1. Product Structure

STANDARD CodeFree Plus Blood Glucose Monitoring System

STANDARD Glucose Check Strip

STANDARD CodeFree Plus Blood Glucose Meter

3V battery type CR2032

STANDARD CodeFree Plus NFC Blood Glucose Monitoring System

STANDARD Glucose Check Strip

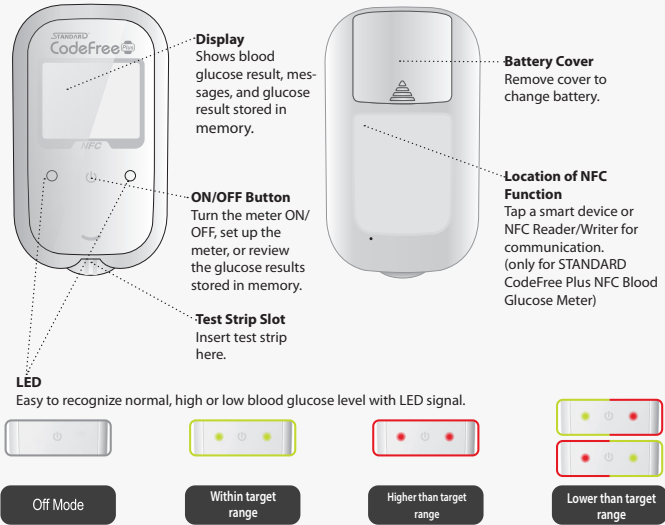STANDARD CodeFree Plus NFC Blood Glucose Meter

3V battery type CR2032

<Options>
- STANDARD CodeFree Plus Blood Glucose Test Strip
- Lancing Device (with a white cap for fingertip testing & a clear cap for Alternative Site Testing)
- Lancet
- STANDARD Glucose Control Solution
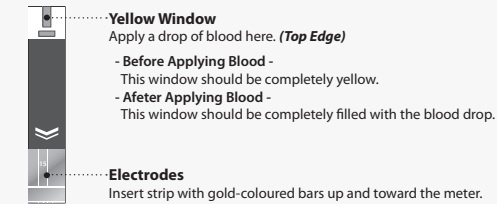
STANDARD CodeFree Plus/Plus NFC Blood Glucose Meter

Display
Shows blood glucose result, messages, and glucose result stored in memory.

ON/OFF Button
Turn the meter ON/OFF, set up the meter, or review the glucose results stored in memory.

Test Strip Slot
Insert test strip here.

Battery Cover
Remove cover to change battery.

Location of NFC Function
Tap a smart device or NFC Reader/Writer for communication.
(only for STANDARD CodeFree Plus NFC Blood Glucose Meter)

LED
Easy to recognize normal, high or low blood glucose level with LED signal.

| Off Mode | Within target range | Higher than target range | Lower than target range |

NOTE The front side design is different between STANDARD CodeFree Plus Blood Glucose Meter and STANDARD CodeFree Plus NFC Blood Glucose Meter. Also, NFC function is provided for only STANDARD CodeFree Plus NFC Blood Glucose Meter.

STANDARD CodeFree Plus Blood Glucose Test Strip

Yellow Window
Apply a drop of blood here. *(Top Edge)*
- Before Applying Blood -
This window should be completely yellow.
- Afeter Applying Blood -
This window should be completely filled with the blood drop.

Electrodes
Insert strip with gold-coloured bars up and toward the meter.

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2. Blood Collection

Lancing Device / Lancet

Release Button

Arming Knob

Cap & Comfort dial with puncture depth selection

Lancet

1 Turn the lancet insert cap counterclockwise to remove it.

2 Insert the lancet into the lancing device holder and push down firmly until it is fully seated. Twist the lancet protective disk until it separates from the lancet.

3 Replace the cap and turn it clockwise, until it is snug.

4 Adjust the puncture depth setting by turning the comfort dial. The dial has 1 to 5 steps, and the higher the step number, the stronger the blood sampling pressure on the puncture site.

