Precision XceedPro

Point of Care System

Operator's Manual

for Blood Glucose Monitoring

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Abbott

Table of Contents

This Operator's Manual provides basic information about the Precision Xceed Pro System. It is organized into three sections. First, the overview in Chapter 1 describes the components of the Precision Xceed Pro System and the physical features of the monitor. Next, Chapters 2 through 8 give step-by-step procedures to operate the monitor. Finally, Chapters 9 through 12 provide additional information to help care for the monitor.

1. Overview

Intended Use

The Precision Xceed Pro Point of Care System for Blood Glucose Testing is intended for *in vitro* (outside the body) diagnostic use for the quantitative measurement of glucose in fresh capillary whole blood. The Precision Xceed Pro System is for home (lay user) or professional use. The Precision Xceed Pro System is not for use in diagnosis or screening of diabetes mellitus, but is to be used as an aid in monitoring the effectiveness of diabetes control programs. The Precision Xceed Pro System may also be used by healthcare professionals for the quantitative measurement of glucose in venous, arterial or neonatal whole blood, provided the sample is used within 30 minutes.

The Precision Xceed Pro System simplifies point-of-care testing for healthcare professionals, providing features that enhance the reliability of the testing process and that support compliance with point-of-care policies.

TrueID

Easy Data Entry — Choose between the built-in barcode scanner and the alphanumeric keypad for entering data as required by point-of-care policy. The monitor can be configured to accept patient identification, operator identification, test strip lot number, comment code, and up to two free text fields for other data such as physician name.

Patient ID Confirmation — The monitor can display the patient name, date of birth and gender for confirmation, supporting positive patient identification procedures. Entry of the year of birth also can be required for confirmation.

Data Integrity — Many options are available to help ensure that correct data is collected with each test including: specifying the minimum and maximum length of an ID, restricting the types of bar codes to be accepted, using a check digit to verify the bar code, or requiring repeated entry of data on the keypad if the bar code scanner is not used. The monitor also records the method of patient and operator identification data entry (scanned versus manually entered on the keypad) to help Point of Care Coordinators identify and correct errors.

TrueMeasure

Fast, Simple Testing — To perform a test, simply insert a strip into the monitor's port, apply a small drop of blood and wait for the countdown to complete. For convenience, the sample may be applied to either the top or end of the test strip. The test will not start until adequate sample has been applied.

Simple Calibration — Scanning the barcode label on each test strip foil packet prior to use automatically calibrates the monitor and checks the expiration date, helping ensure reliable and accurate test results. Testing can also be restricted to approved strip lots.

QC Lock-out — The monitor can be configured to require periodic testing using control solutions, and to lock out access to the system if these tests are not completed. QC results can be displayed as pass/fail only, preventing patient testing while in control test mode.

TrueAccess

Operator Management — Access to the monitor can be restricted to certified operators, locking out untrained users. A warning can also be displayed to an operator whose ID is set to expire in the near future.

Results Storage — The Precision Xceed Pro monitor can store up to 2,500 patient test results and 1,000 control test results, in addition to 20 proficiency test results and 1 linearity panel. All stored data can be automatically uploaded to the data management system using the docking station (optional) or a data upload cable (optional).

Network Connectivity — Precision Xceed Pro Monitors can upload data and be configured via a central data management system, across the organization's computer network. This provides a simple and automated way to manage multiple instruments, monitor point of care testing, and report test data to the Laboratory Information System (LIS) or Hospital Information System (HIS) for inclusion in the patient's Electronic Medical Record (EMR).

Icons and Warnings

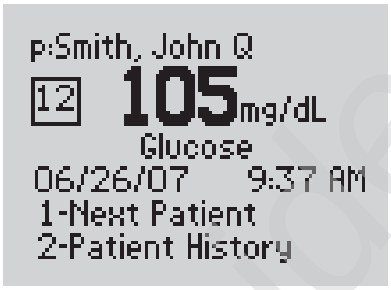
Information that is of particular relevance to the reader is called out in gray boxes throughout the manual, with an appropriate icon and warning level.

IMPORTANT: ***Indicates that inconvenience to the operator or danger to the patient may result if the instruction is not followed.***

Note: *Provides or refers the operator to additional or background information that may be helpful to them.*

Conventions

The glucose unit of measure is set using the data management system. It is not changed via the monitor keypad. In this manual, when a monitor screen shot shows a glucose test result in one unit of measure (e.g. mg/dL) the equivalent value in the other unit of measure (e.g. mmol/L) appears below the image.



5.8 mmol/L

IMPORTANT: ***Please confirm that the correct unit of measure shows on your monitor with every glucose result.***

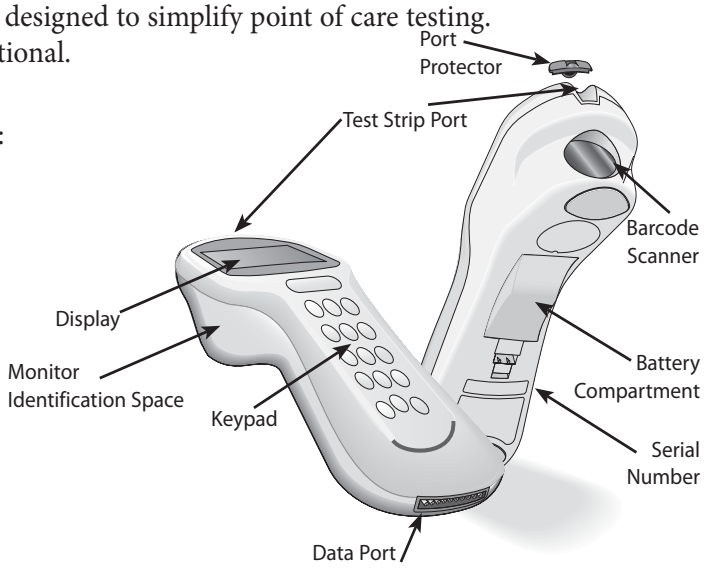
System Components

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.

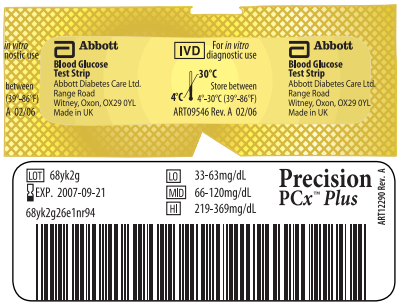
IMPORTANT: ***Do not apply blood to the test strip when the test strip is out of the monitor. Do not use wet, bent, scratched or damaged test strips.***

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

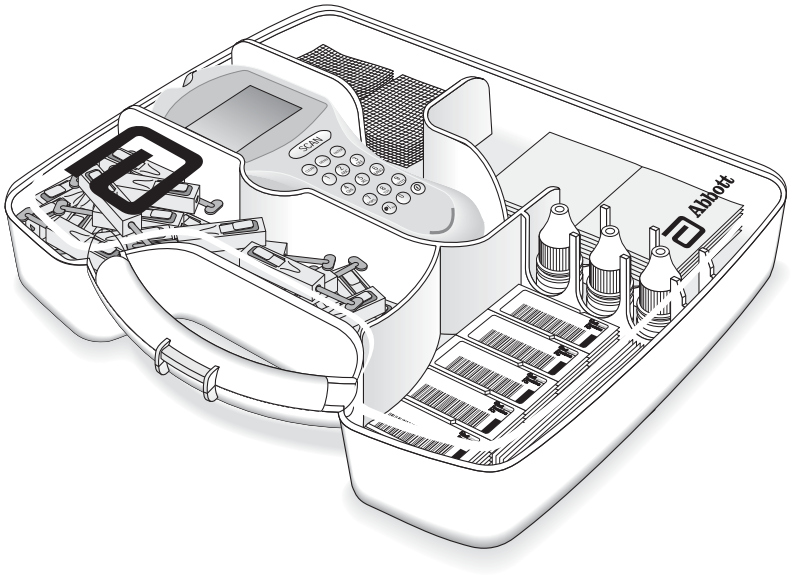
RNA Medical® brand Glucose Calibration Verification Controls may also be used to confirm the calibration and analytical measurement range of the monitor. This is called linearity testing and requires a kit with 5 levels of control solution. Linearity testing is further described in Chapter 7.

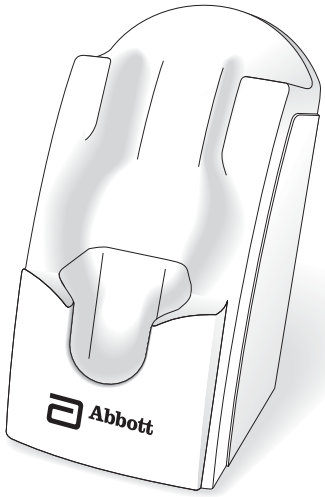
Isolation Bag (optional)

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.

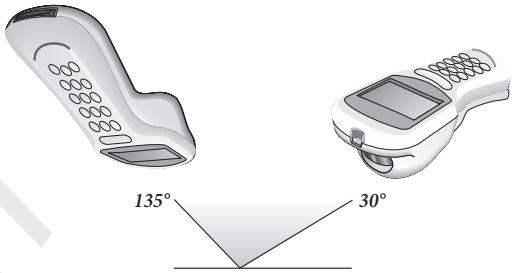
Data Management System

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.

2. 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.

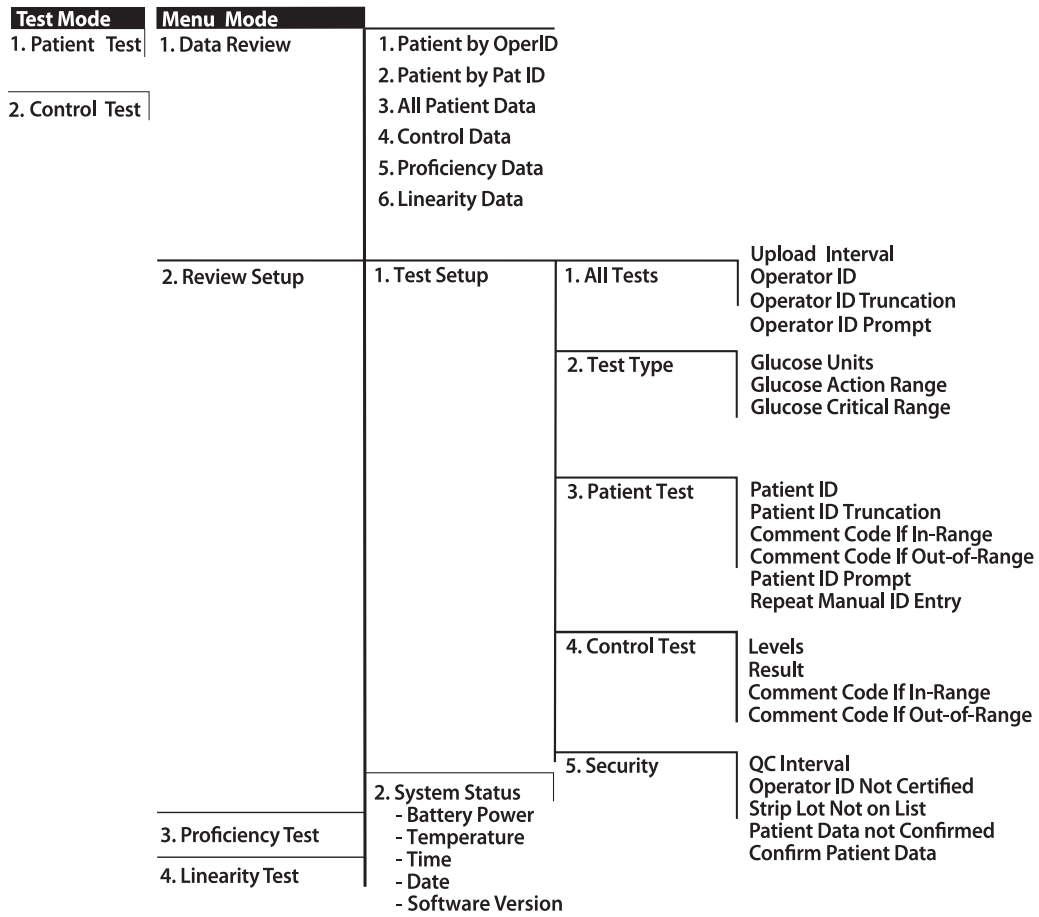
Monitor Identification

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.



3. Patient Test

Patient Test

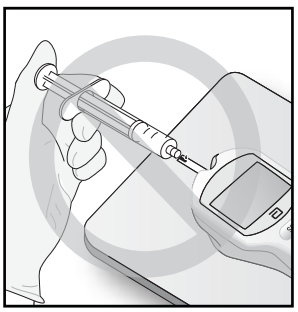
This chapter describes the steps to be taken to test patient blood glucose levels in fresh whole blood using the Precision Xceed Pro System. Inside each box of test strips is a package insert with detailed instructions for use.

