

# Accu-Chek Inform System Setup and Maintenance

## General Policies for Storage and Maintenance of the Accu-Chek Inform System

- The Accu-Chek Inform System is handled with care. Sudden shocks caused by dropping or rough treatment may affect performance. If the Accu-Chek Inform System is dropped, performance is verified by quality control testing.
- The Accu-Chek Inform System is stored away from direct sunlight and extreme temperatures.
- A list of all Accu-Chek Inform System serial numbers, assigned inventory numbers, and locations is maintained by POCT coordinator.
- Accu-Chek Inform serial numbers are updated if Accu-Chek Inform Systems are replaced.
- Cleaning and maintenance of the Accu-Chek Inform System is performed monthly and/or otherwise indicated.
- Disposable latex gloves are worn when performing preventive maintenance and cleaning on the Accu-Chek Inform System and blood glucose testing equipment..
- Cleaning and maintenance of the Accu-Chek Inform System is performed by qualified operator.
- If personnel are unable to correct a problem with the Accu-Chek Inform System, it is removed from service and sent to Lab for repair/replacement. The Accu-Chek Inform System must be cleaned and disinfected before it is sent out for repair or replacement.
- Use only the battery pack available from Roche Diagnostics (Cat. No. 3034844) in the Accu-Chek Inform System. Using any other type of battery pack may damage the system.
- If the Accu-Chek Inform System is to be stored for a long period of time, the battery is removed to avoid leakage or damage.
- When storing or disposing of batteries, keep or replace in manufacturer's packing material. Incorrect storage or disposal of batteries could result in a hazardous condition.

## Initial Setup of the Accu-Chek Inform System

- The initial setup of the Accu-Chek Inform System is the responsibility of POCT coordinator.

- The following are established at initial setup
  - Setting the Time
  - Setting the Date
  - ID Requirements
  - Device Setup
  - Control Lockout Setup
- Any updates or changes to the initial setup are performed as needed by POCT coordinator
- The procedures for initial setup can be found in the *Accu-Chek Inform System Operator's Manual* and configuration software.
- Before any new meter can be put into service, both linearity and quality control testing must be done. See those procedures, listed in this manual.

## **Routine Maintenance of the Accu-Chek Inform System**

### **1. Daily Maintenance:**

Each day of use the Accu-Chek Inform System requires 2 levels of Quality Control. See the *Accu-Check Inform Quality Control* procedure in this manual for details.

### **2. Monthly Maintenance:**

- A. The POCT coordinator is responsible for uploading information from each glucometer throughout the hospital once each month. To transfer data from an Accu-Chek Inform System, refer to the Datacare program user's manual. NOTE: Once data is uploaded into Datacare, it is deleted from the Inform meter.
- B. Once data is successfully uploaded into the Datacare computer, it is the responsibility of the POCT coordinator to review data.

To review patient data:

- Select PENDING SAMPLES
- Highlight the first sample and click on "DONE"
- If patient information is present (Auto Save for HI or LO results), select save.
- If no patient information is present, enter a comma (,) for the medical records number and press enter. Select SAVE

- Return to SAMPLES and repeat the steps above till all samples are resolved.

To review QC data:

- Select QC PENDING
- Highlight the first QC
- Select VIEW QC
- Select SAVE QC.
- Tab to the ACCEPTABLE? Line and select NO for outliers.
- Tab to CORRECTIVE ACTION and enter the appropriate response
- Select DONE

C. After data has been reviewed, print monthly reports. See the *Printing Reports* procedure in this manual for step-by-step instructions. Please note that some, not all, of the reports must be reviewed by the Medical Director or designee.

D. The Accu-Chek Inform Meters should be cleaned by the POCT coordinator at least monthly. See the As needed maintenance portion of this procedure for details.

### 3. Semiannual Maintenance

A. **Linearity Testing** is required for each Accu-Chek Inform meter at least once every 6 months. Linearity is used to validate the Analytical Measurement Range (AMR) of the glucometer. See the POCT Linearity Testing procedure for details.

B. **Split sample analysis** is performed once each 6 months to correlate patient results performed by glucometer with those of the house method (DADE Dimension). See the policy titled *Validation of Performance of Accu-Chek Inform using Split specimen with an established in house method* for testing specifications. Split sample analysis is performed in the months of April and October.

