

CombiFlash[®] Companion[®] XL

Installation Qualification



Part Number 60-5242-018
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CombiFlash[®] Companion[®] XL

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CombiFlash[®] Companion[®] XL

Section 1 Installation Qualification

The Teledyne Isco CombiFlash Companion XL system (hereby referred to as “Companion XL”) is a standard product with few customizable options and is designed to support liquid chromatography purifications at research scale. The system has several subsystems all of which are necessary for typical use.

The Companion XL flash chromatography system gives you high-productivity automation, programmable gradients, and full-spectrum UV detection and peak separation. It is a high capacity system that purifies samples up to 150 grams. Yet, its small size makes the system well suited for operation in chemical hoods.

WARNING

Avoid hazardous practices! If you use this instrument in any way not specified in this manual, the protection provided by the instrument may be impaired; this may increase your risk of injury.

Control of the Companion XL is through a simple to use interface. This interface can be accessed through a Windows computer directly connected to the instrument or through a standard computer network. The Companion XL can also be configured with an optional touch-panel display. In all, you have the flexibility to program, operate, and monitor the Companion XL at the instrument, from a computer in the lab, or from remote locations.

The Companion XL uses Teledyne Isco RediSep[®] columns. Compatible sizes range from 120 to 1500 grams, which can accept sample sizes from 0.1 to 150 grams. Applications include purification of organic compounds for drug discovery, as well as research in agrochemicals, petrochemicals, natural products, polymers, and catalysts.

This system is designed to operate at high flow rates using components selected for reliability. The Companion XL system is optimized for difficult separations that use rigid large diameter particulate (40–60 µm) adsorbents packed into chromatography columns ranging in adsorbent mass of 120 grams through 1500 grams. The flow path is designed to provide safe operation at process conditions, and to provide reliable long-term operation.

Companion XL systems are commonly used in the pharmaceutical industry to purify bulk drug compounds and synthetic intermediates. Many purification processes use organic solvents,

ranging from non-polar solvents including alkanes, alkenes, aromatics, esters, and chlorinated organics to water miscible solvents such as alcohols, acetonitrile, and acetone.

Companion XL systems are used for batch processing and provide safe and reliable operation. Teledyne Isco provides a documentation package to assist clients with their system Installation Qualification and Operational Qualification.

The Companion XL is designed for performing high-throughput liquid chromatography on a research scale. It is an integrated unit consisting of a pumping system, UV detector, column module, a sample loading cap, an injection valve, and a fluid valve for flow path control. An external fraction collector is used in this system. As requirements evolve different means of fraction collection racks may be applied.

The Companion XL is ideal for research scale purification, and offers the following features:

- Sample Loading Cartridges for use with mildly soluble/solid samples
- Injection Valve for the direct injection of liquid samples
- Automated Fraction collector for collection of samples in various sizes of test tubes
- Variable wavelength diode array detector capable of detection from 200 to 360 nm
- Choice of either PC based or touch panel system control
- Ethernet connection
- Binary gradient capability

The *Companion XL Installation and Operation Guide* contains figures which illustrate the main system.

Major Companion XL system components are labeled on these general system figures. Detailed descriptions and close-up figures of each of the major components follow the general system drawings within the documentation delivered with the system.

The Companion XL's capabilities may be expanded by adding additional fraction collectors.

1.1 Installation Qualification

An IQ evaluation establishes confidence that the equipment is properly installed. The installation must meet the manufacturer's specified guidelines. The information required for an IQ evaluation is equipment identification, required documentation, equipment utility requirements, major component specifications, materials of construction, and equipment safety features.

The IQ format in this document is based on Phil Cloud's *Pharmaceutical Equipment Validation*, 1998, 2002; Interpharm Press.

