



Veterinary Haematology Analyser Operator's Manual





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Section 1 Introduction

1.1 Intended Use

The InSight 5 Diff Retic Veterinary Haematology Analyser is a quantitative, automated haematology analyser for veterinary use in clinical laboratories. The InSight 5 Diff Retic is intended for determining a variety of haematologic parameters on peripheral blood, including:

WBC - White Blood Cell or Leucocyte Count **NE# - Neutrophil Count NE% -** Neutrophil Percent Band# - Band Count Band% - Band Percent LY# - Lymphocyte Count LY% - Lymphocyte Percent MO# - Monocyte Count MO% - Monocyte Percent EO# - Eosinophil Count EO% - Eosinophil Percent BA# - Basophil Count **BA%** - Basophil Percent NRBC# - Nucleated Red Blood Cell Count NRBC% - Nucleated Red Blood Cell Percent HCT - Haematocrit or Relative Volume of Erythrocytes RBC - Red Blood Cell or Erythrocyte Count Hb - Haemoglobin Concentration MCV - Mean Corpuscular Volume Erythrocyte MCH - Mean Corpuscular Haemoglobin Erythrocyte MCHC - Mean Corpuscular Haemoglobin Concentration RDW - Red Cell Distribution Width Erythrocyte **RSD** - Red Cell Standard Distribution Retics# - Reticulocyte Count Retics% - Reticulocyte Percent MCVr# - Mean Corpuscular Volume Reticulocyte RDWr% - Red Cell Distribution Width Reticulocyte PLT - Platelet or Thrombocyte Count **PCT** - Plateletcrit MPV - Mean Platelet Volume

PDW - Platelet Distribution Width





1.2 Purpose

The purpose of the InSight 5 Diff Retic is to accurately determine values for haematologic parameters in order to distinguish between normal patients and those who need additional study of any of these parameters. These additional studies usually include examining the blood smear to evaluate RBC, WBC and Platelet morphology and differential, and may also include biochemical investigation. The InSight 5 Diff Retic is designed to automatically flag for haematologic abnormalities.

1.3 Quality Control

Since no single Quality Control technique can routinely provide sufficient data for effective quality assurance, the recommended Quality Control Program for the InSight 5 Diff Retic includes the following three techniques:

- Daily Analyser Checks
- Use of Approved Commercial Patient Controls
- Manual Review of Patient Samples

These techniques, used in combination, will provide for a comprehensive Quality Control Program for the InSight 5 Diff Retic and its operators.

Section 2 Theory of Operation

2.1 Methodology and Method History

Visual Haemocytometry, originated in 1855 with Cramer's description of a counting chamber. Haemocytometry continues to play an important role in many clinical and research facilities. However, it is a labour-intensive and imprecise method, requiring much patience and time.

The methods employed in the InSight 5 Diff Retic to derive the many haematologic parameters, are refinements of well-established methods of counting, sizing and differentiating in combination with an automatic diluting and mixing device for sample processing and single-beam photometer for haemoglobinometry. The InSight 5 Diff Retic incorporates a fluid flow design using a solid state displacement syringe system which delivers:

- Cell-by-cell analysis that occurs over an extended operating range, ensuring accuracy even for very high cell counts
- Sample volume metering via the syringe system, ensuring precision of results

Effective operation of the InSight 5 Diff Retic requires the use of the InSight 5 Diff Retic haematology reagents which have well-controlled properties. A diluent is required to disperse the erythrocytes, leucocytes, and thrombocytes (platelets) without fixing or distorting these cells during analysis.

Because cell size (volume) is measured, the effect of the diluent must be tightly controlled. Also, the diluent must be particle-free and contain antimicrobial agents to prevent the growth of bacteria and fungi.

In order to count the leucocytes and measure haemoglobin, the lysing agent simultaneously lyse the erythrocytes and convert the haemoglobin to a stable pigment, while allowing the leucocytes to remain intact. The haemolysis which occurs renders the cell stroma transparent. The lysing agent converts the haemoglobin released by the lysing reagents to a stable cyanmethemoglobin pigment. The absorption of cyanmethemoglobin is directly proportional to the haemoglobin concentration of the sample. The accuracy of this method is equivalent to that of the cyanmethemoglobin method (the reference method for haemoglobinometry) recommended by the International Committee for Standardisation in Haematology (ICSH Standard EP 6/2: 1977).

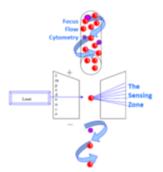
2.2 System Operation

Only 20 microlitres of an EDTA treated blood sample is required for sample analysis. Choose "Single Test" or "Autosampler". Enter the patient demographics and place a well mixed blood sample under the sample probe. The operator simply presses the "RUN" button. The 20 microlitre sample is aspirated into the analyser. Programmed into the InSight 5 Diff Retic are all the necessary settings that take into account the characteristics of size and complexity of the patients' platelets, erythrocytes and leucocytes. In addition, pre-programmed normal ranges for each haematologic parameter are utilised to compare the results of the sample analysis against the normal or expected values. When results fall outside these ranges, appropriate message(s) are generated and accompany the results of the blood sample analysis.

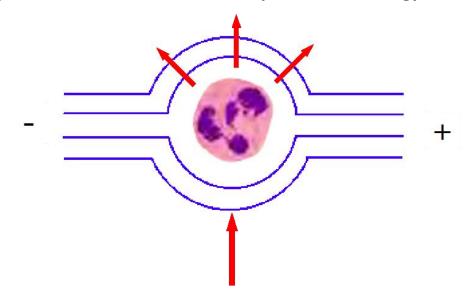
Both RBC and WBC dilutions are made by the analyser utilising the InSight 5 Diff Retic Reagents. The diluent in the system maintains the physical integrity of the erythrocytes, leucocytes and platelets. Proprietary Lysing reagent is added to the WBC dilution. Although the erythrocyte membranes are lysed, the leucocyte membranes are physically maintained and are intact i.e. there is no stripping of the leucocyte membrane leaving a bare nucleus. At the same time, the haemoglobin liberated from the lysed red blood cells, is ultimately converted to cyanmethemoglobin and measured. After the WBCs are analysed and the haemoglobin measured, the RBCs and Platelets are analysed.

The InSight 5 Diff Retic utilises unique design features including focus flow cytometry, impedance and laser technology. The injecting of the diluted blood sample is accomplished through the use of a solid state syringe which maintains the physical integrity and characteristics of the cells. The unique design maintains the blood dilution in the centre of the sensing zone. As individual cells pass into the sensing zone, on a cell-by-cell basis, multiple signals are generated around and through the blood cell. Uniformity of the sample stream is maintained, the sample flow is restricted to a narrow beam in order to prevent the recirculation of any cells back into or near the sensing zone.

The proprietary reagents aid in the effectiveness of the multiple signals in determining not only cell size but more importantly intracellular complexity. The reagents work in concert with the physiology of the cells' membrane.



2.3 InSight 5 Diff Retic: Dual Laser and Impedance Technology



Counting Technology – Focus Flow Cytometer:

- Cells are injected through the counting orifice utilising solid state syringes. The cells are surrounded by a sheath fluid that protects and ensures that they are counted one-cell-at-a-time.
- The solid state syringes prevent and minimise any clot or clogging of the analyser. These syringes are also used to make precise dilutions of the blood sample.

Impedance Technology – Counting and Sizing:

- Impedance Technology is the "Gold Standard" for sizing and counting blood cells.
- As the blood cell passes through the electrical field, it displaces a precise amount of saline creating a resistance pulse that is directly proportional to the size (volume) of the blood cell. The analyser at this point counts and sizes each cell in order to produce the haematocrit (packed cell volume).
- Platelets, red blood cells and all white blood cells are counted separately.

Laser Technology – Light Scatter:

- Laser technology is "State of the Art" for determining the complexity of the blood cell.
- As each cell passes through the Laser, the laser beam shines through the cell and the light is scattered depending on the contents of the blood cell. A single nucleus versus a lobulated nucleus versus granularity create a unique signature for each type of blood cell.

