Wake Forest Baptist Medical Center	Point of Care Blood Glucose Monitoring Formerly PPB: NCBH-76	Туре:	Tier 2	
		Effective Date:	10/2013	
		Revised Date:	N/A	
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I. General Procedure Statement:

Department specific personnel are responsible for performing point of care blood glucose monitoring with an order from a Physician, Nurse Practitioner (NP), or Physician Assistant (PA). The results obtained will be used as a screening mechanism, or as a basis for treatment as determined by a Physician, NP, or PA's order. Confirmatory testing will be performed at the Physician, NP, or PA's discretion and with an order. Refer to the Abbott Precision Exceed Pro Users Manual for information not found in this document.

A. Scope:

This document establishes procedures and guidelines for staff to safely perform point of care blood glucose monitoring.

- 1. Responsible Department/Party/Parties:
 - a. Procedure owner: Clinical Laboratory Point-of-Care Testing Manager/Coordinator
 - **b. Procedure:** Any Wake Forest Baptist Medical Center (WFBMC) site performing POC glucose testing shall adhere to processes outlined in this document.
 - c. Supervision: The Medical Director for Point-of-Care Testing and/or the CLIA director shall oversee the person(s) performing activities outlined in this document
 - d. Implementation: Each applicable POCT site manager is responsible for ensuring compliance with the processes stated in this document.

II. Definitions:

- A. Point-of-Care Testing (POCT)—defined as tests designed to be used at or near the site where the patient is located, that do not require permanent dedicated space, and that are performed outside the physical facilities of the clinical laboratory. Point-of-Care abbreviated as POC in this document.
- **B. Point of Care Waived Tests (POCWT)**—Tests that are so simple and accurate that there is little risk of error if the test is performed incorrectly.
- C. Clinical Laboratory Improvement Amendments (CLIA)—United States federal regulatory standards that apply to all laboratory testing performed on humans.
- D. Quality Control (QC)—processes to ensure the test system is performing as expected.
- E. Quality Assurance (QA)—a system for ensuring a desired level of quality. The POCT program incorporates activities to monitor the quality of processes and the test system.
- F. Quality Improvement (QI)—activities implemented to improve the quality of processes

- G. Proficiency Testing (PT)—Unknown samples sent to a lab/test site by an approved PT provider. PT providers must be approved by the Centers for Medicare and Medicaid Services (CMS).
- H. Technical Limits/Reportable Range: The range at which the glucose meter has been verified to obtain accurate results. The technical limit for the Abbott Precision Xceed Pro meter is 20 500mg/dl.
- I. Normal (Reference) Range: The range of normal values for the average patient population. For the adult patient, the defined normal range using the Abbott PXP device is 70- 150mg/dl. This range was previously established by the Department of Endocrinology at North Carolina Baptist Hospital.
- J. Treatable Values: Point of care waived blood glucose values between 60mg/dl and 70mg/dl; or between 150 and 400mg/dl should be treated as per Physician, NP, or PA's orders. If no order exists, notify the Physician, NP, or PA. Treatable values should be treated as a critical value if the patient's condition warrants (i.e. diaphoresis, decreased level of consciousness, etc).
- K. Action Range Values: Represent an emergency condition and must be reported immediately to the patient's Physician, NP, or PA. Notification should be documented in the patient care record.
 - 1. Adult Action Range Values at WFBMC: < 60mg/dl and >400mg/dl
 - a. As defined by the Department of Endocrinology
 - 2. Neonate Action Range Values at WFBMC: <50mg/dl and >180mg/dl
 - a. As defined by the Neonatal Intensive Care Unit (NICU) medical director
 - b. Neonatal and pediatric patients under one year of age; refer to the ICN specific policy "Blood Glucose Monitoring," PPB-NCBH-NUR-ICN/IMN-215.
- L. Upload/Download/Docking Meter: Refers to the action of connecting the glucose meter to the WFBMC network to allow transmit of patient results and Admit/Discharge/Transfer (ADT) data to and from the glucose meter.
- M. ADT (Admit/Discharge/Transfer): Refers to visit-specific demographics for a patient
- N. CSN (Contact Serial Number): Refers to Electronic Healthcare Record encounter—related to account Number
- O. AC: Part of the CSN that is stored in Wake One. Included in the linear barcode on the patient armband. For example, AC12345678901. AC is NOT included in the document label CSN barcode. For example, 12345678901

III. Procedure

- A. Staff Education and Competence
 - Only staff and faculty educated and evaluated as competent may perform point-of-care (POC)
 glucose testing.
 - 2. Competency testing must be performed initially and then annually by at least 2 of the following methods of assessment:
 - a. Performance of the test on an unknown/blind specimen. (Results are unknown at the time of testing but can be evaluated against the known range after testing)
 - b. Periodic observations of glucose testing to be completed by an authorized site preceptor.
 - c. Monitoring of quality control performance.
 - d. Use of a written test specific to Abbott PXP glucose testing. Required passing score is at least 80% correct.
 - e. Other approved methods, as listed in the Joint Commission Waived Testing Standards.

 The successful completion of competency requirements must be documented by the department manager.
 - 3. If an employee fails to achieve these passing requirements, then re-education and re-assessment must be completed and documented, prior to performing additional patient testing.

B. Reporting Results

- 1. POC blood glucose values should be documented in the Electronic Healthcare Record (EHR) in the indicated area. Normal (reference) ranges and units of measure (mg/dl) should accompany each patient result.
- 2. Treatable values should be documented in the EHR, and the existing order for treatment should be initiated. If no order exists, the Physician, NP, or PA must be notified. Notification should be documented in the patient care record.
- 3. Action Range Values (<60mg/dl and >400mg/dl for adults and <50mg/dl and >180mg/dl for neonates) should be called to the attention of a Physician, NP, or PA. A "HIGH" with a " \uparrow " or a "LOW" with a " \downarrow " will be displayed on the glucose meter screen.
- 4. Results that are verbally reported need to be confirmed by verbal read back of results.
- 5. A reading of <20 or >500 mg/dl falls outside the Abbott Precision Xceed Pro meter's reportable range. These results must be called to the Physician and verified through laboratory testing. The RN, after obtaining a physician order, must verify the results by obtaining a glucose laboratory specimen. The RN is responsible for obtaining and acting on the results of the follow-up laboratory specimen.

C. Patient Testing: Identification of Patient

1. When obtaining a sample for POC glucose testing, PRIOR to performance of testing, verify patient identification by using two forms of patient-specific identification: Patient first and last name and the Date of Birth or medical record number, if necessary. The correct CSN for the specific visit should also be verified.