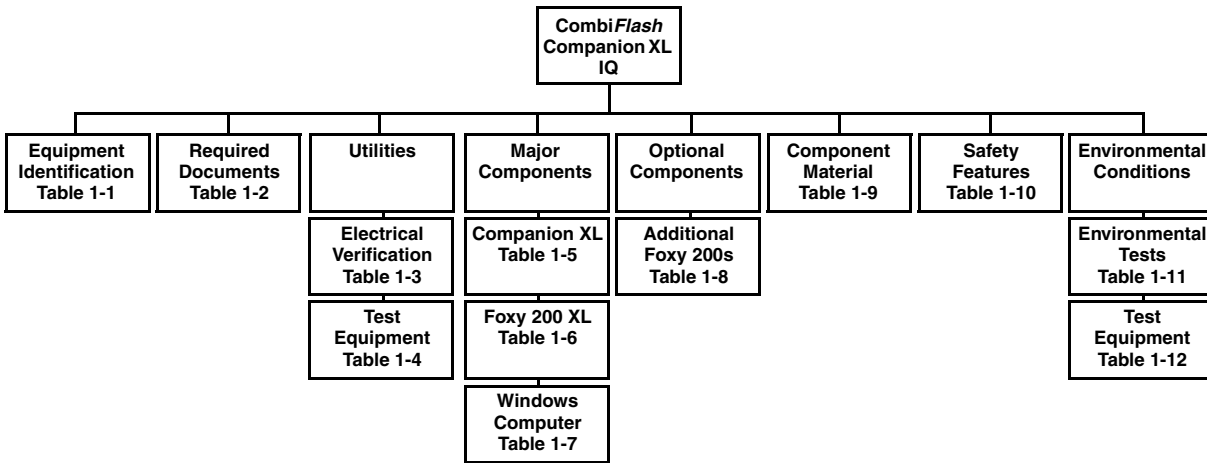


Figure 1-1 IQ Elements of the CombiFlash Companion XL

1.1.1 Equipment Identification

1.1.1.1 Overview and Purpose

The purpose of this section is to identify the owner/user/operator of the instrument, the instrument itself, the place and date of installation, and the installer of the instrument.

Record the equipment identification numbers in Table 1-1 along with the following information: purchase order number, model number, serial number, owner assigned asset number, and the location of the equipment.

1.1.1.2 System Identification Procedure

The system identification section of the IQ checklist should be filled out as follows:

1. The Customer Name field should include the name of the company that purchased and is using the instrument.
2. The Operator Name field should list the person designated as the primary user of the instrument.
3. The Site Address field should completely identify the location where the instrument is being installed. This should include the building, room number, and location in the lab.
4. The Phone field should contain the phone number of the Operator, and the lab where the instrument is located.
5. The System Serial Numbers field should contain the serial number of the Companion XL and the Foxy 200 XL being installed. (Additional fraction collector serial numbers can be recorded in Table 1-8.)
6. The Controller Serial Number field should list the serial numbers of all personal computers that have been configured for use with the system.

Table 1-1 Equipment Identification	
Required Information	
Customer Name:	
Operator Name:	
Site Address:	
Operator Phone Number:	
Supplier:	
Manufacturer:	Teledyne Isco, Inc. Lincoln, NE USA www.isco.com
Model Name and Number:	CombiFlash Companion XL 60-5240-001 Foxy 200 XL 62-2130-015
System Serial Numbers:	
Controller Serial Number(s):	
Purchase Order Number:	
Teledyne Isco Factory Order Number:	
Installer Name and Organization:	
Installer Phone Number:	
Date Installation Completed:	

7. The Installer field should identify the individual installing the instrument and the organization they are representing. Include the installer's phone number.
8. The Purchase Order Number, Factory Order Number, and Date Installation Completed, fields should be filled out with the correct information.

1.1.2 Required Documentation

The documentation listed in Table 1-2 should be on hand.

Table 1-2 Manufacturers' Manuals, Drawings and SOPs	
Number	Description
69-5243-040	CombiFlash Companion XL Installation Guide ^a
60-5242-006	CombiFlash Companion XL Replacement Parts List ^b
60-5242-018	Installation Qualification ^a

- a. The current revision of this document can be downloaded from www.isco.com.
- b. The replacement parts list is included in the *CombiFlash Companion Service Manual*, part number 69-5232-001. The current revision of this document can be downloaded from www.isco.com.

Note
Companion XL installations with additional Foxy 200 XL fraction Collectors will require Instruction Sheet 60-2133-156, *Connecting Multiple Foxy 200s to a CombiFlash Companion XL* (April 2005).