5 Cock the lancing device back.

6 Hold the lancing device firmly against the side of finger and then press the release button.

---

3. Test Procedure

1 Insert the 3V battery (type CR2032) into the compartment with "+" side facing you.

2 Insert the test strip into test strip slot until it will go no further with gold-colored bars printed arrow symbol facing up and toward the meter.
Then, the meter turns on automatically.

3 Obtain a drop of blood sample using the lancet and lancing device.

4 Touch and hold drop of blood to the edge of the strip until the yellow window is completely filled with blood. The blood will be drawn into the strip automatically.

CAUTION

Important steps for using the system are inside this guide. Please read it carefully.

If you have questions, we are here to help.
Please contact SD Biosensor, Inc.
Tel : +82-31-300-0400 Fax : +82-31-300-0499
website : www.sdbiosensor.com

You can also visit **www.sdbiosensor.com** for diabetes management tools and product demonstrations.

Please refer to the instructions with following symbols in this User Instruction Guide.

| **CAUTION** | To identify conditions or practices that could result in damage to equipment or other property. |
| **NOTE** | To provide an additional useful information. |

CHAPTER 1: STANDARD CodeFree Plus/STANDARD CodeFree Plus NFC Glucose Monitoring System

1. Intended Use

[STANDARD CodeFree Plus Glucose Monitoring System]
STANDARD CodeFree Plus Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip, palm, upper arm, or forearm. It is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system should not be used for the diagnosis of or screening for diabetes. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

[Only for STANDARD CodeFree Plus NFC Glucose Monitoring System]
This system is intended to be used to transmit glucose values to compatible mobile application or PC software through use of radio frequency communication.

2. Product Description and the Principle of the use

STANDARD CodeFree Plus Blood Glucose Test Strip is designed with an electrode that measures glucose levels. Glucose in the blood sample mixes with reagent on the test strip that cause a small electric current. The amount of current that is created depends on how much glucose is in the blood.
The meter measures the current that is created and converts the measurement to the amount of glucose that is in the blood. The blood glucose result is displayed on the screen.
By touching a drop of blood to the tip of the test strip, the strip's reaction chamber automatically draws the blood into the strip through capillary action. When the chamber is full, the meter starts to measure the blood glucose level. It is a simple and practical system for the daily monitoring of your blood glucose level.

3. Reagent Composition: Active Ingredient (per 100 strips)
- Glucose oxidase (GOD) 300 units
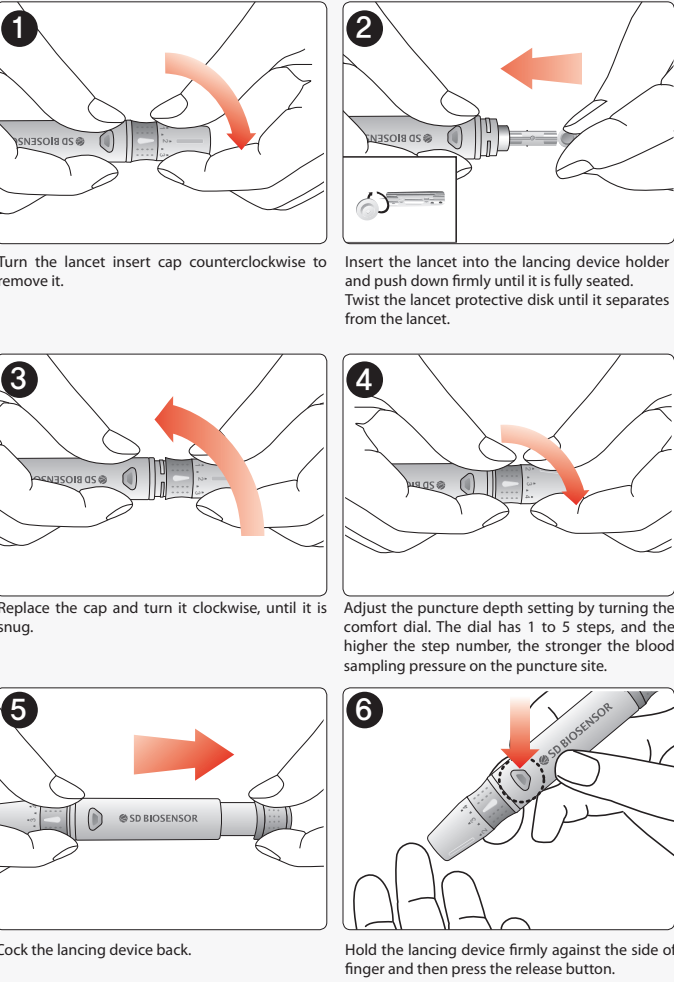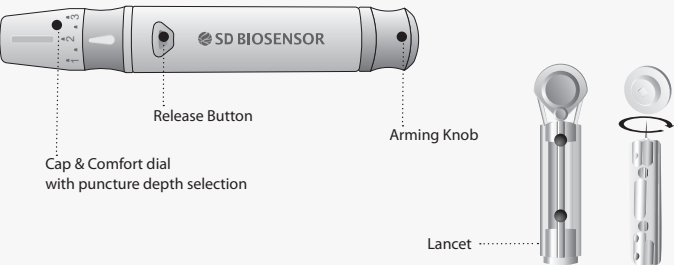- Potassium ferricyanide (mediator) 9.0 mg

