LIQUID QUALITY CONTROL SCHEDULE AND LOCKOUT CUSTOMIZATION ON THE i-STAT® 1 HANDHELD

OVERVIEW

As part of the on-going READi initiative (Responds, Enhances, And Delivers Innovation), Abbott Point of Care (APOC) has released a new Liquid Quality Schedule and Lockout feature for the i-STAT® 1 handheld. This new feature allows a system administrator (e.g. Point of Care Coordinator or Laboratory Administrator) to define a liquid quality control plan for their i-STAT 1 handhelds and enables them to enforce quality control (QC) compliance by invoking automatic lockout of patient and proficiency testing pathways if QC requirements in the plan are not fulfilled. By default, the feature is turned off.

This feature can be used in conjunction with the new Liquid QC Pass/Fail customization to automate and manage liquid quality control testing on the i-STAT 1 handheld. Please see the Technical Bulletin “Liquid Quality Control Pass/Fail Customization on the i-STAT 1 Handheld” for more information.

Functionality

Previously, system administrators had to “manually” manage and enforce QC requirements for the i-STAT 1 System, since no automated liquid QC lockouts were provided. With this new customization feature, the system administrator can define a customized QC plan that includes:

- which cartridge types and liquid QC fluids must be run,
- which cartridge types are enabled by running the liquid QC, and
- under what schedule the liquid QC is to be performed.

A. QC Profile

Using the Customization Workspace in the i-STAT CDS application or i-STAT/DE, the system administrator defines a number of QC cartridge sets, consisting of:

- a QC cartridge type (i.e. the cartridge type to be tested with specified liquid QC fluids during the QC procedure), as well as
- any number of dependent cartridge types (i.e. associated cartridge types that will be enabled by the analyzer if the QC requirements for a given cartridge set are met on that analyzer. A QC cartridge set is allowed to have zero dependent cartridges).

Note: A QC cartridge in one QC cartridge set cannot be a dependent cartridge in another QC cartridge set within the same schedule, but it can be a dependent cartridge in a QC cartridge set belonging to a different schedule.

The system administrator also creates a QC test profile by associating the defined cartridge set with up to six (6) specific QC fluids (i.e. specified types and levels of liquid control fluid). All APOC control fluids as well as three generic (user-defined) fluids are available for selection in the QC test profile.
B. QC Scheduling
The system administrator associates each QC test profile with at least one of three definable liquid QC schedules. Each schedule can accommodate up to eight (8) QC test profiles. The liquid QC schedule has an administrator-definable “Due Time” and “Grace Period”. The Due Time sets the time when QC Cycles (a test run in the Control pathway consisting of a QC cartridge and a corresponding QC fluid) will begin to count toward completing QC test profiles, i.e. when QC will become “due to start”. The Grace Period is the period of time, starting from the Due Time, during which the QC test profile must be completed before the corresponding cartridge set is locked out.

There are a number of options to allow flexibility in the liquid QC schedules. QC Due Times can be set to daily (every day), weekly (on a specified day of the week, e.g. every Tuesday) or monthly (on a specified day of the month e.g. every first Saturday) on selected months and at a defined time of the day. The Grace Period is set in hours, up to 23 hours for daily schedules, up to 167 hours for weekly schedules and up to 255 hours for monthly schedules. The minimum Grace Period is one hour for any schedule type.

C. QC Lockout
By defining a QC test profile with a specified schedule, the system administrator enables the lockout of the corresponding cartridge sets when the QC profile has not been satisfied within the Grace Period. “Lockout” means that the i-STAT 1 Patient and Proficiency pathways are disabled until the QC test profile is satisfied. A QC test profile is satisfied when at least one of each required QC cycle is run and is determined to have “passed”. Once a given cartridge set is locked out, its corresponding QC test cycles can still be run on the QC pathway, i.e. the QC pathway is never locked out.

The following important lockout rules apply:

1. Even if multiple Due Times have passed, the QC test profile will only need to be satisfied once to unlock testing (i.e. there is no “build up” of overdue QC cycles).

2. If liquid QC is due for a given schedule, and some of the required QC test profiles are successfully completed but others are not, then when the profile becomes due again, all of the QC test profiles within the schedule need to be re-run.

3. If a handheld is configured for information-first with cartridge lot enabled, when the cartridge lot number is scanned in the patient or proficiency pathways, if the cartridge type is locked out, the test cycle will not proceed.

