



DS2® Automated ELISA System

Operator's Manual

Part No. 91000200

For Use with DS-Matrix™ version 1.34 and above

IMPORTANT

Please read carefully before using the DS2

Revision History

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This publication is for the operators of the DYNEX DS2 Automated Microplate Processing System using DS-Matrix software.

Due to continuing software improvements, dialog boxes displayed in this manual may differ from those actually seen in the software screens. Every effort has been made to ensure the information in this manual is accurate, updated and consistent with the product it describes. Dynex Technologies (DYNEX) reserves the right to make technical improvements to the DS2 and documentation without prior notice as part of a continuous program of product development.

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This manual supersedes all previous editions and is published by DYNEX Technologies, Inc.

Questions or comments regarding the content of this manual can be directed to the address below or to your supplier.

Part No. 91000200

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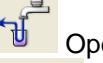
EC REP

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About This Manual

The following instructions for using the DS2 Automated ELISA Processing System (DS2) are included in this manual:

- Installing the *DS2*
- Configuring the *DS2* hardware for specific application requirements
- Creating or modifying assays using the *DS2*
- Running assays by using worklists
- Performing required preventive maintenance
- Performing the *DS2* arm calibration
- Troubleshooting

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Chapter 1 Overview

1.1 Introduction

The DS2 Automated ELISA Processing System is a computer-controlled microplate processing system that fully automates the following steps of microplate ELISA assays:

- Sample dilution and distribution
- Reagent addition
- Incubation
- Plate washing
- Signal detection

The DS2 is intended for use in clinical, research, and industrial laboratories.

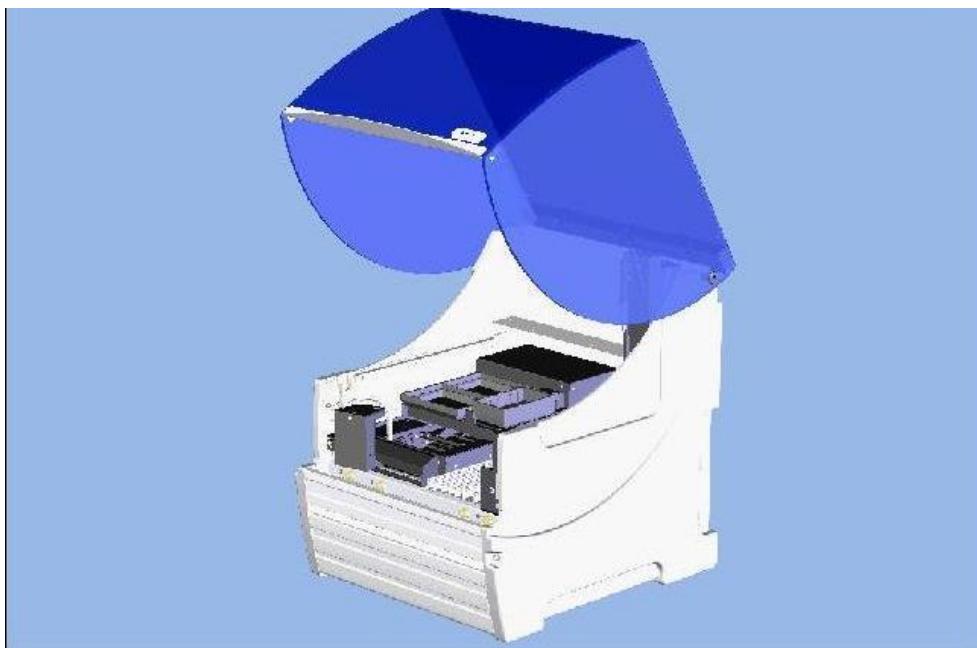


Figure 1-1: The DS2 Automated ELISA Processing System (Cover Open)

1.2 DS2 Specifications

DS2 Instrument Dimensions	
<i>Width</i>	540 mm (21.3 inches)
<i>Depth</i>	680 mm (26.8 inches)
<i>Height</i>	660 mm (26.0 inches)
<i>Weight</i>	48 kg (106.0 lbs.)

Power Supply	
<i>Voltage</i>	100-240 V auto-switching
<i>Frequency</i>	50/60 Hz
<i>Power Consumption</i>	≤ 360 VA

Reader Specifications	
<i>Dynamic Range</i>	-0.100 to 3.00 OD
<i>Spectral Range</i>	405 nm to 690 nm
<i>Precision</i>	<1% CV (<2.00 OD); <2% CV (2.00-3.00 OD)
<i>Accuracy</i>	± 0.005 OD or 2.5% (whichever is greatest)
<i>Read Time</i>	<30 sec (single wavelength)

Washer Specifications	
<i>Manifold Configuration</i>	8-Way
<i>Dispense Volume Range</i>	50 to 1000 µL
<i>Wash Buffers</i>	2 x 2 L
<i>Input connector for external clean fluid bottle provided</i>	Clean fluid bottle must be provided (any size)
<i>Waste Container</i>	1 x 1.5 L
<i>Residual Wash Volume</i>	<3 µL with super sweep

Incubator Specifications	
<i>Temperature Range</i>	Ambient plus 4°C up to 40°C
<i>Temperature Accuracy</i>	± 1°C at 37° C
<i>Shaking</i>	Independent linear motion 14-20 Hz periodic or continuous

Instrument Capacity	
<i>Number of Plates</i>	2
<i>Number of Assays/Run</i>	12
<i>Number of Sample Tubes</i>	100 (5 racks of 20)
<i>Number of Reagents</i>	10 x 15 mL tubes and 8 x 25 mL tubes (when using the Dynex workspace)
<i>Number of Standards/Controls</i>	24 x 2 mL tubes (when using the Dynex workspace)
<i>Number of Sample Tips</i>	216
<i>Number of Dilution Deep Wells</i>	96
<i>Sample Tube Dimensions</i>	10 to 16 mm external diameter 40 to 100 mm height
<i>Number of Reagent Tips</i>	20

Sample Pipetting Specifications	
<i>Sample Tip Size</i>	300 µL
<i>Single-shot Sample Pipetting Volume</i>	10 to 250 µL
<i>Time to Dispense 96 x 50 µL</i>	<20 minutes
<i>Single-shot Dispense Precision</i>	<3% CV (10 – 250 µL)

Reagent Pipetting Specifications	
<i>Reagent Tip Size</i>	1300 µL
<i>Reagent Pipetting Volume</i>	20 to 1000 µL
<i>Single Shot Dispense Precision</i>	<3% CV (20 – 1,000 µL)

1.3 Description of Hardware Components

1.3.1 System Cover

The system cover encloses the workspace, the arm and the pipette module. The cover should be closed during operation to prevent accidents.



CAUTION: *The system cover prevents accidental interaction with the arm.*

To open the cover, lift the cover handle until the cover is in the upright position. To close the cover, pull down on the cover handle until the cover is fully closed. The system cover will rest on the side panels when it is completely closed (unless the DS2 External Waste Trap is in use, in which case the cover should not close completely).



CAUTION: *Pinching hazard. Be sure that your hands and fingers are clear of the cover when closing.*

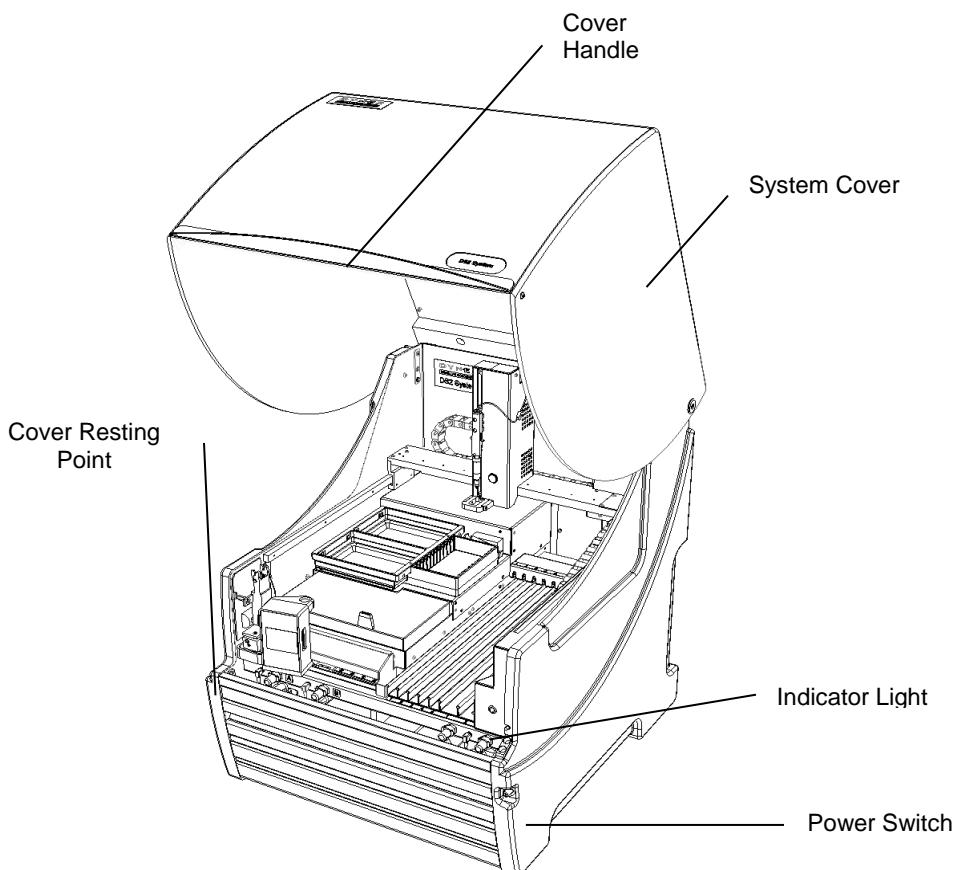


Figure 1-2: External Components of the DS2 System

1.3.2 Workspace Components

- X-Drive (front to back), Y-Drive (left to right) and the Z-Drive (up and down)
- Reader Assembly (which contains the Incubation Chamber, Reading Optics (under the Sample Tip Trays) and the Pipetting/Washing area (under the Sliding Cover))
- Barcode Scanner
- Wash Head

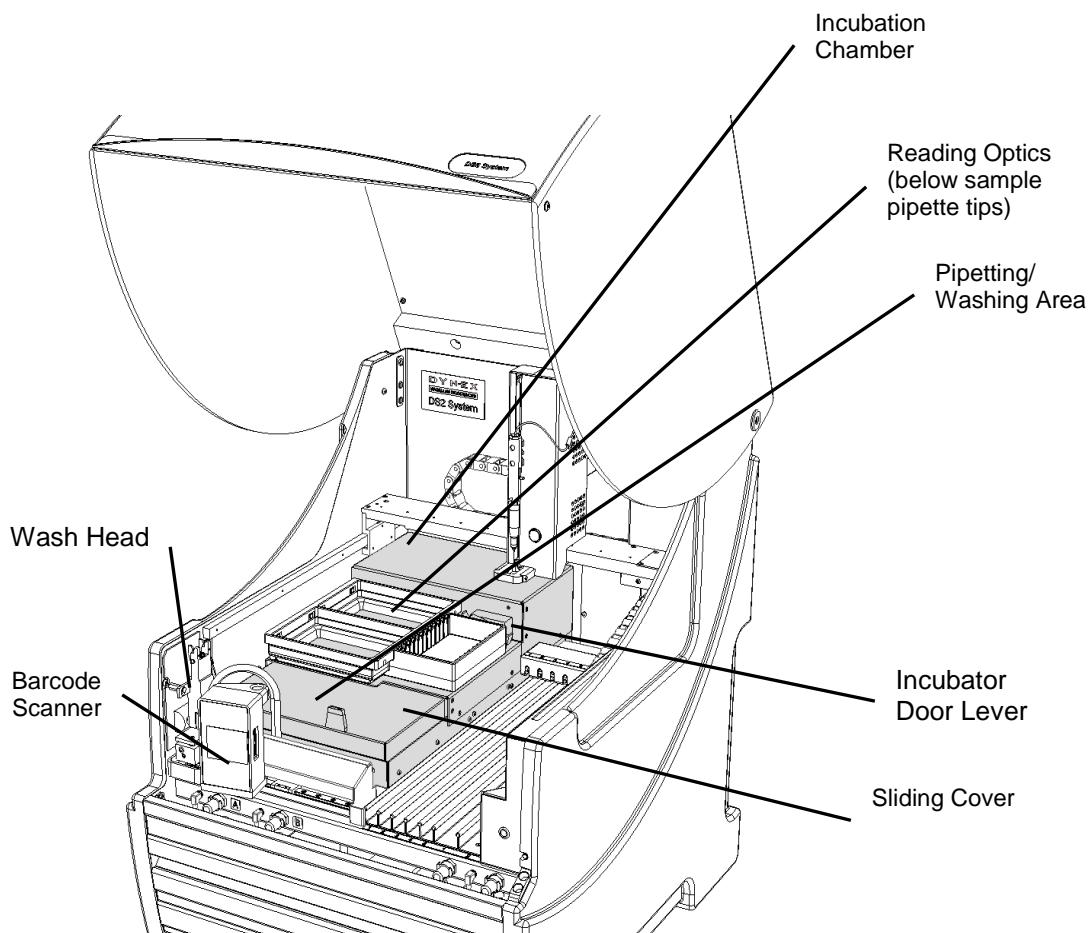


Figure 1-3: Workspace Components of the DS2 System

1.3.3 Microplate Incubation Chamber

The incubation chamber can hold up to two microplates during a run. During an incubation step, the incubator door is closed to ensure proper temperature equilibration.

1.3.4 Barcode Scanner

The barcode scanner reads barcode labels on the sample tubes as well as the positioning barcode labels located on the sample tube racks.

The barcode scanner is an IEC60825-1+A2:2001 Class 1 Laser Product that complies with 21 CFR1040.10 and 1040.11 except for deviations pursuant to Laser Notice 50 dated 7-26-01.



CAUTION: *The barcode scanner has a maximum radiated power output of 1.0 milliwatt. Do not stare into the beam of the barcode scanner without appropriate protective equipment (e.g. protective glasses). Obey the warning label (shown below) that is on the front of the barcode scanner.*



1.3.5 Pipette Module

The Pipette Module travels in the x -, y -, and z - directions to pipette samples, controls and standards, dispense reagents, and to perform dilutions. The Pipette Module is also used to slide the reader cover open and closed, to open and close the Incubation Chamber, as well as to pick up and eject the Wash Head Assembly.

The pipette module has the following sub-components and functions:

Component	Function(s)
<i>Pipetting (liquid level and clot detection)</i>	Pippettes samples, standards and controls (using disposable sample pipette tips) and reagents (using disposable reagent pipette tips). Liquid level and clot detection is performed by sensing pressure changes.
<i>Tip Detection</i>	Verifies that a tip has been picked up or ejected.
<i>Wash Head Detection</i>	Verifies that the Wash Head Assembly has been picked up or ejected.

The pipetting system of the *DS2 Automated ELISA System* includes ESP™ (Electronic Signature Pipetting) software. ESP™ software automatically detects pipetting inaccuracies

caused by bubbles, foam, and mucus. A profile for each specific fluid must be created by the user to enable the ESP functionality.

1.3.6 Wash Head Assembly

The DS2 uses a modular Wash Head Assembly that is stored in the front left corner of the workspace. The Wash Head Assembly is picked up by the pipetting arm to perform wash operations. The Wash Head Assembly is designed to wash 8 well strips (column) of a full or partial 8 x 12 microplate.

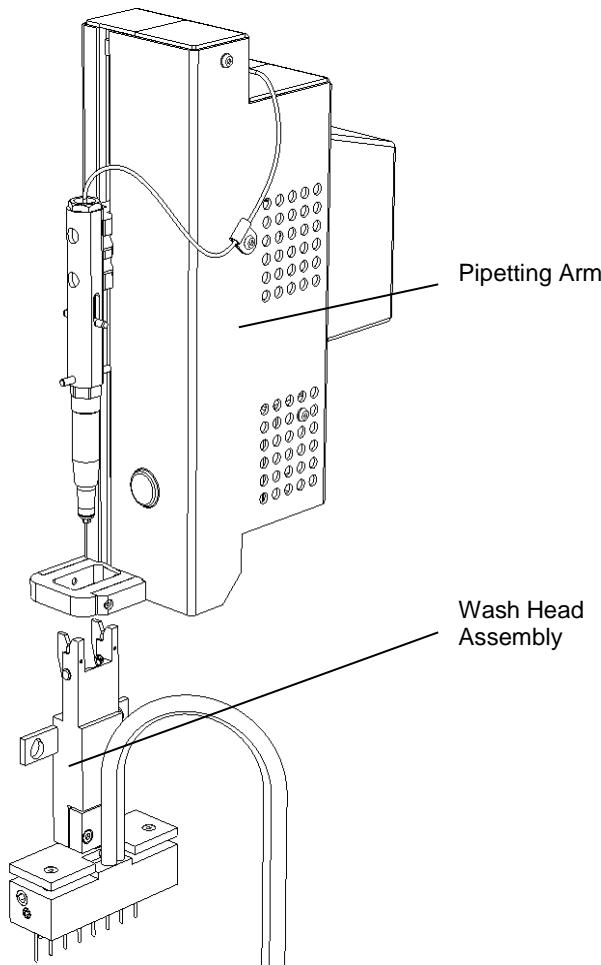


Figure 1-4: Pipetting Arm Picking Up the Wash Head Assembly

1.3.7 Wash Head

The Wash Head portion of the Wash Head Assembly contains two sets of pins. The shorter pins (the dispense pins) dispense fluid and the longer pins (the aspirate pins) aspirate fluid. The aspirate pins and the dispense pins are closely spaced so that fluid can be aspirated from and dispensed into wells of a microplate at the same time.

During operation, the Wash Head Assembly is automatically lowered to insert the pins into the microplate wells or raised to remove the pins from the wells. Lowering the Wash Head Assembly allows the aspiration of the well contents, or performing a wash cycle at the well bottom. Raising the Wash Head Assembly allows the movement of the wash head to another column for filling or washing.

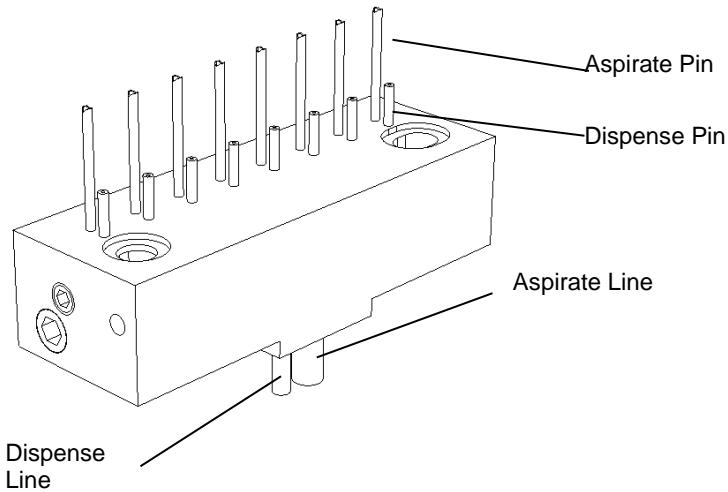


Figure 1-5: Wash Head with Wash Pins

1.3.8 Wash Buffer Containers

Different wash buffers may be placed in the two wash buffer containers (A and B) located at the front left of the instrument.

The maximum capacity of the wash buffer containers is 2 L. The wash buffer container must have a minimum of 500 mL of fluid for a wash operation to take place.

A Wash Buffer Fluid Level Sensor alerts the operator when the amount of wash buffer is insufficient.

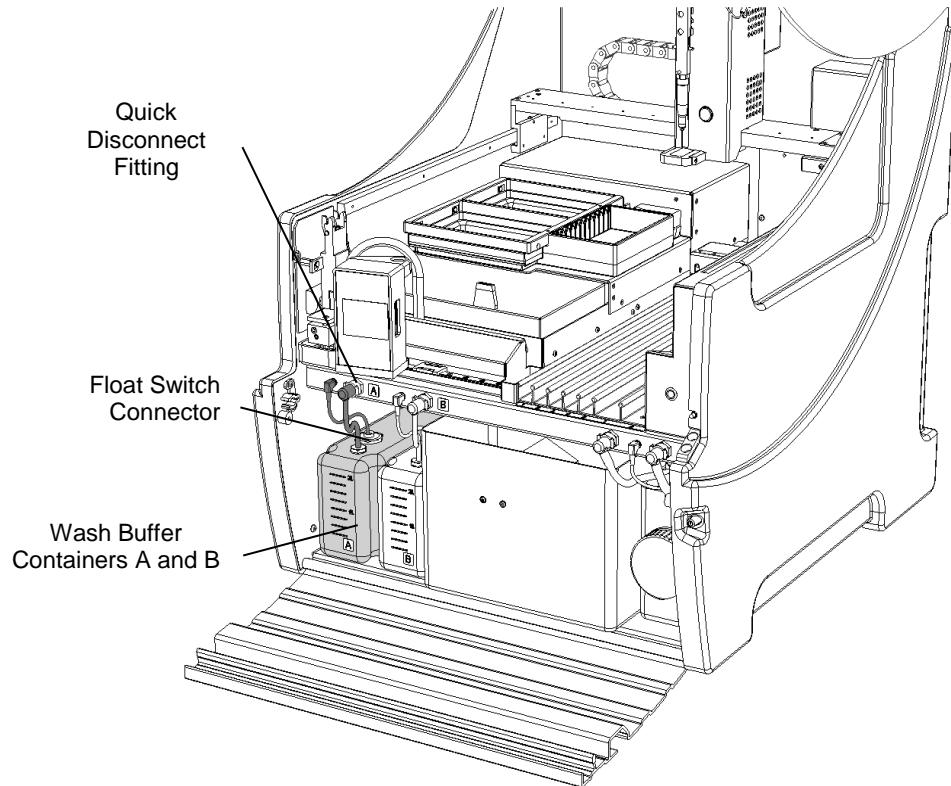


Figure 1-6: Wash Buffer Containers A and B

1.3.9 Wash Head Cleaning Fluid Container (Container C)

Distilled or deionized water may be used to clean the wash head after plate washing is complete. The user must program this step into the assay using the Assay Editor. A user supplied bottle (Container C) is attached to the rear of the DS2 using the supplied tubing. The supplied tubing is attached to the Quick Disconnect valve located at the right rear of the DS2. A level sensor does not exist for this container. The operator is responsible to verify sufficient liquid for performing assays.

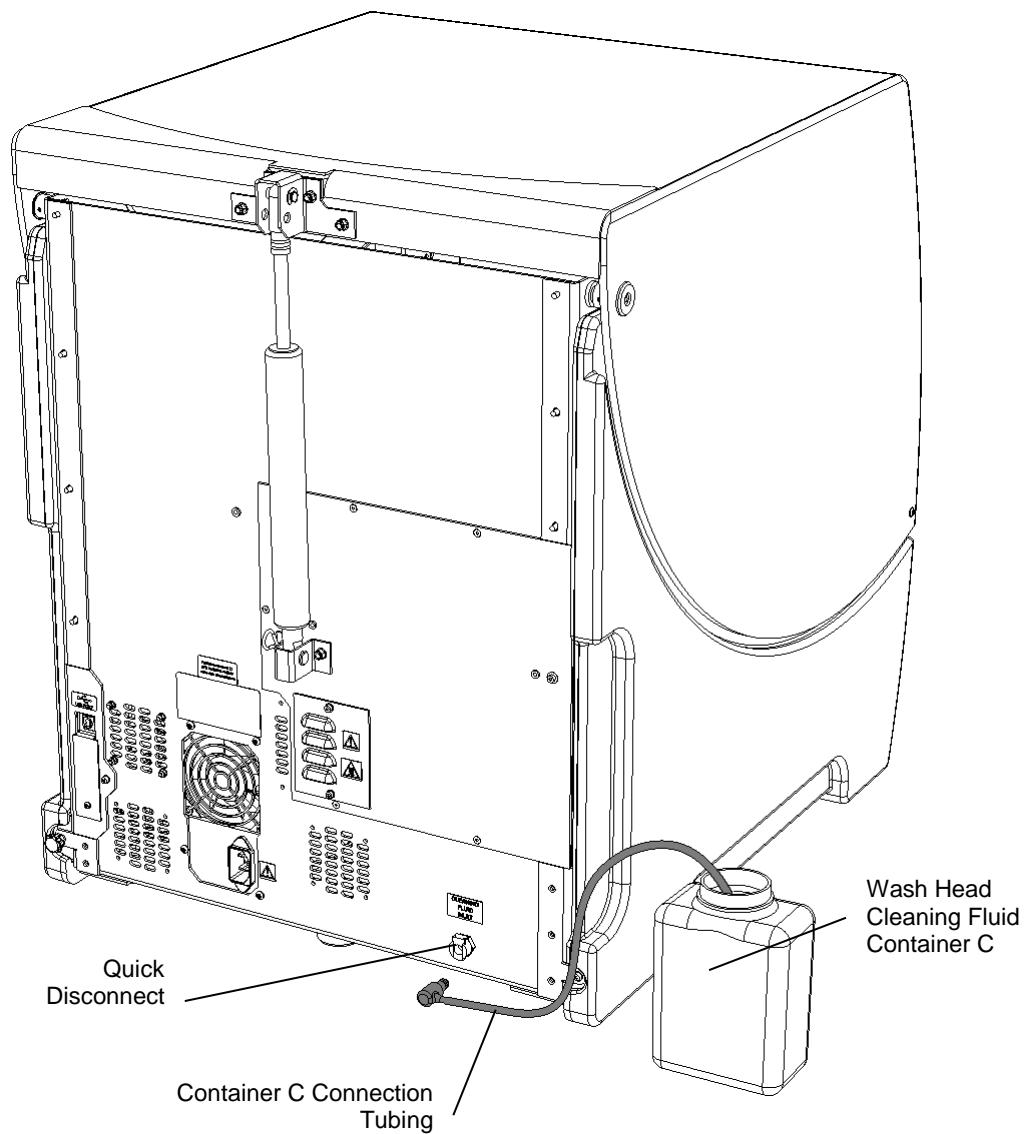


Figure 1-7: Wash Head Cleaning Fluid Container C

1.3.10 Waste Containers

Fluid that is used during wash operations is collected in the Liquid Waste Container. Used sample and reagent pipette tips are ejected into the Tip Waste Container. Both waste containers are located at the front of the instrument. The Tip Waste Container is not equipped with a sensor to indicate it is full.

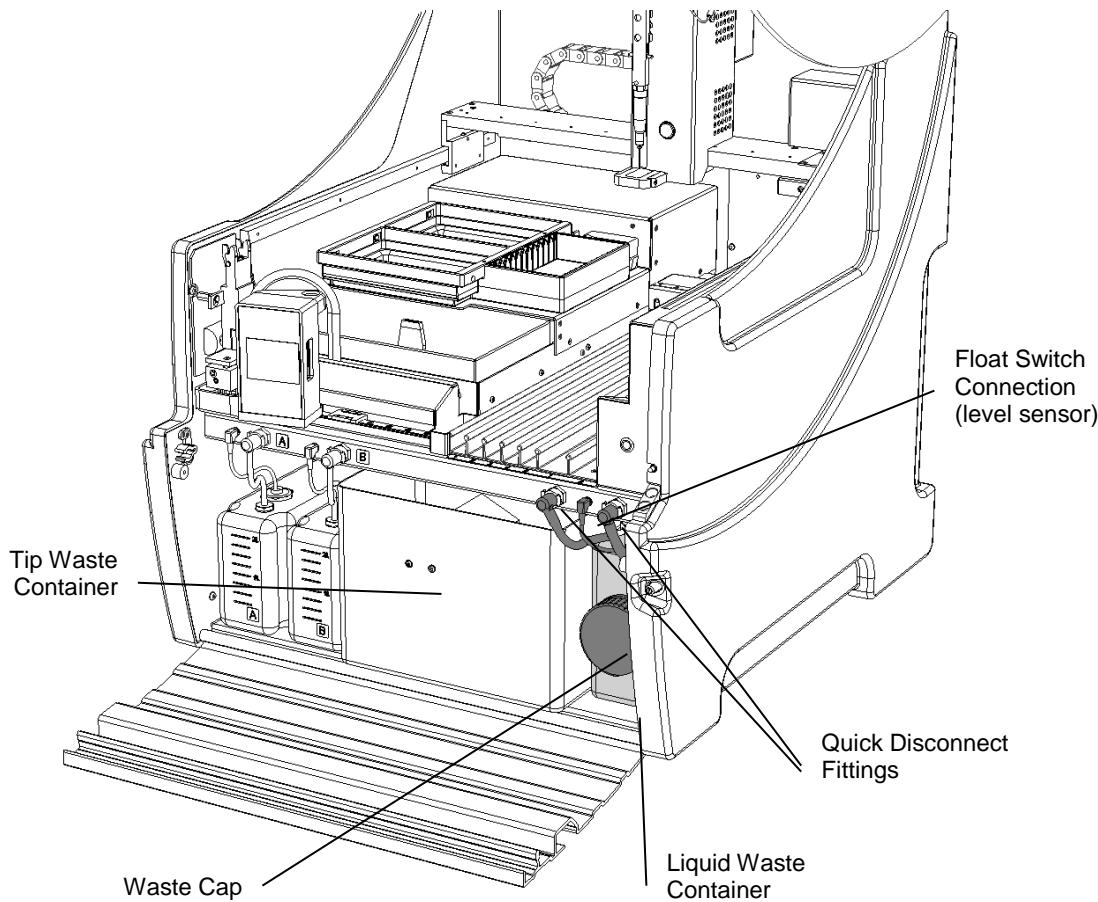


Figure 1-8: Waste Containers

The Liquid Waste Container holds up to two 2 L of waste. A Waste Fluid Level Sensor alerts the operator when the Liquid Waste Container is full and should be emptied.

There is an optional External Waste Trap for the DS2 (Product Number 13002610; See Figure 1-9). The External Waste Trap is designed for use with assays which have foamy wash buffer, to trap foam in the External Waste Trap that would otherwise enter the DS2 pump. Failure to install the External Waste Trap with certain assays may void warranty/service contract coverage for the DS2 pump.



Figure 1-9 DS2 External Waste Trap

1.3.11 Absorbance Module

The Absorbance Module measures the optical density (OD) of the microplate wells. The wavelength(s) at which the optical density is measured is specified when programming the assay.

1.3.12 Single and Dual Wavelength Modes

The DS2 Reader is able to take readings in two different wavelength modes:

- Single - using one analytical test wavelength
- Dual - using one reference wavelength and one analytical test wavelength

The single wavelength mode is sufficient for most applications.

1.3.12.1 Blanking

The Reader allows subtraction of a reference value from well ODs. Air is automatically used as a reference, but the absorbance of a reagent solution or empty well can also be subtracted from the test result. Blank wells may be single wells or an average of multiple wells.

1.4 Software Description

DS-Matrix software (also known as Matrix) is used to control the *DS2 Automated ELISA Processing System*. The software automates the sample distribution, incubation, reagent addition, and washing and detection steps of assays as defined by the user. The DS-Matrix software also provides the user interface for configuration of the DS2 and management of consumables.

The Matrix software includes assay definition options that allow the user to customize assay parameters, assay steps, OD reading settings, result calculations, quality control checks, and report formats.

1.5 Software Functions

1.5.1 DS2 Configuration

The following DS2 System parameters can be configured from the Tools menu: database maintenance, pipetting options, OD read limits, system configuration, Levey-Jennings assay parameters, absorbance filter selection, and user notifications.

1.5.2 Consumables Definitions

The DS-Matrix software stores parameters for all consumables and fluids used on the DS2 in a database. A consumable or fluid must be defined in the database before it can be selected for use in an assay.

The parameters for fluids and consumables that are stored in the database are summarized below:

Consumable	Parameters
<i>Bottles</i>	Dimensions, capacity, and shape of reagent and standard/control bottles, sample tubes, reagent tubes, microtiter plates, and deep well strips
<i>Plates</i>	Type, dimensions, well characteristics
<i>Neat Fluids</i> <i>(Sample and Reagent Fluids)</i>	Fluid name and type, pipetting profile, load settings (location, bottle type).
<i>Wash Fluids</i>	Fluid name and load position
<i>Tip Type</i>	Length, capacity, and maximum fill volume
<i>Rack Type</i>	Specifies sample and reagent rack definition
<i>Barcode Script</i>	Custom programming for use with Custom Racks

1.5.3 Assay Programming

The **Assay Editor** screen allows the user to program the sequence of pipetting, incubation, dispensing, washing, and reading operations performed on samples. Data reduction and reporting are also programmed using the Assay Editor screen.

1.5.4 Worklist Creation

The worklist defines the sample ID which corresponds to each sample tube and the assay(s) to be run on each sample tube. A worklist includes information for up to two microplates. More than one assay can be performed on a plate if the assays have the same incubation, washing, reading, and shaking specifications.

- **Note:** *An assay must be created before it can be assigned to a worklist.*

1.5.5 Worklist Execution

Once a worklist is created, the operator is prompted to load any samples, microplates and consumables that are required at the beginning of the run.

1.5.6 Data Analysis

The Optical Density results for each sample ID in the worklist are analyzed according to the criteria specified in the assay.

1.5.7 Results Reporting

The run report may be viewed, printed and transmitted when the assay is complete.

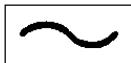
Transmitting results to a Laboratory Information System requires Dynex Technologies' LIS-Link software solution. The LIS-Link software version is dependent on the version of Matrix software utilized.

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Chapter 2 Safety

2.1 Warning Labels

The *DS2 Automated ELISA System* and its components contain labels that warn the user of a hazard or an electrical connection. The labels are described below. Potential personal injury to the operator or damage to the DS2 can result if the labels are not followed.

Label	Description
	Alternating current is present
	Caution symbol. Refer to the <i>Routine Maintenance</i> chapter
	Caution, motion hazard
	Caution, pinching or mechanical hazard
	Caution, hot surface
	Laser radiation – Do not stare into beam
	Protective conductor terminal
	Earth (ground) terminal
	Caution, risk of electric shock
	Caution, biohazard

2.2 Warnings and Safety Precautions

The following information aids in the safe and efficient use of the DS2.

In addition to the warning labels and other cautions previously described in this manual, consider the following:

1. Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging static discharges that may cause erroneous results.
2. It is the user's responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the device will perform as intended. The electromagnetic environment should be evaluated prior to operation of the DS2.
3. Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with proper operation.
4. If the DS2 is used in an unspecified manner, the protection provided by the equipment may be impaired.
5. Do not position the DS2 so that it is difficult to disconnect the DS2 from the power supply.
6. Do not use decontamination or cleaning agents that could cause a HAZARD as a result of reaction with parts of the equipment or with material contained in it. 70% isopropyl or ethyl alcohol as well as laboratory disinfectants containing quaternary ammonium sulfates are approved for use to clean and disinfect the DS2. Please contact your instrument provider if there is any doubt about the compatibility of decontamination or cleaning agents with the DS2. **Use of bleach is not recommended as it will damage components and interfere with assay performance.**
7. The DS2 is tested and compliant to IEC 61326-1:2005 & IEC 61326-2-6:2005 standard for Electrical equipment for measurement, control and laboratory use with particular requirements for in-vitro diagnostic devices
8. All parts and accessories of DS2 are required to be examined or supplied only by the manufacturer or its partners. The sample and reagent pipette tips are defined as accessories. Only the DYNEX tips have been found to meet the stated precision and accuracy specifications. **Use of off-brand tips may void warranties and parts of service agreements.**
9. This equipment has been designed and tested to CISPR11, Class A. In a domestic environment it may cause radio interference, in which case you may need to take measures to mitigate the interference.
10. Appropriate precautions must be taken when working with biohazards. Technicians must be trained in the safe handling and cleanup of potential blood borne pathogens. Universal precautions, appropriate hygiene, and decontamination of surfaces are recommended. Consult the reagent kit manufacturer for precautions on handling potentially hazardous substances.

11. Appropriate personal safety precautions must be made when opening and closing the DS2 cover. A gas spring holds the tension to keep the cover open. The DS2 cover should be able to be opened 8 inches (approximately 203mm) without falling. If the cover drops instantly above this height then the gas spring should be replaced. The cover may creep down slowly from this point due to the nature of gas springs and this is acceptable. Gas springs will inevitably lose pressure depending on frequency of use, so it is important for the user to take note if the cover begins to give way over time and notify the service provider of this circumstance. As a safety precaution, the user is responsible to do this check monthly.
12. When the cover is up and the run has started, do not encroach upon the work area unless prompted by the software for user input of materials or manual intervention.
13. Attend to error messages when the system prompts and stops. These messages indicate a need for user action.
14. Sample tubes must be pushed down in the sample racks to prevent the pipette module from being obstructed.
15. Place the sample and reagent racks securely onto the DS2. Push the rack firmly towards the back of the DS2 so that the rack clicks in place.
16. Periodically inspect the sample rack springs to ensure proper tube alignment. Replace the springs as necessary.
17. Barcode quality is critical to successful sample tube barcode scanning. Scanning is in accordance with ASTM E1466-92 defining barcode quality, position, and orientation of barcode labels. The use of non-standard barcodes or barcodes with poor print quality may be problematic. Barcode labels should be applied using a vertical orientation. The barcode label should be oriented so that it faces out of the opening in the sample rack.
18. Periodic back up of assay and data files is recommended. Copy the files to a disk for storage or archive the data on a secure server
19. Changes made to assay files may impact the suitability and plotting of data using the Levey-Jennings control-charting feature.

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Chapter 3 Installation

3.1 Unpacking

3.1.1 Packing List for DS2 Installation

(DYNEX Part Number 62000)

P/N	Description	Qty
13500010	DS2 Automated Instrument	1
50600167	USB Cable	1
N/A	Power Cord (dependent upon order request configuration)	1
352101800	Cleaning Wire, 0.018 " (Dispense)	2
352104000	Cleaning Wire, 0.040 " (Aspirate)	2
62800-113	CD Containing Matrix Software Setup (numbers after the hyphen may change depending on the current version)	1
62820-03	DS2 Toolbox CD (numbers after the hyphen may change depending on the current version)	1
91000200	DS2 Operator's Manual (this document)	1
92000040	CD Containing DS2 Operator's Manual	1
N/A	Instrument Configuration Report (Check List)	1
13500560	Wash Buffer Container	2
13500430	Liquid Waste Container	1
13500770	Tip Waste Container	1
24900065	Reagent Rack	2
13500501	Sample Rack	5
13500100	8-Way Wash Head Assembly	1
24900081	Purge Tray, Wash Head	1
22500810	Transit Bracket	1
DS2FIX017	Calibration Tool	1
DS2FIX029	Calibration Collar	1
65910	Sample Tips (Four Racks of 108)	1

65921 or 65920 (Partial)	Reagent Tips (One Rack of 108) <i>Part numbers have equivalent function and either may be used and packed at the discretion of Dynex Technologies.</i> <i>(Standard for Part No. 65921: Four Racks)</i>	1
62910 (Partial)	Deep Well Strips (Sample Pack: 12 Strips) <i>(Standard for Part No. 62910: 250 Strips)</i>	1
62920	Reagent Tubes, 25 mL (Pack of 10)	1
62930	Reagent Tubes, 15 mL (Pack of 10)	1
65940	Control Vials (Pack of 33)	1
394000100	Purge Tray, Wash Calibration	5
42000810	Hex Key, 2mm	1
816400700	Tubing, 3mm x 5mm	1 (Meter)
43000491	Elbow Fitting	1
DSFIX044	DS2 Calibration Plate	1
42000070	Hex Key, 2.5mm	1
42000830	Hex Key, 4mm	1
9055720009	Warranty Card	1
N/A	Declaration of Conformity	1
N/A	Customer Installation Report	1

3.1.2 Unpacking the Components

► **IMPORTANT:** *These installation procedures are intended for trained personnel*

Unpacking the Components:

1. Cut open the lid of the cardboard carton containing the DS2.
2. Remove the Accessory box and packing materials, including the foam inserts and wooden supports from the box.
3. Obtain a wheeled cart or lift capable of holding the weight of the DS2. Remove the crate clips holding the top of the carton to the bottom of the carton. The clips can be removed by squeezing the two white grips together and lifting upward. They are located around the base of the box. Once all the clips are removed, lift the top of the cardboard carton off the base. Unwrap the DS2 from the plastic bag and lift the DS2 onto the cart.



CAUTION: *The contents of the crate are heavy. Two people are required to lift the DS2 safely. The DS2 should be lifted from the bottom of the instrument. Do not use the cover handle or the plastic molded sides to lift the DS2.*

4. Place the DS2 near the bench or table where it will be located.
5. Examine the packaging to verify that all of the materials listed in the packing list have been removed. Store the packaging material for future use.
6. Inspect the DS2 and its components for damage. If damage is observed, contact your shipper or service representative.

Positioning the Instrument:

1. Determine where the DS2 will be located. The bench space requirement for the *DS2 Automated ELISA System* is approximately:
 - 54 cm (21.3 inches) wide
 - 75 cm (29.5 inches) deep
 - 110 cm (43.3 inches) high, with the cover open
2. The DS2 must be positioned on a sturdy level surface that does not support other devices that produce vibration (centrifuges, shaker bath, etc.).

3. If the instrument may be used with the cover up, avoid positions that allow the instrument to be subjected to direct sunlight or strong internal lighting. This will interfere with tip sensing and barcode reading.
4. There must be at least 25 cm (9.75 inches) clearance at the rear of the DS2.
5. Additional considerations must be made for the customer supplied Wash Head Cleaning Fluid Container C as well as the External Waste Container (optional equipment).

3.2 Connecting the Computer System

3.2.1 Computer Minimum Specifications

The computer system that is used for operation of the DS2 Automated ELISA Processing System must meet the following minimum specifications:

Windows 7 Requirements:

- 1) Intel Core/Core2/Pentium/Celeron family or compatible processor recommended
- 2) 2 GHz or higher processor clock speed recommended; 1.8 GHz minimum required
- 3) 10 GB or larger hard drive with at least 100 MB of free space
- 4) Microsoft® Windows® 7 Professional operating system (32- or 64-bit)
- 5) Microsoft® Windows® compatible display adapter (card or built into motherboard) with 32-bit color (Highest setting) at 1024x768 or more pixel resolution
- 6) 4 gigabyte (GB) of random-access memory (RAM)
- 7) One unused USB port is required for connecting the computer to the DS2 Automated ELISA System
- 8) Mouse or other pointing device supported by Windows®
- 9) Microsoft® Windows® compatible CD-ROM or DVD Drive
- 10) Microsoft® Windows® compatible printer (color recommended) and sound card.
- 11) Network/LAN connection, 10/100 network interface (Optional)
- 12) Serial Port (Optional for LIS interfacing)

Windows 8.1 Requirements:

- 1) Processor: 1 gigahertz (GHz) or faster with support for PAE, NX, and SSE2
- 2) RAM: 1 gigabyte (GB) (32-bit) or 2 GB (64-bit)
- 3) Hard disk space: 16 GB (32-bit) or 20 GB (64-bit)
- 4) Graphics card: Microsoft DirectX 9 graphics device with WDDM driver

3.2.2 Connecting the Computer

Connecting the Computer System:

1. Place the computer, mouse, keyboard, monitor, and printer next to the DS2.
2. Plug the USB communication cable into an unused USB port on the computer.

► **Note:** Refer to the instructions accompanying the computer for the location of the ports and for information on connecting components.

3. Plug the other end of the USB communication cable into the USB port on the right rear side of the instrument. **Only the USB cable that ships with the DS2 should be used to connect the DS2 to the computer.** Use of other cables could result in software freezes and loss of runs.
4. Connect the keyboard, monitor, and printer cables to the computer.
5. Connect the power cords to the computer, monitor, and printer.

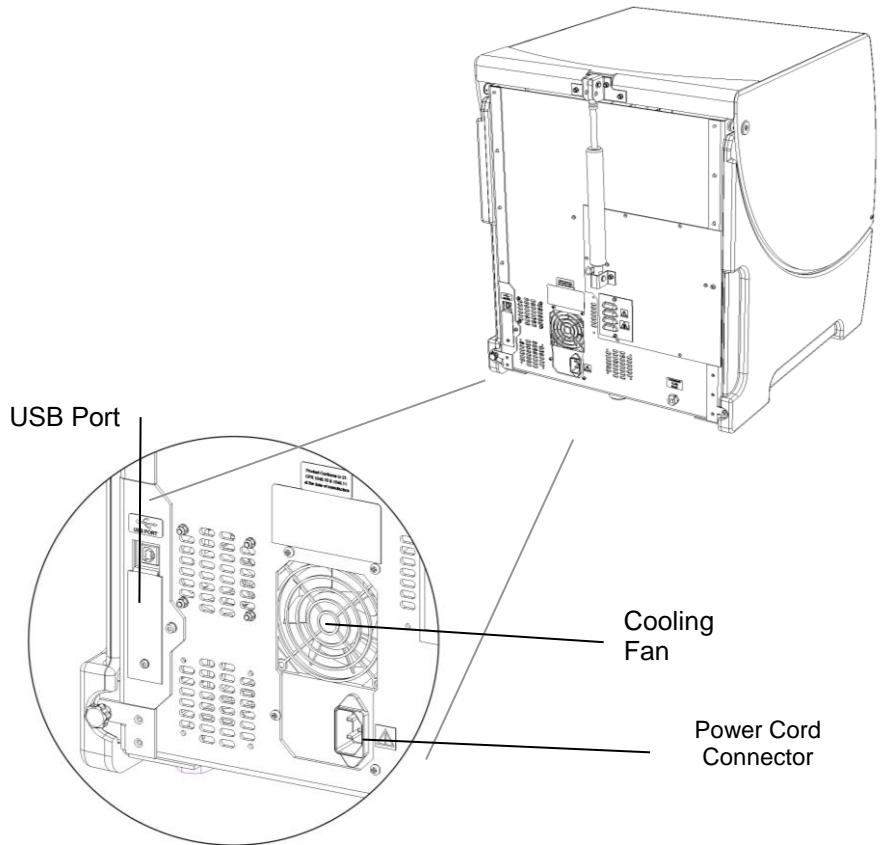


Figure 3-1: View of the Rear of the DS2 Automated ELISA System

3.3 Connecting the DS2 Power Cord

The power cord connection to the DS2 is located in the rear of the system.

- ▶ **Note:** Depending upon local electrical codes and electrical service quality, an optional uninterruptible power supply (UPS) may be required in your laboratory. The use of a UPS is optional but strongly recommended. A UPS may be purchased from Dynex Technologies.



CAUTION: The DS2 System must be connected to a properly grounded electrical outlet. Obtain assistance from a qualified electrician to verify that your electrical outlet is properly grounded.

Before connecting the power cable, be sure that the components have been connected to each other as outlined in the previous section.

Connecting the Power Cord:

1. Plug the power cord into the connector at the rear of the instrument.
2. Connect the other end of the power cord to the laboratory electrical supply outlet or UPS if available.

3.4 Dongle Installation

The use of a dongle will be needed to unlock certain features in future versions of software. The locking of feature(s) provides accountability to Dynex on which customers are using the feature(s). It also ensures that customers have been trained on how to properly use any new features.

To use the dongle license, simply insert the dongle into a valid USB port on your computer. You can tell the dongle is working properly if a static red LED lights up on the dongle like this:



Figure 3-2 Dongle Red LED Light

3.5 Installation of DS-Matrix™ Software

Installation Instructions

1. Insert the installation CD into the CD ROM. The InstallShield® Wizard for Matrix starts automatically.
 - ▶ *Note: If the InstallShield wizard does not start automatically, select Start and then Run from the Windows task bar.*
In the Run dialog box, browse to the CD ROM drive, select setup.exe, click Open, and then click OK.
2. Click **Next** and follow the wizard instructions.
3. **InstallShield Wizard Complete** is displayed when the installation is done. Click **Finish** and remove the installation CD from the CD ROM.
4. Access Matrix software from the Windows program group: **Dynex Technologies > DS-Matrix > DS-Matrix**.

- **Note:** A printer driver must be installed for reports to be printed using the Matrix software.

3.5.1 Creating a Shortcut on the Desktop

A shortcut should automatically be created during installation. In the event it is not, follow the instructions below:

To place a Matrix shortcut icon on your computer desktop:

1. Open Microsoft Windows Explorer.
2. Locate the Matrix program:
C:\Program Files\Dynex Technologies\DS-Matrix.
3. Click **MatrixApp (.exe)** to highlight it.
4. Select **File > Create Shortcut** from the Windows menu toolbar.
5. Resize the window so the desktop and window are both visible.
6. Drag the shortcut matrixapp.exe to the desktop.
7. Close Microsoft Windows Explorer.

3.6 Starting the System



CAUTION: Before starting the system, be sure that all racks are properly seated and that the lids are removed from all tubes, plates, and sample tip racks.



CAUTION: Power is on to the system whenever the blue indicator on the DS2 is illuminated.

- **Note:** The DS2 and DS-Matrix software must be shut-down once every twenty-four hours to ensure proper DS2 performance.

Starting the DS2 System

1. Power on the DS2 System pressing the power switch as seen in Figure 1.
2. If not powered on, power ON the computer, monitor, and printer.
3. A “Found New Hardware” wizard may appear as the computer recognizes the DS2. The new hardware wizard must be completed prior to attempting to connect to the DS2 via the DS-Matrix software.
4. Double-click the **DS- Matrix** shortcut icon to present the Run Mode dialog box.

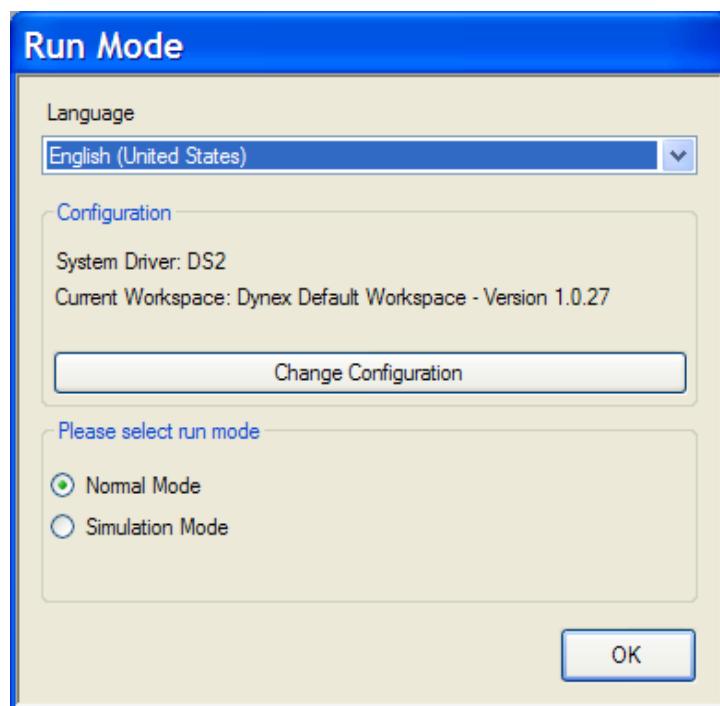


Figure 3-3: Matrix DS2 Run Mode Dialog Box

Select the desired language from the drop down list.

5. Ensure the desired workspace configuration is selected. If the Current Workspace is not the desired workspace configuration, click the **Change Configuration** button.
 - a. The **Choose Configuration To Use** dialog box appears. Select the desired **Workspace Definition** from the drop down list and click **OK**.

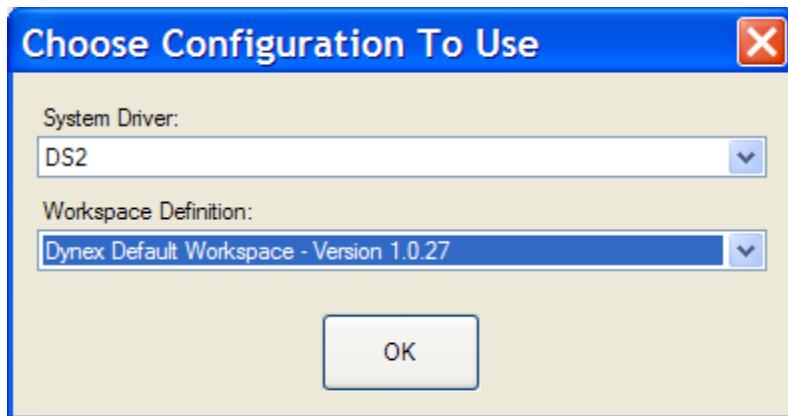


Figure 3-4: Choose Configuration Dialog Box

6. Select the run mode. Select **Normal Mode** to operate the DS2 System. Select **Simulation Mode** to operate the software without connecting to the DS2.
7. The DS2 performs a series of self tests before the instrument is available for running an assay (Section 3.6).

3.7 Initialization

The DS2 will perform a series of initializations before it is ready to start a run, including picking up the wash head assembly, opening and closing the incubator door, and moving the microplate carrier to and from the incubation and reader chambers.



CAUTION: Do not interrupt the DS2 while it is performing the initialization procedure.

A self test report is displayed following the initialization procedure. The self test report must be closed for the DS-Matrix software to finish its initialization. Following initialization, the main DS-Matrix screen is displayed.

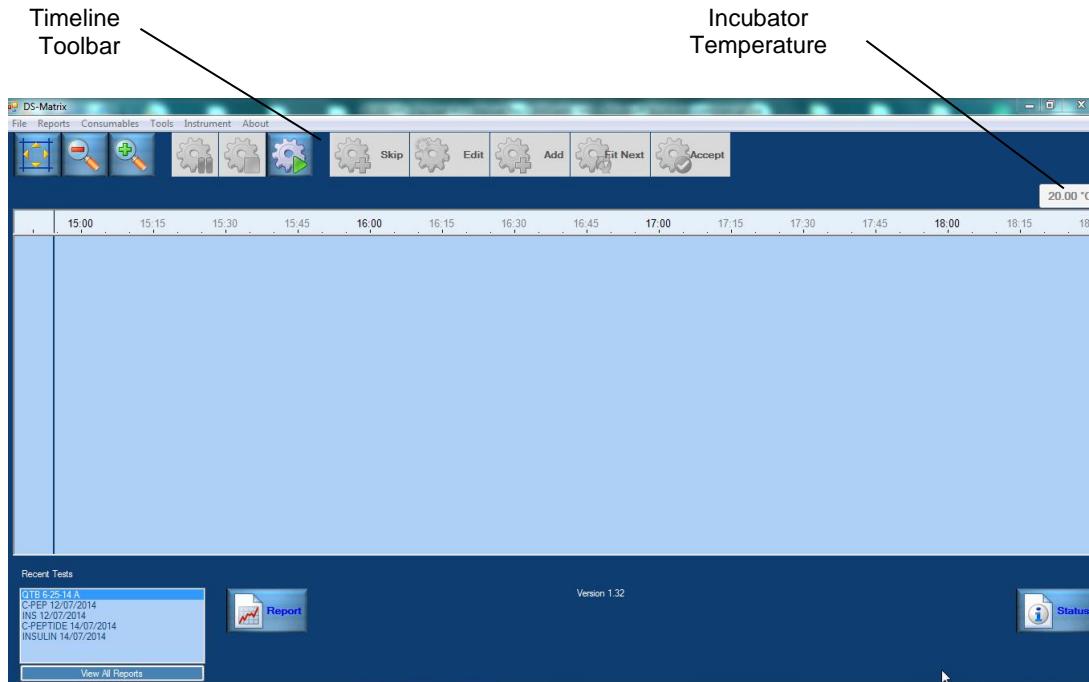


Figure 3-5: Main Runtime Screen

The Timeline toolbar contains icons for starting and stopping the run, changing the display, and setting run options. Certain functions may not be available depending upon the run status.

Chapter 4 Setting System Parameters

4.1 Overview

The DS2 Matrix software contains a set of system parameters that are set globally for all assays. These parameters can be found in the **Tools** menu, and are listed below:

- Database Maintenance
- System Configuration
- User Notification
- Absorbance Filter
- Import/Export
- Reset Auto Recovery
- View Event Log
- Levey-Jennings Criteria
- ESP Calibration
- Fluid Level Tracking

4.2 Database Maintenance

The DS-Matrix software database includes a description of all consumables (plates, racks, and tips) and fluids (reagent controls, standards, wash buffers, stop solutions, substrates, etc.) used on the DS2. A consumable or fluid must be defined in the database in order for it to be available for selection from a drop-down list when creating or editing an assay.

Editing Parameters for Consumables

- ▶ **Note:** Factory provided settings are read-only and cannot be modified. Settings can be duplicated by copying a consumable or fluid and saving the settings under a different name.
- ▶ **IMPORTANT:** It is the burden of the user to perform appropriate validation of any consumable parameters to ensure proper assay performance. Factory defined consumable settings will not necessarily work with all consumables.

See Appendix E for defining a new tube and Appendix F for defining a new plate.

1. Select **Tools > Database Maintenance** from the menu bar.
2. Select the appropriate consumable category using the drop-down menu to present the Database Maintenance Screen (Figure 4-1). The Database Types are:
 - BottleType, PlateType, NeatFluid
 - WasherFluid, TipType, RackType, Barcode Scripts

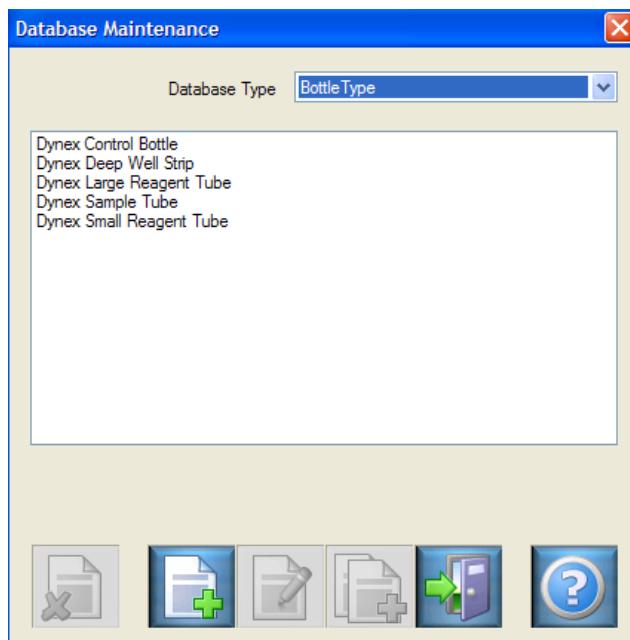


Figure 4-1: Database Maintenance Screen

3. To update an existing definition, highlight the desired consumable and click the **Edit** button (Figure 4-2). Factory defined consumables are read-only and cannot be edited.
4. Definitions may be changed by editing the values in the text boxes.
5. Click **Save** to save the new parameters.

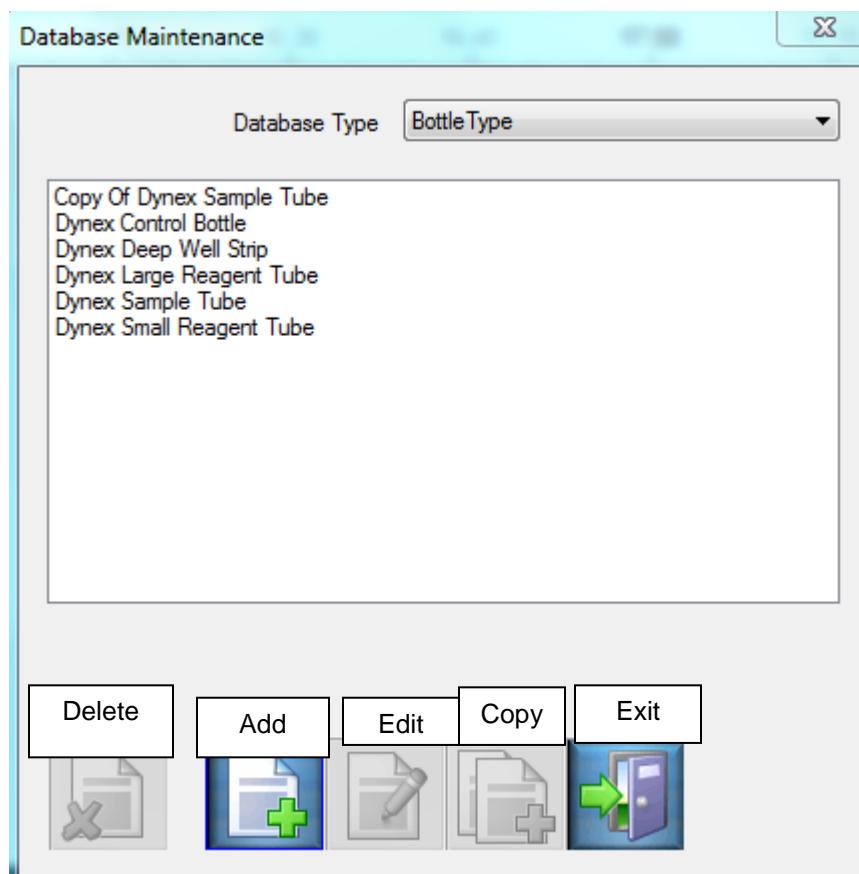


Figure 4-2: Database Maintenance Screen – Button Definitions

Adding a Consumable

1. Click on the **Add** button (Figure 4-2), enter the consumable name and click **OK**.
 - a. Consumables from the same assay should have a similar beginning to the name so that they are grouped together in the drop down list. This will make fluids easier to locate when writing assays and easier for the customer to identify when loading fluids. For example:
 1. Lyme Substrate
 2. Lyme Positive Control
 3. Lyme Cutoff Calibrator
 - b. If fluids are used universally across many assays they may be given a generic name, such as the name of the kit manufacturer. For example:
 1. Dynex Wash Buffer
 2. Dynex Stop Solution
 3. Dynex Substrate Solution
 - c. Once the consumable name is entered, the data entry window opens (Figure 4-3 presents an example). Enter the required parameters.

