

**Cover page**

Thank you for selecting **Inspire Advance** Blood Glucose Monitoring System. The system was produced in close association with diabetes healthcare professionals, most importantly, people with diabetes.



This manual contains important information you must know about the system. Please read it thoroughly and carefully. For short simple instructions, a quick reference card is provided for your convenient use. If you have any questions or enquiries, please contact your local distributor or us for help.

The **Inspire Advance** is designed to help you and your healthcare professionals monitor your blood glucose levels. All questions about interpreting the results should be directed to your healthcare professionals.

The **Inspire Advance** is the latest technology for blood glucose monitoring, easy to use and will give you fast and accurate results with a minimal sample of blood.

The **Inspire Advance** Meter:

- Requires no coding; allowing you to save time and avoid human error due to coding.
- Allows you to perform Alternative Site Testing (AST).
- Has memory and data management capabilities. It gives you and your healthcare professional powerful graphic tools to manage your diabetes.

## **IMPORTANT SAFETY INSTRUCTIONS**

### **READ THIS BEFORE USING.**

The following basic safety precautions should always be taken.

1. Close supervision is necessary when the device is used near children, handicapped persons or invalids.
2. Use the device only for the intended use described in this manual.
3. Do not use test strips and control solutions which are not supplied by the manufacturer.
4. Do not use the device if it is not working properly, or if it has suffered any damage.
5. Before using any product to test your blood glucose, read all instructions thoroughly and practice the test. Do all quality control checks as directed and consult with a diabetes healthcare professional.

**Warning:** Keep the test strips vial away from children; the vial cap and the test strips can be a potential choking hazard. Never chew or swallow a test strip. If this occurs, please seek medical assistance immediately.

**KEEP THESE INSTRUCTIONS WITH YOU.**

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## **IMPORTANT HEALTH-RELATED INFORMATION**

1. Apply only capillary whole blood sample to test your blood glucose. Applying other substances or plasma, serum will cause wrong results.
2. Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.
3. If you are experiencing symptoms that are not consistent with your blood glucose test results and you have followed all instructions described in this user's manual, consult your healthcare professional.
4. Test results below 60 mg/dL (3.3 mmol/L)\*1 may mean low blood glucose (hypoglycemia). Test results greater than 240 mg/dL (13.3 mmol/L)\*2 may mean high blood glucose (hyperglycemia). If your results are below 60 mg/dL(3.3mmol/L) or above 240 mg/dL(13.3 mmol/L), repeat the test, and if the results are still below 60 mg/dL(3.3 mmol/L) or above 240 mg/dL(13.3 mmol/L), follow the treatment advice of your healthcare professional.
5. Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.
6. Abnormal red blood cell counts (hematocrit levels below 20% or above 60%) may cause false results. Please consult your healthcare professional if you do not know your hematocrit level.
7. Interference: Reducing substances occurring in the blood naturally (uric acid) or from therapeutic treatments (ascorbic acid, acetaminophen) will not significantly affect **Inspire Advance** test results. However, elevated concentrations of these substances may affect test

results. The compounds listed in the tables were found to have no affect at the concentration indicated.

Compounds	Uric Acid	Gentisic Acid	Acetaminophen	Hydroxyurea	Ascorbic Acid
Lowest concentrations tested at which no interference occurred	≤ 8.0 mg/dL (0.48 mmol/L)	≤ 5.0 mg/dL (0.32 mmol/L)	≤ 8.0 mg/dL (0.53 mmol/L)	≤ 3.0 mg/dL (0.39 mmol/L)	≤ 5.0 mg/dL (0.28 mmol/L)

Compounds	Dopamine	L-dopa	Methyldopa	Tolbutamide	Triglycerides
Lowest concentrations tested at which no interference occurred	≤ 2.0 mg/dL (0.11 mmol/L)	≤ 10 mg/dL (0.51 mmol/L)	≤ 3.0 mg/dL (0.13 mmol/L)	≤ 400 mg/dL (14.8 mmol/L)	≤ 2000 mg/dL (22.6 mmol/L)

Compounds	Aspirin	Bilirubin	Cholesterol	Creatinine	Galactose	Maltose
Lowest concentrations tested at which no interference occurred	≤ 60 mg/dL (3.33 mmol/L)	≤ 90 mg/dL (1.54 mmol/L)	≤ 500 mg/dL (12.9 mmol/L)	≤ 5.0 mg/dL (0.44 mmol/L)	≤ 900 mg/dL (50 mmol/L)	≤ 900 mg/dL (26.3 mmol/L)

8. Please refer to your test strip package insert for additional important information.

## REFERENCE:

- \*1: Jabbour, Serge, Elizabeth A. Stephens, Irl Bennett Hirsch. Type 1 Diabetes in Adults. USA: CRC Press, 2007
- \*2: Unger, Jeff. Diabetes Management in Primary Care. USA: Lippincott Williams & Wilkins, 2006

### ABOUT ALTERNATIVE SITE TESTING(AST)

There are important limitations for doing AST. Please consult your healthcare professional before you perform AST.

#### ***What is AST?***

Alternative Site Testing (AST) means you can use parts of the body other than your fingertips to check your blood glucose levels. The **Inspire Advance** allows you to test your palm, forearm, upper arm, calf, or thigh with equivalent results to fingertip testing.

#### ***What is the advantage?***

Fingertips feel pain more readily because they are full of nerve endings (receptors). At other body sites, nerve endings are not so numerous and you will not feel as much pain as you will experience at the fingertip.