4. A failed QC cycle in itself will not cause a cartridge set to be locked out. Lockout occurs only when a QC test profile is past the set grace period and has not been satisfied.

GENERAL NOTES AND CONSIDERATIONS

1. The Liquid QC Schedule and Lockout 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 create Liquid QC Schedules, users must have the i-STAT 1 handheld and either the Central Data Station Version 5 or i-STAT/DE data management applications. This feature is not customizable through the i-STAT 1 handheld keypad.
CAUTION

Use of the Liquid Quality Control Scheduler and Lockout customization features will result in handhelds being unavailable for patient testing when Quality Control requirements are not met.

MINIMUM SOFTWARE REQUIREMENTS

The minimum handheld and data management requirements for use of the Liquid Quality Control Schedule and Lockout customization features are summarized as follows:

<table>
<thead>
<tr>
<th>System Component</th>
<th>Minimum Software Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>i-STAT 1 handheld</td>
<td>≥ JAMS132</td>
</tr>
<tr>
<td>Central Data Station Version 5.x</td>
<td>≥ Version 5.26a</td>
</tr>
<tr>
<td>i-STAT/DE</td>
<td>≥ Version 2.3</td>
</tr>
</tbody>
</table>
Customizing Liquid QC Schedules on the i-STAT 1 Handheld Using CDS Version 5

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

2. Type in your password and click **OK**. The default password is the word *istat*. Note: Abbott Point of Care Inc. recommends changing the default password.

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 **Cartridge QC** tab.

6. Click on the **Liquid QC Settings** at the bottom of the screen.

7. In the Control Pass/Fail Determination section, click the radio button for the way in which you will determine the acceptability of liquid QC results:

   - **None**: Disables the QC Pass/Fail and QC Schedule feature.
   - **Automatic via EVAS**: choosing this option indicates that the handheld will automatically determine whether the liquid QC run passed or failed, based upon QC ranges contained on an electronic Value Assignment Sheet (eVAS) file downloaded into the i-STAT 1 handheld. Please see the Technical Bulletin “Liquid Quality Control Pass/Fail Customization on the i-STAT 1 Handheld” for instructions on activating and using this feature.
   - **Manual**: the user will manually compare the liquid QC results to a Value Assignment Sheet downloaded or printed from the Abbott Point of Care (APOC) website at [www.abbottpointofcare.com/valsheets](http://www.abbottpointofcare.com/valsheets) and indicate on the handheld whether the QC run passed or failed.

**Note 7.1:** The Manual Control Pass/Fail Determination feature is also customizable through the i-STAT 1 handheld keypad.

1. Power on the i-STAT 1 handheld and press **MENU** to get to the Administration Menu
2. Press **4 – Customization**
3. Press **2 – Change**
4. Type in your password and press **ENT** (If no password is set, just press **ENT**)
   **Note:** Abbott Point of Care Inc. recommends changing the default password.
5. Press **4 – QC Tests**
6. Press **2 – Cartridge QC**
7. Press **1** to set Pass / Fail Method
8. If you want users to enter a Comment Code when liquid QC results are in-range, out-of-range, or under both situations, check the appropriate box in the Control Test Settings section and then use the drop down menu to select whether entering the Comment Code is optional (Allow no Comment) or Required (Require Comment).

Note 8.1: Comment Code options can only be selected if one of the Control Pass/Fail Determination methods has been selected (Step 7).

Note 8.2: The Control Test Settings feature is also customizable through the i-STAT 1 handheld keypad.

1. Power on the i-STAT 1 handheld and press MENU to get to the Administration Menu
2. Press 4 – Customization
3. Press 2 – Change
4. Type in your password and press ENT (If no password is set, just press ENT)
   Note: Abbott Point of Care Inc. recommends changing the default password.
5. Press 4 – QC Tests
6. Press 2 – Cartridge QC
7. Press 2 to set Comment Codes for in range results or press 3 to set Comment Codes for out of range results

9. Select the way in which you would like control results to be displayed.

   • Numeric: liquid QC results are displayed in numeric format
   • Suppressed: the following symbol “< >” is displayed next to each liquid QC test name in place of the quantitative (numeric) results.

Note 9.1: The “Suppressed” option should only be chosen if “Automatic via EVAS” is chosen for the liquid QC Pass/Fail Determination.

Note 9.2: The Control Results Display Format is also customizable through the i-STAT 1 handheld keypad.

