VISION PROTOCOL MANAGER USER GUIDE

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Document Revision History

REVISION	DATE	DESCRIPTION
A	01 Jan 2017	Initial release.
B	29 Mar 2017	Updated several sections emphasizing key procedures and topics. Added installation troubleshooting section 14.
C	20 Dec 2021	Updated formatting. Removed Windows 7 as an operating system option. Added information for the CD14 tester.

Note: To confirm that you have received the latest version of this user guide, contact Teledyne Hanson Technical Support.

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Section 1 – Overview

This document contains information on how to install, configure, maintain, and work with the Vision® Protocol Manager™ (VPM) desktop software program from Teledyne Hanson.

The program enables users to quickly access and manage protocols, data backups, and test results associated with their Teledyne Hanson Vision® G2™ dissolution systems and CD14 instruments more efficiently than ever before. It eliminates all connectivity and storage limits by connecting the Vision G2 and CD14 instruments to a centralized protocol
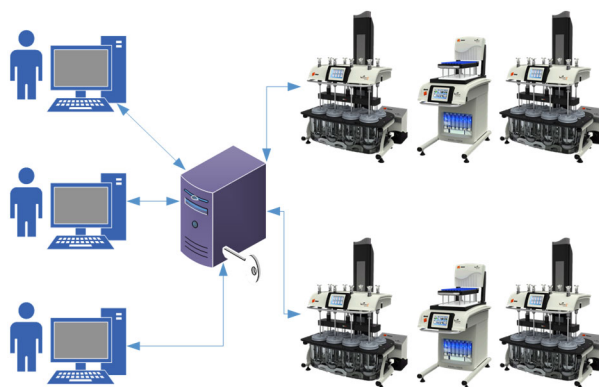
database.

Figure 1-1: Vision Protocol Manager Overview

- Manage all instruments, protocols and instrument data from one desktop view.

- The use of a modern client-server architecture accommodates unlimited users, instruments and instrument groups.

- Data transfers to and from instruments are validated by local network controls, without the need of a flash drive.

- The program implements the essential technical requirements of 21 CFR Part 11 in order to facilitate 21 CFR Part 11 compliance by the user.

- Test resultant dissolution test reports are digitized, documented with electronic signatures and automatically archived.

- The program's audit trail records all changes to permissions and protocols, including what was changed, when and by whom.

- Each instrument's separate event, error and test logs are automatically backed up to the program's database where the data can be sorted, filtered and archived.

- Archived test results cannot be deleted or altered; edited and deleted protocols are logged in the audit trail.

- On any revised or deleted protocol, the version stored with the archived test run is maintained.

- A tool especially beneficial to users of more than one Vision G2 or CD14 dissolution instrument.

- Protocol information fields are fully searchable and filterable.

- Works with CD14 instruments, Vision G2™ AutoPlus™ autosamplers, Vision G2™ dissolution testers and Vision AutoFilter™ changers.

Architecture

The program is a PC-compatible desktop software product for users of the CD14 and Vision G2 instruments. It works on the Windows 10 (64-bit) operating system.

Vision Protocol Manager (VPM) consists of two main pieces of software communicating in the client-server architectural model. Each user interacts with VPM using the client program. Multiple users (clients) can be connected simultaneously to a single data server. See Figure 1-2.

The dissolution instruments are connected to a network switch and then to the local network where they are accessed by the server program exclusively. The server is in charge of backing up instrument records including protocols and data logs and managing Vision Protocol Manager security. The retrieved data is maintained in a database. See Figure 1-2.

Configuration

The first step in the installation and configuration of the VPM program is for the lab IT department to set up the database and the user required for database access. This is done outside of the Vision Protocol Manager environment.

The server program is installed, and its network and database access are configured.

The client programs are installed in each computer that will be used to access VPM. The client is configured with the server location.

Once this is done, instruments, users, security, and other preferences can be finalized using the client user interface.

When adding an instrument to the system, the user adds the instrument IP address and serial number. VPM then connects to the instrument and downloads the instrument type and configuration.

The dissolution instruments that may be added to the system are: CD14, Vision G2™ Elite 8™ and Classic 6™ tester; Vision G2 AutoPlus; AutoFilter changer.
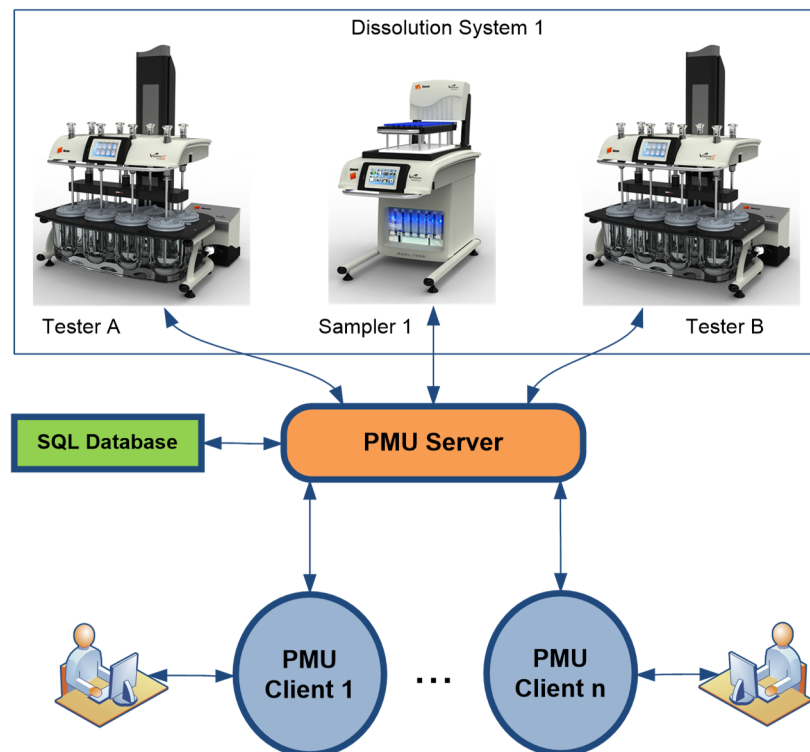

Figure 1-2: Vision Protocol Manager Architecture

Security

Vision Protocol Manager manages user security independent of instrument security. Basically, VPM security overrules instrument security.

VPM manages inactivity timeouts, password strength settings, password validity times and unsuccessful login attempts.

Users need to log in using the client program so that their permissions can be determined.

The program allows the administrator to set up groups and users with specific permissions (actions allowed by the program) within the security module. A user group can be created, and its group permissions defined. A user can be created, and his individual permissions defined.

Audit Trail

Vision Protocol Manager maintains an audit trail (also called audit log), which is a security-relevant chronological record that provides documentary evidence of the sequence of activities that have affected the program, the instruments, and the users at any given time.

Each record will contain a reference number, the time and date, the current username, and a description of the activity.

Instruments will maintain their logs as usual, however, when VPM performs a task on a particular instrument, the task will be logged on the instrument stating it was performed remotely.

The VPM audit trail will log all of the major events of the program, especially those where data is changed. See Section 12 – Audit Logs for details.

The user is able to search and filter through the audit trail records by content and date range.

The user is able to print a report containing the search results.

Data Management

The server program will use a Microsoft SQL Server database for data storage. The data stored in the database will include dissolution protocols, VPM security configurations, user profiles, program preferences, instrument configurations, VPM audit trails, instrument tests, error logs, event log backups and dissolution test reports with electronic signatures.

It is up to the IT department of the lab to schedule periodic backups of the database itself.

The server program handles all instrument and database interaction, security, and scheduled backups of instrument logs.

VPM will NOT keep track of protocol states (e.g., drafted, released) and will NOT keep track of which versions of the same protocol exist in the database vs. the instruments. It is up to the user to make sure that an instrument has the proper versions of the required protocol. However, protocol states can be easily maintained with the label fields. Refer to Section 9 – Protocol Management, "Using Labels and Filters to Manage Release Stages."

When a dissolution test finishes, the event log, error log and test log of the instrument that just finished the test is automatically backed up by the server. The version of the protocol that was used for the test is also archived. This version can be retrieved at a later date if required.

VPM only retrieves data that has been generated since the last backup. The data for each instrument is displayed as a single contiguous backup without repeated items.

In addition, after a test finishes, the test report (in the same format that it would be printed) is retrieved by the server and stored in the database. This report, now permanently stored in the database, can be retrieved, electronically signed, and printed from the client program.

VPM allow users with the proper permissions to search, open, view and print the records within a backup file.

The program does not allow anyone to edit a backup file.

The program allows a user with the proper permissions to create, edit and transfer protocols between the instruments and the server's database.

VPM will only retrieve error log, maintenance log and status data from the Vision AutoFilter changer. It will not upload or download protocol or test log data from the filter changer.

21 CFR Part 11 Statement

This section provides details on how the Vision Protocol Manager desktop software deals with electronic records in order to aid the user with 21 CFR Part 11 compliance. No single software program can ensure compliance without the proper procedures and controls. Compliance is the responsibility of the facility. It is required to provide "appropriate controls over systems documentation."

VPM aids the user to be 21 CFR Part 11 compliant as follows:

- It meets the criteria of a "closed system" in which "access is controlled by persons who are responsible for the content of electronic records that are on that system."

- It limits access to authorized individuals. Each time the program is started, the user is prompted to log in. If the user successfully logs in with the proper username and password, they are allowed to interact with the program.

- The level of interaction of each user and/or user group is determined by the individual user or group permissions assigned by the system administration.

- No two individuals are allowed to have the same username and password combination.

- Password strength, inactivity timeout, user lockouts and password expiration times are enforced.

- The system administration can configure users, groups, program settings, user permissions, security settings such as password strength, inactivity timeout, allowable login failure attempts, etc.

- Audit trail events are "secure, computer-generated, time-stamped" and independently recorded events. Events are also referenced by the username or instrument serial number.

- VPM provides "protection of records to enable their accurate and ready retrieval throughout the records retention period."

- VPM archives the dissolution protocol (method) used with each dissolution test result in case the protocol is revised in the future.

Section 2 – Prerequisites and Requirements

Overview

This section describes the installation and initial configuration of the Vision Protocol Manager (VPM) and related software. The installation and configuration should be done by persons who are familiar with installing and configuring software, such as IT personnel. In addition, the person installing the software needs to have administrator level access on the computers where the software is being installed. If an already existing SQL Server is going to be used for the database, the person configuring the database needs to have the necessary permissions to access the SQL Server and create and configure a database.

List of Software Packages and Prerequisites for the Server

The VPM server software runs as a Windows service. The server software requires the presence of .NET Framework version 4.5 or newer, a SQL Server database, and PostScript to PDF conversion software. The SQL Server itself, depending on the version and options being installed, might require a different version of .NET Framework installed, and if it requires an older version of the .NET Framework, such as version 3.5, that version of .NET Framework must be installed in addition to .NET Framework version 4.5.

.NET Framework (Server)

The .NET Framework is a programming infrastructure created by Microsoft for building, deploying, and running applications and services that use .NET technologies, such as desktop applications and web services. Windows 10, Windows Server 2012, and Windows Server 2012 R2 operating systems already come with .NET Framework 4.5 or newer installed. On Windows Server 2008 it might be necessary to install .NET Framework 4.5 or newer. Note that given that Microsoft ended the support for .NET Framework 4.5 and 4.5.1 on January 12, 2016, it is recommended that .NET Framework 4.5.2 or newer be installed on computers running VPM software.

Section 2 – Prerequisites and Requirements

SQL Server

The VPM server needs SQL Server 2008 or newer, SQL Server 2016 or newer is the recommended version. Any edition of the SQL Server could be used, including Express, as long as that edition supports Full-Text Search. If the server computer already has one of those SQL Server versions installed, it can be used. If there is a suitable SQL Server available on the network, that SQL Server could be used instead, as long as the network and the server computers can provide necessary performance. Note that the Express edition of the SQL Server is available for free, and as long as its performance and database size limitations are acceptable (10 GB database storage maximum, 1 GB memory usage maximum, 1 processor utilization maximum), it can be installed and used if there is no SQL Server already available. When installing SQL Server Express edition, the option that supports Full-Text Search should be chosen, such as Express with Advanced Services, or Custom, or Full package. Different versions of SQL Server Express name the option that supports Full-Text Search differently.

