701169

PortAll Software Version 2

User Manual

11/2013, Edition 6

Section 1 General information

The information in this manual has been carefully checked and is believed to be accurate. However, the manufacturer assumes no responsibility for any inaccuracies that may be contained in this manual. In no event will the manufacturer be liable for direct, indirect, special, incidental or consequential damages resulting from any defect or omission in this manual, even if advised of the possibility of such damages. In the interest of continued product development, the manufacturer reserves the right to make improvements in this manual and the products it describes at any time, without notice or obligation.

Revised editions are found on the manufacturer's website.

1.1 Safety information

Please read this entire manual before unpacking, setting up or operating this equipment. Pay attention to all danger, warning and caution statements. Failure to do so could result in serious injury to the operator or damage to the equipment.

Make sure that the protection provided by this equipment is not impaired, do not use or install this equipment in any manner other than that specified in this manual.

1.1.1 Use of hazard information

⚠WARNING

Indicates a potentially or imminently hazardous situation which, if not avoided, could result in death or serious injury.

⚠CAUTION

Indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury.

NOTICE

Indicates a situation that is not related to personal injury.

Note: *Information that supplements points in the main text.*

1.2 General product information

PortAll Version 2 Software retrieves and stores count data from one or more particle counting devices in local or remote environments. The count information is shown in spreadsheet format.

PortAll also allows the user to graph and save data. Tabular data can be saved as a .csv file using either a comma separator or TAB separator. Graphed results can be exported in several formats: .jpg, .bmp, .png or text only. Calculated results in the compliance standards reports can be exported in several formats: .pdf, .slx, .doc or .rtf.

The count data can be retrieved automatically at pre-scheduled times, or retrieved on demand. All retrieved raw data is saved in a secure database.

PortAll Version 2 provides an EU GMP Annex 1 report in addition to FS209E, ISO 14644-1, and BS5295 reports.

1.2.1 Standard vs. Life Sciences version

The Life Sciences version of PortAll adds specific capabilities to Standard PortAll, including expanded user security and audit trails. These differences are listed in Table 1. The possibility to access the Life Science functionality is determined by the license code.

Table 1 Standard vs. Life Sciences PortAll

Standard Version	Life Sciences Version
Password required only for: • Adding new hardware • Editing hardware descriptions • Scaling/normalization configuration • New location setup • Editing groups • Adding or revising schedules	Unique login required for all functions
Password required to login	Unique user ID and password required to login
One level of user permissions	Two levels of user permissions: • Operator • Administrator
Password protection	Password protection that includes: • Minimum password and user ID length • Password expiration dates • Lock-out features after a number of failed attempts • Automatic lock-out after a period of inactivity • Ability to temporarily or permanently lock-out individual user accounts
No audit trail	Secure audit trail

1.2.2 Supported particle counters

The particle counters that are supported by PortAll Version 2 are shown in Table 2. Firmware revision numbers are current at time of publication; contact the manufacturer for the most current information.

Table 2 Buffered particle counters supported by PortAll Version 2

Counter Model	Brand	Firmware Revision
CNC 1104	MET ONE	2081814-1-D
227	MET ONE	2082513-1B
237	MET ONE	2084270-1-D
WGS 267	MET ONE	2081407-1E
21xx	MET ONE	2084265-1-L
22xx	MET ONE	2084265-1-L
2400	MET ONE	2084265-1-L

Counter Model	Brand	Firmware Revision
2408	MET ONE	2084265-1-L
3300 Series	MET ONE	2084053-1-L
3400 Series	MET ONE	4.02.06
3411 Series	MET ONE	4.02.06
HHPC-2	ARTi, MET ONE	CS100015
HHPC-6	ARTi, MET ONE	2087005-1-D

Section 2 Installation

NOTICE

Installing PortAll to comply with standards and regulations such as 21 CFR Part 11 requires that the files and installation CD-ROM be kept in a secure location. This requires administrator-level permissions in the Microsoft® Windows environment. Make sure that the user installing PortAll is a Windows administrator before proceeding.

2.1 Computer requirements

Hardware Minimum Recommended

CPU type Intel® Pentium® IV 1 GHz processor 32bit (x86) or 64bit (x64)

Free Disk Space 1.5 GB

Memory: RAM 512 MB (32bit (x86) or RAM 1 GB RAM 64bit (x64)

Video Display: SVGA 800X600 256 Colors

Serial port required for 237, 2100, 2400, 3300 etc. series particle counter.

One available USB port required for 3400 series particle counters

Supported Operating Systems

- Microsoft Windows XP Professional (SP2 or greater)
- Microsoft® Vista Professional (32 bit and 64 bit)
- Microsoft® Windows 7 (32 bit and 64 bit)
- Microsoft® Windows 8 (32 bit and 64 bit)
- Microsoft Internet Explorer® 5.x or greater

2.2 Install PortAll

Complete the following steps to install PortAll Software Version 2 on a computer:

1. Before installing PortAll, exit all other open applications.
2. Insert the CD into the CD-ROM drive. The installation program will automatically start.
3. A pop-up window opens to confirm that Internet Explorer 5.x or higher is used. Click **OK**.
4. The InstallShield Wizard opens. Click **NEXT** to proceed with installation.
5. Follow the installation instructions and accept the terms of the licensing agreement.
6. When installation is complete, click **FINISH**. A PortAll icon is shown on the desktop.

2.3 Install the license

When PortAll is started for the first time, the user will be presented with a login window that has a button labeled “License”. This allows the user to license the software without having to login first. If the software is not licensed at this stage it will open in demonstration mode, without particle counters connected. To connect particle counters to PortAll, the license must be installed. License files (*.lic) are available by email from the manufacturer. For all licenses, an administrator-level user must load the license.

1. Double-click the **PORTALL** icon on the desktop or go to **Start** > **Programs** > **PortAll**. A login window opens.
2. Enter the default User ID and password:

- User ID: **admin**
- Password: **123456**

3. Click **LOGIN**. PortAll opens in demonstration mode (Figure 1).

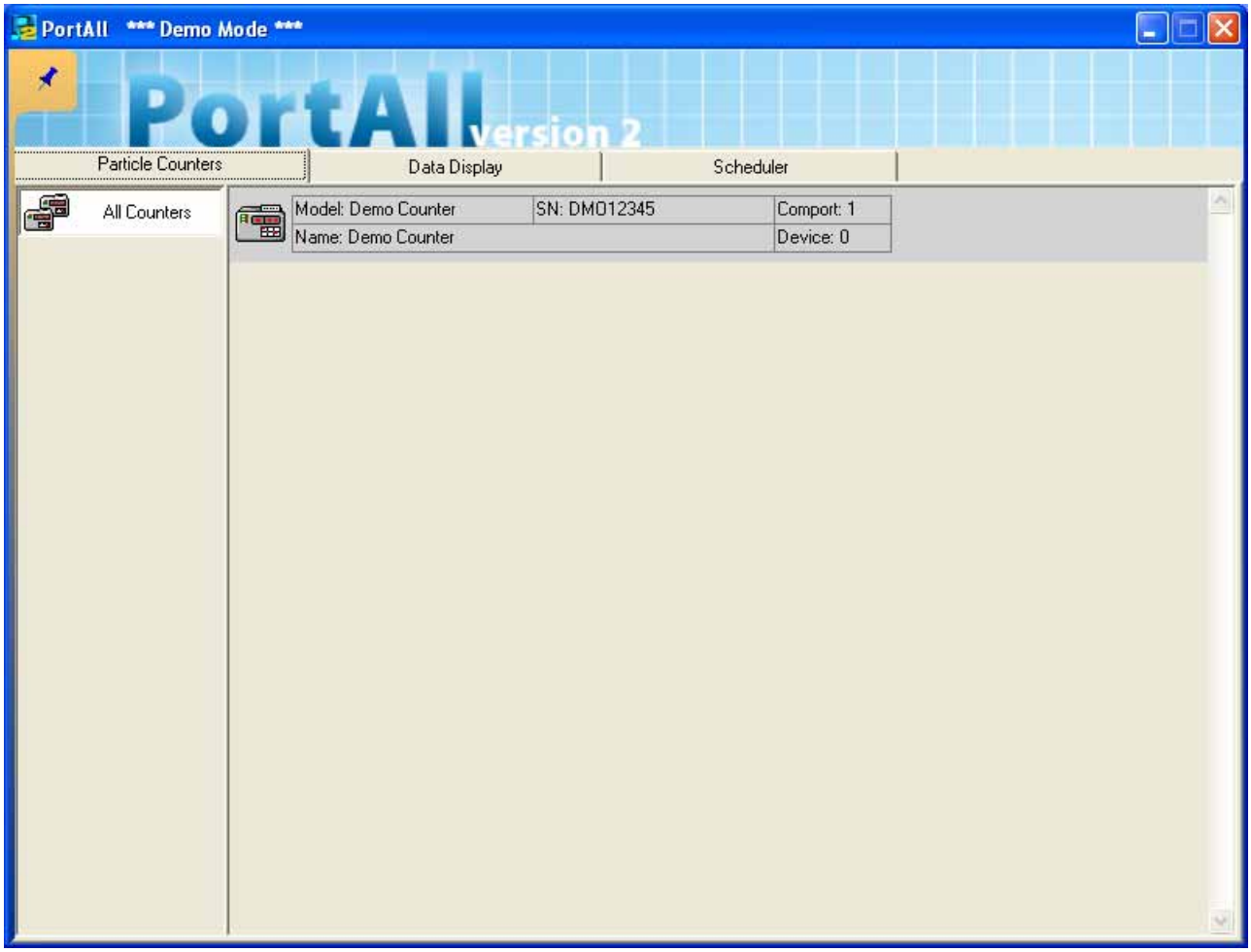


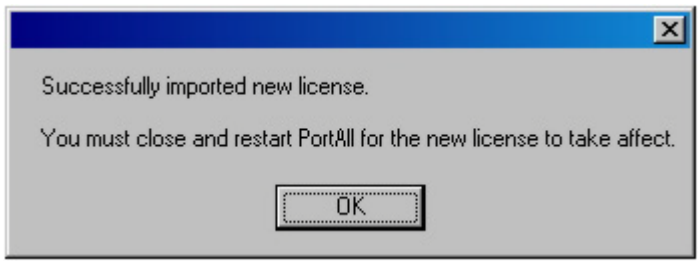
Figure 1 PortAll Window—Demo Mode

4. Move the mouse over the thumbtack icon to show additional icons.

5. Click on the **HELP ABOUT** icon. The About PortAll screen opens (Figure 2).

Figure 2 About PortAll Screen

6. Click **LICENSE**. The File Open window opens.
7. Navigate to the license file location and click **OPEN**. When complete, a confirmation window is shown. Click **OK**.



8. Click **YES** to restart PortAll.

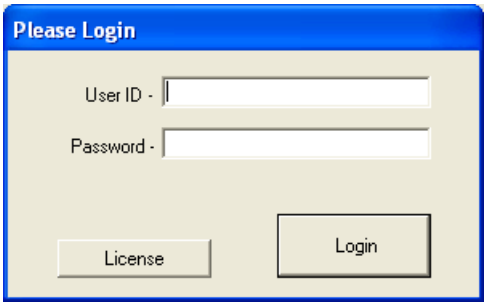
Section 3 Operation

3.1 PortAll Overview

Particle counters can be connected to a computer for data collection. For the 3400 particle counters, a USB port is used. The appropriate USB device driver is automatically installed with PortAll.

Once PortAll is installed, start the software.

1. Double-click the **PORTALL** icon on the desktop or go to **Start** > **Programs** > **PortAll**. A login window opens.



2. Enter the User ID and password.

   Note: *On initial startup, enter* ***admin*** *for the User ID and* ***123456*** *for the password.*

3. Click **LOGIN**. The main PortAll screen opens (Figure 3).

3.1.1 Main screen description

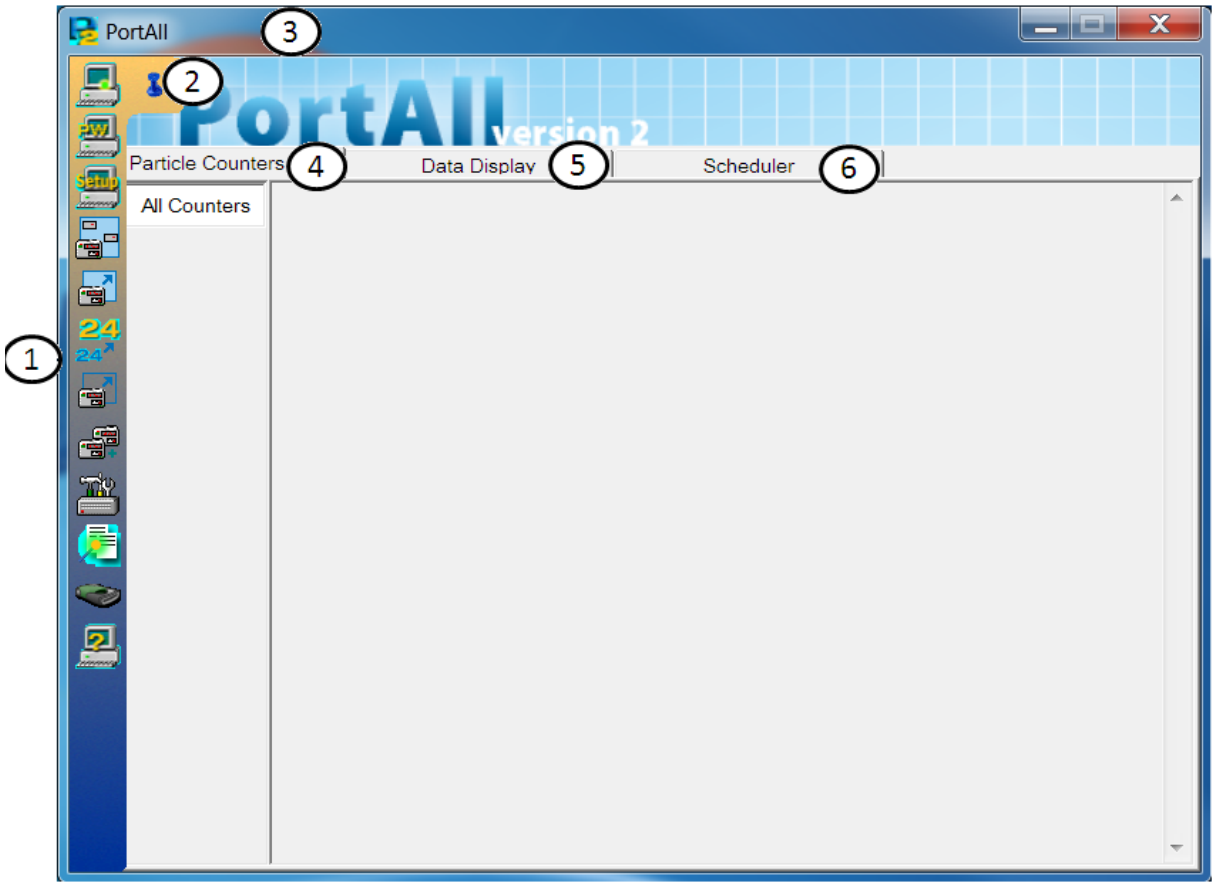


Figure 3 PortAll Main Screen

1	Icon tools—	**4**	Particle counters tab—section 3.3 on page 14
2	Thumbtack icon—	**5**	Data Display tab—section 3.4 on page 24
3	Title bar	**6**	Scheduler tab—section 3.4.2 on page 30

3.1.2 Icon descriptions

Put the mouse over the thumbtack icon to show the icon tools. Click to make the icons stay in view. For a description of the icon tools, refer to Table 3.

Table 3 Main screen icon description

Icon	Name	Description	Icon	Name	Description
	Login/Logout	Open the Login screen		Setup Locations	Add a Location ID and Location Name for a particle counter (section 3.3.3 on page 19)
	Change Password	Open the Change Password screen (section 3.2.1 on page 11)		Edit Groups	Add or edit group names for particle counters (section 3.3.4 on page 20)
	Setup Users—(Life Sciences version only)	Add users and set security criteria (section 3.2.3 on page 11)		Audit Trail—(Life Sciences version only)	View or print an audit trail (section 3.8 on page 45)

Table 3 Main screen icon description

Icon	Name	Description	Icon	Name	Description
	Add Hardware	Add particle counters to the system (section 3.3.1 on page 14)		Reports	Create reports with compliance calculations (section 3.7 on page 37)
	Edit Hardware	Edit particle counter descriptions (section 3.3.2 on page 18)		USB imports	Import data from a USB storage device (section 3.4.1.3 on page 28)
	Scaling/ Normalization	Set up criteria to automatically normalize data (section 3.3.6 on page 22)		Help About	Install license and get version information (section 2.3 on page 5)

3.2 Set up PortAll

3.2.1 Set passwords

Complete the following steps to set a new password.

1. Click on the **PASSWORD** icon. The Change Password window opens.
2. Enter the Old Password.
3. Enter the New Password and click **OK**.

3.2.2 Recover admin password

Important Note: *To support standards and regulations such as 21 CFR Part 11, the PortAll installation CD-ROM should be handled in accordance with the organization's Standard Operating Procedure (SOP) addressing the use of appropriate controls over systems documentation.*

To reset the administrator password:

1. Load the PortAll CD-ROM.
2. In Windows Explorer, open the **Admin Utility** folder.
3. Double-click on the **DefaultAdmin.exe** file.
4. Click the **CREATE DEFAULT ADMINISTRATOR** button.
5. When prompted, navigate to the Settings database directory and select **Settings.mbd**.

Note: *In demonstration mode, select the DemoSettings.mbd file.*

6. The default administrator's password is reset to **123456**.

3.2.3 Establish users (Life Sciences version only)

Complete the following steps to create a new user.

1. Click the **SETUP USER** icon. The User Manager window opens (Figure 4).
2. To create a new user, click the **ADD USER** button. The User Details window opens (Figure 5).