1. Power on the i-STAT 1 handheld and press MENU to get to the Administration Menu
2. Press 4 – Customization
3. Press 2 – Change
4. Type in your password and press ENT (If no password is set, just press ENT)
   Note: Abbott Point of Care Inc. recommends changing the default password.
5. Press 4 – QC Tests
6. Press 2 – Cartridge QC
7. Press 4 to set Result Format
10. Select the method in which control lot number information will be entered into the handheld.

- Scan or Enter: allows the user the option of manually entering the liquid QC lot information into the handheld, or scanning it from the barcode on the quality control vial being tested.
- Scan only: the fluid lot information must be entered by scanning the barcode on the control vial being tested.

**Note 10.1:** The APOC Fluid Lot Entry Method is also customizable through the i-STAT 1 handheld keypad.

1. Power on the i-STAT 1 handheld and press **MENU** to get to the Administration Menu
2. Press **4 – Customization**
3. Press **2 – Change**
4. Type in your password and press **ENT** (If no password is set, just press **ENT**)
   
   *Note: Abbott Point of Care Inc. recommends changing the default password.*
5. Press **4 – QC Tests**
6. Press **2 – Cartridge QC**
7. Press **5** to set APOC Fluid Lot Method

11. To set up a Liquid QC Schedule, click on the **Liquid QC Schedule 1** tab at the bottom of the screen.

12. Select the frequency at which you want liquid QC to be run under this schedule.

- Off: Disables the selected QC Schedule
- Daily
- Weekly: A particular day of the week (e.g. every Monday)
- Monthly: A particular day of the month (e.g. the second Tuesday of the month).

13. Enter the QC Time. The QC Time sets the time when QC Cycles (a test run in the Control pathway consisting of a QC cartridge and a corresponding QC fluid) will begin to count toward satisfying the QC test profiles, i.e. when QC will become “due to start”.

   **Note 13.1:** Use the 24 hour clock designation to indicate the time when QC is due. For example, if QC will be due at 2 pm, enter 14:00 for the time.
14. The Grace Period is the period of time, starting from the Due Time, during which the QC test profile must be completed before the corresponding cartridge set is locked out.

Enter the Grace Period in hours:

- up to 23 hours for daily schedules,
- up to 167 hours for weekly schedules, and
- up to 255 hours for monthly schedules.

The minimum Grace Period is one hour for any schedule type.

15. Select the months of the year in which you want this schedule to apply.

- All months
- Selected months. Check the box next to the months to which you want this schedule to apply.

16. To define the Cartridge QC Profile, click **Edit** to the right of the cartridge and fluid lot columns.

The Cartridge Liquid QC Scheduling window will open.
17. Select the QC cartridge type from the drop-down menu. The QC cartridge is the cartridge type to be tested with specified liquid QC fluids during the QC procedure.

![QC Cartridge Selection](image)

**Note 17.1:** Selecting [None] will cease your ability to proceed through the remaining QC Schedule settings.

18. In the Dependent Cartridges section, check the box(es) next to any associated cartridge types that will be enabled by the handheld if the QC requirements for a given cartridge set are met on that handheld.

![Dependent Cartridges](image)

19. In the Cartridge QC Fluids section, select up to six (6) types and levels of control fluid that will be required to be run on the handheld during this QC cartridge schedule timeframe and click **OK**.

![Cartridge QC Fluids](image)

**Note 19.1:** All i-STAT control fluid types and levels are listed in the drop-down menu, along with three (3) generic user-defined fluids. For a list of the control fluids and their corresponding drop-down menu titles, see the Appendix at the end of this Technical Bulletin.

20. The Cartridge QC profile will then appear on the Liquid QC 1 tab page.

![Cartridge QC Profile](image)

Seven (7) additional Cartridge QC profiles can be created for this Liquid QC Schedule. To create additional Cartridge QC profiles for this schedule, click on **Edit** to the right of the blank Cartridge QC profile and proceed with steps 17-19 above.

21. Once all profiles have been created for a Liquid QC Schedule, additional Liquid QC Schedules can be created by clicking on the next numbered Liquid QC Schedule tab at the bottom of the Cartridge QC tab page. Follow steps 12-20 above to create the additional schedules. Up to three (3) schedules can be created.
22. Once all schedules have been created and defined, click **OK** and answer **YES** to the question about changing the Preferences.