The CSN is used to post results electronically to the patient record. Thus, it is imperative that the correct patient CSN be entered into the glucose meter at the time of testing.

a. Inpatient testing and Procedural Areas where patient wears armband):

(Sterile Procedures—see below)

- (1.) The bar-coded armband ON the patient should be scanned to enter patient ID into the glucose meter. The barcode on the armband contains "AC" + the 11 digit CSN number. When scanning patient ID, the AC will not display on the meter. Only the numeric portion of the CSN will display.
- (2.) In the event the barcode on the armband cannot be scanned by the glucose meter, the 11 digit CSN number can be manually entered into the meter. Duplicate entry is required to ensure correct patient identification/patient safety. Do NOT enter the leading AC.

b. Outpatient Testing: (where patient does not wear armband)

- (1.) It is acceptable to use the barcode on the patient document label, <u>provided</u> the patient name, medical record number, date of birth, and correct CSN for that visit are verified <u>prior</u> to scanning ID into the glucose meter.
- (2.) The 11 digit CSN can be manually entered into the glucose meter. Duplicate entry is required to ensure correct patient identification/patient safety.

c. Non-Registered Patients:

- (1.) When patient testing is needed prior to patient registration in the WFBMC system, a generic/emergency patient identifier should be used.
- (2.) The generic/emergency ID must be an approved ID to ensure results don't inadvertently post to an incorrect patient record.
- (3.) The testing staff member is responsible for sending correct patient identification to the appropriate individual(s), once the patient is registered. Refer to Appendix D for detailed instructions.

(4.) In addition, manual entry of the glucose result into the electronic healthcare record should occur to allow timely viewing of the result in the EHR.

d. Sterile Procedures:

During sterile procedures, the armband on the patient may not be accessible. If the armband is not accessible during a sterile procedure, adhere to the following process.

- (1.) Print extra patient armband that matches the armband that is on the patient.
- (2.) If the patient has been admitted, the inpatient admission armband must be used.
- (3.) The extra armband must be verified against the armband that is on the patient, Including: full patient name, date of birth, medical record number, and CSN.
- (4.) Verification of the second armband should be documented on the time-out form during time-out procedures.
- (5.) This extra armband can be used to scan patient ID into point-of-care devices, such as i-STAT and the glucose meter, <u>only during sterile procedures</u>.
- (6.) Once the case is completed, the extra armband should be destroyed.

e. Employee Health Services

Employee Health Services uses a separate EHR. Therefore, samples tested in this location will utilize the medical record number as the identifier that is entered into the glucose meter at the time of testing. Results will be manually entered into Employee Health Service's patient record by the individual that performs testing. Result should be accompanied by units of measure (mg/dl) and the reference/normal range (70-150mg/dl)

f. Clinical Research Unit (CRU)

CRU does not report POC glucose results into a patient record. Therefore, samples tested in this location will utilize the participant study ID number as the patient ID that will be entered into the glucose meter at the time of testing. Results will be manually documented on CRU-specific documentation. Results will not post electronically to any record.

2. If a specimen is taken away from the bedside for testing, it must be labeled in the presence of the patient immediately after collection. The label should include the patient name, date of birth, and CSN.

D. Important Notes:

- 1. All POC glucose testing performed on a patient must only be provided by using an approved professional -use glucose meter.
- 2. WFBMC glucose meters should never be used by staff for personal glucose testing. Staff members, who need to monitor their blood glucose levels, need to use a personal home meter or go to the Employee Health Services for evaluation.
- 3. Home meters may be used by a patient for personal record keeping only. These results will not be utilized by staff for decision-making or documented in the patient care record.
- 4. Adhere to proper storage conditions for glucose test strips and QC materials, as posted on packaging and inserts.
- 5. Do not use expired products for testing.

See Appendix A: Patient Testing Procedure.

See Appendix 8: Finger Puncture Procedure.

E. Quality Control Testing and Monitoring

- 1. Quality control testing consists of performing a High and Low QC test which verifies instrument and test strip performance. QC testing must be performed:
 - a. once every 24 hours of patient use;
 - b. when monitor or strip performance is questioned;
 - c. if the meter has been dropped.

- 2. Areas where meter usage is infrequent must perform the Quality Control prior to patient use.
- 3. Quality control results must be reviewed by the testing personnel to ensure the meter and strips are functioning within acceptable limits.
- **4.** If QC checks are not performed within 24 hours on the Abbott Precision Xceed Pro glucose meter, the meter will lock until successful QC has been tested. The glucose meter will warn 30 minutes before the lockout occurs.
- 5. Results of QC testing will be maintained in the Abbott Precision Web (PWeb) data base.
- Quality assurance activities will include monitoring and analysis of reports available from the p-Web system.
 - Department specific reports may be evaluated and performance improvement plans will be implemented as indicated.
- 7. Control solution vials must be dated when opened with a 3 month expiration date, not to exceed the manufacturer's expiration date.
- 8. Unused solutions must be discarded three months from open date or by the manufacturer expiration date, whichever comes first.
- 9. The Department manager or designee is responsible for staff compliance with quality control testing and documentation.

See Appendix F: Quality Control Procedure.

F. Electronic Transferring of Data

- 1. Each department will have access to an electronic connection to upload/download/dock the glucose meter, either by a docking cradle or direct serial cable connection to a PC.
- 2. The blood glucose meter must be electronically connected at least every 4 hours or more frequently for inpatient care areas.

Meters will prevent patient testing if upload/download/docking does not occur each 4 hours.

Procedural and Transport areas will be required to upload/download/dock after each case/transport.

- a. This will allow transmit of patient results to the patient electronic healthcare record for resulting.
- **b.** When the meter is uploaded/downloaded/docked, glucose results post into the electronic healthcare record.

See Appendix C: Data Transfer Procedure

G. Cleaning and Disinfection

1. The blood glucose meter should be disinfected with a Caviwipe <u>after each patient use</u> and if dirt, blood, or lint is present.

2. ISOLATION ROOMS:

- a. Do not take the glucose meter case into the patient room.
- b. Only take in the glucose meter, inside a 6 x 9 clear bag, along with a test strip.
- c. The 6 x 9 clear bags are available from the Storeroom.
- d. When finished testing, remove bag, wipe meter with the wipe/disinfectant appropriate to the type of isolation
 - (1.) i.e. Dispatch Bleach wipes for Special Enteric Isolations
 - (2.) Caviwipe or other WFBMC-approved disinfectant for all other Isolation precautions.

