Distek Opt-Diss 405
Document: 3881-0001
Revision: 2.0.0
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Installation and Operations Manual
Distek Opt-Diss 405

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Introduction
1 Introduction

This chapter contains an overview of the instrument and safeguards that need to be followed when installing and using the instrument. This manual contains important information regarding the safe operation and maintenance of your Distek Opt-Diss 405.
1.1 Notices

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Manual Part Number
3881-0001

Document Revision History

<table>
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| 2.00     | 15 Mar 2015 | • Combined the installation and operation manual as one.  
|          |          | • Converted the manual using H&M software.  
|          |          | • Software now supports 32 and 64 bit Windows 7 |

Warranty
The Material in this document is provided as is, and is subject to changes without notice in future revisions.

Distek disclaims all warranties, either express or implied, with regard to this manual and any information contained herein, including but not limited to the implied warranties of merchantability and fitness for a particular purpose.

Distek shall not be liable for errors or for incidental or consequential damages in connection with the furnishing, use, or performance of this document or of any information contained herein.
1.2 Overview

Opt-Diss 405™ is a multi-channel, fiber optic-based UV spectrometer system optimized for measuring the dissolution rates of pharmaceutical dosage forms. The basic measurement principle is identical to conventional UV spectroscopy, wherein dissolved component concentrations are proportional to the amount of light absorbed by the sample. In the Opt-Diss 405™ system, conventional cuvettes are replaced by fiber optic probes (or cuvettes with transmit/receive fiber optics). Fiber optic probe light paths (the distance light travels through the sample solution) are directly equivalent to cuvette path lengths.

Up to twelve (eight in 405LT™) probes are illuminated with UV light through optical fibers terminated at a low-noise Deuterium light source. Light passing through the samples passes through optical fibers terminated at the inlet slit to a spectrograph. The spectrograph separates light into different wavelengths and simultaneously images the light beams onto a two-dimensional CCD array detector.

Light intensity data are transferred to the computer, where the Opt-Diss 405™ software calculates and displays absorbance values and percent dissolved for each channel at user-selected time points and wavelengths. Currently up to 12 (eight in 405LT™) vessels can be monitored simultaneously. The actual image acquisition time depends on the required Exposure Time (typically 5 – 2000 ms).
At each user-selected time point, the Opt-Diss™ software acquires and saves complete UV spectra for all configured channels. The collected data at a given time point is referred to as a data set. The effect of different analytical wavelengths and/or baseline correction techniques can be immediately observed by changing the desired parameters.

Reference blank intensity spectra are acquired for both sample and standard blank solutions prior to the dissolution test. Prior to all image acquisitions the software automatically acquires a background or dark current reading that is subtracted from the light intensity reading. Since the background reading also contains a room light component, all light intensity and absorbance values are also corrected for any room light that may be entering through the fiber optic probes. The actual time required to acquire the background and sample intensities and transfer the data to the computer will vary depending on the amount of signal averaging, the Exposure Time, and number of channels in use. Acquisition times of 5 seconds or less are easily achieved.

Percent dissolved calculations are based on measurements of standard solutions and the expected amount of the target ingredient in the sample. The software has different options for correcting both sample and standard absorbance values for baseline variations related to light scattering turbidity and/or source drift.
1.3 Safety Information

The following general safety precautions must be observed during all phases of operation, repair and service of this instrument. Failure to comply with these precautions or warnings elsewhere in this manual violates the safety standard of the design, manufacture and intended use of this instrument. Distek Inc. assumes no liability for the customer or end-user to comply with these requirements.

Operation

Before applying power, make sure the instrument complies with the installation requirements. Additionally, the following must be observed:

- Do not remove instrument covers when operating.
- Instrument must be connected to a protective earth ground socket. Any interruption of the protective earth grounding will cause a potential shock hazard that could result in serious personal injury.
- Make sure that only fuses with the required current rating and of the specified type are used for replacement.
- Any service should be only carried out by a skilled person who is aware of the hazard involved and properly trained in the service and repair of the instrument.
- Do not operate the instrument in the presence of flammable gases or fumes.
- Do not install substitute parts or make any unauthorized modification to the instrument.

Safety Symbols

<table>
<thead>
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<th>SYMBOL</th>
<th>Description</th>
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<td><strong>WARNING</strong>: This symbol denotes a hazard. It calls attention to the operating procedures and safety practices. If procedures are not performed correctly or if safety standards are not adhered to, it could result in damage to the instrument or harm to the user.</td>
<td></td>
</tr>
<tr>
<td><strong>HIGH VOLTAGE</strong>: This symbol denotes the presence of high voltage.</td>
<td></td>
</tr>
<tr>
<td><strong>CAUTION</strong>: This symbol denotes a hazard. It calls attention to the operating procedures and safety practices. If procedures are not performed correctly or if safety standards are not adhered to, it could result in damage to the instrument or harm to the user.</td>
<td></td>
</tr>
<tr>
<td><strong>UV Warning</strong>: This symbol denotes a hazard. It calls attention to the operating procedures and safety practices. If procedures are not performed correctly or if safety standards are not adhered to, it could harm to the user.</td>
<td></td>
</tr>
<tr>
<td><strong>NOTES</strong>: This symbol denotes helpful information.</td>
<td></td>
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</tbody>
</table>
1.4 Site Requirements

This chapter contains information regarding the recommended minimum available bench space and electrical requirements when installing your instrument.
1.4.1 Physical Site Considerations

The dimensional requirements specified below are adequate for the installation of the Opt-Diss 405:

1. The minimum bench depth needed (front edge of bench to the back splash or wall) is 20 inches (51cm). However, the minimum recommended bench depth is 24 inches (61cm) for proper ventilation.

2. The minimum linear bench space requirement is 30 inches (76cm). Distek recommends that at least 36 inches (91cm) be allocated whenever manual operations are required to be performed adjacent to the system.

3. There must be no obstruction (cabinet, shelf, or outlet) that intrudes into the minimum footprint where the unit is to be installed.

4. The bench must be capable of sustaining the weight of the unit and all of its accessory parts without significant bending.

1.4.2 Operating Environment

1. Verify that the component (UV source, detector controller, computer, and monitor) line voltage power inputs match the line voltage for the country/region where the system will be installed.

2. The system must be installed in a humidity and temperature-controlled room where the temperature must be within 20 - 27°. Do not install in areas of strong sunlight or high humidity.

3. Clear an area of bench space, approximately 18 inches wide by 18 inches deep, preferably to the right of the dissolution bath and centered for two bath configurations.
1.4.3 Electrical Requirements

The instrument can operate on line voltage of 115V ± 15V 50/60Hz or 230V ± 15V 50/60Hz. The instrument is factory configured for either 100-115 VAC or 220-240 VAC only.

Disconnect the instrument from the AC line by pulling out the power cord. The power supply still stores some power, even if the power switch is turned off or the power cable is unplugged.

Other accessories, such as printers, accept nominal line voltage of 115 or 230 VAC at 50 or 60 Hertz. For more information, see the documentation that came with your accessories.

**WARNING** Do not connect your instrument to a line voltage that is higher than the specified voltage. Shock hazard or damage to your instrument can occur.

Power cords are offered in different configurations depending on the particular country or region of intended use. For all cables, the female end of the supplied power cord is identical and it plugs into the power inlet socket located on the right side of the instrument. The male end of each supplied power cord is different and designed to match the wall outlet of the intended country or region of use.

**WARNING** Always use the power cord supplied with your instrument. Always plug in your instrument with a properly grounded wall outlet.
1.5 Environmental Considerations

Distek & the WEEE Directive
Ambient Laboratory Temperature
Ambient Laboratory Humidity
Air Quality Considerations

This chapter contains information regarding the recommended laboratory conditions such as humidity, room temperature and air quality when installing your instrument. It also contains information regarding environmental considerations when disposing of the instrument.
1.5.1 Distek & the WEEE Directive (Waste Electrical & Electronic Equipment)

Distek, Inc. is committed to protecting the environment and understands the importance of proper recycling. The "crossed out wheelie bin" symbol on the product or on its packaging indicates that this product must not be disposed of with domestic household waste. Instead, it is the user’s responsibility to dispose of their waste equipment by handing it over to a designated collection point for the recycling of electrical and electronic equipment waste. The separate collection and recycling of your waste equipment at the time of disposal will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment.

For more information about where you can drop off your waste equipment for recycling, please contact your local city office, your local distributor or Distek, Inc.

1.5.2 Ambient Laboratory Temperatures

Distek recommends that the laboratory temperature control system be kept on at all times.

**Maximum Conditions:**
To achieve the full range of controlled operation (20 to 27°C) within specified tolerances, the instrument is designed to be installed and operated in laboratories where the maximum operating temperature does not exceed 27°C. The maximum allowable ambient operation temperature is 30°C.

**Minimum Conditions:**
To assure controlled operation within specified tolerances, the instrument is designed to be operated in laboratories where minimum operating temperatures do not drop below 20°C.

**Variability or Short Term Fluctuations:**
To assure controlled operation within specified tolerances, the system used to control the temperature of the laboratory where the instrument is installed must be able to maintain the ambient air temperature within ±2.5°C of set point (worst case).
For laboratories where temperature control is critical, installation of several dissolution units may require that the system be re-balanced. Thermostats may need to be relocated to maintain temperature uniformity inside the laboratory.

1.5.3 Ambient Laboratory Humidity

If possible, Distek recommends that the laboratory humidity control system fans be kept on at all times.

**Maximum:**
The dissolution bath on which the Opt-Diss instrument is connected may add to the humidity of the laboratory during operation. Any vessels filled and left uncovered can raise humidity levels. Water vapor and/or hydrogen chloride vapor from dissolution media can cause serious effects when condensed on electrical components and contacts. The laboratory environmental controls should maintain the humidity level below the dew point, to minimize the risk of condensation.

**Minimum:**
It is important that the humidity level be kept at or above 30% and 80% relative humidity, to minimize the risk of damage to control circuits caused by static discharge.

1.5.4 Air Quality Considerations

Distek instruments are designed to be operated in a laboratory environment that has no visible dust problem, and with organic solvent vapor levels as low as possible. Operation is not recommended in dusty lab environments, or in labs with significant chlorinated or reactive solvent vapor levels. These dust or vapor levels may have serious effects on system components.
2 Installation and Setup

Unpacking
Power Installation
Fiber Bundle Installation
Dissolution Bath Communication
Printers

This chapter contains information on how to properly unpack the instrument, connecting power to the instrument, installing the fiber bundle, connecting the dissolution baths as option for the software to control the baths and connecting a printer.
### 2.1 Unpacking

Please take a few moments when unpacking the instrument to check for all items indicated on the packing list. Notify Distek or your shipper immediately of any discrepancies or damage to cartons or contents upon receiving.

**CAUTION** To avoid injury, a minimum of two people should carry and remove the instrument from its shipping container.

Packing must be removed before operating this instrument. To remove packing:

1. Cut the straps that hold the shipping box together. Open the large box.

2. Locate and carefully remove the packaged accessories and set them aside in a safe area.

3. Remove all remaining packaging inserts.

4. Lift the instrument out of the box and onto a stable cart or directly on the bench top where the instrument will be installed.

5. Open the main instrument enclosure left side panel and remove the packaging around the camera.

   **Notes** If the camera is shipped separately, unpack it and carefully install it into the Opt-Diss enclosure.

6. Reinstall and secure the left side panel.

7. Install the computer shelf using the supplied screws.

8. Dispose of the remaining packaging properly.
2.2 Power and USB Installation

- Depending on the AC line condition and quality based on region or country where the instrument will be installed, a voltage line conditioner may be necessary to prevent the instrument from transient noise or voltage spikes.
- The AC cord type will depend on the region or country where the instrument will be installed.

1. With the instrument positioned properly on the bench, locate the two AC power inlets, one for the instrument and the other for the power supply unit (PSU)/controller.

2. Connect the power cords to the power inlets. Plug the other end of the power cords to the appropriate wall outlet.

3. Connect the USB cable to the instrument USB port. **DO NOT** plug the other end of the USB cable to the PC.

   Before connecting the USB cable into the PC, be sure that the software is already installed and configured. Refer to section Software and Device Installation Procedure.

4. Connect the PSU connector to the front of the controller.
2.3 Fiber Bundle Installation

To install the Opt-Diss fiber bundle and Arch probes, follow the procedure below:

1. Connect the unified end (single SMA adapter) of the source fiber bundle to the UV source SMA input jack.

2. Connect each leg of the source fiber bundle to the bottom connector of each probe.

3. Connect the unified end (large polished aluminum cylinder) of the detector fiber bundle into the keyed spectrograph input receptacle on the front left of the main enclosure.

