MediSense®

Precision PCx™

Point-of-Care System

Healthcare Professional

Operator's Manual

for Blood Glucose

Monitoring

ABBOTT

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Introduction

Welcome to the MediSense Precision PCx™ Point-of-Care System, the portable hospital whole blood testing system. The Precision PCx System simplifies patient monitoring for point-of-care whole blood glucose testing by nurses, physicians, diabetes educators, laboratory staff and other healthcare professionals who need quick, accurate results. The Precision PCx System includes the following:

Features and Benefits

Hand-Held Monitor	The hand-held design of the monitor allows it to be easily brought to the patient for testing.
Simplified Data Entry	The monitor contains a built-in barcode scanner which allows the operator to enter patient identification, operator identification, test strip lot number and other pertinent data by simply scanning a barcode.
Easy Operation	To perform a test, a test strip is inserted into the monitor's test strip port, and a small drop of blood is applied to the target area on the test strip.
Rapid Test Results	The monitor automatically begins testing as soon as the sample is detected on the test strip. Results are displayed in 20 seconds.
Easy Home Training	The monitor's design and operation are similar to other MediSense monitors, making it easy to educate patients on home self-testing procedures.
Infection Control	The risk of contamination to operator and patient is minimized since the blood does not enter the monitor.
Improved Test Strip Technology	The Precision PCx System uses unique biosensor technology to obtain accurate results over a broad range of patient hematocrit levels and sample types. Precision PCx Test Strips and Precision PCx *Plus* Test Strips with TrueMeasure™ Technology are approved for use with arterial, venous, capillary and neonatal whole blood samples.
Minimal Maintenance	The monitor's exterior surface needs only to be wiped down once a day, or as needed, and the batteries need to be replaced or recharged when necessary.

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Accurate Calibration	The barcode on each test strip packet label ensures accurate calibration before each test begins.
Built-In Security Options	Options in the Precision PCx Monitor enable the requirement of Patient and Operator IDs, to include minimum and maximum lengths. Other security options include:

> **QC Interval** – requires quality control tests at regular intervals.
> **Operator Security** – limits access to the list of certified operators.
> **Strip Lot Security** – test only with approved test strip lots.
> **Test Security** – reports control test as Pass/Fail only. This is to prevent patient testing from being performed while the monitor is in control test mode.

Patient and Quality Control Data Management	The Precision PCx Monitor can store up to 4,000 patient tests and 1,000 control tests. All stored data can be automatically uploaded to the MediSense® QC Manager™ Data Management System using the docking station (optional) or serial cable.
Data Networking	The QC Manager Data Management System provides a simple and automated way to collect, report and send data to the Laboratory Information System (LIS) or Hospital Information System (HIS).
Battery Power	The monitor uses 2 standard alkaline AA batteries, or the rechargeable MediSense battery pack.

The Precision PCx Point-of-Care System Operator's Manual provides basic information about the Precision PCx Monitor and contains easy-to-follow, step-by-step procedures for using it.

The Precision PCx System operates using menu-driven software. The software consists of two main menus, Test Mode and Menu Mode. Test Mode is used to perform Patient Tests and Control Tests. Menu Mode is used to set up the monitor's options. (See page 1-2).

The menu portion of the software is set up like a tree, with various levels of sub-menus branching out from the main trunk. The menu diagram on the next page, called the Precision PCx Menu Tree, illustrates the multiple sub-menu layers. For ease of understanding in using the monitor, this manual is organized into sections which follow the menu.

It is recommended that the Introduction and Overview sections of this manual be read thoroughly prior to using the monitor for testing. These sections will acquaint users with the Precision PCx Point-of-Care System's features and operating controls so it can be used more effectively.

Questions? Refer to Page 10-13 For Customer Care Information.

1-1

Precision PCx Menu Tree

Test Mode

1. Patient Test

2. Control Test

Menu Mode

1. Data Review

    1. Patient History sort by:
        All Tests
        Patient ID
        Operator ID
        Action Range
        Comment Code
        Date

    2. Control History sort by:
        All Tests
        Operator ID
        Outside Range
        Comment Code
        Date

    3. Proficiency Data

    4. Linearity Data

2. Proficiency Test

3. Linearity Test

4. Review / 5. Change Setup

    1. Test Setup

        1. All Tests
            Upload Interval
            Operator ID Format

        2. Patient Test
            Patient ID Format
            Comment Code
            Memory Full

        3. Control Test
            Levels
            Results Format
            Comment Code
            Memory Full

        4. Security
            QC Interval
            Operator ID
            Strip Lot

        5. Test Type
            Glucose
                Units
                Sample Type
                Action Range

    2. System Setup
        Language
        Beeper On/Off
        Date Format
        Time Format
        Password
        Factory Settings

    3. System Status
        Battery Power
        Temperature
        Memory Gauge
        Software Version

    4. Date and Time

    5. Edit Lists

        1. Operator List
            Add
            Delete
            Change

        2. Strip Lot List
            Add
            Delete
            Change

Understanding the Precision PCx Point-of-Care System

The Precision PCx Point-of-Care System is a portable whole blood testing system which performs tests with quick and accurate results. This section is intended to provide an overview of the Precision PCx System's components and basic operations. Use product and accessories only as directed. Failure to operate the product(s) in accordance with the manufacturer's documentation may impair the product safety.

MediSense Precision PCx Point-of-Care System Components
The MediSense Precision PCx Point-of-Care System includes the following items:
• The Precision PCx Monitor
• Precision PCx and Precision PCx *Plus*
Blood Glucose Test Strips
• Accessory / Carry Case (optional)
• Docking Station (optional)

The Precision PCx Monitor includes:
• Test Strip Port
• Large LCD Display
• Barcode Scanner
• Keypad
• Data Port
• Audible Indicator

Precision PCx Blood Glucose Test Strips
The Precision PCx and Precision PCx *Plus* Blood Glucose
Test Strips offer the latest advances in biosensor technology. Each test strip is wrapped in a foil packet with a barcode label. This label holds the calibration information about the test strip including the lot number, the expiration date and expected control solution ranges.

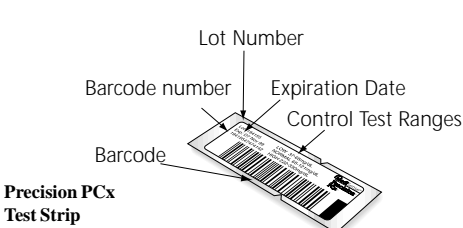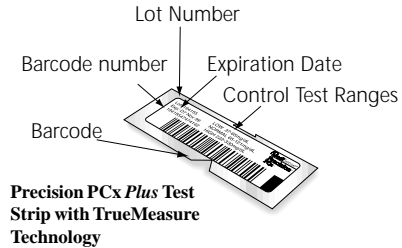Questions? Refer to Page 10-13 For Customer Care Information.

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Precision PCx Test Strips

There are now two types of Precision PCx test strips that may be used for testing with this system. The target area of the original Precision PCx biosensor test strip is on the top of the strip. The target area of the new Precision PCx *Plus* Test Strip with TrueMeasure™ Technology is at the end of the strip. Only Precision PCx branded test strips should be used for testing with this system. Note: For data management, Precision PCx *Plus* Test Strips can be used only in conjunction with QC Manager 3.0.
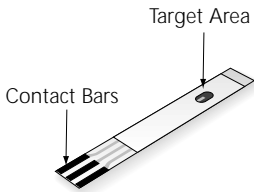
Inside each carton of test strips are test strip instructions for use. The instructions contain important information about the test strip such as: Storage and Handling, Sample Collection and Preparation, Quality Control and Limitations of the Procedure. The section "Limitations of the Procedure" contains the operating ranges for the system and the test strips. **Please read the instructions for use carefully.**
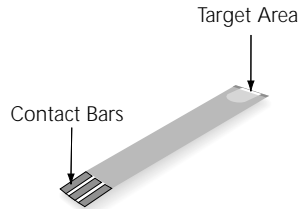
Lot Number

Barcode number | Expiration Date
Control Test Ranges
Barcode

**Precision PCx
Test Strip**

Lot Number

Barcode number | Expiration Date
Control Test Ranges
Barcode

**Precision PCx *Plus* Test
Strip with TrueMeasure
Technology**

Target Area

Contact Bars

**Precision PCx Test Strip
For Use with Precision PCx v2.0, v2.1 and v2.2**

Target Area

Contact Bars

**Precision PCx *Plus* Test Strip with
TrueMeasure Technology
For Use with Precision PCx v2.2 Only**

Target area: A small green and white oval where you place a drop of blood on top of the test strip.

Target area: A white area where you place a drop of blood at the end of the strip. You can apply blood to the edge of the strip or on the top of the strip within this white area.

Contact bars: At the opposite end of both test strips are three black contact bars to be inserted into the test strip port of the monitor.

Accessory / Carry Case (optional)

The light yet rugged accessory/carry case holds the hand-held monitor, test strips, glucose control solutions and other supplies in a convenient manner.

A transparent cover allows the operator to check the supply status without opening the case. The overall form is compact, allowing the convenient storage of many cases in a small area.
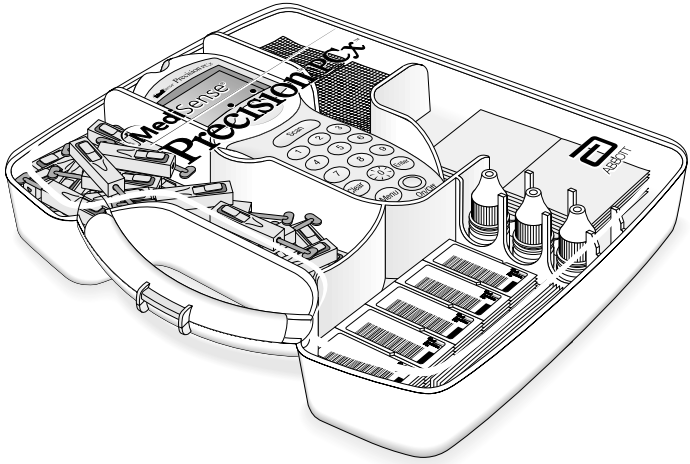
The case holds the Precision PCx Monitor and the following items:

• Precision PCx or Precision PCx *Plus* Test Strips
• Single-use Lancing Devices
• Gauze Pads
• Glucose Control Solutions
• Quick Reference Guide

Docking Station (optional)

The optional docking station will automatically upload the data from the monitor into a central computer via the MediSense QC Manager Data Management System.

To start the upload of data, simply place the Precision PCx Monitor into the Precision PCx Docking Station.

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The monitor will automatically upload data to the MediSense QC Manager Program. Please refer to the QC Manager Operator's Manual for more information.

The docking station has an additional role as a recharge station for the MediSense rechargeable battery pack (optional). The rechargeable battery pack must be in the monitor to take advantage of this option.

Identifying Monitor Functions

Through the monitor, the operator can view information, make selections and enter information. The location of all the monitor functions are shown on the following page.

Test Strip Port

After the operator scans the barcode or manually enters* information via the monitor keypad, the operator will insert a new test strip into the test strip port to perform a test.

Display

Here is where menu options, error codes, and test results are viewed. Press and hold ☼ on the keypad to turn on or off the backlight for the monitor display.

Keypad

The keypad contains the following controls:

On/Off
Press this button to turn the monitor on or off. The monitor will automatically turn off after 4 minutes if the monitor is left on but has not been used.

Scan
Press the Scan button to use the laser barcode scanner. The barcode scanner enables the operator to scan the information into the monitor instead of manually entering the data by using the keypad. The scanner can automatically enter the test strip information (calibration, control range, lot number and expiration date), as well as the operator ID, patient ID, and control lot number.

* Manual entry of strip lots with alpha-numeric barcodes is not supported.

Numbers

The 10-digit keypad can be used to enter identification numbers or to select an option that appears on the display.

Clear

The operator can press Clear to perform the following functions:
• To back up one space while entering numbers on the keypad.
• Clear a numerical code from the monitor after pressing Enter.
• Clear a barcode scanned by mistake.
• Return to a previous screen.
• When Clear is pressed two times, all entered numbers shown in the display will be cleared.

Menu

When the Menu key is pressed, the following functions can be performed:
• Return to the top of the menu.
• Switch between Test Mode and Menu Mode.

Test Strip Port

Display

Keypad
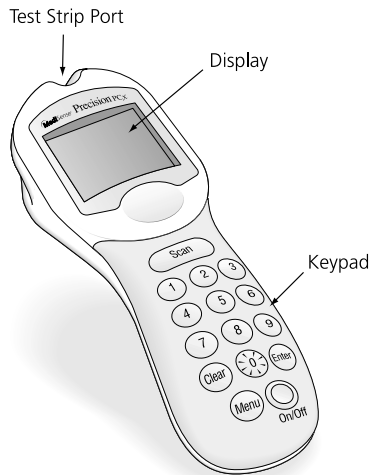
Enter

When the Enter key is pressed, it will confirm the information that was manually entered.

Barcode Scanner

The Barcode Scanner is used to scan barcode information into the monitor. The operator will hold the barcode scanner 3-12 inches from the barcode to be scanned. When first using the barcode scanner, some precautions should be taken while mastering the device.

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Place the object to be scanned on a flat surface, by itself. This will prevent other items from being accidentally scanned.

Press and hold down the Scan button to start the barcode scanner. A visible red beam will be emitted from the monitor. Slowly move this beam over the barcode on the item to be scanned. When the monitor accepts the barcode, it will beep in acknowledgement. Without releasing the Scan button, look down at the monitor. The operator can view the data that was scanned by the monitor. Release the Scan button to stop the scan and continue with the next step.

CAUTION: Never look into the barcode scanner beam or point it toward anyone's eyes. The beam could cause permanent damage to the eye.

Class II and IIa Laser Product: Avoid Long Term Viewing of Direct Laser Light.

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 connector to a PC, laptop, Laboratory Information System (LIS), or Hospital Information System (HIS).
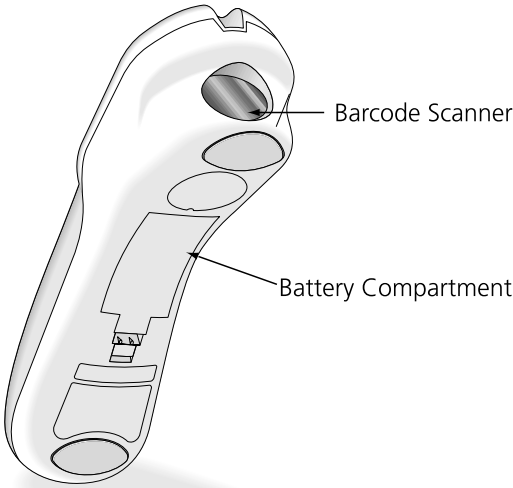
Battery Compartment

The monitor holds two AA alkaline batteries to power the monitor. A rechargeable battery pack is also available from MediSense. The rechargeable battery pack can recharge itself while the monitor is in the optional docking station. To prolong the battery life of the monitor, the monitor should be turned off when not in use. If the monitor is left on and has not been used for 4 minutes, it will automatically shut itself off.

Audible Indicator (not visible)

The monitor will beep to indicate one of the following:

• A successful barcode entry.
• Sample detection.
• At three seconds before the result is to appear.
• When an error occurs.
• At thirty seconds before automatic shutoff.

Barcode Scanner

Battery Compartment

Data Port

Questions? Refer to Page 10-13 For Customer Care Information.

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This section describes the steps to be taken to test patient blood samples using the Precision PCx Monitor.

Operating Guidelines for All Samples

Please follow the recommended guidelines so the most accurate results will be obtained.

- Always wear gloves and follow your facility's biohazard safety policies and procedures when performing tests involving patient blood samples.
- Use only control solutions approved for use on the test strip instructions for use to verify the performance of the Precision PCx and Precision PCx *Plus* Test Strips and the Precision PCx Monitor.
- Use the test strips before their expiration date.
- Do not use test strips that are wet, bent, scratched or damaged. Use the test strip immediately after opening its foil packet.
- Do not scan a packet's barcode and use a test strip from another packet. This may cause incorrect assay results to be generated.
- Cover the entire target area of the test strip with the blood sample. The test results will not be affected if the target area has been briefly touched with the patient's finger, a capillary tube or pipette.
- If the test fails to start, apply a second drop of blood to the target area within 30 seconds. If the test fails to start after the second drop is applied, or if more than 30 seconds have passed, discard the used test strip and repeat the test.
- After the blood is applied to the test strip and the count down begins, do not remove or disturb the test strip.
- Use a new test strip when repeating a patient test.
- Refer to the instructions for use in the test strip box for specific directions on storage and use of the test strips.

Questions? Refer to Page 10-13 For Customer Care Information.

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Collecting Blood Samples

How to Obtain a Capillary Blood Sample:

- Use only fresh whole blood samples.
- Make sure no water remains on the puncture site.
- Collect the capillary blood using a lancing device and an appropriate technique.

Precision PCx Test Strip For Use with Precision PCx v2.0, v2.1 and v2.2.

Precision PCx *Plus* Test Strip with TrueMeasure Technology For Use with Precision PCx v2.2 Only

- Avoid squeezing the puncture site excessively.
- Apply the drop of blood directly to the target area of the test strip, covering the entire area.
- If necessary, the blood can be collected in a capillary tube coated with sodium heparin, lithium heparin, or EDTA, and then applied to the test strip.

How to Obtain a Venous Blood Sample:

- Use only fresh whole blood samples.
- Collect the venous blood sample in a collection tube containing sodium heparin, lithium heparin

Precision PCx Test Strip For Use with Precision PCx v2.0, v2.1 and v2.2.

Precision PCx *Plus* Test Strip with TrueMeasure Technology For Use with Precision PCx v2.2 Only

or EDTA ensuring that the test tube is completely filled.

- 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 syringe that contains sodium heparin, lithium heparin or EDTA.
- 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.
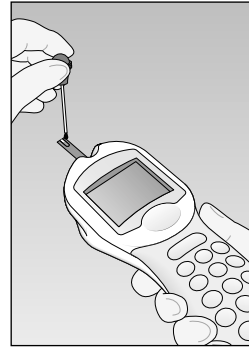
- Apply a drop of blood directly to the target area on the test strip, covering the entire area.

Note: Use VENOUS MODE only for venous samples that have been in capped tubes and have not been mixed with air. Use CAPILLARY or ARTERIAL MODE for all other samples.

How to Obtain an Arterial Blood Sample:

- Use only fresh whole blood samples.
- Clear the arterial line before drawing a blood sample into a syringe that contains sodium heparin, or lithium heparin or EDTA.
- Use the sample within 30 minutes of collection.
- Mix the syringe several times immediately before applying the sample to the target area on the test strip.
- Allow a drop of blood to form at the tip of the syringe.
- Cover the entire target area on the test strip with the blood sample. The syringe can briefly touch the test strip without affecting the test result.
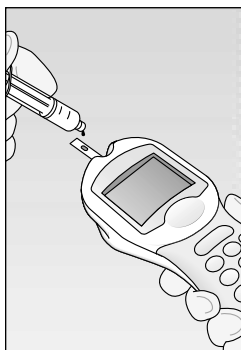
Precision PCx Test Strip For Use with Precision PCx v2.0, v2.1 and v2.2.
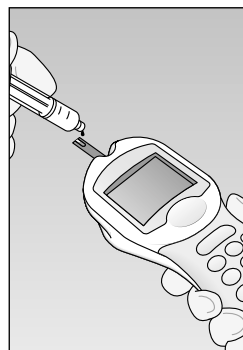
Precision PCx *Plus* Test Strip with TrueMeasure Technology For Use with Precision PCx v2.2 Only

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

Use the following procedure to perform patient tests.

Note: The word "Strip" on the display always refers to the test strip. If the monitor displays a message not indicated in these procedures, please refer to section 10, *Troubleshooting.*
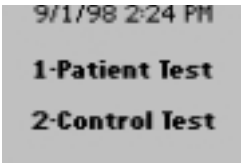
Questions? Refer to Page 10-13 For Customer Care Information.

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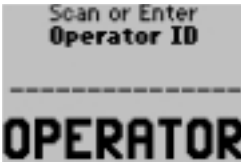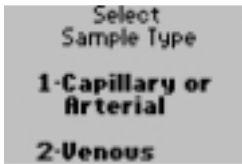| What You See on the Display	What You Do	Comments
ABBOTT	**1.** Press **On/Off** to turn on monitor.	The Abbott logo screen will appear for a few seconds followed by the product name, software version screen and then the Test Mode menu.
9/1/98 2:24 PM **1-Patient Test** **2-Control Test**	**2.** Press **1** to select Patient Test.	After the patient test is selected, the Operator ID screen will appear, if this setting has been enabled. **Note:** If an Operator ID prompt is not seen, skip down to step 4.
Scan or Enter **Operator ID** ----------- **OPERATOR**	**3.** Press **Scan** to scan the Operator ID barcode, or manually enter the Operator ID via the keypad, then press **Enter.**	The display will prompt for a Patient ID to be entered, if this setting has been enabled. **Note:** If a Patient ID prompt is not seen, skip down to step 5.
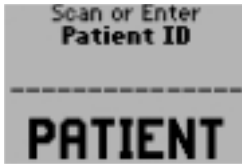
|		
Scan or Enter **Patient ID** - - - - - - - - - - - - - **PATIENT**	**4.** Press **Scan** to scan the Patient ID barcode, or manually enter the Patient ID via the keypad, then press **Enter**.	After entering the Patient ID, the test strip lot screen appears next.
Scan or Enter **Strip Lot** - - - - - -	**5.** Press **Scan** to scan the test strip barcode, or manually enter* the test strip lot number via the keypad, then press **Enter.**	After the test strip lot number has been entered, the Sample Type screen will appear if this setting has been enabled. If it does not appear, skip down to step 7.
Select **Sample Type** **1-Capillary or** **Arterial** **2-Venous**	**6.** The operator can select one of the following: Press **1** – Capillary or Arterial. Press **2** – Venous.	**Note:** Use VENOUS MODE only for venous samples that have been in capped tubes and have not been mixed with air. Use CAPILLARY or ARTERIAL MODE for all other samples.
	7. Open the foil test strip packet at the notch and tear up or down to remove the test strip.	
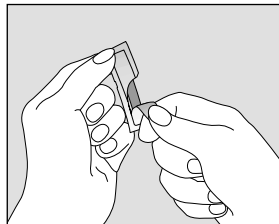
* Manual entry of strip lots with alpha-numeric barcodes is not supported.

