User Guide

PHARMSPEC 2 SOFTWARE

HACH ULTRA™

EXCELLENCE IN PROCESS ANALYTICS

KSS - March 2006 - Edition 3

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Manual Overview

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Revision History

- PharmSpec 2 User Guide, Revision 3, March 2006, Hach Ultra Analytics, Inc.
- PharmSpec 2.0 User's Manual, Revision 2.0, May 2003, Pacific Scientific Instruments.

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1 Introduction

PharmSpec is a Microsoft® Windows® application that works in conjunction with HIAC's particle counters and samplers as a data acquisition and analysis system. It is fully compatible with the HIAC 9703 and 9705 Systems. These systems collect data and analyzes it using the USP<788>, EP, JP or KP procedural standards, or user-defined test procedures.

- The 9703 System consists of a Model 9703 sampler plus a liquid sensor.
- The 9705 System includes both the sampler and a sensor in one unit.

This manual provides the basic information about Version 2.0 of the PharmSpec software. The main features of the PharmSpec 2 software are listed below:

- Compliance to requirements of the FDA 21 CFR Part 11
- Data analysis using the USP<788>, EP, JP and KP procedural standards or using user-defined test procedure
  - Analysis of single or multiple runs
  - Up to 16 channels
  - Ability to review / approve test results
- Historical Report capabilities
  - Ability to print out reports or view them on screen
- Historical data backup, archive, restore
- Procedure Builder to define custom test procedures

1.1 What’s new in PharmSpec 2.1?

Compatibility with the HIAC 9705 Liquid Particle Counting System

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2 Installation

2.1 System Requirements

a) Hardware Specifications

A PC with following recommended configuration:

Minimum Configuration

- Pentium @ 133 MHz
- 96 MB RAM
- Video 1024 x 768 (minimum)
- 320 MB Free Hard Disk space
- RS-232 serial communications port

Recommended Configuration

- Pentium III-class processor @ 450 MHz
- 128 MB or 256 MB RAM (128 is OK;256 is preferred)
- Video 1024 x 768 (minimum)
- 500 MB Free Hard Disk space
- RS-232 serial communications port

HIAC 9705 System, or

HIAC 9703 System consisting of

- An HRLD-150, HRLD-400, or HRLD-600 sensor
- Model 9703 Sampler (firmware version 1.1 or higher)
- A counter PCB (internal) with firmware version 12 or higher

b) Software Specifications

- Operating Systems supported:
  - Microsoft Windows NT 4.0 Workstation (Service Pack 6a or later)
  - Microsoft Windows 2000 Microsoft Windows
  - Microsoft Windows XP Microsoft Windows
- Microsoft .NET framework
- Internet Explorer 5.5 or greater
- Microsoft Excel (to access PharmSpec 1.4 reports)

2.2 Installation Procedure

PharmSpec provides a simple mechanism for installing the software using an Installation Wizard.

Note:
Installation of this program requires that you have ADMINISTRATOR privileges on the computer. If necessary, contact your IT department to verify if you have ADMINISTRATOR privileges in order to proceed with the installation.

To install the software, insert the installation disk into the appropriate drive. If AUTORUN is active on your system, the installation Setup software will automatically be started.

Note:
*If the installation software does not automatically start, from Windows Explorer, double-click the **Setup.EXE** file from the CD-ROM drive.*

Click the **OK** button if the default installation location is acceptable or else browse and specify a different location. The next step will ask which drive will be used for creating the PharmSpec Database.

Note:
A complete installation of the main application, .NET environment and MSDE support may take up to 15 minutes to complete.

The Wizard then takes you through a series of installation screens, and in each of these, you have to proceed by clicking on the “Next” button.

PharmSpec 2 consists of the main PharmSpec user application and add-on applications like Procedure Loader, Database Restoration Module etc. The user can configure PharmSpec 2 during the installation set up. The following pre-requisites have to be specified at the time of installation:

Language selection

You can select a language of your choice during installation. This language is used in PharmSpec 2 for all controls. This cannot be reset later. **In this release, only English is available.**

Date and Time format

The user can configure the format for displaying date and time. This format is used for displaying all date and time fields in PharmSpec 2. **The date/time format cannot be reset later.**

Security Level

The user can select the level of security. This controls how the system will operate in response to an attempt to reset the system after a System Lock-out has occurred due to an invalid access attempt. There are 2 levels of security, HIGH and LOW. When the system has been installed with HIGH security, then only someone with “Administrator” rights can restart the software before the end of the LOCKOUT TIME period. If the system was installed with HIGH security, then any valid user other than the USER ID that caused the LOCKOUT will be able to access the software with a proper login.

Note:
The installation program automatically creates a PharmSpec program group, and a shortcut on your Windows desktop.

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2 Setting up the System

Once you have installed the PharmSpec software, you need to configure the system for use with your equipment. This configuration includes providing information concerning channel settings, sensor calibration, and run parameters, as well as information on your specific hardware configuration.

PharmSpec acquires data according to the setup parameters that you specify, and will save this data in database. Data analysis will be based on the particle distribution and on the pass/fail classifications of the test procedures.

The following chapters will guide you through the system configuration and the user administration steps.

Note:
Before starting the software, verify the following settings in the Windows Operating System (OS):

- **Display Settings** are set for **Small Fonts**
- **Decimal Separator** [typically either the decimal “.” or comma “,” character] is set correctly for your use.

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3 System Configuration

3.1 Hardware Settings

You have to set up the hardware and the operating parameters before starting to use the system with the 9703 or 9705 sampler. Otherwise the software can be used only in the Simulation (Demo) mode.

The software will prompt the user to configure the 9703 or 9705 on first use by opening the Hardware Settings dialog is the user has the appropriate permissions.

Configure the system during initial set up or whenever there is a change in the hardware components or the operating parameters used. You can set up the hardware by selecting ***Setup > Hardware Settings***. This invokes the **Hardware Settings** dialog. This menu is enabled only for a user who has the required privilege to do this.

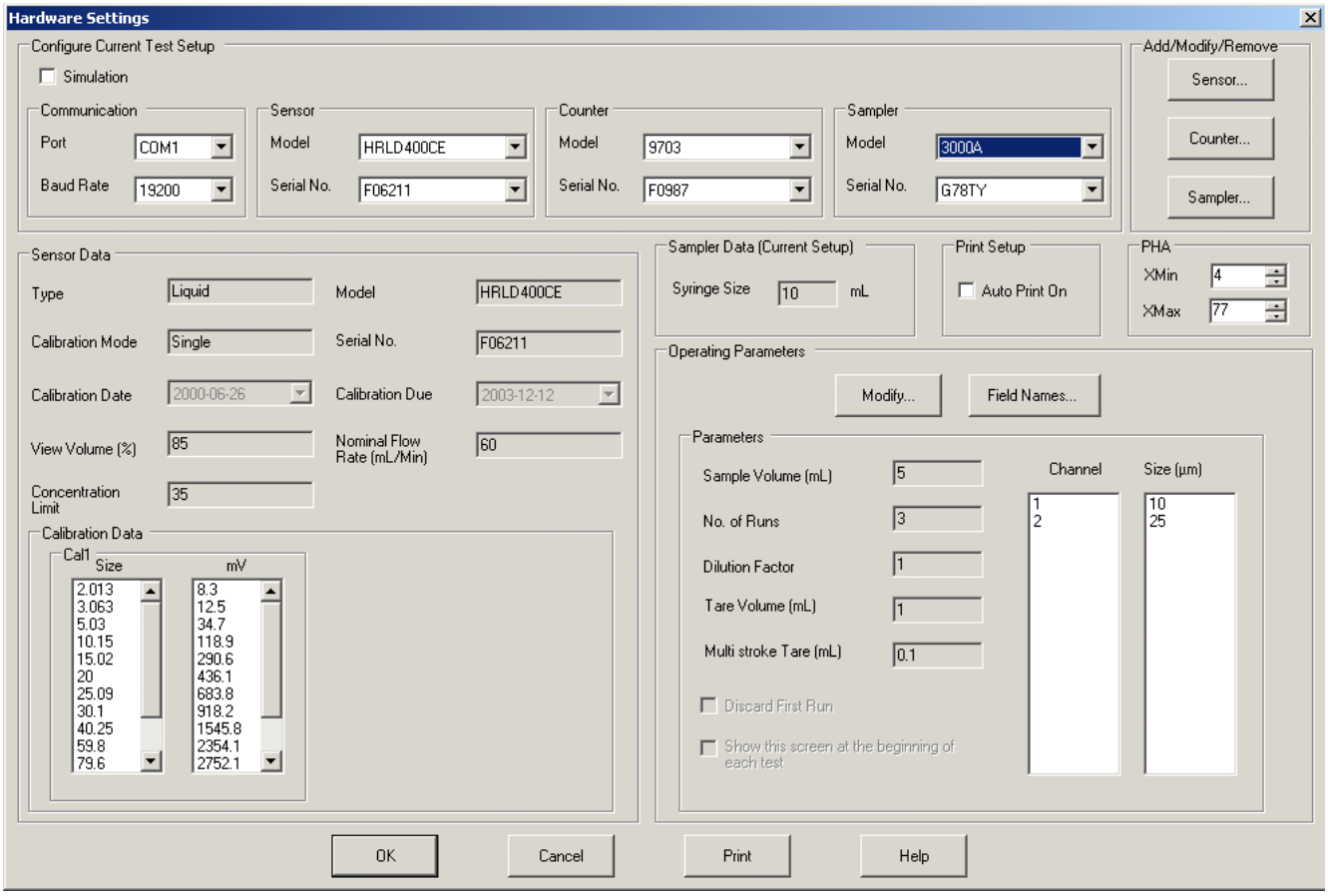

Fig 3-1 : Hardware Settings Dialog

This dialog is organized into multiple sections. Each section is explained below.

To set up a new system, the first step is to configure or add Sensor(s), Counter(s) and the Sampler(s). The next step is to define the current setup components by selecting the Sensor,

Counter and the Sampler used in the system and the communication parameters such as the Port number and the Baud rate. Then you need to set the Operating Parameters.

- The 9705 uses sensors and counters.
- The 9703 uses sensors and samplers.

a) Configure Current Test Set-up

A user can have an inventory of more than one Sensor, Counter and Sampler, but only one each of these components will be used in a test setup at any given time. In addition to this, the COM port of the computer to which the hardware unit is connected and the Baud rate need to be set. The *Configure Current Test Setup* group allows the user to configure all these.

Communication

The user can select the port and baud rate required for communicating with the HIAC 9703 or 9705. The available options for Port number are COM1, COM2, COM3 and COM4.

Note:
For the 9705, set the Baud Rate to USB.

Sensor

The user can select the model and serial number of the sensor used in the current test set up.

Counter

The user can select the model and serial number of the counter used in the current test set up.

Sampler

The user can select the model and serial number of the sampler used in the current test set up.

Simulator

There is a check box named Simulator. The user selects this to run the system in simulation mode. This invokes a confirmation message prompting the user to confirm the change to simulator mode.

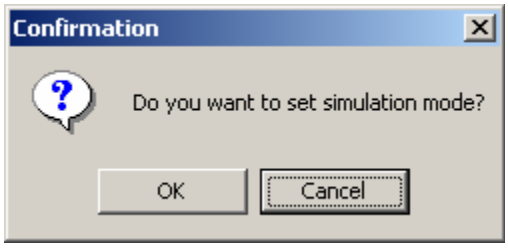

Fig 3-2 : Simulator Mode Confirmation Dialog

The user can select the simulator mode by clicking the *Yes* button on this confirmation message. All the other controls in the *Configure Current Test Set Up* are disabled in this case. In simulation mode, the application will not communicate with the hardware.

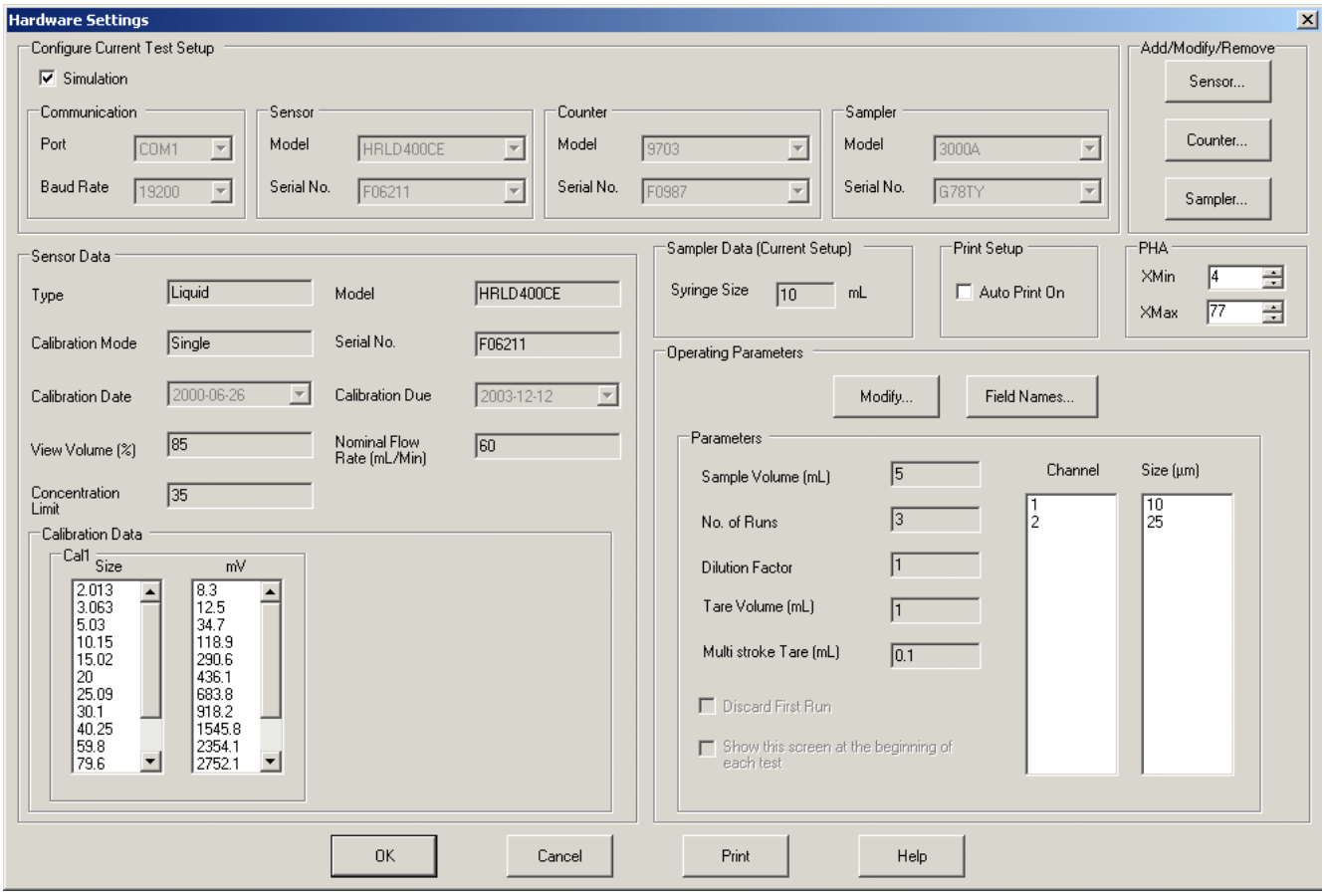

Fig 3-3 : Simulator Selection

b) **Add / Modify / Remove (Sensor, Counter, Sampler)**

The user can add new hardware components (sensor, counter and sampler) to the existing inventory or modify the parameters of the existing ones. The user can also remove a hardware component from the inventory.

Sensor

The user can add new sensors to the system, modify existing sensor data or remove a sensor from the inventory. There is an additional option to import sensor data from a file so that the user need not enter the data manually. While configuring the current test setup, user has to choose a sensor from the sensor inventory. To add / modify / remove a sensor, click the *Sensor* button in the *Hardware Settings* dialog. This invokes the *Add Sensor* dialog.

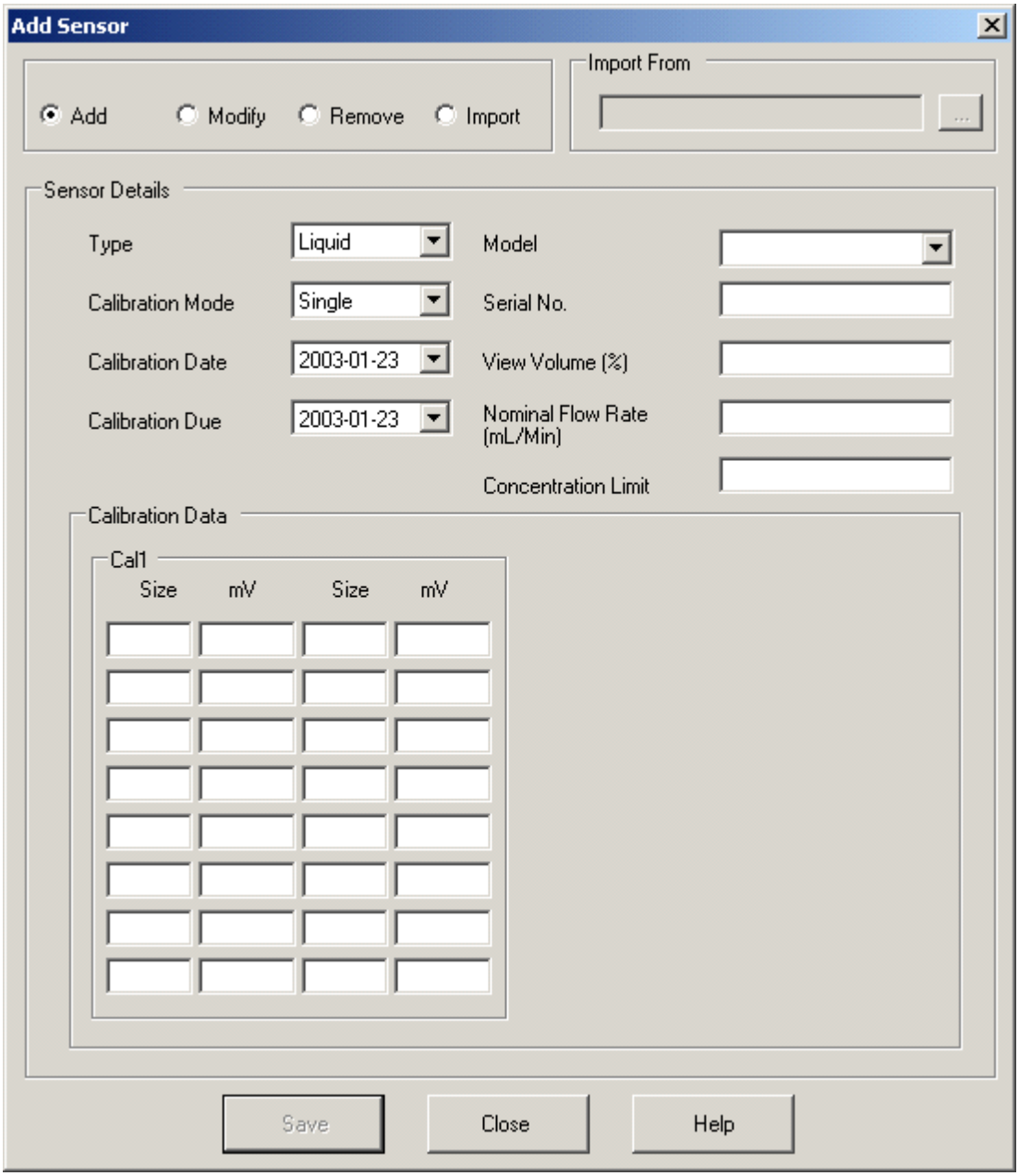

Fig 3-4 : Add Sensor Dialog

The user can perform any one of the following operations:

Add a Sensor	User can add a new sensor to the system. User has to check the radio button corresponding to Add. User has to specify all the details including type, model and serial number in this case. All controls on the dialog will be enabled in this case.
Modify Sensor Data	User can modify the parameters (Calibration data in most cases) of an existing sensor. For this, user has to select the radio button corresponding to Modify. The user has to first select the Model and then the Serial No. of the sensor and then modify the details. User will not be allowed to modify the type, model and serial number.
Import Sensor Data	Instead of adding a new sensor using the “Add” option and by entering the sensor data, the user can import sensor data from a file. For this, the sensor data should be available in a predefined format in a file. This sensor details file shall have an extension “.sen”. To import the sensor data, select the radio button corresponding to import, following which, the *Import From* control is enabled. The user is then allowed to select the path and file from which the user has to import the sensor. An Open File dialog is displayed from which the user can select the path and file. User can import it and modify the details (if required) excluding type, model and serial number.
Remove Sensor	You can remove a sensor from the system. The currently selected sensor is deleted by clicking on the Remove button.

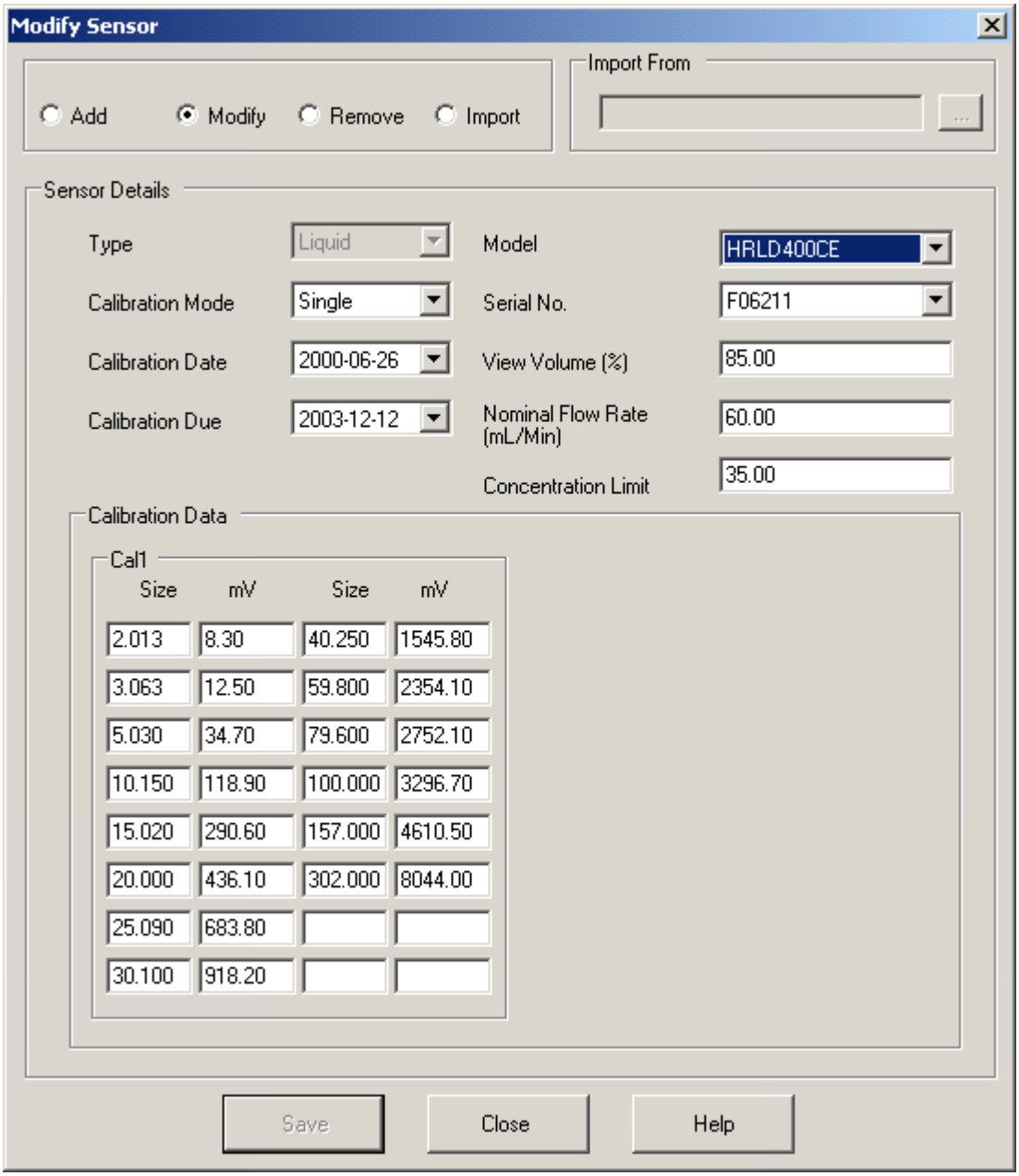

Fig 3-5 : Modify Sensor Dialog

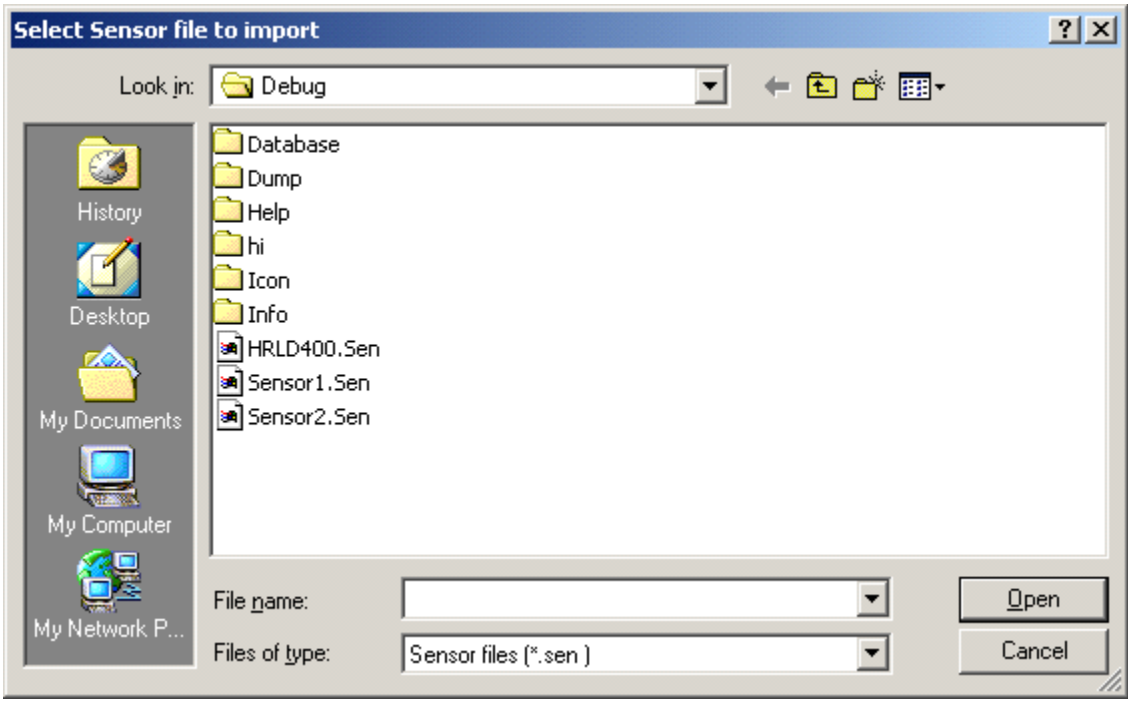

Fig 3-6 : Import Sensor Dialog

The sensor data consists of following parameters. When you add a new sensor, you need to define all these parameters. In the “Modify” mode, it allows you to modify most of these parameters except the model and the serial number.

- Type of the sensor (Liquid / Air)
- Model of the sensor (Enter the model number or select one from the list)
- Calibration mode

Note:
Only liquid sensors are supported at this time.

The Sensor Calibration mode could be either “single” or “dual.” In case of “Dual” mode, there are two sets of calibration data to be entered:*Cal 1* and *Cal 2*. The second set is disabled in case of the “single” mode sensors.

Note:
Dual mode is not supported at this time.

- Serial number of the sensor
- Expiration date for the calibration
- Nominal Flow Rate
- Date of calibration
- View Volume
- Concentration Limit

User shall enter the particle sizes for the calibration and the millivolt values for the size. There must be a minimum of four sizes and millivolt values. The user can then save the details by clicking on the **Save** button.

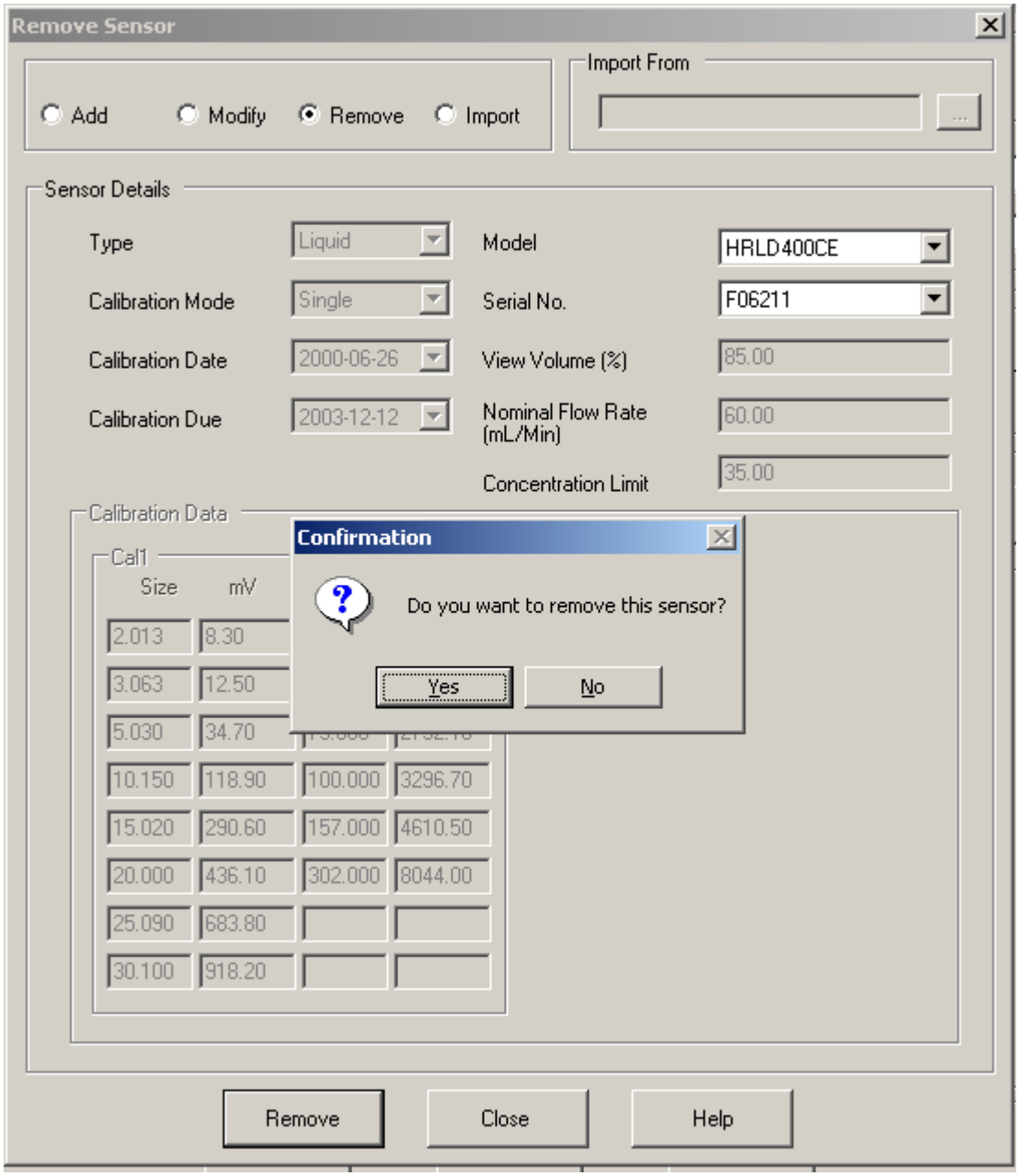

Fig 3-7 : Remove Sensor Dialog

3.2 Counter

Add Counter

The user can add a new counter to the system. Clicking on the *Counter* button in *Hardware Settings* dialog does this. This invokes the *Add Counter* dialog.

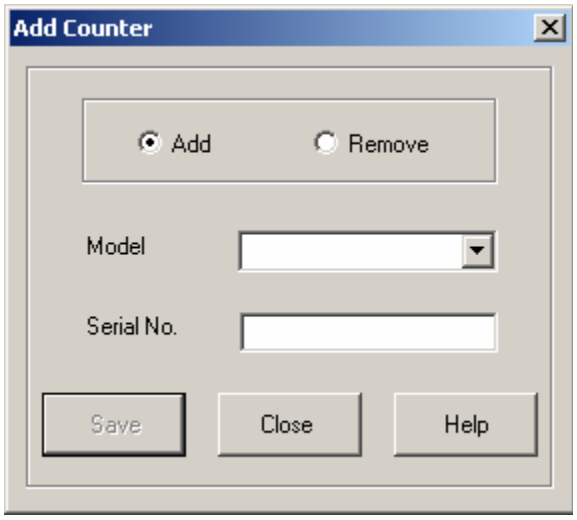

Fig 3-8 : Add Counter Dialog

The user has to enter the model and serial number of the counter. You can also select the model number from the list (if available). You can save these details by clicking on the **Save** button, for later retrieval and use.

Remove Counter

You can remove a counter, which is no longer in use from the system. The title of the dialog becomes Remove Counter, and the caption of the *Save*. When the *Remove* button is clicked, a confirmation message is displayed prompting the user to confirm removal of the counter.

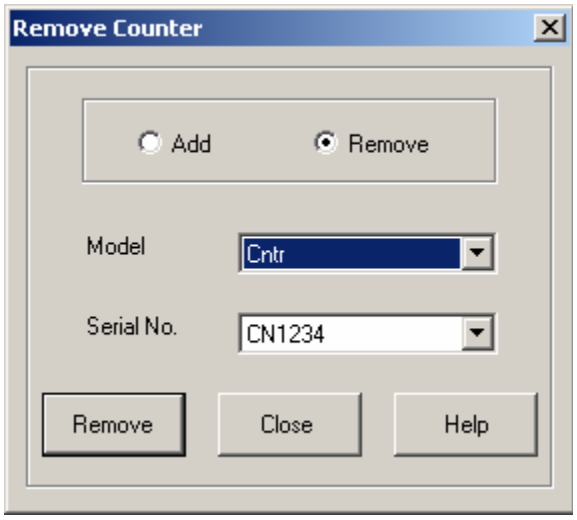

Fig 3-9 : Remove Counter Dialog

a) Sampler

Add / Modify Sampler

The user can add a new sampler or edit an existing sampler. To do this, click the Sampler button in Hardware Settings dialog. This invokes the Add Sampler dialog.

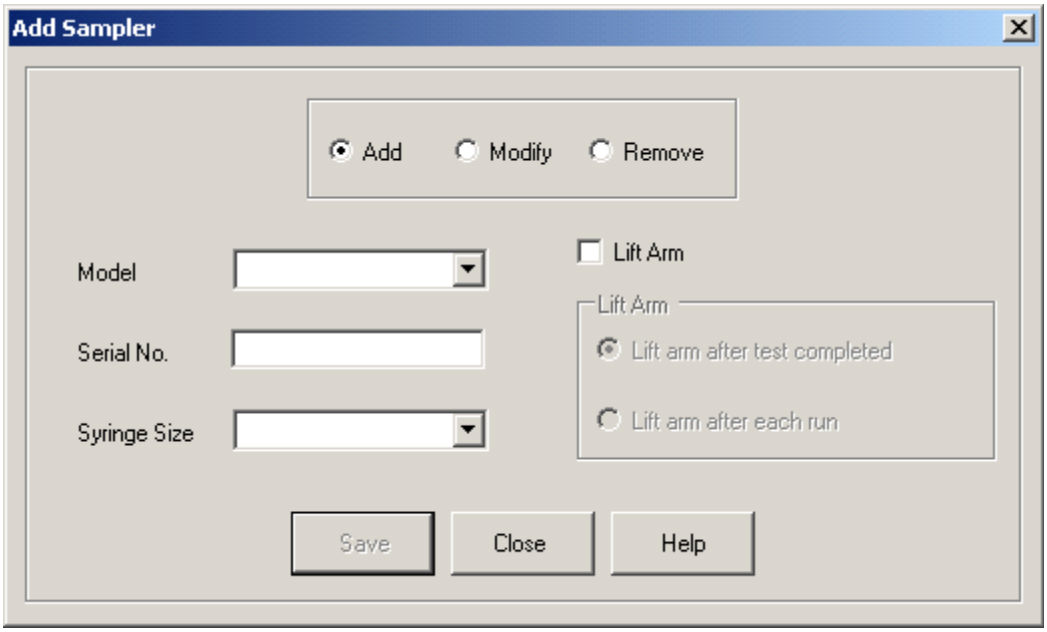

Fig 3-10 : Add Sampler Dialog

You can add new sampler details by clicking on the Add radio button. You can enter the value for model, serial number and select a syringe size from the Syringe Size selection window selection window for the sampler. Available syringe sizes are 1 ml, 10 ml and 25ml. You can also select the model number from the list, if available.

On the 9703, you also have to select the option for lifting the arm (lift the arm after each run or after the completion of the test). You can then save the details, by clicking on the Save button, for later retrieval and use. If you prefer to manually raise the arm at the end of each test or sample, then simply do not check the box for Lift Arms database. User can select a model and serial number from the existing list and change the syringe size of the selected sampler and the lift arm behavior. You can then save the details, by clicking on the *Save* button, for later retrieval and use.

Note:
The HIAC 9705 does not use an arm for sampling, so this option is not available to 9705 users.

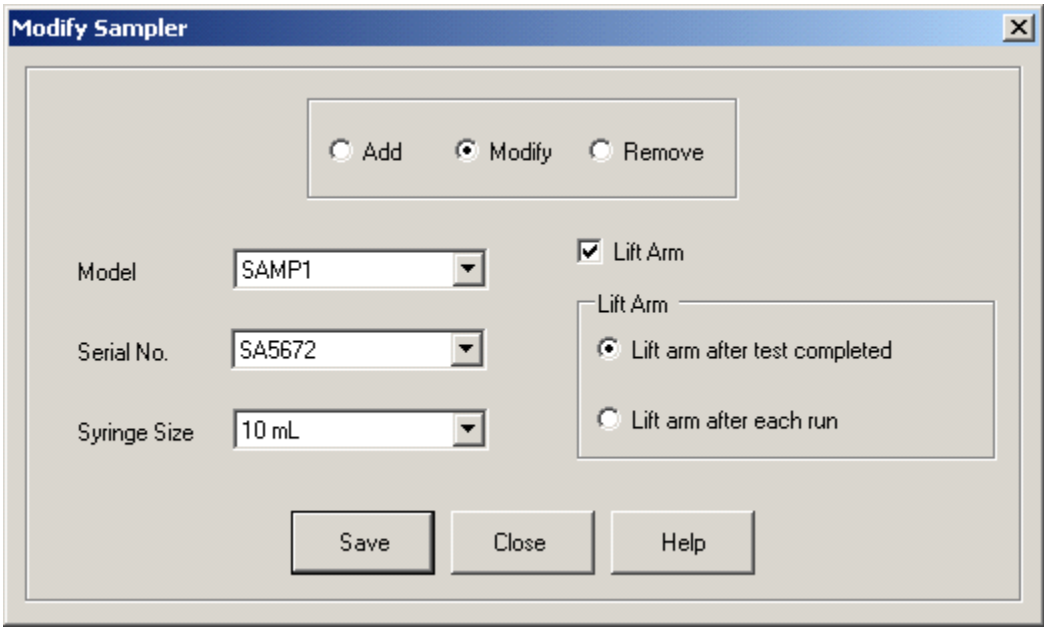

Fig 3-11 : Modify Sampler Dialog

Remove Sampler

You can delete a sampler, which is not in use, from the system. The title of the dialog becomes Remove Sampler and the caption of the Save button becomes Remove. By clicking on the Remove button, the user is prompted for confirmation before the Sampler is deleted.

