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EC REP

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St. Ingbert, Germany

Owner's Booklet

AUTO-CHEK® t

Blood Glucose Monitoring System

No Coding
Easy & Accurate Testing

0.5 μl
Very Small Sample
(● :actual size shown)

5 Sec
Rapid Test Result

GSM
Data Transmission

Welcome to the AutoChek t BGMS Blood Glucose Monitoring System

Thank you for purchasing the AutoChek t Blood Glucose Monitoring System.
The system provides you with safe, convenient, and painless blood glucose *in vitro* (i.e., outside the body) diagnostic monitoring. You can obtain accurate results in just 5 seconds with a small (0.5 $\mu\ell$) blood sample.

The AutoChek t Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips and alternative sites such as the forearm, palm, thigh, and calf.

The AutoChek t Blood Glucose Monitoring System is intended for self testing outside the body (*in vitro*) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control.

The AutoChek t is capable of sending test results to AutoChek t's remote database by using cellular data transmission. AutoChek t securely uploads and manages blood glucose readings, eliminating the need to maintain personal logbooks.

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Important Information : Read This First!

To receive safe and optimum system benefits, please read the entire manual contents before the system.
Please note the following instructions:

- **Do not use the system for the diagnosis of diabetes or for testing newborns.**
- **Use only fresh capillary whole blood samples for testing.**
- **Alterative site and fingertip test result may differ significantly due to rapid change in the glucose level post meal, insulin injection, or exercise.**

The following chart explains the symbols you'll find in the AutoChek t User Manual, product packaging, and product inserts.

For *in vitro* diagnostic use

This product fulfills the requirements for Directive 98/79/EC [0123] *In vitro* diagnostic medical devices

Cautions for safety and optimum product use

Consult instruction for use

Manufacturer

Serial number

Authorized representative

Do not reuse

Temperature limitations

Batch code

Use by (unopened or opened test strip container)

Do not discard this product with other household-type waste

Important Information

- **The AutoChek t blood glucose monitoring system is intended for self-testing outside the body (*in vitro* diagnostic use).**
- **The glucose in the blood sample mixes with special chemicals on the test strip where to produce a small electrical current. The AutoChek t meter detects this electrical current and measures the amount of glucose in the blood sample.**
- **The AutoChek t blood glucose meter is designed to minimize code related errors in monitoring by using the no-coding function.**
- **The AutoChek t blood glucose meter should be used only with the AutoChek t strip.**
- **Do not use the system for testing newborns or pregnant women because test results may be affected by the red blood cell count (hematocrit).**
- **Very high (60% or more) or very low (20% or less) hematocrit can lead to incorrect test results.**
- **A glucose value of less than 3.9 mmol/L may indicate hypoglycemia and a value of more than 13.3 mmol/L may indicate hyperglycemia.**

If you need assistance, please contact your authorized i-SENS sales representative or visit www.i-sens.com for more information.

Specifications

- Product specifications

Reported result range	20 ~ 600 mg/dL(1.1 ~ 33.3 mmol/L)
Sample size	Minimum 0.5 ㎕
Test time	5 seconds
Sample type	Fresh capillary whole blood
Calibration	Plasma-equivalent
Assay method	Electrochemical
Power	3.7V Lithium – Polymer Battery (Rechargeable Type)
Memory	250 test result
Size	45L x 96.9W x 18H (mm)
Weight	66.1g

- Operating ranges

Temperature	10~40℃(50 ~ 104 °F)
Relativity humidity	10 ~ 90%
Hematocrit	20 ~ 60%

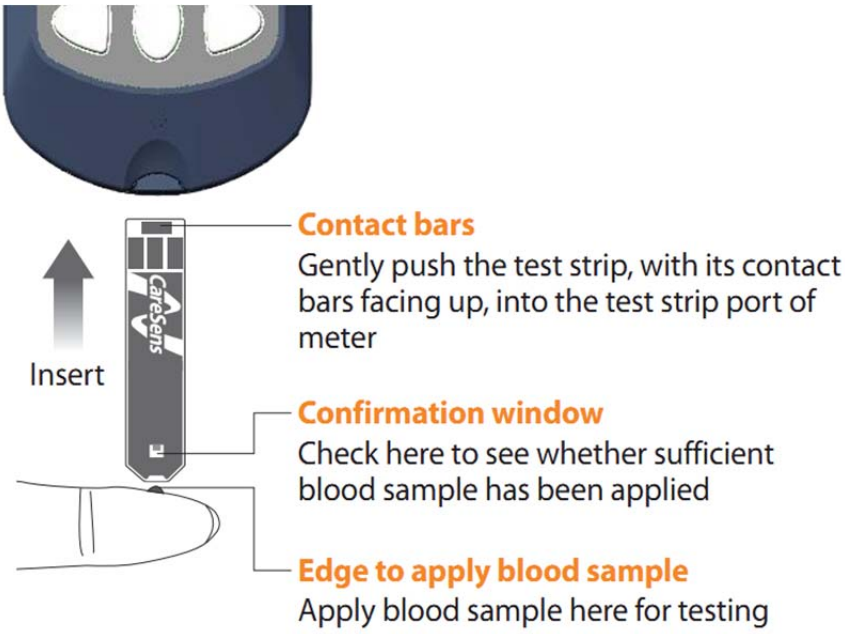
•Components

①**Glucose Meter**
②**Lancing Device**
③**Lancets(10)**
④**Owner's Booklet**
⑤**Quick Reference Guide**
⑥**Logbook**
⑦**Carrying Case**
⑧**Test Strip**

- Certain components may not be included depending on the place of purchase
- Check all the components after opening the AutoChek t blood glucose monitoring system package.
  The exact contents are listed on the main box
- The cable for data transmission can be ordered separately.
  Please contact your authorized i-SENS sales representative.