Questions? Refer to Page 10-13 For Customer Support Information.

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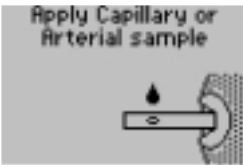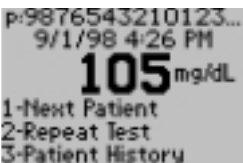| What You See on the Display	What You Do	Comments
Insert Strip	**8.** With the contact bars facing up, insert the test strip into the test strip port until it stops.	The Apply Sample screen will appear.
Apply Capillary or Arterial sample	**9.** Apply a drop of blood directly from the patient's finger or from a syringe to the target area on the test strip.	The monitor beeps when the sample is accepted. The Sample Accepted screen will appear. For detailed description of the test strip target area, refer to page 2-2.
Sample Accepted		The test starts automatically, as the sample is accepted.
Analyzing Sample **Result in** **20** **seconds**	**10.** Wait for the monitor to analyze the sample and display the test result.	The monitor counts down 20 seconds, then displays the test result.
p:9876543210123... 9/1/98 4:26 PM **105** mg/dL 1-Next Patient 2-Repeat Test 3-Patient History (5.8 mmol/L)	**11.** Note the test result and whether it falls outside the action range.	If the test result is above or below the action range, an up or down triangle appears in front of the test result.

What You See on the Display	What You Do	Comments

**Outside
Action Range
▲395** mg/dL
Scan or Enter
Comment Code
--

(▲21.9 mmol/L)

For Out-of-Range results, refer to your institution's protocol.

NOTE: The Outside 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 set up.

B. The test result is out of the Action Range.

105 mg/dL
Scan or Enter
Comment Code
--

(5.8 mmol/L)

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 12.

NOTE: The In-Range Action Range screen will appear if the Patient Test In-Range Comment Code is enabled and the following conditions are met:

A. The action range is defined.

B. The test result is within the Action Range.

**Remove
Strip**

12. Remove the test strip from the monitor when finished testing.

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p:9876543210123... 9/1/98 4:26 PM **105** mg/dL 1-Next Patient 2-Repeat Test 3-Patient History (5.8 mmol/L)	**13.** The operator can select one of the following options: Press **1** – Next Patient. Press **2** – Repeat Test. Press **3** – Patient History.	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 Scan or Enter Strip Lot screen will appear. Return to step 5 to repeat the test. If 3 is selected, the monitor will display the last test result for this patient as well as allow the operator to view previous results. Refer to the section entitled Data Review for Patient History 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 your healthcare professional 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).

This section describes the steps to be taken to test Control Solutions in order to verify the performance of the Precision PCx Monitor and Precision PCx and Precision PCx *Plus* 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 any variation of this depending on the facility's policy
- Tests of Control Solutions at regular times or time intervals, or by number of patient tests
- Control test results will appear as Numeric or Pass/Fail.

These quality control features can be set through the Menu Mode menu (Change Setup/Test Setup Menu).

Operating Guidelines for Control Solution Testing

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

- Use only control solutions approved for use on the test strip instructions for use to verify the performance of the Precision PCx and Precision PCx *Plus* Test Strips and the Precision PCx Monitor.
- When opening a new bottle, write the current date on the bottle label. Each bottle of control solution is stable for 90 days after opening (replace cap tightly after each use). Discard all unused solutions 90 days after opening.
- 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 nozzle of the bottle.
- Do not scan one test strip packet's barcode and use a test strip from another packet. This may cause incorrect assay results to be generated.
- Replace the correct cap on the bottle and tighten the cap immediately after each use.
- Store the control solutions at temperatures between 39º and 86ºF (4º and 30ºC).
- Do not use control solutions after the expiration date printed on the bottles and the box. The Precision PCx Monitor does not accept control solutions that have passed their expiration date.
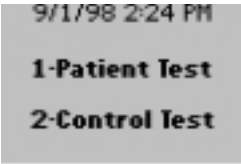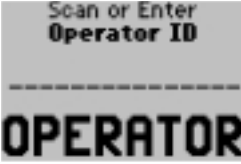
When To Test Control Solutions
- As required by your facility's quality policy or local regulatory requirements.
- When you question blood glucose results
- When you open a new lot of test strips

4-1

Questions? Refer to Page 10-13 For Customer Care Information.

Control Test Procedure

Use the following procedure to perform control tests.

Note: The word "Strip" on the display always refers to the test strip. If the monitor displays a message not indicated in these procedures, please refer to section 10, *Troubleshooting.*

| What You See on the Display	What You Do	Comments
ABBOTT	**1.** Press **On/Off** to turn on the monitor.	The Abbott logo screen will appear for a few seconds followed by the product name, software version and then the Test Mode menu.
9/1/98 2:24 PM **1-Patient Test** **2-Control Test**	**2.** Press **2** – Control Test.	After the control test is selected, the Operator ID screen may appear, if the setting has been enabled.
Scan or Enter **Operator ID** ----------- **OPERATOR**	**3.** Press **Scan** to scan the Operator ID barcode, or manually enter the Operator ID via the keypad, then press **Enter.**	If the Operator ID is not required, just press enter. After the Operator ID is entered, the Low Level Solution Lot screen will appear.
Scan or Enter **Low Level Solution Lot** -----	**4.** Scan or manually enter the low control solution lot number via the keypad, then press **Enter.**	The Strip Lot screen will appear next.
Unexpected Level Low expected **High entered** 1-ReEnter Lot 2-Continue		If the Unexpected Level screen appears, the operator may either: 1. Enter 1 to ReEnter the expected level. 2. Enter 2 to continue to test the unexpected level.

5. Scan or manually enter* the test strip lot number via the keypad, then press **Enter.**

After the test strip lot number is entered, the monitor will prompt for a test strip to be inserted into the test strip port.

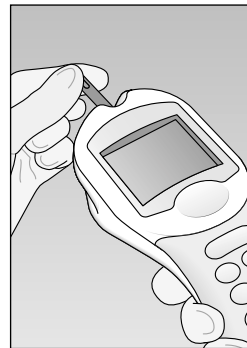**6.** Open the foil test strip packet at the notch and tear up or down to remove the test strip.
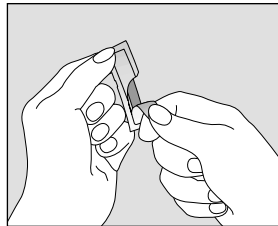
7. With the contact bars facing up, insert the test strip into the test strip port until it stops.

The monitor will prompt the operator to apply the desired control solution to the test strip.
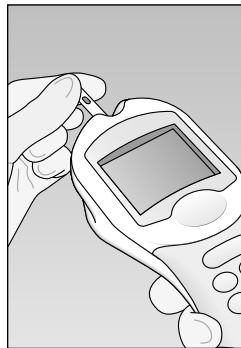
Precision PCx Test Strip For Use with Precision PCx v2.0, v2.1 and v2.2.

Precision PCx *Plus* Test Strip with TrueMeasure Technology For Use with Precision PCx v2.2 Only

* Manual entry of strip lots with alpha-numeric barcodes is not supported.

Questions? Refer to Page 10-13 For Customer Care Information.

4-3

What You See on the Display	What You Do	Comments

Apply Low solution

8. Gently invert the required control solution bottle 3-4 times then apply a drop to the target area on the test strip.

The monitor beeps when the sample is accepted. The Sample Accepted screen will be displayed. Recap the control solution bottle tightly.
For a detailed description of the test strip target area, refer to page 2-2.
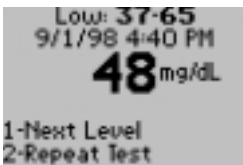
Sample Accepted

The test starts automatically as the sample is accepted.

Analyzing Sample
Result in
20
seconds

9. Wait for the monitor to analyze the control solution and display the test result.

The monitor counts down 20 seconds then displays the test result.

Low: 37-65
9/1/98 4:40 PM
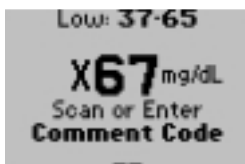**48** mg/dL
1-Next Level
2-Repeat Test

(2.7 mmol/L)

10. Note the test result and whether it falls within the acceptable range.

Control test results can appear as numeric or PASS/FAIL, depending on how the test is setup.

The display also shows the control level, the control range, date and time.
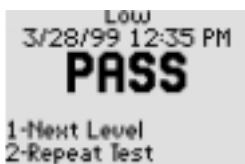
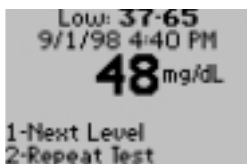| What You See on the Display	What You Do	Comments
Low 3/28/99 12:35 PM **PASS** 1-Next Level 2-Repeat Test	**11.** Note the test result and whether it falls within the acceptable range.	The display shows the control level, PASS/FAIL, date and time.
Low: **37-65** X**67**mg/dL Scan or Enter **Comment Code** -- (x3.7 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.	An "X" will appear in front of a test result that is Out-of-Range.
Remove Strip	**13.** Remove the test strip from the monitor when finished testing.	
Low: **37-65** 9/1/98 4:40 PM **48**mg/dL 1-Next Level 2-Repeat Test (2.7 mmol/L)	**14.** The operator 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.	If 1 is selected, the next level test will appear. The operator may 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.

Questions? Refer to Page 10-13 For Customer Care Information.

4-5

Patient History

The Precision PCx Monitor stores up to 4,000 patient tests that can be retrieved by the following categories:

All Tests: This option displays all patient test results, starting with the most recent test results (reverse chronological order).

Patient ID: This will display the test results for a particular patient, starting with the most recent test.

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

Action Range: This will display the test results that fall outside of the action range.
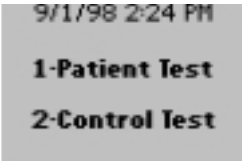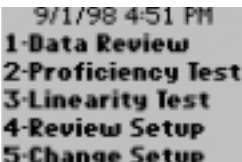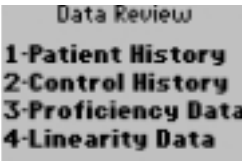
Comment Code: This shows the test results for all tests tagged with a specific comment code.

Date: This will display all the test results for a specific date, starting with the most recent test done on that date.

Questions? Refer to Page 10-13 For Customer Care Information.

5-1

Data Review:

Follow these steps to access the Data Review menu:
If the monitor displays a message not indicated in these procedures, please refer to section 10, *Troubleshooting*.

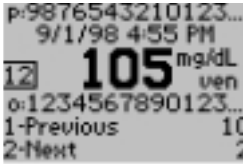| What You See on the Display	What You Do	Comments
a ABBOTT	**1.** Press the **On/Off** button to turn the monitor on.	The Abbott logo screen will appear for a few seconds, followed by the product name, software version and then the Test Mode menu.
9/1/98 2:24 PM **1-Patient Test** **2-Control Test**	**2.** Press the **Menu** button.	The Menu Mode screen will appear next.
9/1/98 4:51 PM **1-Data Review** **2-Proficiency Test** **3-Linearity Test** **4-Review Setup** **5-Change Setup**	**3.** Press **1** – Data Review.	The Data Review menu appears.
Data Review **1-Patient History** **2-Control History** **3-Proficiency Data** **4-Linearity Data**		At this point, Patient History, Control History, Proficiency Data as well as Linearity Data can be viewed.

Data Review for Patient History by All Tests:

Please refer to page 5-2 of the Data Review section for the step-by-step instructions to access the Data Review menu.

Note: If no information is stored for the desired category that was selected, the following message will be displayed on the monitor: "No Stored Tests".

Note: If no tests match the criteria specified, this message will be displayed on the monitor: "No Tests Match Request". If the monitor displays a message not indicated in these procedures, please refer to section 10, *Troubleshooting.*

What You See on the Display	What You Do	Comments
Data Review 1-Patient History 2-Control History 3-Proficiency Data 4-Linearity Data	**1.** Press **1** – Patient History.	The Patient History menu now appears.
Patient History 1-All Tests 2-Patient ID 3-Operator ID 4-Action Range 5-Comment Code 6-Date	**2.** Press **1** – All Tests.	The monitor shows the most recent patient test result.

Questions? Refer to Page 10-13 For Customer Care Information.

5-3

What You See on the Display	What You Do	Comments

p:9876543210123...
9/1/98 4:55 PM
12 **105** mg/dL ven
o:1234567890123...
1-Previous   10
2-Next   2

(5.8 mmol/L)

3. The operator can select one of the following options:

Press **1** – Previous, view the previous test result.

Press **2** – Next, view the next test result.

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:

p: Patient ID

o: Operator ID

12 : Comment Code

ven: Venous Sample

p:9876543210123...
9/1/98 4:31 PM
▲395 mg/dL
o:1234567890123...
1-Previous   7
2-Next   5

(▲21.9 mmol/L)

4. When finished reviewing the data, the operator can:

Press **Clear** to return to the Patient History menu.

Press **Menu** to return to the Menu Mode menu.
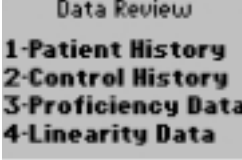
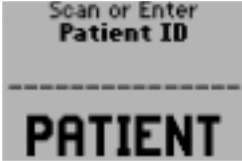Press **On/Off** to turn off the monitor.

Data Review for Patient History by Patient ID:

Please refer to page 5-2 of the Data Review section for the step-by-step instructions to access the Data Review menu.
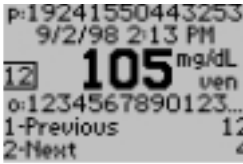
Note: If no information is stored for the desired category that was selected, the following message will be displayed on the monitor: "No Stored Tests".

Note: If no tests match the criteria specified, this message will be displayed on the monitor: "No Tests Match Request".

If the monitor displays a message not indicated in these procedures, please refer to section 10, *Troubleshooting.*

What You See on the Display	What You Do	Comments
Data Review 1-Patient History 2-Control History 3-Proficiency Data 4-Linearity Data	**1.** Press **1** – Patient History.	The Patient History menu now appears.
Patient History 1-All Tests 2-Patient ID 3-Operator ID 4-Action Range 5-Comment Code 6-Date	**2.** Press **2** – Patient ID.	The monitor will prompt for the Patient ID to be scanned or entered.
Scan or Enter **Patient ID** ------------- PATIENT	**3.** Scan or manually enter the Patient ID via the keypad, then press **Enter.**	

Questions? Refer to Page 10-13 For Customer Care Information.

5-5

What You See on the Display	What You Do	Comments

p:19241550443253
9/2/98 2:13 PM
12 **105** mg/dL
ven
o:1234567890123...
1-Previous   12
2-Next   4

(5.8 mmol/L)

4. The operator can select one of the following options:

Press **1** – Previous, view the previous test result.

Press **2** – Next, view the next test result.

5. When finished reviewing the data, the operator can:

Press **Clear** to return to the Patient ID 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:

p: Patient ID

o: Operator ID

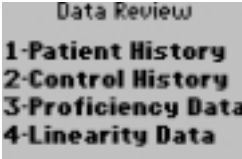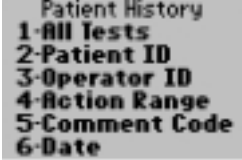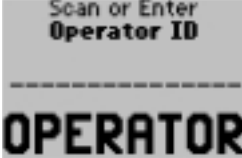12 : Comment Code

ven: Venous Sample

Data Review for Patient History by Operator ID:

Please refer to page 5-2 of the Data Review section for the step-by-step instructions to access the Data Review menu.

Note: If no information is stored for the desired category that was selected, the following message will be displayed on the monitor: "No Stored Tests".

Note: If no tests match the criteria specified, this message will be displayed on the monitor: "No Tests Match Request".

If the monitor displays a message not indicated in these procedures, please refer to section 10, *Troubleshooting.*

What You See on the Display	What You Do	Comments
Data Review 1-Patient History 2-Control History 3-Proficiency Data 4-Linearity Data	**1.** Press **1** – Patient History.	The Patient History menu now appears.
Patient History 1-All Tests 2-Patient ID 3-Operator ID 4-Action Range 5-Comment Code 6-Date	**2.** Press **3** – Operator ID.	The monitor will prompt for the Operator ID to be scanned or entered.
Scan or Enter Operator ID ------------ OPERATOR	**3.** Scan or manually enter the Operator ID via the keypad, then press **Enter.**	The monitor shows the result of the operator's most recent patient test result.

Questions? Refer to Page 10-13 For Customer Care Information.

5-7

What You See on the Display	What You Do	Comments

p:19241550443253
9/2/98 2:13 PM
12 **105** mg/dL
ven
o:1234567890123...
1-Previous   12
2-Next   4

(5.8 mmol/L)

4. The operator can select one of the following options:

Press **1** – Previous, view the previous test result.

Press **2** – Next, view the next test result.

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:

p: Patient ID

o: Operator ID

12 : Comment Code

ven: Venous Sample

5. When finished reviewing the data, the operator can:

Press **Clear** to return to the Operator ID screen.

Press **Menu** to return to the Menu Mode menu.
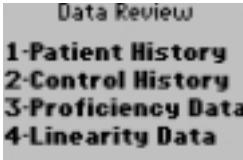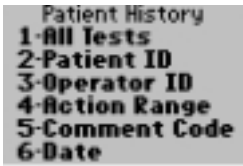
Press **On/Off** to turn off the monitor.

Data Review by Patient History for Action Range:

Please refer to page 5-2 of the Data Review section for the step-by-step instructions to access the Data Review menu.

Note: If no information is stored for the desired category that was selected, the following message will be displayed on the monitor: "No Stored Tests".

Note: If no tests match the criteria specified, this message will be displayed on the monitor: "No Tests Match Request".

If the monitor displays a message not indicated in these procedures, please refer to section 10, *Troubleshooting.*

What You See on the Display	What You Do	Comments
Data Review 1-Patient History 2-Control History 3-Proficiency Data 4-Linearity Data	**1.** Press **1** – Patient History.	The Patient History menu now appears.
Patient History 1-All Tests 2-Patient ID 3-Operator ID 4-Action Range 5-Comment Code 6-Date	**2.** Press **4** – Action Range.	The monitor displays the most recent test result that is outside the action range.

Questions? Refer to Page 10-13 For Customer Care Information.

5-9

What You See on the Display	What You Do	Comments

p:19241550443253
9/2/98 2:16 PM

12 ▲**363** mg/dL
ven
o:1234567890123...
1-Previous   4
2-Next   2

(▲ 20.1 mmol/L)

3. The operator can select one of the following options:

Press **1** – Previous, view the previous test result.

Press **2** – Next, view the next test result.

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:

p: Patient ID

o: Operator ID

12 : Comment Code

ven: Venous Sample

▲ Indicates above action range

▼ Indicates below action range

4. When finished reviewing the data, the operator can:

Press **Clear** to return to the Patient History menu.

Press **Menu** to return to the Menu Mode menu.

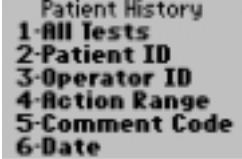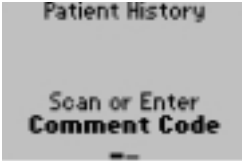Press **On/Off** to turn off the monitor.

Data Review for Patient History by Comment Code:

Please refer to page 5-2 of the Data Review section for the step-by-step instructions to access the Data Review menu.

Note: If no information is stored for the desired category that was selected, the following message will be displayed on the monitor: "No Stored Tests".

Note: If no tests match the criteria specified, this message will be displayed on the monitor: "No Tests Match Request".

If the monitor displays a message not indicated in these procedures, please refer to the section 10, *Troubleshooting.*

What You See on the Display	What You Do	Comments
Data Review **1-Patient History** **2-Control History** **3-Proficiency Data** **4-Linearity Data**	**1.** Press **1** – Patient History.	The Patient History menu now appears.
Patient History **1-All Tests** **2-Patient ID** **3-Operator ID** **4-Action Range** **5-Comment Code** **6-Date**	**2.** Press **5** – Comment Code.	The monitor will prompt for the comment code to be scanned or entered.
Patient History **Scan or Enter** **Comment Code**	**3.** Scan or manually enter the desired comment code via the keypad, then press **Enter.**	The monitor will show the most recent test result for the selected comment code.

Questions? Refer to Page 10-13 For Customer Care Information.

5-11

What You See on the Display	What You Do	Comments

(5.8 mmol/L)

4. The operator can select one of the following options:

Press **1** – Previous, view the previous test result.

Press **2** – Next, view the next test result.

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:

p: Patient ID

o: Operator ID

12 : Comment Code

ven: Venous Sample

5. When finished reviewing the data, the operator can:

Press **Clear** to return to the Comment Code screen.

Press **Menu** to return to the Menu Mode menu.

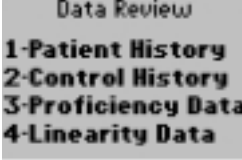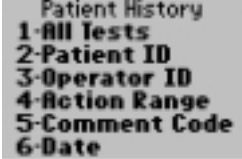Press **On/Off** to turn off the monitor.

Data Review for Patient History by Selected Date:

Please refer to page 5-2 of the Data Review section for the step-by-step instructions to access the Data Review menu.

Note: If no information is stored for the desired category that was selected, the following message will be displayed on the monitor: "No Stored Tests".

Note: If no tests match the criteria specified, this message will be displayed on the monitor: "No Tests Match Request".

If the monitor displays a message not indicated in these procedures, please refer to the section 10, *Troubleshooting.*

What You See on the Display	What You Do	Comments
Data Review 1-Patient History 2-Control History 3-Proficiency Data 4-Linearity Data	**1.** Press **1** – Patient History.	The Patient History menu now appears.
Patient History 1-All Tests 2-Patient ID 3-Operator ID 4-Action Range 5-Comment Code 6-Date	**2.** Press **6** – Date.	The monitor will now prompt for the desired date to be entered.
Patient History **Enter Date** mo/dy/yr __/__/__	**3.** Enter the desired date for review then press **Enter.**	The operator will enter in the date using two digits for month/day/year. For example, June 8, 2001 becomes 06/08/01.

Questions? Refer to Page 10-13 For Customer Care Information.

5-13

What You See on the Display	What You Do	Comments

p:9876543210123...
9/1/98 4:55 PM
12 **105** mg/dL
ven
o:1234567890123...
1-Previous   10
2-Next   2

(5.8 mmol/L)

4. The operator can select one of the following options:

Press **1** – Previous, view the previous test result.

Press **2** – Next, view the next test result.

