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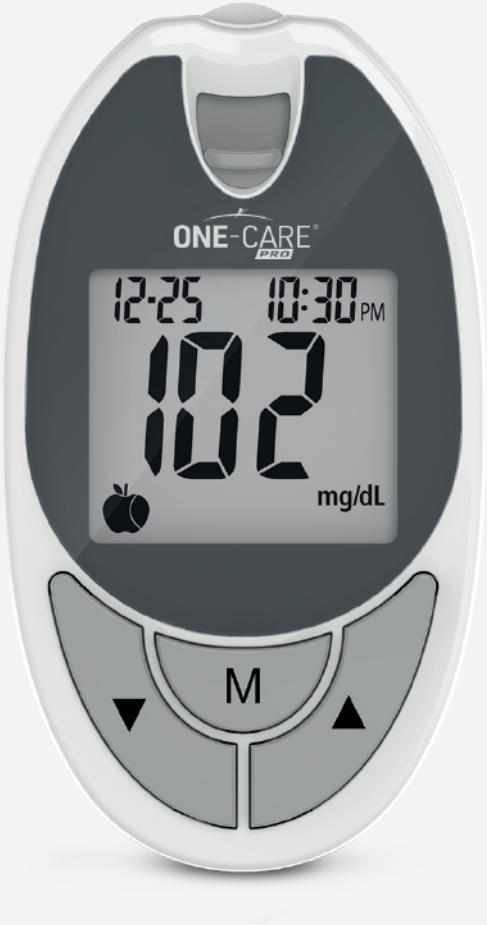
ONE-CARE® PRO



Operations & Procedures Manual

ONE-CARE® PRO Blood Glucose Monitoring System (Model AC500 PRO)

For in vitro diagnostic use only

TABLE OF CONTENT

INTRODUCTION

Thank you for choosing the ONE-CARE® PRO (Model AC500 PRO) Blood Glucose Monitoring System. As you already know, self monitoring of blood glucose (SMBG) is a necessary part of the treatment plan of people with diabetes mellitus. Adapted for its ease of use and quick response time, the ONE-CARE® PRO (Model AC500 PRO) Blood Glucose Monitoring System has the ability to process accurate results utilizing only a small volume of blood for in vitro diagnostics.
The ONE-CARE® PRO (Model AC500 PRO) Blood Glucose Monitoring System is been designed with auto coding feature. It means the meter will code itself automatically every time you insert a test strip.

Please read the entire User's Manual carefully before using this product.

INTENDED USE STATEMENT

The ONE-CARE® PRO (Model AC500 PRO) Blood Glucose Monitoring System is Intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip, palm, or forearm. The ONE-CARE® PRO (Model AC500 PRO) Blood Glucose Monitoring System is intended for testing outside the body (in vitor diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. This system should only be used with auto disabling, single-use lancing devices.
The ONE-CARE® PRO (Model AC500 PRO) Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).
The ONE-CARE® PRO (Model AC500 PRO) Blood Glucose Test Strips are for use with the ONE-CARE® PRO (Model AC500 PRO) Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

IMPORTANT SAFETY INSTRUCTIONS

• Users need to adhere to Standard Precautions when handling or using this device. All parts of the glucose monitoring system should be considered potentially infectious and are capable of transmitting bloodborne pathogens between patients and healthcare professionals. For more information, refer to "Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007", http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html.
• The meter should be disinfected after use on each patient. This Blood Glucose Monitoring System may only be used for testing multiple patients when Standard Precautions and the manufacturer's disinfection procedures are followed.
• Only auto-disabling, single use lancing devices may be used with this device.
Cleaning Solution and Disinfecting Solution: CaviCide Surface Disinfectant (Metrex Research Co., EPA Reg. No. 46781-6) For more product information, contact Metrex at 1-800-841-1428 or visit website at www.metrex.com.

ABOUT THE PRODUCT

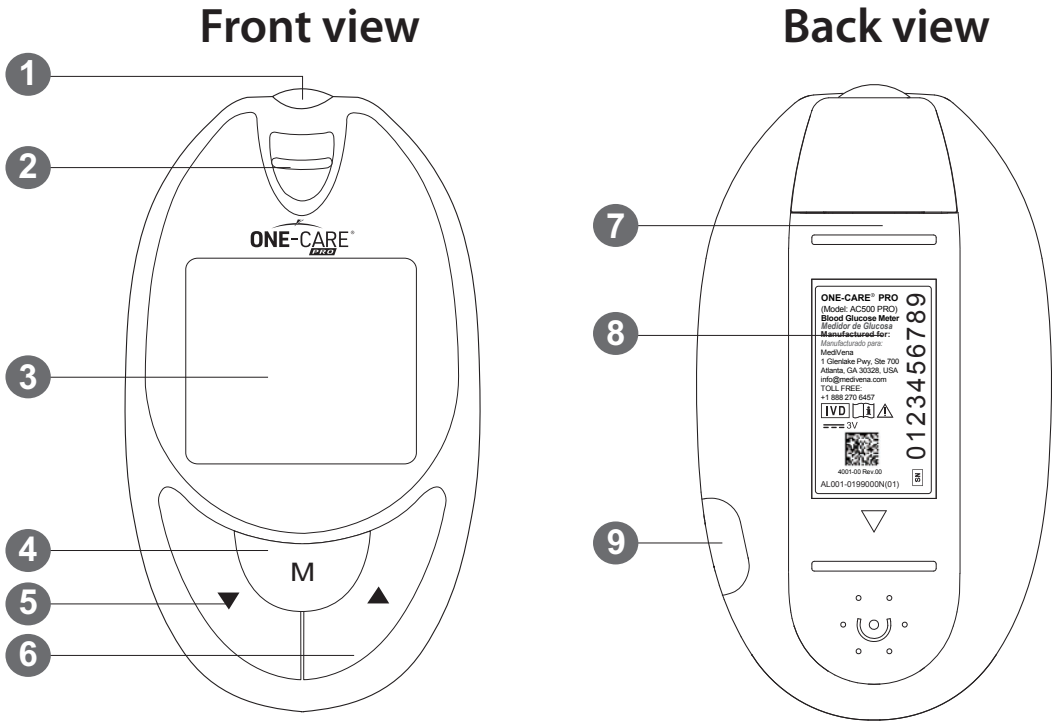
Your ONE-CARE® PRO (Model AC500 PRO) Blood Glucose Monitoring System is made up of several components. This booklet is designed to guide you through the operation of the system with detailed directions and pictures. Your ONE-CARE® PRO (Model AC500 PRO) Blood Glucose Monitoring System contains:

- ONE-CARE® PRO (Model AC500 PRO) Blood Glucose Meter
- ONE-CARE® PRO (Model AC500 PRO) User Manual

Note: 50 test strips vial can be purchased individually.

