FreeStyle

Precision Pro

Blood Glucose and β-Ketone Monitoring Meter

Operator's Manual

for Healthcare Professionals

Abbott

Table of Contents

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

Questions? Refer to Pages 10–22 For Technical Support Instructions.

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Intended Use

The FreeStyle Precision Pro Blood Glucose and β-Ketone Monitoring Meter is an *in vitro* medical device intended for the automated quantitative measurement of blood glucose and blood β-ketones (β-hydroxybutyrate).

The system comprises the meter and test strips and is suitable for professional use as an aid in the monitoring of diabetes mellitus and ketosis including diabetic ketoacidosis (DKA). Healthcare professionals can use this system to check patients' blood glucose and ketone values.

The samples for glucose measurement must be from venous, arterial or capillary (fingerstick or neonatal heelstick) whole blood samples and ketone in capillary (fingerstick) or venous whole blood samples.

The meter may only be used with FreeStyle Precision Pro Blood Glucose Test Strips and FreeStyle Precision Pro Blood β-Ketone Test Strips.

The system should not be used for the diagnosis of diabetes mellitus or diabetic ketoacidosis (DKA). The system is not intended for use on neonatal or arterial blood for ketones. The system is only suitable for use outside the body.

Important Safety Instructions

DANGER

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

READ THIS BEFORE USING THE EQUIPMENT

- Do not place the equipment in liquid, or put it where it could fall into liquid.
- Use the equipment only for the purpose described in the instructions for use.
- Do not use accessories which are not supplied or recommended by the manufacturer.
- Do not use the equipment if it is not working properly, or if it has suffered any damage.

  NOTE: Examples of typical defects include:

  - damage caused by dropping the equipment;

  - damage caused by dropping the equipment into water or splashing water onto it.

- Do not let the equipment come into contact with surfaces which are too hot to touch.
- Do not place anything on top of the equipment.
- Unless specifically instructed to do so by the instructions for use, do not drop or put anything into any opening in the equipment.
- Do not use the equipment outdoors.

Reporting of Serious Incidents

If a serious incident has occurred in relation to this device it should be reported to Abbott Diabetes Care. Please go to www.MyFreeStyle.com or refer to the Customer Service phone number. In European Union Member States, serious incidents should also be reported to the competent authority (the government department responsible for medical devices) in your country. Please refer to your government website for details of how to contact your competent authority.

A 'serious incident' means any incident that directly or indirectly led, might have led or might lead to:

- The death of a patient, user or other person.
- The temporary or permanent serious deterioration of a patient's, user's or other person's state of health.

TrueID

Easy Data Entry

Choose between the built-in barcode scanner, compatible with one dimensional (1D) and two dimensional (2D) barcodes, and the alphanumeric keypad for entering data as required by point-of-care policy. The meter can be configured to accept patient identification, operator identification, test strip lot number, comment code and up to two free text fields for other data such as physician name.

Patient ID Confirmation

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

Data Integrity

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

TrueMeasure

Fast, Simple Testing

To perform a test, simply insert a strip into the meter's port, apply a small drop of blood and wait for the countdown to complete. For convenience, the sample may be applied to either the top or end of the test strip. The test will not start until adequate sample has been applied. This safeguard is designed to prevent errors, strip wastage and unnecessary repeat tests due to short-sampling.

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 1: Overview

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Automatic Calibration	Scanning the barcode label on each test strip foil packet prior to use automatically calibrates the meter and checks the expiry date, helping ensure reliable and accurate test results. Testing can also be restricted to approved strip lots.
QC Lock-out	The meter can be configured to require periodic testing using control solutions, and to lock out access to the system if these tests are not completed. QC results can be displayed as pass/fail only, preventing patient testing while in control test mode.

TrueAccess

Operator Management	Access to the meter can be restricted to certified operators, locking out untrained users. A warning can also be displayed to an operator whose ID is set to expire in the near future.
Results Storage	The FreeStyle Precision Pro meter can store up to 2,500 patient test results and 1,000 control test results, in addition to 20 proficiency test results. All stored data can be automatically uploaded to the data management system using the docking station (optional), a data upload cable (optional) or wirelessly (optional) in a WiFi-enabled facility when the meter and data management systems are properly configured.
Network Connectivity	FreeStyle Precision Pro meters can upload data via docking station, cable or wirelessly. The uploaded data can then be configured via a central data management system, across the organisation's computer network. This provides a simple and automated way to manage multiple instruments, meter point-of-care testing and report test data to the Laboratory Information System (LIS) or Hospital Information System (HIS) for inclusion in the patient's Electronic Medical Record (EMR).

Results Transmission The FreeStyle Precision Pro meter allows results transmission via a docking station, upload cable or via wireless communication (if enabled). If your data management system and individual meters are enabled, data will be updated in real-time through your facility's wireless network. For additional information about the wireless option refer to the Wireless Setup Utility User's Guide.

Notes and Warnings

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

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

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

Meter Display Icons

Your FreeStyle Precision Pro meter screen may reflect informational icons to indicate system status. Common icons and their meaning are listed in the table below.

Icons	Indication	Explanation
For All Meters		
	Battery Strength	Indicates current battery strength of the meter. A completely black battery symbol indicates full battery strength.
	Progress Status Bar	Indicates progress status of an active task such as a download.
For Wireless-Enabled Meters Only (optional)		
	Data Pending Transmission	Indicates meter has stored test results that have not yet been transmitted to the data management system.
	Wireless Enabled	Indicates the meter is enabled for wireless transmission.
	Wireless Transmission	Indicates active wireless data transmission. Note: The data transmission icon is animated.
	Wireless Hardware Error	Indicates a problem with the meter's wireless hardware module.
	Signal Strength	Indicates strength of wireless signal. Five vertical bars indicate maximum signal strength.

Conventions

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

```
p:Smith, John Q
12   5.6 mmol/L
        Glucose
07/01/20 11:12
1-Next Patient
2-Patient History
```
100 mg/dL

```
p:Smith, John Q
2   0.3 mmol/L
        Ketone
07/01/20 11:12
1-Next Patient
2-Patient History
```
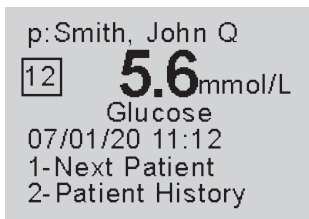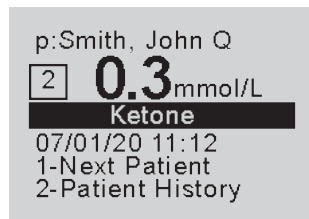
⚠️ **IMPORTANT:** *Please confirm that the correct unit of measure shows on your meter with every glucose result.*

System Components

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

FreeStyle Precision Pro System Components

The FreeStyle Precision Pro System includes the following items:

- FreeStyle Precision Pro Blood Glucose and β-Ketone Monitoring Meter
- FreeStyle Precision Pro Blood Glucose Test Strips and/or FreeStyle Precision Pro Blood β-Ketone Test Strips
- MediSense Glucose and Ketone Control Solutions

Package Contents:

- FreeStyle Precision Pro Blood Glucose and β-Ketone Monitoring Meter
- CD Manual
- 2 AA Lithium Batteries

Optional components for use with the FreeStyle Precision Pro System include:

- Calibration Verification Controls
- FreeStyle Isolation Bags
- Carry Case
- FreeStyle Precision Pro Strip Port Module Replacement
- Abbott Single Use Lancet
- Docking Station
- Data Upload Cable
- Wireless Setup Utility software
- Data Management Systems
  - Siemens UniPOC and POCcelerator data management systems
  - Abbott AEGIS POC data management system

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

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

Meter

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

At the top of the meter is the test strip port module. The strip port module is designed to minimise liquid and other potential contaminants entering the meter through the strip port (Chapter 11 provides instructions for changing the strip port module). Underneath this is the window for the barcode scanner. On the back of the meter is the battery compartment (Chapter 11 also provides instructions for changing the batteries). Just above the battery compartment is a label with the unique serial number of the meter. A unique serial number label of the meter is inside the battery compartment. On the side of the meter is the meter identification space.

Strip Port Module

Test Strip Port

Barcode Scanner

Display

Serial Number

Meter Identification Space

Keypad

Battery Compartment (Serial Number Label Inside)

Data Port

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 1: Overview

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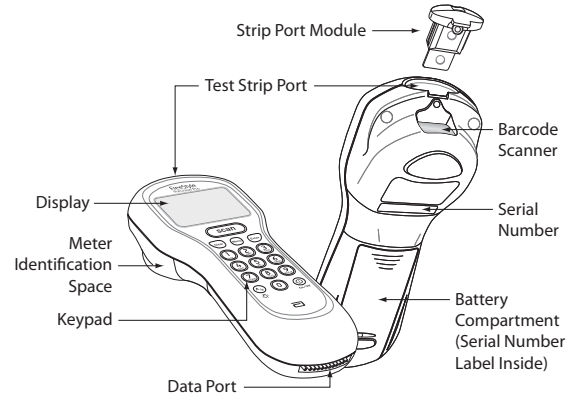
This untextured area (.875 inch wide x .483 inch high, 22 mm wide by 12 mm high) provides a space in which to apply a facility-specific location label. At the bottom is the data port for connecting the meter to a data upload cable or docking station (Chapter 9 provides information on uploading data to a data management system).

Each FreeStyle Precision Pro meter is shipped with this Operator's Manual and two AA batteries.

⚠️ **IMPORTANT:** *Avoid getting dust, dirt, blood, control solution, water or any other substance in the meter's test strip port.*

Test Strips

FreeStyle Precision Pro Test Strips offer the latest advancements in biosensor technology. The test strips work by first inserting the contact bars into the meter. Then the sample is applied to the target area, covering both the working electrode and the reference electrode. This area is coated with active ingredients that react in the presence of glucose or ketone to make a small electric current. This current is passed through the strip to the contact bars and the meter, which calculates a glucose or ketone result.

FreeStyle Precision Pro Blood Glucose Test Strips use proprietary glucose-specific chemistry that includes the glucose dehydrogenase enzyme, NAD cofactor and PQ mediator (GDH-NAD). This chemistry is used for testing glucose because it is not affected by maltose, icodextrin and other common substances at elevated levels. It also ensures minimal measurement bias from oxygen and haematocrit.

FreeStyle Precision Pro Blood β-Ketone Test Strips are available for use with the FreeStyle Precision Pro system. These test strips have chemistry to specifically measure β-hydroxybutyrate, the primary ketone produced when a patient is developing ketoacidosis.

Both glucose and ketone test strips also have exclusive blood application features to ensure reliable sampling. First, the target area may be filled by applying a drop of sample to the top of the test strip or by touching the end of the test strip to the sample. Second, the fill trigger electrode ensures that the test will only start once sufficient blood has been applied. Together, these features minimise the possibility of errant results due to sample application technique.

Fill Trigger Electrode
Working Electrode
Reference Electrode
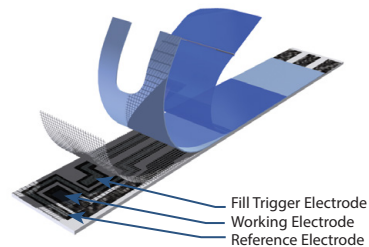
⚠ **IMPORTANT:** *Do not apply blood to the test strip when the test strip is out of the meter. Do not use wet, bent, scratched or damaged test strips.*

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

⚠ **IMPORTANT:** *Do not scan a packet's barcode and use a test strip from another packet. Use the test strip immediately after opening its foil packet. Do not use the test strip if the foil packet has a puncture or tear in it. Failure to follow instructions can cause incorrect results to be generated.*

There are two types of test strips that may be used for testing with the FreeStyle Precision Pro system: the FreeStyle Precision Pro Blood Glucose Test Strips (blue foils) for testing glucose levels in fresh whole blood and the FreeStyle Precision Pro Blood β-Ketone Test Strips (purple foils) for testing ketone levels in fresh whole blood. Inside each box of test strips is a package insert with detailed instructions for use and performance characteristics.

FreeStyle Precision Pro Blood Glucose Test Strip

FreeStyle Precision Pro Blood β-Ketone Test Strip
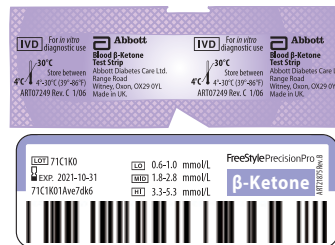
⚠ **IMPORTANT:** *The FreeStyle Precision Pro system will only work with FreeStyle Precision Pro brand test strips. Use of any other test strips will cause erroneous results.*

Control Solutions

Control solutions are used to perform regular quality control checks on the meter to ensure it is functioning correctly. Control testing is further described in Chapter 4. Use MediSense Glucose and Ketone Control Solutions with the FreeStyle Precision Pro system. These control solutions are available in one, two or three level configurations.

Replacement Strip Port Module

A replacement strip port module is available if the system becomes disabled as a result of blood, fluid or other contaminant entering the strip port. Repeated strip port error messages may also indicate the need for replacement. The strip port module replacement procedure is described in Chapter 11.

Data Management System

A data management system is required for device configuration and to facilitate data transmission from the FreeStyle Precision Pro meter. Data upload from remote locations requires either terminal servers or networked PCs running Abbott's Data Repeater software. Data can also be uploaded through a wireless network when the individual meters and data management system are properly enabled. Wireless configuration details are described in the Wireless Setup Utility User's Guide. Data management systems that interface with FreeStyle Precision Pro include but are not limited to Abbott's AEGISPOC™ Point of Care Management Solutions, Siemens Healthineers' UniPOC™ and POCcelerator™ Data Management Systems.

FreeStyle Isolation Bag (optional)

FreeStyle Isolation Bags are disposable plastic bags for use with the FreeStyle Precision Pro system. The isolation bag provides a partial barrier between the point-of-care monitoring device and the patients in isolation for infection control. There is no need to prep the meter prior to using the bag and the bag does not affect any meter functions. The FreeStyle Precision Pro system is only compatible with Abbott isolation bags (including the FreeStyle isolation bag). Other isolation bags can not be used with the FreeStyle Precision Pro system. Note that Abbott isolation bags are not sterilised.