Autochek t Blood Glucose Test Strip

The AutoChek t blood glucose monitoring system measures blood glucose quickly and accurately. It automatically absorbs the small blood sample applied to the narrow edge of the test strip.

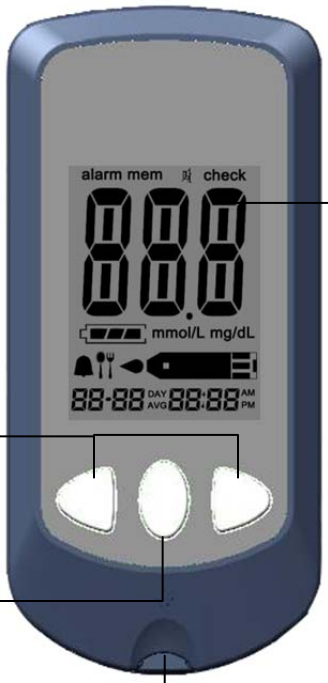


Warning!

- **The AutoChek t test strip should be used only with fresh capillary whole blood samples.**
- **Do not reuse test strips.**
- **Do not use test strips past the expiration date.**
- **Test strips in new, unopened containers and test strips in containers that have been opened can be used up until the expiration date printed on the test strip box and container label if the test strips are used and stored according to its storage and handling methods.**
- **Store test strips in a cool and dry place at a temperature**
- **of 1 ~ 30˚C (34 ~ 86˚F).**
- **Keep away test strips from direct sunlight or heat and do not refrigerate or freeze.**
- **Store test strips only in their original vial.**
- **Close the vial tightly after removing a test strip for testing and use the strip immediately.**
- **Handle test strips only with clean and dry hands.**
- **Do not bend, cut, or alter test strips in any way.**
- **For detailed storage and usage information, refer to the AutoChek t test strip package insert.**

Caution:
Keep the meter testing supplies away from young children.

Autochek t Blood Glucose Meter



Display
Shows results and messages

▲▼ Buttons
Select or changes information

S Button
Turns the meter on/off and confirms menu selections

Test Strip Port
Insert test strip here

SIM Card Slot
Insert a Mobile SIM Card

Communication port
Charging the Battery or Used to transfer data from the meter to a computer a Mini USB Cable

Note:
The mini USB cable for data transmission to PC can be ordered Separately, Please contact your authorized i-SENS sales representative.

Autochek t Blood Glucose Meter Display

mem
Appears when test result stored in the memory are displayed

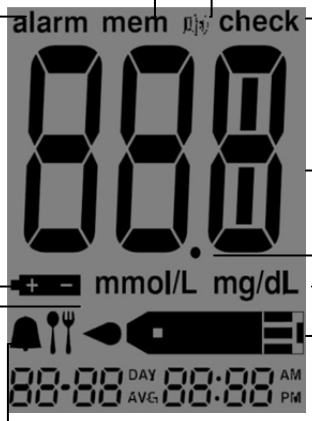
alarm
Appears when the time alarm has been set

mmol/L
Unit for measuring blood glucose

Battery icon
Battery level indicator

Post-meal test flag
Appears during post-Meal testing and When post-meal test Result are displayed

Alarm icon
Appears when the post -meal alarm has been set



Sound icon
Appears only when the sound is set to OFF

check
Appears when test result have not been saved

Test result
Test results displaying panel

Decimal point
Appears when the blood glucose measuring unit is set to mmol/L

mg/dL
Unit for measuring blood glucose

Blood insertion icon
Unit for measuring blood glucose

Setting up Your System

Press and hold the **S** button for 3 seconds to turnon the meter. After all settings are finished, press and hold the **S** button for 3 seconds to turn off the meter.
Press ▲ or ▼ to reach the accurate value. Press and hold ▼ to scroll faster

Adjusting the Date, Time and Unit

Step 1 Entering the SET Mode

Press and hold the **S** button for 3 seconds to turnon the meter. After all the segments flash across the screen, the 'SET' character icon will be displayed on the screen.
Press the **S** button again to enter the year setting mode.

Step 2 Select the automatic time adjusting mode

Enter the **SET** mode and press the **S** button until the 'AUT' appears on the screen.
By pressing the **S** button one more time, the meter will automatically adjust itself to the correct current time.
(refer the **Automatic time adjusting)**

Step 3 Setting the Year

If user didn't select the 'automatic time adjusting mode ' at the "Step 2", The number that appears on the screen after the meter is turned on indicates the year of manufacture. Press and release the or to adjust until the correct year appears. Press and hold the button to scroll through the numbers quickly. After setting the year, press the **S** button to confirm your selection and enter the month setting mode

Step 4 Setting the Month

A number indicating the month will be blinking on the left corner of the screen. Press the ▲ or ▼ until the correct month appears. Press the **S** button to confirm your selection and enter the date setting mode.