PostScript to PDF Conversion

The VPM server software needs an external tool for converting the test reports obtained from instruments into PDF documents. Normally the test reports are generated for printing to PostScript printers, thus the server obtains them from the instrument in PostScript format and uses an external tool for converting them to PDF documents. Any PostScript to PDF conversion program can be used for this, as long as it can be controlled through command line parameters. Ghostscript version 9 is the recommended program.

List of Software Packages and Prerequisites for the Client

VPM client software is a regular Windows Desktop application. VPM client software requires the presence of .NET Framework version 4.5 or newer.

.NET Framework (Client)

The .NET Framework requirements for the VPM client are the same as for the VPM server, see the .NET Framework (Server) section above.

Section 2 – Prerequisites and Requirements

Computer Requirements

The computer requirements are different for the client and for the server, and if both the client and the server are running on the same computer, the computer requirements for the server should be followed. Also, based on the version of the operating system, SQL Server, .NET Framework and PostScript to PDF conversion program, the requirements might be different than listed below.

Requirements for the Server

Memory: Minimum 8 GB. Recommended 16 GB

Processor type: x64. Minimum Intel Core i-5, or AMD equivalent. Recommended Intel Core i-7, or AMD equivalent

Processor speed: Minimum 1.7 GHz. Recommended: 4.10 GHz, with at least 6 cores

Hard disk free space: At least 30 GB

Operating system: Windows 10, Windows Server 2008 or newer

Requirements for the Client

Memory: Minimum 4 GB. Recommended: 8 GB or more

Processor type: Minimum Intel Core i-5 or AMD equivalent, 64-bit

Processor speed: Minimum 1.7 GHz. Recommended: 4.10 GHz, at least 6 cores

Hard disk free space: At least 10 GB

Operating System: Windows 10

Section 3 – Preparing Server Computer

To prepare the server computer to run the Vision Protocol Manager (VPM) server software and the SQL Server database, one or more user accounts might be needed to be added to the computer or to the network.

Adding a User for the VPM Server Software

VPM server software is run as a Windows service. As such, it needs to run under some account. It is recommended that a new user be created so that Vision Protocol Manager runs under a specific user account that is created specifically for this purpose. However, it is acceptable and sometimes simpler to run the VPM Service under a Local System account, or under an existing user account, as long as it has the necessary permissions. If using a new user account, the new user account is added to the computer, if not using networking, or the new user account is added to the network, if using network-based authentication such as Active Directory. The newly added user account needs to have permissions to run the VPM server software, permission to access the network, so it can communicate with the VPM client software, and permission to access the Vision Protocol Manager database on the SQL Server software. The VPM server software might be configured to generate log files, and it is recommended that those log files be written to this user's directories. In addition, it is also recommended that only this user and IT have the necessary permissions to access this user's directories as well as the VPM server software directories.

Adding a User for the SQL Server Administration (Optional)

If SQL Server needs to be installed, a user account needs to be specified as the SQL Server administrator. That user can be one of existing users, most likely an IT person, or a new user account can be created for administering SQL Server. Note that using the user account created for running the VPM server software for administering SQL Server is not recommended, preferably those should be different accounts.

Section 4 – Installing Server Software

NOTE: Any previous installation of Vision Protocol Manager server service must be uninstalled before starting the installation of the server software.

Installing .NET Framework

If the server computer already has .NET Framework 4.5 or newer installed, there is no need to install the .NET Framework. To check whether the server computer has .NET Framework installed and its version, you need to access the Windows command prompt shown below.

Hold down the Windows key and the "R" key simultaneously ⊞ + Ⓡ and type "cmd" and Enter to invoke the Windows command prompt.

Type the following command exactly as shown after the ">":

reg query "HKEY_LOCAL_MACHINE\SOFTWARE\Microsoft\NET Framework Setup\NDP\v4\full" /v version
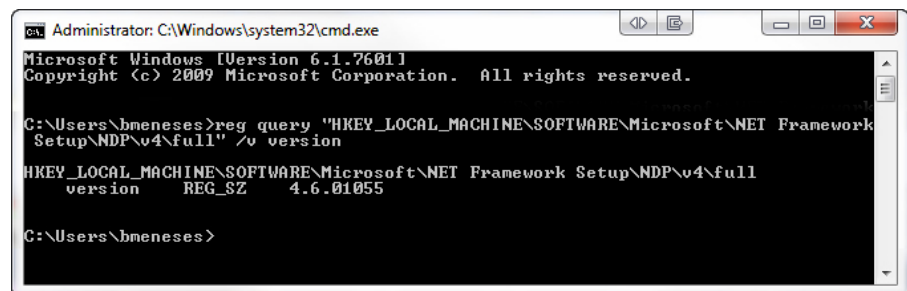
Figure 4-1: .NET Framework Registry Query Window

The current version will be returned as shown above: 4.6.01055, which meets the requirement.

NOTE: If you get the error message, "The system was unable to find the specified registry key or value," check for spelling, letter case errors and proper back and forward slashes.

If .NET Framework 4.5 or a newer version is not found, download .NET Framework 4.5.2 or a newer version from the Microsoft website. If an internet connection is available on the computer in which it will be installed, the web installer can be used, otherwise the offline installer should be used. After downloading the installer, run it and select the default options for the installation.

Section 4 – Installing Server Software

Installing SQL Server

If SQL Server needs to be installed on the server, determine the SQL Server edition most suitable for your needs and obtain the installer for it. For example, the free SQL Server Express edition can be downloaded from the Microsoft website. An edition needs to be chosen that includes the Full-Text Search feature.

NOTE: Various versions of SQL Server Express name the download option that supports Full-Text Search differently, such as Advanced Services, or Custom or Full. That option to download usually is their largest download, typically over 1 GB. Usually, the Basic option does not include the Full-Text Search and should not be chosen.

The installation steps described below are for the SQL Server Express edition. For a different edition of SQL Server, the installation steps might be somewhat different.

1. Run the installer.

2. Select the Installation panel.

3. Select New SQL Server stand-alone installation.

4. Read and accept the Microsoft license agreement. Click Next to proceed.

5. On this page, it asks to check for updates. Check for updates, install them and click Next to proceed.

6. The installer checks for required components and if necessary, it might install the required components, such as the .NET Framework used by SQL Server. Then it will proceed to the Feature Selection panel.

7. On the Feature Selection panel make sure that Database Engine Services is selected. Also make sure that Full-text for Search or similar is selected.

8. You can keep the default directories or specify different directories. Click Next to proceed.

9. On the Instance Configuration panel make sure that the Named Instance is selected. Make sure to write down the instance name, as it will be needed when configuring the VPM server software.

   Instance Name:

   The default Instance name is "SQLExpress". Click Next to proceed.

10. On the Server Configuration panel specify the account to run the SQL Server Database Engine or keep the default value. Keeping the default value is recommended. Click Next to proceed.

11. On the Database Engine Configuration panel provide the following information:

    a. Make sure that Windows authentication mode is selected. Note that VPM server software by default is configured for using Windows authentication for accessing SQL Server. However, if for some reason, the SQL Server authentication mode needs to be used, it is possible to manually configure VPM server software to use SQL Server authentication to access SQL Server.

    b. Specify an administrator user for SQL Server. It could be a user account added specifically for this purpose (see Section 3 – Preparing Server Computer) or one of the IT administrator accounts.

    c. Click on the Data Directories tab and specify data directories or use the default values (recommended) for the SQL Server data directories.

12. Select Install and Configure and click Next to proceed with completing the installation.

13. Make sure that the installation completes successfully and click Close to exit the SQL Server setup wizard.

Installing SQL Server Management Studio (Optional)

To simplify administering SQL Server, it is possible to download and install SQL Server Management Studio from the Microsoft website (a free version is available) however it is not necessary for the correct operation of the VPM server software.

Installing the PDF Conversion Tool

In order for the VPM server software to make test reports available for viewing, a PostScript to PDF conversion tool, which supports control through command line parameters, needs to be available on the server computer. There are a number of such tools available, and VPM server software has been tested with Ghostscript version 9, which is available for free by Googling "Ghostscript 9.09 download" and downloading the 32-bit version of the program. Installation instructions for Ghostscript are available from the Ghostscript website.

By default, VPM server software is configured to work with Ghostscript version 9.09, installed at the default location, for doing the PostScript to PDF conversions. By default, it expects the conversion tool at the following location: C:\Program Files (x86)\gs\gs9.09\bin\gswin32c.exe

It is possible to install Ghostscript at a different location or install another PDF conversion tool or another version of Ghostscript. In that case, VPM server software needs to be configured to use that tool.

Installing VPM Server Software

1. Locate files setup.exe and SetupService.msi within the Server Installation folder of the distribution media. Note: Both files must be together in the same path to work properly.

2. Run the setup.exe program as an administrator.

3. Read and accept the licensing agreement, and click Next to proceed.

4. Select the installation directory for the VPM server software and click Next to proceed with the installation.

5. Once the installation is completed, verify that it completed successfully and click Close to exit the setup wizard.

6. Note that the VPM server software should not be run at this point.

Configuring VPM Server Software and Database

Prior to running the VPM server software for the first time, but after installing the VPM server software the VPM database needs to be created and configured and the VPM server software needs to be configured.

The next sections will show you how to use the VPM server configuration tool for configuring the VPM server software and the VPM database. For security reasons (see the topic called, "Adding a Default Administrator Account for VPM" below) the access to this tool should be restricted, e.g., to IT personnel only or only to those who have direct access to the VPM database through the SQL Server command line or the SQL Server management tool.

Enabling Server Software Windows Service

The Protocol Manager Server Software need to be configured as a Windows Service. A Windows Service can run under a specific Windows user account, an option that allows more customization of user account permissions, or as a Local System account, an option that might be simpler to configure. Before configuring the Protocol Manager Service, you need to decide under which account it will run. Afterwards the Protocol Manager Service can be configured.

1. Open the Services application from Windows (e.g., by typing Services in the Search Programs and Files prompt of the Windows Start menu).
2. Locate Protocol Manager Service in the list of services, select it, right-click and select Properties from the context menu.
3. The Protocol Manger Service Properties window will be shown.
4. On the General panel, select Automatic (Delayed Start) for Startup Type.
5. On the Log On panel, select the Local System account, if the Protocol Manager Service will run under the Local System account.

6. On the Log On panel, make sure This Account is selected, if the Protocol Manager Service will run under a Windows user account.
7. Specify the user name, including the domain, if applicable, of the account that the Protocol Manager Server Software will run under for this account (see Section 3 – Preparing Server Computer, "Adding a User for the VPM…"). You can browse for the user names to select this user.
8. Specify the Password and Confirm Password for this user name.
9. Click OK to save the changes and close Protocol Manger Service Properties.
10. Locate Protocol Manager Service in the list of services, select it, right-click and select Start from the context menu.
11. Wait for Protocol Manager Service to start.
12. Locate Protocol Manager Service in the list of services, select it, right-click and select Stop from the context menu.
13. Wait for Protocol Manager Service to stop.
14. The reason the Protocol Manager Service is stopped at this stage is because the database is not created yet.

Creating the Protocol Manager Database

Normally, a database just for the VPM server will be used for the VPM server database, so a database needs to be added to SQL Server to be used by VPM. While it is conceptually possible to use an existing database for the VPM server, the VPM server has been tested only with a database that is designed just for the VPM server. By default, VPM server software expects the VPM database to be named PmuData. If a different database name is chosen, VPM server software can be configured to use that name.

Section 4 – Installing Server Software

The VPM server configuration tool is installed by default at:

C:\Program Files(x86)\Teledyne Hanson Research\Vision Protocol Manager Service\ConfigTool\ ProtocolManagerConfigTool.exe

1. Run the VPM server configuration tool as an administrator (right-click and select Run As Administrator). The person running this tool needs to have the necessary access permissions to the SQL Server to be able to create and configure a database. If this person is the one who installed the SQL Server, they are likely to have the necessary permissions. If using an already existing SQL Server, make sure they have the necessary permissions to the SQL Server.

