44-1202 Glucometer, Abbott Precision Xceed Pro

Copy of version 2.1 (approved and current)

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Organization 92 MDSS/SGSL

Comments for version 2.0 (last major revision)

Team,

I have SCOURED the CAP POC checklists and have made some major revisions to the OI for Ambulance Crew. This is not the management of the program, that OI is 44-1201.

Please give me your input so I can fix it promptly or approve.

-TSgt Tisdale

Comments for version 2.1 (this revision)
Title of section 13 was corrected to Troubleshooting/Precautions.

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	9/11/2017	2.0	Brent Hjermstad	
Periodic review	Designated Reviewer	8/10/2017	1.0	Ryan Comes	
Approval	Lab Director	9/16/2014	1.0	DR. HJERMSTAD	Recorded when document uploaded to MediaLab
Periodic review	Designated Reviewer	9/16/2014	1.0	DR. HJERMSTAD	Recorded when document uploaded to MediaLab

Approvals and periodic reviews that occured before this document was added to the MediaLab Document Control system may not be listed.

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
2.1	Approved and Current	Minor revision	9/28/2017	9/28/2017	Indefinite
2.0	Retired	Major revision	8/10/2017	9/11/2017	9/28/2017
1.0	Retired	First version in Document Control	12/13/2016	10/15/2013	9/11/2017

DEPARTMENT OF THE AIR FORCE
92D MEDICAL GROUP (AMC)
Fairchild AFB, WA 99011-8701

SGSL OPERATING INSTRUCTION 44-1202

8 Aug 2017

Point of Care Testing

GLUCOMETER, ABBOTT PRECISION XCEED PRO

COMPLIANCE WITH THIS PUBLICATION IS MANDATORY

SUMMARY OF CHANGES: Changed formatting. Added compliance items from the current College of American Pathologists checklists. Updated terms and divided the operating instruction up by chapters to align more closely with AFI 33-360, Publications and Forms Management. Added a table of contents. Updated operating instruction (OI) review schedule and validation process. Added tables and updated reference ranges per the Advanced Life Support/Basic Life Support (ALS/BLS Protocol. This operating instruction applies to all test sites registered under the Laboratory's clinical Laboratory Improvement Program (CLIP) certificate.

Supersedes: SGSL OI 44-1202, 5 Oct 13
OPR: 92 MDSS/SGSL

Certified by: Lt Comes
Distribution: Point Of Care Testing
Pages: 16

1. PURPOSE: This instruction implements Air Force Instruction (AFI) 44-102, *Patient Care and Management of Clinical Services,* and prescribes the procedures for Point of Care Testing. Any changes to this operating instruction must be approved by the Laboratory Medical Director. This instruction applies to test sites registered under the 92 MDSS Laboratory's Clinical Laboratory Improvement Program (CLIP) certificate.

2. SCOPE: CLIA Waived blood glucose testing by glucose monitoring devices cleared by the FDA is the only test performed as part of the Laboratory's POCT program. This is accomplished with the use of the *Precision Xceed Pro Point of Care System for Blood Glucose Monitoring*.

3. PRINCIPLE: The Precision Xceed Pro System allows rapid measurement of blood glucose by using an electrochemical detection technique.

3.1. Precision PCx Plus Blood Glucose Test Strips offer the latest advancements in biosensor technology. The test strips work by first inserting the contact bars into the monitor. Then the sample is applied to the target area, covering both the working electrode and the reference electrode. This area is coated with enzymes that react in the presence of glucose to make a small electric current. This current is passed through the strip to the contact bars and the monitor, which calculates a glucose result.

3.2. Precision PCx Plus Glucose Test Strips use proprietary glucose-specific chemistry that includes the glucose dehydrogenase enzyme, NAD cofactor and PQ mediator (GDH-NAD/PQ). This chemistry is used for testing glucose because it is not affected by maltose, icodextrin, and other common substances at normal therapeutic levels. It also ensures minimal measurement bias from oxygen, hematocrit and other physiological variables.

