i-STAT® TECHNICAL BULLETIN

REPORTABLE RANGE CUSTOMIZATION ON THE i-STAT® 1 HANDHELD

OVERVIEW

As part of the on-going READi initiative (**R**esponds, **E**nhances, **A**nd **D**elivers **I**nnovation), Abbott Point of Care (APOC) has released a new Custom Reportable Range feature for the i-STAT 1 handheld. This new feature allows a system administrator (e.g. Point of Care Coordinator or Laboratory Administrator) to limit the displayed Reportable Range of each i-STAT analyte (except for ACT Celite or ACT Kaolin) on the i-STAT 1 handheld, on printouts, and in the electronic test record sent to the Data Manager.

The display ranges on the i-STAT 1 handheld are currently set to factory default values. While system administrators are not able to broaden the display range wider than the default values, this new Custom Reportable Range feature enables them to restrict the display range to custom values to meet clinical and regulatory needs. For example, system administrators may wish to limit the display ranges to values that have been verified using calibration verification materials.

GENERAL NOTES AND CONSIDERATIONS

1. The Custom Reportable Range feature is only available on the i-STAT 1 handheld, and not the i-STAT Portable Clinical Analyzer (i-STAT 200 series model).

2. In order to use the Custom Reportable Range feature, users must have the i-STAT 1 handheld and either the Central Data Station Version 5 or i-STAT/DE data management applications. <u>This feature is not customizable through the i-STAT 1 handheld keypad.</u>

3. **Changes to the reportable range may require a change to the LIS interface. Please contact your interface vendor.**

CAUTIONS

1. Narrowing reportable ranges from the default settings may reduce the clinical utility of test results. Therefore, ensure all Custom Reportable Ranges meet the clinical requirements for testing at your facility.

2. The Custom Reportable Range feature applies to the Patient, Proficiency, and Control test pathways on the i-STAT 1 handheld, but not to the Cal Ver pathway.

Abbott Point of Care

Abbott Point of Care Inc. • Abbott Park, IL 60064 • USA
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Note: When running controls, if the handheld is customized for User Defined Reportable Ranges and Auto Pass/Fail detection, the handheld will display the control result based upon the customized Reportable Range setting, but will base the Auto Pass/Fail determination on the measured value, irrespective of the Reportable Range settings.

3. Narrowing the reportable range of certain tests may affect the presentation of other dependent test results. In the table below, if any of the results in the first column are outside the reportable range, the dependent test results listed in the second column will be suppressed (displayed as <>).

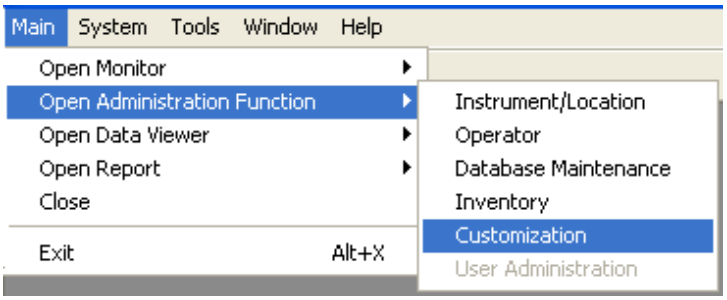
Reportable Range Limitations	
Test (Outside the Reportable Range)	**Dependent Suppressed Tests (displayed as <>)**
Na	K, Cl, BUN, Anion Gap, Hgb, Hct
Hct	Cl, BUN, Anion Gap, Hgb
PCO_2	TCO_2, Anion Gap, Base Excess, HCO_3, sO_2
pH	TCO_2, Anion Gap, Base Excess, HCO_3, sO_2
HCO_3	TCO_2, Anion Gap, Base Excess, sO_2
Cl	Anion Gap
K	Anion Gap
TCO_2	Anion Gap
PO_2	sO_2
PT/INR	PT WBT

MINIMUM SOFTWARE REQUIREMENTS

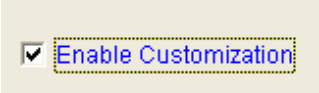
The minimum handheld and data management requirements for use of the Custom Reportable Range feature are summarized as follows:

