i-STAT/DE v2.11
USER GUIDE

Abbott

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Table of Contents

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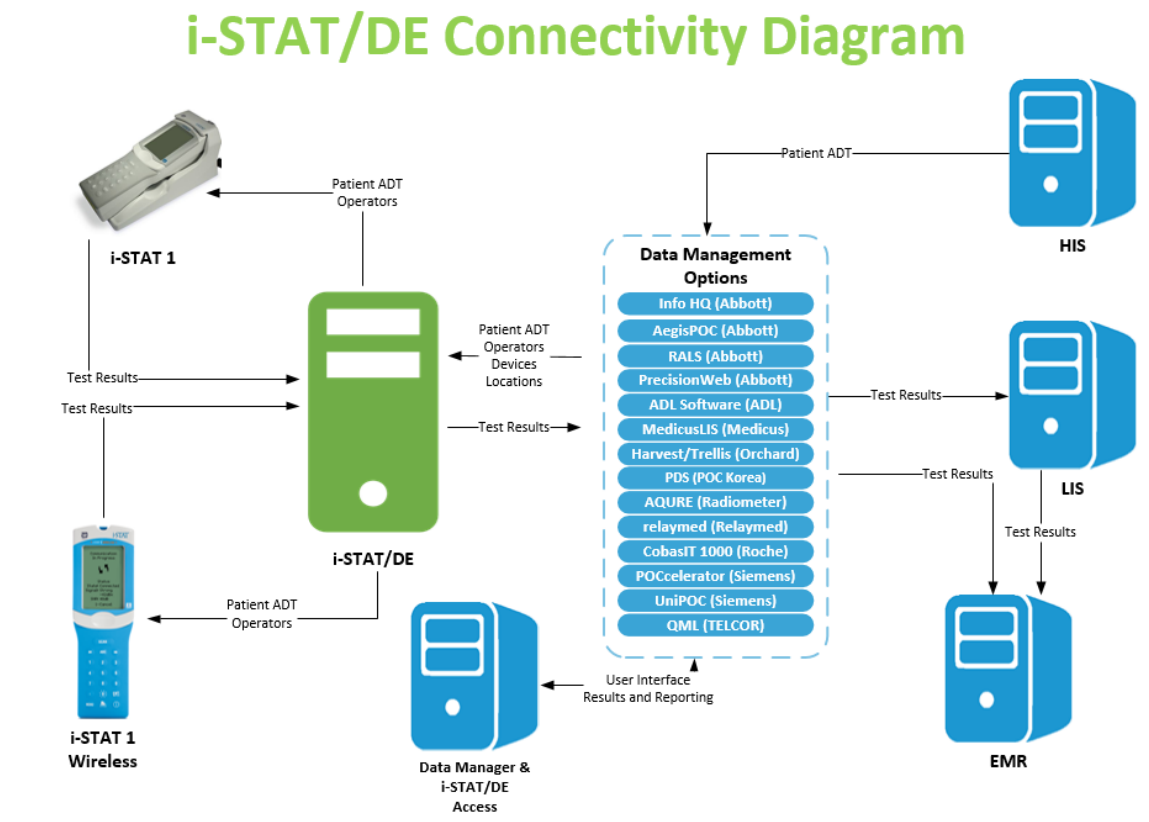
Preface

This reference contains instructions on how to install, configure, and use the Abbott Point of Care (APOC) i-STAT/DE system.

Intended use

i-STAT/DE is a web-based software application that enables communication between i-STAT 1 devices and Info HQ (Abbott's point-of-care data management system) or another vendor's data management system.



For in vitro diagnostic use only.

Not all products available in all markets. Check with your local Abbott Point of Care Representative for availability.

About this manual

This manual is organized as follows:

Section	Content
1. Introduction	Information on installation planning, hardware and software requirements, and technical considerations.
2. Installing and Configuring	Using the i-STAT/DE setup utility, configuration options, and upgrading i-STAT/DE software.
3. Customization Workspace	Information on customization profile options, software updates, uploading an eVAS file, Positive Patient Identification (PPID) feature and STATNotes feature.
4. Troubleshooting	Symptoms of and solutions for problems with installing/ upgrading i-STAT/DE webpages and customization.
5. Support	Contact information and support data collected for i-STAT/DE software.
Appendix	Quality check code categorization table for data management reports.

Release Notes

i-STAT/DE version 2.11 includes these enhancements:

- System allowed an Active Directory View-only user to edit certain customization settings under specific conditions – updated the edit capability to be reserved for Administrator-type users.
- System allows authentication of users in nested Active Directory groups.
- System allows user to enable search in nested groups during the configuration of Active Directory authentication.
- Includes a fix that allows multiple browser windows of authenticated applications to be opened on a single computer at the same time without opening a new instance of the browser application - alleviating possible conflicts between different applications or different windows for the same application (i.e. i-STAT/DE Customization and System pages can be opened at the same time on a single PC in the same browser application).
- Analyte and cartridge name change from Tnl-Nx to hs-Tnl in multiple tabs throughout Preference pages.
- Update PTplus control fluid names in the Cartridge QC tab within Preferences.
- Update system to be compatible with Google Chrome web browser.
- Update to hardware, software and Operating System requirements and prerequisites to remove Microsoft Windows 7, Windows Server 2008, Windows Server 2008 R2 and update minimum requirements.
- System allows enabling HTTPS when performing a new installation of i-STAT/DE. The setup utility provides the option to configure the i-STAT/DE web pages to utilize HTTPS using an SSL certificate already installed by the user. HTTPS support is available with Windows 10 and Windows Server 2016 operating systems.

1. Introduction

i-STAT/DE is the communication and customization software for the i-STAT 1 device. A web-based application, i-STAT/DE manages communication between a data management system, such as Info HQ, and i-STAT 1 devices.

This guide includes information for installing i-STAT/DE, selecting options to customize it, and upgrading software.

Note: The i-STAT/DE software is installed and updated using the setup utility contained on the i-STAT/DE CD-ROM. The setup utility can be run only by a user who is a local administrator on the machine on which the i-STAT/DE software is being installed or updated.

1.1 Technical Specifications

Before installing i-STAT/DE, review the following requirements.

Computing Environment

Hardware	Recommended
Architecture:	IBM-Compatible
Processor:	Speed: 2 GHz or faster
Memory:	4 GB RAM or greater
Disk drives:	• Hard drive: 100 GB or larger • CD-ROM or other means to transfer large files to the server
Network Interface Card (NIC):	10/100 Ethernet NIC

Software Requirements

Component	Requirement
Operating System[1]	• Windows Server 2012 R2 Standard Edition • Windows Server 2016 Standard Edition • Windows 10 64-bit including N and KN variants
Data Protection	Anti-virus software (not included)
System Maintenance	Disk defragmenting tool (not included)
Browser	• Windows Internet Explorer 11 • Google Chrome

[1] Operating system must be provided by user.

Client hardware and software requirements

The i-STAT/DE software is browser-based. Any Windows-based PC or workstation that has access to the organization's LAN/WAN can access i-STAT/DE.

1.2 Installation Planning

Before installing i-STAT/DE software, review the following information:

Additional Prerequisites

On all the Windows versions discussed in Software Requirements, i-STAT/DE also requires the following to be installed:

- Microsoft Internet Information Services (IIS)
- Compatible web browser, compatible with your version of Windows with 128-bit encryption. Refer to Section 1.1 Technical Specifications for browser compatibility.
- Microsoft .NET Framework version 4
- Use of Windows Update mechanism and apply all applicable roll-ups, patches and updates.
- If the option to configure the i-STAT/DE web pages to use HTTPS will be utilized, the URL Rewrite Module for IIS (https://www.iis.net/downloads/microsoft/url-rewrite) must also be installed.

Windows Server 2016 Standard Edition

Using the **Add Roles and Features Wizard** of **Server Manager:**

- Add the following Roles:
    - Under **Web Server (IIS)→Web Server→Common HTTP Features**
        - Default Document
        - Directory Browsing
        - HTTP Errors
        - Static Content
    - Under **Web Server (IIS)→Web Server→Health and Diagnostics**
        - HTTP Logging
    - Under **Web Server (IIS)→Web Server→Performance**
        - Static Content Compression
    - Under **Web Server (IIS)→Web Server→Security**
        - Request Filtering
    - Under **Web Server (IIS)→Web Server→Application Development**
        - .NET Extensibility 4.x
        - ASP.NET 4.x
        - ISAPI Extensions
        - ISAPI Filters
    - Under **Web Server (IIS)→Management Tools**
        - IIS Management Console
    - Under **Web Server (IIS)→Web Server→IIS 6 Management Compatibility**
        - IIS 6 Metabase Compatibility
- Add the following Features:
    - Under **.NET Framework 4.x Features**
        - .NET Framework 4.x
        - ASP.NET 4.x

Windows 10 64-bit

The following must be installed through Windows Features accessed via
Control Panel→Programs and Features→Turn Windows Features on or off:

- Under **Internet Information Services→Web Management Tools**
  - IIS Management Console
  - IIS Management Scripts and Tools
  - IIS Management Service
- Under **Internet Information Services→Web Management Tools→IIS 6 Management Compatibility**:
  - IIS Metabase and IIS 6 configuration compatibility
- Under **Internet Information Services→World Wide Web Services→Application Development Features**:
  - ASP.NET 4 (checking this will check other items automatically; leave those other items checked)
- Under **Internet Information Services→World Wide Web Services→Common HTTP Features**:
  - Default Document
  - Directory Browsing
  - HTTP Errors
  - Static Content

Windows Server 2012 R2 Standard Edition

The following server roles must be installed through the **Add Roles and Features** wizard (accessed via **Control Panel→Programs and Features→Turn Windows Features on or off.** Then click **Next >** twice):

- Under **Web Server (IIS)→Web Server→Common HTTP Features**:
  - Default Document
  - Directory Browsing
  - HTTP Errors
  - Static Content
- Under **Web Server (IIS)→Web Server→Application Development**:
  - .NET Extensibility 4
  - ASP.NET 4
- Under **Web Server (IIS)→Management Tools→IIS 6 Management Compatibility**:
  - IIS 6 Metabase Compatibility

1.3 Positive Patient Identification (PPID) Feature Implementation

The PPID feature helps hospitals improve the accuracy of patient identification by obtaining at least two forms of patient identification prior to diagnostic testing.

The PPID feature is available only through the i-STAT 1 or i-STAT 1 Wireless analyzer and requires the use of Info HQ or a third-party data manager software with i-STAT/DE.

Implementation of PPID requires an interface to the facility's ADT feed be implemented in the Info HQ or third-party data management software. Contact your local Abbott Point of Care representative for information on having this interface implemented with Info HQ or third-party data management system.

Patient List Requirements

The i-STAT 1 PPID feature maintains one active patient list per facility, ensuring patients are recognized wherever they are located in the facility.

This active patient list is obtained from the facility ADT database by the data manager. **The maximum number of active patients permitted on the i-STAT 1 patient list is 6000 per facility.**

Identifier Formats

The format for the primary and secondary identifiers displayed on the analyzer screen is as follows:

Primary Identifier	Format
Patient ID (e.g., Medical Record Number or Account Number)	Up to 15 characters
Secondary Identifier	**Format**
Last Name	Up to 15 characters
First Initial	Single Character
Middle Initial	Single Character
Date of Birth (DOB)	DDMMMYYYY
Gender: Male, Female, Other, Unknown	Single Character (M, F, O, U)

NOTE 1: If desired, the secondary identifiers can be configured to print with test results on the i-STAT or Martel printers. Default behavior is to not print the secondary identifiers.

NOTE 2: When patient test results are transmitted to the data manager, the secondary identifiers along with a status flag indicating whether the patient ID was confirmed are included in the transmitted test record.

Third-party data management software considerations

Microsoft .NET version

The i-STAT/DE software is web-based and utilizes Microsoft .NET version 4. For proper functionality of the i-STAT Positive Patient Identification (PPID) feature for patient date of birth, Microsoft .NET version 4 is required to be utilized by the Third-party data management software.

1.4 Technical Considerations

This section provides technical considerations regarding the system environment where the i-STAT/DE software will reside to ensure functionality of the i-STAT/DE software and to prevent i-STAT/DE service interruptions.

Windows Firewall

If i-STAT/DE is installed on a machine which has the Windows Firewall in use, several configuration parameters will need to be set. These settings are accessed through the Control Panel, Windows Firewall applet. Exceptions will need to be applied to allow proper operation. Instructions below describe one way to apply firewall exceptions.

Enable access to the i-STAT/DE web pages by selecting the Windows Firewall, Advanced tab page and clicking:

- Settings... in the Network Connection Settings group box.
- When the Advanced Settings dialog opens, check Web Server (HTTP) and then click OK.

Enable the service application that communicates with the i-STAT analyzers to do so through the Windows Firewall:

1. Select the Exceptions tab page on Add Program
2. Browse to the Bin folder in the Istat32 or APOC\DE folder:

   For users whose initial installation of i-STAT/DE was version 2.9 or earlier: C:\Istat32\Bin

   For new installations or users whose initial installation of i-STAT/DE was version 2.10 or greater: C:\ProgramFiles(x86)\APOC\DE\Bin
3. Select DeComSrv.exe and click OK.

Windows Update(s)

It is recommended that the latest Microsoft security patches be applied. Use the Windows Update mechanism and apply all applicable security roll-ups, patches and updates.

When automatic restart is enabled, the i-STAT/DE services may be interrupted. It is recommended to verify that the following i-STAT/DE services are running post Windows Update and/or perform a controlled restart:

- i-STATDE Data Processor Service
- i-STATDE Update Monitor
- i-STATDeComSrv
- i-STATEVASSrv
- SQL Anywhere – iSTATDEDB

Registry Permissions

The default access permissions for the following registry keys should not be changed.

- HKEY_LOCAL_MACHINE\Software\WOW6432Node\i-STAT
- HKEY_LOCAL_MACHINE\Software\WOW6432Node\ODBC\ODBC.INI\i-STAT DE

Application and Operating System Software

The following exclusions should be applied to ensure that there is no disruption to the functionality of the i-STAT/DE Software.

Exclusions

The following Exclusions are recommended for uninterrupted functionality of the i-STAT/DE Software installation:

- For new installations or users whose initial installation of i-STAT/DE was version 2.10 or greater with the APOC website and APOC folder location:
    - C:\Program Files (x86)\APOC*.*
    - C:\Program Files (x86)\SQL Anywhere 17*.*
    - C:\Windows\SysWOW64\inetsrv\w3wp.exe
- For users whose initial installation of i-STAT/DE was version 2.9 or earlier with Default website and Istat32 folder location:
    - C:\istat32*.*
    - C:\Program Files (x86)\SQL Anywhere 17*.*
    - C:\inetpub\wwwroot\ActiveX*.*
    - C:\inetpub\wwwroot\IstatDeSystem*.*
    - C:\inetpub\wwwroot\iSTATDMI*.*
    - C:\Windows\SysWOW64\inetsrv\w3wp.exe

IMPORTANT NOTE(S):

- The folders may be required to be placed in “bypass mode” when exclusions do not resolve i-STAT/DE service interruptions.
- When the directory and subdirectories are not able to be excluded, the following file type extensions may be excluded as they are utilized by the i-STAT/DE software and its components: .bin, .clw, .exe, .log, .db, .dat, .txt, .dll, .vas, and .ini.

Web Browser Security - HTTPS

HTTPS allows bidirectional encryption of communications between client and server. i-STAT/DE v2.11 and above allow enabling HTTPS on new installations of i-STAT/DE for improved security when accessing the i-STAT/DE Customization Workspace and i-STAT/DE System web pages.

The setup utility provides the option to configure the i-STAT/DE web pages to utilize HTTPS using an SSL certificate supplied and installed by the user.

Enabling the HTTPS feature requires the following components/prerequisites:

- i-STAT/DE v2.11 or above.
- Windows 10 or Windows Server 2016 operating systems.
- A regular certificate installed locally in either the Personal or Web Hosting certificate store.
- The effective script execution policy on the machine must be either RemoteSigned or Unrestricted. Server versions of Windows default to RemoteSigned; desktop versions default to Restricted.

Once Installed, the i-STAT/DE Customization Workspace and i-STAT/DE System pages will load as secure 'https' webpages and the traffic between the two endpoints will be encrypted.

Socket Port Utilization for Network Communication

The i-STAT/DE Software with the i-STAT 1 system utilizes your sites LAN. This section provides information for ports utilized for network communication and diagnostic support.

TCP Ports

- TCP 80: i-STAT/DE Web pages, Third-Party Data Management Communication and i-STAT 1 Downloader/Recharger (DRC-300) Configuration
- TCP 443: i-STAT/DE webpages when HTTPS is enabled.
- TCP 6004: i-STAT 1 data transmissions
- TCP 9999: i-STAT Network Downloader and Network Downloader/Recharger Configuration (DN-300/DRN-300)

Backups and Recovery

It is recommended that backups be performed by backing up the i-STAT/DE database backup directory. See Enable Automatic Backup in Section 2.3 Configuration, Configuration Options.

The i-STAT/DE performs a daily backup which is overwritten in the C:\DEAUTOBACKUP folder.

Browser

Client side cookies are used by the i-STAT/DE Customization Workspace web application to maintain session information. Cookie usage will need to be enabled in the web browser for pages served up by the i-STAT/DE server.

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2. Installing and Configuring

Installing i-STAT/DE for the first time.

2.1 Installation of i-STAT/DE

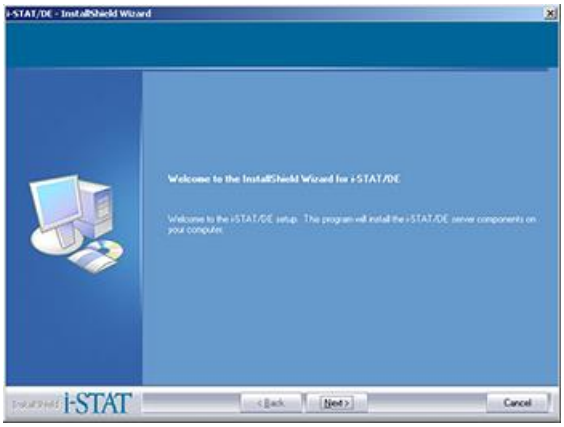
NOTE:

- Screens shown here are examples only. During installation, a screen's appearance may differ slightly from the example. In addition, some screens may display very briefly, or not display at all.
- If the application does not start automatically, it may be necessary to run it manually.
- If a security prompt displays, you will need to give permission to allow the application to run.

Installation Procedure

Insert the i-STAT/DE CD-ROM and follow the installation steps shown:

1. **Welcome Dialog:** When installing the i-STAT/DE components, the Welcome dialog will be initially displayed. (Figure 2.1.1).

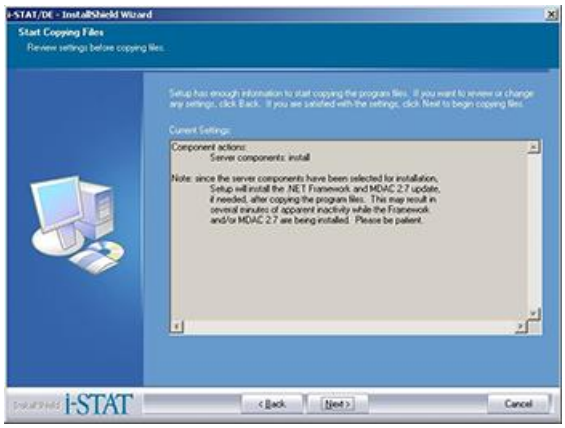


(Figure 2.1.1)

2. **OEM Software Distribution Agreement Dialog:** After clicking **Next>**, the OEM Software Distribution Agreement dialog is presented. (Figure 2.1.2) You must agree to the terms listed to proceed with the installation. Click *Yes* to agree to the terms.

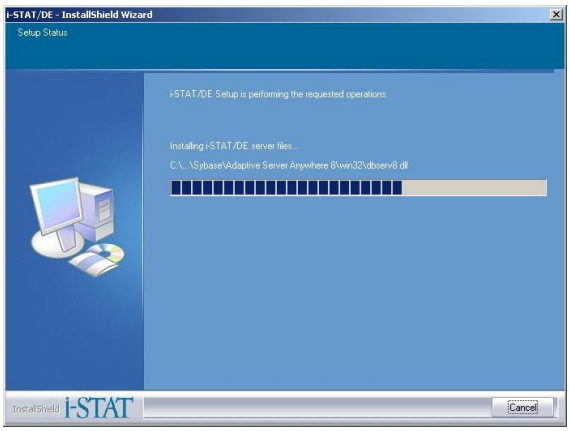
(Figure 2.1.2)

3. **Summary Dialog:** After clicking Yes in the OEM Software Distribution Agreement dialog, a dialog containing a summary of the installation choices is shown (Figure 2.1.3). Click N*ext>* to proceed.



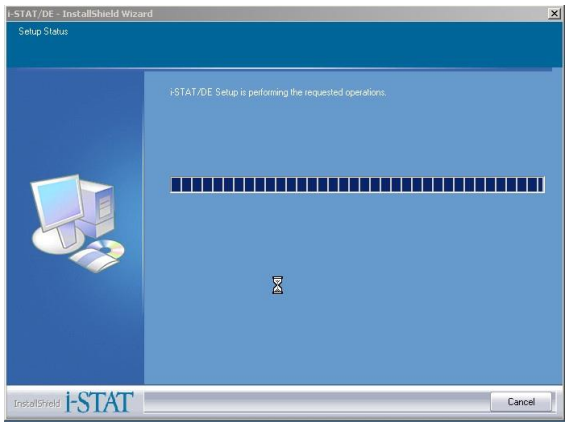
(Figure 2.1.3)

4. **Setup Status Dialog:** The Setup Status dialog (Figure 2.1.4) is displayed while the files are being delivered.



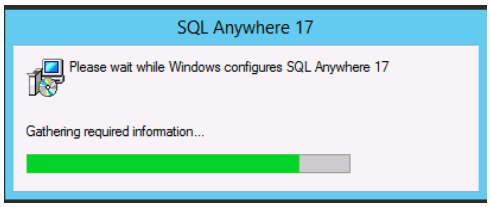
(Figure 2.1.4)

During a new installation of i-STAT/DE, it may be necessary for the setup utility to install the Microsoft Data Access Components. In this case, the Setup Status dialog (Figure 2.1.5) may appear as shown below for several (1 to 5) minutes while this is taking place. Hard drive activity can be observed during this time.



(Figure 2.1.5)

5. **SQLAnywhere17 Setup:** After the files required for the installation of the server components have been delivered, the setup utility for SQL Anywhere 17 (Figure 2.1.6) will be launched by the i-STAT/DE setup utility. This setup requires no user interaction and should be allowed to run to completion.



(Figure 2.1.6)

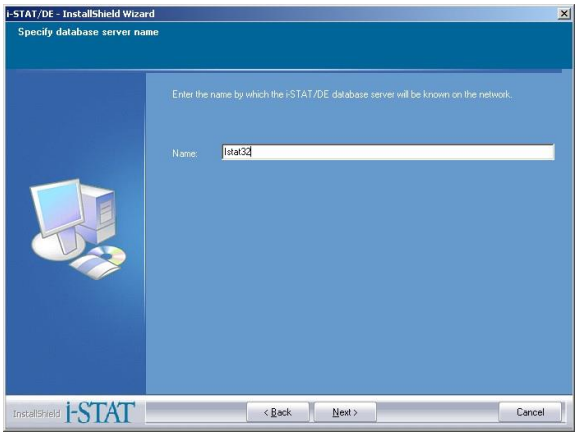
6. **Configuration Tasks:** After the i-STAT/DE Customization Workspace setup utility has completed, the i-STAT/DE setup utility proceeds to perform configuration tasks.

   The **Specify i-STAT/DE Database Server Name** panel (Figure 2.1.7) displays with the default server name: **Istat32**

   Use the default server name or specify a different name. The only reason to specify a name other than the default of **Istat32** is the case where multiple i-STAT/DE servers will be installed on the same network.

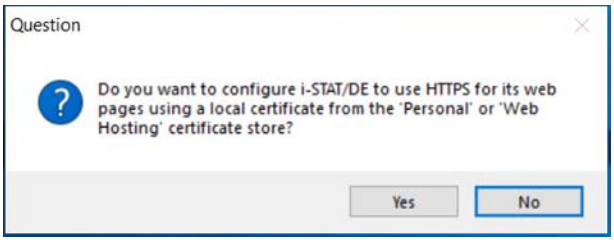
   NOTE: The i-STAT/DE database server name **must be unique** on a network. Conflicts and issues can occur if there is more than one instance of i-STAT/DE with the same database server name anywhere on the LAN or WAN (health system, IDN, etc.).

   After accepting the default name for the i-STAT/DE database server or specifying a name, click **Next>**.



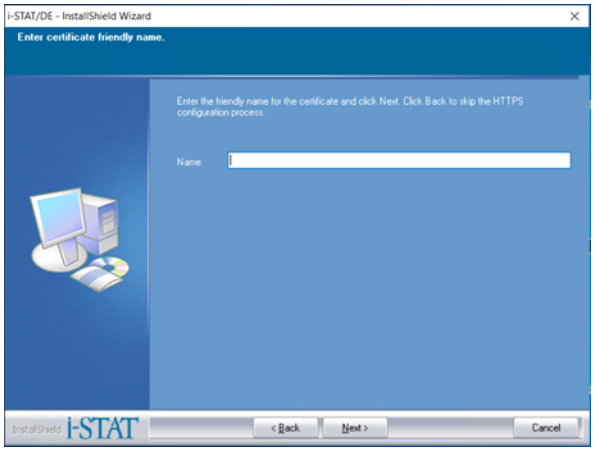
(Figure 2.1.7)

7. **HTTPS configuration option:** After completing the configuration tasks, a prompt will be presented (Figure 2.1.8) asking if the user wishes to configure the i-STAT/DE web pages to utilize HTTPS.



(Figure 2.1.8)

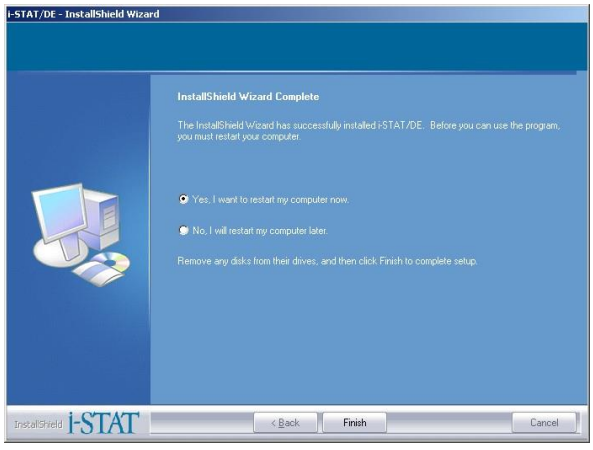
If No is clicked, the setup skips this step. If Yes is clicked, the user will be prompted to enter the friendly name of the certificate to be used (Figure 2.1.9).



(Figure 2.1.9)

Enter the certificate's friendly name and click **Next>**. The HTTPS configuration process will take place silently. Clicking **<Back** will skip the HTTPS configuration process.

8. **Setup Complete:** After completing all actions, the following dialog is presented (Figure 2.1.10). Select **Yes, I want to restart my computer now** option and click **Finish.**



(Figure 2.1.10)

Confirming installed components

To verify the successful installation of i-STAT/DE:

1. Open the i-STAT/DE System Status & Configuration web application in a compatible web browser by specifying the following address:

   http://*computer_ip_or_name*/istatdesystem

   where *computer_ip_or_name* is the IP address or machine name of the server on which i-STAT/DE is installed.

   Refer to Section 1.1 Technical Specifications for browser compatibility.

   Confirm the following:

   - Under Database, Version is shown as 2.11
   - Under Services, all the following services have a Status of Started or Running
     - Data Communications Manager (DeComSrv)
     - Data Processor (DeDpSrv)
     - Update Monitor (DeUpdateMonitor)
     - eVAS Monitor (evassrv)
   - Click Data Manager Interface (DMI). Confirm all numbers under Test Record Statistics are zero or greater for the following:
     - Number of All Test Records
     - Number of Unsent Test Records
     - Number of Pending Records
2. Open Control **Panel→Add/Remove Programs** or **Control Panel→Programs and Features** (depending on the Windows version). The following should be listed:
   - i-STAT/DE Version 2.11
   - SQL Anywhere 17

Website and Physical File Locations for New Installations

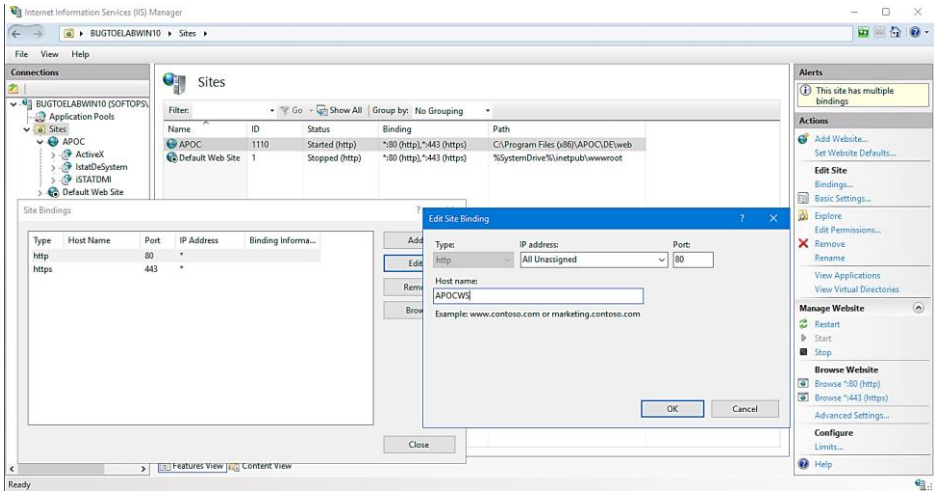
The i-STAT/DE web applications and web service are installed as noted in the table below:

Item	New Installation of version 2.11 or upgrade of i-STAT/DE initially installed as 2.10 or later
Website	APOC (setup utility creates this web site and disables Default Web Site)
Folder location under which the physical files of the web components are installed	<ProgFilesX86>\APOC\DE\web where <ProgFilesX86> is the 32-bit Program Files folder as given in the Registry.
Folder location under which the non-web components (service applications, database files, CLEW files, etc.) are installed	<ProgFilesX86>\APOC\DE

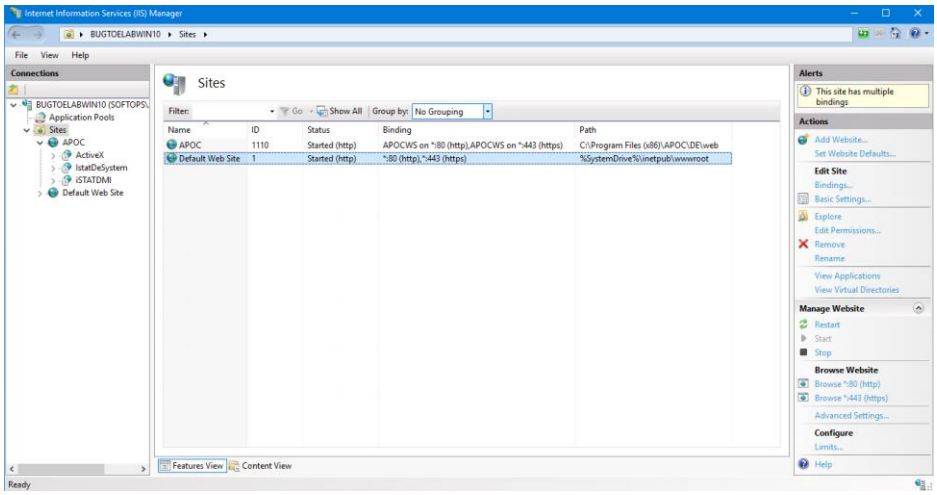
Updating Website Location for New Installations

If the organization or facility desires to have web applications and web services installed to Default Web Site, the following steps are a suggested option:

1. Edit the protocol bindings for the *APOC* web site (Figure 2.1.11) and assign them a host name. Any host name can be used; for example purposes *APOCWS* is used. (Figure 2.1.11). Binding is saved/updated, and Default Web Site started (Figure 2.1.12).

