Alliance

Blood Glucose Monitoring System

DS-1

Owner's Booklet
Easy Use

CE 0123

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INTENDED USE
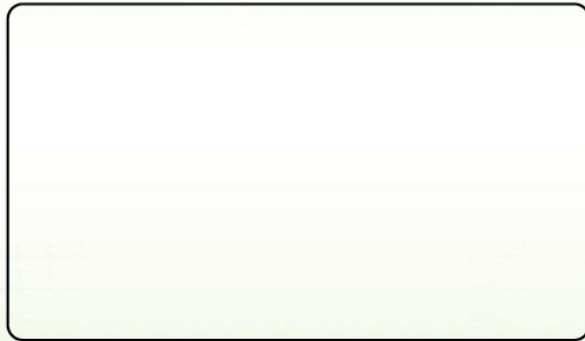
The DS-1 Glucose System is intended for use outside the body (in vitro diagnostic use). It should be used only for testing purposes and only with fresh whole blood samples. It should not be used for the diagnosis of diabetes.

About the DS-1 Glucose Meter

Display

Shows blood
glucose result,
message, and
glucose results
stored in memory.

Main Button

Press to control the meter
on and off, recalls memory,
change the value of data,
time and unit setting.

Strip Slot

Insert test strip,
check card and
code card here.

Data Port

Transfer the information stored in the meter's memory to a computer to view, analyze and print.

DS-1 BLOOD GLUCOSE METER
For *in vitro* diagnostic use.
SERIAL NO.
BATTERY CR2032×1 3V ⎓ CE
0123

Setting Button

Setting the date, time and unit. Located In the battery compartment.

Battery Cover

Slide cover to change battery.
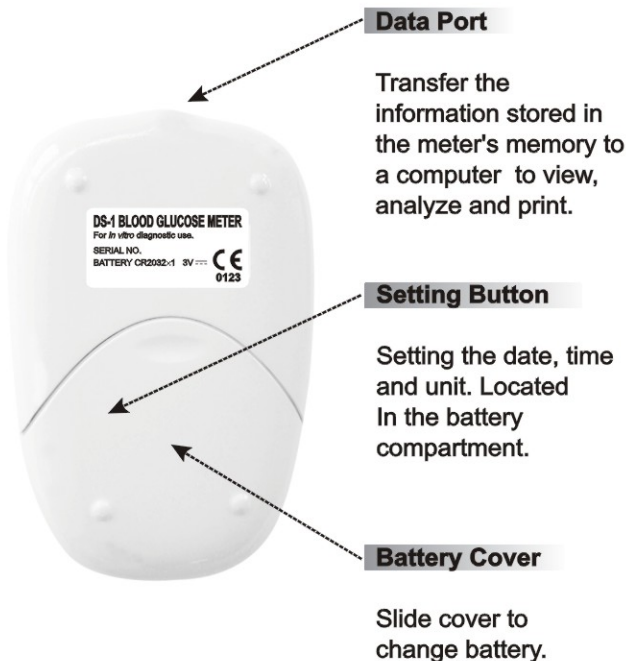
About the DS-1 Glucose Test Strip

Black Bars

Insert strip with black bars up and toward the meter.

Apply Curve

Touch drop of blood here, the blood will be sucked automatic.

Reaction Zone

After applying blood, this part should be completely filled with the blood drop.

Test Strip Handle

Hole these part to insert the test strip into the slot.

Note:

Do not apply blood on the top of the strip.

About the Check Card & Code Card
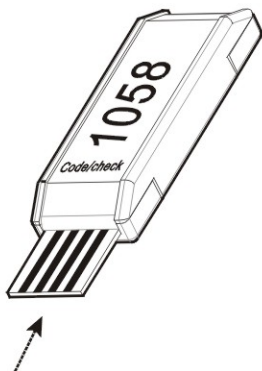
Code & Check Card

The code card is designed specifically, you have to coding the number in the meter or the result will be incorrect. Insert this end in to meter.

Note:

The Check card with code card that you can find in the each set of the glucose meter.

