



**Remote Care  
Partners**

## Blood Glucose Meter

Model # ADF-B27/ADF-B27A



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Model # ADF-B27/ADF-B27A  
INSTRUCTION MANUAL

## INTRODUCTION

This Blood Glucose Meter is provided to by Remote Care Partners (RCP), for use exclusively with the health monitoring program from your provider.

Please read this manual carefully and keep it handy for future reference.

## NOTES ON SAFETY

**Please read this section carefully to familiarize yourself with the features and operations before using the unit.**

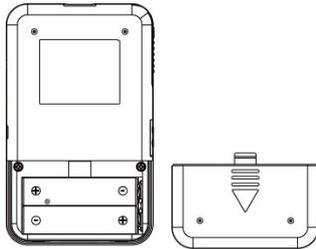
- 1. Do not allow other people to use your blood glucose meter. The meter is specifically assigned to you and you only. Allowing other people to use your meter can mislead your provider.**
2. All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have cleaned and disinfected all parts.
3. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
4. Do not place the device in liquid or put it where it could fall into the liquid.
5. Use of this device is only for the intended use described in this manual.
6. Only use AndesFit testing strips supplied by RCP.
7. Do not allow the device to contact surfaces that are too hot to touch.
8. Do not use the device where aerosol sprays are being used.

(Continued on Next Page)

9. Do not use the device if it is not working properly, or if it has been damaged.
10. Read the entire manual before using the product to test your blood glucose.
11. 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.

## INSTALLING THE BATTERIES

1. Open the battery cover on the back of the meter.



2. If replacing the batteries, remove the used batteries.
3. Insert 2 new (AAA) batteries with correct +/- direction.
4. Close the battery cover.

### Handling batteries properly

As soon as old batteries run out, replace them with new batteries.

- Do not use old and new batteries together.
- Align the polarities of batteries correctly.
- When the unit will not be used for more than 3 months, remove the batteries. Otherwise, batteries may leak and cause damage to the unit.

## QUICK START

**Prepare:** Wash your hands with soap and water. Dry thoroughly.

**Gather supplies:** Lancing device, lancet, tissue (for blotting blood from your finger after the puncture).

**Prepare the lancing device:** Unscrew the cap, push the lancet firmly into the device, remove the rounded end of the lancet by turning (save this piece), screw the cap back on, and adjust the puncture depth (usually 3).

**Prepare the meter:** Insert a test strip into the meter. When looking at the screen of the meter, the blue side of the strip should be facing you. The arrow on the strip should be pointing down so that the contact bars of the test strip are going into the meter. Push the strip into the meter until it stops and the meter turns on.

**Perform the test:** Place the lancet device on the finger you wish to use and press the blue button. Place a drop of blood into the absorbent hole of the test strip. Use the tissue to absorb any extra blood from your finger. The reading will display in the LCD window within 5 seconds.

**Cleanup up:** Unscrew the lancet device cap, use the long blue slider to eject the lancet into a sharps container or stab the lancet into the rounded end piece that was saved in step 3, pull out the testing strip from the meter and throw it away.

## INTRODUCTION

### Intended Use

- This meter is intended for self-testing by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It should be used only for testing glucose (sugar) and only with fresh capillary whole blood samples taken from the finger and the alternative sites including the palm, the forearm. It should not be used for the diagnosis or screening of diabetes. This meter is not for use with newborns.
- Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).
- The ADF-B27GTS Test Strips are the only strips to be used with this meter.

## HOW IT WORKS

The test is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the strip. The meter measures the current and displays the corresponding blood glucose level. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

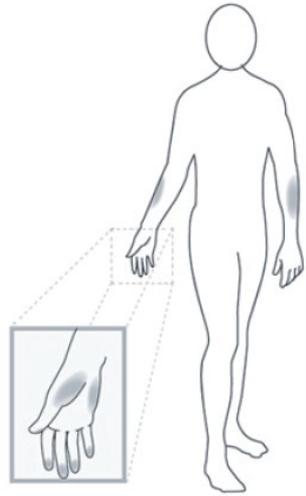
## ALTERNATIVE SITE TESTING (AST)

AST can be used only during steady-state blood glucose conditions described in the section of “About AST”.