4. Connect each leg of the detector fiber bundle to top connector of each probe.
2.4 Dissolution Bath Communication

The Opt-Diss software can remotely access and control the dissolution bath instrument.

The software is designed to work with Distek's line of dissolution baths. It is capable of controlling the Model 2500, EVO 6100, EVO 6300 and symphony 7100 dissolution baths, and in the process can acquire data useful for purposes of reporting. In order to control dissolution baths through the software, an RS-232 serial cable needs to be connected using available PC's serial port(s), and the software needs to be configured with the type of bath(s) that will be used with the instrument.

EVO 6100 and 6300 requires that a standard RS-232 cable be used. For Model 2500 and symphony 7100, a NULL RS-232 cable is used.
2.4.1 Connecting Dissolution Baths

If using a USB to Serial adapter, refer to the installation instructions in setting and configuring the adapter.

1. Complete these steps only if one or more Distek dissolution baths (models 6100, 6300, 2500 and 7100 only) will be controlled and monitored from the OPT-DISS™ software.

2. Right click on My Computer and select Manage.

3. Select the Hardware tab and then select Device Manager button.

4. On the left pane select the Device Manager and on the right pane expand the item Ports(COM & LPT). This will show available COM or Serial Ports.

5. Determine the physical serial connectors or USB-to-Serial adapters on the computer that is associated with the available COM Ports. If necessary, refer to the computer reference manual or other documentation describing the USB-to-Serial adapter if such a device is used.

6. Connect a serial cable (9-pin straight-through male/female) between the bath(s) and physical serial connector(s).

7. Record the COM Ports used. They must be known in order to configure bath communications from OPT-DISS™.

8. Exit Device Manager and the Computer Management screen.

9. Power up the dissolution bath(s). Refer to the dissolution bath manual for specific details on setting the bath unit address.
2.5 Printers

Printers with a USB port connection can be used to connect directly to the PC available USB port. If the PC is connected to a server, you may need to contact your IT technical support to allow the PC to use the server printer.
Part III
Software Installation Guide
3 Software Installation Guide

System Requirements
Software and Device Installation Procedure
Configuring Security

This chapter contains information regarding the requirements for the software and on how to properly install the Opt-Diss software. Generally, the software is already installed and configured from the factory. This chapter is for the installation or re-installation of the Opt-Diss software due to PC problems or replacement.
3.1 System Requirements

An OPT-DISS™ system installation consists of application and supporting software installed on a Windows compatible computer interfaced to a multi-channel CCD array spectrometer. Data files may be stored in a secured folder located on the local computer hard drive (standalone workstation) or on a networked file server. Users may be authenticated locally or from a domain server. Before proceeding, determine which installation is applicable.

**OPT-DISS™ installations in a networked environment must be coordinated between vendor and customer IT staff. New OPT-DISS™ systems are shipped with all required software pre-installed and security is configured for a standalone workstation installation.**

3.1.1 Hardware Requirements

OPT-DISS™ may be installed on a Windows compatible computer that adequately supports the Windows 7 operating system. The following are minimum and preferred requirements:

- Genuine Windows® 7 Professional, 32 or 64-bit, US English Version Only
- 1.5 GHz CPU (or better)
- 4GB RAM minimum
- 250GB 2.5 SATA 3.0Gb/s and 16MB (or larger)
- CD-ROM drive (option, not mandatory)
- OPT-DISS™ Spectrometer using a Synapse or Syncerity camera/detector
- 1 USB port for the spectrometer interface
- Distek Model 2500, EVO 6100 or 6300 and symphony 7100 dissolution bath (if Distek bath control is used)
- 1 or 2 Serial Ports or USB-to-Serial adapter (if Distek bath control is used)

3.1.2 Software Requirements

OPTDISS™ software is designed to help users comply with FDA requirements for the generation and maintenance of electronic records according to federal regulations 21 CFR Part 11. The system computer requires the following software:

- Windows 7 Operating System, latest service pack (Service Pack 2 is recommended) and with latest Windows Update
- Storage drive formatted with the NTFS File system
• OPT-DISS™ Software
• OPT-DISS™ Synergy SDK Instrument Driver Software
• Microsoft .net Version 2.0 or later

After performing the Windows Update, Distek recommends that the Windows Update be turned off as this can cause the software to become unstable.

3.1.3 User Account Control Settings

The UAC (User Account Control) is a security tool for Windows to help standard users perform administrator tasks and to encourage users not to run as administrator. When any program requires administrator privileges, the UAC prompt asks users for permission to proceed. For the Opt-Diss 405™ software to install correctly, the UAC needs to be disabled temporarily to make the necessary changes to the computer during installation. Also, the virtual store needs to be turned off for the software settings and configuration to be available to all end-users.

Disabling the UAC (User Account Control)

• Before making any changes write or take a screen shot of the UAC setting.
• After the software installation and system configurations are completed, set the UAC setting back to its original setting.

1 To begin, login as the administrator. Click on Start and type "UAC" in "Search programs and files" text box then Enter as shown.

Opening up UAC
2 Temporarily set the UAC setting to "Never Notify" then OK to accept the changes as shown.

Disabling the UAC Virtual Store

Disabling this feature prevents the creation of virtual drive for each user that affects each user when using the Opt-Diss 405™ software.

1 To begin, login as the administrator. Click on Start and type "secpol.msc" in "Search programs and files" text box then Enter as shown.
2  Expand the following folders; "Local Policies" and "Security Options". Scroll to the policy window and double-click on "User Account Control: Virtualize file and registry write failures to per-user locations" and change the security setting to "Disable" as shown.

![Disabling the virtual store](image)

3  Apply OK and restart the PC.

3.1.4  Windows Power Options Settings

It is necessary to disable Windows' default power management settings in order for the OPT-DISS™ software not to be interrupted during tests. The steps below will assist in disabling these settings.

1  To begin, open your Control Panel from your Start menu.

![Opening the Control Panel](image)
2. Click on *Hardware and Sound*.

![Opening Hardware and Sound](image1)

3. Click on *Power Option*.

![Opening Power Option](image2)

4. Click on *"Change plan settings"* as shown.

![Selecting "Change plan settings"](image3)
5 Click on "Change advanced power settings" as shown.

6 Expand "Hard Disk" and set the "Turn off hard disk after" to "Never" as shown. Expand "Sleep" and set the following criteria: "Sleep after" to "Never", "Allow hybrid sleep" to "Off", "Hibernate after" to "Never" and "Allow wake timers" to "Disable". Expand "USB settings" and set the "USB selective suspend setting" to "Disabled" as shown.

7 Select "OK" to accept the changes. Close the Control Panel window.
3.2 Software and Device Installation Procedure

An OPT-DISS™ system installation consists of application and supporting software installed on a Windows compatible computer interfaced to a multi-channel CCD array spectrometer. Data files may be stored in a secured folder located on the local computer hard drive (standalone workstation) or on a networked file server. Users may be authenticated locally or from a domain server. Before proceeding, determine which installation is applicable.

OPT-DISS™ installations in a networked environment must be coordinated between vendor and customer IT staff. New OPT-DISS™ systems are shipped with all required software pre-installed and security configured for a standalone workstation installation.

3.2.1 Installing & Configuring Instrument Driver Software

All software installation and configuration steps must be completed by logging in locally as the Administrator. Complete steps in the listed order.

HJY SDK Software Installation Wizard

1  Turn off the power switch on the spectrometer.

2  Connect a USB cable to the spectrometer but do not connect the cable to the computer. If connected, disconnect the USB cable from the computer.

3  Start the computer and log in locally as the Administrator. Close any executing programs.

4  Insert the installation flash drive into an available USB port (or CD into the CD-ROM drive).

5  Browse into the Synergy SDK folder located on the installation media.
6. Select and run the Setup.exe application as shown.

7. Select Next for the HJY Wizard to start.

8. Select I accept the terms of the license agreement, then select Next to agree on the license agreement.
9. Select **Next** after entering the system owner or contact person and company name.

10. Select **Next** to install the program using the default location.

11. Select **Install** to continue installing the program.
USB Driver Installation Wizard

1. Select "Next" to start the USB driver installation wizard.

   ![Select Next to start USB driver installation wizard]

2. Select "Next" after agreeing to accept EULA (End User License Agreement).

   ![Select Next to accept EULA]

3. Select "Finish" after successfully installing the driver.

   ![Select Finish after successful driver installation]
4 After the installation, the computer needs to be re-started to complete the changes made.

3.2.2 Initializing the USB Interface and Configuring the Device

1 Connect the spectrometer USB cable to a USB port on the computer.

2 Switch on power to the spectrometer.

3 If the Hardware Configuration Wizard appears, select the option *No, not at this time.* Select *Next.* Verify that *Install the software automatically* is selected. Select *Next.* When the hardware installation dialog appears, select *Continue Anyway.* Select *Finish.*

Configuring the Device

1 Select the **Start** button on the Windows toolbar to start the device configuration wizard *(Start | All Programs | Jobin Yvon | SDK | Config Wizard)*

   ![Device configuration wizard]

2 Select **Go** to configure new device.

   ![Configuring new device]
3. Choose **Detector** as your device type, then **Next**.

4. Choose **Multi-Channel Detector** as your device sub-type, then **Next**.

5. Choose **HJY USB** for the **Controller Special Types**. Depending on the camera type, choose either **Synapse** or **Syncerity** for the **Model**, then **Next**.

Configure communication parameters
6 Type in **Opt-Diss** as the *Device Display Name*, then **Next**.

7 Verify the following items:
   - Selected Controller Type as Synapse
   - (For Windows 32 bit) CCD table file path and search directory as C:\Program Files \Jobin Yvon
   - (For Windows 64 bit) CCD table file path and search directory as C:\Program Files (x86)\Jobin Yvon
   then **Next**.

8 Compare the Summary configuration from your settings as shown,
   then select **Validate Hardware** to establish communication with the instrument.
   Click OK to accept.
   **Select Finish** to complete the configuration.
9 Select Cancel then Yes to close the instrument configuration dialog window.

3.2.3 Configuring the Instrument Identifier/Serial Number

1 Select the “Start” button on the Windows Toolbar.

2 Type in the word regedit in the search box as shown, then select regedit.exe to access Windows registry.

3 Win7 32-bit: Browse to the key Computer\HKEY_LOCAL_MACHINE\SOFTWARE\Jobin Yvon \Components\Detectors\CCD1 as shown.
Win7 64-bit: Browse to the key `Computer\HKEY_LOCAL_MACHINE\SOFTWARE \Wow6432Node\Jobin Yvon\Components\Detectors\CCD1` as shown.

4. Right-Click on the folder named `CCD1` and select `Rename`. Enter the text `CCD-DI-xxxxxx` (where “xxxxxx” = spectrometer Serial Number) in the editable field. The entry must include the `CCD` prefix (e.g., CCD-DI-1001).
Select the re-named folder and right-Click on the szUniqueID item in the right-hand pane. Select Modify. Again enter CCD-DI-xxxxxx (where “xxxxxx” = spectrometer Serial Number e.g., CCD-DI-1001) in the Value data field and select OK.

Renaming the folder and szUniqueID

This step is the same for either the 32 bit or 64 bit operating system.

5 When completed correctly, the Registry Editor should look as shown. Exit the Registry Editor. Now users will be able to view and select the spectrometer Serial Number from within the OPT-DISS™ Tools-System Configuration screen. The selected spectrometer Identifier/Serial Number will be displayed on printed reports.
3.2.4 Installing the Opt-Diss Software

All software installation and configuration steps must be completed by logging in locally as the Administrator.

Installing the OPT-DISS™ Software

1. Browse into the root folder located on the installation media.

2. Select and double-click the setup.exe application file as shown.

3. Follow the installation wizard prompts to complete the installation. Restart the computer after the installation is completed.
Adding the local Administrator to Optra-Administrators Group

1. Log in to the PC.

2. Select Start | Computer right-click then select Manage as shown.

Accessing the Computer Management screen

3. Expand the Local Users and Groups item, select Groups, select group named optra-administrators then Add to Group... as shown.

Accessing to Add to Group...
4 In the *Select Users* dialog window, enter the name *Administrator* then *OK* to accept the changes as shown.

