University of California, San Francisco – Department of Laboratory Medicine
Zuckerberg San Francisco General Hospital and Trauma Center – Clinical Laboratory
1001 Potrero Avenue, San Francisco, CA 94110
Barbara Haller, MD, PhD, Director

48667.248 Accu-Chek® INFORM II Blood Glucose Determination

Copy of version 1.0 (approved and current)

Last Approval or Periodic Review Completed	10/02/2017
Next Periodic Review Needed On or Before	10/02/2019
Effective Date	10/02/2017

Controlled Copy ID 112740

Location For POCT website

Organization San Francisco General Hospital Clinical Lab

Author
Gracialle de Guzman and R. Clayton Hooper (Revised by Caroline Tolman-Salinas)

Comments for version 1.0

Initial version

8/29/17 changes by Caroline Tolman-Salinas:

- Standardized to MediaLab format
- Removed from "Test Strips" section: "The vial must be dated with the MM/DD/YR when opened."

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	10/02/2017	1.0	Barbara Haller, MD, PhD Barbara Haller	
Approval	Laboratory Manager	9/18/2017	1.0	Mary Eugenio-Allen Mary Allen	
Approval	POCT Supervisor	9/12/2017	1.0	DEBORAH NEGRI	

Prior History

Date of Original: January 17, 2014

Original Prepared by:	Job Title:
Gracialle de Guzman	CLS
R. Clayton Hooper, MSN, RN, CPOCS, CNL	Point of Care Manager

Original approved by:	Job Title:
Alan Wu	Division Chief, Chemistry
Eberhard Fiebig, MD	Clin Lab Director

Original Implementation Date: February 5, 2014

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
1.0	Approved and Current	Initial version	8/29/2017	10/02/2017	Indefinite

Author: Gracialle de Guzman and R. Clayton Hooper (Revised by Caroline Tolman-Salinas)
Approved by Barbara Haller on 10/02/2017.
Reviewed by Barbara Haller on 10/02/2017.

ACCU-CHEK INFORM II BLOOD GLUCOSE DETERMINATION

PURPOSE

The Accu-Chek INFORM II meter is considered a **waived** test by the FDA used to obtain rapid assessment of blood glucose concentration results at the point of care. The test is to be used for monitoring glucose levels and should not be used for diagnosis.

PRINCIPLE

The Accu-Chek INFORM II meter is used for Quantitative determination of glucose in whole blood specimens. The enzyme on the test strip, a mutant variant of glucose dehydrogenase converts the glucose in the blood sample to gluconolactone. This reaction creates a harmless electrical current that the meter interprets as a glucose concentration in mg/dL.

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 a NIST standard.

TESTING PERSONNEL

Qualified Licensed Registered Nurses (RNs) and approved Health Care Providers

EQUIPMENT

- Accu-Chek INFORM II Glucose Meter
- Accu-Chek INFORM II Meter Base Unit (docking and charging station)
- Accu-Chek INFORM II Test Strips (50 strips per vial)
- Accu-Chek INFORM II Glucose Controls (High and Low; 2.5 mL volume per bottle)
- Accu-Chek INFORM II Linearity Kit (Level 1 – Level 6; 2.5 mL volume per bottle)
- Accu-Chek INFORM II Carrying Case/Accessory Box
- Lancets – single use
- Disposable Gloves
- Alcohol Wipes
- Gauze
- Clorox Germicidal Wipes (EPA* reg. no. 67619-12) or Super Sani-Cloth Germicidal Disposable Wipes (EPA* reg. no. 9480-4) for cleaning meters, base units, and base unit hubs.

REAGENTS, STORAGE AND HANDLING

A. **Test Strips**
   a. Store test strips at room temperature 15-30◦C (59-86◦F).
   b. Do not refrigerate or freeze. Strips stored at room temperature remain stable until the expiration date printed on the vial.
   c. Do not use test strips beyond expiration date.
   d. Quality Control must be performed on all new vials of test strips when first opened.

e. Keep the test strips in the original container, immediately replacing the vial cap after removing a test strip. Exposure to moisture may cause the meter to give an error message or an incorrect result.