Installing the Battery

The meter is shipped with one 3.0 volt Lithium coin battery that need to be installed before testing. Battery life will very depending on usage, so always keep spare on hand.

The meter saves battery power by automatically turning off after 1 minute of non-use. If the meter does automatically shut off, any tests in memory are saved.
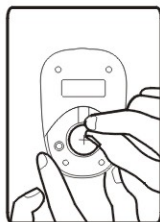
Note:
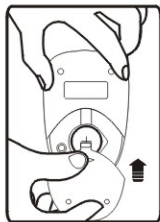Time and date will need to be reset when the battery are replaced.
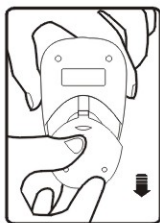
1. Slide battery cover from back of meter.

2. Insert the 3.0 volt Lithium coin battery.

3. Side battery cover back in place. Wait 5 seconds, then turn Meter On.

Draw-In Glucose Test Strip Specification

1. Strip size: 45mm x 6mm x 0.6mm
2. Required blood sample: 3 ul
3. Test result time: depends on strip
4. Sample type: fresh capillary whole blood
5. Test range: 20~600 mg/ dL (depends on strip)
6. Operating condition: 14°C~40°C
7. Storage/Transportation condition: 4°C~32°C, below 85% R.H.
8. Validity: test strip packaging: to be used within 90 days after first opening or within 18 months from production date; unit of packaging: 2X25 test strips/ box.

⚠️

1. Do not use any expired strips.
2. These strips are only to be used with this glucose meter.
3. Do not use any blood which has been preserved (e.g by fluoride).
4. It is not recommended to use this test with new-borns.
5. High density of vitamin C and uric acid may influence the blood glucose level, which may cause inaccurate test results.
6. Hematocrit above 55% may cause a lower blood glucose level.
7. To protect the environment, dispose of used lancets and strips at appropriate collection sites according to national or local regulations. Avoid other people touching the used lancets or strips which may cause cross infection via one's wounds.
8. Keep the test strip vial away from children; the cap is a choking hazard. Also, the cap may contain drying agents that are harmful if swallowed or inhaled and may cause skin or eye irritation.

DS-1 Glucose Meter Specification

01 Dimension : 81mm x 53mm x 20mm

02 Weight : 46.5g

03 Power source : CR2032 3V Lithium coin battery x1

04 Battery life : Over 1,000 determinants

05 Display : Large LCD

06 External output : RS232 PC interface

07 Memory :
180 measurement results with date and time

08 Auto electrode inserting detection

09 Auto sample loading detection

10 Auto reaction time count-down

11 Sleeping mode :
Power consumption less than 20uA

12 Auto turn-off after one minute without action

13 Temperature warning

14 Operating condition : $14^{\circ}C \sim 40^{\circ}C$

15 Storage/Transportation condition:
$4^{\circ}C \sim 32^{\circ}C$, below 95% R.H.

16 Measurement Units : Either mg/dL or mmol/L

LCD Screen

Display Symbols

The blood glucose monitor makes use of symbols to guide you through the test and to help you determine if test strip and display function properly. To check that all display symbols are working, just Press the main button or insert the test electrode into the meter. When a test 、 check card or code card is inserted, the display will turn on automatically. Each time the meter is turned on all symbols should appear briefly.

Screen Description-Symbol Definition

Code Number and Code Message

The number on the display must match the code number which can be found on the test strip package. Make sure you check if the numbers match each time you use a new package of test strips.

Test Strip Message

Indicates how to push the test strip (in arrow direction) firmly into the insertion site until it stops. The correct insertion is confirmed by a sound signal.

Blood Sample Apply

That shows you to apply the blood on the test strip after you inserted the strip correctly.

Reading Result Symbol

After you have correctly inserted the test strip and applied the blood, this symbol is displayed until the result is shown.

Test Result

The meter indicates results from 1.1 bis 33.5mmol/ L
(20-600 mg/ dL) with date and time.

HI Message

In all cases above 33.5 mmol/L
600mg/ dL), the symbol HI is
indicted on the display.