4. Meter Set up
STEP-1: Setting the Audible Beep
1. In Strip Stand-by Display, if you press the ON/OFF button for at least 1 second, the display for setting the beep will appear.
2. Set the beep mode on or off by pressing the ON/OFF button and then selecting the preferred feature by pressing the ON/OFF button for 1 second. If you select the beep on feature, a 'beep' sound is made at the same time; otherwise, if you select the beep off feature, no sound is made.
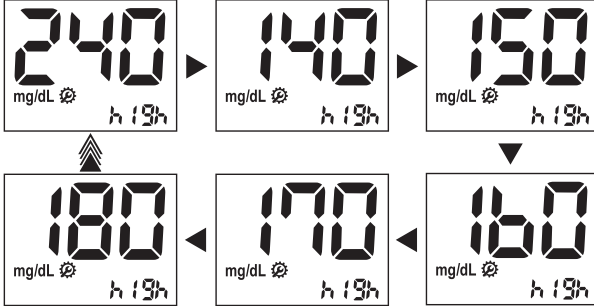
STEP-2: Setting the hyper warning

NOTE
- You can set the meter to let you know when your result indicates a possible high blood glucose (hyperglycemia).
- If the result value is higher than you set (hyper warning value), the right/left red LED blinks 6 times with beep sounded.
- In review mode, hyperglycemia can be confirmed by turning on the right red LED. In addition, hypoglycemia can be confirmed by turning on the left red LED.

1. After setting the beep, the display for setting hyper warning will automatically appear.
2. Set the value by pressing the ON/OFF button. This can be set by 10 mg/dL in the range of 140 to 240mg/dL.
3. Select the target value by pressing the ON/OFF button for 1 second.
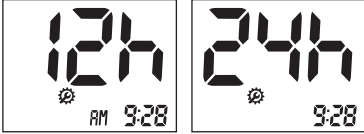
STEP-3: Setting the date and time

NOTE Your new meter comes with a preset time and date. You may need to change the time to your time zone. Having the right time and date in your meter is important if you use the meter memory. It also helps your healthcare team interpret your results. After inserting a new battery, the Date / Time setting mode is set immediately when the unit is turned on.

[Date Setting]
1. After setting the hyper warning, the display for setting Date & Time will automatically appear. Set the year by pressing the ON/OFF button and then select the correct year by pressing the ON/OFF button for 1 second.
2. Set the month and day by pressing the ON/OFF button and select the correct month and day by pressing the ON/OFF button for 1 second.