The InSight 5 Diff Retic combines the power of both the "Gold Standard" and "State of the Art" Technologies for Cell-by-Cell analysis simultaneously.

2.4 Specifications

Power:

Input Supply Requirements*: 100-240vAC 2A 50/60Hz Consumption: <60 W (<40 W standby)

Temperature (Ambient Operating): 17-32°C (62-90°F) **Humidity:** 0-95° without condensation

Dimensions: 30 (H) x 23 (W) x 49 (D) cm (11.5 x 9 x 19") **Weight:** 12kg (26.5 lbs) approximate

Waste: Plastic waste container or a chemically resistant open drain

Recommended Reagent Kit:

InSight 5 Diff Retic multispecies Haematology Reagent Kit. Contains Diluent, Lyse and Cleanser.

Sample Volume Required: 20µl whole blood

*To minimize the possible effects of power line transients and other interference that may be induced into the power lines by various kinds of electrical equipment, Woodley Equipment Company recommends that an input power line capable of supplying 15 A (8 A for the 230 V configuration) be used. The ground line should be free of transient currents that might be induced from other electrical equipment.

Colour Touch Screen: Displays messages, menus and enables user input.

- **Electronic Stability:** Change in calibration of the electronic measurement system is less than 1% per month when measured in accordance with this manual and compared at monthly intervals.
- Carryover:Carryover of all InSight 5 Diff Retic's parameters is less than
2.0%. Verification of such low carryover requires the averaging
of the results of at least 10 carryover assays.

Output Capabilities: High Resolution Laser Jet Printer (or equivalent).

Data Output: RS232C compatible.

2.5 Performance Specifications

The performance specifications listed for this analyser apply only to an analyser that has been properly maintained, as indicated in this manual, and uses Woodley Equipment Company authorised reagents. If the average room ambient temperature should vary more than 6°C (10°F) from the calibrating temperature, verify calibration and recalibrate if required to ensure conformance to specifications.

2.6 Precision

Precision is defined as a Coefficient of Variation (CV) based on at least 31 determinations of the same sample, see Table 2-1.

Table 2-1 Precision

| (n>31) | | | | |
|-----------------------------------------------------------------------------------|------------------|--|--|--|
| Parameter | CV | | | |
| WBC at 6.0 – 15.0 x 10 ³ cells/mm ³ (x10 [^] 9/L) | <u><</u> 3.0% | | | |
| RBC at 3.00 – 6.00 x 10 ⁶ cells/mm ³ (x10 ¹² /L) | <u><</u> 3.0% | | | |
| Hb at 10.0 – 18.0 g/dL | <u><</u> 2.0% | | | |
| MCV at 50.0 – 70.0 fL | <u><</u> 3.0% | | | |
| PLT at 200 – 500 x 10 ³ cells/mm ³ (x10 ⁹ /L) | <u><</u> 7.0% | | | |
| MPV at 5.0 – 20.0 fL | <u><</u> 3.0% | | | |
| RDW at 12.0 – 15.0 % | <u><</u> 3.0% | | | |

2.7 Accuracy

The InSight 5 Diff Retic can be adjusted, within the resolution of the readout, to agree with a predetermined reference value at any point in the operating range.

2.8 Operating Range Linearity Limits

When tested using dilutions made from a sample having no interfering substances, the InSight 5 Diff Retic's value will be equal to the expected value within the limits given in Table 2-2. To obtain the same results, multiple readings must be taken at each point in order to eliminate the statistical effects of imprecision. Linearity of size measurements (e.g. MCV) are tested using appropriate techniques.

| Parameter | Linearity Range | Limits (whichever is greater) | | |
|--------------------------------------------------------------------|-----------------|-------------------------------|--|--|
| WBC x 10 ³ cells/mm ³ (x10 ⁹ /L) | 0.0 to 240.0 | +/- 3.0 or 5.0% | | |
| RBC x 10 ⁶ cells/mm ³ (x10 ¹² /L) | 0.00 to 20.00 | +/- 0.05 or 5.0% | | |
| Hb g/dL | 0.0 to 34.0 | +/- 0.2 or 3.0% | | |
| MCV fL | 30 to 300 | +/- 1.5 or 2.0% | | |
| PLT x 10 ³ cells/mm ³ (x10 ⁹ /L) | 0 to 5000 | +/- 10 or 10% | | |

| Table | 2-2 | Linearity | Limits |
|-------|-----|-----------|---------------|
|-------|-----|-----------|---------------|

2.9 Carryover

High to low carryover on InSight 5 Diff Retic parameters is less than or equal to 2.0%.

2.10 Interfering Substances

The known interfering substances which can affect the parameter results of the InSight 5 Diff Retic are as follows:

| WBC | Certain unusual RBC abnormalities that resist lysing, clumped platelets, fragmented WBC, any unlysed particle greater than 35fL may cause flagging conditions. Heparin may cause the WBC differentials to be inaccurate. |
|-----------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| RBC | Very high WBC count, high concentration of very large platelets, agglutinins. |
| Hb | Very high WBC count, severe lipaemia, heparin, certain unusual RBC abnormalities that resist lysing. |
| MCV | Very high WBC count, agglutinins. |
| PLT | Very small erythrocytes or leucocytes or cell fragments may cause flagging conditions in some cases. The System provides accurate PLT counts in the presence of most haemolytic disorders. Chemotherapy may affect certain samples. |
| HCT, MCH, MCHC, NE, LY, MO, EO BA, NRBC, RETIC, PCT | Known interferences related to the parameter used in the computation of these parameters. |

2.11 Reagents

CAUTION: The InSight 5 Diff Retic reagent system was specially developed for use with the InSight 5 Diff Retic Haematology Analyser. The reagents are not compatible with other haematology systems. Do not mix reagent systems.

Reagent Subsystem: The InSight 5 Diff Retic requires specialised reagents consisting of a diluent, an enzymatic cleaning agent and multispecies lytic agent, which are introduced into the analyser via the tubing supplied. The reagents are drawn from the reagent kit's individual containers and are dispensed automatically in precise, measured amounts during each operating cycle.

Woodley Equipment Company recommends the following reagents for use with the InSight 5 Diff Retic Haematology Analyser. All listed performance characteristics refer to the InSight 5 Diff Retic Haematology Analyser using only the InSight 5 Diff Retic reagents. Refer to the reagent inserts for detailed information before using the reagent.

Diluent: An azide-free, isotonic stabilising electrolyte diluent intended to dilute whole blood in the InSight 5 Diff Retic Haematology Analyser.

Lysing Agent: A multispecies lysing agent intended for use with the InSight 5 Diff Retic Haematology Analyser. This azide-free reagent rapidly lyses erythrocytes, freeing the Hb and reducing the size of cellular debris to a level that does not interfere with leucocyte counts. It also causes a conversion of haemoglobin to a stable cyanmethemoglobin pigment, the absorbance of which is directly proportional to the Hb concentration over the clinically useful range.

Cleaning Agent: A cleaning agent intended for use with the InSight 5 Diff Retic Haematology Analyser. This enzymatic deproteinising reagent effectively cleans and rinses the InSight 5 Diff Retic's cuvette and tubing. It removes blood components and residue and reduces the residual particulate count to an insignificant level. The enzymatic deproteinising solution must be used with the InSight 5 Diff Retic reagents.

ProbeClean™: A cleaning agent intended for cleaning the sample probe immediately after running non-whole blood specimens.

Section 3 Operating Instructions

3.1 Operating Summary

Summary of a Quick Start to running a sample on the InSight 5 Diff Retic

- 1. Check that power is on and the Home Screen is displayed.
- 2. Sample Analysis: Mix the specimen carefully and thoroughly. Ensure there are no clots in the sample.
- 3. Choose "Run Single Test" until you get to the "Single Test Run" Menu.