B. **Quality Control Solutions**
   a. Store the controls at room temperature 15-30◦C (59-86◦F).
   b. Do not refrigerate or freeze. Unopened control solutions remain stable up to their printed expiration date when stored at room temperature.
   c. **Control vials must be dated with MM/DD/YR when opened**.
   d. Opened Control solutions are good for **3 months** from date opened – or the preprinted expiration date – whichever comes first.
   e. **Expiration date MM/DD/YR must be written on the vials when opened**.

C. **Meter Touchscreen**
   a. Use only your finger to touch the screen elements.
   b. Using a sharp-edged object (such as the tip of a pen) can damage the touchscreen.
   c. Do not use the system in direct sunlight.
   d. Direct sunlight may reduce the life expectancy and functionality of the display, as well as, the integrity of the test strips.
   e. Handle the meter and its system components carefully. Avoid dropping or banging it.
   f. Protect the base unit from dripping liquid.
   g. Do not **immerse or drench** the meter and/or base unit in any liquid.
   h. Do not expose the meter to excessive sources of heat for prolonged periods of time when performing a test. Potential sources of heat include, but are not limited to:
      i. Leaving the meter under a bilirubin light or photo therapy light.
      ii. Leaving the meter on a bed warmer.
      iii. Leaving the meter in an isolette.
      iv. Leaving the meter on a bedside table by the window.

D. **Code Key**
   a. New test strip codes are uploaded into all meters by the Clinical Laboratory when the new lot of strips is validated for use. The properties of the test strips are downloaded as a code file from the Clinical Lab and sent to all meters. The code file is stored in the meter. **The operators will not need to insert a code key.**

E. **Data Management**
   a. Data management is maintained through the RALS system in the Clinical Laboratory by the Point of Care Testing Services Team.

CALIBRATION

A. Linearity solutions (L1-L6) and QC (high and low) are performed on new, replacement, and repaired meters by the Clinical Laboratory.
B. Linearity testing is performed to validate the reportable range. Level 1 – Level 6 linearity

solutions are run in duplicate and results are plotted against reference values. The ideal linearity should be a straight line.

SPECIMEN REQUIREMENTS AND INTERFERENCES

A. Use Capillary whole blood samples obtained from fingerstick. For children under 12 months of age, samples are obtained from heel-stick. **Fingerstick and heel stick samples must be tested immediately**. Do not use plasma, serum, or Cord Blood samples.
B. Wipe away the first drop of blood with gauze and use the second free-flowing drop of blood from the fingerstick site for testing.
C. Venous, arterial, or neonatal blood sample collected in **lithium heparin syringes** are also acceptable. **Sample must be tested within 30 minutes of drawing** to minimize the effects of glycolysis.
D. Alternate site capillary testing (such as an arm or leg) is unacceptable in a hospital setting. (Due to the potential for less vascular circulation in alternate sites, a 30 minute lag time may occur in detecting hypoglycemia from alternate site capillary samples.)
E. Patients who have peeled fresh fruit or handled other foods that contain glucose may have falsely high glucose levels. Patients should wash their hands with water and soap prior to having fingerstick glucose performed.

QUALITY CONTROL

A. **Quality Control (QC) testing must be performed:**
    a. Each day of use (once every 24 hours) **prior to patient testing**.
    b. When a new vial of test strips is opened.
    c. If a vial of test strips was found left open.
    d. If the previous control result is out of range.
    e. If the meter has been dropped.
    f. When the test strips or QC solutions have been exposed to extreme heat, humidity, or cold (when the room temperature reading is out of range).

B. Results for Low QC (Level 1) and High QC (Level 2) should fall within the acceptable QC ranges. **The meter cannot be used for patient testing if it fails any quality control test, in which case, the meter will lock out and not permit patient testing**.