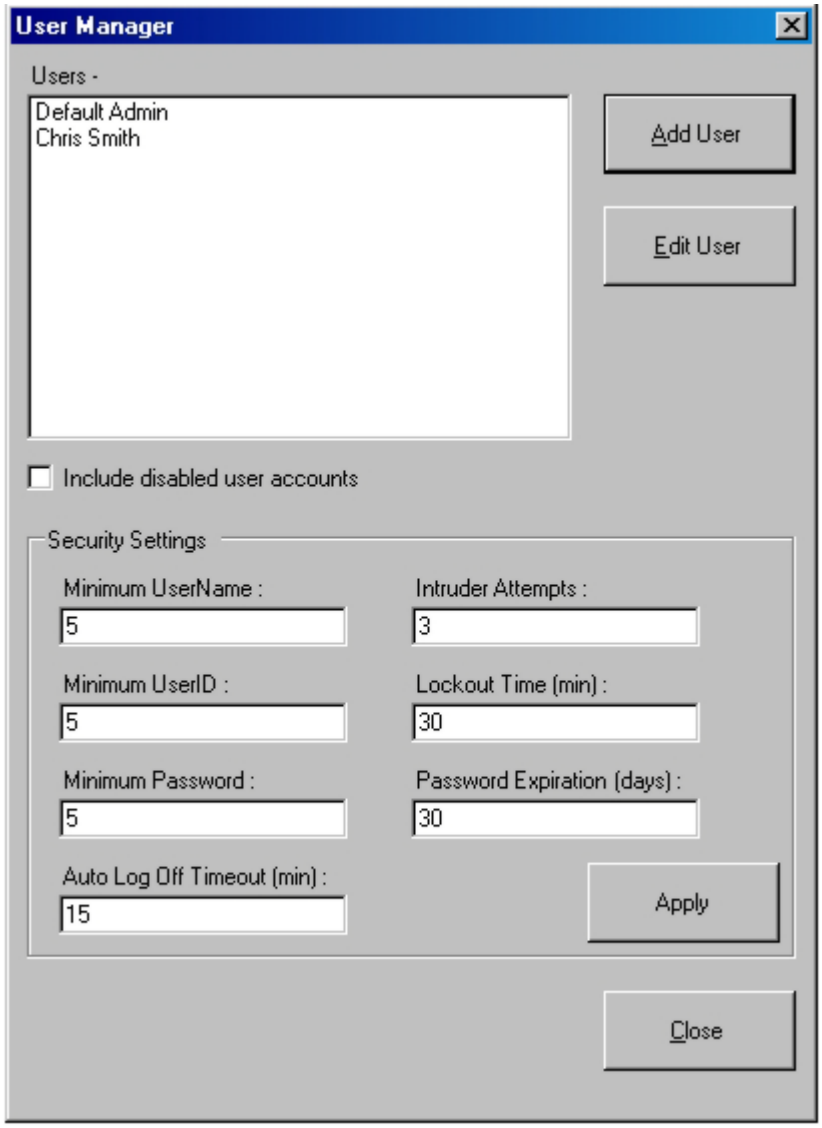


Figure 4 User Manager Window

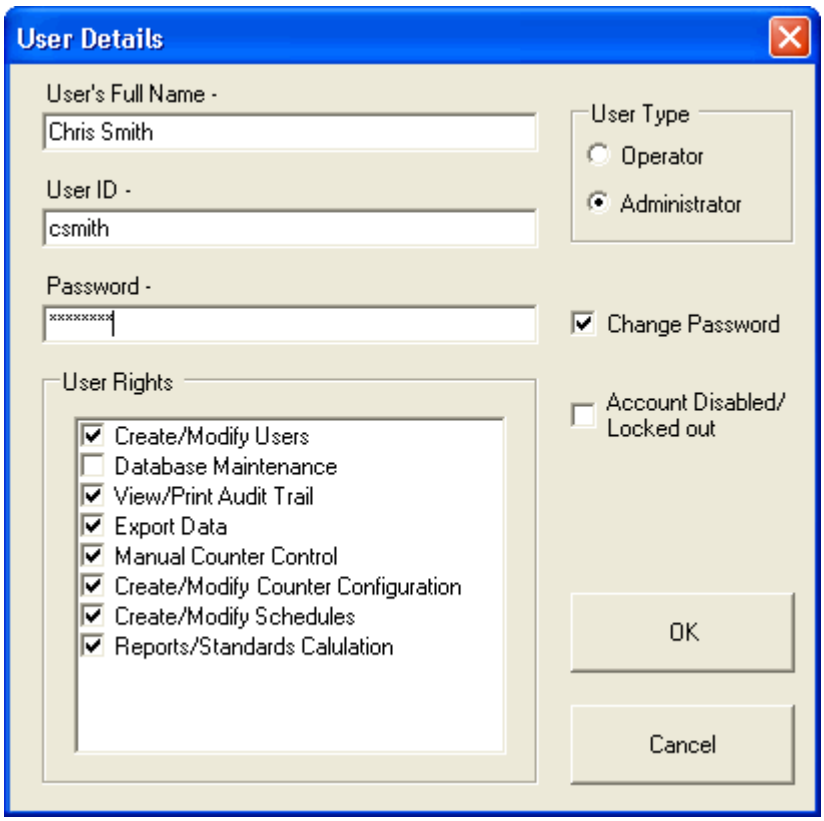


Figure 5 User Details Window

3. Enter the user's full name as it should appear in audit logs, the user ID he or she will use to log into PortAll Version 2, and an initial password.
   - User names, IDs, and passwords must be unique, alphanumeric, and contain no symbols. They must be at least 5 characters and no longer than 25 characters.
   - User names and passwords are case-sensitive.

Note: *As a user is created, a checkmark will appear in Change Password. PortAll's default is to ask each user to change the password on initial login.*

4. Indicate whether the user will have operator- or administrator-level privileges by selecting the appropriate user type.
   - **Operators** have limited access to the system. Their default user rights are manual counter control, view data, graph data, change their own passwords, print data, and print graph. Operators may also clear counter buffers, counter configuration, remote modem configuration, scheduling, view historical data, and standards calculations if so designated.
   - **Administrators** may access anything within PortAll Version 2. In addition to the rights of an operator, administrators may also access user configuration, system configuration, view/print the audit trail, and database maintenance (backup and archive). All rights are optional.
5. Click **OK** to create the user account and return to the User Manager Window.
6. In the User Manager Window, the user account appears. The options listed in the User Manager Window apply to all users:
   - Minimum User Name
   - Minimum User ID

- Minimum Password
- Auto Log Off Timeout (min)
- Intruder Attempts
- Lockout Time (min)
- Password Expiration (days)

7. Click **APPLY** to save the changes.
8. Click **CLOSE** to exit the User Manager.

3.3 Set up particle counters

Be aware that once a particle counter is added to the system, it may not be modified or removed from the system. To change the address location of a particle counter, the particle counter must be completely re-entered and the old location cannot be deleted.

Note: *Some counters, like the MET ONE 3400 Series Portable Airborne Particle Counters, will automatically be recognized and added to the list by PortAll. Users may be prompted to enter a counter name. In this case, click on the counter that automatically appears in the counter list to complete the setup process.*

3.3.1 Add particle counters

Before adding a particle counter to the PortAll Version 2 system:

- Make sure all physical connections between the particle counter and the computer have been made.
- Turn on the particle counter.

1. From the PortAll main screen, click the **ADD NEW HARDWARE** icon. The Add New Hardware Wizard opens.
2. Click **NEXT** to continue. The Identify New Device screen is show. (Figure 6)
3. Enter the information about the particle counter:
   - Select the model number of the particle counter from the drop-down list.
   - Enter the serial number of the particle counter.
   - Name the device so that it is easily recognized within PortAll Version 2 screens and data file. (Figure 7)
4. Click **NEXT**. The Enter IP Address screen opens. (Figure 8).
5. Enter the IP address and click on NEXT or just click on NEXT and have PortAll scan for the counter. (Figure 9)
6. If a Firewall is enabled, a Security alert may appear. Select UNBLOCK or ALLOW ACCESS to allow PortAll to communicate over the network.
7. Click on the found counter to highlight it and then select NEXT. A summary screen is shown (Figure 10). Review the information and click FINISH to add the particle counter to the PortAll system.
8. Click on the Particle Counter tab on the main screen and verify that the particle counter is shown in the list. (Figure 11)

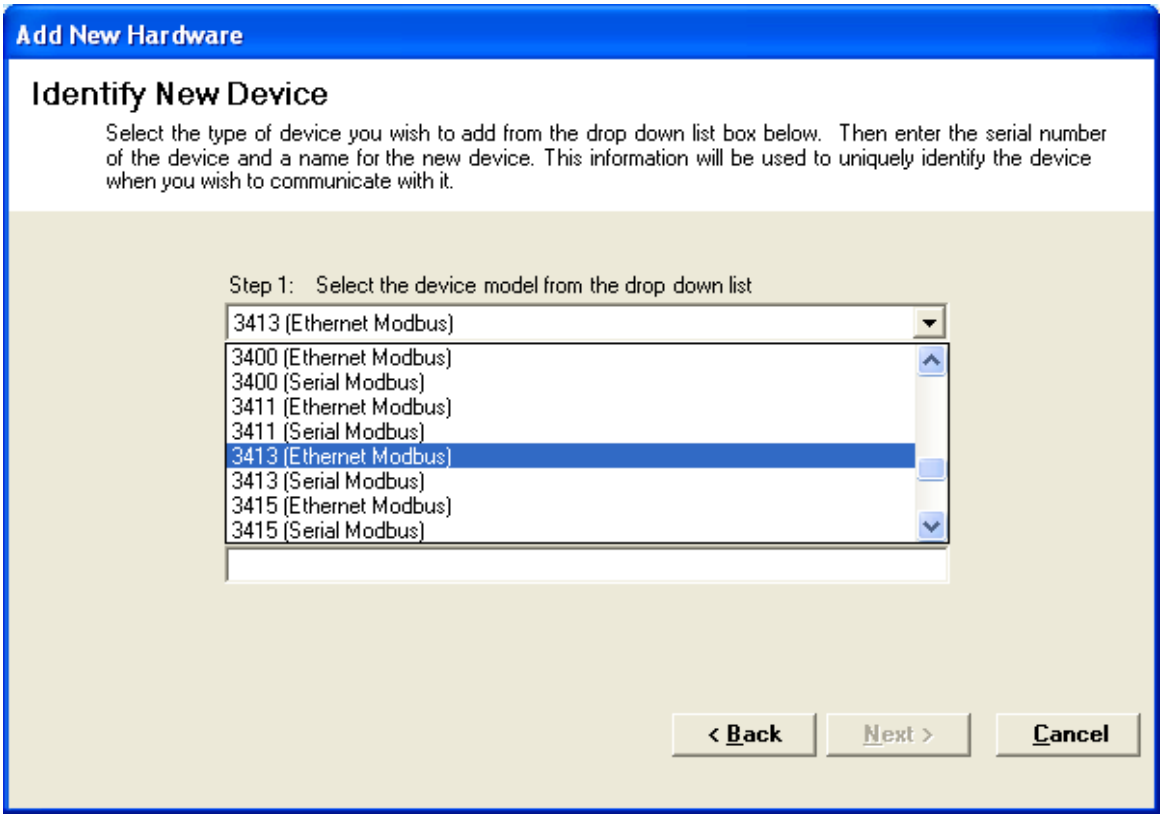


Figure 6 Identify New Device

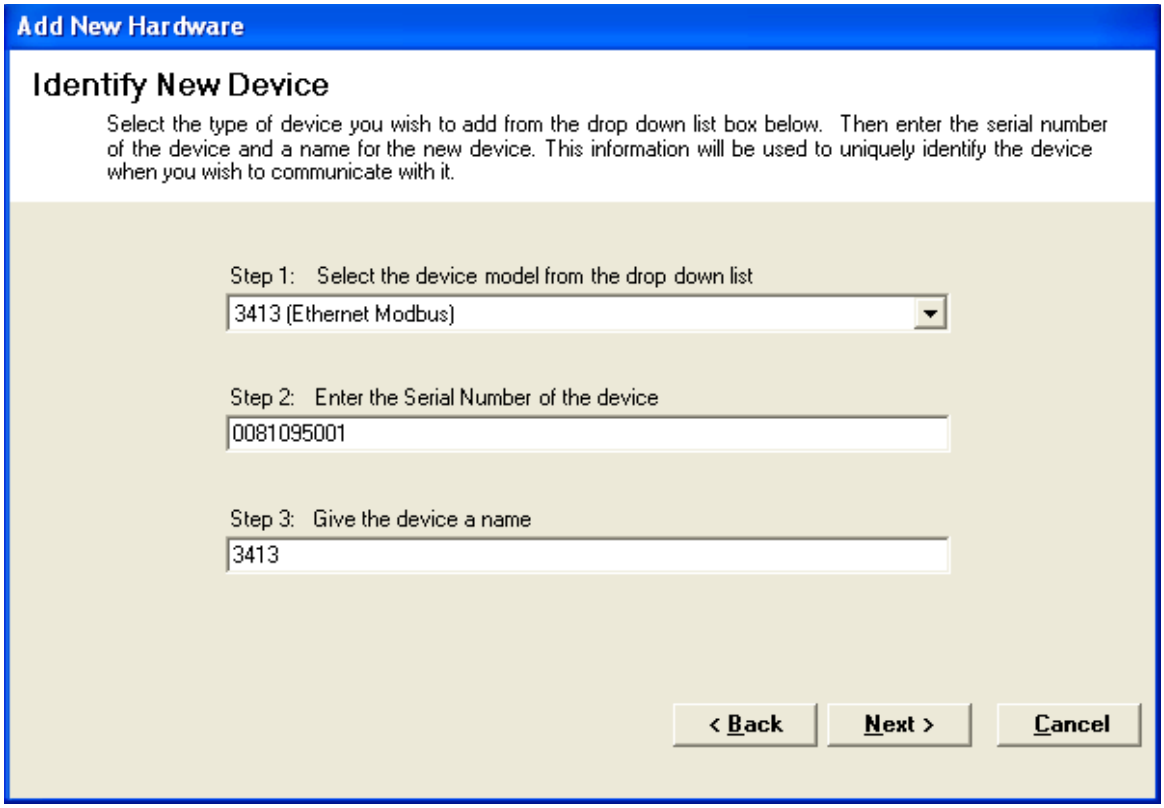


Figure 7 Name Device

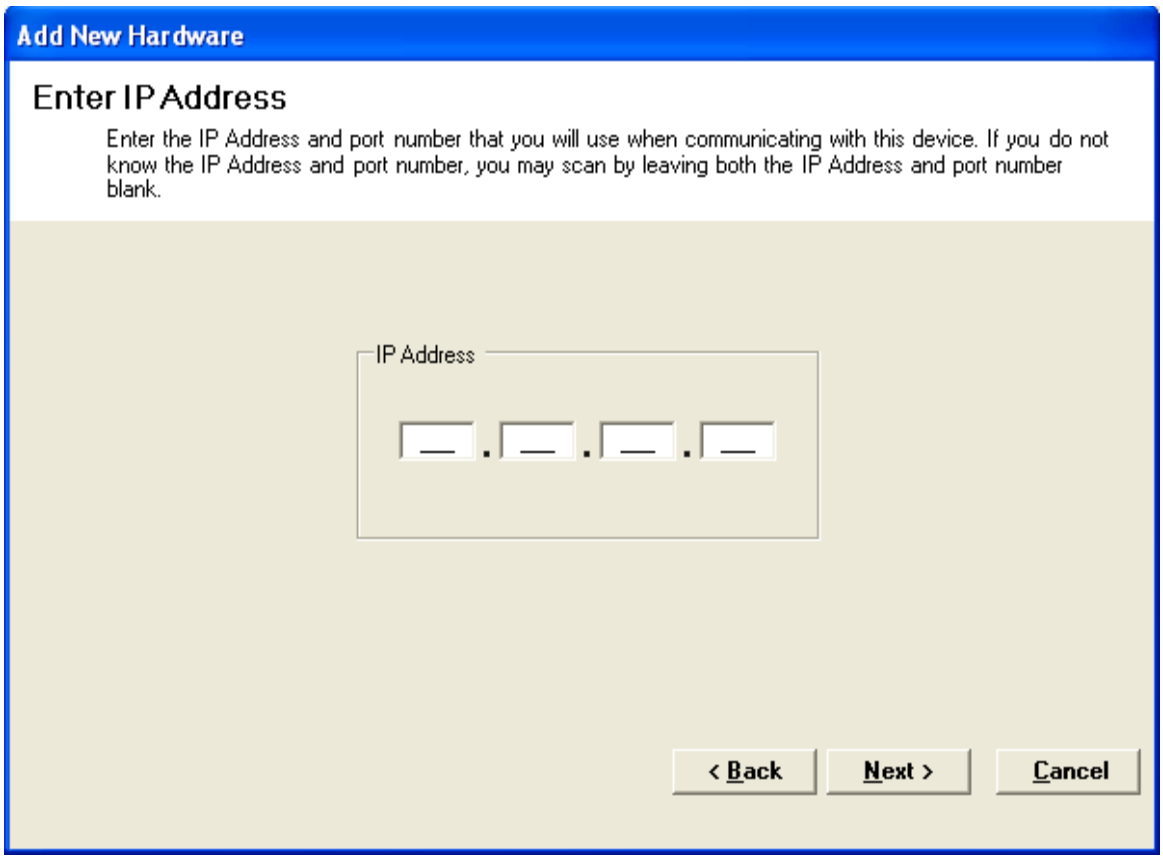


Figure 8 Enter IP Address.

