SIEMENS Healthineers

UniPOC™

Point of Care Ecosystem™ Enabled

Configuration Manual

HemoCue Glucose 201 DM

HemoCue Hemoglobin 201 DM

HemoCue Glucose 201 DM RT

From software version 1.7

Origin US
Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591-5097 USA

Global Siemens Headquarters
Siemens AG
Wittelsbacherplatz 2
80333 Muenchen
Germany

Siemens Healthineers Headquarters
Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen
Germany
Phone: +49 9131 84-0
siemens-healthineers.com

Global Division
Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591-5097
USA
www.siemens.com/diagnostics

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 following HemoCue devices:

- HemoCue Glucose 201 DM (Glu 201 DM)
- HemoCue Glucose 201 DM RT (Glu 201 DM RT)
- HemoCue Hemoglobin 201 DM (Hb 201 DM)

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

2 Intended Use

This software allows you to configure and use the HemoCue Glu 201 DM, Glu 201 DM RT, and Hb 201 DM devices with the UniPOC™ Point of Care Data Management System. The UniPOC product is not for in-vitro diagnostic use.

3 Instrument Configuration Pages

Important: Configuration settings can change based on the UniPOC application version and device driver pack versions installed. For example, a device driver pack may be updated to support a new or changed configuration setting but if you are using an older version of the UniPOC application that does not support the change, you will not see the updated configuration setting in the UI.

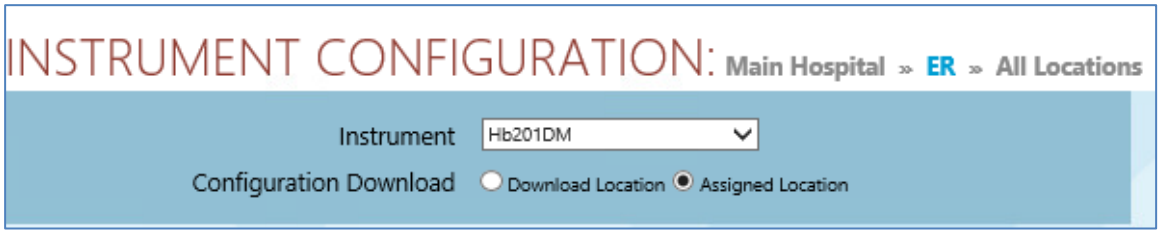
The following **Instrument Configuration** pages are described in this manual.

- Download Options
- Format Options
- Order ID Options
- Output Options
- Patient Options
- Patient ID Options
- QC Options
- Reagent Lot Options
- Sample System Options
- Unit Options
- User ID Options
- QC Lockout Options
- Instrument Settings

4 Configuration Screens

The **Instrument Configuration** screens in UniPOC allow you to view and edit the HemoCue Glu 201 DM, Glu 201 DM RT and Hb 201 DM configuration data for a specific location. These devices can be configured for the entire Organization or an individual Facility**,** Department **or** Location**.**

Note: *Siemens Healthineers 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.
2. From the menu, select **Instruments** > **Configuration**.
   The **Instrument Configuration** screen appears.
3. Select an Instrument from the **Instrument** drop-down list.
4. 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: • Configuration settings to be downloaded to the device • Supported lists downloaded to the device • Location where all test data are uploaded to in the Tree
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: • Configuration settings to be downloaded to the device • Supported lists downloaded to the device • Location where all test data are uploaded to in the Tree ***Note:*** *UniPOC will automatically update the device's location in the Tree when it communicates to UniPOC.*

5. 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.

6. Do one of the following:
   - Click the **Save Configuration** button to save the settings.

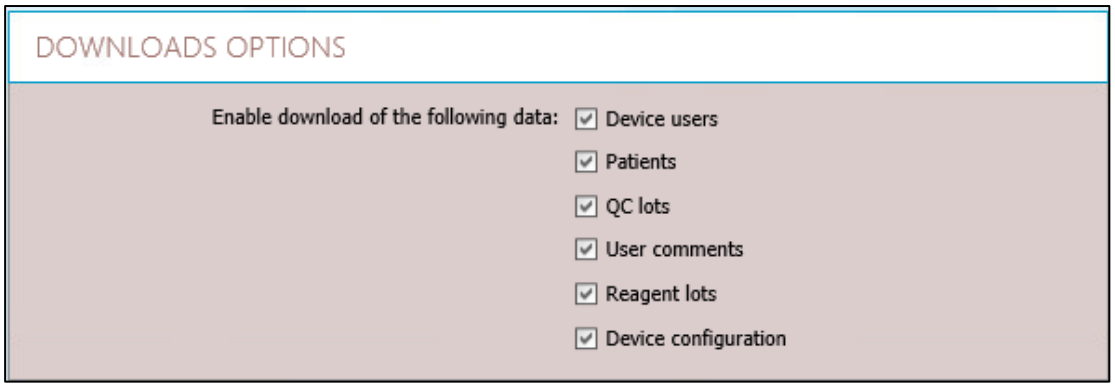
     This will break the Parent-Child relationship and save the configuration as a new one, even if no changes were made. Saving an instrument configuration for a lower level of the Tree (Department or Location) will sever the relationship between the child and its parent level on the Tree. Breaking the Parent-Child relationship is necessary to enable configuration settings different from the global Organization or Facility.