[Time Setting]
1. Next, the display for setting the 12 or 24 Hour clock format will appear. The meter can display the time in either the 12h format or the 24h format. Set the time format by pressing the ON/OFF button and select the preferred format by pressing the ON/OFF button for 1 second.
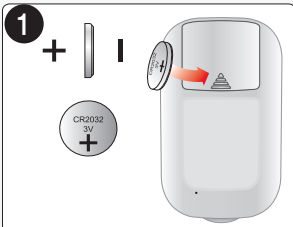
2. Next, the time setting will appear. Set the time by pressing the ON/OFF button and select the correct time by pressing the ON/OFF button for 1 second.
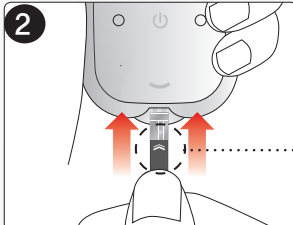If you complete setting the time, the Strip Stand-by Display will appear.

5. NFC Function (only for STANDARD CodeFree Plus NFC Blood Glucose Meter)
NFC(Near field communication) is a set of standards for smart device and similar devices to establish radio communication with each other by touching them together or bringing them into close proximity.
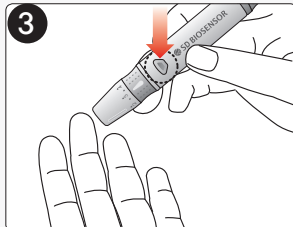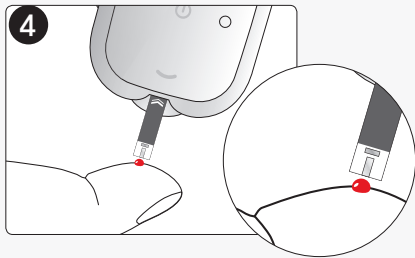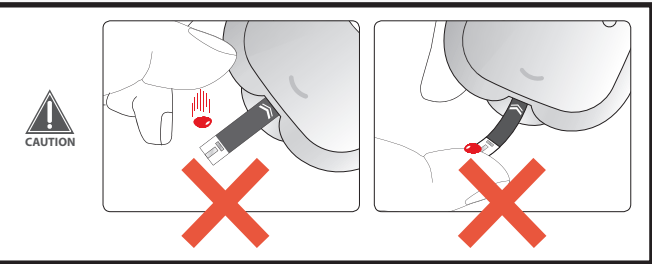

This function is comfortable for test results back-up at PC or smart device. So, you can easily monitor your blood glucose results.

[How to use GlucoNavii App]
1. Search 'GlucoNavii' or 'sd biosensor' on Google Play store and install GlucoNavii application in your smart device.
2. Smart device must be turned on NFC Read/Write mode.
3. Please put the meter NFC antenna spot and smart device NFC antenna spot together. Every smart device has slightly different contact points, so please memorize the exact point.
4. Please tap the meter NFC to your smart device. And then, the app will be executed and data will automatically be uploaded to the smart device.

[How to use STANDARD DMS]
1. Download the software at www.sdbiosensor.com. And then, start the software.
2. Tap the meter with NFC Reader/Writer plugged with PC. And then, start the communication.

CAUTION Changes or modifications made to this equipment not expressly approved by SD Biosensor, Inc. for compliance could void the user's authority to operate the equipment.

NOTE This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to ETSI EN 301 489-1 and 3. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different.
- From that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

6. Precaution and Warning
- This system is not designed to be a substitute for pathology laboratory equipment and should not be used for the diagnosis of diabetes.
- Do not use this system to test neonates. It has not been validated for neonatal use.
- Never make significant changes to your diabetes control program or ignore physical symptom without consulting with your healthcare professional.
- Do not use this device to measure blood glucose in people who are experiencing cardiovascular collapse (severe shock) or decreased peripheral blood flow.