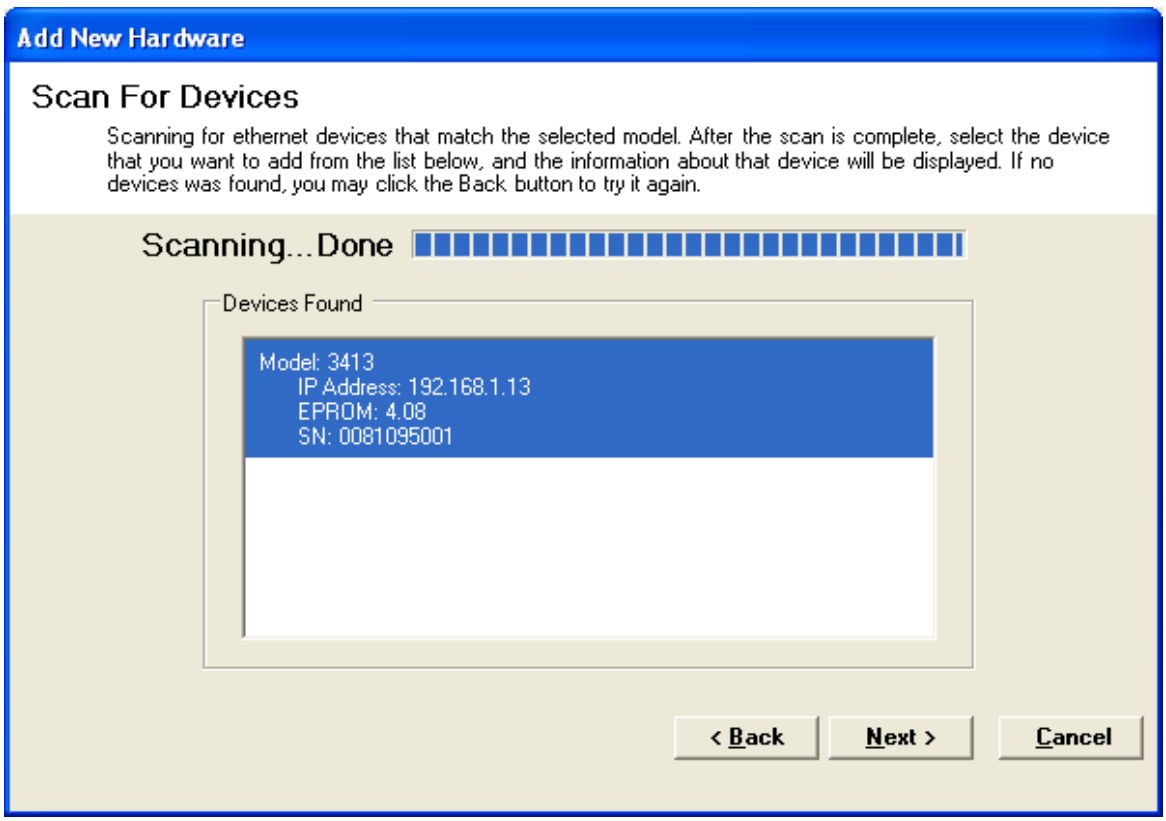


Figure 9 PortAll Scan for counter

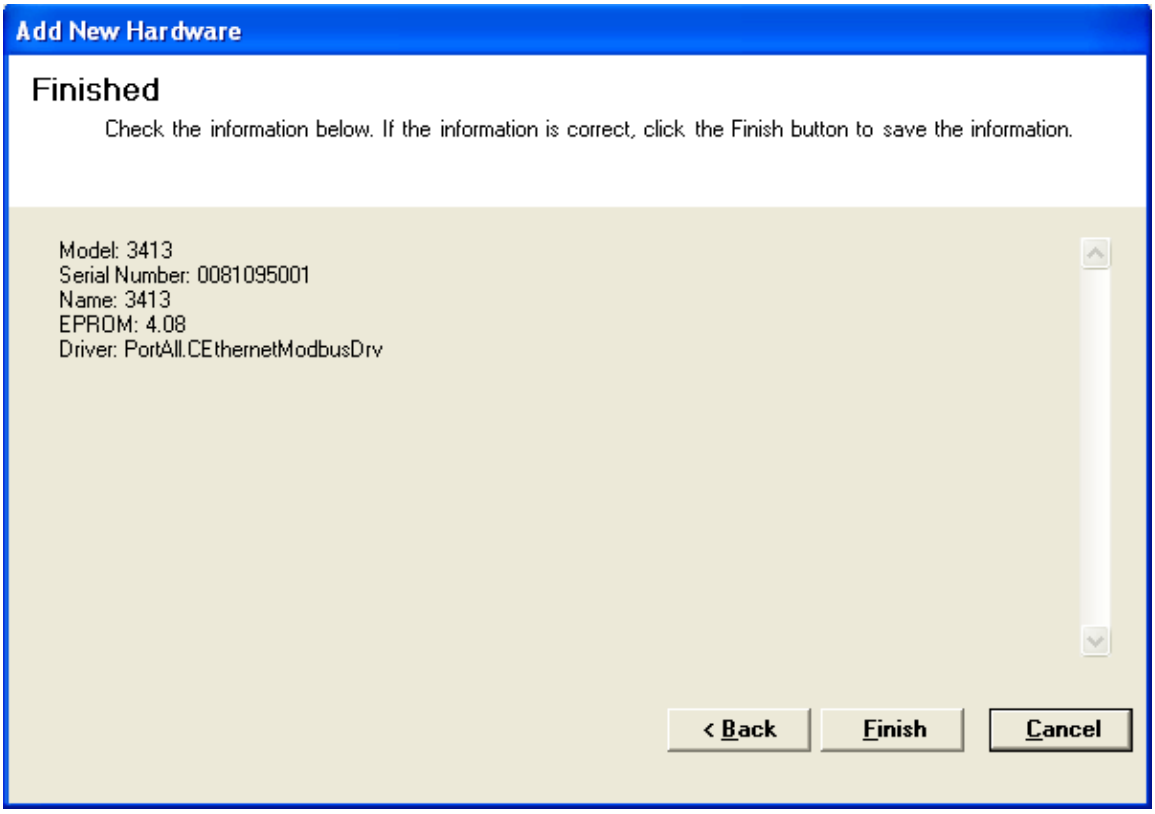


Figure 10 Summary Screen

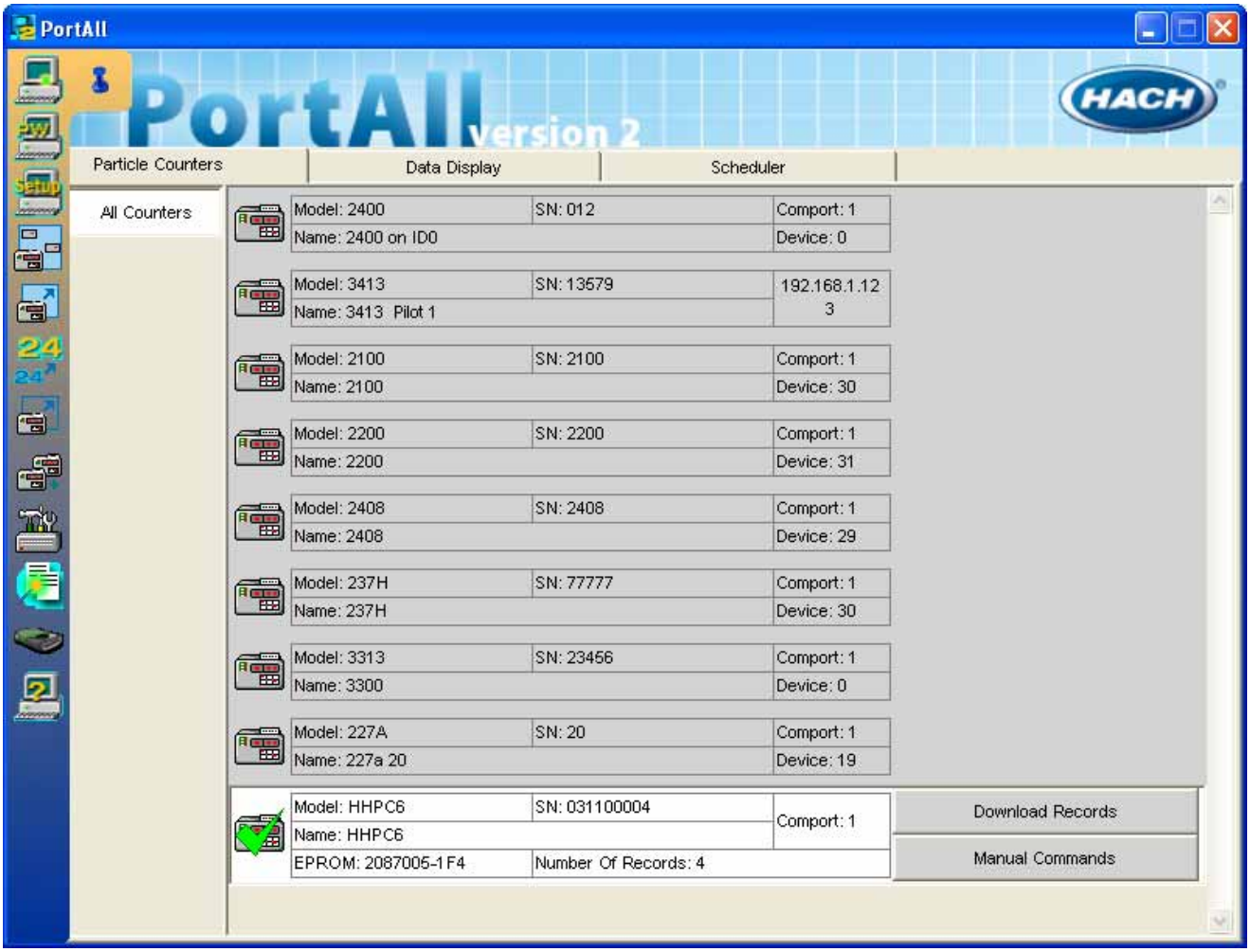


Figure11 Particle Counter tab.

3.3.2 Edit descriptions

Complete the following steps to edit the name of a counter.

1. From the PortAll main screen, click the **EDIT HARDWARE** icon. The Active Counters screen opens (Figure 12).

   Note: *Unchecking the box next to the counter name in the Active Counters screen will remove that counter from the* ***Particle Counter*** *tab list.*

2. Highlight the counter to edit. The information for the counter is shown.
3. Edit the name in the **Name** field and click **OK**. The new name is shown on the **Particle Counters** tab in the Main Screen.

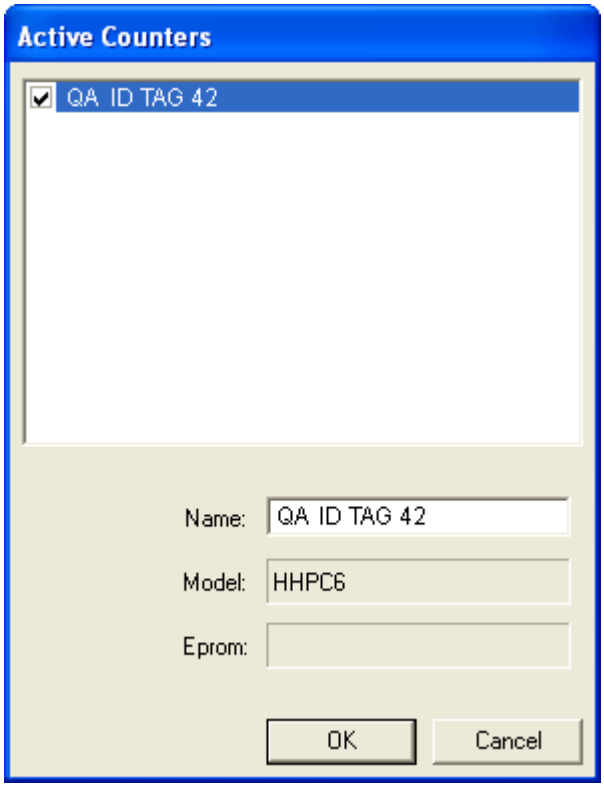


Figure 12 Active Counters screen

3.3.3 Set up locations

A location is an identifying label for the purposes of the audit trail and cleanliness classification reports. A location consists of three parts:

- Particle counter(s) associated with that location
- Location ID
- Location Name

1. From the PortAll main screen, click the **SETUP NEW LOCATIONS** icon. The Add Locations screen opens (Figure 13).
2. Select a counter from the drop-down list. The serial number for the unit will automatically display.
3. Enter a location ID. This should correspond to the Location ID number in the particle counter. This ID will be displayed throughout PortAll Version 2, including any printed cleanliness standard reports.

   Note: *Multiple particle counters may be assigned the same location ID.*

4. Enter the location name as it should appear in the audit trails and data files.
5. Press **OK** to save changes.

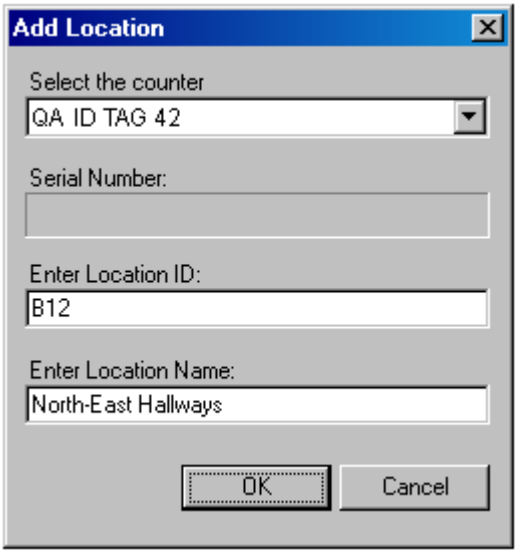


Figure 13 Add Location screen

3.3.4 Set up groups

Groups are a set of particle counters sharing some common element, whether it is function, frequency of sampling, or parameter measured. Establish groups to make it easier to assess environmental conditions or to streamline sampling schedules.

1. From the PortAll main screen, click the **EDIT GROUPS** icon. The Edit Groups screen opens (Figure 14).
2. Click **ADD GROUP**. The Add New Group screen opens (Figure 15).
3. Enter a name for the group and click **OK**.
4. Add particle counters to the group as described in Edit groups on page 21.

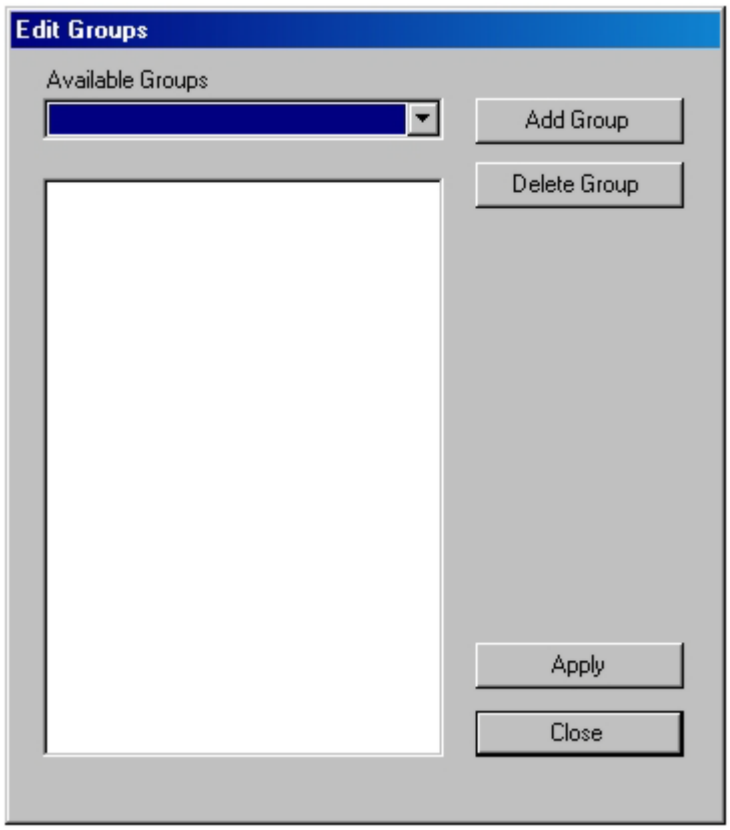


Figure 14 Edit Groups screen

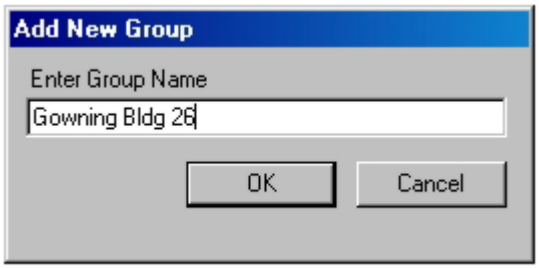


Figure 15 Add New Group screen

3.3.5 Edit groups

Complete the following steps to edit a group.

1. From the PortAll main screen, click the **EDIT GROUPS** icon. The Edit Groups screen opens.
2. Select a group from the drop-down list. All connected particle counters are shown (Figure 16)
3. Select the particle counters to add to the group, or clear the boxes to remove particle counters from the group.

   Note: *A single particle counter may be part of many different groups.*

4. Click **APPLY** to save changes.
5. Click **CLOSE**.

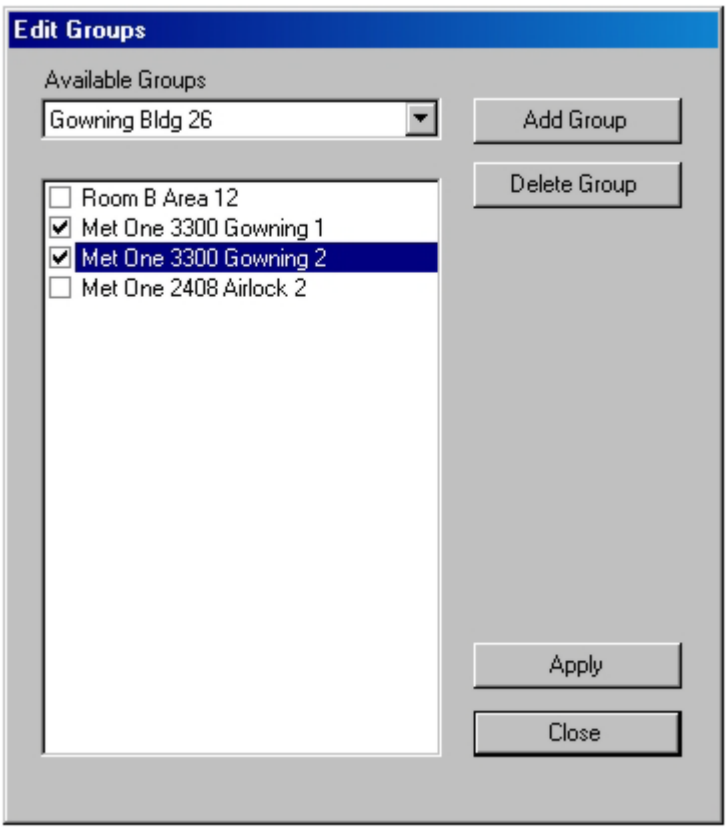


Figure 16 Edit Groups screen—group with associated particle counters

3.3.6 Normalize count data

PortAll can automatically convert raw data received from the instrument to normalized values. For particle counts, raw data would be total counts; whereas normalized values would be counts-per-unit-volume, such as equivalent counts-per-cubic-foot of air or counts-per-milliliter of water.

Users may view data in counts-per-cubic-foot, then modify the scaling and view the data as counts-per-cubic-meter, which may be useful when trying to meet multiple regulations and standards.

Many instruments support accessory sensors to collect values related to particle counts, such as relative humidity, temperature, air velocity, or differential pressure. The raw data for these accessory sensors are often not pre-scaled to the proper engineering units before they are sent to the computer. PortAll will also automatically scale these values.

For an environmental sensor connected to the counter, the data should be normalized to receive meaningful sensor (or analog) data.

Access automatic normalization settings as follows:

1. From the PortAll main screen, click the **SCALING/NORMALIZATION** icon. The Scaling Setup screen opens (Figure 17).
2. Select the counter from the drop-down list.
3. In the **Count Scaling** section, select the desired unit volume. The default is Raw.
    - **Raw** refers to data downloaded directly from the particle counter. Once downloaded, the data will immediately be transferred into the database. This data cannot be modified and is maintained in the database indefinitely until it is archived.

- For **airborne particle counters**, select particles per cubic foot or cubic meter. Scaled data is not stored in the database.
- For **liquid particle counters**, select particles per milliliter, 100 milliliters, or liter. Scaled data is not stored in the database.

4. In the **Analog Scaling** section, check the **Scale Analogs** box to produce normalized data for the selected environmental sensor or analog input device. Analog data is any environmental data included with the particle count data in the data record, such as flow rate, relative humidity, or temperature.
5. Enter the input maximum and minimum values for the instrument in **Emin** and **Emax** fields.
6. Enter the output maximum and minimum values for the instrument in the **Fmax** and **Fmin** fields.
7. When finished, click the **APPLY** button. This information is saved so that next time an environmental sensor is connected to this particle counter, retrieved data are normalized.

Normalization remains in effect until the **Raw** option is selected and the **Scale Analogs** box is unchecked.