**Important:** There are limitations for using AST. Please consult your healthcare professional before you do AST.

### What is AST?

Alternative site testing (AST) means that people use parts of the body other than the fingertips to check their blood glucose levels. This meter allows you to test on the palm or the forearm with the equivalent results to fingertips testing.



### The Advantage of AST

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

### When to use AST

Food, medication, illness, stress, and exercise can affect blood glucose levels. Capillary blood at the fingertip reflects these changes faster than capillary blood at other sites. Therefore, when testing blood glucose during or immediately after

a meal, physical exercise, or any other event, take a blood sample from your finger only.

Perform AST **ONLY** in the following instances:

- 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 exercising.

**NOTE:**

- AST should not be used to calibrate continuous glucose monitoring systems (CGMs).
- Results from alternative site testing should not be used in insulin doses calculations.

Do NOT use AST if:

- You think your blood glucose is low.
- You are testing for hypoglycemia (low blood sugar).
- You are testing for hyperglycemia (high blood sugar).
- Your AST results do not match the way you feel.
- Your routine glucose results are often fluctuating.

## CONTENTS OF YOUR KIT

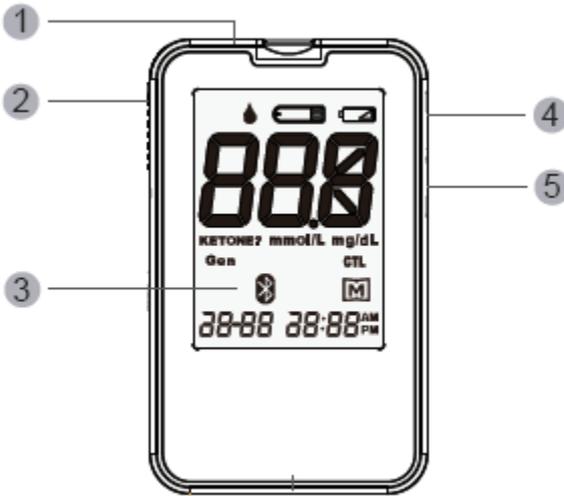
- A Meter
- Storage Bag
- Lancing Device
- Sterile lancet (Optional)

### NOTES:

- The Lancing Device can be used several times **however** the lancet should be changed after each use.
- Sterile lancets are not included in the standard kit

## PRODUCT OVERVIEW

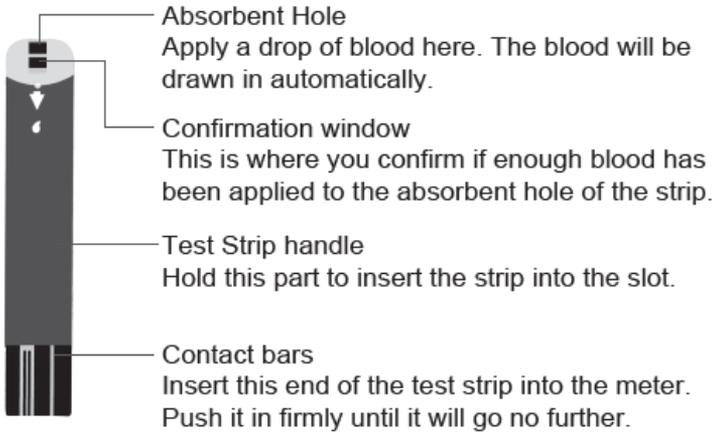
### The Blood Glucose Meter



- STRIP PORT  
Where you insert the test strip. The meter will turn on automatically
- STRIP EJECTOR  
Slide forward to eject the test strip after test
- LCD DISPLAY  
It guides you through the test using symbols and simple messages
- “M” BUTTON  
It is used to turn on the meter, enter the memory mode
- “S” BUTTON  
It is used to set up the meter

## The Test Strip

Each strip can be used only once. The test strip consists of the following parts:



