

Draft (PL3)

Title: A120_SRD006-002 Backup/Restore and Export Software Requirements Document (SRD)

Abstract: The Backup/Restore function of the ADVIA 120 allows the user to save data to disk or other device for later retrieval. Information can also be exported from the ADVIA 120 environment into a text file format. This is the second of two documents that outline the software requirements necessary to further enhance the Backup/Restore and Export features. Backup/Restore and Export features as it relates to the data manager are addressed in a separate SRD.

	Name	Signature	Date	Role
Authors	<i>Felicia A. Williams</i>	_____	_____	Author, Requirements Team
	<i>Chui-Ching Au</i>	_____	_____	Author, Development Team
Approval	<i>Pat Frank</i>	_____	_____	Marketing Manager
	<i>Ranjan Sadarangani</i>	_____	_____	Development Functional Manager

	<i>Judy Chall</i>	_____	_____	Requirements and Validation
Authoriza- tion	<i>Corinne Cassaday</i>	_____	_____	Requirements Functional Manager
	<i>David Okrongly</i>	_____	_____	Core Team Leader

Section 2: Introduction	2
Summary	2
Purpose and Scope.....	2
Assumptions and Overview.....	2
Section 3: Restore.....	3
Section 4: Export: Raw Data and Exported Results	5
Exporting Logs	6
Export: Message Log	11
Export: Reagent Log - Reagent History	14
Export: Reagent Log - Cumulative Inventory	16
Export: Reagent Log - Reagent Inventory.....	19
Export - Service History Log.....	22
Export: Startup Log	25
Export: User Notepad - QC Comments.....	27
Export: User Notepad - User Notes.....	29
Export : Workload Log - Cumulative Workload Log	31
Export: Workload Log - Interim Workload Log	34
Export: Workload Log - System Timers.....	37
Section 5: Database Repair	40
System Reboot after Database Repair.....	40
Printed Report Format.....	40
Section 6: Incidents Addressed in this SRD.....	42
Section 7: References.....	44
Section 8: Test Strategy	45
Section 9: On Line Help.....	46
Section 10: What's This Help	47
Section 11: Implement Requirements as identified in the IR's listed below:	48
Section 12: Hazard Analysis	49
Section 13: Appendix 1 - Requirements Traceability Matrix	50

Section 2: Introduction

2.1. Summary

The purpose of the Backup/Restore function of the ADVIA 120 is to allow the user to save data to disk or other device for later retrieval. By backing up data, the user will be able to reinstate the computer to an operable state in the event the hard disc data later becomes corrupted or accidentally deleted. In addition to backing up information, data may also be exported from the ADVIA 120 environment into a text file format.

This document outlines requirements necessary to further enhance and expand the existing (PL2) Backup/Restore and Export functionality as it relates to the Instrument Manager portion of the software. Backup/Restore and Export features as it relates to the data manager are not addressed in this document.

2.2. Purpose and Scope

The purpose of this document is to outline the software requirements necessary to enhance the Backup/Restore and Export functionality and to address several outstanding incidents as directed by the incident review board for the ADVIA 120.

The scope of this document specifies Instrument Manager software requirements only.

2.3. Assumptions and Overview

This document is written with the assumption that an approved and signed URD (A120_URD006) is in place and the PL2 software requirements as outlined in A120_SRD006-001 have been implemented according to specifications.

It is also assumed that the requirements as specified in this document shall be implemented in all appropriate languages and all reference to date and time formats will be properly adjusted to comply with the appropriate regional format.

It is assumed that the requirements outlined in this document shall also apply to the Multi-Species software

It is assumed that this document shall address the Export function only for those incidents that make reference to both the Print and Export functionality.

It is also assumed that this document shall detail the back up and restore of numerical results only. Backup and restore of Graphics are not included.

Throughout this document any reference made to user input, i.e., clicking an **OK** or **Cancel** button will be in bold print. Any reference to system responses, such as message box text will be in *quotes, underlined and italicized*.

Section 3: Restore

Upon restoring previously backed up data, the system shall automatically print a report at the end of the restoration process. The user will also have the ability to print a report on demand by clicking the Print Report command button. (IR 8290) All other functionality of this screen remains as currently implemented.

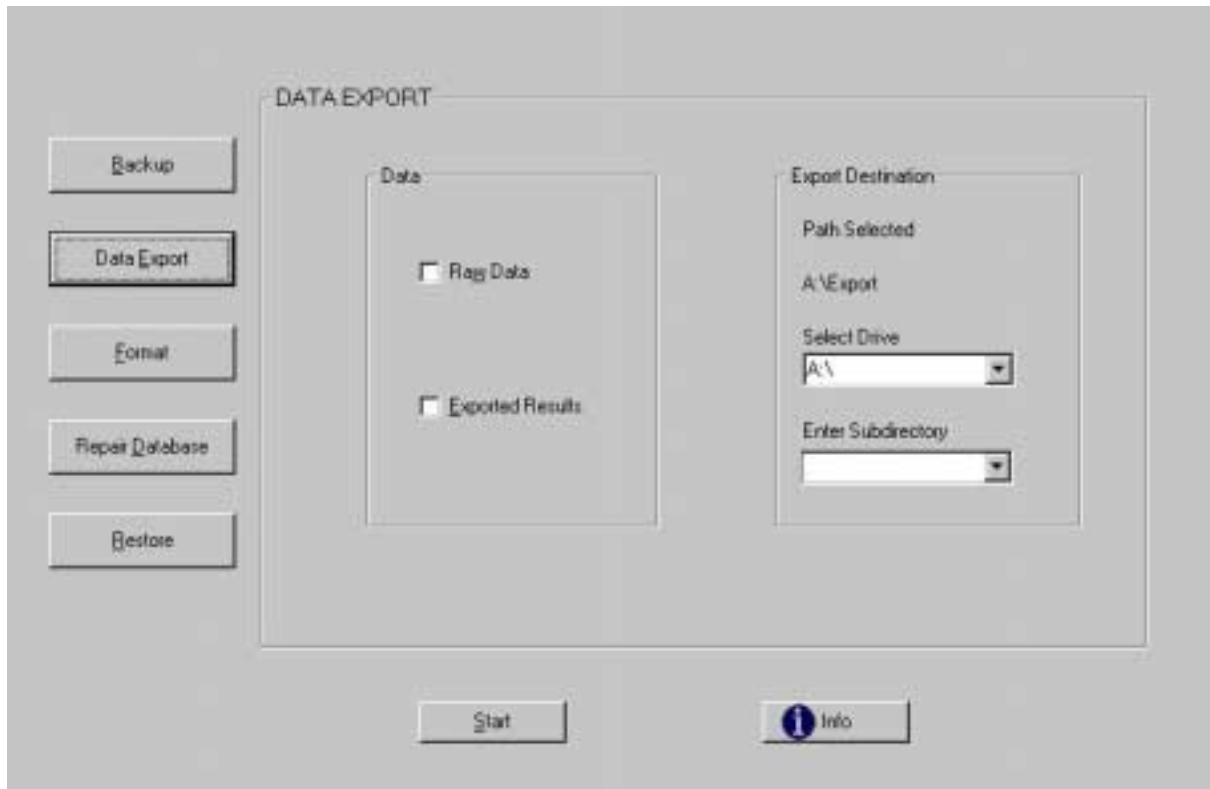


Figure 4: Sample Restore Screen

Purpose	This screen enables the user to identify files to restore, where the files are restored from (source of file backup), and to print a report of the restored files on demand.
Pre-Condition	A user must be logged on and the ADVIA 120 must not be running any analytical cycles.
Screen Format <i>(Please refer to figure 1)</i>	The user interface shall remain consistent with the remainder of the ADVIA software. The navigational command buttons shall remain on the left of the screen and the Start , Print Report and Info buttons are located at the bottom of the screen. The screen shall use a large frame to encapsulate the subsets of the Restore screen (Restore Selection and Restore From)
Input	To access this screen the user selects Utilities from the menu and clicks on the Backup/Restore tab. The user will then click on the Restore command button to navigate to the Restore Screen. Within the Restore screen, the user will choose what to restore and where to restore from.

	Check box
Output	Upon completion of the Restore process, the files are retrieved from the backup source and a report is automatically printed. The user has the additional option of printing the report on demand by clicking the Print Report command button
Command Buttons	<p>Start – (Accelerator Key = Alt + S) Upon selection a warning message “<i>This process requires a shut down and restart of the ADVIA 120 workstation. Upon completion , your system will automatically shut down and re-start. (Please be sure to exit all other programs.) Do you want to continue?</i>” Yes, No. If the user selects Yes, the restore will proceed. Upon completion of the restore, a restore report is automatically generated After the report is printed, the system shall wait until all hydraulic cycles are completed and then will begin shutdown. (See IR# 8166)</p> <p>If the user selects No, the restore process is aborted.</p> <p>Print Report (Accelerator Key = Alt + P) - Upon selection, a Restore Report is printed. The report shall be able to be printed via any networked or local printer. The format is as follows:</p> <p>HEADER</p> <p>Report Title</p> <p>System Name</p> <p>User Code</p> <p>Date</p> <p>Time</p> <p>BODY OF REPORT</p> <p>Time Backup Initiated:</p> <p>Options Selected for Restoration</p> <p>Listing of each file restored.</p> <p>Status: Successful or Failed.</p> <p>Info – (Accelerator Key = Alt + I) Upon selection, the help files are displayed.</p>

Section 4: Export: Raw Data and Exported Results

Initially, the logs were exportable from the Export screen of the Backup Restore Tab. It has been deemed appropriate to export each log from its particular log screen. I.e., give the user the ability to export Service Logs from the Service Log screen, Maintenance Logs from the Log Maintenance screen, etc. As a result, only Raw Data and Exported Results will be exported from the Data Export screen. Section 6.2.1 addresses Log Exportation.

