

Chromatography Data System

GCsolution version 2.4

Instruction Manual

Administration

Read the instruction manual thoroughly before you use the product.
Keep this instruction manual for future reference.

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Introduction

Thank you very much for purchasing the GCsolution software for Shimadzu gas chromatography workstations (hereafter called "GCsolution").

GCsolution allows you to control the Gas Chromatograph (hereafter called "GC") from your personal computer, acquire chromatograms and other different kinds of data, and reanalyze the acquired data under different parameters on your personal computer.

This manual explains the operational procedures and basic idea of system administration and data management using GCsolution. It is provided as a PDF file so that it can be referred to on-line whenever operations related to system administration are needed.

As separate volume, the Operation manual is attached as printed manual, and the Reference manual is attached as PDF file on GCsolution CD-ROM.

The Operation manual has been put together in order to familiarize you with the basic knowledge required to operate GCsolution. Be sure to read it thoroughly before using this software. After reading the manual, keep it in a safe place so that it can be accessed whenever necessary.

The Reference manual covers the on-line help information in PDF format. For detailed information on the functions of GCsolution, refer to this.

This manual assumes that the reader is knowledgeable of basic operations of Windows®. For the operation of Windows®, refer to the instruction manual that comes with that product.

This is the common manual for both GCsolution and GCsolution Lite.

Using the instruction manual

Kinds of instruction manuals

The GCsolution package contains the following information that describes the operational procedures and functions

Name	Media	Description
Operation manual for GCsolution	Printed document	Explains the operational procedures for data acquisition and analysis using GCsolution.
On-line help	GCsolution program	Provides detailed information on parameters and setting ranges. This is accessible from the Help menu in GCsolution. (For using the on-line help, refer to section 12.1.1 Using Help in Operation manual.
Operation manual for GCsolution (PDF version)	CD-ROM disk for installation	Provides the operations volume of the instruction manual as a PDF file so that it can be viewed on your personal computer. It is accessible from the Help menu in GCsolution. (For using this PDF, refer to section 12.1.2 Using the Online Manual in Operation manual.
Quick manual for GCsolution (PDF version)	CD-ROM disk for installation	Provides the Quick manual as a PDF file so that it can be viewed on your personal computer.
References manual for GCsolution (PDF version)	CD-ROM disk for installation	Provides the Reference manual as a PDF file so that the on-line help can be printed out. The general table of contents is available, including all the instruction manuals (PDF versions). This is the common manual for both GCsolution and GCsolution Lite.
Administration manual for GCsolution (PDF version)	CD-ROM disk for installation	Expands the operational procedures and basic idea of system administration and data management using GCsolution. This manual is provided as a PDF file so that it can be referred whenever operations related to system administration are needed. The general table of contents is available, including all the instruction manuals (PDF versions). This is the common manual for both GCsolution and GCsolution Lite.

Legends for instruction manual

This manual uses the following legends:

Legend	Meaning
❗	Gives you tips.
< >	Shows a window or view name; e.g., <Data Acquisition> window or <Method> view.
[]	Shows a parameter, tab, column, cell, bar name, menu command, that can be selected from the menu bar.
[]-[] command	Shows a sequence of selecting the menu in the first [] and then selecting the command in the second []. For example, [File]-[Print] command means that you should click on the File menu and then select the Print command from the displayed list of commands.

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1 GxP Support Functions

1.1 Overview of GxP Support Functions

1.1.1 What is GLP/GMP?

GLP is an abbreviation for “Good Laboratory Practices”. GMP is an abbreviation for “Good Manufacturing Practices”.

Both terms are usually used by their abbreviations alone.

Note: Many items and functions are common for GLP and GMP methodology, and this software also uses these functions as GxP support functions.

This function ensures the reliability of inspection by keep openness of inspection to the public. For that purpose, all inspection operations are standardized through documents, and all inspection progress are recorded and kept. Also, the reliability guarantee section and the actual inspection section are separated, and precision and machine condition are checked periodically.

In order to assure the quality of the finally obtained result (data), this method allows you to control the entire process (validation, workflow, and data) involved in acquiring that result, record it, and then trail it (audit trail)

- ① GLP/GMP are guidelines/laws for performing correct analyses and inspections. Even if the use of GLP/GMP is not specifically required for your laboratory, these functions are useful and effective for performing any operations correctly and smoothly.

1.1.2 What is FDA 21 CFR Part 11?

It stands for the FDA (Food and Drug Administration) 21 Code of Federal Regulations Part 11, which states that the FDA approves an electronic record with an electronic signature as equivalent to a document record with a handwritten signature so far as that record conforms to this code.

The code is intended to speed up the FDA’s process for approving new drugs. In the U.S., the electronic signature in the global/commercial trade is legislated and the legal status of the electronic signature is established. The above code may be regarded as a common regulation for handling computer-based documents as they are in the electronic format.

Since this trend is worldwide, electronic data output from a computerized analysis system conforming to the FDA 21 CFR Part 11 can be used throughout the world not only in the medical, pharmaceutical, and food categories, but also in other categories. The use of such electronic data provides effective means taking the place of long-term storage of paper-based data.

The FDA 21 CFR Part 11 mainly refers to the data security (function and access restrictions through security), data integrity (all-in-one file structure and data that can be rolled back), audit trail, and login authentication, all of which are covered by the GxP support functions.

1 GxP Support Functions

1.2 GxP Support Functions

The LabSolutions/GCsolution supports the conformance to the GLP/GMP and the FDA 21 CFR Part 11 through the following functions:

- *System Administration*

Establishment of user administration policy
Establishment of system administration policy
Registration of right groups
Registration of users and permission of rights to users

- *Work Flow Management*

Login authentication and screen lockup
Operational restrictions by specifying rights
Support for standard operation procedures based on batch tables
Support for standard operation procedures based on templates

- *Audit Trail*

All-in-one data file structure
Audit trail log in file
Operation log and system administration log
Data rollback

- *Validation*

Hardware validation
Software validation
System suitability test
Method validation

- *Data Administration*

Data management and search based on sample information
Automatic generation of data file names
Creation and management of files in general-purpose formats such as AIA ANDi/PDF.
Functions associated with CLASS-Agent

The use of the GxP support functions available in the LabSolutions/GCsolution is optional, but will powerfully support and save your GLP/GMP-related work that tends to become troublesome.

Note: For electronic signatures for reviews and approvals of electronic records or for long-term storage of such records, the combination with the optionally available CLASS-Agent conforms to the FDA 21 CFR Part 11.

2 System Administration

2.1 Reviewing System Administration

This software includes a “System Administration” function. Users can use this function to limit the use of functions and programs to specific individuals to protect programs and data.

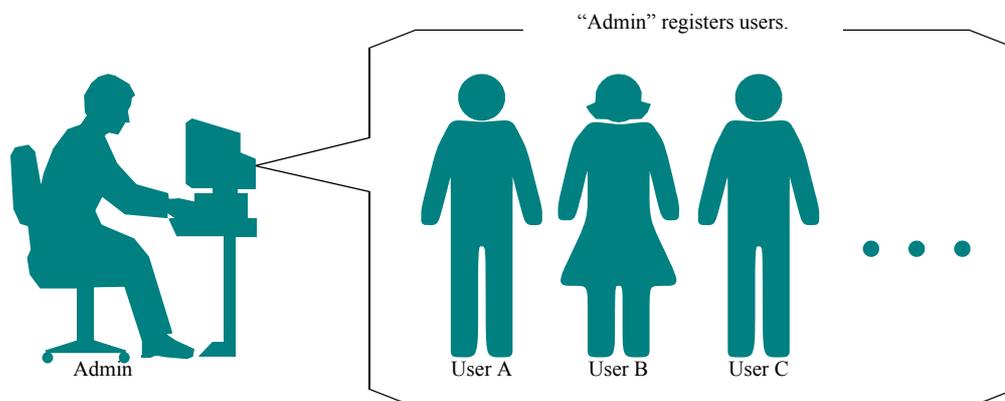
By utilizing this function, your laboratory can conform with GLP/GMP, such as for analysis environment and analysis data reliability and management. This section explains the overall concept of the system administration function.

2.1.1 What is System Administration?

The system administration function will administer the following items:

❖ User

When this software is installed, an “Admin” who has a complete access right (i.e., system administration right) is registered. When you use the system administration function for the first time, use the “Admin” setting to register one person who uses this software as a “User”.



To register a user, enter the following settings:

Parameter	Description
User ID User Name	Enter a user ID for login or a user name for display. Since the same name/ID can be used only one time in this software, you can enter your full name or detailed information in the [Description] field and an abbreviated name or alias in the [User Name] field.
Description	Enter a comment for the user ID/user name.
Password	Enter a password to be registered, if used.
Group	Select groups where the user belongs. The user can use all functions that his/her group has the rights to use.
Instrument	Select the analytical instrument that the user can use.

To use functions that require their usage rights, the user needs to enter his/her registered ID and password in the <Login> window displayed when each program starts up.

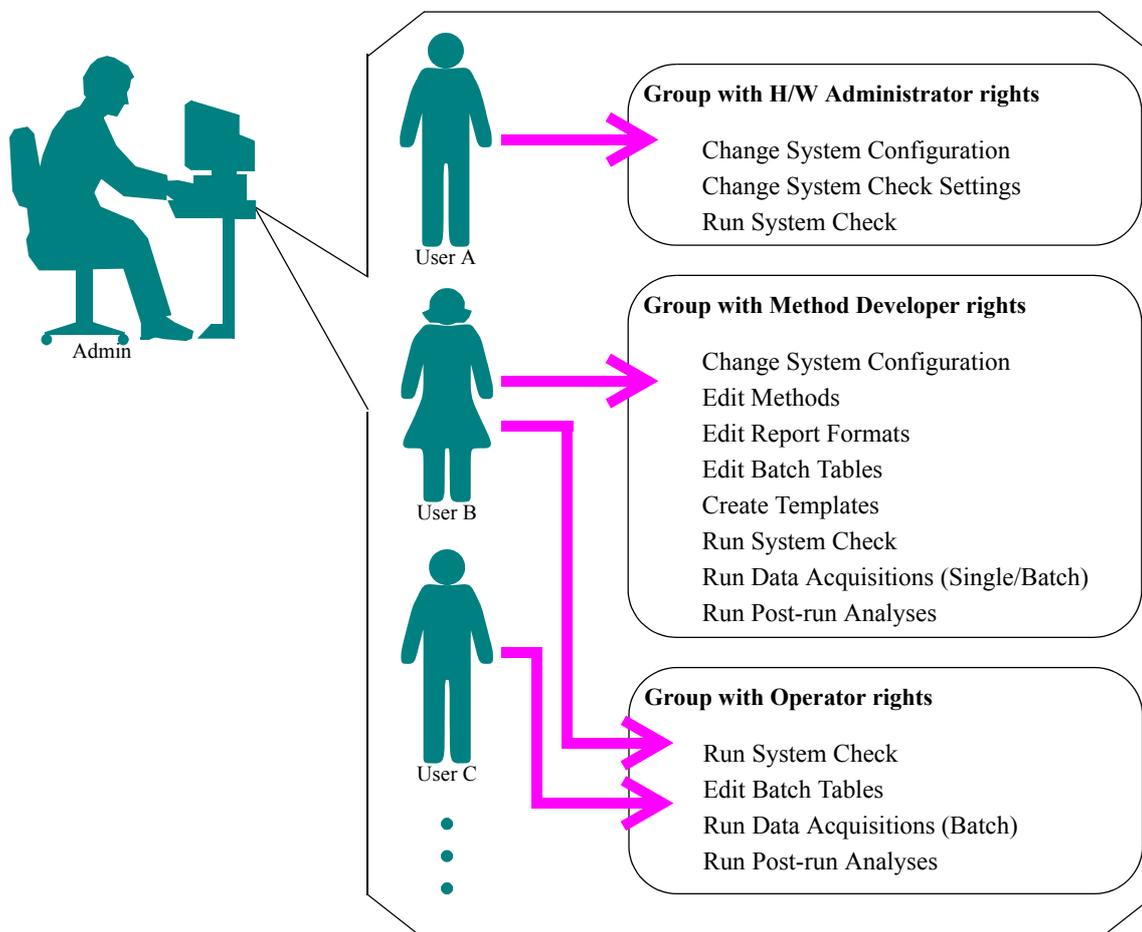
If an ID or password entered in the <Login> window is different from the ones registered, the program will not start up.



❖ Rights (Group)

The [Rights] setting can limit the functions that can be used, using the system administration function.

The following groups with the rights shown have been registered. Registering a user to a group that has the necessary rights enables the user to have the same usage rights.



Note: A user can belong to more than one group. In this case, that user will have all the rights of whichever groups he/she belongs.

Note: The “System Administrator” will have complete rights.

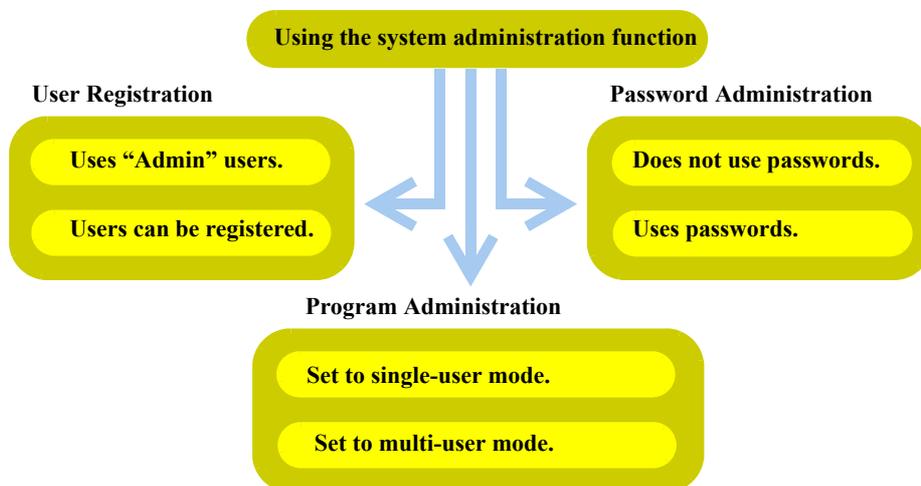
Note: You can create a new group that has the desired rights.

For more information about creating new rights groups, refer to “2.3.2 Registering (Changing/Deleting) Rights Groups”.



2.1.2 System Administration Application

When performing system administration, select the level of administration you require from the following:



❖ Performing User Registration

Use the User Registration feature to clarify who the users are and specify which Analytical Instruments and functions each user can use.

◆ Uses “Admin” users.

Installing this software registers an “Admin” user with complete rights.

If the System Administration function is not necessary, any person can use the “Admin” User ID when the software is installed (no password and no [Normal Login] mode). To use this setting, simply click [OK] in the <Login> window at program startup, and all users will have complete usage rights.

◆ Users can be registered.

If the user registration feature is needed, the Analytical Instrument and functions allowable by each user can be limited (i.e., usage rights can be specified). Also, complete rights can be given to all registered users as system administrators, to use their usage rights in the same way as being an “Admin” user.

Note: In this case, user names can be recorded in the history information without setting passwords. Using this feature also improves system reliability compared with using the Admin-only setting.

❖ Performing Password Administration

A password is used to limit the software to particular users.

◆ Does not use passwords.

Entering only a correct User ID in the <Login> window and leaving the [Password] field blank will enable the program to start.

◆ Uses passwords.

If the registered password is not entered correctly in the [Password] field in the <Login> window, the program will not start.

Note: Even when password entry is not used, if the [Normal Login] mode (explained later) has been set, User ID entry is required. Therefore, based on the User ID confidentiality management levels, a certain level of security can be obtained.

You must change the user ID of “Admin” (only possible at the initial time) because the user ID “Admin” is known. Even when a password is registered, setting the [Normal Login] mode will provide a more secure environment.



❖ **Select single-user or multi-user mode.**

Select whether each user's usage rights are administered for each program.

◆ **Single-User Mode**

In single-user mode, after a user first logs into either the <GC Real Time Analysis/Analysis (Editor)> or <GC Postrun> window, no further login procedures will be required after that to start other programs. Exiting all programs indicates that the user has logged out of the system.

Although this mode facilitates operation when someone uses a personal computer, if one user has logged into the system, other users then do not need to log in and can immediately use any programs.

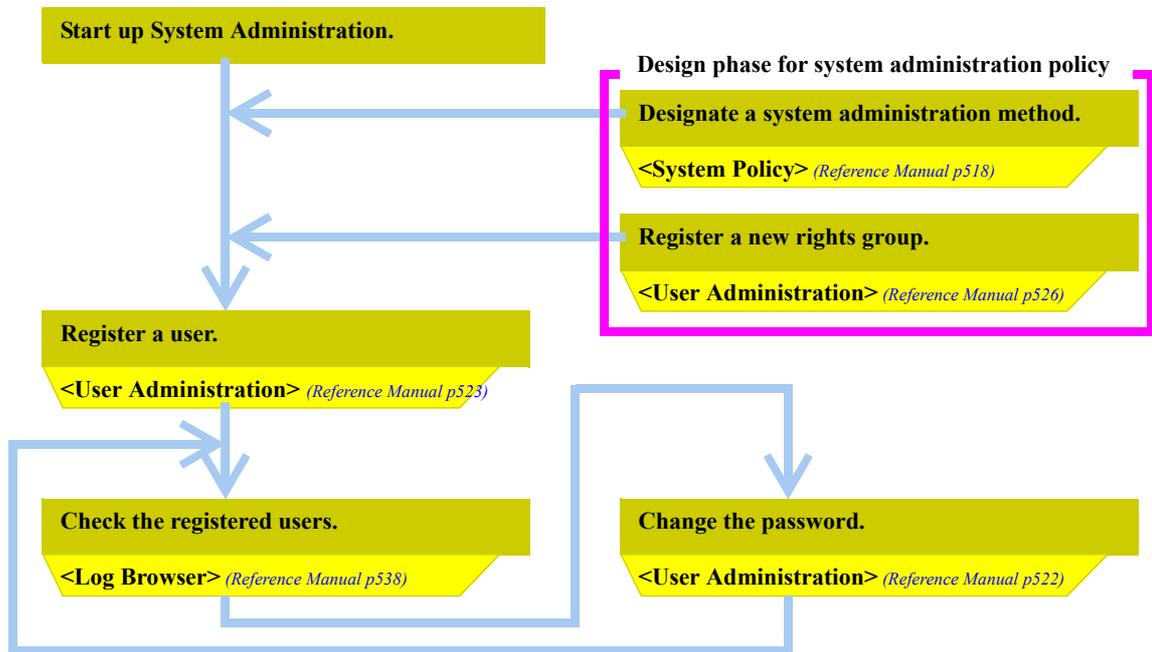
◆ **Multi-User Mode**

In multi-user mode, each time a program is started, the login procedure is required. With this feature, when you start the <GC Real Time Analysis/Analysis (Editor)> program for each Analytical Instrument, if multiple Analytical Instrument are connected to one personal computer, or start the <GC Postrun> program multiple times, you must log in each time. Therefore, you can administer logged in users for each program.

Since the logged-in user names are recorded in the history information and usage right settings can be performed for each user, the advanced function usage will be enabled.

2.1.3 System Administration Flow

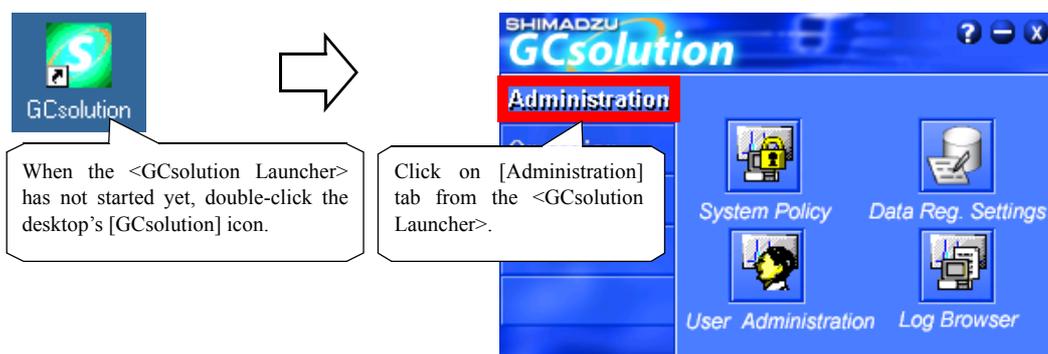
System administration will be performed in the following flow:



2 System Administration

2.2 Using the System Administration Tools to Set Available Items

When using any functions related to system administration, call up the System Administration Tools.



Note: The settings entered <System Policy> and <User Administration> will become effective from the next time the program window is started (logged in).

◆ Functions available in the “System Administration” tools

Function	System Administration Right		Remarks
	Yes	No	
<System Policy>			
Set general system administration parameters.	√		
<User Administration>			
Create a new rights group.	√		
Change group registration information.	√		Cannot delete the group that the user currently logged belongs to. After changing settings, new settings become effective from the next time the program is started.
Register a new user.	√		
Change user registration information.	√		Cannot delete (= hidden) a user currently logged in nor the “Admin” user registered at software installation.
Change the password.	√	√	Regular users can change only his/her password.
<Log Browser>			
Display event logs.	√	√	
Maintain event logs.	√		

2 System Administration

2.3 Starting the System Operation

2.3.1 Setting User Administration Policies

To use the system administration function in this software, set the policies like login method and password limitations.

When the <GCsolution Launcher> has not started yet, double-click the desktop's [GCsolution] icon.

