

# CareTouch<sup>®</sup>

Blood Glucose and  $\beta$ -Ketone Monitoring System



**Owner's Manual**

### Dear Care Touch System Owner:

Thank you for choosing the **Care Touch** Blood Glucose and  $\beta$ -Ketone Monitoring System. This manual provides important information to help you to use the system properly. Before using this system, please read the following contents thoroughly and carefully.

The System measures blood glucose, and  $\beta$ -ketone. Regular monitoring of your blood glucose and  $\beta$ -ketone levels can help you and your doctor gain better control of your diabetes. Due to its compact size and easy operation, you can use the **Care Touch** Blood Glucose and  $\beta$ -Ketone Monitoring System to easily monitor your blood glucose and  $\beta$ -ketone levels by yourself anywhere, any time.

If you have other questions regarding this product, please contact the local customer service or place of purchase.

### Intended Use

Care Touch Blood Glucose and  $\beta$ -Ketone Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood from the finger, and for the quantitative measurement of  $\beta$ -ketone (beta-hydroxybutyrate) in fresh capillary whole blood from the finger. The Care Touch is intended for in vitro diagnostic use and is intended for single-patient use as an aid to monitor the effectiveness of a diabetes control program. The system should not be used for the diagnosis of or screening for diabetes.

# IMPORTANT SAFETY PRECAUTIONS

## READ BEFORE USE

- 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!
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

For more information, please visit

1. “FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication” (2010)

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>

2. “CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens” (2010)

<http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>

1. Use this device ONLY for the intended use described in this manual.
2. Do NOT use accessories which are not specified by the manufacturer.
3. Do NOT use the device if it is not working properly or if it is damaged.

4. Do NOT use the equipment in places where aerosol sprays are being used, or where oxygen is being administered.
5. Do NOT under any circumstances use the device on neonates or infants.
6. This device does NOT serve as a cure for any symptoms or diseases. The data measured is for reference only.
7. Before using this device, read all instructions thoroughly and practice the test. Carry out all the quality control checks as directed.
8. Keep the device and testing equipment away from young children. Small items such as the battery cover, batteries, test strips, lancets and vial caps are choking hazards.
9. Do not use this instrument in close proximity to sources of strong electromagnetic radiation, as this may interfere with the accurate operation.
10. Proper maintenance and periodically control solution test are essential to the longevity of your device. If you are concerned about your accuracy of measurement, please contact your local customer service or place of purchase for help.

**KEEP THESE INSTRUCTIONS IN A SAFE PLACE**

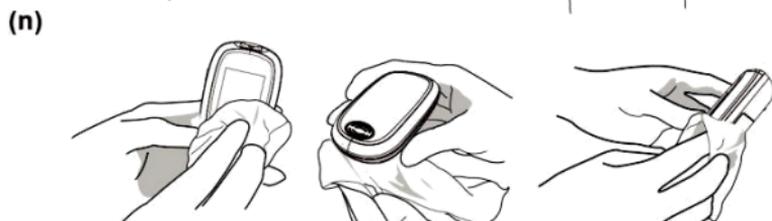
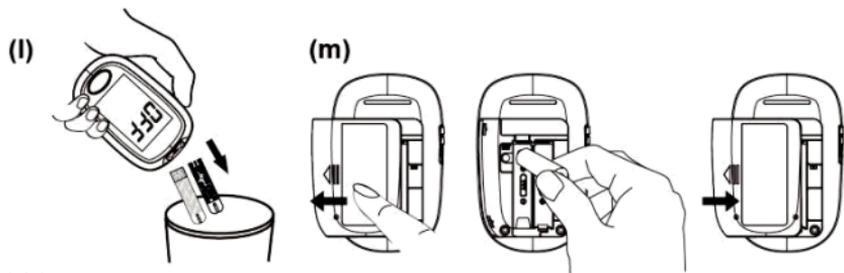
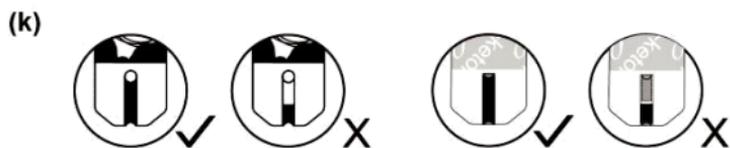
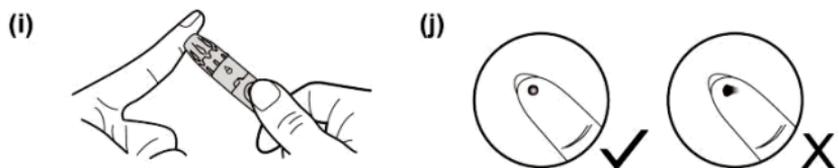
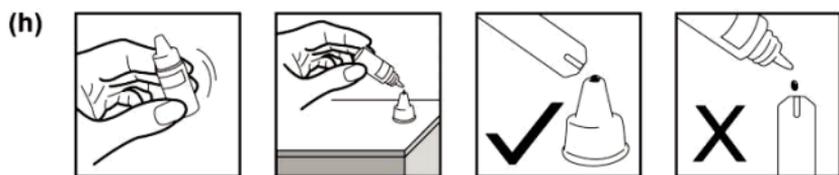
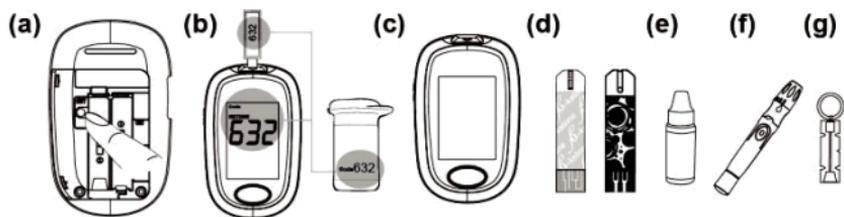
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# BEFORE YOU BEGIN

