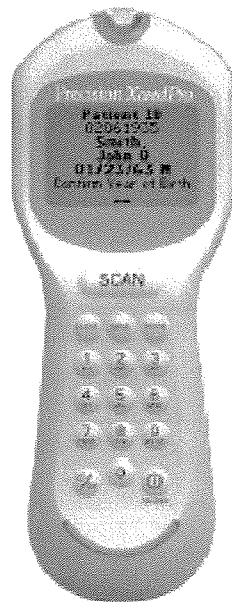


Enloe Medical Center
Nursing Orientation

Precision Xceed Pro Blood Glucose
Monitoring System
Safe-T-Pro Plus Lancet
Insulin Administration



Enloe Education Center
2008

ENLOE MEDICAL CENTER NURSING ORIENTATION

Precision Xceed Pro Point of Care System, Safe-T-Pro Plus Lancet & Insulin Administration

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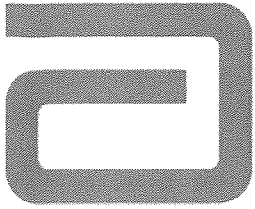
Orientation Performance Criteria

This orientation module has been developed to enable licensed nursing personnel to become certified in the performance of blood glucose monitoring using the Precision Point of Care System.

Registered Nurses and Licensed Vocational Nurses must be certified in the performance of Precision Xceed Pro before performing a blood glucose evaluation in the clinical setting.

To complete certification:

1. Successfully pass the Learning Assessment test.
2. Perform a blood glucose test at the bedside while being observed by another licensed and Precision Xceed Pro certified nurse and complete the Training Checklist.
3. Return the Training Checklist and Learning Assessment to your educator and/or Manager.



Precision Xceed Pro™ Blood Glucose Monitor Operator System Overview

For facilities converting from the Precision PCx® Blood Glucose Monitor

System Overview

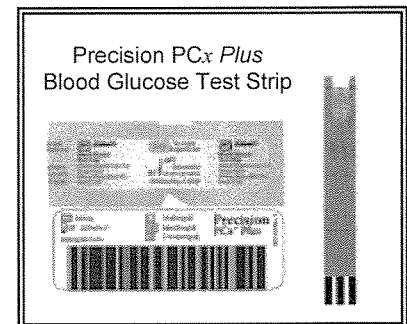
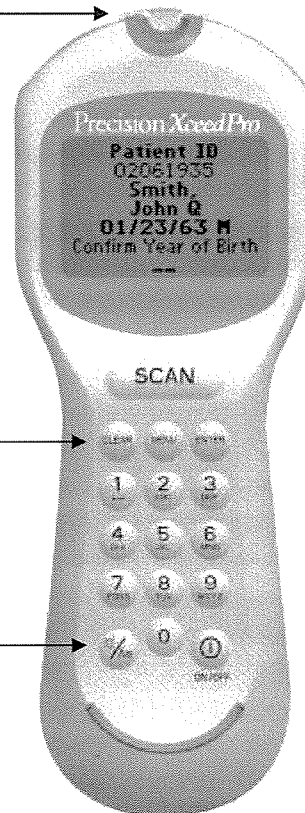
The Precision Xceed Pro Blood Glucose Monitoring System with the Precision PCx Plus Blood Glucose Test Strip includes all of the same great features of the Precision PCx Blood Glucose Monitoring System including:

- Easy to use, ergonomic design
- Individually foil protected and bar-coded test strips
- Top-fill or end-fill target for easy sample application
- Small sample size: 2.5 microliters (μ l)
- Designed not to start until adequate sample has been detected (fill-trigger)
- Re-application of sample within 30 seconds of first drop if test does not start immediately
- Result in 20 seconds

Test Strip Port
with Port Protector

CLEAR, MENU
AND ENTER Keys

Alphanumeric /
Backlight Key



Precision Xceed Pro™ Blood Glucose Monitor

Monitor:

- For use with **Precision PCx Plus Blood Glucose Test Strips** (gold foil packet)
- **Test Strip Port Protector** – *Designed to minimize the possibility of liquid entering the monitor through the strip port*
 - Check for presence of blood or control solution and replace port protector if contaminated
 - Check to confirm port protector is installed correctly (verify there are no gaps between the port protector and the monitor around the edges)
- **Clear, Menu and Enter Keys** re-located to top of keypad
- **Alphanumeric keypad**
 - Enter an alpha character (keys 2 – 9) by pressing a particular key multiple times when in alpha mode
 - Enter a SPACE (key 1) character in alpha mode
 - Alpha mode is identified with a lower or uppercase indicator in the bottom right of the display
- **Battery symbol and power status on display**
- **Automatic Shut-off**
 - Monitor shuts off after 4 minutes of inactivity (default)
 - Automatic shut-off may be pre-configured from 4-10 minutes following patient testing only
Patient testing Automatic Shut-off configured for _____ mins
- **Operator ID Expiration Warning** – *When you scan or enter your Operator ID you may receive a prompt (up to 90 days in advance) that your Operator ID certification is due to expire*