1.1.3 Utilities


Table 1-3 Utilities			
Utility	Specified	Measured Results	Acceptable (Y/N)
Mains Voltage	85-265 VAC		
Mains Current	20 amp circuit	N/A	N/A
Power Supply Source			

Table 1-4 Instruments Used to Measure Mains Voltage		
Instrument Used		
Test Instrument	ID Number	Calibration Due Date
Multimeter:		

1.1.4 Major Components

Table 1-5 Companion XL Specifications	
Overall Dimensions	
Height:	64 cm (25")
Width:	37 cm (14.5")
Depth:	40 cm (15.75")
Weight	23.5 kg (51.7 lbs)
Power Options	Input voltage range from 85 to 265 VAC, 2.0 Amps maximum
Line Frequency	47 to 63 Hz
Ambient Temperature	20 to 40°C (maximum temperature must be at least 10°C below the boiling point of the solvent)
Humidity (when connected to power)	95% relative humidity maximum at 20 to 40°C
Flow Rate Range	50 to 450 ml/min
Flow Rate Accuracy	±5%
Pressure Limit	50 psi
Pressure Accuracy	±5 psi
Peak Detection Modes	Slope or threshold
UV Spectrum	200 to 360 nm
Wavelength Accuracy	±5 nm
Flow Cell Pathlength	0.1 mm, ±25%
Tube Fill Accuracy	±[.6 + (1.3 x flow rate) / 60] ml (for all tubes except bottles)
Pollution Degree	2
Electrical Safety per EN 61010-1	
Installation Category	II
Maximum Altitude	2000 meters

Table 1-6 Foxy 200 XL Specifications

Collection Vessels	(144) 1.5 ml micro centrifuge tubes; (288) 12 or 13 mm tubes; (200) 16 mm tubes; (144) 18 mm tubes or MiniVials; (72) 25 mm tubes or 28 mm scintillation vials; (21) 400 ml or 500 ml bottles; (26) funnels for remote collection; (512) containers with user-definable custom positioning; (50) containers with user-definable random positioning; (72) disposable collection rack					
Collection Basis	TIME: 1 second - 99 hours 59 minutes: 59 seconds (HH:MM:SS) DROP: 1 to 999 drops VOLUME: 1 to 999 volumes					
Program Storage/restart After Power Failure	7 days					
Anti-drip Delay	0.8 second when TIME or VOLUME collection basis is used.					
Advancement Speed	12/13 mm tubes 0.34 second 16 mm tubes 0.35 second 18 mm tubes 0.39 second 28 mm scintillation vials 0.45 sec.					
Maximum Drop Speed	5.5 drops/sec					
Serial Communication Baud Rate(s) Supported (for External Computer)	110, 300, 600, 1200, 2400, 4800, 9600, 19200					
Dimensions	Length: 24 inches (60.96 cm) Height: 15 inches (38.1 cm) Width: 11.4 inches (28.96 cm)					
Weight	23 pounds (10.5 kg)					
For Indoor Use Only! Power Requirements (Mains Voltage Line Cord Is a "Disconnect Device.")	 <table style="display: inline-table; vertical-align: middle;"> <tr> <td>100 Vac +10%, 0.7 Amps</td> <td rowspan="3" style="font-size: 2em; vertical-align: middle;">}</td> <td rowspan="3">Factory-Set</td> </tr> <tr> <td>117 Vac +10%, 0.7 Amps</td> </tr> <tr> <td>234 Vac +10%, 0.35 Amps</td> </tr> </table>	100 Vac +10%, 0.7 Amps	}	Factory-Set	117 Vac +10%, 0.7 Amps	234 Vac +10%, 0.35 Amps
100 Vac +10%, 0.7 Amps	}	Factory-Set				
117 Vac +10%, 0.7 Amps						
234 Vac +10%, 0.35 Amps						
Line Frequency	50 to 60 Hertz					
Power Consumption	32 watts nominal 62 watts maximum					
Line Voltage Noise Tolerance	±170% of nominal line voltage, 10 microseconds at any phase angle					

Ambient Temperature Range	5 to 40°C
Humidity	80% relative humidity if left connected to the power mains
Pollution Degree	2
Installation Category	II
Maximum Altitude	2,000 Meters

Processor	Pentium class, 266 MHz or higher processor speed
RAM	The computer must have the minimum recommend RAM for the operating system.
Display	SVGA display, 800 × 600 pixels, minimum
Communications	Ethernet port with TCP/IP services installed
Operating System	Microsoft Windows (98 Second Edition; Windows NT4; Windows 2000 with Service Pack 3; Windows XP Professional; or later)
Internet Browser	Microsoft Internet Explorer 5.5 or later, with support for ActiveX controls and plug-ins

1.1.5 Optional Components

The CombiFlash Companion XL's fraction collection capacity can be increased by adding additional Foxy 200 XL fraction collectors. Up to four fraction collectors may be connected to the Companion XL—the original Foxy 200 XL that shipped with the system and three additional units.

