DISTEK®
CREATING A STIR™

Evolution 4300
Dissolution Sampler

Operation Manual

Distek Model Evolution 4300 Dissolution Sampler

Operation Manual

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Document Revision History

Rev	*Date*	*Notes*
A	5/06/2004	Initial Release of Evolution 4300. See CN #0431.
B	6/28/2005	Updated Appendix A: Spare Parts & Accessories. See CN #0509.
C	7/22/2014	• Added WEEE statement. • Removed references to 2100B control. • Added statement that 5100 firmware revision 3.00 control is no longer supported. • Added setup configuration and operation for symphony 7100 and Model 2500. • Removed reference of “slave” to “remote” mode. • Corrected the labels for RS-485 and RS-232 in Fig. 2-6 • New feature added for operator to enter the Lot and Batch number at the end of the test • Change maximum volume specification and sampling to 10mL. • Update Fig. 3-8 to reflect new values for Line 1 and 2. • Maximum number of reports was changed. • Added note regarding the importance of the “Cool Chip”. • Added notes to appendix printout reports for 2500, 6100, 6300 and 7100. • Added Appendix E for User Interface Flow Chart

Contents

About this Manual

About This Manual includes information about what is contained in this manual and the conventions used.

Purpose

This manual covers the installation, routine operation, maintenance and repair of your Distek Evolution 4300 Dissolution Sampler. It has information regarding the commands, menus, indicators and controls. Chapter 1 provides an overview of the Evolution 4300. Chapter 2 covers the steps to unpacking and installation of the system. Chapter 3 includes operation and programming information. Chapters 4 and 5 cover maintenance and troubleshooting. Please read Chapters 1, 2 and 3 before proceeding.

Audience

This manual is written for any person responsible for maintaining, operating or troubleshooting the Distek Evolution 4300 Dissolution Sampler.

Contents

This manual is divided into chapters. The pages of the manual are numbered providing easy navigation to assist in finding information quickly. The following list describes the material covered in each chapter:

Chapter 1 - Introduction	Provides a general overview and warnings about the instrument.
Chapter 2 - Installation	Describes how to unpack and properly install the unit.
Chapter 3 - Operation	Describes the functionalities of the system and how to run the unit.
Chapter 4 - Maintenance	Explains the steps necessary to maintain the unit.
Chapter 5 - Troubleshooting	Provides a troubleshooting chart and description of error messages to assist the user if a problem arises.
Appendix A – Spare Parts and Accessories	Provides a table of recommended and optional spare parts.
Appendix B - Pre-Installation Considerations: Electrical Power Supply	Recommendation information pertaining to electrical power supply.

Appendix C - CE Declaration of Conformity	CE Declaration of Conformity certificate.
Appendix D - Sample Printouts from Parallel Printer	Sample printouts for a parallel printer.
Appendix E – User Interface Flow Chart	Flow chart diagraming the various screens found on the user interface.

Prerequisites

This manual assumes that you understand the principles of dissolution testing.

Documentation

This manual contains important information regarding the safe operation, maintenance and repair of your Distek Evolution 4300 Dissolution Sampler.

Conventions

 **WARNING**	Warning statements are used in this manual to prevent injury to personnel.
CAUTION	Caution statements are used to prevent damage to equipment.
	High voltage warning.
 *NOTES*	*Notes contain helpful information.*
REQUIRED ACTION	Required Action is used where necessary to distinguish the action needed from the Warnings, Cautions and Notes.

1 Introduction

This chapter provides an overview of the Evolution 4300 and system specific specifications.

Overview

The Distek Evolution 4300 Dissolution Sampler is a media sampling instrument capable of sampling into test tubes or directly injecting into HPLC vials. The system can be configured as a single or dual bath capable unit via one or two eight channel syringe pump(s).

This manual contains important information regarding the safe operation, maintenance and repair of your Evolution 4300.