Operating Guidelines for All Samples

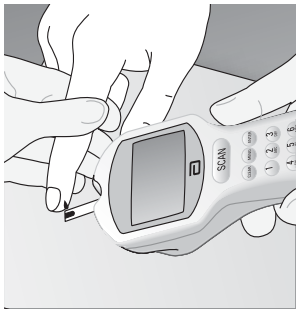
Please follow the recommended guidelines for the most accurate results:

- 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.***

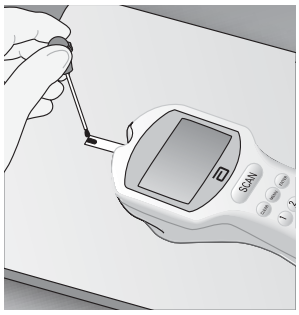


Collecting Blood Samples



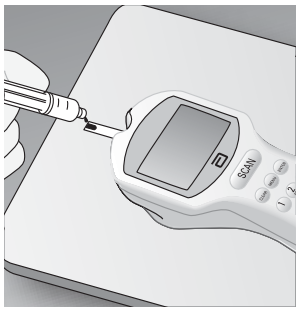
How to Obtain a Capillary Blood Sample:

- 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.



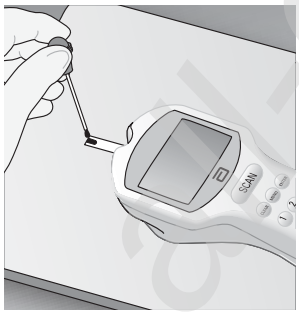
How to Obtain a Venous Blood Sample:

- 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

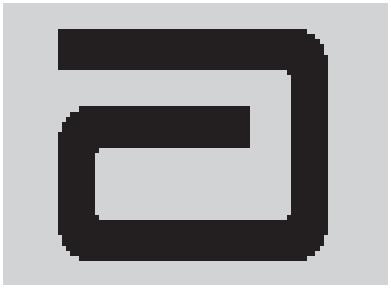
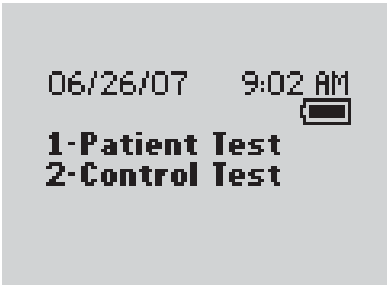
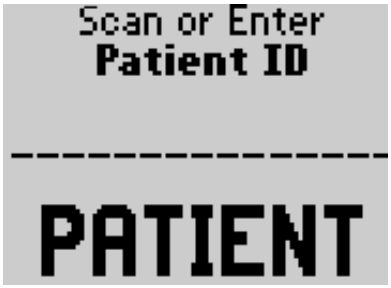
Observe the following guidelines when disposing of biohazardous waste:

- 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.

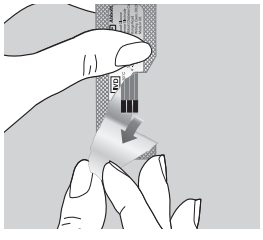
Patient Test Procedure - Glucose

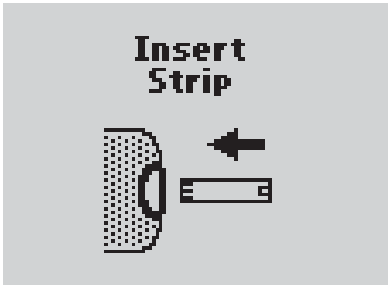
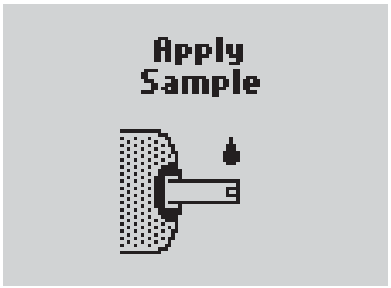
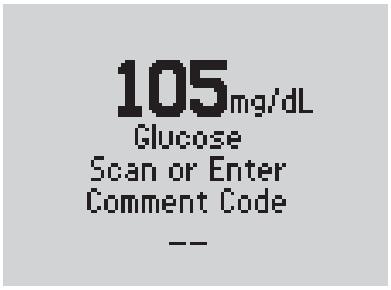
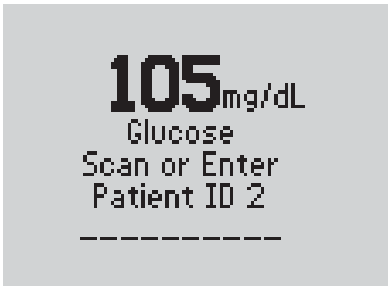
Use the following procedure to perform a patient test using the Precision PCx Plus Blood Glucose Test Strip.

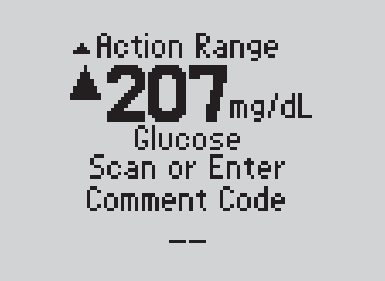
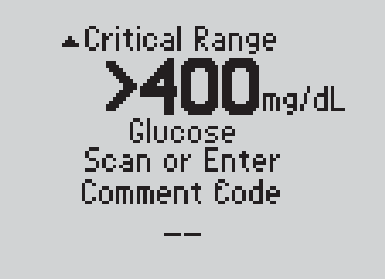
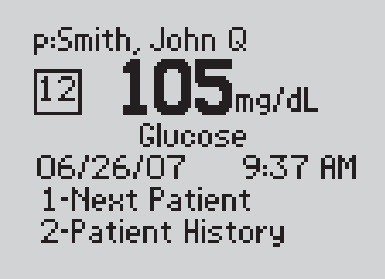
Note: *The following section illustrates some common settings. Depending on your institution's specific settings, some screens will display differently or not at all. If the monitor does not display the screens shown, please refer to Chapter 10, Troubleshooting.*

What You See on the Display	*What You Do*	*Comments*
	**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.

What You See on the Display	What You Do	Comments
 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.
 >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.
 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).***

4. Control Test

Operating Guidelines for Control Solution Testing

Control Test Procedure - Glucose

This chapter describes the steps for running a control test with control solutions. Control tests verify the performance of the Precision Xceed Pro Monitor and Test Strips.

The quality control features of the monitor can be customized to fit the requirements of each facility.
The monitor can be set to require:

- Tests of low, normal and high control solutions or a variation depending on the facility's policy.
- Tests of control solutions at relative times (e.g. every 24 hours) or fixed times (e.g at 6:00 a.m., 2:00 p.m., and 10:00 p.m.).
- Control test results to appear as numeric value or Pass/Fail.

These quality control features can be set through the data management system.

Operating Guidelines for Control Solution Testing

Observe the following guidelines to obtain optimal quality control results using the Precision Xceed Pro System:

- Use only control solutions approved for use with Precision PCx Plus Test Strips to verify the performance of the Precision Xceed Pro Point of Care System.
- When opening a new bottle, write the discard date on the bottle label. Each bottle of control solution is stable for 90 days after opening or until the expiration date printed on the label, whichever comes first.
- Do not use control solutions after the expiration date printed on the bottles and the box. After the bottle has been opened, do not use after the discard date written on the bottle.
- Invert the control solution bottle several times to ensure thorough mixing before use.
- Invert and tap the capped control solution bottle to remove air bubbles from the tip of the bottle.
- Wipe the control solution nozzle with a clean gauze or tissue before and after each test.
- Do not scan one test strip foil packet's barcode and use a test strip from another foil packet. This may cause incorrect results to be generated.
- Replace the correct cap on the bottle and tighten the cap immediately after each use.

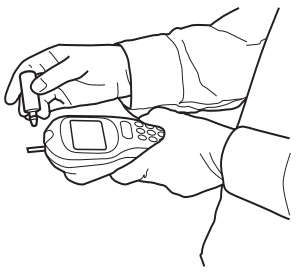
When To Test with Control Solutions

- As required by your facility's quality policy or local regulatory requirements.
- To verify the performance of the Point of Care System.

Workflow

The monitor expects to run control tests in the following order. If a control level is disabled, the monitor will expect to skip it.

1. Low Glucose
2. Mid-range Glucose
3. High Glucose

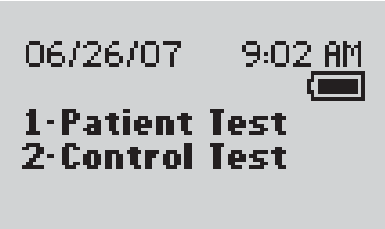
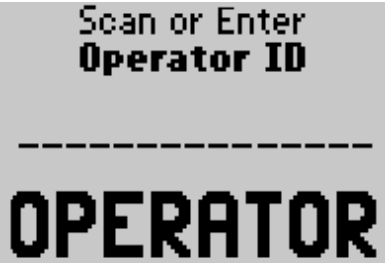
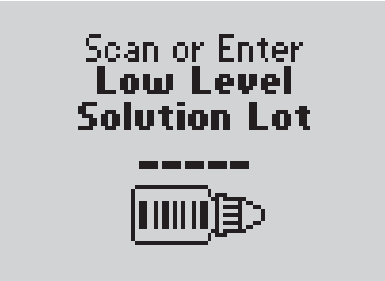
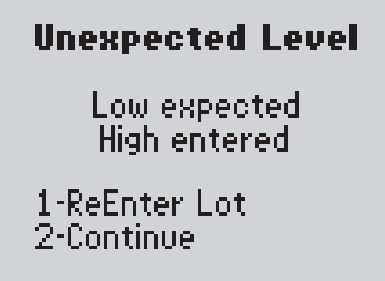


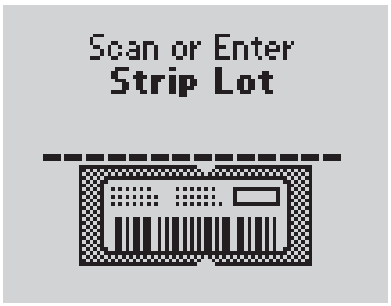
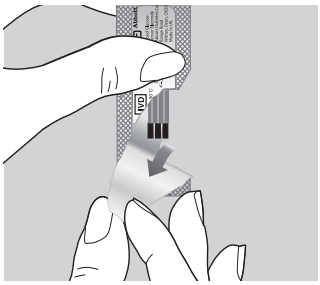
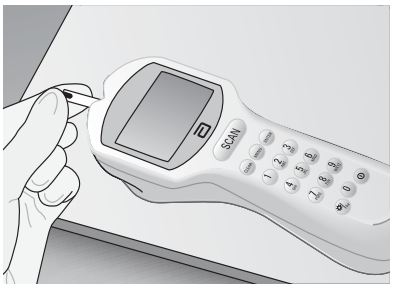
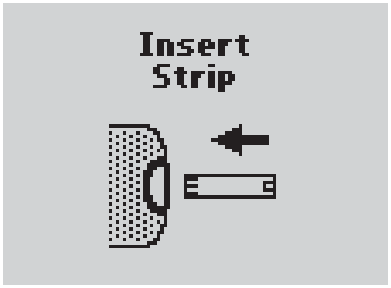
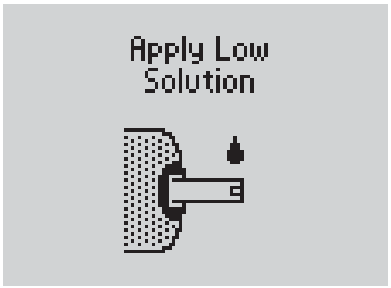
IMPORTANT: ***Do not allow control solution to drip down into monitor port.***

Control Test Procedure - Glucose

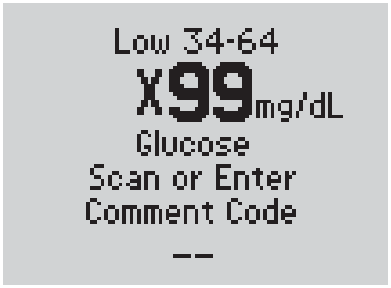
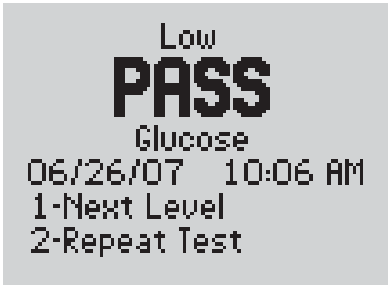
Use the following procedure to perform glucose control tests.

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.
	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.

What You See on the Display	What You Do	Comments
	**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.
		