See Appendix E: Abbott Precision Xceed Pro Meter Cleaning and Disinfecting Procedure

- H. Known Limitations: Do NOT use Abbott Precision Xceed Pro Meter in these circumstances:
 - Very high hematocrits (above 70% in children, adults, and neonates) may cause results lower than laboratory findings. Very low hematocrits (< 20%) in whole blood samples may cause higher than expected results.
 - 2. Excessive water loss or dehydration may cause inaccurate low results. Test results may be erroneously low if the patient is severely dehydrated or severely hypotensive, in shock or in a hyperglycemic-hyperosmolar state (with or without ketosis).
 - 3. Serum or Plasma samples used for testing instead of whole blood samples; testing with these sample type's cause glucose results to be higher than expected.
 - 4. Patients in hyperglycemic-hyperosmolar state (with or without ketosis); testing samples from these patients' cause glucose results to be lower than expected.
 - 5. Water or alcohol remaining on puncture site; testing in this case causes glucose results to be lower than expected.
 - 6. Venous or arterial whole blood sample not tested within 30 minutes after collection; testing in this case causes glucose results to be lower than expected.
 - 7. Patients receiving IV infusions of high-dose ascorbic acid or during xylose absorptions testing.
 - 8. Failed QC results. Troubleshooting must occur and QC failure resolved, prior to proceeding with patient testing.
- I. Troubleshooting

See Appendix Z: Troubleshooting

IV. Review/Revision/Implementation

- A. Review Cycle: This document shall be reviewed by the appropriate CLIA certificate director or a qualified designee
 - 1. Before initial use of the test for patient testing
 - 2. At least once each 3 years
 - 3. When changes in procedures occur.
- B. Office of Record: The Clinical Laboratory Section on Point-of-Care Testing
- C. Implemented: October 2013

V. Related Policies

PPB-WFBMC-69 Provider/Physician Orders

PPB-WFBMC-83 Patient Identification

PPB-NCBH-75 Point of Care Waived Testing

PPB-NCBH-NSG-219 Nursing Staff Competency

PPB-MC-07 Wake Forest Baptist Medical Center Information Security Policy

PPB-NCBH-NSG-114 Administration of Regular Insulin Drip

Recommended Practices for Preventing Blood borne Pathogens Transmission during Blood Glucose Monitoring and Insulin Administration in Healthcare Settings

PPB-NCBH-NUR-ICN/IMN-215 Intensive and Intermediate Care Nurseries Unit-Based Practice Council WFBMC-104 Intravenous Medication Therapy for the Adult Patient, Infusion Guide for Adult IV Medication Therapy NCBH-PPB-NSG-310 Sterile Body Fluid and Blood Collection, including Blood Cultures from Venipuncture, Arterial Lines and Central Lines

Policies and Procedures from Lexington Medical Center and Davie Medical Center related to Point-of-Care Glucose Testing

VI. Governing Law/Regulations/References

1. Comprehensive Accreditation Manual for Hospitals, 2013 by the Joint Commission on Accreditation of Healthcare Organizations (Waived Testing Chapter, Standards: WT.01.01.01, WT.02.01.01, WT.03.01.01, WT.04.01.01, WT.05.01.01)

- 2. Chapter IV-Centers for Medicare and Medicaid Services, Department of Health and Human Services Part 493- Laboratory Services
- 3. 2013 Hospital National Patient Safety Goals by The Joint Commission
- 4. Standards of Medical Care in Patients with Diabetes Mellitus by the American Diabetes Association. 2013 http://care.diabetesjournals.org/content/36/Supplement 1/S11.full.pdf+html Standards of Care in Diabetes in medical care 2013
- 5. Abbott Precision Xceed Pro Operator Training Guide, Abbott Diabetes Care Inc., 1360 South Loop Road, Alameda, CA 94502 USA, DOC21223 Rev B. 5/13 (2013), Pages 1 24.
- 6. Abbott Precision Xceed Pro test strip package insert, Abbott Diabetes Care Inc., 1360 South Loop Road, Alameda, CA 94502 USA, ART12964 Rev C. 01/12 (2012), Pages 1 2.
- Wake Forest Baptist Medical Center, PPB-NCBH-76, Point of Care Blood Glucose Monitoring, revision 3/29/2011

VII. ATTACHMENTS:

Appendix A: Patient Testing Procedure
Appendix B: Finger Puncture Procedure
Appendix C: Data Transfer Procedure

Appendix D: Emergency/Generic Patient Identifier and ID Resolution for Testing Performed on Non-

Registered Patients

Appendix E: Abbott Precision Xceed Pro Meter Cleaning and Disinfecting Procedure

Appendix F: Quality Control Procedure

Appendix G: Precision Xceed Pro Test Strip Package Insert

Appendix H: Procedure to Unlock Glucose Meter in the Event of Network Downtime or Power Failure

Appendix 1: Resolution of Patient Result Errors in P-Web

Appendix J: True ID Procedure Appendix Z: Troubleshooting



Appendix A: Patient Testing Procedure Revision 10/2013

I. Equipment:

- A. Abbott Precision Xceed Pro Blood Glucose Meter
- B. Abbott Precision Xceed Pro Test Strips
 - 1. Store according to manufacturer requirements. (39-86°F)
 - 2. Do NOT use past expiration date
- C. Clean disposable gloves
- D. Appropriate disinfecting solution to wipe meter AFTER EACH PATIENT USE
- E. 6x9 clear bag for isolation patients

II. Procedure:

A. Procedure for Testing

Do NOT use the glucose meter for patients that meet criteria explained in the test strip package insert and in section III.H. **Known Limitations**: Do NOT use Abbott Precision Xceed Pro Meter in these circumstances:

- 1. Press the On/Off button to turn on the meter. The time, date, and battery status will appear when powered on.
- 2. If the meter displays, 'Date/Time Not Set', replace the batteries and download the meter.
- 3. Select Patient Test from the Main Menu. Press "1-Patient Test".
- 4. Scan or enter glucose meter operator ID. Use employee-specific WFBMC Employee ID Number, press enter.
 - **a.** To scan a barcode, press and hold the SCAN keypad on the analyzer, until the glucose meter beeps, indicating the barcode has scanned.
 - b. Do not share glucose operator ID's.
 - c. Do not enter your operator ID for another individual to perform testing.

5. Inpatient Testing/Procedural Areas:

PRIOR TO SCANNING OF ENTERING THE PATIENT ID INTO THE GLUCOSE METER:

- a. Verify patient identification verbally (name and date of birth (DOB).
- b. Compare verbal identification to armband ON the patient.
- c. Scan or manually enter the CSN from the armband that is ON the patient and explain the procedure to the patient.
- d. The CSN is the identifier that is bar-coded on the patient armband. The correct CSN for the inpatient admission must be used to facilitate correct posting of results to the electronic healthcare record.
- e. 'AC' precedes the CSN and will not display on the meter when the barcode is scanned. Only the 11 digit CSN will display.
- f. Continue with step 7

6. Outpatient Testing:

PRIOR TO SCANNING OF ENTERING THE PATIENT ID INTO THE GLUCOSE METER:

- a. Verify patient identification verbally (name and date of birth (DOB).
- **b.** Compare verbal identification to the document label that will be used to scan/enter ID into the glucose meter. You must verify:
 - (1.) Patient full name
 - (2.) Medical record number
 - (3.) Date of Birth (DOB)
 - (4.) Correct CSN—Must use CSN for Date/Clinic-specific visit.