#### ***When to use AST?***

Food, medication, illness, stress and exercise can affect blood glucose levels. Capillary blood at fingertip reflects these changes faster than capillary blood at other sites. Therefore, if you are testing blood glucose level during or immediately after meal, physical exercise or stressful event, take the blood sample from your fingertip only.



### **Use AST only:**

- In a pre-meal or fasting state (more than 2 hours since the last meal).
- Two hours or more after taking insulin.
- Two hours or more after exercise.
- During steady state blood glucose conditions.

### **Do NOT use AST if:**

- You have reason to believe you have hypoglycemia or hyperglycemia.
- Your routine glucose results are often fluctuating.
- You are pregnant.

### ***How to increase the accuracy?***

- Stimulating blood perfusion by rubbing the puncture site prior to blood extraction has a significant influence on the glucose value obtained.
- Blood from the site without rubbing exhibits a measurably different glucose concentration than blood from the fingertip. When the puncture site was rubbed prior to blood extraction, the difference was significantly reduced.

**Important:** To increase the accuracy when using AST, rub the puncture site more than 20 seconds before extracting blood.

## ABOUT Inspire Advance SYSTEM

### Intended Use

**IVD** The system is intended for use outside the body (*in vitro* diagnostic use only). It should be used only for testing blood glucose (blood sugar) and only with fresh capillary whole blood samples. The system is intended for use in the home and in clinical settings. It should not be used for the diagnosis of diabetes or for the testing of newborns.

### Test Principle

Blood glucose is measured by an electrical current that is produced when a blood samples mixes with the reagent (special chemicals) of the test strip. The electrical current changes with the amount of glucose in the blood sample. The **Inspire Advance** meter measures the strength of the electrical current, calculates your blood glucose level and then displays your result in either mg/dL or mmol/L.

### About the System

The **Inspire Advance** system uses the latest technology to provide you with easy and comfortable testing. The system requires only a 0.7 $\mu$ L of blood sample to complete the testing in only 5 seconds.

The **Inspire Advance** system consists of

1. **Inspire Advance** Blood Glucose Meter
2. **Inspire Advance** meter Blood Glucose Test Strips
3. **Inspire Advance** meter Control Solution

These products have been designed, tested and proven to work together as a system to produce accurate blood glucose test results.

**Important:** Use only **Inspire Advance** test strips and control solutions with your **Inspire Advance** meter. Use other test strips and control solutions with this meter can produce inaccurate results.

## **Caution**

1. The user should not take any decision of medical relevance without first consulting his or her medical practitioner.
2. Call your doctor immediately if you experience symptoms that are not consistent with your blood glucose test results.
3. A sample with large amount of reducing substances such as ascorbic acid and uric acid may cause result slightly higher than the actual glucose level.
4. High altitudes above 3,402 meters (11,158 feet) may affect the test results.
5. Temperatures outside the range of 5°C to 45°C (41 °F to 113°F) may affect the test results. Do not test beyond the temperature range.

### CONTENTS OF THE SYSTEM

The **Inspire Advance** complete kit includes:

**Inspire Advance** Blood Glucose Meter X 1

**Inspire Advance** meter Blood Glucose Test Strips X 5\*

Lancing device X 1

Lancets X 5\*

Carrying bag X 1

User's manual X 1

Quick reference guide X 1

Strip instruction X 1\*

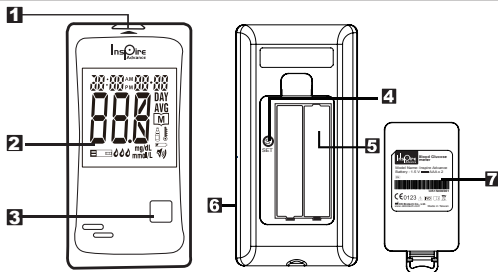
Battery (AAA x 2)

**NOTE:** The **Inspire Advance** meter is available as a meter only or as a complete kit. Contents might vary by different package. For meter only, products with \* mark are excluded. Please review the contents of your purchase. If any items are missing, please return your meter to the place of purchase.

## KEY FUNCTIONS OF THE METER

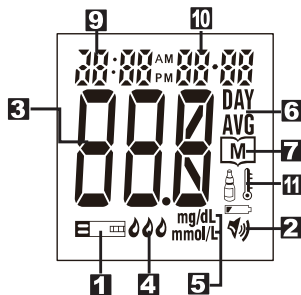
Study this diagram and become familiar with all the parts of your **Inspire Advance** meter.

1. **STRIP SLOT:** Insert the test strip here. The meter will turn on automatically.
2. **LCD DISPLAY:** The large, easy to read display shows test results, messages, test results stored in memory.
3. **MAIN BUTTON:** Press button to turn the meter on or perform other functions described in this manual.
4. **SET BUTTON:** Located in the battery compartment; press button to enter meter setting. Refer to "SETTING YOUR METER" section of this user's manual for details.
5. **BATTERY COMPARTMENT:** Holds TWO 1.5v AAA alkaline batteries.
6. **DATA PORT:** Allows you to transfer the information stored in the meter to a computer to view, analyze and print. Refer to "REVIEWING RESULTS ON A PERSONAL COMPUTER" Section of this user's manual for details.
7. **METER LABEL:** Each meter has its unique number on it. It can be used when you want to obtain warranty service. Please do not alter or tear the label off.



