COMMUNITY MEDICAL CENTER

From day one.

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Blood Glucose Meter Checks at the Patient Bedside, PH1582

PURPOSE:.

To provide guidelines and procedure steps for checking the blood glucose level at the patient bedside on hospital patients using the Accu-Chek Inform II Glucose meter system.

INDICATIONS:

Healthcare provider ordered blood glucose checks to rule out hypoglycemia, hyperglycemia and to monitor insulin therapy. **DO NOT use Capillary blood testing on patients with decreased peripheral blood flow or who have increased interstitial fluid. The Accu-Chek glucose meters may NOT be used in critically ill patients. Critically ill patients are defined as patients in the ED, ICU, or PICU who are severely dehydrated, hypotensive, in shock or in a hyperglycemic-hyperosmolar state (with or without ketosis). Glucose testing in these patients must be performed using venous or arterial sampling and sent to the laboratory for testing.**

WHO MAY USE THE METERS:

RN, LPN, CNA, EMT-P (with documented training). 2 forms of competency must be performed annually to be certified as an Operator. These 2 forms of competency testing are: successfully completing a Healthstream quiz every year during 'CMC's Care Days' and performing 2 levels of liquid Quality Controls during the MONTH your department has been assigned the task of performing liquid Controls. The Clinical Educator will notify the department manager when it is the required month for the 2 levels of controls. If either of these two forms of competency is not performed when required the Operator will be LOCKED OUT of the glucose until they have successfully completed the required competency.

IMPORTANT POINTS TO REMEMBER:

1. In critical care settings, it is important to assess whether or not it appropriate to use a glucose meter. Any patient who meets the criteria of Critically ill (severely dehydrated, hypotensive, in shock or in a hyperglycemic-hyperosmolar state with or without ketosis) must have all glucose testing performed from a venous or arterial sample and tested using an approved method OTHER than the glucose meter.
2. On the Roche Accu-Chek Inform meter, a reading of LO means that the blood glucose is less than 10 mg/dl; a reading of HI means that the blood glucose is greater than 600 mg/dl.

3. The patient can NOT use their own glucose meter for testing while they are in the hospital. The Inform II glucose meters are the ONLY glucose meters that may be used for patient testing in the hospital setting because these meters and all of the supplies used for testing are maintained in accordance with the manufacturers requirements at all times! To verify that the patient's glucose meter and testing system is working correctly as they are preparing to leave the hospital a correlation test can be performed by testing the patient's meter with a sample of heparinized (green Top) venous blood which will then be sent to the Laboratory for a venous glucose. These values should agree within +/- 10% if the patient's meter system is working correctly. Anytime the patient's meter does not agree with the Inform II meter or the venous glucose performed in the Laboratory the patient's meter should be cleaned, checked and calibrated per manufacturer instructions.
4. Be sure to leave the meter laying on a flat surface until the strip is removed. Failure to do so may result in contamination of the reading electrode.

PROCEDURE STEPS:

1. Order Handling:
    a. Scheduled blood glucose checks are handled in the following manner:
    b. The healthcare provider will order all POC testing directly into the EHR as a NURSING task
    c. The nursing staff will review the orders in patient's chart and sign them which will activate the order. Once activated the EHR will send a task notice to the nurse to perform the capillary Glucose, so the nursing staff will perform the blood collection at assigned time, **WHICH WILL BE EQUAL TO OR LESS THAN ONE HOUR BEFORE DIABETIC MEDICATIONS ARE GIVEN.**
    d. The Inform II glucose meter will upload the glucose results to the EHR wirelessly once the result is finalized in the meter. After that time the Glucose results will be available for review in the EHR listing the glucose result, date, time and any comments which were added in the glucose meter before the results were finalized. This result should be referenced when manually documenting the glucose value in the MAR when a patient is given Insulin, according to the '24 hour Glucose Pattern Record policy and procedure'.
    e. Nursing will check the MAR for insulin type and oral diabetes medications. Nursing will time the glucose check so that the best action of the insulin or diabetes medication in relation to the meal can be obtained, WHICH MEANS THE BLOOD GLUCOSE CHECK WILL BE LESS THAN 1 HOUR OLD. If the Blood Glucose value was obtained greater than 1 hour the Glucose test will be repeated to ensure the proper dosage of Diabetic medication is given.
    f. If the meal time or the type of insulin or oral diabetes medication has changed, nursing may adjust the time of the blood glucose check to provide for the optimum action of the insulin or oral medication in relation to the meal.
    g. In most cases, pediatric patients have Type 1 Diabetes and will be using insulin. In the rare instance that a pediatric patient has Type 2 Diabetes, oral diabetes medications may be in use; consult the medication handbooks, Micro MEDEX or ask pharmacy about the proper timing of these medications and proper timing of blood glucose checks.
2. For STAT blood glucose meter checks, an order must be obtained and documented on the patient's chart.

