



# Instruction Manual





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# **Chapter One: Introduction**

InSight HCT Meter is designed for use only with InSight HCT Test Strips from Woodley Equipment Co Ltd, for the measurement of haematocrit and total haemoglobin in capillary and venous whole blood.

### **Kit Contents**

- InSight HCT Meter
- InSight HCT Test Strips (10)
- InSight HCT Code Cards Cat , Dog and Horse
- Lancets (10)
- Lancing Device
- Instruction Manual
- CR2032 Batteries (2)
- Carry Case

### **Chapter Two: Technical Specifications**

| Parameter:           | Haematocrit and Haemoglobin in fresh whole blood                 |  |
|----------------------|--|--|
| Measuring Principle: | Optical reflectance  |  |
| Strip:               | InSight HCT Test Strips  |  |
| Display:             | LCD  |  |
| Weight:              | < 58g (Battery included)   |  |
| Outer dimension:     | 102mm×50mm×19mm  |  |
| Power:               | DC 6V (Two CR2032 Battery)                                       |  |
| Operating Temp:      | <b>15∼30°</b> C;   |  |
| Ultimate Temp:       | RH ≤80% non-condensing<br>-20 ~55 °C;<br>RH < 90% non-condensing |  |
| Others:              | Internal trouble check and display                               |  |

## **Chapter Three: Principal of Operation**

The InSight HCT meter utilises optical reflectance for determination of the total haemoglobin and calculated haematocrit (HCT). The test strip is inserted into the meter and a background blank reading is automatically determined. A drop of whole blood is applied to the test spot on the strip. Blood immediately disperses within the membrane. contacts the reagent, then reacts. The meter's optical detector automatically measures the change in membrane reflectance. The intensity of reflectance is inversely proportional to the haemoglobin concentration. The meter calculates and displays the total haemoglobin concentration in gram/deciliter (g/dL) in 30 seconds based on a mathematical conversion and calculates the haematocrit result reporting HCT as a percentage (%).

### **Chapter Four: Blood Sample Collection**

- 1. Fresh capillary or EDTA anticoagulated venous whole blood may be used.
- 2. If an EDTA-treated sample is refrigerated, allow it to be at room temperature prior to use. EDTA-treated blood samples should be mixed using end to end inversions at least 8 times prior to use, and should be tested within 24 hours.
- 3. For fresh venous whole blood samples, collect approximately 0.1mL into an anticoagulant free plastic syringe.

# **Chapter Five: Note**

- 1. InSight HCT Meter is designed for use only with InSight HCT Test Strips from Woodley Equipment Co Ltd. Prior to inserting test strips, read the Manual carefully and input the Code Card in to the meter.
- 2. Insufficient blood sample volume and inadequate mixing of EDTA-treated samples will affect results.
- As all diagnostic tests, test results should be evaluated according to the specific patient's condition. Any results demonstrating the inconsistency with the patient's clinical status should be repeated or supplemented with additional test data.
- 4. In order to test the heamatocrit accurately, please use and maintain the meter correctly. Review this manual prior to the first use of the meter.
- 5. While the test is in progress, do not disturb or move the meter or strip or press any keys.

- 6. Strong electromagnetic waves will interfere with the meter. Keep a distance of 2 meters between the meter and a microwave oven.
- 7. High temperatures and humidity will affect the meter.
- 8. Operating Temperature 15 °C-30 °C.
- 9. Avoid any liquid from permeating the meter.

### A Warning:

1. Blood plasma and serum should not be used as samples. Inaccurate results will report if using arterial blood.

2. Anticoagulants other than EDTA are **NOT** recommended for use, such as sodium citrate and heparin.

# Chapter Six: Appearance and function

### 1. Appearance:

The meter is composed of keys, LCD, circuit board, optical system, strip holder, cover and battery



## 2. Function:

Power switch: Meter on and confirm key (turning meter off is confirmation)

▲ key: up

# ▼key: down

Strip holder: hold strips

SET key: set function (under the strip holder, refer to Chapter Seven)

# **Chapter Seven: Settings**

### 1. Setting Meter Options

Prior to the first use of the InSight HCT Meter, the user must enter the following settings:

- Time and date format.
- Current time and date.

## 2. Enter Settings

Step 1: Lift the test strip holder off the meter.

Step 2: Turn the meter on by pressing the Power switch key. Wait until the meter displays the Lot Code, time and date.

The meter can now be customised for time and date format, current time and date.

## 3. Selecting Time and Date Format:

The user can select to display the time and date in 12-hour AM/PM time clock with mm/dd date format or in a 24-hour time clock with dd/mm date format.

Note: The date format only contains day and month, not year.

Step 1: Press the SET key once the date and time will display. Press and hold the SET key again until the time and date flash.