## Important Information

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- Severe dehydration and excessive water loss may cause readings which are lower than actual values. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.
- If your blood glucose results or  $\beta$ -ketone are lower or higher than usual, and you do not have any symptoms of illness, first repeat the test. If you have symptoms or continue to get results which are higher or lower than usual, follow the treatment advice of your healthcare professional.
- Use only fresh whole blood samples to test your blood glucose or  $\beta$ -ketone. Using other substances will lead to inaccurate results.
- If you are experiencing symptoms that are inconsistent with your blood glucose or  $\beta$ -ketone test results and you have followed all the instructions given in this owner's manual, contact your healthcare professional.
- The device should not be used on severely hypotensive individuals or patients in shock. Readings which are lower than actual values may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis. Please consult the healthcare professional before use.
- Limitation

The device should not be used on individuals in hyperglycemic-hyperosmolar state, with or without ketosis; not for neonatal use; not for use on critically ill patients.

## Test Principle

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Your system measures the amount of sugar (glucose) or  $\beta$ -ketone in whole blood. The glucose or  $\beta$ -ketone testing is based on the measurement of electrical current generated by the reaction of glucose or  $\beta$ -ketone with the reagent of the strip. The meter measures the current, calculates the blood glucose or  $\beta$ -ketone level, and displays the result. The strength of the current produced by the reaction depends on the amount of glucose or  $\beta$ -ketone in the blood sample.

## Contents of System

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Your new blood glucose and  $\beta$ -ketone monitoring system kit includes:

1. Meter
2. Owner's Manual
3. Protective Wallet
4. Quick Start User Guide

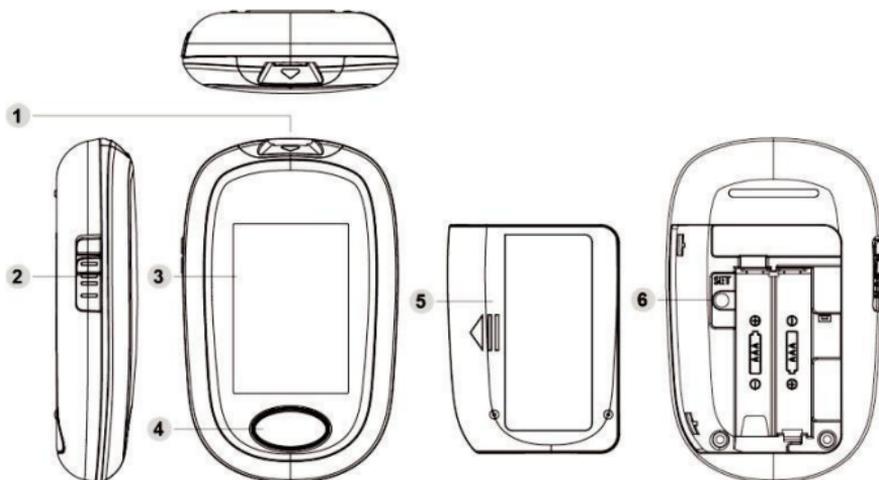
Test strips (d), control solutions (e), sterile lancets (g) or lancing device (f) are not included in the kit. They must be purchased separately. Please make sure you have those items needed for a test beforehand.

