SIEMENS Healthineers

UniPOC™

Point of Care Ecosystem™ Enabled

# Configuration Guide

# Precision Xceed Pro

from software version 1.7

Precision Xceed Pro Configuration Guide



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The information in this manual was correct at the time of printing. However, Siemens Healthcare Diagnostics continues to improve products and reserves the right to change specifications, equipment, and maintenance procedures at any time without notice.

If the UniPOC™ system is used in a manner differently than specified by Siemens Healthcare Diagnostics, the protection provided by the equipment may be impaired. Observe warning and hazard statements.

# Table of Contents

# 1 Introduction

This manual describes the use of the UniPOC™ Point of Care Data Management System software to configure the Precision Xceed Pro Blood Glucose and ß-Ketone Monitoring System. We are confident that the Precision Xceed Pro device with UniPOC will help you manage your Point of Care program more effectively and efficiently.

Please read this configuration guide for step-by-step instructions and illustrations on how to configure the devices prior to placing them in service.

# 2 Intended Use

This software allows you to configure and use the Precision Xceed Pro device with the UniPOC™ Point of Care Data Management System. The UniPOC product is not for diagnostic use.

# 3 Instrument Configuration Pages

The following Instrument Configuration pages are described in this manual:

- All Test Options
- Patient Test Options
- Control Test Options
- Security Options
- Profile Options
- Test Type Options
- System Options
- Special Monitor Options

# 4 Glossary

| | |
|---|---|
| Administrator | Administrator of the UniPOC Data Management System. The Administrator may be the Point of Care Coordinator. |
| Location | The Location Tree selection in UniPOC. Location selections include the Organization, Facility, Department or Location level of the Tree. |
| MeterCom | A component of the UniPOC system that manages communications with point of care instruments such as the Precision Xceed Pro device. |
| Operator | Operator of the Precision Xceed Pro device. |
| POCC | Point of Care Coordinator. The Point of Care Coordinator is typically responsible for setting site-specific configurations for the Precision Xceed Pro device. |
| UniPOC™ | The UniPOC™ Point of Care Health Management System, referred to hereafter as UniPOC, is a browser-based software application that allows you to manage your Point of Care (POC) program from any computer throughout your healthcare facility. |
| **Barcode Types** | |
| **I 2 of 5** | Interleaved 2 of 5 (I 2 of 5) is a numeric-only barcode widely used in warehouse and industrial applications. The data must consist of an even number of digits. |
| **Code 128** | A barcode type that provides excellent density for all-numeric data and good density for alphanumeric data. The Code 128 standard is maintained by AIM (Automatic Identification Manufacturers). |
| **Codabar** | Codabar is a self-checking, numeric-only barcode. Codabar can encode the digits 0 through 9, six symbols (- : . $ / +) and the start/stop characters A, B, C, D, E, *, N or T. Codabar is used in libraries, blood banks, the overnight package delivery industry and a variety of other information processing applications. |
| **Code 93** | A barcode type that encodes exactly the same characters as Code 39 but uses nine barcode elements per character instead of 15. |
| **Code 39** | A barcode type that is widely used in many industries and is the standard for many government barcode specifications, including the U.S. Department of Defense. Code 39 is defined in American National Standards Institute (ANSI) standard MH10.8M-1983. |
| **RSS** | RSS is an abbreviation for Reduced Symbology Set, which produces very small barcodes suitable for labeling electronic components and healthcare devices. There are seven different types of RSS barcodes. RSS can encode at maximum 74 characters. |
| **EAN** | EAN is an abbreviation for European Article Numbering. EAN-13 is used worldwide for marking retail goods. It encodes 13 characters: the first two are a country code, followed by 10 data digits and a checksum. Two-digit and five-digit supplemental barcodes may be added for a total of 14 or 17 data digits. EAN-8 code is a shortened version of the EAN-13 code. It includes a two-digit country code, five data digits and a checksum digit. Two-digit and five-digit extension barcodes may be added. |

**Note**: *Control characters and non-alphanumeric characters (e.g., $) are displayed as spaces in the Precision Xceed Pro device. Some barcodes may contain control characters and non-alphanumeric characters*.

# 5 Setting up Reagent and Control Lots

Before you can download lot information to the Precision Xceed Pro device, set up the following in UniPOC:

- Reagent lots with ranges
- Control lots (optional)

**Important**: You should refer to the *UniPOC User Manual* for detailed procedures on how to set up reagent and control lots.

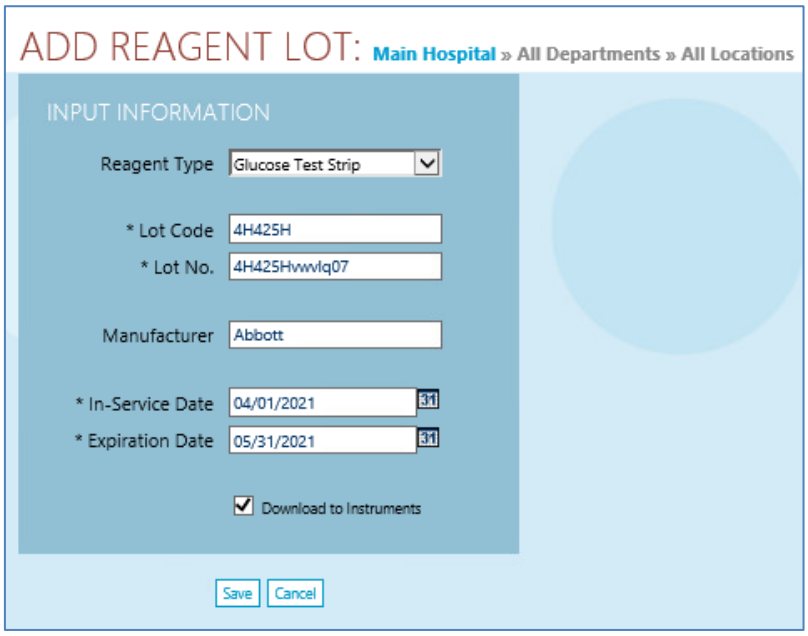
## 5.1 Set up Reagent Lots

For strip lots to download successfully to the device, you must add the reagent test strip lot information to UniPOC keeping in mind the following:

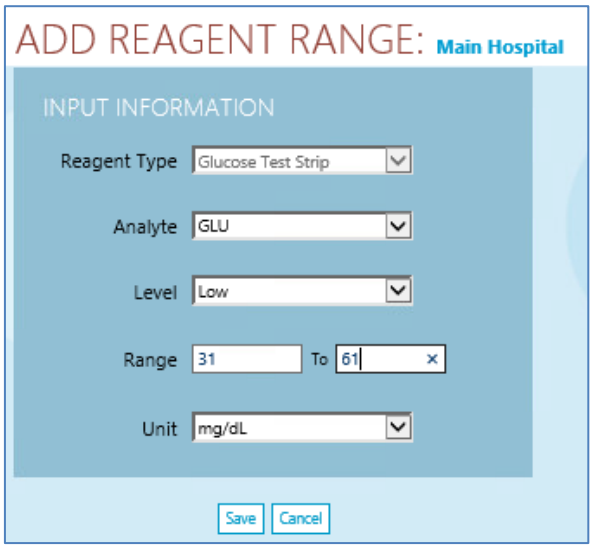
1. You should enter reagent lot data at the Facility level when possible.
2. You must define range information for reagent lots to ensure that graph-based reports, such as the Levey-Jennings Graph report, generate plot points correctly.
3. You should verify that the reagent lot you want to add does not already exist in the system. To do so, deselect the **Hide Expired Lots** filter on the **Reagent Lot** screen for the desired device type so that all lots display in the table.

   **Tip**: If the **Lot Code** field for the lot you want to add contains 6 characters and the **Lot No**. field displays 2 hyphens (--), it indicates that the reagent lot already exists. In that case, you must edit the current reagent lot information using the **Edit Reagent Lot** screen instead of adding a new lot.

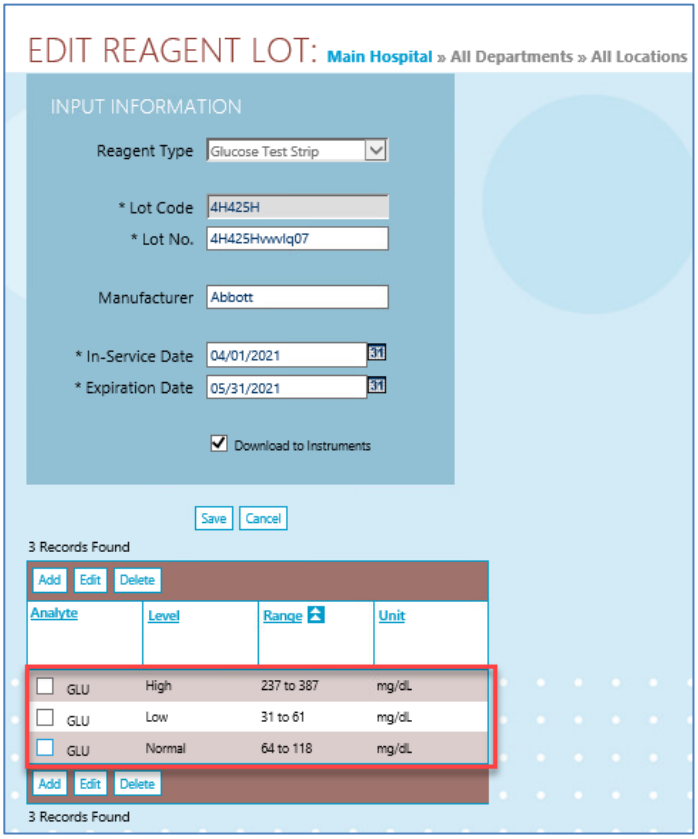
4. When setting up reagent lots on the **Add Reagent Lot** screen:
   a. For **Reagent Type**, be sure to select the correct type of test strip (Glucose or Ketone).
   b. For **Lot Code**, enter the first 6 characters from the Abbott glucose test strip reagent lot barcode.
   c. UniPOC automatically displays the 6 characters entered in the **Lot Code** field in the **Lot No.** field. To download the reagent lot to glucometer devices, you must enter the additional 8 characters from the Abbott reagent test strip lot barcode.
   d. Select the **Download to Instruments** checkbox to enable reagent lot downloads.