Patient Testing:

- The patient testing process is the same as Precision PCx, however, you may receive additional prompts if the following are enabled:
 - **Patient Testing**
 - ❖ Patient ID/Operator ID prompt description may be different
Patient ID Prompt: _____ **Operator ID Prompt:** _____
 - ❖ Additional Patient ID confirmation screen (only one will appear)
 - **Confirm [patient] Year of Birth** – *Enter patient's 2-digit year of birth*
 - **Confirm [patient ID]** – *Select "Confirm" to continue*
 - **Confirm [manually entered] Patient ID** – *Repeat manual patient ID entry*
 - ❖ **Post Testing Prompts:**
 - Outside **Action Range** – *Enter Comment Code if prompted*
 - Outside **Critical Range** – *Enter Comment Code if prompted*
 - Free Text Prompts – *Used to gather additional information*
Free Text 1 = _____
Free Text 2 = _____

Data Review:

- If your Operator ID is required for patient testing, then you will be prompted to enter your ID prior to viewing test data under Data Review

Maintenance:

- Acceptable cleaning solutions include alcohol and ammonia based solutions
- Recommended solutions include: **Sani-Cloth® HB, Sani-Cloth® Plus and Super Sani Cloth®**
- Cleaning solutions that are not recommended for use include: Hype-Wipe®, Dispatch® and Virox® 5
- **Batteries** - 2 AA or 2 Rechargeable NiMH

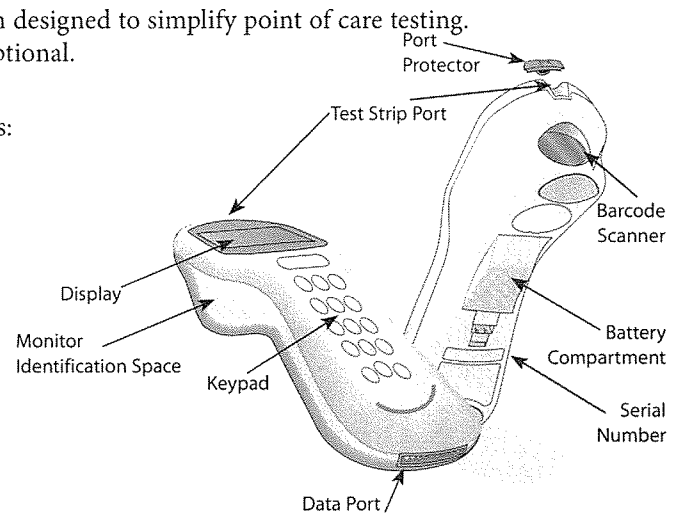
System Components

The Precision Xceed Pro Monitor is part of an overall system designed to simplify point of care testing. These components are purchased separately and some are optional.

Precision Xceed Pro System Components

The Precision Xceed Pro System includes the following items:

- Monitor (figure to the right)
- Port Protector
- Blood Glucose Test Strips
- Control Solutions
- Calibration Verification Controls (optional)
- Isolation Bags (optional)
- Carry Case (optional)
- Docking Station (optional)
- Data Upload Cable (optional)
- Data Management System



IMPORTANT: *Observe caution when using around children. Small parts may constitute a choking hazard.*



IMPORTANT: *Use product and accessories only as directed. Failure to operate the product(s) in accordance with the manufacturer's documentation may impair product safety.*

Monitor

The Precision Xceed Pro Monitor has many features designed to help simplify testing. It can be used with one hand, either the left or the right. The display has large text and is backlit to make reading easy. The keypad is similar to a telephone and each button clicks when pressed. Use of the monitor is described in Chapters 2 through 8 of this Operator's Manual and in the Quick Reference Guide (available separately).

At the top of the monitor is the test strip port, covered by the port protector. The port protector is designed to minimize liquid entering the monitor through the strip port (Chapter 11 provides instructions for changing the port protector). Underneath this is the window for the bar code scanner. On the back of the monitor is the battery cover (Chapter 11 also provides instructions for changing the batteries). Just below the battery compartment is a label with the unique serial number of the monitor. On the side of the monitor is the meter identification space. This untextured area (.875 inch wide x .483 inch high) provides a space in which to apply a facility-specific location label. At the bottom is the data port for connecting the monitor to a data upload cable or docking station (Chapter 9 provides information on uploading data to a data management system).