### 4. As Needed Maintenance

A. **Cleaning:** Wipe the surface of the Accu-Chek Inform System with a soft cloth slightly dampened (not wet) with one of the following solutions. (**Note:** Do not spray the Accu-Chek Inform System directly with solution,

as this could cause solution to enter the case and damage the electronic components.)

- A freshly mixed solution of 1:10 bleach in water (1 part bleach in 9 parts water)
- 70% isopropyl alcohol, full strength
- Warm soapy water

**B. Coding (Calibration)** of the Accu-Check Inform Meter is performed each time a new vial of test strips is opened.

To code (calibrate) a meter:

1. Gather the meter to be tested and the test strips with the appropriate Code Key. Verify that the meter is turned off.
2. Remove the Code Key from the test strip box.
3. Compare the three-digit number on the Code Key with the number on the test strip vial.
4. Remove the old key from the meter, if necessary.
5. Snap the new Code Key (slots facing towards the meter) into the Code Key slot with the printed side facing up.
6. Leave the Code Key in the meter.

**C. Entering Test Strip Codes:**

The test strip code displayed by the Accu-Chek Inform System must match the code of the test strips in use. If not, the meter must be recoded (recalibrated) and the new code information must be entered in the Accu-Chek Inform System. Refer to the above Coding/Calibration section of this procedure for the procedures.

Test strip code information must be verified and/or re-entered in the Accu-Chek Inform System by the operator whenever a patient or quality control test is performed.

To enter the test strip code on the Accu-Chek Inform System (if reagent editing is allowed):

1. Press the power ON button. A self-test is automatically performed when Inform meters are powered up. If the unit detects errors, the error message screen will appear with the appropriate error message. The battery symbol shows the status of the battery charge.
2. Enter the operator ID (6 digit billing number –example 258495) and press the forward arrow button. The operator is to use ONLY their ID number.
3. Select Control Test or Patient Test.
  - If Control Test was selected, select a control level and verify the solution lot number.

- If Patient Test was selected, enter the patient ID and press the forward arrow button.
4. Verify the strip code information.
    - If “YES” is selected, the user will be prompted to insert a test strip and begin testing.
    - If “NO” is selected, the user will be prompted to replace the Code Key, if necessary.
    - Choose “YES” to add a new strip lot.
    - Enter the expiration date from the test strip vial label. Press the forward arrow button.
    - Verify/enter the minimum and maximum values for each level of control solution (Level 1, Level 2).
    - Verify the strip code information.
  5. Proceed with patient or QC testing.

**D. Entering Quality Control Lot information:** See the *Accu-Chek Inform Quality Control* Procedure in this manual for details.

## Documentation and Replacement

- Any maintenance or repair to an Accu-Chek Inform meter on service sheets.
- All blood glucose monitoring equipment is available from Lab/Stores A replacement is available if a meter continues to malfunction after proper troubleshooting procedures.
- If nursing personnel are unable to correct a problem with the Accu-Chek Inform meter, the meter must be removed from service and sent to Lab for repair or replacement. The Accu-Chek Inform System must be cleaned and disinfected before it is sent out for repair or replacement.
- The unit supervisor or POCT coordinator will review the preventive maintenance log for completion monthly.
- If any deficiencies are noted, a report is submitted to Pathologist. This report is reviewed and any corrective action is noted
- All questions and/or malfunctioning glucometers are referred to lab on first shift. The off shift questions and/or malfunctioning glucometers are instructed to call Accu-chek Customer Care 1-800-440-3638 or Nursing Supervisor.

## References

1. Mor, Juan-R. and Guarnaccia, Rocco: Assay of Glucose Using an Electrochemical Enzymatic Sensor, *Analytical Biochemistry*, 79:319-328 (1977).