Evolution 4300 Site Requirements

The site requirements to install the Evolution 4300 are as follows:

Table 1: Site Requirements

Requirements	Description
Power	See Table 2 below.
Bench Space	38”W x 24”D x 18”H (Dual Pump System)
Clearance	Sampler drive head must be free of obstructions

Specification

Table 2: System Specifications

System Collector	
Tube/Vial/Rack Capacity:	8 x 16 per bath, HPLC Vials or 10mL Test Tubes (13 x 100mm)
Maximum Number of Sample Sets:	32
Internal Method Storage	16 methods
Operator Privileges:	User and Manager Accounts
Interface Ports:	RS-232 and RS-485 (2)

Power Requirements:	100-240VAC 50/60 Hz 2.5A

Syringe Pump	
Volume:	0.1mL to 20ml, Programmable
Accuracy:	± 0.1ml
Flow Rate:	Up to 25ml/min.
Tubing Type:	1/16” OD Teflon Tubing
Interface Ports:	RS-232 and RS-485 (2)
Power Requirements:	100-120/200-240 VAC 50/60 Hz 3.0A
Dimensions	
System Collector:	16.5” W x 24” D x 16.5” H
Syringe Pump:	8.5” W x 13” D x 17” H
Weight	
Sample Collector:	43 lbs.
Syringe Pump:	29 lbs.

Physical Site Requirements

The dimensional requirements specified below are adequate for the installation of a dual pump Evolution 4300 system:

1. The minimum bench depth (front edge of bench to the back splash or wall) needed is 24” (0.61m). However, the minimum recommended bench depth is 25” (0.64m).
2. The minimum linear bench space requirement is 38” (0.97m). Distek recommends that at least 39” (.99m) be allocated to allow for adequate clearance to power off the syringe pumps.
3. There must be no obstruction (cabinet, shelf, or outlet) that intrudes into the minimum footprint of the unit up to a height of 18” (.46m) above the bench surface 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. Because the entire mass of the

collector and syringe pump(s) are transferred to the bench surface through four (4) circular feet on each unit, the bench surface should be strong enough to withstand the entire load of the unit.

5. Because of the limitation in travel of the leveling feet, the bench slope should be less than 0.75" (1.9cm) from front to back or from side to side over the unit's foot print.

Environmental Considerations

Ambient Laboratory Temperatures

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

Maximum Conditions:

1. The Evolution 4300 is designed to be installed and operated in laboratories where the maximum operating temperature does not exceed 25°C.
2. The maximum allowable ambient operation temperature is 30°C.

Minimum Conditions:

To assure controlled operation within specified tolerances, the Evolution 4300 is designed to be operated in laboratories where minimum operating temperatures do not drop below 15°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 Evolution 4300 is installed must be able to maintain the ambient air temperature within ±2.5°C of set point (worst case).

Ambient Laboratory Humidity

Maximum:

Water vapor and/or hydrogen chloride vapor, from dissolution media, can cause serious effects when condensed on electrical components and contacts. The lab's environmental controls should maintain humidity well below the dew point, to minimize corrosion and the risk of condensation.

Minimum:

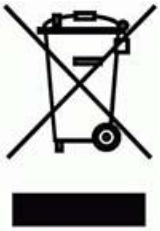
It is important that the humidity level be kept at or above 30% relative humidity, to minimize the risk of damage to control circuits caused by static discharge.

Air Quality Considerations

Distek autosampling systems are designed to be operated in a lab 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. Absorption of vapors into dissolution media may bias test results. Some dissolution tests may require dissolution and drug release media prepared from USP quality water. Absorbed vapors may cause difficulty in complying with USP requirements.

Distek & WEEE Directive (Waste Electrical and Electronic Equipment)

Distek, Inc. is committed to protecting the environment and understands the importance of proper recycling. The “crossed out wheeled 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.

Operation Warnings and Notes

For your safety, the information in this manual must be followed to minimize the risk of fire or explosion, electrical shock, or to prevent property damage, personal injury or loss of life.

Use this equipment only for its intended purpose as described in this Operation Manual.

Never attempt to operate this instrument if it is damaged, malfunctioning, partially disassembled, or has missing or broken parts, including a damaged cord or plug.