5. When finished reviewing the data, the operator can:

Press **Clear** to return to the Enter Date 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 monitor also shows:

p: Patient ID

o: Operator ID

12 : Comment Code

ven: Venous Sample

Control History

The Precision PCx monitor can store up to 1,000 control tests that can be retrieved by the following categories:

All Tests: This shows all control test results in memory starting with the most recent test result in memory (reverse chronological order).

Operator ID: This shows the control test results that were performed by a particular operator, starting with the most recent test.

Outside Range: This shows all the control test results that fell outside of the acceptable ranges.

Comment Code: This shows all the control test results by comment code.

Date: This shows the control test results performed on a specific date, starting with the most recent test of the day.
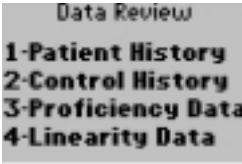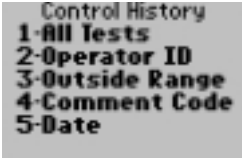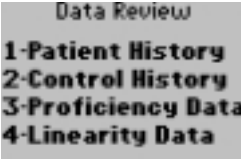
Data Review for Control History for All Tests:

Please refer to page 5-2 of the Data Review section for the step-by-step instructions to access the Data Review menu.

Note: If no information is stored for the desired category that was selected, the following message will be displayed on the monitor: "No Stored Tests".

Note: If no tests match the criteria specified, this message will be displayed on the monitor: "No Tests Match Request".

If the monitor displays a message not indicated in these procedures, please refer to section 10, *Troubleshooting.*

What You See on the Display	What You Do	Comments
Data Review 1-Patient History 2-Control History 3-Proficiency Data 4-Linearity Data	**1.** Press **2** – Control History.	The Control History menu now appears.
Control History 1-All Tests 2-Operator ID 3-Outside Range 4-Comment Code 5-Date	**2.** Press **1** – All Tests.	The monitor shows the result of the most recent control test.

Questions? Refer to Page 10-13 For Customer Care Information.

5-15

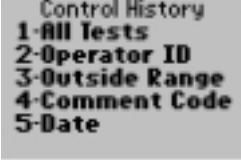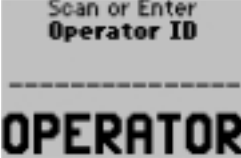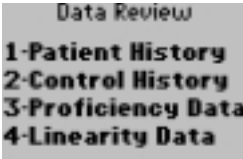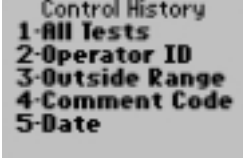|		
Low: **30-60** 8/29/98 12:58 PM [0] **42** mg/dL o:1234567890123... 1-Previous 10 2-Next 3 (2.3 mmol/L)	**3.** The operator can select one of the following options: Press **1** – Previous, view the previous test result. Press **2** – Next, view the next test result. **4.** When finished reviewing the data, the operator can: Press **Clear** to return to the Control History 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 the acceptable range for this test and: o: Operator ID 0 : Comment Code

Data Review for Control History by Operator ID:

Please refer to page 5-2 of the Data Review section for the step-by-step instructions to access the Data Review menu.

Note: If no tests are stored for the desired category that was selected, the following message will be displayed on the monitor: "No Stored Tests".

Note: If no tests match the criteria specified, this message will be displayed on the monitor: "No Tests Match Request".

If the monitor displays a message not indicated in these procedures, please refer to section 10, *Troubleshooting.*

What You See on the Display	What You Do	Comments
Data Review **1-Patient History** **2-Control History** **3-Proficiency Data** **4-Linearity Data**	**1.** Press **2** – Control History.	The Control Test History menu now appears.
Control History **1-All Tests** **2-Operator ID** **3-Outside Range** **4-Comment Code** **5-Date**	**2.** Press **2** – Operator ID.	The monitor will prompt for the Operator ID to be scanned or entered.
Scan or Enter **Operator ID** ------------ **OPERATOR**	**3.** Scan or manually enter the Operator ID via the keypad, then press **Enter.**	The monitor will display the Operator's most recent control test result.

Questions? Refer to Page 10-13 For Customer Care Information.

5-17

Low: **30-60**
8/29/98 12:58 PM
☐ **42** mg/dL
o:1234567890123...
1-Previous   10
2-Next   3

(2.3 mmol/L)

4. The operator can select one of the following options:

Press **1** – Previous, view the previous test result.

Press **2** – Next, view the next test result.

5. When finished reviewing the data, the operator can:

Press **Clear** to return to the Operator ID 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:

o: Operator ID

0 : Comment Code

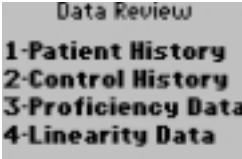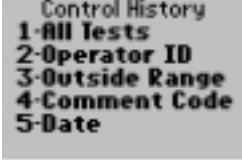## Data Review for Control History by Outside Range Results:

Please refer to page 5-2 of the Data Review section for the step-by-step instructions to access the Data Review menu.

Note: If no tests are stored for the desired category that was selected, the following message will be displayed on the monitor: "No Stored Tests".

Note: If no tests match the criteria specified, this message will be displayed on the monitor: "No Tests Match Request".

If the monitor displays a message not indicated in these procedures, please refer to section 10, *Troubleshooting*.

What You See on the Display	What You Do	Comments
Data Review 1-Patient History 2-Control History 3-Proficiency Data 4-Linearity Data	**1.** Press **2** – Control History.	The Control Test History menu now appears.
Control History 1-All Tests 2-Operator ID 3-Outside Range 4-Comment Code 5-Date	**2.** Press **3** – Outside Range.	The monitor shows the most recent control test result that is outside the acceptable range.

Questions? Refer to Page 10-13 For Customer Care Information.

5-19

```
Low: 30-60
9/2/98 2:31 PM
 2    X 64 mg/dL
o:1234567890123...
1-Previous         3
2-Next             1
```
(X3.5 mmol/L)

3. The operator can select one of the following options:

Press **1** – Previous, view the previous test result.

Press **2** – Next, view the next test result.

4. When finished reviewing the data, the operator can:

Press **Clear** to return to the Control History 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 the acceptable range for this test as well as:

o: Operator ID
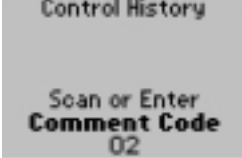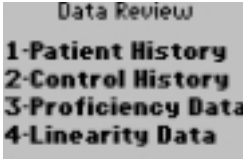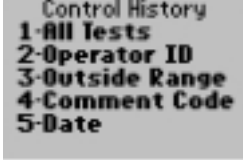
2 : Comment Code

X: Outside Range

Data Review for Control History by Comment Code:

Please refer to page 5-2 of the Data Review section for the step-by-step instructions to access the Data Review menu.

Note: If no tests are stored for the desired category that was selected, the following message will be displayed on the monitor: "No Stored Tests."

Note: If no tests match the criteria specified, this message will be displayed on the monitor: "No Tests Match Request".

If the monitor displays a message not indicated in these procedures, please refer to section 10, *Troubleshooting.*

What You See on the Display	What You Do	Comments
Data Review 1-Patient History 2-Control History 3-Proficiency Data 4-Linearity Data	**1.** Press **2** – Control History.	The Control Test History menu now appears.
Control History 1-All Tests 2-Operator ID 3-Outside Range 4-Comment Code 5-Date	**2.** Press **4** – Comment Code.	The monitor will prompt for the comment code to be scanned or entered.
Control History Scan or Enter **Comment Code** 02	**3.** Scan or manually enter the comment code via the keypad, then press **Enter.**	The monitor will display the result of the most recent control test for the specified comment code.

Questions? Refer to Page 10-13 For Customer Care Information.

5-21

Low: **30-60**
9/2/98 2:31 PM
2 X**64** mg/dL
o:1234567890123...
1-Previous
2-Next

(X3.5 mmol/L)

4. The operator can select one of the following options:

Press **1** – Previous, view the previous test result.

Press **2** – Next, view the next test result.

5. When finished reviewing the data, the operator can:

Press **Clear** to return to the Comment Code 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:

o : Operator ID
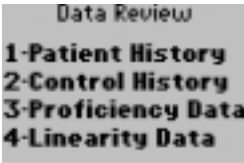
2 : Comment Code

X: Outside Range

Data Review for Control History for Selected Date:

Please refer to page 5-2 of the Data Review section for the step-by-step instructions to access the Data Review menu.

Note: If no tests are stored for the desired category that was selected, the following message will be displayed on the monitor: "No Stored Tests".

Note: If no tests match the criteria specified, this message will be displayed on the monitor: "No Tests Match Request".

If the monitor displays a message not indicated in these procedures, please refer to section 10, *Troubleshooting*.

What You See on the Display	What You Do	Comments
Data Review 1-Patient History 2-Control History 3-Proficiency Data 4-Linearity Data	**1.** Press **2** – Control History.	The Control Test History menu now appears.
Control History 1-All Tests 2-Operator ID 3-Outside Range 4-Comment Code 5-Date	**2.** Press **5** – Date.	The monitor will prompt for a specified date to be entered.
Control History Enter Date mo/dy/yr __/__/__	**3.** Enter a date then press **Enter.**	The monitor will display the most recent control test result for the specified date.

Questions? Refer to Page 10-13 For Customer Care Information.

5-23

```
Low: 30-60
8/29/98 12:58 PM
  □    42 mg/dL
o:1234567890123...
1-Previous          10
2-Next              3
```

(2.3 mmol/L)

4. The operator can select one of the following options:

Press **1** – Previous, view the previous test result.

Press **2** – Next, view the next test result.

5. When finished reviewing the data, the operator can:

Press **Clear** to return to the Enter Date 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:

o : Operator ID

0 : Comment Code

Data Review for Proficiency Data

The monitor stores the last 60 proficiency test results.

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

Note: If no tests are stored for the desired category that was selected, the following message will be displayed on the monitor: "No Stored Tests".
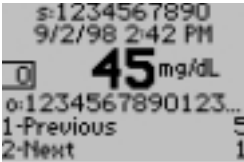
If the monitor displays a message not indicated in these procedures, please refer to section 10, *Troubleshooting.*

What You See on the Display	What You Do	Comments
Data Review 1-Patient History 2-Control History 3-Proficiency Data 4-Linearity Data	**1.** Press **3** – Proficiency Data.	The monitor now shows the most recent proficiency test result.
s:1234567890 9/2/98 2:42 PM 0 **45** mg/dL o:1234567890123... 1-Previous 2-Next (2.5 mmol/L)	**2.** The operator can select one of the following options: Press **1** – Previous, view the previous test result. Press **2** – Next, view the next test result. **3.** When finished reviewing the data, the operator 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: s : Sample Type or ID o : Operator ID 0 : Comment Code

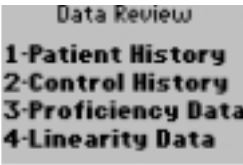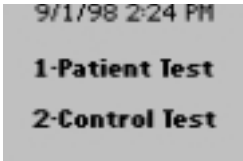Questions? Refer to Page 10-13 For Customer Care Information.

5-25

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 the Data Review section for the step-by-step instructions to access the Data Review menu.

Note: If no tests are stored for the desired category that was selected, the following message will be displayed on the monitor: "No Stored Tests".

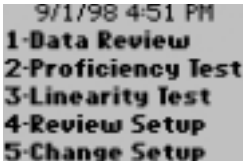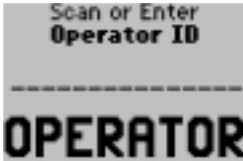If the monitor displays a message not indicated in these procedures, please refer to section 10, *Troubleshooting.*

What You See on the Display	What You Do	Comments
Data Review 1-Patient History 2-Control History 3-Proficiency Data 4-Linearity Data	**1.** Press **4** – Linearity Data.	The monitor now shows the most recent Linearity Test. At the top of the display the test level is indicated. The Level indicates Level 1-5 while Test indicates 1-4 replicates at that level.
Level 4 Test 1 9/2/98 3:02 PM **276** mg/dL o:1234567890123... 1-Previous 12 2-Next (15.3 mmol/L)	**2.** The operator can select one of the following options: Press **1** – Previous, view the previous test result. Press **2** – Next, view the next test result. **3.** When finished reviewing the data, the operator 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 following: o: Operator ID

*It is **outside the intended use** of the PCx/QCM system to perform a test in linearity mode on a PCx instrument and change the test result record to a patient result in QCM Data Management System. Linearity test results outside the test strip assay range should only be used to set linearity performance on the PCx instrument. The performance of the test strips has not been verified outside the assay range listed on the test strip instructions for use.

The Proficiency Test menu enables the operator to perform unknown sample test challenges if required by facility policy.

Use the following procedures to perform a proficiency test.

If the monitor displays a message not indicated in these procedures, please refer to section 10, *Troubleshooting*.

What You See on the Display	What You Do	Comments
ABBOTT	**1.** Press the **On/Off** button to turn on the monitor.	The Abbott logo screen appears for a few seconds, followed by the product name, the software version screen, then the Test Mode menu.
9/1/98 2:24 PM **1-Patient Test** **2-Control Test**	**2.** Press **Menu.**	The Menu Mode screen now appears.
9/1/98 4:51 PM **1-Data Review** **2-Proficiency Test** **3-Linearity Test** **4-Review Setup** **5-Change Setup**	**3.** Press **2** – Proficiency Test.	The monitor will prompt for the Operator ID to be scanned or entered.
Scan or Enter **Operator ID** ------------ **OPERATOR**	**4.** Scan or manually enter the Operator ID via the keypad, then press **Enter.**	The monitor will prompt for the Sample ID to be scanned or entered.
Scan or Enter **Sample ID** 1234567890 **PROF**	**5.** Scan or manually enter the Sample ID via the keypad, then press **Enter.**	The monitor will prompt for the Strip Lot number to be scanned or entered.

Questions? Refer to Page 10-13 For Customer Care Information.

6-1

What You See on the Display	What You Do	Comments

**6.** Scan or manually enter* the test strip lot number via the keypad, then press **Enter.**

The monitor will prompt the operator to insert the test strip.

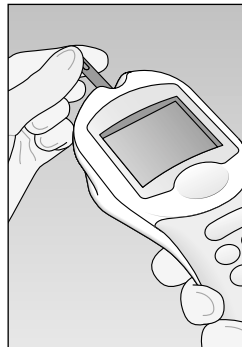**7.** Open the foil test strip packet at the notch and tear up or down to remove the test strip.
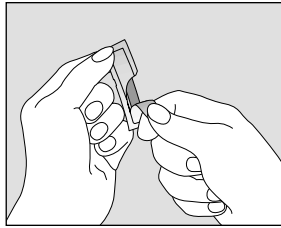
8. With the contact bars facing up, insert the test strip into the test strip port until it stops.

The monitor will prompt the operator to apply the sample to the test strip.
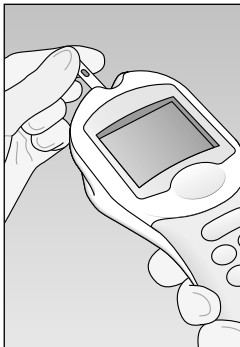
Precision PCx Test Strip For Use with Precision PCx v2.0, v2.1 and v2.2.

Precision PCx *Plus* Test Strip with TrueMeasure Technology For Use with Precision PCx v2.2 Only

* Manual entry of strip lots with alpha-numeric barcodes is not supported.
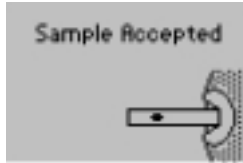
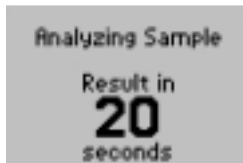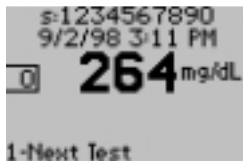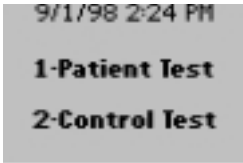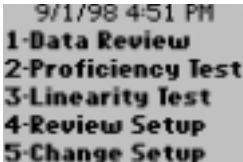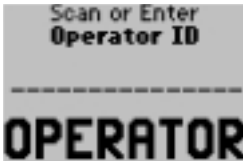| What You See on the Display	What You Do	Comments
Apply Sample	**9.** Gently invert the sample bottle 3-4 times then apply a drop of the sample to the target area on the test strip.	The monitor beeps when the sample is accepted. The Sample Accepted Screen will be displayed.
Sample Accepted		The test starts automatically, as the sample is accepted.
Analyzing Sample Result in **20** seconds	**10.** Wait for the monitor to analyze the sample and display the test result.	The monitor counts down 20 seconds then displays the test result.
264 mg/dL Scan or Enter **Comment Code** — (14.6 mmol/L)	**11.** If the operator is prompted to enter a comment code, continue to step 12; otherwise skip forward to step 13.	
264 mg/dL Scan or Enter **Comment Code** 00 (14.6 mmol/L)	**12.** Scan or manually enter the comment code via the keypad, then press **Enter.**	The monitor returns to the Results menu. The comment code number that was entered will appear in a box to the left of the test result.
s:1234567890 9/2/98 3:11 PM □ **264** mg/dL 1-Next Test (14.6 mmol/L)	**13.** The operator will 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.	The operator can refer back to step 5 for the steps to perform any additional proficiency testing at this time.

Questions? Refer to Page 10-13 For Customer Care Information.

6-3

The Linearity Test menu enables the operator to verify method linearity using a Linearity Assessment Kit.*

Please use the following procedures to perform a Linearity Test.

If the monitor displays a message not indicated in these procedures, please refer to section 10, *Troubleshooting.*

What You See on the Display	What You Do	Comments
ABBOTT	**1.** Press **On/Off** to turn on monitor.	The Abbott logo screen will appear for a few seconds, followed by the product name, the software version, then the Test Mode menu.
9/1/98 2:24 PM **1-Patient Test** **2-Control Test**	**2.** Press **Menu.**	The Menu Mode menu will appear.
9/1/98 4:51 PM **1-Data Review** **2-Proficiency Test** **3-Linearity Test** **4-Review Setup** **5-Change Setup**	**3.** Press **3** – Linearity Test.	The monitor will prompt for the Operator ID to be scanned or entered.
Scan or Enter **Operator ID** ------------ **OPERATOR**	**4.** Press **Scan** or manually enter the Operator ID via the keypad, then press **Enter.**	The monitor will next prompt for the Linearity Kit lot number to be scanned or entered.

*It is **outside the intended use** of the PCx/QCM system to perform a test in linearity mode on a PCx instrument and change the test result record to a patient result in QCM Data Management System. Linearity test results outside the test strip assay range should only be used to set linearity performance on the PCx instrument. The performance of the test strips has not been verified outside the assay range listed on the test strip instructions for use.

7-1

Questions? Refer to Page 10-13 For Customer Care Information.

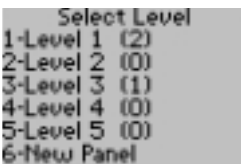| What You See on the Display	What You Do	Comments
Scan or Enter **Linearity Kit Lot** 1234567890 **LIN**	**5.** Scan or manually enter the linearity kit lot number via the keypad, then press **Enter.** If the monitor prompts for a level to be entered, skip to step 7.	If the linearity kit lot number that was entered is different from the previous one, the monitor will prompt the operator to do one of two actions: either re-enter the existing linearity kit lot number or replace the existing linearity kit lot number with the new linearity kit lot number.
New Panel **1234567890** **will replace Old Panel** 1-ReEnter Kit Lot 2-Replace Panel 9876543210	**6.** The operator can perform one of the following actions: Press **1** – ReEnter Kit Lot. Press **2** – Replace Panel.	If 1 is pressed, the monitor will return to the previous screen so the operator can scan or enter the linearity kit lot number. The monitor will prompt the operator to select a level.
Select Level 1-Level 1 (0) 2-Level 2 (0) 3-Level 3 (0) 4-Level 4 (0) 5-Level 5 (0)	**7.** Enter the number of the level of the next test to be run.	There can be up to 4 replicates per level. The number in the parenthesis indicates the number of replicates already run for that level. When a level is full, the menu item (1-Level 1) will no longer appear.
Select Level 1-Level 1 (2) 2-Level 2 (0) 3-Level 3 (1) 4-Level 4 (0) 5-Level 5 (0) 6-New Panel	**8.** If the operator presses 6 for a new panel, the monitor will again prompt the operator to select a level. The monitor will prompt the operator to scan or manually enter the test strip lot number.	
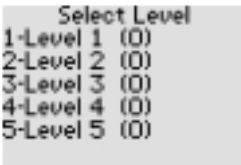
Scan or Enter Strip Lot

9. Scan or manually enter* the test strip lot number via the keypad, then press **Enter.**
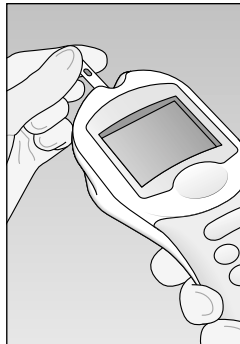
The monitor will prompt for a new test strip to be inserted into the test strip port.

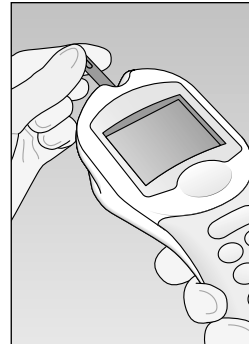**10.** Open the foil test strip packet at the notch and tear up or down to open the packet, then remove the test strip.
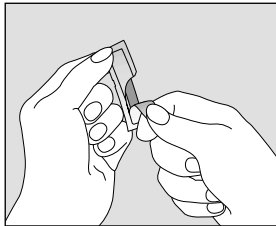
Insert Strip

11. With the contact bars facing up, insert the test strip into the test strip port until it stops.

The monitor will prompt the operator to apply the sample to the test strip.

Precision PCx Test Strip For Use with Precision PCx v2.0, v2.1 and v2.2.

Precision PCx *Plus* Test Strip with TrueMeasure Technology For Use with Precision PCx v2.2 Only

* Manual entry of strip lots with alpha-numeric barcodes is not supported.

Questions? Refer to Page 10-13 For Customer Care Information.

