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ACCU-CHEK Inform II Glucose Meter

ROCHE ACCU-CHEK INFORM II GLUCOSE METER

PRINCIPLE

This is a definitive test. Results which are within the established reportable ranges that correlate with the patient's clinical condition may be acted upon without further confirmation.

Testing can be done only by staff who are trained to perform this procedure, and who satisfactorily participate in required competency assessment.

The ACCU-CHEK Inform II system quantitatively measures glucose in whole blood. The enzyme on the test strip, a 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 is calibrated with venous blood containing various glucose concentrations 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 ACCUCHEK Inform II test strips are for testing fresh capillary, venous, arterial, or neonatal whole blood. Cord blood samples cannot be used.
- If peripheral circulation is impaired, collection of capillary blood from the approved sample sites is not advised as the results might not be a true reflection of the physiological blood glucose level. This may apply in the following circumstances: severe dehydration as a result of diabetic ketoacidosis or due to hyperglycemic hyperosmolar non-ketotic syndrome, hypotension, shock, induced hypothermia, decompensated heart failure NYHA Class IV, or peripheral arterial occlusive disease.
- The ACCU-CHEK Inform II should not be used in patients with the following conditions, who may or may not be critically ill:
 - Hematocrit less than 10 or greater than 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.)

SPECIMEN REQUIREMENTS/PATIENT HANDLING

Establish positive patient identification prior to sample collection by asking the patient (or family member) to state their name and date of birth and comparing to their armband.

1. Blood Collection

- Assess the patient for compromised peripheral blood flow. Fingertips should be warm and pinkish when the hand is gently massaged from the palm outward to the fingertips. Fingertips should not appear pale, bluish or mottled. Patients with compromised peripheral blood flow are not good candidates for fingerstick testing. Use venous or arterial blood instead.
- Capillary whole blood samples may be obtained with a lancet from either a fingerstick or a heel puncture (infants only). Ensure adequate blood flow to the puncture site before sticking the finger or heel.
- Gloves must be worn by the person collecting the capillary sample and by any person who assists in holding the patient.
- Proper aseptic technique requires thorough cleansing of the puncture site with soap and water or alcohol wipe. Alcohol must be allowed to dry thoroughly before performing the puncture.
- See Policy "Blood Drawing Procedures".

2. Type of Specimen

- Fresh whole blood - capillary, venous, or arterial - may be used. (Neonatal cord blood must not be used.) Venous and capillary blood may differ in glucose concentration by as much as 70 mg/dL, depending on the time of blood collection after food intake. Factors affecting peripheral circulation may also cause discrepancies between capillary and venous glucose results.
- Anticoagulants such as heparin and EDTA may be used. Do not use preservatives which contain fluoride (gray top tubes).
- Do not use serum or plasma samples.

3. Handling Conditions

- Test the blood sample as close as possible to the time the sample was collected. The test should be performed within 30 minutes of sample collection to minimize glycolysis. If using fresh whole blood in the absence of an anticoagulant, test immediately to prevent clotting from affecting the result.
- When testing whole blood in a tube with anticoagulant, invert gently to mix thoroughly before testing.

EQUIPMENT AND MATERIALS

1. Roche ACCU-CHEK Inform II Glucose Meter, fully charged
2. Cotton or rayon ball.
3. Lancet devices (obtain from Distribution, Product #161967).
4. Alcohol wipes

5. Gloves
6. Clorox Germicidal Bleach Wipes or Super Sani-Cloth Bleach Germicidal Wipes
7. Soft, lint-free tissue.

REAGENTS

1. ACCU-CHEK Inform II Control Level 1 (Low) and Control Level 2 (High), the lot and range information will be available in meter.
2. ACCU-CHEK Inform II test strip vial

NOTE about reagents: Reagents are not to be used past their expiration date. ACCU-CHEK Inform II strips expire on the date printed on the strip vial label. ACCU-CHEK Inform II Control and linearity solutions expire on the date printed on the vial label, or 3 months from opening, whichever comes first. Whenever an operator opens a vial of controls or linearity solution, he/she must handwrite the open date, if the vial doesn't have an expiration sticker applied to it.