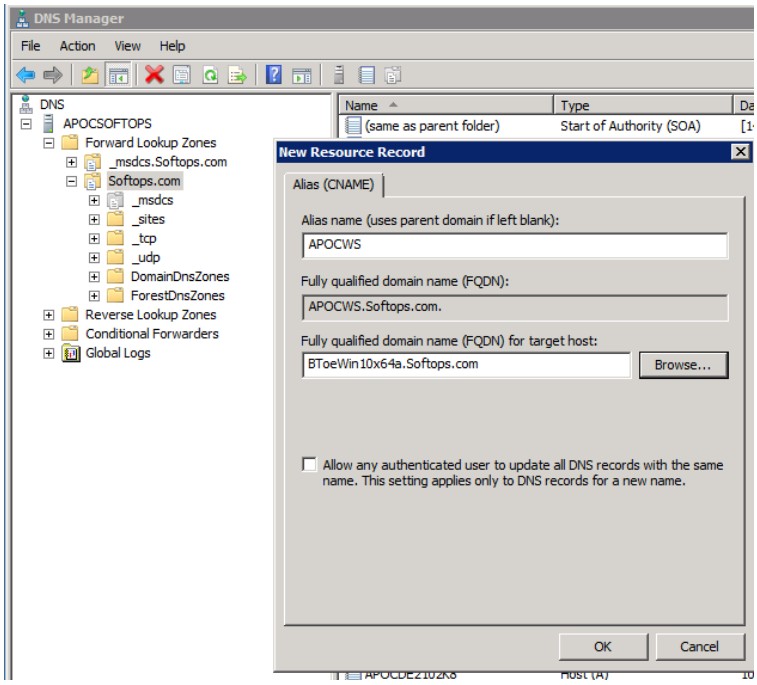


(Figure 2.1.11)



(Figure 2.1.12)

2. Add to the facility's local DNS server an entry mapping the host name of *APOCWS* to the server's machine name. The following is an example:



(Figure 2.1.13)

2.2 Installing a Software Upgrade

When the setup utility is run on a system that already has i-STAT/DE installed on it, the setup utility automatically runs in upgrade mode. In upgrade mode the machine is automatically rebooted after the setup utility completes its execution.

Upgrade Notes

- Sites are advised to back up the customization profiles before performing an upgrade. See section 3.4, Customization Profile Management for instructions on backing up customization profiles.
- When running in upgrade mode, in the **OEM Software Distribution Agreement** dialog, the user must click **Yes**.

Website and Physical File Locations for Upgrades

The setup utility for i-STAT/DE version 2.9 and earlier installed the following:

- i-STAT/DE web applications and web service under Default Web Site in Internet Information Services (IIS).
- i-STAT/DE web components under C:\Inetpub\wwwwroot.
- i-STAT/DE non-web Components under C:\Istat32

If i-STAT/DE is being upgraded and it was initially installed as version 2.9 or earlier, the web site and physical file locations used will be unchanged as displayed in the table below.

Item	Upgrade of i-STAT/DE initially installed as 2.9 or earlier
Web site	Default Web Site
Folder location under which the physical files of the web components are installed	C:\Inetpub\wwwroot
Folder location under which the non-web components (service applications, database files, CLEW files, etc.) are installed	C:\Istat32

Updating Website and Physical File Locations for Upgrade Installations:

If an Organization or Facility wishes to update the website and physical file locations to that of the new installation model introduced with version 2.10 and higher, the following steps may be performed:

1. Upgrade the existing i-STAT/DE instance to version 2.11
2. Capture a screen shot of the configuration page in the System Status & Configuration web application (http://localhost/istatdesystem/istatdesys_config.aspx)
3. Stop the *SQL Anywhere – iSTATDEDB* service
4. Copy the database files C:\Istat32\bin\Istat32.db and C:\Istat32\bin\Istat32.log to a safe location
5. Uninstall *i-STAT/DE Version 2.11* from *Programs and Features*
6. Delete these folders, if they exist:
    - C:\Istat32
    - C:\Inetpub\wwwroot\ActiveX
    - C:\Inetpub\wwwroot\IstatDeSystem
    - C:\Inetpub\wwwroot\iSTATDMI
7. Delete the following registry keys:

- HKEY_LOCAL_MACHINE\Software\WOW6432Node\i-STAT
- HKEY_LOCAL_MACHINE\Software\WOW6432Node\ODBC\ODBC.INI\i-STAT DE

8. Install i-STAT/DE Version 2.11, but elect not to reboot after the setup completes
9. Stop the SQLAnywhere – iSTATDEDB Service
10. Copy the database files saved earlier to:
    - C:\Program Files (x86)\APOC\DE\bin
11. Reboot
12. Open the configuration page in the System Status & Configuration web application (http://localhost/istatdesystem/istatdesys_config.aspx) and make/save any changes needed to match the settings captured earlier
13. Reboot

2.3 Configuration

Server Settings

The i-STAT/DE System Status & Configuration Web application can be used to configure various system settings. It is accessed through a web browser using the following URL:

http://*computer-ip-or-name*/istatdesystem

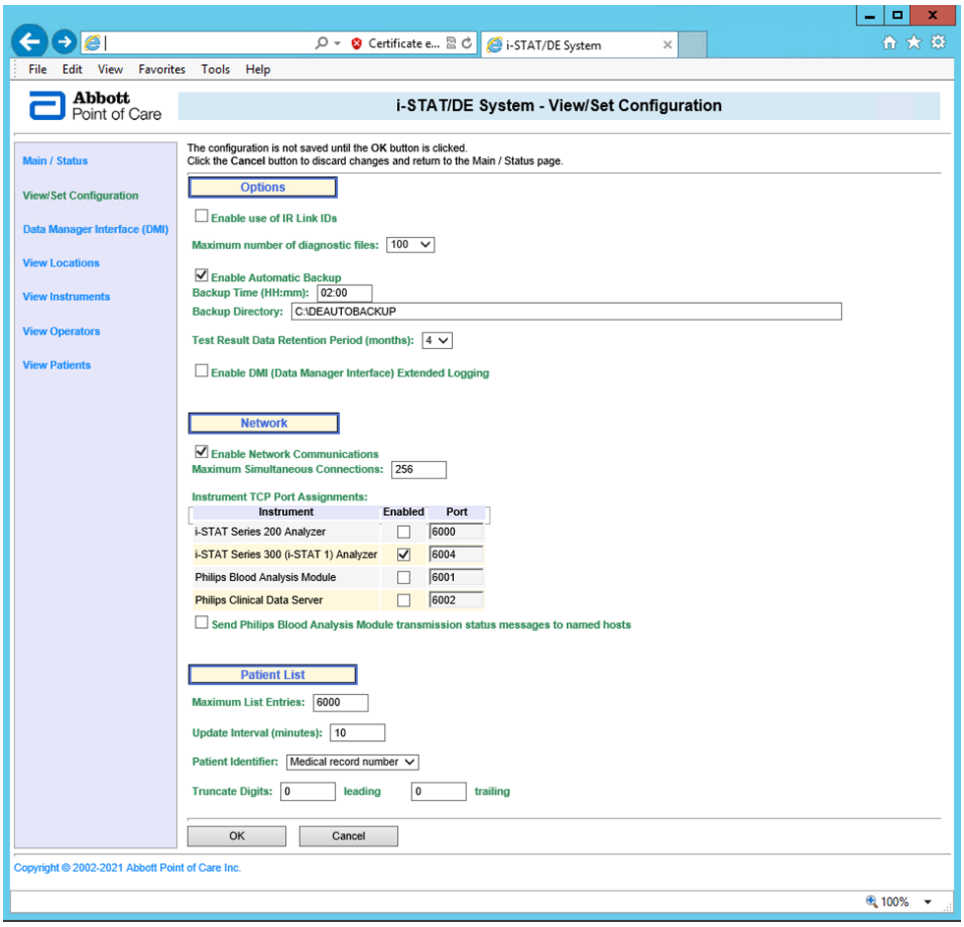
Where *computer-ip-or-name* is the machine name or IP address of the i-STAT/DE server.

Click **View/Set Configuration** to access the page where various i-STAT/DE system settings can be configured. After making changes, click **OK**. If the settings were successfully validated and recorded a new page reporting the success will be presented. If any errors were encountered, they will be reported on the configuration page.

NOTE:

- Screens shown here are examples only. A screen's appearance may differ from the example.
- Values shown in the example below are for reference only. They do not represent default values.

View/Set Configuration Page



Configuration Options

Enable use of IR Link IDs:

This is no longer supported. Allow the setting to remain **unchecked**, which is the default.

Maximum number of diagnostic files:

Determines the maximum number of diagnostic files to be kept. When the maximum number is reached, the oldest file is overwritten. Diagnostic files contain information that can be useful in troubleshooting cartridge problems. This number may be changed at the request of an i-STAT Technical Services Support Specialist.
Default setting: Default value is **100**.

Enable Automatic Backup:

Enable/disable the automatic backup of the i-STAT/DE database files on a daily basis. The backup will occur daily at or after the time specified by the **Backup Time** (HH:mm) setting and the backup destination will be the location specified by the **Backup Directory** setting.
Default settings: This feature is checked by default, Backup Time is **02:00** local time, and the default Backup Directory is **C:\DEAUTOBACKUP**.

Note: The path specified as the backup directory must exist and be accessible to the *LocalSystem* account of the i-STAT/DE server or the backup will fail silently.

Test Result Data Retention Period (months):

Defines the number of months (1 to 6), relative to the timestamp of the test record, that a test record will be retained in the i-STAT/DE database after being successfully forwarded to, and acknowledged by, the host data management system.
Default setting: Default value is **4.**

Enable DMI (Data Manager Interface) Extended Logging

Enable/disable logging of every web method call made to the DMI web service. When enabled, all calls are logged to the DMI error log file:

For users that upgrade with 32-bit or 64-bit Windows:

C:\Istat32\Log\iSTATDMI Errors.txt

For new installations and upgrades that updated the folder location:

64-bit Windows - C:\Program Files(x86)\APOC\DE\Log\iSTATDMI Errors.txt

32-bit Windows - C:\Program Files\APOC\DE\Log\iSTATDMI Errors.txt

This can be useful in documenting and troubleshooting the interaction between the web service and the third- party data manager.

Default setting: This feature is **unchecked** by default.

Note: When an i-STAT/DE software upgrade is installed, the feature is reset to unchecked.

Configuration Network Options

Enable Network Communications:

Enable/disable the reception of data transmissions by i-STAT/DE. Do not change this setting unless you are directed to do so by an i-STAT Technical Services Support Specialist.
Default setting: This feature is **checked** by default.

Maximum Simultaneous Connections:

Determines the maximum number of simultaneous analyzer downloads that will be supported by i-STAT/DE.
Default setting: Default value is **256.**

Instrument TCP Port Assignments:

For each listed instrument, the TCP Port number can be specified and the reception of individual instrument types can be enabled/disabled.
Default settings: All items in the box are **checked**, the values are: **6000, 6004, 6001, 6002**.

Send Philips Blood Analysis Module transmission status messages to named hosts:

This feature applies to the Philips Blood Analysis Module, which is no longer supported. Leave this feature in its default state of **unchecked.**

Configuration Patients List options

NOTE: Options in this section should be changed only by your data management vendor.

Maximum List Entries:

Specifies the maximum number of entries allowed in a single institution's patient list. If this number is exceeded in the DataSet passed to the SetPatientsAll() or SetPatientsOne() web methods, an exception will be returned. Allowable values are in the range 1 to 6000.
Default setting: **6000**.

Update Interval (minutes):

Specifies the minimum amount of time in minutes that must pass between two successive calls to SetPatientsAll() or between calls to SetPatientsOne() for a given institution. If the calls occur before this time period elapses, an exception will be returned. Allowable values are in the range 1 to 60.
Default setting: **10**.

Patient Identifier:

Records the identifier to be used as the Patient ID in the DataSet passed to SetPatientsAll() or SetPatientsOne(). Informational only; no validation is performed against this setting.
Default setting: Default value is **Medical record number**.

Truncate Digits:

Controls the number of leading and trailing digits to be trimmed from the patient identifiers received from the ADT feed. Informational only; no validation is performed against this setting.
Default setting: **no truncation**.

2.4 Authentication/Authorization via Active Directory for i-STAT/DE Webpages

The i-STAT/DE utility program deAuthConfigapp.exe may be utilized to enable/disable authentication and authorization for the following i-STAT/DE web applications utilizing an organization's Active Directory:

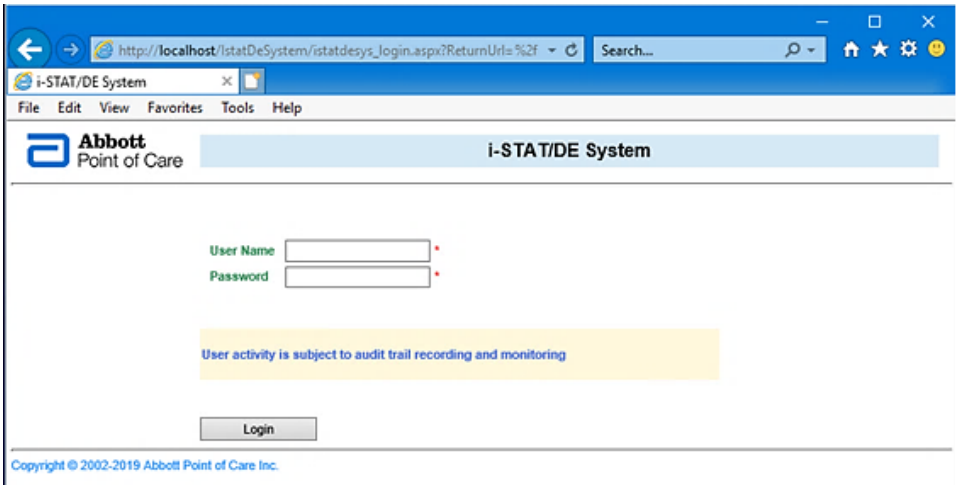
- i-STAT/DE Customization Workspace
- i-STAT/DE System Status and Configuration

When enabled, audit trail entries are recorded in the Application Log of the Windows Event Viewer.

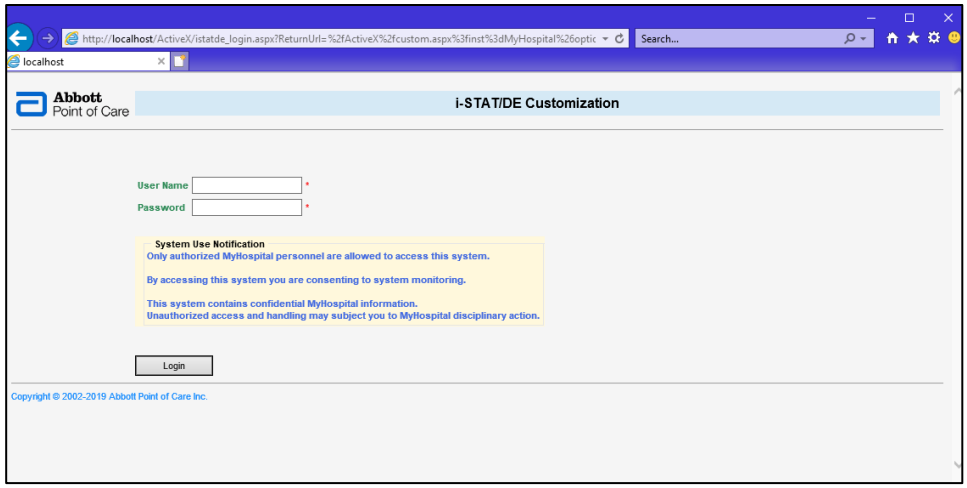
Functionality

When the authentication and authorization is enabled for the i-STAT/DE web applications, the user will be presented with a login screen when they access the i-STAT/DE System (Figure 2.4.1) and Customization Workspace (2.4.2) web pages. The users Active Directory group membership will dictate whether they have Full access (Figure 2.4.3) or Read-only access to the webpage (2.4.4).

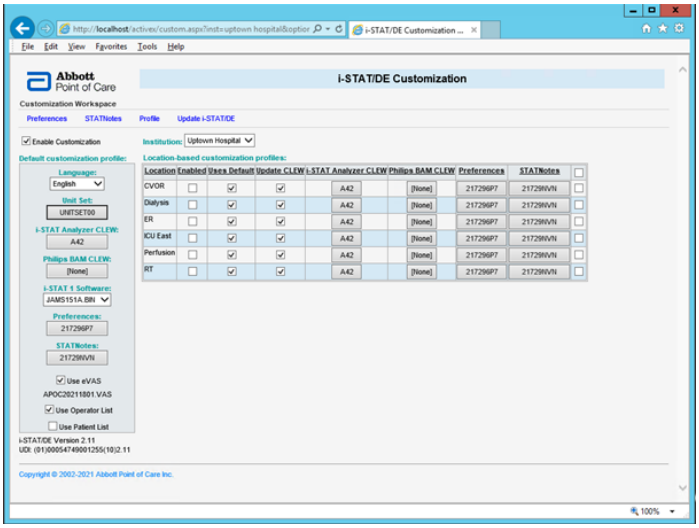
The Organization's users that are provided with Full access will be able to apply updates and changes within the i-STAT/DE System and Customization workspace web pages. Users that are provided Read-only access may only view the information with the i-STAT/DE System and Customization Workspace pages.



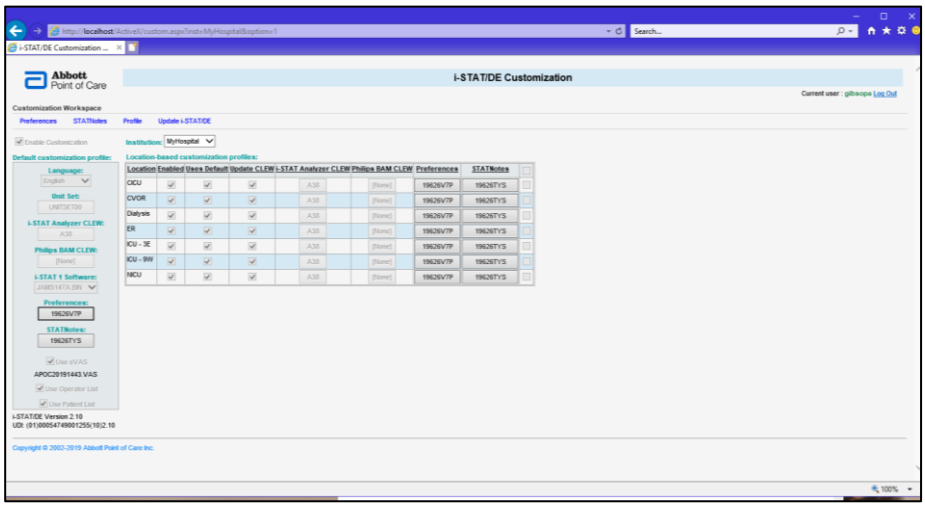
(Figure 2.4.1)



(Figure 2.4.2)



(Figure 2.4.3)



(Figure 2.4.4)

Caution(s)

Access is governed by the organization's user assignment within the organization's Active Directory user group.

Issues pertaining to the user access may be referred to the organization's IT department.

User access is not managed within the i-STAT/DE software or web applications.

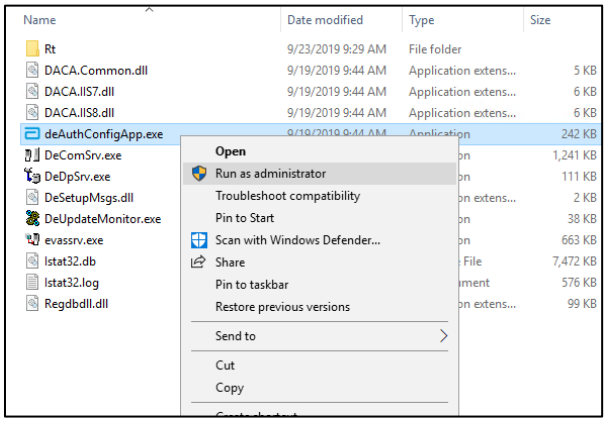
Requirement(s)

The following are the requirements when enabling the authentication and authorization for the i-STAT/DE Web applications:

1. i-STAT/DE version 2.11 installed successfully.
2. The i-STAT/DE server must be a member of the domain specified in Step 3.b under the following section "Enabling Authentication and Authorization for i-STAT/DE web applications" in order for authentication to be possible.
3. The i-STAT/DE deAuthConfigapp.exe must be run as an Administrator.
4. Organization may secure access to the i-STAT/DE deAuthConfigapp.exe through Windows File permissions.
5. Two Active Directory user groups, if applicable
    - Active Directory user group that provides assigned users **full access** to the web applications.
    - Active Directory user group that provides assigned users **read-only access** to the web applications

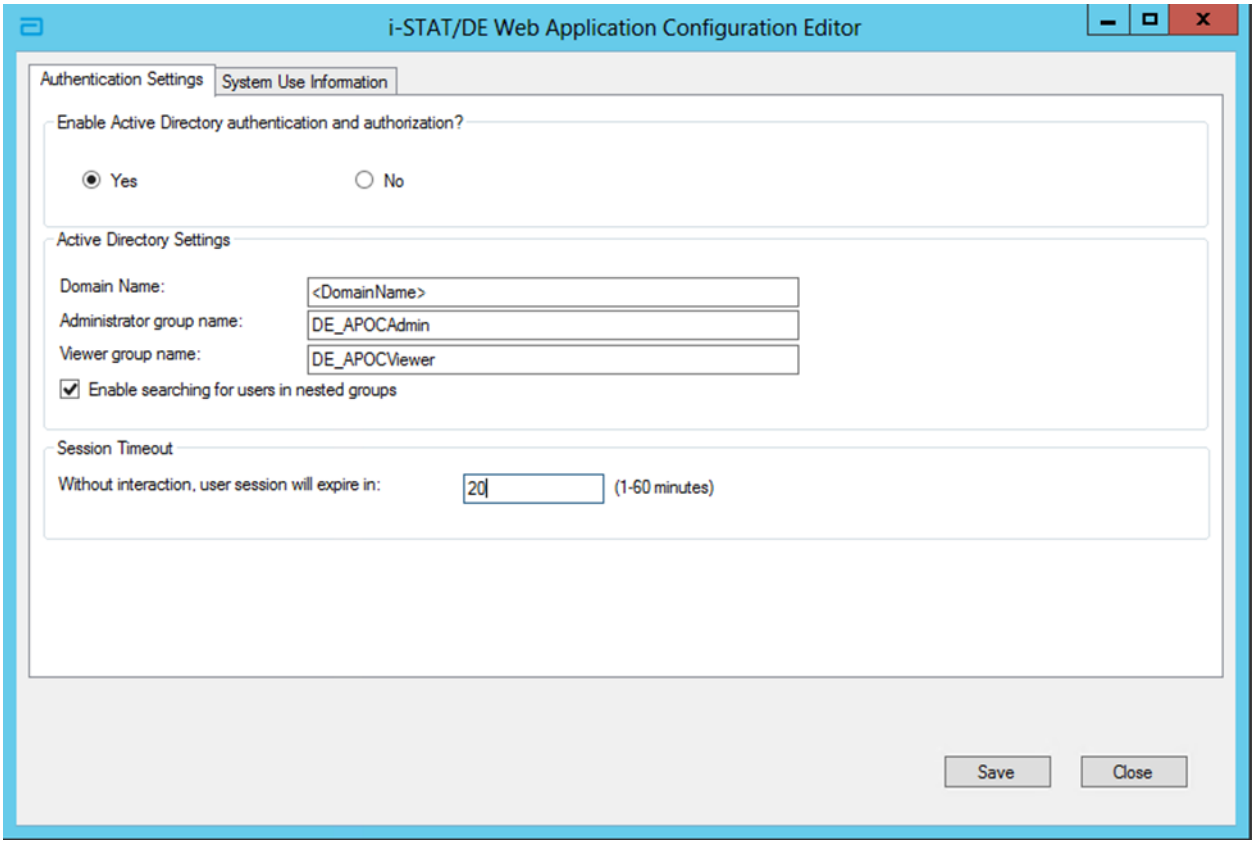
Enabling Authentication and Authorization for i-STAT/DE Web Applications

1. Go to the Istat32 or DE program folder:
    - For users where i-STAT/DE was initially installed as version 2.9 or earlier: C:\Istat32\Bin
    - For new installations and for users where i-STAT/DE was initially installed as version 2.10 or later: C:\ProgramFiles(x86)\APOC\DE\Bin
2. Open the i-STAT/DE folder, right-click **deAuthConfigApp.exe** and select **Run as Administrator** (Figure 2.4.5):



(Figure 2.4.5)

3. On the ***Authentication Settings*** **tab** (Figure 2.4.6):
    a. **Select *Yes,*** to enable Active Directory authentication and authorization.
    b. **Enter the *Domain Name***, the domain on which the Active Directory used for authentication and authorization is located.
    c. **Enter the *Administrator group name***, name of the Active Directory group holding the users who have full access to the two web applications.
    d. **Enter the *Viewer group name***, name of the Active Directory group holding the users who have view-only access to the two web applications.
    e. If desired, check **Enable searching for users in nested groups** to allow authentication to be performed against child groups of the Administrator and Viewer groups.
    f. **Enter the *Session Timeout*,** number of minutes of inactivity that will trigger expiration of authentication and authorization. Enter a number, in minutes: 1 to 60.

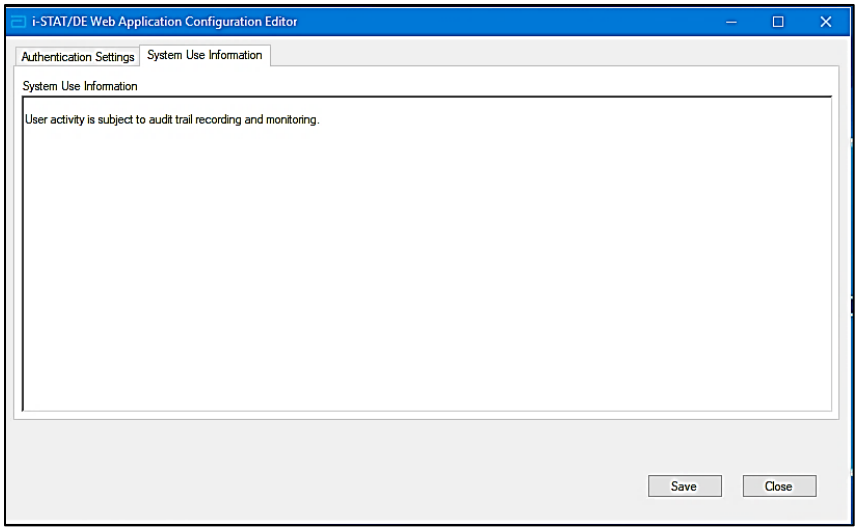


(Figure 2.4.6)

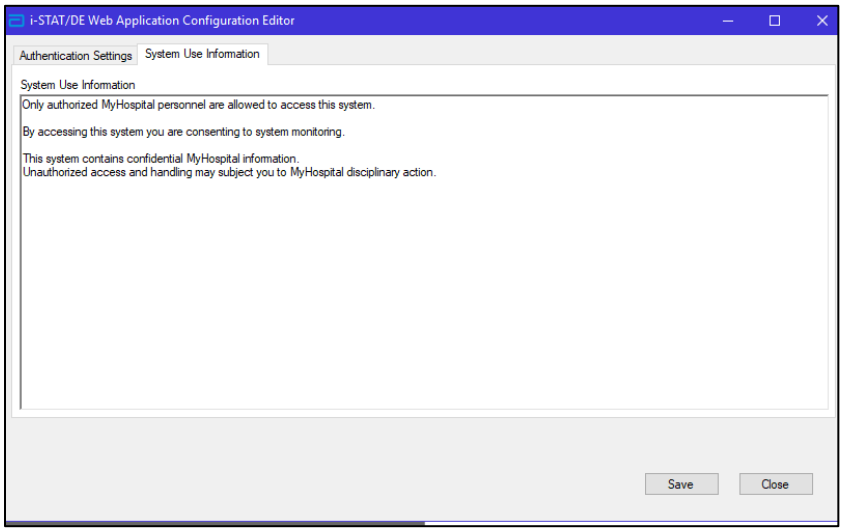
4. On the ***System Use Information*** **tab** (Figure 2.4.7 and Figure 2.4.8): Enter the message, if applicable, to be displayed on the login screen. Message is customized by the organization.

   Note(s):

   - User is responsible for breaking the text into separate lines.
   - Do not rely on the text wrapping – insert line breaks.