System Component	Minimum Software Requirements
i-STAT 1 handheld	≥ JAMS132
Central Data Station Version 5.x	≥ Version 5.26a
i-STAT/DE	≥ Version 2.3

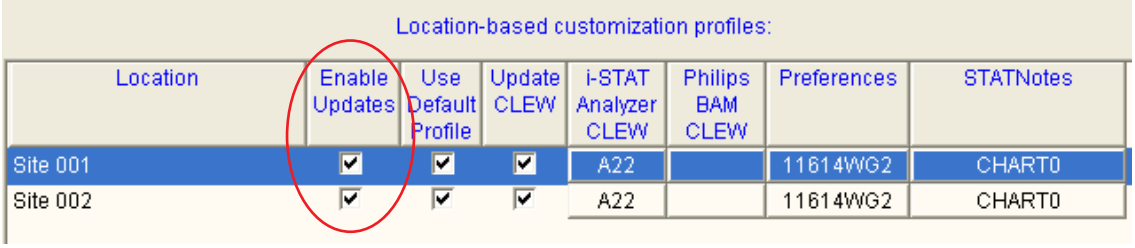
1. Click on **Main** → **Open Administration Function** → **Customization**



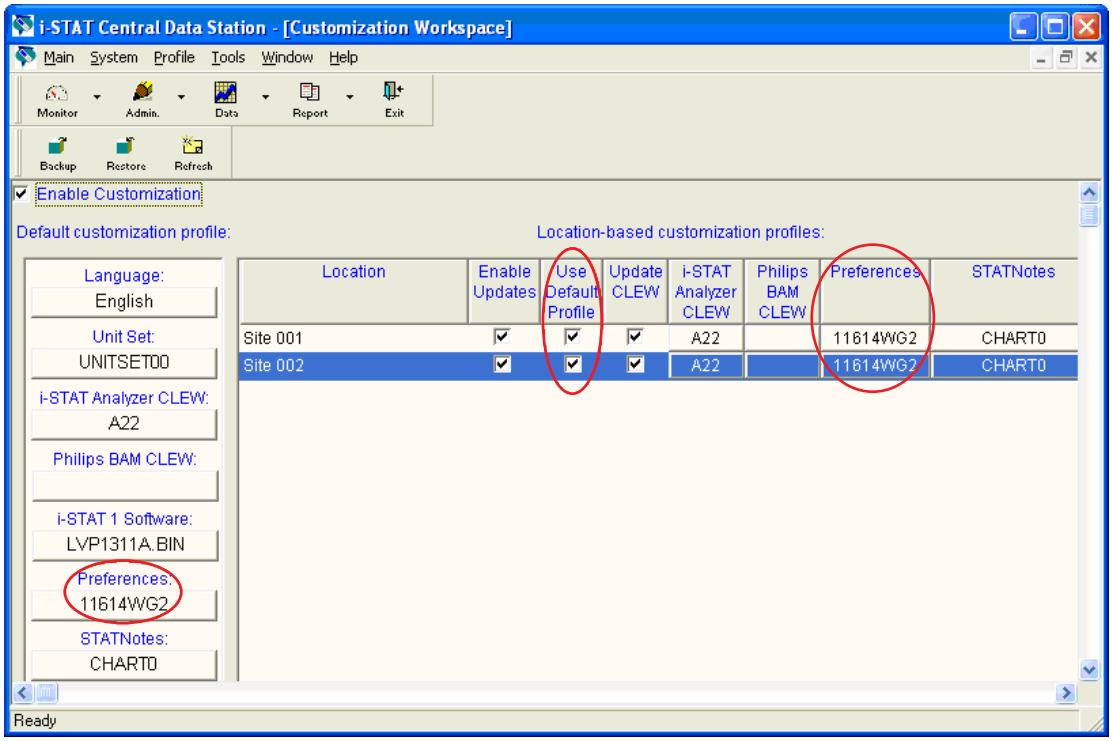
2. Type in your password and click **OK**. The default password is the word *istat*.
3. Make sure the **"Enable Customization"** box has a check mark in it.