     Refer to the *UniPOC User's Manual* for more information about the Location Tree Parent-Child Relationship.
   - 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.

4.1 Downloads Options

When a device is placed into operation for the first time, all data that can be downloaded from UniPOC to the model are automatically activated from this screen. This tab is used to set the download options. When you enable a download, all pre-existing data of that type stored on the device will be overwritten. Once enabled, options can be disabled at any time.

***Note**: If you disable (uncheck) a download option, the data of that download type will no longer be sent to the device, and any previously downloaded configuration data will be retained on the device.*



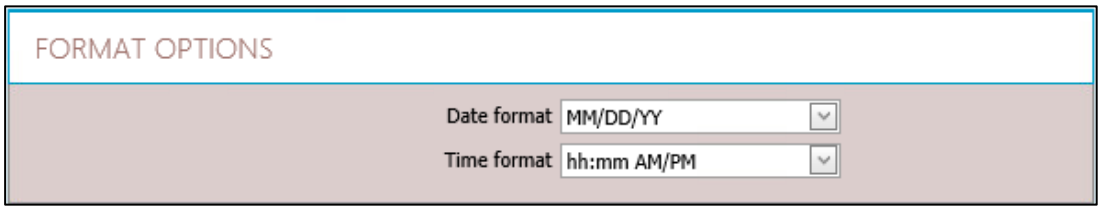
Explanation of the parameters

Enable download of the following data:	
☑ Device users	If selected, device users' data will be downloaded.
☑ Patients	If selected, patients' data will be downloaded.
☑ QC lots	If selected, QC lots data will be downloaded.
☑ User comments	If selected, user comments will be downloaded.
☑ Reagent lots	If selected, reagent lots data will be downloaded.
☑ Device configuration	If selected, device configuration data will be downloaded.

Table 1: Downloads Options

4.2 Format Options

This screen displays the system default settings for *Format Options*. The screen allows you to customize the appearance of the data displayed on the device.

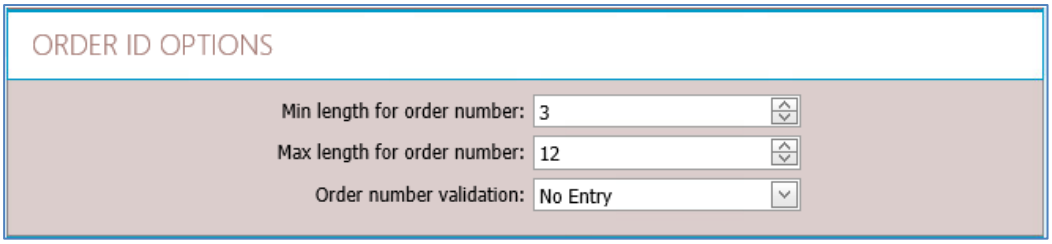


Explanation of the parameters

Date format	Choose the format in which you would like the date format to appear on the device's final result display.
MM/DD/YY	MM/DD/YY (Default) (e.g. 12/28/20)
DD.MM.YY	
YY-MM-DD	
Time format	Choose the format in which you would like the time format to appear on the device's final result display.
hh:mm AM/PM	12-hour time (Default: 12:00 AM.)
HH:mm	24-hour time