Carry Case (optional)

The carry case holds the meter, test strips, control solutions and other accessories needed for testing. A transparent cover allows you to check supply status without opening the case.
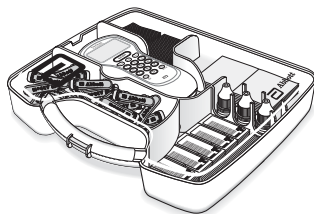
Docking Station (optional)

The docking station provides a convenient way to upload the data from the meter to the data management system. When the meter is placed in the docking station, it will automatically upload data to the data management system and then shut down. Docking the meter also allows you to complete software upgrades with the data management system. Docking the meter for software upgrades is also required for meters enabled for wireless data upload. Data upload is further described in Chapter 9.
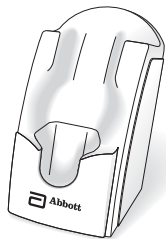
Data Upload Cable (optional)

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

2. Using the Meter

Barcode Scanner

Data Entry Keypad

Audible Indicator

Data Port

Battery Compartment

Strip Port Module

Optional Wireless Network Connection

Meter Identification

Menu Tree

Barcode Scanner

The barcode scanner enables you to scan barcode information, using specified 1D and 2D barcode formats (please refer to Chapter 12), into the meter instead of manually entering the data using the keypad. Scanning the barcode on the test strip foil packet automatically enters the test strip information (calibration, control range, lot number and expiry date). The scanner may also be used to enter Operator ID, Patient ID, control lot number and expiry date, comment code and free text fields. To operate the meter:
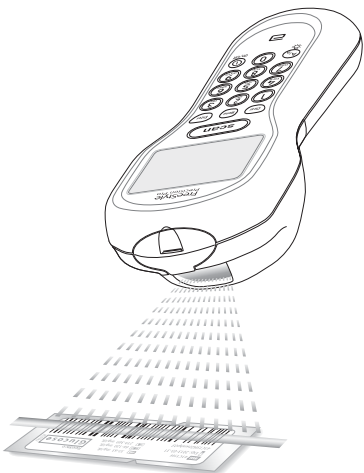
Step 1: Hold the barcode scanner 2.5-7 inches (6-18 cm) from the barcode to be scanned, and at a 50 to 130 degree angle to the barcode.

Step 2: Press and hold down the Scan button until a visible green beam is emitted by the meter.
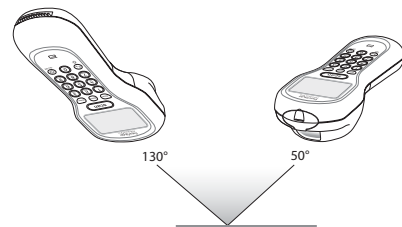
Note: *A scattered red light is emitted by the scanner along with the green beam for illumination.*

Step 3: Slowly move the meter, if needed, so that the green beam is directly over the barcode.

Step 4: The meter will beep in acknowledgement when it accepts the barcode.

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

When first learning to use the barcode scanner, some precautions should be taken. It is important that you place the object to be scanned on a flat surface or hold it by itself. This will prevent other items from being accidentally scanned.

If data has been manually entered, scanning data will erase the manually entered data (unless the Enter key has been selected to confirm manual entry) and replace it with the scanned data. This entry will be considered scanned. Upon a successful barcode scan, this system will automatically proceed to the next screen. The scanning beam shuts off in three seconds if nothing is detected.

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 2: Using the Meter

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Data Entry Keypad

The data entry keypad allows you to enter identification numbers and letters (only the 26-letter English alphabet) or to select an option that appears on the display. The keypad contains a 10-digit telephone-style keypad with the keys for the numbers 0-9. The 2-9 keys also have letters printed below the number. The keypad also has six special keys, including a Scan button, On/Off button, Backlight/Alphanumeric, Clear, Menu and Enter keys.

Scan

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

On/Off

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

Press and hold this button for 2 seconds to turn the meter off. The meter will automatically shut itself off after 4 minutes to conserve battery life. The length of time for automatic shut-off can be configured from 4 to 10 minutes following patient tests only.

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 2: Using the Meter

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Backlight/Alphanumeric ☼

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

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

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

Clear

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

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

Menu

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

Enter

Press the Enter button after entering data on the keypad to proceed to the next screen.
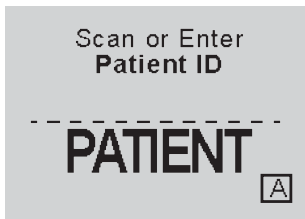
Audible Indicator

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

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

Data Port

The data port is located at the bottom of the meter. This port enables the meter to automatically transfer the data through a cable or docking station to the data management system. Data may be transferred through a cable or docking station even if the meter is wireless-enabled.

Battery Compartment

The meter holds two AA batteries to power the meter.

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 2: Using the Meter

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Strip Port Module

The strip port module should be replaced if the meter becomes disabled as a result of liquid or other contaminant entering the strip port. Replacement is also indicated in the case of repeated strip port module errors. Chapter 11 provides instructions for replacing the strip port module.

Optional Wireless Network Connection

If your data management system and individual meters are enabled for wireless transmission, your system is capable of automatic and secure wireless data transmission. The meter has dual-band coverage which is compatible with IEEE 802.11/a/b/g wireless (WiFi) bands. The optional wireless function must be configured in your data management system and enabled in each meter by your system administrator. Wireless specifications are described in the Wireless Setup Utility User's Guide.

The Wireless Enabled icon (antennae) is displayed on the meter's screen whenever the wireless function is enabled.

Meter Identification

Each meter has a unique serial number. The FreeStyle Precision Pro meter also features an untextured area on the side of the device. This 22 mm (.875 inch) wide x 12 mm (.483 inch) high area allows a facility to apply a label with information pertaining to the meter. Please refer to Chapter 1 for an illustration of this feature.

Menu Tree

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

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

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 2: Using the Meter

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Menu Tree

Test Mode

1. Patient Test

2. Control Test

Menu Mode

1. Data Review
- 1. Patient by OperID
- 2. Patient by PatID
- 3. All Patient Data
  - 4. Control Data
  - 5. Proficiency Data
  - 6. Linearity Data*

2. Review Setup
- 1. Test Setup
  - 1. All Tests
    - Upload Interval
    - Operator ID
    - Operator ID Truncation
    - Operator ID Prompt
  - 2. Test Type
    - Glucose Units
    - Glucose Action Range
    - Glucose Critical Range
    - Ketone Action Range
    - Ketone Critical Range
  - 3. Patient Test
    - Patient ID
    - Patient ID Truncation
    - Comment Code If In-Range
    - Comment Code If Out-of-Range
    - Patient ID Prompt
    - Repeat Manual ID Entry
  - 4. Control Test
    - Levels
    - Result
    - Comment Code If In-Range
    - Comment Code If Out-of-Range
  - 5. Security
    - QC Interval
    - Operator ID Not Certified
    - Strip Lot Not on List
    - Patient Data Not Confirmed
    - Confirm Patient Data
    - Strip Port Quality Control Security

3. Proficiency Test

4. Linearity Test*

- 2. System Status
  - - Battery Power
  - - Temperature
  - - Time
  - - Date
  - - Software Version
  - - Wireless Timeout

5. Wireless Menu
- 1. Enable/Disable
- 2. Network
  - Server
  - Port
  - Timeout
  - DHCP
  - IP
  - MASK
  - GW
  - MAC
- 3. Signal
  - Freq
  - RSS
  - SNR
- 4. Security
  - SSID
  - Authentication
  - EAP
  - User Account

*Linearity kits are not available in this market.

3. Patient Test

Operating Guidelines for All Samples

Collecting Blood Samples

How to Obtain a Capillary Blood Sample
(For Glucose or Ketone Testing)

How to Obtain a Venous Blood Sample
(For Glucose or Ketone Testing)

How to Obtain an Arterial Blood Sample
(For Glucose Testing)

How to Obtain a Neonatal Capillary Blood Heel Stick Sample
(For Glucose Testing)

Disposing of Waste

Patient Test Procedure-FreeStyle Precision Pro Glucose

Patient Test Procedure-Ketone

Patient Test

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

Operating Guidelines for All Samples

Please follow the recommended guidelines for the most accurate results:

- Always wear gloves and follow your facility's biohazard safety policies and procedures when performing tests involving patient blood samples.
- Make sure that the meter and test strips are at room temperature. If the meter is moved to an area that is warmer or cooler than where it was before, allow the meter to reach the new room temperature before testing.
- Use only control solutions specified in the test strip instructions for use to verify the performance of the FreeStyle Precision Pro meter.
- Use FreeStyle Precision Pro Test Strips with the FreeStyle Precision Pro meter.
- Refer to the test strip package insert for specific directions on storage and use of the test strips.
- Do not use the test strips beyond the expiry date printed on the barcode label and outer box.
- Do not use the test strip if the foil packet has a puncture or tear.
- Do not use test strips that are wet, bent, scratched or damaged. Use the test strip immediately after opening its foil packet.

- Do not use test strips if the strip port module is not fully inserted. User will receive an error message if the strip port module is not secure.
- Use each test strip only once.
- Do not scan a test strip packet's barcode and then use a test strip from a different packet. This may cause inaccurate results.
- Apply a drop of blood to the target area at the end of the test strip. The test results will not be affected if the target area has been briefly touched with the patient's finger, a capillary tube, syringe or pipette.
- After the blood is applied to the test strip and the test countdown begins, do not remove or disturb the test strip.

> ⚠ **IMPORTANT:** *Do not allow blood or other solution to run down the test strip into the meter's test strip port. The strip port module should be replaced if the meter becomes disabled as a result of liquid or other contaminants entering the strip port.*

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 3: Patient Test

3-2
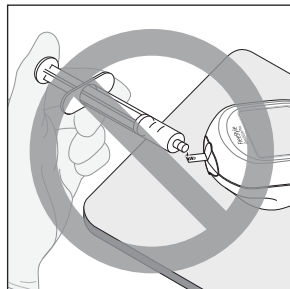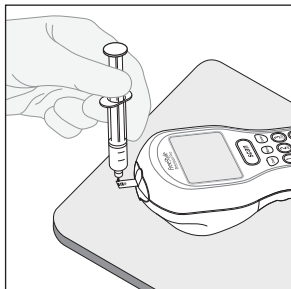
Collecting Blood Samples
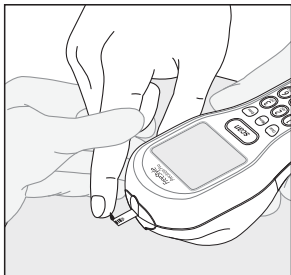
How to Obtain a Capillary Blood Sample (For Glucose or Ketone Testing)

- Only auto-disabling single use lancing devices should be used.
- Use a new pair of clean gloves for each patient.
- Use only fresh whole blood samples.
- Make sure that the sampling site is clean and dry before lancing.
- Collect the capillary blood using an auto-disabling, single use lancing device and an appropriate technique.
- Apply a drop of blood to the target area at the end of the test strip.
- If necessary, blood can be collected in a capillary tube coated with heparin or EDTA, and then be applied to the test strip within 30 minutes of collection. Mix the blood specimen well immediately before applying the sample to the target area of the test strip.
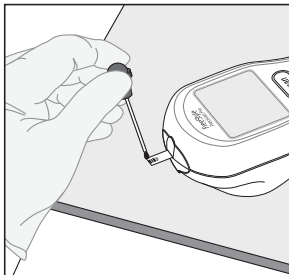
How to Obtain a Venous Blood Sample (For Glucose or Ketone Testing)

- Use a new pair of clean gloves for each patient.
- Use only fresh whole blood samples.
- Collect the venous blood sample in a collection tube containing heparin or EDTA. Make sure that the tube is filled to the stated volume. Do not under-fill.
- Do not use collection tubes that contain fluoride or oxalate.
- If the blood is collected from an intravenous line, clear the line before drawing the sample into a heparinised syringe.
- Use the sample within 30 minutes of collection.
- Invert the tube with the sample several times immediately before removing the sample.
- Use a disposable transfer pipette to obtain a sample from the centre of the collection tube.
- Apply a drop of blood to the target area at the end of the test strip.
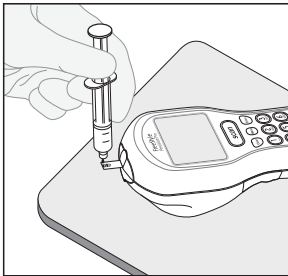
How to Obtain an Arterial Blood Sample (For Glucose Testing)

- Use a new pair of clean gloves for each patient.
- Use only fresh whole blood samples.
- Clear the arterial line before drawing a blood sample into a heparinised syringe.
- Use the sample within 30 minutes of collection.
- Mix the blood specimen well immediately before applying the sample to the target area of the test strip.
- Allow a drop of blood to form at the tip of the syringe.
- Apply a drop of blood to the target area at the end of the test strip.

How to Obtain a Neonatal Capillary Blood Heel Stick Sample (For Glucose Testing)

- Use a new pair of clean gloves for each patient.
- Use only fresh whole blood samples.
- Collect the capillary blood using an auto-disabling, single use lancing device and an appropriate technique.
- Apply a drop of blood to the target area at the end of the test strip.

- The blood can be collected in a capillary tube coated with heparin, and then applied to the test strip. Mix the blood specimen well immediately before applying the sample to the target area of the test strip.

- Alternatively, you can use the heel-to-strip method: Allow a hanging drop of blood to form from the heel and apply to the target area of the test strip. Results will not be impacted by gently touching the heel to the test strip.

Disposing of Waste

Observe the following guidelines when disposing of biohazardous waste:
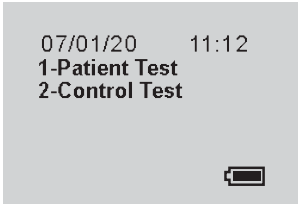
- Dispose of used lancets in an approved sharps container.

- Discard used capillary tubes, disposable transfer pipettes or tips, used strip port modules and test strips in an approved biohazard container.

- Follow your facility's biohazard disposal policy.

Patient Test Procedure - FreeStyle Precision Pro Glucose

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

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

What You See on the Display	What You Do	Comments
	1. Press **On/Off** to turn on the meter.	The Abbott logo screen will appear in black for a few seconds and then will appear in grey to ensure that the display is functioning properly. Next, the software version will briefly appear.
07/01/20　　11:12 1-Patient Test 2-Control Test	2. Press **1** to select **Patient Test**.	The meter starts in **Test Mode**. The Menu button will toggle the meter to **Menu Mode**.