C. **Corrective Actions for failed QC:**
    a. If QC fails, select "**SFGH Will Repeat**" in the pre-programmed comments on the meter.
    b. Check expiration date of the control solutions and test strips.
    c. Check the test strip lot number on the meter display and make certain it matches the lot number on the vial of test strips being used.
    d. Repeat QC using the same control solution and test strip vial.
    e. If QC still fails, discard the control solution and open a new bottle of controls.
    f. Repeat QC with the newly opened controls.
    g. If the QC still fails, discard the test strips and open a new vial of test strips.
    h. Repeat QC on the new vial of test strips.

i. If the QC still fails, remove meter from service and notify POCT Service Monday-Friday 0800-1600.

D. The meter will lock down at **0300** each morning and the message "**QC Due: Immediately**" will appear on screen. QC must be performed and successfully passed in order to initiate patient testing for the day.

E. **QC Testing Procedure:**

a. Press the power ON/OFF button to turn on the meter. The meter will perform self-checks.
b. Touch the forward icon or wait 5 seconds to automatically proceed to the Operator ID screen.
c. Press and release the barcode button.
d. Hold the meter so that the window of the barcode scanner is approximately 4-8 inches above the barcode you wish to read. The meter beeps once the barcode has been read successfully. (Barcode IDs are imbedded with unique identifiers to each operator. They are akin to a computer password and **sharing of barcode IDs is not allowed**.)
e. From the Main Menu screen, touch Control Test.
f. Scan the lot number barcode on the control vial Level 1 (low) or Level 2 (high). If the lot number is incorrect, this message appears:

Control lot not found. **Please enter an existing Control lot or** **See your System Administrator**

i. Make sure you are scanning the control vial and not the test strips.
ii. Check the expiration date and lot number.
iii. If the control vial is not expired, but won't work, contact the POCT Service Team.

g. Touch the check mark button to confirm the selected control solution lot number.
h. Scan the lot number barcode on the test strip vial when prompted to verify test strip lot number. The meter will perform the code key/code file checks. Make sure the code file displayed in the meter match the lot number of the test strips used.
i. Touch the check mark button to confirm the selected test strip lot number.
j. Remove the test strip from the test strip vial and close the vial with the cap immediately.
k. Hold the test strip so the lettering "Accu-Chek" is **facing upward**.
l. Slide the test strip into the test strip port as far as it goes in the direction indicated by the arrows on the test strip. The meter beeps indicating the strip has been detected.
m. Wipe the tip of the control solution bottle with gauze before and after use.
n. When flashing drop appears in the display, apply a drop of glucose control solution to the front **edge** of the test strip. (Do not apply the control solution to the top of the strip.) The control solution is pulled into the test strip by capillary action. Tightly close the cap of the control solution after use.
o. The meter beeps when an adequate sample is applied and an hourglass is displayed while the test is running.
p. The test takes 5 seconds to complete, an audible beep is heard and the

quantitative result is displayed.

q. If the result is out of range, you will be required to enter a comment.
    i. Touch the comment bubble icon to display the pre-programmed and custom comment options. Up to three comments can be entered.
    ii. Select "**SFGH Will Repeat**" as one of your comments.
    iii. For a custom comment, press the double lined comment bubble icon to enter other or additional pertinent customized comment(s).
    iv. Once the selected or custom comment(s) are entered, press the check mark icon to return to the Results Screen.
r. Remove the test strip and discard in a biohazard waste container.
s. Repeat all steps to run the second level of QC.
t. Proceed to patient testing or Power OFF button to turn the meter off.
u. Placing the meter in the docking station ensures downloading of QC information to the POCT Services Team and charges the battery simultaneously.

PATIENT BLOOD GLUCOSE TESTING

A. **Patient Preparation:**
    a. For **Capillary** Glucose Testing:
        i. Only fingerstick and heelstick for infants are approved test sites. The site must be cleaned, dried, and punctured via **a single use lancet**. (**One Lancet: One Patient: One Time Use**)
        ii. Discard lancet in biohazard sharps container.
        iii. Wipe the first drop of blood with gauze and use the second free flowing drop of blood for testing.
        iv. Do not squeeze the puncture site too hard as it may result in tissue fluid contamination.
        v. Alcohol used to cleanse the puncture site for capillary samples must be thoroughly dry or an error code / inaccurate result may occur.

    b. For **Venous, Arterial, or Neonatal** blood collection in Lithium Heparin:
        i. Use only the blood drawing syringe assigned to the patient. Do not share blood drawing syringes between patients. (**One Syringe: One Patient: One Time Use**)
        ii. Discard blood drawing syringe in biohazard sharps container.