2. Make sure Installation is selected.

3. Specify the SQL Server instance name. Both the server name and instance name must be specified. If the SQL Server software is running on the same computer as the VPM server software, then it will look something like below (without <>):

   .\<SQL Server Instance Name>
   (see the above topic "Installing SQL Server," item 9)

   If the SQL Server software is running on a different computer, then it will look something like below (without <>):

   <SQL Server Name>\<SQL Server Instance Name>

4. Click Find Server.

5. If SQL Server (and Instance) is found, the database name for the VPM database will be shown.

6. The default database name is PmuData. You can change the name to a different name, or if using an already existing database name, specify that name.

7. Check the checkbox: Use the Username selected on Log On Tab. The software will automatically get the User Name from the Protocol Manager Service properties.

8. Alternatively, you can manually specify the user name that is going to be used as the account to run the VPM server software service (see Section 3 – Preparing Server Computer, "Adding a User for the VPM…"), that is the user account that is going to be specified on the Log On tab of the Protocol Manager Service Properties in Windows Services (see Section 4 – Enabling Server Software Windows Service). If the user is part of a domain, the domain needs to be specified too. If not part of a domain, the format should be COMPUTERNAME\User.

   NOTE: The configuration tool will add the database access permissions (data reader, data writer and executor) for that user account when it generates the database.

   NOTE: If the Protocol Manager Service is going to run under a Local System account, the special user name 'NT AUTHORITY\SYSTEM' (without quotes) needs to be specified for the user name.

   NOTE: On some localized versions of Windows the special user name for the Local System account is different than the one listed above, so the equivalent name should be used instead.

   NOTE: If the user name that is specified already has access to the SQL Server, such that it is the user name of the person who installed the SQL Server, an error will be generated by the database configuration tool. This error can be ignored.

9. Once the database name and user name are specified, click Generate Database.

10. The configuration tool at this point will create the database (if necessary), create the database tables and default indexes, create the database user matching the specified user name, and assign the necessary permissions.

11. At this point the VPM database is configured, and you can continue using the configuration tool to configure the VPM server software (proceed to the next topic), or exit the tool.

Adding a Default Administrator Account for VPM

Since Vision Protocol Manager is using its own login authentication and permission-based authorization security, a default administrator account for VPM needs to be configured after configuring the VPM database.

Continuing from the topic above, once the VPM database is configured, the VPM server configuration tool provides the option to Add or Reset Default Admin Account. Click Add or Reset Default Admin Account to add a default administrator account and password to VPM. Afterwards you can continue using the configuration tool to configure the VPM server software (proceed to the next topic) or exit the tool.

Specifying the Network Port Used by the Server Software

While using the VPM server configuration tool:

1. Specify the network port to use, or keep the default value of 8001 for the port.

2. Continue to the next topic to save the VPM server software configuration.

Saving the Updated Configuration

After specifying the VPM server configuration options using the VPM server configuration tool, the updated configuration can be saved to the VPM server software configuration file. The tool will display the configuration options that will be updated in the configuration file, such as the VPM database name or network port number.

Click Update Service Configuration File to save the updated configuration options to the configuration file. Once the updates are successfully saved, exit the configuration tool.

Manually Specifying the PDF Conversion Tool

If the default values used for the PostScript to PDF conversion tool (see Installing the PDF Conversion Tool) are acceptable, there is no need to manually specify the PDF conversion tool and you can skip to the next step. Otherwise, the VPM server software configuration file needs to be updated with the correct values for the PDF conversion tool:

Section 4 – Installing Server Software

1. Locate the VPM server software configuration file ProtocolManagerService.exe.config in the directory where the VPM server software is installed. (By default C:\Program Files(x86)\Teledyne Hanson Research\Vision Protocol Manager Service\)

2. You might want to create a backup copy of this file before making any changes to it.

3. Open that file for editing, e.g., by using Notepad (note that an editor that is friendlier for editing XML files, such as Notepad++ will be easier to use for this task and is recommended). Note that you might need to open the file using the Run As Administrator option when starting the editor on some Windows versions, in order to be able to save the changes after updating the file.

4. Locate the <service.Properties.Settings> section in the <applicationSettings> section.

5. Locate the setting pdfConverter. Its <value> specifies the full path to the executable file that should be used for PDF conversion.

6. Change its <value>. Specify the full path to the executable file to use for PDF conversion.

7. Locate the setting pdfConverterParameters. Its <value> specifies the parameters, other than the page size, to pass to the executable file used for PDF conversion.

8. Change its <value>. Specify the parameters to pass to the executable file for PDF conversion. The parameters should not include the page size. If there are no parameters to pass, make <value> blank, e.g., <value></value>.

9. Locate the setting pdfPaperSizeLetter. Its <value> specifies the parameters to use when specifying the Letter size for pages when doing the PDF conversion.

10. Change its <value>. Specify the parameters to pass to the executable file to select the Letter size pages for PDF conversion. If there are no parameters to pass, make <value> blank, e.g., <value></value>.

11. Locate the setting pdfPaperSizeA4. Its <value> specifies the parameters to use when specifying the A4 size for pages when doing the PDF conversion.

12. Change its <value>. Specify the parameters to pass to the executable file to select the A4 size pages for PDF conversion. If there are no parameters to pass, make <value> blank, e.g., <value></value>.

13. Save the updates to the file and exit the editor.

Starting Server Software Windows Service

Once the VPM server software and VPM database are configured, the VPM server software (Protocol Manager Service) can be started as a Windows service.

1. Open the Services application from Windows (e.g., by typing Services in the Search programs and files prompt of the Windows Start menu).

2. Locate Protocol Manager Service in the list of services, select it, right-click and select Start from the context menu.

3. Wait for about a minute and verify that no errors are being reported.

4. Verify that Protocol Manager Service Status shows Started or Running.

5. Close the Services application.

6. At this point the VPM client can run and connect to the VPM server.

7. Next time when the computer in which Vision Protocol Manager server software is installed is restarted, make sure to verify using the Services application that for Protocol Manager Service the Status shows Started or Running (depending on the operating system).

Section 5 – Installing Client Software

NOTE: Any previous installation of Vision Protocol Manager Client in the target computer must be uninstalled before starting the installation of the client software.

NOTE: In installations where the client and the server are in separate computers, the client computer and the server computer MUST be able to ping each other. Pinging makes sure that both computers are communicating over the network and must be the first step before adding a client. Consult Section 14 – Installation Troubleshooting, "Pinging Devices," for details.

Installing .NET Framework

The steps for installing the .NET Framework for the VPM client software are the same as the steps for installing the .NET Framework for the VPM server software, see Section 4 – Installing Server Software, "Installing .NET Framework." Note that if the VPM client software is being installed on the same computer as the VPM server software, then the .NET Framework would have already been installed as part of the VPM server software installation.

Installing VPM Client Software

1. Locate files setup.exe and SetupClient.msi within the Client Installation folder of the distribution media.

2. Run the setup.exe program as an administrator.
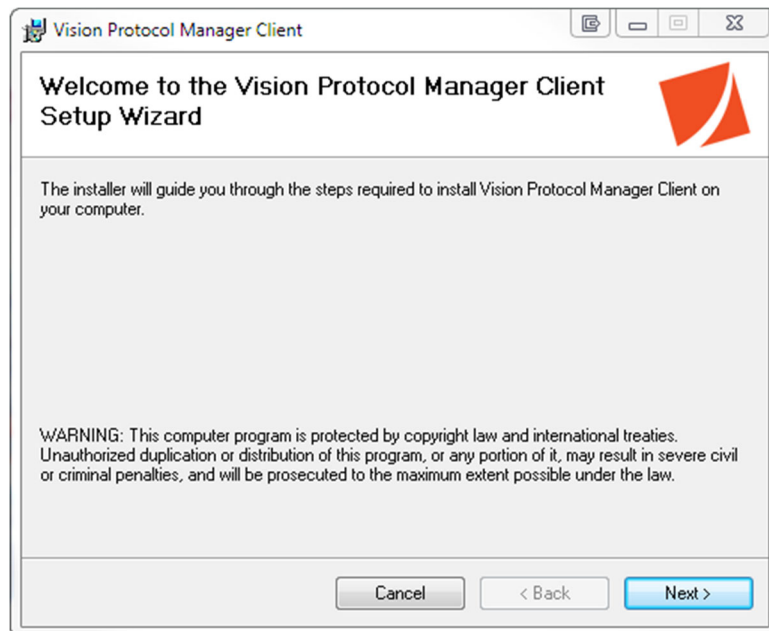
Figure 5-1: Client Installation Wizard

3. Click Next to continue.

4. Read and accept the licensing agreement, click Next to proceed.
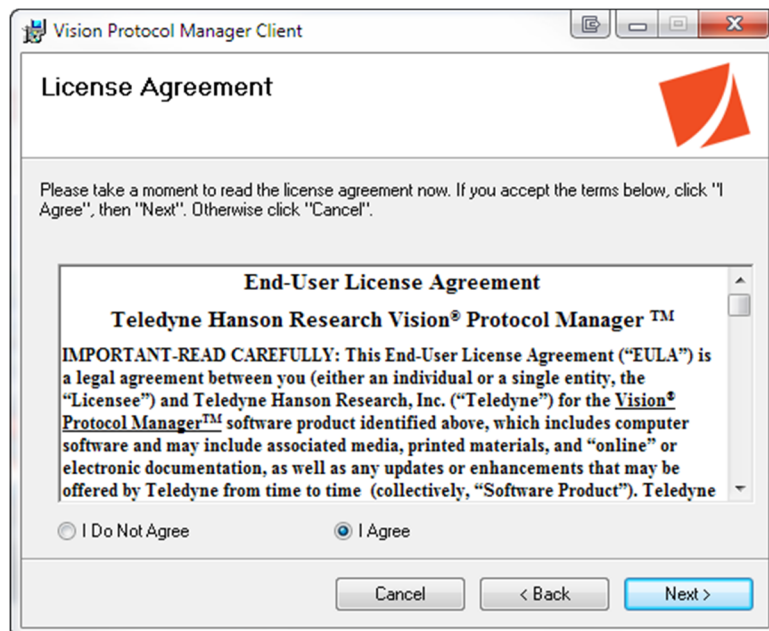
Figure 5-2: Installation License Agreement

5. Select the installation directory for the Vision Protocol Manager Client software.

6. If multiple users have access to the client computer, select Everyone otherwise select Just Me.

7. Click Next to start the installation process.
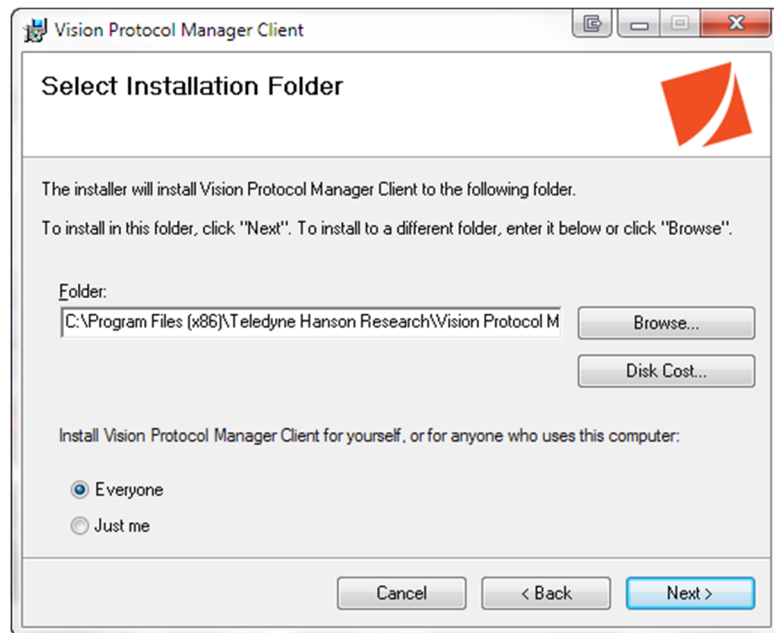
Figure 5-3: Client Installation Folder

8.   Once the installation is completed, verify that it completed successfully and click Close to exit the setup wizard.
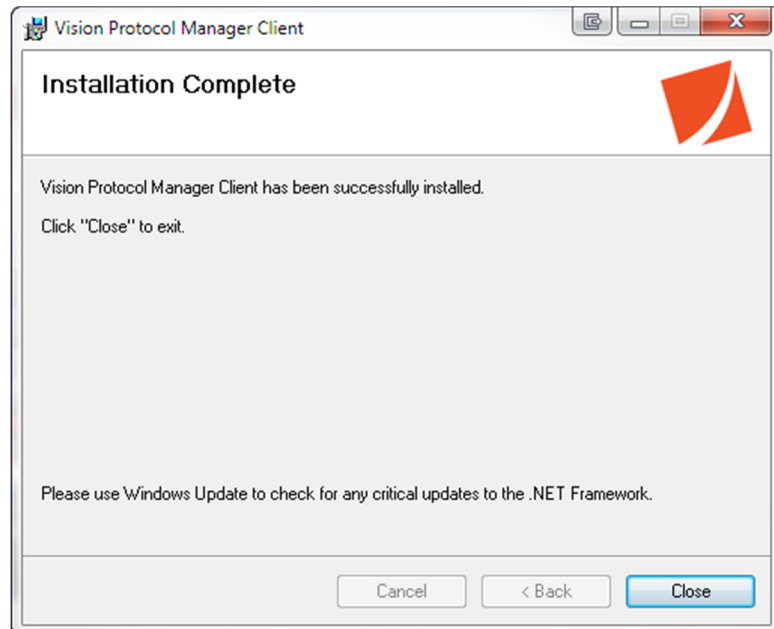
Figure 5-4: Client Installation Complete

Configuring VPM Client Software

Before configuring the VPM client software, make sure that the VPM server software is installed and configured per instructions outlined in Section 4 – Installing Server Software, and that VPM Server Software Windows Service is running. (See Section 4 – Installing Server Software, "Enabling Server Software Windows Service," item 10.)