(Figure 2.4.7)



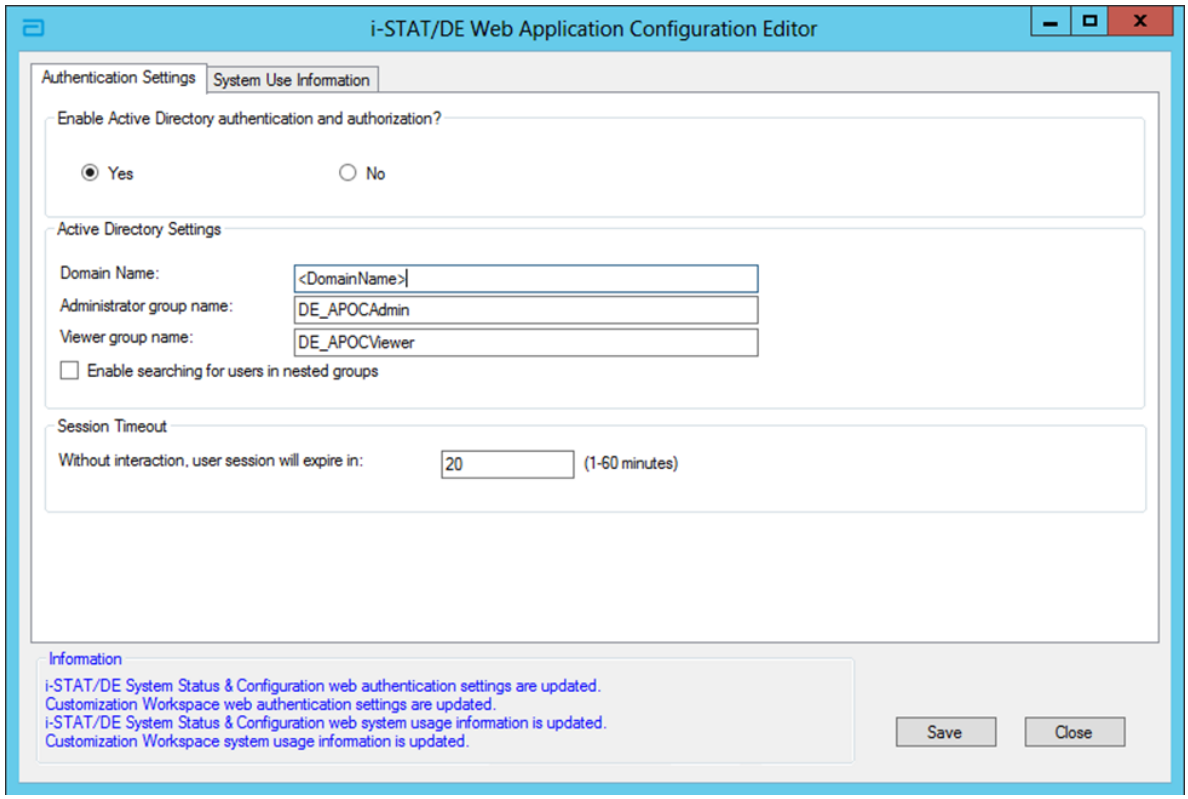
(Figure 2.4.8)

5. Click ***Save***. Status messages are displayed in the ***Information*** section (Figure 2.4.9).

    a. Success message is displayed, if the Active Directory store can be contacted and the user groups verified:

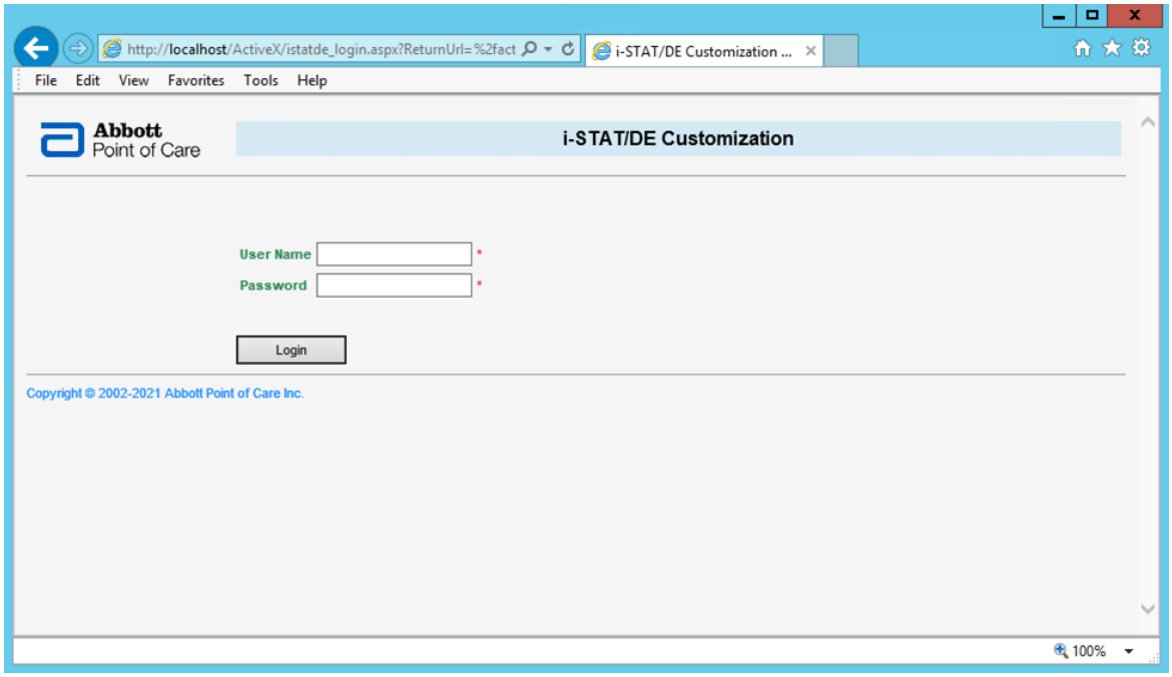
        - Active Directory must exist on the specified domain
        - The Administrator Active Directory group must exist
        - The Viewer Active Directory group must exist
        - Session timeout must be a number from 1 to 1440 (one minute to one day)
        - Active Directory nested groups are supported.

    b. Failure message is displayed in the same area of the window.



(Figure 2.4.9)

6. When a user attempts to access one of the i-STAT/DE webpages, a login page will now be displayed (Figure 2.4.10)



(Figure 2.4.10)

Audit Trail Logging

When authentication/authorization via Active Directory is enabled, audit trail entries are recorded in the Application Log of the Event Viewer. The amount of event history available is dependent on the Organization's IT policy and/or procedures.

Audit Trail Logging for i-STAT/DE Customization Workspace webpage

Audit trail entries from the i-STAT/DE Customization Workspace web application will have a source of *CustomWorkspaceWeb*, and the following events are recorded:

Event recorded	Description
Successful login	Documents that the user logged in successfully.
Unsuccessful login attempt	Documents an unsuccessful login attempt by a user.
CLEW selection changed	Documents the user and CLEW selection change.
Preferences saved	Documents the user and when the Preferences were saved.
Preferences deleted	Documents the user and when the Preferences were deleted.
Preferences applied	Documents the user and when the Preferences were applied.
STATNotes saved	Documents the user and when the STATNotes were saved.
STATNotes deleted	Documents the user and when the STATNotes were deleted.
STATNotes applied	Documents the user and when the STATNotes were applied.
Profile restored	Documents the user and when the Profile was restored.

Audit Trail Logging for i-STAT/DE System Status and Configuration webpage

Audit trail entries from the i-STAT/DE System Status & Configuration will have a source of *IstatDeSysWeb*, and the following events are recorded:

Event recorded	Description
Successful login	Documents that the user logged in successfully.
Unsuccessful login attempt	Documents an unsuccessful login attempt by a user.
Configuration Settings Saved	Documents the user that clicked the *OK* button on the View/Set Configuration page.

2.5 Enable HTTPS for DE webpages

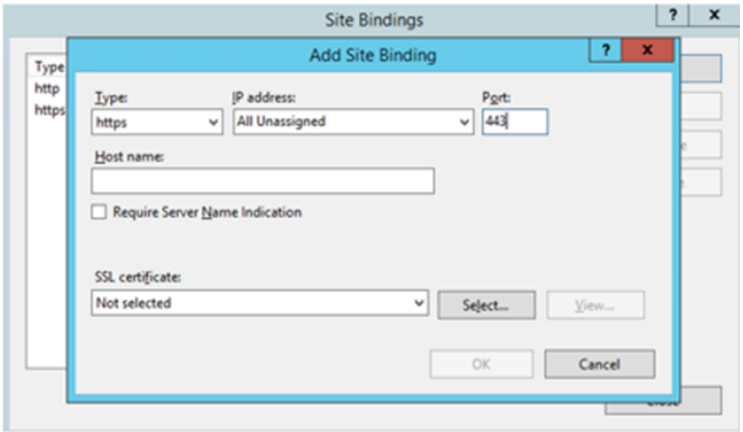
Note: This setup assumes the following:

1. i-STAT DE (DE) is installed and fully functional
2. User has administrator access to the host server for DE
3. An SSL Certificate (issued by an authorized CA or self-assigned) is installed on the server
4. URL Rewrite module is installed under IIS.

Step 1 – Enable Listener on Default Web site in IIS

Modern Data Manager/Middleware products are web-based. They are installed as subsites within the Default Web Site in IIS.

a. Open **Internet Information Services** (IIS)
b. Expand **SITES** and right click on **DEFAULT WEB SITE**. Select **EDIT BINDINGS.**
c. In the **Site Bindings** window, click **ADD.** Select type=https, IP address="customer provided", port=443. Host name is optional. Under SSL certificate, select the appropriate certificate and click **OK**. The SITE BINDINGS window should show HTTPS now enabled.

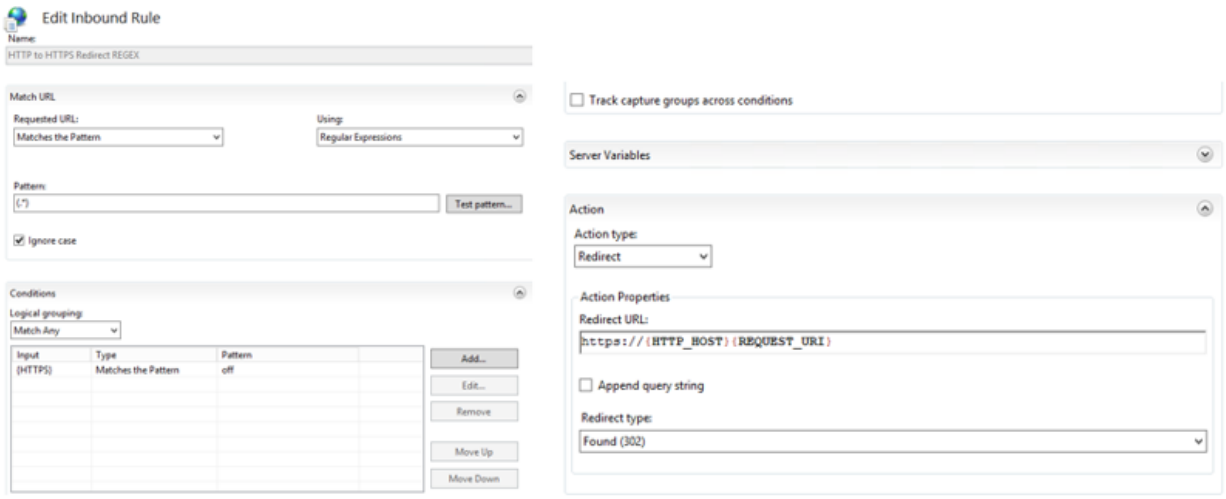


(Figure 2.5.1)

Step 2 – Enable HTTP to HTTPS auto redirect

This step can be done under the DEFAULT WEB SITE or in any specific sub site. If enabled under the DEFAULT WEB SITE, it is inherited by all sub sites.

a. Open **URL REWRITE**
b. Click **ADD RULE,** from the right-side menu and select **BLANK RULE**
c. Choose the following options:
    a. Name = HTTP to HTTPS Redirect
    b. Match URL – Requested URL MATCHES THE PATTERN, Using REGULAR EXPRESSION and Pattern (.*)
    c. Under **CONDITIONS**, select **MATCH ANY,** click the Add button and Conditioning Input {HTTPS}, Check if input String matches the pattern, and Pattern OFF (Pattern value is not case sensitive).
    d. Scroll to the Action menu, change Action Type to REDIRECT, under Redirect URL, type in https://{HTTP_HOST}{REQUEST_URI}
    e. UNCHECK Append Query String
    f. Change Redirect Type to Found(302)
    g. Click APPLY on the right-side menu



(Figure 2.5.2)

3. Customization Workspace

The Customization Workspace is used to apply settings to i-STAT 1 analyzers. Settings are applied by location, and locations ae organized into groups under an Institution. The Customization Workspace helps manage a fleet of distributed analyzers across multiple facilities or a healthcare system, including delivery of software updates and Electronic Value Assignment Sheets (eVAS).

The Customization Workspace is accessible via web browser and is validated for use with a compatible web browser. Refer to Section 1.1 Technical Specifications for browser compatibility.

To allow access to the Customization Workspace users must first set up their data management application to interact with and send location hierarchy information to i-STAT/DE. Check the documentation for your data management application for instructions on setting up integration with i-STAT/DE.

3.1 Accessing the Customization Workspace

When the data management application is configured to communicate location hierarchy information to i-STAT/DE, the institution information will populate in i-STAT/DE, and the Customization Workspace becomes accessible. An example of the hyperlink that is needed to access the Customiczation Workspace is shown here:

- http://[***computer-ip-or-name***]/ActiveX/custom.aspx?inst=[***InstitutionName***]&Option=1
- http://[***computer-ip-or-name***]/ActiveX/custom.aspx?inst=[***InstitutionName***]&Option=2

Where [***computer-ip-or-name***] is replaced by the IP address or machine name of the i-STAT/DE computer, and [***InstitutionName***] is replaced by the name of the institution whose settings will be displayed.

When Option=1, the user can view/change the settings of any institution in the healthcare system.

When Option=2, the user can view/change the settings of only the institution given by [***InstitutionName***].

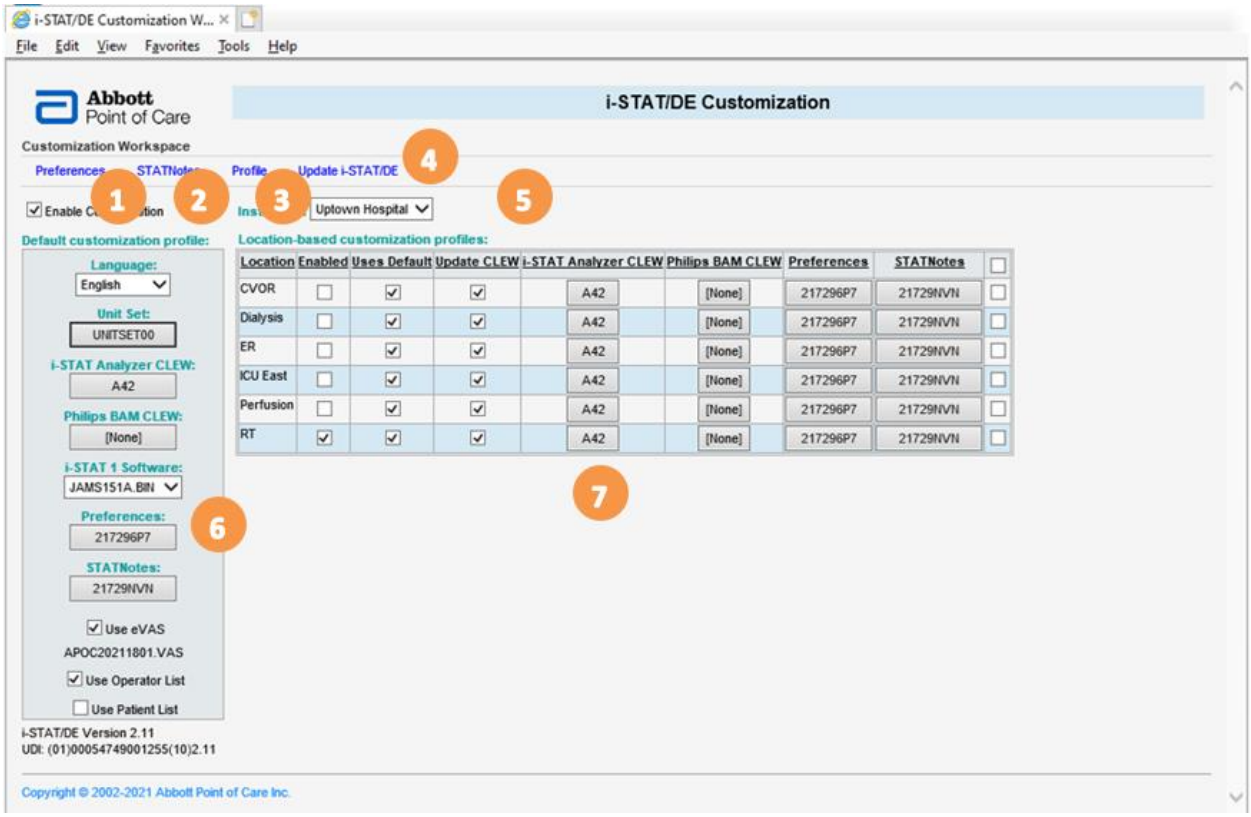
3.2 Customization Workspace

The Customization Workspace is used to help define behavior for i-STAT analyzers. Contents of the web page are described below. For exisitng and replacement analyzers, verify that the analyzer customization settings support running the cartridge prior to use.

The contents description number corresponds to the numbered areas in the graphic (Figure 3.2.1).

Note: The screen shown here is an example only. A screen's appearance may differ from the example.

1. **Preferences** – Various settings available for the i-STAT 1 analyzer. Preferences can differ by location. To apply Preferences or delete unused Preferences, hover on the **Preferences** link and choose **Apply Preferences** or **Delete Preferences**. (See *To apply Preferences*.) Preferences have a unique system-generated name to distinguish them from one another.
2. **STATNotes** – Option that allows users to collect additional patient-specific testing parameters in the i-STAT analyzer during the testing. Contact your local representative to discuss the benefits of enabling STATNotes.
3. **Profile** – A Profile consists of the entire contents of the Default customization profile plus all Preferences and STATNotes used in the Location-based customization profiles. To backup or restore a Profile, hover over the **Profile** link and choose **Backup Profile** or **Restore Profile**. (See *To backup Profiles* and *To restore Profiles*.)
4. **Update i-STAT/DE** – Hover over **Upload Update File** and select **Upload Update File** to upload files that have been backed up or downloaded from the Abbott Point of Care website. When updating, the system will write the various files to appropriate locations based on the file type.
5. **Institution Selector** – Allows users to toggle between institutions available within the location hierarchy as defined by an integrated data management system. Each institution (sometimes known as a facility) can have different preferences.
6. **Default Customization Profile Pane** – Displays the customization settings applied to all i-STAT 1 analyzers unless overriden by settings specified in the Location-based customization profiles grid. The following settings apply to all analyzers regardless of the location to which they are assigned:
   - Language
   - UNITSET
   - i-STAT 1 Software
   - Use eVAS
   - Use Operator List
   - Use Patient List
7. **Location-based Customization Profiles Pane** – Displays locations within i-STAT/DE and the settings specific to each location. Use this pane to enable/disable Profile updates for a location, indicate whether or not a location uses the default profile, enable/disable CLEW updates for a location, specify the CLEW for a location, and set the Preferences and STATNotes for a location. Depending on the number of locations in a system's hierarchy there may be multiple pages of locations. These can be accessed by clicking on the numbered page links at the bottom right corner of the pane. Location name has a character limit of 20.


i-STAT/DE Customization W...
File Edit View Favorites Tools Help
Abbott Point of Care
i-STAT/DE Customization
Customization Workspace
Preferences
Profile
Update i-STAT/DE
1
2
3
4
5
6
7
Uptown Hospital
Default customization profile:
Language:
English
Unit Set:
UNITSET00
i-STAT Analyzer CLEW:
A42
Philips BAM CLEW:
[None]
i-STAT 1 Software:
JAMS151A.BIN
Preferences:
217296P7
STATNotes:
21729NVN
Use eVAS
APOC20211801.VAS
Use Operator List
Use Patient List
i-STAT/DE Version 2.11
UDI: (01)00054749001255(10)2.11
Location-based customization profiles:
Location Enabled Uses Default Update CLEW i-STAT Analyzer CLEW Philips BAM CLEW Preferences STATNotes
CVOR A42 [None] 217296P7 21729NVN
Dialysis A42 [None] 217296P7 21729NVN
ER A42 [None] 217296P7 21729NVN
ICU East A42 [None] 217296P7 21729NVN
Perfusion A42 [None] 217296P7 21729NVN
RT A42 [None] 217296P7 21729NVN
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(Figure 3.2.1)

3.3 Customization Profile Options

This section describes the parameters that can be customized for site-specific testing requirements and the factory default settings.

A customization profile consists of selections made from four major pages: Language, UNITSET, CLEW and Preferences. The Preferences page consists of six tabs: Instrument, ID Entry, Test, Cartridge QC, Results, and Analyte Enable.

When making initial selections, or updating selections on the page:

- To save preferences, click the OK button.
- To cancel changes to the preference, click the CANCEL button.

Note: Pressing the Enter Key on your keyboard may result in the following default preferences to be applied (DEFAULT0) and displayed in the selection area.

Important Note: Verify that the analyzer customization settings support running the cartridge prior to use.

For i-STAT CG4+ Cartridges (P/N 03P85-51): Incorrect customization of the Reference and Action range for pH, PO2, or PCO2 will result in a display message, “Invalid Cart, See Admin” and inability to obtain test results when scanning the cartridge pouch barcode for
i-STAT CG4+ Cartridges (P/N 03P85-51).

Customization Profile Page: Default Customization

LANGUAGE: Drop-down menu to select Language for text displayed on analyzer: English, Japanese, German, Italian, Dutch, Spanish, French, Swedish, Portuguese, Danish, and Finnish.

Default Setting: English

UNIT SET PAGE: Reporting units for results. Select from predefined sets or by analyte. Seventeen predefined UNITSETs available. UNITSET99 allows the name and units for each test to be defined individually. UNITSET applies to all customization profiles within the institution selected.

See i-STAT Cartridge Instructions for Use (IFU) or Cartridge and Test Information (CTI) sheets, located at www.globalpointofcare.abbott for more information on analytes and available units.

Default Setting: UNITSET00

Note: Reference Ranges, Action Ranges, and Custom Reportable Ranges (if applicable) in the Preferences Window must be changed when changing units.

To Set the UNITSET:

From the Customizatio**n** Workspace Web page, under the Default Customization Profile area, select UNITSET.

1. Click on **Select a UNITSET** and select a UNITSET from the drop-down menu.
   - The default is UNITSET00 and is pre-defined.
   - A customizable UNITSET99 may be used to select the name and unit, if available.
2. To select the analyte, click on the select button and select from the displayed options.
3. Click Okay to **Save** the Unit Set selection or **Cancel** to cancel the UNITSET selection.

For details on the options available within the UNITSET, see tables below:

TABLE: UNITSET Options – 00, 99, 01 thru 06								
Label	**00 (Default)**	**99 (Customizable)**	**01**	**02**	**03**	**04**	**05**	**06**
Na	mmol/L	mmol/L, mEq/L	mmol/L	mmol/L	mmol/L	mEq/L	mmol/L	mmol/L
K	mmol/L	mmol/L, mEq/L	mmol/L	mmol/L	mmol/L	mEq/L	mmol/L	mmol/L
Cl	mmol/L	mmol/L, mEq/L	mmol/L	mmol/L	mmol/L	mEq/L	mmol/L	mmol/L
BUN	mg/dL	mg/dL	N/A	N/A	N/A	N/A	N/A	N/A
UREA	N/A	g/L, mg/dL, mmol/L	mmol/L	mmol/L	mg/dL	mg/dL	mg/dL	mg/dL
Crea	mg/dL	µmol/L, mg/dL	µmol/L	µmol/L	mg/dL	mg/dL	mg/dL	mg/dL
Glu	mg/dL	mmol/L, mg/dL, g/L	mmol/L	mmol/L	mmol/L	mg/dL	mg/dL	mg/dL
Lac	mmol/L	mmol/L, mg/dL, g/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L
AnGap	mmol/L	mmol/L, mEq/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mEq/L
Hct	%PCV	%PCV, [None]	[None]	%PCV	%PCV	%PCV	%PCV	%PCV
Hb	g/dL	mmol/L, g/dL, g/L	g/L	g/L	g/dL	g/dL	g/dL	g/dL
iCa	mmol/L	mmol/L, mEq/L, mg/dL	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L
pH	[None]	[None]	[None]	[None]	[None]	[None]	[None]	[None]
PCO2	mmHg	kPa, mmHg	kPa	kPa	mmHg	mmHg	mmHg	mmHg
PO2	mmHg	kPa, mmHg	kPa	kPa	mmHg	mmHg	mmHg	mmHg
HCO3	mmol/L	mmol/L, mEq/L	mmol/L	mmol/L	mEq/L	mmol/L	mmol/L	mEq/L
TCO2	mmol/L	mmol/L, mEq/L	mmol/L	mmol/L	mEq/L	mmol/L	mmol/L	mmol/L
BE	mmol/L	mmol/L, mEq/L	mmol/L	mmol/L	mEq/L	mmol/L	mmol/L	mEq/L
sO2	%	%, [None]	%	%	%	%	%	%
ACT WBT	sec	sec	sec	sec	sec	sec	sec	sec
aPTT**	sec	sec	sec	sec	sec	sec	sec	sec
PT+**	sec	sec	sec	sec	sec	sec	sec	sec
INR+**	[None]	[None]	[None]	[None]	[None]	[None]	[None]	[None]
PT	sec	sec	sec	sec	sec	sec	sec	sec
INR	[None]	[None]	[None]	[None]	[None]	[None]	[None]	[None]
hs-TnI**	ng/mL	µg/L, ng/mL, pg/mL, ng/L	ng/L	ng/L	ng/L	ng/L	ng/L	ng/L
cTnI	ng/mL	µg/L, ng/mL	ng/mL	ng/mL	ng/mL	ng/mL	ng/mL	ng/mL

Notes:

- There are no units for pH or for hematocrit when reported as decimal fraction.
- There is no unit selection for INR.
- **Denotes future cartridge development.
- For intended use and complete product information, visit www.globalpointofcare.abbott.
- Not all products are available in all regions. Check with your local Abbott representative for availability.

TABLE: UNITSET Options – 00, 99, 01 thru 06, continued								
Label	**00 (Default)**	**99 (Customizable)**	**01**	**02**	**03**	**04**	**05**	**06**
CK-MB	ng/mL	µg/L, ng/mL	ng/mL	ng/mL	ng/mL	ng/mL	ng/mL	ng/mL
BNP	pg/mL	ng/L, pg/mL	pg/mL	pg/mL	pg/mL	pg/mL	pg/mL	pg/mL
BhCG	IU/L	IU/L	IU/L	IU/L	IU/L	IU/L	IU/L	IU/L
hCG	QUAL	QUAL	QUAL	QUAL	QUAL	QUAL	QUAL	QUAL
TSH**	mIU/L	mIU/L, µIU/mL	mIU/L	mIU/L	mIU/L	mIU/L	mIU/L	mIU/L

Notes:

- There are no units for pH or for hematocrit when reported as decimal fraction.
- There is no unit selection for INR.
- **Denotes future cartridge development.
- For intended use and complete product information, visit www.globalpointofcare.abbott.
- Not all products are available in all regions. Check with your local Abbott representative for availability.

TABLE: UNITSET Options, 07 thru 16										
Label	**07**	**08**	**09**	**10**	**11**	**12**	**13**	**14**	**15**	**16**
Na	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mEq/L	mmol/L
K	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mEq/L	mmol/L
Cl	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mEq/L	mmol/L
BUN	N/A	N/A	N/A	N/A	N/A	mg/dL	N/A	N/A	mg/dL	N/A
UREA	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	N/A	mmol/L	mmol/L	N/A	g/L
Crea	µmol/L	µmol/L	µmol/L	µmol/L	µmol/L	mg/dL	µmol/L	µmol/L	mg/dL	µmol/L
Glu	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mg/dL	mmol/L	mmol/L	mg/dL	g/L
Lac	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L
AnGap	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mEq/L	mmol/L
Hct	%PCV	[None]	[None]	[None]	[None]	%PCV	%PCV	%PCV	%PCV	%PCV
Hb	mmol/L	g/L	g/dL	g/dL	g/dL	g/dL	g/dL	mmol/L	g/dL	g/dL
iCa	mmol/L	mmol/L	mmol/L	mmol/L	mg/dL	mg/dL	mmol/L	mmol/L	mEq/L	mmol/L
pH	[None]	[None]	[None]	None]	[None]	[None]	[None]	[None]	[None]	[None]
PCO2	kPa	mmHg	mmHg	kPa	kPa	mmHg	mmHg	mmHg	mmHg	mmHg
PO2	kPa	mmHg	mmHg	kPa	kPa	mmHg	mmHg	mmHg	mmHg	mmHg
HCO3	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mEq/L	mmol/L
TCO2	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mEq/L	mmol/L
BE	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mEq/L	mmol/L
sO2	%	%	%	%	%	%	%	%	%	%
ACT WBT	sec	sec	sec	sec	sec	sec	sec	sec	sec	sec
aPTT**	sec	sec	sec	sec	sec	sec	sec	sec	sec	sec
PT+**	sec	sec	sec	sec	sec	sec	sec	sec	sec	sec
INR+**	[None]	[None]	[None]	[None]	[None]	[None]	[None]	[None]	[None]	[None]
PT	sec	sec	sec	sec	sec	sec	sec	sec	sec	sec
INR	[None]	[None]	None]	[None]	[None]	[None]	[None]	[None]	[None]	[None]
hs-TnI**	ng/L	ng/L	ng/L	ng/L	ng/L	ng/L	ng/L	ng/L	ng/L	ng/L
cTnI	ng/mL	ng/mL	ng/mL	ng/mL	ng/mL	ng/mL	ng/mL	ng/mL	ng/mL	ng/mL

Notes:

- There are no units for pH or for hematocrit when reported as decimal fraction.
- There is no unit selection for INR.
- **Denotes future cartridge development.
- For intended use and complete product information, visit www.globalpointofcare.abbott.
- Not all products are available in all regions. Check with your local Abbott representative for availability.

TABLE: UNITSET Options, 07 thru 16, continued										
Label	**07**	**08**	**09**	**10**	**11**	**12**	**13**	**14**	**15**	**16**
CK-MB	ng/mL	ng/mL	ng/mL	ng/mL	ng/mL	ng/mL	ng/mL	ng/mL	ng/mL	ng/mL
BNP	pg/mL	pg/mL	pg/mL	pg/mL	pg/mL	pg/mL	pg/mL	pg/mL	pg/mL	pg/mL
BhCG	IU/L	IU/L	IU/L	IU/L	IU/L	IU/L	IU/L	IU/L	IU/L	IU/L
hCG	QUAL	QUAL	QUAL	QUAL	QUAL	QUAL	QUAL	QUAL	QUAL	QUAL
TSH**	mIU/L	mIU/L	mIU/L	mIU/L	mIU/L	mIU/L	mIU/L	mIU/L	mIU/L	mIU/L

Notes:

- There are no units for pH or for hematocrit when reported as decimal fraction.
- There is no unit selection for INR.
- **Denotes future cartridge development.
- For intended use and complete product information, visit www.globalpointofcare.abbott.
- Not all products are available in all regions. Check with your local Abbott representative for availability.

i-STAT 1 ANALYZER AND PHILIPS BAM CLEW PAGES: Standardization data. All non-expired versions listed. The CLEW software has an expiration date. If an expired CLEW remains in a customization profile, a warning will be displayed.

Note: Philips BAM CLEW is no longer active and does not apply to the i-STAT 1 system

i-STAT 1 SOFTWARE: Drop-down menu for JAMS functionality data. Users can remotely request a JAMS update for an i-STAT 1 analyzer from i-STAT/DE. See the "Network Options for Updating the i-STAT 1 Handheld" Technical Bulletin, located on the www.globalpointofcare.abbott website.

PREFERENCES PAGE: Options and default settings are listed under six headings: Instrument, ID Entry, Test, Cartridge QC, Results, and Analyte Enable.

STATNOTES PAGE: Feature allows users to customize the Chart Page on their i-STAT 1 Analyzers in order to capture user-defined information such as ventilator settings. See Section 3.6 STATNotes for full details and contact your local APOC representative for information on activating and implementing this feature.

Default Setting: Chart0

Use eVAS: This Feature can automatically determine if the results of a liquid QC test run on an i-STAT cartridge are within APOC's published quality control ranges.

Default Setting: Not enabled

Note: The current eVAS File uploaded to i-STAT/DE is displayed for all facilities that utilize i-STAT/DE and utilized when enabled by each facility individually.

USE OPERATOR LIST: 4200 operator IDs can be stored in the analyzer along with certification start and end dates for cartridge testing. Operator lists are created in the Operator Management area of the data management software. This check box cannot be enabled if the Operator List is empty in the Operator Management Area of the data management software for all Departments (other than the one labeled "Unassigned").

Default Setting: Not enabled

USE PATIENT LIST: 6000 patient IDs can be stored in the analyzer. The maximum number of active patients permitted on the i-STAT 1 patient list is 6000 per facility. See Sections 1.3 Positive Patient ID (PPID) Feature Implementation and 3.7 Positive Patient Identification (PPID) Customization in this user guide for full details.

Default Setting: Not Enabled

Preferences Page: Instrument Tab for Instrument Options

PASSWORD: Password to access Set Clock, the Change function in Customization, and Utility under the Administration Menu. Password protection for the Set Clock function can be enabled or disabled. See below.

Number of Digits: 0 to 5

Default Setting: No Password

Note: Abbott Point of Care Inc. recommends changing the default password setting.

DATE FORMAT: For Clock Set function only.

Options: mm/dd/yy or dd/mm/yy

Default Setting; mm/dd/yy

INACTIVITY TIMEOUT: Number of seconds after a result is displayed and no operator intervention that an analyzer will turn off. Enabling of Auto Chart presentation and/or mandatory items will override the inactivity timeout to 15 minutes.

Analyzer allowable range: 45 to 1620 seconds

Data Entry Field range: 1 to 65535

Default Setting: 120

SOUND: If enabled, the analyzer will emit a beep after each successful key press, when results are ready or when a Quality Check message is displayed. If Sound is disabled, the analyzer will only beep after a successful barcode entry.

Default Setting: Beep enabled

ENABLE WIRELESS COMMUNICATION: Enable the wireless functionality in an i-STAT 1 Wireless analyzer. See the following technical bulletins, located at www.globalpointofcare.abbott, for more information: "Configuring Wireless Settings in an i-STAT 1 Wireless Analyzer" and "Procedure for Using the i-STAT 1 Wireless Analyzer".