Each Precision Xceed Pro Monitor is shipped with this Operator's Manual, one Port Protector installed, and two AA Batteries.




IMPORTANT: *Do not put blood or foreign objects into the test strip port of the monitor.*

Test Strips


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.

Precision PCx Plus Blood 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.

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 or by dipping the end of the test strip in the sample. 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.

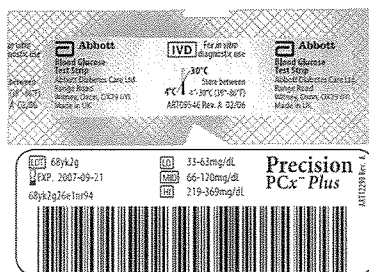
 **IMPORTANT:** *Do not apply blood to the test strip when the test strip is out of the monitor. Do not use wet, bent, scratched or damaged test strips.*


Each test strip comes wrapped in a foil packet bearing a barcode label. The individual foil packet maintains the integrity of each test strip by protecting it from exposure to air and moisture, and accidental contamination. The bar code label holds information about the test strip including the lot number, calibration, expiration date, and expected control solution ranges. One quick scan provides the monitor with all this information at the time of the test.

 **IMPORTANT:** *Do not scan a packet's bar code and use a test strip from another packet. This may cause incorrect results to be generated. Use the test strip immediately after opening its foil packet. Do not use the test strip if the foil packet has a puncture or tear in it.*

The Precision Xceed Pro monitor is compatible with Precision PCx Plus Test Strips. Precision PCx Plus Test Strips are protected by a gold foil packet and are identified on the barcode label. Inside each box of test strips is a package insert with detailed instructions for use.

Precision PCx Plus Blood Glucose Test Strip



 **IMPORTANT:** *The Precision Xceed Pro System will only work with Precision PCx Plus brand test strips. Use of any other test strip may cause erroneous results.*

Control Solutions

Control solutions are used to perform regular quality control checks on the monitor to ensure it is functioning correctly. Control testing is further described in Chapter 4. Precision, Optium, or MediSense® Control Solutions may be used with the Precision Xceed Pro System. These control solutions are available in one, two or three level configurations.

Calibration Verification Controls

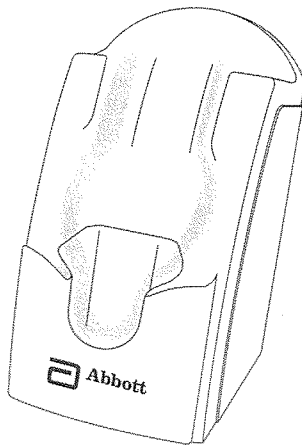
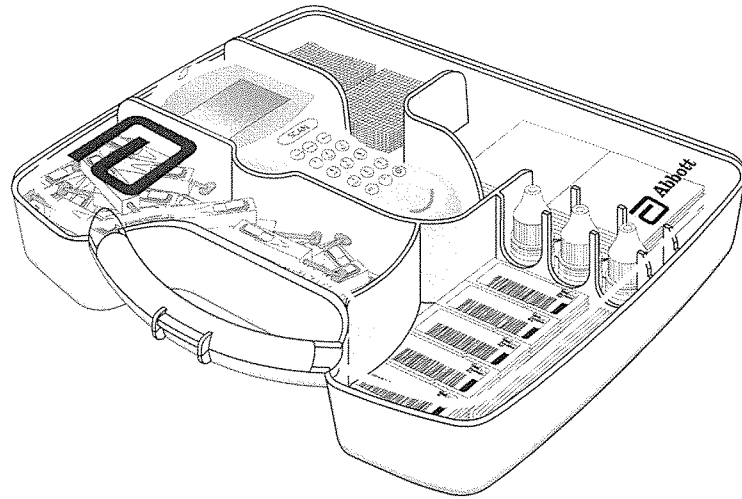
RNA Medical® brand Glucose Calibration Verification Controls may also be used to confirm the calibration and analytical measurement range of the monitor. This is called linearity testing and requires a kit with 5 levels of control solution. Linearity testing is further described in Chapter 7.

Isolation Bag (optional)

Abbott Isolation Bags are disposable plastic bags for use with the Precision Xceed Pro System. The Isolation Bag provides a partial barrier between the point of care monitoring device and the patients in isolation for infection control. There is no need to prep the monitor prior to using the bag and the bag does not affect any monitor functions. Note that Abbott Isolation Bags are not sterilized.

