



Glucose Measurement

CHAPTER 7: GLUCOSE MEASUREMENT

Procedure: Whole blood glucose using the Precision PCx System

PRINCIPLE

A small drop of blood is applied to a MediSense Precision PCx test strip. The biosensor system utilizes a dry reagent strip technology, based on the glucose oxidase reaction to allow rapid measurement of blood glucose. Each reagent strip utilizes an electrode containing the enzyme glucose oxidase (*Aspergillus niger*). When a blood drop is added to the reagent strip, the oxidation of glucose in the drop produces gluconic acid. During this reaction, electrons are transferred by an electrochemical mediator to the surface of the electrode which results in a measurable current. The size of the current is proportional to the amount of glucose present in the blood drop.

CLINICAL SIGNIFICANCE

Blood glucose levels of patients with hypoglycemia or hypoglycemia can be monitored with the Medisense PCx. Patient management can be initiated immediately upon obtaining results, thereby avoiding any interruption of patient care. Certified personnel may perform glucose testing using the Medisense PCx.

MATERIALS AND EQUIPMENT

PRECISION PCX HAND HELD MONITOR

Keep the Precision PCx monitor level when performing testing. If liquid is allowed to flow down the test strip into the monitor, the monitor could be damaged.

BARCODE SCANNER

The Barcode Scanner is used to scan barcode information into the monitor. Hold the barcode scanner 3-12 inches from the barcode to be scanned. It may help to place the object to be scanned on a flat surface, by itself. This will prevent other items from being accidentally scanned.

Press and hold down the scan button to start the barcode scanner. A red beam will be emitted from the monitor. Slowly move this beam over the barcode on the item to be scanned. When the monitor accepts the barcode, it will beep in acknowledgement. Without releasing the scan button, look down at the monitor to view the data that was scanned by the monitor. Release the scan button to stop the scan and continue with the next step.

WARNING: Never look into the barcode scanner beam or point it toward anyone's eyes. The beam could cause permanent damage to the eye.

BATTERY COMPARTMENT

The monitor holds two AA alkaline batteries to power the monitor. To prolong the battery life of the monitor, the monitor should be turned off when not in use. If the monitor is left on and has not been used for 4 minutes, it will automatically shut itself off.

PRECISION PCX BLOOD GLUCOSE TEST STRIPS

Each test strip is wrapped in a foil packet with a barcode label. This label holds the calibration information about the test strip, including the lot number, the expiration date and expected control solution ranges. When opening the foil test strip packet at the notch and **tear up or down** to remove the test strip.

1. Use the test strips before their expiration date.
2. Do not use test strips that are wet, bent, scratched or damaged. Use the test strip

- immediately after opening its foil packet.
3. Do not scan a packet's barcode and use a test strip from another packet. This may cause incorrect assay results to be generated.
 4. Use each test strip only once.
 5. Unopened test strips should be stored at room temperature

QUALITY CONTROL SOLUTIONS

MediSense Control solutions are available from UMDNJ-RWJMS Point of Care Testing program at the telephone number shown on the contact list. Expected results for these glucose control solutions are specific to the test strip reagent lot and can be found in the package insert which accompany the reagent strips. This information is entered into the meters at the time of reagent lot validation and insures that units that are not operating properly will be blocked from use.

Control solutions are supplied by Abbott Laboratories, Bedford, MA 01730

1. Store control solutions at room temperature (between 39° and 86°F) with their bottle caps fully tightened.
1. After opening, each bottle of control solution is stable for 90 days if tightly closed after each use. When you first open a new bottle, write the current date on the bottle label, your initials and the calculated expiration date. Discard all unused solutions once the calculated expiration date has passed.
3. After each use, replace the correct cap on each bottle and immediately tighten the cap.
4. Do not use control solutions after the expiration date printed on the bottles and the box. The Precision PCx Monitor does not accept control solutions that have passed their expiration date.

SPECIMEN COLLECTION AND HANDLING

Universal Precautions apply. Follow UMDNJ - Robert Wood Johnson Medical School universal precautions and biohazard disposal policy when handling patient specimens and used MediSense reagent strips.

COLLECTING CAPILLARY BLOOD SAMPLES

1. Collect the capillary blood using a lancing device and an appropriate technique.
2. Avoid squeezing the puncture site excessively.
3. Apply the drop of blood directly to the target area of the test strip, covering the entire area.
4. Since you are using whole blood without an anticoagulant, test immediately to prevent clotting from affecting the results.

CALIBRATION and LINEARITY TESTING PROCEDURES

CALIBRATION and LINEARITY testing are performed by the POCT program staff and are not the responsibility of the testing site staff. However, it is the responsibility of the testing site staff to discontinue using any MediSense monitor that fails any of the checks outlined in this procedure, and to notify the POCT program Administrator.. The monitor will then be repaired or replaced before testing can resume.