3.3. Precision PCx Plus Blood Glucose Test Strips also have exclusive blood application features to ensure reliable sampling. First, the target area may be filled by applying a drop of sample to the top of the test strip. Second, the fill trigger electrode ensures that the test will only start once sufficient blood has been applied. Together, these features minimize the possibility of errant results due to sample application technique.

4. INTENDED USE: The Precision Xceed Pro is intended for *in vitro* (outside the body) diagnostic use for the quantitative measurement of glucose in fresh capillary whole blood. It is intended for home (lay user) or professional use. It is not for use in diagnosing or screening of diabetes mellitus, but is to be used as an aid by healthcare professionals for the quantitative measurement of glucose.

4.1. The intended users are the 92 Medical Group Ambulance Crew. Use by individuals outside of the Ambulance Crew will be approved on a case by case basis from the Laboratory OIC.

5. REAGENTS/SUPPLIES:

5.1. Abbott Precision Xceed Pro glucometer. Storage temperature: -4 °F to 122 °F (-20 °C to 50 °C); operating temperature: 59 °F to 104 °F (15 °C to 40 °C).

5.2. Precision PCx Plus Blood Glucose Test Strips: DMLSS part# 70932-01. Storage temperature: -4 °F to 122 °F (-20 °C to 50 °C); operating temperature: 59 °F to 104 °F (15 °C to 40 °C).

5.3. Medisense Glucose Control Solution: DMLSS part# 1128365405505.

5.4. Glucose and Ketone Calibration Assessment Kit from Abbott, DMLSS# 70906-01. Calibration can also be accomplished using CAP linearity samples. Calibration verification will be performed by Laboratory.

5.5. 70% Isopropyl alcohol wipes/swabs.

5.6. Non-bleach Sani-wipes, approved by the facility infection control team.

5.7. Bandages.

5.8. Lancets.

5.9. Two AA alkaline batteries.

5.10. Replacement port protector provided by Abbott for free. Contact the Laboratory POCC to request replacements.

6. SAFETY/SPECIAL PRECAUTIONS: The safety of patients and health are personnel is a number one priority when performing tests.

6.1. Do not use during intravenous infusion of high-dose ascorbic acid or during xylose absorption testing.

6.2. Equipment & Electrical safety:

6.2.1. Misuse of electrical equipment can cause electrocution, burns, fire and other HAZARDS.

6.2.2. Basic safety precautions should always be taken, including those listed below.

6.2.3. Close supervision is necessary when equipment is used on or near children, individuals with physical disabilities, or individuals with mental illness or psychiatric disability.

6.2.4. Do not place the equipment in liquid, nor put it where it could fall into liquid.

6.2.5. Use the equipment only for the purpose described in the instructions for use.

6.2.6. Do not use accessories which are not supplied or recommended by the manufacturer.

6.2.7. Do not use the equipment if it is not working properly, or if it has suffered any damage. Examples include damage caused by dropping the instrument, dropping the instrument into liquid, or splashing liquid onto it.

6.2.8. Do not let the equipment come into contact with surfaces which are too hot to touch.

6.2.9. Do not place anything on top of the equipment.

6.2.10. Unless specifically instructed to do so by the instructions for use, do not drop or put anything into any opening in the equipment.

6.3. Test strips:

6.3.1. Do not use test strips after their expiration date.

6.3.2. Do not use test strips that are wet, bent, scratched or damaged. Use the test strip immediately after opening its foil packet.

6.3.3. Do not scan one strip package barcode and use a strip from a different barcode package. This may cause incorrect assay results to be generated.

6.3.4. Continue applying blood to the white target area of the test strip until the test begins.

6.3.5. **If the test fails to start, sufficient blood sample may not have been applied to the test strip. Discard the current test strip and repeat with new strip.**

6.3.6. Do not touch the test strip after the blood is applied.

6.3.7. Use each test strip only once.

7. QUALITY CONTROL: Two levels of quality control (QC) will be run every 24 hours if meter is in use for patient testing. If QC fails or is not run, the meter will auto-lock until acceptable QC has been performed.