	**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.
	**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.*

5. Data Review

Data Review

The Precision Xceed Pro Monitor stores the results of up to 2,500 patient tests, 1,000 control tests, 20 proficiency tests and 1 linearity panel. This data can be retrieved by the following categories:

Patient by Operator ID (OperID): This will show test results performed by a particular operator, starting with the most recent test.

Patient by Patient ID (PatID): This will show test results performed for particular patient, starting with the most recent test.

All Patient Data: This will display the test results for all patients, starting with the most recent test.

Control Data: This will show control test results, starting with the most recent test.

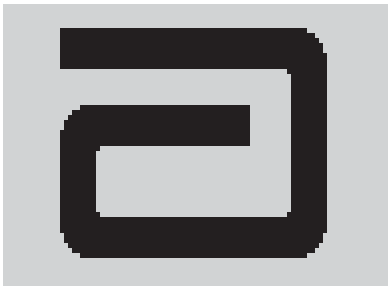
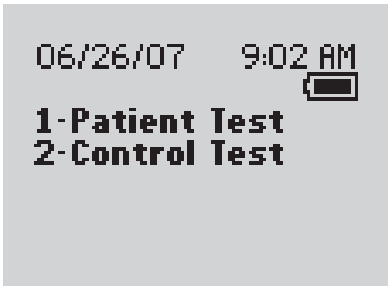
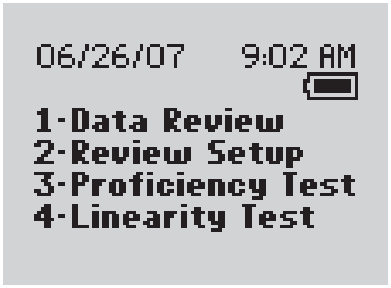
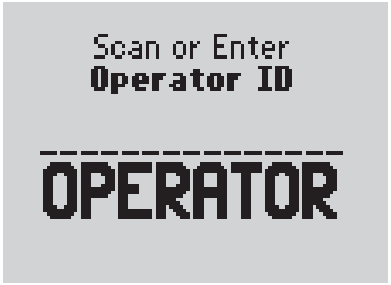
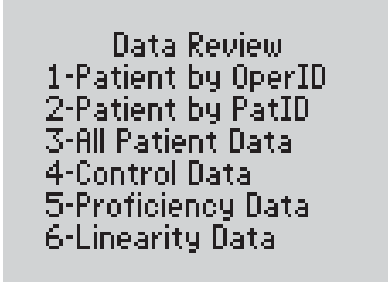
Proficiency Data: This will show proficiency test results, starting with the most recent test.

Linearity Data: This will show linearity test results, by level and order.

Note: *The monitor may be configured to require a valid Operator ID to view results.*

Follow these steps to access the Data Review menu:

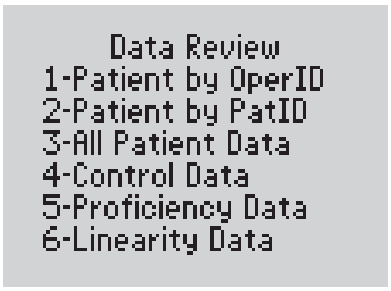
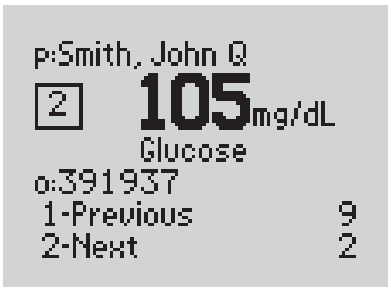
Note: *The following section illustrates some common settings. Depending on your institution's specific settings, some screens will display differently or not at all. If the monitor does not display the screens shown, please refer to Chapter 10, Troubleshooting.*

What You See on the Display	What You Do	Comments
	**1.** Press the **On/Off** button to turn the monitor on.	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 the **Menu** button.	The monitor starts in **Test Mode**. The Menu button will toggle the monitor to **Menu Mode**.
	**3.** Press **1** to select **Data Review**.	.
	**4.** 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.
	**5.** Choose the category of data to review..	

Data Review for Patient by Operator ID

Please refer to the beginning of this Data Review chapter for step-by-step instructions to access the Data Review menu.

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 **1** to select **Patient by OperID**.	The monitor shows the result of the most recent patient test you performed.
 5.8 mmol/L	**2.** You can select one of the following options: Press **1** – **Previous** Press **2** – **Next** When finished reviewing the data, you can: Press **Clear** to return to the Data Review menu. Press **Menu** to return to the **Menu Mode** menu. Press **On/Off** to turn off the monitor.	The number that appears to the right of **1-Previous** and **2-Next** on the monitor indicates the number of tests available for review. The display also shows: **Patient ID or Name** (**p:** prompt) **Comment Code** (Number in box) **Test Type** (Glucose) **Date and Time of test** **Operator ID** (**o:** prompt) Note that test date and time alternates with Operator ID.

Data Review for Patient by Patient ID

Please refer to the beginning of this Data Review chapter for step-by-step instructions to access the Data Review menu.

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
Data Review 1-Patient by OperID 2-Patient by PatID 3-All Patient Data 4-Control Data 5-Proficiency Data 6-Linearity Data	**1.** Press **2** to select **Patient by PatID**.	The monitor shows test results for a specific patient.
Scan or Enter **Patient ID** _____ **PATIENT**	**2.** 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.
p:Smith, John Q 2 **105** mg/dL Glucose o:391937 1-Previous 9 2-Next 2	**3.** You can select one of the following options: Press **1** – **Previous** Press **2** – **Next** When finished reviewing the data, you can: Press **Clear** to return to the Patient ID entry screen. Press **Menu** to return to the **Menu Mode** menu. Press **On/Off** to turn off the monitor.	The number that appears to the right of **1-Previous** and **2-Next** on the monitor indicates the number of tests available for review. The display also shows: **Patient ID or Name** (**p:** prompt) **Comment Code** (Number in box) **Test Type** (Glucose) **Date and Time of test** **Operator ID** (**o:** prompt) Note that test date and time alternates with Operator ID.

5.8 mmol/L

Data Review for All Patient Data

Please refer to the beginning of this Data Review chapter for step-by-step instructions to access the Data Review menu.

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*
Data Review 1-Patient by OperID 2-Patient by PatID 3-All Patient Data 4-Control Data 5-Proficiency Data 6-Linearity Data	**1.** Press **3** to select **All Patient Data**.	The monitor shows the most recent patient test result.
p:Smith, John Q 2 **105** mg/dL Glucose o:391937 1-Previous 9 2-Next 2 5.8 mmol/L	**2.** You can select one of the following options: Press **1** – **Previous** Press **2** – **Next** When finished reviewing the data, you can: Press **Clear** to return to the Data Review screen. Press **Menu** to return to the **Menu Mode** menu. Press **On/Off** to turn off the monitor.	The number that appears to the right of **1-Previous** and **2-Next** on the monitor indicates the number of tests available for review. The display also shows: **Patient ID or Name** (**p:** prompt) **Comment Code** (Number in box) **Test Type** (Glucose) **Date and Time of test** **Operator ID** (**o:** prompt) Note that test date and time alternates with Operator ID.

Data Review for Control Data

The monitor stores the last 1000 control test results. Please refer to the beginning of this Data Review chapter for step-by-step instructions to access the Data Review menu.

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*
Data Review 1-Patient by OperID 2-Patient by PatID 3-All Patient Data 4-Control Data 5-Proficiency Data 6-Linearity Data	**1.** Press **4** to select **Control Data**.	The monitor shows the result of the most recent control test.
Low **PASS** Glucose 06/26/07 10:06 AM 1-Previous 1 2-Next 2	**2.** You can select one of the following options: Press **1** – **Previous** Press **2** – **Next** When finished reviewing the data, you can: Press **Clear** to return to the Data Review screen. Press **Menu** to return to the **Menu Mode** menu. Press **On/Off** to turn off the monitor.	The number that appears to the right of **1-Previous** and **2-Next** on the monitor indicates the number of tests available for review. The display also shows the acceptable range for this test and: **Comment Code** (Number in box) **Level** (low, mid, high) **Range** (if numeric) **Test Type** (Glucose) **Date and Time of test** **Operator ID** (**o:** prompt) Note that test date and time alternates with Operator ID.

Data Review for Proficiency Data

The monitor stores the last 20 proficiency test results. Please refer to the beginning of this Data Review chapter for step-by-step instructions to access the Data Review menu.

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*
Data Review 1-Patient by OperID 2-Patient by PatID 3-All Patient Data 4-Control Data 5-Proficiency Data 6-Linearity Data	**1.** Press **5** to select **Proficiency Data**.	The monitor shows the most recent proficiency test result.
s:123456 12 **105** mg/dL Glucose 06/26/07 9:51 AM 1-Previous 9 2-Next 2 5.8 mmol/L	**2.** You can select one of the following options: Press **1** – **Previous** Press **2** – **Next** When finished reviewing the data, you can: Press **Clear** to return to the Data Review screen. Press **Menu** to return to the **Menu Mode** menu. Press **On/Off** to turn off the monitor.	The number that appears to the right of **1-Previous** and **2-Next** on the monitor indicates the number of tests available for review. The display shows the following: **Sample ID** (**s:** prompt) **Comment Code** (Number in box) **Test Type** (Glucose) **Date and Time of test** **Operator ID** (**o:** prompt) Note that test date and time alternates with Operator ID.

Data Review for Linearity Data

The monitor stores the last linearity panel that includes a maximum of 4 replicates for 5 levels (20 tests). Please refer to the beginning of this Data Review chapter for step-by-step instructions to access the Data Review menu.

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
Data Review 1-Patient by OperID 2-Patient by PatID 3-All Patient Data 4-Control Data 5-Proficiency Data 6-Linearity Data	**1.** Press **6** to select **Linearity Data**.	The monitor shows linearity tests first by level (1, 2, 3, 4, 5) then by order within each level. If no tests are stored for a level, then that level is skipped. At the top of the display the level (1 through 5) and test replicate (1 through 4) are displayed.
Level 1 Test 1 **45** mg/dL Glucose 06/26/07 10:33 AM 1-Previous 9 2-Next 2 2.5 mmol/L	**2.** You can select one of the following options: Press **1** – **Previous** Press **2** – **Next** When finished reviewing the data, you can: Press **Clear** to return to the Data Review screen. Press **Menu** to return to the **Menu Mode** menu. Press **On/Off** to turn off the monitor.	The number that appears to the right of **1-Previous** and **2-Next** on the monitor indicates the number of tests available for review. The display shows the following: **Comment Code** (Number in box) **Level** (1, 2, 3, 4, or 5) **Test Type** (Glucose) **Date and Time of test** **Operator ID** (**o:** prompt) Note that test date and time alternates with Operator ID.

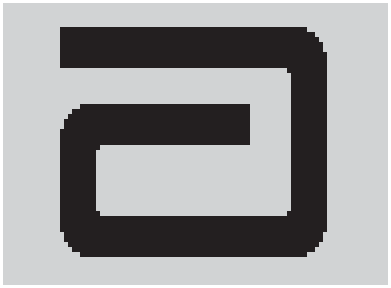
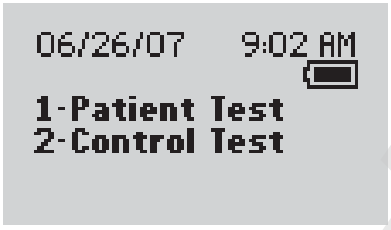
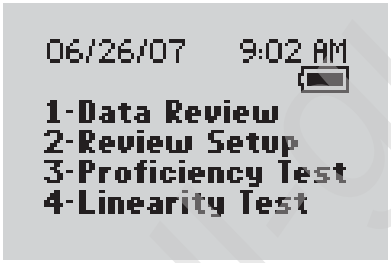
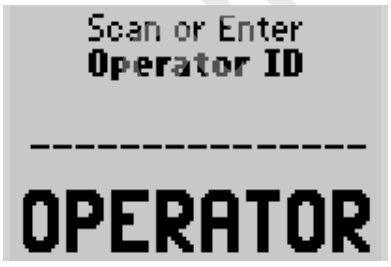
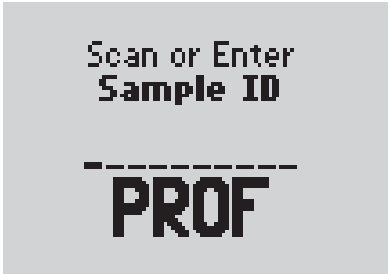
6. Proficiency Test