QUALITY CONTROL

WHEN TO TEST CONTROL SOLUTIONS

1. Either once daily or prior to running a patient specimen. The glucose monitor has been set to require tests of Low and High Control Solutions, daily whenever patient specimens are being run.
2. When you question blood glucose results.
3. When your test strips have been exposed to temperatures outside the storage conditions (39

degrees - 86 degrees F., 4 degrees - 30 degrees C.).

4. Prior to distributing a new lot of reagent strips to UMDNJ-RWJMS practice sites, strips will be validated centrally.

CONTROL TEST PROCEDURE

1. Turn on the monitor.
2. Press 2-Control Test.
3. Scan or enter your Operator ID.
4. Scan or enter the low control solution lot number. If the Unexpected Level screen appears, your instrument is not programmed to use the control you are using. Make sure you are using the correct solutions.
5. Scan or enter the test strip lot number.
6. The monitor will prompt for a test strip to be inserted into the test strip port. Open the foil test strip packet at the notch and **tear up or down** to remove the test strip. With the contact bars facing up, insert the test strip into the test strip port until it stops.
7. Invert the control solution bottle several times to ensure thorough mixing before use. Tap the capped control solution bottle to remove air bubbles from the nozzle of the bottle.
8. Apply a drop to the target area on the test strip. The monitor will beep when the sample is accepted. The test starts automatically, as the sample is accepted.
9. Recap the control solution bottle tightly.
10. Wait for the monitor to analyze the control solution and display the test results.
 - Note the result and whether it falls within the expected range.
 - Control test results will appear as a PASS/FAIL.
 - The display will show the control range, date and time.
 - An "X" will appear in front of a test result that is out of range.
11. Remove the test strip.
 - If the control test result is within range, Press 1 to continue to the next control, or Press Menu if both controls are done.
 - If the control test is out of range, check to see whether you can identify and fix a problem. If so, Press 2 to repeat the test. If you cannot solve the problem, call for assistance and do NOT perform patient testing.

PROFICIENCY TESTING

Periodically, the lab will be presented with proficiency testing solutions of unknown glucose concentration from a regulatory agency. Follow the following steps to analyze these specimens:

1. Turn on the monitor.
2. Press Menu, then Press 2 – Proficiency Test.
3. Scan or manually enter the Operator ID via the keypad, then press Enter.
4. Enter the Sample ID, then press Enter.
5. Scan, or manually enter the test strip lot number and press Enter.
6. Open the foil test strip packet at the notch and tear up or down to remove the test strip. With the contact bars facing up, insert the test strip into the test strip port until it stops.
7. Gently invert the sample bottle 3-4 times then apply a drop of the sample to the target area on the test strip. The monitor will beep when the sample is accepted. The test starts automatically, as soon as the sample is accepted.
8. Recap the sample bottle tightly.
9. Wait for the monitor to analyze the sample and display the test results.
10. The display counts down the seconds it takes to analyze the proficiency test sample (20 seconds), then displays the result.
11. If the operator is prompted to enter a comment code, continue to step 13; otherwise skip forward to step 14.
12. Scan or manually enter the comment code via the keypad, then press Enter.
13. The monitor returns to the Results menu. The comment code number that was entered will appear in a box to the left of the test result.
14. The operator will select one of the following options:

- Press 1 - Next Test.
- Press Menu to return to the Menu Mode.
- Press On/Off to turn off the monitor.
- The operator can refer back to step 5 for the steps to perform any additional proficiency testing at this time.

PATIENT TEST PROCEDURE

1. Turn on monitor.
2. Press 1 to select Patient Test.
3. Scan or enter your Operator ID.
4. Manually enter the Patient ID via the keypad, then press Enter.
5. Scan or enter test strip barcode.
6. Press 1-Capillary or Arterial
7. Open the foil test strip packet at the notch and tear up or down to remove the test strip. With the contact bars facing up, insert the test strip into the test strip port until it stops.
8. Apply a drop of blood directly from the patient's finger to the target area on the test strip.
 - The test starts automatically, as soon as the sample is accepted. Cover the entire target area of the test strip with the blood sample. The test results will not be affected if the target area has been briefly touched with the patient's finger, a capillary tube or pipette.
 - If the test fails to start, apply a second drop of blood to the target area within 30 seconds. If the test fails to start after the second drop is applied, or if more than 30 seconds have passed, discard the used test strip and repeat the test.
 - After the blood is applied to the test strip and the test starts, do not touch the test strip.
9. Wait for the monitor to analyze the sample and display the result.
10. **If the result exceeds action limits (< 70 or > 400 mg/dL):**
 - An up or down triangle appears in front of the test result.
 - **Inform the patient's physician**
 - **Repeat testing and/or send a sample to lab.**
 - **If repeat testing on a result > 400 mg/dL differs by more than 50, or if repeat testing on a result < 70 differs by more than 10 mg/dL, sent a STAT glucose to the lab.**
11. Remove the test strip from the monitor and discard it in the proper container.
12. The operator can select one of the following options:
 - Press 1-to test another patient
 - Press 2-to repeat the test on the same patient
 - Press 3-to view the patient's previous results. Refer to the section entitled Data Review for Patient History for further information.