2. D'Costa, E.J., Higgins, I.J., et al., Quinoprotein Glucose Dehydrogenase and its Application in an Amperometric Glucose Sensor, *Biosensors*, 2:71-87 (1986).
3. Hauge, J.G., Glucose Dehydrogenase of Bacterium Anitratum: an Enzyme with a Novel Prosthetic Group, *Journal of Biological Chemistry*, 239:3630-3639 (1964).
4. Tietz, N.W., *Textbook of Clinical Chemistry*, p. 2190 (1994).
5. American Diabetes Association Position Statement, *Diabetes Care*, Vol. 19 (suppl. 1), p. S4 (1996).
6. Atkin, S.H.; Dasmahapatra, A.; Jaker, M.A.; Chorost, M.I.; Reddy, S., Fingerstick Glucose Determination in Shock, *Annals of Internal Medicine*, 114:1020-1024 (1991).
7. Sandler, M.; Low-Beer, T., Misleading Capillary Glucose Measurements, *Practical Diabetes*, 7:210 (1990).
8. Wickham, N.W.R.; Achar, K.N.; Cove, D.H., Unreliability of Capillary Blood Glucose in Peripheral Vascular Disease, *Practical Diabetes*, 3:100 (1986).

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# Accu-Chek Inform System Quality Control Testing

## Principal:

Data produced by the Accu-Chek Inform System directly affects patient care. This data must be accurate, precise, and useful. To assure the accuracy of the patient data that is reported, it is necessary to insure that quality control is performed on a routine basis. Personnel performing patient glucose testing will perform quality control testing. Quality control testing will be performed in the same manner as patient testing.

Control tests are performed at the following times

- Each time a new vial of test strips of a different lot number
  - Each 24 hours as determined in Setup
  - When the test strips have been exposed to extreme heat, humidity, or cold
  - Otherwise indicated (troubleshooting)
- 
- If a quality control test result falls within the acceptable control range, it is acceptable to proceed with patient testing.
  - If a quality control test result falls outside of the acceptable control range and a repeat control test fails, the Troubleshooting section of the *Accu-Chek Inform Operator's Manual* is referenced, if needed, and the problem is corrected before proceeding with patient testing.
  - Any quality control result that falls outside of the acceptable control range, along with any corrective action to restore that result to acceptable range, must be recorded.
  - In areas where the Accu-Chek Inform System is not being used daily, quality control will be performed before patient testing
  - Internal proficiency testing to verify meter accuracy and operator competency will be performed according to policy.
  - Glucose control solutions must be stored at room temperature. Do not freeze. Glucose control solutions are stable for three months after opening or until the expiration date, whichever comes first. The date the vial is opened should be written on the vial label.
  - Any outdated glucose control solutions will be discarded.
  - The test strip lot number and the acceptable glucose control ranges are found on the label of each vial of test strips.
  - Test strips must be stored at room temperature. Do not refrigerate or freeze. Test strips are stable until the expiration date. Test strips must be stored in the same capped vial in which they were packaged, and the vial cap must be immediately replaced after removal of a test strip. Outdated test strips will be discarded.

- Quality Control records will be retained for a minimum of two years.

## Reagents and Equipment:

The following equipment is needed for quality control testing:

- Accu-Chek Inform System
- Accu-Chek Comfort Curve test strips with Accu-Chek Comfort Curve Glucose Control Solutions 1 Level (cat No. 2030365) 2-level (Cat. No. 2030365)

## Procedure:

1. Put on disposable latex gloves.
2. Press power ON button.
3. Enter your operator ID, then press the forward arrow button.
4. Select Control Test.
5. Select the desired control level: Level 1, and Level 2.
6. Verify the lot number of control solution displayed on the Accu-Chek Inform System.
  - Select YES if the lot number is correct.
  - Select NO if the lot number is incorrect. Enter lot number and expiration date from control solution bottle.
7. Verify that the strip code number on the test strip vial matches the code number on the Accu-Chek Inform System.
  - Select YES if the code numbers match.
  - Select NO to enter a new code.
8. Remove a test strip from the vial and replace the vial cap immediately.
9. When the flashing strip icon appears on the meter display, gently insert test strip with the yellow target area or test window facing up. (Insert the end with the silver bars.)  
**Note:** Insert test strip BEFORE dosing.
10. If using the Accu-Chek Comfort Curve test strip:
  - Touch and hold drop of glucose control solution to the curved edge of the yellow target area.
  - The glucose control solution is drawn into the test strip automatically.
11. An hourglass (26 seconds) will be displayed on the Accu-Chek Inform meter while waiting for the result.
12. Enter the appropriate comment(s), if needed. Then press the forward arrow button to record the test and to test the next level of control or to proceed to patient testing.
13. Remove the used test strip(s) and disposable latex gloves and discard them as biohazard items
14. Return the meter to the base unit for charging.

