DOCUMENTATION AND SOFTWARE UPDATE FOR THE i-STAT SYSTEM: OCTOBER 2006

In addition to important updates to documentation about the i-STAT® System, this package contains the necessary items to perform the required software upgrades on your i-STAT System. Items enclosed are detailed in the table below. Please follow instructions carefully. Thank you for your prompt attention in performing this upgrade.

Contact i-STAT Technical Support at 1-800-366-8020, option 1, if you have any questions or need further assistance.

DOCUMENTATION UPDATES		SENT TO		
ITEM	COMMENT	all users	i-STAT 1 users only	users of CDS ver. 5
Add/Delete sheet, i-STAT 1 System Manual	Lists which sections should be replaced with updated sections.		X	
Add/Delete sheet, i-STAT System Manual	Lists which sections should be replaced with updated sections.	X		
Cartridge and Test Information Sheet for Ionized Calcium	New or revised information that should be retained.	X		
Cartridge and Test Information Sheet for B-Type Natriuretic Peptide / BNP	New or revised information that should be retained.		X	
Technical Bulletin: The i-STAT BNP Cartridge	New or revised information that should be retained.		X	
i-STAT and i-STAT 1 System Manual: Introduction to the CTI Section	New or revised information that should be retained.	X		
i-STAT System Manual Section 12: Quality Control	New or revised information that should be retained.	X		
i-STAT System Manual Section 13: Calibration Verification	New or revised information that should be retained.	X		
i-STAT System Manual Section 18: Central Data Station 5	New or revised information that should be retained.	X		
i-STAT 1 System Manual Section 10: Sample Collection	New or revised information that should be retained.		X	
i-STAT 1 System Manual Section 14: Quality Control	New or revised information that should be retained.		X	
i-STAT 1 System Manual Section 15: Calibration Verification	New or revised information that should be retained.		X	
i-STAT 1 System Manual Section 22: Central Data Station 5	New or revised information that should be retained.		X	

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SOFTWARE UPDATES		all users	i-STAT 1 users only	users of CDS ver. 5
DOCUMENT	**COMMENT**			
Control and Calibration Verification Value Assignment Sheet Notice	Directs customer to www.abbottpointofcare.com for printing new value assignment sheets.	X		
Product Update: JAMS054 / JAMS121 / HPCA054	Describes changes in new software and summarizes updates to documentation.	X		
Disk: i-STAT Software for Analyzers	One disk contains all versions of software.	X		
Technical Bulletin: Updating Analyzer Software	For use in updating software using a computer with Windows 95 or higher. These instructions must be used for updating i-STAT 1 Analyzers.	X		
Technical Bulletin: Instructions for Updating Software: Jammit Utility	For use in updating software from a computer with Windows 3.1.	X		
Confirmation Postcard	Complete and return to i-STAT after upgrade has been performed.	X		

i-STAT® PRODUCT UPDATE

SOFTWARE AND CARTRIDGE TEST INFORMATION UPDATE: OCTOBER 2006

This update includes new software for the i-STAT 1 Analyzer, i-STAT Portable Clinical Analyzer and Philips Medical Systems Blood Analysis Module. The appropriate materials required for your institution to perform the update are included.

This is a mandatory update. If you did not receive a disk or CD-ROM with the correct software for your analyzers (see list below), please call to request one. In the US, call i-STAT Technical Support at 800-366-8020, option 1. Outside the US, please contact your local support representative.

ANALYZERS

The correct version of software and CLEW to install in your analyzers is listed below.

STANDARD SOFTWARE		
i-STAT Portable Clinical Analyzer	**i-STAT 1 Analyzer**	**Blood Analysis Module**
JAMS054 & CLEW A12	JAMS121 & CLEW A12	HPCA054 & CLEW H12
Japan: JAMS054 & CLEW C12	Japan: JAMS121 & CLEW A12	Japan: HPCA054 & CLEW J12

Expiration Date

Please note that the current software expires 13 December 2006.

Fifteen days before the software expires, a message will be displayed to alert the user of the pending expiration date. If this update is not performed by 13 December 2006, the analyzer and Blood Analysis Modules will display "INVALID OR EXPIRED CLEW – SEE MANUAL" (quality check code 12).

The new software expires 20 June 2007.

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Art: 717185-00A Rev. Date: 08/23/06

Portable Clinical Analyzer

The application of the "CPB Always" setting will be removed when running Proficiency cycles. When an i-STAT Portable Clinical Analyzer is configured for "CPB Always" and a user runs a Proficiency cycle, the "CPB Always" setting will be ignored, and the cycle will run with the default setting of "Prompt CPB", which does not apply the CPB correction unless the user consciously navigates to the analyzer Chart Page and selects "CPB" as the Sample Type

i-STAT 1 Analyzer

The i-STAT 1 Analyzer will not allow CPB to be selected when running Proficiency cycles. When an i-STAT 1 analyzer runs a Proficiency cycle, that cycle will run with "CPB Never" configuration, regardless of the analyzer's current customization setting. It will not be possible to select CPB as a Sample Type.

The i-STAT 1 Analyzer will now store the Operator ID with Internal Simulator records, even if the Operator ID entry is completed following the internal simulator cycle.

i-STAT and i-STAT 1 System Manuals

The Expected Values table of the Introduction to the Cartridge and Test Information Section for both the i-STAT and i-STAT 1 System Manuals has been updated to reflect a change in the BNP reportable range to 15 - 5000 pg/mL (ng/L).

The Sample Collection, Quality Control and Calibration Verification sections in the i-STAT 1 System Manual have been updated with information regarding the use of the new BNP cartridge.

a). The Sample Collection section indicates that the use of glass vessels is not recommended because the BNP molecule has been shown to be unstable in glass tubes.

b). The Quality Control and Calibration Verification sections contain updated mixing recommendations for the BNP control and calibration verification material.

The Quality Control and Calibration Verification sections of both the i-STAT and the i-STAT 1 System Manuals have been updated with information regarding the room temperature storage of the RNA® Medical Controls and Calibration Verification material for hematocrit.

Section 18 of the i-STAT System Manual and Section 22 of the i-STAT 1 System Manual have both been updated to include all of the CDS Version 5 changes from October 2004 to the present.

Please replace your corresponding sections of the System Manual with these new updated versions.

CENTRAL DATA STATION

Central Data Station Version 4

There is no update to CDS Version 4.

Central Data Station Version 5

Update your CDS Version 5 program to Version 5.20 by using the CD included in this software update packet. **This is a mandatory update**.

This update includes performance enhancements required to maintain compatibility with new cartridges.

i-STAT DE

There is no update to the i-STAT/DE.

STANDARDIZATION

CLEW Update

The i-STAT System is designed to eliminate operator influence on delivered results. With the exception of the immunoassay cartridges, the user is not required to enter lot-specific calibration information into the instrument. The micro-fabricated sensor technology produces very repeatable devices from lot to lot which allow the Analyzers to use the same set of standardizing values for extended periods of time.

Nevertheless, continuous manufacturing process improvements made by i-STAT necessitate re-establishing standardization values from time to time to maintain long-term consistency. This is equivalent to adjusting calibration on a traditional analyzer. It has been our practice to accomplish this with periodic releases of software. This new CLEW re-establishes the standardization and incorporates refinements to the internal quality monitoring system.

Future shipments of cartridges may require the installation of this software prior to the use of the cartridges. Failure to update prior to using these cartridges will result in quality check code 69, "CARTRIDGE TYPE NOT RECOGNIZED".

This software supports all current non-expired cartridges.

CARTRIDGE AND TEST INFORMATION SHEETS

An updated ionized calcium CTI sheet is enclosed. Recent studies indicate that falsely elevated ionized calcium results do not occur with cartridge freezing. Therefore, this statement in the Factors Affecting Results section of the CTI sheet has been removed. However, the general recommendation against freezing cartridges remains.

For i-STAT 1 Analyzer customers, a new CTI sheet for B-Type Natriuretic Peptide/ BNP is also enclosed.

TECHNICAL BULLETINS

For i-STAT 1 Analyzer customers, a new Technical Bulletin is enclosed which describes the use of the new BNP cartridge.

i-STAT® TECHNICAL BULLETIN

UPDATING ANALYZER SOFTWARE

JAMMLITE UTILITY

The JammLite Utility must be used to update software in the i-STAT®1 Analyzer and can be used to update the i-STAT Portable Clinical Analyzer and the Blood Analysis Module. The JammLite procedure is simple with just one screen for all analyzer types and software versions.

To use this utility, you must have a computer with Windows® 95 or higher. An i-STAT Central Data Station Version 5 or a Point of Care Central Workstation meet this requirement and can be used. An i-STAT/DE server is not recommended for use with this utility.

If this is the first time you are updating your analyzer, follow the Detailed Procedure. If you just need reminders, follow the Summary of the Procedure.

SUMMARY OF THE JAMMLITE PROCEDURE

How to	Step	Page
Check battery voltage Save the data on Portable Clinical Analyzers	1	2
Disable Customization on the Central Data Station	2	2
Shut down all programs on the computer	3	2
Connect an IR Link or Downloader* to the computer	4	3
Access the C:\> prompt	5	4
Transfer the files from the JAMS disk to the computer	6	4
Access the JammLite Utility	7	5
Select the instrument (analyzer) type to be updated	7	5
Select the local port or select TCP\IP and enter the IP address	7	5
Select the Application software and CLEW	7	5
Click on Update and follow the directions on the screen	7	6
DO NOT move analyzer during update	7	6
Click on Close	7	6
Click on Exit or X in upper right corner of screen	7	6
Re-start the CDS, update CLEW, re-eanable Customization	8	6
Insert an Electronic Simulator into each updated analyzer	9	7

* It is not neccessary to connect a serial Downloader if using network protocol to update i-STAT 1 Analyzer.

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Art: 714329-00J Rev. Date: 08/14/06

Step (1)

Save Stored Results & Check Battery Voltage

Save Data: All test records are erased in the i-STAT Portable Clinical Analyzer (series 200) when the application software is updated. Download each analyzer to the Central Data Station (CDS) program or ensure that all test records have been transcribed before updating a Portable Clinical Analyzer. Test records are not erased from the i-STAT1 Analyzer (series 300).

- There are two types of software in the analyzers: application (JAMS) and CLEW.
- The Product Update lists the software that is to be updated.
- Test records will not be erased if only the CLEW software is updated.

Check Battery Voltage: Analyzers consume power during the software update. For the software update, the battery voltage should be well above the 7.5 V point at which the low battery message is displayed.

Step (2)

Disable Customization on CDS

If you do not use Customization or Customization is disabled, skip this step. If you use Central Data Station Version 5 and your CDS is on Version 5.18a or higher, skip this step.

If you are not sure if Customization is disabled, follow the steps below. The steps to disable customization differ for the Central Data Station Version 4 and Central Data Station Version 5. If you are not sure which CDS you have, click **Help** on the main menu bar, then click on **About....**

Central Data Station Version 4:

1. Click on the i-STAT Analyzer Customization Profile Utility icon or access by clicking Programs and i-STAT CDS.
2. Type in the Password. The default password is istat.
3. Click on File on the menu bar.
4. Click on Disable Customization.
5. Click Yes to the confirmation messages and the Utility will close.

Central Data Station Version 5:

1. Click on Administration in the main menu bar.
2. Click on Customization.
3. Type in the Password. The default password is istat.
4. Click off the checkmark in the box beside Enable Customization at the top left of the window.

Step (3)

Shut Down All Programs

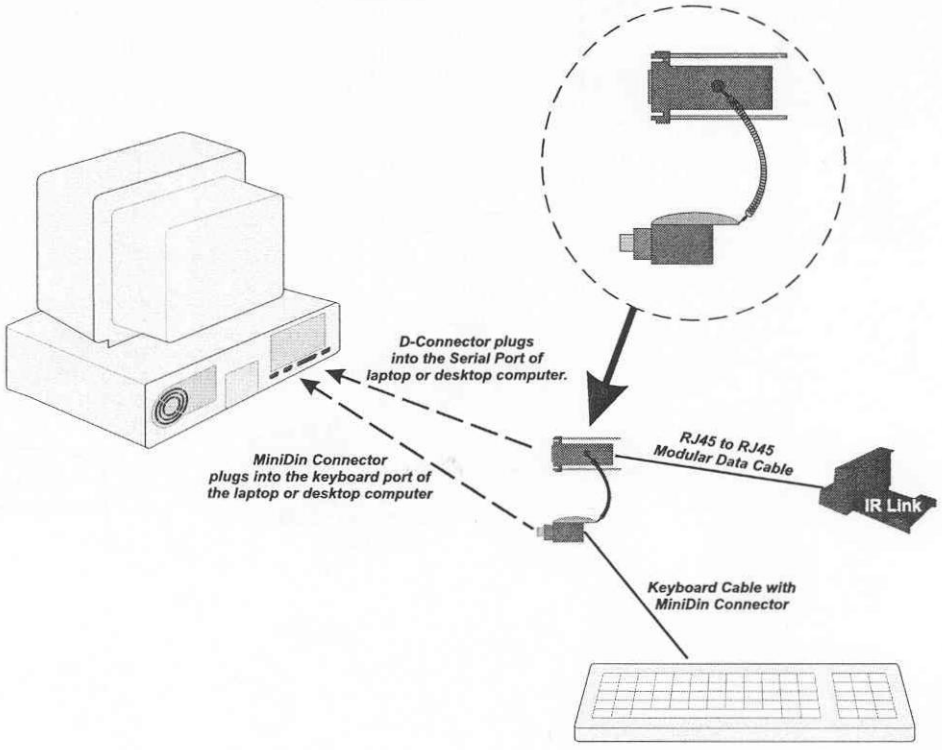
Exit the CDS and all other open programs.

Step (4)

Connect the IR Link and/or Downloader

IR Link connection:

- If using a Central Data Station Version 5, a Central Data Station Version 4 with digiboard, or any other computer using Windows 95 or above, connect the IR Link to a 9 pin COM port using an i-STAT Software Update Kit as illustrated below.



- If using a Central Data Station Version 4 with quad cards: Connect the IR Link to COM5 on the back of the CDS using a Modular Data Cable (i-STAT grey flat cable with RJ45 connectors). COM5 is first port from the inside on the lower row.

Blood Analysis Module connection:

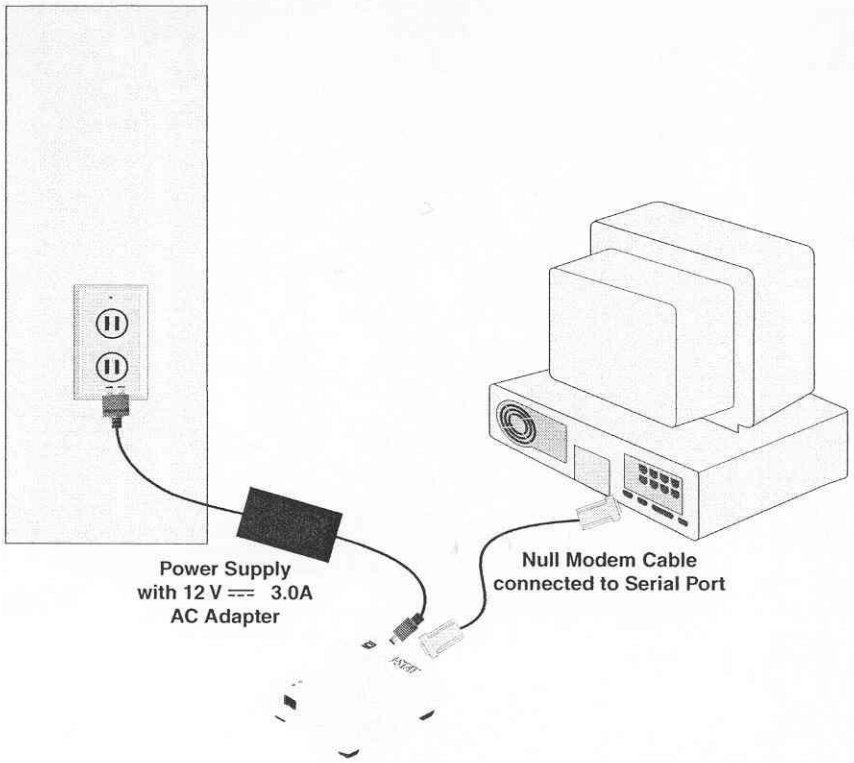
- If using a Central Data Station Version 4, connect the BAM to COM5 on the back of the CDS using a Modular Data Cable (i-STAT grey flat cable with RJ45 connectors).

- If using a Central Data Station Version 5 or another computer, connect the BAM to a 9 pin COM port using the D-Connector and Mini Din Connector from an i-STAT Software Update Kit.

Note: Do not connect the BAM until instructed to do so by the JammLite program.

Serial Downloader connection:

- Connect a serial Downloader to a COM port using a DB9-DB9 Null Modem cable and plug the Downloader's power adapter into a wall outlet.



Network Downloader connection:

- Connect a network Downloader to the network using a network patch cable and plug the Downloader's power adapter into a wall outlet. The computer must also be connected to the network. The computer must support the TCP/IP network protocol.

Step (5)

Access the Command Prompt

- Click Start in the lower left corner of the window.
- Click Run.
- Type: **command** and press the Enter key.

Note: If you do not have access to the **Run** command, contact your Point-of-Care Coordinator or Information Technology (IT) department.

Step (6)

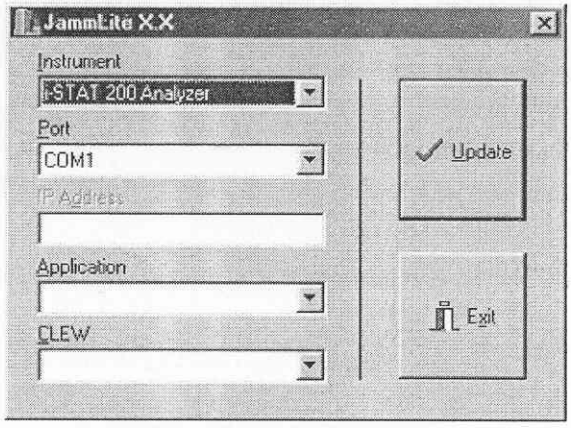
Transfer the Files

Place the JAMS diskette into the A:drive. At the Command prompt, type **A:transfer** and press the Enter key.

Step (7)

Using the JammLite Utility

1. At the C:\>bins prompt, type **jammlite** and press the Enter key. The following screen will be displayed with the new application and CLEW.



X.X is the current version of JammLite software.

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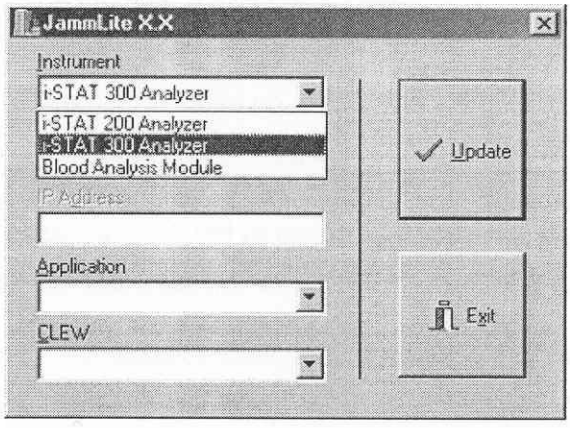
2. Select the appropriate instrument from the Instrument drop-down list.



Note: i-STAT 200 Analyzer is the Portable Clinical Analyzer and the i-STAT 300 Analyzer is the i-STAT 1 Analyzer.

3. Select the port for the instrument being updated from the "Port" drop-down list. The JammLite program will list only available ports on the computer. For updates using a network Downloader, select TCP/IP. (The TCP/IP option is available only if i-STAT 300 is selected from the "Instrument" drop down list.) Enter the IP address of the Downloader in the "IP Address" box.

4. Select the appropriate Application and CLEW from the Application and CLEW drop-down lists. Refer to the update package for the correct Application and CLEW. If the update is for CLEW only, select None for Application. Note that there are different application versions for the i-STAT 1 Analyzer, the Portable Clinical Analyzer and the Blood Analysis Module. JammLite will display all application software and CLEW appropriate for the selected instrument.

5. Click on the Update button to start the update. Appropriate instructions will be displayed. Follow the directions on the screen. The selected application and CLEW will be displayed on the Update Line.

6. During the update, do not move the analyzer or unplug the Blood Analysis Module until a screen is displayed indicating the update was successful.

7. Click on Close. The JammLite program will return to step 7 to allow any selections to be changed before starting another update.

8. When all analyzers have been updated, click on Exit or the X in the upper right corner of the DOS window.

Step (8)

Restarting the Central Data Station

If using a Central Data Station, re-start the software, update the Customization Profile(s) with the new CLEW and enable Customization if desired.

Central Data Station Version 4:

1. Click on the i-STAT Analyzer Customization Profile Utility icon or access by clicking Programs and i-STAT CDS.

2. Type in the Password. The default password is istat.

3. Click on Setup Mode.

4. Click on NEXT for the Language window.

5. Click on the new CLEW in the CLEW window and click on NEXT.

6. Click on NEXT in the Unit Set window.

7. Click on FINISH in the Preference window.

8. Click on FILE and Exit Program or click on the x in the upper right corner of the Utility window.

9. Click on the Central Data Station icon.

Central Data Station Version 5:

1. Click on the Central Data Station icon.

2. Click on Administration.

3. Click on Customization.

4. Type in the Password. The default password is istat.

5. Click the i-STAT Analyzer CLEW button.

6. Click the new version of CLEW and click OK.

7. If "Use Default Profile" is not check-marked beside any localization-based customization profiles, double click the box with the CLEW under the i-STAT Analyzer column (or Agilent BAM CLEW) and click the new version of CLEW.

8. Click a checkmark in the box beside Enable Customization at the top left of the window.

9. Click the x in the upper right corner of the Customization window to close it.

Step (9) *Verifying the Update*

Run an external Electronic Simulator on updated analyzers and check the Analyzer Status page for the new Application software and/or CLEW.

TROUBLESHOOTING

PROBLEM	RECOMMENDED ACTION
The Com port to be used for the update is not listed in the Port List	Exit the JammLite program and ensure that there are no other programs running which may be using the port (such as the Central Data Station). Restart the JammLite program to determine if the port is now listed.
A message appears on the screen that the port specified for the update could not be opened.	Verify that no other programs are using the port and that the correct port was selected.
A message appears on the screen that the specified application file could not be opened, has an error, or is not a valid application file.	Verify that all other programs are closed and that the proper application was selected before re-attempting the update.
A message appears on the screen that the IR Link could not be configured to perform the application update.	Verify that the IR Link is connected to the COM port, that the LED on the IR Link is red, and that the proper port is selected.
A message appears on the screen that there was an error encountered during communication with the analyzer.	Ensure that the instrument is located properly in the IR Link or Downloader, and this it is not removed before the update is completed.
A message appears on the screen that the specified CLEW file could not be opened, has an error, or is not a valid CLEW file.	Ensure that all other programs are closed and that the correct CLEW is selected before re-attempting the update.
A message appears on the screen that the IR Link could not be configured to perform the CLEW update.	Verify that the IR Link is connected to the COM port, that the LED on the IR Link is red, and that the proper port is selected.
A message appears on the screen that the Downloader could not be configured to perform the update	Verify that the Downloader is connected to the COM port, the Downloader is powered, and that the proper port is selected.
A message appears on the screen indicating that nothing was selected for the update.	Select an Application and/or a CLEW prior to clicking on the Update button.

Quality Check Code 13 - Invalid or Expired CLEW after on-line customization is restored

If this quality check code occurs after successfully downloading new software and restoring on-line customization, the CLEW has not been updated to the new version in the Customization Profile. Update CLEW in the customization profile(s) and download the analyzers. The new CLEW will be installed in the analyzers.

Unsuccessful with Windows 95

Some computers with Windows 95 will not run JammLite. In this case, Jammit must be used to update analyzers. Before accessing the Jammit Utility, the computer must be rebooted.

ANALYZER-TO-ANALYZER SOFTWARE UPDATES

i-STAT 1 Analyzer

1 Any updated analyzer can be used as the sending analyzer. Select the Utility option under the Administration Menu on the sending analyzer. The Utility menu can be password protected. Enter the password or press the Enter key if no password has been specified. From the Utility Menu select **1-Send Software**. Select **1 – JAMS and CLEW** or **2-CLEW** as required for the update. The message "Waiting to Send" will be displayed.

2 Ensure that the receiving analyzer is off.

3 Place the sending and receiving analyzers facing each other on a flat surface about 30cm (1 foot) apart and align their IR windows. Move one analyzer toward the other until the message "Sending..." is displayed on the sending analyzer and a scrolling banner appears on the receiving analyzer.

4 Do not move the analyzers until the "Sending..." message is removed from the sending analyzer's display. The sending analyzer will return to the Send Software option and will display the result of the last software update as "Successful" or "Unsuccessful."

5 Select the Analyzer Status option under the Administration menu on the receiving analyzer and check that the new JAMS and/or CLEW are listed.

i-STAT Portable Clinical Analyzer

1 Any updated analyzer can be used as the Sending Analyzer. Run the external Electronic Simulator on the Sending Analyzer.

2 Transmit all data from the analyzer being updated (the Receiving Analyzer) to the Central Data Station. Data stored in the handheld analyzer will be lost after an application software update.

3 With the Simulator test results showing on the display of the Sending Analyzer, press and hold the DIS key and press the soft key for MENU. This displays the Utility Menu.

4 In the Utility Menu, select 3 - Send Software. The display will show the JAMS version and the CLEW in this analyzer. Verify that these are the appropriate versions. The analyzer screen will also say "Waiting to send".

5 Set both analyzers on a flat surface and align the Infrared Light-Emitting Diode (IR LED) windows so they directly face each other. (Refer to the analyzer picture on page 2-1 of the i-STAT System Manual for the location of the IR LED.)

6 On the Receiving Analyzer, make sure the display is off. Press and hold the * key and press the DIS key. The Sending Analyzer will begin sending software to the Receiving Analyzer. The display on the Sending Analyzer will change from "Waiting to send" to "Sending...", and a countdown bar will be displayed.

Note: Do not move the analyzers while the software is being sent.

7 When the display of the Sending Analyzer changes back to the Electronic Simulator result, the sending of software is complete. Do not press the DIS key on the Receiving Analyzer. Run the Electronic Simulator on the Receiving Analyzer.

8 To update software in another analyzer, repeat these instructions from Step 2.

PERFORMING A JAMS AND CLEW UPDATE ON AN i-STAT 1 ANALYZER USING THE CUSTOMIZATION WORKSPACE

1. ***Transfer the Files***

   - Place the JAMS diskette into the A: drive.
   - Click **Start** ⇨ **Run...**
   - Type: **a:transfer** and press the **Enter** key.

Note: If you do not have access to the **Run...** command, contact your Point-of-Care Coordinator or Information Technology (IT) department.

2. ***Start the Central Data Station Application (if not already open)***

   - Click on the Central Data Station icon.

3. ***Access the Customization Workspace***

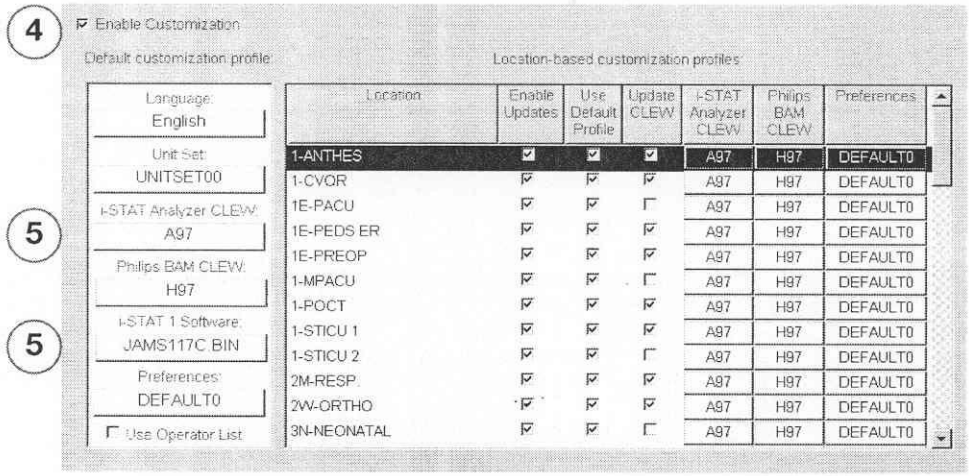
   - Click on **Main ⇨ Open Administration Function ⇨ Customization**
   - Type in the Password. The default password is **istat**.

4. ***Enable Customization***

   - If the Enable Customization box is not already checked, click the box next to this listing.
   - Under the "Location-based customization profile:" section, make sure Enable Updates is checked for every location from which you wish to perform software updates on your i-STAT 1 Analyzers.

5. ***Select the Desired Analyzer CLEW and i-STAT 1 Software***

   - Under the "Default customization profile:" column, click on the i-STAT Analyzer CLEW button. Click the new version of CLEW and click OK.
   - Under the "Default Customization profile:" column, click on the i-STAT 1 Software button. Click the new i-STAT 1 software file and click OK.



6. ***Update the Software in the i-STAT 1 Analyzer***

   - Go to the location where the i-STAT 1 Analyzers you wish to update are located.
   - Press the On/Off button on the analyzer to turn the display on.
   - Press the Menu key to bring up the Administration Menu.
   - Press 7 for Utility. The Utility menu may be password protected. Enter the password or press the Enter key if no password has been specified.
   - From the Utility Menu, select **3-Receive Software**. The "Waiting to Send" message will appear on the analyzer display.
   - Place the analyzer in the downloader or downloader/recharger. A Communication in Progress message will appear on the screen. After this message disappears, the analyzer display will stay blank for approximately 5-10 seconds. Please note that this blank screen is normal analyzer behavior during this part of the procedure.
   - A scrolling bar will then appear on the analyzer display. This bar indicates that the software is uploading into the analyzer. Do not move the analyzer while the scrolling bar appears on the display screen. When the upload process is complete, the scrolling bar will disappear and the analyzer display will again go blank for approximately 5-10 seconds. Please note that this blank screen is normal analyzer behavior during this part of the process.

- A Waiting to Send message followed by a Communication in Progress message will then appear on the analyzer display. After these messages disappear, the analyzer display will go blank, and the update process is complete.

7. ***Verify the Update***

   - Run an external Electronic Simulator on updated Analyzers and check the Analyzer Status page for the new Application software and/or CLEW.

i-STAT® TECHNICAL BULLETIN

Updating Analyzer Software: JAMMIT Utility

This Technical Bulletin contains the instructions for updating application software and CLEW in the i-STAT Portable Clinical Analyzer and Philips Medical Systems Blood Analysis Module. Unless you have a Central Data Station 3.1 or a PC with a Windows software below 95, we recommend that you use the JAMMLITE Utility rather than this JAMMIT Utility to update your analyzers and Blood Analysis Modules. If you have any questions, please call i-STAT Technical Support at (800) 366-8020.

SETTING UP THE COMPUTER

If using an i-STAT Central Data Station

if using an i-STAT Central Data Station (CDS) to update the Analyzers, follow the steps below for setting up the computer:

Step	Action
1	If updating handheld analyzers, transmit all data from the handhelds to the CDS. Data stored in a handheld analyzer will be lost after an application software update. **Attention:** If the Analyzer Customization Profile Utility is enabled in your Central Data Station, disable it prior to starting this process. The profile can be saved for restoration. For additional information on doing this, refer to the i-STAT Technical Bulletin, "Instructions for the Analyzer Customization Profile Utility" or in newer manuals, "Customization Utility" in the Central Data Station 4 section. Once Analyzers are updated, the function to restore the profile can be used to re-enable on-line customization, if desired. **However, be sure to first select the new CLEW in the profile.**
2	Connect a Modular Data Cable to the COM5 port on the back of the CDS. If your Central Data Station has one quad card (four ports for data cables), COM 5 is the innermost port closet to the fan. If your CDS has two quad cards, COM 5 is the innermost port on the bottom row of ports. If updating handheld analyzers, connect an IR Link to the opposite end of the cable.
3	Click on *Exit* to close the Central Data Station application.
4	Exit the Windows application following the instructions below for your platform: **Windows 3.1 platform:** Click on FILE and then EXIT in the Program Manager. **Windows 95/98 platform:** Click the Start button, select Shut Down..., then select Restart in DOS mode.

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Windows NT platform: Click the Start button, select Programs, then select Command Prompt.

With Windows 95/98 and NT platforms, you will be at the C:\WINDOWS prompt on exiting. Return to the root directory by typing cd\ and pressing the **Enter** key.

5 Place the JAMS diskette into the A: drive.

6 At the C:\> prompt, type **A:TRANSFER** and press the ENTER key. Wait for the DOS prompt C:\BINS> to appear. Ignore any "File Not Found" or "Directory Already Exists" messages that may appear.

7 At the C:\BINS> prompt, type **JAMMIT** and press the ENTER key. The i-STAT Configuration Utility will appear.

8 Proceed with the section of this document titled "Downloading to an Analyzer".

If you are using any other IBM PC compatible/ Point-of-Care Central Workstation

If using any other IBM PC compatible to update the analyzers, follow the steps below for setting up the computer:

Step	Action

1 If updating handheld analyzers, transmit all data from the handhelds to the CDS. Data stored in a handheld analyzer will be lost after an application software update.

2 Connect a Modular Data Cable to one of the 9-pin connector COM ports on the PC using the power adapter according to instructions supplied with it or the picture below. If updating handheld analyzers, connect an IR Link to the opposite end of the cable.