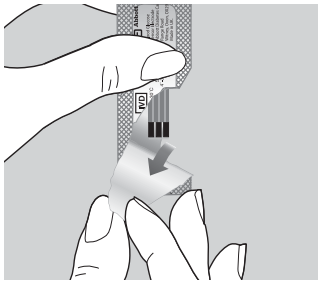
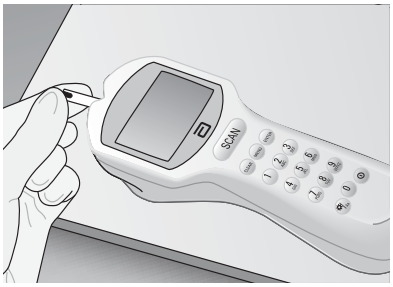
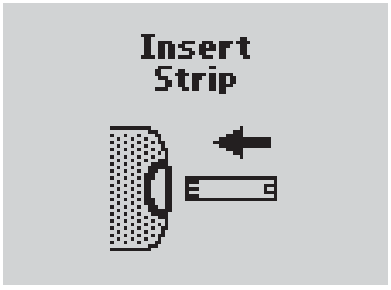
Proficiency Test

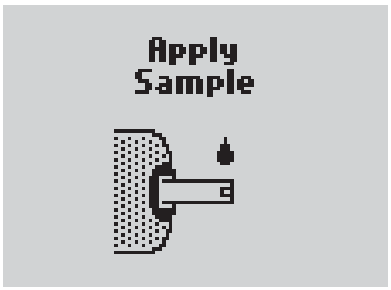
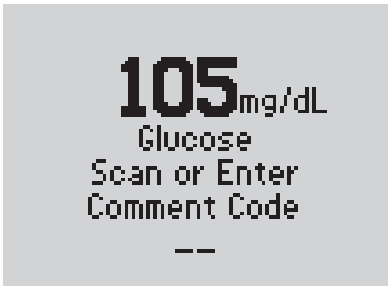
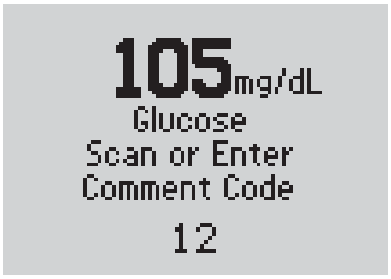
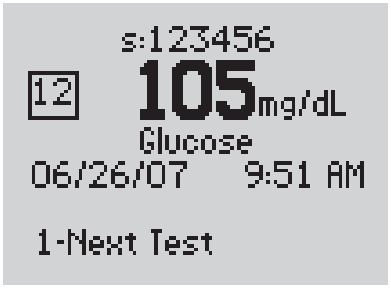
Please use the following procedures to perform a proficiency test. The Proficiency Test menu enables you to perform unknown sample test challenges if required by your institution's policy. This functionality may or may not be available depending on the configuration of the monitor through the data management system. The Proficiency Test is based on the Patient Test comment code.

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.*

IMPORTANT: ***Patient testing should be run in patient test mode only.***

What You See on the Display	What You Do	Comments
	**1.** Press the **On/Off** button 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 the **Menu** button.	The monitor starts in **Test Mode**. The Menu button will toggle the monitor to **Menu Mode**.
	**3.** Press **3** to select **Proficiency Test**.	
	**4.** 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.
	**5.** Scan or manually enter the Sample ID via the keypad, then press **Enter**.	The monitor will prompt for the Sample ID to be scanned or entered. PROF indicates proficiency test.

What You See on the Display	What You Do	Comments
	**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. 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.
		
	**8.** 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.

What You See on the Display	What You Do	Comments
	**9.** Bring proficiency survey specimens to room temperature. Mix each specimen well according to instructions from the survey provider. Wipe away any specimen on the tip of the vial before squeezing the vial and applying a drop to the test strip target area, covering the entire area. After applying the sample, recap the vial tightly.	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.
	**10.** 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	**11.** If you are prompted to enter a comment code, continue to step 12; otherwise, skip forward to step 13.	
 5.8 mmol/L	**12.** Scan or manually enter the comment code via the keypad, then press **Enter**.	The monitor displays the **Results** screen. The comment code number that was entered will appear in a box to the left of the test result.
 5.8 mmol/L	**13.** You may select one of the following options: Press **1** – **Next Test**. Press **Menu** to return to the **Menu Mode**. 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.	You can refer back to step 5 for the steps to perform any additional proficiency testing at this time.

7. Linearity Test

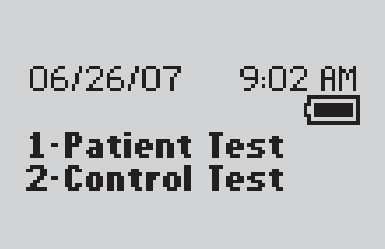
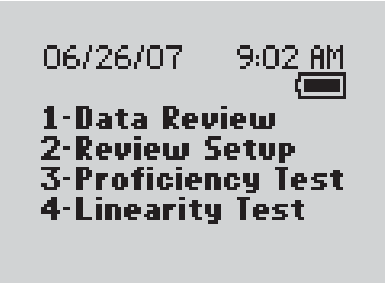
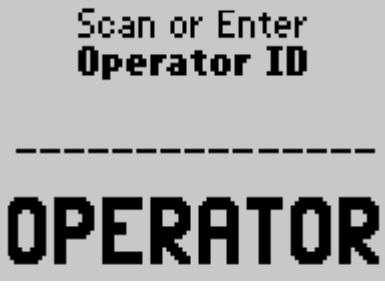
Linearity Test

The Linearity Test menu enables you to verify method linearity using a RNA Medical® brand Glucose Calibration Verification Control (CVC) kit. This kit contains assayed materials for use in confirming the calibration and linearity of glucose at the upper and lower limits of the reportable range and at three (3) points within the range. Each CVC kit is designed for specific test strip types. Please refer to the CVC package insert for compatible test strip types and detailed instructions for use.

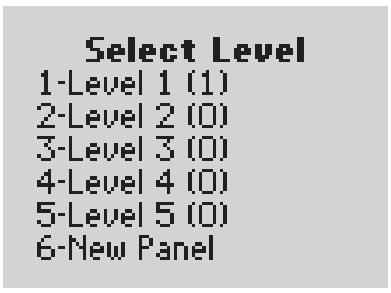
Please use the following procedure to perform a Linearity Test. This functionality may or may not be available depending on the configuration of the monitor through the data management system.

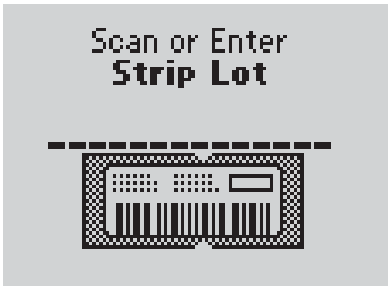
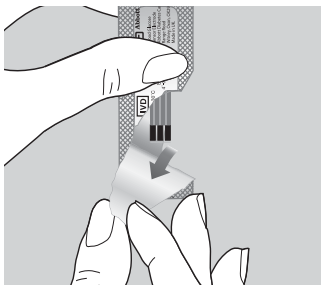
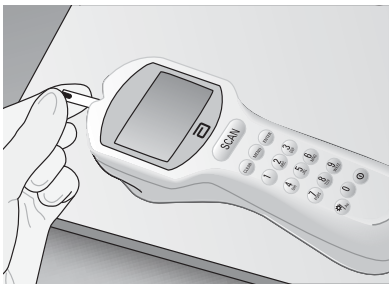
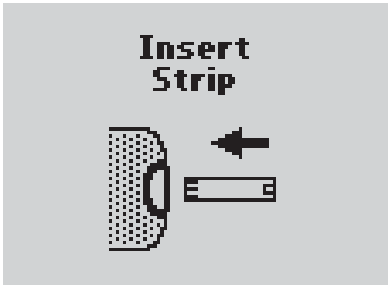
Note: *This section is only for Point of Care Coordinators, not operators. It illustrates some common settings. Depending on your institution's specific settings, some screens will display differently or not at all. If the monitor does not display the screens shown, please refer to Chapter 10, Troubleshooting.*

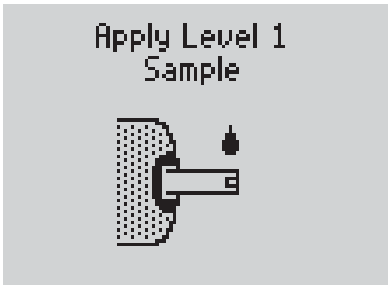
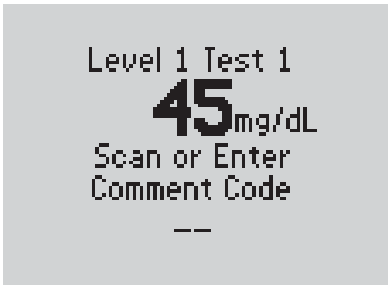
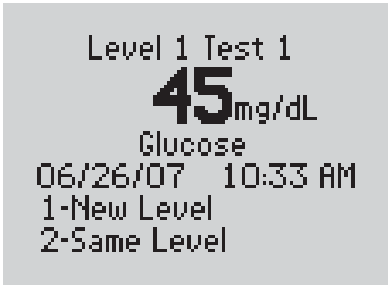
IMPORTANT: ***Patient testing should be run in patient test mode only. Results obtained in Linearity test mode should only be used to assess system linearity performance.***

What You See on the Display	What You Do	Comments
	**1.** Press **On/Off** to turn on 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 the **Menu** button.	The monitor starts in **Test Mode**. The Menu button will toggle the monitor to **Menu Mode**.
	**3.** Press **4** to select **Linearity Test**.	
	**4.** Press **Scan** 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.

Note: *You must use the same strip lot for the entire panel when performing a Linearity Test.*

What You See on the Display	What You Do	Comments
	**5.** Scan or manually enter the CVC kit lot number via the keypad, then press **Enter**.	LIN stands for Linearity.
	**6.** If the **New Panel** screen appears you may either: Press **1** – **ReEnter Kit Lot**. Press **2** – **Replace Panel**.	If the CVC kit lot number that was entered is different from the previous one, the monitor will prompt you to do one of two actions: Either re-enter the existing lot number or replace the existing lot number with the new lot number.
	**7.** Select the number of the level of the next test to be run. If you press **6** for a **New Panel**, the monitor will prompt you to confirm that you wish to replace the existing panel.	There can be up to 4 replicates per level. The number in the parentheses indicates the number of replicates already run for that level. When a level is full, the number 4 will appear in parentheses, indicating that all four replicates have been completed for this level. For example **1 - Level 1(4)**.

What You See on the Display	What You Do	Comments
	**8.** 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.
	9. 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.
		
	**10.** 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. The monitor will prompt you to apply the sample to the test strip.

What You See on the Display	What You Do	Comments
	**11.** Follow the instructions in the CVC kit package insert. Then apply a drop of the sample to the target area.	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.
	**12.** 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.
 2.5 mmol/L	**13.** Note the result. 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 14.	The display includes the level and test numbers, date and time. **Level** indicates Level 1-5. **Test** indicates replicates 1-4 for that level.
 2.5 mmol/L	**14.** You can do one of the following options: Press **1 – New Level**. Press **2 – Same Level**. Press the **Menu** button to return to the **Menu Mode**. Press **On/Off** to turn off monitor. Remove the test strip from the monitor and discard it when finished testing. Follow your facility's biohazard disposal policy.	You can press **2** to perform more tests for the **Same Level** (return to step 8) or press **1** to perform tests for **New Level** (return to step 7).

8. Review Setup

Monitor Configuration

The Precision Xceed Pro Monitor configuration settings are enabled via the data management system. These settings can be viewed on the hand-held device, but cannot be changed on it. Settings that are configured through the data management system are:

Upload interval

- Length of time between data uploads.
- Whether you can continue to test ("allow test" or "warn") or not ("lockout").

Operator ID

- Whether the Operator ID is required, optional, or not used for all tests.
- Define the Operator ID prompt
- The number of digits that are acceptable for the Operator ID (can set a minimum and maximum number of digits, between 1 and 30).
- With manual entry of the Operator ID, determine whether a check digit is required (modulus 10 or 11).
- Decide acceptable formats for the Operator ID barcode. The administrator selects one or more of the following:
    - Interleaved 2 (I 2) of 5 (with USS Check Digit, with OPCC Check Digit or without a check digit)
    - Code 128
    - Codabar
    - Code 93
    - Code 39 (with USS Check Digit, with OPCC Check Digit, with an alphanumeric check digit, with full ASCII check digit or without a check digit)
    - RSS
    - EAN (see Chapter 12 for additional information on barcodes)
- The monitor can truncate (ignore) the leading digits and/or the last digits of an Operator ID. The monitor can be set to select specific digits of an Operator ID. The number of digits is configured in the data management system.