Improper servicing or adjustment practice can cause equipment failure or serious physical injury. This equipment must be adjusted and serviced by qualified electrical maintenance personnel who are familiar with the construction and operation of the equipment and the hazards involved. Take diligent care during adjustment. All exposed points on the control circuit boards are electrically hot with respect to earth ground.

HIGH VOLTAGE IS EXPOSED WHEN THE REAR COVER IS OPENED ON THE COLLECTOR AND SYRINGE PUMP. Dangerous voltages exist on the circuit boards when powered. Disconnect AC power from the units while troubleshooting. Be alert. High voltage can cause serious or fatal injury.

External cables (excluding power cable) are limited to less than 3 meters length in order to maintain electromagnetic compliance.

Some forms of electromagnetic interference may cause unexpected operation. If this occurs, the unit will return to normal operation once the interference is removed.

2 Installation

This chapter will describe the steps necessary to properly unpack and install the instrument.

Unpacking

Please take a few moments when unpacking unit to check for all items indicated on packing list. Notify DISTEK or your shipper immediately with any discrepancies or damage to cartons or contents in transit.

The Evolution 4300 will arrive in 1 box containing the collector and either one or two pumps depending on the purchased configuration.

To avoid injury, two people should remove Evolution 4300 from the shipping carton.

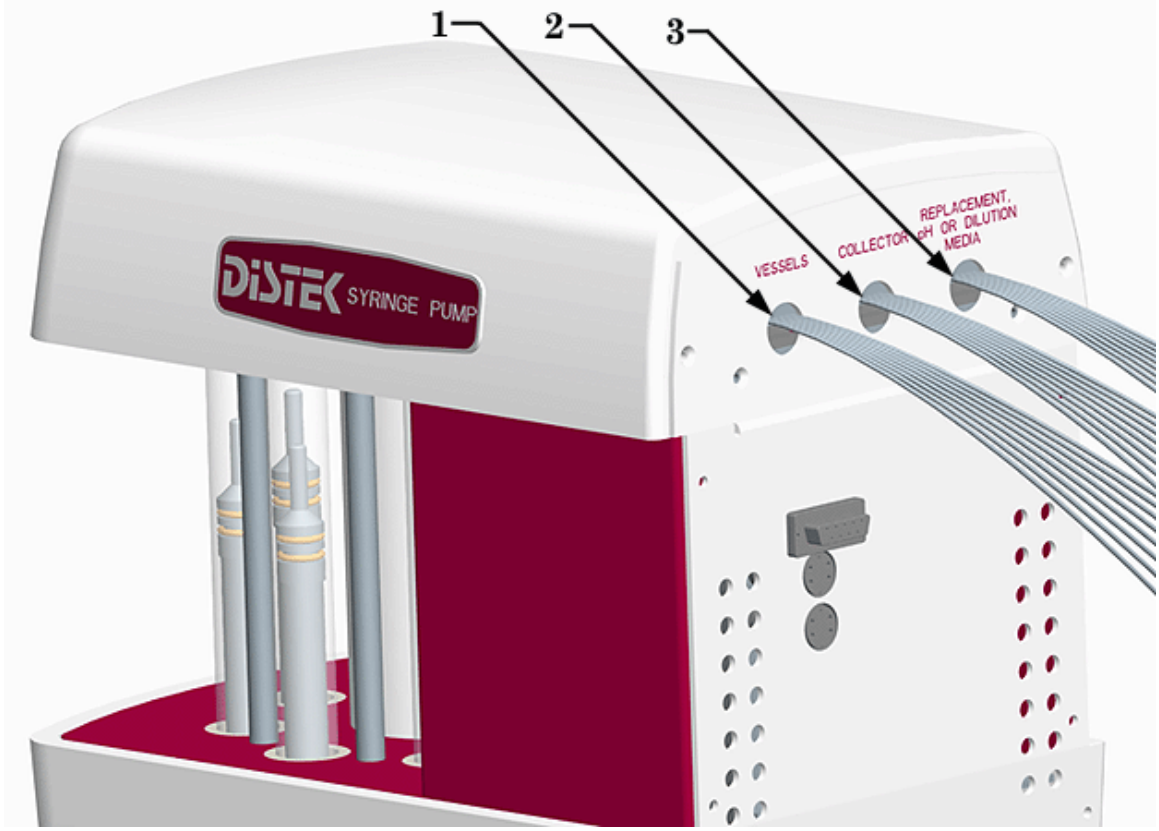
1. Cut through the tape at the top of carton. Open the four top flaps.
2. Carefully remove the packing inserts and lift the instrument from the shipping carton. See warning above.
3. If applicable, identify and remove all tie-wraps from the various locations on the unit.