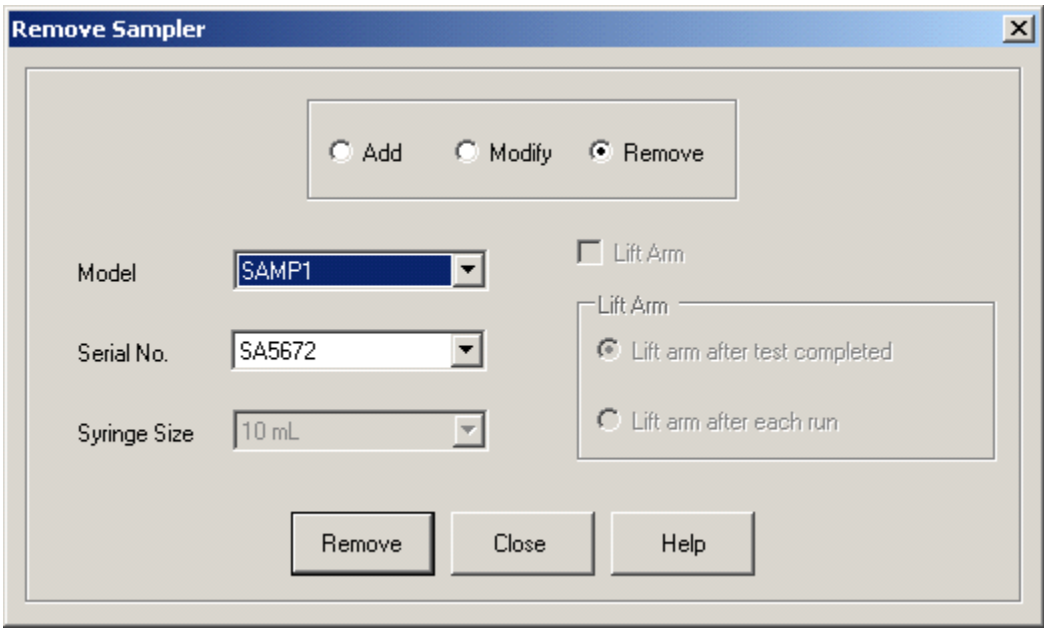

Fig 3-12 : Remove Sampler Dialog

b) Sensor Data

You can view the details of the currently selected sensor (as per the Current Test Set up) in the *Sensor Data* section of the *Hardware Settings* dialog. Sensor details include the type, model, calibration mode, serial number, calibration date, calibration due date, volume, flow rate and concentration limit. This also lists the calibration data.

c) Sampler Data

You can view the syringe size for the currently selected sampler (as per the Current Test Set up) in the *Sampler Data* section of *Hardware Settings* dialog.

d) Print Setup

You can opt for auto print of test result after running the test. To do this, check the *Auto Print* On checkbox in the *Print Setup* section.

e) PHA

For the 9703, you can configure the Xmin and XMax parameter values of PHA graph from the PHA section. These are the starting and ending points for the x-axis on the PHA display. The value for the ending point must be at least 30 units greater than the starting point.

f) Operating Parameters

You can view the operating parameters such as sample volume, number of runs, dilution factor, Channel sizes, tare volume, etc. in *the Operating Parameters* section of *Hardware Settings* dialog. Most of these Operating Parameters except for the tare parameters are used exclusively for the "***RUN Counter***" test. The tare parameters (Tare Volume and the Multi-stroke Tare) are used by other tests also.

The ***Modify*** button in the *Hardware Settings* dialog can be used to modify these parameters. Clicking on the *Modify* button invokes the O*perating Parameters* dialog.

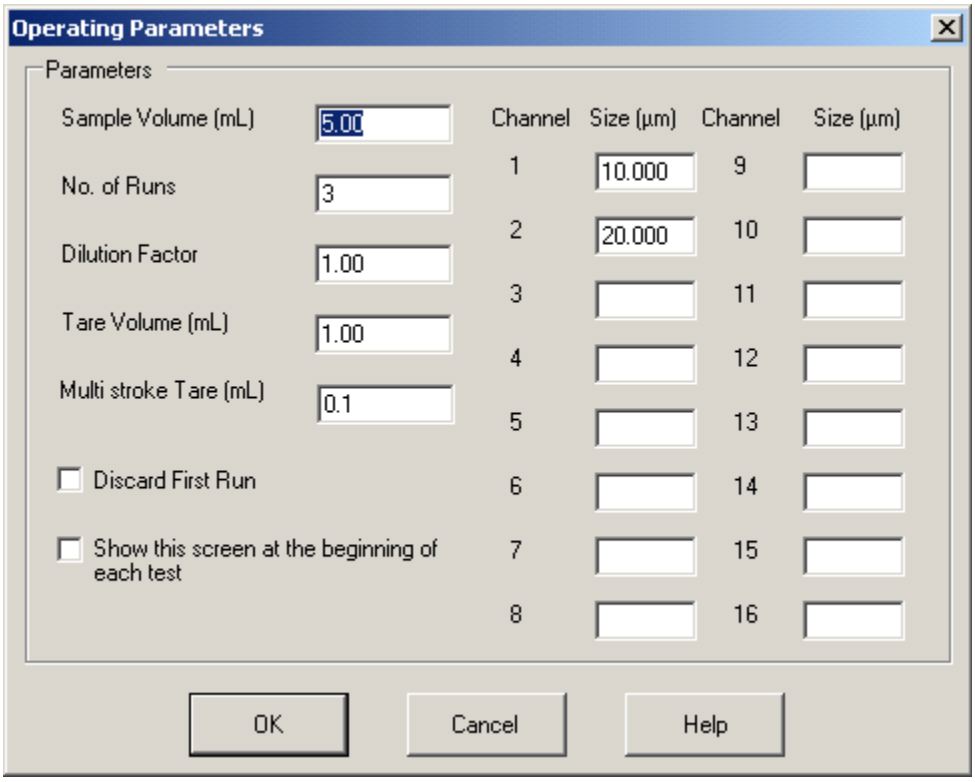

Fig 3-13 : Operating Parameters Dialog

You can enter the channel setting details. These are:

- Sample Volume for the Run Counter test
- Number of runs for the Run Counter test
- Dilution factor for the Run Counter test
- Tare volume: a volume drawn preceding the SAMPLE volume. It occurs on the first stroke of a given run. This is to remove any fluids from a previous run (or bubbles etc. if the tubing is empty) and to ensure that the sample data obtained is only from the fluid from the container currently in place on the 9703 or 9705.
- Multi-stroke tare: drawn to bring the fluid up to speed.
- Channel: PharmSpec supports up to 16 size channels.

User can also specify following conditions:

- Discard first run: If this option is selected, for the Run Counter Test, the test results of the first run will be ignored in the computations but will still be displayed and stored.
- Show this screen at the beginning of each test: If this option is selected while running the Run Counter Test, the Operating Parameters dialog will be displayed at the beginning of the test. This is intended to provide information to the operator before running a test, enabling the operator to confirm that these settings are correct for the test they are about to run.

You can configure the sample identifiers (Sample IDs) for the Run Counter Test by clicking on the *Sample ID* button in the *Hardware Settings* dialog. This invokes the *Configure Sample ID* dialog, which allows the user to enter the sample ID values.

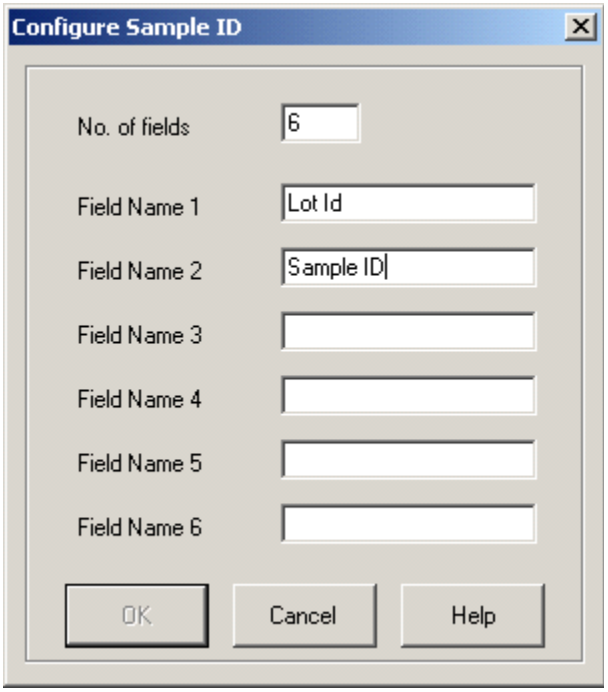

Fig 3-14 : Configure Sample ID Dialog

You have to enter the number of sample ID fields. A maximum of six sample ID fields can be entered. The numbers of edit boxes for entering the sample id depends on this number. You can then save it by clicking the *OK* button or discard it by clicking on the *Cancel* button.

3.3 Disable Obsolete Procedures

The Supervisor Administrator can disable any one of the obsolete test procedures if he/she has the privilege to do so. All the obsolete procedures are moved to obsolete mode and thereby will not be available for running the tests. The obsolete procedures can be reactivated by a supervisor / administrator. Operator is permitted to use only the active procedures to run a procedural test (only the active procedures are listed in the choices for *Standard Procedures* selection window on the PharmSpec toolbar).

To disable / enable test procedures, the user has to choose ***Set-up > Disable Obsolete Procedures***. On clicking the *Disable Obsolete Procedures* menu, *Disable Obsolete Procedures* dialog is displayed.

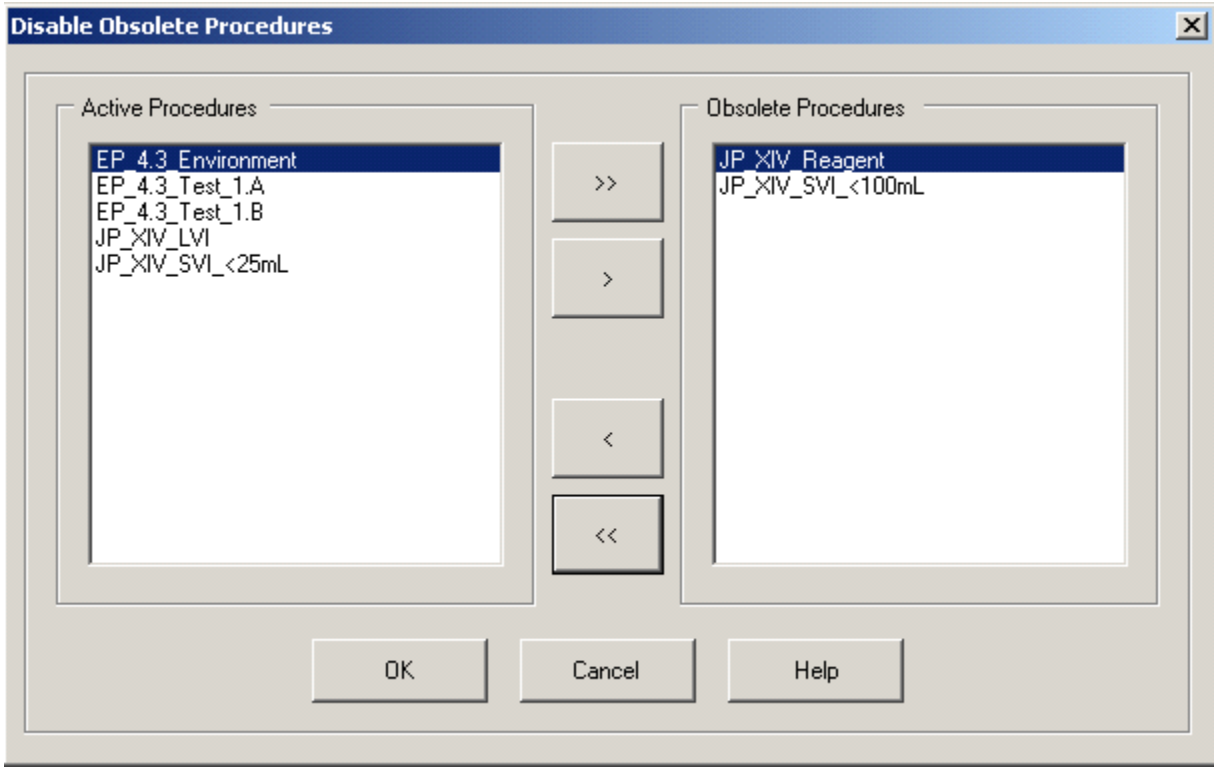

Fig 3-15 : Disable Obsolete Procedures Dialog

In the Disable *Obsolete Procedure* dialog, *Active Procedures* lists all the active *Procedures* configured in the system. You can select a *Procedure* from this and move it to the *Obsolete Procedures* by clicking on the > button. You can move all the *Procedures* from the *Active Procedures* list to the *Obsolete Procedures* list be clicking on the >> button. You can select a *Procedure* from the *Obsolete Procedures* list and make it active by clicking on the < button. All the *Procedures* can be made active by clicking on the << button. On clicking the *OK* button, all the *Procedures* in the *Active Procedures* list are listed in the *Standard Procedures* selection window on the main screen toolbar.

3.4 9703 Sampler Control

For the 9703, you can initiate some of the hardware commands (mechanical movements, get firmware version number etc.) directly for initializing or setting up the hardware. The commands are sent directly to the hardware through the driver. To do this, choose **Set-up > *Sampler Control***. On doing so, the *Sampler Control* dialog is displayed.

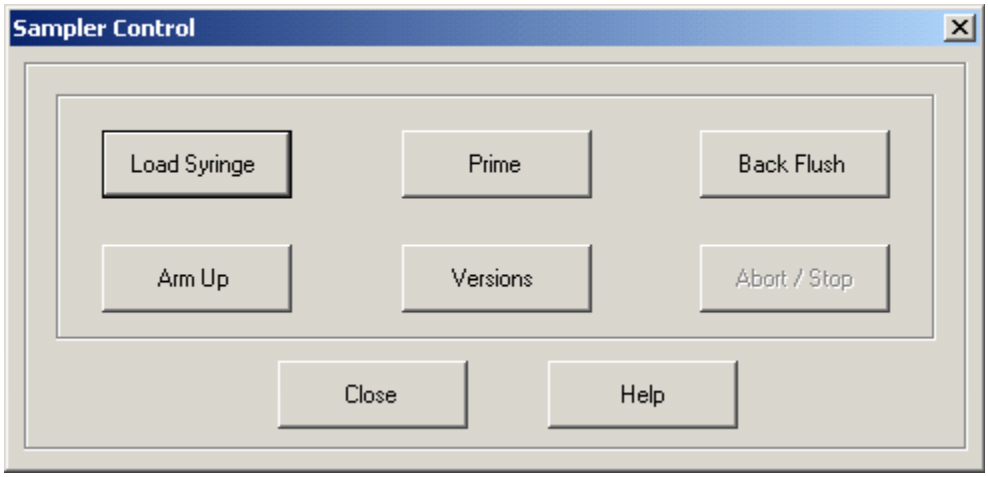

Fig 3-16 : Sampler Control Dialog

Sampler Control dialog supports the following commands:

Load Syringe	Load Syringe moves the syringe plunger to its maximum extension to allow removal of the syringe.
Prime	This command causes the sample to be drawn into the sampler in order to eliminate air, and to ensure that the sample is present in the sensor when counting commences.
Back Flush	This command reverses the sample flow through the 9703/9705 system to provide a way of clearing sensor blockages.
Arm Up	This command raises the sensor arm to allow removal and/or interchange of sample bottles. 9703 only.
Version	This command retrieves the version of the firmware and the model of sampler.
Abort/Stop	This command cancels the above operations.

3.5 Report Type

Note:
This functionality is disabled for PharmSpec 2.1. All reports appear in English.

You can select the language of reports. For this, choose ***Set Up > Report Type***. On selecting this option, the *Report Type* dialog is displayed.

Fig 3-17 : Report Type Dialog

To view the reports in the local language, select the *Local language* option. On doing so, the reports are displayed in the local language (the language selection is made at the time of installation). [Note: In PharmSpec version 2.0, only English is supported. Local Language support will be available in future releases.] If you choose *International*, then reports are displayed in the local language with English sub-titles. If you choose *English Only*, the report is displayed in English, but the review/approval comments would be in the local language if they were written in the local language

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4 Getting Started

4.1 User Interface

PharmSpec user interface consists of the following:

Table 4-1 : User Interface Components

Component	Function
PharmSpec Main Application	Used to configure the test set up, run the tests and view results / reports /activity logs
Procedure Builder	Used to create custom Test Procedures. This is an optional module. It is needed only if the user wants to create his/her own test procedures.
Procedure Loader	Used to import new Test Procedures into the current setup.
Database Restorer	Used to recover lost data; can restore data from the backup or archived files.
License Update Tool	Used to upgrade the license key for the PharmSpec Software.
Simulation Application	Used to set some pre-defined result values that will be received by the PharmSpec application while running the tests.
Admin Tool	Used to reset the administrator password. This application is not installed in the system. To run this utility, user needs the PharmSpec CD. This shall be used only in emergency conditions.

To launch the PharmSpec main application, any one of the following methods could be used:

- Go to ***Start → Programs →*** **PharmSpec 2** ***→ PharmSpec***
- Double click the shortcut to *PharmSpec*, on the desktop.

Before beginning to use the software, you have to first log in to the system. Log in using a User ID and password. The administrator assigns a User ID and password to a new user. The software comes with a default administrator user with User ID ‘admin’ and password ‘123456’. On your first log into the software, you are by default prompted to change your password. However, the administrator can disable this feature.

The login dialog is shown in Figure 4-1.

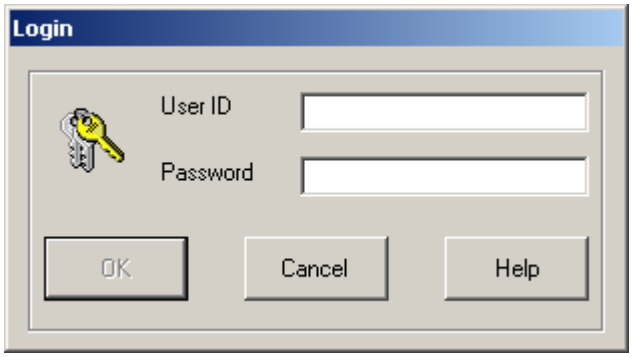

Fig 4-1 : User Login Dialog

After logging in successfully, the PharmSpec 2 application will be available. The PharmSpec 2 Main Application window consists of an upper portion with menus for various user actions and selection window boxes to select the test procedures for running the tests, and a status bar at the bottom, which consists of three parts. On the left-most portion of the bottom display will be any status message and on the right-most side, one icon to indicate the busy/idle state of the system and another icon to show whether the system is in simulation mode or online

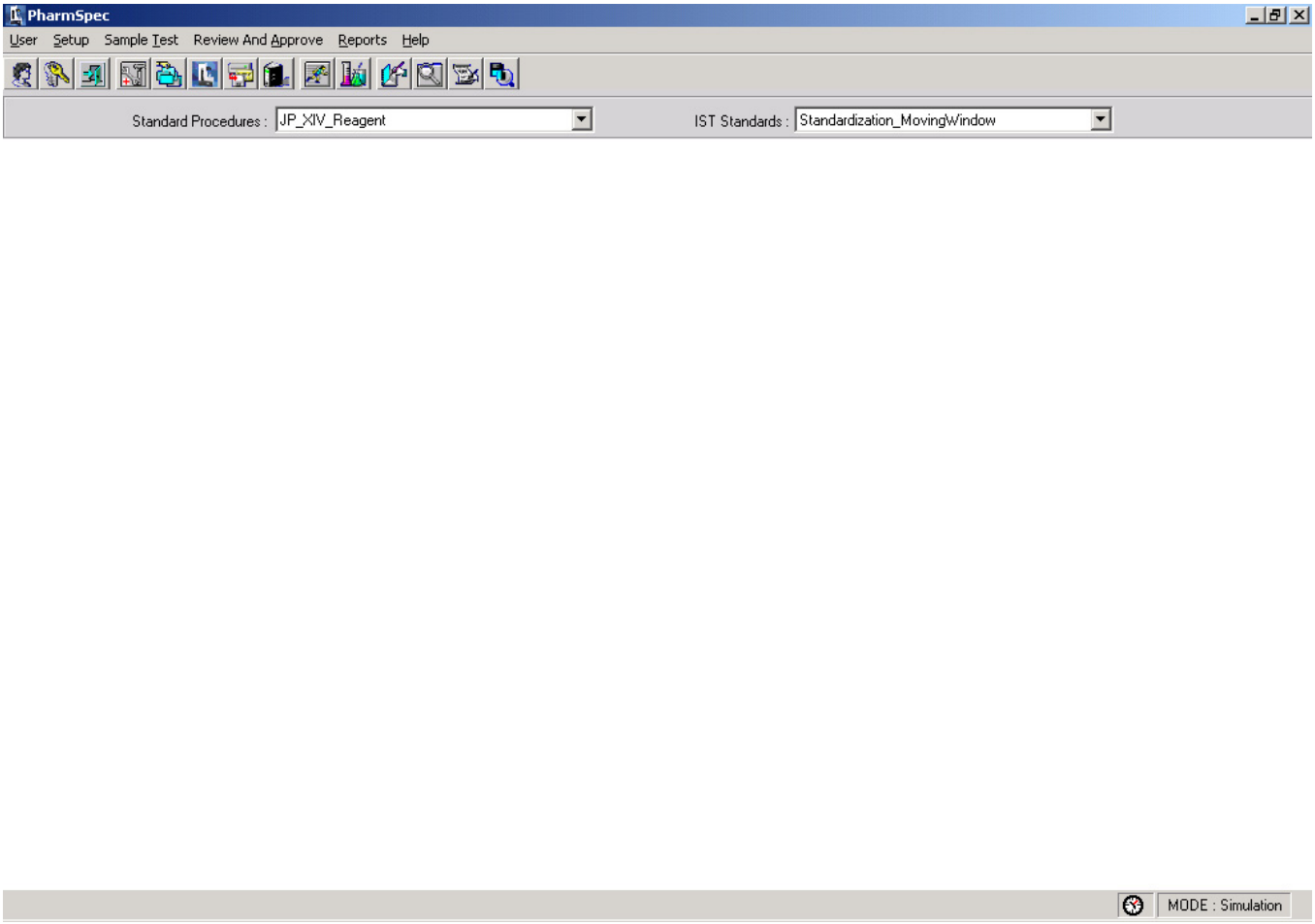

Fig 4-2 : PharmSpec Main Window

4.2 Main Menu Details

a) User

This is the main menu for the user activities. The user activities include viewing the profile of a user, changing password, log out the currently logged in user, and exiting the application.

b) Setup

This is the main menu for all set-up activities of the system. There are options under this menu for setting up the hardware, Administration set up, disabling obsolete test procedures, sampler control, data storage activities, and selecting the report type.

c) Sample Test

This is the main menu for running the tests. This menu contains options for running a Procedural Test, Run Counter Test or the Instrument Standardization Test.

d) Review And Approve

This is the menu for reviewing and approving test results.

e) Reports

This menu contains options for viewing all the reports. You may view activity logs, historical reports and PharmSpec 1.4 reports.

f) Help

This menu provides a choice of these HELP-related functions: Using Help, Help on Shortcut Keys, Contents and About PharmSpec 2.

4.3 Sub Menu Details

a) View Profile

Each user can to view his/her profile and the name of administrator who created the user. For this, go to ***User > View Profile***. This displays the *User profile* dialog for the logged in user. The *User Profile* dialog lists all the rights of the user. It also lists the user role (operator, supervisor, calibration technician or administrator) and the administrator who has created the user. This menu item is available for all user roles.

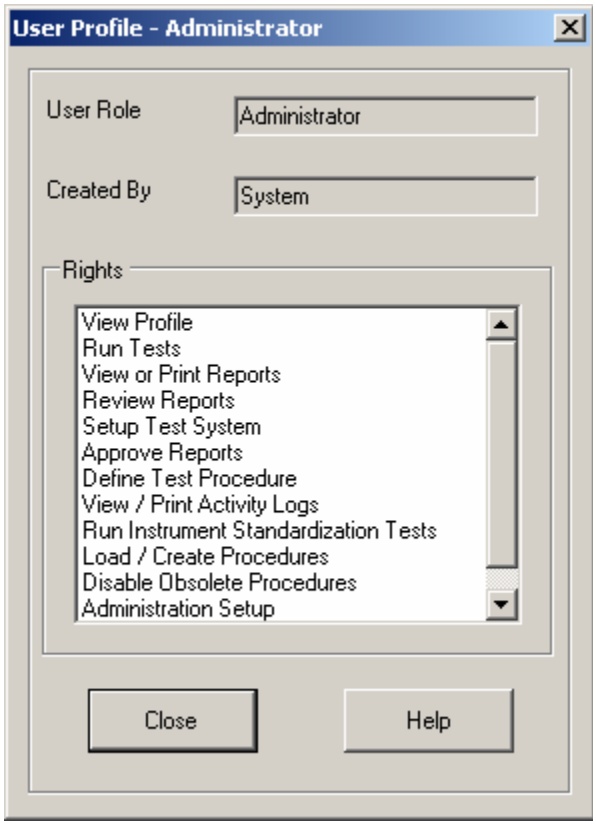

Fig 4-3 : User Profile Dialog

b) Change Password

Each user must be able to change his password. The user can change the password by choosing ***User > Change Password***. This displays the *Change Password* dialog.

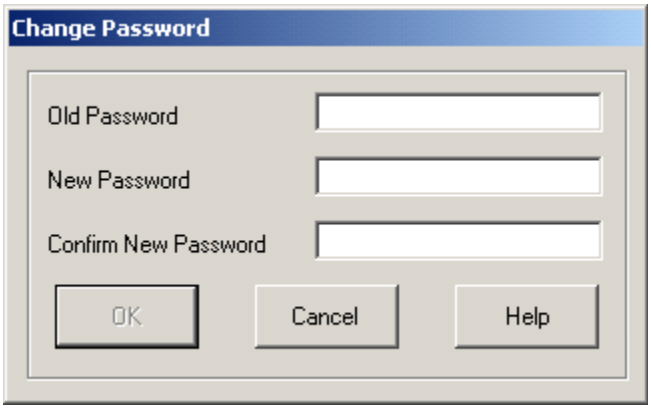

Fig 4-4 : Change Password Dialog

You have to enter the old password followed by your new password. Re-enter the new password for confirmation. The administrator sets the minimum number of characters for the password. This menu option is available for all users.

During first login, this dialog is automatically displayed (if this feature is set by the administrator) and in such cases the user cannot proceed without changing the password. This dialog also invokes on expiry of the password.

c) Logout

The user can logout from the system by choosing **User > *Logout***. A confirmation message is displayed prompting the user to confirm logging out action.

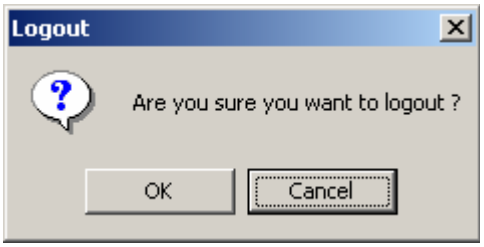

Fig 4-5 : Logout Confirmation Dialog

You can log out of the system by clicking on the *OK* button or cancel the logout by clicking on the *Cancel* button. You may not be allowed to logout while running a test. You can log out only after you have completed the running of the current test. If you attempt to log out without saving the test run details, a confirmation message is displayed prompting you to save the unsaved changes, if any.

It is possible for a different user to log in after you have logged off.

d) Exit

You can exit the application by choosing ***User > Exit***. This invokes a confirmation to the user.

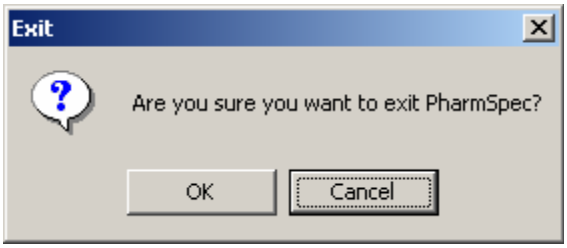

Fig 4-6 : Exit Confirmation Dialog

On clicking on the OK button of this confirmation dialog, the current user is logged out and you exit the application. Exit menu is not enabled if a test is currently running.

5 User Administration

5.1 Administration

Administrator manages the user and the system settings. A new user is added, or the details of an existing user can be modified. The Administrator also sets the system parameters. To do this, choose ***Set Up > Administration***. This invokes the *Administration* dialog. Only an administrator can access this menu, and this option is disabled for all other users.

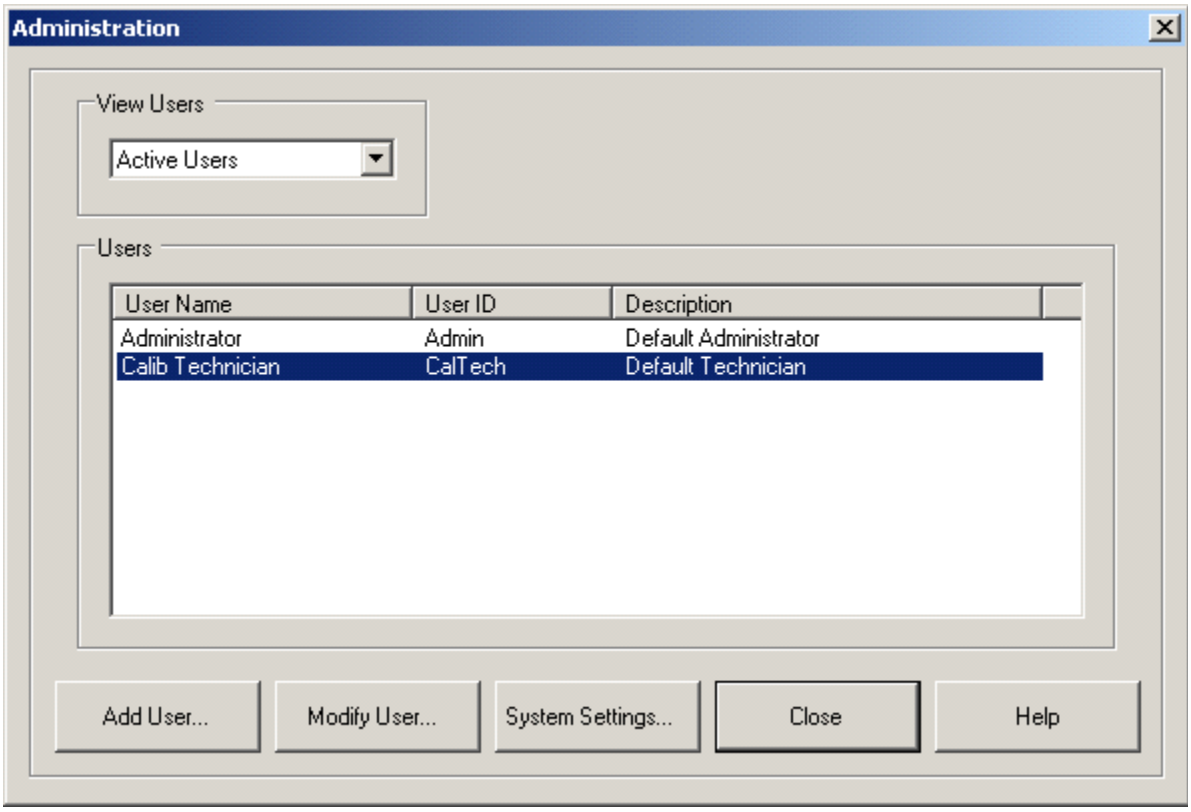

Fig 5-1 : Administration Dialog

The *Administration* dialog lists all the available users. The users listed depend on the user type selected. User type can be selected from the *View Users* combo selection box. The user list can be filtered using the following three options:

- All users
- Active users
- Inactive users

5.2 User Levels

The users operating the system are organized into the four groups or levels shown in Table 5-1. When new users are added to the system, they only receive the default priviledges of their role unless the Administrator specifically grants them additional privileges.

Users can view their role, privileges, and the name of the administrator responsible from the **View Profile** menu option.

Table 5-1 : Default Role Privileges

Privileges	Operator	Supervisor	Calibration Technician	Administrator
Run tests		√	√	√
View and print reports	√	√	√	√
View profile	√	√	√	√
Set up test system hardware and operating parameters				√
Approve test results				√
Load and create test procedures, including report templates				√
Enable/disable test procedures				√
View and print activity logs				√
Perform instrument standardization tests				√
Administer user accounts				√
Backup and archive databases				
Configure system		√	√	√

a) Add User

Administrator can add a new user and set the details for the new user by clicking on the *Add User* button. This invokes the *Add a New User* dialog.

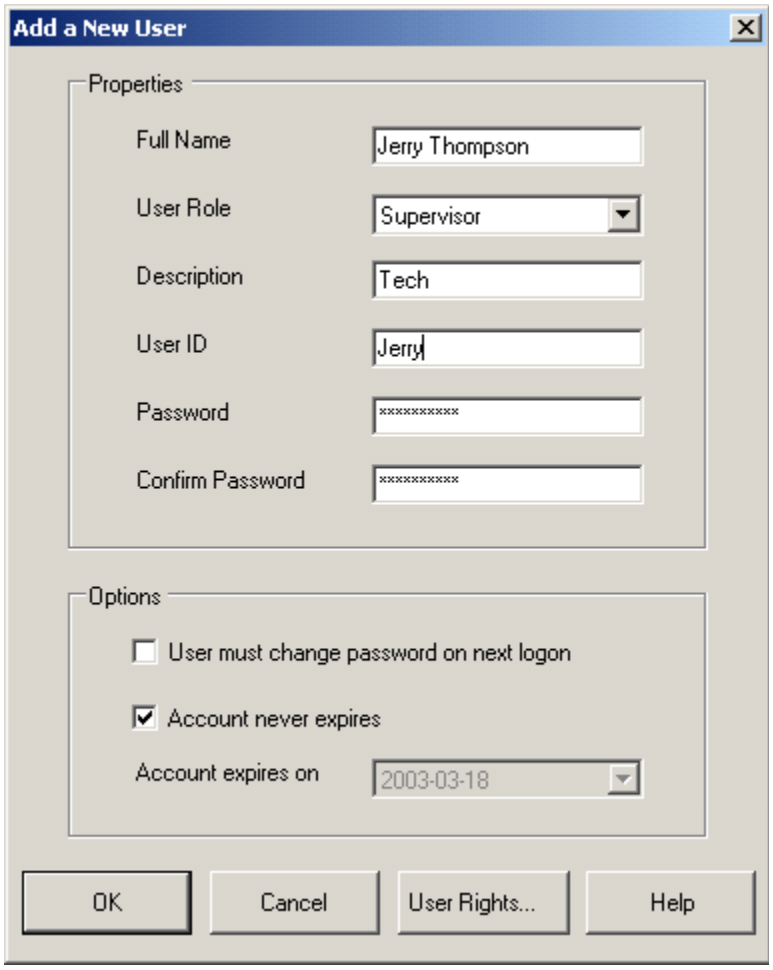

Fig 5-2 : Add New User Dialog

Administrator assigns a User ID, user name, user role and password to the new user. The maximum number of characters for the password is twenty. Minimum length of User ID and user name is four. Administrator sets certain options for the new user. The options are:

Change the password on the next login

If this option is set, the user must change the password on next login. C*hange password* dialog invokes at user login.

Account Never Expires

If it is not set then the user becomes an inactive user after the specified date. The expiry date will show the current date by default.

Administrator then assigns the privileges to the user by clicking on the *User Rights* button in the *Add User* dialog. This invokes the *User Rights* dialog. This dialog is based on the user type (selected in the previous screen as the User *Role* selection window).

If the user is an Operator, then the user rights dialog displayed is as follows:

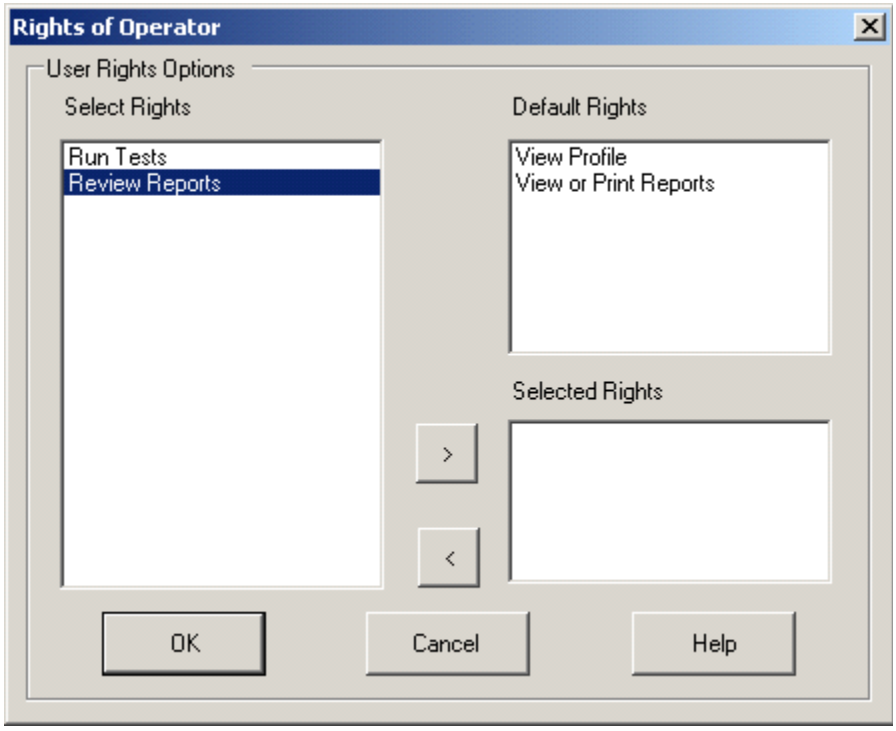

Fig 5-3 : Operator User Rights Dialog

An Operator has the privilege to View profile, View or print reports along with certain additional privileges. The Administrator can assign the privileges to a user. The privileges available for an Operator are *Run Test*s and Review Reports.