Default Setting: Not enabled

NOTE: The i-STAT 1 Wireless analyzer is currently available in the US and Canada. Limited availability internationally, please contact your local APOC representative for availability in your country/region.

AUTO TRANSMIT: Analyzer transmits results when placed in Downloader or Downloader/Recharger. When an i-STAT 1 analyzer is powered off and placed in the Downloader or Downloader/Recharger it will power on and automatically transmit unsent results. An i-STAT 1 Wireless analyzer when configured for wireless will attempt three times to transmit wirelessly prior to transmitting via the Downloader or Downloader/Recharger.

Default: Enabled

MEMORY FULL ACTION: Memory Full refers to when the unsent records as recorded on the 'Analyzer Status' screen reaches 1000. Uploading does not erase the data from the analyzer's memory.

Options are:

Not enabled: overwrite the oldest record without warning.

Enabled: Warn user (start-up warning) or Lockout (testing disabled until upload occurs).

Default: Not Enabled

BATCH MODE TIMEOUT: Not active at this time.

Default: Not enabled

DISPLAY PASSWORD FOR CLOCK PAGE:

Default: Enabled

SYNCHRONIZE CLOCK TO CDS: Will synchronize or update the real-time clock in the i-STAT 1 analyzer to the server/workstation clock at the time of each download. This eliminates the need to reset the analyzer's clock at the beginning and end of Daylight Savings Time.

Default: Not enabled

Note: This feature does not support user systems that have facilities in multiple time zones. Facilities in the time zone of the server/workstation may utilize the feature, while facilities outside of the time zone may require the analyzers to have their time manually set in the analyzer.

APPLY OPERATOR LIST TO VIEWING STORED PATIENT RECORDS: Requires operator to enter their operator ID number to access stored patient results on the i-STAT 1 analyzer.

Default: Not enabled

LIMIT NUMBER OF RECORDS IN TRANSMIT ALL: Allows the user to apply a date range limit to the Transmit All function in the i-STAT 1 analyzer. If not limited, the Transmit All function sends all stored results.

Data Entry Field Range (in Days): 1 to 65535

Default Setting: Disabled

UPLOAD SCHEDULE: Options are Off, or every X hours, where X can be 1 to 65535 hours. If enabled, the behavior of the analyzer if the schedule is not met can be specified. If no upload schedule is specified and the Memory Full warning is ignored and Auto-transmit disabled, data will eventually be overwritten. However, if an analyzer has not been used and the upload interval is exceeded, this analyzer will be inoperable if the lockout option is used.

Options are: Warn User (start-up warning message) or Lockout (testing disabled until upload occurs)

Default Setting: Off, no warning or lockout.

Preferences Page: ID Entry Tab for Operator and Patient ID Options

For fields, other than Operator and Patient ID, only the default setting for the barcode type can be scanned. These are Code I2 of 5 with USS Check Digit and Code 39 Full ASCII with Check Digit.

OPERATOR ID: Minimum and maximum allowed operator ID length (scanned or manually entered). If operator IDs are a fixed length, the min. and max. settings should both be equal to the ID length.

Default Setting: Min = 0 Max = 15

REPEAT MANUAL/SCANNED ID ENTRY: Operator must enter ID twice. Analyzer prompts operator to start again if IDs do not match. This option can be set for manual and/or scanned ID Entry.

Default Setting: Enabled: Repeat Required

INCLUDE ID ON PRINTOUT: Enables/Disables printing of operator IDs on printouts from the Martel or i-STAT printer. Disabling the printing of operator IDs can prevent uncertified

operators from learning the IDs of certified operators.

Default Setting: Enabled

BARCODE OPTIONS: The type of barcodes used for Operator ID and Patient ID.

The i-STAT 1 analyzer recognizes one-dimensional barcodes.

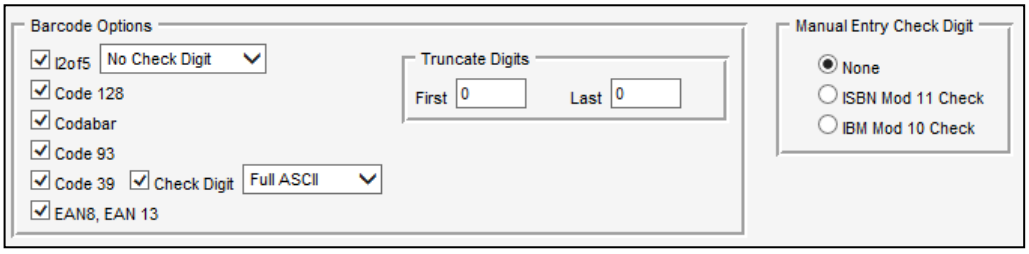
Default Settings: All Barcode Types Enabled

Note: Barcode Label Quality

To ensure that printed barcode labels are reliably read by i-STAT analyzers, the best available printing methods and settings should be used. However, as specified in the Health Industry Bar Code (HIBC) Provider Applications Standard (ANSI/HIBC 1.3-2010), the quality of printed labels should meet the minimum grade level of 1.5.

To Select the Barcode Type:

1. Click on box to enable or disable the barcode type that the i-STAT 1 analyzer may scan (Figure 3.3.1).



(Figure 3.3.1)

For details on barcode types, see barcode options table below:

Barcode Type	Barcode Options and Default Setting
I2 of 5	Options: No Check Digit, USS Check Digit, OPCC Check Digit Default Setting: USS Check Digit
Code 128	Barcode type Code 128 will support USS 128 and UCC/EAN 128, but not ISBT 128 Default Setting: Enabled
Codabar	Default Setting: Enabled
Code 93	Default Setting: Enabled
Code 39	Options: Check Digit or No Check Digit; Full ASCII or Alphanumeric Default Setting: Enabled Check Digit; Full ASCII
EAN8, EAN13	Default Setting: Enabled
Truncate Digits	The analyzer will accept up to 15 characters for operator and patient IDs. User can select how to truncate digits from a scanned operator and/or patient ID: **First:** enter number of leading characters to be stripped from the barcode. **Last:** enter number of trailing characters to be stripped from the barcode Options: First, Last Default Setting: No Truncation Data Entry Field Range(s) in digits: 0 to 255 **Note:** There is no current option to truncate digits in the middle of the barcode string.

2. Click Okay to **Save** or **Cancel** to cancel.

MANUAL ENTRY CHECK DIGIT: A Check Digit is a decimal (or alphanumeric) digit added to a number for the purpose of detecting typical data entry errors. If a facility makes use of a supported Check Digit algorithm when creating Operator or Patient IDs, the i-STAT 1 analyzer can verify the entered ID format by calculating the check digit and comparing it to the entered ID number. If the Check Digits don't match, the ID is rejected.

For more information on manual entry check digit see, Section 3.5 Minimizing ID Entry Errors with the i-STAT 1 Analyzer Customization Features

Options: None, ISBN Modulus 11 Check, and IBM Modulus 10 Check.

Default: None

Note: The i-STAT System supports the Mod 10 and Mod 11 check digit algorithms described in the HL7 Table 0061 (Check Digit Scheme) in the HL7 Specification (Rev 1.4). Please contact your LIS/HIS or IT departments to help determine if your facility uses Check Digits in the creation of operator and/or patient ID numbers, and if so, what algorithm is used.

INVALID OPERATOR: This option should not be enabled if the Use Operator List option is disabled. Behavior of analyzer when Operator ID not in stored list or certification date expired.

Options are: Not enabled (continue without warning), Warn User (prompt to continue), and Lockout (block testing until a valid Operator ID is scanned/entered).

Default: Not enabled (continue without warning)

EXPIRATION NOTIFICATION: Allows a System Administrator to define a time period (1 to 255 days) in which the operator will be notified by a message on the i-STAT 1 analyzer display of their competency expiration date.

PATIENT ID: Minimum and maximum allowed patient ID length (scanned or manually entered). If patient IDs are a fixed length, the min. and max. settings should both be equal to the ID length.

Default Setting: Min = 0 Max = 15

REPEAT MANUAL/SCANNED ID ENTRY: Operator must enter patient ID twice. Analyzer prompts operator to start again if IDs do not match. This option can be set for manual and/or scanned ID Entry.

Default Setting: Repeat ID enabled

PATIENT ID RECALL: Operator can recall last patient ID when analyzer prompts for Patient ID. The most recent patient ID is recalled by pressing the → key.

Default Setting: Enabled

BARCODE OPTIONS: The type of barcodes used for Operator ID (see table Barcode Options). The i-STAT 1 analyzer recognizes one-dimensional barcodes.

Default Settings: All Barcode Types Enabled

MANUAL ENTRY CHECK DIGIT: For more information on manual entry check digit see, Section 3.5 Minimizing ID Entry Errors with the i-STAT 1 Analyzer Customization Features

Options: None, ISBN Modulus 11 Check, and IBM Modulus 10 Check.

Default: None

POSITIVE PATIENT ID: The i-STAT 1 PPID feature maintains one active patient list per facility, ensuring patients are recognized wherever they are located in the facility. This active patient list is obtained from the facility ADT database by the data manager. The maximum number of active patients permitted on the i-STAT 1 patient list is 6000 per facility.

See Section 3.7 Positive Patient Identification (PPID) Customization for more information on Positive Patient Identification (PPID) Customization for full details.

Preferences Page: Test Tab for Test Options

AUTO-CHART PRESENTATION: If any information on the Chart Page is mandatory for the site, Auto-Chart Presentation is recommended. When this option is enabled it automatically will display the Chart Page for 15 minutes to provide time for mandatory items to be handled by the operator. Those 15 minutes supersede the inactivity timeout setting and may result in delayed transmission of results if the analyzer is left unattended and mandatory items are not addressed by the operator.

This option should not be enabled if there are no mandatory items. Enabling the "Auto-Chart Presentation" when no mandatory items are selected will result in the analyzer displaying a blank Chart Page for 15 minutes before powering off, delaying transmission of results if the analyzer is left unattended.

Options: Enabled (the Chart Page will be displayed automatically), Not Enabled (The operator must press the → key to display the Chart Page).

Default: Not Enabled

CARTRIDGE PATIENT TEST:

The behavior for the following features is set by the analyzer firmware and no longer requires customization:

- Require Information before Running Cartridge
- Enter Lot Number
- Scan Cartridge Barcode

These two options were instituted for the release of the RIBS data integration feature.

- Third Party Result Output
- Require analyzer to be in Downloader

Default Setting: Not Enabled

NOTE: These options SHOULD NOT be activated by users until the data integration process is complete, as misconfiguring your analyzers using these features can cause testing to be disabled.

PATIENT TEST COMMENT CODE: A comment code of up to three characters is allowed. Care should be taken to select combinations that make sense. In the case of a missed required Comment Code, the results will be stored and "_ _ _" will be entered as the Comment Code.

Options are: No prompt or Prompt

- Prompt for Comment Code, All Results in Range (action range).
- Prompt for Comment Code, Any Result out of Range (action range).

Comment Code can be optional (Allow no Comment) or mandatory (Require Comment).

Default Setting: No prompt

SAMPLE TYPES FOR CARTRIDGE: Drop down menus for each sample type allow the six sample types to be re-ordered or changed. Up to 4 user-definable characters are allowed for each sample type. To select from the options, click on the down arrow.

The sample type is stored with the test record and is included on the printout from the i-STAT 1 printer and in the record in the Data Management Software. See Technical Bulletin "Sample Type Customization on the i-STAT 1 Analyzer" located at www.globalpointofcare.abbott for full details.

Options: ART, VEN, MIX, CAP, CORD

Data Entry Field Limit: 4 characters

Note: For a sample type of Other, the following abbreviation may be used: OTHR

CHART PAGE: Any item on the Chart Page can be deleted by clicking off the check mark in the Display column or be made mandatory by clicking a check mark in the Mandatory column. If any item is set as mandatory, the Chart Page will be displayed automatically after the Patient ID is entered.

The following Field items are available in the CHART Page:

- Sample Type
- Free Field 1
- Free Field 2
- Free Field 3
- Patient Temperature
- FIO2
- CPB

Note: Free Field items are not able to be renamed and will have a character limit of nine.

The items on the Chart page can also be rearranged by setting the number in the order column. Items may be marked as mandatory by selecting the box pertaining to the item in the mandatory column.

Default Setting: All items set to not mandatory

Preferences Page: Cartridge QC Tab - Electronic QC Settings

Electronic QC Settings Tab: For the quality control of i-STAT analyzers, Abbott Point of Care recommends the use of the Electronic Simulator. i-STAT's recommendation for the frequency of the Electronic Simulator is once every 24 hours. More frequent use or use according to number of patient tests may be required by accreditation and regulatory bodies.

EXTERNAL SIMULATOR SCHEDULE: The behavior of the analyzer if the schedule is not met can also be specified: Warn or Lockout (testing disabled until Simulator used).

Options:

- Off (No Prompt)
- Every *X* hours
- Every *X* Patient Tests

(Where *X* is a number within the data entry field limits)

Data Entry Filed Limits: Hours: 1-65535, Patient Tests: 1-65535

Scheduled Options: Enabled, Disabled; Lockout, Warn

Default Settings: Off (No Prompt)

INTERNAL SIMULATOR SCHEDULE: Time interval when the internal Electronic Simulator test will be run. The behavior of the analyzer if the simulator test fails can also be specified. If the Schedule Option Lockout is selected, the analyzer will continue to perform the simulator test and will continue to display "FAIL" on subsequent cartridges until the test passes. If Lockout is not selected, the simulator test will not be initiated again until next scheduled time.

Options: Off, 8/24 (every 8 hours for blood gases, coagulation, hematocrit and immunoassays, and every 24 hours for other tests), Every *X* hours, Every *X* Patient Tests (Where *X* is a number within the data entry field limits).

Data Entry Filed Limits: Hours: 1 to 65535, Patient Tests: 1 to 65535

Scheduled Options: Enabled, Disabled; Lockout, Warn

Default Settings: Interval 24 hours, Lockout

Preferences Page: Cartridge QC Tab – Liquid QC Settings

Liquid QC Settings Tab:

CONTROL PASS/FAIL DETERMINATION: Describes the way in which the System Administrator will determine the acceptability of liquid QC results.

Options:

- None: Disables the QC Pass/Fail and QC Schedule feature.
- Automatic via EVAS: Choosing this option indicates that the analyzer 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 analyzer.
- 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.globalpointofcare.abbott and indicate on the analyzer whether the QC run passed or failed.

CONTROL TEST SETTINGS: If the System Administrator wants users to enter a Comment Code when liquid QC results are in-range, out-of-range, or under both situations, they would check the appropriate box and then use the drop-down menu to select whether entering the comment code is optional (Allow no comment) or Required (Require Comment). Comment Code options can only be selected if one of the Control Pass/Fail Determination methods has been selected.

Default Setting: Disabled

CONTROL RESULTS DISPLAY FORMAT: The "Suppressed" option should only be chosen if "Automatic via EVAS" is chosen for the liquid QC Pass/Fail Determination.

Options:

- 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.

Default Setting: Numeric

APOC FLUID LOT ENTRY METHOD:

Options:

- Scan or Enter: allows the user the option of manually entering the liquid QC lot information into the analyzer 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 vial being tested.

Default Setting: Scan or Enter

SCHEDULE STATUS: Displays the status of previously defined Liquid QC Schedules

Preferences Page: Cartridge QC Tab – Liquid QC Schedule (1,2 or 3)

Liquid QC Schedule (1,2 or 3) Tab: The tabs will be grayed out unless “Auto via eVAS" or “Manual” is selected in the Liquid QC Settings Tab under CONTROL PASS/FAIL DETERMINATION.

QC FREQUENCY: Describes the frequency at which the System Administrator wants the liquid QC run under this schedule.

Options:

- 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)

Default Setting: Off

QC TIME: The QC Time sets the time when the 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”.

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.

A QC Time can only be chosen if QC Frequency has been activated. 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.

Enter the Grace Period in hours: The minimum Grace Period is one hour for any schedule type.

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

Default Setting: Disabled

APPLY QC SCHEDULE TO: The months of the year to which this schedule will apply.

Options:

- All months
- Selected Months: Check the box next to the months to which this schedule will apply.

Default Settings: All months

CARTRIDGE QC PROFILE: A Cartridge QC Profile can only be edited or created if QC Frequency has been activated. The System Administrator then associates the defined cartridge set with up to six (6) specific QC fluids.

The System Administrator defines a QC cartridge set 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).

Default Setting: Disabled

Preferences Page: Result Tab for Results Reporting Options

IMPORTANT NOTE : Incorrect customization of the Reference and Action range will result in a display message, “Invalid Cart, See Admin” and inability to obtain test results when scanning the cartridge pouch or portion pack barcode. See Section 3.14 Customizing Reference and Action Ranges for full details.

REFERENCE RANGES: Reference ranges can be defined for each test. The ranges will be depicted as tic marks on the bar graphs on the result pages of the analyzer. There are no bar graphs for blood gas, coagulation, and immunoassay tests.

Ranges will be displayed on the Customization screen of the analyzer under the Administration Menu. Only one range is allowed for each test in a particular analyzer. However, different customization profiles can be set up in specific analyzers used for specific patient populations. Care should be taken to enter the same units as selected in the UNITSET Window.

Default Settings: Ranges are listed in the i-STAT Cartridge Instructions for Use (IFU) or Cartridge and Test Information (CTI) sheets.

ACTION RANGES: High and low action ranges can be defined for each test. Care should be taken to enter Action Ranges within the reportable ranges of the tests. Care should be taken to enter the same units as selected in the UNITSET Window.

Default Settings: Disabled, (-99999.9 to 99999.9)

NOTE: Action Ranges customized by the System Administrator may require adjustments to obtain the action range needed for generating the expected alert on the i-STAT 1 analyzer.

CUSTOM REPORTABLE RANGES: High and low custom Reportable Ranges can be defined for each analyte (except ACT). See Section 3.13 Custom Reportable Range Feature for full details.

Default Settings: Disabled, (-99999.9 to 99999.9)

PRINT REFERENCE RANGES: Reference Ranges can be printed with results. Ranges will print only if the record to be printed is stored with the active Preference set in the analyzer. The active reference set in the analyzer is listed as “Custom” on the ‘Analyzer Status’ page and the Preference set stored with the record is displayed on the Chart Page when the record is recalled and is printed with the results.

Default Settings: Disabled

OPERATOR TEST SELECTION: This option facilitates compliance with Medicare/Medicaid regulations in the USA. Requires the operator to select tests to be reported from a cartridge test panel.

NOTE: When enabled and the operator does not select a test, no results will be displayed with the analytes.

IMPORTANT NOTE: There is no ability to retrieve the results for tests that were not selected within the i-STAT analyzer or within the data management software.

Default Setting: Disabled

ACT OPTIONS (i-STAT 1 Analyzer Only): Please see the Technical Bulletin "ACT Test Result Calibration Options: PREWARMED vs. NON-PREWARMED Result Calibration Modes for the i-STAT 1 Analyzer”, located at www.globalpointofcare.abbott for more details. The user can select between the current

37 °C (PREWRM) result calibration and "NON-PREWARM" (ambient temperature) result calibration for both Celite ACT and Kaolin ACT cartridges.

Default Setting: PREWRM for both cartridge types.

HEMATOCRIT OPTIONS: Analyzers can be customized by location. For more information on Hematocrit and options please see the following Section of the i-STAT 1 System Manual and Technical Bulletins, located at www.globalpointofcare.abbott:

- i-STAT 1 System Manual, “Section 2 Theory”
- i-STAT Technical Bulletin:
    - “K2EDTA and K3EDTA Customization for Hematocrit on the i-STAT System”

REFERENCE ANTICOAGULANT: Reference anticoagulant used to calculate hematocrit result: K3EDTA or K2EDTA/Heparin/None (NaEDTA is included in this option and None means no anticoagulant).

Default Setting: K3EDTA

HCT, CPB ADJUSTMENT: Analyzers customized for "CPB: Always" should not be used for reporting Proficiency Testing results

- Prompt: asks user whether to apply CPB compensation when cartridge includes Hematocrit sensor.
- Never: CPB correction is never applied when running a cartridge with a hematocrit sensor.
- Always: apply CPB correction every time it runs a cartridge with a hematocrit sensor.

Default Setting: Prompt CPB

DECIMAL SEPARATOR: Select comma (,) or period (.)

Default Setting: Period

BASE EXCESS CALCULATION: Select Base Excess of Extracellular Fluid (BEecf) or Base Excess of Blood (BEb). See i-STAT Cartridge IFU for PCO2 for formulas.

Default Setting: BEecf

i-STAT RESERVED (1 to 8): Not for general use.

Default Setting: 0

Preferences Page: **Analyte Enable Tab for Analyte Enable Options**

NOTE: The global disabling of an analyte takes precedence over the same analyte enabled on a Panel/Cartridge.

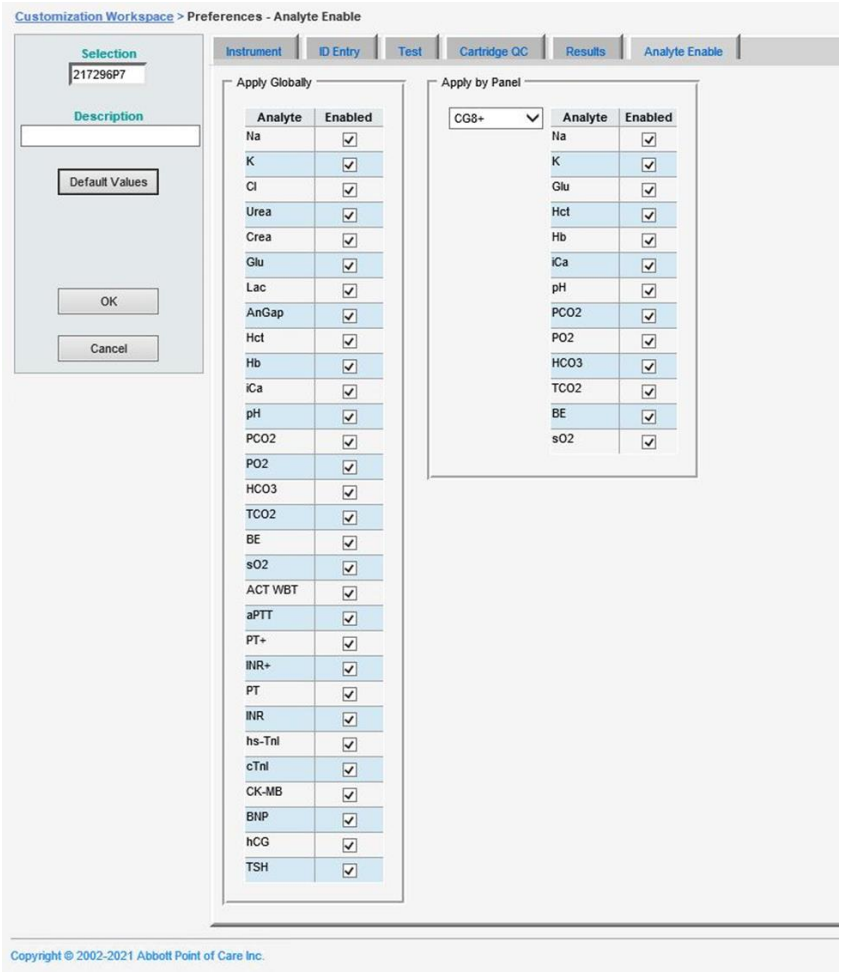
APPLY GLOBALLY: Test(s) can be disabled for all cartridge types. To enable/disable a particular analyte on all cartridge types, simply check/uncheck the box next to the analyte name in the Apply Globally section (Figure 3.3.2).

Default Setting: All tests enabled

APPLY BY PANEL: Test(s) can be disabled for individual cartridge types. To enable/disable a particular analyte on a specific cartridge type, make sure the analyte is first checked under the Apply Globally section (Figure 3.3.2). Then click on the cartridge type under the Apply by Panel section (Figure 3.3.2), and then check/uncheck the box next to the analyte name.

Default Setting: All tests enabled for all cartridge types.

For more information, see Section 3.15 Customizing Analyte Enable Options in this user guide.



(Figure 3.3.2)

3.4 Customization Profile Management

From the Customization Workspace Web page, you can perform tasks such as backing up, restoring, and applying preferences to Profiles.

Things to consider prior to backing up and/or restoring profiles

Profiles created in older versions of i-STAT/DE can be backed up and restored to newer versions. For instance, a profile created and saved in i-STAT/DE version 2.8 can be restored to i-STAT/DE version 2.10 if the following conditions are met:

- JAMS/CLEW version must be the same
- When migrating an old profile, make note of the existing UNITSET (UNITSET00, UNITSET01, etc.) assigned in older system (e.g. v2.8) in the Customization Workspace and ensure to assign the same UNITSET to the new system (e.g. v2.11).

To Backup Profiles:

1. Hover over the **Profile** link and select **Backup Profile** to create a backup of all profiles (location-based and default) and STATNotes.
2. The File Download dialog box displays. Click **Save as** to create a backup.
3. Select a location, enter a file name for the backup and select **Save**.
4. Click **X** when the download is complete.

To Restore Profiles:

1. Hover over the **Profile** link and select **Restore Profile** to recover Preferences/STATNotes from a backup.
2. The File Upload dialog box displays.
3. Click **Browse** to select the Profile to be restored.
4. Click **Open**, then click **Restore Profile**.
5. The restore information window displays. Select **Restore Settings**/**Restore STATNotes Settings** as appropriate.
6. Click **OK** to continue with restore and click **OK** to the message from web page.
7. **Restore STATNotes Settings** is unchecked by default.

   Note:

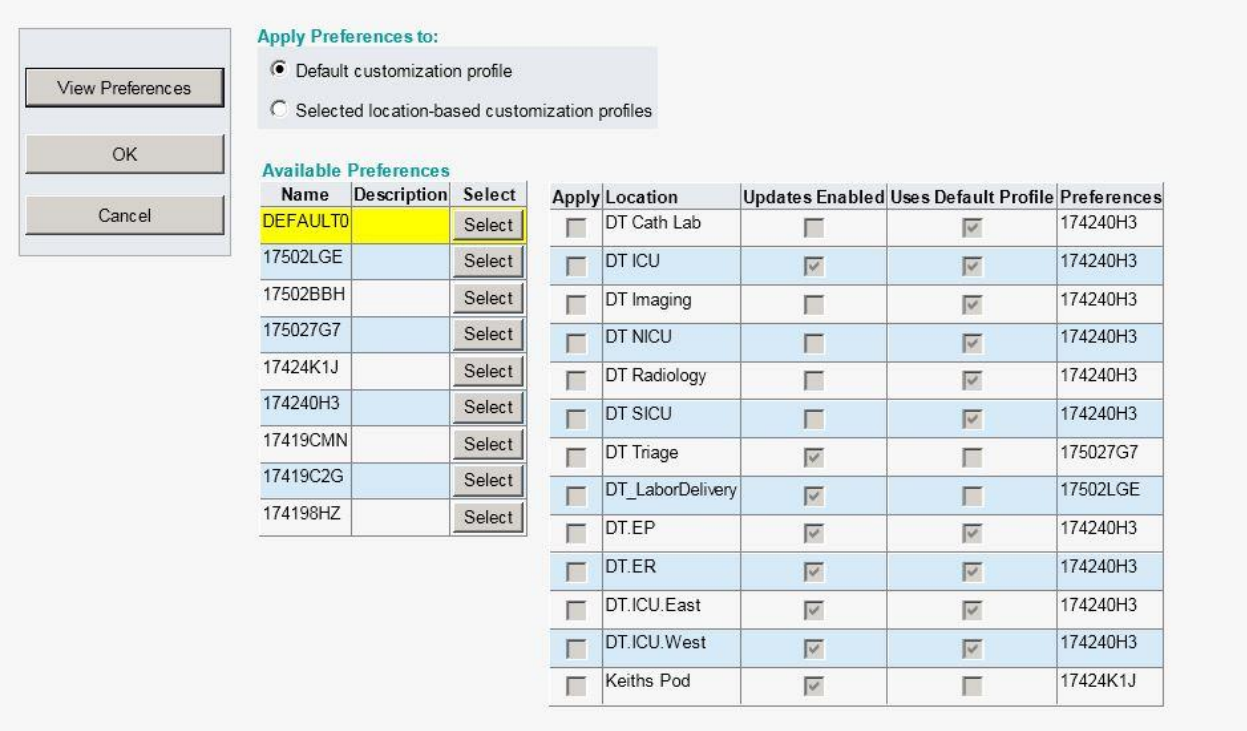
   Restoring the STATNotes settings will COMPLETELY REPLACE ALL EXISTING STATNotes SETTINGS. After doing so, the default profile will show the restored chart page set name and all location-based settings that do not use the default profile will show CHART0.

   Due to the severity of this action, a backup of the existing profile is created in the ProfileBackup folder prior to restoring the chart page settings. This file is never overwritten.

- For users with upgrade of i-STAT/DE initially installed as 2.9 or earlier: C:\Istat32\ProfileBackup
- For users with a new installation of versions 2.11 or upgrade of i-STAT/DE initially installed as 2.10 or later: C:\ProgramFiles(x86)\APOC\DE\ProfileBackup

To Apply Preferences:

In the **Apply Preferences** page (Figure 3.4.1), previously created Preferences can be applied to the Default profile or to selected location-based profiles.



(Figure 3.4.1)

Preferences can be applied to either the default profile or to selected location-based profiles.

To Apply Preferences to Default Customization Profile:

1. Hover over the **Preferences** link and select **Apply Preferences** from the dropdown. The Apply Preferences web page displays.
2. Select **Apply Preferences** to **Default customization profile**.
3. From the **Available Preference** list, in the row for the desired Preference set, click **Select**.
4. On the left side of the customization page click **OK**.
5. A confirmation message displays asking if you want to change the Preference set(s). Click **OK** to proceed.
6. Click **OK** to the message regarding Preference update successful.

7. The Main Customization web page opens, and you can view the selected Preference set applied to all the locations that use Default customization profile.

To Apply Preferences to Selected Location-based Customization Profiles:

1. Hover over the **Preferences** link and select **Apply Preferences** from the dropdown. The Apply Preferences web page displays.
2. Select **Apply Preferences** to **Selected location-based customization profiles**
3. From the list **of** Available Preferences, in the row for the desired Preference set, click **Select**.
4. Check the **Apply** box(es) next to the Location column in the location(s) where you want to apply the desired Preference set.
5. On the left side of the customization page click **OK.**
6. A confirmation message displays asking if you want to change the Preference set(s). Click **OK** to proceed.
7. Click **OK.**
8. The Main Customization web page opens, and you can view the selected Preference set applied to the selected locations.

Modifying Preferences

To modify Preferences, on the Customization Workspace web page, first click on a specific preference, either under **Default customization profile** on the left side of the web page, or in the **Preferences** column of the **Location-based customization profiles** grid. When modifying a preference, the settings are organized into a set of tabs which are selected by clicking on a tab's title. For details on these settings, see the Section 3 Customization Workspace.

3.5 Minimizing ID Entry Errors with i-STAT 1 Analyzer Customization Features

This section describes eight i-STAT 1 analyzer Customization features that can help minimize Patient and Operator ID entry errors. Except for Operator List and Patient List, all ID Entry Customization features described below are available using the i-STAT 1 analyzer keypad customization. Operator and Patient List features are available within the i-STAT/DE Customization Workspace.

1. **Barcode Scanning** - Instead of users entering Operator and Patient IDs manually using the analyzer keypad, the i-STAT 1 analyzer also accepts scanned Operator and Patient ID information from six (6) valid barcode formats and provides the following benefits:
    - Using barcodes is the single most effective method of eliminating ID entry errors in the i-STAT System.
    - It eliminates manual entry related errors (i.e., transposed numbers, repeated numbers, etc…).
    - It provides faster ID entry.
    - Customizing an analyzer to only accept a specific barcode type helps prevent users from scanning the wrong barcode type for Patient and/or Operator ID entry.
2. **Use Patient List** – See Section 3.7 Positive Patient Identification (PPID) Customization) for full details.
3. **Use an Operator List** - Using an Operator List allows the Administrator to maintain a list of up to 4000 operators. Each operator in the list can be certified for i-STAT testing for a set time period, defined by the Administrator. Once the operator list is created, it is then uploaded to each analyzer.