Leveling: Evolution 4300

1. Trained personnel should lift the unit onto the bench and slide it into position.
2. Loosen locking nuts on front leveling feet of the system collector using the appropriate wrench.
3. Level the unit from front to back and side to side by adjusting the leveling feet under the instrument.
4. Tighten locking nuts on each foot.
5. Mark the location of leveling feet on bench to prevent changes in level due to moving the instrument.
6. Check the level after completing installation or after moving the Evolution 4300 to a new location. Verify the level using a carpenter's level. Check from front to back and side to side.

Installing the Fluid Connections

The syringe pump comes equipped with 3 sets of outlet tubes each containing 8 separate lines. The tubes go to the dissolution vessels, collector/sampler and replacement media. See Figure 2-1 for specific locations on the rear of the syringe pump. The end of each line contains a ferrule and fitting.



1. To Dissolution Vessels
2. To Collector/Sampler
3. To Replacement, pH or Dilution Media

Figure 2-1: Tubing Outlet Diagram from Syringe Pump

Follow these steps for installation:

1. Attach the sampling probes to the fittings at the end of each tubing line exiting the syringe pump (quantity 6 or 8) from the set labeled VESSELS. If the Syringe Filter Adapter was purchased see Installing the Syringe Filter Adapter (If Applicable) on page 2-4.
2. If media replacement will be used, place the replacement media lines into a reservoir of replacement media.
3. Connect the collector lines (green ¼-28 fittings) to the manifold in the rear of the collector/sampler (See Figure 2-2). The lines exiting the syringe pump will be labeled 1 through 8 and should be screwed into the corresponding number on the manifold in the rear of the sampler.

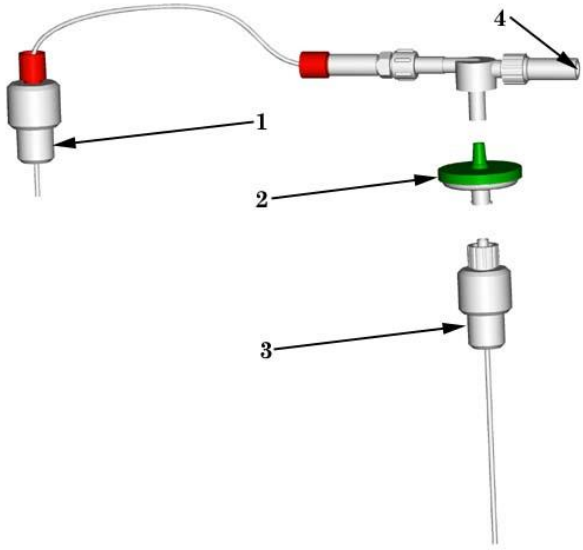
Figure 2-2: Installing the Fluid Connections

Installing the Syringe Filter Adapter (If Applicable)

One of the option accessories for the Evolution 4300 is a syringe filter adapter. The adapter enhances the unit's performance when a syringe filter will be utilized. For more information contact Distek and ask about Part Number 2800-0110.

The following steps describe the installation:

1. Attach the Syringe Filter Adapter to the fittings at the end of each tubing line exiting the syringe pump (quantity 8) from the set labeled VESSELS. See item number 4 in Figure 2-3.
2. When ready for use, simply unattached the sampler probe and nut (attached to the top of the probe), screw the syringe filter (luer adapter fitting) on the nut and slip the other end into the valve. See Figure 2-3.