Step 5 Setting the Date

Press the▲ or ▼until the screen displays The correct date. Press the **S** button to confirm the date and enter the time setting mode.

Step 6 Setting the Time

The meter can be set in AM/PM 12-hour or 24-hour clock format. Press the▲ or ▼ to select a format. The AM / PM icon is not displayed in the 24-hour format. After selecting the format press the **S** button to enter the hour setting mode.

Step 7 Setting the Hour

Press the ▲ or ▼ until the correct hour appears. After the hour is set, press the **S** button to enter the minute setting mode.

Step 8 Setting the Minute

Press the ▲ or ▼ until the correct minute appears. After setting the minute, press the **S** button to enter the unit setting mode

Setting the Sound On/Off

Step 9

On the sound option menu, pressing the ▲ or ▼, the screen will display the On or OFF. Press the **S** button to confirm the selection.

The meter will beep in the following instances, if the meter's sound is set to On.

- When the test strip is inserted in the meter
- When the blood sample is absorbed into the test strip and the test starts
- When the test result is displayed
- When you push the **S** button or ▲button to check the memory
- When you push the ▲ button to set the post-meal (PP2) alarm
- When it is time for a preset blood glucose test

If the sound is set to OFF, none of the sound functions will work

Note:
Only when the sound is set to OFF, icon appears on the display

Setting the Cellular function On/Off

Step 10

Enter the **SET** mode and press the **S** button until the '**CEL**' appears on the screen. On this screen, the cellular function of the meter can be activated or deactivated.

Step 11

From the '**CEL**' screen, press the ▲ or ▼ button until the '**On**' character icon appears on the screen. Press the **S** button to turn on the cellular function of the meter.

From the '**CEL**' screen, press the ▲ or ▼ button until **OFF**' appears on the screen. Press the **S** button to turn off the cellular function of the meter.

Step 12

Once the cellular function of the meter is turned on, the meter can immediately transmit the test result data to the designated server by choosing **Transfer Mode 1 (T1 mode)**. After turning on the cellular function is turned on, the ‘T1’ will be appeared, once the ‘T1’ appears, press the **S** button to choose Transfer Mode 1

Step 13

Once the cellular function of the meter is turned on, the meter can transmit the test result data to the designated SMS server once a day at a reserved time by choosing **Transfer Mode 2 (T2mode).**

In order to choose Transfer Mode 2, press the ▲ or ▼ until **‘T2’** appears from the **‘T1’** screen. Once the **‘T2’** appears, press the **S** button and the **‘OFF’** will blink. Press the ▼ button to turn on Transfer Mode 2.

Step 14

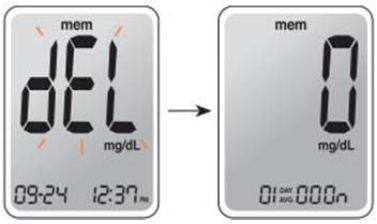
Once Transfer Mode 2 is turned on, press the ▲ or ▼ until the correct hour appears. After the hour is set, press the **S** button to enter the minute setting mode. Press the ▲ or ▼ until the correct minute appears. Once correct hour and minutes are set, press **S** button to confirm the schedule.

Setting the ‘Test Result Reset’ (Deleting all the saved test result)

Step 15

In this mode all the test results stored in the meter can be deleted.
Please note that if you select YES, all the stored test results will be deleted and cannot be restored.

After the beeper mode is set,
press the **S** button to enter the ‘Test Result Reset’ mode.



The ‘dEL’ will blink on the screen.
Press the ▲ or ▼ to alternate between ‘YES’ or ‘no’. To delete all the stored test results press the **S** button when the screen displays ‘YES’. Then, all the test results stored in the meter will be deleted and the screen will be similar to the picture on the right.
If you do not want to delete the results press the **S** button when the screen displays ‘no’. Then, the screen will return to step 2. Please, see page 12.

Note:
At any stage, If the S button is pressed for 3 seconds, Time, Date another setting mode will finish and meter will be turned off.
Press and hold the ▼ to scroll through number quickly

Checking the System

You may check your meter and test strips using the AutoChek t Control Solution.
The AutoChek t Control Solution contains a known amount of glucose and is used to check that the meter and the test strips are working properly.
The test strip vials have AutoChek t Control Solution ranges printed on their labels. Compare the result displayed on the meter to the AutoChek t Control Solution range printed on the test strip vial.
Before using a new meter or a new vial of test strips, you may conduct a control solution test following the procedure on page 18.

Note:

- Use only the AutoChek t Control Solution.
- Check the expiration dates printed on the vial. When you first open a control solution vial, record the discard date (date opened plus three months) in the space provided on the label.
- Make sure your meter, test strips, and control solution are at room temperature before testing. Control Solution tests must be done at room temperature (20 ~ 25˚C, 68 ~ 77˚F).
- Before using the control solution, shake the vial, discard the first few drops and wipe the tip clean.
- Close the control solution vial tightly and store at a temperature of 8 ~ 30˚C (46 ~ 86˚F).