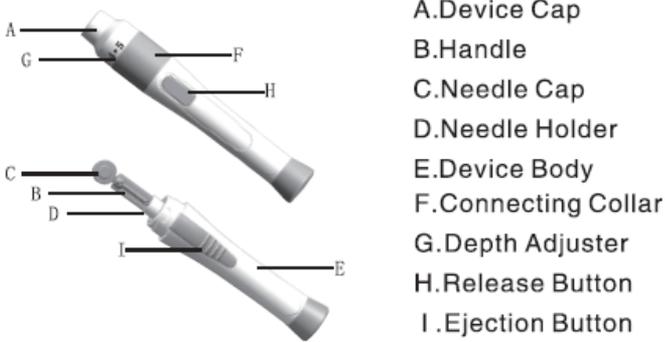
**Attention!**

Test results might be wrong if the contact Bar is not fully inserted into the test slot.

The front side of the test strip should face up when inserting the test strip.

The illustrations show a hand inserting a test strip into a meter slot. The top illustration shows the strip being inserted with the front side facing up, indicated by a downward arrow. The bottom left illustration shows the strip inserted with the front side facing up, marked with a checkmark and the word 'Front'. The bottom right illustration shows the strip inserted with the front side facing down, marked with an 'X' and the word 'Reverse'.

## The Lancing Device



If your lancing device is different from the one shown here, please refer to the manufacturer's manual to ensure proper usage.

### **To reduce the chance of infection:**

Never share a lancet or the lancing device.

Always use a new sterile lancet. Lancets are for single use only.

Wash your hands thoroughly before handling the lancing device or a lancet. Avoid getting hand lotion, oils, or dirt on the lancets.

## SETTING UP THE METER AND DELETING THE MEMORY

### Setting the date and time

|   |   |
|---|---|
| <p><b>Setting the Year</b><br/>Press and Hold “S” button for 3 seconds, until the last two digits of the year will flash on the screen. Press “M” button until the correct year appears. Press “S”.</p> |    |
| <p><b>Setting the month</b><br/>With the month flashing, press “M” until the correct month appears. Press “S”</p>   |    |
| <p><b>Setting the day</b><br/>With the day flashing, Press “M” until the correct day appears. Press “S”</p>   |    |
| <p><b>Setting AM/PM</b><br/>With the AM or PM flashing, Press “M” until the correct one appears. Press “S”.</p>   |   |
| <p><b>Setting the hour</b><br/>With the hour flashing, Press “M” until the correct hour appears. Press “S”</p>  |  |
| <p><b>Setting the minutes</b><br/>With the minute flashing, Press “M” until the correct minute appears. Press “S”.</p>  |  |

### Clearing the memory

Press "S". "dEL" will display along with a flashing "M".



Press "M" once to confirm that you want to clear the memory. If you want to cancel the process at this time, press "S". To continue and clear the memory, press "M" again. The meter will then display "OK" to confirm that the member has been cleared.

#### NOTES:

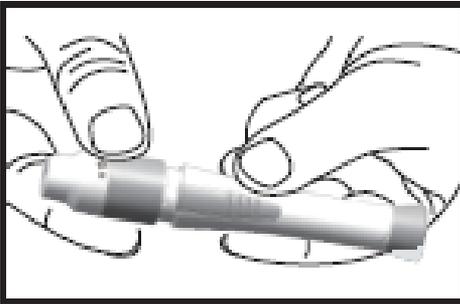
- The set date, set time, and clear memory functions can only be done when the meter is in the set-up mode.
- When the meter is in set-up mode, if no button is pressed within 3 minutes, the meter will automatically turn off.