[Meter]
- Keep the test strip slot free of dust.
- Protect the internal meter from humidity.
- The carrying case is designed to let you store a variety of supplies you may need and helps to protect your meter.
- If you keep the meter with the battery inserted, then keep it in a low humidity environment.

[Test Strip]
- Only use STANDARD CodeFree Plus Blood Glucose Test Strips. Using other test strips with this meter can cause inaccurate results.
- After removing a test strip from the container, replace the container cap immediately and close it tightly.
- Store test strip containers in a cool, dry place at 2-32°C(36-90°F). Keep away from direct sunlight and heat. Do Not refrigerate test strips.
- Do Not expose strips to heat, moisture or humidity. Temperatures outside the required range, as well as moisture and humidity (e.g. bathroom, kitchen, laundry room, car, or garage) can damage your test strips and lead to inaccurate results.
- Store test strips in their original container only to avoid damage or contamination. After pulling out the test strip from its container, close a container cap of the test strip immediately.
- Do Not use test strips from any container that is damaged or left open to air.

- Write the opening date on the container label when you first open it. Discard remaining test strips after the discard date. (6 months after first opening from the container)
- Do Not use test strips beyond the expiration (printed on package) or discard date, whichever comes first, because they may cause inaccurate results.
- STANDARD CodeFree Plus Blood Glucose Test Strips are for single use only. Never reuse a test strip that has had either blood or control solution applied to it.
- Avoid getting dirt, food or liquids on the test strip. With clean, dry hands, you may touch the test strip anywhere on its surface.
- Do Not bend, cut, or alter the test strips in any way.
- Use only fresh capillary blood. Do not use serum or plasma or venous whole blood.
- Not following these precautions can lead to inaccurate results.
- Severe dehydration (excessive water loss) may cause false low results. If you believe you are suffering from dehydration, consult your healthcare professional right away.
- Extremes in hematocrit may affect test results. Hematocrit levels less than 20% may cause falsely high readings. Hematocrit levels greater than 60% may cause falsely low readings.
- Interferences : the following compounds, elevated levels of ascorbic acid, uric acid, acetaminophen, total bilirubin and triglycerides may affect results.

Material	Limitation
Acetaminophen	> 6mg/dL
Ascorbic Acid	> 4mg/dL
Bilirubin	> 40mg/dL
Total cholesterol	> 506mg/dL
Creatinine	> 30mg/dL
Dopamine	> 5mg/dL
EDTA	> 0.1mg/dL
Galactose	> 60mg/dL
Gentisic Acid	> 1.8mg/dL
Glutatione	> 4.6mg/dL
Hemoglobin	> 200mg/dL
Pralidoxime Iodide	> 1.3mg/dL
Heparin	> 3,000U/L
Ibuprofen	> 50mg/dL
Levodopa	> 4mg/dL
Maltose	> 60mg/dL
Methyl-Dopa	> 2mg/dL
Sodium Salicylate	> 20mg/dL
Tolazamide	> 8.4mg/dL
Tolbutamide	> 4mg/dL
Triglycerides	> 1,026mg/dL
Uric Acid	> 9mg/dL
Xylose	> 60mg/dL
Icodextrin	> 750mg/dL
Metformin	> 4mg/dL
Fructose	> 16.5mg/dL
Mannitol	> 810mg/dL
Warfarin	> 1.1mg/dL

[Lancet and Lancing device]
- The needle of lancet is sharp, keep the lancet away from children.
- Keep the lancet and lancing device dry and do not store in direct sunlight, or high heat and humidity locations.
- A lancet should not use for the other intended use except sampling blood.
- A lancet is for single use only. Do not reuse.
- Before using, check a packaging condition, if there is any problem, you should not use it.
- If a lancet protective disk is loosed or needle of a lancet is exposed, you should not use it.
- To reduce the chance of infection for the used lancet, discard it.