5. After you add the reagent lot (be sure to click **Save**), use the **Add Reagent Range** screen to add ranges for each analyte per lot level, Low, Normal (Mid), and High.
6. Verify that the correct **Unit** is selected so that report statistics are calculated correctly.
7. After you add ranges for **Low**, repeat the process for **Normal** (Mid) and then **High** levels.



8. When done, the **Edit Reagent Lot** screen will show the reagent ranges for each level at the bottom of the screen.

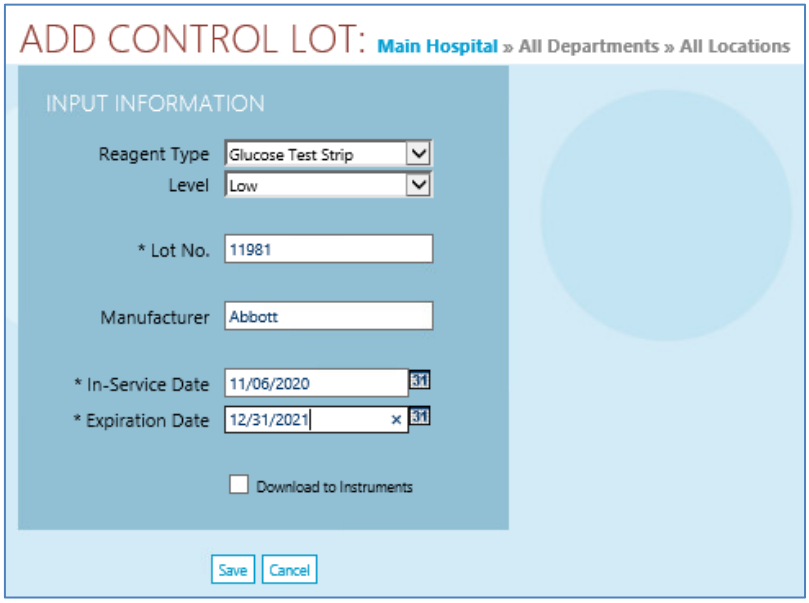


## 5.2 Set up Control Lots

If you want to use UniPOC to manage control lots, you must set up control lot information in UniPOC. For example, you should add control lots if you want to manage expiration dates, receive alerts, or run statistical reports such as the Control Data Statistics, Control Outlier Log, or QI Representative by Instrument & Reagent report.

When setting up control lot information, keep in mind the following:

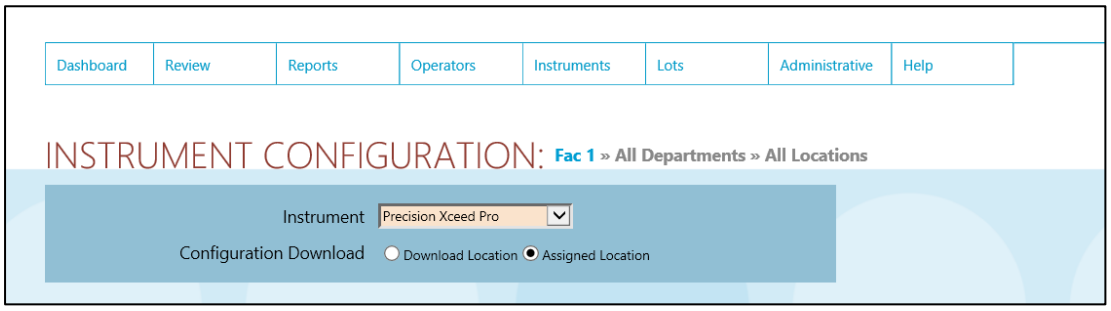
1. You should enter control lot data at the Facility level when possible.
2. When setting up control lots on the **Add Control Lot** screen:
    a. For **Reagent Type**, be sure to select the correct type of test strip (Glucose or Ketone).
    b. For **Level**, select **Low**.
    c. For **Lot No.**, enter the 5-digit numerical value on the control bottle label.
    d. Do not select the **Download to Instruments** checkbox.
    e. After you add the lot information for **Low**, click **Save** and then repeat the process for **High** and optionally, **Normal** (Mid) levels.



# 6 Configuration Screens

The **Instrument Configuration** screens in UniPOC allow you to view and edit the Precision Xceed Pro configuration data for a specific location. These devices can be configured for the entire Organization or an individual Facility**,** Department **or** Location**.**

***Note**: Siemens recommends entering configuration data at the Facility level when possible. Department level settings should then be used to vary the instrument configurations only as needed. The Organization level settings then remain available for reference as default values.*




**Procedure:**

1. Select a Facility, Department or Location in the tree.
   From the menu, select **Instruments** > **Configuration**. The **Instrument Configuration** screen appears.
2. Select **Precision Xceed Pro** from the **Instrument** drop-down list.
3. Select one of the following **Configuration Download** options:

| | |
|---|---|
| **Assigned Location** | (**Recommended**) If you select this option, UniPOC uses the Location where the device's serial number or name resides in the Location Tree regardless of where the device is used or docked (Default). This location will determine the:<br>• Configuration settings to be downloaded to the device<br>• Supported lists downloaded to the device<br>• Location where all test data are uploaded to in the Tree<br>***Note**: When test results are uploaded via wireless communication, UniPOC uses **Assigned Location** logic.* |
| **Download Location** | (**Not Recommended**) If you select this option, UniPOC uses the Location where the device's or docking station's IP address resides in the Location Tree. This location will determine the:<br>• Configuration settings to be downloaded to the device<br>• Supported lists downloaded to the device<br>• Location where all test data are uploaded to in the Tree |

4. Select the desired configuration tab and set the options.

   ***Note**: Be sure to note the selected Tree level prior to saving the instrument configuration settings to ensure the settings are applied to the appropriate locations.*
5. Do one of the following:

   - Click the **Save Configuration** button to save the settings.

     This will break the Parent-Child relationship and save the configuration as a new one, even if no changes were made. Saving an instrument configuration for a lower level of the Tree (Department or Location) will sever the relationship between the child and its

parent level on the Tree. Breaking the Parent-Child relationship is necessary to enable configuration settings different from the global Organization or Facility.

Refer to the “Location Tree Parent-Child Relationship” section of the UniPOC User’s Manual for further information.

- Click the **Restore Default Configuration** button to re-establish a Parent-Child relationship that was severed in error or when the configuration settings should be the same as its parent (Facility, Department or Location). This action will save the configuration from the parent.
- To cancel the configuration action without saving, go to a screen other than the Instrument Configuration screen.

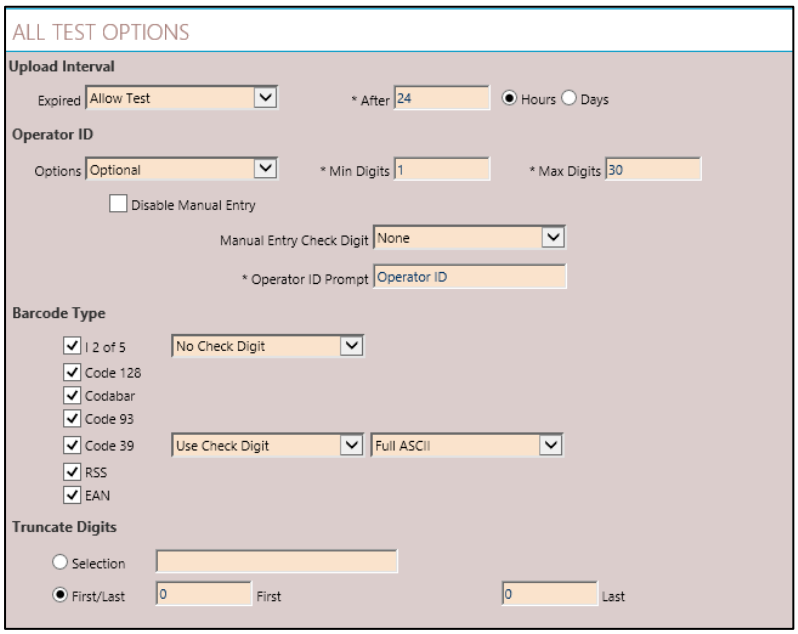
## 6.1 All Test Options

The **All Test Options** screen defines the Upload Interval, Operator ID, and Barcode requirements.

***Note**: Fields marked with an asterisk (*) are mandatory.*

The screen is divided into the following sections:

- Upload Interval
- Operator ID
- Barcode Type
- Truncate Digits




### 6.1.1 Upload Interval

The Upload Interval setting enables the device to warn or lock out from testing if the device has not been uploaded at a regularly scheduled interval.

**Explanation of the parameters**

| | |
|---|---|
| **Expired** | The Expired field has the following drop-down options: |
| Allow Test | Allows the testing to continue. No message will appear on the monitor. |
| Warn | Allows the testing to continue, but Operator will receive a message to upload if the interval has expired. |
| Lockout | Does not allow any testing until the data has been uploaded. If Upload Interval is expired, the monitor will prevent an Operator from testing until the stored data is uploaded. Some functions, such as data review and review setup, will still be possible. |
| ***After** | This field allows you to determine the maximum number of **hours** or **days** between data uploads.<br>• Select the time interval that will activate the instrument upload expiration settings.<br>The field entry must be between 1 and 99. |

In the event that the upload requirement is past due and communication attempts with UniPOC are unsuccessful, the monitor will override the Upload Interval Expired security setting if Lockout is enabled. If the upload interval is expired and if the network is down, the monitor will consider this as a successful dock event, resetting the upload timer. In this situation, the following events occur:

1. Operator is prompted with message “Test Memory Upload Required”. The device is set to Upload Lockout, thus testing cannot continue until the monitor is uploaded.
2. Operator attempts upload, the Precision Xceed Pro attempts to communicate - three times (every 15 sec).
3. If there is no response from the UniPOC (after 45 seconds) then the Precision Xceed Pro will override the upload lockout.