Reagents and Equipment:

1. **Accu-Chek Inform II Test Strips (Lawson no. 11762) Refer to the package insert or the electronic**

copy attachment listed on the last page of this document for more information. Test strips must be stored at room temperature. Do not freeze. Test strips are stored in the same tightly capped vial in which they are packaged. The vial cap is immediately replaced after removal of a test strip. When a new package of test strips is opened, write the date on the vial label. The test strips are stable until the expiration date on the vial. Outdated test strips are discarded. Each bottle of strips has a coordinating Code chip in the box . This CODE CHIP IS NOT USED IN THE METER! Verify the CODE number listed on the Bottle of test strips matches the CODE listed in the glucose meter especially when the hospital has more than one Lot Number available!! If you have another Code than what is listed in the meter you must choose the CODE number which matches the test strips you are using and perform daily Quality Control again even if it has been less than 24 hours.
Test strips can ONLY be obtained from the Materials Management department.

2. **Accu-Chek Inform II Glucose Control Solutions (Lawson no. 11763) refer to the package insert or the electronic copy attachment for more information.** Level 1 and Level 2 are ready to use and stable unopened at room temperature until expiration date on the bottle. Do not allow controls to freeze. When opening new vials, label with date opened and date of expiration. Open bottles of control solution are stable for three months or the expiration date, whichever comes first. Replace cap on vial of Glucose Control Solution immediately after use. Glucose Control Solutions can be obtained from the Materials Management department
3. **Accu-Chek Inform II glucose meter.** Handle meter with care. Sudden shocks caused by dropping or rough treatment may affect performance. If the meter is dropped, performance must be verified by quality control (QC) testing. If the meter becomes cracked and broken notify the Laboratory POCC. Store meter away from direct sunlight and extreme temperatures.
    - Wash hands thoroughly with soap and water before and after testing each patient.
    - Always wear a new pair of clean gloves for each patient.
    - Never use capillary devices for more than one person. Use auto-disabling, single-use capillary devices for assisted monitoring of blood glucose.

Cleaning/Disinfection of the System-Read and follow the ACCU-CHEK Inform II cleaning and disinfecting instructions found in the *ACCU-CHEKInform II Operator's Manual.* (Refer to the last page of this policy for the electronic copy attachment of the Operator's Manual and pages 128-131 which describe in detail How to Clean/Disinfect the meter and document this task in the meter). The meter must be disinfected/ cleaned after EACH patient and document this disinfection process EVERY time you perform such in the MAINTENANCE section of the Inform II glucose meter according to CMC policy. This documentation in the meter is MANDATORY and must be done before you turn off the meter for the disinfection/cleaning procedure. The ACCU-CHEK Inform II system may only be used for testing multiple patients when Standard Precautions and the ACCU- CHEK Inform II system cleaning/disinfecting procedures are followed.