If the user is a Supervisor then the user rights dialog screen displayed would be as follows:

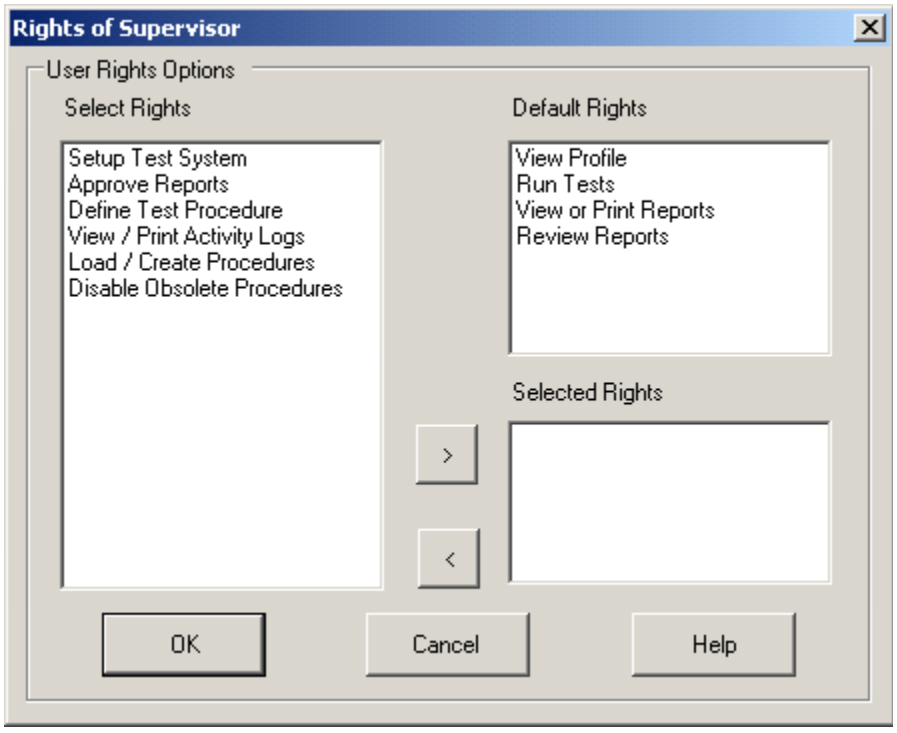

Fig 5-4 : Supervisor User Rights Dialog

The Supervisor has all the privileges of an Operator. The Administrator can set some additional privileges to the supervisor.

If the user is a Calibration Technician then the user rights dialog displayed would be as follows:

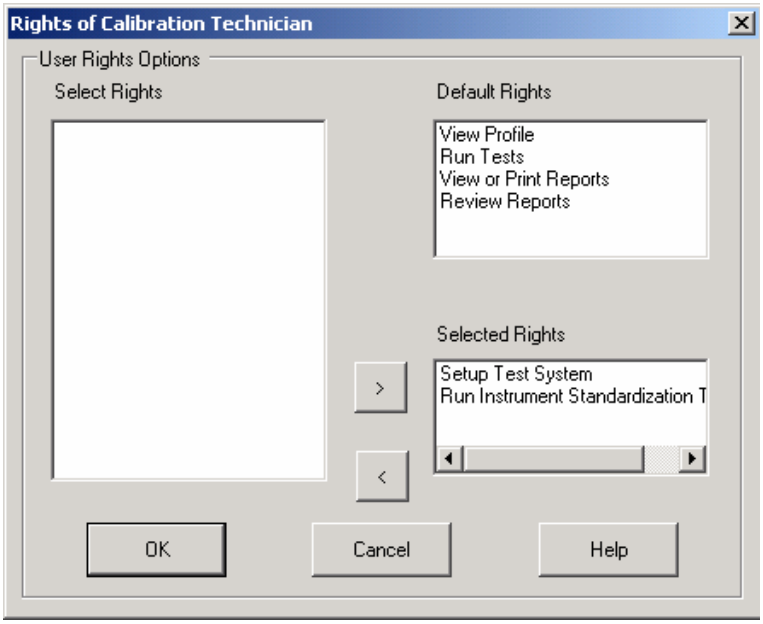

Fig 5-5 : Calibration Technician User Rights Dialog

The Calibration Technician is a type of user who will perform Instrument Standardization Tests. This person will be either a person from Hach Ultra Analytics or a person trained by Hach Ultra Analytics.

If the user is an Administrator then the user rights dialog displayed would be as follows:

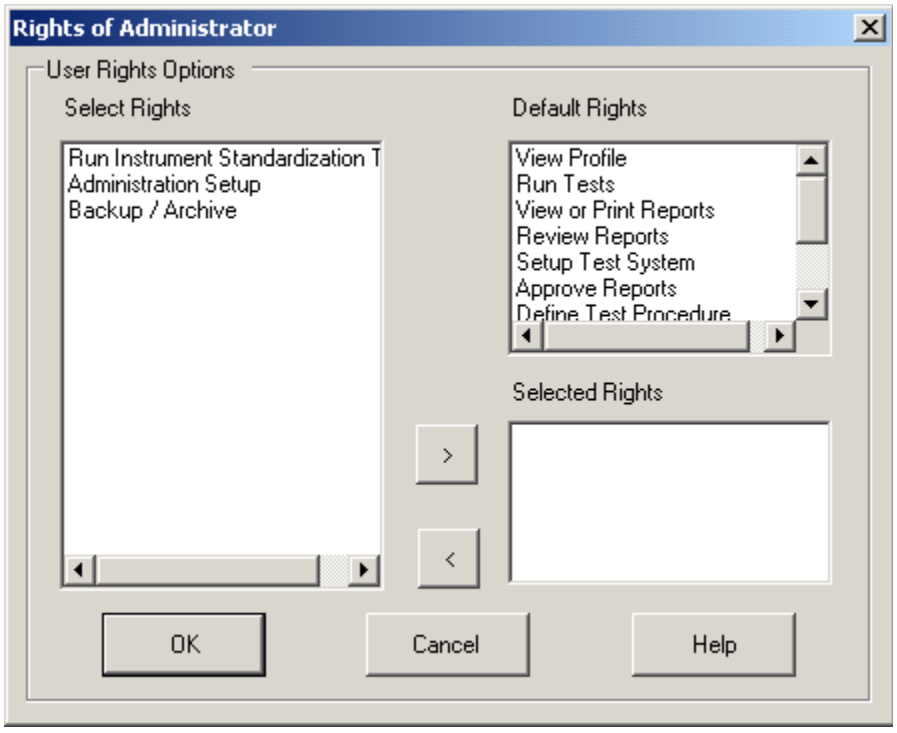

Fig 5-6 : Administrator User Rights Dialog

An Administrator has all the privileges of the Operator, Calibration Technician and Supervisor.

To set the Rights for a user, select the required right from the *Select Rights* list and click the > button. The selected right will now be listed under *Selected Rights*. To remove a Right, select the required Right from the *Selected Rights* and click the < button.

After assigning all required Rights, click the *OK* button of the U*ser Rights* dialog. The new or modified User is added to the system on clicking the *OK* button of the *Add a New User* Dialog.

b) **Modify User**

The user details can be modified later if required. The Administrator can modify the user details by clicking on the *Modify User* button. This invokes the *Modify User Details* dialog. The Password and Confirm Password dialogs contain a predefined number of asterisks. This is not the same as the number of characters in the password of that user.

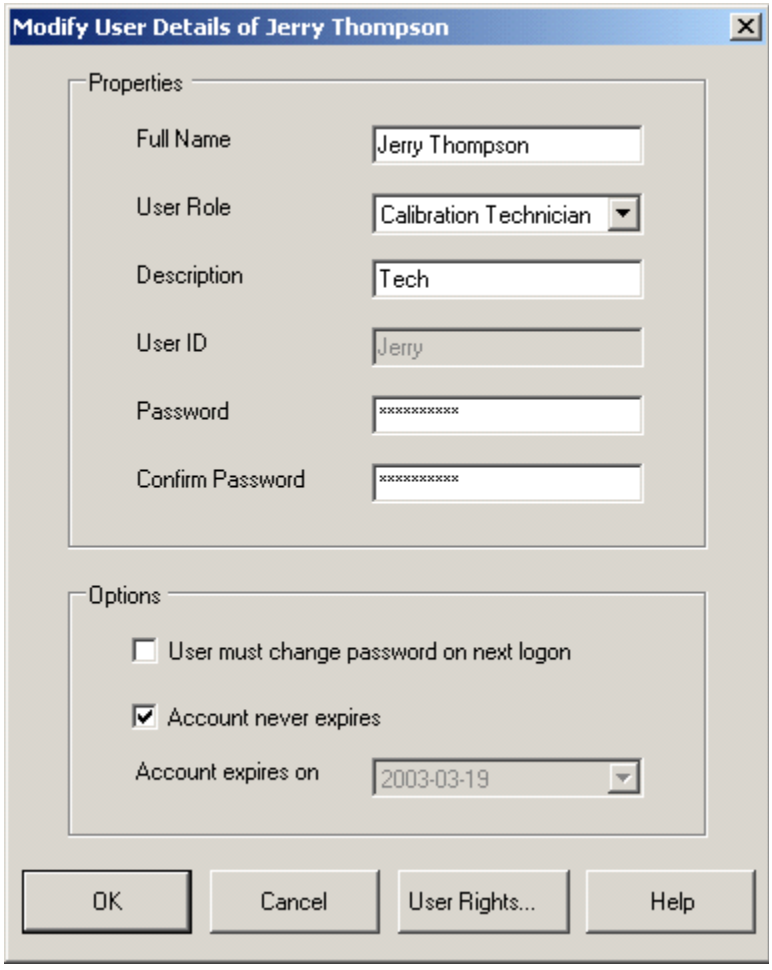

Fig 5-7 : Modify User Details Dialog

You cannot modify the User ID. Administrator can set or reset the user rights for the user by clicking on the *User Rights* button. The *User Rights* dialog is displayed with the current privileges of the user.

c) System Settings

Administrator can set the system setting parameters. To do this, click the *System Settings* button in the *Administrator* dialog. On doing so, the *System Settings* dialog is displayed.

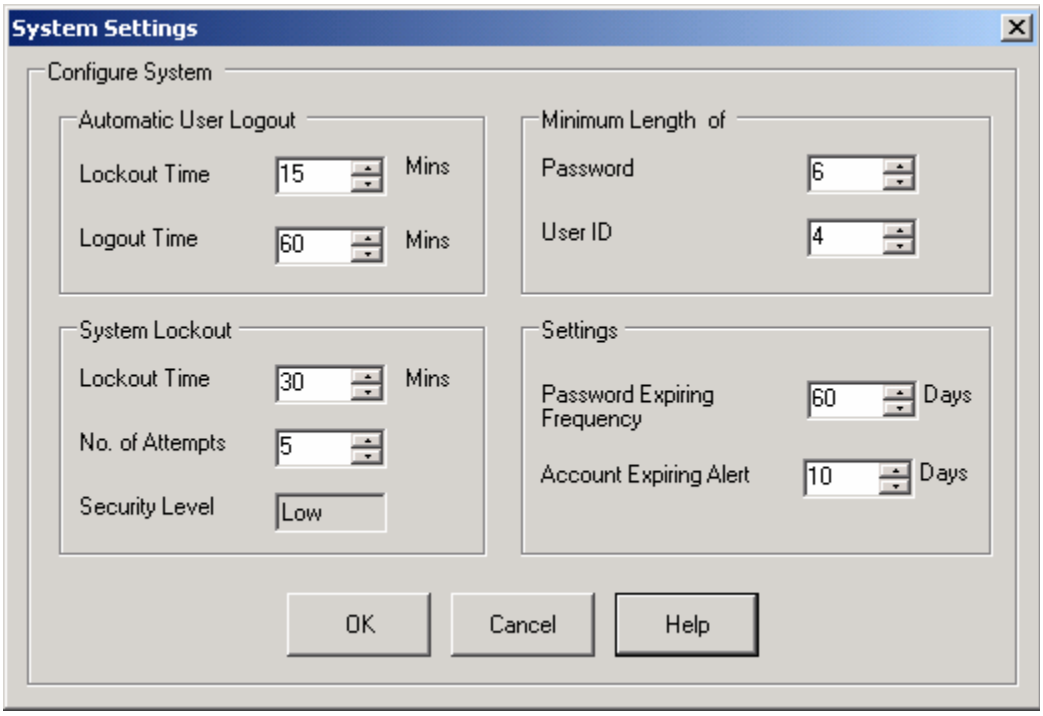

Fig 5-8 : System Settings Dialog

The Administrator can set the parameters related to Auto Lockout, Auto Logout, System Lockout and periodic revision of Password. These parameters are:

- Auto Lockout time
- Auto Logout time
- System Lockout time
- Number of consecutive unsuccessful login attempts

The system is locked or the user is logged out after the specified timeouts. The administrator can also set the minimum number of characters permitted for User ID and password.

The password expiring frequency and the user account expiring alert are also configured from this dialog. The parameter *Password Expiring Frequency* decides the frequency (days) at which the user has to change the password. If a user account is due for expiry, the user will get an alert in advance and the parameter *Account Expiring Alert* represents this period. Once a user account is expired, the account will be disabled and the user cannot log into the system. On receiving the alert, the user can contact the administrator and initiate actions to extend the validity of the account if required.

The level of security (HIGH or LOW) selected during installation is displayed in the *System Settings* dialog but cannot be changed once it is initially set in the Installation process.

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6 System Configuration

6.1 Hardware Settings

You have to set up the hardware and the operating parameters before starting to use the system with the 9703 or 9705 sampler. Otherwise the software can be used only in the Simulation (Demo) mode. You have to configure the system during initial set up or whenever there is a change in the hardware components or the operating parameters used. You can set up the hardware by selecting ***Setup > Hardware Settings***. This invokes the *Hardware Settings* dialog. This menu is enabled only for a user who has the required privilege to do this.

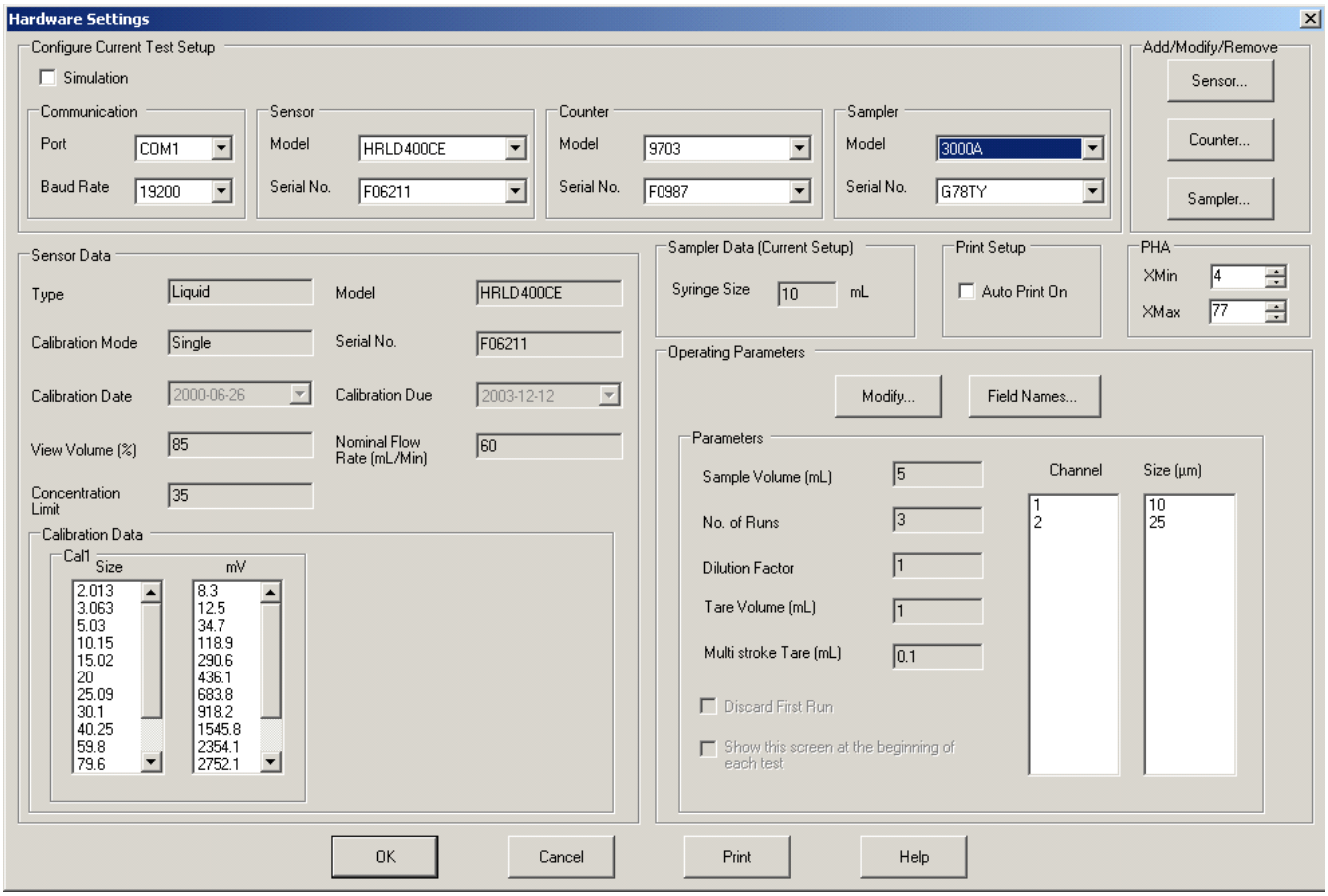

Fig 6-1 : Hardware Settings Dialog

This dialog is organized into multiple sections. Each section is explained below.

To setup a new system, the first step is to configure or *Add* Sensor(s), Counter(s) and the Sampler(s). The next step is to define the current setup components by selecting the Sensor, Counter and the Sampler used in the system and the communication parameters such as the Port number and the Baud rate. Then you need to set the Operating Parameters.

a) Configure Current Test Set-up

A user can have an inventory of more than one Sensor, Counter and Sampler, but only one each of these components will be used in a test setup at any given time. In addition to this, the COM port of the computer to which the hardware unit is connected and the Baud rate need to be set. The *Configure Current Test Setup* group allows the user to configure all these.

Communication

The user can select the port and baud rate required for communicating with the HIAC 9703 or 9705. The available options for Port number are COM1, COM2, COM3 and COM4.

Note:
For the 9705, the COM port is set to USB and the baud rate cannot be selected.

Sensor

The user can select the model and serial number of the sensor used in the current test set up.

Counter

The user can select the model and serial number of the counter used in the current test set up.

Sampler

The user can select the model and serial number of the sampler used in the current test set up.

Simulator

There is a check box named Simulator. The user selects this to run the system in simulation mode. This invokes a confirmation message prompting the user to confirm the change to simulator mode.

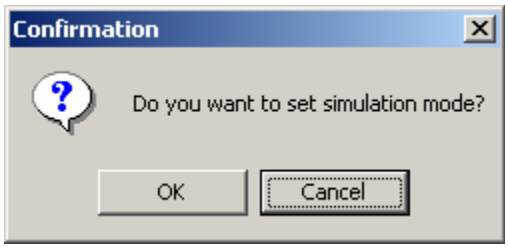

Fig 6-2 : Simulator Mode Confirmation Dialog

The user can select the simulator mode by clicking the *OK* button on this confirmation message. All the other controls in the *Configure Current Test Set Up* are disabled in this case. In simulation mode, the application will not communicate with the hardware.

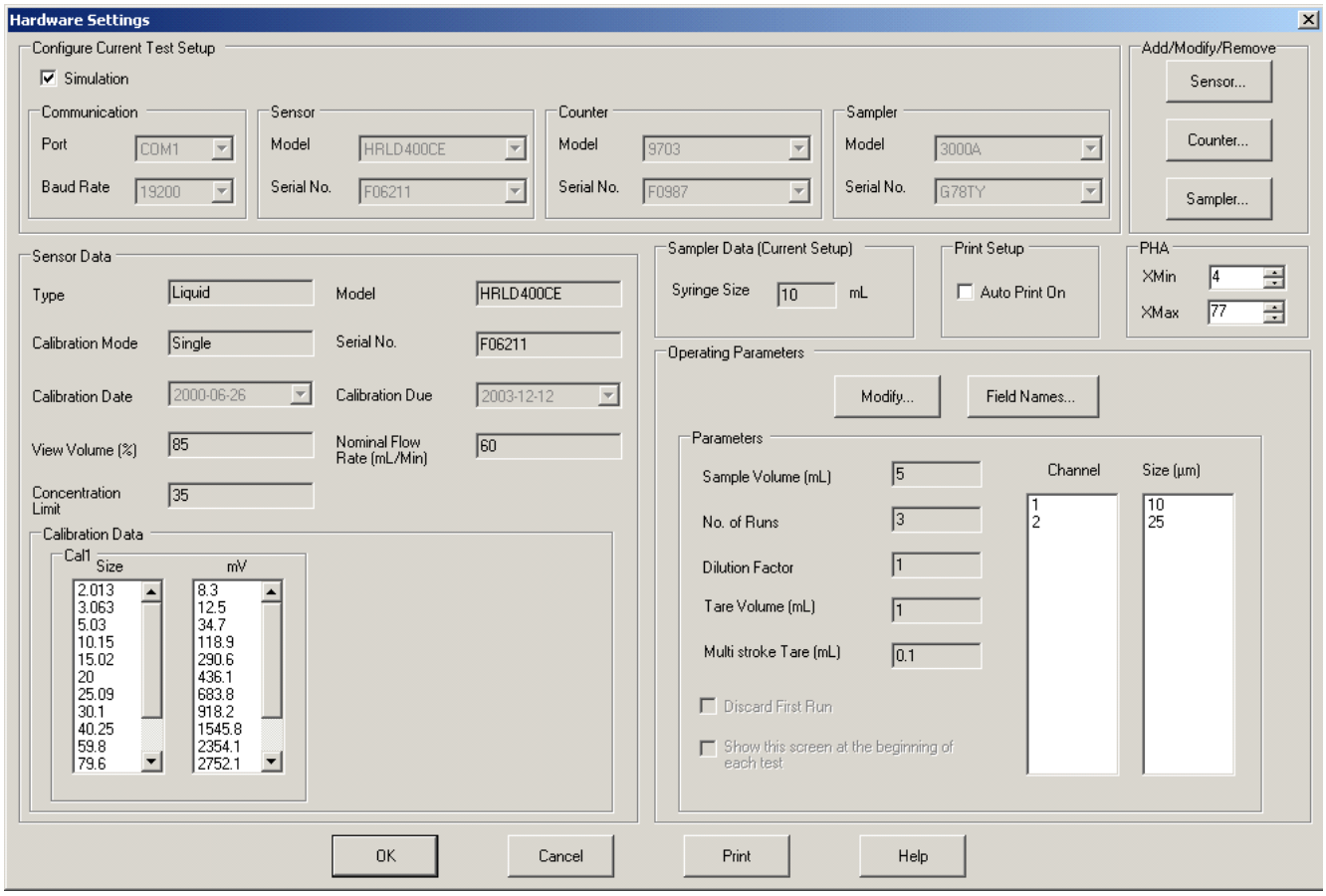

Fig 6-3 : Simulator Selection

b) **Add / Modify / Remove (Sensor, Counter, Sampler)**

The user can add new hardware components (sensor, counter and sampler) to the existing inventory or modify the parameters of the existing ones. The user can also remove a hardware component from the inventory.

Sensor

The user can add new sensors to the system, modify existing sensor data or remove a sensor from the inventory. There is an additional option to import sensor data from a file so that the user need not enter the data manually. While configuring the current test setup, user has to choose a sensor from the sensor inventory. To add / modify / remove a sensor, click the *Sensor* button in the *Hardware Settings* dialog. This invokes the *Add Sensor* dialog.

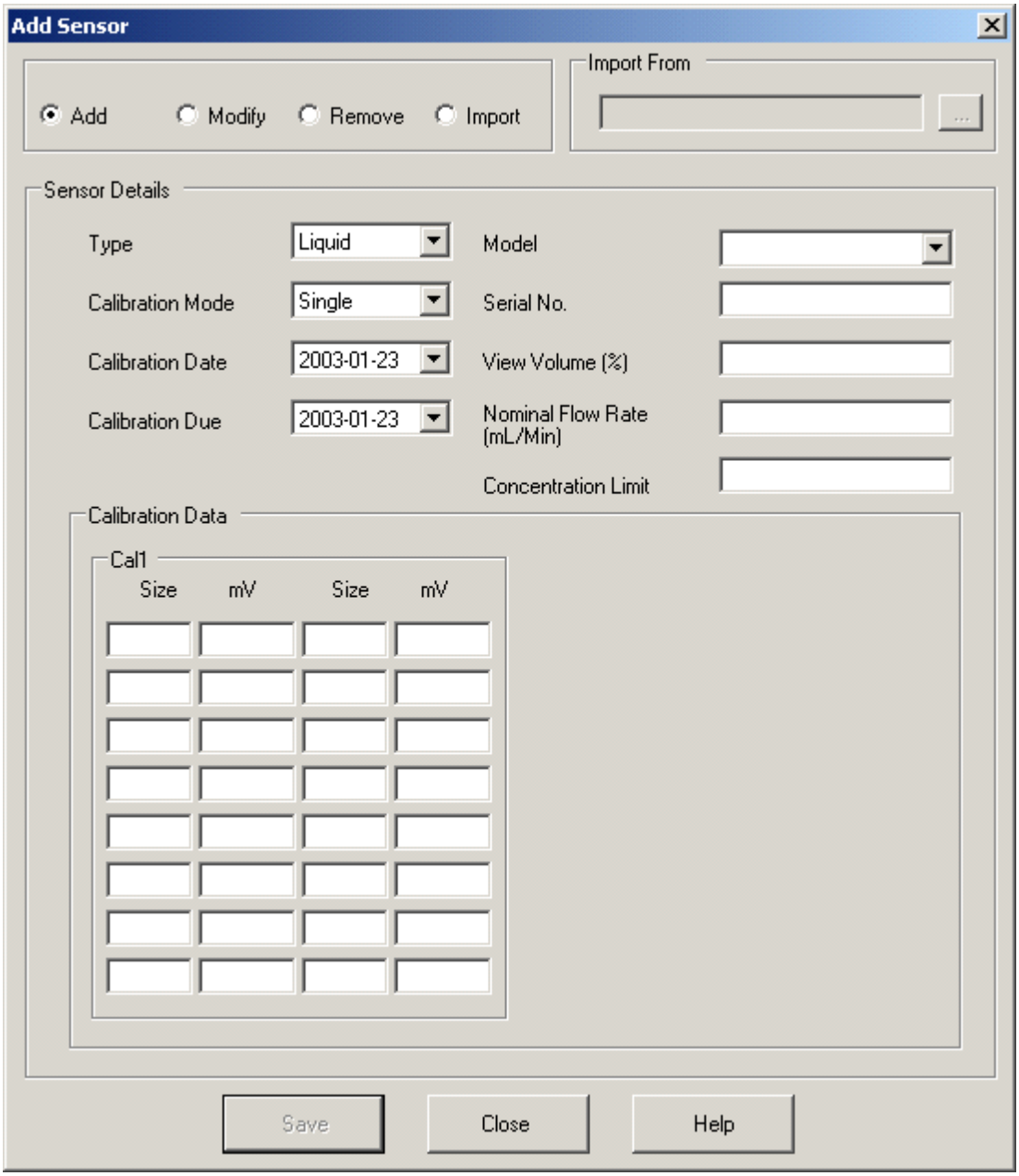

Fig 6-4 : Add Sensor Dialog

The user can perform any one of the following operations:

Add a Sensor	User can add a new sensor to the system. User has to check the radio button corresponding to Add. User has to specify all the details including type, model and serial number in this case. All controls on the dialog will be enabled in this case.
Modify Sensor Data	User can modify the parameters (Calibration data in most cases) of an existing sensor. For this, user has to select the radio button corresponding to Modify. The user has to first select the Model and then the Serial No. of the sensor and then modify the details. User will not be allowed to modify the type, model and serial number.
Import Sensor Data	Instead of adding a new sensor using the “Add” option and by entering the sensor data, the user can import sensor data from a file. For this, the sensor data should be available in a predefined format in a file. This sensor details file shall have an extension “.sen”. To import the sensor data, select the radio button corresponding to import, following which, the *Import From* control is enabled. The user is then allowed to select the path and file from which the user has to import the sensor. An Open File dialog is displayed from which the user can select the path and file. User can import it and modify the details (if required) excluding type, model and serial number.
Remove Sensor	You can remove a sensor from the system. The currently selected sensor is deleted by clicking on the Remove button. The caption of the ***Save*** when the Remove radio button is selected.

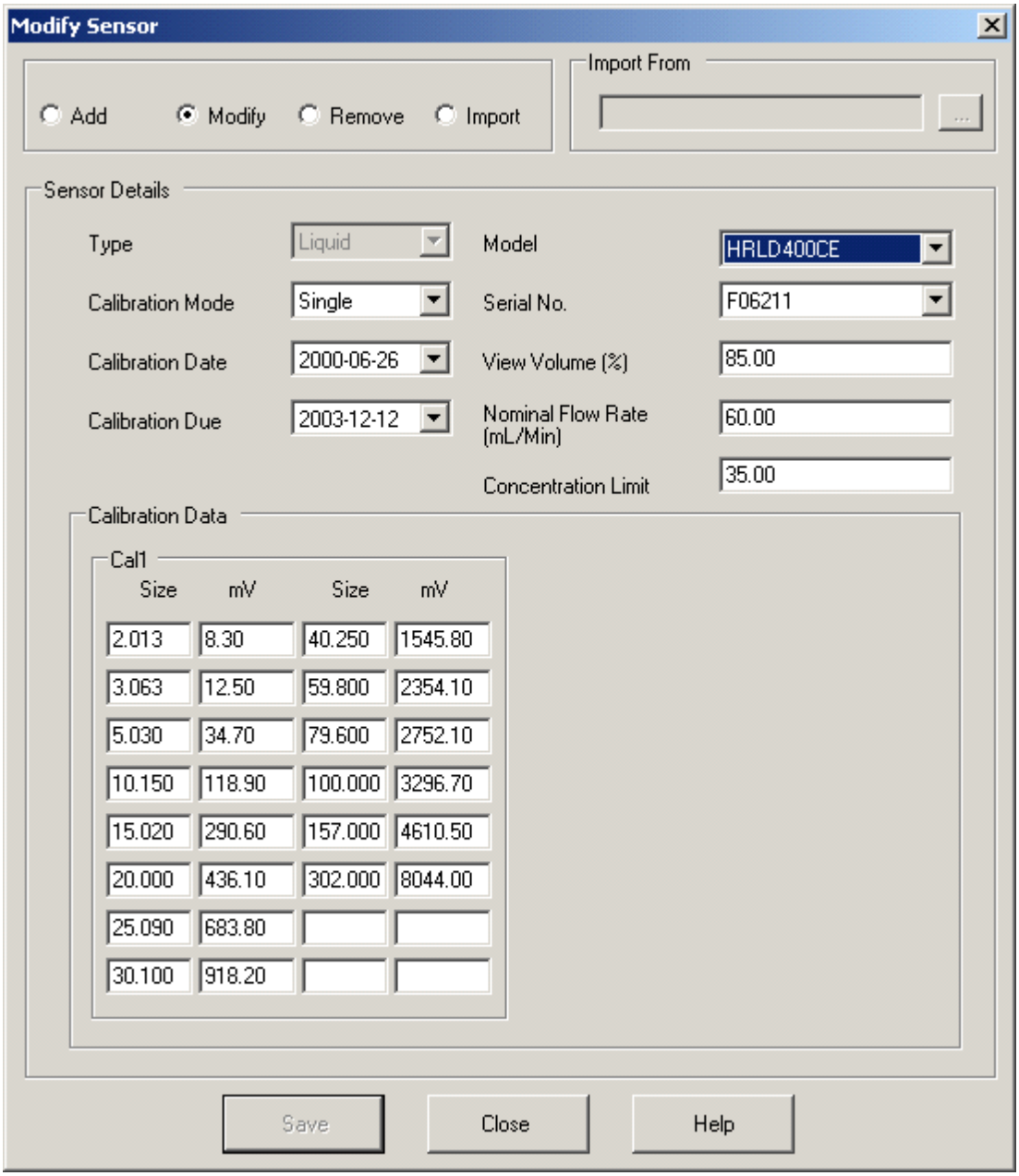

Fig 6-5 : Modify Sensor Dialog

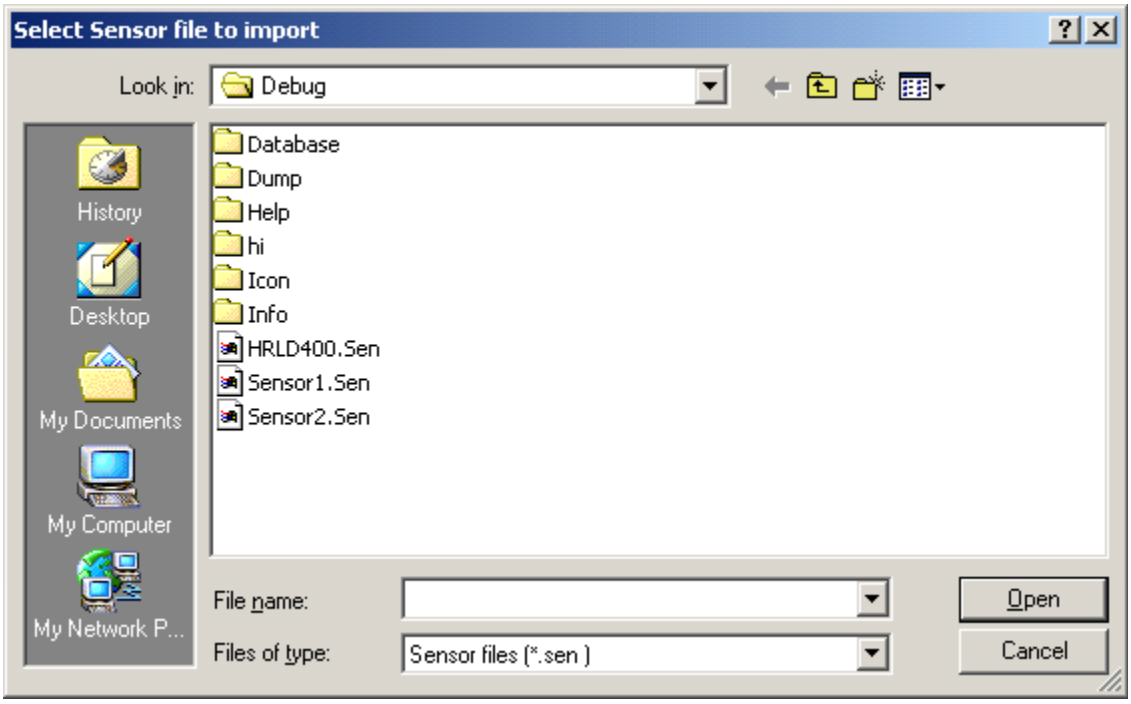

Fig 6-6 : Import Sensor Dialog

The sensor data consists of following parameters. When you add a new sensor, you need to define all these parameters. In the “Modify” mode, it allows you to modify most of these parameters except the model, type and serial number.

- Type of the sensor (Liquid / Air)
- Model of the sensor (You can enter the model number or select one from the list)
- Calibration mode

The Sensor Calibration mode could be either “single” or “dual”. In case of “Dual” mode, there are two sets of calibration data to be entered *Cal 1* and *Cal 2*. The second set is disabled in case of the “single” mode sensors.

Note:
Dual mode is not available in PharmSpec 2.1.

- Serial number of the sensor
- Date of calibration
- Expiration date for the calibration
- View Volume
- Nominal Flow Rate
- Concentration Limit
- User shall enter the particle sizes for the calibration and the millivolt values for the size. There must be a minimum of four sizes and millivolt values.

The user can then save the details by clicking on the *Save* button.

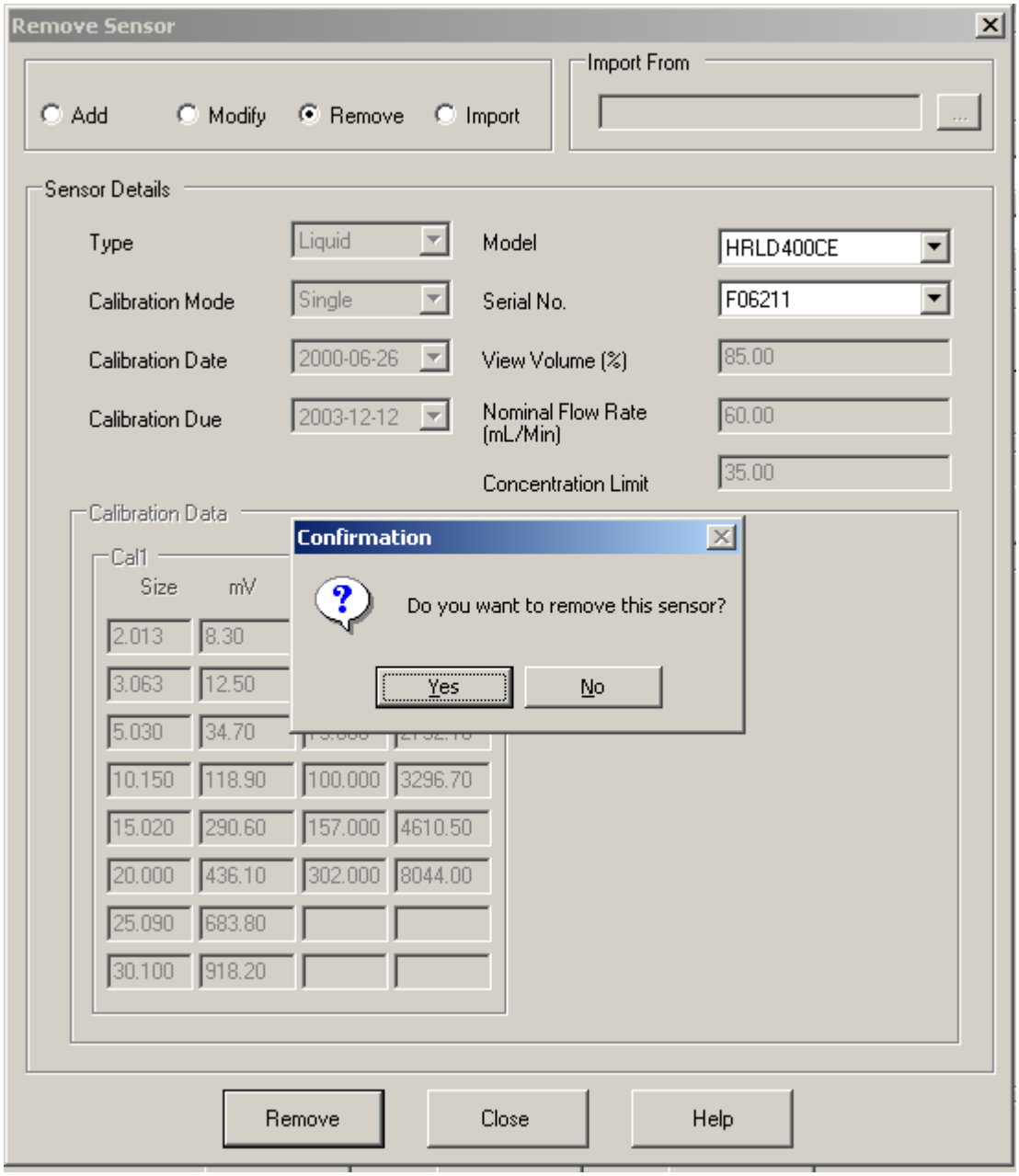

Fig 6-7 : Remove Sensor Dialog

6.2 Counter

Add Counter

The user can add a new counter to the system. Clicking on the *Counter* button in *Hardware Settings* dialog does this. This invokes the *Add Counter* dialog.