7.1. QC validates instrument performance and proper operator techniques.

7.2. QC should be re-run if there is a questionable blood glucose result.

7.3. QC should be repeated if the strips have been exposed to temperatures outside the manufacturer's storage requirements.

7.4. If at any time the monitor displays a message not indicated in this OI, please refer to section 10, Troubleshooting, in the Precision Xceed Pro operator's manual.

7.5. Each bottle of control solution is stable for 90 days after opening or until the expiration date printed on the label if not opened. When opening a new bottle of QC, write the open date, the corrected expiration date, and the technician's initials on the bottle.

7.6. With the cap on, mix the QC by gentle inversion to prevent the creation of bubbles several times to ensure thorough mixing before use.

7.7. When applying the QC to the test strip, perform a test drop to remove bubbles. Place the correct cap on the bottle and tighten after each use.

7.8. To prevent build-up of dried-on QC liquid and accumulation of bubbles, it is a good practice to use a clean lint free cloth or piece of gauze to wipe the nozzle before and after each use.

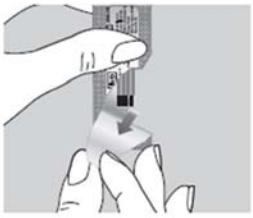
7.9. The following diagram will be followed for daily QC testing.

Control Test Procedure - Glucose

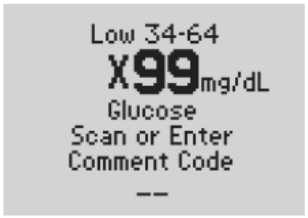
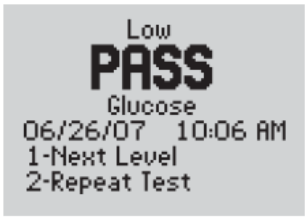
Use the following procedure to perform glucose control tests.

Note: *The following section illustrates some common settings. Depending on your institution's specific settings, some screens will display differently or not at all. If the monitor does not display the screens shown, please refer to Chapter 10, Troubleshooting.*

What You See on the Display	What You Do	Comments
	**1.** Press **On/Off** to turn on the monitor.	The Abbott logo screen will appear in black for a few seconds and then will appear in gray to ensure that the display is functioning properly. Next, the software version and then the **Test Mode** menu screens will appear.
	**2.** Press **2** to select **Control Test**.	The monitor starts in **Test Mode**. The Menu button will toggle the monitor to **Menu Mode.**
	**3.** Press **Scan** to scan the Operator ID barcode or manually enter the Operator ID via the keypad, then press **Enter**.	While the Operator ID may be up to 30 digits, not all digits will fit on the display. The monitor may also be set to truncate (ignore) leading, trailing, and/or selected digits of the barcode.
	**4.** Scan or manually enter the low control solution lot number via the keypad, then press **Enter**.	You can scan or manually enter the information from the control solution's barcode. For manual entry, key in the five numeric digits of the lot number printed on the control solution bottle. You do not need to enter the alpha character that appears at the end of the five-digit number. The **Strip Lot** screen will appear next.

What You See on the Display	What You Do	Comments
Unexpected Level Low expected High entered 1-ReEnter Lot 2-Continue	If the **Unexpected Level** screen appears, you may either: 1. Enter **1** to **ReEnter** the expected level. 2. Enter **2** to **Continue**.	The monitor is programmed to expect Low, Mid, and High Glucose controls in this order. A warning message will appear if the controls are used in a different order, however you may still proceed with the test.
Scan or Enter **Strip Lot**	**5.** Press **Scan** to scan the test strip barcode or manually enter the test strip lot number via the keypad, then press **Enter**.	Scanning the barcode identifies the strip type, calibrates the monitor, ensures the expiry date has not passed, records the strip lot used, and checks that the lot has been approved for use by your institution.
	Note: *Place monitor on a flat surface while running control tests.*	
	6. Open the foil test strip packet at the notch and tear down to remove the test strip.	With clean, dry hands, you may gently touch the test strip anywhere when removing it from the foil to insert it into the monitor.
		