Step 2: Press the  $\blacktriangle$  or  $\blacktriangledown$  key to select date format.

- Step 3: Pressing the SET key to enter the current time and date. If entering current time and date is not required, and then turn the meter off to accept the selected time and date format.
- ▲ **Note:** Once accepted, the time and date format will be changed for all stored test results.



### 4. Entering Current Time and Date

The user must enter the current time and date for correct stamping of test results. If proceeding from Select Time and Date Format instructions above, go directly to Step 2. Otherwise, start from Step 1.

Step 1: Press and hold the SET key until the time and date flash. Press the SET key again.

Step 2: The hour (with AM/PM if 12 hr format

selected) will flash. Press the  $\blacktriangle$  Or  $\blacktriangledown$  key to enter the hour. Press the SET key to accept.

Step 3: The minute will now flash. Press the 🔺 or

▼ key to enter the minute. Press the SET key to accept.

Step 4: The first date selection will flash (mm or dd). Press the  $\blacktriangle$  or  $\blacktriangledown$  key to enter the first date selection. Press the SET key to accept. Step 5: The second date selection will flash (dd or mm). Press the  $\blacktriangle$  or  $\blacktriangledown$  key to enter the second date selection. Press the SET key to accept. Step 6: Turn the meter off to accept the entering time and date.

▲ Note: Once accepted, the reporting units will be changed for all stored test results.Once the selection of meter settings has been completed, replace the strip holder onto meter.

### 5. Saving Test Results

InSight HCT Meter automatically stores 250 test results with a date and time stamp. Upon storage of more than 250 test results, the oldest test result is automatically erased. Test results are stored in ascending chronological order: The first test result displaying (sequence 001) is the newest test result, and the last test result displaying (up to sequence 250) is the oldest test result. A test result is stored automatically when the meter shuts off (either by pressing the key or automatic shut off after two minutes of inactivity).

### 6. Viewing Saved Test Results

Step 1: Turn the meter on by pressing the Power switch key. Wait until the meter displays the Lot Code, time and date. Press the ▲ key to display the test result and its sequence number (a flashing MEM will display to the lower left of the test result). After releasing the key, the test result with its time and date and a flashing MEM will display.

Step 2: Continue pressing the  $\blacktriangle$  or  $\blacktriangledown$  key to scroll through test results.

Step 3: Turn meter off to exit the memory.

### 7. Deleting Test Results

Test results can be deleted using two methods: deleting the recent results by CLE or deleting all result by CLA.

User could turn the meter off to stop deleting test results before MEM displays. Step 1: Lift the strip holder, turn the meter on. Wait until the meter displays the Lot Code, time and date.

Step 2: Press SET key twice, CLE displays.

#### Delete the recent results:

Step 3: Continue pressing **SET** key till CLE flashes. Release **SET** key, the last result will display. To delete this result, keep holding **SET** key and the result will flash and then be deleted.

### Delete all results:

Step 4: Press **SET** key one more time, CLA will display. Hold pressing **SET** key, CLA flashes, Release **SET** key, ALL will display. Continue pressing **SET** key, all the results will be changed into MEM.

After completing all steps, turn off the meter and cover the strip holder.

▲ Note: If you want to exit CLE without deleting test results, you can shut off the meter directly.

# **Chapter Eight: Operation**

### 1. Turn the meter on

Press the **Power switch** key to turn the meter on. The meter automatically monitors its internal circuitry and components during a brief self-check. The meter is ready when the test strip prompt, Lot Code and time/date are displayed.

△ Note: To conserve the battery power, the meter will automatically shut off after 2 minutes of inactivity. If this happens, turn the meter on again.

## 2. Input Lot Code Strip

Change the numbers as follows:

1) Press the Power switch to turn the meter off

2) Insert code card provided with the strips correctly into the **Code slot**. Press the **Power switch** to turn the meter on, the meter will read the code automatically and display the code on the screen. After reading the code, the meter will automatically turn off.

3) Remove the code card. Turn the meter on again, check the code matches then accept a test.

## 3. Prepare Sample

Clean the sample area with alcohol and wipe dry with a sterile gauze pad. Obtain fresh capillary or EDTA anticoagulated whole blood sample.

## 4. Prepare the Test Strip

Take a test strip from its container. Examine the test strip. Do not use if there are tears, wrinkles or debris. Do not touch the test spot membrane. Reseal remaining test strips in the original container.

# 5. Insert the Test Strip

Insert the test strip into the strip holder with the notched end in first and the hole facing up. The notched end on the top of the strip should no longer be visible when the test strip is inserted correctly.