You may do a control solution test:

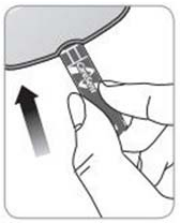
- When using the meter for the first time.
- Whenever you open a new vial of test strips.
- If the meter or test strips do not function properly.
- If your symptoms are inconsistent with the blood glucose test results, and when you feel that the meter or test strips are not working properly
- If you drop or damage the meter.

Caution:
If all the results you get from testing continuously (at least three times)are within the range printed on the test strip, the meter and test strips are working properly and you may use them for your blood glucose test.

Control Solution Testing

Step 1

Insert a test strip into the meter's test strip port, with the contact bars facing upwards.
Gently push the test strip into the port until the meter beeps.
Be careful not to break the strip while pushing it in.
The icon will be displayed on the screen.



Step 2

Shake the AutoChek t Control Solution vial before each test.
Remove the cap and squeeze the vial to discard the first drop. Then wipe the tip with a clean tissue or cloth. After the symbol appears on the display, apply the solution to the narrow edge of the test strip until the meter beeps.
Make sure the confirmation window fills completely.

Note:
The meter may be turned off, if the blood sample is not applied within
2 minutes of the  icon appearing on the screen.
If the meter is turned off, remove the strip, reinsert, and start from step 1.

Step 3

A test result will appear after the meter counts down from 5 to 1.
After your control solution result appears on the display, press the ▼ for 3 seconds until the 'check' icon appears on the display. When the 'check' icon is displayed, the result is not stored in the meter's memory and is not included in the averages.

Step 4

Compare the result displayed on the meter to the range printed on the test strip vial. The result should fall within the range on the test strip vial.
Used strips should be discarded and disposed.

Caution:

- If the results you get are not within this range, the meter and test strip may not work properly. Then, stop using the meter and contact the nearest i-SENS representative.
- The range printed on the test strip vial is for the AutoChek t Control Solution only. It does not have any connection to your blood glucose level.

Comparing the Control Solution Test Results

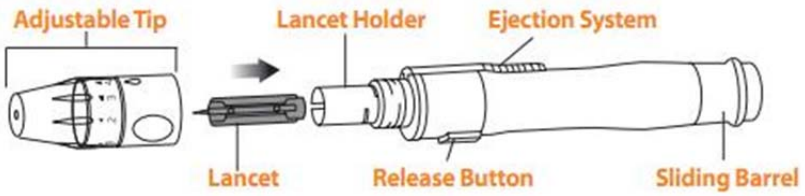
Repeat the control test if the test result falls outside the range printed on label of the test strip vial. Out of range results may occur due to the following factors:

- When the control solution vial was not shaken well,
- When the control solution is past its expiration date or is contaminated,
- When the meter, the strip or the control solution were exposed to high or low temperatures,
- When the first few drops of the control solution were not discarded or the tip of the vial was not wiped clean,
- When the test strip is past its expiration date,
- When the meter is not functioning properly.

Note:
The AutoChek t Control Solution can be purchased separately. Please contact your authorized i-SENS sales representative.

Using the Lancing Device

You will need a lancing device in order to collect a blood sample. You may use the lancing device contained in the AutoChek t Blood Glucose Monitoring System or any other medically approved lancing device.



- The lancing device should be used by one individual and communal use is strongly discouraged
- Use a soft cloth or tissue to wipe the lancing device. If necessary, a small amount of alcohol on a soft cloth or tissue may be used.

Caution:

To avoid infection when drawing a sample, use a lancet *only* one time, and:

- Do not use a lancet that has been used by others.
- Always use a new sterile lancet.
- Keep the lancing device clean.

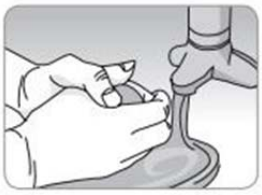
Note:

Repeated puncturing at the same sample site may cause pain or skin calluses. Choose a different site each time you test.

Preparing the Lancing Device for Blood Sample Retrieval

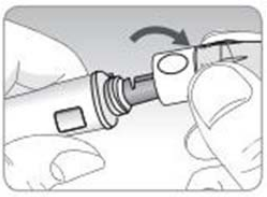
Step 1

Wash hands and fingertip sample site with soap and warm water.
Rinse and dry thoroughly.



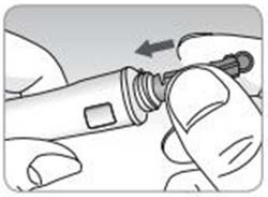
Step 2

Unscrew the lancing device tip



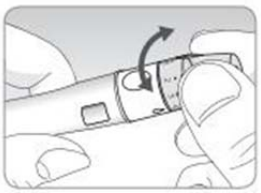
Step 3

Firmly insert the new lancet into the lancet holder. Hold lancet firmly.
Gently twist to pull off the protective disk.
Save the disk to recap the lancet after use.
Replace the lancing device tip.