STANDARDS AND CALIBRATION (Coding)

Each box of test strips contains a code key. Each code key belongs to a single lot and provides important information about the lot-specific properties of the ACCU-CHEK Inform II test strip. The properties of each lot number of test strips are downloaded (as a code file) from the code key into the ACCU-CHEK Inform II system by means of the code key reader. This process is performed by the Lab Point of Care Coordinator when a new lot is received.

Operators select the correct lot number of strips by scanning the bar code on the vial of test strips. If a lot number of test strips is encountered that has not been introduced to the PRMCE Inform II system, notify the POCC.

UPLOADING A NEW TEST STRIP CODE FILE USING THE CODE KEY READER:

(Performed by POCC only)

Materials:

Gather the following materials in preparation for uploading a new test strip lot code file into the ACCU-CHEK Inform II system:

1. A single ACCU-CHEK Inform II meter – Fully charged
2. A code key from the new strip lot
3. A code key reader
4. A downloading (network connected) base unit
5. Cobas IT and Telcor

Procedure:

1. Turn on the ACCU-CHEK Inform II meter.

2. Enter or barcode scan your operator ID
3. From the *Main Menu*, touch the forward arrow button to open the *Main Menu 2* screen.
4. Touch *Strip Lots* to open the test strip lot code file menu.
5. Touch *Add* if you want to add the information for a new test strip lot from a new code key. The *Add Strip Lot* screen opens.
6. Insert the new code key in the opening of the code key reader. A LED starts flashing green to signal that the code key reader is ready to transfer data.
7. Place the code key reader on a level surface such as a bench or table
8. Hold the meter 4-6 in (10-15 cm) above the code key reader so that a connection can be made between the infrared window on the bottom of the meter and the infrared window on the top of the code key reader.
9. Touch the forward arrow key to begin downloading data.
10. Successful transmission will display two progress messages: "Please Wait – Connecting to code key reader and "Please Wait – Receiving Code Key Contents."
11. A *Strip Lot Confirmation* screen will ask you to confirm use of the suggested values for the test strip lot
12. Touch the button to store the data for this test strip lot number in the meter without changes, or Touch the button to modify the data for this test strip lot number (see the ACCU-CHEK Inform II Operator's manual for detailed instructions on editing parameters of the test strip lot.)
13. You will then see a *Make 'Current'* screen asking you if you want to make the test strip lot that you are entering the current test strip lot.
14. Touch the button to confirm that you want this lot number to be the lot number currently in use, or touch the button to store the entries without making the lot number the current lot number.
15. Touch the *Main Menu* icon in the center of the bottom of the screen to return to the *Main Menu*.
16. Dock the meter in the network connected base unit to send the new test strip lot information from the meter into the data management system for centralized test strip lot distribution.

PERFORMING TESTS ON THE ACCU-CHEK INFORM II SYSTEM:

Quality Control Testing

When to perform Quality Control Tests:

Quality control testing is performed as a primary means of ensuring on-going proper performance of the ACCU-CHEK Inform II system. Low and high quality control testing is performed on the following occasions:

1. Every 24 hours of patient testing. Meters are programmed to lock out after 24 hours and will not allow testing to be done until both High and Low controls are successfully tested.
2. When a new test strip vial is opened and placed into service. Write "QC ✓" on vial to indicate QC testing has been done.
3. When a meter is dropped.
4. When a meter displays questionable test results repeatedly

5. If a vial of strips was left open.



How to perform Quality Control Tests:

Materials:

Gather the following materials in preparation for running quality controls.

1. ACCU-CHEK Inform II meter – fully charged and coded to the test strip lot you intend to use.
2. ACCU-CHEK Inform II Control Level 1 (Low) and Control Level 2 (High), the lot and range information will be available in meter.
3. ACCU-CHEK Inform II test strip vial

Procedure:

1. Turn on the ACCU-CHEK Inform II meter.
2. Enter or scan your operator ID. **NOTE:** If the operator ID you enter is not accepted, attempt to re-enter it. If it is still rejected, contact your supervisor or Point of Care Coordinator. **DO NOT** attempt to perform tests under another operator's ID.
3. From the *Main Menu*, touch *Control Test*.
4. Select the level of control that you wish to test by scanning the barcode of the control.
5. Scan the barcode on the vial of test strips.
6. The meter will display a picture of a test strip with a downward flashing arrow on the meter when it is time to insert a test strip into the meter. Remove a test strip from the vial and immediately recap the vial. Insert the test strip into the meter in the direction of the arrows and with the "ACCU-CHEK" lettering facing upward. The meter will display a flashing "blue bottle" above the test strip icon when the test strip is properly inserted and this indicates it is time to apply control solution.
7. Apply control solution to the front edge of the test strip. The solution will fill the yellow sample chamber by capillary action. Do not apply sample to the top of the test strip. Once sufficient sample has been detected, the measurement begins. An hourglass icon indicates that the measurement is in progress. You will get an error message if the sample is insufficient. If this occurs, you will need to repeat the test.
8. The measurement is complete when the result is displayed on the meter screen. See the "Interpretation of Results" and "Troubleshooting" sections below for guidance on what to do if your result is "Fail" or shows an "out of range" message associated with the result.
9. Remove the test strip and dispose of it in the trash.
10. Touch the comment button () to enter an appropriate comment(s).
11. Touch the  button to confirm the result and send the result from the meter wirelessly or place the meter in the base unit to send the result and record the result into the electronic data management system. The base unit also charges the meter.

Interpretation of Quality Control Results:

1. Results are displayed on the screen as Pass or Fail. Any result that shows an "out of range" message or "Fail" is an indication that the system may not be performing correctly for patient testing.

2. Patient testing may not be performed if quality control testing results are not within acceptable limits and the meter will not display the patient testing option if scheduled quality control results exceed acceptable limits.
3. Document all actions taken if the results of QC testing did not meet expected ranges by entering appropriate comments, selected from the list on the "Enter Notes" screen.
4. If unable to obtain QC values within acceptable ranges, refer to "Troubleshooting Guide".
5. If troubleshooting does not resolve the problem, notify the Point of Care Coordinators, whose phone numbers are posted in the Glucose meter tote boxes.

Patient Testing

NOTE: If patient is experiencing symptoms which are **not** consistent with the blood glucose result obtained, and the test procedure described below has been followed:

1. Provide appropriate medical care, monitor patient **AND**
2. Confirm the blood glucose results with a laboratory test. (Order "Glucose Meter Recheck")

Patient testing with the ACCU-CHEK Inform II system quantitatively measures glucose in fresh venous, arterial, neonatal heelstick and capillary whole blood from the finger and is used as an aid in monitoring the effectiveness of glucose control. The procedure below describes the steps taken to perform patient testing on the ACCU-CHEK Inform II system. General patient testing policies are as follows:

1. Patient testing must be ordered according to established test ordering policies and procedures.
2. Patient samples are collected according to established phlebotomy procedures.
3. Patients are identified by means of their encounter (csn) number.
4. Patient identification numbers are entered into the ACCU-CHEK Inform II system by means of barcode scanning. The meter then displays the patient's name and date of birth and asks if this is correct. If it's correct, select ✓.
 - a. Proceed with caution if "Patient Not Found" message appears when scanning an armband. Carefully compare the CSN number on the patient's armband with the number displaying on the meter. If you have confidence that the CSN number is correct, select ✓.
5. **Special Patient Identification Conditions:** Occasionally, a barcoded armband may not be available. (Such as ER, newborn infants or STAT tests on patients without an established ID, or when an armband will not scan). In those circumstances where a glucose must be performed when a barcoded armband is not available, scan the "Emergency" bar code that is in the tote. Notify POCC (via telephone or email) as soon as possible and provide the patient's name, DOB, time of testing and glucose value.
6. **Critical limits** for patient testing (older than a year) are less than 50 and greater than 500. Always follow Nursing Policies regarding patient testing and notification of providers.
7. **Reportable limits** for patient testing are 10-600. Results that fall outside reportable limits will display as Low and High. A lab glucose should be obtained when no numerical value is displayed on the meter. (Order Glucose Meter Recheck)
8. **Repeat Testing:** When repeating a test, perform the repeat within 10 minutes so the patient doesn't get a duplicate charge.

How to Perform Patient Testing

Materials:

Gather the following supplies in preparation for patient testing:

1. ACCU-CHEK Inform II meter – fully charged and coded to the test strip lot you intend to use.
2. ACCU-CHEK Inform II test strip vial. Note about reagents: Reagents are not to be used past their expiration date. ACCU-CHEK Inform II strips expire on the date printed on the strip vial label.
3. Supplies for collecting a blood sample as required by established phlebotomy procedures, such as cotton balls, alcohol preps, approved auto-disabling single-use lancing device, (See appropriate sample collection procedures).
4. Gloves
5. Biohazard and sharps container
6. Transfer pipette or syringe as needed if testing a venous, arterial or line draw sample.