### **NOTE:**

If any items are missing from your kit or opened prior to use, please contact local customer services or place of purchase for assistance.

## Meter Overview (awaits update)

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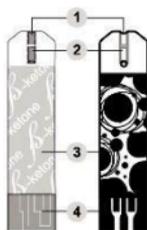
- 1. Test Strip Slot & Strip Indicator**  
Insert test strip here to turn the meter on for testing. Connect strip port cable for data transmission.
- 2. Test Strip Ejector**  
Eject the used strip by pushing up this button.
- 3. Display Screen**
- 4. M Button (M)**  
Enter the meter memory and silence a reminder alarm.
- 5. Battery Compartment**
- 6. SET Button (S)**  
Enter and confirm the meter settings.

## Display Screen

1. Glucose Symbol
2. Ketone Symbol/  
Ketone Warning
3. Test Result
4. Warning Symbol
5. Low Battery Symbol
6. Day Average
7. Memory Symbol
8. Date/Time
9. Measurement Unit
10. Measurement Modes  
*AC – before meal PC – after meal Gen – any time of day  
QC – control solution test*
11. Test Strip Symbol
12. Blood Drop Symbol
13. Code



## Test Strip



1. Absorbent hole
2. Confirmation window
3. Test strip handle
4. Contact bars



### Attention:

The front side of the test strip should face up when inserting the test strip. Test results might be wrong if the contact bar is not fully inserted into the test slot.

## NOTE:

The **Care Touch Blood Glucose and  $\beta$ -ketone Monitoring System** should only be used with **Care Touch Test Strips**. Using other test strips with this monitoring system may produce inaccurate results

## SETTING THE METER

Before using your meter for the first time or if you change the meter battery, you should check and update these settings.

### Entering the Setting Mode (a)

Start with the meter off (no test strip inserted). Press **SET (S)**.

#### 1. Setting the date

The sequence of the date setting is: YEAR → MONTH → DAY. With the YEAR/MONTH/DAY flashing in sequence, press **M button (M)** until the correct year/month/day appears. Press **S**.

#### 2. Setting the time format

Press **M** to select the desired time format (12h or 24h). Press **S**.

#### 3. Setting the time

With the Hour/Minute flashing in sequence, press **M** until the correct hour/minute appears. Press **S**.

#### 4. Setting the measuring unit

With the measuring unit flashing, press **M** to switch between mg/dL or mmol/L. Press **S**.

#### 5. Setting the buzzer

With the  flashing, press **M** to switch between "On" and "Off". Press **S**.

#### 6. Deleting the memory

With "dEL" and a "" symbol on the display, press **M** and select

“no” to keep the results in memory then press **S** to skip. To delete all the results, press **M** and select “yes” to delete all memory records.

#### 7. **Setting the reminder alarm**

The meter has four reminder alarms. The meter will display “OFF” and “AL1”. If you don’t want to set an alarm, press **S** to skip this step; or press **M** to select “On”, then press **S**. With the hour/minute flashing in sequence, press **M** to select the correct hour/minute. Press **S** and go to the next alarm setting.

#### NOTICE:

When the alarm beeps, press **M** to switch it off. Otherwise, it will beep for 2 minutes then switch off.

#### 8. **Setting the backlight**

The default setting for meter backlight (“BL”) is set to ON. Press **M** to switch between “On” and “OFF”. Press **S**.

**Congratulations! You have completed all settings!**

#### NOTE:

- These parameters can **ONLY** be changed in the setting mode.
- If the meter is idle for 3 minutes during the setting mode, it will switch off automatically.

## THE FOUR MEASURING MODES

The meter provides you with four modes for measuring: General, AC, PC and QC. You can switch between each mode by:

1. Start with the meter switched off. Insert a test strip to turn on the meter. The screen will display a flashing blood drop and “Gen”.
2. Press **M** button to switch between General, AC, and PC modes.

## BEFORE TESTING

### Calibration

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You must calibrate the meter every time you begin to use a new vial of  $\beta$ -Ketone test strips by setting the meter with the correct code. Test results may be inaccurate if the code number displayed on the monitor does not match the number printed on the strip vial.

### How to Code Your Meter (for $\beta$ -Ketone)(b)

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1. Insert the code strip when the monitor is off. Wait until the code number appears on the display.

#### **NOTICE:**

Make sure the code number on display, code strip, and test strip vial are the same. The code strip should be within the expiry date; otherwise, an error message may appear.

2. Remove the code strip, the display will show "OK". This tells you that the meter has finished coding and is ready for  $\beta$ -ketone testing.

