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11-62-0110-0203 V2-SEP21

1. Introduction to the System

Intended Use/Indications for Use

Easy Plus II

The **Easy Plus II** Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the forearm. It is intended for use by healthcare professionals and people with diabetes mellitus at home and as an aid in monitoring the effectiveness of a diabetes control program.

Easy Plus II

USER GUIDE

Blood Glucose Monitoring System

Home Aide

Model 6276-S

The **Easy Plus II** Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes mellitus, nor for use with neonates.

The alternative site testing (forearm) in this system can only be used during steady-state blood glucose conditions.

This User Guide has been prepared to describe the proper use of the **Easy Plus II** Blood Glucose Monitoring System.

Please read this User Guide and the package insert that comes with the Easy Talk/Plus II Glucose Test Strips before testing. Keep this user guide for future reference. The Easy Plus II Glucose Meter can be used with the **Easy Talk/Plus II** Glucose Test Strips and/or control solutions.

The principle of the method

Home Aide Diagnostics, Inc.

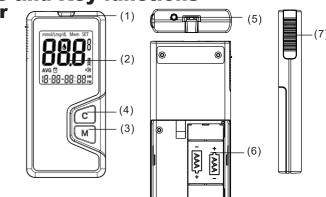
1072 S. Powerline Road, Deerfield Beach, FL 33442 1 (800) 915 - 0116

www.homeaide.us

When glucose reacts with the reagents on the test strips, an electrical current is produced, which is proportional to the glucose concentration in the blood sample. The glucose concentration is calculated by the meter and based on the current measured.

* Your meter has the back light feature, it will turn on with in every operation to increase the legibility in operation, helping the user to operate the meter more smoothly.

2. Appearance and Key functions of the meter



1. Test strip slot – When the strip is inserted into the slot, the meter will automatically turn on.

NOTE: For information about the name of the manufacturer of the lancing device and

3. M Key – Power ON/OFF, also for memory recalling mode, please refer to manual for detailed function description.

4. C Key – Setting mode, please refer to manual for detailed function description.

1. Slide down the battery cover on the back of the meter by pushing the

cover in the direction of the arrow and put the cover aside.

site direction of the arrow to close the cover into position.

2. LCD Display – Guide you through the test using symbols and simple messages.

5. RS232 port – Cable connection and data transmitting.

6. Battery Compartment – Where batteries are located.

5. Installing the battery

3. Insert 2 new batteries with correct +/- direction.

(Battery: AAA 1.5V 2 Alkaline 24A LR03)

7. **Ejector** – Remove used strip.

2. Remove the two used batteries.

3. Safety Information

Please use this device only for the intended use described in this user guide.

Before using this system to test your blood glucose, please read instructions thoroughly and practice the test when you first use this system. Do a quality check on the system following the controls solution test instructions and consult with your healthcare professionals for questions or problems.

Be aware of the safety of young children or handicapped persons near you when you conduct a glucose test using this system.

The Easy Plus II glucose monitor can only be used with the Easy Talk/Plus II Glucose Test Strips and control solution.

Please keep the test strip vial away from children. The test strips and vial cap can present a choking hazard.

Never share a lancet or a lancing device with anyone. Always use a new, sterile lancet. Lancets are for single use only.

Please be cautious when removing the lancet. Take the lancet out carefully. Always place the protective cap back on the exposed tip or (if using a twist lancet) place the cap on a hard surface and push the exposed tip into the protective cap and discard of properly.

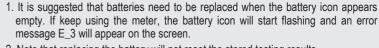
Always test your blood glucose using either **Easy Plus II** or **Easy Talk** meter, test strips and control solutions. Mixing other brands will give invalid results.

4. Quick Testing Instructions

- 1. With the meter off, insert a new test strip with the contacts facing up in the test strip slot. The meter will turn on. You will see a full screen display briefly, and then a blinking blood drop icon will appear on the screen.
- 2. Lance the finger and let a blood drop form.
- 3. Apply the blood drop to the front edge of the test strip when the blood drop icon is still blinking on the meter. Wait for 6 seconds, and the meter will display the test result.
- 4. Remove the used strips by hand or by pushing the ejector and the meter will power off, with "OFF" appearing on the screen.