Acceptable Samples:

1. The following fresh whole blood sample types may be used:
 - a. Venous whole blood
 - b. Arterial whole blood
 - c. Capillary (non-neonate fingerstick and neonate heelstick) whole blood
2. The following anticoagulants are acceptable (do not use any other anticoagulants for meter testing):
 - a. Lithium or Sodium Heparin
 - b. EDTA

Patient Testing Procedure Notes:

1. Good sample quality is essential for reliable results. The following tips will help you to optimize the quality of a fingerstick capillary sample:
 - a. Assess the patient for signs of reduced peripheral circulation such as cold hands, pale, mottled or bluish nailbeds and administration of vasopressor medications. If peripheral circulation is impaired, collection of capillary blood from approved sites is not advised, as the results might not be a true reflection of the physiologic blood glucose level. This may apply in the following circumstances: severe dehydration as a result of diabetic ketoacidosis, or due to hyperglycemic hyperosmolar non-ketotic syndrome, hypotension, shock, decompensated heart failure NYHA class IV, or peripheral arterial occlusive disease.
 - b. Always take basic steps to stimulate blood flow to the intended puncture site. Even if the patient's peripheral circulation is not impaired this will help you to procure a sufficient and free flowing sample, especially in patients who are sedentary. Common methods for stimulating blood flow include:
 - Warming the site
 - Positioning the hand below the heart

- Gently massaging the hand by stroking from the palm outward to the fingertip
 - Asking the patient to move and flex his/her arm, wrist, hand and fingers while you are gathering supplies and preparing for testing
- c. Be sure to allow the cleansing agent to completely dry before puncturing the intended site.
 - d. Wipe away the first drop of blood. This ensures that the alcohol is dry, it stimulates the blood flow and clears interstitial fluid from the sample
2. Do not place the meter on bedding after applying blood to the test strip. This can cause the blood to be wicked out of the test strip by the bedding.
 3. Recap the test strip vial immediately after you remove the test strip you plan to use. Never use test strips found loose outside the vial.
 4. If you find a vial of test strips that are uncapped, run QC on that vial. If QC passes, snap the lid down and continue to use the strips. If the QC fails, discard the entire vial of strips.

Patient Testing Procedure:

1. Carefully assess the patient for any indication that bedside glucose testing may not be appropriate . (See Limitations section, above)
2. Take the meter and testing supplies to the patient location.
3. Wash hands and don personal protective equipment (gloves, gowns, etc.) as required by infection control and isolation policies and procedures.
4. Greet and identify the patient. Ask the patient or family member for name and date of birth and compare to armband. Explain the procedure to the patient. Turn on the ACCU-CHEK Inform II meter.
5. Enter your operator ID by means of barcode scanning of your badge and/or manual entry of your badge ID number.
 - a. **NOTE:** If the operator ID you enter is not accepted, attempt to re-enter it. If it is still rejected, contact your supervisor or Point of Care Coordinator. **DO NOT** attempt to perform tests under another operator's ID. It is unsafe and against policy.
6. From the **Main Menu**, touch **Patient Test**.
7. Enter the patient identification in the ACCU-CHEK Inform II system by scanning their armband.
8. Scan the test strip vial's barcode. Contact your supervisor or Point-of-Care Coordinator if the lot number of the test strip vial is rejected.
9. You will now see a picture of a test strip with a downward flashing arrow on the screen indicating it is time to insert a test strip into the meter.
10. Remove a test strip from the vial and immediately recap the vial. Insert the test strip into the meter in the direction of the arrows and with the "ACCU-CHEK" lettering facing upward. The meter will display a flashing drop above the test strip icon when the test strip is properly inserted indicating that you are ready to apply a blood sample.
11. Collect an acceptable blood sample according to established procedures (See the "Procedure Notes" section below for tips on optimizing sample quality)
 - a. **Fingerstick or neonate heelstick samples:** Test immediately as the sample is collected.
 - b. **Venous, arterial or line draw samples:** Test as soon as possible and no later than 30 minutes

following collection. Be sure they are well mixed and that line draw samples have been thoroughly cleared of line fluids. Do not allow bubbles to enter the test strip-sampling chamber.