### Checking the Code Number

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You need to make sure that the code number displayed on the meter matches the number on your test strip vial before you proceed. If it matches, you can proceed with your test. If the codes do not match, please stop testing and repeat the calibration procedure. If the problem persists, contact Customer Service for help.

#### **NOTICE:**

The codes used in this manual are examples only; your meter may display a different code.

## **WARNING:**

- It is important to make sure that the LCD displayed code is the same as the code on your test strip vial before testing. Failure to do so will get inaccurate results.
- The code number for  $\beta$ -Ketone strip is three-digits; please ensure you are using the correct strips for the test.
- If the LCD displayed code is not the same as the code on your test strip vial and the code number cannot be updated, please contact Customer Service for assistance.

## **Control Solution Testing**

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Our Control Solution contains a known amount of glucose that reacts with test strips and is used to ensure your meter and test strips are working together correctly.

### **Do a control solution test when:**

- You first receive the meter
- At least once a week to routinely check the meter and test strips
- You begin using a new vial of test strips
- You suspect the meter or test strips are not working properly
- Your blood glucose or ketone test results are not consistent with how you feel, or if you think the results are not accurate
- Practicing the testing process, or
- You have dropped or think you may have damaged the meter

## **Performing a Control Solution Test**

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To perform a control solution test, you will need: (c), (d) and (e).

1. Insert the test strip into the meter. There will be a strip light indicating the test strip is inserted into the test slot. Wait for the meter to display “” and “”.

2. **Press M to mark this test as a control solution test**

With “QC” displayed, the meter will store your test result in memory under “QC”. If you press **M** again, the “QC” will disappear and this test is no longer a control solution test.

3. **Apply Control Solution (h)**

Shake the control solution vial thoroughly before use. Squeeze out a drop and wipe it off, then squeeze out another drop and place it on the tip of the vial cap. Hold the meter to move the absorbent hole of the test strip to touch the drop. Once the confirmation window fills completely, the meter will begin counting down. To avoid contaminating the control solution, do not directly apply control solution onto a strip.

4. **Read and Compare the Result**

After counting down to 0, the control solution test result will appear on the display. Compare this result with the range printed on the test strip vial and it should fall within this range. If not, please read the instructions again and repeat the control solution test.

With “QC” displayed, the meter will store your test result in memory under “QC”.

**Out-of-range results**

If you continue to have test results fall outside the range printed on the test strip vial, the meter and strips may not be working properly. Do **NOT** test your blood. Call customer service at 1.866.890.8500 for help.

**NOTE:**

- The control solution range printed on the test strip vial is for control solution use only. It is not a recommended range for your blood glucose or ketone level.
- See **MAINTENANCE** section for important information about your control solutions.

## TESTING WITH BLOOD SAMPLE

### WARNING:

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.
- Avoid getting hand lotion, oils, dirt, or debris in or on the lancets and the lancing device.
- Wash and dry your hands thoroughly after handling the meter, lancing device and test strips to prevent infection. For more information, please refer to the “**Cleaning and Disinfection**” section.
- If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be decontaminated prior to use by the second person.

**Sharing the lancing device and lancets may increase the risk of contracting infectious diseases. Lancing device must not be used for more than one person.**

### Preparing the Lancing Device for Blood Testing

Please refer to the manufacturer’s instructions for the lancing device to collect a blood sample.

### Preparing the Puncture Site

Stimulating blood perfusion by rubbing the puncture site before blood extraction significantly reduces variations between measurements.

Please follow the suggestions below before obtaining a drop of blood:

- Wash and dry your hands before starting.
- Select the puncture site at fingertips

- 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.

### **Fingertip testing (i)**

Press the lancing device's tip firmly against the lower side of your fingertip. Press the release button to prick your finger, then a click indicates that the puncture is complete.

#### **NOTE:**

- Choose a different spot each time you test. Repeated punctures at the same spot may cause soreness and calluses.
- It is recommended that you discard the first drop of blood as it might contain tissue fluid, which may affect the test result.

## Performing a Blood Glucose / $\beta$ -Ketone Test

To perform a blood glucose or  $\beta$ -ketone test, you will need: meter (c), strip (d), sterile lancet (g) and lancing device (f).

### 1. **Insert the test strip to turn on the meter**

Wait for the meter to display ““ ” and “GLU”, or “KETONE”.