B. **Patient Testing Procedure:**
    a. Using two patient identifiers, verify patient identification, and explain procedure to patient and/or family.
    b. Observe universal precautions; wear gloves and other personal protective equipment as appropriate.
    c. Press the Power ON/OFF button to turn on the meter. The meter will perform Self-Checks.
    d. Touch the forward icon or wait 5 seconds to automatically proceed to the Operator ID screen.
    e. Press and release the barcode button.
    f. Hold the meter so that the window of the barcode scanner is approximately 4-8 inches above the barcode you wish to read. The meter beeps once the barcode has been read successfully. If you have a working barcode ID, then you have approval to perform patient testing. If you do not have a working barcode ID, then

you do not have approval to perform patient testing. **Sharing barcode IDs is strictly prohibited**.

g. From the Main Menu screen, touch Patient Test.
h. Scan the patient's ID band barcode or manually enter the patient's medical record number by using the touch keypad on the display screen.
i. Confirm patient's ID is correct. If correct, touch the check mark icon to confirm the selection. If not correct, start over.
j. Scan in the lot number barcode on the test strips vial when prompted to verify the test strip lot number. The meter will perform the code key checks. Make sure the code file displayed in the meter match the lot number of the test strips used.
k. Touch the check mark icon to confirm the selected test strip lot number.
l. Remove the test strip from the test strip vial and securely close the vial with the cap immediately.
m. Hold the test strip so the lettering "Accu-Chek" is **facing upward**.
n. Slide the test strip into the test strip port as far as it goes in the direction indicated by the arrows on the test strip. The meter beeps indicating the strip has been detected.
o. Obtain patient sample. (Refer to "Patient Preparation" above.) Wait until the flashing drop appears in the display before applying the blood sample.
p. Apply a free flowing drop of blood **to the front edge of the test strip**. Do not apply the blood to the top of the strip. Blood is pulled into the test strip by capillary action. Blood on top of the test strip is not available for testing.
q. The meter beeps when an adequate sample is applied and an hourglass is displayed while the test is running.
r. Once the test is completed, an audible beep is heard and the result is displayed.
s. Make note the result. If result is in the critical range, the following message will appear:

REPEAT TEST and CONSIDER sending a STAT specimen to the lab.

t. If a result is in the critical range, a comment **must** be entered to continue meter use.
    i. Touch the comment bubble icon to display the pre-programmed and custom comment options:

        1. **SFGH WILL REPEAT**
        2. **SFGH NOTIFY MD**
        3. **SFGH REFER TO CHART**

u. If a test strip is bad or if the patient result is between 0-10 mg/dL, an error code will be displayed. Repeat test.

Strip Defect Error Extremely Low Blood Glucose Sample, Below the meter's reading range, or a bad strip

    i. Important: "**Strip Defect Error**" can be caused by a:
        1. Low glucose result (<10 mg/dL)
        2. Defective test strip
        3. Adding the sample to the test strip before the flashing drop icon

appears on the meter display

ii. Perform QC on new vial of test strips and repeat patient test with this new vial of test strips.

v. If repeat test still gives "**Strip Defect Error**", consider immediately sending STAT glucose specimen to the Clinical Lab to determine if error message is due to an extremely low glucose result (<10 mg/dL) or some other reason.
   i. Do not use the meter (remove from service) and notify the POCT Service Team Monday-Friday 0800-1600 (not BioMed).

w. Remove the test strip from the meter and discard in biohazard container.
x. Press the OFF button to turn the meter off.
y. Clean the meter, then discard gloves and wash hands or use hand sanitizer.
z. Place meter in docking station to ensure downloading of QC and patient result information, as well as, to keep the meter battery charged.