NOTE: When Vision Protocol Manager Client is run for the first time, it should be run with Run as Administrator (navigate to the program's installation folder and run ProtocolManagerClient.exe with Run as Administrator). That way, when the server connection information is entered and saved, it will be saved for all the users. Otherwise on Windows 10 that information might be saved on a per user basis, so each user who logs in to Windows and uses VPM Client for the first time, would need to enter server connection information. If the user runs VPM Client again, it will not ask for that information.

Section 5 – Installing Client Software

1.   Run the Vision Protocol Manager Client software by clicking on the spirit icon. Please read the note above.
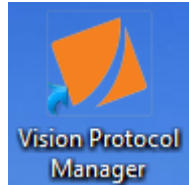
2.   When run for the first time, or when it cannot communicate with the VPM server software when started, the VPM client software goes into special mode and displays the Server Connection Configuration tool allowing the user to specify VPM server information.

3.   Provide the following information using the Server Connection Configuration tool:

4.   For Server Name, specify the name of the computer in which the VPM server software is running. If both the VPM client and VPM server software are running on the same computer, specify localhost.

5.   For Server Port, specify the network port number that the VPM server software is using. (See Section 4 – Installing Server Software, "Specifying the Network Port Used by the Server Software.")

6.   For Service User Name, specify the full user name, including the full domain name, if applicable, of the user account under which the VPM server software Windows service is running. (See Section 3 – Preparing Server Computer, "Adding a User for the VPM…") If not in a domain, an example of the service name would be:

    .\UserAccountName@COMPUTERNAME
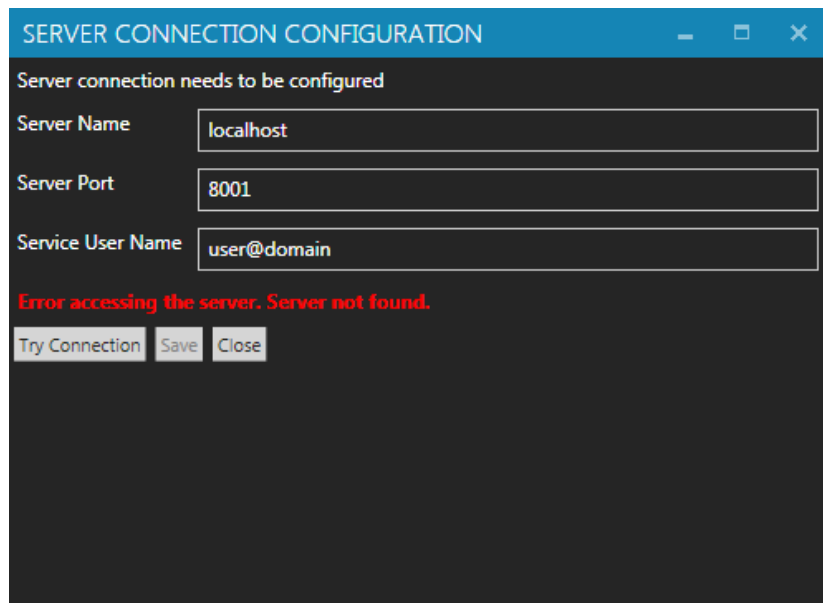
Figure 5-5: Server Connection Configuration

7. Click Try Connection.

8. The configuration tool will attempt to communicate with the VPM server software.

9. Verify that there are no errors and the Server Connection Successful message is displayed.

10. Click Save to store the configuration settings for VPM Client.

11. Exit the Server Connection Configuration tool.

12. At this point, VPM Client is configured and ready to run.

NOTE: Consult Section 14 – Installation Troubleshooting, "Pinging Devices," if you encounter difficulties during the installation.

Section 6 – Getting Started

Each time the VPM client software starts it asks the user to log in. For the first run of the client software for the site where Vision Protocol Manager is installed, only the default administrator user is available, with the default password. (See Section 4 – Installing Server Software, "Adding a Default Administrator Account…") Thus, that user name and password need to be used to log in to VPM. Afterwards more users can be added, the default user password can be changed, or the default user can be deleted, however it is important to have at least one other administrator user account in VPM that has the necessary permissions for adding new users, before deleting the default administrator user.

Starting Vision Protocol Manager

1. Run Vision Protocol Manager client software by clicking on the spirit icon.

2. The Login To Protocol Manager screen will be displayed.
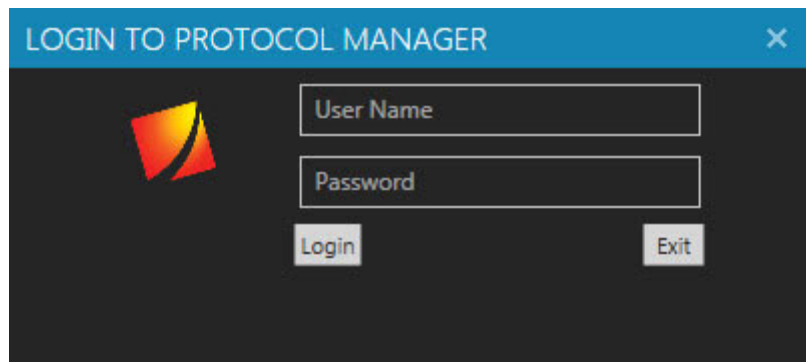
Figure 6-1: Vision Protocol Manager Login Screen

3. Provide the user name. The default administrator user name is admin.

4. Provide the password. The default administrator user password is admin.

   Note that only the password is case sensitive.

   NOTE: A caution symbol appears in the Password input field when Caps Lock is enabled.

5.   Click Login to submit the username/password combination or click Exit to close the client session.

6.   In order for the login to be successful, the inputted password must be associated with the user name and the user name must not be locked out.

7.   The administrator can configure the resulting behavior of a failed login. This includes the number of failed attempts before a user is temporarily locked out and the length of the lockout (Refer to Section 7 – Security Configuration).

8.   Once a user logs in successfully, he or she is able to implement the actions dictated by the permissions configured in their user profile.

9.   The VPM main screen is displayed after a successful login.

Log Out of the Program/ Changing Password
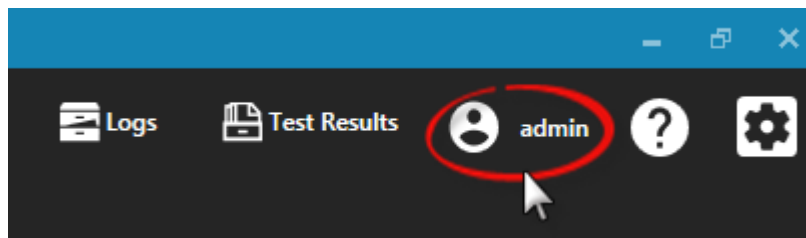
Figure 6-2: User Icon

1.   Click on the user icon on the main toolbar on the top.
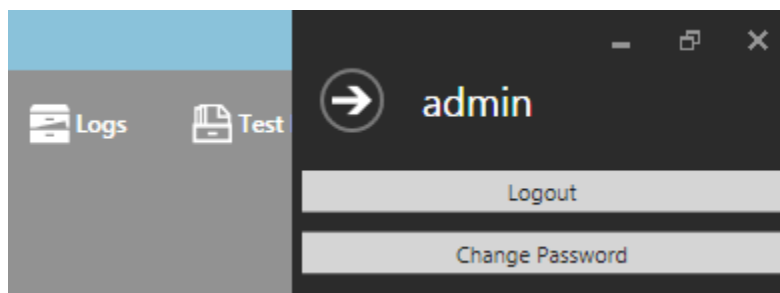
Figure 6-3: User Logout/ Change Password

2.   Click on the Logout button to log out of the program or click on the Change Password button to change the password of the current user.

User Interface

The principal components of the main screen are three panes and the toolbar.

Toolbar

Database Protocols   Systems & Instr.   Instrument Dashboard
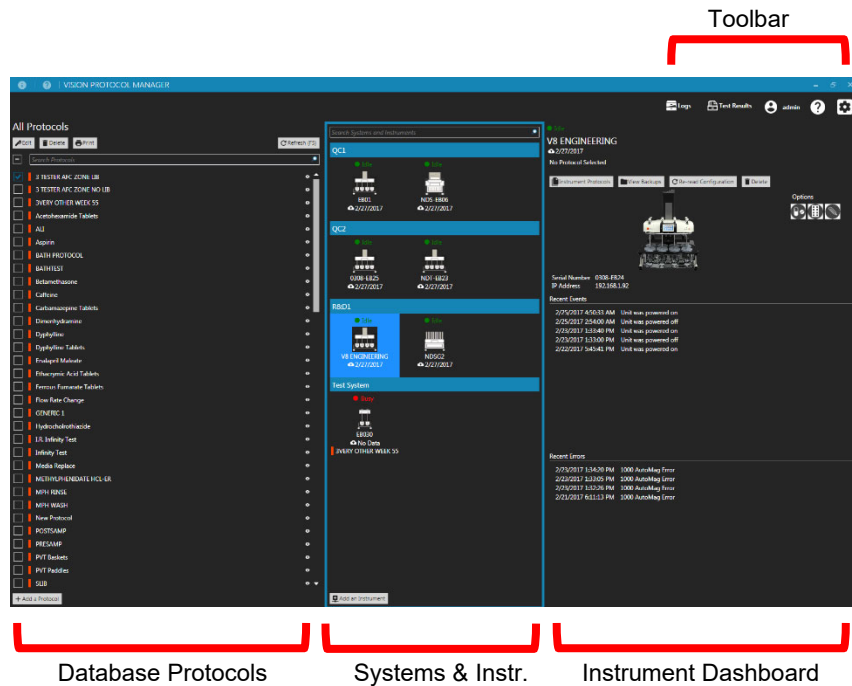
Toolbar (Top-Right Corner)

⊟ Logs	Search and view audit trail, event, and error logs for all instruments. See Section 12 – Audit Logs for details.
🖫 Test Results	Search, view, and sign dissolution test results. See Section 10 – Backups and Test Reports, "Dissolution Test Reports," for details.
👤 admin	Allows the current user to log out and change the password. See Section 6 – Getting Started, "Login Out of the Program/Changing Password," for details.
❓	Get context sensitive help about using VPM. See Section 13 – Getting Help, "Context Sensitive Help," for details.
⚙	Access to security and program configuration. See Section 7 – Security Configuration for details.

NOTE: Some of the toolbar icons shown above may not appear if the user does not have the permissions required to implement the actions associated with them.

