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Chapter 1. About Your HemoSmart™ Hemoglobin Screening System

Thank you for choosing the HemoSmart™ Hemoglobin Screening System. All of the information that will be needed to use and maintain the HemoSmart™ System is included in this manual. Read it carefully before using the system.

Utilizing Biosensor Technology, the HemoSmart™ System provides an easy and precise way of measuring the level of total hemoglobin in whole blood. The results are referenced by CBC cell counter method, which means the data gathered from the HemoSmart™ Screening System is comparable to the results in a clinical laboratory.

The HemoSmart™ Hemoglobin Screening System is intended for use outside the body (in vitro diagnostic use) and is useful for quantitative screening of hemoglobin in the range of 4 g/dL to 20 g/dL. The HemoSmart Screening System is for a low or a high concentration of hemoglobin for the health of the patient (e.g. anemias (low Hb), erythrocytosis (high Hb), thalassemias (aberrant chain synthesis), and sickling disorders (abnormal complex shape)).

Contents of Kit

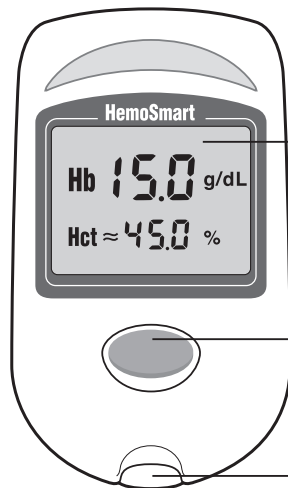
The HemoSmart™ kit package includes the following items.

- HemoSmart™ Meter (1)
- User's Manual (1)
- Monitor Checker (1)
- Carrying Case (1)
- Adjustable Lancing Device (1)

*The kit contents may vary in some certain areas.
Contact the dealer if you find difference from the above.

HemoSmart™ Meter

Front



Display Screen

Large, easy-to-read window guides you through testing, displaying results, and error messages using simple words or symbols.

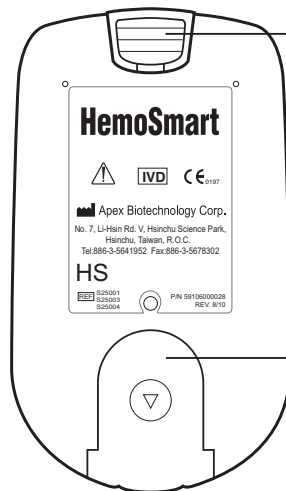
Push Button

- Recalls test results in the memory. Refer to chapter 4 p.20 "Using Meter Memory" for details .

Test Strip Holder

Insertion site for test strips and monitor checker.

Back



Code Card Port

Insertion site for the code card.

Battery Compartment

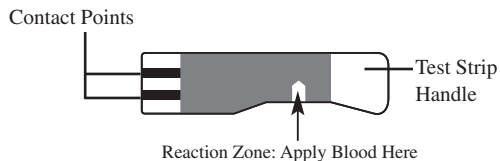
Holds one 3V Lithium coin cell battery (CR2032). Refer to Chapter 6, p.23 "Changing the Battery" .



Monitor Checker

Use to confirm the Meter is functioning properly. Refer to Chapter 2 p.9 "Monitor Checker Test" for details.

HemoSmart Hemoglobin Test Strip (Sold Separately)





- Contact PointsSense the position and orientation of the Test Strip.
- Test Strip Handle.....The only area to be touched when handling the Test Strip.
- Reaction ZoneThe area where the blood sample is applied.

The HemoSmart™ Hemoglobin Test Strip is a biosensor-based test strip uniquely designed to specifically detect total hemoglobin in whole blood using the HemoSmart™ Meter. The Test Strips come in a moisture-proof, light-protected bottle . It is important the bottle is kept well sealed at all times. Replace cap immediately after taking a strip out of the bottle.

HemoSmart™ Control Solution (optional)



Solution with standard concentration of reactive substance in hemoglobin. It is required to perform the "Quality Control Testing" in Chapter 2, p.10 . Use the solution to check for system accuracy, practice test procedure, and when using a new lot of HemoSmart™ Hemoglobin Test Strips.