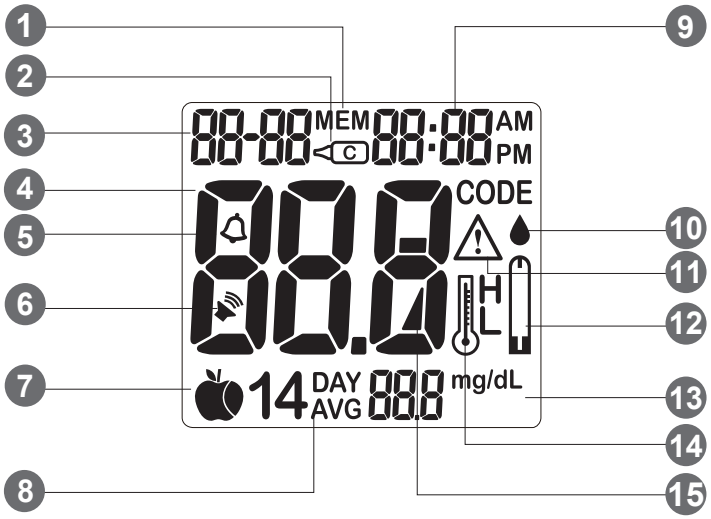
ABOUT THE METER

1. Test Port	Insert the test strip here.
2. Strip Eject Button	Press this button to ejects the test strip.
3. Display	Shows blood glucose results and messages.
4. M Button	Press this button to set the year/date/time; to view results and test average in memory; to enter control solution test mode or to turn the meter off.
5. ▼Button	Press this button to decrease number/move forward in meter setting. Press this button to set the reminder alarm and HI / LO alarm.
6. ▲Button	Press this button to increase number/move backward in meter setting.
7. Battery Cover	Slide cover to install and replace batteries.
8. Label	Contains meter serial number and customer service phone number.
9. Data Port (Side of the meter)	Connect interface cable to transfer data.



ABOUT THE METER DISPLAY

1. **Memory Symbol**
   Indicates in memory mode.
2. **Control Solution Test**
   Appears when doing a control solution test and marking the result as a control solution test.
3. **Date**
4. **Test Result Area**
   Display test results.
5. **Alarm Function Symbol**
   Appears when the clock alarm is set.
6. **Buzzer Icon**
   Appears when buzzer is ON
7. **Meal Indicator**
   Pre-meal and post-meal
8. **Day Average Symbol**
   Shows the average value of test results.
9. **Time**
10. **Blood Drop Symbol**
    Flashes when it is ready to apply sample to test strip.
11. **Warning Symbol**
    Appears when result is out of the range of your setting reference value.
12. **Test Strip Symbol**
    Appears to tell you when the meter is ready for test.
13. **Unit of Measurement**
    Unit of mg/dL will appear with the test result
14. **Temperature Message**
    Appears if your meter is out of operating temperature range.
15. **Battery Symbol**
    Appears when the battery is low or must be replaced.

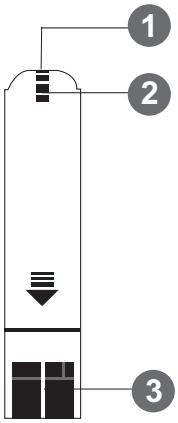


ABOUT THE TEST STRIP

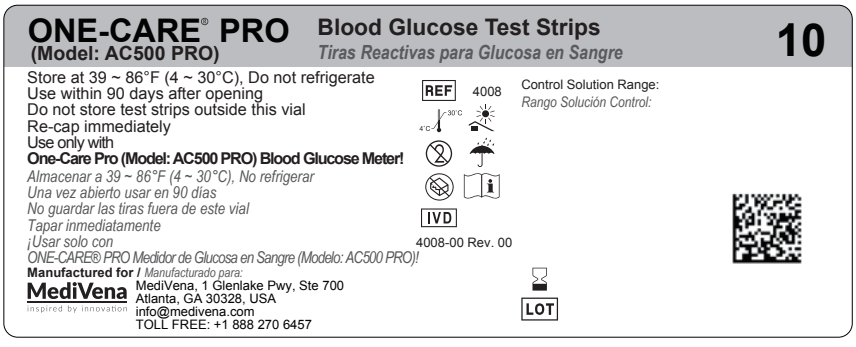
Each strip can be used only once.

The test strip consists of the following parts:

1. **Target Area**
   This is where blood is drawn into the test strip.
2. **Confirmation Window**
   This is where you can confirm that enough blood has been applied to the target area.
3. **Contact Bar**
   This end of the test strip is inserted into the test port to activate the meter. (white side face up).



ABOUT THE TEST STRIP VIAL

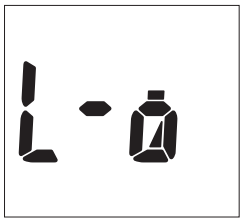


Test Strip Vial Label

Test Strip Vial

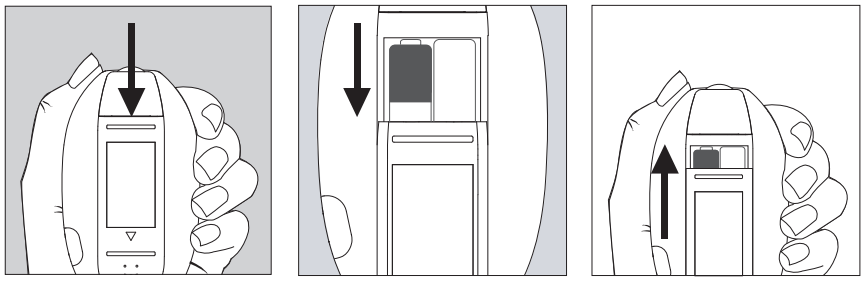
INSTALLING/REPLACING THE BATTERY

When the battery is low, the meter will show a warning signal. When this display appears, it is time to replace a new battery. When the low battery warning signal is shown, the meter will provide accurate results for approximately 50 more measurements.



How to Replace the Battery

1. From the back of the meter, gently slide and remove the battery cover.
2. Insert the batteries (two AAA) with the + and – ends matching the marks in the battery compartment.
3. Slide battery cover back into place.

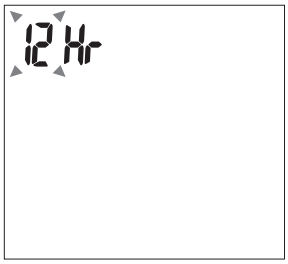


SETTING UP THE METER

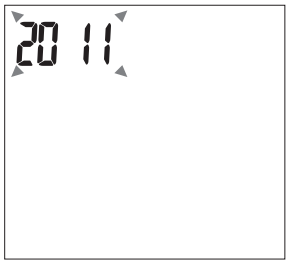
To turn the meter on, first install the batteries, then proceed with the following instructions.