12. Wipe away the first drop of blood. This is advantageous because it ensures that the cleansing agent is dry, it stimulates blood flow and it clears interstitial fluid from the sample.
13. Apply blood to the front edge of the test strip. The sample will fill the yellow sample chamber by capillary action. Do not apply sample to the top of the test strip.
14. Once sufficient sample has been detected, the measurement begins. An hourglass icon indicates that the measurement is in progress.
15. After the sample has been obtained, apply gentle pressure to the puncture with a clean gauze square or cotton ball site for several minutes. If the patient is conscious and capable, enlist the patient's assistance with applying pressure.
16. The measurement is complete when the result is displayed on the screen. Depending upon how high or low the result is, it may appear in a numeric or non-numeric format. See *Interpretation of Results* section below for interpretation of each result format.
17. Remove the test strip and dispose of it in the trash or biohazard container.
18. Touch to enter up to three appropriate comment(s) as suggested in the Result Reporting section of this manual.
19. Touch the button to confirm the result and send the result from the meter wirelessly or place the meter in the base unit to send the result and record the result into the electronic data management system. The base unit also charges the meter.
20. Record the result in EPIC in the "Preliminary Glucose" line on the Vital Signs Flowsheet.
21. Follow up on any results that exceed critical or reportable limits according to policy.
22. Clean and disinfect with bleach wipes after each patient test.

Interpretation of Patient Results

1. Results may appear in any of the following formats and may require follow-up:
 - a. A numeric value
 - b. "HIGH" or "LO" meaning that the result is above or below the upper or lower reading limits of the ACCU-CHEK Inform II system (>600 mg/dL or <10 mg/dL). The test must be repeated on the meter.
 - c. Obtaining a lab glucose is recommended when repeat meter testing continues to result as "HIGH" or "LO".

REVIEW RESULTS

The ACCU-CHEK Inform II meter system stores up to 2,000 results in the meter memory. Results may be reviewed in the meter by any certified operator as needed in the course of patient care or system maintenance.

Review Results Procedure:

1. Turn on the ACCU-CHEK Inform II meter.
2. Enter your operator ID by means of scanning the barcode on your badge or manual entry. **NOTE:** If the

operator ID you enter is not accepted, attempt to re-enter it. If it is still rejected, contact your supervisor or Point of Care Coordinator. **DO NOT** attempt to review results under another operator's ID.

3. From the **Main Menu**, touch **Review Results**
4. A chronological list of all test results are displayed on the meter screen. The most recent results appear at the top of the list.
5. Touch to display older results. Touch to display more recent results.
6. Touch any result on the list to view result details. The following information will be displayed: Patient ID, QC level or sample ID, the lot number of the reagent(s) used to perform the test, the test result, the date and time the test was performed, and comments that were entered at the time the test was performed.
7. Touch to return to the previous screen.
8. Touch **Patient** to specify a patient whose result you wish to display.
9. Barcode scan or manually enter the patient ID for the patient whose results you wish to display. Use the up and down arrow buttons to scroll through the patient's results.
10. Touch QC to review all QC results. Use the up and down arrow buttons to scroll through the QC results.
11. Touch any QC result to view result details. Touch to return to the previous screen.
12. Touch to return to the **Main Menu**

TRANSFERRING DATA

Data is transferred from the meter into EPIC and Telcor as follows:

1. **Wireless Data Transfer:** Results will automatically transfer wirelessly into EPIC if a wireless connection is currently available upon completion of a test.
 - a. A wireless connection is activated when the testing operator touches \checkmark upon completing a test. An available wireless connection is confirmed by the presence of the wireless icon at the bottom of the screen. If is not present, a wireless connection is not currently available. If a wireless connection is not currently available the meter will automatically send results as soon as a wireless connection is established.
 - b. The meter will connect to EPIC every 10 minutes and transfer new data when a wireless connection is available even if the meter is powered off. This connection gives the meter the most up to date settings and ADT information when available.

RESULT REPORTING

Record results electronically in EPIC as a Preliminary POC Glucose test. Meter comments can be added to a glucose result and will appear in EPIC with the result. Up to three "canned" comments and one free text comment can be attached to a result.