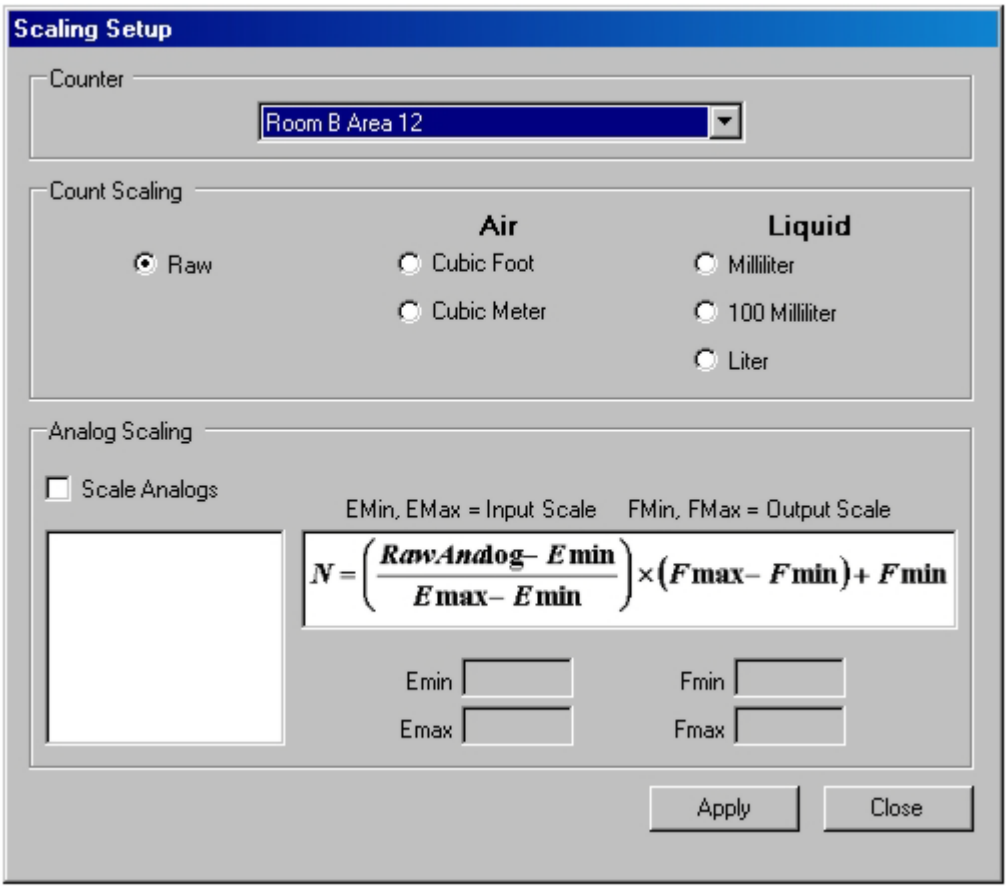


Figure 17 Scaling Setup screen

3.4 Collect data

Data may be collected from the particle counters at any time (section 3.4.1). Schedules can also be set so that PortAll collects buffered data automatically (section 3.4.2 on page 30). With automatic operation, the risk of buffer overflows is minimized. Data from a MET ONE 3400 particle counter can be imported directly from the counter or from a USB device (section 3.4.1.3 on page 28).

3.4.1 Manual data collection

Data can be collected manually at any time.

3.4.1.1 Set up manual operation

Complete the following steps to manual collect data.

1. Open and login to PortAll Version 2.
2. On the **Particle Counter** tab, highlight the particle counter that contains the data to be downloaded (Figure 11 on page 18).
3. Click the **MANUAL COMMANDS** button. The Manual Commands screen opens (Figure 18). All available commands for the selected model of counter are shown in the left-hand section. Commands vary from model to model but commonly include:
   - Start Count
   - Stop Count
   - Set Sample Time
   - Set Delay/Hold Time
   - Get Firmware Version
   - Get Buffer Size
   - Get Sample

   Note: *Older particle counters may not support all commands. Contact the manufacturer for support.*
4. Execute a command by highlighting it in the Commands section and clicking the **SEND COMMAND** button.
5. The executed commands and their status are listed in the right-hand History section.
6. To close the Manual Commands screen, click **CLOSE**.

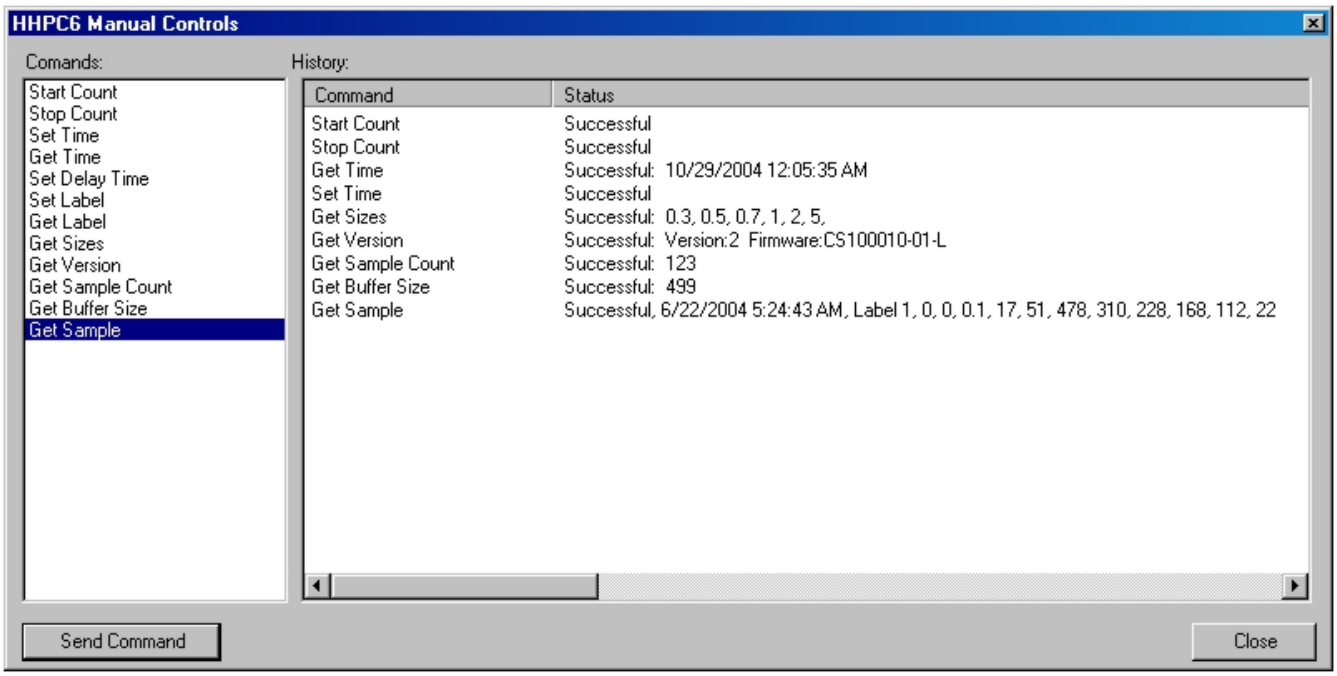


Figure 18 Manual Commands Screen

3.4.1.2 Download data

Complete the following steps to download data.

1. Open and login to PortAll Version 2.
2. On the **Particle Counter** tab, highlight the particle counter from which to download data (Figure 11 on page 18).
3. Click the **DOWNLOAD RECORDS** button. A **Downloading Records...** screen opens (Figure 19), that shows:
   - the number of records downloaded
   - the number of good records
   - the number of records with errors
   - the number of duplicate records

   When all the records are downloaded, the **Downloading Records** screen closes.
4. If a location is not set up, the Add Location window automatically opens to allow the user to define the location within PortAll (refer to figure 13 on page 20).
5. As soon as the download is complete, the Data Display Window opens (Figure 20).
6. Click on the column headings to sort by column as shown in Figure 21, or drag headings into the gray area below the menu bar to group data as shown in Figure 22.
7. Return to the main screen of PortAll and click on the **Data Display** tab.
8. A **Query** link appears in the window. To view the records, either double-click the **Query** link or first select the start date and time and end date and time of the query, then:
   - Select the location from the drop-down list.
   - Select the counter from the drop-down list.

9. Click **QUERY DATABASE** to show a list of records matching the specified criteria in the **Data Display** tab, as shown in Figure 23. The records display in a format similar to those shown in Figure 20, Figure 21, or Figure 22.

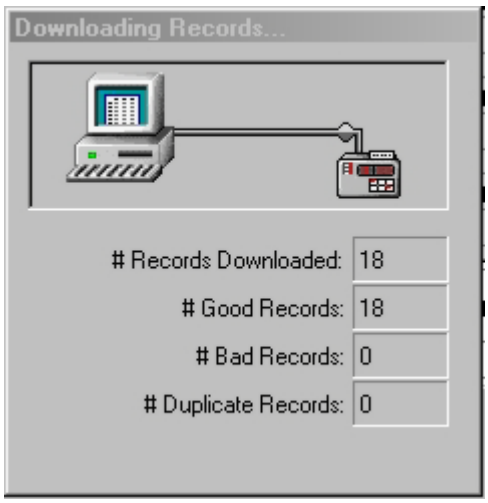


Figure 19 Downloading Records screen

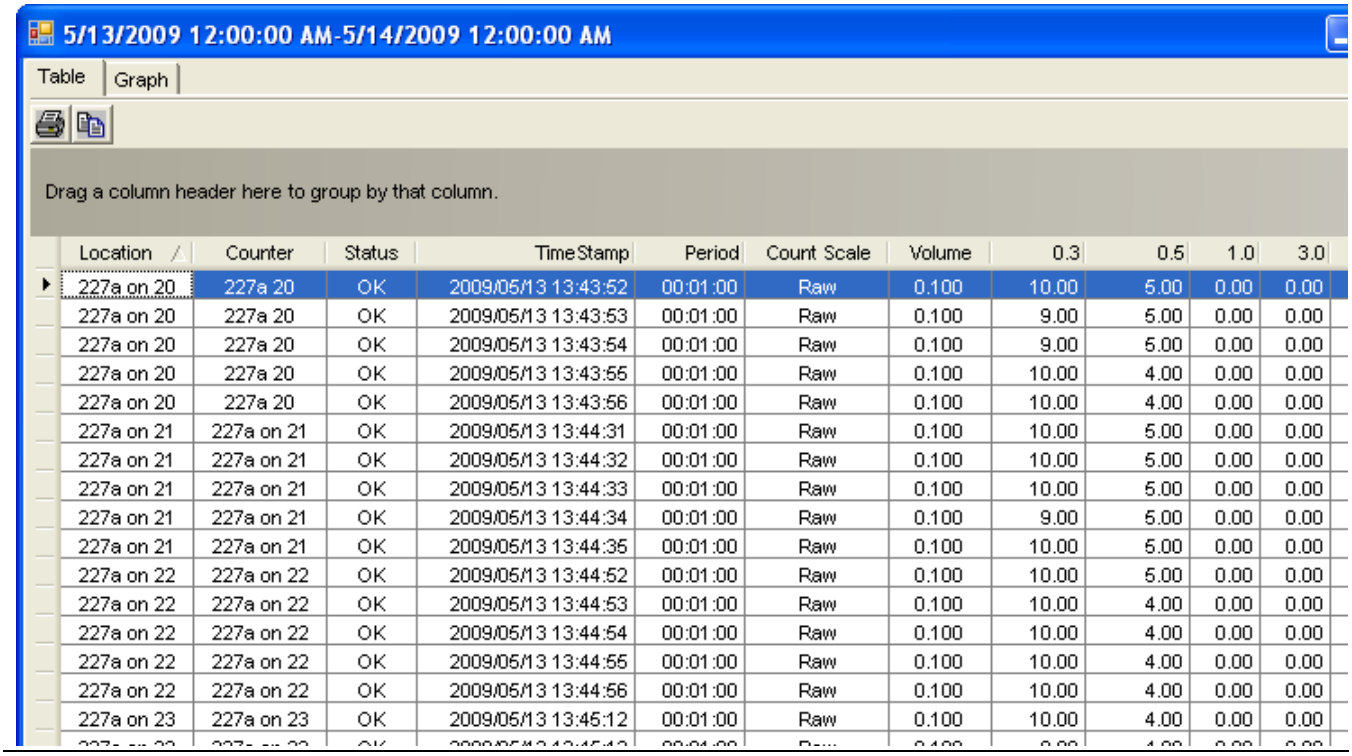
5/13/2009 12:00:00 AM-5/14/2009 12:00:00 AM

Table | Graph

Drag a column header here to group by that column.

Location	Counter	Status	TimeStamp	Period	Count Scale	Volume	0.3	0.5	1.0	3.0
5295	5295	OK	2009/05/13 10:01:12	00:01:00	Cubic Meter	0.027	333.33	3333.33		
5295	5295	OK	2009/05/13 10:01:13	00:01:00	Cubic Meter	0.027	370.37	3370.37		
5295	5295	OK	2009/05/13 10:01:14	00:01:00	Cubic Meter	0.027	370.37	3444.44		
5295	5295	OK	2009/05/13 10:01:15	00:01:00	Cubic Meter	0.027	370.37	3555.56		
5295	5295	OK	2009/05/13 10:01:16	00:01:00	Cubic Meter	0.027	370.37	3481.48		
5295	5295	OK	2009/05/13 10:21:47	00:01:00	Cubic Meter	0.027	333.33	3592.59		
5295	5295	OK	2009/05/13 10:21:48	00:01:00	Cubic Meter	0.027	370.37	3555.56		
5295	5295	OK	2009/05/13 10:21:49	00:01:00	Cubic Meter	0.027	333.33	3444.44		
5295	5295	OK	2009/05/13 10:21:50	00:01:00	Cubic Meter	0.027	370.37	3481.48		
5295	5295	OK	2009/05/13 10:21:51	00:01:00	Cubic Meter	0.027	333.33	3444.44		
5295 #2	5295 #2	OK	2009/05/13 10:22:08	00:01:00	Cubic Meter	0.027	333.33	3444.44		
5295 #2	5295 #2	OK	2009/05/13 10:22:09	00:01:00	Cubic Meter	0.027	333.33	3481.48		
5295 #2	5295 #2	OK	2009/05/13 10:22:10	00:01:00	Cubic Meter	0.027	333.33	3555.56		
5295 #2	5295 #2	OK	2009/05/13 10:22:11	00:01:00	Cubic Meter	0.027	370.37	3481.48		
5295 #2	5295 #2	OK	2009/05/13 10:22:12	00:01:00	Cubic Meter	0.027	333.33	3592.59		
5295 #3	5295 #3	OK	2009/05/13 10:22:32	00:01:00	Cubic Meter	0.027	333.33	3592.59		
5295 #3	5295 #3	OK	2009/05/13 10:22:33	00:01:00	Cubic Meter	0.027	370.37	3407.41		
5295 #3	5295 #3	OK	2009/05/13 10:22:34	00:01:00	Cubic Meter	0.027	333.33	3555.56		
5295 #3	5295 #3	OK	2009/05/13 10:22:35	00:01:00	Cubic Meter	0.027	333.33	3555.56		
5295 #3	5295 #3	OK	2009/05/13 10:22:36	00:01:00	Cubic Meter	0.027	370.37	3592.59		
5295 #4	5295 #4	OK	2009/05/13 10:22:51	00:01:00	Cubic Meter	0.027	333.33	3481.48		

Figure 20 Data Display Window



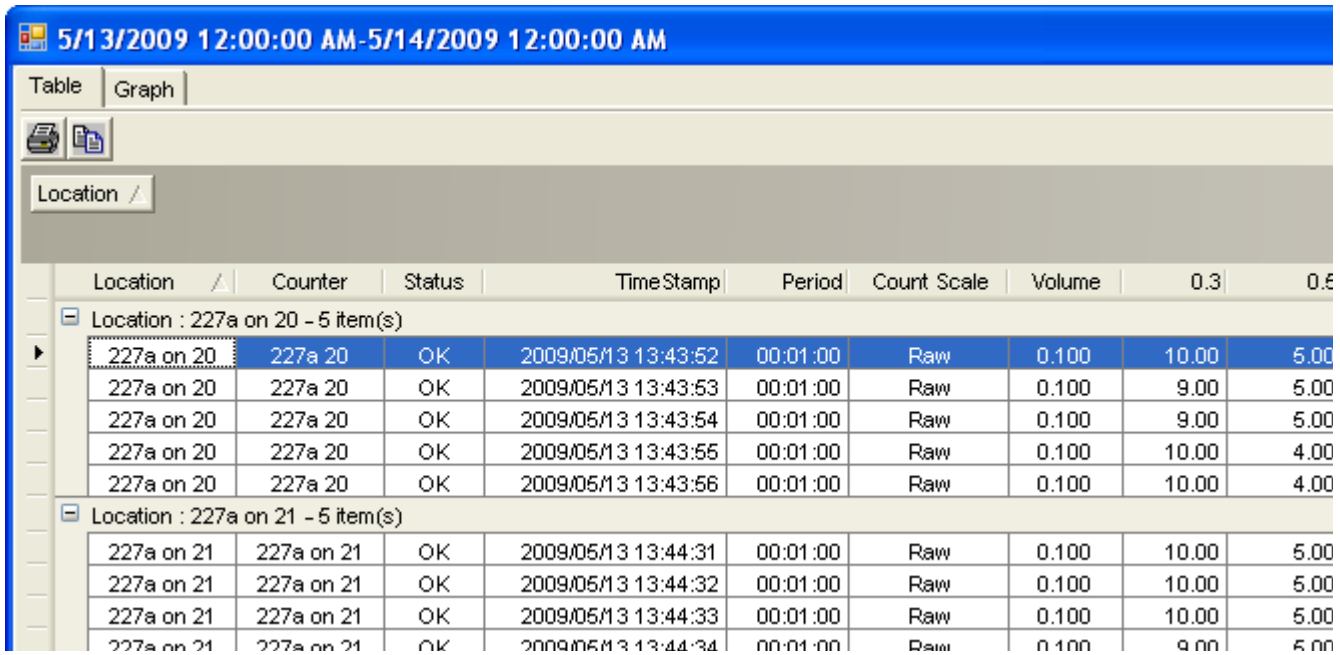
5/13/2009 12:00:00 AM-5/14/2009 12:00:00 AM

Table | Graph

Drag a column header here to group by that column.

