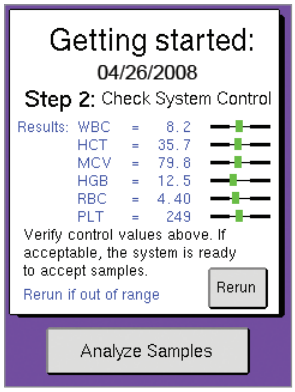
5. When complete, the control results are displayed. If control results are acceptable, the startup sequence is complete. Press **ANALYZE SAMPLES** to go to the main screen, and follow instructions in the following sections to analyze samples.

NOTE: If control sample results have a H (high) or L (low) indicator press RERUN to analyze control sample again.





Refer to the following two sections for instructions to perform background or control analysis at times other than in the startup sequence.

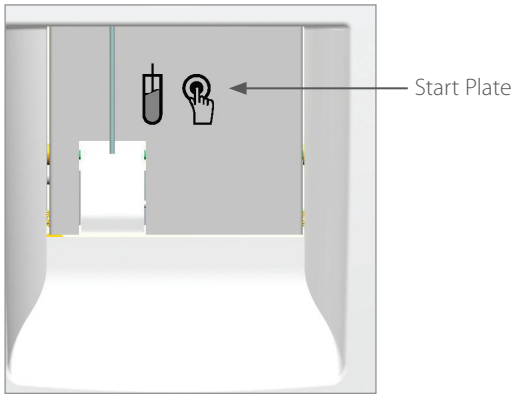


8.2 Background Count

Background Check:

The following sequence is performed to check the background count if not using the startup screens. It is recommended to run a background check at the beginning of each day and when switching between different analysis modes.

1. From the main screen press **NEW SAMPLE**.
2. Press **NEXT PROFILE** or **PREV PROFILE** to scroll to [Background].
3. Press the **WHOLE BLOOD START PLATE**, which is located behind the whole blood sample probe.



NOTE: The aspiration time is approximately 10 seconds. After ~10 seconds the analyzer will time out due to no detection of blood, and continue its cycle.

Accepted Background Values:

The background count should not be higher than the values shown below. Rerun sample if values are not acceptable. If second background count is not acceptable, refer to *Appendix A–High Background Counts* flowchart, or contact Heska Technical Support Services at 800.464.3752, option 3.

Parameters	Values Accepted
RBC	≤ 0.03 (10^6/µl)
WBC	≤ 0.2 (10^3/µl)
HGB	≤ 0.2 (g/dL)
PLT	≤ 10 (10^3/µl)

8.3 Quality Control (QC)

Control Analysis:

Good laboratory practice indicates that the performance of the HemaTrue Veterinary Hematology Analyzer is checked daily with certified blood controls authorized by Heska. For good laboratory practice controls may also be used for troubleshooting purposes, when changing to a new lot of reagents, and to check for damage during transport or after storage. Comparing the analyzer results to the known assay values provides assurance that the analyzer is functioning properly.

IMPORTANT

- **Please refer to the Blood Control Product Insert for complete instructions for handling and use of blood control materials.**
- **Never use an open vial longer than recommended by the manufacturer or subject any vial to excessive heat or agitation.**
- **Wipe the sample probe with a Kimwipes® tissue or equivalent before each control run. Not performing this step may lead to decreasing parameter values due to dilution of the control material.**

1. Follow directions on Assay Sheet to scan in barcodes for the lot of control material in use.
2. Select either [List, Sample, or Menu] to begin control analysis.
3. Using installed barcode reader, scan the Control ID from the blood control vial label or manually enter in barcode.
4. Aspirate the blood control and wait for the results. The HemaTrue Analyzer will identify this ID and match the results with the previously defined assay values.
5. Compare control results to assay values on results screen.

8.4 Sample Identification

This section describes the different methods of inputting Sample IDs (Identification).

ID Input Methods:

The sample ID can be entered with the following methods:

- Manually (touch screen or external keyboard)
- Barcode

Character Input and Limitations:

- 16 Characters

1. From the main screen press **NEW SAMPLE** or begin sample aspiration, which automatically opens NEW SAMPLE MENU.
2. Press letter, number or symbol keys to enter sample ID or scan in the ID barcode from the sample tube.
3. Select [Next Profile] or [Prev Profile] to scroll to desired profile (species). If barcode is scanned from control vial, bypass this step.
4. Aspirate sample following selected procedures in *Sections 8.5–8.6*

NOTE: Sample ID entry and profile selection can be performed up to 30 seconds after sample aspiration. Follow the screen instructions.

Operator ID:

The Operator ID is an optional feature which can be entered prior to analyzing a sample or when exiting Standby Mode. To enter an Operator ID press the specified button and enter up to a 4-digit numerical or alphabetic ID. The Operator ID will stay the same until Operator ID button is pressed again and changed, or when the analyzer goes into Standby Mode.

8.5 Sample Collection and Handling

Anticoagulant Recommendation:

EDTA K3 (Ethylene Diamine Tetracetic Acid, Tri-potassium) liquid and EDTA K2 (Ethylene Diamine Tetracetic Acid, Di-potassium) spray-dried solution. Recommended by ICSH and NCCLS.

Sample Collection

- Obtain the sample by means of a clean venipuncture to minimize platelet aggregation.
- Collect the appropriate volume as specified by the EDTA tube being used.
- If collecting blood for hematology and chemistry, fill the EDTA tube first.
- Avoid use of needles smaller than 22 gauge. If a smaller needle is used, the blood should be transferred to the EDTA tube with no tube top and needle removed.
- Avoid transfer of blood to the tubes by turbulent force. The vacuum should be allowed to fill the tubes if passing through a needle.

Handling of Samples

- Immediately gently invert the EDTA tube 6-8 times to adequately mix the blood sample with the anticoagulant.
- Place blood tubes immediately in the HemaTrue Analyzer on-board blood tube mixer until analysis.
- If blood is delivered to the lab area within 5 minutes and placed in the on-board blood tube mixer, it may be analyzed after 1 minute of mixing.
- Minimum time in the mixer is as follows:
  - For small animal samples, place the sample in the on-board blood tube mixer for a minimum of 2 minutes.
  - For horse samples, place the sample in the on-board blood tube mixer for a minimum of 3 minutes.

The time in the mixer can be longer, for example if sample analysis is batched. A sample cannot be mixed too long.

IMPORTANT

The sample should be kept at room temperature and analyzed within 4 hours. Excessive cold or heat could cause erroneous results.

- Avoid use of needles smaller than 22 gauge. If a smaller needle is used, the blood should be transferred to the EDTA tube with no tube top and needle removed.
- Avoid transfer of blood to the tubes by turbulent force. The vacuum should be allowed to fill the tubes if passing through a needle.

Handling of Samples:

- Immediately gently invert the EDTA tube 6-8 times to adequately mix the blood sample with the anticoagulant.
- Place blood tubes immediately in the HemaTrue Analyzer on-board blood tube mixer until analysis.
- If blood is delivered to the lab area within 5 minutes and placed in the on-board blood tube mixer, it may be analyzed after 1 minute of mixing.
- Minimum time in the mixer is as follows:
  - For small animal samples, place the sample in the on-board blood tube mixer for a minimum of 2 minutes.
  - For horse samples, place the sample in the on-board blood tube mixer for a minimum of 3 minutes.

The time in the mixer can be longer, for example if sample analysis is batched. A sample cannot be mixed too long.

IMPORTANT

The sample should be kept at room temperature and analyzed within 4 hours. Excessive cold or heat could cause erroneous results.

8.6 Analyzing the Sample (Open Tube)

This section describes how to aspirate and analyze a sample with the "Open Tube" procedure. The analyzer aspirates the blood sample through the sample probe.

Analyzer and Sample Preparation:

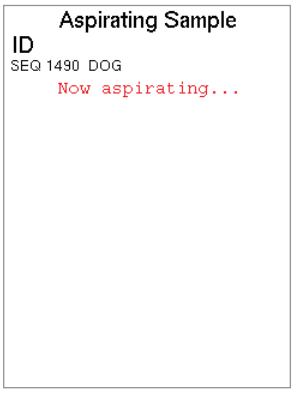
Refer to *Section 8.5* for blood sample preparation and then follow the procedure below:

1. From the main screen press **NEW SAMPLE**. Enter ID and select species. (See *Section 8.4*)
2. Wipe probe with a Kimwipes tissue or equivalent. Aspirate the sample through the sample probe by gently inserting sample probe into the sample tube then press the whole blood start plate behind the sample probe.
3. Follow the instructions on the screen as to when to remove the sample tube. A beep is an audible indication that the sample should be removed from the sample probe.

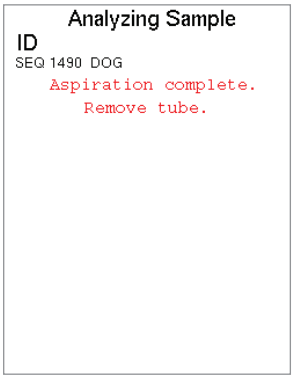
IMPORTANT

- **Make sure the blood sample tube is not touching the upper part of the sample probe.**
- **Do not remove sample prematurely; incomplete aspiration could occur, causing erroneous results.**
- **Do not allow the sample probe to come in contact with the bottom of the sample tube.**
- **Not removing the sample tube after aspiration could result in incorrect washing of the sample probe.**

Sample Aspiration Display:



4. The analyzer now switches to the sample analysis screen.



5. Sample ID and profile can still be added.
6. Approximately 30 seconds after aspiration the display switches to that in Figure 8.13 and no further ID entry is possible.

7. <1 minute after aspiration, results will be displayed on LIST or SAMPLE MENU. For more information about results refer to *Section 8.8*.
8. When **NEW SAMPLE** button returns to green, the operator can begin analysis of the next sample.

8.7 Analyzing the Sample (Micropipette Adapter, MPA)

This section describes how to analyze capillary whole blood samples with the use of the Micropipette Adapter (MPA).

Micropipettes:

ONLY Heska supplied, plastic, high precision EDTA micropipettes should be used when running the MPA. Glass micropipettes can cause damage to the analyzer.

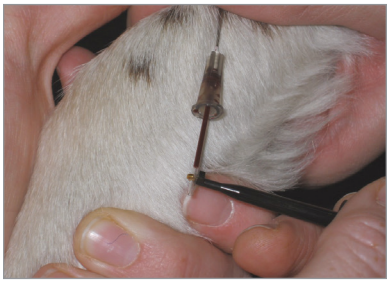
Analyzer and Sample Preparation:

Follow the procedure below to operate the MPA:

1. From the main screen press **NEW SAMPLE**. Enter ID and select species. (See *Section 8.4*)
2. Pull out the MPA adapter. (The analyzer will instruct the operator to reinsert the loaded MPA adapter to start the analysis cycle.)
3. Remove the previous sample micropipette (if applicable).
4. Gently wipe dry with a Kimwipes tissue or equivalent and place the adapter on the table.