15. Document the result(s).

## Documentation of Quality Control Results:

- The date, time, initials or ID of the operator, meter serial number, and quality control result are recorded in the meter automatically.
- If a quality control test result falls within the acceptable control range, it is acceptable to proceed with patient testing.
- If a quality control test result falls outside of the acceptable control range, and a repeat control test fails, the meter is now in QC lockout and no patient testing can be performed until the problem is corrected. See “Troubleshooting” section of the Accu-Chek Inform System Operator’s Manual.
- Any quality control result that falls outside the acceptable control range, along with any corrective action to restore that result to acceptable range, is recorded as a comment in the meter. This comment will show on monthly reports.
- The POCT coordinator will review the quality control records for completion, as well as note any trends that may indicate potential problems. These trends include gradual drifting of values, sudden shifts in glucose control values while using the same lot of strips, and operator performance. These records are reviewed in the laptop after downloading and printed out monthly for review by the Laboratory director.

## References:

1. Mor, Juan-R. and Guarnaccia, Rocco: Assay of Glucose Using an Electrochemical Enzymatic Sensor, *Analytical Biochemistry*, 79:319-328 (1977).
2. D’Costa, E.J., Higgins, I.J., et al., Quinoprotein Glucose Dehydrogenase and its Application in an Amperometric Glucose Sensor, *Biosensors*, 2:71-87 (1986).
3. Hauge, J.G., Glucose Dehydrogenase of Bacterium Anitratum: an Enzyme with a Novel Prosthetic Group, *Journal of Biological Chemistry*, 239:3630-3639 (1964).
4. Tietz, N.W., *Textbook of Clinical Chemistry*, p. 2190 (1994).
5. American Diabetes Association Position Statement, *Diabetes Care*, Vol. 19 (suppl. 1), p. S4 (1996).
6. Atkin, S.H.; Dasmahapatra, A.; Jaker, M.A.; Chorost, M.I.; Reddy, S., Fingerstick Glucose Determination in Shock, *Annals of Internal Medicine*, 114:1020-1024 (1991).
7. Sandler, M.; Low-Beer, T., Misleading Capillary Glucose Measurements, *Practical Diabetes*, 7:210 (1990).
8. Wickham, N.W.R.; Achar, K.N.; Cove, D.H., Unreliability of Capillary Blood Glucose in Peripheral Vascular Disease, *Practical Diabetes*, 3:100 (1986).

# Accu-Chek Inform System

## Patient Testing

### **Clinical Significance:**

Glucose is the major energy source for the human body. It is derived mostly from dietary carbohydrates, from body stores of carbohydrates, and the synthesis of glucose from protein and the glycerol moiety of triglycerides. When glucose intake exceeds the daily amount needed, the excess is converted to fat and stored in adipose tissue. If the daily calorie intake is not met, glucose is produced from the breakdown of the carbohydrate stores.

The glucose level is kept within a fairly narrow range through several mechanisms. This provides the body with energy to keep it running internally for body heat and metabolism and externally for muscular activity and work. Levels above or below the normal range usually indicate disease. High blood glucose due to diabetes mellitus is the most commonly encountered disorder of carbohydrate metabolism. Glucose is also elevated in pancreatitis and Cushing's syndrome. Hypoglycemia is infrequent and is almost always due to a serous extrapancreatic tumors, hepatic disease, or endocrine disorders.

The Accu-Chek Inform system allows for the rapid, accurate monitoring of blood glucose levels.

### **Principal:**

The enzyme glucose dehydrogenase converts the glucose in the blood sample to gluconolactone. This reaction liberates an electron that reacts with a coenzyme electron acceptor, the oxidized form of the mediator hexacyanoferrate (III), forming the reduced form of the mediator, hexacyanoferrate (II). The Accu-Chek® Comfort Curve® test strips employ the electrochemical principle of amperometry. The meter applies a voltage between two identical electrodes, which causes the reduced mediator formed during the incubation period to be reconverted to an oxidized mediator. This generates a small current that is read by the meter.