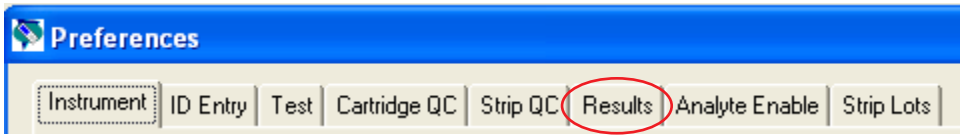
Also, make certain that the **Enable Updates** box is checked for the particular location to which the i-STAT 1 handheld is assigned.



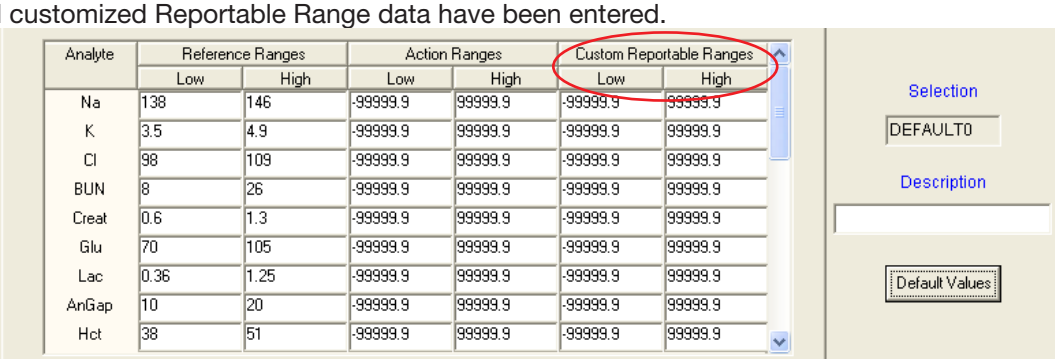
4. If the location where this handheld is assigned has a check mark under **Use Default Profile**, under the **Default customization profile:** column, double click the alphanumeric code under **Preferences**. Otherwise, double click the alphanumeric code under the **Preferences** column for the specific location to which this handheld is assigned.



5. Once the **Preferences** window opens, click on the **Results** tab.



6. In the **Custom Reportable Ranges** section, scroll down to the analyte row which you wish to customize, and click on the corresponding Low or High box for that analyte. Type in the customized Reportable Range value for the Low or High Reportable Range. Repeat step 6 until all customized Reportable Range data have been entered.



Analyte	Reference Ranges		Action Ranges		Custom Reportable Ranges	
	Low	High	Low	High	Low	High
Na	138	146	-99999.9	99999.9	-99999.9	99999.9
K	3.5	4.9	-99999.9	99999.9	-99999.9	99999.9
Cl	98	109	-99999.9	99999.9	-99999.9	99999.9
BUN	8	26	-99999.9	99999.9	-99999.9	99999.9
Creat	0.6	1.3	-99999.9	99999.9	-99999.9	99999.9
Glu	70	105	-99999.9	99999.9	-99999.9	99999.9
Lac	0.36	1.25	-99999.9	99999.9	-99999.9	99999.9
AnGap	10	20	-99999.9	99999.9	-99999.9	99999.9
Hct	38	51	-99999.9	99999.9	-99999.9	99999.9

Note 6.1: All analytes listed in the table can be customized, with the exception of ACT Celite and ACT Kaolin results.

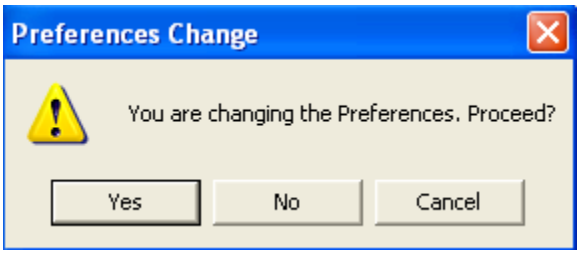
Note 6.2: Users may customize either the upper or lower limit of the Reportable Range, or both. Analytes in the Custom Reportable Ranges table that are left with the default cell value of -99999.9 or +99999.9 will continue to report the default Reportable Ranges listed in the Cartridge and Test Information Sheet section of the i-STAT 1 System Manual.