3 Exit all applications. You must be at the MS DOS prompt. (See Step 4 under *"If Using an i-STAT Central Data Station."*)

4 Place the JAMS diskette into the A: drive.

5 At the C:\> prompt, type **A:TRANSFER** and press the ENTER key. Wait for the DOS prompt C:\BINS> to appear. Ignore any "File Not Found" or "Directory Already Exists" messages that may appear.

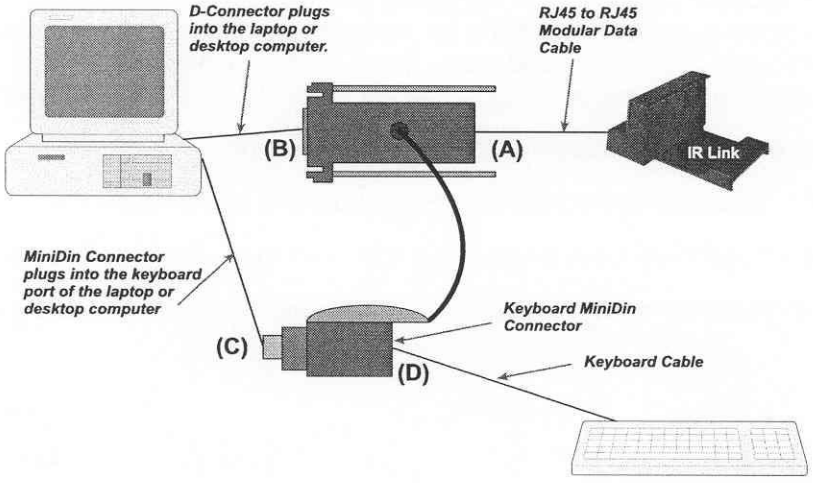
6 At the C:\BINS> prompt, type **JAMMIT** and press the ENTER key. The i-STAT Configuration Utility will appear.

7 Using the UP/DOWN arrow keys, highlight **Utility Setup** and press the ENTER key.

8 Using the UP/DOWN arrow keys, highlight **COM Port**. Using the RIGHT/LEFT arrow keys, select 1 or 2, depending on where the 9-pin connector is connected.

9 Using the UP/DOWN arrow keys, highlight **Return to Main Menu** and press the ENTER key.

10 Proceed with the section of this document titled "Downloading to an Analyzer".



DOWNLOADING SOFTWARE TO AN ANALYZER

Downloading to a handheld analyzer

Follow the steps below to download software to a handheld analyzer:

Step	Action
1	Highlight **Software** and press the ENTER key. The window **Select Files to Download** appears. The menu items **Application** and **CLEW** will automatically be set to the newest version.
2	Confirm the setting for **Application** and **CLEW** against the Product Update accompanying the diskette. If, under specific instruction from i-STAT, different versions are to be downloaded, highlight the menu item you are to change using the UP/DOWN arrow keys and use the LEFT/RIGHT arrow keys to set the proper version. **Note:** If the software upgrade is only a **CLEW**, select "None" for application.
3	Highlight **Download Selection** and press the ENTER key.
4	Follow the instructions on the computer screen. **Do not move the analyzer while download is in progress. Do not press the DIS key. When download is complete, run the Electronic Simulator in the Analyzer.** **Note:** On the handheld status page, the Application name is displayed on the line labeled **Ver:** and the CLEW is displayed on the line labeled **CLEW**.
5	After the update of all handheld analyzers is complete, the function to restore the Customization Profile can be used to re-enable on-line customization if desired. **Be sure to select the new CLEW in the profile first. Failure to do this will result in Quality Check Code 13.**

Downloading to a Blood Analysis Module

Follow the steps below to download software to a Blood Analysis Module:

Step	Action
1	Highlight **Utility Setup** and press ENTER key. The window Utility Setup appears.
2	Using the UP/DOWN arrow keys, highlight **Analyzer**. Using the RIGHT/LEFT arrow keys, select **HP Blood Analysis Module.**
3	Highlight **Return to Main Menu** and press the ENTER key.
4	Highlight **Software** and press the ENTER key. The window **Select Files to Download** appears. The menu items **Application** and **CLEW** will automatically be set to the newest version.
5	Confirm the setting for **Application** and **CLEW** against the Product Update accompanying the diskette. If, under specific instruction from i-STAT, different versions are to be downloaded, highlight the menu item you are to change using the UP/DOWN arrow keys and use the LEFT/RIGHT arrow keys to set the proper version. **Note:** If the software upgrade is only a **CLEW**, select "None" for application.
6	Highlight **Download Selection** and press the ENTER key.
7	Follow the instructions on the computer screen. **Do not unplug the module while the download is in progress.** **Note:** When the module is returned to a monitor, the CLEW can be viewed in the Blood Analysis Setup screen.

8 After the update of all modules is complete, the function to restore the Customization Profile can be used to re-enable on-line customization if desired. Be sure to select the new CLEW in the profile first.

Sending Software from handheld to handheld

To send software from one handheld analyzer to another, follow the instructions below:

Step	Action
1	Any updated analyzer can be used as the **Sending Analyzer**. Run the external Electronic Simulator on the Sending Analyzer.
2	Transmit all data from the analyzer being updated (the **Receiving Analyzer**) to the Central Data Station. Data stored in the handheld analyzer will be lost after an application software update.
3	With the Simulator test results showing on the display of the Sending Analyzer, press and hold the DIS key and press the soft key for MENU. This displays the Utility Menu.
4	In the Utility Menu, select 3 - **Send Software**. The display will show the JAMS version and the CLEW in this analyzer. Verify that these are the appropriate versions. The analyzer screen will also say "Waiting to send".
5	Set both analyzers on a flat surface and align the Infrared Light-Emitting Diode (IR LED) windows so they directly face each other. (Refer to the analyzer picture on page 2-2 of the i-STAT System Manual for the location of the IR LED.)
6	On the Receiving Analyzer, make sure the display is off. Press and hold the * key and press the **DIS** key. The Sending analyzer will begin sending software to the Receiving Analyzer. The display on the Sending Analyzer will change from "Waiting to send" to "Sending...", and a countdown bar will be displayed. **Do not move the analyzers while the software is being sent.**
7	When the display of the Sending Analyzer changes back to the Electronic Simulator result, the sending of software is complete. **Do not press the DIS key. Run the Electronic Simulator on the Receiving Analyzer.**
8	To update software in another analyzer, repeat these instructions from Step 2.

TROUBLESHOOTING

Error message relating to the IR Link

If you are using any other IBM PC compatible computer, another application relating to the may be monopolizing the COM port. Close all other open applications. Ensure the utility is set to use the proper COM port in the Utility Setup option from the main menu. If the setting is proper, quit the Utility, turn off the computer, unplug and replug the IR Link, restart the computer, and try the download again.

UPDATE .cfg not found

Ensure you run A:TRANSFER from an i-STAT software diskette. Ensure you run **JAMMIT** from C:\BINS>

Block count stops incrementing

If the block count on the status line of the computer screen stops incrementing for more than 10 seconds during a download, press the **Esc** key to abort the download. If updating an handheld analyzer, take it out of the IR Link, remove and replace the batteries to reset. If updating a Blood Analysis Module, unplug the cable and plug it in again.

This can happen if you try to run **JAMMIT** under Microsoft Windows (Windows 3.1 or 95/98 platform). You must exit Windows and run the program in the DOS mode. Try the download again.

Nothing happens OR Handheld displays results or error message when *DIS is pressed as prompted

Remove and replace the batteries to reset the handheld. Ensure the handheld display is off. Place the handheld back in the cradle, ensure it is properly seated. Press and hold the * key for 2 seconds, then press the **DIS** key while keeping the * key pressed.

LEDs on the module are OFF

Possibly the cable or the COM port is defective. Try another cable and/or configure another port to "HP Blood Analysis Module" and try again.

Quality Check Code 13 - Invalid Expired CLEW after on-line customization is restored

If this quality check code occurs after successfully downloading new software and restoring on-line customization, the CLEW has not been updated to the new version in the Customization Profile. Refer to i-STAT Technical Bulletin "Instructions for the Analyzer Customization Profile Utility.

i-STAT

Important!

i-STAT® System Manual Update

As of October 2006, the current i-STAT® System Manual has been updated. Please **ADD** and **DELETE** the sheets as listed below. Once the updates have been completed these instructions may be discarded. If you have any questions about these instructions, please contact your i-STAT support provider.

A ▶ ADD SHEET ◀ D DESTROY SHEET

	Item	Art#
A▶	Ionized Calcium Information Sheet	714179-00G
◀D	Ionized Calcium Information Sheet	714179-00F
A▶	i-STAT System Manual: Introduction to the Cartridge and Test Information Section	714258-00K
◀D	i-STAT System Manual: Introduction to the Cartridge and Test Information Section	714258-00J
A▶	i-STAT System Manual Section 12: Quality Control	715014-00E
◀D	i-STAT System Manual Section 12: Quality Control	715014-00D
A▶	i-STAT System Manual Section 13: Calibration Verification	715015-00F
◀D	i-STAT System Manual Section 13: Calibration Verification	715015-00E
A▶	i-STAT System Manual Section 18: Central Data Station 5	715021-00C
◀D	i-STAT System Manual Section 18: Central Data Station 5	715021-00B
◀D	Technical Bulletin: October 2004 Update to the i-STAT CDS Version 5	716134-00A
◀D	Technical Bulletin: April 2005 Update to the i-STAT CDS Version 5	716244-00A
◀D	Technical Bulletin: October 2005 Update to the i-STAT CDS Version 5	716657-00A

END

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IONIZED CALCIUM/ICA

Ionized calcium is measured by ion-selective electrode potentiometry. In the calculation of results for ionized calcium concentration is related to potential through the Nernst equation. Results are measured at 37°C.

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for ionized calcium, as part of the i-STAT System, is intended for use in the *in vitro* quantification of ionized calcium in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of ionized calcium, a list of reactive ingredients is indicated below:

Reactive Ingredient
Calcium (Ca^{2+})

Metrological Traceability

The i-STAT System test for ionized calcium measures ionized calcium (*i.e.* free calcium ion) amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. Ionized calcium values assigned to i-STAT's controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM956. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point Care Inc..

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range[2]
Ionized Calcium/iCa	mmol/L	0.25 – 2.50	1.12 – 1.32
	mg/dL	1.0 – 10.0	4.5 – 5.3

*The i-STAT System can be configured with the preferred units.

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Art: 714179-00G

To convert a result from mmol/L to mg/dL, multiply the mmol/L value by 4. To convert mmol/L to mEq/L multiply the mmol/L value by 2.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

Although most of the calcium in blood is bound to protein or complexed to smaller anionic species, the biologically active fraction of calcium is free ionized calcium. Through its role in a number of enzymatic reactions and in membrane transport mechanisms, ionized calcium is vitally important in blood coagulation, nerve conduction, neuromuscular transmission and in muscle contraction. Increased ionized calcium (hypercalcemia) may result in coma. Other symptoms reflect neuromuscular disturbances, such as hyperreflexia and/or neurologic abnormalities such as neurasthenia, depression or psychosis. Decreased ionized calcium (hypocalcemia) often results in cramps (tetany), reduced cardiac stroke work and depressed left ventricular function. Prolonged hypocalcemia may result in bone demineralization (osteoporosis) which can lead to spontaneous fractures. Measurements of ionized calcium have proven of value under the following clinical conditions: transfusion of citrated blood, liver transplantation, open heart surgery, neonatal hypocalcemia, renal disease, hyperparathyroidism, malignancy, hypertension and pancreatitis.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A[3]. Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System and on the comparative methods within 10 minutes of each other.

Deming regression analysis[4] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on CLSI guideline EP7-P.[5]

* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".3 The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mmol/L)

Aqueous Control	Mean	SD	%CV
Level 1	1.60	0.017	1.1
Level 3	0.84	0.012	1.4

Method Comparison (mmol/L)

	Radiometer ICA1	Nova STAT Profile
n	47	57
Sxx	0.009	0.017
Syy	0.017	0.017
Slope	0.925	0.960
Int't	0.113	0.062
Sy.x	0.035	0.029
Xmin	0.46	0.53
Xmax	2.05	2.05
r	0.982	0.982

Factors Affecting Results*

Venous stasis (prolonged tourniquet application) and forearm exercise may increase ionized calcium due to a decrease in pH caused by localized production of lactic acid[6]. Exposing the sample to air will cause an increase in pH due to the loss of CO_2 which will decrease ionized calcium.

Heparin binds calcium. Each unit of heparin added per mL of blood will decrease ionized calcium by 0.01 mmol/L.[6] Therefore, the correct ratio of heparin anticoagulant to blood must be achieved during sample collection. Intravenous injection of 10,000 units of heparin has been shown in adults to cause a significant decrease of ionized calcium of about 0.03 mmol/L.[6] Use only unheparinized sample transfer devices when using i-STAT's aqueous control and calibration verification materials.

Hemodilution of the plasma by more than 20% associated with priming cardiopulmonary bypass pumps, plasma volume expansion or other fluid administration therapies using certain solutions may cause clinically significant error on sodium, chloride, ionized calcium and pH results. These errors are associated with solutions that do not match the ionic characteristics of plasma. To avoid these errors when hemodiluting by more than 20%, use physiologically balanced multi-electrolyte solutions containing low-mobility anions (e.g. gluconate) such as Normosol®-R (Abbott Laboratories), Plasma-Lyte®-A (Baxter Healthcare Corporation), and Isolyte®-S (B Braun Medical) rather than solutions such as normal saline or Ringer's Lactate.

Interferent	Effect
β-hydroxybutyrate	20 mmol/L β-hydroxybutyrate will decrease ionized calcium results by 0.1 mmol/L.
Lactate	20 mmol/L lactate will decrease ionized calcium results by 0.05 mmol/L.
Magnesium	1.0 mmol/L magnesium above normal will increase ionized calcium results by 0.04 mmol/L.
Salicylate	4.34 mmol/L salicylate will decrease ionized calcium results by 0.1 mmol/L.

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

References

1. D.S. Young, Effects of Drugs on Clinical Laboratory Tests, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

2. P.C. Painter, J.Y. Cope, J.L. Smith, "Reference Ranges, Table 41–20" in Tietz Textbook of Clinical Chemistry—Second Edition, C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

3. CLSI. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline.* CLSI document EP9-A [ISBN 1-56238-283-7]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1995.

4. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," Clinical Chemistry 25:3, 432 (1979).

5. CLSI. *Interference Testing in Clinical Chemistry; Proposed Guideline.* CLSI document EP7-P [ISBN 1-56238-020-6]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1986.

6. D. Fraser, G. Jones, S.W. Kooh, and I. Raddle, "Calcium and Phosphate Metabolism" in Tietz Textbook of Clinical Chemistry—Second Edition, C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

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CARTRIDGE AND TEST INFORMATION

i-STAT sensors are available in a variety of panel configurations. Sensors are contained in cartridges with microfluidic components and, in some cartridges, calibration solution. i-STAT cartridges are used with the i-STAT Portable Clinical Analyzer, the i-STAT 1 Analyzer* and the Philips Medical Systems Blood Analysis Module** for the simultaneous quantitative determination of specific analytes and coagulation parameters in whole blood.

CARTRIDGE SPECIFICATIONS

Shelf Life:

Refrigerated at 2 to 8°C (35 to 46°F) until expiration date.

Room temperature at 18 to 30°C (64 to 86°F) for two weeks.

Preparation for Use:

Individual cartridges may be used after standing five minutes at room temperature. An entire box of cartridges should stand at room temperature for one hour.

All cartridges should be used immediately after opening pouch. If the pouch has been punctured, the cartridge should not be used.

Sample Type:

Fresh whole blood from arterial, venous, or skin punctures

(Note: Skin puncture is NOT a recommended sample type for ACT, cTnI, CK-MB, or BNP testing.)

cTnI and CK-MB cartridges require the use of heparinized whole blood or plasma, or non-heparinized whole blood tested within one minute of patient draw.

BNP cartridges require the use of EDTA whole blood or plasma samples.

Sample Volume:

17µL, 20µL, 40µL, 65µL, or 95µL depending on cartridge type.

Test Timing:

Immediately after collection

- Samples for the measurement of ACT, PT/INR and Lactate

Within 3 minutes after collection

- Samples collected in capillary tubes, both with and without anticoagulant
- Samples collected in evacuated or non-evacuated tubes and syringes without anticoagulant

Within 10 minutes after collection

- Samples collected with anticoagulant for the measurement of pH, $\boldsymbol{P}CO_2$, $\boldsymbol{P}O_2$ and iCa. Maintain anaerobic conditions. Remix before filling cartridge.

Within 30 minutes after collection

- Sodium, potassium, chloride, glucose, BUN/urea, creatinine, hematocrit, troponin I, CK-MB, and BNP. Remix thoroughly before testing.

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* The cTnI, CK-MB, and BNP cartridges can only be used with the i-STAT 1 analyzer bearing the  symbol. The CHEM8+ cartridge can only be used with the i-STAT 1 analyzer.

** Blood Analysis Module supports neither the PT/INR, the CHEM8+, the cTnI, the CK-MB nor the BNP cartridge.

Analysis Time:

- ACT cartridge: to detection of end point - up to 1000 seconds (16.7 min.)
- PT/INR cartridge: to detection of end point – up to 300 seconds (5 min.)
- cTnI and BNP cartridges: 600 seconds (10 min.)
- CK-MB cartridge: 300 seconds (5 min.)
- Other cartridges: typically 130 to 200 seconds

Cartridges	Collection Options			
	Syringes	**Evacuated Tubes**	**Capillary Tubes**	**Directly from Skin Puncture**
Cartridges which measure ionized calcium	• Without anticoagulant • With balanced heparin anticoagulant (syringe must be filled to labeled capacity)	• Without anticoagulant • With sodium or lithium heparin anticoagulant (tubes must be filled to capacity)	• Without anticoagulant • With balanced heparin anticoagulant	• Not recommended
Cartridges which perform ACT	• Without anticoagulant ONLY • Syringes must be plastic	• Without anticoagulant, clot activators, or serum separators ONLY • Tubes must be plastic • Devices used to transfer sample to cartridge must be plastic	• Not recommended	• Not recommended
Cartridges which perform PT/ INR	• Without anticoagulant ONLY • Syringes must be plastic	• Without anticoagulant, clot activators, or serum separators ONLY • Tubes must be plastic • Devices used to transfer sample to cartridge must be plastic	• Not recommended	• Recommended
Cartridges which perform Troponin I or CK-MB	• With Sodium or lithium heparin anticoagulant. • Without anticoagulant if tested within one minute of patient draw.	• With Sodium or lithium heparin anticoagulant. • Without anticoagulant if tested within one minute of patient draw. • Samples should not be used unless the blood collection tube is filled at least half full.	• Not recommended	• Not recommended

Cartridges	Collection Options			
	Syringes	Evacuated Tubes	Capillary Tubes	Directly from Skin Puncture
Cartridges which perform BNP	• With EDTA anticoagulant. • Syringes must be plastic.	• With EDTA anticoagulant. • Tubes must be plastic. • Samples should not be used unless the blood collection tube is filled at least half full.	• Not recommended	• Not recommended
All other cartridges	• Without anticoagulant • With lithium, sodium, or balanced heparin anticoagulant	• Without anticoagulant • With lithium or sodium heparin anticoagulant	• Without anticoagulant • With balanced heparin anticoagulant • With sodium or lithium heparin if labeled for the measurement of electrolytes	• While a sample can be transferred directly from a skin puncture to a cartridge, a capillary tube is preferred.

Note Regarding System Reliability

The i-STAT System automatically runs a comprehensive set of quality checks of analyzer and cartridge performance each time a sample is tested. This internal quality system will suppress results if the analyzer or cartridge does not meet certain internal specifications (see Quality Control section in System Manual for detailed information). To minimize the probability of delivering a result with medically significant error the internal specifications are very stringent. It is typical for the system to suppress a very small percentage of results in normal operation given the stringency of these specifications. If however the analyzer or cartridges have been compromised, results may be persistently suppressed, and one or the other must be replaced to restore normal operating conditions. **Where unavailability of results while awaiting replacement of analyzers or cartridges is unacceptable, i-STAT recommends maintaining both a backup i-STAT System analyzer and cartridges from an alternate lot number.**

EXPECTED VALUES

Measured:

TEST	UNITS	REPORTABLE RANGE	REFERENCE RANGE	
			(arterial)	*(venous)*
Sodium/Na	mmol/L (mEq/L)	100 – 180	138 – 146	138 – 146
Potassium/K	mmol/L (mEq/L)	2.0 – 9.0	3.5 – 4.9	3.5 – 4.9
Chloride/Cl	mmol/L (mEq/L)	65 – 140	98 – 109	98 – 109
Glucose/Glu	mmol/L mg/dL g/L	1.1 – 38.9 20 – 700 0.20 – 7.00	3.9 – 5.8 70 – 105 0.70 – 1.05	3.9 – 5.8 70 – 105 0.70 – 1.05
Lactate/Lac	mmol/L mg/dL	0.30 – 20.00 2.7 – 180.2	0.36 – 1.25 3.2 – 11.3	0.90 – 1.70 8.1 – 15.3
Creatinine/Crea	mg/dL µmol/L	0.2 – 20.0 18 – 1768	0.6 – 1.3 53 – 115	0.6 – 1.3 53 – 115

Measured: (cont.)

TEST	UNITS	REPORTABLE RANGE	REFERENCE RANGE	
			(arterial)	*(venous)*
pH		6.5 – 8.2	7.35 – 7.45	7.31 – 7.41
***P*CO_2**	mmHg kPa	5 – 130 0.67 – 17.33	35 – 45 4.67 – 6.00	41 – 51 5.47 – 6.80
TCO_2 (on the CHEM8+ cartridge only)	mmol/L (mEq/L)	5-50	23 – 27	24 – 29
***P*O_2**	mmHg kPa	5 – 800 0.7 – 106.6	80 – 105 10.7 – 14.0	
Ionized Calcium/iCa	mmol/L mg/dL	0.25 – 2.50 1.0 – 10.0	1.12 – 1.32 4.5 – 5.3	1.12 – 1.32 4.5 – 5.3
Urea Nitrogen/BUN **Urea**	mg/dL mmol/L mg/dL	3 – 140 1 – 50 6 – 300	8 – 26 2.9 – 9.4 17 – 56	8 – 26 2.9 – 9.4 17 – 56
Hematocrit/Hct	%PCV Fraction	10 – 75 0.10 – 0.75	38 – 51 0.38 – 0.51	38 – 51 0.38 – 0.51
Celite Activated Clotting Time / ^{Celite}ACT	seconds	50 – 1000	74 – 125 (Prewrm) 84 – 139 (Nonwrm)	74 – 125 (Prewrm) 84 – 139 (Nonwrm)
The range from 80 - 1000 seconds has been verified through method comparison studies.				
Kaolin Activated Clotting Time / ^{Kaolin}ACT	seconds	50 – 1000	74 – 137 (Prewrm) 82 – 152 (Nonwrm)	74 – 137 (Prewrm) 82 – 152 (Nonwrm)
The range from 77 - 1000 seconds has been verified through method comparison studies.				
Prothrombin Time / PT	INR	0.9 – 8.0		
Performance characteristics have not been established for INRs above 6.0.				
Troponin I / cTnI	ng/mL (µg/L)	0.00 – 50.00		0.00 – 0.03* 0.00 – 0.08**
Performance characteristics have not been established for cTnI values above 35.00 ng/mL. ** Represents the 0 to 97.5% range of results.* *** Represents the 0 to 99% range of results.*				
Creatine Kinase MB / CK-MB	ng/mL (µg/L)	0.0 – 150.0		0.0 – 3.5***
****Represents the 0 to 95% range of results.*				
B-Type Natriuretic Peptide / BNP	pg/mL (ng/L)	15 – 5000		<15 – 50#
# Represents the 0 to 95% range of results.				

Calculated:

TEST	UNITS	REPORTABLE RANGE	REFERENCE RANGE	
			(arterial)	*(venous)*
Hemoglobin/Hb	g/dL	3.4 – 25.5	12 – 17	12 – 17
	g/L	34 – 255	120 – 170	120 – 170
	mmol/L	2.1 – 15.8	7 – 11	7 – 11
TCO_2 (on all cartridges but the CHEM8+)	mmol/L (mEq/L)	5-50	23 – 27	24 – 29
HCO_3	mmol/L (mEq/L)	1.0 – 85.0	22 – 26	23 – 28
BE	mmol/L (mEq/L)	(-30) – (+30)	(-2) – (+3)	(-2) – (+3)
Anion Gap/AnGap	mmol/L (mEq/L)	(-10) – (+99)	10 – 20	10 – 20
sO_2	%	0 – 100	95 – 98	

CARTRIDGE CONFIGURATIONS AND SAMPLE VOLUME

i-STAT $^{EC}8^{+}$ (65µL)
Sodium (Na)
Potassium (K)
Chloride (Cl)
pH
PCO_2
Urea Nitrogen (BUN)/Urea
Glucose (Glu)
Hematocrit (Hct)
TCO_2*
HCO_3*
BE*
Anion Gap* (Angap)
Hemoglobin* (Hb)

i-STAT 6^{+} (65µL)
Sodium (Na)
Potassium (K)
Chloride (Cl)
Urea Nitrogen (BUN)/Urea
Glucose (Glu)
Hematocrit (Hct)
Hemoglobin* (Hb)

i-STAT $^{EC}4^{+}$ (65µL)
Sodium (Na)
Potassium (K)
Glucose (Glu)
Hematocrit (Hct)
Hemoglobin* (Hb)

i-STAT $^{E}3^{+}$ (65µL)
Sodium (Na)
Potassium (K)
Hematocrit (Hct)
Hemoglobin* (Hb)

i-STAT G (65µL)
Glucose (Glu)

i-STAT CREA (65µL)
Creatinine (Crea)

i-STAT $^{EG}7^{+}$ (95µL)
Sodium (Na)
Potassium (K)
Ionized Calcium (iCa)
Hematocrit (Hct)
pH
PCO_2
PO_2
TCO_2*
HCO_3*
BE*
sO_2*
Hemoglobin* (Hb)

i-STAT $^{EG}6^{+}$ (95µL)
Sodium (Na)
Potassium (K)
Hematocrit (Hct)
pH
PCO_2
PO_2
TCO_2*
HCO_3*
BE*
sO_2*
Hemoglobin* (Hb)

i-STAT $^{G}3^{+}$ (95µL)
pH
PCO_2
PO_2
TCO_2*
HCO_3*
BE*
sO_2*

i-STAT $^{CG}4^{+}$ (95µL)
pH
PCO_2
PO_2
Lactate
TCO_2*
HCO_3*
BE*
sO_2*

*Calculated

i-STAT $^{CG}8^{+}$ (95µL)
Sodium (Na)
Potassium (K)
Ionized Calcium (iCa)
Glucose (Glu)
Hematocrit (Hct)
pH
PCO_2
PO_2
TCO_2*
HCO_3*
BE*
sO_2*
Hemoglobin* (Hb)

i-STAT ^{Celite}ACT (40µL)
Celite® ACT

i-STAT ^{KAOLIN}ACT (40µL)
Kaolin ACT

i-STAT PT/INR (20µL)
Prothrombin Time

i-STAT cTnI (17 µL)
Troponin I

i-STAT CK-MB (17µL)
Creatine Kinase MB

i-STAT BNP (17µL)
B-type Natriuretic Peptide

i-STAT CHEM8+ (95µL)
Sodium (Na)
Potassium (K)
Chloride (Cl)
Urea Nitrogen (BUN)/Urea
Glucose (Glu)
Creatinine (Crea)
Ionized Calcium (iCa)
TCO_2
Hematocrit (Hct)
Anion Gap* (Angap)
Hemoglobin* (Hb)

Celite is a registered trademark of Celite Corporation, Santa Barbara, CA, for its diatomaceous earth products.

QUALITY CONTROL 12

Overview

This section describes the steps to be taken to verify the performance of the analyzer and cartridges. The rationale for the i-STAT catridge and analyzer quality regimen is described in the Theory section of this manual.

Customization

The quality control behavior of the analyzer can be customized via the Central Data Station to:

- turn the external Electronic Simulator reminder on or off.
- prompt the operator to use the external Electronic Simulator at scheduled intervals.
- turn the internal Electronic Simulator on or off , and select the simulator test cycle intervals.
- disable further cartridge testing when the internal Electronic Simulator test fails.

See the Customization section for default values.

Data Retention

Quality control data is transmitted to the Central Data Station. If a Central Data Station is not being used, the charts at the end if this section can be used to record liquid and electronic control results.

QUALITY CONTROL FOR i-STAT CARTRIDGES AND THE ANALYZER'S CARTRIDGE TEST CYCLE

Verify Newly Received Cartridges

1. Verify that the transit temperatures were satisfactory using the four-window temperature indicator strip included in the shipping container.
2. From each lot in each shipment of cartridges, analyze multiple levels of i-STAT controls (and Meter Trax™ or RNA® Medical controls if testing for hematocrit) using any verified analyzer.

Verify Performance of Analyzers Daily

Verify the performance of each analyzer on site using the Electronic Simulator (external or internal) once a day on the days the analyzers are in use. Note that regulatory or accreditation requirements may dictate more frequent intervals.

Check Refrigerator Storage Daily

Verify that the cartridges stored in the refrigerator are within the expiration date printed on the boxes.

Verify that the storage refrigerator did not exceed the temperature limits of 2 to 8 °C (35 to 46 °F). If storage conditions are in doubt, use controls to verify that the cartridges are performing properly. This is especially important if freezing conditions are suspected at the back of the refrigerator.

Check Room Temperature Storage Daily

Verify that the cartridges stored at room temperature are within the expiration date and that the cartridges have been out of the refrigerator less than two weeks. If the temperature at which the cartridges are stored is in doubt, use controls to verify that the cartridges are performing properly.

Check Thermal Control System Twice a Year

i-STAT analyzers contain a thermal control subsystem consisting of two thermal probes with thermistors and heating contact wires. When measurements are performed at a controlled temperature, the thermal probes in the analyzer contact the metalized area under the chips in the cartridge and maintain the temperature of the sensors and the fluids that come into contact with these sensors at the required temperature ± 0.15°C.

A quality check is performed on the thermal probes each time the external Electronic Simulator is used. To complete this check, the surface temperature of the external Electronic Simulator must not fluctuate. If this condition is not met, the thermal probe check is not completed. Therefore, i-STAT recommends that the thermal probe check be verified twice a year.

Check the Analyzer Ambient Temperature Reading Once a Year

The analyzer uses ambient temperature measurements to ensure that the temperature is within the operating range and in the extrapolation of ambient temperature measurement results for ionized calcium, pH and PCO_2 to 37 °C results.

CONTROLS FOR BLOOD GAS/ELECTROLYTE/METABOLITE CARTRIDGES

Control Solutions

Aqueous assayed control fluids are available for verifying the integrity of newly received cartridges. i-STAT Level 1, 2 and 3 Control are formulated at three clinically relevant levels with known pH and with known concentrations of:

Sodium	PCO_2	Glucose
Potassium	PO_2	Lactate
Chloride		BUN/Urea
Ionized Calcium		Creatinine

Each level of control is packaged in a box of 10 ampules with a sheet with target values and acceptable ranges. Control solutions are contained in 1.7 mL glass ampules.

The control solutions do not contain human serum or serum products, but do contain buffers and preservatives.

Reactive Ingredients

Analyte	Calibration Verification Level 1	Calibration Verification Level 2 and Control Level 1	Calibration Verification Level 3 and Control Level 2	Calibration Verification Level 4 and Control Level 3	Calibration Verification Level 5
Na (mmol/L)	108	127	141	169	187
K (mmol/L)	2.3	3.1	4.0	6.8	8.5
Cl (mmol/L)	71	85	100	122	133
Glu (mmol/L)	1.8	2.5	7.3	17	35
Urea (mmol/L)	44.6	18	4	2.7	1.8
iCa (mmol/L)	2.5	1.6	1.3	0.8	0.2
Lac (mmol/L)	19.5	8.4	2.3	1	0.6
Crea (µmol/L)	1486	386	155	46	17
PO_2 (mmHg)	43	61	100	140	400
PCO_2 (mmHg)	95	66	30	22	18
H^+ (pH)	6.81	7.15	7.41	7.60	7.95

Storage

Refrigerated storage at 2 to 8 °C (35 to 46 °F) should be maintained until the printed expiration date on the box and ampule labels.

Control solutions may also be stored at room temperature for up to 5 days (18 to 30 °C or 64 to 86 °F). Prolonged storage at temperatures greater than 30 °C (86 °F) may cause changes in the values of some analytes. Do not use beyond the expiration date on the box and ampule labels.

Best Results

For best results, ampules, cartridges and analyzer should be at the same temperature.

Ampule Use

When using cartridges that contain sensors for pH, PCO_2, PO_2 and ionized calcium, a separate ampule must be used for each cartridge being tested.

Do not use the solution left in a syringe, ampule or capillary tube for additional testing of cartridges that contain sensors for ionized calcium, pH, PCO_2, or PO_2. However, cartridges without these sensors may be tested with remaining fluids if within 10 minutes of opening the ampule.

Before Use

i-STAT control solutions require different temperature stabilization times depending on whether or not oxygen is to be measured. If oxygen is to be measured, equilibrate the ampule for 4 hours. If not, equilibrate the ampule for approximately 30 minutes at room (ambient) temperature.

Procedure

STEP	ACTION
1	Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule.
2	Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.
3	Immediately transfer the solution from the ampule into a capillary tube or syringe, and then immediately transfer the solution into a cartridge.
4	Immediately seal the cartridge and insert it into an analyzer – it is important not to expose the solution to room air since this will alter the results. Note: Since aqueous based solutions such as controls lack the buffering capabilities of whole blood, the transfer process from ampule to cartridge must be more expedient than with a patient sample.