### **Reagents and Equipment:**

The Accu-Chek Inform System works with the following sets of reagents:

- Accu-Chek Comfort Curve Test Strips (Cat. No. 2030365)
- Accu-Chek Comfort Curve Glucose Control Solutions 1 –Level (Cat. No 2030365) 2-level (Cat. No.2030365)
- Accu-Chek Comfort Curve Linearity Test Kit (Cat No. 2030357)

## Specimen Collection and Handling:

- Capillary, venous, neonatal (including cord blood), and arterial whole blood specimens may be used for testing on the Accu-Chek Inform System with Accu-Chek Comfort Curve test strips.
- The capillary sample must be tested immediately after collection.
- Blood glucose determinations using venous and arterial blood specimens should be performed within 30 minutes of specimen collection to avoid glycolysis. Mix samples thoroughly.
- For best results with arterial and venous blood, the following anticoagulants/preservatives are recommended: heparin and EDTA.
- Serum separator tubes and red-topped tubes are acceptable if blood is used immediately before the clotting process begins.
- Iodoacetate or fluoride/oxalate should not be used as a preservative.
- Caution should be taken to clear arterial lines before blood is drawn and dosed on the test strip.
- Caution is advised in the interpretation of neonate glucose values below 40 mg/dL.
- Sufficient sample size is required to ensure accurate results.

## Quality Control:

Personnel performing patient glucose testing will perform quality control testing. Quality control testing will be performed in the same manner as patient testing. **See the Accu-Chek Inform Quality Control Testing Procedure for step-by-step testing information.**

Control tests are performed at the following times

- Each time a new vial of test strips of a different lot number
  - Each 24 hours as determined in Setup
  - When the test strips have been exposed to extreme heat, humidity, or cold
  - Otherwise indicated (troubleshooting)
- 
- If a quality control test result falls within the acceptable control range, it is acceptable to proceed with patient testing.
  - If a quality control test result falls outside of the acceptable control range and a repeat control test fails, the Troubleshooting section of the *Accu-Chek Inform Operator's Manual* is referenced, if needed, and the problem is corrected before proceeding with patient testing.
  - Any quality control result that falls outside of the acceptable control range, along with any corrective action to restore that result to acceptable range, must be recorded.
  - In areas where the Accu-Chek Inform System is not being used daily, quality control will be performed before patient testing

- Internal proficiency testing to verify meter accuracy and operator competency will be performed according to policy.
- Glucose control solutions must be stored at room temperature. Do not freeze. Glucose control solutions are stable for three months after opening or until the expiration date, whichever comes first. The date the vial is opened should be written on the vial label.
- Any outdated glucose control solutions will be discarded.
- The test strip lot number and the acceptable glucose control ranges are found on the label of each vial of test strips.
- Test strips must be stored at room temperature. Do not refrigerate or freeze. Test strips are stable until the expiration date. Test strips must be stored in the same capped vial in which they were packaged, and the vial cap must be immediately replaced after removal of a test strip. Outdated test strips will be discarded.
- Quality Control records will be retained for a minimum of two years.

## **Procedure for Patient Testing:**

**NOTE: Only a certified operator may perform a blood glucose test on the Accu-Chek Inform System.**

1. The following equipment should be at the patient's bedside prior to testing:
  - Accu-Chek Inform System
  - Accu-Chek Comfort Curve test strips
  - Single-use, disposable lancets Safe-T-Pro
  - Alcohol swab
  - Cotton ball, tissue or gauze for wiping finger after stick
  - Disposable latex gloves
2. Check patient's armband to properly identify patient for testing and when entering into Inform meter (manually or scanning). Two patient identifiers should be used.
3. Explain the purpose of the test and the steps of the testing procedure to reassure the patient.
4. Wash your hands and put on disposable gloves prior to testing. Because of the hazardous nature of handling blood products, it is required that disposable gloves be used when collecting specimens and performing test procedures. Universal precautions shall be observed for handling all blood specimens.
5. If the patient is able, ask the patient to wash his/her hands with warm water and soap, rinse and dry well prior to testing capillary samples. If the patient is unable, cleanse the puncture site with an alcohol swab and allow it to thoroughly dry. (Alcohol at the puncture site must be dry or an error code/inaccurate result may occur.
6. Press power ON button.
7. Enter your operator ID. Press the forward arrow button.
8. Select Patient Test.