SETTING THE DATE, TIME

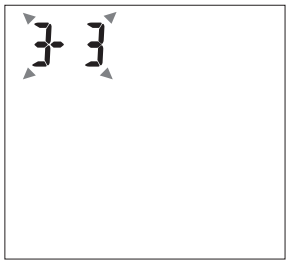
1. Press and hold M for 4 seconds with meter turn off to enter this mode.
2. Press ▲ or ▼ to select "24hr" or "12hr" setting. Press M to set. (Fig.1)
3. The year will now appear and flash. Press ▲ or ▼ to select the year. Press M to set. (Fig.2)
4. The number in the month position will now flash. Press ▲ or ▼ to select the month. Press M to set. (Fig.3)
5. The day will now flash. Press ▲ or ▼ to select the date. Press M to set. (Fig.3)
6. The number in the hour position will now flash. Press ▲ or ▼ to select the hour. Press M to set. (Fig.4)
7. The minute will now flash. Press ▲ or ▼ to select the minute. Press M to set. The date and time you set will show on the display screen. Press M to turn off the meter. You have now completed the meter date/ time setting. (Fig.4)



(Fig.1)



(Fig.2)



(Fig.3)

(Fig.4)

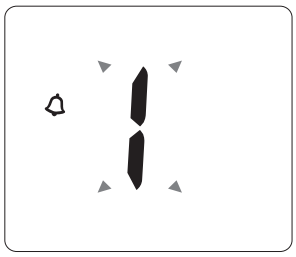
SETTING THE REMINDER ALARM

The meter provides four user setting reminder alarms for worry free testing. (Default is alarm off.)

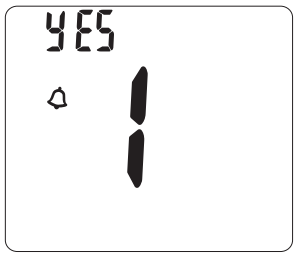
1. Press and hold ▼ for 4 seconds with meter turn off to enter this mode.
2. The first reminder alarm will appear on the display. (Fig.5). Press ▲ or ▼ to seclect which alarm you want to set (number 1 to 4). Press **M** to confirm.
3. Press ▲ or ▼ to select "YES" or "NO". If "NO" is chosen and **M** is pressed, the meter goes back to reminder alarm setting mode. If "YES" is chosen, press **M** to confirm and the time will appear. (Fig.6)
4. The number in the hour position will now flash. Press ▲ or ▼ to seclect hour. Press **M** to set. (Fig.7)
5. The minutes will now flash. Press ▲ or ▼ to select the minutes. Press **M** to set and meter will goes to reminder alarm setting. (Fig.8)
6. Press ▲ or ▼ to seclect reminder alarm 2 to 4. Repeat steps 3 to 5 to set the next three reminder alarms. (if needed).
7. After finishing reminder alarm setting, Hl alarm setting appear.

NOTE:

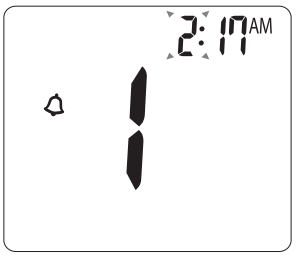
When the alarm is ringing, press any one button to turn off or the alarm will turn off automatically after 30 sec.



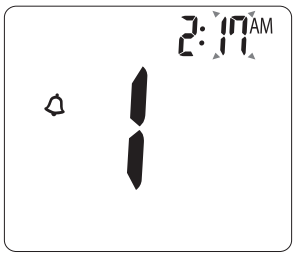
(Fig.5)



(Fig.6)



(Fig.7)

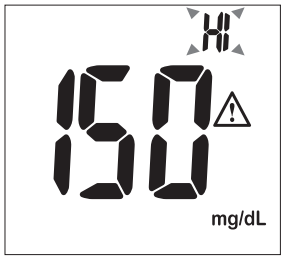


(Fig.8)

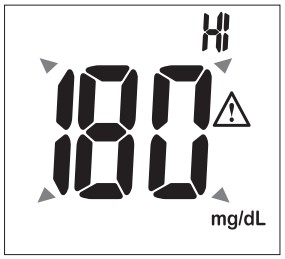
SETTING THE HI / LO ALARM

1. Press and hold ▼ for 4 seconds with meter turn off to enter this mode.
2. Press and release▼ to move through reminder alarm setting, the HI alarm setting will appear. Press **M** to confirm. (Fig.9)
3. To change HI alarm setting, press ▲ or ▼ until you reach your desired HI setting and then press **M** to set. (The HI alarm value range is 100-400mg/dL / 6.0-21.0mmol/L, default is 180mg/dL / 10mmol/L.) (Fig.10)
4. To change LO alarm setting(Fig.11), press ▲ or ▼ until you reach your desired value and then press **M** to set. (Fig.12). You have now completed the meter alarm setting. Press **M** to turn off the meter. (The LO alarm value range is 30-90mg/dL / 2.4-5.8mmol/L, default is 70mg/dL / 4.0mmol/L.)

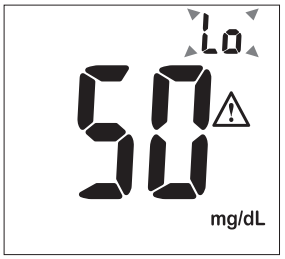
NOTE:
The hypoglycemic (LO) and hyperglycemic (HI) alarm glucose values should be selected in consultation with your health care provider.



(Fig.9)



(Fig.10)

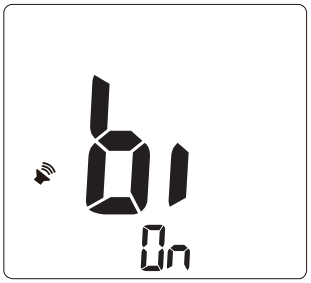


(Fig.11)

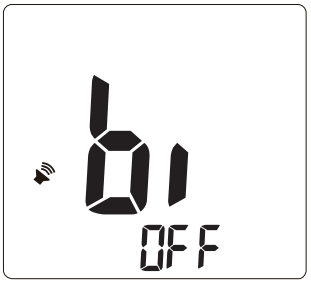
(Fig.12)

SETTING THE SOUND

1. Press and hold ▲ for 4 seconds with meter turn off to enter this mode. The "bi and speaker icons" display will appear. (Fig.13)
2. If you want to hear a beep sound during testing, press ▲ or ▼ to select "On", then press **M** to set. To turn the beep sound off, press ▲ or ▼ to select "OFF", then press **M** to set. (Fig.14)