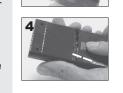
4. Put the battery cover back in place by pushing the cover in the oppo-

2. Note that replacing the battery will not reset the stored testing results.

3. You need to reset the time and date after the batteries are replaced.

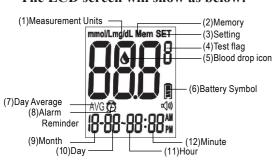
4. If there is any unexpected symbol on the display, please follow the above procedure to replace the batteries again.

Please dispose of batteries according to your local ordinances.



6. Settings (Language/Date /Time/Alarm/ **Measuring Unit/Memory Deletion/Voice Volume)**

The LCD screen will show as below:



- 1. Appears with the test result either in mg/dL or in mmol/L. 2. Appears when you recall the memory.
- 3. Appears when you are in setting mode. 4. Appears for control solution test flag (c).
- 5. Indicates the meter is ready to take the blood sample when it flashes.
- Indicates the battery status. 7. Indicates current displayed result is an
- average. 8. Appears when alarm is on.
- 9. Month 10. Day 11. Hour

12. Minute

mg/dL

The LCD screen for Power Off - When the meter is off, the date, time, measurement unit, battery icon and "OFF" will be still on the screen. If the voice is on or the alarm reminder is on, the speaker icon and the alarm will be displayed as well.

- 1. Set the Year Press C key to adjust the year until the desired year is displayed and then press the M key to confirm the year setting. After the year setting is confirmed, you will see the month segment flashing on the screen.(Please see
- 2. Set the Month Press C key to adjust the month until the desired month is displayed and then press M key to confirm the month setting. You will then see the day segment is flashing on the screen. (Please see Figure 6-2.)
- 3. Set the Day Press C key to adjust the day until the desired day appears and then press the M key to confirm the day setting. You will then see the hour segment is flashing on the LCD screen. (Please see the Figure 6-3.)
- 4. Set the Hour Press C Key to adjust the hour until the desired hour appears on the screen and then press the M key to confirm the setting. You will then see the minute segment is flashing on the screen. (Please see Figure 6-4.)







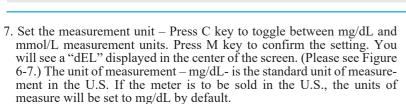


- 5. Set the Minute Press C Key to adjust the minute until the desired minute appears on the screen and then press the M key to confirm the setting. You will then see an "AL" displayed on the screen center. (Please see Figure 6-5.)
- 6. Set the Alarm Reminder Press C key to toggle between the alarm reminder setting or no-setting mode. "If you see the LCD display a small flashing icon of alarm clock in the lower left corner with a time segment display, it means that you are in the alarm setting mode. (Please

see Figure 6-6.) If you see only AL without the icon of the small alarm clock, it means that you are not in the alarm setting mode. Press M key to confirm the alarm setting mode. If you select the alarm setting mode, alarm clock icon will stop flashing and the hour of the time segment will start flashing. Press C key until the desired alarm hour appears and then press M key to confirm the hour setting. Then the minute segment will start flashing. Press C key until the desired minute appears on the screen and then press M key to confirm the minute setting. You will see the measuring unit flashing on the upper left corner of the LCD display. (Please see Figure 6-7.)



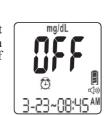
6-7



8. Delete Memory – Press C key to toggle between a flashing "dEL" for memory deletion and a non-flashing "dEL". If you want to delete all memory, press M key while the "dEL" is flashing. If you do not want to delete all memory, press M key when the "dEL" is not flashing. Once the M key is pressed, the LCD display will display "OFF" and turn off automatically after 2 seconds. (Please see Figure 6-8.)



9. Power off Screen – When the meter is off, the time, date, measurement unit, and battery icon will be still on the screen as Figure 9. If the alarm reminder has been set, then the alarm icon will appear on the power off screen as well. The LCD screen will display "OFF".



Note: Your meter can show results either in "mg/dL" or "mmol/L" units. Mg/dL is the unit used in the U.S., please contact the manufacturer if your meter does not display mg/dL when you turn it on. The factory set default for the meter is mg/dL, in the event that the meter loses power or the batteries are changed, the factory set default is mg/dL. It is very important to use the correct unit of measurement to properly manage your diabetes. If you live in the USA you should use mg/dL; your results will never have a decimal point. If you live in Canada and some European countries you should use mmol/L; your results will always have a decimal point. The mg/dL display is on by default.