Patient Tests / Patient ID

- Determine whether the Patient ID is required, optional, or not used for patient tests.
- Define the Patient ID prompt.
- The number of digits are acceptable for the Patient ID (can set a minimum and maximum number of digits, between 1 and 30).
- Permission for manual entry of the Patient ID.
- Determine whether duplicate entry of a manually entered ID is required.
- With manual entry of the Patient ID, determine whether a check digit is required (modulus 10 or 11).
- Decide acceptable formats for the Patient ID barcode. The administrator selects one or more of the following:
    - I 2 of 5 (with USS Check Digit, with OPCC Check Digit, or without a check digit)
    - Code 128
    - Codabar
    - Code 93
    - Code 39 (with USS Check Digit, with OPCC Check Digit, with an alphanumeric check digit, with full ASCII check digit or without a check digit)
    - RSS
    - EAN (see Chapter 12 for additional information on barcodes)
- The monitor can truncate (ignore) the leading digits and/or the last digits of a Patient ID. The monitor can be set to select specific digits of a Patient ID. The number of digits is configured in the data management system.
- Decide whether confirmation of the Patient ID required.
- Determine how the ID will be confirmed.
- Decide whether comment code is required, optional, or not used for patient tests that are in the acceptable range for the facility and the test strip.
- Decide whether comment code is required, optional, or not used for patient tests that are outside of the acceptable range for the facility and the test strip.

Control Tests

- Set which levels of control solution are required, optional, or not used by your facility. The monitor can be configured to run any combination of low, mid, and high control solution tests.
- Set whether control solution test results display as numeric or as Pass/Fail.
- Determine whether a comment code is required, optional, or not used for control tests that are within the acceptable range for the facility and the test strip.
- Decide whether a comment code required, optional, or not used for control tests that are outside of the acceptable range for the facility and the test strip.

QC Interval

- Determine how frequently QC tests need to be run. This can be set to a number of hours or up to three specified times during the day.
- Decide whether the operator can continue to test ("allow test" or "warn") or not ("lockout") when the QC interval is expired.

Operator ID

- Decide whether an operator can continue to test ("allow test" or "warn") or not ("lockout") when the Operator ID has expired.
- Decide the number of days before the Operator ID is set to expire that the operator will see a notification on the monitor.

Strip Lot

- Decide whether an operator can continue to test ("allow test" or "warn") or not ("lockout") when a strip lot is scanned or entered to the monitor for a lot of strips that is not on the approved strip lot list. The maximum number of glucose strip lots that can be downloaded to the Precision Xceed Pro monitor is 18.

Other

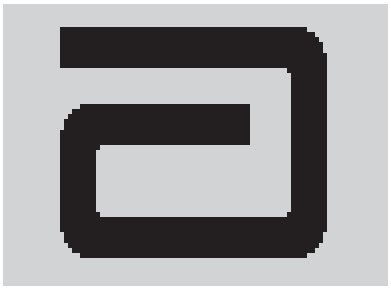
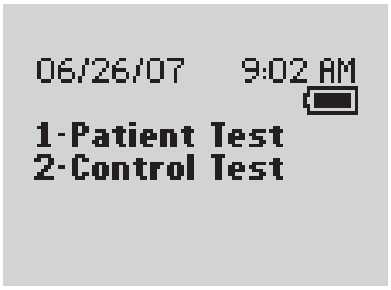
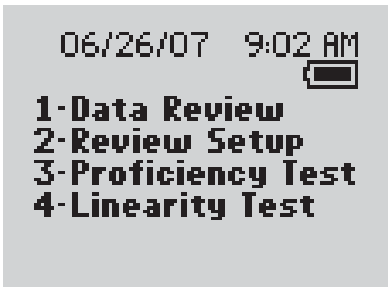
- Decide what additional information to download to a monitor through the data management system: Lists of operators, lists of strip lots, or lists of patients.
- Determine whether the monitor displays results in mg/dL or mmol/L.
- Decide whether any additional free text comments are stored with a test record. These can be required, optional or not used.
- Decide whether to configure the monitor for proficiency tests.
- Decide whether to configure the monitor for linearity tests.
- Determine what language (such as English) displays on the monitor.
- Turn the audible indicator off/on.
- Configure the monitor to use alkaline or rechargeable batteries.
- Decide whether, after a patient test, the monitor will automatically turn off after 4 - 10 minutes.
- Date display configuration on the monitor. The date can be configured to the following formats:
    - mm/dd/yy
    - dd/mm/yy
    - dd-mm-yy
    - mm-dd-yy
- Time display configuration on the monitor. The time can be configured to the following formats:
    - hh:mm AM/PM
    - h:mm AM/PM
    - AM/PM h:mm
    - hh:mm (24 hour)

Action Range/Critical Range

- Decide whether to set an action range, and what the range will be.
- Decide whether to set a critical range, and what the range will be.

Review Setup

Note: *This section illustrates some representative settings.*
If the monitor does not display these screens, 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 the **Menu** button.	The monitor starts in **Test Mode**. The **Menu** button will toggle the monitor to **Menu Mode**.
	**3.** Press **2** to select **Review Setup**.	

Review Test Setup for All Tests

Note: *This section illustrates some representative settings.*
If the monitor does not display these screens, please refer to Chapter 10, Troubleshooting.

What You See on the Display	What You Do	Comments
Review Setup 1-Test Setup 2-System Status	**1.** Press **1** for **Test Setup**.	
Test Setup 1-All Tests 2-Test Type 3-Patient Test 4-Control Test 5-Security	**2.** Press **1** for **All Tests** to continue to the **All Tests Upload Interval** screen.	
All Tests Upload Interval **Allow Test** **24 hours** 1-Next	**3.** Press **1-Next** to continue to the **All Tests Operator ID** screen.	
All Tests Operator ID **Optional** **1 - 30 digits** 1-Next	**4.** Press **1-Next** to continue to the **All Tests Operator ID Truncation** screen.	
All Tests Operator ID Truncation **First/Last** 1-Next	**5.** Press **1-Next** to continue to the **Operator ID Prompt** screen.	
All Tests Operator ID Prompt **Operator ID** 1-Next	**6.** Press **1-Next** to return to the **Test Setup** menu.	

Review Test Setup for Test Type

Note: *This section illustrates some representative settings.*
If the monitor does not display these screens, please refer to Chapter 10, Troubleshooting.

What You See on the Display	What You Do	Comments
Review Setup 1-Test Setup 2-System Status	**1.** Press **1** for **Test Setup**.	
Test Setup 1-All Tests 2-Test Type 3-Patient Test 4-Control Test 5-Security	**2.** Press **2** for **Test Type** to continue to the **Test Type Glucose Units** screen.	
Test Type Glucose Units **mg/dL** 1-Next	**3.** Press **1**-**Next** to continue to the **Test Type Glucose Action Range** screen.	
Test Type Glucose Action Range **Disabled** 1-Next	**4.** Press **1**-**Next** to continue to the **Test Type Glucose Critical Range** screen.	
Test Type Glucose Critical Range **Disabled** 1-Next	**5.** Press **1**-**Next** to continue to the **Test Setup** menu.	

Review Test Setup for Patient Test

Note: *This section illustrates some representative settings.*
If the monitor does not display these screens, please refer to Chapter 10, Troubleshooting.

What You See on the Display	What You Do	Comments
Review Setup 1-Test Setup 2-System Status	**1.** Press **1** for **Test Setup**.	
Test Setup 1-All Tests 2-Test Type 3-Patient Test 4-Control Test 5-Security	**2.** Press **3** for **Patient Test** to continue to the **Patient Test Patient ID** screen.	
Patient Test Patient ID **Optional** **1 - 30 digits** 1-Next	**3.** Press **1**-**Next** to continue to the **Patient Test Patient ID Truncation** screen.	
Patient Test Patient ID Truncation **First/Last** 1-Next	**4.** Press **1**-**Next** to continue to the **Patient Test Comment Code If In-Range** screen.	
Patient Test Comment Code If In-Range **Disabled** 1-Next	**5.** Press **1**-**Next** to continue to the **Patient Test Comment Code If Out-of-Range** screen.	
Patient Test Comment Code If Out-of-Range **Disabled** 1-Next	**6.** Press **1**-**Next** to continue to the **Patient Test Patient ID Prompt** screen.	
Patient Test Patient ID Prompt **Patient ID** 1-Next	**7.** Press **1**-**Next** to continue to the **Patient Test Repeat Manual ID Entry** screen.	
Patient Test Repeat Manual ID Entry **Disabled** 1-Next	**8.** Press **1**-**Next** to return to the **Test Setup** menu.	

Review Test Setup for Control Test

Note: *This section illustrates some representative settings.*
If the monitor does not display these screens, please refer to Chapter 10, Troubleshooting.

What You See on the Display	What You Do	Comments
Review Setup 1-Test Setup 2-System Status	**1.** Press **1** for **Test Setup**.	
Test Setup 1-All Tests 2-Test Type 3-Patient Test 4-Control Test 5-Security	**2.** Press **4** for **Control Test** to continue to the **Control Test Levels** screen.	
Control Test Levels **(Low, High)** 1-Next	**3.** Press **1**-**Next** to continue to the **Control Test Result** screen.	
Control Test Result **Pass/Fail** 1-Next	**4.** Press **1**-**Next** to continue to the **Control Test Comment Code If In-Range** screen.	
Control Test Comment Code If In-Range **Disabled** 1-Next	**5.** Press **1**-**Next** to continue to the **Control Test Comment Code If Out-of-Range** screen.	
Control Test Comment Code If Out-of-Range **Disabled** 1-Next	**6.** Press **1**-**Next** to return to the **Test Setup** menu.	

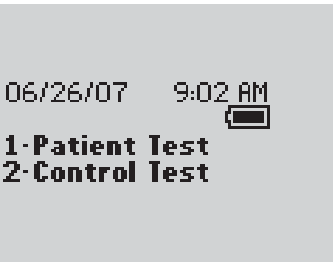
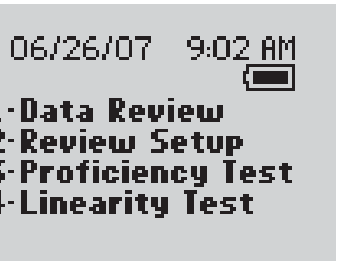
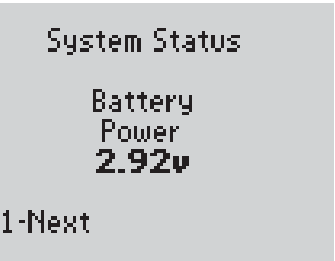
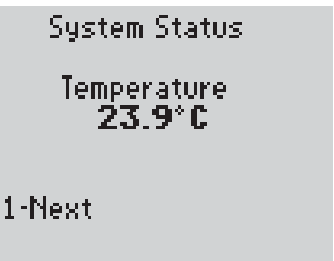
Review Test Setup for Security

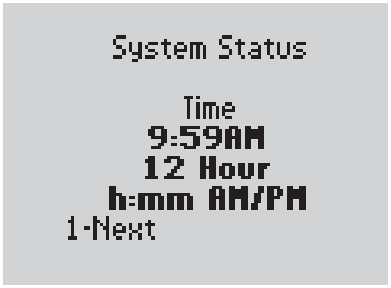
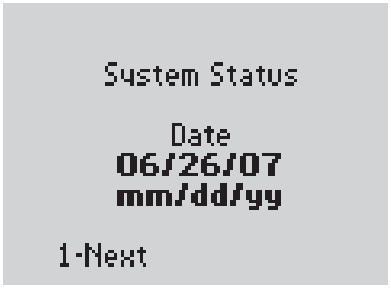
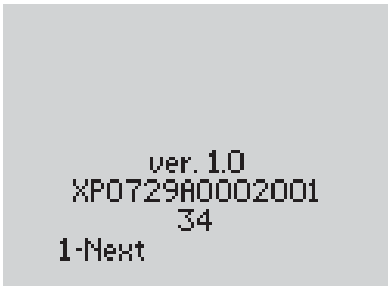
Note: *This section illustrates some representative settings.*
If the monitor does not display these screens, please refer to Chapter 10, Troubleshooting.

What You See on the Display	What You Do	Comments
Review Setup 1-Test Setup 2-System Status	**1.** Press **1** for **Test Setup**.	
Test Setup 1-All Tests 2-Test Type 3-Patient Test 4-Control Test 5-Security	**2.** Press **5** for **Security** to continue to the **Security QC Interval** screen.	
Security QC Interval **Allow Test** **24 hours** 1-Next	**3.** Press **1**-**Next** to continue to the **Security Operator ID Not Certified** screen.	
Security Operator ID Not Certified **Allow Test** 1-Next	**4.** Press **1**-**Next** to continue to the **Security Strip Lot Not on List** screen.	
Security Strip Lot Not on List **Allow Test** 1-Next	**5.** Press **1**-**Next** to continue to the **Security Patient Data Not Confirmed** screen.	
Security Patient Data Not Confirmed **Allow Test** 1-Next	**6.** Press **1**-**Next** to continue to the **Security Confirm Patient Data** screen.	
Security Confirm Patient Data **Year of Birth** 1-Next	**7.** Press **1**-**Next** to return to the **Test Setup** menu.	