A kit, 60-2139-026, is required for each additional fraction collector. This kit includes one Foxy 200 XL fraction collector, and the hardware and instructions (60-2133-156) necessary to install this option.

If additional Foxy 200 XL fraction collectors are added to the system, record their serial numbers in Table 1-8 below.

Fraction Collector 2	
Fraction Collector 3	
Fraction Collector 4	

1.1.6 Component Material

Table 1-9 advises the operator of materials that may contact samples and solvents used in the system. The operator should initial and date the fields in the table.

Table 1-9 Component Materials List			
Component	Materials	Initials	Date
RediSep Cartridge	Virgin Polypropylene, silica-based media, polyethylene (HDPE) frits		
Process Tubing	Teflon		
Drain Tubing	Vinyl with Teflon liner		
Process Valves	PEEK		
Sample Loading Cap	6061-T651 Aluminum, 303 SS		
Sample Loading Cap O-ring	SIMRIZ SZ485		
Injection Valve	Teflon, PEEK		
Flowcell	303 SST, Type ES Quartz, SIMRIZ SZ485		

1.1.7 Equipment Safety Features

Table 1-10 Safety Features	
Feature	Description
Vapor level sensor	Internal solvent vapor level sensor inside shuts down the pumping system if vapor levels exceed user-set limits.
Overpressure detection	System pressure sensor reduces flow rate when over pressure conditions exceed factory-set limits.
Static dissipative tubing	Used throughout the system to eliminate static discharge as a point of ignition

1.2 Setup and Installation

1.2.1 Overview and Purpose

The purpose of this section is to check the instrument for any shipping damage and to make sure that the site chosen for operation is appropriate. This section also outlines the steps needed to install the instrument.

This section will refer to the *CombiFlash Companion XL Installation Guide*, PN 69-5243-040, for detailed information about various procedures. This manual was shipped with your *CombiFlash Companion XL* and must be available for IQ.

1.2.2 Environmental Requirements Reviewed

Review the spatial requirements as described in Table 1-5 above and Section 2 of the installation manual to ensure sufficient space to complete the installation. Review power requirements listed in Table 1-1 of the installation manual (including the number of outlets needed) to complete the installation. Ambient temperature required for the instrument is 20 to 40°C (maximum temperature must be at least 10°C below the boiling point of the solvent). Humidity at the location of installation (when connected to power) should not exceed 95% relative humidity at 20 to 40°C.

Temperature and humidity should be measured and recorded in Table 1-11. Record temperature and humidity measurement instrument data in Table 1-12.

Environmental Parameter	Specified Range	Measured Results	Acceptable (Y/N)
Temperature	20 to 40°C		
Humidity	Less than 95%		

Instrument Used		
Test Instrument	Identification Number	Calibration Due Date

Installer	Date	Operator	Date
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

1.2.3 Complete order received and check for shipping damage

Before unpacking, carefully inspect the exterior of all shipping cartons for evidence of any damage. This includes water stains, cuts, punctures, or deep indentations in the container, and crushed corners or excessively abraded edges. Report and document any problems found with Teledyne Isco and the shipping company.

As the units are unpacked, carefully check them for external damage. If there is any damage, report and document the damage found.

Have a copy of the packing slip and, if possible, copies of the original sales order available, as the units are unpacked. If a copy of the order is present, compare the order to the shipping papers to make sure that everything on the order was shipped. If something is missing from the shipping paper but was on the order, check to see if the shipping paper state that a partial order was shipped. If a partial order was shipped, then proceed. If the order should have been complete, record the items in Table 1-13 and contact Teledyne Isco to report the missing items.

Table 1-13 Missing Item Log	
Part Number	Description

Once the order and the shipping papers have been checked, open the boxes and check to see that all of the parts were shipped. Also make sure that all of the appropriate accessory kits are present.

Installer	Date	Operator	Date

1.2.4 Voltage Selection

The *CombiFlash* Companion XL is compatible with all voltages and is pre-configured for the destination country. No adjustments have to be made to set the proper voltage.