### 2. **Select the appropriate measuring mode by pressing M.**

### 3. **Obtaining a blood sample (j)**

Use the pre-set lancing device to puncture the desired site(i). Wipe off the first appeared drop of blood with a clean cotton swab. Gently squeeze the punctured area to obtain another drop of blood. The volume of blood sample must be at least 0.9 microliter (  $\mu$ L) for blood glucose test, 1.0 microliter ( $\mu$ L) for blood  $\beta$ -Ketone test. Be careful **NOT** to smear the blood sample.

### 4. **Apply the Sample (k)**

Gently apply the drop of blood to the absorbent hole of the test strip at a tilted angle. Confirmation window should be completely filled if enough blood sample has been applied. Do **NOT** remove your finger until you hear a beep sound.

#### **NOTE:**

- Do not press the punctured site against the test strip or try to smear the blood.
- If you do not apply a blood sample to the test strip within 3 minutes, the meter will automatically turn off. You must remove and reinsert the test strip to start a new test.
- The confirmation window should be filled with blood before the meter begins to count down. **NEVER** try to add more blood to the test strip after the drop of blood has moved away. **Discard the used test strip and retest with a new one.**

- If you have trouble filling the confirmation window, please contact your health care professional or the local customer service for assistance.

## 5. Read Your Result

The result of the blood glucose test /  $\beta$ -ketone will appear after the meter counts down to 0. The blood glucose /  $\beta$ -ketone test result will automatically be stored in the memory.

## 6. Remove the used test strip and lancet (m)

Eject the test strip by pushing the eject button on the side. Use a sharp bin to dispose of used test strips. The meter will switch itself off automatically.

**Always follow the instructions in the lancing device package insert when removing the lancet.**

### **WARNING:**

- The used lancet and test strip may be biohazards. Please follow your healthcare provider's recommendations for proper disposal.
- Wash your hands thoroughly with soap and water after handling the meter, lancing device and test strips to avoid contamination. For more information, please refer to the "**Cleaning and Disinfection**" section.

## **METER MEMORY**

The meter stores the 1000 most recent blood glucose or  $\beta$ -ketone test results along with respective dates and times in its memory. To enter the meter memory, **start with the meter switched off.**

## Reviewing Test Results

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### 1. **Press and release M.**

“**M**” will appear on the display. Press **M** again, and the first reading you see is the last blood glucose or  $\beta$ -ketone test result along with date, time and the measurement mode.

### 2. **Press M** to recall the test results stored in the meter each time you press. After the last test result, press **M** button again and the meter will be turned off.

## Reviewing Blood Glucose Day Average Results

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### 1. **Press and release M.**

When “**M**” appears on the display, keep pressing **M** for 3 seconds until the flashing “**DAY AVG**” appears. Release **M** and then your 7-day average result measured in general mode will appear on the display.

### 2. **Press M to review** 7-, 14-, 21-, 28-, 60- and 90- day average results stored in each measuring mode in the order of Gen, AC, and then PC.

### 3. **Exit the meter memory.** Keep pressing the **M** button and the meter will turn off after displaying the last test result.

#### **NOTE:**

- Any time you wish to exit the memory, keep pressing **M** button for 5 seconds or leave it without any action for 3 minutes. The meter will switch off automatically.
- Control solution results are **NOT** included in the day average.

## DOWNLOADING RESULTS TO A COMPUTER

### Data transmission via cable

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You can use the meter with a strip port cable and the Health Care Software System to view test results on your personal computer. To learn more about the Health Care Software System or to obtain a strip port cable separately, please contact local customer services or the place of purchase for assistance.

1. Obtaining the required cable and installing the software.
2. To download the Health Care Software System, please visit the TaiDoc's website: [www.taidoc.com](http://www.taidoc.com).

3. Connecting to a personal computer

Connect the strip port cable to a cable port on your computer. With the meter switched off, insert the other end of the strip port cable to the meter data port. "PC" will appear on the meter display, indicating that the meter is in communication mode.

4. Data transmission

To transmit data, follow the instructions provided with the software. Results will be transmitted with date and time. Remove the cable and the meter will automatically switch off.

#### **WARNING:**

While the meter is connecting to the personal computer, it will be unable to perform a blood glucose /  $\beta$ -ketone test.

# MAINTENANCE

## Battery

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Your meter comes with two 1.5 V AAA size alkaline

### batteries. **Low Battery Signal**

The meter will display one of the messages below to alert you when the meter power is getting low.

1. The “” symbol appears along with display messages:  
The meter is functional and the result remains accurate, but it is time to change the batteries.
2. The “” symbol appears with E-b and “ **LOW**”:  
The power is not enough to do a test. Please change the batteries immediately.