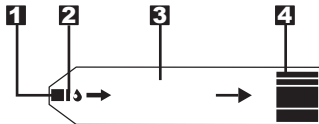
### METER DISPLAY

1. **TEST STRIP SYMBOL:** Appears when the meter is turned on and waiting for inserting a test strip.
2. **VOICE SYMBOL:** Appears while using **Inspire Advance** talking version.
3. **BATTERY SYMBOL:** Appears when battery is weak.
4. **BLOOD DROP SYMBOL:** Flashes when it is ready to apply the blood sample.
5. **MEASUREMENT UNIT:** Appears with the test result in mg/dL or mmol/L.
6. **AVERAGE:** Appears in the memory mode while recalling 7/14/21/28 day test averages.
7. **MEMORY SYMBOL:** Appears when in the memory mode.
8. **CTL SYMBOL:** Appears when doing a control solution test.
9. **TIME :** The meter is programmed for a 12 hour period format.
10. **DATE:** Display month and date.
11. **THERMOMETER SYMBOL:** Appears when ambient temperature is above or below the acceptable range needed for testing.




## KEY FUNCTIONS OF THE TEST STRIP

1. **ABSORBENT CHANNEL:** apply a drop of blood here, the blood will be drawn in automatically.
2. **CONFIRMATION WINDOW:** this is where you confirm if enough blood has been drawn into the test strip's absorbent channel.
3. **TEST STRIP HANDLE:** hold this part to insert the test strip into the meter slot.
4. **CONTACT BARS:** Insert this end of the test strip into the meter until it will go no further.



### **Important Test Strip Information**

1.  Test strips are for single use only.
2. Store the vial in a cool, dry place below to 40°C/104°F and above 4°C/39°F. Do not refrigerate.
3. Store your test strip in their original vial only. Do not transfer them to a new vial or any other container.
4. With clean, dry hands, you may touch the test strip anywhere on its surface when removing it from the vial or inserting it into the meter.
5. Immediate use a test strip after removing it from the vial, replace the vial cap and close it tightly.
6. Only apply a blood sample or a control solution sample to the test strip's absorbent channel. Applying other substances to the test strip's absorbent channel will cause inaccurate results.
7. Do not use test strips beyond the expiration date indicated on the strip vial label.
8. Do not place in direct heat or sunlight.
9. Do not carry loose test strips in your carrying case.

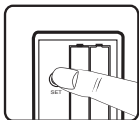
10. Do not use damaged test strips or test strips changed in any way.

**Warning:** Keep the test strips vial away from children; the vial cap and the test strips can be a potential choking hazard. Never chew or swallow a test strip. If this occurs, please seek medical assistance immediately.



## SETTING YOUR METER

Your **Inspire Advance** meter comes with the date, time, and unit of measurement preset. However, if you change the time or replace the battery, you should check and update the time and date.



### STEP 1. Enter Setting Mode

Start with the meter off, and press SET BUTTON. The meter will turn on and enter to the setting mode.







### STEP 2. Set the Year

The year appears with the number flashing. Press and release the MAIN BUTTON to obtain the desired year. Press SET BUTTON to confirm and move to next MONTH setting.



### STEP 3. Set the Month

The month appears with the number flashing. Press and release the MAIN BUTTON to obtain the desired month. Press SET BUTTON to confirm and move to next DATE setting.

	<p><b>STEP 4. Set the Date</b></p> <p>The date appears with the number flashing. Press and release the MAIN BUTTON to obtain the desired date. Press SET BUTTON to confirm and move to next HOUR setting.</p>
	<p><b>STEP 5. Set the Hour</b></p> <p>The hour appears with the number flashing. Press and release the MAIN BUTTON to obtain the desired hour. Press SET BUTTON to confirm and move to next minutes setting.</p>
	<p><b>STEP 6. Set the Minutes</b></p> <p>The minute appears with the number flashing. Press and release the MAIN BUTTON to obtain the desired minute. Press SET BUTTON to confirm and the meter will enter to next unit setting.</p>
	<p><b>STEP 7. Set the Unit of Measurement</b></p> <p>The existing unit (for example mg/dL) will appear and flashing. Press and hold the MAIN BUTTON for 3 seconds to change the unit to mmol/L. Press SET BUTTON to confirm and the meter will enter to next delete all memory setting.</p>



## **STEP 8. Delete Memory**

When the dEL symbol and the flashing memory symbol appear on the display, you can choose to clear the memory. If you do not want to clear the memory, press the SET BUTTON again to skip this step. If you want to clear ALL memory, press and hold MAIN BUTTON for 3 seconds. The “---” image will appear on the LCD screen to indicate that all memory has been deleted.



## **STEP 9. Complete Setting**

After delete memory, the meter will display “OFF” before shut down. The meter setting is now completed.

**IMPORTANT:**

1. The time, date and unit of measurement can **ONLY** be changed in the setting mode. Therefore, when you perform a blood glucose testing, it is not possible to change those parameters.
2. Your meter displays 7, 14, 21, and 28-day averages which you can access from the meter memory. These averages are calculated from the date of your latest result to 7, 14, 21, and 28 days before.
3. Your meter can display test result in milligram per deciliter (mg/dL) or millimoles per liter (mmol/L). The mg/dL unit is standard in the United States. The mmol/L unit is standard in Canada and European countries. We will preset by standard unit of each country. When you turn off the meter or replace the battery, the unit will not be changed.
4. Use of the wrong unit of measure may cause you to misinterpret your blood glucose level, and may lead to incorrect treatment. Please always consult with your healthcare professionals before you reset the unit of measure.
5. While the meter is in the setting mode, if no button is pressed for 1 minute, the meter will turn off automatically.