INTERPRETATION: REPORTING RESULTS

Point of Care Results are to be conveyed to the attending physician as soon as they are completed.

If the glucose result is **below 70** or **above 400** mg/dL, follow the instructions for repeat testing or laboratory confirmation of the result, as outlined in the PATIENT TEST PROCEDURE section of this policy.

PATIENT HISTORY DATA REVIEW

The Precision PCx Monitor stores up to 4,000 patient tests. Control, Proficiency and Linearity Data can also be reviewed. Follow these steps to access to Patient History Data Review:

1. Turn on the monitor.
2. Press the Menu button.
3. Press 1 - Data Review.
4. Press 1 - Patient History.

5. Press 2 - Patient ID.
6. Scan or manually enter the Patient ID via the keypad, then press Enter.
7. Select one of the following options:
 - Press 1 - Previous, view previous test results.
 - Press 2 - Next, view the next test result.
 - The monitor shows the result of the patient's most recent test result.
 - If there are other test results to view, the bottom line of the monitor shows the following menu options: 1-Previous and 2-Next.
 - The numbers that appear to the right of Previous and Next indicate the number of tests available for review.
 - The display also shows:
 - P: Patient ID
 - O: Operator ID
 - 12: Comment Code
 - ven: Venous Sample
8. When finished reviewing the data:
 - Press Clear to return to the Patient ID screen.
 - Press Menu to return to the Menu Mode menu.
 - Press On/Off to turn off the monitor.

If a printed patient history is needed please contact POCT staff.

PROCEDURE NOTES

If the monitor displays a message not indicated in these procedures, please refer to the troubleshooting section below, or to section 10, Troubleshooting, in your operation manual.

TROUBLESHOOTING:

Troubleshooting sequence:

In order to insure that POCT program administration is aware of generic problems with the Medisense glucose meters, we would request that you use the following sequence to obtain help for your meter:

1. Attempt to duplicate the problem.
2. If possible, re-run the High and Low control solutions
3. Call the POCT clinical coordinator at the number shown on the contact sheet. If the POCT clinical coordinator is not available, contact UDL Central Administration.
4. After a preliminary review, a decision will be reached as to whether to contact PCx technical support.
5. If appropriate, the POCT program will 'swap' out the problematic unit for a validated instrument spare maintained centrally.

Errors with glucose meters can be either technical, due to some failure of the instrument, operator performance or reagents. Occasionally instrument failure is due to the technical limitations of the methodology. Many apparent errors are actually purposely programmed into the instrument due to the selected options chosen for the RWJMS POCT program. This would include the inability of untrained operators to perform testing prior to certification and the updating of the instruments to reflect an updated list of reagents.

Sources of error in patient tests:

Glucose Results Higher than Expected:

1. Hematocrit < 20%
2. Serum or plasma samples used instead of whole blood
3. Room temperature > 104 °F (40 °C)
4. Relative humidity > 90%

- 5. Venous blood tested in capillary or arterial mode
- Glucose Results Lower than Expected
- 1. Hematocrit > 70%
 - 2. Room temperature < 59 °F (15 °C)
 - 3. Relative humidity < 10%
 - 4. Acetaminophen > 100 µg/mL
 - 5. Hyperglycemic-hyperosmolar state (with or without ketosis)
 - 6. Severe dehydration, hypotension or shock
 - 7. Water or alcohol remaining on the puncture site
 - 8. Venous or arterial whole blood sample not tested within 30 minutes after collection

Troubleshooting Out of Range Control Test Results:

Repeat the test to insure that the following conditions are met:

- 1. No air bubbles are in the control bottle's nozzle.
- 2. Calibrate the monitor using the bar-code for the test strip used.
- 3. Enter the correct 5-digit lot number for the control solution (note that there are different lot numbers for the High Control and for the Low Control).
- 4. Check storage temperatures. Solutions and test strips must be stored between 39 °F and 86 °F (4 – 30 °C).
- 5. Check that the temperature and humidity conditions in the room where the test is being performed are within the acceptable range (see Test Strip package insert).
- 6. Check that the control solutions have not been open for more than 90 days.
- 7. Make sure that only PCx strips are used.

If in doubt repeat the test using a new box of control solutions and/or test strips.

REFERENCES

- 1. ABBOTT Precision PCx Point-of-Care System Operation Manual
Abbott Laboratories
PN 125-085
Revision 0 10/98

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