7-3

| --- | --- | --- |
Apply Level 2 Sample	**12.** Gently invert the sample 3-4 times then apply a drop of the sample to the target area on the test strip.	The monitor beeps when the sample is accepted. The Sample Accepted Screen will appear.
Sample Accepted		The test starts automatically, as the sample is accepted.
Analyzing Sample **Result in** **20** **seconds**	**13.** Wait for the monitor to analyze the sample and display the test result.	The monitor counts down 20 seconds then displays the test result.
Level 2 Test 1 9/2/98 3:23 PM 12 **264** mg/dL 1-New Level 2-Same Level (14.6 mmol/L)	**14.** Note the result. If the operator is prompted to enter a comment code, continue to step 15, otherwise skip to step 16.	The display includes the level and test numbers, date and time. Level indicates Level 1-5. Test indicates replicates 1-4 for that level.
Level 2 Test 1 **264** mg/dL Scan or Enter **Comment Code** 12 (14.6 mmol/L)	**15.** Press **Scan** or manually enter the comment code via the keypad then press **Enter.**	The monitor will return to the results screen. The comment code number that was entered will appear in a box to the left of where the result is displayed.
Level 2 Test 1 9/2/98 3:23 PM 12 **264** mg/dL 1-New Level 2-Same Level (14.6 mmol/L)	**16.** The operator can do one of the following options: Press **1** – Next Level. Press **2** – Same Level. Press the **Menu** button to return to the Menu Mode. Press **On/Off** to turn off monitor.	The operator can press **2** to perform more tests for the same level (return to step 9) or press **1** to perform tests for another level (return to step 8).

The Precision PCx Monitor provides setup options to customize the testing procedures and requirements. These standards promote good laboratory practices for operators.

Since the steps to review or change setup options are similar, the two sub-menus are combined in one section. Any operator can review the setup information; only an administrator (manager) with the password can change the setup information.

The Review Setup feature enables an operator to review only the settings for Test Setup, System Setup, System Status and Date and Time.

The Change Setup feature enables an administrator to review or change the settings for Test Setup, System Setup, System Status, Date and Time, and Edit Lists.

The Test Setup menu includes: All Tests, Patient Test, Control Test, Security and Test Type.

The System Setup menu defines the look or appearance of the data as it is displayed on the monitor, such as language and formats. The menu includes: language, beeper on/off, date format, time format, set password and restore defaults.

The System Status menu allows a review of the current status of the monitor's operating system: battery power, temperature, memory gauge and software version.

The Date and Time menu displays the current date and time.

The Edit Lists menu changes the approved Operator ID or Test Strip Lot lists.

The Precision PCx Menu Tree on the following page will outline the above menus and the sub-menus.

Questions? Refer to Page 10-13 For Customer Care Information.

8-1

Precision PCx Menu Tree

Test Mode | **Menu Mode**

1. Patient Test

2. Control Test

1. Data Review
- 1. Patient History sort by:
  - All Tests
  - Patient ID
  - Operator ID
  - Action Range
  - Comment Code
  - Date
- 2. Control History sort by:
  - All Tests
  - Operator ID
  - Outside Range
  - Comment Code
  - Date
- 3. Proficiency Data
- 4. Linearity Data

2. Proficiency Test

3. Linearity Test

4. Review / 5. Change Setup

1. Test Setup
- 1. All Tests
  - Upload Interval
  - Operator ID Format
- 2. Patient Test
  - Patient ID Format
  - Comment Code
  - Memory Full
- 3. Control Test
  - Levels
  - Results Format
  - Comment Code
  - Memory Full
- 4. Security
  - QC Interval
  - Operator ID
  - Strip Lot
- 5. Test Type
  - Glucose
    - Units
    - Sample Type
    - Action Range

2. System Setup
- Language
- Beeper On/Off
- Date Format
- Time Format
- Password
- Factory Settings

3. System Status
- Battery Power
- Temperature
- Memory Gauge
- Software Version

4. Date and Time

5. Edit Lists
- 1. Operator List
  - Add
  - Delete
  - Change
- 2. Strip Lot List
  - Add
  - Delete
  - Change

Moving Around the Review/Change Setup Menu

The Review and Change Setup menu options offer the same additional sub-menus (as shown in the Precision PCx Menu Tree). The operators may have to select additional options to access the desired change or review option.

To access these sub-menus or options in both the Review and Change Setup menus, the message 1-Next appears at the bottom of the display. The operator presses 1 to move to the next option. The monitor also allows the operator to go back to the previous option by pressing Clear. The current status or selection for the option appears in bold type on the display.

To change an option, the administrator must access the Change Setup menu (this is password protected). In addition to the 1-Next message that appears at the bottom of the option screen, there is the 2-Change message. The administrator presses 2 to change the option. The active selection for the option now appears in bold type.

When finished reviewing or changing the options, the operator or administrator can press Menu once to return to the beginning of Menu Mode or press Menu twice to go to Test Mode.
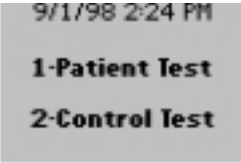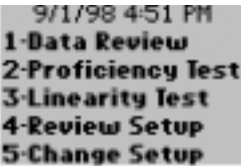
In this section the majority of the directions refer specifically to how to change various settings. However, these same directions can be followed as well for reviewing settings under its own menu option.

Differentiation is made between the password protected sections in the Change Setup Menu Option, where only administrators can access the screens, and the non-password protected sections in the Review Setup Menu Option, where operators and administrators can access the screens.

8-3

Questions? Refer to Page 10-13 For Customer Care Information.

Review Setup:

If the monitor displays a message not indicated in these procedures, please refer to section 10, *Troubleshooting.*

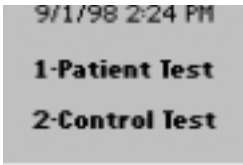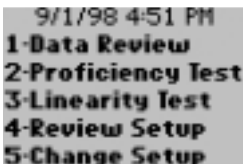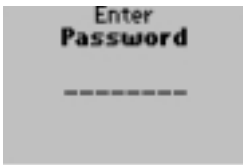Use the following steps to access the Review Setup menu:

What You See on the Display	What You Do	Comments
ABBOTT	**1.** Press **On/Off** to turn on the monitor.	The Abbott logo screen will appear for a few seconds followed by the product name, the software version screen and then the Test Mode menu.
9/1/98 2:24 PM **1-Patient Test** **2-Control Test**	**2.** Press **Menu.**	The Menu Mode menu will appear.
9/1/98 4:51 PM **1-Data Review** **2-Proficiency Test** **3-Linearity Test** **4-Review Setup** **5-Change Setup**	**3.** Press **4** for Review Setup.	The Review Setup Menu will appear.
Review Setup **1-Test Setup** **2-System Setup** **3-System Status** **4-Date and Time**		The operator can review Test Setup, System Setup, System Status and Date and Time by following the appropriate steps for these procedures.

Change Setup:

If the monitor displays a message not indicated in these procedures, please refer to section 10, *Troubleshooting.*

Use these steps to access the Change Setup menu:

What You See on the Display	What You Do	Comments
ABBOTT	**1.** Press **On/Off** to turn on the monitor.	The Abbott logo screen will appear for a few seconds followed by the product name, the software version screen and then the Test Mode menu.
9/1/98 2:24 PM **1-Patient Test** **2-Control Test**	**2.** Press **Menu.**	The Menu Mode menu will appear.
9/1/98 4:51 PM **1-Data Review** **2-Proficiency Test** **3-Linearity Test** **4-Review Setup** **5-Change Setup**	**3.** Press **5** for Change Setup.	The display prompts the operator to enter a password of up to 8 characters. The password is displayed as asterisks on the monitor.
Enter Password --------	**4.** Key in the password, then press **Enter.** If the password is entered incorrectly, the monitor displays error message: "Incorrect Password." Press **Clear** twice, verify the password then re-enter the correct password and press **Enter.**	The factory set password is 123. Once in the Change Setup Mode, it is suggested that the administrator change the password. This can be done in the System Setup/Set Password option.

Questions? Refer to Page 10-13 For Customer Care Information.

8-5

Change Setup
1-Test Setup
2-System Setup
3-System Status
4-Date and Time
5-Edit Lists

The administrator can change Test Setup, System Setup, System Status, Date and Time and Edit Lists by following the appropriate steps for these procedures.

Review/Change Setup for Test Setup

The Review/Change Setup menus enable the operator to review/change the test settings.

Under the Test Setup Menu, the following options can be viewed or changed:
• All Tests
• Patient Test
• Control Test
• Security
• Test Type

In the All Tests menu, the following options can be viewed or changed:
• Upload Interval for sending stored data to other systems.
• Establish Operator ID requirements and barcode format.

In the Patient Test menu, the following options can be viewed or changed:
• Establish Patient ID requirements and barcode format.
• Set the requirement for out-of-range and/or in-range comment codes.
• Management of memory full overwrite.

In the Control Test menu, the following options can be viewed or changed:
• Enable high, normal and/or low control testing.
• Control test results presented as numeric or Pass/Fail.
• Set the requirement for in-range and/or out-of-range comment codes.
• Management of memory full overwrite.

In the Security menu, the following options can be viewed or changed:
• Set QC interval requirements.
• Set requirements to prevent testing by non-certified operators.
• Set requirements to prevent testing using test strip lots that have not been qualified for use.

In the Test Type menu, the following options can be viewed or changed:
• Set units of measurement.
• Set sample type prompts.
• Set action ranges. The action range can also be changed in QC Manager. Refer to the QC Manager Operator's Manual for more information. Note: Default action range is 20-600.

Questions? Refer to Page 10-13 For Customer Care Information.

8-7

Review/Change Test Setup for All Tests:

The options that are associated with the Review/Change Test Setup for All Tests apply to all test types.

Use this menu to review or change these options for all tests.

Upload Interval
The monitor can be set up to warn or lockout a task if the monitor has not been uploaded at a regularly scheduled interval. The upload interval options are:
- Allow Test–allows the testing to continue. No message will appear on the monitor.
- Warn–allows the testing to continue but the operator will receive a message that the upload interval (as specified below) has expired.
- Lockout–does not allow any testing until the data has been uploaded. This option is set to designate a required maximum number of hours or days (from 1 to 99) between data uploads. When a task is selected and the upload interval has expired, the operator will receive a message that the Upload Interval has expired. If Upload Interval is expired, the monitor will prevent an operator from doing other tasks until the stored data is uploaded.

Operator ID
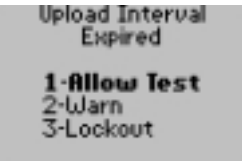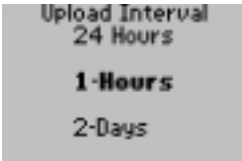The Operator ID menu has the following options which can be viewed or changed:
- Disabled, Optional or Required entry of an Operator ID for all testing.
- Require a minimum and a maximum number of digits for the length of an Operator ID.
- Allow any combination of five common barcode formats used in the facility:
    I2 of 5 (with or without check digit)
    Code 39 (with or without check digit, alphanumeric or
            ASCII format)
    Code 128
    Codabar
    Code 93
- Truncate (ignore) leading and/or trailing barcode digits.
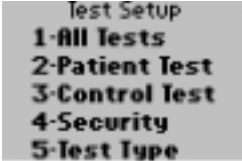
Note: The display shows selected options in bold type.

Review/Change Setup for All Tests:

Refer to the beginning of the Review/Change Setup Section for step-by-step instruction to access the appropriate setup menu.

If the monitor displays a message not indicated in these procedures, please refer to section 10, *Troubleshooting.*

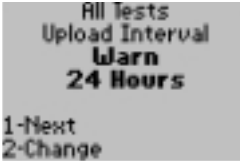| What You See on the Display	What You Do	Comments
Change Setup **1-Test Setup** **2-System Setup** **3-System Status** **4-Date and Time** **5-Edit Lists**	**1.** Press **1** for Test Setup.	The display shows the Test Setup menu.
Test Setup **1-All Tests** **2-Patient Test** **3-Control Test** **4-Security** **5-Test Type**	**2.** Press **1** for All Tests.	The display shows the Upload Interval menu.
All Tests **Upload Interval** **Allow Test** 1-Next 2-Change	**3.** The administrator will select one of the following options: Press **1** – Next; skip forward to step 8. Press **2** – Change.	The display shows the current settings in bold. If 2 is pressed, the display shows the Upload Interval options.
Upload Interval **Expired** **1-Allow Test** 2-Warn 3-Lockout	**4.** The administrator will select one of the following options: Press **1** – Allow Test; skip forward to step 7. Press **2** – Warn. Press **3** – Lockout.	If 2 or 3 is pressed, the display will show the upload interval hours and days option.
Upload Interval **24 Hours** **1-Hours** 2-Days	**5.** The administrator will select one of the following options: Press **1** – Hours. Press **2** – Days.	The display prompts for the number of days/hours to be entered.

Questions? Refer to Page 10-13 For Customer Care Information.

8-9

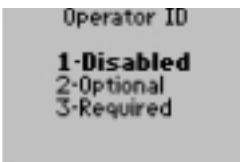| What You See on the Display	What You Do	Comments
Upload Interval 24 Hours — Hours __	**6.** Enter 1-99 hours or 1-99 days then press **Enter.**	The All Tests Upload Interval screen will be displayed.
All Tests Upload Interval **Warn** **24 Hours** 1-Next 2-Change	**7.** Press **1** to continue to the All Tests Operator ID screen.	The display shows the All Tests Operator ID menu.
All Tests Operator ID **Disabled** 1-Next 2-Change	**8.** The administrator will select one of the following options: Press **1** – Next, return to the Test Setup menu. Press **2** – Change.	The display shows the Operator ID options.
Operator ID **1-Disabled** 2-Optional 3-Required	**9.** The administrator will select one of the following options: Press **1** – Disabled; skip forward to step 13. Press **2** – Optional. Press **3** – Required.	If Disabled is selected, the display will not prompt for Operator ID. If Optional or Required is selected, the administrator can enter a minimum and maximum number of digits, between 1-15 digits.
Operator ID 1-15 digits Minimum __ Maximum	**10.** The administrator will enter minimum and maximum numbers between 1-15. Key in the minimum number of digits for an operator ID then press **Enter.** Key in the maximum number of digits for an operator ID then press **Enter.**	The display shows the Operator ID Barcode options.

Operator ID Barcode
1-I2of5uss
2-Code 39c
3-Code 128
4-Codabar
5-Code 93   6-〉

11. The administrator may customize **I2** of **5** by pressing **1** if **I2** of **5** is **bolded** (enabled). Press **1** again to access the Operator ID Barcode screen.

Activated barcodes appear in **bold type**. More than one Barcode format can be active at one time. Any Barcode can be deactivated by selecting the corresponding number.
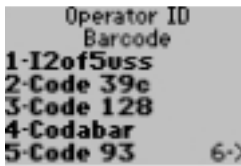
Note: Only Barcodes 1 and 2 can be customized.

Operator ID Barcode I2of5
1-No Check Digit
2-USS Check Digit
3-OPCC Check Digit

12. The administrator will select one of the following:
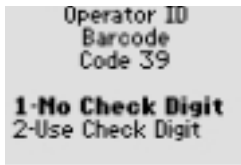1. No Check Digit
2. USS Check Digit
3. OPCC Check Digit

The display returns to the Operator ID Barcode screen.

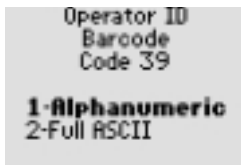**USS** or **OPCC** will appear after the format, if selected.

Operator ID Barcode
1-I2of5uss
2-Code 39c
3-Code 128
4-Codabar
5-Code 93   6-〉

13. The administrator may customize **Code 39** by pressing **2** if **Code 39** is bolded (enabled). Press **2** again to access the Operator ID Barcode screen.

Operator ID Barcode Code 39
1-No Check Digit
2-Use Check Digit

14. The administrator will select one of the following:
1. No Check Digit
2. Use Check Digit

The display shows the Alphanumeric, Full ASCII screen.

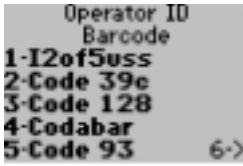**Operator ID Barcode Code 39**
1-Alphanumeric
2-Full ASCII

15. The administrator will select one of the following:
1. Alphanumeric
2. Full ASCII
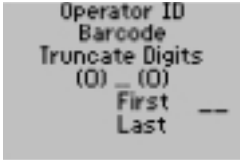
The display returns to the Operator ID Barcode screen.

C will appear after the format if Check Digit is selected.

F will appear if Full ASCII is selected.

Questions? Refer to Page 10-13 For Customer Care Information.

8-11

Operator ID Barcode 1-I2of5uss 2-Code 39c 3-Code 128 4-Codabar 5-Code 93 6->	**16.** To access the Truncate Digits screen, press **6** and continue forward to step 17.	The display shows the Operator ID Barcode Truncate Digits screen.
Operator ID Barcode Truncate Digits (0) _ (0) First -- Last	**17.** Press **Enter twice** for no truncation of leading or trailing digits; otherwise enter the number of leading and trailing barcode digits to truncate (ignore).	The monitor can be set to ignore a specific number of leading and/or trailing barcode digits. The display returns to the All Tests, Operator ID screen.
All Tests Operator ID **Optional** **1-15 digits** **Barcode** 1-Next 2-Change	**18.** The administrator will select one of the following options: Press **1** – Next, return to the Test Setup menu. Press **Menu** to return to the Menu Mode. Press **On/Off** to turn off the monitor.	

Review/Change Test Setup for Patient Test:

The options set with this menu will apply to all Patient Tests.

The Patient ID option uses a patient identification number to perform tests. Patient ID uses the following options:
- Disable, Require or make Optional the entry of a Patient ID.
- Require a minimum and maximum number of digits for the length of the Patient ID.
- Allow any combination of five common barcode formats used in the facility.
    - I2 of 5 (with or without check digit)
    - Code 39 (with or without check digit, alphanumeric or
        - ASCII format)
    - Code 128
    - Codabar
    - Code 93
- Truncate (ignore) leading and/or trailing barcode digits.

Comment Code option allows the following to be selected:
- Disable the prompt for a Comment Code.
- Prompt for a Comment Code with the option of not requiring it.
- Require a Comment Code for every test result out-of-range and/or in-range of the action range. (See Test Type setup options).

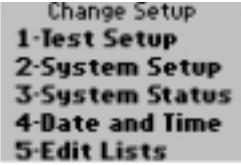The Memory Full option will notify the operator that the patient test memory has reached its limit (4000 tests that have not been uploaded). Memory Full provides the following options:
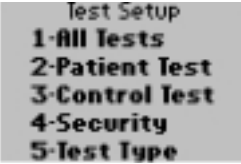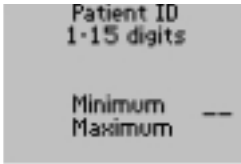- Lockout additional tests until the data is uploaded.
- Prompt the operator to upload data before overwriting old test results with new ones.
- Automatically overwrite oldest test results with new ones.

Questions? Refer to Page 10-13 For Customer Care Information.

8-13

Review/Change Test Setup for Patient Test:

Refer to the beginning of the Review or Change Setup section for step-by-step instructions to access the appropriate setup menu.

If the monitor displays a message not indicated in these procedures, please refer to section 10, *Troubleshooting.*

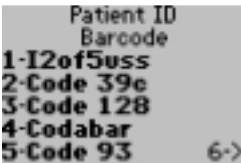| What You See on the Display	What You Do	Comments
Change Setup 1-Test Setup 2-System Setup 3-System Status 4-Date and Time 5-Edit Lists	**1.** Press **1** – Test Setup.	The display shows the Test Setup menu.
Test Setup 1-All Tests 2-Patient Test 3-Control Test 4-Security 5-Test Type	**2.** Press **2** – Patient Test.	The display shows the Patient Test, Patient ID Barcode screen.
Patient Test Patient ID **Disabled** 1-Next 2-Change	**3.** The administrator will select one of the following options: Press **1** – Next; skip forward to step 14. Press **2** – Change; to change Patient ID.	The display shows the Patient ID options.
Patient ID 1-Disabled 2-Optional 3-Required	**4.** The administrator will select one of the following options: Press **1** – Disabled; (returns to the previous screen). Press **2** – Optional. Press **3** – Required.	If Disabled is selected, the display will not prompt for Patient ID. If Optional or Required is selected, the operator can enter a minimum and maximum number of digits, between 1-15 digits.

What You See on the Display	What You Do	Comments

Patient ID
1-15 digits

Minimum __
Maximum

5. The administrator will enter minimum and maximum numbers between 1-15.

Key in the minimum number of digits for a Patient ID number then press **Enter.**

Key in the maximum number of digits for a Patient ID number then press **Enter.**

The display returns to the Patient Test, Patient ID Barcode Menu.

Patient ID
Barcode
1-I2of5uss
2-Code 39c
3-Code 128
4-Codabar
5-Code 93   6->

6. The administrator may customize **I2** of **5** by pressing **1** if **I2** of **5** is **bolded** (enabled). Press **1** again to access the Patient ID Barcode screen.

Activated barcodes appear in **bold type**. More than one Barcode format can be active at one time. Any Barcode can be deactivated by selecting the corresponding number.
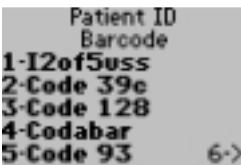
Note: Only Barcodes 1 and 2 can be customized.

Patient ID
Barcode
I2of5

1-No Check Digit
2-USS Check Digit
3-OPCC Check Digit

7. The administrator will select one of the following:

1. No Check Digit

2. USS Check Digit

3. OPCC Check Digit

The display returns to the Patient ID Barcode screen.

USS or **OPCC** will appear after the format, if selected.

Patient ID
Barcode
1-I2of5uss
2-Code 39c
3-Code 128
4-Codabar
5-Code 93   6->

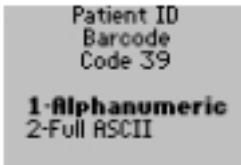**8.** The administrator may customize **Code 39** by pressing **2** if Code 39 is bolded (enabled). Press **2** again to access the Patient ID Barcode screen.

Patient ID
Barcode
Code 39

1-No Check Digit
2-Use Check Digit

9. The administrator will select one of the following:

1. No Check Digit

2. Use Check Digit

The display shows the Alphanumeric, Full ASCII screen.

Questions? Refer to Page 10-13 For Customer Care Information.