    This feature prevents uncertified or untrained operators from running tests. If the Operator List does NOT contain the ID entered by the user or if the operator is not certified, the user can be warned or locked-out from running a test.

    This feature also requires the use of data management software, as the operator management is done through the data management software. i-STAT/DE provides view only access to the Operator and Patient lists through the i-STAT/DE System Status and Configuration webpage.
4. **Exclude Operator IDs from Analyzer Printout** - Enabling this feature will exclude the operator ID from all analyzer printouts. Disabling the printing of operator IDs can help prevent uncertified operators from learning the IDs of certified operators and using those ID numbers for analyzer testing.

5. **Set Max/Min ID Length** - The i-STAT System provides the ability for the POCC to set minimum and maximum ID lengths. Once the Administrator defines the minimum and maximum limits through customization, the analyzer will then only accept ID numbers that contain the specified number of digits. This has the following benefits:

    - It forces users to enter a specific ID length.
    - It does NOT allow blank ID numbers when Minimum Length is set to one (1) or greater.
    - It helps prevent the user from making ID entry errors such as missing digits or repeating digits.

6. **Set Manual Entry Check Digits** - A Check Digit is a decimal (or alphanumeric) digit added to a number for the purpose of detecting typical data entry errors. If a facility makes use of a supported Check Digit algorithm when creating Operator or Patient IDs, the i-STAT 1 analyzer can verify the entered ID format by calculating the check digit and comparing it to the entered ID number. If the Check Digits don't match, the ID is rejected.

    It helps prevent users from making the following ID entry errors:

    - Interchanging adjacent digits (i.e., 67 becomes 76)
    - Doubling the wrong digit (i.e., 445 becomes 455)
    - Thinking an 8 is a 0 when reading a number from a wristband
    - Omitting or adding a digit

    Note: The i-STAT System supports the Mod 10 and Mod 11 check digit algorithms described in the HL7 Table 0061 (Check Digit Scheme) in the HL7 Specification (Rev 1.4). Please contact your LIS/HIS or IT departments to help determine if your facility uses Check Digits in the creation of operator and/or patient ID numbers, and if so, what algorithm is used.

7. **Manual Repeat ID Entry** - This feature forces a user to manually enter an ID number twice. If the two entries are not identical, the ID will not be accepted and the user must start again. The number of IDs to be corrected/edited by the Administrator in the Data Management system should theoretically decrease, as a user is less likely to type an ID number wrong twice.

8. **Scanned Repeat ID Entry** - This feature forces an i-STAT 1 analyzer user to scan an ID barcode number twice. If the two entries are not identical, the ID will not be accepted and the user must start again. The number of IDs to be corrected/edited by the POCC in the Data Management system should theoretically decrease, as a user is less likely to consecutively scan an ID number wrong twice.

3.6 STATNotes

STATNotes, a feature available with the i-STAT 1 analyzer, allows a user to record relevant patient information at the time of a patient test. STATNotes allows data to be captured on the i-STAT analyzer during the testing sequence with data transmitted to the patient chart. Through use of a series of prompts, users may enter data in order to record additional information such as

- Respiratory parameters,
- Physician identification number,
- Secondary patient identificaiton number,
- Result Accept/Reject,
- Physician notification,
- Competency Assessment management, etc.

STATNotes is configured with the customization workspace. The i-STAT 1 analyzer can be customized to present a STATNotes page providing Data Entry items and Selection List items. Data Entry items allow a user to scan data or to enter alphanumeric data using the analyzer keypad. Selection List items allow a user to select from a customizable list of choices.

STAT*Notes* pages can be assigned for presentation when a particular cartridge is run on a location-specific basis, to provide flexibility in meeting each department's needs for data collection.

Contact your local representative to discuss the benefits of enabling STATNotes.

STATNotes Overview

This section describes how STATNotes may be customized to suit various data recording needs by providing customizable Data Entry items and Selection List items.

- Data Entry items allow a user to scan or enter alphanumeric data using the analyzer keypad.
- Selection List items allow a user to select from a customized list of choices.
- Customized STATNotes may be created on a location-specific basis and on a cartridge-specific basis within each location to provide additional convenience.

The following table provides a list of STATNotes Components and their description:

Component	Description
Base Page	This is the initial page that the user will see when they press the page button from the results screen. A base page is assigned to each location and then each cartridge type.
Base Page Item	Defines a specific entry on the Base Page. These items are added to Base Pages to create a specific Base Page configuration.
DelSys	This is a special item that can appear on the Base Page which provides a selection list for parameter items pertaining to the Delivery System (DelSys) used at the facility.

Component	Description
Parameter Page	These pages hold the parameter items. Base Page items should not appear as parameter items.
Mode Selection Page	This is the special Parameter Page that holds a single item: the MODE Parameter Item.
Parameter Page Item	Defines a specific entry on the parameter page.
MODE	This is a special Parameter Page item that appears on the Mode Selection Page and is a selection list that opens to a mode specific Parameter Pages.

The following figures, illustrate the use of STATNotes:

Figure 1 shows the analyzer Chart Page and **Figure 2** shows an example of a Chart Page customized for STATNotes to include one Data Entry item (PtTemp) and five Selection List items (CPB, Sample Type, Site, Allen's Test, and DelSys).

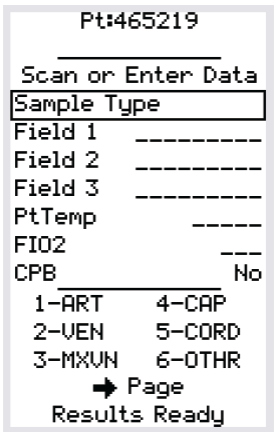


Figure 1
i-STAT 1 Analyzer
Chart Page

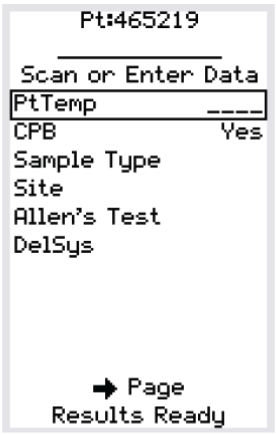


Figure 2
Custom Chart Page
Example

Figure 3 shows the custom Chart Page with the first three Chart Page items completed and the Site Selection List item highlighted. Pressing the Menu key displays the available choices for Draw Site (**Figure 4**). Pressing the number key of the desired Draw Site will complete the selection list entry (**Figure 5**).

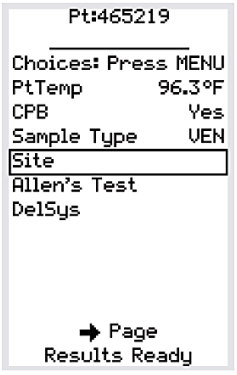


Figure 3

Pressing Menu key displays the Selection List for the Site item.

Figure 4

Pressing the 4 key selects L Brachial as the Site and returns the user to the Chart Page.

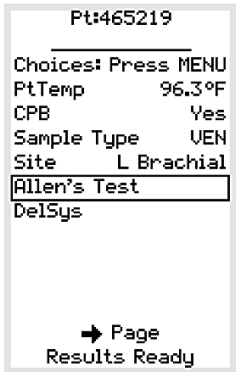


Figure 5

The selected Site (L Brachial) appears beside the Site prompt on the Chart Page.

STATNotes customization also provides the ability to create unique respiratory parameter entry pages that can appear depending on the selection of a Respiratory delivery system defined by the DelSys Selection List item. **Figure 6** shows the custom Chart Page with the DelSys Selection List item highlighted. Pressing the Menu key displays the available choices for Delivery System (**Figure 7**). Pressing the number key of the desired Delivery System will display the appropriate Parameter Page **(Figure 8**).

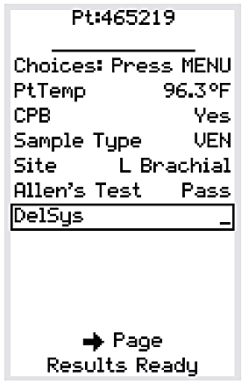


Figure 6

Pressing Menu key displays the DelSys Selection List.

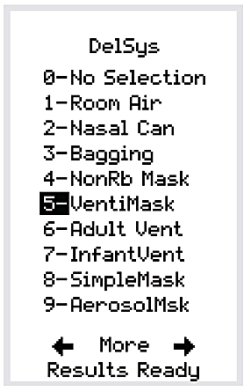


Figure 7

Pressing the 5 key selects VentiMask as the Delivery System and moves the user to the Parameter Page

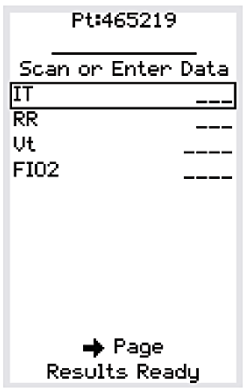


Figure 8

Parameter Page assigned to VentiMask.

If desired, a Mode Selection List can also be assigned to a DelSys Selection List member in order to choose ventilator modality. In this example, the Mode Selection List is assigned to Adult Vent (**Figures 9-10**). A unique Parameter Page can be assigned to each Mode. **Figure 11** shows the Parameter Page assigned to SIMV+PS.

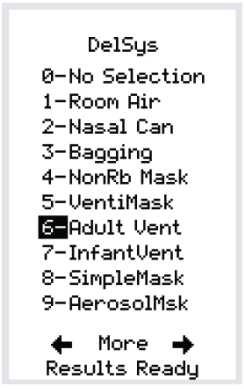


Figure 9

Selecting Adult Vent displays the Mode Selection Page

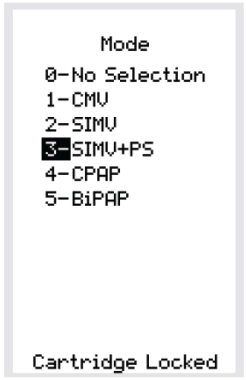


Figure 10

Mode selection determines which Parameter Page appears.

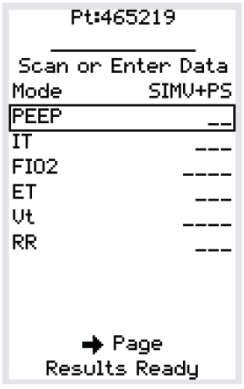
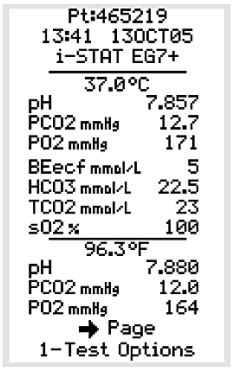


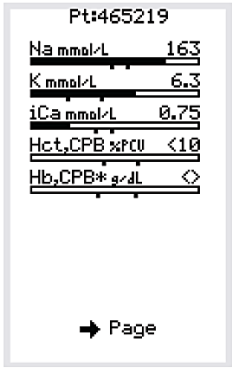
Figure 11

Parameter Page assigned to Mode SIMV+PS

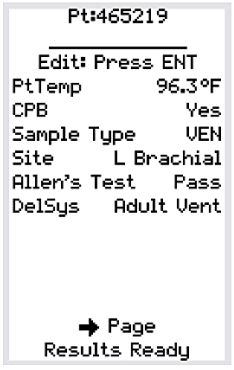
Once all Chart Page and Parameter Page items are entered and the results are ready, the following screens can be viewed (**Figure 12**):



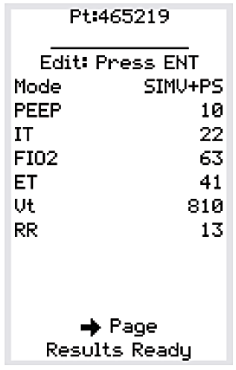
Results Page 1



Results Page 2



Main Chart Page



Parameter Page

Figure 12

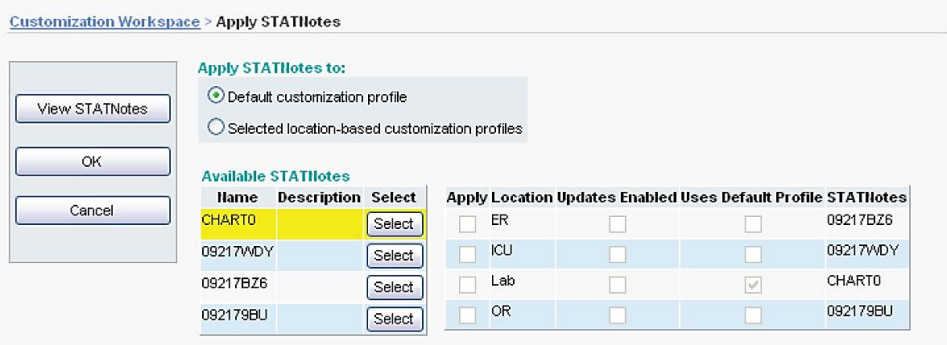
STATNotes data may be edited after entry prior to performing another test, before transmission of results, or before powering off the analyzer.

Applying STATNotes

Prior to making any changes, please consult your local Abbott Point of Care Representative, as changes may affect interfacing of test results.

To Apply STATNotes:

1. Click **STATNotes** → **Apply STATNotes** in the menu. The '**Apply STATNotes'** web page will then open.



2. Users may either Apply STATNotes to the *Default customization profile* or to *Selected location-based customization profiles* by clicking the appropriate radio button.

   a) To apply a particular STATNotes to the default customization profile:

   - Click the *Default customization profile* radio button.
   - In the *Available* STATNotes section, click **Select** in the row containing the STATNotes you wish to apply.
   - If you wish to view the contents of the selected STATNotes before applying it, click **View STATNotes**.
   - Click **OK**.
   - A confirmation message will appear asking if you want to proceed in changing the
   - STATNotes. Click **Yes** to apply the STATNotes.

   b) To apply a particular STATNotes to a location-based customization profile:

   - Click the *Selected location-based customization profiles* radio button.
   - In the *Available* STATNotes section, click **Select** in the row containing the STATNotes you wish to apply.
   - If you wish to view the contents of the selected STATNotes before applying it, click **View STATNotes**.
   - Under the *Apply* column, check the box(es) next to the destination location(s) where the STATNotes is to be applied.
   - Click **OK**.
   - A confirmation message will appear asking if you want to proceed in changing the STATNotes. Click **Yes** to apply the STATNotes.

Applying Existing STATNotes preferences

To apply to a different/new cartridge

Note: Any cartridge containing Hgb/HCT requires CPB as part of the Page contents for that cartridge's Base Page. If current STATNotes is applied to a cartridges that have Hgb/HCT it can be added to other cartridges that contain Hgb/HCT. If not, please contact Technical Services for submission of an implementation assistance request.

1. Access the customization workspace.
2. Click the Default customization profile **STATNotes** preference or the location-based **STATNotes** preference to access the **Current STATNotes Configuration** section.
3. In the **Assign base pages to cartridges** section, click on the down arrow next to the cartridge type that needs to be updated and select the Base page.
4. Once the base page has been selected for the cartridge type, click **OK** to save changes or **Cancel**.
5. Upon clicking on **OK**, a confirmation message will appear asking if you want to proceed in changing the STATNotes. Click **Yes** to apply the STATNotes.

To apply another existing base page to a cartridge in the same location

1. Access the customization workspace.
2. Click the Default customization profile **STATNotes** preference or the location-based **STATNotes** preference to access the **Current STATNotes Configuration** section.
3. In the **Pick up to six base pages to be used** section, click on the down arrow and add additional base page(s) to be used.
4. Once the additional base page(s) have been added go to the **Assign base pages to cartridges** section and click on the down arrow next to the cartridge type that needs to be updated and select the Base page.
5. Once the base page has been selected for the cartridge type, click **OK** to save changes or **Cancel**.
6. Upon clicking on **OK**, a confirmation message will appear asking if you want to proceed in changing the STATNotes. Click **Yes** to apply the STATNotes.

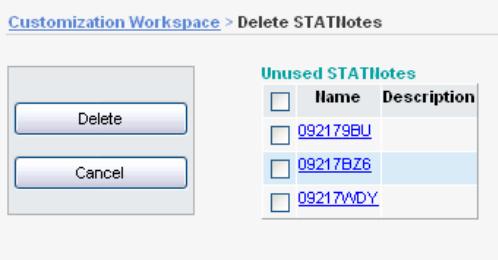
Modifying STATNotes after Initial Build

Modification of STATNotes after has been built and implemented, may affect the LIS/EMR interface. Please contact Technical Services for available options for assistance with modification or for submission of an implementation assistance request.

Deleting STATNotes

To Delete Unused STATNotes:

1. Click **STATNotes** → **Delete STATNotes** in the menu. The **Delete STATNotes** web page will then open.



2. To delete selected unused STATNotes:
   - Check the box next to the Name(s) of the STATNotes you wish to delete.
   - If you wish to view the contents of the selected STATNotes before deleting it, click on the STATNotes name.
   - Click **Delete**.
   - A confirmation message will appear asking if you want to want to delete the selected STATNotes. Click Yes to delete the STATNotes.

Editing STATNotes:

Changing STATNotes can seriously affect the successful acceptance and processing of results to and by the LIS interface, please consult with your local Abbott Point of Care Representative prior to making any changes.

Restoring STATNotes:

Please consult with your local Abbott Point of Care Representative as restoring the STATNotes settings will COMPLETELY REPLACE ALL EXISTING STATNotes SETTINGS!

After doing so, the default profile will show the restored chart page set name, and all location-based settings that do not use the default profile will show CHART0.

Restoring the STATNotes settings will COMPLETELY REPLACE ALL EXISTING STATNotes SETTINGS. After doing so, the default profile will show the restored chart page set name and all location-based settings that do not use the default profile will show CHART0.

Due to the severity of this action, a backup of the existing profile is created in the ProfileBackup folder prior to restoring the chart page settings. This file is never overwritten.

- For users with upgrade of i-STAT/DE initially installed as 2.9 or earlier: C:\Istat32\ProfileBackup
- For users with a new Installation of version 2.11 or upgrade of i STAT/DE initially installed as 2.10 or later: C:\Program files (x86)\APOC\DE\ProfileBackup

STATNotes Precautions and Limitations

This section provides information pertaining to precautions and limitations of the STATNotes feature.

PRECAUTIONS:

- If a page is needed that is very similar to an existing page, do not edit the existing page and give it a new name. Create a new page from scratch.
- If an item is needed that is very similar to an existing item, do not edit the existing item and give it a new name. Create a new item.
- Items on a parameter page are only mandatory if all the items leading to it are mandatory; i.e., the DelSys or DelSys+Mode items leading to the parameter page are mandatory on their respective pages.
- Always exit the "Manage STATNotes Pages" portion of the customization workspace page by returning to the main page of the customization workspace.

LIMITATIONS:

Parameter Items:

A maximum of 29 unique items can be created for building parameter pages.

- 26 of the 29 items can be Data Entry Items.
- 3 of the 29 items can be Selection List Items. One selection list is pre-defined and cannot be deleted (Mode), so one can add only 2 more selection lists.

Parameter Pages:

- The length of the Prompt + the length of the Value + the length of the Separator (1 space) can be up to 16 characters.
- There is 1 predefined parameter page (Mode - can't be deleted).
- Each parameter page can contain up to 9 unique parameter items.
- Parameter pages cannot contain any item more than once.
- Each item in a parameter page can be set to mandatory or optional.
- A parameter page can be assigned to each Mode Selection List member.

Base Page Items:

A maximum of 20 unique items can be created for building Base Pages.

- Data Entry Items: 13 of the 20 items can be Data Entry Items.
- Selection List: 7 of the 20 items can be Selection List Items.

Note:

1. 5 selection lists are pre-defined and cannot be deleted (Site, Sample Type, Sample, DelSys and Allen's Test). So, you can add only 2 more selection lists.
2. Each selection list may have a maximum of 27 selection list items that can be entered. 'Sample Type' and 'Sample' selection lists are limited to 18 entries.

Base Pages:

There are two pre-defined base pages (Basic Page and Basic Blood Gas Page).

- Each base page can contain a maximum of 10 unique base page items
- Each item in a base page can be set to mandatory or optional.
- Base pages cannot contain any duplicate items.

Note:

1. The length of the Prompt + the length of the Value + the length of the Separator (1 space) can be up to 16 characters.
2. A unique parameter page can be assigned to each DelSys selection list value.
3. Parameter pages cannot be added to any other base page selection lists.

3.7 Positive Patient Identification (PPID) Customization

Prior to customizing please refer to Section 1.3 Positive Patient Identification (PPID) Implementation for implementation, patient list, and identifier requirements.

When the PPID feature is enabled, each time the i-STAT 1 analyzer is downloaded, the facility-wide list of valid patient ID numbers and associated secondary identifiers stored in the analyzer is updated. During subsequent cartridge testing, when the operator scans a barcoded wrist band or manually enters a patient ID number, the analyzer verifies the entered patient ID is found in the analyzer's patient list.

If the patient ID is found in the analyzer's patient list, the analyzer will display the patient's name, birth date and gender on the screen. The operator can then verify that these identifiers match the patient being tested. Optionally, display of the birth date can be suppressed, and the operator will have to enter the birth date correctly to confirm the patient ID. After successful patient ID confirmation, the cartridge testing process would proceed as usual.

PPID Customization Options

There are a number of customization options available to tailor the analyzer's PPID behavior to meet the specific needs of the facility. Customization options are selected from the Customization Workspace in i-STAT/DE.

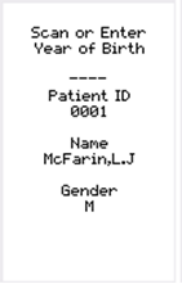
Confirmation Method:

The system administrator (e.g., Point of Care Coordinator or Laboratory Administrator) can select among 3 methods for operators to confirm the patient identity.

Options: Confirm, Replicate Year of Birth and Enter Year of Birth.

Note: If Year of Birth is required for confirmation, but no Year of Birth is available in the patient list, the patient ID will be considered not on the list.

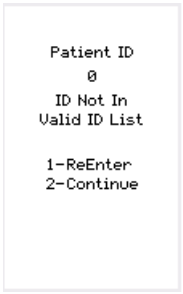
Confirmation Method	Operator Action	Analyzer Display Example
Confirm (Default setting)	The operator confirms the patient ID by selecting "Continue" (Figure 3.7.1).	 (Figure 3.7.1)

Confirmation Method	Operator Action	Analyzer Display Example
Replicate Year of Birth	The operator enters the four digits of the patient's year of birth to confirm the patient ID. The date of birth is displayed on the analyzer screen (Figure 3.7.2).	 (Figure 3.7.2)
Enter Year of Birth	The operator enters the four digits of the patient's year of birth to confirm the patient ID. The date of birth is not displayed on the analyzer screen (Figure 3.7.3).	 (Figure 3.7.3)

Action, Not on List:

The system administrator can select the desired behavior when the entered patient ID is not found in the analyzer's patient list.

Options: Disabled (Default Settings), Warn, and Lockout.

Action	Action Definition	Analyzer Display Example
Disabled (Default setting)	The PPID is not active. No warning or lockout is displayed on the analyzer.	Not Applicable
Warn	The operator is warned that the patient ID is not found in the active patient list (Figure 3.7.4).	 (Figure 3.7.4)

Action	Action Definition	Analyzer Display Example
Lockout	Testing cannot be performed using this Patient ID (Figure 3.7.5).	 (Figure 3.7.5)

Lockout Override: If Lockout is chosen, the system administrator can choose to enable or disable a lockout override. If the override is enabled, the operator can override the lockout by selecting option 2 to continue.

Options: Disable (Default), Enable

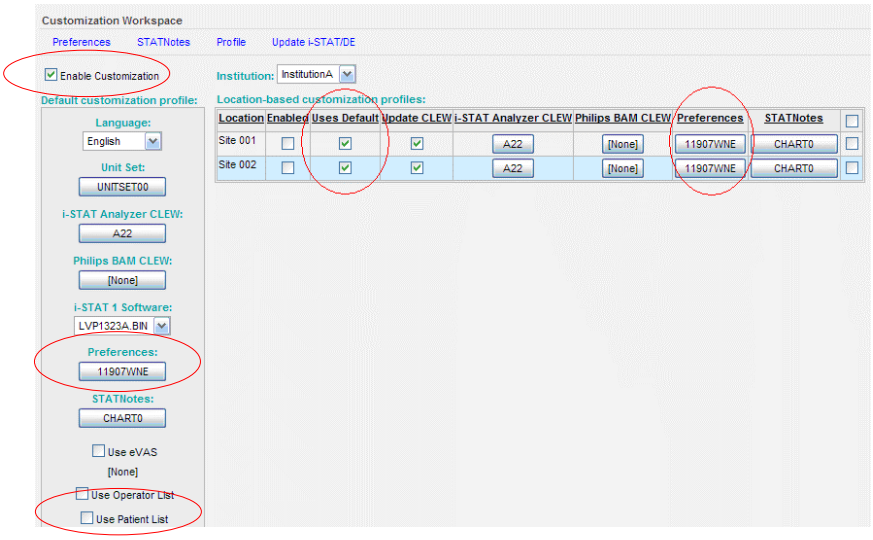
Print ID Attributes

The system administrator can select whether secondary patient identifiers (Name, DOB, Gender) print with test results on the i-STAT printers.

PPID Customization Procedure

1. Access the Customization Workspace.
2. Ensure Enable Customization is checked (Figure 3.7.6).
3. Ensure Enabled is checked for the particular location to which the i-STAT 1 analyzer is assigned.
4. At the bottom of the Default Customization profile area, check Use Patient List (Figure 3.7.6).
5. If the location where this analyzer is assigned has a check in the Uses Default column (Figure 3.7.6), click the button displaying the alphanumeric code under Preferences in the Default customization profile area (Figure 3.7.6).

   Otherwise, click the button displaying the alphanumeric code in the Preferences column (Figure3.7.6) for the specific location to which this analyzer is assigned.

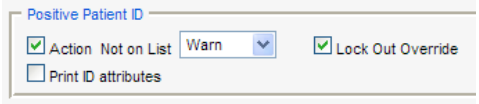


(Figure 3.7.6)

6. Once the Preferences page is displayed, click on the ID Entry tab (Figure 3.7.7) to access the Patient ID Entry Section.

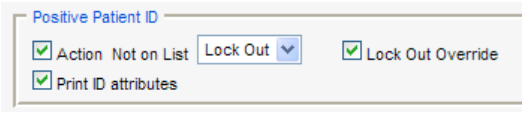
(Figure 3.7.7)

7. When the Action Not on List is disabled, the i-STAT 1 analyzer will not take any action if the entered Patient ID is not found on the analyzer's patient list. To enable, in the Positive Patient ID section at the bottom of the page, check Action Not on List (Figure 3.7.8) and select the desired behavior when the entered patient ID is not found in the analyzer's patient list:



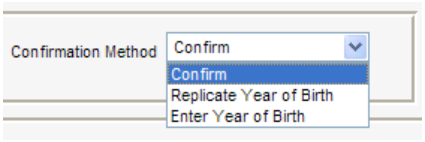
(Figure 3.7.8)

8. If Lock Out is chosen in step 7 above, check Lock Out Override (Figure 3.7.8) if you want operators to be able to override the lockout by entering the patient ID number twice. If you do not want the override to be activated, leave the option unchecked.
9. The enable secondary patient identifiers (Name, DOB, Gender) to print with test results on the i-STAT or Martel printers, check Print ID attributes (Figure 3.7.9).



(Figure 3.7.9)

10. Using the drop-down menu, select the Confirmation Method the operator will use to confirm the patient identity:

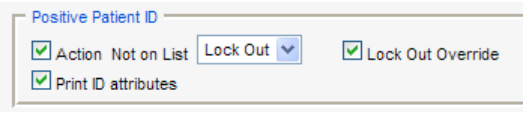


(Figure 3.7.10)

- **Confirm**: The operator confirms the patient ID by selecting “Continue”.
- **Replicate Year of Birth**: The operator enters the four digits of the patient’s year of birth to confirm the patient ID. The date of birth is displayed on the analyzer screen.
- **Enter Year of Birth**: The operator enters the four digits of the patient’s year of birth to confirm the patient ID. The date of birth is not displayed on the analyzer screen.

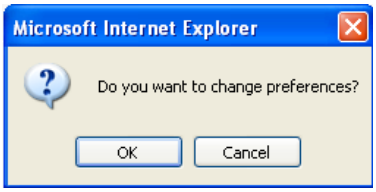
11. Check the box next to Print ID attributes if you want secondary patient identifiers.

    (Name, DOB, Gender) printed with test results on the i-STAT or Martel printers.



(Figure 3.7.11)

12. Once all options have been chosen, click OK and select OK to confirm preference changes when prompted ‘Do you want to change preferences?’



(Figure 3.7.12)

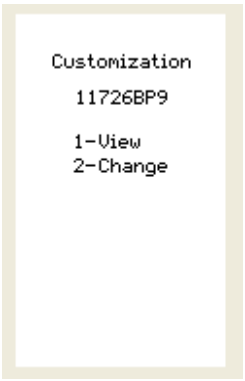
PPID List Confirmation Procedure for i-STAT 1 Analyzer

To confirm that the patient list has been transferred from i-STAT/DE to the i-STAT 1 analyzer, the following steps may be taken using the i-STAT 1 analyzer:

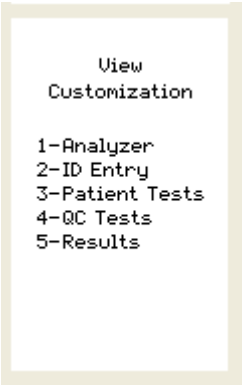
1. Power on the i-STAT 1 analyzer and press **MENU** once to get to the Administration Menu (Figure 3.7.13).
2. Press **4-Customization** (Figure 3.7.13).
3. Press **1-View** (Figure 3.7.14).
4. Press **2-ID Entry** (Figure 3.7.15).
5. Press **2-Patient ID** (Figure 3.7.16).
6. Press the right arrow button twice to view the Patient List Number (Figure 3.7.17) that has been transferred to the i-STAT 1 analyzer.

NOTE: The details of the PPID list and patient demographics are not displayed via this method. Patient information is viewable only during the scan or entry of a patient ID in the patient test pathway, and then only one patient at a time.