Adding the user Administrator to optra-administrators group

5 The local Administrator is now part of the optra-administrators group as shown. Close the Computer Management window.

Adding the local Administrator to optra-administrator group
3.2.5 Configuring Program Settings and Initial Checkout

You must log on to the computer as a Local Windows Administrator and as a member of the optra_administrators group. If you only log on with optra_administrators privileges, you will be able to change the location of the data folder for that session, but when you start another session, the data folder will be set back to the default location.

1. Turn on power to the spectrometer by moving the rear On/Off switch to On.
2. Start the computer and logon as a local Administrator who also belongs to the OPT-DISS™ Administrators Group. Wait at least 30 sec before going to the next step.
3. Double-click the OPT-DISS shortcut icon on the Desktop to start the OPT-DISS™ program. Enter your password at the windows dialog prompt.
4. Select Tools | System Configuration.
5. From the CCD Camera Settings-Detector Model pull down list, select the Instrument Serial Number as shown. This must be done in order for the Instrument Serial Number to be listed on printed reports.

6. In the Gain and AD selection, select the Update button.

7. Under Bath Configuration select the COM Port(s) which are connected to dissolution bath(s) RS-232, select the instrument address and the number of vessels the instrument is configured with. Select none if bath control will not be used.
8 The Fiber Detection Settings are set at the factory. Change the settings as shown if they are not set correctly.

9 Under Data Folder Location enter or browse to the secured OPT-DISS™ data folder (established in OPT-DISS™ Data Folder Security). Select the folder and select OK to accept the folder assignment.

The wavelength Calibration File remains blank during the initial software installation. It is filled automatically after the wavelength calibration is performed.

10 Select OK and enter your password at the prompt to accept changes to the setting and exit the System Configuration screen.

11 Exit the program to ensure that settings are saved. Restart the program and enter your password at the log in prompt.

12 Select Tools | Initialize Camera and select OK at the system prompt. The camera should initialize with no errors.
13 Select **Tools | Read Temperature**. A prompt should be displayed showing the CCD chip actual and set point temperatures.

![Reading the CCD Camera Temperature](image)

14 Click **OK** and exit the program.

Refer to the OPT-DISS™ User’s Manual for detailed instructions on configuring detector channels and performing a wavelength calibration.

### 3.2.6 Configuring Desktop Shortcuts

If the Opt-Diss executable shortcut was not automatically created during the software installation, follow the procedure below to create and configure the shortcut icon to open the Opt-Diss software.

1. Log on to the OPT-DISS™ workstation as the Administrator.
2. From Windows Explorer browse to the folder `C:\Documents and Settings\All Users\Desktop`.
3. Right-click inside the folder and select **New-Shortcut**.
4. Browse to the folder `C:\Program Files\Distek\OPT-DISS\`, and select the file `opt-diss.exe`.
5. Select **OK**, select **Next**, and change the shortcut name to **OPT-DISS**. Select **Finish** to accept the changes.
6 Right-click the application shortcut, and then click Properties as shown.

![Opt-Diss shortcut properties](image)

7 In the Properties dialog box, click the Compatibility tab.

8 To apply the setting to the currently logged-on user, select the Run this Program as an administrator check box as shown, and then click OK.

![Opt-Diss shortcut setting](image)
### 3.3 Configuring Security for a Standalone Workstation

This section is applicable to installations where both OPT-DISS™ security groups and user accounts are established on the local OPT-DISS™ computer and data are stored on the local hard drive. These steps must be completed by a Windows Administrator.

#### 3.3.1 Configuring Local OPTDISS™ Security Groups

1. The following groups comprise the Windows authentication security system. Users that are added to these groups will have controlled access to different system functions as described in the User’s Manual.
   - optra_administrators
   - optra_developer
   - optra_operator
   - optra_reviewer

2. The local Windows groups listed above are created automatically during software installation.

3. From the **Control Panel** open **Administrative Tools** and then the **Local Security Policy** folder as shown.

![Accessing Local Security Policy folder](image)

4. Under **Security Settings** explode the **Local Policy** folder and select **User Rights Assignment**.

5. Add each OPTDISS™ group to each of the following Rights on the local computer:
• Act as part of the operating system.

Optra Groups act as part of the operating system

• Logon as batch job

Optra Groups log on as a batch job

6 Select the right **Deny logon as batch job** and make sure no OPT-DISS™ Group is listed.
7 Click **OK** as required to exit each window. Close the *Administrative Tools Control Panel*.

8 Restart the computer.

### 3.3.2 Calibration Security Settings

1 Select the **Start** button on the Windows Toolbar.

2 Type in the word **regedit** in the search box as shown, select **regedit.exe** to access Windows registry.
3. **Win7 32-bit:** Browse to the key `Computer\HKEY_LOCAL_MACHINE\SOFTWARE\H&A Scientific\Hidra\Current Version` as shown. Select the `Current Version` folder. Select `Edit-Permissions` from the main menu to open the `Permissions for Current Version` dialog box as shown.

![Registry Editor window](image1.png)

**Win7 64-bit:** Browse to the key `Computer\HKEY_LOCAL_MACHINE\SOFTWARE \Wow6432Node\H&A Scientific\Hidra\Current Version` as shown. Select the `Current Version` folder. Select right-click `Edit-Permissions` from the main menu to open the `Permissions for Current Version` dialog box as shown.

![Registry Editor window](image2.png)
The following steps are the same for either the 32 bit or 64 bit operating system.

4 In the Permissions for CurrentVersion dialog window, select the Advanced button.

5 Unchecked the Include inheritable permissions from this object’s parent.

6 Select Remove in Windows Security dialog window, then OK. This will delete all the groups except the Administrators.

7 Add the Windows Administrator, optra-adminstrators and optra_developer groups. Assign them both Full Control privileges.

8 Add the optra-operator and optra_reviewer groups. Assign them both Read only privileges.

9 The box should appear as shown in the following example for each Group.

10 Click the OK button to accept the entries. Exit the Registry Key editor. Restart the computer.
3.3.3  **OPTDISS™ Data Folder Security**

A default data folder is created in a default location during the software initial setup. Follow the steps below if a new data folder needs to be created whether locally or networked.

1. Create a folder on an NTFS partition that will be used to hold OPTDISS™ data files. The folder should be empty before proceeding with the following steps.
2. Use Explorer to locate the folder. If more than one folder will be used, the following steps will need to be repeated for each folder.
3. Right-click the folder and select Properties as shown.

![Data Folder Properties](image)
4 Select the **Security** tab. Click on the **Advanced** button and make sure that the checkbox next to **Include inheritable permissions from this object parents** is unchecked. If it is checked, uncheck it.

**Data Folder Advanced Security Settings**

5 A dialog box will appear. Click the **Remove** button. This will remove all groups and users that currently have access to the folder. **DO NOT** click the **Apply** button.

6 Click the **Add** button and add the **Administrators Group**. In the **Permission Entry** screen that appears, enable the **Permissions** listed for **Administrators** as listed in the following table. Click the **Apply** button.
### Optra-Groups Effective Permission Table

<table>
<thead>
<tr>
<th>Effective Permissions:</th>
<th>Administrators</th>
<th>optra_administrators</th>
<th>optra_developer</th>
<th>optra_operator</th>
<th>optra_reviewer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Control</td>
<td>Checked</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Traverse Folder/Execute File</td>
<td>Checked</td>
<td>Checked</td>
<td>Checked</td>
<td>Checked</td>
<td>Checked</td>
</tr>
<tr>
<td>List Folder/Read Data</td>
<td>Checked</td>
<td>Checked</td>
<td>Checked</td>
<td>Checked</td>
<td>Checked</td>
</tr>
<tr>
<td>Read Attributes</td>
<td>Checked</td>
<td>Checked</td>
<td>Checked</td>
<td>Checked</td>
<td>Checked</td>
</tr>
<tr>
<td>Read Extended Attributes</td>
<td>Checked</td>
<td>Checked</td>
<td>Checked</td>
<td>Checked</td>
<td>Checked</td>
</tr>
<tr>
<td>Create Files /Write Data</td>
<td>Checked</td>
<td>Checked</td>
<td>Checked</td>
<td>Checked</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Create Folders /Append Data</td>
<td>Checked</td>
<td>Checked</td>
<td>Checked</td>
<td>Checked</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Write Attributes</td>
<td>Checked</td>
<td>Checked</td>
<td>Checked</td>
<td>Checked</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Write Extended Attributes</td>
<td>Checked</td>
<td>Checked</td>
<td>Checked</td>
<td>Checked</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Delete Subfolders and Files</td>
<td>Checked</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Delete</td>
<td>Checked</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Read Permissions</td>
<td>Checked</td>
<td>Checked</td>
<td>Checked</td>
<td>Checked</td>
<td>Checked</td>
</tr>
<tr>
<td>Change Permissions</td>
<td>Checked</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Take Ownership</td>
<td>Checked</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>
7 Repeat the previous step (Add the Group and configure Permissions) for each of the remaining Groups listed in the above table. When adding the Groups make sure each Locations box has the local workstation name in it. If it is pointing to your domain, change it to the local workstation. After all the Optra groups are added, the Data Folder properties dialog window should look as shown.

![Optra Groups Permission](image1)

8 Select the Owner tab and make sure that the Administrators Group is listed as the Current owner.

If this is not the case, select the Administrator Group in the Change owner to: pane and then click the Apply button.

![Data Folder Current Owner](image2)
9 Click the **OK** button in the Properties window to accept all entries.

10 Start the OPT-DISS™ program and log on as an OPT-DISS™ Administrator. Select **Tools | System Configuration**. In the **Data Folder Location** entry box, browse to and select the data storage folder configured in the previous steps. Select **OK** and enter your password to exit the **System Configuration** window.

![Setting the Data Folder Location](image)

### 3.3.4 Adding New OPTDISS™ Users

- There must be at least one user that is a member of the local workstation Administrators group and also a member of the OPT-DISS™ Administrators Group (optra_administrators).
- Contact your IT group if you are not familiar adding users.

1 Right click on **My Computer** and select **Manage**.

2 Expand the **Local Users and Groups** item.

3 On the main menu, select **Action** then select **New User**.
4 Fill in the appropriate information for the new user, making sure to un-check the **User Must Change Password at Next Logon** option and checking **User Can Not Change Password** and **Password Never Expires** as shown.

![Creating a new user](image)

5 After adding new users, make sure to go back and make them a member of the appropriate OPT-DISS™ group by double-clicking each user and selecting the **Member Of** tab.

6 Click the Add button and type in the name of the group they are to be a member of, either `optra_administrators`, `optra_developer`, `optra_operator`, or `optra_reviewer`.

7 Click the OK button and close the Computer Management console.
3.4 Configuring Security in a Networked Environment

This section is applicable to installations where user accounts and network groups are established on a Windows network domain controller and data are stored either locally or on a network drive.

3.4.1 Creating and Using Network Groups

1. OPT-DISS™ user functional privileges are determined by membership in the following local groups established automatically during system installation:
   - optra_administrators
   - optra_developer
   - optra_operator
   - optra_reviewer

2. Network groups and/or network accounts must be added to the above local groups for OPT-DISS™ users to be able to start the application software, have the expected functional privileges, and be authenticated from a domain controller.

3. When using network authentication it is recommended to establish network groups which mirror the above four groups. The names do not have to be exactly the same, but it is recommended to use the same terminology ("admin", "developer", "operator", "reviewer") in establishing network groups. This approach will simplify establishing data folder security permissions and management of user accounts.

4. At the server console, go to Start | Programs | Administrative Tools | Active Directory Users and Groups.

5. Right click on the Users section in the left hand pane and select New | Group.

6. Enter the name of the OPT-DISS™ Administrator group into the group name box. Click on OK.

7. Repeat steps 2 and 3 for the remaining Developer, Operator, and Reviewer groups.

8. When done, close the Active Directory Users and Groups console.
3.4.2 Populating Local OPT-DISS™ Groups

1 Local OPT-DISS™ security groups must be present. These groups are created automatically during system installation.

2 Right click on *My Computer* and choose *Manage* as shown.

   ![](My_Computer_-_Manage.png)

3 Expand the *Local Users and Groups* item. Select the *Groups* folder. Double-click the *optra_administrators* group. Click the *Add* button. Make sure that the *Location* box is pointing to the domain and not the local workstation as shown.

   ![](Adding_the_domain_group.png)

4 Enter the name of the OPT-DISS™ Administrator group created in *Creating and Using Network Groups* and click *OK*. Then click *Check Names* to verify the presence of the network group.