Drawing Blood and Sample Preparation:

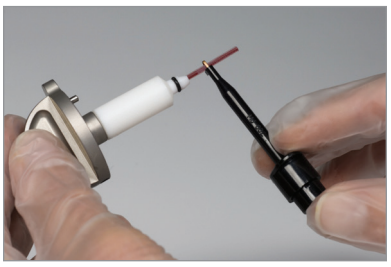
1. Collect the sample as shown below. Grasp an EDTA micropipette using the MPA holder. Fill the micropipette tube from the hub of needle inserted in a vein.



IMPORTANT

- **Fill the micropipette completely with fresh whole blood and wipe off excessive blood on the outside surface.**
- **Be careful not to wick blood from open ends of the micropipette.**
- **Ignoring these instructions may cause incorrect and non-reproducible results**

2. Insert the micropipette into the MPA device as shown below. Hold the capillary as horizontally as possible.



3. Insert the MPA into its holder and the analyzer will automatically start the analysis sequence.

IMPORTANT

Do not remove the MPA during sample aspiration or analysis. Removal prior to completion of analysis may cause erroneous results.

4. Refer to *Section 8.6, Steps 4–8* for remainder of analysis sequence.

8.8 Viewing Results

After a sample has been analyzed, results can be viewed in the three screen displays:

Sample View 1:

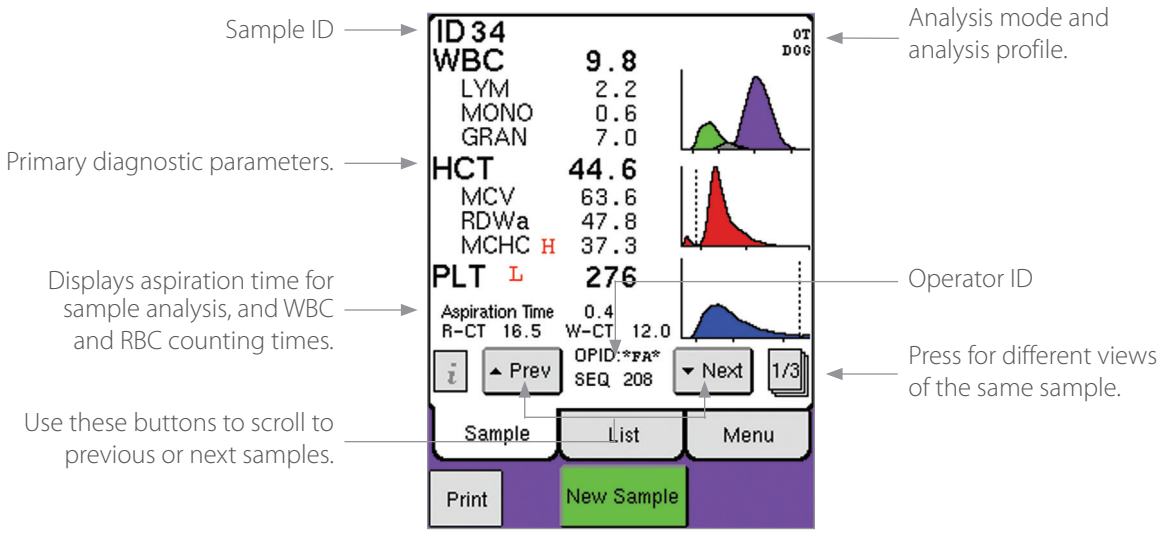
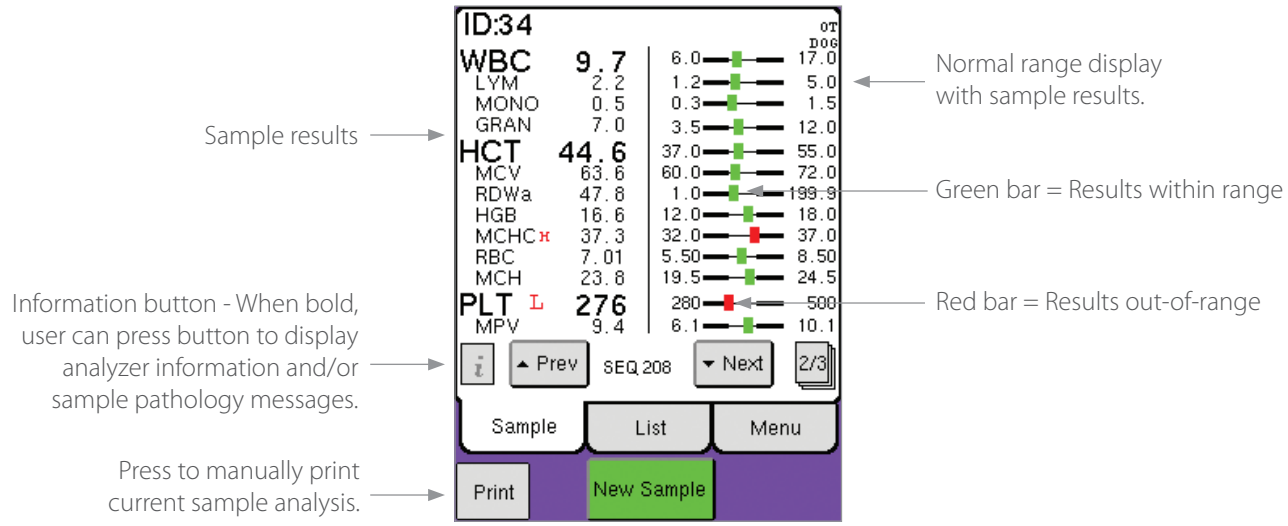
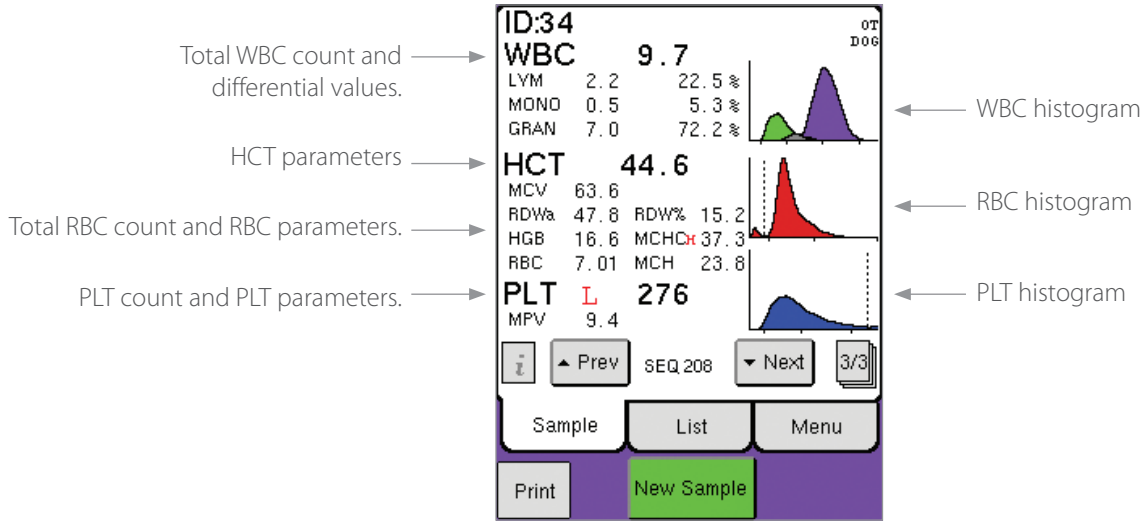


Figure 8.18

Sample View 2:



Sample View 3:



The HemaTrue Analyzer is equipped with a QC memory capable of displaying and printing Levey-Jennings plots.

9.1 Quality Control (QC)

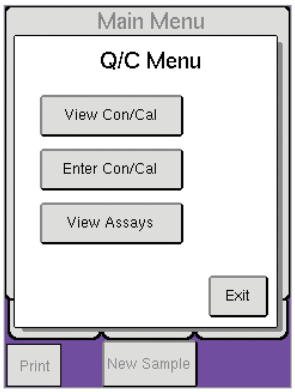
This section describes the procedures to be performed for running control samples.

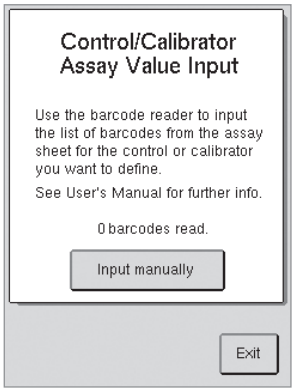
QC Menu and CON/CAL Assay Values Input:

Follow the instructions below to access the QC MENU and to input Control/ Calibrator Assay Values from the Assay Sheet.

1. Enter the QC MENU by selecting [QC] from the menu tab.
2. Select [Enter CON/CAL].
3. Refer to the Assay sheet for instructions on how to input control assay values. (Assay sheets are delivered with authorized Heska blood controls.)

NOTE: Assay values for 12 different lots can be stored simultaneously. When renewing the assay values, the previously scanned CON/CAL assay values will be removed in a chronological order starting with the assay values that were entered first.





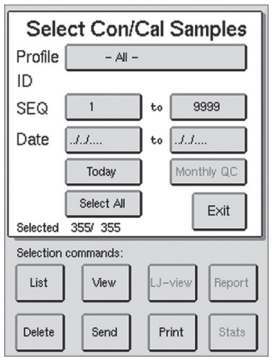
Control Analysis:

For instructions on running a control, refer to *Section 8.3*.

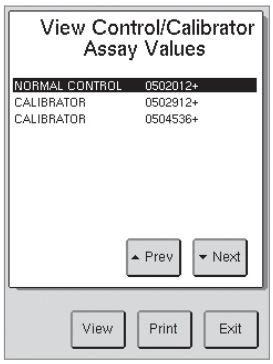
Search Function:

Each blood control lot can be found by lot number, date or sequence number.

1. Enter the QC MENU and select [View CON/CAL].
2. Input the search criteria to be used.



3. Pressing the **PROFILE** bar will display, in which one particular lot or level can be selected. Highlight the desired lot and press **OK**.
4. Press **LIST** to display the selected samples. To view individual runs, press **SAMPLE**.
5. Once samples are displayed they can also be printed out in a Monthly QC summary report.
   - After the control lot (profile) has been selected the **Monthly QC** button will become active.
   - Press **MONTHLY QC**, use the **PREV** and **NEXT** buttons to scroll to desired month, and press **EXIT**.
   - The Monthly QC button will turn green when lot and month have been chosen. Press **REPORT** to print out report.