System Status

Note: *This section illustrates some representative settings.*
If the monitor does not display these screens, 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 the **Menu** button.	The monitor starts in **Test Mode**. The **Menu** button will toggle the monitor to **Menu Mode**.
	**3.** Press **2** select **Review Setup**.	
	**4.** Press **2** to continue to the **System Status Battery Power** screen.	
	**5.** Press **1**-**Next** to continue to the **System Status Temperature** screen.	
	**6.** Press **1**-**Next** to continue to the **System Status Time** screen.	

What You See on the Display	What You Do	Comments
	**7.** Press **1-Next** to continue to the **System Status Date** screen.	
	**8.** Press **1-Next** to continue to the **System Status Software Version and Serial Number** screen.	
	**9.** Press **1-Next** to continue to the **Review Setup** menu.	The number that appears on your monitor may be different from the number that appears here.

9. Data Upload

Docking Station

Connecting Cables to the Docking Station

Mounting Instructions

Data Upload

Once the test results have been collected during a prescribed period of time, they can be uploaded into the data management system. The data management system provides a simple and automated way to collect, report and transfer data.

To start the upload of data, simply place the Precision Xceed Pro Monitor into the docking station. The monitor will first turn on if it isn't already, and then automatically upload data to the data management system. After upload is complete, the monitor will display **Upload Successful, Turning Off** and then shut down.

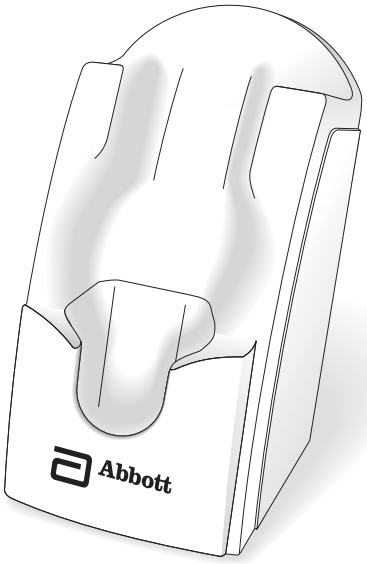
During communications, this screen appears and the arrows rotate to indicate that the system is working. The arrows may occasionally pause. During data upload, the monitor cannot be used for testing.

Note: *If the monitor is removed before data transmission is complete, some data may not be uploaded. The data will be uploaded as part of the next data transmission.*

If a problem occurs with the data upload, an error message may appear on the monitor. If the monitor is removed from the docking station while an upload is in process, the monitor will display **Last upload incomplete, Redock meter, Turning Off**. The monitor will then shut down. Error messages are shown in Chapter 10 Troubleshooting chapter. Further troubleshooting information for any data upload question is provided in the data management user manual.

After a data upload error has occurred, the monitor will display a warning each time it is turned on. The monitor may still be used for testing by pressing **1** to **Continue**. Once the monitor has successfully been docked, the warning will disappear.

Docking Station



The Precision Xceed Pro System offers an optional docking station that provides a means for hands-free, automatic data transfer (upload/download) between the Precision Xceed Pro Monitor and a PC running the data management application software.

Set up the docking station outside patient vicinity. The docking station has a hinged base that allows it to sit on a desktop or to be mounted to a wall using the mounting plate supplied by Abbott Diabetes Care (ADC).

The Precision Xceed Pro Monitor is compatible with older Abbott docking stations that have LED lights, lit with an optional AC Adapter. The following LED information applies only to older docking stations.

The green LED indicates that the docking station is connected to a power supply.

The yellow LED (steady) indicates that the monitor has been properly placed into the docking station.

The yellow LED (flashing) indicates data transfer (upload/download) is in process.

The AC Adapter is not required. If the AC adapter is not used, data transfer will still occur but the LEDs will not light up.

Note: *Use only the AC adapter supplied by ADC. Use of any other adapter may cause serious damage to the docking station and to the Precision Xceed Pro Monitor while it is in the docking station.*

Connecting Cables to the Docking Station

The docking station has two ports located on the back: an AC adapter port (older docking stations only), and a data transfer port ⇄. The data transfer port connects the docking station to a variety of transfer options using the RS-232 communications cable supplied by ADC.

The following network connections can be established (Figures 1-2).

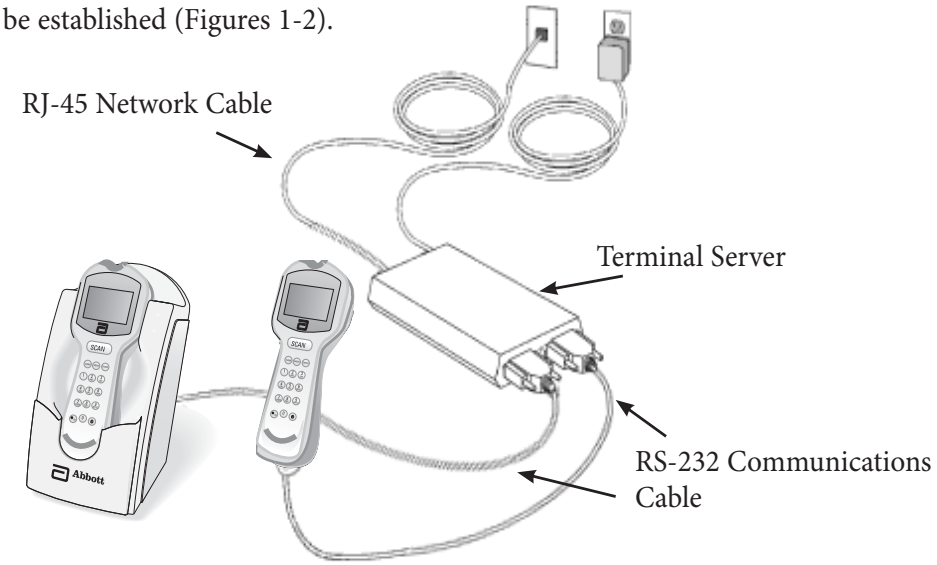


Fig. 1 - Connection to Data Management System via Terminal Server

1. Connect the terminal server AC adapter to a power source.
2. Connect the RS-232 cable to the terminal server and to the docking station data transfer port.
3. Connect the network cable to the RJ-45 network jack.

Note: *For plug-connected equipment where protecting grounding is required, plug the equipment into a supply outlet that has a ground connection.*

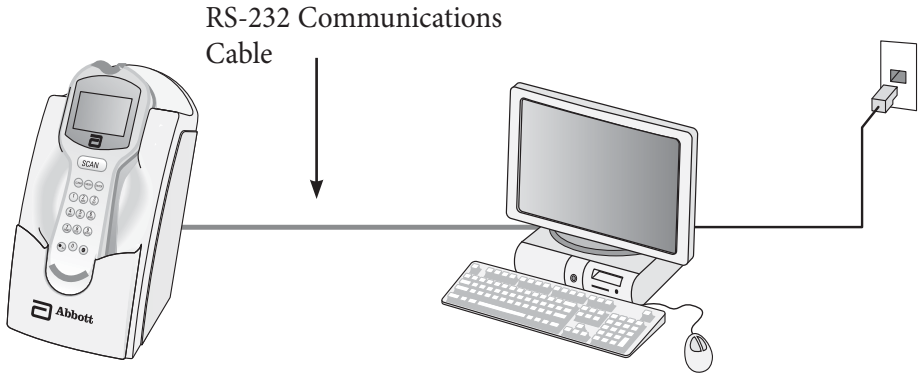


Fig. 2 - Connection to Data Management System via Networked PC Running Data Repeater Software

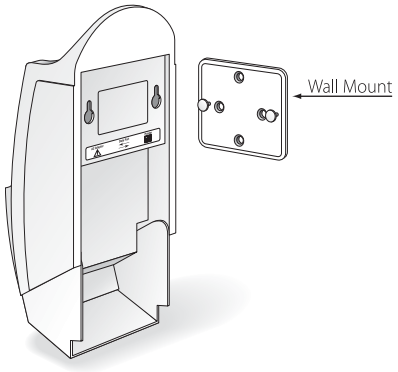
1. Connect the RS-232 cable to a serial port on a networked PC at the nurses' station and to the docking station data transfer port.
2. Ensure that the Networked PC has power and a working network connection. Instructions for installing Abbott Data Repeater are available separately.

Mounting Instructions

The docking station may be mounted vertically if desired. This operation is similar to mounting a telephone on the wall.

Instructions:

1. Drill the holes to match to the wall mount.
2. Place the wall mount on the wall and insert the four enclosed screws.
3. Align the two holes in the dock station with the two mounting anchors.
4. After aligning the holes, press in and then down to secure the docking station.



10. Troubleshooting

Troubleshooting Patient Test Results

This section describes conditions that can cause erroneous patient test results. Refer to the Precision PCx Plus Test Strip package insert for test strip specification information 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.

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.
- Arterial or capillary blood tested in venous mode.

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, call Abbott Technical Support at 1-877-529-7185. Outside the United States, 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 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.
- Check storage temperatures: Control solutions and test strips must be stored within ranges specified on the respective carton inserts for control solutions and test strips.
- Check that the temperature conditions in the room where the tests are being performed are within the acceptable operating range. Refer to 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 PCx Plus 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, call Abbott Technical Support at 1-877-529-7185. Outside the United States, contact your local Abbott Diabetes Care office or distributor.

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.
- Check storage temperature. For CVC kit storage temperature range, please refer to the package insert in the CVC kit. Test Strips must be stored within ranges specified on the test strip carton insert.
- Check that the temperature conditions in the room where the tests are being performed are within the acceptable operating range. Refer to the Precision PCx Plus Test Strip and CVC kit instructions for use.
- Check CVC bottle for open bottle expiration date.
- Use a new test strip for each test.
- Use only Precision PCx Plus 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, call Abbott Technical Support at 1-877-529-7185. Outside the United States , contact your local Abbott Diabetes Care office or distributor.

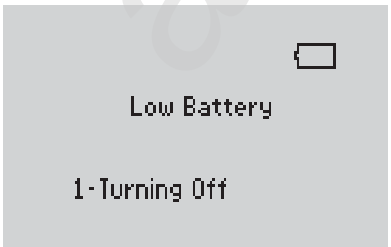
Error Messages

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

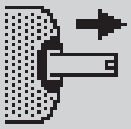
For each corresponding message, an explanation is given and appropriate responses are described. In many situations, it may be possible to proceed with some of the functions, at least temporarily, before attending to the problem. (For example, when the batteries are too low to permit testing, it may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

If any problem persists, record the error message displayed, which may include a four-digit error code, and call Abbott Technical Support at 1-877-529-7185. Outside the United States, contact your local Abbott Diabetes Care office or distributor.

When You Turn on the Monitor, or During Use:

Symptom/Error Message	Explanation	How To Respond
The display is blank.	The monitor has little or no power.	Verify proper battery installation. If the problem persists, install new batteries. See Chapter 11, Maintenance for more information.
	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:

Symptom/Error Message	*Explanation*	*How To Respond*
Configuration Required 1-Turn Off	The monitor is shipped from the factory without configuration. This screen will appear the first time you turn on the meter 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.
Last upload incomplete Redock meter 1-Continue	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.
Meter Error nnnn 1-Turn Off	The monitor may have a problem that prevents it from operating properly. One of several four-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 four digit error code and contact Abbott Technical Support.
Remove Strip 	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.

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 Abbott Technical Support or your local Abbott office or distributor.*

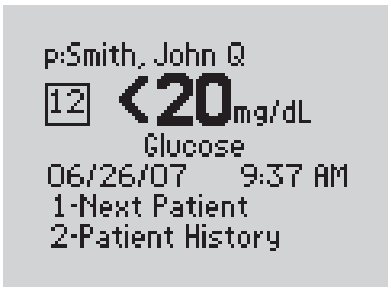
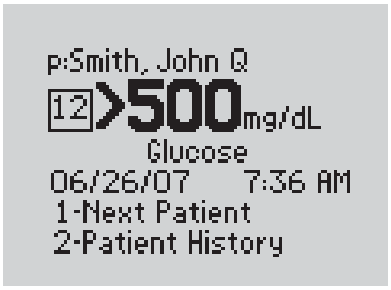
When a Test is Selected:

Symptom/Error Message	*Explanation*	*How To Respond*
Low, High **Control Test** **Required** 1-Exit 2-Continue	The 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 control tests indicated in the message.
Test Memory Upload Required 1-Exit 2-Continue	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.
Patient ID 03091971 **Patient Data** **Not Found** 1-ReEnter ID 2-Continue	The system cannot confirm the Patient ID.	Press **1** to **ReEnter** the Patient ID. Or, Press **2** to **Continue** testing.
Scan or Enter **Patient ID** _____ **Invalid ID** Strip Lot	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.