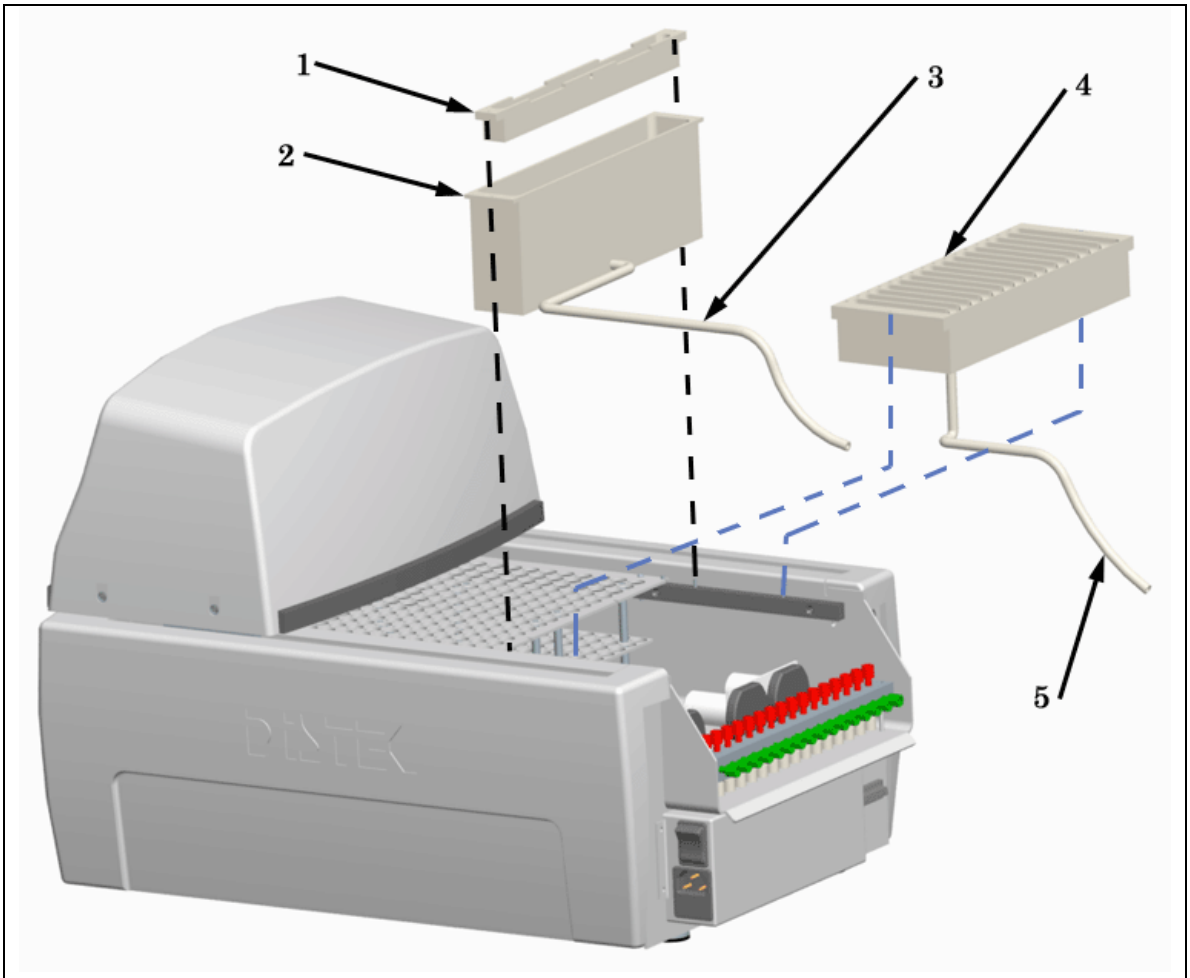


1. Return Probe
2. Syringe Filter
3. Sampling Probe
4. To Syringe Pump

Figure 2-3: Syringe Filter Adapter

Routing the Waste Tubes

Exiting the rear of the collector are 2 fluid lines: the recycle bin/needle rinse station overflow and the needle rinse station pump media. The larger diameter clear tube (5/16" O.D.) is a waste line and should be placed into a waste container (See Figure 2-4). The waste tube empties the rinse tank and recycle bin by the use of gravity, therefore it is critical that the waste tube is positioned well below the collector!