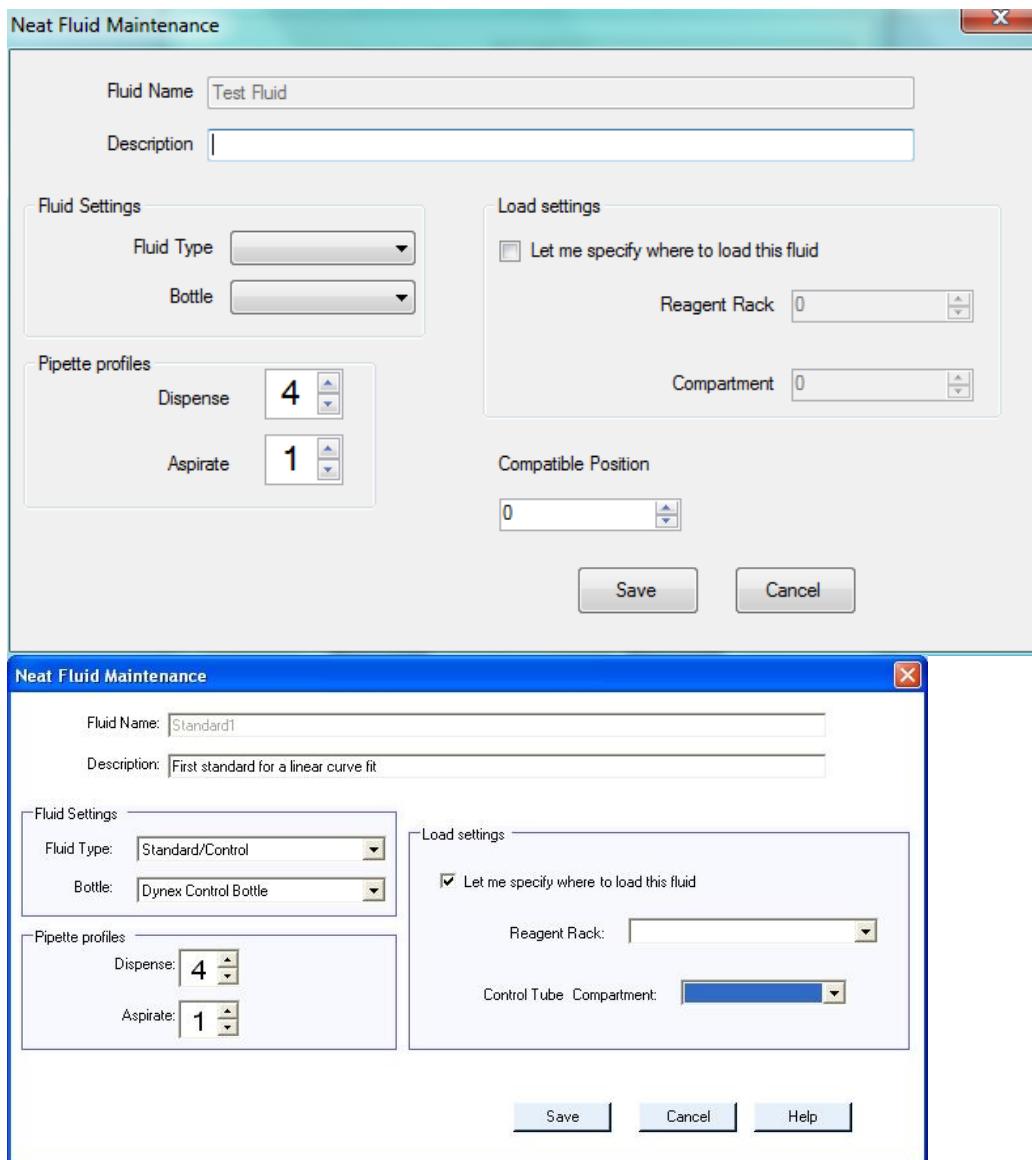


Figure 4-3: Neat Fluid Addition Screen

3. Click **Save**. The new consumable will be added to the database for selection from the drop down list.
4. To edit a consumable, highlight the desired consumable and click the **Edit** button (Figure 4-1). Change the desired parameters, and save the changes.
5. To copy a consumable, click the **Copy** button (Figure 4-1). Copied consumables must be saved under a different name.
6. When finished editing the consumables database, click the **EXIT** button (Figure 4-1).

4.3 System Configuration

System configuration parameters are universal for every assay that is run on the DS2. Changing any of the parameters on the System Configuration screen will update the parameters used for every assay.

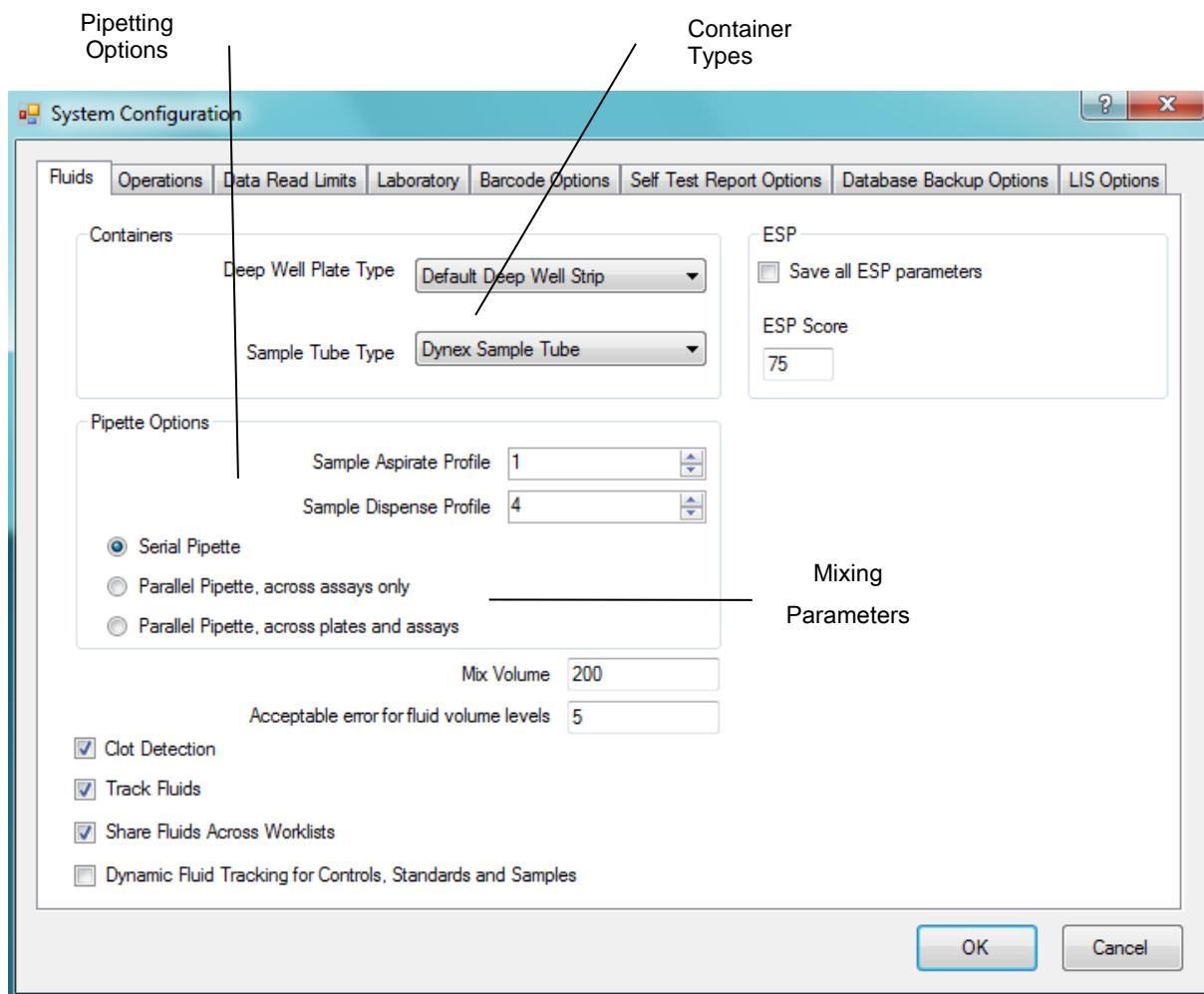


Figure 4-4: System Configuration Fluids Screen

Defining System Configuration Fluids Parameters

1. Select **Tools > System Configuration** from the main Matrix screen. The window opens to the **Fluids** tab.
2. The **Deep Well Strip** type and **Sample Tube** type that will be used on the system are set to the default types. The **Deep Well Strip** type should not be changed by the user unless instructed to do so by Dynex personnel.
3. **Mix Volume** (μL) is the amount of fluid that will be aspirated and dispensed into a deep well strip to mix the sample during dilution steps. If using a smaller dilution volume, the mix volume should be changed accordingly to avoid bubbles. Changing this setting will change the mix volume for all assays.
4. **Acceptable error for fluid volume levels** (μL) provides a range of tolerance for volume when performing fluid level tracking on a new bottle type. For example if the maximum volume in the bottle definition is 2000 μL , then a value of 5 in the **Acceptable Error for fluid volume levels** text box indicates that the software indicates the expected weight range as within $\pm 5\%$ of the expected volume.
5. By enabling the **Clot Detection** check box, the system will alert the user if a clot (which prevents aspiration) is detected. Clot detection will not alert the user if subtle fluid aspiration changes occur.
6. **Track Fluids** controls how Matrix treats live bottle information. By enabling **Track Fluids**, the software will remember rack locations already assigned to fluids when scheduling. If this option is disabled, a fluid location will be free once the required volume for the fluid reaches 0 μL .
7. **Share Fluids Across Worklists** is intended to prevent mixing fluids from different kit lots. By enabling **Share Fluids Across Worklists**, the system will allow fluids used in previous worklists to be used on the current worklist. If more fluid is required to run the new worklist, the software will ask the user to add more fluid to the bottle in its current location. If the option is disabled, the software will always request new fluids for a worklist. The software will not use fluids already loaded on the system and will not request users to add fluid to existing bottles. New bottles will be used.
8. **Dynamic Fluid Tracking for Controls, Standards and Samples** is intended to prevent false level detects when using bubbly fluids. When this option is disabled (unchecked) the system will level detect in a control, standard, or sample each time a new pipette tip is used. **If this option is enabled (checked), the system will only level detect each fluid once per worklist.**
9. Enable the **Save all ESP (Electronic Signature Pipetting) parameters** option to create an ESP calibration profile for each fluid in the system. This option allows users with engineering capabilities to monitor fluid aspirations and dispenses for uniformity. Statistics generated by this feature can only be viewed in engineering mode.
10. The **ESP score** is also used in engineering mode. The ESP score defines the passing calibration score for all fluids when monitoring the ESP calibration data. Ramp times, pipetting speeds and pressures are all taken into account when calculating the ESP score.

Specifying Pipetting Options

1. The aspirate and dispense profiles specify the rate at which the samples are aspirated or dispensed from the pipette tip. Only sample aspirate and dispense speeds are specified in system configuration on the fluids tab. The higher the number, the faster the rate of the aspiration or dispense, therefore use caution when setting these profiles. At a higher velocity bubbles or aerosols may occur which can affect the accuracy and precision of an assay. These settings are global and will be applied to all sample types used on the DS2.



Note: For any pipetting device, fluid properties such as viscosity and surface tension can influence the aspirate and dispense accuracy. DYNEX Technologies calibrates and verifies all pipettes using an aqueous calibration fluid which, when used with a special calibration apparatus, provides traceability to a NIST standard and gravimetric method.



It is the burden of the user to perform the validation studies necessary to assure proper assay performance.

2. Serial vs. Parallel Pipetting: If the same sample is used on multiple plates or within multiple assays on the same plate, the user can choose to pipette the samples serially or in parallel. Serial pipetting pipettes all samples and controls in the specified well order, starting with well A1 and pipetting down columns to well H12 (unless the pipetting order dictates differently (see the pipetting operation section of the assay editor section). The “Parallel Pipette, across assays only” option will pipette a sample into all assigned wells on plate 1 before pipetting the next sample. Once plate 1 has been completely pipetted, the samples will be pipetted in the same manner on Plate 2. The “Parallel Pipette, across plates and assays” option will pipette a sample into all assigned wells on Plate 1 and Plate 2 prior to pipetting the next sample. Matrix selects serial pipetting by default.

Defining System Configuration Operations Parameters:

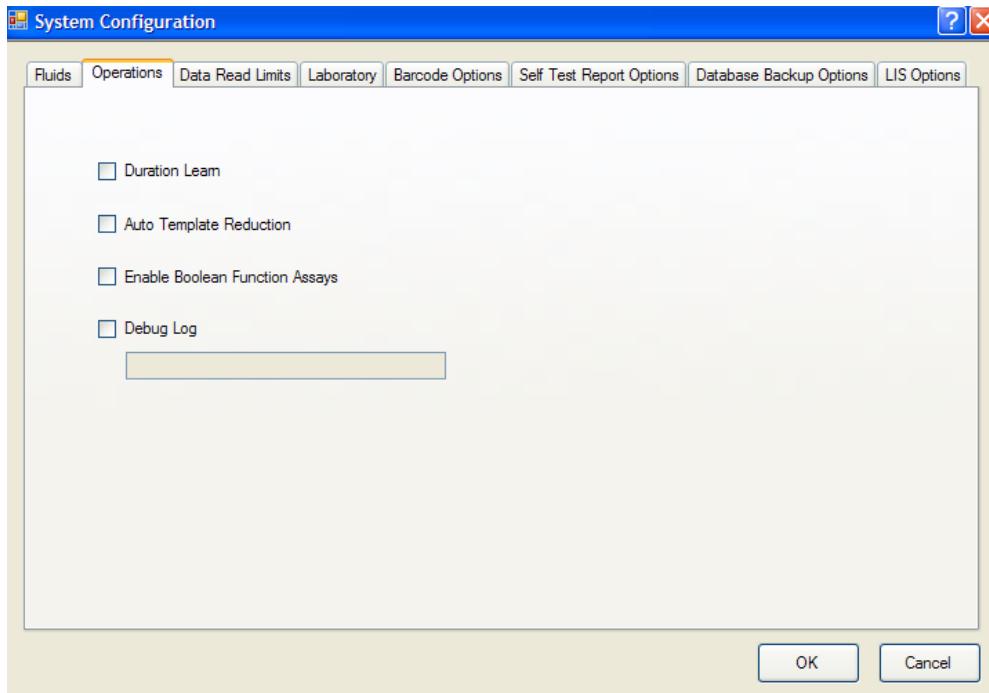


Figure 4-5: System Configuration - Operations Tab

1. Enable the **Duration Learn** feature by checking the check box.
 - a. When the **Duration Learn** feature is enabled (the check box is checked), the DS2 will collect timing information on individual runs in order to improve timing estimates when scheduling assay steps.
 - b. **Duration Learn** should not be used during assay development and validation. **Duration Learn** should only be used once assays are in their final configuration.

2. Enable **Auto Template Reduction** by checking the check box. **Auto Template Reduction** allows the user to define control or calibrator wells at the end of the assay template and have those controls or calibrators pipetted following the last specimen well, instead of being pipetted into the wells exactly as depicted in the template. For an example, please refer to the assay template pictured in Figure 4-6.

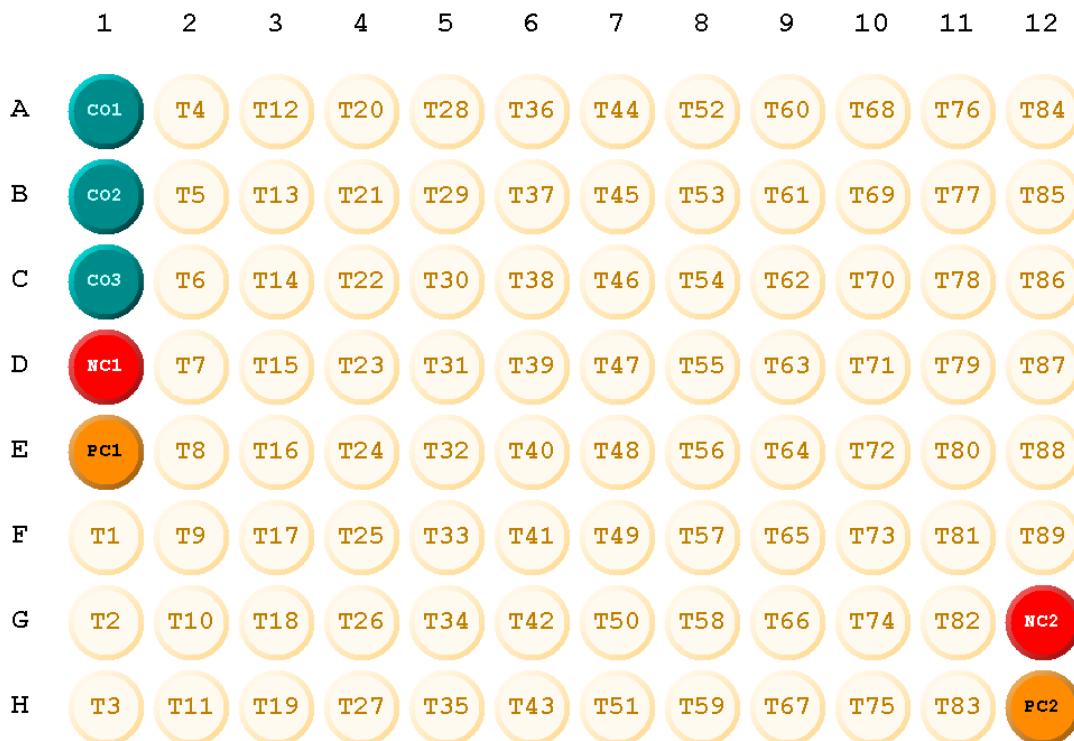


Figure 4-6: Microplate Pipetting Template with Controls

In this example, we assume that 3 samples will be run on this assay in the worklist defined by the user. If **Auto Template Reduction** is enabled, the wells NC2 and PC2 would be pipetted into the first available wells (A2 and B2). If **Auto Template Reduction** is not enabled, the NC2 and PC2 wells will be pipetted in G12 and H12. All other wells in column 12 will remain empty, as will wells in columns 2-11.

3. Enable the **Enable Boolean Function Assays** option by checking the check box. This option enables spreadsheet functionality necessary to perform data reduction for certain unique assays. Contact Dynex Technologies Technical Support for more information on this functionality.
4. Enable the **Debug Log** by checking the check box.
- The **Debug Log** is used to determine the root cause of a system crash. Dynex recommends that this feature be enabled (check box is checked) so better technical assistance can be provided.

Defining System Configuration Data Read Limits:

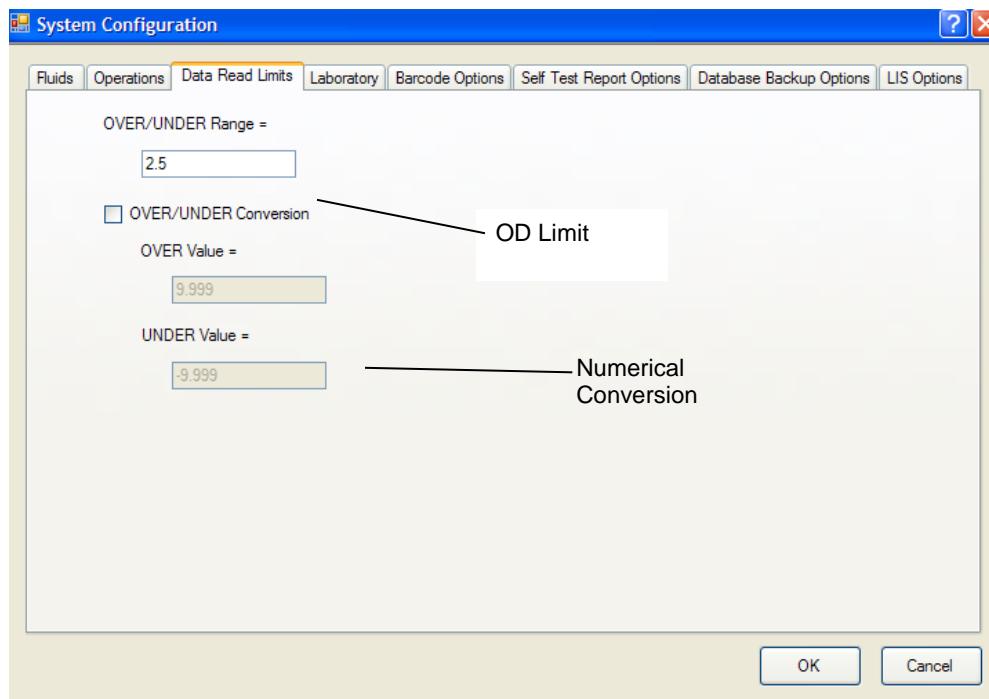


Figure 4-7: Over / Under OD Conversion

1. Set the OD OVER/UNDER Range for plate data results. The OVER/UNDER Range indicates the highest allowable OD to be reported. The reader is accurate between 0 to 3 OD (2.5 OD if reading for a quantitative assay). If a value is over the specified over range or below 0, no result for the sample will be reported and “*****” will appear as the OD result for the sample.
2. When the OVER/UNDER Conversion option is enabled (the check box is checked), any values over or under the specified detection limit will be changed to reflect the values specified in the OVER Value and UNDER Value text boxes. Therefore, an OD result will appear on the report and a result can be calculated for the sample. The values in the Over Value and Under Value text boxes are user configurable.

Defining System Configuration Laboratory Information:

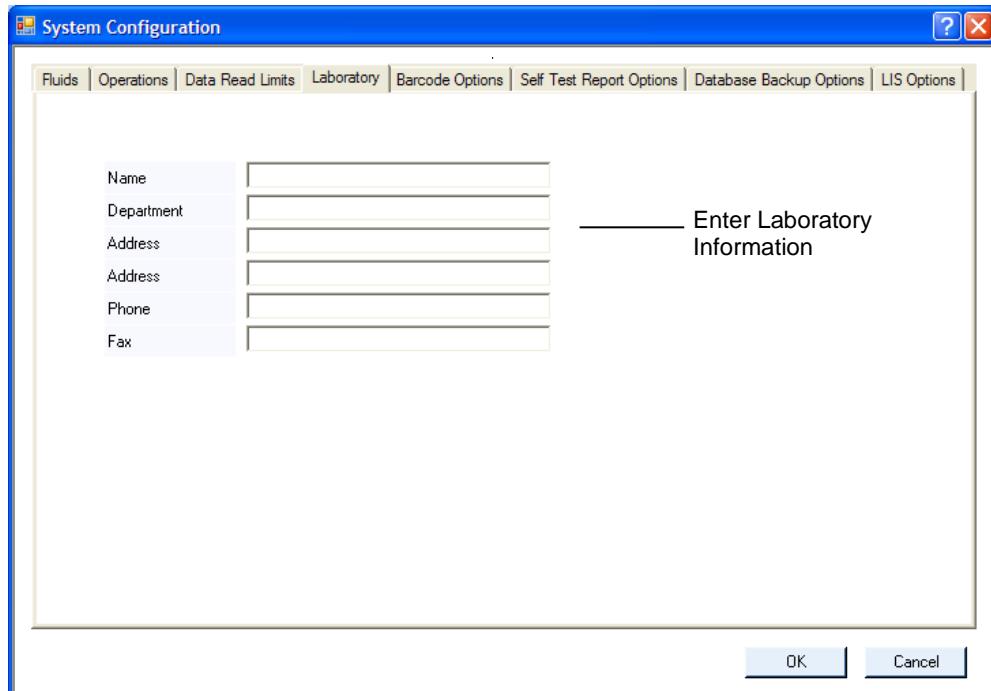


Figure 4-8: Laboratory Information Entry

1. Enter the desired laboratory information into the designated information fields. This information will be automatically inserted into assay reports if the user has configured the report to contain laboratory information.

Defining System Barcodes:

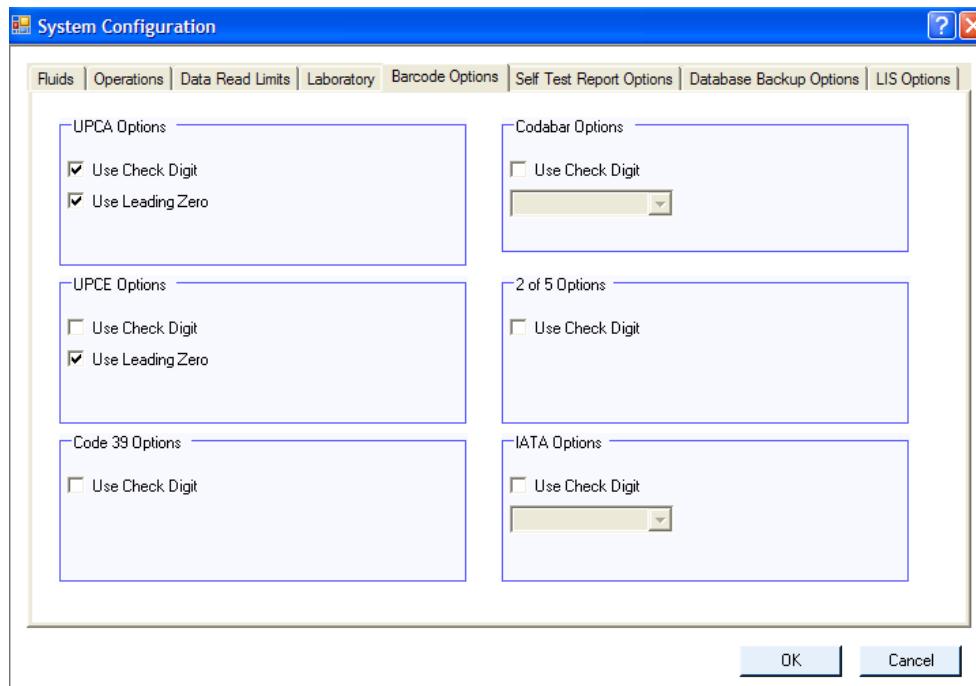


Figure 4-9: Barcode Options Tab

The DS2 Barcode Scanner is able to read 6 different symbologies (Figure 4-9).

1. Enable the check box **Use Check Digit** if the last numerical digit is used to verify that the rest of the barcode is correct. If enabled, the Check Digit will not appear as part of the sample ID. If disabled the last number in the bar code will be part of the sample ID.
2. Enable the check box **Use Leading Zero** if the first numeric digit in the bar code is a 0.
3. The **Codabar** barcode symbology drop-down menu becomes available if **Use Check Digit** is enabled. The options listed in the menu are Modulo 10, Modulo 16, and Modulo 7, which are calculations used to produce the Check Digit number.
4. The **IATA** barcode symbology drop-down menu becomes available if the **Use Check Digit** is enabled. The options listed in the menu are Coupon+Form+Serial, Form+Serial, and All Data, which are formulas used to produce the Check Digit number.

Defining System Configuration, Self Test Report Options:

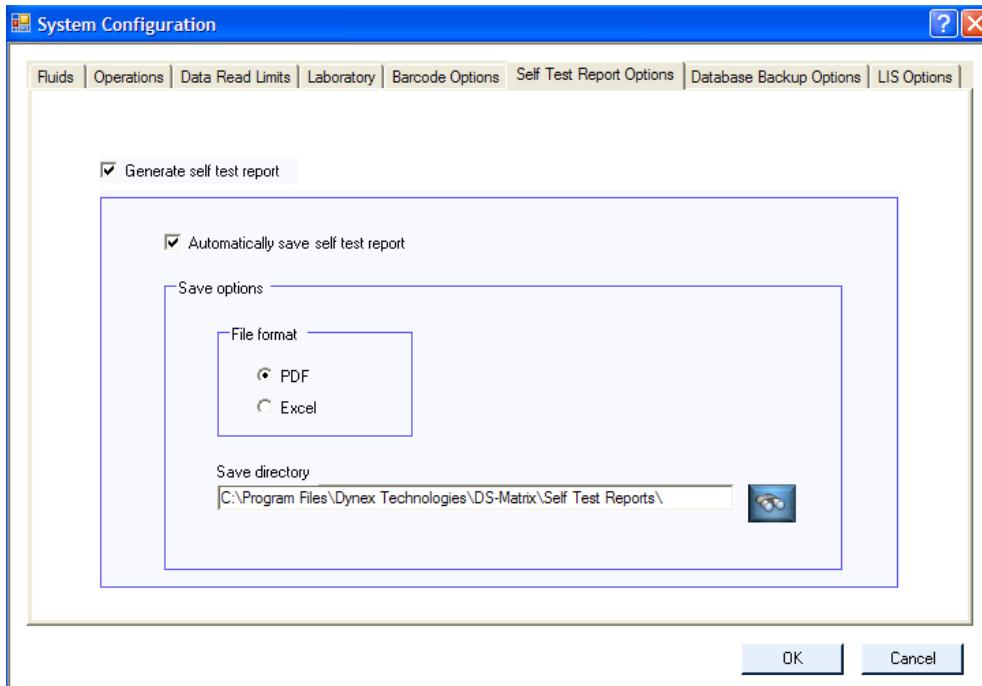


Figure 4-10: System Configuration: Self Test Report Options Tab

1. If the **Generate self test report** option is enabled, the system will generate a self test report during system start-up. Dynex recommends that this option be enabled.
2. If the **Automatically save self test report** check box is enabled, the user may select the format for which the report should be saved (either Excel® or PDF) and the location the file should be saved in the Save directory. The default location to store the file is the self-test report folder in the DS-Matrix directory as shown above. Dynex recommends that you do not change the default location.

Defining System Configuration, Database Backup Options:

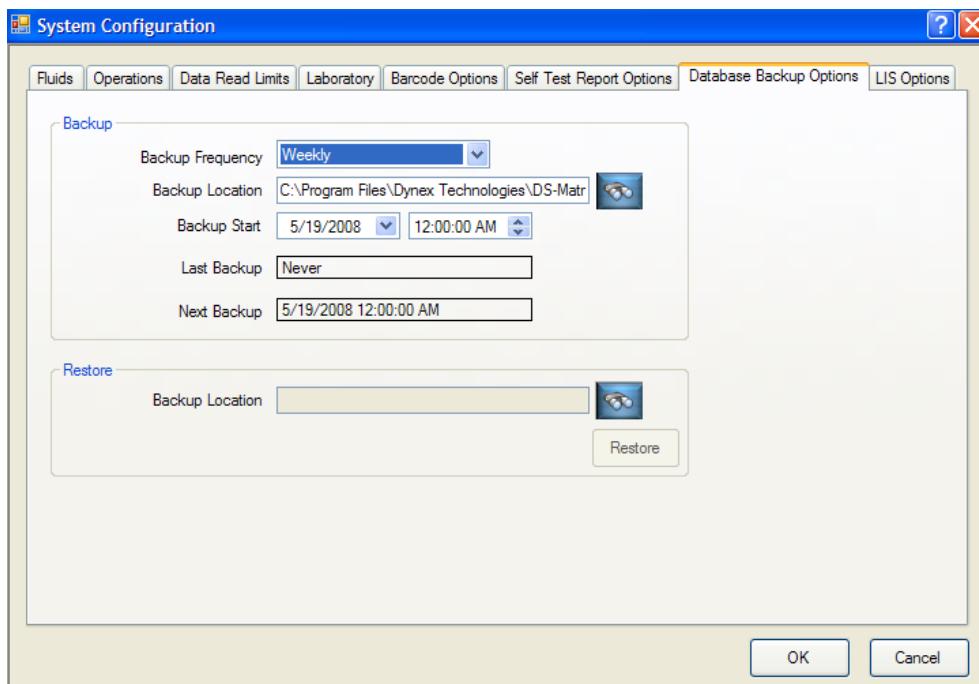


Figure 4-11: System Configuration: Database Backup Options Tab

1. Set the **Backup Frequency.**

- Select the desired database backup frequency from the drop down list. Dynex recommends performing a database backup weekly.
- The default location for database backup files is: **C:\Program Files\Dynex Technologies\DS-Matrix\DatabaseBackup**. Dynex recommend that you do not change the default file location.
- The user may specify the date and time when the specified backup frequency should begin.
- The Matrix software will display when the last back-up took place and when the next back-up will take place

2. The user may choose to **Restore a database from the Database Backup Options tab.**

- Click on the  button to browse the desired backup database.
- Click **Restore** to update the current database display with the selected database information. Any information in the current working database will be over-written and any changes made since the most recent back-up was performed will be lost.

3. The user should empty the database backup folder, with the exception of one or two early clean databases and some of the more recent databases, on a bi-annual basis to prevent software performance issues.

Defining System Configuration, LIS Options:

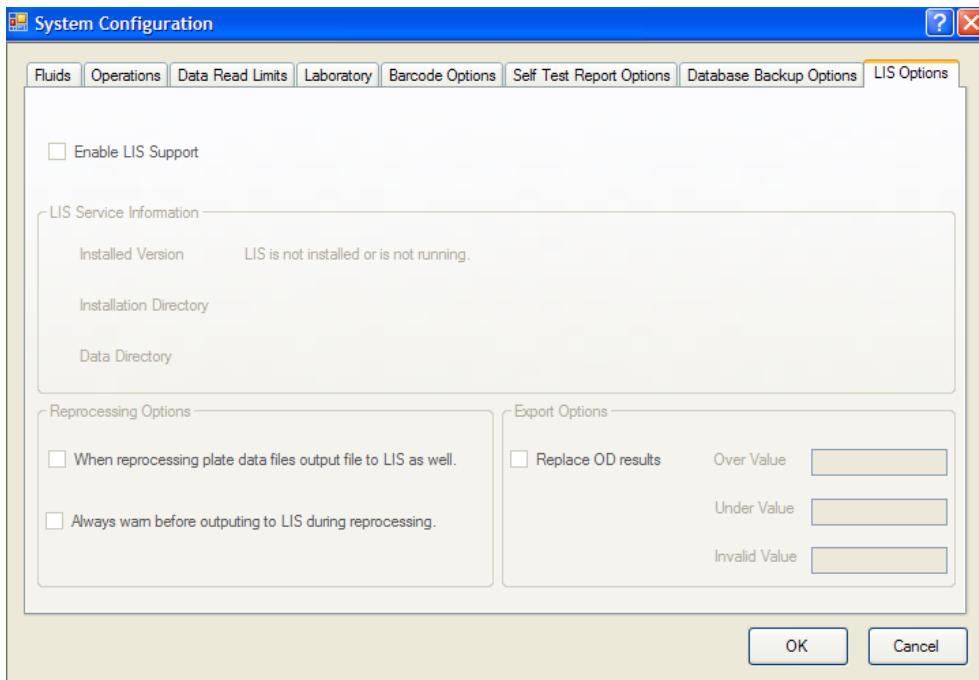


Figure 4-12: System Configuration, LIS Options Tab

3. When the LIS-Link software is installed the **Enable LIS Support** checkbox will be active.
4. Click the **Enable LIS Support** checkbox to activate the LIS option within Matrix.
5. The LIS Service Information will automatically fill in when connectivity is achieved.
6. Enable the Reprocessing and Export Options as desired.

4.4 DS-Matrix User Notification

DS-Matrix software can be configured to send E-mail to a specified E-mail address when system error conditions occur.

- ▶ **Note:** An E-mail server and internet connection are required.

Configuring the DS-Matrix User Notification

1. Click on **Tools > User Notification** from the main Matrix menu toolbar. The following screen will be displayed:

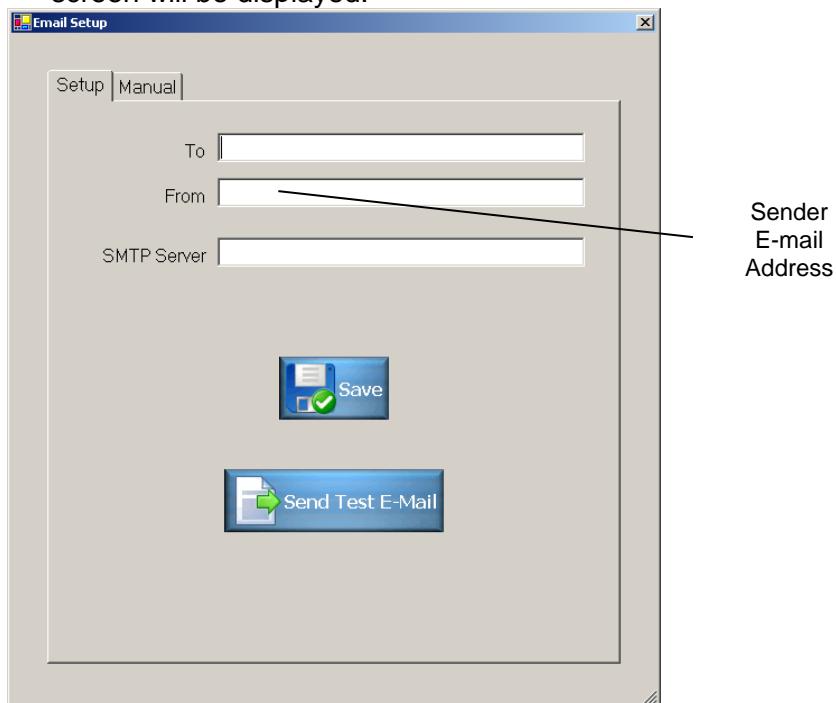


Figure 4-13: User Notification Options Dialog Box

2. Click on the **Setup** tab. In the **To** textbox, type in the E-mail address for the recipient of the user notification E-mail sent from the DS2 Matrix software.
3. In the **From** textbox, type in the E-mail address of the sender (for example the E-mail address of the lab manager).
4. In the **SMTP Server** textbox, type in the SMTP server for the sender's E-mail address.
5. Click on the **Save** button to save these parameters, or click the **Send Test E-Mail** button to test the settings.
6. Click on the **Manual** tab to send e-mails manually. The screen below will be displayed:

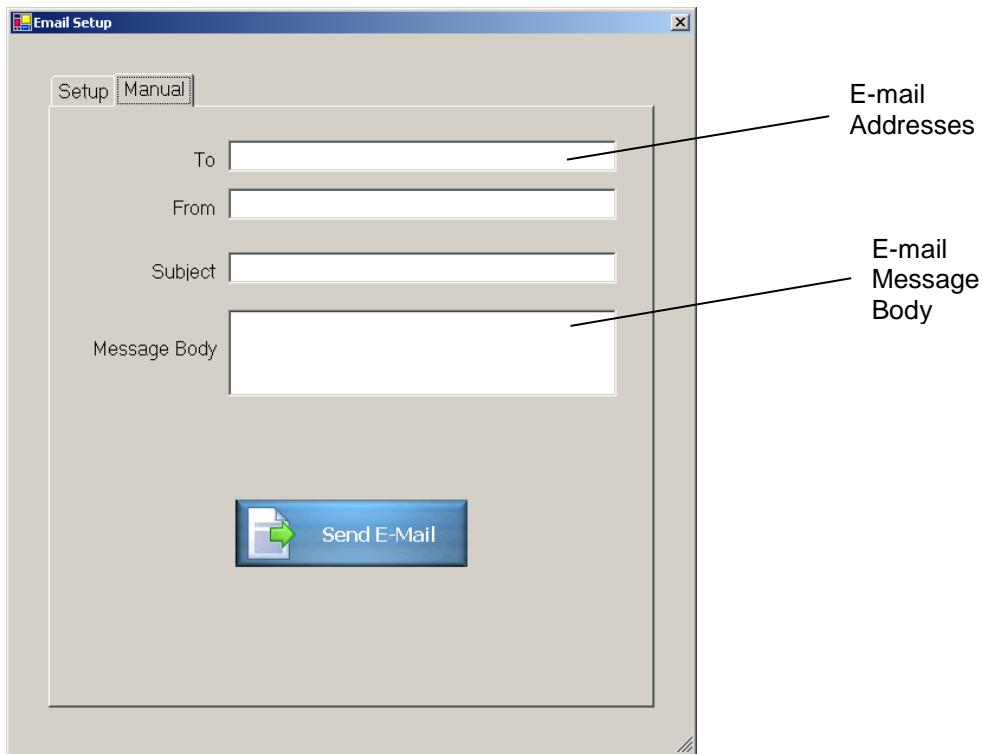


Figure 4-14: E-mail Setup Screen for User Notification

7. Fill in the recipient's email address and the sender's E-mail address, along with the E-mail text.
8. Click the **Send E-Mail** button to send the e-mail.

4.5 Absorbance Filter

Four standard absorbance filters are included with the DS2. The wavelengths of these filters are 405, 450, 490, and 620 nm. The user may order a custom filter set specific to their assay(s) by purchasing them from the supplier. Up to 6 filters may be installed in the DS2 filter wheel.

- ▶ **Note:** *It is important that the filter wavelength matches the position of the filter that is installed, or the assay results will be affected.*

Editing Absorbance Filter Definitions:

1. Click on **Tools > Absorbance Filter** from the main Matrix menu toolbar.
 2. Edit the wavelength values for Filters 1-6.
- ▶ **Note:** *The 405 nm filter must be in Position 1 of the filter wheel or the self-test will fail.*
3. If no filter is installed at any position, list the wavelength value as "0" for this position.
 4. Click **OK** when finished to save changes made. At this point the system will self test the reader and the changes will be saved. To exit without saving changes, click **Cancel**.

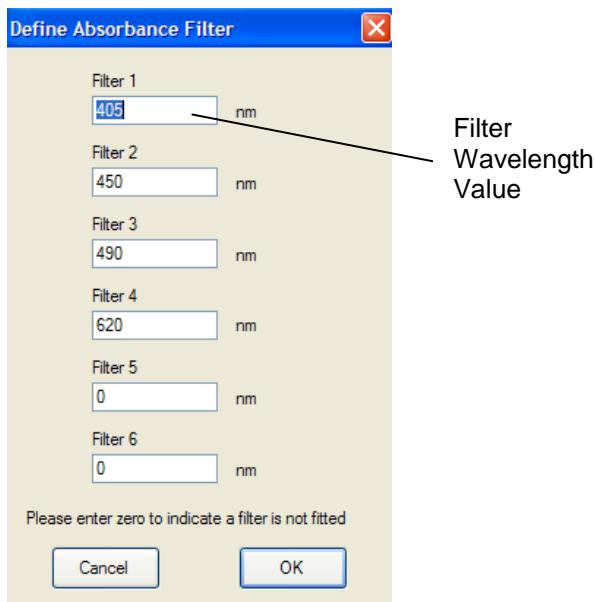


Figure 4-15: Absorbance Filter Designation

4.6 Import/Export

Assay and OD data files may be imported or exported for use in other DS2 instruments or in other software applications.

Exporting an Assay File

1. Click on the **Export** radio button.
2. Enable the **Assay** checkbox. Highlight the desired assay.
3. The Assay File **Filter** will sort the assay names displayed by name, category, or Last Edited Date.



4. Click on and browse to the desired file location. Enter a file name. An *.xml extension will be assigned to the file when it is saved.
5. Click **Export**.

► **Note:** Assay files cannot be opened in document or spreadsheet applications. DS-Matrix assays can **only** be imported back into DS-Matrix.

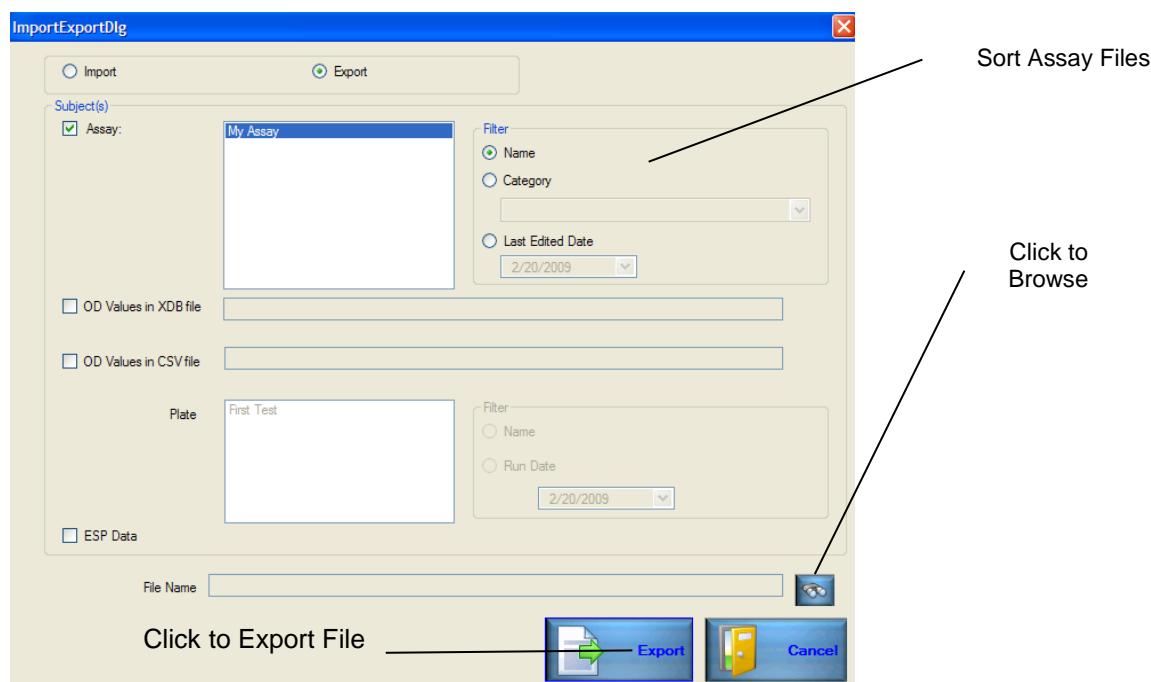


Figure 4-16: Import/Export Dialog Screen (export options)

Importing an Assay File

1. Click on the **Import** selection button.

2. Select the filename to be imported by clicking on the  button and navigate to the current file location.
3. Select the desired assay file (*.xml files only).
4. Click the **Import** button.

► **Note:** Only files that have been generated using DS-Matrix software programs can be imported into DS-Matrix software.

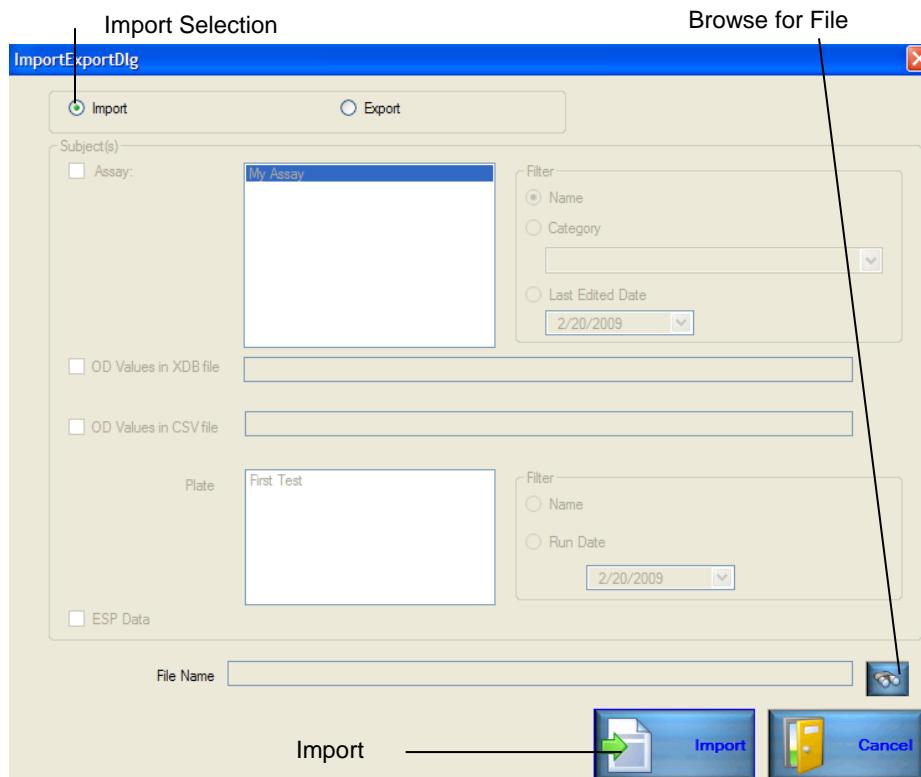


Figure 4-17: Import/Export Screen (import options)

Exporting a Data File

1. Click on the **Export** radio button.
2. Choose to export the data as either an XDB (Matrix) format or as a CSV comma delimited spreadsheet type file. Click on the  button in the center of the right side of the screen (not the browse button at the bottom), find the desired file location, and name the export file, and click **Save**. DS-Matrix will assign the file extension.
 - a. If you export the file as an XDB file, the data file can only be opened in DS-Matrix.
 - b. If you export the file in CSV format, only OD data will be exported.
3. Choose plate data by highlighting the desired plate identifier in the list.
4. Click **Export**.
5. If the data is imported into a spreadsheet, the well location data will be in the first column and the OD data will be in the second column.

Importing a Data File

1. Click on the **Import** radio button.
2. Click on the  button and find the desired files.
 - ▶ **Note:** Plate Data files must have the *.XDB extension. Assay files must have the *.XML extension
3. Click the **Import** button.
 - ▶ **Note:** Only Plate Data files that were created using DS-Matrix and saved as *XDB files can be imported. Data cannot be imported into DS-Matrix from other software applications such as spreadsheet (*.CSV) files.
4. When plate data is imported into a database, the associated assay information will also be imported into the database.

4.7 Reset Auto Recovery

Auto Recovery is a mechanism that allows the DS2 Matrix software to automatically recover from errors during a run without user intervention. When an error occurs, Matrix will display a list of potential corrective actions, and the user is prompted to select the most appropriate action in order to correct the problem (Figure 4-18).

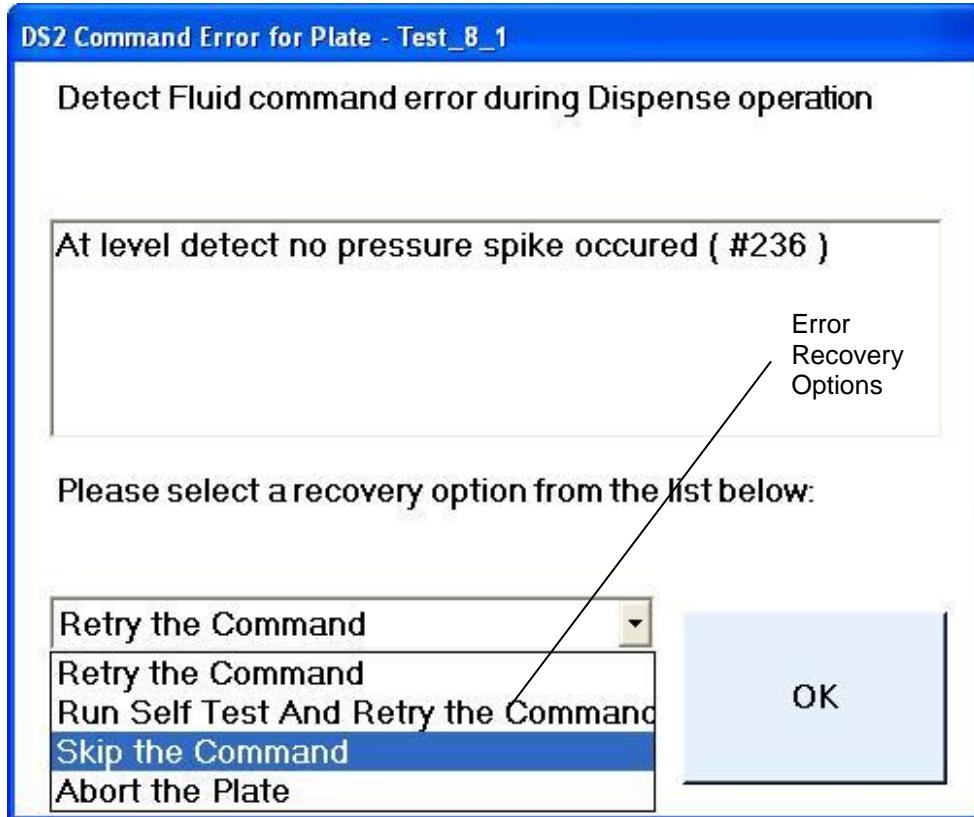


Figure 4-18: Error Recovery Screen

On the same screen (underneath the drop down list options), the user can check the **Auto Recovery** checkbox to instruct Matrix to carry out the same action the next time the exact same error is encountered. Matrix can then carry out some corrective actions without any user interaction. Dynex does not recommend using Auto Recovery.

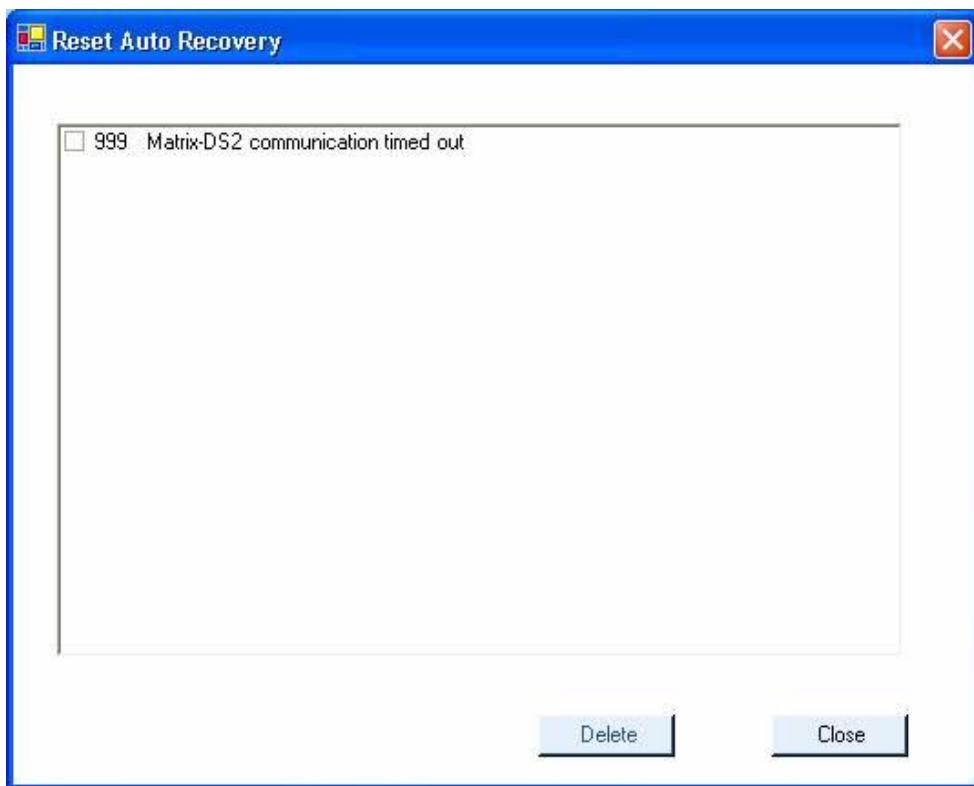


Figure 4-19: Reset Auto Recovery Screen

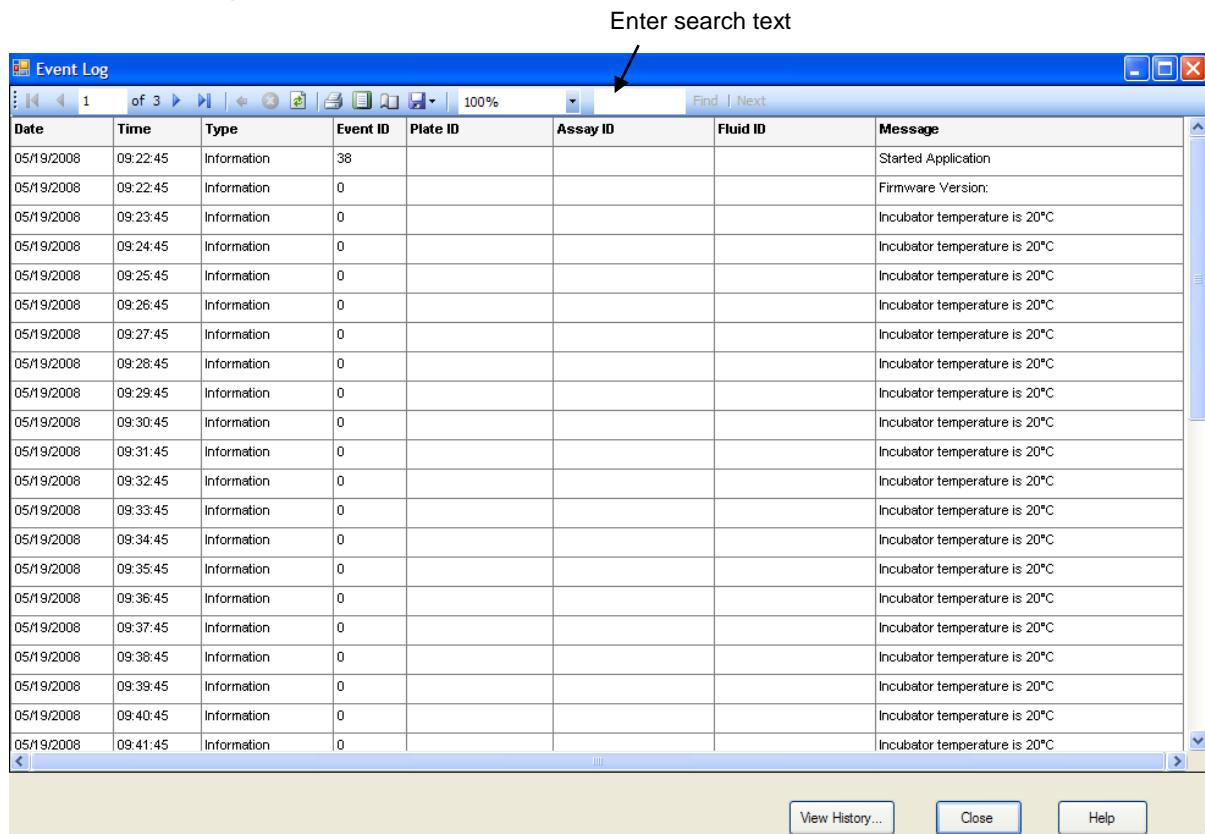
The Reset Auto Recovery function (Figure 4-19) erases the settings for the user-selected corrective action for a particular error. The next time the error occurs, Matrix will prompt the user to select a corrective action instead of carrying out corrective actions without user intervention. To remove a specified auto recovery action from Matrix, check the checkbox associated with the undesired recovery action and then click **Delete**. Auto recovery will no longer be performed the next time the error is encountered.

- ▶ **Note:** Use the Reset Auto Recovery and Auto Recovery function with great caution.

4.8 Event Log

The Event Log lists every function the DS2 performs during an assay. To view the event log, click **Tools > View Event Log**, and the Event Log will display a list of events which occurred since the current software session began. A new Event Log is created each time the software is started.

1. To view logs from previous software sessions performed on a prior date, click the **View History** button.
2. Choose a date on the calendar, highlight the desired Event Log and click **Open**. Each operation performed is recorded in the event log.
3. To search for a particular text string (such as “error”), enter the desired text into the text box at the top of the screen. Click **Find** to locate the first instance of the text. Click **Next** to find subsequent instances.



The screenshot shows the 'Event Log' window with the following details:

- Title Bar:** Event Log
- Search Bar:** Enter search text (with an arrow pointing to it)
- Toolbar:** Includes icons for Back, Forward, Home, Print, and others.
- Table Headers:** Date, Time, Type, Event ID, Plate ID, Assay ID, Fluid ID, Message
- Data Rows:** 24 rows of log entries, all categorized as 'Information'. The 'Message' column contains entries like 'Started Application', 'Firmware Version:', and 'Incubator temperature is 20°C' repeated multiple times.
- Bottom Buttons:** View History..., Close, Help

Date	Time	Type	Event ID	Plate ID	Assay ID	Fluid ID	Message
05/19/2008	09:22:45	Information	38				Started Application
05/19/2008	09:22:45	Information	0				Firmware Version:
05/19/2008	09:23:45	Information	0				Incubator temperature is 20°C
05/19/2008	09:24:45	Information	0				Incubator temperature is 20°C
05/19/2008	09:25:45	Information	0				Incubator temperature is 20°C
05/19/2008	09:26:45	Information	0				Incubator temperature is 20°C
05/19/2008	09:27:45	Information	0				Incubator temperature is 20°C
05/19/2008	09:28:45	Information	0				Incubator temperature is 20°C
05/19/2008	09:29:45	Information	0				Incubator temperature is 20°C
05/19/2008	09:30:45	Information	0				Incubator temperature is 20°C
05/19/2008	09:31:45	Information	0				Incubator temperature is 20°C
05/19/2008	09:32:45	Information	0				Incubator temperature is 20°C
05/19/2008	09:33:45	Information	0				Incubator temperature is 20°C
05/19/2008	09:34:45	Information	0				Incubator temperature is 20°C
05/19/2008	09:35:45	Information	0				Incubator temperature is 20°C
05/19/2008	09:36:45	Information	0				Incubator temperature is 20°C
05/19/2008	09:37:45	Information	0				Incubator temperature is 20°C
05/19/2008	09:38:45	Information	0				Incubator temperature is 20°C
05/19/2008	09:39:45	Information	0				Incubator temperature is 20°C
05/19/2008	09:40:45	Information	0				Incubator temperature is 20°C
05/19/2008	09:41:45	Information	0				Incubator temperature is 20°C

Figure 4-20: Example Event Log

4.9 Levey-Jennings Criteria

Levey-Jennings charts monitor the performance of an assay over time. Levey-Jennings charts include plots of the individual results versus assay data to analyze the dispersion of results about the cumulative mean value. Typically, a specific well or sample type is used, such as a control or other sample type, for which an expected value is available.

Levey-Jennings charts on the DS2 can be displayed by Matrix software for specified wells on an assay plate using raw OD values or calculated results (concentrations or ratios). Westgard Rules may also be applied.

Specifying Levey-Jennings Criteria

1. Select **Tools > Levey-Jennings** from the Matrix main menu toolbar.
2. The following options screen will be displayed.