During Any Test:

Symptom/Error Message	*Explanation*	*How To Respond*
Scan or Enter **Strip Lot** **----------** **Invalid Lot** Barcode	The barcode just scanned was not read correctly. 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.** Re-enter the lot number using the barcode scanner or keypad. **2.** Notify the system administrator. The problem may be the printing of the barcode or the setup.
Scan or Enter **Strip Lot** **----------** **Invalid Lot** Date Expired	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.
Scan or Enter **Linearity Kit Lot** **-----------** **Invalid ID** Too Long	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.
Strip Lot 05013640170502 **Is Not on the** **Strip Lot List** 1-ReEnter Lot 2-Continue	The ID or lot number just scanned or entered is not on the list of acceptable ID's or lot numbers defined for this monitor. (The menu items **1– ReEnter Lot** and **2 – Continue** appear 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.

Symptom/Error Message	Explanation	How To Respond
Operator ID 123456789 **Is Not on the Operator List** 1-ReEnter ID 2-Continue	The Operator ID just entered is not on the list of acceptable Operator ID's defined for this monitor. (The menu items **2 – Continue** appear 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.
Operator ID 12345678 **Is Not on the Operator List** 1-ReEnter ID	The Operator ID entered is not on the list of acceptable Operator ID's defined for this monitor.	**1.** Press **1** to **ReEnter** the Operator ID. **2.** If the problem persists, contact the system administrator for further information on operator certification.
Operator ID 123456789 **Date Expired** 1-ReEnter ID 2-Continue	The Operator ID entered has expired. (The menu item **2 – Continue** appear only if this option is set to Warn.)	**1.** Press **1** to **ReEnter** the ID using the barcode or keypad. Or, Press **2** to **Continue** testing using the Operator ID already entered. **2.** If the problem persists, notify the system administrator.
Operator ID Expires in nn Days 1-Continue	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 on operator certification.

Symptom/Error Message	Explanation	How To Respond
 1.1 mmol/L	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.
 >27.8 mmol/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.	**1.** Remove the old test strip. **2.** 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:	**1.** Press **1** to repeat the test with a **New Strip** or **2** to **Exit**. **2.** If the error occurs again, record the four-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.

Symptom/Error Message	Explanation	How To Respond

When a Control Test is selected:

Unexpected Level Low expected High entered 1-ReEnter Lot 2-Continue	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:

New Panel **456789** **will replace** **Old Panel** **123456** 1-ReEnter Kit Lot 2-Replace Panel	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.	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.

When Data Review is Selected:

No Stored Tests 1-Exit	There are no stored test results for the type of data requested	Press **1** to **Exit** and return to the **Data Review Menu**.
XXX 1-Previous 6 2-Next 3	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					
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

Federal regulations in the United States adopted pursuant to the Occupational Safety and Health Act (See 29 C.F.R. 1910.1030) require that contaminated instruments/equipment be decontaminated and packaged prior to shipping in a manner which minimizes the risk of exposing those persons involved in handling or transporting this equipment. You are responsible for complying with these regulations.

At a minimum, before returning an instrument 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 call Abbott Technical Support at 1-877-529-7185 for instructions. Outside the United States, 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 Point of Care System. For technical assistance, please call Abbott Technical Support at 1-877-529-7185, twenty-four (24) hours per day. Outside the United States, contact your local office or distributor listed below.

ASIA

Australia and New Zealand
Abbott Australasia
Abbott Diabetes Care
Victoria, Australia
Australia Tel: +1-800-801-478
New Zealand Tel: +0800-106-100

China
Abbott Laboratories Ltd.
Shanghai, China
Tel: +800-820-3959

Hong Kong
Abbott Laboratories Ltd.
North Point, Hong Kong
Tel: +852-2806-4488

Indonesia
Abbott Indonesia
Jakarta Selatan, Indonesia
Tel: +62-21-52961529

Japan
Abbott Japan Co., Ltd.
Chiba-ken, Japan
Tel: +0120378-055

Korea
Abbott Korea Ltd.
Seoul, Korea
Tel: +080-014-5757

Malaysia
Abbott Laboratories (M) Sdn. Bhd.
Shah Alam, Selangor, Malaysia
Tel: +00-603-5569-1919

Pakistan
Abbott Laboratories (Pakistan) Ltd
Karachi, Pakistan
Tel: +92-21-504-5680

Philippines
Abbott Laboratories
Metro Manila, Philippines
Tel: +632-6890-495

Singapore
Abbott Laboratories (S) Pte Ltd
Singapore
Tel: +65-6272-2881

Taiwan
Abbott Laboratories LTD
Taipei, Taiwan
Tel: +0800-521-125

Thailand
Abbott Laboratories Ltd
Bangkok, Thailand
Tel: +66-2-252-2004

EUROPE

Austria
Abbott Ges.m.b.H
Abbott Diabetes Care
Vienna, Austria
Tel: +0800-930-093

Belgium and Luxembourg
Abbott Diabetes Care
Louvain-la-Neuve, Belgium
Belgium Tel: +0800 167-72
Luxembourg Tel: +32 10 475 480

Czech Republic
Abbott Laboratories s.r.o
Abbott Diabetes Care
Prague, Czech Republic
Tel: +800-189-564

Denmark
Abbott Laboratories A/S
Abbott Diabetes Care
Gentofte, Danmark
Tel: +45-3977-0190

Finland
Abbott Oy
Abbott Diabetes Care
Espoo, Finland
Tel: +0800-555-500

France

Abbott France
Abbott Diabetes Care
Rungis, France
Tel: +0800-10-11-56

Germany
Abbott GmbH & CO. KG
Abbott Diabetes Care
Wiesbaden, Germany
Tel: +0800-519-9519

Greece
Abbott Diabetes Care
Athens, Greece
Athens Tel: +30-210-998-5220
Thessaloniki Tel: +30-231-047-2947

Ireland
Abbott Diabetes Care
Dublin, Ireland
Tel: +1-800-776-633

Italy
Abbott Diabetes Care Italia
Roma, Italia
Tel: +800-334-216

Netherlands
Abbott B.V.
Abbott Diabetes Care
Amersfoort, Nederlands
Tel: +0800-022-8828

Norway
Abbott Norge as
Abbott Diabetes Care
Fomebu, Norway
Tel: +800-87-100

Poland
Abbott Laboratories
Poland Sp.z o.o
Abbott Diabetes Care
Warszawa, Poland
Tel: +0-801-379-799

Portugal
Abbott Laboratórios, Lda-
Abbott Diabetes Care
Amadora, Portugal
Tel: +800-200-891

Spain
Abbott Cientifica S.A.
Madrid, Spain
Tel: +900-300-119

Sweden
Abbott Scandinavia AB
Abbott Diabetes Care
Solna, Sweden
Tel: +020-190-11-11

Switzerland
ABBOTT AG
Abbott Diabetes Care
Baar, Switzerland
Tel: +041-768-44-47

United Kingdom
Abbott Diabetes Care
Maidenhead, Berkshire, UK
Tel: +0500-467-466

LATIN AMERICA

Argentina
Abbott Laboratorios de Argentina SA
Buenos Aires, Argentina
Tel: +0800-800-6334

Brazil
Abbott Laboratorios do Brasil Ltda
São Paulo, Brasil
Tel: +0800-703-0128

Chile
Abbott Laboratorios de Chile Ltda.
Santiago, Chile
Tel: +800-80-2226

Colombia
Abbott Laboratorios de Colombiá SA
Bogotá, Colombiá
Tel: +01-8000-522268

Dominican Republic
Abbott Laboratorios Republica Dominicana
Santo Domingo, Dominican Republic
Tel: +809-566-7181 (ext 263)

Guatemala

Abbott Laboratorios Guatemala
Cotio, Guatemala
Tel: 597-4109

Mexico
Abbott Laboratorios Mexico
Cuidad de Mexico, Mexico
Tel: +01-800-711-2208

Peru
Abbott Laboratorios Peru
Lima, Peru
Tel: +0-800-1-1215

Uruguay
Abbott Laboratorios Uruguay SA
Montivideo, Uruguay
Tel: +000-4054-342

Venezuela
Abbott Laboratories C.A.
Caracas, Venezuela
Tel: +0-800-Glucosa

MIDDLE EAST AND AFRICA

Israel
ILEX Medical Ltd.
Rosh-Ha'ayin, Israel
Tel: +972-3-938-5501

Turkey
Abbott Diabetes Care
Goztepe-Istanbul, Turkey
Tel: +0500-467-466

Saudi Arabia
Abbott Diabetes Care
Mediserv
Riyadh, Saudi Arabia
Tel: +800-0124-1238

South Africa
ADC South Africa
Abbott Laboratories
Gauteng, South Africa
Tel: +27-11-858-2000

NORTH AMERICA

Canada
Abbott Diabetes Care
Mississauga, Ontario, Canada
Tel: +1-800-387-8378 (English)
Tel: +1-800-465-2675 (French)

Puerto Rico
Abbott Laboratories
Abbott Diabetes Care
San Juan, Puerto Rico, USA
Tel: +1-787-750-5454

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

11. Maintenance

Cleaning the Exterior Surface

Replacing the Port Protector

Battery Life

Replacing the Batteries

The Precision Xceed Pro Monitor requires little routine maintenance. During testing, the sample remains outside the monitor, which significantly reduces the possibility of contamination. Follow your facility's procedures for maintenance and inspection of the system.

This chapter describes the maintenance tasks for the monitor.

- Cleaning the exterior surface of the monitor.
- Replacing the port protector.
- Replacing the batteries.

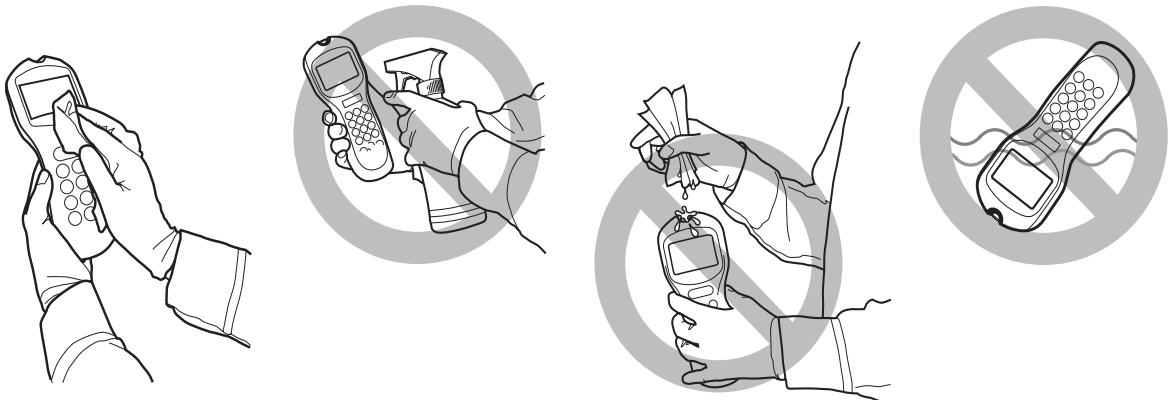
Cleaning the Exterior Surface

Cleaning the exterior surface of the Precision Xceed Pro Monitor daily is recommended. Follow your facility's policies and procedures for infection control, which may require more frequent cleaning.

IMPORTANT: ***The Joint Commission recommends cleaning after each patient for infection control.***

The monitor needs to be cleaned only with a damp cloth or a sponge and a mild detergent. It is suggested that the monitor be turned off while it is being cleaned. Do not immerse or autoclave the monitor or flood it with any liquid. Acceptable cleaning solutions include alcohol and ammonia based cleaners. Recommended solutions are Sani-Cloth® HB, Sani-Cloth® Plus, and Super Sani-Cloth®.

Bleach or hydrogen peroxide based cleaners will fade the monitor keypad. Hype-Wipe®, Dispatch® and Virox® 5 wipes are not recommended as they may fade the monitor keypad. Cleaning solutions not listed have not been tested and may damage the monitor. Contact Abbott Technical Support or your local Abbott office or distributor for the most up-to-date information on cleaning solutions.

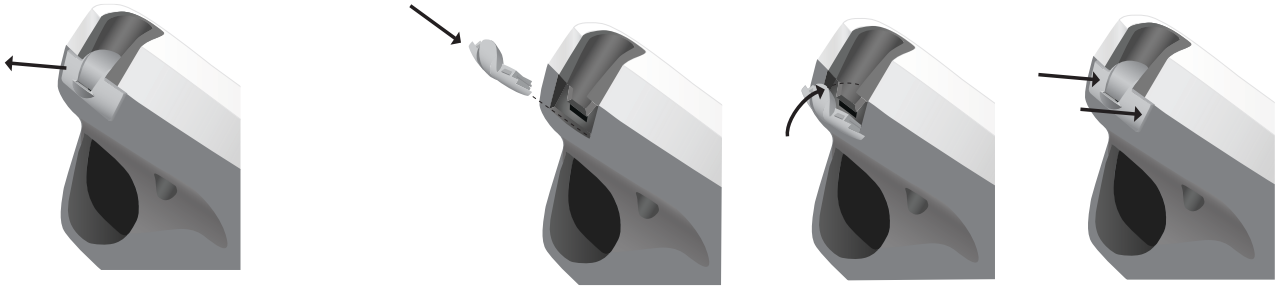


IMPORTANT: ***If a pre-packaged wipe is used for cleaning, excess fluid should be squeezed out to keep liquid from entering the monitor. Permanent damage could occur.***

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.