Transfer with Capillary Tube

Plain capillary tubes are recommended to transfer an aqueous control from the ampule to the cartridge. When using a capillary tube (fresh capillary tubes with sufficient fill capacity are recommended), fill from the bottom of the ampule to avoid drawing air into the capillary tube. Avoid drawing solution from the surface by placing a finger over the far end of the tube as it is inserted into the ampule. Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.

Transfer with Syringe

Plain syringes are recommended to transfer an aqueous control from the ampule to the cartridge. When using a syringe (fresh 1cc or 3cc sterile syringe with 16 - 20 gauge needles are recommended), slowly draw approximately 1mL of solution from the bottom of the ampule.

If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the tip of the syringe.

If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe.

Expel one or two drops from the syringe before filling the cartridge.

Target Values

Target values (determined by testing multiple ampules of each level using multiple lots of cartridges and i-STAT analyzers that have passed the Electronic Simulator test) are printed on a value assignment sheet included with each box of control ampules.

Always be sure that the lot number printed on the insert matches the lot number on the label of the ampule in use, and that the software revision above the target value table matches the software revision in the analyzer.

Ranges

The ranges displayed represent the maximum deviation expected when controls and cartridges are performing properly.

Should results outside the ranges be obtained, refer to the Troubleshooting section that follows the Procedure for Testing Controls.

Target Values are specific to the i-STAT System. Results obtained from these aqueous controls with other methods may differ due to sample matrix effects.

Correction of PO_2 at Extreme Altitude

The partial pressure of oxygen in a solution will change as it equilibrates to the surrounding ambient pressure. The rate of change is faster in aqueous solutions than in whole blood due to the absence of red blood cells containing hemoglobin which binds oxygen molecules. This is of practical significance when testing aqueous solutions on blood gas analyzers as there will be a detectable shift in the partial pressure of oxygen in the sample as it equilibrates to the pressure in the flowpath of the analyzer.

The ranges for i-STAT aqueous control solutions are established for the degree of oxygen equilibration which occurs in the cartridges at or near sea level. PO_2 results for aqueous solutions, including i-STAT controls and Calibration Verification Set and proficiency (external quality control) samples, can be corrected for higher altitude environments using the following equations. Observed PO_2 values should be corrected before comparing them to the values in the value assignment sheet included with each box of i-STAT controls.

Equations:

For PO_2 values below 150 mmHg:

PO_2 corrected = PO_2 observed + (0.067 x (760 – BP))

Where BP is the barometric pressure reading from the Analyzer Status screen.

(Approximate change: For every decrease of 15 mmHg in pressure from 760 mmHg, add 1 mmHg to observed value.)

For PO_2 value above 150 mmHg:

PO_2 corrected = PO_2 observed + (0.029 x (760 – BP))

Where BP is the barometric pressure reading from the Analyzer Status screen.

(Approximate change: For every decrease of 35 mmHg in pressure from 760 mmHg, add 1 mmHg to observed value.)

RNA® MEDICAL HEMATOCRIT CONTROL

Intended Use

RNA Medical Hematocrit Control is a quality control material used for verifying the performance of hematocrit sensors in i-STAT cartridges.

Product Description

Hematocrit controls are provided in three (3) levels for monitoring cartridge performance at different points within the clinical range. The controls are packaged in sealed glass ampules, each containing 1.7 mL of solution. Ampules are packaged ten (10) per box.

Active Ingredients

This product is a buffered aqueous solution containing electrolytes and non-conductive ingredients. This control contains no red blood cells, and no human or biological material.

Storage

RNA Medical Hematocrit Control is stable until the expiration date stated on the ampule when stored at temperatures of 2-25 °C. Do not freeze or expose ampules to temperatures greater than 30 °C.

If stored refrigerated, the control material should be equilibrated to room temperature for at least four (4) hours prior to testing.

The product may turn slightly yellow in color over its shelf life if stored at room temperature. This coloration is normal and does not affect product performance.

Directions For Use

For each lot of i-STAT cartridges received, use a representational number of cartridges to analyze multiple levels of RNA Medical Hematocrit controls.

1. Gently invert the ampule to mix the solution. Tap the ampule to restore the liquid to the bottom of the ampule.
2. Open the ampule by snapping off the tip at the neck. Use gauze, tissue, gloves, or an appropriate ampule opener to protect fingers from cuts.
3. Fill and seal a cartridge and insert immediately into the analyzer.
4. Compare the i-STAT System Hematocrit result to the package insert value. If the result is within the expected range, use the cartridges as needed.
    i. If the results are outside of the expected range, consult page 12-9 of this section for troubleshooting recommendations.
    ii. Note: this product is a buffered aqueous solution containing electrolytes and non-conductive ingredients. The only value assigned to this fluid is for hematocrit. All other cartridge analyte results obtained with this control material should be ignored.
5. If available, transmit results to the Central Data Station.

METER TRAX™ CONTROLS FOR HEMATOCRIT SENSOR

Meter Trax™ Whole Blood Reference Control for Glucose, Hemoglobin and Hematocrit (Meter Trax is a trademark of Hematronix, Inc., now BIO-RAD) is recommended as a control solution for the hematocrit sensor. Meter Trax is available in three levels: Low, Mid and High in boxes of one level (6x2mL) or boxes of three levels (6x2mL or 3x2mL).

CONTROLS FOR ACT CARTRIDGES

Intended Use

The i-STAT® ACT Control Level 1 and ACT Control Level 2 are intended for use to verify the integrity of newly received i-STAT ACT cartridges. The controls produce clotting times expected for moderate and high level heparinization to indicate that the cartridges are functioning properly.

Contents

Each level of control is packaged as a box of 5 vials of lyophilized human plasma and 5 vials of 9.5 ± 1.5 mmol/L calcium chloride diluent.

Storage

i-STAT ACT controls, Levels 1 and 2, are contained in 6-mL vials. Separate 6-mL vials contain 1-3 mL of calcium chloride solution for reconstitution. Refrigerated storage at 2 to 8°C (35 to 46°F) should be maintained until the printed expiration date on the box and vial labels. Do not use beyond the expiration date on the box and vial labels.

Control solutions may also be stored at room temperature for up to 4 hours (18 to 30°C or 64 to 86°F). If left out longer than 4 hours at room temperature, they should be discarded.

Warnings and Precautions

Handle this product using the same safety precautions used when handling any potentially infectious material. The human plasma used in the preparation of this product has been tested by FDA approved test methods and found negative/non-reactive for HIV-1, HIV-2, HBsAg, and HCV. However, no known test method can offer complete assurance that products derived from human blood will not transmit infectious disease.

Dispose of this product as biohazardous waste according to all local, state, and national regulations.

Directions for Use

Prior to testing, vials containing the lyophilized plasma and $CaCl_2$ reconstituting fluid should stand at room temperature (18 - 30°C or 64 - 86°F) for a minimum of 45 minutes. For best results, vials, cartridges, and analyzers should be at the same temperature.

Reconstitute only one level of control plasma at a time. CONTROL SOLUTIONS MUST BE USED IMMEDIATELY (less than 30 seconds) AFTER COMPLETING THE RECONSTITUTION AND MIXING STEPS.

STEP	ACTION
1	After 45 minute room temperature equilibration, remove the cap and stopper from one lyophilized human plasma control vial and remove the cap from one vial of calcium chloride reconstituting fluid.
2	Pour the entire contents of the calcium chloride vial into the lyophilized human plasma control vial. Place the stopper back in the reconstituted control vial, sealing the vial appropriately so that the contents do not leak or spill out.
3	Allow the vial to sit at room temperature for 1 minute.
4	Mix the contents of the vial by swirling gently for 1 minute, then inverting slowly for 30 seconds. **Note:** To minimize foaming of the control sample, avoid vigorous or rapid mixing motion. Visually inspect the control vial to ensure that the sample is fully reconstituted. If not, discard the reconstituted fluid and start over with fresh vials.
5	Using a plastic transfer pipette, plastic syringe, or plastic capillary tube with no anticoagulant, immediately transfer the solution from the vial into the ACT cartridge
6	Immediately seal the cartridge and insert it into an analyzer. **Note:** Additional ACT cartridges may be tested with the remaining fluid if used within 30 seconds of complete reconstitution of the sample.

Control Target Values and Expected Ranges

Target values (determined by testing multiple vials of each level using multiple lots of i-STAT cartridges with analyzers that have passed the Electronic Simulator test) are printed on a value assignment sheet included in each box of control vials. The ranges displayed represent the maximum deviation expected when controls and cartridges are performing properly. Should results outside the range be obtained, refer to the Troubleshooting portion of this section of the i-STAT System Manual (page 12-9). Always be sure that the lot number printed on the value assignment sheet matches the lot number on the label of the vial in use, and that the software revision above the table matches the software revision in the analyzer (check the status page on the analyzer).

Note: Target values are specific to the i-STAT System; results obtained from these reconstituted control plasmas may differ if used with other methods.

CONTROLS FOR PT/INR CARTRIDGES

Intended Use

The i-STAT® PT Control Level 1 (normal) and PT Control Level 2 (abnormal) are used to verify the integrity of newly received PT/INR cartridges.

Contents

Each level of control is packaged as a box of 5 vials of lyophilized human plasma and 5 vials of calcium chloride diluent. The Level 1 control vials contain 9.5 ± 1.5 mmol/L calcium chloride, while the Level 2 control vials contain 12 ± 2.0 mmol/L calcium chloride.

Storage

i-STAT PT controls, Levels 1 and 2, are contained in 6-mL vials. Separate 6-mL vials contain 1-3 mL of calcium chloride solution for reconstitution. Refrigerated storage at 2 to 8°C (35 to 46°F) should be maintained until the printed expiration date on the box and vial labels. Do not use beyond the expiration date on the box and vial labels.

Control solutions may also be stored at room temperature for up to 4 hours (18 to 30°C or 64 to 86°F). If left out longer than 4 hours at room temperature, they should be discarded.

Warnings and Precautions

Handle this product using the same safety precautions used when handling any potentially infectious material. The human plasma used in the preparation of this product has been tested by FDA approved test methods and found negative/non-reactive for HIV-1, HIV-2, HBsAg, and HCV. However, no known test method can offer complete assurance that products derived from human blood will not transmit infectious disease.

Dispose of this product as biohazardous waste according to all local, state, and national regulations.

Directions for Use

Prior to testing, vials containing the lyophilized plasma and $CaCl_2$ reconstituting fluid should stand at room temperature 18-30°C (64-86°F) for a minimum of 45 minutes. For best results, vials, cartridges, and analyzers should be at the same temperature.

Reconstitute only one level of control plasma at a time. CONTROL SOLUTIONS MUST BE USED IMMEDIATELY (less than 30 seconds) AFTER COMPLETING THE RECONSTITUTION AND MIXING STEPS.

STEP	ACTION
1	After 45 minute room temperature equilibration, remove the cap and stopper from one lyophilized human plasma control vial and remove the cap from one vial of calcium chloride reconstituting fluid.
2	Pour the entire contents of the calcium chloride vial into the lyophilized human plasma control vial. Place the stopper back in the reconstituted control vial, sealing the vial appropriately so that the contents do not leak or spill out.
3	Allow the vial to sit at room temperature for 1 minute.
4	Mix the contents of the vial by swirling gently for 1 minute, then inverting slowly for 30 seconds. **Note:** To minimize foaming of the control sample, avoid vigorous or rapid mixing motion. Visually inspect the control vial to ensure that the sample is fully reconstituted. If not, discard and start over with fresh vials.
5	Using a plastic transfer pipette, plastic syringe, or plastic capillary tube with no anticoagulant, immediately transfer the solution from the vial into the PT/INR cartridge.
6	Immediately seal the cartridge and insert it into an analyzer. **Note:** Additional PT/INR cartridges may be tested with the remaining fluid if used within 30 seconds of complete reconstitution of the sample.

Control Target Values and Expected Ranges

Target values (determined by testing multiple vials of each level using multiple lots of i-STAT cartridges with analyzers that have passed the Electronic Simulator test) are printed on a value assignment sheet included in each box of control vials. The ranges displayed represent the maximum deviation expected when controls and cartridges are performing properly. Should results outside the range be obtained, refer to the Troubleshooting portion of this section of the i-STAT System Manual (page 12-9). Always be sure that the lot number printed on the value assignment sheet matches the lot number on the label of the vial in use, and that the software revision above the table matches the software revision in the analyzer (check the status page on the analyzer).

Note: Target values are specific to the i-STAT System; results obtained from these reconstituted control plasmas may differ if used with other methods.

TROUBLESHOOTING OUT-OF-RANGE RESULTS

Troubleshooting

Verify that the following conditions are met and then repeat the test:

- The correct expected values insert is being used and the correct cartridge type and lot number listing is being used.
- Expiration date printed on cartridge pouch and control ampule or vial have not been exceeded.
- Room temperature expiration date for cartridge and control have not been exceeded.
- Cartridge and control have been stored correctly.
- The control has been handled correctly: See the directions for use.
- The analyzer being used passes the Electronic Simulator test.

If the results are still out of range despite meeting the above criteria, repeat the test using a new box of control solutions and/or cartridges. If the results are still out of range, refer to Support Services information in the Troubleshooting section.

INTERNAL ELECTRONIC SIMULATOR

Procedure for the Internal Electronic Simulator

The internal Electronic Simulator test cycle is automatically activated when a cartridge is inserted after the customized interval is reached. If the analyzer passes the simulator test, the cartridge test cycle proceeds. If not, the analyzer displays "ELECTRONIC SIMULATOR FAIL." If the analyzer is customized to block testing when it fails the simulator test, the same cartridge can be reinserted immediately after the FAIL message is displayed. If the analyzer fails the simulator test again, see the Troubleshooting section that follows the Procedure. If less than three minutes has elapsed, the cartridge can be inserted into another analyzer. If the analyzer is not customized to block testing after a failed simulator test, the internal simulator test will not repeat until the programmed interval has elapsed.

EXTERNAL ELECTRONIC SIMULATOR

Procedure for External Electronic Simulator on Analyzer

Display	Step	Analyzer Response and Notes
Enter ID# Below Contacting Cartridge LCK #------- Operator #, ENT	Insert the simulator into the analyzer with the "i" facing up. Do not touch the contact pads,	If the simulator has a blue cover over the contact pads, remove it. The simulator will activate the analyzer when properly inserted
Enter ID# Below Time to Results LCK #------- Operator#, ENT	Enter an Operator ID	Do not attempt to remove the simulator until the LCK prompt disappears from the screen.
ELECTRONIC SIMULATOR PASS READY FOR USE Operator ID # Time and Date	Remove the simulator. If PASS is displayed, continue to use the analyzer.	If FAIL is displayed, see Troubleshooting section below. Record results in log or transmit results to Central Data Station. Replace the blue cap if applicable. Replace the simulator in a protective box or plastic bag.

Caution

The analyzer will continue to initialize test cycles when the external Electronic Simulator reminder is missed, when a FAIL result for an external Electronic Simulator is ignored, and when the analyzer fails the internal Electronic Simulator test and the lockout feature is not enabled.

TROUBLESHOOTING FAILED ELECTRONIC SIMULATOR TEST

Introduction

With both the internal and external Electronic Simulator, an analyzer may occasionally fail a simulator test even though it is in proper operating condition due to the extremely sensitive nature of the test.

External Simulator

Run the test again or try another simulator, as it is possible that the test will pass on a second try. The test can also fail if the external Electronic Simulator is malfunctioning such as after being dropped.

Occasionally when an analyzer is moved from a cold environment to a warm, humid environment, moisture may condense on the internal connector. An analyzer in this condition will fail the electronic test and the failure code "L" will be displayed. Allow the analyzer to sit for half an hour to allow the moisture to evaporate, then insert the Electronic Simulator again. If the analyzer passes the second electronic test, continue using it. If the analyzer fails the second time, record the letter or Quality Check Code displayed with the FAIL message and refer to Support Services information in the Troubleshooting section.

Internal Simulator

Lockout Enabled: Rerun the cartridge in the same analyzer to ensure the FAIL was not due to a one-time spike of electrical noise. If the test fails again, rerun the cartridge in another analyzer if immediately available. Note that the cartridge should not be run if there is more than a three minute delay from the time it is filled. If the cartridge fails in more than one analyzer, use another cartridge. When Lockout is enabled, the analyzer will continue to perform the internal Electronic Simulator test each time a cartridge is inserted until the test (internal or external) passes.

Lockout Not Enabled: Rerun the cartridge in another analyzer if immediately available. Note that the cartridge should not be run if there is more than a three minute delay from the time it is filled. When Lockout is not enabled, the analyzer will run the next cartridge without performing the internal Electronic Simulator test until the specified time has elapsed. Verify the analyzer using an external Electronic Simulator.

CHECKING THE THERMAL PROBES IN THE i-STAT ANALYZERS

Verification for Portable Clinical Analyzers

Verify the thermal probe check for the i-STAT Portable Clinical Analyzer and i-STAT 1 Analyzer as follows:

- External Electronic Simulator used routinely and results transmitted to a Central Data Station Version 4: On the CDS, click on **System**, then on **Simulator Results**. Look under the Delta column. Check that there is a value equal to or less than 0.1 (≤ 0.1) listed for each analyzer in use in the last 30 days. A value of "--.--" indicates that the conditions to complete the thermal probe check were not met. Use the procedure below to check any analyzer that does not have a numeric value listed.
- External Electronic Simulator used routinely and results transmitted to a Central Data Station Version 5: On the CDS, click on **Data Viewer**, then on **Simulator**. Look under the Probe Delta column. Check that there is a value equal to or less than 0.1 (≤ 0.1) listed for each analyzer in use in the last 30 days. A value of "--.--" indicates that the conditions to complete the thermal probe check were not met. Use the procedure below to check any analyzer that does not have a numeric value listed.
- External Electronic Simulator used routinely, results not transmitted to a Central Data Station: Use the procedure below to check the thermal probes on each analyzer twice a year.
- Internal Electronic Simulator used routinely: Use the procedure below to check the thermal probes on each analyzer twice a year.

Procedure for Portable Clinical Analyzers

Check the thermal probes on the i-STAT Portable Clinical Analyzer and i-STAT 1 Analyzer as follows:

1. If the analyzer and simulator have been stored separately in areas where the ambient temperature differs by more than 3°C (5°F), allow the simulator and analyzer to stand in the same place, out of drafts, for 30 minutes before inserting the simulator into the analyzer. Handle the simulator as little as possible to maintain its thermal uniformity and stability.
2. Insert the simulator into the analyzer.
3. When results are displayed, the difference between the thermal probes can be viewed on the analyzer's screen:
   - Portable Clinical Analyzer: while holding down the DIS key, press the 1 key.
   - i-STAT 1 Analyzer: press the period key.
4. Interpretation of the thermal probe check value:
   - Acceptable: a value equal to or less than 0.1 (≤ 0.1)
   - Not acceptable: a FAIL message with a "t" Quality Check Code or a value greater than 0.1. Repeat the procedure to confirm results. Contact your Technical Support representative if the repeat thermal check value is greater than 0.1.
   - Repeat the procedure: if "--.--" is displayed. Take care to handle the simulator a little as possible. It may help to partially insert the simulator into the analyzer and let it stand for 15 minutes before inserting all the way.

Verification of BAMs

Verify the thermal probe check on a Philips Medical Systems Blood Analysis Module (BAM) and Central Data Station Version 5 as follows:

- External Electronic Simulator used daily and results transmitted to a Central Data Station Version 5: On the CDS, click on **Data Viewer**, then on **Simulator**. Click on **Record** in the Main Menu, then click on **Extended Electronic Simulator Report**. Look under the Pot6P column. Check that there is a value equal to or less than 0.1 (≤ 0.1) listed for each BAM in use in the last 30 days. No recorded value indicates that the conditions to complete the thermal probe check were not met. Use the procedure below to check any BAM that does not have a numeric value listed.
- Internal Electronic Simulator used routinely: Use the procedure below to check the thermal probes on each BAM twice a year.

Procedure for BAMS Check the thermal probes on a BAM as follows:

1. Insert the simulator partially into the BAM and wait for 15 minutes before inserting the simulator all the way into the BAM. Handle the simulator as little as possible to maintain its thermal uniformity and stability.
2. When results are displayed, transmit the results to the Central Data Station.
3. View the probe check value on the CDS:
   1) Click on Data Viewer
   2) Click on Simulator
   3) Click on Record in the Main Menu task bar
   4) Click on Extended Electronic Simulator Report
   5) Look under the Pot6P column
4. Interpretation of the thermal probe check value:
   - Acceptable: a value equal to or less than 0.1 (≤ 0.1)
   - Not acceptable: a FAIL message with a "t" Quality Check Code or a value greater than 0.1. Repeat the procedure to confirm the results. Contact your Technical Support representative if the repeat thermal check value is greater than 0.1.
   - No value: repeat the procedure. Take care to handle the simulator as little as possible. It may help to increase the time in step 2 to 30 minutes.

Documentation of Results The results of the thermal probe check are stored in the Central Data Station. If the Central Data Station is not available, use the form included with this Technical Bulletin to record the results.

PROCEDURE TO CHECK ROOM TEMPERATURE MEASUREMENT

Step	Action
1	Place the analyzer with a calibrated thermometer suspended near the analyzer and away from air currents for one hour.
2	Check the temperature reading on the Analyzer status page. The temperature should be ± 1 °C of the thermometer's reading.

i-STAT System Incoming Cartridge QC Log

CatridgeType:__________ Lot No.:__________ Rec'd Date:__________ Exp. Date:__________ Quat:__________ Temp. Strip*:__________

Control Name: __________ Level: __________ Lot No.: __________ Exp. Date: __________

TEST	TEST	TEST	TEST	TEST	TEST	TEST	TEST
RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE

Control Name: __________ Level: __________ Lot No.: __________ Exp. Date: __________

TEST	TEST	TEST	TEST	TEST	TEST	TEST	TEST
RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE

Control Name: __________ Level: __________ Lot No.: __________ Exp. Date: __________

TEST	TEST	TEST	TEST	TEST	TEST	TEST	TEST
RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE

Control Name: __________ Level: __________ Lot No.: __________ Exp. Date: __________

TEST	TEST	TEST	TEST	TEST	TEST	TEST	TEST
RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE

Lot/Shipment accepted by:__________________ Date:__________________

i-STAT System QC Log: Expiration Date and Storage Conditions

				REFRIGERATED 2 TO 8° C (35 TO 46° F)			REFRIGERATED 2 TO 8° C (35 TO 46° F)				
DATE	LOCATION	CARTRIDGE TYPE	LOT #	QTY	EXP. DATE	TEMP	QTY	EXP. DATE	TEMP	ACTIONS	INSP.

i-STAT Cartrdige Quality Control Action Log

DATE	TIME	CONTROL LEVEL	CONTROL LOT	CARTRIDGE LOT	PROBLEM	CORRECTIVE ACTION	OPERATOR

i-STAT Analyzer Thermal Probe Check

Year: ________

Analyzer Serial No.: ____________________

DATE	SIMULATOR SERIAL NO.	THERMAL PROBE DELTA RESULT (LIMIT: ± 0.1° C)	COMMENTS	OPERATOR

Analyzer Serial No.: ____________________

DATE	SIMULATOR SERIAL NO.	THERMAL PROBE DELTA RESULT (LIMIT: ± 0.1° C)	COMMENTS	OPERATOR

Analyzer Serial No.: ____________________

DATE	SIMULATOR SERIAL NO.	THERMAL PROBE DELTA RESULT (LIMIT: ± 0.1° C)	COMMENTS	OPERATOR

Analyzer Serial No.: ____________________

DATE	SIMULATOR SERIAL NO.	THERMAL PROBE DELTA RESULT (LIMIT: ± 0.1° C)	COMMENTS	OPERATOR

i-STAT Electronic Simulator Log for Analyzer Serial Number:_____ Year:_____

DATE	TIME	PASS FAIL	SIMULATOR ID	OPERATOR	TIME	PASS FAIL	SIMULATOR ID	OPERATOR	TIME	PASS FAIL	SIMULATOR ID	OPERATOR

i-STAT Electronic Simulator Action Log

DATE	TIME	ANALYZER	FAILURE CODE OR LETTER	SIMULATOR ID	ACTION	OPERATOR

CALIBRATION VERIFICATION FOR ANALYTES 13

CALIBRATION VERIFICATION FOR BLOOD GAS/ELECTROLYTE/METABOLITE CARTRIDGES

Purpose

Calibration Verification is a procedure intended to verify the accuracy of results over the entire measurement range of a test. The performance of this procedure at defined intervals may be required by regulatory or accreditation bodies. While the Calibration Verification Set contains five levels, verification of the measurement range could be accomplished using the lowest, highest and mid levels.

Overview of Procedure

i-STAT recommends that each sensor type be included in the Calibration Verification procedure using a selection of the analyzers that have passed the Electronic Simulator check. See the Technical Bulletin "Calibration Verfication and the i-STAT System" for more information.

Calibration Verification Solutions for Cartridges

A five-level Calibration Verification Set is available to verify the calibration of i-STAT cartridges throughout the reportable ranges for:

Sodium	pH	Glucose
Potassium	PCO_2	Lactate
Chloride	PO_2	BUN/Urea
Ionized Calcium		Creatinine

There are four 1.7mL glass ampules of each level in the set.

Reactive Ingredients

See the table on page 12-2 of the Quality Control section for full information.

Storage

Refrigerated storage at 2 to 8 °C (35 to 46°F) should be maintained until the printed expiration date on the box and ampule labels. Calibration Verification fluids may also be stored at room temperature for up to 5 days (18 to 30 °C or 64 to 86°F). Prolonged storage at temperatures greater than 30 °C (86°F) may cause changes in the values of some analytes. Do not use beyond the expiration date on the box and ampule labels.

Ampule Use

When using cartridges that contain sensors for pH, PCO_2, PO_2 and ionized calcium, a separate ampule must be used for each cartridge being tested. If these sensors are not present, the contents of one ampule may be used to fill more than one cartridge as long as the cartridges are filled and inserted into an analyzer within 10 minutes of opening the ampule.

Best Results

For best results, ampules, cartridges and analyzers should be at the same temperature.

i-STAT CALIBRATION VERIFICATION SET

Before Use

i-STAT Calibration Verification solutions require different temperature stabilization times depending on whether or not oxygen is to be measured. If oxygen is to be measured, equilibrate the ampule to room (ambient) temperature for 4 hours. If not, equilibrate the ampule to room (ambient) temperature for 30 minutes.

Procedure

STEP	ACTION
1	Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule.
2	Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.
3	Immediately transfer the solution from the ampule into a plain capillary tube or plain syringe, and then immediately transfer the solution into a cartridge.
4	Immediately seal the cartridge and insert it into an analyzer – it is important not to expose the solution to room air since this will alter the results.

Note: Since aqueous based solutions such as controls lack the buffering capabilities of whole blood, the transfer process from ampule to cartridge must be more expedient than with a patient sample.

Transfer with Capillary Tube

Plain capillary tubes are recommended to transfer aqueous calibration verification material from the ampule to the cartridge. When using a capillary tube (fresh capillary tubes with sufficient fill capacity are recommended), fill from the bottom of the ampule.

Avoid drawing solution from the surface by placing a finger over the far end of the tube as it is inserted into the ampule.

Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.

Transfer with Syringe

Plain syringes are recommended to transfer aqueous calibration verification material from the ampule to the cartridge. When using a syringe (fresh 1cc or 3cc sterile syringes with 16 - 20 gauge needles are recommended), slowly draw approximately 1mL of solution from the bottom of the ampule.

If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the front of the syringe.

If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe.

Expel one or two drops from the syringe before filling the cartridge.

Acceptable Criteria

Target values (determined by testing multiple ampules of each level using multiple lots of i-STAT cartridges with analyzers that have passed the Electronic Simulator test) and acceptable ranges are printed on a Value Assignment Sheet included with each Calibration Verification Set.

Calibration throughout the reportable range of each analyte is verified if each analyte value falls within the corresponding range in the Value Assignment Sheet.

If the result for a level is outside the range published in the Value Assignment Sheet, two additional cartridge runs should be performed on this level and the three results averaged and then compared to the Value Assignment Sheet range. If this average value is still outside the acceptable range, troubleshooting may be required.

Note: If the Calibration Verification Set is to be used to assess linearity, plot the analyte value against the mean value of the acceptable range. The concentrations of analytes in the Calibration Verification Set are not intended or prepared to be equally spaced.

If testing at extreme altitude refer to Correction of PO_2 at Extreme Altitude under Controls for Blood Gas/Electrolyte/Metabolite Cartridges in the Quality Control section of the manual.

RNA® MEDICAL HEMATOCRIT CALIBRATION VERIFICATION CONTROL

Intended Use

RNA Medical Hematocrit Calibration Verification Control is a quality control material used for verifying the calibration and linearity of hematocrit sensors in i-STAT cartridges.

Product Description

Hematocrit Calibration Verification Controls are provided in five (5) levels for verifying the accuracy of hematocrit measurements throughout the reportable range. The controls are packaged in sealed glass ampules, each containing 1.7 mL of solution. Ampules are packaged in kits containing four (4) ampules of each level.

Active Ingredients

This product is a buffered aqueous solution containing electrolytes and non-conductive ingredients. This control contains no red blood cells, and no human or biological material.

Storage

RNA Medical Hematocrit Calibration Verification Control is stable until the expiration date stated on the ampule when stored at temperatures of 2-25 °C. Do not freeze or expose ampules to temperatures greater than 30 °C.

If stored refrigerated, the calibration verification material should be equilibrated to room temperature for at least four (4) hours prior to testing.

The product may turn slightly yellow in color over its shelf life if stored at room temperature. This coloration is normal and does not affect product performance.

Directions For Use

1. Beginning with Level 1, gently invert the ampule to mix the solution. Tap the ampule to restore the liquid to the bottom of the ampule.
2. Open the ampule by snapping off the tip at the neck. Use gauze, tissue, gloves, or an appropriate ampule opener (a Snapper is included for this purpose) to protect fingers from cuts.
3. Fill and seal a cartridge and insert immediately into the analyzer.
4. Record the results on the Data Collection and Linearity Worksheet provided.

5. Test Levels 2, 3, 4, and 5 in the same manner. Record all values on the worksheet.

    i. Note: this product is a buffered aqueous solution containing electrolytes and non-conductive ingredients. The only value assigned to this fluid is for **hematocrit**. All other cartridge analyte results obtained with this control material should be ignored.

6. Compare the the i-STAT System Hematocrit result value for each level to the package insert value.

    i. If your result is within the assigned value range, circle **Y** at the question **OK?**.

    ii. If the result is outside of the expected range, run two (2) additional cartridges.

        a. Report the mean of the three (3) results.

        b. If your mean is within the assigned value range, circle **Y** at the question **OK?**.

        c. If this result is also out of the expected range, circle **N** and contact your i-STAT Support Representative.

7. If available, transmit results to the Central Data Station.

VERIFICATION PROCEDURE FOR HEMATOCRIT

Preparation of Hematocrit Samples

1. Draw 4 lithium heparin green top tubes from a fasting person with a normal hematocrit or MCHC. 7mL vacuum tubes are suggested. Label the tubes 1, 2, 3, and 4.
2. Centrifuge tubes 3 and 4 for 10 minutes at 3,000 rpm to pack the cells.
3. Remove two thirds the volume of whole blood from tube 1. This blood should be held in a clean plain tube in case it is needed to make adjustments later.
4. Transfer all of the plasma from tube 4 to tube 1.
5. Remove three fourths of the plasma from tube 3. This plasma should be held in a clean plain tube in case it is needed to make adjustments.
6. Gently invert tubes 1, 2 and 3 to resuspend the cells.
7. Measure the hematocrit of the blood in tubes 1, 2, and 3 using one cartridge for each tube. Adjust the hematocrit in tube 1 until it reads close to, but not less than, 10%. Adjust the hematocrit in tube 3 until it reads close to, but not more than, 75%.

Measurement

1. Gently invert tubes 1, 2, and 3 to resuspend the cells.
2. Measure the hematocrit of the blood in tubes 1, 2, and 3 three times each by the i-STAT and microcentrifuge methods.
3. Inspect the data for outliers. Repeat a measurement if necessary.
4. Calculate the mean of the three measurements of the three hematocrit levels for both methods.

Interpretation of Results

The i-STAT hematocrit method using blood anticoagulated with lithium heparin is calibrated to give results equivalent to the reference microhematocrit method using blood anticoagulated with K_3EDTA. Since the blood used for the microhematocrit determination here is anticoagulated with lithium heparin, adjustment must be made to the observed i-STAT values to compensate for the anticoagulant difference.

1. To calculate the adjusted i-STAT hematocrit mean, multiply the mean of the observed i-STAT results by 1.0425.
2. The adjusted i-STAT hematocrit mean should be within ±3%PCV of the microhematocrit mean.

   For example: the microhematocrit method mean for the mid level sample is 36%PCV. The i-STAT method mean is 34%PCV. 34 x 1.0425 = 35.445. Acceptable range for the adjusted i-STAT mean: 33 - 39%PCV.

Note: If your analyzers are customized for K_2EDTA/Heparin/None, the above calculation is unnecessary.

Notes on the Procedure

1. If a higher hematocrit value is needed in tube 1 or 3, packed cells can be obtained by centrifuging the whole blood retained from tube 1 in step 3. If a lower hematocrit value is needed, add plasma retained in step 5.
2. The highest hematocrit that should be tested on the i-STAT System is 75%. Whole blood samples with hematocrit values greater than 75% will be flagged as >75. The lowest hematocrit that should be tested on the i-STAT System is 10%. Whole blood samples with hematocrit values less than 10% will be flagged as <10.