Database Protocols (Left Pane)

The left pane allows the user to work with dissolution protocols that are stored in the VPM computer database. These are protocols that have been either created with the program or copied to the database from an instrument. The protocols are listed in alphabetical order. Enter a keyword in the Search Protocols field to view only the protocols that contain the keyword within its labels tab.

Select a protocol, then edit, delete or print it.

Check the box on the left of the filename to select the protocol.

Click on the "eye" icon to quickly view the protocol parameters.
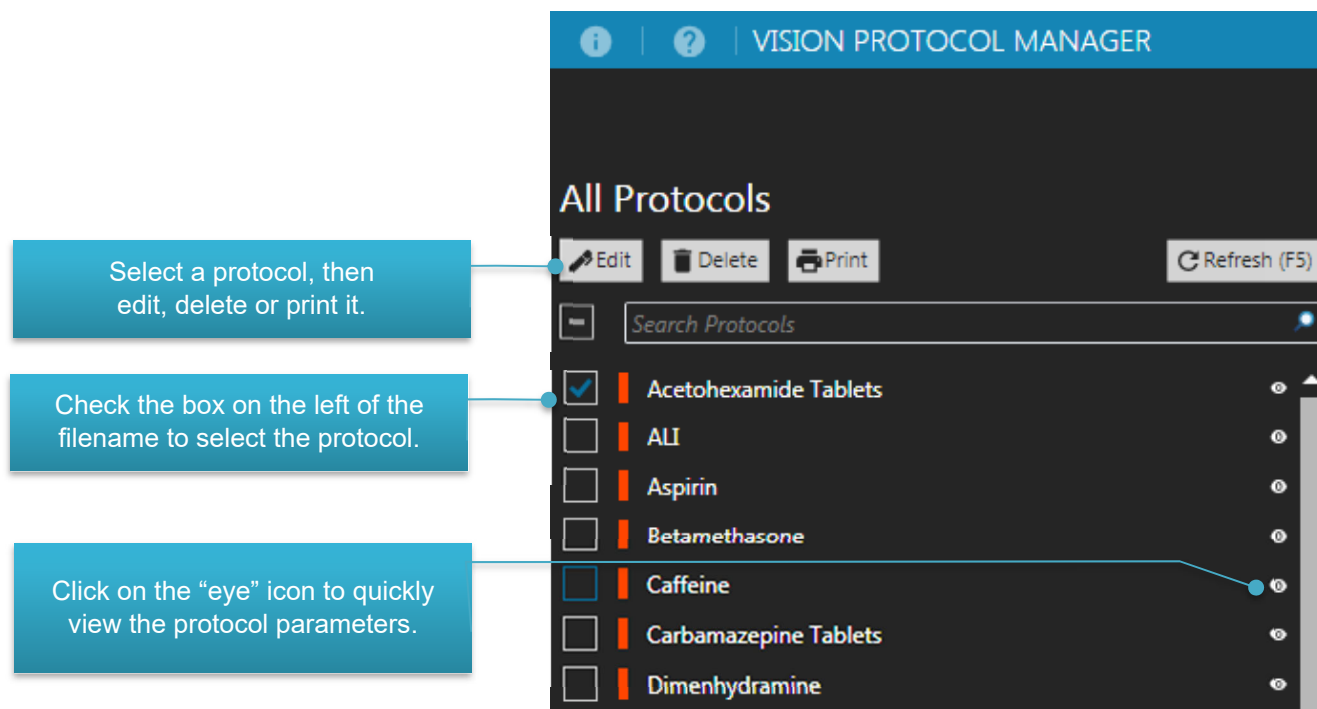
Systems and Instruments (Center Pane)

The center pane allows the user to work with instruments and groups. Protocols selected from the left pane can be dragged and dropped into the instrument icons in the center pane. Automatic sampling protocols are used by the sampler and manual sampling protocols are used by the tester.

Figure 6-4 shows a system group called "QC1" which contains two Vision G2 testers (NDTG1 and NDTG2) and one AutoPlus sampler (NDSG2). Instruments in a system group are normally connected together fluidically. All three instruments shown below are currently idle. The date next to the cloud icon shows the last time a successful backup was performed on that instrument.

Select an instrument by clicking on its icon and you can view detailed information on its dashboard.
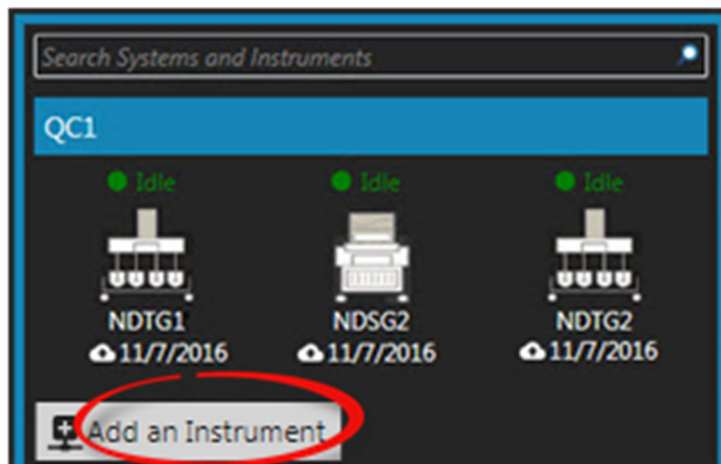
Figure 6-4: Systems and Instruments Pane

Instrument Dashboard (Right Pane)

The right pane is a dashboard which shows information pertaining to the instrument that was selected.

Current instrument state: idle, busy, offline

Instrument ID and the date of the last successful backup

Current protocol being used in the instrument

List protocols stored in the instrument, view backups from this instrument, refresh instrument options, delete instrument from a system group

Options configured such as magazine, digital temp. probes, auto dosage delivery, etc.

Instrument serial number and IP address

Recent instrument events and errors

● Idle

V8 ENGINEERING
☁ 11/7/2016

Acetohexamide Tablets

📄 Instrument Protocols   📁 View Backups
↻ Re-read Configuration   🗑 Delete

Options

Serial Number   0308-EB24
IP Address   192.168.1.92

Recent Events

11/7/2016 2:31:38 PM	Instrument ID was changed
11/7/2016 2:29:44 PM	Instrument ID was changed
10/27/2016 7:03:05 PM	Unit was powered on

Recent Errors

10/27/2016 7:02:39 PM	1505 Heater Comm. Shut
10/25/2016 8:35:41 AM	1000 AutoMag Error
10/24/2016 1:41:06 PM	1000 AutoMag Error

Instrument Options

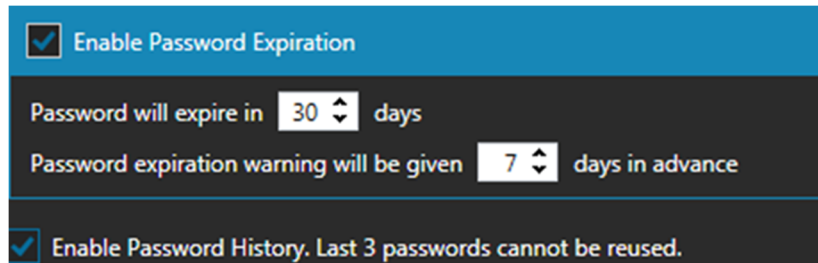|	
	This instrument is configured with the Automatic Dosage Delivery (ADD) option. See Section 11 – Editing Protocols, "Options Tab," for details.
	This system is fluidically connected through an AutoFilter changer. See Section 11 – Editing Protocols, "Options Tab," for details.
	This instrument is configured with a magazine carrier. See Section 11 – Editing Protocols, "Options Tab," for details.
	This instrument is configured with digital temperature probes. See Section 11 – Editing Protocols, "Dissolution Tab," for details.
	The CD14 instrument is configured with autosamplers. See Section 11 – Editing Protocols, "Sampling Tab," for details.
	This sampler has a port configured for automatic media replace. See Section 11 – Editing Protocols, "Sampling Tab," for details.
	This sampler is configured to use the media retrieval option. See Section 11 – Editing Protocols, "Sampling Tab," for details.
	This sampler is configured with a wash port. See Section 11 – Editing Protocols, "Sampling Tab," for details.

NOTE: When copying protocols from the server to an instrument fails, make sure that the target instrument has the configuration that the protocol requires.

Section 7 – Security Configuration

The program allows a user with permission to manage users and groups to edit the security configuration. The Security configuration is divided into password policy, and users and groups.

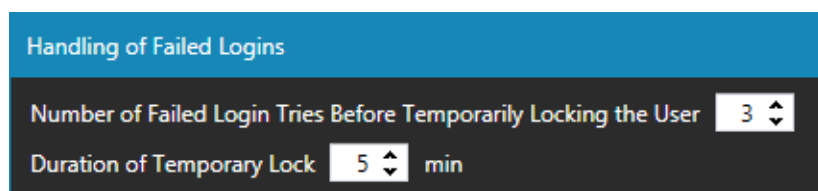**Enable Password Expiration Screen**

Password will expire in "nn" days: The password will expire and must be reset after the number of days entered in this setting.

Password expiration warning will be given "nn" days in advance: A message, warning of impending password expiration will be given in advance as per this setting.

Enable Password History: When this check box is set, the user is prevented from reusing his last 3 passwords.
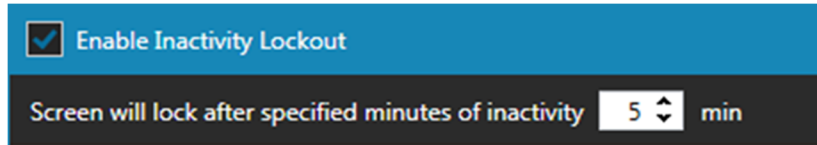
Handling of Failed Logins Screen

Number of Failed Login Tries Before Temporarily Locking the User: The user will be locked out of the system after the number of failed login attempts entered in this setting.

Duration of Temporary Lock: Once the user is locked out, they will not be able to retry to log in for the period entered in this setting.

NOTE: A user with permission to Manage Users and Groups may remove a temporary lock or add/remove a permanent lock to another user at any time.

Enable Inactivity Lockout Screen

Screen will Lock After Specified Minutes of Inactivity: After the specified time of inactivity, the program will lock out program use. The user that was logged in is still the current user, but they must enter their password to continue using the program. At this point, entering the password of the current user will unlock the program. Clicking on the logout button will allow a different user to log in.

Managing Users and Groups

A user can be added, and his individual permissions defined.

NOTE: Changes to a user's profile such as permissions, lock status, etc. take effect the next time the user logs back in.

Manage Users and Groups: This permission allows the user to control all the aspects of managing users and groups. This includes adding and deleting users and groups and configuring their individual permissions. It also includes managing the global password policy settings of the program.

Manage Protocols in Database: This permission allows the user to control all the aspects of managing the protocols that reside in the computer database. This includes copying, adding, deleting, and editing. In order to be able to copy protocols back and forth between the database and the instruments you need this permission and the permission to manage instrument protocols, described below.

Manage Systems and Instruments: This permission allows the user to add and remove dissolution instruments and the systems in which they reside.

Manage Instrument Protocols: This permission allows the user to control all the aspects of managing the protocols that reside within the dissolution instruments. This includes copying, adding, deleting, and editing. In order to be able to copy protocols back and forth between the database and the instruments you need this permission and the permission to manage database protocols, described above.

View Audit Logs: This permission allows the user to view the audit logs.

View Test Reports: This permission allows the user to view test reports.

Sign Test Reports: This permission allows the user to electronically sign test reports.

NOTE: When a user is added to a group, that person inherits the group permissions in addition to their individual permissions.

NOTE: When a user is removed from a group or the group to which they belong is deleted, only the permissions contributed by the group are removed.

Section 8 – Managing Systems & Instruments

Users with permission to Manage Systems and Instruments (Refer to Section 7 – Security Configuration, "Managing Users and Groups.") can add instruments to the program and make them part of a system group.

Configuring Instruments

1. Configure and document the instrument ID and the IP address of the dissolution instrument that you want to add to the VPM database.

Figure 8-1: Instrument ID and IP Address

2. Configure and document the serial number of the dissolution tester that you want to add to the VPM database.

Figure 8-2: Instrument Serial Number

NOTE: These three parameters: instrument ID, IP address and instrument serial number must be unique to each instrument, or the configuration attempt will fail or yield unexpected results.