Table 2: Format Options

4.3 Order ID Options

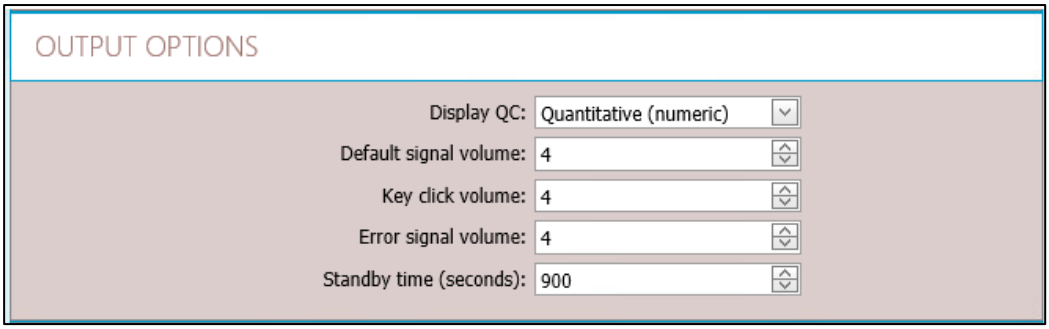


Explanation of the parameters

Min length for order number	This is used to check the minimum length of the order number. **Note**: The min. length must be less than or equal to the max. length. Possible choice: 1 to 15 characters Default: 3 characters
Max length for order number	This is used to check the maximum length of the order number. Possible choice: 1 to 15 characters Default: 12 characters
Order number validation	Defines whether the entry of an order number is required for each measurement.
No entry	If selected, there is no field displayed on the device to enter an order number so order number validation is disabled. (Default)
No checking	If selected, there is a field displayed on the device to enter an order number, but it is not required and there is no validation of the order number, meaning every order entry is accepted, including an empty entry.
For length	If selected, the order number entered is checked for its correct length defined in the “Min./Max. length for order number” fields.

Table 3: Order ID Options

4.4 Output Options



Explanation of the parameters

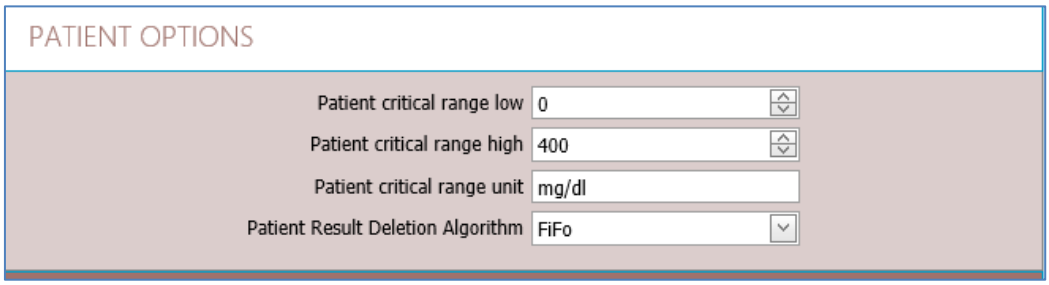
Display QC Quantitative (numeric) Qualitative	Defines how QC results are displayed. The QC result is shown in numeric format and with Passed or Not passed. (Default) The QC is shown only with Passed or Not passed.
Default signal volume	An acoustic signal will sound after each measurement. This is used to define the acceptable volume of the signal. Possible choice: 0 (OFF) to 4 (max. volume) Default: 4
Key click volume	An acoustic signal will sound after each entry by using the built-in keypad. This is used to define the acceptable volume of the signal. Possible choice: 0 (OFF) to 4 (max. volume) Default: 4
Error signal volume	An acoustic signal will sound after a failed QC or if the entry is not accepted. This is used to define the acceptable volume of the signal. Possible choice: 0 (OFF) to 4 (max. volume) Default: 4
Standby time (seconds)	Defines the time (per seconds) until the device is switched to standby mode. Possible choice: 300 up to 1800 seconds – in an interval of 5 minutes Default: 900 seconds (15 minutes)

Table 4: Output Options

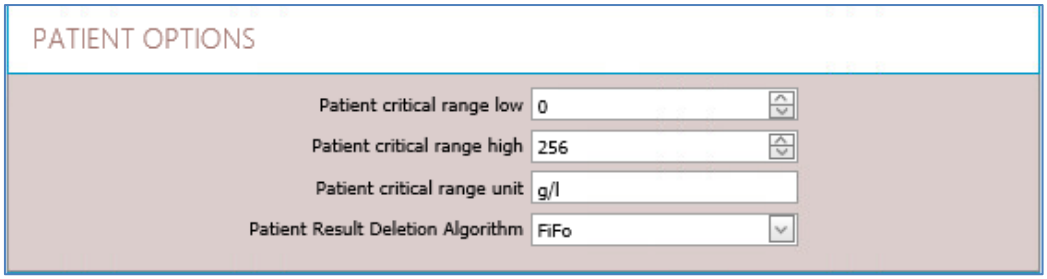
4.5 Patient Options

Note: Case number is more commonly known as the Patient ID.