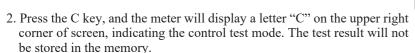
Note:

- 1. When you change the date and time backward, you will not change the test results in the meter memory. 2. You need to move through the language, year, month, day, hour, minutes, alarm, unit dEL and VoL to save the meter settings and turn off the meter
- 3. The average readings in the meter memory are calculated from the results obtained during the 7, 14, 28, 60, and 90 calendar days preceding the current date and time settings.

7. Running a Control Solution Test

IMPORTANT: Always make sure you press C key for Control Solution test, otherwise in the control solution test result will be stored in the memory, and affect your "AVG" results.





- 3. Squeeze a small amount of Control Solution on a flat surface and apply to the front edge of the test strip.
- 4. Wait for 6 seconds, and the meter will display the result.
- 5. Remove the used strip by hand or by pushing the ejector and the meter will power off with a display of "OFF" on the screen.



IMPORTANT!!!

(3) The test strips are damaged or outdated.

- 1. If the meter, test strips and control solutions are moved from one temperature to another, allow thirty (30)
- minutes for them to adjust to the new temperature before performing a control solution test. 2. You must push the C key to distinguish the control solution test from the blood glucose test. Do not perform the blood test in Control Solution mode. (If you perform the blood test in Control Solution mode, the test result will not be stored.)
- 3. Use **Easy Plus II** or **Easy Talk** Control Solutions with **Easy Plus II** Glucose Meter. 4. Control Solutions are used to check that the meter and the test strips are working together as a system and
- that you are performing the test correctly. 5. Control Solution contains a known amount of glucose that reacts with test strips. The Low and High level Control Solutions are intended to check the monitoring system in different measurement ranges.
- 6. Shake the vial, discard the first drop of control solution, and wipe off the dispenser tip to ensure a good sample and an accurate result. 7. Use only for 3 months after fist opening. Record the open date on the Control Solution vial. Discard after
- outside the expected range may indicate: (1) You may not be doing the test correctly; repeat the test, by shaking the control solution vial well and carefully following instructions. Please make sure the test is done within the temperature range. (2) The Control Solution is expired or contaminated.

8. Compare your Control Solution test results with the expected range printed on the test strips vial label. If

your glucose control results fall outside the expected range; repeat the test. Results that repeatedly fall

(4) You may have applied the Control Solution before the blood drop appears on the screen. This will cause incorrect glucose measurement. (5) Meter malfunction.

8. Blood Glucose Testing

Alternate Site Testing (AST)

What is AST?

Sampling from anatomical sites (parts of the body) other than the fingertip (i.e. forearm, upper arm, thigh, calf, palm) to check the blood glucose levels. This system allows you to test on the forearm with the equivalent results to fingertip testing.

There are important limitations to AST. Please consult your healthcare professional before you use What is the advantage?

It is more painful feeling when taking blood sample from fingertips because fingertips have many

nerve endings. Other body sites do not have as many nerve endings, so you will not feel as much pain as at the fingertip.

When to use AST? Medication, stress, illness, food and exercise can affect blood glucose levels. Capillary whole blood at the fingertip can reflect test changes faster than capillary blood at other sites of body. If you test your blood glucose level during or immediately after a meal, physical exercise or stressful events, take the

blood sample from your fingertip instead of from other sites.

- **Use AST only:** 1. 2 hours or more after taking insulin;
- 2. 2 hours or more after a meal; 3. 2 hours or more after exercise.

Do not use AST if you are pregnant, or if you are aware that your glucose level is not as stable as usual, or if you think you have hypoglycemia (low blood sugar) or hyperglycemia (high blood sugar). Do not use AST if you think your blood glucose is low and your AST results do not match the way you feel.

5. Open the test strip vial. Take one new test strip out of the vial and 9. Runnig A Blood Glucose Test recap the vial quickly and firmly.

Note 1: Note 1: To reduce the chance of infection: Never share a lancet or a lancing device with anyone. Always use a new, sterile lancet. LANCETS ARE FOR SINGLE USE ONLY. Note 2: If the meter and test strips are moved from one temperature to another, allow thirty (30) minutes for them to adjust to the new temperature before performing a blood glucose test.