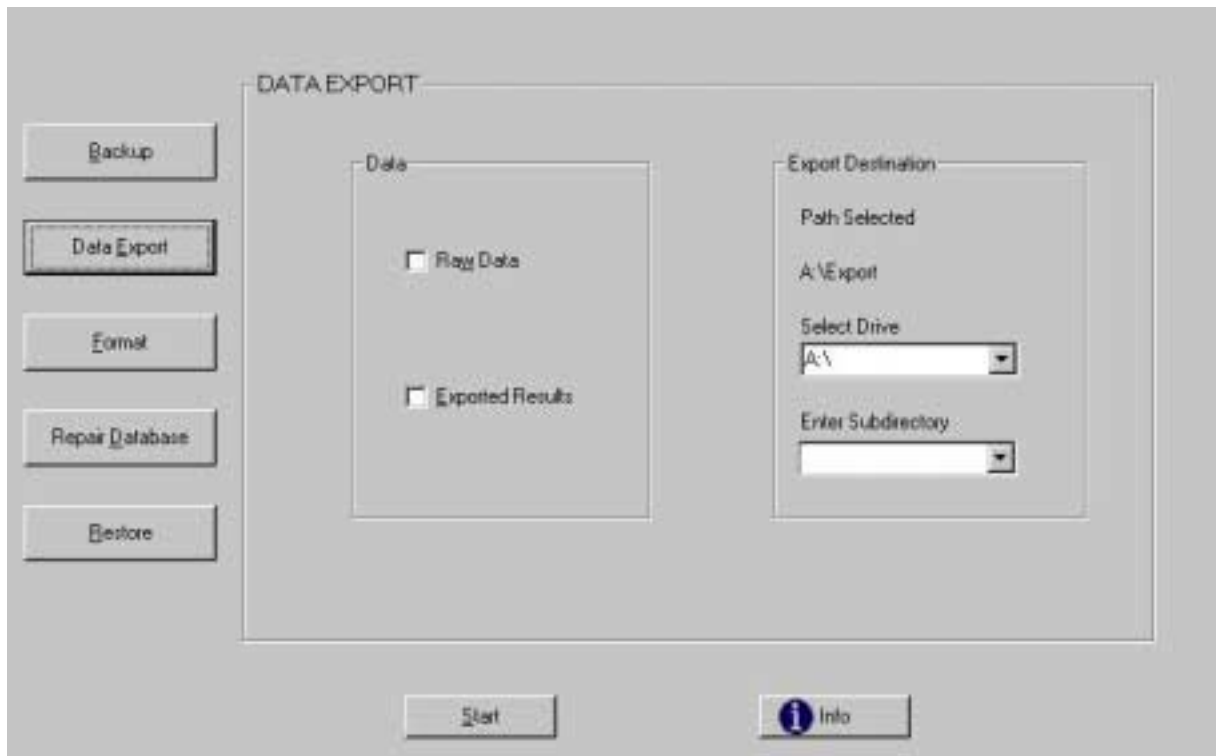


Figure 5: Sample Export Screen

Purpose	This screen enables the user to identify Raw Data and Exported Results for export and select the location to export them to.		
Pre-Condition	A user must be logged on and the ADVIA 120 must not be running any analytical cycles.		
Screen Format see figure 2	The user interface will remain consistent with the remainder of the ADVIA software. The navigational command buttons will remain on the left of the screen and the Start and Info buttons will remain at the bottom of the screen. The screen will use the large frame entitled 'DATA EXPORT' to encapsulate the two subsets of the screen (Data and Export Destination).		
Input	This screen is accessed via Utilities, Backup/Restore, Data Export.		
	Function	Controls	Properties

	Data Export	Frame entitled 'Data' which encases the export log selections	<p>The functionality of this screen has changed in that the ability to export logs from the Export screen has been removed. All other functionality remains the same.(see section 6.21 for log export)</p> <p>By deleting the logs from this screen, the GUI objects must be re-arranged. The Raw Data and Exported Results check-boxes are moved to the left side of the screen. The Export Destination frame is enlarged and it's contents spaced in a fashion to visually balance the remaining screen real estate on the right-hand side of the screen. (refer to figure2)</p>
Output			The selected Raw Data and/or Exported Results are copied to the selected Drive and subdirectory. (No change to current PL2 implementation)

4.1. Exporting Logs

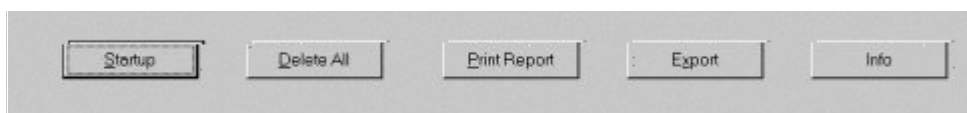


Figure 5: Sample Export Command Button Setup

For consistency an **Export** command button (accelerator key = Alt + X) will be added to the left of the **Info** button for each of the following Log screens

- Message Log
- Reagent Log - Reagent History
- Reagent Log - Cumulative History
- Reagent Log - Reagent Inventory
- Service Log - Service History
- Startup Log
- User Notepad - QC Comments
- User Notepad - User Notes
- Workload Log - Cumulative Workload
- Workload Log - Interim Workload
- Workload Log - System Timers

The functionality of the Export command button on each log screen is explained in detail in this document. The logic behind the behavior of the Export command button is based on the Print Report command button. Those screens in which the user has the option to print All or Selected records shall also have the option to Export All or Selected records. Similarly, those screens that

only allow the printing of All records shall only allow the Export of All records.

Upon clicking the Export command button, the Export to File dialogue box is invoked.

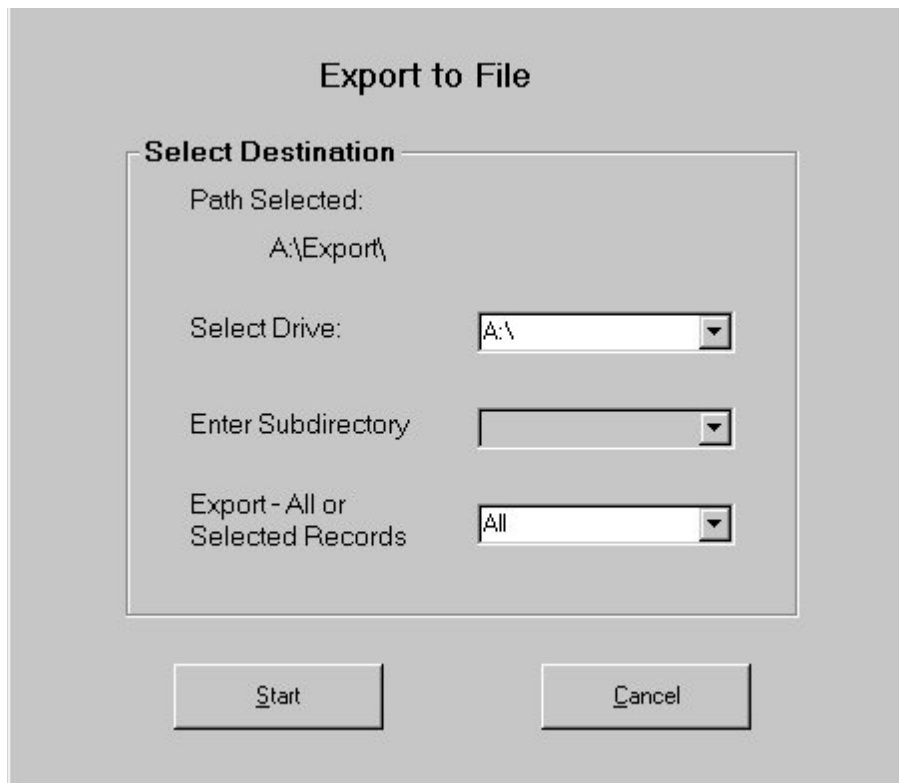


Figure 6: Sample Export to File Screen

<p>Control</p> <p>Label entitled: Select Destination</p> <p>Combo Boxes entitled:</p> <p>'Select Drive'</p> <p>'Enter Subdirectory'</p> <p>'Export – All or Selected Records'</p>	<p>PROPERTIES</p> <p>Title: Export to File</p> <p>Beneath the title 'Select Destination' is a static label which is populated by the information from the Select Drive and Enter Subdirectory combo boxes.</p> <p>Below the static label are three combo boxes, Select Drive, Enter Subdirectory and Export – All or Selected Records:</p> <p><u>Select Drive:</u></p> <p>The 'Select Drive' combo box consists of a text box with a down arrow to the right. The user can either select the A:\ default drive shown in the text box or click the down arrow which will invoke a list box consisting of all available drives for export.</p> <p>Upon selecting a drive the system will automatically create, if not already created, a directory called "Export" on the selected drive. In the event the user has selected the C:\ drive, the records will be exported to C:\Export\ this will prevent the user from exporting to critical system files on the C:\drive.</p> <p>Upon selecting the drive for export, the list box will collapse keeping the user's selection visible within the textbox and the static label. The static label will show both the drive letter and the "Export" directory.</p> <p><u>Enter Subdirectory:</u></p> <p>The 'Enter Subdirectory' combo box consists of a text box with a down arrow to the right</p> <p>The user can either type in an existing directory or,</p> <p>Click the down arrow that will invoke a list box consisting of all available directories within the Export directory for export. Upon selecting the sub directory for export, the list will collapse keeping the user's selection visible within the combo box and static label. Or,</p> <p>The user can type a non-existing directory name and the system will create a new directory.</p> <p><u>Export – All or Selected Records:</u></p> <p>The 'Export' combo box allows the user to choose whether to export all records of the log or user-selected records of the log by:</p> <p>Accepting the default 'All' which appears in the combo box. By selecting All, the system shall update the information in the log (refresh) prior to export, . (All is defined as all records displayed on the within the Log's grid - including those records requiring the use of the scroll bars to view), or</p> <p>By clicking the down arrow to the right of the text box that will invoke the drop-down list box that displays 'Selected'.</p> <p>Upon clicking 'Selected' the drop-down list box will close while the user's selection remains visible within the text box.</p> <p>The selected records for export are determined by the user's choices in each individual log screen.</p>
---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Output	<p>System will access the appropriate log in the database for export to the user-defined destination.</p> <p>The system will generate a file name for each exported log file. The naming convention is Log Name (see listing of abbreviated log file names below), Date, Time. i.e., a Message Log that is exported on 1/1/98 at 10:14:08 am, will be named ML_19980101_101408.</p> <table border="1" data-bbox="464 436 1484 1073"> <thead> <tr> <th data-bbox="464 436 980 489">Listing of Log Names:</th> <th data-bbox="980 436 1484 489">Abbreviated File Name:</th> </tr> </thead> <tbody> <tr> <td data-bbox="464 489 980 541">Message Log</td> <td data-bbox="980 489 1484 541">ML</td> </tr> <tr> <td data-bbox="464 541 980 594">Reagent Log - Reagent History</td> <td data-bbox="980 541 1484 594">RLRH</td> </tr> <tr> <td data-bbox="464 594 980 646">Reagent Log - Cumulative History</td> <td data-bbox="980 594 1484 646">RLCH</td> </tr> <tr> <td data-bbox="464 646 980 699">Reagent Log - Reagent Inventory</td> <td data-bbox="980 646 1484 699">RLRI</td> </tr> <tr> <td data-bbox="464 699 980 751">Service Log - Service History</td> <td data-bbox="980 699 1484 751">SLSH</td> </tr> <tr> <td data-bbox="464 751 980 804">Startup Log</td> <td data-bbox="980 751 1484 804">SL</td> </tr> <tr> <td data-bbox="464 804 980 856">User Notepad - QC Comments</td> <td data-bbox="980 804 1484 856">UNQC</td> </tr> <tr> <td data-bbox="464 856 980 909">User Notepad - User Notes</td> <td data-bbox="980 856 1484 909">UNUN</td> </tr> <tr> <td data-bbox="464 909 980 961">Workload Log - Cumulative Workload</td> <td data-bbox="980 909 1484 961">WLCW</td> </tr> <tr> <td data-bbox="464 961 980 1014">Workload Log - Interim Workload</td> <td data-bbox="980 961 1484 1014">WLIW</td> </tr> <tr> <td data-bbox="464 1014 980 1073">Workload Log - System Timers</td> <td data-bbox="980 1014 1484 1073">WLST</td> </tr> </tbody> </table>	Listing of Log Names:	Abbreviated File Name:	Message Log	ML	Reagent Log - Reagent History	RLRH	Reagent Log - Cumulative History	RLCH	Reagent Log - Reagent Inventory	RLRI	Service Log - Service History	SLSH	Startup Log	SL	User Notepad - QC Comments	UNQC	User Notepad - User Notes	UNUN	Workload Log - Cumulative Workload	WLCW	Workload Log - Interim Workload	WLIW	Workload Log - System Timers	WLST
Listing of Log Names:	Abbreviated File Name:																								
Message Log	ML																								
Reagent Log - Reagent History	RLRH																								
Reagent Log - Cumulative History	RLCH																								
Reagent Log - Reagent Inventory	RLRI																								
Service Log - Service History	SLSH																								
Startup Log	SL																								
User Notepad - QC Comments	UNQC																								
User Notepad - User Notes	UNUN																								
Workload Log - Cumulative Workload	WLCW																								
Workload Log - Interim Workload	WLIW																								
Workload Log - System Timers	WLST																								
Command Buttons	<p>Start (Accelerator key = Alt + S) - Upon clicking Start the Export process begins. Upon completion of the export, a message box "<i>Operation successfully completed</i>" is invoked. User will click OK to navigate out.</p> <p>Cancel (Accelerator key = Alt + C) – Upon clicking Cancel the user is taken back to the previous screen.</p>																								
Error Handling/ Notifications	<p>Drive not available or disk write protected - If a user attempts to export to a drive that is not available, i.e., selects A:\ drive and does not have a floppy in the drive, a message box stating "<i>Drive not read.</i>" OK, is invoked.</p> <p>Disc full/insufficient space - If a user attempts to export to a disc/directory that is either full or does not have enough space to export the log, a message box stating "<i>Insufficient disc space.</i>" OK.</p> <p>If a user elects to export "Selected" records but did not <i>select</i> records to export, an information message "Please select records to export" OK.</p> <p>If the user selects Export and the database is empty, a message shall display: "<i>Data-base Empty</i>" OK</p>																								