Acceptable active ingredients and products for cleaning and disinfecting are listed below according to Roche product information:

— Clorox® Germicidal Wipes (EPA* reg. no. 67619-12)
Pre-moistened disinfecting cloths (active ingredient 1% (or less) solution of sodium hypochlorite in water) THE LIQUID FROM THE DAMP WIPE MUST BE LEFT ON METER FOR A MINIMUM OF 1 MINUTE AND MUST BE USED WHEN PATIENT HAS CLOSTRIDIUM DIFFICILE. **DO NOT WRAP THE METER**

WITH THE WIPE FOR 1 MINUTE!

— Super Sani-Cloth® Germicidal Disposable Wipes (EPA* reg. no. 9480-4)
Pre-moistened disinfecting cloths (active ingredient 0.5% quaternary ammonium chlorides and up to 60% isopropanol)
THIS TYPE OF WIPE MUST BE USED FOR ALL OTHER PATIENTS AND THE LIQUID MUST BE LEFT ON METER FOR AT LEAST 2 MINUTES. **DO NOT WRAP THE METER IN THE WIPE!**

The following parts of the meter and system components may be cleaned and disinfected:

- The area around the test strip port
- The meter display (touchscreen)
- The meter housing (entire meter surface)

Do not allow liquid to enter the test strip port or allow pooling of liquid on the touchscreen. If liquid does get into the test strip port, immediately dry the components with a dry cloth or gauze. If solution is allowed to collect in any meter opening, severe damage to the system can occur.

If you notice any of the following signs of deterioration after cleaning or disinfecting of your meter system, stop using the system component and contact the POCC at 4214 or Clinical Laboratory at 4017 for assistance:

- clouding of the touchscreen display
- on/off button malfunction
- Clouding of the infrared data port and/or barcode scanner, or quality control results outside of the specified range.

4. **Calibration (Coding=Code Key) Of the Accu-Chek Inform II System:**
Whenever a new lot of reagent strips is received in the Material Management department they will notify the Point of Care Coordinator who will remotely update the hospital meters according to the procedures listed in the *ACCU-CHEK Inform II Operator's Manual* section 6'Storing Test Strip, Control Solution, and Linearity Solution Information in the Meter' page 65.

Quality Control (QC) Testing:

Frequency:

- Level 1 and 2 Controls must be run every 24 hours of patient testing and when the "RUN QC" is displayed on the meter. The meter is programmed so QC must be run every 24 hours and you will not be able to use the meter until acceptable QC is done.

Additional situations that require QC include

- If the meter is dropped or has been reset
- EVERYTIME a new bottle of test strips is opened, even if it is the same lot number of strips!
- Any time the patient result contradicts the clinical impression
- Anytime a new lot number of strips/Code is entered into the meter

QC Testing procedure:

1. Gather the following equipment :

a. Accu-Chek Inform II System
b. Accu-Chek Inform II test strips
c. Accu-Chek Comfort Inform II Control Solutions

2. Put on disposable gloves.
3. Press power ON button.
4. Enter (or scan) your operator ID, then press the forward arrow button.
5. Select Control Test.
6. Select the desired control level: Level 1, or Level 2.
7. Scan the bar code on the solution bottle
8. Scan the vial of test strips and verify that the CODE number is the same as that listed on test strip bottle.
9. Remove a test strip from the vial and replace the vial cap immediately.
10. 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 gold bars.)
11. Note: Insert test strip BEFORE dosing
12. Touch and hold drop of glucose control solution to the curved edge of the yellow target area at the front edge of the strip. Do NOT apply the control solution to the Top of the test strip. The glucose control solution is drawn into the test strip automatically and the meter will beep.
13. An hourglass will be displayed on the Accu-Chek Inform meter while waiting for the result. When the test is completed and the result is ready, the meter beeps again. The results of the control test will be displayed as either PASS if QC is okay or FAIL if the QC results are not okay. All QC results are recorded in the Inform II monitor memory and downloaded wirelessly to the RALS data manager system. If control FAILS, enter the appropriate comment(s), if needed. When finished press the Check button to record the test and to repeat the same level of control. If the QC result is PASS, press the check button to record the test results. Patient testing can only be done if QC passes on both levels. The monitor will **not** allow patient testing if QC fails.)
    Notes:
    1. If a quality control test result passes on both levels of control, it is acceptable to proceed with patient testing.
    2. If a quality control test result fails on either level of control solution, try a repeat test with same control material or try a new bottle of control. If control still fails, please call the Point of Care Testing Coordinator in the laboratory ext. 4214 or 4017. The meter cannot be used for patient testing until the problem is corrected. Use another meter that has passed quality control.
14. Remove the used test strip(s) and disposable latex gloves and discard them according to infection control policy.