(For use with generic lancing devices). Not included with meter. Unscrew the lancing device by turning the end cap counter clockwise. A clear cap will come with the package of a meter kit or a lancing device. The clear cap on the lancing device will make it easy for you to get a drop of blood for AST.

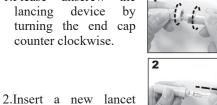
1.Please unscrew the lancing device by turning the end cap counter clockwise.

firmly into the lancet

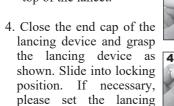
IMPORTANT:

after use.

holder



3. Twist off the protective **3** top of the lancet.



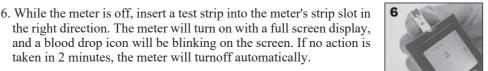
device for a deeper punc-

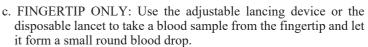


7. Use a single lancing device to take a blood sample from the finger-

taken in 2 minutes, the meter will turnoff automatically.







a. AST ONLY: Select a soft, fleshy area on your forearm that is

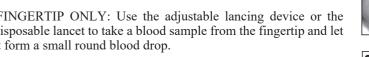
clean and dry, away from bone and free of visible veins and hair.

b. AST ONLY: Massage the selected area gently to increase blood

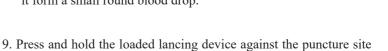
flow to the puncture site. Clean the test location with an alcohol

8. CHOOSE PUNCTURE SITE

wipe or with soap and water.



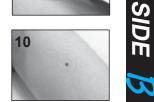






10. Wait for a few seconds until the blood drop forms. Make sure you have sufficient blood to fill the small window of the test strip. For individuals who experience difficulty in getting sufficient blood for a test, it may be helpful to rub the puncture site a little longer before using the lancing device.

for a few seconds, then press the puncture button.



11. Apply a small blood drop (• actual size)to the front edge of the test strip, and the blood should be pulled into the test strip before the meter begins to count down. Do not push your finger against the test strip or try to apply a smeared blood sample.



12. The meter will start counting down for 6 seconds and your test result will be displayed on the screen. Remove the used test strip by hand or by pushing the ejector button. The meter will turn off and the test result is stored automatically

center of screen if a used strip is inserted into the meter.



the control test result will not be added to memory.)

A. Using the Meter Memory

stored in memory.

B. Recalling the Test Results from the Meter Memory 1. With meter off, press M key to turn on the meter, the meter will display the total number of test data stored in memory. Then the screen will display "001" as the sequential number of the most recent test result in memory. The memorized test data will be displayed next. If there is no memorized result in the meter, "---" is displayed and the meter will turn off after 60 seconds if no action is taken.

10. Recalling the Memory and Viewing the Average

The test results for blood sample will be stored in the memory automatically. The meter can

store up to 500 of the most recent rest results. You can also view the average of test results

for various periods of 7, 14, 28, 60 and 90 days. The control solution test results will not be

(Note: Please make sure that you press C key when you run a Control Solution test, so that

(The meter will display "---" if no previous results were memorized.)

- 2. The screen will display each of the memorized test data in sequence. Press M and C key to review your test results in memory forwards and backwards.
- 3. To turn off the meter, press M key for 2 seconds, or the meter will turn off automatically after 60 seconds of no activity.

C. Viewing the Average (AVG) of Test Data in Memory

- 1. To display the average (AVG) test result, please turn meter off. Press C and M keys at the same time and hold for about 2 seconds, wait for AVG displayed on screen, then release the two buttons. The meter will be in the average mode with "AVG" font displayed.
- 2. When the "AVG" is flashing at the lower left corner of screen, the number 7 will be displayed under AVG and the average of the last 7 days test results will be displayed in the center of the screen. The number of tests done in the last 7 days will be also displayed at the lower right corner of screen. If you want to see the average of 14, 28, 60 and 90 days, keep pressing the M key to move the LCD display forward from 7 day average to 90 day average. The average display will move from 90 days backward to 7 days if you continue to press C key.
- 3. Press the M key and hold for 2 seconds to exit the recall mode and turn off the meter, or the meter will automatically power off after 60 seconds.
- 4. W hen "---" is displayed, showing that there are no test results in memory.

Calculations:

The 7 days average is the average of the last 7 day test results. The 14 days average is the average of last 14 day test results. The 28 days average is the average of last 28 day test results. The 60 days average is the average of last 60 day test results. The 90 days average is the average of last 90 day test results.

in the memory. 2. Do not insert the strip into the meter when you want to recall the test results.