Using Another Comparative Method

Methods other than the reference microhematocrit procedure may be used to verify calibration and reportable range of the i-STAT hematocrit. However, the following requirements apply:

- Blood should be drawn from a fasting donor with a normal hematocrit and a normal MCHC (calculated from hemoglobin and hematocrit values determined using reference methods) and be free of specific interferences which degrade the accuracy and/or precision of the alternative comparative method or the i-STAT method.
- Calculation of results must correct for any systematic bias between the reference microhematocrit method and the alternative comparative method selected.

Reference Method

NCCLS recommends that the blood samples anticoagulated with Na_2EDTA or K_2EDTA be used for the microhematocrit method.* However, EDTA will interfere with the electrolyte measurements which are used in the calculation of hematocrit results on the i-STAT System.

* NCCLS. *Procedure for Determining Packed Cell Volume by the Microhematocrit Method;* Approved Standard– Third Edition. NCCLS document H7-A3 (ISBN 1-56238-413-9). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2000.

VERIFICATION PROCEDURE FOR ACT

See Technical Bulletin: i-STAT Celite and i-STAT Kaolin ACT Heparin Linearity Procedure

Procedure for Cartridges

Calibration Verification and linearity solutions can be tested via a test path accessed from the Utility menu on the i-STAT Portable Clinical Analyzer. (This test path is not available on the BAM.) The same standardization CLEW is used to calculate both patient sample results and calibration verification/linearity sample results. The difference is that in the Calibration Verification test path, the application software does not apply measurement range flags so that results for samples below and above the measurement ranges can be reported.

Note: Because the Utility menu also includes a Clear Stored Results option, it may not be wise to give end users access to the Utility menu.

The ID # (corresponds to Patient ID # in the standard test path) can be used to identify these samples and the cartridge lot number. Note that each of the five levels in the i-STAT Calibration Verification kit has its own lot number. The lot number for Level 1 can be used to identify the kit or each lot number can be used to identify each sample. The letters in the Calibration Verification and cartridge lot numbers can be ignored. For example: Cal Ver level 1 and lot number 1109 plus cartridge lot 02089: 1110902089.

Note: Samples should be prepared and ready to test before starting this procedure since the analyzer will wait for only 5 minutes after the "INSERT CARTRIDGE" message is displayed before powering down.

Display	Action	Analyzer Response
OFF (blank) or ON with a result displayed.	Insert Electronic Simulator	Electronic Simulator test cycle will commence.
Electronic Simulator PASS result displayed.	Hold down the DIS key and press the MENU soft key.	Utility Menu will be displayed.
Utility Menu 1 Clear Stored Results 2 Printer Setup 3 Send Software 4 Cal Ver 5 Proficiency	Press 4 for Cal Ver	Insert cartridge prompt will be displayed.
Cal Ver INSERT CARTRIDGE	Insert filled cartridge into analyzer cartridge port. If the display turns OFF before the cartridge is inserted, turn the analyzer ON using the DIS key. You must re-enter the Utility menu and select the Cal Ver option before inserting the filled cartridge.	Test cycle will commence. If at any point during the test cycle a quality check fails, the test cycle will halt and a message will be displayed indicating the condition and the corrective action.
_ _ _ _ _ _ _ Operator #, ENT	Enter Operator ID and press ENT.	
#_ _ _ _ _ _ _ Repeat #, ENT	Repeat Operator ID and press ENT.	Repeat of Operator ID entry may not be required depending on analyzer customization settings. If the repeated ID does not match the original, the ID must be re-entered.

#_ _ _ _ _ _ _ _ _ _ _ _ ID, ENT	Enter sample ID and Press ENT.	
#_ _ _ _ _ _ _ _ _ _ _ _ Repeat #, ENT	Repeat the sample ID number and press ENT.	Repeat of sample ID entry may not be required depending on analyzer customization settings. If the repeated ID does not match the original, the ID must be re-entered.
Select Tests (Available tests will be dependent on cartridge type).	Use the number keys to select tests to be reported. (Press a number key a second time to deselect a test.) Press PAGE key when all desired tests are selected.	Test selection may not be required depending on analyzer customization settings.
Chart Page	Use the number and ENT keys to enter test information if desired. Press PAGE key when all information entry is complete.	Automatic display of the Chart Page is dependent on analyzer customization settings.
Results Displayed	If results are not displayed, but RESULTS READY message is visible, press the PAGE key until the results page is shown. Remove the cartridge and discard in a biohazard container. Print or transcribe results.	Analyzer unlocks cartridge and is ready for another cartridge. If another cartridge is inserted into the analyzer without pressing DIS and MENU, it will be run as a patient sample. To run another Cal Ver sample continue to next instruction.
Results Displayed	To run another Cal Ver sample, hold down the DIS key and press the MENU key.	Utility Menu will be displayed.
Utility Menu 1 Cal Ver 2 Proficiency	Press 1 for Cal Ver	Insert Cartridge prompt will be displayed. Follow sequence from the Insert Cartridge screen as shown above to complete the test cycle.

Troubleshooting Cartridge Tests

See the Troubleshooting Out-of-Range Results paragraph in the Quality Control Section in this manual.

ABBOTT POINT OF CARE INC. LICENSE AGREEMENT AND WARRANTY FOR CENTRAL DATA STATION PROGRAM

EULA

For new users of CDS software the license and warranty information in the End User License Agreement (EULA) will be in effect.

License

The i-STAT Central Data Station software is licensed to the authorized user by Abbott Point of Care Inc.. Portions of the software are licensed to you by Abbott Point of Care Inc. under sublicense from other original software providers. By accepting and using this software, the user/licensee agrees to the following:

- The user/licensee will not make copies of the software programs or any of the program software files generated by the programs, the manual or other documentation except for archive copies made as part of user/licensee's regular back-up procedures.
- The user/licensee will protect the programs from unauthorized use, illegal reproduction (including reproducing any of the software files generated by the programs) or illicit distribution.
- The user/licensee will not change or reverse engineer the programs or any of their software files by debugging, decompiling, disassembling, reprogramming, rewriting the programs' macros, revising the programs' forms or any other means.

If the user/licensee makes any use, transfer or disclosure of the programs in violation of any of the foregoing, the sub-license will, at the option of Abbott Point of Care Inc., immediately terminate without demand or notice and the user/licensee will immediately give to Abbott Point of Care Inc. the programs, the manuals and all copies thereof in the user/licensee's possession.

Warranty

Abbott Point of Care Inc. warrants the licensed software and accompanying physical documentation to be free of defects for a period of thirty days from the date of installation. If notified of defects within the warranty period, Abbott Point of Care Inc. will replace the defective software or documentation as soon as practical for the nature of the defect. The remedy for breach of this warranty is limited to replacement and shall not encompass any other damages including but not limited to loss of profit, and special, incidental, consequential or other similar claims. Abbott Point of Care Inc. specifically disclaims all other warranties, expressed or implied, including but not limited to implied warranties of merchantability and fitness for a particular purpose, with respect to the software, accompanying documentation and the license granted herein.

INSTALLATION OF THE CENTRAL DATA STATION

Hardware

The PC on which the CDS software resides must meet specifications provided by Abbott Point of Care Inc. and should be installed following the PC manufacturer's directions. Install the printer if applicable.

Software Installation: License Key

A license key is required to install the Central Data Station software. The license key ensures that the end user agrees to the License Agreement which is displayed during installation. To obtain the license key, follow the instructions on the screen and listed below.

1. Insert the CDS CD and the installation will begin automatically.
2. Click **Next>** in the Welcome dialog.
3. The End-User License Agreement will be displayed. Read the agreement and if you agree to abide by the agreement, click **Yes** to proceed with the installation. If you do not agree, click **No** to abandon the installation.
4. Record the serial number of the CDS displayed in the *Enter License Key* dialog.
5. Go to the Abbott Point of Care Inc. web site at http://www.abbottpointofcare.com and click on the i-STAT panel in the lower left corner of the screen. Click on the link under **CDS Key Generator** in the right hand column. You can also access this link directly at http://www.abbottpointofcare.com/cdslicense. (In the USA, the license key can also be obtained from Technical Support.)
6. If you are already registered, skip to step 8. If you are not registered, fill out the required information, select Basic Access, and click **Register.**
7. Go back to the i-STAT web site as directed in step 5.
8. Enter your username and password and click **Login**.
9. You may now enter the serial number recorded in step 4, and click **Submit**.
10. If successful, a message will appear indicating that your key has been e-mailed to the address with which you registered.
11. Obtain the key from the e-mail and enter it in the space provided on the CDS.
12. Click **Next** to proceed with the installation.

Caution

The use of other software that was not provided as part of the system on the same PC with the Central Data Station software may compromise the system, including permanent loss of patient records.

Site Specific Customization of the CDS

During installation, the CDS must be customized to properly communicate with i-STAT 1 Downloaders and Downloader/Rechargers, i-STAT IR Links and Philips Medical Systems Blood Analysis Modules throughout the hospital. The procedure to customize the CDS is described under the Customization section below.

The date displayed with results can be changed to any Short Date format and separator listed in the computer's Control Panel under Regional Options (or something similar, depending on the version of Microsoft Windows in use). If an unsupported format or separator is detected, the user will be notified and given the opportunity to change to a supported format/separator combination.

Connectivity

Basic information needed to connect the Downloaders, Downloader/Rechargers, and the portable printer to the PC are in the Downloader Wiring and Programming section of this manual.

For assistance in programming the Downloader, Downloader/Recharger and IR Links, contact your i-STAT support representative.

Interface

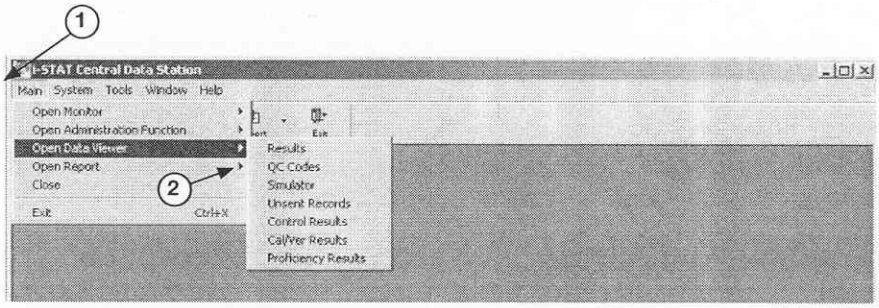
Basic information on interfacing can be found in the "Interface" paragraph under "Customization of the Central Data Station" in this section of this manual and in section 8.

Overview

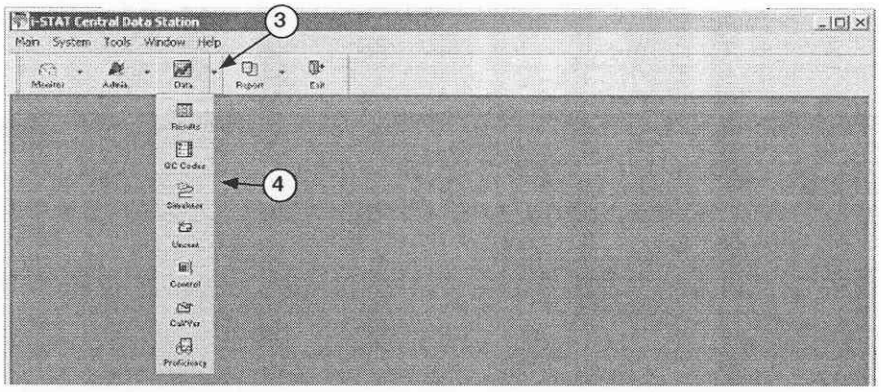
The CDS software follows typical Microsoft® Windows® conventions and procedures. The illustrations below are used to point out the use of the menu bar, toolbars, tabs and buttons.

Selecting Menu Options

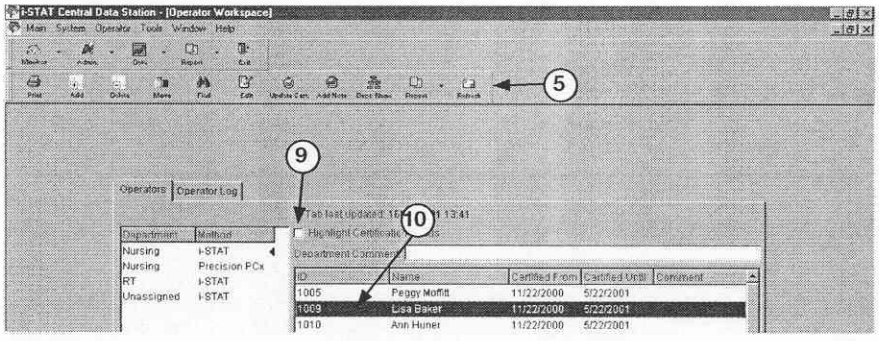
Clicking an item on the menu bar (1) will drop down the menu for that item. If any of the items in the drop down menu has a submenu, the submenu will open to the right of the ▶symbol next to the item when the item is highlighted (2).



Clicking the ▼ beside a toolbar button (3) will drop down a submenu toolbar (4).



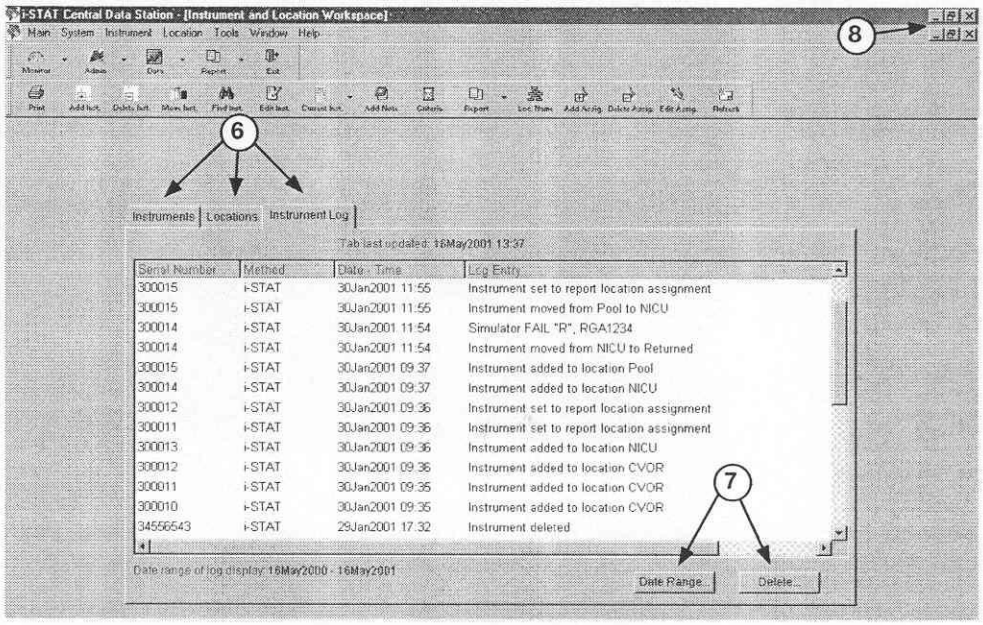
Clicking the desired menu option will open the item's window or will perform the item's function. The menu items and toolbar for the active window will be displayed (5).



Selecting Functions in a Window

Tabs: A window may have several functional groupings that are contained in tabs (6) with multiple pages. Clicking the text on the tab will display the corresponding page.

Buttons: Use to activate a function within a window (7) or to confirm (OK) or cancel a function or to manipulate a window. All windows can have the following buttons in the upper right hand corner (8):



 This button causes the window to be maximized.

 This button causes the window to be minimized.

 This button causes the window to be moveable and resizable.

 This button causes the window to close.

If a window does not have a close button, it can be closed by selecting **Main** then **Close** on the menu bar.

Check boxes: Click the box to enable or disable a single option (9).

Radio buttons: Click the circle to select from a list of mutually exclusive options.

Highlight bar: Use to select the line or lines on which to apply a function (10).

Drop down list: Click the ▼ button to drop down a list or scroll downward in a window.

Refreshing/ Updating the Data in a Window

The **Refresh** toolbar button refreshes the data content in the active window with the most recent data available. The refresh function is also available under the Window option on the menu bar. Pressing **F5** will also refresh the data.

Sorting Data in a Window

In most cases, when data is presented in a table, clicking a column header will sort the display based on the data in that column. In the Data Viewers, repeating values, such as a patient ID, will be sorted in descending Date/Time order. Clicking the header again will reverse the order of the sort. To return the data to chronological order, click the Date-Time column header.

Selecting Multiple Lines

In many functions, multiple lines can be selected for the desired action. To select consecutive multiple lines, click the first line and, while holding down the **Shift** key, click the last line. To select multiple lines that are not consecutive, click the desired lines while holding down the **Ctrl** key.

Opening Multiple Windows

Multiple windows can be open at the same time. The **Windows** item on the menu bar can be used to select the desired window from the list of open windows and bring it to the forefront. Close windows by clicking the **Close** button at the top right of the window or by selecting **Close** from the **Main** menu.

Column Ordering

Columns in the Data Viewers can be placed in any order. Use the mouse to grab a column header and drag the column to the desired position.

Column Widths

To adjust a column's width in Data Viewers, place the mouse pointer on the edge of the column header. When the mouse pointer turns into two arrows, hold the left mouse key and drag column to the desired width.

Toolbars

Helpful Hint!

Select **Tools** ➪ **Customize Toolbars...** to select options for the way toolbars appear. Checking **Large Buttons** displays descriptive text under toolbar buttons. This may be helpful while learning the application. Checking **Show Tooltips** displays a description of a button when the mouse pointer is placed over a toolbar button.

CUSTOMIZATION OF THE CENTRAL DATA STATION

Overview

The Customization options are:

Site Information	Institution name and technical support phone number
Serial Ports	Enables/Disables serial communications and allows individual ports to be selected and configured
Network	Enables/Disables network communications and allows specification of TCP port numbers
Interface	Enables/Disables external interfacing and allows protocol to be selected
Options	Allows various general system behaviors to be specified
Security	Enables/Disables the CDS Security features which allow for the creation of security profiles providing different levels of access to various areas and functions of the CDS application.

To access the Customization screen, close the CDS application, access the Run dialog box by clicking **Start** ➪ **Run...**. Type **wcds32 config** at the **Open:** prompt, then click **OK**.

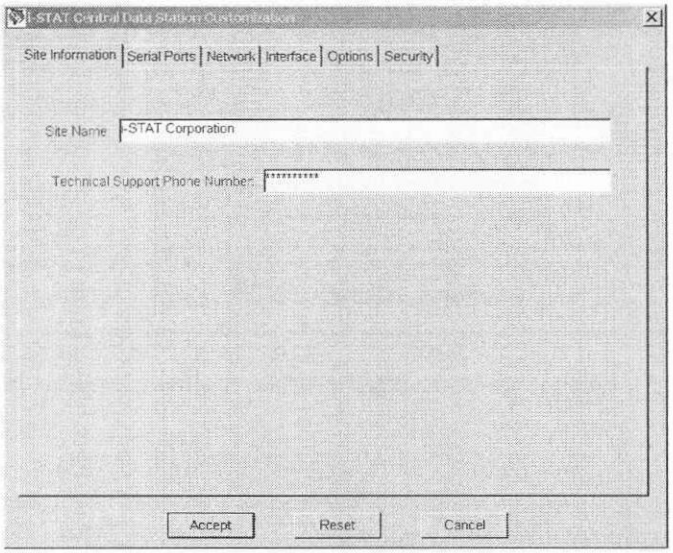
If **Run...** is not on the **Start** menu, double click the **Command Prompt** shortcut. At the **C:\>** prompt in the window that opens, type **c:\istat32\bin\wcds32.exe config** and press **Enter**.

When the Customization screen appears, click a tab to display the desired tab page. The information in each field can be specified. When all tabs are customized as desired, click the **Accept** button to save the information. Click the **Reset** button to disregard changes and restore the previous information. Click the **Cancel** button to ignore any changes and retain the current settings. When customization is complete, the CDS application will open automatically.

Site Information

A site name and address of up to 60 characters can be entered into this field.

The appropriate Technical Support Phone Number for the country will be listed or can be entered.



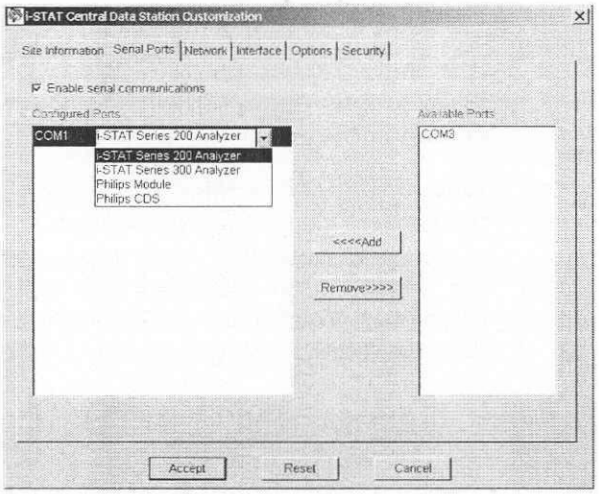
Serial Ports

The Central Data Station program resides on a PC with multiple serial ports (DB9). Available ports will automatically be listed under **Available Ports** on the Serial Ports tab page. The following components can be connected to the Central Data Station via serial ports:

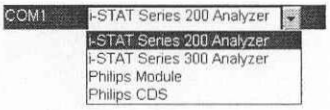
- **i-STAT Series 200 Analyzer:** IR Link transmits data to and from the i-STAT Portable Clinical Analyzer.
- **i-STAT Series 300 Analyzer:** Downloader or Downloader/Recharger transmits data to and from the i-STAT 1 Analyzer.
- **Philips Module:** a local connection to the CDS is needed to transmit software updates and customization profiles to the Blood Analysis Module.
- **Philips CDS:** The CDS server transmits patient data from the Blood Analysis Module to the Data Manager.

Click the **Enable serial communications** box to check it and enable serial communications.

Click the desired port(s) under **Available Ports** and click the **<<<<Add** button. The port(s) will now be listed under **Configured Ports.**



Click the port and select an instrument for that port.



Serial ports on the PC might also be needed for a local PCx Docking Station and connection to an interface.

Network

Click the **Enable network communications** box to check it and enable network communications.

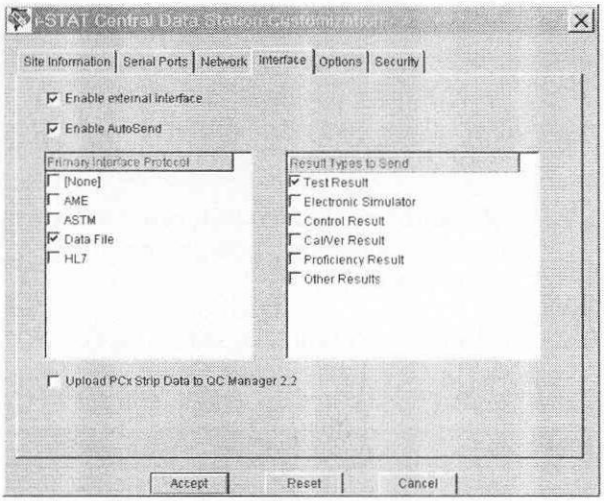
The default TCP service port assignments are listed in the Network tab page. If not using the default ports, click the port and type in the new assignment. Port numbers must be unique and in the range of 1024 to 65535.

Note: If a PCx Docking Station is sharing the ethernet port with an i-STAT Downloader, the PCx port assignment is made in QC Manager.

Interface

The appropriate interface protocol and the types of records to be sent to another data management system are selected in the Interface tab page. This configuration will typically be done by the interface provider.

Select the desired primary interface protocol. Then select the result types to be sent to the interface.



Primary Interface Protocol Choices	Explanation	Which Result Type(s) May be Transmitted
None	Indicates no primary protocol in use. Select when no external interface is used and PCx glucose test strip data is to be uploaded to QC Manager 3	N/A
AME	Automatic Manual Entry – Installed by Abbott Point of Care Inc.	1. Test Result 2. Electronic Simulator 3. Control Result 4. Cal/Ver Result 5. Proficiency Result
ASTM	Data Transmission conforms to ASTM E1381-95 and ASTM E1394-97	Patient Test Results ONLY
Data File	Formats the CDS for third-party use.	1. Test Result 2. Electronic Simulator 3. Control Result 4. Cal/Ver Result 5. Proficiency Result
HL7	Data transmission conforms to HL7 (version 2.4) and is based on the CIC Observation Reporting Interface distributed by the National Committee for Clinical Laboratory Science in the USA under Document POCT-1-A. This option is installed by Abbott Point of Care Inc.	Patient Test Results ONLY

Click **Enable external interface** box to check it and enable this function.

Click **Enable AutoSend** box to check it and enable this function. When AutoSend is enabled, new records will be automatically sent from the Central Data Station to another data management system whenever they are received by the Central Data Station. Checking this box will cause the CDS program to start up with AutoSend enabled on startup. AutoSend can be temporarily enabled/disabled from the CDS program as well. Records can also be sent manually from the Data Viewers.

When MediSense Precision PCx glucose test strips are being run on the i-STAT 1 Analyzer, the glucose test strip data can be made available to QC Manager data management program. Click the **Upload PCx Strip Data to QC Manager 2.2** box to enable this function.

Options

Confirmation message on exit: When this option is enabled, a confirmation message is displayed prior to exiting the CDS program.

Enable use of IR Link IDs: When enabled, the IDs programmed into the IR Links are used in determining the download location of the results instead of the actual serial port or IP address. To use this function, all IR Links must be of the self-identifying type. This option is not typically used but is available in case the functionality is needed.

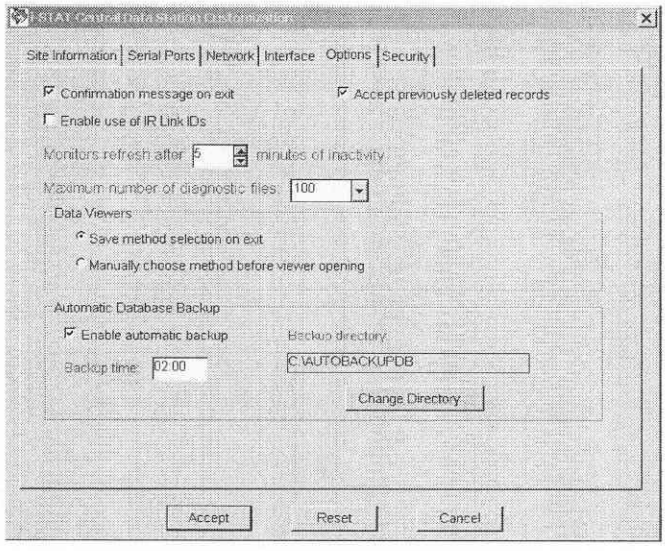
Accept previously deleted records: When disabled, this option prevents previously deleted records from being stored when re-transmitted to the Central Data Station.

Monitor refresh: The status reports in the Download and Interface Monitors will be updated after the period of inactivity specified.

Maximum diagnostic files: Diagnostic files contain information that can be useful in troubleshooting cartridge problems. The default number is 100 and is changed at the request of a Customer Support representative.

Data Viewers: Selecting **Save method selection on exit** will cause each Data Viewer to save whichever method was selected when the viewer is closed or the **Exit** button clicked. The next time the viewer or CDS software is opened, the saved method will be displayed. When **Manually choose method before viewer opening** is selected, the user will be prompted to choose a method before a data viewer is opened.

Automatic Database Backup: When enabled, the CDS database files will be backed up to the selected location at the time of day entered. Should there be a malfunction resulting in the corruption of the database, a Customer Support representative may be able to retrieve the lost data from the backup copy. Each backup replaces the previous one. Backup time depends on the size of the database but usually does not take longer than 15 minutes.

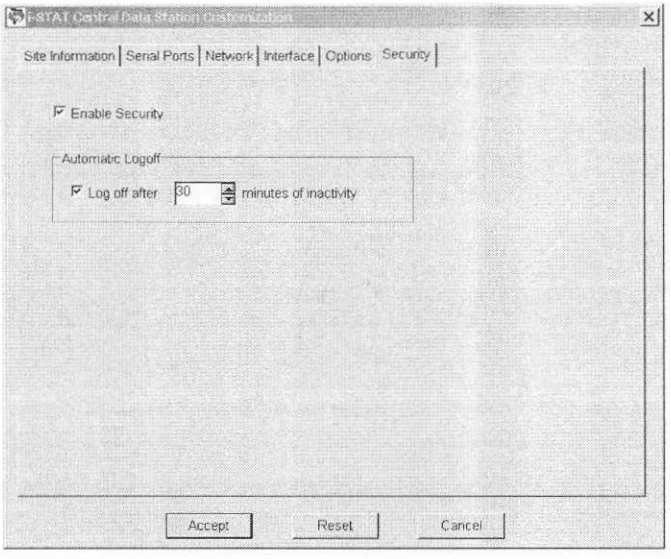


Security

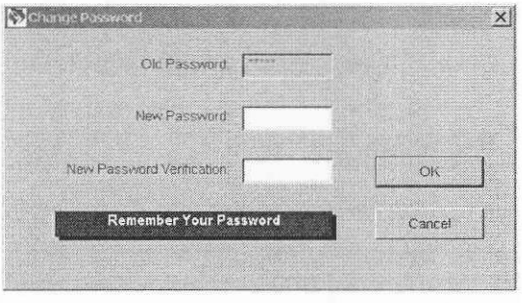
The security features allow for the creation of security profiles providing different levels of access to various areas and functions of the CDS application. Individual users can then be assigned to a security profile, and then choose their own individual CDS log-on password. The system also has capabilities for manual and automatic logoffs.

The security features should only be activated by the administrator of the System; i.e. the person ultimately in charge of the CDS who will be creating the security profiles and assigning users to them.

The security features can be activated by performing the following steps:



1. Check the box next to "Enable Security".
2. After enabling security, the user also has the option of selecting an inactivity interval after which the CDS will log off the current user. Simply click on the "Log Off" box and use the up/down arrows to choose the desired log off interval.
3. Click **Accept** at the bottom of the window.
4. A password dialog will then appear asking for a User Name and a Password. Type the User Name of **admin**, and the password **istat**. Then click on **OK**.
5. Another dialog box will appear prompting you to change your password.



6. Type in a New Password of your choosing in the space provided. Then retype that same password on the New Password Verification line and click **OK**. This will automatically bring you to the CDS application.

INTERFACE PROGRAM CUSTOMIZATION

Overview

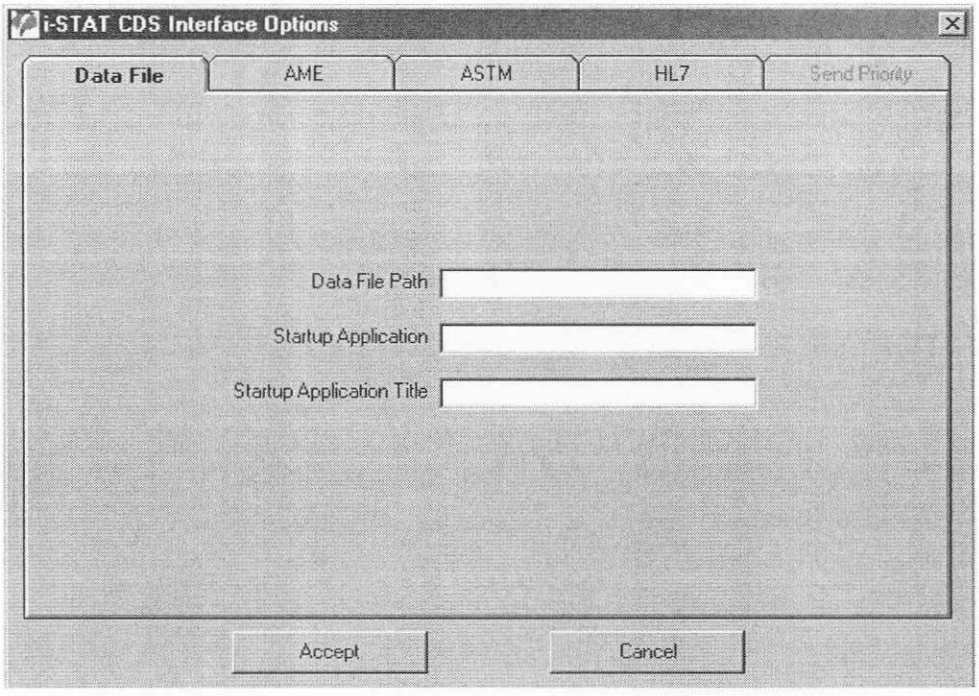
The Central Data Station can output results to an external computer system such as an LIS or HIS. The Central Data Station also provides a function that, when enabled, will also transmit all of the Precision PCx results generated on the i-STAT 1 Analyzer to QC Manager so they can be managed as part of the overall Blood Glucose Testing program.

The Central Data Station needs to be customized for the interface type using the procedures below. Tabs are presented for the options available. Each tab represents a protocol that the Interface Component of the CDS supports. Depending on the particular installation, one or more of these will be used.

Procedure

Exit the CDS application. Access the Run dialog box by clicking **Start** ➪ **Run...** Type **c:\istat32\bin\interface32.exe** at the **Open:** prompt, then click **OK**. If **Run...** is not on the Start menu, double click the **Command Prompt** shortcut. At the C:\> prompt in the window that opens, type **c:\istat32\bin\interface32.exe** and press **Enter**. Click **File** ➪ **Options**. The following screen will be displayed.

These tabs are used by the interface provider to configure the interface Component of the CDS for the protocol that will be used.