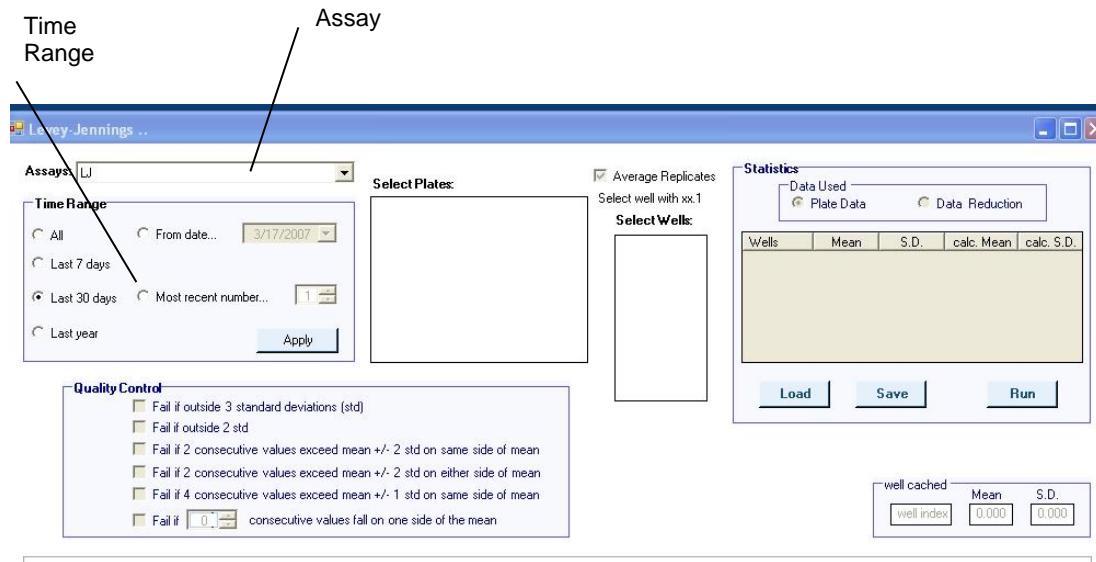


Figure 4-21: Levey-Jennings Criteria Parameters Screen

3. Select the **Assay** for which the Levey-Jennings analysis is to be carried out by highlighting the desired assay in the drop down list.
4. Select the **Time Range** over which the assay will be analyzed. Selecting **All** displays data for every run of that assay stored in the plate database. If you do not want to view all data, select a time frame of one week, one month or one year to analyze data generated within that time period. The user may also choose a starting date and all data generated from that point in time will be analyzed. Alternatively, a number of the most recent data sets (1,2,3,4...) can be selected.
5. Click **Apply**.

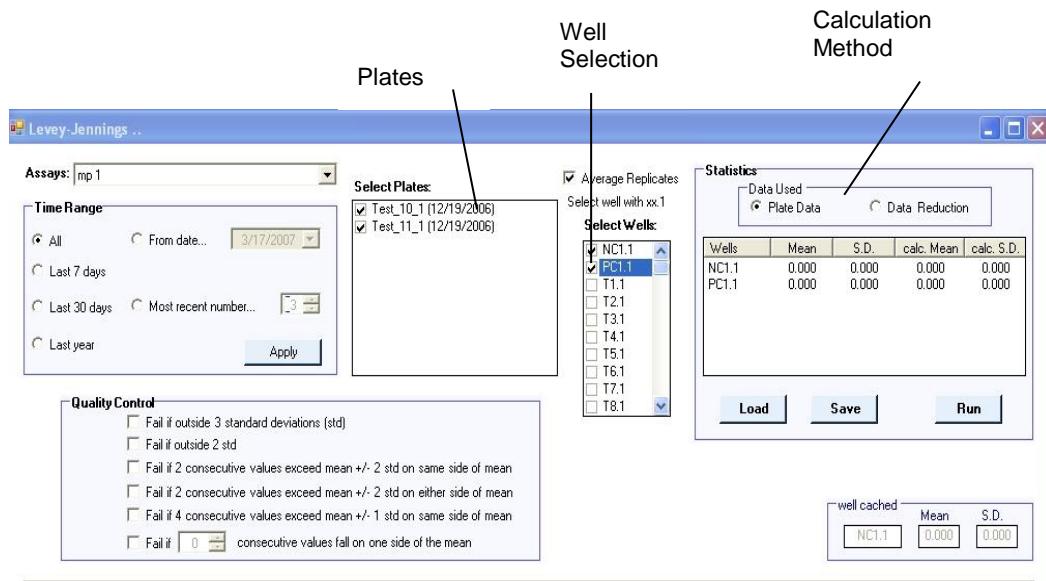


Figure 4-22: Levey-Jennings Plate and Well Selection

6. Select the **Plates** to be analyzed. Uncheck the check box for a plate if the data for the specified plate should not be analyzed. When selecting plates, make sure all plates were tested with the current version of the assay. If plates are selected which were tested with a prior assay version, the Levey-Jennings program will not be able to analyze the data. A new assay version is created whenever an assay is saved.
7. Check the check box for the wells containing the control (or other sample type) to be used in the Levy-Jennings plot. Click the **Average Replicates** box if desired.
8. The number of plates chosen will equal the number of points on the graph.
9. If Raw OD data is used to generate the graph, select the **Plate Data** radio button. To use calculated data following a Curve Fit, Threshold, or Ratio Operation, select the **Data Reduction** radio button.
10. If pass/fail criteria are to be used, select the appropriate **Quality Control** cutoffs.
11. Click **Run** to display the plotted results in the lower portion of the window.

Chapter 4 Setting System Parameters

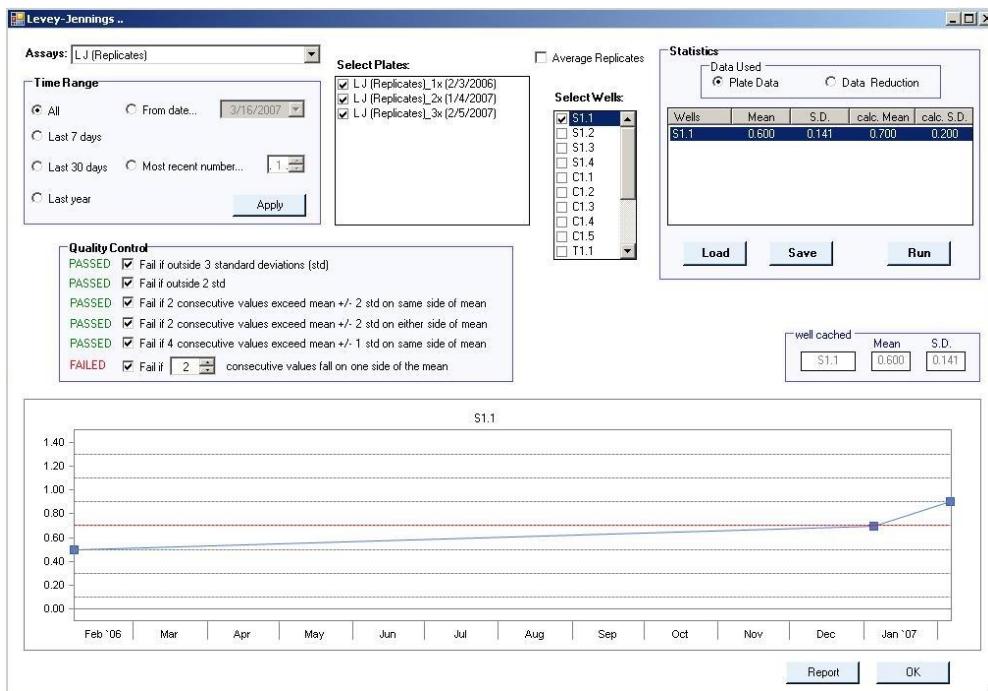


Figure 4-23: Levey-Jennings Results

12. Click on the **Report** button to bring up a printable version of the results, including the graph with header information containing the assay name, quality control test results, etc.
13. To save the data, click on the **Save** button.
14. To retrieve saved data and re-graph, click on the **Load** button. Data must be saved prior to trying to load it, or a message will appear that no results are available.
15. Click the **OK** button to close the Levey-Jennings window.

4.10 ESP Calibration

Electronic Signature Pipetting (ESP™) is a sophisticated technique used by the DS2 for detection of gross pipetting errors often caused by the presence of particulate matter, clots, foam, or bubbles in the sample.

Correct use of ESP requires calibration of acceptable sample transfers for a given fluid with a given pipetting profile and volume. This data is collected and stored in a database and is used by Matrix as a reference for good data to compare against subsequent dispenses. Insufficient sample transfer can therefore be detected and reported to the operator during a run.

Performing ESP Calibration

1. Click on **Tools > ESP Calibration** from the main Matrix screen.
2. The following screen will be displayed (Figure 4-24).
3. Type in the **Fluid Name** (e.g.: water), Volume, and Aspirate and Dispense profiles. The aspirate and dispense profiles should match the programmed aspirate and dispense profile values for the fluid in the fluids database. The volume must match the volume programmed to be pipetted during an assay.
4. Specify the number of transfers to calculate the calibration values. .
5. Select the source of the fluid being calibrated.
6. Select the destination of the fluid being calibrated.
7. Click **Run**
8. Follow the instructions in the load wizard to prepare the system and click **Done**. The DS2 will then perform the fluid transfer and display the results (Figure 4-25).

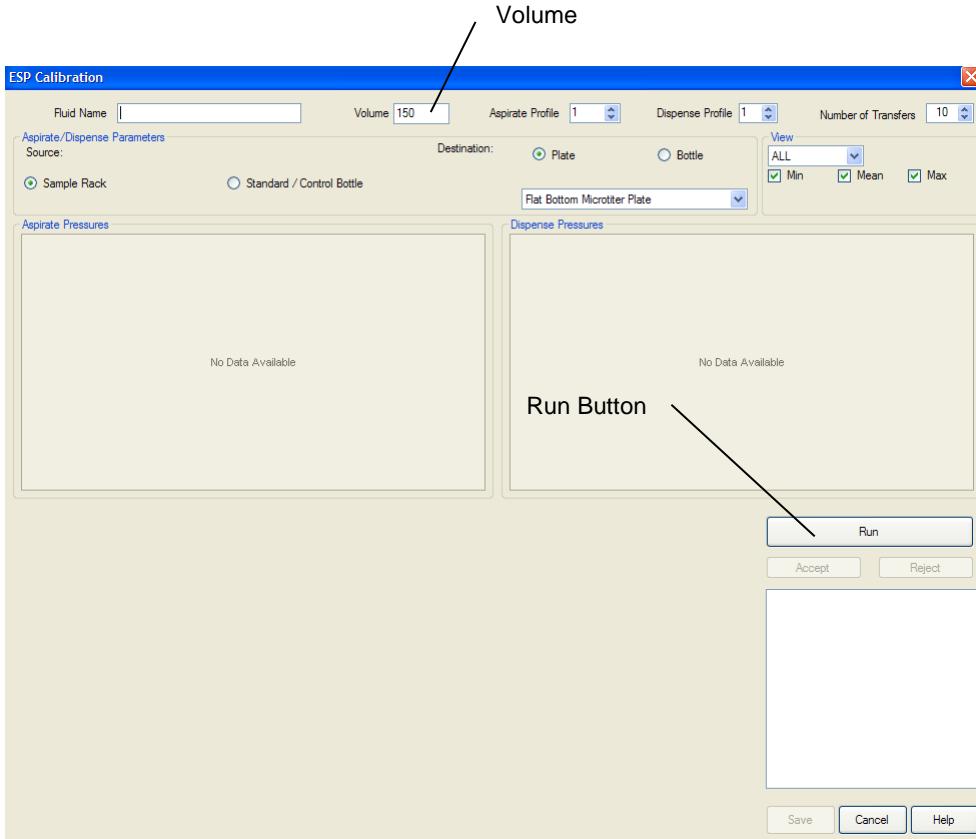


Figure 4-24: ESP Calibration Main Screen

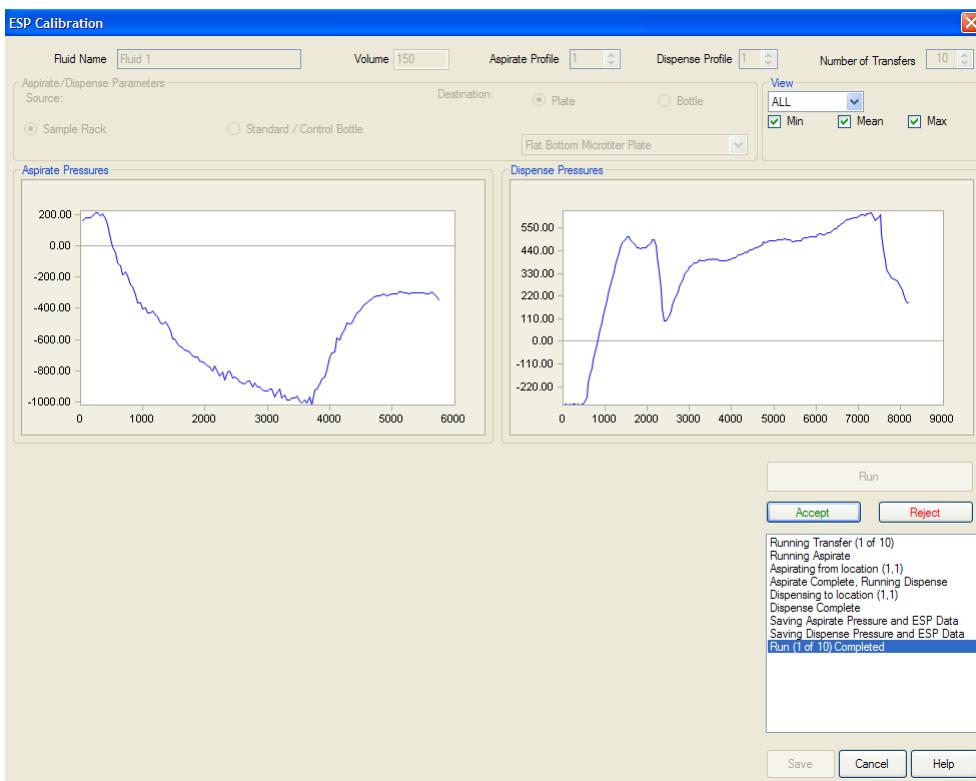


Figure 4-25: ESP Calibration – Results

9. Click **Accept** to accept the calibration results and click **Reject** if the results are not acceptable for that particular transfer. The profile should appear relatively smooth without unexpected sharp peaks or dips.
10. Repeat steps 7 and 9 for all transfers (see the value in **Number of Transfers**). The load wizard will only appear once.
11. The data displayed can be changed by changing the selections in the **View** area. The user may select all to view data for all transfers, or the user may select the specific transfer number. Checking the checkbox for **Min** will display the data compared to the minimum value for the data set. Checking the check box for **Max** will display the data compared to the maximum value for the data set. Checking the checkbox for **Mean** will display the data compared to the mean of the data set. The user may choose to have all three checkboxes selected at the same time as this may assist in determining if the transfer is within acceptable ranges.
12. If the calibration results are acceptable, click **Save**.
13. If the calibration results are not acceptable, click **Done**. Select **Yes** in response to the prompt to leave the ESP calibration window without saving data.

4.11 Fluid Level Tracking

- **Note:** Do not use Fluid Level tracking with default Dynex supplied bottles and vials. Fluid Level tracking is only required when using user supplied bottles and vials.

Fluid level tracking requires gravimetric calibration for each liquid in a specified bottle or tube. During the calibration routine, the operator adds a set volume of liquid to the bottle or tube to be calibrated (e.g.:1000 µL to a test tube).

During the fluid level tracking procedure, the DS2 aspirates a set volume of liquid from the bottle or tube (e.g. 100 µL) and dispenses the liquid into a waste container. The operator is then prompted to reweigh the bottle or tube. This aspirate and weigh cycle is repeated several times, and the resulting weights are entered on the calibration screen.

Performing Fluid Level Tracking Calibration

1. To start the fluid level tracking calibration, click Tools > **Fluid Level Tracking**. The DS2 will provide detailed instructions on the completion of the calibration routine in the Message Center text box in the instruction screens (Figure 4-26)
2. Additional screens with instructions on collecting weight data before and after the DS2 aspirates liquid from the bottle will be displayed. Follow the instructions on the screens to complete the calibration.

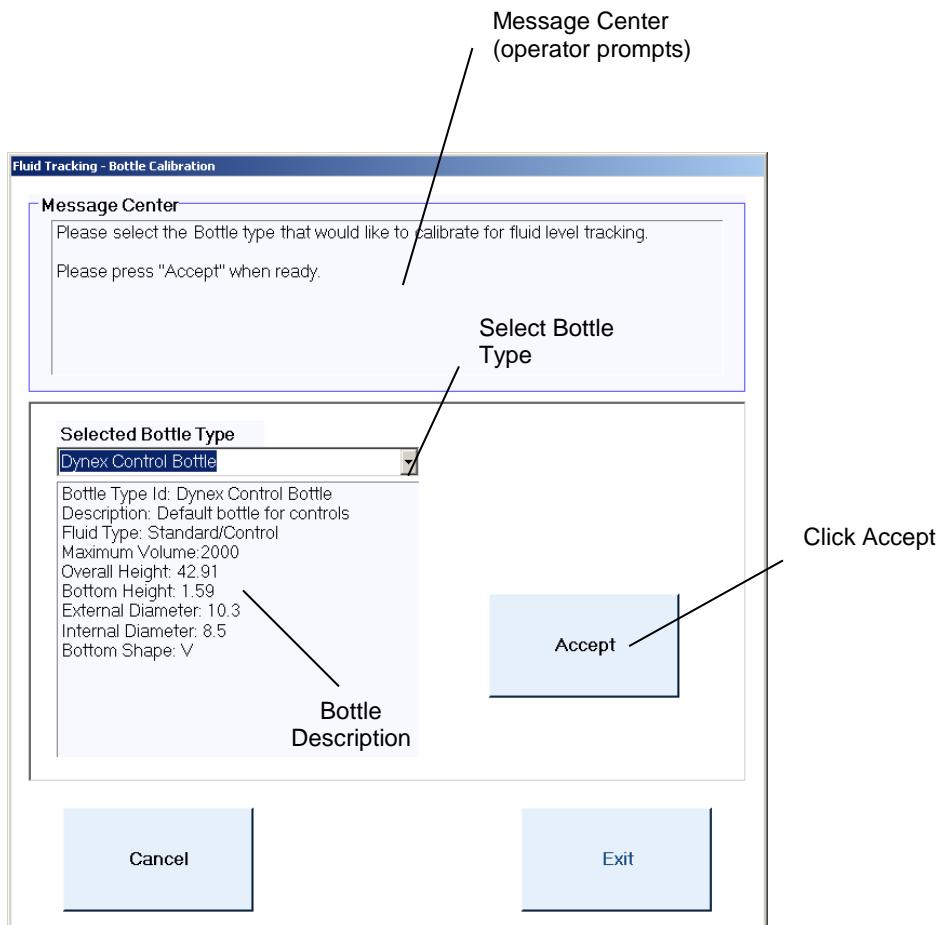


Figure 4-26: Fluid Tracking Calibration Start Screen

Fluid Level Tracking Calibration Steps

1. Select the bottle or tube type.

► **Note:** The user defined bottle or tube must be entered in the Bottle Type database in order for the bottle or tube to be selectable from the drop down list.

2. Click **Accept**.

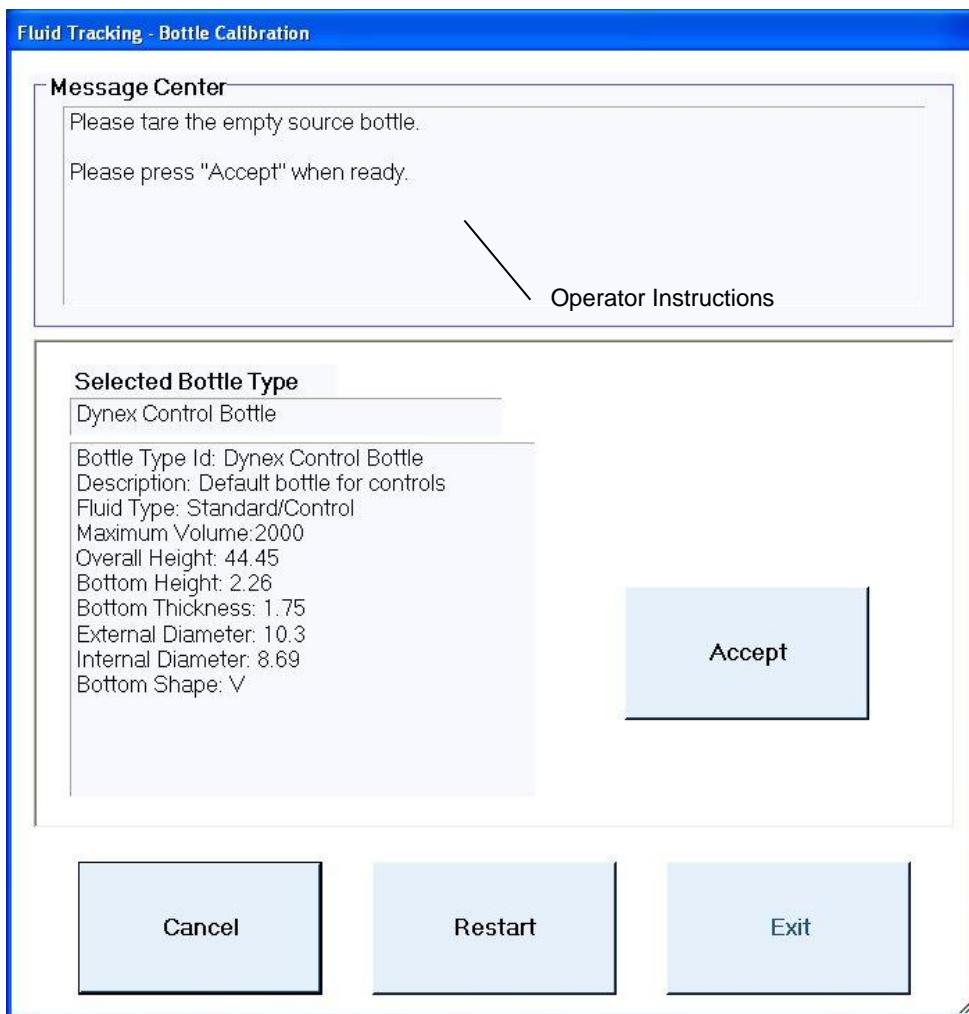


Figure 4-27: Fluid Tracking Calibration Data Entry Screen

3. Tare the empty bottle or tube to use for fluid tracking.

► **Note:** An analytical balance that can weigh to the nearest 0.001 g is needed to complete the calibration routine.

4. Click **Accept**

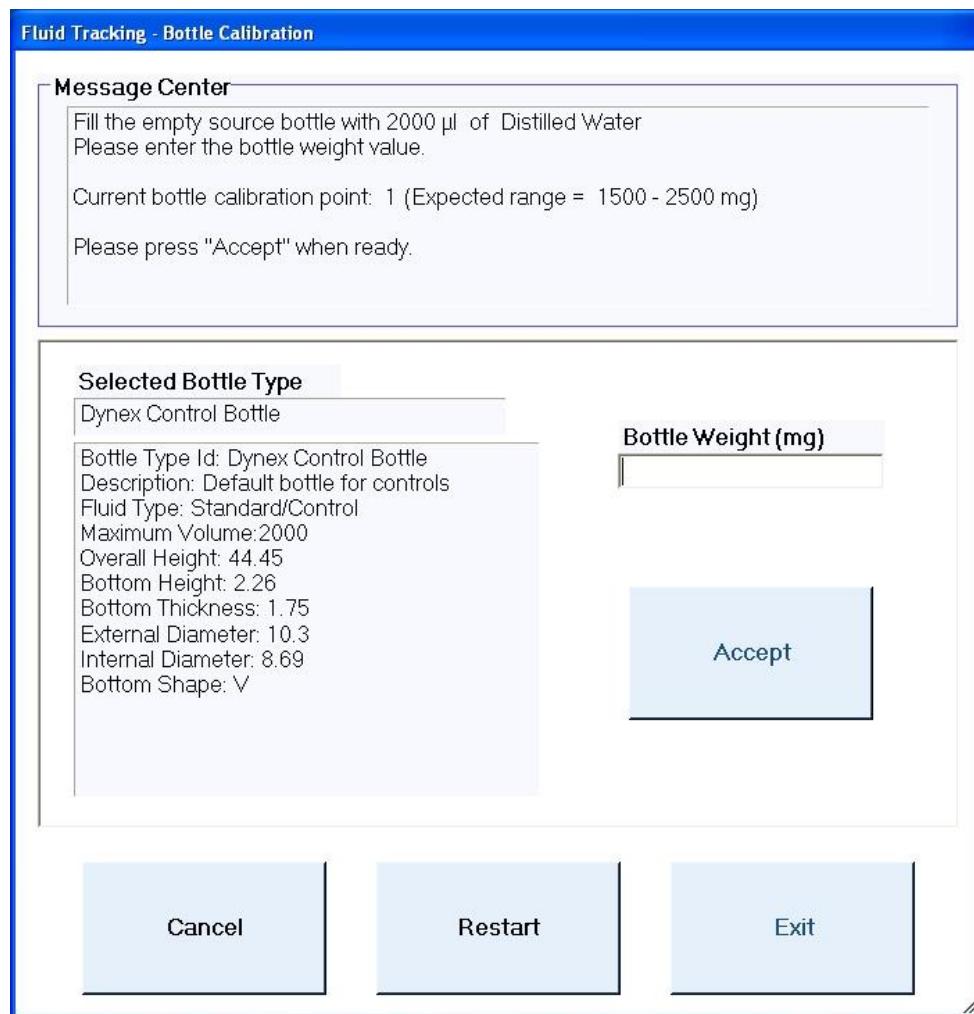


Figure 4-28: Fluid Tracking First Fluid Weight Entry

5. Follow the instructions in the **Message** Center and enter the first bottle weight. Press **Accept**.
6. Follow the Load wizard prompts to prepare the system for the fluid tracking calibration procedure.
7. Click **Done** when the load wizard is complete.
8. Click **Accept** to confirm that the items specified in the message center have been loaded on the instrument.
9. Close the system cover and click **Accept** to begin the calibration procedure.
10. The DS2 will pick up a tip, aspirate fluid from the source bottle, dispense the fluid into the waste bottle, prompt the user to weigh the bottle for the second time, and to enter the second weight.
11. The range of weights to be entered is displayed. A different amount of water will be used for different bottle types.

12. A total of ten calibration points are used. Decreasing bottle weights will be entered as fluid is aspirated out of the source bottle.
13. At any time during the fluid level tracking procedure, click **Cancel** to cancel the calibration program, or **Restart** to reset the program.

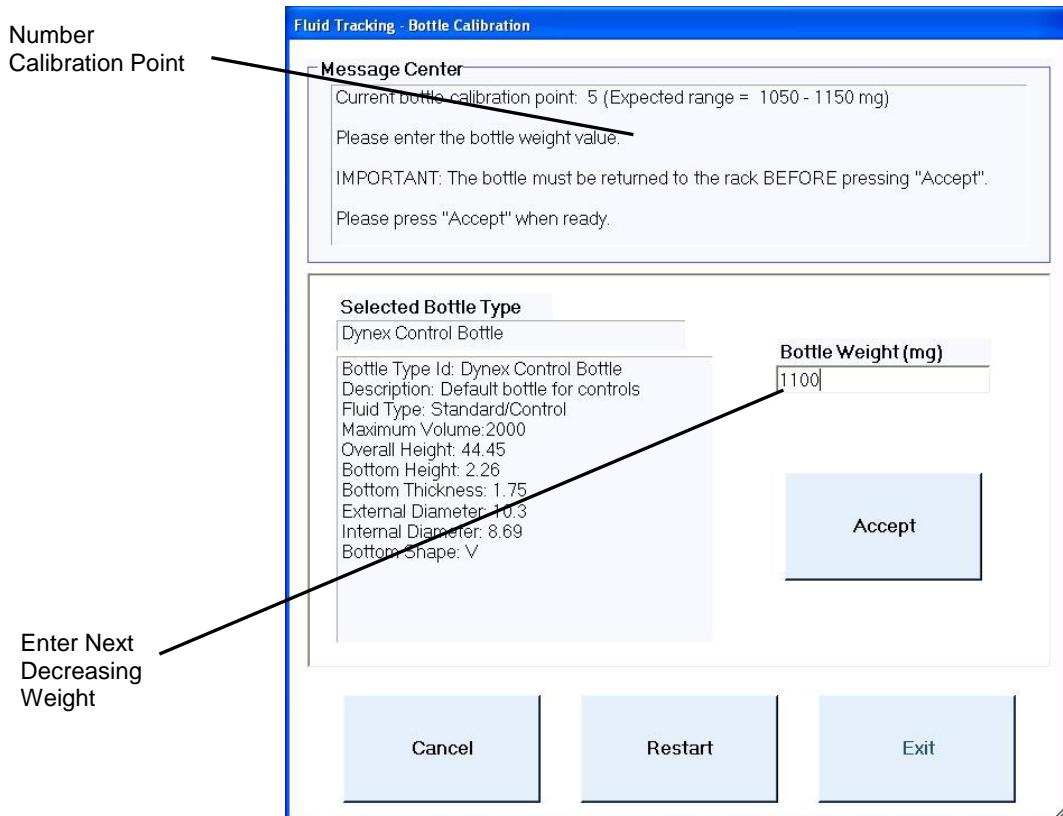


Figure 4-29: Fluid Tracking Calibration Point 5 Weight Entry

Chapter 5 Programming a New Assay

5.1 Defining Assay Parameters

The first step in programming a new assay is to define the assay parameters. Select **File > Assay Editor** from the main Matrix menu. All assays must include the three default icons shown in the Assay Screen (Assay Title Page, Microplate Pipetting Template, and Report Format Set-up) *plus* at least one operation, such as a read or dispense operation. All assays open to the Assay Title Page (Figure 5-1).

Assay operation icons must be dragged from the Operations toolbar into the Programming toolbar in their proper sequence.

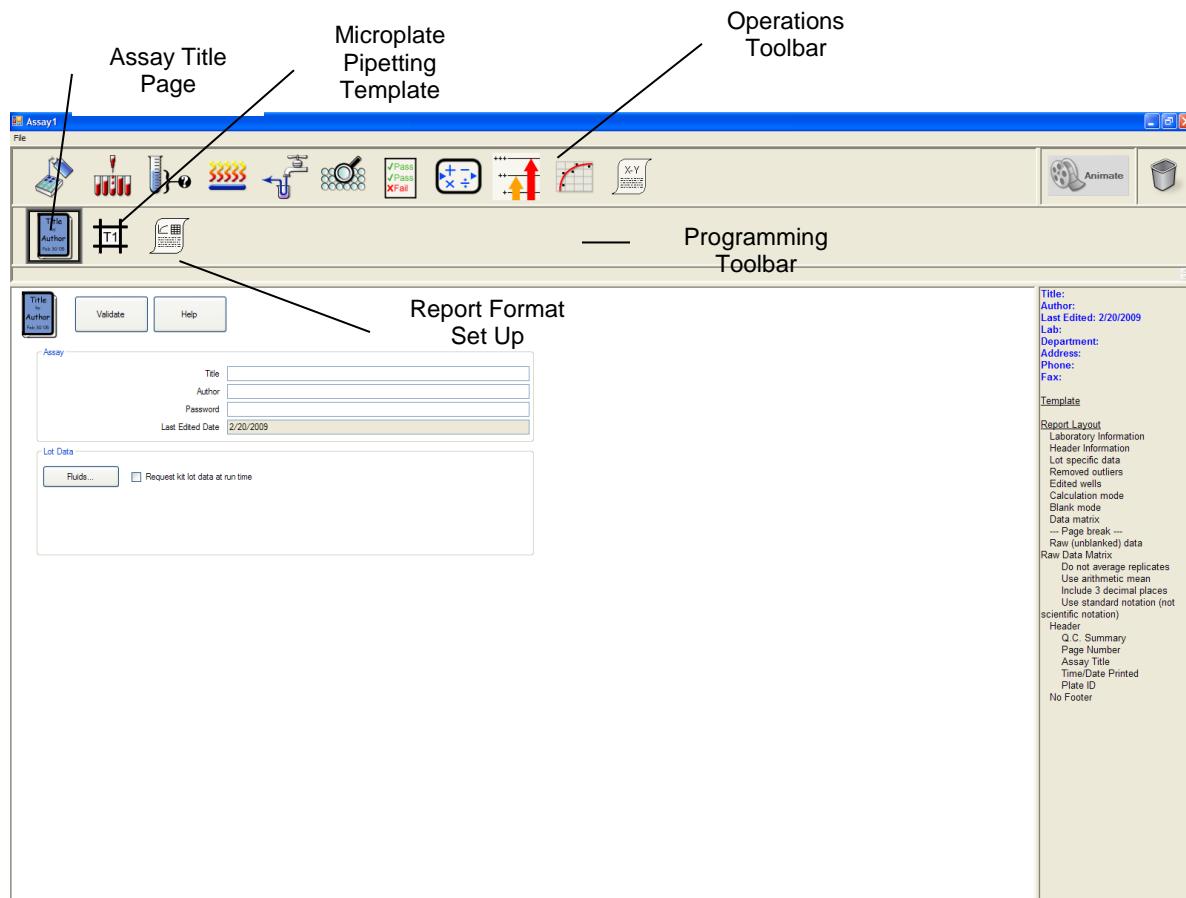


Figure 5-1: Assay Title Page Screen

- **Note:** At least one assay must be created before a worklist can be defined and run.

5.2 Creating an Assay

5.2.1 The Assay Title Page

1. Select **File > Assay Editor** from the menu bar

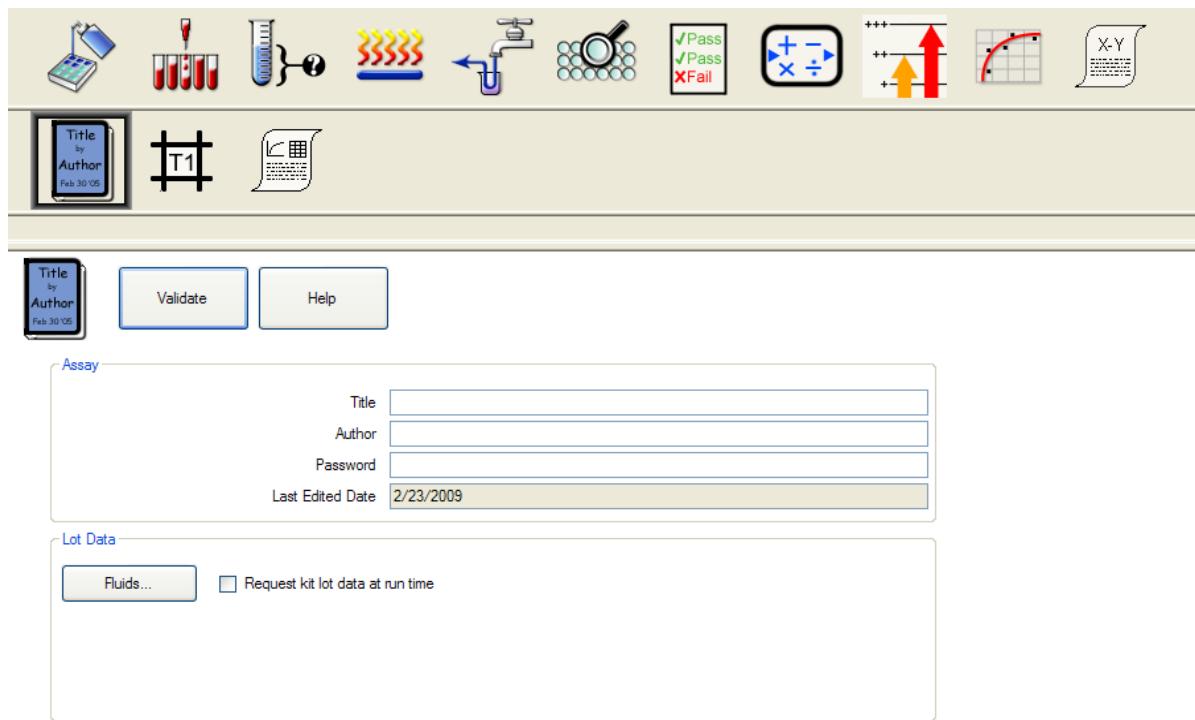


Figure 5-2: Assay Title Page

2. The assay opens with the **Assay Title Page** displayed. Enter the Assay Title and Author in the text boxes. The assay title may be different from the filename under which the assay is saved. If a password is entered, subsequent attempts to open the assay will require the user to enter the password in order to edit the assay parameters. The assay may be opened as “Read Only” to view the assay parameters without making changes.
3. Kit lot information can be requested at run time when the consumables are loaded.
 - If the user checks the check box for **Request kit lot data at runtime**, the user will be prompted to enter lot and expiration information for all consumables and fluids each time the assay is run. The user can choose not to enter lot information when prompted.
4. Click **Validate** when finished.

5.2.2 The Microplate Pipetting Template

The Microplate Pipetting Template allows users to determine the plate position of well types such as Standards, Controls, and Test Samples..

Defining Wells (Figure 5-3)

1. Click on the **Microplate Pipetting Template icon** in the Programming toolbar.
 2. Click on the **Clear All** button to clear the plate so wells can be defined.
 3. Click on the radio button for the desired **Well Type** definition (NC, negative control; PC, positive control; CO, cut-off control, etc.). To change a well type definition, refer to Section 5.2.3 (Well Type Definitions).
- **Note:** If a curve fit is used in the data reduction, the default **Standard** well type must be used to define the assay standards on the template
4. Select the number of **Replicates** desired by clicking the up and down arrows.
 5. Determine if the replicates are to be oriented **By Row** or **By Column** by selecting the appropriate radio button in the **Replicates** area. When replicates are added by row, one replicate will be placed (for example) in column 1 (A1) and one replicate will be placed in column 2 (A2). Replicates which are added by column will be added to the template serially (A1, B1).
 6. The user can click on each well individually, or the user can click and drag the cursor over the desired wells to define them as the selected well type.
 7. Repeat steps 3 through 6 until the entire plate has the desired well definitions for standards, controls, samples, etc.
 8. To clear an individual well, click the **Empty** radio button, and then click on the desired well location in the template. Click on the Clear All button to reset all well types.
 9. Choose the microplate type which will be used for the assay from the **Microplate** drop-down list. Only microplate types which are defined in the Plates database will appear in the drop-down list.
 10. Click **Validate** when finished.

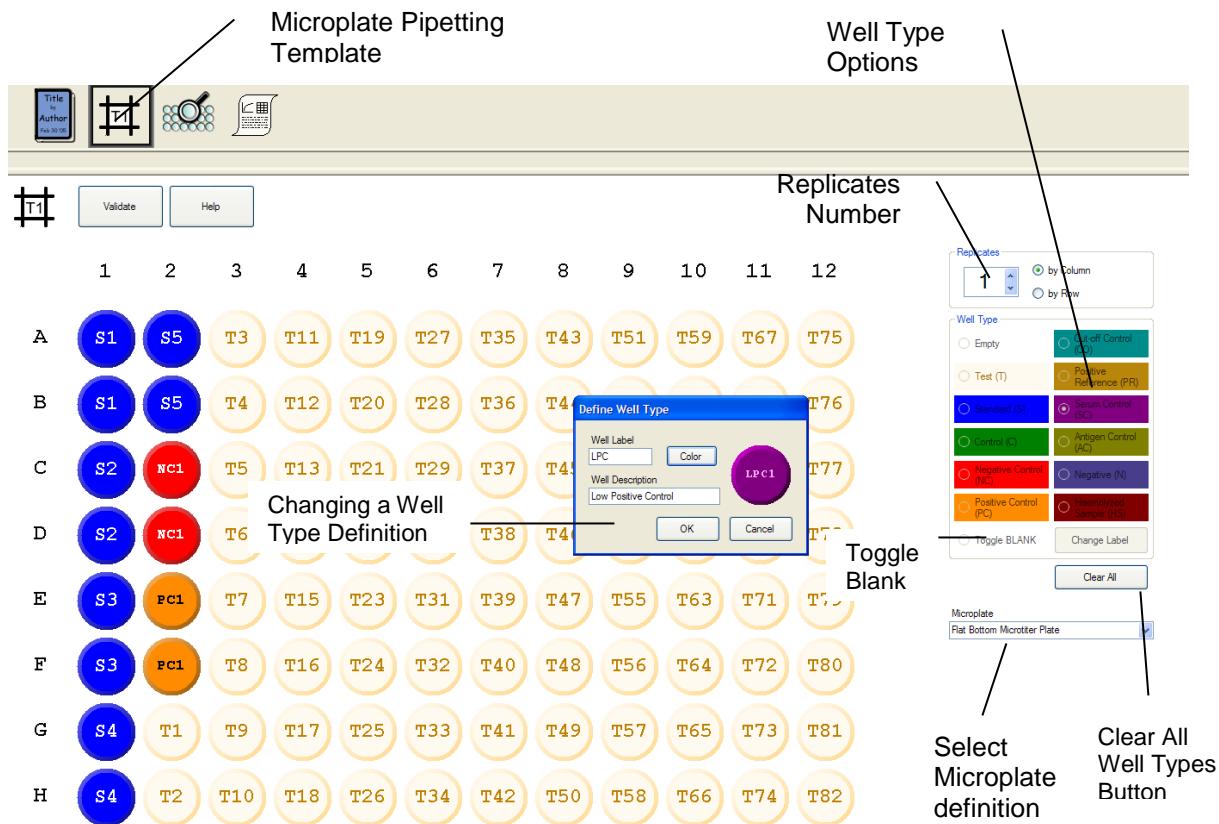


Figure 5-3: Microplate Pipetting Template with Wells Defined

5.2.3 Well Type Definitions

By default, all 96 well positions in the microplate template are defined as test wells (T1, T2, etc.). When Well Types have been assigned, the well becomes color coded for the well-type defined by the user, and will be labelled with a symbol for the well type followed by a sample number. Wells that are dispensed as replicates will have the same sample number (e.g. T1).

Labels for **Control** wells can be changed and custom color-coded by clicking on the “Change Label” button, with the exception of **Standard (S)** and **Control (C)**, which cannot be changed by the user.

Any well on the template can be made a Blank well by clicking the **Toggle Blank** radio button, then clicking on the desired well (s) on the template that will be used as blanks. If more than one well is selected to be a blank, the ODs will be averaged from the specified wells and the average subtracted from all other wells on the plate.

5.2.4 Well Type Labels

Label	Definition
S	Standard
C	Control
T	Test Sample
NC	Negative Control
PC	Positive Control
CO	Cut-off Control
PR	Positive Reference
SC	Serum Control
AC	Antigen Control
N	Negative

5.2.5 Report Format Set-up

- **Note:** This is the last step that will be programmed while programming an assay. Report Format must be programmed once all data reduction operations have been added to the assay, otherwise the report will be incomplete.

Report Layout Tab (Figure 5.4)

1. Click on the **Report Format Set-up** icon
2. Click on the **Report Layout** tab.
3. By default all the information in the left column will be included in the final report. To remove unwanted information from the report printout, highlight an item in the right column and then click on the **Remove** button. The order in which information is displayed on the report can be changed by highlighting the report topic in the right column and clicking the **Move Up** and **Move Down** buttons. Clicking **Add** will add the highlighted item in the left column to the bottom of the right column. Clicking **Insert** will insert the highlighted item in the left column above the highlighted item in the right column. **Add All** will add all items in the left column to the right column in the order it appears in the left column. Information that already exists in the right column will be duplicated. **Clear** will remove all items from the right column.
4. Dynex recommends including Laboratory Information, Header Information, Data Matrix and the final data reduction step in the assay as a minimum. If data is blanked Dynex recommends showing raw (unblanked) data and/or blank mode on the report. If a curve

fit is in use in the assay, always add a curve fit to the column on the left so the curve fit graph will be displayed. Other items are optional and at user discretion to add to the report.

- Click **Validate** when finished and continue to the Report Format tab (see figure 5.5).

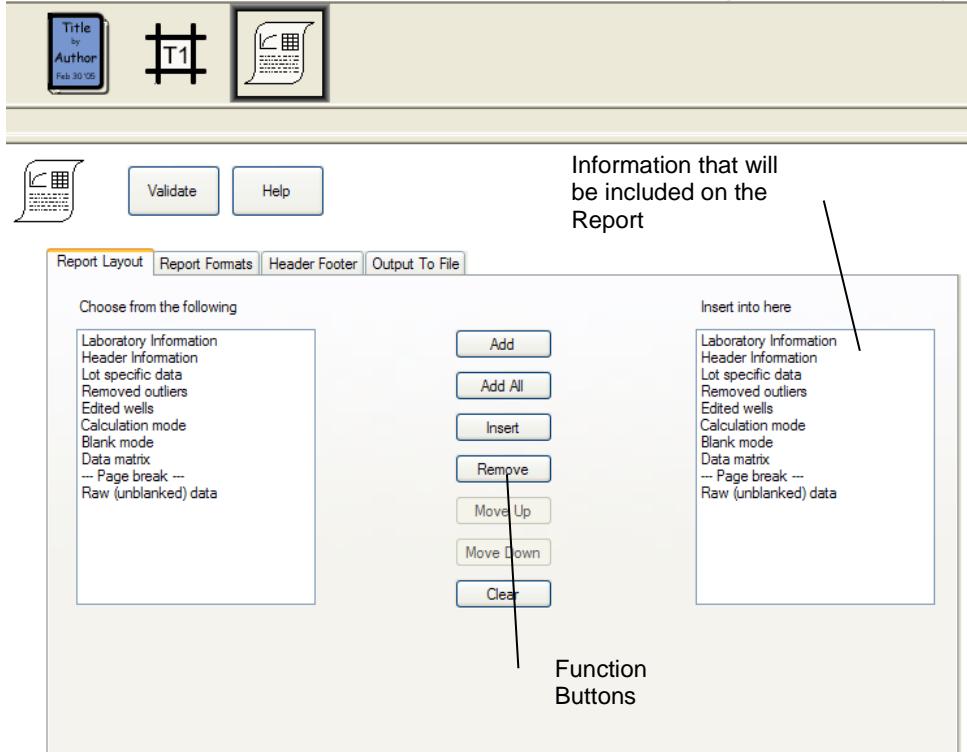


Figure 5-1: Report Layout Definition Screen

Report Formats Tab (Figure 5.5)

- Click on the **Report Formats** tab.
- Select **Format Type** by selecting the appropriate radio button (raw data, ratio, threshold, curve fit, or spreadsheet). Data will be reported according to one or more of these options as programmed in the assay. The user must define a format type for each of the different operation types that will appear in the assay report. **If a format type (create matrix or create table checkbox) is not selected for a data reduction operation, even if the operation is selected to appear on the report on the previous tab, only the operation heading will appear on the report, no data will appear.**
- Check the **Create Matrix** check box for results to be displayed in an 8 x 12 array format.
- Check the **Create Table** check box for data to be displayed in a tabular format. Use the check boxes in the **Table Options** area to indicate which data to include in the table. In the **Results Order** area of Table Options, select the order of results. Each well type is identified in the column on the left. For data for a certain well type to appear on the report, the well type must appear in the column on the right. Well types can be added to or removed from the right column via the following method:

- a. Highlight the desired well type, and then click on the Add  button to add the well type to the report.
 - b. Highlight the desired well type from the list, and then click on the Remove  button to remove it from the report.
 - c. Click on the Add All  button to move all well types into the list.
 - d. Click on the Remove All  button to remove all well types from the list.
 - e. Click the up or down arrow next to the right column to move highlighted well types up or down in the list.
 - f. Click **Validate** when finished.
5. In the **Numeric Options** area, check the check box to **Average the replicates** if needed. Enter the desired number of decimal places the numeric data should be rounded to. In the **Mean** area:
- a. Select the radio button for **Arithmetic mean** to perform calculations using addition (+), subtraction (-), multiplication (*), and division (/). The arithmetic mean of replicate determinations will be reported.
 - b. Select the radio button for **geometric mean** to perform calculations using the antilog of the mean of the logarithms of replicates. Reporting the geometric mean is useful when there is imprecision built into the result data.

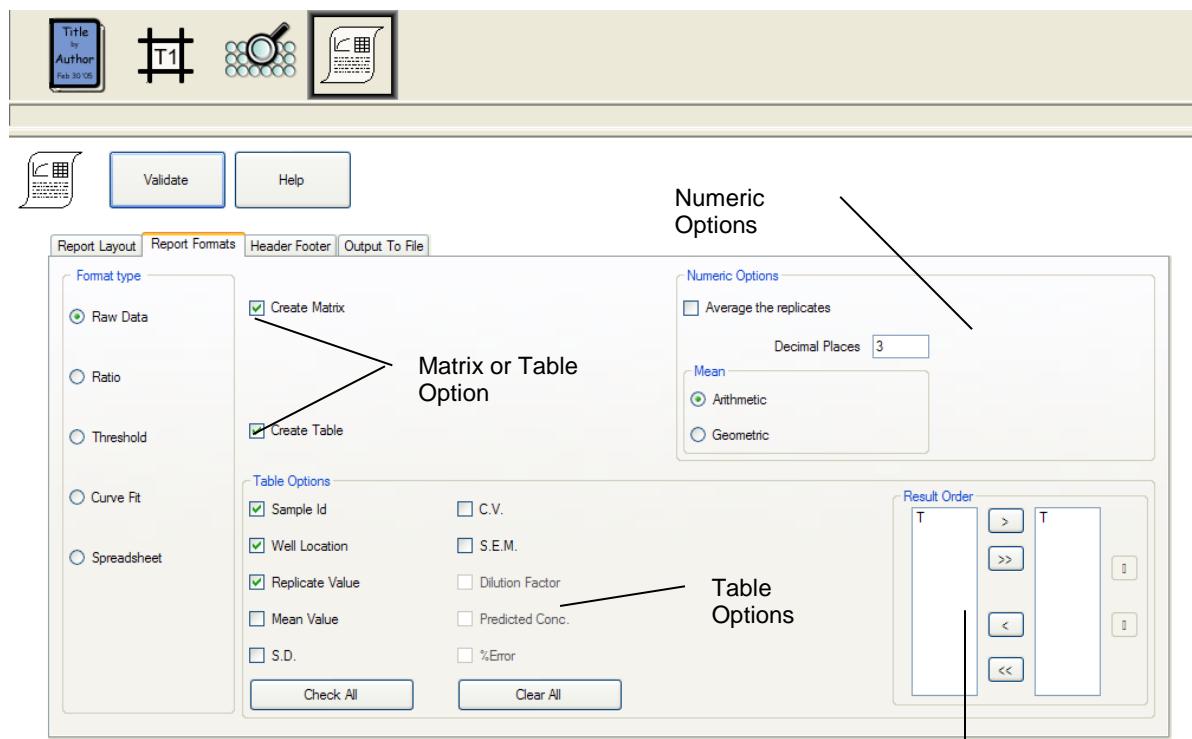


Figure 5-2: Report Format Definition Screen

Result
Order
Selections

Header Footer Tab (Figure 5-6)

1. Click on the **Header Footer** tab.
2. Select the desired Header and Footer options to be put at the top and /or bottom of each report page by checking the check boxes associated with each piece of information.
3. Click **Validate** when finished.

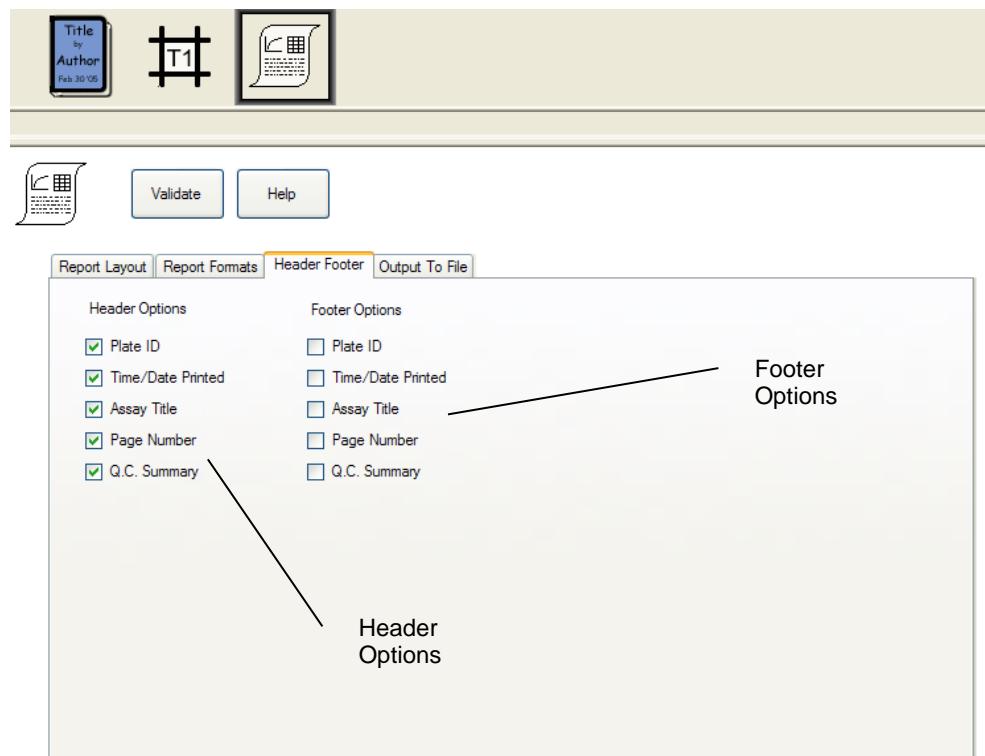


Figure 5-3: Header / Footer Options Screen

Output to File Tab

1. Click on the **Output to File** tab.
2. If the data report is to be used with software such as external spreadsheets, check the **Enabled** check box.
3. Information can be divided for export using a tab, comma, space or semi-colon separator by choosing the radio button associated with the desired option in the **Separator** area. Dynex recommends using the comma separator.
4. Select the data to be exported by checking the check box associated with the desired data in the **Select Data to Export** area.
5. Assign a file name and path where the output files will be exported by clicking on the  button in the **Output File Name** area. The selected data will automatically export as a CSV (text type) file every time the assay is run.
6. Click **Validate** when finished.



Note: A printer driver must be installed for reports to be viewed using the Matrix software.

5.3 Programming Assay Operations

The following Operations can be programmed into an assay:

1. Dilution of controls, standards, and test samples
2. Dispensing of reagents
3. Pipetting standards, controls, and test samples based on the microplate pipetting template
4. Well-fill verification (to verify pipetting volumes)
5. Plate incubation (from ambient to 50°C)
6. Plate shaking
7. Plate washing
8. Plate reading at a specified wavelength
9. Quality Control assay verification
10. Ratio, Threshold, Curve Fit, Spreadsheet, and Boolean (custom) data reduction

Adding, Deleting, and Changing the Order of Operations in an Assay

1. To add operations to an assay, click on the desired operation icon, hold down the mouse button and drag and drop the operation icon to the desired location in the programming toolbar.
2. Define the parameters of the operation by clicking on the icon in the programming toolbar and setting the parameter values in the operation programming screen.
3. Delete operations from the assay by clicking on the operation icon in the programming toolbar, holding down the mouse button, and dragging and dropping the icon into the trash can icon in the upper right corner of the Assay Editor window. Click **OK** to confirm the action. Click **Cancel** if the assay should remain unchanged.
4. The order of operations may be changed by dragging and dropping an icon before or after another icon in the programming toolbar.
5. As the assay is created, text describing the actions taking place in each assay operation appears on the right side of the screen. Text describing the operation icon which is currently highlighted will have blue font. Text describing all other operations will have black font.

5.3.1 Programming Assay Operations

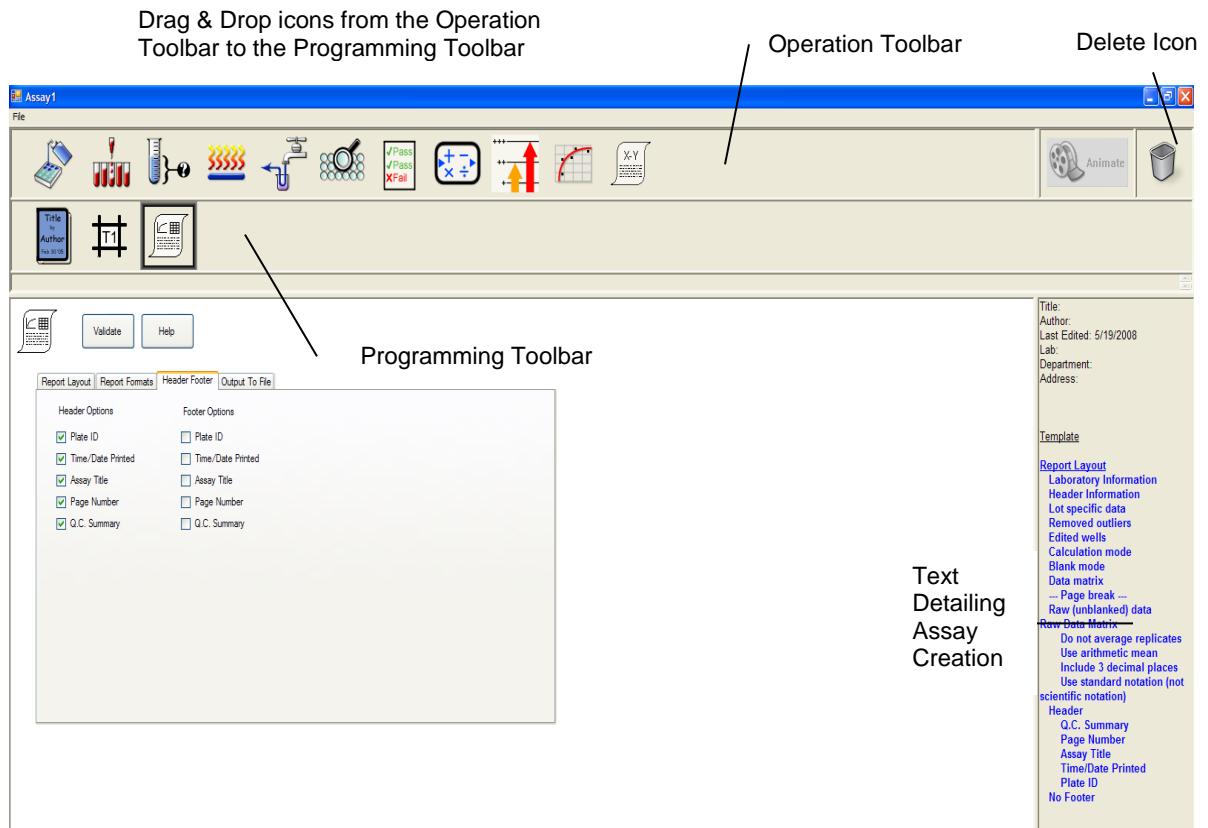


Figure 5-4: Assay Programming Screen

5.3.2 Dispense Operation

Defining Dispense Parameters

The dispense operation is used to pipette reagents (reagent blanks, conjugate, substrate, etc.) to the microplate. A reagent tip is used for dispense operations. Fluids defined as standards, controls and specimens cannot be transferred to the plate using a dispense operation.

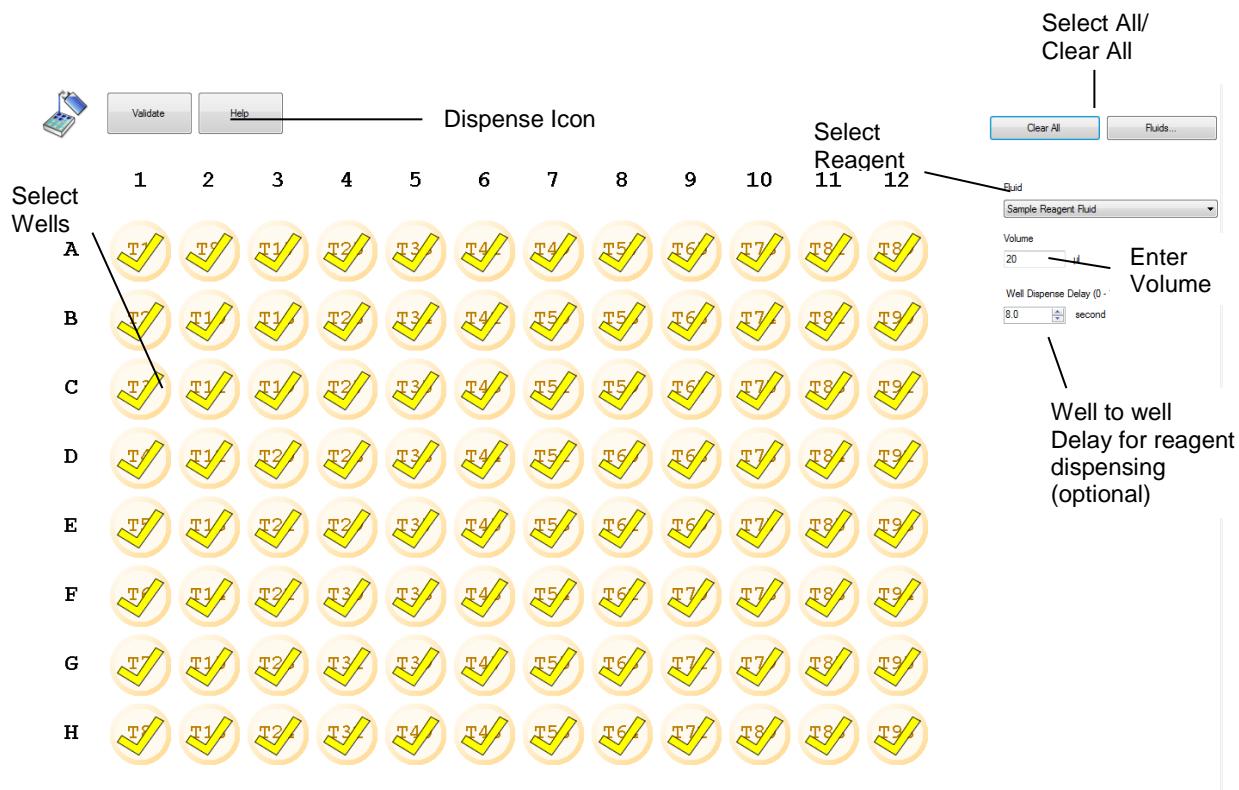


Figure 5-5: Programming Dispense Operation

1. Select the wells the selected reagent will be dispensed to by clicking and dragging the cursor over center of the wells, by clicking on each well individually, or by clicking the **Select All** button.
2. Selected wells will have a yellow / mark.
3. Use the Fluid drop-down list to select the reagent to be dispensed.