9. Enter the patient ID—enter the patient ID by scanning the wrist band (patient account number) and verifying name—verify account number on the Inform screen or manually type in the patient account number and verifying name. Press forward arrow key.
10. Verify that the code number on the test strip vial corresponds to the code number on the Accu-Chek Inform System.
  - Select YES if the code numbers correspond.
  - Select NO if the code numbers do not correspond. See *Entering Test Strip Code* section of the Accu-Chek Inform Set-up and Maintenance Procedure.
11. Remove a test strip from the vial. Immediately replace the cap on the vial.
12. When the flashing strip icon appears on the meter display, gently insert test strip. The yellow target area (test strip window) should face up. (Insert the end with the silver bars.)

**Note:** Insert test strip BEFORE dosing.
13. When the flashing drop icon appears on the meter display, obtain a blood sample. You may use a whole blood capillary, venous, arterial or neonatal (including cord) blood sample. Blood glucose determinations using venous and arterial blood specimens should be performed within 30 minutes of specimen collection to avoid glycolysis. See the POCT fingerstick procedure for capillary collection. Capillary samples must be tested immediately after collection. Be sure to wipe away the first drop of blood and apply the second drop to the strip when using capillary specimens.

Using the Accu-Chek Comfort Curve test strip:

  - Touch and hold drop of blood to the curved edge of the yellow target area.
  - The blood is drawn into the test strip automatically.

**Important:** If you see any yellow color in the target area or test strip window after you have applied the initial drop of blood, a second drop of blood may be applied to the strip within 15 seconds of the first drop. If more than 15 seconds have passed, the test result may be erroneous, and you should discard the test strip and repeat the test.
14. An hourglass will appear on the display while waiting for the result.
15. Press the forward arrow button to record the test and return to the Main Menu screen in order to run the next test.
16. Remove the test strip from the meter and discard in biohazard manner.
17. Press the power OFF button to turn the Accu-Chek Inform System off.
18. Remove gloves and dispose. Wash hands thoroughly with soap and water.
19. Return the meter to the base unit for charging.
20. Document the blood glucose result in diabetic section of CPSI

## Interpretation of Results:

Nursing staff is to follow physician's orders for the patient once a glucose level is obtained. If patient glucose is inconsistent with the patient's clinical presentation, troubleshoot the meter according to Operator's Manual and/or repeat test.

- First, retest the patient and/or a control
- Verify Inform operation and procedure (correct test strip and code key???, adequate specimen – yellow window full???, test strips expired???)

If results are still inconsistent, notify physician

## Guidelines

1. Blood glucose tests with the Accu-Chek Inform System must be ordered by a physician unless the patient is experiencing symptoms of hypoglycemia or hyperglycemia, and quality care dictates a STAT test.
2. Any patient result that exceeds the critical range (<50 or >400 mg) is followed-up by the operator ordering blood glucose draw.
3. A physician will be notified according to parameters specifically ordered. A STAT blood glucose test performed by the laboratory is ordered whenever the blood glucose result is less than 50 mg/dL or greater than 400 mg/dL
4. If HI is displayed, the blood glucose result may be higher than the reading range (linearity) of the meter (600 mg). If this contradicts the patient's condition, perform a quality control check with glucose control solution and a new test strip. If the control result is within the acceptable range, review proper testing procedure and repeat the blood glucose test with a new test strip. If HI still appears on the patient test, follow critical value policy and order blood draw. If the control result is not within the acceptable range, refer to the *Accu-Chek Inform System Operator's Manual* before proceeding with patient testing.
5. If the error message "testing error-133 A glucose overflow error has occurred, type 71" appears on the display, the blood glucose result may be extremely high and above the meter's reading range. If this contradicts the patient's condition, perform a quality control check with glucose control solution and a new test strip. If the control result is within the acceptable range, review proper testing procedure and repeat the blood glucose test with a new test strip. If the error still appears on the patient test, follow you critical value policy and order blood draws. If the control result is not within the acceptable range, refer to the *Accu-Chek Inform System Operator's Manual* before proceeding with patient testing.
6. If LO is displayed, the blood glucose result may be lower than the reading range of the meter (10 mg). If this contradicts the patient's condition, perform a quality control check with glucose control solution and a new test strip. If the control result is within the acceptable range, review proper testing procedure and repeat the blood glucose test with a new test strip. If LO still appears on the patient test, follow critical value policy and order blood draw. If the control result is not within the acceptable range, refer to the *Accu-Chek Inform System Operator's Manual* before proceeding with patient testing.