REFERENCE RANGES

Fasting:

Normal	70-99 mg/dL	3.86-5.45 mmol/L
Impaired Fasting Glucose (Pre-diabetes)	100-125 mg/dL	5.51-6.89 mmol/L
Diabetes	≥ 126 mg/dL	≥ 6.94 mmol/L

Random:

Normal per Age	< 1 day	36-110 mg/dL	1.98-6.06 mmol/L
	1 - 6 days	47-110 mg/dL	2.59-6.06 mmol/L
	7 days - < 6 mos	54-117 mg/dL	2.98-6.45 mmol/L
	6 mos - < 1 year	70-126 mg/dL	3.86-6.94 mmol/L
	≥ 1 year	70-139 mg/dL	3.86-7.66 mmol/L

Impaired Glucose Tolerance	140-198 mg/dL	7.71-10.91 mmol/L
Diabetes	≥ 199 mg/dL	≥ 10.96 mmol/L

Critical Values:

Glucose	< 50 or > 500 mg/dL	< 2.76 or > 27.55 mmol/L
Neonates	< 30 or > 170 mg/dL	< 1.65 or > 16.53 mmol/L

REPORTING RESULTS

A. Results exceeding the reportable and critical range of the system require follow up.
B. If an incorrect medical record number has been used or the patient has been misidentified, complete an unusual occurrence report.
C. The INFORM II system can read results from 25-600 mg/dL Reportable Range. Results outside of this range will read either "LO" or "HI".
D. LO or HI results obtained should prompt the operator to repeat the test; if again obtained on a repeated test, the user should **consider sending a STAT specimen** to the Clinical Laboratory **prior to treating the patient**. (Waiting for the STAT results is not necessary before treating the patient, but the specimen must be drawn/sent prior to treating the

patient in order to gain a comparable/accurate/real-time test result.)

E. Individual patient results are documented in the patient's medical record by downloading the meter. If for some reason the results do not download, it is the testing employee's responsibility to manually enter the test results into the patient's medical record – ensuring test result documentation.

CLEANING / PREVENTIVE MAINTENANCE

A. For efficiency, daily cleaning and disinfecting are companion procedures and should be done when QC is performed.
    a. Cleaning removes visible soil and organic material prior to disinfecting.
    b. Disinfecting destroys most pathogenic organisms.
B. Do not clean or disinfect meter while performing any test.
C. Remove the meter from the base unit and turn it OFF prior to cleaning and disinfecting. **At a minimum, clean and disinfect the meter between each new patient use and when soiled** with a Sani-Cloth Germicidal Disposable Cloth.
D. The towelette should only be **slightly damp**, **NEVER dripping wet** (**wring it out**).
E. If it is suspected that moisture has entered the strip port, attempt a QC test. If test fails, remove meter from service and notify the POCT Service Team Monday-Friday 0800-1600.
F. The accessory box and docking station base can be cleaned with the same cleaning products. Unplug docking station from electrical power prior to cleaning.
G. Prevent electrical damage. Do not pour or spray solutions directly onto meter or docking stations. Do not immerse in liquids. Do not wet electrical connectors on the back of the base unit.
H. All components must be dry **before** returning meter to docking station.

METER DOCKING AND BATTERY CHARGING

A. The Accu-Chek INFORM II meter contains a rechargeable battery pack that is recharged when connected to the base unit docking station.
B. In order to maintain the battery charge, the Accu-Chek INFORM II **meter should be stored on the docking station when not in use**. (Do not leave meter at bedsides, in hallways, or at nurse's stations in anticipation of next use.)
C. When the meter is in the docking station, the battery with lightning icon is displayed indicating electrical power is available and the meter is charging.
D. The meter must be docked in order to transmit data to and from the Clinical Laboratory and to the patient's electronic medical record.