## CONTROL SOLUTION TEST

### ***Inspire Advance meter Control Solution***

**Inspire Advance** meter control solutions contain a known amount of glucose that reacts with **Inspire Advance** meter test strips. By testing your control solution and comparing the test results with the expected range printed on the test strip vial label, you can make sure that the meter and the test strips are working properly 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 accurate results.

### ***Why perform a control solution test?***

1. To ensure that your meter and test strip are working properly together.
2. To allow you to practice testing without using your own blood.

### ***When should the control solution test be performed?***

1. When you first get your **Inspire Advance** meter. Before use this system to test your blood, you can practice the procedure by using control solution. When you can do three tests in a row that are within the expected range, you are ready to test your blood.
2. Once a week (to make sure that you continue to get accurate results).
3. When you begin using a new vial of test strips.
4. Whenever you suspect that the meter or test strips are not working properly.
5. When your blood glucose test results are not consistent with how you feel, or when you think your results are not accurate.
6. When test strips are exposed to extreme environmental conditions.

7. If you drop the meter.
8. After changing the batteries.

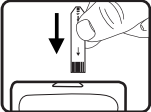
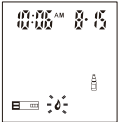


### ***Important Control Solution Information***

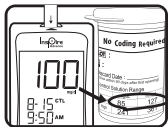
1. Use only **Inspire Advance** meter control solution.
2. Check the expiration date on the control solution bottle. Do not use if expired.
3. Control solution, meter, and test strips should come to room temperature (20-30°C/68-86 °F) before testing.
4. Shake the control solution bottle before use, discard the first drop of control solution after squeezing, wipes off the dispenser tip to avoid contaminations. These steps ensure you will get a good sample and an accurate result.
5. Store the control solution closed at temperatures between below 30°C (86°F). Do not refrigerate.

#### **NOTE:**

1. There are two levels of control solution (normal and high) available to choose from. The control solution supplied with the meter kit is normal range. Please contact with your local distributor for other level of control solution.
2. The control solution range printed on the test strip vial is for **Inspire Advance** meter Control Solution only. It is used to test meter and strip performance. It is not recommended range for your blood glucose level.

## How to Perform a Control Test

	<p><b>STEP 1. Insert Test Strip</b></p> <p>Insert a new test strip into the strip slot, the meter will activate.</p>
	<p><b>STEP 2. Mark as a Control Solution Test</b></p> <p>After the blood symbol(♂) appears, press MAIN BUTTON and "CTL" appears on the display indicating you are in the Control Solution Mode. The meter will not store your test result in the memory when you preset the test as a control solution test. If you decide not to perform a control solution test, press MAIN BUTTON again and the "CTL" will disappear.</p>
	<p><b>STEP 2. Squeeze a drop of Control Solution</b></p> <p>Shake control solution bottle well. Remove the cap. Squeeze the bottle, discard the first drop and wipe off the dispenser tip with a clean tissue paper or cotton. Squeeze the bottle again to get the second drop onto a clean non-absorbent surface or on your fingertip first.</p>
	<p><b>STEP 3. Apply Control Solution</b></p> <p>Apply the drop to the opening of the strip absorbent channel until the confirmation window is filled. The meter begins to count down.</p>

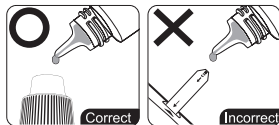


### STEP 4. Check if the test result is in range

After the meter counts down from 05 to 01, the test result shows up. Compare the test result with the range printed on the test strip vial. The result should fall within the printed range.

### NOTE:

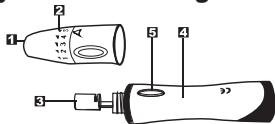
1. Be sure that you are in Control Solution Mode so that the test result will not be stored in the meter memory. To avoid contaminating the control solution with the content of the test strip, **DO NOT APPLY THE CONTROL SOLUTION DIRECTLY TO THE TEST STRIP!**
2. If test result falls outside the range printed on the test strip vial, repeat test first. If you continue to get the result falling outside the range, your meter and test strip may not be working properly. **DO NOT** use the system to test your blood until you get a test result falls within the control range. If you are unable to resolve the problem, please contact your local distributor for help.





## PREPARE FOR BLOOD SAMPLING

### Adjustable Lancing Device



1. Lancing Device Cap
2. Depth Selector
3. Lancing Holder
4. Cocking Control
5. Release Button

### Lancet



1. Protective cap


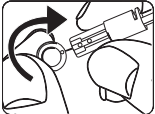
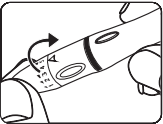
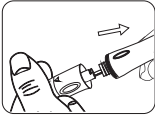
Your lancing device and lancets are used for obtaining capillary blood samples from the puncture site.

### **⚠ Important Lancing Device and Lancets Information**

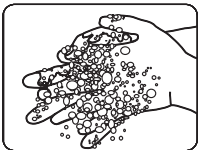
1. ⓧ Lancet is for single use only.
2. Keep lancing device and lancets clean.
3. Use caution when removing the used lancet from the device and when disposing the used lancet.
4. The lancing device and lancets are in conformity with MDD 93/42/EEC. Refer to product labels for contact information of manufacturer and CE marking.

Important : The meter and lancing device are for single patient use.  
Do NOT share them with anyone including other family members !  
Do NOT use on multiple patients !