Carry Case (optional)

The carry case holds the monitor, test strips, control solutions, the quick reference guide and other accessories needed for testing. A transparent cover allows you to check supply status without opening the case.



Docking Station (optional)

The docking station provides a convenient way to upload the data from the monitor to the data management system. When the monitor is placed in the docking station, it will automatically upload data to the data management system and then shut down. Data upload is further described in Chapter 9.

Data Upload Cable (optional)

Alternatively, a data upload cable is available to connect the monitor to the computer running the data management system.

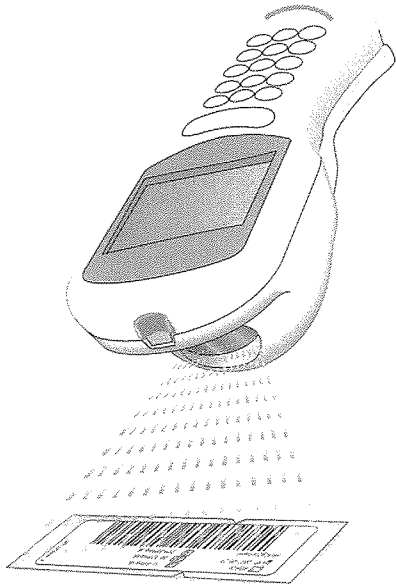
Data Management System

A computer running a data management system is necessary to configure and upload results from the Precision Xceed Pro Monitor. Abbott's PrecisionWeb Point of Care Data Management System and software from other vendors are available. Data upload from remote locations requires either Terminal Servers or networked PCs running Abbott's Data Repeater software.

Using the Monitor

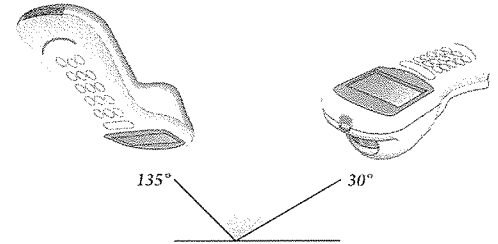
Barcode Scanner

The barcode scanner enables you to scan the information into the monitor instead of manually entering the data using the keypad. Scanning the barcode on the test strip foil packet automatically enters the test strip information (calibration, control range, lot number and expiration date). The scanner may also be used to enter Operator ID, Patient ID, control lot number, comment code and free text fields. To operate the monitor:



Step 1: Place the barcode on a flat surface.

Step 2: Hold the barcode scanner 3-12 inches from the barcode to be scanned, and at a 30 to 135 degree angle to the barcode.



Step 3: Press and hold down the Scan button until a visible red beam is emitted by the monitor.

Step 4: Slowly move the monitor, if needed, so that the red beam is directly over the barcode.

Step 5: The monitor will beep in acknowledgement when it accepts the barcode.

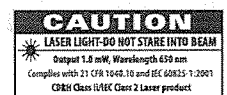


Note: If you hold the Scan button for three seconds, the scanner stops. Reposition scanner and try again. Optimal distance depends on bar code type.

When first learning to use the barcode scanner, some precautions should be taken. It is important that you place the object to be scanned on a flat surface or hold it, by itself. This will prevent other items from being accidentally scanned. If data has been manually entered, scanning data will erase the manually entered data (unless the Enter key has been selected to confirm manual entry) and replace it with the scanned data. This entry will be considered scanned. Upon a successful barcode scan, this system will automatically proceed to the next screen. The scanning beam shuts off in three seconds if nothing is detected.



IMPORTANT: Never look into the barcode scanner beam or point it toward anyone's eyes. The beam could cause permanent damage to the eye. CDRH Class II/IEC Class 2 Laser Product: Avoid Long Term Viewing of Direct Laser Light.

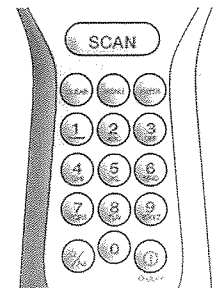


Data Entry Keypad

The data entry keypad allows you to enter identification numbers and letters (only the 26 letter English alphabet) or to select an option that appears on the display. The keypad contains a 10 digit telephone-style keypad with the keys for the numbers 0-9. The 2-9 keys also have letters printed below the number. The keypad also has six special keys, including a scan button, on/off button, backlight/alphanumeric, clear, menu, and enter key.

Scan

Press this button to operate the bar code scanner. If the audible indicator is enabled, the monitor will beep once a barcode has been successfully scanned. Continuing to hold the scan button will display the scanned barcode on the display until the button is released. If no information is scanned after 3 seconds, the scanner will turn off.