**Do not allow other people to use your blood glucose meter. The meter is specifically assigned to you and you only. Allowing other people to use your meter can mislead your provider.**

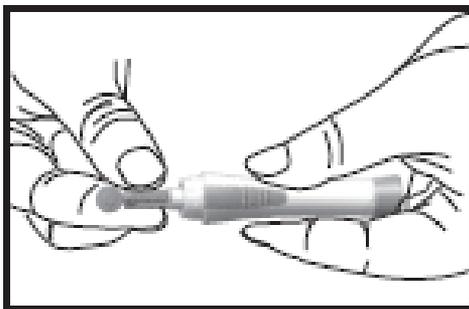
## TAKING A MEASUREMENT

**Wash your hands thoroughly with soap and warm water before taking a measurement**

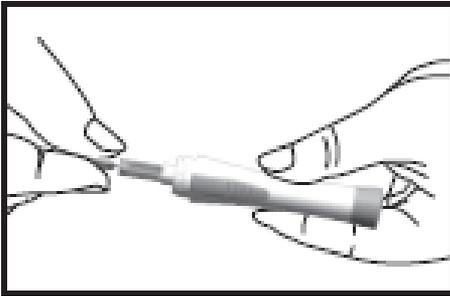
Set Up the Lancing Device



*1. Unscrew the cap from the lancing device*

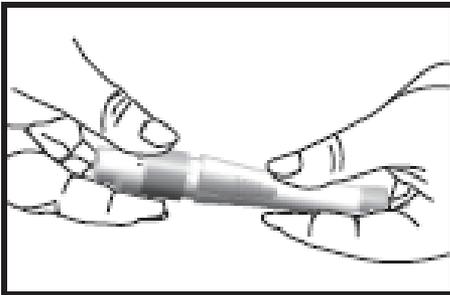


*2. Push the lancet all the way into the holder*

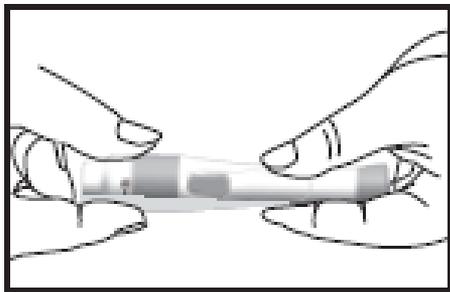


3. Gently turn and pull the needle cap to remove.

Save the needle cap so that the lancet needle can be safely capped for disposal after the test.



4. Replace the device cap



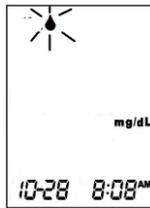
5.. Adjust the puncture depts (usually 3)

The lancing device is now ready to use.

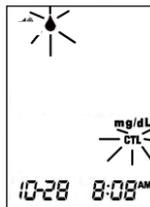
### Insert a test strip into the meter

With clean dry hands remove a single test strip from its vial. Do not bend, cut, or modify the test strips in any way.

Insert the test strip into the STRIP PORT at the top of the meter. When looking at the meter, the blue side of the strip should be facing you and the arrow on the strip is pointing down. The contact bars of the test strip are going into the meter. Push the strip into the meter until it stops and the meter turns on. The “blood drop” icon will flash at the top of the screen

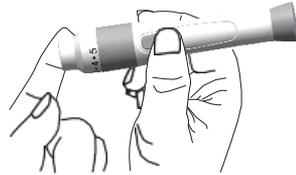


If the letters “CTL” show below the label “mg/DL” you have accidentally put the device in a calibration mode. **DO NOT TEST** if CTL is shown. Put the device back in test mode by pressing the “S” button on the right side of the device. This will clear the letter “CTL” and return the device to testing mode.



### Fingertip Testing

Hold the lancing device firmly against your fingertip. Press the release button on the side of the lancing device. You will hear a click, indicating that the puncture is complete.



### NOTES:

- Choose a different spot each time you test. Repeated punctures at the same spot may cause soreness and calluses.
- If you want to use AST please consult your physician.
- You should discard the first drop of blood from the puncture, as it might contain tissue fluid, which may affect the test result.

### Alternative Site Testing

**If you want to use Alternative Site Testing (AST) please consult your physician.**

- Determine AST location (palm/forearm)
- Rub the puncture site for about 20 seconds before penetration.
- Clean the puncture site using cotton moistened with 70% alcohol and let it air dry.

### Transfer blood to the test strip

Touch the blood sample to the absorbent hole at top of the test strip.