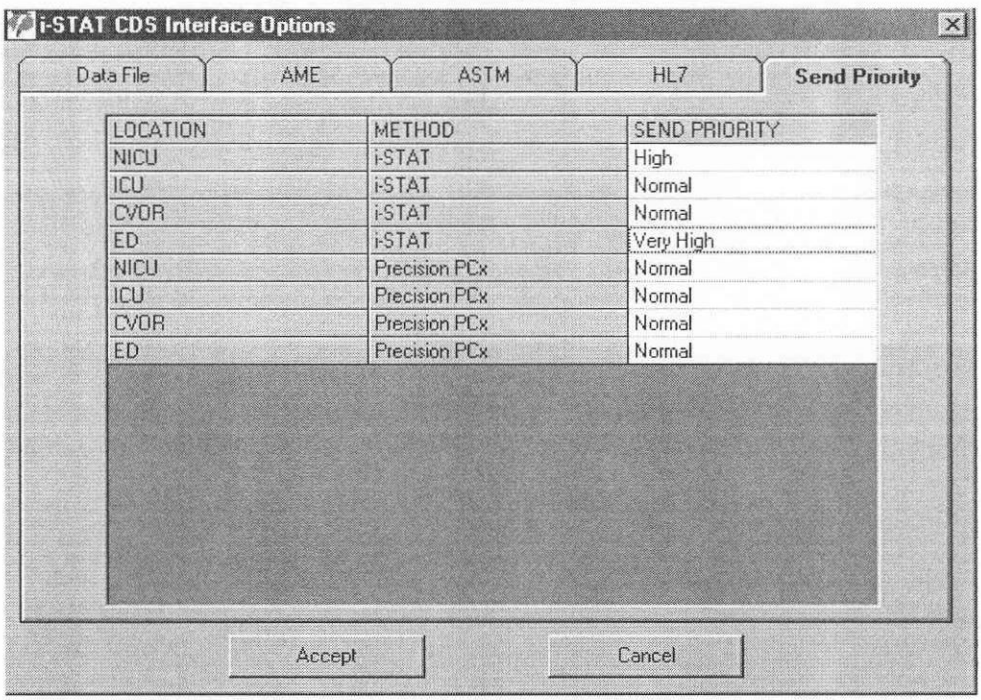


Send Priority

This function will prioritize the queue of results in the CDS database being processed by the Interface Component of the CDS program. This capability can be used by the interface provider to prioritize handling of results from one location over another.

Procedure

1. The CDS program must be running and the external interface must be enabled.
2. Double click the i-STAT interface icon in the system tray (next to the clock in the lower right hand corner of the screen) to open the interface program's main screen.
3. Click **File** ⇨ **Options**...
4. Click the **Send Priority** tab. (The other tabs will be available for viewing only.)
5. Click the Location/Method line to prioritize.
6. Right click under the **Send Priority** column and select the priority: Normal, High, Very High, from the drop down list.
7. Click **Accept** to finish.



OVERVIEW OF THE CENTRAL DATA STATION PROGRAM

The Central Data Station (CDS) software includes the following point-of-care testing process management functions:

- Managing Instruments
- Managing Operators
- Managing Inventory
- Managing Policy Compliance
- Monitoring Operator Competence
- Reviewing Patient and Quality Results
- Managing Analyzer Customization Profiles
- Maintaining Database Contents and Size
- Monitoring External Interface Activities
- Monitoring Analyzer Download Intervals
- Managing LIS entry exceptions

These functions are listed under the main menu option in four main groupings: monitors, viewers, workspaces and reports.

Central Data Station Software Function Overview and Toolbar Buttons


Monitor


Download


Interface


Administration Tools (Workspaces)


Instrument/Location


Operator


Database Maintenance


Inventory


Customization


User Administration


Data Viewer


Results (patient)


QC Codes


Simulator


Unsent Records


Control Results


Calibration Verification


Proficiency Tests


Report


Reagent Management


Method Competence


Method Compliance

ADMINISTRATION TOOLS

Overview

Administration Tools include Workspaces for Instruments and Locations, Operators, Database Maintenance, Inventory, Customization, and User Administration.

INSTRUMENT AND LOCATION WORKSPACE

Overview

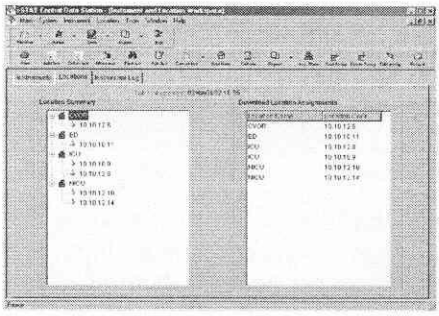
This workspace is used to:

- assign names to download locations,
- assign instruments to locations,
- configure the reporting and monitoring options for each instrument, and
- set required download intervals for each location.

The following sequence of tasks is used to set up the Central Data Station's management function for instruments:

1. Assign Location Names to Location Codes. Location Codes are the physical port addresses for the download devices.
2. Assign Instruments to Download Locations.

Locations



❑ Edit Location Name

The location name can be changed from a letter/number code to the name of a nursing unit, department, site, etc.. Up to 17 characters can be used to identify a location. Click **Location ⇨ Edit Location Name...** in the menu or click **Loc. Name** in the toolbar.

Note: Interface logic should be considered before editing.

❑ Add New Download Location Assignment

Download locations can be added manually. Click **Location ⇨ Add Download Location Assignment...** in the menu or click the **Add Assig.** in the toolbar. Download locations will also be added automatically when a transmission is received from a download device with a location that is not already on the list. The name assigned is A_xx, where xx is the download device's IP address or serial port. This name can be changed as described under **Edit Download Location Assignment**.

To assign instruments to a location without a download device, enter a Location Name or another descriptive word as the Location Code.

❑ Delete Download Location Assignment

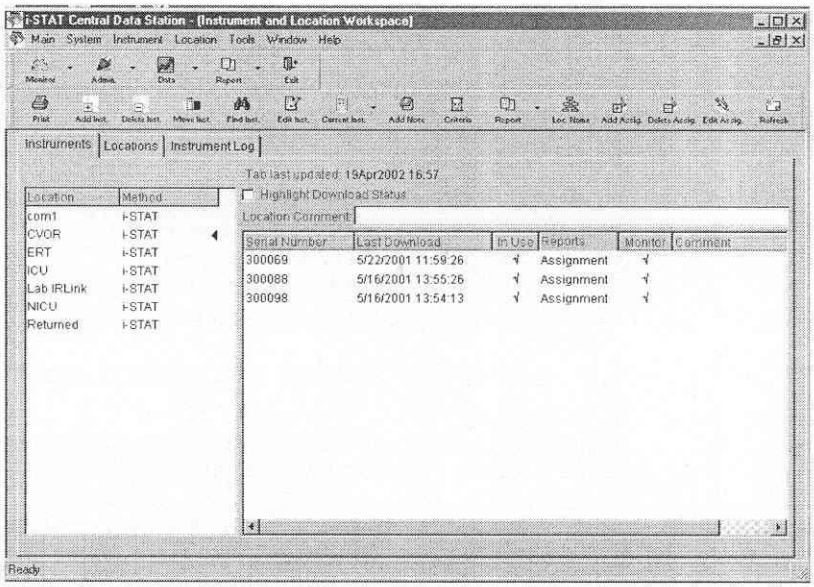
Click **Location ⇨ Delete Download Location Assignment...** from the menu or click **Delete Assig.** in the toolbar.

❑ Edit Download Location Assignment

Click **Location ⇨ Edit Download Location Assignment...** from the menu or click **Edit Assig.** in the toolbar.

Instruments

Once physical download locations have been given location names, the Instruments tab page will be the focus of management activities.



Location: Instruments are assigned to locations. This assignment is made when an instrument is manually added in the Instruments page or when an instrument downloads to the Central Data Station for the first time.

Method: The CDS is designed to accept results from any instrument that can be downloaded to the CDS program. The i-STAT method in the Instrument window refers to the i-STAT Portable Clinical Analyzer, the i-STAT 1 Analyzer (both i-STAT cartridge and MediSense Precision PCx and PCx Plus Glucose Test Strips) and the Philips Blood Analysis Module.

Clicking a Location/Method on the left side of the window will list the status of all instruments for that location and method in the right side of the window. A ◄ symbol indicates which location and method has been selected.

Highlight Download Status: Checking this box will highlight locations with instruments that have exceeded the required interval for downloading as well as noncompliant instruments within the location selected.

❑ Add Instrument

The Add instruments window is used to add an instrument to the system. Click **Instrument ⇨ Add...** from the menu or click **Add Inst.** in the toolbar. Select a method from the drop down list.

Note: If using the i-STAT 1 Analyzer for cartridge and/or test strip runs, select i-STAT as the method.

Select a location from the dropdown list. If the location is not listed, add the location using the instructions under Add New Download Location Assigment. If the location does not have a download device associated with it, such as an instrument used for transporting patients, a location name can be typed in. (In this case the Location Code on the Locations tab page will be SYSCODExxxxxx.) Up to 17 characters can be used.

There are two options for Download Result Reporting, both of which apply to the i-STAT PCA, i-STAT 1 Analyzer, and the Philips Blood Analysis Module:

1. **Always report location as this assignment:** The results from this instrument will appear with the location of the instrument's assignment regardless of the download device used to transmit the results. This option is useful when an instrument is assigned to a functional group that may download from various areas in the institution. The instrument will be designated "Assignment" under the Reports column in the Instruments tab page.

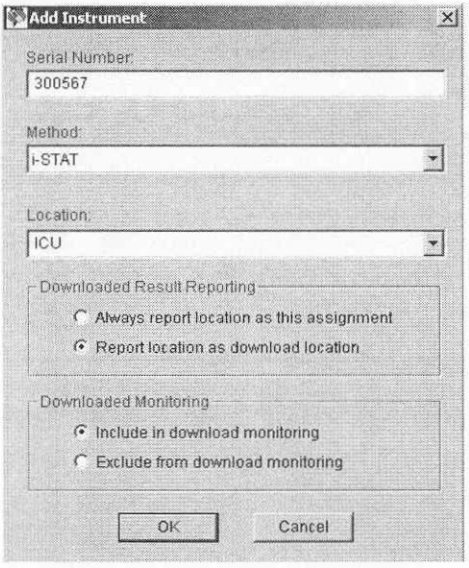
2. **Report location as download location:** The results from this instrument will appear with the location for the download device that was used to transmit results to the Central Data Station. The instrument will be designated "Download" under the Reports column on the Instruments tab page.

   If the instrument is not manually added to the list and it transmits to the CDS, it is automatically assigned to the location of the download device and is set to report "Download." If the download device location has not been manually added, a default location A_xx (B_xx, C_xx, etc.), where xx is the IP address or serial port of the download device, will be used.

There are two options for Download monitoring:

1. **Include in download monitoring:** Includes this Serial Number in download monitoring.

2. **Exclude download monitoring:** The download status of the instrument will not be reported by the Download Monitor. (Blood Analysis Modules and infrequently used or spare analyzers might be exempted from the Download Monitor report).



❑ Delete Instrument

Click the Location/Method for the instrument to be deleted and then the serial number of the instrument to be deleted. Click **Instrument ⇨ Delete...** from the menu or click **Delete Inst.** in the toolbar.

❑ Move Instrument

Click the Location/Method for the instrument to be moved and then on the serial number of the instrument to be moved. Click **Instrument ⇨ Move...** from the menu or click **Move Inst.** in the toolbar. Select the new location from the drop down list or type in a new location.

❑ Find Instrument

Click **Instrument ⇨ Find...** from the menu or click **Find...** in the toolbar. Enter the serial number of the instrument and select the Method from the drop down list.

❑ Edit Instrument Comment

Click the instrument serial number, click **Instrument ⇨ Edit Comment** from the menu or click **Edit Inst.** in the toolbar. Enter a comment of up to 16 characters.

❑ Change Current Instrument Setttings

Reporting: Click the instrument serial number. Click **Instrument ⇨ Current Instrument ⇨ Change Reporting** from the menu or click the down arrow next to **Current Inst.** and then **Reporting** in the toolbar to toggle between **Download** and **Assignment**.

In Use: Click the instrument serial number. Click **Instrument ⇨ Current Instrument ⇨ Toggle In Use** from the menu or click the down arrow next to **Current Inst.** and then **In Use** in the toolbar to check (in use) or un-check (out of use) the analyzer in the In Use column.

Instruments that are not checked "In Use" do not have a download criteria applied to them. You would use this for instruments you do not expect to be downloaded. When an analyzer that is not marked "in use" downloads, it is set back in use and the download criteria is applied.

Monitoring: Click the instrument serial number. Click **Instrument ⇨ Current Instrument ⇨ Change Monitoring** from the menu or click the down arrow next to **Current Inst.** and then **Monitoring** in the toolbar to check or un-check the analyzer in the Monitoring column.

❑ Add Instrument Note

Click **Instrument ⇨ Add Note...** from the menu or click **Add Note** in the toolbar. A note of up to 50 characters can be entered. The note will appear as a Log Entry in the Instrument Log tab page.

❑ Change Download Monitoring Criteria

Compliance to download policy can be monitored by the CDS program. Click on the Location/Method. Click on **Instrument ⇨ Download Criteria...** from the menu or click **Criteria** in the toolbar. Enter the required download interval. An interval of up to 1000 hours is allowed.

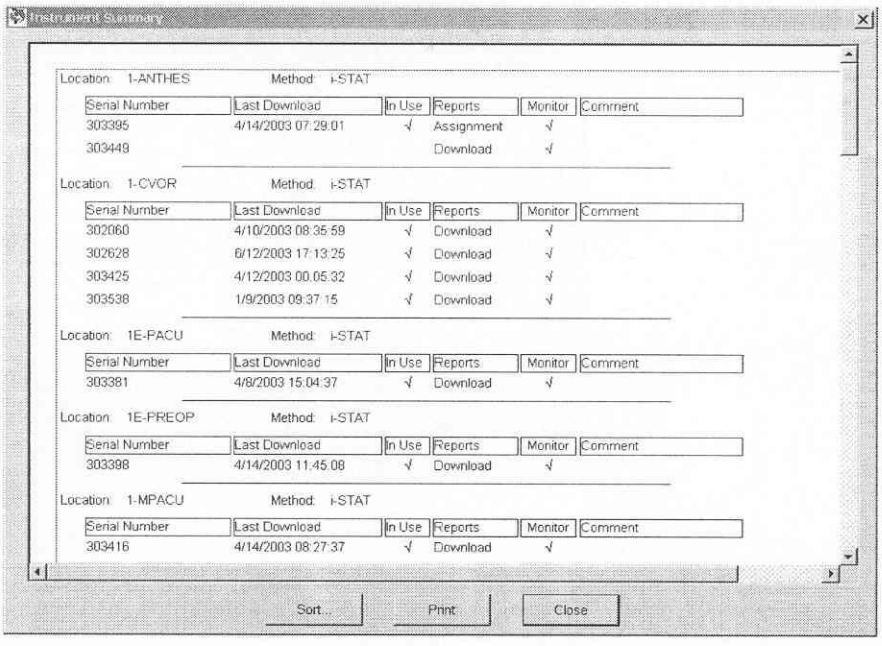
Compliance with the criteria can be observed by checking the Highlight Download Status check box or by going to the Download Monitor. Individual Download criteria can be set for each location and method pair.

Note: The i-STAT 1 Analyzer can also be customized either to warn the end users that a download is required or to lockout end users if the time for a download has been reached or exceeded. The download criteria for analyzers and for the CDS monitor should be selected to make sense.

❑ Instrument and Location Summary

The Instrument and Location Summary provides a report of the current instrument assignments and the last download for each instrument. Click **Main ⇨ Open Report ⇨ Instrument Summary** from the menu or click the down arrow next to **Report** and then **Summary** in the toolbar. Summaries can be viewed and printed by:

- This method and location only (location and method selected with ◄ symbol)
- This method, all locations (method selected with ◄ symbol)
- All methods, all locations



Instrument Log

The Instrument Log tracks all changes made in the Instruments tab page. Additional comments can be added to the log by clicking **Add Note** in the toolbar.

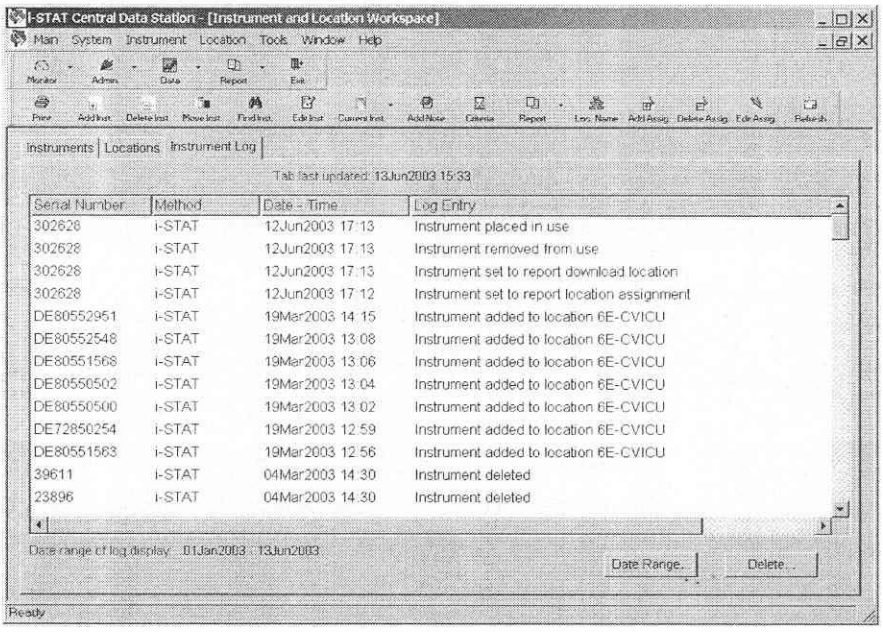
❑ Date Range...

Data can be viewed within a user defined default range or by a manually entered range.

❑ Delete...

The **Delete** button allows selected or all entries within the date range selected to be deleted.

To print the log press the **F2** key or select **Print** from the Main menu or toolbar.



OPERATOR WORKSPACE

Overview

This workspace is used to:

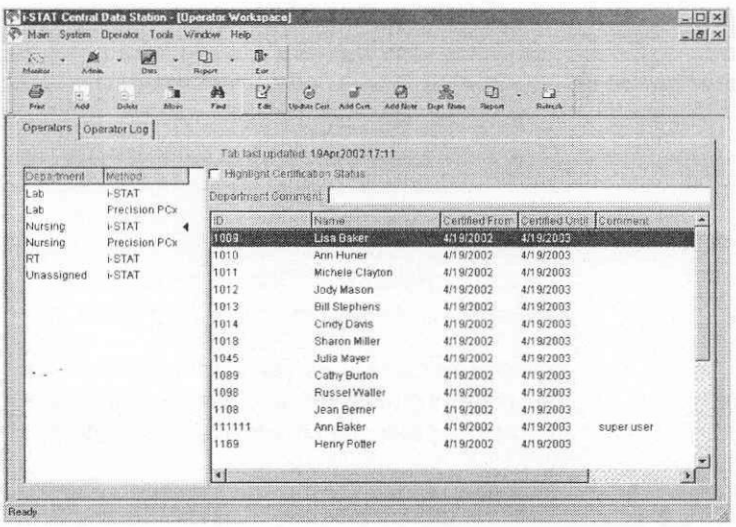
- Record operator names and identification numbers
- Record certification dates and certification expiration dates
- Assign operators to departments
- Add comments

When the i-STAT 1 Analyzer is customized to use the operator list created here, the analyzer can be customized to warn or lockout operators if they are not on the list or their certification has expired.

Operators

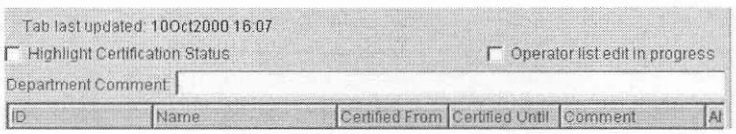
Operators are listed by Department and Method as indicated by the◄symbol. Operators are added to the operator list by department and by method.

When a record is received with an Operator ID that is not listed in any Department, the operator is placed in the "Unassigned" department.



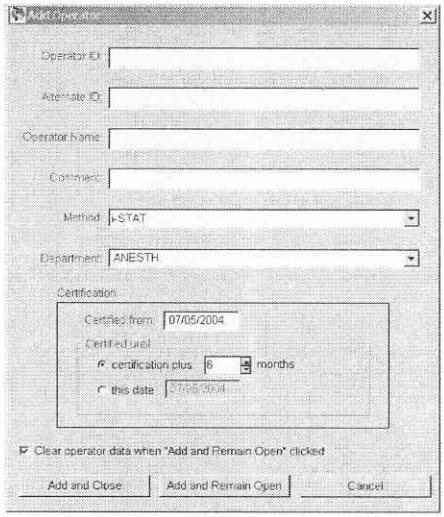
❑ Operator list edit in progress

When editing the operator list, check this box to delay updating i-STAT 1 analyzers until all editing is complete. When editing is complete, click the box to remove the checkmark. This box will appear when Serial or Network Communications are enabled, Customization is enabled and Use Operator List is enabled.



❑ Add Operator

This function is used to add new operators to the list of operators. Alternatively, operator lists can be imported (see Operator List Import at the end of this section). Click **Operator ⇨ Add...** from menu or **Click** on **Add** in the toolbar.



Enter the ID number that the operator will enter into the analyzer on the Operator ID line. If a different ID number is used to access the LIS, this number should be recorded on the Alternate ID line. An Operator Name of up to 40 characters can be entered. A comment of up to 16 character can be added. If operators are to be certified for more than one method, such as for the i-STAT cartridge and the PCx glucose test strip, certify each operator for one method and use the **Add Cert.** toolbar button to certify all applicable operators at one time for the method. To add the first operator to a department, type the department name (up to 10 characters). Once a department has been added, it can be selected for additional operators from the drop down menu.

Check the **Clear Operator data when "Add and Remain Open" clicked** box to specify whether or not the operator information fields should be cleared when the Add and Remain open button's clicked.

❑ Delete Operator

Select the operator or operators. Click **Operator ⇨ Delete...** from the menu or click **Delete** in the toolbar to delete the operator or operators. When the last operator from a department is deleted, the department is removed from the system.

❑ Move Operator

Select the operator or operators. Click **Operator ⇨ Move...** from the menu or click **Move** in the toolbar, and select a new department from the drop down list. If the department is not in the list, type in the new department name.

❑ Find Operator

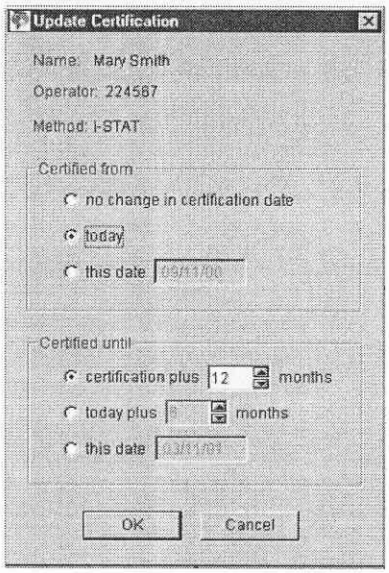
Click **Operator ⇨ Find...** from the menu or click **Find** in the toolbar, select the method for which the operator is certified, and type in the operator ID. A box will appear around the found operator.

❑ Edit Operator Data

Click the operator. Click **Operator ⇨ Edit** from the menu or click **Edit** in the toolbar. The operator ID, name, comment and alternate ID can be edited.

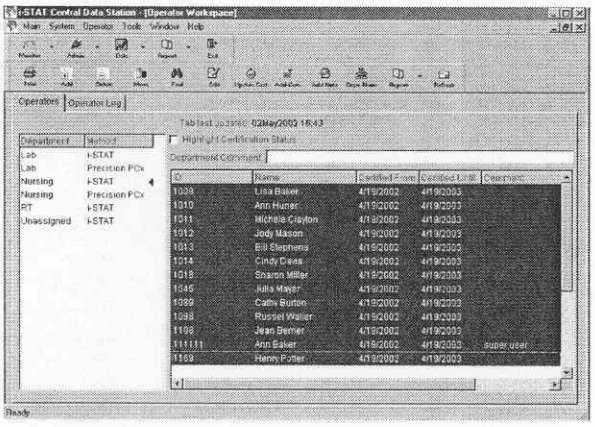
❑ Update Certifications

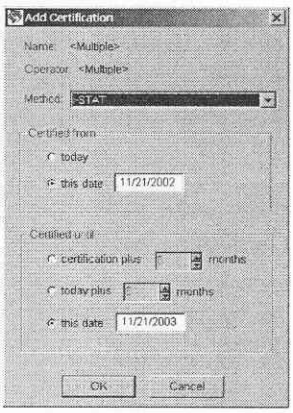
Select the operator or operators. Click **Operator ⇨ Update Certification...** from the menu or click **Update Cert.** in the toolbar and complete the Update Certification form.



❑ Add Certification

The Add Certification button allows operators who are certified for one method to be certified for another method without having to complete a new Add Operator form. Highlight the operator or operators in the Operator tab window that are to be certified for another method. Click **Operator ⇨ Add Certification...** from the menu or click the **Add Cert.** button on the toolbar. Select the other method for which these operators are to be certified, then specify the certification dates.





❑ Add Note

Click the operator. Click **Operator ⇨ Add Note...** from the menu or click **Add Note** in the toolbar. An Operator Log Note of up to 50 characters can be typed.

❑ Edit Department Name

Click the department name to edit. Click **Operator ➪ Edit Department Name** from the menu or click **Dept. Name** in the toolbar. The Unassigned designation cannot be changed.

❑ Operator and Certification Reports

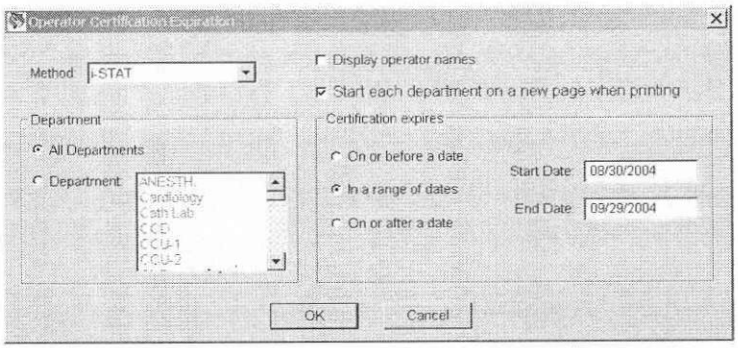
Click on the down arrow next to **Report** in the Operator Workspace toolbar and click on **Summary** or **Expiration**.

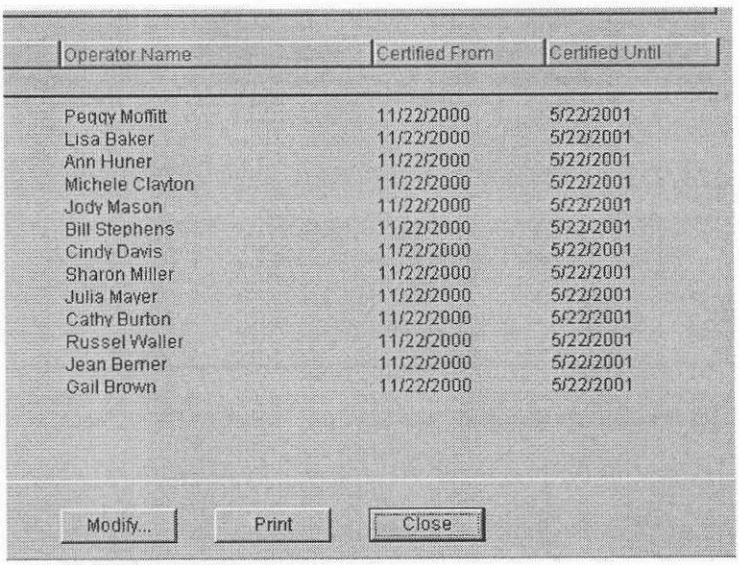
Operator Summary: Summaries of operators can be viewed and printed by:

- This method and department only (department and method selected with ◄ symbol)
- This method, all departments (method selected with ◄ symbol)
- All methods, all departments

The reports include operator IDs, operator names, certified from date, certified until date, comments, a checkmark if certification has expired and the operator's alternate IDs grouped by department and method.

Operator Certification Expiration: This report allows the certification status of operators to be viewed.



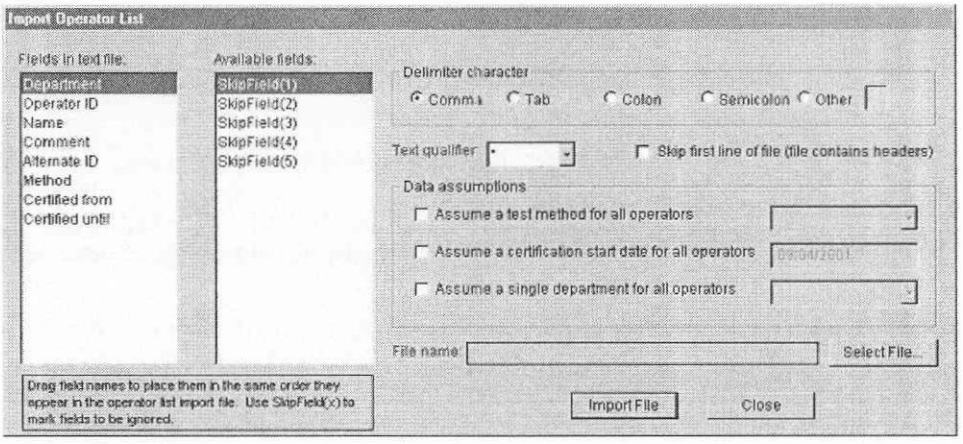


Operator Log

The Operator Log tracks changes made and "Add Note" entries made in the Operator tab page. The **Date Range...** button can be used to specify a time period to be viewed and the **Delete...** button to delete entries. To print the log press the **F2** key or select **Print** from the Main menu.

OPERATOR LIST IMPORT

This function in the Operator Workspace on the CDS5 allows an operator list to be imported from a text file. To access this function, click on **Main** ➪ **Open Administration Function** ➪ **Operator** from the main menu to open the Operator Workspace. Select **Operator** ➪ **Import List...** from the main menu to open the Import Operator List window. This window is used to describe the format of the text file containing the list to be imported into the CDS.



Import List Instructions

1. Under **Fields in text file:**, use the mouse to drag and drop the field names so they match the order in which the fields appear in the text file containing the list to be imported. If a field does not appear in the text file, drag it to the **Available fields**: list. If the text file contains a field that should be ignored, drag a **SkipField(x)** field to the **Fields in text file:** list to mark where that field appears.

2. Fields in the text file containing the list to be imported must be separated by a comma or other delimiter character. Specify the separator in the **Delimiter character** box.

3. If a qualifier character is used to enclose the data contained in each the field in the text file containing the list to be imported, select this character from the **Text qualifier:** list.

4. If the first line of the text file is a header line listing the names of the fields in the text file containing the list to be imported, click **Skip first line of file (file contains headers)**. The import function cannot process header lines.

5. If all operators in the text file containing the list to be imported are to be certified for one method, click **Assume a test method for all operators** and select **i-STAT** for cartridge testing or **Precision PCx** for the MediSense Precision PCx or PCx Plus Glucose Strip testing on the i-STAT1 Analyzer. If this option is selected, the text file does not need to contain a **Method** field. If this option is selected and the text file does contain a **Method** field, its contents will be ignored

6. If all operators will be certified from the same date, click on **Assume a certification start date for all operators** and enter the start date. If this option is selected, the text file does not need to contain a **Certified from** field. If this option is selected and the text file does contain a **Certified from** field, its contents will be ignored.

7. If all operators are to be assigned to the same department, such as Nursing or Perfusion, click on **Assume a single department for all operators** and enter or select the department from the drop down list. If this option is selected, the text file does not need to contain a **Department** field. If this option is selected and the text file does contain a **Department** field, its contents will be ignored

   Example from list to be imported:

   "ICU", "12345", "Smith, Judy", "none", "98765", "i-STAT", "2001-08-08", "2002-08-08"

8. Click **Select File...** and select the name of text file containing the list to be imported.

9. Click **Import File** to import the list from the text file.

Note: operator data that already exits in the CDS5 database takes precedence over any data imported from a text file.

Export List

After a list has been imported or created, it can be exported for backup purposes.

DATABASE MAINTENANCE

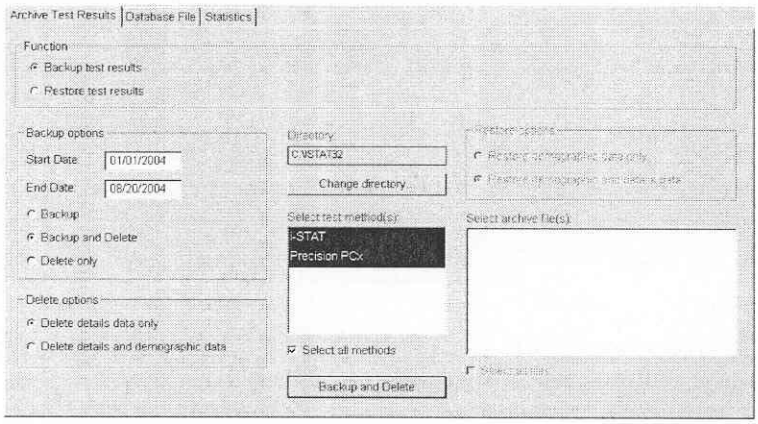
Overview

This workspace allows the database to be backed up, deleted and restored. A "Statistics" tab page also allows users to view a summary page of Result Types contained in the database.