Store the HemoSmart™ Control Solution at temperatures at 2°C to 8°C  (36°F to 46°F). See the HemoSmart™ Control Solution insert for more information.

Please contact your local supplier to order control solution.

Chapter 2. Before Testing


Monitor Checker Test

The Monitor Checker Test will help ensure that the electronics in your HemoSmart™ Meter is working properly. This test should be done on a brand new meter or when the performance of the meter needs to be confirmed.

Materials you will need:

- Monitor Checker (included in kit)
- Your HemoSmart™ Meter

Step 1: Insert the Monitor Checker (Arrow end) into the Test Strip Holder until you hear a “beep”.

Step 2: When the Meter Display Screen shows ☺ (happy face) means your Meter is functioning properly. If the display screen shows ☹ (sad face) then repeat the procedure once more. If ☹ continues to appear, refer to Chapter 7, p. 24  “Messages Interpretation & What to do.”

Quality Control Testing

Perform Quality Control Testing when:

- You first get your Meter, before performing a hemoglobin test.
- You first begin to use a new package of HemoSmart™ Hemoglobin Test Strips.
- You suspect your HemoSmart™ Meter and Test Strips are not working properly.
- When your Test Strips have been exposed to extreme temperatures (see HemoSmart™ Hemoglobin Test Strip insert for temperature ranges).
- Practice the test procedure.

⚠ IMPORTANT:

- The acceptable range for the control solution is listed on the package of test strips.
- Use only the HemoSmart™ Control Solution.
- Always check the expiration date ☞ . DO NOT use control solution if expired.
- Newly opened bottle of control solution must be marked with the date opened; discard any unused control solution 1 months after opening or expiration date.
- DO NOT freeze Control solutions should be stored at 2°C to 8°C $\pm 0.5^\circ\text{C}$ (36°F to 46°F).
- If a control solution test is not within the expected range that is printed on the test strip


package, DO NOT use the meter to test. Repeat the test until a control solution test performs within the expected range. If the results continue falling outside the expected range, call the authorized dealer for service.

- DO NOT touch the test area with the tip of the control solution bottle.
- DO NOT apply a second drop of control solution to the test strip.
- Replace the bottle cap on the control solution bottle immediately after use.

Materials you will need:

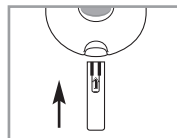
- HemoSmart™ Control Solutions (optional items, contact our authorized dealer for purchasing information).
- A fresh, new HemoSmart™ Hemoglobin Test Strip.
- Your HemoSmart™ Meter.

⚠ IMPORTANT:

- Please make sure the HemoSmart™ meter is properly coded. Refer to Chapter 3, p. 14 "Coding the Meter" .

Step 1: Insert the Monitor Checker (arrow end) into the Test Strip Holder until you hear a "beep".

Step 2: When the Meter Display Screen shows smiling face ☺, remove the Monitor Checker.

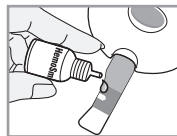


Step 3: The screen will then display the current code number being used. Verify that code number on screen is the same with the code number printed on the strip package.



Step 4: Remove a brand new HemoSmart™ Hemoglobin Test Strip from the strip bottle and insert it into the test strip holder of the meter. The screen will show "**ctr.**" This will ensure the control results will not be stored into memory.

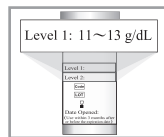
Step 5: When the screen show a symbol 💧, apply a drop of HemoSmart™ Control Solution at the reaction zone of the test strip as shown.



Step 6: The display screen will show timing bars"-----". The bars will flash and gradually diminish for countdown.

Step 7: After the timing bars disappear (approximately 10 seconds), the screen will show test result. Compare the reading on the screen to the control range indicated on the test strip bottle.

The test result falling within the range means the Meter and the Test Strip are working together properly.



Step 8: Remove the Test Strip. The meter will turn off automatically.

⚠ IMPORTANT:

1. Do not use test strip that has expired. Check the expiration date 📅 that is printed on the strip bottle.
2. Use each test strip immediately after removing it from the strip bottle
3. Do not use wet, bent, or scratched strips.
4. Do not reuse test strips and lancets. ⓧ
5. Keep away from direct sunlight and heat ☀. Store the strips in a dry, cool place.
6. If the test result is not within the expected range, repeat the control solution testing. If the results continue falling outside the expected range, call our authorized dealer.