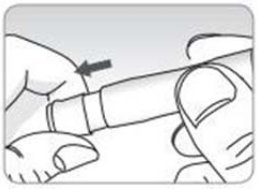
Step 4

Select a desired depth of one-to-five (1-5) on the lance's adjustable tip. Rotate the to align the desired number with the
A beginning setting of three (3) is recommended.



Step 5

To cock the lancing device, hold the tip in one hand. Pull the sliding barrel on with the other hand. The lancing device is cocked when you feel a click.



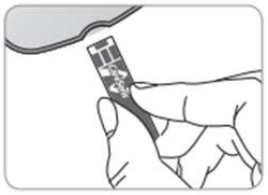
Note:

The skin depth to retrieve samples will vary for various people at different sample sites. The lance's adjustable tip allows the best depth of skin penetration for an adequate sample size.
A beginning setting of three (3) is recommended.

Preparing the Meter and Test strip

Step 6

Insert a test strip with the contact bars
facing upwards into the meter port.
Push the strip in gently until the meter beeps.
Be careful not to bend the test strip.
The symbol will appear on the screen.



Flagging Post-meal Test Result

The AutoCheck t meter allows you to flag a result of an post-meal test with the ( ) icon.
The post-meal test flag ( ) can be attached just before applying the blood sample.
Once you attach the post-meal flag ( ) to the test results, it cannot be deleted.

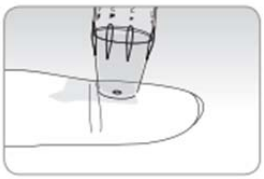
Step 7

If you want to attach an post-meal flag ( )
to a test result, press and hold the ▼ for 3
seconds after inserting the test strip.
The post-meal flag( ) and the symbol
will appear on the screen
The test result will also be displayed with the post
-meal flag( ).
If you do not want to save the result the result as a
Postmeal test, move on to the step 8 after the step 6.

Applying Blood Sample

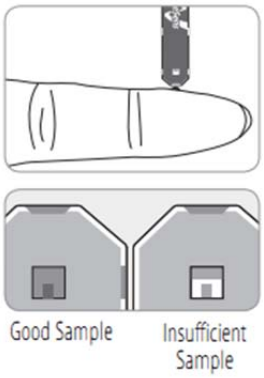
Step 8

Obtain a blood sample using the lancing device. Place the device against the pad of the finger. The best puncture sites are on the middle or ring fingers. Press the release button. Remove the device from the finger. Wait a few seconds for a blood drop to form. A minimum volume of 0.5 microliter is needed to fill the Confirmation window. (actual size of 0.5㎕ : •)



Step 9

After the symbol appears on the screen, Apply the blood sample to the narrow end of the test strip till the meter beeps. If the confirmation window filled before the meter Finishes down then discard the test strip new one. If confirmation window is not filled in because of Abnormal viscosity or insufficient volume, Er4 message will appear.



Note:
The meter may switch off if the blood sample is not applied within 2 minutes of The icon appearing on the screen. If the turns off, remove the strip and reinsert into the meter.

Step 10

The test result will appear after the meter counts down from 5 to 1. The result will be automatically stored in the meter's memory.

If the test strip is removed after the test result is displayed, the meter will be automatically turned off after 3 seconds.

Discard used test strips safely and dispose.

Result Data Transmission I

Step 1

In the “T1” mode, the measured data is sent to a server immediately after each measurement.
(Refer the **Setting the Cellular function On/Off**)
After measuring Blood glucose and discard an used test strip, the meter
will starting the data transfer operation. ‘Snd’ will be appeared on the screen.

Step 2

Once the data transfer begins, the progress indication dash dot (blinking) will be appeared at the bottom of the screen.

Step 3

When the meter successfully sent the test result, ‘SUCC ESS’ will be appeared at the bottom of the screen.

Result Data Transmission II

Step 1

Transfer mode 2 (T2 Mode)
(Refer the **Setting the Cellular function On/Off**)
User can set the schedule, then BGM sends
all test results to the server once a day only at a
reserved time.

Step 2

At the reserved time, GSM meter wakes up
automaticallyandgathering all measured data of the day
The data will be sentto the server. “Snd” appears during the
data transfer.

Step 3

At the bottom of thescreen,
it displays the progress indicator dots.

Step 4

When the meter successfully sent the test result, ‘SUCC ESS’ will be appeared at the bottom of the screen.

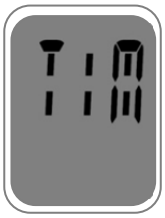
Automatic time adjusting

Step 1

In the sleep mode, press the ▼ button until display “TIM”

Step 2

When “TIM” appears, release the ▼ button



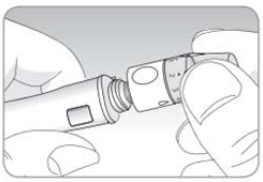
Step 3

When the Autochek t retrieve cellular network
time, it will display the local time at the bottom of the screen.

Discarding Used Lancets

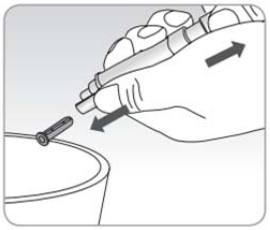
Step 1

Unscrew the general lancing device tip.