LIMITATIONS

A. The Accu-Chek INFORM II test strips are for testing fresh capillary, venous, arterial, or neonatal whole blood. Cord blood samples cannot be used.
B. Hematocrit should be between 10-65%.
C. Lipemic samples (triglycerides) in excess of 1800 mg/dL may produce elevated results.
D. Blood concentrations of galactose >15 mg/dL will cause overestimation of blood glucose results.
E. Intravenous administration of ascorbic acid which results in blood concentrations of ascorbic acid >3 mg/dL will cause overestimation of blood glucose results.

F. 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, decompensated heart failure NYHA Class IV, or peripheral arterial occlusive disease.
G. This system has been tested at altitudes up to 10,000 feet.

ALTERNATIVE TEST METHODS

A. Blood plasma glucose testing is performed in the Clinical Laboratory.
B. POCT glucose testing **may not** be performed by the patient or by using the patient's own glucose monitoring device in the hospital setting at SFGH.
C. Alternate site (such as arm or leg) capillary testing is unacceptable in a hospital setting. Due to the potential for less vascular circulation in alternate sites, a 30 minute lag time may occur in detecting hypoglycemia from alternate site capillary samples.

STAFF EDUCATION, ORIENTATION & TRAINING, COMPETENCY, & BARCODE IDs

A. Each operator using the Accu-Chek INFORM II glucose meter at SFGH becomes approved to perform this POCT through completion of Orientation & Training and Competency Testing which includes successful demonstration of skills and knowledge. This Competency Testing is required upon initial training, twice during the first year, and annually thereafter.
B. Once approved to test, the new operator will be issued a barcode ID with their unique identifiers imbedded within the barcode. Those renewing their annual Competency will not require a new barcode ID; rather, their current barcode ID will be updated via the POCT Service.
C. If an operator's barcode ID is active (is working), it signifies the operator has completed all prerequisites for patient testing and is currently approved to perform this POCT.
D. If an operator's barcode ID is not active (not working), it signifies the lack of approval for performing this POCT and the need to renew their Competency test.
E. If an employee loses or damages their barcode ID, they may request a new barcode ID from the POCT Services.
F. Barcode IDs are to be secured to the employee's hospital or university ID badge.
G. Barcode IDs are to be treated like secure passwords and thus the sharing of barcode IDs in not allowed.
H. All activity occurring under an employee's barcode ID is the responsibility of that employee.
I. Students are not trained, nor approved, to perform this POCT at SFGH. Their educational experience may be gained only when an employee with an active barcode ID is with them at the patient's bedside supervising and taking full responsibility for the experience, results, documentation, and follow-up actions.

RECORD KEEPING

All records for QC Testing, Patient Testing, Orientation & Training, Competency Testing, Meter Validation, Patient Comparisons, Maintenance, and Testing Issues will be kept on file in the Clinical Laboratory for at least three years. Patient results are documented in their medical record for perpetuity.

RETRIEVAL OF STORED RESULTS FROM THE METER

A. From the **Main Menu**, press **Review Results**.
B. The **Review Results** screen displays the most recent stored results on top. The meter memory stores up to 2,000 results.
C. Select any result to view result details.
    a. The following information will be displayed:
        i. Patient ID (MRN)
        ii. QC level
        iii. The lot number of the reagents used to perform the test, the test result, the date and time the test was performed, and any comments that were entered at the time the test was performed.
D. Press the UP arrow to view most recent tests.
E. Press the DOWN arrow to view previous tests.
F. Select **PATIENT** to view a specific patient's result.
    a. Barcode scan or manually enter the patient's 8 digit medical record number.
    b. Press the arrow buttons to scroll through the patient results.
    c. Select any result to view patient result details.
    d. Press the back arrow to return to the previous screen.
    e. Select **ALL** to return to viewing ALL RESULTS.
G. Select **QC** to review QC results only:
    a. Use the arrow buttons to scroll through the QC results.
    b. Touch any QC result to view result details.
    c. Touch the back arrow to return to the previous screen.
    d. Press the **Main Menu** icon to return to the Main Menu.