   **Note**: *In this situation only, the* Precision Xceed Pro *applies a successful upload to satisfy the upload requirement, thus allowing the use of the device until the upload requirement is due again*.

4. Operator is prompted with message “Last Upload Incomplete Redock Meter’ and the option to continue testing.
5. Once the lockout interval has expired, the upload will be required again, and the Lockout will be reset.

After the monitor receives its first response to the initial message, the normal upload lockout security setting will apply. The lockout will not be overridden during that communication session.

### 6.1.2 Operator ID

The Operator ID fields allow you to manually enter or scan an Operator ID into the device. A scanned Operator ID will be accepted by the device if the barcode format is enabled in the Operator ID configuration options. (See Barcode Type below.)

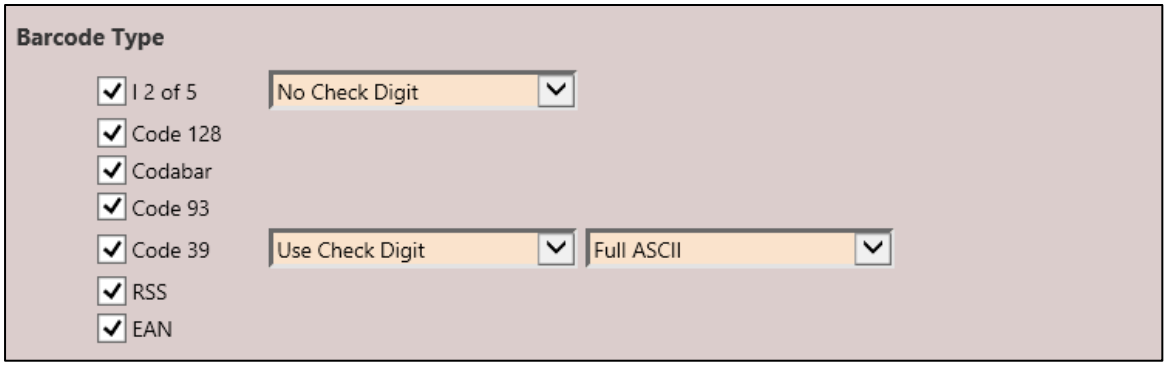
**Explanation of the parameters**

| **Options** | **Description** |
|---|---|
| Disabled | The display on the device will not prompt for an Operator ID. |
| Optional | The device prompts for an Operator ID, but entry is optional. |
| Required | Operator ID entry is required for all testing.<br>If the Operator ID is set to **Required** and the number of characters entered is outside the min/max range, then the ID will not be accepted. If the entry is set to **Optional** and the number of characters is greater than the maximum number, then the ID is not accepted.<br>If an Operator ID is entered, it will appear on the final result display on the device.<br>If **Optional** or **Required** is selected, you must enter a minimum and maximum number of digits, as described below.<br>To prevent manual entry of Operator IDs, select the Disable Manual Entry checkbox below the Options field.<br>**Note**: *If you select **Disable Manual Entry**, make sure that one of the barcode types is enabled for scanning. A field with a name proceeded by an asterisk (*) indicates a required field.* |
| ***Min Digits and *Max Digits** | If the Operator ID is scanned and the *Options* field is set to **Required**, the length of the scanned Operator ID must be equal to or less than the length requirement specified in the ***Max Digits** field and equal to or greater than the length requirement of the ***Min Digits** field.<br>If the Operator ID is scanned and the *Options* field is set to **Optional**, the length of the scanned Operator ID must be equal to or less than the length |

| | |
|---|---|
| | requirement specified in the ***Max Digits** field.<br>Operator IDs longer than 15 characters will be displayed with ellipses (…) in the last character space on the device.<br>The minimum required characters will be displayed as bold dashes on the device, if the *Operator ID Options* field is set to **Required**.<br>The scanned Operator ID, prior to truncation, cannot be longer than 64 characters. (See Truncate Digits below.) After truncation, the maximum length of a scanned Operator ID is 30 printable characters.<br>Maximum and minimum length requirements will be applied to the **Operator ID** field after applying any truncation or selection to the ID. (See Truncate Digits below. |
| **Manual Entry Check Digit** | The **Manual Entry Check Digit** field applies only to manually entered Operator IDs. It is useful for ensuring that the correct ID is entered when manual entry is used. |
| None<br>Mod10<br>Mod11 | This setting has the following options: None, Mod10, Mod11.<br>A Mod10 or Mod11 check digit can be required. If Mod10 or Mod11 is used, a numeric-only ID must be used. |
| **Operator ID Prompt** | You can configure the device to prompt the Operator with specific text whenever an Operator ID is required. Whatever text you enter in this field will be displayed on the device. The text in this field will default to 'Operator ID'. This field is limited to 15 characters. |

### 6.1.3 Barcode Type

The Barcode Type section of the screen allows you to set all barcode data entry options for the Operator ID. The types of barcodes selected determine what codes can be scanned into the device.




The device will accept a scanned Operator ID if the barcode type is enabled in the Operator ID configuration options. The Barcode scanner is capable of reading the following formats:

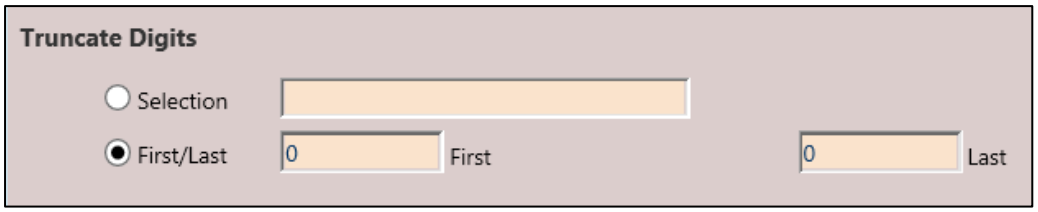
**Explanation of the parameters**

| | |
|---|---|
| **Barcode Type** | Interleaved 2 of 5 (I 2 of 5)<br>Code 128<br>Codabar<br>Code 93<br>Code 39<br>EAN<br>RSS<br>See the Glossary of terms used in this manual for barcode terminology. Select |

| | | |
|---|---|---|
| | all the barcode types used at your Facility, Department or Location.<br>Entry fields to the right of the **I 2 of 5** and **Code 39** barcode type checkboxes allow you to specify accepted barcode types by choosing from the dropdown options. | |
| **I 2 of 5** | No Check Digit<br>USS Check Digit<br>OPCC Check Digit | |
| **Code 39** | No Check Digit<br>Use Check Digit | Alphanumeric<br>Full ASCII |

### 6.1.4 **Truncate Digits**

You can set the method of truncation for scanned Operator IDs to **Selection** or **First/Last**. This instructs the device to select certain characters from the scanned barcode; the selected characters are used as the effective ID string. The remaining Operator ID, after truncation, cannot be longer than 30 characters.




**Explanation of the parameters**

| | |
|---|---|
| Selection | You can specify exact character locations of the scanned Operator ID in the **Selection** field. Using the **Selection** mode, you do not specify character positions to be truncated (removed); rather, you specify character positions to be retained.<br>Use numbers to identify the location selection. Use commas (‘,’) and hyphens (‘-’) to identify the selection pattern.<br>The numbers represent positions to select from the barcode; hyphens allow you to select a range of positions, and commas allow you to select more than one position or range of positions.<br>• For example, if the barcode reads “abcdefghi1234567890” and the selection pattern is “2,5-8,11-14” then the ID will be interpreted as “befgh2345”. If the selection pattern is “3-4”, then the ID will be “cd”.<br>• In each number range, the beginning number must be smaller than the finishing number. For example, “3-5” is a valid range, but “5-3” is **not** a valid range.<br>• The end of each number range must be smaller than the beginning of the next number range. For example, “3-6,7-9” is a valid selection, but “3-6,6-9” is **not** a valid selection and “3-6,5-9” is **not** a valid selection. Also, “7-9,3-6” is **not** a valid selection.<br>• The first position (the position furthest to the left) is numbered position “1”.<br>• The remaining Operator ID cannot be longer than the maximum ID size entered in the Max Digits field or shorter than the minimum ID size entered in the Min Digits field.<br>• You may not enter two or more commas or hyphens together. For example “2--5”, “2-5,, 7-10” and “2,-5” are all **invalid** ranges. |
| First/Last | These fields allow you to truncate (ignore) leading and/or trailing barcode characters from the scanned barcode. |