Glu 201 DM



Hb 201 DM



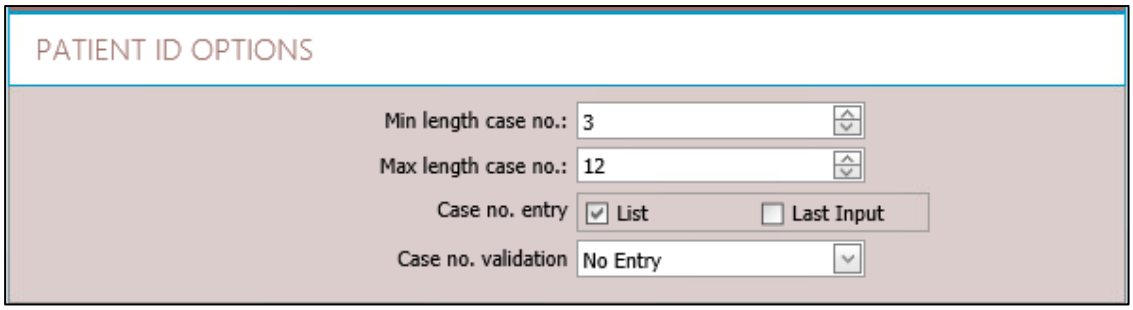
Explanation of the parameters

	Glu 201 DM: This is used to define the critical measurement ranges for measuring blood glucose. **Hb 201 DM**: This is used to define the critical measurement ranges for measuring hemoglobin.
Patient critical range low	Define the lower critical limit for patient measurements.
Patient critical range high	Define the upper critical limit for patient measurements. **Glu 201 DM**: Results above 400 mg/dl (22.2 mmol/l) will be displayed as HHH (over range) on the device. **Hb 201 DM**: Results above 256 g/l (25.6 g/dl, 15.9 mmol/l) will be displayed as HHH (over range) on the device.
Patient critical range unit	This is used to set the unit of measure for patient critical range values. Enter the unit in the free-text field depending on the device model: **Glu 201 DM**: mg/dl – Values are displayed in milligrams per deciliter. (Default) mmol/l – Values are displayed in millimoles per liter. **Hb 201 DM**: g/l – Values are displayed in grams per liter. (Default) g/dl – Values are display in grams per deciliter. mmol/l – Values are displayed in millimoles per liter.

Patient Result Deletion Algorithm	This setting is used to determine how patient results are automatically removed from the device.
FiFo	First in – First out: If this option is selected, results will be stored until the buffer is full. Then the result first in is automatically the first to be deleted.
Lockout	If this option is selected, the device will be locked when the patient result memory is full. Additional patient tests cannot be performed until archived results are deleted.

Table 5: Patient Options

4.6 Patient ID Options

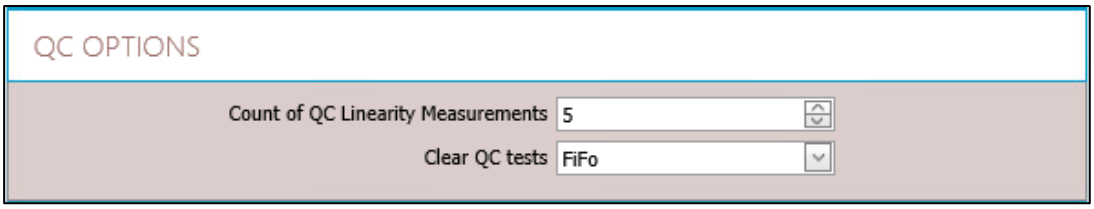


Explanation of the parameters

Min length case no.:	This is used to check the minimum length of the Patient ID. Possible choice: 1 to 15 characters Default: 3 characters **Note**: The Min. length has to be smaller or equal to the Max length.
Max length case no.:	This is used to check the maximum length of the Patient ID. Possible choice: 1 to 15 characters Default: 12 characters
Case no. entry	Mode to check the validity of the entered Patient ID. Both options can be selected.
☑ List	If selected, the device's internal Patient list is used for positive Patient ID (PPID). When a Patient ID is entered either manually or scanned via barcode, and the Patient ID exists on the list, the display will show the Patient ID and corresponding Patient Name (if the patient list function is activated on the device). (Default) If this option is not selected, the program checks whether the Patient ID entered is available in the device's internal Patient list. This option depends on the "Case no validation" setting.
☑ Last input	If selected, the system displays the last entered Patient ID.
Case no. validation	Used to validate the Patient ID.
No Entry	If selected, Patient ID entry is not required, and no entry field is shown on the device.
No Checking	If selected, there is a field displayed on the device to enter a Patient ID but it is not required and there is no validation of the Patient ID, meaning every entry is accepted, including an empty entry. (Default)
For Length	If selected, the Patient ID entered is checked for its length defined in the "Min./Max length case no." fields.