Step 2

Place the protective cover on the lancet. Push the lancet ejector forward with the thumb and simultaneously pull out the sliding barrel to dispose the used lancet into a proper biohazard container.



Cautions:
The lancet is for single use only. Never share or reuse a lancet. Always dispose of lancets properly.

Alternative Site Testing

What is AST(Alternative Site Testing)?

AutoChek t BGMS is caplable of testing your blood glucose from your palm, arms, tight, or calves, usually referred to as an alternative site test, or AST.
Alternate site testing can be less painful than fingertip testing,. However, because of the physiological differences between your fingertip and palm, AST results may be significantly different.
While AST may reduce the pain during testing, it may not be simple for everyone and the following precautions should be observed during testing.

You should consult with your doctor before using alternate site testing.

Things to know when using AST

Please understand the following informationbefore testing outside of the fingertip
(palm, arms, thighs, or calves).
The capillary blood of the fingertip shows the change in glucose more rapidly than AST.
Therefore, the test results from the fingertip test and AST may differ.
This might caused by lifestyle or ingested food have an effect on glucose levels.

Acceptable situation for AST

- Fasting period
- Before a meal
- Before sleeping

Situation requiring fingertip test

-
-
-
-

AST Precautions

- Do not ignore the symptoms of hyperglycemia or hypoglycemia.
- When the results of the test do not reflect one's opinion, retest using the fingertip test. If the test results do not reflect one's opinion, please consult a doctor.
- Do not rely on the AST results for changing one's treatment method
- The amount glucose in alternative sites differs from person to person
- Before using AST, please consult your regular physician

Note:

Results from alternative site and fingertip samples may appear differently as there is a time lag for the glucose levels to reach the same value. Use a fingertip for drawing if you suffer from hypoglycemia or have experienced hypoglycemic shock or symptoms.
drawing if you suffer from hypoglycemia or have experienced hypoglycemic shock or symptoms.

Note:

If the sample drop of blood runs or spreads due to contact with hair or with a line in you palm, do not use that sample. Try puncturing again in a smoother area.

HI Message

The meter displays results between 20 ~ 600 mg/dL (1.1 ~ 33.3 mmol/L). The Hi icon will be appeared when the blood glucose level is more than 600 mg/dL (33.3 mmol/L) and indicates hyperglycemia.
If the Hi icon is displayed again on re-testing, please contact your healthcare professional immediately.

Lo Message

The Lo icon appears when the result is less than 20 mg/dL (1.1 mmol/L) and indicates hypoglycemia
If the Lo icon is displayed again on re-testing, please contact your healthcare professional immediately.

Note:
Please contact your authorized i-SENS sales representative, if such messages are displayed even though you do not have hyperglycemia or hypoglycemia.

Target Blood Glucose Ranges

Reminders

Time of day	*Your target ranges from your healthcare expert*
Before breakfast	
Before lunch or dinner	
1 hour after meals	
2 hour after meals	
Between 2 a.m. and 4 a.m.	

Source : *Diagnosis of Diabetes*, NIH Publication No. 05-4642, January 2005

Meter Memory

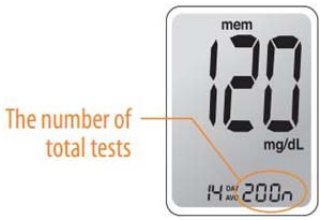
The AutoChek t meter can save up to 500 glucose test results with time and date. If the memory is full, the oldest test result will be deleted and the latest test result will be stored.

The AutoChek t meter calculates and displays the averages of total test results, pre-meal test (Pr) results, and post-meal test ( ) results from the last 1, 7, 14, 30 and 90 days.

Viewing Test Result Stored in the Meter's Memory

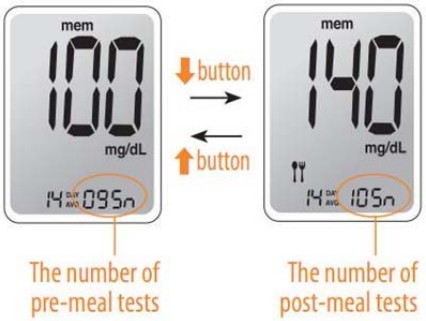
Step 1

Press the ▲ or **S** button to turn the meter on.
The current date and time will be displayed at the bottom of the screen for 2 seconds, followed by the 1 day average value and the number of the test results saved within the last 14 days.



Step 2

Press the ▼ button
to view the average value and
the number of tests performed before a meal
for the last 14 days.
Press the ▼ button again to check the average value and the number of tests performed after a meal for the last 14 days.



Step 3

Use the ▼ button to scroll through the test results, starting from the most recent and ending with the oldest. Press the ▲ button to return to the result seen previously.
After checking the stored test results, press the **S** button to turn off the meter.

Note:

Bypressing the ▼ button ,the latest test result saved in the meter's memory will be displayed on the screen along with the date and time.
Press and hold the▼ button to scroll through the test results.