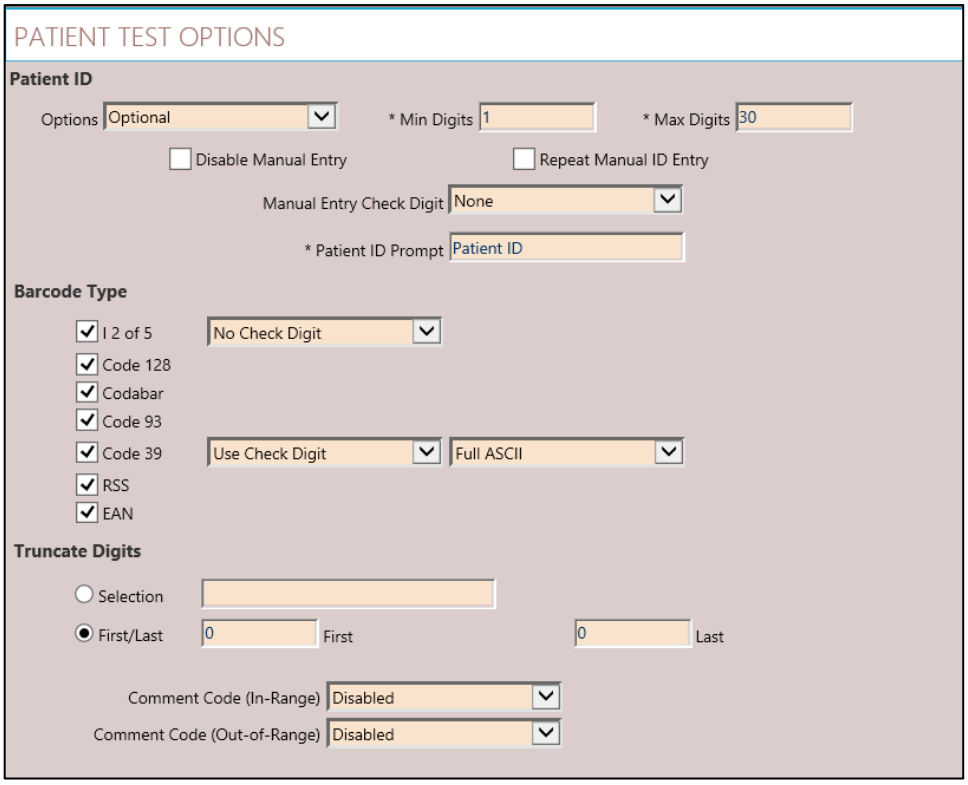
| | |
|---|---|
| | You can determine the number of characters to truncate from the beginning or the ending of the scanned Operator ID.<br>For example, if the scanned code is 1234567890 and you entered **3** into the **First** field and **1** into the **Last** field, then the resultant ID is 456789.<br>To ignore any beginning and/or ending values, specify the number of characters to truncate from the beginning/end of the scanned Operator ID. |

## 6.2 Patient Test Options

This screen displays the system default settings fo**r Patient Test Options**. It defines the Patient ID and Barcode requirements. The Patient Test Options screen is divided into the following sections:

- Patient ID
- Barcode Type
- Truncate Digits
- Comment Codes

***Note**: Fields marked with an asterisk (*) are mandatory.*




### 6.2.1 Patient ID

The Patient ID fields allow you to manually enter or scan a Patient ID into the device. The device will accept a scanned Patient ID if the barcode format is enabled in the Patient ID configuration options. (See Section 6.2.2 Barcode Type.)

**Explanation of the parameters**

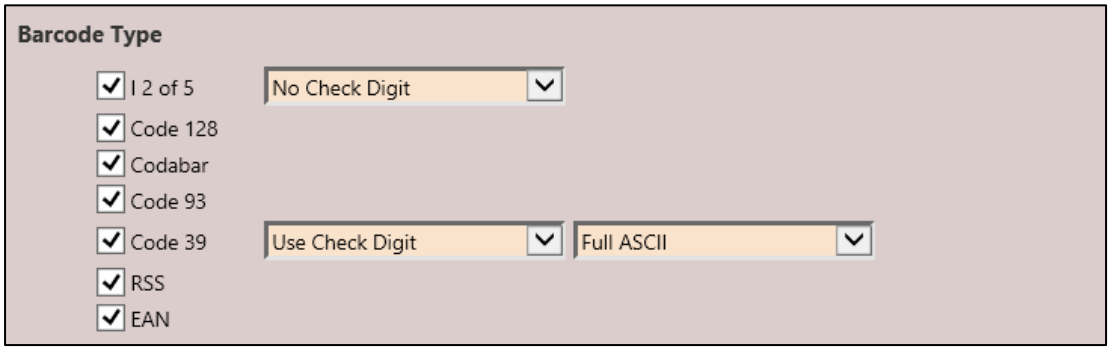
| | |
|---|---|
| **Options** | |
| Disabled | The display on the device will not prompt for a Patient ID. |
| Optional | The device prompts for a Patient ID, but entry is optional. |
| Required | Patient ID is required for all patient tests.<br>If the Patient ID is set to **Required** and the number of characters entered is outside the min/max range, then the ID will not be accepted. If the entry is set to **Optional** and the number of characters is greater than the maximum number, then the ID is not accepted.<br>If a Patient ID is entered, it will appear on the final result display on the device. |

## Explanation of the parameters

| | |
|---|---|
| | If **Optional** or **Required** is selected, you must enter a minimum and maximum number of digits, as described below.<br>To prevent manual entry of Patient IDs, select the **Disable Manual Entry** checkbox below the Options field.<br>If manually entered Patient IDs are allowed, their accuracy can be ensured by selecting the **Repeat Manual ID Entry** checkbox below the ***Min Digits** and ***Max Digits** field. This feature is active only if the box is checked and the **Patient Data Not Confirmed** field on the Security Options screen is set to **Allow Test** (when the Patient Data Not Confirmed option is set to Lockout or Warn, Repeat Manual ID Entry is not active, even if it is checked).<br>When this feature is active, the Precision Xceed Pro device will require Operators to enter the Patient ID a second time, but only when it was manually entered the first time. If the Patient IDs do not match on the second entry, the operator will be prompted to re-enter again.<br>**Note**: A *field with a name preceded by an asterisk (*) indicates a required field.* |
| ***Min Digits and *Max Digits** | If the Patient ID is scanned and the *Options* field is set to **Required**, the length of the scanned Patient ID must be equal to or less than the length requirement specified in the ***Max Digits** field and equal to or greater than the length requirement of the ***Min Digits** field.<br>If the Patient ID is scanned and the *Options* field is set to **Optional**, the length of the scanned Patient ID must be equal to or less than the length requirement specified in the ***Max Digits** field.<br>Patient IDs longer than 15 characters will be displayed with ellipses (…) in the last character space on the device.<br>The minimum required characters will be displayed as bold dashes on the device, if the *Patient ID Options* field is set to **Required**.<br>The scanned Patient ID, prior to truncation, cannot be longer than 64 characters. (See Truncate Digits below.) Subsequent to truncation, the maximum length of a scanned Operator ID is 30 printable characters.<br>Maximum and minimum length requirements will be applied to the Patient ID field after applying any truncation or selection to the ID. (See Truncate Digits below. |
| **Manual Entry Check Digit**<br><br>None<br>Mod10<br>Mod11 | The **Manual Entry Check Digit** field applies only to manually entered Patient IDs. It is useful for ensuring that the correct ID is entered when manual entry is used.<br>This setting has the following dropdown options: None, Mod10, Mod11.<br>You can configure the device to require no check digit, or a “mod10” or “mod11” check digit. If Mod10 or Mod11 is used, a numeric-only ID must be used. |
| **Patient ID Prompt** | You can configure the device to prompt the Operator with specific text whenever a Patient ID is required. Whatever text you enter in this field will be displayed on the device. The text in this field will default to ‘Patient ID’. This field is limited to 15 characters. |

### 6.2.2 Barcode Type

The Barcode Type section of the screen allows you to set the barcode data entry options for the Patient ID. The types of barcodes selected determine what codes can be scanned into the device.



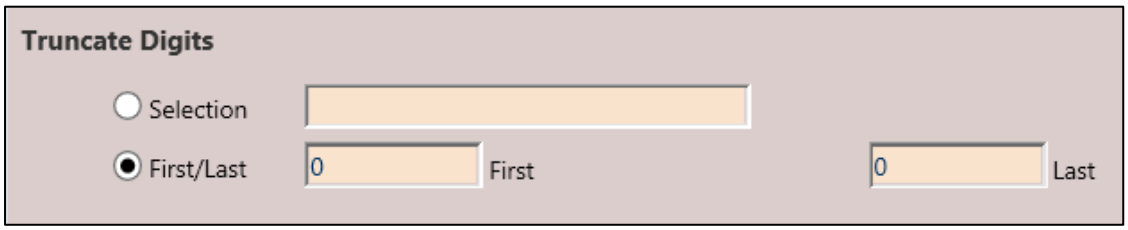

The device will accept a scanned Patient ID if the barcode type is enabled in the Patient ID configuration options. The Barcode scanner is capable of reading the following formats:

**Explanation of the parameters**

| | | |
|---|---|---|
| **Barcode Type** | Interleaved 2 of 5 (I 2 of 5)<br>Code 128<br>Codabar<br>Code 93<br>Code 39<br>EAN<br>RSS<br>See the Glossary of terms used in this manual for barcode terminology. Select all the barcode types used at your Facility, Department or Location.<br>Entry fields to the right of the **I 2 of 5** and **Code 39** barcode type checkboxes allow you to specify accepted barcode types by choosing from the dropdown options. | |
| **I 2 of 5** | No Check Digit<br>USS Check Digit<br>OPCC Check Digit | |
| **Code 39** | No Check Digit<br>Use Check Digit | Alphanumeric<br>Full ASCII |

### 6.2.3 Truncate Digits

You can set the method of truncation for scanned Operator IDs to **Selection** or **First/Last**. This instructs the device to select certain characters from the scanned barcode; the selected characters are used as the effective ID string. The remaining Operator ID, after truncation, cannot be longer than 30 characters.