5 Click *OK* to add the network OPT-DISS™ Administrator group to the local *optra-administrators* group.
6 Repeat steps above for the remaining OPTDISS™ groups (optra_developer, optra_operator, and optra_reviewer). When done select the Close button.

7 Close the Computer Management Console.

8 From the Control Panel open Administrative Tools and then the Local Security Policy folder as shown.

Accessing Local Security Policy folder

9 Under Security Settings explode the Local Policy folder and select User Rights Assignment.

10 Add each OPTDISS™ group to each of the following Rights on the local computer:

- Act as part of the operating system.

Optra Groups act as part of the operating system
• Logon as batch job

11 Click OK as required to exit each window. Close the Administrative Tools Control Panel.

12 Restart the computer.

3.4.3 Calibration Security Settings

1 Select the Start button on the Windows Toolbar.

2 Type in the word regedit in the search box as shown, then Enter to access Windows registry.
3 Win7 32-bit: Browse to the key `Computer\HKEY_LOCAL_MACHINE\SOFTWARE\H&A Scientific\Hidra\Current Version` as shown.
Select the `Current Version` folder. Select `Edit-Permissions` from the main menu to open the `Permissions for Current Version` dialog box as shown.

 ![Registry Editor window](image)

Win7 64-bit: Browse to the key `Computer\HKEY_LOCAL_MACHINE\SOFTWARE\Wow6432Node\H&A Scientific\Hidra\Current Version` as shown.
Select the `Current Version` folder. Select `Edit-Permissions` from the main menu to open the `Permissions for Current Version` dialog box as shown.

 ![Registry Editor window](image)

4 In the `Permissions for CurrentVersion` dialog window, select the `Advanced` button.

5 Unchecked the `Include inheritable permissions from this object’s parent`.

6 Select `Remove` in `Windows Security` dialog window, then `OK`. This will delete all the groups except the `Administrators`. 
Add the Windows Administrator, optra-administrators and optra_developer groups. Assign them both Full Control privileges.

Add the optra-operator and optra_reviewer groups. Assign them both Read only privileges.

The box should appear as shown in the following example for each Group.

Click the OK button to accept the entries. Exit the Registry Key editor. Restart the computer.
3.4.4 OPTDISS™ Data Folder Security

1 The data folder may be located on the local workstation hard drive or a network drive. Create a folder on an NTFS partition that will be used to hold OPTDISS™ data files. The folder should be empty before proceeding with the following steps.

2 Use Explorer to locate the folder. If more than one folder will be used, the following steps will need to be repeated for each folder.

3 Right-click the folder and select **Properties** as shown.

4 Select the **Security** tab. Click on the **Advanced** button and make sure that the checkbox next to **Include inheritable permissions from this object parents** is unchecked. If it is checked, unchecked it.

5 A dialog box will appear. Click the **Remove** button. This will remove all groups and users that currently have access to the folder. **DO NOT** click the **Apply** button.
6 Click the **Add** button and make sure the **Look In** box has the Windows Domain (i.e. where domain is **your** domain name) listed.
Double click the **Administrators group** to add it to the list.
In turn, locate and double click the network groups created in *Creating and Using Network Groups* and add them to the list.
Click the **OK** button to go back to the previous screen.

7 Set Permissions for the **Administrators Group** as shown.

![Administrators Group Permission](image)

8 Set Permissions for the **OPT-DISS™ Administrator, Developer, and Operator Groups** as shown.

![Optra-Administrators, Developer and Operator Groups Permission](image)
9 Set Permissions for the OPT-DISS™ Reviewer Group as shown.

![Optra-Reviewer Group Permission](image)

10 Click the OK button. Do not select the Advanced button and make changes to the Permissions setting in the Advanced window.

11 Right click on the new folder and select Sharing.

12 In the Share name box, type OPTDISS Data. Click OK. If additional data folders were created, share them accordingly with an appropriate share name.
3.4.5 Adding OPTDISS™ Users to Network Groups

Contact your IT group if you are not familiar adding users.

1. At the server console, go to Start | Programs | Administrative Tools | Active Directory Users and Groups.

2. In the User folder, create any new users as you would for typical network users.

3. Make each new user a member of the appropriate network group.

4. Add any existing users to the appropriate network group.
Part IV

Pre-requisites Before Dissolution Test
4 Pre-requisites Before Dissolution Test

This chapter contains information regarding the requirements necessary before performing any analysis. The instrument needs to be checked for proper operation and must be optimized to get the maximum performance from the instrument.

1 The end-user should be familiar with the OPT-DISS™ parameter settings and various commands.

2 The system has been installed and the Find Channel Positions and Wavelength Calibration procedures completed. Normally these procedures are completed from Distek and or will be completed by a Service Representative. Unless the system fails to meet wavelength calibration verification criteria, is bumped vigorously or moved, these procedures need not be repeated. It is recommended that the wavelength calibration be verified at 6 – 12 month intervals as is typically done for conventional UV spectrometers.

3 The system manufacturer, Distek Inc., recommends performing system Operational Qualification tests under the following circumstances:
   - During initial installation after passing the system Installation Qualification tests
   - After regularly scheduled maintenance (in either 6-12 month intervals)
   - When the system is moved to a new location
   - When any of the following components are replaced, removed for repair/inspection, or realigned/focused:
     - Lamp Source
     - Source Shutter
     - Source Module
     - Detector
     - Grating
     - Detector/Grating Module

Changing/replacing of components such as power supplies, instrument electronic controllers, fiber optic cables, probes, cuvette holders, or cuvettes do not require re-qualification of the spectrometer.

4 If one or more dissolution baths will be controlled from OPT-DISS™, the appropriate Bath Configuration parameters must have been entered and saved by a System Administrator using the Tools | System Configuration | Bath Configuration parameters.
5 As part of the installation procedure, the optimum probe, source fiber, and detector fiber/channel configurations should have been determined. Each probe in a probe set should be labeled according to the detector channel to which it is connected. Fiber optic cables should be routed such that the bath drive head can be moved freely up and down without pinching the cables.

6 Probe sampling heights should be adjusted appropriately for the media volume used during the dissolution test. Procedures for adjusting probe sampling heights will vary depending on the probe type. For ARCH™ probes loosen the two clamp screws, re-locate the clamp, and re-tighten the screws. Do not over tighten. An adapter is available for ARCH™ probes that allows use of the same probe clamp position for both 500 and 900 mL. The adapter must be in place for 900 mL and is removed for 500 mL. Contact your Sales Representative for additional information on other available probe types.
4.1 Deuterium Lamp Start and Timer

Distek recommends that the deuterium lamp be on for at least 45 minutes before doing any analysis with the instrument.

1 On the front panel of the instrument, press **UV Start** to turn on the lamp as shown. The lamp heater will first turn on indicated by the amber light and after several seconds the UV red light should turn on, indicating that the lamp has turned on successfully.

2 After the lamp is on, check the lamp timer by lifting the Distek panel as shown. The lamp has usable lifetime of **1000 hours**. If the lamp is older than 1 year or the lamp usage has exceeded 1000 hours it should be changed by Distek or a Distek authorized distributor in order to obtain optimum results. Failure to do so may adversely affect the precision of the instrument.
4.2 CCD Chip Temperature

Wait for about 10 to 15 minutes after the instrument is powered on before checking the temperature. This will give the camera enough time for the temperature to stabilize.

1. From the main menu, select **Tools | Initialize Camera**.
2. Select **Tools | Read CCD Temperature** to read the camera's temperature.
3. The **CCD chip** temperature should read **-30 °C ±5°C** as shown.
4.3 Probe Balancing Responses

Cleaning Probes and Optical Fibers

1. Use a lint-free paper or high-quality lens cloth moistened with methanol for cleaning of **ALL** fiber terminations.
2. Clean the probe tips in the light path and the exposed SMA fiber tips on all probes, the detector bundle, and source bundle.
3. Remove the source bundle where it is connected to the UV source and clean the tip of the multi-channel termination adapter.
4. If the above cleaning procedure appears to be inadequate contact Distek before pursuing more aggressive cleaning procedures.

**WARNING** Do Not Sonicate probes or fiber bundles. Sonication will permanently damage the optical fibers beyond repair.

Probe Balancing of Responses

This procedure is performed by the Distek or distributor service representative during initial system installation and need not be repeated routinely.

Variation of responses between channels is normal and a characteristic of the transmission efficiency of individual probes and optical light paths. Provided there is sufficient light intensity for each channel, channel-to-channel differences in light intensity do not adversely affect data quality.

1. Remove all attenuator rings (if any are installed) from all probes and/or fiber bundle SMA connectors.
2. Clean probes and fibers as described in "Cleaning Probes and Optical Fibers".
3. Collect spectra images by connecting the stronger (more highly transmitting) probes to channels 1 - 2 and/or 7-8 or 11 - 12.
4. The goal at this stage of instrument setup is to obtain an image, View-Spectra (Alt+2) then Acquire-Image (F2), where channel responses can be seen.
5. Make changes to one probe at a time. After each change (switching a probe, adding an attenuator, or removing an attenuator), acquire (F2) and observe the spectra image. It may be necessary to adjust the Exposure Time during this process. When installing attenuator rings always add to the detector connection on the probe as shown.
**TIP:** Locate which ARCH probe has the least transmittance and use it as your reference then adding attenuators to the ARCH probes with stronger response. To maximize the probes transmittance, do not let the adjustment go below the ARCH probe with the least transmittance.

Place attenuators on the detector side of the ARCH probe:
- Silver = 6.0 dB
- Gold = 5.5 dB
- Green = 4.8 dB
- Blue = 3.6 dB
- Red = 2.5 dB
- Blue SMA (not shown) = 12.0 dB

Installing the attenuator rings

6 Reduce transmittance of strong probes by first adding an attenuator ring to the detector connector end (top connector, longer fiber leg) of the probe. Remove the SMA adapter, insert the attenuator, and then reinstall the SMA adapter. Attenuators are color-coded as Silver, Gold, Green, Blue, and Red in order of decreasing attenuation. As much as possible, only add attenuators to the detector connector end of the probe to maximize the light throughput.

- Care must be taken when adding and removing attenuator rings to not touch the optical surface. If you do, then clean as explained above.
- Since attenuation is primarily probe-specific, do not add attenuators to either of the fiber bundle connectors.
7 The figure below shows example of a 12-channel intensity spectra from well-balanced probe responses. The difference between the minimum and maximum intensities should be greater than 40%.
4.4 Data Acquisition Test

1. Turn on the system power switch located on the rear panel.

2. Press the UV Start button to turn on deuterium lamp located on the front panel. **Wait for the deuterium lamp to stabilize for 45 minutes.**

3. Make sure all probes are optically coupled to the source and detector and are immersed in DI water.

4. From the main menu select **File | New.**

5. From the main menu select **Tools | Calibration | Acquire Full Image (F4).** This will trigger the shutter and capture a full image which will automatically be displayed in the new window as shown.

![Acquiring a Full Image (F4) 12-Channel Deuterium Source Image](image)

The image should have the following characteristics if the system is installed correctly:

- **Data from each of the operating probes should be displayed as separate channels on the image.**
  
  **If not:** Check that all optical couplings are secure, and that each probe has a source and detection fiber connected to it. Determine by a process of elimination (disconnection) which channel(s) are not transmitting properly, and determine whether it is a probe problem by swapping out with other probes.

- **The channels should be approximately horizontal in relation to the boundaries of the image.**
  
  **If not:** The CCD detector is incorrectly aligned with the spectrograph. Contact your Distek representative. This alignment must be carried out by a qualified person.
The channels should be spatially separated with no bleed between them.

If not: If the light from one channel spreads into the region of adjacent channels, this indicates that the chip may be saturated in these regions and there is too much light reaching the detector. Reduce the exposure time and take another image. Verify that the bundle termination is fully inserted into the mount on the spectrograph. If a reduction in exposure time eliminates saturation but does not reduce the bleeding, contact Distek for technical support.

The intensity of light for each channel is represented by color mapping. A reddish brown color indicates that the signal is saturating the detector input. The ideal maximum response is represented by red.