What You See on the Display	What You Do	Comments
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**.	While the Operator ID may be up to 30 digits, not all digits will fit on the display. The meter may also be set to truncate (ignore) leading, trailing and/or selected digits of the barcode.
Scan or Enter **Patient ID** - - - - - - - - - - - **PATIENT**	**4.** Press **Scan** to scan the Patient ID barcode or manually enter the Patient ID via the keypad (if enabled).	While the Patient ID may be up to 30 digits, not all digits will fit on the display. The meter may also be set to truncate (ignore) selected digits of the barcode.
Confirm **Patient ID** - - - - - - - - - - - **PATIENT**	**5.** Confirm the Patient ID (if prompted). You may see one of the following four screens: Re-enter the ID using the keypad.	If you enter the ID manually, you may be required to enter it a second time to ensure it is correct.

|---|---|---|
Patient ID 02061935 **Smith, John Q 01/01/63 M** 1- ReEnter ID 2- Confirm	Press **2** to **Confirm** the Patient ID or **1** to **ReEnter** the ID.	
Patient ID 02061935 **Smith, John Q 01/01/63 M** Confirm Year of Birth --	Enter the year of birth (e.g. enter '63' for 1963; enter '01' for 2001) then press the **Enter** button.	Press **Clear** to re-enter the ID. If numbers have been entered, the Clear key will erase those first. Multiple presses of the Clear key may be required to return to the **Patient ID** entry screen in step 4.
Patient ID **Patient Data Not Found** 1- ReEnter ID 2- Continue	Press **2** to **Continue** testing or **1** to **ReEnter** the ID.	

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 3: Patient Test

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

Scan or Enter
Strip Lot

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

Scanning the barcode identifies the strip type, calibrates the meter, ensures the expiry date has not passed, records the strip lot used and checks that the lot has been approved for use by your institution.

Enter
Sample Type

1-Arterial/Capillary
2-Venous

7. The **Sample Type** screen will appear. You can select one of the following:

Press 1-**Arterial/Capillary**, or

Press 2-**Venous**.

Use **Venous** mode only for venous samples that have been in capped tubes and that have not been mixed with air. Use **Arterial/Capillary** mode for all other samples.

If the **Sample Type** screen is not seen, continue with step 8.

8. Make sure your hands or gloves are clean and dry before opening the foil packet. Open the foil test strip packet at the notch and tear down to remove the test strip.

What You See on the Display	*What You Do*	*Comments*
Insert Strip	**9.** With the contact bars facing up, insert the test strip into the test strip port until it stops and **Strip Inserted** is displayed.	Prior to inserting the test strip, ensure that the strip port module is installed and that it is clean and dry. Replace if necessary. The display will alternate between **Insert Strip** and **Glucose**.
Apply Sample	**10.** When Apply Sample is displayed, apply a drop of blood from the patient's finger, transfer pipette or syringe to the target area of the test strip.	When sufficient sample has been applied, the meter beeps, displays **Sample Accepted** and automatically starts the test.

For a detailed description of the test strip target area, refer to the Test Strips section of Chapter 1. |

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 3: Patient Test

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Analysing Sample **5**	**11.** Wait for the meter to analyse the sample and display the test result.	The meter counts down, then displays the test result. If an error is detected during the assay, the assay is terminated and no result is displayed. Once the assay begins, all key presses are ignored until the assay is completed.
5.6 mmol/L Glucose Scan or Enter Comment Code -- 100 mg/dL	**12.** If required, scan or manually enter the comment code and press **Enter**. If there is no prompt to enter a comment code, skip down to step 13.	The meter may be enabled to scan or enter a 1- to 2-digit comment code.
5.6 mmol/L Glucose Scan or Enter Patient ID 2 ---------- 100 mg/dL	If prompted, scan or manually enter the free text information and press **Enter**. If there is no prompt to enter free text, skip down to step 13.	The meter may be enabled to scan or enter the free text information. Up to two free text fields may appear.

What You See on the Display	What You Do	Comments
▲Action Range ▲**16.0**mmol/L Glucose Scan or Enter Comment Code — 288 mg/dL **Above Action Range**	For out-of-range results, refer to your institution's policy.	Your institution may establish an **Action Range**. The meter will display results outside of this range. A comment code may be required for results outside the action range.
▲Critical Range ❯**22.2**mmol/L Glucose Scan or Enter Comment Code — >400 mg/dL **Above Critical Range**	For out-of-range results, refer to your institution's policy.	Your institution may establish a **Critical Range**. The meter will not display results outside of this range. A comment code may be required for results outside the critical range.

```
p:Smith, John Q.
12   5.6mmol/L
     Glucose
07/01/20   11:12
1-Next Patient
2-Patient History
```

100 mg/dL

13. You can select one of the following options:

Press **1-Next Patient**.

Press **2-Patient History**.

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

Remove the test strip from the meter and discard it when finished testing. Follow your facility's biohazard disposal policy.

The display shows:

Patient ID or Name (**p:** prompt)
Comment Code (Number in box)
Date and Time of test
Test Type (Glucose)

If **1** is selected, the **Scan Patient ID** screen will appear. Return to step 4 to continue with testing on the next patient.

If **2** is selected, the meter will display the last test result for this patient as well as allow you to view previous results.

Refer to the section titled Data Review for Patient by Patient ID in Chapter 5 for further information.

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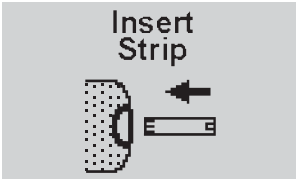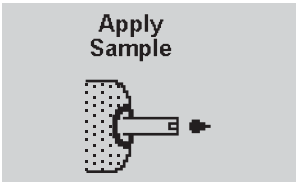
Results that are incorrect may have serious medical consequences. Consult the prescribing physician before making any changes to diabetes medication plans.

Patient Test Procedure - Ketone

Use the following procedure to perform patient tests with the FreeStyle Precision Pro Blood β-Ketone Test Strip. The FreeStyle Precision Pro meter recognises the type of test strip based on the scan of the strip barcode.

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

What You See on the Display	What You Do	Comments
Insert Strip	**1.** Follow steps 1 to 7 in the last section on the Glucose Patient Test. Insert the purple Blood β-Ketone Test Strip into the test strip port until it stops and **Strip Inserted** is displayed. The meter will recognise the strip based on the barcode.	Prior to inserting the test strip, ensure that the strip port module is installed and that it is clean and dry. Replace if necessary. The display will alternate between **Insert Strip** and **Ketone**.
Apply Sample	**2.** When **Apply Sample** is displayed, apply a drop of blood from the patient's finger, transfer pipette or syringe to the target area of the test strip.	When sufficient sample has been applied, the meter beeps, displays **Sample Accepted** and automatically starts the test. For a detailed description of the test strip target area, refer to the Test Strips section of Chapter 1.

What You See on the Display	*What You Do*	*Comments*
Analysing Sample 10	**3.** Wait for the meter to analyse the sample and display the test result.	The meter counts down then displays the test result. If an error is detected during the assay, the assay is terminated and no result is displayed. Once the assay begins, all key presses are ignored until the assay is completed.
0.3mmol/L Ketone Scan or Enter Comment Code	**4.** If prompted, scan or manually enter the comment code and press **Enter**. If there is no prompt to enter a comment code skip down to step 5.	The meter may be enabled to scan or enter a 1- to 2-digit comment code. The meter may display out-of-range results similar to those for Glucose if enabled for ketone testing. The meter may be also be enabled to scan or enter up to two free text information fields.

p:Smith, John Q 2 0.3mmol/L Ketone 07/01/20 11:12 1-Next Patient 2-Patient History	**5.** You can select one of the following options: Press **1-Next Patient**. Press **2-Patient History**. Press Menu to return to **Menu Mode** menu. Press **On/Off** to turn off the meter. Remove the test strip from the meter and discard it when finished testing. Follow your facility's biohazard disposal policy.	The display shows: **Patient ID or Name** (**p:** prompt) **Comment Code** (Number in box) **Date and Time of test** **Test Type** (Ketone) If **1** is selected, the **Scan Patient ID** screen will appear. Continue with testing on the next patient. If **2** is selected, the meter will display the last test result for this patient as well as allow you to view previous results.

Questions? Refer to Pages 10–22 For Technical Support Instructions.

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4. Control Test

Operating Guidelines for Control Solution Testing

Control Test Procedure-Glucose

Control Test Procedure-Ketone

Control Test

This chapter describes the steps for running a control test with control solutions. Control tests verify the performance of the FreeStyle Precision Pro meter and test strips.

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

- Tests of low, mid and high control solutions or a variation depending on the facility's policy.
- Tests of control solutions at relative times (e.g. every 24 hours) or fixed times (e.g. at 6:00, 14:00 and 22:00.).
- Tests of control solutions after strip port module replacement.
- Control test results to appear as numeric value or Pass/Fail.

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

Operating Guidelines for Control Solution Testing

Observe the following guidelines to obtain optimal quality control results using the FreeStyle Precision Pro system:

- Use only MediSense Glucose and Ketone Control Solutions with compatible test strips to verify the performance of the FreeStyle Precision Pro meter and test strips.
- When opening a new bottle, write the discard date on the bottle label. Each bottle of control solution is stable for 90 days after opening or until the expiry date printed on the label, whichever comes first.
- Do not use control solutions after the expiry date printed on the bottles and the box. After the bottle has been opened, do not use after the discard date written on the bottle.

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 4: Control Test

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- Invert the control solution bottle several times to ensure thorough mixing before use.
- Invert and tap the capped control solution bottle to remove air bubbles from the tip of the bottle.
- Wipe the control solution nozzle with a clean gauze or tissue before and after each test.
- Do not scan one test strip foil packet's barcode and use a test strip from another foil packet. This may cause incorrect results to be generated.
- Replace the correct cap on the bottle and tighten the cap immediately after each use.

When To Test with Control Solutions

- As required by your facility's quality policy or local regulatory requirements.
- To verify the performance of the FreeStyle Precision Pro system.

Workflow

The meter expects to run control tests in the following order. If a control level is disabled, the meter will expect to skip it. If ketone testing is disabled, the operator will not receive a prompt to perform this test.

1. Low Glucose
2. Mid Glucose
3. High Glucose
4. Low Ketone
5. Mid Ketone
6. High Ketone
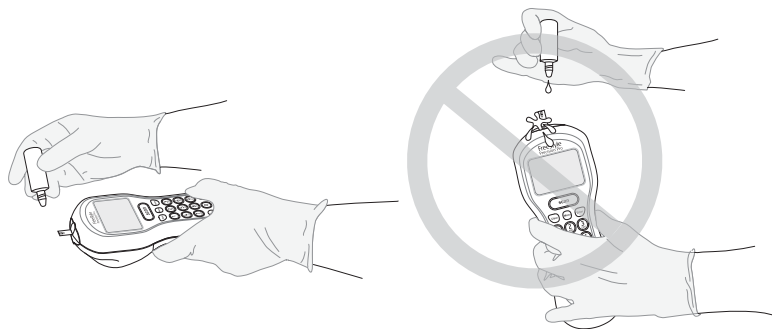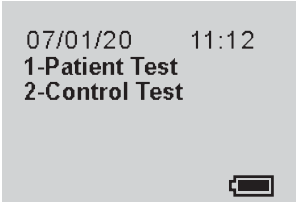
> ⚠️ **IMPORTANT:** *Do not allow control solution to drip down into meter port.*

Control Test Procedure - Glucose

Use the following procedure to perform glucose control tests.

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

What You See on the Display	What You Do	Comments
	1. Press **On/Off** to turn on the meter.	The Abbott logo screen will appear in black for a few seconds and then will appear in grey to ensure that the display is functioning properly. Next, the software version will briefly appear.
07/01/20 11:12 1-Patient Test 2-Control Test	**2.** Press **2** to select **Control Test**.	The meter starts in **Test Mode**. The Menu button will toggle the meter to **Menu Mode**.

What You See on the Display	What You Do	Comments
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**.	While the Operator ID may be up to 30 digits, not all digits will fit on the display. The meter may also be set to truncate (ignore) leading, trailing and/or selected digits of the barcode.
Scan or Enter **Low Level Solution Lot**	**4.** Scan or manually enter the low control solution lot number via the keypad, then press **Enter**.	You can scan or manually enter the information from the control solution's barcode. For manual entry, key in the five numeric digits of the lot number printed on the control solution bottle. You do not need to enter the alpha character that appears at the end of the 5-digit number. The **Strip Lot** screen will appear next.

What You See on the Display	*What You Do*	*Comments*
Unexpected Level Low expected Mid entered 1- ReEnter Lot 2- Continue	If the **Unexpected Level** screen appears, you may either: 1. Enter **1** to **ReEnter** the expected level. 2. Enter **2** to **Continue**.	The meter is programmed to expect Low, Mid and High Glucose, then Low, Mid and High Ketone control tests in this order. A warning message will appear if the controls are used in a different order; however, you may still proceed with the test.
Scan or Enter **Strip Lot**	**5.** Press **Scan** to scan the test strip barcode or manually enter the test strip lot number via the keypad, then press **Enter**.	Scanning the barcode identifies the strip type, calibrates the meter, ensures the expiry date has not passed, records the strip lot used, programs control solution range and checks that the lot has been approved for use by your institution.

Note: *Place meter on a flat surface while running control tests to avoid control solution from dripping into the test strip port.*

6. Make sure your hands or gloves are clean and dry before opening the foil packet. Open the foil test strip packet at the notch and tear down to remove the test strip.

Insert
Strip

7. With the contact bars facing up, insert the test strip into the test strip port until it stops and **Strip Inserted** is displayed.

Prior to inserting the test strip, ensure that the strip port module is installed and that it is clean and dry. Replace if necessary. The display will alternate between **Insert Strip** and **Glucose**.
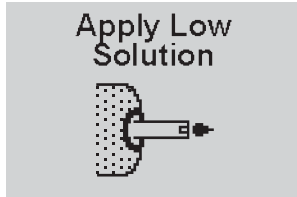
What You See on the Display	*What You Do*	*Comments*
Apply Low Solution	**8.** Gently invert the required control solution bottle 3-4 times. Remove the cap of the control solution bottle and wipe the nozzle with a clean gauze or tissue. Apply a small drop of solution to the test strip target area. Wipe the nozzle of the control solution bottle before replacing the cap.	When sufficient sample has been applied, the meter beeps, displays **Sample Accepted** and automatically starts the test. For a detailed description of the test strip target area, refer to the Test Strips section of Chapter 1.

✎ Note: *Do not lift the meter to view the display until after the test strip has been removed. Tipping the meter while the test strip is inserted may cause the control solution to drip into the strip port, contaminating the strip port. If the meter becomes disabled as a result of liquid or other contaminants entering the strip port, the strip port module should be replaced.*

Analysing Sample 5	**9.** Wait for the meter to analyse the sample and display the test result. When using FreeStyle Precision Pro test strips the countdown will begin at 5 seconds.	The meter counts down, then displays the test result. If an error is detected during the assay, the assay is terminated and no result is displayed. Once the assay begins, all key presses are ignored until the assay is completed.
Low 1.6-3.2 X5.1 mmol/L Glucose 07/01/20 11:12 1-Next Level 2-Repeat Test 92 mg/dL	**10.** Note the test result and whether it falls within the acceptable range. If required, scan or manually enter the comment code and press **Enter**. If there is no prompt to enter a comment code skip down to step 11.	Control test results can appear as numeric or PASS/FAIL, depending on how the test is set up. If numeric, an 'X' will appear in front of a test result that is out-of-range. The meter may be enabled to scan or enter a 1- to 2-digit comment code.