On/Off

Press this button to turn the monitor on. Each time the monitor is turned on, the Abbott logo screen will appear in black for a few seconds and then will appear in gray. This provides an opportunity to ensure that all the pixels are working correctly.

Press and hold this button for two seconds to turn the monitor off. The monitor will automatically shut itself off after 4 minutes to conserve battery life. The length of time for automatic shut-off can be configured from 4 to 10 minutes following patient tests only.

Backlight/Alphanumeric

Press and hold this button for approximately 2 seconds to activate the display backlight.

Press this button while manually entering data to toggle between numeric, uppercase alpha mode and lower case alpha mode during manual data entry. When in alpha mode, enter alpha characters on the screen by pressing the 2 through 9 buttons multiple times to cycle through the characters. Enter a SPACE character in alpha mode by pressing the 1 key.

The monitor displays which mode you are in with a lowercase/uppercase alpha indicator in the lower right side of the display.

Clear

Press this button to back up one space while entering alphanumeric information on the keypad.

This button is also used to return to a previous screen if necessary.

Menu

Press this button to switch the monitor from Test Mode to Menu Mode. These two modes are described in the next section. When viewing configuration information in Menu Mode, pressing this button one time will return to the top of the menu tree. Pressing the button a second time will switch to Test Mode.

Enter

Press the Enter button after entering all needed information.

Audible Indicator (not visible)

The monitor has an audible indicator that can be turned on or off. This indicator emits two tones, a high pitched tone to indicate success and a low pitched tone to indicate a problem. If enabled, the monitor will beep to indicate the following actions:

- The operator has successfully scanned a barcode;
- The monitor has detected an adequate sample and is starting test analysis;
- The monitor is nearing completion of test analysis (3 beeps with final countdown);
- The monitor has displayed the test result;
- An error has occurred (see Chapter 10 for troubleshooting information);
- The monitor will automatically shut off in thirty seconds (2 beeps);
- The operator has pressed an unexpected button;
- The operator has pressed the **Off** button.

Data Port

The Data Port is located at the bottom of the monitor. This port enables the monitor to automatically transfer the data through a cable or docking station to the data management system.

Battery Compartment

The monitor holds two AA batteries to power the monitor. To prolong the battery life of the monitor, the monitor should be turned off when not in use. Data is not affected if batteries are removed.

Port Protector

The port protector covers the test strip port. 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 dried and the port protector replaced. Chapter 11 provides instructions for replacing the port protector.