4. "Single Test Run" Menu.

| GENX | Sin | gle Test Run | T |
|-----------|-----|---------------------|---|
| Species D | | | |
| (Secto) | | | |
| A None to | ња | J ^{an} Aun | |

5. If you need to change the species, click "Species", then select by pressing the assigned button.

| | t Species - | |
|---------|-------------|-----------|
| HATY | 200 | A 220 000 |
| erres) | - | ARROCAT |
| POAL. | HORE | AGED |

6. Enter Patient Demographics. Press "DONE" to accept.



7. Hold the sample in the EDTA tube up to the probe until it touches the bottom. Press "RUN" to run a test.

| ^{senx} Sing | gle Test Run | |
|----------------------|--------------|--|
| Species DOG | | |
| Pathent ID SAMMY | | |
| Chent 10 | | |
| ft Home to tack | Fini | |

8. While the sample is still being held up to the probe, hold the sample in place for 2-3 seconds until you hear or see the probe moving up.

3.2 Processing Samples

Always try to fill the EDTA tube so it is at least 50% full. If you have a short draw (less than 50%), the sample can still be processed (InSight 5 Diff Retic only requires 20uL). Keep in mind that the sample will be diluted by excess EDTA, causing the values to be lower and the cells may be crenated, causing the cell size to be smaller.

Important Considerations

If the InSight 5 Diff Retic reports the following:

- "REVIEW SLIDE" Analyser detects an abnormality. Recommend rerunning the blood sample and reviewing a blood smear. Parameters affected are the WBC and differential.
- "RERUN SAMPLE" Analyser detects a problem when processing the sample. Recommend rerunning the blood sample. If "RERUN SAMPLE" persists, look at sample integrity for clumps, clots or lipaemia.
- If the blood sample is lipaemic, this excess "fat" may interfere with Haemoglobin (Hb) and Platelets (PLT), causing the values to be elevated. If the sample is severely clumped or clotted, all parameters may be affected.

Whenever **"SEVERE"** is flagged next to a parameter, review blood smear. If a sample reads:

| WBC | <2.00 | or | >50.00 |
|-----|-------|----|--------|
| RBC | <2.00 | or | >9.00 |
| PLT | <50 | or | >850 |
| LY | | | >75% |
| MO | | | >20% |
| EO | | | >20% |

Recommend rerunning the sample and reviewing the blood smear.

3.3 Automatic Probe Retraction

If the unit is not used for 10 minutes, the probe will automatically move up into the analyser. When you are ready to run a sample, choose "Setup Autosampler" or "Run Single Test". The probe will be lowered for single test. The unit will now say "READY".

PURPOSE: This process will keep the probe from collecting dust and residues from animal fur and skin.

3.4 Replacing Reagents

CAUTION: When replacing reagents, discard the remaining portion of reagents from the old kit. Do not mix with the new kit. Always check the expiration date on the new kit to avoid using an expired kit. Keep the containers inside the kit. Check and clean the fan filter if needed.

- 1. Make sure the new reagents have been stored at room temperature and do not contain precipitate, turbidity, particulate matter or unusual colour. If any of these are evident, DO NOT use the reagent.
- 2. There are 3 containers in each kit. Remove the cap from the new Diluent (largest container clear) and then remove tube and cap from the empty Diluent container. Replace tube and cap onto your full Diluent container making sure the metal sinker is at the bottom of the new Diluent container. Repeat the process for the Lyse and Cleanser. Always check to make sure you have connected each tube to the correct container.
- 3. Make sure the appropriate tubing is connected to the Lyse bottle and that the metal sinkers for the Diluent and Cleanser containers are inserted completely to the bottom of the bottle.
- 4. Connecting recently shaken reagents to the InSight 5 Diff Retic can introduce bubbles into the syringe pump assembly and should be avoided.

5. With the InSight 5 Diff Retic "Home Screen" displayed, press the "Load Kit" button. Choose either 50, 200 or 500 depending on the size of your kit, then press "Okay". When uploading the reagents is complete, the InSight 5 Diff Retic is ready to run and will return to the "Home Screen".

3.5 Specimen Collection and Handling

Approximately 20 microlitres of whole blood is introduced undiluted into the analyser. Collect and prepare the specimen as follows:

 Collect the specimen by venipuncture and use tripotassium ethylenediaminetetraacetic acid (K3 EDTA) as the anticoagulant. For detailed information on the collection of the whole blood by venipuncture, refer to "Standard Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture" (ASH-3), published by the National Committee for Clinical Chemistry Laboratory Standards (NCCCLS).

IMPORTANT: The use of heparin may cause a bias in WBC, Hb, and Differential readings. The blood tube used can be no longer than 75mm.

- 2. Mix the blood specimen and the K3 EDTA carefully and thoroughly as follows:
 - Place the specimen on a roller mixer for a minimum of five minutes.
 - Remove the specimen from the mixer and gently invert the tube three (3) times.
 - Observation of the specimen before and during mixing can lead to detection of problems such as gross haemolysis, lipaemic plasma or blood clots.

3.6 Specimen Storage

Since blood platelets disintegrate rapidly, whole blood cell counts that include PLT should be performed within 4 hours after drawing (CAT specimen within 20 minutes) for optimum results. Whole-blood specimens for PLT and differential counts must be run at room temperature.

3.7 Operator's Responsibilities

CAUTION: Prior to operating, perform a visual inspection to ensure sufficient level of reagents and verify there are no kinks in the reagent tubes.

It is the operator's responsibility to:

- 1. Become thoroughly familiar with the information in this section before operating the InSight 5 Diff Retic.
- 2. Clean external surfaces of the analyser with a damp clean cloth. Do not spray liquids or cleansers directly onto the analyser.

- 3. Perform the recommended procedures as described in the "Special Procedures", presented later in this section, as required.
- 4. Refer to Section 6 "Troubleshooting Guide" when:
 - The analyser does not perform as described in this section.
 - The variation from the performance characteristics and specifications exceeds the tolerance established by your laboratory.
 - The analyser produces unacceptable data.

| Operation | Description |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Power-Up Make sure power cord is plugged in, then press ON/OFF switch on back of analyser. When the "Not Ready Screen" appears, select "Start Up" or "Load" if reagent has not been primed. | The Power-Up cycle takes approximately 2 minutes. At the end of the cycle, follow instructions displayed on the screen. Note: For maximum stability, it is highly recommended that the analyser remain powered-up at all times. Power consumption is relatively low (less than 40 Watts in the idle mode). |
| 2. Sample Analysis A. Choose "Setup Autosampler" or "Run Single Test". B. Select species and enter patient name. C. Mix the K₃ EDTA anti-coagulated blood specimen carefully and thoroughly for a minimum of five minutes. D. Uncap the specimen tube and present the specimen to the sample probe. E. Remove and cap the specimen. | A. Refer to Specimen Collection and Handling. B. Make sure the probe is fully immersed into the specimen during the entire aspiration process. C. The InSight 5 Diff Retic will aspirate 20 μL of specimen which will take approximately two seconds. The probe will then retract into the analyser. Do not remove the specimen tube until the probe fully retracts. D. The analyser will add additional Diluent and Lyse, mix the dilution and transfer it out for analysis of the WBC and Hb parameters. The message "ANALYSING SAMPLE" will be displayed. The mixing cuvette is then rinsed twice with diluent. The aliquot of diluted sample retained in the sample probe is then dispensed, mixed and transferred for analysis of the RBC and PLT |

3.8 Special Procedures

This section covers details of procedures which are to be performed under special circumstances.

- 1. Procedure for running Joint/Abdominal Fluid
 - Mix sample.
 - Verify that sample does not have clumps or clots.
 - Verify that sample is not overly viscous (very thick).
 - DO NOT RUN if overly viscous or clumps/clots are present.
 - Select from Species Menu "JOINTFLUID" or "ABDOMINAL"
 - Sample near top of fluid, not from bottom of the collection tube.
 - After processing Joint/Abdominal Fluid sample, immediately run a sample using Probe Clean™ as the sample.

3.9 Maintenance

There is no routine maintenance required by the operator. After installation, the InSight 5 Diff Retic should remain on and left on the "Home Screen" for the system to perform the Automated Maintenance schedule which is monitored and regulated by Smart SoftwareSM. The system is ready to analyse a sample 24 hours a day, no start-ups, no shutdowns and no weekly maintenance.