4. If a new fluid must to be added to the Fluids Database, click on the **Fluids** button. Click

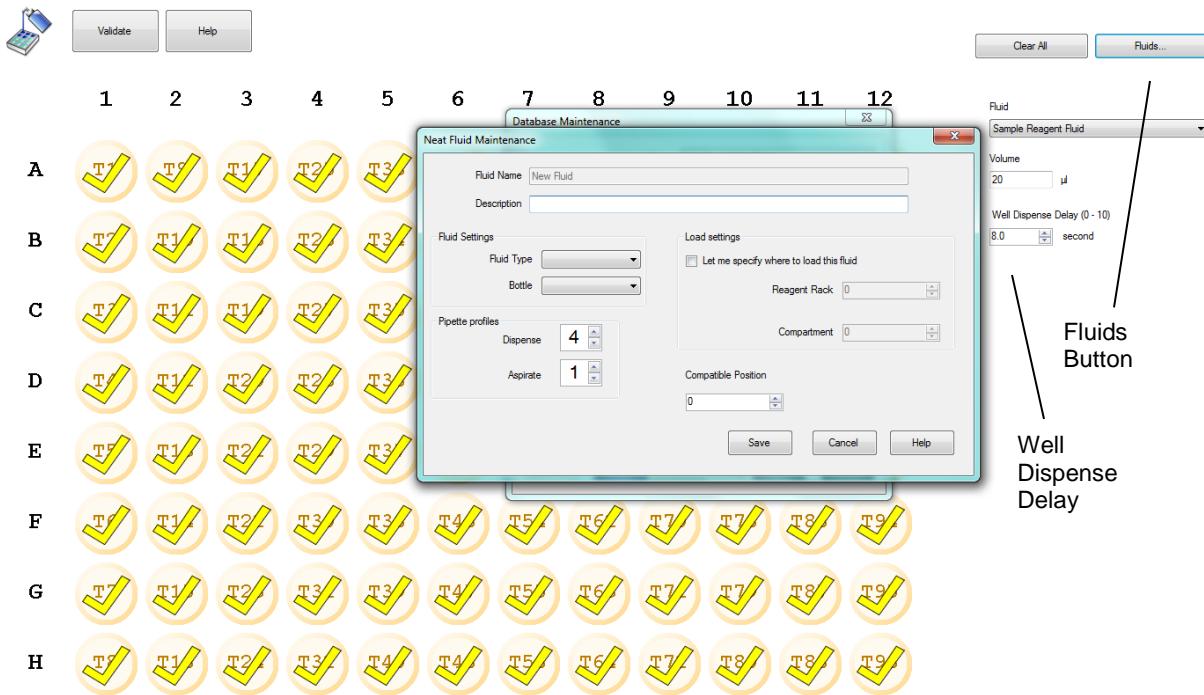
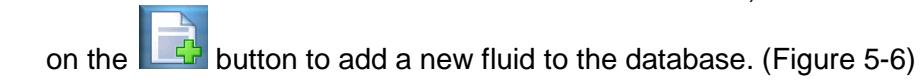


Figure 5-6: Add Fluids Dialog Box

5. Enter the **Volume** of the reagent fluid to be dispensed.
6. **(Optional)** Specify a **Well Dispense Delay**. The delay can be specified from 0.1 to 10.0 seconds. The DS2 will pause in between each well for the specified period of time while dispensing reagent to the plate. This feature can be used to synchronize dispense timings for reagents to eliminate assay drift.
7. Click **Validate**.

5.3.3 Pipetting Operation

5.3.3.1 About Diluting Samples

The *DS2 Automated ELISA Processing System* can dilute samples, controls and standards. Dilutions can be performed in a single stage in standard microplates or in two stages using deep-well strips. The DS2 adds diluent to a plate or deep well before the sample is added. Clicking once on a well or well type in the microplate pipetting template allows dilution in the deep-well strips. The selected wells are outlined red. Clicking a second time on the template allows dilution in the plate. The outlines around the selected wells will change from red to green. If the well is clicked a third time, the well will no longer be selected for dilution (no colored circle around the well).

The dilution ratios allowed for various dilution options are described below:

Dilution Mode	Allowed Dilution Ratios
<i>Microplate Dilution</i>	Ratios of sample to diluent range from 12.5:1 to 1:29 (e.g. 10 µL sample combined with 290 µL of diluent to yield a 1:29 dilution).
<i>Deep-well Strip Dilution</i>	Ratios of sample to diluent range from 12.5:1 to 1:199 (e.g. 10 µL sample combined with 1990 µL of diluent to yield a 1:199 dilution).
<i>Two Stage Deep-well Strip Dilution</i>	Ratios of sample to diluent range from 156:1 to 1:39,601 (e.g. 10 µL sample combined with 1990 µL of diluent in a deep-well, from which 10 µL is combined with 1990 µL of diluent in a second deep-well to yield a 1:39,601 dilution).

Setting Dilution Parameters

1. Drag the pipetting operation icon into the programming toolbar.

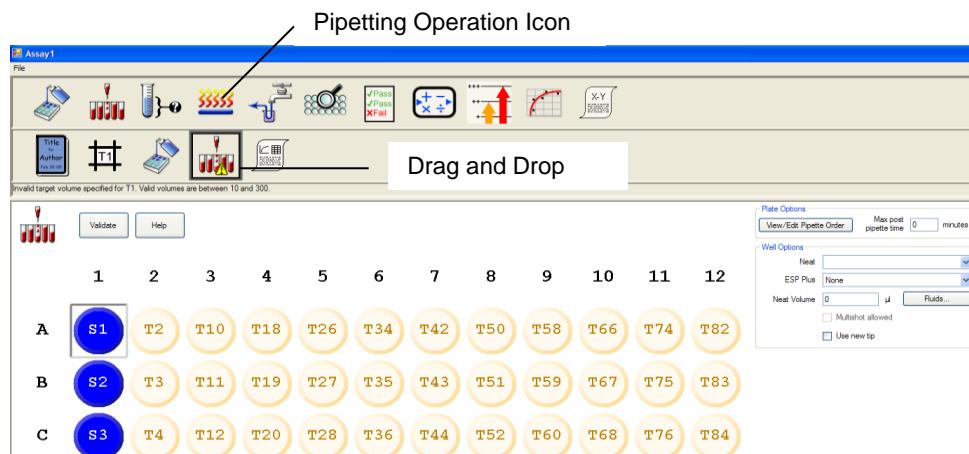


Figure 5-7: Programming the Pipetting Operation

2. Click the well locations on the template which will contain a diluted sample, control or standard.

- a. If clicked **once**, a **red circle** will appear around the well, indicating that dilution will take place in a deep well.
- b. If clicked **twice**, then a **green circle** will appear around the well, indicating that dilution will take place directly in the well on the plate.

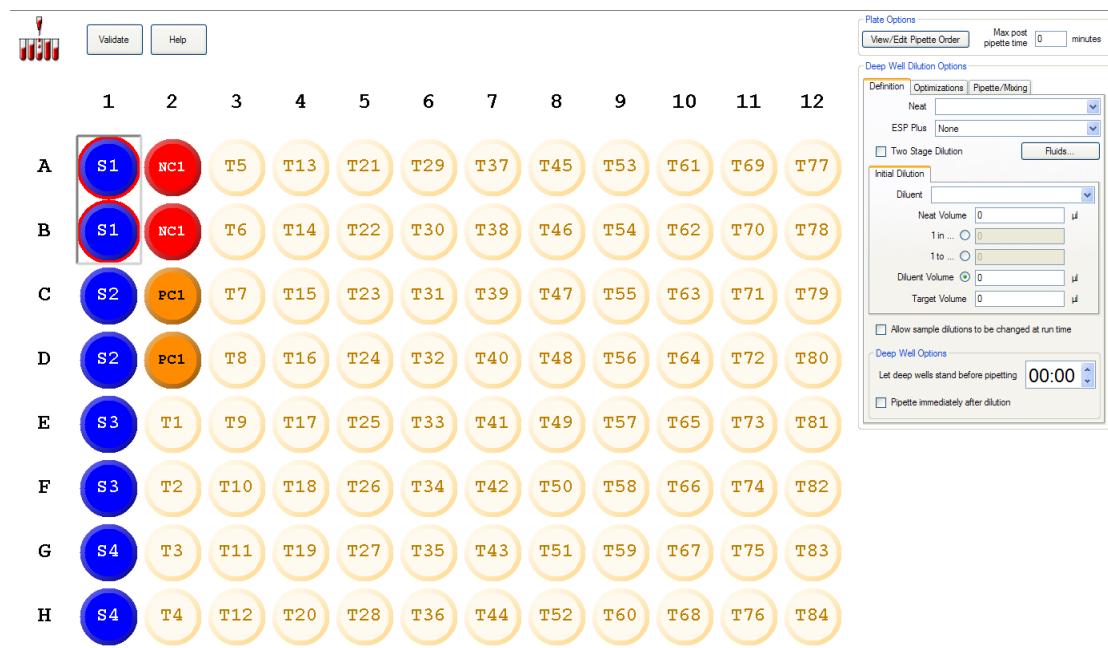


Figure 5-8: Dilution in Deep-Well

3. Click on the **Definition** tab.
4. Choose the “neat” fluid to be used from the drop-down menu.

► **Note:** When a Test Well type is selected, the neat fluid will automatically be designated as “sample” and cannot be changed by the user.

5. Choose the **Diluent** to be used from the drop-down menu (Fluids may be added to the database by clicking the **Fluids** button).
6. Select the dilution ratio or absolute volume.

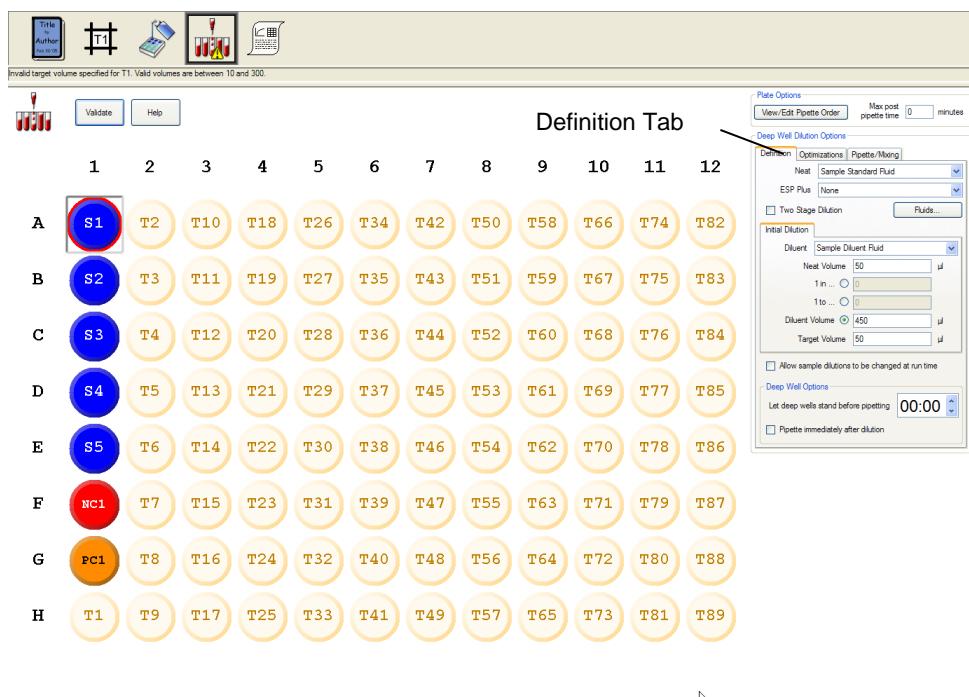


Figure 5-9: Programming Pipette / Dilution Operation

7. Enter the desired dilution formula for each well:

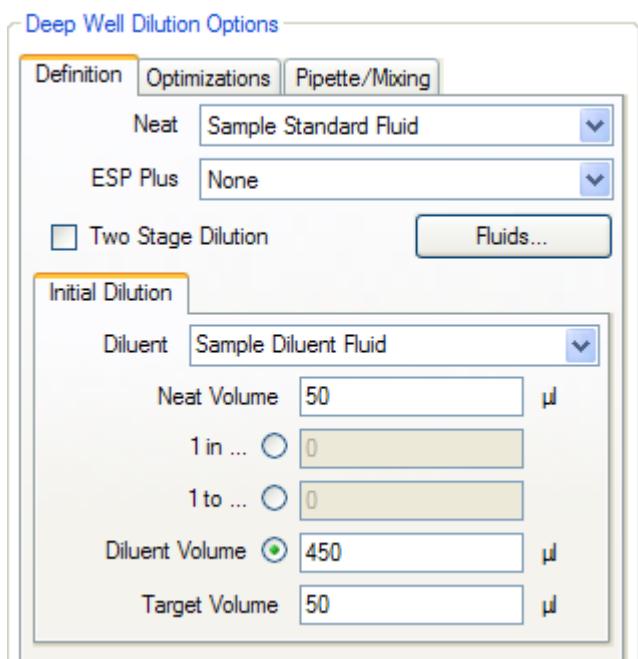


Figure 5-10: Programming the Pipette Operation (Example of defining a specified volume)

Dilution Formula	Explanation
1 to	A ratio of one part concentrate to a specified number of parts diluent, for a total of parts C + D. <i>EX:</i> 1 to 10 parts is made up of 1 part concentrate plus 10 parts diluent for a total of 11 parts.
1 in	A factor of one part concentrate in a total number of specified parts. <i>EX:</i> 1 in 10 equals 1 part concentrate and 9 parts diluent for a total of 10 parts.
Volume specified	The exact amount of volume of diluent will be pipetted into deep-well strip or plate. Enter a neat fluid volume and a diluent volume. If using a deep well for dilution, specify the target volume. The target volume is the volume of diluted specimen to be transferred to the microplate from the deep well following the dilution step.

9. To perform a two stage dilution in the deep well strip, check the “Two Stage Dilution” checkbox. Enter in the dilution formula information on the **initial dilution** tab, then select the **secondary dilution** tab and enter in the dilution formula information for the secondary dilution tab.
10. When performing the assay, if the user should be able to change the dilution volumes at runtime, enable the option to **Allow sample dilutions to be changed at runtime**.

11. When diluting specimens in the deep wells, the user may elect to have the specimens stay in the deep wells for a specified length of time prior to being transferred to the plate by entering the desired time into the **Let deep wells stand before pipetting** field. Deep wells may incubate for up to 60 minutes prior to transfer.

12. Click on the **Optimizations** tab.

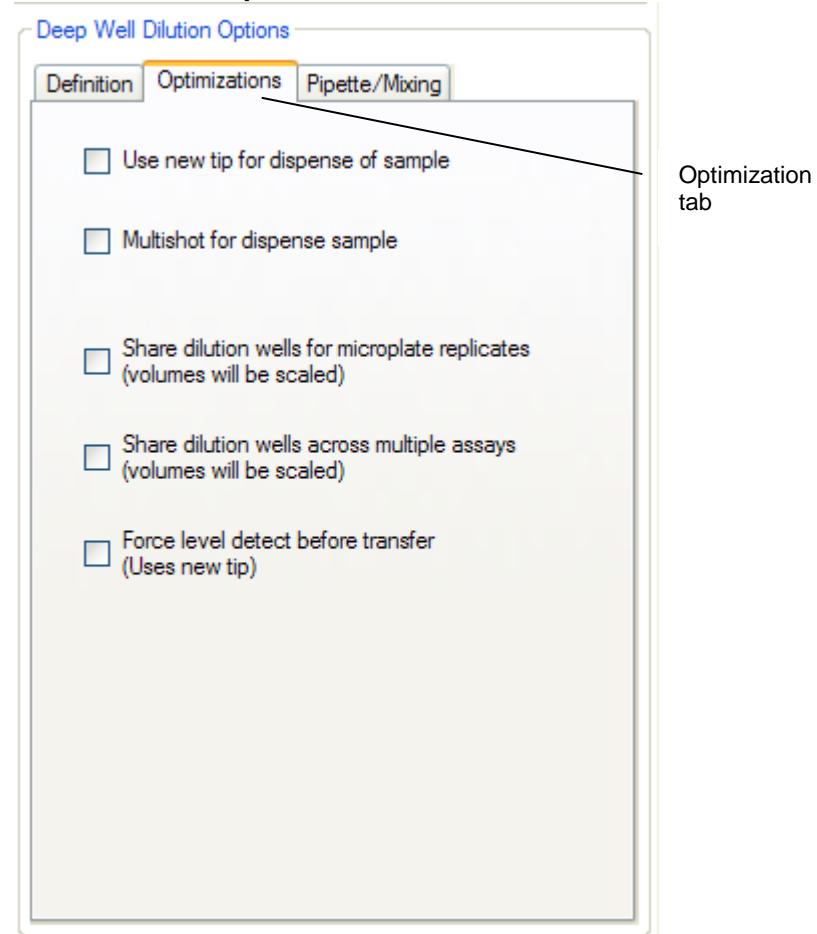


Figure 5-11: The Optimizations Tab

13. Select an option by checking the checkbox to the left of each option. When diluting in the microplate, the bottom three options are unavailable.

Option	Description
Use new tip for dispense of sample	A new sample tip will be used to pipette each well.
Multishot for dispense sample	The same sample tip will be used for replicates. If fluid for more than one dispense can be aspirated at one time, the required number of dispenses will be aspirated at once and pipetted into the required wells.
Share dilution wells for microplate replicates (volume will be scaled)	Only one dilution will be made for an individual sample. The dilution will be used for all replicates in the assay.
Share dilution wells for microplate replicates (volume will be scaled)	Only one dilution will be made for an individual sample. The dilution will be used for replicates in all assays on the current worklist that share a common sample diluent.
Force level detect before transfer (uses new tip)	If selected, a liquid level sense is performed on each deep well prior to pipetting the sample to the plate. Choosing this option will increase the pipetting time from the deep well strip to the plate. Dynex does not recommend using this feature as bubbles generated during dilution mixing may cause inaccurate level detection.

14. Click on the Pipette/Mixing tab (Figure 5-12).

- a. Enter the desired speed profile (speed that pipetting takes place).
- b. Enter the number of desired mix cycles (the number of times the dilution mixture will be aspirated and dispensed to ensure thorough mixing before final pipetting).



Note: Mixing Cycles can **only** be set for deep well strips. Mixing functions are not available for dilutions taking place in microplates.

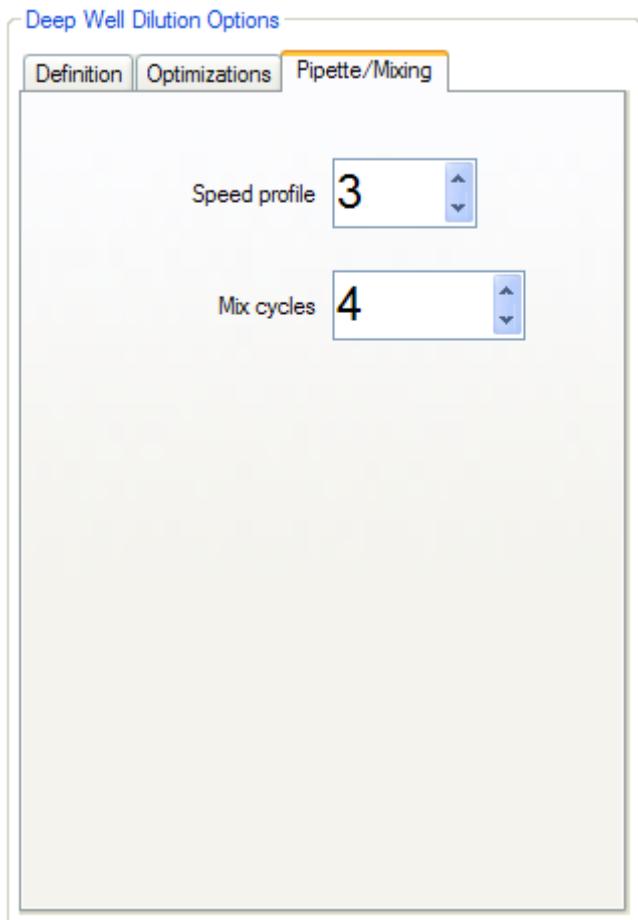


Figure 5-12: Pipetting/Mixing Tab

5.3.3.2 Pipetting without Dilution

The Pipette operation pipettes a specified fluid into selected wells. To pipette a control, standard, or specimen directly from the vial to the plate:

1. Click and drag the **Pipette** icon onto the assay programming bar if the Pipette Operation is not already present.
2. Click on the desired (target) well.
3. Select the desired **Neat** fluid from the drop down list.
 - a. To add a new neat fluid, click the fluids button.
 - b. Define the Neat Volume by entering the volume (in μL) into the text box. The Neat Volume is the volume of neat fluid which will be pipetted directly into the microplate well.

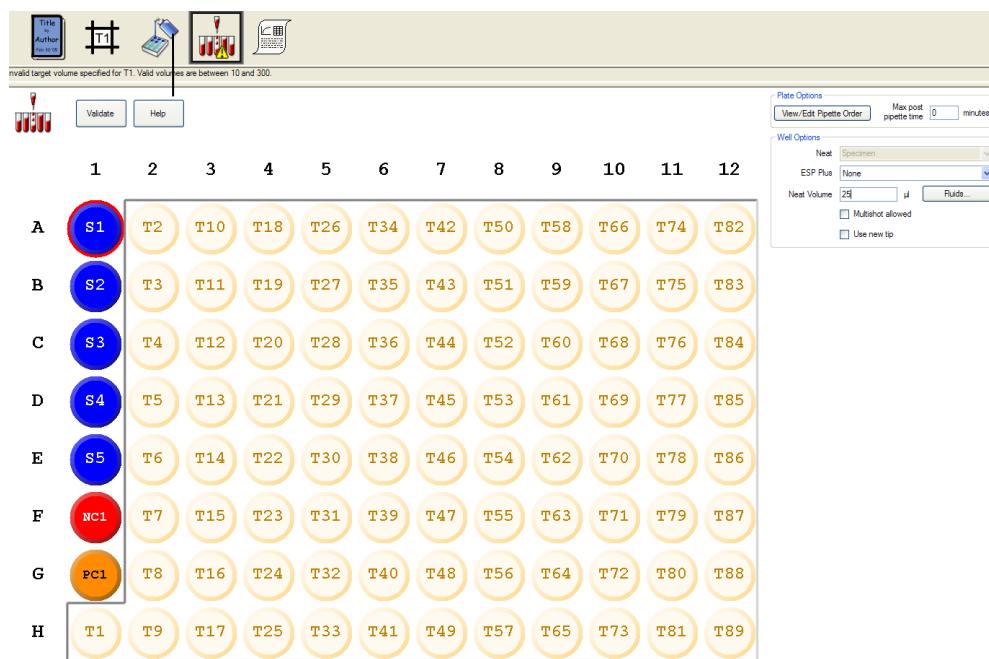


Figure 5-13: Pipette Test Samples

- c. Select Multishot Allowed or Use New Tip if either option is desirable. If Multishot is selected, fluid will be aspirated in one tip to dispense all replicates of an individual test sample or reagent (up to the volume capacity of the tip). If neither option is selected, if replicates are present on the microplate pipetting template, the same tip will be used to dispense all replicates, but multishot will not take place.
4. (Optional) Select an **ESP Plus** profile (Electronic Signature tracking to ensure pipetting was done properly) if desired. In order for an ESP Plus profile to be available in the drop-down list, an ESP calibration must be performed for the sample type and the calibration values must be saved (**Tools>ESP Calibration**).

5. By clicking on the **View / Edit Pipette Order** button, the user can program which wells will be pipetted to the plate first. For example, if the user intends to pipette a negative control in the beginning of the plate (NC1), then samples, then a negative control at the end of the plate (NC2), then the pipetting order must indicate this sequence. In addition, if the pipetting order is changed from the default order indicated by the software, the user must select **Use new tip for dispense of sample** when pipetting diluted controls or **Use new tip** when pipetting directly from the vial to the plate to ensure the pipetting order is followed.
6. **Max post pipette time** is the acceptable amount of time that a plate can sit prior to the next scheduled event being performed once pipetting is completed. This feature is useful when pipetting plates in parallel, so that one plate is not inactive for extended periods of time while operations are being performed on the other plate.
7. Click **Validate** to save the information.

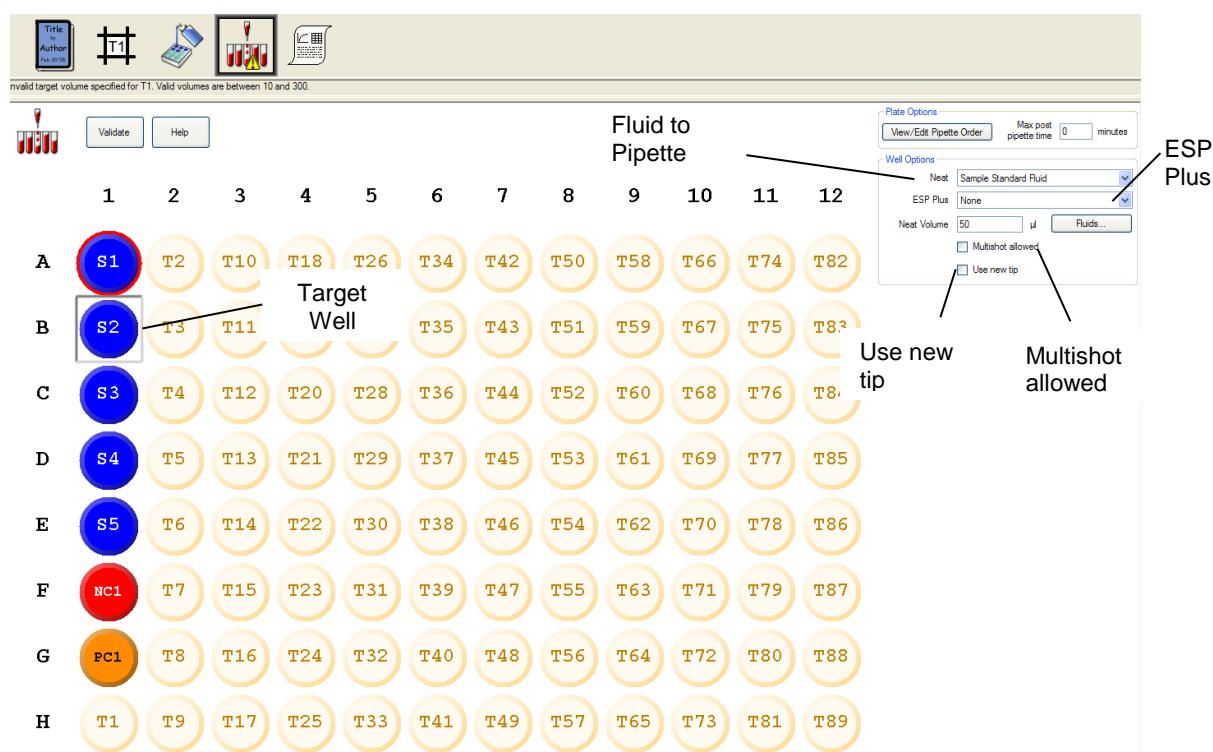


Figure 5-14: Pipette Standards and Controls

5.3.4 Verify Operation

Well Fill Verification is used to track accurate pipetting of fluids into specified wells based on their OD readings. The solution in the wells at the time of well fill verification must be a colored solution.

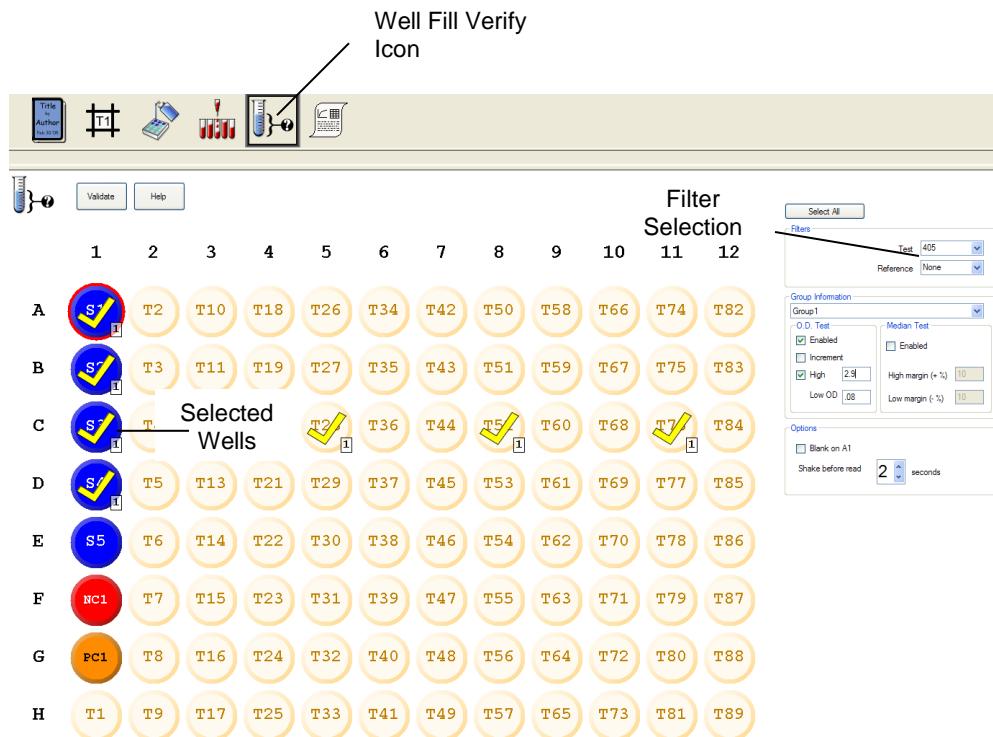


Figure 5-15: Well Fill Verification Operation

Setting Well Fill Verify Parameters

1. Click and drag the **Well Fill Verify** icon to the programming toolbar to add it to the assay sequence.
2. Select the wells for the well fill verify operation by clicking on the desired wells. A yellow ✓ will appear in selected wells.
3. Select the test and reference **Absorbance Wavelengths** the plate will be read at. Usually a single wavelength is suitable.

4. Well fill verification can be accomplished in several different ways. The user can:
 - a. Select the **Enabled** check box for **OD Test**. The absorbance from each selected well will be expected to fall within the specified OD range.
 - i. To test that each OD falls within a range, check the **High OD** check box, enter the highest acceptable OD for each well and enter the lowest acceptable OD for each well. The user may choose to enter a High OD value only and leave the low OD value blank. It is also acceptable to uncheck the check box for the High OD and enter only the lowest acceptable OD for each well. Select **Increment** if the previous well fill verification results should be subtracted from the active set before performing the test.
 - b. Select the **Enabled** check box for **Median Test**. Set high and low margins as percentages around the median. Matrix will calculate the mean OD from the group of wells, and then calculate an acceptance range based on the entered percentages.
 5. Well fill verification parameters may be entered for more than one group of wells. To create parameters for more than one group of wells, select a new group number from the drop down list, select the wells to be included in the new group, and enter in the verification parameters that apply to these wells.
 6. If **Blanking** on A1 is enabled, the OD from well A1 will be subtracted from all the other wells before the verification is performed.
 7. The user may add a shake step before reading takes place to ensure that no air bubbles interfere with the reported OD. The user can specify a shake time of up to 9 seconds.
 8. If any of the wells fail the defined well fill verification criteria, the software will stop and an alert message will display which requires user interaction to continue. Therefore it is very important that the user return to the DS2 when a well fill verification is taking place to ensure no user interaction is required to continue the timeline.

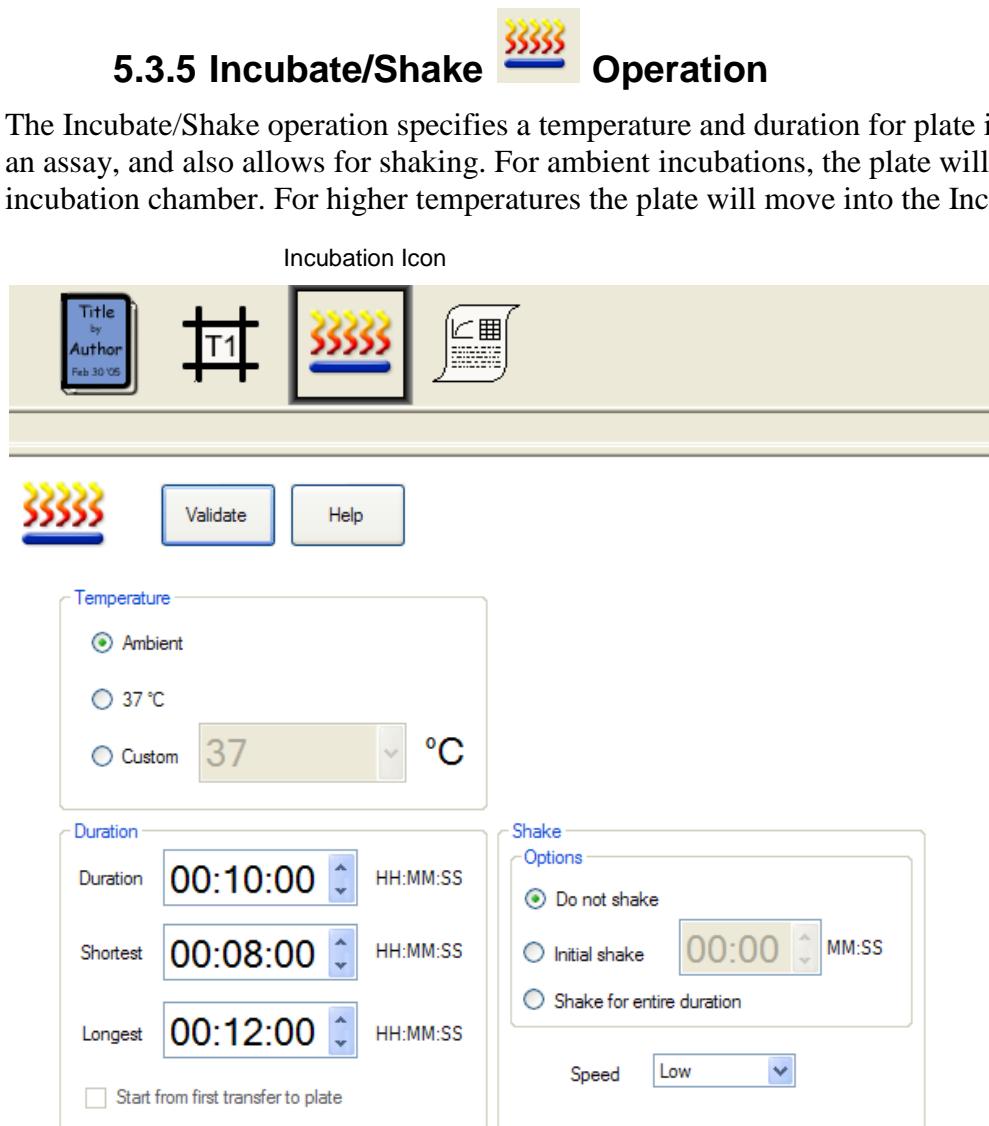


Figure 5-16: Incubate/Shake Operation Screen

Incubate/Shake Settings

1. Drag and drop the Incubation Operation icon into the Programming toolbar.
2. Define the Duration by clicking on hours, minutes, or seconds, then clicking on the up and down arrows. Incubation durations can last up to 23 hours, 59 minutes and 59 seconds.
3. Set the Shortest and Longest duration allowed for incubation. The incubation duration may be modified from the specified duration to fall within the given shortest and longest limits by Matrix in order to best-fit assay operations.
4. Set the Temperature. Matrix will monitor the temperature of the incubation chamber, showing the current temperature in the upper right corner of the Timeline screen.
5. If the temperature selected is Ambient, the user may choose to time the incubation starting with the first transfer of specimen to the plate by checking the Start from first transfer to plate checkbox. This check box can only be selected when ambient temperature incubation is chosen and when there are no operations inserted in the program between the pipette operation and the incubation operation (for example, no dispense may be present between the pipette operation and the incubation operation).
6. Select the radio button for the desired shaking option. The default for shaking while incubating is *off* or *Do not shake*. The user may choose to:
 - a. Perform a short initial shake by selecting the **Initial Shake** radio button and specifying a shaking time.
 - b. Shake the entire incubation time by selecting the **Shake for entire duration** radio button.
7. Select the Speed at which the shaking will take place. Shaking is linear.
 - a. Low - shakes at 14hz with an amplitude of 1.5mm (~840 RPM)
 - b. Medium - shakes at 17hz with an amplitude of 1.5mm (~1020 RPM)
 - c. High - shakes at 20hz with an amplitude of 1.0mm (~1200 RPM)
8. Click **Validate** to save the settings.

5.3.6 Wash Operation

A Wash operation can consist of Purge, Dispense, Fill, Aspirate, Clean and Soak settings.

Summary of Wash Operations

Operation	Description
<i>Purge</i>	Dispenses fluid from the dispense wash pins while the wash head is positioned over the purge tray. A Purge is carried out at the beginning of a wash protocol to fill the lines to the wash head with the correct wash buffer and to remove any air bubbles in the tubing lines. Dynex recommends not using less than 3000 µL to perform a purge.
<i>Clean</i>	Dispenses fluid from the clean line from the dispense wash pins while the wash head is positioned over the purge tray. A Clean cycle is carried out at the end of the wash protocol to prevent buffers from crystallizing inside the tubing lines and causing blockages. Dynex recommends programming a clean cycle as part of every wash operation using no less than 5000ul of water.
<i>Dispense</i>	Aspirates the contents of the well and then dispenses a specified amount of fluid into the wells. If a bottom wash is specified, the wash head is then lowered to the bottom wash position. The fluid will be aspirated from the bottom of the wells as wash fluid is being dispensed.
<i>Fill</i>	Allows the user to fill the wells with a specific volume. No aspiration will occur.
<i>Aspirate</i>	Removes the contents of a well by positioning the wash pins at the aspiration height in the well and aspirating the liquid from the wells.
<i>Sweep</i>	The aspiration pins move from side to side inside the well during aspiration.
<i>Super Sweep</i>	The aspiration pins move in a four-step X pattern across the well during aspiration.
<i>Soak</i>	The contents of the wells sit for the specified number of seconds after each dispense cycle. Once the soak cycle is complete, the fluid is aspirated.

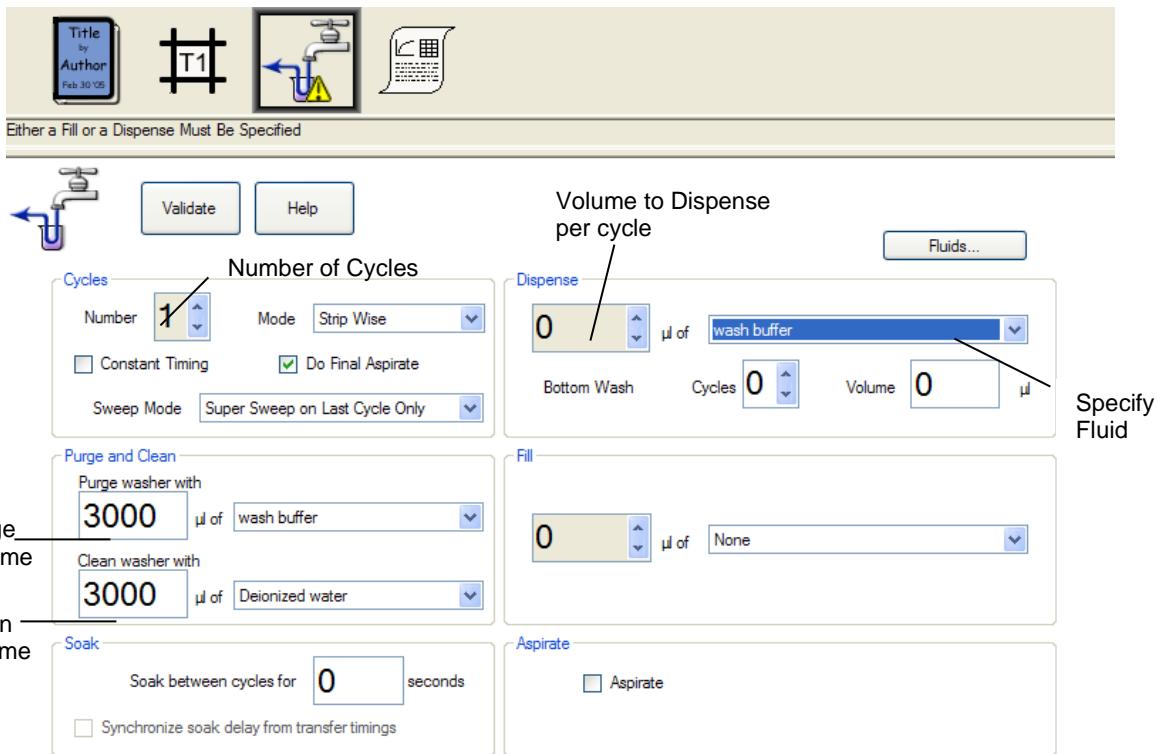


Figure 5-17: Wash Operation Parameters Screen

Setting Wash Parameters

1. Drag and drop the **Wash Operation Icon** into the programming toolbar.
2. Set the number of **Wash Cycles** to be performed, according to the assay protocol. The number of cycles can be 1 – 9.

► *Note: The plate frame must contain whole strips for a wash operation to be performed. Dummy wells may be used to fill in empty spaces to create a whole strip.*
3. Select to wash the plate **Stripwise** or **Platewise**.
 - If washing **Stripwise**, all cycles are completed on one strip before moving to the next strip. For example: 3 cycles are programmed with a 5 second soak after each aspirate-dispense cycle. The DS2 will aspirate and dispense the first strip, wait 5 seconds, and then repeat this cycle 2 more times on the first strip prior to performing any cycles on the second strip.
 - If washing **Platewise**, each cycle is completed on all strips on the plate before another cycle begins. Using the same example scenario as the stripwise mode, the washer will aspirate/dispense into the first strip, move to the second strip and so on down the plate, soak the whole plate for 5 seconds, and then begin the second cycle.
4. **Constant Timing** can be set if the time the wash operation lasts should be kept consistent regardless of number of strips (samples) processed on a given day. Matrix will add waiting time when washing partial plates in order to simulate the time to wash a complete plate.

EX: 3 strips on the plate are being washed in stripwise mode. After finishing the third strip, the washer will step through the remaining nine columns as if a whole plate were being washed for three cycles per strip and the wash head will then be parked. If cycles are performed in plate-wise mode, the washer will complete the first cycle and stay stationery over the third strip for the time it would take to aspirate / dispense the remaining nine strips. The washer then moves back to the first strip for the second cycle, and continues in this manner for the rest of the number of cycles programmed.
5. **Do Final Aspirate** is used to empty wells before the next operation is performed. If **Do Final Aspirate is not checked, wash solution will remain in the wells following the wash step.**

6. Select a **Sweep Mode** if extra aspiration is required to completely empty the wells of droplets of wash buffer before the next operation is performed. Sweep mode options are:

- None – normal aspiration will take place. The wells will contain fluid when the wash cycle is complete.
- Sweep – Normal aspiration takes place, then the aspirate pins move once across the well in a right to left motion to remove wash buffer which may be pooled at the well edges.
- Sweep on last cycle only – Sweep takes place only on the last programmed cycle.
- Super sweep – Normal aspiration takes place, then the aspirate pins move across the well in an x-patterned aspiration.
- Super sweep on last cycle only – Super sweep takes place only on the last programmed cycle.

► **Note:** Select **No Sweep** and disable bottom washing whenever a C-bottom, U-bottom, or V-bottom plate is being used.

► **Note:** **Sweep** should be used carefully to avoid scratching the bottom of the microwells.

7. Set the **Purge** volume and select the desired wash buffer.

- Purging fills the tubing lines with the specified wash buffer prior to beginning the wash cycle.
- Purging prevents the first few strips from getting air or bubbles dispensed into them.

8. Set the **Clean** volume and select the desired clean fluid.

► **Note:** A fluid must be added to the Washerfluid database with the load position specified as the “clean line” in order for options to appear in the drop down list.

- Cleaning uses fluid from the external bottle attached to the rear of the DS2 (bottle C) to clean the tubing lines following the last wash cycle.
- A clean step should be programmed after each wash operation in the assay.

9. Set a soak time in seconds by entering the desired time into the **Soak between cycles for** data entry field.

10. The **Synchronize Soak Delay from Transfer Timings** check box can be enabled to minimize OD drift across the plate due to differing incubation times between the strips.

- The DS2 will synchronize column soak time based on the time taken to transfer samples to the microplate. For example, if pipetting takes 15 minutes, and plate washing takes 3 minutes, the first samples will be incubated for the correct amount of time, while the later samples would incubate a shorter amount of time. This timing problem can be resolved by synchronization.
- There *must* be a **Pipette** step in the assay preceding the Wash operation in order for the synchronization checkbox to be enabled.
-
- The synchronization check box is only available when washing in *strip-wise* mode.

11. Enter the **Dispense** volume by using the up and down arrow keys. Dispense volumes may be from 50 to 1000 µL.

- Choose the wash buffer from the washerfluid database drop-down list.
- To add a wash buffer to the washerfluid database, click on the **Fluids** button. Follow the prompts to name and define the fluid. The user may select either the A or B bottle location, but Dynex recommends not to specify a location if multiple wash solutions will be used on the instrument.

12. Use **Bottom Wash** if fast washing is required.

- Bottom wash will squirt bursts of buffer into the well, while aspirating at the same time. Bottom wash can save time and buffer if used instead of an extra wash cycle. Bottom wash may be used with either plate or strip washing mode.
- Specify the number of **Cycles** and the **Volume** of wash buffer to use by using the up and down arrow buttons next to the associated parameter. 0 - 5 bottom wash cycles may be programmed using 0-1000 µL.

13. Check the **Fill** check box to dispense fluid. The Dispense and Bottom Wash options must be set to zero for the **Fill** option to become available. **Fill** may be used in either strip or plate-wise mode.

- The **Fill** operation may be used if a long soak time is needed. Program the **Fill** in the Wash operation, then program an Incubation operation for the length of time needed, then program another Wash operation into the assay.
- **Fill** may also be used for well fill verification to test the washer dispense accuracy.

14. Check **Aspirate** if wells only need to be emptied of fluid and do not need washing. The Aspirate checkbox does need not to be checked if wells are being washed normally.

5.3.7 Read



Operation

The Read operation allows the user to choose the appropriate wavelength filters for use with the assay and instructs the DS2 to read the absorbance of each well containing fluid.

Setting Read Parameters

1. Drag the **Read Operation Icon**  into the programming toolbar.
2. Select the **Primary Test Filter** and the **Primary Reference Filter** (if dual wavelength mode is used). To change the default filter wavelength settings, use the **Tools > Absorbance Filter** menu. To install new filters, refer to the Service and Maintenance section of this manual.

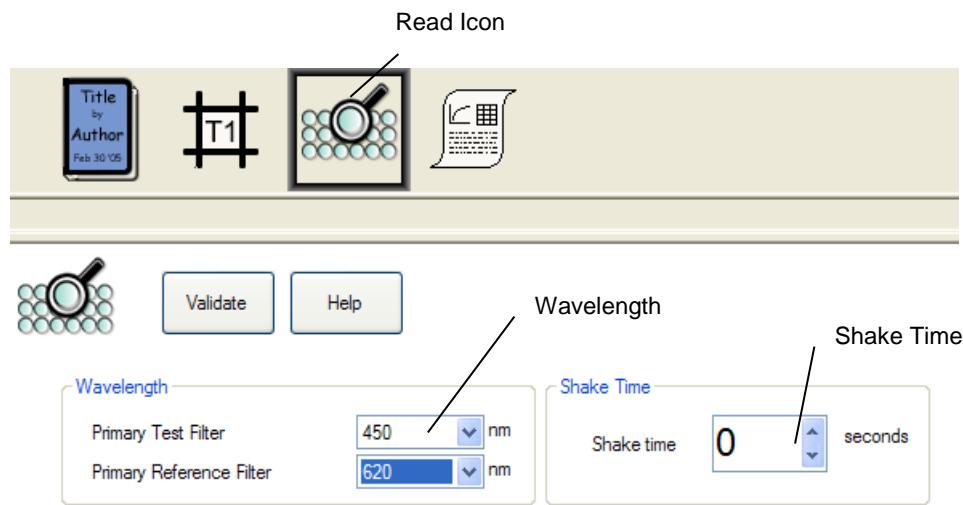


Figure 0-18: Read Operation Parameters Screen

Wavelengths: Wavelengths for OD readings are determined by the specific filters installed in the reader. The correct wavelength values must be entered for the installed filters in the Absorbance Filters menu for valid results.

If using single-mode, a primary test filter wavelength must be entered. If using dual mode, both filter wavelengths must be entered.

5.3.8 Dual Wavelength Mode

The dual wavelength mode can be used if necessary to reduce errors caused by dirt and scratches on the bottom of the wells as these artifacts tend to scatter radiation equally, regardless of wavelength.

The choice of test and reference wavelengths for the dual wavelength mode depends on the particular enzyme/substrate reaction being tested. However, the following rules should usually be followed:

1. The test wavelength (λ_t) should be at or near the maximum absorbance of the reaction product.
2. The reference wavelength (λ_r) should lie outside the absorbance band of the reaction.

The Reader subtracts the absorbance at the reference wavelength (λ_r) from the absorbance at the test wavelength (λ_t) to minimize the effect of background noise.

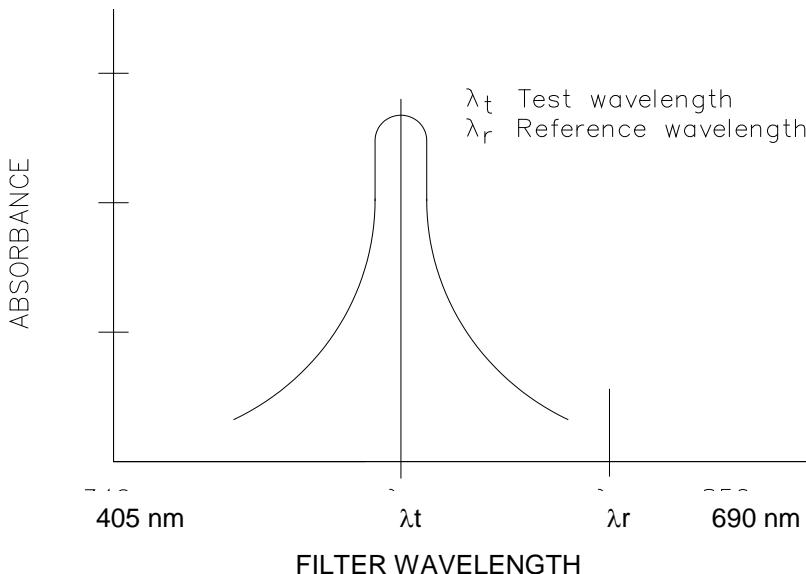


Figure 0-19: Dual Wavelength Selection

Shake Time: The shake time (in seconds) is performed prior to reading the plate. Plate shaking may be used to eliminate air bubbles from the sample and to give the sample an even meniscus.

Blank Mode: Wells to be used as blanks are specified in the microplate pipetting template. If no blank wells are specified, Matrix will use air as the reference level for 100% transmission.

If more than one well is selected to be a blank in the microplate pipetting template, the ODs of the average of the blank wells will be subtracted from all other wells on the plate.

5.3.9 Quality Control Operation

Quality Control Operation equations are used to ensure that an assay is valid and that the data generated can be accepted. The QC equations place criteria on the raw OD data, or data generated by a curve fit, threshold, ratio or spreadsheet operation.

1. Well ODs are accepted or rejected using criteria specified in the kit product insert (such as comparison against a control well or against a numerical value).
2. QC equations may be applied to any Well Type that has been defined in the template. If the QC equation fails, the user may elect to suppress all data from being output to subsequent operations.
3. Quality Control operations are context sensitive, as some QC equations may only be applicable to the results of a Curve Fit operation or to the results of a Threshold operation.

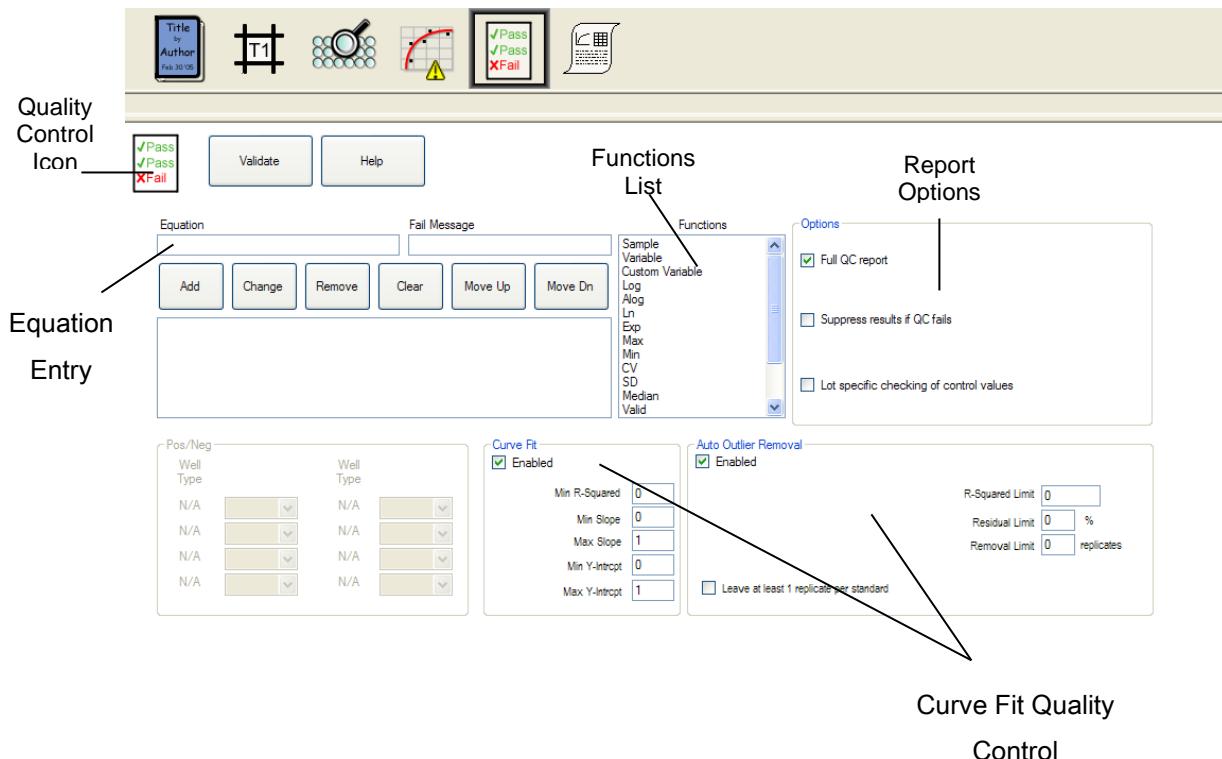


Figure 5-20: Quality Control Operation Screen

Setting Parameters for the Quality Control Operation



1. Drag the **Quality Control Operation icon** into the programming toolbar.
2. There can be more than one Quality Control operation in an assay. A quality control operation only applies to the data reduction operation immediately preceding the Quality Control operation. Therefore, if the kit package insert specifies that some QC equations are based on raw data results and some QC equations are based off of another type of data reduction output (i.e. concentration); the assay would require two Quality Control Operations.
3. Double click on the desired **Function** to add it to the equation. Functions are used to generate the equations. Continue to add functions until the equation is defined.
 - a. Mathematical functions (such as +, -, =, >, <) may be typed into the equation box.
4. Type in a **Fail Message** if desired. This message will be displayed in the report when the equation criteria have not passed.
5. Click on the **Add** button to add the equation to the list of quality control acceptance criteria.
6. Click on the **Clear** button to reset the Equation and Fail boxes so additional equations can be created.
7. To change an equation already added to the list, highlight the equation to be edited, make the desired changes in the equation text box, and click **Change**.
8. To remove an equation from the list, highlight the desired equation and click **Remove**.
9. The Quality Control equation checks will be performed in the order they appear in the list. Therefore if one equation depends on another equation taking place first, the equation which must be performed first must appear closer to the top of the list before the dependent equation (for example: the “i” function equation must appear closer to the top of the list than the “valid” function equation). To change the order of the equations, highlight the desired equation and click **Move Up** or **Move Dn**.
10. Options for QC Report handling include the default reporting of all QC results (**Full QC Report**). If the QC fails, all other results can be suppressed by checking the **SUPPRESS RESULTS IF QC FAILS** checkbox. This feature may be important if data is automatically being exported from Matrix into other files. QC results can also be related to an individual reagent lot by checking the **Lot specific checking of control values** checkbox (the **REQUEST KIT LOT DATA AT RUNTIME** checkbox must be enabled in the Assay Title Page screen for the lot information to be available for reporting).
11. Select options for Pos/Neg, Curve Fit, and/or Auto Outlier Removal, if the options are available. A Curve Fit or Threshold operation must be included in the programming toolbar before Quality Control Operation icon in order for these choices to be enabled.

5.3.9.1 *Quality Control Functions*

See **Appendix C** for function descriptions and examples which can be entered into Quality Control Equations.

5.3.9.2 *Typical Quality Control Equations*

Example: the template includes 4 NCs and 3 PCs

1. If any NC OD value is greater than 25% higher or lower than the mean OD value of all the NC's, it must be rejected, enter:

$$0.75 * NC \leq NC_i \leq 1.25 * NC$$

2. If the test must be rejected if one of the NC OD value fails the first Quality Control equation, enter:

$$\text{valid}(NC) \geq 3$$

3. If the average OD value of the Negative Controls must be more than 0.5 OD, enter:

$$NC > 0.5$$

4. If the average OD value of the Positive Controls must be greater than 20% of the average OD value of the Negative Controls, then write:

$$PC > 0.2 * NC$$

5. If the average Negative Control OD value must be less than half of the average PC OD values, enter:

$$NC < PC / 2$$

6. If the CV% of the Negative Control must be less than 15%, enter:

$$CV(NC) * 100 < 15$$

5.3.10 Ratio Operation

The Ratio equation is used to convert raw data using mathematical equations, which often expresses sample results as a ratio of a control value. Ratio calculations are frequently used in competitive inhibition assays or when detecting an increase in some factor over a normal baseline value. Every value on the plate is fed into the equation and the resulting values are reported and passed on to subsequent operations. Ratio operations can also be used to multiply wells on the plate by a correction factor, or to perform any calculation which is required for further data processing.

EX: In the equation “Sample/PC”, all sample OD values will be converted to a ratio of the average OD value of the Positive Controls.

Results from the ratio equation may be flagged with a user defined “result” or “flag” by clicking on the **Results Flagging** tab.

EX: In the equation “Sample>NC then SICK” data calculated from the “Sample/PC” equation will be flagged based on whether the results are higher or lower than the calculated negative control value.

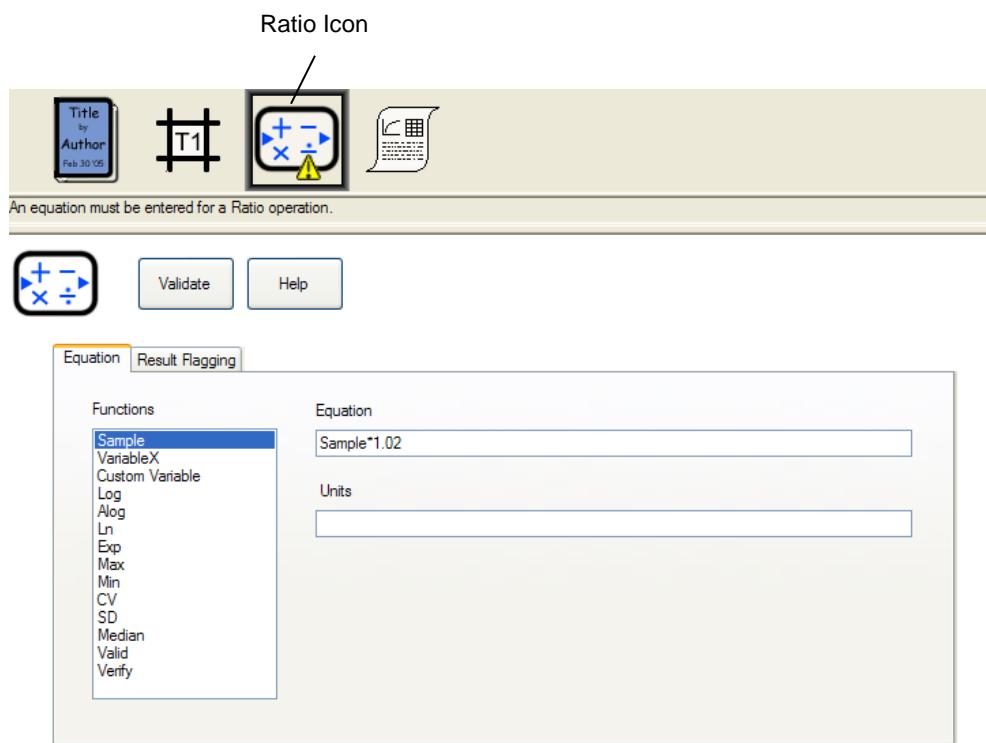


Figure 5-21: Ratio Operation Screen



1. Drag the **Ratio Operation icon** into the programming toolbar.
2. To create a Ratio equation, double-click on the **Functions** which will make up the working components of the equation.
3. Common arithmetic functions, such as addition (+), subtraction (-), multiplication (*), or division (/), etc. may be typed into the equation box.
4. Enter the **Units** the data is to be reported in, such as "mg/dL".