## 6. Prepare the Meter for Sample Application

The meter will automatically perform a

background blank reading. It will display a flashing prompt to indicate that it is ready to test a sample. The meter will allow 2 minutes for application of the blood sample

## 7. Apply Blood Sample to the Test Strip

Immediately apply a drop of blood to the test strip by touching the hanging blood drop to the test spot, ensure the blood drop is large enough to completely cover the test spot. A capillary transfer tube may also be used to transfer the blood sample to the test strip.

## NOTE:

- Use a drop of whole blood (refer to the instruction of Strips for detail)
- Do not use a strip to touch blood, prior to being inserted in the meter. Apply only a hanging blood to the test spot.
- Do not touch the test spot membrane.
- Do not apply a superfluous amount of blood.
- Each test strip is for single use only.

### 8. Read Result

The blood sample will migrate and the meter will automatically begin the test. During the test, do not disturb or move the meter or strip, or press any meter keys.

The test result will be displayed in less than 30 seconds.

Once the test is completed, remove the test strip and check if the test strip spot is completely covered by the blood. If not completely covered then an inaccurate result may report.

After the test is finished, the meter will automatically shut off after 2 minutes of inactivity, or can be turned off manually by pressing the Power switch key. The test result will be stored automatically with date and time.

# 9. Disposal

Discard the used test strip into clinic waste

# Chapter Nine: Trouble-shooting

| Error Code | Possible Cause                    | Correction  |
|------------|-----------------------------------|---|
| E0, E1     | Hardware or software<br>error     | Turn off and on. If the<br>error still exists, please<br>contact your local<br>distributor.   |
|            | Meter used in bright<br>sunlight  | Bright sunlight disturbs<br>meters optical system.<br>Turn off and on. Repeat<br>test with new test strip.  |
| E2         | Temperature out of range          | Allow meter to adjust to<br>15 to 30°C. Turn off and<br>on. Repeat test with new<br>test strip.   |
|            | Removing the strip before testing | Do not remove test strip<br>until the test is complete.<br>Turn off and on. Repeat<br>test with new test strip.   |
|            | Insufficient sample<br>volume     | Remove the test strip and<br>turn meter off. Turn on<br>and repeat test with new<br>strip. Confirm the blood<br>sample size is sufficient.                            |
|            | Strip is damaged                  | Remove the test strip and<br>turn meter off. Turn on<br>and repeat test with new<br>strip. Confirm there are<br>not tears, wrinkles or<br>debris.                     |
|            | Incorrect blood sample            | Do not use incorrect blood<br>samples, such as plasma.<br>Repeat test with the<br>correct blood sample: fresh<br>capillary or EDTA-<br>anticoagulated whole<br>blood. |

| E4  | Damaged strip<br>inserted                                    | Remove the test strip and<br>turn meter off. Turn on<br>and repeat test with new<br>strip. Confirm there are<br>no tears, wrinkles or<br>debris. |
|---|--|--|
|   | Optical detector<br>needs cleaning                           | Remove strip holder<br>and clean lenses.   |
|   | Optical detector<br>does not read the<br>background<br>blank | Do not apply blood sample until the t<br>background blank reading is complet   |
|   | Optical detector is<br>clogged                               | Check the Optical detector,<br>ensure it isn't covered by blood.<br>If blocked, remove the<br>strip holder and clean it.<br>Refer to the Manual. |
|   | Used Strip<br>Inserted                                       | Remove the test<br>strip and turn meter off. Turn on<br>and repeat test with a new test<br>strip.  |
|   | Inserted strip<br>error                                      | Review Insert Strip instructions.  |
|   |  | Remove the test<br>strip and turn meter off. Turn on<br>and repeat test with a new test<br>strip.  |
| Meter<br>immediately<br>shuts off once<br>turned on or<br>during the<br>testing process | Replace battery  | Replace battery referring to the Manual.   |
|   | Strip moved<br>during the test                               | The meter will turn off<br>automatically in 4 seconds if<br>the test strip is moved. Repeat<br>test with new a test strip.                       |

# **Chapter Ten: Maintenance**

# 1. Routine maintenance and cleaning

Cleaning must be completed if excess blood is applied. Lift up the strip holder, so that it can be removed and cleaned. Wipe away blood or hair left on the holder or meter using gauze with disinfectant (10% bleach dilution or, 0.6% hypochlorite solution).

If there is superfluous blood on the optical detector, clean it using a cotton bud with detergent. Wipe the strip holder and optical detector completely using a lint free tissue or lens cloth. Avoid any liquid permeating the meter. Do not wipe the surface of optical detector with any polished or corrosive detergent to avoid the damage of meter and optical detector.

# 2. Battery replacement

Open the battery cover, take the battery out and replace with two new CR2032 batteries with cathodes facing down and close the cover.

# **Chapter Eleven: Symbols**



SN



- CR2032 Use CR2032 as power supply
  - Manufacturer
- Ø
- Recovery



Protect from heat and radioactive sources