Archive Test Results

Backup test results: This function allows test results to be backed up onto a disk, CD or other directory. (Note: a 1.44MB disk will only store about 1000 test records.)

1. Click on **Main ⇨ Open Administration Functions ⇨ Database Maintenance.**
2. After the workspace opens, click the **Archive Test Results** tab.

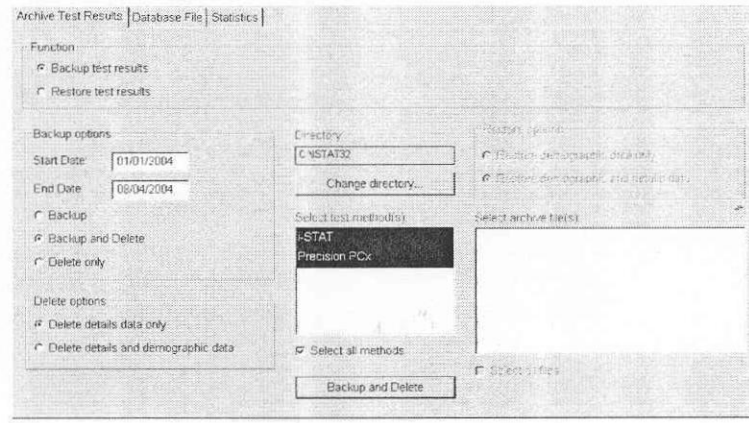


3. Click the **Backup** test results radio button.
4. Specify a date range for the function.
5. Select a Backup Option: **Backup**, **Backup and Delete**, or **Delete only**.
6. If an option that includes Delete is selected, then select a Delete Option: **Delete details data only** or **Delete details and demographic data.** Details data includes:
   - Original Operator and Patient ID
   - Patient Name
   - LIS order number
   - Sent status
   - Analyte values
   - Extra data

   Demographic data can be used to generate reports. Demographic data includes:
   - Test type (test result, simulator, proficiency,...)
   - Test panel (such as EC8+, CG8+, PCx Glucose)
   - Test Method (i-STAT, Precision PCx...)
   - Patient ID
   - Operator ID
   - Test date/time

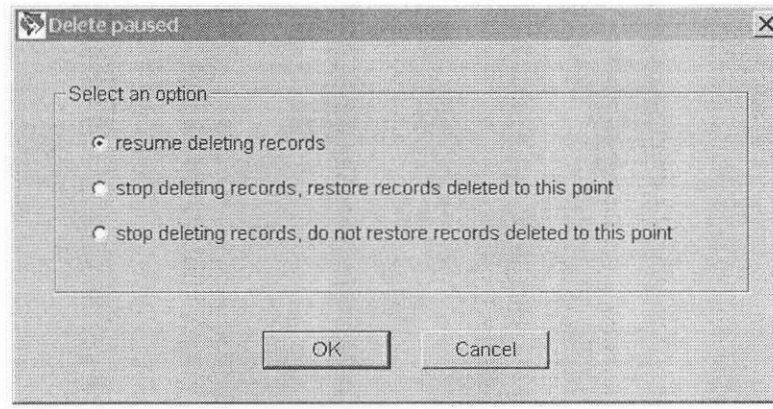
- Location
- Comment
- Interface comment
- Serial number
- Department

7. Select a Directory.
8. Select a method or methods to back up or click **Select all methods**.



9. Click the button marked **Backup** or **Backup and Delete** and follow the prompts.

Note: When results are being deleted as part of a backup and delete or a delete only operation, the deletion can be cancelled. Simply click on the **Cancel** button to stop the operation. Once the **Cancel** button is clicked, depending on the amount of data being deleted and the size of the database, there may be a significant lag time of a few minutes before a dialog box appears indicating that the deletion has been paused, asking you to select one of three options:



The reason for the lag time is that the program needs to complete whatever portion of the deletion operation it was performing when the **Cancel** button was clicked before it can display the dialog box. Once the dialog box is displayed, simply click on the desired radio button and then click **OK**.

Restore test results: This function allows test results that have been deleted from the CDS but backed up elsewhere to be restored to the database.

1. Click on **Main** ➪ **Open Administration Functions** ➪ **Database Maintenance.**
2. Insert disk or CD where files are located.
3. Click the **Restore test results** radio button.
4. Select the directory for the stored results.
5. Select the method or methods to be restored.
6. Select a restore option: **Restore demographic data only** or **Restore demographic and details data.** (Demographic data can be used to generate reports.)
7. Select the files to be restored or select all files.
8. Click the **Restore** button.

Database File

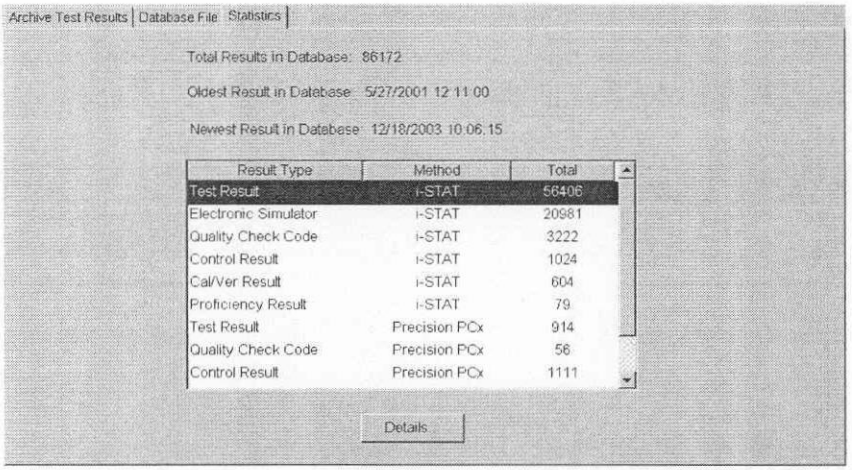
Backup Database File: This function allows the user to manually perform the same operation that occurs when the automatic database backup occurs. It creates a complete backup of the database file to the specified drive/directory.

Compact Database File: When the backup and delete or delete only functions are executed, the deleted data is removed from the database but the disk space the data occupied in the database file is not. The compaction function creates a new copy of the database with the excess space removed, creating a smaller, better organized and, therefore, more responsive database. If CDS functions such as opening or refreshing a data viewer grow noticeably less responsive over time, compaction of the database may help. It is recommended that compaction function be executed at least once a year.

Statistics

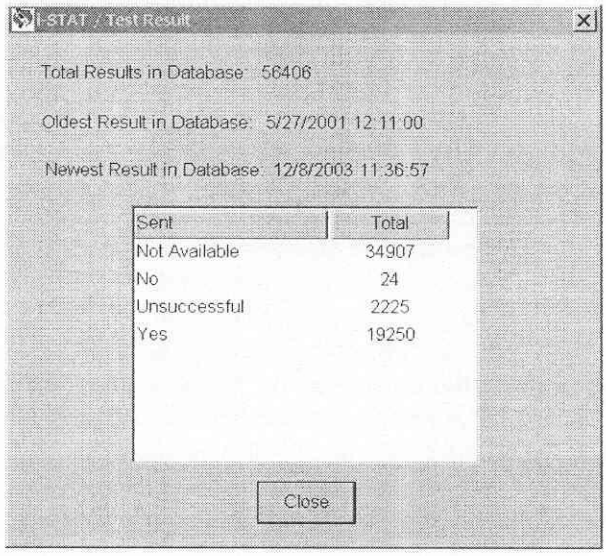
A "Statistics" tab page allows users to view a summary page that lists:

1. The total results in the database,
2. The date and time of the oldest result in the database,
3. The date and time of the newest result in the database, and
4. A breakdown of the total results in the database by Result Type and Method.



Selecting an individual Result Type and then clicking on Details allows you to view a similar statistical breakdown for that particular Result Type:

1. The total number of that particular Result Type in the database,
2. The date and time of the oldest result of that type in the database,
3. The date and time of the newest result of that type in the database,
4. A breakdown of the number of this particular result type that have been sent successfully (Yes), unsuccessfully, or not sent at all (No) to the LIS/HIS. Note: a listing in this window for "Not Available" indicates that there are records of this type in the database where the details data have been deleted, so the application cannot determine whether that particular record was sent or not.



INVENTORY WORKSPACE

Overview

The Inventory Workspace is organized under five tabs with the following functions:

- Stock: define reorder triggers, view and edit inventory
- Distribution: track items distributed from central stock to different locations
- Orders: track pending and received orders, view reports on received items
- Items: define inventory items
- Inventory log: view a log of major user actions

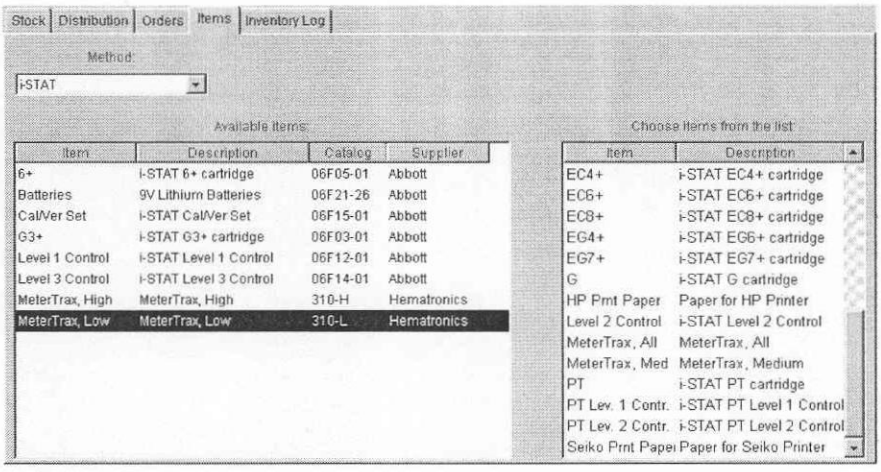
Populate the Items tab first, followed by the Stock tab where current inventory should be entered and reorder triggers defined.

Items

The Items tab is used to define the inventory items for the i-STAT System and other point-of-care tests.

To select an item available from i-STAT and its distributors, highlight the item in the **Choose items from the list** on the right side of the window, then click the arrow next to the **Add** button in the tool bar and click the **Selected** button. The item will move to the **Available items** list on the left side of the window.

To add an item not available from i-STAT and its distributors, click the arrow next to the **Add** button in the tool bar, then click the **New** button and complete the displayed information form.



To delete an item from the Available items list, highlight the item, then click the **Delete** button in the tool bar. If the item was selected from **Chose items from the list**, the item will be moved from **Available items** back to this list.

To edit information under the **Available items** list, click the **Edit** button in the tool bar.

Stock

The Stock tab includes both Inventory and Estimated Inventory statistics.

Inventory: The number of given items as counted and entered by the user. The inventory is automatically updated when new orders are received under the Orders tab.

Estimated Inventory: The number of i-STAT cartridges and MediSense PCx and/or PCx Plus glucose test strips as estimated by the workspace software. The initial Estimated Inventory is taken from the Inventory column. Every time a cartridge or glucose test strip result is transmitted to the Central Data Station software, the count of the estimated inventory decreases by 1. The Estimated Inventory is automatically updated when new orders are received under the Orders tab. The Estimated Inventory item count is adjusted to the Inventory count whenever the Inventory column is manually edited.

Startup Option

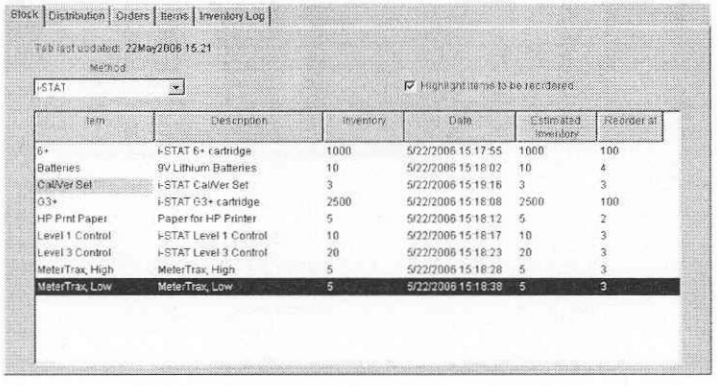
The items added under the Items tab will be listed under the Stock tab with **Inventory** and **Reorder** set to 0. There are two ways to populate the Inventory column.

1. Count current stock. Go to the Stock tab, click on the **Edit** button in the tool bar, and enter the current inventory. Lot numbers and Expiration dates will not be tracked for inventory entered by this method.

2. Count current stock along with lot numbers, expiration dates and locations. Go to the Order tab and enter and receive the POs for the existing stock. Go to the Stock tab and manually adjust the Inventory to the current stock count. (Alternatively, receive only the current stock count.) This option allows the user to take advantage of the lot number and expiration date tracking capabilities of the workspace.

Click on the Edit button on the tool bar and enter the reorder trigger numbers.

Click a check mark next to **Highlight items to be reordered**. Items that need to be reordered will be highlighted. (See CalVer Set in illustration below.) Reorders are highlighted based on the **Estimated Inventory**.



The inventory can be edited by highlighting the item and clicking the **Edit** button or by clicking the **Adjust Invent** button, selecting the item from the drop down menu, and adding or subtracting units. When the **Inventory** is edited, the **Estimated Inventory** is automatically made equal to the **Inventory**.

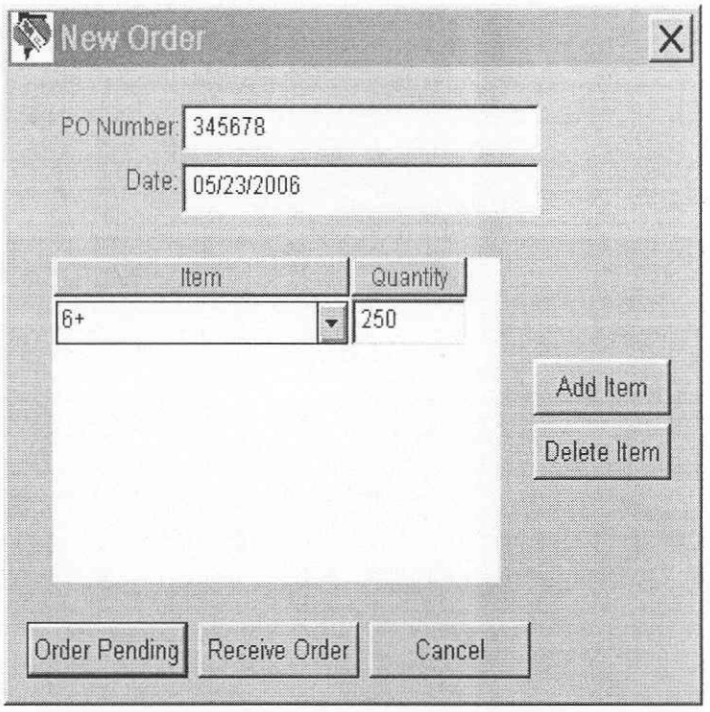
The **Estimated Inventory** for i-STAT cartridges and MediSense PCx glucose test strips will automatically begin updating with the next analyzer transmission. Click the **Refresh** button to update the workspace for transmitted data. Both the **Inventory** and the **Estimated Inventory** are updated automatically when orders are received under the Orders tab.

Periodically, the **Estimated Inventory** should be updated manually. This is necessary to account for other consumables as well as for cartridges and strips that are discarded before testing, such as expired inventory. Click the **Estim. Invent.** button in the tool bar to adjust the **Estimated Inventory**.

Orders

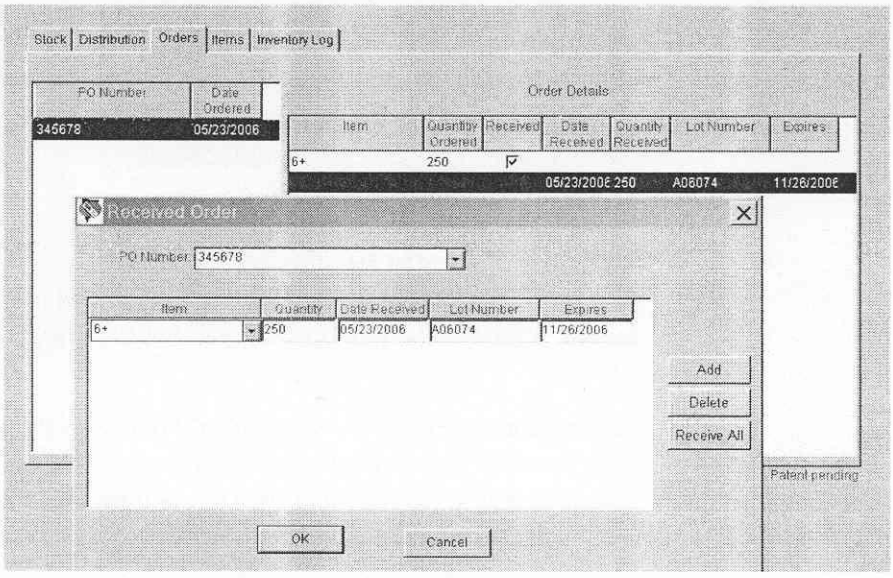
To record a new order, click on the **Add** button in the tool bar. Select the item from the drop down menu under **Item** and enter the quantity. Click the **Add Item** button to add another item or the **Delete Item** button to delete an item.

To enter information about a received order right away, click on the **Receive Order** button. To enter information about a received order later, click the **Order Pending** button.

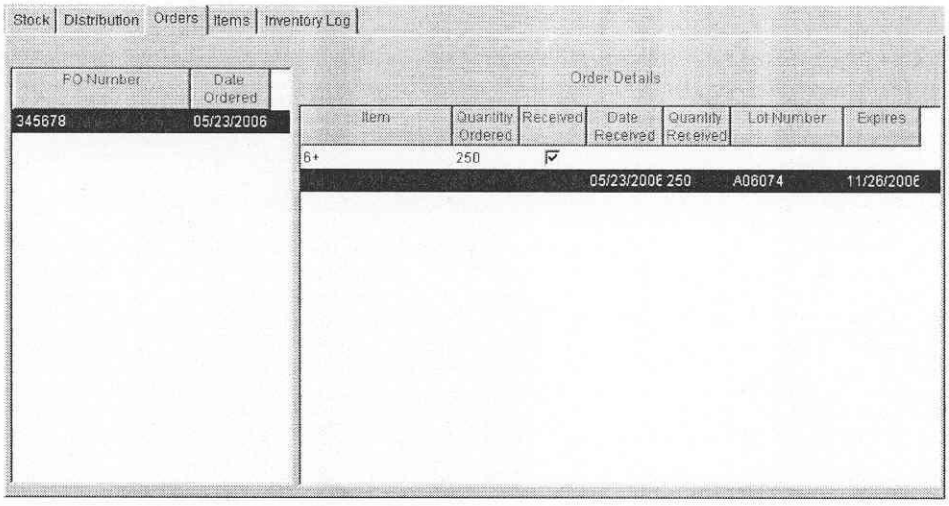


To receive an item or to edit order information, click the **Edit/Receive** button in the tool bar. Highlight the PO Number and enter the **Order Details**.

Note: The lot number and expiration date are used in the Distribution tab. Therefore, PO, lot number and expiration date information for consumables in inventory should be entered here. The PO number field can accommodate up to 20 characters.



Click the **Add** Button to add another item or the **Delete** Button to delete an item. Click the **Receive All** Button to automatically enter items and quantities, as they were ordered.



Use the **Delete** button on the tool bar to delete an order.

Use the **Find Lot** and **Find Next** buttons on the tool bar to find the PO associated with a received lot.

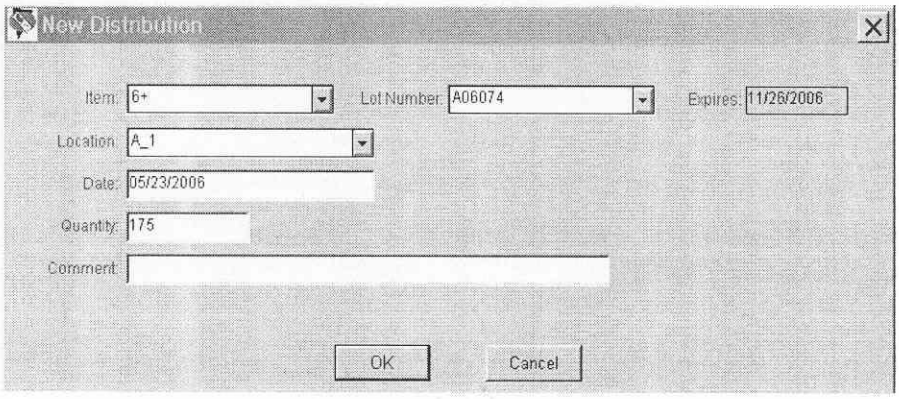
Use the **Delete Lot** button on the tool bar to delete a lot number that has expired or has been used up.

The **Report** button on the tool bar is used to view all received items by date range.

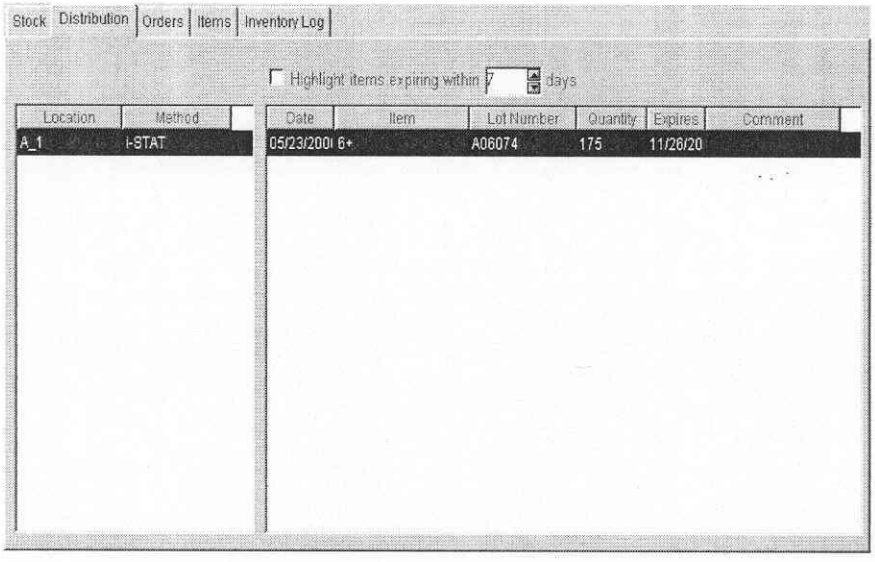
Use the **Add Note** button on the tool bar to add a note to the **Inventory Log**.

Distribution

Use the **Add** button in the tool bar to record the distribution of consumables. The Item drop down menu includes all consumables entered in the Items tab. The Location drop down menu includes all locations entered in the Instrument and Location Workspace. The Lot Number drop down menu includes lot numbers for the selected items received in the Order tab. The expiration date is entered automatically. A comment of up to 16 characters can be entered.



The Distribution tab will list each location with its consumables. Define an alert date and click a check mark next to **Highlight items expiring within xx days** to alert you to transfer stock to a different location where it can be used before its expiration date.



Use the **Delete** button on the tool bar to delete a distribution.

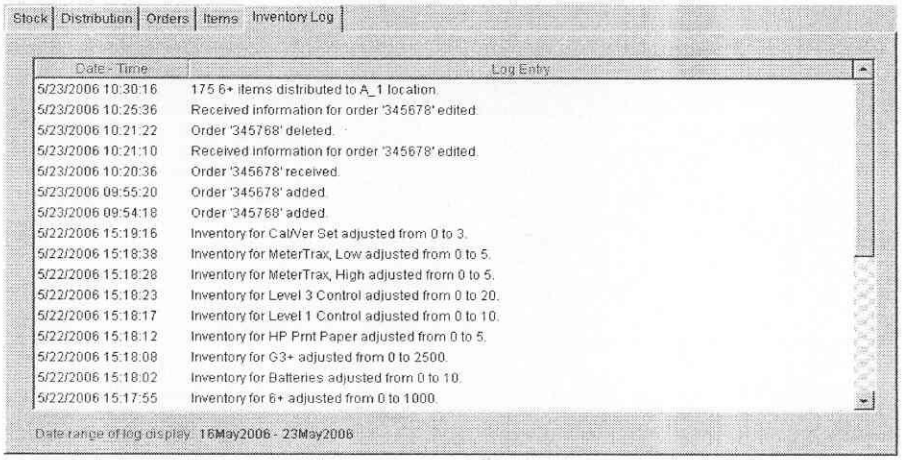
Use the **Transfer** button in the toolbar to move consumables from one location to another.

Use the **Find Lot** button to find a location where a consumable of a specific lot has been distributed. Click the **Find Next** button to find other locations for this lot.

Use the **Add Note** button to add a note to the Inventory Log.

Inventory Log

The Inventory Log documents each action taken in the Items, Stock, Distribution and Orders tabs. Click the **Date Range** button in the toolbar to select the a Default date range or a Start and End date for this report. Click the Delete button to delete entries in the log.



CUSTOMIZATION WORKSPACE

Overview

This workspace is used to create profiles with site specific test characteristics for the analyzers. See the Customization section of this manual for details of items that can be customized and their default settings.

Password

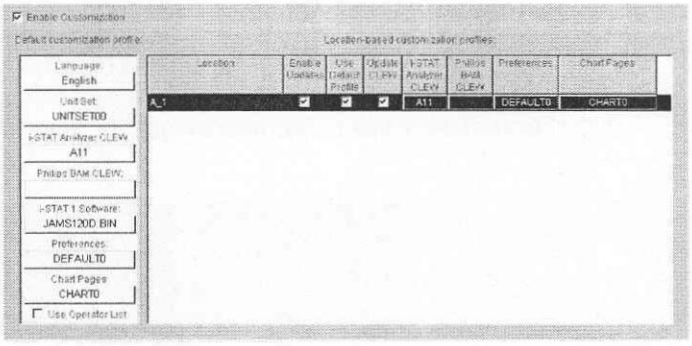
The Customization Workspace is password protected. If the Security feature is disabled, the default password is **istat**. If the Security feature is enabled, the user uses the same password as their CDS application logon password. To change the password, select **Tools** and **Change Password** from the menu bar. A password from 3 to 8 characters can be used.

Enabling Customization

To enable customization, click the box to check it. When customization is enabled, the Central Data Station will check the Customization Profile for the location each time an analyzer is downloaded. If the location has the **Enable Updates** option checked, the Central Data Station will update the analyzer with the current Customization Profile for that location as noted below.

- Analyzers designated to Report location as download location in the Instrument workspace will be updated with the Customization Profile assigned to the download location, regardless of the location to which the instrument is assigned. Care should be taken when downloading instruments from locations other then their assigned location.

- Analyzers designated to Always report location as this assignment in the Instrument workspace will always be updated with the Customization Profile for the instrument's assigned location, regardless of the physical location from which it downloads.

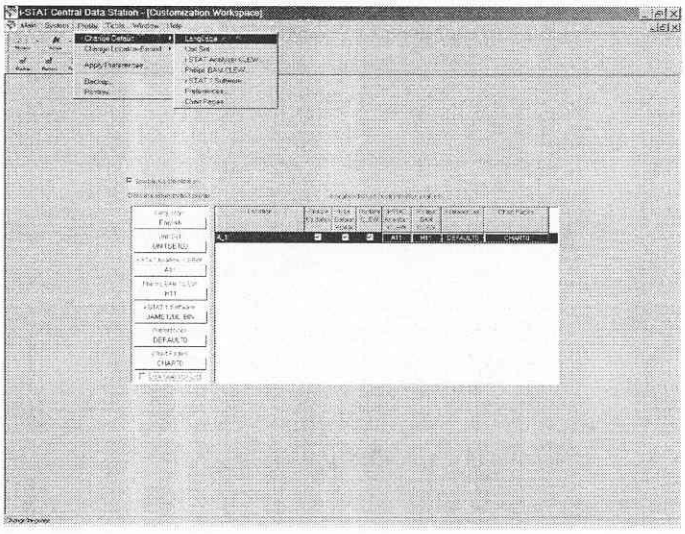


If a location has the **Enable Updates** option unchecked, downloading from that location will result in no customization changes being made to analyzers designated to **Report location as download location.** Analyzers designated to **Always report location as this assignment** will not be updated if the assignment location for the instrument has the **Enable Updates** option unchecked, regardless of the setting associated with the physical location from which it downloads.

User can also disable/enable CLEW updates by location. The default setting is to have the CLEW updates occur automatically for all locations. To disable a particular location, simply click on the corresponding check box under **Update CLEW** to remove the check mark.

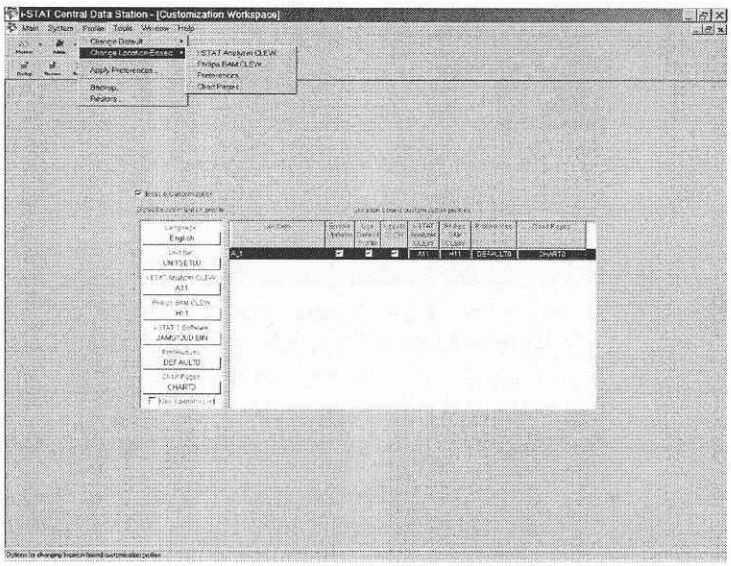
Default Customization Profile

The first step in customization is to create a default customization profile. This is the profile initially assigned to every new location. To change the default profile, use the directions under Making Selections or click the menu option **Profile ⇨ Change Default** and the item to be changed. The changes in the default profile are automatically applied to every location using the default profile.

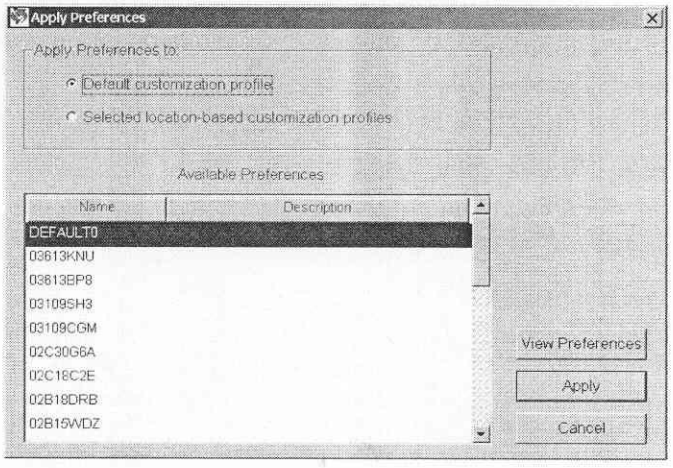


Location-based Customization Profiles

Different customization profiles can be created for different locations. Uncheck the **Use Default Profile** box for the location and double click **i-STAT Analyzer CLEW** or **BAM CLEW** to change the CLEW or double click **Preferences** to change any of the preferences. Alternately, select the menu option **Profile ⇨ Change Location-Based** and the item to be changed. Changes in the customization profile can be made for several locations at once by selecting the locations and then selecting the appropriate option from the Profile Menu. If a location has the **Use Default Profile** option checked, its customization settings will not be changed even if it is selected. Note that Language and the Unit Set from the default customization profile are always used.



Preferences for locations can also be changed by selecting an existing preference from the Apply Preferences submenu. Select the location or locations to be changed. Click **Profile ⇨ Apply Preferences.** Select the desired preferences and click **Apply**. Click **View Preferences** to review a set of preferences.

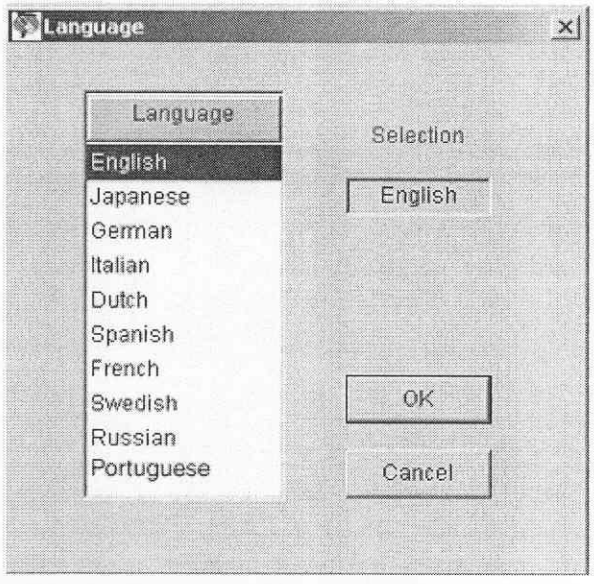


Making Selections

Selections are made from options in the following ways:

- Select one of the seven main Customization options by double clicking the box for **Language**, **Unit Set**, **i-STAT Analyzer CLEW, Philips BAM CLEW, i-STAT 1 Software, Preferences, or Chart Pages**.
- After making a selection in the Language, Unit Set and CLEW window, click the **OK** button to save the selection or click the **Cancel** button to return to the previous selection.