NOTE: Unless you are able to ping the IP address of the target dissolution instrument from the server computer, you will not be able to add the instrument to the system. Pinging makes sure that the target instrument and the server are communicating over the network. Consult Section 14 – Installation Troubleshooting, "Pinging Devices," for details.

Adding Instruments

The configured instrument can be added by clicking on the Add an Instrument button at the bottom of the center pane. The three instruments shown below belong to the system QC1. The Add Instrument panel will appear.
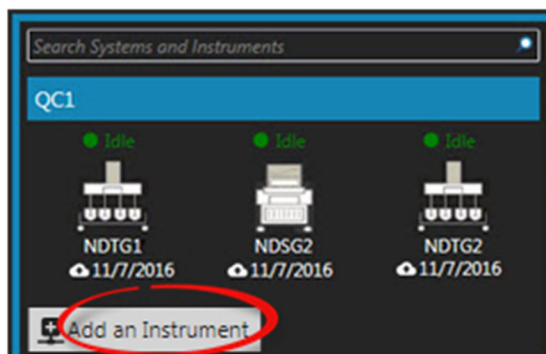
Figure 8-3: Add an Instrument Button

Figure 8-4: Add Instrument Panel

1. For the field, Specify system name, enter a new name or select an existing group from the list.

2. Enter the serial number and IP address for the desired instrument which was configured earlier.

3. Press OK to add the new instrument to the desired system.

NOTE: Adding an instrument to the database will fail if:

- The serial number does not match with the IP address provided.

- An instrument with that serial number already exists in the database.

- The instrument to be added is offline or not connected to the network.

- The firmware version of the instrument is too old and doesn't support VPM. Consult the VPM Info (Versions) screen for the instrument's firmware versions that support VPM.

Section 9 – Protocol Management

Protocol management is, of course, the main function of Vision Protocol Manager (VPM). The program can be used to copy protocols from instruments to the computer database and vice versa. The computer database can hold thousands of protocols and its total number is not limited by the program. The program can be used to copy protocols from instrument to instrument. It can be used to create and develop protocols from scratch in a user-friendly environment with a large screen monitor and a full-size keyboard. Vision G2 protocols have an orange ribbon displayed to the left of their names in the list of All Protocols. CD14 methods have a blue ribbon displayed to the left of their names in the list of All Protocols.

Searching and Filtering Protocols

After a while, the number of protocols may grow much larger than the 100-protocol limit of a single dissolution instrument. To make the list easier to manage, the user may filter the information presented to very specific information. In the search field, enter a string such as "Aspirin" or "100 mg" or "Tablets."

Click on the Search icon within the search field and only the protocols matching that string will be displayed. Search will also find partial matches to the search string.
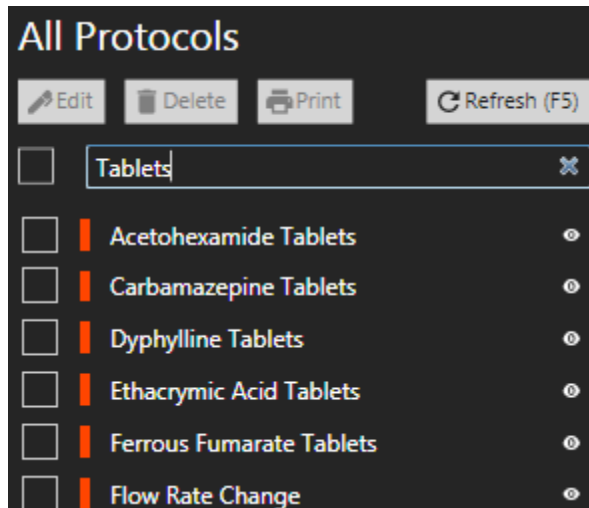
The example above shows what happens when the user enters the word Tablets into the search field. The list shows 5 protocols which have the word Tablets in the Protocol Name field and one which has the word Tablets in one of the other label fields.

VPM searches the following fields in the labels tab of the protocol:

- Protocol Name

- Drug Name

- Dosage

- Protocol ID

- Apparatus

- Media Type

- Media Volume

- User Label 7

- User Label 8

- Comment

Using Labels and Filters to Manage Release Stages

The manager can put various words like: Draft, Pending, Waiting for Approval, Released, etc. in the comment or any of the other label fields.

If the user then enters the word Released in the search field, only the protocols with a Released label will appear. This label can be used exclusively to manage the release stages of the protocol and can be changed by a lab manager accordingly.

For more information regarding protocol labels, refer to Section 11 – Editing Protocols, "Labels Tab."

Selecting Protocols to Use

To select one or several protocols, check the box to the left of each name.
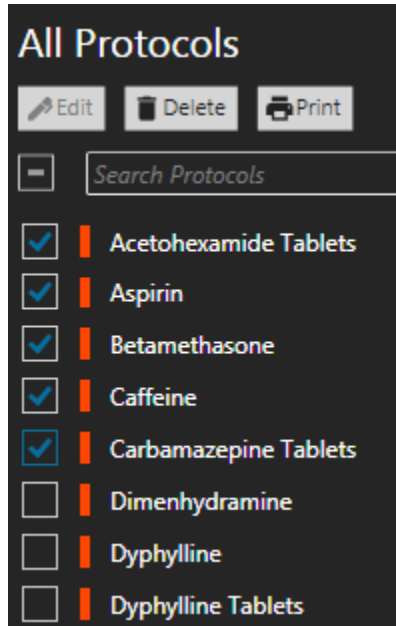
Clicking the box to the left of the Search Protocols field selects or unselects all the protocols in the list.

Click on the eye icon to the right of the name to view the protocol parameters of the selected protocol. This only allows the user to view the protocol parameters.

You must have only one protocol selected to edit, delete, or print a protocol.

Remember that you must have the proper user or group permissions to edit or delete a protocol.

Copying Protocols

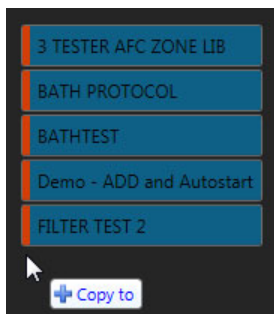### Copying Protocols From an Instrument to the Database

1. Select an instrument from the center pane and click on the Instrument Protocols button on the right.

2. Select the protocol from the source instrument by checking the box to the left of the protocol name. Multiple protocols may be selected in the same manner. All protocols may be selected by clicking on the box to the left of the search box.

3. Drag the selected protocols from the right pane and drop them over the database list on the left pane. As you are dragging the protocols, you will see the enhanced cursor image with the names of the protocols selected and the + Copy To caption. Only operations of 10 protocols or less will display the protocol names.

Copying Protocols From the Database to an Instrument

There are two ways of copying a protocol from the database to an instrument, each implemented slightly differently. Both ways must be verified.

1. Select the protocol from the database on the left pane by checking the box to the left of the protocol name. Drag the protocol name from the left pane and drop it over the instrument icon in the center pane. This procedure considers the instrument's configuration and does not allow instruments that do not meet the requirements of the protocol to receive it.

2. Select the protocol from the database on the left pane by checking the box to the left of the protocol name. Click on the Instrument Protocols button on the right pane and reveal the list of protocols within the instrument. Drag the protocol name from the left pane to the instrument protocol list on the right. This procedure copies the protocol and ignores the instrument's configuration.

Copying Protocols From an Instrument to Another Instrument

1. Select an instrument from the center pane and click on the Instrument Protocols button on the right.

2. Select the protocol from the source instrument by checking the box to the left of the protocol name. Multiple protocols may be selected in the same manner. All protocols may be selected by clicking on the box to the left of the search box.

3. Drag the selected protocols from the right pane and drop them over another instrument's icon in the center pane.

File Management Issues

There are several reasons why VPM may refuse to copy a file to an instrument or vice-versa. The main two reasons are that the user does not have the required permission to implement the copy or that the target instrument is not suited (or configured) for the actions required by the protocol.

Issue	Solution
Trying to copy a file without the proper user permissions	Make sure that your user profile permissions allow you to copy protocols from the instruments to the database and from the database to the instruments.
Trying to copy a file which requires a magazine to sampler configuration that does not have the sampling probe on the sampler set to magazine	In the autosampler's configuration screen, make sure to set the sampling probe on the sampler to magazine.
Trying to copy a file which requires digital temperature probes to a tester or autosampler which is not configured for them	Make sure that both the tester and autosampler in the system are configured to have digital temperature probes.
Trying to copy a file which requires a media replace or retrieval option	Make sure that both the tester and autosampler in the system are configured to have the required accessories.

Section 10 – Backups and Test Reports

Instruments automatically back up their event logs, error logs and dissolution test reports soon after they complete a dissolution test.

Instrument Data Backups

Click on the Logs icon in the main tool bar to access the logs from all the instruments in the system. The VPM audit trail, instrument event logs and error logs are arranged in columns which can by filtered and sorted.

Dissolution Test Reports

Click on the Test Results icon in the main tool bar to access the screen below. Sort and filter all available test results by entering a date range or a keyword in the Search Test Reports field. View the actual test report by clicking on the PDF icon to the right of the serial number column. At this point, a user with the proper permissions may sign the resultant test report by entering his user password.
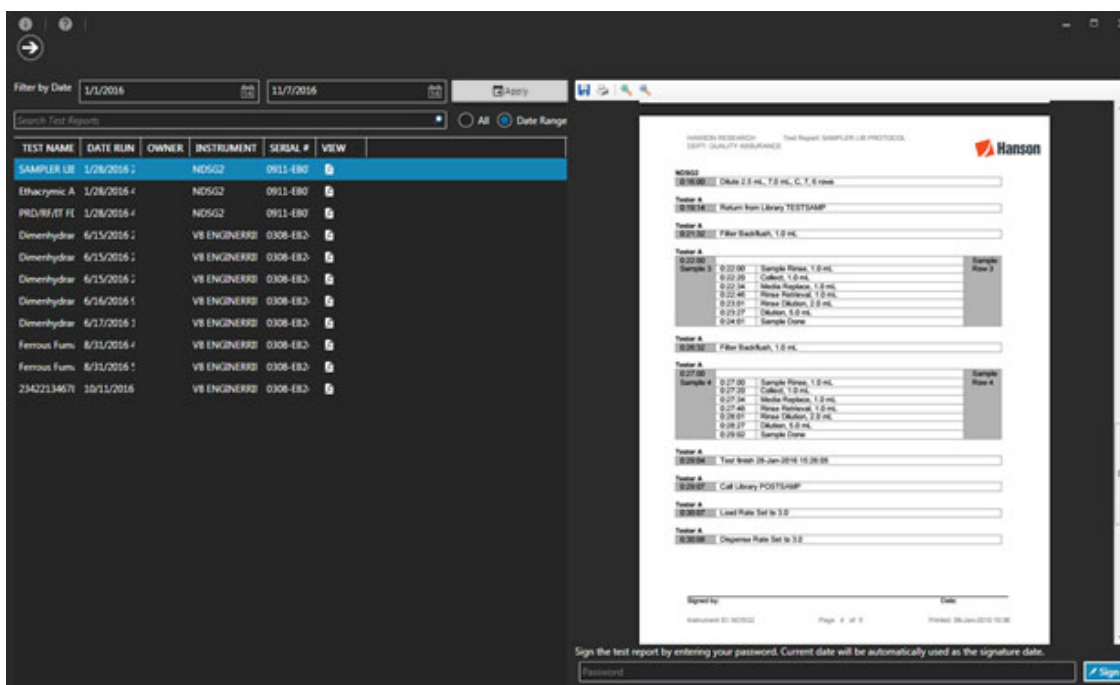
A test report that was generated on a Vision G2 instrument can be signed up to two times, if the test report includes a signature line (it is configured on the instrument itself.)

A test report that was generated on a CD14 instrument can be signed up to three times, based on the signature labels configuration on the instrument itself. The signature labels are used for the text on the buttons that can be used to sign the test report, and based on the button clicked, the signature will be applied to the corresponding label line on the test report PDF. For example, if there is a signature label named 'Performed by:' on the test report, there will be a button named 'Performed by:' that can be used to sign the test report line labeled 'Performed by:'.