TROUBLESHOOTING GUIDE

A. **On Screen Messages**

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 message types are:	
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 the notification of a **DECISION** point. Decision notifications provide the operator with a choice based on contextual information.

B. **Error Codes**

Display Symptom Error Code	POSSIBLE REASON AND SOLUTION
The meter does not power on.	**Battery pack might be dead.** 1. Place meter in the base unit for at least one hour to recharge the battery pack. 2. If error persists, bring meter to the Clinical Laboratory and trade it for a Loaner Meter.
Meter displays: "Type Bad Dose"	**Insufficient amount of blood on the test strip.** 1. Repeat the test using a new test strip, ensuring proper sample dosing application (review proper testing procedure). 2. If error persists, bring meter to the Clinical Laboratory and trade it for a Loaner Meter.
Meter displays: "Glucose Error"	**Detection of an unexpected HARDWARE ERROR.** 1. Perform QC on new vial of test strips and repeat patient test with this new vial of test strips. 2. Refresh/Reboot the meter by turning off the meter, wait 10 seconds, then turn on the meter. 3. Reset the meter by following the Meter Reset Procedure. 4. If error persists, bring the meter to the Clinical Laboratory and trade it for a Loaner Meter.
Meter displays: "Unexpected SW Error"	**Detection of an unexpected SOFTWARE ERROR.** 1. Perform QC on new vial of test strips and repeat patient test with this new vial of test strips. 2. Place meter into a connected base unit and let it download completely to synchronize configurations with the data management system. 3. Reset the meter by following the Meter Reset Procedure. 4. If error persists, bring the meter to the Clinical Laboratory and trade it for a Loaner Meter.
Meter displays: "QC Due: Immediately"	**QC needs to be done.** 1. Run controls immediately 2. Patient testing cannot proceed until control tests are successfully run.
Meter displays: "LO" or "HI"	**Patient's result is possibly critical.** 1. Refer to "**REFERENCE RANGES & REPORTING RESULTS**" portions of this policy.
Meter displays: QC "FAIL" or "Out of Range"	**Quality Control result has failed or is out of range.** 1. Repeat QC. Refer to "**QC Testing Procedure**" for step-by-step instructions.
Battery Low	**Meter left off docking station for too long.** 1. Charge the battery by placing the meter in the docking unit.
Battery Critically Low	**Meter left off docking station for too long.** 1. Charge the battery by placing the meter in the docking unit. 2. If meter does not re-charge, bring to the Clinical Laboratory and trade it for a Loaner Meter.
The Accu-Chek INFORM II meter is	**There is some disconnect in the system.** 1. Reset the meter using the reset button.

unable to communicate with the data management system.	2. Ensure all wiring is connected, nothing is unplugged. 3. If meter still will not download results to patient's medical record, notify the POCT Service Team Monday-Friday 0800-1600.
Automatic shutdown (powers off)	**To conserve energy the meter may automatically shut down.** 1. Press the ON/OFF button to turn meter back on.
Base Unit LED is not illuminated.	**Base Unit is not connected to power supply unit or power supply unit is defective, or power outlet is not active.** 1. Disconnect the base unit power supply cord from the base unit and electrical outlet and then reconnect it again. Make sure all the cords are tightly connected to the base unit. 2. If error persists, notify the POCT Service Team Monday-Friday 0800-1600.
LED flashes red	**Communication or configuration error.** 1. Ensure all cords are plugged in. 2. If problem persists, notify the POCT Service Team Monday-Friday 0800-1600.

C. **Meter Reset Procedure**

1. Place the meter face down on a level surface.
2. Press the reset button in the middle of the battery pack using a tool such as a screwdriver or paper clip.
3. Turn the meter over (right side up).
    a. The Roche logo should be displayed.
    b. If the Roche logo does not appear within 60 seconds, place the meter on a base unit for a minimum of 15 minutes to recharge the battery.
    c. Within a short period of time, the meter's version screen will appear, displaying the version numbers of the meter components.
4. To ensure successful troubleshooting, dock the meter in the base unit and let it download completely.
5. Finally, the Power up/Stand By screen and the Main Menu are displayed.