Low **PASS** Glucose 07/01/20 11:12 1-Next Level 2-Repeat Test	**11.** You may select one of the following: Press **1-Next Level**. Press **2-Repeat Test**. Press **Menu** to return to the **Menu Mode** menu. Press **On/Off** to turn off the meter. Remove the test strip from the meter and discard it when finished testing. Follow your facility's waste disposal policy.	The display shows: **Level** (Low, Mid, High) **Comment Code** (Number in box) **Test Type** (Glucose) **Date and Time of test** **Operator ID** (**o:** prompt) Note that test date and time alternates with Operator ID. If **1** is selected, the **Scan or Enter Control Lot** screen will appear. Return to step 4 to perform the **Next Level** control test. If **2** is selected, the **Scan or Enter Strip Lot** screen will appear. Return to step 5 to **Repeat Test** at the same level.

Note: *If ketone testing is disabled, then following a complete set of Glucose controls, 1-Next Level becomes 1-Exit.*
If ketone testing is enabled and Glucose QC is run first, then following a complete set of Glucose controls, 1-Next Level becomes 1-QC Ketone.
If ketone testing is enabled and Ketone QC is run first, then following a complete set of ketone controls, 1-Next Level becomes 1-QC Glucose.
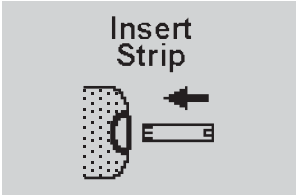
Control Test Procedure - Ketone

Use the following procedure to perform ketone control tests if ketone testing is enabled.

> ✍ Note: *The following section illustrates some common settings. If the meter does not display the screens shown, please refer to Chapter 10, Troubleshooting.*

What You See on the Display	What You Do	Comments
Insert Strip	**1.** Repeat steps 1 to 6 from the previous Glucose Control Test Procedure. Insert the purple Blood β-Ketone Test Strip into the test strip port until it stops and **Strip Inserted** is displayed. The meter will recognise the strip based on the barcode.	Prior to inserting the test strip, ensure that the strip port module is installed and that it is clean and dry. Replace if necessary. The display will alternate between **Insert Strip** and **Ketone**.

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

Apply Low Solution

2. Gently invert the required control solution bottle 3-4 times. Remove the cap of the control solution bottle and wipe the nozzle with a clean gauze or tissue. Apply a small drop of solution to the test strip target area. Wipe the nozzle of the control solution bottle before replacing the cap.

When sufficient sample has been applied, the meter beeps, displays **Sample Accepted** and automatically starts the test. For a detailed description of the test strip target area, refer to the Test Strips section of Chapter 1.

Analysing Sample

10

3. Wait for the meter to analyse the sample and display the test result.

The meter counts down then displays the test result. If an error is detected during the assay, the assay is terminated and no result is displayed. Once the assay begins, all key presses are ignored until the assay is completed.

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 4: Control Test

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Low 0.6-1.0 **X3.4**mmol/L Ketone Scan or Enter Comment Code --	**4.** Note the test result and whether it falls within the acceptable range. If required, scan or manually enter the comment code and press **Enter**. If there is no prompt to enter a comment code skip down to step 5.	Control test results can appear as numeric or PASS/FAIL, depending on how the test is set up. If numeric, an 'X' will appear in front of a test result that is out-of-range. The meter may be enabled to scan or enter a 1- to 2-digit comment code.
Low 12 **PASS** Ketone 07/01/20 11:12 1-Next Level 2-Repeat Test	**5.** You may select one of the following: Press **1-Next Level**. Press **2-Repeat Test**. Press **Menu** to return to the **Menu Mode** menu. Press **On/Off** to turn off the meter. Remove the test strip from the meter and discard it when finished testing. Follow your facility's waste disposal policy.	The display shows: **Level** (Low, Mid, High) **Comment Code** (Number in box) **Test Type** (Ketone) **Date and Time of test** **Operator ID** (**o:** prompt) Note that test date and time alternates with Operator ID. If **1** is selected, the **Scan or Enter Control Lot** screen will appear. Return to step 1 to perform the **Next Level** of control test. If **2** is selected, the **Scan or Enter Strip Lot** screen will appear. Repeat the test.

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 4: Control Test

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5.   Data Review

Data Review for Patient by Operator ID

Data Review for Patient by Patient ID

Data Review for All Patient Data

Data Review for Control Data

Data Review for Proficiency Data

Data Review

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

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

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

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

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

Proficiency Data: This will show proficiency test results, starting with the most recent test.
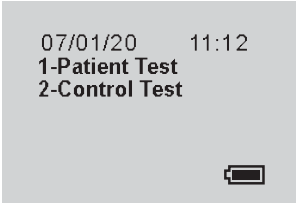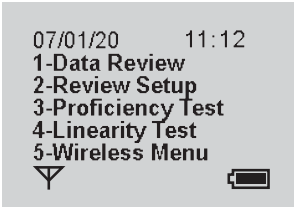
> Note: *The meter may be configured to require a valid Operator ID to view results. Once authenticated, the Operator ID will not be displayed on each data review screen.*

Follow these steps to access the Data Review menu:

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

What You See on the Display	What You Do	Comments
	1. Press the **On/Off** button to turn the meter on.	The Abbott logo screen will appear in black for a few seconds and then will appear in grey to ensure that the display is functioning properly. Next, the software version will briefly appear.
07/01/20 11:12 1-Patient Test 2-Control Test	**2.** Press the **Menu** button.	The meter starts in **Test Mode**. The Menu button will toggle the meter to **Menu Mode**.

What You See on the Display	What You Do	Comments
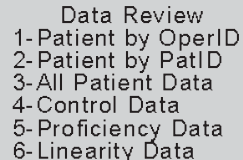
3. Press **1** to select **Data Review**.

```
07/01/20      11:12
1-Data Review
2-Review Setup
3-Proficiency Test
4-Linearity Test
5-Wireless Menu
```

4. Press **Scan** to scan the Operator ID barcode or manually enter the Operator ID via the keypad, then press **Enter**.

While the Operator ID may be up to 30 digits, not all digits will fit on the display. The meter may also be set to truncate (ignore) leading, trailing and/or selected digits of the barcode.

```
Scan or Enter
Operator ID

- - - - - - - - - -
OPERATOR
```

5. Choose the category of data to review.

```
Data Review
1-Patient by OperID
2-Patient by PatID
3-All Patient Data
4-Control Data
5-Proficiency Data
6-Linearity Data
```

Data Review for Patient by Operator ID

Please refer to the beginning of this Data Review chapter for step-by-step instructions to access the Data Review menu.
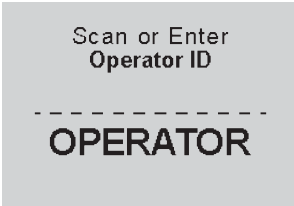
> ✍ Note: *The following section illustrates some common settings. Depending on your institution's specific settings, some screens will display differently or not at all. If the meter does not display the screens shown, please refer to Chapter 10, Troubleshooting.*

What You See on the Display	*What You Do*	*Comments*
Data Review 1-Patient by OperID 2-Patient by PatID 3-All Patient Data 4-Control Data 5-Proficiency Data 6-Linearity Data	**1.** Press **1** to select **Patient by OperID**.	The meter shows the result of the most recent patient test you performed.

p:Smith, John Q. ☐2 **5.6**mmol/L Glucose o:391937 1-Previous 27 2-Next 1 100 mg/dL	**2.** You can select one of the following options: Press **1-Previous** Press **2-Next** Selection **2-Next** will be displayed only when there is new data for review. When finished reviewing the data, you can: Press **Clear** to return to the **Data Review** menu. Press **Menu** to return to the **Menu Mode** menu. Press **On/Off** to turn off the meter.	The number that appears to the right of **1-Previous** and **2-Next** on the meter indicates the number of tests available for review. The display also shows: **Patient ID or Name** (**p:** prompt) **Comment Code** (Number in box) **Test Type** (Glucose or Ketone) **Operator ID** (o: prompt) **Date and Time of test** Note that test date and time alternates with Operator ID.

Questions? Refer to Pages 10–22 For Technical Support Instructions.
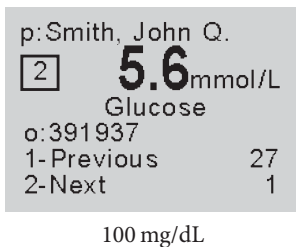
Chapter 5: Data Review   **5-5**

Data Review for Patient by Patient ID

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

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

What You See on the Display	What You Do	Comments
Data Review 1-Patient by OperID 2-Patient by PatID 3-All Patient Data 4-Control Data 5-Proficiency Data 6-Linearity Data	**1.** Press **2** to select **Patient by PatID**.	The meter shows test results for a specific patient.
Scan or Enter **Patient ID** - - - - - - - - - - - - - - PATIENT	**2.** Press **Scan** to scan the Patient ID barcode or manually enter the Patient ID via the keypad (if enabled).	If you enter the ID manually, you may be required to enter it a second time to ensure it is correct. While the Patient ID may be up to 30 digits, not all digits will fit on the display. The meter may also be set to truncate (ignore) selected digits of the barcode.

```
p:Smith, John Q.
 ☐2    5.6 mmol/L
       Glucose
o:391937
1- Previous        27
2- Next             1
```

100 mg/dL

3. You can select one of the following options:

Press **1-Previous**

Press **2-Next**

Selection **2-Next** will be displayed only when there is new data for review.

When finished reviewing the data, you can:

Press **Clear** to return to the **Patient ID** entry screen.
Press **Menu** to return to the **Menu Mode** menu.
Press **On/Off** to turn off the meter.

The number that appears to the right of **1-Previous** and **2-Next** on the meter indicates the number of tests available for review. The display also shows:

Patient ID or Name (**p:** prompt)
Comment Code (Number in box)
Test Type (Glucose or Ketone)
Operator ID (o: prompt)
Date and Time of test

Note that test date and time alternates with Operator ID.

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 5: Data Review

5-7

Data Review for All Patient Data

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

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

What You See on the Display	What You Do	Comments
Data Review 1-Patient by OperID 2-Patient by PatID 3-All Patient Data 4-Control Data 5-Proficiency Data 6-Linearity Data	1. Press **3** to select **All Patient Data**.	The meter will show all patient test results, starting with the most recent results.

p:Smith, John Q. ☐2 **5.6**mmol/L Glucose o:391937 1-Previous 27 2-Next 1 100 mg/dL	**2.** You can select one of the following options: Press **1-Previous** Press **2-Next** Selection **2-Next** will be displayed only when there is new data for review. When finished reviewing the data, you can: Press **Clear** to return to the **Data Review** screen. Press **Menu** to return to the **Menu Mode** menu. Press **On/Off** to turn off the meter.	The number that appears to the right of **1-Previous** and **2-Next** on the meter indicates the number of tests available for review. The display also shows: **Patient ID or Name** (**p:** prompt) **Comment Code** (Number in box) **Test Type** (Glucose or Ketone) **Operator ID** (**o:** prompt) **Date and Time of test** Note that test date and time alternates with Operator ID.

Data Review for Control Data

The meter stores the last 1,000 control test results. Please refer to the beginning of this Data Review chapter for step-by-step instructions to access the Data Review menu.

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

What You See on the Display	What You Do	Comments
Data Review 1-Patient by OperID 2-Patient by PatID 3-All Patient Data 4-Control Data 5-Proficiency Data 6-Linearity Data	**1.** Press **4** to select **Control Data**.	The meter shows the result of the most recent control test.

What You See on the Display	What You Do	Comments

```
        Low
     PASS
      Glucose
07/01/20    11:12
1-Previous         4
2-Next             4
```

2. You can select one of the following options:

Press **1-Previous**

Press **2-Next**

Selection **2-Next** will be displayed only when there is new data for review.

When finished reviewing the data, you can:

Press **Clear** to return to the **Data Review** screen.
Press **Menu** to return to the **Menu Mode** menu.
Press **On/Off** to turn off the meter.

The number that appears to the right of **1-Previous** and **2-Next** on the meter indicates the number of tests available for review. The display also shows the acceptable range for this test and:

Comment Code (Number in box)
Level (low, mid, high)
Range (if numeric)
Test Type (Glucose or Ketone)
Operator ID (**o:** prompt)
Date and Time of test
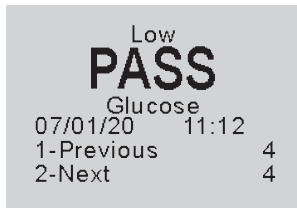
Note that test date and time alternates with Operator ID.

Data Review for Proficiency Data

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

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

What You See on the Display	What You Do	Comments
Data Review 1-Patient by OperID 2-Patient by PatID 3-All Patient Data 4-Control Data 5-Proficiency Data 6-Linearity Data	**1.** Press **5** to select **Proficiency Data**.	The meter shows the most recent proficiency test result.

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 5: Data Review

5-12

```
        s:4567
 23    5.6 mmol/L
        Glucose
07/01/20      11:12
1-Previous          1
2-Next              1
```

100 mg/dL

2. You can select one of the following options:

Press **1-Previous**

Press **2-Next**

Selection **2-Next** will be displayed only when there is new data for review.

When finished reviewing the data, you can:

Press **Clear** to return to the **Data Review** screen.
Press **Menu** to return to the **Menu Mode** menu.
Press **On/Off** to turn off the meter.

The number that appears to the right of **1-Previous** and **2-Next** on the meter indicates the number of tests available for review. The display also shows:

Sample ID (**s:** prompt)
Comment Code (Number in box)
Test Type (Glucose or Ketone)
Operator ID (**o:** prompt)
Date and Time of test
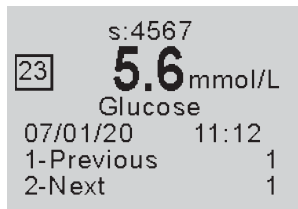
Note that test date and time alternates with Operator ID.