NOTE: The date range defaults to displaying the last three months of data in order to speed up presenting the most current information. Adjust the date range as needed to view additional (and older) information.

Section 11 – Editing Protocols

Protocols (called methods on CD14 instruments) are a list of parameters and events that are required to perform a dissolution test. These parameters can be modified to accommodate the user's needs. While a Vision G2 dissolution instrument can store up to 100 protocols internally, VPM can store virtually an unlimited number of protocols in its database.

In addition, VPM has more extensive tools for checking for possible timing conflicts. (See the last topic in this section.)

To create a new protocol for a Vision G2 instrument, click on the Add a G2 Protocol button from the main screen. To create a new method for a CD14 instrument, click on the Add a CD14 Method button from the main screen.

To edit an existing protocol (method), click on the protocol name from the list and click on the Edit button.

Automatic or Manual Sampling

Protocols must first be designated to be either automatic or manual sampling.

Automatic Vision G2 protocols are loaded to the Vision G2 AutoPlus autosampler only. When a protocol is selected to run from the touch screen of the AutoPlus, it takes care of sending the dissolution parameters to the selected testers in its system. Manual Vision G2 sampling protocols are loaded to Vision G2 testers only. Automatic CD14 methods can be loaded to CD14 testers that have automatic samplers in their configurations. Manual CD14 methods can be loaded to any CD14 tester.

Labels Tab

This tab allows the user to edit the protocol labels. Labels are static descriptions and have no physical impact on the performance of the protocol but are useful for documentation and management.

Only text that can be shown on the instrument can be used for the protocol name. For all other labels, any text can be used, but only text that can be shown on an instrument will be sent to the instrument with the protocol.

Protocol Name: Only text that can be shown on the instrument can be used.

Drug Name: The name of the drug being tested (e.g., Aspirin).

Protocol ID: A secondary identifier for the protocol. This does not need to be unique.

Apparatus: Refers to the attachments that go inside the vessel and stir the media during a dissolution test. The most common are USP Apparatus 1, a basket on the end of a shaft, and USP Apparatus 2, a paddle blade mounted on the end of a shaft.

Media Type: The type of media in which the tablet will dissolve (e.g., water).

Media Volume: This is the volume of media in the dissolution vessel. This parameter is typically stated in milliliters (mL). In some calculations, it is the initial volume at the beginning of the test.

Custom Labels: Labels 7 and 8 are for general use. They are available only on Vision G2 protocols.

Comment: A field to allow the user to add any items of interest at the user's discretion. Please refer to Section 9 – Protocol Management, for additional tips on using the Comment field.

Dissolution Tab

This tab allows the user to edit the parameters that pertain specifically to the dissolution test.

Drive Speed: The target drive speed for a dissolution test. Valid values are 0, 25 – 250 rpm.

Speed Tolerance: The tolerance of the motor speed of a dissolution test. If the speed goes beyond this value during a test, an alarm sounds, and an error is generated. Values are 0, 1 – 10%. A typical value is 4%.

Bath Tolerance: The target temperature of the dissolution tester water bath. The range is 0, 25.00 to 55.00 °C for Vision G2 protocols. The range is 0, 25.00 to 51.00 °C for CD14 methods.

Temperature Tolerance: The tolerance for the primary temperature probe or digital (vessel) temperature probes during a test. If a value is recorded that falls outside of the tolerance an error is generated. The range is 0, 0.10 to 5.00 °C. A typical value is 0.5 °C.

Use AutoMag: If the dissolution tester is equipped with the AutoMag accessory, the user may enable or disable its use by setting this parameter's checkbox. When enabled, the AutoMag will use the value of the Magazine Travel parameter.

Use Digital Temperature Probes: If the dissolution tester is equipped with digital temperature probes, the user may enable or disable their use by setting this parameter's checkbox.

Vessel Goal Temperature: The intended temperature of the media in the vessels during a dissolution test. The temperature tolerance value is applied to this when reading through the digital temperature probes. This parameter is only applied when the Use Digital Temperature Probes parameter is enabled. The range is 0, 25.00 to 55.00 °C for Vision G2 protocols. The range is 0, 25.00 to 51.00 °C for CD14 methods.

Test Length: The total time of the dissolution test. The range is 0 – 999:00 (hhh:mm).

Print Interval (Log Interval): The interval at which the tester status (speed, temperature, vessel temperature) is recorded. The valid range is 0 – 999:00 (hhh:mm). For CD14 methods, it's named Log Interval.

Infinity Test: The setting of this checkbox determines if an infinity test is performed at the end of the test.

Infinity Test Length: Defines the length of time the drive of the tester will spin the paddles or baskets at the infinity test speed. This time occurs after the test length has elapsed. The range is 0:00 to 9:59 (h:mm).

Infinity Test Speed: Defines the speed the baskets or paddles will spin during the infinity test. The range is 0, 25 to 250 rpm. 200 to 250 rpm is typical.

Sampling Tab

This tab allows the user to edit the parameters that pertain specifically to automated sampling. However, for manual sampling, the Sampling Mode parameter should always be set to Manual.

Sampling Mode: Determines the type of sampling procedure.

For Vision G2 protocols the automatic sampling modes are Collect Only and Collect and Detect.

- Manual: Can be run on a tester only. Indicates the user would collect a sample by hand using a syringe.

- Collect Only: Indicates the AutoPlus sampler will collect the samples. No allowance for UV\Vis spectrophotometer readings are made.

- Collect and Detect: A sample is collected and the system will pause for a read delay to allow the UV/Vis spectrophotometer to read the absorbance of the sample.

For CD14 methods the automatic sampling modes are Midpoint and At Point. In both of those cases the CD14 AutoPlus sampler will collect the samples. Please refer to the CD14 User Guide for more details and examples about these sampling modes.

- Midpoint: The instrument calculates how long it will take to load the sample, and then it adjusts operations such that the midpoint of the complete sampling cycle occurs at the specified sample time point. In this mode the syringe will begin to load the sample just prior to the programmed time point such that the midpoint of the cycle will fall within a few seconds of the specified sampling time.

- At Point: The syringe begins loading the sample volume (collect volume) within a few seconds of the programmed sampling time point. All rinse and backflush-filter operations (if any) will occur before the programmed sample time.

Rack Type: Defines the rack used for sample collection. For Vision G2 protocols, the options are 16 x 100 mm, 13 x 100 mm, 12 x 32 mm, UPLC 12 x 32, T 12 x 32, and SA 12 x 32. Consult the sampler user guide for proper rack implementation. For CD14 methods, the rack options are 16 x 100 mm, 13 x 100 mm, and 12 x 32 mm. If the wrong rack is placed in the AutoFill collector, the test will not start.

Rinse Volume: A volume of media that is pulled from a dissolution tester and pushed through the lines to ensure material from the tester is being read by the UV/Vis spectrophotometer or collected. The range is 0 – 99.9 mL. This volume may be removed from the vessel depending on the system configuration and may or may not need to be accounted for with a volume correction algorithm.

Collect Volume: This is the volume that is collected into the vials or test tubes of the rack. It is removed from the test and must be accounted for with a volume correction algorithm. The range is 0 – 99.9 mL.

Use Media Replace: When an AutoPlus sampler is configured with a media replace source and this parameter is checked, a volume of clean media is pumped (immediately after sampling) into the vessel to make up for loss due to rinsing, collection, or evaporation. The amount replaced is the value of the Media Replace Volume parameter. The CD14 AutoPlus sampler is always configured with a media replace option.

Media Replace Volume: The volume used during media replace. This volume must be accounted for with a volume correction algorithm. The parameter range is 0 – 99.9 mL.

Use Retrieval: If the Vision G2 AutoPlus sampler is equipped with the retrieval accessory, the user may enable or disable its use by setting this parameter's checkbox. This option is not available for CD14 methods.

Retrieval Volume: This is the volume pumped at the end of a sampling cycle which is meant to empty the retrieval accessory. This media is not removed from the vessels for volume corrections. Check your sampler user guide for proper implementation of the retrieval option. The valid range is 0 – 99.9 mL. This option is not available for CD14 methods.

Use Filter: Enable use of the AutoFilter changer accessory. Valid selections are enabled or disabled. This option is not available for CD14 methods.

Tester Offset: On Vision G2 instruments, this is the time between starting tests on individual dissolution testers to avoid samples being collected at the same time (which is not possible with a Vision G2 AutoPlus sampler). This option is not available for CD14 methods.

Use AutoMag: If the dissolution tester is equipped with the AutoMag accessory, the user may enable or disable its use by setting this parameter's checkbox. When enabled, the AutoMag will use the value of the Magazine Travel parameter.

Magazine Travel: This is the distance the magazine will travel when reading temperatures with digital temperature probes or when collecting samples. The range is 0 – 140 mm for Vision G2 protocols. The range is 0 – 105 mm for CD14 methods.

Pre-Start Rinse Time: This allows a user to have the Vision G2 AutoPlus autosampler begin pumping sooner than the specified sample points in the protocol to adjust the sampling window. If a user sets this value to 60 seconds and had a sample point at one hour, the sampler would begin pumping at 59 minutes. The range is 0 – 3600 seconds. This option is not available for CD14 methods. On a CD14, the time when the syringe starts loading the sample is automatically calculated by the instrument based on the Sampling Mode (Midpoint or At Point).

Backflush Filter: When enabled, the AutoPlus autosampler will withdraw 1 mL of sample and return it to the source before the sampling cycle begins to clean material out of any installed filters. The options are Yes or No. This process starts on the second sample point of a test and is repeated for all future sample points of that test.

Detect Volume: On the Vision G2 AutoPlus, a specified amount of the collect volume that is held for the read delay before pumping. This allows the user to ensure the sample read by the UV/Vis spectrophotometer is identical to the sample that is collected. The range is 0 – 99.9 mL. This option is not available for CD14 methods.

Read Delay: This is the time that the Vision G2 AutoPlus autosampler will wait before pumping the detect volume. The range is 0 – 12000 seconds. Typical values would be near 90 seconds. This option is not available for CD14 methods.

Options Tab

This tab allows the user to edit the parameters that pertain specifically to options added to the instruments such as the AutoMag, ADD Covers, the AutoFilter changer, etc.

Use AutoMag and ADD Covers: If the dissolution tester is fitted with ADD (Auto Dosage Delivery) vessel covers, checking this parameter would enable their use. An AutoMag magazine is required for the use of ADD covers.

Auto Dosage Delivery: If the dissolution tester is fitted with ADD (Auto Dosage Delivery) vessel covers, checking this parameter allows the Pill Drop Delay and Auto-Start options to be configured.

Auto Wash At End: When enabled, the instrument will perform a wash routine at the end of the test. The wash routine is defined in the Automatic Syringe Control screen of the AutoPlus sampler.

Use AutoFilter: If the Teledyne Hanson AutoFilter changer is connected to the Vision G2 system, this parameter enables integration into the test. It adds the With Filter option to many of the sampling volumes such as Rinse, Collect, Retrieval, etc. This option is not available for CD14 methods.

Number of Vessels: Allows to select whether the CD14 method will run on 6 vessels (either side A or B, to be selected during the test start) or on all 12 vessels. This option is not available for Vision G2 protocols.

Use Test Start Pill Drop and Manual Sampler Guide: When selected, the Test Start Pill Drop and Manual Sampler Guide screen will be displayed to help with starting the test when running the method. This option is not available for Vision G2 protocols.

NOTE: There are two additional protocol parameters that can only be changed with an event. Events are features which are unique to Teledyne Hanson G2 dissolution instruments and are described in the next topic below.

Events Tab

Events are actions that can be programmed to occur at any time before, during and/or after the dissolution tests. Events are by default, sampling events that can only occur during the dissolution tests. Other events, such as actions to change a parameter value, can be programmed before, during and/or after the test. The maximum number of allowed events that a Vision G2 protocol can have is 50. There is no limit on the number of events that a CD14 method can have.

Sampling Events: Sampling events are the default event. They trigger an automatic sampling procedure using the parameters in the Sampling tab such as Rinse and Collect Volumes, Rack Type, etc.

Task Events: Task events perform a one-time only task. Some of the events are available on Vision G2 protocols only.