1. Rinse Tray
2. Rinse Tank
3. Rinse Waste Tube
4. Recycle Bin
5. Recycle Bin Waste Tube

Figure 2-4: Rinse Station, Recycle Bin and Waste Tubes

Setting Up the Rinse Station

The Evolution 4300 is equipped with a needle rinse station. The rinse station is used to clean the outside sleeve of the collector needles between methods or sampling intervals. The majority of the rinse station is configured prior to shipment. The only step required to complete the rinse station setup is to place the section of peristaltic tubing (0.170" OD) into a bin containing media to be used for the needle rinse.

Installing the Rack Assembly

The Evolution 4300 comes configured with a split rack that can be configured for both test tubes and HPLC vials. Depending on what was purchased the unit will be equipped with two test tube racks or two vial racks, or a combination of the two. Please see Appendix A for information on ordering additional racks.

1. Slide the rack assembly into the waste tray located on the sampler/collector. The top plate of the racks contains a screw on each side. Be sure this screw engages the sensor block located on the sidewall of the sampler. See Figure 2-5.

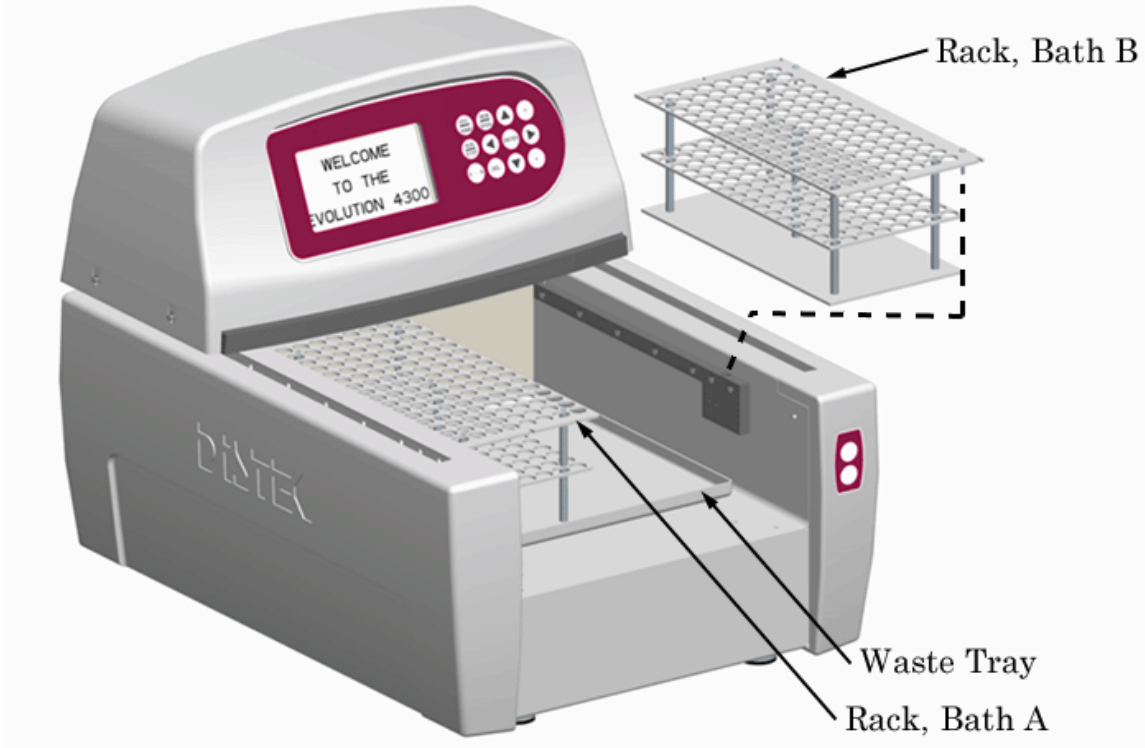


Figure 2-5: Rack Installation

Setting Up the Power and Communication Connections

1. Connect the power cord from the rear of the syringe pump to a power outlet. Repeat for additional pump in a dual bath configuration. See Appendix B for power requirements.
2. Connect the power cord from the rear of the sampler unit to a power outlet.
3. Connect the RS-485 cable from the rear of the syringe pump (either RS-485) to the rear of the sampler. The communications will work using either port (each unit contains two RS-485 connections). Repeat the connection for an additional pump in a dual bath configuration.
4. If the Evolution 4300 will be connected to a Distek dissolution instrument an additional RS-485 connection is necessary. Connect an open RS-485 port on the rear of the syringe pump to the RS-485 on the rear of the dissolution system or the TCS.