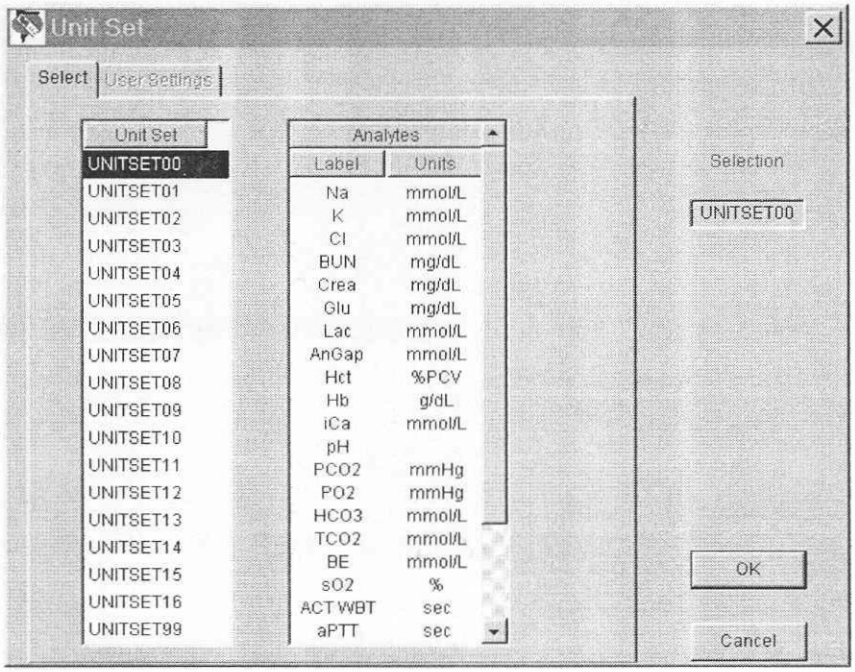
Language Window



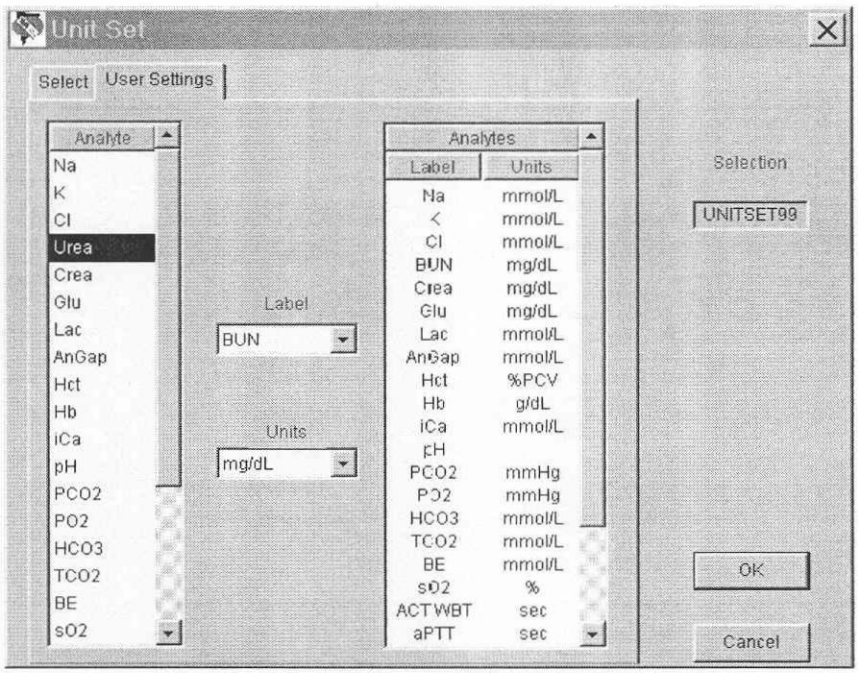
Note: Russian is available only on the i-STAT Portable Clinical Analyzer and Portuguese, Danish, and Finnish are available only on the i-STAT 1 Analyzer.

Unit Set Window

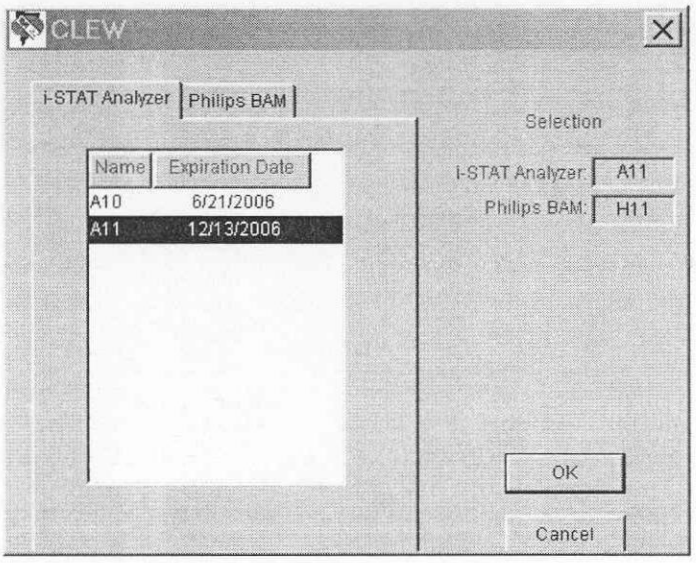
Details of each unit set are displayed under the Analytes column. Details are also listed in the Customization section in this manual.



To create a unique unit set, click **UNITSET99** and then the **User Settings** tab. Then select the name and units for each analyte or test.



i-STAT Analyzer and Philips BAM CLEW Windows

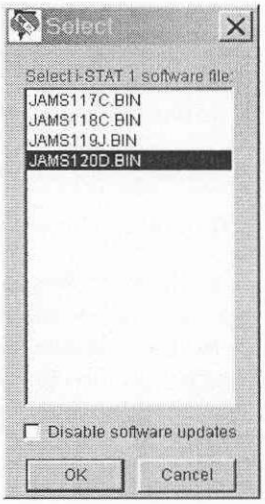


A new CLEW is added to the window via the software update process twice a year. If the **Update CLEWs** feature is active, the Default customization profile must be updated after each new CLEW is added. Click the new CLEW and click OK. Note that there are separate CLEWs for the i-STAT analyzer and the Philips Blood Analysis Module.

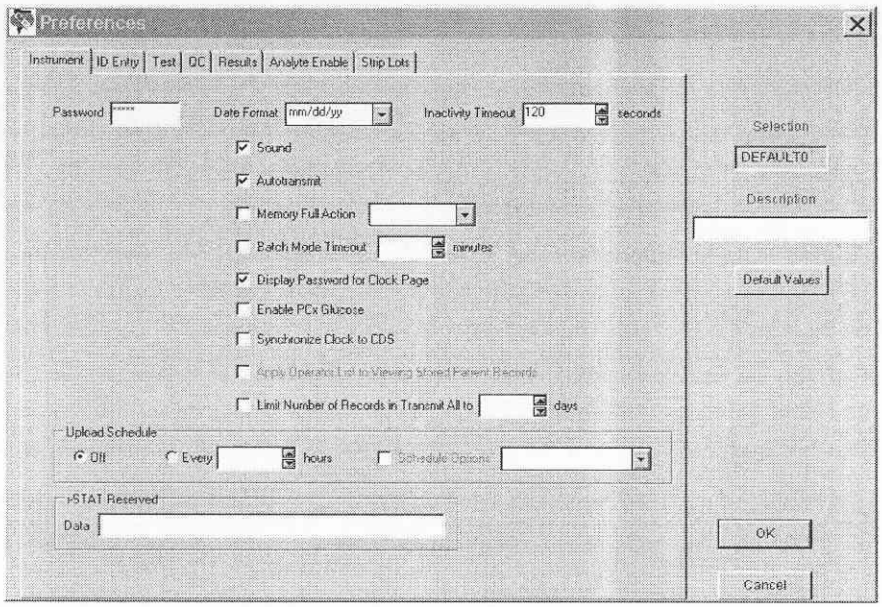
Note: Before changing to a new CLEW ensure that all analyzers have been updated to a compatible application software version.

i-STAT 1 Software Window

A new JAMS application software is added to the window via the software update process twice a year. Click the new JAMS and click OK. Selecting the new JAMS aloows users the option of updating their i-STAT 1 analyzers remotely or locally using the Customization Workspace. Please see the Technical Bulletin "Updating Analyzer Software" for full details on performing this procedure. Checking "Disable Software Updates" disables this feature.



Preferences Window



For detailed descriptions of the preferences, see section 9, Customization. The Preferences Window has seven tab pages. Click the tab to display the desired page. The following conventions are used in the Preferences pages:

- Enable/disable an option by clicking the check box to check/uncheck it.
- Change a numeric setting by clicking and holding the ▲ or ▼ symbol or manually entering the number.
- Select an option from a list by clicking the ▼, and selecting the option from the list.
- Select from multiple options by clicking the radio button next to the desired option.
- Enter values into fields, such as for Reference Ranges and Strip Lot Numbers.

When all information has been entered, a button is pressed:

- **Default Values** will restore the default settings to the open window.
- **OK** will store the new settings.
- **Cancel** will ignore any new settings and restore the current settings.

Each Customization Profile is assigned a unique name by the CDS program. This name appears under the Preferences column in the Customization Workspace window, on the Customization screen on the i-STAT 1 Analyzer, on the Analyzer Status screen on the i-STAT Portable Clinical Analyzer and on the Blood Analysis Setup screen of the Blood Analysis Module.

A description can be associated with a profile using the **Description** field in the Preferences Window.

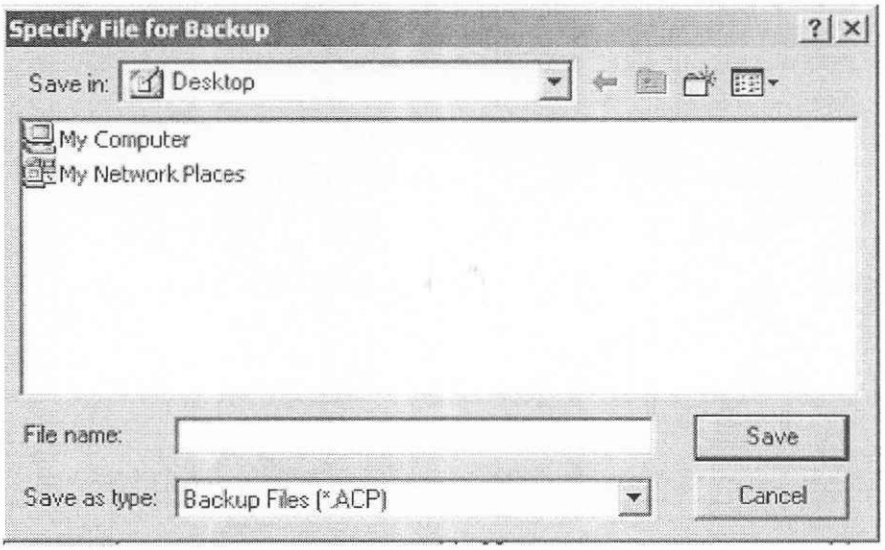
Caution: Close the Customization Workspace when finished to prevent inadvertent changes.

Chart Page Selection Box

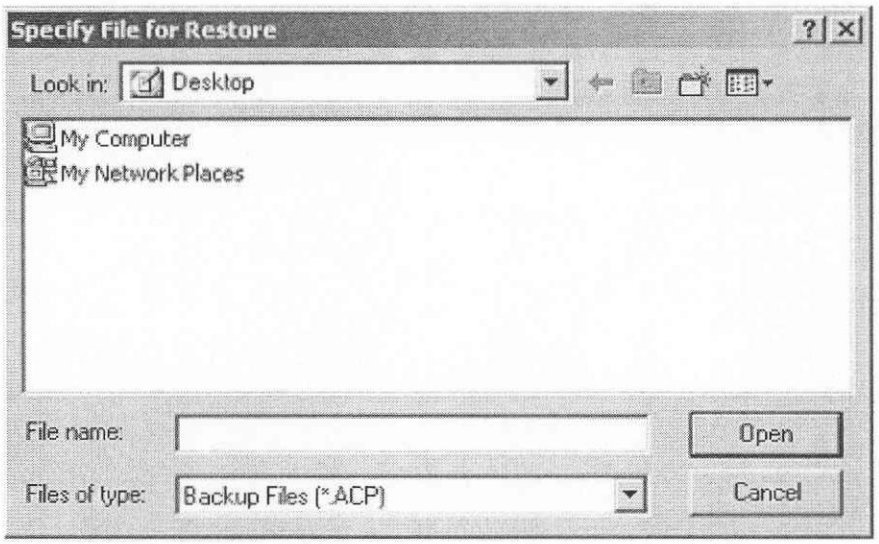
The Chart Page selection box is part of a feature allowing users to customize the Chart Page on their i-STAT 1 analyzers in order to capture user-defined information such as ventillator settings. See the "i-STAT 1 Analyzer Chart Page Customization" Technical Bulletin for full details.

Backup and Restore Profile

The current customization profile can be stored by selecting **Profile ⇨ Backup...** from the menu bar or by clicking the **Backup** toolbar button, selecting the directory where the profile is to be stored, typing in a file name for the profile, and clicking the **Save** button.



To restore a profile to the CDS, click **Profile ⇨ Restore...** or the **Restore** toolbar button. Select the directory and backup file to restore and click the **Open** button.



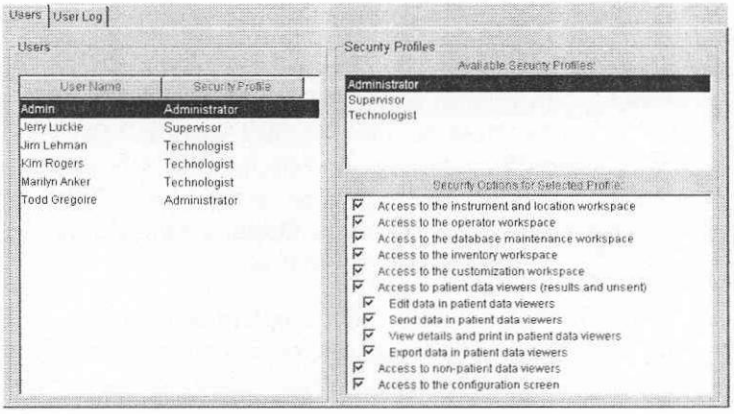
USER ADMINISTRATION WORKSPACE

Overview

The User Administration Workspace is designed as a tool for system administrators. It allows administrators to manage security profiles (a set of security settings determining the access to different CDS screens and functions), manage users, and assign users to security profiles.

Access

Only users designated as administrators can access the User Administration Workspace in the CDS by clicking on **Main** ➪ **Open Administration Function** ➪ **User Administration**. A Password dialog will then appear. Type in your CDS log-in password and click on **OK**.

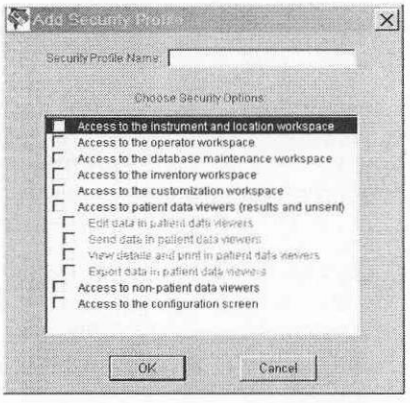


Creating Security Profiles

Once the User Administration Workspace is activated, the Administrator will need to determine how many different security profiles are needed for their facility, and what workspaces and functions should be available to users at those different security levels. Once those decisions have been made, the next step is to create the desired security profiles in the User Administration Workspace.

Please note that an Administrator profile will always exist in the User Administration Workspace. It cannot be edited or deleted, and allows access for those designated users to all CDS Workspaces and functions.

To create a new security profile: click on **Profile** ➪ **Add...** An "Add Security Profile" dialog will then appear.



Type in the name of the new Security Profile, then check off the different workspaces and functions users assigned to that security level will be allowed to access, and then click **OK**. The newly created security profile will then be added to the Available Security Profile list.

Deleting Security Profiles

To delete an existing Security Profile, click on the profile you want to delete in the Available Security Profiles window. Click on **Profile** ➪ **Delete**, and answer **"Yes"** to the confirmation message that appears on the screen.

Please note that a Security Profile can only be deleted if all of the Users assigned to that particular profile have first been deleted from the Users window. If all of the users have not first been deleted, "Error Accessing Database" and "Error Deleting Profile" messages will appear.

The Administrator Security Profile is permanent and cannot be deleted.

Editing Security Profiles

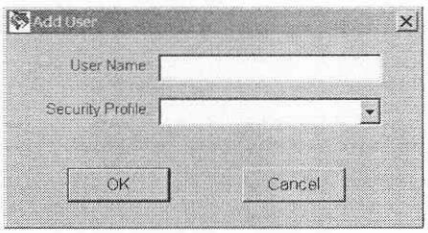
To edit an existing Security Profile, click on the profile you want to edit in the Available Security Profiles window. Click on **Profile** ➪ **Edit**. The name of the profile will then be highlighted in blue. If you wish to edit the profile name, simply type in the new profile name. Then select or deselect the desired listings under the "Security Options for Selected Profile" window by clicking on the corresponding check box.

When all edits are complete, simply click on **Profile** ➪ **Edit**, and answer **Yes** to the confirmation message that appears about saving the new changes.

Adding Users

Once all the Security Profiles have been created, the next step is to create users and assign them to the various security profile levels.

To add a user to a security profile when in the User Administration Workspace, click on **User** ➪ **Add...**. An Add User box will then appear on the screen.



Type in the User Name in the first line, then choose the appropriate Security Profile from the drop down list and click **OK**. The new user listing will then appear in the User window.

Deleting a User

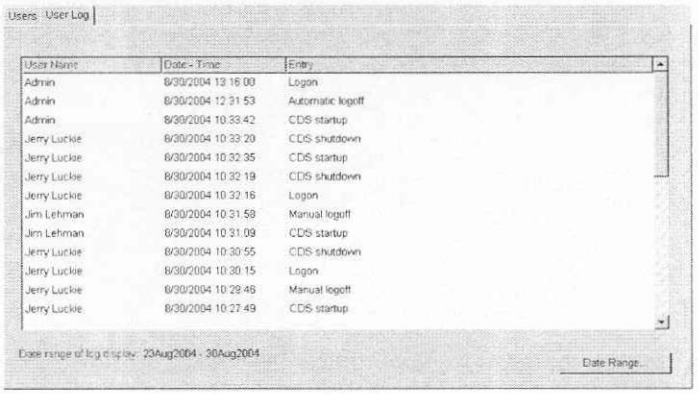
To delete a user, select the user to be deleted, click on **User** ➪ **Delete**, and answer **Yes** to the confirmation message. Note: the user who is currently logged on cannot be deleted.

Assigning a User to a Different Profile

To assign an existing user to a different Security Profile, click on **User** ➪ **Assign Profile**. A drop down menu will appear next to the user's name. Simply click on the desired Security Profile, then click on **User** ➪ **Assign Profile**, and answer **Yes** to the confirmation message that appears asking if you want to save changes.

User Log

The User Log tracks the following user activities: CDS Startup and Shutdown, User Logon, Manual and Automatic User Logoff, and Disabling of the Security feature via the Customization Screen.

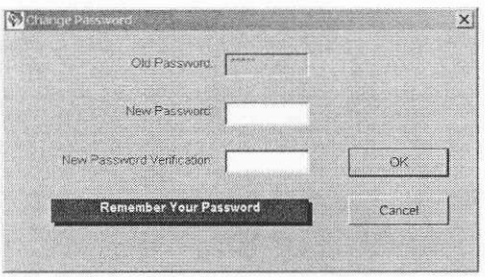


PASSWORD MANAGEMENT

Passwords

Once all the Security Profiles are created, and all CDS users are assigned to the appropriate Profiles, the Administrator should provide the users with their assigned User Names. Their initial password is **istat**.

When a user logs on to the CDS application for the first time, a dialog box asking for a User Name and Password will appear. They should input their assigned User Name supplied by the Administrator, and the password **istat**. A dialog will then appear indicating that they must change their password. After clicking on **OK**, the following dialog will appear:



The user should type in a unique password of their choosing in the space provided, then retype that same password on the New Password Verification line and click **OK**. The password must have a minimum length of 3 alphanumeric characters, and a maximum length of 12 alphanumeric characters.

Once the password is changed, the user will then use their new password for all subsequent CDS log-ons.

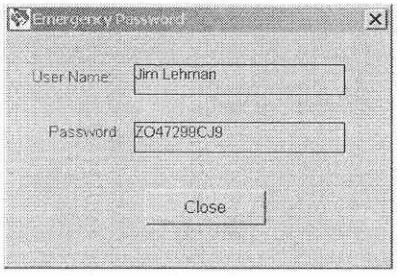
Emergency Passwords

If a user forgets their User Name or Password, they have two options for accessing the CDS application:

1. If available, the Administrator can log onto the User Administration Workspace and look up the User Name from the User Window. An Emergency Password for this particular user can then be obtained by performing the following:

a. Click and highlight this particular user's listing in the User Window.

b. Click on **User ➪ Emergency Password**. A box will appear with an Emergency Password that this particular user can use. Note: Once this user uses the Emergency Password to log in, they will be immediately prompted to change their password for future CDS log-ins. They cannot continue to use the Emergency Password for log-in purposes.



2. If the Administrator is not available, the user can contact their local Support Representative for an emergency User Name and/or password. As with option 1 above, once this user uses the Emergency Password to log in, they will be immediately prompted to change their password for future CDS log-ins. They cannot continue to use the Emergency Password for log-in purposes.

Changing a Password

If a user is logged on to the CDS application, they can choose to change their password at any time by clicking on **Tools ➪ Change Password**. A dialog box will appear asking them to enter their Old Password, as well as their New Password (twice). After entering this information, the user clicks on **OK** and answers Yes to the question that appears asking if they really want to change password.

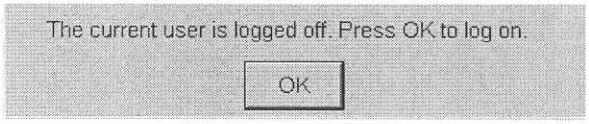
SYSTEM LOGOFFS

Overview

The CDS provides the capability for manual and automatic user logoffs. In the logged off state, the majority of CDS screens and functions are not available. However, analyzer and BAM data can continue to be transmitted to the application, and subsequently sent to the LIS/HIS (if applicable). Also, the monitors remain open if they were open prior to logoff.

Manual Logoff

Once a user has completed their CDS tasks, they can log off by clicking on **System ➪ Log Off**. A box will then appear on the screen indicating that the current user has logged off.



Automatic Logoff

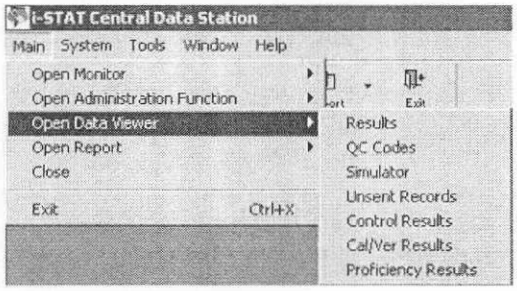
Automatic logoffs are optional and can be enabled in the i-STAT CDS Customization screen, as described in the Security section above on page 22-13.

Overview

Data from instruments downloaded to the CDS are viewed in the Data Viewers.

Data downloaded from the i-STAT 1 Analyzers can be viewed in separate Data Viewers for Results, QC Codes, Simulator, Unsent Results, Control Results, Calibration Verification (or Linearity) Results and Proficiency Results (external quality control).

Control, Calibration Verification and Proficiency Results from the Portable Clinical Analyzers and Blood Analysis Modules will appear in the Results Data Viewer.

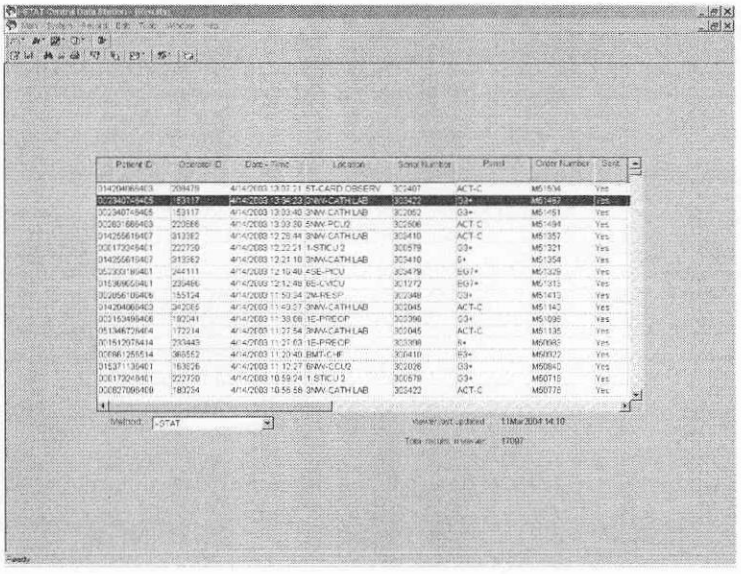


Data from the Medisense Precision PC*x* Plus Glucose Test Strips can now be viewed in the Data Viewers, alongside the data from the Precision PC*x* strip. To determine which strip type was used on a particular testing run, look at the column entitled **Panel**. Precision PC*x* Plus strip runs will be labeled **PCx Plus Glucose**, while Precision PC*x* strip runs will be labeled **PCx Glucose**.

Information in Data Viewers

Data for only one method at a time, such as the i-STAT cartridges, is displayed in a viewer. To switch to a different method, select the method from the selection list in the lower left corner of the viewer. The exception is the Unsent Results Data Viewer which displays results from all methods. Records are listed based on which column is being sorted. Data can be displayed in ascending or descending order by clicking a column as described above.

Example: Results Data Viewer



Refreshing the Data

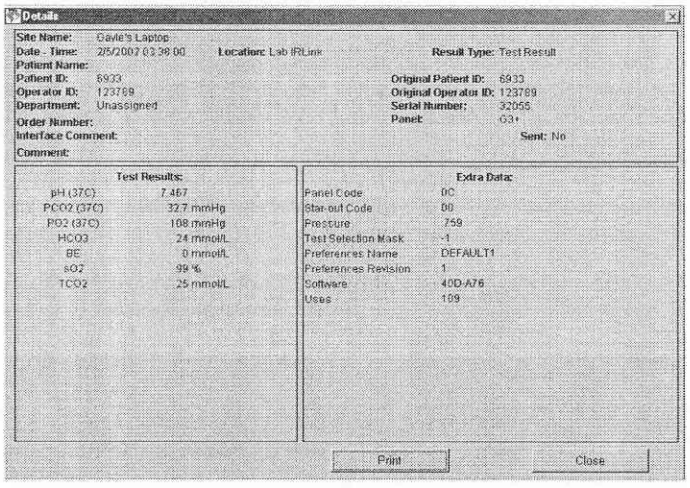
Data is received continuously by the CDS. Updating the viewers with the continuous incoming stream of data would make viewing the data difficult. Therefore, new data is not added to a viewer until the **Refresh** button is pressed. The window can also be refreshed by pressing **F5** or selecting **Refresh** from the **Window** option menu on the menu bar. The date and time of the latest refresh are listed on the bottom right of the window.

Viewing Details

The details of records in the Results, Control, Cal/Ver, Proficiency and Unsent Results Viewers can be viewed by double clicking the record, by selecting the record and clicking the **Details** toolbar button, or by selecting **Record ➪ View Details...** from the Menu.

Many of the Extra Data details may be helpful to the Customer Support representative in troubleshooting.

Example of Details for Results Viewer

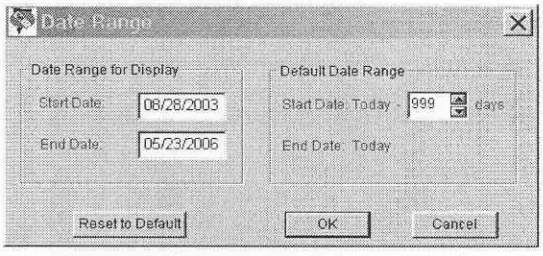


Customizing the Data Viewers

The viewers can be customized for individual preferences. The following aspects of the viewers are user configurable.

❑ **Selecting a Date Range**

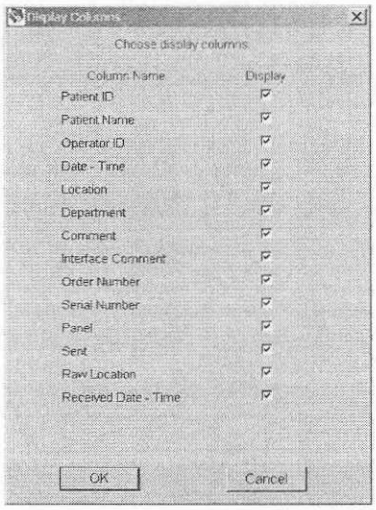
The initial default date range for data in a viewer is the current date and back 7 days. The initial default range can be changed by selecting **Tools ➪ Customize Viewer ➪ Date Range...** from the text menu, or by clicking the arrow next to the **Customize** toolbar button, then the **Date Range** button. A default date range can be set but overridden by entering a different date range for display. The maximum default date range allowed is 999 days.



The selection of a shorter date range enhances the system performance by limiting the amount of information needing to be presented. It is always possible to expand the range to view results from earlier and then reset to a more limited default period. The date range function only limits what is presented, not what is in the database.

❑ Selecting Columns to View

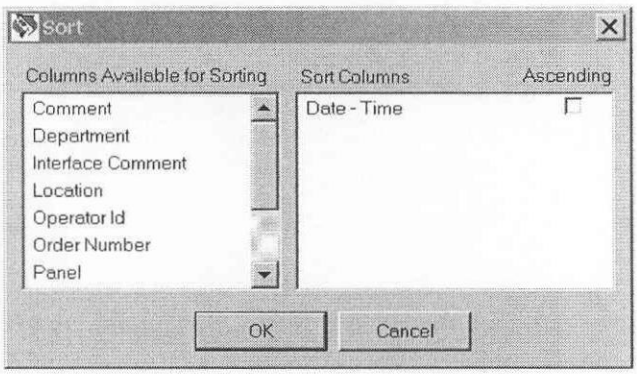
Columns can be hidden. Select **Tools ➪ Customize Viewer ➪ Display Columns** or click the arrow next to the **Customize** toolbar button, then the **Columns** button. To hide a column, click the box following the column's name to uncheck it and then click **OK**. To make the column visible again, click the empty box following the column's name to check it and click the **OK** button.



The Raw Location and the Receive Date/Time columns allow users to track the location where particular analyzers are being downloaded, plus the time intervals in which users are transmitting data to the Central Data Station.

❑ Sorting Data

For customers who want to sort data in the Data Viewers by multiple column criteria, a new multilevel sorting feature has been added. To access this feature, open the desired Data Viewer, click on **Tools ➪ Customize Viewer ➪ Sort...**, or click the arrow next to the **Customize** toolbar button, then the **Sort** button.



A two-sided Sort dialog will then appear, listing **Columns Available for Sorting** on the left, and **Sort Columns** on the right. Simply click the listing under **Columns Available for Sorting** that you wish to sort your data by, and then drag that column title to the right hand side of the screen under the **Sort Columns section**. Once all of the columns you wish to sort by are under the **Sort Columns** section, check whether you want that particular column to be sorted by ascending or descending order, by placing or removing the check mark in the **Ascending** box.

Once all selections have been made, simply click on **OK** and the sort process will be completed, taking you back to the Data Viewer screen.

Note: By default, the Date/Time column is automatically placed under the **Sort Columns** section with descending order selected. If you do not wish to sort by Date/Time, simply click on that column listing and drag it back to the left side of the screen under **Columns Available For Sorting**.

Editing a Record

To edit a record, highlight the record to be edited, click **Record** ➪ **Edit Record** in the menu bar or click the **Edit** toolbar button.

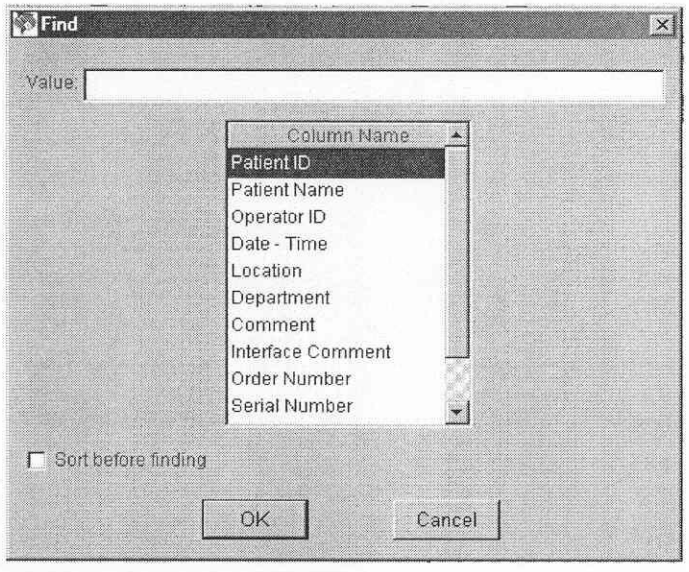
Different viewers have different editable items. Results that have been successfully sent to the LIS or HIS have only an editable Comment. Results marked as **Pending** or **In Progress** cannot be edited.

The Patient ID, Patient Name, Operator ID, Comment, Interface Comment and Order Number can be edited in the Results Viewer. Use the **Tab** key or the mouse to move across the line. The original Patient and Operator IDs will appear along with the edited IDs in the Details window.