[Control solution]
- Keep STANDARD Glucose Control Solution in 8-30℃ (46-86°F) environment.
- Do not refrigerate or freeze.
- Do not use STANDARD Glucose Control Solution that has passed the expiration date.
- STANDARD Glucose Control Solution can be used for 3 months after opening the container. Write the opened date on the container when you first opened.
- No reconstitution or dilution is necessary.
- Wipe the container tip clean and reseal the container tightly after each use.

7. Understanding your testing result
[Normal blood glucose result]
- The fasting adult blood glucose range for a person without diabetes[1].
  - Before meals < 100 mg/dL (5.55 mmol/L)
  - After meals < 140 mg/dL (7.8 mmol/L)
- Consult with your healthcare professional for the blood glucose range that is appropriate for you.
- You can set your blood glucose target range between 70mg/dL and 240mg/dL with STANDARD CodeFree Plus/Plus NFC Blood Glucose Monitoring System.

[Hyper/Hypo Result]
1. If the result value is under 70mg/dL, green and red LED lights will flash 12 time salternately with 'beep' sound (only if the beep sound setting is "On").
2. If the result value is higher than you set (hyper warning value), red LED lights will flash 6 times with 'beep' sound (only if the beep sound setting is "On").

[Test Result Range]
The meter reads blood glucose results at 10-600 mg/dL.
1. If 'Hi' is displayed, your blood glucose result may be higher than 600 mg/dL. You may have high blood glucose.
2. If 'Lo' is displayed, your blood glucose result may be lower than 10 mg/dL. You may have low blood glucose.

High or low blood glucose results can indicate potentially serious medical conditions. In case of an unexpected result, you should repeat the test immediately using a new test strip. If your reading is still unexpected or the reading is not consistent with how you feel, you should treat as prescribed by your healthcare professional and/or contact your healthcare professional immediately.

After performing a test with STANDARD CodeFree Plus NFC Blood Glucose Monitoring System, you can set a meal mark that correlates with your result by pressing the ON/OFF button. If you want to display the pre-meal icon(b), press the ON/OFF button one time. If you want to display the post-meal icon(A), press the ON/OFF button one more time. Also, if you want to display the fasting icon(F), press the ON/OFF button one more time.

CHAPTER 2: Control Material
Why you do control solution / Check strip test ;
- STANDARD Glucose Control Solution is used to check that the meter and the test strips are working together as a system and that you are performing the test correctly.
- It is very important that you do this simple check routinely to make sure you get an accurate result.

When you do a quality control test ;
- You open a new box test strips.
- You left the test strip container open or you think your test strips have been damaged.
- Your test strips were stored in extreme temperatures and/or humidity.
- You want to check the meter and test strips.
- You dropped the meter.
- Your test result does not agree with how you feel.
- You want to check if you are testing correctly.
- When you want to easily check the performance of the meter.
- Before using your meter for the first time.
- Whenever your result does not agree with the level you feel.
- If you have repeated a test and the blood glucose result is still lower or higher than expected.

Before you begin ;
- Use only STANDARD Glucose Control Solution.
- Check the expiration date on the control solution container. Record the opening date on the container label. Do Not use after expiration or discard date (date opened plus three months), whichever comes first.
- Control solution, meter, and test strips should be at room temperature 18-30℃ (64-86°F) before testing with control solution.
- Shake the container, discard the first drop of control solution, and wipe off the tip to ensure a proper sample and an accurate result.

- Store control solution tightly closed at temperatures between 8-30℃ (46-86°F). Do Not refrigerate.

⚠ CAUTION
- Do not swallow control solution; it is not for human consumption.
- Do not apply control solution to the skin or eyes as it may cause irritation.
- The Check Strip test does not replace the control solution test.
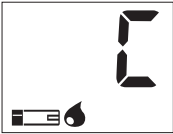
1. Performing a Control Solution Test
You need the meter, a test strip, and control solution Level M or Level H. The control level is printed on the test strip label.