LO Message

In all cases below 1.1 mmol/ L
(20mg/ dL), the symbol LO is
indicated on the display.

Error Message

In all cases in which you operate incorrectly, the
message E- is displayed. For a more precise
definition of error messages see below.
(1)E-b Battery low
(2)E-U Used strip
(3)E-C Code card (code strip)
(4)E-t Temperature HI or LO
(5)E-E Memory error
(6)E-O Bad Strip

Memory Result and Memory Message

The meter can save up to 100 blood glucose test
results with their respective dates and times in
its memory. Every time you turn on the device
and press the main button, it will automatically
recall and display the last result with its date. If
you like to review past test results, just press the
main button continuously and the last 180
results will be recalled in order.

Units of Test Result Display

You can change the unit from mmol/ L or mg/ dL by using the setting button. The unit will be displayed along with the test result as soon as the result appears.

Date and Time Message

When you use the glucose meter for the first time you need to set the data. The information will remain displayed as long as the meter is turned on.

Battery Message

If this symbol is flashing, the battery is low.

Smiley Message

The message will be appeared when the check card is tested well.

```
12:08  12.06
     OK
```

Temperature Message

The meter is not within the given temperature test range.
(The workable range is 14°C~40°C)

```
12:08  12.06

E-t
```

System Operational Description

Turning on the Monitor

You have two ways to do it.

1. Insert the test strip, check card or code card into the insertion site/test port as far as possible. The display will turn on automatically after the strip has been inserted.

2. Press the main button to activate the meter.

Turning off the Monitor

You have two ways to do it.

1. In the test or check situation:
   Remove any strip from the insertion site/test port. The monitor will turn off automatically after the strip has been removed.

2. In the recall memory situation:
   After you have reviewed past test results, the display will automatically turn off after 1 minute.
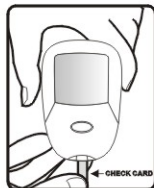
Checking the System

Important

When you first used the meter, it is recommended to use the check card to ensure that the device functions properly.

You can find a system check card in each original meter set.

Step 1: Insert check card into the meter. The meter turns on automatically and quickly goes through a series of internal checks.

Step 2: This brief test allows you to make sure your meter is functioning properly. The "OK" symbol should appear on display.

NOTE:
If this display appears E-b, turn meter OFF and repeat step 1. If this error message appears again, your meter is not working correctly. Please call during office hours.

Coding the Monitor

Important

Each time the monitor is used, the current code will appear on the screen when it turned on. Verify that the code displayed on screen matches the code number on the package of test strip before each use of the monitor. The code needs to be set only once for each package of test strips. The monitor will memorize the code until it is changed.

The number on the meter screen not matching the code number on the test strip package will create an inaccurate blood glucose test result.
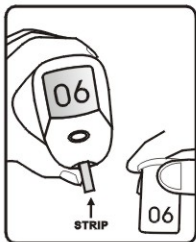
NOTE:
There is a code card package in each box of test strips. The code card is designed specifically for use with the test strips in that particular package.

How to start

Step 1: Push the test strip into the holder until it stops. The monitor will be automatically turned on after the test strip is inserted in.
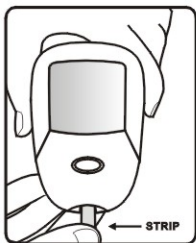
Step 2: The code number will display on the meter screen. Verify the code number on the screen with that on the test strip package should be the same.


NOTE:
Finished the step 1~2 above, the monitor will memorize the code number till you want to change it.

Getting a Drop of Blood Sample

1. Unscrew the lancing device tip and insert the lancet firmly into the carrier.

2. The lancing device tip offers 5 different setting options with regard to the penetration depth which you may set according to your individual skin structure by turning the tip.