Location	Counter	Status	TimeStamp	Period	Count Scale	Volume	0.3	0.5	1.0	3.0
227a on 20	227a 20	OK	2009/05/13 13:43:52	00:01:00	Raw	0.100	10.00	5.00	0.00	0.00
227a on 20	227a 20	OK	2009/05/13 13:43:53	00:01:00	Raw	0.100	9.00	5.00	0.00	0.00
227a on 20	227a 20	OK	2009/05/13 13:43:54	00:01:00	Raw	0.100	9.00	5.00	0.00	0.00
227a on 20	227a 20	OK	2009/05/13 13:43:55	00:01:00	Raw	0.100	10.00	4.00	0.00	0.00
227a on 20	227a 20	OK	2009/05/13 13:43:56	00:01:00	Raw	0.100	10.00	4.00	0.00	0.00
227a on 21	227a on 21	OK	2009/05/13 13:44:31	00:01:00	Raw	0.100	10.00	5.00	0.00	0.00
227a on 21	227a on 21	OK	2009/05/13 13:44:32	00:01:00	Raw	0.100	10.00	5.00	0.00	0.00
227a on 21	227a on 21	OK	2009/05/13 13:44:33	00:01:00	Raw	0.100	10.00	5.00	0.00	0.00
227a on 21	227a on 21	OK	2009/05/13 13:44:34	00:01:00	Raw	0.100	9.00	5.00	0.00	0.00
227a on 21	227a on 21	OK	2009/05/13 13:44:35	00:01:00	Raw	0.100	10.00	5.00	0.00	0.00
227a on 22	227a on 22	OK	2009/05/13 13:44:52	00:01:00	Raw	0.100	10.00	5.00	0.00	0.00
227a on 22	227a on 22	OK	2009/05/13 13:44:53	00:01:00	Raw	0.100	10.00	4.00	0.00	0.00
227a on 22	227a on 22	OK	2009/05/13 13:44:54	00:01:00	Raw	0.100	10.00	4.00	0.00	0.00
227a on 22	227a on 22	OK	2009/05/13 13:44:55	00:01:00	Raw	0.100	10.00	4.00	0.00	0.00
227a on 22	227a on 22	OK	2009/05/13 13:44:56	00:01:00	Raw	0.100	10.00	4.00	0.00	0.00
227a on 23	227a on 23	OK	2009/05/13 13:45:12	00:01:00	Raw	0.100	10.00	4.00	0.00	0.00

Figure 21 Data Display Window - Sort by column



5/13/2009 12:00:00 AM-5/14/2009 12:00:00 AM

Table | Graph

Location /

Location	Counter	Status	TimeStamp	Period	Count Scale	Volume	0.3	0.5
Location : 227a on 20 - 5 item(s)								
227a on 20	227a 20	OK	2009/05/13 13:43:52	00:01:00	Raw	0.100	10.00	5.00
227a on 20	227a 20	OK	2009/05/13 13:43:53	00:01:00	Raw	0.100	9.00	5.00
227a on 20	227a 20	OK	2009/05/13 13:43:54	00:01:00	Raw	0.100	9.00	5.00
227a on 20	227a 20	OK	2009/05/13 13:43:55	00:01:00	Raw	0.100	10.00	4.00
227a on 20	227a 20	OK	2009/05/13 13:43:56	00:01:00	Raw	0.100	10.00	4.00
Location : 227a on 21 - 5 item(s)								
227a on 21	227a on 21	OK	2009/05/13 13:44:31	00:01:00	Raw	0.100	10.00	5.00
227a on 21	227a on 21	OK	2009/05/13 13:44:32	00:01:00	Raw	0.100	10.00	5.00
227a on 21	227a on 21	OK	2009/05/13 13:44:33	00:01:00	Raw	0.100	10.00	5.00

Figure 22 Data Display Window - Sort by groups

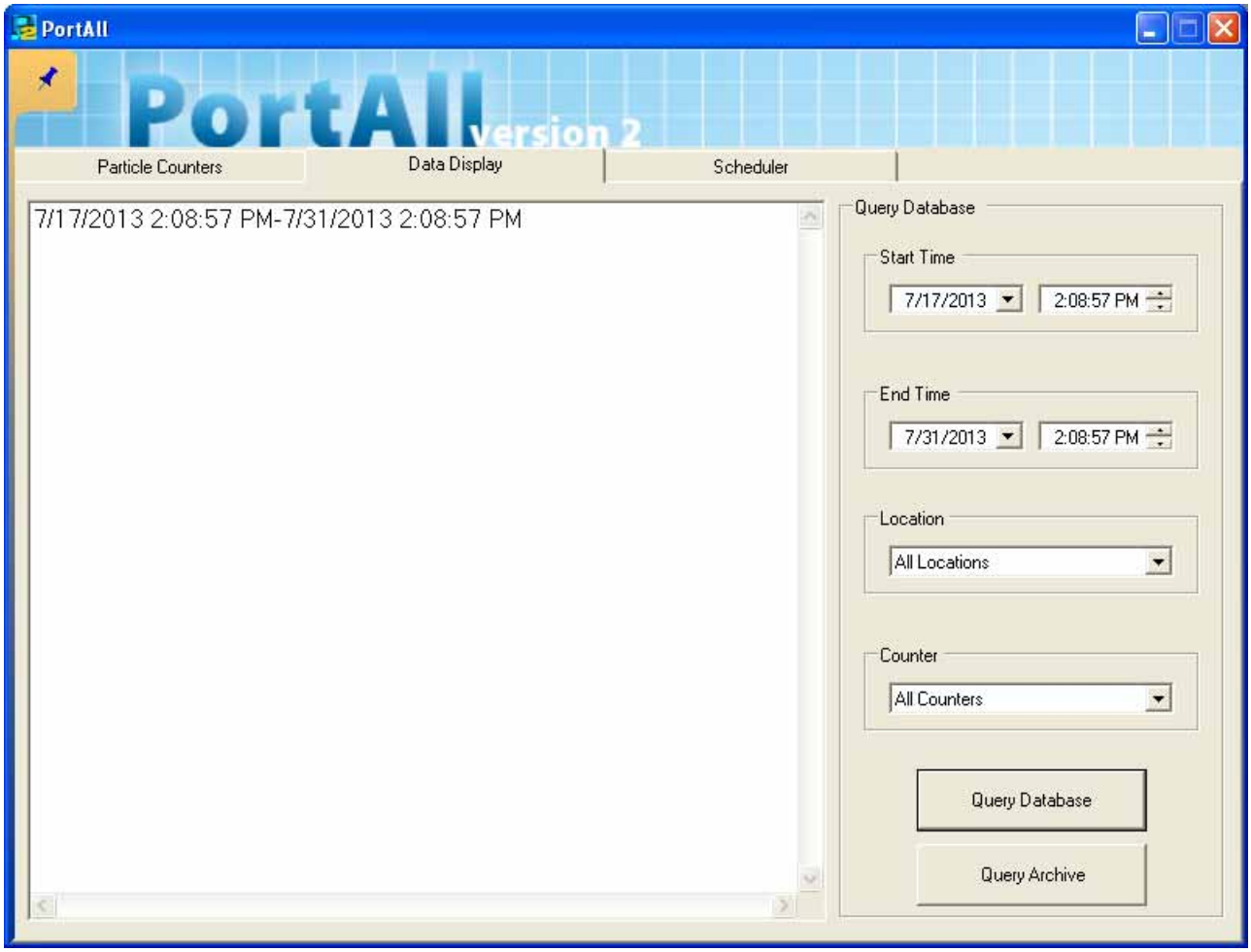


Figure 23 Data Display Window - Query results

3.4.1.3 Import MET ONE 3400 data

Data from a MET ONE 3400 particle counter can be saved on a USB storage device and then imported into PortAll.

1. With the MET ONE 3400 particle counter powered on, insert a supported USB storage device into the 3400 USB port.
2. From the MET ONE 3400 counter user interface software, press **EXPORT** from the main menu. The Export Sample Data window opens (Figure 24).
3. In the **Output File Type** section, select **PortAll**. Enter a file name and click **EXPORT**. The data transfer to the USB device begins.

When the Sample Data Exported screen is shown, click Ok.. Note that for 3400 series counters, once the export is complete, the MET ONE 3400 goes back to the “Counter Navigation” screen.

4. Remove the USB flash drive from MET ONE 3400 counter and insert it to the computer with the PortAll software.

   Note: *Before the data can be imported, the MET ONE 3400 counter needs to be set up in PortAll using the instructions provided in* *Set up particle counters on page 14**.*

5. Click on the **USB IMPORT** button in PortAll. A file navigation window opens.
6. Browse to where the encrypted file is located. Select the file and click **OPEN**.

   Note: *Multiple encrypted files can be imported at the same time.*

7. Data is added to PortAll (Figure 24) (MET ONE 3400 series specific) and then displayed in the data grid.

   Note: *The Data contains the User name associated with collection of the raw data from the MET ONE 3400.*

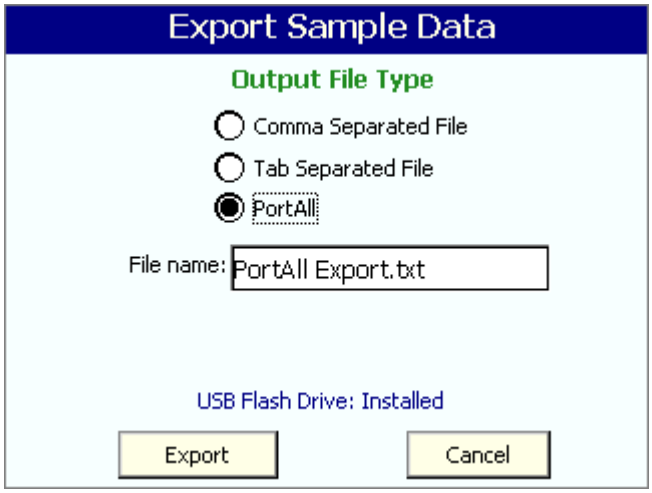


Figure 24 Export Sample Data screen from MET ONE 3400s

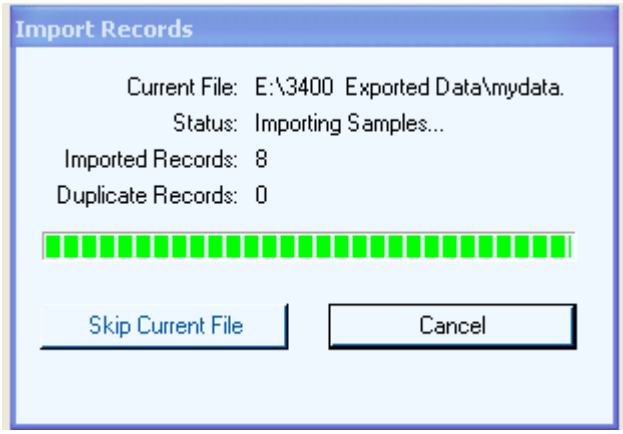


Figure 25 Import Records screen

3.4.1.4 Save data

Data can be saved as a character separated (comma or tab delineator) value (*.csv) file for use in other applications.

1. From the Data Display window, click the **EXPORT DATA** icon. The Table Export window opens (Figure 26).
2. Make the following selections:
   - **Data Selection**—Selected or All
   - **Data Destination**—File or Clipboard
   - **Data Separator**—Comma or Tab
3. Click **EXPORT** to copy the data.
4. If File was selected for Data Destination, a Save CSV File window opens. Navigate to the location where the file will be stored. Name and save the file.

5. Close the Table Export window.

Note: *If Clipboard was selected in step 2, remember to paste the data into another application before copying another set of data.*

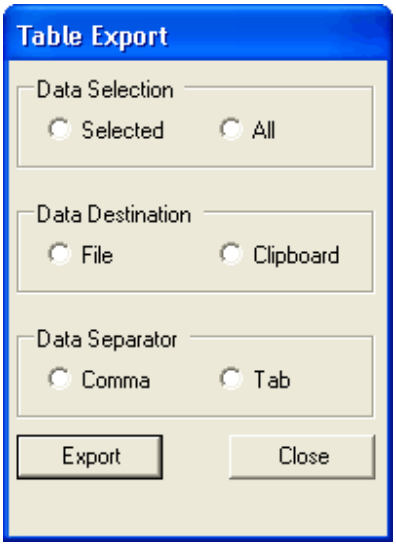


Figure 26 Export Data screen

3.4.1.5 Print data

Data can be printed in the table format as it appears in the Data Display window.

From the Data Display window, click the **PRINT** icon. All data from the Data Display window is sent to the default printer.

3.4.2 Automatic data collection

PortAll can be set to retrieve count data for any or all particle counters at predetermined times and dates. PortAll must remain open for the schedule function to work.

3.4.2.1 About schedules

Use the **Scheduler** tab to download data automatically. Schedules can be set for one time use, daily use, or weekly use.

The two main advantages of schedules are:

- Prevents losing count data due to a full rotating buffer.
- Automatic regular retrieval presents a better picture of the environment.

To keep from losing data due to a full rotating buffer, determine if a schedule is needed by calculating the number of records taken between start and stop times from equation (1):

$$(1)\quad \frac{\text{Total elapsed time (mins)}}{\text{sample time (mins) + hold time (mins)}} = \text{Total number of records taken}$$

Compare the result with the maximum number of records that the buffer can hold (shown in Table 4).

- If the calculated value is less than the value in the table, there is no risk of data loss.
- If the calculated value is greater than the value in the table, schedule at least one retrieval time during sampling.

Table 4 Particle counter buffer maximums

Counter model number	Maximum number of records
CNC 1104	500
227	200
237	500
WGS 267	250
21xx	400
22xx	400
2400	400
2408	400
3313, 3315	2000
3400/3411	5000[1]
HHPC-2	100
HHPC-6	500
HHPC-6 with option EX	2000

[1] By default, the MET ONE 3400 series counter does not operate on a first-in, first-out buffer rotation. Once the buffer is full, the buffer must be cleared before more samples can be taken. After a manual download or at the completion of a schedule, users are prompted to delete the contents of the buffer. Select the "Rotating Buffer" option to change to a first-in, first-out buffer rotation. The default buffer size on a 3400 is 3000 records. The user can change the value up to 5000.

3.4.2.2 Set up a schedule

Complete these steps to add a schedule for automatic download. Refer to Figure 27. Schedule the start, download and stop times relative to the sample interval and size of the buffer.

Note: *No schedules will run until the* ***Enabled*** *checkbox is selected.*

1. From the main screen, select the **Scheduler** tab.
2. Click **ADD NEW SCHEDULE**.
3. Select the frequency:
   - **Once**—data is downloaded on one specified day at a specified time.
   - **Daily**—data is downloaded every day at a specified time.
   - **Weekly**—data is downloaded once a week at a specified day and time.
4. Set the specified **Start Time** and **End Time** and day, if applicable.
5. Set the **Download Interval**. The interval value may be between 1 and 500 minutes.
6. Select the **Counter** from the drop-down list.
7. To make the schedule active immediately, select the **Enabled** checkbox.
8. Click **APPLY CHANGES**. The new schedule is shown in the **Scheduler** tab.

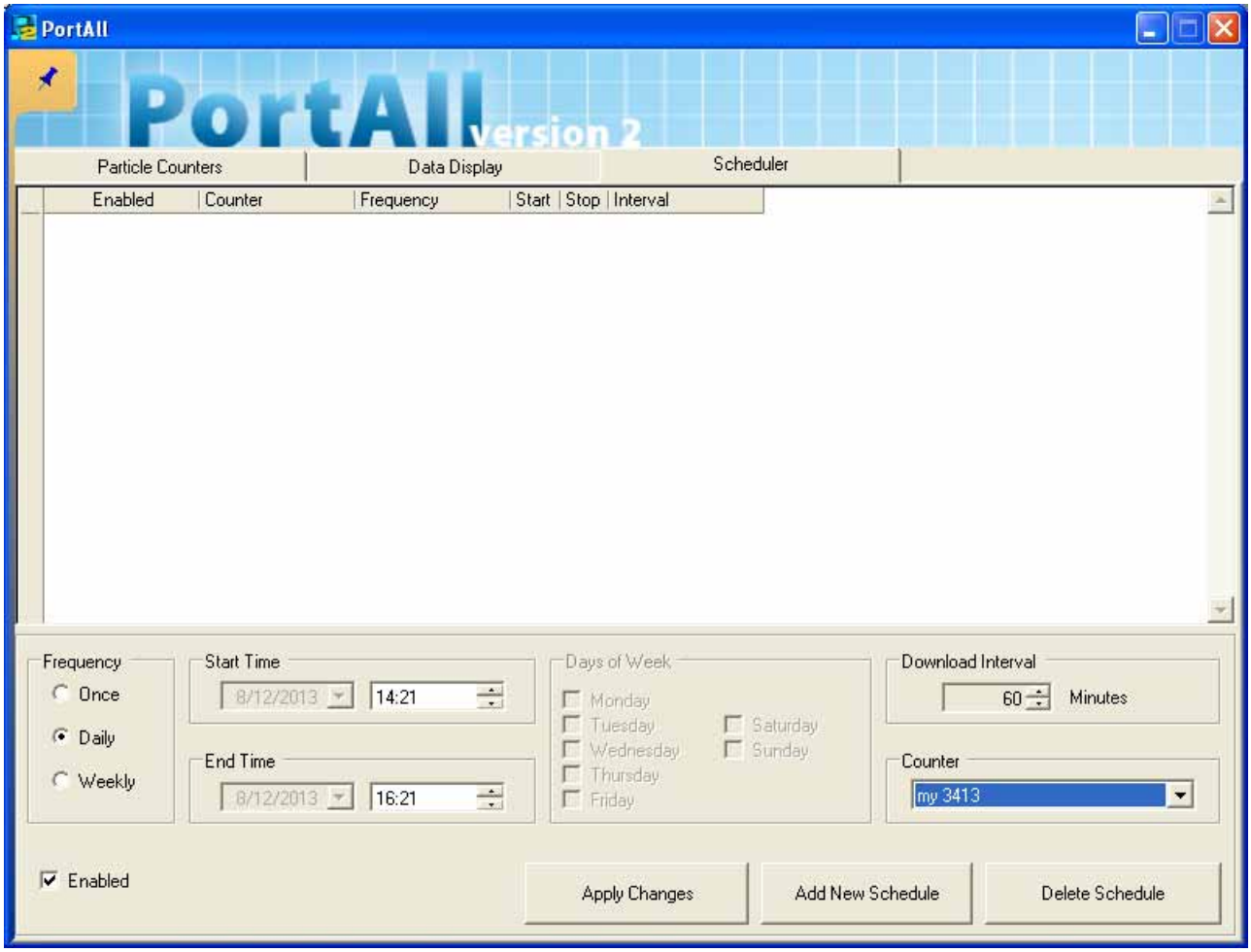


Figure 27 Schedule screen — daily

3.4.2.3 Enable schedules

Schedules can be turned on or off with the enabled checkbox. Complete these steps to enable a schedule:

1. From the main screen, select the **Scheduler** tab.
2. Highlight the schedule to enable.
3. Select the **Enabled** checkbox.
4. Click **APPLY CHANGES**. The schedule will run at the specified time.

3.4.2.4 Sort schedules

Schedules can be sorted by column:

- Enabled
- Counter name
- Frequency
- Start time
- Stop time
- Download interval

1. From the main screen, select the **Scheduler** tab.

2. Click on the heading of a column to sort the schedules by that column.

3.5 Graph data

Data can be viewed as a graph after download. The default graph view is a line graph that displays the entire data set. The graph can be printed.

3.5.1 Show graph of data

Any particle counter data can be displayed as a graph.

1. From the Data Display window, highlight the samples to graph.
2. Click the **GRAPH** tab. The data is shown by default as a line graph (Figure 28).