![Preferences Change dialog box]

23. 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 23 for all handhelds from the same location to be customized. To customize handhelds from other locations for the same features, return to step 1 of this section.
Customizing Liquid Quality Schedule and Lockout Features on the i-STAT 1 Handheld Using i-STAT/DE

1. Access the Customization Workspace
   - RALS-Plus Users:
     o Within the RALS-Plus application, pick i-STAT from the drop-down menu.
     o Click on Device Customization.
   - PrecisionWeb Users::
     o Enter the DE i-STAT Customization Workspace.

2. Make sure the “Enable Customization” box has a check mark in it.

   ![Enable Customization]

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

   ![Location Enabled]

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 **Cartridge QC** tab.

5. Click on **Liquid QC Settings** at the top of the screen.

6. In the Control Pass/Fail Determination section, click the radio button for the way in which you will determine the acceptability of liquid QC results:

   - **None**: Disables the QC Pass/Fail and QC Schedule feature.
   - **Auto via eVAS**: choosing this option indicates that the handheld will automatically determine whether the liquid QC run passed or failed, based upon QC ranges contained on an electronic Value Assignment Sheet (eVAS) file downloaded into the i-STAT 1 handheld. Please see the Technical Bulletin “Liquid Quality Control Pass/Fail Customization on the i-STAT 1 Handheld” for instructions on activating this feature.
   - **Manual**: the user will manually compare the liquid QC results to a Value Assignment Sheet downloaded or printed from the Abbott Point of Care (APOC) website at [www.abbottpointofcare.com/valsheets](http://www.abbottpointofcare.com/valsheets) and indicate on the handheld whether the QC run passed or failed.

   **Note 6.1**: The Manual Control Pass/Fail Determination feature is also customizable through the i-STAT 1 handheld keypad.

   1. Power on the i-STAT 1 handheld and press **MENU** to get to the Administration Menu
   2. Press **4 – Customization**
   3. Press **2 – Change**
   4. Type in your password and press **ENT** (If no password is set, just press **ENT**)  
      Note: Abbott Point of Care Inc. recommends changing the default password.
   5. Press **4 – QC Tests**
   6. Press **2 – Cartridge QC**
   7. Press **1** to set Pass / Fail Method

7. If you want users to enter a Comment Code when liquid QC results are in-range, out-of-range, or under both situations, check the appropriate box(es) in the Control Test Settings section and then use the drop down menu to select whether entering the Comment Code is optional (Allow no Comment) or Required (Require Comment).

   **Note 7.1**: Comment Code options can only be selected if one of the Control Pass/Fail Determination methods has been selected
Note 7.2: The Control Test Settings feature is also customizable through the i-STAT 1 handheld keypad.

1. Power on the i-STAT 1 handheld and press MENU to get to the Administration Menu
2. Press 4 – Customization
3. Press 2 – Change
4. Type in your password and press ENT (If no password is set, just press ENT)
   Note: Abbott Point of Care Inc. recommends changing the default password.
5. Press 4 – QC Tests
6. Press 2 – Cartridge QC
7. Press 2 to set Comment Codes for in range results or press 3 to set Comment Codes for out of range results
8. Select the way in which you would like control results to be displayed.

   ![Control Results Display Format](image)

   - Numeric: liquid QC results are displayed in numeric format
   - Suppressed: the following symbol “< >” is displayed next to each liquid QC test name in place of the quantitative (numeric) results.

Note 8.1: The “Suppressed” option should only be chosen if “Auto via eVAS” is chosen for the liquid QC Pass/Fail Determination.

Note 8.2: The Control Results Display Format feature is also customizable through the i-STAT 1 handheld keypad.

1. Power on the i-STAT 1 handheld and press MENU to get to the Administration Menu
2. Press 4 – Customization
3. Press 2 – Change
4. Type in your password and press ENT (If no password is set, just press ENT)
   Note: Abbott Point of Care Inc. recommends changing the default password.
5. Press 4 – QC Tests
6. Press 2 – Cartridge QC
7. Press 4 to set Result Format
8. Select the method in which control lot number information will be entered into the handheld.

   ![APOC Fluid Lot Entry Method](image)

   - Scan or Enter: allows the user the option of manually entering the liquid QC lot information into the handheld, or scanning it from the barcode on the quality control vial being tested.
   - Scan only: the fluid lot information must be entered by scanning the barcode on the control vial being tested.
**Note 9.1:** The APOC Fluid Lot Entry Method is also customizable through the i-STAT 1 handheld keypad.