(Fig.13)



(Fig.14)

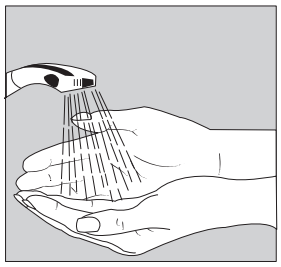
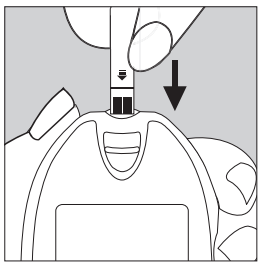
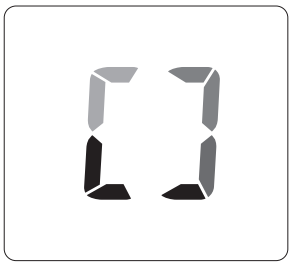
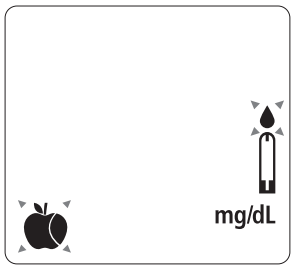
You have to know before testing

- Always keep the test strips in the original vial only. Tightly close the vial immediately after removing a test strip.
- Do not use test strips and control solutions beyond the expiration date printed on the package since this may cause inaccurate results.
- Use each strip immediately after removing it from the vial. Each test strip can be used once.
- **Any change or administer of medication based on the ONE-CARE® PRO (Model AC500 PRO) blood glucose test results without the consent and advice of a physician or healthcare fessional is not recommended.**
- Low or high blood glucose readings can indicate a potentially serious medical condition. If your blood glucose reading is unusually low or high, or if you do not feel the way your reading indicates, repeat the test with a new test strip. If your reading is not consistent with your symptoms or if your blood glucose result is less than 60 mg/dL (3.3 mmol/L) or higher than 240 mg/dL (13.3 mmol/L) you should contact your healthcare fessional and follow his or her treatment advice.

Before testing blood glucose, you need the following items:
1. ONE-CARE® PRO (Model AC500 PRO) meter
2. ONE-CARE® PRO (Model AC500 PRO) test strip
3. Single use disposable safety lancet

PREPARING THE TEST STRIP

1. Wash hands using soap and warm water. Rinse and dry thoroughly.
2. Pull out a test strip from the vial and re-cap the vial immediately.
3. Insert the test strip, white side face up, into the test port. The meter will automatically turn on.
4. A beep will sound, and a clockwise moving dotted lines will appear.
5. After system checking ok, a flashing "💧" symbol will appear. You can press ▲or▼ to select the meal indicator for marking the test as premeal or postmeal test (default premeal).
6. Now you are ready to obtain a blood sample.

OBTAINING A BLOOD SAMPLE

SAMPLE MAY BE OBTAINED FROM FINGER, PALM or FOREARM

1. Twist and pull off protective tab to break seal on lancet and place in disposal.
2. Position lancet firmly against puncture site as illustrated. Press down firmly until an audible click is heard.
3. To obtain sufficient blood sample, hold the puncture site downward and gently apply intermittent pressure to the surrounding tissue.
4. Dispose of used lancets at the point of use in an approved sharps container. Never reuse lancets.



Note:
Auto-disabling, single use lancing device is commonly available at medical supply distributors or drug stores.
CAUTION:
All parts of the glucose monitoring system should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and healthcare professionals.
To reduce the chances of infection:

- ***Only an auto-disabling, single use lancing device should be used.***
- ***Wear gloves during any procedure that involves potential exposure to blood or body fluids. A new pair of clean gloves should be worn by the user before testing each patient.***
- ***Whenever possible, blood glucose meters should be assigned to an individual person and not be shared.If blood glucose meters must be shared, the device should be cleaned and disin fected after every use,to prevent carry-over of blood and infectious agents.***
- ***Refer to section "Cleaning and disinfection procedure" (page.45) for how to clean / disinfect the meter.***
- ***Wash hands throughly with soap and water after handling the meter, lancing device, or test strips.***

Please refer the following practice guidelines:

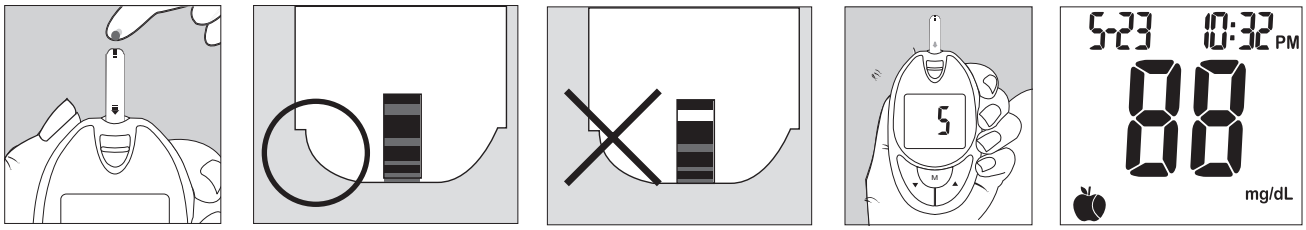
- *Biosafety in Microbiological and Biomedical Laboratories (BMBL) found at http://www.cdc.gov/biosafety/publications/bmbl5/*
- *"Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guide line-Third Edition" Clinical and Laboratory Standards Institute (CLSI) M29-A3.*

APPLYING BLOOD SAMPLE TO THE TEST STRIP

1. After obtaining a blood sample, discard the first drop of blood prevent the contamination of body fluid, touch the tip of the test strip to the drop of blood. Blood is automatically drawn into the test strip. Hold the tip of the test strip touching the blood drop until the meter beeps.
2. As soon as enough blood has filled the confirmation window (see picture) of the test strip, the meter will starts the countdown from 5 to 1. Your blood glucose result will appear on the display and will be stored into the meter memory automatically.

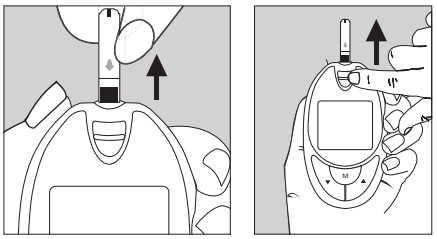
NOTE:

To ensure accurate results, make sure the confirmation window of the test strip is completely filled with your blood sample.



3. After the test result appears, if no further tests are performed, the meter will automatically shut off after 3 minutes. After finishing the test, you can push the strip eject button to remove the used strip or use a tissue to remove test strip from the meter for proper disposal.
Warning: Always discard the used test strip into suitable waste container.