- 1. After every test, the system uses Diluent to rinse away excess blood and clean the fluidics. Focus Flow prevents proteins from building up on the aperture. The positive displacement pumps inject the sample using Focus Flow Cytometer and after each count reverse flush the aperture, virtually eliminating any potential for clots.
- 2. The InSight 5 Diff Retic will do an electronic check once every hour to ensure proper operation.
- 3. Every 12 hours, a small amount of diluent is moved through the system to remove air bubbles and ensure the ability to run samples 24 hours a day.
- 4. After 20 tests, an Automated Clean Cycle is performed using Cleanser. The Automated Clean Cycle will take 10 minutes and does not reduce or decrement the number of tests from your kit. Each 50 Test Kit and 200 Test Kit has additional reagents built-in to complete the Automated Maintenance.
- 5. If a Manual Clean Cycle is recommended by Technical Support, the cycle will take 30 minutes and uses 3 tests. The Manual Clean Cycle should not be routine.

6. If the power is turned off or if the system has not been used for 72 hours, when the Start Cycle is initiated, 1 test is used and decremented.

Section 4 Special Requirements, Installation and Precautions

4.1 Special Requirements

The InSight 5 Diff Retic Haematology Analyser is intended for use in a conventional veterinary in-clinical laboratory environment. Before deciding on a location for the analyser, consider all of the following special requirements:

Space and Accessibility: In addition to the space required for the individual unit(s), make sure the location you choose offers:

- Comfortable working height. Beyond a matter of convenience, proper work height helps provide for the most efficient operation of the InSight 5 Diff Retic.
- Easy access to the left side and rear of the InSight 5 Diff Retic is required for maintenance and servicing.

IMPORTANT: Ensure to provide enough space for placement of the InSight 5 Diff Retic Reagent Kit on the left side of the analyser. Keep containers inside the kit. Reagents must be at the same height as the analyser.

Electrical Input: The InSight 5 Diff Retic Haematology Analyser should be powered with electricity from an independent, protected circuit. A three-wire grounded outlet providing 100-240v AC 2A 50/60Hz, single-phase input power is required. Current carrying a capacity of 15 A is recommended, although the actual power consumption is less than 110 W (see Section 2). The safety ground path must be capable of carrying the full current of the circuit (confirmed third-wire earth ground). The 1.5-m (6 ft) primary power cord on the rear of the analyser must be plugged directly into the electrical outlet. Do not use an extension lead.

Ambient Temperature and Humidity: The analyser can be installed in a room with a temperature range of $17 - 32^{\circ}C$ (62 - 90°F). Humidity may be up to 95% without condensation.

Ventilation: The analyser's ventilation fan, located on the rear panel, must be placed at least 8 cm (3") away from any wall or obstruction which could interfere with airflow. Failure to do so can result in inadequate cooling of the analyser and system malfunctioning.

Drainage: The waste drain tubing located on the left rear of the analyser can be connected to either a chemically resistant open drain less than 76 cm (30") above the floor, or a waste container with a minimum capacity of 10 litres (2.5 gal). In either case, the maximum waste line length is 3.7 m (12 ft). When using a drain, be sure the end of the waste tube is above the normal drain level.

WARNING: Disposal of any chemical or biohazardous wastes must be in accordance with all applicable environmental laws.

Connectors: The InSight 5 Diff Retic is supplied with all necessary power cables, signal cables, tubing and lines.

4.2 Installation

Every InSight 5 Diff Retic is thoroughly tested before it is sent out to the customer.

- Upon receipt of the InSight 5 Diff Retic, carefully inspect the carton(s) and all packaging for evidence of damage or mishandling. If signs of damage or mishandling are evident, notify Woodley Equipment Company immediately.
- Your Installation Representative is responsible for the original installation of the InSight 5 Diff Retic.
- If the analyser has been returned to the manufacturer for servicing or updates, it must, upon return to your facility, undergo a set-up procedures as follows:
 - 1. Slowly remove the analyser from the shipping carton.

IMPORTANT: Please keep the shipping carton. It may be needed at a later date for service purposes or for analyser updates. **DO NOT THROW AWAY**.

2. Place the analyser on a permanent lab counter location.

IMPORTANT: Allow the analyser to reach room temperature before proceeding further. The outside of the analyser should be approximately room temperature to the touch.

- 3. Plug the analyser power cord into the rear of the analyser and the other end into an AC 100-240V, 50-60Hz mains power supply.
- 4. Use an InSight 5 Diff Retic Reagent Kit that has been stored at room temperature. Place the reagent pack on the left side of the analyser. Do not place the Reagent Kit or any liquid containers on top of the analyser. Open the carton but do not remove bottles from the box.
 - Take the cap off the tubing that fits the Diluent reagent container and connect it with that container. This is the largest size cap with the metal sinker and connect to the largest container. The other end of the tubing connects with the white fitting on the back of the analyser. This is the first fitting from the top.
 - Take the cap off the tubing that fits the Cleanser reagent bottle and connect it with that bottle. The other end connects with the green fitting on the back of the analyser. This is the second fitting from the top.

Note: The third fitting from the top does not receive a tube.

- Take the cap off the tubing that fits the Lyse reagent bottle, the thinnest tubing and connect it with that bottle. The other end connects with the smallest white fitting. This is the fourth fitting from the top.
- Take the cap off the tubing that fits the Waste container, the longest tubing with the largest cap. Expand the Waste container and connect to the cap. The other end connects with the black fitting on the back of the analyser. This is the fifth fitting from the top.
- Make certain that the metal sinkers on the end of each tube touch the bottom of each of the reagent containers. Check that the tubing is connected between the appropriate reagent container and fitting.

| Fitting Location from the Top | Fitting Colour | Reagent |
|-------------------------------|----------------|----------|
| 1 st | White | Diluent |
| 2 nd | Green | Cleanser |
| 3 rd | Small Black | None |
| 4 th | Small White | Lyse |
| 5 th | Black | Waste |

- Check that lines are not bent or kinked. Check that there are no obstructions in the tubing.
- 5. Turn power on. The power switch is located on the back of the analyser. The display screen will be blank for a few minutes until the analyser powers up. Once main screen appears, proceed.

IMPORTANT: If an error message appears on the display screen, do not proceed any further. Contact Woodley Equipment Company.

6. Press the "HOME" button from the "Not Ready Screen" to access the "Menu Screen" or the "MENU" button if this option is displayed. Once on the "Menu Screen", press for "AutoSampler". Once on the "AutoSampler Screen", press "Initialize". Wait until analyser becomes silent. Press "Probe Out". Wait until analyser becomes silent. Press "Probe Will not be in the centre). Wait until analyser becomes silent. Press "BACK". Press "Initialize", this will test the syringes. Wait until analyser becomes silent.

IMPORTANT: If there is a grinding noise or an error message, do not proceed any further. Contact Woodley Equipment Company.

- 7. Running a Valve Test
 - Press "Test Valves".

Note: For each valve being tested you will hear seven (7) clicks and the number of that valve.

IMPORTANT: If any other clicks are missed, do not proceed any further. Refer to the "Troubleshooting" section of this manual.

- Press "Set-Up". Check accuracy of date and time (24-hour).
- Choose "Printers". Choose appropriate printer, chosen printer will be highlighted.
- Press "BACK" to return to the main screen.
- 8. Press the "Load Kit" button. Choose the kit test size located on the box. Press "Okay" to upload the reagents. This process takes about 5 minutes. If any solution is leaking, turn the analyser off and refer to the "Troubleshooting" section.

IMPORTANT: If an error message appears on the display screen, do not proceed any further. Refer to the "Troubleshooting" section of this manual.

- 9. The "Home Screen" will appear. The screen should show "Number of tests Remaining". The InSight 5 Diff Retic is now ready to run.
- 10. The test counter on the main screen will say 0 when the kit needs to be replaced.

IMPORTANT: For maximum stability, it is highly recommended that the analyser remains powered-up at all times. Power consumption is relatively low (less than 40 Watts in idle mode).

4.3 Shutdown

Proper shutdown is essential to keeping the analyser in optimal condition for shipping, moving or when it is not going to be used for 2 weeks or longer.