8-15

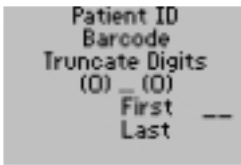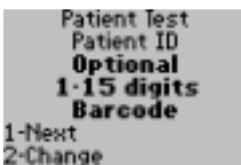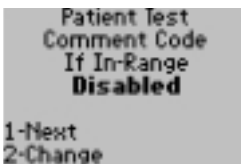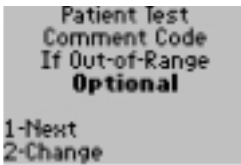|		
Patient ID Barcode Code 39 **1-Alphanumeric** 2-Full ASCII	**10.** Select one of the following: 1. Alphanumeric 2. Full ASCII	The display returns to the Patient ID Barcode screen. C will appear after the format if Check Digit is selected. F will appear if Full ASCII is selected.
Patient ID Barcode 1-I2of5uss 2-Code 39c 3-Code 128 4-Codabar 5-Code 93 6->	**11.** To access the Truncate Digits screen, press 6 and continue forward to step 12.	The display shows the Patient ID Barcode Truncate Digits screen.
Patient ID Barcode Truncate Digits (0) _ (0) First Last --	**12.** Press **Enter** twice for no truncation of leading or trailing digits; otherwise enter the number of leading and trailing barcode digits to truncate (ignore).	The monitor can be set to ignore a specific number of leading and/or trailing barcode digits. The display returns to the Patient Test, Patient ID Barcode screen.
Patient Test Patient ID **Optional** **1-15 digits** **Barcode** 1-Next 2-Change	**13.** Press **1** – Next; continue to the next menu.	The display shows the In-Range Comment Code screen.
Patient Test Comment Code If In-Range **Disabled** 1-Next 2-Change	**14.** The administrator will select one of the following options: Press **1** – Next, and continue to step 17. Press **2** – Change, to change the In-Range Comment Code.	The display shows the In-Range Comment Code options. The Comment Code options can be set to Disabled, Optional or Required for test results that fall in the action range.

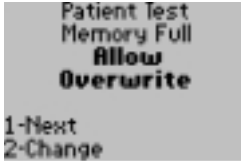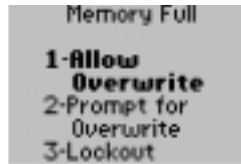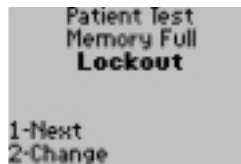|		
Comment Code If In-Range **1-Disabled** 2-Optional 3-Required	**15.** The administrator will select one of the following options: Press **1** – Disabled. Press **2** – Optional. Press **3** – Required.	The display is returned to the Patient Test Comment Code If In-Range screen.
Patient Test Comment Code If In-Range **Optional** 1-Next 2-Change	**16.** Press **1** – Next; continue to the next menu.	The display shows the Out-of-Range Comment Code menu. The comment code options can be set to Disabled, Optional or Required for test results that fall outside the action range.
Patient Test Comment Code If Out-of-Range **Disabled** 1-Next 2-Change	**17.** The administrator will select one of the following options: Press **1** – Next, and continue to step 20. Press **2** – Change, to change the Out-of-Range Comment Code.	The display shows the Out-of-Range Comment Code options.
Comment Code If Out-of-Range **1-Disabled** 2-Optional 3-Required	**18.** The administrator will select one of the following options: Press **1** – Disabled. Press **2** – Optional. Press **3** – Required.	The display shows the Patient Test Comment Code If Out-of-Range screen.

Questions? Refer to Page 10-13 For Customer Care Information.

8-17

What You See on the Display	What You Do	Comments
Patient Test Comment Code If Out-of-Range **Optional** 1-Next 2-Change	**19.** Press **1** – Next; continue to the next menu.	The display shows the Memory Full screen.
Patient Test Memory Full **Allow** **Overwrite** 1-Next 2-Change	**20.** The administrator will select one of the following: Press **1** – Next, and continue to next menu. Press **2** – Change, to change Memory Full option.	The display shows the Memory Full options. Once the Patient Test storage bank is full, the following can be set by the monitor: lockout additional tests; prompt for overwrite option; or automatically overwrite the oldest stored tests.
Memory Full **1-Allow** **Overwrite** 2-Prompt for Overwrite 3-Lockout	**21.** The administrator will select one of the following options: Press **1** – Allow Overwrite. Press **2** – Prompt for Overwrite. Press **3** – Lockout.	The display is returned to the Patient Test Memory Full screen.
Patient Test Memory Full **Lockout** 1-Next 2-Change	**22.** The administrator will select one of the following options: Press **1** to return to Test Setup menu. Press **Menu** to return to the Menu Mode. Press **On/Off** to turn off the monitor.	

Review/Change Test Setup for Control Tests

The options associated with this menu apply to all Control Tests.

Control levels can be any combination of low, normal, and high. At least one level must be selected.

The Results Format has the following options:
Show test results in a Numeric or Pass/Fail format.

Comment Code prompts have the following options:
• Disable the prompt for a comment code
• Prompt for a comment code with the option of not requiring it
• Require a comment code for every in-range and/or out-of-range test result.

The Memory Full option can notify the operator that the control test memory has reached its limit (1000 tests that have not been uploaded). Memory Full has the following options:
• Lockout additional tests until data is uploaded
• Prompt to overwrite old test results with new ones
• Automatically overwrite oldest test results with new ones.
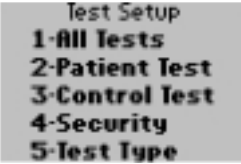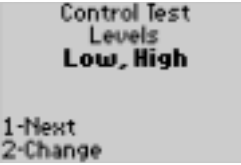
Questions? Refer to Page 10-13 For Customer Care Information.

8-19

Review/Change Test Setup for Control Tests:

Refer to the beginning of the Review or Change Setup section for step-by-step instructions to access the appropriate setup menu.

If the monitor displays a message not indicated in these procedures, please refer to section 10, *Troubleshooting*.
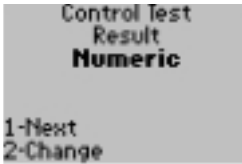
What You See on the Display	What You Do	Comments
Change Setup **1-Test Setup** **2-System Setup** **3-System Status** **4-Date and Time** **5-Edit Lists**	**1.** Press **1** – Test Setup.	The display shows the Test Setup menu.
Test Setup **1-All Tests** **2-Patient Test** **3-Control Test** **4-Security** **5-Test Type**	**2.** Press **3** – Control Test.	The display shows the Control Test Levels screen. The monitor can be set to perform any combination of low, normal and high control tests.
Control Test Levels **Low, High** 1-Next 2-Change	**3.** The administrator will select one of the following options: Press **1** – Next, to review Control Test Result; skip forward to step 6. Press **2** – Change, to change Control Test Levels option.	The display shows the Control Test Levels options.
Control Test Levels 1-Low 2-Normal 3-High 4->	**4.** The administrator will select one or a combination of the following options: Press **1** – Low, to activate low control. Press **2** – Normal, to activate normal control. Press **3** – High, to activate high control. Press **4** – to return to Control Test Levels screen.	The activated control level(s) are in bold type.

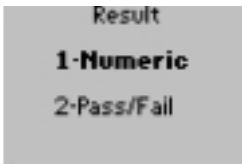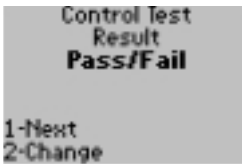| What You See on the Display	What You Do	Comments
Control Test Levels **Low, High** 1-Next 2-Change	**5.** Press **1** – Next, to continue to the Control Test Result menu.	The display shows the Control Test Result option. The control test results can be set to appear as numeric or Pass/Fail.
Control Test Result **Numeric** 1-Next 2-Change	**6.** The administrator will select one of the following options: Press **1** – Next, to review In-Range Comment Code; skip forward to step 9. Press **2** – Change, to change the result to Numeric or Pass/Fail.	The display shows the Control Test Result menu. Pass/Fail indicates whether the control test result is in-range or out-of-range.
Result **1-Numeric** 2-Pass/Fail	**7.** The administrator will select one of the following options: Press **1** – Numeric. Press **2** – Pass/Fail.	The display is returned to the Control Test Result menu.
Control Test Result **Pass/Fail** 1-Next 2-Change	**8.** Press **1** – Next.	The display shows the Control Test Comment Code If In-Range screen.
Control Test Comment Code If In-Range **Disabled** 1-Next 2-Change	**9.** The administrator will select one of the following options: Press **1** – Next, to continue to Control Test Comment Code If Out-of-Range menu. Skip forward to step 12. Press **2** – Change, to change the In-Range Comment Code option.	The display shows the Comment Code If In-Range options.

Questions? Refer to Page 10-13 For Customer Care Information.

8-21

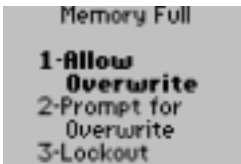| What You See on the Display	What You Do	Comments
Comment Code If In-Range **1-Disabled** 2-Optional 3-Required	**10.** The administrator will select one of the following options: Press **1** – Disabled. Press **2** – Optional. Press **3** – Required.	The display returns to the Control Test Comment Code If In-Range screen.
Control Test Comment Code If In-Range **Required** 1-Next 2-Change	**11.** Press **1** to continue to the next option.	The display shows the Control Test Comment Code If Out-of-Range screen.
Control Test Comment Code If Out-of-Range **Disabled** 1-Next 2-Change	**12.** The administrator will select one of the following options: Press **1** – Next, to continue to Memory Full menu. Skip forward to step 15. Press **2** – Change, to change the Comment Code If Out-of-Range options.	The display shows the Comment Code If Out-of-Range options.
Comment Code If Out-of-Range **1-Disabled** 2-Optional 3-Required	**13.** The administrator will select one of the following options: Press **1** – Disabled. Press **2** – Optional. Press **3** – Required.	The display returns to the Control Test Comment Code If Out-of-Range screen.
Control Test Comment Code If Out-of-Range **Required** 1-Next 2-Change	**14.** Press **1** – Next, to continue to the Memory Full menu.	The display shows the Control Test Memory Full options.
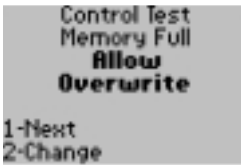
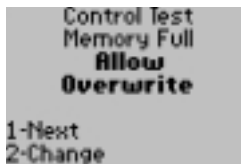| What You See on the Display	What You Do	Comments
Control Test Memory Full **Allow** **Overwrite** 1-Next 2-Change	**15.** The administrator will select one of the following options: Press **1** – Next, return to the Test Setup menu. Press **2** – Change, change the Memory Full options.	Allow Overwrite will automatically overwrite the existing data. Prompt for Overwrite will notify the operator that the data will be overwritten, giving the operator the choice to overwrite the data or not. Lockout will lockout the operator from overwriting any data until the data has been uploaded.
Memory Full **1-Allow** **Overwrite** 2-Prompt for Overwrite 3-Lockout	**16.** The administrator will select one of the following options: Press **1** – Allow Overwrite. Press **2** – Prompt for Overwrite. Press **3** – Lockout.	The display is returned to the Control Test Memory Full screen.
Control Test Memory Full **Allow** **Overwrite** 1-Next 2-Change	**17**. The administrator will select one of the following options: Press **1** – Next, return to Test Setup menu. Press **Menu** to return to the Menu Mode. Press **On/Off** to turn off the monitor.	

Questions? Refer to Page 10-13 For Customer Care Information.

8-23
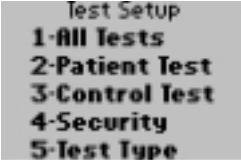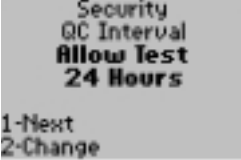
Review/Change Test Setup for Security

The Test Setup for Security menu enables the monitor to establish that certain criteria be met before a test can be performed.

- In all situations, the monitor can be set to Allow Test (allow the operator to test), Warn (tell the operator about the situation and still test) or Lockout (no testing can be done).
- QC Interval can require control tests to be run at certain time intervals. For example, every 12 hours, at specified times (7 a.m., 3 p.m. and 11 p.m.), or after a specified number of patient tests (1-250).
- The Operator ID can require that the operator ID is on the list of qualified/certified operators to continue.
- The Strip Lot (Test Strip Lot) can require that the test strip lot is on the list of qualified test strip lots to continue.

Review/Change Test Setup for Security:

Refer to the beginning of the Review or Change Setup section for the step-by-step instructions to access the appropriate setup menu.

If the monitor displays a message not indicated in these procedures, please refer to section 10, *Troubleshooting.*

What You See on the Display	What You Do	Comments
Change Setup 1-Test Setup 2-System Setup 3-System Status 4-Date and Time 5-Edit Lists	**1.** Press **1** – Test Setup.	The display shows the Test Setup menu.
Test Setup 1-All Tests 2-Patient Test 3-Control Test 4-Security 5-Test Type	**2.** Press **4** – Security.	The display shows the Security QC Interval menu.
Security QC Interval **Allow Test** **24 Hours** 1-Next 2-Change	**3.** The administrator will select one of the following options: Press **1** – Next, to continue to Security Operator ID Not Certified screen and skip forward to step 10. Press **2** – Change, to change the QC Interval Controls Expired option.	The display shows the options for the QC Interval Controls Expired menu. The options are to Allow Test, even if the QC interval has expired; Warn the operator that even though the QC interval has expired, the test may continue; or Lockout the system until the required control tests are performed.

Questions? Refer to Page 10-13 For Customer Care Information.

8-25

| What You See on the Display	What You Do	Comments
QC Interval Controls Expired **1-Allow Test** 2-Warn 3-Lockout	**4.** The administrator will select one of the following options: Press **1** – Allow Test. Press **2** – Warn. Press **3** – Lockout.	The display shows the QC Interval Security menu. The operator can choose between QC intervals. The settings are: • Time Interval – QC Interval based on a set number of hours between control tests. • Time of Day – choose up to three times during the day that QC Interval will take place. • Number of Patient Tests – QC Interval based on the number of patient tests specified.
QC Interval Security **1-Time Interval** 2-Time of Day 3-Patient Tests	**5.** The administrator will select one of the following options: Press **1** – Time Interval: continue to step 6. Press **2** – Time of Day: skip to step 7. Press **3** – Patient Tests: skip to step 8.	QC Time Interval option, the Time of Day option, or the Number of Patient Tests option.
QC Interval 24 Hours Hours __	**6.** Enter a Time Interval number between 1-99, then press **Enter.** Skip forward to step 9.	The display returns to the Security QC Interval menu.
Time of Day 1: 6:00 AM 2: 2:00 1-AM 2-PM 3:	**7.** Enter up to 3 times of the day in chronological order, starting at midnight. Press **Enter** to confirm each time. Skip forward to step 9.	The display returns to the Security QC Interval menu.
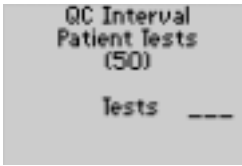
| | **8.** Enter number of patient tests between 1-250, then press Enter. | The display returns to the Security QC Interval menu. |

QC Interval
Patient Tests
(50)

Tests ___

| | **9.** Press **1** to continue to the Security Operator ID Not Certified screen. | The display shows the Security Operator ID Not Certified screen. |

Security
QC Interval
Lockout
24 Hours

1-Next
2-Change

| | **10.** The administrator will select one of the following options:

Press **1** – Next, to continue; skip forward to step 13.

Press **2** – Change, to change Operator ID Security. | The display shows the Operator ID Not Certified options. |
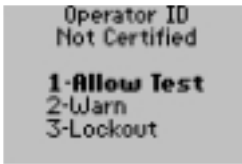
Security
Operator ID
Not Certified
Allow Test

1-Next
2-Change

| | **11.** The administrator will select one of the following options:

Press **1** – Allow Test.

Press **2** – Warn.

Press **3** – Lockout. | The display is returned to the Security Operator ID Not Certified screen. |

Operator ID
Not Certified

1-Allow Test
2-Warn
3-Lockout

| | **12.** Press **1** to continue to the Security Strip Lot Not on List screen. | The display shows the Security Strip Lot Not on List screen. |

Security
Operator ID
Not Certified
Lockout

1-Next
2-Change

Questions? Refer to Page 10-13 For Customer Care Information.

8-27

Security Strip Lot Not on List **Allow Test** 1-Next 2-Change	**13.** The administrator will select one of the following options: Press **1** – Next, to return to the Test Setup menu. Press **2** – Change, to change the Strip Lot Not on List options.	The display shows the Strip Lot Not on List options. 1. **Allow Test** – a test strip lot not on the test strip lot list. 2. **Warn** – the test strip lot is not on the test strip lot list (operator may continue with test). 3. **Lockout** – a test strip lot that is not on the test strip lot list (operator may not continue).
Strip Lot Not on List **1-Allow Test** 2-Warn 3-Lockout	**14.** The administrator will select one of the following options: Press **1** – Allow Test. Press **2** – Warn. Press **3** – Lockout.	The display returns to the Security Strip Lot Not on List screen.
Security Strip Lot Not on List **Lockout** 1-Next 2-Change	**15.** The administrator will select one of the following options: Press **1** to return to the Test Setup menu. Press **Menu** to return to the Menu Mode. Press **On/Off** to turn off the monitor.	
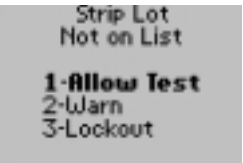
Review/Change Test Setup for Test Type

The options set with the Review/Change Test Setup for Test Type apply to different tests that may be performed, such as glucose. Use this menu to review or change these setups for Test Type:

Units:
Display test results in certain measurement units. The options are:
- mg/dL
- mmol/L

Sample Type:
Distinguish between different types of blood samples used for patient tests. The options are:
- Prompt to select the blood sample type for each patient test.
- Default to Capillary or Arterial for all patient tests.
- Default to Venous for all patient tests.
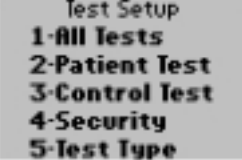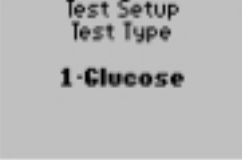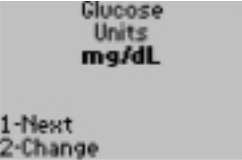
Action Range:
Set the range (low and high) when action should be taken based on the patient result obtained. The options are:
- Disable the action range.
- Enable and set the action range.

Questions? Refer to Page 10-13 For Customer Care Information.

8-29

Review/Change Test Setup for Test Type:

Refer to the beginning of the Review or Change Setup section for the step-by-step instructions to access the appropriate setup menu.

If the monitor displays a message not indicated in these procedures, please refer to section 10, *Troubleshooting.*

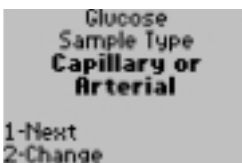| What You See on the Display	What You Do	Comments
Change Setup 1-Test Setup 2-System Setup 3-System Status 4-Date and Time 5-Edit Lists	**1.** Press **1** – Test Setup.	The display shows the Test Setup menu.
Test Setup 1-All Tests 2-Patient Test 3-Control Test 4-Security 5-Test Type	**2.** Press **5** – Test Type.	The display shows the Test Setup, Test Type menu.
Test Setup Test Type 1-Glucose	**3.** Press **1** to continue to Glucose Units option.	The display shows the Glucose Units screen.
Glucose Units mg/dL 1-Next 2-Change	**4.** The administrator will select one of the following options: Press **1** – Next, to continue to Glucose Sample Type menu; skip forward to step 7. Press **2** – Change, to change the test measurement units.	The display shows the Units options.
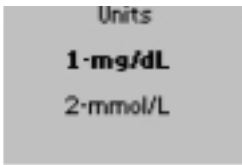
What You See on the Display	What You Do	Comments
Units **1-mg/dL** 2-mmol/L	**5.** Choose one of the following options: Press **1** – mg/dL. Press **2** – mmol/L.	The display is returned to the Glucose Units screen.
Glucose Units **mg/dL** 1-Next 2-Change	**6.** Press **1** to continue to the next menu.	The display shows the Glucose Sample Type screen.
Glucose Sample Type **Prompt** 1-Next 2-Change	**7.** The administrator will select one of the following options: Press **1** – Next, to continue to Glucose Action Range menu; skip forward to step 10. Press **2** – Change, to change Sample Type prompt.	The display shows the Sample Type options.
Sample Type **1-Prompt** 2-Capillary or Arterial 3-Venous	**8.** The administrator will select one of the following options: Press **1** – Prompt. Press **2** – Capillary or Arterial. Press **3** – Venous.	The monitor can be set to always prompt for the sample type or to always default to either Capillary or Arterial, or Venous blood samples. The display is returned to the Glucose Sample Type screen.
Glucose Sample Type **Capillary or Arterial** 1-Next 2-Change	**9.** Press **1** to continue to the Glucose Action Range menu.	The display shows the Glucose Action Range screen.
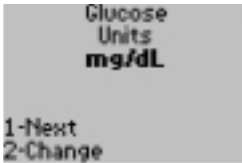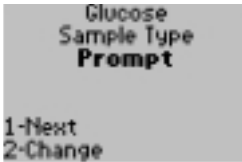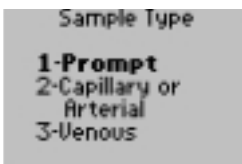
Questions? Refer to Page 10-13 For Customer Care Information.

8-31
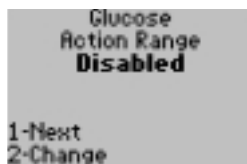
Glucose Action Range **Disabled** 1-Next 2-Change	**10.** The administrator will select one of the following options: Press **1** – Next, to return to Test Setup Test Type. Press **2** – Change, to change action range.	If the action range is disabled, the display is returned to the Test Setup Test Type screen. If the action range is enabled, the display shows the action range. The display shows the Glucose Action Range options.
Action Range **1-Disabled** 2-Enabled	**11.** The administrator will select one of the following options: Press **1** – Disabled. Skip forward to step 13. Press **2** – Enabled.	The display shows the Action Range screen. When the action range is enabled, the display shows an Action Range Low and High values screen. Enter a low action range value and a high action range value.
Action Range < 20 - 600 > Low 20 High 600 (1.1 mmol/L, -33.3 mmol/L) Precision PCx Test Strip Action Range < 20 - 500 > Low 20 High 500 (1.1 mmol/L, -27.8 mmol/L) Precision PCx Plus Test Strip	**12.** Enter the low value and press **Enter**. Enter the high value and press **Enter.**	The display is returned to the Glucose Action Range screen. **Refer to test strip instructions for use for Action Range.**
Glucose Action Range **Disabled** 1-Next 2-Change	**13.** Press **1** – Next to return to the Test Setup Test Type Screen.	
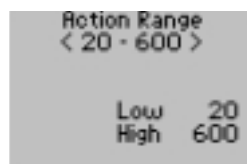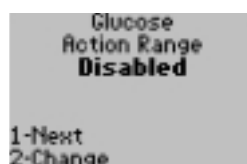
14. The administrator will select one of the following options:

Press **Clear** to return to Test Setup menu.