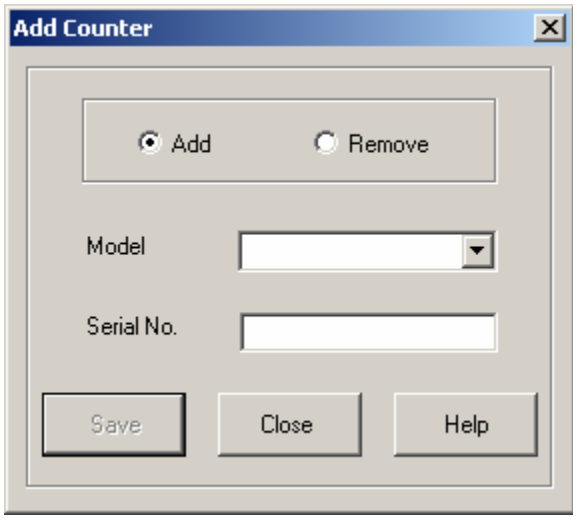

Fig 6-8 : Add Counter Dialog

The user has to enter the model and serial number of the counter. You can also select the model number from the list (if available). You can save these details by clicking on the *Save* button, for later retrieval and use.

Remove Counter

You can remove a counter, which is no longer in use from the system. The title of the dialog becomes Remove Counter. When the *Remove* button is clicked, a confirmation message is displayed prompting the user to confirm removal of the counter.

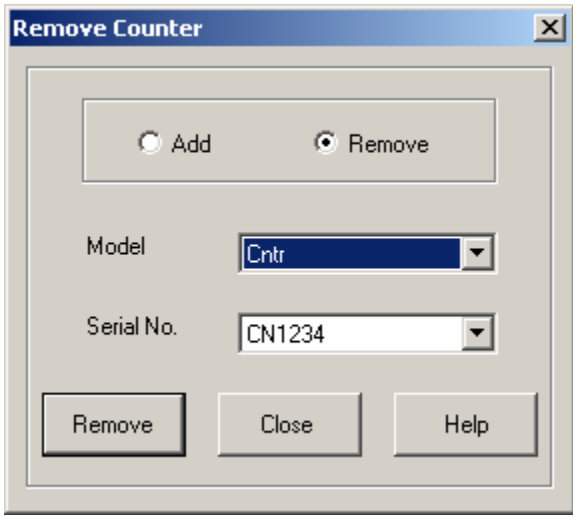

Fig 6-9 : Remove Counter Dialog

a) Sampler

Add / Modify Sampler

The user can add a new sampler or edit an existing sampler. To do this, click the Sampler button in Hardware Settings dialog. This invokes the Add Sampler dialog.

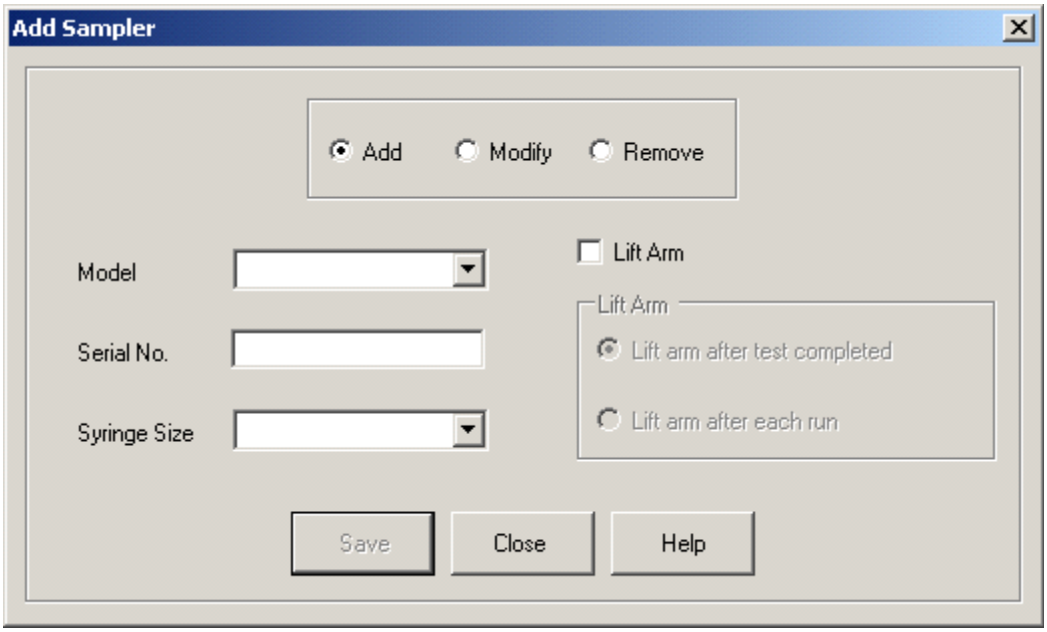

Fig 6-10 : Add Sampler Dialog

You can add new sampler details by clicking on the Add radio button. You can enter the value for model, serial number and select a syringe size from the Syringe Size selection window for the sampler. Available syringe sizes are 1 ml, 10 ml and 25ml. You can also select the model number from the list (if available).

On the 9703, you also may select the option for lifting the arm (lift the arm after each run or after the completion of the test). You can then save the details, by clicking on the Save button, for later retrieval and use. If you prefer to manually raise the arm at the end of each test or sample, then simply do not check the box for Lift Arm. User can select a model and serial number from the existing list and change the syringe size of the selected sampler and the lift arm behavior. You can then save the details, by clicking on the *Save* button, for later retrieval and use.

Note:
This option is unavailable on the 9705.

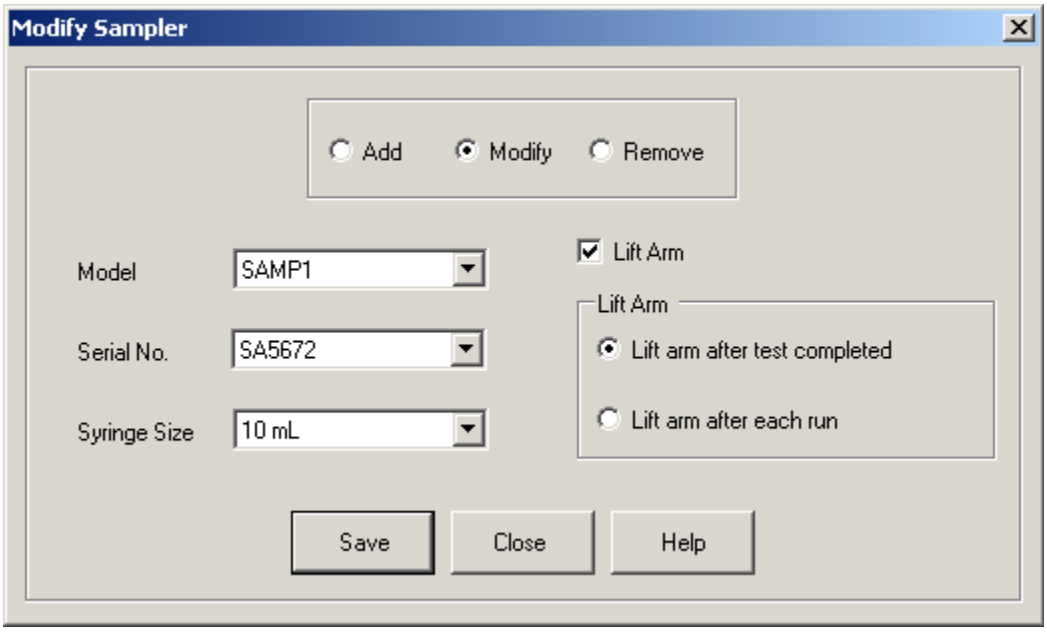

Fig 6-11 : Modify Sampler Dialog

Remove Sampler

You can delete a sampler, which is not in use, from the system. The title of the dialog becomes Remove Sampler and the Save button becomes Remove. By clicking on the Remove button, the user is prompted for confirmation before the Sampler is deleted.

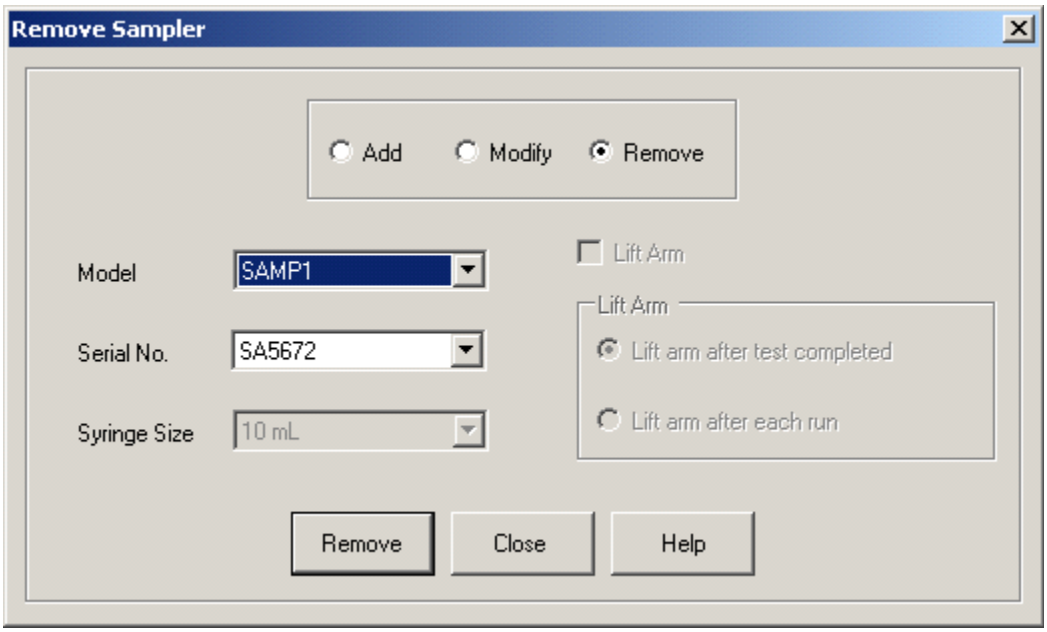

Fig 6-12 : Remove Sampler Dialog

b) Sensor Data

You can view the details of the currently selected sensor (as per the Current Test Set up) in the *Sensor Data* section of the *Hardware Settings* dialog. Sensor details include the type, model, calibration mode, serial number, calibration date, calibration due date, volume, flow rate and concentration limit. This also lists the calibration data.

c) Sampler Data

You can view the syringe size for the currently selected sampler (as per the Current Test Set up) in the *Sampler Data* section of *Hardware Settings* dialog.

d) Print Setup

You can opt for auto print of test result after running the test. To do this, check the *Auto Print* On checkbox in the *Print Setup* section.

e) 9703 Only: PHA

For the 9703, you can configure the Xmin and XMax parameter values of PHA graph from the PHA section. These are the starting and ending points for the x-axis on the PHA display. The value for the ending point must be at least 30 units greater than the starting point.

f) Operating Parameters

You can view the operating parameters such as sample volume, number of runs, dilution factor, Channel sizes, tare volume etc. in *the Operating Parameters* section of *Hardware Settings* dialog. Most of these Operating Parameters except for the tare parameters are used exclusively for the "***RUN Counter***" test. The tare parameters (Tare Volume and the Multi-stroke Tare) are used by other tests also.

The ***Modify*** button in the *Hardware Settings* dialog can be used to modify these parameters. Clicking on the *Modify* button invokes the O*perating Parameters* dialog.

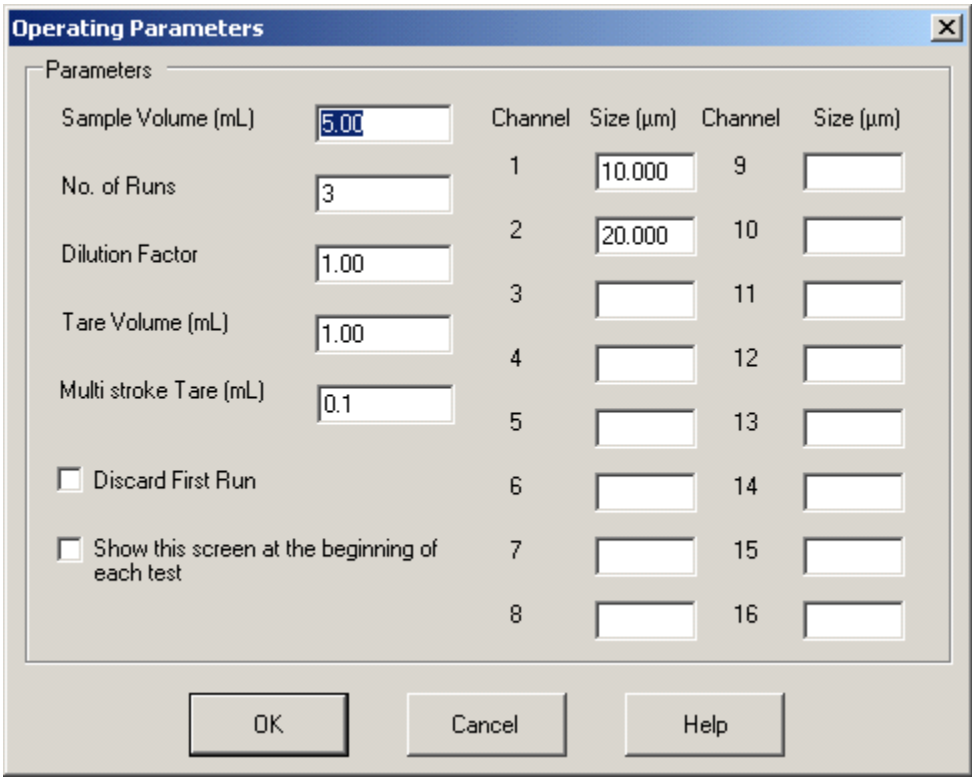

Fig 6-13 : Operating Parameters Dialog

You can enter the channel setting details. These are:

- Sample Volume for the Run Counter test
- Number of runs for the Run Counter test
- Dilution factor for the Run Counter test
- Tare volume: a volume drawn preceding the SAMPLE volume. It occurs on the first stroke of a given run. This is to remove any fluids from a previous run (or bubbles etc. if the tubing is empty) and to ensure that the sample data obtained is only from the fluid from the container currently in place on the 9703 or 9705.
- Multi-stroke tare: gets the liquid up to speed.
- Channel: PharmSpec supports up to 16 size channels.

User can also specify following conditions:

- Discard first run: If this option is selected, for the Run Counter Test, the test results of the first run will be ignored in the computations but will still be displayed and stored.
- Show this screen at the beginning of each test: If this option is selected while running the Run Counter Test, the Operating Parameters dialog will be displayed at the beginning of the test. This is intended to provide information to the operator before running a test, enabling the operator to confirm that these settings are correct for the test they are about to run.

You can configure the sample identifiers (Sample IDs) for the Run Counter Test by clicking on the *Sample ID* button in the *Hardware Settings* dialog. This invokes the *Configure Sample ID* dialog, which allows the user to enter the sample ID values.

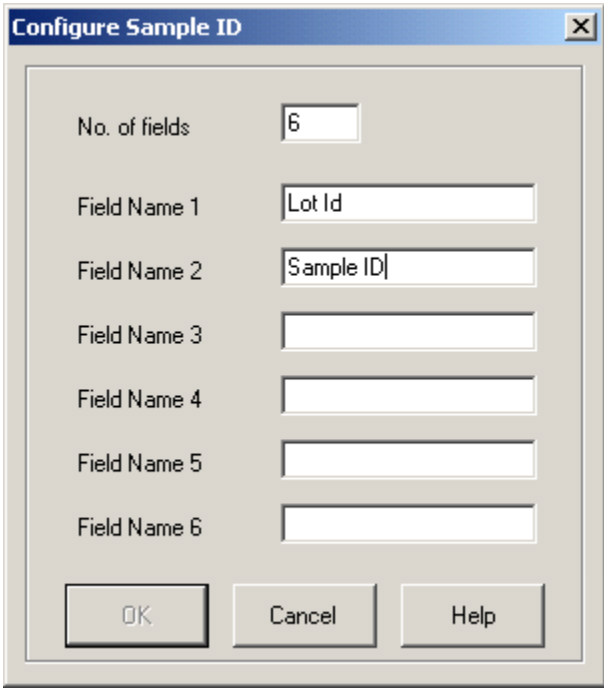

Fig 6-14 : Configure Sample ID Dialog

You have to enter the number of sample ID fields. A maximum of six sample ID fields can be entered. The numbers of edit boxes for entering the sample id depends on this number. You can then save it by clicking the *OK* button or discard it by clicking on the *Cancel* button.

7 Running Sample Tests and Reviewing Results

7.1 Run Procedural Test

You can run a procedural test by choosing ***Sample Tests > Run Procedural Test***. You can also run the Procedural test by pressing the *F7* key on the keyboard.

To run a procedural test, you have to first select the test procedure. Steps for running the tests are discussed below.

1) The currently selected test procedure name can be seen in the *Standard Procedures* selection window on the PharmSpec main screen toolbar. If you do not want to change this, you can ignore this step and go directly to step#2. If you want to run a test procedure other than the one shown in the toolbar, click the *Standard Procedures* selection window. The available list of test procedures is listed here. You can select the required test procedure from this list.
2) click the *Sample Tests* > *Run Procedural Test* menu. This invokes the *Sample Identification* dialog. You have to first enter the sample identifier data configured for the selected test procedure.

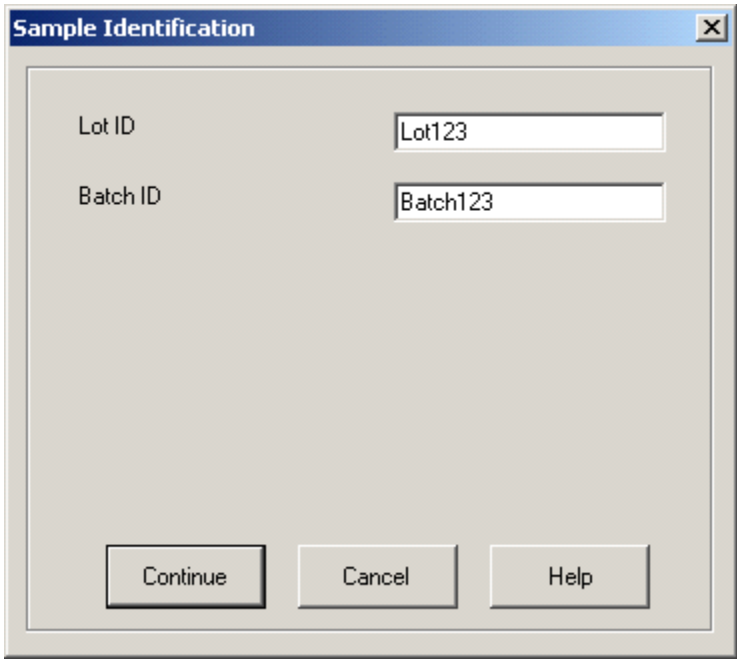

Fig 7-1 : Sample Identification Dialog

The sample identifiers listed are the ones pre-configured for a particular test procedure. For example, the sample IDs for a particular test procedure could be “Lot ID” and “Batch ID” and you are asked to enter the value for these sample identifiers.

3) On entering the sample ID values, and clicking the continue button, the ***Procedural Test*** window is displayed. The *Procedural Test* window contains:
   - The top left corner of each screen provides the operator with instructions specific to the test the operator is performing.
   - The section immediately below the instructions lists the parameters required to run the test. Each parameter shows a default value. The user can change these values within permissible limits. The most common parameters for a test are sample volume and the number of runs.
   - The right side of the screen consists of the report area for the test. The results of the test are displayed here. The result data displayed can vary procedure to procedure. The test outcome (PASS or FAIL) will be displayed at the bottom after completion of all test runs.
   - The lower part of the screen has buttons the operator could use to access help files, print the results, run / stop the test, review / approve result, queue or save the result and close the dialog.

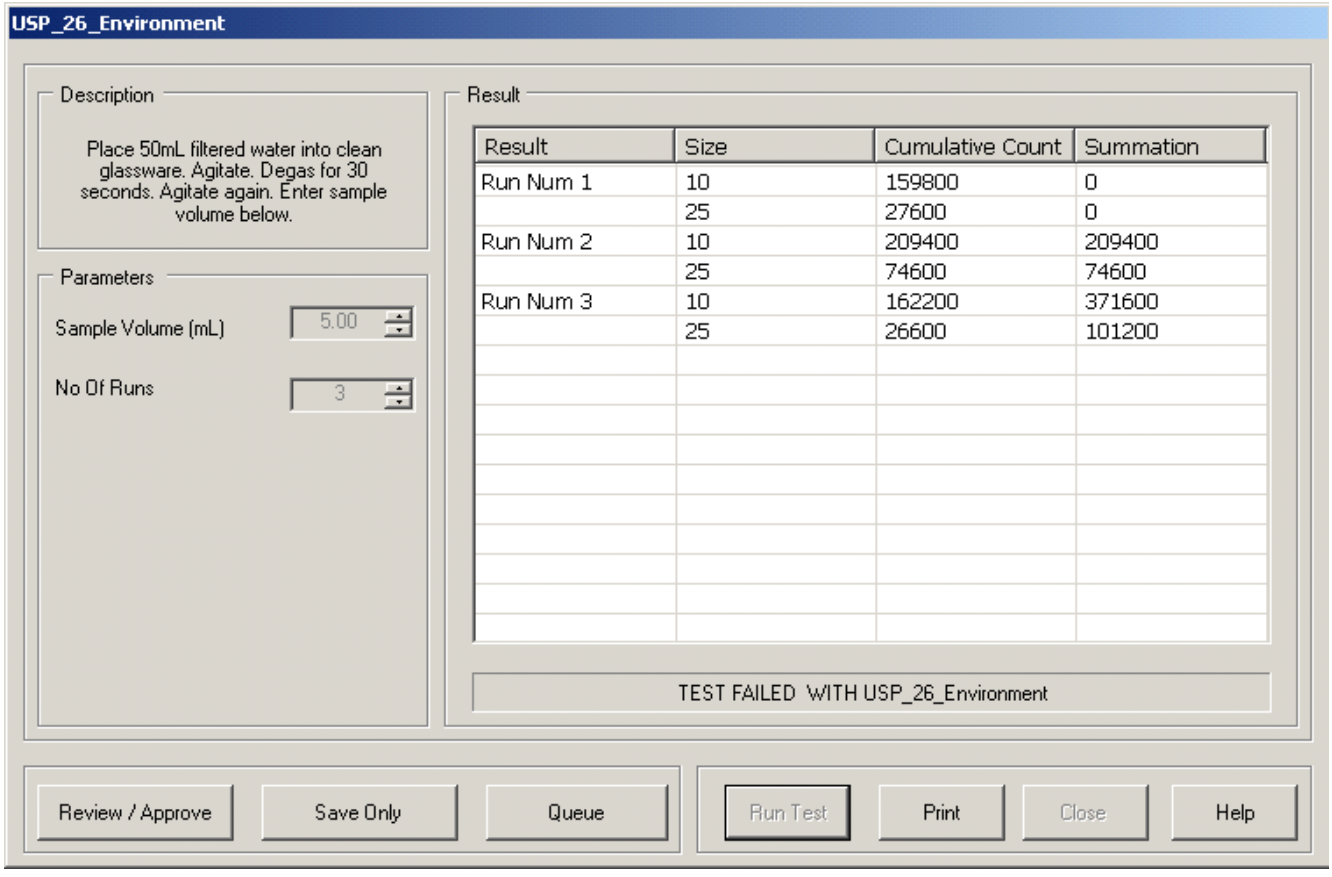

Fig 7-2 : Run Test Dialog

4) You have to click the *Run Test* button to run the test. The test result is displayed after running the tests. The caption on the *Run Test* button changes to *Stop Test* while the

test is running. You can stop the test run by clicking on the *Stop Test* button. A ticker is displayed on the screen to inform the operator that the test run is in progress.

5) After running the test, the operator can perform any one of the following actions:

Save Only	This option is used either for informal tests (you do not want to review/approve these tests) or when you want to put the signatures on the hard copy (printout of the test report). In this case, the operator can just save the results. For this, click the *Save Only* button.
Queue	The user queues the result for the purpose of reviewing and approving it on-screen later. For this, click the *Queue* button.
Review / Approve	If the user has the appropriate privileges, he/she may review and approve the results after running the test. To do this, click the *Review / Approve* button. On doing so, the *Review / Approve Comments* dialog is displayed.

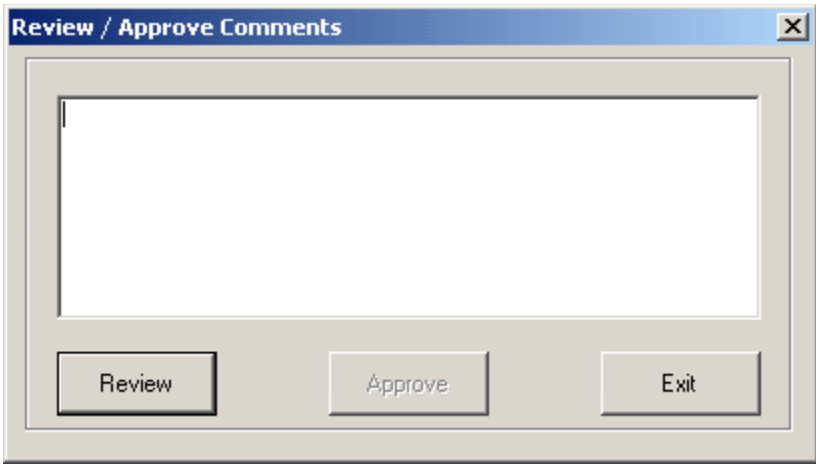

Fig 7-3 : Review / Approve Comments Dialog

In the *Review / Approve Comments* dialog, you can enter the review comments and then press the Review button. When this button is pressed, the user authentication dialog will pop up, prompting you enter your password.

Fig 7-4 : User Authentication Dialog

If you have the privilege to approve the test results, you can enter the approval comments and then press the *Approve* button. As in the case of review, the user authentication dialog will pop up, prompting you enter your password.

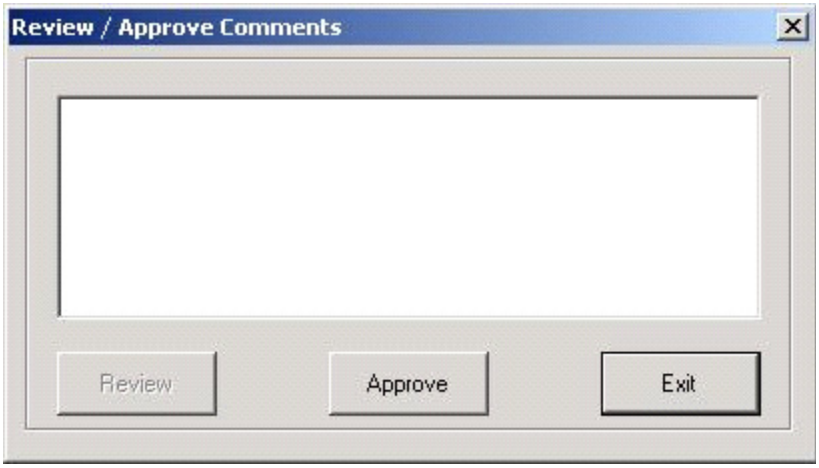

Fig 7-5 : Review / Approve Comments Dialog

The user can also print the result by clicking on the Print button.

7.2 Run Counter

You can run the Run Counter Test by choosing ***Sample Tests > Run Counter***. You can also run this test by pressing the F9 key on the keyboard.

Setup details for the Run Counter Test are set from the *Hardware Settings* dialog (Operating parameters). Once all the Setup procedures are completed, the user can run the Run Counter test and collect the data. This is a non-procedural test (default test without any Pass/Fail checking) that uses only the Operating Parameter values.

Clicking on *Run Counter* menu invokes the *Sample Identification* dialog.

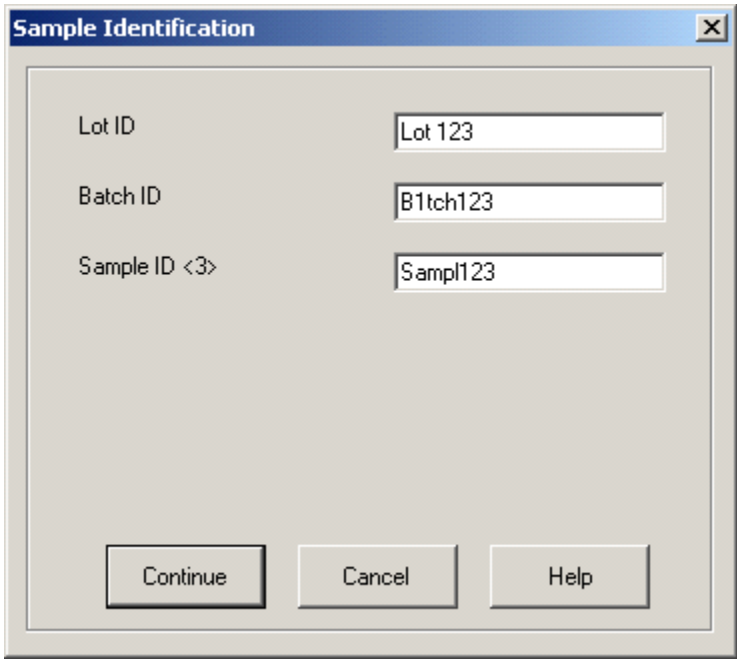

Fig 7-6 : Sample Identification Dialog

Sample Identification dialog displays the sampled identifiers configured for the Run Counter Test. You have to enter the values for these sample identifiers (for example, the values for the Lot ID, Batch ID, etc.) and then click the *Continue* button. This invokes the *Run Counter* dialog. This dialog displays the results obtained from the counter and the calculated result. It also displays the user who has run the test, date of running the test, sample IDs etc. You can print the result by clicking on the *Print* button.

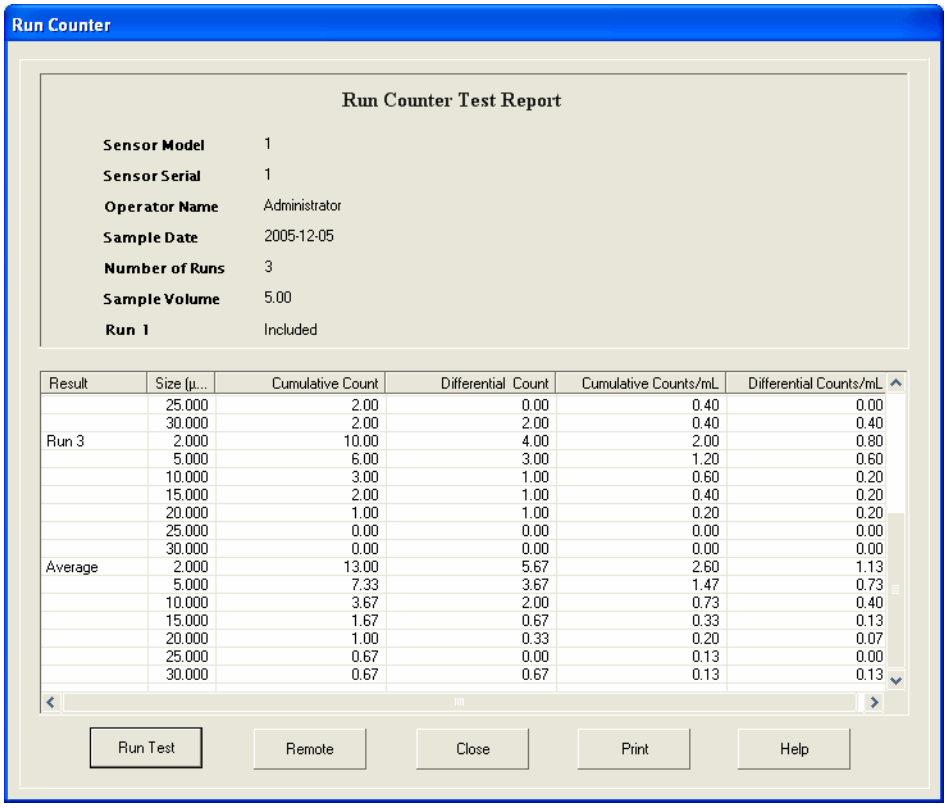

Fig 7-7 : Run Counter Window

7.3 Review and Approve

Once a procedural test is run, the test results have to be reviewed and approved. Special privileges are needed for the user to do the same. The user can Review/Approve the results by choosing ***Review And Approve*** *menu*. This invokes the *Review And Approve* dialog.

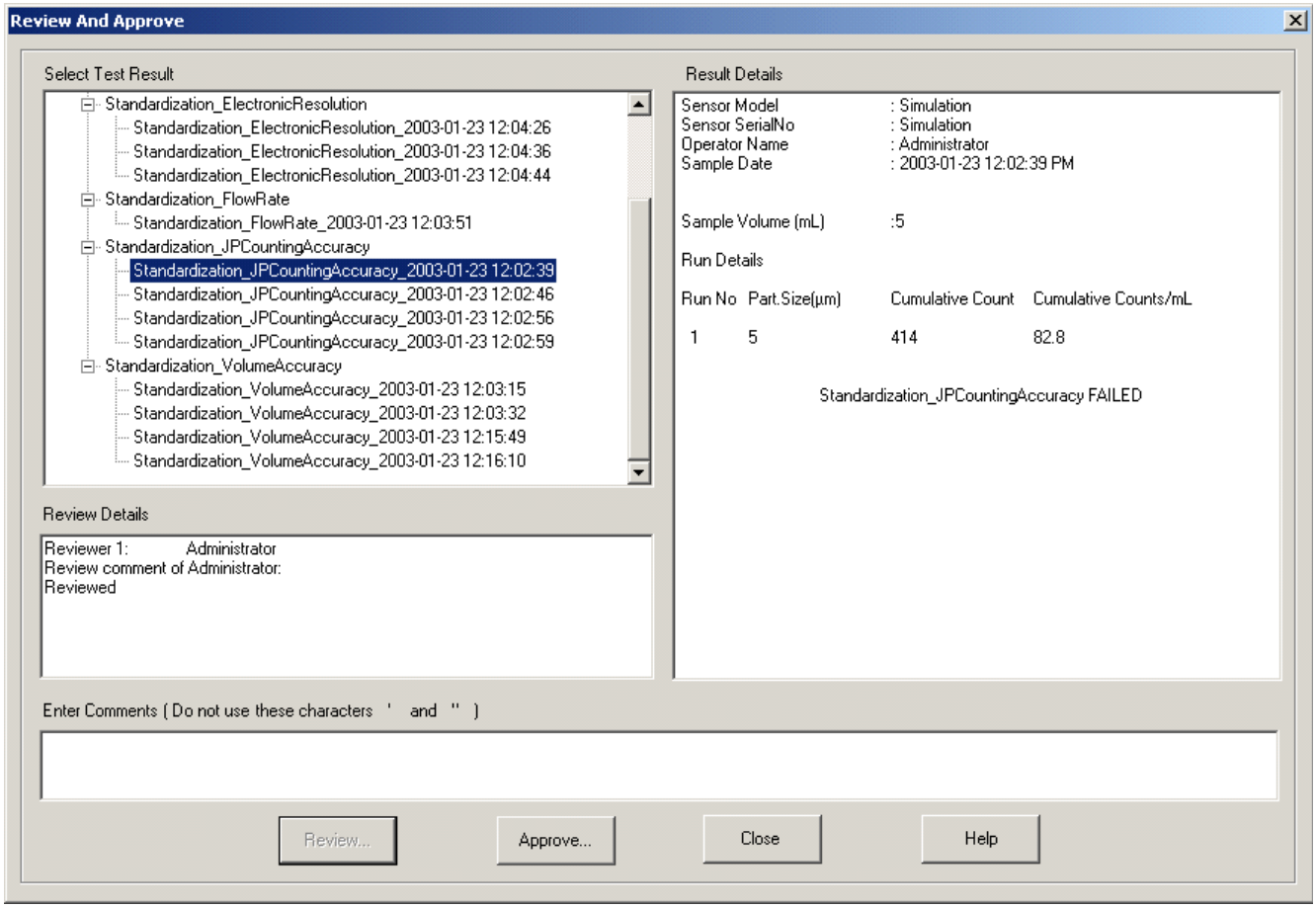

Fig 7-8 : Review and Approve Dialog

The *Review And Approve* dialog lists all the test results that are not approved in the *Select Test Result* area, in a tree structure. Expanding a test procedure node displays the test results for this procedure that are not approved. The user can select any of the tests from the list. The Review button is enabled only if less than four users have reviewed the selected result and not yet approved. The *Approve* button is enabled if the selected test result is reviewed by at least one user and not yet approved.

The *Review* and *Approve* buttons will be enabled only if you have the corresponding privileges.

The user can review the result by entering the review comments and clicking on the ***Review*** button. At least one reviewer and a maximum of four reviewers can review any test result. A test result can be approved if at least one person has reviewed it. To approve a test result, the user has to enter the approval comments and click the ***Approve*** button. Only one user can approve a result. A report once approved cannot be reviewed anymore.

To review / approve a test, the user has to first select the required test from the *Select Test Result* group. Under each test type (procedure), the tests due for review / approval are listed. These are identified by the date & time values that correspond to the date/time at which the test was run. Results for the selected test are listed on the right pane of the dialog (*Result Details*). The review data (name of the reviewer, and review comments, date of review) are listed in the

Review Details field. The current user cannot modify the comments written by another reviewer.

The user has to enter comments and click the ***Review*** or ***Approve*** button as appropriate. On clicking the Review or Approve button, the user is prompted to enter the password again. The *Secure Operation* dialog is displayed, wherein the user has to enter his password.