4.1. Export: Message Log

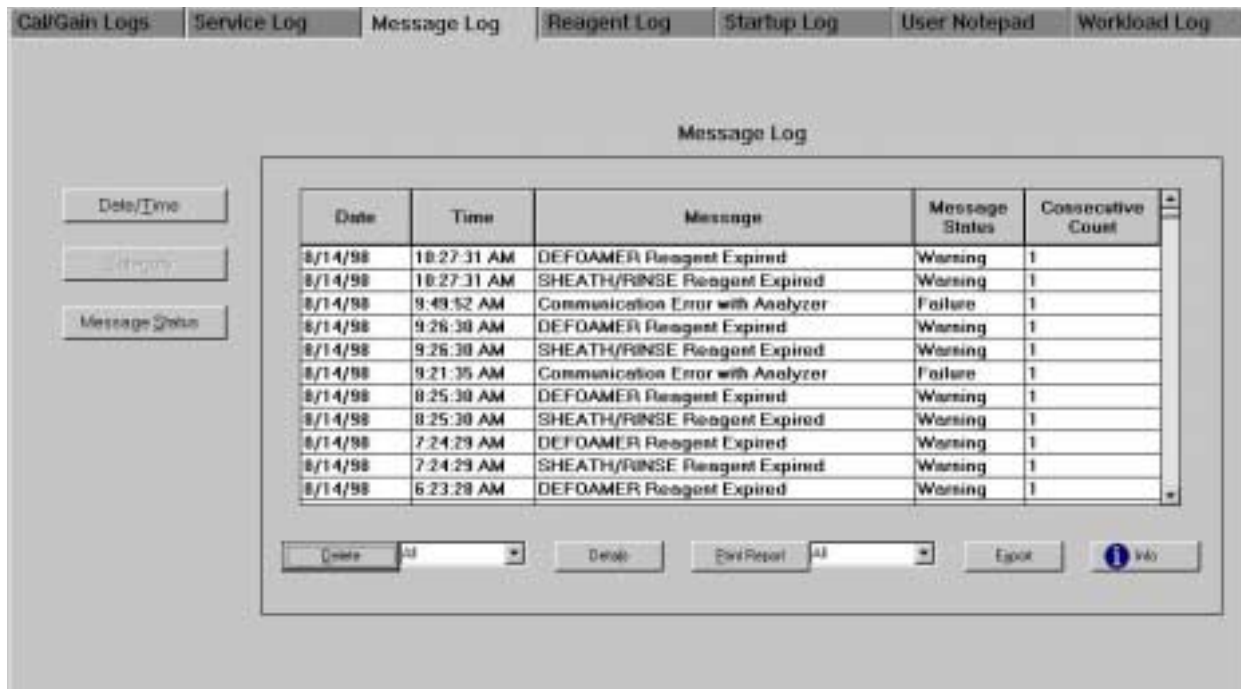


Figure 5 - Message Log

- Have the message log respond as it does when printing.

Purpose	The Message Log provides the user with information regarding the date, time, status level and types of error messages that have occurred while operating the ADVIA 120. For troubleshooting and record keeping purposes, the user would like to be able to export the information contained in this log.
Pre-Condition	A user must be logged on and the ADVIA 120 must not be performing any analytical cycles.

Input	<p>To export from this screen, the user selects System Logs menu ⇒ Message Log tab and clicks on the Export command button.</p> <p>Upon entering the Message Log screen, the database is refreshed to ensure the most current information is displayed allowing for the most current information to be transmitted upon clicking Print or Export. (IR #3368). If in the process of performing an export, additional messages are sent to the Message Log, the on screen display shall not refresh to accommodate the new messages. Similarly, the exported records shall contain only those records displayed on the Message Log screen.</p> <p><u>Exporting All Records:</u></p> <p>The user would click Export to invoke the 'Export to File' screen.</p> <p>After selecting the Drive and Subdirectory, the user would accept the default selection 'All' in the 'Export – All or Selected records' textbox.</p> <p>Click Start</p> <p><u>Exporting Selected Records:</u></p> <p>Within the Message Log screen, the user shall be able to select records for export by highlighting rows (consecutively or non consecutively).</p> <p>Once the selection is made, the user would click Export to invoke the Export to File screen.</p> <p>After selecting the Drive and Subdirectory, the user would select 'Selected' from the 'Export – All or Selected records' text box.</p> <p>Click Start</p>
-------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>Output</p>	<p>The user's selection (All or Selected) shall be exported.</p> <p>The exported format shall appear as follows:</p> <p>Columns are separated by tabs</p> <p>Rows are separated by line feeds/carriage returns</p> <p>The exported report shall contain the log title: Message Log</p> <p>The column titles and information shall appear in the following order:</p> <p>Column 1 = Date</p> <p>Column 2 = Time</p> <p>Column 3 = Message</p> <p>Column 4 = Message Status</p> <p>Column 5 = Consecutive Count</p> <p>The data populating the columns shall not be encoded. The user will be able to view and read the information in each column without requiring a separate manual to decode the data (IR# 3029)</p>
<p>Command Buttons</p>	<p>This section shall serve to confirm the proper assignment of accelerator keys. There is no change in functionality to the existing command buttons and the newly implemented Export command functions are described in detail in section 6.2.1 above.</p> <p><u>D</u>elete (Accelerator key = Alt + D)</p> <p><u>D</u>etails (Accelerator key = Alt + L)</p> <p><u>P</u>rint (Accelerator key = Alt + P)</p> <p><u>E</u>xport (Accelerator key = Alt + X)</p> <p><u>I</u>nfo (Accelerator key = Alt + I)</p> <p><u>D</u>ate/<u>T</u>ime (Accelerator key = Alt + T)</p> <p><u>C</u>ategory (Accelerator key = Alt + C)</p> <p><u>M</u>essage <u>S</u>tatus (Accelerator key = Alt + S)</p>
<p>Error Handling</p>	<p>If the user clicks Export while analytical functions are being performed, an error message, "<i>Records cannot be exported while analytical cycles are running.</i>" OK</p>

4.2. Export: Reagent Log - Reagent History

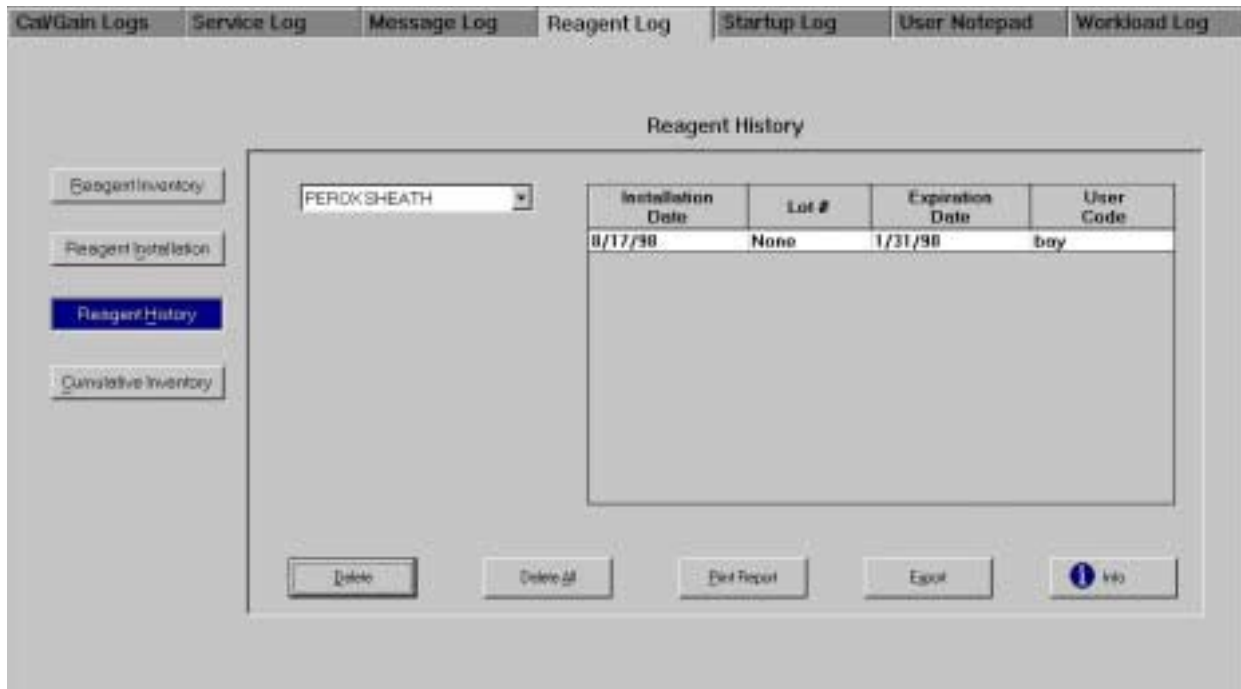


Figure 6 - Reagent History Log

Purpose	The Reagent History Log provides the user with information regarding every reagent container used in the system. For inventory purposes, the user might want to export the information contained in this log.
Pre-Condition	A user must be logged on and the ADVIA 120 must not be performing any analytical cycles.