Table 6: Patient ID Options

4.7 QC Options

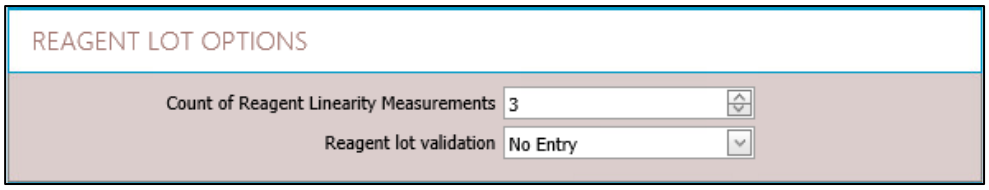


Explanation of the parameters

Count of QC Linearity Measurements	Defines the number of levels to use for a linearity test. Possible choice: 3, 4 or 5 levels Default: 5
Clear QC tests	Defines the method of automatic removal of QC tests from the device.
FiFo	First in – First out: If selected, QC tests will be stored until the buffer is full. The QC test first-in is automatically the first to be deleted. (Default)
Lockout	If selected, the device will be locked when the QC memory is full. Additional QC tests cannot be performed until archived results are deleted.

Table 7: QC Options

4.8 Reagent Lot Options

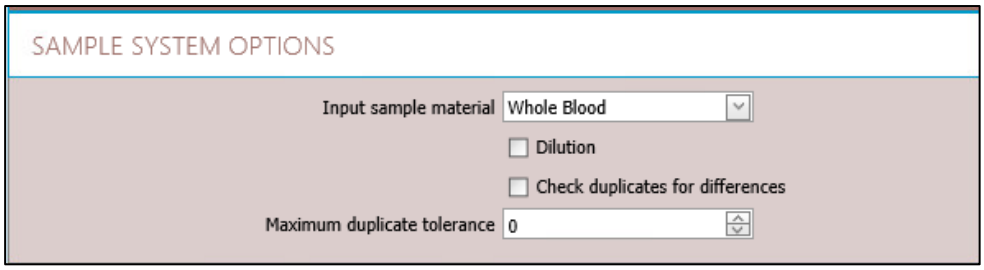


Explanation of the parameters

Count of Reagent Linearity Measurements	Define the number of cuvettes per level for a linearity test. Possible choice: 1 to 20 cuvettes Default: 3
Reagent lot validation	This is used to validate the reagent lot number that the user enters.
No entry	If selected, the input of a reagent lot number is not required, and no entry field is shown on the device. (Default)
For length	If selected, the input of a reagent lot number is required.
List and length	If selected, the reagent lot number entered is checked against the device's internal reagent list. If there is no match, the reagent lot number is rejected.

Table 8: Reagent Lot Options

4.9 Sample System Options

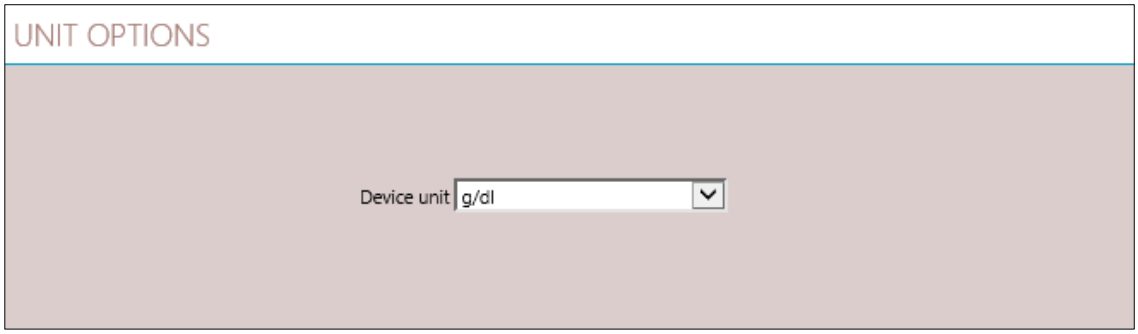


Explanation of the parameters

Input sample material Whole blood Plasma	**Glu 201 DM:** Defines if the glucose (Glu 201 DM) is obtained from whole blood or plasma.
Dilution	If selected, measurement is performed with a diluted sample. Whole Blood: The measuring range may be extended to 800 mg/dL (44.4 mmol/L) by dilution with saline, 1+1. Plasma Equivalent: The measuring range may be extended to 888 mg/dL (49.2 mmol/L) by dilution with saline, 1+1. **Note**: Refer to the User's Manual of the manufacturer for further information on the dilution function.
Check duplicates for differences	If the difference between two measurements (measurement and repetition measurement for the same patient) is greater than the Max. difference for duplicates (mg/dL), both measurements receive a comment before they are transferred to UniPOC.
Maximum duplicate tolerance	This is used to set the limit value for the "Check duplicates for differences" function.
mg/dl	**Glu 201 DM**: You can only enter this value in mg/dl even if the device unit is set to mmol/l. The device will change the unit to mmol/l internally and use it correctly.
g/l	**Hb 201 DM**: You can only enter this value in g/l even if the device unit is set to mmol/l. The device will change the unit to mmol/l internally and use it correctly.