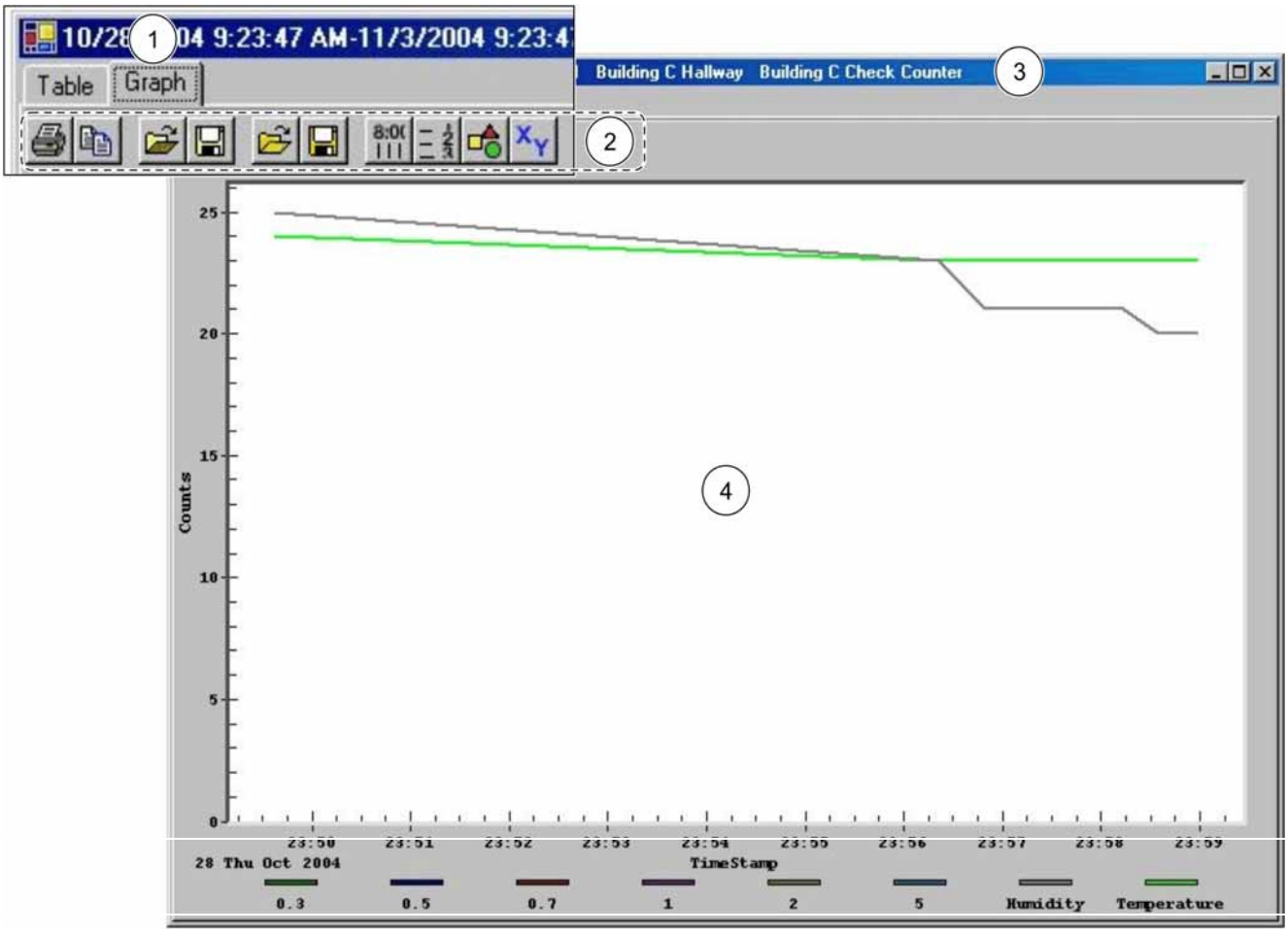


Figure 28 Graph Window

1	Graph tab	**3**	Title bar—locations and counters
2	Graph toolbar	**4**	Main graph window

3.5.2 Edit graphs

To change the appearance of graphs, use the graph toolbar (Figure 29) or double-click the graph to open the Customization Window (Figure 30).

Figure 29 Graph Toolbar

Table 5 Graph toolbar description

Icon	Name	Description	Icon	Name	Description
	Print	Send a graph to the default printer		Save Custom Configuration	Save the current configuration as a custom graph configuration.
	Export Data	Export a graph for use with another application (section 3.5.4)		X-axis Grid Lines	Show or hide grid lines on the x-axis
	Load Configuration File	Load a graph configuration file (*.graph)		Y-axis Grid Lines	Show or hide grid lines on the y-axis
	Save Default Configuration	Save the current configuration as the default graph configuration.		Data Points	Show or hide data points
	Load Custom Configuration	Load a custom graph configuration file (*.graph)		Data Labels	Show or hide data labels

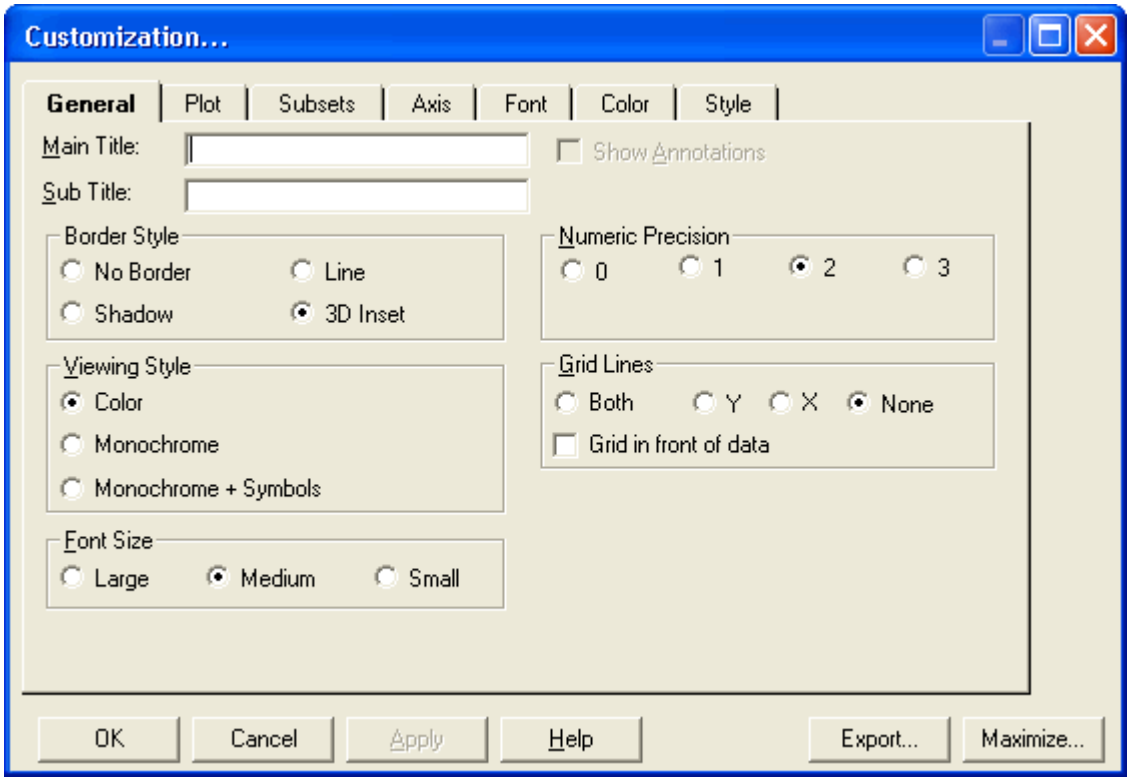


Figure 30 Graph Customization Window

3.5.3 Print graphs

To print a graph to the default printer, click the **PRINT** icon on the graph toolbar.

3.5.4 Export graphs

Complete the steps that follow to export a graph to another application.

1. On the graph toolbar, click the **EXPORT** icon. The Exporting Window opens (Figure 31).
2. Select the type of file to export, the destination and the object size.
3. Click **EXPORT** to export the graph.

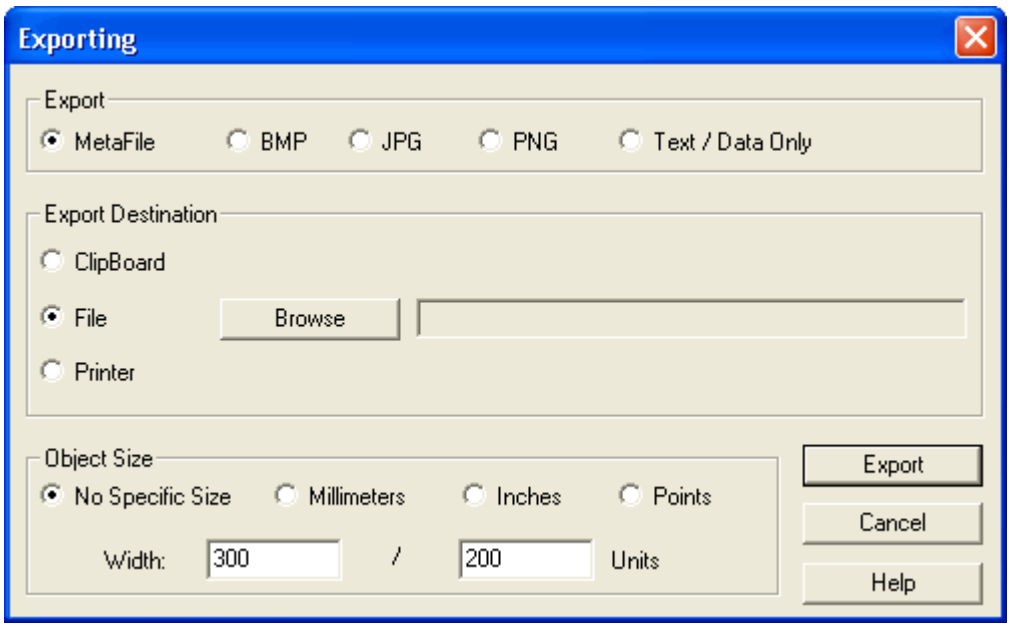


Figure 31 Export Window

3.6 Archive data or backup databases

There are two options for saving data.

- Use an archive to keep particle counter data. An archive removes older data from the database and places the data in a separate file. This file cannot be restored or copied back into the main PortAll database.
- Use a backup to make a copy of the database. No data is removed. These files can be repaired.

3.6.1 Create an archive

PortAll must be closed before an archive file can be created.

1. Close PortAll.
2. Open the **PortallDatabasebackup.exe** file located in C:\Program Files\PortAll or from the user-specified location. The PortAll Database Utility opens (Figure 32).

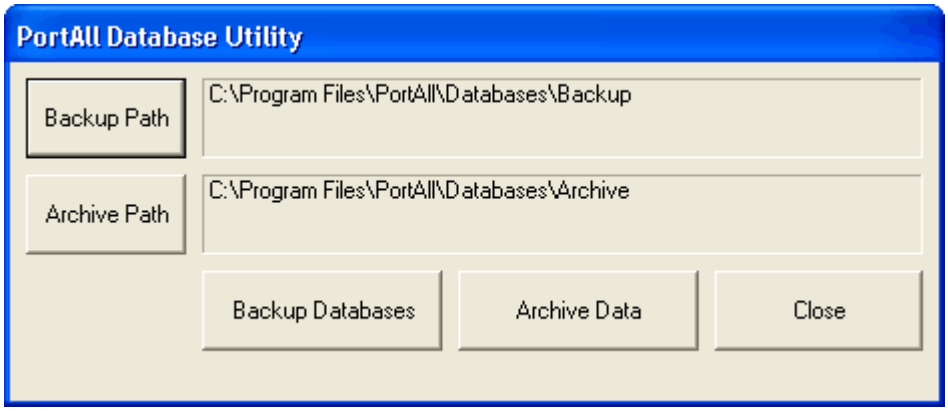


Figure 32 PortAll Database Utility

3. Enter the admin user name and password.

   Note: *If an administrator level user has logged on initially to PortAll and has the user rights for database maintenance (Figure 5 on page 13), the user can use the same user ID and password to archive data.*

4. Click the **ARCHIVE PATH** button to specify a location for the archive files.
5. Browse to the folder where archive files will be stored and click **OK**. The path to the specified folder is shown in the text box next to the **ARCHIVE PATH** button.
6. Click the **ARCHIVE DATA** button.
7. Select the end date for the archived data and click **OK**. The archive process begins.

   All data collected before this date and including this date will be archived. All data collected after this date remains in the local database.

8. When the message “Archive was successful” is shown, click **OK**.

   The archive files are named with the date format **YYYYMMDD.mdb**. For example, a file that is archived on February 9, 2005 has the file name **20050209.mdb**.

9. Click **CLOSE** to close the Database Utility.

3.6.2 View an archive

Open an archive file (*.mdb format) in PortAll to view historical data.

1. Open and login to PortAll.
2. Click on the **Data Display** tab and select the start date and time and end date and time of the archived data.
3. Select the location from the drop-down list.
4. Select the counter from the drop-down list.
5. Click **QUERY ARCHIVE** to open a file navigation window.
6. Select the appropriate archive file and click **OPEN**. The archived data is shown in table format, similar to Figure 21 on page 27.

3.6.3 Back up the database

PortAll must be closed before a backup database file can be created. Files created in the backup directory include:

- atdb.mdb
- atdb.mdw
- PortallData.mdb
- PortallData.mdw
- Settings.mdb
- Settings.mdw

1. Close PortAll.
2. Open the **PortallDatabasebackup.exe** file located in C:\Program Files\PortAll or from the user-specified location. The PortAll Database Utility opens (Figure 32).
3. Enter the admin user name and password.
4. Click the **BACKUP PATH** button to specify a location for the backup files.
5. Browse to the folder where backup files will be stored and click **OK**. The path to the specified folder is shown in the text box next to the **BACKUP PATH** button.
6. Click the **BACKUP DATABASES** button. The backup process begins.
7. When the message “Backup was successful” is shown, click **OK**.
8. Click **CLOSE** to close the Database Utility.

3.6.4 Restore the database

Complete the following steps to restore the database.

1. Open the backup folder.
2. Copy the files that reside in that folder.
3. Open the Portall\Databases directory. The default location is C:\Program Files\Portall\Databases.
4. Paste the files to this directory. The files will be copied to the Databases directory.
5. Click **OK** to replace files with duplicate names, if necessary.

3.7 Make compliance reports

PortAll can perform calculations on downloaded data to meet various regulatory standards. The Report Wizard performs the calculations automatically without altering the particle count data. The calculated information is not stored in the database.

The user must enter the following information for the Report Wizard to perform the calculations:

- Room identification
- Room size
- Class to meet

Note: *Refer to Appendix A on page 47 for detailed information on calculations.*

3.7.1 Make a report

Complete the following steps to make a report.

1. From the PortAll main screen, click the **REPORTS** icon. The Report Wizard opens to the Report Types screen (Figure 33).
2. Select the type of report and click **NEXT**. The Third-Party Certifier Information screen opens (Figure 34).
   - FS209E (Figure 35)
   - ISO 14644-1 (Figure 36)
   - BS5295 (Figure 37)
   - EU GMP Annex 1 (Figure 38)
   - Custom (For a custom report, contact the manufacturer.)
3. If there is a third-party certifier, fill in the information and click **NEXT**. The selected report type Calculation Information screen is shown.
4. If there is no third-part certifier, uncheck the **Add third-party certifier information to report** box and click **NEXT**. The selected report type Calculation Information screen is shown.
5. Enter the required information and click **NEXT**:
   - Room name
   - Room size in meters squared
   - Target cleanliness class
   - Particle sizes monitored to be included in the calculation
   - Room State (such as As Built, At Rest, Operational)

Figure 33 Report Wizard—Report Types

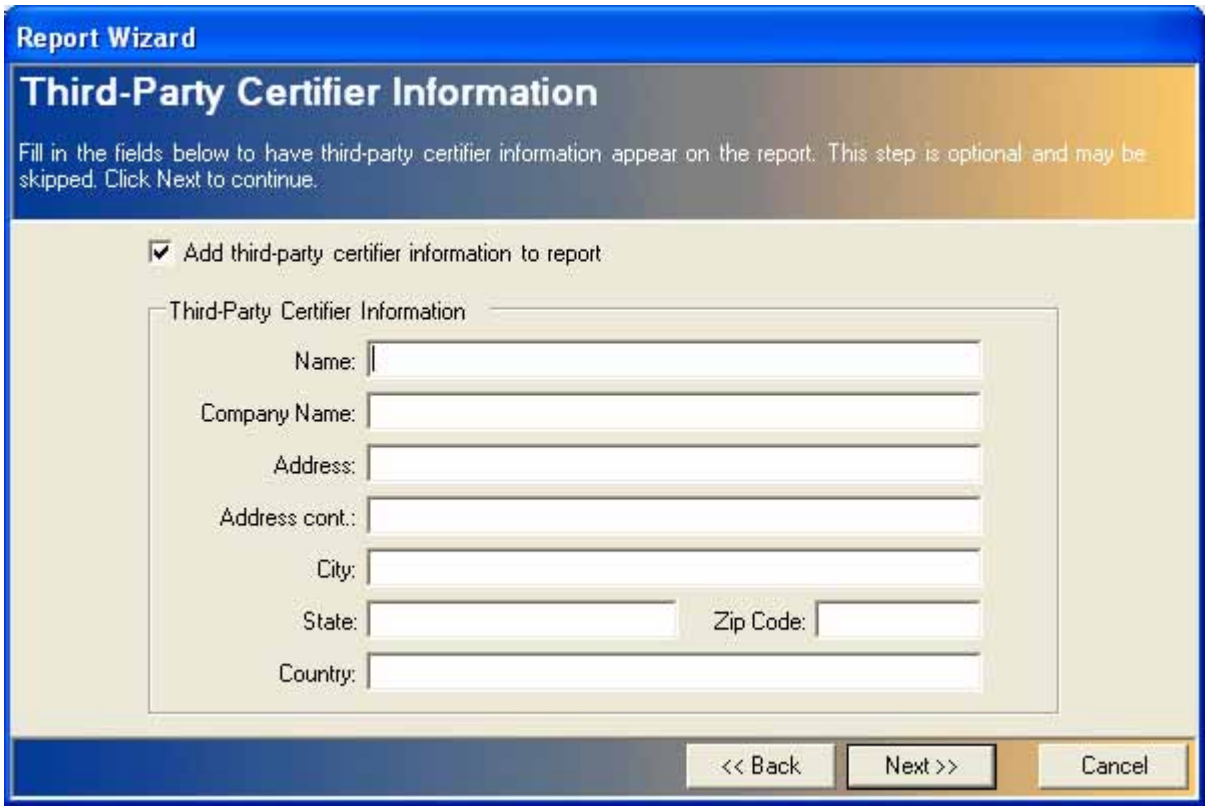


Figure 34 Report Wizard—Third-Party Certifier Information (Version 2.4 or higher)