6. To exclude a sample from the Monthly QC or LJ Diagram summary reports perform the following steps prior to Step 5 above:
   - Scroll to the control sample to be excluded using **PREV** and **NEXT** in the CON/CAL Sample or List tabs.
   - Then press **EXCLUDE/INCLUDE**. An "X" will be placed next to excluded sample.
   - To include the sample press **EXCLUDE/INCLUDE** again.

9.2 Levey-Jennings Plots

Procedure Instruction:

This section describes selecting, viewing, and printing Levey-Jennings Plots.

L-J Plots:

Levey-Jennings (L-J) plots are used to monitor the long term stability of the analyzer using Heska blood controls.

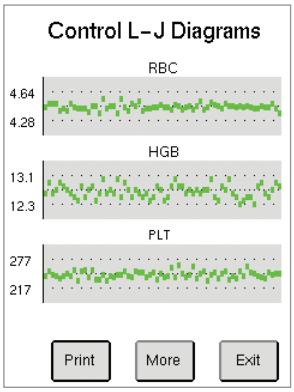
Blood Controls:

To be able to use L-J plots, the Control/Calibrator Assay values for the blood controls must be scanned with the installed barcode reader. Follow directions to scan in CON/CAL Assay values.

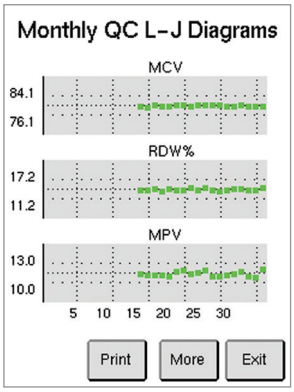
Display and Print L-J Plots:

To display and print the L-J plots, follow the instructions below:

1. Enter the QC MENU and select [View CON/CAL].
2. Scan the barcode label on the blood control tube with the barcode reader, select control from Select CON/CAL SAMPLE MENU by pressing the profile bar, or manually enter in value.
3. Select [L-J View] to display the Levey-Jennings plots.
   The image below is constructed from several samples and will not be seen as shown below until a sufficient amount of samples have been analyzed.



4. Scroll through parameters by pressing **MORE**.
5. Print diagrams by pressing **PRINT**.
6. A Monthly QC L-J Diagram report can also be viewed and printed:
   - Follow *Steps 5–6*, in *Section 9.1* to select control lot and month.
   - Press **L-J VIEW** to view the monthly diagrams. The Monthly L-J diagrams will differ from the normal L-J plots as the x-axis uses the expected range for its out-of-bounds criteria and on the y-axis the points can be visibly traced to which day of the month it was analyzed on.
   - To print the diagrams on the displayed page, press **PRINT** or to print all diagrams, scroll to the last display page without plots and press **PRINT**.



Parameters Displayed on L-J Plots:

The L-J plots are displayed for all parameters defined in the CON/CAL ASSAY VALUES page.

NOTE: In case a control shows an error or warning flag SE, OF, LO, HI, NG, TU, TL or TB, the parameter values of such control will not be included in the L-J plots.

This section describes the step-by-step procedure for calibration of the HemaTrue Analyzer. Heska has calibrated the analyzer prior to shipment. Good laboratory practice, however, requires regular checks and calibration of the directly measured parameters.

10.1 Preparations Before Calibration

- It is advisable that the performance of the HemaTrue Analyzer is checked daily with a certified blood control authorized by Heska.
- Analyze control blood once in the open tube mode and compare results with the assigned values prior to calibration.
- Verify that nothing is erratic with the control blood, the reagents, or the analyzer before calibrating the analyzer.
- Prior to calibration print Calibration Log, if connected directly to a printer. Select [Advanced] from MAIN MENU ▶ [Calibration] ▶ [Calibration Log] ▶ **PRINT**.

IMPORTANT

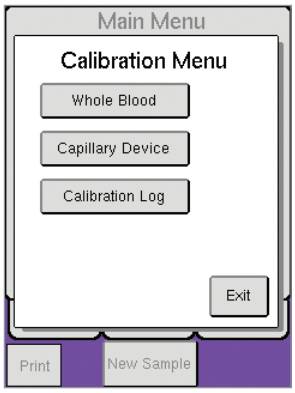
- **The user should be thoroughly familiar with the analyzer and the calibration procedure before performing a calibration.**
- **Please refer to the Calibrator Product Insert for complete instructions for handling and use of blood calibration materials.**
- **Handle and prepare the calibrator in accordance to the calibrator package insert.**
- **Never use an open vial longer than recommended by the product insert or subject any vial to excessive heat or agitation.**
- **Wipe the sample probe with a Kimwipes tissue or equivalent before each calibrator run. Not performing this step may lead to decreasing parameter values due to dilution of the calibrator material.**

10.2 Calibration

Whole Blood Calibration – Open tube:

The following instructions are used to calibrate the Open Tube mode. Follow the instructions below to calibrate:

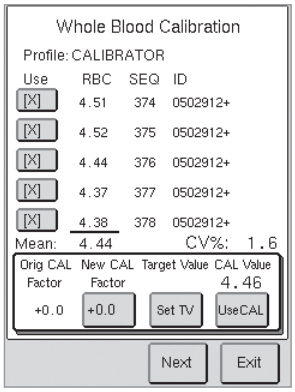
1. Follow directions on Assay Sheet to scan 9 barcodes which program in calibrator assay values.
2. Select either [List, Sample, or Menu] to begin calibrator analysis.
3. Using the installed barcode reader, scan the Calibrator ID from the calibrator vial label.
4. To perform a calibration, five calibration analyses must be performed in consecutive order through the open tube mode.
5. When analyses are complete select [Advanced] from the MENU tab.
6. Select [Calibration] ▶ [Whole Blood].



NOTE: Calibration analysis must be the last analysis performed on the analyzer for parameter values to be shown in CALIBRATION MENUS. (*e.g.*, no values will show if in the middle of calibration a patient sample analysis was performed.)

7. Scroll through parameter screens by using **NEXT** and verify that the CVs for the following parameters meet the limits below:

Parameter	OT CV %	MPA CV%
RBC	< 2.2	< 3.2
MCV	< 1.8	< 1.8
PLT	< 5.8	< 6.2
HGB	< 1.8	< 2.9
WBC	< 4.2	< 4.8



The MPV screen will display between PLT and HGB. Press **NEXT** to bypass this screen.

8. If CV values are not within range the operator will be unable to perform the calibration. (Analyses with analyzer information messages will automatically inactivate that analysis from the CV calculation and, depending on messaging, may not be stored on the list at all.) If a known sample handling error or erroneous result is present, then that sample can be inactivated by pressing the button to the left of that particular analysis, resulting in empty brackets [ ].
9. If all parameters have acceptable CVs proceed to the next step. If not, repeat calibration following the steps above.

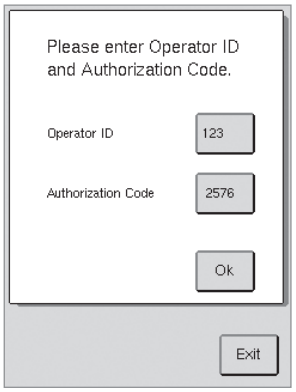
10. The new calibration factor can be entered in two ways:
    - The recommended method is to press **USE CAL** button which will automatically calculate the new calibration factor using the target range from the CON/CAL assay value sheet. This method can only be used if running a vial of calibrator.
    - The second method, if using a vial of control, is to perform Steps 4–9 using target values from an assay value sheet. The target values can be entered pressing **SET TV**, and manually entering in the target values. [Ok] must be selected after manually entering each target value.
11. In both methods the calibration factor is automatically calculated once either **USE CAL** is pressed or the target value is entered.
12. Once the first calibration factor has been entered using one of the methods above, the operator will be prompted to enter an Operator ID (Operator ID is recommended for in-house records of calibration operator, but is not required) and Authorization Code (REQUIRED) before the new value can be changed or updated.

NOTE: The Authorization Code prompt is displayed only once per calibration sequence when **USE CAL, TARGET VALUE**, or **NEW CAL FACTOR** buttons are pressed.

13. The authorized operator can update or change the calibration factor by inputting the Authorization Code [2576].

After the authorization code has been entered, press **OK** twice.

14. Perform Step 10 for RBC, MCV, PLT, HGB, and WBC parameters. To move to the next parameter press **NEXT**.
15. It is recommended not to change preset calibration factors for RDW%, RDWa and MPV. If necessary, please contact Heska's Technical Support Services at 800.464.3752, option 3 for procedure.
16. Once parameters are calibrated, press **EXIT** twice and a screen will be displayed asking the operator if a calibration report is desired. [Send], [Print], or [Exit] can be selected. It is recommended that calibration reports be printed and archived in case they may be needed for future reference. However, this can only be printed if the HemaTrue Analyzer is connected directly to a printer.
17. It is recommended to run controls after calibration to verify that all parameters have been calibrated correctly and that calibration is synchronized with the control program. See *Section 8.3* to perform QC.



Capillary Device Calibration:

To calibrate the MPA follow Steps 1–17 above except select [Calibration] and then choose [Capillary Device] instead of Whole Blood calibration in Step 6 and use MPA mode for analysis. See *Section 8.7* for details on capillary device sample analysis.

This section contains information that is crucial for maintaining, transporting and storing the HemaTrue Analyzer.

11.1 Daily Cleaning

The majority of the analyzer's cleaning procedures are automated to keep the user maintenance to an absolute minimum.

External Cleaning Procedure:

The daily cleaning instructions are as follows:

1. Clean the sample probe using a Kimwipes tissue or equivalent moistened with a 70% alcohol solution.
2. Remove possible traces of salt crystals or blood at the top of the sample probe and probe rinse cup using a Kimwipes tissue or equivalent moistened with the alcohol solution.

Automatic Cleaning Mode/Standby:

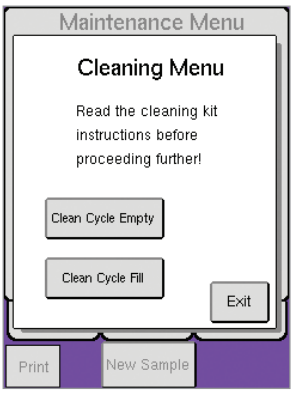
The HemaTrue Analyzer has been designed to clean internal components on a daily basis. The analyzer uses the enzymatic cleaner to flush and clean all components that come into contact with blood when in standby or power off mode. The analyzer remains filled with enzymatic cleaner until it is powered back on or taken out of standby. This automatic daily cleaning increases the longevity of the analyzer and decreases the need for lengthy maintenance procedures. After 8 hours of inactivity the analyzer will automatically go into standby and fill with enzymatic cleaner. If, after 12 hours (total) the analyzer is still in standby the enzymatic cleaner will automatically be flushed out of the tubing and the analyzer will fill with reagents and a background cycle will be run. If the analyzer remains idle after the background cycle, it will again fill automatically with enzymatic cleaner and remain in standby.