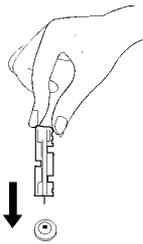
As soon as enough blood has filled the confirmation window of the test strip, you will hear a beep letting you know the test has begun. A countdown of 5 seconds starts

Your blood glucose level, along with the date and time, appears on the display. Blood glucose results are automatically stored in the memory and transferred to your provider's office.

### Reset your meter and lancing device

Eject the used test strip from the meter by sliding the strip ejector upward. Once the test strip is ejected, the meter will automatically turn off.

Unscrew the cap of the lancing device. Remove the lancet by sliding the ejection button upward.



Recap the lancet with the original cap.

## **Safely dispose of the test strip and the lancet**

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## UNDERSTANDING THE RESULTS

Reference value:

|                            |                         |
|----------------------------|-------------------------|
| Time of day                | People without diabetes |
| Before breakfast (fasting) | <100 mg/dL              |
| Two hours after meals      | <140 mg/dL              |

Source: American Diabetes Association. Standards of Medical Care in Diabetes-2012. Diabetes Care 2012,35 (Suppl.1)S11-S63. Please work with your doctor to determine a target range that works best for you.

## CARE AND STORAGE

- Handle the meter with care. Dropping or throwing the meter may cause damage to the device.
- Do not expose the meter or test strips to extreme conditions, such as high humidity, heat, freezing cold, or dust.
- Store test strips at temperatures between 39°F and 86°F. Humidity < 85%RH.
- Store the meter at temperatures between 40°F and 131°F, Humidity < 80%RH.
- Always wash your hands with soap and water and rinse and dry completely before handling the meter and test strip.
- Use disinfecting baby wipes to clean the Blood Glucose Monitoring System.
- Discard the used lancet into a container for sharp objects.

## CLEANING AND DISINFECTION

The cleaning and disinfection are absolutely necessary to maintain test accuracy and to minimize the chance of infection. **The meter should be cleaned and disinfected following use.**

## SPECIFICATIONS

|                      |   |
|----------------------|---|
| Model                | ADF-B27 / ADF-B27A*                           |
| Machine size         | 90mm (L)×54mm (W)×13mm(H)                     |
| Weight               | 73g (excluding batteries)                     |
| Measuring method     | Amperometric technology using glucose oxidase |
| Result range         | 20 mg/dL ~600 mg/dL (1.1 mmol/L ~33.3mmol/L)  |
| Glucose Units        | Either mg/dL or mmol/L*(ADF-B27A)             |
| Memory               | 500 blood glucose tests                       |
| Display              | LCD display with backlight                    |
| Power source         | DC 3V (AAA×2 alkaline batteries)              |
| Battery Life         | Approx. 500 normal tests                      |
| Storage (strips)     | 39°F and 86°F.<br>Humidity<85%RH.             |
| Storage (meter)      | 40°F and 131°F<br>Humidity<80%RH.             |
| Operating conditions | 50°F and 104°F<br>Humidity<80%RH.             |
| Blood Source         | Fresh capillary whole blood                   |
| Blood Volume         | Minimum 0.7 microliters.                      |
| Use life             | five years                                    |

## LIMITATIONS OF USE

- The meter is not intended for use on newborns.
- The meter is not intended for use on artery blood, newborns.
- The meter should be used with Andesfit test strips. (ADF-B27GTS)
- The system can be used up to an altitude of 10744 feet.
- Do not use a clotted blood sample.