Note 6.3: Users may not broaden the displayed Reportable Range beyond the default values. If a value outside the default Reportable Range is entered, the handheld will continue to display the default Reportable Range values for that analyte.

Note 6.4: Users should enter range values consistent with the resolution of the analyte/unit being customized. For example, since sodium results are reported in whole numbers on the handheld, users should select customized range values in whole numbers.

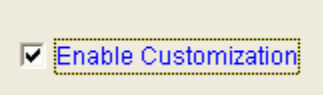
Note 6.5: Users are responsible for ensuring that the entered Reportable Range values are appropriate for the Unit Set in use in the handheld.

7. Click **OK** and answer **YES** to the question about changing the Preferences.

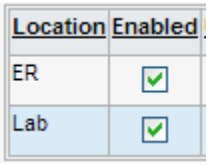


8. Download the handheld(s) to the CDS from a downloader in the location to which the handheld is assigned. This action will upload the chosen customization features into the handheld. Repeat step 8 for all handhelds from the same location to be customized. To customize handhelds from other locations for the same features, return to step 1.

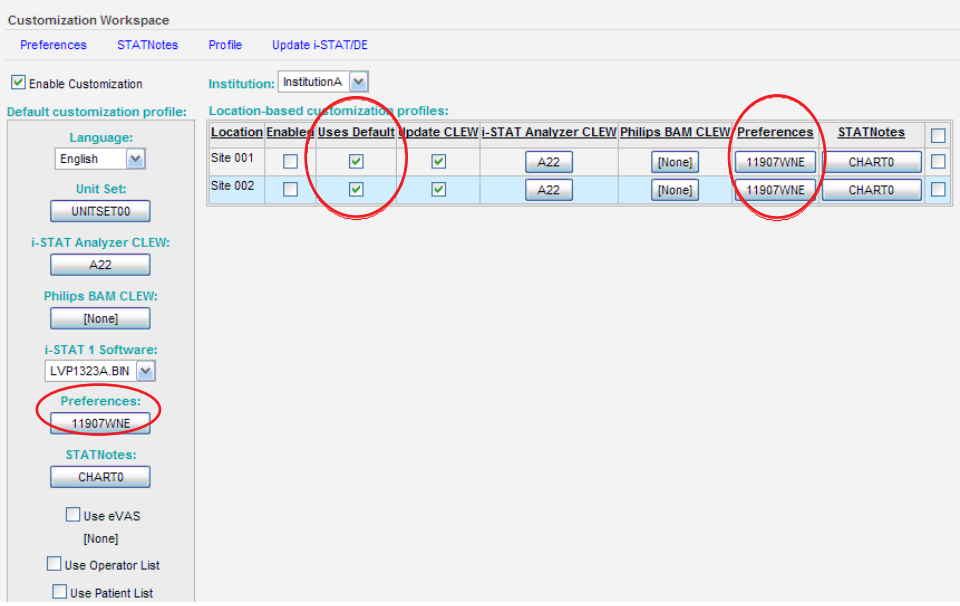
1. Access the Customization Workspace
    - RALS-Plus Users:
        - RALS-Plus application, pick i-STAT from the drop-down menu.
        - Click on **Device Customization**.
    - PrecisionWeb Users::
        - Enter the DE i-STAT Customization Workspace.
2. Make sure the **"Enable Customization"** box has a check mark in it.



Also, make certain that the **Enabled** box is checked for the particular location to which the i-STAT 1 handheld is assigned.



3. If the location where this handheld is assigned has a check mark under **Uses Default**, under the **Default customization profile:** column, double click the alphanumeric code under **Preferences**. Otherwise, double click the alphanumeric code under the **Preferences** column for the specific location to which this handheld is assigned.