6.   Proficiency Test

Proficiency Test-Glucose

Proficiency Test-Ketone (Beta-Hydroxybutyrate)

Proficiency Test - Glucose

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

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

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

What You See on the Display	What You Do	Comments
	1. Press the **On/Off** button to turn on the meter.	The Abbott logo screen will appear in black for a few seconds and then will appear in grey to ensure that the display is functioning properly. Next, the software version will briefly appear.
	2. Press the **Menu** button.	The meter starts in **Test Mode**. The Menu button will toggle the meter to **Menu Mode**.
	3. Press **3** to select **Proficiency Test**.	
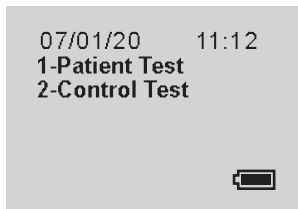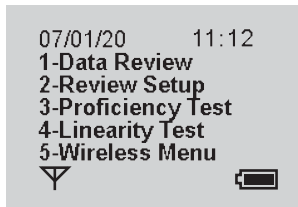
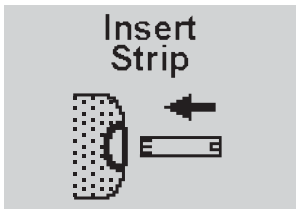| What You See on the Display	What You Do	Comments
Scan or Enter **Operator ID** ---- OPERATOR	**4.** Press **Scan** to scan the Operator ID barcode or manually enter the Operator ID via the keypad, then press **Enter**.	While the Operator ID may be up to 30 digits, not all digits will fit on the display. The meter may also be set to truncate (ignore) leading, trailing and/or selected digits of the barcode.
Scan or Enter **Sample ID** ---- PROF	**5.** Scan or manually enter the Sample ID via the keypad, then press **Enter**.	The meter will prompt for the Sample ID to be scanned or entered. **PROF** indicates proficiency test.
Scan or Enter **Strip Lot** ----	**6.** Press **Scan** to scan the test strip barcode or manually enter the test strip lot number via the keypad, then press **Enter**.	Scanning the barcode identifies the strip type, calibrates the meter, ensures the expiry date has not passed, records the strip lot used and checks that the lot has been approved for use by your institution.

What You See on the Display	What You Do	Comments

7. Make sure your hands or gloves are clean and dry before opening the foil packet. Open the foil test strip packet at the notch and tear down to remove the test strip.

Insert Strip

8. With the contact bars facing up, insert the test strip into the test strip port until it stops and **Strip Inserted** is displayed.

Prior to inserting the test strip, ensure that the strip port module is installed and that it is clean and dry. Replace if necessary. The display will alternate between **Insert Strip** and **Glucose**.

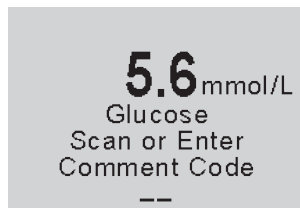| What You See on the Display	What You Do	Comments
Apply Sample	**9.** Ensure proficiency survey specimens are at room temperature. Mix each specimen well according to instructions from the survey provider. Wipe away any specimen on the tip of the vial before squeezing the vial and applying a drop to the test strip target area. After applying the sample, recap the vial tightly.	When sufficient sample has been applied, the meter beeps, displays **Sample Accepted** and automatically starts the test. For a detailed description of the test strip target area, refer to the Test Strips section of Chapter 1.
Analysing Sample 5	**10.** Wait for the meter to analyse the sample and display the test result. When using FreeStyle Precision Pro test strips the countdown will begin at 5 seconds.	The meter counts down then displays the test result. If an error is detected during the assay, the assay is terminated and no result is displayed. Once the assay begins, all key presses are ignored until the assay is completed.

5.6mmol/L Glucose Scan or Enter Comment Code -- 100 mg/dL	**11.** If required, scan or manually enter the comment code and press **Enter**. If there is no prompt to enter a comment code, skip down to step 12.	If the comment code option is enabled in the patient test configuration through the data management system, the meter will be enabled to scan or enter a 1 or 2 digits comment code.
s:12345 12 **5.6**mmol/L Glucose 07/01/20 11:12 1-Next Test 100 mg/dL	**12.** You can 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 meter. Remove the test strip from the meter and discard it when finished testing. Follow your facility's biohazard disposal policy.	The display shows: **Sample ID** (**s:** prompt) **Comment Code** (Number in box) **Test Type** (Glucose) **Date and Time of test** **Operator ID** (**o:** prompt) Note that test date and time alternates with Operator ID. If **1** is selected, the **Scan or Enter Sample ID** screen will appear. Return to step 5 to perform the **Next Test** with another proficiency sample.

Proficiency Test - Ketone (Beta-Hydroxybutyrate)

Please use the following procedures to perform a ketone proficiency test.

What You See on the Display	What You Do	Comments
Insert Strip	**1.** Follow steps 1 through 8 in the last section on the Glucose Proficiency Test. Make sure you use the purple Blood β-Ketone Test Strip for the blood Ketone Proficiency Test. The meter will recognise the strip based on the barcode.	Prior to inserting the test strip, ensure that the strip port module is installed and that it is clean and dry. Replace if necessary. The display will alternate between **Insert Strip** and **Ketone**.
Apply Sample	**2.** Ensure proficiency survey specimens are at room temperature. Mix each specimen well according to instructions from the survey provider. Wipe away any specimen on the tip of the vial before squeezing the vial and applying a drop to the test strip target area. After applying the sample, recap the vial tightly.	When sufficient sample has been applied, the meter beeps, displays **Sample Accepted** and automatically starts the test. For a detailed description of the test strip target area, refer to the Test Strips section of Chapter 1.

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 6: Proficiency Test

6-7

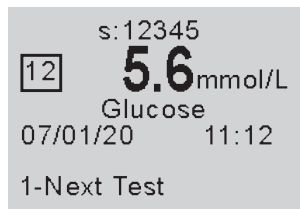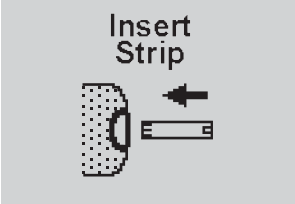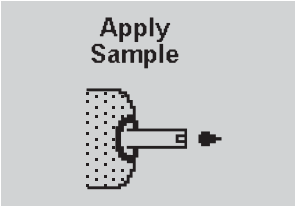| --- | --- | --- |
| **Analysing Sample** **10** | **3.** Wait for the meter to analyse the sample and display the test result. | The meter counts down then displays the test result. If an error is detected during the assay, the assay is terminated and no result is displayed. Once the assay begins, all key presses are ignored until the assay is completed. |
| **2.2**mmol/L
Ketone
Scan or Enter
Comment Code
-- | **4.** If required, scan or manually enter the comment code and press **Enter**. If there is no prompt to enter a comment code, skip down to step 5. | If the comment code option is enabled in the patient test configuration through the data management system, the meter will be enabled to scan or enter a 1 or 2 digits comment code. |

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 6: Proficiency Test   **6-8**

s:123456 □12 **2.2**mmol/L Ketone 07/01/20 11:12 1-Next Test	**5.** You can select one of the following options: Press **1-Next Test**. Press **Menu** to return to **Menu Mode** menu. Press **On/Off** to turn off the meter. Remove the test strip from the meter and discard it when finished testing. Follow your facility's biohazard disposal policy.	The display shows: **Sample ID** (**s**: prompt) **Comment Code** (Number in box) **Test Type** (Ketone) **Date and Time of test** **Operator ID** (**o:** prompt) Note that test date and time alternates with Operator ID. If **1** is selected, the **Scan or Enter Sample ID** screen will appear. Return to step 1 to perform the **Next Test** with another proficiency sample.

# 7.	Review Setup

Meter Configuration

Review Setup

Review Test Setup for All Tests

Review Test Setup for Test Type

Review Test Setup for Patient Test

Review Test Setup for Control Test

Review Test Setup for Security

System Status

Meter Configuration

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

Upload Interval

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

> ✍ Note: *Wireless enabled systems will transfer data automatically without user interaction. Non-wireless enabled systems will require the user to utilise the docking station or cable to transfer data at specified intervals.*

Operator ID

- Whether the Operator ID is required, optional or not used for all tests.
- Define the Operator ID prompt.
- The minimum and maximum number (between 1 and 30) of digits that are acceptable for the Operator ID.
- With manual entry of the Operator ID, determine whether a check digit is required (modulus 10 or 11).

- Decide acceptable formats for the Operator ID barcode. Refer to the Barcode Types in Chapter 12 for available formats.
- The meter can truncate (ignore) the leading digits and/or the last digits of an Operator ID. The meter can be set to select specific digits of an Operator ID. The number of digits is configured in the data management system.

Patient Tests/Patient ID

- Determine whether the Patient ID is required, optional or not used for patient tests.
- Define the Patient ID prompt.
- The minimum and maximum number (between 1 and 30) of digits that are acceptable for the Patient ID.
- Permission for manual entry of the Patient ID.
- Determine whether duplicate entry of a manually entered ID is required.
- With manual entry of the Patient ID, determine whether a check digit is required (modulus 10 or 11).
- Decide acceptable formats for the Patient ID barcode. Refer to the Barcode Types in Chapter 12 for available formats.
- The meter can truncate (ignore) the leading digits and/or the last digits of a Patient ID. The meter can be set to select specific digits of a Patient ID. The number of digits is configured in the data management system.
- Decide whether confirmation of the Patient ID is required.
- Determine how the ID will be confirmed.
- Decide whether to display Patient DOB on Patient ID prompt screen.
- Decide whether comment code is required, optional or not used for patient tests that are in the acceptable range for the facility and the test strip.
- Decide whether comment code is required, optional or not used for patient tests that are outside of the acceptable range for the facility and the test strip.

Control Tests

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

QC Interval

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

Operator ID

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

Strip Lot

- Decide whether an operator can continue to test ('allow test' or 'warn') or not ('lockout') when a strip lot is scanned or entered to the meter for a lot of strips that is not on the approved strip lot list. The maximum number of strip lots that can be downloaded to the FreeStyle Precision Pro meter is 36: 18 Glucose and 18 Ketone.

Other

- Decide what additional information to download to a meter through the data management system: lists of operators, lists of strip lots or lists of patients.
- Determine whether the meter displays results in mmol/L or mg/dL (Glucose only).
- Decide whether any additional free text comments are stored with a test record. These can be required, optional or not used.
- Decide whether to configure the meter for proficiency tests.
- Determine what language (such as English) displays on the meter.
- Turn the audible indicator off/on.
- Determine whether to use alkaline, lithium or rechargeable batteries in the meter.
- Decide how soon the meter automatically turns off (4-10 minutes) after a patient test.
- Decide whether to enable ketone testing.

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 7: Review Setup

7-4

- Date display configuration on the meter. The date can be configured to the following formats:
  - mm/dd/yy
  - dd/mm/yy
  - dd-mm-yy
  - mm-dd-yy
- Time display configuration on the meter. The time can be configured to the following formats:
  - hh:mm AM/PM
  - h:mm AM/PM
  - AM/PM h:mm
  - hh:mm (24 hour)

Action Range/Critical Range

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

Wireless Settings (for wireless enabled systems only/optional)

- Decide the wireless time-out interval. Decide the number of seconds of inactivity allowed before the meter reverts to wireless standby to save battery power (wireless time-out interval).
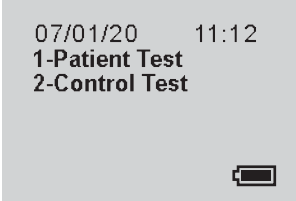
The following features are configured through the optional Wireless Setup Utility. Configuration can not be changed through the data management system. Feature status can be viewed on the FreeStyle Precision Pro meter.

- View wireless network server information
- View signal strength and frequency information
- View wireless security information

Review Setup

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

What You See on the Display	What You Do	Comments
	1. Press **On/Off** to turn on the meter.	The Abbott logo screen will appear in black for a few seconds and then will appear in grey to ensure that the display is functioning properly. Next, the software version will briefly appear.
07/01/20　　11:12 **1-Patient Test** **2-Control Test**	**2.** Press the **Menu** button.	The meter starts in **Test Mode**. The **Menu** button will toggle the meter to **Menu Mode**.

07/01/20   11:12
1-Data Review
2-Review Setup
3-Proficiency Test
4-Linearity Test
5-Wireless Menu

3. Press **2** to select **Review Setup**.

Review Test Setup for All Tests

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

What You See on the Display	What You Do	Comments
Review Setup 1-Test Setup 2-System Status	**1.** Press **1** for **Test Setup**.	
Test Setup 1-All Tests 2-Test Type 3-Patient Test 4-Control test 5-Security	**2.** Press **1** for **All Tests** to continue to the **All Tests Upload Interval** screen.	

All Tests Upload Interval **Allow Test** **1 days** 1-Next	**3.** Press **1-Next** to continue to the **All Tests Operator ID** screen.	
All Tests Operator ID **Optional** **5 - 20 digits** 1-Next	**4.** Press **1-Next** to continue to the **All Tests Operator ID Truncation** screen.	

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 7: Review Setup

7-9

All Tests Operator ID Truncation **First/Last** 1-Next	**5.** Press **1-Next** to continue to the **All Tests Operator ID Prompt** screen.
All Tests Operator ID Prompt **Operator ID** 1-Next	**6.** Press **1-Next** to return to the **Test Setup** menu.

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 7: Review Setup

7-10

Review Test Setup for Test Type

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

What You See on the Display	What You Do	Comments
Review Setup 1-Test Setup 2-System Status	**1.** Press **1** for **Test Setup**.	
Test Setup 1-All Tests 2-Test Type 3-Patient Test 4-Control test 5-Security	**2.** Press **2** for **Test Type** to continue to the **Test Type Glucose Units** screen.	

What You See on the Display	What You Do	Comments

Test Type
Glucose
Units
mmol/L

1-Next

3. Press **1-Next** to continue to the **Test Type Glucose Action Range** screen.

Test Type
Glucose
Action Range
Disabled

1-Next

4. Press **1-Next** to continue to the **Test Type Glucose Critical Range** screen.

Test Type Glucose Critical Range **Disabled** 1-Next	**5.** If Ketone testing is enabled, press **1-Next** to continue to the **Test Type Ketone Action Range** screen; otherwise, press **1-Next** to continue to the **Test Setup** menu.
Test Type Ketone Action Range **Disabled** 1-Next	**6.** Press **1-Next** to continue to the **Test Type Ketone Critical Range** screen.
Test Type Ketone Critical Range **Disabled** 1-Next	**7.** Press **1-Next** to continue to the **Test Setup** menu.

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 7: Review Setup

7-13

Review Test Setup for Patient Test

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

What You See on the Display	What You Do	Comments
Review Setup 1-Test Setup 2-System Status	**1.** Press **1** for **Test Setup**.	
Test Setup 1-All Tests 2-Test Type 3-Patient Test 4-Control test 5-Security	**2.** Press **3** for **Patient Test** to continue to the **Patient Test Patient ID** screen.	