STEP-1:
1. Remove a new test strip from container. Be sure to tightly replace container cap after removing test strip.
2. Insert a test strip (yellow window printed arrow symbol facing up) into test strip slot. The meter turns on automatically.

STEP-2:
1. Press the ON/OFF button for 3 seconds to check the testing system using a control solution in Blood Stand-by Display.
2. Shake the control solution container and discard the first drop of solution. Gently squeeze the container to form one small drop. Bring the drop to the edge of the strip, and allow the strip to automatically draw the control solution into the yellow window. When control solution is applied to the test strip, the meter counts down from 5 to 1 second on the display. Tightly replace the cap on control solution.

3. The control solution result appears on the display in just 5 seconds.
4. Compare control solution result to the range printed on the test strip container. If the results are not within the control range printed on the test strip container, then the meter and strips may not be working properly. Repeat the control solution test.
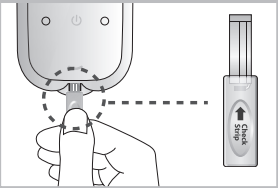

5. Remove the used test strip for control solution from the meter and discard it.

2. Performing Check Strip Test
[How to Use STANDARD Glucose Check strip]
1. Insert a Check Strip (facing up 'check strip' printed in arming knob) into test strip slot. The meter turns on automatically.

2. If the Check Strip is inserted properly, the meter will start the check.
3. The check result appears on the screen in just 5 seconds. If there isn't any problem for the meter, 'OK' message appears on the screen. Otherwise, 'EEE' error message appears with both red LED lighting on.
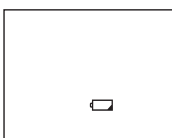

['OK' Message]   ['EEE' Error Message]

CHAPTER 3: Maintenance and Troubleshooting
Screen Messages and Troubleshooting Message Description

📝 NOTE If an error occurs, both red LED will light on.

[Replace battery]
Battery power is low. Replace the battery immediately. If you press the ON/OFF button after discharging of the battery, the battery icon will flash and then after ten seconds the meter will turn off automatically.
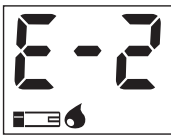
[Internal Error Message for a meter]
Turn off a meter. Then turn on the meter again.

[Strip Error]
Defective test strip or the test strip is damaged or inserted improperly. Discard this test strip and test again using new test strip.

[Blood Sample Error]
An insufficient amount of blood was applied. Discard this test strip and test again using new test strip and a larger sample, making sure blood is placed to the narrow channel in the top edge of the test strip.

[Temperature Error]
The environmental temperature is above or below the operating range of a meter. Move to an area between 10-45℃ (50-113°F), wait for 30 minutes, and perform a test. Do not artificially heat or cool the meter.

CHAPTER 4: Product Technical Specification

Result Range	10 - 600 mg/dL (0.6 - 33.3 mmol/L)
Calibration	Plasma-equivalent
Sample	Fresh capillary whole blood
Sample Size	0.9 μℓ
Test Time	5 seconds
Assay Method	Glucose Oxidase Biosensor
Power Source	One replaceable 3 V Lithium Battery type CR2032
Battery Life	Around 1,000 tests