Insert Strip	**7.** With the contact bars facing up, insert the test strip into the test strip port until it stops and **Strip Inserted** is displayed.	Prior to inserting the test strip, ensure that the port protector is installed and that it is clean and dry. Replace if necessary.
Apply Low Solution	**8.** Gently invert the required control solution bottle 3-4 times. Remove the cap of the control solution bottle and wipe the nozzle with a clean gauze or tissue. Apply a small drop of solution to the test strip target area, allowing the target area to fill completely. Wipe the nozzle of the control solution bottle before replacing the cap.	When sufficient sample has been applied, the monitor beeps, displays **Sample Accepted** and automatically starts the test. For a detailed description of the test strip target area, refer to the Test Strips section of Chapter 1.

Note: *Do not lift the monitor to view the display until after the test strip has been removed. Doing so may cause control solution to drip onto the port protector or into the strip port, damaging the monitor. If the port protector becomes wet, replace it with a new one.*

What You See on the Display	What You Do	Comments
	**9.** Wait for the monitor to analyze the sample and display the test result.	The monitor counts down then displays the test result. If an error is detected during the assay, the assay is terminated and no result is displayed. Once the assay begins, all key presses are ignored until the assay is completed.
 5.5 mmol/L	**10.** Note the test result and whether it falls within the acceptable range. If required, scan or manually enter the comment code, and press **Enter.** The monitor may be enabled to scan or enter a 1- to 2-digit comment code. If there is no prompt to enter a comment code, skip down to step 11.	Control test results can appear as numeric or PASS/FAIL, depending on how the test is set up. If numeric, an "X" will appear in front of a test result that is Out-of-Range.
	**11.** You may select one of the following: Press **1** – **Next Level**. Press **2** – **Repeat Test**. Press **Menu** to return to the **Menu Mode** menu. Press **On/Off** to turn off the monitor. Remove the test strip from the monitor and discard it when finished testing. Follow your facility's biohazard disposal policy.	If **1** is selected, the **Next Level** test will appear. Perform the next level control test by returning to Step 4. If **2** is selected, the **Scan or Enter Strip Lot** screen will appear. Return to step 5 to repeat the test.

Note: *Following a complete set of Glucose controls, 1-Next Level becomes 1-Exit.*

7.10. Upon receipt of new test strips or control material, parallel testing must be performed. Bring the new supplies to the Laboratory and the POCC will assist with this task and associated documentation.

7.11. Document performance of QC on maintenance log.

7.12. Any repeat QC or troubleshooting must be documented on the lab form 4.

8. SPECIMEN REQUIREMENTS & COLLECTION:

8.1. This section describes the requirements for testing and collection of the capillary blood sample. A small drop of whole blood from a capillary puncture is needed for testing.

8.2. Identifying the patient with at least two patient identifiers is the first step when providing care, treatment and services. Name and date of birth must be used at a minimum. This information may be verified using the patient's identification card.

8.3. Specimens tested immediately at the point of service (e.g., capillary glucose), require only patient verification, as there is no sample container.

8.4. Begin by performing applicable hand hygiene procedures. Hand washing if available or approved antimicrobial hand sanitizer.

8.5. Handle all specimens adhering to Standard Precautions and using appropriate Personal Protective Equipment (PPE). All specimens/materials should be handled as if they are capable of transmitting disease.

8.6. Gloves must be worn during testing events. Follow biohazard and bloodborne pathogen safety policies and procedures when performing tests involving blood samples. Gloves must be changed between patients.

8.7. The capillary blood specimen is obtained using only an auto-disabling single-use fingerstick device or lancet. The device is designed for use on one patient only and should never be reused. After the blade has retracted, it is no longer usable and should not be modified. After use it must be discarded into the nearest sharps container.