(Figure 3.7.13)



(Figure 3.7.14)



(Figure 3.7.15)

(Figure 3.7.16)

(Figure 3.7.17)

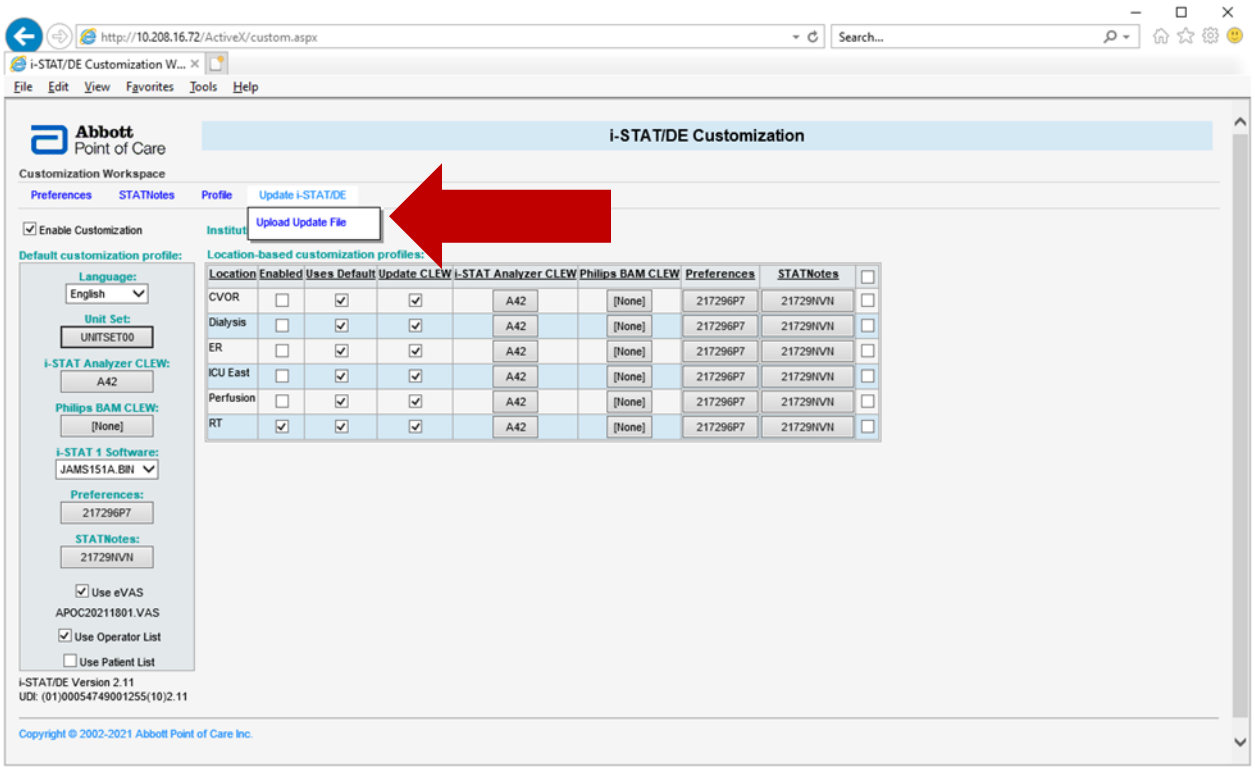
3.8 Uploading a JAMS/CLEW update to the i-STAT/DE Server

A JAMS/CLEW update is a regularly scheduled update to the i-STAT/DE software. This update can be uploaded to the server where it will then be available for selection in the Customization Workspace.

NOTE: Screens shown here are examples only. A screen's appearance may differ from the example.

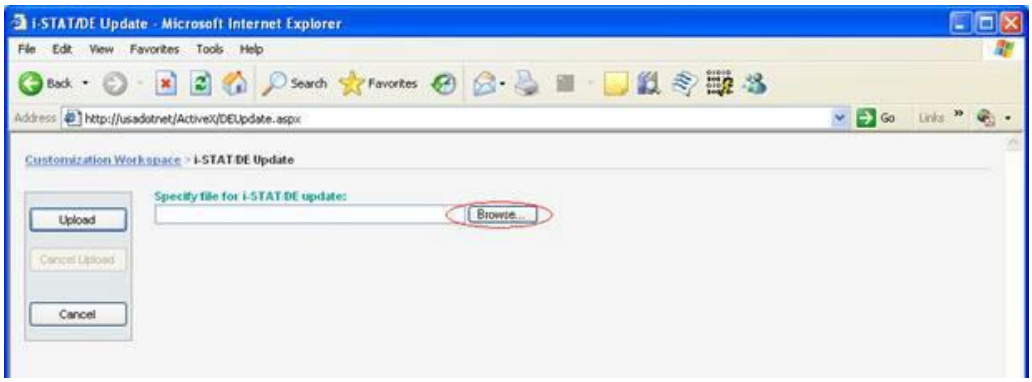
To Upload an Update:

1. Insert the JAMS/CLEW update CD.
2. Upload the JAMS/CLEW update to the server.
3. Open the Customization Workspace and hover over the link **Update i-STAT/DE.** Then select **Upload Update File** from the menu (Figure 3.8.1).



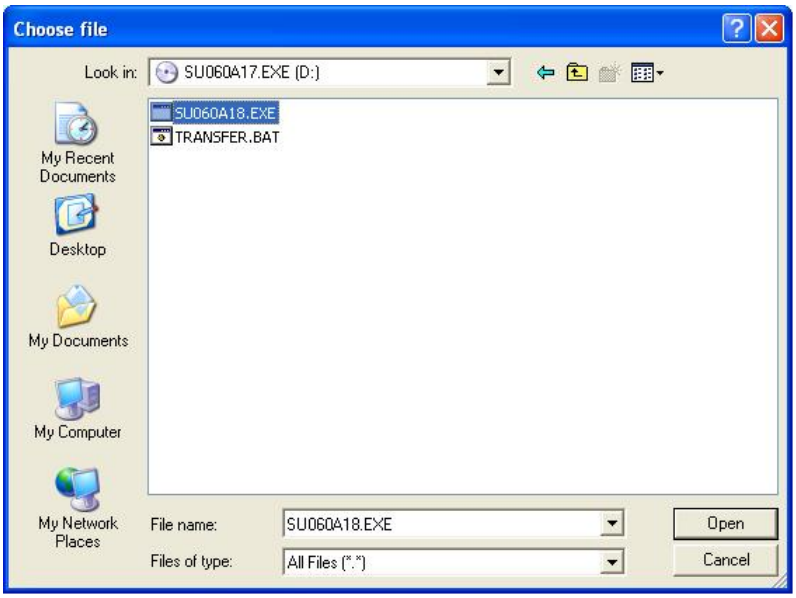
(Figure 3.8.1)

4. This displays the following screen, Click **Browse** (Figure 3.8.2).



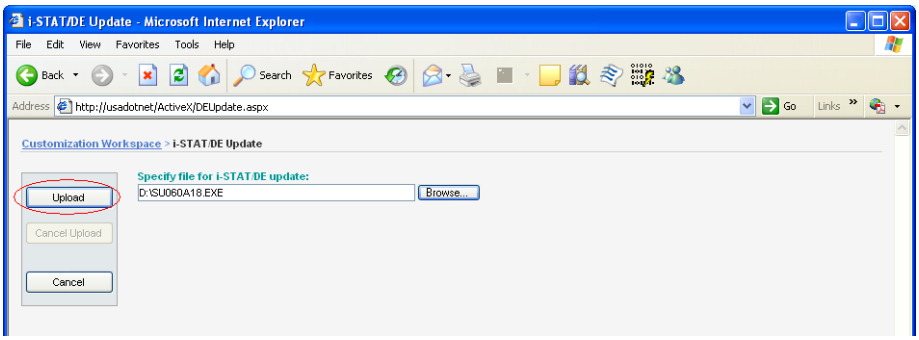
(Figure 3.8.2)

5. Select the CD drive (usually **D:**), select the file with a name similar to **SUnnnnnn.EXE**, and click **Open**.



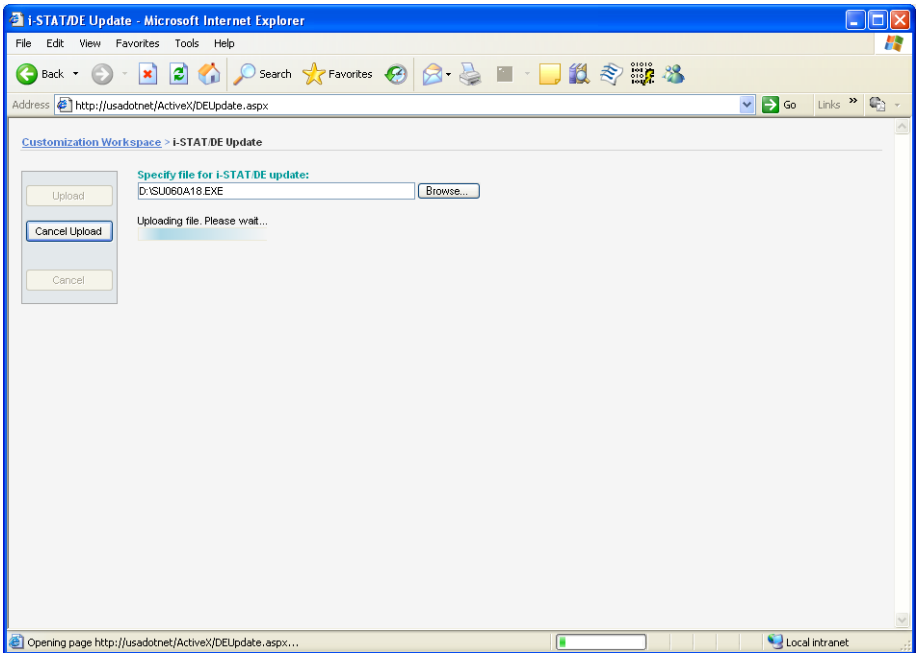
(Figure 3.8.3)

6. This displays the following screen (Figure 3.8.4), Click **Upload.**



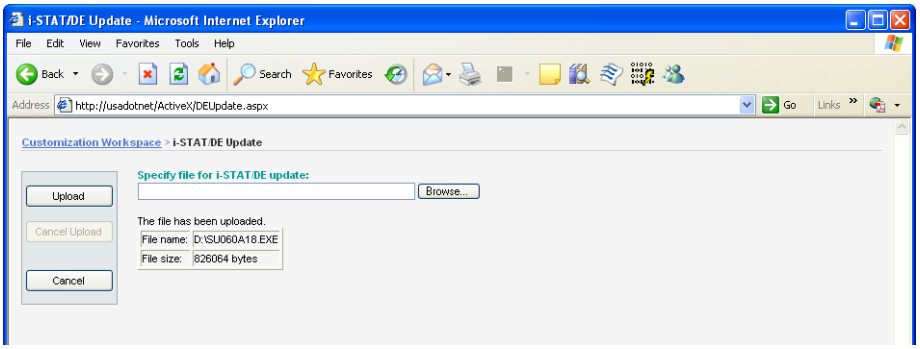
(Figure 3.8.4)

7. While the file is uploading, the page appears as shown below (Figure 3.8.5).



(Figure 3.8.5)

8. When the upload completes, information about the uploaded file is displayed (Figure 3.8.6).



(Figure 3.8.6)

9. The new JAMS and CLEW updates are now available for selection on the main page of the Customization Workspace.

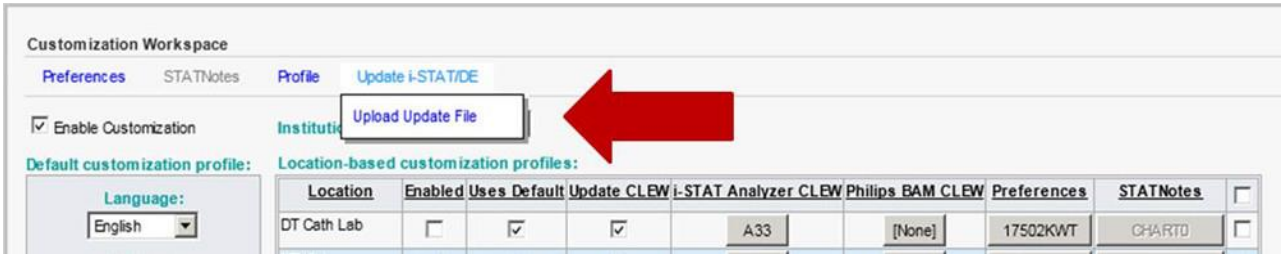
3.9 Uploading a New eVAS File to the i-STAT/DE Server

When an electronic value assignment sheet file (eVAS) is available on the APOC website, a system administrator can download and save the eVAS file to a specified directory.

The eVAS file can then be uploaded to the server where it will be available for automatic update of analyzers. After the eVAS file has been downloaded and saved, use the following steps to make it available on the server.

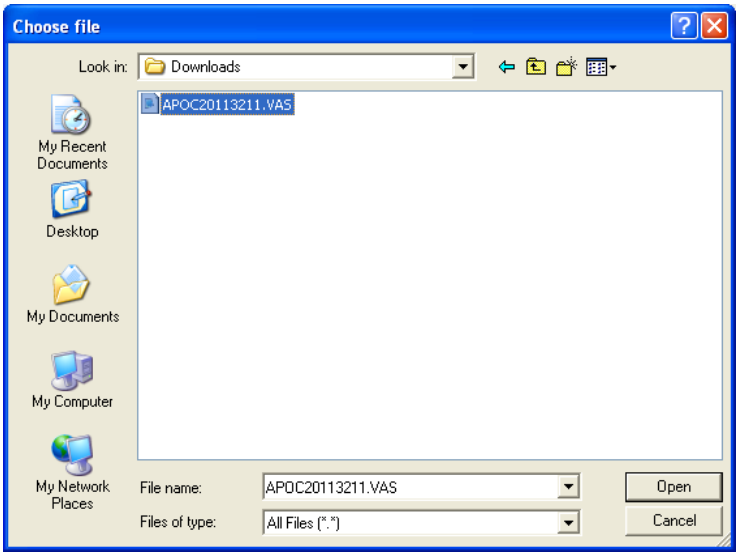
NOTE: Screens shown here are examples only. A screen's appearance may differ from the example.

1. Open the Customization Workspace and hover over the link **Update i-STAT/DE.** Then select **Upload Update File** (Figure 3.9.1) from the menu.



(Figure 3.9.1)

2. The following page displays (Figure 3.9.2), Click **Browse**…

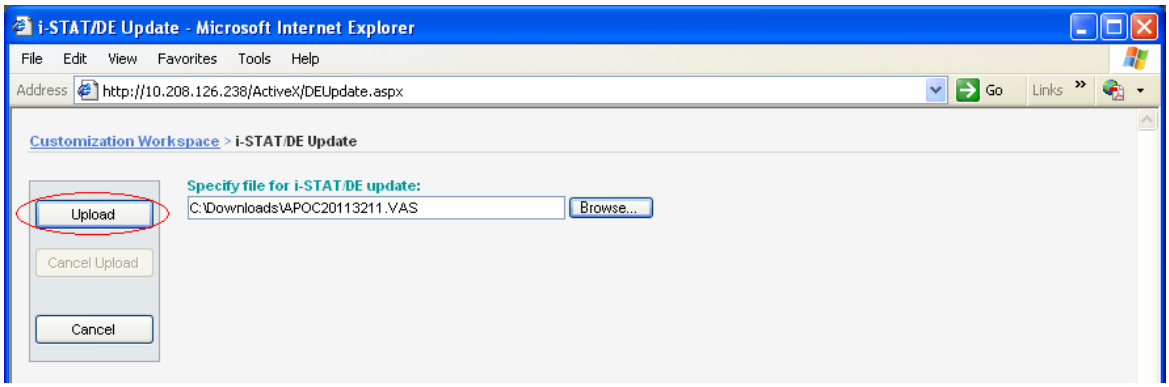


(Figure 3.9.2)

3. Select eVAS file from the location to which it was saved when downloaded from the APOC website and click **Open**.

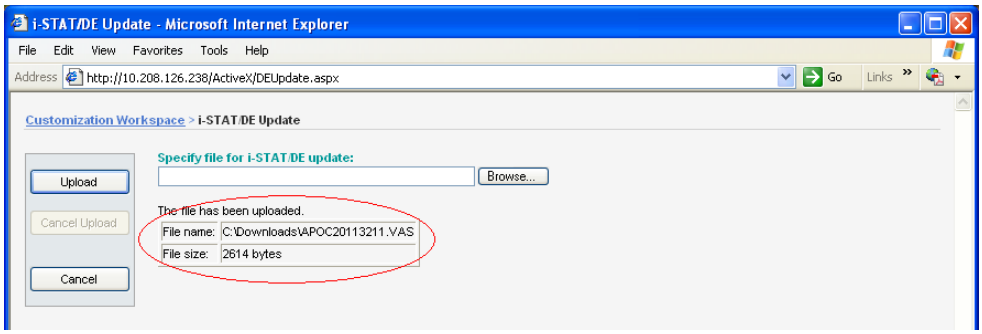
   Note: Verify that the filename, type and default application have not changed. It is not recommended that the eVAS file be opened.

4. The selected file is displayed. Click **Upload** (Figure 3.9.3.)



(Figure 3.9.3)

5. When the upload completes, information about the uploaded file is displayed (Figure 3.9.4).



(Figure 3.9.4)

6. If the eVAS file passes validation, its name will be displayed in the default profile in the Customization Workspace and will be distributed to i-STAT 1 analyzers moving forward.

3.10 Liquid Quality Control Pass/Fail Feature

The Liquid Quality Control Automatic Pass/Fail (QC Auto P/F) customization feature for the i-STAT 1 handheld can automatically determine if the results of a liquid QC test run on an i-STAT cartridge are within APOC's published quality control ranges. Since control ranges vary with the handheld's CLEW software version and with i-STAT cartridge and control lot numbers, manually applying the correct control limits can be cumbersome; with QC Auto P/F, the potential for this human error is avoided. Used in conjunction with the Liquid QC Schedule and Lockout customization features, QC Auto P/F helps a system administrator (e.g., Point of Care Coordinator or Laboratory Administrator) ensure compliance with QC requirements. By default, the feature is turned off.

For more information on the Liquid QC Schedule and Lockout customization features, please refer to Section 3.11 Liquid Quality Control Schedule and Lockout Customization in this user guide.

Functionality of Liquid Quality Control Pass/Fail Customization

With the QC Auto P/F feature, the system administrator can go to the APOC website and download an electronic value assignment sheet (eVAS) file: an electronic file containing the complete set of the data from the current i-STAT QC Value Assignment Sheets. For more information on uploading the e-VAS file to i-STAT/DE, please refer to Section 3.9 Uploading a New e-VAS File to the i-STAT/DE Server.

Once the file is downloaded and the eVAS feature is enabled in the Customization Workspace, the file is transferred to individual i-STAT 1 handhelds the next time they download data to the i-STAT/DE applications. Each i-STAT 1 handheld will then have a complete database of all current i-STAT control ranges stored in its memory. When testing liquid QC samples with i-STAT cartridges on an i-STAT 1 handheld customized for the QC Auto P/F feature, the user scans barcodes from both the control fluid vial and the cartridge pouch. Using this information, the handheld automatically evaluates each measured test result for acceptability against the control ranges defined in the eVAS. A "Pass" or "Fail" status is determined for each result, and an overall determination of "Pass" is made if every measured analyte in the test panel passes.

The status of individual failed results will be displayed on the handheld as either an up-arrow (↑) for out-of-range high results, or a down-arrow (↓) for out-of-range low results. The overall determination for the QC test panel is indicated by a PASS or FAIL message being displayed above the results.

Caution(s)

1. When testing liquid 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 analyte value, irrespective of the Reportable Range settings.
2. Use caution to protect against cuts if scanning a barcode from an open glass control ampule.
3. Electronic value assignment sheet (eVAS) files must be downloaded on a regular basis and uploaded to i-STAT/DE Customization Workspace to ensure the latest information is available on the analyzers. Administrators are encouraged to check regularly.

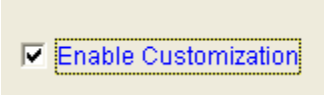
General Notes and Considerations

1. In order to use the QC Auto P/F customization feature, users must have the i-STAT 1 handheld and the i-STAT/DE software application.
2. The QC Auto P/F customization feature is designed to work in the i-STAT 1 handheld control testing pathway with all liquid QC products that are assigned control ranges in APOC's Value Assignment Sheets (available on the APOC website: www.globalpointofcare.abbott).
3. QC Auto P/F is not available for third-party control materials or for APOC Calibration Verification product.
4. With each liquid QC run, the following information is transmitted when results are downloaded to i-STAT/DE and passed with the result record to the data management application:
    - The QC results,
    - The eVAS file name,
    - The i-STAT cartridge and control fluid lot numbers, and
    - The overall Pass/Fail result determined for the liquid QC test run.
5. Unless numerical results have been suppressed through customization, when the results of a liquid QC run are printed, each analyte value is displayed on the printout, along with the corresponding control range. The symbol "<< >>" is used to indicate out-of-range results on the printout.
6. When the i-STAT 1 handheld is customized for QC Auto P/F, non-APOC controls may be tested in the control pathway, but the Pass/Fail assignment must be performed manually.

Customizing Liquid QC Pass/Fail Feature

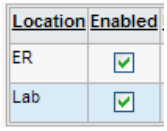
Prior to customizing the i-STAT 1 Handheld for Liquid QC Pass/Fail, upload the e-VAS file to the i-STAT/DE server. For more information, see Section 3.9 Uploading a new eVAS file to the i-STAT/DE Server in this guide. Once an eVAS file has been uploaded to the i-STAT/DE Server, the following may be performed:

1. Access the Customization Workspace.
2. Make sure the "**Enable Customization**" box (Figure 3.10.1) has a check mark in it.



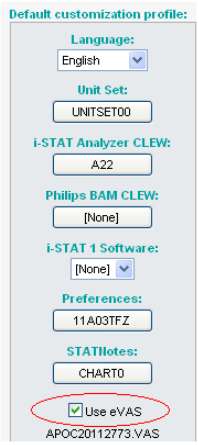
(Figure 3.10.1)

Also, make certain that the **Enabled** box (Figure 3.10.2) is checked for the particular location to which the i-STAT 1 handheld is assigned.



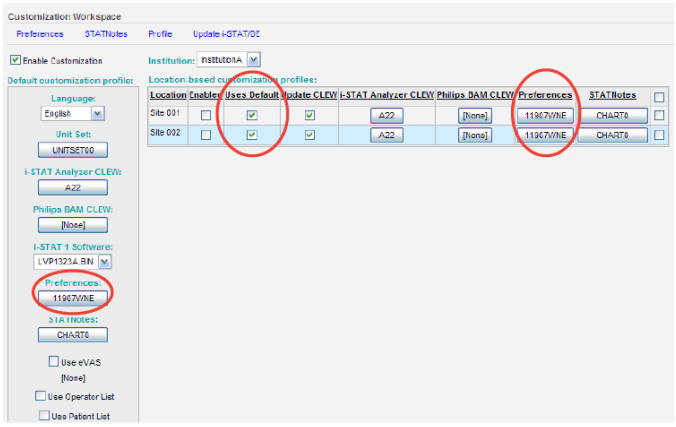
(Figure 3.10.2)

3. At the bottom of the **Default customization profile:** column (Figure 3.10.3), check the **Use eVAS** box.



(Figure 3.10.3)

4. If the location where this handheld is assigned has a check mark under **Uses Default**, under the **Default customization profile:** column (Figure 3.10.4), double click the alphanumeric code under **Preferences** (Figure 3.10.4). Otherwise, double click the alphanumeric code under the **Preferences** column (Figure 3.10.4) for the specific location to which this handheld is assigned.



(Figure 3.10.4)

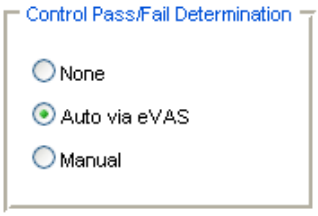
5. Once the Preferences windows opens, click on the cartridge QC Tab (Figure 3.10.5).

(Figure 3.10.5)

6. Click the **Liquid QC Settings** (Figure 3.10.6) at the top of the screen.

(Figure 3.10.6)

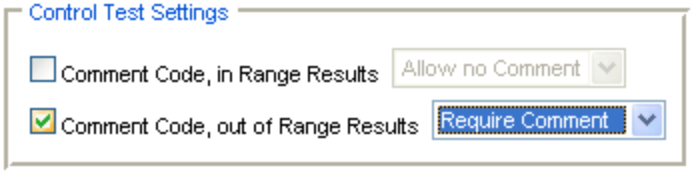
7. In the Control Pass/Fail Determination section (Figure 3.10.7), click the **Auto via eVAS** radio button. Choosing this option indicates that the handheld will automatically determine whether the liquid QC run passed or failed, based upon QC ranges contained on an electronic Value Assignment Sheet (eVAS) file downloaded into the i-STAT 1 handheld.



(Figure 3.10.7)

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

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(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) (Figure 3.10.8).



(Figure 3.10.8)

Note 8.1: The Control Test Settings feature is also customizable through the i-STAT 1 handheld keypad.

9. Select the way in which you would like control tests to be displayed (Figure 3.10.9).

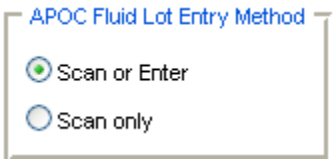
(Figure 3.10.9)

- **Numeric:** Liquid QC results are displayed in Numeric format or Suppressed: the following '<>' is displayed.
- **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.

10. Select the method in which control lot number information will be entered into the handheld (Figure 3.10.10).



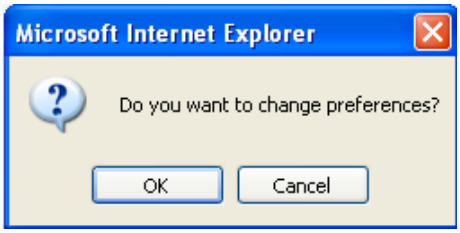
(Figure 3.10.10)

- 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: If customizing handhelds for Auto QC P/F, users must scan the barcode on the APOC control vial when testing APOC liquid QC samples. If testing non-APOC controls, users may scan the barcode from the control vial or enter the control lot number manually.

Note 10.2: The APOC Fluid Lot Entry Method is also customizable through the i-STAT 1 handheld keypad.

11. Click OK and answer OK to the question about changing the Preferences (Figure 3.10.11).



(Figure 3.10.11)

12. 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 12 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.

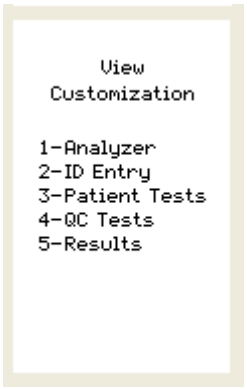
Confirming that the eVAS has been transferred to the i-STAT 1 Handheld from i-STAT/DE

To confirm that the eVAS has been transferred to the i-STAT 1 Handheld, power-on the i-STAT 1 handheld and follow these steps:

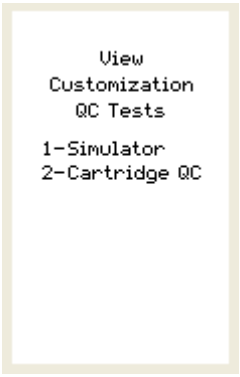
1. Press **MENU** once to get to the Administration Menu (Figure 3.10.12).
2. Press **4-Customization** (Figure 3.10.12).
3. Press **1-View** (Figure 3.10.13).
4. Press **4-QC Tests** (Figure 3.10.14).
5. Press **2-Cartridge QC** (Figure 3.10.15).
6. Press the right arrow button on the i-STAT 1 handled keypad, to view the eVAS Name that has been transferred to the handheld (Figure 3.10.16).

(Figure 3.10.12)

(Figure 3.10.13)



(Figure 3.10.14)



(Figure 3.10.15)

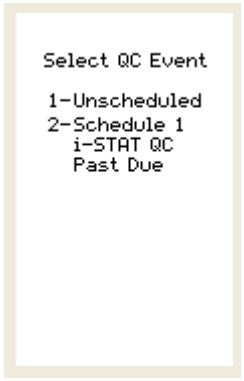
(Figure 3.10.16)

i-STAT 1 Handheld Display Screens for the Liquid QC Pass/Fail Feature

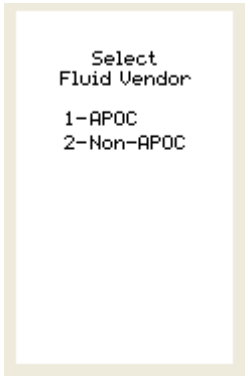
After Customizing the i-STAT 1 Handheld for the Liquid QC Auto Pass/Fail customization features, users will encounter the following display screens:

Quality Tests Menu

If the Liquid QC Auto Pass/Fail customization feature is being used in conjunction with the Liquid QC Schedule customization feature, and the user has selected 1-Control in the Quality Tests Menu on the handheld, a “Select QC event” screen (Figure 3.10.17) will appear on the display. If the user selects 1-Unscheduled, and then enters/scans their Operator ID, the handheld will display a “Select Fluid Vendor” screen (Figure 3.10.18) requesting that they select a Fluid Vendor. Once a Fluid Vendor is selected, the user will then be asked to select a fluid level at the “Select Fluid” screen (Figure 3.10.19). If a Non-APOC Fluid has been selected, the user will then be asked to scan or enter the control lot number at the “Scan or Enter Control Lot Number” screen (Figure 3.10.20). If an APOC fluid has been selected, the user will then be asked to scan the Control Lot Number at the “Scan Control Lot Number” screen (Figure 3.10.21)



(Figure 3.10.17)



(Figure 3.10.18)

(Figure 3.10.19)

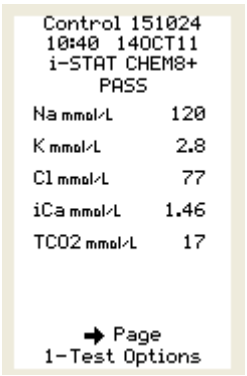
(Figure 3.10.20)

(Figure 3.10.21)

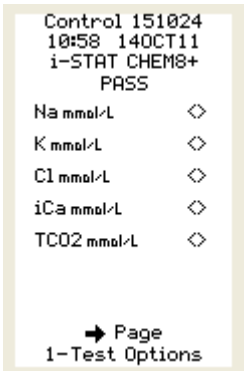
Liquid QC Results Screens

If the i-STAT 1 handheld is customized for the QC Auto P/F feature, the Liquid QC results screen appearance will vary, depending on whether the handheld is customized to display control results in a Numeric format, or whether they are Suppressed, along with whether the QC run Passed or Failed.

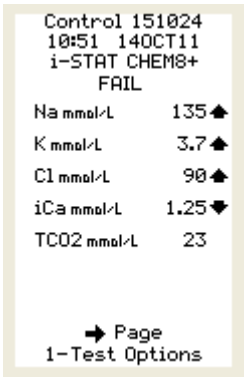
- **Numeric Control Result Display with a Passed QC run (Figure 3.10.22):** All analyte results will display a numeric value and the overall Pass assessment appears at the top of the display screen above the results.
- **Suppressed Control Result Display with a Passed QC run (Figure 3.10.23):** All analyte results will display a <> symbol and the overall Pass assessment appears at the top of the display screen above the results.
- **Numeric Control Result Display with a Failed QC run (Figure 3.10.24):** The status of individual failed results is displayed on the handheld as either an up-arrow (↑) for out-of-range high results, or a down-arrow (↓) for out-of-range low results.
- **Suppressed Control Result Display with a Failed QC run (Figure 3.10.25):** All analyte results will display a <> symbol and the overall Fail assessment appears at the top of the display screen above the results. The status of individual failed results is displayed on the handheld as either an up-arrow (↑) for out-of-range high results, or a down-arrow (↓) for out-of-range low results.



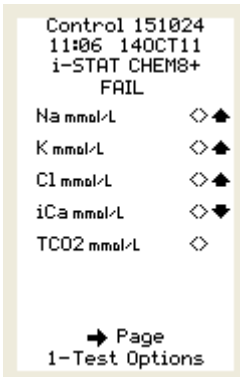
(Figure 3.10.22)



(Figure 3.10.23)



(Figure 3.10.24)



(Figure 3.10.25)

i- STAT 1 Handheld Display Messages for the Liquid QC Pass/Fail Feature

The following table provides information on display messages that may occur when the Liquid QC Pass/Fail feature is utilized.

Display Message	Cause	Resolution
Invalid eVAS	The eVAS file does not exist or is invalid.	Download current eVAS file from www.globalpointofcare.abbott.
Lot Not in eVAS	The entered cartridge or control lot number could not be found in the eVAS file.	Download current eVAS file from www.globalpointofcare.abbott.
Does Not Match Selected Level	The entered control solution lot number does not match the user selected control level.	Scan the control solution lot number that matched the control level to be selected.
Invalid Length	A blank control solution lot number was entered.	Scan or enter the control solution lot number.
Lot Expired	The entered control solution lot number or cartridge lot number is expired.	Scan a control solution lot number or cartridge lot number that is not expired.
Invalid Number	The scanned APOC lot number has an invalid format.	Scan the APOC lot number that is represented by the one-dimensional barcode on the cartridge or control solution.