1. HI/LO results are not stored

11. Expected Values Reference

Blood glucose levels normally will vary from time to time depending on food intake, medication dosages, health, stress or exercise. Consult your physician or healthcare professional for the target glucose value appropriate for you.

1. Never reuse a test strip or a lancet. An "E_5" error message will be displayed in the

2. Discard the test strip and lancet immediately in a puncture-proof container with a lid

Expected plasma blood glucose values for normal, nondiabetic adults are as follows. Before eating < 100 mg/dL

Two hours after meals < 140 mg/dL

Easy Plus II meter gives plasma equivalent results.

12. Transmitting Results

Easy Plus II Glucose Meter allows you to transfer the test results stored in its memory to your personal computer. However, you will need to order software and a Data Download Cable separately from your

Please download the software and its data download procedure from our website. https://homeaide.us/. You can also check with your distributor for the software download option. The meter still keeps the results in the memory after transmitting.

- 1. Before transmitting test data, you will need to set up the download software and USB driver on your PC. The complete installation procedures for software application could be found in the first section of User Guide: Download Software for meter on CD. 2. Launch the software application (Meter Download) on PC after installation is complete. Then
- connect your meter and PC with the download cable before starting the data download. Hit the "Connect (Download)" button on PC screen to get ready for data receiving. For more detailed information and procedures about data download from meter to PC, please refer to User Guide: Download Software for meter on CD. 3. With the meter off, hold the M and C key down at the same time for 5 seconds until "PC" is
- 4. Press the C key to start transmitting. The meter will display a flashing "PC" during the transmission process. When the "PC" on the screen stops flashing, it indicates the transmission is completed. The meter will power off if no action is taken in 60 seconds or M key is pressed for 2 seconds.
- 5. Once the download is completed, the download report could be exported to Microsoft Excel file. You can view, rename or delete the exported excel files on PC if needed.

13. Maintenance of your system

Please, treat this meter with proper care, and keep it in good condition.

- 1. Store your meter in its case, in a clean dry place at 46~86°F (8~30°C).
- 2. Always clean your meter after use. Wipe and clean surface of the meter with a soft cloth that has been slightly dampened with mild detergent.
- 3. Please handle with care and do not drop the meter.
- 4. If this meter is used by healthcare professional infection control policies should be strictly followed.
- 5. The meter has a shelf-life of 2 years.

We suggest you should periodically compare the test system to another test system which is well maintained and monitored by a healthcare provider.

14. Troubleshooting

Following is a summary of all Error Messages. These messages help to identify certain problems, but do not appear in all cases when a problem has occurred. Improper use may cause an inaccurate result without producing an error message or a symbol. In the event of a problem, refer to the information in the table under Solution.

Error messages:

- E_1 : The temperature is too low. E 2: The temperature is too high.
- E 3: Battery Low. E 4: Memory damaged. E 5: The strip is wet or used.
- E 6: Error in meter or strip. HI: The glucose level is too high.
- LO: The glucose level is too low.
- Note: Your meter can show results either in "mg/dL" or "mmol/L" units. Mg/dL is the unit used in the U.S., Please contact the manufacturer if your meter does not display mg/dL when you turn it on. The factory set default for the meter is mg/dL, in the event that the meter loses power or the batteries are changed, the factory set default is mg/dL. It is very important to use the correct unit of measurement to properly manage your diabetes. If you live in the USA you should use mg/dL; your result will never have a decimal point. If you live in Canada and some European countries you should use mmol/L; your result will always have a decimal point. The mg/dL display is on by default.