1.2.5 Electrical and Fluid Connections to the Instrument

Follow the procedure detailed in Section 2 of the Installation Guide including the following:

1. Assemble the Foxy 200 XL fraction collector.
2. Connect the Foxy 200 XL control cable, PN 480-7996-00, between the 9-pin Foxy 200 Control port on the back of the Companion XL and the 25 pin SERIAL connector on the back of the Foxy 200 XL. If additional Foxy 200 Fraction Collectors are to be used with the system, refer to instruction sheet 60-2133-156 connect the additional fraction collectors using the supplied “Y” cables.
3. Use the supplied IEC power cords to connect the Companion XL and Foxy 200 to mains power.
4. Attach the Solvent A and B lines to the fittings on the back of the Companion XL. Place the weighted ends of the solvent tubing in their respective solvent containers. The solvent ports at the back of the Companion XL can be rotated so that tubing can be routed easily. To rotate the fitting, loosen the Swagelok® nut, rotate the elbow fitting to the desired position, then re-tighten the nut.
5. Attach tubing to the Foxy 200 port on the back of the Companion XL and route it to the inlet port on the Foxy 200's Diverter Valve. Attach tubing to the Diverter Valve's Waste port and route it to a suitable collection container. If additional Foxy 200 Fraction Collectors are to be used with the system, plumb the fraction collector liquid connections according the instructions in the connection package.
6. There are two drains on the Companion XL that are used to manage spilled fluids. One drain is the located on the side of each Foxy 200 tray (Figure 1-2). This drain carries away fluid that spills in the tray beneath the tube rack. Attach tubing and route it to a suitable waste fluid collection container.
7. The other drain is located on the top shelf of the Companion XL. Route the tubing attached to the bottom of this drain (Figure 2-2) to a suitable waste fluid collection container. This will carry away spills on the top shelf.

 Note

Refer to section 2 of the Companion XL Installation Guide, 69-5243-040 for additional information and diagrams.



Figure 1-2 Foxy 200 XL drain

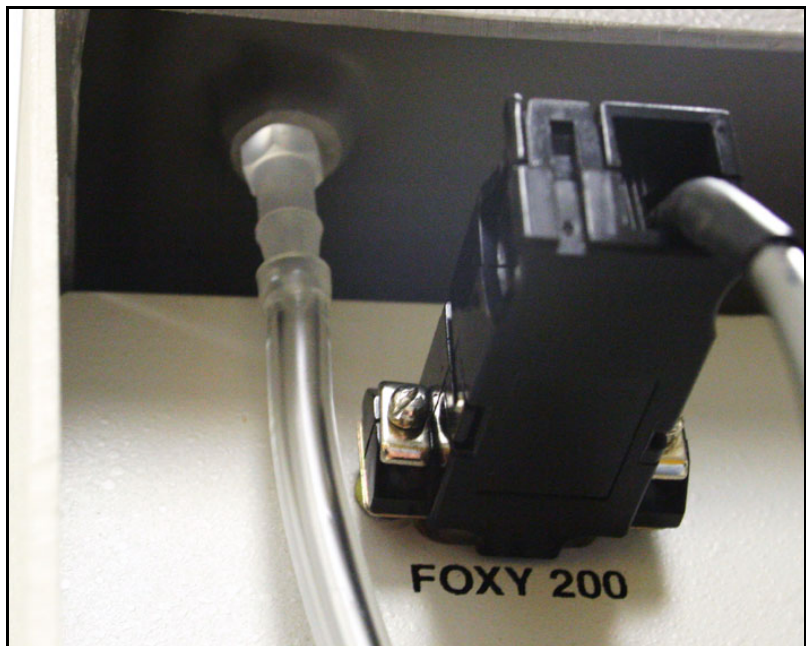


Figure 1-3 Companion XL top shelf drain

After completing system electrical and fluid connections, initial and date the certification box.