<p>Input</p>	<p>To export the Reagent History Log, the user selects System Logs menu ⇒ Reagent Log tab ⇒ Reagent History.</p> <p>Upon entering the Reagent History screen, the database is refreshed to ensure the most current information is displayed allowing for the most current information to be transmitted upon clicking Print Report or Export. (IR #3368)</p> <p><u>Exporting All Records:</u></p> <p>The user would click Export to invoke the Export to File screen.</p> <p>The user would choose the Export Destination by selecting a Drive and/or Subdirectory.</p> <p>The user will be forced to accept the default 'All' as they will not have the option to choose 'Selected'. As a result, the 'Export – All or Selected Records' combo box shall be disabled and grayed with the word 'All' displayed.</p> <p>Click Start</p> <p><u>Exporting Selected Records:</u></p> <p>The user shall not have the ability to choose 'Selected' records.</p>
<p>Output</p>	<p>The user's selection (All) shall be exported.</p> <p>The exported format shall appear as follows:</p> <p>Columns are separated by tabs</p> <p>Rows are separated by line feeds/carriage returns</p> <p>The exported report shall include the log title: Reagent History</p> <p>The column titles and information shall appear in the following order: (IR 3030):</p> <p>Column 1 = Reagent</p> <p>Column 2 = Installation Date</p> <p>Column 3 - Lot #</p> <p>Column 4 = Expiration Date</p> <p>Column 5 = User Code</p>

Command Buttons	<p>This section shall serve to confirm the proper assignment of accelerator keys. There is no change in functionality to the existing command buttons and the newly implemented Export command functions are described in detail above</p> <p>Delete (Accelerator Key = Alt + D)</p> <p>Delete All (Accelerator Key = Alt + A)</p> <p>Print Report (Accelerator Key = Alt + P)</p> <p>Export (Accelerator Key = Alt + X)</p> <p>Info (Accelerator Key = Alt + I)</p> <p>Reagent Inventory (Accelerator Key = Alt + R)</p> <p>Reagent Installation: To accommodate the Info accelerator key, the Reagent Installation accelerator key shall be changed from Alt + I to Alt + N.</p> <p>Reagent History (Accelerator Key = Alt + H)</p> <p>Cumulative Inventory (Accelerator Key = Alt + C)</p>
Error Handling	<p>If the user clicks Export while analytical functions are being performed, an error message, <i>“Records cannot be exported while analytical cycles are running.”</i> OK</p>

4.3. Export: Reagent Log - Cumulative Inventory

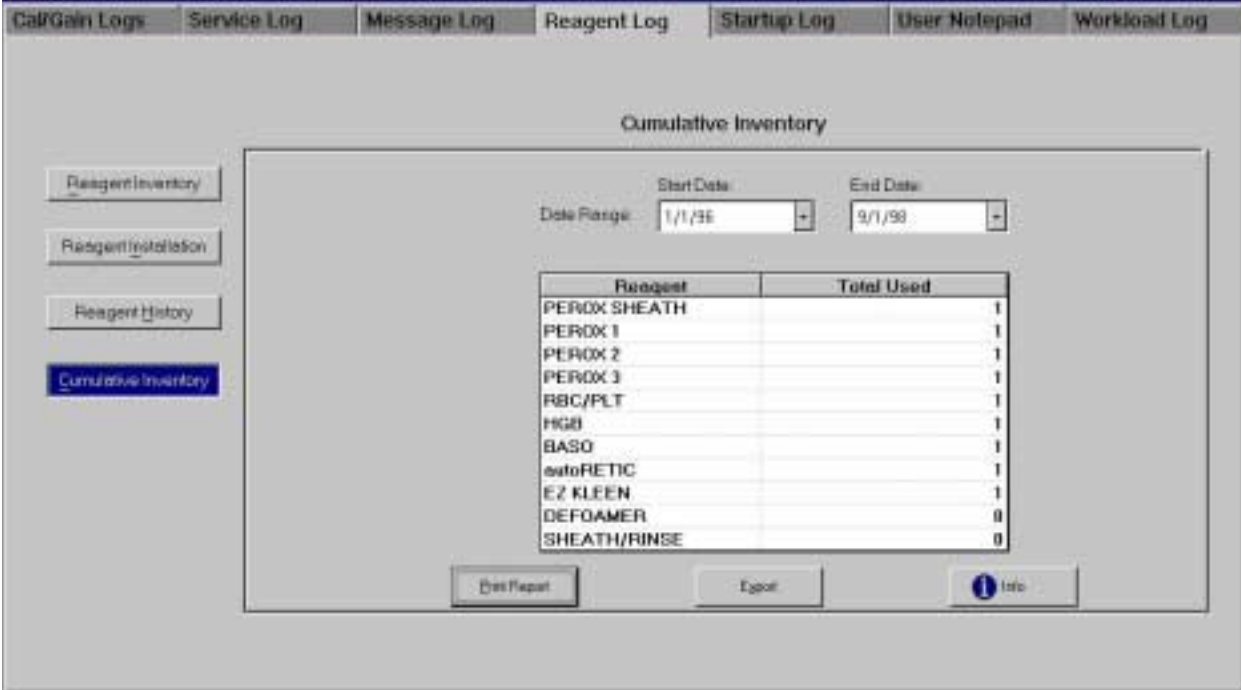


Figure 7 - Reagent Cumulative Inventory Log

Purpose	The Reagent Cumulative Inventory Log provides the user with an historical record of the system's reagent consumption. For inventory and troubleshooting purposes, the user might want to export the information contained in this log.
Pre-Condition	A user must be logged on and the ADVIA 120 must not be running any analytical cycle
Input	<p>To export the Reagent Cumulative Inventory Log, the user selects System Logs menu ⇒ Reagent Log tab ⇒ Cumulative Inventory command button.</p> <p>Upon entering the Cumulative Inventory screen, the database is refreshed to ensure the most current information is displayed allowing for the most current information to be transmitted upon clicking Print Report or Export. (IR #3368)</p> <p><u>Exporting All Records:</u></p> <p>Within the Cumulative Inventory, the user would select the criteria for export.. I.e., records that fall within a certain Start/End Date.</p> <p>Once the selection is made, the user would click Export to invoke the Export to File screen.</p> <p>The user will be forced to accept the default 'All' as they will not have the option to choose 'Selected'. As a result, the 'Export – All or Selected Records' combo box shall be disabled and grayed with the word 'All' displayed..</p> <p>Click Start.</p> <p><u>Exporting Selected records:</u></p> <p>The user shall not have the ability to choose 'Selected' records</p>

Output	<p>The user's selection (All) shall be exported</p> <p>The exported format shall appear as follows:</p> <p>Columns are separated by tabs</p> <p>Rows are separated by line feeds/carriage returns</p> <p>The first line of the exported report shall display the log title: Cumulative Inventory</p> <p>The next line shall display: Date Range</p> <p>The next line shall display: Start Date: followed by the user selected Start Date</p> <p>The next line shall display: End Date: followed by the user selected End Date</p> <p>The column titles and information shall appear in the following order:</p> <p>Column 1 = Reagent</p> <p>Column 2 = Total Used</p>
Command Buttons	<p>This section shall serve to confirm the proper assignment of accelerator keys. There is no change in functionality to the existing command buttons and the newly implemented Export command functions are described in detail above</p> <p>Print Report (Accelerator key = Alt + P)</p> <p>Export (Accelerator key = Alt + X)</p> <p>Info (Accelerator key = Alt + I)</p> <p>Reagent Inventory (Accelerator Key = Alt + R)</p> <p>Reagent Installation: To accommodate the Info accelerator key, the Reagent Installation accelerator key shall be changed from Alt + I to Alt + N.</p> <p>Reagent History (Accelerator Key = Alt + H)</p> <p>Cumulative Inventory (Accelerator Key = Alt + C)</p>
Error Handling	<p>If the user clicks Export while analytical functions are being performed, an error message, "<i>Records cannot be exported while analytical cycles are running.</i>" OK</p>

4.4. Export: Reagent Log - Reagent Inventory

Reagent	Cycles Remaining	Alarm Criteria	Stop Criteria	Days Remaining	Lot #	Expiration Date
PEROX SHEATH	51	10	1	64	None	01/31/99
PEROX 1	25	10	1	40	None	01/31/99
PEROX 2	25	10	1	40	None	01/31/99
PEROX 3	25	10	1	40	None	01/31/99
RBC/PLT	25	10	1	10	None	01/31/99
HGB	25	10	1	10	None	01/31/99
BASO	25	10	1	10	None	01/31/99
autoRETIC	25	10	1	40	None	01/31/99
E2 KLEEN	10	2	1	50	None	01/31/99
DEFOAMER	N/A				None	01/31/90
SHEATH/RINSE	OK				None	01/31/90

Figure 8 - Reagent Inventory Log

Purpose	The Reagent Inventory Log provides the user with information regarding how much reagent is currently available and how long the reagents will remain useable.
Pre-Condition	A user must be logged on and the ADVIA 120 must not be running any analytical cycles.