Press **Menu** to return to the Menu Mode menu.

Press **On/Off** to turn off the monitor.

Questions? Refer to Page 10-13 For Customer Care Information.

8-33

Review/Change Setup for System Setup

System Setup enables the look or appearance of the data shown on the display to be customized. The monitor can be formatted to present information in a way that is more comfortable or familiar to work with. Use this menu to review or change the setup for these features:

Language
This option presents the data in English or another language.

Beeper
This option turns the monitor beeper on or off. (The monitor beeps to alert the operator of certain functions).

Date Format
This option presents the date in mm/dd/yy, dd/mm/yy, or yy/mm/dd format. The user can select the punctuation that separates month, day and year.

Time Format
This option presents time in a 12 or 24-hour clock and separates numbers with different punctuation.

Set Password
This option allows the password to be changed.
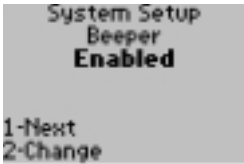
Restore Defaults
This option restores the monitor to factory settings.

Review/Change Setup for System Setup:

Refer to the beginning of the Review or Change Setup section for the step-by-step instructions to access the appropriate setup menu.

If the monitor displays a message not indicated in these procedures, please refer to section 10, *Troubleshooting.*

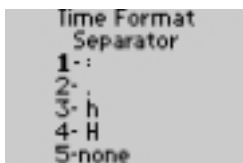| What You See on the Display	What You Do	Comments
Change Setup **1-Test Setup** **2-System Setup** **3-System Status** **4-Date and Time** **5-Edit Lists**	**1.** Press **2** – System Setup.	The display shows the System Setup Language menu.
System Setup Language **English** 1-Next 2-Change	**2.** The administrator will select one of the following: Press **1** – Next, to continue to System Setup Beeper menu; skip forward to step 5. Press **2** – Change, to change the language.	The display shows the Language setup options.
Language **1-English** 2-Français 3-Deutsch	**3.** The administrator will select the appropriate language.	The display returns to the System Setup Language menu.
System Setup Language **English** 1-Next 2-Change	**4.** Press **1** – Next, to go to System Setup Beeper.	The display shows the System Setup Beeper menu.
System Setup Beeper **Enabled** 1-Next 2-Change	**5.** The administrator will select one of the following options: Press **1** – Next, to go to System Setup Date Format menu; skip forward to step 8. Press **2** – Change, to change the beeper setting.	The display shows the Beeper option.

Questions? Refer to Page 10-13 For Customer Care Information.

8-35

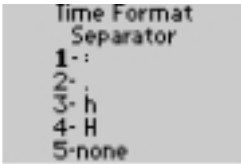|		
Beeper **1-Enabled** 2-Disabled	**6.** The administrator will select one of the following options: Press **1** – Enabled. Press **2** – Disabled.	The display returns to the System Setup Beeper menu.
System Setup Beeper **Disabled** 1-Next 2-Change	**7.** Press **1** – Next.	The display shows the System Setup Date Format menu.
System Setup Date Format **mo/dy/yr** 1-Next 2-Change	**8.** The administrator will select one of the following options: Press **1** – Next, to continue to System Setup Time Format menu. Skip forward to step 12. Press **2** – Change, to change the Date Format option.	The display shows the Date Format options. The date is listed using 2 digits for the month, day and year. For example, June 27, 1999 becomes 06 27 99.
Date Format **1-mo/dy/yr** 2-dy/mo/yr 3-yr/mo/dy	**9.** The administrator will select one of the following options: Press **1** – month/day/year. Press **2** – day/month/year. Press **3** – year/month/day.	The display shows the Date Format Separator options. The numbers can be separated with a slash (/), dash (-), period (.) or no punctuation.
Date Format Separator 1- / 2- - 3- . 4-none	**10.** The administrator will select one of the following options: Press **1** – slash (/). Press **2** – dash (-). Press **3** – period (.). Press **4** – none.	The display is returned to the System Setup Date Format menu.

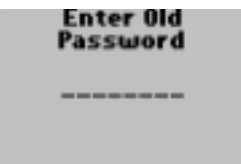| What You See on the Display	What You Do	Comments
System Setup **Date Format** **dy.mo.yr** 1-Next 2-Change	**11.** Press **1** to continue to System Setup Time Format menu.	The display shows the System Setup Time Format menu.
System Setup **Time Format** **4:57 PM** 1-Next 2-Change	**12.** The administrator will select one of the following options: Press **1** – Next, to continue to System Setup Password; skip forward to step 19. Press **2** – Change, to change the Time Format.	The display shows the Time Format options. The four options to use are: 12 hour clock using capital AM/PM; 12 hour clock using lowercase am/pm; a 0-24 hour clock; and a 01-24 hour clock.
Time Format 1- **1-12 AM/PM** 2- 1-12 am/pm 3- 0-23 4- 00-23	**13.** The administrator will select one of the following options: Press **1** – 1-12 AM/PM. Press **2** – 1-12 am/pm.	The display shows the Time Format Separator screen for hours. The 5 options are separators for hours.
Time Format Separator **1**-: 2- . 3- h 4- H 5-none	**14.** The administrator will select one of the following options: Press **1** – colon (:). Press **2** – period (.). Press **3** – h. Press **4** – H. Press **5** – none.	The display returns to the System Setup Time Format screen.
Time Format 1- **1-12 AM/PM** 2- 1-12 am/pm 3- 0-23 4- 00-23	**15.** If the administrator selects one of the following options: Press **3** – 0-23. Press **4** – 00-23.	The display shows the Time Format Separator screen for hours. The 5 options are separators for hours.
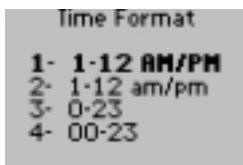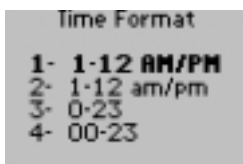
Questions? Refer to Page 10-13 For Customer Care Information.

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What You See on the Display	What You Do	Comments
Time Format Separator 1-: 2-. 3-h 4-H 5-none	**16.** The administrator will select one of the following options: Press **1** – colon (:). Press **2** – period (.). Press **3** – h. Press **4** – H. Press **5** – none.	The display shows the Time Format Units screen for minutes. The 4 options are separators for minutes.
Time Format Units 1-m 2-' 3-h **4-none**	**17.** The administrator will select one of the following options: Press **1** – m. Press **2** – apostrophe ('). Press **3** – h. Press **4** – none.	The display returns to the System Setup Time Format screen.
System Setup Time Format **16h58h** 1-Next 2-Change	**18.** Press **1** to continue to System Setup Password.	The display shows the System Setup Password screen.
System Setup Password 1-Next 2-Change	**19.** The administrator will select one of the following options: Press **1** – Next, to continue to the System Setup Change all settings to Factory Defaults menu. Skip forward to step 24. Press **2** – Change, to change the Password.	The display will prompt the operator to enter the current Password.
Enter Old Password --------	**20.** Enter the current Password, up to 8 digits, then press **Enter.**	The display prompts the operator to enter a New Password.
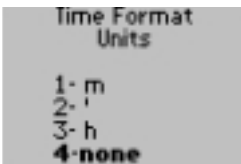
What You See on the Display	What You Do	Comments
Enter New Password ‒‒‒‒‒‒‒‒	**21.** Enter the New Password, then press **Enter.**	The display asks the operator to re-enter the password to confirm the New Password, then press **Enter.**
Verify New Password ‒‒‒‒‒‒‒‒	**22.** Re-enter New Password; press **Enter** to confirm.	The display returns to the System Setup Password menu.
System Setup Password 1-Next 2-Change	**23.** Press **1** to continue to System Setup Change all settings to Factory Defaults menu.	The display shows the System Setup Change all settings to Factory Defaults menu.
System Setup **Change all settings to Factory Defaults** 1-Next 2-Change	**24.** The administrator will select one of the following options: Press **1** – Next, to return to Change Setup menu. Press **2** – Change, to change all settings to Factory Defaults.	The display shows the Confirm options.
Confirm 1-Change to Factory Defaults 2-Don't Change	**25.** The administrator will select one of the following options: Press **1** – Change to Factory Defaults. Press **2** – Don't Change.	The display is returned to the System Setup Change all settings to Factory Defaults menu.
System Setup **Change all settings to Factory Defaults** 1-Next 2-Change	**26.** The administrator will select one of the following options: Press **1** to return to Change Setup menu. Press **Menu** to return to the Menu Mode. Press **On/Off** to turn off the monitor.	
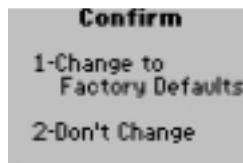
Questions? Refer to Page 10-13 For Customer Care Information.

8-39

Review/Change Setup for System Status

The Review/Change Setup menu allows the operator or administrator to review important information about the monitor operating status. The operator scrolls through the various screens, in the order they are listed below, by pressing 1 – Next.

Battery Power
This option checks the amount of battery power available for a rechargeable or disposable battery.

Temperature
This option measures the current temperature of the area where the monitor is.

Memory
This option indicates the percentages of memory available for Patient Test results and Control Test results.
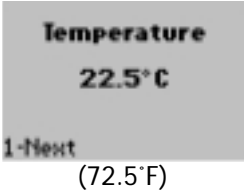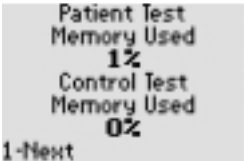
Software Version
This option displays the software version in the monitor.

Review/Change Setup for System Status:

Refer to the beginning of the Review or Change Setup section for step-by-step instructions to access the appropriate setup menu.

If the monitor displays a message not indicated in these procedures, please refer to section 10, *Troubleshooting.*

What You See on the Display	What You Do	Comments
Change Setup 1-Test Setup 2-System Setup 3-System Status 4-Date and Time 5-Edit Lists	**1.** Press **3** to review System Status.	The display shows the Battery Power menu. The black bar in the battery image drops as the battery power drains. When the power drains below a certain limit, the monitor will display a warning message. Power can be boosted by inserting new alkaline batteries into the monitor or by recharging the MediSense rechargeable battery pack in the docking station.
Battery Power 2.9v 1-Next	**2.** Press **1** – Next, to view the Temperature.	The display shows the temperature of the area where the monitor is.
Temperature 22.5°C 1-Next (72.5°F)	**3.** Press **1** – Next, to view the Patient Test and Control Test Memory Used.	The display shows the amount of memory that has been used to store patient test results and control test results.
Patient Test Memory Used 1% Control Test Memory Used 0% 1-Next	**4.** Press **1** – Next, to view the Software Version.	The display shows the software version screen.

Questions? Refer to Page 10-13 For Customer Care Information.

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MediSense
Precision PCx
ver. 1.0
           MB000-SIM
1-Next       699296
```

5. The administrator will select one of the following options:

Press **1** – to return to Review/Change Setup menu.

Press **Menu** – to return to Menu Mode.

Press **On/Off** – to turn off the monitor.

Review/Change Setup for Date and Time

The Review/Change Setup menu allows the date and time to be reviewed or changed. Depending on the format selected for date and time (this function is performed in Test Setup/System Setup/Date Format and Time Format menu), the instructions that appear on the display will vary.

The date and time formats used on the following page to illustrate how to review/change the date and time are as follows:
Date – month, day, year.
Time – 12 hours.
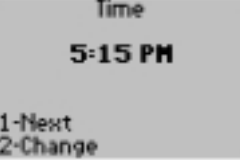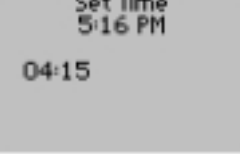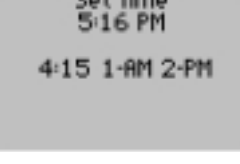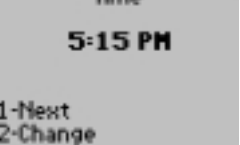
If another date and/or time format is selected (other than the ones stated above), the monitor will guide the operator or administrator through screens that are very similar to the ones that appear on the following pages.

Questions? Refer to Page 10-13 For Customer Care Information.

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Review/Change Setup for Date and Time:

Refer to the beginning of the Review or Change Setup section for step-by-step instructions to access the appropriate setup menu.
If the monitor displays a message not indicated in these procedures, please refer to section 10, *Troubleshooting.*

What You See on the Display	What You Do	Comments
Change Setup 1-Test Setup 2-System Setup 3-System Status 4-Date and Time 5-Edit Lists	**1.** Press **4** for Date and Time.	The display shows the Time menu.
Time 5:15 PM 1-Next 2-Change	**2.** The administrator will select one of the following options: Press **1** – Next, to continue to Date menu; skip forward to step 6. Press **2** – Change, to change current time.	The display shows the Set Time option.
Set Time 5:16 PM 04:15	**3.** Enter the time in hours and minutes then press **Enter.** Include leading zeros: 04 for 4.	The display is returned to the Set Time menu.
Set Time 5:16 PM 4:15 1-AM 2-PM	**4.** Select either 1 – AM or 2 – PM.	The display shows the user selected time.
Time 5:15 PM 1-Next 2-Change	**5.** Press **1** – Next, to continue to Date menu.	The display shows the Date menu.

Date mo/dy/yr **9/17/98** 1-Next 2-Change	**6.** The administrator will select one of the following options: Press **1** – Next, to return to Change Setup menu. Press **2** – Change, to change the date.	The display shows the Set Date menu.
Set Date 9/17/98 mo/dy/yr __/__/__	**7.** Enter the current date, then press **Enter.** Include leading zeros: 09 for 9.	The display is returned to the Date menu.
Date mo/dy/yr **9/18/98** 1-Next 2-Change	**8.** The administrator will select one of the following options: Press **1** – Next, to return to the Review/Change Setup menu. Press **Menu** to return to the Menu Mode. Press **On/Off** to turn the monitor off.	

Questions? Refer to Page 10-13 For Customer Care Information.

8-45

Change Setup for Edit Lists

The Precision PCx Monitor maintains two lists for the purpose of system security.

1. The Operator List contains the ID numbers of operators who are authorized to perform tests. When the operator enters an Operator ID, the monitor checks the ID against the current list stored in the monitor. The monitor can be set to one of the following options:

    Allow Test – No checking will occur.

    Warn – The monitor displays a warning message but allows the operator to continue testing.

    Lockout – The monitor will not allow the operator to continue testing.

The Change Setup for Edit Lists is used to make changes to the Operator ID List. When a name is added to the list, an expiration date (the date the operator's access to the monitor expires) must also be entered. A single Operator ID or the whole list can be deleted or changed. The Expiration Date for operators can also be changed.

2. The Strip Lot List contains the strip lot numbers of valid test strip lots in the current inventory. When the operator enters a test strip lot number (via the barcode scanner or by manually entering* the 14-digit lot number), the monitor checks the number against the current list stored in the monitor. The monitor can be set to one of the following options:

    Allow Test – No checking will occur.

    Warn – The monitor displays a warning message but allows the operator to continue testing.

    Lockout – The monitor will not allow the operator to continue testing.

The Change Setup for Edit Lists is used to make changes to the Strip Lot List. The Strip Lot List can have test strip lots added or deleted. The minimum and maximum control values for the test strip lots can be customized to meet tighter default values needed by a facility.
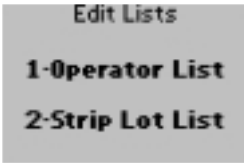
If you have questions, please refer to page 10-13 for Customer Care information.

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* Manual entry of strip lots with alpha-numeric barcodes is not supported.
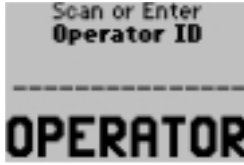
Change Setup for Edit Lists:

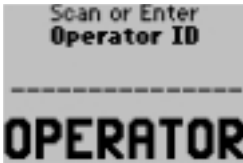Refer to the beginning of the Change Setup section for step-by-step instructions to access the Change Setup menu.

If the monitor displays a message not indicated in these procedures, please refer to section 10, *Troubleshooting.*

What You See on the Display	What You Do	Comments
Change Setup 1-Test Setup 2-System Setup 3-System Status 4-Date and Time 5-Edit Lists	**1.** Press **5** – Edit Lists.	The display shows the Edit Lists options. The Operator List or the Strip Lot List can be edited.
Edit Lists 1-Operator List 2-Strip Lot List Operator ID List of 16 1-Add 2-Delete 3-Change	**2.** Press **1** – Operator List.	The display shows the Operator ID options and the number of operators on the list. (This example shows a list of 16). The list can be edited by adding, deleting or changing entries. **NOTE:** • If there are no IDs on the list, the display shows **List Empty**. The **Delete** and **Change** options will not appear. • If the list is full, the **Add** option will not appear.

Questions? Refer to Page 10-13 For Customer Care Information.

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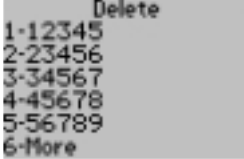
Add an Operator to the Operator List:

What You See on the Display	What You Do	Comments
Operator ID List of 16 1-Add 2-Delete 3-Change	**1.** Press **1** – Add.	The display shows the Scan or Enter Operator ID screen.
Scan or Enter **Operator ID** -------------- **OPERATOR**	**2.** Press **Scan** or manually enter the Operator ID via the keypad and press **Enter.**	The display shows the Operator ID Expiration Date menu. Enter a certification Expiration Date for the operator, using the two-digit number format for the date.
Operator ID 123456789012345 **Expiration Date** mo/dy/yr __/__/__	**3.** Enter the expiration date then press **Enter.**	The display is returned to the Operator ID List menu.
Operator ID List of 16 1-Add 2-Delete 3-Change	**4.** The administrator will select one of the following options: Press **Clear** to return to the Edit Lists menu. Press **Menu** to return to the Menu Mode. Press **On/Off** to turn off the monitor.	

Delete One Operator on the Operator List by Entering ID:

What You See on the Display	What You Do	Comments
Operator ID List of 16 1-Add 2-Delete 3-Change	**1.** Press **2** – Delete.	The display shows the Delete Operator ID menu.
Delete Operator ID 1-Enter ID 2-Select ID 3-Delete All	**2.** Press **1** – Enter ID.	The display shows the Scan or Enter Operator ID menu. Enter the Operator ID.
Scan or Enter Operator ID —————————— OPERATOR	**3.** Press **Scan** or manually enter the Operator ID via the keypad and press **Enter.**	The display prompts the operator to verify the delete.
Operator ID 23456 **Verify** **Delete** 1-ReEnter ID 2-Delete	**4.** The administrator will select one of the following options: Press **1** – ReEnter ID. Return to step 3. Press **2** – Delete.	The ID is deleted from the list and the display returns to the Delete Operator ID menu.
Delete Operator ID 1-Enter ID 2-Select ID 3-Delete All	**5.** The administrator will select one of the following options: Press **Clear** to return to the Operator ID List Menu. Press **Menu** to return to the Menu Mode. Press **On/Off** to turn off the monitor.	

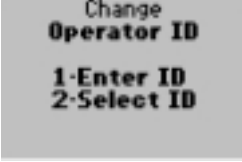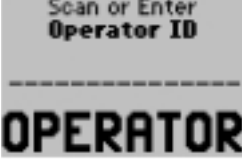Questions? Refer to Page 10-13 For Customer Care Information.

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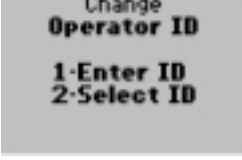
Delete One Operator on the Operator List by Selecting ID:

What You See on the Display	What You Do	Comments
Operator ID List of 16 1-Add 2-Delete 3-Change	**1.** Press **2** – Delete.	The display shows the Delete Operator ID menu.
Delete **Operator ID** 1-Enter ID 2-Select ID 3-Delete All	**2.** Press **2** – Select ID.	The display shows the list of Operator IDs.
Delete 1-12345 2-23456 3-34567 4-45678 5-56789 6-More	**3.** The administrator will select one of the following options: Press the number of the ID to be deleted. Press **6** to see any additional IDs, then press the number of the ID to be deleted or Press **6** – Exit	The display prompts the operator to Verify Delete.
Operator ID 23456 **Verify** **Delete** 1-ReEnter ID 2-Delete	**4.** The administrator will do one of the following options: Press **1** – ReEnter ID. Return back to step 3. Press **2** – Delete.	The ID is deleted from the list and the display returns to the Delete Operator ID menu. To delete additional IDs, return to step 2.
Delete **Operator ID** 1-Enter ID 2-Select ID 3-Delete All	**5.** The administrator will select one of the following options: Press **Clear** to return to the Operator ID List menu. Press **Menu** to return to the Menu Mode. Press **On/Off** to turn off the monitor.	

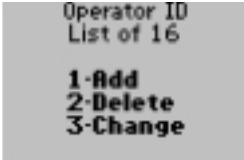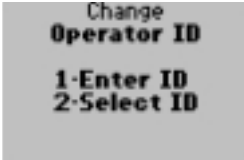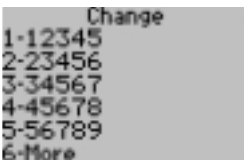## Delete All Operators on the Operator List:
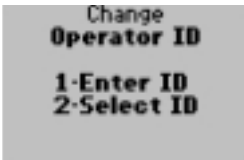
What You See on the Display	What You Do	Comments
Operator ID List of 16 1-Add 2-Delete 3-Change	**1.** Press **2** – Delete.	The display shows the Delete Operator ID menu.
Delete **Operator ID** 1-Enter ID 2-Select ID 3-Delete All	**2.** Press **3** – Delete All.	The display prompts the operator to verify the delete.
Operator ID **All IDs** **Verify** **Delete** 1-Don't Delete 2-Delete All	**3.** The administrator will do one of the following options: Press **1** – Don't Delete. Return back to step 2. Press **2** – Delete All.	The IDs are deleted from the list and the display returns to the Operator ID List menu.
Operator ID List Empty **1-Add**	**4.** The administrator will select one of the following options: Press **Clear** to return to the Edit Lists menu. Press **Menu** to return to the Menu Mode. Press **On/Off** to turn off the monitor.	

Questions? Refer to Page 10-13 For Customer Care Information.

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Change One Operator on the Operator List by Entering ID:

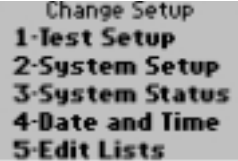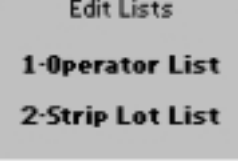| What You See on the Display	What You Do	Comments
Operator ID List of 16 1-Add 2-Delete 3-Change	**1.** Press **3** – Change.	The display shows the Change Operator ID menu.
Change **Operator ID** 1-Enter ID 2-Select ID	**2.** Press **1** – Enter ID.	The display shows the Scan or Enter Operator ID menu.
Scan or Enter **Operator ID** _____ **OPERATOR**	**3.** Press **Scan** or manually enter the Operator ID via the keypad and press **Enter.**	The display shows the Operator ID Expiration Date and prompts the operator to enter a new expiration date.
Operator ID 23456 9/9/99 mo/dy/yr __/__/__	**4.** Enter a new expiration date and then press **Enter.**	The Operator ID expiration date is changed. The display returns to the Change Operator ID menu.
Change **Operator ID** 1-Enter ID 2-Select ID	**5.** The administrator will select one of the following options: Press **Clear** to return to the Operator ID List menu. Press **Menu** to return to the Menu Mode. Press **On/Off** to turn off the monitor.	

Change One Operator on the List by Selecting ID:

What You See on the Display	What You Do	Comments
Operator ID List of 16 1-Add 2-Delete 3-Change	**1.** Press **3** – Change.	The display shows the Change Operator ID menu.
Change **Operator ID** 1-Enter ID 2-Select ID	**2.** Press **2** – Select ID.	The display shows a list of Operator IDs.
Change 1-12345 2-23456 3-34567 4-45678 5-56789 6-More	**3.** The administrator will select one of the following options: Press the number of the ID to be changed. Press **6** – More, to view additional IDs or Press **6** – Exit.	The display lists the Operator ID expiration date. The display will prompt for a new expiration date to be entered.
Operator ID 23456 **9/9/99** mo/dy/yr __/__/__	**4.** Enter a new expiration date for each operator then press **Enter.**	The Operator ID expiration date is changed. The display returns to the Change Operator ID menu.
	5. To change another ID, return to step 2.	
Change **Operator ID** 1-Enter ID 2-Select ID	**6.** When finished, the operator will select one of the following options: Press **Clear** to return to the Operator ID menu. Press **Menu** to return to the Menu Mode. Press **On/Off** to turn off the monitor.	

Questions? Refer to Page 10-13 For Customer Care Information.

8-53

Change Setup for Edit Test Strip Lot List:

Refer to the beginning of the Change Setup section for step-by-step instructions to access the Change Setup menu.

If the monitor displays a message not indicated in these procedures, please refer to section 10, *Troubleshooting*.

What You See on the Display	What You Do	Comments
Change Setup 1-Test Setup 2-System Setup 3-System Status 4-Date and Time 5-Edit Lists	**1.** Press **5** – Edit Lists.	The display shows the Edit Lists options. The Strip Lot List can be edited by adding, deleting or changing a test strip lot number.
Edit Lists 1-Operator List 2-Strip Lot List	**2.** Press **2** – Strip Lot List.	The display shows the Strip Lot List menu and the number of items on the list. (The example provided is a list of 3). The list can be edited by adding, deleting or changing entries.
Strip Lot List of 3 1-Add 2-Delete 3-Change		**NOTE:** • If there are no test strip lots on the test strip lot list, the display shows **List Empty**. The **Delete** and **Change** options will not appear. • If the list is full, the **Add** option will not appear.

Add a Test Strip Lot to the Strip Lot List:

What You See on the Display	What You Do	Comments
Strip Lot **List of 3** **1-Add** **2-Delete** **3-Change**	**1.** Press **1** – Add.	The display shows the Scan or Enter Strip Code screen.
Scan or Enter **Strip Code** --------------	**2.** Press **Scan** or manually enter* the test strip lot number via the keypad and press **Enter.**	The display shows the Strip Code option. The operator can return to the Strip Lot menu to add additional test strip lots or can continue to the next menu to set minimum and maximum control solution ranges for the test strip lot.
Strip Code **19133538503151** **1-Continue** **2-Change Control** **Ranges**	**3.** The administrator will select one of the following options: Press **1** – Continue. Press **2** – Change, to change the control ranges.	The display prompts the operator to enter in the test strip lot minimum and maximum values for the low control test.
Strip Lot **193165** **Low: 30-60** Minimum ___37 Maximum	**4.** Key in the minimum and maximum values for the low control, press **Enter** after each value entered.	The display prompts the operator to enter in the test strip lot minimum and maximum values for the normal control test.
Strip Lot **193165** **Normal: 59-115** Minimum ___62 Maximum	**5.** Key in the minimum and maximum values for the normal control, press **Enter** after each value entered.	The display prompts the operator to enter in the test strip lot minimum and maximum values for the high control test.

* Manual entry of strip lots with alpha-numeric barcodes is not supported.

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Questions? Refer to Page 10-13 For Customer Care Information.

What You See on the Display	What You Do	Comments

Strip Lot
193165
High: **211-340**

Minimum   216
Maximum

6. Key in the minimum and maximum values for the high control, press **Enter** after each value entered.

The display returns to the Strip Lot List menu.

Strip Lot
List of 4
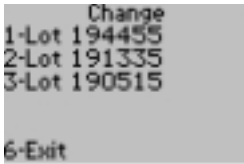
1-Add
2-Delete
3-Change
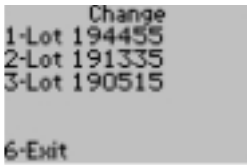
7. The administrator will select one of the following options:

Press **Clear** to return to the Edit Lists menu.

Press **Menu** to return to the Menu Mode.

Press **On/Off** to turn off the monitor.

Delete Test Strip Lots from the Strip Lot List:

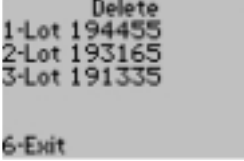| What You See on the Display	What You Do	Comments
Strip Lot List of 3 1-Add 2-Delete 3-Change	**1.** Press **2** – Delete.	The display shows the Delete list where test strip lot codes can be viewed.
Delete 1-Lot 194455 2-Lot 193165 3-Lot 191335 6-Exit	**2.** Press the number of the test strip lot to be deleted. Press **6** – Exit.	
Strip Lot 193165 **Verify Delete** 1-ReEnter Lot 2-Delete	**3.** The administrator will be prompted to verify the delete. Press **1** – ReEnter Lot. Return to step 2. Press **2** – Delete.	The display is returned to the Delete List. The display is returned to the Strip Lot List menu.
Strip Lot List of 2 1-Add 2-Delete 3-Change	**4.** The administrator will select one of the following options: Press **2** – Delete, to continue deleting test strip lots. Press **Clear** to return to the Edit Lists menu. Press **Menu** to return to the Menu Mode. Press **On/Off** to turn off the monitor.	

Questions? Refer to Page 10-13 For Customer Care Information.

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Change Test Strip Lot on the Strip Lot List:

What You See on the Display	What You Do	Comments
Strip Lot List of 3 1-Add 2-Delete 3-Change	**1.** Press **3** – Change.	The displays shows the change list where test strip lot codes can be viewed. Press the number of the test strip lot to change the control solution ranges.
Change 1-Lot 194455 2-Lot 191335 3-Lot 190515 6-Exit	**2.** Press the number of the test strip lot to be changed.	The display prompts the operator to enter in the test strip lot minimum and maximum values for the low control test.
Strip Lot 193165 Low: **30-60** Minimum _37 Maximum	**3.** Key in the minimum and maximum values for the low control, press **Enter** after each number.	The display prompts the operator to enter in the test strip lot minimum and maximum values for the normal control test.
Strip Lot 193165 Normal: **59-115** Minimum _62 Maximum	**4.** Key in the minimum and maximum values for the normal control, press **Enter** after each number.	The display prompts the operator to enter in the test strip lot minimum and maximum values for the high control test.
Strip Lot 193165 High: **211-340** Minimum 216 Maximum	**5.** Key in the minimum and maximum values for the high control, press **Enter** after each number.	The display returns to the Change Lot menu.