Chapter 3. Hemoglobin Testing

Coding the Meter

Before you can begin testing on your HemoSmart™ Meter, you must code the meter. Coding the Meter ensures accurate test results when you perform a test. A new code card is packaged along with each box of HemoSmart™ Hemoglobin Test Strips.

Materials you will need:

- A code card for the HemoSmart™ Hemoglobin Test Strips
- A HemoSmart™ Hemoglobin Test Strip
- Your HemoSmart™ meter


⚠ NOTE:

Make sure the HemoSmart™ Hemoglobin Test Strips are not expired. Check the test strip expiration date on the box and the test strip bottle. The month printed refers to the end of the month.

Step 1: Locate the code card () in the package of Test Strip.

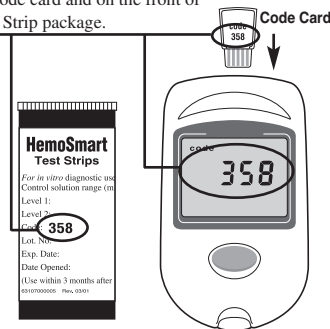
Step 2: Verify that the code number on the code card matches the code number on the Test Strip package.

Step 3: Insert the code card with the code number facing up firmly and completely into the code card port on the backside of the meter.

Step 4: Obtain a Test Strip () and insert the strip into the test strip holder located at front bottom of the meter. The meter will turn on with a beep sound. Close the Test Strip bottle immediately after you take out a strip.

Step 5: A 3-digit code number will display on the meter screen. Verify the code number on the screen with that on the code card and that on the test strip package. All three sets of numbers should be the same.

The code number displayed on the Meter should match the code number on the code card and on the front of the Test Strip package.



⚠ NOTE:

1. The code card found in the HemoSmart™ Hemoglobin Test Strip package is for use with that particular package only. Different packages of HemoSmart™ Hemoglobin Test Strips

and other brands of test strips will produce inaccurate results.



2. Re-coding needs to be done when a new package of test strip is opened for use.
3. Code number displayed on screen not matching the code number printed on the test strip bottle or package will create an inaccurate test result.

Performing a Hemoglobin Test




Materials you will need:

- A brand new HemoSmart™ Hemoglobin Test Strip
- Your HemoSmart™ Meter


⚠ IMPORTANT:

1. Do not use test strip that has expired. Check the expiration date  that is printed on the Test Strip Bottle and Box.
2. Use each Test Strip immediately after removing it from the bottle.
3. Close the bottle cap immediately after removing a Test strip.
4. Do not use wet, bent, or scratched Test Strip.
5. Keep away from direct sunlight and heat. Store the Test Strip bottle in a dry, cool place .
6. Record the "date opened" on the Test Strip bottle label when you first open it. After 1

months since first opened date, discard the bottle and any remaining test strips.
7. Do not reuse test strip and lancets.

Step 1: After you have performed the previous section, "**Coding the Meter**," the meter will now self-test the environment temperature. If the temperature is below or above operation range, the screen will display the flashing symbol of thermometer . When the temperature is within the testing range of 18°C to 38°C  (64°F to 100°F), the screen will show  and the Meter is ready to test.

△NOTE:

If the temperature is outside of the operating range, the Meter needs to be moved to an area that is within the Meter's operating range of 18°C to 38°C  (64°F to 100°F) and allow 10 to 15 minutes for it to reach the new temperature before use. Measurement outside the temperature range will affect accuracy of test result.

Step 2: Wash hands with soap and warm water and dry thoroughly.

Step 3: Hold the lancing device (puncture) or lancet against the side of the finger and lance the finger. Follow manufacturer's instruction for how the lancing device (puncture) or lancet should be used.

Step 4: Apply blood as shown. When the reaction zone has filled completely the Meter will beep, indicating that blood has been received by the test strip.

Gently massage your hand and finger toward the puncture site to form a drop of blood (approximately: ●). Do not "milk," or squeeze around the puncture site.



Step 5: The meter screen will display timing bars "-----" that will flash and gradually diminish for countdown.