11.2 Annual Cleaning

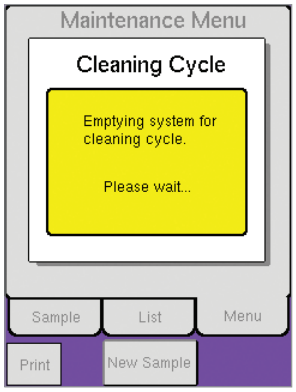
To increase the life of the analyzer's internal tubing, Heska strongly recommends performing the following cleaning procedure annually.

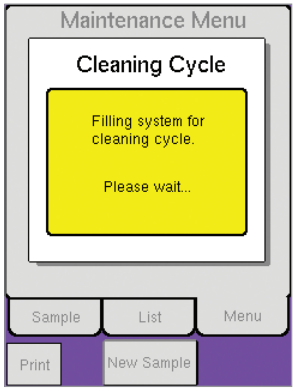
Cleaning Procedure:

- Select [Advanced] from MENU ▶ [Maintenance] ▶ [Cleaning Menu] to enter the CLEANING MENU.



- Follow the instructions for the Heska's Cleaning Kit to clean the analyzer. (Instructions for use are supplied with the Heska's Cleaning Kit solutions).
- The Annual Cleaning procedure takes approximately one hour and 15 minutes to complete.





Heska Cleaning Kit:

Heska Cleaning Kit contains the following items:

- Hypochlorite (2%)
- Enzymatic cleaner
- Detergent cleaner

LCD Display:

When necessary, gently clean the display with a soft cloth, slightly moistened with water and a mild soap. Dry carefully.

11.3 Relocating of Analyzer (within the laboratory)

Before Relocating:

If the analyzer is in "standby" mode do not unplug analyzer. Make sure that the analyzer is in Sample or List MENU before turning off.

1. Detach the reagent tray from the analyzer but DO NOT detach the reagent tube assemblies or the electronic sensors. Move these components together.
2. Remove the waste tube from waste container or sink, but do not detach tube from analyzer.
3. Disconnect all electrical connections (*i.e.*, power cord, printer cable, computer interface cable).

Relocating:

Make sure that the analyzer is lifted from beneath to avoid unnecessary stress on the front cover.

After Relocating:

1. Place the waste tube in the waste container or drain.
2. Reattach reagent bottle tray.
3. Reconnect the electrical connections.

11.4 Short Term Transport (< 12 hr) or Shipping Analyzer

This section describes the procedure performed before transporting the analyzer over short distances outside the usual facility. This procedure should also be performed when shipping the analyzer back to Heska.

Empty Analyzer:

1. Remove the reagent tube assemblies from the reagent bottles. (The analyzer will not perform the empty cycle if reagent tube assemblies are not removed from the bottles).
2. Remove reagent bottles from reagent bottle tray.
3. Select [Advanced] on the MAIN MENU.
4. Select [Maintenance] and then [Empty Analyzer].
5. When the empty procedure is complete, the following statement will appear on screen: "Analyzer is empty and ready for fill or power off."
6. Take the three reagent tubes and place them in a container filled with distilled water.
7. Press **FILL ANALYZER**.
8. When the filling procedure is complete, remove tube assemblies from the bottle of distilled water and repeat Steps 4 and 5 above.
9. Switch off power and then unplug analyzer.

Before Relocating:

After analyzer is powered off, detach reagent tube assemblies, waste tubing, reagent bottle tray, electronic sensors and all electrical connections. Package all components carefully for transport.

Guidelines For Transport:

- The analyzer should be transported in temperature conditions between 41° to 86°F (5° to 30°C).
- Humidity should be less than 80%.

NOTE: Refer to *Section 6: Installation*.

11.5 Repackaging and Long Term Storage or Transport (>12 hr)

This section describes the procedure when transporting or shutting down the analyzer for a longer period of time (>12 hours).

IMPORTANT

It is very important to follow the instructions below for preparing the analyzer for long term transport or storage, to avoid erroneous results upon reinstallation.

Long Term Shut-down:

1. Remove the reagent tube assemblies from the reagent bottles.
2. Select [Advanced] on Menu. Select [Maintenance] and then [Cleaning Menu] and then [Clean Cycle Empty].
3. If the analyzer will be shut down for longer than 3 days, perform a cleaning procedure (See *Section 11.2*). Follow the instructions for the Heska Cleaning Kit. (Instructions are supplied with the Heska Cleaning Kit.)
4. After emptying or completing the cleaning of the analyzer, insert the reagent tube assemblies into distilled water. Select [Clean Cycle Fill] from CLEANING MENU.
5. When the analyzer has been filled with distilled water, press **EXIT**. Select [Probe Flush] from MAINTENANCE MENU. Repeat.
6. After the two Probe Flushes are complete, remove reagent tube assemblies and select [Clean Cycle Empty] from CLEANING MENU.
7. When the analyzer is emptied, disconnect the main supply cable and all other connections such as reagent tube assemblies, reagent bottle tray, and waste tubing.
8. Pack the analyzer using the original shipping container.
9. Mark the container with DELICATE ANALYZER, FRAGILE and THIS SIDE UP.
10. Follow Guidelines For Transport below.

Guidelines For Transport:

The analyzer in its export package should fulfill the following transport/storage conditions:

- Does not exceed -40°F (-40°C) for ≥ 24 hours.
- Does not exceed a dry heat of 158°F (+70°C) for ≥ 24 hours.
- Is not exposed to dramatic change of temperature between -40°F (-40°C) and 86°F (+30°C).
- Does not exceed a damp heat steady state of 90% RH and 104°F (+40°C) during 48 hours.
- Does not exceed a damp heat cycle of 90–100% RH and 77°F/104°F (+25°F/+40°C) 24 hours.

NOTE: Refer to *Section 6: Installation*.

11.6 Permanent Shut-Down and Storage

Prepare the analyzer using the same procedures as *Section 11.5: Repackaging and Long Term Storage or Transport(>12 hr).*

11.7 Disposal Information

Customers are advised to be knowledgeable of applicable local, state and federal requirements, and the content of effluent streams, before disposing of waste in public sewer analyzers.

Manufacturer Guidelines:

- Place the analyzer close to a waste container or drain suitable for disposal of used reagents.
- Check that the drainage is suitable for disposal of chemical and biological waste.
- Check that the waste tubing is securely fastened in the drain.

MANDATORY ACTION

Always use protective gloves when working with the waste container and the waste tubing.

Disposal Materials

- Used reagents
- Reagents mixed with potentially biohazardous material
- Analyzer and analyzer components
- Controls and calibration material

WARNING

Always use gloves when in contact with potentially biohazardous materials.

12.1 Communication Issues

This section contains information regarding errors associated with printers and serial data communication.

Printer Issues:

See *Section 7.3, Advanced Setup* for further detail.

If	Then	Possible Cause
The printout has unusual layout or strange characters.	1. Verify printer type matches the printer being used. 2. Verify the correct paper format has been selected for the printer paper.	1. New printer was connected but not matched with analyzer setup. 2. Printer may need maintenance or may need to be reset.
Results are not printing out after sample or control analysis.	1. Verify Auto Print Mode is NOT set to "0".	1. Auto Print Mode was turned off and not reset.
	1. Printer is not ready to print. Wait until printer has finished with previous printout. 2. Verify printer is connected to the analyzer. 3. Verify the setup of the analyzer is correct for the printer in use. 4. Verify printer power is turned on.	1. The printer is not connected to the analyzer or the printer setup is incorrect. 2. The printer has not completed last printout. 3. The printer is not on.
	1. The printer is connected to the analyzer and on, but not activated. 2. Verify the printer is not in standby or offline. 3. Verify the printer is set to print and not serial port only setup.	1. The printer has timed out. 2. Printer paper may need to be refilled. 3. Incorrect setup for information transmission.

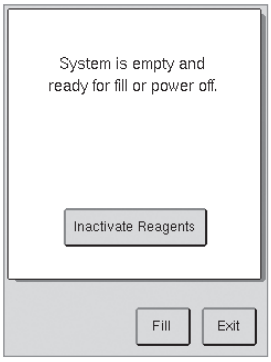
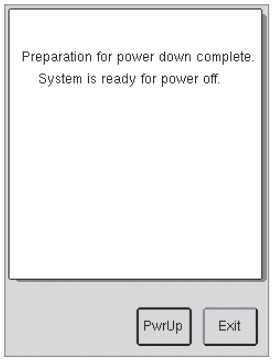
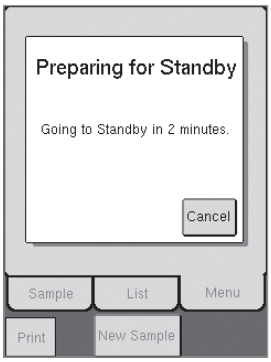
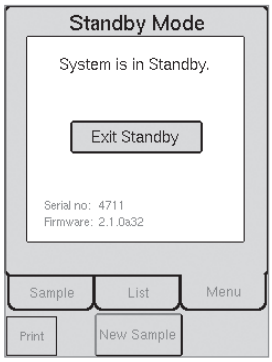
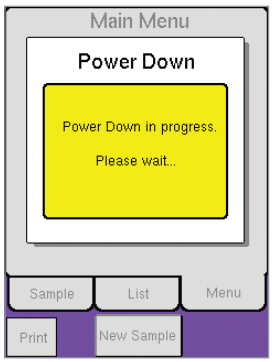
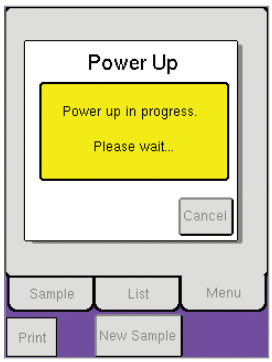
Serial Data Issues:

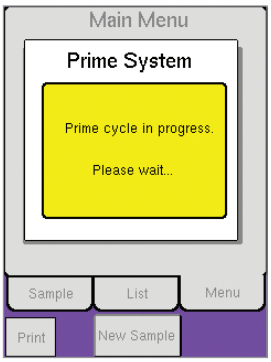
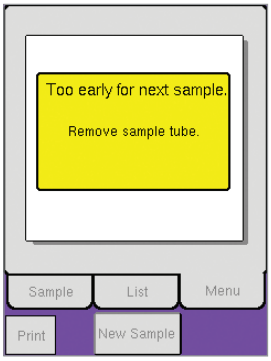
See *Section 7.3, Advanced Setup* for further detail.