- 1. Remove the reagent tubes from the Diluent, Cleanser and Lyse bottles. Do not remove the tubes from the fittings on the back of the analyser.
- 2. Place the three reagent tubes in a cup of distilled water.
- 3. Press the "Load Kit" button.
- 4. Press "50 TEST KIT".
- 5. Press "Okay".
- 6. After the completion of this cycle, remove the three reagent tubes from the cup of distilled water. Place them on a clean paper towel.
- 7. Repeat steps 3-5.
- 8. After the completion of the second cycle, disconnect the reagent tubes from the fittings on the back of the analyser. Rinse with distilled water. Store in a clean "ziplock" type plastic bag to prevent contamination (store the reagent lines separate from the waste line).
- 9. Press the "MENU" button.

10. Press the "Autosampler" button.

11. Press "Initialize". Wait until the analyser stops.

IMPORTANT: If there is a grinding noise or an error message at any time during the shutdown, do not proceed any further. Refer to the "Troubleshooting" section of this manual.

- 12. Unplug the power cord from the back of the analyser.
- 13. Place the analyser in the original manufacturer issued carton. Pack with included packing foam. Include the reagent tubes and power cord in the box.
- 14. Securely tape the carton shut.

4.4 Precautions, Limitations and Hazards

Precautions are inserted in the text of this manual where they are applicable. Precautions are as follows:

WARNING: May cause injury. CAUTION: May cause damage to the analyser. IMPORTANT: May cause misleading results.

Limitations

The InSight 5 Diff Retic Haematology Analyser is designed for veterinary use only.

Substitution of reagents, calibrators, controls and components manufactured by other companies may adversely affect the performance of the analyser.

All servicing and repairs should be performed by Woodley Equipment Company authorised personnel.

Location

An authorised representative must install the analyser. The InSight 5 Diff Retic should be placed on a hard, level surface. The workstation should have non-porous, non-absorbing work surfaces and flooring which can be cleaned and disinfected easily using recommended procedures. Place the system:

- Away from direct sunlight.
- Away from the path of a cooled or heated air outlet.
- Away from centrifuges, x-ray equipment, CRT's, video terminals, computers and copiers.
- Place reagent containers on the left side and same level as the analyser.
- 8cm (3") clearance is required behind the analyser to ensure proper ventilation. Care should be taken to prevent blocking of the air vents on the rear of the analyser.

Reagent Storage and Handling

Store reagents, calibrators and controls according to the directions on the labels and in the package inserts that accompany them.

IMPORTANT: Prior to each use, check there is adequate reagent in the reagent bottles. Failure to maintain sufficient fluid levels will produce erroneous results and the operator will be instructed to re-run the sample analysis.

Protect reagents from extreme heat and freezing during storage. Temperatures below 0°C (32°F) may cause layering that changes the conductivity of the reagent. If freezing occurs, wait until reagents are at room temperature and look for any precipitant. Do not use if precipitant are present.

Never add remaining reagent from a container being replaced to a freshly opened container. This may contaminate the new reagent.

IMPORTANT: Check the back of the analyser to be certain that the Diluent, Cleaning and Lysing reagent tubes are inserted in the proper reagent bottle. Verify that the lines are connected to the coloured fittings as follows:

| White | = | Diluent |
|-------------|---|----------|
| Green | = | Cleanser |
| Small Black | = | Spare |
| Small White | = | Lyse |
| Black | = | Waste |

Make sure the waste line is connected to the appropriate outlet and routed to a suitable waste container.

Section 5 Data Interpretation and Flagging

5.1 Interpreting Printed Results

Table 5-1 lists the parameters reported by the InSight 5 Diff Retic, their definitions, the international units of measure, the standard units of measure and the formulas for equivalent unit conversion.

| Parameter | | | Conventional | Equivalent Unit |
|------------------|---------------------|------------------------------|-------------------|---------------------|
| 14/20 | N. school of | Measure | Units of Measure | Conversion |
| WBC | Number of | Billions of leucocytes | Thousands of | 109/1- |
| White Blood Cell | leucocytes in the | per litre of whole | leucocytes per | 10 ⁹ /L= |
| (Leucocyte) | specified volume of | blood: 10 ⁹ /L | microlitre of | $10^{3} / \mu L =$ |
| Count | whole blood. | | whole blood: | Κ/μ L |
| | Directly measured. | | Κ/μ L | |
| NF # | Absolute number | Billions of | Thousands of | 10 ⁹ /L= |
| NE # | of leucocytes that | neutrophils per litre | neutrophils per | $10^{3}/\mu$ L = |
| | are neutrophils. | of blood: 10 ⁹ /L | microlitre of | ΙΟ /μ L = Κ/μ L |
| | Directly measured. | | blood: K/µ L | NμL |
| | Directly measured. | | | |
| NE % | Percent of | Percent | Percent | None |
| INE 70 | leucocytes that are | % | % | |
| | neutrophils. | | | |
| | | | | |
| | | | | |
| Band # | Absolute number | Billions of | Thousands of | 10 ⁹ /L= |
| | of leucocytes that | neutrophils per litre | neutrophils per | $10^{3}/\mu$ L = |
| | are Bands. Directly | of blood: | microlitre of | K/μ L |
| | measured. | 10 ⁹ /L | blood: K/ μ L | |
| | Percent of | Percent | Percent | None |
| Band % | leucocytes that are | % | % | |
| | Bands. | | | |
| | | | | |
| | | | | 4.09 // |
| N/ // | Absolute number | Billions of | Thousands of | 10 ⁹ /L= |
| LY # | of leucocytes that | lymphocytes per | lymphocytes per | $10^{3}/\mu$ L = |
| | are lymphocytes. | litre of blood: | microlitre of | Κ/μ L |
| | Directly measured. | 10 ⁹ /L | blood: K/μ L | |
| | Percent of | | | |
| LY % | leucocytes that are | Percent | Percent | None |
| ,, | lymphocytes. | % | % | |
| | ., | ,,, | ,0 | |

| MO # | Absolute number of leucocytes that are monocytes. Directly measured. Percent of | Billions of monocytes per litre of blood: 10 ⁹ /L Percent | Thousands of monocytes per microlitre of blood: K/µ L Percent | 10 ⁹ /L= 10 ³ /μ L = Κ/μ L None |
|--------|-------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|---------------------------------------------------------------------------|----------------------------------------------------------------|
| MO % | leucocytes that are monocytes. | % | % | |
| EO # | Absolute number of leucocytes that are eosinophils. Directly measured. | Billions of eosinophils per litre of blood: 10 ⁹ /L | Thousands of eosinophils per microlitre of blood: K/µ L | 10 ⁹ /L= 10 ³ /μ L = K/μ L |
| EO % | Percent of leucocytes that are eosinophils. | Percent % | Percent % | None |
| NRBC# | Absolute number of erythrocytes that are immature nucleated red blood cells. Directly measured and flagged. | Billions of NRBC's per litre of blood: 10 ⁹ /L | Thousands of NRBC's per microlitre of blood: Κ/μ L | 10 ⁹ /L= 10 ³ /μ L = K/μ L |
| NRBC % | Percent of erythrocytes that are nucleated red blood cells flagged. | Percent % | Percent % | None |