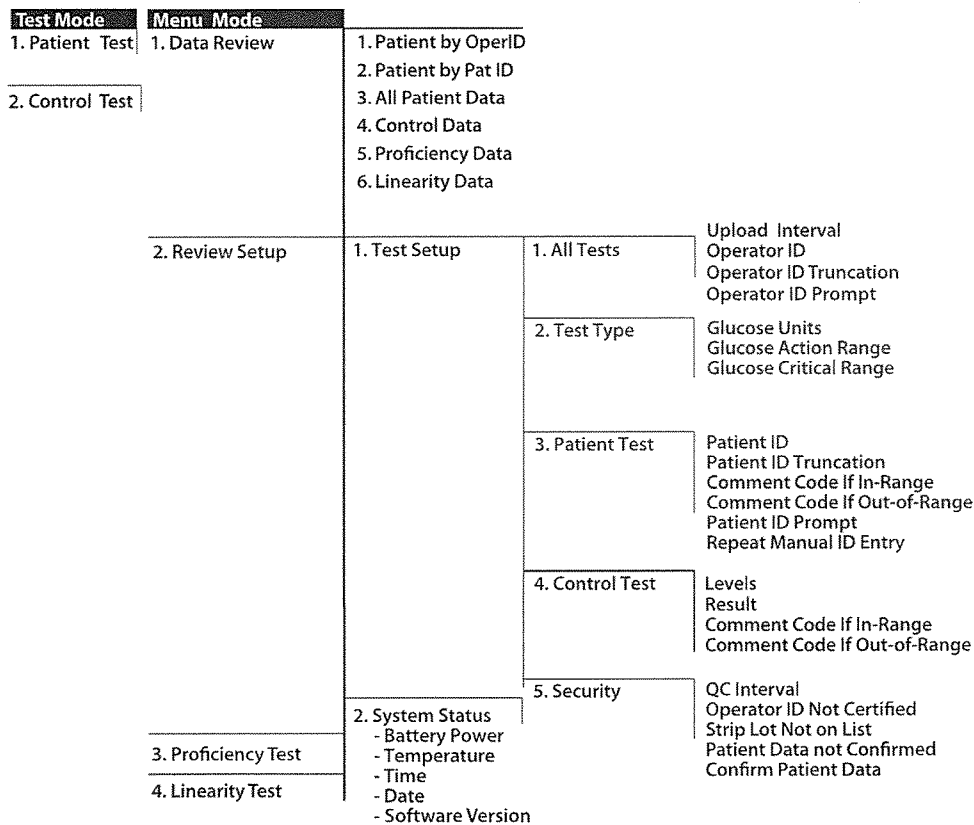
Monitor Identification

Each monitor has a unique serial number listed on the back of the device just below the battery compartment. The Precision Xceed Pro Monitor also features an untextured area on the side of the device. This .875 inch [22 mm] wide x .483 inch [11 mm] high area allows a facility to apply a label with information pertaining to the monitor. Please refer to Chapter 1 for an illustration of this feature.

Menu Tree

When using the Precision Xceed Pro Monitor, you will navigate between two main menus, Test Mode and Menu Mode. Test Mode is used to perform patient tests and control tests. Menu Mode is used to perform linearity and proficiency tests and review the monitor's configuration settings and status (e.g. battery voltage). The configuration options shown in Menu Mode must be configured using a data management system. You can visually verify existing monitor settings, but cannot change them.

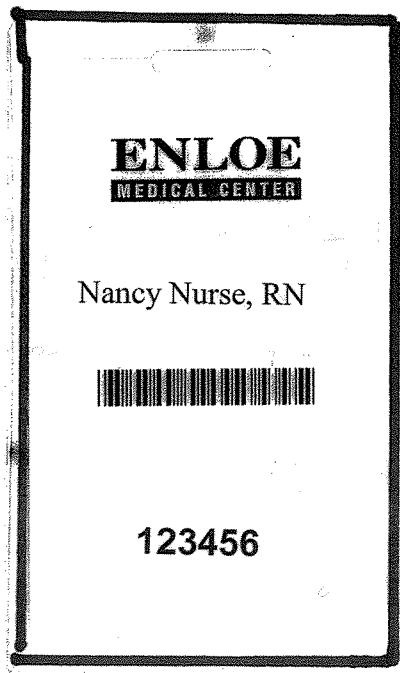
The Menu Mode portion of the software is set up like a tree, with various levels of sub-menus. The Precision Xceed Pro Menu Tree, shown below, illustrates the multiple sub-menu layers.



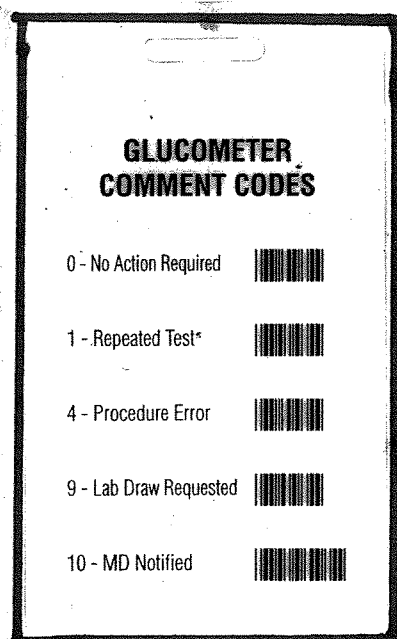
Name Badge with Bar Codes for Precision Xceed Pro Use

1. You will use this badge to scan your identification.
2. The comment codes cannot be scanned. Enter the comment code number.
3. An additional comment code not listed on the card is:
 - a. 11 - Initiated Protocol

Front



Back



Patient Test

This chapter describes the steps to be taken to test patient blood glucose levels in fresh whole blood using the Precision Xceed Pro System. Inside each box of test strips is a package insert with detailed instructions for use.

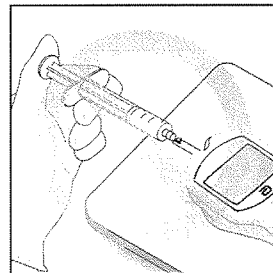
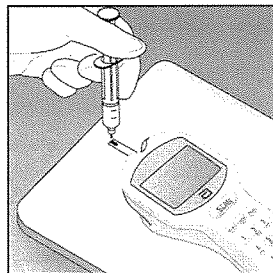
Operating Guidelines for All Samples

Please follow the recommended guidelines for the most accurate results:

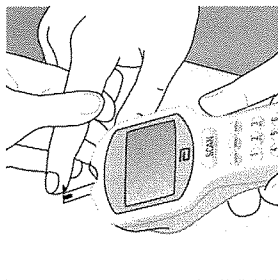
- Always wear gloves and follow your facility's biohazard safety policies and procedures when performing tests involving patient blood samples.
- Make sure that the monitor and test strips are at room temperature. If the monitor is moved to an area that is warmer or cooler than where it was before, allow the monitor to reach the new room temperature before testing.
- Use only control solutions specified in the test strip package insert to verify the performance of the Precision Xceed Pro Monitor.
- Use only Precision PCx Plus Test Strips with the Precision Xceed Pro Monitor.
- Refer to the package insert for specific directions on storage and use of the test strips.
- Do not use the test strips beyond the expiry date printed on the foil packet and outer box.
- Do not use the test strip if the foil packet has a puncture or tear.
- Do not use test strips that are wet, bent, scratched or damaged. Use the test strip immediately after opening its foil packet.
- Use each test strip only once.
- Do not scan a test strip packet's barcode and then use a test strip from a different packet. This may cause inaccurate results.
- Apply a drop of blood to the target area at the end of the test strip. Allow the entire target area to fill with blood. The test results will not be affected if the target area has been briefly touched with the patient's finger, a capillary tube, syringe, or pipette.
- If the test fails to start, apply a second drop of blood to the test strip. Refer to the test strip package insert for the number of seconds you have to apply a second drop. If the countdown still does not start, or if the time to apply a second drop has passed, discard the test strip and repeat the test.
- After the blood is applied to the test strip and the test countdown begins, do not remove or disturb the test strip.



IMPORTANT: Do not allow blood or other solution to run down the test strip into the monitor's test strip port, as it may cause irreparable damage to the monitor.

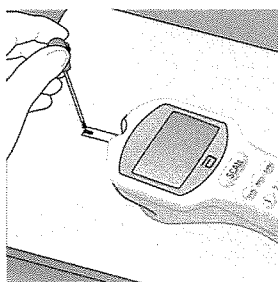


Collecting Blood Samples



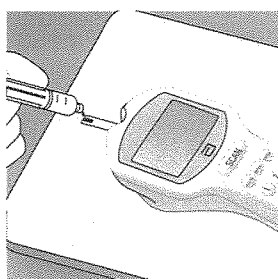
How to Obtain a Capillary Blood Sample:

- Use only fresh whole blood samples.
- Make sure that the sampling site is clean and dry before lancing.
- Collect the capillary blood using a lancing device and an appropriate technique.
- Apply a drop of blood to the target area at the end of the test strip. Allow the entire target area to fill with blood.
- If necessary, blood can be collected in a capillary tube coated with heparin or EDTA may be applied to the test strip within 30 minutes of collection.



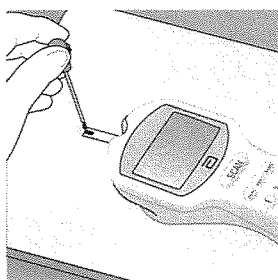
How to Obtain a Venous Blood Sample:

- Use only fresh whole blood samples.
- Collect the venous blood sample in a collection tube containing heparin or EDTA. Make sure that the tube is filled to the stated volume. Do not under fill.
- Do not use collection tubes that contain fluoride or oxalate.
- If the blood is collected from an intravenous line, clear the line before drawing the sample into a heparinized syringe.
- Use the sample within 30 minutes of collection.
- Invert the tube with the sample several times immediately before removing the sample.
- Use a disposable transfer pipette to obtain a sample from the center of the collection tube.
- Apply a drop of blood to the target area at the end of the test strip. Allow the entire target area to fill with blood.



How to Obtain an Arterial Blood Sample:

- Use only fresh whole blood samples.
- Clear the arterial line before drawing a blood sample into a heparinized syringe.
- Use the sample within 30 minutes of collection.
- Mix the blood specimen well immediately before applying the sample to the target area of the test strip.
- Allow a drop of blood to form at the tip of the syringe.
- Apply a drop of blood to the target area at the end of the test strip. Allow the entire target area to fill with blood.



How to Obtain a Neonatal Capillary Blood Sample (heel stick):

- The following procedures should only be performed by a trained professional.
- Use only fresh whole blood samples.
- Collect the capillary blood using a lancing device and an appropriate technique.
- Apply a drop of blood to the target area at the end of the test strip. Allow the entire target area to fill with blood.
- The blood can be collected in a capillary tube coated with heparin or EDTA, and then applied to the test strip.
- Alternately, you can use the heel-to-strip method: Allow a hanging drop of blood to form from the heel and apply to the target area of the test strip. Results will not be impacted by gently touching the heel to the test strip.