## Set Lancing Device

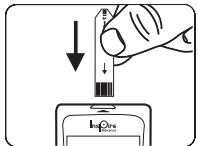
	<p>1. Screw off the cap of lancing device. Insert a lancet into the lancet holder and push down until it is fully seated.</p>
	<p>2. Twist off the protective cap until it separates from the lancet.</p>
	<p>3. Replace the lancing device cap and set the puncture depth to the desired number.  <b>Note: the depth selector offers 5 levels of skin:</b>  <b>1-2 for soft or thin skin</b>  <b>3 for average skin</b>  <b>4-5 for thick or calloused skin</b></p>
	<p>4. Pull back the cocking control until it makes a click, and then release. If it does not click, the device may have been cocked when the lancet was inserted.</p>

## PERFORMING BLOOD TEST



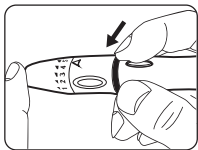
### STEP 1. Wash Your Hands and the Puncture Site

Wash your hands in warm, soapy water. Rinse and dry completely. Warm your fingers to increase blood flow.



### STEP 2. Insert Test Strip

Remove a new test strip from vial. Be sure to tightly replace vial cap after removing test strips. Insert test strip immediately into strip slot as illustrated. The meter turns on automatically. When the blood symbol blinking, you are ready to perform a test.



### STEP 3. Select and Lance a Puncture Site

**\*For Fingertip**

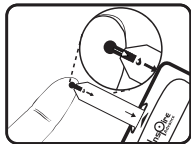
Hold the prepared lancing device firmly against the side of your fingertip. Press release button.

**\*For AST**

Please refer to the "About Alternative Site Testing (AST)" Section. Please consult your healthcare professional before obtaining blood from site other than your fingertip.

**STEP 4. Obtain a Blood Sample**

Gently massage your finger or puncture site to obtain the required blood volume. To perform the test, you need only 0.7 $\mu$ L of blood sample. Do not smear the blood sample. To obtain best accurate result, wipe off the first drop of blood and gently squeeze another drop of blood.

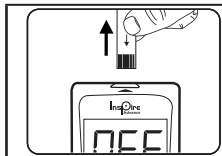
**STEP 5. Apply Blood Sample**

Apply the blood sample to the opening of absorbent channel of test strip until the confirmation window is fully covered with blood. Then the meter begins to count down and displays test result in 5 seconds.

**STEP 6. Read Your Result**

The result of your blood glucose test will appear after the meter counts down to 0. This blood glucose result will automatically be stored in the memory.

This default value is only for your reference, please consults your healthcare professional to find out your target blood glucose value.



### **STEP 7. Remove Strip to Turn Meter Off**

Your blood glucose result is automatically stored in the meter memory. Turn the meter off by removing the test strip. Discard the used strip and lancet safely in a puncture resistant container.

**IMPORTANT:**

1. The **Inspire Advance** only requires a tiny sample of blood to perform a test. Choose a different spot each time you test. Repeat puncture in the same spot may cause soreness and calluses.
2. The first drop of blood usually contains tissue and serum, which may affect the test result. It should be discarded.
3. The blood should be completely filled the confirmation window before the meter begins to count down. If you find that the confirmation window is not filled with blood when the meter is counting, NEVER try to add more blood to the test strip. Discard the test strip and retest with a new one.
4. If you do not apply a blood sample within four (4) minutes, the meter will automatically turn off. You must remove the test strip and re-insert it again to turn on the meter and restart the test procedure.
5. If you have trouble filling the test strip, please contact your local distributor for assistance.

## UNDERSTANDING YOUR TEST RESULT

### ***Normal Blood Glucose Range***

The normal blood glucose range is 70 to 105 mg/dL (3.9 to 5.8 mmol/L) for a fasting, non-diabetic adult, but less than 140 mg/dL (7.8 mmol/L) two hours after meals. Consult your healthcare professional to find out your target blood glucose value.

If your blood glucose result seems unusually high or low, or inconsistent with your previous results, check the following:

1. Was the blood sample applied immediately to the test strip after removing it from the vial?
2. Was the volume of the blood sample sufficient?
3. Was the test strip vial cap tightly sealed?
4. Was the test strip used before the expiration date?
5. Were the test strips stored away from extreme temperatures in very cold or hot weather or from areas of high humidity?

Then run a control test with **Inspire Advance** meter control solution. If the control test result is within the acceptable range, review testing procedure and repeat your blood glucose test with a new test strip. If your blood glucose value is still inconsistent with your previous results, glucose trend, or how you feel, contact your doctor immediately for help.

## COMPARING WITH LABORATORY RESULTS

The result you obtain from your meter may differ somewhat from your laboratory result due to normal variation. Meter results can be affected by factors and conditions that do not affect laboratory results in the same way. To make an accurate comparison between meter and laboratory results, follow the guidelines below.

### ***Before you go to the lab***

1. Perform a control solution test to make sure that the meter is working properly.
2. It is best to fast for at least eight (8) hours before doing comparison tests.
3. Take your meter with you to the lab.

### ***While at the lab***

1. Make sure that the samples for both tests (the meter test and the lab test are taken and tested within 15 minutes of each other).
2. Wash your hands before obtaining a blood sample.
3. Never use your meter with blood that has been collected in a gray-top test tube.
4. Use fresh capillary blood only.