If not: The intensity is directly related to the exposure time. If the image is saturated, reduce the exposure time. If the intensity is too low, increase the exposure time. These changes are made under Method-Run.
5 Operation

System Functions Overview
Quick Access Buttons and Control Keys
File Operations
Edit Operations
Acquire Operations
View Menu Options
Method Settings

This chapter describes the operation of the instrument including the main menu, shortcuts or icons, creating a method and edit operations, acquiring and viewing the data.
5.1 System Functions Overview

Once the system components have been powered up, the OPT-DISS™ software controls all functions. Data acquisition, processing, storage, display, and reporting are addressed through pull-down menus listed below.

**OPT-DISS™ Top-level Menu Items**

<table>
<thead>
<tr>
<th>Menu Items</th>
<th>Available Functions</th>
</tr>
</thead>
</table>
| **File** (Alt + F) | - *New* files created  
- *Open* existing files  
- *Close* open files  
- *Export* files in text format  
- *Save* data and image files  
- *Save As* existing data  
- *Save As Method* existing method  
- *Save As Image* current image  
- *Page Setup* report layout  
- *Print* selected file  
- *Exit* closes the software |
| **Edit** (Alt + E) | - *Copy* data in selected window |
| **View** (Alt + V) | - Image screen is displayed  
- Spectra screen is displayed  
- Report screen is displayed  
- Dissolution Curve screen is displayed  
- Event Log screen is displayed  
- Data Sets screen is displayed  
- Next  
- Previous  
- Autoscale  
- Display Latest Data  
- Light Intensity  
- Options |
| Method (Alt + M) | General...  |
|                 | Sample...   |
|                 | Run...      |
|                 | Analytical...|
|                 | Report...   |
|                 | Standards...|
|                 | Bath...     |
|                 | Enable Bath(s) using Current Method(s) |

| Acquire (Alt + A) | Image (F2) |
|                  | Exposure Auto-Set (F6) |
|                  | Standard A |
|                  | Standard Blank A |
|                  | Standard B |
|                  | Standard Blank B |
|                  | Sample Blank |
|                  | Start Run |
|                  | Abort Run |

| Tools (Alt + T) | System Configuration... |
|                | Initialize Camera |
|                | Read CCD Temperature |
|                | Bath Control Verification |
|                | Calibration |

| Windows (Alt + W) | New Window |
|                  | Cascade |
|                  | Tile Horizontally |
|                  | Tile Vertically |
|                  | Close All |
- Manual
- About OPT-DISS...

**Help (Alt + H)**
5.2 Quick Access Buttons and Control Keys

Shortcut buttons located on the main (top-level) menu bar are assigned to the frequently used functions listed in the Table below.

<table>
<thead>
<tr>
<th>Shortcut Buttons (Icons)</th>
<th>Available Functions</th>
<th>Shortcut Buttons (Icons)</th>
<th>Available Functions</th>
</tr>
</thead>
<tbody>
<tr>
<td>![File Icon]</td>
<td>New File</td>
<td>![Previous Icon]</td>
<td>View Previous</td>
</tr>
<tr>
<td>![Open Icon]</td>
<td>Open File</td>
<td>![Next Icon]</td>
<td>View Next</td>
</tr>
<tr>
<td>![Save Icon]</td>
<td>Save File</td>
<td>![Data Sets Icon]</td>
<td>View Data Sets</td>
</tr>
<tr>
<td>![Print Icon]</td>
<td>Print File</td>
<td>![Image Window Icon]</td>
<td>View Image Window</td>
</tr>
<tr>
<td>![Copy Icon]</td>
<td>Copy</td>
<td>![Spectra Icon]</td>
<td>View Spectra Window</td>
</tr>
<tr>
<td>![Settings Icon]</td>
<td>Settings, Method</td>
<td>![Report Icon]</td>
<td>View Report Window</td>
</tr>
<tr>
<td>![Run Icon]</td>
<td>Run/Start Method</td>
<td>![Dissolution Icon]</td>
<td>View Dissolution Curve</td>
</tr>
<tr>
<td>![Abort Icon]</td>
<td>Abort Method</td>
<td>![Image Icon]</td>
<td>Acquire an Image</td>
</tr>
</tbody>
</table>
5.3 File Operations

Data File Contents
All OPT-DISS™ files are stored in the same file format. An OPT-DISS™ file consists of acquired data (either an image or a set of spectra), the wavelength calibration spectra that were active when the data were acquired, and the method parameters used to define the acquisition and processing. Raw data consists of background (dark current) corrected intensity spectra for all spectral data sets acquired while the file is open. These data sets also include the “ad hoc” spectra, acquired before, after, and during a run with the “Acquire Image” command.

Saving Files
Files may be saved under the same name using the “File-Save” command. The command “File-Save as” simply saves a copy of the source file. If the file is for a completed test, it cannot be used to start another dissolution run. The “File-Save as Method” command removes run data and saves only the method parameters and standards data into a new file. This new file can be used to start another dissolution test. The original Audit Trail event log is transferred when either “File-Save as” or “File-Save as Method” is used. It is not recommended to use the “File-Save as Method” command to generate a file from a source file that was also created using the “File-Save as Method” command as this will progressively increase the file size and include Audit Trail information not directly related to the current file.

Saving Image Files
Image data from all time points during a run are available until the data file is closed. Image data are not saved once the file is closed. Single image displays can be saved using the “File-Save As Image” option.

Several data files may be open at once, each may be open in multiple windows and with different views.

Exporting Data to Files
Use the File-Export command to export data to text files. When either “File-Export-Intensity Data” or “File-Export-Absorbance Data” options are selected, all raw data (including samples, blanks, standards, and ad hoc data) will be exported to a text file named either “Int.txt” or “Abs.txt”. When the “File-Export-Report” option is selected, only the final results (identical to the Method view) will be exported. The text file will be created in the same folder where the data file is stored. When data are exported to text files, wavelength values are interpolated to even integers.
5.4 Edit Operations

Exporting a Single Data Set via the Clipboard

Select the desired data set, select the desired view format, and then press Control-C. Switch to Excel. Press Control-V or the available Paste command. If the data set is spectral data, the results will be \( n \) pairs of columns where \( n \) corresponds to the number of channels selected under Method-Reports. The first column in each pair will be the wavelength values (in nm). The second column will be either the intensity value or absorbance value according to the selected view. Wavelength values are not interpolated. The reported wavelengths correspond exactly to horizontal pixels on the CCD detector.

If the view is Method, the tabulated results will be exported as displayed with the individual values in individual cells.
5.5 Acquire Operations

The Acquire menu commands are used to acquire ad hoc images (F2), Full Images (F4, used during system calibration), standard spectra, and reference blank spectra. The Exposure Auto-Set(F6) command will automatically determine and set the optimum Exposure Time.

Acquire Menu

Acquisition of Standard and Sample Blank Spectra
Although standard and sample blank solutions may be identical or very similar in nature with respect to spectral absorbance properties, OPT-DISS™ does not require or assume them to be identical. The system does require that standard and sample blank spectra be acquired as separate events. The recommended practice is to always use Blank solutions that are appropriate for the measurement type. The Blank solution should contain all components in the solution except the analyte. For example, if the standard solution consists of the analyte dissolved in a 10% methanol:water mixture, the standard blank solution should consist of 10% methanol:water. For dissolution testing, the sample blank should be acquired immediately prior to starting a run with the probes immersed in dissolution media in the vessels.

Ad Hoc Images
Ad hoc images are images that are not acquired as part of a run. They may be used to verify the status of blank solutions, manually optimize the exposure time, or for spectral acquisition not specifically part of a run.

Starting and Aborting Runs
When an instrument is connected and appropriate method parameters entered, it is possible to start a dissolution run with the Start Run command. During a dissolution run, the run can be stopped using the Abort Run command.
5.6 View Menu Options

The following Views of the acquired data and processed results are available from the View menu:

- Image (color-mapped pixel response as seen by the CCD detector)
- Spectra (absorbance or intensity versus wavelength)
- Report (tabulated report of method parameters and results)
- Dissolution Curve (% Dissolved or Concentration versus time)
- Event Log (Audit Trail)
- Data Sets (list of all collected spectral data sets)

Use the appropriate Hot Button or select one of the above menu items to switch the active window to the selected view. To see more than one view at a time, open additional windows by selecting Window-New.

Reviewing Spectral Data – View-Data Sets Menu

All data acquired and saved with a file can be reviewed with the View-Data Sets function which is only active if the spectral view (View-Spectra) is selected.
By default the run-time display displays the latest data set (if Display Latest Data is checked). It is possible at any time from this menu to select and display other data sets from the list. Data sets are always appended to the list. No data sets are ever deleted. Each data set is numbered sequentially and is labeled with either its time stamp (for run data) or it’s calibration type.

Ad hoc spectra, data acquired using the Acquire-Image command, are also saved with the file. These data sets are numbered starting with 0001.

When the Exposure Auto-Set (F6) is used each image used to determine this value is created as an ad hoc image and added to all data files.

Use View-Options to select from different color maps for the image display, and to select whether or not to show fiber positions in the image view.

During a run, in Spectral and Image Views, the last data set is displayed as soon as it becomes available.

If Light intensity is checked then raw intensity values, as digitized A/D counts, are displayed in Spectral View instead of absorbance values.

View Event Log
This option allows the data file Event Log or audit trail to be viewed or printed. The Event Log documents all changes made to a data file with respect to the logged on user ID, time and date of the change, and a description of the change. This function is required for installations that must be compliant with the Federal Regulation 21 CFR Part 11. An example Event Log screen is shown below.
5.7 Method Settings

Method parameters define how data are acquired, processed, and displayed. To define a Method, first open the desired file for editing or create a new file. Select any of the available method options to open a dialog box with the method category tabs.

Menu Method Settings

General Settings
The Operator field is automatically completed by the program and contains the computer account name (ID) of the user who originally created the file. This field cannot be changed.

The Note field can be used to document the dissolution test.

Sample Information
The Unit Dosage and Calculation Volume are required entry in order for Percent Dissolved to be calculated according to standard practices. If a value of zero (0.0) is entered, the calculation of Percent Dissolved will use the standard absorbance to represent 100% Dissolved.
Other optional field labels are pre-defined to facilitate entry of stability sample information.

Run Settings
The Exposure Time is a critical setting that defines the dynamic range for all channel responses and must be set correctly to optimize the detector dynamic range and signal-to-noise ratio. Use Exposure Auto-Set to optimize the exposure time that applies to all spectral data types. Once a run is initiated, the Exposure Time cannot be changed.

The Path Length field is optional and ranges from 0.25 mm to 10 mm ARCH probes.

Signal averaging is defined by the Num Scans parameter which defines the number of spectra to be acquired at each time point. Signal data at each wavelength will be averaged to produce a single value that is used in subsequent calculations. Increasing the number of scans will reduce noise by a factor of \( N^{1/2} \). Thus increasing the number of scans from 1 to 4 will decrease noise by a factor of \( 1/2 \) or increase signal-to-noise ratio by a factor of 2. The maximum possible number of scans is 16.

A Phase is a period of time defined on the basis of the number of readings (acquisition of entire spectral data sets) to be made and the interval between them. Phases can be used to optimize the amount of data collected according to the anticipated shape of the dissolution curve. Separate phases can be configured for different sections of the dissolution curve. For example, during the early portion of the curve, when the active ingredients is being rapidly released, data can be acquired to fully characterize the curve shape. The minimum collection interval is approximately 5 seconds. Up to 32 phases may be defined.

- The program will not allow a combination of settings that will produce a data acquisition time greater than a Phase time interval setting.
- The maximum total number of Phases is 2045 time points.
Modify an existing Phase by selecting the desired row and then clicking the *Edit* button. A dialog box is displayed that allows the *Number of Readings* and the *Interval* to be changed.

To add a new Phase select “Add” and enter values for Number of Readings and Reading Interval. Remove an existing reading Phase by selecting the desired row and click the “Remove” button.

Although the program will allow up to 1000 readings per phase, it is not recommended to collect a large number of time points, particularly with more than 4 scans per time point. The recommended practice is to collect just the number of time points needed to characterize the dissolution curve. It is unnecessary to “paint the curve” with time points. This practice, when combined with a large number of scans, can potentially solarize the source fiber bundle and reduce system response at lower wavelengths (< 230 nm).
### Analytical Settings

The analytical settings define how the spectral data will be processed. The *Analytical Wavelength* is typically $\lambda_{\text{max}}$, a wavelength where the maximum absorbance occurs for the analyte component.

![Method-Analytical Settings](image)

#### Baseline Correction Techniques

Different options (see Table as shown below) are available to correct the absorbance at the Analytical Wavelength for baseline changes due to instrument drift, light scattering, and response from placebo materials. The selected correction technique is applied to sample, standard, and ad hoc absorbance data. The corrected absorbance ($A_{\text{corr}}$) is used to compute Concentration and % Dissolved results.