7. If a Strip Defect error message appears on the display, the test strip may be damaged or the test was not performed correctly. The test strip should be inserted into the meter prior to applying blood to the test strip. If this display appears *before* blood is placed on the strip, remove the test strip and reinsert. If the error display remains, repeat the test with a new strip.
8. If the meter displays “Error 88-Bad Dose”, there is an incorrect amount of blood on the strip. A second drop of blood may be applied to the test strip within 15 seconds of the first drop. If more than 15 seconds have passed, the test result may be erroneous and you should discard the test strip and repeat the test.
9. If the temperature-warning message appears on the display, the temperature is above or below the operating range of the test strips. Move to a testing area that is between 57° and 104° F (14° and 40° C) and wait five minutes before repeating the test. Do not artificially heat or cool the meter.

## **Documentation of Blood Glucose Results:**

1. Record the date, time, RN/LPN performing the test, and the glucose result in CPSI.
2. Indicate the fasting state (or the time of last food intake) of the patient per policy. This is important if the glucose result is higher or lower than expected.
3. In the event that the patient is not yet admitted in the computer (newborn, or unresponsive patient in ER), results should be recorded on Blood Glucose Patient Results forms located on those units.
4. Patient results will be retained in their medical records.

## **Expected Values:**

- The normal fasting blood glucose range for a non-diabetic adult is 70-100mg/dL.
- One to two hours after meals, normal blood glucose levels for a non-diabetic adult should be less than 140 mg/dL.

## **Critical Values:**

- Physician notification and treatment for hypoglycemia will be initiated if the blood glucose value is less than 50 mg/dL.
- Physician notification and treatment for hyperglycemia will be initiated if the blood glucose value is greater than 400 mg/dL.
- Any patient with results falling in the critical value range (<50 mg/dl or >400 mg/dl) will have a confirmation glucose drawn by lab.
- POCT heelstick blood glucose on newborns of < 40mg/dl must be verified by repeat heelstick performed by lab personnel. Pediatric doctors request no upper glucose limit for neonates.

- Nursing personnell must notify doctor, then refer to the hypoglycemic or hyperglycemic protocol as stated in nursing manual

## Limitations:

Test strips give dependable test results if the following limitations are understood:

- Use only Accu-Chek Comfort Curve test strips (Cat. No. 2030365)) for testing capillary, venous, neonatal (including cord), and arterial whole blood samples.
- Blood glucose determinations using venous and arterial blood specimens should be performed within 30 minutes of specimen collection to avoid glycolysis. Avoid air bubbles if dosing with pipettes. Air bubbles may cause erroneous results.
- For best results with arterial and venous blood, the following anticoagulants/preservatives are recommended: heparin and EDTA.
- Serum separator tubes and red-topped tubes are acceptable if blood is used immediately before the clotting process begins.
- Iodoacetate or fluoride/oxalate should not be used as a preservative.
- Caution should be taken to clear arterial lines before blood is drawn and dosed on the test strip.
- Caution is advised in the interpretation of neonate glucose values below 40 mg/dL.
- Do not use during xylose absorption testing.
- No effect was found at 20% to 65% hematocrit and glucose concentrations up to 200 mg/dL.
- At glucose concentrations above 200 mg/dL, low hematocrits (below 20%) may cause elevated results and high hematocrits (above 55%) may cause reduced results versus a whole blood reference.
- System measurement range is 10-600 mg/dL.
- The Accu-Chek Inform System has been tested at altitudes ranging from sea level to 10,150 feet.
- The following compounds, when determined to be in excess of their limitations, may produce elevated glucose results:

<b>Compound</b>	<b>Limitation</b>
<u>Galactose</u>	<u>&gt;10 mg/dL</u>
<u>Maltose</u>	<u>&gt;16 mg/dL</u>
<u>Bilirubin (unconjugated)</u>	<u>&gt;20 mg/dL</u>
<u>Lipemic Samples</u>	<u>&gt;5000 mg/dL</u>
<u>Acetaminophen</u>	<u>&gt;8 mg/dL</u>
<u>Uric Acid:</u>	
<u>Hypoglycemic range</u>	<u>&gt;10 mg/dL</u>
<u>Euglycemic range</u>	<u>&gt;12 mg/dL</u>
<u>Hyperglycemic range</u>	<u>&gt;16 mg/dL</u>

- In situations of decreased peripheral blood flow, fingerstick blood testing may not be appropriate as it may not reflect the true physiological state. Examples would include but are not limited to: severe dehydration caused by diabetic ketoacidosis or the hyperglycemic hyperosmolar nonketotic state, hypotension, shock, or peripheral vascular disease.
- See the “Safety Alert” at the end of this portion of the procedure for additional drug interferences.