Patient Test Patient ID **Optional** **4 - 30 digits** 1-Next	**3.** Press **1-Next** to continue to the **Patient Test Patient ID Truncation** screen.	
Patient Test Patient ID Truncation **First/Last** 1-Next	**4.** Press **1-Next** to continue to the **Patient Test Comment Code If In-Range** screen.	
Patient Test Comment Code If In-Range **Enabled** 1-Next	**5.** Press **1-Next** to continue to the **Patient Test Comment Code If Out-of-Range** screen.	

Patient Test Comment Code If Out-of-Range **Optional** 1-Next	**6.** Press **1-Next** to continue to the **Patient Test Patient ID Prompt** screen.	
Patient Test Patient ID Prompt **Patient ID** 1-Next	**7.** Press **1-Next** to continue to the **Patient Test Repeat Manual ID Entry** screen.	
Patient Test Repeat Manual ID Entry **Enabled** 1-Next	**8.** Press **1-Next** to return to the **Test Setup** menu.	

Review Test Setup for Control Test

What You See on the Display	What You Do	Comments
Review Setup 1-Test Setup 2-System Status	**1.** Press **1** for **Test Setup**.	
Test Setup 1-All Tests 2-Test Type 3-Patient Test 4-Control test 5-Security	**2.** Press **4** for **Control Test** to continue to the **Control Test Glucose Levels** screen.	

Control Test Glucose Levels **(Mid, High)** 1-Next	**3.** Press **1-Next** to continue to the **Control Test Glucose Result** screen.	
Control Test Glucose Result **Pass/Fail** 1-Next	**4.** If Ketone testing is enabled, press **1-Next** to continue to the **Control Test Ketone Levels** screen, otherwise, press **1-Next** to skip down to step 7.	
Control Test Ketone Levels **(Mid)** 1-Next	**5.** Press **1-Next** to continue to the **Control Test Ketone Result** screen.	

| | **6.** Press **1-Next** to continue to the **Control Test Comment Code If In-Range** screen. | |

Control Test
Ketone
Result
Pass/Fail

1-Next

| | **7.** Press **1-Next** to continue to the **Control Test Comment Code If Out-of-Range** screen. | |

Control Test

Comment Code
If In-Range
Optional

1-Next

| | **8.** Press **1-Next** to return to the **Test Setup** menu. | |

Control Test

Comment Code
If Out-of-Range
Optional

1-Next

Review Test Setup for Security

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

What You See on the Display	What You Do	Comments
Review Setup 1-Test Setup 2-System Status	**1.** Press **1** for **Test Setup**.	
Test Setup 1-All Tests 2-Test Type 3-Patient Test 4-Control test 5-Security	**2.** Press **5** for **Security** to continue to the **Security Glucose QC Interval** screen.	

Security Glucose QC Interval **Warn** **04:00 12:00** **18:00** 1-Next	**3.** If Ketone testing is enabled, press **1-Next** to continue to the **Security Ketone QC Interval** screen, otherwise, press **1-Next** to skip down to step 5.	
Security Ketone QC Interval **Allow Test** **8 Hours** 1-Next	**4.** Press **1-Next** to continue to the **Security Operator ID Not Certified** screen.	
Security Operator ID Not Certified **Allow Test** 1-Next	**5.** Press **1-Next** to continue to the **Security Strip Lot Not on List** screen.	

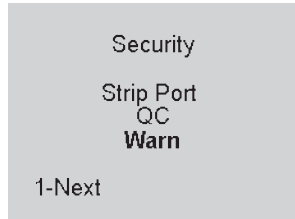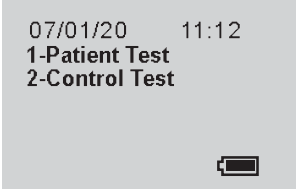| What You See on the Display	What You Do	Comments
Security Strip Lot Not on List **Allow Test** 1-Next	**6.** Press **1-Next** to continue to the **Security Patient Data Not Confirmed** screen.	
Security Patient Data Not Confirmed **Warn** 1-Next	**7.** Press **1-Next** to continue to the **Security Confirm Patient Data** screen.	
Security Confirm Patient Data **Year of Birth** 1-Next	**8.** Press **1-Next** to continue to the **Strip Port Quality** screen.	

Security Strip Port QC **Warn** 1-Next	**9.** Press **1-Next** to return to the **Test Setup** screen.	

System Status

What You See on the Display	What You Do	Comments
	1. Press **On/Off** to turn on the meter.	The Abbott logo screen will appear in black for a few seconds and then will appear in grey to ensure that the display is functioning properly. Next, the software version will briefly appear.
07/01/20 11:12 **1-Patient Test** **2-Control Test**	**2.** Press the **Menu** button.	The meter starts in **Test Mode**. The **Menu** button will toggle the meter to **Menu Mode**.

What You See on the Display	What You Do	Comments

3. Press **2** to select **Review Setup**.

```
07/01/20      11:12
1-Data Review
2-Review Setup
3-Proficiency Test
4-Linearity Test
5-Wireless Menu
```

4. Press **2** to continue to the **System Status Battery Power** screen.

```
Review Setup

1-Test Setup
2-System Status
```

5. Press **1-Next** to continue to the **System Status Temperature** screen.

```
System Status

Battery
Power
3.29v

1-Next
```

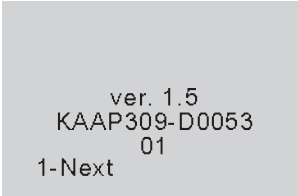| What You See on the Display	What You Do	Comments
System Status Temperature 23.4°C 1-Next	**6.** Press **1-Next** to continue to the **System Status Time** screen.	
System Status Time 11:12 24 Hour hh:mm 1-Next	**7.** Press **1-Next** to continue to the **System Status Date** screen.	
System Status Date 07/01/20 dd/mm/yy 1-Next	**8.** Press **1-Next** to continue to the **System Status Software Version and Serial Number** screen.	

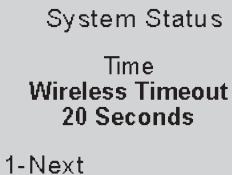| What You See on the Display	What You Do	Comments
ver. 1.5 KAAP309-D0053 01 1-Next	**9.** Press **1-Next** to continue to the **Wireless Communication Timeout Menu** (optional).	The number that appears on your meter may be different from the number that appears here.
System Status Time **Wireless Timeout** **20 Seconds** 1-Next	**10.** Press **1-Next** to return to the Review Setup screen.	

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 7: Review Setup

7-27

8. Review Setup for Wireless Communication (Optional)

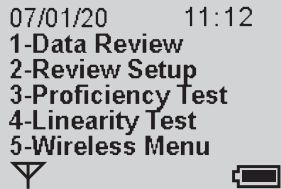Meter Wireless Configuration

Review Setup for Wireless Communication (Optional)
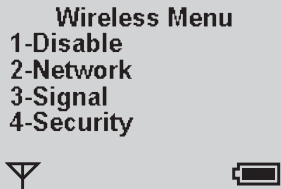
Meter Wireless Configuration

The FreeStyle Precision Pro meter wireless configuration settings are enabled via the Wireless Setup Utility. These settings can be viewed on the hand-held device, but cannot be changed on it except Enable/Disable meter wireless module. Reference the Wireless Setup Utility User's Guide for the instructions to activate, configure and enable the wireless module for individual FreeStyle Precision Pro meters.

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

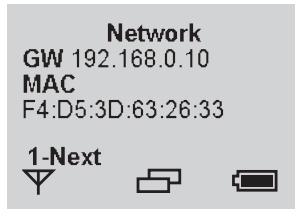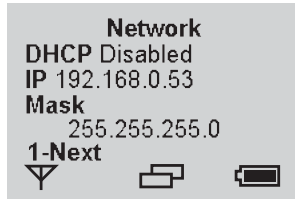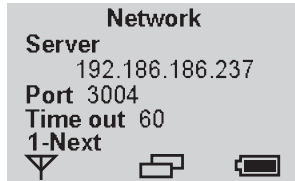| What You See on the Display	What You Do	Comments
07/01/20 11:12 1-Data Review 2-Review Setup 3-Proficiency Test 4-Linearity Test 5-Wireless Menu ▽	**1.** Press **5** for **Wireless Menu**.	▽ is displayed when the meter is wireless enabled. ▱ is displayed when there is stored data in the meter pending transmission.
Wireless Menu 1-Disable 2-Network 3-Signal 4-Security ▽	**2.** Press **1** to disable the meter wireless function.	Screen displays the wireless and network information menu. Press **2** for network setting, press **3** for wireless signal status and press **4** for wireless security settings.

Network
Server
192.186.186.237
Port 3004
Time out 60
1-Next

Network
DHCP Disabled
IP 192.168.0.53
Mask
255.255.255.0
1-Next

Network
GW 192.168.0.10
MAC
F4:D5:3D:63:26:33

1-Next

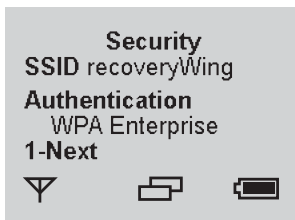**3.** Press **2** for additional network settings.

Screen displays the wireless network settings configured through the Wireless Setup Utility. The timeout interval is set through the data management system. This value indicates that the meter will go into wireless stand-by mode to save energy. Wireless stand-by mode is when the meter requests a wireless communication to server and receives no response in 60 seconds.

Reference the Wireless Setup Utility User's Guide for more detailed information about the other network settings.
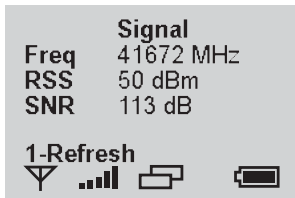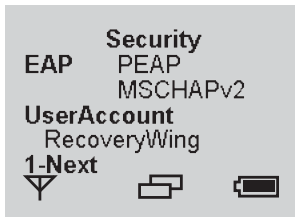
Signal Freq 41672 MHz RSS 50 dBm SNR 113 dB 1-Refresh	**4.** Signal status screen.	Screen displays the wireless band frequency (Freq), the received signal strength (RSS) and the signal noise ratio (SNR) at the time of the last wireless transmission. Press **1** to refresh the screen for the current signal status.
Security SSID recoveryWing **Authentication** WPA Enterprise 1-Next	**5.** Security settings screen.	Screen displays the security settings configured through the Wireless Setup Utility. If there are additional security settings, press 1 to go to the next screen.
Security EAP PEAP MSCHAPv2 **UserAccount** RecoveryWing 1-Next	**6.** Press **1-Next** to continue to the **Wireless Menu** screen.	

Note: *For information on wireless data transfer see the Wireless Transfer section in the Data Upload chapter.*

9.   Data Upload

Docking Station Upload

Wireless Transfer (if enabled)

Docking Station

Mounting Instructions

Enabling Data Upload

Data Upload

Once the test results have been collected they can be uploaded into the data management system. Data may be uploaded remotely utilising the docking station or through use of the optional wireless function if the data management system and meters are properly enabled. The data management system provides a simple and automated way to collect, report and transfer data.

Docking Station Upload

To start the upload of data, simply place the FreeStyle Precision Pro meter into the docking station. The meter will first turn on if it isn't already and then automatically upload data to the data management system.

Please Wait
Data Uploading

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

After upload is complete, the meter will display **Upload Successful, Turning Off** and then shut down.

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

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

```
Last upload
incomplete
Redock meter


1-Continue
```

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

Wireless Transfer (if enabled)

If the data management system and meters are properly configured and the wireless function is enabled, data will be uploaded automatically once the user leaves the test results screen. Active transmission is verifiable via the wireless transmission icon.

Wireless Enabled Icon

The meter screen will display the Wireless Enabled icon when the wireless function is enabled. After each test is performed, the data is stored in the meter database. Wireless-enabled meters will automatically establish communication and transfer stored meter data wirelessly to the data management system. The meter's wireless module automatically reverts to power-saving standby mode when not actively transferring data.

⊘ Wireless Hardware Error

Please Wait
Data Uploading

⇌

The Wireless Hardware Error icon will be displayed when there is a failure of wireless hardware module. Turn the meter off and back on again to re-establish wireless connectivity. If the problem persists, contact your local Abbott Diabetes Care office or distributor.

The following applies if the optional Wireless Communication is enabled:
When the meter turns off with test results still pending to send (**Data Transmission Pending**), it will automatically attempt to send those results. This will occur when the monitor is turned off by pressing and holding the power button for 2 seconds or if it shuts itself off automatically. The Data Uploading screen shown here will display until the meter completes transferring pending results and then it will power off automatically. The Operator does not need to take any action for this to occur. While Data Uploading screen is displayed, the Operator can turn the meter off immediately by holding the power button for 2 seconds. If the Operator does turn the meter off, wireless communication will stop and pending results will not be transmitted. Pending results will be transferred the next time the meter establishes wireless communication or the meter is docked, whichever comes first.

Docking Station

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

Set up the docking station outside patient vicinity. The docking station has a hinged base that allows it to sit on a desktop or to be mounted to a wall using the included mounting plate.
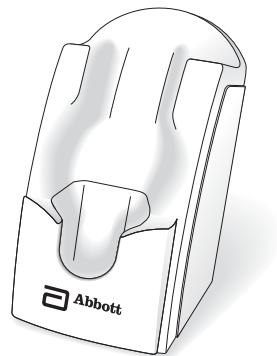
Mounting Instructions

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

Instructions:

1. Drill the holes to match to the wall mount.

2. Place the wall mount on the wall and insert the four enclosed screws.

3. Align the two holes in the docking station with the two mounting anchors.

4. After aligning the holes, press in and then down to secure the docking station.
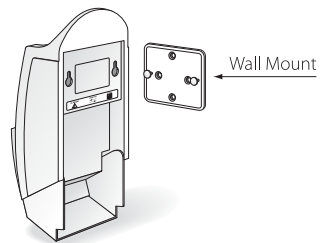
Enabling Data Upload

Data Upload Using Docking Station

The docking station has a data transfer port ⇄ located on the back. The data transfer port connects the docking station to a variety of transfer options using the included serial cable.

A connection to the data management system may be established directly, via a networked computer or via a terminal server. These connections are illustrated in Figures 1 and 2.
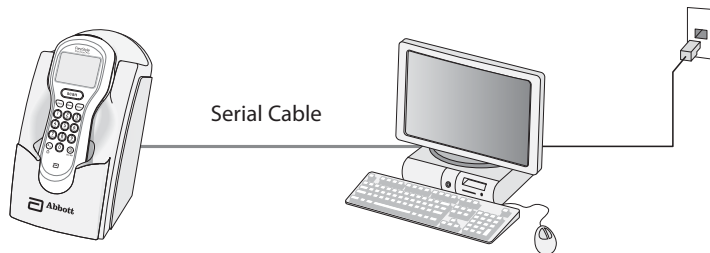

Serial Cable

Figure 1

Figure 1-Data Upload via Direct Connection or Networked Computer

1. Connect the serial cable between the docking station data transfer port and the computer.
2. Ensure that the computer has power, and if desired, a working network connection.
3. Ensure that the data management system (for serial connection) or data transmission software (for a networked connection) is operational and correctly configured. This software and its installation instructions are available separately.