You may still have a variation from the result because blood glucose levels can change significantly over short periods of time, especially if you have recently eaten, exercised, taken medication, or experienced stress\*1. In addition, if you have eaten recently, the blood glucose level from a finger stick can be up to 70 mg/dL (3.9 mmol/L) higher than blood drawn from a vein (venous sample) used for a



lab test\*2. Therefore, it is best to fast for eight hours before doing comparison tests. Factors such as the amount of red blood cells in the blood (a high or low hematocrit) or the loss of body fluid (severe dehydration) may also cause a meter result to be different from a laboratory result.

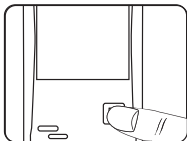
### REFERENCE:

- \*1. Surwit, R.S., and Feinglos, M.N.: Diabetes Forecast (1988), April, 49-51.
- \*2. Sacks, D.B.: "Carbohydrates." Burtis, C.A., and Ashwood, E.R. (ed.), Tietz Textbook of Clinical Chemistry. Philadelphia: W.B. Saunders Company (1994), 959.

## MEMORY RECALL

The **Inspire Advance** automatically stores 450 test results, letting you review them in order from the most recent to the oldest. The meter also calculates and displays 7, 14, 21, and 28-day averages. You can review the individual or average test result by entering the memory mode.

### *Recall the Memory*



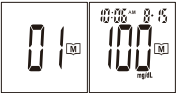

#### **STEP 1. Enter the Memory Mode**

While the meter is turned off, press MAIN BUTTON for twice to enter memory mode.



#### **STEP 2. Recalling Average Test Results**

When entering the memory mode, the 7-day average will appear. If you continue to press the MAIN BUTTON, the 14-day, the 21-day, and the 28-day averages will display in order.

	<b>STEP 3. Recalling Individual Test Results</b> After 28-day average, the most recent test result with date and time will be shown. Press MAIN BUTTON once and the next most recent test result will appear. Each time you press and release the MAIN BUTTON, the meter will recall up to your last 450 test results in order. When the memory is full, the oldest result is dropped as the newest is added.
	<b>STEP 4. Exit the Memory Mode</b> After reaching the last set of result, the meter will turn Off. Anytime in the memory mode, you can press and hold MAIN BUTTON for three (3) seconds to turn off the meter.

**NOTE:**

1. The control solution results are NOT stored in the memory if you preset the control test correctly. (Please refer to the “CONTROL SOLUTION TEST” Section for details). The list of past results and the result average are for blood glucose results only.
2. When using the meter for the first time, “----” is displayed. When you recall the test results or review the average result, it means that there is no test result in memory.
3. The averages are calculated from your latest result obtained during the last 7, 14, 21, and 28 days.
4. Anytime in memory mode, you can press MAIN BUTTON for 3 seconds to exit the memory mode.
5. While in the memory mode, if you leave the meter alone without any action for one (1) minute, the meter will turn off automatically.

### REVIEWING RESULTS ON A PERSONAL COMPUTER

Results in memory can be transmitted to a personal computer. **Inspire Advance** meter Diabetes Management Software and an interface cable are required before installation. The software and interface cable are optional accessories. To learn more about **Inspire Advance** meter Diabetes Management Software or to obtain an interface cable sold separately, please contact your local retailer or distributor.

#### STEP 1 Install Software

Install the **Inspire Advance** meter Diabetes Management Software on your computer step by step.

#### STEP 2 Connect to Personal Computer

Connect the transferring cable to your computer.

With the meter turned off, connect the Interface Cable to the data port of the meter. The meter will turn on and "PC" will appear on the display, indicating that the meter is ready to transmit data.

#### STEP 3 Transmit Data

Follow the instructions provided in the software to transmit data. Results transmitted will include date and time. Remove the transferring cable and the meter will automatically turn off.

#### NOTE:

While the meter is connected to the PC, it is unable to perform a blood glucose test.

## REPLACING THE BATTERY

The **Inspire Advance** comes with TWO 1.5v AAA alkaline batteries.

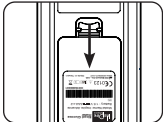
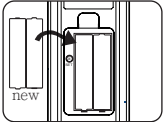
Battery life will vary depending on usage, so always keep a spare battery on hand.

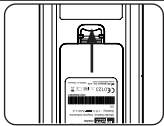
The battery should last about 1000 tests or 12 months when testing 3 times a day.

When the battery symbol appears on the meter display, battery is getting low. You will still be able to test with low battery, but you should replace it as soon as possible.

When battery symbol and E-b shows up in the meter display, the meter will no longer give results and you must replace the battery immediately. Please always have spare batteries with you to ensure that you can replace the battery anytime.


### *How to replace the battery*

 A line drawing of the back of the glucose meter. A downward-pointing arrow indicates the battery cover is being slid open.	<p>1. Make sure the meter is turned off. Let the front of the meter rest in the palm of your hand. Slide battery cover open.</p>
 A line drawing of the back of the glucose meter with the battery cover open. An arrow points to the old battery being removed. To the left, a new battery is shown with the word 'new' written below it.	<p>2. Remove the old batteries and replace with two (2) new 1.5V AAA size alkaline batteries.</p>



4. Close battery cover.

### NOTE:

1. Replacing the battery does not affect the test result stored in memory. However the time and date may need to re-set.
2. As with all small objects, the battery should be kept away from small children as a safety precaution. If the battery is swallowed, seek medical assistance immediately.
3. Batteries might leak chemicals if not used for a long time. Remove the batteries if you are not going to use the device for extended (i.e., 3 months or more).
4.  Please discard the used or dead batteries properly according to the regulations of your country.