Step 6: After the timing bars disappear (approximately 10 seconds), the screen will display test result along with a calculated Hematocrit (Hct.) value. Both the hemoglobin test result and the calculated haematocrit value are automatically stored into the Meter's memory, refer to Chapter 4, p.20" Using Meter Memory" . The meter will automatically turn off after the Test Strip is removed or after 3 minutes.

IMPORTANT:

- The HemoSmart™ Hemoglobin Screening System is primarily use for the assay of hemoglobin value in the indicated range of 4 g/dL to 20 g/dL only, and is not intended as a tool for the diagnosis of anemia or any other hemoglobin related illnesses. If "LO" (under 4

g/dL) or "HI" (over 20 g/dL) readings appears, a more suitable method may be required to perform further testing.

- Discard used test strip and lancets according to your local disposal regulations where applicable.
- Carefully discard used test strip and lancets in proper waste containers.
- DO NOT touch the target area of the test strip.
- DO NOT smear the blood drop onto the target area.
- DO NOT add or apply a second drop of blood. This may cause false result.
- DO NOT proceed testing if the yellow window is not full of blood sample. Insufficient blood sample may cause inaccurate test result.



Understanding the test result

Ideal range for male is 13-18 g/dL, Ideal range for female is 11.5-16 g/dL

If the result is lower than 10 g/dL, it could be low hemoglobin or iron deficiency anemia.

If the result is higher than 19 g/dL, it could be erythrocytosis.

If the result is higher than 19 g/dL or lower than 10 g/dL, please contact your physician or healthcare professional immediately.

Chapter 4. Using Meter Memory

Your HemoSmart™ Meter can automatically store 10 test results. When more than 10 test results are stored, the oldest result will be dropped from memory each time a new result is added. When the test results are recalled from memory, the most recent result is always displayed first.

To recall results from memory:

- Step 1: Press the push button to turn on the Meter. The screen will display the latest test result stored in memory.
- Step 2: Repeat pressing the push button for reviewing further test results in memory.

Chapter 5. Caring for the Meter

Cleaning the Meter

Your HemoSmart™ Meter does not require special cleaning. If the Meter gets dirty, use a moist (NOT WET) lint-free cloth dampened with a mild detergent.

⚠ NOTE:

1. DO NOT get water inside the HemoSmart™ Meter. Never immerse the meter or hold it under running water.
2. DO NOT use glass cleaners or household cleaners on the Meter.
3. DO NOT try to clean the Test Strip Holder.
4. DO NOT contaminate the strip holder with blood or control solution.


⚠ Storage and Precautions:

- Handle the Meter with care: Severe shock, such as dropping the Meter, could damage the electronics.
- The Meter and the Test Strips are designed to be used within the temperature ranges be-

tween 18°C to 38°C (64°F to 100°F) .

- Avoid leaving the Meter in extremely hot or cold place, such as near a heat source or in an extremely hot or cold car.
- Do not store or use the Meter or Test Strips where they may be exposed to high humidity levels, such as in a bathroom or kitchen.
- Never immerse or hold the Meter under running water.
- Always replace the bottle cap immediately after removing a Test Strip and make sure the test strip bottle is closed tightly.
- **DO NOT** take the HemoSmart™ Meter apart. If there are technical problems or questions in use of the meter, call the authorized dealer.

Chapter 6. Changing the Battery

The HemoSmart™ Meter operates on one 3V Lithium coin cell battery. When the LCD screen displays , this indicates the battery is low and should be replaced as soon as possible.

NOTE:

- To save battery power, the HemoSmart™ Meter will turn itself off after 3 minutes of non-use. All results stored in memory will be saved even if the meter shuts off automatically.
- Discard used battery according to your local regulation.

To replace the battery:

Step 1: Open battery compartment cover on backside of the Meter.


Step 2: Remove the old battery and replace with one new 3V Lithium coin cell battery.




Step 3: Replace the battery compartment cover.


Chapter 7. Messages Interpretation & What to Do

If there is a problem with the way you are performing a test or if there is a problem with your HemoSmart™ Meter, any of the following messages may appear on the meter screen.

If you have further questions after reviewing these messages, call our authorized dealer.