<table>
<thead>
<tr>
<th>Baseline Correction Techniques</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>$A_{\text{corr}} = A_{1}$, where $A_{1}$ is the absorbance at the Analytical Wavelength.</td>
</tr>
<tr>
<td>Single Wavelength</td>
<td>$A_{\text{corr}} = A_{1} - A_{2}$, where $A_{2}$ is the absorbance at a “reference” wavelength. Usually the reference wavelength corresponds to an absorbance valley or flat part of the spectrum.</td>
</tr>
<tr>
<td>Double Wavelength</td>
<td>$A_{\text{corr}} = A_{1} - A_{bl}$, where $A_{bl}$ is the absorbance at $l_{\text{max}}$ at a baseline formed by the regression line between $A_{2}$ and $A_{3}$. This is also called the “perpendicular drop” technique.</td>
</tr>
</tbody>
</table>
### Average Over Range

\[ A_{corr} = A_1 - A_{mean} \]

where \( A_{mean} \) is the average absorbance of all absorbance values between \( A_2 \) and \( A_3 \).

### Second Derivative

\[ A_{corr} = \text{the second derivative of absorbance with respect to wavelength.} \]

Data are smoothed according to the Smoothing parameter setting.

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**Standard Information**

In order to correctly calculate % Dissolved or Concentration for the samples being tested, a correct value must be entered into one or both, as appropriate, of the Concentration fields. The concentration units must be identical to the Unit Dosage and Target Volume units. Typically the concentration is entered as mg/mL. The Standard Name and Expiry are optional information fields. Information can be entered for two standard solutions. The solutions can be the same or different preparations or even different compounds. The Use Which Standard button allows selection of Standard A, Standard B, or the Average response of both to be used as the basis for quantitative calculation.

---

**Report Settings**

Check the report items which are to be included. Select the Calculation mode and the displayed decimal places for reported results. Highlight the channels which are to be included in the display. To select more than one, hold down the Ctrl key while clicking with the mouse on the required channels.
Bath Settings

These settings are only applicable for dissolution baths that can be controlled by OPT-DISS™. These settings will only be available if one or two baths are connected to the system and enabled. For each connected/enabled dissolution bath, check the vessels that will be used and the stirring element type.
5.8 **Automatic Optimization of Exposure Time**

The Exposure Time must be optimized to ensure that data are acquired at the maximum possible dynamic range and that detector pixels are not saturated at wavelengths used in % Dissolved or Concentration calculations. When a pixel is saturated the signal strength exceeds the input range of the A/D converter and response data acquired from that pixel is not valid.

For the majority of circumstances the recommended approach is to always use the built-in function, **Acquire - Exposure Auto-Set command (F6)** for automatically determining and setting Exposure Time. This function will ensure that the maximum pixel response within the calibrated channels is as close as possible to the maximum signal strength without being saturated.

The exposure time must be optimized with the solution (typically pure water or blank dissolution media) that transmits the most light (e.g. exhibits the lowest absorbance) during a run. A sample blank solution is defined as the solution that contains all components except the sample (the dosage form being tested). A standard blank contains all components except the analyte to be measured. For most dissolution applications, the sample blank solution is the dissolution media. For many applications, the nominal exposure time can be determined with pure water.

Infrequently there are situations when it may be desirable to override the automatic setting and set the Exposure Time manually. The following section describes the procedure for manually setting the exposure time. The Exposure Auto-Set command will optimize exposure times within the range 3 – 30,000 ms. Exposure times outside this range must be set manually.

### Manual Optimization of Exposure Time

Refer to procedure in "Probe Balancing Responses" for detailed instructions.

1. Start all system components and allow the system to equilibrate for at least **30 minutes**.
2. Prepare the solution (standard, sample blank or DI water) that will be used.
3. Use one of the supplied rectangular tanks with the eight-position probe holder and ensure that all probes are immersed in the solution.
4. Select **View-Spectra**. Set the exposure time to **100 ms** or the last known acceptable exposure time. Click **Acquire Image (F2)**, and observe the response on the spectra display. The following figure is an example of a saturated intensity spectrum on channel 7 and 9 where the deuterium peak starts to flatten.
5 Optimized the exposure time accordingly until saturated channels have the acceptable peaks as shown.

6 Reduce transmittance of strong probes by first adding an attenuator ring to the source connector end (bottom connector, short fiber leg) of the probe.

Care must be observed when adding and removing attenuator rings to not touch the optical surface. If you do, use a lint-free paper or high-quality lens cloth moistened with methanol.
In some circumstances it may be desirable to deliberately saturate the spectrum in the vicinity of 240nm (the deuterium peak) in order to increase signal response at longer wavelengths (> 300nm) where the source emission is weaker. This approach can improve the signal-to-noise ratio for data acquired at the longer wavelengths. When this is done it is critical to ensure that pixels are not saturated at any of the wavelengths (Analytical Wavelength and Baseline Correction Wavelengths) associated with % Dissolved or Concentration calculations.
5.9 Defining OPT-DISS™ Method Parameters

1. Select menu Method-General and enter additional information in the Note field that can be useful to document the dissolution test as shown.

   ![Method-General dialog window](image)

2. Select Sample tab and enter the requested information as shown. The Unit Dosage and the Calculation Volume must be entered in mg and mL respectively for the results to be computed correctly. Other values are reported and saved but not used in calculations.

   ![Method-Sample dialog window](image)

3. Select Run tab as shown. With the probes in blank media, select Exposure Auto-Set (F6) to automatically set the optimized exposure time.

   ![Method settings dialog window](image)
Enter the Path Length for the probes. The value is saved and reported but is not used in calculations.

Enter the Num Scans (number of scans). A setting of four scans is recommended for the majority of applications. Use one scan only when very rapid data acquisition is required. Signal-to-noise performance is increased by the square root of the number of scans. Thus use of four scans improves signal-to-noise by a factor of 2 over one scan. In theory, sixteen scans will improve signal-to-noise by a factor of 4 over one scan. However, unless exposure times are short (less than 100ms) the improvement may not be significant. Use of a large number of scans (10 – 16) is only recommended for runs or phases greater than four hours when the data collection intervals are 15 minutes or greater. Use of a large number of scans in combination with a large number of data points (i.e. “painting the dissolution curve”) is not recommended.

Add Phases to define the time points for dissolution test. Use this option to define different data collection intervals and different numbers of time points for different parts of the dissolution test.

- Although the software can acquire spectra very rapidly (at 5 sec intervals) it is not recommended to “paint a dissolution curve” with data points. Acquire only as many time points as are needed for the application.
- The software will not allow a combination of settings that will cause the data acquisition time to be greater than a Phase reading interval.

4 Select Analytical tab as shown.

Enter the Analytical Wavelength ($\lambda_{\text{max}}$) for the component to be tested. Select which Baseline Correction method to be used. The Single Wavelength or Average-Over-Range techniques are most common. Choose a valley or flat part of the spectrum as close as possible to the analytical wavelength.
5 Select Report tab as shown.
Choose the Report Items that will be included on the report printout.
Select which Calculation Mode results (Concentration or % Dissolved) to be displayed and reported.
Select the Channels which will be used (i.e. that are connected to probes used during the test).
Choose the number of decimal places you want to show appropriately on the test results.
6 Select **Standard Information** tab as shown. Choose **Use Which Standard** to use for calculation. Enter the appropriate **Standard A Information**. Enter the appropriate **Standard B Information** if necessary.

![Method-Standard Information dialog window](image1)

7 If software is configured to control the dissolution bath(s), select **Bath** tab as shown. Choose **Enable Bath** if you want Opt-Diss to control the dissolution bath. Choose the appropriate **Apparatus** for the test. Enter the appropriate bath parameters for the test (temperature, RPM, media and volume of media in vessel). Choose the appropriate number of vessels for the test.

![Method-Bath dialog window](image2)
5.10 Acquiring Standard Spectra

Each probe will be individually calibrated to the response of a standard solution. The OPT-DISS™ software treats each probe/detector channel combination as separate UV spectrometers by computing a Response Factor (Corrected Absorbance/Concentration) for each channel. Currently, the OPT-DISS™ software supports single-point standards. One or two standard solutions (Standard A and Standard B) can be measured. Either the Response Factor for Standard A or B or the average of the both Response Factors can be used as the basis for quantitative calculation.

- Distek recommends that the bath dissolution media temperature has reached the target value before acquiring standard spectra.
- A minimum of 125 mL of solution is needed in the tank for the end of the probes to be fully immersed.

1 With all the probes positioned with the tank cover, add a minimum of 125 mL of the Standard Blank solution into each tank. Move each tank in a forward/backward motion to ensure good solution contact with probe tips. Verify that the probes are fully immersed in the blank solution and no bubbles are present in the optical paths. If necessary, move the probes up and down to remove any bubbles trapped in the light paths.

2 Set the optimum Exposure Time using the Acquire-Exposure Auto-Set (F6) while probes are fully immersed in the Standard Blank solution.

3 With all probes immersed in a Standard Blank solution, select Acquire-Standard Blank A (and or B).
Select the probe/channel(s) to be calibrated then select OK and proceed with the Standard Blank spectra acquisition. Click the View-Spectra button to observe the intensity spectra and to verify that spectra were acquired. If necessary, repeat for Standard Blank A or B as needed.
4 Add a minimum of 125 mL of Standard solution to another solution tank. Using the tank cover, move all probes from the blank solution tank and gently dry the probe tips with lint free tissue. Transfer the probes to the Standard solution tank. If necessary, move the probes up and down to remove any bubbles trapped in the light paths.

If an additional tank is not available, remove probes from the tank used to measure blank spectra, rinse/dry the tank interior, and add Standard solution.

5 Select Acquire-Standard A (and or B) as necessary. Then select the probe/channel(s) to be calibrated.
Select the probe/channel(s) to be calibrated then select OK and proceed with the Standard spectra acquisition.
Observe the standard absorbance values. They need not be identical but should not show a wide variation indicative of bubbles in the light path. If necessary, repeat Acquire-Standard A (and or B) as needed.

6 Select File-Save to save all method parameter entries/changes and spectral into the data file.

- If all probes are not being calibrated simultaneously, repeat Step 5 as needed to acquire standard spectra for each probe. The preferred method is to measure all probes simultaneously.
- Standard response values may be stored in “template” data files and used later for subsequent test runs by using the “File-Save as Method” command.
5.11 Starting the Dissolution Run

Be sure that one or two standard solutions (Standard A and Standard B) are already defined. Either the Response Factor for Standard A or B or the average of the both Response Factors can be used as the basis for quantitative calculation.

1 Fill the vessels with the appropriate media for the test.

2 Remove probes from the solution tank, rinse thoroughly, dry with lint free tissue, and transfer the probes to their respective locations in each dissolution vessel covers. Tap or move the probes up and down to remove any bubbles in the light path. Verify that each probe is seated into the vessel cover or adapter and will not interfere with the stirring element.

3 Select **Acquire | Sample Blank** to acquire reference blank spectra for all vessels. Use **View | Spectra** to verify that all spectra were acquired. Acquire at least one additional **Sample Blank** to verify that the response is stable.

Since the spectral absorbance properties of the blank dissolution media and Standard Blank solution may not always be identical and if this is the case, it is recommended to perform the *Exposure Time* using the dissolution media. Set the optimum *Exposure Time* using the *Exposure Auto-Set* (F6) while probes are fully immersed in the dissolution media in the dissolution vessels. Ensure that no bubbles are present in the optical paths.

4 If OPT-DISS™ is not controlling the bath, start the stirring and temperature at the prescribed bath parameters.

**OPT-DISS™ Bath Control**

To start the bath, select the shortcut **Start Run** icon as shown.

A dialog window is displayed prompting the user that the bath has been found. Select **Yes** to continue.

Another dialog window prompts the user that the bath will be enabled. Follow the prompt and select **OK** to close the dialog window.
The dissolution bath can be enabled manually thru the software by selecting **Method | Enable Bath(s) using Current Method(s)**. This will allow the dissolution bath to start pre-heating the media in the vessels.

5 If OPT-DISS™ is not controlling the bath, stop the stirring elements rotation. Place the test sample dosage forms near the cover openings or into tablet droppers if they are available on the bath.