1. Lighted Power Switch
2. Power Cord Connection
3. RS-485 Connection
4. RS-232 Connections

Figure 2-6: Syringe Pump and Communication Connections

Setting Up Communication with Distek Model 2100C

- If the Evolution 4300 will be controlling two dissolution systems, all addresses must be unique.
- The firmware revision for a Model 2100C must be 2.30 or higher.
- The firmware revision for the TCS must be 1.30 or higher.

The Evolution 4300 is capable of controlling a Distek Model 2100C Dissolution system. Follow these steps to configure the connection:

1. The Model 2100C must be configured to run in Remote mode in order to accept commands from the Evolution 4300. When the bath is powered on the LED display should indicate "L 16" where L designates the unit is set for Remote mode. If an A is displayed the unit is set to Master mode and must be changed. The DIP switch settings control this option and are located on the Motor Control Module (MCM) on the Model 2100. The following steps can be used to change the unit to Remote mode:
    a. Disconnect the power cord and all other cords from the rear of the Motor Control Module (MCM).
    b. Carefully support and remove the MCM by unscrewing the two knobs and two Phillips flat head screws that attach it to the 2100C frame.
    c. Remove the four screws from the bottom panel of the MCM.
    d. Remove four more screws at the rear of the MCM (at four corners of back panel).
    e. Check the DIP switch settings and change switch 6 to enable Remote mode. See chart below.

Model 2100 DIP Switch Functions

	1	2	3	4	5	6	7	8
ON	+1	+2	+4	+8	+16*	MASTER*	24 HR TIME	ZYMARK
OFF	ADDRESS					Remote*	AM/PM	

* Denotes default setting.

    f. Put the top cover back on and replace the four screws on the rear panel.
    g. Replace the four screws at the bottom of the MCM.
    h. Re-install the MCM on the frame.
    i. Connect all external cables to connectors on the rear of the unit. Connect the power cord. Ensure all cables are firmly in place, including the black four-pin DIN cable for RS-485.
    j. Turn on unit and check for proper functioning. Upon powering on the unit it should now display "L XX".

2. Connect an RS-485 from the rear of the Syringe Pump to an open RS-485 on the Model 2100.
3. The Evolution 4300 now needs to be configured with the address of the 2100 and the TCS. These addresses can be obtained by turning the power off and then on. The unit's display will flash "L XX" where the XX represents the unit's address.
4. **The TCS address must be 27 or greater** (not required for TCS firmware 1.4 or higher). Follow the steps below to reset the TCS address:
    a. Connect the RS-485 port of the 2100 to the TCS using the RS-485 cable.
    b. Hook up a PC which has a terminal program (such as HyperTerminal) to the RS-232 port of the 2100.
    c. Turn on the PC, the 2100C and then the TCS.
    d. Open the PC's terminal program.
    e. The factory default address of the TCS is 10.
    f. Type the following command, including brackets and spaces: [10 Z:N aa] where 10 is the current address and aa is the new address of the TCS. You should get an exclamation point [!] response from the TCS.
    g. Save the new address in the TCS memory by typing [aa M] where aa is the new address. You should get an exclamation point [!] response from the TCS.
5. On the Evolution 4300's Main screen highlight ADMIN and press ***ENTER***.
6. From the Admin screen highlight CONFIG and press ***ENTER*** (see Figure 3-7).
7. Highlight the bath type field, using the + and - keys change the value to 2100C.
8. Highlight the Bath A or Bath B field, using the + and - keys change the value to the address of the 2100 determined in step 5.
9. Highlight the TCS field, using the + and - keys change the value to the address of the TCS determined in step 5.