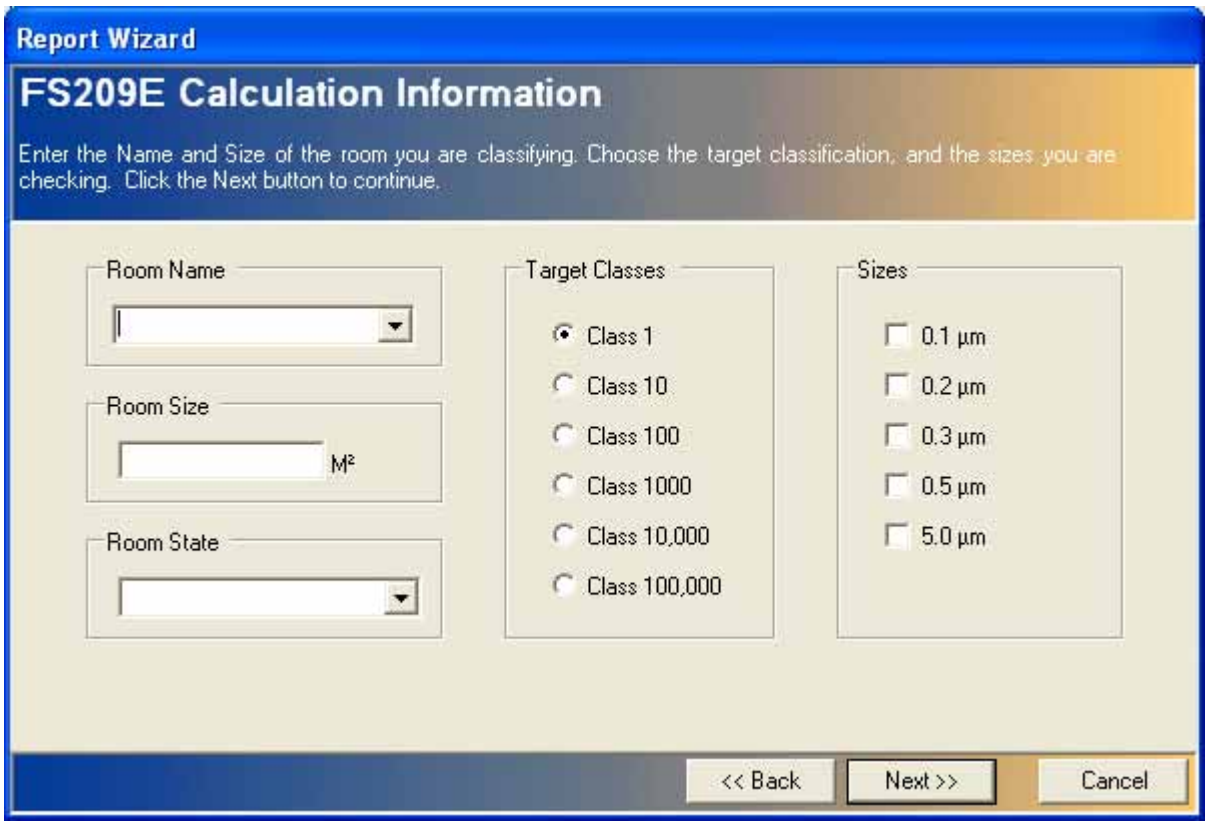


Figure 35 Report Wizard—FS209E

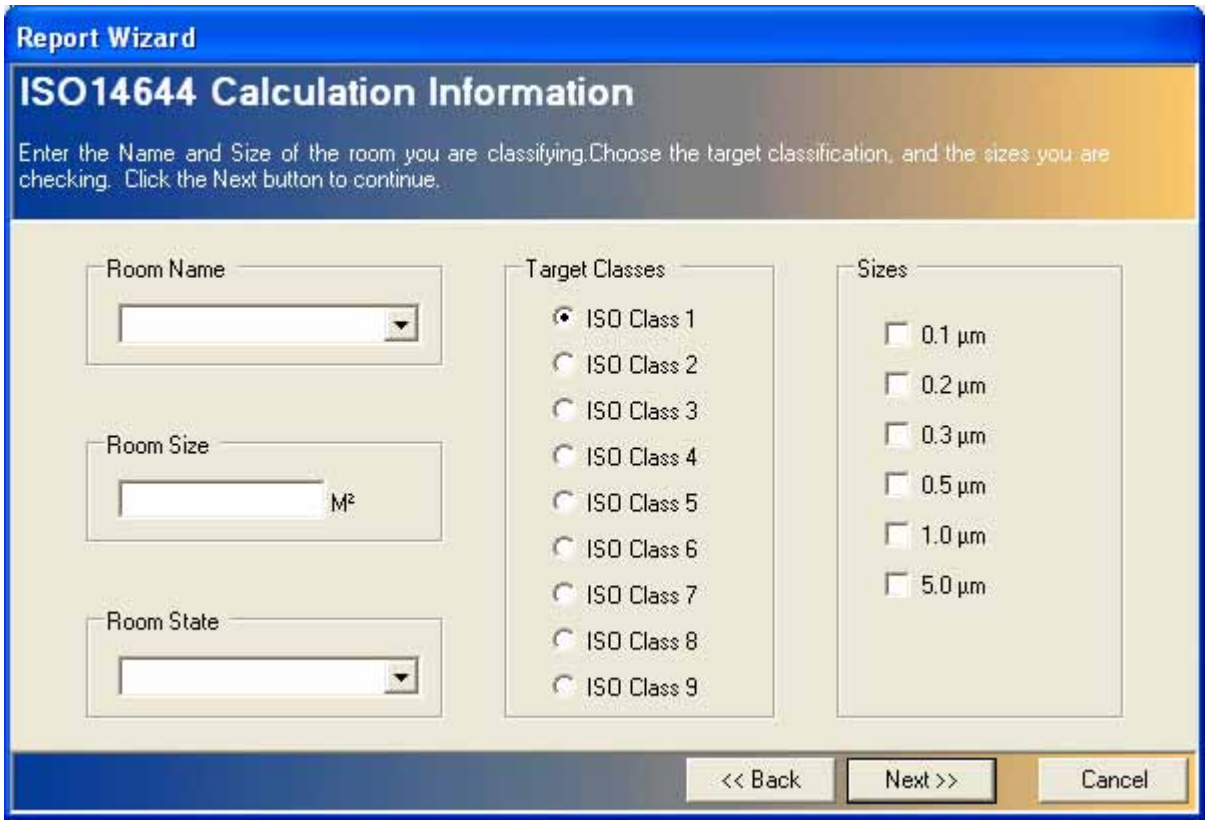


Figure 36 Report Wizard—ISO14644

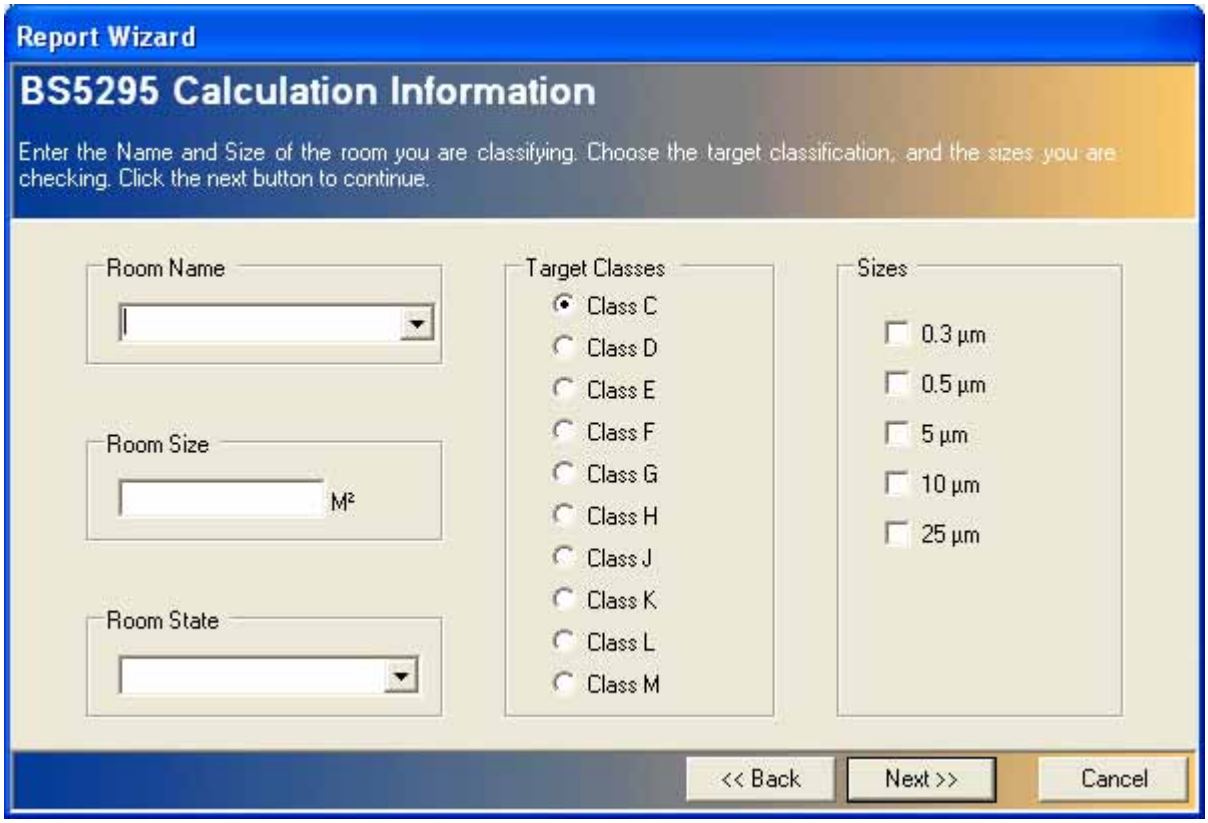


Figure 37 Report Wizard—BS5295

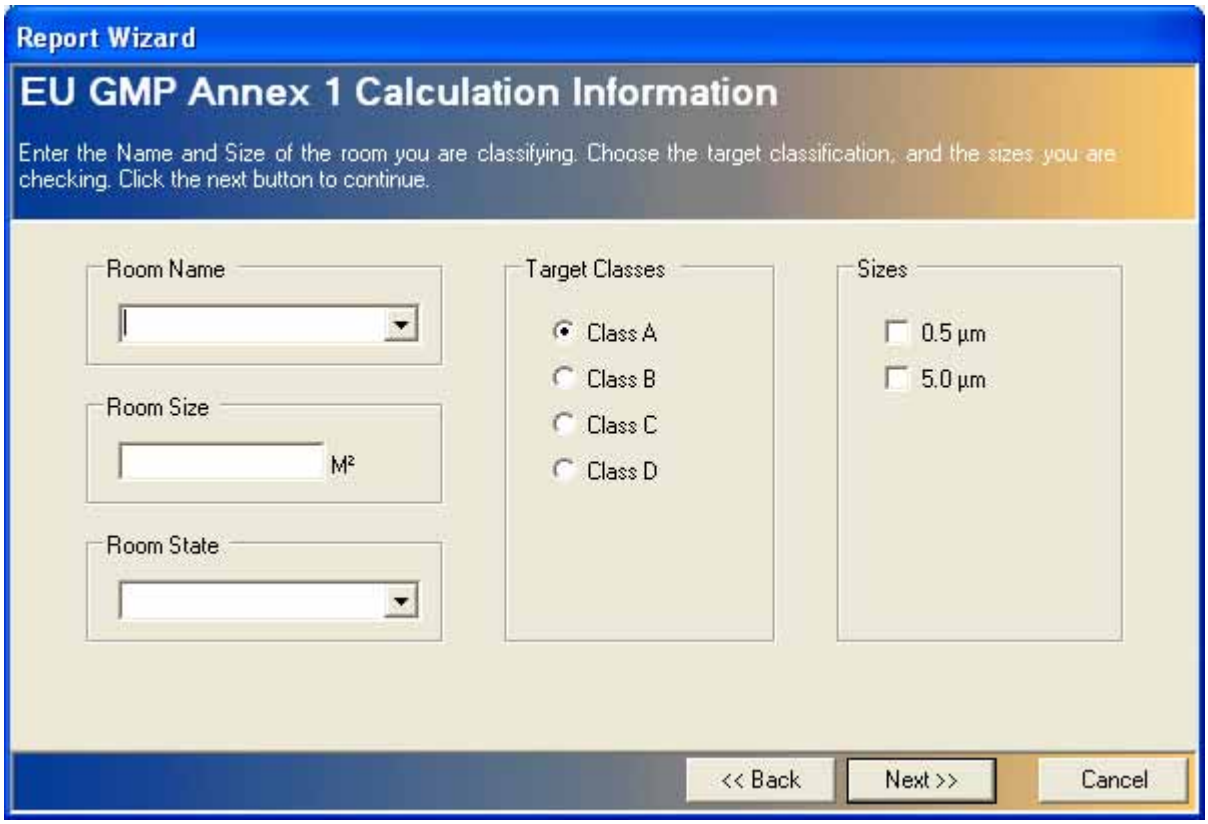


Figure 38 Report Wizard—EU GMP Annex 1

6. In the Date Range screen, select the collection start date and time for the report (Figure 39). Select the collection stop date and time for the report and click **NEXT**.

   Note: *Start times and dates refer to the times and dates of collection, not when the file download occurred. The times and dates for each data record are based on the settings of the particle counter.*

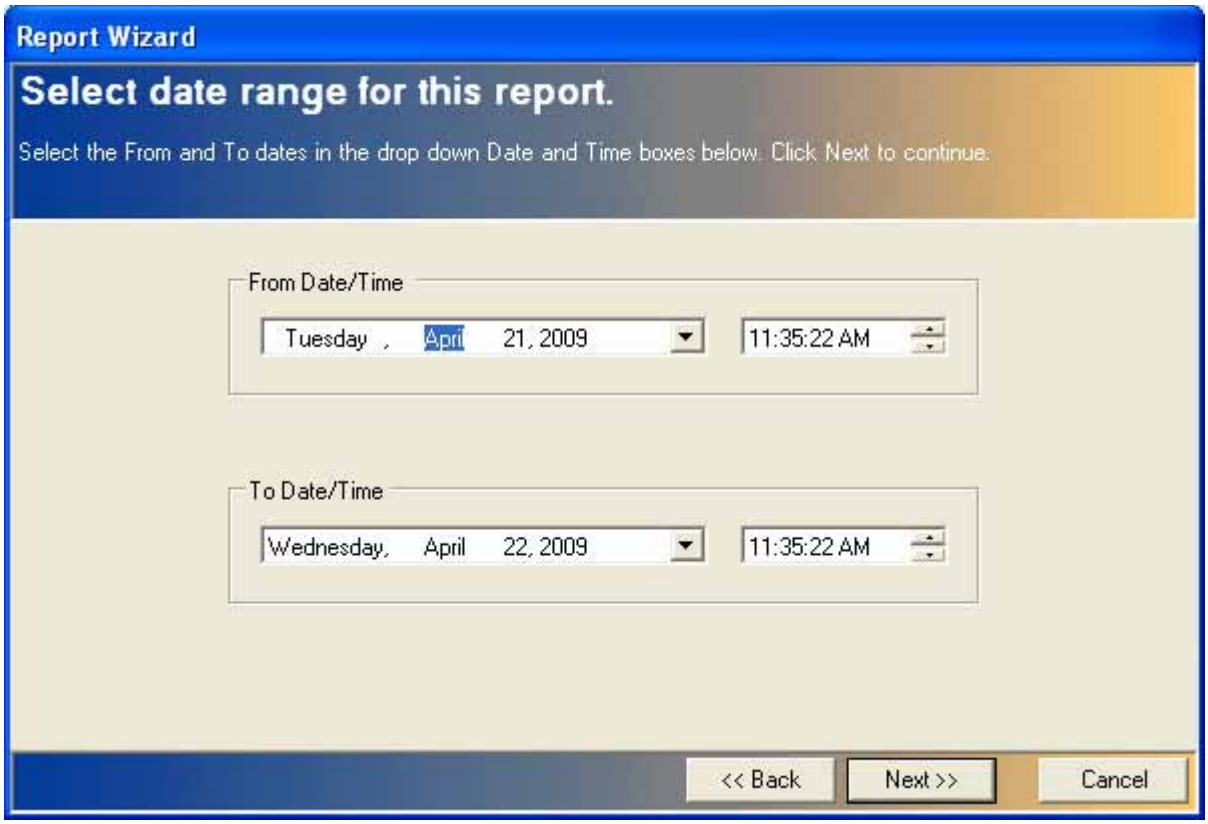


Figure 39 Report Wizard—Date Range

7. In the Locations screen, select the locations for the report (Figure 40).
   - FS209E requires at least two different locations
   - ISO 14644-1 requires different minimums for different cleanliness classes and the number of locations monitored, starting with at least one location
   - BS5295 requires different minimums for different cleanliness classes, ranging from four to fifty different locations
   - EU GMP Annex 1 requires different minimums for different cleanliness classes and the number of locations monitored, starting with at least one location

Note: *If no locations are shown in the Locations screen, refer to* *Set up locations on page 19**.*

8. Click **NEXT** to create the report (Figure 41)

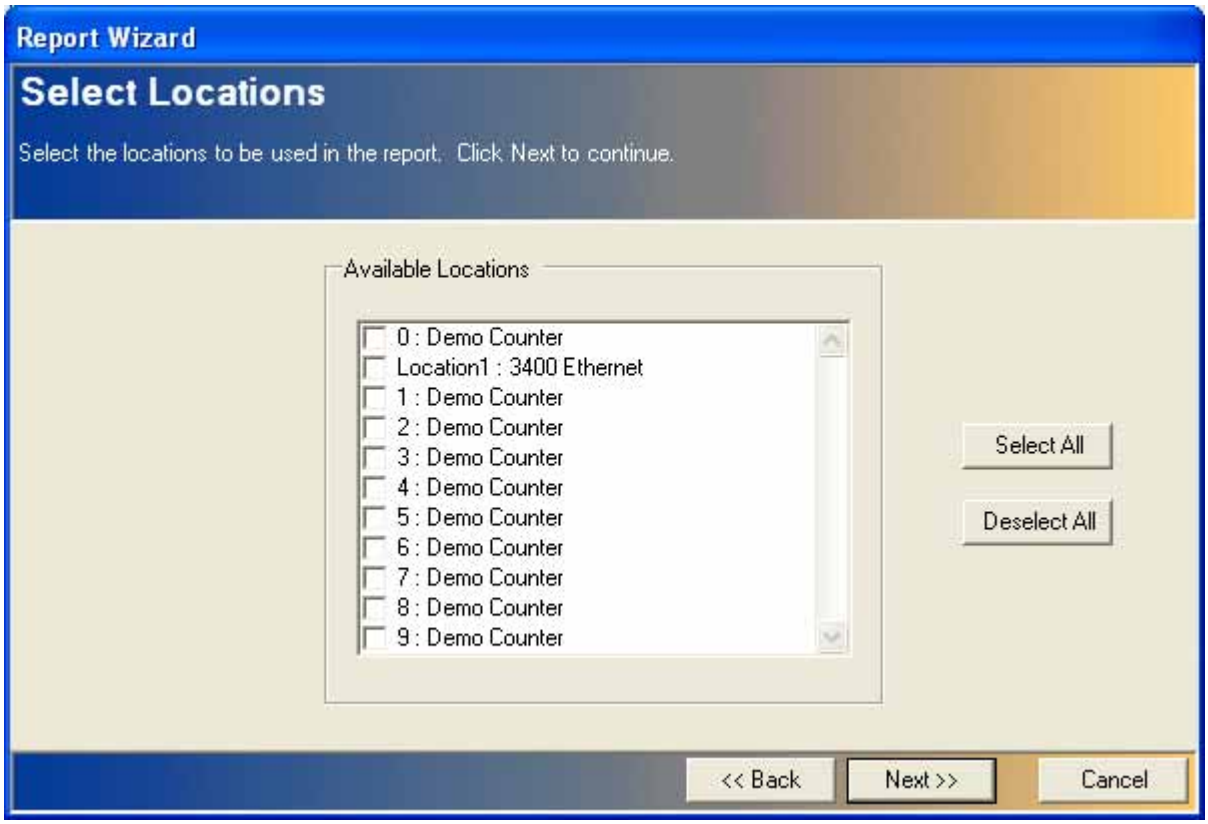


Figure 40 Report Wizard—Select Locations

3.7.2 Report description

A sample of a report is shown in Figure 41.A description of the icons in the report window is shown in Table 6. The registered company name will appear on all reports once the software has been shifted from the DEMO mode by the installation of a valid license code.