| HCT Haematocrit | Relative volume of erythrocytes. Computed from RBC and MCV: (RBC X MCV) ÷ 10 | Percent % | Percent % | L/L = <u>%</u> 100 |
|--------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|-------------------------------------------------------------------------------|---------------------------------------------------------|
| RBC Red Blood Cell (Erythrocyte) Count | Number of erythrocytes in the specified volume of whole blood. Directly measured. | Trillions of erythrocytes per litre of whole blood: 10 ¹² /L | Millions of erythrocytes per microlitre of whole blood: M/μ L | 10 ¹² /L= 10 ⁶ /μ L = Μ/μ L |
| Hb Haemoglobin | Mass or weight of haemoglobin in the specified volume of whole blood. Directly measured. | Grams of haemoglobin per decilitre of whole blood: g/dL | Grams of haemoglobin per decilitre of whole blood: g/dL | g/L = g/dL x 10 |
| MCV Mean Corpuscular (Erythrocyte) Volume | Average volume of individual erythrocytes in whole blood. Directly measured. | Femtolitre: fL | Femtolitre: fL | $fL = \mu^3$ |
| MCH Mean Corpuscular (Erythrocyte) Haemoglobin | Mass or weight of haemoglobin in the average individual erythrocyte. Compute from Hb and RBC: 10 x (Hb ÷ RBC) | Pictograms of haemoglobin per erythrocyte: pg | Pictograms of haemoglobin per erythrocyte: pg or 10- ¹² g | None |
| MCHC Mean Corpuscular (Erythrocyte) Haemoglobin (Concentration) | Average mass or weight of haemoglobin in specified volume of erythrocytes. Computed from Hb and Hct: 100 x (Hb ÷ Hct) | Grams of haemoglobin per decilitre of erythrocytes: g/dL | Grams of haemoglobin per decilitre of erythrocytes: g/dL | g/L = g/dL x 10 |
| RDW Red Cell (Erythrocyte Volume) Distribution Width | The size- distribution spread of the erythrocyte population expressed as the coefficient of variation of the red cell distribution. | Percent % | Percent % | None |

| RSD | The size- | | | |
|-------------------|----------------------|-----------------------|-----------------------|----------------------|
| Red Cell | distribution spread | | | |
| (Erythrocyte) | of the erythrocyte | | | |
| Standard | population | | | |
| | expressed as the | Femtolitre: fL | Femtolitre: fL | $fL = \mu^3$ |
| Deviation | standard deviation | | | ·- /* |
| | of the red cell | | | |
| | distribution. | | | |
| | Directly measured. | | | |
| RETICS # | Number of | | | |
| (Reticulocytes) | immature | | | |
| (Reticulocytes) | nonnucleated | Billions of | Thousands of | 10 ¹² /L= |
| | erythrocytes in the | reticulocytes per | reticulocytes per | 10^{6} / μ L = |
| | specified volume of | litre of whole blood: | microlitre of | K/μ L |
| | whole blood. | 10 ¹² /L | whole blood: K/ μ | |
| | Directly measured | | L | |
| | and flagged. | | | |
| RETICS % | Percent of | | | |
| (Reticulocytes) | immature | | | |
| (Reflection yres) | nonnucleated | | | |
| | erythrocytes in the | Percent | Percent | None |
| | specified volume of | % | % | |
| | whole blood. | | | |
| | Flagged. | | | |
| MCVr # | Average volume of | | | |
| Mean | individual | | | |
| Corpuscular | Reticulocytes in | Femtolitre: fL | Femtolitre: fL | $fL = \mu^3$ |
| (Reticulocyte) | whole blood. | | | |
| Volume | Directly measured. | | | |
| RDWr | The size- | | | |
| Red Cell | distribution spread | | | |
| (Reticulocyte | of the reticulocyte | | | |
| Volume) | population | Percent | Percent | None |
| , Distribution | expressed as the | % | % | |
| Width | coefficient of | | | |
| | variation of the red | | | |
| | cell distribution. | | | |
| PLT | Number of | | | |
| Platelet | platelets | Billions of | Thousands of | 10 ⁹ /L= |
| (Thrombocyte) | (thrombocytes) in | thrombocytes per | thrombocytes per | $10^{3}/\mu$ L = |
| Count | the specified | litre of whole blood: | microlitre of | 10 /μ L = K/μ L |
| | volume of whole | 10 ⁹ /L | whole blood: | 17 m = |
| | blood. | | Κ/μ L | |
| | Directly measured. | | | |

| PCT Plateletcrit | Relative volume of platelets (thrombocytes). Computed from PLT and MPV: (PLT x MPV) ÷ 10 | Percent % | Percent % | L/L = <u>%</u> 100 |
|----------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|----------------|-----------------------|
| MPV Mean Platelet (Thrombocyte) Volume | Average volume of individual platelets (thrombocytes) in whole blood. Directly measured. | Femtolitre: fL | Femtolitre: fL | $fL = \mu^3$ |
| PDW Platelet (Thrombocyte Volume) Distribution Width | The size distribution spread of the platelet (thrombocyte) population expressed as the coefficient of variation of the platelet distribution. | Percent % | Percent % | None |

Band # and %: The NE # and % will exclude the Band Population when Band is reporting. The NE plus the Band equals the Total Neutrophil Population.

NRBC # and %: The NRBC # and % will be excluded from the Total WBC (White Blood Count) and WBC differentials. The Total WBC is corrected for the presence of NRBC to report the corrected WBC. NRBC # and % are "stand alone".

Quality Control Solution is available from Woodley Equipment Company.

- 1. The InSight 5 Diff Retic is run through a Quality Series and Calibrated at the factory.
- 2. Quality Control Solution is processed at installation to verify calibration and it is recommended that after 2 weeks of use Quality Control Standards are reprocessed to verity calibration stability.
- 3. Woodley Equipment recommend that Quality Control Solution is tested at least with each lot change of reagents.
- 4. Several Quality Comparisons are performed on each test to ensure accurate results. The electro-optical focus flow cytometer performs 5 sequential counts for the white blood count, the red blood count and platelets on every sample. If the count segments are not consistent, the total count is rejected and dashes (---) will appear in place of the numeric result. If the Hb and MCHC do not match internal standards, a "RERUN SAMPLE" will appear. If the Hb LED is out of internal standards, Hb will be blank, ---, or HIGH will appear, see Troubleshooting section. The QC process for each

sample consistently searches for morphological and distributional abnormalities and will flag when detected.

Leucocyte Differential: The InSight 5 Diff Retic generates a WBC differential by constructing a distribution cytogram based on the relative size (impedance) and complexity (light scatter) of cells in a blood sample. Each cell passing through the analyser's sensing zone is analysed, compared to known criteria and placed in a corresponding area in the cytogram, based on these criteria. For example, a cell with the size and internal complexity of neutrophils is placed in the neutrophil "area" in the cytogram. Percentages and absolute cell numbers are then calculated.

Thrombocyte/Erythrocyte Analysis: Platelet and erythrocyte enumeration is accomplished in much the same way as the WBC count and differential. Cells passing through the analyser are analysed, placed in a corresponding area in the cytogram and compared to known criteria for identification.

Flags: Certain conditions cell distributions trigger the following flags to alert the operator that abnormal conditions may exist.

Note: Message appears in the Diagnostic Considerations section of the report to clarify these conditions.

The following suspect message may appear adjacent to the leucocyte, erythrocyte or thrombocyte parameters.

L – Indicates that the number or percentage is below the preset normal range.

H – Indicates that the number or percentage is above the preset normal range.

If a particular leucocyte, erythrocyte or thrombocyte parameter is above the analyser's linearity limit, the word "HIGH" will appear in place of a numeric result. See diluted sample below.

If an error occurs in the calculation of a particular leucocyte, erythrocyte or thrombocyte parameter, dashes (----) will appear in place of the numeric result.

Diluted Samples: When the WBC, RBC, Hb or PLT parameters are above the analyser's linearity limit, meaningful results may still be obtained by rerunning a diluted sample and multiplying the results by an appropriate factor. For example, equal parts of specimen and dilution can be mixed for a 1:2 dilution and the printed results multiplied by 2 to obtain the actual values. This technique applies only to WBC, RBC, Hb and PLT parameters. The remaining parameters must be verified by other methods (e.g. Reference Methods).

Raw Input Data and Calculation Errors: The InSight 5 Diff Retic alerts errors in raw input data or calculation errors. A blank on the printed report for any parameter indicates that

the InSight 5 Diff Retic detected an error in raw input data with respect to that parameter. A series of dashes (----) on the printed report for any parameter indicates that a calculation error occurred with respect to that parameter.

Data Checks: As the Key Operator, you should review the patient sample analysis results. The following are suggested guidelines you may want to include in your review.

Before reporting any patient sample analysis results, check the printout using the checklist below.