Input	<p>To export the Reagent Inventory Log, the user selects System Logs menu ⇒ Reagent Log Tab ⇒ Reagent Inventory. The user would then click on the Export command button.</p> <p>Upon entering the Reagent Inventory screen, the database is refreshed to ensure the most current information is displayed allowing for the most current information to be transmitted upon clicking Print Report or Export. (IR #3368). If in the process of performing an export, a non-analytical cycle is performed, the on screen display shall not refresh to accommodate the change in reagent count. Similarly, the exported files shall contain only those records displayed on the Reagent Inventory screen. The refresh shall occur upon leaving and re-entering the screen.</p> <p><u>Exporting All Records:</u></p> <p>The user would click Export to invoke the Export to File screen.</p> <p>The user would choose the Export Destination by selecting a Drive and/or Subdirectory.</p> <p>The user will be forced to accept the default 'All' as they will not have the option to choose 'Selected'. As a result, the 'Export – All or Selected Records' combo box shall be disabled and grayed with the word 'All' displayed.</p> <p>Click Start</p> <p><u>Exporting Selected records:</u></p> <p>The user shall not have the ability to choose 'Selected' records.</p>
-------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>Output</p>	<p>The user's selection (All) shall be exported.</p> <p>The exported format shall appear as follows:</p> <p>Columns are separated by tabs</p> <p>Rows are separated by line feeds/carriage returns</p> <p>The exported report shall include the log title: Reagent Inventory Log</p> <p>The column titles and information shall appear in the following order:</p> <p>Column 1 = Reagent</p> <p>Column 2 = Cycles Remaining</p> <p>Column 3 = Alarm Criteria</p> <p>Column 4 = Stop Criteria</p> <p>Column 5 = Days Remaining</p> <p>Column 6 = Lot #</p> <p>Column 7 = Expiration Date</p>
<p>Command Buttons</p>	<p>This section shall serve to confirm the proper assignment of accelerator keys. There is no change in functionality to the existing command buttons and the newly implemented Export command functions are described in detail above</p> <p>Prime: To maintain consistency for the Print Report accelerator key, the Prime accelerator key shall be changed from Alt + P to Alt + E</p> <p>Cancel Prime (Accelerator key = Alt + M)</p> <p>Print Report (Accelerator key = Alt + P)</p> <p>Export (Accelerator key = Alt + X)</p> <p>Info (Accelerator key = Alt + I)</p> <p>Reagent Inventory (Accelerator Key = Alt + R)</p> <p>Reagent Installation: To accommodate the Info accelerator key, the Reagent Installation accelerator key shall be changed from Alt + I to Alt + N.</p> <p>Reagent History (Accelerator Key = Alt + H)</p> <p>Cumulative Inventory (Accelerator Key = Alt + C)</p>
<p>Error Handling</p>	<p>If the user clicks Export while analytical functions are being performed, an error message, "<i>Records cannot be exported while analytical cycles are running.</i>" OK</p>

4.5. Export - Service History Log

Cal/Gain Logs Service Log Message Log Reagent Log Startup Log User Notepad Workload Log

History

Scheduled
 Unscheduled
 Field Service
Service History

Procedure	Logged Sample Count	Sample Interval	Date Due	Date Performed	User Code	Ca
Clean Air-Circulation Filter	0	0	8/18/98	8/18/98	bay	Pn
Clean the PEROX reaction chamber	0	1000	8/18/98	8/18/98	bay	Hy
Clean the PEROX reaction chamber	0	1000	8/19/98	8/19/98	bay	Hy
Clean Air-Circulation Filter	0	0	8/19/98	8/19/98	bay	Pn
Measure and adjust RBC pre-amp voltage	0	0		8/25/98	bay	Op
Replace the 1000-uL syringe plungers	0	16000	4/98 12:00:01	8/26/98	bay	Hy
Adjust PEROX temperature	0	0		8/29/98	bay	El
Replace the autosampler needle	0	8000	9/16/98	8/29/98	bay	Se

Details Delete Print Report Export Info

Figure 9 - Service History Log

Purpose	The Service History log provides the user with a cumulative record of all service activities for a specific period of time.
Pre-Condition	A user must be logged on and the ADVIA 120 must not be running any analytical cycles.

Input	<p>To export the Service History Log, the user selects System Logs menu ⇒ Service Log tab ⇒ Service History. The user would then click on the Export command button.</p> <p>Upon entering the Service History screen, the database is refreshed to ensure the most current information is displayed allowing for the most current information to be transmitted upon clicking Print Report or Export. (IR #3368)</p> <p><u>Exporting All Records:</u></p> <p>The user would click Export to invoke the Export to File screen.</p> <p>The user would choose the Export Destination by selecting a Drive and/or Subdirectory.</p> <p>The user will be forced to accept the default 'All' as they will not have the option to choose 'Selected'. As a result, the 'Export – All or Selected Records' combo box shall be disabled and grayed with the word 'All' displayed.</p> <p>Click Start</p> <p><u>Exporting Selected records:</u></p> <p>The user shall not have the ability to choose 'Selected' records.</p>
-------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Output

The user's selection (All) shall be exported to the chosen destination

The exported format shall appear as follows:

Columns are separated by tabs

Rows are separated by line feeds/carriage returns

The exported report shall include the log title: Service History

The column titles and information shall appear in the following order:

Column 1 = Procedure

Column 2 = Logged Sample Count

Column 3 = Sample Interval

Column 4 = Date Due

Column 5 = Date Performed

Column 6 = User Code

Column 7 = Category

Column 8 = Intervention Type

Column 9 = Comments

Command Buttons

This section shall serve to confirm the proper assignment of accelerator keys. There is no change in functionality to the existing command buttons and the newly implemented **Export** command functions are described in detail above

Details (Accelerator key = Alt + E)

Delete (Accelerator key = Alt + D)

Print Report (Accelerator key = Alt + P)

Export (Accelerator key = Alt + X)

Interface (Accelerator key = Alt + I)

Scheduled (Accelerator key = Alt + S)

Unscheduled (Accelerator key = Alt + U)

Field Service (Accelerator key = Alt + F)

Service History

Error Handling	If the user clicks Export while analytical functions are being performed, an error message, " <i>Records cannot be exported while analytical cycles are running.</i> " OK
----------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

4.6. Export: Startup Log

The screenshot shows a software window titled "Startup Log" with a menu bar containing "Cal/Gain Logs", "Service Log", "Message Log", "Reagent Log", "Startup Log", "User Notepad", and "Workload Log". The main area contains a table with the following data:

Date	Time	WBC	PLT	HGB Trans	User Code
08/14/98	3:25:35 PM	1.00	2	3.000	bay
08/17/98	12:00:18 PM	1.00	2	3.000	bay
08/17/98	12:10:23 PM	1.00	2	3.000	bay
08/18/98	2:31:56 PM	1.00	2	3.000	bay
08/21/98	3:09:02 PM	1.00	2	3.000	bay
08/24/98	8:51:37 AM	1.00	2	3.000	bay
08/24/98	1:04:35 PM	1.00	2	3.000	bay

Below the table are five buttons: "Startup", "Delete All", "Print Report", "Export", and "Info".

Figure 10 - Startup Log

Purpose	The Startup Log provides the user with background count information for BASO WBC, PLT and the HGB baseline transmission obtained during each startup. It also displays the date, time and User Code of the individual who was logged on during startup.
Pre-Condition	A user must be logged on and the ADVIA 120 must not be running any analytical cycles.

Input	<p>To export the Startup Log, the user selects System Logs menu ⇒ Startup Log tab. The user would then click on the Export command button.</p> <p>Upon entering the Startup Log screen, the database is refreshed to ensure the most current information is displayed allowing for the most current information to be transmitted upon clicking Print Report or Export. (IR #3368)</p> <p><u>Exporting All Records:</u></p> <p>The user would click Export to invoke the Export to File screen.</p> <p>The user would choose the Export Destination by selecting a Drive and/or Subdirectory.</p> <p>The user will be forced to accept the default 'All' as they will not have the option to choose 'Selected'. As a result, the 'Export – All or Selected Records' combo box shall be disabled and grayed with the word 'All' displayed.</p> <p>Click Start</p> <p><u>Exporting Selected Records:</u></p> <p>The user shall not have the ability to choose 'Selected' records.</p>
Output	<p>The user's selection (All) shall be exported to their chosen destination.</p> <p>The exported format shall appear as follows:</p> <p>Columns are separated by tabs</p> <p>Rows are separated by line feeds/carriage returns</p> <p>The exported file shall contain the log title: Startup Log</p> <p>The column headings shall appear in the following order:</p> <p>Column 1 = Date</p> <p>Column 2 = Time</p> <p>Column 3 = WBC</p> <p>Column 4 = PLT</p> <p>Column 5 = HGB Tran</p> <p>Column 6 = User Code</p> <p>The information populating the columns shall not be encoded. The user will be able to view and read the information in each column without requiring a separate manual to decode the data (IR #3030).</p>

<p>Command Buttons</p>	<p>This section shall serve to confirm the proper assignment of accelerator keys. There is no change in functionality to the existing command buttons and the newly implemented Export command functions are described in detail above</p> <p>Startup (Accelerator key = Alt + S)</p> <p>Delete All (Accelerator key = Alt + D)</p> <p>Print Report (Accelerator key = Alt + P)</p> <p>Export (Accelerator key = Alt + X)</p> <p>Interface (Accelerator key = Alt + I)</p>
<p>Error Handling</p>	<p>If the user clicks Export while analytical functions are being performed, an error message, <i>“Records cannot be exported while analytical cycles are running.”</i> OK</p>

4.7. Export: User Notepad - QC Comments

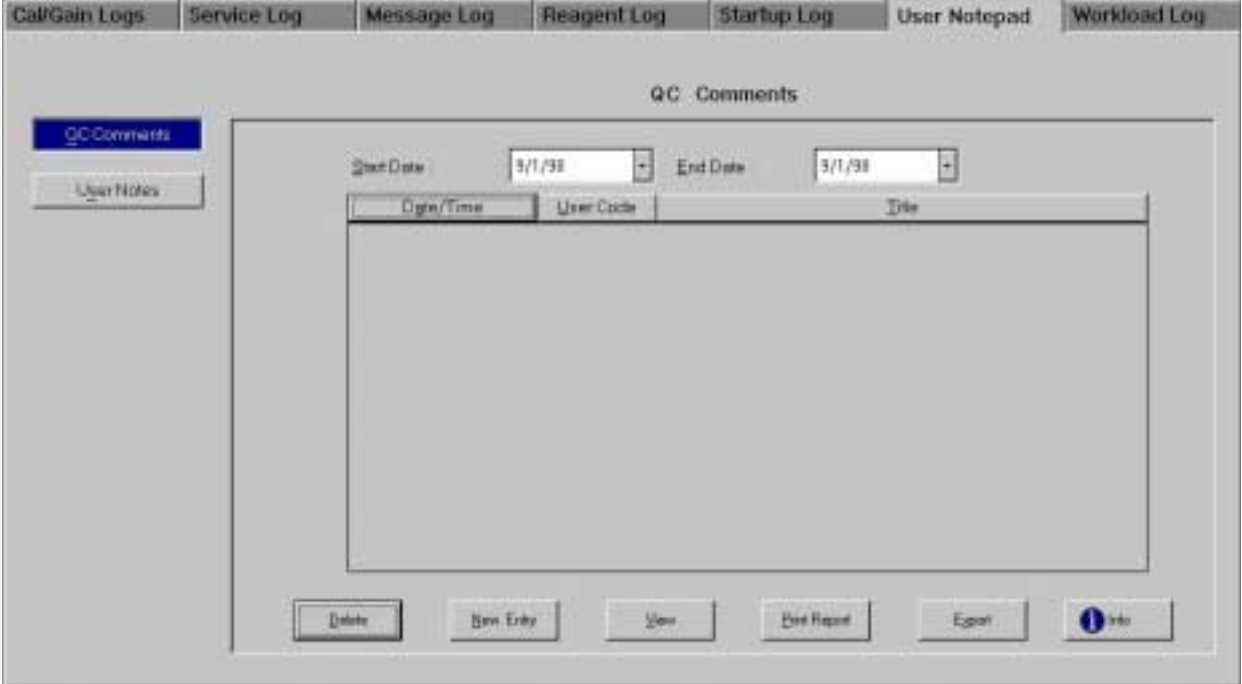


Figure 11 - QC Comments

<p>Purpose</p>	<p>QC Comments usually includes user’s comments regarding the analyzer’s performance.</p>
----------------	-------------------------------------------------------------------------------------------