Installer	Date	Operator	Date
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

**1.2.6 Peripheral Accessories
 Connected and
 Operating**

Connect and test for proper communication:

1. If the Companion XL will be used with a direct connection to a PC, connect the CAT 5 crossover cable, PN 480-6545-02 to the Ethernet port on the rear of the instrument. Refer to sections 3, 4, 5, or 6 of the Installation Guide to configure the network connection according to the PC's Windows operating system.
2. If the Companion XL will be used with an existing network, the instrument will need to be configured for direct communications before it can be installed on the existing network. Connect the CAT 5 crossover cable, PN 480-6545-02 to the Ethernet port on the rear of the instrument. Refer to sections 3, 4, 5, or 6 of the Installation Guide to configure the network connection according to the PC's Windows operating system. After direct communication has been established, refer to section 8 of the Installation Guide to set up network communication.
3. The Companion XL is shipped with a default IP address of 192.168.1.51. If the CombiFlash Companion XL's IP address was changed (see section 8 of the Installation Guide), record the new address in Table 1-14.

Table 1-14 Companion XL IP Address	
IP Address:	

Installer	Date	Operator	Date

1.2.7 Sign Off

Once you are finished with sections 1.2.1 through 1.2.6, initial and date the Setup and Installation section of the IQ and have the instrument operator sign and date it.

Installer	Date	Operator	Date

**1.3 Instrument
 Verification**

1.3.1 Overview and Purpose

The instrument verification section of the IQ procedure is designed to ensure that the instrument executes all of its basic functions. This is not a test of the actual instrument performance. To test the performance of the instrument, use the OQ procedures for the CombiFlash Companion XL.

1.3.2 Fraction Collector Drain Line

In the event that solvents fall onto the fraction collector a drain (shown in Figure 1-2) exists to collect and divert solvents away from instrument. The drain tubing carries away the collected solvents to a waste container. Please note the waste container is not provided by Teledyne Isco, Inc.

Verify that the drain tubing is properly connected and secured to the fraction collector drain fitting by connecting a vacuum or air supply source to the exit end of the drain tube and verify the existence of such vacuum or air supply source on the drain fitting. After the proper connection of the drain tube has been verified disconnect the drain tube from the air/vacuum supply and place it in a user supplied waste container.

Note

Refer to Section 2.6 in the *CombiFlash Companion XL Installation Guide*.

Installer	Date	Operator	Date

1.3.3 Top Shelf Drain Verification

If solvents should spill on the case top of the Companion XL a drain is located on the top shelf of the instrument (Figure 1-3). Route the tubing attached to the bottom of this drain to a suitable user-supplied waste fluid collection container. This will carry away spills on the top shelf.

Verify that the drain tubing is properly connected and secured to the top shelf drain fitting by connecting a vacuum or air supply source to the exit end of the drain tube and verify the existence of such vacuum or air supply source on the drain fitting. After the proper connection of the drain tube has been verified disconnect the drain tube from the air/vacuum supply and place it in a user supplied waste container.

Note

Refer to Section 2.6 in the *CombiFlash Companion XL Installation Guide*.

Installer	Date	Operator	Date

**1.3.4 Fraction Collector Arm
Homes Correctly**

When the Foxy 200 XL is powered on, it will go through a series of events. One of these events is the homing of the fraction collector arm. The arm should move to the left rear corner of the fraction collector. While the arm is moving the software revision screen will be shown on the display. Once the arm has reached its home position the screen will change to either the CREATE PROGRAM screen or the READY/EDIT/LOAD screen. If the arm is in the home position and the software revision screen is still displayed, there is a problem with the homing of the arm. Check for any obstructions that would hinder the movement of the arm or drop former such as tubing or cables.

Installer	Date	Operator	Date

1.3.5 Ready Light is ON

Once the operating system inside the instrument has loaded the ready light on the front of the instrument should turn green.

Installer	Date	Operator	Date

**1.3.6 Computer/Network
Communications
Tested and Passed**

In section 1.2.6 of the IQ connections to peripheral devices were made. To verify that the peripheral device is communicating with the instrument we must establish a connection between the peripheral and the instrument. To establish a connection:

1. *(Windows PC Only)* Start Internet Explorer.
2. *(Windows PC Only)* In the address bar on the PC enter <http://192.168.1.51/login>.

✓ Note

192.168.1.51 is the factory assigned IP address for the CombiFlash Companion XL. If the IP address has been changed, substitute the new IP address in this step. (The new address should be recorded in Table 1-14.)