Click on [System Policy] Icon from the <GCsolution Launcher>.

Allows you to select the preset policy settings by clicking on the [Setting] button.

Level	Description
Level 1	No restriction is required for system operation.
Level 2	No restriction is required, but the system is operated by multiple users.
Level 3	The system must comply with GLP/GMP regulation.
21CFR P11	High The system must comply with the FDA 21 CFR Part 11.

If the check is removed, User ID can be selected from a pull-down list at login, and at the next login, the previous user ID will be assumed as the default value. (see the following figure)

If checked, login is required at each time a program is started.

Minimum number of password characters used for user registration and user password changes.

If a program is started after expiration date of password, window appears to change password. If not changed, user cannot log in.

If login failures exceed the specified number of times, all the users on the PC or network will become unable to log into the PC or network for the specified period of time.

If this is checked, the user having the same user ID as the Windows® user name will be automatically logged in so far as he or she is already registered.

Allows you to disable to set password with using dictionary word.

If this is set, different password is required at changing in specified times memorized.

If this is checked, the Use Password check box will be selected on the Add User window and locked.

<System Policy>
(Reference Manual p518)

Note: Log in with a User ID that has system administration right.

Note: The settings on the <System Policy> window will become valid at the next login.

Note: If “User Authentication Mode” is selected in “SHIMADZU User Authentication Tool” at GCsolution Installation, these policy setting parameters are restricted along setting range of “SHIMADZU User Authentication Tool”.

<Login> (Reference Manual p5)



Normal Login Mode



Easy Login Mode

To set the system administration policies other than user administration, use the right half of the <System Policy> window.

Note: The above setting to protect against overwriting files is not applicable when the contents of a file are modified and then saved. If data acquisition is in progress or if the file is saved using [Save As] function, no existing file can be overwritten any longer. If file editing itself is the problem, use User Rights Settings to specify whether or not to authorize each user with the right to perform edit and post-run analysis, or enable the audit trail for method/data files and record the modification log when saving the file.



2.3.2 Registering (Changing/Deleting) Rights Groups

When this software is installed, a number of standard rights groups are set up such as H/W Administrator, Method Developer, Operator.

This section explains how to register (change/delete) a rights group.

When the <GCsolution Launcher> has not started yet, double-click the desktop's [GCsolution] icon.

Click on [User Administration] Icon from the <GCsolution Launcher>.

Click [Remove] and a highlighted group name in group list is deleted.

<User Administration> - [Groups] Tab (Reference Manual p526)

Note: Log in with a User ID that has system administration right.

Click [Add] to display <Add Group> window. Settings are same as <Group Properties> as follows.

Click

Enter a group name.

Select desired item from [Rights List] and move to [Selected Rights] using [Add]. Those rights are given to the group.

For more information about types of rights that can be selected and types of software standard rights groups, refer to Reference Manual "12.3.4 Right Types and Rights Groups"

<Group Property> (Reference Manual p527)

Select desired item from [Selected Rights] and move to [Rights List] using [Remove].

Note: To specify a system administrator, use the <Add User> or <User Property> window.

2 System Administration

2.4 Registering (Changing/Deleting) Users

Users can be registered not only to limit who can use this software, but also to understand each user's program usage conditions.

When the <GCsolution Launcher> has not started yet, double-click the desktop's [GCsolution] icon.

Click on [User Administration] Icon from the <GCsolution Launcher>.

<User Administration> - [Users] Tab (Reference Manual p523)

Click [Add] to display <Add User> window. Settings are same as <User Property> as follows.

Clicking on the [Remove] button hides the user highlighted in the users list as deleted user.

Click

Cannot skip User ID/user name entry.

Click here to use password.

If checked, system administrator settings will be used. Regardless of [Selected Groups] settings, user will have all rights.

Select desired item from [Group List] and move to [Selected Groups] using [Add>>]. User will have group's rights.

Select desired item from [Selected Instrument items] and move to [Instrument Item List] using [<<Remove]. User can't use that Analytical Instrument.

Enter password twice for confirmation. Password length must be longer than that specified on <System Policy>'s [Minimum Password Length]. Input will display with '*' marks.

<User Property> (Reference Manual p524)

Note: Log in with a User ID that has system administration right.

Note: If you try to register a user with the same user ID/user name as that of a previously deleted user through the <Add User> window, a dialog box will be opened prompting you to confirm whether or not to restore the previous user.

2 System Administration

2.5 Short Time after System Operation Has Been Started

After the system has been used for a while, recheck to see whether the parameters set in “2.3 Starting the System Operation” (or the default settings used by registering a user) have met your purpose.

If the password validity is set, you will need to change the password after the expiry has come.

2.5.1 Viewing the History of System Administration

The system administration is traceable since changes in the system administration settings and operations performed on the “System Administration Tools”, such as password changes and user registrations are recorded as event logs.

When the <GCsolution Launcher> has not started yet, double-click the desktop's [GCsolution] icon.

Click on [Log Browser] Icon from the <GCsolution Launcher>.

Enter search parameters and click [Search] button to pickup the records of Log.

<Log Browser> (Reference Manual p538)

Event log data can be converted to text file as input to commercial spreadsheet software such as MS-Excel®.

If log data is not necessary, it can be deleted.

The screenshot shows the GCsolution Administration interface with icons for System Policy, Data Reg. Settings, User Administration, and Log Browser. The Log Browser window is open, displaying search parameters and a table of event logs.

Type	Message	Date	Time	Code	User Name	Applical
E	Failed to initialize a connecti	8/1/2002	5:23:06 PM	0x23e8	Admin	GC Real
E	Failed to initialize a connecti	8/1/2002	5:23:08 PM	0x240d	Admin	GC Real
E	Failed to initialize a connecti	8/5/2002	11:37:44 AM	0x23e8	Admin	GC Real
E	Failed to initialize a connecti	8/5/2002	11:39:42 AM	0x23e8	Admin	GC Real
E	Failed to initialize a connecti	8/5/2002	12:49:35 PM	0x23e8	Admin	GC Real
E	Failed to initialize a connecti	8/5/2002	12:52:23 PM	0x23e8	Admin	GC Real
E	No peak has been detected. FID1 (C:\GCsolution\Data\	8/5/2002	8:00:33 PM	0x1901	Admin	GC Real
E	No peak has been detected. FID1 (C:\GCsolution\Data\	8/6/2002	10:44:30 AM	0x1901	Admin	GC Real
E	No peak has been detected. FID1 (C:\GCsolution\Data\	8/6/2002	10:46:29 AM	0x1901	Admin	GC Real

2.5.2 Changing Passwords

You can change your own password at any time, whether you are a system administrator or a regular user. Also, if a password expiration date is set with the system administration settings, anytime to start a program after this date will bring up a dialog box prompting to change the password after the <Login> window appears. At this time, use the procedure below and change the password.

When the <GCsolution Launcher> has not started yet, double-click the desktop's [GCsolution] icon.

Click on [User Administration] Icon from the <GCsolution Launcher>.

<User Administration> - [Password] Tab
(Reference Manual p522)

Enter current password for security.

Enter new password twice for confirmation. Password length must be longer than that specified on <System Policy>'s [Minimum Password Length]. Input will display with '*' marks.

If a user logs in who doesn't have system administration right, <User Administration> window displays only [Password] tab.

Note: A user with the system administration right can perform initial settings/resettings of all users' passwords in the [Users] tab's <User Property> window.

For more information about of the initial settings/resettings of users' passwords, refer to "2.4 Registering (Changing/Deleting) Users".

3 Work Flow Management

3.1 Using the Security Support Functions

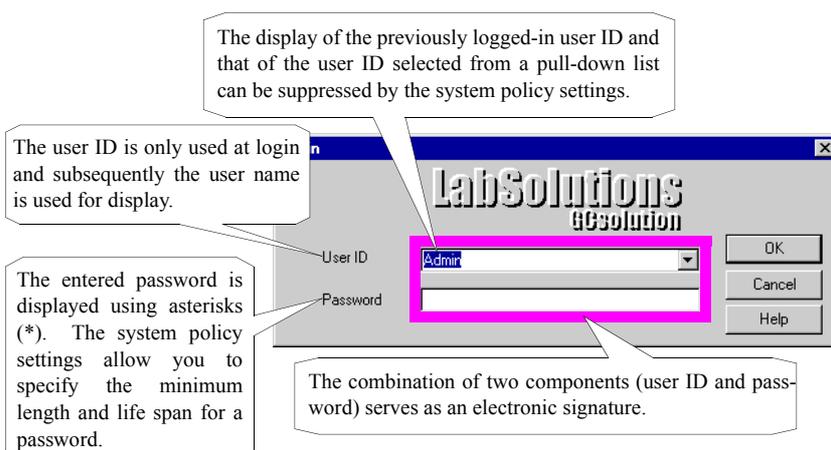
The use of the security support functions facilitates controlling the workflow and improves the reliability of the obtained data.

3.1.1 Login Authentication

To clarify a user when he/she uses a program, the system administration function uses user ID and password confirmation to start a program. This is called the login procedure.

In particular, the FDA 21 CFR Part 11 clearly accepts login authentication as an electronic signature. Unless the requirements are satisfied, no electronic data can replace data on paper.

The concept of user ID and the function of password are in a mutually supplemental relation. When both of them become valid, the requirement as an electronic signature is satisfied and the effect of controlling the workflow of each user is exerted.



Note: Adoption of two distinct components in an electronic signature such as combination of a user ID and password is mandatory for compliant systems; however, it is meaningful only when accompanied by proper user management.

Below are examples of some common practices that must be avoided.

- Multiple individuals use the same user ID (i.e. "Admin") for login. This practice is dangerous as it inhibits the ability to identify who handled the data, and to prevent unauthorized access to the system.
- Registers multiple user IDs with no password. Users can use any user IDs easily and there is no record who actually performed the operations.

See "2.3.1 Setting User Administration Policies", "2.4 Registering (Changing/Deleting) Users".

3.1.2 Current User Display

One of the GLP/GMP requirements is to display the current user name in each window.

When logging in using a correct user ID using the system administration function, the user name will be displayed in each window's title area.



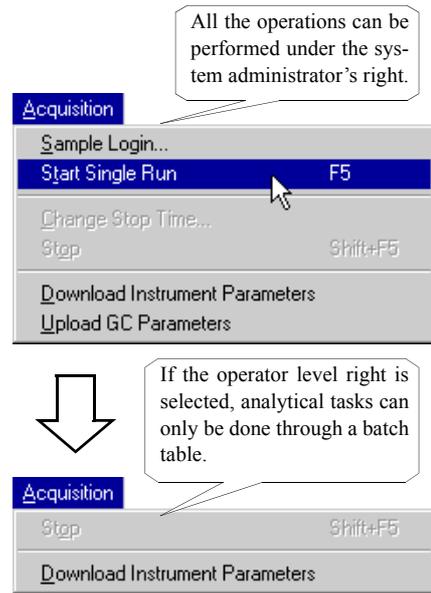
3.1.3 Restricting the Operations according to User Rights

In order to restrict a task so as to be performed in accordance with the standardized procedure or to certify that the task has been done under that restriction, the system administration functions allow you to restrict the operable functions.

Note: The GLP/GMP assures the quality of the acquired data by showing the fact that the section for securing the reliability has been separated from that for actually carrying out the inspection and analysis and by certifying that the tasks are performed in accordance with the standardized procedures.

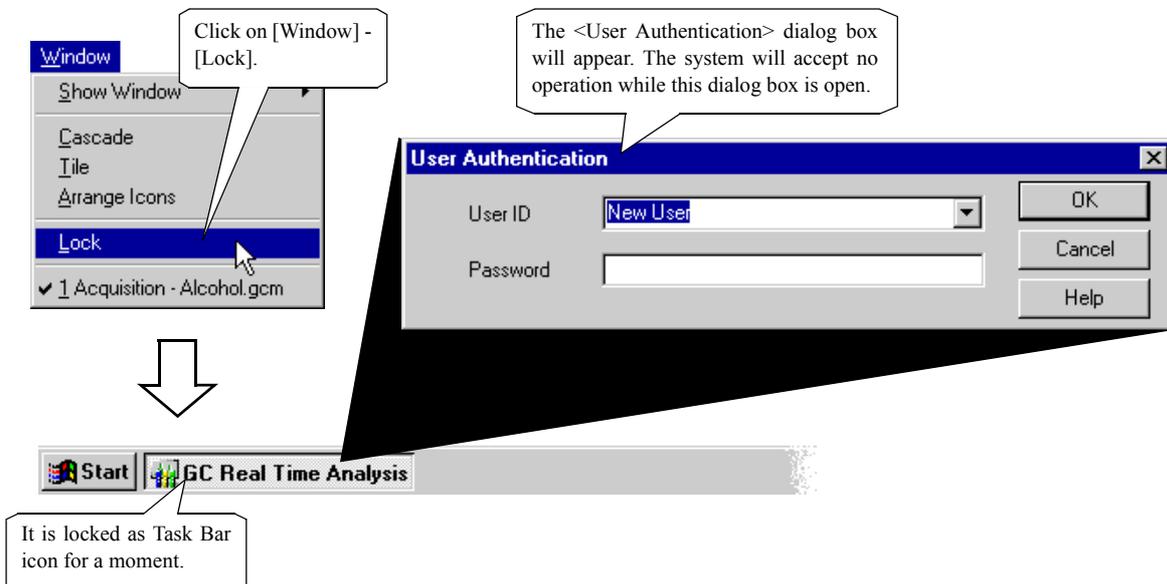
- ① This function is also effective for preventing wrong operations and decreasing the time required for mastering the operations by hiding the unnecessary functions.

See "2.4 Registering (Changing/Deleting) Users", "2.3.2 Registering (Changing/Deleting) Rights Groups".



3.1.4 Protecting an Analytical Task by Locking the Screen

The locking function is available to protect the data from any accident through operations by another operator or any malicious operation when you temporarily leave the workstation during the automatic analysis or for any other reason.



3.2 Work Flow Management

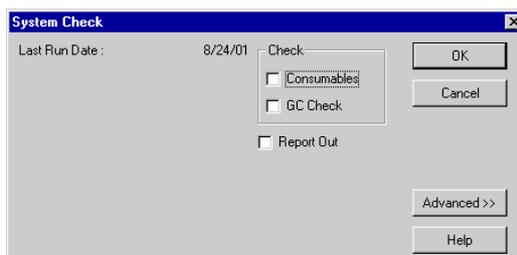
3.2 Using the Batch Advanced Function

The standard procedure for a series of analytical tasks can be included in a batch table and used for the workflow management.

3.2.1 Performing a System Check before Batch Processing

When performing real-time batch processing, the [System Check] function can be performed for each batch row. [System Check] will be performed immediately before data in the batch row with this function designated is processed.

Note: This is the same as the <System Check> window (*See Reference Manual page 181*) that is opened by selecting [Instrument] - [System Check] on the <Data Acquisition> window. From the <System Check> window, however, the system check cannot be directly performed and no check result can be displayed.



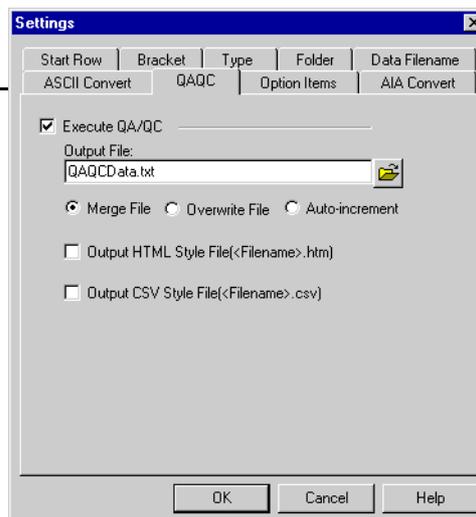
3.2.2 Performing a QA/QC Criteria Check After Batch Processing

The QA/QC function will perform statistical processing on a series of analysis results and other processing. This function is only available with batch processing.

Use the [Batch] Assistant Bar's [Settings] icon - <Settings> window - [QA/QC] tab to set the use of the QA/QC function (i.e., used or not used), QA/QC text output file name, and file overwrite/merge conditions.

Note: Also perform the QA/QC criteria checking condition settings for the method file. (*See Reference Manual page 541*)

Note: Using the QA/QC criteria condition settings, the QA/QC calculation timing can be selected from either the time a series of identical sample type data processing is finished, or the time the batch is completed.

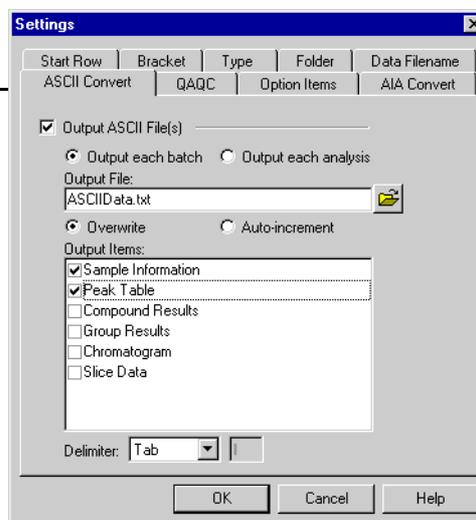


3.2.3 Outputting Batch Processing Results in Common Format

Batch data processing results can be output in common format like text.

On the [Batch] Assistant Bar's - [Settings] icon - <Settings> window - [ASCII Convert] tab, set the actions to be performed when outputting batch processing results in text format.

- ① The [AIA Convert] tab allows you to convert a data file into the AIA ANDi format and then output it.
- ① When saving a batch table using [File Type] - [txt], the batch table will be saved in text format. Any file saved in text format can be loaded.





3.2.4 Setting Action Items

From the batch table's [Action] settings, batch progress control (stop/pause) and external program* startup performed based on QA/QC or system check criteria checking results can be set.

* The [Action] settings can be performed independently from the user program settings (described later).

Note: When checking criteria from the QA/QC results, click the [Execute QA/QC] check box on the [Batch] Assistant Bar's [Settings] icon - <Settings> window - [QAQC] tab. Also, when checking criteria from the system check results, select the system check function for batch rows. (System check can only be performed when real-time batch processing is performed.)

Note: When checking criteria from the QA/QC results, the timing must be matched for the [Action] setting and QA/QC result output. QA/QC result comes out only the end of series of the same sample type (or end of batch processing = meaningless for [Action]). The technic to change sample type intentionally at the timing of [Action] by QA/QC criteria should be effective.

Note: Be aware that, if QA/QC calculation or system check used to check criteria has not been set up on a batch row where action settings have also been entered, the results of the criteria checking will be "No Error" (i.e., passed).

Note: If starting an external program here, information such as a data file name cannot be sent to the program. To do so, preliminary settings are required such as specifying the file name to send.

See the appropriate section of Reference Manual "9.10.6 <Schedule Action> Window".

3.2.5 Setting User Programs

A program to be started before and after a batch row run can be entered into a batch row's [User Program] field.

The two kinds of user programs below can be started separately from an external program started based on the previously described action function's. checking results.

- Program activated before a batch row run (pre-data acquisition run program)
- Program activated after a batch row run (post-data processing run program)

The following parameters can be set for programs run after data processing (Post-run):

- | | |
|--------------------------------|---|
| • Vial # | • Line # |
| • Data File Name | • Method File Name |
| • Sampler File Name | |
| • ASCII Format Data File Name* | • QA/QC Output File Name (Text/HTML/CSV)* |

* This is only available when the output setting is enabled.

See the appropriate section of Reference Manual "9.10.4 <User Program> Window".

3 Work Flow Management

3.3 Using a Template

When a new file is created, an available format can be loaded from a template.

3.3.1 Creating a New File Using a Template

Can also select a template. Can always create new files using selected templates.

Click [New].

Acquiring data will create a data file.

Create new file in <Data Acquisition> and <Calibration Curve> windows.

<File New> (Reference Manual p576)

Note: New files cannot be created using the <Data Analysis> and <Data Comparison> windows in the <GC Postrun> program.

Note: When creating a new file in the <Data Explorer> window, the new file type will be determined based on the application window that is active at the time.

Select whether or not to use a template to create new files by following the steps below.

Click here.

Selecting [Prompt on File New], the <File New> will appear.

Settings can be done for each file.

Selecting [From Template], new file is always created from a template.

Click [Select...] to search for a file.

Click [Change...] to change the templates folder.

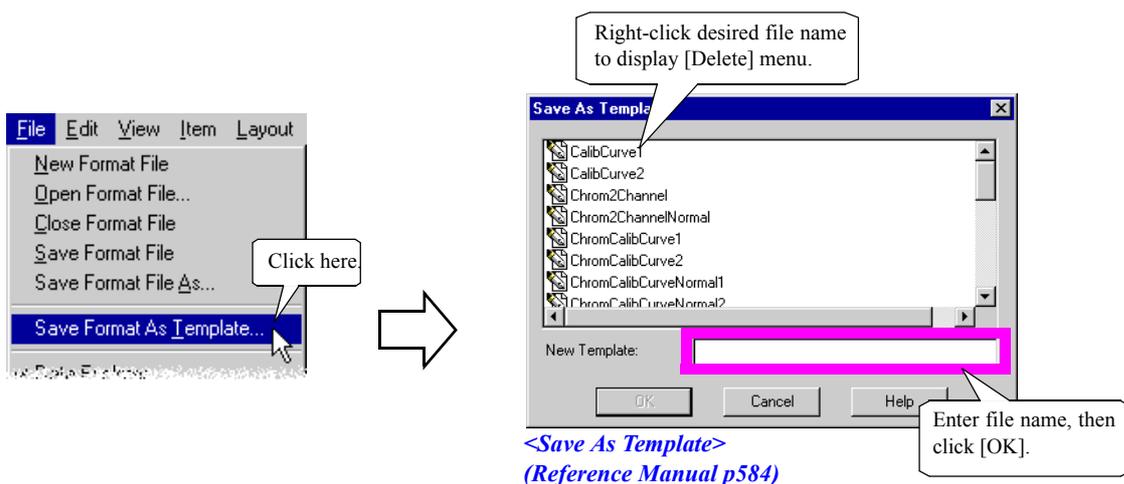
<Setting Options> (Reference Manual p578)



3.3.2 Saving a File as a Template

Any file can be saved as a template and used later.