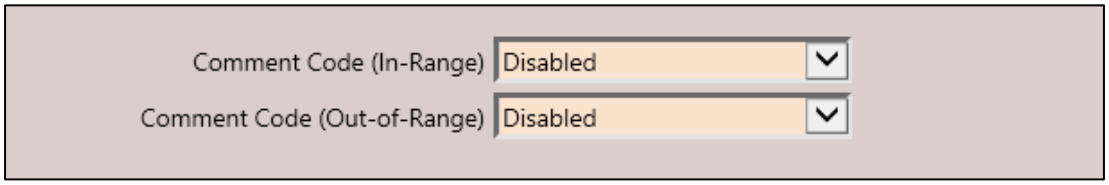



**Explanation of the parameters**

| | |
|---|---|
| **Selection** | You can specify exact character locations of the scanned Operator ID in the **Selection** field. Using the **Selection** mode, you do not specify character positions to be truncated (removed); rather, you specify character positions to be retained.<br>Use numbers to identify the location selection. Use commas (‘,’) and hyphens (‘-’) to identify the selection pattern.<br>• The numbers represent positions to select from the barcode; hyphens allow you to select a range of positions, and commas allow you to select more than one position or range of positions.<br>For example, if the barcode reads “abcdefghi1234567890” and the selection pattern is “2,5-8,11-14” then the ID will be interpreted as “befgh2345”. If the selection pattern is “3-4”, then the ID will be “cd”.<br>• In each number range, the beginning number must be smaller than the finishing number. For example, “3-5” is a valid range, but “5-3” is **not** a valid range.<br>• The end of each number range must be smaller than the beginning of the next number range. For example, “3-6,7-9” is a valid selection, but “3-6,6-9” is **not** a valid selection and “3-6,5-9” is **not** a valid selection. Also, “7-9,3-6” is **not** a valid selection.<br>• The first position (the position furthest to the left) is numbered position “1”.<br>• The remaining Operator ID cannot be longer than the maximum ID size entered in the Max Digits field or shorter than the minimum ID size entered in the Min Digits field.<br>• You may not enter two or more commas or hyphens together. For example “2--5”, “2-5,, 7-10” and “2,-5” are all **invalid** ranges. |
| **First/Last** | These fields allow you to truncate (ignore) leading and/or trailing barcode characters from the scanned barcode.<br>You can determine the number of characters to truncate from the beginning or the ending of the scanned Operator ID.<br>For example, if the scanned code is 1234567890 and you entered **3** into the **First** field and **1** into the **Last** field, then the resultant ID is 456789.<br>To ignore any beginning and/or ending values, specify the number of characters to truncate from the beginning/end of the scanned Operator ID. |

### 6.2.4 Comment Codes

The fields Comment Code (In-Range) and Comment Code (Out-Of-Range) allow you to add a comment code that will appear on the final result display on the device.

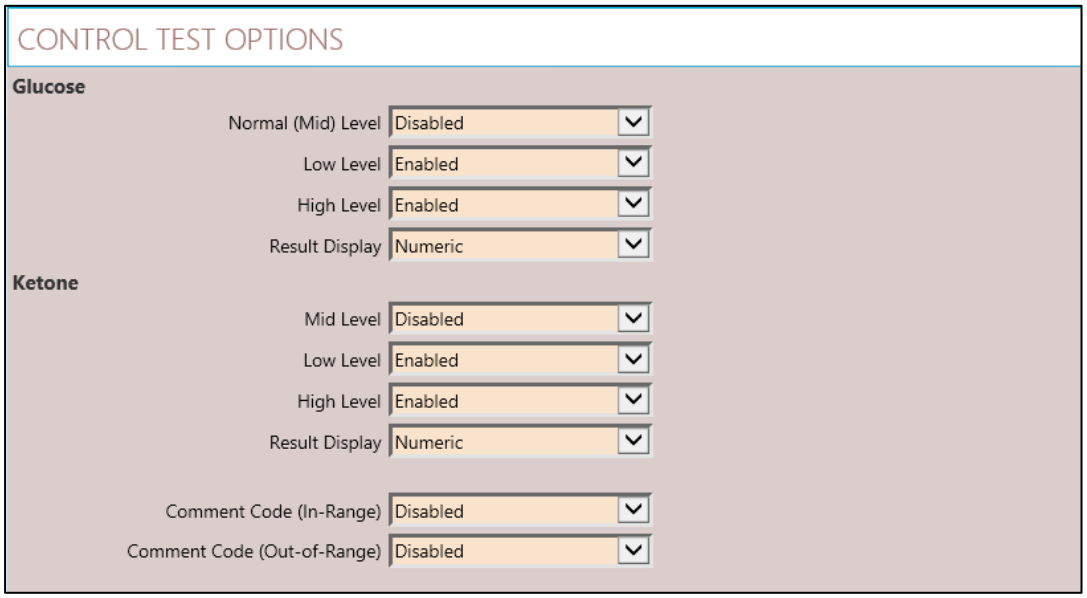



**Explanation of the parameters**

| | |
|---|---|
| **Comment Code (In-Range)** | |
| **Disabled** | The display on the device will not prompt the Operator to enter a comment code. |
| **Optional** | The device prompts the Operator to enter a comment code, but it is not required. |
| **Required** | The Operator is required to enter a comment code.<br>The In-Range screen will appear on the device if the Patient Test In-Range Comment Code is enabled. If you enable the comment code, the comment code will appear based on the narrowest range enabled. This will be either the critical range, action range or the assay range of the test strip. (One of these ranges will always be applicable.)<br>**Note***: The settings for the Patient Test In-Range Comment Code will also be applied to the Proficiency Test, if Proficiency Tests are enabled. If the Patient Test In-Range Comment Code is set to disabled, then there will never be a comment code field displayed for Proficiency Tests. If the Patient Test In-Range Comment Code is set to required or optional then there will always be an optional comment code field displayed for Proficiency Tests.* |
| **Comment Code (Out-Of-Range)** | The out-of-range screen will appear on the device if the Patient Test Out-of-Range Comment Code is enabled.<br>Select from the dropdown options: |
| Disabled | The display on the device will not prompt the Operator to enter a comment code. |
| Optional | The device prompts the Operator to enter a comment code, but it is not required. |
| Required | The Operator is required to enter a comment code. |

## 6.3 Control Test Options

This screen displays the system default settings for **Control Test Options**.




The quality control features of the device can be customized to fit the requirements of each Facility. The options associated with this screen apply to Glucose and Ketone control tests:

- Low, Normal (Mid) and High control solution tests can be configured independently for Glucose and Ketone, depending on the Facility's policy. At least one level must be selected for each test type.
- Control test results are displayed in numeric format or as Pass/Fail.
- Comment codes can be configured for in-range or out-of-range results.

**Note**: *The settings for the Control Test In-Range Comment Code will also be applied to the Linearity Test, if Linearity Tests are enabled. If the control test in-range comment code is set to disabled, then there will never be a comment code field displayed for linearity tests. If the control test in-range comment code is set to required or optional then there will always be an optional comment code field displayed for linearity tests.*

### Explanation of the parameters

| | |
|---|---|
| **Normal (Mid) Level**<br>Disabled / Enabled | Select the **Disabled** or **Enabled** option for the device to prompt for one, two or three levels of controls [Normal (Mid) Level, Low and/or High Level). |
| **Low Level**<br>Disabled / Enabled | Only the **Enabled** levels will appear on the device. |
| **High Level**<br>Disabled / Enabled | Only the **Enabled** levels will appear on the device. |
| **Result Display** | |
| Numeric | Control Test results can appear on the device as **Numeric** or **Pass/Fail**, depending on how the test is configured. If the assay completes successfully and the Result Display option is set for Numeric, the result will be displayed in the units set under Test Type Options. |
| Pass | **Pass** will be displayed if the result is inside the acceptable range for the particular control and strip (in-range). |
| Fail | **Fail** will be displayed if the result is outside the acceptable range (out-of-range). |

**Note**: *At least one Glucose and Ketone level under Control Test Options must be set to "Enabled"*.

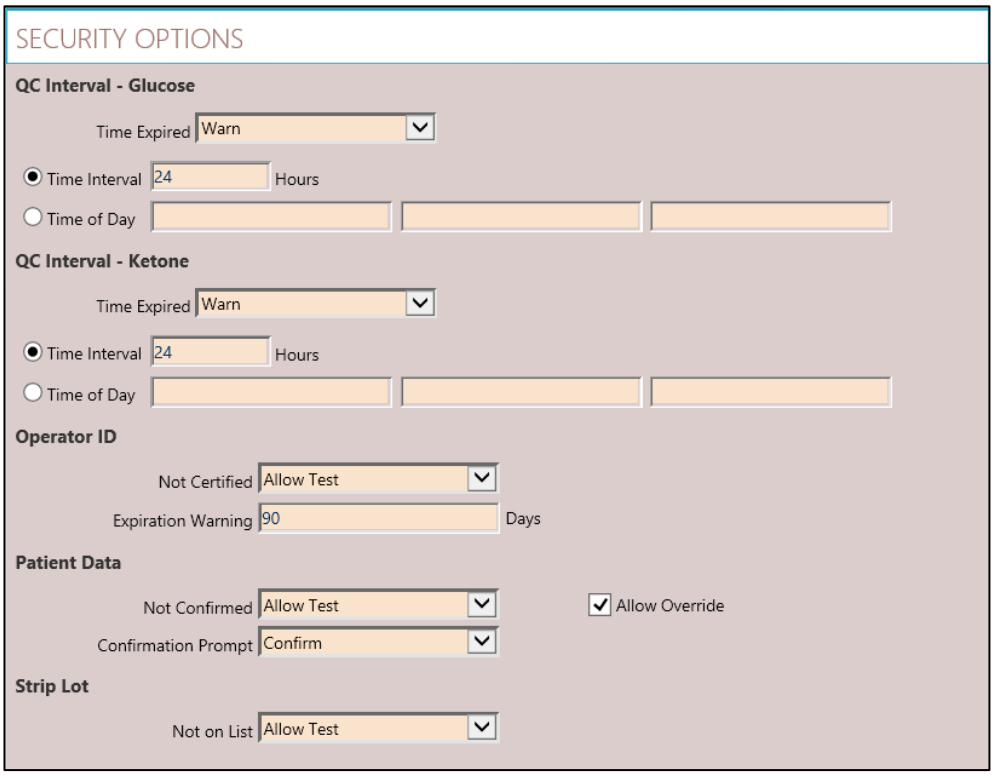
**Explanation of the parameters**

| | |
|---|---|
| **Comment Code (In-Range)** | The device may be enabled to scan or manually enter a one- to two-character comment code. |
| Disabled | Disables the prompt for the comment code. |
| Optional | Prompts for the optional entry of a comment code. |
| Required | Requires a comment code entry for every in-range test result. |
| **Comment Code (Out-Of-Range)** | The device may be enabled to scan or manually enter a one- to two-digit comment code for a failing control test.<br>Select from the dropdown options: |
| Disabled | Disables the prompt for the comment code. |
| Optional | Prompts for the optional entry of a comment code. |
| Required | Requires a comment code entry for every out-of-range test result. |

## 6.4 Security Options

This screen displays the system default settings for **Security Options**. It establishes the QC Interval for Glucose and Ketone, Operator ID certification and Strip Lot Download requirements for the device. The QC Interval for Glucose and Ketone can be configured independently, depending on the Facility's policy. The Security Options screen is divided into the following sections:

- QC Interval - Glucose
- QC Interval - Ketone
- Operator ID
- Patient Data
- Strip Lot



### 6.4.1 QC Interval

The field definitions apply to both the **Glucose** and **Ketone** option settings.