Pre-Condition	A user must be logged on and the ADVIA 120 must not be running any analytical cycles.
Input	<p>To export QC Comments, the user selects System Logs menu ⇒ User Notepad tab ⇒ QC Comments.</p> <p><u>Exporting All Records:</u></p> <p>The user would click Export to invoke the Export to File screen.</p> <p>After selecting the Drive and Subdirectory, the user would accept the default selection 'All' in the 'Export – All or Selected records' textbox.</p> <p>Click Start</p> <p><u>Exporting Selected records:</u></p> <p>Within the QC Comments screen, the user shall be able to select records for export by highlighting rows (consecutively or non consecutively)</p> <p>Once the selection is made, the user clicks Export to invoke the Export to File screen.</p> <p>After selecting the Drive and Subdirectory, the user would choose 'Selected' from the 'Export – All or Selected records' text box.</p> <p>Click Start</p>
Output	<p>The user's selection (All or Selected) shall be exported to the chosen destination.</p> <p>The exported format shall appear as follows:</p> <p>Columns are separated by tabs</p> <p>Rows are separated by line feeds/carriage returns</p> <p>The exported report shall include the log title: QC Comments</p> <p>The column titles and information shall appear in the following order:</p> <p>Column 1 = Date/Time</p> <p>Column 2 = User Code</p> <p>Column 3 = Title</p> <p>Column 4 = Message (Chui to provide text limitations)</p>

<p>Command Buttons</p>	<p>This section shall serve to confirm the proper assignment of accelerator keys. There is no change in functionality to the existing command buttons and the newly implemented Export command functions are described in detail above</p> <p>Delete (Accelerator Key = Alt + D)</p> <p>New Entry (Accelerator Key = Alt + N)</p> <p>View (Accelerator Key = Alt + V)</p> <p>Print Report(Accelerator Key = Alt + P)</p> <p>Export (Accelerator Key = Alt + X)</p> <p>Info (Accelerator Key = Alt + I)</p> <p>QC Comments (Accelerator Key = Alt + Q)</p> <p>User Notes (Accelerator Key = Alt + S)</p>
<p>Error Handling</p>	<p>If the user clicks Export while analytical functions are being performed, an error message, <i>“Records cannot be exported while analytical cycles are running.”</i> OK</p>

4.8. Export: User Notepad - User Notes

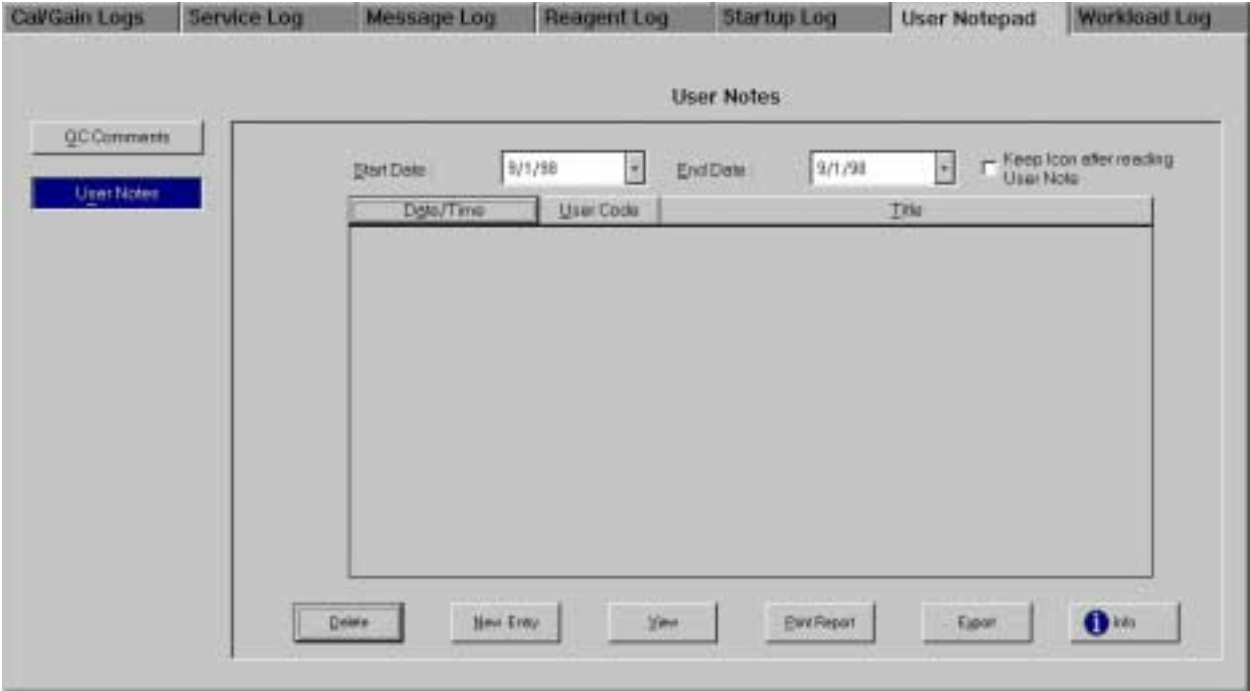


Figure 12 - User Notes

Purpose	User Notes contains general comments that the user deemed necessary to record.
Pre-Condition	A user must be logged on and the ADVIA 120 must not be running any analytical cycles.
Input	<p>To export User Notes, the user selects System Logs menu ⇒ User Notepad tab ⇒ User Notes Command button.</p> <p><u>Exporting All Records:</u></p> <p>The user would click Export to invoke the Export to File screen.</p> <p>After selecting the Drive and Subdirectory, the user would accept the default selection 'All' in the 'Export – All or Selected records' textbox.</p> <p>Click Start</p> <p><u>Exporting Selected records:</u></p> <p>Within the User Notes screen, the user shall be able to select records for export by highlighting the rows (consecutively or non consecutively)</p> <p>Once the selection is made, the user clicks Export to invoke the Export to File screen.</p> <p>After selecting the Drive and Subdirectory, the user would choose 'Selected' from the 'Export – All or Selected records' text box.</p> <p>Click Start</p>
Output	<p>The user's selection (All or Selected) shall be exported to their chosen destination.</p> <p>The exported format shall appear as follows:</p> <p>Columns are separated by tabs</p> <p>Rows are separated by line feeds/carriage returns</p> <p>The exported report shall display the log title: User Notes</p> <p>The column titles and information shall appear in the following order:</p> <p>Column 1 = Date/Time</p> <p>Column 2 = User Code</p> <p>Column 3 = Title</p> <p>Column 4 = Message</p>

<p>Command Buttons</p>	<p>This section shall serve to confirm the proper assignment of accelerator keys. There is no change in functionality to the existing command buttons and the newly implemented Export command functions are described in detail above</p> <p>Delete (Accelerator Key = Alt + D)</p> <p>New Entry (Accelerator Key = Alt + N)</p> <p>View (Accelerator Key = Alt + V)</p> <p>Print Report(Accelerator Key = Alt + P)</p> <p>Export (Accelerator Key = Alt + X)</p> <p>Info (Accelerator Key = Alt + I)</p> <p>QC Comments (Accelerator Key = Alt + Q)</p> <p>User Notes (Accelerator Key = Alt + S)</p>
<p>Error Handling</p>	<p>If the user clicks Export while analytical functions are being performed, an error message, <i>“Records cannot be exported while analytical cycles are running.”</i> OK</p>

4.9. Export : Workload Log - Cumulative Workload Log

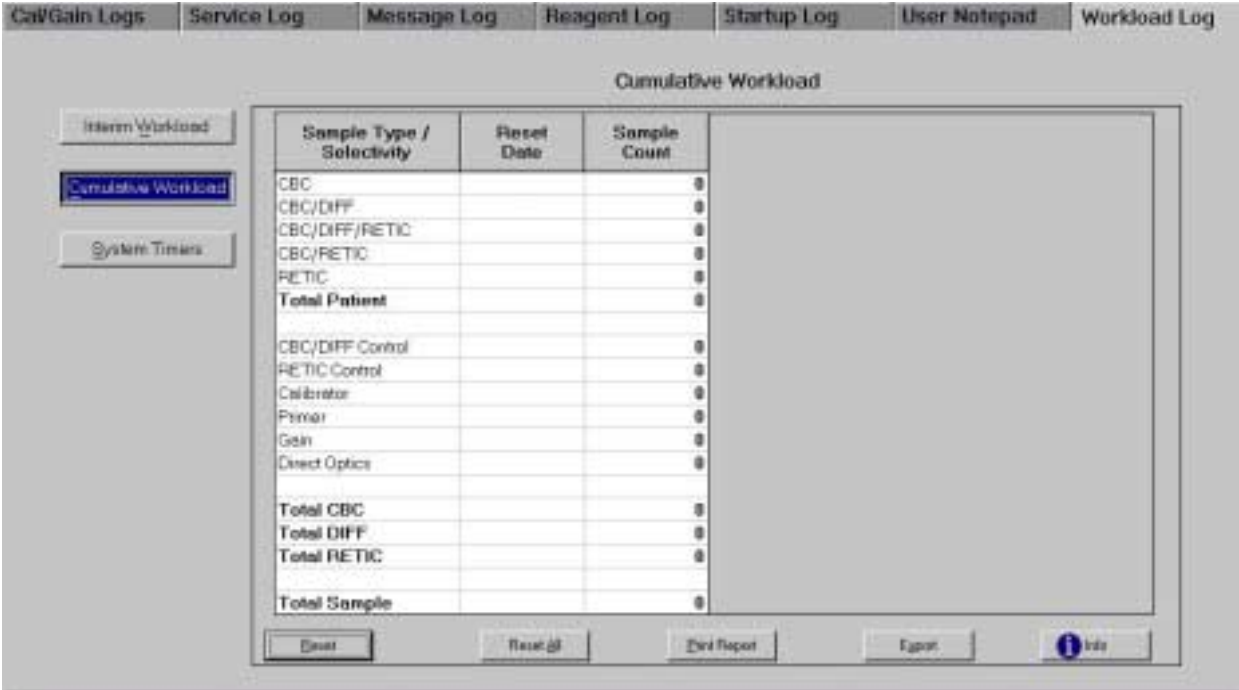


Figure 13 - Cumulative Workload

Purpose	The Cumulative Workload log provides the user with throughput statistics collected since the installation of the system.
Pre-Condition	A user must be logged on and the ADVIA 120 must not be running any analytical cycles.
Input	<p>To export the Cumulative Workload Log, the user would select System Logs from the menu ⇒ Workload Log ⇒ Cumulative Workload. The user would then click on the Export command button.</p> <p>Upon entering the Cumulative Workload screen, the database is refreshed to ensure the most current information is displayed allowing for the most current information to be transmitted upon clicking Print Report or Export. (IR #3368)</p> <p><u>Exporting All Records:</u></p> <p>The user would click Export to invoke the Export to File screen.</p> <p>The user would choose the Export Destination by selecting a Drive and/or Subdirectory.</p> <p>The user will be forced to accept the default 'All' as they will not have the option to choose 'Selected'. As a result, the 'Export – All or Selected Records' combo box shall be disabled and grayed with the word 'All' displayed.</p> <p>Click Start</p> <p><u>Exporting Selected Records:</u></p> <p>The user shall not have the ability to choose 'Selected' records</p>