Table 9: Sample System Options

4.10 Unit Options



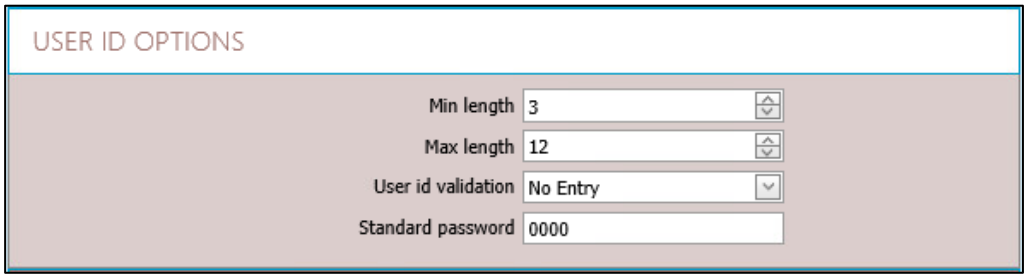
Explanation of the parameters

Device unit	Sets the unit of measure that the device will use to measure results. Depending on the device model, the following units for test results are available:
	Glu 201 DM:
mg/dl	Results are displayed in milligrams per deciliter.
mmol/l	Results are displayed in millimoles per liter.
	Hb 201 DM:
g/dl	Results are displayed in grams per deciliter.
g/l	Results are displayed in grams per liter.
mmol/l	Results are displayed in millimoles per liter.

Table 10: Unit Options

4.11 User ID Options

Note: User ID is more commonly known as the Operator ID.