**Explanation of the parameters**

| | |
|---|---|
| **Time Expired** | **Note**:<br>*QC Interval options for Glucose and Ketone can be set independently. For example, QC Interval for Glucose can be set to "Warn" and QC Interval for Ketone can be set to "Allow test".* |
| Allow Test | Allows the testing to continue even if the QC interval has expired. No message will appear on the device. |
| Warn | Allows the testing to continue even though the QC interval has expired, but the Operator will receive a warning message if a control test is due. The specific control levels that are required will be displayed. There will be an option to continue the test and bypass the QC requirement. |
| Lockout | Does not allow any testing until the appropriate control tests have been performed. The specific control levels that are required will be displayed. The Operator will be prompted with only those levels that are expired and required to remove the lockout. |
| **Time Interval** | This field allows you to enter a number between 1 and 999 that determines the QC Interval based on a set number of hours between passing QC control tests. |
| **Time of Day** | These fields allow you to choose up to three times during the day that quality control tests will be required. You must enter the time in the following format: hh:mm AM/PM. |

### 6.4.2 Operator ID

**Explanation of the parameters**

| | |
|---|---|
| **Not Certified** | |
| Allow Test | Allows any Operator, certified or not, to test. No message will appear on the device. |
| Warn | The Operator List contains the ID numbers of Operators who are authorized to perform the tests. When the Operator enters an Operator ID, the device checks the ID against the current device list. If this field is set to **Warn**, an entry that is not on the Operator ID list will result in a warning screen on the device. There will be an option to continue the test. |
| Lockout | If this field is set to Lockout, only certified Operator IDs will be accepted. If a non-certified ID is entered, the device will not allow the test. |
| **Expiration Warning xx Days** | Allows you to set the number of days prior to expiration that an Operator will be notified that his/her certification is due to expire.<br>You may set it between 0 and 90 days.<br>Entering a number from 1 to 90 will configure the device to display a warning if the Operator's ID is set to expire within the configured number of days.<br>If you enter 0 days, the expiration screen will not display.<br>The Operator will be required to acknowledge the warning in order to continue with the test |

### 6.4.3 Patient Data

The Precision Xceed Pro can store up to 6,000 Patient IDs and the following demographics: First Name, Last Name, Middle Initial, Date of Birth and Gender. This information may be used to confirm scanned or entered Patient IDs.

The **Patient Data Not Confirmed** fields allow you to choose how the device will confirm Patient IDs that are entered against the device's stored information, and what action should be taken if an ID does not match.

The field allows you to determine what action the device will take if the entered Patient ID does not match. The field allows the device to be set to one of following options:

**Explanation of the parameters**

| | |
|---|---|
| **Not Confirmed** | |
| Allow Test | Allows the testing to continue whether or not the Patient ID is found in the database. Also, if the Patient ID was entered manually, and "Repeat Manual ID Entry" is enabled on the Patient Options configuration page, the Patient ID must be entered a second time. **Allow Test** is the field default. |
| Warn | Allows the testing to continue even though the Patient ID is not found in the devices' stored information, and the device will display a warning message. When the Patient ID is found in the device's stored information, the Patient ID is further confirmed as indicated below (Confirm or Year of Birth). |
| Lockout | When the Patient ID is not found in the device's stored information, an error message is displayed, and a different Patient ID can be entered. |
| ☑ Allow Override | If the **Allow Override** field is checked, the tests are allowed if the Operator successfully enters the same Patient ID two times in a row. This feature ensures that tests can be performed in an emergency situation. The field is checked by default. |
| **Confirmation Prompt** | Allows you to instruct the device how to proceed after the Patient ID has been entered. The **Confirmation Prompt** field allows the device to be set to one of the following options: |
| Confirm | Defaults to "Confirm". If "Confirm" is selected, then the device will display the patient data with options to re-enter or confirm the ID. |
| Year of Birth | If "Year of Birth" is selected, then the device will display the patient data and require the Operator to confirm the ID by entering the patient's year of birth. |

### 6.4.4 Strip Lot

The **Strip Lot** list contains the strip lot numbers of valid test strip lots in the current inventory. When the Operator enters a test strip lot number (via the barcode scanner or by manually entering the 14-digit lot number), the device checks the number against the device's stored information.

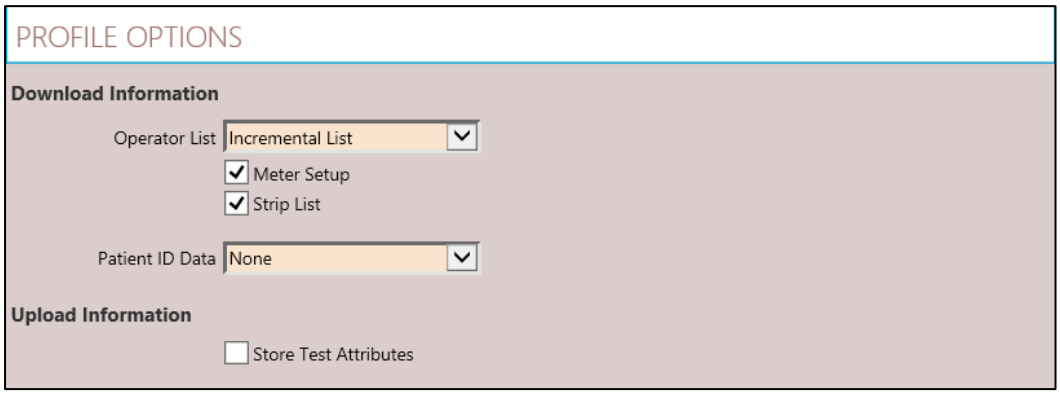
**Explanation of the parameters**

| | |
|---|---|
| **Not on List** | Allows you to set the device to one of the following options: |
| Allow Test | Allows any strip lot to be used for testing. No message will appear on the device. **This is the default**. |
| Warn | If set to **Warn**, the device displays a warning message if the strip lot entered is not on the device's Strip Lot list but allows the Operator to continue testing. |
| Lockout | If set to **Lockout**, the device will display a warning message if the strip lot entered is not on the device's Strip Lot list. The Operator will **not** be allowed to proceed with the test unless the strip lot entered is on the device's Strip Lot list. |

## 6.5 Profile Options

This screen displays the system default settings for **Profile Options**. The Profile Options screen allows you to set download and upload options for the devices using Abbott Docking Stations for data transmission. The screen is divided into the following sections:

- Download Information
- Upload Information




### 6.5.1 Download Information

**Explanation of the parameters**

| | |
|---|---|
| **Operator List** | Allows you to determine if the device will receive Operator ID data when it is docked. This field has the following dropdown options: |
| None | The Operator list will not be downloaded to the device. |
| Full List | The entire Operator list will be downloaded each time the device is docked. |
| Incremental List | Only changes made to the Operator list since the last download will be send to the device. |
| ☑ Meter Setup | Check this option to download configuration settings to the device when it is docked. |
| ☑ Strip List | Check this option to download the approved strip lot list to the device when it is docked. |
| **Patient ID Data** | Allows you to determine if the device will receive Patient ID data when it is |

| | |
|---|---|
| | docked. This field has the following dropdown options: |
| None | Patient ID data will not be downloaded to the device. |
| Full List | The entire Patient ID list will be downloaded each time the device is docked. |