8.8. The puncture site for fingertips is the dorsal surface of the last segment of a finger proximal to the nail bed. Skin punctures should not be performed on the fingers of infants.

8.9. On adults, the puncture should be in the center of the last segment and not at the side or tip of the finger because the tissue is half as thick as in the center of the finger. The 5th finger (pinky) should not be punctured because the tissue is considerably thinner than the rest.

8.10. The skin puncture site should be warm and not swollen, as accumulated fluid (edema) in the tissue will contaminate the blood specimen. Warming can be accomplished with a warm, moist towel covering the site for 3 minutes or with the use of a heel warmer for no longer than 5 minutes.

8.11. Cleanse the site with 70% isopropyl alcohol. Allow the site to dry completely. Betadine should not be used to clean the skin puncture sites.

8.12. Remove the safety device from the lancet once the selected site has dried and you are ready to begin your capillary puncture.

8.13. Apply gentle pressure around the puncture site to hold the skin taut.

8.14. Place the lancet on the site and active the device. A spring loaded blade will puncture the skin and retract in one continuous motion.

8.15. Dispose of the lancet in the nearest sharps container.

8.16. Using a clean gauze, wipe away the first drop of blood. The next drop of blood is suitable for use with the glucometer test strips.

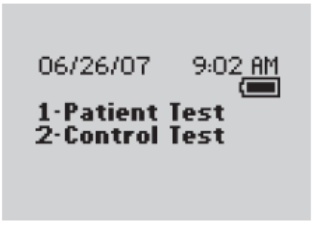
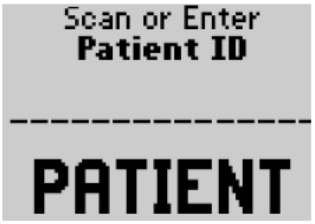
8.17. After completion of testing, place a gauze pad over the puncture site, apply pressure, and if able, elevate the area until bleeding has stopped. An adhesive bandage may be applied if desired.

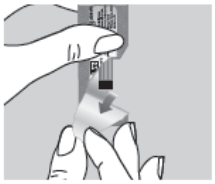
9. PATIENT TESTING: Use the following procedure to perform patient tests.

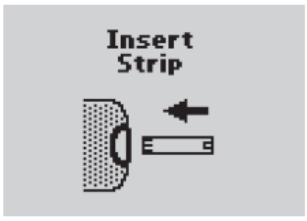
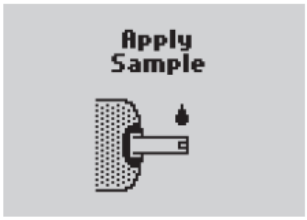
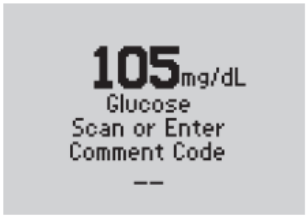
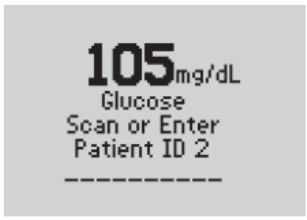
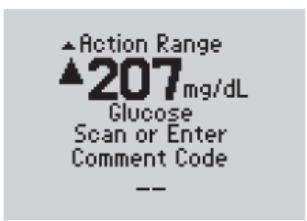
Patient Test Procedure - Glucose

Use the following procedure to perform a patient test using the Precision PCx Plus Blood Glucose Test Strip.