```
           Change
1-Lot 194455
2-Lot 191335
3-Lot 190515


6-Exit
```

6. The administrator will select one of the following options:

Press the number of another test strip lot to continue changes.

Press **6** to Exit to the Strip Lot List menu.

Press **Menu** to return to the Menu Mode.

Press **On/Off** to turn off the monitor.

Questions? Refer to Page 10-13 For Customer Care Information.

8-59

Once the test results have been collected during a prescribed period of time, they will then be uploaded into the MediSense QC Manager Data Management System. The QC Manager Data Management System provides a simple and automated way to collect, report and transfer data to a personal computer (PC).

Data upload is initiated by the computer and requires no special steps by the operator, as long as the monitor is connected properly and the QC Manager Program is running. For the data upload to begin, either the monitor must be in the optional docking station or the communications cable must be plugged into the data port on the monitor. Once the connection is established, communication between the monitor and the PC will begin automatically.

The monitor can send and receive data. During data upload, the monitor cannot be used for testing. When this occurs, the monitor will display the following message, "Please Wait for Data Upload". Testing is preempted while the monitor is sending or receiving data.

The technical details of the data upload are described in the QC Manager manual. Data is transferred in ASTM E-1381 format.

If the monitor is removed before data transmission is complete, no data will have been 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. Error messages are shown in the Troubleshooting section of this manual. Further troubleshooting information for any data upload question is provided in the QC Manager manual.
Error Messages:

Questions? Refer to Page 10-13 For Customer Care Information.

9-1

Docking Station

The Precision PCx System offers an optional docking station that provides a means for hands-free, automatic data transfer (upload/download) between the Precision PCx Monitor and a PC running the QC Manager application software. The QC Manager program will allow messages to be monitored and managed from a variety of MediSense monitors and systems that will be used throughout the hospital. (Please refer to the QC Manager Manual for more information).

The docking station must be connected to a power source (for battery recharge only) via the AC adapter supplied with the docking station. Once the monitor is placed into the docking station and a connection is established, data will be automatically transferred. The docking station also serves as a battery recharge station for the Precision PCx Monitor equipped with the optional rechargeable battery pack.

Note: Use only MediSense rechargeable battery pack.

The docking station has a swivel base that allows it to sit on a desktop or to be mounted to a wall using the mounting plate supplied by MediSense. (Instructions for installing the mounting plate are described later in this section).

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.

Note: Use only the AC adapter supplied by MediSense. Use of any other adapter might cause serious damage to the docking station and to the Precision PCx Monitor while it is in the docking station.

Connecting Cables to the Docking Station

The docking station has three ports located on the back: an AC adapter port, data transfer port and printer port (Figure 1). When connected, the AC adapter supplies power to the docking station for battery recharge. The data transfer port connects the docking station to a variety of transfer options using the RS-232 communications cable supplied by MediSense. The printer (serial) port connects the docking station to a printer.

Figure 1

The following network connections can be established (Figures 2-4).

Figure 2
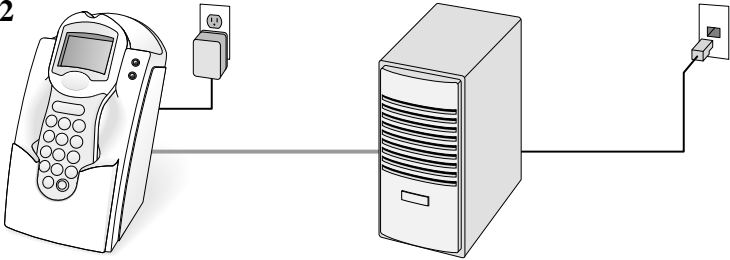
1. Connect the AC adapter to a power source.

   Note: For plug connected equipment where protecting earthing is required, plug the equipment into a supply outlet that has an earth connection.

2. Connect the RS-232 cable to the terminal server and to the docking station data transfer port.

Questions? Refer to Page 10-13 For Customer Care Information.

9-3

3. Connect the network cable to the RJ-45 network jack and to the serial
   port of the terminal server.

Figure 3

1. Connect the AC adapter to a power source.
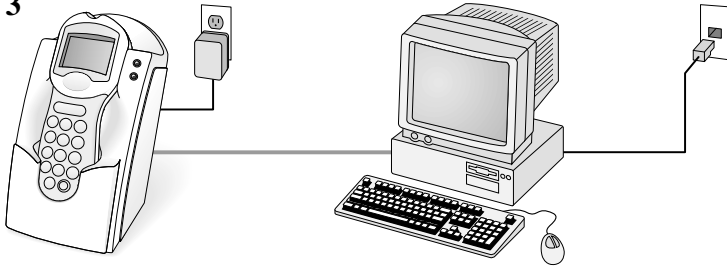2. Connect the RS-232 cable to a serial port on a networked PC at the
   nurses' station and to the docking station data transfer port.
3. Connect the network cable to the RJ-45 network jack and to the serial
   port of the networked PC at the nurses' station.

Figure 4
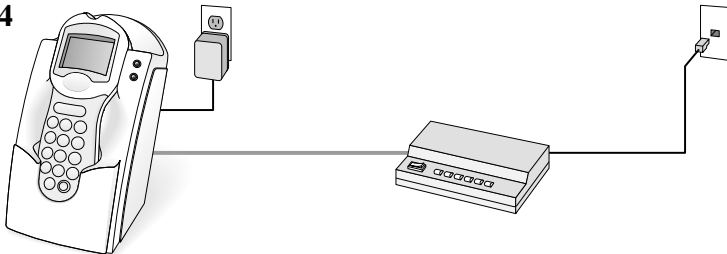
1. Connect the AC adapter to a power source.
2. Connect the RS-232 to an approved external modem and to the
   docking station data transfer port.
3. Connect the approved external modem to a standard telephone jack
   using a modem connection.

Note: This connection may require a special adapter to convert the
9 pin serial cable end to a 25 pin connector.

Mounting Instructions
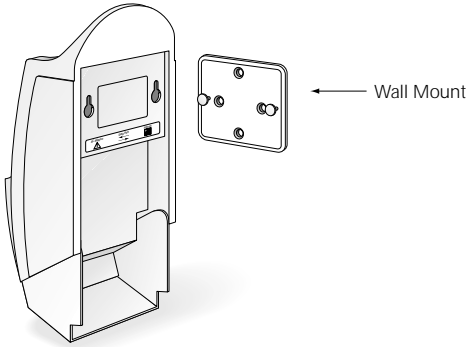
Wall Mount

Instructions:

(This operation is similar to mounting a telephone on the wall).

1. Drill the holes according to the wall mount.
2. Place the wall mount on the wall and insert the enclosed four 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.

Questions? Refer to Page 10-13 For Customer Care Information.

9-5

Troubleshooting: Patient Test Results

This section describes conditions that can cause out-of-range patient test results. Refer to the Precision PCx or Precision PCx *Plus* Test Strip instructions for use for test strip specification information.

Reasons Glucose Results May Be Higher than Expected:
• Hematocrit is lower than the acceptable limit for the test strips, as indicated on test strip instructions for use.
• Serum or plasma samples were used instead of whole blood.
• Room temperature >104°F (40°C).
• Relative humidity >90%.
• Venous blood tested in capillary or arterial 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 instructions for use.
• Room temperature < 59°F (15°C).
• Capillary or arterial blood tested in venous mode.
• Relative humidity < 10%.
• 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.

Troubleshooting: Out-of-Range Control Test Results

Repeat the test for that control solution to make sure that the operator meets the conditions in this checklist:
• No air bubbles are in the control bottle's nozzle.
• Calibrate the monitor using the barcode for the test strip used.
• Enter the correct 5-digit lot number for the control solutions.
• Check storage temperatures: Solutions and test strips must be stored between 39°F and 86°F (4°C and 30°C).
• Check that the temperature and humidity conditions in the room where the tests are being performed are within the acceptable operating range. Refer to the Precision PCx or Precision PCx *Plus* Test Strip instructions for use.
• Check that the bottles have not been open for more than 90 days.

- Use a new test strip for each test.
- Use only Precision PCx or Precision PCx *Plus* Test Strips.

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 Customer Care at 1-877-529-7185. Outside the United States, contact the local Abbott Laboratories/MediSense office or distributor.

Troubleshooting: Out-of-Range Linearity Test Results

Repeat the test for that linearity solution to make sure that the operator meets the conditions in this checklist:

- No air bubbles are in the linearity bottle's nozzle.
- Calibrate the monitor using the barcode for the test strip used.
- Enter the correct lot number for the linearity solutions.
- Check storage temperature. For solution storage temperature range, please refer to linearity kit instructions for use. Test Strips must be stored between 39°F and 86°F (4°C and 30°C).
- Check that the temperature and humidity conditions in the room where the tests are being performed are within the acceptable operating range. Refer to the Precision PCx or Precision PCx *Plus* Test Strip and linearity kit instructions for use.
- Check linearity kit insert for open bottle expiration date.
- Use a new test strip for each test.
- Use only Precision PCx or Precision PCx *Plus* Test Strips.

If test results are out of range despite meeting the above criteria, please repeat the test using a new linearity kit and/or test strips. If the results are still out of range, call Customer Care at 1-877-529-7185. Outside the United States, contact your local Abbott Laboratories/MediSense office or distributor.

Error Messages

In this section, you will find information relating to error messages that appear on the display when errors are detected by the Precision PCx Monitor.

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, include the three-digit error code (if any), and call Customer Care at 1-877-529-7185. Outside the United States, contact the local Abbott Laboratories/MediSense office or distributor.
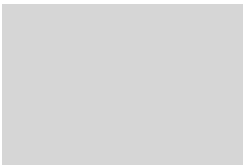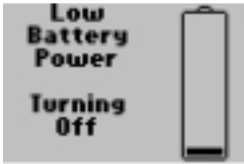
Note: Check Precision PCx display for proper performance before every test. If at any time the display screen becomes difficult to read, discontinue use of monitor and call Customer Care or your local Abbott Laboratories/MediSense office or distributor.

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. See Maintenance for further information.
		If the problem persists, do one of the following:
		• Install new batteries. See Maintenance for more information.
		• Place the monitor into the docking station to recharge the battery pack (if the system has this option).
Low Battery Power	Battery power is getting low. Testing will be available for a limited time.	Do one of the following:
		• Install new batteries. See Maintenance for more information.
		• Place the monitor into the docking station to recharge the battery pack (if the system has this option).
		Press **1** to continue.

Questions? Refer to Page 10-13 For Customer Care Information.

10-3

When You Turn on the Monitor, or During Use:

Symptom/Error Message	Explanation	How To Respond
Low Battery Power **Turning Off**	Battery power is too low for testing. The monitor will turn off in 10 seconds.	Do one of the following: Install new batteries. See Maintenance for further information. Place the monitor into the docking station to recharge the battery pack (if the system has this option).
⊗ 001	The monitor has a problem that prevents it from operating.	**1.** Turn off the monitor. Turn it on and repeat the function. **2.** If the problem persists, record the three-digit error code and contact Customer Care.
Error nnn (Error codes 311-319)	There may be a problem in the stored data.	Contact Customer Care.
Error nnn (Error codes: 611-623)	The monitor may have a problem that prevents it from operating properly.	Contact Customer Care.
Error nnn (Error codes: 711-739)	The monitor may have a problem that prevents it from operating properly.	**1.** Turn off the monitor. Turn it on and repeat the function. **2.** If the problem persists, record the three-digit error code and contact Customer Care.

When a Test is Selected:

Symptom/Error Message	Explanation	How To Respond
Low, High Control Tests Required 1-Exit	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 control tests indicated in the message. Press **1** to Exit. or If it appears, press **2** to continue patient testing.
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.** To upload data, do one of the following: Place the monitor in the docking station (if the system has this option). Plug the communications cable into the data port and connect to the laptop. (Refer to QC Manager Manual). **2.** If the problem persists, notify the system administrator. Press **1** to exit. or If it appears, press **2** to continue testing.
Temperature Outside Range 48.5°C **Testing Disabled** 1-Exit (119.3°F)	The room temperature is outside the limits for testing. Data Review and Review/Change Setup functions are available.	Ensure that the room temperature is within the specified limits. Allow time for the monitor to stabilize to room temperature. Please refer to test strip instructions for use for appropriate operating temperature range. Press **1** to exit.

Questions? Refer to Page 10-13 For Customer Care Information.

10-5
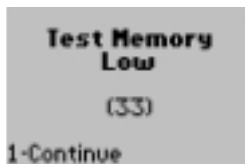
Symptom/Error Message	Explanation	How To Respond
Test Memory Low (33) 1-Continue This screen appears only when Patient Test or Control Test is selected.	Less than 50 test data records are available in test memory for the selected test type. The Test Memory Full option for that test type is set to Prompt for Overwrite or Lockout. The number of test records available is displayed. Data should be uploaded as soon as possible.	For data upload: **1.** To upload the data, do one of the following: • Place the monitor in the docking station (if the system has this option). • Plug the communications cable into the data port and connect to the laptop. (Refer to QC Manager manual). **2.** If the problem persists, notify the system administrator. Press **1** to continue testing.
Test Memory Full 1-Exit 2-Continue This screen appears only when Patient Test or Control Test is selected.	Test memory for the selected test type is full. The Test Memory Full option for that test type is set to Prompt for Overwrite or Lockout. (The menu item 2 – Continue appears only if this option is set to Prompt for Overwrite. Tests may be performed; the oldest stored test results of the selected type will be overwritten with new results). If the option is set to Lockout, data must be uploaded before testing can start. (Memory space becomes available once records have been uploaded. They do not have to be erased).	**1.** To upload the data, do one of the following: Place the monitor in the docking station (if the system has this option). Plug the communications cable into the data port and connect to the laptop. (Refer to QC Manager manual). **2.** If the problem persists, notify the system administrator. Press **1** to exit to other functions. or Press **2** to continue testing and overwrite the oldest stored results.
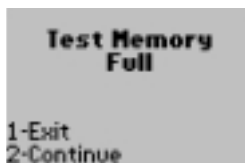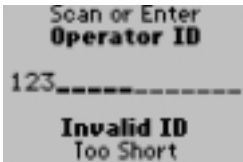
During Any Test:

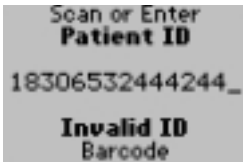| Symptom/Error Message	Explanation	How To Respond
Scan or Enter Patient ID 18306532444244_ **Invalid ID** Barcode	The barcode just scanned was not read correctly. Possible reasons are: • The red scanner beam did not pass across all the bars of the code. • The scanner was not held between 3 and 12 inches from the barcode. • The barcode was damaged or poorly printed. • The barcode was not of the type specified for this ID or lot number.	1. Rescan the barcode or manually enter the ID or lot number. 2. Notify the system administrator. The problem may be the printing of the barcode or the setup.
Scan or Enter Operator ID 123_____ **Invalid ID** Too Short The reason may also be: 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. 2. Manually enter the ID or lot number. 3. If the problem persists, notify the system administrator.
Strip Lot 193165 **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 IDs or lot numbers defined for this monitor.	1. Verify and re-enter the ID or lot number using the barcode scanner. 2. Manually enter* the ID or lot number. 3. If the problem persists, notify the system administrator.

* Manual entry of strip lots with alpha-numeric barcodes is not supported.

Questions? Refer to Page 10-13 For Customer Care Information.

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Symptom/Error Message	Explanation	How To Respond
Operator ID 18333 **Is Not on the Operator List** 1-ReEnter ID 2-Continue	The Operator ID just entered is not on the list of acceptable Operator IDs defined for this monitor. The menu item 2 – Continue appears and testing is permitted because the Security: Operator ID Not Certified option is set to Warn.	**1.** Verify and re-enter the ID using the barcode scanner. **2.** Manually enter the ID. **3.** If the problem persists, notify the system administrator. Press **2** to continue.
Scan or Enter **Operator ID** 23456789_____ **Invalid ID** Not on List	The Operator ID entered is not on the list of acceptable Operator IDs defined for this monitor.	Testing cannot continue because the Security Operator ID Not Certified option is set to Lockout.
Operator ID 123456789012345 **Date Expired** 1-ReEnter ID 2-Continue	The Operator ID entered has expired. 2 – Continue appears and testing is permitted because Security Operator ID Not Certified option is set to Warn.	**1.** Verify and re-enter the ID using the barcode scanner. **2.** Manually enter the ID. **3**. If the problem persists, notify the system administrator. Press **2** to continue with testing, using the Operator ID already entered.
Scan or Enter **Operator ID** 12345678_____ **Invalid ID** Date Expired	The Operator ID or test strip lot number scanned or entered has expired.	Testing cannot continue because the Security Operator ID Not Certified Option is Set to Lockout.
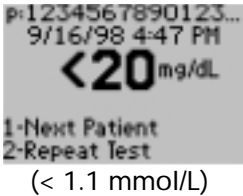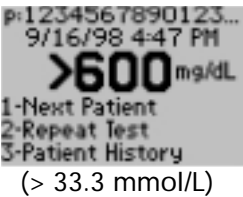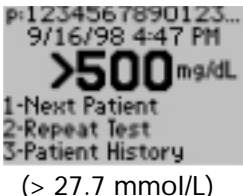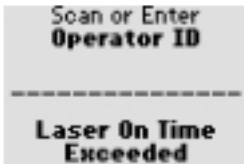
Symptom/Error Message	Explanation	How To Respond
Scan or Enter **Strip Lot** 345667 **Invalid Lot** Format	The lot number or test strip code is invalid.	**1.** Verify the lot number or test strip code. **2.** If the problem persists, notify the system administrator.
p:1234567890123... 9/16/98 4:47 PM **<20** mg/dL 1-Next Patient 2-Repeat Test (< 1.1 mmol/L)	The test result is below the measuring limit of the system.	Press **2** – Repeat Test - verify result using laboratory reference instrument.
p:1234567890123... 9/16/98 4:47 PM **>600** mg/dL 1-Next Patient 2-Repeat Test 3-Patient History (> 33.3 mmol/L) Precision PCx Test Strip	The test result is above the measuring limit of the system.	Press **2** – Repeat Test - verify result using laboratory reference instrument. Refer to test strip instructions for use for assay range of test strips.
p:1234567890123... 9/16/98 4:47 PM **>500** mg/dL 1-Next Patient 2-Repeat Test 3-Patient History (> 27.7 mmol/L) Precision PCx *Plus* Test Strip		
Strip Error nnn 1-New Strip 2-Exit **(Error codes 211-212)**	The test strip or the test 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 test strip. Press **2** to exit to the Test Menu.
Assay Error 111 1-New Strip 2-Exit	The test strip was removed from the test port during testing.	Press **1** to continue testing with a new test strip. Press **2** to exit to the Test Menu.

Questions? Refer to Page 10-13 For Customer Care Information.

10-9

Symptom/Error Message	Explanation	How To Respond