## CARING FOR YOUR METER AND TEST STRIP

To avoid the meter and test strips getting dirt, dust or other contaminants, please wash and dry your hands thoroughly before use.

### *Cleaning*

Your meter does not require special maintenance. As long as no blood or control solution comes in direct contact with the meter, there is no special cleaning required.

1. To clean the meter exterior, wipe with a cloth moistened with tap water or a mild cleaning agent, then dry the device with a soft and dry cloth. Do not flush with water.
2. Do not use organic solvents to clean the meter. Your meter is a precision instrument. Please handle it with care.

## **Storage**

### **1. Meter Storage**

- Storage condition: -20°C~50°C (-4°F~140°F), below 90% relative humidity.
- Always store or transport the meter in its original storage case.
- Avoid dropping and strong impact.
- Avoid direct sunlight and humidity.

### **2. Strip Storage**

- Storage condition: 4°C~40°C (39°F~104°F), and between 10~85% relative humidity. Do not refrigerate.
- Store your test strips in their original vial only.
- Do not transfer to other container.
- Store test strip packages in a cool and dry place. Keep away from direct sunlight and heat.
- After removing a test strip from the vial, immediately replace the vial cap and close it tightly.
- Touch the test strip with clean and dry hands.
- You may touch the test strip anywhere with clean, dry hands when removing it from the vial or inserting it into the meter.
- Use each test strip immediately after removing it from the vial.
- Do not bend, cut, or alter a test strip in any way.

- Keep the strip vial away from children since the cap and the test strip can be a potential choking hazard. If swallowed, please seek medical assistance immediately.

### 3. Control solution storage

- Storage condition: Store the control solution tightly closed at temperatures below 30°C (86°F). Do not refrigerate.

## PERFORMANCE CHARACTERISTIC

### ***Accuracy***

>95% in A zone of EGA vs YSI 2300 glucose analyzer:

Within  $\pm 12$  mg/dL at glucose concentration < 75 mg/dL and within 15% glucose concentration  $\geq 75$  mg/dl

### ***Precision***

CVs %  $\leq 5\%$ , when glucose concentration  $\geq 75$  mg/dL

The device has been certified to meet the following standards:

98/97/EC, IEC 60601-1, IEC 61010-1, IEC 60601-1-2, IEC 61326, and ISO 15197



## SYSTEM SPECIFICATIONS



Model Name	<b>IMC-619 Inspire Advance</b>
Assay Method	Electrochemical biosensor
Test Sample	Capillary Whole Blood
Test Result	Referenced to plasma glucose value
Alternative Site Testing	YES (palm, forearm, upper arm, calf, or thigh)
Sample Size	0.7 $\mu$ L
Measuring Time	5 seconds
Measuring Range	20 – 600 mg/dL (1.1 – 33.3 mmol/L)
Acceptable Hematocrit Range	20~60%
Operating Condition	5°C~45°C(41°F~113°F), between 10-85% R. H.
Storage/Transportation Condition	4°C~40°C(39°F~104°F), between 10-85% R. H.
Memory Capacity	450 test results with time and date
Average Calculation	7, 14, 21, and 28 days
Power Supply	Two (2) 1.5-volt AAA Battery
Battery Life	Approximately 1,000 tests
Automatic shut-off	In 3 minutes
Dimensions	99 x 50 x 19.6 mm
Weight	58g (without battery)

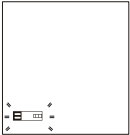


## DISPLAY MESSAGES AND PROBLEM-SOLVING GUIDE



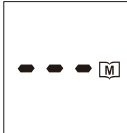
The following is a summary of some display messages and symbols. These messages help to identify certain problems but do not appear in all cases when a problem has occurred.


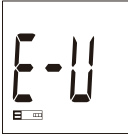

Improper use may cause an inaccurate result without producing an error message.



In the event of a problem, refer to information under “action to take”.

DISPLAY	DESCRIPTION	ACTION TO TAKE
	Display check	If some parts of the display are not working. Contact your local distributor for help.
	Display check	Meter is in the program check, wait to next meter display.






 A small icon of a test strip with a blinking arrow pointing to it, indicating the meter is waiting for a strip to be inserted.	Blinking Strip	The meter is waiting for test strip be insert.
 An icon showing a digital display with '00:00 AM 0:15' at the top and a blinking blood drop icon at the bottom, indicating the meter is ready for blood application.	Blinking Blood.	The meter is ready for blood applying into test strip.
 An icon showing a digital display with '00:00 AM 0:15' at the top and a large '100' in the center, with 'mg/dL' below it, indicating a test result.	Test result	Appears 5 seconds after applying the blood into test strip.

	<p>Test result is lower than 20 mg/dL (1.1 mmol/L)</p>	<p>High or low blood glucose levels can indicate a possibly serious medical condition. If this is not confirmed by the way you feel, review proper testing procedure and perform a control test. Repeat blood test, if the display still appears, please call medical assistance immediately.</p>
	<p>Test result is higher than 600 mg/dL (33.3 mmol/L)</p>	
	<p>Deleting memory</p>	<p>Deleting is complete</p>

	<p>Battery is dead</p>	<p>Replace battery now</p>
	<p>Maybe</p> <ol style="list-style-type: none"> <li>1. Used strip or moistened strip</li> <li>2. Defective meter.</li> </ol>	<p>You have to:</p> <ol style="list-style-type: none"> <li>1. Repeat test with a new test strip.</li> <li>2. Contact your local distributor for help.</li> </ol>
	<p>Temperature is below the operating range.</p>	<p>The meter is not working. Move to an area with temperature between 5°C to 45°C (41°F - 113°F) and wait at least 30 minutes. Do not artificially heat or cool the meter.</p>