1. Comments are added by selecting the "dialogue" icon that appears when the result is displayed. Comments are then selected from the list that appears by touching the desired comment on the touch screen. You may also free text one comment.
2. Available comments:
 - "Procedure Error" (for erroneous results, keeps results from crossing the interface)
 - "Will order lab" (use with a result to indicate lab glucose will be ordered)

- "Pt symptomatic" (use with obviously hypoglycemic patients, repeat not required)
- "Will repeat test" (use when you are going to repeat the test for any reason)
- "Use this result" (use if this is the result that you will be acting upon)
- "Use prev result" (use if the previous result is the one that you will be acting upon)
- "Questionable result" (use to indicate this is not necessarily a reliable result)

RESULTS IN EPIC (INTERFACE INFORMATION)

1. All results with proper patient ID will be sent to EPIC and will appear in Lab Results under the test "POC glucose". Results that are manually charted will appear under "Preliminary POC glucose."
2. Results with the comment "Procedure Error" will NOT cross the interface.
3. Only one charge will be generated provided that repeat tests are performed within 10 minutes of each other.

CRITICAL VALUES

For patients less than one year old:

Critical low:	< 46 mg/dL
Critical high:	>149 mg/dL

For all other patients:


Critical low:	< 51 mg/dL
Critical high:	> 499 mg/dL

CRITICAL VALUE POLICY for all patients:

Follow Nursing Protocol for appropriate treatment of patient and notification of physician.

- Results which do not correlate with the patient's clinical condition should be verified by repeat testing and/or testing by the hospital laboratory. Perform repeats within 10 minutes to avoid duplicate charge to the patient.
- Results outside the reportable range (where the meter reads "LO" or "HIGH") must be repeated on the meter and should be confirmed by laboratory testing.
- Acceptable (but not required) options for follow-up patient testing when results exceed critical limits but are within the reportable range are to repeat the test on the same or another meter, and/or confirm with a lab draw (Order "Glucose Meter Recheck"). Always treat the patient according to Nursing Protocol and notify the physician.

TROUBLESHOOTING

Call ACCU-CHEK Customer Care at 1-800-440-3638  for assistance any time you have questions or concerns regarding the ACCU-CHEK Inform II system.

1. **Troubleshooting meter operational issues:** If the meter fails to function at any point in the procedure or

if you get an error message associated with the result, make a note of the malfunction or error message and attempt to repeat the test. If the error persists, sequester the meter and test strip vial involved and notify the Point of Care Coordinators at x83659 for advanced troubleshooting.

- If the error message "**Strip Defect Error**" appears on the display, the test strip may be defective or the blood glucose result may be extremely low and below the meter's measurement range. Repeat the blood glucose test. If the meter displays "**Type Bad Dose**," there may be insufficient amount of blood on the test strip. Repeat the test using a new test strip, ensuring proper sample application, or refer to the test strip package insert.

2. **Guidance for interpreting on-screen message and error codes:**

All error messages displayed by the system have a letter identifying the message type, a number and a description of the error to help the operator take action to resolve the problem. The different message types are in the table below.

E	Identifies the notification as an Error. The information notifies the operator that an error has occurred.
W	Identifies the notification as a Warning. The information does not block the operator from continuing, but rather gives the operator information that may suggest an alternate workflow is required.
I	Identifies the notification as Informational only. Informational notifications present the operator with contextual information, and allow the operator to proceed after confirming the notification.
D	Identifies a Decision point. Decision notifications provide the operator with a choice based on contextual information.

3. **Troubleshooting out-of-range quality control results:** Quality control results will be displayed as Pass or Fail. Take the following actions if your results are not within established limits (if the result is displayed as Fail): Repeat the test. If it fails again, repeat with a fresh vial of strips. If it still fails, get a new bottle of control and try again. If still out of control range, set the meter aside and call the Point of Care Coordinator for assistance. Add appropriate comments to the "Fail" results.

4. **Troubleshooting questionable patient results:**

- Consider whether the result is consistent with the patient's history and clinical presentation.
- Consider the following actions if you question the reliability of the result for any reason:
 - Add a comment(s) to the result indicating that the result is in question. Repeat the test.
 - If still questionable: Perform quality control testing using the same meter and test strips.
 - If quality control test results are within range, repeat the patient test using the same test strips and meter.
 - If the quality control tests are not within range, sequester the meter and test strip vial involved and deliver them to the Point of Care Coordinator for advanced troubleshooting.
 - Repeat patient testing using another meter and test strip vial that have passed routine quality control testing.