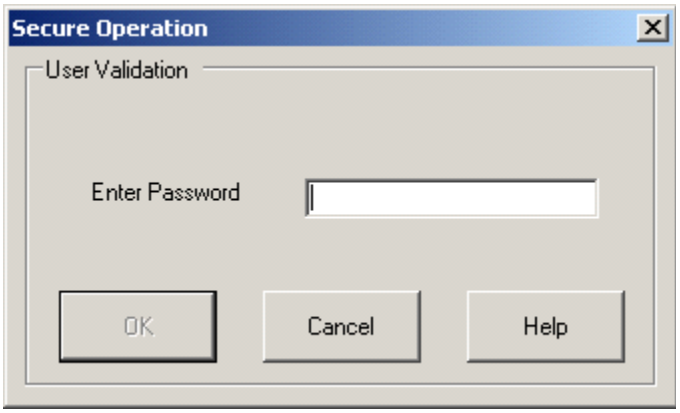

Fig 7-9 : Secure Operation Dialog

The comment is accepted only if the entered password is that of the logged-in user. The maximum number characters permitted for comments are 166. On entering the comments and clicking on the *Review* or *Approve* button, the entered comments and the user details are updated.

Note:
*If four persons have already reviewed the result, the **Review** button is disabled. If the user does not have the "approve" privilege, the **Approve** button is disabled.*

8 View the Audit Trail (Activity Log)

8.1 View Activity Logs

The Administrator / Supervisor can view the activity log of system. To do this, select ***Reports > View Activity Logs***. This invokes the *View Activity Logs* dialog.

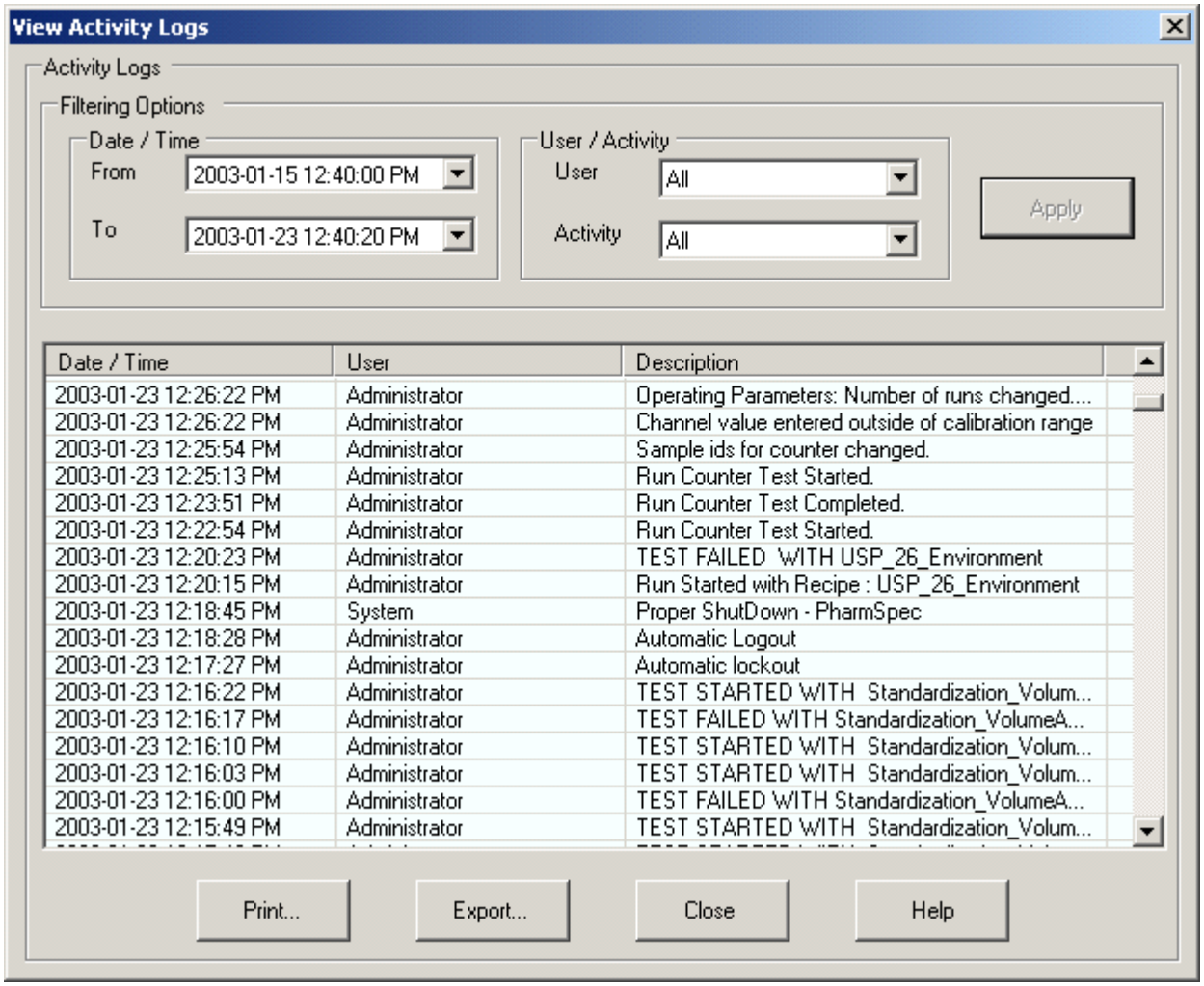

Fig 8-1 : View Activity Logs Dialog

The user can retrieve information stored in the logs based on a given criteria. The criteria could be one among the following:

- Range (From / To) of DATE and TIME
- User name (All / specific user name)
- Type of activity or action (All / specific activity)

The user can specify the criteria and view the logs based on the criteria. The Activity selection window lists following activities:

- All
- System Lockout
- Password Change
- Database Archive / Backup
- Database Corrupted
- Run started / completed / stopped
- Test Result Review / Approve
- User Login / Logout
- Shutdown
- Automatic Lockout / Logout
- Configuration Change
- Procedure Created / Loaded
- Run Counter
- System Date Modified

On clicking the *Apply* button, the reports for the specified criteria are displayed. The activities are displayed in the reverse chronological order of date.

It is possible to export the output to common formats such as EXCEL or WORD or CSV by clicking on the *Export* button. In case of exporting to CSV format, you have to specify the separator (delimiter).

You can print the log by clicking on the *Print* button.

9 Generating Historical Data Reports

9.1 Historical Reports

The user can generate (view / print) the reports for the tests run in the past in a pre-defined format. For this, choose ***Reports > Historical Reports***. This invokes the *Historical Reports* dialog.

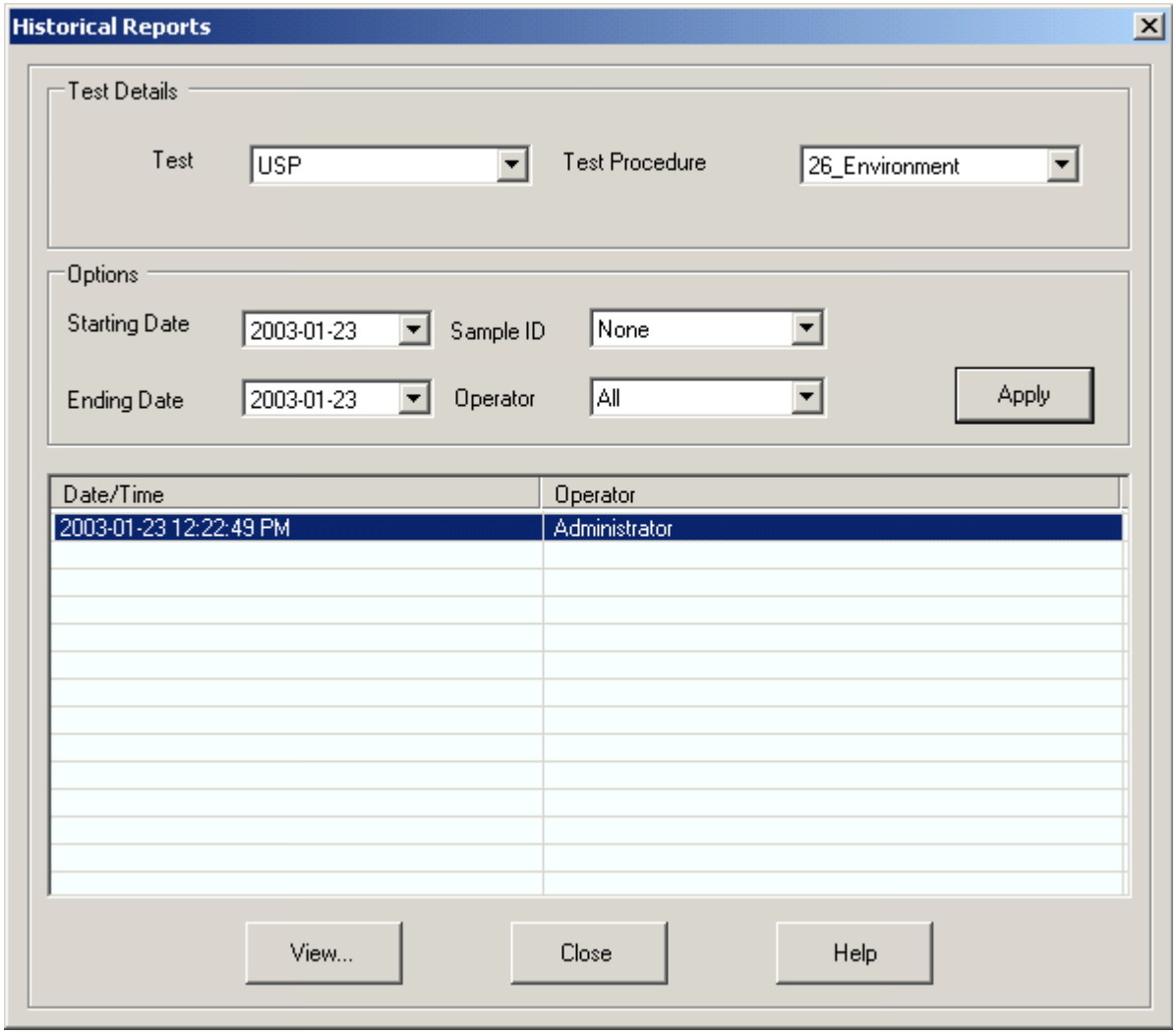

Fig 9-1 : Historical Reports Dialog

The user has to first select the type of test (USP / EP / JP / KP/ User-Defined / Run Counter / Standardization) from the *Test* selection window. Test procedures for the selected test type are then listed in *Test Procedure* selection window. The user then selects a test procedure from the *Test Procedure* selection window and then further filters the list using the keys Starting Date & Ending Date, Operator Name, and Sample ID. After selecting the filtering options, the user has to click the *Apply* button. This action filters the test results as per the given criteria and displays

the filtered list in the reverse chronological order of date. This filtered list contains the Date/ Time information and the Operator name. Finally, selecting one of the reports from the list displays the test report by a click the *View* button or a double click the selected report item, and it can be printed if required.

Operator selection window lists all the users of the system. *Sample ID* selection window lists the sample IDs corresponding to the selected test procedure. Sample ID will have “None” as the default selection. User has to select the required sample ID from the selection window and then the edit box for entering the sample ID value will be shown. The user has to select a sample ID and the edit box for entering the sample ID is displayed. The user will then have to enter the value of the sample ID for which he has to view the reports.

The *Starting date* and the *Ending date* fields display the current date by default. You may or may not specify the other fields. On Selecting the *Apply* button, it displays all the reports for the selected test procedure for the current date for all the users. If the user selects a sample ID then the value for that sample ID is also listed in the report details. The user can select a particular report and click the *View* button or double click the report. This invokes the *View Report* dialog.

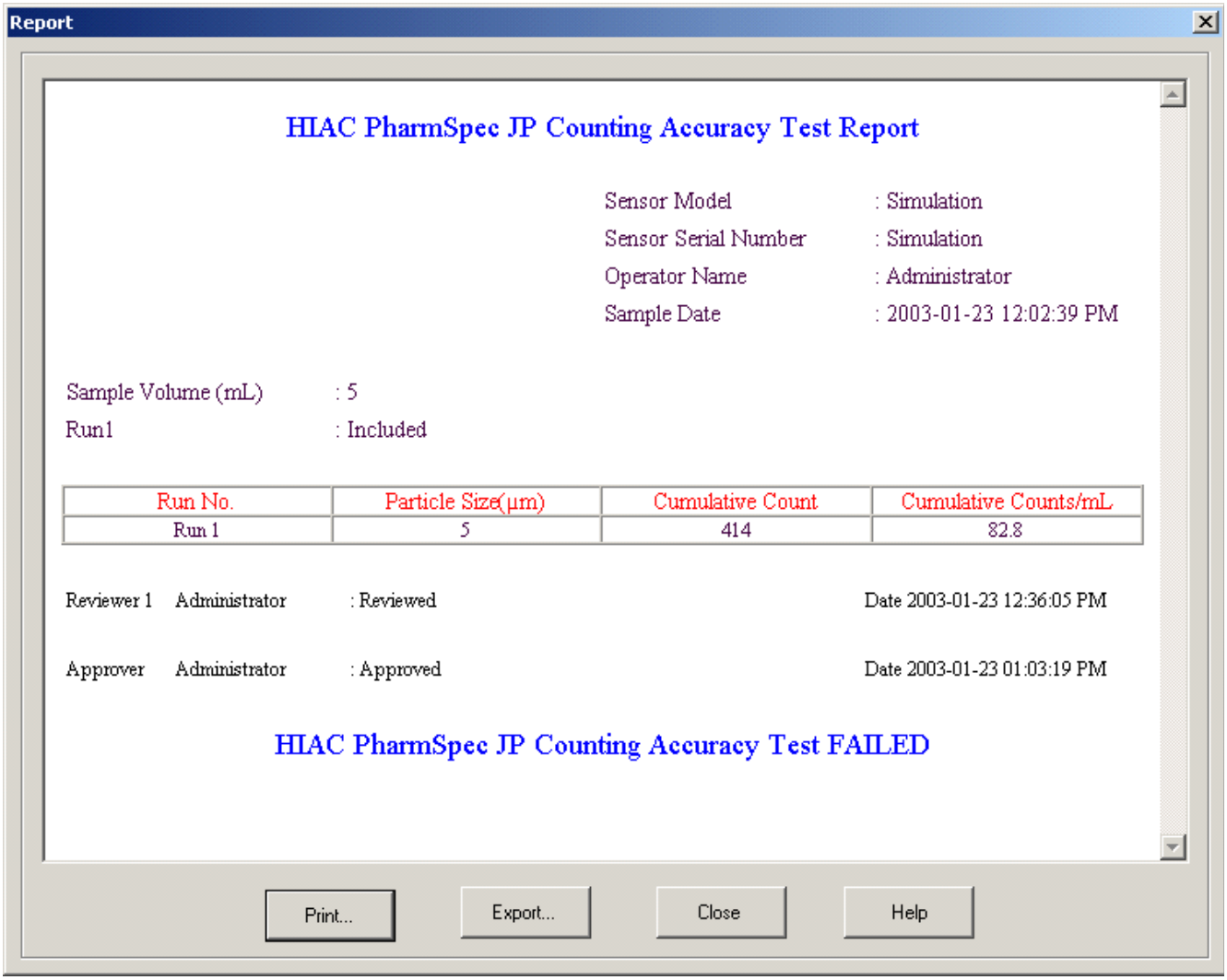

Fig 9-2 : View Report Dialog

The result is displayed in detail in the selected procedure format on clicking the *View* button. The details include the sample ID values, user input values, test results, the user who had run the test, date of running the test, and review and approve details for the test report.

The report will also display following details:

- Whether the data of the first run was discarded / included in the calculations
- Pass Criteria for the test
- Space for manual signatures in case of "*Save Only*" type of reports.

You can print the generated report on clicking the *Print* button.

You can also export it to EXCEL or any CSV format by clicking on the *Export* button. In case of exporting to CSV format, you have to specify the separator (delimiter).

9.2 Old Version (PharmSpec 1.4) Reports

The software allows the user to read historical test results data generated by PharmSpec 1.4 and generate reports. This can by done by selecting ***Reports > Pharm 1.4 Reports***. This invokes the *Pharm1.4 Reports* Dialog.

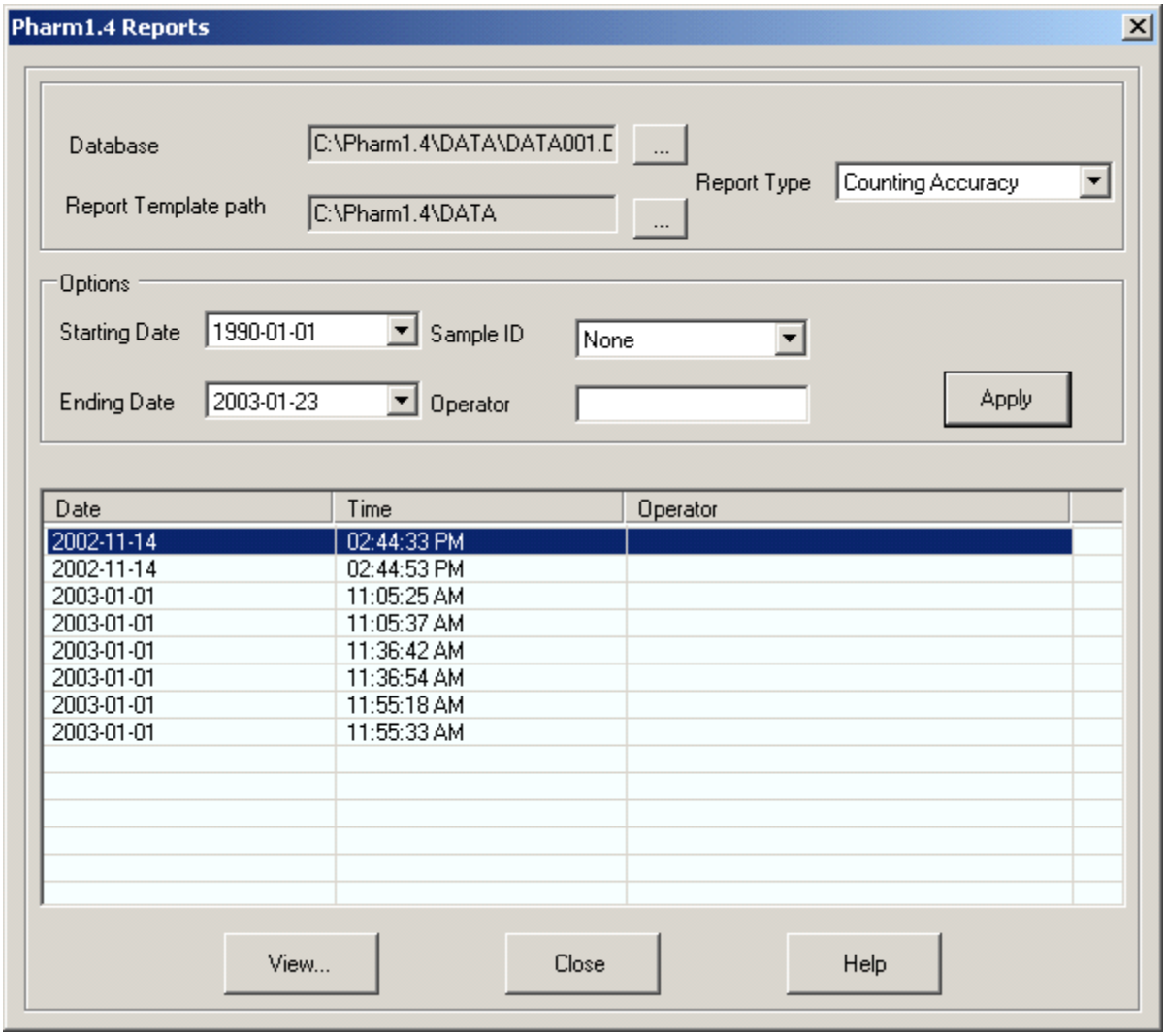

Fig 9-3 : Older Version Report Dialog

You have to first select the database (file) that contains the test results from PharmSpec 1.4 and also the Report template path (path for .SDF / .RDF files). The reports (type) available in this database are displayed in the *Report type* selection window and the user can select the required one from this list. Use the DATE (*Starting Date* & *Ending Date*) / Operator / Sample identifier filters to select the required test and then click the *Apply* button. This action filters the test results as per the given criteria and displays the filtered list in the reverse chronological

order of date. This filtered list contains the Date/Time information and the Operator name. The user can view a result in detail by selecting the required report from this list and clicking on the *View* button or double click the selected report item.

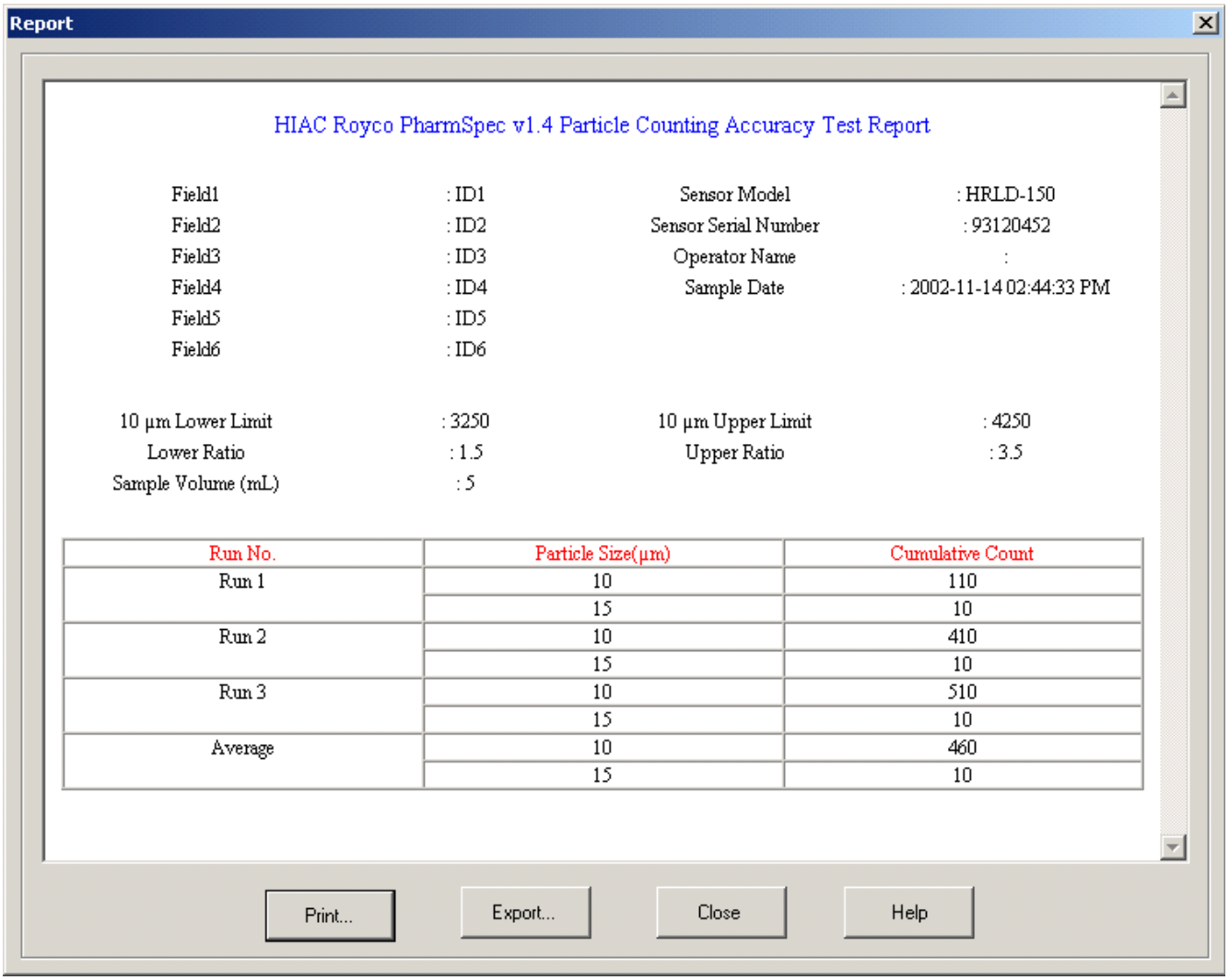

Fig 9-4 : Previous Version Report Dialog

You can print the generated report by clicking on the *Print* button.

You can also export it to EXCEL or any CSV format by clicking on the *Export* button. In case of exporting to CSV format, you have to specify the separator (delimiter).

10 Data Backup / Archival

a) Data Storage

The *Data Storage* Menu contains menu options for data reconstruction. The *Backup* and *Archive* menu options facilitate this.

b) Backup

It is possible to take a backup of the current system data. You can configure the details for the backup. For this, click the ***Setup > Data Storage > Backup*** menu. On doing so, the *Backup Configuration* dialog is displayed.

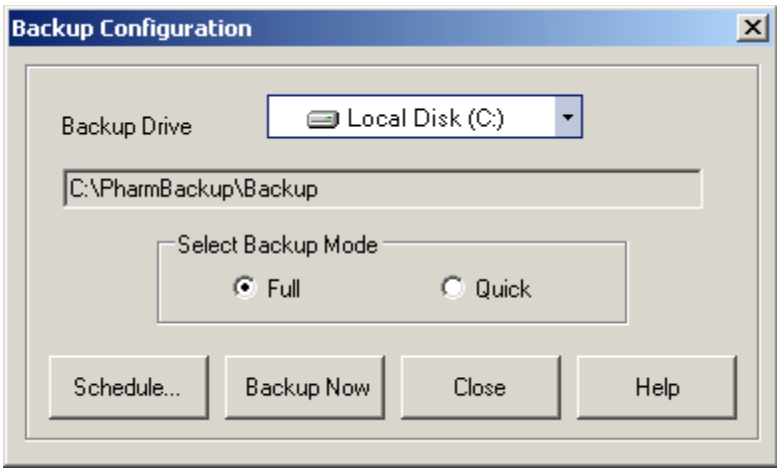

Fig 10-1 : Backup Configuration Dialog

Here, you can select the location to which the backup has to be taken. You can opt for complete (FULL) backup or differential (QUICK) backup by clicking on the radio button *Full* or *Quick*. The “Quick” selection will cause a backup of only the data that has been added since the previous backup occurred. A “Full” backup will cause a complete copy of the current database to occur. After selecting the backup mode, you can initiate the backup action by clicking on the *Backup Now* button.

You can also schedule the backup activity so that the backup is taken automatically at scheduled intervals. To configure the backup frequency (daily, weekly, every week days, time etc.), click the *Schedule* button. On clicking this button, the *Schedule Backup* dialog is displayed.

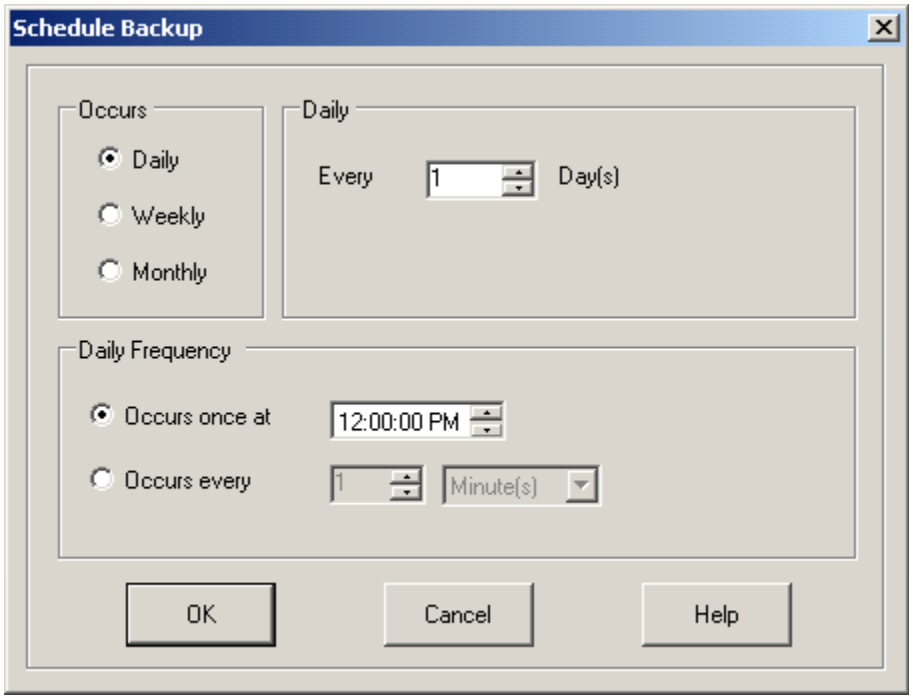

Fig 10-2 : Schedule Backup Dialog

Click the OK button to save the details.

c) Archive

Archiving data makes the database smaller. Once data has been archived, it cannot be merged back into the PharmSpec without losing the current data. Only archive data that is no longer needed.

You can archive the data in the system to a selected folder. Click the ***Setup > Data Storage > Archive*** menu to access the Archive dialog. On doing so, *Archive Configuration* dialog is displayed.

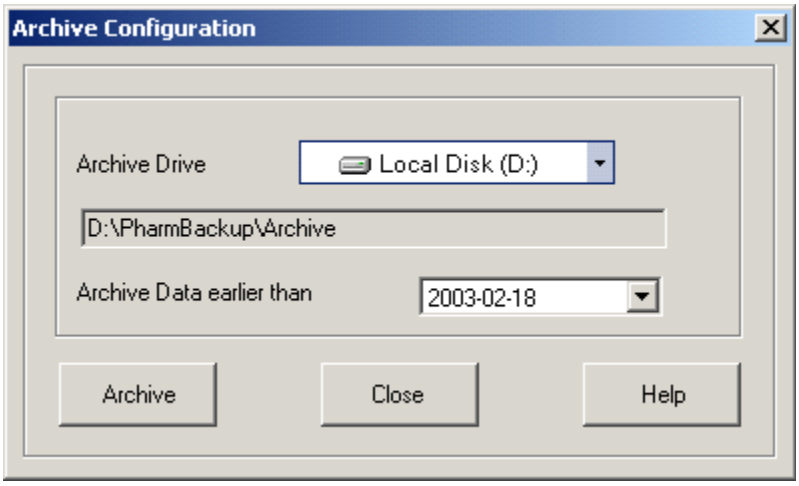

Fig 10-3 : Archive Configuration Dialog

You can select the archive location (Drive) and can initiate the archive action by clicking on the *Archive* button. When the data is archived, the corresponding test results and the activity log data will be deleted from the current PharmSpec database.

User can also configure the amount of data to be archived by setting the “Archive Data earlier than” field.

Archiving of historical data is strictly a manual operation, and is only available to the Administrator level of user.

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11 Running Instrument Standardization Tests

You can run an instrument standardization test by selecting an instrument standardization test from the *IST Standards* selection window and then clicking the Run IST menu. You can also do this by using the function key F2. This operation is only available to a user with the CALIBRATION TECHNICIAN role or as a type of ADMINISTRATOR with this additional right assigned.

The *IST Standards* selection window contains Volume Accuracy test, Flow Rate test, Moving Window test, Sensor Resolution test, Electronic Resolution test, USP Counting Accuracy test, JP Counting Accuracy test, and KP Counting Accuracy test. Based on the license key of the installed software, the list may or may not show all of these tests.

Steps for running an Instrument Standardization Test are discussed below.

1) The currently selected IST name can be seen in the IST Standards selection window on the PharmSpec main screen toolbar. If you do not want to change this, you can ignore this step and go directly to step #2. If you want to run a test procedure other than the one shown in the toolbar, click the IST Standards selection window. The available list of IST procedures is shown here. You can select the required test procedure from this list.
2) click the **Sample Test > Run IST** menu. This invokes the Test window corresponding to the IST selected. The test window contains:
    - The top left corner of each screen provides the operator with instructions specific to the test the operator is performing.
    - The section immediately below the instructions lists the parameters required to run the test. Each parameter shows a default value. The user can change these values within permissible limits.
    - The right side of the screen consists of the report area for the test. The results of the test are displayed here. The result data displayed can vary procedure to procedure.
    - The lower part of the screen has buttons the operator could use to access help files, print the results, run / stop the test, Review / Approve result, Queue or save the result and close the dialog.
3) You have to click the *Run Test* (or *Continue Test)* button to run the test. The test result is displayed on completion of the test. The caption on the *Run Test* button changes to *Stop Test* while running the test. You can stop (abort) the test by clicking on the *Stop Test* button.
4) After running the test, the operator can perform any one of the following actions:

Save Only	This option is used either for informal tests (you do not want to review/ approve these tests) or when you want to put signatures on the hard copy (printout of the test report). In this case, the operator can just save the results. For this, click the *Save Only* button.
Queue	The user queues the result for the purpose of reviewing and approving it later. For this, click the *Queue* button.

Review / Approve	If the user has the appropriate privileges, he/she may review and approve the results, after running the test. To do this, click the Review/ Approve button. On doing so, the Review/Approve Comments dialog is displayed.

In the *Review/Approve Comments* dialog, you can enter the review comments and then press the *Review* button. When this button is pressed, the *User Authentication* dialog will pop up, prompting you enter your password.

If you have the privilege to approve the test results, if you desire, you can enter the approval comments and then press the *Approve* button. As in the case of review, the user authentication dialog will pop up, prompting you enter your password.

After performing *Save Only*, Queue or Review Approve, the *Run Test* button will set its status to *Start Again*. On clicking this button, the test will start over again.

The user can print the result by clicking on the Print button.

11.1 Volume Accuracy

The user can run the Volume Accuracy Test by selecting *Standardization_VolumeAccuracy* from *IST Standards* selection window and then clicking the **Sample Test > Run IST** menu. This invokes the *Volume Accuracy Test* dialog.

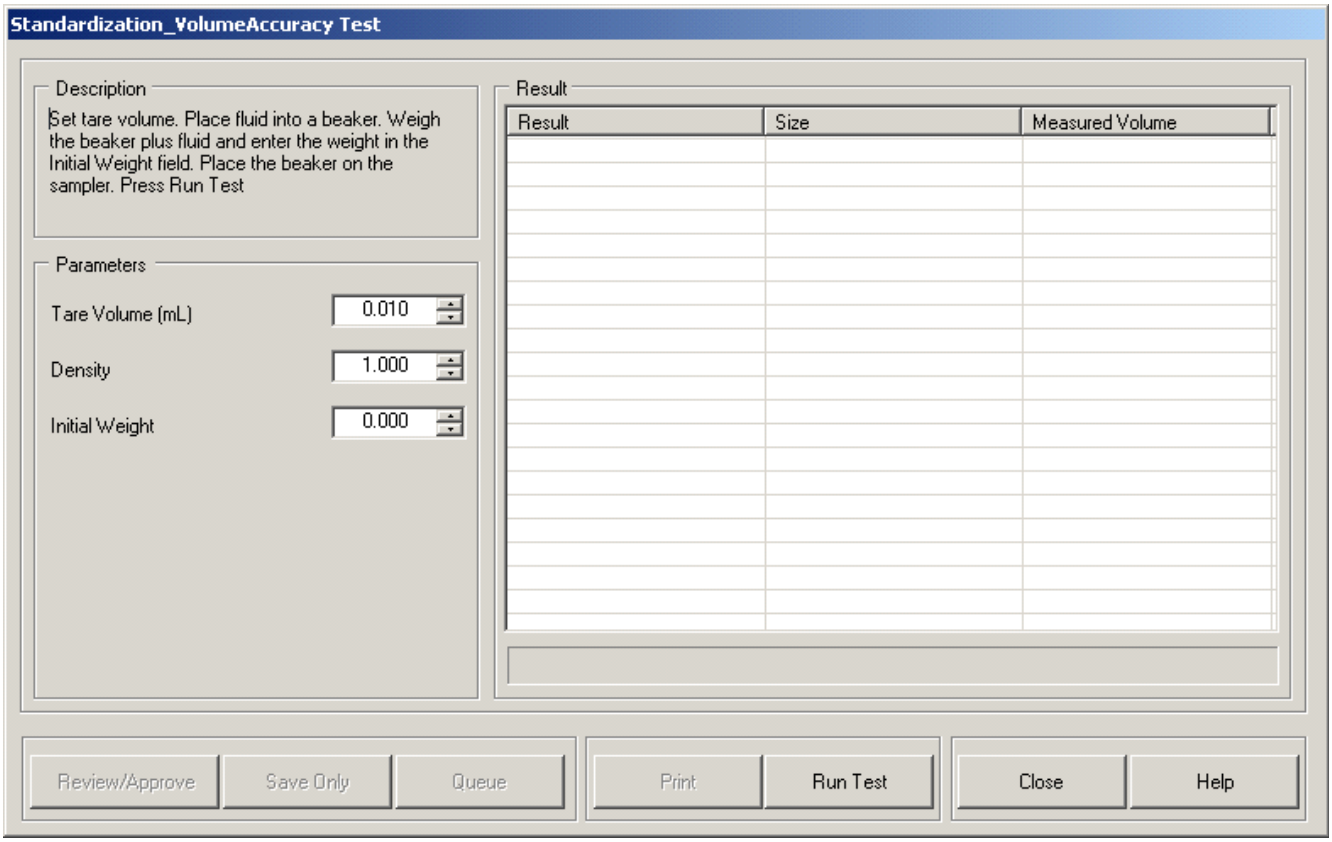

Fig 11-1 : Volume Accuracy Test Dialog

This test is designed to ensure that the sampler volume is accurate to within a 5% range of the desired volume.

11.2 Flow Rate

The user can run the Flow Rate Test by selecting Standardization_FlowRate from *IST Standards* selection window and then clicking the **Sample Test > Run IST** menu. This will pop up the *Flow Rate* dialog.

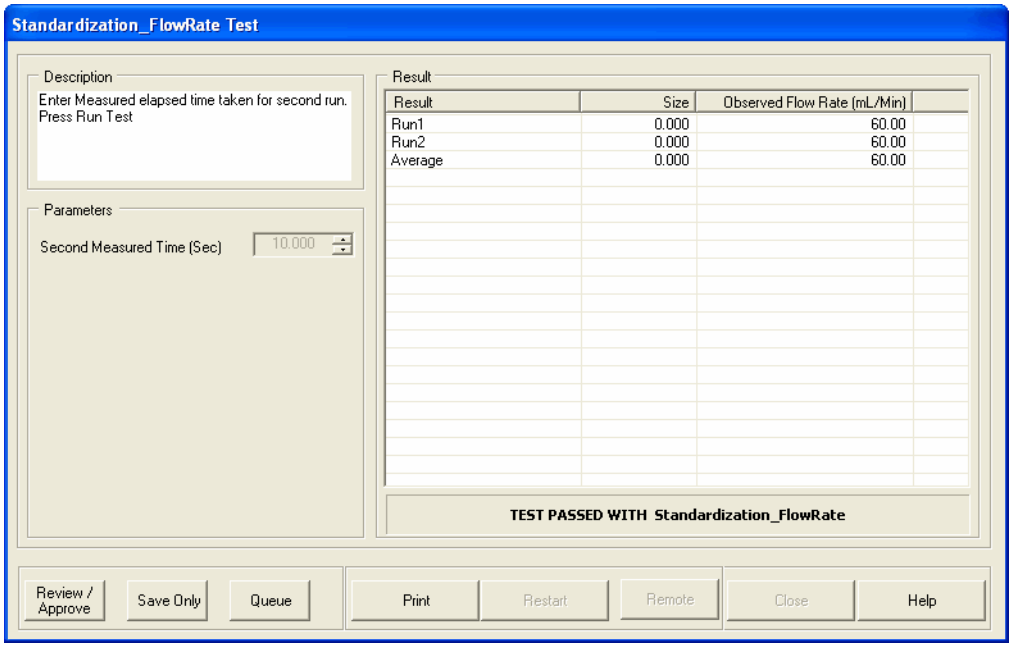

Fig 11-2 : Flow Rate Dialog

This test requires the use of a certified chronometer or stopwatch to determine the beginning and end points of the counting process. The user will need to time the process and record the data from two successive runs. The resulting values are averaged to determine the flowrate of the system.