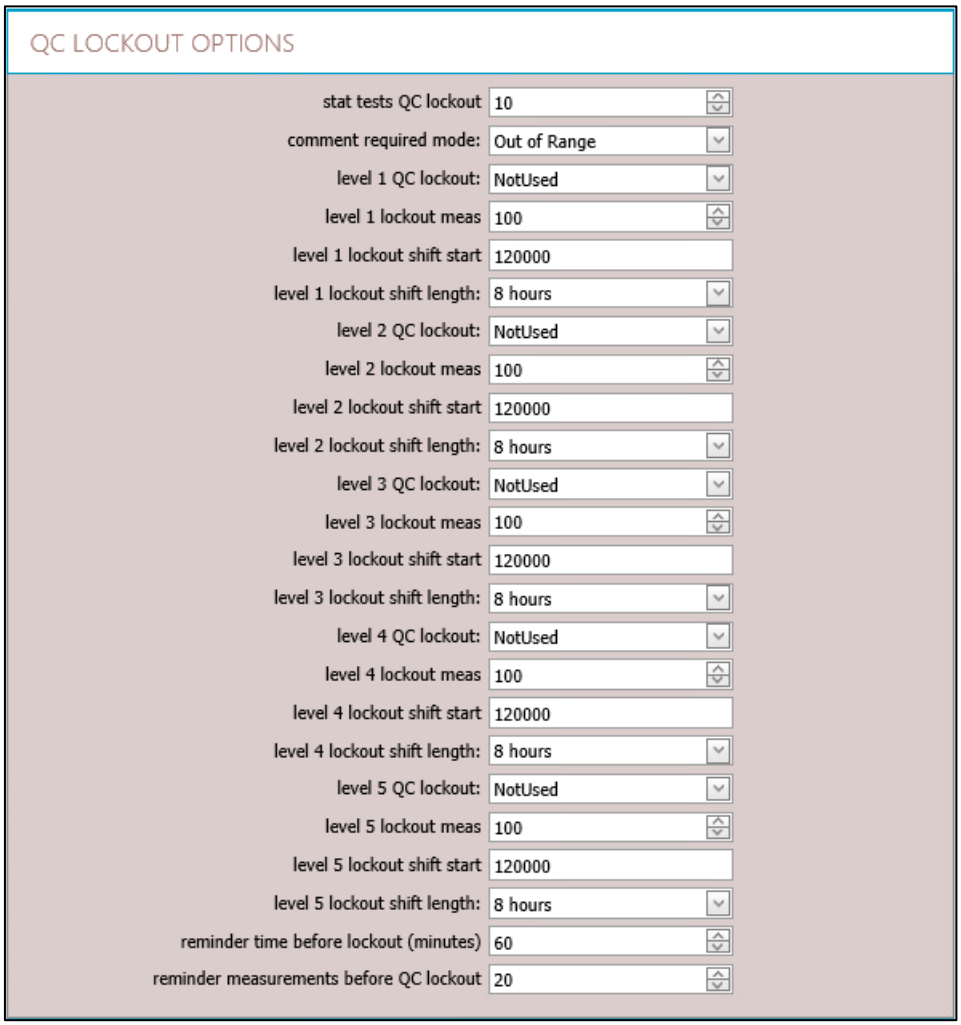


Explanation of the parameters

Min length	Used to check the minimum length of the Operator ID. The Min length must be smaller than or equal to the Max length. Possible choice: 1 to 15 characters Default: 3 characters
Max length	Used to check the maximum length of the Operator ID. Possible choice: 1 to 15 characters Default: 12 characters
User id validation No entry For length List and length	Mode to check the validity of the entered Operator ID. If selected, there is no field displayed on the device to enter an Operator ID. (Default) If selected, the Operator ID entered is checked for its length defined in the “Min./Max length user ID” fields. If selected, the program checks whether the Operator ID entered matches with the device’s internal operator list and if the Operator ID matches the length defined in the “Min./Max length” fields.
Standard password	Used to enter an alphanumeric password for the setup area. Possible length: 1 to 10 characters Default: 0000 **Note**: If no password is defined, the request to enter a password is skipped.

Table 11: User ID Options

4.12 QC Lockout Options



Explanation of the parameters

stat tests QC lockout	Number of emergency measurements that are possible after the device has been blocked because of a missing valid QC measurement (STAT-tests). After this number of emergency measurements, a valid QC measurement is required to do further patient measurements. Possible number of STAT-tests: 1 to 100 measurements Default: 10 measurements
comment required mode Out of range Never	This option defines whether a QC comment is required to be entered. If selected, a comment is required on all out-of-range QC results (Default). If selected, a comment is not required.
level 1 QC lockout Not used Shift Measurements	Type of monitoring of QCs on the device. If selected, QC Lockout is disabled. Tests can be performed at any time. (Default) If selected, a QC measurement is required in every shift. If selected, after a defined number of patient measurements, a QC measurement is required.

level 1 lockout meas	If “Measurements” is selected in “level 1 QC lockout”, define the number of patient measurements for level 1. Possible number of measurements: 2 to 200 measurements. Default: 100 measurements
level 1 lockout shift start	If Shift is selected for ‘level 1 QC lockout’, define shift start (Time of day). Default is 120000 (noon). Shift length is defined in ‘level 1 lockout shift length’ field.
level 1 lockout shift length	Define shift length for level 1. In every shift a QC measurement is required. Possible length of shift: 1, 2, 3, 4, 6, 8, 12 or 24 hours, as well as 2, 3, 4, 5, 6 or 7 days. The default is 8 hours.
level 2 QC lockout	Type of monitoring of QCs on the device.
Not used	If selected, QC Lockout is disabled. Tests can be performed at any time. (Default)
Shift	If selected, a QC measurement is required in every shift.
Measurements	If selected, after a defined number of patient measurements, a QC measurement is required.
level 2 lockout meas	If “Measurements” is selected in “level 2 QC lockout”, define the number of patient measurements for level 2. Possible number of measurements: 2 to 200 measurements Default: 100 measurements
level 2 lockout shift start	If Shift is selected for ‘level 2 QC lockout’, define shift start (Time of day). Default is 120000 (noon). Shift length is defined in ‘level 2 lockout shift length’ field.
level 2 lockout shift length	Define shift length for level 2. In every shift a QC measurement is required. Possible length of shift: 1, 2, 3, 4, 6, 8, 12 or 24 hours, as well as 2, 3, 4, 5, 6 or 7 days. The default is 8 hours.
level 3 QC lockout	Type of monitoring of QCs on the device.
Not used	If selected, QC Lockout is disabled. Tests can be performed at any time. (Default)
Shift	If selected, a QC measurement is required in every shift.
Measurements	If selected, after a defined number of patient measurements, a QC measurement is required.
level 3 lockout meas	If “Measurements” is selected in “level 3 QC lockout”, define the number of patient measurements for level 3. Possible number of measurements: 2 to 200 measurements Default: 100 measurements
level 3 lockout shift start	If Shift is selected for ‘level 3 QC lockout’, define shift start (Time of day). Default is 120000 (noon). Shift length is defined in ‘level 3 lockout shift length’ field.
level 3 lockout shift length	Define shift length for level 3. In every shift a QC measurement is required.