Select **Start Run** shortcut icon (or **Method-Start Run**) to initiate the test. Enter an appropriate amount of time required to drop the dosage form samples into the vessels.

**OPT-DISS™ Bath Control**

Wait for the dissolution bath to complete the pre-heating cycle. The dissolution bath will prompt the user what to do to introduce the dosages.

If dissolution bath was enabled manually using the software, wait for the bath to complete the pre-heating cycle. Once pre-heating is completed, select the shortcut **Start Run** icon and follow the prompts to continue test.

6 OPT-DISS™ will collect the first data set at time zero.

7 During the test, tabulated results (% Dissolved) or the dissolution curve can be monitored by selecting **View-Report** or **View-Dissolution Curve** or by selecting the equivalent hot-buttons. Absorbance spectra can be monitored by selecting **View-Spectra**.

**Aborting a Test:** Terminate tests by selecting the **Abort Run** icon.

All data collected to that point will be saved. It is not possible to resume an aborted run.
5.12 Concluding the Test and Cleanup

1. The run will continue until the last data set is collected. Data are saved automatically at each time point. At the end of the run select **File-Close** to close and save the open data file.

**OPT-DISS™ Bath Control**
At the end of the test, the dissolution bath will automatically stop the stirring and turns off the heat (ONLY on EVO 6100 and symphony 7100).

2. Remove each probe and rinse with deionized water; if necessary, with methanol, then rinse with deionized water. Gently dry the probes and store them in their respective slots in a holder above an empty rectangular tank.

3. Raise the bath drive head.

4. Clean the stirring elements and vessels according to the recommended laboratory procedures.
5.13 Viewing Results

Use *File-Print* to print a report of the currently active view. The *Method* view is a tabulated report of method parameters, absorbance values, and Concentration or % Dissolved for all time points. Only data for the channels selected under *Method-Reports* will be reported.

Reprocessing Results

All method parameters, except the exposure time, can be changed after a test has been completed. Once the new parameter values are entered, the results are calculated immediately and displayed in the selected view format. This feature may be used to quickly optimize the analytical method parameters (analytical wavelength and baseline correction options). Printed *Method* reports list the new parameter values with the results (absorbance and %Dissolved or concentration values).
5.14 Calculations

Uncorrected Absorbance

Uncorrected absorbance \( A_1 \) at the Analytical Wavelength is calculated from background (dark current) corrected light intensity values according to the following equation:

\[
A_1 = -\log_{10}(I / I_0)
\]

where:

\[
I_0 = I_{\text{blank for spl or std}} - I_{\text{background for spl or std blank}}
\]

\[
I = I_{\text{spl or std}} - I_{\text{background for spl or std}}
\]

Uncorrected values are smoothed, according to the OPT-DISS™ Administrator-specified smoothing window in the Tools-System Configuration settings. The program uses a “binomial” smoothing algorithm that applies coefficients derived from Pascal’s triangle. Baseline-corrected absorbance values \( A_{corr} \) are calculated as described in the following section.

Corrected Absorbance – Baseline Corrections

Absorbance values from standards, samples, and ad hoc spectra can be corrected to account for baseline shifts. The corrected absorbance \( A_{corr} \) is used to compute Concentration and %Dissolved results. Equations used for each available correction method are described below.

None

\[
A_{corr} = A_1
\]

where:

\( A_1 \) is the uncorrected absorbance at the Analytical Wavelength.

Single Wavelength

\[
A_{corr} = A_1 - A_2
\]

where:

\( A_2 \) is the absorbance at a reference wavelength. Usually the reference wavelength is selected from an absorbance valley or flat part of the spectrum.
Two Wavelengths

\[ A_{\text{corr}} = A_1 - A_{bl} \]

where:

\[ A_{bl} \] is the absorbance at \( \lambda_{\text{max}} \) on the regression line between \( A_2 \) and \( A_3 \).

This is also called the “perpendicular drop” baseline correction technique. The regression line and \( A_{bl} \) are calculated as follows:

- The program uses the selected points, \((\lambda_2, A_2)\) and \((\lambda_3, A_3)\), plus one additional point on each side of these points to form a 6-point regression data set.
- The program performs a linear regression by standard statistical calculations on the six data pairs of wavelength and absorbance values.
- The Baseline Response \( (A_{bl}) \) at the Analytical Wavelength is calculated from the slope and intercept of the linear regression.

Average over Range

\[ A_{\text{corr}} = A_1 - A_{\text{mean}} \]

where:

\[ A_{\text{mean}} \] is the average absorbance of all absorbance values between \( A_2 \) and \( A_3 \).

Second Derivative

\[ A_{\text{corr}} = \text{Second derivative of absorbance with respect to wavelength}. \]

Second derivative values are smoothed, according to the operator-specified smoothing setting, using a “binomial” smoothing algorithm that applies coefficients derived from Pascal’s triangle.
Response Factors

Quantitation in terms of either concentration or percent dissolved is done using channel-specific Response Factors calculated from the absorbance, measured for each probe/channel, and concentration of standard solutions. Response factors, RF, are calculated and reported for each calibrated channel.

If one standard is used:

\[ RF = \frac{A_{corr\ STD}}{\text{Concentration STD}} \]

If the “Average” is used:

\[ RF = \frac{A_{RF\ for\ STD\ A} + A_{RF\ for\ STD\ B}}{2} \]

Response Factors Ratio

The Standards QC check ratio is calculated using the following equation:

\[ RF\ Ratio = \frac{A_{corr\ SPL}}{RF} \]

Concentration

The sample concentrations at each time point and for ad hoc data are calculated using the following equation:

\[ \text{Concentration} = \frac{\text{RF for STD A}}{\text{RF for STD B}} \]

Percent Dissolved

Percent dissolved results at each time point and for ad hoc data are calculated using the following equation:

\[ \%\ Dissolved = \left( \frac{A_{corr\ SPL} \times \text{Target Volume}}{\text{Unit Dosage}} \times RF \right) \times 100\% \]

If zero is entered for Unit Dosage, the following equations will be used.

One standard is used:

\[ \%\ Dissolved = \left( \frac{A_{corr\ SPL}}{A_{corr\ STD}} \right) \times 100\% \]

Average standard is used:

\[ \%\ Dissolved = \left( \frac{A_{corr\ SPL}}{\text{Average} A_{corr\ STD}} \right) \times 100\% \]
Instrument Calibration
This chapter describes the calibration of the instrument which includes probe balancing, finding the channel positions and performing the wavelength calibration.
6.1 Balancing the Arch Probes

This procedure is performed by the Distek or distributor service representative during initial system installation and need not be repeated routinely.

Variation of responses between channels is normal and a characteristic of the transmission efficiency of individual probes and optical light paths. Provided there is sufficient light intensity for each channel, channel-to-channel differences in light intensity do not adversely affect data quality.

1. Remove all attenuator rings (if any are installed) from all probes and/or fiber bundle SMA connectors.
2. Clean probes and fibers as described in Cleaning Probes and Optical Fibers.
3. Collect spectra images by connecting the stronger or highly transmitting probes to channels 1 - 2 and/or 7-8 or 11 - 12.
4. The goal at this stage of instrument setup is to obtain an image, View-Spectra (Alt+2) then Acquire-Image (F2), where channel responses can be seen.
5. Make changes to one probe at a time. After each change (switching a probe, adding an attenuator, or removing an attenuator), acquire (F2) and observe the spectra image. It may be necessary to adjust the Exposure Time during this process. When installing attenuator rings always add to the detector connection on the probe as shown.
TIP: Locate which ARCH probe has the least transmittance and use it as your reference then adding attenuators to the ARCH probes with stronger response. To maximize the probes transmittance, do not let the adjustment go below the ARCH probe with the least transmittance.

6 Reduce transmittance of strong probes by first adding an attenuator ring to the detector connector end (top connector, longer fiber leg) of the probe. Remove the SMA adapter, insert the attenuator, and then reinstall the SMA adapter. Attenuators are color-coded as Silver, Gold, Green, Blue, and Red in order of decreasing attenuation. As much as possible, only add attenuators to the detector connector end of the probe to maximize the light throughput.

- Care must be observed when adding and removing attenuator rings to not touch the optical surface. If you do, then clean as explained above.
- Since attenuation is primarily probe-specific, do not add attenuators to either of the fiber bundle connectors.

7 The figure below shows example 12-channel intensity spectra from well-balanced probe responses. The difference between the minimum and maximum intensities should be within than 40%.
6.2 Find Channel Positions

**WARNING**

Unless directed to do so by Distek or Distek-authorized distributor do not attempt this procedure.

You must be logged in as part of the optra-administrator group to perform this action.

1. Connect the maximum number of probes that will be used. They should all be of the same path-length. Immerse the probes in deionized water.

2. Select **Tools-System Configuration**, enter the following settings as shown:

![System Configuration when performing Find Channel Positions](image)

3. Select the current entry for **Wavelength Calibration Settings- Calibration File** and delete it.

4. Select **OK** and enter your password to save the settings.

5. Create a new method by selecting **File-New** (name it Find Channel mmddyyyy-time). This allows the user to quickly locate the file for troubleshooting purposes.
6 Acquire a Full Image by selecting **Acquire-Acquire Full Image (F4)**.

![Acquiring a Full Image (F4)](image)

7 If necessary, adjust the exposure time and collect **Full Images** until the light bands are near saturated to the degree as shown.

![Full Image acquired with near saturated exposure time](image)
8 Select **Tools-Calibration-Find Channel Positions** as shown and enter the password to continue.

![Selecting Tools-Calibration-Find Channel Position](image)

9 Select **OK** at the next prompt to initiate the **Find Channels** procedure as shown. The following window dialog should be displayed indicating the number of configured or connected probes/channels detected.

![Probes/Channels are detected](image)

10 If the number of probes/channels is correct, select **Yes** to accept the channels calibration. Otherwise select **No** and adjust the threshold setting, exposure time, and/or balance the probes and repeat the previous calibration steps.
It is recommended to acquire an additional Full Image (F4) and select File | Save Image to retain a copy of the Full Image result.

11 Save the method. Exit the program. *You must exit the program in order for the channel location settings to be saved.*
6.3 Wavelength Calibration

**WARNING** Unless directed to do so by Distek or a Distek-authorized distributor do not attempt this procedure.

- Probe responses should be reasonably well balanced before starting the wavelength calibration. Refer to section Balancing Arch Probes.
- You must be logged in as part of the optra-administrators group to perform this action.

Requirements:

- Recommended: 10 mm Arch Probes
- OPT-DISS™ HG-1 Lamp kit, warm-up period of at least 10-15 minutes before use (refer to Distek Document 3800-0142 HG-1 Installation Manual)

1. Create a new method by selecting **File-New** (name it Wavelength Calibration mmddyyyy-time). This allows the user to quickly locate the file for troubleshooting purposes.

2. Select **Tools-System Configuration**, enter the following settings as shown:

System Configuration when performing Wavelength Calibration
3 With the probes immersed in deionized water, switch the view to spectra screen (View-Spectra).

4 Disconnect the source fiber bundle from the deuterium light source and connect it to the OPT-DISS™ HG-1 Lamp kit as shown.

5 Install the other end of the BNC cable extension into the rear BNC connector of the Opt-Diss instrument.

6 Optimize the exposure time by selecting Acquire-Exposure Auto-Set (F6). Refer to section Balancing the Arch Probes if adjustments are needed.

7 Acquire an image by selecting Acquire-Image (F2) to show the mercury emission bands as shown.
Check that the mercury spectral peak heights are optimized as shown. The peaks should not be saturated. The band near 250 may be much higher than that shown below. It is most critical that, for each channel, the band near 400 be higher than the band between 275-300 (2nd peak from the left).

Select **Tools-Calibration-Wavelength Calibration** to initiate the calibration procedure as shown. Select **OK** on the dialog window that warns the user that the calibration will now take place.
10 On the next dialog window as shown, the screen lists the reported system-calculated values for the four calibration wavelengths for each configured channel. Verify that each channel meets the wavelength calibration criteria as follows:

- $253.7 \pm 2.0\text{nm}$
- $313.2 \pm 2.0\text{nm}$
- $365.0 \pm 2.0\text{nm}$
- $404.7 \pm 2.0\text{nm}$

Select **Yes** if all channels meet the criteria and activate this calibration profile.