Finding a Record

Different viewers have different lists from which to select for a search based on the data presented. Click **Record** ➪ **Find...** on the menu bar or click the **Find** toolbar button. Selecting **Sort before finding** before clicking **OK** will present the records in ascending order for the value after the first record matching the search is found.

Type on the Value line the desired parameter then highlight that parameter and click **OK** to find.



Printing Selected Records

With a Data Viewer open, highlight the records to be printed, click **Record** ➪ **Print Selected Records** or click the **Print** toolbar button.

Send Selected Records

With a Data Viewer open, highlight the records to be sent, click **Record** ➪ **Send Selected Records** or click the **Send** toolbar button.

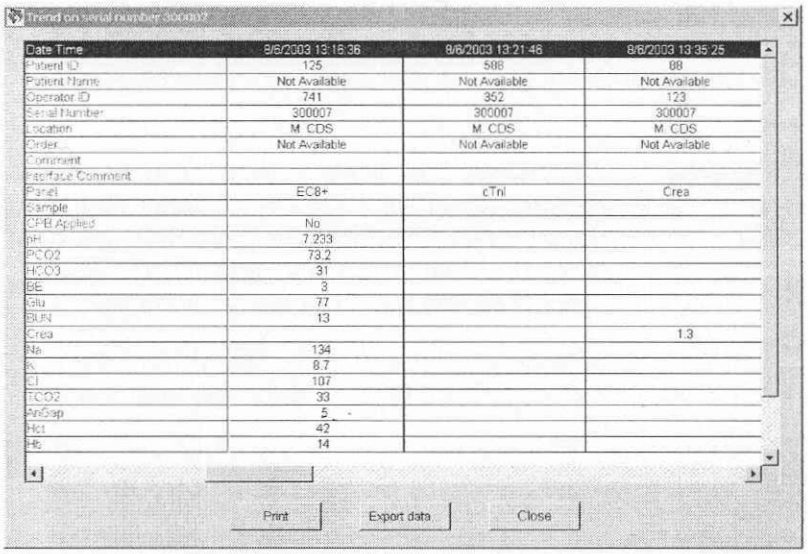
Trending Results

Results records in the Results, Control Results, Cal/Ver Results, Proficiency Results and Unsent Results Viewers can be selected for Trend reports. Trends can be performed on Patient ID, Control Lot Number, Calibration Verification Kit Number, Proficiency ID, Operator ID, Analyzer Serial Number or by a selection of records.

With the Data Viewer open, click **Record** ➪ **Trend,** then the trend option from the menu bar or click the arrow beside the **Trend** toolbar button and click the desired trend option. Up to 25 records are presented from oldest to newest data.

To trend by selection, highlight the records to be included in the trend report then perform the Trend function.

Example of a Result Trend by Serial Number



Date Time	8/6/2003 13:16:36	8/6/2003 13:21:48	8/6/2003 13:35:25
Patient ID	125	588	88
Patient Name	Not Available	Not Available	Not Available
Operator ID	741	352	123
Serial Number	300007	300007	300007
Location	M. CDS	M. CDS	M. CDS
Order	Not Available	Not Available	Not Available
Comment			
Interface Comment			
Panel	EC8+	cTnI	Crea
Sample			
CPB Applied	No		
pH	7.233		
PCO2	73.2		
HCO3	31		
BE	3		
Glu	77		
BUN	13		
Crea			1.3
Na	134		
K	8.7		
Cl	107		
TCO2	33		
AnGap	5		
Hct	42		
Hb	14		

QC Codes Viewer

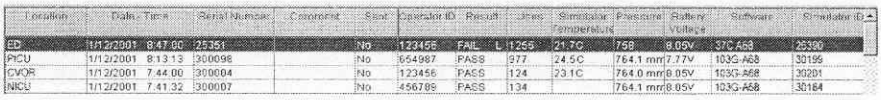
All Quality Check Codes are listed in chronological order. To add a comment, click the record, then **Record** ➪ **Edit Record** on the menu bar or click the **Edit Record** toolbar button. To sort the Quality Check Codes by type, click the Quality Code column header. To list again in chronological order, click the Date-Time column header.

Note: Panel is a binary code for the cartridge types.

Operator ID	Date - Time	Location	Serial Number	Sent	Comment	Quality Code	Pa
3148	12/12/2003 14:04:12	M. CDS	300007	No		CODE 147	26
35789	12/8/2003 13:47:13	M. CDS	300007	No		CODE 147	26
486	12/8/2003 13:40:11	M. CDS	300007	No		CODE 147	26
1245	12/8/2003 11:46:16	M. CDS	300007	No		CODE 147	26
444	8/5/2003 14:01:24	M. CDS	300007	No		CODE 147	26
222	8/5/2003 13:59:21	M. CDS	300007	No		CODE 147	26
255	8/4/2003 09:59:21	M. CDS	300007	No		CODE 145	26
33	7/29/2003 08:49:56	M. CDS	300007	No		CODE 147	26
220666	4/14/2003 14:09:43	5NW-PCU2	302508	Yes		CODE 43	20
183197	4/14/2003 10:01:42	1E-PREOP	303398	Yes		CODE 43	07

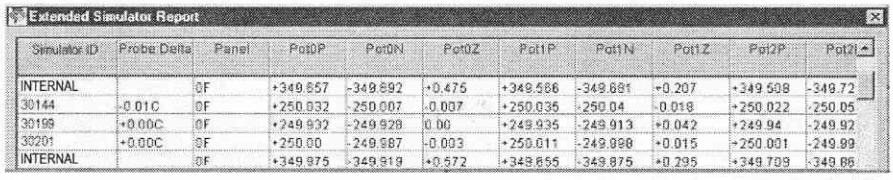
Electronic Simulator Viewer

All Electronic Simulator results, both external and internal, are listed in chronological order with the newest result at the top of the screen. To view all simulator results together for each analyzer, click the **Serial Number** column header to sort the analyzers by serial number or use the **Find...** option and sort for one analyzer. To list in chronological order again, click the **Date-Time** header.



Location	Date-Time	Serial Number	Comment	Sent	Operator ID	Result	Lines	Simulator Temperature	Pressure	Battery Voltage	Software	Simulator ID
ED	1/12/2001 8:47:00	25351		No	123456	FAIL L	1255	21.7C	758	8.05V	37C A68	25390
PICU	1/12/2001 8:13:13	300098		No	654987	PASS	977	24.5C	764.1 mm	7.77V	103G-A68	30199
CVOR	1/12/2001 7:44:00	300004		No	123456	PASS	124	23.1C	764.0 mm	8.05V	103G-A68	30201
NICU	1/12/2001 7:41:32	300007		No	456789	PASS	134		764.1 mm	8.05V	103G-A68	30184

To view the actual readings taken during the Electronic Simulator check, click **Record ➪ View Extended Simulator Report...** Note that the **Simulator ID** and **Probe Delta** columns can be viewed in the screen above by scrolling to the right.



Extended Simulator Report

Simulator ID	Probe Delta	Panel	Pot0P	Pot0N	Pot0Z	Pot1P	Pot1N	Pot1Z	Pot2P	Pot2I
INTERNAL		0F	+349.857	-349.892	+0.475	+349.566	-349.681	+0.207	+349.508	-349.72
30144	-0.01C	0F	+250.032	-250.007	-0.007	+250.035	-250.04	-0.018	+250.022	-250.05
30199	+0.00C	0F	+249.932	-249.928	0.00	+249.935	-249.913	+0.042	+249.94	-249.92
30201	+0.00C	0F	+250.00	-249.987	-0.003	+250.011	-249.998	+0.015	+250.001	-249.99
INTERNAL		0F	+349.975	-349.919	+0.572	+349.655	-349.875	+0.295	+349.709	-349.86

Unsent Records Viewer

This viewer is available only if an external interface installed by i-STAT is enabled in the Central Data Station Customization function. This data viewer displays records that have not been sent from the Central Data Station to an external computer system, such as an LIS. The incorrect information can be corrected using **Edit** and the corrected record resent.

Unsent results can be removed from the viewer by highlighting the record, clicking on **Record ➪ Mark Selected Records as Sent,** or by pressing the **F8** Key.

Sent Column Values

Sent Column Value	Definition	Can the record be resent?
No	This is the initial value when a data record is entered into the database.	Yes
Pending	This value means that the record is in the queue waiting to be processed by the Interface.	No
In Progress	This value means that the record is currently being processed by the Interface.	No
Forwarded (HL7 Protocol Only)	This indicates that the Record has been forwarded to the receiving system but has not yet received the Application acknowledgement indicating whether or not the LIS successfully processed the record.	Yes
Yes	This value means that the i-STAT Interface application successfully processed the record. For Data File Protocol Only: • "Yes means that the Data File was successfully created in the c:\ istat32\send directory. It does not necessarily mean that the record was processed by the LIS. • It is up to the receiving system to provide a status update to the CDS (See INTER32-SPC-011.doc)	No
Unsuccessful	This value means that the record send was not successful. The Interface Comment will provide some limited information as to why the record send was unsuccessful.	Yes

A data export option is available in the following areas of the Central Data Station application:

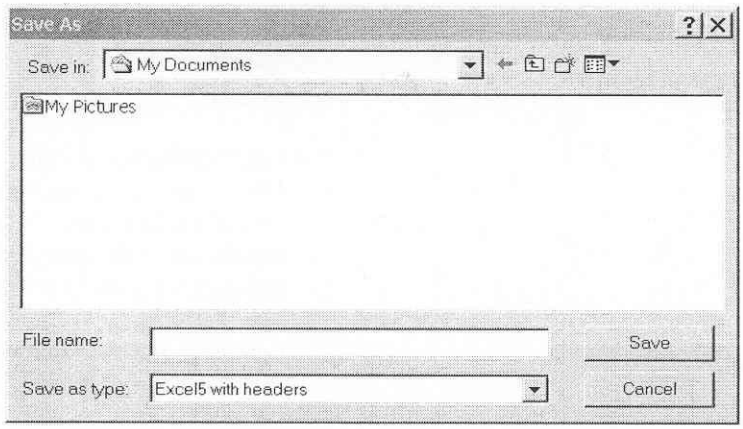
a. Data Viewers

b. Reports

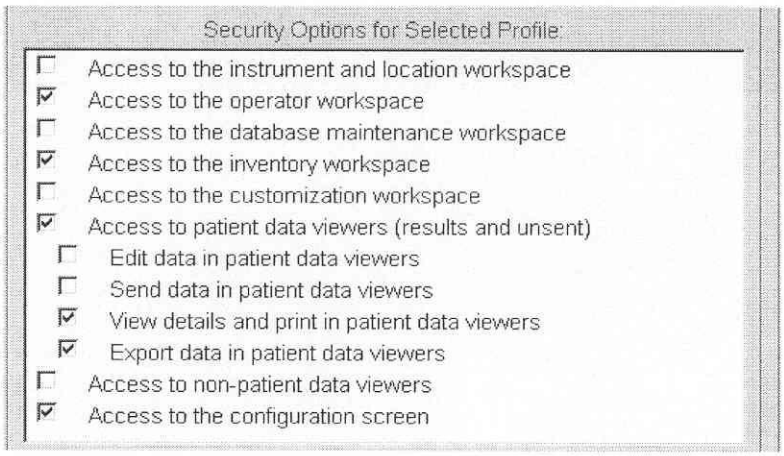
c. Trend report, and

d. the Extended Simulator report screen

To access this option from any of the Data Viewers or Reports, click on **Window ⇨ Export**. From a Trend report or the Extended Simulator report screen, click on the **Export data...** button at the bottom of the report. A dialog box will then appear on the screen. Choose the file destination location and the type of file you want the exported data saved as from the drop-down menus, then type in the File Name and click on Save.



Note: Users can be blocked from or allowed access to this data export feature through the User Administration Workspace by using the check box **"Export data in patient data viewers"** under the **Security Options for Selected Profile** section.



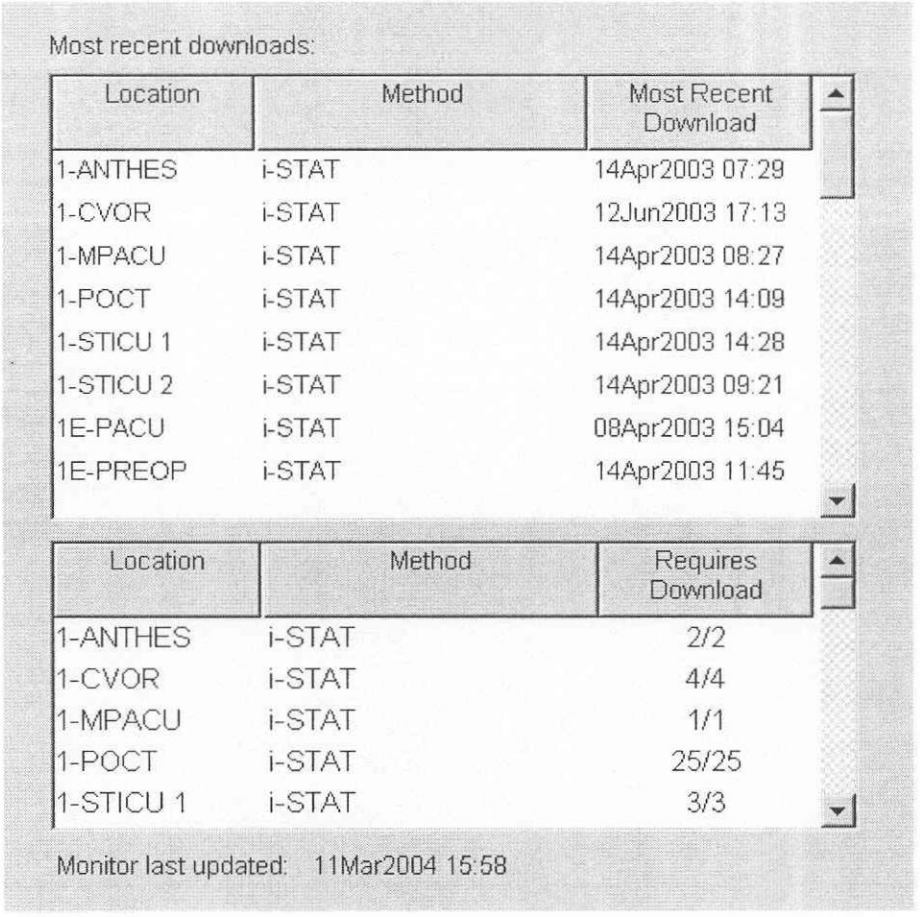
Download Monitor

The download monitor quickly identifies the download status of all locations and any locations that have instruments out of download compliance.

The upper portion of the monitor shows the last time an analyzer from the listed locations was downloaded. These columns can be sorted by clicking the column heading.

The maximum time allowed between downloads from the instrument to the CDS is defined under **Download Criteria** in the Instrument/Location workspace. The download status of each location is recorded in the Download Monitor. The **Requires Download** column indicates how many of the total number of analyzers reporting to a location have exceeded the **Download Criteria**. Clicking the location will open the Instrument and Location workspace where noncompliant analyzers will be highlighted.

The monitors are updated or refreshed according to the schedule selected during the customization of the CDS. The data can be manually refreshed by clicking the **Refresh** toolbar button or by pressing the **F5** key.



Most recent downloads:

Location	Method	Most Recent Download
1-ANTHES	i-STAT	14Apr2003 07:29
1-CVOR	i-STAT	12Jun2003 17:13
1-MPACU	i-STAT	14Apr2003 08:27
1-POCT	i-STAT	14Apr2003 14:09
1-STICU 1	i-STAT	14Apr2003 14:28
1-STICU 2	i-STAT	14Apr2003 09:21
1E-PACU	i-STAT	08Apr2003 15:04
1E-PREOP	i-STAT	14Apr2003 11:45

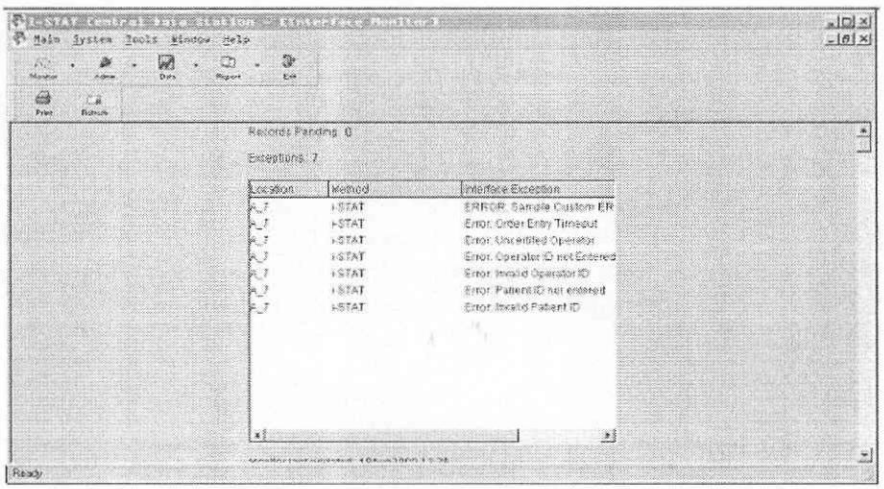
Location	Method	Requires Download
1-ANTHES	i-STAT	2/2
1-CVOR	i-STAT	4/4
1-MPACU	i-STAT	1/1
1-POCT	i-STAT	25/25
1-STICU 1	i-STAT	3/3

Monitor last updated: 11Mar2004 15:58

Interface Monitor

The Interface Monitor accessed via the menu bar functions with an interface installed by Abbott Point of Care Inc.. To access the the interface monitor for an interface installed by a third party, click on the **Interface Manager** button in the tray at the bottom of the screen.

The Interface Monitor identifies quickly the status of the Interface to an external computer. The number of pending results is shown as well as any exceptions in the last 72 hours. Clicking an exception takes you to the Unsent Results viewer to address the exception.

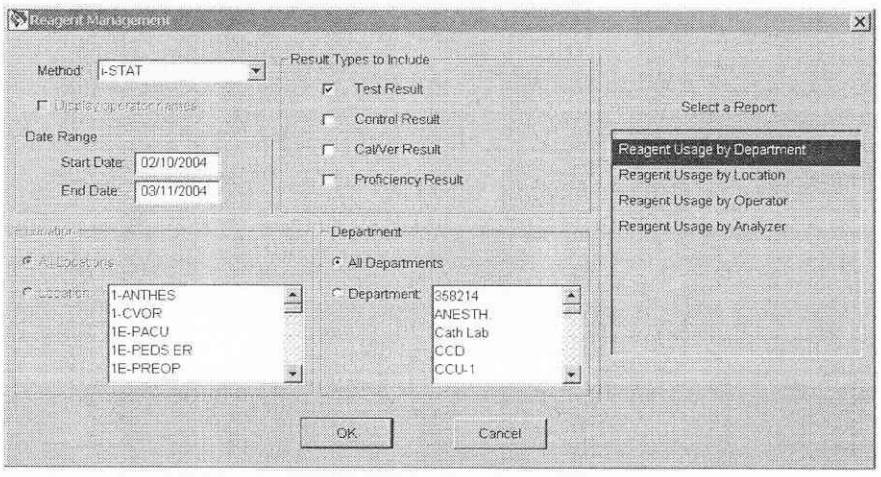


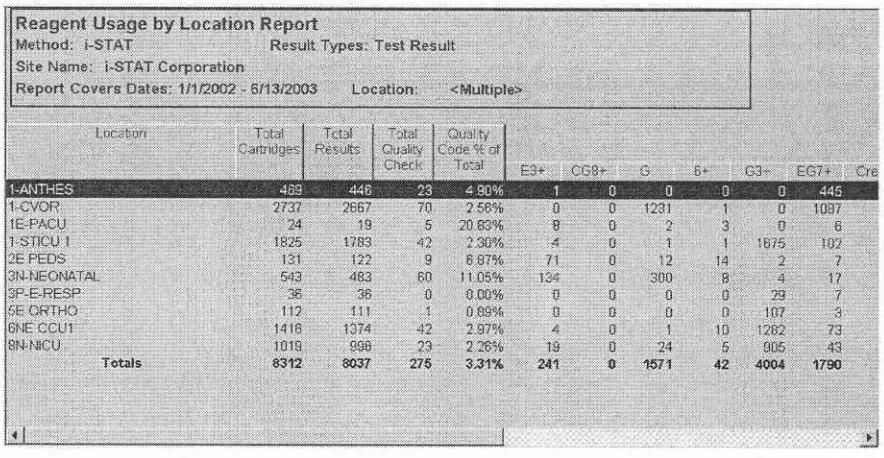
Overview

Reports for managing the point-of-care testing process are available from the CDS program. Three reports can be generated: Reagent Management, Method Competency and Method Compliance. These show information summarized by operator, location, department, or analyzer. Reports can be printed.

Reagent Management

This is a report of cartridge usage by Department or Location. Select a date range for the report. Data in reports, with the exception of "Operator", can be sorted by clicking on the column headers. By Operator data is pre-sorted by department. Select a report by **Reagent Usage by Department, Reagent Usage by Location**, **Reagent Usage by Operator,** or **Reagent Usage by Analyzer,** and then select either **All Locations** or **All Departments**, or select one **Location** or one **Department** from the drop down menu. Select the desired result types (Test, Control, Car/Ver, Proficiency) and then click the **OK** button.





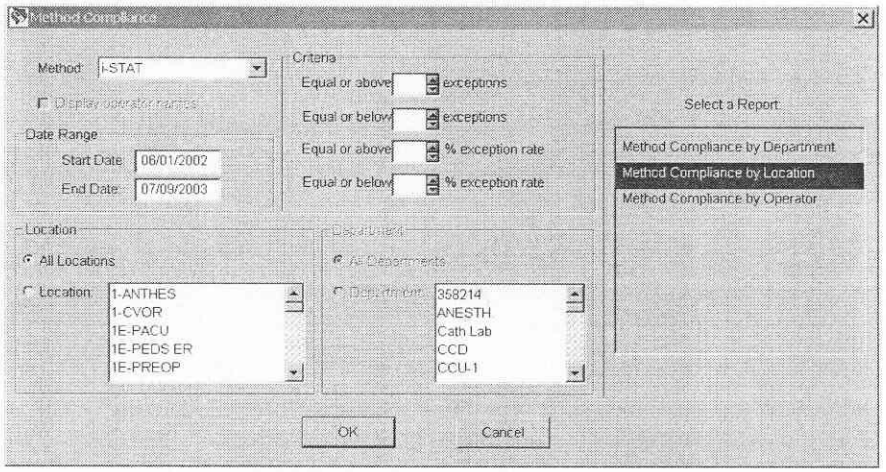
Reagent Usage by Location Report
Method: i-STAT Result Types: Test Result
Site Name: i-STAT Corporation
Report Covers Dates: 1/1/2002 - 6/13/2003 Location: <Multiple>

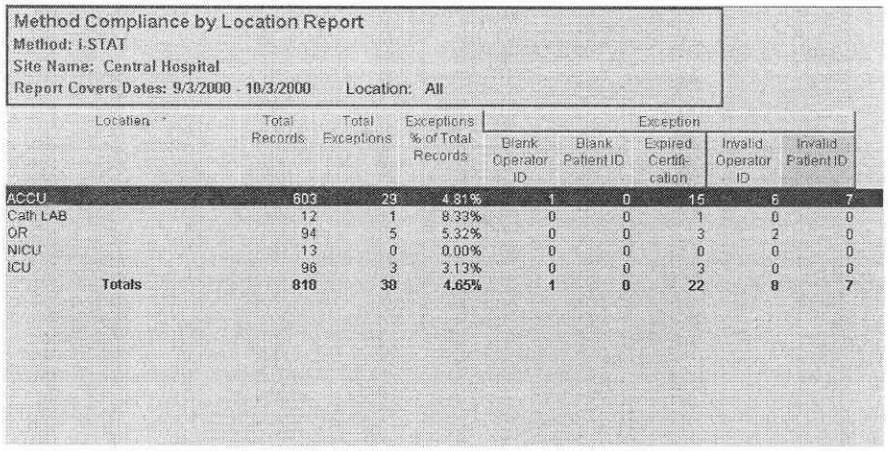
Location	Total Cartridges	Total Results	Total Quality Check	Quality Code % of Total	E3+	CG8+	G	6+	G3+	EG7+	Cre
1-ANTHES	469	446	23	4.90%	1	0	0	0	0	445	
1-CVOR	2737	2667	70	2.56%	0	0	1231	1	0	1087	
1E-PACU	24	19	5	20.83%	8	0	2	3	0	6	
1-STICU 1	1825	1783	42	2.30%	4	0	1	1	1675	102	
2E PEDS	131	122	9	6.87%	71	0	12	14	2	7	
3N-NEONATAL	543	483	60	11.05%	134	0	300	8	4	17	
3P-E-RESP	36	36	0	0.00%	0	0	0	0	29	7	
5E ORTHO	112	111	1	0.89%	0	0	0	0	107	3	
6NE CCU1	1416	1374	42	2.97%	4	0	1	10	1282	73	
8N-NICU	1019	998	23	2.26%	19	0	24	5	905	43	
Totals	**8312**	**8037**	**275**	**3.31%**	**241**	**0**	**1571**	**42**	**4004**	**1790**	

Method Compliance

This is a report of exceptions of policy and procedure for cartridge testing by Department, Location or Operator. This information is available when there is an interface to an external computer.

Select a date range for the report. Select a **Report by Department**, **Location,** or **Operator**, then select **All Locations** or **All Departments** or select one **Location** or **Department** from the list. Click on **Display operator names** if desired. When **Method Compliance by Operator** is selected, operators will be listed by department. Select the filtering criteria for the report and then click the **OK** button.





Method Compliance by Location Report
Method: i-STAT
Site Name: Central Hospital
Report Covers Dates: 9/3/2000 - 10/3/2000 Location: All

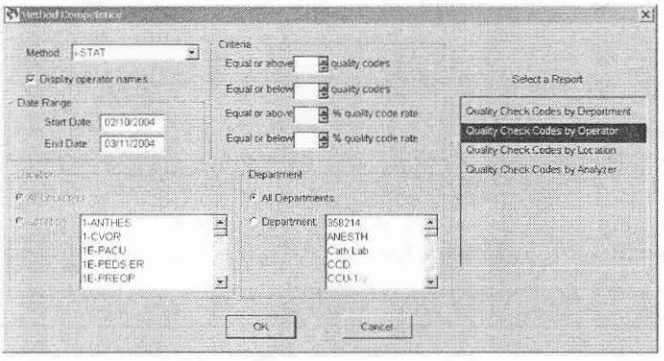
Location	Total Records	Total Exceptions	Exceptions % of Total Records	Exception				
				Blank Operator ID	Blank Patient ID	Expired Certification	Invalid Operator ID	Invalid Patient ID
ACCU	603	29	4.81%	1	0	15	6	7
Cath LAB	12	1	8.33%	0	0	1	0	0
OR	94	5	5.32%	0	0	3	2	0
NICU	13	0	0.00%	0	0	0	0	0
ICU	96	3	3.13%	0	0	3	0	0
Totals	**810**	**38**	**4.65%**	**1**	**0**	**22**	**8**	**7**

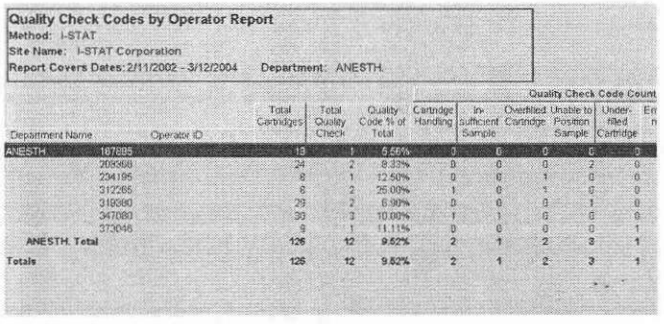
Method Competence

This is a report of Quality Check Code occurrence for cartridges by Department, Operator, Location or Analyzer.

Select a date range for the report. Select a **Report by Department**, **Location, Operator**, or **Analyzer** and then select **All Locations** or **All Departments** or select one or more **Locations** or **Departments** from the list. Click on **Display operator names** if desired. Select the filtering criteria for the report. Then click the **OK** button.

When **Quality Check Codes by Department** is selected, operators will be listed by Department.



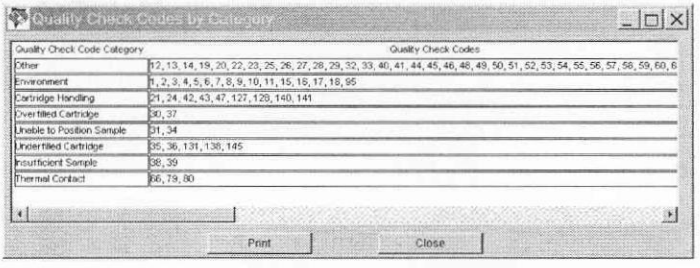


Quality Check Codes by Operator Report
Method: i-STAT
Site Name: i-STAT Corporation
Report Covers Dates: 2/11/2002 - 3/12/2004 **Department:** ANESTH

Department Name	Operator ID	Total Cartridges	Total Quality Check	Quality Code % of Total	Quality Check Code Count: Cartridge Handling	Insufficient Sample	Overfilled Cartridge	Unable to Position Sample	Underfilled Cartridge	En n
ANESTH	167695	13	1	7.69%	0	0	0	0	0	
	209368	24	2	8.33%	0	0	0	2	0	
	224195	8	1	12.50%	0	0	1	0	0	
	312285	8	2	25.00%	1	0	1	0	0	
	319380	29	2	6.90%	0	0	0	1	0	
	347080	30	3	10.00%	1	1	0	0	0	
	372046	9	1	11.11%	0	0	0	0	1	
ANESTH Total		126	12	9.52%	2	1	2	3	1	
Totals		126	12	9.52%	2	1	2	3	1	

A legend mapping individual code numbers to their respective quality check code categories is available for viewing. To access this legend:

1. Create the desired Quality Check Code report.
2. With the report still on the screen, click on **Report ➪ View QC Codes by Category...** The following dialog will appear for viewing or printing.



For details of these Quality Check Codes, see the Technical Bulletin: Analyzer Coded Messages.

Customization: Central Data Station Settings

Configuration of the CDS can be viewed.

Customization: i-STAT Analyzer Settings

Customization profiles of the i-STAT analyzers can be viewed.

AutoSend

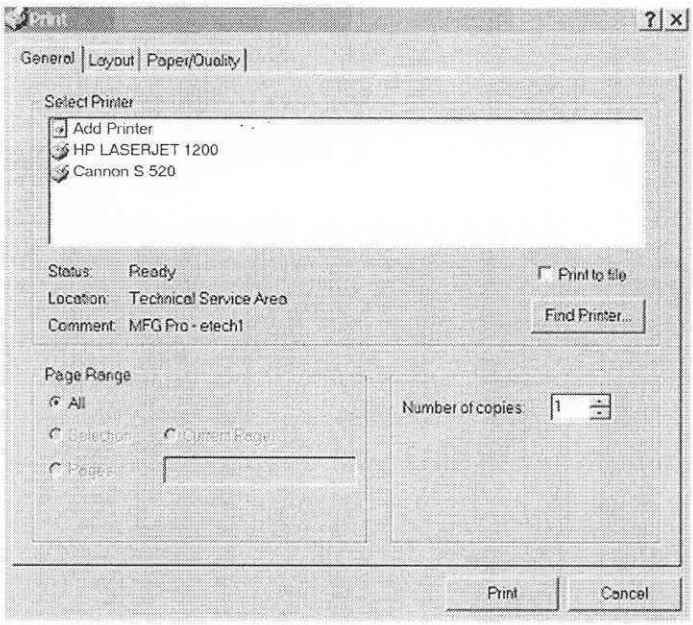
When enabled, data will be transmitted automatically from the CDS to the LIS or other information management system when received by the CDS. If AutoSend is not enabled, results can be sent to the LIS manually. Highlight the records to be sent in the appropriate Data Viewer Results viewer then click **Record ⇨ Send Selected Records**. If AutoSend is enabled, it will be checkmarked under the System option on the menu bar. If an external interface is not enabled, AutoSend will appear in grey typeface.

Print Option

A Printer Dialog box has been added so that when Print is selected from the menu, the user can choose from a list of installed printers. This allows the user the option to utilize their own network printer. To access this feature, you must perform one of the following:

a. Click on **Main ⇨ Print**, or

b. Click on **Records ⇨ Print Selected Records**



HELP

Technical Support Phone number for your Customer Support Representative.

About... Software version of the Central Data Station.

WINDOWS OPERATING SYSTEM AND LANGUAGE SUPPORT

Windows Version/ Service Pack	Windows Language	Supported CDS Language(s)
NT 4.0, SP6a	English	English
2000 Professional, SP4	English	English, German, Italian, Spanish, Swedish
2000 Professional, SP4	German	German, English
2000 Professional, SP4	Italian	Italian, English
2000 Professional, SP4	Spanish	Spanish, English
2000 Professional, SP4	Swedish	Swedish, English
XP Professional, SP2	English	English, German, Italian, Spanish, Swedish
XP Professional, SP2	German	German, English
XP Professional, SP2	Italian	Italian, English
XP Professional, SP2	Spanish	Spanish, English
XP Professional, SP2	Swedish	Swedish, English

During the initial installation or upgrade of the CDS 5 software, all U.S. customers should choose "English" when the language choice drop down menu appears. Failure to do so will result in the following consequences:

1. If the wrong language was chosen during the initial installation of the Version 5 software, all CDS screens will appear in the language chosen. Contact your i-STAT Support Representative if this has occurred.

2. If the wrong language was chosen during an upgrade of the CDS 5 software, the i-STAT installation instructions will appear in the language chosen, but the CDS screens will remain in English.