- c. Scan/enter ID into the glucose meter and explain the procedure to the patient.
- d. The CSN is the identifier that is bar-coded on the document label. The correct CSN for the clinic-specific visit must be used to facilitate correct posting of results to the electronic healthcare record.
- **e.** Continue with step 7. 7. Scan the test strip lot found on the outside of the individual test strip.
- a. To obtain accurate results, you must scan the barcode on the test strip that is used for each patient test.
- b. Expired test strips should never be used and will not scan into the glucose meter
- 8. Peel away the foil containing the test strip and remove the test strip. Insert the test strip fully into the meter's test strip port within four minutes of entering operator and patient ID information.
- 9. The blue side of the strip should be facing up when inserted into the meter.
- 10. The glucose meter will display, "Apply Sample".
 - a. Specimen must be of venous, arterial, or capillary whole blood
 - b. For information on how to perform a finger stick, see Appendix B, Finger Puncture Procedure.
- 11. Apply the blood to the tip of the test strip by carefully touching the drop of blood on the patient's finger or by touching the end of the syringe, <u>continuously until the meter beeps</u>. The strip must continuously touch the drop of blood until the analyzer beeps. Otherwise, erroneous/invalid results may be obtained.
- 12. The meter screen shows, "Sample Accepted."
- 13. If meter is removed prematurely from the blood on the patient's finger/syringe before the beep and sample is accepted, then remove the strip, enter 1 on the meter keypad for new strip, and try again.
- 14. Place the meter on a flat surface while the meter is analyzing the sample. The patient test result appears in approximately 20 seconds.
- 15. Enter into the meter the appropriate Comment Code number. Comment code numbers will translate in the patient electronic healthcare record as indicated below. Ensure use of the correct comment codes, as certain codes will prevent results from posting to the patient record (code 0) and others will prevent billing from occurring (code 5).

O translates to Procedure Error

- (1.) Results flagged with comment code 0 will not post to the patient electronic healthcare record.
- (2.) This code should be used when the staff member does not believe the result and feels an error was made in testing.
- 1 translates to Pre-Meal
- 2 translates to Post-Meal
- 3 translates to NPO/no enteral feeding
- 4 translates to Continuous enteral feeding
- 5 translates to Recheck/confirm
 - (1.) Results flagged with comment code 5 will post to the patient electronic healthcare record but the patient will not be billed for testing.
- 6 translates to To notify MD/RN
- 7 translates to To send lab glucose
- 8 translates to Feed and Repeat
- 16. Remove the test strip and dispose in regular trash.
- 17. Press the On/Off button to turn the meter off, or press 1-for Next Patient or press 2-for Patient History

- **18.** Upload/download/dock the meter (See Appendix C: Data Transfer Procedure). Manually document the patient's blood glucose in the EHR, as appropriate.
- 19. Meters should be uploaded/downloaded/docked as soon as possible after testing to ensure an accurate and up-to-date electronic healthcare record.

III. Result Considerations:

A reading of <20 or >500 mg/dl falls outside the Abbott Precision Xceed Pro meter's reportable range. These results must be called to the Physician, NP, or PA and verified through laboratory testing. The RN, after obtaining a physician order, must verify the results by obtaining a glucose laboratory specimen. The RN is responsible for obtaining and acting on the results of the follow-up laboratory specimen.

- A. When the result is greater than 500 mg/dL, and proper procedures are followed, the meter will display >500.
- **B.** When the result is less than 20 mg/dL, and proper procedures were followed, the meter will display <20.
- C. NOTE: When the result obtained is inconsistent with patient symptoms and you feel there has been an error in the testing procedure, mark the result with Comment Code "0" ("Procedure Error") before performing a second test.
 - 1. Results marked with Comment Code "0" will Not post to the patient's electronic record.
 - 2. For example, a test result of <20 mg/dl on an alert patient should be marked with Comment Code "0" and IMMEDIATE repeat testing on a freshly drawn sample Must occur.
- D. NOTE: When the result obtained is inconsistent with patient symptoms and you feel there has been no error in the testing procedure, mark the result with Comment Code "5" (Recheck/confirm) before performing a second test.
 - 1. Results marked with Comment Code "5" will post to the patient's electronic record.

Appendix B:

Finger Puncture Procedure

A. EQUIPMENT

- 1. Gauze pad (2 X 2)
- 2. Alcohol pad
- 3. Sterile Lancet—WFBMC-approved Sterile auto-disabling single-use self-retracting Lancet
- 4. Biohazard sharps container

B. PROCEDURE

- 1. Choose a finger that is not cyanotic, cold, or swollen. If possible the puncture should be at the tip of the fourth or ring finger of the non-dominant hand.
- 2. Gently massage the finger five or six times from base to tip to aid blood flow.
- 3. With an alcohol pad, clean the ball of the finger. Allow to air dry.
- 4. Remove the cover from the lancet without touching the tip.
- 5. Wearing gloves hold the patient's finger firmly with one hand and make a swift, deep puncture with the lancet, Halfway between the center of the ball of the finger and its side to produce a large round drop of blood.
- 6. Wipe the first drop of blood away with a clean dry gauze pad.
- 7. Gently massage the finger from base to tip to obtain the proper amount of blood for the test.
- 8. Once blood sample has been obtained; apply pressure to the puncture site using dry gauze.

 Gloves must be changed and hands cleansed between each patient when performing a finger puncture procedure.
- 9. Discard lancet in biohazard sharps container.

Appendix C:

Data Transfer Procedure

I. Purpose

When the glucose meter is placed in the docking station or connected to a data upload cable, data is transferred to the patient electronic healthcare record.

Results are then matched against ADT information in PWeb, and if a CSN match is found, results are posted via an interface to the patient electronic healthcare record.

It is imperative that glucose meters are frequently uploaded/downloaded/docked to ensure timely reporting of patient results to the electronic patient record.

Most areas will be required to upload/download/dock each 4 hours. The meter will lockout testing until the meter is uploaded/downloaded/docked.

II. Procedure

- A. First Turn OFF meter.
- B. Place the meter into the docking station or connect the meter to the data upload cable.
- **C.** Once the meter is placed in the docking station or connected to the data upload cable, the meter will automatically turn on and data transfer will begin.
- D. The following message will appear on the meter display, "Please Wait Data Uploading".
 - 1. Do not remove the meter while data is being transferred.
 - 2. If the meter is removed before data transmission is complete, some data may not be uploaded.
 - 3. Unsent data will be transmitted with the next upload/download/dock.
- E. When the data transfer is complete, the meter will show message, "Upload Successful, Turning Off", and then it will power off.
- F. If a problem occurs with the data upload, the meter will display the following message, "Last Upload Incomplete, Redock meter, Turning Off".
 - 1. The meter will then power off.
 - 2. The meter will continue to display this warning each time it is turned on, but the meter may be used by pressing, "1-Continue".
 - 3. This warning message will finally disappear after the next successful upload.
 - **4.** If the meter continues to indicate that transfer is not complete, check battery status. Replace AA batteries if battery level is low, then repeat meter docking or re-connecting meter to direct serial cable.
 - 5. If a meter continues to indicate that transfer is not complete, notify the HELP Desk at ext. 64357.