Figure 5-22: Results Flagging for the Ratio Operation

5. (Optional) Click on the **Results Flagging** tab in order to specify a phrase that either replaces a numerical result or is displayed next to a result. The phrase will be initiated whenever the numerical result meets the criteria programmed. Results Flagging is optional and should not be used if an LIS is being used.
 - The **Condition** is the Results Flagging expression, such as "Sample>NC". If text is to be reported instead of a numerical result, it can be typed into the **Result** box. Use of a **Flag** indicates the entered text will be reported along with the numerical result. Either a Result or a Flag can be entered, but not both.
 - **Examples** of Results Flagging:
 - The text "20 mg/dL" may be displayed instead of the actual numeric value whenever a test result is less than 20 mg/dL if the text string is entered into the **Result** field.
 - A flag of "Abnormal Low" might be displayed along side the numeric result if the result is less than 20 mg/dL and the text string is entered into the **Flag** field.

5.3.10.1 Ratio Function Entries

See **Appendix D** for possible mathematic and function entries which can be used to write Ratio equations.

Typical Ratio Equations

1. To convert all sample OD values to a ratio of the average OD of the Positive Control replicates, enter the equation: Sample/PC.
2. To convert all values into larger numbers than the OD units, enter an equation such as: sample/0.25.
3. Using an equation such as T1/PC (The result of Test well 1 divided by the positive control) will cause DS-Matrix to replace all values on the plate with the result of this calculation. In other words, if T1/PC=25, then every single well on the plate would have a value of 25 on the report.
4. To multiply all values on the plate by a correction factor
 - Sample*VariableX (where X is replaced by an integer)

When these equations using VariableX or Custom Variable are entered, the user will be prompted at the beginning of the load wizard to enter the value for the variable.

► **Note:** Check the **Ratio** radio button when setting up the **Report Format** in an assay to have ratio information included on the report in either a Matrix or Table format.

► **Note:** When creating ratio equations, use the Well Symbols from the Template to create the equations.

5.3.11 Threshold Operation

The Threshold operation converts either raw OD data or calculated result data (i.e. concentrations) into symbols or phrases denoting positive and/or negative results which fall above or below a user defined threshold. In order to use this operation, Threshold limits must be defined.

A negative limit is set using the “–” data label and a positive limit set using the “+” data label. These positive and negative limits are required to use the limits function. Three additional positive results levels (++, +++, and +++) are also available, but not required.

Threshold limits may be entered directly into the equation textbox as absolute numbers. A result that falls above or below the value entered will be recorded as positive (+) or negative (-) instead of the actual value. The value entered for the threshold limit may be based off of raw data, ratio, curve fit or spreadsheet output (which ever data reduction operation immediately precedes the threshold operation).

If the – value is lower than or equal to the + value then results below the –value are negative and results above the + value are positive.

If the – value is higher than the + value, then results below the + value are positive and results above the – value are negative.

Alternatively, conditions may be introduced into the limits equations. For example, test sample result values may be compared to control result values or to the average of a number of samples to determine if they are a positive or negative result.

DS-Matrix leaves a grey zone when there is a gap present between the values programmed for the – and + equations.

The user can change threshold labels to any descriptive words or numbers. For example, the default “–“ label may be changed to “Negative” by clicking on the text box and typing in the desired text.

Equation

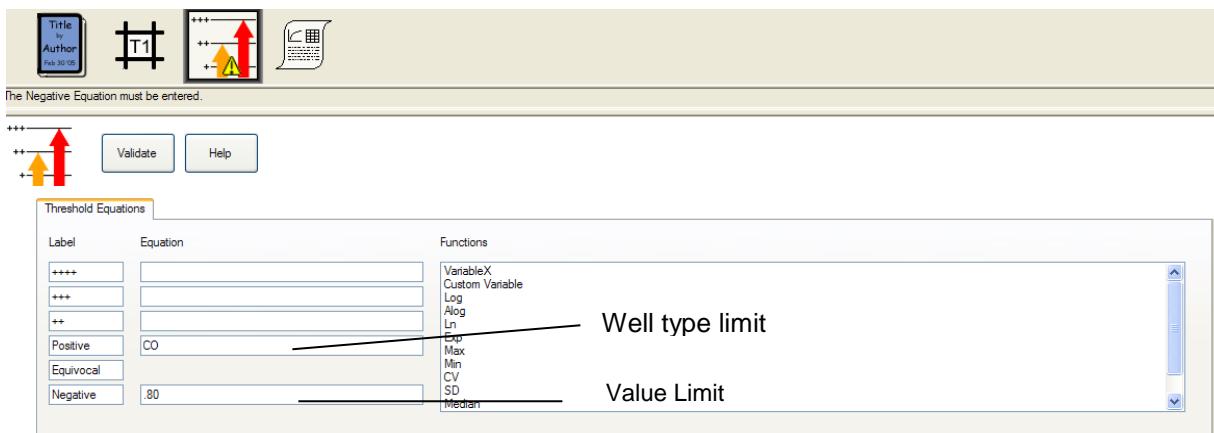


Figure 5-23: Threshold Operation Screen

Entering Threshold Equations

1. Drag and drop the **Threshold Operation icon**  into the programming toolbar.
2. Enter absolute values (OD, concentration, etc.) for the positive and negative limit levels (if values are output from another operation (such as a curve fit), that operation must appear in the programming toolbar before the Threshold Operation).
3. Alternatively, the user may double-click on a function in the **Functions** list box to enter this function. Arithmetic operators may be entered.

*EX: PC*2 for limit level +++*

4. In the Label column, change the default labels to words or other labels as desired.

5. When all equations and labels have been entered, click **Validate**.

The DS-Matrix program ensures each equation is valid and contains no errors. If any of the equations are not valid, the DS-Matrix program will display an error message. If this occurs, edit the equation as required for correctness.

5.3.12 Curve Fit Operation

In the Curve Fit operation, DS-Matrix software constructs a standard curve graph using OD values from standards of known concentrations.

From the graph, the concentrations of test samples are determined by finding the concentration that corresponds to a given OD reading. Concentration data is always plotted on the X-axis, and OD data is always plotted on the Y-axis.

To use the Curve Fit operation, standards of increasing concentrations must be included in the assay template.

Only one curve fit operation can be programmed into any given assay. To test data using more than one curve fit, another assay must be created. When the Report is generated from the first assay, data can be recalculated and another curve fit generated by clicking on the Recalculate Databutton in the report viewer toolbar and generating a report using a different assay.

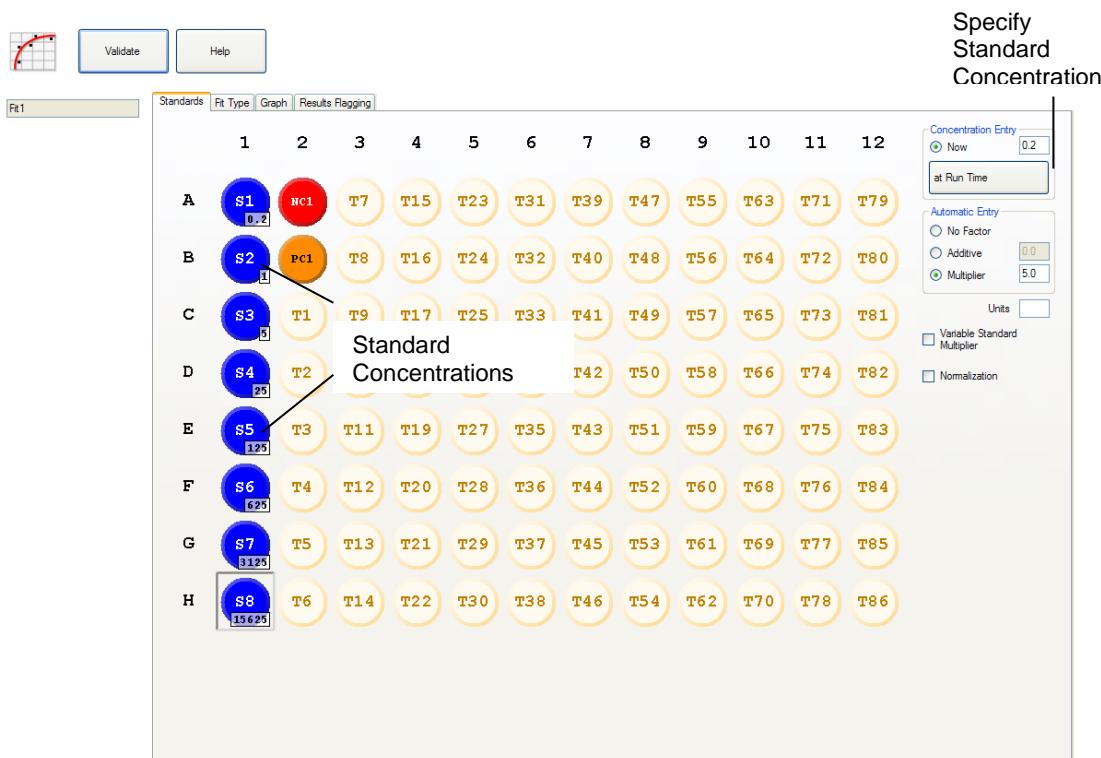


Figure 5-24: Curve Fit Concentration Entry

Entering Standard Concentrations

1. The plate template is displayed in the Curve Fit Operation **Standards** tab screen.
2. To enter **Standard Concentrations** permanently into the assay, select the **Now** radio button. If standard concentrations will be changed frequently, the user may select the **At run time** button to enter standard concentration values at run time. To enter the standard concentrations using the **Now** radio button, enter the concentration for Standard 1 (S1) into the **Concentration Entry** box. Click on the Standard 1 well(s). A small box will appear in the lower right of the well, showing what concentration was entered for that standard.

► **Note:** *If entering standard concentrations at runtime, the results cannot be generated using the “Recalculate Data” feature in the report.*

3. Enter the concentration value for the second standard in the Concentration Entry box. Click on the wells for the Standard 2 to set the concentration for Standard 2 (S2). Continue this process until all standards have an associated concentration.

► **Note:** *If performing a log/log curve fit, a standard with a concentration of zero should not be defined in the curve fit operation.*

4. To increment each standard concentration by a specific amount, click the **Additive Factor** radio button and enter the number to be added.

EX: Standard 1 (S1) has a concentration of 1 and an Additive Factor of 2 is used. The next standard (S2), upon clicking the well, will automatically be assigned a value of 3. The next standard selected will be assigned a value of 5 and so on until all standards have an assigned concentration.

5. A **Multiplication Factor** can be used to increment each successive standard by a specified amount. Click on the **Multiplication Factor** radio button and enter the multiplication factor. The first standard must be greater than 0 for this feature to work properly.

EX: If the first standard (S1) has a concentration of 2, and the Multiplication Factor is 4, then the next standard well selected (S2) will automatically be assigned a concentration of 8.

6. **Normalization** can be enabled by checking the **Normalization** checkbox. If the dilution value is changed at run time, checking the normalization will normalize the concentration value to the original assay dilution value.

7. A **Variable Standard Multiplier** can be used for standards entry. The **Multiplier Factor** radio button must be selected and the **Variable Standard Multiplier** box must be checked.

- The first standard concentration must be greater than zero.
- Click on the first set of standard wells (S1) to enter the first concentration. Enter the multiplier for the next standard in the Multiplier box, then click on the second set of Standard wells (S2). Enter a third multiplier for the third set of standard wells. Click on the third set of standard wells (S3). Continue until all standards have an assigned concentration.

EX: If the concentration of the first standard (S1) is 1, and the first multiplier is 2, then the first standard (S1) will have a concentration of 1 and the second standard (S2) will have a concentration of 2. If a multiplier of 4 is then entered the third standard (S3) will have a concentration of 8.

8. **Units** can be entered as mg/mL, µg/mL, etc. by entering the desired units in the **Units** box.

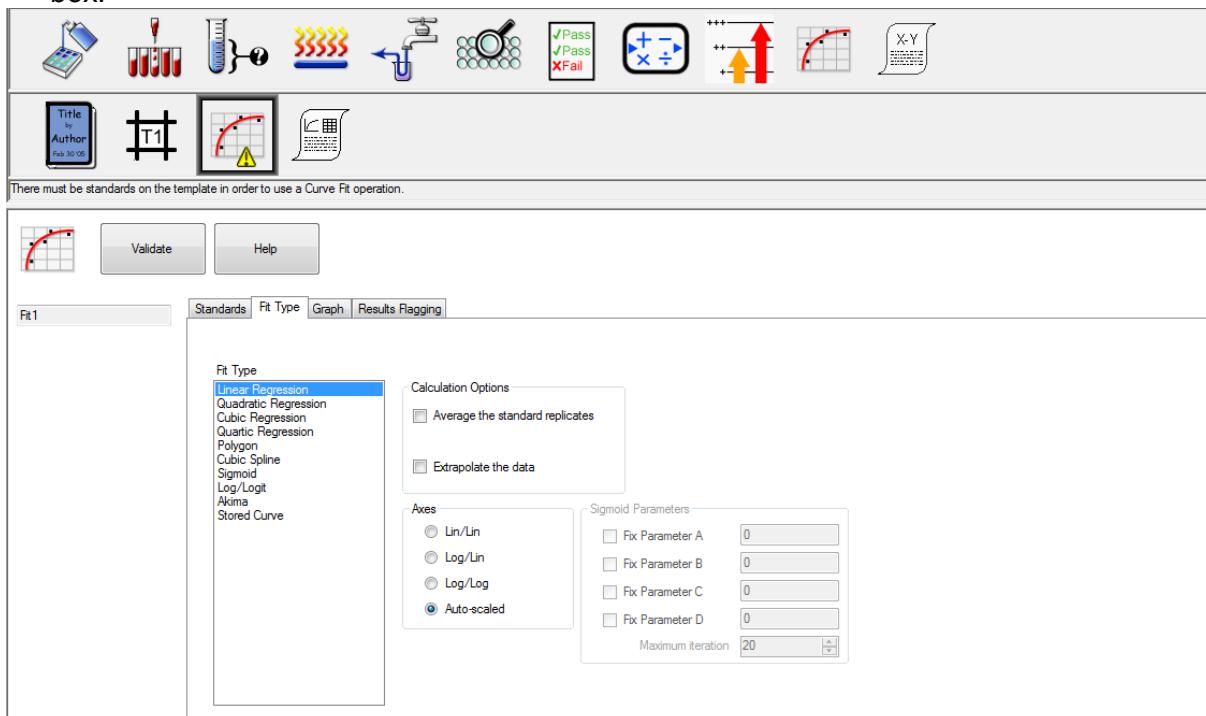


Figure 5-25: Curve Fit Type Selection Screen

Fit Selection

1. Click on the **Fit Type** tab in the Curve Fit operation.
2. Highlight the type of regression DS-Matrix should use to generate the graph. See Appendix C for equations defining curve fits.

Fit Type	Description
Linear	Linear polynomial regression
Quadratic	Quadratic polynomial regression
Cubic	Cubic polynomial regression
Quartic	Quartic polynomial regression
Polygon	Point to point straight line fit
Cubic Spline	Smooth curve cubic spline fit
Sigmoid	S-shaped curve fit with four definable parameters
Log/Logit	S-shaped curve fit with definable parameters
Akima	Smooth curve which passes through all data points
Stored Curve*	Users may apply previously generated curve fits to newly generated data. *The “Stored Curve” option is only visible and available for selection once a curve fit has been saved for use as a stored curve. See the section “Stored Curve Fit Functionality” for more information.

Calculation Options

1. Check the **Average the standard replicates** checkbox to have the mean of the standard replicates used to generate the curve, rather than individual replicate points. Averaging the replicates will make the graph easier to interpret.
2. Data can be extrapolated beyond the lower and higher ends of the graph if the **Extrapolate the data** checkbox is checked. According to generally accepted analytical chemistry practice, the standard values should always cover the entire range of expected sample OD values. Extrapolation is generally not recommended but it may be approved for data reduction according to reagent kit documentation. Extrapolation should not be used with a sigmoidal fit.

Calculation Option	Description
<i>Average the Standard</i>	Replicate values for standards are averaged before they are used in curve

<i>Replicates</i>	fitting.
<i>Extrapolate the Data</i>	The graph is extended beyond the plotted data points by extending the curve.

3. There are 4 axes options for data plotting. To select an **Axis Scaling** option, click on its corresponding radio button.

Axes Selection

Axes Scaling	X-Axis	Y-Axis
<i>Lin/Lin</i>	Linear	Linear
<i>Log/Log</i>	Logarithmic	Logarithmic
<i>Log/Lin</i>	Logarithmic	Linear
<i>Auto</i>	Selected by Matrix	Selected by Matrix

4. Any scaling options that are not compatible with the chosen curve fit type will be disabled.

EX: If a Sigmoid fit type is highlighted, the axes selections will be disabled, but the **Sigmoid Parameters** options will be active.

5. All four of the Sigmoid, S-shaped curve **Sigmoid Parameters** are user-definable. To define a parameter, check the box for the desired parameter and type a number in the textbox. If no options are selected, Matrix will set the A parameter to the lowest standard concentration and the D parameter to the highest standard concentration. Matrix will then define the other standard points to obtain an S-shaped curve.
6. The number entered for maximum **Iterations** is the maximum number of times Matrix software will attempt to construct a satisfactory plot before aborting the operation. The default value of 20 is suitable for most applications, however the minimum allowable number of iterations is 1 and the maximum number of iterations is 29999.

5.3.12.1 Stored Curve Fit Functionality

Creating a Stored Curve Fit

1. In order to store a curve fit for a particular assay, the assay must be run with standards on the plate on the DS2 in order to have a curve fit available for use on future plates.
 - a. Run the Assay
 - b. Open the report generated
 - c. If the curve fit is acceptable and the assay quality control is valid, click the “Save Concentration Curve” button at the top of the screen (red circle).

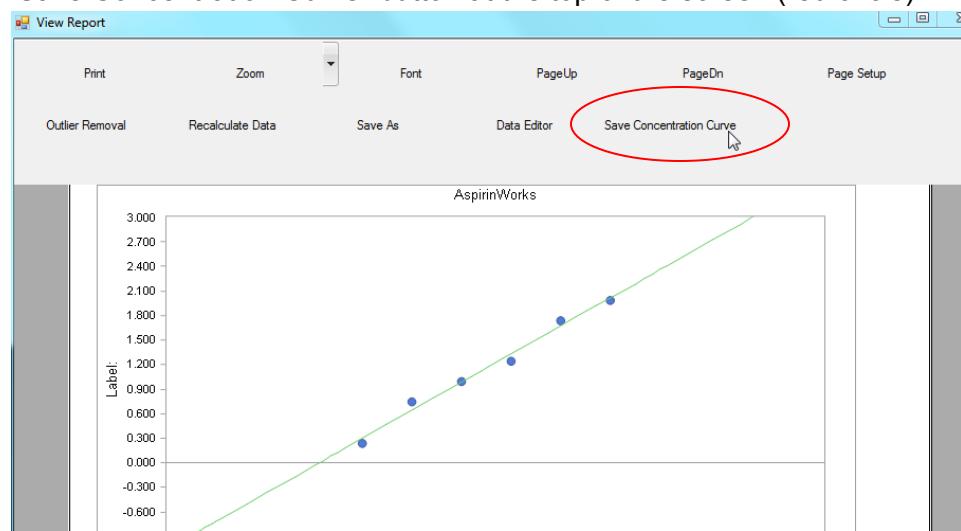


Figure 5-26: Save Concentration Curve Button

- d. The dialog box below will open:

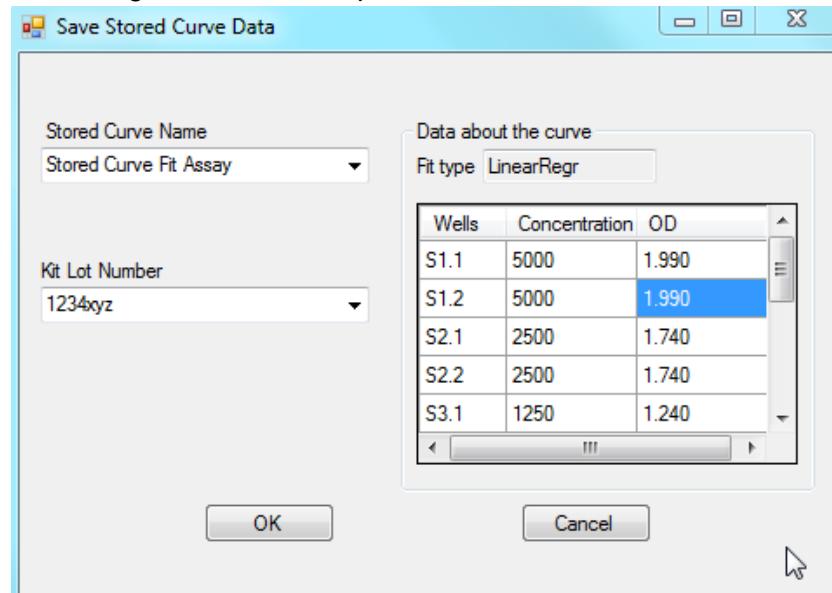


Figure 5-27: Save Stored Curve Data Dialog

- i. Enter in a name for the “stored curve name” which is easily identifiable. The text box will auto populate with the assay file name used to create the report, but this name may be changed.
- ii. Enter in the “kit lot number”
- iii. The box on the right is for display only and shows the fit type in use and the concentration and OD of the standards used to generate this curve fit.
- iv. Once all pertinent data has been entered, click “OK” to continue.

Creating an Assay to Use with a Stored Curve Fit

You may either copy and edit the original curve fit assay file or generate a new assay file for use with the stored curve fit. Instructions for both options are included below.

1. **Copying and editing the original curve fit assay file:**

- a. Go to File/Assay Editor
- b. Select the assay file used to make the curve fit that is stored on the system and click “OK”.

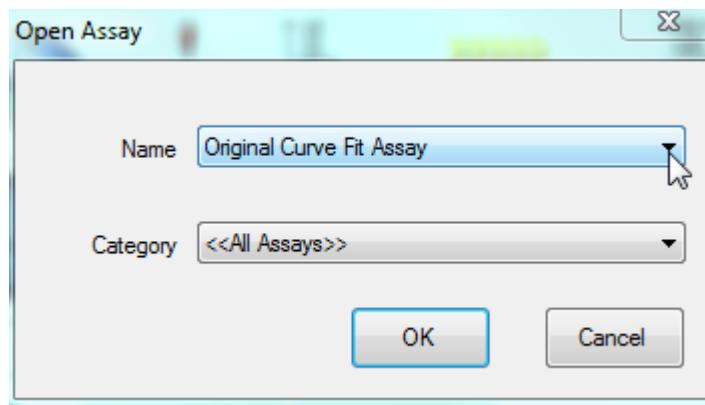


Figure 5-28: Editing Assay File: Open Assay Dialog

- c. Go to File/Save As and rename the assay. Click OK. This is the assay that will be used in all subsequent runs until a new curve fit is desired.

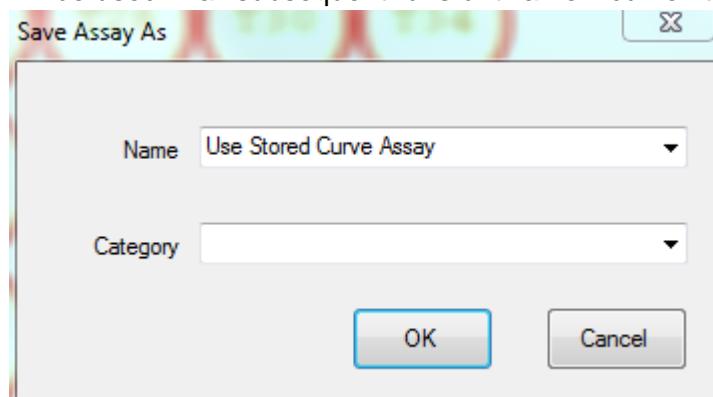


Figure 5-29:Renaming Assay: Save Assay As Dialog

- d. Navigate to the template screen. Remove the standards from the template by selecting the “empty” well type (circled red) and clicking on template positions containing standards.

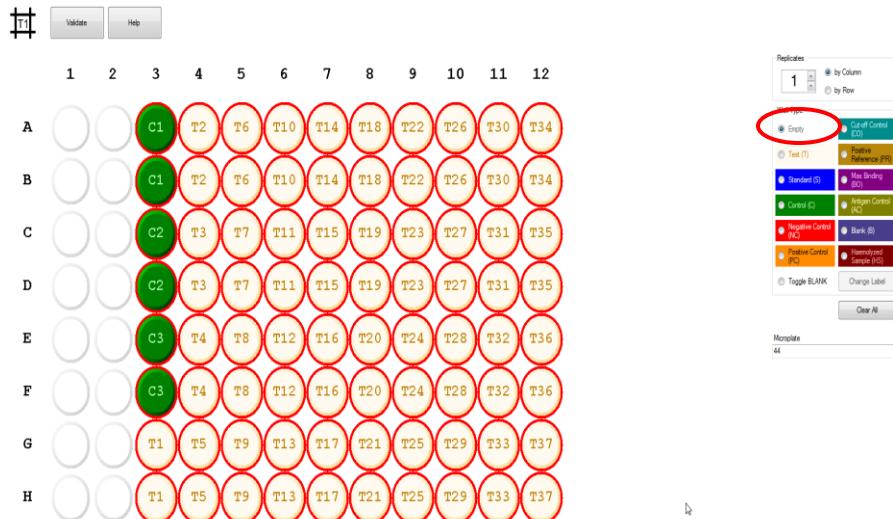


Figure 5-30: Remove Standards from Template

- e. Replace the standards with the desired well type. Standard wells were converted to test wells in this example. Users may also relocate control wells to column one, as was done in this example.

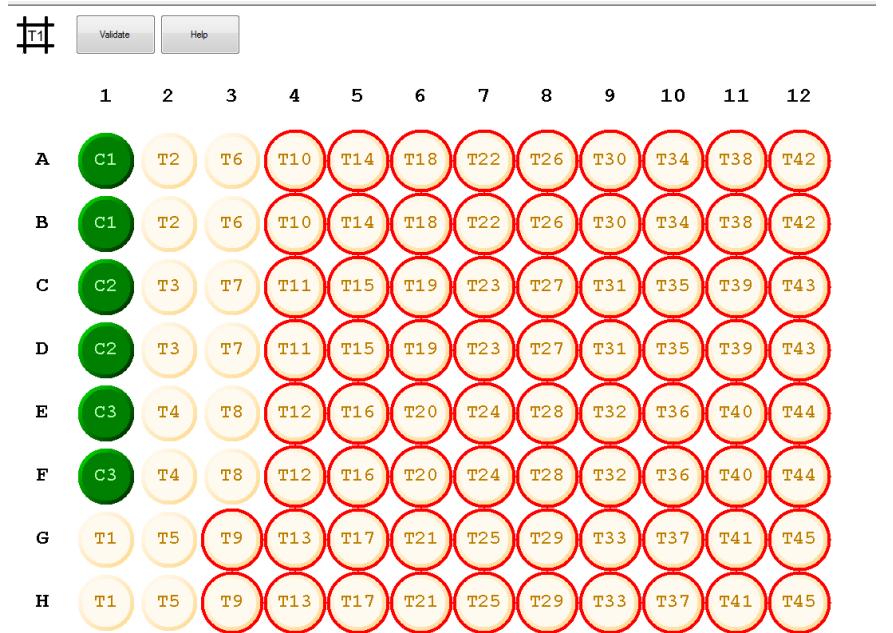


Figure 5-31: Create a New Template Without Standards

- f. Delete the Pipette Step. The pipette step should be rewritten from scratch since changes were made to the assay template. Delete the pipette step by dragging it over to the trash can in the upper right corner of the screen. Dynex also recommends verifying Dispense Operation and Well Fill Verify Operation programming is still programmed as desired.

- g. Click and drag a new pipette step into the assay. Reprogram the pipette step for each well, as is done when writing an assay from scratch. Click Validate when reprogramming is complete.

- h. Click on the curve fit operation and select the Fit Type tab. Select “Stored Curve” from the list of available fit types. Select the stored curve to use with this assay from the drop down list in the window that appears. Click OK.

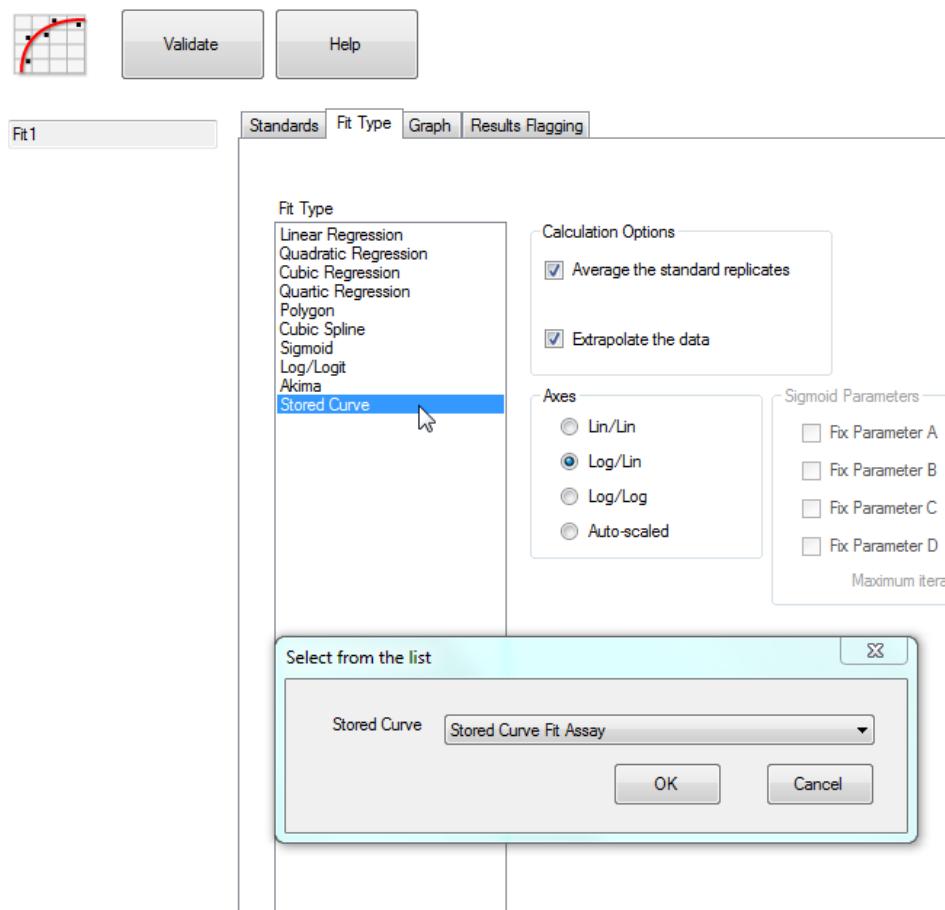


Figure 5-32: Choosing Stored Curve Fit Type

After selecting the curve, information about the stored curve fit will appear on the Fit Type screen.

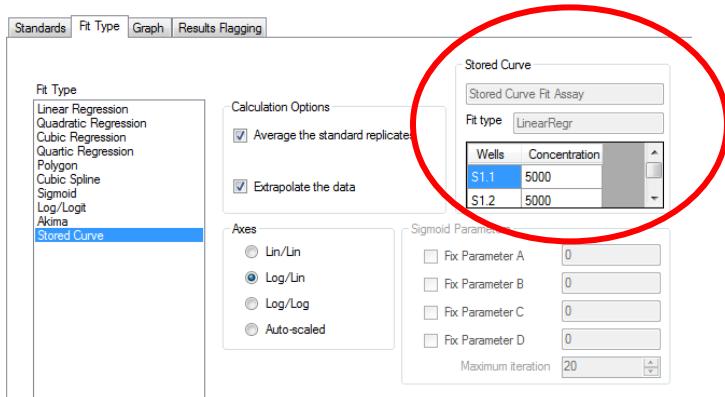


Figure 5-33: Confirm Selected Stored Curve Information

If an incorrect stored curve has been chosen, click on Stored Curve in the Fit Type list and the window will appear and allow you to choose a different stored curve fit.

- i. Click Validate
 - j. Go to File/Save to save the assay file.
2. Creating a new assay file for use with a stored curve:
 - a. When creating the template, do not put any standard wells on the template. Only put test wells (required) and control wells (optional) on the template.
 - b. When programming the curve fit operation:
 - i. Do not enter any information on the Standards tab
 - ii. On the fit type tab select “Stored Curve” from the list of available fit types. Select the stored curve to use with this assay from the drop down list in the window that appears. Click OK.

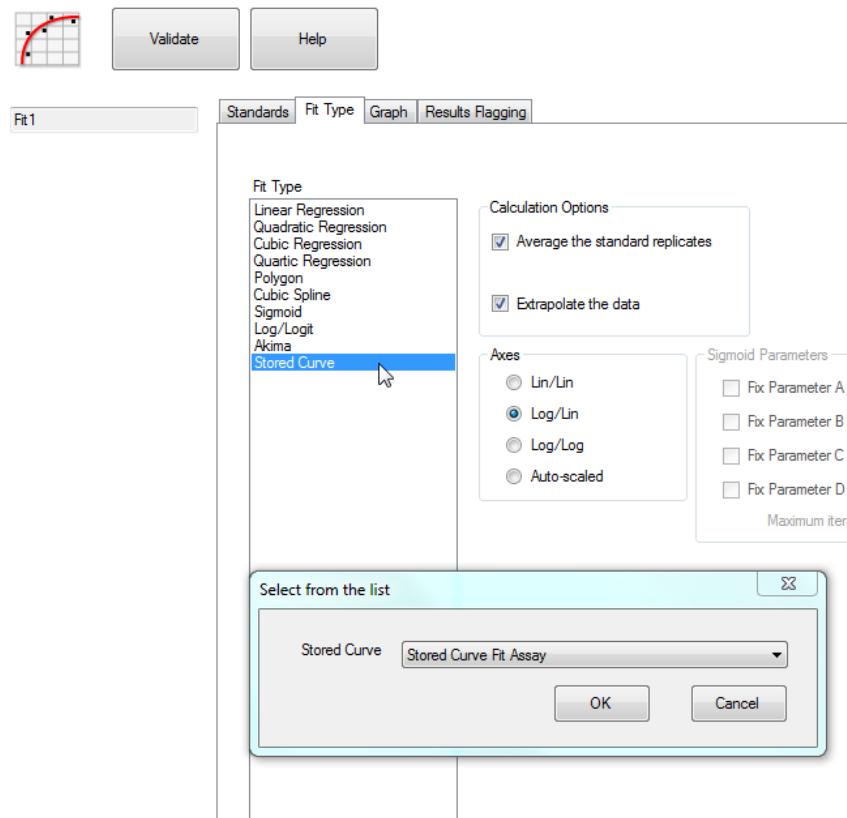


Figure 5-34: Choosing Stored Curve Fit Type

After selecting the curve, information about the stored curve fit will appear on the Fit Type screen.

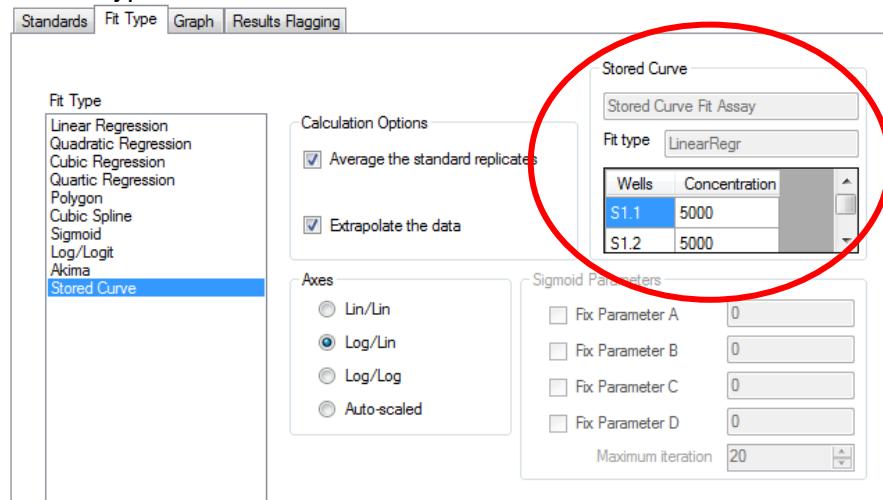


Figure 5-35: Confirm Selected Stored Curve Information

If an incorrect stored curve has been chosen, click on Stored Curve in the Fit Type list and the window will appear and allow you to choose a different stored curve fit.

- c. Program all other operations as necessary according to the kit package insert.
- d. Select File and Save.

- e. Name the assay file and Click OK.

Running an Assay that Uses a Stored Curve Fit

1. There are no changes to creating a worklist. Create the worklist as done previously.
2. During the load wizard, when loading the plate and the green check mark is clicked, a window will appear asking the user to confirm the stored curve fit which will be used to generate data for this plate.

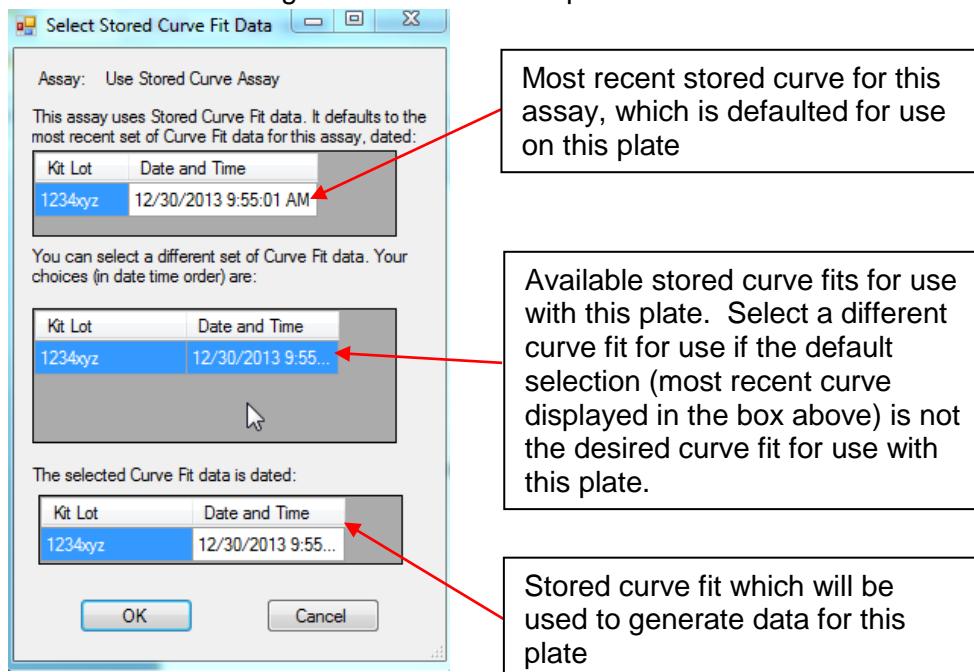


Figure 5-36: Confirm Stored Curve Information During Load Wizard

3. When the “Select Stored Curve Fit Data” window appears, ensure the desired curve fit is selected for use with the plate and click “OK” to continue. Select “Cancel” to return to the plate load screen and abort the worklist.

Reports Using a Stored Curve Fit

1. After running an assay which uses a stored curve fit, there are some differences of note on the report.
 - a. The curve fit display on the report will include information about the stored curve which was used on the plate (the curve fit ID and kit lot information provided when the curve was stored)

CURVE FITTING

Linear Regression, Fit1

Using OD/Conc data from stored curve fit: Stored Curve Fit Assay, kit lot: 1234xyz

Figure 0-37: Report Display of Stored Curve Information

- b. Any data reduction which displays standard data in a table will still display the standard data from the stored curve fit, however the well position will be displayed as columns 13, 14, etc (as required).

RATIO RESULTS

Ratio equation	:	Sample*Variable1				
Result units	:					
Sample ID	Location	Data	Mean	S.D.	C.V.	Result
S1	A13	4765.025	4765.025	0.000	0.000%	238251.228
	B13	4765.025				
S2	C13	2874.512	2874.512	0.000	0.000%	143725.593
	D13	2874.512				
S3	E13	1046.073	1046.073	0.000	0.000%	52303.654
	F13	1046.073				
S4	G13	631.046	631.046	0.000	0.000%	31552.298
	H13	631.046				
S5	A14	380.680	380.680	0.000	0.000%	19033.995
	B14	380.680				
S6	C14	138.534	138.534	0.000	0.000%	6926.724
	D14	138.534				

Figure 5-38: Stored Curve Standard Information as Displayed on Report

Importing an Assay which uses a Stored Curve Fit

1. A Stored Curve itself cannot be imported onto the DS2. Every time an assay which uses a stored curve is imported into the DS-Matrix software on a new DS2, the user will receive the following error message (assay names are examples and will vary):

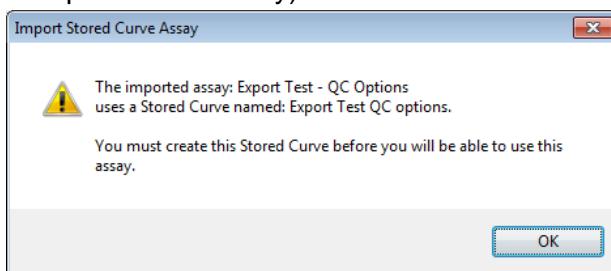


Figure 5-39: Warning When Importing Stored Curve Assay

2. The original assay file containing the standards must be imported and run once on the new DS2 in order to generate a stored curve fit for use with assays which use a stored curve. If the customer attempts to use the stored curve fit assay without generating a stored curve fit on the DS2, they will receive the following error message when the green check mark is clicked on the plate load screen (assay names are examples and will vary):

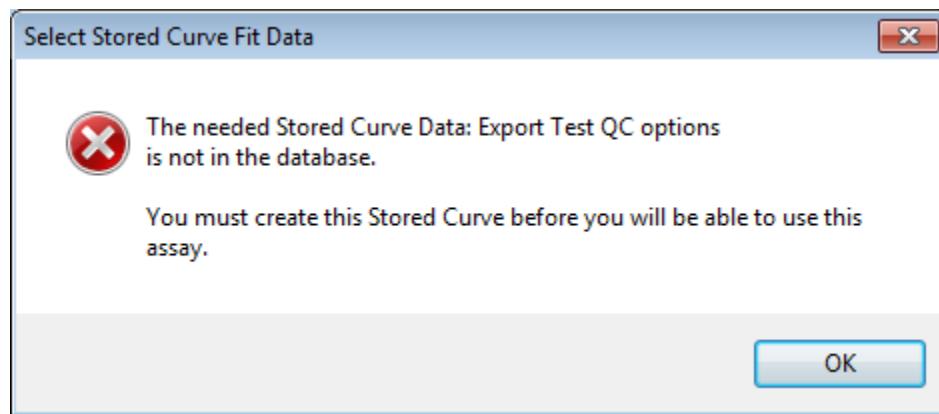


Figure 5-40: Error When No Stored Curve Exists

3. If the customer receives this error on the plate load screen, they have no option but to abort the worklist. Stored curve fit assays must have a unique stored curve generated on each DS2 prior to use.

5.3.12.2 Graphing Options

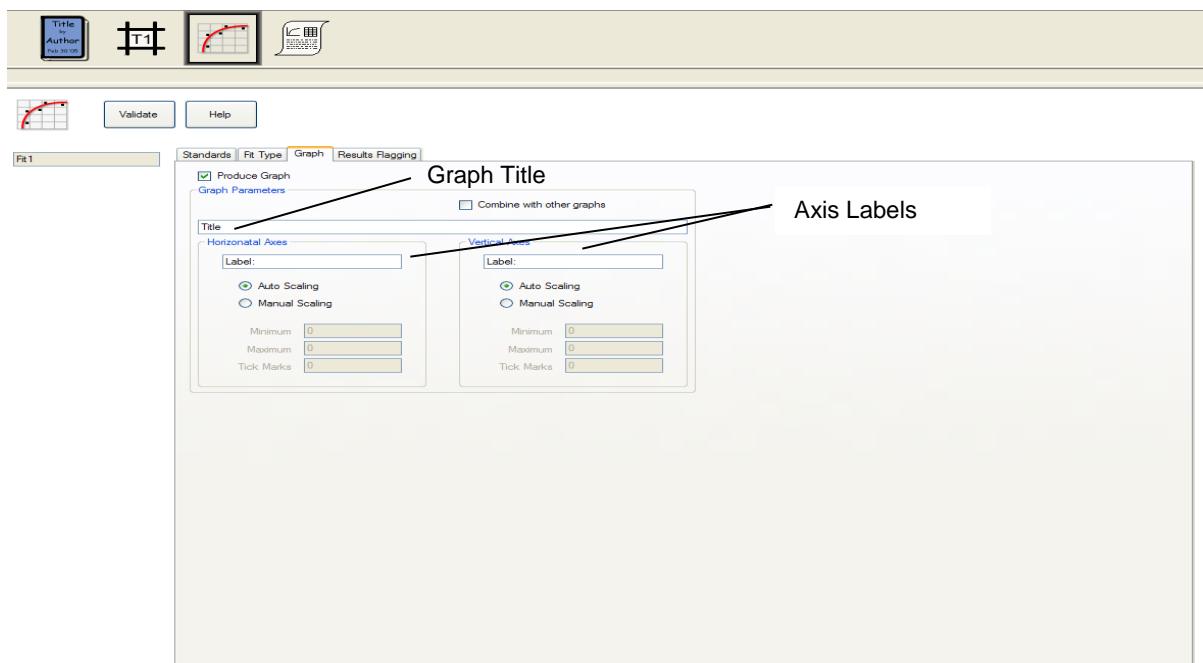


Figure 5-41: Options for Graph Scaling

Graphing Options

1. Click on the **Graph** tab in the Curve Fit operation. By default, a graph will always be produced based on the regression chosen.
2. Enter a title for the graph (if desired) by entering the title in the **Title** textbox.

3. Titles can also be entered for the vertical and horizontal axes by entering the desired titles in the **Label:** text boxes.
4. By default Matrix will use **Auto Scaling** to determine the best fit for the vertical and horizontal axes based on the range of data.
5. If **Manual** scaling is chosen, the user can then define the minimum and maximum numbers to be used to define the axis when the curve fit is displayed graphically. In the *Minimum* box the lowest value for either the standard concentration or OD may be entered. In the *Maximum* box a higher OD or standard concentration may be entered. **Tick Marks** will divide the axis evenly between the min and max entered numbers, incrementing by the value entered into the text box.

Results Flagging

1. Click on the **Results Flagging** tab in the Curve Fit operation.
2. Results Flagging equations are used to specify criteria for generating a text flag when the specified results are encountered.

The **Condition** is the Results Flagging equation.

The **Result** is the text to be reported instead of the numerical value.

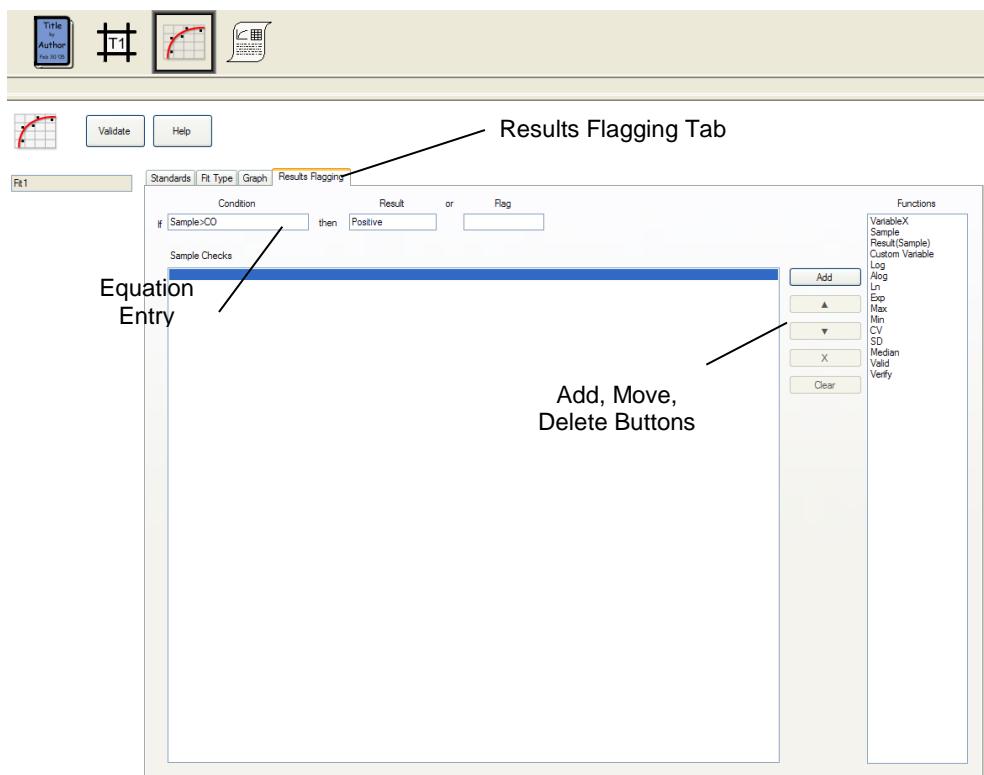


Figure 5-42: Results Flagging Tab

The **Flag** is the text to be reported along with a calculated numerical value.

3. An unlimited number of Results Flagging expressions can be defined for an assay.

5.3.13 The Spreadsheet Operation



The spreadsheet operation allows the user to create a table or matrix of data. The user can manually input the calculation to be performed on a well by highlighting the well and entering an equation (For example: B2-C2). Using Auto Difference Mode allows the user to select options which can be applied to the whole spreadsheet. A custom functionality is also built into the spreadsheet operation (Boolean Function Assay). This functionality should only be used by those performing certain assays. Contact Dynex Technologies for more information on the use of this feature.

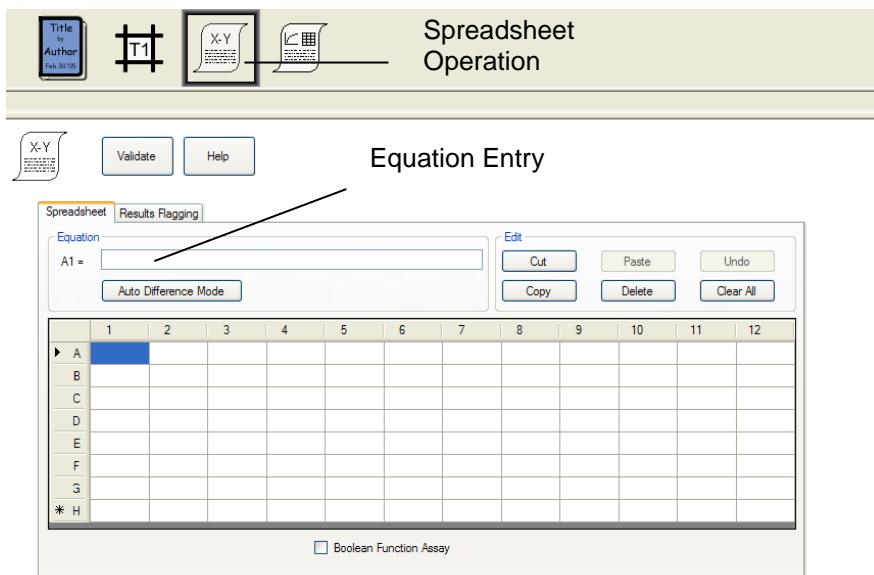


Figure 5-43: Spreadsheet Operation Screen

The Spreadsheet Operation

1. Click on the Spreadsheet Operation Icon and drag it into the programming toolbar.
2. Highlight a cell in the spreadsheet and enter a calculation or formula for that individual well, for example A1 – H12. (This will take the incoming data reduction result from the well at H12 and subtract it from the incoming data reduction result from the well at A1.) The resulting value will be the output for that cell. This result will be passed to the next data reduction step.
3. Use the buttons to facilitate spreadsheet equation entry:
 - Select the **Cut** button to remove a calculation from a cell, and then use the **Paste** button to paste the calculation into the desired cell.
 - Select **Copy** to copy a formula, and **Paste** to move the formula from one cell to another (the calculation cells will offset to reflect the selected cell).
 - Select **Delete** to remove a calculation from a cell and permanently remove the calculation from the spreadsheet.
 - **Clear All** will remove calculations from all cells in the spreadsheet operation.
4. Alternatively, the user may select the **Auto Difference Mode** button and select a formula to be applied across the entire spreadsheet. Auto Difference Mode offers the user pre-programmed automatic subtraction equations (see Table: Auto Difference Equations)

Auto Difference Equations

Equation	Calculation performed					
Rows A-B	A-B C-D E-F G-H					
Rows B-A	B-A D-C F-E H-G					
Rows B-C *	B-C D-E F-G					
Rows C-B *	C-B E-D G-F					
Columns 1-2	1-2	3-4	5-6	7-8	9-10	11-12
Columns 2-1	2-1	4-3	6-5	8-7	10-9	12-11
Columns 2-3 *	2-3	4-5	6-7	8-9	10-11	
Columns 3-2 *	3-2	5-4	7-6	9-8	11-10	
Halves 1-7	A1-A7.....H6-H12					
Halves 7-1	A7-A1.....H12-H6					
Halves 2-7 *	B2-B7.....G6-G11					
Halves 7-2 *	B7-B2.....G11-G6					
Halves A-E	A1-E1.....D12-H12					
Halves E-A	E1-A1.....H12-D12					
Halves B-E *	B2-E2.....B11-E11					
Halves E-B *	E2-B2.....E11-B11					

* These options ignore Columns 1 and 12, Rows A and H.

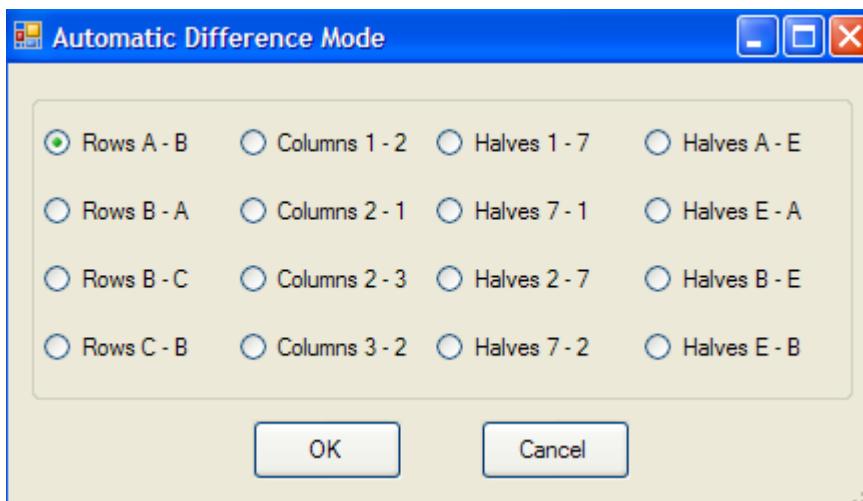


Figure 5-44: Selecting an Auto Difference Mode Equation

	1	2	3	4	5	6	7	8	9	10	11	12
A	A1-B1	A2-B2	A3-B3	A4-B4	A5-B5	A6-B6	A7-B7	A8-B8	A9-B9	A10-B10	A11-B11	A12-B12
B												
C	C1-D1	C2-D2	C3-D3	C4-D4	C5-D5	C6-D6	C7-D7	C8-D8	C9-D9	C10-D10	C11-D11	C12-D12
D												
E	E1-F1	E2-F2	E3-F3	E4-F4	E5-F5	E6-F6	E7-F7	E8-F8	E9-F9	E10-F10	E11-F11	E12-F12
F												
G	G1-H1	G2-H2	G3-H3	G4-H4	G5-H5	G6-H6	G7-H7	G8-H8	G9-H9	G10-H10	G11-H11	G12-H12
*												
H												

Figure 5-45: Auto Difference Mode Equation applied to spreadsheet (Row A-B)

Results Flagging

1. Click on the **Results Flagging** tab in the Spreadsheet operation.
2. Results Flagging equations are used to specify criteria for generating a text flag when the specified results are encountered.
The **Condition** is the Results Flagging equation.
The **Result** is the text to be reported instead of the numerical value.
The **Flag** is the text to be reported along with a numerical value.
3. An unlimited number of Results Flagging expressions can be defined for an assay.

Saving an Assay Program

1. When all of the operations in an assay have been programmed, click on **File > Save As** from the main Matrix toolbar.
2. Type in an **Assay Name** (required) and **Category** (optional). Assays may be grouped into categories for ease of retrieval.
3. Click **OK**.

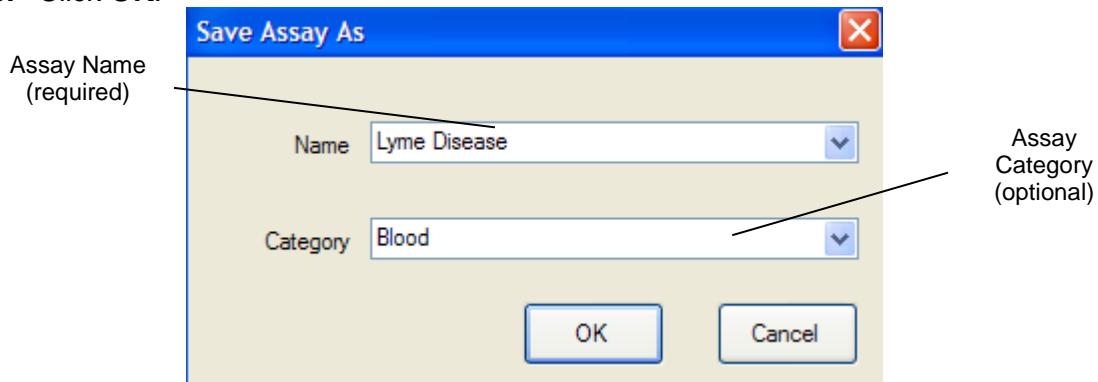


Figure 5-46: Save Assay As Dialog Box

Modifying an Assay

1. Select **File > Assay Editor** from the main Matrix menu bar. Select **File > Open** from the Assay Editor menu bar. The **Open Assay** dialog box is displayed (Figure 5-47).
2. Select the assay to be modified from the drop-down list, and then click **OK**.
3. Modify the assay operations and/or data reduction steps as desired.
4. After modifying assay settings, save the changes to the assay using **File > Save**.

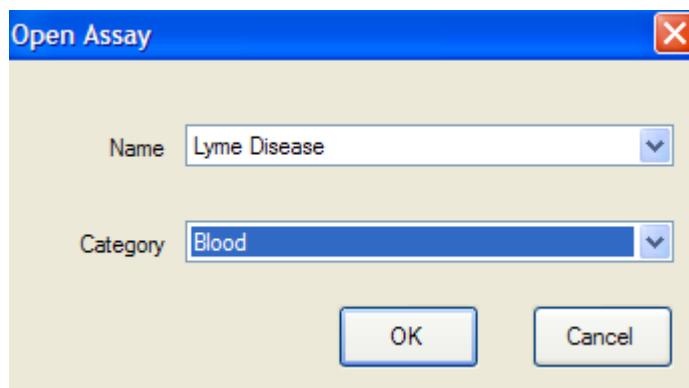


Figure 5-47: Open Assay File Dialog Box

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Chapter 6 The Worklist

6.1 Creating a Worklist

A **Worklist** is created to define which assays will be run on which specific specimens. The worklist specifies the samples that are to be run, their location in the sample rack, and the assay(s) to be run on each sample.

► **Note:** *A worklist can be created only after at least one assay has been created. The worklist can include assays run on one or two different microplates.*

Up to 12 assays can be run on one plate if the assays have the same incubation, reading, washing, and shaking specifications. All assays must also have the same number of operations.

Only one worklist can be open at a time, although multiple worklists may be entered on the Timeline.

To Create a New Worklist

1. Select **File > Worklist Editor** from the Matrix menu bar.
2. Select a new or saved **Sample Batch** from the drop-down list. A sample batch is defined by its size (the number of samples entered, up to 100) and by the sample IDs assigned to the physical location of the sample tubes. Once a Sample Batch has been defined, it is saved. The Matrix software default name for a batch is **Sample Batch** followed by the next available sequential number. This name can be changed by the user by entering the desired sample batch name into the **Sample Batch ID** text box.
3. When creating a new worklist, select the number of samples by clicking on sample tube icon associated with the last rack position containing a tube or by changing the number in the **Number of Samples** text box. The rack locations containing tubes will turn green and unused rack positions will remain gray.

Assigning Sample IDs

1. Sample identification can be auto-assigned or barcoded. If sample ids are automatically assigned, the name will default to be the sample batch id followed by a sequential number. For example: if a sample batch named "SAM" is being run, the sample IDs will be auto-assigned as SAM-1, SAM-2, etc. If the sample batch is named "02262009" the sample id's will be auto-assigned as "02262010", "02262011" unless a "-" is included at the end of the sample batch ID. Click **Assign** to assign the specimen IDs,
or
2. If the user wants the specimen ID to begin with text other than the sample batch id, then the user should check the **Use Pattern** checkbox. Matrix will use the text entered in the **Use Pattern** textbox for all sample IDs, followed by sequential sample numbering. *For Example:* If the pattern ABC is entered, the sample ID's will be ABC-1, ABC-2, ABC-3, etc. Click **Assign** to assign the specimen IDs.
3. Click the  **Next** button.

Entering Sample IDs by Bar Code

1. Click the **Scan Bar Codes** radio button.
2. Click **Next**. The "Please Load Samples Now" dialog box displays. Load the sample racks, and click **OK** when done. Samples may also be loaded prior to creating a worklist.
 - ▶ **Note:** All five sample racks must be in place prior to clicking the "OK" button. If all sample racks are not in place, the barcode scanner will timeout and the barcodes cannot be scanned.
3. The robotic arm will move to the scanner. Pull out each sample rack containing sample tubes and push it back in so the scanner can read each bar code labels.
 - ▶ **Note:** The user is given 30 seconds to barcode scan each rack (30 seconds per rack in use, using firmware version 1.08 or greater). Make sure to scan all racks within the designated timeframe or the barcode scanner will timeout and the barcodes cannot be scanned.
4. If a sample barcode is successfully scanned, the text box next to the sample tube icon will be green and will populate with the barcode information. If the sample barcode is not scanned successfully, the sample tube icon will turn red. The user may attempt to rescan the rack until all barcodes have been successfully scanned, or information can be manually entered for tubes with barcodes that are not capable of being scanned. Upon successful entry of a manual sample ID, the sample tube icon will turn orange.