### 6.5.2 Upload Information

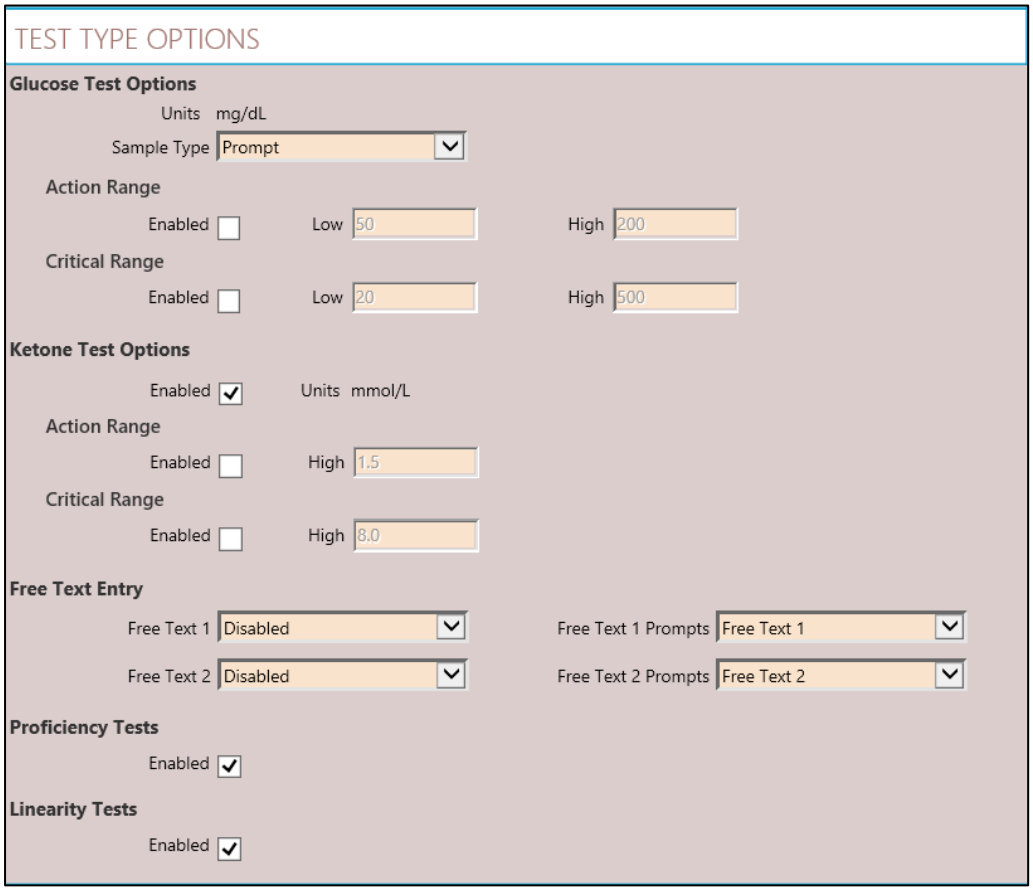
#### Explanation of the parameters

| | |
|---|---|
| ☑ Store Test Attributes | If you check the Store Test Attributes option, the test attributes will be saved and displayed on the **Edit Results** screen, and optionally the **All Results** screen, when results associated with these tests are viewed. See Section 7, **Test Result Features** for a full listing of Test Attributes.<br>• Test attributes (e.g., temperature) will be saved and displayed on the **Edit Results** screen and optionally on the **All Results** screen.<br>• Not all test attributes will be present for each test, as items are dependent on configuration settings and other variables. |

## 6.6 Test Type Options

This screen displays the system default settings for **Test Type Options**. The screen allows you to define the patient test **Action Range**, **Critical Range** and **Free Text** entry fields and to enable **Proficiency** and **Linearity** testing on the device. It is divided into the following sections:

- Glucose Test Options
- Ketone Test Options
- Free Text Entry
- Proficiency Tests
- Linearity Tests




### 6.6.1 Glucose Test Options

#### Explanation of the parameters

| | |
|---|---|
| Units | The unit of measure for Glucose is locked. It will be locked to **mg/dL or mmol/L** during installation of UniPOC.<br>The static text indicating the installed unit of measure will be displayed next to **Units**. |
| **Sample Type** | The Sample Type specifies the sample type that the instrument will use for glucose tests.<br>The sample type may be set to one of the following options: **Capillary/Arterial**, **Venous**, or **Prompt**. This setting applies only to tests run with the Precision PCx Test Strip. |

## Explanation of the parameters

| | |
|---|---|
| **Action Range** | This Action Range defines the action range for glucose tests. The device can be set to warn the operator when a patient glucose test result is outside the user-defined Action Range. |
| Enabled ☐ | Selecting the **Enabled** checkbox option will enable the glucose Action Range in the device. |
| Low<br>High | • If the **Action Range** is enabled, the device will check the patient glucose test result against the range.<br>• If you do not check this box, the **Action Range** option will be disabled.<br>• Specify the limits for **Low** and **High**. The values of both the Low and High fields must be between 20 mg/dL and 500 mg/dL (1.1 mmol/L and 27.7 mmol/L).<br>• The **Action Range** must be narrower than (within) the **Critical Range**. (See below)<br>• If the result is above the upper Action Range limit, but less than the upper Critical Range limit (see below), the result will display with an up arrow to indicate an above-normal result.<br>• If the result is below the lower Action Range limit, but greater than the lower Critical Range limit (see below), the result will display with a down arrow to indicate a below-normal result. |
| **Critical Range** | The device can be set to warn the Operator when a patient glucose test result is outside the user-defined Critical Range. |
| Enabled ☐ | Selecting the **Enabled** checkbox option will enable the glucose Critical Range in the device. |
| Low<br>High | • If the **Critical Range** is enabled, the device will check the patient glucose test result against the range.<br>• If you do **not check** the Critical Range enabled box, the **Critical Range** option will be disabled.<br>• Specify the limit for **Low** and **High**. The values of both the Low and High fields must be between 20 mg/dL and 500 mg/dL (1.1 mmol/L and 27.7 mmol/L).<br>• The **Critical Range** must be broader (outside) than the Action Range (see above), but narrower than (within) the assay range of the test strip.<br>• For the Precision Xceed Pro system, the assay range is 20 mg/dL to 500 mg/dL (1.1 mmol/L to 27.7 mmol/L). The system will display results within the assay range of the system.<br>• If the result is above or below the Critical Range limit, the result will display as “> upper critical range” or “< lower critical range”, respectively. |

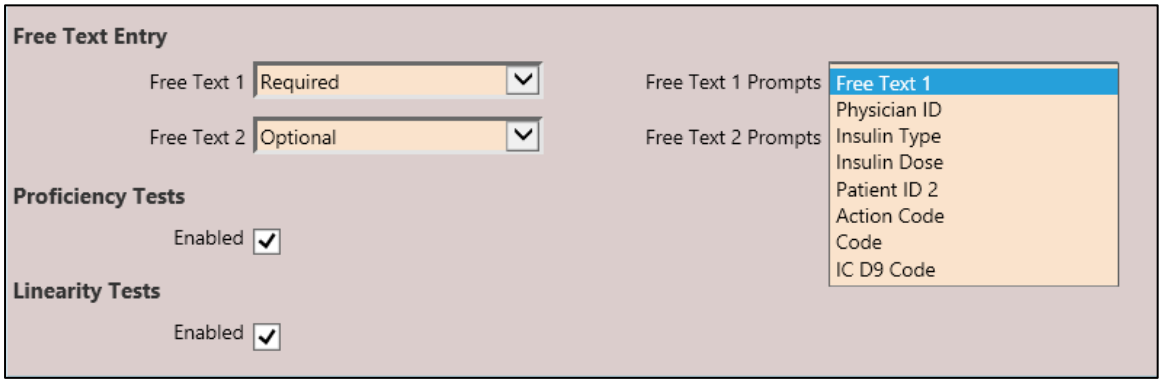
## 6.6.2 Ketone Test Options

### Explanation of the parameters

| | |
|---|---|
| Enabled ☐ | Selecting the Ketone Tests Enable box will enable ketone tests. This field is checked by default. |
| Units | The static text “Units mmol/L” is displayed to the right of the check box. |
| Action Range | This Action Range defines the Action Range for ketone tests. The device can be set to warn the Operator when a patient ketone test result is outside the user-defined Action Range. |
| Enabled ☐ | Selecting the action range **Enabled** checkbox option will enable the Ketone Action Range in the device. |
| High<br>Low | • If the **Action Range** is enabled, the device will check the patient ketone test result against the range.<br>• If you do not check this box, the **Action Range** option will be disabled.<br>• Specify the limit for **Ketone Action Range High**. The value of the Low and High fields must be between 0.0 mmol/L and 8.0 mmol/L.<br>• The **Action Range** must be narrower than the **Critical Range**.<br>• If the result is above the upper **Action Range** limit, but less than the upper Critical Range limit (see below), the result will display with an **up arrow** to indicate an above-normal result.<br>• If the result is below the lower **Action Range** limit, but greater than the lower Critical Range limit (see below), the result will display with a **down arrow** to indicate a below-normal result. |
| Critical Range | This Critical Range defines the critical range for ketone tests. The device can be set to warn the operator when a patient ketone test result is outside the user-defined Critical Range.<br>Selecting the Enabled checkbox option will enable the Ketone Critical Range in the device.<br>• If the Critical Range is enabled, the device will check the patient ketone test result against the range.<br>• If you do not check the Critical Range enabled box, the ketone Critical Range option will be disabled.<br>• Specify the limit for Ketone Critical Range High. The value of the High field must be between 0.0 mmol/L and 8.0 mmol/L.<br>• The Critical Range must be broader than the Action Range (see above), yet narrower than the assay range of the test strip.<br>• For the Precision Xceed Pro system, the assay range is 0.0 – 8.0 mmol/L. The system will display results within the assay range of the system.<br>• If the result is above or below the Critical Range limit, the result will display as “> upper critical range” or “< lower critical range”, respectively. |

### 6.6.3 Free Text Entry

You have the option of entering additional information to test records through the two **Free Text Entry** fields.




**Explanation of the parameters**

| | |
|---|---|
| Free Text 1 / Free Text 2<br>Disabled<br>Optional<br>Required | You can set the Free Text field requirement to **Disabled**, **Optional** or **Required**.<br>If you select Required in either of the two fields, the Operator must manually enter or scan data into the device when it prompts for Free Text. |
| Free Text 1 Prompts<br>Free Text 2 Prompts | You can select the **text prompt** that the Operator will see above each of the **Free Text** fields on the device screen.<br>This can be used to guide the user to enter a specific type of data. The selection for each field is made by choosing from the corresponding **Free Text Prompt** dropdown box. Options for Free Text 1 and Free Text 2 Prompts include:<br>• Free Text 1<br>• Physician ID<br>• Insulin Type<br>• Insulin Dose<br>• Patient ID 2<br>• Action Code<br>• Code<br>• IC D9 Code |

### 6.6.4 Proficiency Tests

You can enable Proficiency Tests on a device by checking the **Enabled** box.

**Explanation of the parameter**

| | |
|---|---|
| Enabled ☐ | If you do not check the box, the ability to run a Proficiency Test on a device is disabled and the option will be removed from the device's menu options |

### 6.6.5 Linearity Tests

You can enable Linearity Tests on a device by checking the **Enabled** box.