## References:

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2. D’Costa, E.J., Higgins, I.J., et al., Quinoprotein Glucose Dehydrogenase and its Application in an Amperometric Glucose Sensor, *Biosensors*, 2:71-87 (1986).
3. Hauge, J.G., Glucose Dehydrogenase of Bacterium Anitratum: an Enzyme with a Novel Prosthetic Group, *Journal of Biological Chemistry*, 239:3630-3639 (1964).
4. Tietz, N.W., *Textbook of Clinical Chemistry*, p. 2190 (1994).
5. American Diabetes Association Position Statement, *Diabetes Care*, Vol. 19 (suppl. 1), p. S4 (1996).
6. Atkin, S.H.; Dasmahapatra, A.; Jaker, M.A.; Chorost, M.I.; Reddy, S., Fingerstick Glucose Determination in Shock, *Annals of Internal Medicine*, 114:1020-1024 (1991).
7. Sandler, M.; Low-Beer, T., Misleading Capillary Glucose Measurements, *Practical Diabetes*, 7:210 (1990).
8. Wickham, N.W.R.; Achar, K.N.; Cove, D.H., Unreliability of Capillary Blood Glucose in Peripheral Vascular Disease, *Practical Diabetes*, 3:100 (1986).

# Accu-Chek Inform System

## User Training and Competency Policy

### **Training Policy:**

Prior to performing testing on the Accu-Chek Inform System, users must be trained in the care and use of the meter. Each user will undergo training with an approved trainer and must demonstrate understanding and use of the meter. Once training is complete, the new user will fill out the Accu-Check Inform Glucometer Training form. This form is signed and dated by the trainer, and retained by the POCT Coordinator for documentation. The POCT Coordinator is responsible for entering the new operator into the Datacare user system once training is complete.

The following skills must be discussed/demonstrated during training:

1	Insert/change Code Key when monitor is turned off.
2	Clean with 70% isopropyl alcohol or 1:10 solution of 1 part bleach in 9 parts water
3	Document opening/expiration dates of control solutions
4	Verify control solution lot number
5	Identify expected ranges of both Level 1 & 2 control solutions
6	Prepare patient for successful finger stick
7	Enter patient id number
8	Check expiration date & dry storage of test strips
9	Verify test strip lot number
10	Obtain blood sample; discard first sample.
11	Apply blood/control solution to fill yellow window on test strip
12	Identify critical range of <50 or >400mg/dL
13	Enter comment codes
14	Dispose of lancets & test strips
15	Document in patient medical record
16	Store monitor in charging dock.

### **Competency Policy:**

Each year, Accu-Chek Inform users are required to perform competency testing. Each user will be given a quiz with basic operating questions to answer. Users are also given an unknown sample for testing. They are asked to sign a statement that they have reviewed the Accu-Check Inform Nursing Policy and Procedures. Once all testing has been performed, the quizzes are returned to the POCT Coordinator for review and documentation. It is the responsibility of the POCT Coordinator to update user profiles in the Datacare System. Any questions about competency testing should be directed to the POCT Coordinator.

Those users who pass with at least a 70% correct will be updated in the Datacare System. These users will be able to continue to use the glucometer. Those who fail to turn in competency quizzes by the required date will be locked out from using the meters. Those users who receive less than a 70% will be locked out from using the meters. Nurses who fail the test will be directed to their supervisor for review of the test. They will be given the opportunity for re-education and re-testing. Repeat testing must be successful before the user can be entered into the system.

Along with annual competency testing, users may be asked to perform CAP Proficiency testing samples. Samples are received three times per year. Testing will be rotated between those nurses who routinely perform patient testing. They are required to perform proficiency testing in the same manner that they would for patients. Results are reviewed by the POCT Coordinator and sent to CAP for evaluation.

Saved as: Accu-Chek Inform System User Training and Competency.