Patient Testing:

Specimen Collection and Handling for capillary bedside glucose testing:

- Proper blood sample collection is an essential and integral part of bedside glucose testing. Capillary,

venous, and arterial whole blood specimens may be used for testing on the Accu-Chek Inform System with Accu-Chek Inform II test strips, unless the patient is identified as critically ill.
- The capillary sample must be tested immediately after collection.
- Blood glucose determinations using venous and arterial blood specimens which have added anticoagulant should be performed within 30 minutes of specimen collection to avoid glycolysis. Mix samples thoroughly. Caution should be taken to clear arterial lines before blood is drawn and dosed on the test strip.
- For best results with arterial and venous blood, the following anticoagulants/preservatives are recommended: heparin (green top tube) and EDTA (purple top tube).
- Serum separator tubes (red top tubes or yellow) and red-topped tubes are acceptable if blood is used **IMMEDIATELY** before the clotting process begins.
- Fluoride or Iodacetateoxalate (grey top tubes) **should not be used** as a preservative.
- Sufficient sample size is required to ensure accurate results. Refer to the test strip package insert for the most current information which is supplied in every box of test strips.

How to perform the Glucose test analysis using the Inform II Glucose Meter:

1. The following equipment should be at the patient's bedside prior to testing:
    a. Accu-Chek Inform II Glucose meters
    b. Accu-Chek Inform II test strips
    c. Single-use, disposable lancets
    d. Alcohol swab
    e. Singly packaged sterile gauze for wiping finger after stick
    f. Disposable gloves and any other appropriate Personal Protection
2. Wash hands and put on gloves and refer to CMC Procedure PH 1461' *Universal Precautions: Infection Control'* for proper procedures. (see PH1461 attached to this procedure)
3. Introduce yourself, identify patient by name and medical record number on patient armband and verifying that the armband has the correct 8 digit account number on it with the prefix ACCMCM (changes if transferred to Ortho, RNU,OB, etc) according to CMC policy PH 1068 *'Patient identification'*, and explain glucose capillary testing procedure. (see PH 1068 attached to this procedure)
4. Press power ON button.
5. Enter (or scan) your operator ID. Press the forward arrow button.
6. Select **Patient Test**
7. Enter (or scan) the patients 8 digit account # with the prefix ACCMCM8the FIN number listed on the **ARMBAND ONLY!! THE CURRENT PATIENT ARMBAND IS THE ONLY ACCEPTABLE BAR CODE TO SCAN FOR THE PATIENT ID!! No other PATIENT LABEL OR BAR CODE must be used because it has NO IDENTIFIABLE PATIENT INFORMATION TO LINK THE GLUCOSE RESULTS TO THE PATIENT!** The patients name should display at the top of the glucose monitor. Verify that this is the correct patient name. Press the **CHECK ✓ button**.

    Manually Entered Patient Identifications:

    - In those departments that have the option of entering a manual ID or when the option to enter the ID

manually is extended to the operator (as listed in the 2 additional emergency policies in this section)- Please enter the **FULL last name and first name, medica**l **record number, FIN#, or for babies list Last name, BABY girl, etc.** For manually entered names in the OB Dept., if you do not list Baby in the name they will be deleted because we cannot discern between Mom and Baby when only a last name is listed!