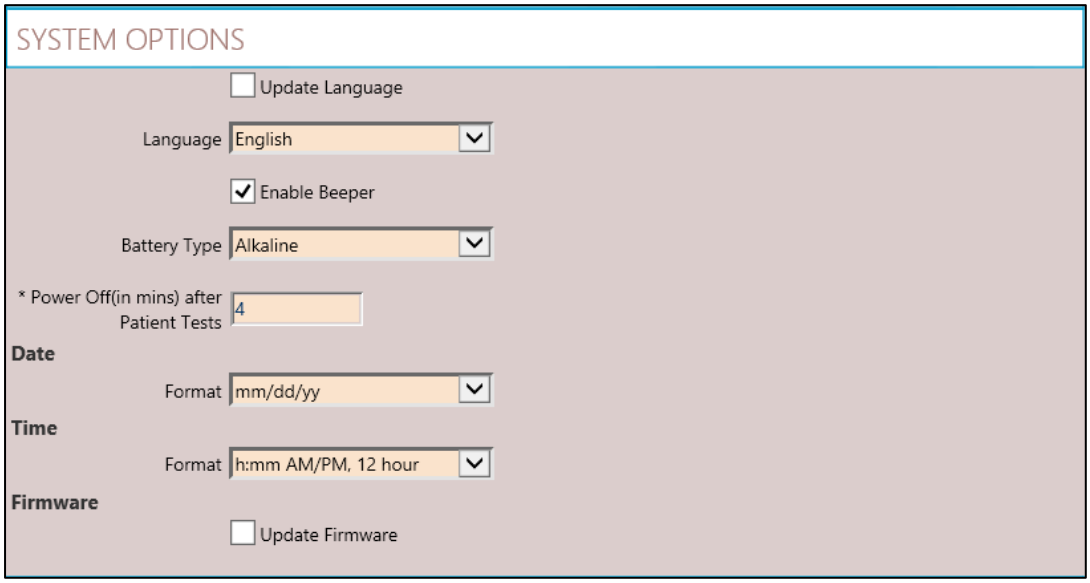
**Explanation of the parameter**

| | |
|---|---|
| Enabled ☐ | If you do not check the box, the ability to run a Linearity Test on a device is disabled and the option will be removed from the device's menu options |

## 6.7 System Options

The **System Options** screen allows you to customize the appearance of the data displayed on the device.

***Note**: Fields marked with an asterisk (*) are mandatory.*



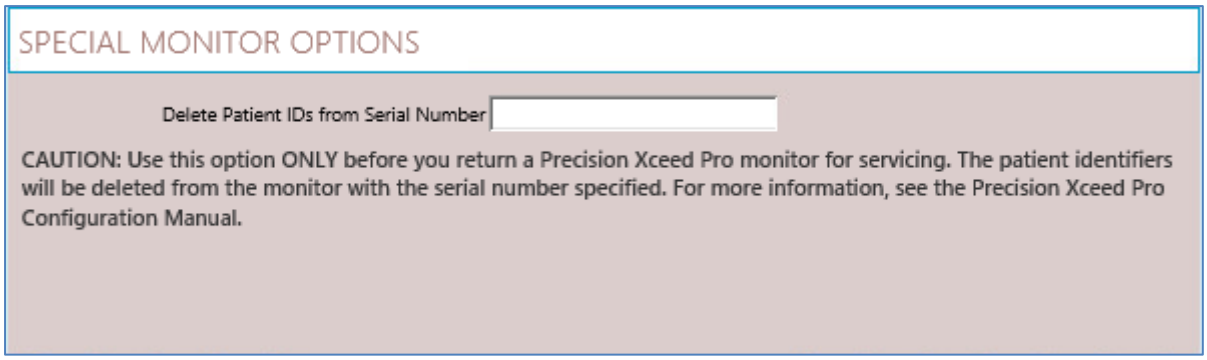

### Explanation of the parameters

| | |
|---|---|
| ☐ Update Language | Check this box to allow the language to be updated.<br>**Note**: *The device must be on the latest supported firmware version to update the language successfully. Select the **Update Firmware** option to enable firmware upgrade to the latest version.* |
| **Language** | Choose the language you would like the device to use on its display. |
| ☑ Enable Beeper | Check this box to turn on the beeper that will alert the operator of certain functions on the device.<br>• a successful barcode entry<br>• sample detection<br>• when a result appears<br>• when an error occurs<br>• thirty seconds before the automatic shut-off<br>• the on/off button is pressed<br>• an incorrect key or button is pressed |
| **Battery Type** | Choose battery type installed in the device: **Alkaline** or **NiMh Rechargeable**. |
| Power Off (in mins) after Patient Tests | This field directs the device's automatic shut-off time after patient test results are displayed. The default shut-off time is four minutes, unless otherwise specified. The values of this field must be between 4 and 10 minutes, in whole digit increments (e.g., 5 minutes, but not 5.5 minutes). |
| **Date**<br><br>Format | Choose the format in which you would like the date to appear in the device's final result display.<br><br>The choices are: dd/mm/yy; mm/dd/yy; dd-mm-yy; or mm-dd-yy |
| **Time** | Choose the format in which you would like the time to appear in the device's final result display. |

| | |
|---|---|
| Format | You can choose to present time in a 12- or 24-hour clock and with different punctuation. |
| **Firmware**<br>☐ Update Firmware | Check the Update Firmware box to allow the device firmware to be upgraded.<br>If it is unchecked, this option is disabled.<br>**Note**: *If you are updating the language, be sure to select this option since the device must be on the latest supported firmware version to update the language successfully.* |

## 6.8 Special Monitor Options

This screen displays the system default settings for Special Monitor Options.




**Explanation of the parameters**

| | |
|---|---|
| **Delete Patient IDs from Serial Number** | This is a special option that should be used only after you have removed a Precision Xceed Pro device from service and prior to returning the device to the manufacturer.<br>This option will remove patient identifiers from all results stored in the specified device. The patient identifiers will be deleted the next time the specified device is docked after the specification has been saved on this screen.<br>**Note**: *Use this option only before returning a device.*<br>For more information, see section 6.8.1 Deleting Patient IDs from Serial Number below. |

### 6.8.1 Deleting Patient IDs from Serial Number

The UniPOC system will allow patient identifiers to be deleted from a specified Precision Xceed Pro device only once; the **Delete Patient IDs from Serial Number** command cannot be applied again to the same serial number. If you re-dock the device after its patient identifiers have been deleted, UniPOC will not re-apply the Delete Patient IDs command to that specific device, even if the device's serial number is shown in the configuration screen.

**Procedure**

1. Enter a Precision Xceed Pro device serial number (e.g., XP0002-0017) on the **Special Monitor Options** screen. You should enter the serial number as it appears on the device identification label using alphanumeric characters and including the dash symbol.
2. Click **Save Configuration**. After saving the configuration, the serial number will continue to be displayed on this configuration page.

   When the specified device is docked next at the location for which this configuration was saved, any results contained in the device will be uploaded normally, including the patient identifiers associated with those results. After the results are uploaded, patient identifiers will be deleted from the results in the device's data storage. Thereafter, the device cannot be used normally, and should be returned to the manufacturer. Result data stored in UniPOC will

not be affected by this command; only the Precision Xceed Pro device's internal results storage will be changed.

Note the following:

- If you clear the serial number from this screen and re-save the screen before the specified device is docked next, the patient IDs will not be removed from the device.
- The **Delete Patient IDs from Serial Number** command will only function when the specified device docked at a location controlled by the settings for this configuration page. For example, if a Location is selected is in the Tree when a Delete Patient IDs configuration is saved, the device will only be affected when it is docked at that Location.

  The device serial number will continue to be displayed on this configuration screen. After the specified device has been docked and it has completed its conversation, you should remove the serial number from this **Special Monitor Options** screen by deleting the serial number from the serial number field and re-saving this configuration screen.

# 7 Test Result Features

These features are displayed in UniPOC result and alarms screens, rather than in the Precision Xceed Pro Configuration pages.

## 7.1 Test Attributes

With each test, the Precision Xceed Pro may supply information coded as **Test Attributes**. If the **Store Test Attributes** option is checked on the **Profile Options** configuration page (see Section 6.5), the test attributes will be saved. Saved attributes will be displayed on the UniPOC **Edit Results** screen, and optionally the **All Results** screen, when results are viewed.

***Note**: All test attributes may not be present for a particular test,* and ***Test Attributes** will not appear on the **Edit Results** screen unless the device's configuration included the **Store Test Attributes** option on the **Profile Options** configuration page at the time of the test. The possible **Test Attributes** are as follows:*

| **Test Attribute Name** | Meaning |
|---|---|
| **Temperature** | Temperature °C measured at the device test port. |
| **Voltage** | Battery voltage in the device's batteries. |
| **Operator ID Manual Entry** | Operator ID was manually entered at device, not scanned. |
| **Strip Lot Manual Entry** | Strip Lot ID was manually entered at device, not scanned. |
| **Comment Code Manual Entry** | Comment Code was manually entered at device, not scanned. |
| **Patient ID Manual Entry** | Patient ID was manually entered at device, not scanned. |
| **Patient ID Deleted** | Patient IDs have been deleted from the device; this Test Attribute will not appear in normal usage. This attribute only appears if the Patient IDs have been deleted from the monitor using the Special Monitor Option. |
| **Outside Reportable Range** | Result Value outside reportable (assay) range. |
| **Field 1** | Content of device Free Text Entry #1. |
| **Field 2** | Content of device Free Text Entry #2. |
| **Instrument Text 1 Manual Entry** | Device Free Text Entry #1 was manually entered, not scanned. |
| **Instrument Text 2 Manual Entry** | Device Free Text Entry #2 was manually entered, not scanned. |
| **Low Level Required** | Low Level Control required. |

| | |
|---|---|
| **Normal (Mid) Level Required** | Normal or Mid-Level Control required. |
| **High Level Required** | High Level Control required. |
| **Control Lot Manual Entry** | Control Lot ID was manually entered at device, not scanned. |
| **Sample ID Manual Entry** | Proficiency ID was manually entered at device, not scanned. |
| **Linearity Lot Manual Entry** | Linearity ID was manually entered at device, not scanned. |

# 8 Support

### Contacting Siemens Support

Siemens is committed to helping you resolve any problems with the UniPOC™ Point of Care Data Management System.

For assistance, contact:

https://www.siemens-healthineers.com/how-can-we-help-you