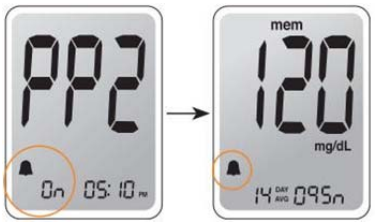
Setting the Alarm Function

Four types of alarms can be set in the AutoChek t meter: one post- meal alarm (PP2 alarm) and three time set alarms (alarm1 ~ 3).
The PP2 alarm goes off 2 hours after setting the alarm.
The alarms ring for 15 seconds and can be silenced by pressing ▲,▼, or the S button.
Also the alarms can be turned of by inserting a test strip.

Setting the post-meal alarm (PP2 alarm)

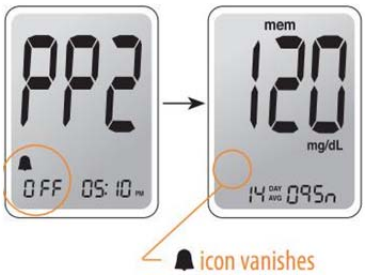
Step 1 Setting the PP2 alarm On

Without inserting a test strip,
press and hold the ▲ button
for 3 seconds to set the
post-meal alarm. The ‘PP2’ character,
the bell ( ) icon and then the ‘On’ character
will be displayed. The screen will then
automatically be switched to the memory
check mode. Thenthe bell ( ) icon,
which indicating that the PP2 alarm has been set,
will be displayed on the screen.



Step 2 Setting the PP2 alarm Off

To turn off the PP2 alarm, press and hold the ▲ button for 3 seconds. The ‘PP2’ character, the bell ( ) icon, and then the ‘OFF’ character will be appeared on the screen. Then the screen will be switched automatically to the memory check mode without the bell ( ) icon being displayed.



Setting the Time Alarms (alarm 1~3)

Step 1

Without inserting a test strip, press the ▲ button and the S button simultaneously for 3 seconds to enter the time alarm mode. The ‘alarm1’ will be displayed while the ‘OFF’ character blinks on the screen.

Step 2

By pressing the ▼ button, the ‘alarm1’ is set and the ‘On’ character will be displayed on the screen. Press the ▼ button again to cancel the ‘alarm1’. The ‘OFF’ icon will be blinked on the screen.

Step 3

Press the ▲ button to adjust the time of the ‘alarm1’. A number representing the time will be blinked on the screen. Press the ▼ button to set the time. Press the ▲ button to end.

Step 4

By pressing the ▲ button, the number indicating the minute will start blinking. Press the ▼ button to set the accurate minute.

Step 5

Press the S button to finish and to enter the ‘alarm 2’ mode.
Repeat steps 2 to 5 to set the remaining time alarms (alarm 2 ~ 3).

Step 6

Press the S button for 3 seconds to finish and turn the meter off.

Charging Your AutoChek t Blood Glucose Meter

Step 1

Plug the mini USB cable into AC adaptor

- Plug the other end of the mini USB cable into the BGM's charging port which is located on the side of the BGM.
- Once the mini USB cable is plugged, the BGM will start charging and the 'Chr' will be displayed on the screen.

Step 2

Once charging is completed, the ‘End’ will be appeared at bottom left of the screen.

Caution :
If the meter won’t charge, please do not attempt to take apart, repair, or modify the meter. Please contact your authorized i-SENS sales representative,

Use a soft cloth or tissue to wipe the meter exterior. If necessary the soft cloth or tissue might be dipped in a small amount of alcohol.
Do not use organic solvents such as benzene, or acetone, or household and industrial cleaners that may cause irreparable damage to the meter.
Store all the meter components in the portable case to prevent loss.

Caution

- Do not expose the meter to direct sunlight or heat for an extended period of time.
- Prevent the entry of dirt, dust, blood, or water at the meter's test strip port.
- Do not drop the meter or submit it to strong shocks.
- Do not try to fix or alter the meter in any way.
- Keep the meter away from strong electromagnetic fields such as cell phones and microwave ovens.
- AutoChek t meter should be used only with AutoChek t strips.
- Keep the meter in a cool and airy place.

Understanding Error and other Message

Message	What It Means	What To Do
	A used test strip was inserted.	Repeat the test with a new test strip.
	The blood or control solution sample was applied before the icon appeared.	Repeat the test with a new test strip and wait until the icon appears before applying the blood sample.
	The temperature during the test was above or below the operating range.	Move to an area where the temperature is within the operating range (10 ~ 40 °C/ 50 ~ 104 °F) and repeat the test after 30 minutes.

Message	What It Means	What To Do
	The blood sample has abnormally high viscosity or insufficient volume.	Repeat the test after inserting a new test strip.
	A non-AutoChek t test strip was used. Test strip was not inserted properly.	Repeat the test with a AutoChek t test strip. Insert a test strip with the contacting bars facing upwards and push in gently until the meter beeps.
	There is a problem with the meter.	Do not use the meter. Contact your authorized i-SENS sales representative.

Note:
if the error messages persist, contact your authorized i-SENS sales representative

Message	What It Means	What To Do
	When battery level is low	Charge the battery.
	SIM Card error: No SIM Card or invalid SIM Card insertion	Check if the SIM card is Properly inserted in the Meter. If the SIM card is Properly inserted. Check If there is any defect on the SIM card
	Radio Signal error: Can't detect GSM Signal Or Signal strength is not enough	Check to see if there is Cellular coverage in your Area. Please move to the Area where you get better Cellular coverage.