- When the EHR system is down for an extended period of time ALL CMC Inform II glucose meters will be programmed to accept MANUALLY ENTERED PATIENT ID'S. Refer to page 3 of CMC AD9051**-** *'Cerner Scheduled and Unscheduled Downtime'* for details.
- A special Glucose meter will be located in the ICU to allow for CODE Blue/RRT incidents according to *'CMC Policy for COLD BLUE-Rapid Response team Roche Inform II glucose METER' (r*efer to the policy which is electronically attached to this procedure).
- To document the proper identification when a medical record, CMC account number or patient name is unavailable the operator will fill out a *'CMC Form to report manually entered Patient Identification Information for capillary blood Glucose Testing at the patient bedside'(attached)* and submit the form to the Clinical Lab according to the details listed on the form.

8. Scan the glucose Test strip vial.
9. Remove a test strip from the vial. Immediately replace the cap on the vial.
10. When the flashing strip icon appears on the monitor display, gently insert test strip with the yellow target area or test strip window facing up. (Insert the end with the gold bars.)
    Note: Insert test strip BEFORE dosing.
11. When the flashing drop icon appears on the meter display the meter beeps again, obtain a blood sample. You may use a whole blood capillary, venous, arterial or neonatal blood sample. Apply the drop of blood to the front edge of the test strip(the yellow target area).Do not apply blood at the top of the strip.
12. The blood is drawn into the test strip automatically by capillary action and blood on top of strip is not available for testing.
13. Important: You CAN NOT add blood to the Inform II test strip as with the Comfort Curve strips. Once a sufficient blood sample has been detected, the meter beeps and the measurement begins. An hourglass will appear on the display while waiting for the result.
14. When the test is completed and the result is ready, the meter beeps again. The result will appear on the display. Enter up to three preprogrammed comments and one custom comment, if necessary. Then press the Check button to record the test and return to the Main Menu screen in order to run the next test.
15. **If the patient's result is in the Critical Value Range as detailed in the table on the next page (same as the table on page1) act accordingly:**
    - Repeat the sample using a different capillary collection sight, document all action you took in the 'Comments' associated with the results on the glucose meter and in the patient's EHR, notify the healthcare provider and collect a blood sample to send to the laboratory for confirmatory blood testing after the patient is treated during an emergent situation. Document all actions according to the CMC Diabetes Management policy and as listed in this policy in the Reporting section.
    - **Hypoglycemic Newborns-** Caution is advised in the interpretation of newborn neonate glucose values below 50 mg/dL. Follow department policy recommendations for continued patient monitoring.
    - **Repeat High Critical Values-**If the Critical Value is a **repeat high value** due to fact the patient is experiencing DKA and the high critical value reflects the patient's condition there is NO NEED to

send another blood collection sample to the laboratory for confirmation.

- Documentation of the actions the staff performed concerning the critical value in the Glucose meter and in the patient's EHR is a Mandatory REQUIREMENT!

Critical Value Limits	LOW	HIGH
Newborn (0-45 Days)	< 40	>300
Child(45days -12 Yrs)	<50	>300
Adult (>12 Yrs)	<50	>400

16. **HI or LO result displayed on meter and no numerical result:** If HI or LO appears on the screen it indicates glucose values >600 mg/dl or less than 10mg/dl respectively. If this result contradicts the patient's condition, repeat QC testing. Otherwise repeat testing using a new site, If HI or LO occurs on repeat testing , document your actions in the meter comments, notify provider, and collect a MANDATORY BLOOD SAMPLE to send to the Laboratory for a CONFIRMATORY blood Glucose level. Also document all action in the patient's EHR according to the CMC 'Diabetes Management policy'.
17. Remove the test strip from the meter and discard it to the biohazard infection control policy. Dispose of the lancet used to obtain the blood sample into the biohazard container for Sharps.
18. Press the power OFF button to turn the Accu-Chek Inform II System off.
19. Remove gloves and dispose of them according to infection control policy. Wash your hands thoroughly with soap and water.
20. The Inform II meters will transmit the results and any added comments wirelessly to the EHR.
21. The glucose meter must be cleaned after each patient and documented on the meter according to the Cleaning/Disinfecting instructions listed on page 128-131 in the *ACCU-CHEKInform II Operator's Manual.*
22. Dock the meter when patient testing is done. Although the results will be transmitted wirelessly the docking stations are required to charge the batteries and update the meters with new patient and reagent information. If the meter is not docked after 6 hours, the meter will warn you that it needs to be docked. Eventually the glucose meter's battery will 'die 'and the meter will not work even if it is DOCKED. At that time, the meter must be reset by the POCC in the Laboratory. So PLEASE DOCK THE METERS SO THE BATTERY DOES NOT DIE!
    The Green light should always be lit and should NOT be blinking.