- 1. Is the ID number on the printout the same as the patient ID number?
- 2. Is the printout normal? Normal includes:
- Within normal ranges or within your laboratory's normal range.
- No Message. If suspect messages are present, it is recommended that the operator review the blood film.
- 3. Is the relationship between associated parameters possible? (RBC, Hb, Hct). For example: a Hb of 12.0 g/dL with a Hct of 50% is not "believable". Normally, there is approximately a 1:3 ratio for Hb to Hct.
- 4. Are the results physiologically possible? For example, a MCHC of 50.2 g/dL is highly improbable. For most mammalians, the MCHC ranges from 31.0 to 37.0.
- 5. Are results consistent with the previous reports available on the patient? If not, check the consistency of the results with the patient's condition.

Patient: Zackary Client ID: 2240

Species: Dog Test No: 198

Date: 01/13/20 Time: 11:45:32

HEMATOLOGY

| N B L' M E B N B L' M E B | VBC land Y IO O A IRBC IRBC IRBC I I I O A | CELL S: (K/µl) (K/µl) (K/µl) (K/µl) (K/µl) (K/µl) (K/µl) (K/µl) (%) (%) (%) (%) (%) | 9.15 H | 6.0 - 17.0 3.0 - 11.8 0.0 - 0.3 1.0 - 4.8 0.2 - 2.0 0.1 - 1.3 0.0 - 0.5 60.0 - 80.0 0.0 - 5.0 12.0 - 30.0 3.0 - 14.0 0.0 - 2.5 | | Mild Severe Mild | HIGH HIGH HIGH HIGH HIGH NORMAL NORMAL NORMAL NORMAL HIGH |
|---------------------------------------------------------------------|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|----------------------------------------|--------------------------------------------------------------------------------------|
| RED BLC H R H M M R R R R R R M | ICT IBC ICV ICH ICHC ICHC ICHC ICHC ICHC ICHC | ELL S: (%) (g/dL) (fL) (pg) (g/dL) (%) (fL) (%) (fL) (%) | 18.7 L 2.67 L 5.8 L 69.9 21.7 31.0 16.5 11.5 28.8 1.08 102.8 H 10.1 | 37.0 - 55.0 5.50 - 8.50 12.0 - 18.0 60.0 - 77.0 19.5 - 24.5 31.0 - 36.0 10.5 - 18.0 0.0 - 60.0 0.00 - 1.20 85.5 - 95.5 12.0 - 16.5 | | Mod. Severe Mod. Mild Mod. | LOW |
| P | ILT CT IPV | (K/µl) (%) (fL) (%) Va on ria oc nt =yt Ly es m ph | 191. L 0.262 13.7 26.5 Ba Segm ad ented Neutr ophi as | 200 500. 5.0 - 15.0 Eo sin op hil | Ba i so (ph ils | Mild Very Large Cells | PI R M DEMAI |

Section 6 Troubleshooting

The purpose of the Troubleshooting Guide is to provide corrective actions for operating problems that may occur so that normal operation can be resumed as quickly as possible. In order to properly detect abnormal operation, it is important that the operator be thoroughly familiar with normal operation as detailed in the Special Procedures section.

6.1 Fault Isolation Table

The Troubleshooting Guide (Table 6-1) consists of fault isolation tables containing a listing of the most commonly encountered problems, their probable causes and corrective actions. Record corrective actions performed in the Corrective Action Log, located in the appendix, by entering the date, condition noted, action taken and your initials.

| Problem | Probable Cause | Corrective Action |
|---------------------------|-------------------------------|--------------------------------|
| | ON/OFF button is in the OFF | Press ON/OFF button to |
| | position. | the ON position. |
| | The power cord is unplugged | Plug power cord firmly into |
| | or loose from the wall outlet | the wall outlet or rear of |
| No power to analyser | or rear of analyser. | the analyser. |
| | Power to the wall outlet is | Check circuit breaker or |
| | off. | fuses in the laboratory. |
| | | Remove fuse holder and |
| | Analyser fuse is blown. | visually inspect fuse. |
| | | Replace if blown. |
| | | Inspect all visible tubing for |
| | | bubbles. To remove |
| | | bubbles, run a Clean Cycle |
| | Bubbles in system. | from the Menu by pressing |
| | | "MENU", then "CLEAN". To |
| | | remove bubbles in the Lyse |
| | | Line, you must reload Kit. |
| | | Replace reagents with a |
| | | new InSight 5 Diff Retic |
| Background check values | | Reagent Kit. CAUTION: |
| are not within acceptable | Insufficient or contaminated | When replacing reagents, |
| limits. | reagents. | discard remaining portion |
| | | of reagents from the old |
| | | kit. Do not mix with the |
| | | new kit. |
| | | InSight 5 Diff Retic must be |
| | | powered from an |
| | Electrical Interference. | independent, protected |
| | | circuit or directly onto a |

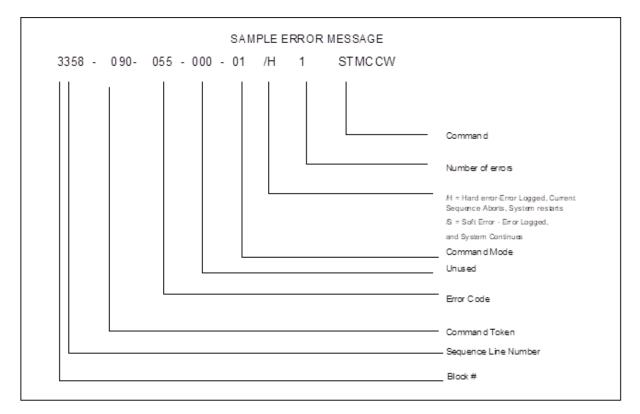
Table 6-1 Troubleshooting Guide

| | | wall outlet. |
|-----------------------------------|-------------------------------|-------------------------------------------------------|
| | | Present Probe Clean to the |
| | Residual blood components | Sample Probe and perform |
| Quality Control check values | causing excessive particulate | Sample Analysis cycle by |
| do not match Control. | count or blood clot in Sample | choosing "Run". Then, run |
| | Cup causing fluidic | a Clean Cycle from Menu |
| | restriction. | by pressing "MENU", then |
| | | "CLEAN". |
| | | Follow procedures for |
| | Improper mixing of Control. | mixing Controls described |
| | | under Special Procedures. |
| | | Use new Control to |
| | | perform quality control |
| | Improper storage or handling | check. Be sure that controls |
| | of Control. | are stored and handled in |
| | | accordance with the |
| | | instructions printed on the QC Assay Sheet. |
| | | Check for disconnected |
| | Disconnected tubing or | tubing. Check that all |
| | leaks. | valves are working properly |
| | | by performing a valve test |
| | | in the settings. |
| | Analyser out of calibration. | Re-calibrate in accordance |
| | | with Special Procedures. |
| | | Check that there is |
| | | sufficient Lyse in the bottle |
| | | and that Lyse tubing is |
| | | connected as indicated on |
| | | the analyser template. |
| Sample Analysis WBC and | Lysing agents not being | Also, check that the tube is |
| Hb parameters abnormally | dispensed properly. | inserted properly in the |
| high or printout reads "HIGH". | | bottle and that there is no |
| пібп . | | air in the Lyse line. If Lyse checks OK, then perform |
| | | Corrective Actions listed |
| | | below for "Sample Analysis |
| | | parameters abnormally |
| | | high or low". |
| Hb only parameter being | | Call Woodley Equipment |
| reported. | Clogged Transducer. | Company Technical |
| | | Support. |
| Hb only parameter dashed, | Hb electronics needs to be | From the Menu Screen, |
| blank or showing HIGH. | reset. | choose "START". |
| | | Perform the following |
| | | procedures in sequence as |
| | | follows: |