11.3 Moving Window

The user can run the Moving Window Test by selecting *Standardization_MovingWindow* from *IST Standards* selection window and then clicking the **Sample Test > Run IST** menu. This invokes the *Sample Identification* dialog to enter the information about the challenge particles used for the test. This information is then stored with the test results and printed out on request. This enables the PharmSpec system to provide a “paperless” history of the calibration work that has been performed on the system. You can enter the sample ID information and then click the *Continue* button. This invokes the *Moving Window Test* dialog.

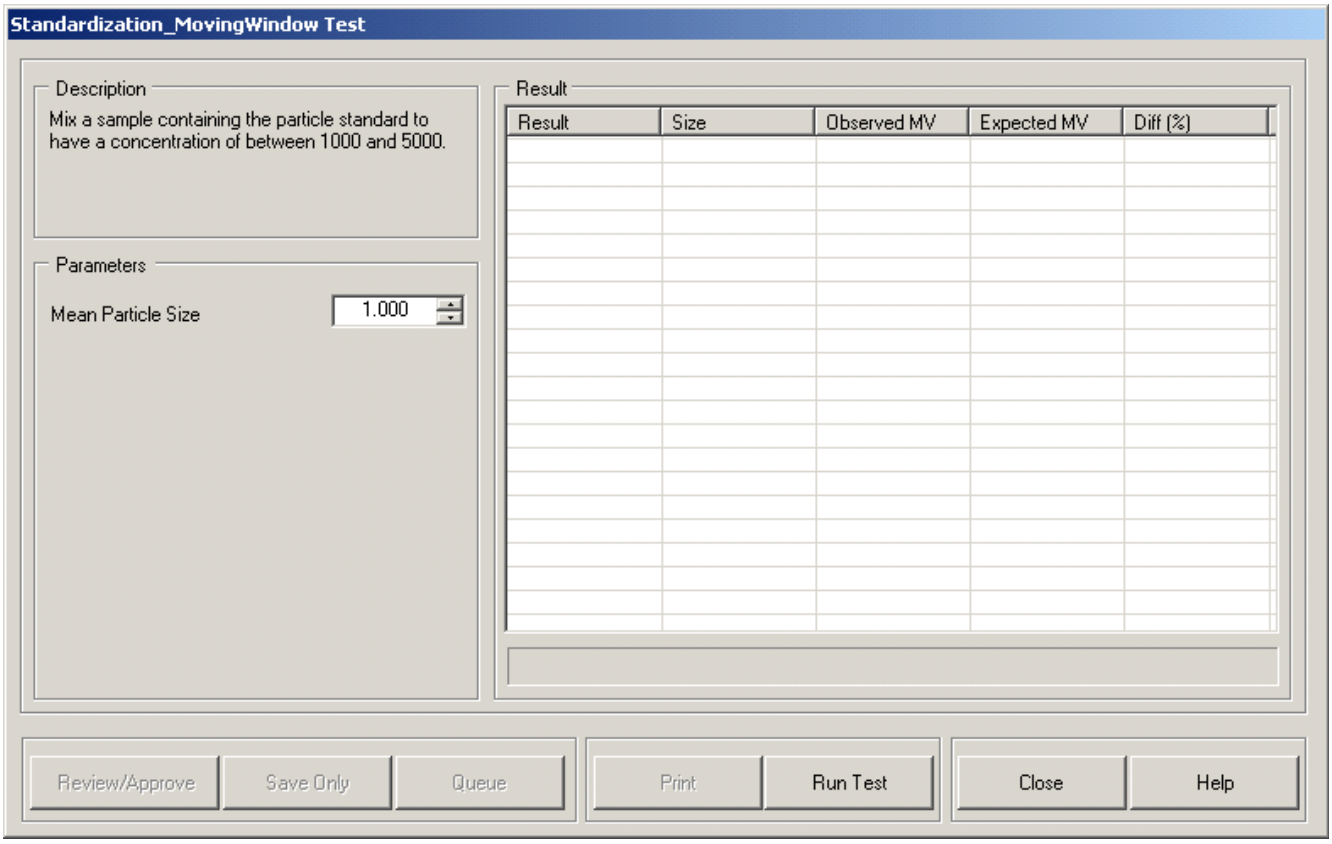

Fig 11-3 : Moving Window Test Dialog

11.4 Sensor Resolution

The user can run the Sensor Resolution Test by selecting *Standardization_SensorResolution* from the *IST Standards* selection window and then clicking the **Sample Test > Run IST** menu. This invokes the *Sample Identification* () dialog to enter the information about the challenge particles used for the test. This information is then stored with the test results and printed out on request. This enables the PharmSpec system, to provide a “paperless” history of the calibration work that has been performed on the system. You can enter the sample IDs and then click the *Continue* button. This invokes the *Sensor Resolution Test* dialog.

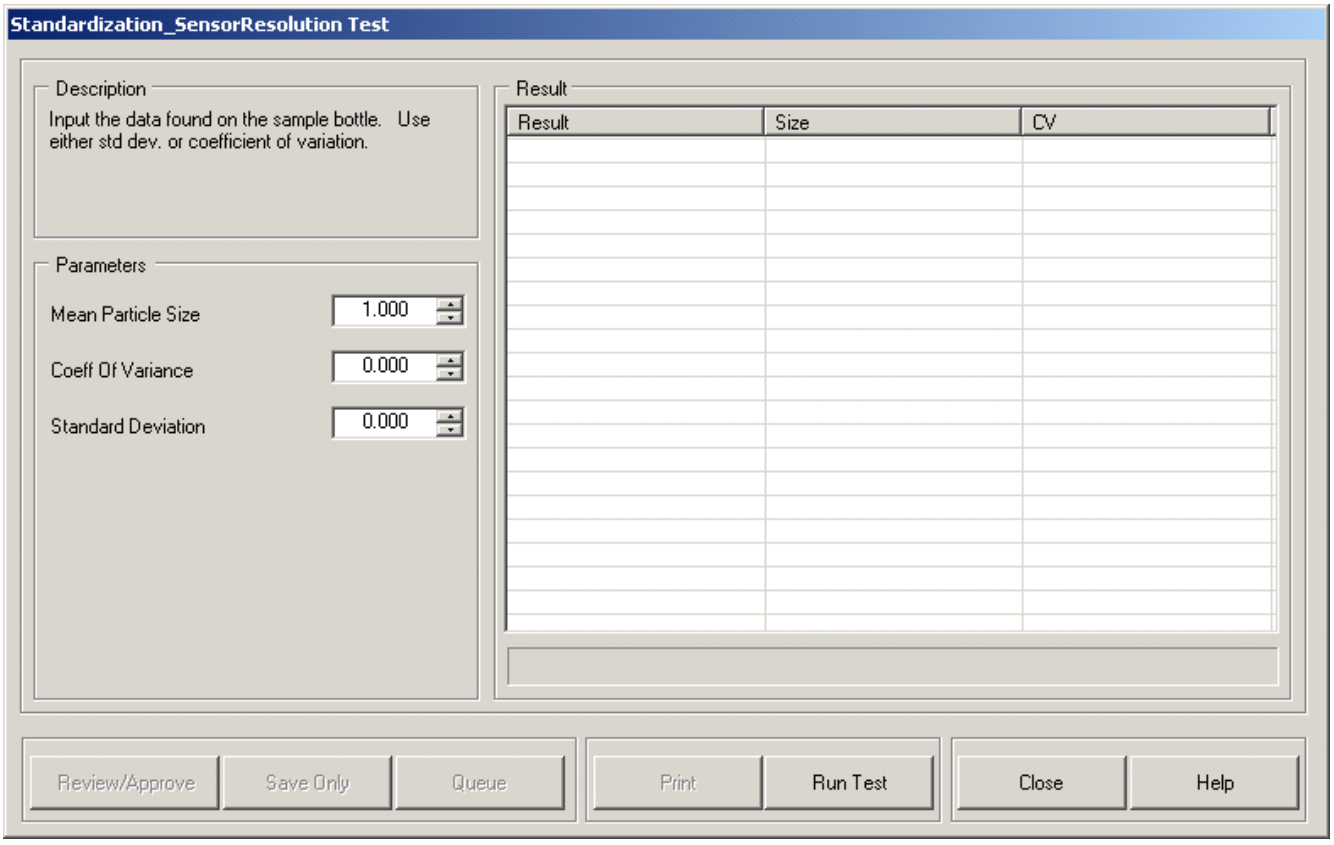

Fig 11-4 : Sensor Resolution Dialog

11.5 Electronic Resolution

The user can run the Electronic Resolution Test by selecting *Standardization_ElectronicResolution* from the *IST Standards* selection window and then clicking the **Sample Test > Run IST** menu. This pops up the *Sample Identification* dialog to enter the information about the challenge particles used for the test. This information is then stored with the test results and printed out on request. This enables the PharmSpec system to provide a “paperless” history of the calibration work that has been performed on the system.

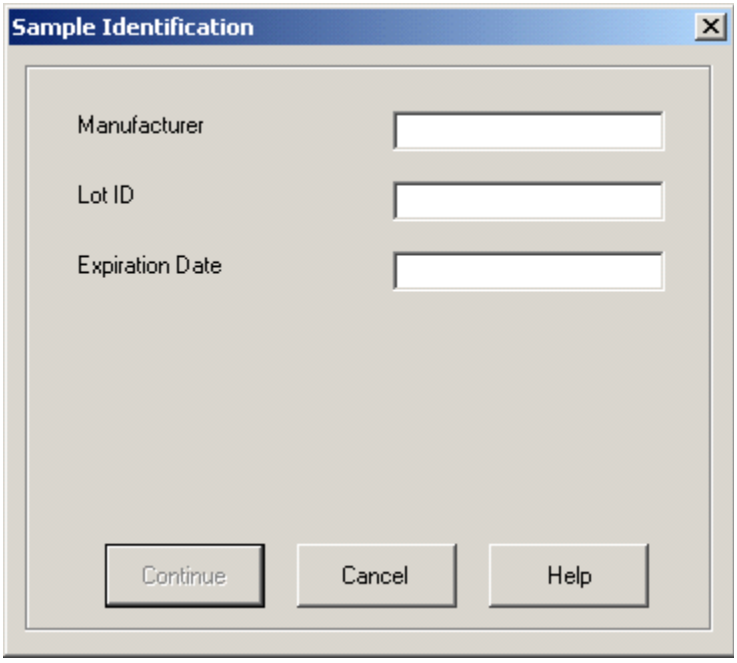

Fig 11-5 : Sample Identification Dialog

You can enter the sample IDs and then click the *Continue* button. This will pop up the *Electronic Resolution* dialog.

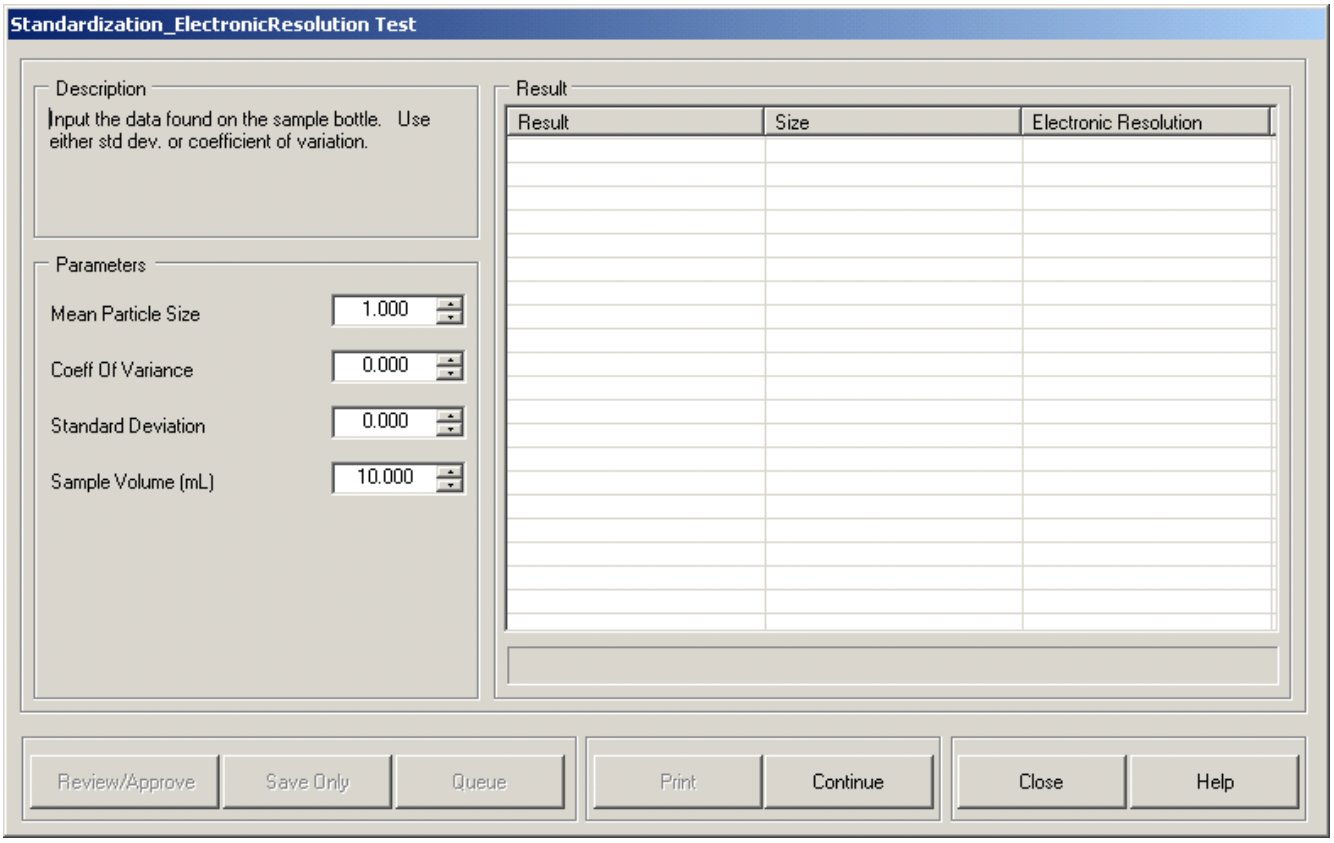

Fig 11-6 : Electronic Resolution Dialog

11.6 USP Counting Accuracy

The user can run the USP Counting Accuracy Test by selecting *Standardization_USPCountingAccuracy* from the *IST Standards* selection window and then clicking the **Sample Test > Run IST** menu. This pops up the *Sample Identification* () dialog to enter the information about the challenge particles used for the test. This information is then stored with the test results and printed out on request. This enables the PharmSpec system to provide a “paperless” history of the calibration work that has been performed on the system. You can enter the sample IDs and then click the *Continue* button. This will pop up the *USP Counting Accuracy* dialog.

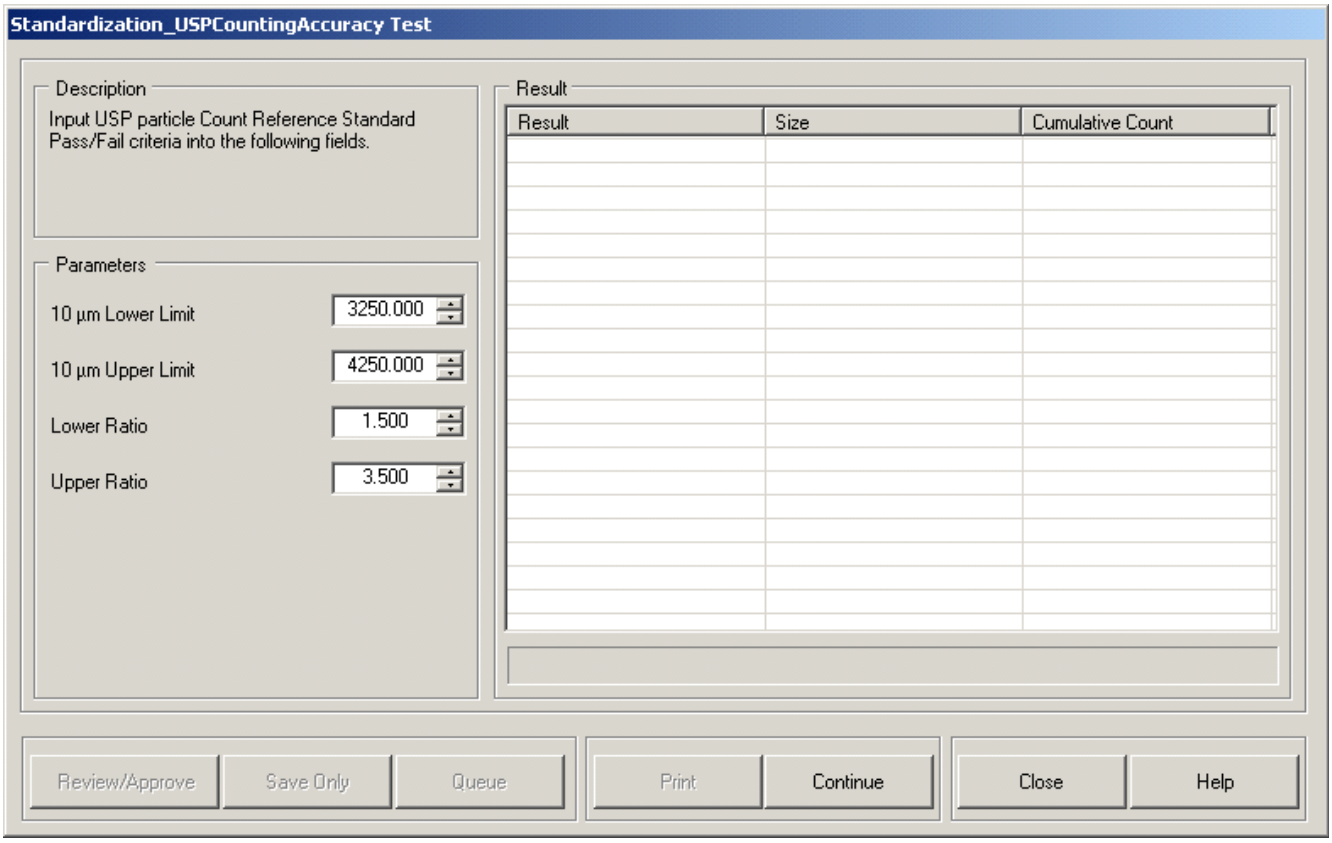

Fig 11-7 : USP Counting Accuracy Dialog

The counting accuracy test is designed to ensure that the particle counter counts fall exactly within the range specified by the USP Particle Count Set. The standard specifies that the count at 10 µm plus the ratio of the counts at 10 and 15 µm need to conform to the values accompanying the USP Particle Count RS (Reference Standard material).

It is recommended that a pre-test using standard 10-micron PSL particles be done before using the USP Particle Count RS.

11.7 JP Counting Accuracy

The user can run the JP Counting Accuracy Test by selecting *Standardization_JPCountingAccuracy* from the *IST Standards* selection window and then clicking the **Sample Test > Run IST** menu. This pops up the *Sample Identification* () dialog to enter the information about the challenge particles used for the test. This information is then stored with the test results and printed out on request. This enables the PharmSpec system to provide a “paperless” history of the calibration work that has been performed on the system. You can enter the sample IDs and then click the *Continue* button. This will pop up the *JP Counting Accuracy* dialog.

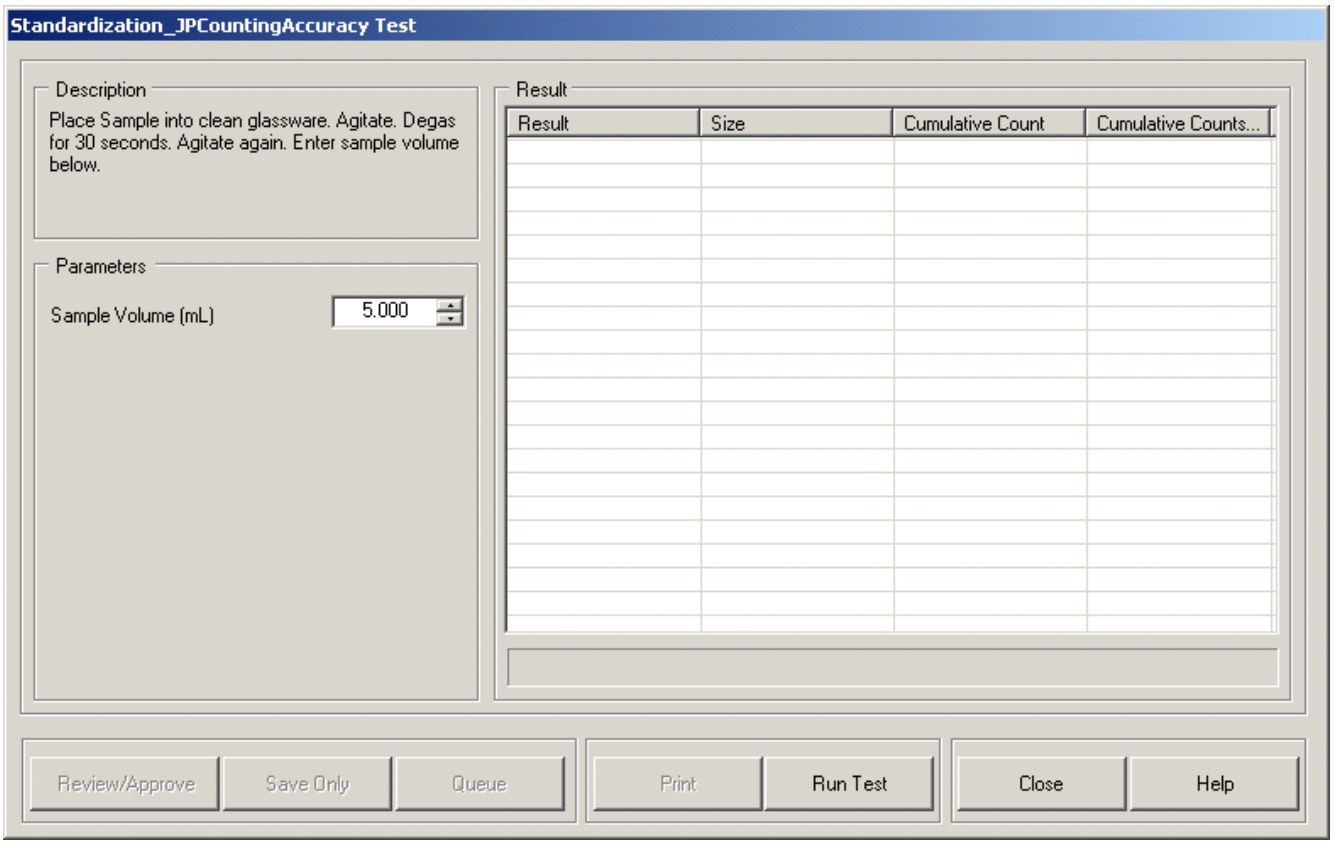

Fig 11-8 : JP Counting Accuracy Dialog

The counting accuracy test is designed to ensure that the particle counter counts fall exactly within the range specified by Supplement I to the Japanese Pharmacopoeia. It is generally recommended to run a pre-test using the less expensive standard 10-micron PSL particles before running the formal test with the RM (Reference Material).

11.8 KP Counting Accuracy

The user can run the KP Counting Accuracy Test by selecting *Standardization_KPCountingAccuracy* from *IST Standards* selection window and then clicking the **Sample Test > Run IST** menu. This pops up the *Sample Identification* () dialog to enter the information about the challenge particles used for the test. This information is then stored with the test results and printed out on request. This enables the PharmSpec system to provide a “paperless” history of the calibration work that has been performed on the system. You can enter the sample IDs and then click the *Continue* button. This will pop up the *KP Counting Accuracy* dialog.

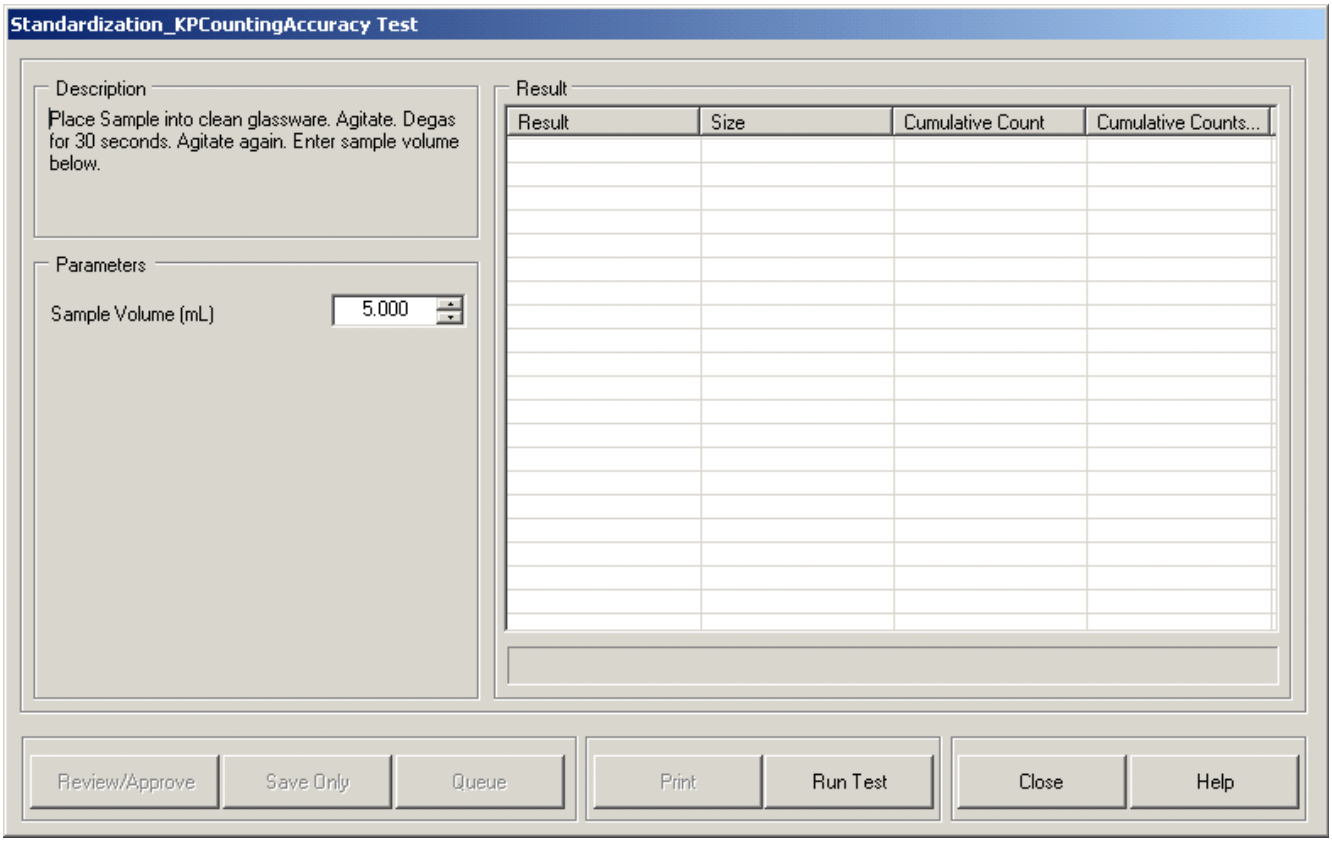

Fig 11-9 : KP Counting Accuracy Dialog

The counting accuracy test is designed to ensure that the particle counter counts fall exactly within the range specified by the Korean Pharmacopoeia. It is generally recommended to run a pre-test using the less expensive standard 10-micron PSL particles before running the formal test with the RM (Reference Material).

12 9703 Only: Pulse Height Analyzer

Note:
This feature is not available for the 9705.

You can view the plot data by clicking on the *PHA* button in any of the Standardization test dialogs. Click the menu **Sample Test → PHA** to bring up the PHA screen. On doing so, the Pulse Height Analyzer screen is displayed. In this screen you can do the following:

1) To determine a specific millivolt response for a given particle size, use the vertical Probe line to point to that area on the graph. Move the Probe using the mouse with “click and drag” or other screen control device. The millivolt response value is displayed below the lower right corner of the graph. [Note: The indicated millivolt response is dependent upon the Calibration Data entered in the current Hardware Settings menu. If the current Calibration Data is not representative of the current sensor being used, erroneous values will be shown.]
2) To zoom in on a portion of the graph, drag and drop the mouse across that portion of the graph while holding the left mouse button. The range of particle sizes displayed on the full graph is set by the calibration limits of the sensor.

The user can view the plotting for differential counts if the user selects the radio button *Differential Counts per mL.*

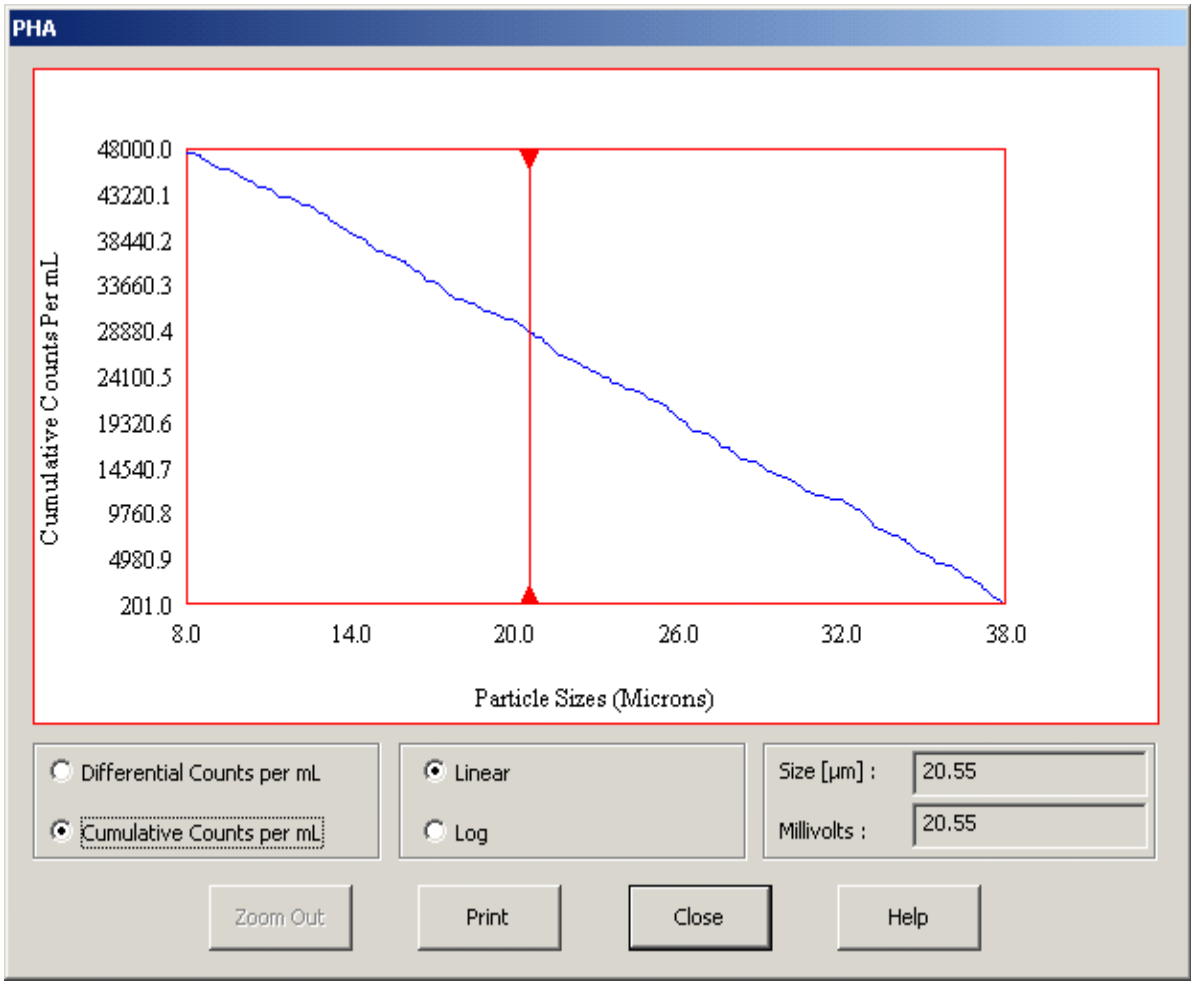

Fig 12-1 : PHA for Cumulative Counts per mL

You can view the plot for cumulative counts if you select the radio button corresponding to *Cumulative Counts per mL*.

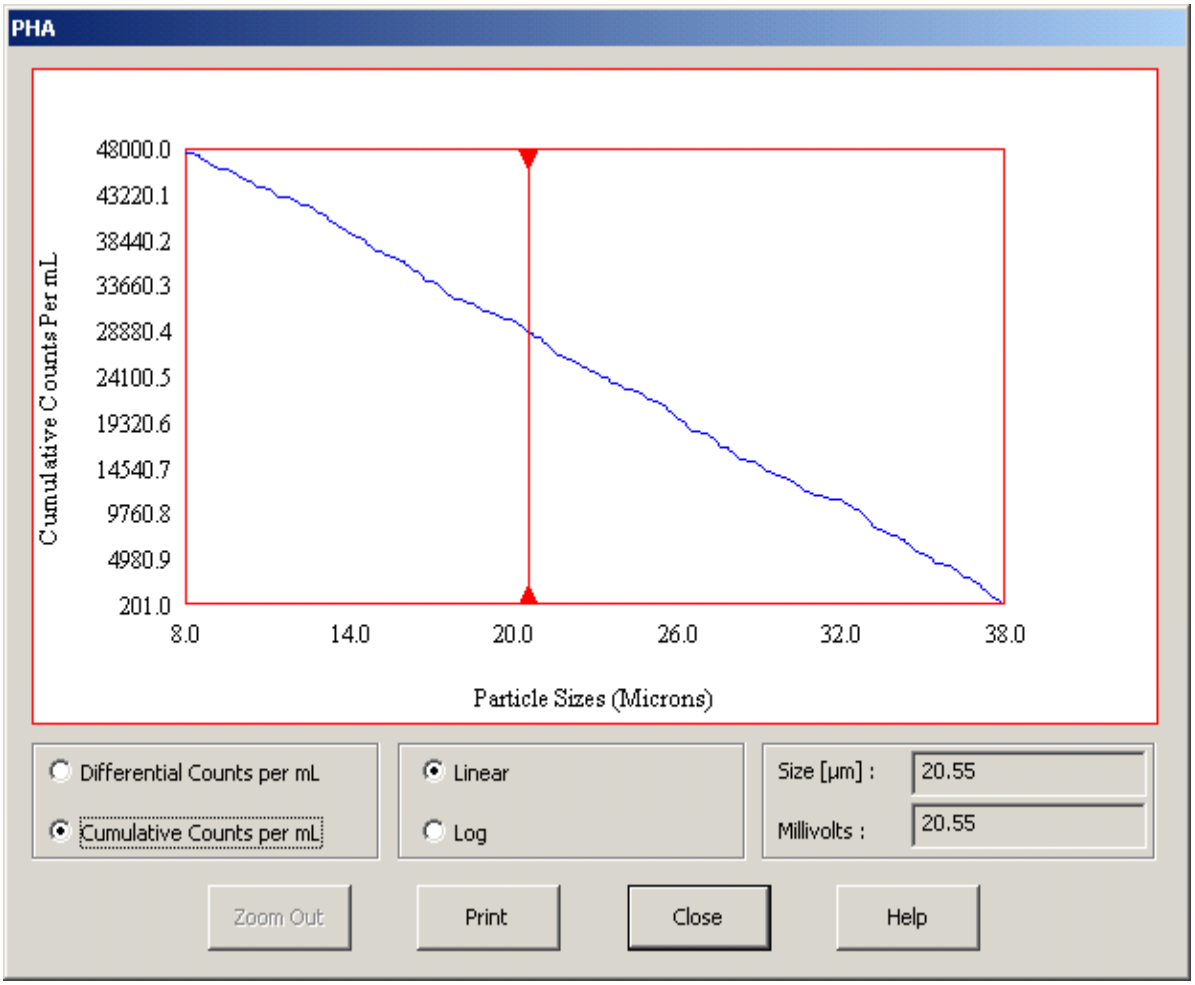

Fig 12-2 : PHA for Cumulative Counts per mL

You can view the PHA results in either Log or Linear format by choosing the corresponding radio buttons. You can also print the resulting graph by clicking on the *Print* button.

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13 Help

Help is provided for all main screen dialogs and controls. Help on using Help, Help for Shortcut Keys, Help Contents and About info of PharmSpec 2 are displayed.

13.1 Using Help

The user can get the details of how to use the help by choosing ***Help > Using help***.

13.2 Help on Shortcut Keys

The user can get help on shortcut keys by choosing ***Help > Help on Shortcut Keys***.

13.3 Contents

The user can get the entire help contents listed by choosing ***Help > Contents*.**

13.4 About PharmSpec 2

The user can get the details about PharmSpec, and its version, by choosing ***Help > About*** PharmSpec 2.

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14 Procedure Builder

Procedure Builder is an optional utility to create custom procedures for PharmSpec 2. It also allows you to load an existing test procedure, copy it, modify the copy and save it under another name. A custom procedure thus created will be available in the PharmSpec 2 procedure list and can be run just like any other licensed test procedure.

Each test procedure is associated with a report template. The Procedure Builder also allows you to define a new report template or import an existing one, copy it, modify the copy and save it in another name.

You can start this utility using: **Start > Programs > PharmSpec 2 > Procedure Builder**.

Before starting this utility, **please close the PharmSpec main application or the Procedure Loader if either of these applications is running on the system.**

Fig 14-1 : Procedure Builder

The access to this utility is restricted only to the privileged users (Supervisor / Administrator). User validation is done using the User ID and password. This module has the System Lockout, user Logout and User Lockout features.