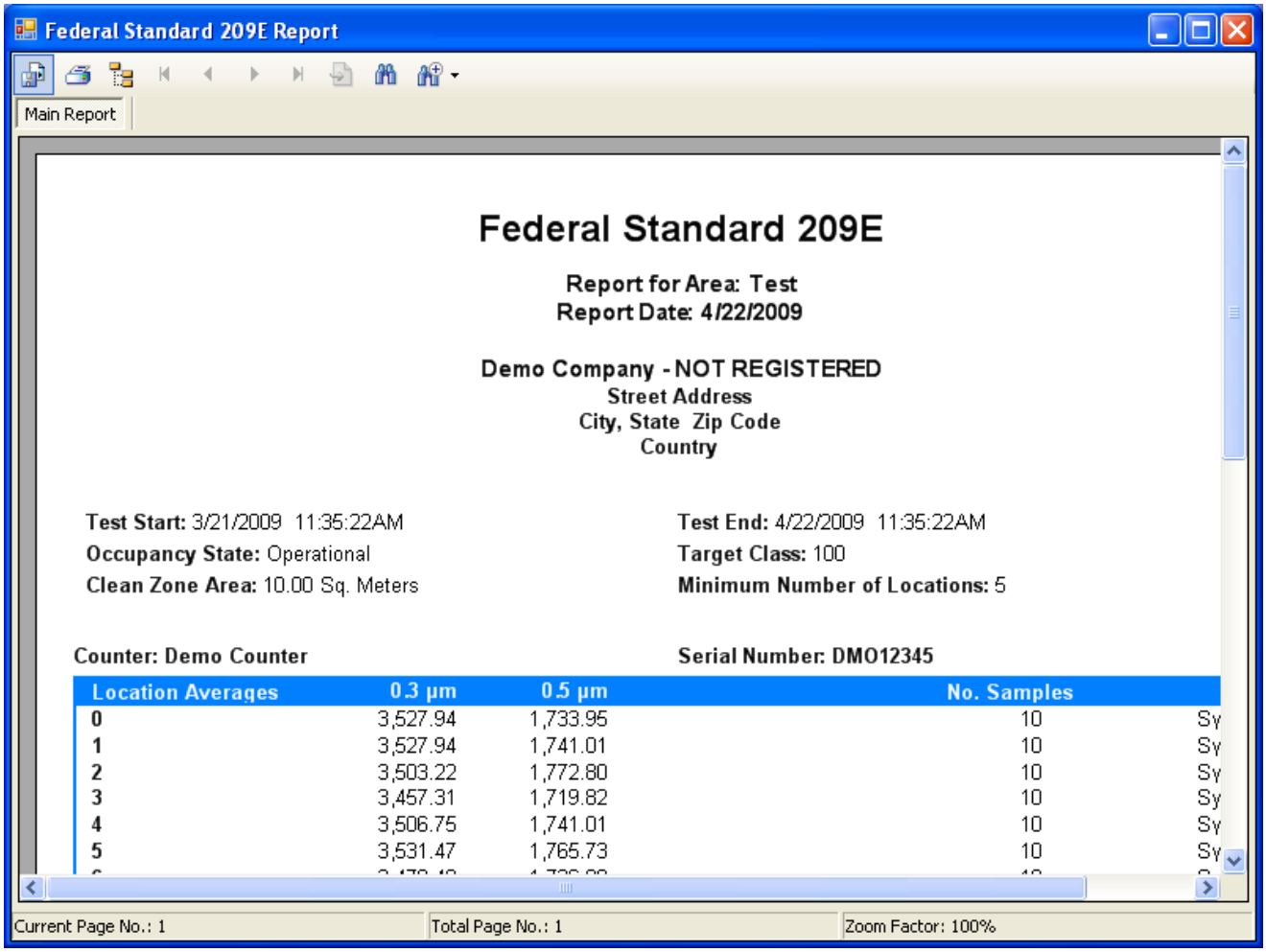
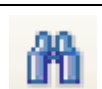


Figure 41 Sample Reporting

Table 6 Report Screen Icon Descriptions

Icon	Name	Description	Icon	Name	Description
	Export	Export the report to pdf, xls, doc or rtf		Next/Previous	Navigation—previous page, next page
	Print	Print the report to the default printer		Refresh	Refresh the report data (not used)
	Group Tree	Show the group tree		Search	Search for specific text
	First/Last	Navigation—first page, last page		Zoom	Enlarge the report view

3.8 Audit Trails—Life Sciences only

Administrators may view the audit trail at any time. The audit trail lists any changes to the configuration of the system. The natural expiration of a schedule is not considered a change to the configuration and is purged from the system without note.

3.8.1 View the audit trail

Any additions, modifications or deletions to the configuration will be noted by a keyword (Added, Modified, or Deleted), the information affected, the old value (if applicable), the new value (if applicable), and the full name of the user performing the operation. In addition, system events, such as logging in, downloading data, scheduled operations, etc., will also be noted in the audit log. The audit trail is stored in English only.

1. Login to PortAll as an administrator.

2. From the PortAll main screen, click **VIEW AUDIT TRAIL**.
3. The Audit Trail Viewer Window opens (Figure 42).
4. Enter a **Start Date** and an **End Date**.
5. Click **GET ENTRIES** or **GET ENTRIES FROM ARCHIVE**.
6. If **GET ENTRIES FROM ARCHIVE** is selected, a File Open window opens. Select the file and click **OPEN**. The Audit Trail Viewer opens (Figure 42).

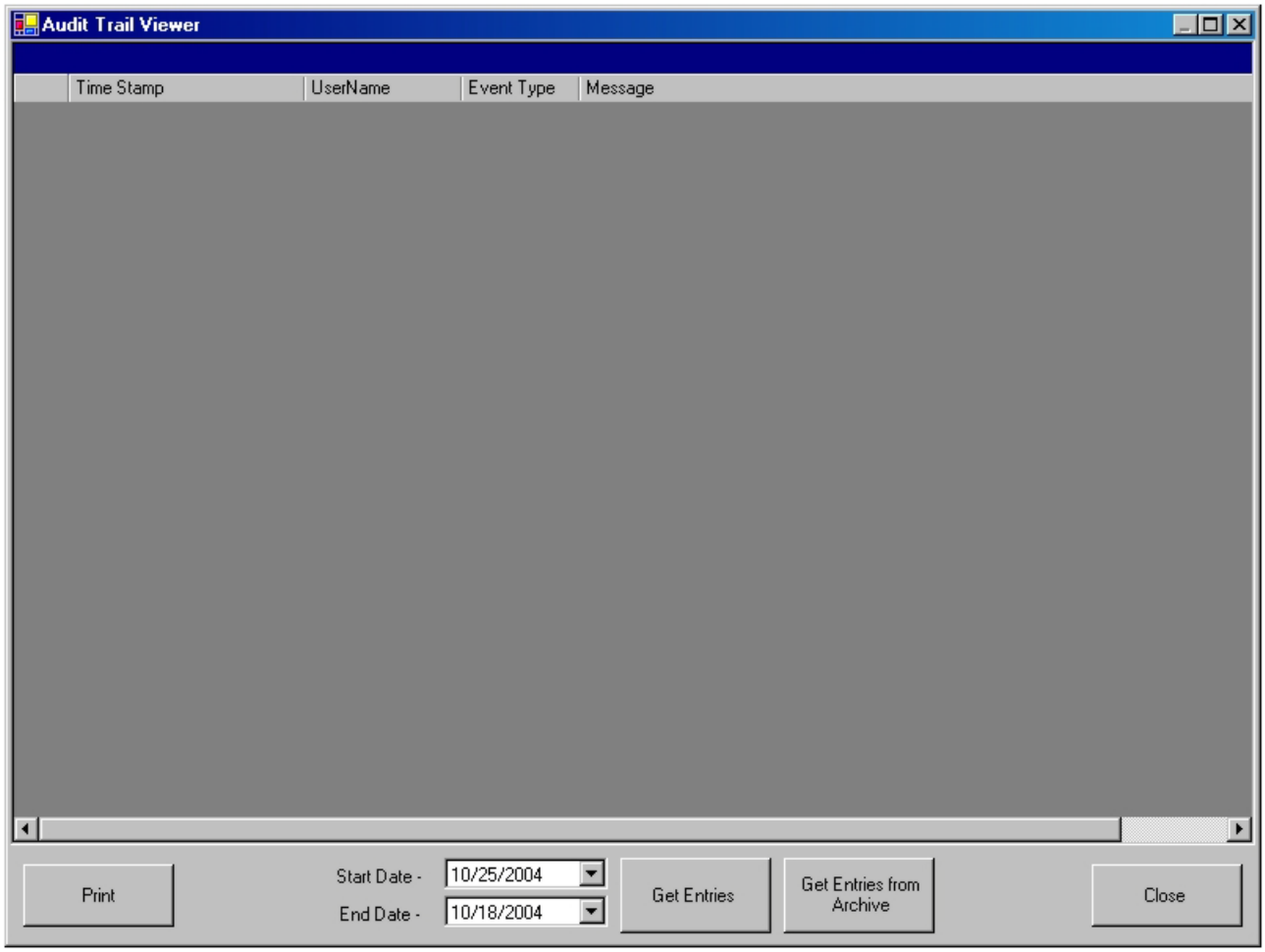


Figure 42 View Audit Trail Window

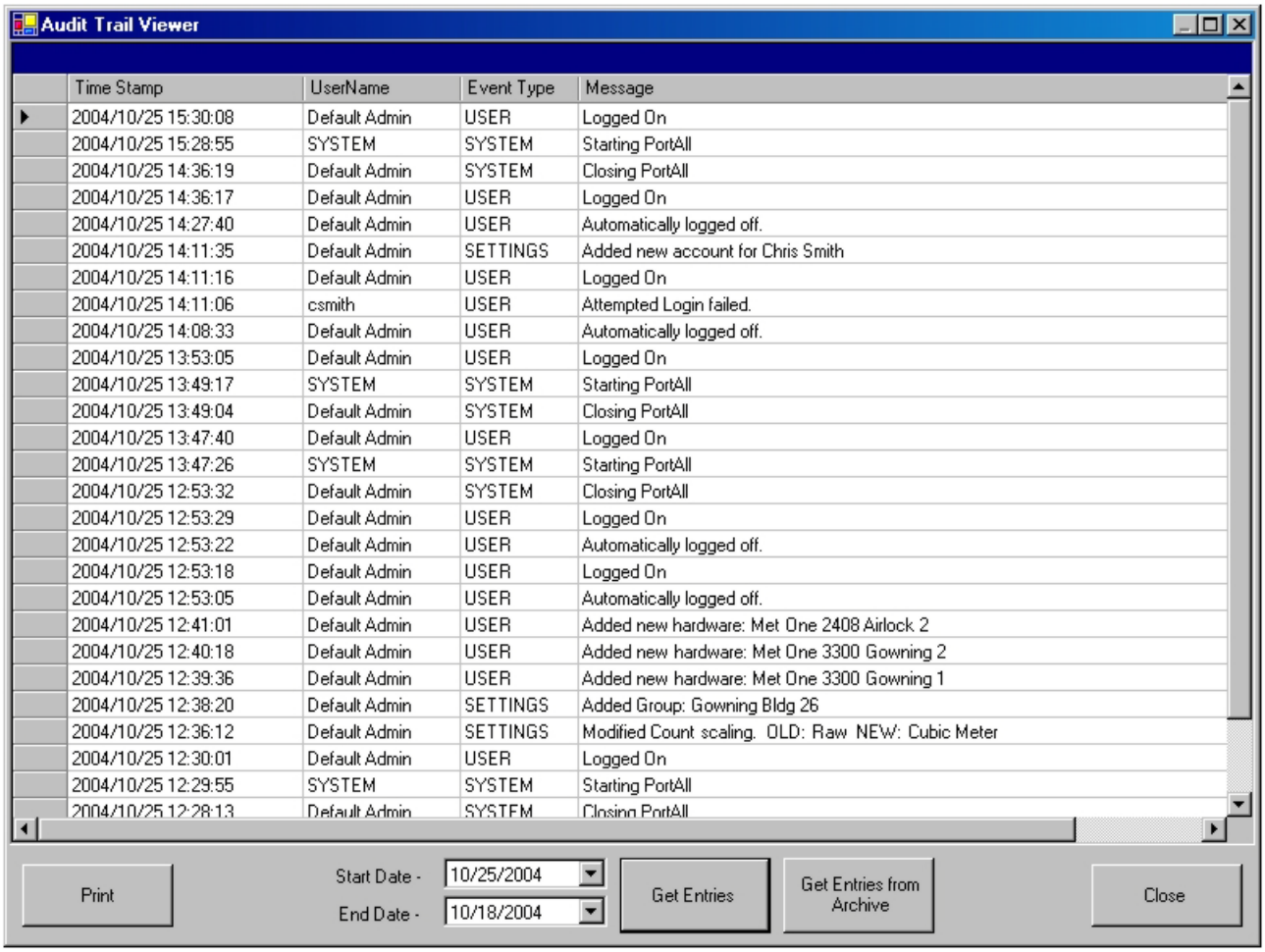


Figure 42 Audit Trail Viewer

3.8.2 Print the audit trail

To print the audit trail, open an audit trail as described in View the audit trail and click **PRINT** in the Audit Trail Viewer Window.

The information is sent to the default printer.

Appendix A Compliance calculations

PortAll can perform calculations for reports in accordance with the following standards:

- FS209E (section A.2 on page 48)
- ISO 14644-1 (section A.2 on page 48)
- BS5295 (section A.3 on page 49)
- EU GMP Annex 1 (section A.4 on page 50)

This information is subject to change without notice. For the most updated information, always check with the appropriate governing body for the most current regulations.

A.1 Sampling requirements

The room size and classification determine the minimum number of locations to sample. The class determines the minimum sample volume per sample and minimum number of samples per location. Room information is saved for future use.

Minimum sample parameters are shown in Table 7. EU GMP Annex 1 follows the same rules as ISO 14644-1 with one exception; in Grade A areas, at least 1 cubic meter of sample air must be taken at each position. Sample volume and location calculations are shown in Table 8.

Table 7 Determining Minimum Sample Requirements

Report Name	Minimum Volume	Minimum Sample Time	Minimum Flow Rate	Minimum Number of Locations	Minimum Number of Samples
ISO 14644-1	2 Liters	1 minute	N/A	1	3
FS209E	2.83 Liters (0.1 ft^3)	N/A	N/A	2	5
BS5295	27 Liters per sample	N/A	0.4 LPS (± 0.05 LPS)	4	Class C: 20 Class D: 10 Class E,F,G: 5 Class H–M: 1

Table 8 Sample Volume/Location Calculations

Report Name	Minimum Volume Calculation Method	Number of Locations Calculation Method
ISO 14644-1	N/A	Calculate the square root of the area of the entry plane (in square meters).
FS209E	20 divided by the particle count limit at the room class and particle size chosen Example: Class 10 room, 0.3 micron particle size, room limit of 30 counts per cubic foot Minimum volume = 20/30 = 0.67 CF	Unidirectional flow room: Divide the area of room or zone (in meters) by 2.32. Directional flow room: Multiply the area of the room or zone (in meters) by 64; divide the result by the square root of 10 raised to the room class value (M) in SI units.
BS5295	N/A	Divide area into approximately equal sub-areas of at least: Class C, D, E: 10 m^2 Class F, G, H, J: 25 m^2 Class K, L, M: 50 m^2

A.2 FS209E and ISO 14644-1 standards

FS209E and ISO 14644-1 calculations determine whether a set of data taken at several points around a cleanroom meet the classification shown in Table 9 and Table 10.

A.2.1 Calculations

Five steps are involved in ISO 14644-1 and FS209E calculation:

1. Average the particle concentration at a location.
2. Calculate the mean of the averages.
3. Calculate the standard deviation of the averages.
4. Calculate the standard error of the mean of the averages.
5. Calculate the 95% Upper Confidence Limit. Based on the 95% UCL, the cleanroom class can be chosen from the appropriate classification table.

Note: *If only 1 or more than 9 locations are used, the 95% UCL is not applicable. In this case, only the average particle concentration per size channel per location is used.*

A.2.2 Classifications

Table 9 FS209E Airborne Particulate Cleanliness Classes

Class name		Class limits									
		0.1 µm		0.2 µm		0.3 µm		0.5 µm		5.0 µm	
SI	English	(m^3)	(ft^3)	(m^3)	(ft^3)	(m^3)	(ft^3)	(m^3)	(ft^3)	(m^3)	(ft^3)
M1		350	9.91	75.7	2.14	30.9	0.875	10.0	0.283		
M1.5	1	1,240	35.0	265	7.50	106	3.00	35.3	1.00		
M2		3,500	99.1	757	21.4	309	8.75	100	2.83		
M2.5	10	12,400	350	2,650	75.0	1,060	30.0	353	10.0		
M3		35,000	991	7,570	214	3,090	87.5	1,000	28.3		
M3.5	100			26,500	750	10,600	300	3,530	100		
M4				75,700	2,140	30,900	875	10,000	283		
M4.5	1,000							35,300	1,000	247	7.00
M5								100,000	2,830	618	17.5
M5.5	10,000							353,000	10,000	2,470	70.0
M6								1,000,000	28,300	6,180	175
M6.5	100,000							3,530,000	100,000	24,700	700
M7								10,000,000	283,000	61,800	1,750

Table 10 ISO 14644-1 Airborne Particulate Cleanliness Classes

ISO classification number (N)	Maximum concentration limits (particles/m³ of air) for particles equal to and larger than the considered sizes shown below.					
	0.1 µm	0.2 µm	0.3 µm	0.5 µm	1.0 µm	5.0 µm
ISO Class 1	10	2				
ISO Class 2	100	24	10	4		
ISO Class 3	1,000	237	102	35	8	
ISO Class 4	10,000	2,370	1,020	352	83	
ISO Class 5	100,000	23,700	10,200	3,520	832	29
ISO Class 6	1,000,000	237,000	102,000	35,200	8,320	293
ISO Class 7				352,000	83,200	2,930
ISO Class 8				3,520,000	832,000	29,300
ISO Class 9				35,200,000	8,320,000	293,000

A.3 BS5295 standard

A.3.1 Calculations

Unlike FS209E and ISO 14644-1 calculations, only one step is performed for calculation:

1. Average the particle concentration at a location.

A.3.2 Classifications

BS5295 calculations determine whether a set of data taken at several points around a cleanroom meet the BS5295 Airborne Particulate Cleanliness classification, shown in Table 11.

Room information will be saved for future use. The room size and classification determine the minimum number of locations to sample. The class determines the minimum sample volume per sample and minimum number of samples per location.

Table 11 BS 5295 Airborne Particulate Cleanliness Classes

Class of environmental cleanliness	Maximum permitted number of particles/m³ (equal to, or greater than, stated size)				
	0.3 µm	0.5 µm	5 µm	10 µm	25 µm
C	100	35	0		
D	1000	350	0		
E	10000	3500	0		
F		3500	0		
G	100000	35000	200	0	
H		35000	200	0	
J		350000	2000	450	0
K		3500000	20000	4500	500
L			200000	45000	5000
M				450000	50000

A.4 EU GMP Annex 1 standard

EU GMP Annex 1 instructs that clean rooms and clean air devices should be classified in accordance with ISO 14644-1. Therefore, cleanroom for a specific grade should be classified as per the equivalent ISO 14644-1 cleanroom class.

Room information will be saved for future use. The room size and classification determine the minimum number of locations to sample. The class determines the minimum sample volume per sample and minimum number of samples per location according to the guideline provided in ISO 14644-1 except for Grade A. For classifying a Grade A cleanroom, the minimum suggested sampling volume is 1 cubic meter. The minimum sampling volume for grade B,C and D is 2.0 liters or sample time of 1 minute, whichever takes longer as per the guideline for ISO 14644-1 in Table 7 on page 47.

A.4.1 Calculations

The calculation steps are the same as ISO 14644-1 described in section A.2 on page 48.

A.4.2 Classifications

EU GMP Annex 1 calculations determine whether a set of data taken at several locations around the cleanroom meet the grade classification shown in Table 12.

Table 12 EU GMP Annex 1 Airborne Particulate Cleanliness Classes

Grade	Maximum permitted number of particles/m^3 (equal to, or greater than, stated size)			
	At rest		In operation	
	0.5 µm	5 µm	0.5 µm	5 µm
A	3520	20	3520	20
B	3520	29	352000	2900
C	352000	2900	3520000	29000
D	3520000	29000	not defined	not defined

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