### **To replace the batteries, make sure that the meter is turned off.** (o)

1. Press the edge of the battery cover and lift it up to remove.
2. Remove the old batteries and replace with two 1.5 V AAA size alkaline batteries.
3. Close the battery cover. If the battery is inserted correctly, you will hear a "beep" afterwards.

#### **NOTE:**

- Replacing batteries does not affect the test results stored in the memory.
- As with all small batteries, these batteries should be kept away from small children. If swallowed, promptly seek medical assistance.
- Batteries might leak chemicals if unused for a long time. Remove

batteries if you are not going to use the device for an extended period (i.e., 3 months or more).

- Properly dispose of batteries according to your local environmental regulations.

## Caring for Your Meter

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To avoid the meter and test strips attracting dirt, dust or other contaminants, please wash hands thoroughly with soap and water before and after use.

### **Why the cleaning and disinfection should be performed**

Cleaning and disinfection are different. Cleaning is the process of removing dirt (e.g. food debris, grease, dust), while disinfection is the process of killing germs (e.g. bacteria and viruses).

### **When to clean and disinfect the meter**

Clean the meter when you see any dirt on it. You should disinfect the meter at least once a week to prevent infection.

### **How to clean and disinfect the meter**

The meter must be cleaned prior to the disinfection. Use one disinfecting wipe to clean exposed surfaces of the meter thoroughly and remove any visible dirt or blood or any other body fluid with the wipe. Use a second wipe to disinfect the meter. **Do NOT use organic solvents to clean the meter.**

We recommend for meter cleaning and disinfection you should use the disinfecting wipes/towelettes from below. The following product with isopropyl alcohol as the active ingredient has been shown to be safe for use with the blood glucose and  $\beta$ -ketone monitoring system:

- Micro-Kill<sup>+</sup>™ (Micro-Kill Plus™) by Medline (EPA Reg. No. 59894-10-37549)

To obtain disinfecting wipes and other information, please contact Future Diagnostics LLC at 1.866.890.8500. You can also purchase it at Amazon ([www.amazon.com](http://www.amazon.com)) or Walmart ([www.walmart.com](http://www.walmart.com)).

## Disinfecting Procedures

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1. Wipe all meter's exterior surface display and buttons by three passes vertically and three passes horizontally with a folded disinfecting towelette. Hold the meter with the test strip slot pointing down and wipe the area around the test slot but be careful not to allow excess liquid to get inside. Keep meter wet with disinfection solution contained in the wipe for a minimum of 2 minutes for Micro-Kill+™ wipes. (o)
2. Remove the wipe. Allow the meter surface to dry completely.
3. Discard the used wipes and never reuse them. Users should wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

Improper system cleaning and disinfection may result in meter malfunction. If you have a question, please contact local customer service at 1.866.890.8500 for assistance.

This device has been validated to withstand up to 10950 cleaning and disinfection cycles using the recommended disinfecting wipe/towelette. The tested number of cycles is estimated by 10 cleaning and disinfection cycles per day over 3 years. The meter should be replaced after the validated number of cleaning and disinfection cycles or the warranty period, whichever comes first.

Stop using the meter if you see any signs of deterioration. For example:

- Meter cannot be turned on
- LCD display cracks or becomes cloudy
- Buttons no longer function
- Meter outer casing cracks
- Data cannot be transmitted to pc

- Color or paint/printing on housing is abnormal
- Scratches or abrasions on meter are higher than acceptable

**Please contact the customer service for a replacement meter if any of the signs of deterioration are noticed.**

**NOTE:**

- Do NOT clean and disinfect the meter while performing tests.
- If the meter is being operated by a second person, the meter and lancing device should be decontaminated prior to use by the second person.
- Do NOT allow cleaning and disinfecting solution to get in the test slot, battery compartment, or strip-ejection button.
- If you do get moisture in the test strip slot, wipe it away with a corner of tissue.
- Always dry the meter thoroughly before using it
- Do not spray the meter directly with cleaning solutions especially those containing water (i.e. soapy water), as this could cause the solution to enter the case inside and damage the electronic components or circuitry

## Caring for Your Test Strips

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- Storage conditions (for the blood glucose /  $\beta$ -Ketone test strip):
  - Temperature: 35.6°F to 86°F (2°C to 30°C)
  - Humidity: 10 to 85%RH
  - Do not freeze
- Store your test strips in their original vial only. Do not transfer to another container.
- Store test strip packages in a cool dry place. Keep away from direct sunlight and heat.
- After removing a test strip from the vial, immediately close the vial cap tightly.
- Touch the test strip with clean and dry hands.
- Use each test strip immediately after removing it from the vial.
- Do not use test strips after the expiration date. This may cause inaccurate results.
- 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 may be a choking hazard. If swallowed, promptly see a doctor for help.