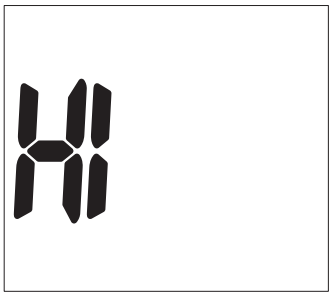
CAUTION:
Used lancets and test strips may be considered biohazardous waste in your area.
Dispose of used lancets and test strips at the point of use in a proper container.
Be sure to follow your local regulations for proper disposal.

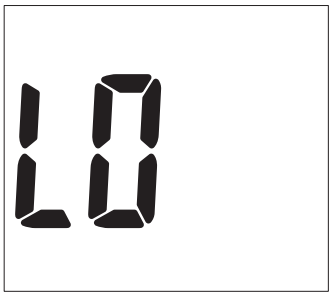


HI and LO Readings

1.The meter is designed to display test results range between 20 to 600 mg/dL (1.1 to 33.3 mmol/L). If a "HI" message appears on the display, your meter has detected that your blood glucose level is higher than 600 mg/dL(33.3 mmol/L).
It is suggested that you review your testing procedure and test again with a new test strip to confirm the result. **If the same result occurs, consult your healthcare professional immediately.**

2. If a "LO" message appears on the display, your meter has detected that your blood glucose level is lower than 20 mg/dL (1.1 mmol/L). It is suggested that you review your testing procedure and test again with a new test strip to confirm the result. **If the same result occurs, consult your healthcare professional immediately.**



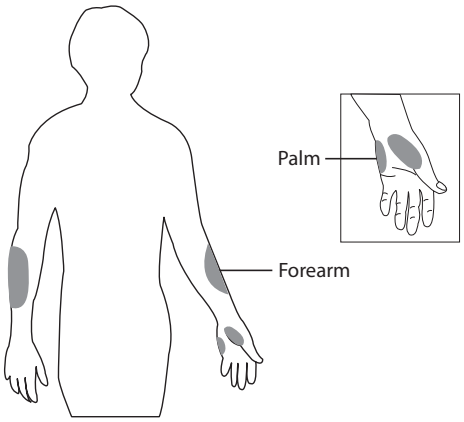


AVAILABLE ALTERNATE SITES TESTING: PALM AND FOREARM

ONE-CARE® PRO (Model AC500 PRO) Blood Glucose Monitoring System provides you alternate sites testing (AST). This system provides you to test on the palm and the forearm with the equivalent results to fingertip testing.

CAUTION:

1. Physiologic differences in the circulation between the finger and other test sites like the forearm and palm may result in differences in blood glucose measurements from the other test sites and your fingertips. Changes in blood glucose may be observed in finger blood samples sooner than blood samples from the forearm and other alternate sites. Rub the alternate test sites about 20 seconds before lancing. If you are testing for hypoglycemia (low blood glucose), or if you suffer from hypoglycemia unawareness, we recommend that you test on your fingertips.



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

2. Talk to your doctor to see if alternate site testing is right for you. With a little bit of education, you can give your fingertips a rest and maybe test more often than you do now. For people with diabetes, more frequent testing is a good thing. Just remember: any time you want to be sure of an accurate, up-to-date blood glucose reading, test on your fingertip.

3. We strongly recommend you do AST ONLY in the following intervals:

- **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.**

DO NOT use AST if:

- **You think your blood glucose is low.**
- **You are unaware of hypoglycemia.**
- **Your AST results do not match the way you feel.**
- **You are testing for hyperglycemia.**
- **Your routine glucose results are often fluctuating.**
- **If you are pregnant.**

Limitations:

(a) AST measurements should never be used to calibrate continuous glucose monitors (CGMs).

(b) AST measurements should never be used in insulin dosing calculations.

The manufacturer recommends both High & Low control solution testing to ensure the meter and test strips are working correctly and that the system is being used properly.

When to Perform a Control Solution Test

1. When you are using your system for the first time.
2. When you are using a new batch of test strips.
3. Anytime you question the performance of the system, or on a regular basis to ensure accuracy, e.g. once a week.
4. When you adjust your diabetic medication plans.
5. When your blood glucose test result is lower or higher than your normal level.

NOTES:

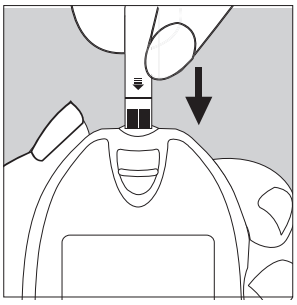
• Use only One-Care Pro control solutions with your One-Care Pro meter.

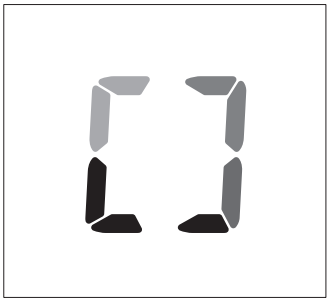
• There are two (2) control solutions (High & Low) that the manufacturer recommends using to ensure the system is working properly.

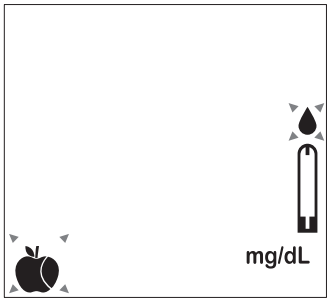
• For more information about the control solution, please read the control solution package insert.

To Perform a Control Solution Test

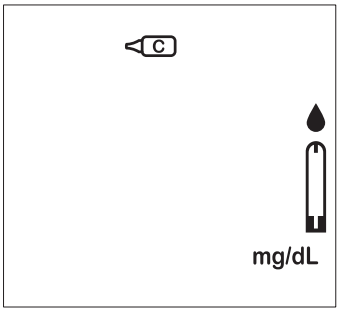
1. Make sure the control solution is at room temperature (59ºF to 82ºF or 15ºC to 28ºC) prior to testing.
2. Insert a test strip, white side face up, contact bar's end first, into the test port. The meter will automatically turn on.
3. All segments of the LCD display will appear, a beep will sound, and a clockwise moving dotted lines will appear.