Appendix D

Emergency/Generic Patient Identifier and ID Resolution for Testing Performed on Non-Registered Patients:

I. Procedure:

- A. Test sites are issued an approved generic/emergency patient identifier barcode.
- **B.** This emergency ID barcode should only be used when the patient has not been registered in the WFBMC system at the time of POC glucose testing. Meaning, no CSN is available to enter as patient ID into the glucose meter at the time of testing.
- C. Once the patient has been registered in the WFBMC system, the person who performed testing must complete the "POC Glucometer Patient Identification Resolution" Form. The form must be completed and submitted to the appropriate individual(s), within the shift that the emergency entry is made.
- **D.** This form is found in the NURSING FORMS LIBRARY under NURSING DEPARMENT on the INTRANET (http://intranet.wakehealth.edu/Departments/Nursing/Forms/Nursing-Forms-Library.htm).
- **E.** The timely completion and return of this form is very important to ensure results are electronically posted to the patient record.
- F. The link to this form is: http://intranet.wakehealth.edu/Departments/Nursing/Forms/Nursing-Forms-Library.htm

Appendix E:

Abbott Precision Xceed Pro Meter Cleaning and Disinfecting Procedure

I. Procedure

- A. Disinfecting the Outside of the Meter for non-isolation patients and all isolation patients except Special Enteric
 - 1. Wipe the outside of the meter with a Caviwipe or other WFBMC-approved disinfectant, including the screen and keypad.
 - 2. Do not use Caviwipe on the camera barcode scanner of the meter because it will cause a film buildup.
 - 3. The meter surface should be wet for <u>2 minutes</u> to ensure proper disinfecting has occurred.
 - 4. Dry the meter thoroughly. Do not get moisture on the strip port.

B. Disinfecting the Outside of the Meter for Special Enteric Isolations

- 1. Wipe the outside of the meter with a Dispatch Bleach wipe, including the screen and keypad.
- 2. Do not use Dispatch Bleach wipe on the camera lens of the meter because it will cause a film buildup.
- 3. The meter surface should be wet for <u>5 minutes</u> to ensure proper disinfecting has occurred.
- 4. Dry the meter thoroughly. Do not get moisture on the strip port.

C. Disinfecting the Docking Cradle

- 1. Wipe the outside of the Docking Cradle with a Caviwipe once per day.
- 2. To avoid corrosion, do not get the pin connections on the docking cradle wet from the Caviwipe.

Appendix F:

Quality Control Procedure

I. Purpose

Quality Control (QC) checks are required to ensure correct performance of the glucose meter and test strips. QC should be tested each 24 hours of patient use. If QC checks are not within acceptable limits, the affected test strips and meters should be removed from patient testing, until the issue is resolved.

II. Procedure

- A. Press the On/Off button to turn on the meter.
- B. Select "2-Control Test" from the Main Menu.
- C. Scan or enter your glucose meter operator ID and press enter.
- D. Select the LO control solution.
- E. Ensure that the LO control solution has not expired.
 - 1. NOTE: when the LO control solution is first opened, the person opening the solution should write the 90 day expiration date on the bottle, not to exceed the manufacturers expiration date.
 - 2. Do not use expired control solution.
- E. Scan or Enter the LO level solution lot number, which is found on the bottle.
- F. Scan or Enter the Strip lot number on the back of the foil containing the individual test strip.
- **G.** Open the foil, remove the test strip, and insert strip in the glucose meter, which should be sitting on a flat surface during testing.
- H. Gently invert the LO control solution bottle 8 times to thoroughly mix the solution before use. Apply one drop of control solution to the tip of the test strip until a beep is heard. The meter takes 20 seconds to analyze the sample.
- I. Verify that the result for the LO Control is within the range shown on the display.
 - 1. If the result displays, "PASS", the QC value is within the acceptable range. Press "1-Next Level".
 - If the result displays, "FAIL", the QC value is outside the acceptable range.If the result is outside the range, the display will show a capital "X" followed by the result.
 - a. Enter in the appropriate QC Comment Code, press "2-Repeat Test", remix control, and repeat the procedure with a new test strip.
 - **b.** If the control fails a second time, refer to troubleshooting tips listed below for out-of-range control test results and comment with the appropriate QC comment code.
 - (1.) QC Comment Codes (should ONLY be used for flagging QC results)
 - (a.) Code 88 indicates: QC issue-repeated QC
 - (b.) Code 99 indicates: Opened fresh bottle of QC
 - c. Do Not use the affected test strips or meter until 2 levels of successful QC results are obtained.
- J. When the Low control PASSES, select the HI control solution.
- K. Ensure that the HI control solution has not expired.
 - 1. NOTE: when the HI control solution is first opened, the person opening the solution should write the 90 day expiration date on the bottle, not to exceed the manufacturer's expiration date.
 - 2. Do not use expired control solution.
- L. Scan or Enter the HI level solution lot number, which is found on the bottle.
- M. Scan or Enter the Strip lot number on the back of the foil containing the individual test strip.
- N. Open the foil, remove the test strip, and insert strip in the glucose meter, which should be sitting on a flat surface during testing.

- O. Gently invert the HI control solution bottle 8 times to thoroughly mix the solution before use. Apply one drop of control solution to the tip of the test strip until a beep is heard. The meter takes 20 seconds to analyze the sample.
- P. Verify that the result for the HI Control is within the range shown on the display.
 - 1. If the result displays, "PASS", the QC value is within the acceptable range. Press "1-Fxit".
 - 2. With both controls within range, the meter is now ready to be used for Patient Glucose Testing.
 - 3. If the result displays, "FAIL", the QC value is outside the acceptable range. If the result is outside the range, the display will show a capital "X" followed by the result.
 - a. Enter in the appropriate QC Comment Code, press "2-Repeat Test", remix control, and repeat the procedure with a new test strip.
 - b. If the control fails a second time, refer to troubleshooting tips listed below for out-of-range control test results and comment with the appropriate QC comment code
 - c. Do Not use the affected test strips or meter until 2 levels of successful QC results are obtained.
- Q. Remove the test strip and properly dispose of it.
- R. If either level of QC is not within acceptable limits after following the troubleshooting tips, return the meter to Clinical Engineering and obtain a replacement.
 - 1. NOTE: If the meter fails quality control checks, the system is not functioning properly. The meter and affected test strips should be removed from patient use, labeled "Failed QC," disinfected, and given to the Unit Manager/Charge Nurse/designee to be returned to Clinical Engineering.
- S. Once another meter has been obtained, successful QC results must be obtained on the test strips prior to proceeding with patient testing.