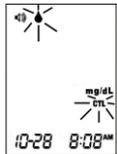
The following substances when used at greater than normal levels may produce inaccurate results by up to 10%:

| <b>Compound</b>    | <b>Limitation</b> |
|--------------------|-------------------|
| Acetaminophen      | ≤8.0mg/dL         |
| Ascorbic Acid      | ≤5.0mg/dL         |
| Bilirubin          | ≤90mg/dL          |
| Cholesterol        | ≤500mg/dL         |
| Creatinine         | ≤5.0mg/dL         |
| Dopamine           | ≤2.0mg/dL         |
| EDTA               | ≤360mg/dL         |
| Galactose          | ≤900mg/dL         |
| Gentisic Acid      | ≤5.0mg/dL         |
| Glutathione        | ≤53mg/dL          |
| Hemoglobin         | ≤500mg/dL         |
| Heparin            | ≤8000U/dL         |
| Ibuprofen          | ≤50mg/dL          |
| Icodextrin         | ≤13mg/dL          |
| L-dopa             | ≤10mg/dL          |
| Maltose            | ≤900mg/dL         |
| Methyldopa         | ≤3.0mg/dL         |
| Pralidoxime Iodide | ≤25mg/dL          |
| Salicylate         | ≤60mg/dL          |
| Tolazamide         | ≤100mg/dL         |
| Tolbutamide        | ≤400mg/dL         |
| Triglycerides      | ≤2000mg/dL        |
| Uric Acid          | ≤8.0mg/dL         |
| Xylose             | ≤100mg/dL         |

These substances do not affect test results in normal concentration.

- Patients undergoing oxygen therapy may yield falsely lower results.
- Not for use for patients in a hyperglycemic-hyperosmolar state, with or without ketosis.
- Not for use on critically ill patients.
- Not to be used for patients who are dehydrated, hypertensive, hypotensive, or in shock.
- Very low (less than 20%) or very high (more than 60%) red blood cell count (hematocrit) can lead to incorrect test results.
- If you do not know your hematocrit level, please consult your health care provider.

## DISPLAY MESSAGES

|   |  |  |
|---|--|--|
|    | <p>Blood glucose level is lower than 20mg/dL (1.1mmol/L)</p>   | <p>The message indicates very low blood sugar. You should seek immediate medical assistance.</p> |
|    | <p>Blood glucose level is higher than 600mg/dL (33.3mmol/L)</p>  | <p>This indicates severely high blood sugar. You should seek immediate medical assistance.</p>   |
|    | <p>Meter is ready to test the control solution under the CTL state.</p>                                  | <p>Please place a drop of control solution onto the test well of the test strip.</p>             |
|    | <p>Battery power is low.</p>   | <p>Please change the battery.</p>  |
|   | <p>The test strip is bad</p>   | <p>Please use a new test strip.</p>  |
|  | <p>Error message indicates that you may remove the strip after applying blood to the absorbent hole.</p> | <p>Try again with a new test strip.</p>  |

|   |  |  |
|---|--|--|
|  | <p>Problem with the meter</p>  | <p>Re-test with a new test strip. If the problem is still unsolved, please call the Customer Care Line for help.</p> |
|  | <p>Problem with the meter</p>  | <p>Re-test with a new test strip. If the problem is still unsolved, please call the Customer Care Line for help.</p> |
|  | <p>Environmental temperature is lower than 10°C (50°F) or higher than 40°C (104°F)</p> | <p>Please test at an environmental temperature within °C (50°F) or higher than 40°C (104°F)</p>                      |

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## TROUBLESHOOTING

| Problem  | Cause  | Solution                                |
|--|--|---|
| Display remains blank after the test strip has been inserted into the Meter. | Batteries may be installed improperly.   | Install the batteries correctly.        |
|  | Battery power is too low for use.  | Replace with new batteries.             |
|  | Too much time has passed between inserting the test strip and performing the test. | Reinsert the test strip into the meter. |
|  | Test strip has not been fully inserted into the meter                              | Reinsert the test strip into the meter. |

| Problem                            | Cause   | Solution   |
|------------------------------------|---|--|
| Test results are inconsistent      | Not enough blood on the test strip.   | Redo test with a new test strip and make sure that enough blood has been added.                                |
|                                    | Test strip has been damaged due to heat or humidity so that the sample cannot be applied or the speed of applying the sample is too slow. | Replace with a new vial of Test Strips   |
|                                    | System is not performing due to the environment being above or below room temperature.  | Bring the meter and strips to room temperature and wait approximately 30 minutes before performing a new test. |
| The Meter countdown did not start. | Test Strip has not been inserted correctly  | Redo test with a new test strip  |