D. **Broken / Inactive Meters**

1. Meters that fail to perform properly or have failed QC cannot be used for patient testing.
2. Meters removed from service must be returned to the Clinical Laboratory for evaluation, inspection, downloading, minor repair and/or meter replacement.
3. Loaner meters are available in the Clinical Laboratory for overnight or over-weekend use or until POCT Services can restore a meter to a unit.

E. **Network Connectivity Problem**

1. Any time data is not communicating between the meter and the Clinical Laboratory or the patient's electronic medical record, be sure all cords are connected and the power supply is working.
2. Be sure the meter is charged.
3. Try to resolve the issue by resetting the meter.
4. If meter will not download, notify Point of Care Testing Services Monday-Friday 0800-1600.

REFERENCES

1. Alere Informatics, Inc. *RALS-Web3 for Accu-Chek Inform II Devices*. March 2013, Alere Informatics, Inc. MAS-3600-5040-0800(2.0). RALS-Web3 for Accu-Check Inform II. Alere Informatics, Inc., 2000 Holiday Drive, Suite 500, Charlottesville, VA, 22901.
2. Clinical and Laboratory Standards Institute. *Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline – Third Edition*. CLSI Document POCT12-A3. CLSI, 950 West Valley Road, Suite 2500, Wayne, PA, 19087 USA. January 2013.
3. Clinical and Laboratory Standards Institute. *Training and Competency Assessment; Approved Guideline – Third Edition*. CLSI Document GP21-A3. CLSI 940 West Valley Road, Suite 1400, Wayne, PA, 19087-1898 USA. 2009.
4. Roche Diagnostics. *Accu-Chek and AccuData Systems Evaluation Protocol*. 2013, Roche Diagnostics. 4481-00-1112 USA. Roche Diagnostics, 9115 Hague Road, Indianapolis, IN 46256.
5. Roche Diagnostics. *Accu-Chek Inform II Glucose Control Solutions Product Insert*. 2012, Roche Diagnostics. 05213525004-1012 USA. Roche Diagnostics, 9115 Hague Road, Indianapolis, IN 46256.
6. Roche Diagnostics. *Accu-Chek Inform II Blood Glucose Monitoring System Operator's Manual*. 2013, Roche Diagnostics. 05234646002 2013-03 USA. Roche Diagnostics, Commercial Education Department, 9115 Hague Road, P.O. Box 50457, Indianapolis, IN, 46250-0457.
7. Roche Diagnostics. *Accu-Chek Inform II Operator's Manual – Base Unit HUB System*. 2013, Roche Diagnostics. 4987-00-0213 USA. Roche Diagnostics, 9115 Hague Road, P.O. Box 50457, Indianapolis, IN, 46250-0457.
8. Roche Diagnostics. *Accu-Chek Inform II Quick Reference Guide for Health Professionals*. 2012, Roche Diagnostics. 05234654001 2012-10 USA. Roche Diagnostics GmbH, 68298 Mannheim, Germany.
9. Roche Diagnostics. *Accu-Chek Inform II Linearity Kit Product Insert*. 2012, Roche Diagnostics. 05871182001-1012 USA. Roche Diagnostics, 9115 Hague Road, Indianapolis, IN, 46256.
10. Roche Diagnostics. *Accu-Chek Inform II Test Strips Product Insert*. 2013, Roche Diagnostics. 05942934003-0113 USA. Roche Diagnostics, 9115 Hague Road, Indianapolis, IN, 46256.
11. Roche Diagnostics. *Sample Template for: Comprehensive Policies, Processes and Procedures Manual for use with Accu-Check Inform II Glucose Monitoring System*. 2012-2013, Roche Diagnostics. 4302-02-0713 USA. Roche Diagnostics, Commercial Education Department, 9115 Hague Road, P.O. Box 50457, Indianapolis, IN, 46250-0457.

DISTRIBUTION

1. Point of Care Testing Services Master Manual
2. All Testing Sites