Note: *The following section illustrates some common settings. Depending on your institution's specific settings, some screens will display differently or not at all. If the monitor does not display the screens shown, please refer to Chapter 10, Troubleshooting.*

What You See on the Display	What You Do	Comments
	1. Press **On/Off** to turn on the monitor.	The Abbott logo screen will appear in black for a few seconds and then will appear in gray to ensure that the display is functioning properly. Next, the software version and then the **Test Mode** menu screens will appear.
	2. Press **1** to select **Patient Test**.	The monitor starts in **Test Mode**. The Menu button will toggle the monitor to **Menu Mode**.
	3. Press **Scan** to scan the Operator ID barcode or manually enter the Operator ID via the keypad, then press **Enter**.	While the Operator ID may be up to 30 digits, not all digits will fit on the display. The monitor may also be set to truncate (ignore) leading, trailing, and/or selected digits of the barcode.
	4. Press **Scan** to scan the Patient ID barcode or manually enter the Patient ID via the keypad (if enabled).	If you enter the ID manually, you may be required to enter it a second time to ensure it is correct. While the Patient ID may be up to 30 digits, not all digits will fit on the display. The monitor may also be set to truncate (ignore) selected digits of the barcode.
	5. Confirm the Patient ID (if prompted). You may see one of the following four screens: Re-enter the ID using the keypad.	

What You See on the Display	What You Do	Comments
Patient ID 02061935 **Smith,** **John Q** **01/23/63 M** 1-ReEnter ID 2-Confirm	Press **2** to **Confirm** the information and continue testing or **1** to **ReEnter** the ID.	
Patient ID 02061935 **Smith,** **John Q** **01/23/63 M** Confirm Year of Birth **--**	Enter the year of birth (e.g. 63) and press **Enter**.	Press **Clear** to re-enter the ID. If numbers have been entered, the Clear key will erase those first. Multiple presses of the Clear key may be required to return to the Patient ID entry screen in step 4.
Patient ID **Patient Data Not Found** 1-ReEnter ID 2-Continue	Press **2** to **Continue** testing or **1** to **ReEnter** the ID.	
Scan or Enter **Strip Lot** **----------** 	**6.** Press **Scan** to scan the test strip barcode or manually enter the test strip lot number via the keypad , then press **Enter**.	Scanning the barcode identifies the strip type, calibrates the monitor, ensures the expiry date has not passed, records the strip lot used, and checks that the lot has been approved for use by your institution.
Enter **Sample Type** 1-Arterial/Capillary 2-Venous	**7.** When using Precision PCx Plus strips, the Sample Type screen may appear. You can select one of the following: Press **1 - Arterial/Capillary** or Press **2 - Venous**	Use VENOUS MODE only for venous samples that have been in capped tubes and that have not been mixed with air. Use Arterial/Capillary mode for all other samples. If the sample type screen is not seen, continue with step 8.
	8. Open the foil test strip packet at the notch and tear down to remove the test strip. 	With clean, dry hands, you may gently touch the test strip anywhere when removing it from the foil to insert it into the monitor. 

What You See on the Display	What You Do	Comments
	**9.** With the contact bars facing up, insert the test strip into the test strip port until it stops and **Strip Inserted** is displayed.	Prior to inserting the test strip, ensure that the port protector is installed and that it is clean and dry. Replace if necessary.
	**10.** Apply a drop of blood from the patient's finger, transfer pipette or syringe to the target area of the test strip.	When sufficient sample has been applied, the monitor beeps, displays **Sample Accepted** and automatically starts the test. For a detailed description of the test strip target area, refer to the Test Strips section of Chapter 1.
	**11.** Wait for the monitor to analyze the sample and display the test result.	The monitor counts down then displays the test result. If an error is detected during the assay, the assay is terminated and no result is displayed. Once the assay begins, all key presses are ignored until the assay is completed.
 5.8 mmol/L	**12.** If required, scan or manually enter the comment code, and press **Enter**.	The monitor may be enabled to scan or enter a 1- to 2-digit comment code. If there is no prompt to enter a comment code, skip down to Step 13.
 5.8 mmol/L	If prompted, scan or manually enter the free text information and press **Enter**.	The monitor may be enabled to scan or enter the free text information. If there is no prompt to enter free text, skip down to step 13. Up to two free text fields may appear.
 11.5 mmol/L Above Action Range	For out-of-range results, refer to your institution's policy.	The **Action Range** screen will appear if the Patient Test Out-of-Range Comment Code is enabled and the following two conditions are met: **A.** The action range is enabled. **B.** The test result is out of the action range.