Possible Cause Problem Solution Repeat the test after the meter and strip are in a The meter is operating in an ambient (1) The meter displays an temperature below 10 °C or 50°F which is the warmer environment and allow the meter warm up E 1 error message. for a while before retesting lowest range of operating temperature The meter is operating in an ambient temperature above 40 °C or 104°F which is Repeat the test after the meter and strip are in a (2) The meter displays an cooler environment and allow the meter sit cooler E 2 error message. for a while before retesting. the cap of operating temperature. (3) The meter displays an The battery is too low to operate the meter. Please replace the two AAA batteries. E 3 error message. The meter can perform the glucose measuring without (4) The meter displays an The memory chip of the meter could storing the test results into the meter's memory. Please E 4 error message. be damaged or malfunctioning. write down the test results into the data logger before you call a customer service representative. Please check the strip if it is damaged or used. In (5) The meter displays an The inserted test strip has been wet or used. either case, please discard the strip and repeat the test E 5 error message. using a new strip. Repeat the test with a new test strip. If E_6 continues The meter is not working properly, either (6) The meter displays an to show up on screen, please call a customer service E_6 error message. because of a defective meter or a defective strip. Test again following the user guide for correct glucose (7) The meter displays The test result is higher than the measuring range measurement process. If you see HI again, please call of 600 mg/dL (33.3 mmol/L). HI on screen. your medical doctor for advice immediately. Test again following the user guide for correct glucose (8) The meter displays LO The test result is lower than the measuring range measurement process. If you see LO again, please call of 20 mg/dL (1.1 mmol/L). on screen. your medical doctor for advice immediately.

15. Customer Service

If you need assistance with your **Easy Plus II** Glucose Monitoring System, please

Home Aide Diagnostics, Inc.

1072 S. Powerline Rd., Deerfield Beach, FL 33442, USA TEL: 1-800-915-0116

Hours: 9 am to 5 pm EST/Mon. to Fri.

Outside of these times, contact your healthcare professional for medical issues or

For questions related to your health condition, please call your doctor or healthcare professional.

16. Limitations

1. No neonatal use Do not sue for neonatal blood glucose testing.

2. Hematocrit range

Hematocrit in the range of 32~56% has been shown not to affect the glucose result. If you do not know your hematocrit level, consult your healthcare professional.

Hemoglobin levels of 500 mg/dL or below will not interfere with blood glucose test results.

4. Elevated Cholesterol and Triglycerides Cholesterol levels up to 500 mg/dL (12.9 mmol/L) and Triglycerides up to 1000 mg/dL has been shown not to affect glucose results.

5. Medications

Interference was observed for therapeutic levels of L-DOPA. No interference was shown for uric acid, acetaminophen, ascorbic acid and ibuprofen in normal therapeutic levels. However, higher concentrations in blood may cause incorrect

Uric acid: >10.9 mg/dL; acetaminophen: >6.2 mg/dL; Ascorbic acid: >4.5 mg/dL; ibuprofen: >37.5 mg/dL.

- 6. The test strips may be used at altitudes up to 5,280 feet (1,609 m) without an effect on test
- 7. Persons suffering from severe dehydration should not be tested using a capillary whole
- 8. Test results below 70 mg/dL indicate low blood glucose (hypoglycemia). Test results greater than 240 mg/dL indicate high blood glucose (hyperglycemia). If you get results below 70 mg/dL or above 240 mg/dL, repeat the test, and if the results are still below 70 mg/dL or above 240 mg/dL, please consult your healthcare professional immediately.
- 9.Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate result may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with a blood glucose meter.

17. Specifications

Weight: ∼72g

Test: Glucose Sample: Whole Blood Principle of the test method: Amperometric, glucose oxidase Test sites: Fingertip, forearm Measurement time: 6 seconds Code required: No code device Measurement Range: 20 ~600 mg/dL (1.1~33.3 mmol/L). Batteries: 2 x AAA 1.5 V Alkaline 24A LR03 Operating Temperature: 10~40°C (50-104°F) Humidity: 20~80% RH Width: 48 mm Length: 99 mm Thickness: 14 mm

18. Warranty Information

Your Easy Plus II Glucose Meter is warranted to be free of defects in materials and workmanship for one year from the date of the original purchase. This warranty does not cover device failure due to owner misuse or negligence, or normal wear and tear.

If you have a question about your **Easy Plus II** Glucose Meter or this warranty, please

Home Aide Diagnostics, Inc.

1072 S. Powerline Rd., Deerfield Beach, FL 33442, USA TEL: 1-800-915-0116

Hours: 9 am to 5 pm EST/Mon. to Fri.

(Outside of these times, contact your healthcare professional)

1. American Diabetes Association: Diabetes Care, January 2015, volume 38 (suppl. I), S8

2. American Diabetes Association-Diabetes Forecast website information: http://www.forecast.diabetes.org/diabetes-101/hyperglycemia http://www.forecast.diabetes.org/diabetes-101/hypoglycemia

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