Message	Meaning	What To Do
"code----", then the meter shuts off in 3 seconds.	The meter has not been coded with a code card.	Code your Meter with a HemoSmart™ Code Card, see Chapter 3, p.14 "Coding the Meter."
"  "	The meter has not been coded with a code card.	Code your Meter with a HemoSmart™ Code Card, see Chapter 3, p.14 "Coding the Meter."

Message	Meaning	What To Do
“  ”	The temperature of the surrounding air is outside of system operation range.	The meter needs to be moved to an area that is within 18°C to 38°C  (64°F to 100°F). Wait for 10~15 minutes to let the meter adjust to the new temperature.
Code number and flashing  display after blood is applied.	Not enough blood sample is applied to the test strip.	Discard the used test strip from the meter and retest with a new test strip.
LO	The hemoglobin result is lower than 4g/dL	Check if you are using the right code card. Repeat testing.


Message	Meaning	What To Do
HI	The hemoglobin result is higher than 20g/dL	Check if your are using the right code card. Repeat testing.
“☹”	<ol style="list-style-type: none">1.A used test strip is inserted.2.The meter does not function properly.	Remove and discard the used test strip ☹, then perform the "Monitor Checker Test" on p.9  . If the problem persists, contact our authorized dealer for service.

If you are unable to correct the problem after following the What To Do procedures, call our authorized dealer in your country and/or contact your healthcare professional with questions and concerns.

Chapter 8. Specifications

Test Strips:	HemoSmart™ Hemoglobin Test Strips
Test Range:	4 - 20 g/dL
Sample Volume	3µL
Reading Time	10 Seconds
Blood Source:	Capillary whole blood
Display Type:	Large LCD screen
Memory:	10 test result
Dimension:	100Lx58Wx21H (mm)
Weight:	64g
Power Supply:	1 x 3V Lithium coin cell battery (CR2032)
Operating Temperature:	18°C to 38°C (64°F to 100°F).
Relative Humidity:	Less than 85% (Storage, Operating and Transportation)
Storage / Transport Condition:	4°C to 55°C (39°F to 131°F) for meter 4°C to 30°C (39°F to 86°F) for test strip
Electromagnetic Compatibility:	This equipment is complying with EMC requirement of EN 60601-1-2

⚠ NOTE:

For more information regarding the test strips, see the test strip package insert found in each box of test strips .

Applied Product Standards:

IEC 61010-1 IEC 60601-1

EN 61010-1 EN 60601-1-2

EN 61326 EN 62366 EN 61010-2-101

EU directive/classification: 98/79/EC Other IVDs

Classification according to IEC/EN 60601-1:

IPXO, not evaluated as AP/APG equipment, continuous operation.












Electromagnetic Compatibility:

This equipment is complying with EMC requirement of EN 60601-1-2.

Chapter 9. Supplies

Part Number	Product Name
S25001	HemoSmart™ Total Hemoglobin Basic
S5636036	HemoSmart™ Total Hemoglobin Test Strips 25's
S5636074	HemoSmart™ Total Hemoglobin Test Strips 2x25's
65235010002	Lancing Device
80050000003	Lancets (28G) 50's
S5800038	HemoSmart™ Hemoglobin control solution

Chapter 10. Symbols Used in this Manual

-  (EXP) Expiration date (use by last day of month)
-  (LOT) Batch code
-  Temperature limitations
-  Consult instructions for use
-  In vitro diagnostic device
-  Caution / warning, consult accompanying documents
-  Product code number
-  Keep away from sunlight/direct light
-  Do not re-use
-  Manufactured by
-  Authorised Representative in the European Community

Chapter 11. Product Warranty

The HemoSmart™ Meter is guaranteed to be free of defects in workmanship and materials under normal use for a period of three (3) years from the date of purchase to the consumer.

The liability of Apex Biotechnology Corp is limited to repair or replacement and in no event shall Apex Biotechnology Corp be liable for any collateral or consequential damages or loss.

Instruments subjected to misuse, abuse, neglect, unauthorized repair or modification will be excluded from this warranty.

This guarantee specifically excludes expendables and consumables (such as test strips and lancets).

All warranty claims must be directed to the Apex Biotechnology Corp authorized dealer responsible for the sale of the system.

The warranty applies only to the original purchaser of the system.