Unit of measure	mg/dL , mmol/L
Display	LCD (Customized)
Controls	1 Button
Size	48 mm x 83.7 mm x 15.3 mm
Weight	29.5g (without the battery)
Automatic Shutoff	After last user action with inserting test strip into the meter – 60 seconds if an error occurs – 120 seconds in Blood Stand-by Display After last user action without inserting test strip into the meter – 120 seconds at setting mode and 30 seconds at data review mode – 30 seconds in Strip Stand-by Display How to turn off the meter manually – Press On/Off button one time, the meter goes into review mode, then press On/Off button for 1 second. The meter will be turned off.
Memory	500 blood glucose tests
Function	– Hypo warning : under 70mg/dL(3.9mmol/L) – Hyper warning : according to setting range ※ 140mg/dL(7.8mmol/L)~240mg/dL(13.3mmol/L) – Pre-meal and post-meal mark : After result, press On/Off button, then "b", "A", "F" letter will be occurred in order. (only for STANDARD CodeFree Plus NFC Blood Glucose Meter) ※ b : before meal / A : after meal / F : fasting – NFC function (only for STANDARD CodeFree Plus NFC Blood Glucose Meter)
Operation Temperature	10℃ - 45℃ (50°F - 113°F)
Operation Altitude	Up to 12,388 feet (3,776 meters)
Test Strip Storage Temperature	2℃ - 32℃ (36°F - 90°F)
Meter Storage & Transport Condition	-20℃ - 50℃ (-4°F - 122°F) and 10% - 93% RH

CHAPTER 5: Performance Characteristic
Performance characteristic of STANDARD CodeFree Plus and STANDARD CodeFree Plus NFC shall be evaluated with a series of measurements within a short interval of time in accordance with EN ISO 15197:2015.

Precision
The acceptance criteria is within standard deviation (STD) 3 mg/dL at glucose concentrations < 100 mg/dL (5.55 mmol/L) and within CV 4% at glucose concentrations ≥ 100 mg/dL (5.55 mmol/L).

1. Repeatability

Glucose reference value (mg/dL)	STD (mg/dL) / CV (%)
47.6	1.1mg/dL
82.8	2.0mg/dL
135.0	2.9%
209.9	3.1%
312.5	2.3%

2. Intermediate Precision

Below 100mg/dL (5.55mmol/L)	Above 100mg/dL (5.55mmol/L)	
Level L	Level M	Level H
STD (mg/dL)	CV (%)	CV (%)
1.4mg/dL	2.9%	2.4%

System Accuracy
The accuracy of the system was assessed by comparing with the blood glucose test results by YSI 2300 STAT Plus, a glucose laboratory instrument, as the reference.

The acceptable criteria for system accuracy are following; 95% of the measured glucose values shall fall within either ±15mg/dL (0,83mmol/L) of the average measured values of the reference measurement procedure at glucose concentrations <100mg/dL (5,55mmol/L) or within ±15% at glucose concentrations ≥100mg/dL (5,55mmol/L).

1. < 100mg/dL (5.55mmol/L)

Within ±5mg/dL (within ±0.28mmol/L)	Within ±10mg/dL (within ±0.56mmol/L)	Within ±15mg/dL (within ±0.83mmol/L)
80.1% (149/186)	98.4% (183/186)	99.5% (185/186)

2. ≥ 100mg/dL (5.55mmol/L)

Within ±5%	Within ±10%	Within ±15%
67.4%(279/414)	97.1% (402/414)	99.8% (413/414)

User Performance
User Performance is performed in accordance with EN ISO 15197:2015. This study evaluating glucose values from fingertip capillary blood samples obtained by 171 lay persons showed the following results;
"100% within ±15mg/dL(0.83 mmol/L) of the medical laboratory values at glucose concentrations below 100mg/dL(5.55mol/L), and 100% within ±15% of the medical laboratory values at glucose concentrations at or above 100mg/dL(5.55mmol/L)."

Electromagnetic Compatibility
This meter meets the electromagnetic immunity requirements as per EN ISO 15197 Annex A. The chosen basis for electrostatic discharge immunity testing was basic standard IEC 61000-4-2.
In addition, it meets the electromagnetic emissions requirements as per EN 61326. Its electromagnetic emission is thus low.
Interference from other electrically driven equipment is not to be anticipated.

References
1. American Diabetes Association: Standards of Medical Care in Diabetes – 2017. Diabetes Care, January 2017, vol. 40, Supplement 1, S11-S24

Return
You must contact our customer service center at +82-31-300-0400 before returning your meter. You will be instructed how to return the meter to SD Biosensor, Inc. Returned meters without this authorization will not be accepted.