- Call (G2 only)

- Change Filter (G2 only)

- Delay

- Dilute (G2 only)

- Discard Filter (G2 only)

- Dispense (Dispense Syringe)

- Load (Load Syringe)

- Pause

- Print Statistics (Log Statistics)

- Probe Down (Lower Magazine)

- Probe Up (Raise Magazine)

- Prompt

- Reuse Filter (G2 only)

- Send to Serial

- Status (Log Status)

- Transfer

- Uncouple and Hold Filter (G2 only)

Parameter Modification Events: These types of events allow the user to change the setting of an existing parameter during the dissolution test. For instance, the Drive Speed event could change the current speed from 50 to 100 rpm in the middle of the test. The Bath Temp event could do the same for the bath temperature. Even the Magazine Travel could be adjusted because of a change in the media level.

The instrument will continue the dissolution test using the new parameter value until the end of the test, or until a later event again changes the parameter. Some of the events are available on Vision G2 protocols only.

- Backflush Filter

- Bath Temp

- Collect Volume

- Detect Volume (G2 only)

- Dilution (G2 only)

- Dispense Flow Rate

- Drive Speed

- Filtered Media Replace (G2 only)

- Filtered Retrieval (G2 only)

- Load Flow Rate

- Magazine Travel

- Media Replace

- Print Interval (Log Interval)

- Read Delay (G2 only)

- Retrieval Volume (G2 only)

- Rinse Volume

- Rinse Volume With Filter (G2 only)

- Speed Tolerance

- Temperature Tolerance

- Valve Delay (G2 only)

- Vessel Goal Temperature

More advanced parameters can only be changed with an event as they do not appear in any of the tabs of the dissolution protocol screen. These parameters are Valve Delay and Dilution.
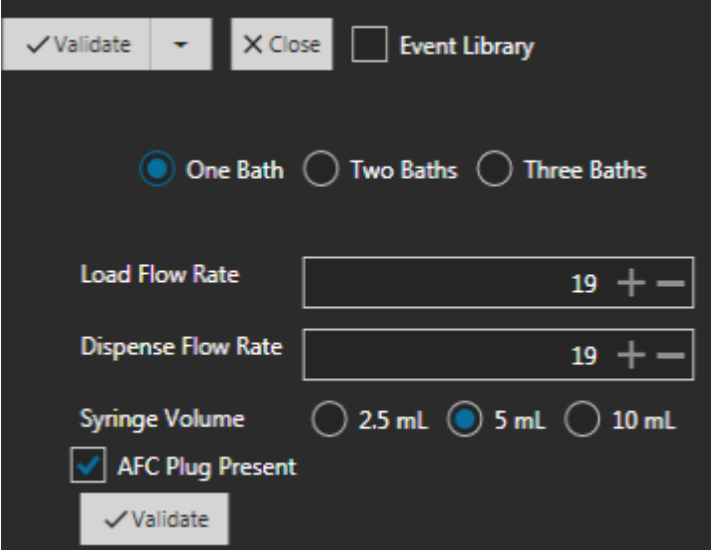
Event Libraries

Event libraries are a feature available on Vision G2 instruments introduced with firmware version 2.3. Event libraries allow users to create a sequence of events, which can be called from a Vision G2 protocol. When called, the event library executes the events during the dissolution test at the point where it is called. This allows for a larger number of events to be reserved for things that may occur only once during the dissolution test. Please consult your respective dissolution instrument user guide for the proper use of event libraries. Event libraries are not available on CD14 instruments.

Checking for Timing Conflicts

The Vision dissolution instruments provide the flexibility to add sampling and task events at any time during the test. This may result in a timing conflict where an event is programmed to start when the previous event may still be running. To check for possible timing conflicts, VPM provides the following tool while editing a Vision G2 protocol:

1. Click on the upper left Validate button to check for timing conflicts using a single bath and default flow rates and the standard 5 mL syringe.


2. Click on the ▼ next to the button to increase the number of testers and modify the default parameters if the protocol is going to run with different parameters.

3. After pressing the lower left Validate button, the feature will indicate whether or not a conflict exists. It will also display the calculated durations of the events to help the user figure out which event may be causing the conflict.

For CD14 methods, the check for timing conflicts is simplified, as the sampling times are not affected by the number of vessels, and only a 10 mL syringe size is available. The instrument default flow rates are assumed when checking for timing conflicts.

Section 12 – Audit Logs
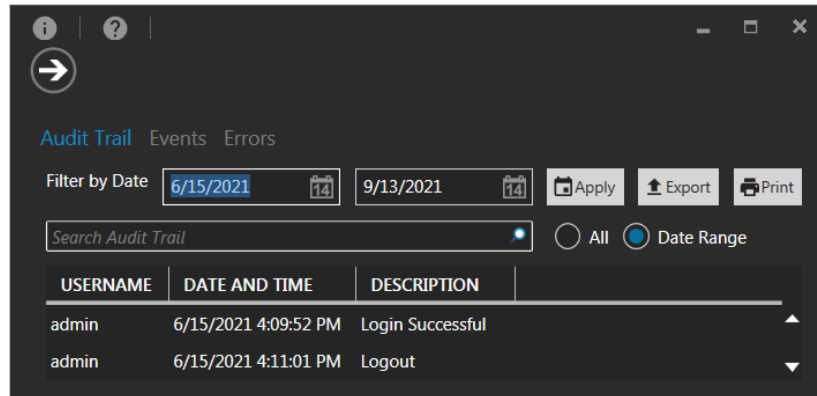
A user with permission to view the audit logs can access them by clicking on the Logs icon from the main toolbar. The Audit Logs screen contains the Audit Trail tab, the Events tab, and the Errors tab (error log). Click on the respective log name to display its information.

VPM provides a powerful and straightforward way to manage instrument logs. The information for each log is presented in tabular form shown in three columns:

* Clicking the heading name of the column causes all the information in the log to sort in ascending order with respect to the data in that column. For example, click on Instrument to sort the information by instrument serial numbers. Click on Instrument again to sort in descending order.

* Similarly, to sort the information by Date and Time of the event, or by event Message, click the respective heading title.

* Select the Date Range radio button to restrict the information presented to a specific date range. Enter the starting and ending dates in the appropriate input fields and click on the Apply button. Use the All radio button to display all available information.

- The user may further filter the information presented to very specific information. Enter a string such as "powered off," or a serial number, or a user name in the Search Events Log field. Click on the Search icon within the field and only the events matching that string will be displayed.

- Click on the Export button to save the presented results into a convenient text file, ready for sharing. These files are suitable for emailing instrument information to Teledyne Hanson Customer Support.

- Click on the Print button to print the presented results.

NOTE: The date range defaults to displaying the last three months of data in order to speed up presenting the most current information. Adjust the date range as needed to view additional (and older) information.

Audit Trail

VPM logs all major program events. The audit trail information is presented in a table with three columns: Username (of the user that was logged in when the event occurred), Date and Time (of the event), and Description (of the event). The following events are logged:

Event Type	Event
Security	• User login and logout • User lockout applied and removed (automatically or manually) • User profile added, deleted or edited • User password changed
Configuration	• Instrument added and deleted • Instrument profile edited • System added • Security configuration edited (password policy, user/group permissions)
Protocols	• Protocol created, deleted (database and instrument) • Protocol copied (source and destination) • Protocol edited
Dissolution Reports	• Signed
Instrument Backup	• Success and failure

Events Log

Vision G2 and CD14 instruments log all their major events. These events include but are not limited to powering on, powering off, running diagnostics, user logins, changes in configuration and changes to protocols. The log will store and maintain the last few hundred events within the instrument. Once this capacity is exceeded, older events are deleted to make room for new events.

VPM automatically downloads and saves all instrument events so that no events are ever lost. The information is presented in a table with three columns: Instrument (represented by serial number), Date and Time (that the event occurred), and Message (describing the event). For event logs downloaded from a CD14 instrument, the message field also contains the username (in parenthesis) of the user who is associated with the event, or (System) if the security is disabled on the instrument.

Error Log

When a Vision G2 or CD14 device detects an instrument error, it stores it in its internal error log. The error log can store just a few hundred errors. Once this capacity is exceeded, older error events are deleted to make room for new events. Refer to the respective instrument user guide to see a list of the possible errors, causes and resolutions.

VPM automatically downloads and saves all instrument errors so that no errors are ever lost. The information is presented in a table with three columns: Instrument, Date and Time, and Message.

Section 13 – Getting Help

If you have any problems or questions, this user guide is the first line of reference and support. Make sure that you have read all of the information provided in the document including the Installation Troubleshooting section. The user guide is provided in PDF format for easy searching of particular topics for understanding and future reference.

Context Sensitive Help

The program provides context sensitive help from the client user interface. Press the F1 key or click on the ? icon to display the Vision Protocol Manager help system detailing information pertaining to the screen in which you are working.

Sales and Support

If after using the context sensitive help and user guide you have a question or technical issue requiring our assistance, please feel free to contact us at any time.

Contacting Teledyne Hanson for Technical Support

For technical support, please submit a TSR form located at:

http://www.teledynehanson.com/tech-support-request

or e-mail hansontechsupport@teledyne.com

If you require phone support, please call 818.882.7266 and select the option for Technical Support. Please have the following information available:

1. Instrument Type

2. Serial Number

3. Firmware Version

4. What is the system configuration? How is the tester connected to other equipment?

5. How long did the equipment work before the problem occurred?

6. How old is the equipment?

7. Were there any recent repairs or maintenance on the unit?

8. How is the system being used? What is the application?

9. Detailed information about the problem. What is working and what is not?

10. The troubleshooting steps that have already been taken.

Section 14 – Installation Troubleshooting

The following troubleshooting suggestions should be performed by persons who are familiar with the target network, such as IT personnel. In addition, the person troubleshooting needs to have administrator level access on the computers where the software is being installed.

Pinging Devices

Pinging an IP address or computer name is a method for making sure that computers and instruments are able to send and receive information to each other through the network connection. Vision Protocol Manager will not work unless the clients and server can ping each other and the instruments.

To ping a device or instrument click Start> All Programs> Accessories> Command prompt> and enter the word ping followed by the IP address of the instrument or the computer name.

- Make sure that the IP addresses are correct for the server, clients and instruments.

- Reboot (cycle the power off and on) every device (including switches) involved.

- Check hardware: LAN cables, switch and network adapters.

- Make sure that a firewall is not blocking ping requests.

- Change the IP addresses, if possible.

Checking That Services are Running

Vision Protocol Manager will not work properly unless both SQL Server and the VPM services are running or started. Make sure that the Status column shows that both the services are started. If they are not running, select the service and click on Restart and make sure the service starts properly.

Click on Start and search for services.msc and press Enter.

Name	Description	Status	Startup Type	Log On As
SQL Server (SQLEXPRESS)	Provides storage, …	Started	Automatic	NT Servic…
Protocol Manager Service	Provides support f…	Started	Automatic (D…	enguser@…

Please note the following:

- The SQL Server service has the name of the database instance name that was given to the VPM database (in parenthesis) when the database was created. (Refer to Section 4 – Installing Server Software, "Installing SQL Server", item 9.)

- The properties of the SQL Server service should have the Startup Type as Automatic.

- The properties of the VPM service (Protocol Manager Service) should have the Startup Type as Automatic (Delayed Start).

Section 15 – General Warranty

Teledyne Hanson is a division of Teledyne Instruments, Inc. Teledyne Hanson products are warranted for one full year including parts and labor. Service contracts and preventive maintenance contracts are available for post-warranty support. International dealer warranties may vary. Teledyne Hanson makes no warranty, expressed or implied, for glassware, consumables, or products not manufactured by Teledyne Hanson, as evidenced by nameplate on the item or other designation. Teledyne Hanson will give reasonable assistance to buyer in obtaining from the respective manufacturer whatever adjustment is available under the manufacturer's own warranty. Teledyne Hanson shall be released from any and all obligations under any warranty, either expressed or implied, if the product covered is repaired or modified by other than its own personnel, or without written authorization from Teledyne Hanson. There are no other warranties, expressed or implied, and Teledyne Hanson shall not be liable under any circumstances for damages of any kind, direct, consequential, or otherwise.

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