For further information, please refer to the test strip package insert.

## Important Control Solution Information

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- Use only our Control Solutions with your meter.
- Do not use the control solution after the expiration date or 3 months after first opening. Write the opening date on the control solution vial and discard the remaining solution after 3 months.
- It is recommended that the control solution test be done at room temperature (68°F ~ 77°F / 20°C ~ 25°C). Make sure your control solution, meter, and test strips are at this specified temperature range before testing.
- Shake the vial before use, discard the first drop of control solution, and wipe off the dispenser tip to ensure a pure sample and an accurate result.

- Store the control solution tightly closed at temperatures between 35.6°F ~ 86°F (2°C ~ 30°C). Do **NOT** freeze.

## SYSTEM TROUBLESHOOTING

If you follow the recommended action but the problem persists, or error messages other than the ones below appear, please contact your local customer service. Do not attempt to repair yourself and never try to disassemble the meter under any circumstances.

### Result Readings

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#### Glucose Test

MESSAGE	WHAT IT MEANS
<b>Lo</b>	< 20 mg/dL (1.1 mmol/L)
<b>KETONE</b>	≥ 240 mg/dL (13.3 mmol/L)
<b>H<sub>i</sub></b>	> 600 mg/dL (33.3 mmol/L)

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#### β-Ketone Test

MESSAGE	WHAT IT MEANS
<b>Lo</b>	< 0.1 mmol/L
<b>H<sub>i</sub></b>	> 8.0 mmol/L

## Error Messages

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MESSAGE	WHAT IT MEANS	ACTION
E-b	Appears when the battery cannot provide enough power for a test.	Replace the battery immediately.
E-2	Expired code strip.	Repeat the test with a new lot of test strip.
E-U	Appears when a used test strip is inserted.	Repeat the test with a new test strip.
E-0	Problem in operation.	Repeat the test with a new test strip. If the meter still does not work, please contact the customer service for assistance.
E-A		
E-E		
E-F	Appears when test strip is removed while counting down, or other problems in operation.	Repeat the test with a new test strip.
E-C	Appears when the wrong code strip is inserted or other coding errors.	Make sure to insert the right code strip for the meter. Check if the code numbers on the code strip and the strip vial label are the same.
E-t	Appears when ambient temperature is below or above system operation range.	System operation range is 46.4°F ~ 113°F (8°C ~ 45°C). Repeat the test after the meter and test strip are in the above temperature range.

## Troubleshooting

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1. If the meter does not display a message after inserting a test strip:

POSSIBLE CAUSE	WHAT TO DO
Battery exhausted.	Replace the battery.
Test strip inserted upside down or incompletely.	Insert the test strip with contact bars end first and facing up.
Defective meter or test strips.	Please contact customer services.

2. If the test does not start after applying the sample:

POSSIBLE CAUSE	WHAT TO DO
Defective test strip.	Repeat the test with a new test strip.
Sample applied after automatic switch-off (3 minutes after last user action).	Repeat the test with a new test strip. Apply sample only when flashing "💧" appears on the display.
Defective meter.	Please contact customer services.

3. If the control solution testing result is out of range.

POSSIBLE CAUSE	WHAT TO DO
Error in performing the test.	Read instructions thoroughly and repeat the test again.
Control solution vial was poorly shaken.	Shake the control solution vigorously and repeat the test again.
Expired or contaminated control solution.	Check the expiry date of the control solution.
Control solution that is too warm or too cold.	Control solution, meter, and test strips should be at room temperature (68°F ~ 77°F / 20°C ~ 25°C) before testing.
Defective test strip.	Repeat the test with a new test strip.
Meter malfunction.	Please contact customer services.
Improper working of meter and test strip.	Please contact customer services.

## DETAILED INFORMATION

### Reference values

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Blood glucose monitoring plays an important role in diabetes control. A long-term study showed that maintaining **blood glucose levels close to normal** can reduce the risk of diabetes complications by up to 60%\*<sup>1</sup>. The results provided by this system can help you and your healthcare professional monitor and adjust your treatment plan to gain better control of your diabetes.

Time of day	Normal plasma glucose range for people without diabetes (mg/dL)
Fasting and before meal	Less than 100 mg/dL (5.6 mmol/L)
2 hours after meals	Less than 140 mg/dL (7.8 mmol/L)

\*1: American Diabetes Association: Diabetes Care, January 2015, volume 38 (Suppl. 1) S8-S16.