Scan or Enter **Operator ID** ---------- **Laser On Time Exceeded**	If the Scan button is pressed and the laser has been on for a total of 60 seconds in the last 15 minutes, the monitor will beep and display **Laser on Time Exceeded**.	Turn the monitor off and wait 15 minutes for the laser time to reset. Note: Remember to release the Scan button before trying to rescan.
Assay Error nnn 1-New Strip 2-Exit **(Error codes 112, 114, 116-118)**	The test was not successful. An error was detected during the analysis sequence.	**1.** Remove the old test strip. **2.** Insert a new test strip. If the error occurs again, record the three-digit error code and contact MediSense Customer Care. Press **2** to exit to the Test Menu.
Assay Error nnn 1-New Strip 2-Exit **(Error codes 113, 115)**	The test strip malfunctioned or the blood glucose level is beyond the measuring capabilities of the system.	**1.** Remove the used test strip. **2.** Insert a new test strip. **3.** Press **1** to continue testing with a new test strip. **4.** If the error appears again, confirm the result by performing a laboratory reference test. Contact MediSense Customer Care.
Low Battery Error 119 1-Exit	During the test, battery power was too low for testing.	Do one of the following: • Install new batteries. See Maintenance for more information. • Place the monitor in the docking station (if the system has this option). Press **1** to exit.

Temperature Error nnn

1-Exit

(Error codes 121, 122)

During the test, the room temperature became unstable or moved outside the limits within which the monitor can perform a test.

Ensure that the room temperature is within the specified limits. Allow the monitor time to stabilize to room temperature. Please refer to the test strip instructions for use for appropriate operating temperature range.

Press **1** to exit.

When a Control Test is selected:

Unexpected Level
Low expected
High entered

1-ReEnter Lot
2-Continue

This screen shows the level of control test the monitor expected to run: Low, Normal, or High, and the level of the lot entered.

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
9876543210
will replace Old Panel
1-ReEnter Kit Lot
2-Replace Panel
1234567890

A new linearity kit lot number has been entered, different from the one in memory. Linearity data has not been uploaded since the last test. (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 enter a different linearity kit lot number (typically, the number of the previous kit).
or
Press **2** to proceed, using the new kit lot number. The existing linearity data will be replaced by data from the new lot.

10-11

Questions? Refer to Page 10-13 For Customer Care Information.

When a Data Review is Selected:
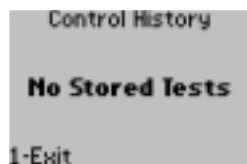
	Explanation	How To Respond
Control History **No Stored Tests** 1-Exit The requested type of results is shown at the top of the screen.	There are no stored test results for the type of data requested.	Press **1** to return to the Data Review Menu.
Patient History **No Tests Match Request** 1-Exit The requested type of results is shown at the top of the screen.	There are no stored test results that match the selected criteria.	Press **1** to return to the previous screen.
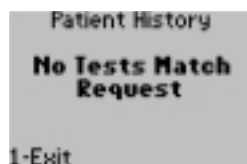
During Data Transfer:

	Explanation	How To Respond
Please Wait for Data Upload	An error has occurred during data transfer. This screen will only appear for three seconds.	**1.** Remove the monitor from the docking station. **2.** Place the monitor back into the docking station. If the error appears again, contact MediSense Customer Care.
Last Upload Incomplete. Redock Meter.	An error has occurred during last data transfer. This screen will appear when you turn on the monitor.	Place the monitor back into the docking station.

Contacting Abbott Laboratories, MediSense Products for Service

Abbott Laboratories, MediSense Products is committed to helping you resolve any problems with the Precision PCx Point-of-Care System. For technical assistance, please call Customer Care at 1-877-529-7185, twenty-four (24) hours per day. Outside the United States, contact your local office or distributor listed below.

Abbott Diagnostics
MediSense Products
Victoria, Australia
Tel: 1-800-801-478
(In New Zealand
Tel: 0800 106 100)

Abbott Gesellschaft m.b.H.
MediSense Produkte
Wien, Österreich
Tel: (01) 891 22 271

ABBOTT S.A./N.V.
Diagnostics Division
MediSense Products
Louvain-la-Neuve, Belgium
Tel: 32 10 47 53 25

MediSense Canada
Ontario, Canada
Tel: 1 800 461 8481

Abbott Danmark A/S
MediSense Produkter
Gentofte, Danmark
Gratis Tel: 8081-5354

Abbott Científica, SA
División MediSense
Madrid, España
Tel: 900 300 119

Abbott Oy, MediSense
Espoo, Finland
Tel: 358 9 7518 418

MediSense France
Rungis, France
Tel: 0800 10 11 56

ABBOTT
MediSense Produkte
Max-Planck-Ring 2
65205 Wiesbaden
Germany
Tel: 0049 612258 1015

MediSense Κλάδος της
Abbott Laboratories
Διεύθυνση: Λ. Βουλιαγμένης
512, 174 56 ΑΛΙΜΟΣ
Tel: 01/99 85 220

MediSense, Abbott Laboratories
Ireland Ltd.
Dublin, Ireland
Tel: 1 800 77 66 33

Abbott S.p.A. Divisione Diagnostici
Prodotti MediSense
Roma, Italia
Tel: 800 334 210

Dainabot
Tokyo, Japan
Tel: 81 3 3589 9580

Abbott Laboratórios-
Divisão MediSense
Amadora, Portugal
Tel: 0800 200 891

Abbott B.V.
MediSense Nederland
Amersfoort, Nederland
Tel: 0 800 0228828

Abbott Norge AS
MediSense Products
Billingstad, Norge
Tel: 66 98 39 03

Questions? Refer to Page 10-13 For Customer Care Information.

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Abbott Scandinavia AB
MediSense Produkter
Solna, Sweden
Tel: 08 546 56700

ABBOTT AG
MediSense Products
Baar, Schweiz/Suisse/Svizzera
Tel: 041 768 44 46

Abbott Laboratories
MediSense Products
Maidenhead, UK
Toll free: 0500 467 466

Abbott Diagnostic Division
Johannesburg, South Africa
Tel: 0800 11 69 41

ADD Argentina
Buenos Aires, Argentina
Tel: 54 11 4382 8788
Tel: 54 11 4383 4286

ADD Brazil
São Paulo, Brazil
Tel: 55 11 536 7215
Tel: 0800 164550

ADD Caribe
Carolina, Puerto Rico
Tel: 1 787 257 4405
Tel: 1 787 257 4444

ADD Chile
Santiago, Chile
Tel: 562 557 2126

ADD Colombiá
Sante Fé de Bogotá, Colombia
Tel: 9800-910353

Abbott Laboratories
ADD/MediSense
Santo Domingo, Dominican Rep.
Tel: 809 566 7181/85

ADD Guatamala
Cotio, Guatamala
Tel: 502 597 4109
Tel: 502 597 4141

ADD México
México, Distrito Federal
Tel: 55 24 41 75
Tel: 01 800 711 2208

ADD Peru
Lima, Peru
Tel: 800 37233

ADD Puerto Rico
Barceloneta, Puerto Rico
Tel: 787 846 8412
Tel: 1 800 981 1244

ADD Uruguay
Montevideo, Uruguay
Tel: 598 2 513 3955

ADD Venezuela
Caracas, Venezuela
Tel: 800 37233

ADD Greater China
North Point, Hong Kong
Tel: 852 25668711

ADD Indonesia
Jakarta, Indonesia
Tel: 62 21 520 1007

ADD Korea
Seoul, Korea
Tel: 82 2 3429 9234

ADD Malaysia
Selangor, Malaysia
Tel: 603 519 1919

ADD Pakistan
Karachi, Pakistan
Tel: 92 21 501 5454

ADD Philippines
Metro Manila, Philippines
Tel: 63 2 637 8253
Tel: 63 2 689 0414

ADD Singapore
World Trade Center, Singapore
Tel: 65 278 8343

ADD Taiwan
Taipei, Taiwan
Tel: 886 22 505 0828

ADD Thailand
Bangkok, Thailand
Tel: 66 2 252 2004

A MediSense representative will address the problem and/or instruct you to return the monitor. Do not return the Precision PCx Monitor or any part of the system for repair until you receive authorization from a MediSense representative.

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

1. Review the troubleshooting information in this section.

2. Obtain the most recent control results and record them below.

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

3. Enter the date the problem occurred:_____

4. Describe the problem and the conditions when it occurred: _____
   _____
   _____
   _____

5. Have the Precision PCx Monitor and testing materials available when calling.

Questions? Refer to Page 10-13 For Customer Care Information.

10-15

Returning an Instrument

The OSHA blood borne pathogen rule requires that contaminated instruments/equipment be decontaminated prior to shipping to minimize the risk of exposing those persons involved in handling or transporting this equipment.

Please perform the following steps before returning an instrument:
1. Remove all potentially contaminated accessories such as lancets, unused test strips or control solution vials.
2. Wipe the surface of the instrument with a detergent solution to remove any soiling.
3. Then wipe the unit with a tuberculocidal disinfectant such as 10% chlorine bleach solution.

Limited Warranty

What is Covered by this Warranty

Abbott Laboratories Inc. (Abbott) warrants, to the original purchaser only, that the Precision PCx Blood Glucose Testing Monitor shall be free from defects in material and workmanship for a period of one year from the date of purchase. Abbott warrants that the Precision PCx Blood Glucose Testing Monitor is fit for the purposes and indications described in the labeling when used in accordance with the directions for use. If the purchaser discovers within one year from the date of purchase a defect in the material and workmanship, the purchaser must promptly notify Abbott in writing. In no event shall such notification be received by Abbott later than 13 months from the date of purchase. Abbott's sole obligation as a result of the breach of any warranty and the purchaser's exclusive remedy for the breach of any warranty shall be limited to, at Abbott's option, the repair or replacement (with a new or reconditioned unit) of the Precision PCx Blood Glucose Testing Monitor.

What is not Covered by this Warranty

The warranty granted by Abbott extends only to defects in material and workmanship discovered within one year from the date of purchase. In addition, Abbott does not warrant (a) damage caused by use of the Precision PCx Monitor for purposes other than those for which it was designed, (b) any products, components, or parts not manufactured by Abbott, including without limitation, any auxiliary equipment or disposable accessories, or (c) any damage caused by any other abuse or misuse by the purchaser.

Disclaimer of Warranty

THE FOREGOING WARRANTIES ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

Limitation of Remedies

In no case shall Abbott Laboratories Inc. (Abbott) be liable for any proximate, special, incidental or consequential damages based upon breach of warranties, breach of contract, negligence, strict tort or any other legal theory. Some states do not allow limitations on warranties, or on remedies for breach in certain transactions. In such states, the limits of this paragraph and the paragraph entitled Disclaimer of Warranty may not apply.

For Warranty Service, purchaser must contact Abbott Laboratories, MediSense Products by calling 1-877-529-7185, twenty-four hours (24) a day, for assistance and/or instructions for obtaining repair or replacement of the Precision PCx Monitor. Outside the United States, contact your local Abbott office or distributor. For return of the Precision PCx Monitor, Abbott will send a return authorization label that must be affixed to the shipping carton. Cartons received without this label will be returned at your expense.

If you are experiencing difficulties with the Precision PCx Monitor, review the troubleshooting information in this section before calling Abbott. Abbott will repair or replace returned monitors at its option. A postage-paid return label will be sent to you to return the defective Precision PCx Monitor. Abbott will cover the postage cost of shipping the new or reconditioned replacement unit to you. If you fail to return the defective monitor to Abbott within 30 days of shipment of the replacement, you will be billed for the balance of the cost for a new Precision PCx Monitor.

Questions? Refer to Page 10-13 For Customer Care Information.

10-17

The Precision PCx Monitor requires little routine maintenance. During testing, the sample remains outside the monitor, which significantly reduces the possibility of contamination.

This section describes the maintenance tasks for the monitor.
– Cleaning the exterior surface of the monitor.
– Replacing the batteries.
It is a good idea to record any maintenance that is performed on the monitor in the Six-Month Maintenance Log that is at the end of this section. The log may be photocopied.

Cleaning the Exterior Surface

Cleaning the exterior surface of the Precision PCx Monitor is recommended daily. The monitor needs only to be cleaned with a water-moistened cloth or a sponge and a mild detergent. It is suggested that the monitor be turned off while it is being cleaned. Do not use any solvents. Do not immerse, flood with any liquid, or autoclave the monitor.

Battery Life

The average alkaline battery life is approximately 60 days, based on an average of 30 tests per day (depending on barcode usage). Please refer to the rechargeable battery pack insert for more information.

Questions? Refer to Page 10-13 For Customer Care Information.

11-1

Replacing the Batteries

Use the following procedure to install new batteries in the Precision PCx Monitor. The Precision PCx Monitor requires two (2) AA alkaline batteries or use the rechargeable battery pack which is available from Abbott Laboratories, MediSense Products.

1. Turn the PCx Monitor off by pressing the On/Off button on the keypad.
2. Turn the monitor over to view the battery compartment.
3. Press the tab on the battery compartment cover and lift the cover up.
4. Remove and discard the used batteries in compliance with your local government regulations.
5. Insert the new batteries, using the + and - symbols in the battery compartment to position the new batteries with the correct polarity.
6. Align the battery compartment cover with the slots on the Precision PCx Monitor, then snap the cover into place.

Precision PCx Blood Glucose Monitor
Six-Month Maintenance Log

from_____ to_____

Daily: Clean the Exterior Surfaces

Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

As Required: Replace the Batteries

Date		
Operator ID		

11-3

Precision PCx Test Strips
The following information regarding the Precision PCx and Precision PCx *Plus* Test Strip can be found in the test strip instructions for use:
• System Operating Ranges
• Storage and Handling
• Quality Control
• Limitations of the Procedure
• Performance Characteristics

Precision PCx Monitor
Dimensions:

Length:	19.7 cm (7.7 in)
Width:	7.5 cm (2.95 in)
Thickness:	5.1 cm (2.0 in)
Weight:	280 grams (10 ounces)
Power Source:	Two standard alkaline AA batteries or optional MediSense rechargeable battery pack.

Battery Life:
Battery performance is a combination function of how often the meter is used and the duration time that testing is conducted.
Alkaline Battery:
(2) cells 1.5 Volts, 2.4 Amp Hours typical capacity
Rechargeable Battery Pack:
(2) cells 1.2 Volts, 1.1 Amp Hours minimum capacity
Note: The MediSense Rechargeable Battery Pack can be recharged for 500 full charge cycles. A considerably higher battery cycle life can be obtained if the Precision PCx monitor is placed in the docking station at the end of each use.

Memory:

Patient Test	4000
Control Test	1000
Proficiency Test	60
Linearity Test	20 (5 levels, 4 replicates per level)

Questions? Refer to Page 10-13 For Customer Care Information.

12-1

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

Environmental Specifications

Product is intended for indoor use

|	
Monitor Operating Temperature:	32°F to 115°F (0°C to 46°C)
Monitor Storage Temperature:	-11°F to 115°F (-24°C to 46°C)
Altitude:	Up to 2,195 meters
Monitor Humidity:	From 10% to 90% within the range of 32°F (0°C) to 115°F (46°C)
Mains Supply Voltage Fluctuations:	±10%
Transient Over-Voltages:	±1.5V
Rated Pollution Degree:	2

Other Information

There are special symbols that appear on the Precision PCx Monitor, Precision PCx and Precision PCx *Plus* Test Strips, and Docking Station. The complete list of symbols and an explanation are listed below. Please note: Some of the symbols listed below will not appear on your Precision PCx Monitor and Docking Station due to differences in local regulatory requirements.

Symbols:

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 also appears on the front panel of the docking station, beneath the LED display. If the LED is steady, this indicates that the monitor is properly placed in the docking station. If the LED is flashing this indicates that data transfer is in process (refer to Data Upload, Section 9).

The CSA mark means that an evaluation of samples of Equipment has been performed by CSA to determine compliance with specific requirements (CSA, CS22.2 No. 601.1).

Classification marking for U.S. This symbol indicates the hazards with respect to which the product has been classified by identifying the Particular Collateral Standards used in evaluation UL2601-1.

Laser Radiation. Do Not Stare Into Beam. Class 2 Laser product. Wavelength 670 nm, Max. Output <1.0 mW. This product meets the requirements of European Standard EN 60825-1 : 1994.

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.

Lot Number

Expiration Date

CE mark applies to the Medical Device Directive 93/42/EEC. The product meets the requirements of 93/42/EEC.

Attention: Refer to manual.

Discard after single use. Use only once.

Re-order Number

Date of Manufacture

Do not drink

Legal Manufacturer under *In Vitro* Diagnostic Medical Devices Directive 98/79/EC - MediSense UK Limited.

Questions? Refer to Page 10-13 For Customer Care Information.

12-3

	Refer to manual
	Recyclable
	For *in vitro* diagnostic use only.
STERILE R	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

Power Supply

1. The Precision PCx Monitor requires two (2) AA alkaline batteries or a rechargeable battery pack.

2. The docking station (optional) requires an AC adapter to be connected from the docking station to a power supply. The docking station also acts as a recharge station for the MediSense rechargeable battery pack.

3. The complete electrical ratings for the AC adapters are as follows:

Reorder No. 98207-01
    120 VAC operation
    Globetek Model WD 1 C2000LCP-A
    Input = 120 VAC, 60 Hz, 35W
    Output = 7.5 VDC, 2A

Reorder No.98212-01
    240 VAC Operation
    Jerome Industries Corp. Model ILDK - 7
    Input = 230 VAC, 50 Hz .1A
    Output = 7.8 VDC, 1.2 A

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 2601.1)

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 2601.1)

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, (7 1/2 feet) above the floor.

Equipment

Equipment shall be classified by marking and/or identification as described:

1. Precision PCx Monitor – Class I (EQUIPMENT energized from an external electrical power source).

2. Docking Station – Class II (EQUIPMENT energized from an external electrical power source).

3. Rechargeable battery pack – Type B (degree of protection against electric shock).

Questions? Refer to Page 10-13 For Customer Care Information.

12-5