If	Then	Possible Cause
The data sent does not seem correct.	1. Make sure that the correct HW handshake and Auto Send Mode has been selected.	1. Serial setup in analyzer is incorrect.
Results are not being sent to computer after sample analysis.	1. Verify Auto Send Mode is NOT set to "0".	1. Auto Send Mode was turned off and not reset.
	1. Serial Output is not ready to transmit. 2. Wait until previous sample has finished transmitting. 3. Re-send selected sample.	1. The analyzer has not completed transmission of last sample.
	1. Make sure that the HW handshake has been selected. 2. Verify the analyzer is connected to computer. 3. Verify the computer is turned on. 4. Verify the analyzer is set to serial output and not print mode only.	1. The serial output has timed out. 2. The computer is not connected to the analyzer or the serial output setup is incorrect.
	1. Make sure the [Send with Ack] has not been selected (empty brackets). 2. Verify the computer is turned on and connected to the analyzer. 3. Verify the computer's receiving program is active.	1. Serial output acknowledgement problem.

12.2 General Information Displays

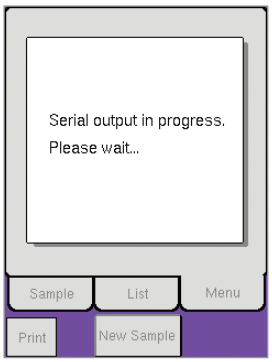
General information displays are informative screen displays that appear after a function has been completed. Instruction is then displayed for the operator on the next step or function to be performed.

Standby, Power Down and Power Up Informational Displays		
		
The analyzer is empty of all liquid and ready to be filled with other liquid or to be stored away. Press **FILL** if you want to refill analyzer or **EXIT** if you want to return to ANALYZER MENU. No analysis can be performed before the analyzer is refilled with reagents.	The analyzer is filled with liquid and is prepared for power off. Press **PWR UP** if you want to return the analyzer to active status or **EXIT** if you want to return to ANALYZER MENU. It is recommended to use **ENTER STANDBY** and that power is always left on, instead of using this feature.	The analyzer has not been used during the preset display saver time. Press **RESUME** to activate the analyzer. Once activated, the analyzer is ready to perform an analysis.
		
Analyzer will enter Standby mode in 2 minutes. Press **CANCEL** to return to ANALYZER MENU.	The analyzer is in the process of going into Standby. Please wait.	The analyzer is in Standby. Press **EXIT STANDBY** to activate the analyzer. Once activated, the analyzer is ready to perform an analysis.
		
The analyzer is preparing the analyzer for analysis mode. If the background check is activated, background result will be displayed. Once activated, the analyzer is ready to perform an analysis.	The analyzer is in process of powering down. Please wait.	The analyzer is in process of powering up. Please wait.

Cycle In Progress Informational Display		
		
The analyzer is priming the analyzer. Please wait.	The analyzer is filling the analyzer. Please wait.	The analyzer is emptying the analyzer. Please wait.
		
The analyzer is cleaning the Open Tube sample probe. Please wait.	Every twelve hours the analyzer performs a wash of the analyzer. During wash cycle the analyzer cannot perform an analysis. Please wait.	The analyzer has finished the count of cells and displays the results, but the analysis cycle is not yet complete; the analyzer still needs to perform a wash cycle for an accurate next sample result. Please wait until the **NEW SAMPLE** button is activated. If sample probe was submerged in next sample by mistake, perform a background count before continuing with the next analysis.

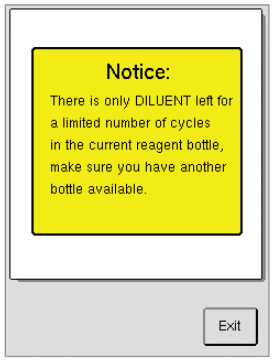
Printer Informational Displays

The printer is in the process of printing. Please wait.

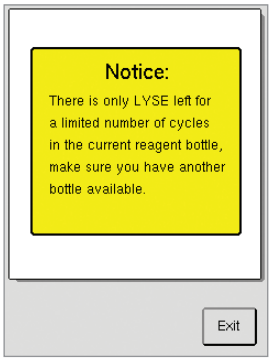


The analyzer is in the process of transmitting serial output data. Please wait.

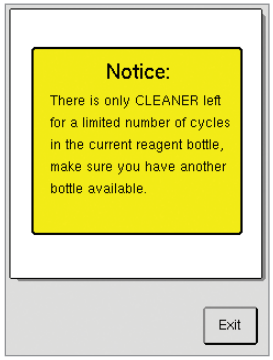
Reagent and Control/Calibration Informational Displays



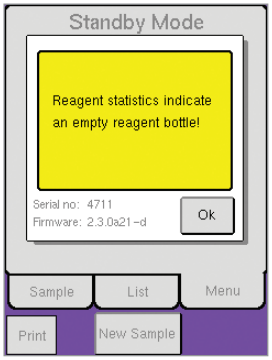
The analyzer displays this notice to inform operator that Diluent reagent will soon need to be changed.



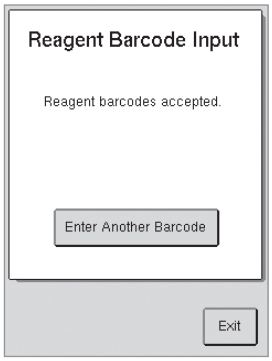
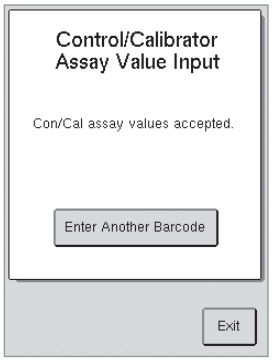
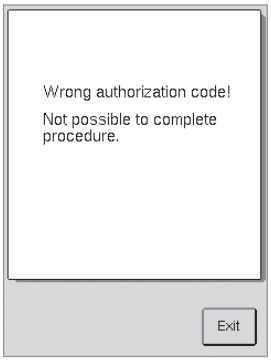
The analyzer displays this notice to inform operator that Lyse reagent will soon need to be changed.



The analyzer displays this notice to inform operator that Cleaner reagent will soon need to be changed.



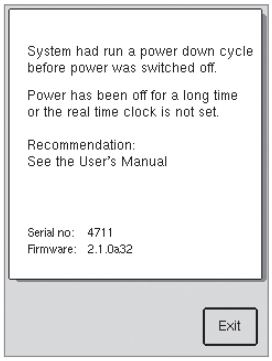
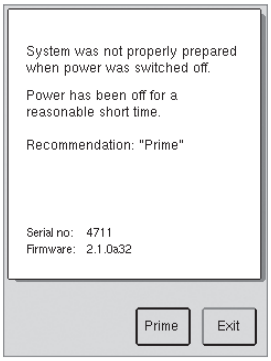
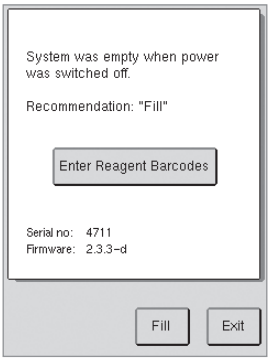
The analyzer displays this notice when reagent bottle or bottles need to be changed. Not changing reagents at this time could cause erroneous results or possible damage to the analyzer.

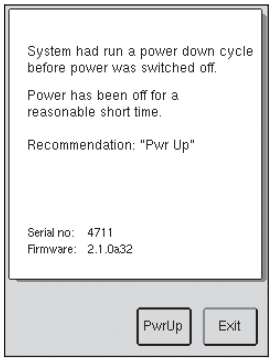
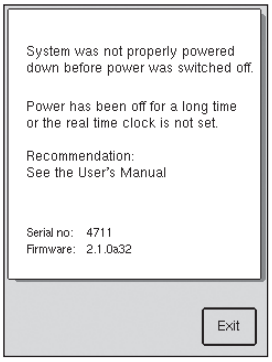
Reagent and Control/Calibration Informational Displays		
		
The reagent barcodes were scanned correctly using the barcode reader and the analyzer has accepted the values.	The CON/CAL Assay Values were scanned correctly using the barcode reader and the analyzer has accepted the values.	Incorrect calibration code was entered. (See *Section 10: Calibration*).

12.3 Displays

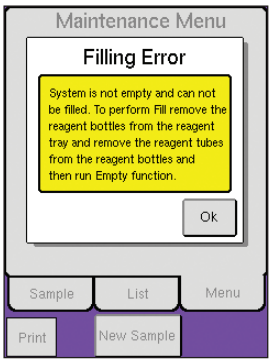
Analyzer Information Displays:

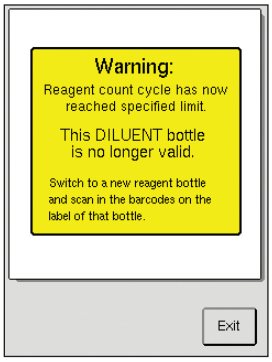
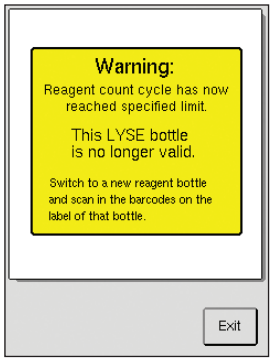
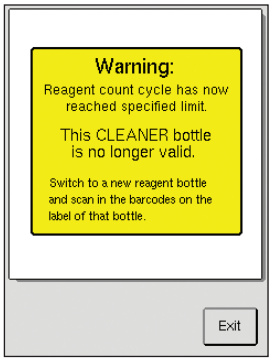
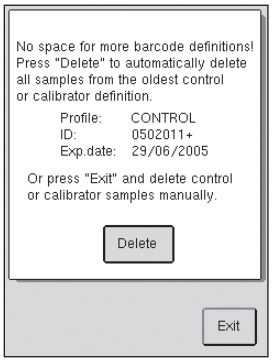
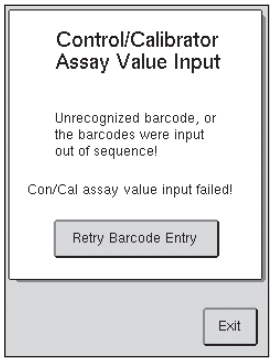
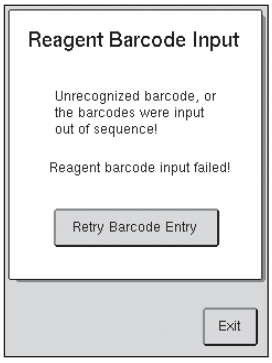
Analyzer information displays appear after a function has been performed incorrectly or to inform the operator that further action is needed to complete the desired task. The analyzer information display describes the situation and instructs the operator on the next step or function to resolve the issue.