Troubleshooting Out-of-Range Control Test Results

Repeat the test for that control solution and make sure that the operator meets the conditions in this checklist:

- Eliminate any air bubbles in the control bottle's tip.
- Wipe the control solution nozzle with a clean gauze or tissue before and after each test. Liquid left on the tip from previous tests may have a Glucose concentration higher than expected.
- Always scan the test strip you sample to Calibrate the monitor properly. Do not scan one strip and open and run another.
- Scan or enter the correct 5-digit lot number for the control solutions and ensure you scan the control you sample and do not reverse them.
- Confirm that control solutions and test strips have been stored within the ranges specified on their respective cartons and package inserts.
- Check that the temperature conditions in the room where the tests are being performed are within the acceptable operating range as specified in the test strip package insert.
- Check that the bottles of control solutions have not been open for more than 90 days.
- Use a new test strip for each test.
- Use only Precision Xceed Pro Test Strips.
- Use only MediSense, Precision or Optium Control Solutions.
- Confirm that the control solution applied and tested (low or high) matches the level requested on the display. If test results "FAIL" and are out-of-range despite meeting the above criteria, please repeat the test using a new box of control solutions and/or test strips.

If the results are still out-of-range, contact Clinical Engineering for assistance.

Appendix H:

Procedure to Unlock Glucose Meter in the Event of Network Downtime or Power Failure

I. Purpose

In the event of a network or power failure and the ability to download the glucose meter(s) is lost and the meter is programmed with download lockout, a procedure is established to 'unlock' the glucose meter to allow additional patient testing.

Manual entry of the glucose result into the electronic healthcare record or authorized paper record should occur to allow timely viewing of the result by clinical providers.

II. Procedure

- A. Download/Upload/Dock (DUD) the meter 3 times.
- B. Let the meter go thru the complete DUD cycle 3 times.
- C. After each attempt, the meter will display, 'Last upload incomplete, redock meter'
- D. After the 3rd attempt, the meter will unlock and allow additional patient testing.
- E. Once power and/or network connectivity is reestablished, the meter can be re-docked and results should flow to the patient record, provided the correct patient CSN was used for testing.

Appendix I:

Resolution of Patient Result Errors in P-Web

I. Purpose:

Each test site shall identify an individual or group of individuals that will be responsible for day-to-day resolution of glucose results that do not post from p-Web into the electronic healthcare record.

Each test site is responsible for resolution of sample identification errors created in their department, which can include but may not be limited to:

- A. Use of an incorrect CSN
- B. Using a CSN that has not had the visit arrived
- C. Using a CSN for a discharged visit
- D. Sample misidentification. Testing performed on wrong patient.
- E. Use of generic/emergency patient identifier

II. Procedure:

- A. Log into P-Web via the web based application.
- B. Review result exceptions, via p-Web dashboard
- C. Review exception and resolve as needed

Appendix J:

True ID Procedure

I. Purpose

Abbott's True ID Technology improves the accuracy of patient identification and helps to prevent patient identification errors, by using two patient identifiers. When the Abbott Precision Xceed Pro Blood Glucose Meter is uploaded/downloaded/docked, patient Admission, Discharge, and Transfer (ADT) information is automatically downloaded into the meter. The meter should be uploaded/downloaded/docked frequently to ensure the optimal benefit of True ID Technology.

- A. When possible, before using the glucose meter for patient testing, complete upload/download/docking of the meter.
- B. If the meter is currently docked or connected to the data upload cable, reseat/reconnect the meter to download the latest ADT information into the meter before using it for patient testing.
- C. On the glucose meter, scan or enter your glucose meter operator ID number at the Meter's Operator Prompt.
- D. Scan the patient's Armband or manually enter the patient's 11 digit CSN number.
- E. True ID Technology will display the Patient's Name, DOB, and Sex on the glucose meter screen.
- F. Ask the patient to verbally confirm their name and date of birth.
- G. Compare the patient response to the glucose meter's display.
- H. If the glucose meter screen and the patient response match, press 'Confirm' on the glucose meter display.
- I. In the circumstances where the patient is unable to respond, verbally confirm correct patient ID with a family member or by referencing the armband that is ON the patient.
- J. In some cases, ADT information may not yet exist in the glucose meter.
 - 1. In these cases, True ID Technology will not be available on the glucose meter.
 - 2. The True ID screen can be bypassed by pressing 'Continue'
- K. Proceed with performance of patient testing.
- L. Upload/download/dock the meter after completing patient testing.

M. Notes for Optimal Performance of True ID Technology

All glucose meters must be uploaded/downloaded/docked on a frequent basis, preferably after each patient test.

1. <u>Inpatient care areas</u> are expected to download after obtaining patient results and will be required to download a minimum of every 4 hours. The meter will not allow testing if it is not uploaded/downloaded/docked each 4 hours. Once the meter is docked and downloaded, testing functionality will resume.

Appendix Z Troubleshooting

When there are issues with glucose meters, contact Clinical Engineering for assistance. Below are troubleshooting tips.

Troubleshooting

Troubleshooting Patient Test Results

This section describes conditions that can cause erroneous patient test results. Refer to the test strip package insert for specifications and detailed instructions for use.

Reasons Glucose Results May Be Higher Than Expected:

- · Hematocrit is lower than the acceptable limit for the test strips, as indicated on test strip package insert.
- Serum or plasma samples were used instead of whole blood.
- Venous blood tested in arterial/capillary mode when using Precision PCx Plus Test Strips.

Reasons Glucose Results May Be Lower Than Expected:

- Hematocrit is higher than the acceptable limit for the test strips, as indicated on test strip package insert.
- Hyperglycemic-hyperosmolar state (with or without ketosis).
- · Severe dehydration, hypotension or shock.
- · Water or alcohol remaining on the puncture site.
- Venous or arterial whole blood sample not tested within 30 minutes after collection.

If test results appear higher or lower than expected for reasons not described above, please repeat the test using a new test strip. If the results still appear higher or lower than expected, contact your local Abbott Diabetes Care office or distributor.

Troubleshooting Out-of-Range Control Test Results

Repeat the test for that control solution and make sure that the operator meets the conditions in this checklist:

- Eliminate any air bubbles in the control bottle's tip.
- Wipe the control solution nozzle with a clean gauze or tissue before and after each test.
 Liquid left on the tip from previous tests may have a Glucose or β-ketone concentration higher than expected.
- · Calibrate the monitor using the barcode for the test strip used.
- Scan or enter the correct 5-digit lot number for the control solutions.
- Confirm that control solutions and test strips have been stored within the ranges specified on their respective cartons and package inserts.
- Check that the temperature conditions in the room where the tests are being performed are within
 the acceptable operating range as specified in the test strip package insert.
- Check that the bottles of control solutions have not been open for more than 90 days.
- Use a new test strip for each test.
- · Use only Precision Xceed Pro Test Strips.
- Use only MediSense, Precision or Optium Control Solutions.
- Confirm that the control solution tested (low or high) matches the level requested on the display.

If test results are out-of-range despite meeting the above criteria, please repeat the test using a new box of control solutions and/or test strips. If the results are still out-of-range, contact your local Abbott Diabetes Care office 1-877-529-7185 for technical assistance and regulatory reporting.