What You See on the Display	What You Do	Comments
▲Action Range ▲207 mg/dL Glucose Scan or Enter Comment Code -- 11.5 mmol/L Above Action Range	For out-of-range results, refer to your institution's policy.	The **Action Range** screen will appear if the Patient Test Out-of-Range Comment Code is enabled and the following two conditions are met: **A.** The action range is enabled. **B.** The test result is out of the action range.
▲Critical Range >400 mg/dL Glucose Scan or Enter Comment Code -- >22.2 mmol/L Above Critical Range	For out-of-range results, refer to your institution's policy.	Your institution may narrow the reportable range for results. This is called the **Critical Range**. The monitor will not report results outside of this range.
p:Smith, John Q 12 105 mg/dL Glucose 06/26/07 9:37 AM 1-Next Patient 2-Patient History 5.8 mmol/L	**13.** You can select one of the following options: Press **1 – Next Patient**. Press **2 – Patient History**. Press **Menu** to return to the **Menu Mode** menu. Press **On/Off** to turn off the monitor. Remove the test strip from the monitor and discard it when finished testing. Follow your facility's biohazard disposal policy.	The display shows: **Patient ID or Name** (**p:** prompt) **Comment Code** (Number in box) **Date and Time of test** **Test Type** (Glucose) If **1** is selected, the **Scan Patient ID** screen will appear. Return to step 4 to continue with testing on the next patient. If **2** is selected, the monitor will display the last test result for this patient as well as allow you to view previous results. Refer to the section entitled Data Review for Patient by Patient ID in Chapter 5 for further information.

⚠ IMPORTANT: *If the blood glucose result appears to be inconsistent (lower or higher than expected), there may be a problem with the test strip. Repeat the test using a new test strip. Results that are incorrect may have serious medical consequences. Consult the prescribing physician before making any changes to diabetes medication plans if:*

- *The blood glucose results are not consistent with the physical symptoms AND you have ruled out common errors in technique.*
- *The blood glucose result is less than 50 mg/dL (2.8 mmol/L) or greater than 300 mg/dL (16.7 mmol/L).*

10. INTERPRETATION & REPORTING RESULTS:

10.1. To ensure patient safety and prevent medical errors, health care workers should not make management decisions based on POC test results unless those results are entered into patient records.

10.2. POC test results may be uploaded into the electronic medical record after decision making.

10.3. If results are hand written, they must be legible.

10.4. Results of all testing must be documented appropriately. During EMS response, the documentation of glucose results is completed on AF Form 552.

10.5. Reference ranges are documented clearly for each patient result in the result box or near the result to clearly identify the range belongs to the test.

10.6. In addition to documentation on the AF Form 552, the result must be documented in the patient's permanent medical record.

10.7. The 552 must be initialed or signed to indicate the performing technician(s).

10.8. Interpretation of the results is based on the ALS/BLS EMS guidelines, current version.

10.9. The EMS team will treat each patient per their protocol along with the guidance of the Medical Officer of the Day (MOD).

10.10. The reference ranges are published on the ALS/BLS guidelines and are copied to the maintenance log/daily checklist for quick reference along with the critical result values, AMR, and contact numbers for the Laboratory during duty hours and after duty hours.

10.11. **Critical results must be repeated to confirm.** Upon confirmation, the MOD or an RN must be notified. Notification must be documented on the AF Form 552 with the date and time of notification, initials or signature of the technician performing the testing & notification, and that 'read back' was performed as required.

11. MAINTENANCE: The Precision Xceed Pro Monitor requires little routine maintenance. Maintenance will be performed as necessary. During testing, the sample remains outside the monitor, which significantly reduces the possibility of contamination.

11.1. Maintenance tasks for the glucometer include cleaning the exterior surface, replacing the port protector, and replacing the batteries.