Figure 2 - Data Upload via Terminal Server

1. Connect the terminal server AC adaptor to a power source.
2. Connect the serial cable to the terminal server and to the docking station data transfer port. Alternatively, connect the data upload cable to the terminal server and to the data port of the FreeStyle Precision Pro meter.
3. Connect the data networking cable to the terminal server and the network jack.
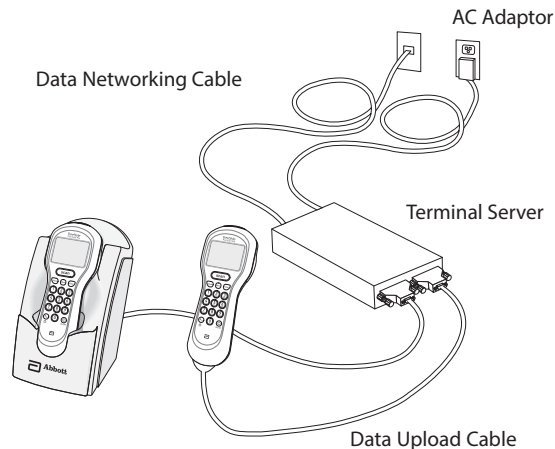

Figure 2

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

Data Upload Using Wireless

The optional wireless function allows for automatic data upload throughout a WiFi-enabled facility when both the data management system and meters are properly configured. Wireless function setup is described in the Wireless Setup Utility User's Guide.

10. Troubleshooting

Troubleshooting Patient Test Results

Troubleshooting Out-of-Range Control Test Results

Troubleshooting Wireless (if enabled)

Troubleshooting Barcode Scanning

Error Messages

Technical Support Instructions

Returning a Meter

Contacting Abbott for Service

Troubleshooting Patient Test Results

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

Reasons Glucose Results May Be Higher Than Expected:

- Haematocrit is lower than the acceptable limit for the test strips, as indicated on test strip package insert.
- Serum or plasma samples were used instead of whole blood.

Reasons Glucose Results May Be Lower Than Expected:

- Haematocrit is higher than the acceptable limit for the test strips, as indicated on test strip package insert.
- Hyperglycaemic-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.

Reasons Ketone Results May Be Higher Than Expected:

- Haematocrit is lower than the acceptable limit for the test strips, as indicated on test strip package insert.
- Serum or plasma samples were used instead of whole blood.

Reasons Ketone Results May Be Lower Than Expected:

- Haematocrit is higher than the acceptable limit for the test strips, as indicated on test strip package insert.
- Water or alcohol remaining on the puncture site.

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

Troubleshooting Out-of-Range Control Test Results

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

- Eliminate any air bubbles in the control bottle's tip.
- Wipe the control solution nozzle with a clean gauze or tissue before and after each test. Liquid left on the tip from previous tests may have a glucose or ketone concentration higher than expected.
- Calibrate the meter using the barcode for the test strip used.
- Scan or enter the correct 5-digit lot number for the control solutions.
- Confirm that control solutions and test strips have been stored within the ranges specified on their respective cartons and package inserts.
- Check that the temperature conditions in the room where the tests are being performed are within the acceptable operating range as specified in the test strip package insert.

- Check that the bottles of control solutions have not been open for more than 90 days and are within the manufacturer's expiry date.
- Use a new test strip for each test.
- Use only FreeStyle Precision Pro compatible test strips.
- Use only MediSense Control Solutions.
- Confirm that the control solution tested (low, mid or high) matches the level requested on the display.

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

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 10: Troubleshooting

10-3

Troubleshooting Wireless (if enabled)

You may verify wireless signal strength through the meter's wireless menu. Turn your meter off then on again if you experience any of the following:

- Your meter screen does not display the Wireless Enabled icon.
- Your meter screen does not display the Wireless Transmission icon, or the Wireless Hardware Error icon is displayed.
- Data is not correctly uploaded to the data management system.

If the problem persists, contact your system administrator to verify proper configurations. Specifications for the wireless function are described in the Wireless Setup Utility User's Guide.

Troubleshooting Barcode Scanning

If you are using an Abbott isolation bag, it must be pulled taut over the meter's barcode scan window for proper scanning.

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 10: Troubleshooting

10-4

Error Messages

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

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

If any problem persists, record the error message displayed, which may include a 4-digit error code, and contact your local Abbott Diabetes Care office or distributor.

When You Turn on the Meter, or During Use:

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

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 10: Troubleshooting

10-5

Symptom/Error Message	Explanation	How To Respond
Low Battery 1-Turn Off	Battery power is getting low. Testing will be available for a limited time.	Install new batteries. See Chapter 11, Maintenance, for more information. Press **1** to turn meter off.
Strip port error Strip port missing 1-Turn Off	The strip port module is not detected by the meter.	Re-install strip port module. If problem persists, replace with a new strip port module. See Chapter 11, Maintenance, for more information.
Strip port error Strip port unrecognised 1-Turn Off	The strip port module has malfunctioned.	Replace with a new strip port module. See Chapter 11, Maintenance, for more information.

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 10: Troubleshooting

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Symptom/Error Message	Explanation	How To Respond
Temperature Outside Range 43.9°C Testing Disabled 1- Exit	Occurs when any test is selected and the temperature is outside the meter operating temperature range.	Press **1** to **Exit**. Turn meter off. Allow the meter to return to room temperature.
Configuration Required 1- Turn Off	The meter is shipped from the factory without configuration. This screen will appear the first time you turn on the meter after receiving it.	Use a data management system to configure the device to your specific institution's requirement prior to using the device.
Last upload incomplete Redock meter 1- Continue	An error has occurred during last data transfer. This screen will appear when you turn on the meter.	Place the meter into the docking station to complete the upload. Once the meter has successfully been docked, the warning will disappear. Or, Press **1** to **Continue** testing.

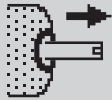| Symptom/Error Message	Explanation	How To Respond
Meter Error n n n n 1- Turn Off	The meter may have a problem that prevents it from operating properly. One of several 4-digit error codes may be displayed. These codes provide Abbott additional information about the problem.	1. Turn off the meter. Turn it on and repeat the function. 2. If the problem persists, place the meter in the docking station to update the configuration files. 3. If the problem still persists, record the 4-digit error code and contact Abbott Technical Support.
Remove Strip	The test strip was inserted at the wrong time. The meter will beep if functions are attempted before the strip is removed or if the test strip is left in when the test calls for the test strip to be removed.	Remove the test strip from the test strip port.

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 10: Troubleshooting

10-8

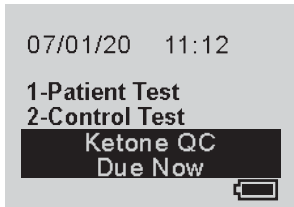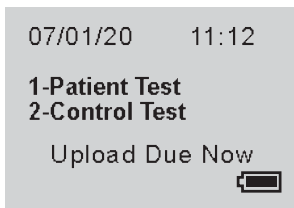| Symptom/Error Message	Explanation	How To Respond
Strip **Error** Ketone expected Glucose entered 1-New Strip 2-Exit	The strip inserted is a Glucose strip, while the meter was expecting a Ketone strip.	1. Press **1**. 2. Remove test strip. 3. Insert new test strip.
07/01/20 11:12 **1-Patient Test** **2-Control Test** Glucose QC Due in 28 Min.	If glucose QC is due soon, the message '**Glucose QC Due in xx min.**' will display on the main screen. The xx is the countdown to expiry. If glucose QC is due now, the message '**Glucose QC Due Now**' will display on the main screen.	1. If '**Glucose QC Due in xx min.**' is displayed, no action is required. Glucose testing can proceed. 2. If '**Glucose QC Due Now**' is displayed, then Glucose QC testing per your facility's procedures may be required before proceeding with a glucose test. 3. Contact your system administrator if the messages continue to display after running the required QC tests.

Symptom/Error Message	Explanation	How To Respond
07/01/20 11:12 **1-Patient Test** **2-Control Test** Ketone QC Due Now	If ketone QC is due soon, the message '**Ketone QC Due in xx min**.' will display on the main screen. The xx is the countdown to expiry. If ketone QC is due now, the message '**Ketone QC Due Now**' will display on the main screen.	1. If '**Ketone QC Due in xx min.**' is displayed, no action is required. Ketone testing can proceed. 2. If '**Ketone QC Due Now**' is displayed, then ketone QC testing per your facility's procedures may be required before proceeding with a ketone test. 3. Contact your system administrator if the messages continue to display after running the required QC tests.
07/01/20 11:12 **1-Patient Test** **2-Control Test** Upload Due Now	If the meter requires an upload to the data management system, '**Upload Due Now**' will display on the main screen.	1. Place the meter in the Abbott Docking Station and wait for the meter to automatically turn off with the message '**Upload Successful, Turning Off**'. 2. Contact your system administrator if the message continues to display after docking the meter.

Symptom/Error Message	Explanation	How To Respond
07/01/20 11:12 **1-Patient Test** **2-Control Test** ⊘ 🔋	If there is a problem with the meter's wireless module, or the meter's self test fails, the **Wireless Hardware Error icon** will appear. Tests may still be uploaded to the data management system via docking station or cable (optional) when the Wireless Hardware Error icon is displayed.	**1.** Turn the meter off and then on again to reestablish wireless communication. If the problem persists, contact your local Abbott Customer Service Office or distributor to troubleshoot the wireless function. Wireless function troubleshooting is described in the Wireless Setup Utility User's Guide.

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

When a Test is Selected:

Symptom/Error Message	Explanation	How To Respond
Mid, High Control Test Required Glucose 1-Exit 2-Continue	The Glucose QC Interval Controls Expired option is set to Warn or Lockout and one or more control tests is past due. (The menu item **2-Continue** appears only if this option is set to Warn. If the option is set to Lockout, each control test shown on the screen must be performed before the patient tests start.)	Perform the remaining glucose control tests indicated in the message.
Test Memory Upload Required 1-Exit 2-Continue	The Upload Interval option is set to Warn or Lockout, and the specified interval has been exceeded. (The menu item **2-Continue** appears only if this option is set to Warn. If the option is set to Lockout, data must be uploaded before testing starts.)	1. Place the meter in the docking station to upload the data. Or, Press **2** to **Continue** testing. 2. If the problem persists, contact the system administrator.

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 10: Troubleshooting   **10-12**

Symptom/Error Message	Explanation	How To Respond
Mid **Control Test** **Required** **Ketone** 1-Exit 2-Continue	The Ketone QC Interval Controls Expired option is set to Warn or Lockout and one or more control tests is past due. (The menu item **2-Continue** appears only if this option is set to Warn. If the option is set to Lockout, each control test shown on the screen must be performed before the patient tests start.)	Perform the remaining ketone control tests indicated in the message.
Patient ID 03091971 **Patient Data** **Not Found** 1-ReEnter ID 2-Continue	The system cannot confirm the Patient ID.	Press **1** to **ReEnter** the Patient ID. Or, Press **2** to **Continue** testing.
Scan or Enter **Patient ID** _____ **Invalid ID** Strip Lot	The scanned Patient ID is similar in format to the test strip barcode.	1. Re-enter the Patient ID using the barcode scanner or keypad. 2. If the problem persists, contact the system administrator.

During Any Test:

Symptom/Error Message	Explanation	How To Respond
Scan or Enter **Strip Lot** ------------ **Invalid Lot** Barcode	The barcode just scanned was not accepted. Possible reasons are: • The green scanner beam did not pass across all the bars of the code. • The barcode was damaged or poorly printed. • The barcode was not of the type specified for this ID or lot number.	1. Rescan the barcode or manually enter the ID or lot number. 2. Notify the system administrator. The problem may be the printing of the barcode or the setup.
Scan or Enter **Strip Lot** ------------ **Invalid Lot** Date Expired	The barcode just scanned is from a foil packet of test strips that has expired.	1. Discard the expired test strips. 2. Repeat the scan with a new, unexpired foil packet of test strips.

Symptom/Error Message	Explanation	How To Respond
Scan or Enter **Linearity Kit Lot** ---------------- **Invalid ID** Too Long	The ID or lot number just scanned or entered is too long or too short, according to format defined during the setup of this meter.	1. Verify and re-enter the ID or lot number using the barcode scanner or keypad. 2. If the problem persists, notify the system administrator.
Strip Lot 44175h2cwJdi06 **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 meter. (The menu item **2-Continue** appears only if this option is set to Warn.)	1. Press **1** to **ReEnter** the ID or lot number using the barcode scanner or keypad. Or, Press **2** to **Continue** testing. 2. If the problem persists, notify the system administrator.

Symptom/Error Message	Explanation	How To Respond
Strip **Error** Glucose expected Ketone entered 1-New Strip 2-Exit	The strip inserted is a Ketone strip, while the meter was expecting a Glucose strip.	Press **1** to replace with the expected test strip. Or, Press **2** to **Exit**.
Scan or Enter **Strip Lot** ---------------- Invalid Strip	This test strip is not compatible with the FreeStyle Precision Pro meter.	Repeat the scan with a FreeStyle Precision Pro compatible test strip.
Operator ID 123456789 **Is Not on the** **Operator List** 1-ReEnter ID 2-Continue	The Operator ID just entered is not on the list of acceptable Operator IDs defined for this meter. (The menu item **2-Continue** appears only if this option is set to Warn.)	1. Press **1** to **ReEnter** the ID using the barcode scanner or keypad. Or, Press **2** to **Continue**. 2. If the problem persists, notify the system administrator.