Note: A template is a file that is the same as this software's regular files (batch, report format and method files) and is saved in a special template folder. This file can also be used as a copy source file when creating a new file. The procedure to save a file as a template is the same as to change file data and to save it under another name. However, since saving a file as a template is effective in preventing overwriting file data by mistake, it is useful to create and use standard template files.



3.3.3 Example of Using a Template

The default values may be changed when you create a new file. If the same settings are required whenever a new file is required, the use of a template would ensure the constant setting quality by saving the settings and preventing any omission in the settings.

In particular, this is effective for creating a blank batch file or a new report format file.

❖ Batch file template

The Table Style and Settings items are saved on a batch-table basis. It would, therefore, be convenient to save settings different from the default values as a template.

- Items that are hidden in a standard table style, but always used must be displayed, For example, a sample name and sample ID are not good enough as items and are supplemented with optional items.
- In a standard table style, highly frequently used table items are not located on the left side and must be rearranged.
- The default value for Autosampler Inj. Volume/Multi-Inj. Counts uses a setting in the method file, but is specified every time since this parameter is set in a batch table.
- A rule for naming a data file is established for the management purpose and the automatic data file naming function for a batch table is used by setting it every time.

❖ Report file template

A report format may include report items that are always laid out or non-report items for which you want to change the default values.

- In a given position on paper, the bit-mapped corporate logo must be printed out.
- The printer restrictions require the paper margins to be changed from the default values.
- The date and user name are always printed out in the header for the management purpose.

4 Audit Trail

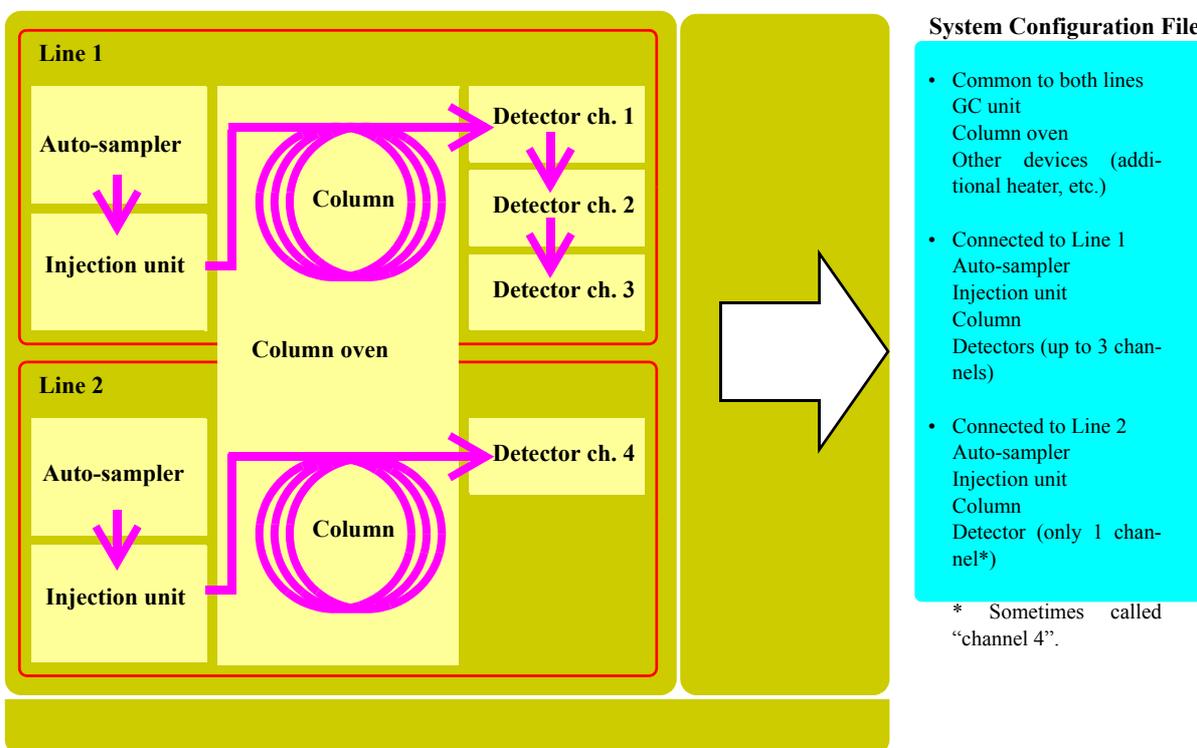
4.1 Important File Concepts for Operation

4.1.1 System Configuration File

The “System Configuration File” stores the connection conditions between the personal computer and Analytical Instruments, as well as installation information for each modules that are connected to the Analytical Instrument. When multiple Analytical Instruments are connected to the PC, this file will be created for each of them.

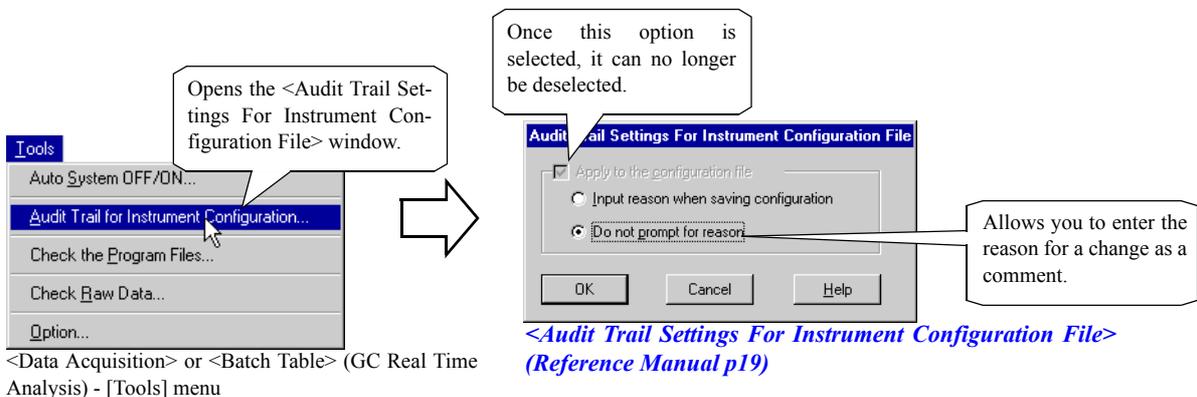
When clicking the [System Configuration] icon on the <GC Real Time Analysis> - [RealTime] Assistant Bar, the <System Configuration> window will appear. Setting data entered in this window will be saved in the “System Configuration File”.

The structure of the “System Configuration File” will reflect the GC’s instrument structure with 2-line analysis performance.



<System Configuration> (Reference Manual p15)

Note: The history of system configuration changes may be saved as audit trail log in the system configuration file.

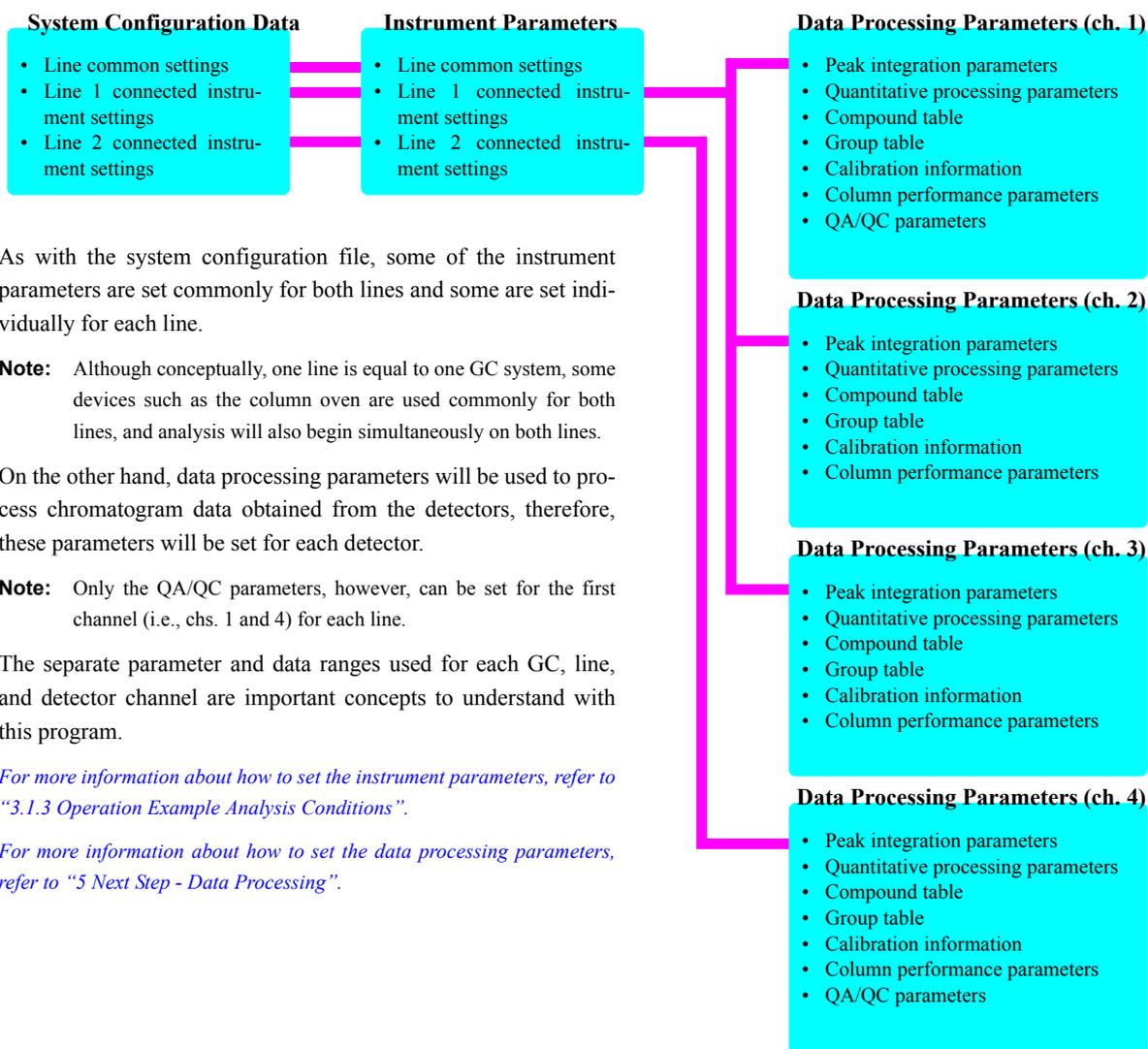




4.1.2 Method File

The “Method File” has an extension of “gcm” and contains the following saved information:

System configuration:	Records system configuration file to check appropriateness of the instrument parameter settings (checking currently connected instruments).
Instrument parameters:	Stores each instrument settings data that has been entered using the <Instrument Parameters> view in the <GC Real Time Analysis> window.
Data processing parameters:	Records calibration curve data, column performance parameters, QA/QC parameters, and peak integration/identification/quantitative parameters, compound/group table data.



As with the system configuration file, some of the instrument parameters are set commonly for both lines and some are set individually for each line.

Note: Although conceptually, one line is equal to one GC system, some devices such as the column oven are used commonly for both lines, and analysis will also begin simultaneously on both lines.

On the other hand, data processing parameters will be used to process chromatogram data obtained from the detectors, therefore, these parameters will be set for each detector.

Note: Only the QA/QC parameters, however, can be set for the first channel (i.e., chs. 1 and 4) for each line.

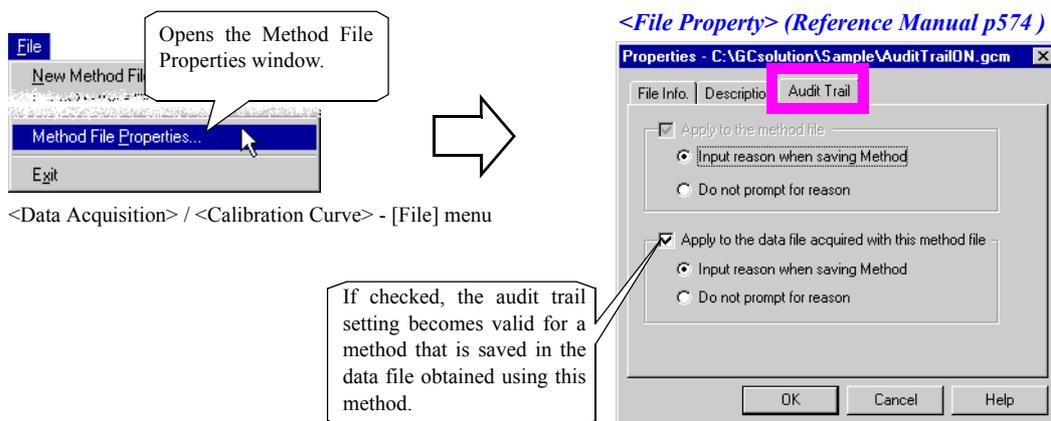
The separate parameter and data ranges used for each GC, line, and detector channel are important concepts to understand with this program.

For more information about how to set the instrument parameters, refer to “3.1.3 Operation Example Analysis Conditions”.

For more information about how to set the data processing parameters, refer to “5 Next Step - Data Processing”.

Note: The history of method changes may be saved as audit trail log in the method file. The history of changes in some parameters including the QA/QC parameter cannot be saved.

- ① Once the audit trail log option is selected, it can no longer be deselected. To cancel the audit trail setting for the method file, create a new method file on the <Data Acquisition> window, specify the method file for which you want to cancel the audit trail setting after selecting [File] - [Load Method...], load that method file, and then save it as another file with the same content.



* The audit trail setting for a method recorded in the data file cannot be changed.

For example, if data is processed using another method file in post-run batch, the presence or absence of the audit trail setting for a method in the data is not affected. If the audit trail setting exists, the log remains as though the data processing parameters were modified in accordance with the details of the method used in post-run batch.

4.1.3 Report Format File

The “Report Format File” has an extension of “gcr” and stores report format settings used to print analysis results.

For more information about report format file settings data, refer to Operation Manual “8 Report Functions”.

Since reports are output for each line, designate a report format file for each line. Therefore, one report can include report items for data up to three detectors.

Note: When using the same report format for both Lines 1 and 2, the same report format file can be designated.

Note: When there are multiple detector channels on Line 1, be sure to designate a report format file for multiple channels.

4.1.4 Batch File

In this software, conditions to be used for multiple data acquisition and data analysis have been set in the batch table in the <Batch Table> window, allowing continuous data processing to be performed.

The “Batch File” has an extension of “gcb” and its parameters for the entire batch, which are set on the <Settings> and <Table Style> windows, are saved in addition to the parameters that can be set in a batch table.

For more information about batch file settings data, refer to Operation Manual “7 Batch Processing”.

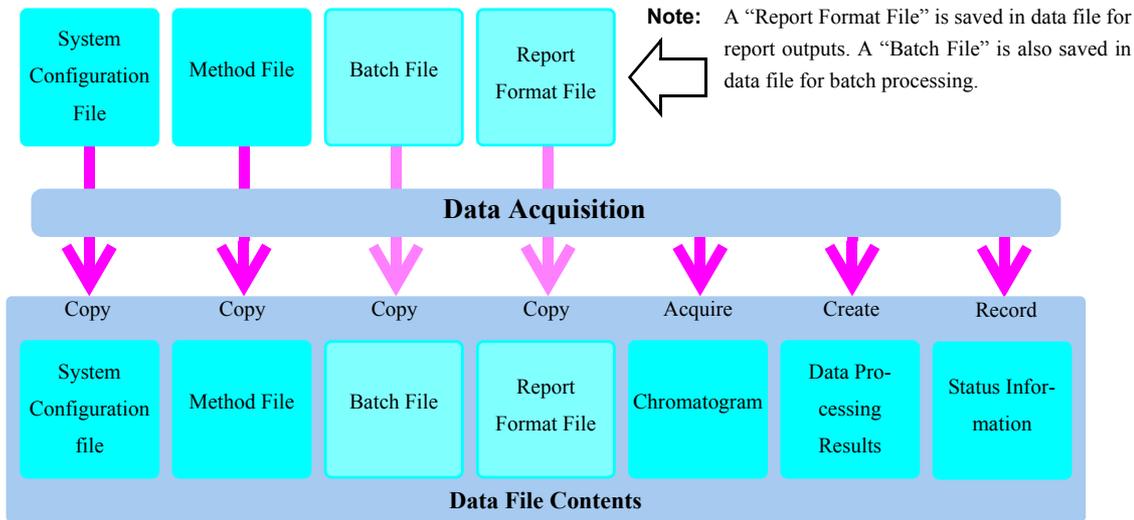
Unlike the case with a report, the 2-line analysis requires that the parameters for 2 lines be set in a single batch table.

Note: Only a single run of analysis batch processing is performed at a time on the <GC Real Time Analysis> window. Therefore, no asynchronous analysis can be carried out creating a batch table for each line.

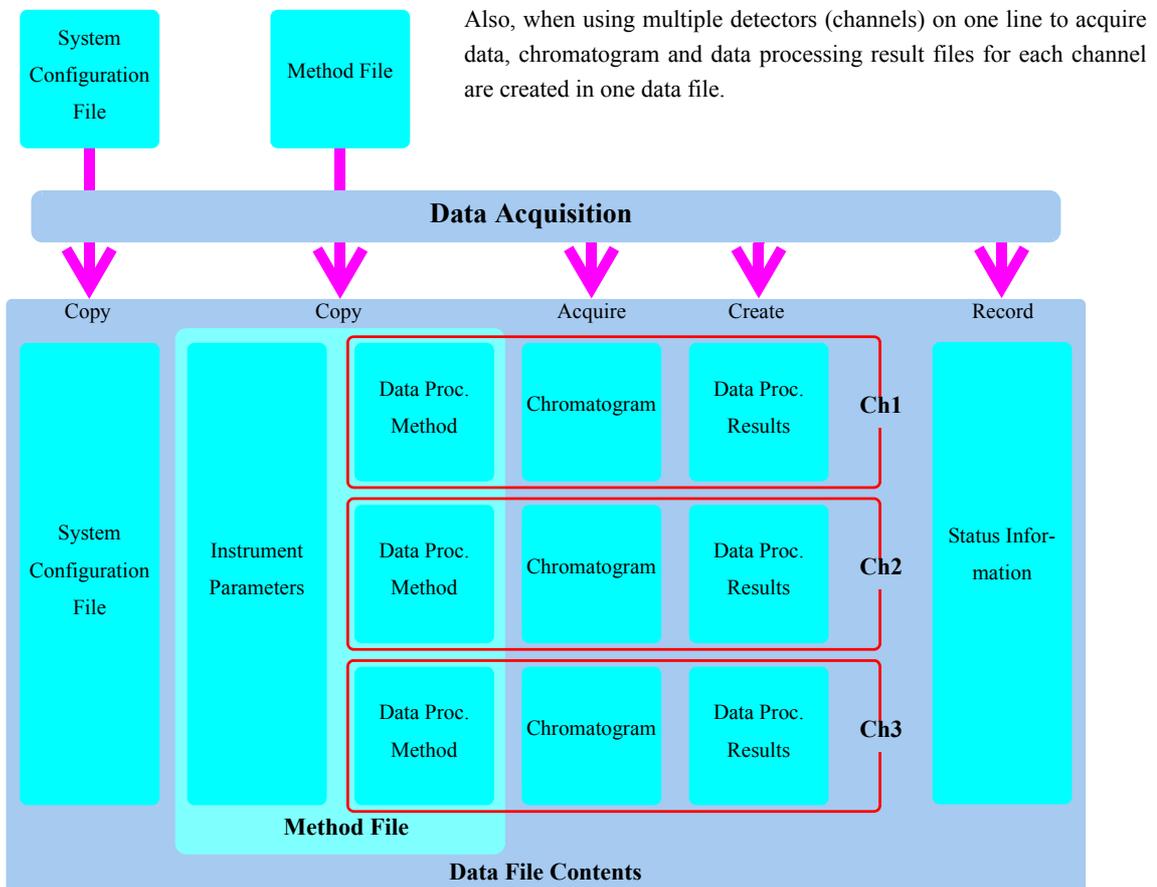


4.1.5 Data File

The “Data File” has an extension of “gcd” and contains data and its meta (= peripheral) data saved in the all-in-one structure. When performing data acquisition, the “System Configuration” and “Method Files” used at that time, “Chromatogram (peak data)” actually acquired, and “Data Processing Results” are all saved in one data file.



When using 2 simultaneous lines to acquire data, a data file is obtained for each line.





❖ Advantages of all-in-one data file structure

- The following information in a Data file may be changed by like <Data Analysis> after data acquisition. The other information will remain unchanged.

Data processing method in a method file (and Audit trail log)

Batch file, Report format file, and Data processing results

- Among the above, the following information is duplexed with information at data acquisition and at final post-run analysis. For data analysis, the information for data processing (latest information) is used with the information at data acquisition (original) remaining unchanged.