The  $\beta$ -Ketone test measures Beta-Hydroxybutyrate ( $\beta$ -OHB), the most important of the three  $\beta$ -Ketone bodies in the blood. Normally, levels of  $\beta$ -OHB are expected to be less than 0.6 mmol/L.

$\beta$ -OHB levels may increase if a person fasts, exercises vigorously or has diabetes and becomes ill. If your  $\beta$ -Ketone result is 0.0 mmol/L, repeat the  $\beta$ -Ketone test with new test strips. If the same message appears again or the result does not reflect how you feel, contact your healthcare professional. Follow your healthcare professional's advice before you make any changes to your diabetes medication programme. If your  $\beta$ -Ketone result is between 0.6 and 1.5 mmol/L, this may indicate development of a problem that could require medical assistance. Follow your healthcare professional's instructions. If your  $\beta$ -Ketone result is higher than 1.5 mmol/L, contact your healthcare professional promptly for advice and assistance. You may be at risk of developing diabetic ketoacidosis (DKA).

**Please consult your doctor to determine a target range that works best for you.**

## Comparing Meter and Laboratory Results

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The meter provides you with whole blood equivalent results. The result you obtain from your meter may differ somewhat from your laboratory result due to normal variation. Meter results may 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 going to the lab:**

- Perform a control solution test to make sure that the meter is working properly.
- Fast for at least eight hours before doing comparison tests, if possible.
- Take your meter with you to the lab.

### **While staying at the lab:**

Make sure that the samples for both tests are taken and tested within 15 minutes of each other.

- Wash your hands before obtaining a blood sample.
- Never use your meter with blood that has been collected in a gray-top test tube.
- Use fresh capillary or venous blood only.

You may still have a variation from the result because blood glucose or  $\beta$ -ketone levels can change significantly over short periods of time, especially if you have recently eaten, exercised, taken medication or experienced stress<sup>\*2</sup>. In addition, if you have eaten recently, the blood glucose level from a finger prick 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<sup>\*3</sup>. 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 (dehydration) may also cause a meter result to be different from a laboratory result.

\*2: Surwit, R.S., and Feinglos, M.N.: Diabetes Forecast (1988), April, 49-51.

\*3: Sacks, D.B.: "Carbohydrates." Burtis, C.A., and Ashwood, E.R.( ed.), Tietz Textbook of Clinical Chemistry. Philadelphia: W.B. Saunders Company (1994), 959.

## SYMBOL INFORMATION

SYMBOL	REFERENT	SYMBOL	REFERENT
	<i>In vitro</i> diagnostic medical device		Do not use if package is damaged
	Consult instructions for use		Humidity Limitation
	Temperature limitation		Do not reuse
	Keep dry		Keep away from sunlight
	Caution, consult accompanying documents		

## SPECIFICATIONS

Model No: Care Touch

Dimension: 96.5 (L) x 60.5 (W) x 22 (H) mm

Weight: 67g

Power Source: Two 1.5 V AAA alkaline batteries

Display: LCD

Memory: 1000 measurement results with respective date and time

External output: Strip port cable communication

Auto electrode insertion detection

Auto reaction time count-down

Auto switch-off after 3 minutes without action

Temperature Warning

Operating Condition: 50°F ~ 104°F (10°C ~ 40°C), 10% to 85% R.H. (non-condensing)

Meter Storage/Transportation Conditions: -4°F ~ 140°F (-20°C ~ 60°C), below 95% R.H.

Glucose Test Strip Storage / Transportation Conditions: 35.6°F to 86.0°F (2°C to 30°C), 10% to 85% R.H. (non-condensing), up to 21 months for un-opened vial

β-Ketone Test Strip Storage / Transportation Conditions: 35.6°F to 86.0°F (2°C to 30°C), 10 to 85% R.H. (non-condensing), up to 18 months for un-opened vial

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

Glucose Measurement Range: 20 to 600 mg/dL (1.1 ~ 33.3 mmol/L)

β-ketone Measurement Units: mmol/L

β-ketone Measurement Range: 0.1 ~ 8.0 mmol/L

This device has been tested to meet the electrical and safety requirements of: IEC/EN 61010-1, IEC/EN 61010-2-101, IEC/EN 61326-1, IEC/EN 61326-2-6.



# CareTouch<sup>®</sup>

**Distributed by**

**Future Diagnostics LLC**

266 47<sup>th</sup> Street

Brooklyn, NY 11220

1.866.890.8500

**Hours of operation 9:00am-5:00pm EST**

For assistance outside of these hours, please contact your healthcare professional.



For self-testing