Symptom/Error Message	Explanation	How To Respond
Operator ID 12345678 **Is Not on the Operator List** 1-ReEnter ID	The Operator ID entered is not on the list of acceptable Operator IDs defined for this meter.	1. Press **1** to **ReEnter** the Operator ID. 2. If the problem persists, contact the system administrator for further information on operator certification.
Operator ID Angie Malmsteen **Date Expired** 1-ReEnter ID 2-Continue	The Operator ID entered has expired. (The menu items **1-ReEnter ID** and **2-Continue** appear only if this option is set to warn.)	1. Press **1** to **ReEnter** the ID using the barcode scanner or keypad. Or, Press **2** to **Continue** testing. 2. If the problem persists, notify the system administrator.
Operator ID Expires in 10 Days 1-Continue	The Operator ID is due to expire. At this time, testing is still allowed.	1. Press **1** to **Continue** with testing. 2. Contact your manager or the system administrator for further information about operator certification.

| --- | --- | --- |
p:Smith, John Q 12 <1.1 mmol/L Glucose 07/01/20 11:12 1-Next Patient 2-Patient History <20 mg/dL	The test result is below the measuring limit of the system.	1. Repeat the test with a new test strip. 2. If the result persists, follow your institution's policy.
p:Smith, John Q 12 >8.0 mmol/L Ketone 07/01/20 11:12 1-Next Patient 2-Patient History	The test result is above the measuring limit of the system.	1. Repeat the test with a new test strip. 2. If the result persists, follow your institution's policy.
Strip Error Wet or Damaged 1-New Strip 2-Exit	The test strip or the test strip port is wet, defective, contaminated or the wrong test strip was inserted.	1. Remove the old test strip. 2. Press 1 to continue testing with a **New Strip**. Or, Press **2** to **Exit** to the **Test Menu**.

Symptom/Error Message	Explanation	How To Respond
Assay Error 4327 1-New Strip 2-Exit	There may be a problem with the test strip. One of several 4-digit error codes may be displayed. These codes provide Abbott personnel additional information about the problem. Errors include:	1. Press **1** to repeat the test with a **New Strip** or **2** to **Exit**. 2. If the error occurs again, record the 4-digit error code and contact Abbott Technical Support.
	4327 - The strip was removed during testing.	Repeat the test with a new test strip.
	4330 - Blood glucose may be too high to be read by the system or there may be a problem with the test strip.	Repeat the test with a new test strip. If the error occurs again, confirm the result by performing a laboratory reference test.

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 10: Troubleshooting

10-19

When a Control Test is Selected:

```
Unexpected Level

Mid expected
Low Entered

1-ReEnter Lot
2-Continue
```

A control solution lot number has been entered for a different level of control test from the one that the meter 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 Data Review is Selected:

```
No Stored Tests




1-Exit
```

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

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

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 10: Troubleshooting

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Symptom/Error Message	Explanation	How To Respond
XXX 1-Previous 1 2-Next 1	The meter is not able to recall a previous test result. This test result may not have been uploaded from the meter.	Press **1** to view the **Previous** result. Or, Press **2** to view the **Next** result.

Technical Support Instructions

When you call, an Abbott representative will address the problem and/or instruct you to return the meter, test strips and/or control solutions. Do not return the FreeStyle Precision Pro meter or any part of the system for repair until you receive authorisation from an Abbott representative.

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

1. Review the troubleshooting information in this section.

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

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

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 10: Troubleshooting

10-22

Returning a Meter

You must follow the instructions provided in the return kit when returning used meter.

Note: Do not return any used sharps in the return kit.

Contacting Abbott for Service

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

EUROPE

Ireland
Abbott Laboratories Ireland Ltd.
Abbott Diabetes Care
Block B
Liffey Valley Office Campus
Quarryvale, Dublin 22
D22 X0Y3
Ireland
1800 77 66 33

United Kingdom
Abbott Laboratories Ltd.
Abbott Diabetes Care
Abbott House
Vanwall Business Park
Vanwall Road
Maidenhead
Berkshire
SL6 4UD
UK
0800 170 1177

Questions? Refer to Pages 10–22 For Technical Support Instructions.

Chapter 10: Troubleshooting

10-23

11. Maintenance

Maintenance

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

This chapter describes the maintenance tasks for the meter.
- Cleaning the exterior surface of the meter.
- Replacing the strip port module.
- Replacing the batteries.

Cleaning the Exterior Surface

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

The meter should be cleaned only with a damp cloth or a sponge and a mild detergent. Acceptable cleaning solutions include mild soap water, bleach, alcohol and ammonia based cleaners. Recommended solutions are Dispatch®, Sani-Cloth Bleach®, Sani-Cloth® HB, Sani-Cloth® Plus, Super Sani-Cloth®, Hype-Wipe® and Virox 5®.

Cleaning solutions not listed have not been tested and may damage the meter. Contact your local Abbott Diabetes Care office or distributor for the most up-to-date information on cleaning solutions.

⚠ **IMPORTANT:** *Abbott Diabetes Care has not evaluated cleaning solutions for disinfection purposes.*

Turn off the meter prior to cleaning. Wipe all surfaces until the meter is visibly clear of soil. Do not apply cleaning solution directly to the meter. If using a pre-packaged wipe, squeeze out excess fluid prior to use. Do not immerse or autoclave the meter or flood it with any liquid. These steps will help keep liquid from entering the meter and causing damage.
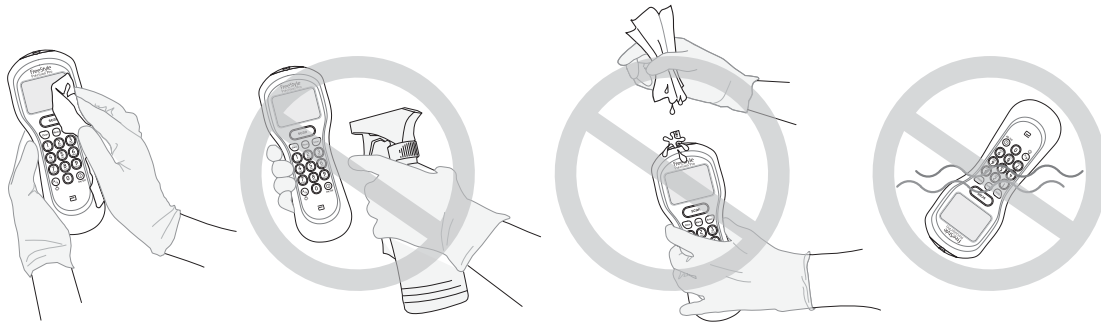
⚠ **IMPORTANT:** *Avoid getting dust, dirt, blood, control solution, water or any other substance in the meter's test strip port.*

Replacing the Strip Port Module

⚠️ **IMPORTANT:** *Do NOT replace batteries and strip port module at the same time. Ensure batteries are installed before replacing strip port module. Rechargeable batteries must be at room temperature before they are placed in the battery compartment. The docking station does not charge the batteries.*

The strip port module is designed to minimise the potential for liquid or debris to enter the meter through the strip port. Should blood, liquid or other contaminant enter into the strip port, the strip port module must be replaced. Make sure the area around the strip port is completely dry prior to installing the replacement strip port module.

Removal

1. Turn the FreeStyle Precision Pro meter off by pressing the On/Off ⏻ button on the keypad.

2. Place the meter, display screen down, on a flat surface. Place one hand on the handle of the meter to secure it. With the other hand use a small cross head (Phillips) screwdriver (not included) to remove the single screw on the back of the strip port module. (Fig. 1)

3. Once the screw is removed, place it aside. Use your hand to carefully slide the strip port module away from the meter. (Fig. 2)

4. Remove the strip port module entirely. Discard it and the screw in accordance with your facility's biohazard disposal policy.
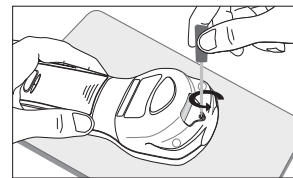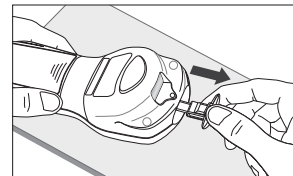

Figure 1

Figure 2

Replacement

1. Obtain a replacement strip port module.

2. Slide the replacement strip port module into position on the meter. (Fig. 3)

3. Insert strip port module firmly into place. (Fig. 4)

4. Use a small cross head (Phillips) screwdriver to insert the new screw. This will secure the strip port module in place. (Fig. 5)
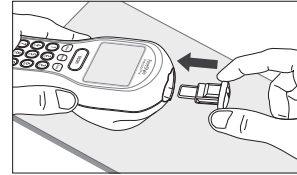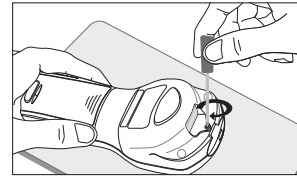

Figure 3

Figure 4

Figure 5

Replacing the Batteries

Use the following procedure to install new batteries in the FreeStyle Precision Pro meter. The FreeStyle Precision Pro meter requires two (2) AA alkaline, lithium or nickel cadmium (NiCad) batteries or nickel-metal hydride (NiMH) rechargeable batteries.

1. Turn the FreeStyle Precision Pro meter off by pressing the On/Off ⓞ button on the keypad.
   On/Off

2. Turn the meter over to remove the battery compartment cover.

3. Press down the cover at the finger grip area firmly. Push to slide the cover off, as indicated by the arrow. (Fig. 1)

4. When slid as far as possible, lift the cover up and away from the meter. (Fig. 2, Fig. 3)
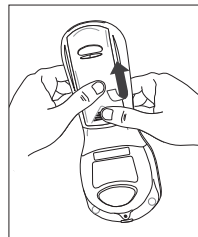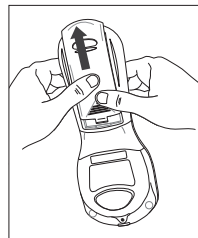

Figure 1
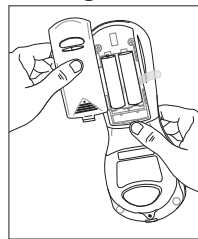

Figure 2

Figure 3

5. Pull the tab to remove the batteries. (Fig. 4)

6. Discard the used batteries in compliance with your local government regulations.

7. Insert the new batteries on top of the tab, using the + and - symbols in the battery compartment to position the new batteries with the correct polarity. (Fig. 5)

8. Align the battery compartment cover with the slots on the FreeStyle Precision Pro meter, then slide the cover into place. (Fig. 6)

Note: *New batteries need to be installed within 24 hours after the old batteries are removed from the battery compartment to maintain the meter date and time.*

Figure 4

Figure 5

The European Battery Directive requires separate collection of spent batteries, aiming to facilitate recycling and to protect the environment. The batteries in this product should be removed and disposed in accordance with local regulations for separate collection of spent batteries. Contact the manufacturer for details.
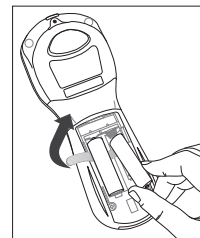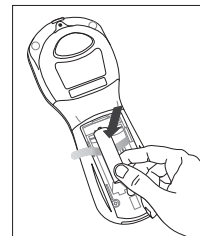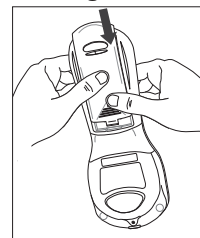

Figure 6

12. Specifications

FreeStyle Precision Pro Meter

Symbols

Barcode Types

Specifications

FreeStyle Precision Pro Meter

Dimension and Weight Specifications:

Length:	7.85 in ± .08 in (19.94 cm ± 2 mm)	Thickness:	1.92 in ± .08 in (4.92 cm ± 2 mm)
Width:	2.93 in ± .08 in (7.45 cm ± 2 mm)	Weight:	10.58 ounces ± .51 ounces (300 grams ± 15 grams)

Power Source:

Two standard alkaline, lithium or NiCad AA batteries or nickel-metal hydride (NiMH) rechargeable batteries. Battery performance is a function of how often the meter is used and the duration time that testing is conducted. The average lithium battery life is approximately 30 days, based on an average of 9 tests per day and meter being shut off within 2 minutes if it is not being used (depending on barcode usage).

Memory:

Patient Test Results: 2,500

Control Test Results: 1,000

Operator IDs: 6,000

Test Strip Lots: 36 (18 Glucose, 18 Ketone)

Proficiency Test Results: 20

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

Environmental Specifications:

Product is intended for indoor use only.

Meter Operating Temperature:	59 °F to 104 °F (15 °C to 40 °C ± 1°C)
Meter Storage Temperature:	-4 °F to 122 °F (-20 °C to 50 °C ± 1°C)
Altitude:	Reference the test strip instructions for use.
Humidity:	From 10% to 90% ± 3%RH noncondensing
Rated Pollution Degree:	2

Wireless Specifications

The optional wireless function requires a WiFi-enabled facility. Your system administrator must enable both the data management system and the individual meters for wireless functionality. Details for enabling the wireless function are described in the Wireless Setup Utility User's Guide (optional).

See the meter wireless specifications in the FreeStyle Precision Pro Wireless Setup Utility User's Guide.

Frequency Bands and Maximum Radio-frequency Power Transmitted

Air Interface	Frequency Range (MHz)	Maximum Output Power (dBm)
WLAN 802.11 b/g	2400-2483.5	20
WLAN 802.11 a	5150-5350	12
	5470-5825	12

Hereby, Abbott Diabetes Care Ltd., declares that the radio equipment type FreeStyle Precision Pro Blood Glucose and β-Ketone Monitoring Meter is in compliance with Directive 2014/53/EU and the Radio Equipment Regulation 2017 (No 2016). The full text of the EU and UK Declaration of Conformity is available at the following Internet address: www.diabetescare.abbott/doc

Symbols

There are special symbols that appear on the FreeStyle Precision Pro meter, test strips and docking station. Please note: Some of the symbols listed below will not appear on your FreeStyle Precision Pro system due to differences in local regulatory requirements.

| Glucose | Indicates a Glucose assay (black text on white) |

| β-Ketone | Indicates a Ketone (β-hydroxybutyrate) assay (white text on purple) |

Data Transfer Port

This Way Up

Temperature Limit

The European Battery Directive requires separate collection of spent batteries, aiming to facilitate recycling and to protect the environment. The batteries in this product should be removed and disposed in accordance with local regulations for separate collection of spent batteries.

LOT   Batch Code

⧗	Use by
⚠	Caution
✍	Note: Provides or refers the operator to additional or background information that may be helpful to them.
⊘	Do not reuse
REF	Catalogue Number
$C\epsilon$	CE Mark
EC REP	Authorised Representative in the European Community / European Union
▲	Manufacturer
▲	Date of manufacture
📖	Consult instructions for use

Symbol	Description
♲	Recyclable
IVD	*In vitro* diagnostic medical device
☣	Biological Risks
UDI	Unique Device Identifier
UK CA	UKCA marking
⚕	For Near Patient Testing

Barcode Types

The FreeStyle Precision Pro system is compatible with both one dimensional (1D) barcodes (Codabar, Code 128, Code 39, Code 93, I 2 of 5, EAN, RSS) and two dimensional (2D) barcodes (Data Matrix, Aztec, PD-417, Micro PDF, QR Code, Maxicode, CODABLOCK F, RSS Composite).

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

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Max-Planck-Ring 2
65205 Wiesbaden
Germany

Patent: https://www.abbott.com/patents

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ART44488-001 Rev. A 01/22

| EC | REP |

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