| Sample Analysis parameters abnormally high or low. | Protein build-up within the system. | Present Probe Clean to the Sample Probe and perform Sample Analysis cycle by choosing "Run Single Test". |
|-------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | Run a Clean cycle from the Menu by pressing "MENU", then "Clean" button. |
| | | 3. Run the Start-Up cycle from the "Menu Screen" by pressing the START button. |
| | | Run Quality Control check. |
| | Syringes leaking. | Contact Woodley Equipment Company Technical Support. |
| | Disconnected tubing or leaks. | Check for disconnected tubing or leaks. Contact Woodley Equipment Company Technical Support. |
| Analyser locked up and display doesn't work. | Power surge. | Turn the analyser off and on, then press "RUN" key. |
| Error message is displayed during normal operation. | Error message can occur when event sequencing is inconsistent with the analyser software program. Normal operation can usually be resumed once the message is cleared and logged. | Press "ENTER" to clear the error message. The message is automatically logged for later reference. Press "RUN" to resume normal operation. |
| Sample not aspirating and blood not dispensing in mixing cuvette. | Clogged Sample Probe. | Use a small needle to attempt to clear probe from bottom. Present Probe Clean to the |
| | | Sample Probe and perform Sample Analysis by choosing "Run Single Test". Then run a Clean Cycle |

| | | from Menu by pressing "MENU", then "CLEAN". |
|-------------------------------------------------------------------|------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|
| | | Straighten tubing to remove any kinks. Reconnect tubing and/or fittings as required. |
| Mixing cuvette overflowing or does not empty after cycling. | Kink in tubing to waste container or blood clot in mixing cuvette, tubing or | Present Probe Clean to the Sample Probe and perform Sample Analysis by choosing "Run Single Test". Then run a Clean Cycle |
| | tube disconnected internally. | from the Menu by pressing "MENU" then "CLEAN". |
| Printer not printing. Power light not lit. | Printer not getting power. | Make sure the printer is turned on and AC adapter is plugged into wall outlet and into power receptacle at rear of printer. |
| Printer not printing. Power light lit. | Interface cable not connected properly at printer or analyser. | Make sure interface cable connections are secure at rear of printer and analyser. |

6.2 Error Messages



| Error Code | Description | |
|------------|-----------------------------------------|--|
| A – F | Block 10 – 15 | |
| 1-9 | Block # | |
| 10 - 17 | Parameter Error | |
| 20 – 27 | Internal Error | |
| 30 – 37 | Range Error | |
| 40 – 47 | Background Error | |
| 50 – 57 | Hardware Status Error | |
| 60 – 67 | Value Error | |
| 70 – 77 | Hardware Time Out Error | |
| 100 – 107 | Overflow Error | |
| 110 – 117 | User Definition Error | |
| 120 – 127 | Password Error | |
| 130 – 137 | Definition Error | |
| 140 - 147 | Application Condition Error | |
| 200 – 207 | Disk – Open/Close Error | |
| 210 - 217 | Disk – Read Error | |
| 220 – 227 | Disk – Write Error | |
| 230 – 237 | Disk Seek/Get File Size Error | |
| 300 – 307 | Application Created Error | |
| 350 – 357 | Used for Debugging Purposes Only | |
| 360 – 367 | Command Token Not Defined | |
| 370 – 377 | Page Stack Overflow | |
| /S | Soft Error – Error is logged and system | |
| | continues | |
| /Н | Hard Error – Error is logged, current | |
| | process is halted and system restarts | |

Explanation

In the sample above, a HARD error has occurred on a syringe stepper motor command in the system. The "055" is the portion of the error code in which we are interested. The explanation given is a Hardware Status Error, meaning the syringe pump was out of position.

Action

The Error is written to the analyser Status Log, as well as the analyser display screen. The Current Cycle Process is terminated and the system restarts.

Section 7 Safety Precautions and Warnings

7.1 Precautions, Limitations and Hazards

Precautions are inserted in the text of this manual where they are applicable. Precautions are as follows:

WARNING: May cause injury. CAUTION: May cause damage to the analyser. IMPORTANT: May cause misleading results.



LASER

Laser emits at an optical wavelength of 635nm. The system is classified to IEC 60825-1 and meets the classification of Class 1.

CAUTION: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous laser radiation exposure.



WEEE

Disposal must be carried out according to national legislation and municipal authorities' regulations.

As the product includes electrical components, it is marked with the label shown on the left. This means that in EU countries, the regulations regarding disposal of electrical and electronic products (WEEE) must be followed, i.e. the product must be handed over to an approved disposal handler for correct disposal.

7.2 Certification Statements



This unit complies with all applicable essential requirements of the following Directives:

EMC Directive: 2004/108/EC Low Voltage Directive: 2006/95/EC

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at their own expense.

Modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment under FCC rules.



This Class A digital apparatus complies with Canadian ICES-003.



This product complies with the conditions of authorisation to carry the C-Tick mark with the supplier number N136.

7.3 Operator's Responsibilities

CAUTION: Prior to operating, perform a visual inspection to ensure sufficient level of reagents and verify there are no kinks in the reagent tubes.

It is the operator's responsibility to:

- Become thoroughly familiar with the information in this section before operating the InSight 5 Diff Retic.
- Clean external surfaces of the analyser with a damp clean cloth. Do not spray liquids or cleaners directly onto the analyser.
- Perform the recommended procedures as described in the Special Procedures, presented later in this section, as required.
- Refer to Section 6, Troubleshooting Guide when:
 - The analyser does not perform as described in this section.

- The variation from the performance characteristics and specifications exceeds the tolerance established by your laboratory.
- The analyser produces unacceptable data.

CAUTION: Do not look directly into the laser light.

7.4 Specimen Collection and Handling

Approximately 20 microlitres of whole blood is introduced undiluted into the analyser. Collect and prepare the specimen as follows:

 Collect the specimen by venipuncture and use tripotassium ethylenediaminetetraacetic acid (K3 EDTA) as the anticoagulant. For detailed information on the collection of the whole blood by venipuncture, refer to "Standard Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture" (ASH-3), published by the National Committee for Clinical Chemistry Laboratory Standards (NCCCLS).

IMPORTANT: The use of heparin may cause a bias in WBC, Hb and Differential readings.

- 2. Mix the blood specimen and the K3 EDTA carefully and thoroughly as follows:
 - Place the specimen on a roller mixer for a minimum of five minutes.
 - Remove the specimen from mixer and gently invert the tube three (3) times.
 - Observation of the specimen before and during mixing can lead to detection of problems such as gross haemolysis, lipaemic plasma or blood clots.

WARNING: Disposal of any chemical or biohazardous waste must be in accordance with all applicable environmental laws.

7.5 Specimen Storage

Since blood platelets disintegrate rapidly, whole blood cell counts that include PLT should be performed within 4 hours after drawing (CAT specimen within 20 minutes) for optimum results. Whole-blood specimens for PLT and differential counts must be run at room temperature.

7.6 Limitations

The InSight 5 Diff Retic is designed for veterinary use only.

Substitution of reagents, calibrators, controls and components manufactured by other companies may adversely affect the performance of the analyser.

All servicing and repairs should be performed by Woodley Equipment Company authorised personnel or representatives.

7.7 Electrical Safety Precautions

Do not disconnect any electrical connection while the power is ON.

For continued protection from electric shock, use only the power cord as supplied and connect the power cord to a properly grounded outlet. Do not use an extension cord.

WARNING: Electrical Shock Hazard. Do not remove any analyser panel cover that is fastened in place by screws. The potential for electrical shock increases whenever these panels are removed.

7.8 Chemical Safety Precautions

Exposure to potential hazards of chemicals used in the operation and maintenance of the InSight 5 Diff Retic should be prevented by the use of information on Material Safety Data Sheets (MSDS), proper personal protective equipment, work procedures and equipment specified on the OSHA Hazard Communication Standards (29 CFR Part 1910.1200).

7.9 Infection Control

All clinical specimens and controls, calibrators, etc. that contain blood or serum are potentially infectious. Use established, good laboratory working practices when handling these samples. Wear gloves, lab coats, suitable eye protection and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule or the equivalent biosafety procedures.

WARNING: Potential Biohazard. Follow established biosafety practices when performing maintenance, service or troubleshooting procedures. Wear gloves, lab coats and suitable eye protection.

7.10 Blood Samples

Decontaminate and dispose of all specimens and potentially contaminated materials in accordance with local, state and federal regulations.

Waste liquid is a possible source of biological and chemical hazard. Handle with extreme care during the disposal process.



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