11 The spectral peaks should now be precisely aligned as shown in the following example. The four strongest bands should be located at 254nm, 313nm, 365nm, and 405nm for each channel. There must be no distorted spectra, or peaks at locations other than those shown in the examples. If all configured channels cannot be calibrated, please contact Distek technical support.
A date-time stamped wavelength calibration file named starting with **WC-yyyymmdd-hhmmss.hdr** (yy = year, mm = month, dd = day, hh = hour, mm = minutes, and ss = seconds) will be **automatically** generated and the file path (C:\Program Files\Distek\OPT-DISS\Data \filename) automatically entered into the **Tools-System Configuration Calibration File** entry box as shown.

The location of the calibration file can differ depending on how and where the Opt-Diss data folder was created.

Exit the program. Select **OK** at the system prompt to save changes to the existing file. (This allows the user to quickly locate the file for troubleshooting purposes.)
7 Maintenance

General Information

Cleaning Probes and Optical Fibers

Cleaning and Replacement of Cooling Fan Filters

Deuterium Lamp Replacement

This chapter describes some maintenance that needs to be perform on the instrument to guarantee the performance of the instrument is not compromised.
7.1 General Information

**CAUTION**

Do not clean plastic and rubber parts with organic solvents.

1. Unit should be cleaned periodically by wiping with a slightly damp cloth. Do not use any harsh chemicals or detergents.
2. Electronics require no customer attention. In the event of a malfunction, please call Distek or Distek authorized distributor before pursuing any repairs.
3. Inspect the internal and external connectors. Make sure that all connectors are fully seated.
4. Inspect the power cords for any frail insulation. Replace if necessary.
### 7.2 Cleaning Probes and Optical Fibers

**WARNING** *DO NOT SONICATE probes, fiber bundles, or accessories. Sonication will permanently damage optical fibers beyond repair.*

#### Cleaning Probes and Optical Fibers

1. Use a lint-free tissue or high-quality lens cloth moistened with methanol for cleaning of **ALL** fiber terminations.
2. Clean the probe tips in the light path and the exposed SMA fiber tips on all probes, the detector bundle, and source bundle.
3. Remove the source bundle where it is connected to the UV source and clean the tip of the multi-channel termination adapter.
4. If the above cleaning procedure appears to be inadequate contact your Distek or Distek authorized distributor before pursuing more aggressive cleaning procedures.

---

**Wipe ends with lint-free tissue or high-quality lens cloth with methanol**

Cleaning all fiber optics termination
7.3 Cleaning & Replacement of Cooling Fan Filters

Proper airflow is required to prevent overheating of the electronic components. There are two cooling fans with accessible filter screens that must be periodically cleaned or replaced. One fan is located on the rear panel of the main Spectrometer enclosure and the other in the external Power Supply Unit (PSU)/Controller. Inspect each external filter periodically at three to six month intervals. Remove any excess dust from the filters or replace them.

Cleaning fan filters
7.4 **Deuterium Lamp Replacement**

The Deuterium lamp has a shelf life of one year and a usable lifetime of 1000 hours. If the lamp is older than 1 year or the lamp usage has exceeded 1000 hours it should be changed by Distek or a Distek authorized distributor in order to obtain optimum results. Failure to do so may adversely affect the precision of the instrument.

- Distek recommends that a Distek trained service engineer should be the only one to replace the deuterium lamp.
- When replacing the deuterium lamp, be sure to reset the lamp timer to zero time.
Part VIII
Troubleshooting
This chapter describes some of the problems that may arise with the instrument during normal operation. The problem can be described as symptoms of malfunction, and the troubleshooting guide will determine of remedying the causes of these symptoms.
## 8.1 Instrument Troubleshooting

<table>
<thead>
<tr>
<th>Problems</th>
<th>Possible Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>End-user cannot log in to Opt-Diss software</td>
<td>End-user does not belong to one of the optra-groups. Add end-user to one of the optra-groups.</td>
</tr>
</tbody>
</table>
| Unable to initialize the camera.              | • PSU/Controller is off.  
• Check external PSU/controller cable.  
• UBS cable is unplugged or not fully seated in the camera connector.  
• Check internal cables on the camera. |
| CCD Chip temperature is out of specifications | • Wait 10 to 15 minutes for temperature to stabilize.  
• Check external PSU/controller cable.  
• Check internal cables on the camera. |
| Dissolution bath is not found                 | • Check the configuration settings (Tools / System Configuration).  
• Bath is not turned on.  
• Verify instrument address.  
• Check USB/RS-232 cable connection.  
• Verify serial port. |
| UV Lamp will not turn on                      | • Source module power is not turned on (internal power switch).  
• Deuterium lamp faulty wiring.  
• Burned out lamp. Replace deuterium lamp. |
| Higher exposure time than usual               | • Check fiber bundle source connector is secured correctly.  
• Check fiber bundle detector plug is secured correctly.  
• Check the lamp time is below 1000 hours. Replace lamp if necessary.  
• Check the media. Verify exposure time with DI water. |
| Difficulty balancing ARCH™ probes            | • Check fiber bundle source connector is secured correctly.  
• Check fiber bundle detector plug is secured correctly.  
• Check SMAs are secured to the ARCH™ probes and fiber bundle assembly.  
• Check if the lamp time is below 1000 hours. Replace lamp if necessary.  
• Check the media. Perform probe balancing with DI water.  
• Clean probes and fiber bundle ends with lint free tissue and methanol. |
| No wavelength calibration                    | • Check calibration file location in Tools / System Configuration  
• Wavelength calibration has not been executed  
• Missing wavelength calibration file |
8.2 Service Contact

If you have a problem with the instrument or need parts information, contact the Distek Service Department by e-mail at support@distekinc.com or call our US toll-free number (888)234-7835 or 1(732)422-7585.

Items returned for repair or exchanges require an R.A. number. Please contact the Distek Service Department to obtain an R.A. number.

Please send the return or repair to:

Distek, Inc.
Service Department
121 North Center Drive
North Brunswick, NJ 08902
Attention: R.A. #
Appendix A: Spare Parts and Accessories
## Appendix A: Spare Parts and Accessories

<table>
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<tr>
<th>Part ID</th>
<th>Description</th>
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</thead>
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<tr>
<td>2500-0010</td>
<td>Attenuator Set for Opt-Diss</td>
</tr>
<tr>
<td>2500-0020</td>
<td>Vessel Cover for Standard Size Arch Probe with Large Center Hole</td>
</tr>
<tr>
<td>2500-0050</td>
<td>Mercury Lamp Kit for Opt-Diss Wavelength Calibration</td>
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<tr>
<td>5900-0001</td>
<td>Arch Probe, 0.25 mm Pathlength</td>
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<td>5900-0002</td>
<td>Arch Probe, 0.5 mm Pathlength</td>
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<tr>
<td>5900-0003</td>
<td>Arch Probe, 1 mm Pathlength</td>
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<tr>
<td>5900-0003-R</td>
<td>Extended Length Arch Probe, 1 mm Pathlength</td>
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<td>5900-0004</td>
<td>Arch Probe, 2 mm Pathlength</td>
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<td>5900-0005</td>
<td>Arch Probe, 5 mm Pathlength</td>
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<td>5900-0005-R</td>
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<td>5900-0006</td>
<td>Arch Probe, 10 mm Pathlength</td>
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<td>5900-0006-R</td>
<td>Extended Length Arch Probe, 10 mm Pathlength with Larger OD Sleeve</td>
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<td>5900-0007</td>
<td>Arch Probe, 1 mm, Mini</td>
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<td>5900-0008</td>
<td>Arch Probe, 5 mm Mini</td>
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<tr>
<td>5900-0009</td>
<td>Arch Probe, 10 mm Mini</td>
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<tr>
<td>5900-0010</td>
<td>Vessel Cover, Mini Arch, for Distek Small Volume Vessel</td>
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<tr>
<td>5900-0032</td>
<td>Arch Probe, 2 mm, Mini</td>
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<tr>
<td>5900-0035</td>
<td>SMA Connector for Opt-Diss, Blue</td>
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<tr>
<td>5900-0036</td>
<td>SMA Connector for Opt-Diss, Silver</td>
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<td>5900-0040</td>
<td>2 mm Tip for Opt-Diss Dip Probe 5900-0046</td>
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<td>5 mm Tip for Opt-Diss Dip Probe 5900-0046</td>
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<td>5900-0043</td>
<td>20 mm Tip for Opt-Diss Dip Probe 5900-0046</td>
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<td>Dip Probe, 1/8 inch OD with 10 mm Fixed Path Length</td>
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<td>Dip Probe, 1/8 inch OD with 20 mm Fixed Path Length</td>
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<td>5900-0046</td>
<td>Dip Probe, 1/8 Inch with 1/4 Inch Tip. Variable Path Length</td>
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<td>Standardization Tank Cover for Mini Dip Probe</td>
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<td>Probe Clamp for Mini Dip Probe</td>
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<td>5900-0057</td>
<td>Evaporation Plug for Vessel Cover</td>
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<td>5900-0059</td>
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<td>5900-0060-BL</td>
<td>Attenuator, Blue, Provides 3.6 dB of Attenuation for Opt-Diss. 10 Per Pack</td>
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<td>5900-0060-GO</td>
<td>Attenuator, Gold, Provides 5.5 dB of Attenuation for Opt-Diss. 10 Per Pack</td>
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<tr>
<td>5900-0060-GR</td>
<td>Attenuator, Green, Provides 4.3 dB of Attenuation for Opt-Diss. 10 Per Pack</td>
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<tr>
<td>5900-0060-RE</td>
<td>Attenuator, Red, Provides 2.8 dB of Attenuation for Opt-Diss. 10 Per Pack</td>
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<td>5900-0060-SI</td>
<td>Attenuator, Silver, Provides 6.0 dB of Attenuation for Opt-Diss. 10 Per Pack</td>
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<td>5900-0065</td>
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<td>Arch Probe, 1 mm for Sotax Opt-Diss</td>
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<td>Arch Probe, 2 mm for Sotax Opt-Diss</td>
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<td>5900-0099</td>
<td>Arch Probe, 10 mm for Sotax Opt-Diss</td>
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<tr>
<td>5900-0150</td>
<td>Cover for Standardization Tank</td>
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<tr>
<td>5900-0151</td>
<td>900 ml Spacer Adapter for Arch Probe</td>
</tr>
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# Appendix B: CE Declaration of Conformity

![CE Declaration of Conformity](image)

**CE DECLARATION OF CONFORMITY**  
**NOT TRANSFERABLE**

**Responsible Company:**  
Distek, Inc.  
121 North Center Dr.  
North Brunswick, NJ 08902

**Equipment Type & Model:**  
Distek Opt-Diss 405:  
Synapse & Symphony Based Systems

**Equipment Classification:**  
Electrical equipment for measurement, control and laboratory use.

**Declared Compliance & Test Standards:**

<table>
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<th>Standards</th>
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</thead>
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<td>EN 55022: 1998, Class A</td>
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<tr>
<td>Radiated Immunity</td>
<td>EN 61000-4-3: 1996</td>
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<tr>
<td>Conducted Immunity</td>
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<td>Flicker</td>
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Jeff Brinker  
President  
July 1, 2012

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Part XI
Appendix C: Limited Warranty
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Limited Warranty

Distek, Inc. warrants our instruments to be free from defects in materials and workmanship for a period of twelve (12) months from the date of installation or for a period of thirteen (13) months from the date of shipment, whichever comes first. During the warranty period, Distek will correct any defects in materials, workmanship, or any failure of the system to conform to specifications, at no charge for parts, labor or shipping, provided that the defective parts are returned to Distek. Customers will be invoiced for parts but will not be charged unless the defective parts are not returned. Distek does not warrant that the product will provide uninterrupted operation and free of error.

This warranty only covers defects arising under normal use and does not cover consumables or components that come in contact with customer samples. Malfunctions or failures resulting from misuse, abuse, neglect, alteration, modification, improper installation or repairs by anyone other than Distek or consumables and components which come in contact with customer sample are not covered. Distek warranties repair parts for a period of ninety (90) days and will replace defective parts used in the repair of Distek product.

Repair or replacement of defective parts or refund of the price shall be the only remedies available to the purchaser. Distek, may at its option, in lieu of a refund, repair or replace your system or any of its components with new or reconditioned parts, and any replaced systems or components become the property of Distek.

To the extent permitted by applicable law, Distek, shall not be liable for incidental or consequential damages, or breach of any express or implied warranty, including but not limited to implied warranties of merchantability and fitness for a particular purpose. This limited warranty gives you specific legal rights. You may have other rights which vary from state to state.

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F: 732-422-7310
www.distekinc.com