1. Lift the port protector from its left or right edge.
2. Pull gently away until the protector separates from the monitor.
3. Rest the flat bottom of the new port protector on the ledge of the test strip port.
4. Gently push both sides of the port protector until you hear the tabs snap into place. There should be no gap between the port protector and the monitor around the edges.



Battery Life

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.

Replacing the Batteries

Use the following procedure to install new batteries in the Precision Xceed Pro Monitor. The Precision Xceed Pro Monitor requires two (2) AA alkaline batteries or nickel-metal hydride (NiMH) rechargeable batteries (not supplied by Abbott Diabetes Care).

1. Turn the Precision Xceed Pro Monitor off by pressing the On/Off ⏻ button on the keypad.
2. Turn the monitor over and remove the battery door.
3. Pull the blue tab to remove the batteries (Figure 1).
4. Discard the used batteries in compliance with your local government regulations.
5. 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. Refer to Figure 2 below.
6. Align the battery compartment cover with the slots on the Precision Xceed Pro Monitor, then snap the cover into place.

⚠ **IMPORTANT:** ***Rechargeable batteries must be at room temperature before they are placed in the battery compartment. The docking station does not charge the batteries.***

Figure 1

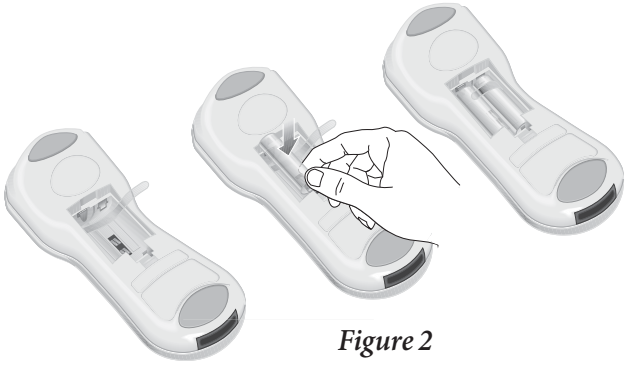


Figure 2

12. Specifications

Precision PCx Plus Test Strips

Precision Xceed Pro Monitor

Symbols

Barcode Types

Important Safety Instructions

The Precision Xceed Pro Point of Care System's performance has been evaluated in clinical studies at three independent sites. In all the studies, the Precision Xceed Pro Monitor was calibrated and used according to the labeling.

Precision PCx Plus Test Strips

The following information regarding Precision PCx Plus Blood Glucose Test Strips can be found in the test strip instructions for use:

- Strip Temperature Ranges for Testing
- Storage and Handling
- Quality Control
- Limitations of the Procedure
- Performance Characteristics

Precision Xceed Pro Monitor

Dimensions:

Length:	19.7 cm (7.7 in)
Width:	7.5 cm (2.96 in)
Thickness:	5.33 cm (2.1 in)
Weight:	256 grams (9 ounces)

Power Source:

Two standard alkaline AA batteries or nickel-metal hydride (NiMH) rechargeable batteries (not supplied by Abbott Diabetes Care). Battery performance is a function of how often the monitor is used and the duration time that testing is conducted.

Alkaline Battery: (2) cells 1.5 Volts, 2.8 Amp Hours typical capacity

Rechargeable NiMH batteries (2) cells 1.2 Volts, 1.1 Amp Hours minimum capacity (not supplied by Abbott Diabetes Care.)

Memory:

Patient Test Results: 2,500

Control Test Results: 1,000

Operator IDs: 6,000

Test Strip Lots: 18 Glucose

Proficiency Test Results: 20

Glucose Linearity Test Results: 20 Results (1 panel, 5 levels, 4 replicates per level)

Patient IDs: 6,000 patient records (name, gender, date of birth)

Environmental Specifications:

Product is intended for indoor use only.

Monitor Operating Temperature:	59 °F to 104 °F (15 °C to 40 °C)
Monitor Storage Temperature:	-4 °F to 122 °F (-20 °C to 50 °C)
Altitude:	Up to 7,200 feet (2,195 meters)
Humidity:	From 10% to 90% noncondensing
Mains Supply Voltage Fluctuations:	±10%
Transient Over-Voltages:	±1.5KV Rated
Rated Pollution Degree:	2

Symbols

There are special symbols that appear on the Precision Xceed Pro Monitor and docking station. The complete list of symbols and explanations are listed below. Please note: Some of the symbols listed below will not appear on your Precision Xceed Pro Monitor and docking station due to differences in local regulatory requirements.

Refers to Type BF Equipment, Per EN60601-1.

Refers to Type B Equipment, Per EN60601-1.

The double arrow symbol indicates the connector to be used for data transfer. The double arrow symbol may appear on the front panel of the docking station, beneath the LED display. (refer to Data Upload, Chapter 9).

Medical Equipment with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1, and CAN/CSA 22.2 NO. 601.1

3LAN

Laser hazard. This product complies with 21 CFR 1040.10 and IEC 60825-1:2001, CDRH Class II/ IEC Class 2 Laser Product.

Caution: Use of controls, adjustments or performance of procedures other than those specified herein may result in hazardous laser light exposure.

Class 2 laser scanners use a low power, visible light diode. As with any very bright light source, such as the sun, the user should avoid staring directly into the light beam. Momentary exposure to a Class 2 laser is not known to be harmful.

This label is permanently adhered to the back of the monitor

This symbol indicates that this product affords electrical protection as Class II equipment as described in IEC 601-1 Part 1.

This Way Up.

Represents the limitations of temperature for storage.

This product must not be disposed of via municipal waste collection. Separate collection for electrical and electronic equipment waste per Directive 2002/96/EC in the European Union is required. Contact the manufacturer for details.

Lot Number

Expiration Date. Use by YYYY-MM-DD or YYYY-MM.

IMPORTANT: Indicates that inconvenience to the operator may result if the instruction is not followed.

Note: Provides or refers the operator to additional or background information that may be helpful to them.

Do not reuse.

Re-order Number/Catalog Number


Date of Manufacture


Do not drink


Legal Manufacturer under *In Vitro* Diagnostic Medical Devices Directive 98/79/EC - Abbott Diabetes Care.


Consult instructions for use.


Recyclable.


For *in vitro* diagnostic use only.


Method of sterility for Lancets only. Sterilized using irradiation (Lancets only).


WARNING: Potential Biohazard. Consider all clinical specimens, reagents, controls, etc., that contain human blood or serum as potentially infectious. Always wear gloves and follow your facility's biohazard safety policies and procedures.

Barcode Types

Codabar:
Codabar is a self-checking, numeric-only barcode. Codabar can encode the digits 0 through 9, six symbols (- : . $ / +) and the start/stop characters A, B, C, D, E, *, N or T. Codabar is used in libraries, blood banks, the overnight package delivery industry and a variety of other information processing applications.

Code 128:
A barcode type that provides excellent density for all-numeric data and good density for alphanumeric data. The Code 128 standard is maintained by AIM (Automatic Identification Manufacturers).

Code 39:
A barcode type that is widely used in many industries and is the standard for many government barcode specifications, including the U.S. Department of Defense. Code 39 is defined in American National Standards Institute (ANSI) standard MH10.8M-1983.

Code 93:
A barcode type that encodes exactly the same characters as Code 39, but uses nine barcode elements per character instead of 15.

I 2 of 5:
Interleaved 2 of 5 (I 2 of 5) is a numeric-only barcode widely used in warehouse and industrial applications. The data must consist of an even number of digits.

EAN:
EAN is an abbreviation for 'European Article Numbering. EAN-13 is used worldwide for marking retail goods. It encodes 13 characters: the first two are a country code, followed by 10 data digits and a checksum. Two-digit and five-digit supplemental barcodes may be added for a total of 14 or 17 data digits. EAN-8 code is a shortened version of the EAN-13 code. It includes a two-digit country code, five data digits and a checksum digit. Two-digit and five-digit extension barcodes may be added.

RSS:

RSS is an abbreviation for Reduced Symbology Set, which produces very small barcodes suitable for labeling electronic components and healthcare devices. There are seven different types of RSS barcodes. RSS can encode at maximum 74 characters.

Note: Control characters and non-alphanumeric characters (e.g. $) are displayed as spaces in the Precision Xceed Pro Monitor. Some barcodes may contain control characters and non-alphanumeric characters. The Barcode Type section of the MeterCom screen allows you to set all barcode data entry options for the Operator ID. and Patient ID. The types of barcodes selected determine what codes can be scanned into the Monitor. Refer to the Meter Component Manual for detailed information.

Important Safety Instructions

DANGER

- Misuse of electrical equipment can cause electrocution, burns, fire and other HAZARDS.
- Basic safety precautions should always be taken, including all those listed below.
- Close supervision is necessary when equipment is used by, on, or near children, handicapped persons or invalids.

READ THIS BEFORE USING THE EQUIPMENT

- Do not place the equipment in liquid, nor put it where it could fall into liquid.
- Use the equipment only for the purpose described in the instructions for use.
- Do not use accessories which are not supplied or recommended by the manufacturer.
- Do not use the equipment if it is not working properly, or if it has suffered any damage.
    - NOTE Examples of typical defects include:
    - damage caused by dropping the equipment.
    - damage caused by dropping the equipment into water or splashing water onto it.
- Do not let the equipment come into contact with surfaces which are too hot to touch.
- Do not place anything on top of the equipment.
- Unless specifically instructed to do so by the instructions for use, do not drop or put anything into any opening in the equipment.
- Do not use the equipment out of doors.

KEEP THESE INSTRUCTIONS

Signal Output and Signal Input Parts

The following is recommended by UL for the "Intended signal input and signal output connections complying with this requirement." (UL 60601-1-1st edition)

The use of ACCESSORY equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:

- Use of the accessory in the PATIENT VICINITY.
- Evidence that the safety certification of the ACCESSORY has been performed in accordance to the appropriate IEC 601-1 and/or IEC 601-1-1 harmonized national standard.

Patient Vicinity (UL 60601-1-1st edition)

In areas in which patients are normally cared for, the patient vicinity is the space with surfaces likely to be contacted by the patient or an attendant who can touch the patient. This encloses a space within the room 1.83 m (6 feet) beyond the perimeter of the bed (examination table, dental chair, treatment booth, and the like) in its intended location, and extending vertically 2.29 meters (7 1/2 feet) above the floor.

Other Information

The device is rated for use in oxygen-rich environments. The device is rated for continuous operation.

This device was evaluated against IEC 60601-1-2. Operation of this device may affect or be affected by other equipment in the vicinity of the device. If an effect is observed, increase the distance between devices.

Standards Compliance

The Precision Xceed Pro Point of Care System has been evaluated against the following standards:

UL 60601-1, 1st ed. Medical Electrical Equipment—Part 1: General Requirements for Safety

CSA C22.2 No. 601.1-M90, Medical Electrical Equipment - Part 1: General Requirements for Safety

EN 60601-1, 2nd ed., Medical Electrical Equipment—Part 1: General Requirements for Safety

CSA 22.2 No. 61010.1-4

EN 60601-1 - Medical Electrical Equipment Part 1: General Requirements for Safety Incorporates Corrigendum July 1994; Includes Amendments A1: 1993, A11: 1993, A12: 1993, A2: 1995 and A13: 1996; IEC 601-1: 1988 + A1: 1991 + A2: 1995 + Corrigendum 1995, Modified

IEC 61010-2-101 (2002-01) - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use Part 2-101: Particular Requirements for *In Vitro* Diagnostic (IVD) Medical Equipment First Edition

EN 60601-1-2 - 2001 Class A - Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests IEC 60601-1-2: 2001

IEC 60601-1 - Medical Electrical Equipment Part 1: General Requirements for Safety Second Edition

IEC 60601-1-1, 2nd ed., Medical Electrical Equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems

IEC 60601-1-2 (1993-04) - Medical Electrical Equipment Part 1: General Requirements for Safety 2. Collateral Standard: Electromagnetic Compatibility - Requirements and Tests First Edition; (CENELEC EN 60601-1-2: 1993)

Precision Xceed Pro Monitor – Class II (EQUIPMENT energized from an internal electrical power source).
Docking Station – Class II (EQUIPMENT energized from an internal electrical power source).