Analyzer Power Down Information Displays		
		
The analyzer has been switched off for a long time period. The analyzer has been powered down with all valves open and filled with liquid. Empty and refill the analyzer with reagents, and perform a background count.	The analyzer was switched off incorrectly. Perform a prime to prepare the analyzer for analysis. Check method for the correct analyzer power down procedure.	The analyzer was manually switched off with analyzer emptied of reagents. Fill the analyzer with reagents to prepare for analysis or exit if only a search of analyzer menus is needed.

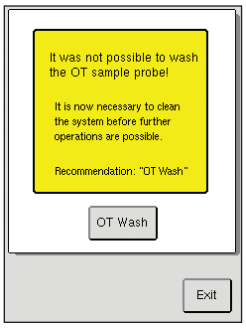
	
The analyzer has been switched off with power down function before power was switched off. Perform a power up to prepare the reagent analyzer for analysis.	The analyzer was powered down with liquid in analyzer and has been idle for long period of time. Perform the cleaning procedure according to cleaning kit instructions. Perform a background check.

Reagent Analyzer Information Displays

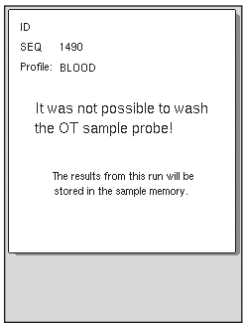
		
The regular 8 hour wash has not been performed. Check if reagent bottles are empty and if the reagent tube assemblies are in contact with reagent.	The regular 12 hour wash has failed. Make sure reagent bottles are filled and the reagent tube assemblies are inserted correctly.	The reagent bottle or bottles are empty. Check if the bottles are empty and if the reagent tube assemblies and electronic sensors are inserted correctly.
		
This message is displayed if reagent bottle or bottles are empty when coming out of Standby. Check if the bottles are empty and if reagent tube assemblies and electronic sensors are inserted correctly.	Reagent tube assemblies must be removed from the reagent bottles when emptying the analyzer. Verify that all tubes have been removed.	Analyzer has detected liquid in the analyzer. The empty cycle must be run prior to a fill cycle. Run the Empty function to remove any extra liquid remaining in the analyzer then fill the analyzer with reagents.

		
Diluent bottle needs to be changed or current bottle was not scanned properly. Not changing reagents at this time could cause erroneous results or possible damage to the analyzer. If bottle has adequate reagent, re-scan barcodes. If this does not resolve the error, connect a new reagent bottle and scan in the barcode on the bottle.	Lyse bottle needs to be changed or current bottle was not scanned properly. Not changing reagents at this time could cause erroneous results or possible damage to the analyzer. If bottle has adequate reagent, re-scan barcodes. If this does not resolve the error, connect a new reagent bottle and scan in the barcode on the bottle.	Cleaner bottle needs to be changed or current bottle was not scanned properly. Not changing reagents at this time could cause erroneous results or possible damage to the analyzer. If bottle has adequate reagent, re-scan barcodes. If this does not resolve the error, connect a new reagent bottle and scan in the barcode on the bottle.
Barcode Analyzer Information Displays		
		
No more space is available to scan in new Con/Cal assay values. Follow the recommendation or manually delete all the controls with same ID to free space for scanning the new assay values.	CON/CAL assay value barcode scanning failed. The assay values or order of scanning in the barcodes may have been incorrect. Verify that setups on the analyzer match the required setup for the barcode reader.	Reagent barcode scanning failed. Barcode printing or order of scanning in the barcodes may have been incorrect. Verify that setups on the analyzer match the required setup for the barcode reader.

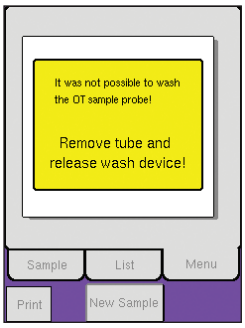
Open Tube Analyzer Information Displays



The analyzer was unable to wash the Open Tube sample probe. Verify that tube is removed and wash rinse cup is in correct position, then perform OT Wash.

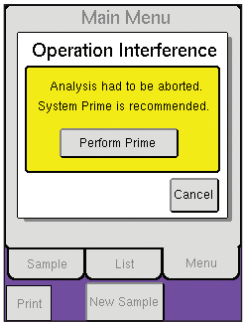


The analyzer was unable to wash the Open Tube sample probe. Verify that tube is removed and wash rinse cup is in correct position. It is recommended that background count is performed before next sample analysis.

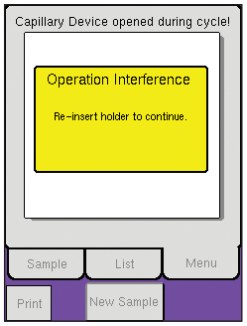


The analyzer is unable to wash the Open Tube sample probe. Verify that tube is removed and wash rinse cup is in correct position. It is recommended that background count is performed before next sample analysis.

Capillary Device Analyzer Information Displays



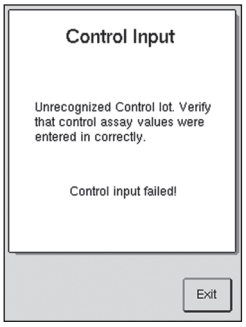
The MPA was opened during an inappropriate time. It is recommended to perform a prime cycle before next analysis.



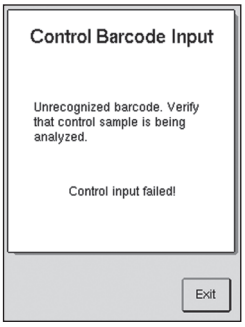
The MPA was opened during a cycle or analysis. Reinsert holder, and follow suggested recommendation.

The MPA holder was opened during an inappropriate menu. The MPA holder should only be opened in LIST, SAMPLE or MAIN MENU.

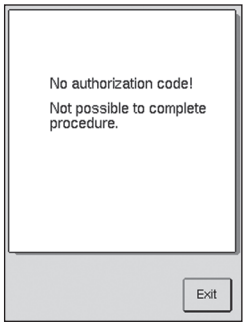
Warning Displays



Assay Value Input failed. The assay sheet or order of scanning in the barcodes may have been incorrect. Verify that setups on the instrument match the required setup for the barcode reader. (See *Section 7.3 & 9.1*)



The barcode scanned in is not recognized as a control sample in the analyzer. Verify that control sample is being scanned in. (See *Section 9.1* for more detail.)



No authorization code was entered. See Calibration section for entry of correct authorization code for calibration, or call 800.464.3752, option 3, for service-related authorization codes.

12.4 Aspiration Issues

This section contains information regarding errors associated with aspiration and the sample probe.

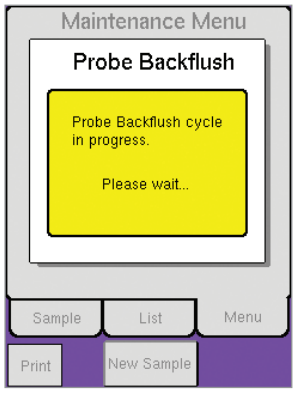
If	Then	Possible Cause
No aspiration of sample is taking place.	1. Suggest performing probe flush procedure (see below). 2. Verify that there are no leaks and tubing is connected properly and not kinked.	1. Blockage of tubing or leak causes sample to not be pulled correctly through needle or shear valve. 2. Valve malfunction. 3. Clot in sample caused by incorrect sample handling or sample pathology.
No cleaning of aspiration probe.	1. Suggest cleaning upper area of sample probe. 2. Verify that there are no leaks and tubing is connected properly and not kinked.	1. Sample tube is touching the upper part of the sample probe when analyzing. 2. Diluent is not flowing correctly through tubing to sample probe.

Probe Flush Procedure:

This process will help operator to remove a clot from the probe and shear valve. This should only be used when the OT sample probe is blocked.

1. From MAIN MENU press **ADVANCED** and then press **MAINTENANCE**.
2. Press **PROBE FLUSH** to begin procedure. Diluent will be flushed through the shear valve and the sample probe, while the waste pump simultaneously turns on and removes excess liquid and clotted matter through the probe rinse cup.
3. When menu screen returns to MAINTENANCE MENU, Probe Flush is complete. Run background count and control to confirm these values are within correct range and continue with next sample analysis.

NOTE: If the sample probe is unable to be flushed, an AF analyzer information indicator will be displayed when background count is analyzed. This indicates that the clot was unable to be removed using the automatic procedure. Contact Heska Technical Support Services at 800.464.3752, option 3, for Manual Clot Removal procedure.



12.5 Troubleshooting Other Issues

Indication Error Codes:

Indications error codes are specific instrument situations that in most cases need the attention of the operator or might need service action.

The first indication display is the most important as it describes the issue and how to solve the problem. The 300 indication series displayed after a two digit indication is added information for the user.

In most cases, the instrument is stopped and the operator has to confirm with (**OK** to continue. Once [Ok] is pressed and instrument returns to display menus, user should repeat previous actions again (*e.g.*, re-analyze sample, printing results, *etc*.). If indication error appears again or a three digit indication was displayed as the first indication message, contact local distributor or authorized service technician.

Indication Series Description:

1–19	Indication series for auxiliary errors like battery faults or similar.
20–29	Indication series for 'Liquid' errors.
30–39	Indication series for Communication errors between the PCBs (CAN bus).
40–49	Indication series for Printer and serial output errors.
50–59	Indication series for General Memory errors.
60–69	Indication series for EEPROM/HPC (High Performance Controller) errors.
70–79	Indication series for Shear Valve problems.
80–89	Indication series for Cap Piercer errors (Closed Tube Adaptor).
90–99	Indication series for Sampling device errors.
100–255	Indication series for internal hardware and software problems, and messages during sub-board firmware upgrades.
300–399	Indication series for cycle aborted indication numbers.

See *Appendix A : Troubleshooting Flowcharts* for other possible issues that may arise.

13.1 General Limitations

Platelet Clumping:

Excessive amounts of platelet clumping may falsely decrease the PLT count. Platelet clumping occurs frequently in cats.

Analysis of Avians, Reptiles or Fish:

These species have nucleated RBCs, which are not hemolyzed as are mammalian RBCs. These un-lysed cells are therefore counted as WBCs, which markedly increases the WBC count beyond the measuring range. It is not recommended to run these species on the HemaTrue Analyzer.