	<p>The test strip was removed. When meter is counting form 05 to 01.</p>	<p>Repeat test with a new test strip.</p>
	<p>Blood sample is not sufficient.</p>	<p>Repeat test with sufficient sample.</p>
<p>No responses when test strip is inserted into the meter.</p>	<p>Maybe:</p> <ol style="list-style-type: none"> <li>1. Battery is dead.</li> <li>2. Wrong test strip be inserted.</li> <li>3. Meter is defective</li> </ol>	<p>You have to:</p> <ol style="list-style-type: none"> <li>1. Replace battery.</li> <li>2. Insert the test strip correctly.</li> <li>3. Contact your local distributor for help.</li> </ol>
<p>No responses when blood sample is applied to the test strip.</p>	<p>Maybe:</p> <ol style="list-style-type: none"> <li>1. Meter is defective.</li> </ol>	<p>You have to:</p> <ol style="list-style-type: none"> <li>1. Contact your local distributor for help.</li> </ol>

## SYMBOLS DESCRIPTION

<b>IVD</b>	For <i>in vitro</i> diagnostic use.		Temperature limitation / Store at.
	Please consult instructions for use.		Use by /Expiry date.
	Do not reuse.	<b>LOT</b>	Lot number.
<b>LOT</b>	Lot number.		Caution, consult accompanying document.
<b>CE 0123</b>	This product fulfils the requirements of Directive 98/79/EC in vitro diagnostic medical device.		

The device has certificated to meet the following standards:

98/79/EC, IEC 60601-1, IEC 61010-1, IEC 60601-1-2, IEC 61326, and ISO 15197.

## CONTACT INFORMATION

CE 0123

**Inspire Medical Corp.**

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Taiwan (R.O.C.)

tel:+886-2-838-4177

fax:+886-2-838-0392

[www.imedisource.com](http://www.imedisource.com)

E-mail: [service@imedisource.com](mailto:service@imedisource.com)



## LIMITED WARRANTY

linspire Medical Corp. warrants that the **Inspire Advance** meter shall be free of defects in material and workmanship for a period of five (5) years. This warranty is valid from the date of purchase. The warranty extends only to the original purchaser and is not transferable.

To obtain warranty service, you must take the Product, or deliver the Product freight prepaid, in either its original packaging or packaging affording an equal degree of protection, to linspire Medical Corp. or your local distributor.

To get full satisfaction, it should be properly used & maintained as per instructions & description provided in the user's manual.

The warranty covers only products purchased.

The Warranty does not cover the following:

1. Transportation costs & risks of transport.
2. Cost of repairs and / or defects resulting from repairs carried out by unauthorized persons.
3. Periodic check-ups, maintenance & repair.
4. Breakage of Display Screen and damage of delicate parts (viz., accidental dropping of the device or that of heavy object on the device).
5. Any exposure of device with dampness / water / spillage of solutions and excessive heat (including direct sunlight) causing damage to the device body, electronic and mechanical parts whether intentionally or otherwise.
6. Alteration / removal / defacing the Serial Number of the device.
7. Failure or wear & tear of accessories besides the main device (Meter) itself.
8. Damages of any kind including personal caused accidentally or by misuse.
9. Battery Replacement is not covered during warranty.

Costs arising due to non-acceptance of a claim (those will be charged for)  
Written notice of the specific manufacturing defect in workmanship or malfunction must be intimated.  
Repair or replacement under the warranty does not give rise to any extension or renewal of the warranty period.

This warranty will be applicable only if the complete product & the warranty card are sent and if the warranty card is completely filled-in & returned within ten (10) days.  
Inspire Medical Corp. & its authorized distributor / resellers reserve the right to refuse warranty services if any unclear information has been given.

**WARNING:** This apparatus may or may not suit all users. For your own safety and other healthcare reasons, you are strongly advised to consult your Doctor.

Disclaimer of warranty:

THIS WARRANTY IS EXPRESSLY MADE IN LIEU OF ANY AND ALL OTHER WARRANTIES EXPRESSED OR IMPLIED INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR USE.

Limitations of Liability:

In no event shall Inspire Medical Corp. & its distributors / resellers be liable for indirect special or consequential damages, even if Inspire Medical Corp. & its distributors / resellers has been advised of the possibility of such damages.

# Blood Glucose

Monitoring System

**Inspire**  
Advance

**FROM**

**STAMP**

**TO**



The manufacturer warrants to the original retail purchaser that this meter will be free from defects in materials and workmanship for 5 years from the date of the original purchase. During the 5 year period, we shall, at no charge, repair or replace a unit found to be defective with an equivalent or current version of the owner's model. The warranty of the repaired meter or replacement will expire on the date of the original warranty expiration or ninety (90) days after shipment of the repaired or replacement system, whichever period is longer. This warranty is limited to replacement due to defects in parts or workmanship. Failure of the meter due to damage by accident, abuse, or use not in accordance with the instructions is not covered by this warranty.

	Local distributor
<b>Inspire Medical Corp.</b> No.7, Ln. 57, Sec. 1, Zhiyu Rd., Shilin Dist., Taipei City 111, Taiwan (R.O.C.) tel:+886-2-838-4177 fax:+886-2-838-0392	

Name:
Address:
Telephone Number:
Email Address:
Meter Serial Number:
Date of Purchase:
Purchased From (Dealer Name):

Dealer stamp