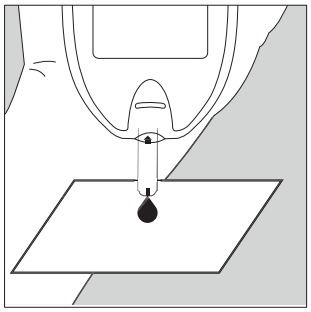


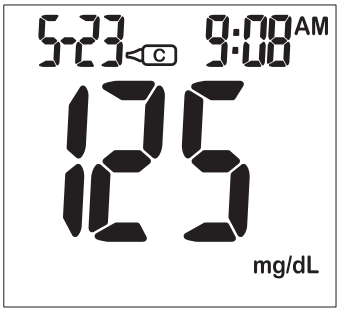




4. After system checking ok, a flashing " ♦ " symbol will appear.
5. Press and hold **M** for 4 sec to switch to control solution mode. The " C " will appear which indicates that the meter will mark your current test as a control solution test. Now you are ready to apply the control solution.
6. Discard the first drop of control solution when opening a new bottle of High or Low Control Solution.
7. Squeeze a small drop of High Control Solution onto the top of the High Control Solution cap. Do not apply control solution to the test strip directly from the bottle. Bring the tip of the test strip to lightly touch the drop of High Control Solution on the bottle cap. Control Solution is automatically pulled into the test strip through the tip. Hold until the meter beeps. The meter will now start the countdown from 5 to 1 and the High Control Solution test result will appear.
8. Compare the High Control Solution test result with the High test range listed on the vial of test strips.
9. Repeat steps 7 & 8 using the Low Control Solution.







CAUTION:
Please remember that in order to prevent contamination, follow the above instructions properly when performing the control solution test.

Comparing Control Solution Results

The system is functioning properly if the result falls inside the specified range printed on the test strip vial. If the test result falls outside the spcified range, repeat the test.

Results falling outside the specified range may be caused by

- Error in performing the test
- Control solution temperature is lower than 59°F(15°C) or higher than 82°F(28°C)
- Expired or contaminated control solution
- Expired or contaminated test strips
- Meter malfunction

Note:
The result will not be included in calculating the average when the meter is set in the control solution test " C " mode. DO NOT use the system if the problem persists. Please contact customer service.

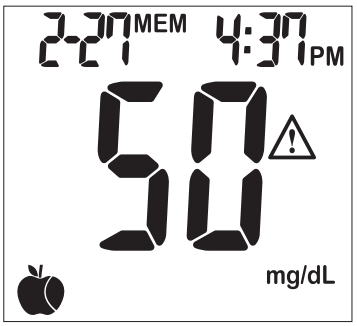
View results stored in the memory

View results stored in the memory

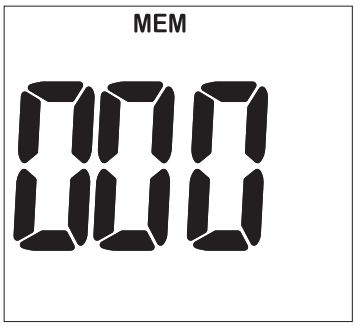
1. Press **M** to turn on the meter. The date and time will appear first.
2. Press ▼ to review previous results. Results will be shown starting with the most recent. Test result memory sequence will display when button is pressed and test result with date and time the test was taken will display when button is released. (Fig.15)
3. You can press ▼ or ▲ to scroll forward or backward through the results. When " 000 " appears on the display, you have viewed all of the results in the memory. (Fig.16). Press **M** to turn off the meter.

Note:

The meter will hold 500 results in the memory. When the memory is full, the oldest result will be removed and replaced with the newest result.



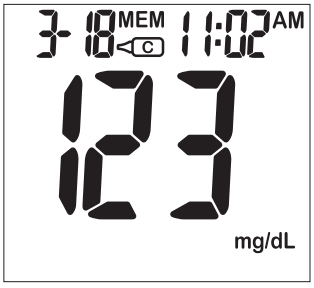
(Fig.15)



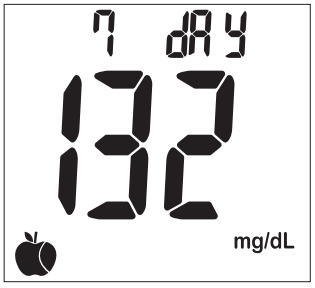
(Fig.16)

View control solution and day average result

1. Press M to turn on the meter. The date and time will appear first. Press M again to view the average results.
2. The control solution result will show on screen first. (Fig. 17) Continue to press and release ▼, the 7-days result marked with a pre-meal indicator and post-meal indicator will be shown on display in sequence. (Fig.18-19)
3. Press ▼ to scroll forward to view 14-days and 30-day averages. You can press ▲ to scroll backward. When " 000 " appears on the display, you have viewed all of the results in the memory. Press M to turn off the meter.



(Fig.17)



(Fig.18)

(Fig.19)

NOTE:

1. The consecutive 7/14/30-day average is calculated from the blood glucose results obtained during the last consecutive 7/14/30-day. If there are not enough testing results for the calculation of 7-, 14-, 30-day averages, the average result will not be shown.
2. A result with a thermometer symbol indicates that the reading was taken outside of the meter's specified operating temperature range and may not be accurate. This value is included in your 7-, 14- and 30-day averages.
3. LO (under 20 mg/dL) and HI readings (over 600 mg/dL) will not be stored in the memory.

Exiting the Memory Mode

1. Press the **M** to turn off the meter at any time.
2. Meter will shut down automatically after 3 minutes with no further action.

To Record Your Results

We have provided a log book for your recording convenience. To learn more about how to record your results, please refer to the log book for further instructions.

TRANSFER TEST RESULTS TO A COMPUTER

You can use your meter with ONE-CARE® Link Health Management Software to transfer test results to your personal computer.

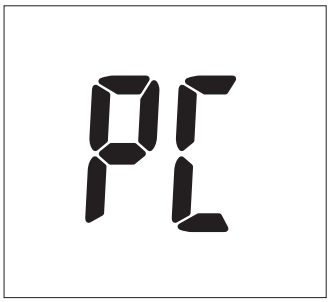
1. ***Obtain the required software and cable***
   For order information please call Customer Service or visit website of www.one-care.com

2. ***Install the software on a computer***
   Follow the instructions provided with software to install the software.

3. ***Get ready to transfer test results***
   With meter turned off, connect the interface cable to a serial port on your computer, then connect the other end of interface cable to the data port located on the side of the meter. The word "PC" will appear on the display, indicating that the meter is in the communication mode.

4. ***Transfer data***
   Follow the instructions provided in the software to download the results from the meter. After finishing the data transfer, press **M** button to turn off the meter.

Note:
While in the communication mode, you will be unable to perform a blood glucose test. If the meter is not in the PC link mode, it will not respond to computer commands.



It is MediVena's policy to advise healthcare professionals to clean and disinfect blood glucose meters between each resident test in order to avoid cross-contamination issues. Whether your facility uses an alcohol based solution or a bleach based solution should depend upon your individual resident requirements and your facility's disinfection protocol.