Data processing method in method file, and Batch file

- If a data processing method is changed through <GC Postrun> - <Data Analysis>, then the latest data processing method in the data is used and the method used for data acquisition remains unchanged.

- ❗ To reflect any change in the method file, export the method file in the data (*See "5.1.1 Import/Export Method File" in the instruction manual for operations*).

- When a method is imported to the data, only different parameters in the latest data processing method are rewritten without overwriting all the parameters.

This allows you to properly save the audit trail log as the parameter changes even if the audit trail function is selected.

Note: If post-run analysis is performed with a method file specified on the post-run batch row, and if a method file is loaded through the <Calibration Curve> window and a data file is registered in the <Data Tree> view, then the method will be imported.

Note: A data processing method can be explicitly imported to a data file when [File] - [Load Method...] is selected on the <Data Analysis> window, or to a method file when [File] - [Load Data Processing Parameters...] are selected on the <Calibration Curve> window. In this case, a method file or data file (a method in which) may be specified as the import destination.

- ❗ Since the latest data processing method is imported, other methods (instrument parameters and original method) are retained as records without being modified. This explains why the original method file (at data acquisition) and the latest method file (at the last post-run analysis) are recorded separately from each other as data file properties.

- If an existing file is specified in exporting data to a method file, only the parameters different from those in the exporting source are rewritten without overwriting all the parameters.

This allows you to properly save the audit trail log as the parameter changes even if the audit trail function is selected.

Note: Selecting [File] - [Save Method As...] on the <Data Analysis> window starts exporting data.

Note: In export to a method file, all data of the method is exported.

- If a data file is loaded by selecting <GC Postrun> - <Data Analysis> and if a Data Report is printed out, then the same output as the finally printed data can be obtained. Even if the report format in the data is changed, the original report format file remains unchanged.

- ❗ To reflect the changes in the report format file, export the report format in the data.

Note: Selecting [File] - [Save Format File As...] on the <Data Report> window means exporting data.

4 Audit Trail

4.2 Referencing a Record in a Data File

A data file contains various conditions such as the system configuration and instrument parameters used at data acquisition, in addition to analysis data and data processing methods. The <Data Analysis> window allows you to reference them.

For the details of the file structure, refer to “4.1 Important File Concepts for Operation”

4.2.1 Referencing Data File Properties

Using [File] - [Data File Properties], sample information for the data acquisition and related files used during the data acquisition/processing can be referred* (viewed) at each tab page.

* Some of the sample information may be edited. In this case, the history of changes is recorded for a data file for which the audit trail setting is valid.

<File Properties> (Reference Manual p569)

Properties - C:\GCsolution\Sample\Alcohol.gcd

File Info	Description	Sample Info	Original Files
Analyzed by:	Your Name		
Analyzed:	12/2/93 11:34:30 AM		
Sample Type:	Standard		
Level#:	1		
Sample Name:	Test Sample		
Sample ID:	00000		
ISTD Amount:	1		
Sample Amount:	100		
Dilution Factor:	1		
Vial#:	1		
Injection Volume:	1.0	x 1	Injections

Properties - C:\GCsolution\Sample\Alcohol.gcd

File Info	Description	Sample Info	Original Files
Method:	C:\GCsolution\Sample\Alcohol.gcm		
Batch:	C:\GCsolution\Sample\Alcohol.gcb		
Report Format:	C:\GCsolution\Sample\ChromSimple.gcr		
Baseline Data:			
Original Data:	C:\GCsolution\Sample\Alcohol001(STD for ID Table)		
Original Method:	C:\GCsolution\Sample\Alcohol.gcm		
Original Batch:	C:\GCsolution\Sample\Alcohol.gcb		
Original Baseline Data:			

In a data file, the [Sample Info.] tab and the [Used Files] tab are added to the File Properties window. The [Used Files] tab allows you to see that the data file name at data acquisition and the method and batch file names used at data acquisition are separately recorded as file names at analysis.

Note: To edit [ISTD Amount], [Sample Amount], and [Dilution Factor], display <Properties> by selecting <Data Analysis> - <Method> view - [Quantitative] tab and clicking on the [Sample Info] button.

① Some of the information displayed here may be viewed on the <Data Analysis> or <Data Explorer> window, and may be printed out as sample information items in a report.



4.2.2 Referring Instrument Parameters and System Configuration Used for Data Acquisition

Select [Method] - [Instrument Parameters] or [Line Configuration] to display the instrument parameter settings or the system configuration only with used instruments at the time of data acquisition recorded in the data file.

The screenshot shows the GC Postrun software interface. In the 'Method' menu, 'Instrument Parameters...' and 'Line Configuration...' are highlighted. An arrow points to the 'Instrument Parameter' dialog box, which has tabs for 'ADC-20i', 'SPL1', 'Column', 'FID1', and 'General'. A callout bubble says 'Click tab for desired unit.' Below this, the 'System Configuration' dialog box is shown with a tree view of modules. A callout bubble says 'Click icon for desired unit.' Below the screenshots, the text '<Line Configuration>' is displayed.

<Instrument Parameters> (Reference Manual p85)

Note: The operations to refer to each unit's settings are identical to operations performed by <GC Real Time Analysis> - <Data Acquisition> - <Instrument Parameters> view area and <System Configuration>.

Note: <System Configuration> (Reference Manual p17) ← The data is available for reference only and cannot be edited.

4.2.3 Referring to Status Information

Status information display if the analysis was performed correctly based on the instrument parameters.

The screenshot shows the GC Postrun software interface. In the 'View' menu, 'Status Information...' is highlighted. An arrow points to the 'Status Information' dialog box. The dialog box displays acquisition details and an acquisition log table.

<Status Information> (Reference Manual p202)

E. Time	Reason for Error	Target	Monitor
0.000	Column oven temperature.	250.00 C	242.60 C

Note: The data is available for reference only and cannot be edited.

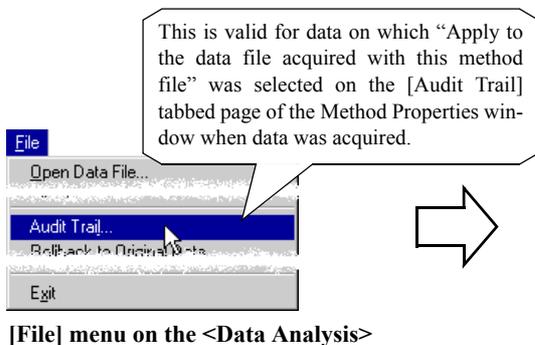
Note: This function is only available on the GC-2010, GC-2014 and GC-2025.



4.2.4 Referencing Audit Trail Log in Data

The change tracking of data processing method can be recorded as audit trail log to the method saved in the data file during post-run analysis.

Using [File] - [Audit Trail] on the <Data Analysis> window allows to view audit trail log.



<Audit Trail> (Reference Manual p577)

Version	Date & Time	User Name
3	3/16/00 2:21:33 PM	Admin
2	3/16/00 2:20:56 PM	Admin
1	3/16/00 2:08:55 PM	Admin

Modification	Reason	Contents
<<Calibration Curve>> [Delete]		LineT: Alcoh002.gcd
<<Calibration Curve>> [Compound Table] Modify Calibration Curve		Ch1

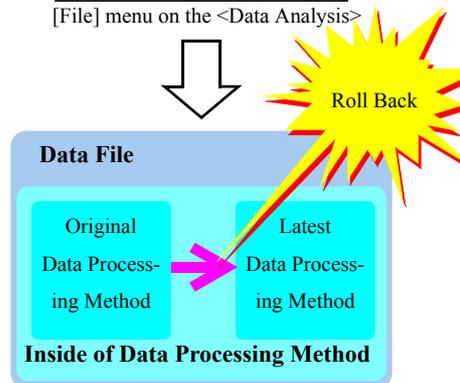
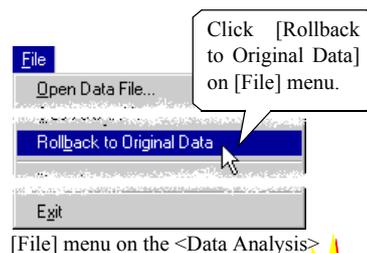
4.2.5 Data Rollback

In the data file, the data processing method (i.e., the original method used for recording during data acquisition) has been duplicated, as well as the latest method to be edited (= the latest method for which the parameters were modified when post-run analysis was performed) in the <Data Analysis> window.

Using [File] - [Rollback to Original Data], the original data processing method will overwrite the latest method and post-run analysis will be performed. Because of this feature, the data processing results can be undone to the status obtained right after data acquisition*.

* When the audit trail feature is selected, this will be recorded in the method update log.

- ① For reference only, close the data file without saving it.
- ① When performing a method export as described above after a data rollback, a method file with the same settings as the original method file can be created.



4.2.6 Export a Batch Table

In a data file that has been analyzed/reanalyzed using a batch table, the batch table is recorded and duplexed into the one at batch analysis and the other at the final batch post-run.

Selecting [Tools] - [Save Batch in Data File As...] allows you to export either of the batch tables recorded in the data by specifying it.



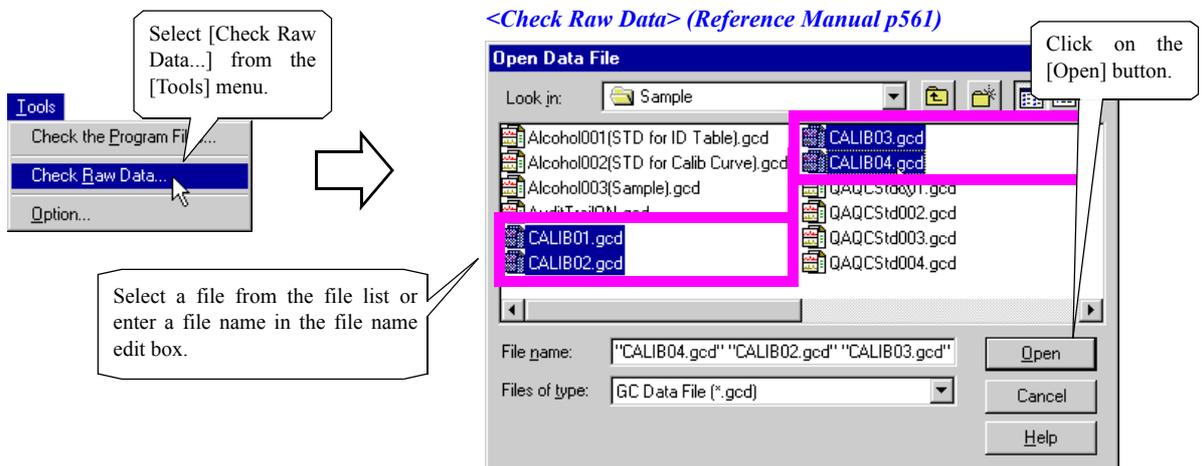
<Select Batch Table> (Reference Manual p206)

4 Audit Trail

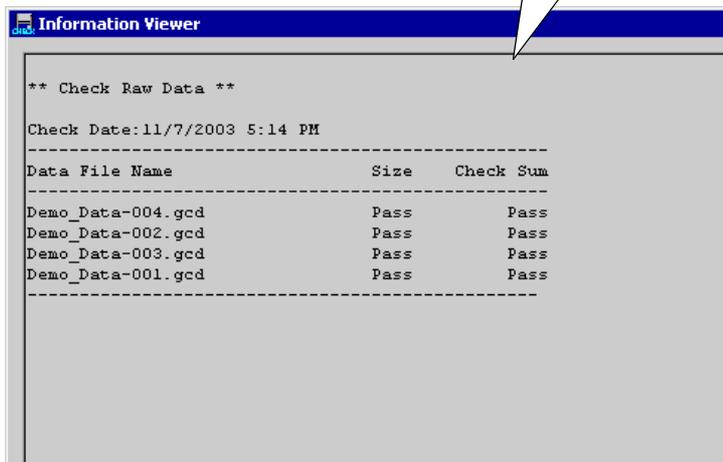
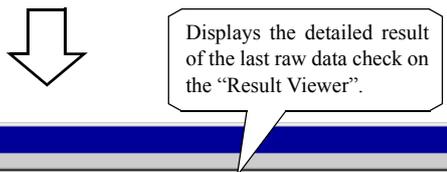
4.3 Check Raw Data Integrity

The LabSolutions/GCsolution provides the function for “Checking Raw Data” for any corruption.

In the LabSolutions/GCsolution, the raw data in an acquired data file cannot be modified. This function can be used to show that the raw data is not affected by a computer virus or illegal file corruption.



Note: If you select two file names on the file list while holding down the Shift key, then the consecutive files between them can be selected. If you select a file name while holding down the Ctrl key, multiple files, even though not consecutive, can be selected. The number of files that may be passed over is dependent upon the maximum number of characters that may be entered in the file name edit box.



Note: The term “Raw Data” used in the range of this function refers to detector signal data such as a chromatogram. The term “Raw Data” (unprocessed original data) as defined in the GLP/GMP differs from that used in the range of this function.

4 Audit Trail

4.4 Checking Other History Information

This software includes an <Output Window> that records users who start and finish programs and their dates, as well as an “Audit Trail” function that records system configuration file and method file change information.

4.4.1 Checking the History on Operations and Errors (Output Window)

Switches <Output Window> display condition (displayed or hidden).

Copy selected range data as text data.

View up to 100 message logs.

View log data of Login/Logout conditions.

Display font is selected via pop-up menu.

Message	SubMessage	Date	Time	Code	Action Name
Login.		3/2/00	11:07:17 AM	0x4050	Time Analysis
Logout.		3/2/00	11:07:54 AM	0x4051	Time Analysis
Login.		3/2/00	11:08:48 AM	0x4050	Time Analysis
Login.		3/2/00	11:09:11 AM	0x4050	Time Analysis

<Output Window> (Reference Manual p559)

4.4.2 Checking the Log in the System Configuration/Method File

Update information for the system configuration and the saved method file can be viewed in the <Audit Trail> window.

Click here after setting at [Audit Trail] tab page in Method File Properties window.

<Data Acquisition> / <Calibration Curve> [File] menu

Can view audit trail logs after method(s) saved in data file via the <Data Analysis> window - [File] - [Audit Trail].

Click on this button after turning On the audit trail setting in the <System Configuration>.

Version	Date & Time	User Name
3	3/16/00 2:21:33 PM	Admin
2	3/16/00 2:20:56 PM	Admin
1	3/16/00 2:08:55 PM	Admin

Modification	Reason	Contents
<<Calibration Curves>>	[Delete]	Line1: Alcohol002.gcd
<<Calibration Curve>>	[Compound Table] Modify Calibration Curve	Ch1

<System Configuration> (Reference Manual p569)

5 Validation

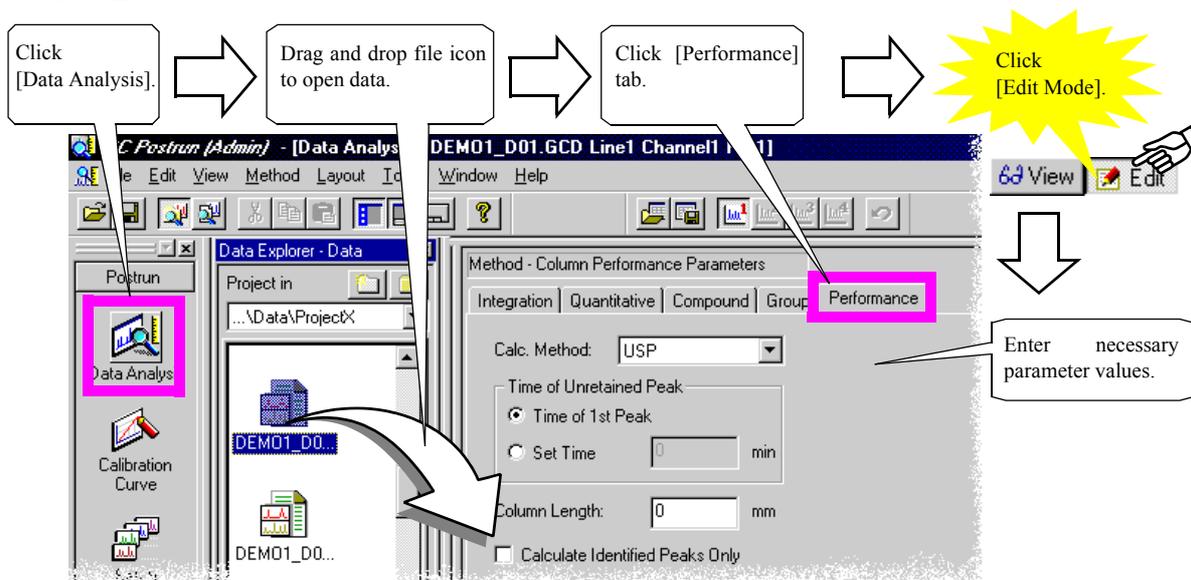
5.1 Testing the System Suitability

To support the system suitability test, the column performance calculation function and the QA/QC functions are available.

Note: These functions may also be used for the method validation and the evaluation of normal analysis results.

5.1.1 Performing Column Performance Calculations

1. Set the column performance parameters on the [Performance] tabbed page of the <Method> view from the <Data Analysis> window.



For more information about column performance calculation setting parameters, refer to Reference Manual "16.7 Column Performance Parameters".

2. Carry out the calculation based on column performance parameter settings.

After editing the <Method> view area's parameters with the [Edit Mode]  button, click the [View Mode]

 button to enter [View] mode. Then, data that has been read into the <Data Analysis> window will automatically be re-analyzed using the <Method> view area's data processing parameters. The column performance marker value can simultaneously be obtained.

Note: If the settings are saved in a method file by clicking on the [Save Method] icon on the [Data Analysis] Assistant Bar, the column performance calculation will be automatically carried out for any subsequent analysis using that method file.

3. Check the column performance calculation result.

Note: The data processing results can be checked on the <Results> view area's [Peak Table]. The processing result may be printed out as a report using the report item for [Peak Table] on the <Report> window. If the column performance marker value column is not displayed on the <Results> view area's [Peak Table], use a right-click shortcut menu on the [Peak Table] to select and display <Table Style> (Reference Manual p567).

Note: If no value from the column performance calculation is printed out using the peak table report item on the <Report> window, set the parameters on the [Format] tabbed page to print the necessary calculation results for the peak table report item.

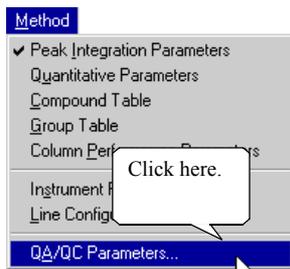


5.1.2 Performing the QA/QC Calculation

1. Set the QA/QC parameters for a method file.

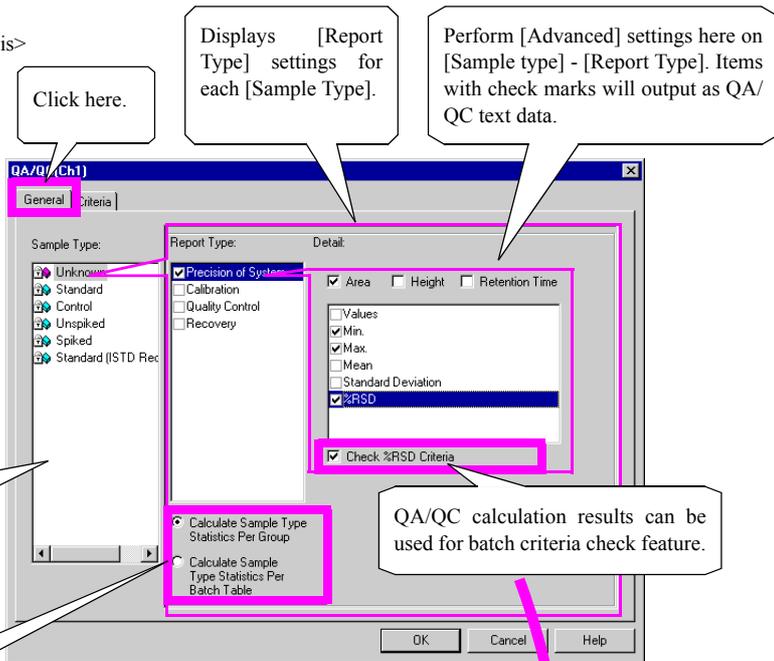
Note: Edit a method file directly from the [Method] menu displayed by selecting <GC Real Time Analysis> - <Data Acquisition> or <GC Postrun> - <Calibration Curve>. If a method in the data is edited by selecting <GC Postrun> - <Data Analysis>, click on the [Save Method] icon on the [Data Analysis] Assistant Bar to export the method to a method file.

[Method] menu using <GC Real Time Analysis>
- <Data Acquisition> or
<GC Postrun> - <Calibration Curve>

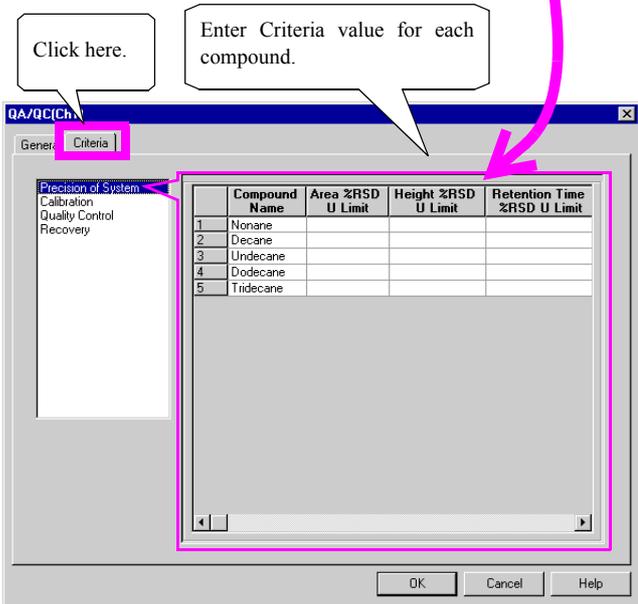


For regular analysis, samples are classified into two kinds: standard samples and others. But, all sample types are available for QA/QC settings. Select desired type in batch table.