Message	What It Means	What To Do
	Network registration error: System can't register at Service network (AT&T, T-mobile or other Service providers)	Check if the SIM card Is properly inserted in The meter or contact The service provider To see if there is any Network issue
	Message Send error: Your data transmission is Not successful	Try to send the test Result data one more time. If the meter fails to send the test result data, Please contact your authorized i-SENS sale representative
	System Error: GSM MODEM Hardware Error occurred	Please contact your Authorized i-SENS sales representative

Problem	Trouble shooting
The display is blank even after inserting a test strip.	● Check whether the test strip is inserted with the contact bars facing up. Check if the strip has been inserted completely till the end. ● Check whether the batteries are inserted with the '+' side facing up. ● Charging the batteries.
The test does not start even after applying the blood sample on the strip	● Check if the confirmation window is filled adequately. ● Repeat the test after inserting a new test strip.
The test result doesn't match your expectation.	● Repeat the test after inserting a new test strip. ● Check the validity period of the test strip. ● Check the meter.
The data transmission is Not successful	● Check the battery level ● Check the SIM card is properly inserted in the meter or if the SIM card is activated. ● If testing indoors, move closer to a window for better cellular reception ● Test outdoors and check see if there is cellular coverage in your area

Note:
If the problem is not resolved, please contact your authorized i-SENS sales representative.

Performance Characteristic

The performance of AutoChek t Blood Glucose Monitoring System Strips has been evaluated in laboratory and in clinical tests.
Accuracy: The accuracy of the AutoChek t BGM System (ModelGM505YAA) was assessed by comparing blood glucose results obtained by patients with those obtained using a YSI Model 2300 Glucose Analyzer, a laboratory instrument
The following results were obtained by 110 diabetic patients at clinic centers.

Slope	0.961
Y-intercept	3.5 mg/dL
Correlation coefficient(r)	0.995
Number of sample	110
Range tested	30 ~ 485 mg/dL

Accuracy results for glucose concentration<75 mg/dL (4.2 mmol/L)

Within±5mg/dL (Within±0.28mmol/dL)	Within±10mg/dL (Within±0.56mmol/dL)	Within±15mg/dL (Within±0.83mmol/dL)
13/17(76%)	16/17(94%)	17/17(100%)

Accuracy results for glucose concentration≧75 mg/dL (4.2 mmol/L)

Within±5%	Within ±10%	Within±15%	Within±20%
45/93(48%)	88/93(96%)	93/93(100%)	93/93(100%)

Precision: The precision of AutoChek t Test strip was estimated with venous blood sample in the laboratory.

Within Run Precision		
Blood average	38.1 mg/dL (2.1 mmol/L)	SD = 1.9 mg/dL (0.11 mmol/L)
Blood average	86.1 mg/dL (4.8 mmol/L)	SD = 3.2 mg/dL (0.2 mmol/L)
Blood average	124.5 mg/dL (6.9 mmol/L)	CV = 4.1%
Blood average	189.1 mg/dL (10.5 mmol/L)	CV = 2.6%
Blood average	334.5 mg/dL (18.6 mmol/L)	CV = 2.8%

Total Precision		
Control average	43.1 mg/dL (2.4 mmol/L)	SD = 2.0 mg/dL (0.11 mmol/L)
Control average	113.4 mg/dL (6.3 mmol/L)	CV = 3.3%
Control average	381.2 mg/dL (21.2 mmol/L)	CV = 4.2%

This study shows that there could be variation of up to 4.2%

Warranty Information

Manufacturer's Warranty

i-SENS, Inc. warrants that the AutoChek t Meter shall be free of defects in material and workmanship in normal use for a period of five (5) years. The meter must have been subjected to normal use. The warranty does not cover improper handling, tampering, use, or service of the meter. Any claim must be made within the warranty period.

The i-SENS company will, at its discretion, repair or replace a defective meter or meter part that is covered by this warranty. As a matter of warranty policy, i-SENS will not reimburse the consumer's purchase price.

Obtaining Warranty Service

To obtain warranty service, you must return the defective meter or meter part along with proof of purchase to your nearest i-SENS Authorized Warranty Station.

*** FCC**

RF Exposure Statement (2.1091)
FCC RF Radiation Exposure Statement: This equipment complies with FCC rf radiation exposure limits set forth for an uncontrolled environment based on the low operational duty cycle for this device. Do not make more than one measurement every 2 hours when using T1 mode.

RF du FCC d'exposition aux radiations: Cet équipement est conforme à l'exposition de la FCC rayonnements RF limites établies pour un environnement non contrôlé. Cet appareil et son antenne ne doivent pas être co-localisés ou fonctionnant en conjonction avec une autre antenne ou transmetteur.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

FCC Part 15.21
Any changes or modifications (including the antennas) made to this device that are not expressly approved by the manufacturer may void the user's authority to operate the equipment.

Part 15.105 (B)
Note : This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. 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.

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