13.2 Species-Specific Information

Dog:

At birth, RBCs of fetal origin are large; MCV is 95–100 fl. As fetal RBCs are replaced by cells of smaller size, MCV becomes reduced, so that by 2–3 months of age, the RBC size will be representative of the normal adult dog. Similarly, the MCH is about 33 pg at birth and decreases to about 22 pg by 2 months of age. RBC, HGB and HCT are high at birth but fall rapidly as the pup begins to nurse. Reduction of these values continues during the first month of life. These changes are related to increased destruction of fetal RBCs as well as rapid growth of the pup whereby the circulating red cell mass is significantly reduced.

Certain poodles have normal macrocytic RBCs with MCV over 80 fl and exhibit morphological abnormalities such as nuclear fragmentation in nucleated RBCs and multiple Howell-Jolly bodies in mature red cells.

The Akita and Shiba Inu breeds may have normally microcytic RBCs with MCV values of 55–65 fl.

Platelet concentrations are normally lower by about 10–20% in venous blood compared to arterial blood. Beagles reach a maximum PLT count at about 18 months of age which subsequently drops to around
250x103/µl at 10 years of age.

Cat:

Several studies have been made on normal hematology of the cat. It is well documented that fright and epinephrine responses may alter the total and differential leukocyte counts, causing the neutrophil and lymphocyte numbers to be considerably elevated. This is particularly true for cats introduced into a strange environment. The same effect may be encountered in cats younger than 1 year of age. This must be considered when interpreting hemograms.

Venipuncture may also impact the CBC in feline patients. If the blood does not flow freely, PLT counts may be compromised. Platelet clumping is particularly common, which will falsely decrease the platelet count.

The mean value for MCV at birth is about 90 fl, in contrast to the RBC of the adult cat, which has mean values of 45–50 fl. Replacement of large fetal red cells by smaller postnatal cells is brisk during the first few weeks after birth. This is reflected in reductions in HCT and HGB values with little changes in RBC counts and concomitant reductions in MCV and MCH.

Horse:

The spleen serves as a large reservoir of RBCs in horses that can be released to the circulation within minutes during excitement or strenuous exercise. The RBC parameters (RBC, HGB and HCT) of the horse increase promptly upon excitement. The slight excitement caused by venipuncture may also result in an increase of the RBC counts by 10–15%. Greater elevations may also be found with physical stress. Large differences might be seen with increasing age in horses. Horses in training exhibit a more pronounced change than those not in training. Normalization of the red cell parameters may take about 40–60 minutes or several hours depending on the extent of excitement.

In general, red cell parameters are high at birth and decrease sharply within 12–24 hours as a result of colostrum consumption. They continue to decline for about 2 weeks to 1 month or longer and then increase to attain highest values from 1–2 years of age. The neutrophil / lymphocyte ratio (N:L) in horses changes over the first 3 months from 2.8:1 at birth to 1.1:1 at an average time period of around 50 days.

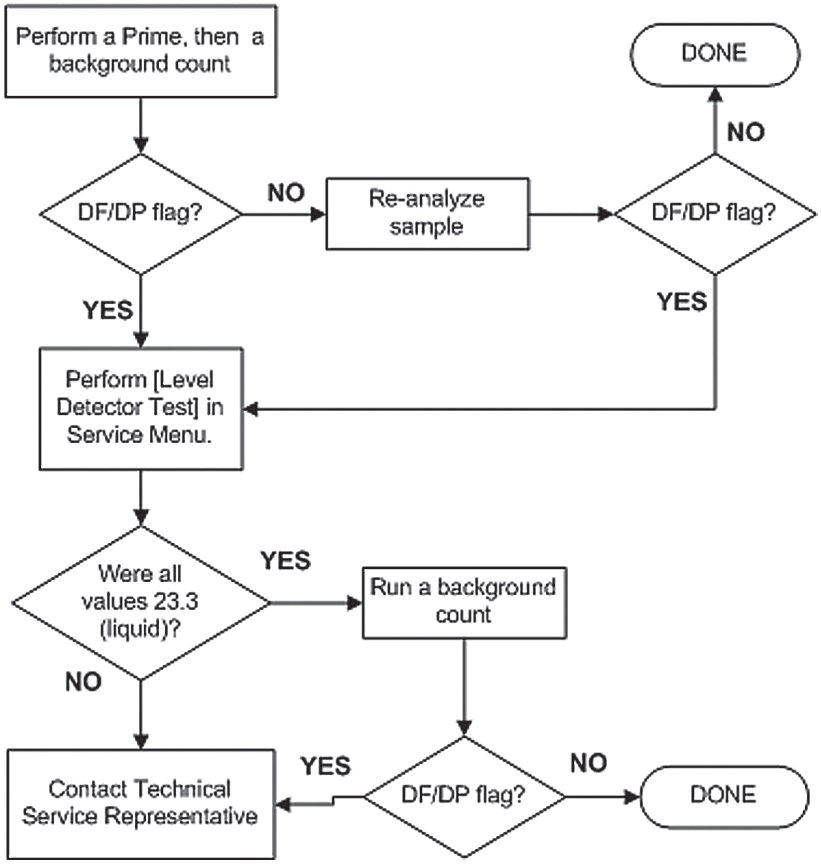
There are also differences in cell concentrations between "hot-blooded" and "cold-blooded" horses. Thoroughbreds have a lower MCV than draft horses. Cold-blooded horses have RBC counts in the range of 5–10 million/µl. Similarly, lower HGB and HCT values are found in cold-blooded horses. The mean neutrophil to lymphocyte ratio in cold-blooded horses is around 1.7:1 compared to 1:1 in Thoroughbreds and Arabians.

The horse is unique among domestic animals in the erythrocyte regeneration response to acute blood loss or hemolytic anemia. Reticulocytes are absent or extremely rare in the circulation during anemia in remission because they are strictly confined to the marrow space during maturation. Equine erythrocytes released during erythrocyte regeneration are macrocytic and the MCV may be increased as a result of prominent regeneration.

DF or DP Errors

Check for the following:

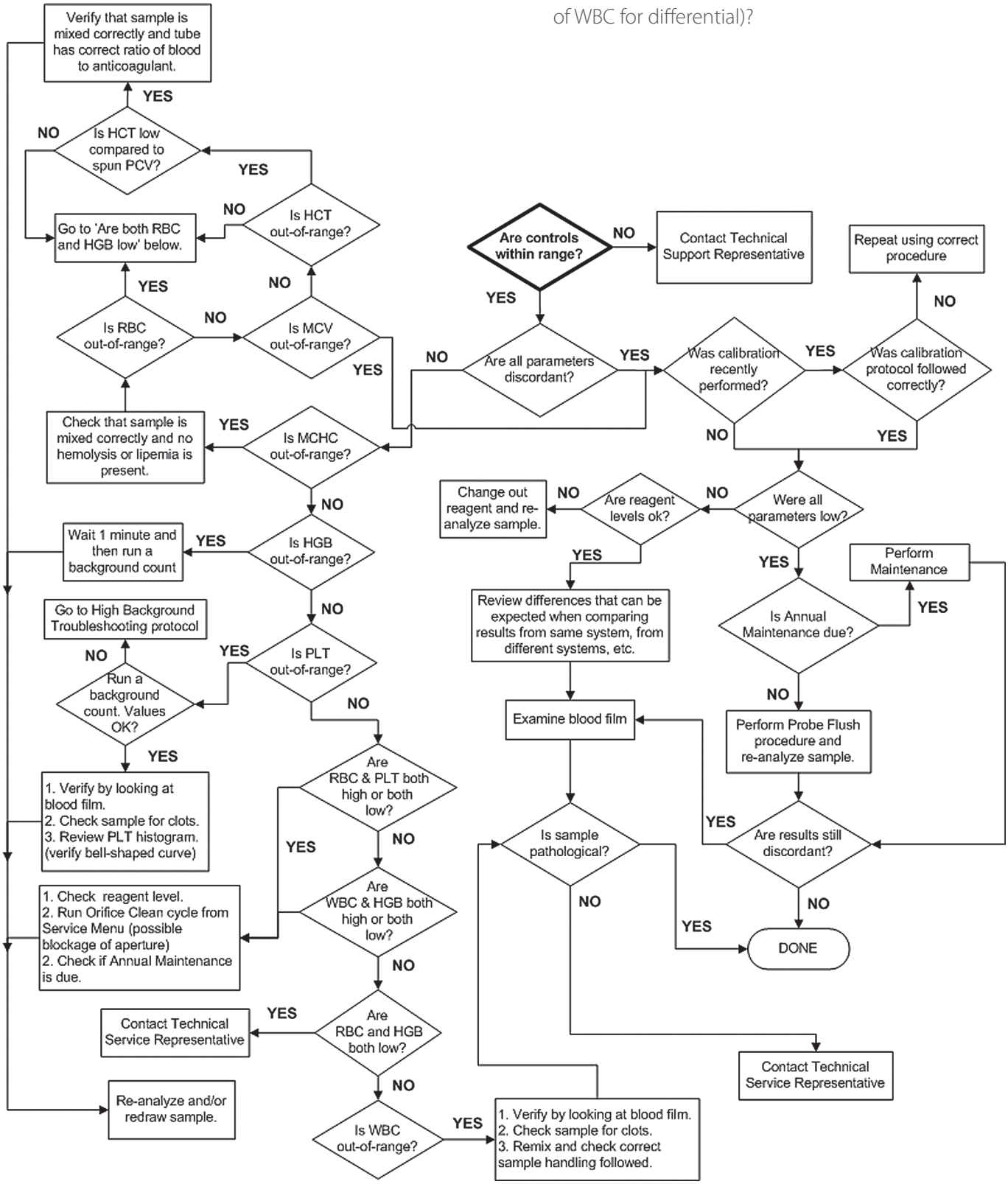
1. Reagent tube assemblies to the back of the analyzer are tight.
2. Leakage under the instrument.
3. Reagen tube assemblies are inserted correctly into the bottles.
4. Pinches or inks in the reagent tubing.