5. Click the  button when done.
6. Select the assays that will be run and click **Done** (for more information see the “Choose Assay” section of this manual).
7. Click the  button when done.
8. Sample ID's will appear on the report when the assay specifies that data reduction operation data should be displayed in a Table format (instead of a Matrix format) and the Sample ID table option is checked.

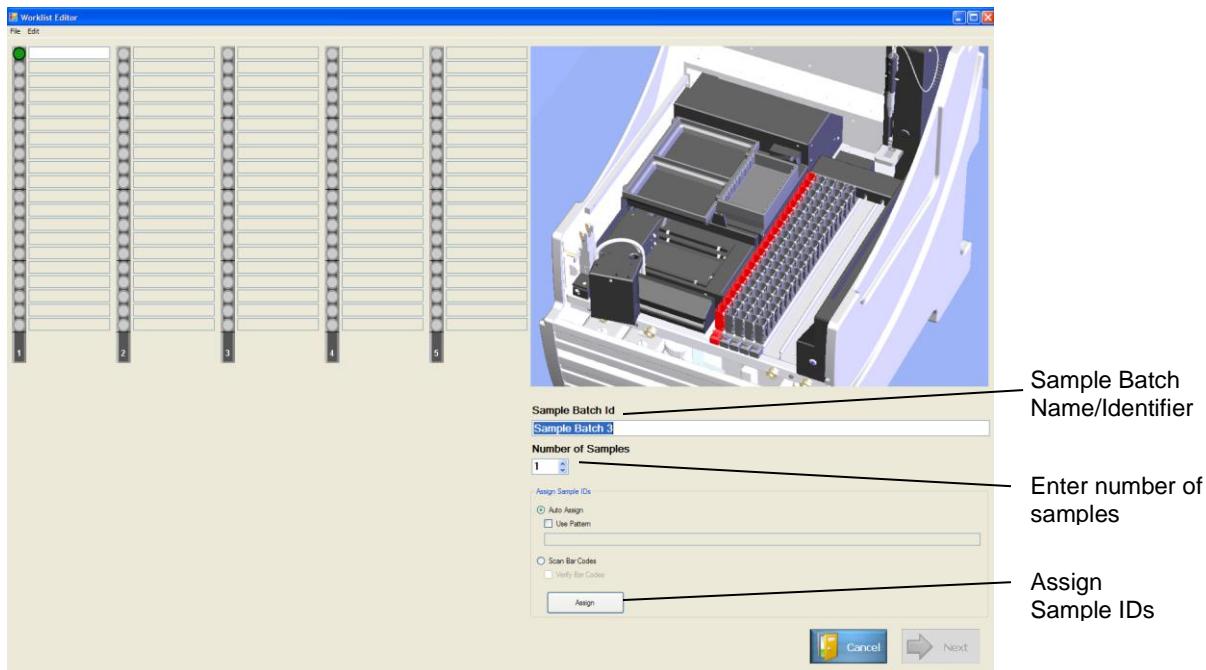


Figure 6-1: Worklist Sample ID Entry Screen

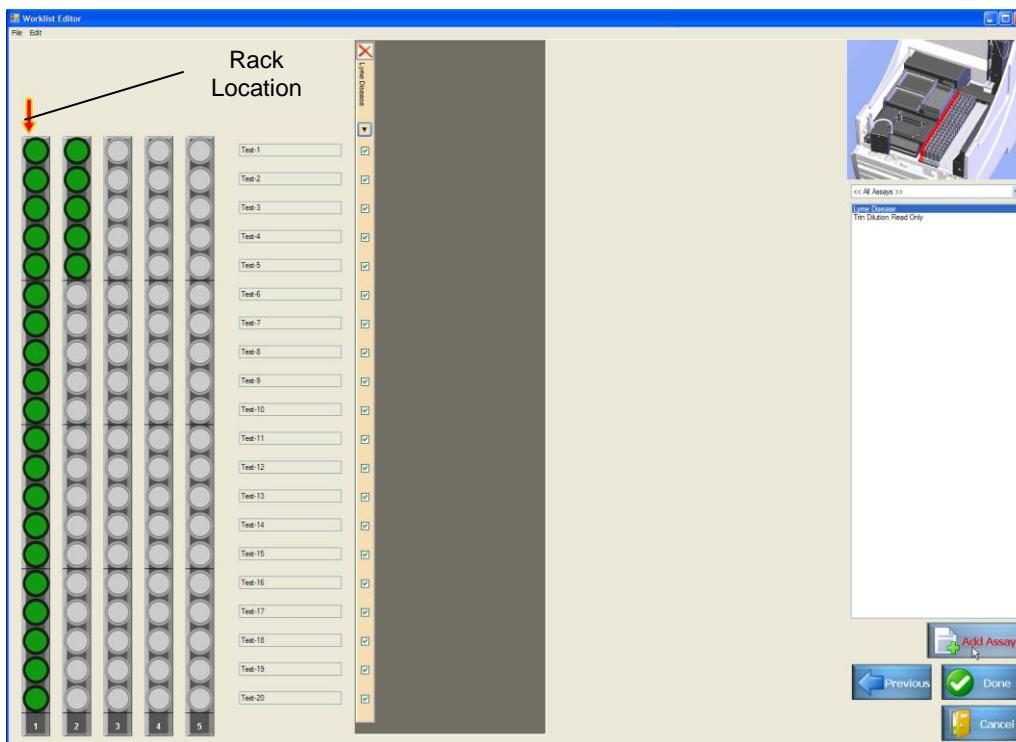


Figure 6-2: Worklist Select Assay Screen

Choose Assay

1. After the sample ID assignment is complete, click the **Next** button.
2. Choose the assay to be run, then either click on the **Add Assay** button or double click on the assay name. An orange strip of check boxes will appear next to the sample ID's.
3. To add additional assays, highlight the desired assay name and click on the **Add Assay** button or double click on the assay name. An additional orange strip of check boxes will appear on the screen.
 - a. The DS-Matrix software automatically assigns each assay to a different plate (as indicated by the dark gray strip in between the assays). To combine an assay with a previous assay on one plate, right click on the assay. A box stating **“Combine with Previous Assay”** will appear on the screen. Click on this box. The dark gray strip separating the assays will disappear, indicating the assays are now being processed on the same plate. If the assays are not able to be processed on the same plate due to conflicts in programming, an error message will appear.

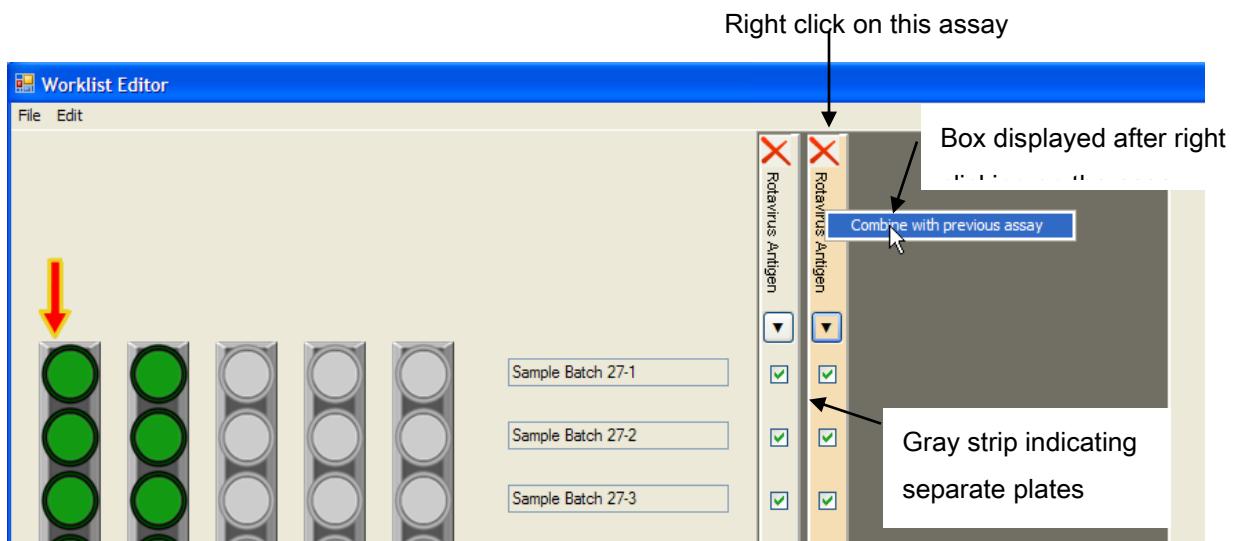


Figure 6-3: Combining Assays on One Plate (before)

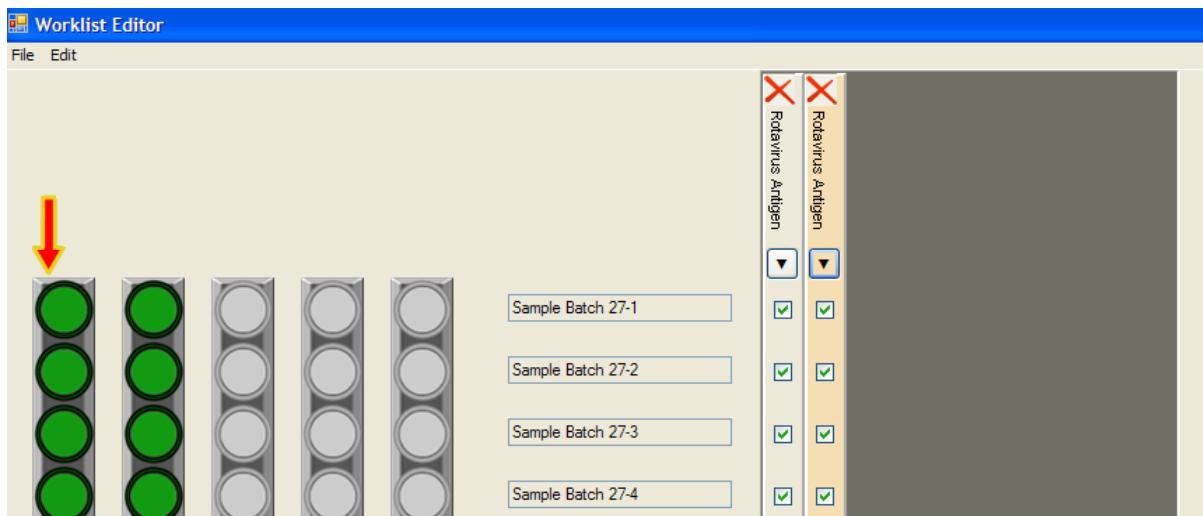
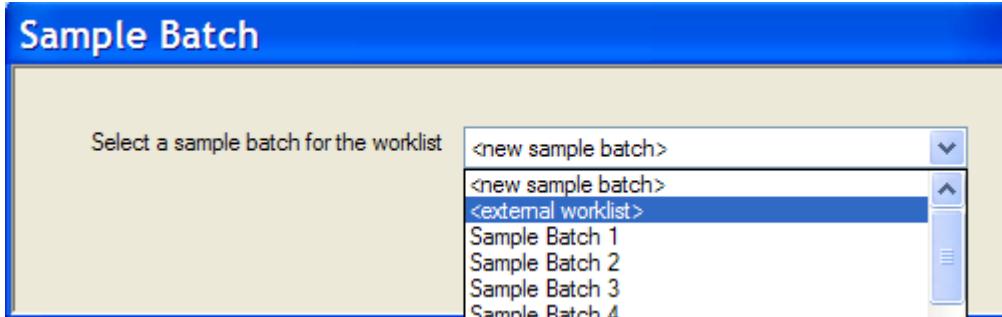


Figure 6-4: Combining Assays on One Plate (after)

4. By default Matrix assumes that all samples are going to be tested using the assays chosen. By unchecking the checkbox next to an individual sample ID, the sample will not be tested using that assay.
5. To save a worklist (optional), go to **File > Save Worklist** after selecting the assay(s) but before clicking the **Done** button. Enter the worklist name, click “OK” and click **Done**.
 - a. To open saved worklist, choose **File>Recent Worklists**. Select a new sample batch or select a saved sample batch. The worklist will open with the assays already assigned.

Using an External Worklist

1. To use an external worklist, select <external worklist> from the drop down list in the sample batch dialog. Click OK.



2. Navigate to the external worklist file location. Highlight the desired file and click OK.
3. The software will open to the sample ID screen. If the tubes contain barcodes and the user wishes to confirm the order of samples in the racks matches the worklist file, select to verify barcodes. Click Next to begin assay processing. To overwrite the sample IDs in the external worklist, enable the scan barcodes check box. All sample IDs contained in the external worklist will be overwritten by the sample barcode scan.

Modifying the Dilution Ratio at Runtime

1. Open a worklist or create a new worklist by clicking on **File > Worklist Editor** from the Matrix main menu. A worklist can also be opened by clicking on **File > Recent Worklists** (only saved worklists will appear in this list).
2. The assay selected in the worklist **must** be programmed to perform a dilution step and the box **must be checked for Allow Sample Dilutions to be Changed at Run Time**. The **Normalization** check box should also be enabled in the curve fit operation to ensure results are calculated correctly.

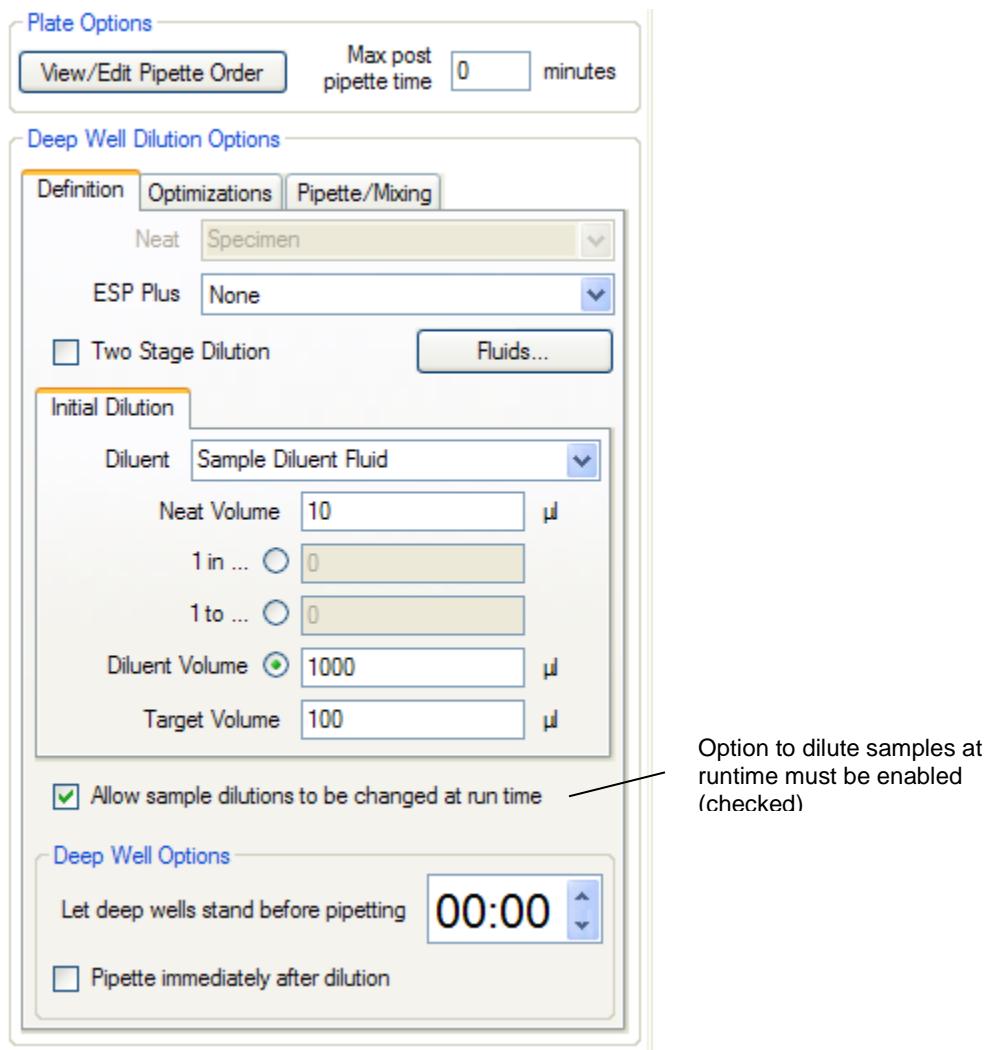


Figure 6-5: Pipette Operation Screen

3. Click on the **Dil** (dilution button) shown in Figure 6-4.

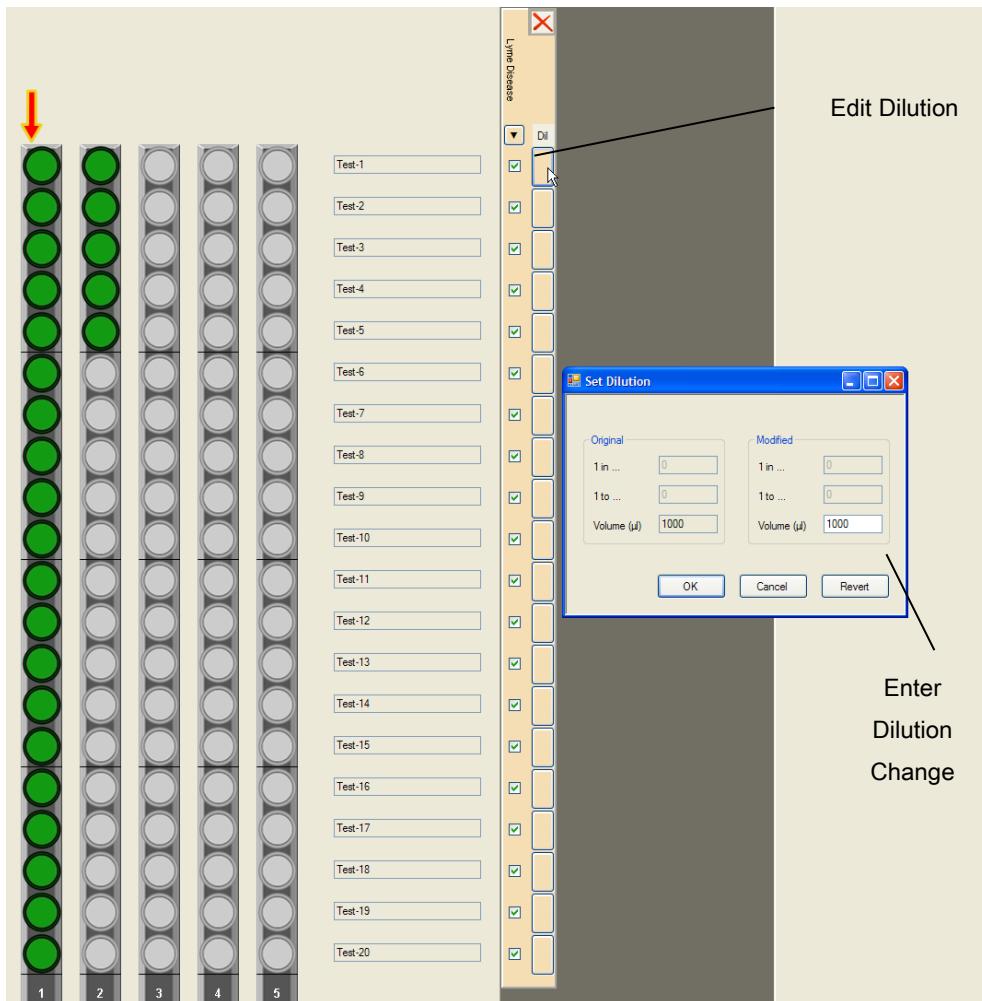


Figure 6-6: Runtime Dilution Change Screen

Modifying the Dilution Ratios

1. The original dilution parameters will be shown in the left column of the **Set Dilution** window.
2. Type in modified parameters for running assay in the right column of the **Set Dilution** window. If changing a set volume dilution, only the volume of diluent can be changed at runtime, not the volume of sample. Change the dilution for each individual test sample as required.
3. Click **OK**. The sample dilution button (**Dil**) for the sample ID will turn green.
4. The **Revert** button erases any edits made and the test sample dilution will be performed according to the original dilution parameters.
5. When the **Done** button is clicked, DS-Matrix will set up a schedule of assay events.

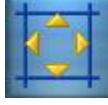
Scheduling and Accepting a Worklist

- Buttons which allow changes to the Timeline Schedule are presented at the top of the Timeline. Active buttons will flash, while inactive buttons will remain grayed out.



Figure 6-7: Timeline Buttons

Button	Symbol	Action
Accept		A start button indicating that the timeline is acceptable. Once Accept is clicked the timeline cannot be changed and will begin processing.
Edit		Allows the sample batch and assay to be changed on a scheduled plate.
Add		Allows a second worklist to be scheduled.
Fit Next		Allows the user to change the scheduling of a second plate or worklist added to the timeline.
Pause		Stops the Timeline at the current operation until the Play button is clicked.
Abort		Stops the Timeline at a convenient stopping point and displays a Yes / No dialog box for aborting a plate or the entire Worklist.
Play		Resumes the Timeline from the point the Pause button was clicked.
Skip		Advances the Timeline by skipping wait times in the schedule. Not all wait times can be skipped.

Zoom IN		Opens up Timeline for closer view
Zoom Out		Backs out Timeline for broader view
Position		Changes Timeline position and zoom on the screen for the optimal view.

2. Click the **Accept** button if no editing or assay additions are needed. The Timeline will go from inactive to active status.

► **Note:** When continuous loading worklists, all reagents and consumables must be ready to load on the DS2 when the Accept button is clicked. Items such as tips and samples may be loaded before clicking the Accept button. Waste may be emptied prior to clicking the Accept button. All reagents (as much as possible) should be in the appropriate vial and ready to load on the DS2 when prompted. If the load procedure is not performed within the specified timeframe, timeline conflicts may occur.

3. The **Load Samples** wizard appears followed by the **Load Consumables** wizard when the assay reaches the start line. The Wizard will request that the sample racks, plates, controls, standards, diluents, reagents, and wash buffers are loaded. The system will complete the wizard by prompting the user to empty the waste containers. The wizard will indicate racks and positions into which fluids should be placed according to what is programmed into each assay operation.
4. Clicking the **Abort** button allows the user to stop the entire worklist.
5. Once the consumables are loaded, the **Skip** button on the main menu bar may be clicked to skip the wait time before the first assay operation.

Continuous Loading

To perform a run using continuous loading in DS-Matrix:

1. Select a Worklist Editor from the File menu
 - a. Enter Sample IDs manually or choose to barcode scan the sample IDs.
 - b. Add the desired assay(s) to the Worklist and click **Done**.
 - c. Accept the worklist.
 - d. Load the samples and consumables as requested by the Load Consumable Wizard.

- e. Allow the Worklist to begin processing. Begin step 2 once the instrument has reached an incubation period.
2. Open the Worklist Editor from the file menu. **It is best to wait until the instrument is in an incubation period before continuous loading.**
- a. If manually entering the sample IDs, continue with step c.
 - b. If barcode scanning the sample IDs, depending on the assay scheduling, the operator may have to wait to scan the IDs until the system resources are available for barcode scanning.
 - c. If there is a delay before scanning (see Figure 6-8), the operator must return to the DS2 prior to the point barcode scanning is to occur.

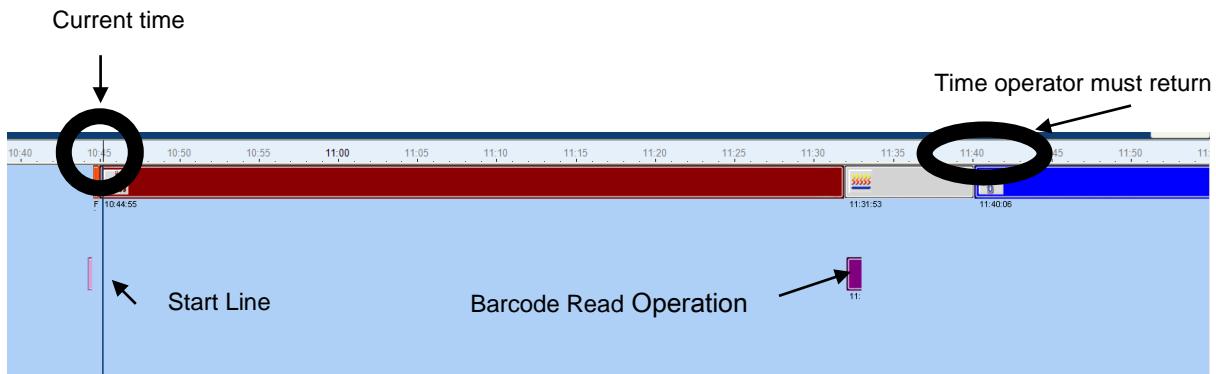


Figure 6-8: Barcode Scanning Samples for Second Worklist in Continuous Load

- d. The sample racks must be prepared and loaded on the instrument when prompted. **All** sample racks must be in place for the barcode reader to be activated. The system will time out if the first sample rack is not scanned within 30 seconds of the prompt (Note: if a firmware version prior to version 1.08 is installed on the system, the system will timeout after 20 seconds). Any subsequent racks are allotted 30 seconds each to be scanned.
- e. Once the barcodes are scanned or IDs are manually entered successfully, add the desired assay(s) to the worklist.
- f. Click **Done**.
- g. The timeline will display with the second assay added to the worklist (see Figure 6-9).
 - i. Click **Accept** to accept the worklist or click **Fit Next** (if available) to see other possible timelines. When the desired timeline is displayed for the second assay Click **Accept**. Prior to clicking accept **ensure that someone will be available to load consumables when requested by the DS2** (see Figure 6-9).

Time to Return to Load Consumables

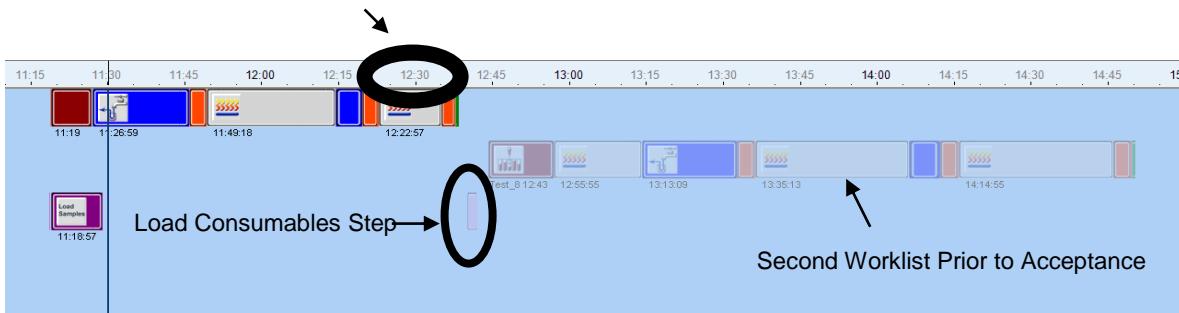


Figure 6-9: Accepting the Second Worklist

3. Once the second worklist has been accepted, make a note of when the Load Consumables step for the second worklist will begin. **All reagents and consumables must be ready to load on the DS2 PRIOR to this time.** The Load Consumables step allots roughly 3 minutes to load reagents and consumables for the second worklist. If this 3 minute period is exceeded, timing for both worklists may be affected and patient results may be compromised .

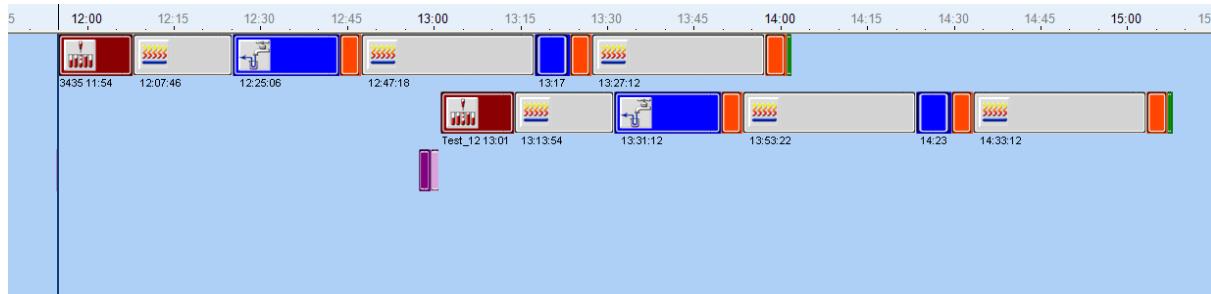


Figure 6-10: Overlapping Worklists with Continuous Loading

6.2 Monitoring Run Status

6.2.1 Timeline View

The Timeline View window displays the scheduled timing of all assay operations. The Timeline View shows the user when events will occur (such as loading consumables), how much time is remaining until worklist/assay completion, and the current assay step.

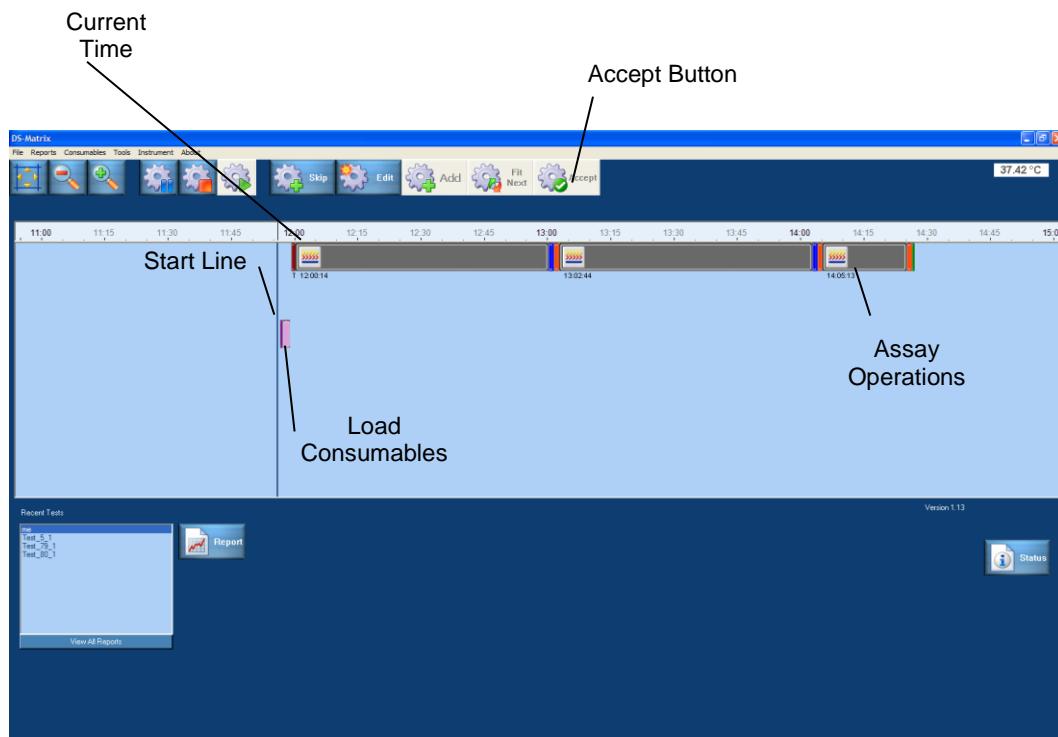


Figure 6-11: Timeline View Window

Checking Consumables Status

- For a report on the status of consumables, click on the  button at the bottom right of the Timeline window. Consumables Status is available after creating the worklist, but prior to accepting it. Consumables status allows the user the opportunity to prepare the reagents required for the worklist prior to accepting the worklist.
 - Consumables that are tracked include all fluids (excluding samples), tips (sample and reagent), plates, and washer fluids.

2. The Consumables Status screen (Figure 6-12) will display the name of the reagent, the reagent volumes, the number of tips left, and which assay is running.

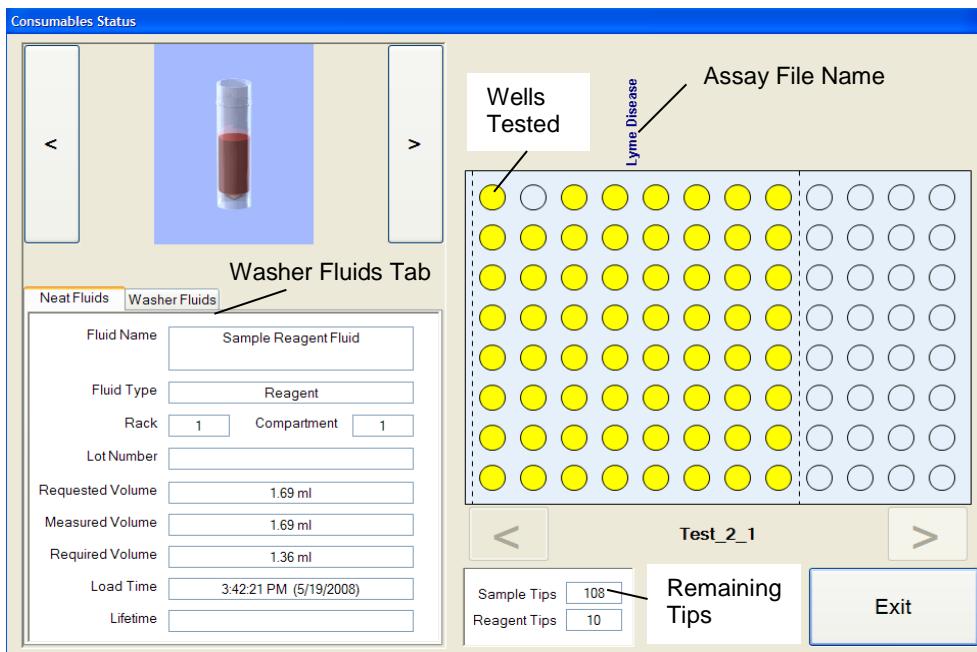


Figure 6-12: Consumables Status Screen

3. To show the status of a different neat fluid (reagent), click the buttons beside the fluid tube. To show the status of a wash buffer, click the **Washer Fluids Tab**.
4. The plate layout shows the wells being tested. At the top of the plate layout is the file name of the assay being run.

6.2.2 The Report

After a plate is finished testing, reports become available to view, save and print. The list of recent reports can be seen on the main DS-Matrix screen.

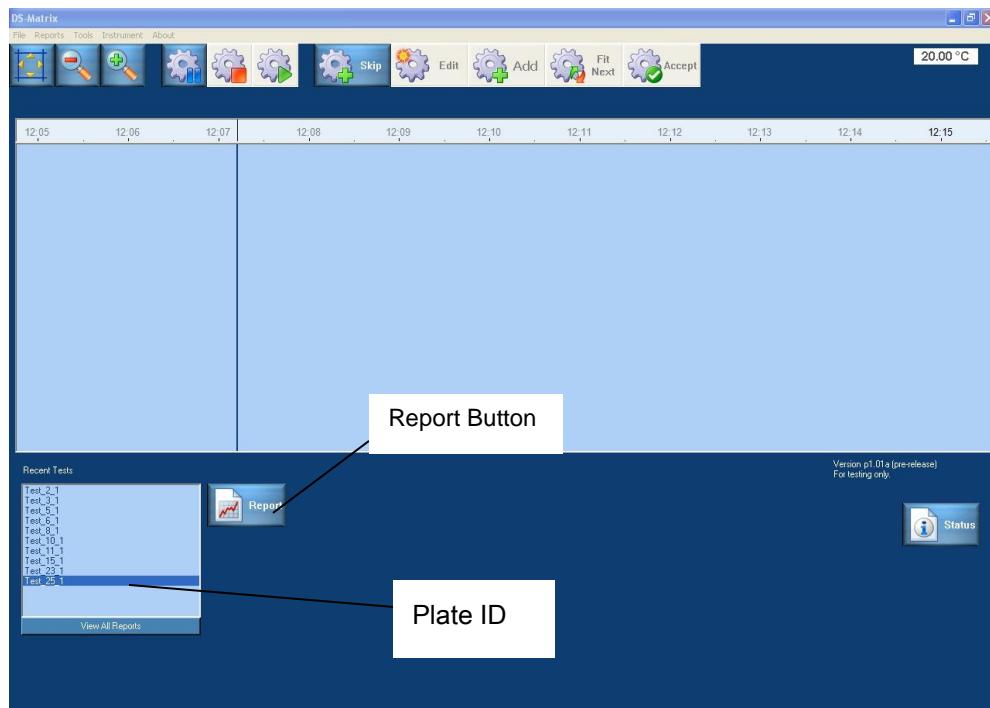


Figure 6-13: Retrieve Report

1. To see the Report immediately after a plate is finished, click on the button. The report for the last completed plate is displayed.
2. To review previous plate data, double click on the desired plate ID or highlight the desired plate ID and click the report button.
3. To sort plate reports or to find the data for a plate tested on a specific date, click the **View All Reports** button.

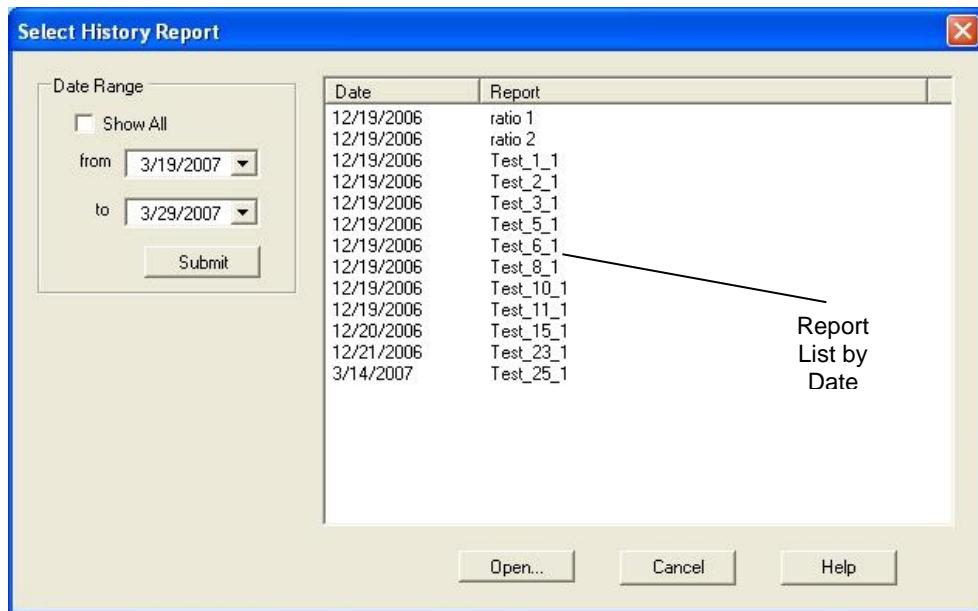


Figure 6-14: Sort Reports Screen

4. Uncheck the **Show All** box, and change the range of dates to search for the desired reports. Click the **Submit** button.
5. Highlight the desired report in the list and click the **Open** button to display the Report. Information included is displayed according to how the report was formatted when the assay was created.

Plate: Test_15_1	Printed on 3/30/2007 at 1:12 PM	Page 1										
Assay: ambient shake												
LABORATORY INFORMATION												
Name : Dynex Technologies Department : Research Address : 14340 Sullyfield Circle : Chantilly, VA 20151 Phone : 1-800-288-2354 Fax :												
TEST INFORMATION												
TEST NAME :												
PLATE :	Test_15_1											
VWL MODE :	SINGLE	DATE : 12/20/2006										
TEST FILTER :	450 nm(s)	TIME : 11:38:01										
REF. FILTER :	*											
REMOVED OUTLIERS												
Outliers removed :	None											
CALCULATION MODE												
OVER Limit :	3											
Calculation Mode :	Endpoint											
BLANKS												
Individual blanks:												
DATA MATRIX/TABLE : OD												
	1	2	3	4	5	6	7	8	9	10	11	12
A	0.330	0.041	0.041	0.043	0.042	0.319	0.043	0.041	0.042	0.044	0.043	0.040
B	0.457	0.044	0.042	0.043	0.043	0.051	0.045	0.043	0.043	0.044	0.041	0.040
C	0.053	0.042	0.038	0.041	0.043	0.043	0.045	0.043	0.044	0.045	0.041	0.035
D	0.086	0.043	0.043	0.043	0.042	0.047	0.049	0.047	0.043	0.048	0.040	0.039
E	0.182	0.042	0.042	0.042	0.049	0.048	0.047	0.047	0.043	0.045	0.041	0.040
F	0.252	0.042	0.050	0.044	0.044	0.046	0.047	0.045	0.043	0.043	0.042	0.044
G	0.201	0.042	0.046	0.041	0.043	0.043	0.045	0.045	0.044	0.042	0.042	0.051
H	0.188	0.040	0.042	0.043	0.043	0.236	0.046	0.053	0.043	0.042	0.040	*****

Figure 6-15: Report Page One

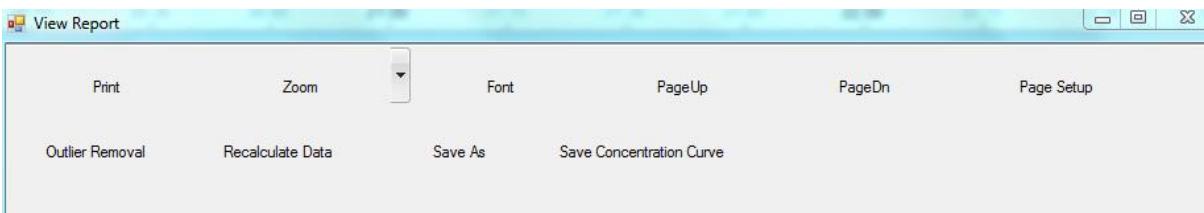


Figure 6-16: Report Viewer Toolbar

6. The **Report Viewer Toolbar** is at the top of the report screen. From this toolbar the Report may be edited and printed. The report view, font type, and font size can be changed. Most reports will be multiple pages. To scroll through the different pages and review all results, use the **Page Up** and **Page Down** buttons.
7. Outliers can be removed by clicking the **Outlier Removal** button. This feature is especially useful to redraw curve fits if one standard replicate or an entire point has an OD that is too high or too low.
 - Highlight the well to be removed by clicking on it, and then check the checkbox associated with the selected well. Click **OK** and the data will be recalculated. More than one well can be removed at the same time.

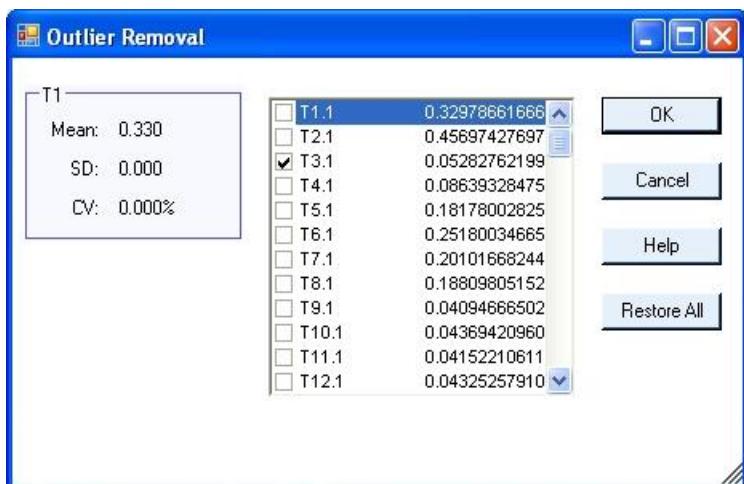


Figure 6-17: Outlier Removal

- When removing outliers, ensure that enough valid data points remain to redraw the curve.
8. To reanalyze the data with a different curve fit, threshold levels, or ratio equation, click the **Recalculate Data** button.

► **Note:** An assay with the desired operations must be created previously in the Assay editor and saved in the assay database to reanalyze data using this feature.

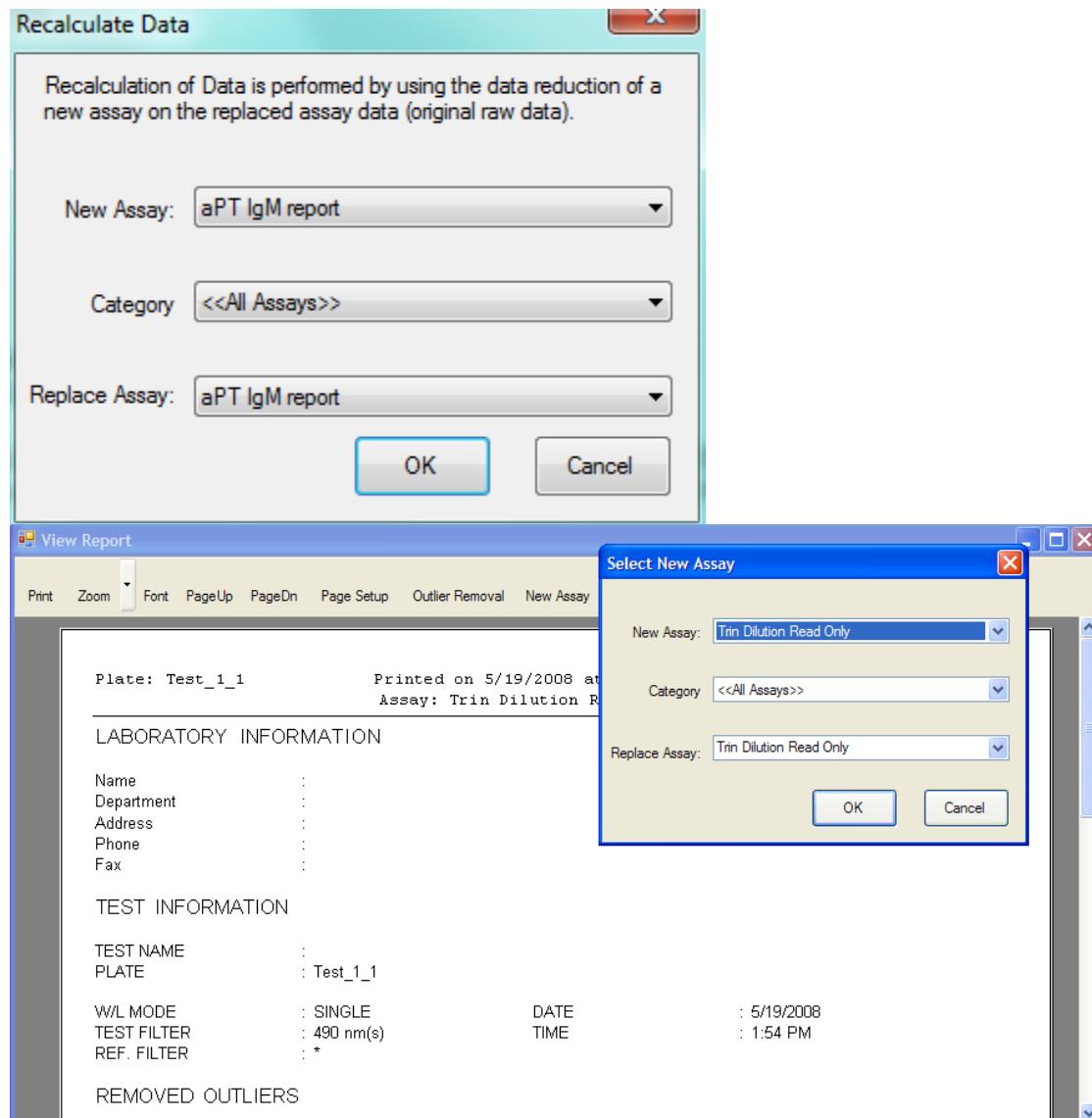


Figure 6-18: Selecting New Assay for Data Reduction

- Select the desired assay with the new data reduction from the drop down list (Figure 6-18).
- Click **OK**. The data will be reanalyzed and displayed with the following warning (Figure 6-19):

“WARNING! Results may have been reproduced using different settings to the original assay.”

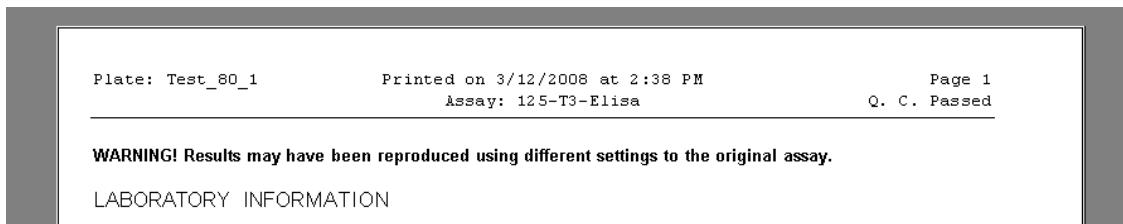


Figure 6-19: Warning on Report

9. To save data which has been recalculated or had outliers removed, click the **Save As** button. This option saves the report containing the new data reduction with a new name (the name is user configurable). The saved report will be added to the list of reports in the Matrix software for later viewing.
10. To save the curve fit generated on the report for use with another data set, click the **Save Concentration Curve** button. Complete instructions for using this functionality are in the “Stored Curve Fit Functionality” section of this manual.

Chapter 7 Starting the Run

7.1 General Considerations

7.1.1 Sample Types

1. Biological samples such as serum, plasma, urine, or spinal fluid are typically analyzed by the system. Adequately prepared, stool and tissue homogenates can also be run on the DS2.



Caution: It is the end user's responsibility to perform full validation on their sample matrix.

2. Sample IDs may be manually entered by the operator or read from barcode labels on the sample tubes.

Using Barcode Labels

1. When using an ink jet label maker, large dot spacing may increase the number of missed scans. **Test the labels before using them in an assay. Print quality is very important to reliable scans.**
2. Ensure the barcode density selected is between 0.005" and 0.013".
3. The Vertical Scanner can read test tube barcodes up to 85 mm in length, including the 5 mm Quiet Zone on each side of the barcode. However, the readable barcode length may vary, depending upon the code type and barcode density. The user should test barcodes to ensure a specific barcode topology can be reliably scanned.
4. Check that the barcode Quiet Zone is sufficiently wide at both ends of the barcode label. This distance must be at least 5 mm from the actual barcode to the end of the label. Be sure that the Quiet Zone is not reduced; otherwise a missed scan could occur.
5. The test tube barcode that is to be scanned must be properly aligned. The barcode label must be visible through the sample rack slot.
6. Check that the digits, letters, and other characters are correct for the barcode symbology that is being used. Also, use the correct number of data digits for a specific barcode symbology.

Supported Barcodes

Codabar	Code 128
Code 39	Standard 2 of 5
Code 93	Interleaved 2 of 5
MSI/Plessy	UPC / EAN / JAN

7. Symbologies with poor internal verification or partial decodes (such as Interleaved 2 of 5, Standard 2 of 5, and MSI/Plessey) should be avoided if possible.
8. Be sure that the barcode scanner module window is clear, clean, and not scratched.

7.2 Preparing the System

Filling the Wash Buffer Containers

1. Disconnect the wash buffer container and remove it from the system.
 - a. To remove the wash buffer container, disconnect the wash line by pressing on the metal tab of the quick disconnect fitting and pull gently on the wash line. Disconnect the liquid level sense connection by removing it from the connector socket (Figure 7-1).

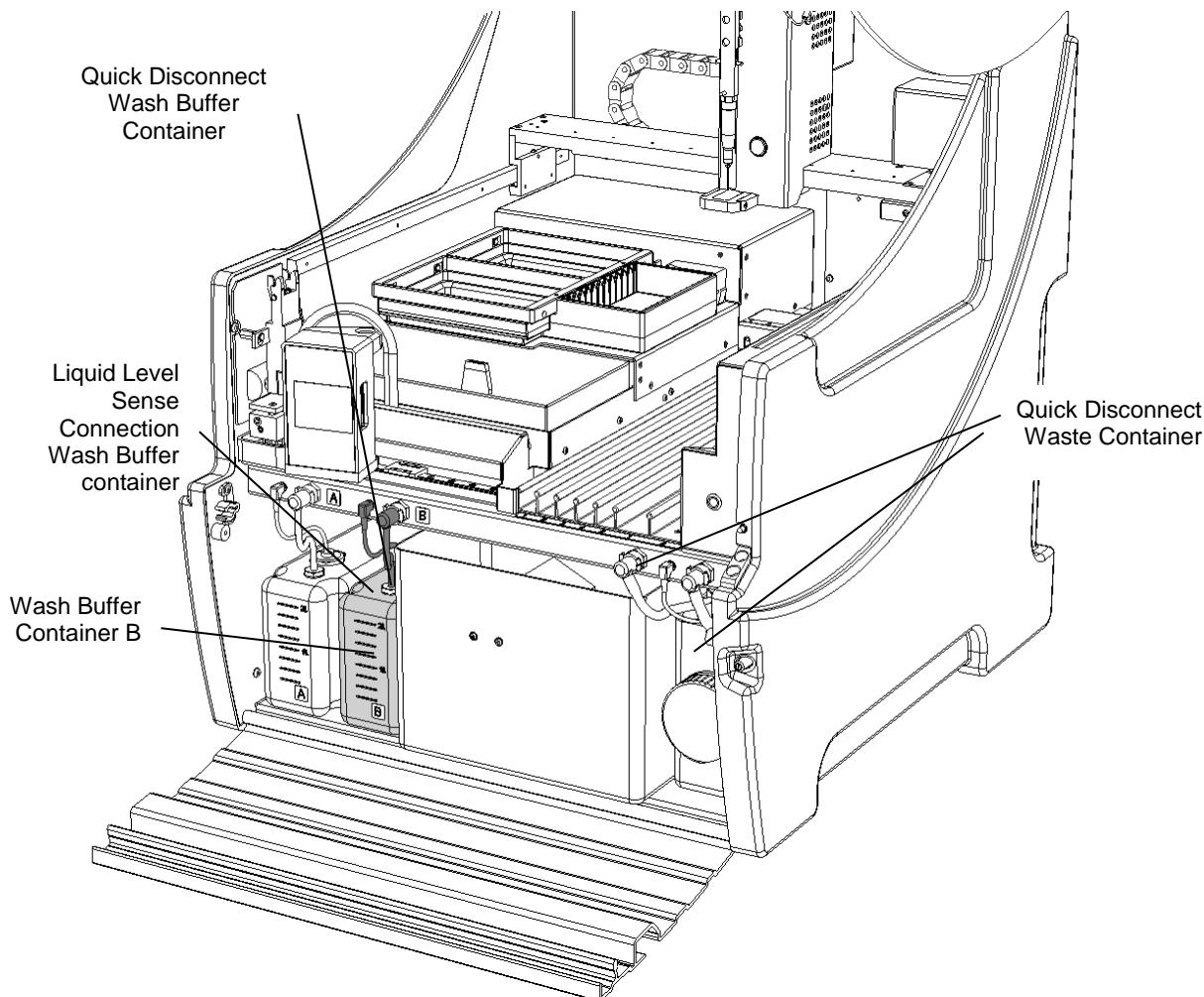


Figure 7-1: Wash Buffer Container B

2. Remove the top cap of the wash buffer container and fill it with the desired wash solution.

- **Note:** *The wash buffer containers can hold up to two liters. DO NOT OVERFILL.*

3. Replace the wash buffer container in its storage location. Reconnect the liquid level sense connection and the quick disconnect fitting.
4. Repeat Steps 1 through 3 for the second wash buffer container (if necessary).

Emptying the Waste Container

1. Two Quick Disconnect fittings connect the liquid and vacuum lines to the Liquid Waste Container (Figure 7-1). Disconnect each one by pressing on the metal tab of the quick disconnect fitting and gently pulling on the line.
2. Disconnect the level sensor Float Switch Connector (Figure 7-1) by pulling it out of the connector socket.
3. Remove the waste container cap and discard the waste in accordance with local regulations.

- **Note:** *Do not remove the Liquid Waste Container cap when the container is in the DS2. Always remove the container first, stand it upright on the bench with the cap pointed up, then remove the cap.*

4. Rinse the waste container with DEIONIZED or distilled water. Discard the rinse water.

- **Note:** *The waste container can be disinfected with 70% ethanol, followed by thorough rinsing with distilled or deionized water.*

5. Replace and tighten the waste cap.

- **Note:** *Be sure that the waste cap is securely tightened. A vacuum leak will occur if the cap is not properly tightened and will cause the software to report a vacuum error condition.*

6. Place the waste container on the system and reconnect the quick disconnect fittings and the liquid level sensor.

7.3 Starting the Run

Starting the Run

See Chapter 6 of this manual (the Worklist) for detailed instructions on creating a worklist.

1. Display the worklist to be run by selecting **File > Worklist Editor** from the main Matrix screen. A dialog box is displayed prompting selection of a batch or group of test samples for the assays to be run.

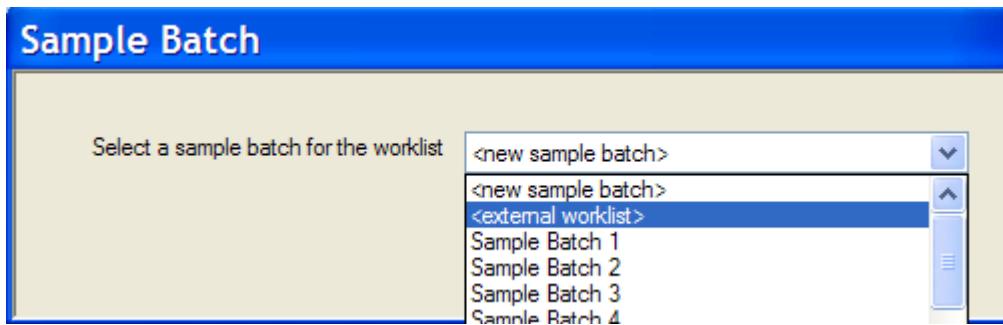


Figure 7-2: Sample Batch Selection

2. Select a previously used sample batch, select to create a new sample batch (<new sample batch>), or select to run an external worklist (<external worklist>). Click the **OK** button. The Worklist Editor screen will be displayed.
3. When creating a new sample batch, select the samples that will be run by clicking on individual tubes or by specifying the number of samples in the text box. By clicking the last tube in a sample rack, the entire rack of tubes can be selected.

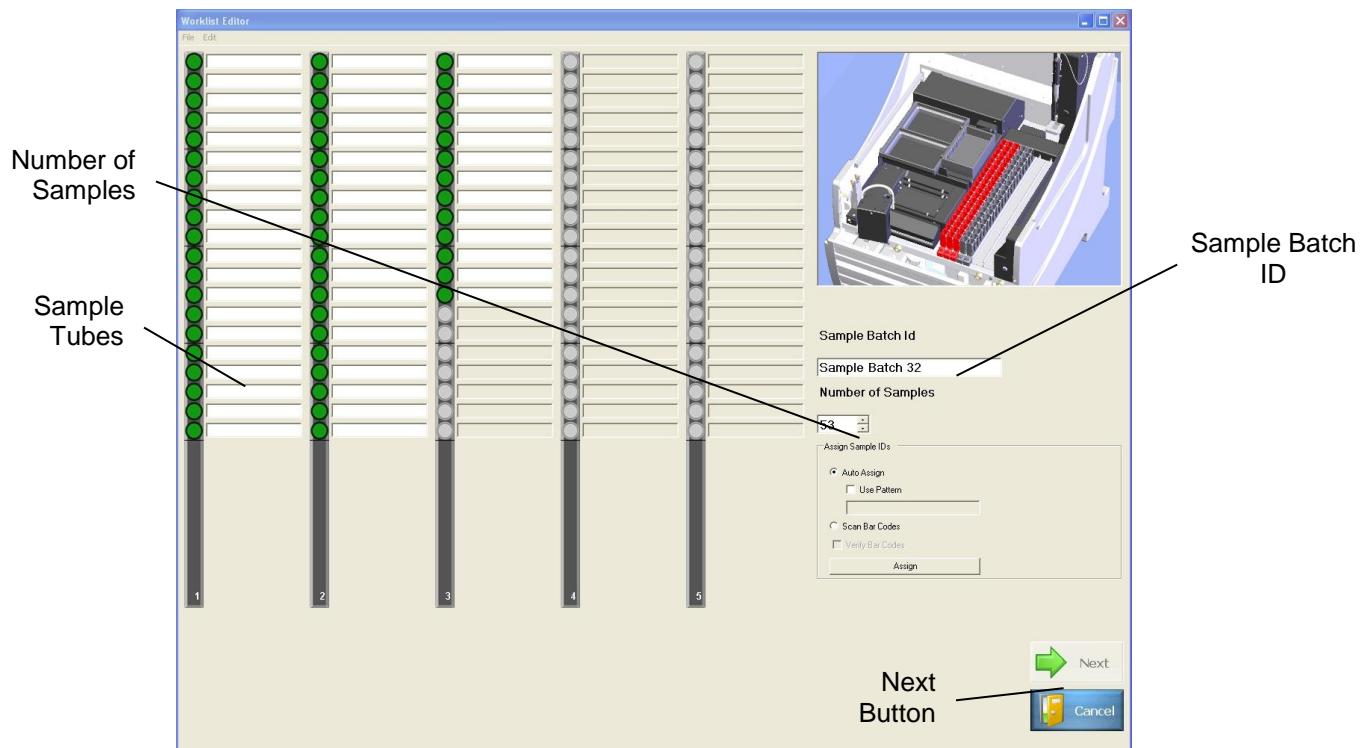


Figure 7-3: New Worklist Screen

4. Enter the Sample Batch ID or use the default name.
5. Create the sample IDs by selecting to have the DS-Matrix software auto-assign individual sample IDs (using the sample batch ID or a pattern) or by selecting to bar code scan the sample IDs.
6. Click the **Cancel** button to abort and restart the worklist. Click **Next** to accept the sample IDs.