	Possible length of shift: 1, 2, 3, 4, 6, 8, 12 or 24 hours, as well as 2, 3, 4, 5, 6 or 7 days. The default is 8 hours.
level 4 QC lockout	Type of monitoring of QCs on the device.
Not used	If selected, QC Lockout is disabled. Tests can be performed at any time. (Default)
Shift	If selected, a QC measurement is required in every shift.
Measurements	If selected, after a defined number of patient measurements, a QC measurement is required.
level 4 lockout meas	If “Measurements” is selected in “level 4 QC lockout”, define the number of patient measurements for level 4. Possible number of measurements: 2 to 200 measurements Default: 100 measurements
level 4 lockout shift start	If Shift is selected for ‘level 4 QC lockout’, define shift start (Time of day). Default is 120000 (noon). Shift length is defined in ‘level 4 lockout shift length’ field.
level 4 lockout shift length	Define shift length for level 4. In every shift a QC measurement is required. Possible length of shift: 1, 2, 3, 4, 6, 8, 12 or 24 hours, as well as 2, 3, 4, 5, 6 or 7 days. The default is 8 hours.
level 5 QC lockout	Type of monitoring of QCs on the device.
Not used	If selected, QC Lockout is disabled. Tests can be performed at any time. (Default)
Shift	If selected, a QC measurement is required in every shift.
Measurements	If selected, after a defined number of patient measurements, a QC measurement is required.
level 5 lockout meas	If “Measurements” is selected in “level 5 QC lockout”, define the number of patient measurements for level 5. Possible number of measurements: 2 to 200 measurements Default: 100 measurements
level 5 lockout shift start	If Shift is selected for ‘level 5 QC lockout’, define shift start (Time of day). Default is 120000 (noon). Shift length is defined in ‘level 5 lockout shift length’ field.
level 5 lockout shift length	Define shift length for level 5. In every shift a QC measurement is required. Possible length of shift: 1, 2, 3, 4, 6, 8, 12 or 24 hours, as well as 2, 3, 4, 5, 6 or 7 days. The default is 8 hours.
reminder time before lockout	Defines the time in minutes before a notification appears on the device that a QC measurement is required. Possible choice: 0 to 240 minutes. The default is 60 minutes.
reminder measurements before QC lockout	Defines the number of measurements before a notification appears on the device that a QC measurement is required.

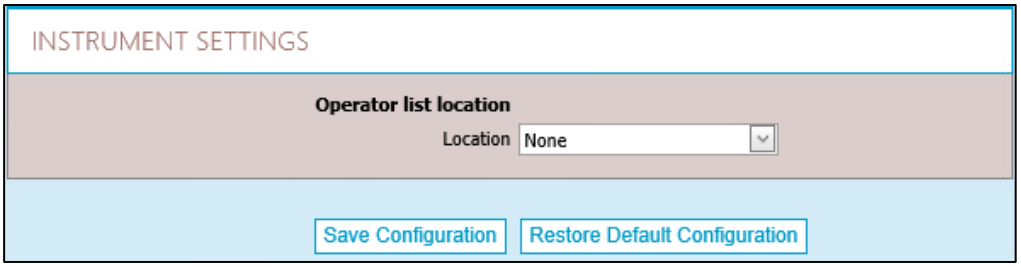
	Possible choice: 1 to 50 measurements. Default is 20 measurements. **Note**: The number has to be less than or equal to the number of measurements under the lockout measurement for the level.

Table 12: QC Lockout Options

4.13 Instrument Settings

Each operator is assigned to a home Location within Facility. Each Facility in the organization maintains a separate operator list. Instrument settings saved at the Facility level affect the Department and Location level as well. Settings saved at the Location level affect only the selected Location.

Note: *Instrument settings saved at the top level of the Tree affect all sub-levels.*



Explanation of the parameters

Operator list location	Choose from four location options to download the operator list.
Location	
Facility	The operator list will be downloaded to all instruments within the Facility. The list will contain all operators certified for the device whose home location is within the Facility.
Department	The operator list will be downloaded to all instruments assigned to location within the associated Department. The list will contain all operators certified for the instrument whose home location is within the Department.
Location	The operator list will be downloaded to all instruments assigned to a location. The list will contain all operators certified for the instrument with a matching home location.
None	The operator list will not be downloaded. (Default)

Table 13: Instrument Settings

5 Support

Contacting Siemens Healthineers Support

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

For assistance, contact POC Informatics Customer Service:

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