3. Draw the lancet by pulling apart the springs.

4. Place the lancing device against the tip of your finger and press the setting button on the lancet.

5. Touch your finger to the tip of the test strip for blood application.
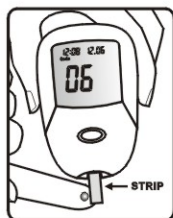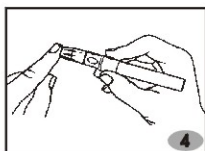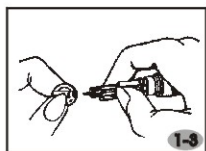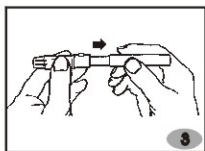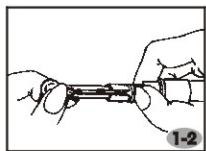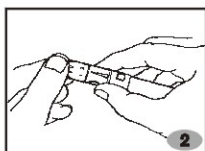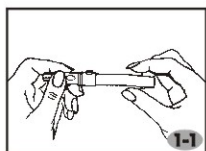
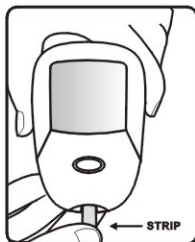# Measuring Your Blood Glucose Level

Test Performance

Step 1: Remove a new test strip from the test strip box and immediately close it afterwards.

Step 2: Now insert the test strip into the meter. The monitor will turn on automatically and display the code number.

STRIP

Step 3: Compare the code number on the display with the code number on the test strip package.

06

STRIP

06
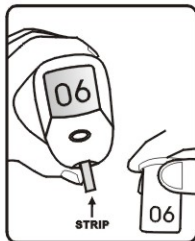
Step 4: The meter will automatically check the ambient temperature. If the temperature is out of range, the symbol of a thermometer will appear on the display. If the temperature is within the test range, the meter will require blood application, indicated by the symbol of a drop of blood.

Step 5: After complete blood application a sound signal is heard and the meter automatically stars with the measurement. If your blood sample has not been sufficient, the result is bad and you have to check again.

Step 6: After the test strip is removed, the meter will turn off automatically.

NOTE:
The meter can save up to 180 blood glucose test results with their respective dates and time in its memory. Every time after you got the new results, it will automatically save in your meter.

Memory Recall & Setting of Time and Date

Memory Recall

Press the main button in order to recall saved test results with data and time.

Setting of Time and Date

Step 1: Make sure that the meter is turned off.

Step 2: Press the setting button. The display symbols for time and data will flash.
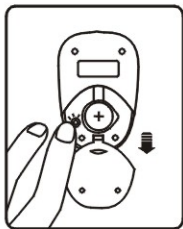
Step 3: By pressing the main button you can make your individual setting. The meter will automatically adapt to your changes.

NOTE:
You have to re-setting the data and coding the meter again when you change the battery.

Easy Use

Step1: Insert strip and check code number.
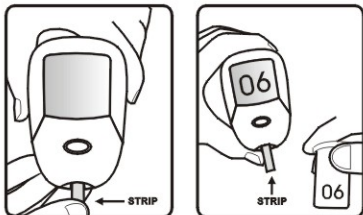
Step 2: Apply blood 3 μl.
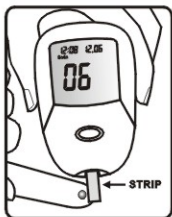
Step 3: Read data in 10 seconds.
(The correct time is depends on strip, please refer to the mark of label on the strip tube)
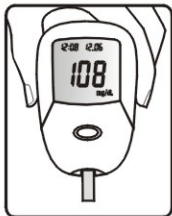
Target Range Note

Time of day	Glucose range for people without diabetes (mg/dL)	Your target range (mg/dL)
Before breakfast	70~105	_____ mg/dL
Before lunch or dinner	70~110	_____ mg/dL
1 hour after meals	Less than 160	_____ mg/dL
2 hours after meals	Less than 120	_____ mg/dL
Between 2AM and 4AM	Greater than 70	_____ mg/dL

Source:
Krall, L.P., and Beaser, R.S.: Joslin Diabetes Manual
Philadelphia: Lea and Febiger (1989), 138.