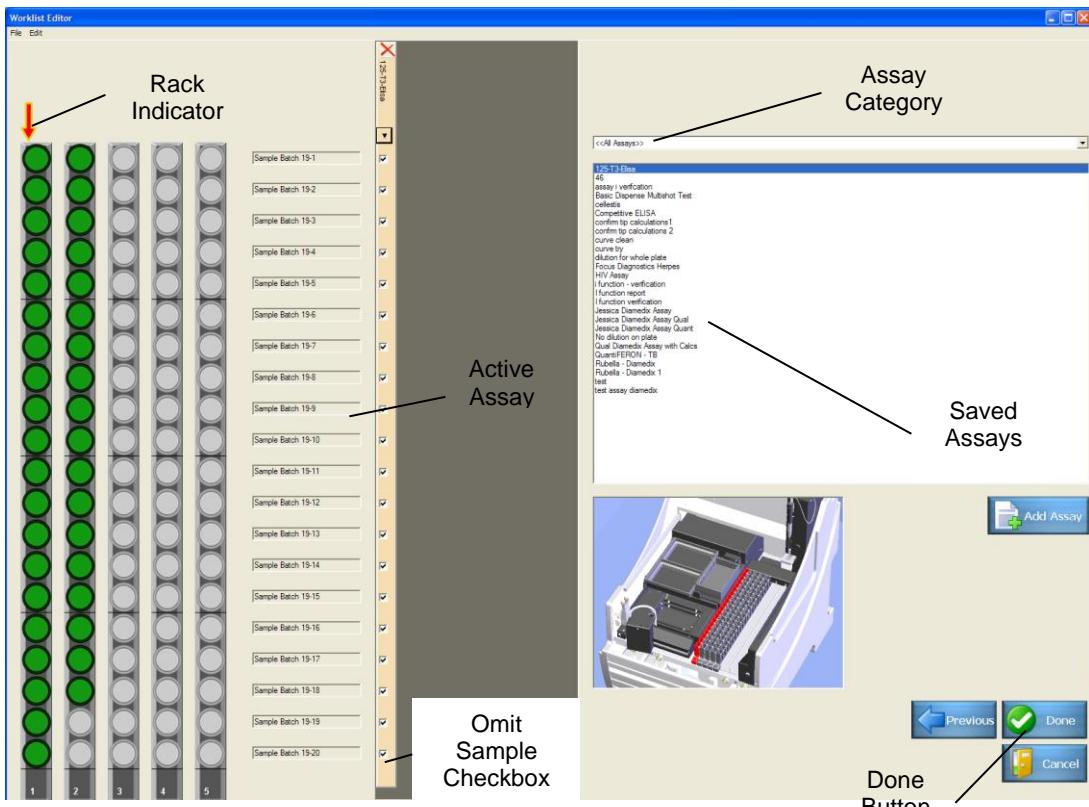


Figure 7-4: Assay Selection Screen

7. Select the assay category (if any) or All Assays in the drop-down list.
8. Select the assay(s) to be run by highlighting the desired assay and clicking the **Add Assay** button or by double clicking on the desired assay. A pale orange strip will appear next to the Sample IDs with the name of the assay at the top. If the check box next to a sample ID is checked, then the sample will be run with the assay.
 - ▶ **Note:** The checkbox can be used to omit an individual sample from the run without editing the sample batch list.
9. To remove an assay, click on the red X at the very top of the orange assay strip. To view the previous screen, which will allow number of samples to be changed, click **Previous**.
 - ▶ **Note:** When more specimens are added by returning to a previous screen, new sample IDs created must be selected to be run on any previously assigned assays. The checkboxes for any added sample IDs will not be automatically selected with previously added assays unless LIS-Link software is in use.
10. To abort the worklist, click **Cancel**, which will bring up a box verifying the worklist is to be aborted.
11. Click **Done** when assay selection is completed. The Timeline screen will be displayed.

The Timeline and Load Wizard

1. The Timeline screen with the assay steps scheduled is displayed (but transparent) once an assay has been assigned to the worklist.
2. The operator must click Accept to start the run.

► **Note:** If continuous loading worklists, prior to accepting the timeline, the user should have all reagents, samples, and consumables lined up and ready to load on the instrument. Items such as tips or sample tube racks should be loaded prior to clicking accept. Failure to load reagents promptly can lead to timeline conflicts.

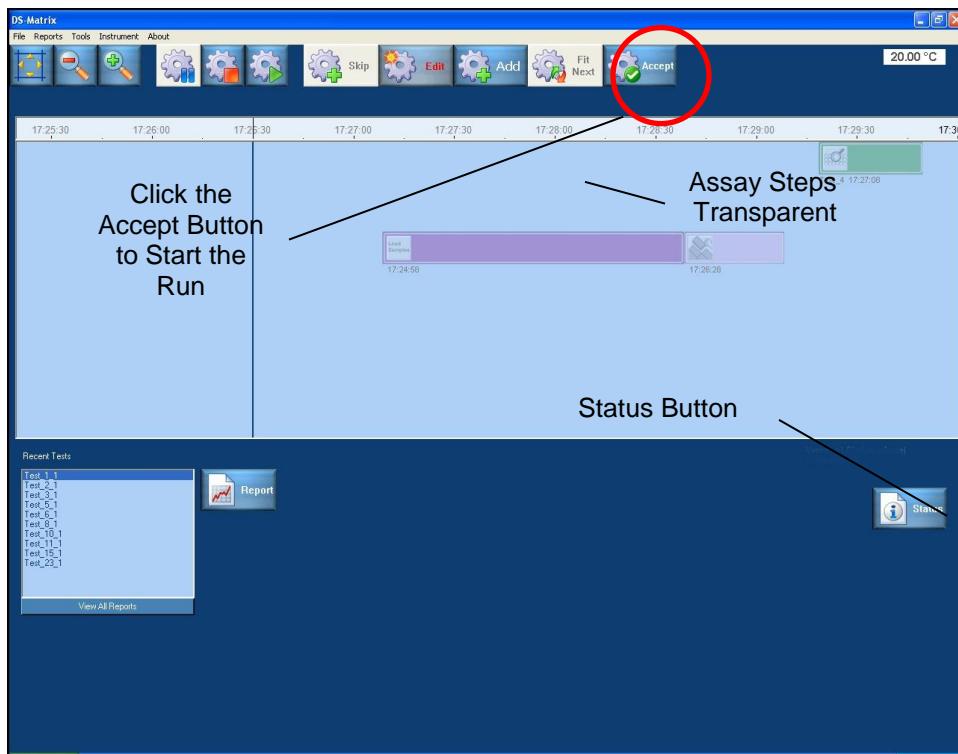


Figure 7-5: Timeline Screen

- After the timeline has been accepted, the software will prompt the user to load sample tube racks and consumables. (Sample tube racks may be loaded prior to clicking the **Accept** button.)
- The Load Tube Rack screen will display the number of samples in the Worklist, along with a diagram of the DS2 with tube racks highlighted. This prompts the operator to load the appropriate sample racks. Sample IDs should not be edited, entered, or changed during the load wizard. This screen is for loading the samples on the instrument only.

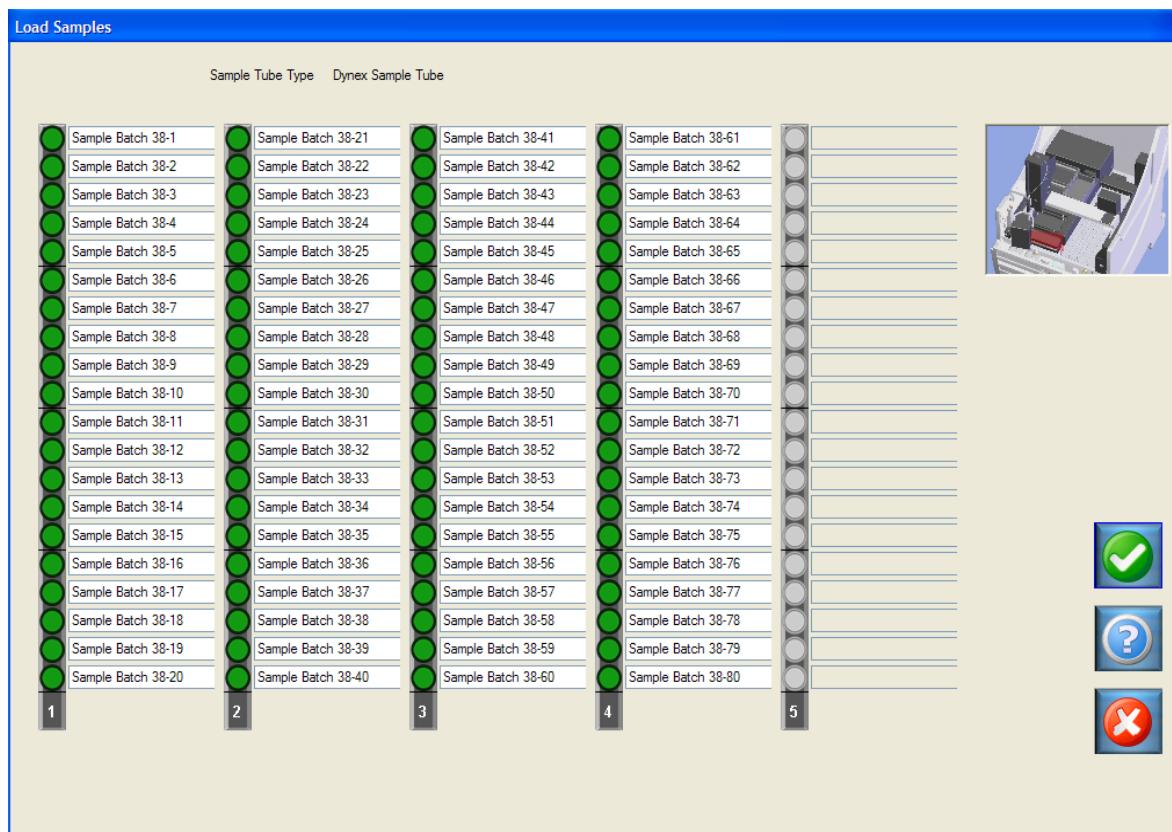


Figure 7-6: Load Tube Rack Screen

- Load the sample racks and click the **Green Check** button.

Loading Consumables

- After loading the samples, the load consumables wizard begins. A table which lists the reagents, standards and controls required for the run will display. The software will prompt the operator to load the fluids in the appropriate position with the appropriate volume. **Small reagent bottles should not be used when the software requests a large reagent bottle for a fluid.** Dynex recommends adding 10 to 20% more fluid than the volume requested to allow room for error.
- After an item is loaded in the designated position with the designated volume and any required information is entered, click the button to display the next prompt.

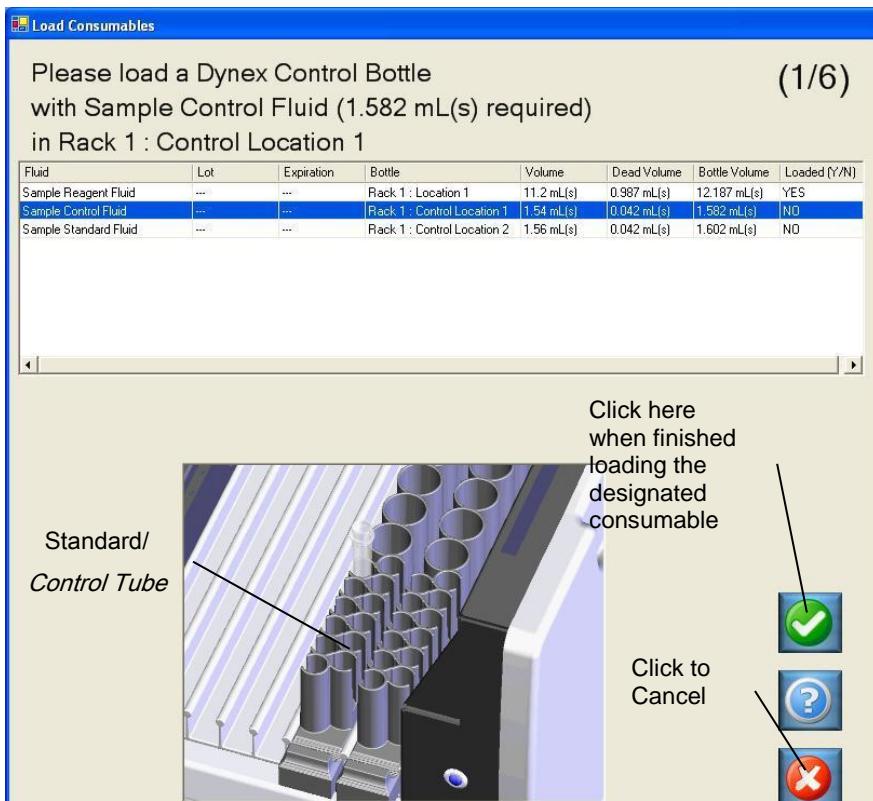


Figure 7-7: Load Consumables Screen

3. Click the button to abort the run.
4. The next screen prompts the operator to load plates and enter plate identifiers. The user must enter a unique plate identifier. The plate identifier will assist the user to identify which report they wish to view upon assay completion. **Do not use slashes, periods or other punctuation in the plate ID.** Plate IDs must not exceed 50 characters. Ensure the plate is seated securely in the plate carrier and that all strips in the plate are pushed down and oriented correctly.
5. The software will prompt the operator to:
 - a. load sample tips (blue)
 - b. reagent tips (clear)
 - c. deep well strips (if needed)
 - d. check the status of the clean line
 - e. load the wash buffer into the wash container
 - f. check the status of the waste containers.
6. After all consumables have been loaded, the run starts.

7.3.1 Timeline View – Run Status

The Timeline View screen displays the scheduled timing of individual assay functions. These time estimates may be updated as more runtime information is available to the DS2.

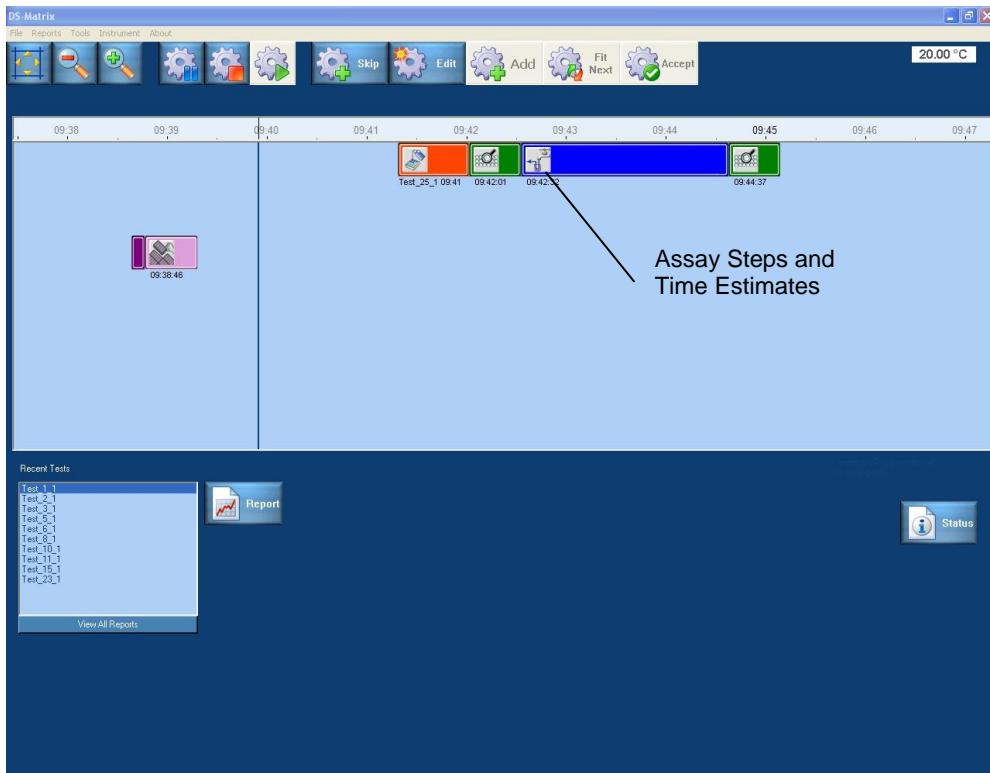


Figure 7-8: Timeline View Screen

Using the Timeline View

1. To expand the Timeline View, click on the  icon.
2. To condense the Timeline View, click on the  icon.
3. To view the entire Timeline (as displayed above), click on the  icon.

Checking Consumables Status

1. For a report on the status of consumables during a run, click on the  **Status** button.
2. The Consumables Status screen will display with the tube types, fluid volumes, sample and reagent tips, and plate maps that are being used in the worklist. During the run, the consumables status is updated as fluids and tips are used.

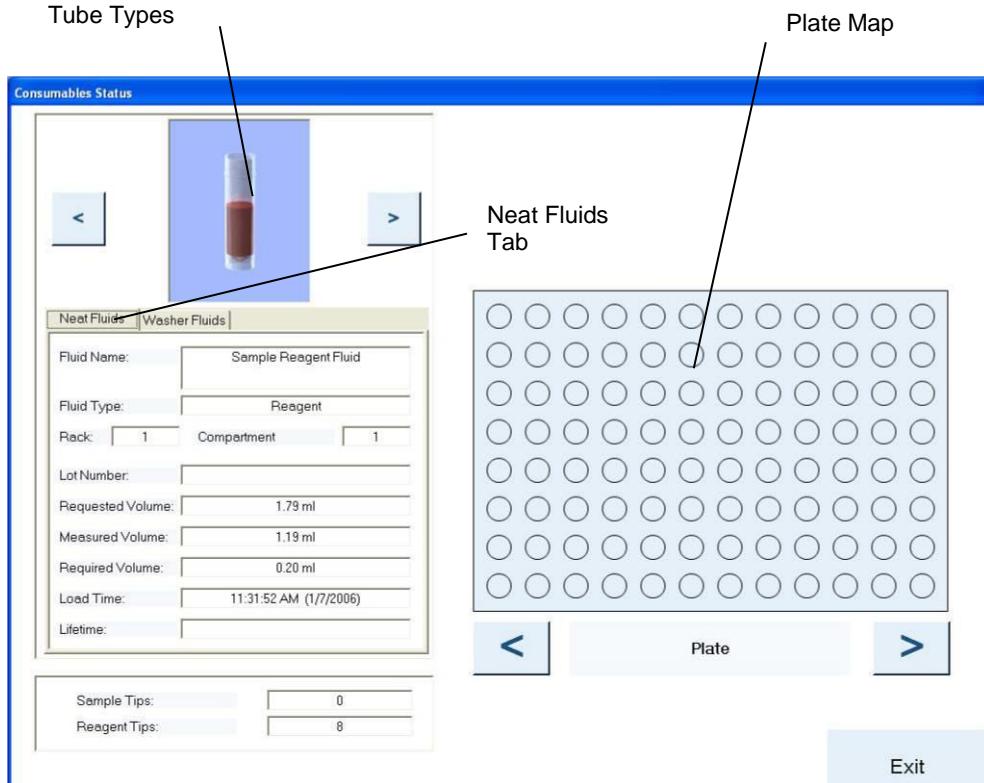


Figure 7-9: Consumables Status Screen

Generating a Run Report

1. To view a report on a completed plate, select the desired plate identifier from the recent tests list and click on the  **Report** button.
2. The report can be viewed and printed from the **View Report** screen by clicking the **Print** button.

► **Note:** A printer driver must be installed for Reports to be viewed and printed using the Matrix software.

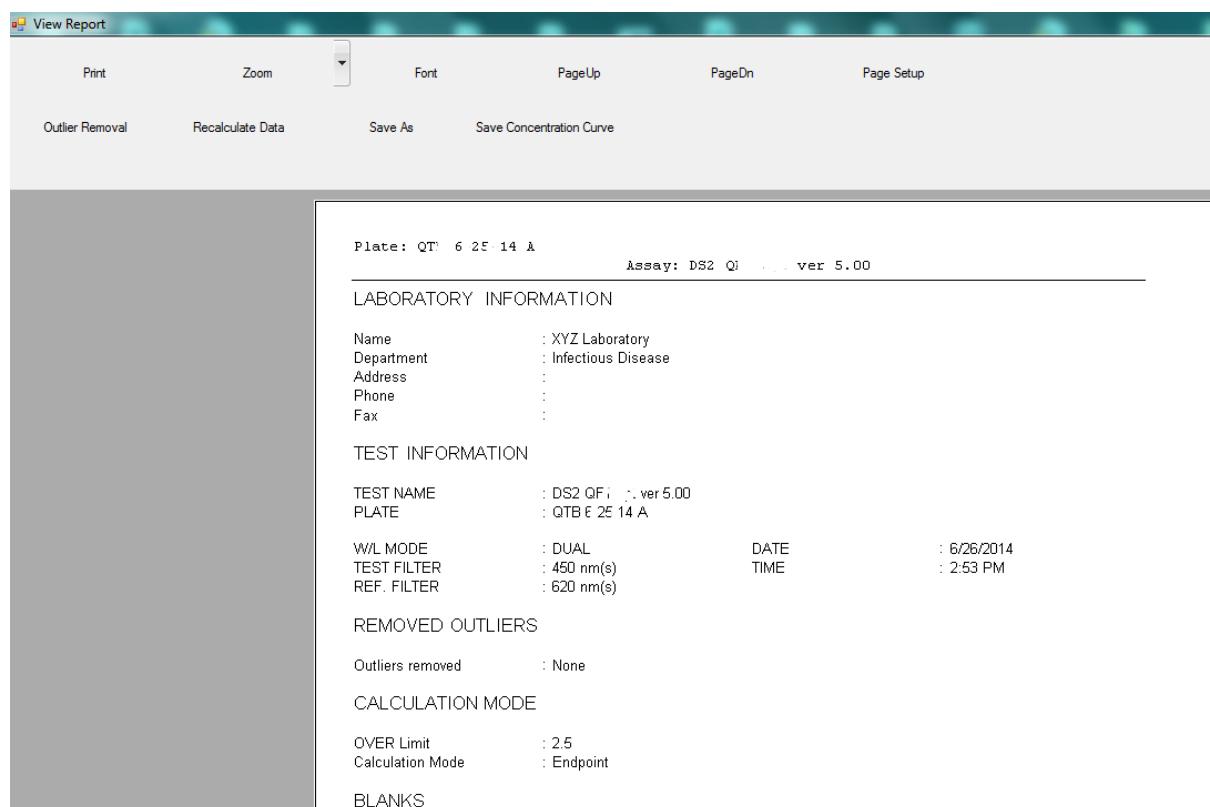


Figure 7-10: View Report Screen

Chapter 8 Routine Service, Maintenance and Troubleshooting

8.1 Routine Maintenance Procedures

- ▶ **Note:** Performing maintenance to the DS2 may expose the operator to hazardous moving parts. Contact DYNEX for proper safety precautions to avoid possible injury.
- ▶ **Note:** The DS2 and DS-Matrix software must be shut down once every twenty-four hours to ensure proper DS2 performance.

Please note that bleach should never be used to clean the DS2 or its accessories. The following periodic maintenance procedures are required for the DS2 Automated ELISA Processing System:

Daily Maintenance (End of Day)

1. Empty and clean the tip waste container.



Warning: While the DS2 alone does not present a biohazard, the samples that are used and all parts and consumables in contact with the samples must be considered biohazards. Always wear protective gloves when handling potentially infectious substances.

2. Empty and clean the liquid waste container as needed.

- ▶ **Note:** If desired, the waste tip container and the liquid waste container can be disinfected with 70% ethanol. The containers must be thoroughly rinsed with deionized water before replacing, as residual alcohol fumes may affect the results of ELISA assays.
- 3. Clean all external surfaces using a towel moistened with 70% alcohol. **Pay special attention to the pipette spigot, the tip sensor area, the wash head sensor, and the wash head assembly.** Remove any residual alcohol with a cloth dampened with distilled water.
- 4. Clean the pipette spigot using a non-fibrous towel moistened with 70% alcohol. Remove residual alcohol with a cloth dampened with distilled water. Ensure the hole in the pipette spigot is clear of dirt and debris.

5. Ensure all assays have a Clean step built into the wash cycle to prevent salt build-up in the wash head.

Weekly Maintenance

1. Empty the wash buffer containers and rinse them several times with deionized water.

Monthly Maintenance

1. Perform an alcohol/disinfectant wash.
 - a. Fill the wash buffer bottles with 70% alcohol or disinfectant.
 - b. Run a wash assay using fluid from wash buffer bottle A.
 - c. Run a wash assay using fluid from wash buffer bottle B.
 - d. Rinse the wash buffer bottles thoroughly with distilled water.
 - e. Fill the wash buffer bottles with distilled water.
 - f. Run several wash assays using fluid from wash buffer bottle A until alcohol/disinfectant is removed from the tubing lines.
 - g. Run several wash assays using fluid from wash buffer bottle B until alcohol/disinfectant is removed from the tubing lines.

6 Month Maintenance

1. Check for gas spring robustness.
 - a. Close the DS2 cover.
 - b. Lift the DS2 cover approximately 8 inches.
 - i. If the cover stays open or closes slowly, the gas spring is acceptable.
 - ii. If the cover falls down rapidly, the gas spring must be replaced.

Annual Maintenance

DS2 Preventative Maintenance: One annual visit includes the following:

- System Self-Test; check that all tests pass
- Clean all exterior surfaces, including the wash head
- Replace tubing set including filter and verify bottles
- Replace lamp (once per year)
- Replace reader fan filter and clean optics
- Inspect bottle fitting O-rings and spigot
- Run washer verification (dispense calibration, residual volume)
- Absorbance Reader (AM Module) verification using verification tools
- Reader filters inspected and cleaned
- Inspect spring clips on plate carriers and replace as needed
- Workspace Calibration Tests performed
- Incubator check
- Perform Pipette Check



Note: *The dispense tubing and aspiration tubing may need to be replaced more frequently than every year, depending upon the frequency of use and the severity of operating conditions.*

Contact DYNEX TECHNOLOGIES for information on replacement tubing.

8.2 Cleaning and Decontamination

The DS2 Automated ELISA Processing System is constructed from materials that resist chemical attack.

Spills should be cleaned as soon as possible. If you need to decontaminate the *DS2 Automated ELISA System* (for example: before servicing the instrument or following a spill), clean the system and then decontaminate it as described below.



Caution: Always disconnect the power cable before cleaning.

To Clean the System

1. Clean external surfaces, waste containers, wash containers and tubing lines with a cloth moistened with mild laboratory detergent.

- ▶ **Note:** If needed, dilute the laboratory detergent according to the manufacturer's instructions before using.
- ▶ **Note:** If there is any doubt about the compatibility of cleaning agents with parts of the DS2, contact DYNEX Technologies.

To Decontaminate the System

1. Wipe the surfaces with a cloth moistened with a 70% (v/v) solution of alcohol.
2. Clean the waste containers, wash containers and tubing lines with 70% alcohol. Run 70% alcohol through the tubing lines. Run deionized water through the tubing lines to remove the alcohol.

- ▶ **Note:** Remove residual alcohol from surfaces with a cloth moistened with deionized water. Residual alcohol may affect the results of ELISA assays.
- ▶ **Note:** If there is any doubt about the compatibility of decontamination agents with parts of the DS2, contact DYNEX Technologies.

8.3 Upgrading the DS-Matrix Software

This procedure outlines the steps required to upgrade the DS-Matrix software. *If the current software version on the DS2 is prior to Matrix 1.17, please see the instructions concerning this upgrade (point #6).*

1. Create a Database Backup

a. Stop the SQL server

- i. For windows XP, follow the instructions on TB105 to stop the SQL server
- ii. For Windows 7, stop the SQL server through Control Panel (Large or small icon view, not category view)

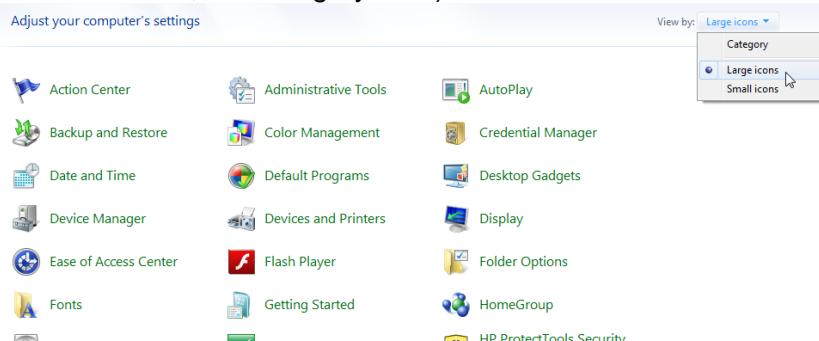


Figure 8-1 Windows 7 Control Panel

- iii. /Administrative Tools/Services. Locate MSSQL\$DYNEXLOCAL in the list of services, highlight it, and click “Stop the Service” in the upper left corner of the screen.

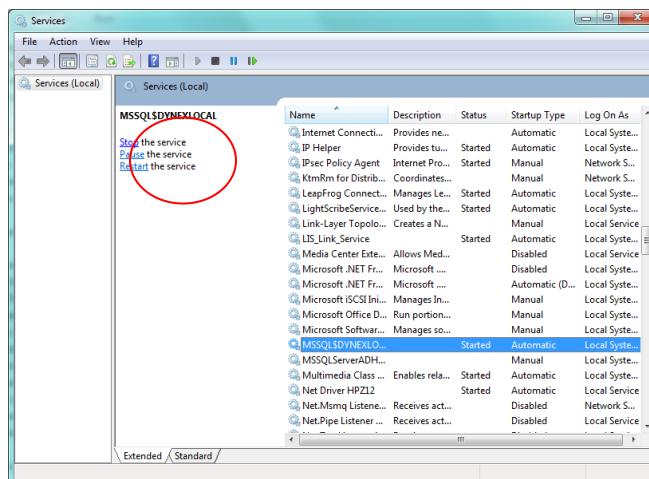


Figure 8-2 Stopping the SQL Server

b. Copy the Database Files

- i. Once the SQL server has been stopped, navigate to C/Program Files/Common Files/Dynex Technologies/Databases/MSSQL\$DYNEXLOCAL/Data.

- ii. Right click inside the Data folder and select “New” from the list. From the secondary list, select “Folder”.

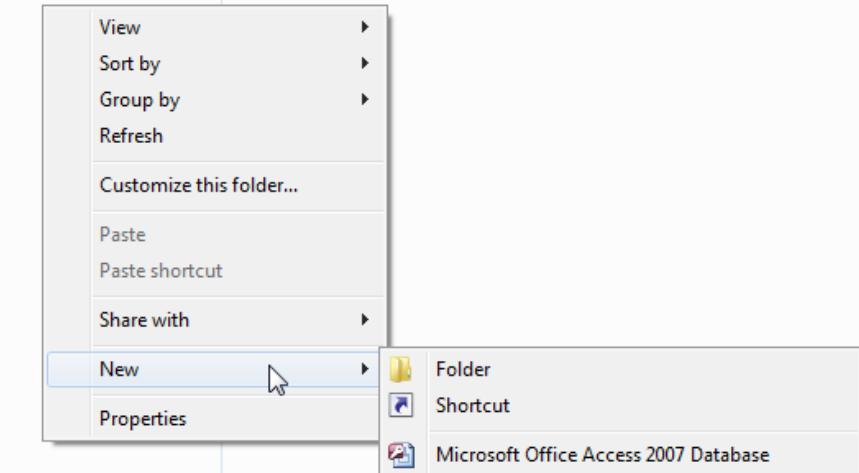


Figure 8-3 Creating a New Folder

- iii. Name the folder “Database Backup (today’s date).”
- iv. Copy the two database files and paste them inside this folder. The database files are called “Matrix.mdf” and “Matrix_log.ldf”

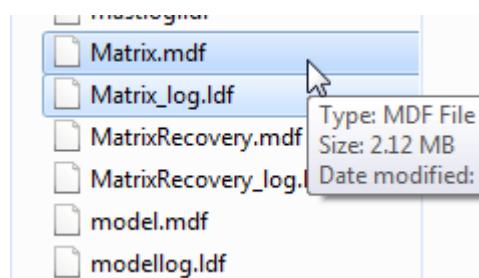


Figure 8-4 Selecting the Database Files

- c. Restart the SQL server by following the instructions in step A, only this time choose either the green play button (Windows XP) or “Start the Service” (Windows 7).

2. Uninstall the old version of the DS-Matrix software

- a. Go to the Control Panel (Large or Small icon view, not category view) and choose “Add or Remove Programs” (Windows XP) or “Programs and Features” (Windows 7).

- b. Find DS-Matrix in the list of programs. Double Click on it. The following window will appear:

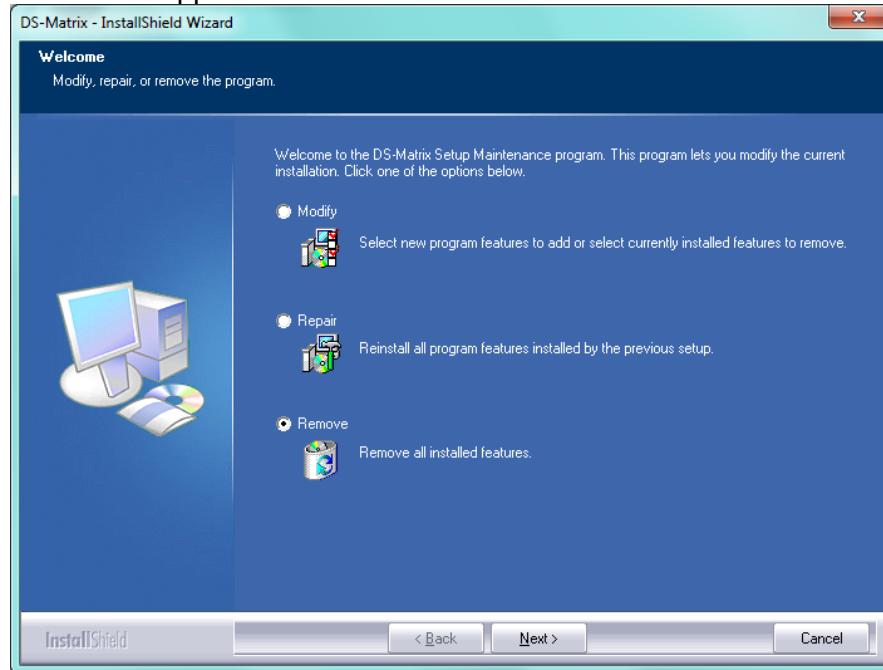


Figure 8-5 Uninstalling the Matrix Software

- c. Select “Remove” and click “Next”. This will uninstall the current version of the DS-Matrix Software.
3. Install the new version of DS-Matrix Software
- If installing from a software CD, the CD should begin to automatically once the CD is inserted into the drive, however you can also look in My Computer and double click the CD location to start the software installation if the CD does not start automatically.
 - If installing from a folder, double click on setup.exe inside the folder. Make sure the software installation folder is located on the desktop of the computer (not a USB drive). For best results, make sure the folder is unzipped and the files are extracted prior to installation.

- c. The software will first prompt the user to install any required programs.

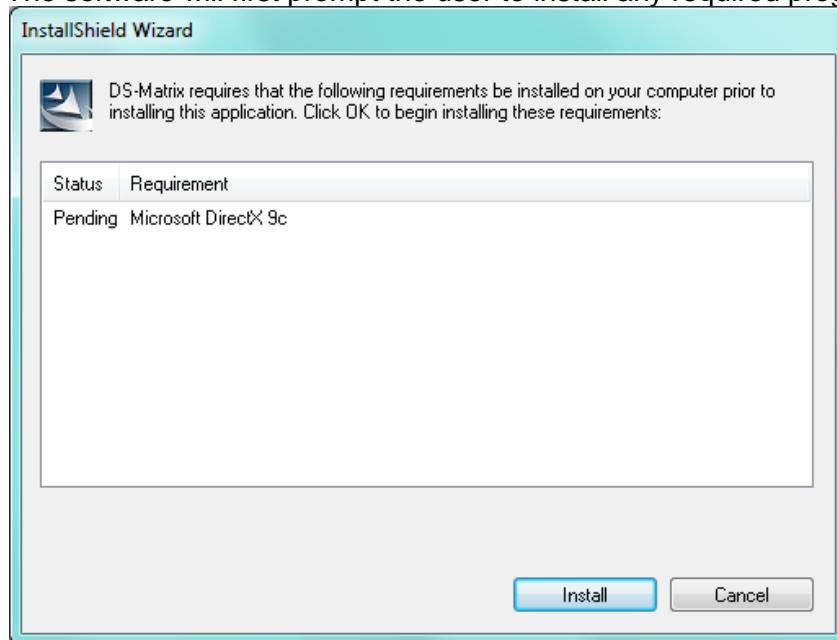


Figure 8-6 Installing the New Software Version

Click install to install the programs. Once these programs finish installing, an installation wizard will appear.

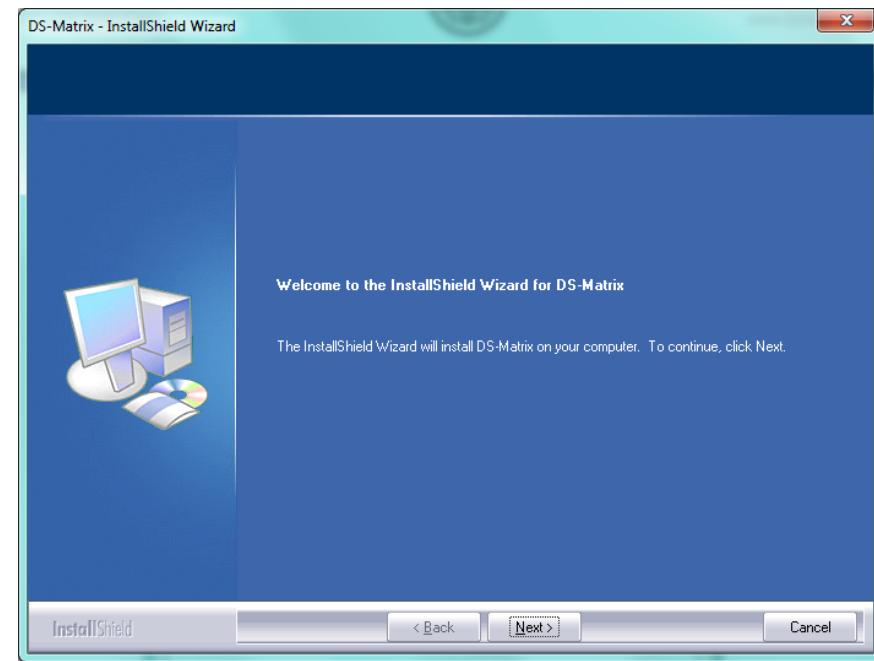


Figure 8-7 Install Wizard

- d. Click "Next", and continue through the wizard, entering in user information or company information as required. There is no need to change any of the default settings.
- e. Click "Finish" when the software has finished installation.

4. Change the Dispense Height setting in the configuration file

- The DS-Matrix software should be closed when updating the configuration file. The configuration file is found using the following pathway:

Program Files/Dynex Technologies/DS-Matrix/MatrixApp.exe.config (*some computers may show this as "MatrixApp.exe". If this is the case, look at the detail view of the files to make sure you are choosing the configuration file type and not the application file type.*)

- Right click on MatrixApp.exe.config and choose the "Open with" option.
- Select to open the file with Notepad and click okay.
- Scroll down through the configuration file until the setting for "MPDispenseHeightMM" comes into view.
- Change the value for this setting from 3.0 to 5.0. Your screen should match the picture below when this has been completed:

```

<!-- "LocalZTravelOffsetMM" defines the default tip position in millimeters
     above the top of a plate when traveling across it.
-->
<add key="LocalZTravelOffsetMM" value="5.0" />
<!--
     "DispenseHeightMM" defines the default tip position in millimeters above
     a fluid at which to dispense fluid when not dispensing to a plate.
-->
<add key="DispenseHeightMM" value="5.0" />
<!--
     "MPDispenseHeightMM" defines the tip position in millimeters above a
     fluid at which to dispense fluid into a microtiter plate.
-->
<add key="MPDispenseHeightMM" value="5.0" />
<!--
     "DWDispenseHeightMM" defines the tip position in millimeters above a
     fluid at which to dispense fluid into a deep well plate/strip.
-->
<add key="DWDispenseHeightMM" value="5.0" />
```

Figure 8-8 Changing the Dispense Height Settings

- Save the configuration file. Exit the file.

5. Start the DS-Matrix Software

- Double click the DS-Matrix software icon.
- The software will perform a database backup upon first start up. Click "OK" and the database backup will automatically be performed. This message will not appear again on subsequent software startups.
- Dynex recommends opening and resaving each assay file following a software upgrade.
 - Go to File. Choose assay editor.
 - Go to File. Choose open. The "Open Assay" dialog box will display.
 - The first assay file is automatically selected. Click OK.
 - Choose File and Save. The assay file is now saved.

- v. Repeat steps i-iv for each assay file, using the drop down arrow in the “Open Assay” dialog box to select the next assay in the list, until all assay files have been opened and saved.
- d. The software upgrade is now complete.

6. Upgrading software versions prior to DS-Matrix version 1.17

- a. Dynex recommends creating brand new database files and assay files when upgrading software versions prior to DS-Matrix 1.17.
 - i. Creating a new database
 1. Follow the instructions for backing up the database in #1 above, however after copying the files into the new folder, delete them from the data folder. When the new version of software is installed, the software will generate brand new database files. This will be similar to doing a new installation, and all system configuration settings will need to be reselected.
 2. All other steps above can be followed as written. Dynex recommends all assay files written in software versions prior to 1.17 be re-written in the current software version to avoid potential compatibility issues.

Please contact Dynex Technologies Technical Support
techservice@dynextechnologies.com with any questions or concerns.

8.4 Replacing an Absorbance Module Filter



Caution: The optics assembly may be hot. Allow at least five minutes for the DS2 to cool after turning off the system before opening the optics assembly.



Caution: Be careful when removing the filter access panel, as there is a possibility that the bulb may have broken.

To Remove a Filter

1. Remove the filter access panel from the rear of the DS2 by unscrewing the two screws (one at the top and one at the bottom of the filter access panel). The filters are mounted on the filter wheel as shown in Figure 8-10.

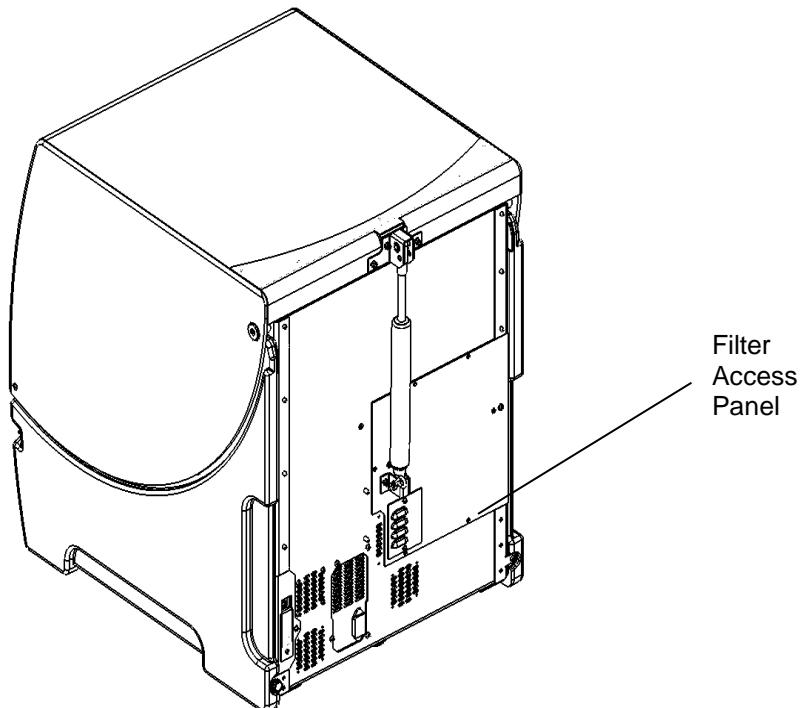


Figure 8-9: Filter Access Panel of DS2

2. Locate the filter that is to be removed.

► **Note:** The absorbance filter 405 must stay in position one on the filter wheel or the DS2 will fail the self-test on start-up.

3. Firmly grasp the exterior filter housing with a pair of needle nose pliers.
4. Pull the filter out of the spring-loaded slot.
5. Replace the filter access panel.
6. Go to the Matrix main menu toolbar and select the **Tools** menu. Select **Absorbance Filter** and change the wavelength in the position the filter was removed from to **0**.
7. Click **OK** to save the changes.

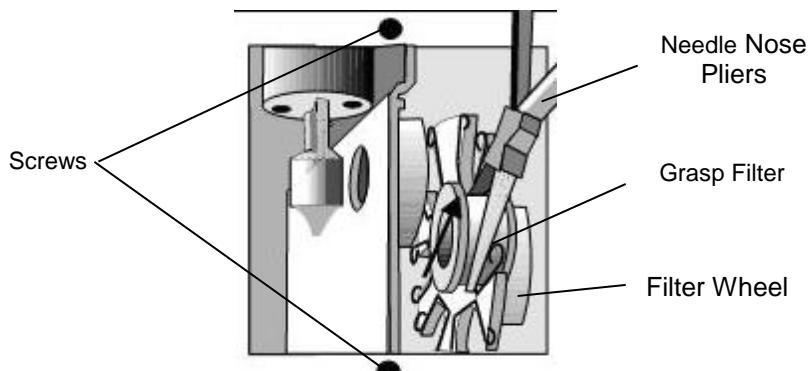


Figure 8-10: Removing a Filter

To Install a Filter

1. Remove the filter access panel from the rear of the DS2 by unscrewing the two screws (one at the top and one at the bottom of the panel). The filters are mounted on the filter wheel.
2. Locate the filter position in which the filter will be installed.

► **Note:** If a new filter is installed in a previously empty position or if the filter is replacing a filter of a different wavelength, the wavelength of the new filter must be entered in the main menu: **Tools > Absorbance Filter**.

► **Note:** The 405 nm filter **must** be installed in Filter Position 1.

3. Firmly grasp the exterior filter housing with a pair of needle nose pliers.

4. Push the filter into the spring-loaded slot.

► **Note:** *The bottom groove of the filter must be firmly seated in the filter wheel. If the groove is aligned with the springs on the filter wheel then the filter has been installed incorrectly and will cause invalid instrument performance.*

5. Replace the filter access panel.

6. Go to the **Tools > Absorbance Filter** menu and type in the wavelength of the installed filter in the corresponding position data entry field.

8.5 Replacing the Tubing

To Replace the Tubing

1. Open the door at the front of the DS2.

► **Note:** *The door is hinged at the bottom. When opening, prevent the door from dropping all the way forward.*

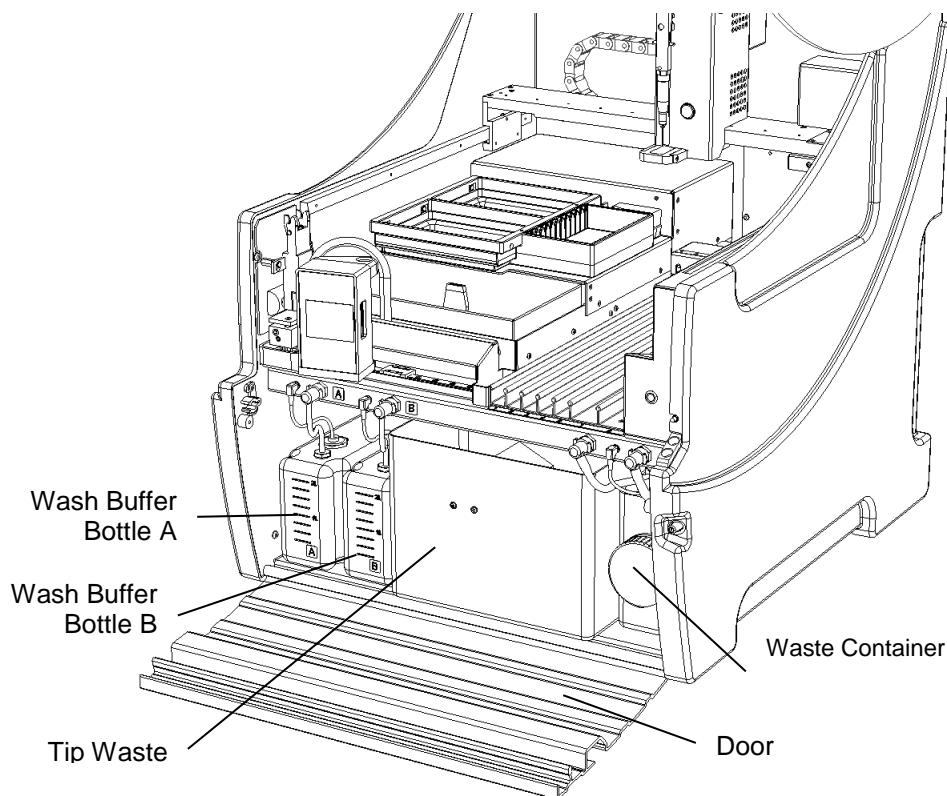


Figure 8-11: Door and Wash Buffer Containers/Waste Containers

2. **Disconnect** the two Wash Buffer Containers and the Waste Containers. Remove the Wash Buffer containers, the Waste Container and the Tip Waste Container.
3. The Pump/Valve Assembly that controls the washer dispense and aspiration functions is behind the Tip Waste Container.

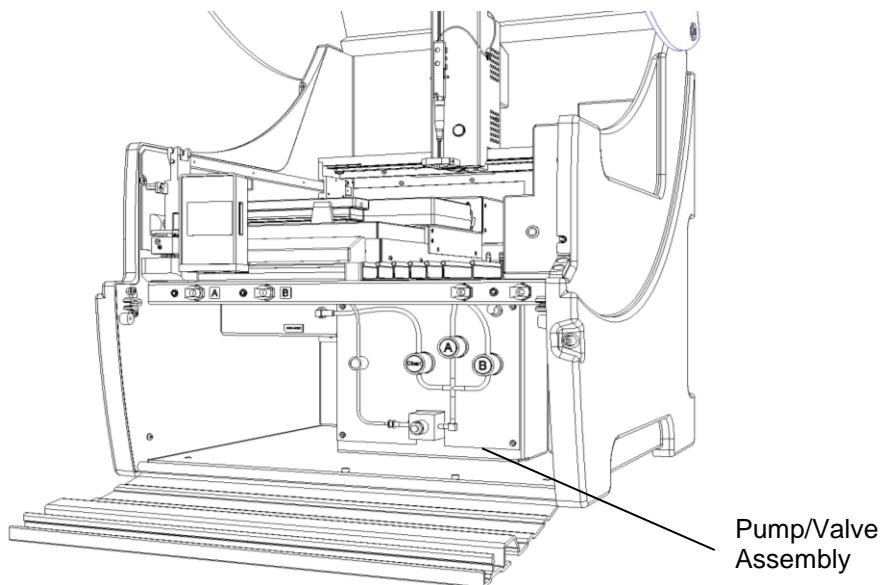


Figure 8-12: Pump / Valve Assembly

4. Disconnect the Wash Head Tubing from the Wash Head Manifold, and unscrew the Manifold Thumb Nut as shown below. The black thumb nut is on the underside of the DS2 platform.

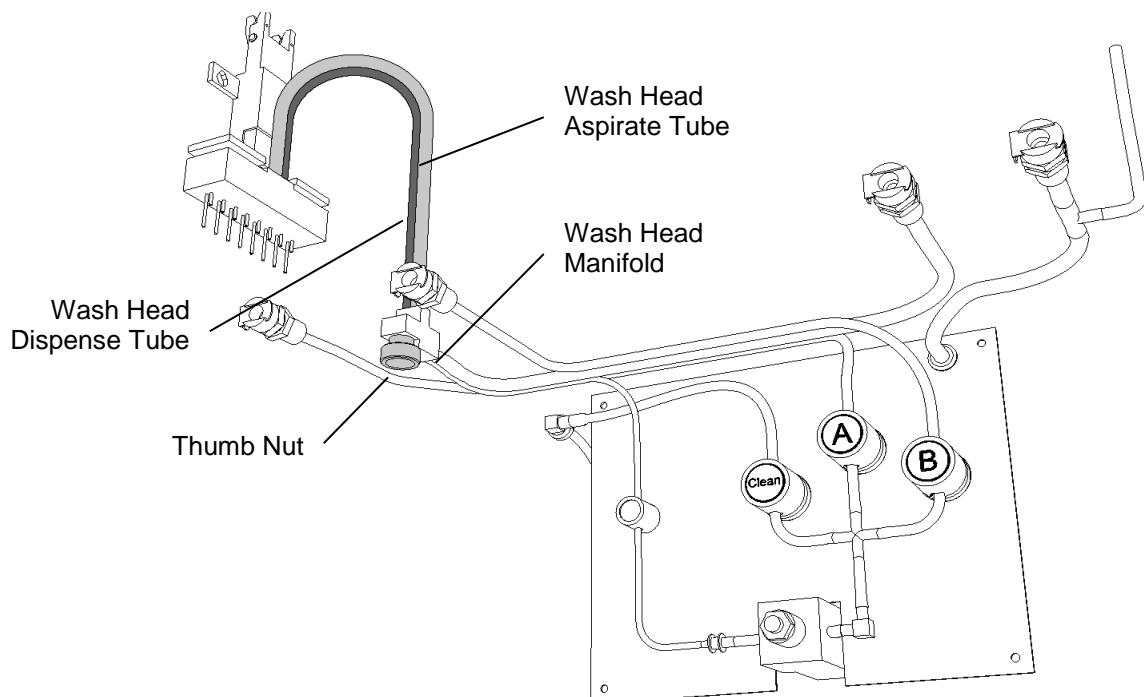


Figure 8-13: Tubing Schematic

5. Disconnect the Aspirate and Dispense tubes from the Wash Head Manifold.
6. Remove the Dispense Tube from the Pinch Valve and disconnect it from the Pump Outlet.
7. Disconnect the other end of the Aspirate tube from the Waste Fitting.

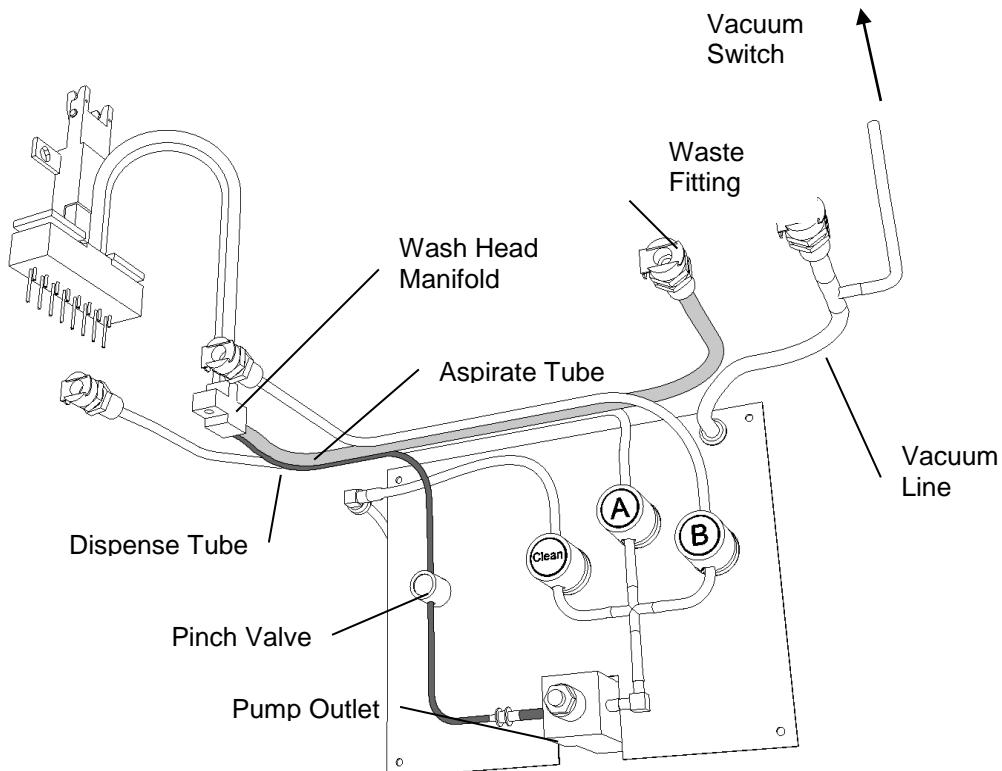


Figure 8-14: Tubing Schematic

8. Disconnect tubing from fittings for Wash Buffer containers A and B.
9. Gently pull the 90° fitting out of the Grommet and disconnect the Bottle C tubing.
10. Remove the tubes from the pinch valves and then disconnect them from the pump inlet.

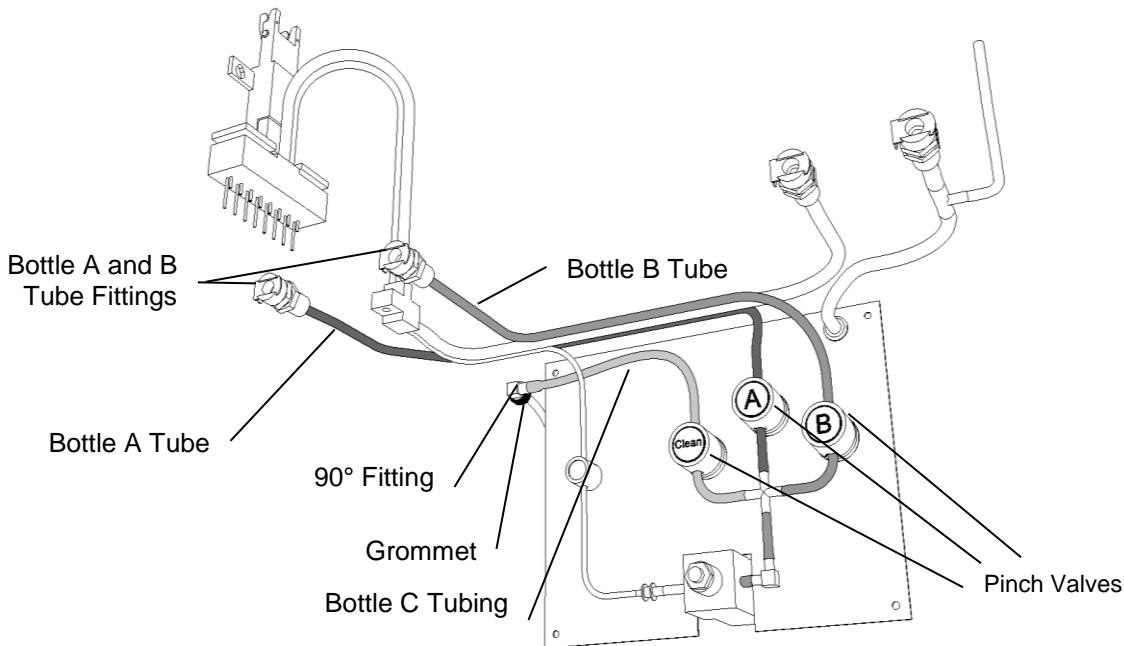


Figure 8-15: Tubing Schematic

11. Insert the replacement tubing for the Pump Valve Assembly in the reverse order of removing the tubing (steps 10 – 14).
12. Lift the Wash Head off its cradle and replace the twin bore tube.
13. Connect the free end of the tube to the Wash Head Manifold. Ensure the Wash Head is oriented as shown below.

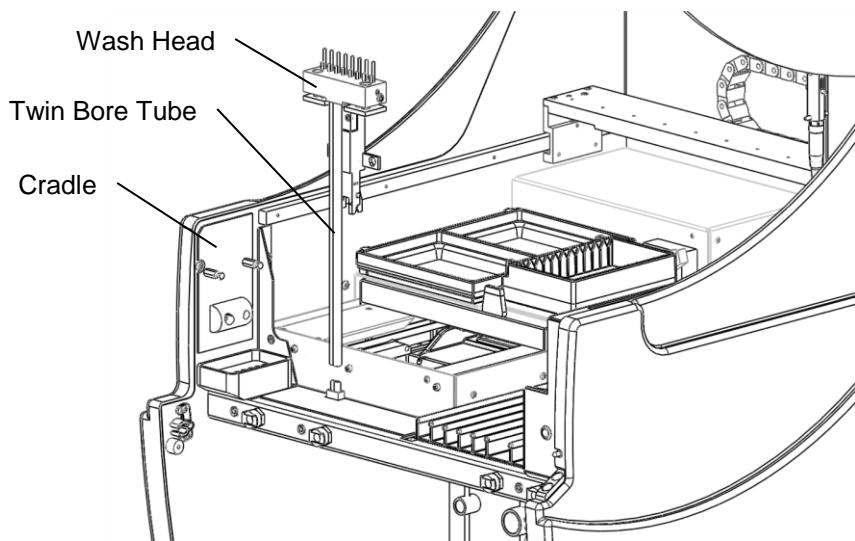


Figure 8-16: Wash Head Fitting

14. Flip the Wash Head over.

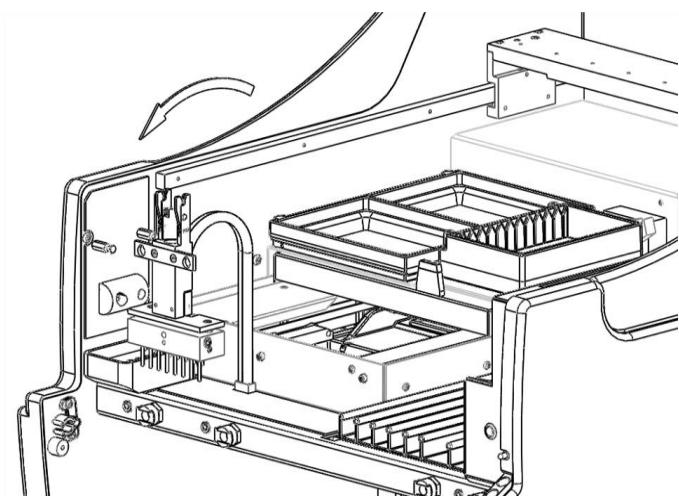


Figure 8-17: Wash Head Fitting

15. Rotate the Wash Head 90 degrees clockwise before locating it onto back onto the cradle. Ensure that the Twin Bore tube is not kinked or twisted in a way that will prevent the flow of fluid to the wash head.