Troubleshooting Out-of-Range Linearity Test Results

Repeat the test for that linearity level and make sure that the operator meets the conditions in this checklist:

- Use only the RNA Medical® brand Calibration Verification Control (CVC) kit that is compatible
 with the type of test strip being used. Please refer to the package insert in the CVC kit for
 compatible test strip types and detailed instructions for use.
- · Eliminate any air bubbles in the CVC bottle's tip.
- · Calibrate the monitor using the barcode for the test strip used.
- Confirm that CVC solutions and test strips have been stored within the ranges specified on their respective cartons and package inserts.
- Check that the temperature conditions in the room where the tests are being performed are within
 the acceptable operating ranges as specified in the respective test strip and CVC kit package
 inserts.
- · Check CVC bottle for open bottle expiry date.
- Use a new test strip for each test.
- Use only Precision Xceed Pro Test Strips.
- Confirm that the CVC solution tested (level 1 5) matches the level requested on the display.

If test results are out-of-range despite meeting the above criteria, please repeat the test using a new CVC kit and/or test strips. If the results are still out-of-range, contact your local Abbott Diabetes Care office or distributor.

Error Messages

In this section, you will find information relating to error messages that appear on the display when the Precision Xceed Pro Monitor detects errors.

For each corresponding message, an explanation is given and appropriate responses are described. In many situations, it may be possible to proceed with some of the functions, at least temporarily, before attending to the problem. (For example, when the batteries are too low to permit testing, it may be possible to review data for a short time.)

If any problem persists, record the error message displayed, which may include a 4-digit error code, and contact your local Abbott Diabetes Care office or distributor. 1-877-529-7185 for technical assistance and regulatory reporting.

When You Turn on the Monitor, or During Use:

The monitor has little or no power. installation.

Verify proper battery

If the problem persists, install new batteries.

See Chapter 11, Maintenance, for more information.



The display is blank.

Battery power is getting low. Testing will be available for a limited time.

Install new batteries.

See Chapter 11, Maintenance, for more information.

Press 1 to turn monitor off.

Occurs when any test is selected and the temperature is outside the monitor operating temperature range.

Press 1 to Exit. Turn monitor off. Allow the monitor to return to room temperature.



When You Turn on the Monitor, or During Use:



The monitor is shipped from the factory without configuration. This screen will appear the first time you turn on the monitor after receiving it.

Use PrecisionWeb or other Abbott- supplied software to configure the device to your specific institution's requirement prior to using the device.

An error has occurred during last data transfer. This screen will appear when you turn on the monitor.

Place the monitor into the docking station to complete the upload. Once the monitor has successfully been docked, the warning will disappear.

Or,

Press 1 to Continue testing.

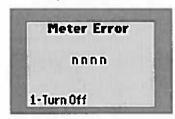


The monitor may have a problem that prevents it from operating properly. One of several 4-digit error codes may be displayed. These codes provide Abbott additional information about the problem.

- 1. Turn off the monitor. Turn it on and repeat the function.
- 2. If the problem persists, place the monitor in the docking station to update the configuration files.



3. If the problem still persists, record the 4-digit error code and contact Abbott Technical Support.



The monitor has detected a problem with the barcode scanner that would prevent the scanner from operating. This is a temporary error and can be corrected by re-booting the monitor.

- 1. Turn off the monitor. Wait at least 5 seconds for the system to reset. Turn on the monitor.
- 2. If the problem persists, repeat step 1 confirming that the monitor has remained off for at least 5 seconds.



3. If the problem still persists, record the 4-digit error code and contact Abbott Technical Support.

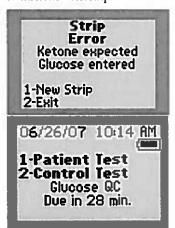
The test strip was inserted at the wrong time. The monitor will beep if functions are attempted before the strip is removed or if the test strip is left in when the test calls for the test strip to be removed.

Remove the test strip from the test strip port.

When You Turn on the Monitor, or During Use:

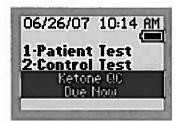
The strip type inserted does not match the type scanned.

- 1. Press 1.
- 2. Remove test strip.
- 3. Insert new test strip.



If glucose QC is due soon, the message "Glucose QC Due In xx min." will display on the main screen. The xx is the countdown to expiration. If glucose QC is due now, the message "Glucose QC Due Now" will display on the main screen.

- 1. If "Glucose QC Due in xx min." is displayed, no action is required. Glucose testing can proceed.
- 2. If "Glucose QC Due Now" is displayed, then Glucose QC testing per your facility's procedures may be required before proceeding with a glucose test.



3. Contact your system administrator if the messages continue to display after running the required QC tests.

If ketone QC is due soon, the message "Ketone QC Due in xx min." will display on the main screen. The xx is the countdown to expiration. If ketone QC is due now, the message "Ketone QC Due Now" will display on the main screen.

- 1. If "Ketone QC Due in xx min." is displayed, no action is required. Ketone testing can proceed.
- If "Ketone QC Due Now" is displayed, then Ketone QC testing per your facility's procedures may be required before proceeding with a ketone test.



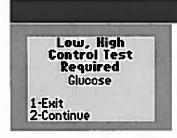
3. Contact your system administrator if the messages continue to display after running the required QC tests.

If the monitor requires an upload to the data management system, "Upload Due Now" will display on the main screen.

- Place the monitor in the Abbott Docking Station and wait for the monitor to automatically turn off with the message "Upload Successful, Turning Off".
- 2. Contact your system administrator if the message continues to display after docking the monitor.

Note: Check the Precision Xceed Pro display for proper performance before every test. If at any time the display screen becomes difficult to read, discontinue use of monitor and call your local Abbott Diabetes Care office or distributor.

When a Test is Selected:



The Glucose QC Interval Controls Expired option is set to Warn or Lockout and one or more control tests is past due.



(The menu item 2-Continue appears only if this option is set to Warn. If the option is set to Lockout, each control test shown on the screen must be performed before the patient tests start.)

Perform the remaining glucose control tests indicated in the message.

The Upload Interval option is set to Warn or Lockout, and the specified interval has been exceeded.



(The menu item 2-Continue appears only if this option is set to Warn. If the option is set to Lockout, data must be uploaded before testing starts.)

1. Place the monitor in the docking station to upload the data.

Or,

Press 2 to Continue testing.

2. If the problem persists, contact the system administrator.

The Ketone QC Interval Controls Expired option is set to Warn or Lockout and one or more control tests is past due.

(The menu item 2-Continue appears only if this option is set to Warn. If the option is set to Lockout, each control test shown on the screen must be performed before the patient tests start.)

The system cannot confirm the Patient ID.

Perform the remaining ketone control tests indicated in the message.

Press1to ReEnter the Patient ID. Or,

Press 2 to Continue testing.



The scanned Patient ID is similar in format to the test strip barcode.

- 1. Re-enter the Patient ID using the barcode scanner or keypad.
- 2. If the problem persists, contact the system administrator.