MediVena's cleaning and disinfecting guidelines are as follows:

One-Care Pro Cleaning Guidelines: If there is visible soil on the meter such as blood and other bodily fluids, using protective disposable gloves, use a lint free cloth dampened with isopropyl alcohol (70%-80%) or an EPA-registered disinfectant wipe to clean the outside of the blood glucose meter. Discard the used disinfecting wipe.

One-Care Pro Disinfecting Guidelines: To disinfect the meter, using protective disposable gloves, dilute 1 mL of household bleach (5% - 6% sodium hypochlorite solution) in 9 mL of water to achieve a 1:10 dilution (final concentration of 0.5% - 0.6% sodium hypochlorite). The solution can be used to dampen a paper towel (do not saturate the towel). Then use the dampened towel to thoroughly wipe down the meter and allow the meter to dry completely.

Or, using protective disposable gloves, remove an EPA-registered disinfecting wipe from its container, carefully wipe the outside of the meter avoiding saturating the test strip dock , data port or battery section. Discard the used disinfecting wipe. Allow the meter to remain wet according to the recommended contact time of the manufacturer of the disinfecting wipe. Allow the meter to dry completely.

Please note that there are commercially available EPA-registered disinfecting wipes, 1:10 quaternary/alcohol wipes and bleach wipes from a variety of manufactures to clean and disinfect the One-Care Pro meter.

- PDI Super Sani-Cloth Germicidal Disposable Wipes
- PDI Sani-Cloth Bleach Germicidal Disposable Wipes
- Clorox Healthcare Bleach Germicidal Wipes

The germicidal wipes mentioned above are EPA-registered wipes that are compliant with the CDC guideline for cleaning and disinfection in healthcare facilities and are readily available through major medical distributors. When using any disinfection wipe, take extreme care not to get liquid in the test strip dock or key code parts of the meter. With all recommended glucose meter cleaning and disinfecting methods, it is crucial that the One-Care Pro meter be completely dry before testing a resident's glucose level. Please follow the disinfectant product label instructions to ensure proper contact and drying time.

While there are many other options for disinfecting blood glucose meters, MediVena has not tested the effectiveness of these products on the One-Care Pro meter. If you use a product or method other than those that we've recommend above, you should document accordingly in your cleaning protocol.

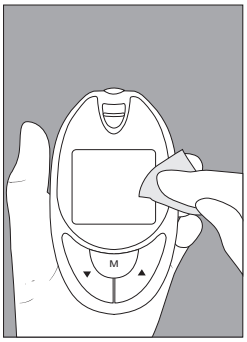
CAUTION:

- ***Ensure that the swab or cloth is only damp, not wet. Liquid entering the meter may cause meter malfunctions.***
- ***Wash hands throughly with soap and water after handling the meter, lancing device, or test strips.***

If you have any questions, please contact Customer Service Hotline (888) 270 6457

Clean and disinfection of Test port, LCD cover or buttons are available. Data port should be avoided when perform the cleaning and disinfecting process. Liquid entering the meter may cause meter malfunctions. The signs of deterioration include that the LCD display are not clear, the meter casing display any cracking or the button icons do not remain legible. If these signs of deterioration are present, please stop using the device and contact customer service for a replacement device.

The meter has been validated for 36,500 cleaning and disinfection cycles. This is representative of cleaning and disinfection 20 times a day for 5 years.



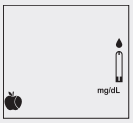
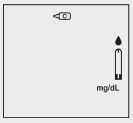
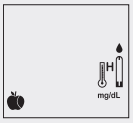
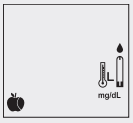
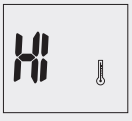
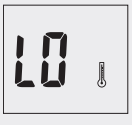
CARE AND STORAGE

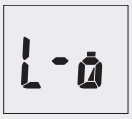
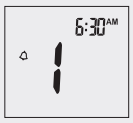
1. Handle the meter with care. Dropping or throwing the meter may cause damage to the device.
2. Do not expose the meter, test strips, and control solution to extreme conditions, such as high humidity, heat, freezing cold or dust.
3. The meter should be stored at room temperature in a dry and clean space. DO NOT STORE IN DIRECT SUNLIGHT OR AREAS WITH HIGH HUMIDITY AND/OR DUST. It is advised that you store the meter and its accessories into the provided carrying case.

For healthcare professionals using this system on multiple patient, please be aware that all items that come in contact with human blood should be handled as potential biohazards. Users should follow the guidelines for prevention of blood-borne transmittable diseases in a healthcare setting for potentially infectious human blood specimens as recommended in the National Committee for Clinical Laboratory Standards, Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids and Tissue: Approved Guideline. NCCLS document M29-A [ISBN 1-56238-339-6].

DISPLAY MESSAGES

ONE-CARE PRO

Display	*Description*	*Action*
	The system is ready to accept a blood sample.	You may now apply a blood sample.
	The system is ready to accept a control solution sample.	You may now apply a drop of control solution sample.
	⚠ appears when the result is HIGHER than the "HI alarm setting" reference range.	For your reference, or you can change the default setting value 180 mg/dL according to page 19.
	⚠ appears when the result is LOWER than the "LO alarm setting" reference range.	For your reference, or you can change the default setting value 70 mg/dL according to page 19.
	Test result is higher than 600 mg/dL (33.3 mmol/L).	Repeat the test using a new test strip. If the result is still HI, consult your physician immediately.
	Test result is lower than 20 mg/dL (1.1 mmol/L).	Repeat the test using a new test strip. If the result is still Low, consult your physician immediately.
	Temperature is high during the test procedure.	Large variation may occur between results due to high or low temperature. Move to the environment (50 - 104˚F or 10 - 40˚C) and wait 15 minutes before re-testing.
	Temperature is low during the test procedure.	Large variation may occur between results due to high or low temperature. Move to the environment (50 - 104˚F or 10 - 40˚C) and wait 15 minutes before re-testing.
	Temperature is too high to perform the test.	Repeat the test in a cooler setting (50 - 104˚F or 10 - 40˚C). Wait 15 minutes before re-testing.
	Temperature is too low to perform the test.	Repeat the test in a warmer setting (50 - 104˚F or 10 - 40˚C). Wait 15 minutes before re-testing.
	An error message indicating a problem with the test strip.	Review the instructions and try again with a new test strip.

Display	Description	Action
	An error message indicating a problem with the meter.	Press "reset" button and check the meter again with the test strip. If the problem persists, contact customer service for help.
	Battery power is low. Meter will provide approximately 50 more measurements.	Replace with two AAA batteries.
	Battery power is too low for further usage.	Replace with two AAA batteries immediately.
	The meter is in the PC commnuication mode.	Follow the instructions provided in the software to download the test results from the meter.
	The preset alarm is ringing to remind it is time to perform blood glucose test.	Press any button to shut off or the alarm will turn off automatically after 30 sec.