## TECHNICAL SPECIFICATION

### Measurement Precision

#### Repeatability

|              |      |      |     |     |     |
|--------------|------|------|-----|-----|-----|
| Mean (mg/dL) | 40.3 | 82.0 | 130 | 202 | 325 |
| SD (mg/dL)   | 2.6  | 3.7  | 5.1 | 6.6 | 8.4 |
| CV (%)       | -    | 4.5  | 3.9 | 3.3 | 2.6 |

#### Intermediate precision

|              |      |       |     |
|--------------|------|-------|-----|
| Mean (mg/dL) | 44.4 | 108.1 | 342 |
| SD (mg/dL)   | 3.2  | 3.3   | 7.1 |
| CV (%)       | -    | 3.3   | 2.0 |

### System Accuracy

|   |                 |                 |
|---|-----------------|-----------------|
| For glucose concentration < 100 mg/dL                       |                 |                 |
| Within±5 mg/dL  | Within±10 mg/dL | Within±15 mg/dL |
| 101/180(56.1%)  | 164/180(91.1%)  | 178/180(98.9%)  |
| For glucose concentration ≥ 100 mg/dL                       |                 |                 |
| Within±5 mg/dL  | Within±10 mg/dL | Within±15 mg/dL |
| 195/420(46.4%)  | 349/420(83.1%)  | 410/420(97.6%)  |
| For glucose concentrations between 40.6 mg/dL and 504 mg/dL |                 |                 |
| Within±15 mg/dL or ±15%(Within ±0.83mmol/L or ±15%)         |                 |                 |
| 588/600(98.0%)  |                 |                 |

### Traceability of the glucose monitoring system

The results of the Blood Glucose Monitoring System were compared to parallel results obtained on YSI-2300, which is the manufacturer's standard measurement procedure.

### User Performance

A study evaluating glucose values from the fingertip, palm, and Forearm capillary blood samples obtained by 100 laypersons showed the following results

For glucose concentrations < 5.55 mmol/L (< 100 mg/dL)

| Puncture site             | Fingertip | Palm  | Forearm |
|---------------------------|-----------|-------|---------|
| ±15mg/dL<br>(±0.83mmol/L) | 96.3%     | 96.3% | 96.3%   |

For glucose concentrations ≥ 5.55 mmol/L (≥ 100 mg/dL)

| Puncture site | Fingertip | Palm  | Forearm |
|---------------|-----------|-------|---------|
| Within ±15%   | 99.3%     | 98.6% | 98.6%   |

### ELECTRICAL AND SAFETY STANDARDS

This meter complies with CISPR 11: Class B (Radiated Only). Emissions of the energy used are low and not likely to cause interference in nearby electronic equipment. The meter has been tested for immunity to Level 3 electrostatic discharge as specified in IEC 61326. This meter complies with immunity to radio frequency interference over the frequency range 80MHz to 2.5GHz at 3V/m as specified in IEC 61326-1 or 61326-2.

The meter meets the requirements for immunity to electrical interference at the frequency range and test level specified in international standard ISO 15197.

**CAUTION: Do not use the equipment where aerosol sprays are being used, or when oxygen is being administered.**

## SYMBOLS INDEX

| Symbol  | Referent                     | Symbol  | Referent                           |
|---|------------------------------|---|------------------------------------|
|  | Use by                       |  | Date of manufacture                |
|  | Consult instructions for use |  | Batch code                         |
|  | CAUTION                      |  | In vitro diagnostic medical device |
|  | Keep away from sunlight      |  | Catalog number                     |
|  | Keep dry                     |  | Serial number                      |
|  | Temperature limitation       |  | Control                            |

## CONTACT INFORMATION AND NOTICES

### **Remote Care Partners**

855-477-7000

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

### **AndseFit LTD**

Unit 513 Lakeside 1,  
No. 8 Science Park West Ave  
Hong Kong Science Park  
Hong Kong

### **FCC Compliance Statement**

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 WARNING

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 the receiver.
- Connect the equipment into an outlet different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.