3.11 Liquid Quality Control Schedule and Lockout Feature

The Liquid Quality Schedule and Lockout feature for the i-STAT 1 handheld, 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 Liquid QC Pass/Fail customization to automate and manage liquid quality control testing on the i-STAT 1 handheld. For more information please refer to Section 3.10 Liquid Quality Control Pass/Fail Feature.

Functionality of Liquid Quality Control Schedule and Lockout Customization

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. However with this 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.

QC Profile

Using the i-STAT/DE Customization Workspace webpage, 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.

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 a “Due Time” and “Grace Period”, that are definable by an administrator. 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.

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.

Caution

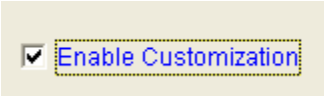
Use of the Liquid Quality Control Scheduled and Lockout Customization features will result in handhelds being unavailable for patient testing when Quality Control Requirements are not met.

General Notes and Considerations

1. The Liquid QC Schedule and Lockout feature is only available on the i-STAT 1 handheld.
2. In order to create Liquid QC Schedules, users must have the i-STAT 1 handheld and i-STAT/DE software. This feature is not customizable through the i-STAT 1 handheld keypad.

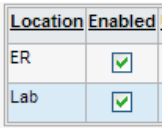
Customizing Liquid Quality Schedule and Lockout Feature

1. Access the Customization Workspace
2. Make sure the "**Enable Customization**" box (Figure 3.11.1) has a check mark in it.



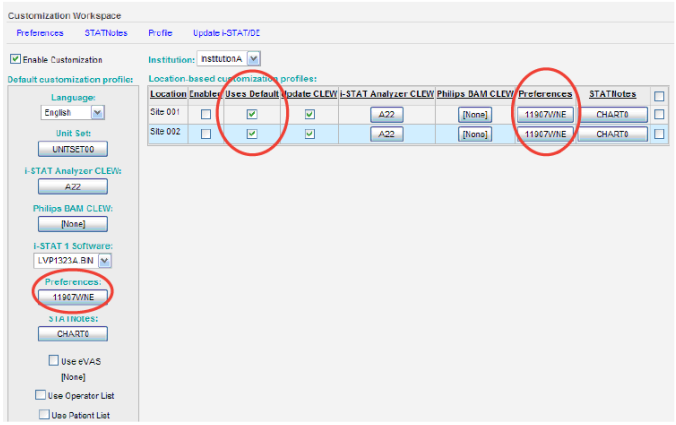
(Figure 3.11.1)

Also, make certain that the **Enabled** box (Figure 3.11.2) is checked for the particular location to which the i-STAT 1 handheld is assigned.



(Figure 3.11.2)

3. If the location where this handheld is assigned has a check mark under **Uses Default**, under the **Default customization profile:** column (Figure 3.11.3), double click the alphanumeric code under **Preferences** (Figure 3.11.3). Otherwise, double click the alphanumeric code under the **Preferences** column (Figure 3.11.3) for the specific location to which this handheld is assigned.



(Figure 3.11.3)

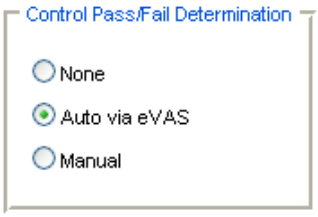
4. Once the **Preferences** windows opens, click on the cartridge QC Tab (Figure 3.11.4).

(Figure 3.11.4)

5. Click the **Liquid QC Settings** at the top of the screen (Figure 3.11.5).

(Figure 3.11.5)

6. In the Control Pass/Fail Determination section (Figure 3.11.6), click the radio button for the way in which you will determine the acceptability of liquid QC results:



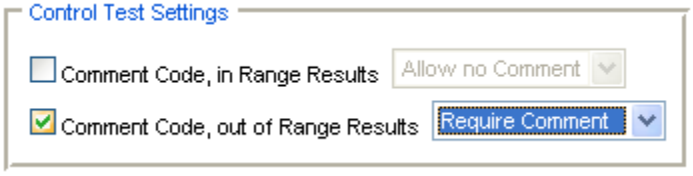
(Figure 3.11.6)

- **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. For more information please refer to Section 3.10 Liquid Quality Control Pass/Fail Customization.
- **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.globalpointofcare.abbott 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.

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) (Figure 3.11.7).

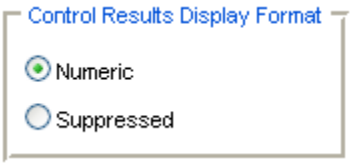


(Figure 3.11.7)

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.

8. Select the way in which you would like control tests to be displayed (Figure 3.11.8).



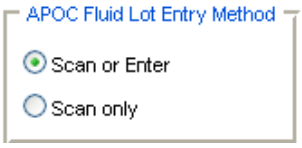
(Figure 3.11.8)

- **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 "Automatic via EVAS" is chosen for the liquid QC Pass/Fail Determination.

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

9. Select the method in which control lot number information will be entered into the handheld (Figure 3.11.9).

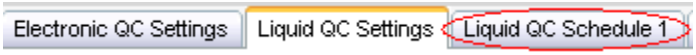


(Figure 3.11.9)

- **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.

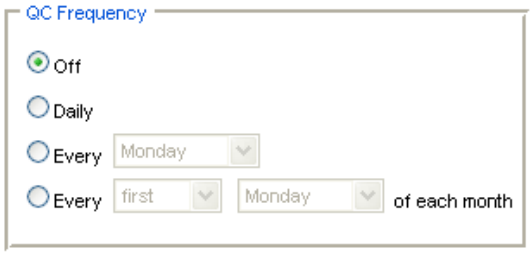
Note 9.1: The APOC Fluid Lot Entry Method is also customizable through the i-STAT 1 handheld keypad.

10. To set up a Liquid QC Schedule, click on the **Liquid QC Schedule 1** tab (Figure 3.11.10) at the top of the screen.



(Figure 3.11.10)

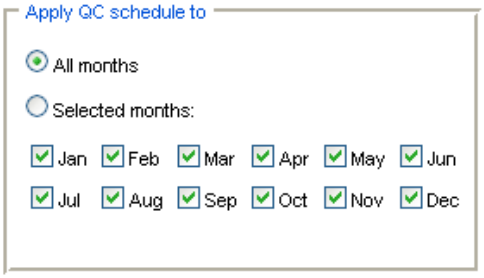
11. Select the frequency at which you want liquid QC to be run under this schedule (Figure 3.11.11).



(Figure 3.11.11)

- **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)

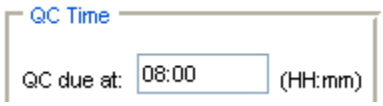
12. Select the months of the year in which you want this schedule to apply (Figure 3.11.12).



(Figure 3.11.12)

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

13. Enter the QC Time (Figure 3.11.13). 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 towards satisfying the QC test profiles, i.e., when QC will become "due to start".



(Figure 3.11.13)

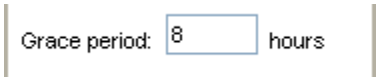
Note 13.1: Use the 24 hour clock designation to indicate the time when QC is due. For example, if QC will be due at 2 pm, enter 14:00 for the time.

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 (Figure 3.11.14):

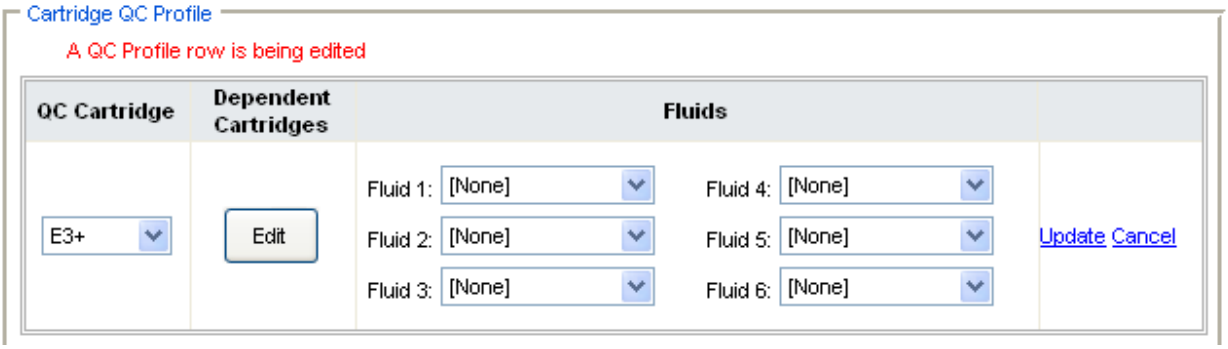
    - up to 23 hours for daily schedules,
    - up to 167 hours for weekly schedules, and
    - up to 255 hours for monthly schedules.

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



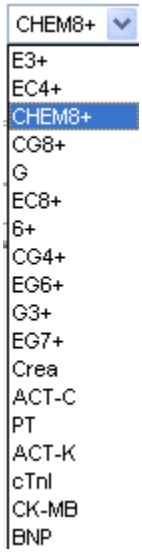
(Figure 3.11.14)

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 (Figure 3.11.15).



(Figure 3.11.15)

16. Select the QC cartridge type from the drop-down menu (Figure 3.11.16). The QC cartridge is the cartridge type to be tested with specified liquid QC fluids during the QC procedure.



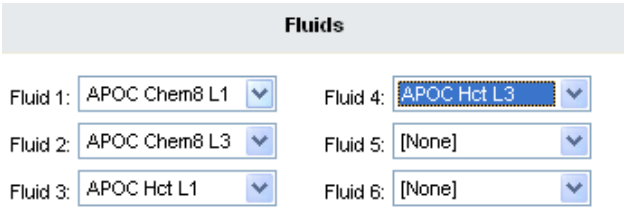
(Figure 3.11.16)

Note 16.1: 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**.

(Figure 3.11.17)

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**.



(Figure 3.11.18)

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. 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.

Control Name	Control Customization Abbreviation
i-STAT cTnI Control Level 1	APOC cTnI L1
i-STAT cTnI Control Level 2	APOC cTnI L2
i-STAT cTnI Control Level 3	APOC cTnI L3
i-STAT BNP Level 1 Control	APOC BNP L1
i-STAT BNP Level 2 Control	APOC BNP L2
i-STAT BNP Level 3 Control	APOC BNP L3
i-STAT CK-MB Control Level 1	APOC CKMB L1
i-STAT CK-MB Control Level 1	APOC CKMB L1
i-STAT CK-MB Control Level 1	APOC CKMB L1
i-STAT Level 1 Control	APOC i-STAT L1
i-STAT Level 2 Control	APOC i-STAT L2
i-STAT Level 3 Control	APOC i-STAT L3
i-STAT CHEM8+ Level 1 Control	APOC Chem8 L1

Control Name	Control Customization Abbreviation
i-STAT CHEM8+ Level 2 Control	APOC Chem8 L2
i-STAT CHEM8+ Level 3 Control	APOC Chem8 L3
RNA Medical Hematocrit Level 1 Control	APOC Hct L1
RNA Medical Hematocrit Level 2 Control	APOC Hct L2
RNA Medical Hematocrit Level 3 Control	APOC Hct L3
i-STAT ACT Level 1 Control	APOC ACT L1
i-STAT ACT Level 2 Control	APOC ACT L2
i-STAT PT Level 1 Control	APOC PT L1
i-STAT PT Level 2 Control	APOC PT L2
Level 1 Control – Non-i-STAT	Non-APOC L1
Level 2 Control – Non-i-STAT	Non-APOC L2
Level 3 Control – Non-i-STAT	Non-APOC L3
i-STAT TriControls Level 1	APOC Combo L1
i-STAT TriControls Level 2	APOC Combo L2
i-STAT TriControls Level 3	APOC Combo L3

19. The Cartridge QC profile (Figure 3.11.19) will then appear on the Cartridge QC tab page.

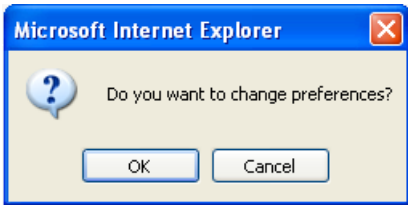
QC Cartridge	Dependent Cartridges	Fluids		
CHEM8+	4	Fluid 1: **APOC Chem8 L1** Fluid 2: **APOC Chem8 L3** Fluid 3: **APOC Hct L1**	Fluid 4: **APOC Hct L3** Fluid 5: [None] Fluid 6: [None]	Edit Delete

(Figure 3.11.19)

Note 19.1: 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 to 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 (Figure 3.11.20).



(Figure 3.11.20)

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.

i-STAT 1 Handheld Display Screens for the Liquid QC Schedule and Lockout Customization Features

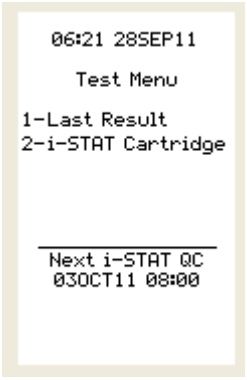
After customizing the i-STAT 1 handheld for the Liquid QC Schedule and Lockout customization features, users may encounter some new handheld display screens.

Test Menu

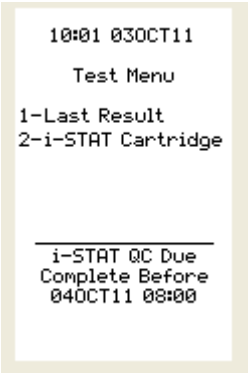
When the On/Off key is pressed on the handheld, and the Test Menu appears, the handheld will now display one of four messages at the bottom of the screen:

1. **"Next i-STAT QC (Date)" (Figure 3.11.21)**: 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.
2. **"i-STAT QC Due – Complete Before (Date)" (Figure 3.11.22):** 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.
3. **"QC Past Due – Not All Cartridges are Active for Testing" (Figure 3.11.23):** 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.

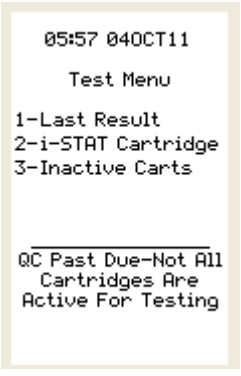
   Note 3.1: If **"Inactive Carts" (Figure 3.11.24)** message appears, users can press the listed number on the handheld keypad to display which cartridges are currently inactive.
4. **"i-STAT QC Past Due – Cartridge Testing Disabled" (Figure 3.11.25):** This message will appear if the liquid QC requirements 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.



(Figure 3.11.21)

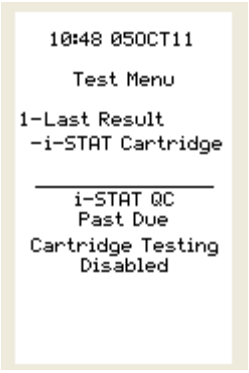


(Figure 3.11.22)



(Figure 3.11.23)

(Figure 3.11.24)



(Figure 3.11.25)

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 (Figure 3.11.26) will then appear on the display.

The user has the following options to choose from on this screen:

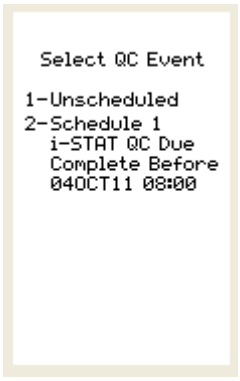
- **1-Unscheduled:** selecting this option allows the user to perform a liquid QC run which will not be applied to a customized liquid QC schedule(s).
- **2-Schedule 1, 3-Schedule 2 (if applicable), or 4-Schedule 3 (if applicable):** selecting one of these options will allow the user to apply the liquid 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 (Figure 3.11.27).

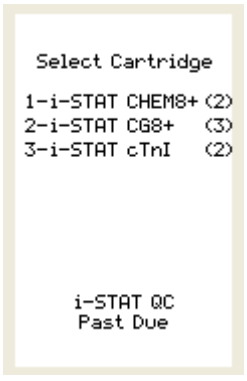
Note: The number in parentheses next to the cartridge name indicates how many control fluids remaining to be run on cartridges of that type and pass, in order to satisfy the QC Profile (Figure 3.11.27).

Once the cartridge type is selected, the user is taken to a screen to select the fluid type being run (Figure 3.11.28).

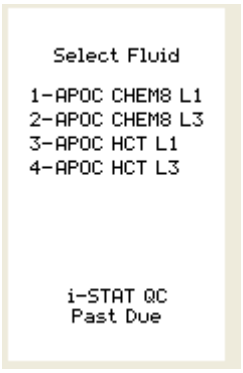
Once the fluid type is selected, the user proceeds as normal.



(Figure 3.11.26)



(Figure 3.11.27)



(Figure 3.11.28)

3.12 Operator Competency Notification Feature

The Operator Competency Notification feature for the i-STAT 1 handheld allows a system administrator (e.g., Point of Care Coordinator or Laboratory Administrator) to define a time period in which the operator will be notified by a message on the i-STAT 1 handheld display of their competency expiration date. By default, the feature is turned off.

Functionality

The system administrator will define a time period of notification in the i-STAT/DE Customization Workspace web page. When the operator scans or enters their operator ID in the i-STAT 1 handheld, if their competency certification will expire within the timeframe set by the system administrator, a message will appear on the handheld display alerting them of the expiration date (Figure 3.12.1).

(Figure 3.12.1)

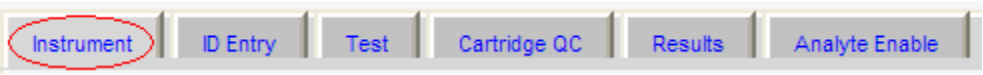
General Considerations

In order to create Operator Competency Notifications, users must have the i-STAT 1 handheld and the i-STAT/DE software. This feature is not customizable through the i-STAT 1 handheld keypad.

Customizing Operator Competency Notification Feature

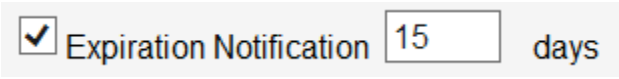
Note: Abbott Point of Care recommends using the current version of i-STAT/DE software.

1. Access the Customization Workspace.
2. If the location to which this handheld is assigned has a check mark under the **Use Default Profile** column, double click the alphanumeric code under **Preferences** in the **Default Customization Profile** column. Otherwise, double click the alphanumeric code under **Preferences** for the specific location to which this handheld is assigned.
3. Once the **Preferences** window opens, click on the **Instrument** tab (Figure 3.12.5).



(Figure 3.12.2)

4. In the Operator ID section, check the Expiration Notification box (Figure 3.12.6) and type in the number of days (between 1 and 255) in which the operator will be notified of their certification expiration.



(Figure 3.12.3)

5. Click **OK** and then answer **YES** to the question about changing the Preferences
6. Download the handheld(s) to i-STAT/DE from a downloader in the location to which the handheld is assigned. This action should upload the chosen customization features into the handheld. Repeat step 6 for all handhelds from the same location to be customized. To customize handhelds from other locations for the same features, return to step 1.

3.13 Custom Reportable Range Feature

The Custom Reportable Range 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, the 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.

Caution(s)

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 and are within the analyte reportable range noted in the i-STAT Cartridge Instructions for Use (IFU) or Cartridge and Test Information (CTI) sheet for reportable range details.
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.

   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 <>).

Note: Test name is displayed as it would be within the i-STAT/DE Customization Workspace.

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
PCO2	TCO2, Anion Gap, Base Excess, HCO3, sO2
pH	TCO2, Anion Gap, Base Excess, HCO3, sO2
HCO3	TCO2, Anion Gap, Base Excess, sO2
Cl	Anion Gap
K	Anion Gap
TCO2	Anion Gap
PO2	sO2
PT/INR	PT WBT

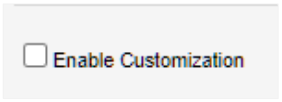
General Notes and Considerations

1. In order to use the Custom Reportable Range feature, users must have the i-STAT 1 handheld and i-STAT/DE software. This feature is not customizable through the i-STAT 1 handheld keypad.
2. **Changes to the reportable range may require a change to the LIS interface. Please contact your interface vendor.**

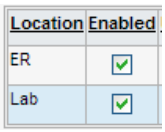
Customizing the Custom Reportable Range Feature

1. Access the Customization Workspace.
2. Make sure the "**Enable Customization**" box (Figure 3.13.1) has a check mark in it.

   Also, make certain that the **Enabled** box (Figure 3.13.2) is checked for the particular location to which the i-STAT 1 handheld is assigned.

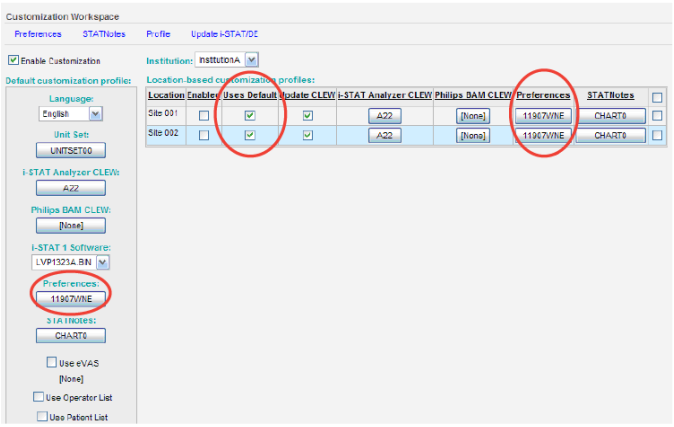


(Figure 3.13.1)



(Figure 3.13.2)

3. If the location where this handheld is assigned has a check mark under **Uses Default**, under the **Default customization profile:** column (Figure 3.13.3), double click the alphanumeric code under **Preferences** (Figure 3.13.3). Otherwise, double click the alphanumeric code under the **Preferences** column (Figure 3.13.3) for the specific location to which this handheld is assigned.



(Figure 3.13.3)

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

(Figure 3.13.4)

5. In the **Custom Reportable Ranges** section (Figure 3.13.5), 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.

Analyte	Reference Ranges Low	Reference Ranges High	Action Ranges Low	Action Ranges High	Custom Reportable Ranges Low	Custom Reportable Ranges 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

(Figure 3.13.5)

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: Analytes in the reportable range 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 i-STAT Cartridge IFU or CTI sheet.

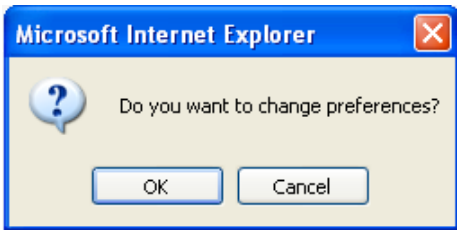
Note 5.3: If a facility wants to disable reportable ranges, then:

- Setting the high reportable range to +99999.9 is recommended to correctly use the default high limit of the reportable range.
- Setting the low reportable range to -99999.9 is recommended to correctly use the default low limit of the reportable range.

Note 5.4: If a facility wants to use customized reportable ranges using i-STAT/DE software, then:

- Ensure that the customized ranges used in the customization profile(s) are at or within the analyte's reportable range listed.
- Users may not broaden the Reportable Range beyond the analyte's reportable range per the cartridge IFU or CTI sheet.
- 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.
- Users are responsible for ensuring that the entered Reportable Range values are appropriate for the Unit Set in use in the handheld.
- Once range customization values have been verified or updated, ensure that the analyzer has received the customization changes.

6. Click **OK** and answer **OK** to the question about changing the Preferences (Figure 3.13.6).



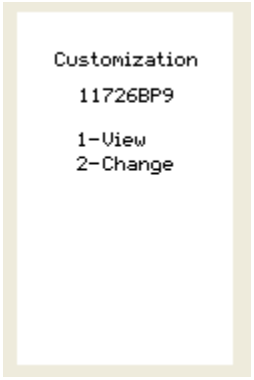
(Figure 3.13.6)

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.

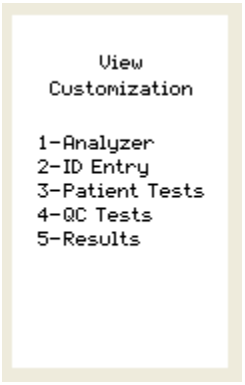
Confirming that the custom Reportable Ranges Have been Transferred to the i-STAT Handheld from i-STAT/DE

1. Power on the i-STAT 1 handheld and press **MENU** once to get to the Administration Menu (Figure 3.13.7).
2. Press **4 - Customization** (Figure 3.13.7).
3. Press **1 - View** (Figure 3.13.8).
4. Press **5 - Results** (Figure 3.13.9).
5. Press **2 - Display Ranges** (Figure 3.13.10).
6. View the displayed Reportable Ranges (Figure 3.13.11). If the analyte customized for Reportable Ranges does not appear on the first page of the screen, press the right arrow button to find the page containing the analyte which has the customized display range and view the customized values. In the example below (Figure 3.13.11), the sodium Reportable Range has been customized to 110-170 mmol/L. Blood Gas analytes (pH, PCO2, and PO2) will display "See IFU" for default and customized Reportable Ranges. See the i-STAT Cartridge IFU or CTI for default Reportable Ranges limits or the i-STAT/DE customization workspace for customized Reportable Range limits.

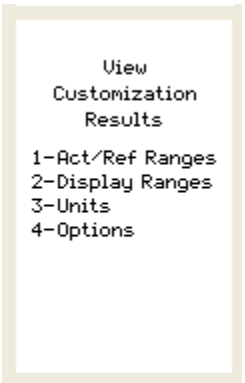
(Figure 3.13.7)



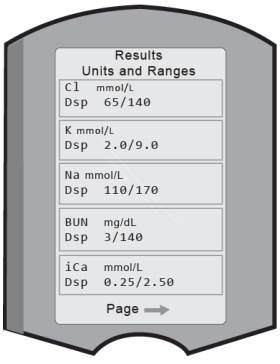
(Figure 3.13.8)



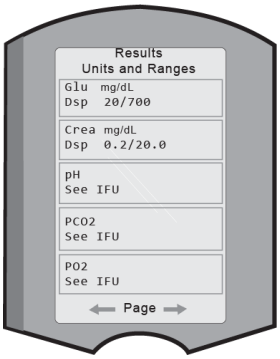
(Figure 3.13.9)



(Figure 3.13.10)



(Figure 3.13.11)



(Figure 3.13.12)

Note: Analyzer display screen images are for representational purposes only.

3.14 Customizing Reference and Action Ranges

The i-STAT/DE customization workspace provides a system administrator (e.g., Point of Care Coordinator or Laboratory Administrator) with the ability to customize the reference range and/or action range for analytes.

The reference ranges on the i-STAT 1 handheld are currently set to factory default values. For details on reference range values, see the i-STAT Cartridge Instructions for Use (IFU) or Cartridge and Test Information (CTI) sheet.

Important Note: Verify that the analyzer customization settings support running the i-STAT cartridge prior to use.

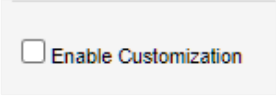
General Notes and Considerations

1. In order to customize an analyte reference or action range, users must have the i-STAT 1 handheld and i-STAT/DE software. This feature is not customizable through the i-STAT 1 handheld keypad.
2. **Changes to the reference and action range may require a change to the LIS interface. Please contact your interface vendor.**
3. **Verify that the analyzer customization settings support running the i-STAT Cartridge prior to use:**
    - **Confirm Action and Reference range limits are within the i-STAT Cartridge IFU or CTI sheets reportable range limits.**
    - **Incorrect customization of the reference and action range will result in a display message "Invalid Cart. See Admin." and inability to obtain test results.**
4. **Ensure all Custom Reference and/or Action Ranges meet the clinical requirements for testing at your facility and fall within the analyte reportable range lower and upper limits noted in the i-STAT cartridge IFU or CTI sheet.**

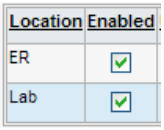
Customizing Reference and Action Ranges

1. Access the Customization Workspace.
2. Make sure the "**Enable Customization**" box (Figure 3.14.1) has a check mark in it.

   Also, make certain that the **Enabled** box (Figure 3.14.2) is checked for the particular location to which the i-STAT 1 handheld is assigned.

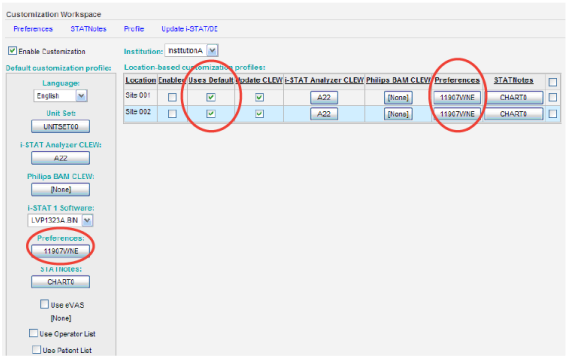


(Figure 3.14.1)



(Figure 3.14.2)

3. If the location where this handheld is assigned has a check mark under **Uses Default**, under the **Default customization profile:** column (Figure 3.14.3), double click the alphanumeric code under **Preferences** (Figure 3.14.3). Otherwise, double click the alphanumeric code under the **Preferences** column (Figure 3.14.3) for the specific location to which this handheld is assigned.

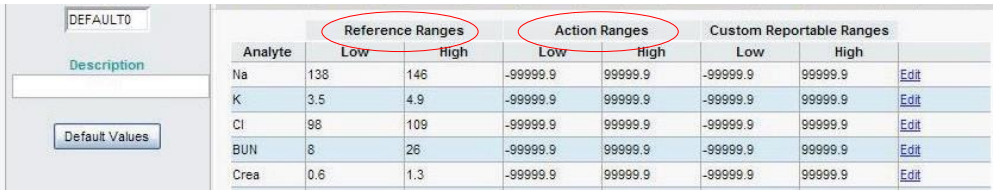


(Figure 3.14.3)

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

(Figure 3.14.4)

5. In the **Reference and/or Action Ranges** section (Figure 3.14.5), 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 Reference and/or Action Range value for the Low or High Range, and then click **Update**. Repeat step 5 until all customized Range data have been entered.



Analyte	Reference Ranges Low	Reference Ranges High	Action Ranges Low	Action Ranges High	Custom Reportable Ranges Low	Custom Reportable Ranges 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

(Figure 3.14.5)

Note 5.1: All analytes listed in the table can be customized.

Note 5.2: Analytes in the Reference or Action Ranges table that are left with the default cell value of -99999.9 or +99999.9 will continue to report the default Reference Ranges listed in the i-STAT cartridge IFU or CTI sheet.

Note 5.3: If a facility wants to disable reference or action ranges, then:

- Setting the high reference or action range to +99999.9 is recommended to correctly disable the high action range.
- Setting the low reference or action range to -99999.9 is recommended to correctly disable the low action range.

Note 5.4: If a facility wants to use customized action or reference ranges using i-STAT/DE software, then:

- Ensure that the customized ranges used in the customization profile(s) are at or within the analyte's reportable range listed.
- 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.
- Users are responsible for ensuring that the entered range values are appropriate for the Unit Set in use in the analyzer.
- Once range customization values have been verified or updated, ensure that the analyzer has received the customization changes.

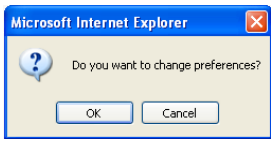
Note 5.5: For i-STAT CG4+ Cartridges (P/N 03P85-51)

- If using i-STAT CG4+ Cartridges (P/N 03P85-51), along with other i-STAT Cartridge configurations that contain blood gases such as i-STAT CG8+ cartridge, the Reference and Action ranges for pH, PO2 and PCO2 must fall within the reportable range limits noted within the IFU for i-STAT CG4+ Cartridge (P/N 03P85-51).
- If using i-STAT CG4+ Cartridges (P/N 03P85-51), along with other i-STAT Cartridge configurations that contain blood gases such as i-STAT CG8+ cartridge and a wider Reference or Action Range is needed for an analyte, such as pH on the i-STAT CG8+ cartridge, then disable pH on the i-STAT CG4+ Cartridge. For instructions on disabling or

enabling analytes, see Section 3.15 Customizing Analyte Enable Options in this user guide.