Select QA/QC calculation timing either as time when a series of same sample data processing is done, or time when batch processing is done.



<QA/QC> - [General] Tab (Reference Manual p543)



<QA/QC> - [Criteria] Tab (Reference Manual p551)

Note: The QA/QC calculation can be performed only using channel 1 and channel 4 (i.e., Line 2's channel 1) in a dual-line configuration. This calculation cannot be performed using channels 2 and 3 when multiple detectors are connected to Line 1.

For more information about QA/QC calculation, refer to Reference Manual "16.8 <QA/QC> Calculation Methods".



2. Specify executing the QA/QC function in the batch table.

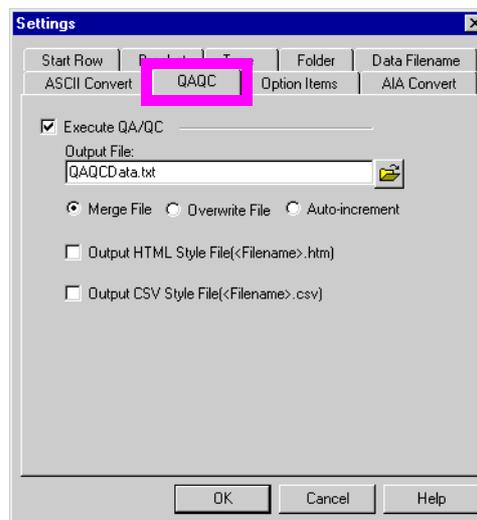
By using the QA/QC function, statistical data processing using a series of analysis results can be performed.

This function is part of a method. However, unlike in column performance calculation, it performs calculations that are impossible to perform using the results from a single analysis. Therefore, this function can be used only with batch processing.

Use the [Batch] Assistant Bar's [Settings] icon - <Settings> window - [QAQC] tab to set the use of the QA/QC function (i.e., used or not used), QA/QC text output file name, file overwrite/merge conditions, and setting whether they are successively saved as different files by automatically numbering them.

Note: The default value is the tab-delimited text format.
The HTML format or the CSV format using commas as delimiters in the text format may be specified depending upon the setting.

<Settings> (Reference Manual p378)



3. Perform the batch processing and the QA/QC calculation.

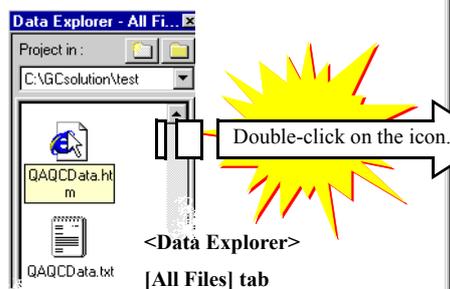
The QA/QC calculation result file is created using the file name and format specified in the reference project (folder) for the batch table, which is displayed in the upper left corner of the batch table, (or those specified in the path that is used to designate the file name on the [QAQC] tabbed page of the <Settings> window).

Note: If the evaluation in each QA/QC category is specified for the action parameter in the batch table, the batch processing can be stopped/paused or the external program can be started in accordance with the evaluation value specified on the [Criteria] tabbed page of the <QA/QC> window for the method. Unless the action parameter in the batch table is set to the timing at which the QA/QC calculation result is output, no evaluation result is output.

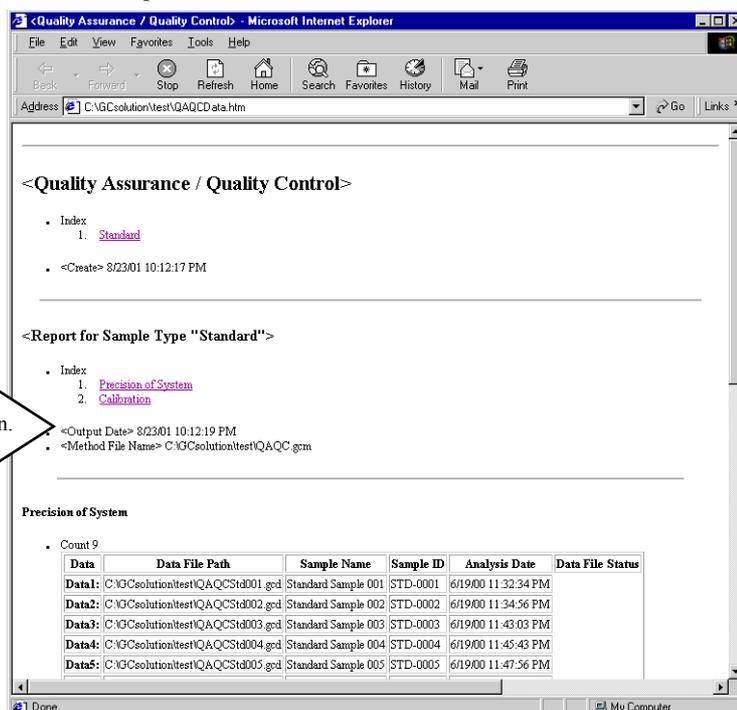
For more information about <Action> setting, refer to Reference Manual "9.10.6 <Schedule Action> Window".

4. Check the QA/QC result.

If the text format (delimited with tabs) or the CSV format is specified for saving the QA/QC result, the result may be used on MS-Excel® or the like. If the HTML format is used, the result may be displayed/printed out using Internet Explorer, which comes with Windows®.



Internet Explorer



5.2 Validation

5.2 Performing Hardware Validation

The LabSolutions/GCsolution provides the “System Check” function, which is used to check the status of the GC and the time for replacing consumables. Prior to performing data acquisition on the GC, be sure to perform a system check and verify that the GC condition is appropriate.

5.2.1 Performing System Checks

Alternatively, you may also click on the button on the Tool bar at the top of the <Data Acquisition> or <Batch Table> (Real Time) window.

Click [System Check] on the [Configuration] Assistant Bar.

When the system check is finished, the evaluation results are displayed.

Indicates the progress of the system check.

Select check items and print condition.

Click on the [Run] button.

Allows checking of the system check results report, on the screen.

Click [PrintOut] to reprint data.

Can read results of past system checks.

Displays previous system check results report.

File name format = “#_YYMMDDHHMM.gcc” (“#” = system number)

Item	Judgment	Ratio	Actual/Standard
<Consumables>			
Back Light	Pass	[] 2+	100/5000 Hour
Motor	Pass	[] 0+	100/100000 Hour
Injection Unit Septum			
Injection Unit Insert			
CRC coolant Used Time			
			0 Hour
Pass			0.00 V
Pass			0.00 V
Pass			0.00 V
Environment			

<System Check> (Reference Manual p181)

<System Check Result> (Reference Manual p183)

Note: This function is only available on the GC-2010, GC-2014 and GC-2025.



5.2.2 After Replacing Consumables

After the system check has completed, if there are any consumables whose check result is “Not Passed”, replace them with new ones as soon as possible.

Click [System Check] on the [Configuration] Assistant Bar.

Alternatively, you may also click on the button on the Tool bar at the top of the <Data Acquisition> or <Batch Table> (Real Time) window.

Click [Reset] to reset replaced consumables' counter.

Click [Reset...].

Click [Advanced] to switch this area's display condition (displayed or hidden). Here, consumable counters are reset and each item's check condition (checked or not checked) is set.

System Check Window: Last Run Date: [] Check: Consumables, GC Check, Report Out. Buttons: Run, Stop, Close, View Result..., Help, Reset... (highlighted in pink).

Consumables Window: Lists consumables like SPL1(INJ#1), SPL2(INJ#2), (INJ#3), and CRG Coolant Used Time. Each has Septum Used Counts and Insert Used Counts (0) and a Reset button (highlighted in pink). Buttons: Close.

<System Check> (Reference Manual p181)

Note: This function is only available on the GC-2010, GC-2014 and GC-2025.

Note: For the consumables check, thresholds are used for comparison. These are data entered in a window displayed via <System Configuration> - [Configured Modules] - [Properties] tab for the unit with consumables - [xxx Maintenance] button.

The standard values for the system check include the manufacturer's recommended values as the default values, which may be changed, as appropriate, considering the accuracy and cost required for your analysis

For more about system check criteria setting, refer to Reference Manual “4.4.2.1 <Coolant consumption> Window”, “4.5.2.1 <Injection port Maintenance> Window”.

5.3 Validation

5.3 Performing Software Validation

5.3.1 Performing Program Checks

The LabSolutions/GCsolution provides the “Program Alteration Check” function, which is used to see whether the program-related files for this software remains unchanged.

This function allows you to find the identity of the software (eliminate any wrong program component and immediately find infection with computer virus after installation).

<Check the Program Files> (Reference Manual p560)

Select [Check the Program Files...] from the [Tools] menu.

Click on the [Execute] button.

Program check result details are viewed via the Result Viewer.

After program check is complete, check results appear.

Previous program check result details are displayed.

Note: To get report of Program Check Result, Click on [Print...] button.

Information Viewer

** Check the Program Files **

Program Name : GCsolution
Version : 2.20.00
Check Date : 2003-11-07 17:10:06

Filename	File.Size	Date.Time	Check.Sum
ChrmFileSrch.exe	Pass	Pass	Pass
ChrmRange.dll	Pass	Pass	Pass
CLFIO32.DLL	Pass	Pass	Pass
CPCN.dll	Pass	Pass	Pass
CRHAKEI.DLL	Pass	Pass	Pass
Crmgraph2.ocx	Pass	Pass	Pass
FCVT.dll	Pass	Pass	Pass
FEMPLR.OCX	Pass	Pass	Pass
GCAAnal.exe	Pass	Pass	Pass
GCAsb.dll	Pass	Pass	Pass
GCBatch.dll	Pass	Pass	Pass
GCBatch.ocx	Pass	Pass	Pass
GCCalc.dll	Pass	Pass	Pass
GCChromData.dll	Pass	Pass	Pass
GCConfig.dll	Pass	Pass	Pass
GCDataProcessing.dll	Pass	Pass	Pass
GCTFile.dll	Pass	Pass	Pass
GCHWErr.dll	Pass	Pass	Pass
GCInst.dll	Pass	Pass	Pass
GCInstTool.dll	Pass	Pass	Pass
GCMMethod.dll	Pass	Pass	Pass
GCMMethodEdit.ocx	Pass	Pass	Pass
GCMntDB.exe	Pass	Pass	Pass
GCHsg.dll	Pass	Pass	Pass
GCPrint.exe	Pass	Pass	Pass
GCPrun.exe	Pass	Pass	Pass
GCqac.dll	Pass	Pass	Pass
GCRawData.dll	Pass	Pass	Pass
GCRReport.dll	Pass	Pass	Pass
GCRes.dll	Pass	Pass	Pass
GCRResultDisp.ocx	Pass	Pass	Pass
GCStatusInfo.dll	Pass	Pass	Pass

Print... Close



5.3.2 Performing the Function Check

Check to see that the installed program is operating normally, using the following procedure.

1. Use the GCsolution function check data group. Please refer following file list.

Data name
Check.gcb
Check.gcm
Check01.gcd
Check02.gcd
Check03.gcd
CheckRep.gcr

Note: The data used here is rewritten whenever the function check is performed. Each time, load the data to the Project folder* on the hard disk from the CD-ROM.

* C:\GCsolution\CheckData (when GCsolution has been installed to C:\GCsolution)
For loading the function check data, refer to "5.3.3 Loading the Function Check Data Group".

2. Execute Check.gcb in the batch post-run mode of GCsolution.

1) Click on [GC Postrun] icon on <GCsolution Launcher>

2) Click on the [Batch Processing] icon.

3) Select the CheckData Project folder.

4) Drag and drop the Check.gcb to the batch table.

5) Click on the [Start] icon. Batch post-run will be carried out and a report will be printed out.

If the list box does not contain the CheckData Project folder, select it from Select Project (Folder).

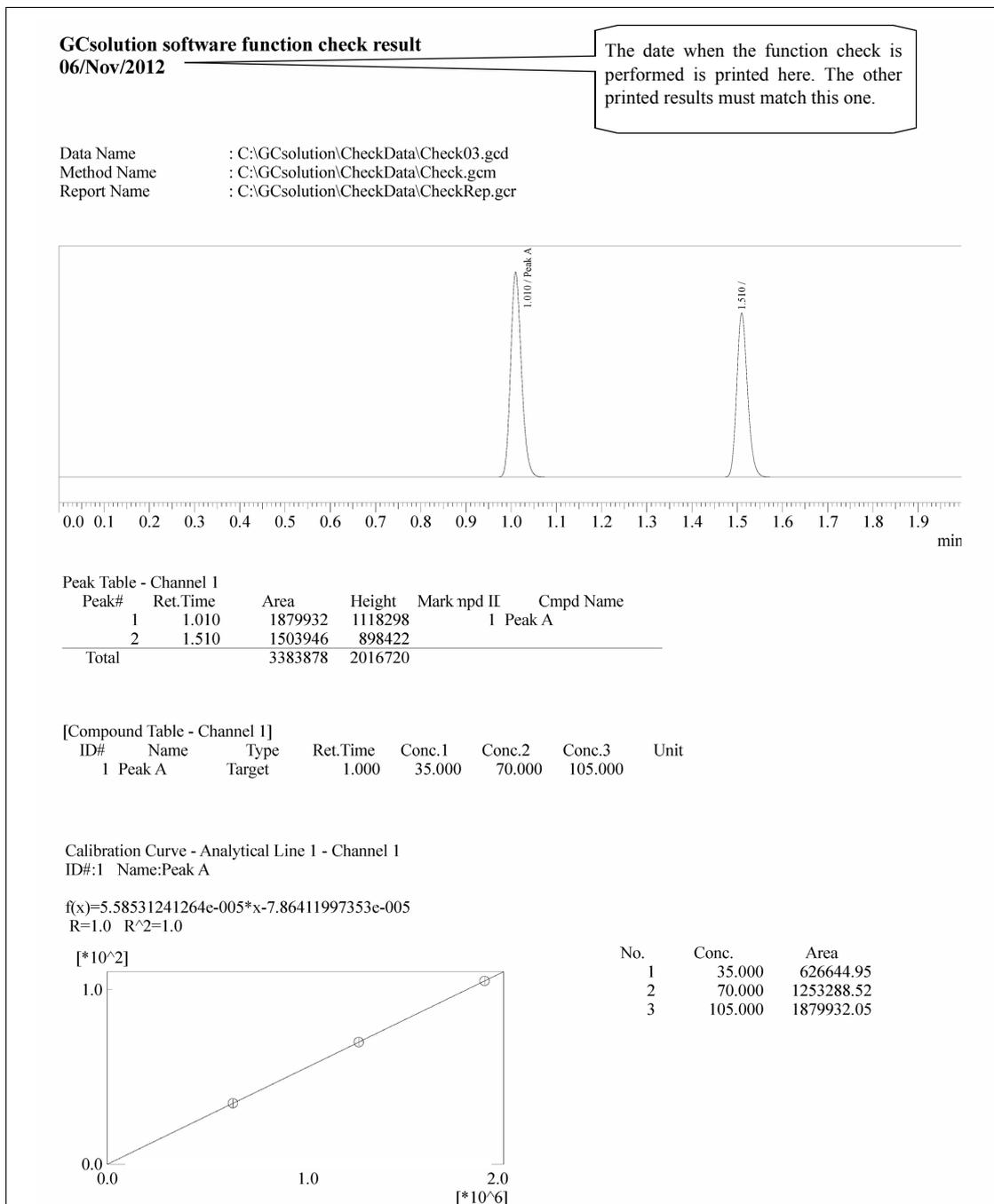
Sample Name	Sample ID	Sample Type
Standard Sample	STD-0001	1:Standard(I)
Standard Sample	STD-0002	1:Standard
Standard Sample	STD-0003	1:Standard

3. Check to see whether the following report result agrees with the output report result.



❖ Evaluation criteria

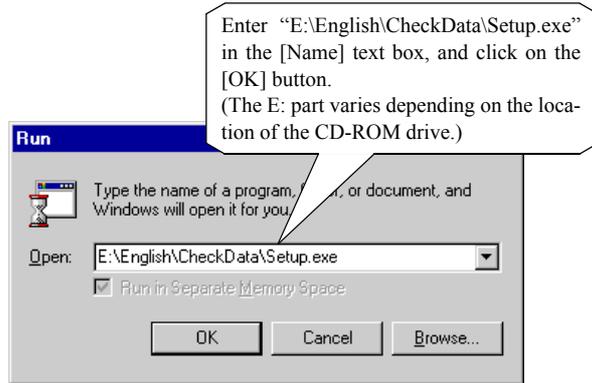
GCsolution is assumed to pass the function check when: the files are used in step **1.** above; the execution of Check.gcb is completed successfully in step **2.** above; and the results agree with each other in step **3.** above.



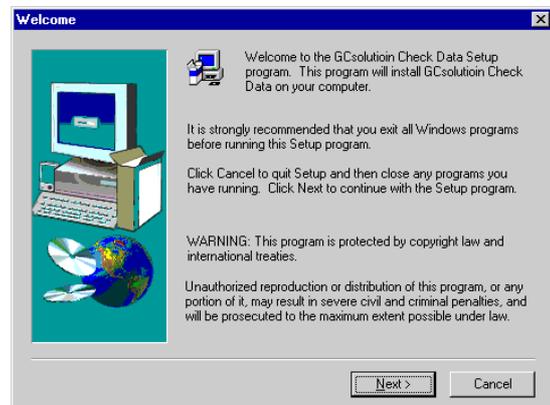
5.3.3 Loading the Function Check Data Group

1. Click on [Run...] on the [Startup] menu of Windows®, and directly start the program for loading the function check data group (setup.exe), which is located in the CheckData folder on the GCsolution CD-ROM.

Note: After the GCsolution CD-ROM has been inserted into the CD-ROM drive, the <LabSolutions GCsolution Setup> screen will open automatically. Since this screen is not used here, click on the [Exit] button to terminate it.

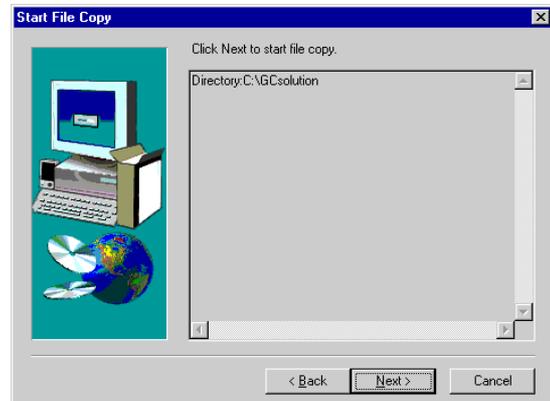


2. The <Welcome> window will appear.

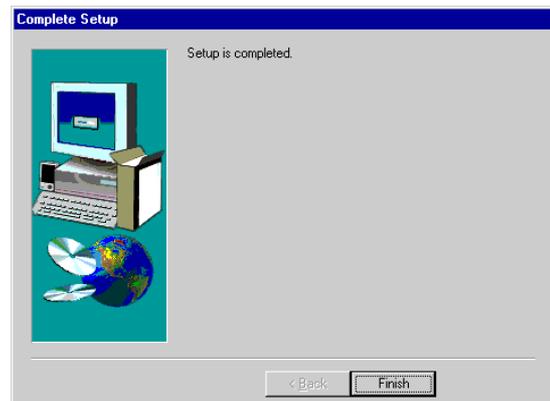


3. Click on the [Next] button in this window.
The <Start File Copy> window will appear.

Note: The install program will automatically detect the location where GCsolution is installed.
Check to see whether the destination of the file to be installed matches with the location where GCsolution is installed.



4. Click on the [Next] button in the <Start File Copy> window. The <Complete Setup> window will appear. Click on the [Finish] button to finish the setup procedure.





Inspection Report for GCsolution

No.: _____

Date: _____

Model No.: _____

Signature: _____

Serial No.: _____

Version: _____

Check item	Action	Result
System check/for GC-2010 & 2014	System check evaluation result	Pass / Fail
Check items (consumables)		
<input type="checkbox"/> LCD Back Light	<input type="checkbox"/> Septum	<input type="checkbox"/> CRG Coolant
<input type="checkbox"/> Fan Motor	<input type="checkbox"/> Insert	
Check items (GC check)		
<input type="checkbox"/> Heat Sensor	<input type="checkbox"/> CPU	<input type="checkbox"/> ECD Cell Frequency
<input type="checkbox"/> DC Voltage	<input type="checkbox"/> Detector ROM	<input type="checkbox"/> Flow Unit Board ROM
<input type="checkbox"/> Environment	<input type="checkbox"/> Detector ADC	<input type="checkbox"/> Flow Unit board ADC
<input type="checkbox"/> Primary Pressure	<input type="checkbox"/> Detector High Voltage	<input type="checkbox"/> Flow Control
	<input type="checkbox"/> Detector Ignite	
Details (If the result is "Fail".)		