Applied Standards

This product conforms to the provisions of the EC directive IVDD (98/79/EC). The following standards apply to design and/or manufacturing of the products:

EN 60601-1
Medical electrical equipment
Part 1: General requirement for safety

EN 60601-1-2
Medical electrical equipment
Part 2: Collateral standard:
      Electromagnetic compatibility requirements and tests

EN 61010-1
Safety requirements for electrical equipment for measurement, control, and laboratory use
Part 1: General requirements

Care and Cleaning

Cleaning

Use a soft, dry cloth to clean the body of blood glucose meter
and the lancet device. Do NOT use abrasive cleansers and
never submerge the bodt of the blood glucose meter in water
or other liquids.

⚠

1. Do NOT expose the blood glucose meter to extreme tem-
   perature, very high humidity, or direct sunlight.
2. Avoid extreme shock or accidental drop-down.
3. Do NOT disassemble the blood glucose meter.

Transferring Data

The Glucose Meter allows you to transfer all the data that you have stored in its memory to a separate software program at PC, so this information can be printed.

The meter allows you to transfer data:
Directly to your computer, use an Interface Cable.
Specialized software will need to be loaded on your computer to review the transferred information.

Note: Use only an Interface Cable to connect to the data port of the Glucose Meter.

The use of accessory equipment (such as a computer or modem) that does not comply with the equivalent safety requirements of this Glucose Meter may lead to a reduced level of safety of the resulting system.

Consider the following when using accessory equipment:
Do NOT run a glucose test when the Glucose Meter is connected to accessory equipment.

Suppies and Accessories

The following supplies and accessories are available from Alliance International Co., Ltd your diabetes association and pharmacies

- Draw-In glucose test strips
- Lancet device
- Lancets
- Battery for device
- DS-1 interface for data transfer

LOT	Lot number	Manufactured by
IVD	For in vitro diagnostic use	Keep away from sunlight
REF	Catalogue number	Keep dry
	Consult instructions for use	Temperature limitation
	Use by	Caution
	Do not re-use	
CE 0123	This product fulfils the requirements of Directive 98/79/EC on in vitro diagnostic medical devices.	

Warranty

DS-1 Glucose Meter
2-year warranty

Alliance International Co., Ltd. warrants that your Glucose Meter will be free from defects in materials and workmanship for two years from the date of purchase. If during this two years period, the meter does not work properly because of a defect in materials or workmanship, Scienco will repair the meter or replace it with a new one.

The warranty of the repaired or replacement meter will expire on the date of the original warranty expiration or ninety days after shipment of a replacement system, whichever period is longer.

This warranty applies only to the original purchaser of the meter.

This warranty does not apply to the performance of a Glucose Meter that has been damaged by accident or has been altered, misused, tampered with or abused in any way. Alliance International Co., Ltd will handle meters thatshow damage or abuse according to its Non-Warranty Service Policy,described below.

The purchaser's exclusive remedy with respect to the Glucose Meter shall be repair or replacement at Scienco option.

In no event shall Alliance InternationCo., Ltd be liable to the purchaser or any other person for any incidental, consequential or punitive damages arising from or in any way connected with the purchase or operation of the Glucose Meter or its parts.

Non-Warranty Service Policy

Alliance International Co., Ltd. non-warranty service policy applies to meters where the above warranty has not become effective, has become intolerable or has expired. Alliance International Co., Ltd will replace at its option meters returned to it for a service charge.

Replacement will be with like or similar product.

Replacement (or repaired) meters will be warranted for a period of 90 days from shipment under a limited warranty providing for replacement of parts and labor at no charge.

Warranty and Service Instructions

All requests for return of DS-1 Glucose Meter under the above warranty or service policy must be made by phoning Alliance International Co., Ltd or the national exclusive distributor.

Customer experiencing difficulties should review Error Message found in this manual. Further inquiries should be directed to Alliance International Co., Ltd or the national exclusive distributor.

Be sure to fill out your warranty form that came with your DS-1 Glucose Meter System and return to Alliance International Co., Ltd or the national exclusive distributor.