- If using i-STAT CG4+ Cartridges (P/N 03P85-51), for reporting Lactate results only the Reference and Action range for pH, PO2 and PCO2 must fall within the reportable range limits noted within the IFU for i-STAT CG4+ (P/N 03P85-51) or the pH, PO2 and PCO2 must be disabled for i-STAT CG4+ Cartridge. For instructions on disabling or enabling analytes, see Section 3.15 Customizing Analyte Enable Options in this user guide.

6. Click **OK** and answer **OK** to the question about changing the Preferences (Figure 3.14.6).



(Figure 3.14.6)

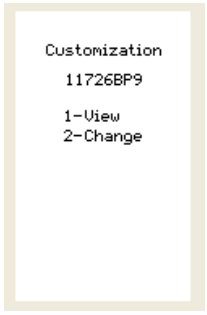
7. Download the handheld(s) to i-STAT/DE from a downloader in the location to which the handheld is assigned. This action will upload the chosen customization features into the handheld. Repeat step 7 for all handhelds from the same location to be customized. To customize handhelds from other locations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

Confirming that the custom Reference and/or Action Ranges Have been Transferred to the i-STAT Handheld from i-STAT/DE

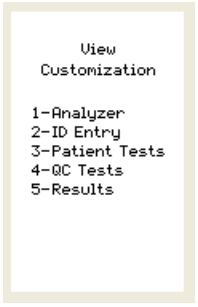
1. Power on the i-STAT 1 handheld and press **MENU** once to get to the Administration Menu (Figure 3.14.7).
2. Press **4 - Customization** (Figure 3.14.7).
3. Press **1 - View** (Figure 3.14.8).
4. Press **5 - Results** (Figure 3.14.9).
5. Press **1- Act/Ref Ranges** (Figure 3.14.10).
6. View the displayed Reference and Action Ranges. If the analyte customized for Reference and Action Ranges does not appear on the first page of the screen, press the right arrow button to find the page containing the analyte which has the customized range and view the customized values.

   Note: Incorrect customization of the Reference and Action range for pH, PO2, or PCO2 will result in a display message "Invalid Cart., See Admin." and inability to obtain test results (Figure 3.14.11) when scanning the cartridge pouch barcode for i-STAT CG4+ Cartridges (P/N 03P85-51).

(Figure 3.14.7)



(Figure 3.14.8)



(Figure 3.14.9)

(Figure 3.14.10)

(Figure 3.14.11)

Note: Analyzer display screen images are for representational purposes only.

3.15 Customizing Analyte Enable Options

The i-STAT/DE customization workspace provides a system administrator (e.g., Point of Care Coordinator or Laboratory Administrator) with the ability to enable/disable a particular analyte on all i-STAT cartridge types that contain that analyte or on a specific i-STAT Cartridge.

Options are provided to enable/disable an analyte globally or by panel. By default all analytes are enabled on the i-STAT Cartridge across all cartridge configurations.

Important Note: Verify that the analyzer customization settings support running the i-STAT cartridge prior to use.

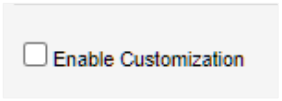
General Notes and Considerations

1. In order to enable or disable an analyte, users must have the i-STAT 1 handheld and i-STAT/DE software. This feature is customizable through the i-STAT 1 handheld keypad to enable/disable analytes globally. To disable analytes by i-STAT Cartridge panel, users must use i-STAT/DE.
2. **Use of the analyte enable options may require a change to the LIS interface. Please contact your interface vendor.**

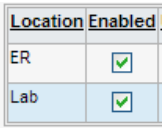
Customizing the Analyte Enable Options

1. Access the Customization Workspace.
2. Make sure the "**Enable Customization**" box (Figure 3.15.1) has a check mark in it.

   Also, make certain that the **Enabled** box (Figure 3.15.2) is checked for the particular location to which the i-STAT 1 handheld is assigned.

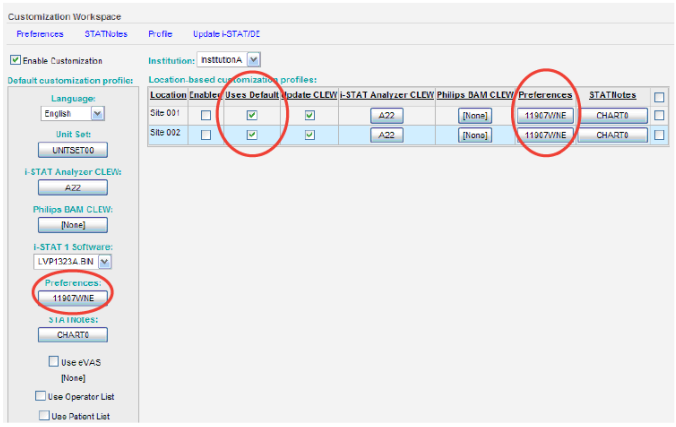


(Figure 3.15.1)



(Figure 3.15.2)

3. If the location where this handheld is assigned has a check mark under **Uses Default**, under the **Default customization profile:** column (Figure 3.15.3), double click the alphanumeric code under **Preferences** (Figure 3.15.3). Otherwise, double click the alphanumeric code under the **Preferences** column (Figure 3.15.3) for the specific location to which this handheld is assigned.



(Figure 3.15.3)

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

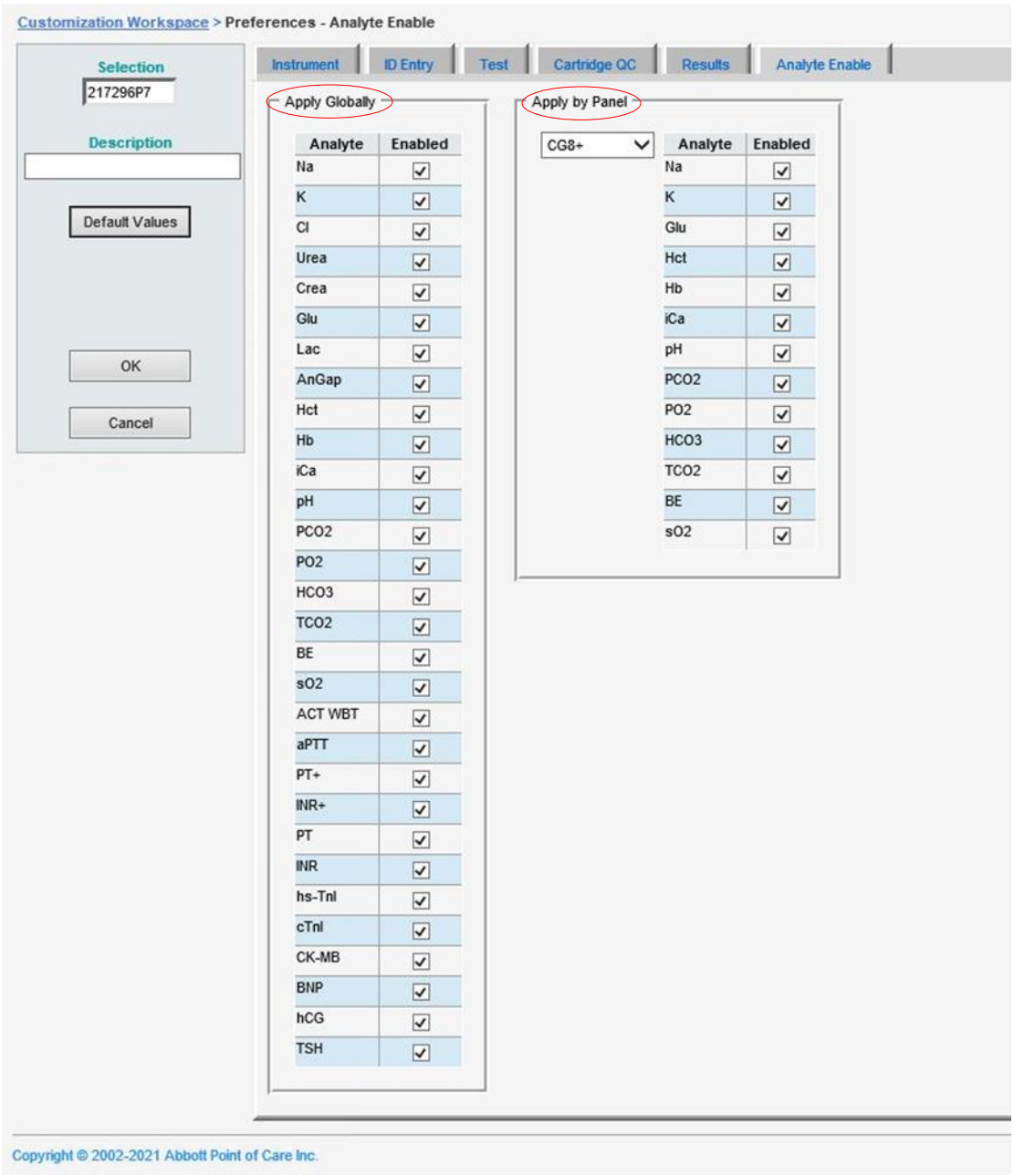
(Figure 3.15.4)

5. In the **Analyte Enable** section (Figure 3.15.5), two options are available:

   Apply Globally: Analyte(s) can be disabled or enabled for all cartridge types.

   Apply by Panel: Analyte(s) can be disabled or enabled by cartridge type.

   Check/Uncheck the box next to the analyte in the Apply Globally and/or Apply by Panel to Enable/Disable the analyzer. Repeat step 5 until all customization has been entered.


Customization Workspace > Preferences - Analyte Enable
Selection
217296P7
Description
Default Values
OK
Cancel
Instrument
ID Entry
Test
Cartridge QC
Results
Analyte Enable
Apply Globally
Analyte
Enabled
Na
K
Cl
Urea
Crea
Glu
Lac
AnGap
Hct
Hb
iCa
pH
PCO2
PO2
HCO3
TCO2
BE
sO2
ACT WBT
aPTT
PT+
INR+
PT
INR
hs-TnI
cTnI
CK-MB
BNP
hCG
TSH
Apply by Panel
CG8+
Analyte
Enabled
Na
K
Glu
Hct
Hb
iCa
pH
PCO2
PO2
HCO3
TCO2
BE
sO2
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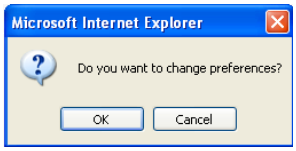
(Figure 3.15.5)

Note 5.1: All analytes listed in the table can be customized.

Note 5.2: When an analyte is enabled and has a customized reference and/or action value outside the Reportable Range, the analyzer will display a message “Invalid Cart. See Admin.” and test results will not be displayed.

6. Click **OK** and answer **OK** to the question about changing the Preferences (Figure 3.15.6).



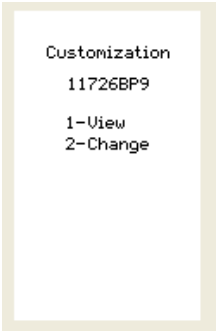
(Figure 3.15.6)

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.

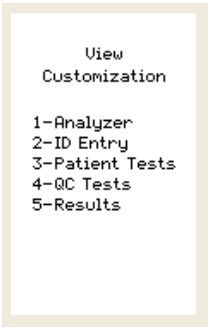
Confirming that the Custom Analyte Enable Options Have been Transferred to the i-STAT Handheld from i-STAT/DE

1. Power on the i-STAT 1 handheld and press **MENU** once to get to the Administration Menu (Figure 3.15.7).
2. Press **4 - Customization** (Figure 3.15.7).
3. Press **1 - View** (Figure 3.15.8).
4. Press **5 - Results** (Figure 3.15.9).
5. Press **3 - Units** (Figure 3.15.10).
6. View the enabled/disabled analytes. Analytes enabled will display ranges and unites of measure. Analytes that are "Disabled" will be indicated as such (Figure 3.15.11). If the analyte does not appear on the first page of the screen, press the right arrow button to find the page containing the analyte to view whether it is enabled or disabled.

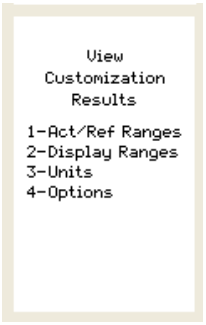
(Figure 3.15.7)



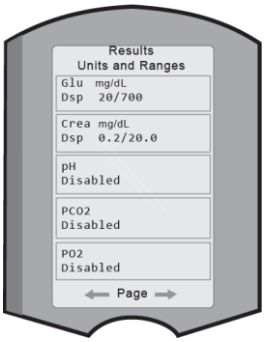
(Figure 3.15.8)



(Figure 3.15.9)



(Figure 3.15.10)



(Figure 3.15.11)

Note: Analyzer display screen images are for representational purposes only.

4. Troubleshooting

4.1 Troubleshooting installation or upgrade of the i-STAT/DE Software

This section provides a table listing the issues, potential cause, and possible resolution for problems that may occur during the installation or upgrade of the i-STAT/DE software.

IMPORTANT NOTES:

- The operating system and application software types listed below will interfere with the installation, upgrade, and functional components of i-STAT/DE software when exclusions or bypass mode options are not utilized to allow the i-STAT/DE software to perform as intended. It is recommended that these operating system and application software types are set with the guidance provided in Section 1.4 Technical Considerations.
    - Anti-Virus and/or Malware Protection Software
    - Non-Malware Protection Software
    - Ransomware Software
    - Threat Hunting Software
    - Application Control Software
    - Storage Management Software

- Attempting to execute the i-STAT/DE software from a location on a shared drive, USB or encrypted USB may cause the installation or upgrade to fail. It is recommended that the i-STAT/DE software installation or upgrade be executed on the target computer, preferably from the disc drive or the local hard drive.

- During an upgrade, the relevant stored procedures are updated, and a check is performed for the existence of STATNotes items having duplicate internal IDs. If duplicate IDs are detected, a warning will be recorded in both the Application Log of the Event Viewer and in the DMI Error Log which can be viewed through the i-STAT/DE Status & Configuration web application. Detection of this condition has no impact on the success of the upgrade. The condition is simply recorded. The text of the message will be:
  A technical issue in your STATNotes configuration has been identified by the setup utility. Please contact your local support organization for assistance.

- The following folder, C:\APOC, will be created as part of the i-STAT/DE version 2.11 installation process for new installations and for upgrades that have updated the website and file locations as per Section 2.2 Installing a Software Upgrade, Websites and Physical File Locations for Upgrades. The installation routine needs to have administrative privileges to the local C drive to ensure proper installation.

  Note: The following folder, C:\Istat32 will be maintained for users that upgrade to i-STAT/DE version 2.11 without updating the website and physical locations. See Section 2.2 Installing a Software Upgrade, Websites and Physical File Locations for Upgrades for more information.

Problem	Cause	Resolution
Unable to install/upgrade and/or "Access Violation Error" Displayed	i-STAT/DE services stopped prior to execution of upgrade	Verify that the following i-STAT/DE services are running and that each service option for **Set all Recovery** is set to **Take No Action**, then execute upgrade: • SQL Anywhere – iSTATDEDB • IstatDeComSrv • i-STAT/DE Update Monitor • i-STAT/DE Data Processor Service • IstatEVASSrv If the services are not running or the service recovery properties are set to **Restart**– then start services or set the services property to **Take No Action.**
	Server windows account is restricted	Verify that the windows account logged into the server has been assigned full administrative rights and/or is not restricted from executing the software upgrade executable package.
	Server windows account is in both users and admin groups	Verify that the windows account logged into the server is part of the admin group only. Having the user in both groups prevents user from having the rights needed to execute installation or upgrade.
	Folder Restrictions: the following folder does not have read/write access to the Istat32 or DE folder:	Verify that there are no restrictions to the Istat32 or DE folder to ensure that the software upgrade can read, write and delete if necessary as part of the upgrade process. For users that upgrade with 32-bit or 64-bit Windows: C:\Istat32 For new installations and upgrades that updated the folder location: 64-bit Windows - C:\Program Files(x86)\APOC 32-bit Windows – C:\Program Files\APOC

Problem	Cause	Resolution
During the software database upgrade process, SQL Anywhere or Borland Database Engine (BDE) launches but does not run	During the SQL anywhere migration process, the i-STAT/DE service(s) restart unexpectedly	Verify that the following i-STAT/DE services are running and that each service option for **Set all Recovery** is set to **Take No Action** then execute upgrade: • SQL Anywhere - iSTATDEDB • IstatDEComSrv • i-STAT/DE Update Monitor • i-STAT/DE Data Processor Service • IstatEVASSrv If the services are not running or the service recovery properties are set to **Restart** – then start services or set the services property to **Take No Action**
	The i-STAT/DE database default settings may have changed post initial installation preventing access to the database or there may be an issue with the software component.	Contact your local technical services group. Please collect and provide the information below: • DE version • Screenshot of any errors on Server/Workstation • Screenshot of web page • Documentation of the link being used • The last time the page was able to display if at all • DE log files • Windows Event logs (System and Application)
Software upgrade installation does not execute from share or alternate drive on server	If performing the software upgrade directly from the file, the software upgrade file must be placed under the root of the C:\ drive to execute successfully	Copy or save the file to the C:\ drive and execute.

4.2 Troubleshooting i-STAT/DE Customization and Configuration web page issues

This section provides a table listing the issues, potential cause, and possible resolution for problems that may occur during use of the i-STAT/DE software web pages.

Problem	Cause	Resolution
Unable to access web page, no error message or number displayed	Unable to log into web page or invalid login message displayed	When the Authentication/Authorization via Active Directory feature is enabled, access to the i-STAT/DE webpages will require a valid user login. Refer user to the System Administrator to verify that their user credentials have been added to the correct Active Directory user group within their Organization.
	User unable to remember user login credential for i-STAT/DE web pages.	When the Authentication/Authorization via Active Directory feature is enabled, access to the i-STAT/DE webpages will require the user to use their Organizations Active Directory Login. Refer user to the System Administrator to verify Active Directory Login credentials.
	Incorrect server hostname or IP address	Verify that the web page link is being created with the IP address or server name that the i-STAT/DE software has been installed on.
	Incorrect web page facility name	Verify that the facility name entered into the data management application is used as the institution ID for the i-STAT/DE customization workspace web page.
	Server where i-STAT/DE software has been installed is powered off or no longer connected to the network	Verify that the server is powered on and connected to the network. May need to work with the IT department to verify that the server is online and powered on. If the server is not powered on or connected to the network – power on the server, log into the server and verify network connectivity.
	Internet Browser Settings or Security software preventing access to unregistered site	Verify that the IT department does not require web page address to be added into the trusted sites in their web browser settings on the computer. Verify that the IT department does not require the web page address to be registered within the software utilized at the facility.

Problem	Cause	Resolution
The components of the i-STAT/DE web page do not display properly or are missing making it difficult to access the component needed	Browser not compatible with the i-STAT/DE web pages.	If using a compatible web browser, contact your local Technical Services group. Otherwise, download and install a compatible web browser and try again. Refer to Section 1.1 Technical Specifications for browser compatibility.
A Microsoft .NET Framework or IIS webpage error is displayed when accessing the webpage	Microsoft .NET and IIS windows components not functioning as expected with i-STAT/DE software	Verify that the Microsoft .NET Framework and IIS windows components have not been modified by updates, security software, domain or network policy changes, user account changes, etc. For information related to the i-STAT/DE website applications and components, refer to the following sections in this User Guide: 1. Section 1.2 Installation Planning 2. Section 1.4 Technical Considerations 3. Section 2.1 Installation of i-STAT/DE 4. Section 2.2 Installing a Software Upgrade

4.3 Troubleshooting Customization for the i-STAT 1 or i-STAT1 Wireless Analyzer

Problem	Resolution
No sound on i-STAT 1 or i-STAT 1 Wireless analyzer	Verify the profile on the i-STAT 1 or i-STAT 1 Wireless analyzer and review the profile's instrument tab settings in the customization workspace to verify that the sound is enabled for the profile displayed in the i-STAT 1 or i-STAT 1 Wireless analyzer.
Date display is incorrect on i-STAT 1 or i-STAT 1 Wireless analyzer.	When the customization preference profile has 'Synchronize Clock to CDS' enabled and the analyzer is in the same time zone as the server where the i-STAT/DE software is installed, upload the i-STAT 1 or i-STAT 1 Wireless analyzer. If the issue persists, contact Technical Services.
i-STAT 1 wireless function does not work	Verify the profile on the i-STAT 1 Wireless analyzer and review the profile's instrument tab settings in the customization workspace to verify that wireless is enabled. Note: Abbott Point of Care recommends updating to the most current version of i-STAT/DE software. Older versions of i-STAT/DE software may not include "enable wireless" selection in instrument options.
Operator barcode will not scan	If the barcode scan beam does not or partially emit(s) when the scan button is pressed, contact Technical Services. Verify the profile on the i-STAT 1 or i-STAT 1 Wireless analyzer and review the profile's ID Entry tab settings in the customization workspace to verify Barcode settings selected for Operator ID barcode being used.

Problem	Resolution
i-STAT 1 analyzer only displays the last 3 numbers or letters of the Operator ID or No Operator ID. **The entire Operator ID should display.**	Check the Operator ID entry selections in the Customization Workspace. Verify that the correct barcode type has been selected and if truncation is being used that the number of first or last digits being truncated is correct.
i-STAT 1 analyzer will not upload operator list	Check and confirm that the Operator List feature is enabled and that there is a data management software with active, certified operators. Verify that the i-STAT 1 analyzer is able to upload successfully.
Patient armband barcode will not scan	Check Barcode settings for Patient ID on the profile assigned to the analyzer.
Patient list will not upload onto the i-STAT 1 analyzer.	Check and confirm that the Patient List feature is enabled and that there is a data management software to provide the patient list (limit of 6000 patient IDs per facility) Verify that the i-STAT 1 analyzer is able to upload successfully.
Custom Analyte reference ranges were created but the i-STAT 1 analyzer displays default analyte reference ranges	Verify the profile on the i-STAT 1 or i-STAT 1 Wireless analyzer and review the profile's reference range settings. Verify that the i-STAT 1 analyzer is able to upload successfully to obtain updated settings.

Problem	Resolution
i-STAT 1 analyzer is displaying the default customization preference ID versus the location-based preference ID	Verify the profile on the i-STAT 1 or i-STAT 1 Wireless analyzer and confirm whether the analyzer is designated as “assigned” or “download” in the data management software. Analyzers that are specified in the data management software as “assigned” will upload the profile for the assigned location. Analyzers that are specified in the data management software as “download” will upload the profile based on the location to which they are uploaded. **NOTE:** Analyzers that are not located under a location in the data management software may appear in the “unassigned” institution within the i-STAT/DE configuration, view instrument webpage. When this occurs that analyzer will not receive updated profile settings, lists and data transmitted may not display in the data management software. The System Administrator must ensure that i-STAT 1 and i-STAT 1 Wireless analyzers are located in the correct location within the correct facility in the data management software.
Unexpected preference, Clew update occurred	When the Authentication/Authorization via Active Directory feature is enabled, audit trails for the i-STAT/DE Customization workspace page is recorded within the Windows Application Event log. See Section 2.4 Authentication/Authorization via Active Directory for i-STAT/DE webpages, Audit Trail Logging for more information. Refer user to the System Administrator to obtain Windows application event logs.
Analyzer displays “Invalid Cart. See Admin.” when scanning an i-STAT CG4+ Cartridge (P/N03P85-51).	Indicates that the Reference and Action ranges for pH, PO_2, or PCO_2 are customized outside of the reportable range noted in the i-STAT CG4+ Cartridge (P/N03P85-51) IFU. Refer to Section 3.14 Customizing Reference and Action Ranges to verify customization supports the use of i-STAT CG4+ Cartridge (03P85-51).

4.4 Miscellaneous Troubleshooting for i-STAT/DE features

Patient List Size

Installations having many facilities with large patient list sizes can result in DataSets being passed to the SetPatientsAll() web method which exceed the default maximum request size of 4096 KB supported by ASP.NET.

The main text of the exception thrown is *"Maximum request length exceeded."*, or, in some cases, *"The request failed with HTTP status 404: Not Found"*.

The maximum supported length can be increased by making the highlighted changes (Figure 1.3.1) to C:\inetpub\wwwroot\iSTATDMI\web.config or C:\Program Files(x86)\APOC\DE\web\iSTATDMI\web.config. The default maximum length is 4096 Kb. In the example shown, this is increased to 8192 Kb (Figure 4.4.1).

Note: the *maxAllowedContentLength* attribute in the *<requestLimits>* tag must be exactly [1024*(*maxRequestLength* attribute in *<httpRuntime>* tag)]. The *maxRequestLength* attribute is in Kb and *maxAllowedContentLength* attribute is in bytes.

```
<?xml version="1.0"?>
<configuration>
  <appSettings/>
  <connectionStrings/>
  <system.web>
    <!--
            Set compilation debug="true" to insert debugging
            symbols into the compiled page. Because this
            affects performance, set this value to true only
            during development.
        -->
    <compilation debug="false" targetFramework="4.0"/>
    <!--
            The <authentication> section enables configuration
            of the security authentication mode used by
            ASP.NET to identify an incoming user.
        -->
    <authentication mode="Windows"/>
    <!--
            The <customErrors> section enables configuration
            of what to do if/when an unhandled error occurs
            during the execution of a request. Specifically,
            it enables developers to configure html error pages
            to be displayed in place of a error stack trace.

        <customErrors mode="RemoteOnly" defaultRedirect="GenericErrorPage.htm">
            <error statusCode="403" redirect="NoAccess.htm" />
            <error statusCode="404" redirect="FileNotFound.htm" />
        </customErrors>
        -->
    <pages controlRenderingCompatibilityVersion="3.5" clientIDMode="AutoID"/>
    <httpRuntime maxRequestLength="8192" />
  </system.web>
  <system.webServer>
      <security>
        <requestFiltering>
            <requestLimits maxAllowedContentLength="8388608" />
        </requestFiltering>
      </security>
  </system.webServer>
</configuration>
```

(Figure 4.4.1)

4.5 Troubleshooting STATNotes Customization

Problem	Resolution
Message from Webpage: "Item belongs to Page(s) and its deletion is not allowed"	When deleting a parameter item and this message "item belongs to page(s) and its deletion is not allowed" appears: This means the parameter item is connected to a parameter page(s) and that parameter item needs to be deleted from those parameter page(s) before the item is deleted.
Message from Webpage: "Page is in use and cannot be deleted"	When deleting a parameter page or base page and this message "Page in use and cannot be deleted" appears: • This means the parameter page that needs to be deleted is connected to a Mode or Delivery System and that parameter page needs to be disconnected from the Mode or a Delivery System it's attached to before it can be deleted. • This means the base page is attached to a cartridge type and needs to be detached before deleting.
Message from Webpage: "No available items"	When building additional selection lists and the message "No available items" appears: This means the maximum limit of selection list base items has been met and no more can be built. There can only be 2 additional selection list base items added. The following should be considered: • Determine what the other pages are and see if they are in use. If not delete them. • Contact Technical Services for other options.
Message from Webpage: "The base page assigned to the cartridge must contain the 'CPB Applied' item"	When applying a STATNotes Base page and the message "The base page assigned to the cartridge must contain the 'CPB Applied' item." appears: This means the cartridge type has Hgb and HCT analytes and it is mandatory to add CPB Mode. The following should be considered: • Add CPB Mode base item to the base page if there is enough room • If not enough room, work with the create another base page specific for that cartridge type and to include the CPB mode base item. • Contact Technical Services for other options.

Problem	Resolution
Message Displayed: "The continued length of prompt and value should not exceed 16 characters"	If the message "The combined length of prompt and value should not exceed 16 characters" appears: This means the prompt name in combination with field length exceeds 16 characters. The following should be considered: • Rename the prompt by shortening the name • Remove any spaces in the prompt • See if the field length can be shortened
STATNotes set does not display	Verify that the STATNotes feature is enabled in the customization workspace. Verify the profile on the i-STAT 1 or i-STAT 1 Wireless analyzer and review the STATNotes profile for the location the analyzer has been assigned to.
Unexpected STATNotes preference applied to analyzer	When the Authentication/Authorization via Active Directory feature is enabled, audit trails for the i-STAT/DE Customization workspace page is recorded within the Windows Application Event log. See Section 2.4 Authentication/Authorization via Active Directory for i-STAT/DE webpages, Audit Trail Logging for more information. Refer user to the System Administrator to obtain Windows application event logs.

5. Support

5.1 Technical Assistance

United States and Canada, please contact Technical Services via email: techsvc@apoc.abbott.com or toll free 1-800-366-8020.

Outside the U.S and Canada, please contact Technical Services via email: oustechsvc@apoc.abbott.com , toll 609-454-9000 or your local APOC representative.

The following information may be collected to assist with support:

1. Description of the Problem and troubleshooting already performed
2. i-STAT/DE and Data Management Software Information
    a. Version of i-STAT/DE
    b. Data Management Software and its version
3. Details of events occurring prior to the problem such as server/workstation patch updates, network policy updates, etc.
4. Web Browser Settings and/or Restrictions
5. Server/Workstation Environment details related but not limited to the following:
    a. Exclusions or bypass settings discussed in Section 1.4 Technical Considerations
    b. Windows User account permissions
    c. Domain, Network, and/or Browser Restrictions
    d. Server/Workstation Image or Drive Backups
6. Customization profile files generated through the i-STAT/DE customization workspace page

7. i-STAT/DE Log files – located in the i-STAT/DE Software Folder.

   Where the “Software Folder Name” is Istat32 or APOC depending on the type of installation and folder location.

   For more information on folder locations, refer to the following sections in this User Guide:

   - Section 1.2 Installation Planning,
   - Section 1.4 Technical Considerations
   - Section 2.1 Installation of i-STAT/DE
   - Section 2.2 Installing a Software Upgrade

   For users that upgrade with 32-bit or 64-bit Windows: C:\Istat32\log

   For new installations and upgrades that updated the folder location:

   64-bit Windows - C:\Program Files(x86)\APOC\DE\log

   32-bit Windows - C:\Program Files\APOC\DE\log

   The **iStatDMIErrors.txt** provides information on the data management interface component of i-STAT/DE and its interaction with the data management software

   The **DECOMSVR_LOGxxx.txt** provides information on the status of the i-STAT/DE communication service

   The **Xmitlogxxxx.txt** provides information on the connection of and customization update of the i-STAT 1 analyzer.

   The **VASLOG.txt** provides information on the status of the i-STAT/DE eVAS service and file update.

   The **DeCustLogX.txt log**, where “X” indicates number, provides information on errors received accessing the customization page.

   Note: The files above do not contain protected health information.

8. i-STAT/DE Configuration and/or Data Manager Interface details located within the i-STAT/DE configuration webpage
9. Server/Workstation Operating System Log files for Application and System events

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Appendix

A1. Quality Check Code Report Categorization

The following table provides the quality check code categorization for data management reports that categorize i-STAT Quality check codes.

Category Name	i-STAT 1 Quality Check Codes
Other	12,13,14,19,20,22,23,25,26,27,28,29,32,33,40,41,44,45,46,48,49, 50,51,52,53,54,55,56,57,58,59,60,61,62,63,64,65,66,67,68, 70,71,72,73,74,75,76,77,78,79,80,81,82,83,84,85,86,87,88,89,90, 91,92,93,94,96,97,98,99,117,118,119,120, 121,122,123,124,125,126,129,130,132,133,134,135,136, 137,139,142,143,144,146,147,148,149,150,151,152,153, 154,155,156,157,158,159,160,161,162,163,164,165,166, 167,168,169,170,171,172, 173,174,175
Environment	1,2,3,4,5,6,7,8,9,10,11,15,16,17,18,95
Cartridge Handling	21,24,42,43,47,127,128
Overfilled Cartridge	30,37
Unable to Position Sample	31,34
Underfilled Cartridge	35,36,131,138,145
Insufficient Sample	38,39

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