Reporting:

1. The Inform II meter automatically records the operator id, the patient id and name, the date and time of the test, the test result, the test strip lot number, any comments entered and the serial number of the meter in its memory. This information is downloaded to the Data Care Management (RALS) computer system wirelessly which in turn downloads the information to the patient's EHR.
2. Record all Insulin administered in the MAR per CMC policy along with the Glucose results if directed.

Linearity:

Testing with the Inform monitor using the Accu-Chek Inform II strips is accurate between the values of 10 mg/dl and 600 mg/dl.
Values below 10 mg/dl will give a patient result of LO and values above 600 mg/dl will give a patient value of HI.

Reference (Normal Adult Fasting) Range: 70 to 109 mg/dl

Linearity testing is performed accordingly by the POCC:

- Yearly on each meter
- After any repair
- When the meter is not performing as expected
- As a troubleshooting tool

The linearity testing results will be reviewed by the laboratory Medical Director and must be within the acceptable range before the meter is approved for patient testing. In the event the results are not acceptable the Roche Service department will be notified for further repair. 800-440-3638.

Method/Principle:

The ACCU-CHEK Inform II system quantitatively measures glucose in whole blood. The enzyme on the test strip, mutant variant of quinoprotein glucose dehydrogenase from Acinetobacter calcoaceticus, recombinant in E. coli, converts the glucose in the blood sample to gluconolactone. This reaction creates a harmless electrical DC current that the meter interprets for a glucose result. The sample and environmental conditions are also evaluated using a small AC signal.

The system was calibrated with venous blood containing various glucose concentrations by Roche and is calibrated to deliver plasma-like results. The reference values are obtained using a validated test method. This test method is referenced to the hexokinase method and is traceable to an NIST standard.

Limitations

The new formulation of the Inform II test strip eliminates the Maltose limitations which existed with the Comfort Curve test strips.

- The ACCU-CHEK Inform II test strips are for testing fresh capillary, venous, arterial, or neonatal whole blood. **Cord blood samples cannot be used**.
- Hematocrit should be between 10-65 %.
- Lipemic samples (triglycerides) in excess of 1800 mg/dL may produce elevated results.
- Blood concentrations of galactose >15 mg/dL will cause overestimation of blood glucose results.
- Intravenous administration of ascorbic acid which results in blood concentrations of ascorbic acid >3 mg/dL will cause overestimation of blood glucose results.
- This system has been tested at altitudes up to 10,000 feet.

References:

- Roche Accu-Chek Inform II test strips package insert (05942934003-0113) 2013 Roche Diagnostics.
- Roche Accu-Chek Inform II Controls (05213525004-1012) 2012 Roche Diagnostics.
- Accu-Chek Inform II Blood Glucose Monitoring Quick Reference Guide for Healthcare Professionals (05234654001) 2012-10 USA
- ACCU-CHEK Inform II Glucose Monitoring System Comprehensive Policies, Processes and Procedures Manual (4302-02-0713) July 2013
- REFER TO THE CMC POLICIES WHICH I REFERENCED WHICH ARE ATTACHED TO THIS ELECTRONIC DOCUMENT ON THE LAST PAGE
- Refer to the MSDS sheets attached to this document.

Attachments

No Attachments

Applicability

Community Medical Center