Disposing of Waste

Observe the following guidelines when disposing of biohazardous waste:

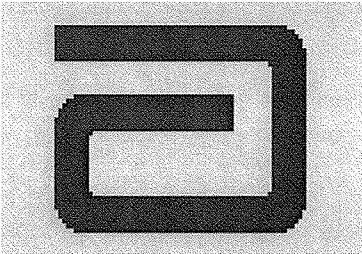
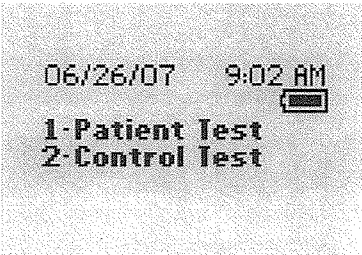
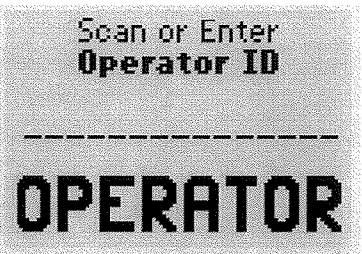
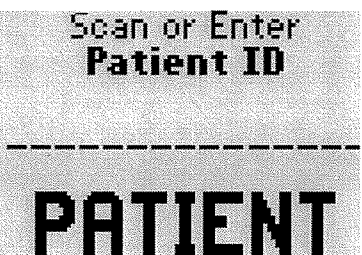
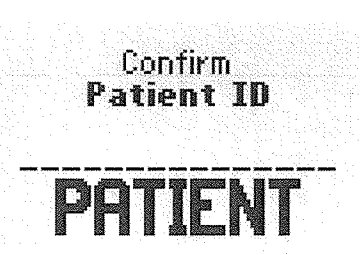
- Dispose of used lancets in an approved sharps container.
- Discard used capillary tubes, disposable transfer pipettes or tips and test strips in an approved biohazard container.
- Follow your facility's biohazard disposal policy.

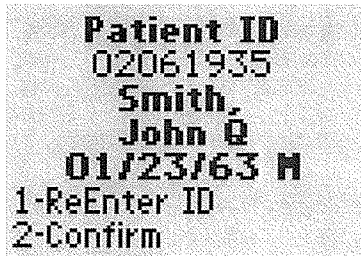
Patient Test Procedure - Glucose

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

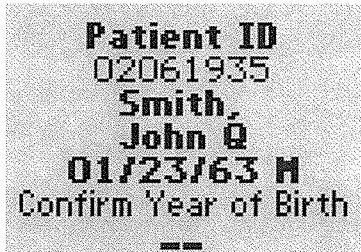


Note: The following section illustrates some common settings. Depending on your institution's specific settings, some screens will display differently or not at all. If the monitor does not display the screens shown, please refer to Chapter 10, Troubleshooting.

What You See on the Display	What You Do	Comments
	<p>1. Press On/Off to turn on the monitor.</p>	<p>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.</p>
	<p>2. Press 1 to select Patient Test.</p>	<p>The monitor starts in Test Mode. The Menu button will toggle the monitor to Menu Mode.</p>
	<p>3. Press Scan to scan the Operator ID barcode or manually enter the Operator ID via the keypad, then press Enter.</p>	<p>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.</p>
	<p>4. Press Scan to scan the Patient ID barcode or manually enter the Patient ID via the keypad (if enabled).</p>	<p>If you enter the ID manually, you may be required to enter it a second time to ensure it is correct.</p> <p>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.</p>
	<p>5. Confirm the Patient ID (if prompted). You may see one of the following four screens:</p> <p>Re-enter the ID using the keypad.</p>	

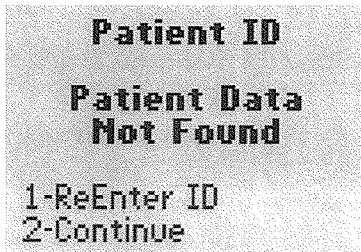


Press **2** to **Confirm** the information and continue testing or **1** to **ReEnter** the ID.

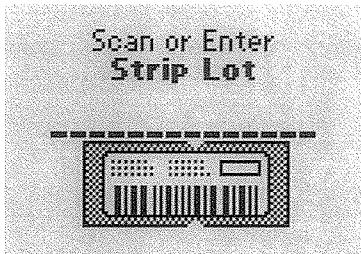


Enter the year of birth (e.g. 63) and press **Enter**.

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.

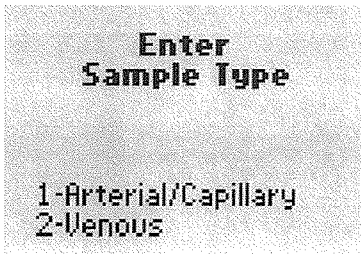


Press **2** to **Continue** testing or **1** to **ReEnter** the ID.



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.



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.