Check item	Action	Result
Program check	Checks of file size and date	Pass / Fail
Details (If the result is "Fail".)		

Check item	Action	Result
Function check	Check of printed result	Pass / Fail
Details (If the result is "Fail".)		

6 Data Administration

6.1 Facilitating File Management

This section describes how to manage the files based on various kinds of information.

6.1.1 Customizing Data Explorer Display Data

Right-click the <Data Explorer> to display a pop-up menu, where you can set/select display items.

In addition to the normal file names and time stamps, the sample information and others included in a data file may be displayed or rearranged. This allows you to easily search for a data file within the same project (folder).

In the preview section, not only the sample information, but also the profile of raw data is displayed. This profile serves as reference in finding a desired data file from its rough data shape.

Allows previewing the highlighted data file. Also allows checking part of the sample information.

The preview can be magnified by dragging it with your mouse.

Same settings as in Windows® Explorer.

Allows you not just to set Explorer, which comes as standard with Windows®, but also to rearrange each additional information item when displaying file information.

Displays additional information (such as sample names) as file information when the "Detail" display mode is selected.

Data Explorer - Data

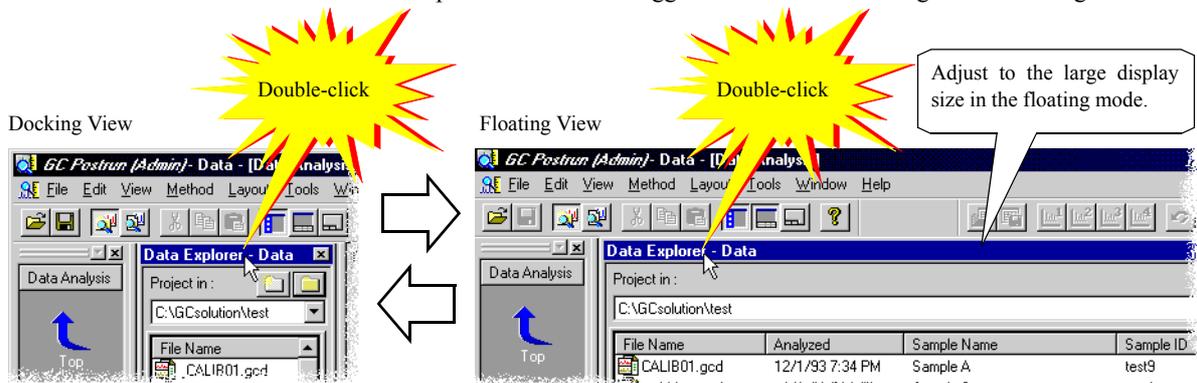
File Name	Acquisition ...	Sample Name	Sample
...	6/20/00 2	Standard	0001

Note: The setting data entered here will be saved for each user.

Note: If the number of files in the project (folder) is too large when the file information is displayed, it may take longer time for display.

① If [File Information] is selected, the displayed information increases. In this case, expand the displayed width of the <Data Explorer> window or dock the window into the top or bottom of the screen so that the window is extended horizontally (Data Preview is laid out to the right). This should make File Information easier to reference. This may cause the other displayed panes to become narrower and more difficult to view. Therefore, change the display as appropriate by the following method:

- Click on the [Data Explorer] button on the toolbar to toggle between On and Off.
- Double-click on the title of the <Data Explorer> window to toggle between the “Docking” and “Floating” modes.



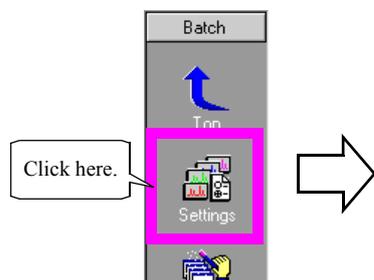
6.1.2 Previously Giving a File Name that is Easy to Manage

Giving an appropriate name to a file makes it easier to manage that file*.

* This involves the following advantages:

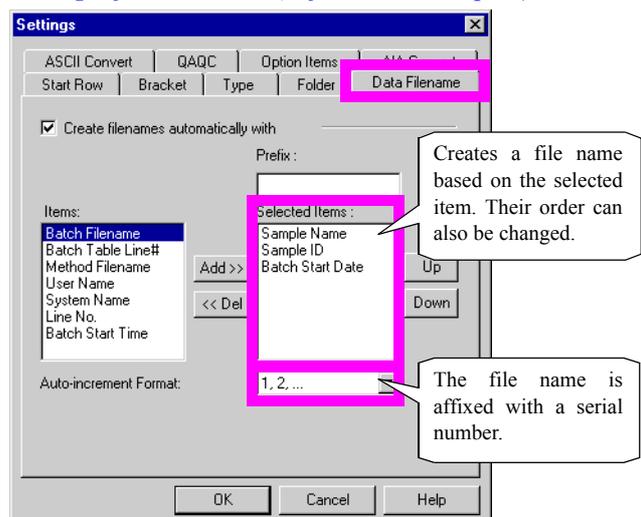
- The sample information in a data file can only be referenced from the LabSolutions/GCsolution and the related products. If a file name is previously given including sample information, the file can be more easily handled outside this software.
- If the [File Information] mode on the <Data Explorer> window is canceled, the file information is displayed faster when the number of files in the same project (folder) is large.
- When the file conversion function is used to convert a file into a format that is required for management (e.g., the AIA ANDi format or Acrobat® (PDF) format), the original file name plus the extension corresponding to the selected format is given to the resulting file.

As the function to support the proper naming of data files, the <Batch Table> window provides the function to automatically create a data file name based on the sample name, sample ID, and other information.



Note: The settings on the <Settings> window are saved for each batch file.

<Settings> for Batch Table (Reference Manual p376)



① In each column for data file names in the batch table for which the automatic data file naming function is selected, the data file name at the last batch analysis is retained. Therefore, the batch post-run analysis using the same batch file can be performed for only the data that has been acquired by the directly previous batch analysis.

To perform the batch post-run analysis under the same conditions as those at batch analysis/post-run analysis for the subsequent data, export the batch table saved in the data file (See “4.2.6 Export a Batch Table”).



6.1.3 Using a Variety of Information for File Searches

File searches can be performed from the program windows' main window at anytime.

Click for <File Search> window.

Click to cancel a running search.

Click **X** to exit file search.

Use file name, type, project (folder) to search for a file.

Use file creation and update date ranges.

Use sample information and comments. (only for *.gcd files)

GC File Search
File Name & Folder | Date | Advanced

File Name :

File Type : GC Data File (*.gcd)

Search Folder : C:\GCsolution\Sample

Look in subfolders

Start
New Search
Stop
File Info
Preview

Please specify File Name and Search Folder.

Date

Created Date :
 Specified Date 3 /14/00 - 3 /15/00
 Last This Week

Modified Date :
 Specified Date 3 /14/00 - 3 /15/00
 Last This Week

Advanced

Generated by : Not Specified

Modified by : Not Specified

Keyword for Comment Search : Not Specified

Sample Name : Not Specified

Sample ID : Not Specified

<File Search> (Reference Manual p498)

Note: For each search condition entry drop-down list box, you can select from among the previous five search conditions.

After entering a search condition, click **Start** to start the file search.

In the lower part of the <File Search> window, the following search results display view will appear.

The image consists of three screenshots of the File Search window, illustrating different views and interactions:

- Top Screenshot:** Shows a list of search results with columns: File Name, Folder Path, File Type, Created Date, and Modified Date. A callout box on the left says "Click item label to sort results in item order upward or downward." with arrows pointing to the column headers. A callout box on the right says "Right-click file list to display menu and select [Detail] or [List]." with an arrow pointing to the file list.
- Middle Screenshot:** Shows the "File Info" tab selected. A callout box on the left says "Can drag and drop file onto application window from <File Search> window." with an arrow pointing to the file list. A callout box on the right says "Click [File Info]." with an arrow pointing to the File Info button. Another callout box on the right says "Displays file information for currently highlighted file in list." with an arrow pointing to the information pane.
- Bottom Screenshot:** Shows the "Preview" tab selected. A callout box on the right says "Click [Preview]." with an arrow pointing to the Preview button. A callout box on the right says "Displays chromatogram when data file is selected." with an arrow pointing to the chromatogram plot. A final callout box on the right says "Changes chromatogram's intensity scale." with an arrow pointing to the intensity scale control.



6.1.4 Search for a File Based on its Contents

If the search based on the file name and sample information is unsuccessful by the above method, then open the data file using the <Data Analysis> window or <Data Comparison> and check the data.

Clicking on a file name instantaneously displays data in the preview section of the <Data Explorer> window, or double-clicking on a file name displays data on the <Data Analysis> window.

Allows you to display a chromatogram for comparison use in the background by selecting [File] - [Open Reference Data File].

Clicking/double-clicking on file names allows you to successively check those files.

Allows you to check the peak information table.

Peak#	Ret.Time	Area
1	1.010	626645
2	1.510	501312

<Data Analysis>
(Reference Manual p189)

Allows you to close all the data at a time by selecting [File] - [Close Data] - [All Data].

If you select 2 files while holding down the Shift key, the series of files located between them are selected. Up to 8 data files can be dragged and dropped at a time.

If the chromatogram display area is enlarged by dragging the splitter, it becomes more comfortable to view.

<Data Comparison> (Reference Manual p311)

6 Data Administration

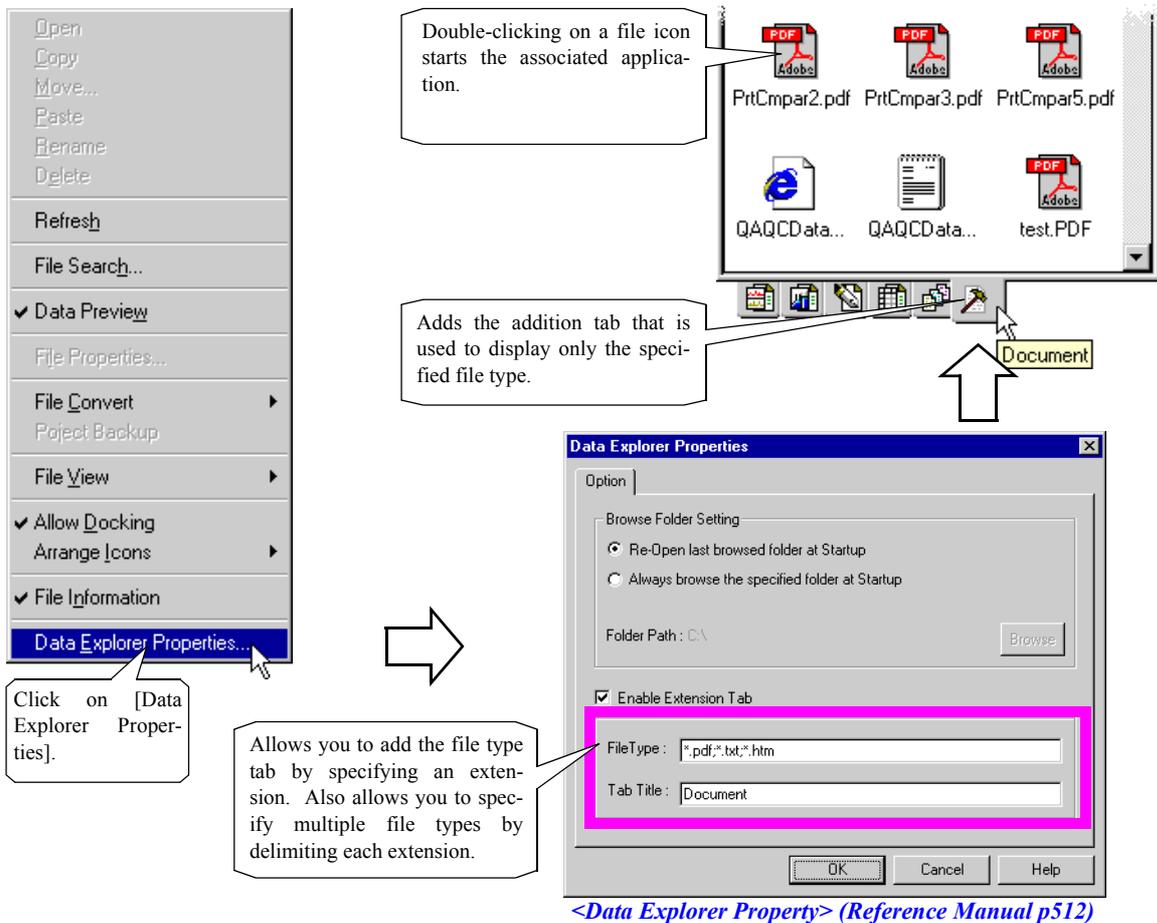
6.2 Handling Other Files

The traceability and management of files other than data, method, batch, and report format files may be required.

For example, files that are output as validation results and print images that have been managed on a paper basis are now managed as electronic records.

6.2.1 Displaying Extension Tab of the <Data Explorer> Window

Click on the right mouse button with the cursor positioned on the <Data Explorer> window. Select [Data Explorer Properties] from the pup-up menu that will appear. The <Data Explorer Properties> window will be opened allowing you to select additional tabs to be displayed.



i This function allows you to carry out the following series of tasks more efficiently:

- After analysis has been finished using a batch table for which the output of QA/QC calculation result in the HTML format is specified, double-click on the *HTML file that has been created on the additional tabbed page. Start the associated WWW browser and then check the QA/QC result.
- After a report image in a data file has been converted into the PDF by the file conversion function of the <Data Explorer> window, start Adobe® Acrobat® by double-clicking on the PDF* file that has been created on the additional tabbed page, and then check the contents of that file.

* If the files are sorted using their time stamps after the <Data Explorer> window has been set to the detailed mode, the last created file can be displayed at the top. This allows you to relatively easily find a desired file.

Note: The settings on the <Data Explorer Properties> window are saved for each user. Therefore, if you log in the system using another user ID, the addition file tab created here will not be displayed.

6 Data Administration

6.3 Reviewing the Long-Term Storage of Data

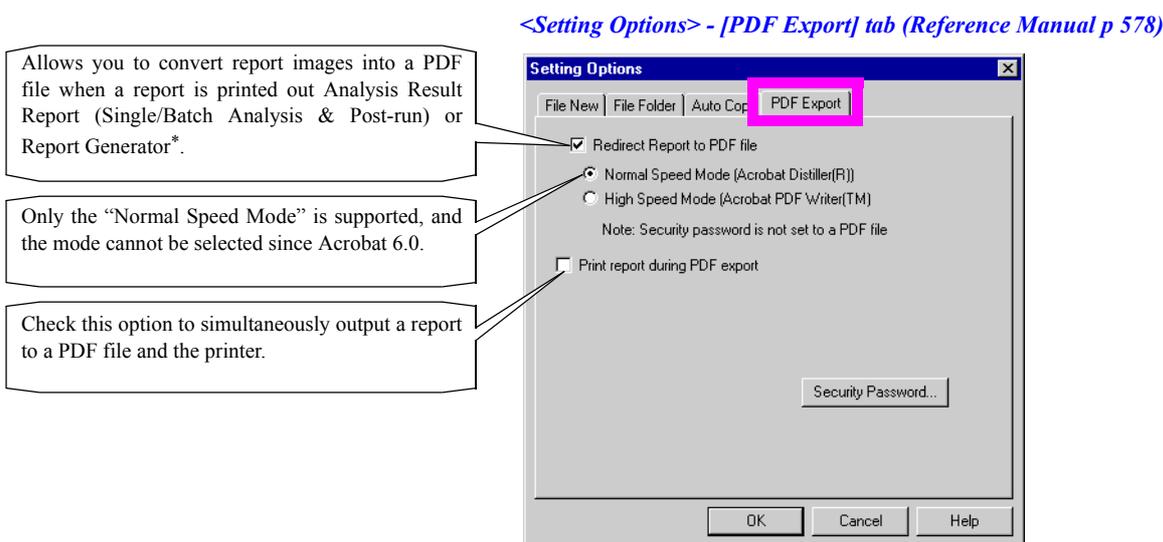
The previous sections describe the functions to support the management of working data. This section explains important points in the long-term storage of data.

6.3.1 Managing the Print Images

Among the existing techniques, printing out a report on paper and then storing it is the most excellent one for the long-term storage of data. This is still true today, but the disadvantage of this method lies in a problem with storage space and costs.

As a solution, print images are photographed on microfilm in some cases. At present, however, an approach for recording reports in an electronic document format that will be supported for a long period of time is adopted. Since some electronic document formats are accepted for formal documents, the electronic recording of documents has become popular.

The GCsolution provides the capability of outputting reports in the PDF (Portable Document Format) among the above electronic document formats when it is used with Adobe® Acrobat®, a tool for the creation, management, and edit of PDF documents.



* Since print images from <Report> are converted into the PDF, the reports from the following functions using those print images can be converted into PDF files:

- Printing of reports within the data on <Data Analysis> window
- [File] - [Print Method] from the <GC Real Time Analysis> window
- [File] - [Print Graph Image] from the <Data Comparison> window

Note: A PDF file has the original file name with its extension changed to PDF and is output to the folder including that original file. When a PDF file is output at Single Run/Postrun (Data Report) or Batch Processing, it is a data file; or when a PDF file is output by selecting [File] - [Print Method File] from the <Data Acquisition> window, it is a method file. Selecting [Print Image] from the <Data Comparison> window, etc. will output the currently displayed data. Therefore, when a specific file name (Data Comparison Report.pdf in this case) is used, the data will be output to the referenced project (folder).

Note: The document information and security are added to the output PDF file. The settings are the same as those shown in the table for conversion into the PDF.



The use of the GCsolution's capability of converting a file into the PDF allows you to obtain a PDF report file created under the following rules, at any time other than report printout, in the same project (folder) that contains the original file:

Source File	Data file	Data file (method in data)	Method file
Output image	Print image of "Data Report"	Print image by selecting [File] - [Print Method File...] from <Data Acquisition>	Print image by selecting [File] - [Print Method File...] from <Data Acquisition>
Output designation method	Specify an Acrobat® document (*.pdf) in File Type by selecting [File] - [Save As] from <Data Analysis>	Specify an Acrobat® document (*.pdf) in File Type by selecting [File] - [Save As] from <Data Analysis>.	Specify an Acrobat® document (*.pdf) in File Type by selecting [File] - [Save As] from <Data Analysis>
	Select [File Convert...] - [Data file to PDF file...] from <Data Explorer> (multiple files can be converted in one lot)		Specify an Acrobat® document (*.pdf) in File Type by selecting File - Save As from <Calibration Curve>
Output file name	Original data file name plus extension changed to pdf	Method file name used at data acquisition, plus extension changed to pdf.	Original method file name plus extension changed to pdf.
Remarks	<p>If the normal mode (Acrobat® Distiller®) is selected on the [PDF Export] tabbed page of the <Setting Options> window and if a password is specified in <Security Password for PDF Document> window, that password is used as the master password and "Not Allowed" in "Changing the Document" setting is selected for the Acrobat standard security.</p> <p>Note: If a PDF file is output using a function shown in the table, the normal/high-speed mode setting on the [PDF Export] tabbed page of the <Setting Options> window becomes active.</p> <p>Note: The other settings for document rights in the normal mode follow the settings in Acrobat® Distiller®.</p> <p>The following general information of the document is given:</p> <ul style="list-style-type: none"> • Title: Original file name • Subtitle: Output source application name (Data Acquisition/Batch (Analysis or Post-run)/Report Generator) • Created by: GCsolution user name at PDF export • Keyword: Data status (reanalyzed without saving and manual integration) • Created as: Product name (GCsolution) and Version No. <p>Note: Other information does not displayed, but some information such as sample information is embedded.</p>		

Note: The use of these functions requires Adobe® Acrobat® 5.0 or later.

Adobe® Acrobat Reader™, which is included in the GCsolution installation disk, can only be used to read electronic documents of the PDF. It does not include the capability of creating a PDF file.

Note: The use of these functions is subject to the prior setup of the PDF export by performing the steps described in "7.3 Setting the PDF Output".

Note: Each file that is not covered by this capability should be loaded using software that can handle it (text editor for a text file or a WWW browser for an HTML file) and then printed out on the printer by specifying PDFWriter™ or Acrobat® Distiller® (PDF output). This is more advantageous in the security setting and others rather than storing such a file in the original format.

For any file that cannot be output as a file, but can only be printed out, specify Acrobat® Distiller® or PDFWriter™ for the printer and then print out the file. This makes management easier without using paper reports. In this case, the document security and brief document information are not added automatically, and should be specified on the Adobe product.



6.3.2 Storing a Data File for a Long Period of Time

In addition to print images, the GCsolution's data files* and those that can be analyzed (machine readable data), such as data files of the AIA ANDi format, may be stored for a long period of time.

❖ Storing a file using an archiver product such as CLASS-Agent

Software in the archiver category, which is dedicated to the long-term storage of data, is commercially available. The GCsolution offers a powerful link* with our data management software including the archive function called CLASS-Agent. Such software products are applicable for the storage of AIA ANDi and PDF files, and some of them, like CLASS-Agent, feature the conformity to the FDA 21 CFR Part 11.

Some of the commercially available electronic document management software for PDF files or the like provide effective capabilities for document management.

* For example, the GCsolution creates a print image file of the PDF at printout if the necessary setup is completed on Agent Registration, and then pass it over to CLASS-Agent (this function can also be used to manage print image files of the PDF on software other than CLASS-Agent). In case of the PDF export at printout, a report file that does not necessarily has a single original data file name will have its extension changed to pdf, e.g., when it is printed out via the <Report> window or [Print Image] on the <Data Comparison> window. If the original data file does not necessarily exists in a single folder as in the latter case, the report file will be output to the current reference project. For other cases, the description in the previous section is applicable.