The barcode just scanned was not accepted. Possible reasons are:

- The red scanner beam did not pass across all the bars of the code.
- The barcode was damaged or poorly printed.
- The barcode was not of the type specified for this ID or lot number.
- 1. Rescan the barcode or manually enter the ID or lot number.
- 2. Notify the system administrator. The problem may be the printing of the barcode or the setup.



The barcode just scanned is from a foil packet of test strips that has expired.

- 1. Discard the expired test strips.
- 2. Repeat the scan with a new, unexpired foil packet of test strips.



The ID or lot number just scanned or entered is too long or too short, according to format defined during the setup of this monitor.

- 1. Verify and re-enter the ID or lot number using the barcode scanner or keypad.
- 2. If the problem persists, notify the system administrator.

The ID or lot number just scanned or entered is not on the list of acceptable IDs or lot numbers defined for this monitor. (The menu item 2 – Continue appears only if this option is set to Warn.)

1. Press 1 to ReEnter the ID or lot number using the barcode scanner or keypad.

Or,

Press 2 to Continue testing.

2. If the problem persists, notify the system administrator.



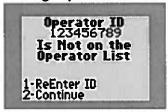
The strip inserted is a Glucose strip, while the monitor was expecting a Ketone strip (or vice versa).

Press 1 to replace with the expected test strip.

Or.

Press 2 to Exit.

During Any Test:



The Operator ID just entered is not on the list of acceptable Operator IDs defined for this monitor. (The menu item 2-Continue appears only if this option is set to Warn.)

1. Press 1 to ReEnter the ID using the barcode scanner or keypad.

Or.

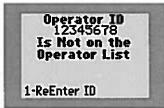
Press 2 to Continue.

2. If the problem persists, notify the system administrator.

The Operator ID entered is not on the list of acceptable Operator IDs defined for this monitor.

1. Press1 to ReEnter the Operator ID.

2. If the problem persists, contact the system administrator for further information on operator certification.



The Operator I Dentered has expired. (The menu items 1 - ReEnter ID and

- 2 Continue appear only if this option isset to warn.)
- Press 1 to ReEnter the ID using the barcode scanner or keypad.
 Or.

Press 2 to Continue testing.

2. If the problem persists, notify the system administrator.



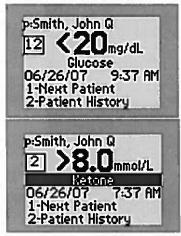
The Operator ID is due to expire. At this time, testing is still allowed.

- 1. Press 1 to Continue with testing.
- 2. Contact your manager or the system administrator for further information about operator certification.

During Any Test:

The test result is below the measuring limit of the system.

- 1. Repeat the test with a new test strip.
- 2. If the result persists, follow your institution's policy.



1.1mmol/L

The test result is above the measuring limit of the system.

- 1. Repeat the test with a new test strip.
- 2. If the result persists, follow your institution's policy.

The test strip or the test strip port is wet, defective, contaminated, or the wrong test strip was inserted.

- Remove the old test strip.
- Press 1 to continue testing with a New Strip. Or,

Press 2 to Exit to the Test Menu.



There may be a problem with the test strip. One of several 4-digit error codes may be displayed. These codes provide Abbott personnel additional

information about the problem. Errors include:

 Press 1 to repeat the test with a New Strip or 2 to Exit. 2. If the error occurs again, record the 4-digit error code and contact Abbott Technical Support.



4327 - The strip was removed during testing.

Repeat the test with a new test strip.

4330 - Blood glucose may be too high to be read by the system or there may be a problem with the test strip.

Repeat the test with a new test strip. If the error occurs again, confirm the result by performing a laboratory reference test.



When a Control Test is Selected:

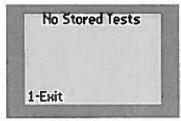
A control solution lot number has been entered for a different level of control test from the one that the monitor expected to run (in the usual low-to- high sequence). The user may choose to enter a different lot number (usually, for the expected level) or to run the level of test that matches the lot number entered.

Press 1 to ReEnter the lot. Or,

Press 2 to run the level of test that matches the lot number already entered.

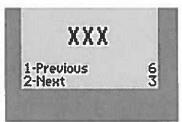


When a Linearity Test is Selected:



When Data Review is Selected:

A new linearity kit lot number has been entered, different from the linearity panel currently stored in the monitor. Only one panel of data is stored. The kit lot number may have been entered incorrectly, or the user may choose to replace the earlier data.



There are no stored test results for the type of data requested.

Press 1 to ReEnter a different linearity kit lot number (typically, the number of the previous kit).

Or.

Press 2 to proceed and Replace Panel, using the new kit lot number. The existing linearity data will be replaced by data from the new lot.

Press 1 to Exit and return to the Data Review Menu.

The monitor is not able to recall a previous test result. This test result may not have been uploaded from the monitor.

Press 1 to view the Previous result. Or,

Press 2 to view the Next result.

Technical Support Instructions

Abbott Technical Support contact information is listed on the following two pages. When you call, an Abbott representative will address the problem and/or instruct you to return the monitor, test strips, control solution and/or linearity kit. Do not return the Precision Xceed Pro Monitor or any part of the system for repair until you receive authorization from an Abbott representative.

To help ensure efficient resolution of the problem, complete the following steps before calling Abbott.

- 1. Review the troubleshooting information in this section.
- 2. Obtain the most recent control results and record them below.

Control Solution	Low (If used)	Mid (If used)	High (If used)
Results			
Expected Range			
Test Strip Lot Number			
Control Solution Lot Number			
Date			

3. Obtain the most recent linearity results and record them below.

Linearity Kit	1	2	3	4	5
Results	552				
Expected Range					
Test Strip Lot Number					
Linearity Solution Lot Number					
Date					

- 4. Enter the date the problem occurred:
- 5. Describe the problem and the conditions when it occurred:
- 6. Have the Precision Xceed Pro Monitor and testing materials available when calling.

Returning an Instrument

Regulations in various jurisdictions, including the United States per 29 C.F.R. 1910.1030, require that medical instruments be decontaminated prior to shipping to minimize the risk of exposing those persons involved in handling or transporting this equipment. You are responsible for complying with these regulations.

Prior to returning an instrument to Abbott you must perform the following steps:

- 1. Remove all potentially contaminated accessories such as lancets, unused test strips or control solution bottles.
- 2. Wipe the surface of the instrument with a detergent solution to remove any soiling.
- 3. Wipe the unit with a tuberculocidal disinfectant or isopropyl alcohol.
- 4. Package and label the instrument(s) as required by the regulations.

To dispose of a monitor, please contact your local Abbott Diabetes Care office or distributor.

Contacting Abbott for Service

Abbott is committed to helping you resolve any problems with the Precision Xceed Pro System. For technical assistance, please contact your local office or distributor listed below.

USA

Abbott Diabetes Care Alameda, CA USA Tel: +1-877-529-7185