3. *(Windows PC Only)* The PC browser will display the PeakTrak Login screen.
4. *(Windows PC and Companion XL system with touch panel display)* Enter password on the PC and PeakTrak software will start.
5. *(Windows PC and Companion XL system with touch panel display)* After loading, the browser screen is replaced by a PeakTrak window. The PeakTrak window will be similar to the one illustrated in Figure 1-4.
6. *(Windows PC and Companion XL system with touch panel display)* After starting PeakTrak, view the CombiFlash

Companion XL's Software version number by selecting the "Help>About PeakTrak" menu option. Record the number in Table 1-15.

Table 1-15 Companion XL Software Version			
Companion XL Software Version Number:			
Installer	Date	Operator	Date

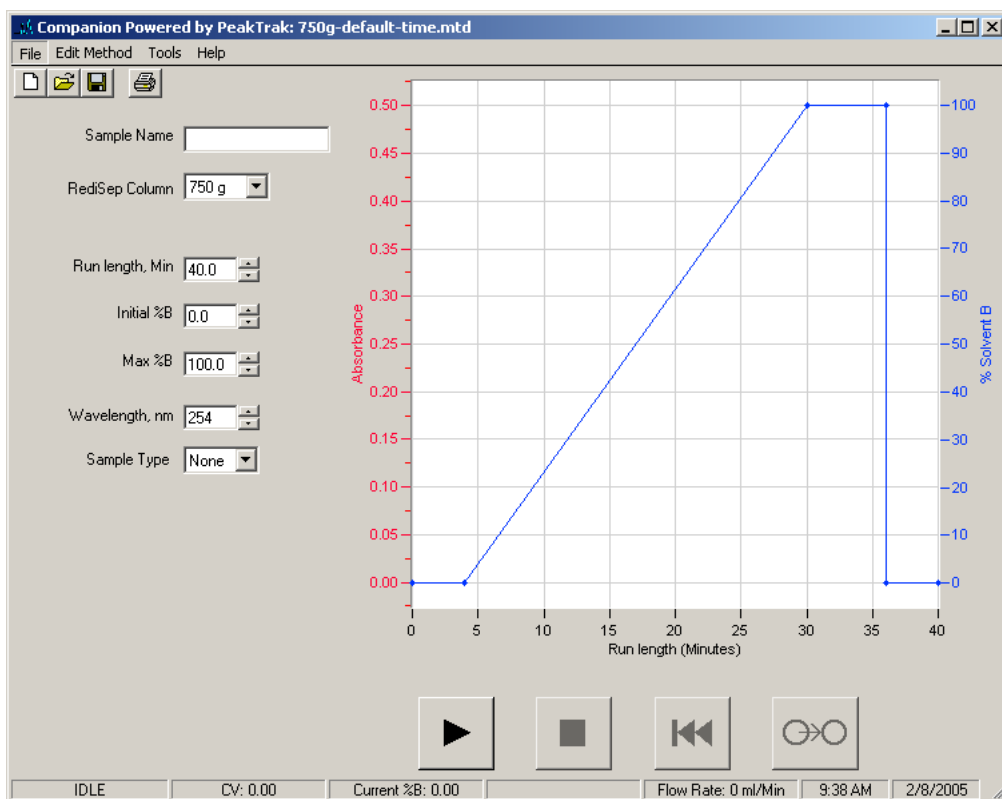


Figure 1-4 PeakTrak for Companion XL Systems (running on Microsoft® Windows®)

1.3.7 Priming the Solvent Inlet Lines

Verification of control is required once communications have been established. Priming of the solvent inlet lines is a simple but effective test for verifying control.

1. Make sure bypass tube PN 60-2134-145 is installed in place of the column. Insert the bypass tubing into the smaller column fittings.
2. From the PeakTrak menu, click on Tools>Auto Prime.

3. The Auto Prime window appears and you should press OK to continue.
4. Pump B will prime first and then Pump A.
 When Auto Prime is finished it will notify you that the “Auto Prime process completed successfully.”

Installer	Date	Operator	Date

1.3.8 Sign Off

Once you are finished with sections 1.3.1 through 1.3.7, initial and date the Instrument Verification Section of the IQ checklist and have the instrument operator sign and date it.

Installer	Date	Operator	Date

1.4 System Acceptance

After completing the preceding Installation Qualification steps, the system is ready for acceptance. Complete Table 1-16 to indicate acceptance of the CombiFlash Companion XL flash chromatography system.

Table 1-16 System Acceptance		
	Signature	Date
Operator:		
Laboratory Supervisor:		
Comments		