❖ Storing a file on CD-R or the like

The GCsolution has the data file format of the All-in-One File Structure. In addition, within the range of normal operations, related files such as method files are managed so that they are included in a single project (folder).

Upon completion of a project, a set of related files on a folder basis should be stored on a non-rewritable media such as CD-R. This facilitates the storage and management of those files.

Note: CLASS-Agent and some of other archiver products that have been described above support the capability of storing files on CD-R.

❖ Transferring a file to the storage destination

When there is an upper computer, a set of files may be transferred to that computer for data storage. The GCsolution supports this procedure by allowing you to specify a file transfer destination after data acquisition/data analysis, on the [Auto Copy] tabbed page of the <Setting Options> window opened by selecting [Tools] - [Option].

<Setting Options> - [Auto Copy] tab (Reference Manual p 578)

Copies a data file when a file is saved on the <Data Acquisition> window or when real-time batch processing is performed.

Copies a data file when a file is saved on the <Data Analysis> window or when post-run batch processing is performed.

The data file existing in the subfolder* under "GCsolution\Data" will be copied at the specified timing through the designated path.
* No data files existing in any other folder will be copied.

Note: If there is no specified path, the files will be copied by creating a folder.

If the same file name exists in the copy destination, the file names will be affixed with serial numbers so that the existing file cannot be overwritten.

Note: If files are transferred to a storage destination where the appropriate security (e.g., the setting for the file operation right for Windows® XP folders) is provided using this capability, the data can be managed more safely.

6.3.3 Devising a Data Storage Method

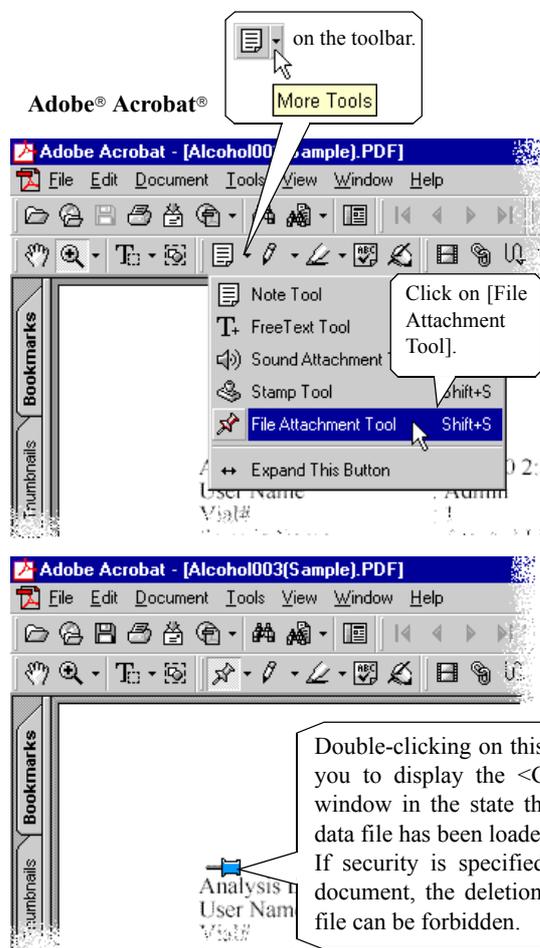
To store both printed image data and machine readable data, the relation between print images and the data files used to acquire them must be maintained.

It is one of the most recommendable methods that data be managed using the abovementioned CLASS-Agent. Agent Manager provides the capability of properly managing GCsolution data files and PDF files for print images.

Even if CLASS-Agent is not used, each data file has the all-in-one structure and self-contained information. Therefore, the following method will make the management easier:

Note: In this case, print images are regarded as equivalent to analysis results (electronic documents that are conventionally created by merely printing out the saved analysis results on paper), and data files as meta data used to obtain analysis results. The meta data must be all the data for obtaining the analysis results. The GCsolution meets the requirements for meta data by providing data files of the all-in-one structure.

In a PDF file for a print image, save GCsolution's data file used to obtain that print image, as an attached file.



The mouse cursor will change over to the shape of . Move it to an appropriate position on the print image for Acrobat® and then click on the mouse button.

The Dialog to select file will appear. Select the data file for GCsolution to be attached and then click on the [OK] button.

The <File Attachment Properties> window will appear. Check the data and then click on the [OK] button.

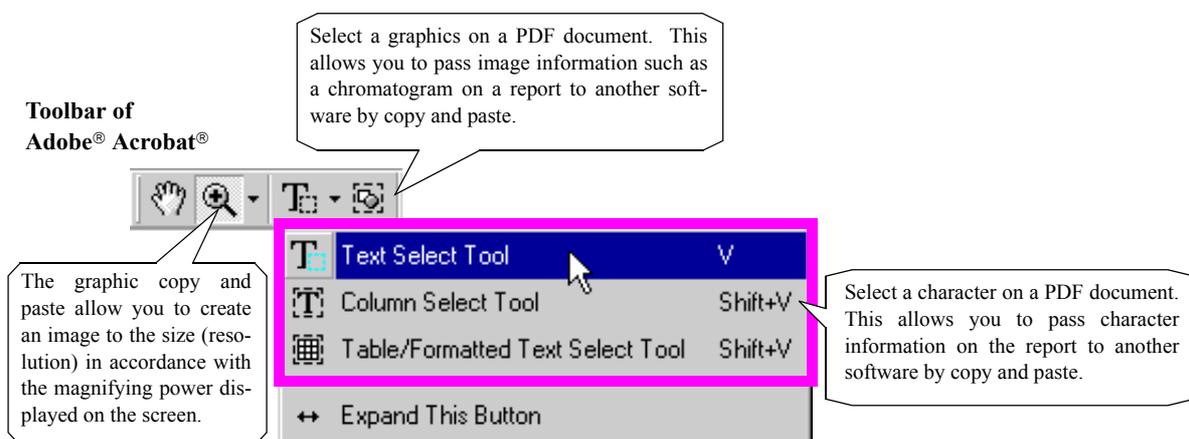
The advantage of this method lies in the point that managing the PDF files as analysis results (print images of reports) allows you to manage all other information as well. Even in the environment without the GCsolution, the use of Adobe® Acrobat® allows you to view analysis results as print images and check the details of data, as appropriate, on the PC having the GCsolution installed.



- ① In this method, data can no longer be searched for based on sample information via the <File Search> window of the GCsolution. However, Acrobat® provides a search plug-in, which allows you to search for all the PDF files based on document information and a character string included in the documents.
- ① The GCsolution itself does not provide the data acceptance function based on electronic signatures, but Acrobat® has the electronic signature function and protects a PDF document with a proper electronic signature including the data files included in that document. This is regarded as effective means conforming to the legal regulations such as the FDA 21 CFR Part 11.
- ① The use of the method for including a data file in a PDF document allows you to manage analysis data on an electronic document management system that can manage PDF documents. Some of the electronic document management systems have the approval/decision function and are regarded as effective means conforming to the legal regulations such as the FDA 21 CFR Part 11.

6.3.4 Using a Print Image

If a report image of an analysis result report is saved as a PDF file, the character information and image information on the report can be utilized on other software.



The [Table/Formatted Text Select Tool] allows you to pass character information of the tabular image, such as a peak report, to MS-Excel® or the like. This will be convenient for creating other reports using an analysis result or gathering multiple analysis results on MS-Excel® and then perform statistic calculations.

In addition, copying and pasting graphics to MS-Word or the like allows you to create a report.

Note: In this case, the copied image is dependent upon the magnifying power for the PDF document. Using the [Graphic Select Tool], define the extent of the image you want to copy, enlarge the displayed image as far as possible, and then copy it. This allows you to obtain a high-quality chromatogram image to the printable resolution at maximum. However, if the image size at the pasted destination is small, it is further reduced there. As a result, lines become thinner and faint or the image may be blurred depending upon the image reduction algorithm of the software at the pasted destination. Therefore, check the actually pasted state and choose the optimal magnifying power for copy and paste.

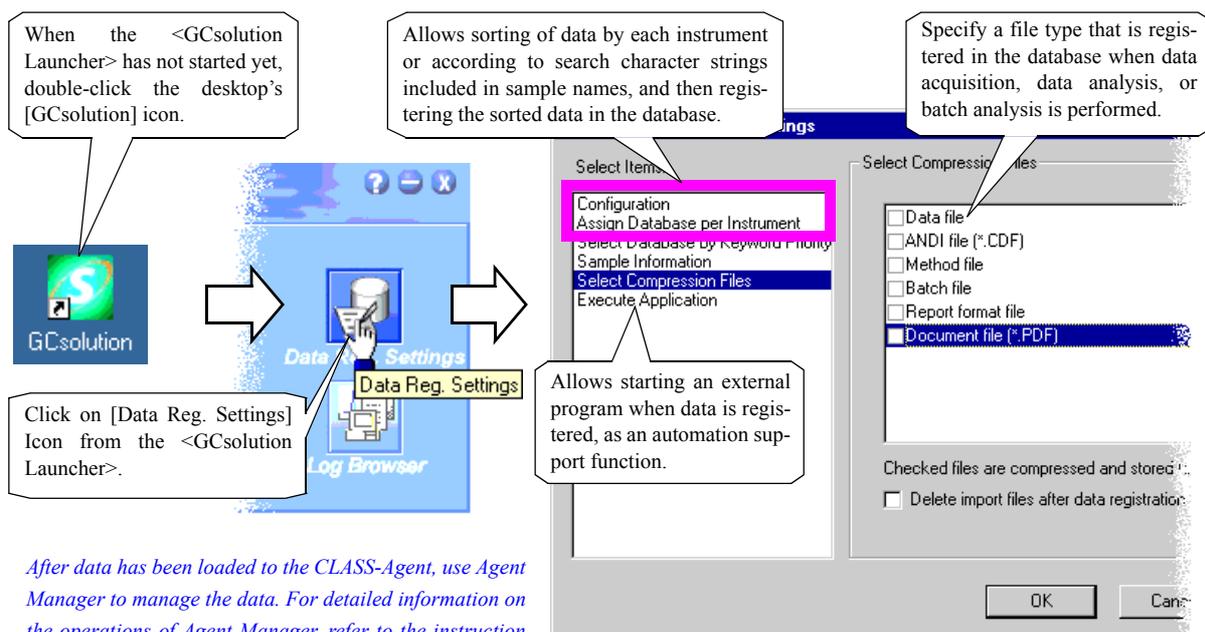
6 Data Administration

6.4 Using CLASS-Agent

This software allows you to carry out optional data management when used in association with our data management product, CLASS-Agent.

6.4.1 Specifying Method of Loading Data to CLASS-Agent

This setting allows you to automatically register the specified file in the Agent database when a data file is created or updated.



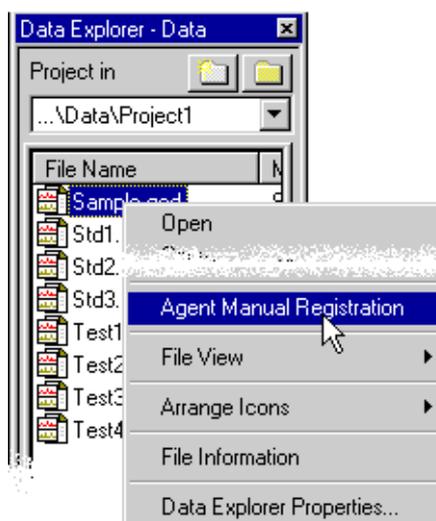
After data has been loaded to the CLASS-Agent, use Agent Manager to manage the data. For detailed information on the operations of Agent Manager, refer to the instruction manual for Agent Manager.

<Agent Registration Settings> (Reference Manual p530)

i You may manually register a data file that is registered in the Agent database at any time except when the data is created or updated, using the menu displayed by right-clicking on the <Data Explorer> window.

Note: When the data acquisition and post-run to tick the [Register Acrobat file to Link File 10 field] check box displayed when "Configuration" is selected by the [Select Items] list, the report image in PDF format is automatically output. It is registered in CLASS-Agent.

Note: The setting of this screen is given to priority more than the [PDF Export] setting. Therefore, please note that the PDF file with the same filename output by the [PDF Export] setting is deleted when [Delete import files after data registration (*.PDF)] setting is effective.



7 Appendices

7.1

Performing the Maintenance of System Management Database

The <Database Maintenance> window allows you to perform maintenance of the database, such as compacting or repairing the database and changing the database file.

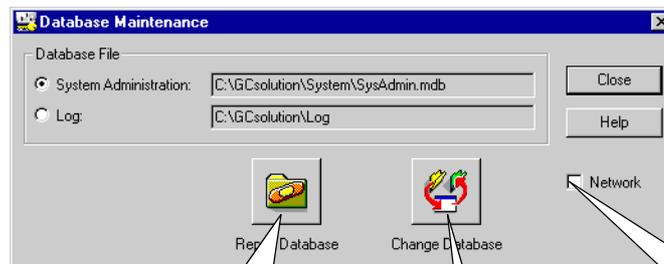
7.1.1 Using the Database Maintenance Tool

The <Database Maintenance> window appears when:

1. Shut down all the LabSolutions programs.
2. Double-click on the GCMntDB.exe  program in C:\GCsolution\Program.
<Login> window will appear.



3. When the user having the system administration right logs in the system, the <Database Maintenance> window will be displayed.



Clicking on this button duplicates the database and then reconstructs the fragmented database into a more compact one or attempts to repair the database having a fault.

After you have selected referencing the common management database on the LAN, checking this option will cause the system administration function to operate in the network mode starting with the next activation.

Clicking on this button displays the <Select File> window. If a file in a new reference source is selected, that management database will be referenced starting with the next activation.

Note: If the network mode is selected, the system administration information (user registration, etc.) entered from one point on the LAN can be shared by all the LabSolutions software.

See "7.2 Managing the System on the Network".

7 Appendices

7.2 Managing the System on the Network

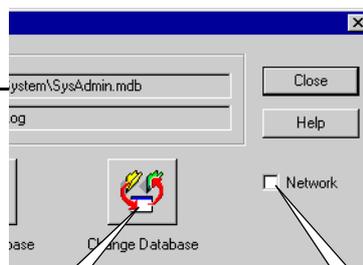
Using the <Maintenance of Instrument Information> window allows you to share the system administration information on the network.

7.2.1 Using the Instrument Maintenance Tool

The <Maintenance of Instrument Information> window is opened when the following steps are performed:

1. Shut down all the LabSolutions programs.

2. Using the <Database Maintenance Tool>, select the network mode for all the LabSolutions software that shares the system administration information, and then disable this tool.



Select referencing the system administration database files that are shared on the network.

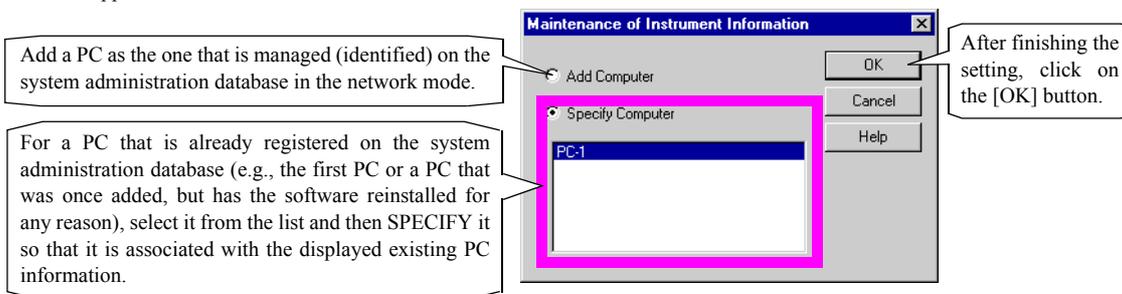
Check this option to select the network mode for the system administration function.

3. Unlike the standalone mode, multiple PCs are managed on the “System Administration Database”. Therefore, using the following “Instrument Maintenance” tool, associate the current PCs with PC information on the “System Administration Database” (or “Add Computer” information if not available). Double-click on GCMntPC.exe in C:\GCsolution\Program. The <Add/Specify Computer> window will appear from the <Instrument Maintenance> window.



4. <Login> window will appear. When the user with the system administration rights logs into the system.

Note: If the Add/Specify Computer option is already selected and if the current PCs are associated with PC information, then this window is skipped.

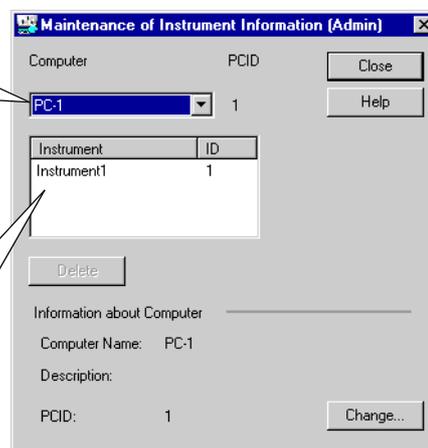


5. The main <Maintenance of Instrument Information> window is displayed.

6. At this point, the network settings for the system administration are complete. After checking that there is any registration in the [Computer] pull-down list, click on the [Close] button to close the <Maintenance of Instrument Information> window.

Displays the list of PCs that are centrally managed on the network.

Analytical Instruments, which are linked with PC above selected, is shown here. The entry of the analysis system selected from the [Instrument] list may be deleted, e.g., when the actual system is abolished.



7 Appendices

7.3 Setting the PDF Output

The GCsolution provides the capability to output a report in the PDF (Portable Document Format) when it is used with Adobe® Acrobat® (Ver. 5.0 or later), a tool for creation, management, and editing of PDF documents. When used with the CLASS-Agent, the GCsolution also provides the capability of outputting such report to the printer and converting print images into a PDF file, which is then sent to the CLASS-Agent.

7.3.1 Before Setting the PDF Output

The following products must be set up before the PDF output capability can be used.

- Adobe® Acrobat® (Ver. 5.0 or later)

To install this software, follow the instructions displayed on the screen that automatically appears when the CD-ROM for Acrobat® is placed into the drive, and perform the standard setup.

Note: This software package does not include Adobe® Acrobat®, which must be purchased separately. Adobe Reader™, which is included in the GCsolution installation disk, can only be used to read electronic documents of the PDF. It does not include the capability of creating a PDF file.

Note: To use the PDF output capability of this software, Acrobat® Distiller® or Acrobat PDFWriter™ is required. The standard setup of Adobe® Acrobat® 5.0 will install Acrobat® Distiller® only. In Adobe® Acrobat® 6.0, Acrobat PDFWriter™ is no longer supported and only Acrobat® Distiller® is installed.

Note: The standard setup of Adobe® Acrobat® 5.0 will not install Acrobat PDFWriter™. To install Acrobat PDFWriter™, specify this installation using the custom setup. In this case, it is recommended that Acrobat® Distiller® be also installed.

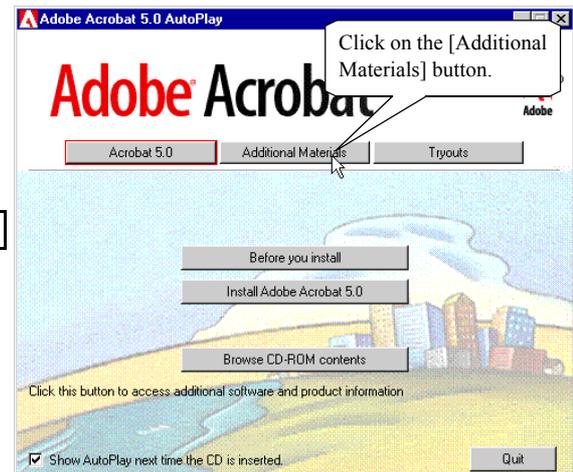
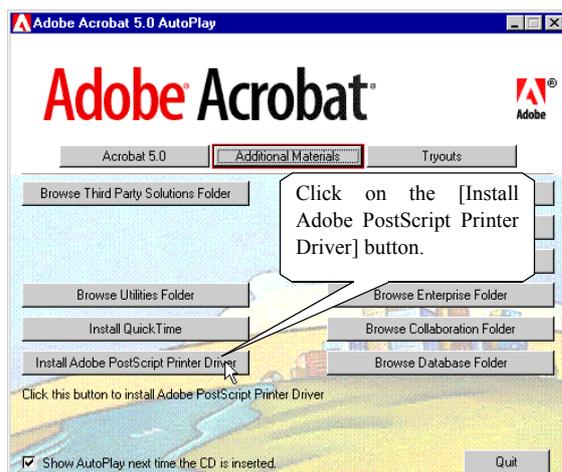
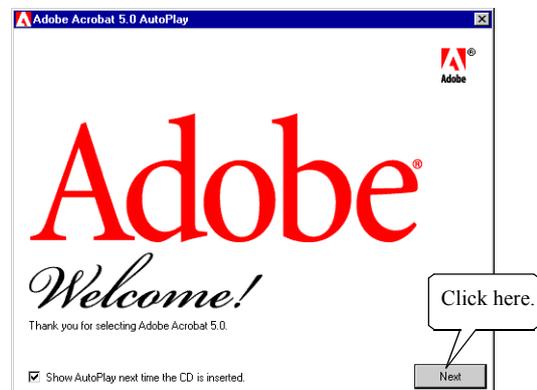
- To make archives in PDF format using CLASS-Agent, set it up in accordance with the installation manual for CLASS-Agent.