<p>Output</p>	<p>The user's selection (All) shall be exported to the chosen destination.</p> <p>The exported format shall appear as follows:</p> <p>Columns are separated by tabs</p> <p>Rows are separated by line feeds/carriage returns</p> <p>The exported report shall include the log title: Cumulative Workload</p> <p>The format of the exported report shall vary depending on whether the software is Clinical or Multi Species. The Multi Species software shall require a "Species" column. This column shall be suppressed in the Clinical software. Therefore, the column headings shall appear as follows:</p> <p>MULTI SPECIES:</p> <p>Column 1 = Species</p> <p>Column 2 = Sample Type/Selectivity</p> <p>Column 3 = Reset Date</p> <p>Column 4 = Sample Count</p> <p>CLINICAL:</p> <p>Column 1 = Sample Type/Selectivity</p> <p>Column 2 = Reset Date</p> <p>Column 3 = Sample Count</p>
<p>Command Buttons</p>	<p>This section shall serve to confirm the proper assignment of accelerator keys. There is no change in functionality to the existing command buttons and the newly implemented Export command functions are described in detail above</p> <p><u>R</u>eset (Accelerator Key = Alt + R)</p> <p>Reset <u>A</u>ll (Accelerator Key = Alt + A)</p> <p>Print <u>R</u>eport (Accelerator Key = Alt + P)</p> <p><u>E</u>xport (Accelerator Key = Alt + X)</p> <p>Info (Accelerator Key = Alt + I)</p> <p>Interim <u>W</u>orkload (Accelerator Key = Alt + W)</p> <p><u>C</u>umulative Workload (Accelerator Key = Alt + C)</p> <p><u>S</u>ystem Timers (Accelerator Key = Alt + S)</p>

Error Handling	If the user clicks Export while analytical functions are being performed, an error message, <i>“Records cannot be exported while analytical cycles are running.”</i> OK
----------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

4.10. Export: Workload Log - Interim Workload Log

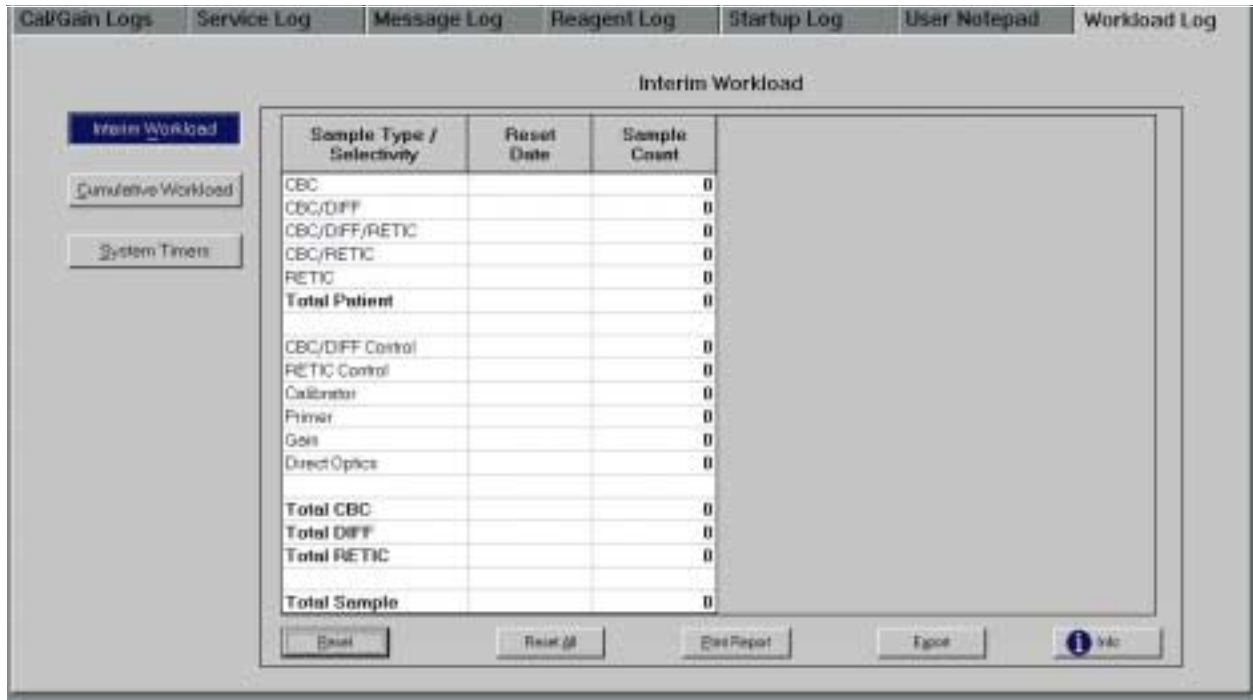


Figure 14 - Interim Workload Log

Purpose	The Interim Workload log provides the user with throughput statistics collected since the last reset
Pre-Condition	A user must be logged on and the ADVIA 120 must not be running any analytical cycles.

Input	<p>To export the Interim Workload Log, the user would select System Logs from the menu ⇒ Workload Log ⇒ Interim Workload. The user would then click on the Export command button.</p> <p>Upon entering the Interim Workload screen, the database is refreshed to ensure the most current information is displayed allowing for the most current information to be transmitted upon clicking Print Report or Export. (IR #3368)</p> <p><u>Exporting All Records:</u></p> <p>The user would click Export to invoke the Export to File screen.</p> <p>The user would choose the Export Destination by selecting a Drive and/or Subdirectory.</p> <p>The user will be forced to accept the default 'All' as they will not have the option to choose 'Selected'. As a result, the 'Export – All or Selected Records' combo box shall be disabled and grayed with the word 'All' displayed.</p> <p>Click Start</p> <p><u>Exporting Selected Records:</u></p> <p>The user shall not have the ability to choose 'Selected' records</p>
-------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>Output</p>	<p>The user's selection (All) shall be exported to their chosen destination.</p> <p>The exported format shall appear as follows:</p> <p>Columns are separated by tabs</p> <p>Rows are separated by line feeds/carriage returns</p> <p>The exported report shall include the title: Interim Workload</p> <p>The format of the exported report shall vary depending on whether the software is Clinical or Multi Species. The Multi Species software shall require a "Species" column. This column shall be suppressed in the Clinical software. Therefore, the column headings shall appear as follows:</p> <p>MULTI SPECIES:</p> <p>Column 1 = Species</p> <p>Column 2 = Sample Type/Selectivity</p> <p>Column 3 = Reset Date</p> <p>Column 4 = Sample Count</p> <p>CLINICAL:</p> <p>Column 1 = Sample Type/Selectivity</p> <p>Column 2 = Reset Date</p> <p>Column 3 = Sample Count</p>
<p>Command Buttons</p>	<p>This section shall serve to confirm the proper assignment of accelerator keys. There is no change in functionality to the existing command buttons and the newly implemented Export command functions are described in detail above</p> <p><u>R</u>eset (Accelerator Key = Alt + R)</p> <p>Reset <u>A</u>ll (Accelerator Key = Alt + A)</p> <p><u>P</u>rint Report (Accelerator Key = Alt + P)</p> <p><u>E</u>xport (Accelerator Key = Alt + X)</p> <p>Info (Accelerator Key = Alt + I)</p> <p>Interim <u>W</u>orkload (Accelerator Key = Alt + W)</p> <p><u>C</u>umulative Workload (Accelerator Key = Alt + C)</p> <p><u>S</u>ystem Timers (Accelerator Key = Alt + S)</p>

Error Handling	If the user clicks Export while analytical functions are being performed, an error message, <i>“Records cannot be exported while analytical cycles are running.”</i> OK
----------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

4.11. Export: Workload Log - System Timers

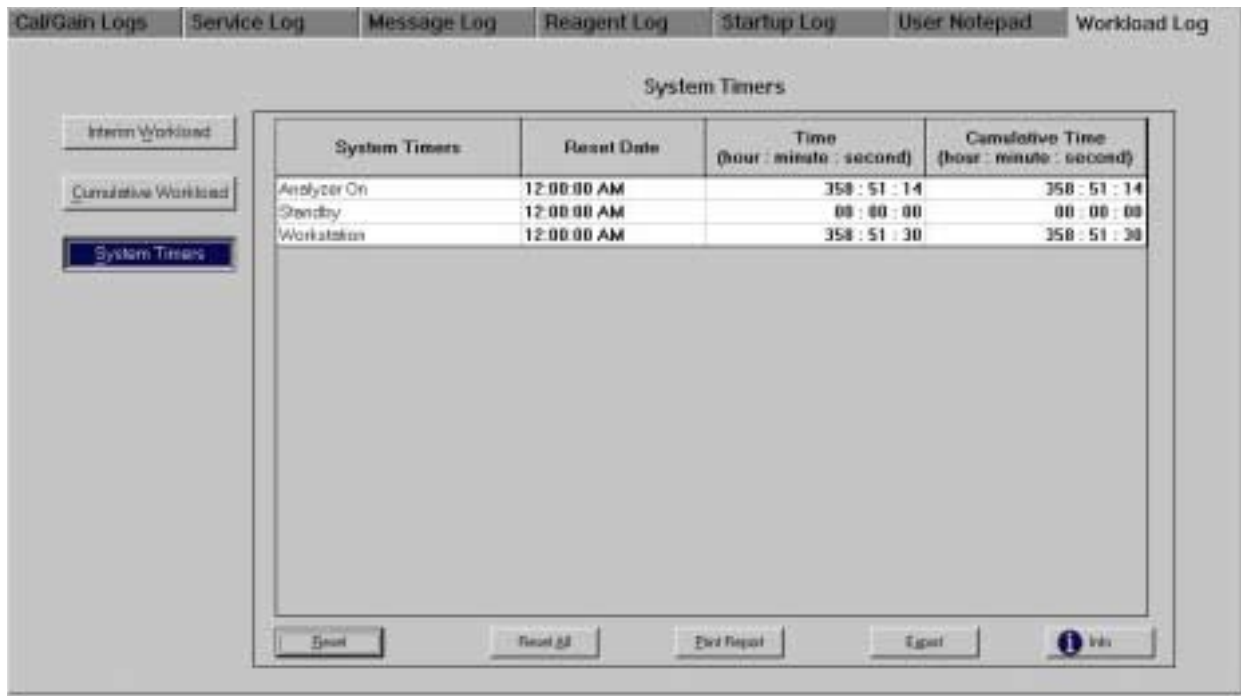


Figure 15 - System Timers

Purpose	The System Timers log provides the user with information regarding the number of hours that the system is on.
Pre-Condition	A user must be logged on and the ADVIA 120 must not be running any analytical cycles.