Discordant Results

Questions to ask:

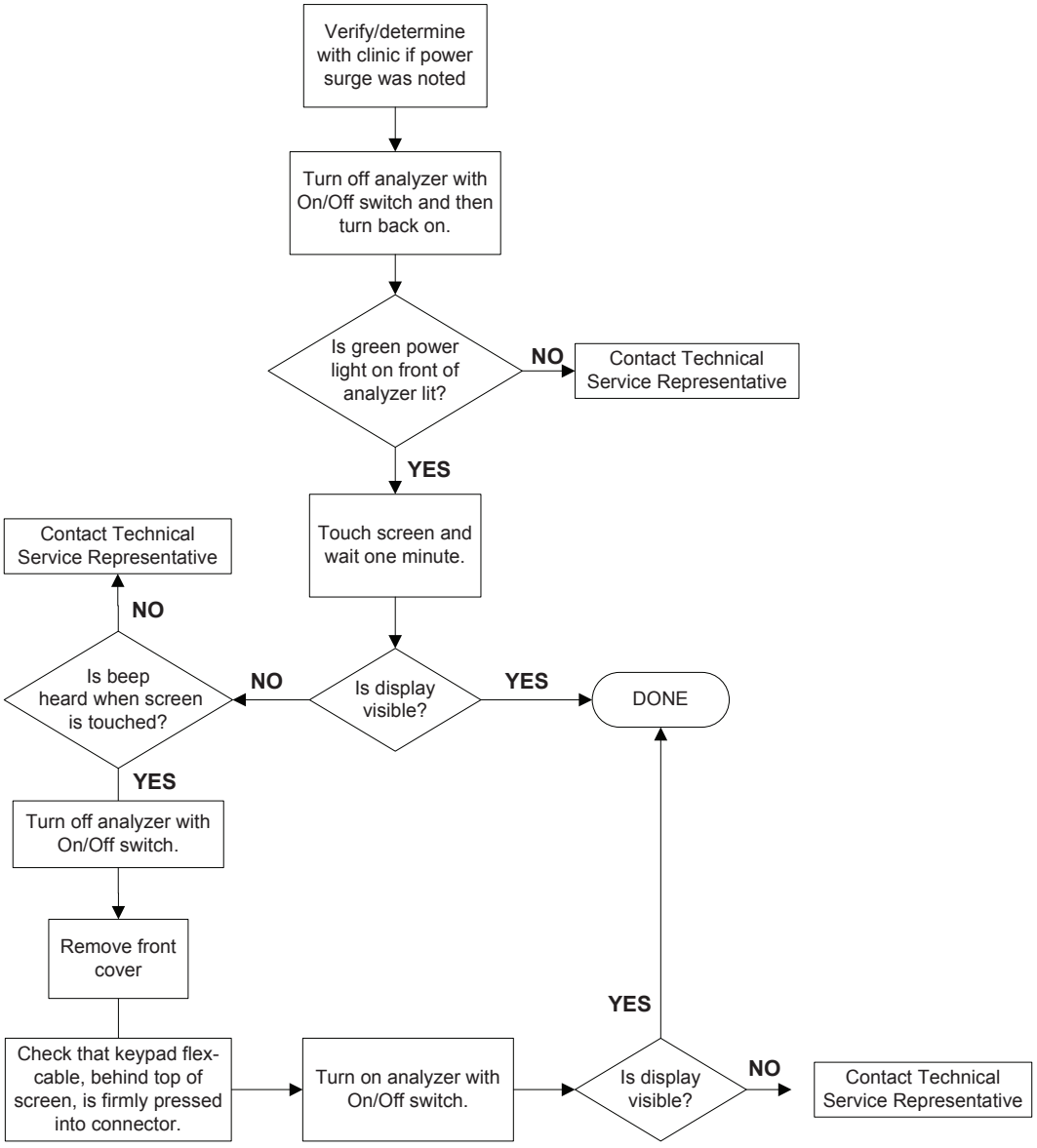
1. Was the sample collected and handled properly?
2. Was the same sample used for both in-house and outside lab analysis?
3. Different blood draw and/or different tube?
4. Could the sample have been switched with another patient?
5. Could discoradenace be due to age changes during shipping or time periods between blood draw and analysis (RBC swelling, platelet clumping, deterioration of WBC for differential)?



Display Issues

Usual cause:

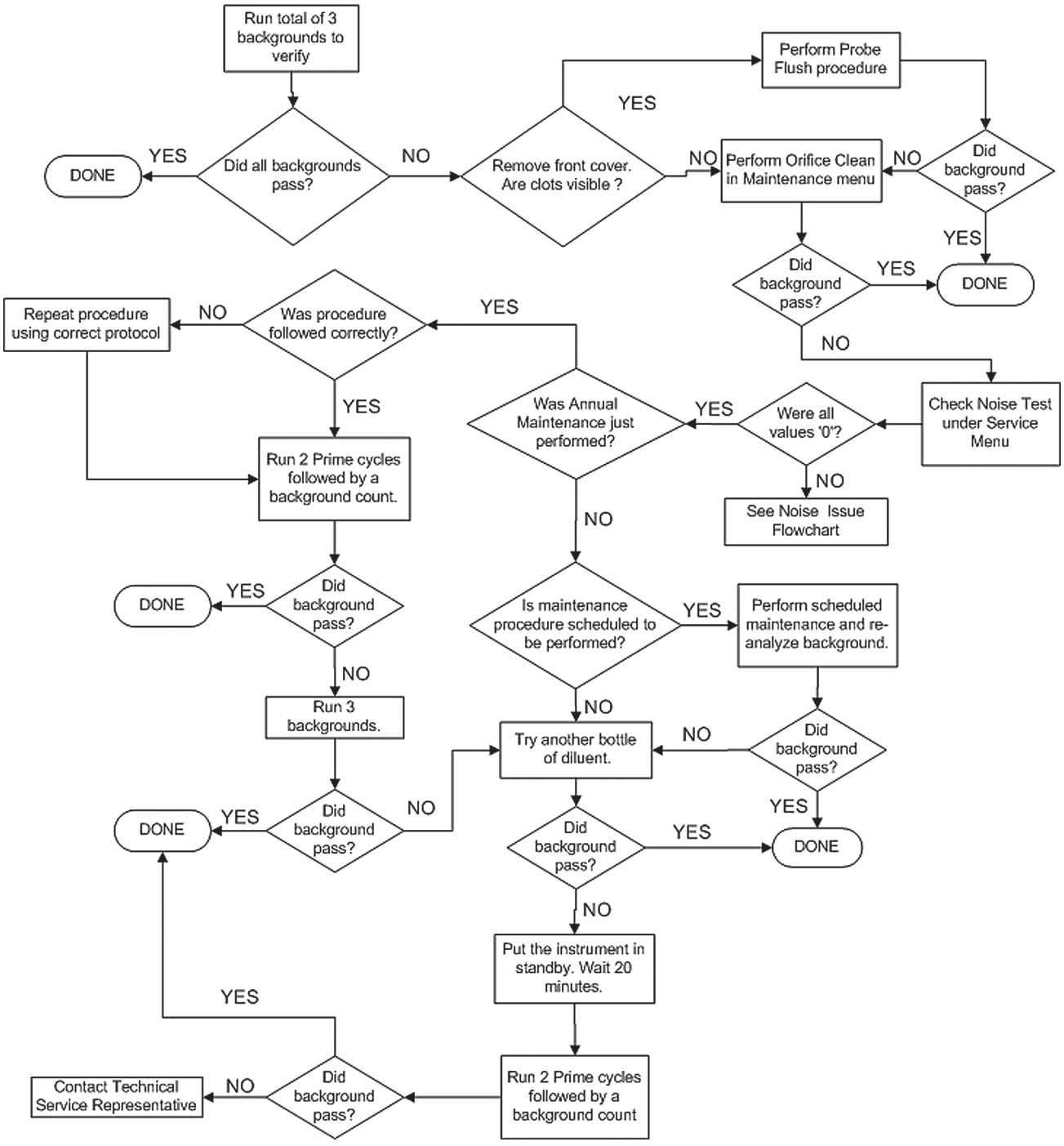
1. Keypad flex-cable loose
2. Static electricity
3. Power outage/lightening



High Background Counts

Initial procedure:

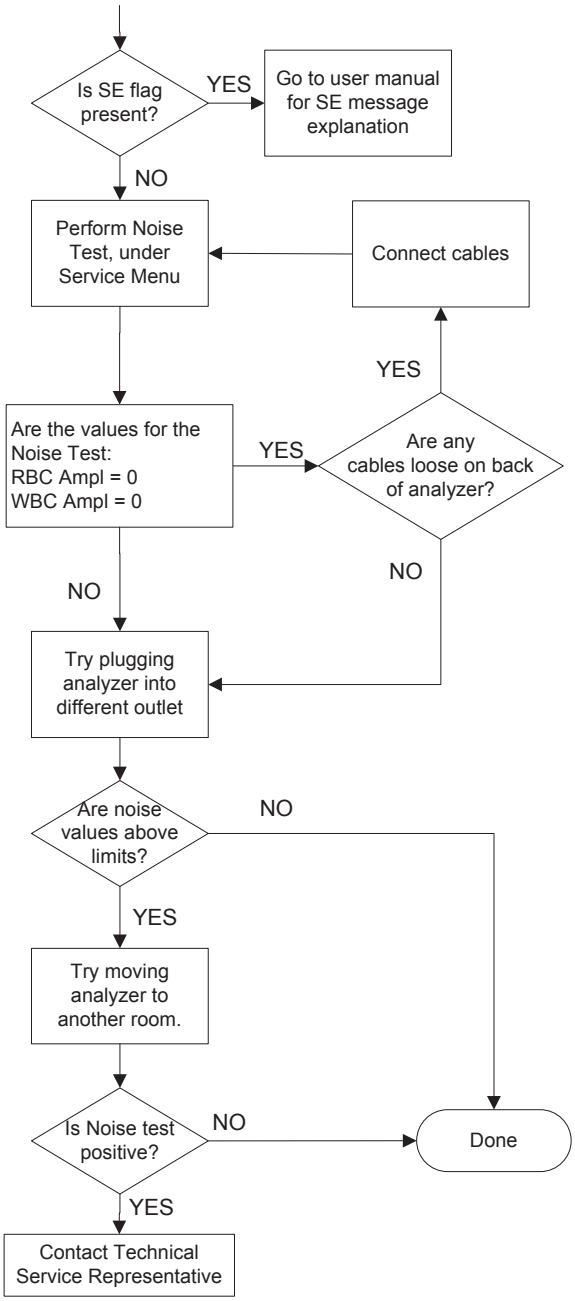
1. Check Dilutent lot number and expiration date
2. Check Diluent age (*i.e.*, when was it opened?)
3. Check reagent tube assemblies on back of analyzer are placed correctly on the reagent bottles and firmly tightened.
4. Check that reagent tube assemblies are in correct reagent bottles (red-Diluent, yellow-Lyse, blue-Cleaner)
5. Check reagent levels
6. Check environmental condition (*i.e.*, extreme temperature fluctuations?)



Noise Issues

Usual cause:

1. Bad electrical outlet in clinic
2. Power outage/lightening
3. Instrument not plugged into line conditioner provided



TU or TL Errors

Check for the following:

1. Check diluent level
2. Check reagent tube assemblies to back of analyzer are tight
3. Check waste tubing
4. Check for kinks in reagent tubing