7.3.2 Setting the PDF Output (for Version 5.0)

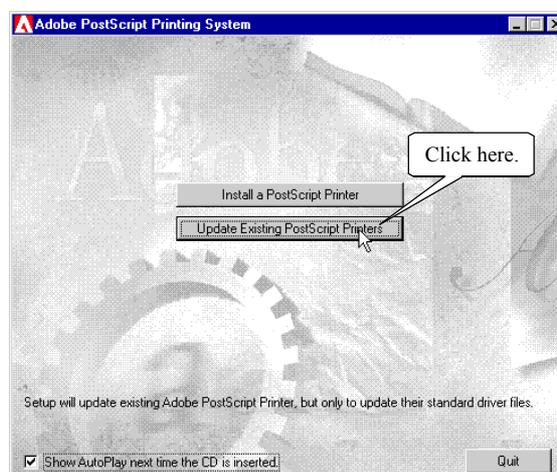
Before using this capability, set up the PDF output by the following steps:

1. On the opening window that automatically appears when the CD-ROM for Acrobat® product is placed into the drive, click on the [Next] button to proceed to the next step.
2. On the displayed window, select the [Additional Material] button. The list of buttons related to additional materials will appear.

From the displayed buttons, select the [Install Adobe PostScript Driver] button and then specify a post-script printer for PDF output.

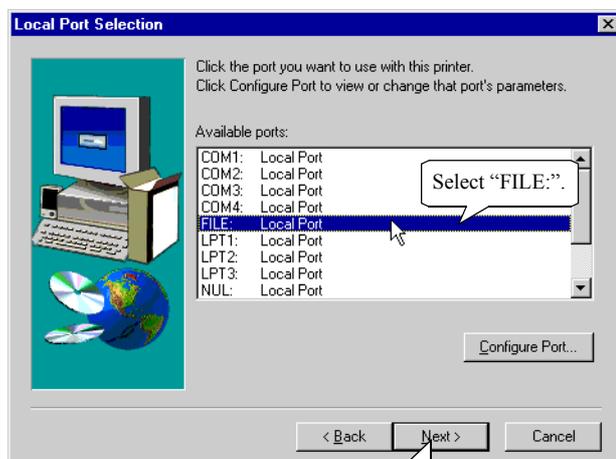


3. Click on the [Update Existing PostScript Printers] button.
Follow the message on each window based on the default values until the <Local Port Selection> window appears.





4. On the <Local Port Selection> window, select FILE: for the port.
Click on the [Next] button. The <Select Printer Model> window will appear.

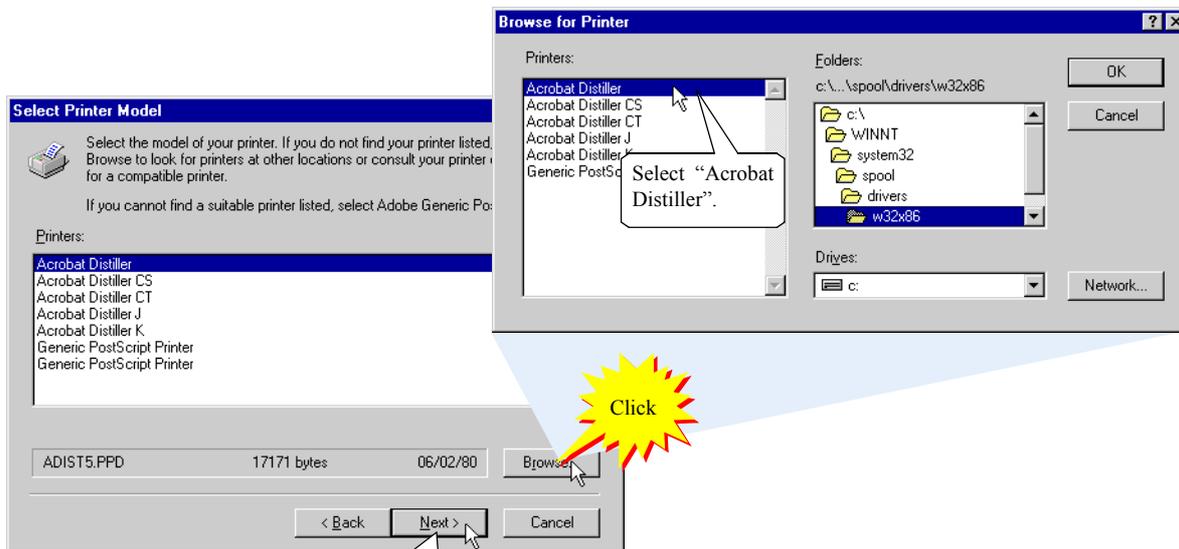


After the selection, click on the [Next] button.

5. Click on the [Browse...] button on the <Select Printer Model> window to display the <Browse for Printer> window.

Change the drive/folder over to “system32\spool\drivers\w32x86” under the Windows folder. Now “Acrobat Distiller” is available for selection from the list of printers. Select it and then click on the [OK] button.

You will return to the <Select Printer Model> window. With “Acrobat Distiller” selected, click on the [Next] button and subsequently go forward based on the default values until the <Printer Information> window appears.

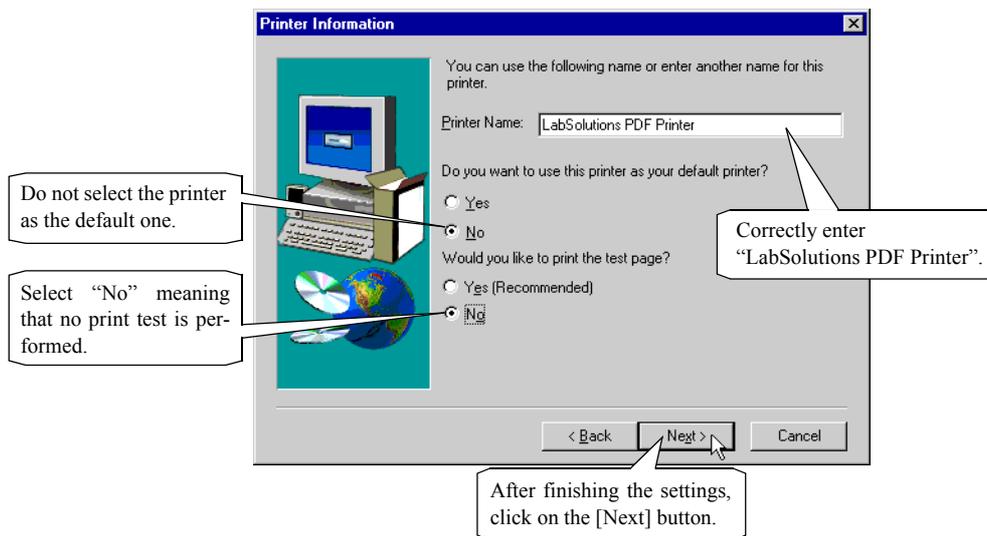


After the selection, click on the [Next] button.

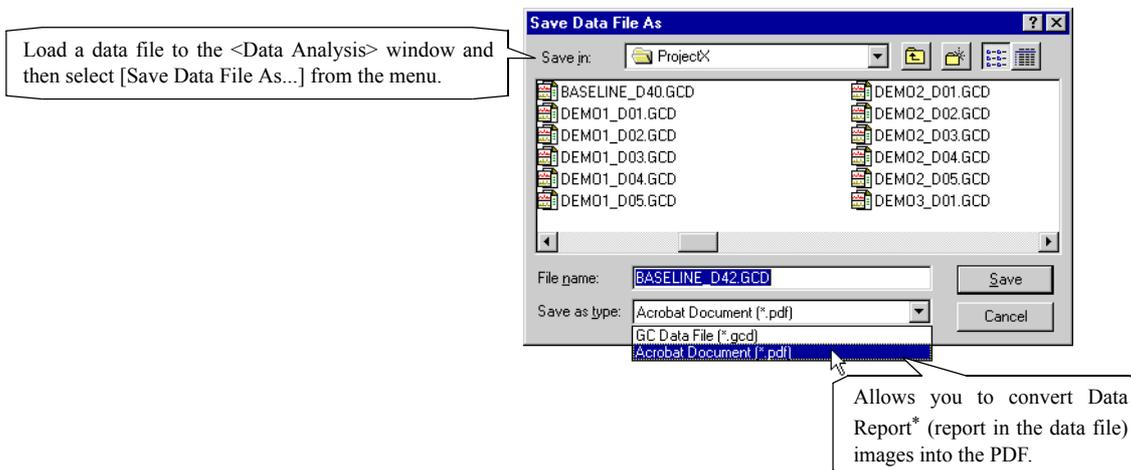
6. On the <Printer Information> window, specify a printer name.
Correctly* type “LabSolutions PDF Printer”.

Now the settings have been completed. Going forward in accordance with the message that will appear on each window completes the installation of the printer driver.

* Each one blank space must be given before and after “PDF”.



7. After the installation has been completed, display the <GC Postrun> window to see whether the PDF output settings are valid.



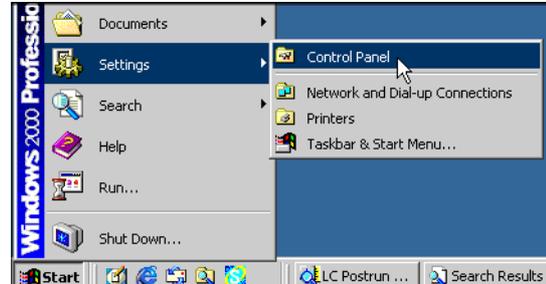
* If a data file in which no report format is recorded is converted into the PDF and then saved, a blank PDF file will be created.



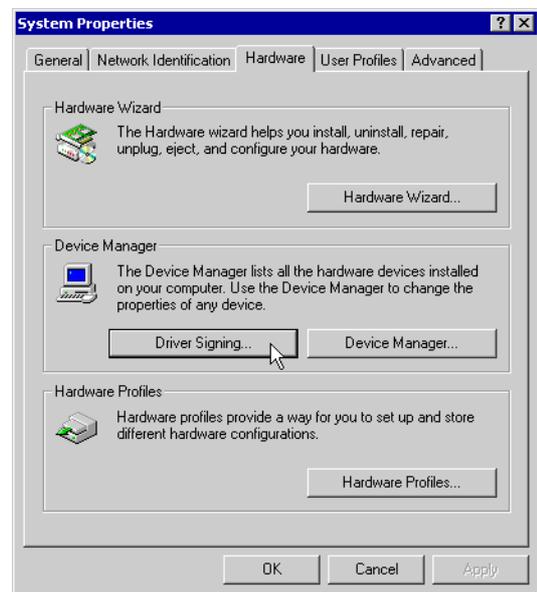
7.3.3 Setting up PDF output (for Version 6.0 or later)

Step 1 - 3 are not needed for Windows Vista and Windows 7.

1. From Windows' [Start] - [Settings], select [Control Panel].
Next, select [System] from [Control Panel]. The <System Properties> dialog box will appear.



2. Select the [Hardware] tab of <System Properties>, and click the [Driver Signing] button.
The <Driver Signing Options> dialog box will appear.



3. Make sure that the [Block] options has NOT been selected in the [File signature verification] area of the <Driver Signing Options> dialog box.
If [Block] has not been selected, click [Cancel]. If it has been selected, select [Warn] and click [OK] to close this screen.





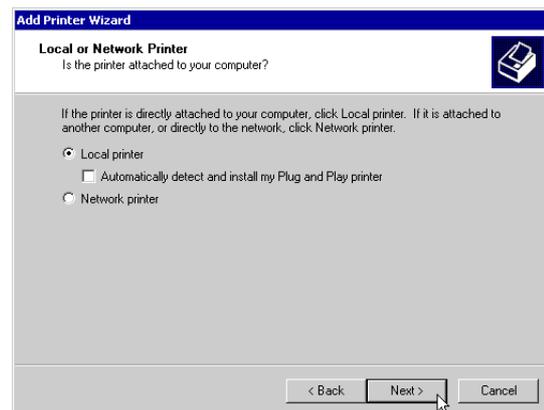
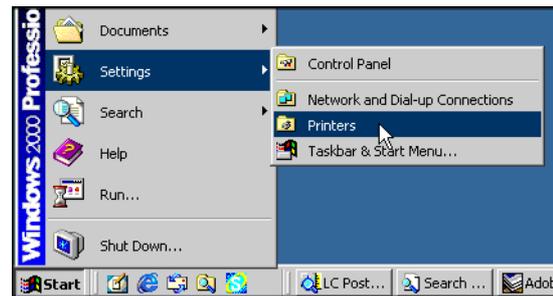
4. From Windows' [Start] - [Settings], select [Printers]. For Windows Vista select [Windows menu]-[Control panel]. And then select [Printer] on the classic view. For Windows 7, select [Windows menu]-[Devices and Printers] .

The <Printers> dialog box will appear.

5. Double-click [Add Printer] in the <Printers> dialog box to start up <Add Printer Wizard>. For Windows Vista and Windows 7, click on [Add a printer].

6. On the "Welcome to the Add Printer Wizard" window, click [Next]. For Windows Vista and Windows 7 is dialog box will not appear, goto step 7. The "Local or Network Printer" window will appear.

7. On the "Local or Network Printer" window, select [Local Printer](for Windows Vista and Windows 7 select [Add a local printer]). At this time, do not select the [Automatically detect and install my Plug and Play printer] option. After setting it, click the [Next] button. The "Select the Printer Port" window will appear.





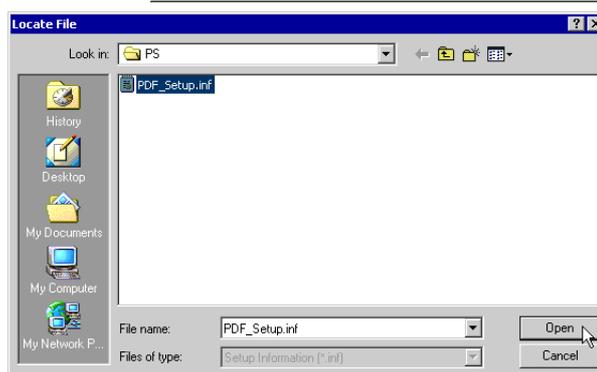
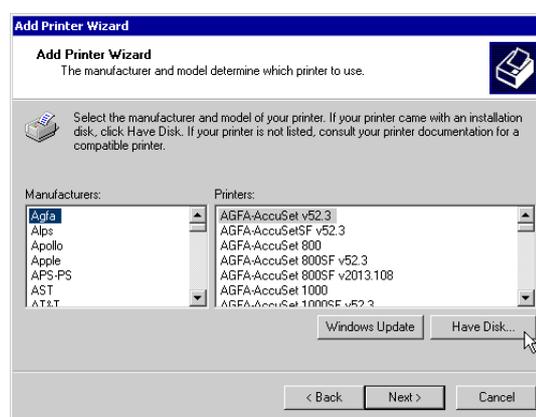
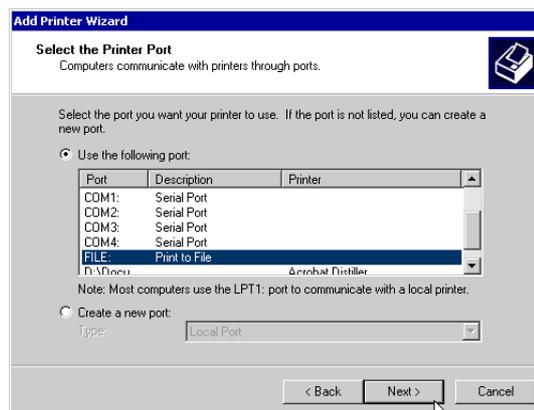
- On the "Select the Printer Port" window, select [Use the following port] (for Windows Vista and Windows 7 select [Use an existing port]) and then [File: (Print to File)] for the port to use.

After setting them, click the [Next] button. The "Add Printer Wizard" window will appear.

- On the "Add Printer Wizard" window, click the [Have Disk] button to open the <Install From Disk> window.

- On the <Install From Disk> window, click the [Browse] button and select PDF_Setup.inf found in "ENGLISH\ACROBAT\PS" folder of the GCsolution Installation CD-ROM, and then click the [Open] button.

- After making sure that the path to the PDF_Setup.inf file is correct in <Install From Disk>, click [OK]. You will return to the "Add to Printer Wizard" window.





12. Printers selectable in your system are listed in the "Add to Printer Wizard" window. Select "LabSolutions PDF Printer" in the list.

Then, click the [Next] button. Even if the above-mentioned printer is not listed, still click the [OK] button. The "Name Your Printer" window will appear.

13. In the "Name Your Printer" window, check to see that the printer name selected in step **12** is correctly shown. You can change the name of the printer if necessary. Select [No] to the [Do you want your Windows-based programs to use this printer as the default printer?] option. (For Windows 7 may be set as default printer automatically.)

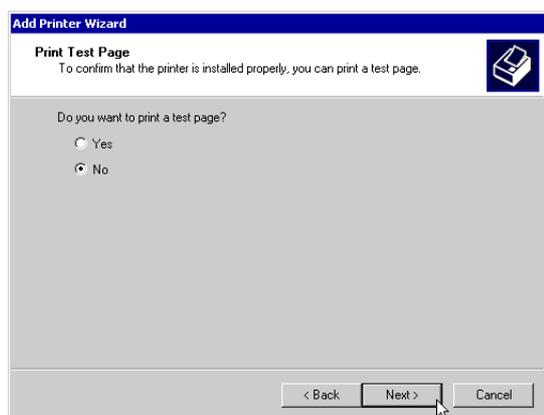
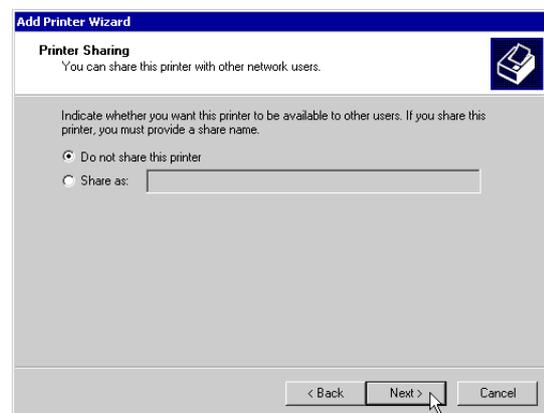
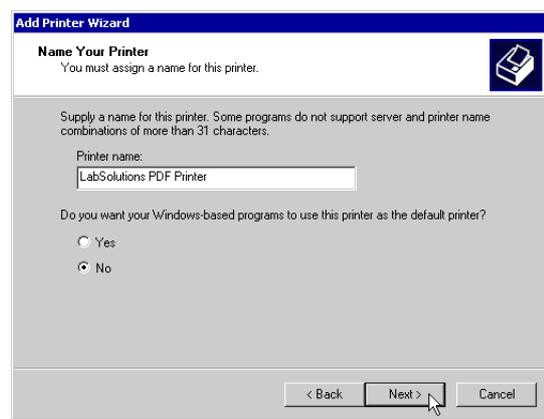
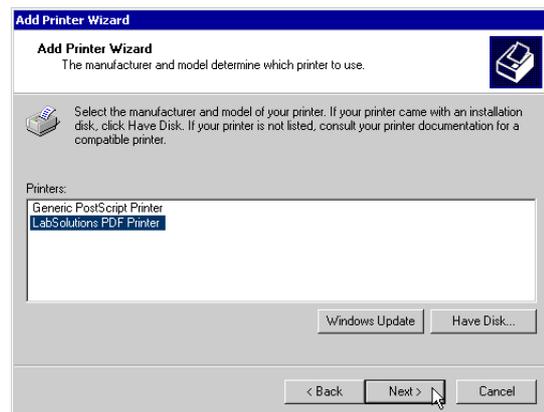
After setting them, click the [OK] button. The "Printer Sharing" window will appear. For Windows Vista and Windows 7, if [Windows Security] message appears, click [Install this driver software anyway].

14. In the "Printer Sharing" window, select the [Do not share this printer] option.

Then, click the [OK] button. The "Print Test Page" window will appear. For Windows Vista and Windows 7, click [Finish] on <Add printer.> then go to step 18.

15. In the "Print Test Page" window, select [No].

Then, click the [OK] button. The "Complete the Add Printer Wizard" window will appear.

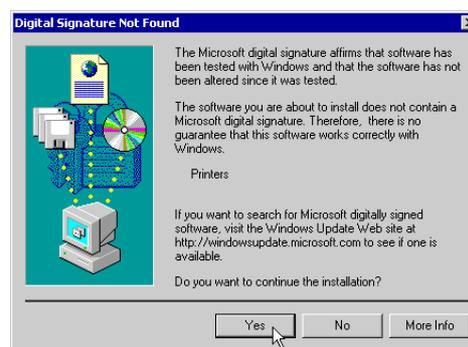




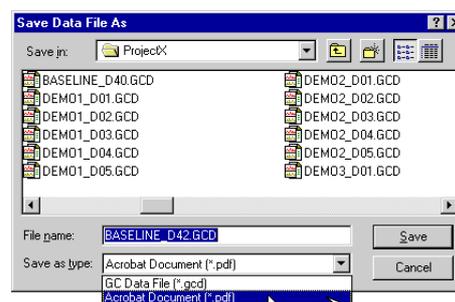
16. In the "Complete the Add Printer Wizard" window, check all the settings and click the [Finish] button to exit the wizard.



17. After the [Finish] button is clicked, the following warning message might appear. In this case, click [Yes]. The installation will be completed.



18. After the installation is successfully completed, start up <GC Postrun> - <Data Analysis> to check if the PDF output feature has been enabled.



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