1. Power on the i-STAT 1 handheld and press **MENU** to get to the Administration Menu
2. Press **4 – Customization**
3. Press **2 – Change**
4. Type in your password and press ENT (If no password is set, just press **ENT**)
   
   Note: Abbott Point of Care Inc. recommends changing the default password.
5. Press **4 – QC Tests**
6. Press **2 – Cartridge QC**
7. Press **5** to set APOC Fluid Lot Method

10. To set up a Liquid QC Schedule, click on the **Liquid QC Schedule 1** tab at the top of the screen.

11. Select the frequency at which you want liquid QC to be run under this schedule.

   ![QC Frequency](image)

   - Off: Disables the selected QC Schedule
   - Daily
   - A particular day of the week (e.g. every Monday)
   - A particular day of the month (e.g. the second Tuesday of the month).

12. Select the months of the year in which you want this schedule to apply.

   ![Apply QC schedule to](image)

   - All months
   - Selected months. Check the box next to the months to which you want this schedule to apply.

13. Enter the QC Time. The QC Time sets the time when QC Cycles (a test run in the Control pathway consisting of a QC cartridge and a corresponding QC fluid) will begin to count toward satisfying the QC test profiles, i.e. when QC will become “due to start”.

   ![QC Time](image)

   **Note 13.1:** Use the 24 hour clock designation to indicate the time when QC is due. For example, if QC will be due at 2 pm, enter 14:00 for the time.
14. The Grace Period is the period of time, starting from the Due Time, during which the QC test profile must be completed before the corresponding cartridge set is locked out.

Enter the Grace Period in hours:

- up to 23 hours for daily schedules,
- up to 167 hours for weekly schedules, and
- up to 255 hours for monthly schedules.

The minimum Grace Period is one hour for any schedule type.

15. To define the Cartridge QC Profile, click **Add a new QC group row...** at the bottom of the screen. The Cartridge QC Profile box will open.

16. Select the QC cartridge type from the drop-down menu. The QC cartridge is the cartridge type to be tested with specified liquid QC fluids during the QC procedure.

**Note16.1:** Selecting [None] will cease your ability to proceed through the remaining QC Schedule settings.

17. In the Dependent Cartridges section, click **Edit.** Check the box(es) next to any associated cartridge types that will be enabled by the handheld if the QC requirements for a given cartridge set are met on that handheld and then click **Update.**
18. In the Fluids section, select up to six (6) types and levels of control fluid that will be required to be run on the handheld during this QC cartridge schedule timeframe and click **Update**.

<table>
<thead>
<tr>
<th>Fluid 1</th>
<th>Fluid 2</th>
<th>Fluid 3</th>
<th>Fluid 4</th>
<th>Fluid 5</th>
<th>Fluid 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>APOC Chem BL1</td>
<td>APOC Chem BL2</td>
<td>APOC Hot L1</td>
<td>APOC Chem BL3</td>
<td>[None]</td>
<td>[None]</td>
</tr>
</tbody>
</table>

**Note 18.1:** All i-STAT control fluid types and levels are listed in the drop-down menu, along with three (3) generic user-defined fluids. For a list of the control fluids and their corresponding drop-down menu titles, see the Appendix at the end of this Technical Bulletin.

19. The Cartridge QC profile will then appear on the Cartridge QC tab page.

<table>
<thead>
<tr>
<th>QC Cartridge</th>
<th>Dependent Cartridges</th>
<th>Fluids</th>
</tr>
</thead>
</table>

Seven (7) additional Cartridge QC profiles can be created for this Liquid QC Schedule. To create additional Cartridge QC profiles for this schedule, click **Add a new QC Group row...** and proceed with steps 16-18 above.

20. Once all profiles have been created for a Liquid QC Schedule, additional Liquid QC Schedules can be created by clicking on the next numbered Liquid QC Schedule tab at the top of the Cartridge QC tab page. Follow steps 11-19 above to create the additional schedules. Up to three (3) Liquid QC Schedules can be created.

21. Once all schedules have been created and defined, click **OK** and answer **OK** to the question about changing the Preferences.

22. Download the handheld(s) to the 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 22 for all handhelds from the same location to be customized. To customize handhelds from other locations for the same features, return to step 1 of this section.
New i-STAT 1 Handheld Display Screens for the Liquid QC Schedule and Lockout Customization Features

After customizing the i-STAT 1 handheld for the new Liquid QC Schedule and Lockout customization features, users may encounter some new handheld display screens.