5. **Troubleshooting a non-responsive meter**

If a meter will not turn on, even when placed into the docking station, a reset is likely required. To reset the meter, press and hold the power button for 25 seconds. The meter should be responsive again. You

must enter the date and time each time the meter is reset. The meter will also require both levels of controls to be tested again.

STORAGE

- Always store the meter in base unit/recharger. Be certain that the word "DOCKED" is displayed on the tab in the upper left and there is a lightning bolt going through the battery icon in the lower right of the screen.
- Do not store the meter in direct sunlight or under extreme temperature conditions.

CLEANING AND DISINFECTING the ACCU-CHEK Inform II system

Cleaning and disinfecting the exterior surface of the meter is, at minimum, recommended daily for dedicated patient devices. Meters used with multiple patients must be disinfected after each use.

Acceptable active ingredients and product for cleaning and disinfecting is:

- Sani-Cloth Germicidal Bleach Wipe (orange lid)

Clean/Disinfect

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)

Disinfecting the meter:

NOTE: The meter should be cleaned (use a Sani-Cloth Germicidal Bleach Wipe) to wipe away any visible contamination) prior to each disinfection step.

- Remember to keep the meter on a level surface prior to disinfecting and powered off.
 - Use a Sani-Cloth Germicidal Bleach Wipe to disinfect the meter. When using commercially available pre-moistened disinfecting cloths, squeeze off excess disinfecting solution or blot on a dry paper towel to remove any excess disinfecting solution before disinfecting the surface of the meter.
1. Use a fresh Sani-Cloth Germicidal Bleach Wipe to disinfect by gently wiping the outside of the meter three times horizontally and three times vertically and carefully wipe around the test strip port area, making sure that no liquid enters the test strip port.
 2. Allow the surface of the meter to remain damp with the recommended disinfecting solution for 4 minutes. The recommended contact time is as follows:
 - a. NOTE: Meter surface should stay moist for the entire contact time.
 3. Dry the meter thoroughly with a dry cloth or gauze. Visually verify that no solution is seen anywhere on the meter at the completion of cleaning and disinfecting. Ensure that the meter is thoroughly dried after cleaning and disinfecting (see safety message "Avoid getting liquid into the test strip port!" and NOTICE in this section).

REFERENCE RANGES

• Birth to 3 days:	40 - 90 mg/dl
• 4 days to 50 yr:	60 - 110 mg/dL
• Older than 50 yr:	60 - 125 mg/dl

REFERENCES

- Roche ACCU-CHEK Inform II Test Strip Product Insert

SUPPLEMENTAL MATERIALS

- Roche ACCU-CHEK Inform II Operator's Guide.
- Nursing Practice Manual Policies.

Referenced Documents

Reference Type	Title	Notes
Documents referenced by this document "Blood Drawing Procedures"		
Applicable Documents		
Documents which reference this document		
Applicable Documents	Hypoglycemia	
Applicable Documents	Hyperglycemia/Diabetic Ketoacidosis	

Referenced Documents

Reference Type	Title	Notes
Documents referenced by this document		
Referenced Documents	Hyperglycemia/Diabetic Ketoacidosis	
Referenced Documents	Hypoglycemia	
Documents which reference this document		
Referenced Documents		

Lucidoc_Number: 42215

Attachments:

- ACCU-CHEK Inform II Patient Direct Observation Checklist
- Accu-Chek Inform II Reagent QC √ Tracking Log
- Accu-Chek Inform II Review Information
- Accu-Chek Inform II Training Checklist for CNAs and HUCs

Accucheck Inform II Training Checklist and Quiz for CNAs and HUCs
Accucheck Inform II Training Checklist and Quiz for RNs and Techs
Anesthesia Accucheck Inform II Training Packet
Anesthesia-Accucheck Inform II Annual Competency quiz

Approval Signatures

Approver	Date
Kirstine Oh	07/2019
Cheri Carmean: Lab Point of Care Coordinator	07/2019
Christine Landerholm: Lab Point of Care Coordinator	07/2019

Applicability

WA - Providence Regional MC Everett

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