OTHER PROBLEMS THAT MAY OCCUR

Description	Action
The test strip has not been inserted into the meter properly.	Review the instructions and re-insert the test strip correctly (white side face up).
Defective test strip.	Replace with a new test strip.
Insufficient blood sample.	Repeat the test with new test strip.
Test strip remains in the test port for more than 3 minutes prior to testing.	Meter will automatically turn-off. Re-insert the test strip to the test port.
LCD display on the meter is blank when trying to perform a test.	Contact Customer Service for help.

SPECIFICATIONS

ONE-CARE PRO

Meter Operating Conditions

Temperature	50°F ~ 104°F (10°C ~ 40°C)
Humidity	10 ~ 90% RH
Hematocrit	20% ~ 60%
Test Sample	Fresh capillary whole blood from fingertip, palm and forearm
Sample Volume	>0.5 µL
Measuring Unit	mg/dL
Measuring Range	20-600 mg/dL (1.1 ~ 33.3 mmol/L)
Test Time	5 sec
Memory Capacity	500 most recent results
Average	7/14/30 days average results
External Output	USB interface
Power supply	Two AAA batteries
Battery Life	Approximately 1000 tests
Dimension	100 x 57 x 24 mm
Weight	58 g without battery

ICON DESCRIPTION

EC REP	Authorised Representative in the European Community
	Do not use if package is damaged
	Temperature limitation
LOT	Batch code
	Use by
	Keep dry
	Do not reuse
SN	Serial Number
	Manufacturer
IVD	In vitro diagnostic medical device
	Consult instructions for use
	Sufficient for
REF	Catalogue number
	Keep away from sunlight
CONTROL	Control
	Caution

Interference substance	Highest tested concentration with no significant interference
Acetaminophen	4.25 mg/dL
Ascorbate(Ascorbic acid)	3 mg/dL
Bilirubin	25 mg/dL
Cholesterol	1200 mg/dL
Creatinine	10 mg/dL
Dopamine	2 mg/dL
EDTA	200 mg/dL
Galactose	500 mg/dL
Gentisic acid	2.5 mg/dL
Glutathione	3.07 mg/dL
Haemoglobin-HUMAN	3000 mg/dL
Heparin	5 IU/mL
Hydrogenated starch hydrolysates (HSH)	0.09 mg/dL
Ibuprofen	50 mg/dL
Icodextrin	750 mg/dL
Isomalt	0.09 mg/dL
Lactitol	0.09 mg/dL
L -DOPA(L-3-4 dihydroxyphenylalanine)	0.5 mg/dL
Maltose	2575 mg/dL
Maltitol	0.09 mg/dL
Mannitol	0.09 mg/dL
Methyldopa	2.5 mg/dL
Pralidoxime iodide (PAM)	5 mg/dL
Salicylate	50 mg/dL
Sodium Carbonate	37.5 mEq/L
Sorbitol	0.09 mg/dL
Tolbutamide	100 mg/dL
Tolazamide	6 mg/dL
Triglycerides	1525 mg/dL
Uric acid	8 mg/dL
Xylose	5 mg/dL
Xylitol	0.09 mg/dL

The ONE-CARE® PRO (Model AC500 PRO) Meter, ONE-CARE® PRO (Model AC500 PRO) Test Strip and
ONE-CARE® PRO Control Solution are in conformity with the IVDD 98/79/EC.

Manufactured for:
MediVena
1 Glenlake Parkway, Ste 700
Atlanta, GA 30328, USA
(404) 514 2586
info@medivena.com
www.medivena.com

The Lancing device and Lancets are in conformity with the MDD 93/42/EEC.

CUSTOMER SERVICE TOLL FREE NUMBER:
(888) 270 6457

Limitations of the Procedure

Caution:
The ONE-CARE® PRO (Model AC500 PRO) Blood Glucose Monitoring System is designed for in vitro diagnostic use only and is not intended to test on newborns. Any change or administer of medication based on the ONE-CARE® PRO (Model AC500 PRO) blood glucose test results without the consent advice of a physician or healthcare professional is not recommended.

The ONE-CARE® PRO (Model AC500 PRO) test strips are designed for use with fresh capillary whole blood samples obtained from the fingertip, palm and forearm. False results may occur when performing the test while severely dehydrated, severely hypotensive, in shock or in a hyperglycemic-hyperosmolar state. If you believe you are suffering from any of the above symptoms, consult a healthcare professional immediately.

SERVICE AND WARRANTY

IMPORTANT
MediVena cannot endorse the performance of the ONE-CARE® PRO (Model AC500 PRO) Blood Glucose Monitoring System when used with test strips other than those designed for the ONE-CARE® PRO (Model AC500 PRO) meter. The ONE-CARE® PRO (Model AC500 PRO) Blood Glucose Monitoring System manufacturer warranty is valid only when used properly within the guidelines of the provided user's manual and is invalid when the ONE-CARE® PRO (Model AC500 PRO) Blood Glucose Monitoring System and ONE-CARE® PRO (Model AC500 PRO) test strip are used improperly.

Manufacturer Warranty
MediVena guarantees that this device will be free of defects in materials and workmanship for a period of three years from the date of original purchase. During the stated three-year period, our company shall repair or replace any ONE-CARE® PRO (Model AC500 PRO) meter found defective with a new ONE-CARE® PRO (Model AC500 PRO) meter.

This warranty does not apply to the performance of a ONE-CARE® PRO (Model AC500 PRO) meter that has been accidentally damaged, altered, misused, tampered with or abused in any way. In no event shall our company be liable to the purchaser or any other person for any incidental, consequential, or punitive damages arising from or in any way connected with the purchase or operation of the ONE-CARE® PRO (Model AC500 PRO) meter or its parts.

For manufacturer warranty services, purchaser must contact MediVena for help.

CUSTOMER SERVICE

If you have any questions or concerns regarding this product or its operation, or any attempt to correct a problem fails, please call our customer service. Our trained specialists will be happy to assist you, train you, or even reaffirm your results.

MediVena
Customer Service Toll Free Number:
(888) 270 6457

When you call our customer service, please have your meter, test strip and all other system supplies available. This will allow us to answer any of your questions with speed and efficiency.

One Care PRO AC500 PRO Blood Glucose Monitoring System Quality Control Results Record

Meter #: ______________ **Month/Year:** ________________ **Results reviewed by:** _______________

Date	Time	Station/shift	Operator	Meter cleaned (Y/N)	Test strip lot #	Test strip expiration date	Low			High			Corrective action
							lot #	range	result	lot #	range	result	

Notes:

Notes:

Distributed by:

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