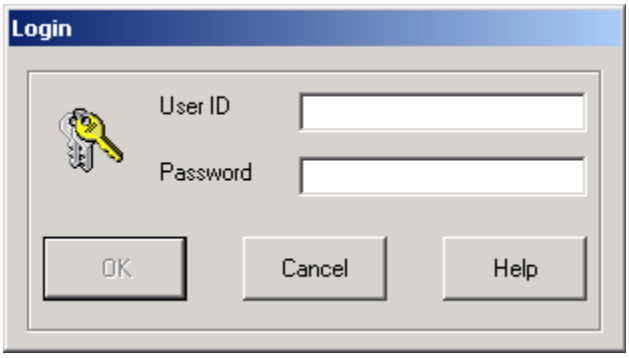

Fig 14-2 : Procedure Builder Login Dialog

Procedure Generation is a step-by-step procedure. You can go back to a previous dialog if required. At each step, the user defines the data to be collected, the calculation to be done with the results, and the rules for running the test. The procedures once created and saved cannot be modified later. To modify an existing procedure, a copy is created. Changes are made to the copy and the modified copy is stored under a new name.

There are 4 options on the main menu:

- **Procedure:** To load or create a test procedure
- **Report:** To load or create a report template
- **Help:** Online Help
- **Exit:** To exit the Procedure Builder application

14.1 Load / Create Test Procedure

From this dialog, you can create a new test procedure or Load an existing test procedure, copy it, modify the copy and then save it under another name. Click the Cancel button to close the dialog.

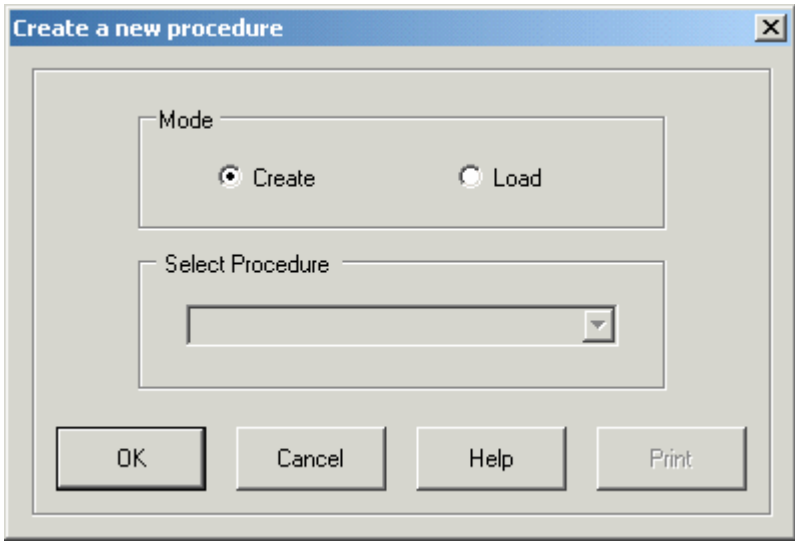

Fig 14-3 : Create New Procedure Dialog

a) **Create**

To create a new test procedure, select the *Create* option (radio button) and click the *OK* button. This will take you to Step 1 of the Procedure Builder steps.

b) **Load**

This option can be used if you want to make some minor user-defined variant of an existing test procedure or to view the details of an existing test procedure. For this, select the *Load* option (radio button). Now, the *Select Procedure* selection window box will be enabled and you can select the required procedure from the list. Click the *OK* button after selecting the required test procedure. This will take you to Step 1 of the Procedure Builder steps.

14.2 Procedure Builder Steps

a) **Step1: Define Sample Identifiers**

You can define the sample identifier names (e.g. Lot ID, Batch ID). A maximum of six sample identifiers can be defined for a procedure. These create fields that the operator must respond to at the beginning of the resulting test process.

You can select the number of sample identifiers required and only that many fields are activated.

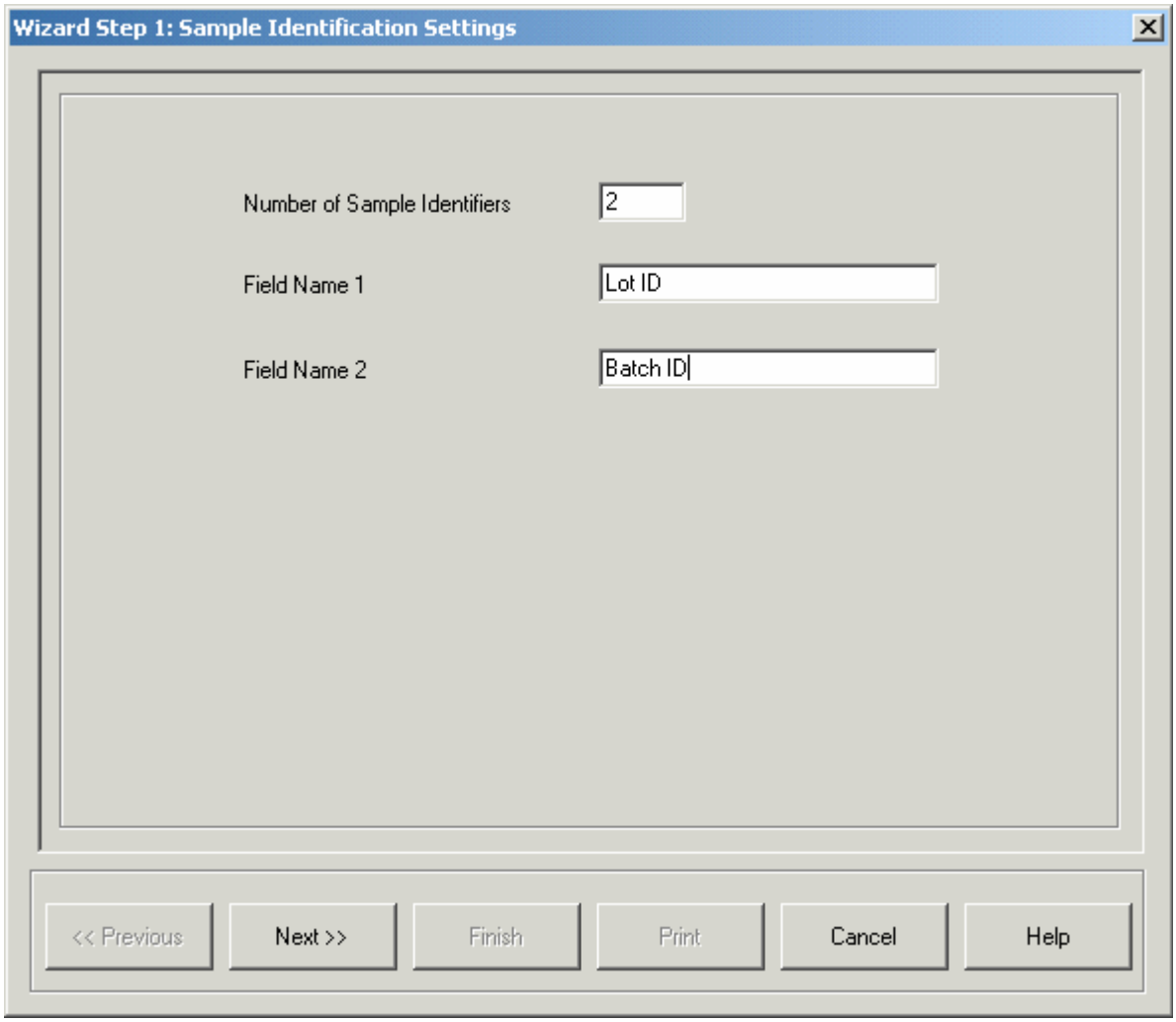

Fig 14-4 : Sample Identification Settings Dialog

After configuring the sample identifier names, click the *Next* >> button.

b) Step 2: Define computation methods and parameters

Next, you configure the computation method, the parameters and their attributes.

First select the Primary Computation method from the selection window box. Based on the Primary Computation method selected, the Secondary computation will be automatically listed.

Parameters for the selected primary computation will be listed in the Computation Parameter Grid. The parameters include the sample Size, Number of containers; minimum number of runs etc. and this depends on the computation method selected. You cannot select a parameter more than once.

Some of these parameters may be constant values and some (like sample volume) need to be collected when the operator runs the test.

Configure the values for the Minimum limit, Default value, Maximum Limit and the mode. The mode shall be Read Only, Read/Write or Invisible.

- Read Only mode means the value cannot be modified while running the test; but the value will be displayed in the screen.
- Read/Write means the value will be displayed in the screen and also can be modified while running the test.
- Invisible mode is used to configure internal parameters which are not required to be visible while running the test.

The check box *Discard First Run* can be checked if the results of the first run of the test should not be included in the calculations. If this option is selected, the data from the first run will be displayed and saved but will not be used in any of the following calculations, such as computing averages, etc.

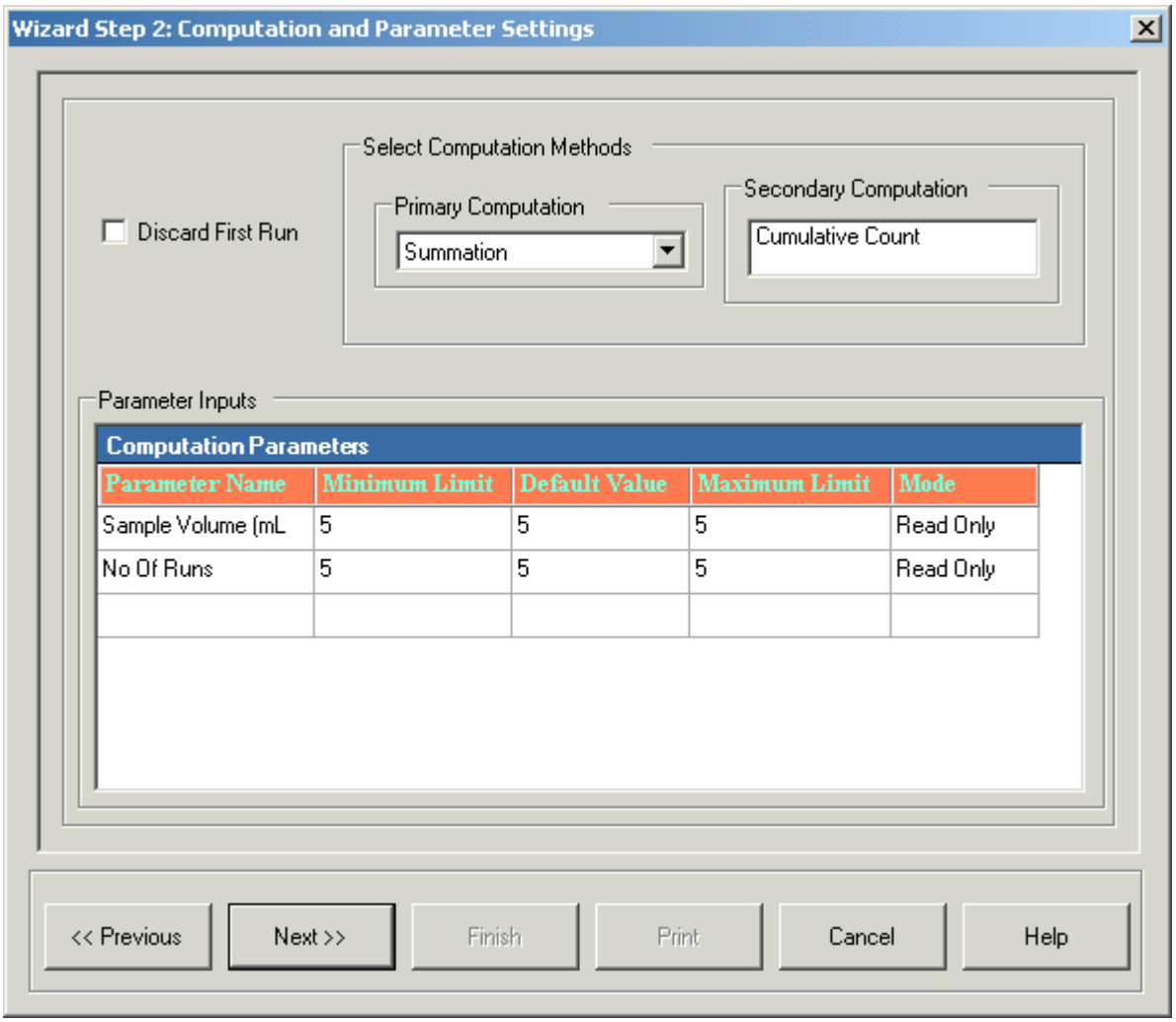

Fig 14-5 : Computation and Parameter Setting Dialog

The *Next* >> button will be enabled when all values are entered. If invalid data is entered, appropriate messages will be shown to the user. To reset the grid select the primary computation once more.

Clicking on the *Next*>> button takes you to the next step.

Clicking on the <<*Previous* button takes you to the previous step. Click the *Cancel* button to close the dialog. Click the *Help* button to get to the Help function.

c) Step 3: Define Pass / Fail Criteria

In this step, you can configure the PASS/FAIL criteria for the test procedure.

The user can define the counts (Sum / Average) of a particular particle size per unit volume (mL / Container) required for the test to be declared, “passed”. The PASS criteria may consist of one or more particle sizes.

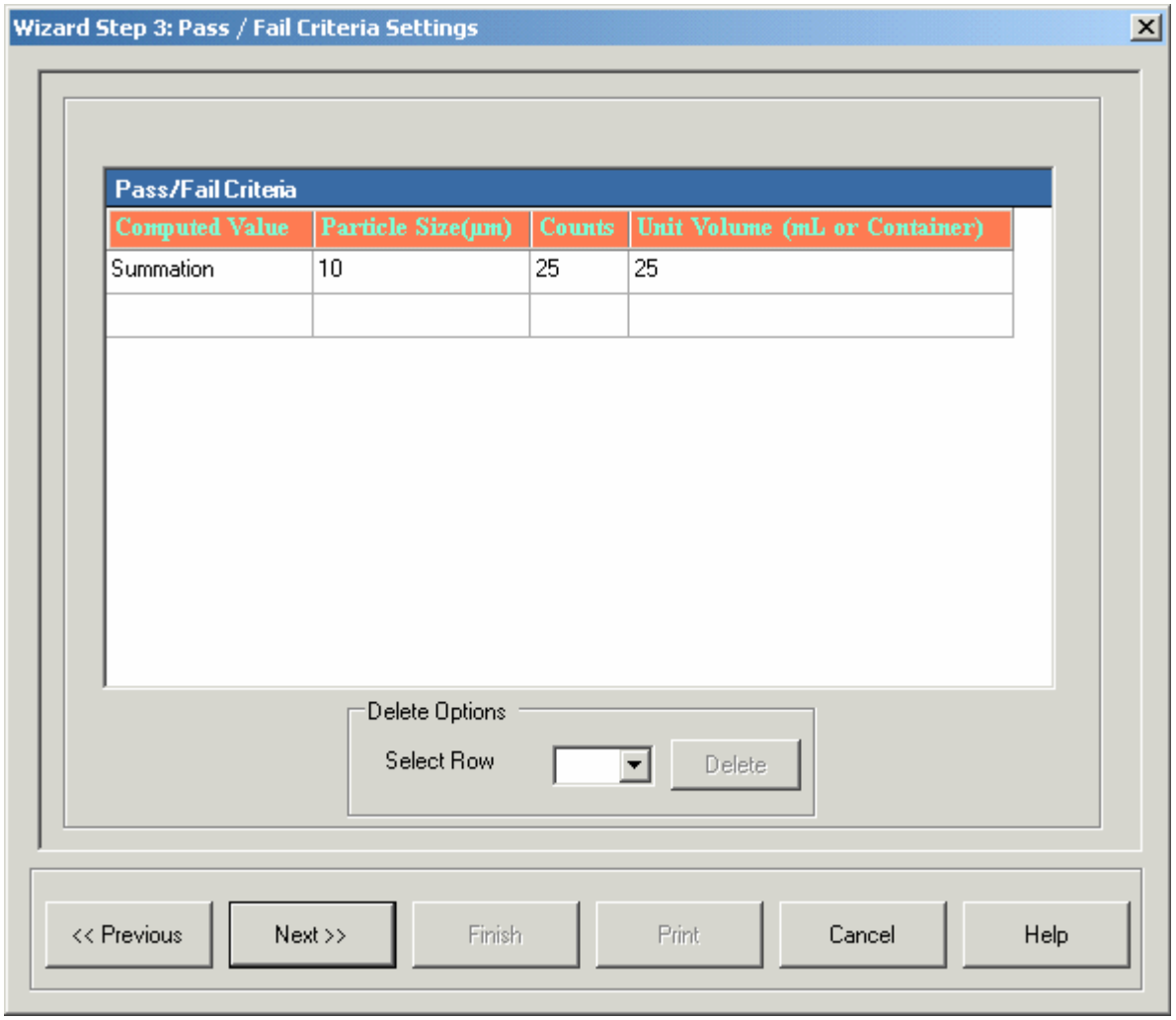

Fig 14-6 : Pass / Fail Criteria Setting Dialog

You can go to the next step by clicking on the *Next*>> button or go back to the previous steps by clicking on the <<*Previous* button

d) Step 4: Define Help Details

In this step, you can configure the operator instructions to be displayed in the screen during the test run. These instructions are displayed on the top left corner of the window while running the test.

Type the required text in the window. The maximum number of characters that can be entered is 166.

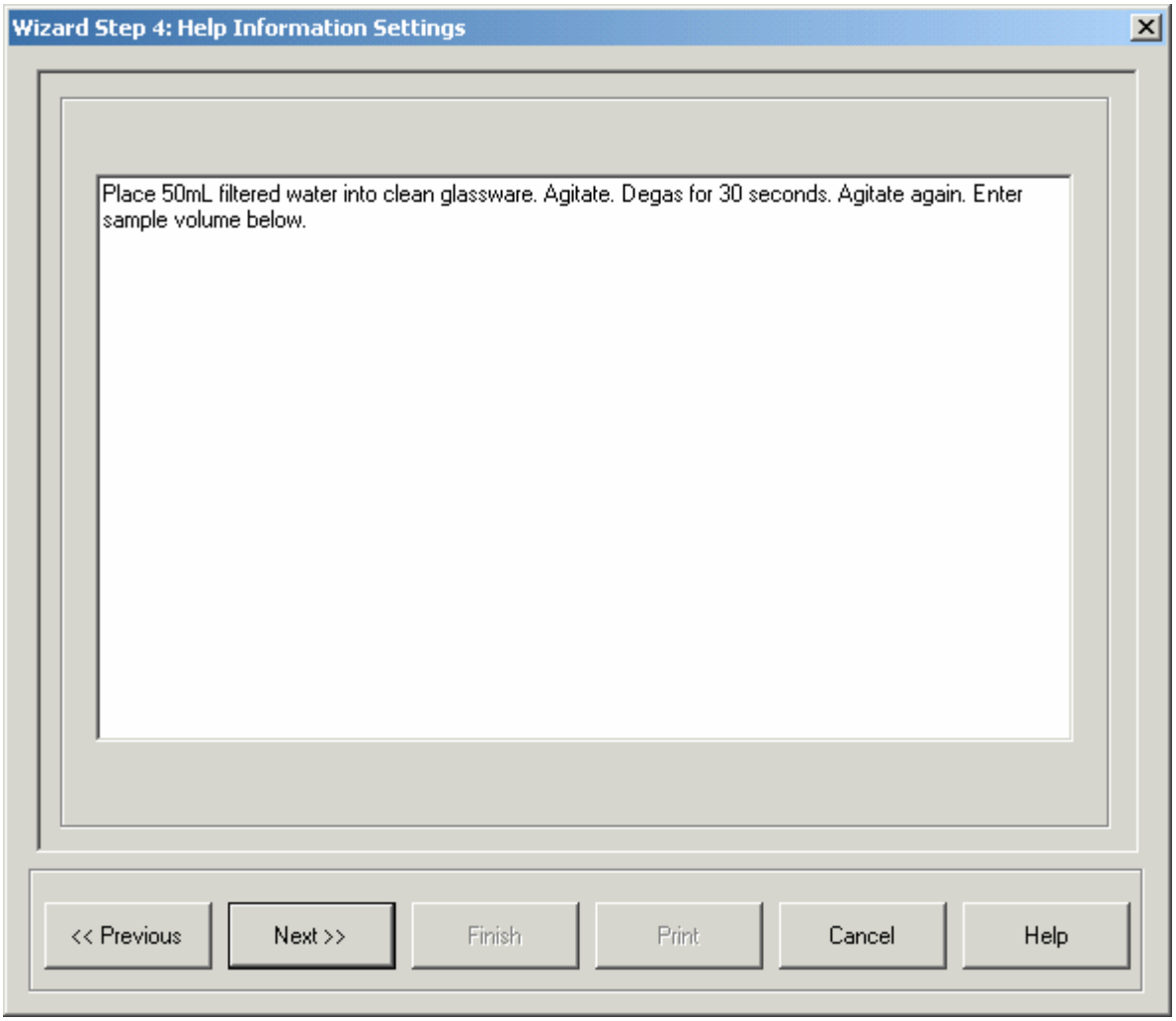

Fig 14-7 : Help Information Setting Dialog

You can go to the next step by clicking on the *Next* >> button or go back to previous steps by clicking on the <<*Previous* button.

e) Step 5: Define Report Template

In this step, you can specify the report template required for the procedure. When the test results are retrieved from PharmSpec, the report will be formatted as per the template configured here.

You can either create a new report template or select an existing one and associate it with the procedure being configured.

As part of the report template configuration, the content (data to be displayed) and the presentation (font, color etc.) information can defined.

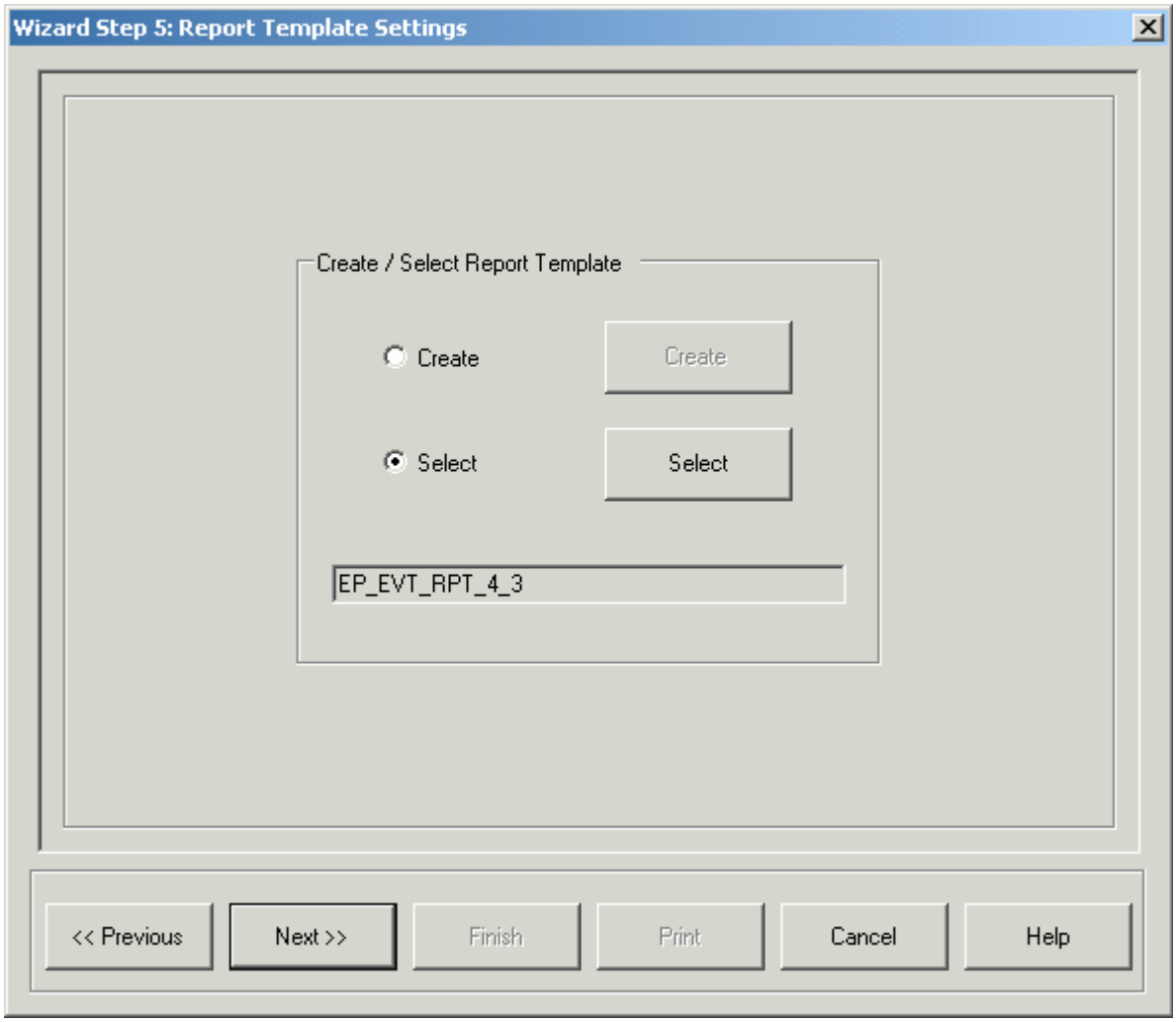

Fig 14-8 : Report Template Settings Dialog

If you want to select a report template from the available list, choose the *Select* option. This will enable the *Select* button. Now, click the *Select* button and this will pop up the report template selection dialog, enabling the user to select an existing template from the list.

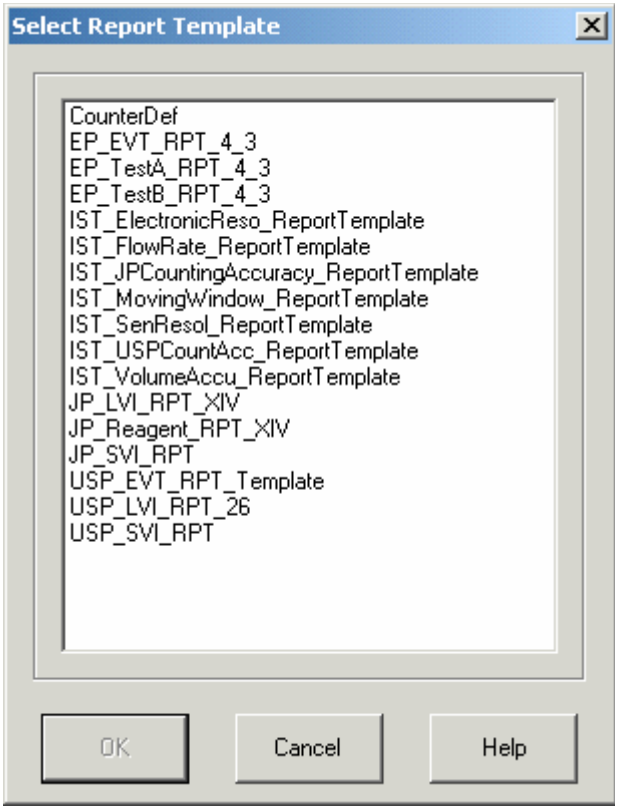

Fig 14-9 : Report Template Select Dialog

To create a new report template, select the Create option. This will enable the Create button. Now, click the Create button and this will pop up Report template wizard. You will now be guided through a series of steps to define the report template.

The user has an alternate option to create a report template from the opening dialog of the Procedure Builder (by selecting the *Report* button).

You can go to the next step by clicking on the ***Next>>*** button or go back to the previous steps by clicking on the ***<<Previous*** button.

f) Step 6: Save the procedure

In this step, you can save the configured procedure by specifying a name. Once saved, the procedure is protected and no one can modify it. If changes are needed, a copy can be created and changes made to the copy but the resulting procedure must then be saved to another name.

To set the Procedure name, first select the test type from *Test Type* selection window. The only option available as of now for the end user is *"User-Defined*". Then enter the test name. The procedure name will automatically be generated.

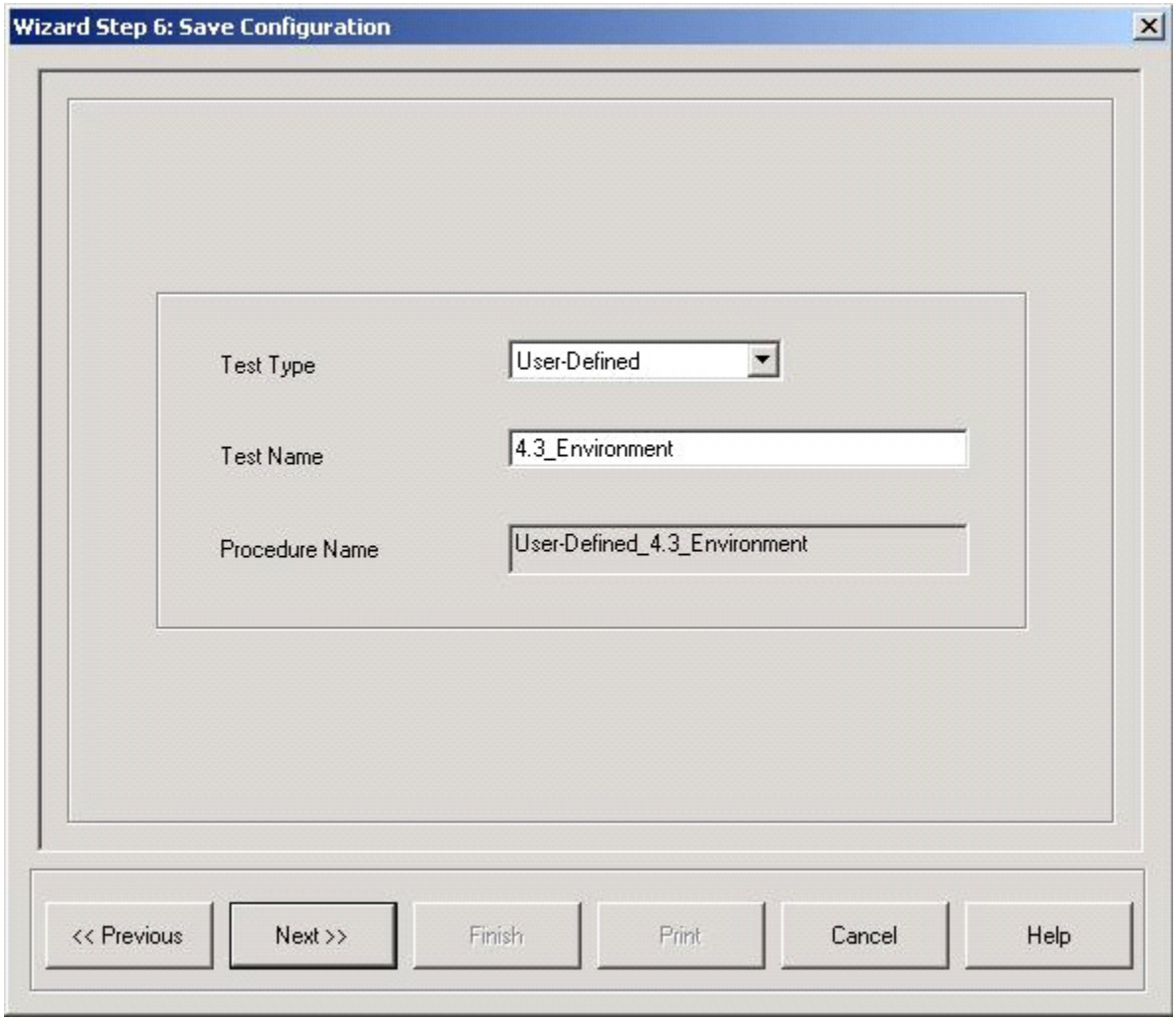

Fig 14-10 : Save Configuration Dialog

Now, click the *Next* >> button.

If the procedure name you specified already exists in the system, the following message will be shown upon clicking the *Next* >> button:

Fig 14-11 : Error Message

You can go to the previous steps by clicking on the ***<<Previous*** button.

g) Step7: Procedure Information

Here, you can view the details of the procedure just configured.

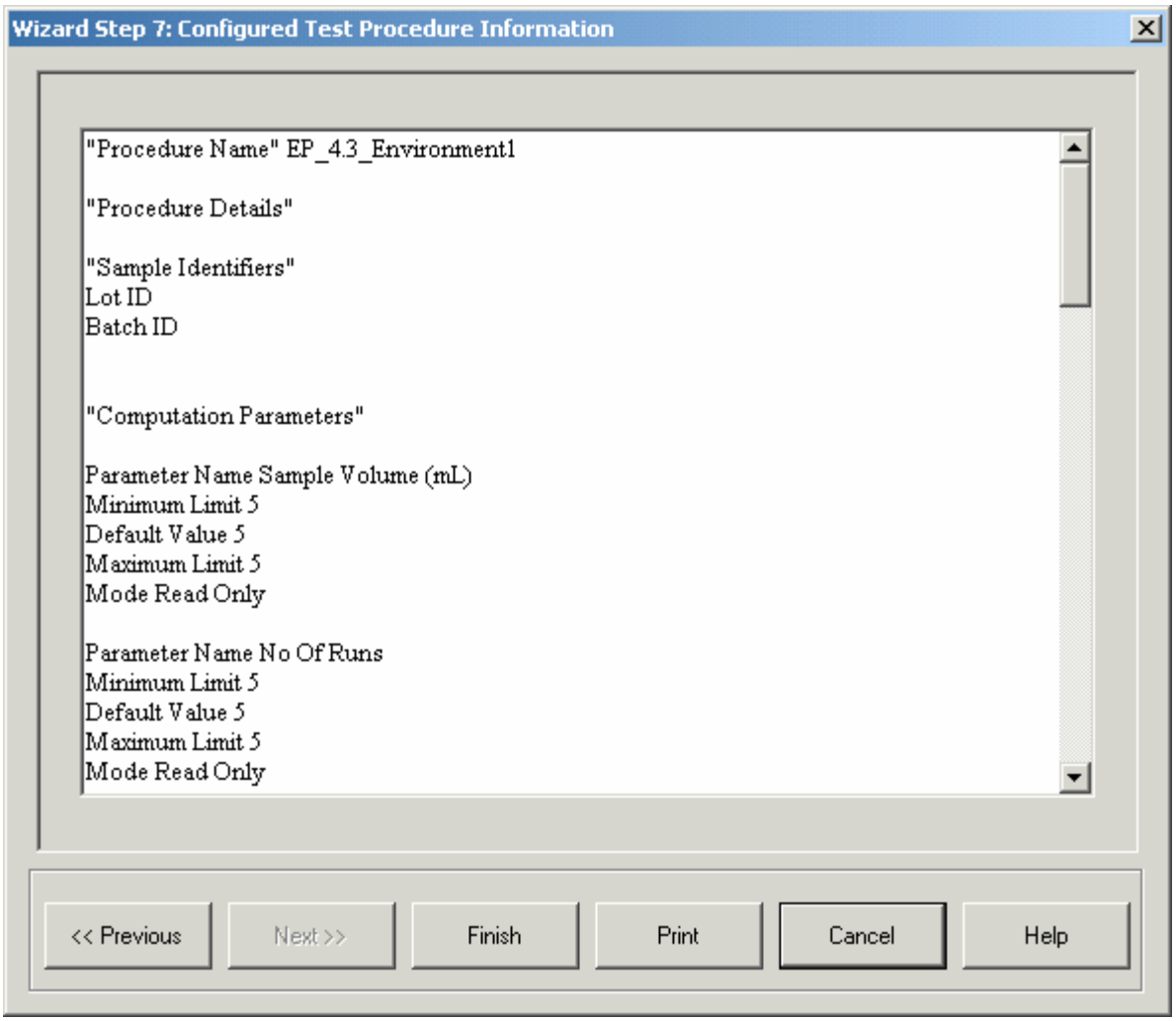

Fig 14-12 : Test Procedure Information Dialog

click the *Previous* button to go to the previous step. Click the *Finish* button to complete the configuration activity and save the procedure. If the procedure saved successfully, the following message will be shown. Click *OK.*

Fig 14-13 : Procedure Created Dialog

click the *Print* button to print the procedure details. Click the *Cancel* button to close the dialog. Click the *Help* button to activate the HELP function.

14.3 Load / Create Report Template

You can create a new report template or edit the details of an existing report template and save it to another name. The buttons ***Load*** and ***Create*** in the *Report Template* facilitate this.

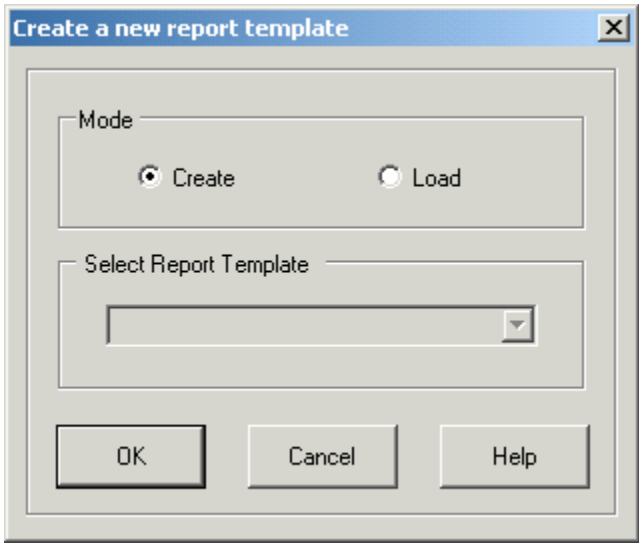

Fig 14-14 : Load / Create Report Template Dialog

a) Create

To create a new report template, select the *Create* option (radio button) and click the *OK* button. This will take you to Step #1 of the Report Template steps.

b) Load

This option can be used if you want to make some minor variant of an existing report template or to view the details of an existing report template. For this, select the Load option (radio button). Now, the Select Report Template selection window box will be enabled and you can

select the required report template from the list. Click the *OK* button after selecting the required report template. This will take you to Step 1 of the Report Template steps.

14.4 Report Template Steps

a) Step1: Configure Report Title Name

This is the first step of configuring a report template. Here, the user configures the Report Titles. A maximum of 4 titles can be configured for a report. For each title, the text of the title, its alignment font and color properties can be configured.