<p>Input</p>	<p>To export the System Timers Log, the user would select System Logs from the menu ⇒ Workload Log ⇒ System Timers</p> <p>Upon entering the System Timers screen, the database is refreshed to ensure the most current information is displayed allowing for the most current information to be transmitted upon clicking Print Report or Export. (IR #3368)</p> <p><u>Exporting All Records:</u></p> <p>The user would click Export to invoke the Export to File screen.</p> <p>The user would choose the Export Destination by selecting a Drive and/or Subdirectory.</p> <p>The user will be forced to accept the default 'All' as they will not have the option to choose 'Selected'. As a result, the 'Export – All or Selected Records' combo box shall be disabled and grayed with the word 'All' displayed.</p> <p>Click Start</p> <p><u>Exporting Selected Records:</u></p> <p>The user shall not have the ability to choose 'Selected' records</p>
<p>Output</p>	<p>The Export to Files screen is invoked. See section 6.2.1 for export details.</p> <p>The exported format shall appear as follows:</p> <p>Columns are separated by tabs</p> <p>Rows are separated by line feeds/carriage returns</p> <p>The exported report shall include the title: System Timers</p> <p>The column titles and information shall appear in the following order:</p> <p>Column 1 = Sample Timers</p> <p>Column 2 = Reset Date</p> <p>Column 3 = Time</p> <p>Column 4 = Cumulative Time</p>

Command Buttons	<p>This section shall serve to confirm the proper assignment of accelerator keys. There is no change in functionality to the existing command buttons and the newly implemented Export command functions are described in detail above</p> <p>Reset (Accelerator Key = Alt + R)</p> <p>Reset <u>A</u>ll (Accelerator Key = Alt + A)</p> <p>Print Report (Accelerator Key = Alt + P)</p> <p>Export (Accelerator Key = Alt + X)</p> <p>Info (Accelerator Key = Alt + I)</p> <p>Interim <u>W</u>orkload (Accelerator Key = Alt + W)</p> <p><u>C</u>umulative Workload (Accelerator Key = Alt + C)</p> <p><u>S</u>ystem Timers (Accelerator Key = Alt + S)</p>
Error Handling	<p>If the user clicks Export while analytical functions are being performed, an error message, "<i>Records cannot be exported while analytical cycles are running.</i>" OK</p>

Section 5: Database Repair

Accessed via: Utilities, Backup Restore, Database Repair

5.1. System Reboot after Database Repair

In order for the system to utilize the newly repaired database, the system must be shut down and re started. As a result, clicking the **Start** command button shall invoke the following warning message *“This process requires a shut down and restart of the ADVIA 120 workstation. Upon completion , your system will automatically shut down and re-start. (Please be sure to exit all other programs.) Do you want to continue?”* **Yes, No.** If the user selects **Yes**, the repair will proceed. Upon completion of the repair a Database Repair Report is automatically generated. After the report is printed, the system shall wait until all hydraulic cycles are completed and then will begin shutdown

If the user selects **No**, the Database Repair shall not take place and the warning message disappears.

5.2. Printed Report Format

The format of the printed report shall be modified to include two additional columns, Database Size – Before repair and database size after repair. The revised report shall contain the following information:

HEADER

- Report Title
- System Name
- User Code
- Date

² Time

BODY OF REPORT

- #
- Table Name
- # of Records Before Repair
- Database Size Before Repair
- # of Records After Repair
- Database Size After Repair

#	Table Name	Before Repair		After Repair	
		# of Records	Database Size	# of Records	Data-base Size

Sample Database Repair Report Format

Section 6: Incidents Addressed in this SRD

Incident Number	Description	Backup Restore SRD - PL3 [A120_SRD00 6-002] Section No
3029	Exported file format for MessageLog is not the desired format. The file only displays the message ID and not the actual message. In order for the user to be able to make sense out of the report, a book has to be provided where all the ID's are explained. It is desired that the message log that the user sees from system logs – message log be the one to be exported.	6.2.2
3030	Reagent History exported file format is not the desired format.	6.2.3
3031	The startup log export file format is not the desired format.	6.2.7
3368	<p>The message log that is exported does not correspond to the log that is printed from Advia. If the user prints a report from the message log screen and prints the exported message file, they do not match. apparently the database is not being refreshed frequently enough. This incident is different than incident # 3029 which refers to the wrong format. Please see attachments. Page #1 is the exported file print out and page #2 is the printout from advia.</p> <p>9-18-97 not corrected in V1.0.12R The exported message log does not contain any messages, it has the ID for the messages. The ID is meaningless to a user unless the user has access to a document where he/she can lookup the definition</p>	6.2.2
4491	Enhance the EXPORT functionality so that Workload Log can be exported from Advia 120. (This is a NEW requirement!)	6.2.10 6.2.11
4636	<p>The files exported for the cumulative history option are the wrong files</p> <p>Export the Cumulative and Interim Workload log.</p>	6.2.10 6.2.11
6421	Implement export to file for all log functions (reagent, service, workload, message)	6.2.2 6.2.3 6.2.6 6.2.10 6.2.11

7239	<p>Backup Restore – Export Logs</p> <p>When exported the following logs do not mirror the on screen ADVIA formatting:</p> <p>Service History, QC Comments, User Notes, Reagent History, Start Up Logs. Each exported log should contain the title of the log, listing each column as it appears on the ADVIA and the contents within each column should be in plain text as it appears on the ADVIA screen.</p>	<p>6.2.3</p> <p>6.2.6</p> <p>6.2.7</p> <p>6.2.8</p> <p>6.2.9</p>
7640	<p>Go to Utilities-Backup/Restore-Export. Select all Exported Logs, Exported Data and A:\ drive as Export destination. Click on “Start” button. Try to pull disk from A:\ drive and the following message will display: ‘There is no disk in the drive. Please insert a disk into drive A:\.’ It has 3 buttons: Abort, Retry and Ignore. According to the requirements if you click on “Abort” button following message should show up “Are you sure?” and if you select OK, the export is aborted. If you click No, you are not sure you want to abort the export, you are prompted to insert the second disk.</p>	6.2.1
7742	<p>To be consistent change the title of Maintenance Log with Service History Log. Utilities-Backup/Restore. Export is selected. On Export screen check the box for Service History Log, Reagent History, Startup Log and User Notes. Click Start. Data is exported and when finished view the contents of Export folder with the Explorer. All logs were exported except the log titled Service History Log, instead the log was titled Maintenance Log.</p>	6.2.6
8290	<p>In Backup/Restore, the “Print Report” button in the Restore screen is hidden and never shown. The operator guide under “Utilities Menu: Backup/Restore tab” step 7 instructs the user to click “Print Report” to print a Restore report. We need to either implement this feature or change the documentation.</p>	6.1

Section 7: References

1. ADVIA 120 Hematology System MPDR [067-C008 Rev. F]
2. ADVIA 120 Hematology System Product Design Requirement (PDR) Post Launch Software Release Phase PL3 [Number to be assigned]
3. Backup Restore URD [A120_URD006_i1.0]
4. Backup Restore SRD PL2 [A120_SRD006-001_d0.5]

Section 8: Test Strategy

- To test the Backup/Restore and Export function of the ADVIA 120 software, the following approach can be taken.
- Compare the exported files with the printed version of the same set of records to ensure consistency of information.
- Compare the exported files with the on screen version of the same set of records to ensure consistency of information.
- The Message Log and Reagent Logs are dynamic and may update during the course of an export. Invoke a non-analytical cycle while performing an export to ensure the database refresh cut off point is consistent between the exported and printed files.
- Invoke a non-analytical cycle and either Restore or Repair the Database to ensure the system allows the ADVIA to complete the cycle before shut down.

Section 9: On Line Help

On line help shall be modified to accommodate the changes outlined in this document.

Section 10: What's This Help

What's this help shall be modified to accommodate the changes as outlined in this document

Section 11: Implement Requirements as identified in the IR's listed below:

Incident	Description/Requirement
8197	<p>Print Report feature on the Backup Screen prints to local printer only. It does not print to a networked printer.</p> <p><u>Requirement:</u> As with the other logs and reports, provide the ability to print the Backup Report to any selected networked printer.</p>
7941	<p>Restore doesn't work for Help Annotations when only Help Annotations are selected.</p> <p><u>Requirement:</u></p> <p>The user shall have the ability to backup and restore one, or more or any combination of the following backup options (depending on their level of security): Registry, Configuration Files, Database and/or Help Annotations.</p>

Section 12: Hazard Analysis

No	Severity	Probability	Risk	Mitigation
1	High	High	Not rebooting the system after a Restore - By not rebooting the system immediately after a restore, important information stored in files such as Message Log, Service Log, Hnext.mdb, Startup, and others will be overwritten when the system is finally rebooted.	Auto Reboot as part of software implementation and verification through Testing and Validation
2	High	High	No reboot after Database repair – By not rebooting the system immediately after a restore, any information stored in the database will be overwritten when the system is finally rebooted.	Auto Reboot as part of software implementation and verification through

Section 13: Appendix 1 - Requirements Traceability Matrix

Backup Restore URD [A120_URD006] Section No	Backup Restore SRD - PL3 [A120_SRD006-002] Section No
4.1.1	
4.1.1.1	
4.1.1.2	
4.1.2	
4.1.2.1	
4.1.2.2	
4.1.2.3	
4.1.3	
4.1.3.1	
4.1.4	
4.1.4.1	
4.1.4.2	
4.1.4.3	
4.1.4.4	
4.2.1	
4.2.1.1	
4.2.1.2	
4.2.2	
4.2.2.1	
4.2.2.2	
4.2.2.3	6.1
4.2.2.4	6.1
4.2.2.5	6.1
4.2.3	
4.2.3.1	

4.3.1	6.2
4.3.1.1	
4.3.1.2	
4.3.1.3	
4.3.1.4	7.1
4.3.1.5	6.2.2, 6.2.3, 6.2.4, 6.2.5, 6.2.6, 6.2.4, 6.2.8, 6.2.9, 6.2.10, 6.2.11, 6.2.12
4.3.1.6	6.2.2, 6.2.3, 6.2.4, 6.2.5, 6.2.6, 6.2.4, 6.2.8, 6.2.9, 6.2.10, 6.2.11, 6.2.12