4. Once the **Preferences** window opens, click on the **Results** tab.

5. In the **Custom Reportable Ranges** section, use the page numbers below the table to find the analyte row which you wish to customize, and click **Edit** at the right end of that row. Type in the customized Reportable Range value for the Low or High Reportable Range, and then click **Update**. Repeat step 5 until all customized Reportable Range data have been entered.

DEFAULT0

Description

Default Values

	Reference Ranges		Action Ranges		Custom Reportable Ranges		
Analyte	Low	High	Low	High	Low	High	
Na	138	146	-99999.9	99999.9	-99999.9	99999.9	Edit
K	3.5	4.9	-99999.9	99999.9	-99999.9	99999.9	Edit
Cl	98	109	-99999.9	99999.9	-99999.9	99999.9	Edit
BUN	8	26	-99999.9	99999.9	-99999.9	99999.9	Edit
Crea	0.6	1.3	-99999.9	99999.9	-99999.9	99999.9	Edit

Note 5.1: All analytes listed in the table can be customized, with the exception of ACT Celite and ACT Kaolin results.

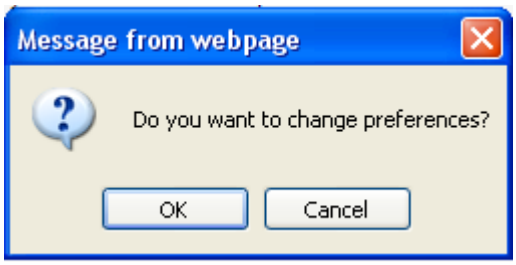
Note 5.2: Users may customize either the upper or lower limit of the Reportable Range, or both. Analytes in the Custom Reportable Ranges table that are left with the default cell value of **-**99999.9 or +99999.9 will continue to report the default Reportable Ranges listed in the Cartridge and Test Information Sheet section of the i-STAT 1 System Manual.

Note 5.3: Users **may not** broaden the displayed Reportable Range beyond the default values. If a value outside the default Reportable Range is entered, the handheld will continue to display the default Reportable Range values for that analyte.

Note 5.4: Users should enter range values consistent with the resolution of the analyte/unit being customized. For example, since sodium results are reported in whole numbers on the handheld, users should select customized range values in whole numbers.

Note 5.5: Users are responsible for ensuring that the entered Reportable Range values are appropriate for the Unit Set in use in the handheld.

6. Click **OK** and answer **OK** to the question about changing the Preferences.



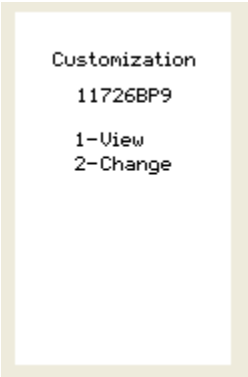
7. Download the handheld(s) to i-STAT/DE from a downloader in the location to which the handheld is assigned. This action will upload the chosen customization features into the handheld. Repeat step 7 for all handhelds from the same location to be customized. To customize handhelds from other locations for the same features, return to step 1.

CONFIRMING THAT THE CUSTOM REPORTABLE RANGES HAVE BEEN TRANSFERRED TO THE i-STAT 1 HANDHELD FROM CDS VERSION 5 OR i-STAT/DE

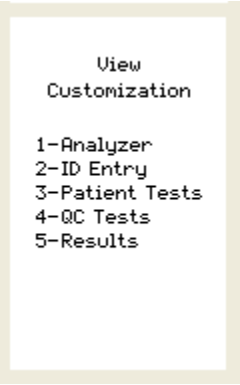
1. Power on the i-STAT 1 handheld and press **MENU** once to get to the Administration Menu.

2. Press **4 -Customization.**

3. Press **1-View.**.



4. Press **5-Results**.



5. Press **2-Display Ranges**.

6. View the displayed Reportable Ranges. If the analyte customized for Reportable Ranges does not appear on the first page of the screen, press the → key to find the page containing the analyte which has the customized display range and view the customized values. In the example below, the sodium Reportable Range has been customized to 110-170 mmol/L.

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