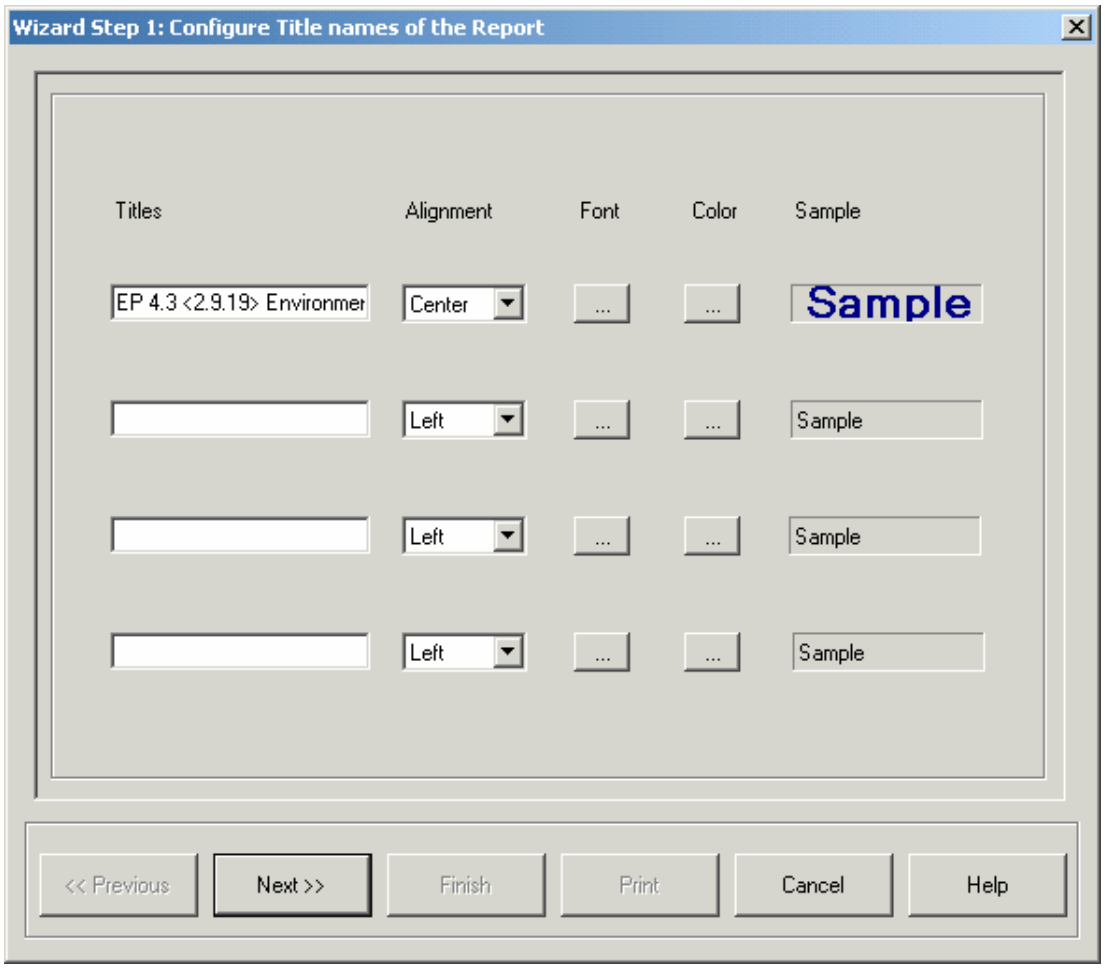

Fig 14-15 : Title Configuration Dialog

Enter the Title name in the Titles edit field. A report should have at least one title. The Next button will not be enabled without this.

You can choose the alignment option (Left, Center or Right) from the Alignment selection window. To configure the Font for the title, click the *Font...* button. To configure the color, click the *Color...* button. If the Font and the Color properties are not configured, it will use the default values. A sample text will be displayed for previewing the font and color properties.

click the *Next>> button* to go to the next step. Click the *Cancel* button to close the dialog. Click the *Help* button to get the help.

b) Step 2: Configure Fields

In this step, you can configure the headers for the data to be shown in the report. The color and font properties of the headers are also set here.

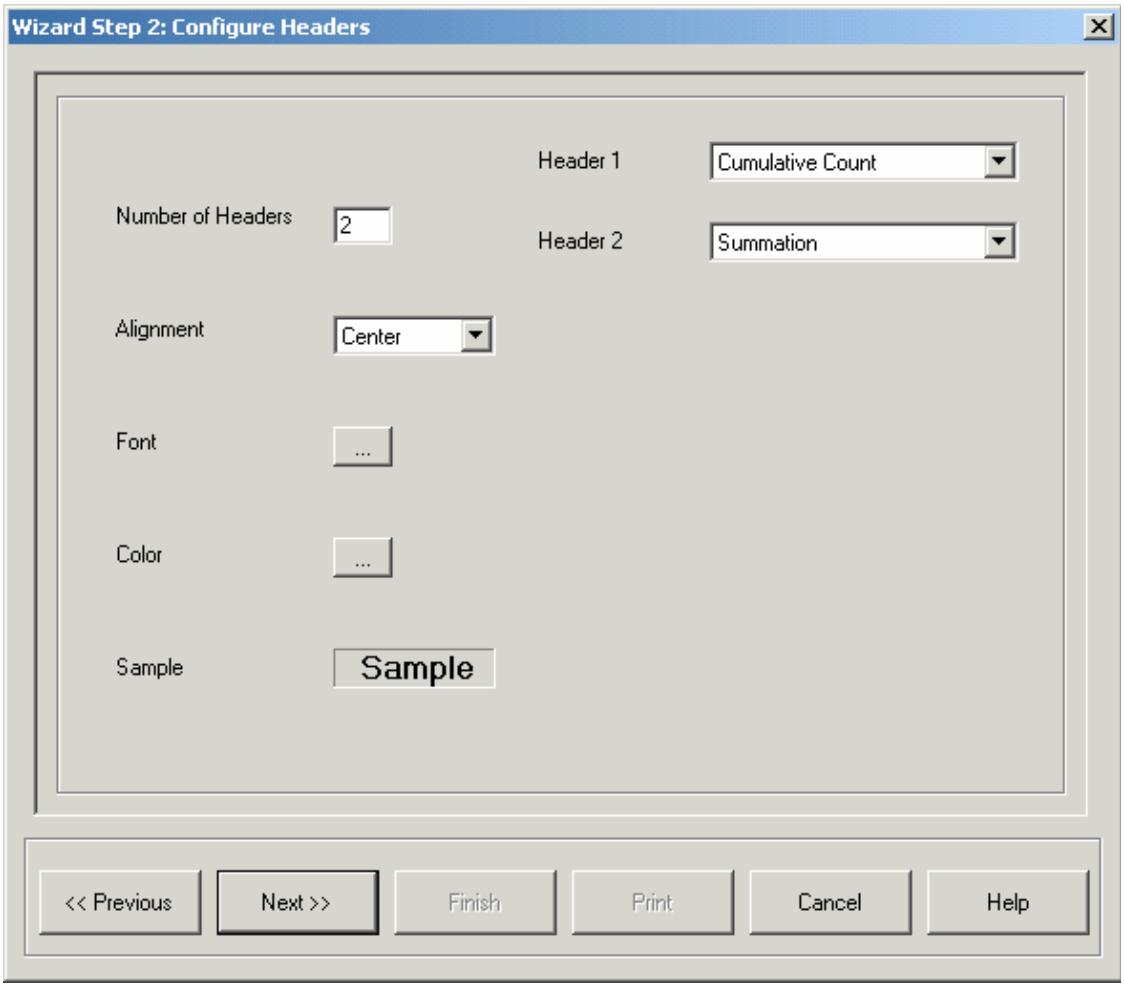

Fig 14-16 : Field Configuration Dialog

Header represents the result data that is displayed for each test run. To configure the headers, first enter the number of headers required. According to the number of headers, the header selection boxes will appear. Select the header names from these boxes. For example it could be Size, Cumulative count or particles/mL The user can configure up to a maximum of 8 fields.

The user can choose the alignment option (Left, Center or Right) for the headers from the Alignment selection window. This will placed the header at the selected position at the top of the related column.

To configure the Font for the headers, click the *Font...* button. To configure the color, click the *Color...* button. If the font and the color properties are not configured, it will use the default values. A sample text will be displayed for previewing the font and color properties.

click the *Next>> button* to go to the next step. Click the *Cancel* button to close the dialog. Click the *Help* button to get the help.

c) Step 3: Configure Test Parameters and Result

Here, you can specify the font and color properties for the parameters (such as sample identifiers, sample volume etc.) and the Result data.

Test parameters are the parameters displayed at the top of the report. These include the sample ids, the user who has run the test, sampler model, sensor serial, sample date, total number of runs, or sample volume. The user can specify the alignment (left, right or center) and the font properties. Font details include the font style, size, color, and the attributes of the font (bold, italic etc.).

Test result is the result obtained after running the test. The user can specify the alignment of the result value in each column (left, right or center) and the font properties. Font details include the font style, size, color, and the attributes of the font (bold, italic etc.).

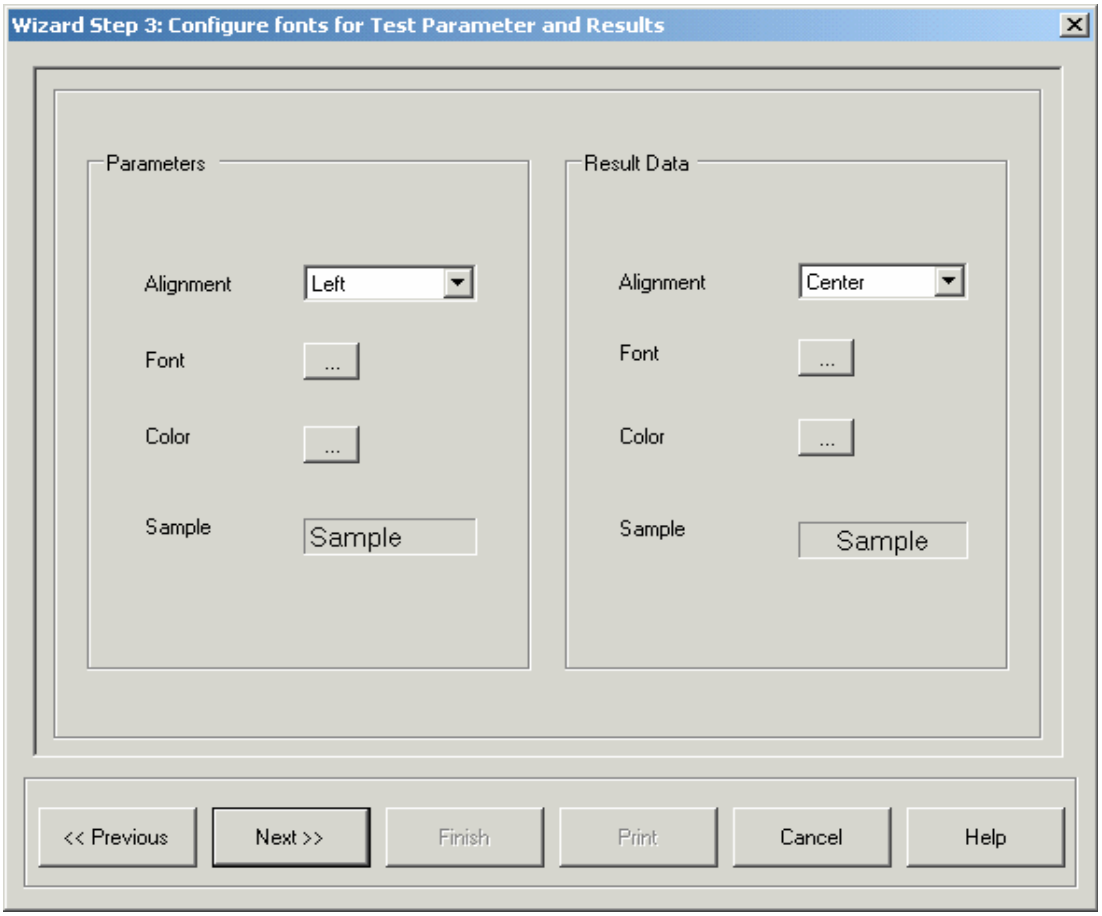

Fig 14-17 : Test Parameters and Result Configuration Dialog

To configure the Font for the parameters, click the *Font...* button in the Parameter group box. To configure the color for the parameters, click the *Color...* button in the Parameter group box. Similarly, the Font and Color can be configured for the Result Data by clicking on the respective buttons in the Result Data group box. If the Font and the Color properties are not configured, it will use the default values. A sample text will be displayed for previewing the font and color properties.

click the *Next>> button* to go to the next step. Click the *Cancel* button to close the dialog. Click the *Help* button to get the help.

d) Step 4: Preview Report Template

Here, you can preview the configured report template.

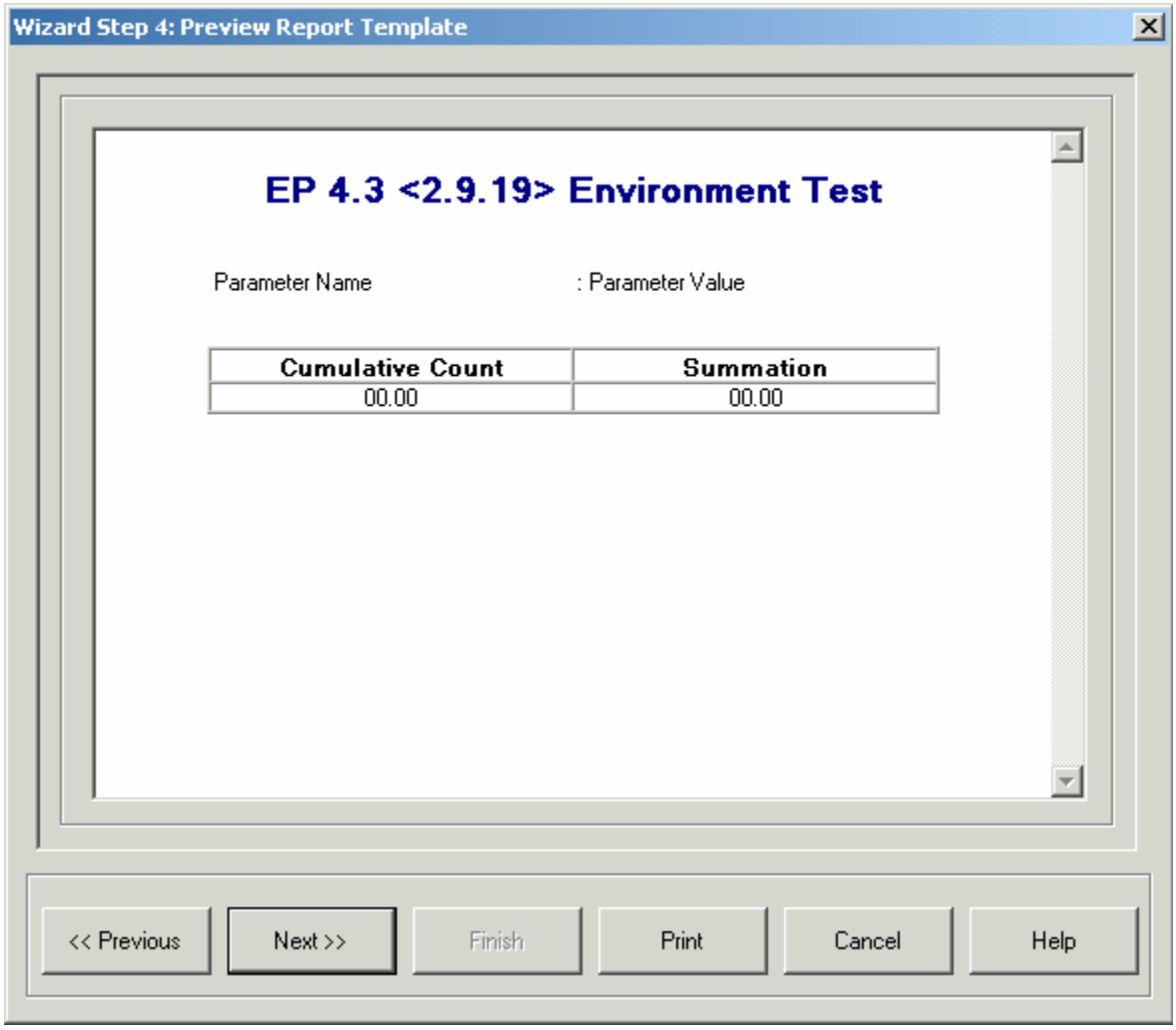

Fig 14-18 : Report Template Preview Dialog

click the Next>> button to go to the next step. Click the Cancel button to close the dialog. Click the Help button to get the help.

e) Step 5: Save Report Template

In this step, you can specify the name for the configured report template and save it.

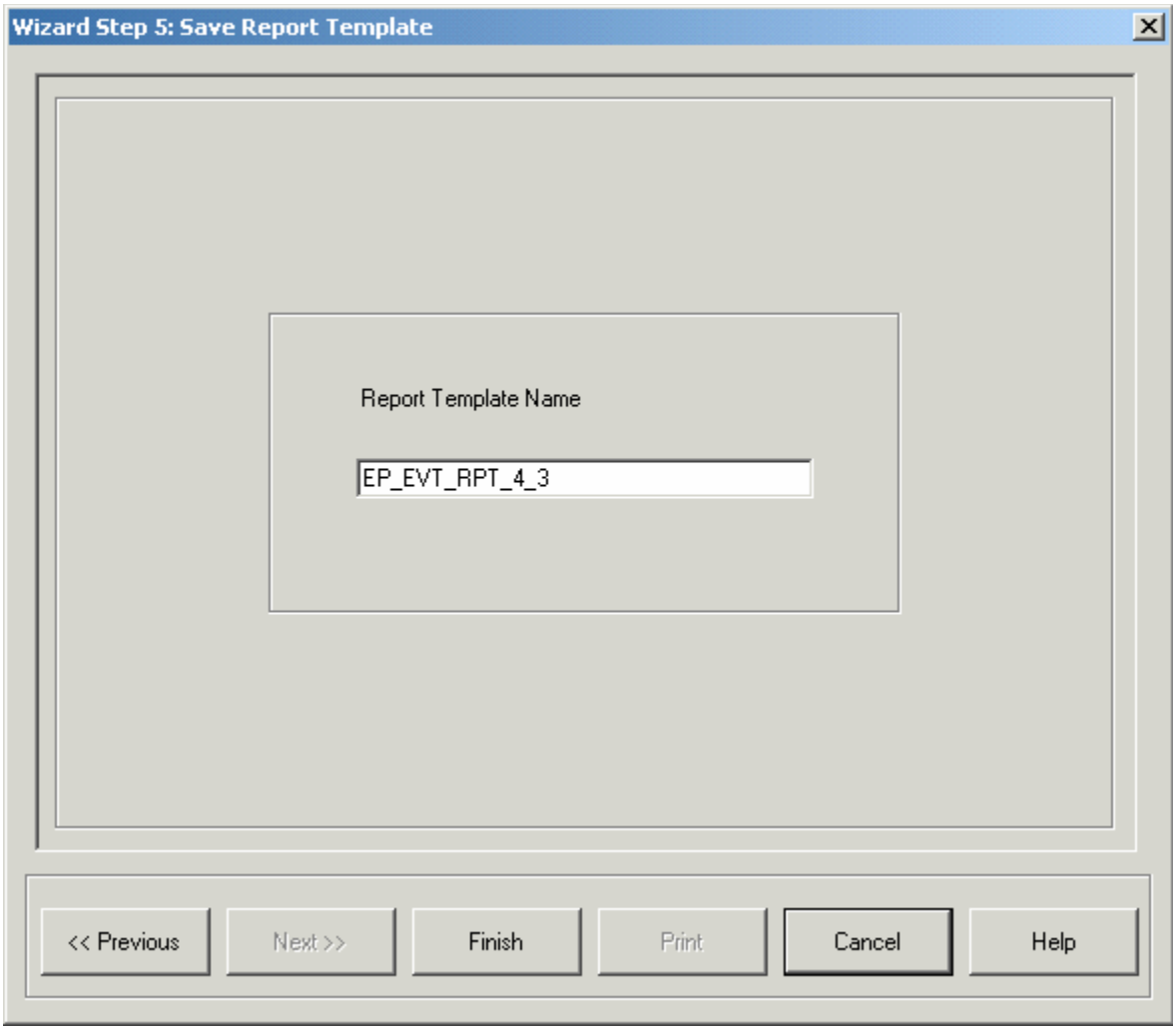

Fig 14-19 : Save Report Template Dialog

click the Previous button to go to the previous step.

You can enter the name for the report template in the edit box and then click the *Finish* button to save the report template.

While saving the template, if the user specified report template name already exists in the system, the following message will be shown.

Fig 14-20 : Save Report Template Error Message

On successful save operation, a confirmation message will be shown.

15 Database Restorer

This utility is used to restore the data from the backup or archived files.

You can start this tool using: **Start > Programs > PharmSpec 2.1 > Database Restorer**.

Before starting this utility, please make sure that the PharmSpec main application / Procedure Builder / Procedure Loader is not running in the system.

The access to this utility is restricted only to the privileged users. Being a database restoration utility, it has a separate user account and does not use the PharmSpec user accounts. User validation is done using the User ID and password. The installation comes with a default User ID “admin” and password “123456”.

After successful login, it pops up the *Database Restore* dialog.

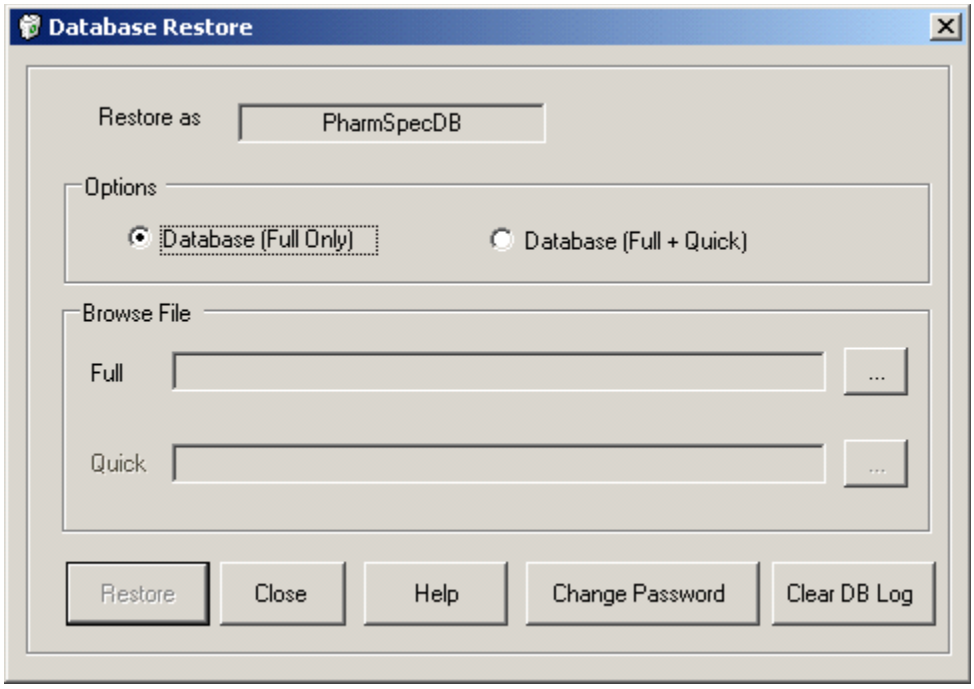

Fig 15-1 : Database Restore Dialog

The “Restore as” field shows the PharmSpec database name.

There are two options for the database restoration:

- Database (Full Only)
- Database (Full + Quick)

After selecting one of the options, you have to select the files (backup / archive) from which the data is to be restored. Based on the restoration option selected (Full Only / Full + Quick), you need to select both or either of the files. To select the file, click the respective button having caption **...**. This will invoke a file selection dialog.

After selecting the file(s), click the *Restore* button.

User must note that *computer should be RESTARTED before running the Restore application.*

You can change the password of this utility by clicking on the *Change Password* button.

16 Procedure Loader

Procedure Loader is a utility to upload licensed test procedure updates from a distributable procedure update pack. Whenever the procedures undergo change, Hach Ultra Analytics personnel will create new test procedures, validate them and generate a distributable pack of the procedure updates for the end users. Hach Ultra Analytics will distribute this to the users (depending on the service agreement or contract terms with Hach Ultra Analytics or at the discretion of Hach Ultra Analytics) in the form of a checksum protected database (MS Access) file. The end users can load the procedure updates from the distributable pack using this utility

You can start this tool using: **Start > Programs > PharmSpec 2 > Procedure Loader**.

Before starting this utility, please make sure that the PharmSpec main application or the Procedure Builder is not running in the system.

Fig 16-1 : Procedure Loader

The access to this utility is restricted only to the privileged users (Supervisor / Administrator). User validation is done using the User ID and password. This module has the System Lockout, User Logout and Lockout features.

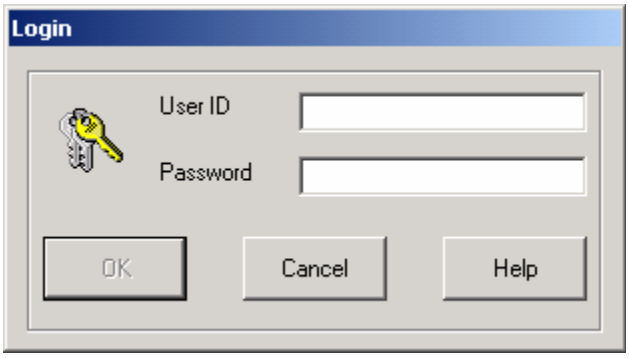

Fig 16-2 : Procedure Loader Login Dialog

This is a separate application. On entering a valid User ID and password, the Procedure Loader is launched.

There are 3 options on the main menu:

- **Load:** To load a test procedure
- **Help:** Online Help
- **Exit:** To exit the Procedure Loader application

To load a new procedure, click the *Load* button. Now, you will be prompted to select the procedure update file (MS Access file with .mdb extension) distributed by Hach Ultra Analytics. It is assumed that the database file is available in one of the local or network drive folders.

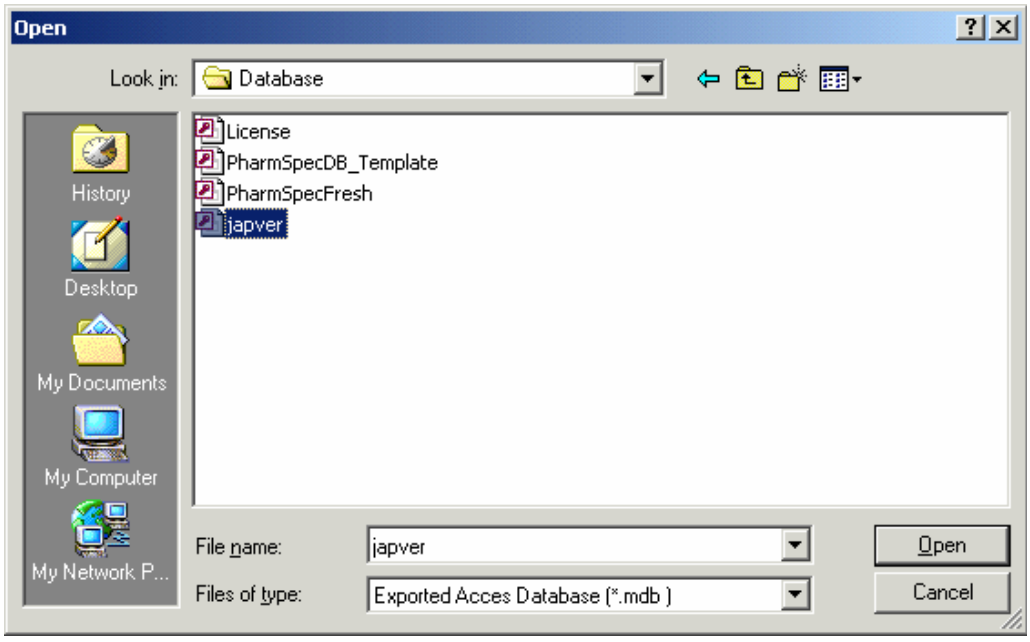

Fig 16-3 : Procedure Export File Selection

After selecting the database which contains the required procedure updates, click the *Open* button.

Now, you will be prompted to enter the license key.

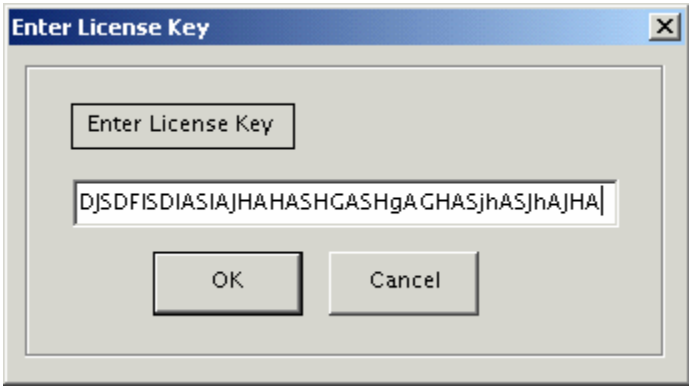

Fig 16-4 : License Key Validation Dialog

After entering the license key, click the OK button to proceed. Click the *Cancel* button to close the dialog and return to main dialog.

If the license key is valid, the *Procedure Loader* dialog will appear on the screen that will list the procedure updates, which are licensed to the user. The Master Procedure(s) list contains the licensed procedure updates.

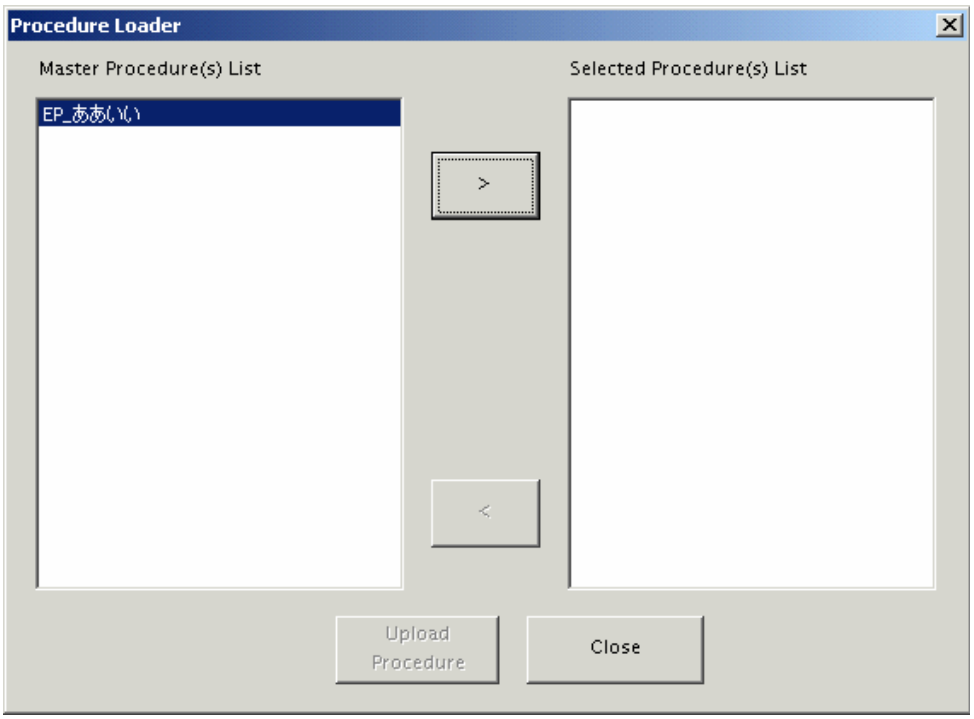

Fig 16-5 : Procedure Selection Dialog

Select the required procedures one by one from this list (selected procedure will be highlighted) and click the > button so that it is moved to the Selected Procedure(s) List.

From Selected procedure list, a procedure can be moved back to the Master procedures list by selecting it and clicking on the < button.

Once the all required procedures are moved to the Selected procedures List, user has to click the Upload Procedure button to upload the procedure updates to the PharmSpec database.

On successful uploading of the procedure updates, a confirmation message will be shown. Click the *Close* button to close this message box.

click the *Close* button from main dialog to exit from the Procedure Loader application.

17 PharmSpec Admin Tool

The PharmSpec Admin tool is used to reset the PharmSpec system configuration.

This application is not installed in your system during PharmSpec installation. You can run this utility directly from the PharmSpec CD (***AdminUtility**\ ***AdminTool.exe***).

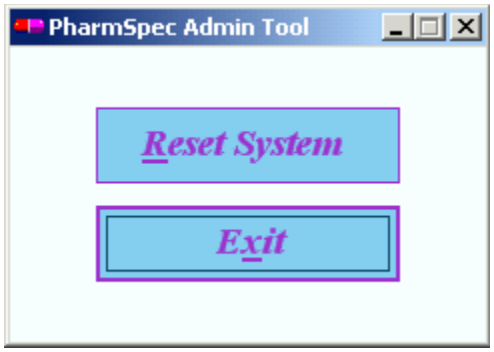

Fig 17-1 : PharmSpec Admin Tool

To reset the PharmSpec System's administrator password to the default password of 123456, click the *Reset System* button.

Click the *Exit* button to exit from the tool.

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18 PharmSpec License Update Tool

This tool is used to update the PharmSpec Software license key. The software can be upgraded to licensed mode even if initially it is installed in the Demo mode. Also the software license can be updated when you buy additional software plug-in modules or the Test Procedures from Hach Ultra.

You can start this tool using: **Start > Programs > PharmSpec 2 > License Update**.

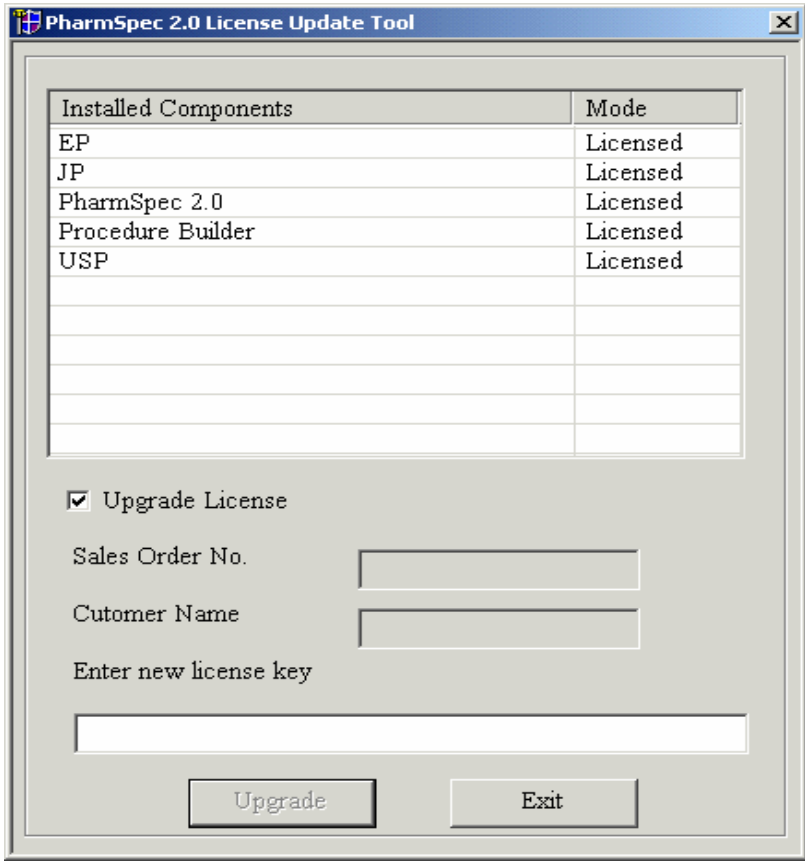

Fig 18-1 : PharmSpec License Update

In this dialog, you can see the current status of installed modules / components and the license mode (licensed / demo) mode.

To update the license, check the *Upgrade License* check box. If PharmSpec was installed in Demo mode, then user will have to enter the Sales Order Number, Customer Name and the license key in the respective fields. If you are already a licensed user, you need to enter only the new license key. After this, click the *Upgrade* button.

The License Tool will validate the license key, and update the license of PharmSpec. If the license key entered is invalid (it will validate the Sales Order Number, Customer name etc.), an error message will be shown. click the *Exit* button to close the License Update Tool.

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19 PharmSpec Simulation Application

This tool is used to set the parameters and ranges for simulated data that is used in the procedures and IST tests while simulation mode is active. The details that are input will be used by the PharmSpec application while in the Simulation (Demo) mode.

You can start this tool using: **Start > Programs > PharmSpec 2 > Simulation Application**.

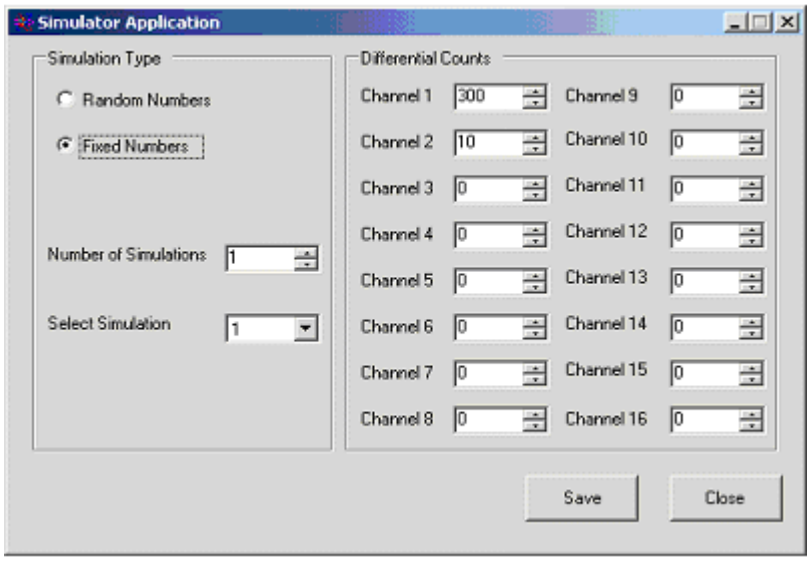

Fig 19-1 : Simulator Application Window

The user can select the Random number mode or a Fixed number mode for the simulation. If the user selects the Random number mode, then all the test run results will be random.

To use the fixed number mode, follow the steps below:

1) Select the number of simulations. There can be a maximum of 10 sequential simulations.
2) From the Select Simulation selection window box, the user can select which one of the simulation sequences (first, second, third, etc. depending on the number of simulations selected) is to be displayed.
3) Once the user selects the simulation from the selection window box, the user can fill in the channel values required. There can be a maximum of 16 channels for each simulation. Please note that this will be the *differential count* and the application will calculate the cumulative counts based on this. The actual number of size channels and the size label for these channels is set in the Main Application using *Hardware Settings.*

At a later stage, if the user wants to cut down the number of simulations from a previous setup (say from 10 to 5), the user can just change the number of simulations to 5 and save. The application will now use only the data listed in 1 through 5 to perform the next simulations.

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Appendix A: Service Information

A.1 Technical Support Information

Technical Support Engineers are available to provide high quality advice and recommendations for applications, product operation, measurement specifications, hardware and software, factory and customer site training.

Please provide name, company, phone, fax, model number, serial number and comment or question.

Call +1 (541) 472-6500
Toll Free (800) 866-8854 (US/CA)
Fax +1 (541) 474-7414
6:00 AM to 5:00 PM Pacific Time
Monday through Friday
Email: TechSupportGP@hachultra.com

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Annex

Tables and illustrations

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User Notes

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