11.2. CLEANING: The exterior surface of the monitor shall be cleaned after each patient for infection control purposes.

11.3. To clean the monitor, first turn it off. Using an approved Sani-Cloth or 70% alcohol wipe, clean the exterior of the unit being careful to not allow the cleaning solution to enter the monitor.

11.4. *Do not use bleach or hydrogen peroxide based cleaners as they may fade the monitor keypad.*

11.5. REPLACING THE PORT PROTECTOR: The port protector is designed to minimize the possibility of liquid entering the monitor through the strip port. Should blood or control

solution come in contact with the port protector, the monitor should be cleaned and the port protector replaced with a new, dry port protector. After cleaning the monitor, dry the area around the port protector thoroughly.

11.6. Lift the port protector from its left or right edge.

11.7. Pull gently away until the protector separates from the monitor.

11.8. Rest the flat bottom of the new port protector on the ledge of the test strip port.

11.9. Gently push both sides of the port protector until you hear the tabs snap into place. There should be no gaps between the port protector and the monitor around the edges.

11.10. REPLACING THE BATTERIES: The average alkaline battery life is approximately 60 days, based on an average of 9 tests per day and monitor being shut off within 2 minutes of it not being used (depending on barcode usage). Battery life will vary based upon actual use.

11.11. Turn the precision Xceed Pro Monitor off.

11.12. Turn the monitor over and remove the battery door.

11.13. Pull the blue tab to remove the batteries.

11.14. Discard the used batteries in compliance with our local facility guidelines.

11.15. Insert the new batteries on top of the strap, using the + and - symbols in the battery compartment to position the new batteries with the correct polarity. Align the battery compartment cover with the slots on the Precision Xceed Pro Monitor, then snap the cover into place.

12. PROCEDURAL LIMITATIONS:

12.1. The *Precision XceedPro* Test Strips are designed for use with fresh, capillary, whole blood samples. Fairchild AFB Laboratory has not validated the use of serum or plasma samples.

12.2. The Hematocrit range is 20 – 70%.

12.3. Test results may be affected by various levels of severe hydration, severely hypotensive, in shock, or in a hyperglycemic-hyperosmolar state (with or without ketosis). Similar observations have been reported in the literature for other blood glucose monitoring systems.

13. TROUBLESHOOTING/PRECAUTIONS:

13.1. The most common error is for the blood sample to be applied incorrectly.

13.2. If the test fails to start, sufficient blood sample may not have been applied to the test strip. Discard the current test strip and repeat with new strip.

13.3. Refer to manufacturer's manual for further troubleshooting procedures.

14. TRAINING/IMPLEMENTATION:

14.1. Training and competency for POC users will be no less than initially upon assignment to Ambulance Crew, again at 6 months, and continue annually afterwards. Additional training may occur if necessary as determined by the Medical Director, Laboratory supervision, or POCC.

14.2. Competency will be tracked on a local form developed by the Laboratory that complies with CAP training guidelines.

14.3. Training may also be available via in-services or through hands on demonstration when requested. All hands on training will be documented in the training folders upon completion.

14.4. All training will be reviewed and signed by the TSV or OIC.

15. REFERENCES:

15.1. College of American Pathologists Point-of-Care-Testing, checklist date 17 August 2016.

15.2. Clinical Laboratory Improvement Program (CLIP), DoDI 6440.02, 29 May 2014.

15.3. Clinical Laboratory Improvement Amendments (CLIA), 42 CFR 493 – Laboratory Requirements, 1 October, 2011.

15.4. National Patient Safety Goals, 2017 The Joint Commission.

This instruction has undergone supervisory reviews and is approved for implementation:

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1	MediaLab - Electronic
2	Laboratory POC Management Binder
3	Ambulance Crew Glucometer Binder

	Original Version Date [dd/mmm/yy]	Revision Date [dd/mmm/yy]	Description of Revisions
Revision History	05/OCT/13	08/AUG/17	Comprehensive rewrite. Now compliant with CAP checklist version 17/AUG/16, National Patient Safety Goals 2017, CLSI, and CLIP