**Test Menu:** When the On/Off key is pressed on the handheld, and the Test Menu appears, the handheld will now display one of four messages at the bottom of the screen:

1. “Next i-STAT QC (Date)”: This message will appear if users have been compliant in running all liquid QC schedules in this handheld within the customized timeframe. It indicates the upcoming date and time when the grace period begins for the next scheduled liquid QC is due.

![Next i-STAT QC (Date) message]

2. “i-STAT QC Due – Complete Before (Date)”: This message will appear to remind users that the grace period has begun for one of the liquid QC schedules, and the date and time before which all requirements under that schedule must be completed before analytes are disabled.

![i-STAT QC Due – Complete Before (Date) message]

3. “QC Past Due – Not All Cartridges are Active for Testing”: This message appears if the liquid QC requirements for a schedule were not completed within the grace period. Some cartridges will be inactive until the schedule requirements are satisfied.

![QC Past Due – Not All Cartridges are Active for Testing message]
**Note 3.1:** If this message appears, users can press the listed number on the handheld keypad to display which cartridges are currently inactive.

4. “i-STAT QC Past Due – Cartridge Testing Disabled”: This message will appear if the liquid QC requirements for a schedule were not completed within the grace period, and if the handheld is configured for “non-information-first” or “information-first with cartridge lot number disabled”. In these scenarios, if any cartridge type is locked out, all cartridge types are disabled.

<table>
<thead>
<tr>
<th>Inactive Cartridge Type</th>
<th>Inactive Cartridge Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>E41</td>
<td>C44</td>
</tr>
<tr>
<td>C41</td>
<td>C36</td>
</tr>
<tr>
<td>G1</td>
<td>G6</td>
</tr>
<tr>
<td>C1</td>
<td>C1a</td>
</tr>
</tbody>
</table>

**Note:** When the handheld is customized for multiple liquid QC schedules, there is a hierarchy which determines which of the four messages above will appear on the Test Menu display. The messages will appear in this order:

- i-STAT QC Past Due – Cartridge Testing Disabled
- QC Past Due – Not All Cartridges Are Active For Testing
- i-STAT QC Due – Complete Before (Date)
- Next i-STAT QC (Date)

**Quality Tests Menu:** When testing liquid QC material and the user has selected 1-Control in the Quality Tests Menu on the handheld, a new “Select QC Event” screen will then appear on the display.
The user has the following options to choose from on this screen:

- **1-Unscheduled:** selecting this option allows the user to perform a liquid QC run which will not be applied to a customized liquid QC schedule(s).

- **2-Schedule 1, 3-Schedule 2 (if applicable), or 4-Schedule 3 (if applicable):** selecting one of these options will allow the user to apply the liquid QC run to one of the customized schedules.

If the user presses 2, 3 (if applicable), or 4 (if applicable) on this screen, they will then be taken to a screen where they can select the cartridge type to be run.

**Note:** The number in parentheses next to the cartridge name indicates how many control fluids remaining to be run on cartridges of that type and pass in order to satisfy the QC Profile.

Once the cartridge type is selected, the user is taken to a screen to select the fluid type being run.

**Manual Pass/Fail Determination:** Once the results appear on the screen, if the handheld is customized for Manual Control Pass/Fail Determination, the user will then be prompted to select an outcome as to whether the liquid QC run passed or failed. The user would check the results against the appropriate Value Assignment Sheet, determine if the run passed, or failed, and then press the appropriate key and answer yes to the resulting question in order to store the pass/fail record in the handheld.

**“Automatic via EVAS” Pass/Fail Determination:** Examples of handheld display screens when the handheld Control Pass/Fail Determination customization is set to “Automatic via EVAS” can be found in the Technical Bulletin: “Liquid Quality Control Pass/Fail Customization on the i-STAT 1 Handheld”.
APPENDIX: LIQUID CONTROL LOT ABBREVIATIONS

The table below lists each i-STAT Control type and corresponding abbreviation used in the Cartridge QC Fluids drop down menus in the Customization Workspace.

<table>
<thead>
<tr>
<th>Control Name</th>
<th>Control Customization Abbreviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>i-STAT cTnI Control Level 1</td>
<td>APOC cTnI L1</td>
</tr>
<tr>
<td>i-STAT cTnI Control Level 2</td>
<td>APOC cTnI L2</td>
</tr>
<tr>
<td>i-STAT cTnI Control Level 3</td>
<td>APOC cTnI L3</td>
</tr>
<tr>
<td>i-STAT BNP Level 1 Control</td>
<td>APOC BNP L1</td>
</tr>
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