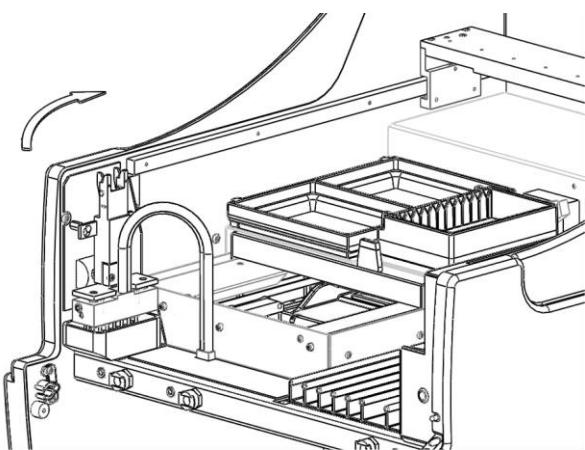


Figure 8-18: Wash Head Fitting

16. Remove and replace the tubing on the two Wash Buffer containers and the Waste container.

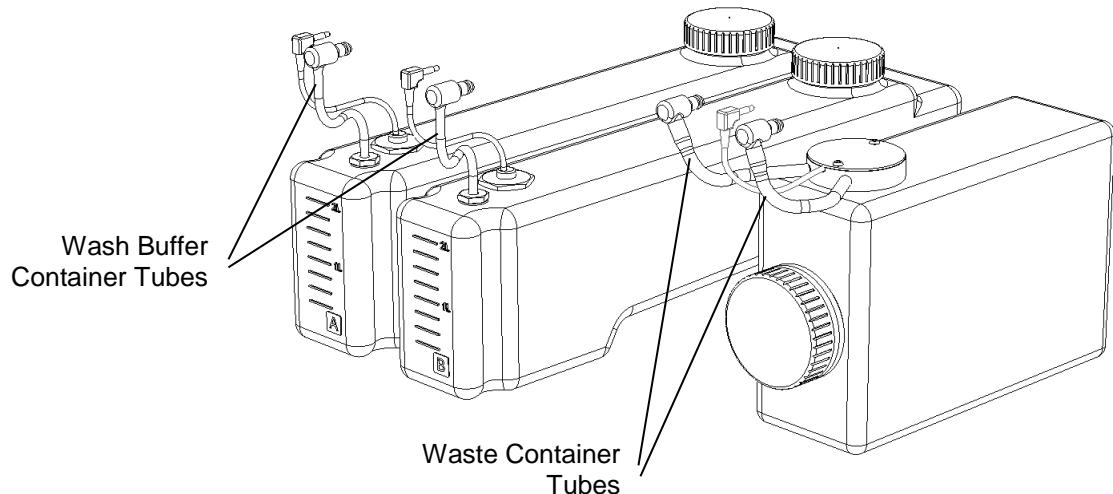


Figure 8-19: Container Tubing

17. Connect the two Wash Buffer Containers and the Waste Container to the DS2. Place the Tip Waste Container in its proper location.

8.6 Cleaning the Wash Head Assembly



Caution: Always disconnect the power before servicing.

To Remove the Wash Head Assembly

1. Grasp the wash head assembly and lift it up from the cradle.
2. Move the wash head assembly and tubing clear of the DS2. If necessary, remove the wash tubing and waste tubing.

To Clean the Wash Head Assembly

1. Pass the Cleaning Wire through the inside of each aspirate pin and dispense pin on the wash head.

► **Note:** There are two sizes of Cleaning Wires. One is for the aspirate pin, and the other is for the dispense pin.

2. If necessary, the wash head may be soaked in disinfectant solution or 70% alcohol.
 - a. Remove the set screws on the sides of the wash head.
 - b. Ensure the wash head is standing upright in a container and fill the disinfectant solution up to the gap on the wash head where the springs are located.
 - c. Soak the wash head for the desired length of time.
 - d. Replace the screws, being careful not to over-tighten the screws as over-tightening may crack the wash head.
 - e. Reconnect the Twin Bore Tubing, ensuring the tubing is not kinked.
 - f. Rinse the wash head thoroughly with deionized water to remove all traces of disinfectant solution. Program the DS2 to perform a wash with water to ensure proper cleaning.

► **Note:** Dynex recommends performing a clean operation with deionized water at the end of every wash operation.

To Replace the Wash Head Assembly

1. Position the wash head assembly back in the cradle.

8.7 Dynex Technologies DS2 Troubleshooting Guide

Symptom	Possible Causes	Resolution
<i>Sample Tip Errors</i>		
Tips are being picked up, but the system is not detecting that a tip was picked up	Tip sensor is dirty Not using Dynex Tips	Clean the tip sensor area (where the red laser is) thoroughly with an alcohol wipe. Ensure in the future that Dynex brand tips are being used.
System is not picking up tips or is dropping tips in transit	Tip pick up location is out of calibration	Calibrate arm, ensuring that the tip used to calibrate the system is put on the instrument as securely as possible.
<i>Wash Head Assembly Errors</i>		
The wash head is not being picked up and/or released successfully.	The pick up location is out of calibration The support posts on the wash head park are not aligned properly Brass clamp may have excess glue.	Calibrate the arm at the wash head pick-up position. If instrument serial number is below 1DSA-0339, see TB149. Check the brass clamp for excess glue. Request a replacement wash head if there is glue.
The wash head is being picked up, but the system does not detect that the wash head was picked up.	Wash head magnet and/or sensor is dirty Wash head sensor is out of calibration	Clean the wash head sensor area (black dot in the metal ring on the pipette) and the magnet on the right side of the wash head with an alcohol wipe. Perform an arm calibration with the wash head detect routine.

Symptom	Possible Causes	Resolution
<i>Plate Washing Errors</i>		
Fluid is left in the plate after washing and aspiration.	The wash head and/or aspiration pins are clogged	Clean the aspiration pins using the cleaning wire. If this does not work, remove the 4 set screws from the sides of the wash head manifold and soak the wash head standing upright in 70% alcohol with liquid filled up to the spring gap in the wash head. Rinse the wash head and run test washes to ensure the problem is resolved.
	The dispense tubing is not in place	Remove the tip waste bucket. The dispense tubing is the thin tubing furthest to the left. Remove the tubing from the pinch valve, roll it and place it back inside the pinch valve.
	The plate definition is incorrect	Open the plate definition for the plate in use. Use the “show” buttons to test that all the plate parameters are programmed correctly, paying particular attention to the aspirate height, the sweep height and the sweep stroke.
	The sweep mode selected may be insufficient.	If no sweep mode is selected in the wash step, try a sweep or super sweep mode for improved aspiration.
	The system is out of calibration	Calibrate the wash positions in the upper and lower plate carrier. Ensure that the aspiration pins are barely touching the bottom of the plate wells, that the pins are centered in the wells, and that the spring gap is not compressed.

Symptom	Possible Causes	Resolution
<i>Plate Washing Errors</i>		
System is not dispensing any fluid during purge and wash	System tubing is sealed in the pinch valve	Remove the tubing from all pinch valves. Roll the tubing and insert it back into the pinch valve.
	Wash buffer bottle quick release valves are not snapped in place	Remove the quick release fitting from the quick release valve. Reinsert the fitting into the valve, ensuring a clicking noise is heard to indicate the fitting is securely connected.
	Pump is not primed or is not functioning properly	Requires a service call.
System is not dispensing wash fluid/dispensing sufficient wash fluid to row "x"	The dispense pin corresponding to row "x" is clogged	Use the cleaning wire to clean all dispense pins.
	There is a clog in the wash head manifold	Remove the four set screws in the wash head manifold and soak the wash head standing straight up in 70% alcohol. Ensure the fluid is only filled to the spring gap. Rinse the wash head thoroughly with water.
Wash buffer is not dispensed to the first few columns during the first wash of the plate	The wash head has not been purged or has not been purged sufficiently.	Ensure all wash steps have a purge programmed. Ensure the purge volume is at least 3000ul.

Symptom	Possible Causes	Resolution
<i>Plate Washing Errors</i>		
Wash fluid is overflowing from the plate	The dispense pins are clogged	Clean the dispense pins with a cleaning wire.
	The aspirate pins are clogged	Clean the aspirate pins with a cleaning wire.
	The wash head manifold is clogged	Remove the 4 set screws from the wash head manifold. Stand the wash assembly straight up and soak it in 70% alcohol or disinfectant. Rinse the wash head, put the screws back in and run a test wash.
	The dispense tubing is not in place or is sealed	Take the dispense tubing out of the pinch valve (far left) and roll it. Insert it back into the pinch valve.
	The plate definition is incorrect	Review the plate definition and ensure all the wash settings are correct (especially aspirate height)
<i>Pipetting and Liquid Level Detection Errors</i>		
System is blowing bubbles in the sample prior and may or may not receive a clot detection error	The tube in the system configuration does not match the sample tube in use	If you are using nesting cups or 100mm tubes where the fluid is above 75mm in height, ensure you have defined a 100mm tube to use with these samples.
	The sample tube positions are not in calibration	Perform an arm calibration on the sample tube positions.
System is not pipetting controls correctly	There are bubbles in the control tube	Double check control tubes as large bubbles may form across the tube diameter and interfere with the liquid level sensing mechanism.
	System control tube locations are out of calibration	Calibrate the control tube locations using the arm calibration software (DS2 Tool box)

Symptom	Possible Causes	Resolution
<i>Pipetting and Liquid Level Detection Errors</i>		
System is not pipetting reagents correctly	An incorrect tube is being used.	If a small reagent tube is being used in place of a large reagent tube, the system could aspirate insufficient fluid or air. Make sure the customer is loading the bottle type requested by the system.
	Too many bubbles in the reagent	Large bubbles will be detected during liquid level sensing. Ensure fluids have no bubbles when loading.
	System reagent tube locations are out of calibration	Calibrate the reagent tube locations using the arm calibration software (DS2 Tool box).
<i>Reader Errors</i>		
Prior to reading the plate, an error appears stating that the system failed the sanity check	The filter wheel or lamp is dusty	Remove the cover from the filter wheel and blow compressed air into the reader optics area.
	The 405nm filter is dirty	Remove the 405 filter and clean it with lens paper. Reinsert the filter into location 1 in the filter wheel.
	The 405nm filter is degraded	Request a replacement 405nm filter.
	The lamp is misaligned or the reader is not functioning properly	Requires a service call.
Prior to reading the plate, you receive a “Channel Variation Error”	Fluid has spilled on the reader optics or the reader optics are dirty.	Power down the DS2 and clean the upper and lower reader optics located underneath the sample tip locations. Allow the optics to dry, turn on the DS2 and the software. Ensure the system self test and a read only assay perform with no errors.

Symptom	Possible Causes	Resolution
<i>Reader Errors</i>		
The system fails self-test at the reader module.	The filter wheel or lamp is dusty	Remove the cover from the filter wheel and blow compressed air into the reader optics area.
	The 405nm filter is dirty	Remove the 405nm filter and clean it with lens paper. Reinsert the filter into location 1 in the filter wheel.
	The 405nm filter is degraded	Replace the 405nm filter
	The filters are inserted improperly	Check that the filters are securely held in place
	The lamp is burned out	Look at the back of the instrument during the self test. You should be able to see light coming from the filter wheel area. If you do not see any light, the bulb is burned out. Replacement requires a service call.
	The lamp is misaligned or the reader is not functioning	Requires a service call.
<i>Vacuum Sensor Errors</i>		
The system gives a vacuum sensor error during self-test or prior to washing a plate	Waste bottle cap is not on tight enough	Make sure the cap is tight, without over tightening.
	Waste bottle cap is cracked or broken	Inspect the waste bottle cap for cracks. Replace the cap if you notice damage.
	Faulty Vacuum pump or holes/cracks in the system tubing.	Requires a service call.
<i>Plate Carrier Errors</i>		
The plate carrier has become stuck inside the DS2.	The plate was not inserted into the plate carrier properly.	Remove the 3 screws holding the metal panel on the left side of the pipetting area. Carefully use the belts underneath the metal panel to pull the plate carrier out.
	The plate strips were not pressed all the way down in the plate frame.	

Symptom	Possible Causes	Resolution
Assay and Database Errors The assay has the same error message at the same point in the assay every time it is run.	The assay file or the database has become corrupted.	Restore an old database Export the assay files and any report files you would like to keep and then create a new database. Re-import desired assays and data files. Rewrite the assay.

8.8 Limited Warranty

8.8.1 Warranty and Special Provisions

DYNEX TECHNOLOGIES products are fully guaranteed for one year against defects in parts, materials, and workmanship. Defective parts and materials will be replaced or, at the discretion of DYNEX TECHNOLOGIES, repaired at no charge for a period of one year and labor required for such replacement or repair will be provided at no charge for a period of one year, provided that the products are utilized and maintained in accordance with the instructions in the applicable operating and servicing manual, and provided further that the products have not, as determined solely by DYNEX TECHNOLOGIES, been subject to misuse or abuse by the Customer or other parties unrelated to DYNEX TECHNOLOGIES. DYNEX TECHNOLOGIES makes no warranty, expressed or implied, as to the fitness of any product for any particular purposes other than those purposes described in the applicable operating and servicing manual, nor does DYNEX TECHNOLOGIES make any other warranty, whether expressed or implied, including merchantability, other than those appearing on the face hereof. Where DYNEX TECHNOLOGIES guarantees any product, whether under this Warranty or as a matter of law, and there is a breach of such guarantee, the Customer's only and exclusive remedy shall be the replacement or repair of defective parts and materials, as described above. This shall be the limit of DYNEX TECHNOLOGIES liability.

Furthermore, DYNEX TECHNOLOGIES shall not be liable for incidental or consequential damages. Failure of the Customer to notify DYNEX TECHNOLOGIES of a claimed defect by registered mail within thirty days of the discovery thereof shall constitute a waiver of any claim for breach of warranty.

When a product is required by DYNEX TECHNOLOGIES to be installed by a DYNEX TECHNOLOGIES engineer or technician, the period of this Warranty shall begin on the date of such installation, provided, however, that any use of the product prior to such installation shall, at the sole election of DYNEX TECHNOLOGIES, void this Warranty. When installation by DYNEX TECHNOLOGIES personnel is not required, the period of this Warranty shall begin on the date of shipment from DYNEX TECHNOLOGIES. The period of this Warranty shall begin as described above whether or not the product has been installed or shipped pursuant to a purchase order, and any trial period shall be deducted from the Warranty period that would otherwise apply under a subsequent placed purchase order for that product.

Limitation of Liability. Notwithstanding anything to the contrary contained herein, the liability of SELLER (whether by reason of breach of warranty, breach of contract, tort, or otherwise), including without limitation under any indemnification provision contained herein, shall be limited to replacement of goods returned to DYNEX TECHNOLOGIES which are shown to DYNEX TECHNOLOGIES reasonable satisfaction to have been nonconforming or to refund the purchase price, or, if not paid, to a credit amount of the purchase price therefore.

THE FOREGOING WARRANTIES ARE EXCLUSIVE AND ARE GIVEN AND ACCEPTED IN LIEU OF ANY AND ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, THE IMPLIED WARRANTY OF MERCHANTABILITY AND THE IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY INCIDENTAL, INDIRECT, SPECIAL, OR CONSEQUENTIAL DAMAGES.

8.9 DYNEX Technologies Contact Information

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In North America, for service and service contract options by factory certified Dynex field service engineers please contact Dynex at **703-361-7800** or **1-800-288-2354** option #4 or email Dynex at techservice@dynextechnologies.com. For service outside North America please contact your Dynex distributor.

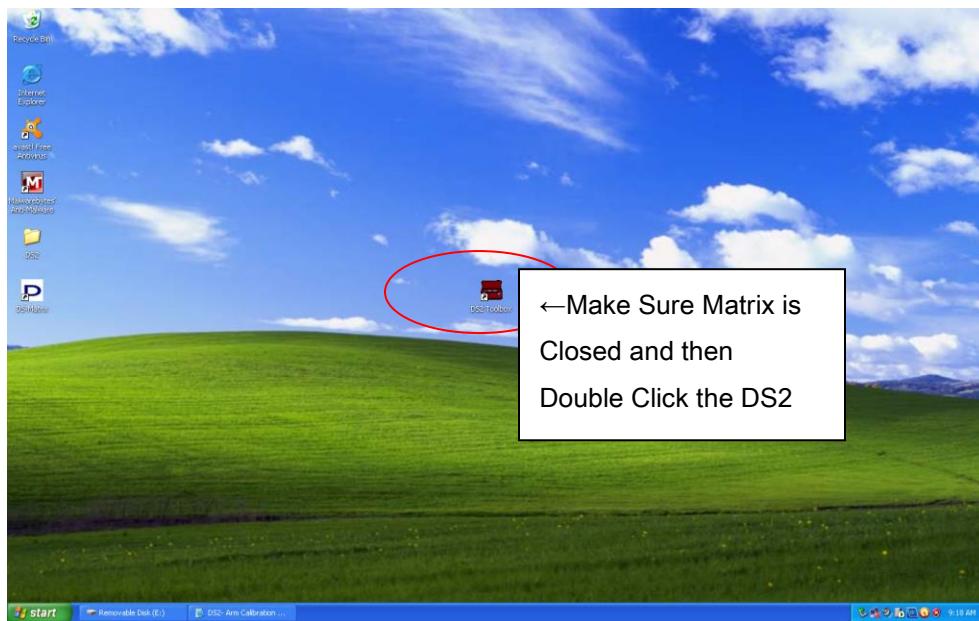
Only Dynex Certified Consumables are specifically designed and produced for Dynex instruments, ensuring proper fit with superior accuracy, performance and continued warranty of Dynex instrument(s). Please visit www.dynextechnologies.com, or contact us in the US at **703-361-7800** or toll free **1-800-288-2354**, option #3.

Appendix A Arm Calibration

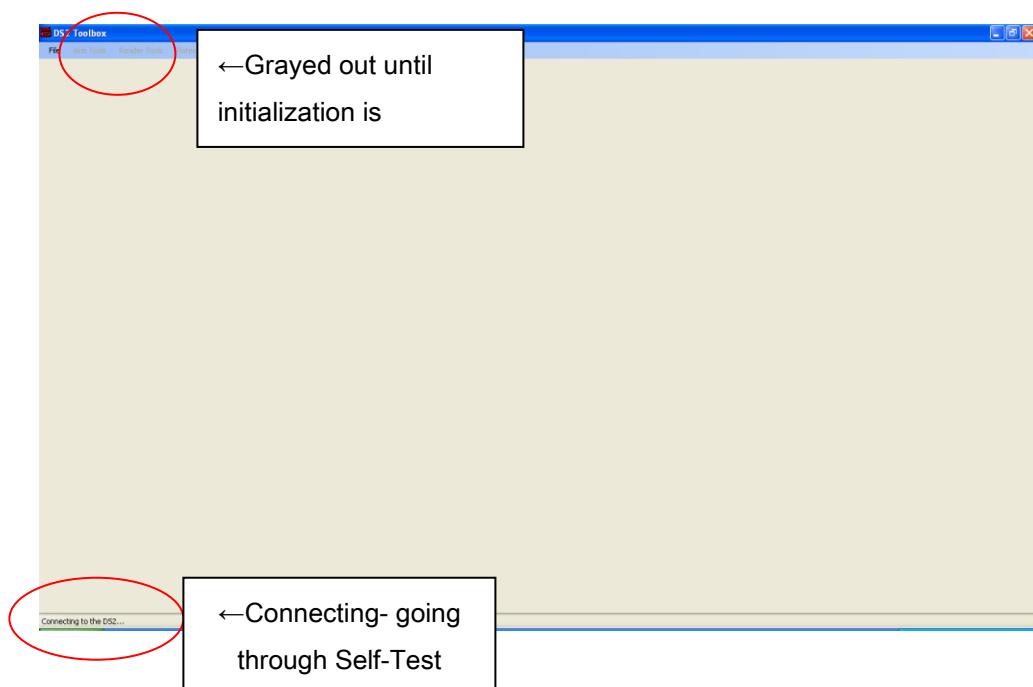
The Arm Calibration Tool is only available if the DS2 Toolbox plug-in software has been installed. Arm Calibration should only be performed by a trained technician.

Prior to begining the arm calibration, please read through the precautions below:

1. Please read all message boxes carefully and perform required actions when prompted.
2. If you are using a Windows language version other than United States English, please note that the decimal separator must be set to “decimal” and not “comma”.
3. When moving the pipette, make sure to grasp the metal pipette spigot, do not use the tubing coming out of the pipette to move the pipette or you will risk damage to the pipette module.

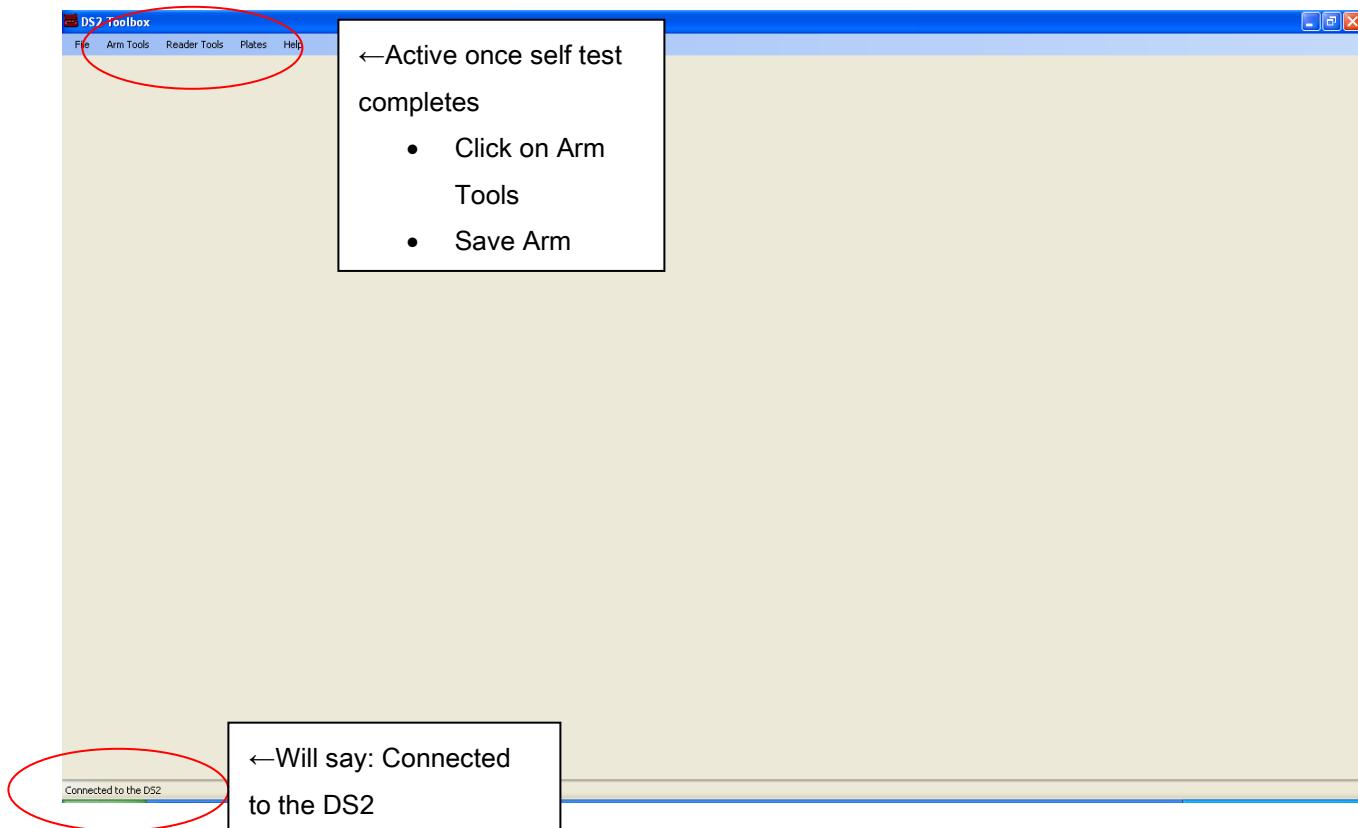


Appendix A Arm Calibration



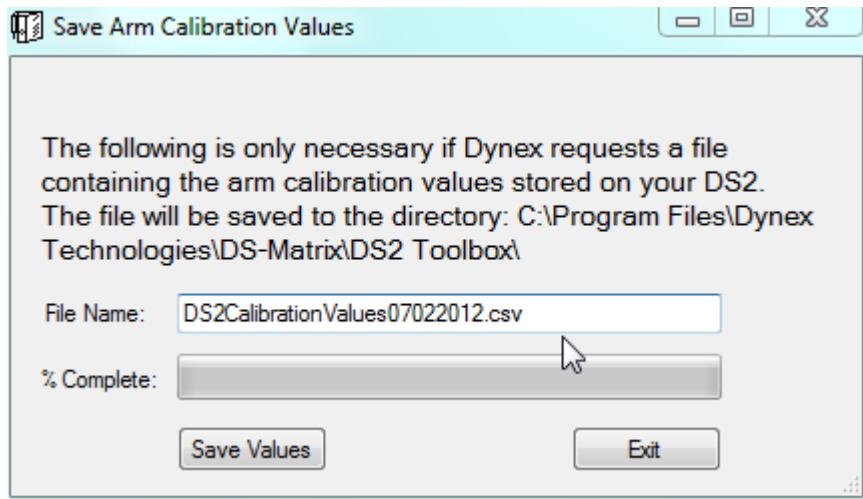
←Connecting- going through Self-Test

Once the DS2 is successfully connected to the arm calibration software, begin by saving the arm calibration values out to a file.



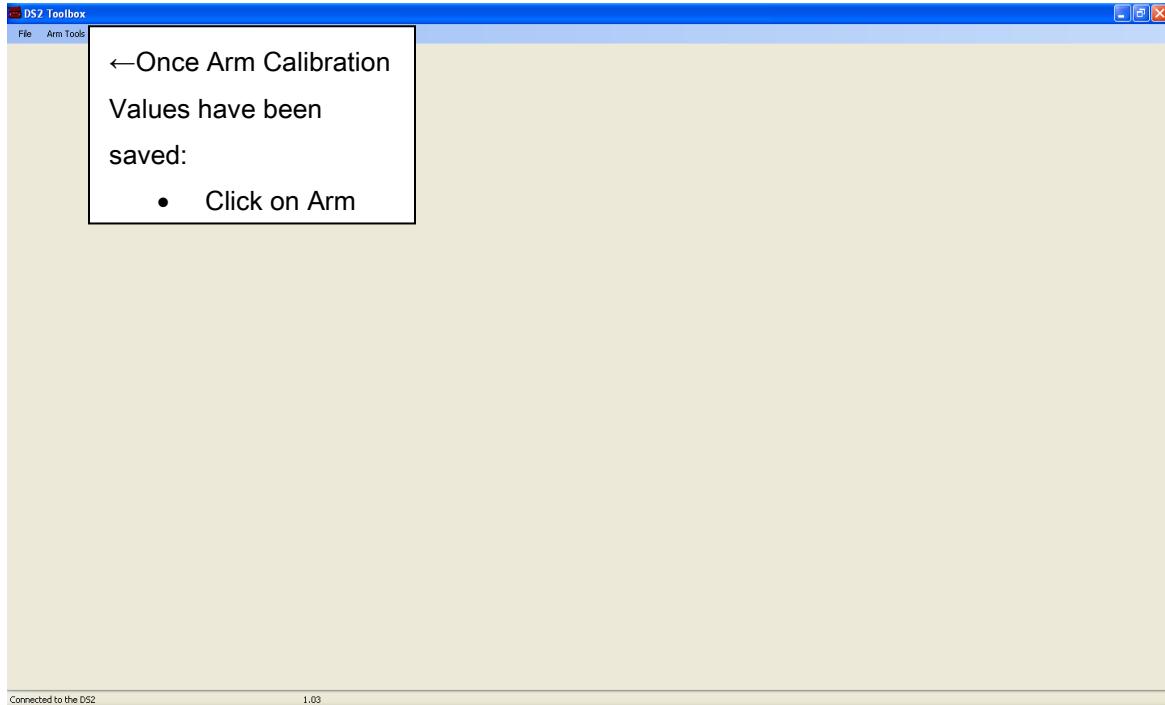
←Will say: Connected to the DS2

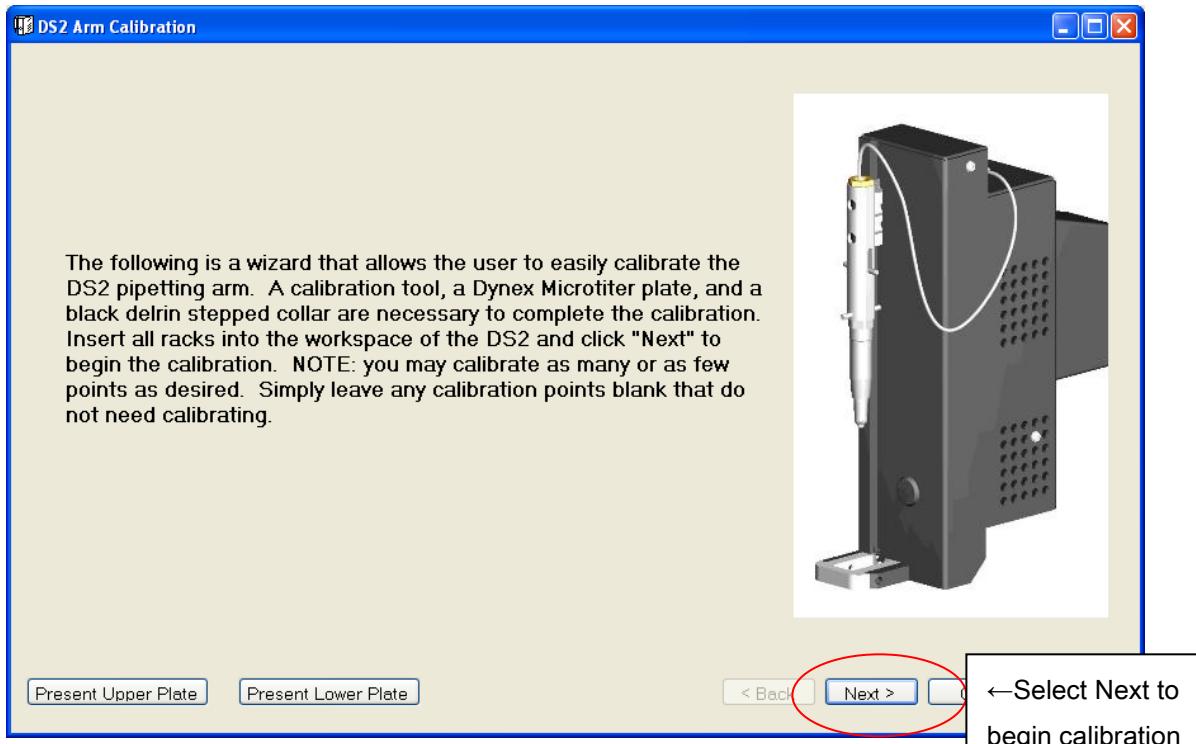
The Save Arm Calibration Values window will appear. The default file name will be "DS2CalibrationValues". Make sure to append this file name with the date (see below) so that the file is easily identifiable and will not overwrite. If you are saving the values multiple times in one day, make sure to append with the date and a unique identifier (a, b, etc).



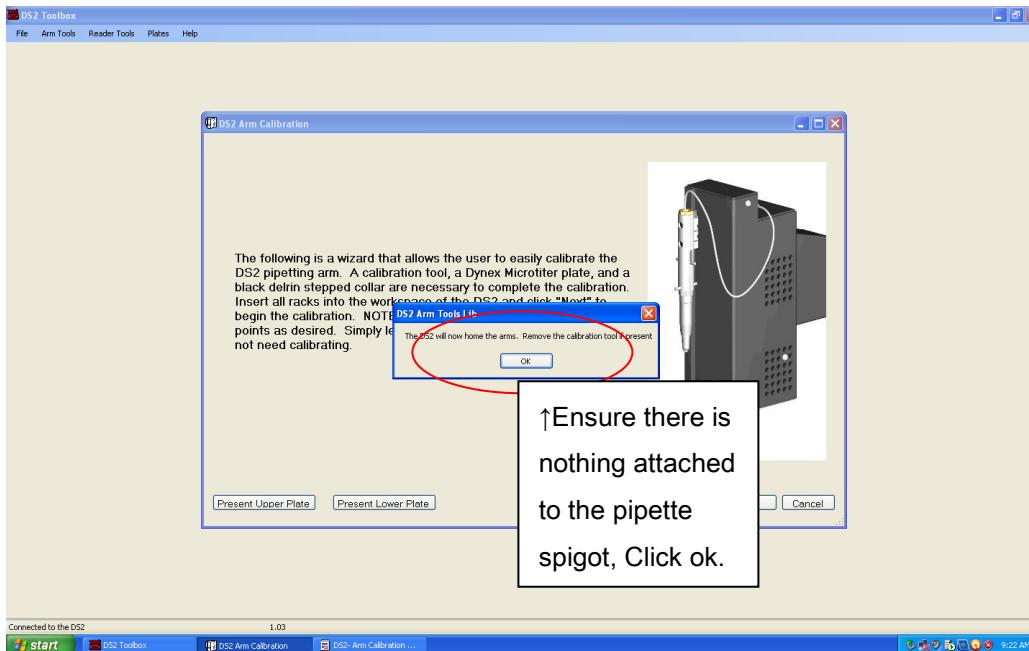
Click Save Values. Once the arm calibration values are saved, click Exit. A file with the values is now saved to C:\Program Files\Dynex Technologies\DS-Matrix\DS2 Toolbox.

Once the values have been saved, begin the Arm Calibration procedure.





Only calibrate positions requiring calibration. It is not necessary to calibrate positions which do not require calibration.

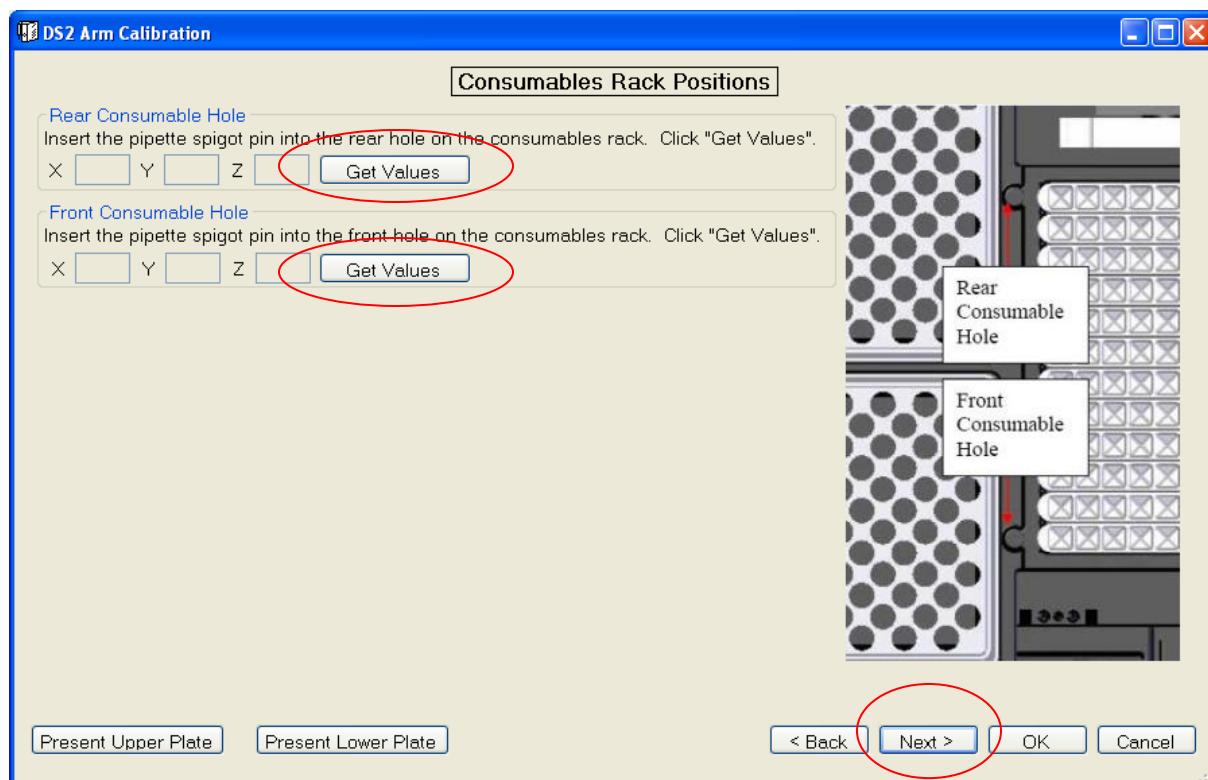


This calibration position is for the **deep well rack positions**.

Calibrate this position if you suspect there are issues pipetting from the deep wells (tip is not centered, pipette does not seem to be finding fluid level accurately), or the incubator door is not completely opening or closing. Calibrating this position calibrates several positions on the instrument platform.

If this position does not require calibration, click **Next**.

To calibrate this position, follow the instructions on the screen and click **Get Values** for each of the two calibration positions. Once the X, Y, and Z values for both positions are populated with values, click **Next** to calibrate other positions or **OK** to finish the calibration.

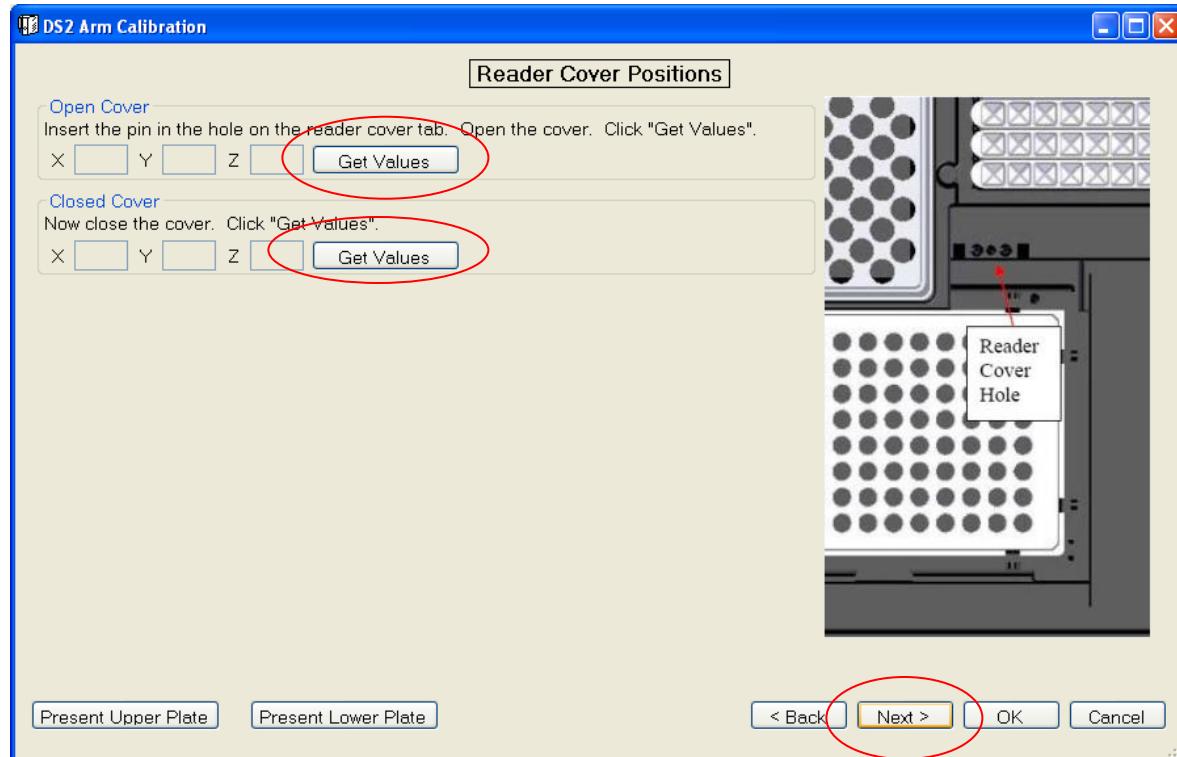


This calibration position is for the **reader cover positions**.

Calibrate this position if the reader cover is not being opened or closed properly.

If this position does not require calibration, click **Next**.

To calibrate this position, follow the instructions on the screen and click **Get Values** for each of the two calibration positions. Once the X, Y, and Z values for both positions are populated with values, click **Next** to calibrate another position or click **OK** to finish calibration and save the values to the DS2.



This calibration position is for the **sample tip (blue tip) pick up positions**.

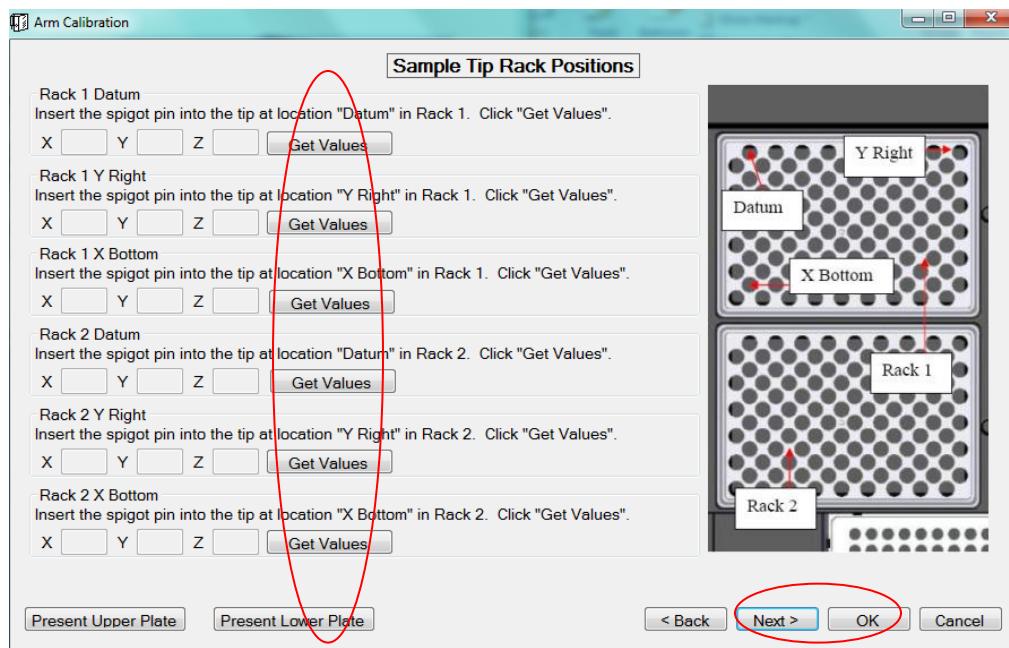
Calibrate this position if the sample tips are not being picked up (spigot is banging between tips), if tips are falling off in transit, or if pipetting issues are suspected.

If this position does not require calibration, click **next**.

Technical Tips:

1. The pipette tip must be put on very, very, *tightly* when performing this calibration. *Failure to put the tip on tightly will result in incorrect calibration and could result in improper pipetting and tips falling off in transit.* I recommend leaving the tip in the rack, bringing the spigot over to the tip rack and using a method similar to when manually pipetting to get the tip on the spigot. Push the spigot into the tip until it cannot go further, then lift the tip up and bring it down firmly in the rack several times to ensure the tip is firmly attached to the spigot. When the tip is on properly it is difficult to remove. Leave the same tip on for all six calibration points.
2. Please note: The X bottom position is not the corner hole, but diagonal from the corner hole.
3. Make sure that the tip containers are placed securely and properly on the deck, otherwise calibration will be affected.

To calibrate this position, make sure there is a tip on the spigot (see technical tips above), remove the tips from the 3 positions in rack one and the three positions in rack 2, leaving them empty so the calibration can be performed with the tip already on the spigot. Follow the instructions on the screen and click **Get Values** for each of the three calibration positions in rack one and each of the three calibration positions in rack 2. Once the X, Y, and Z values for all 6 positions are populated with values, click **Next** to calibrate another position or click **OK** to finish the calibration.



This calibration position is for the **reagent tip pick up positions**.

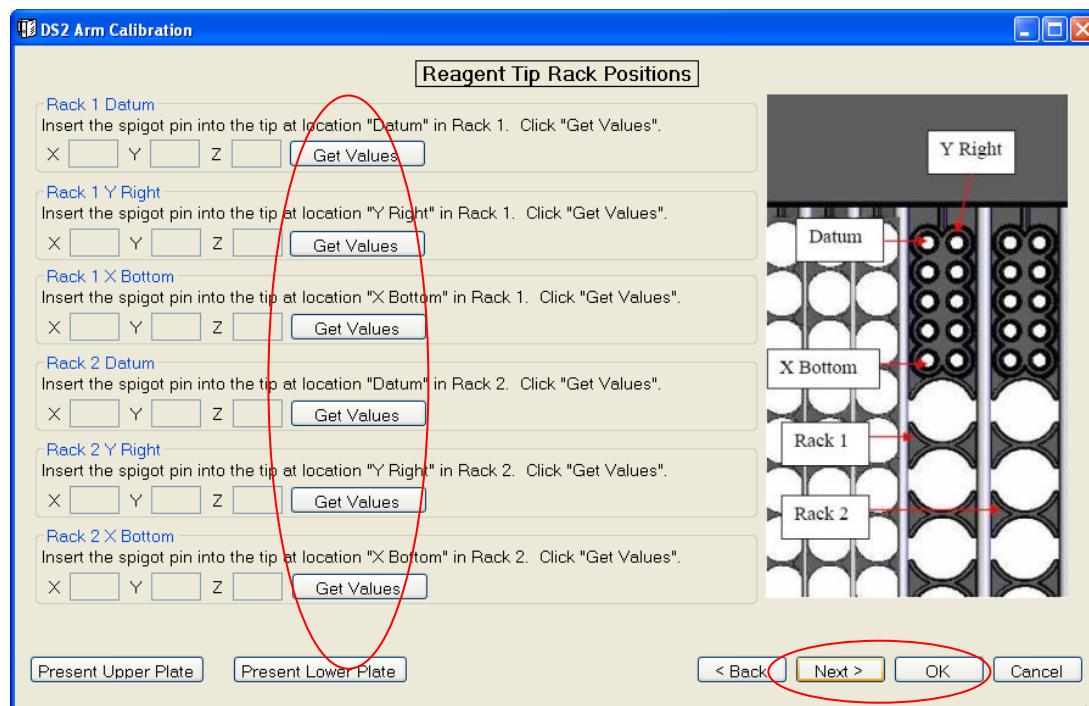
Calibrate this position if the reagent tips are not being picked up (spigot is banging between tips), if tips are falling off in transit, or if pipetting issues are suspected.

If this position does not require calibration, click **Next**.

Technical Tips:

1. The pipette tip must be put on *very, very, tightly* when performing this calibration. *Failure to put the tip on tightly will result in incorrect calibration and could result in improper pipetting and tips falling off in transit.* I recommend leaving the tip in the rack, bringing the spigot over to the tip rack and using a method similar to when manually pipetting to get the tip on the spigot. Push the spigot into the tip until it cannot go further, then lift the tip up and bring it down firmly in the rack several times to ensure the tip is firmly attached to the spigot. When the tip is on properly it is difficult to remove. Leave the same tip on for all six calibration points.
2. Make sure both of the reagent racks are pushed in all the way and that the rack does not tilt to the left or right when inserting the spigot/tip. If the racks are not properly positioned, the calibration points will be incorrect.

To calibrate this position, make sure there is a tip on the spigot (see technical tips above), remove the tips from the 3 positions in rack one and the three positions in rack 2, leaving them empty so the calibration can be performed with the tip already on the spigot. Follow the instructions on the screen and click **Get Values** for each of the three calibration positions in rack one and each of the three calibration positions in rack 2. Once the X, Y, and Z values for all 6 positions are populated with values, click **Next** to calibrate another position or click **OK** to finish the calibration.



This calibration position is for the **barcode scanner position**.

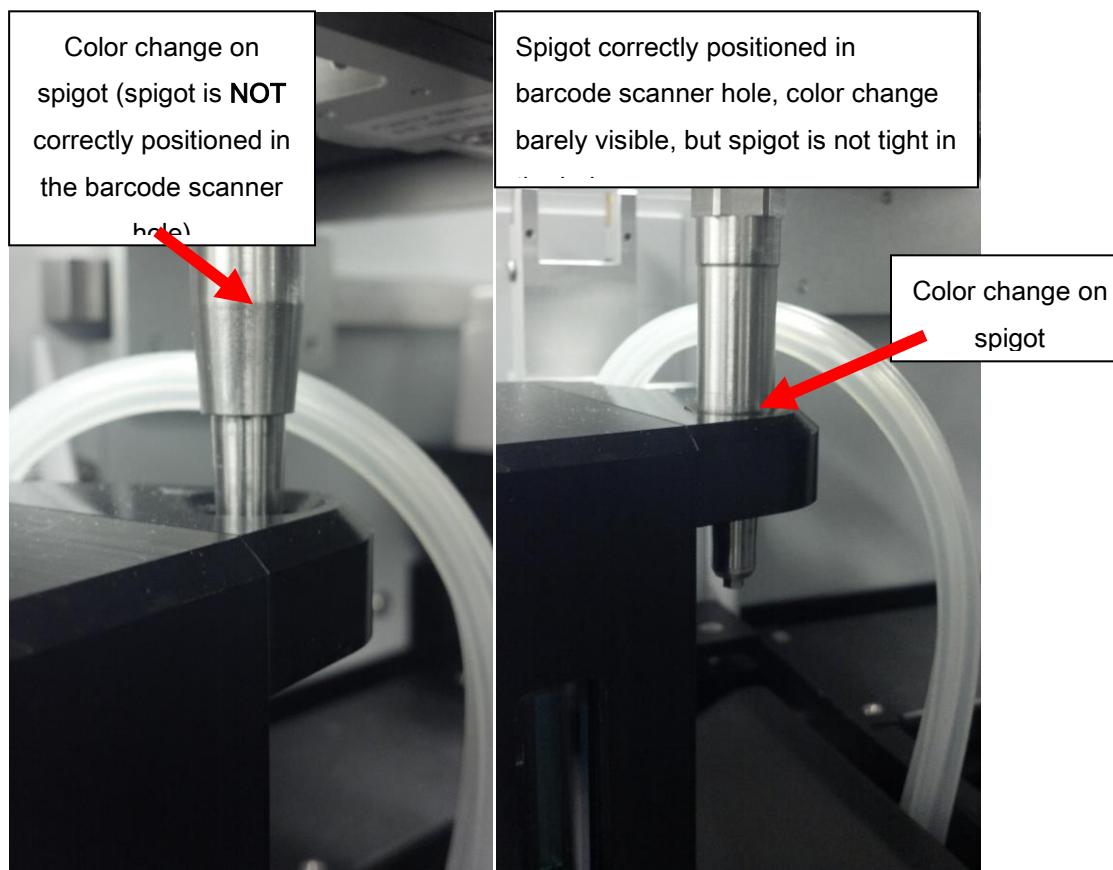
Calibrate this position if barcode scanner is working (there is a red light), but it not reading barcodes or if the barcode scanner is not clicking back into place once barcode scanning is complete, or if the spigot is not engaging the barcode scanner to scan barcodes.

If this position does not require calibration, click **Next**.

Technical Tips:

1. Make sure the barcode scanner is all the way over to the left of the instrument and you can hear it “click” into place. If the scanner is not clicked in all the way to the left, it will not be positioned properly for the calibration and the calibration points will be incorrect.
2. Do not push the spigot so far down in the spigot hole that it is difficult to remove. See below for pictures that show the correct positioning of the spigot for this calibration.

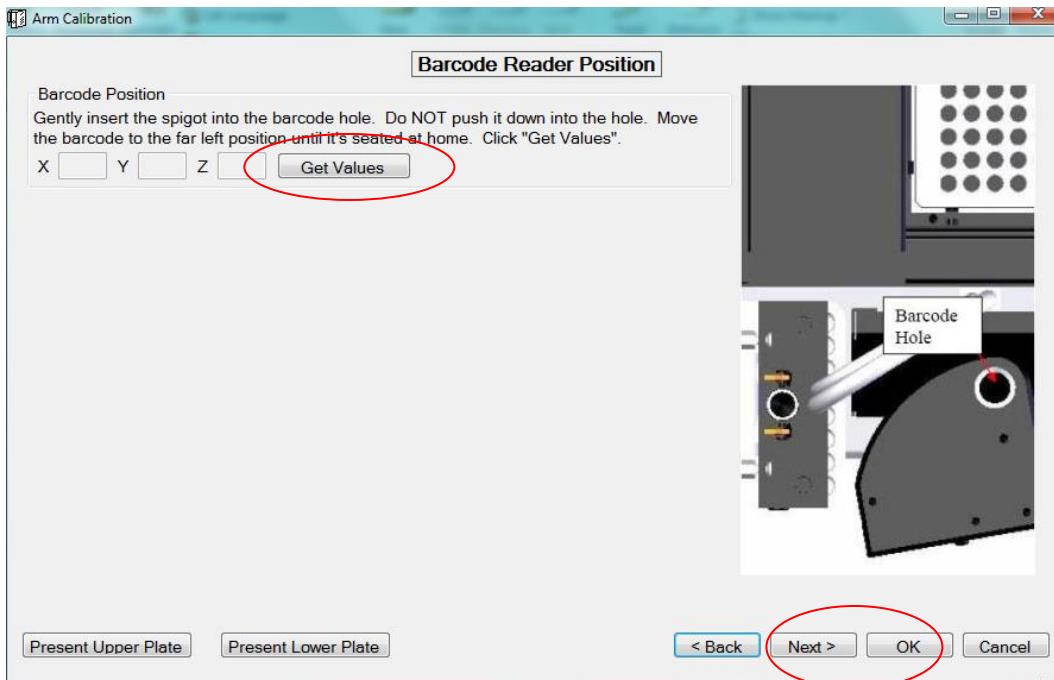
To calibrate this position, make sure the barcode scanner is in the correct starting position (see technical tips above). Look at the spigot and note that there is a *slight* color change in the metal; this is also where the spigot begins to taper from straight to angled (picture 1). Insert the spigot in the hole on the barcode scanner until you can barely see where the color change takes place (picture 2). The spigot should not be tight in the hole. Alternatively, if you have difficulties seeing the color change on the spigot, insert the spigot into the barcode scanner hole all the way and then lift up 1-2mm. Again, the spigot should not be tight in the hole.



Picture 1

Picture 2

Once the spigot is correctly positioned correctly in the barcode hole, click **Get Values**. Once the X, Y, and Z are populated with values, click **Next** to calibrate another position or click **OK** to finish the calibration.



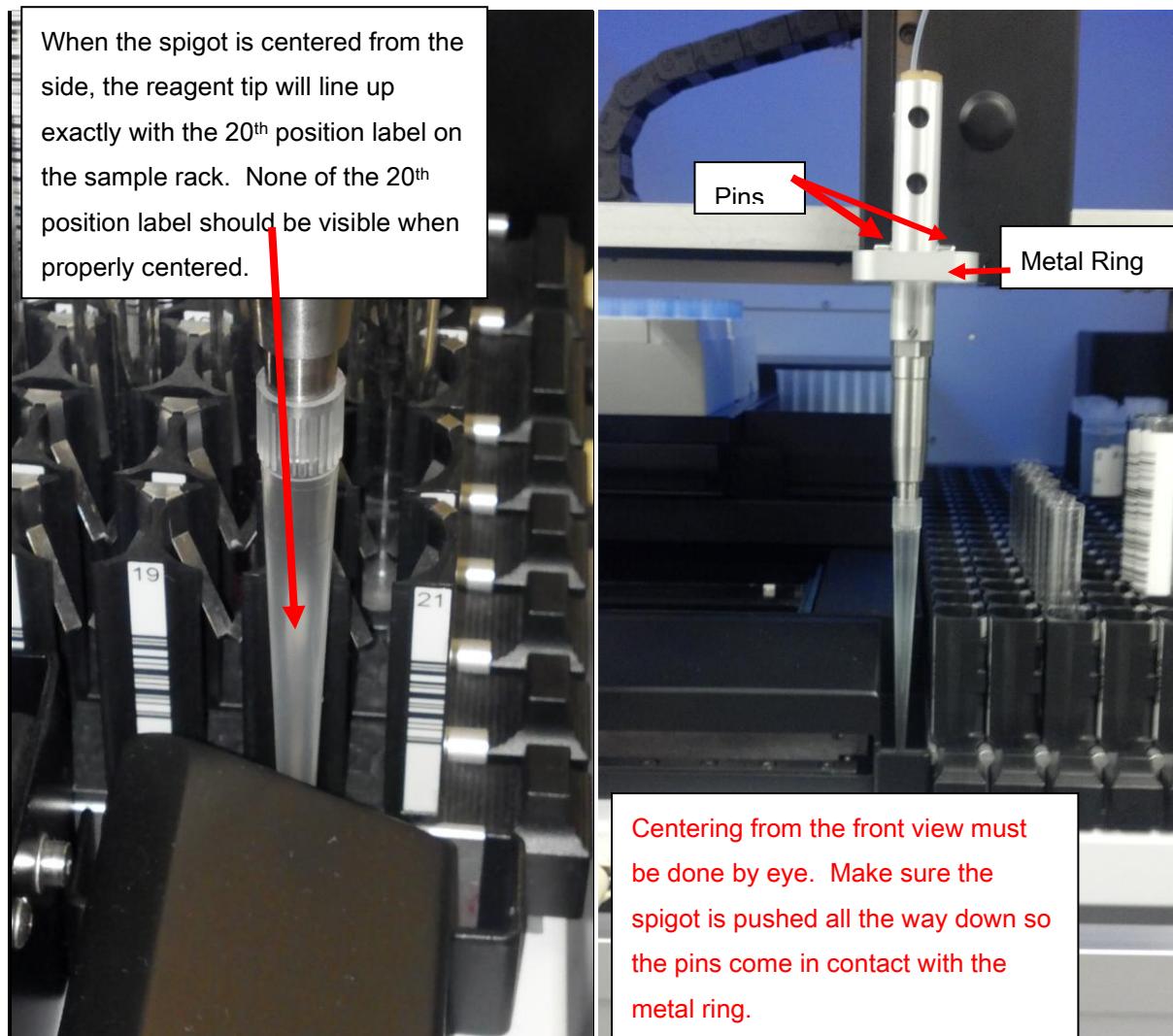
This calibration position is for the **tip eject position**.

Calibrate this position if the tips are not being ejected off the spigot, or if the tips are banging into the instrument deck instead of being ejected.

If this position does not require calibration, click **next**.

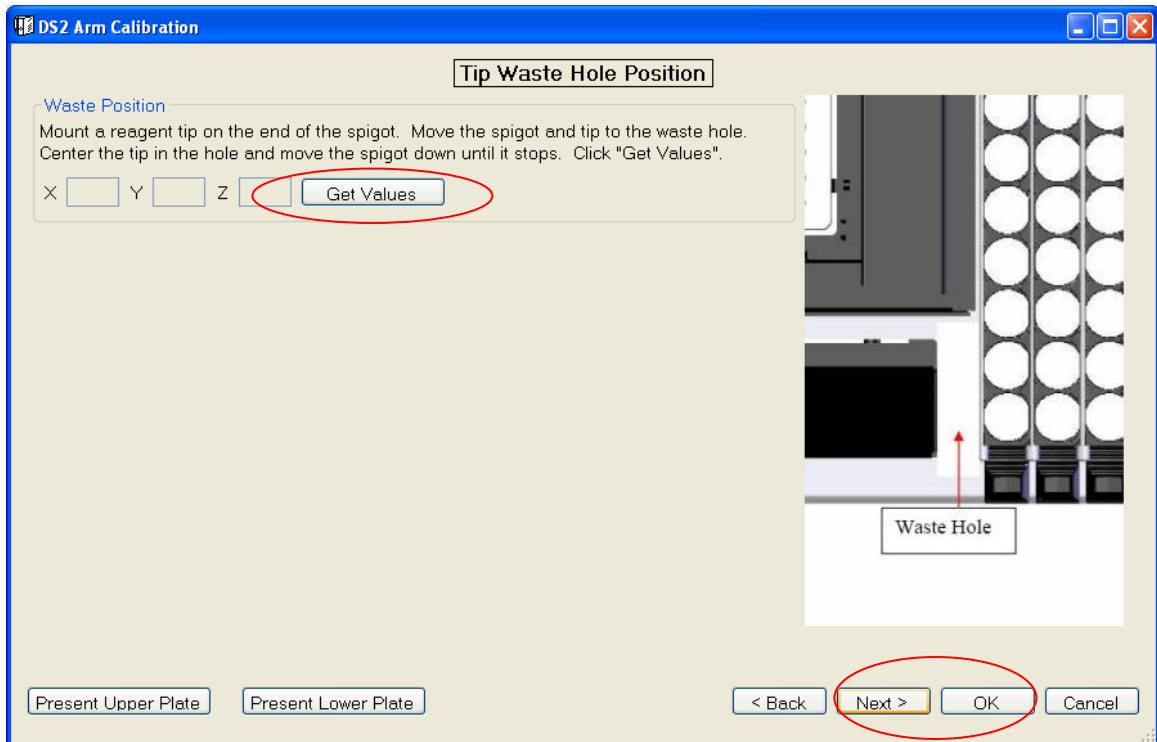
Technical Tips:

1. For this position, a reagent tip is placed on the spigot to help with correct positioning only. It does not need to be on tightly.
2. Make sure to center the spigot from both the front and the side of the instrument, also ensuring the spigot is pushed down until it stops.



To calibrate this position, follow the instructions on the screen and the technical tips above and click **Get Values**. Once the X, Y, and Z are populated with values, click **Next**.

Appendix A Arm Calibration



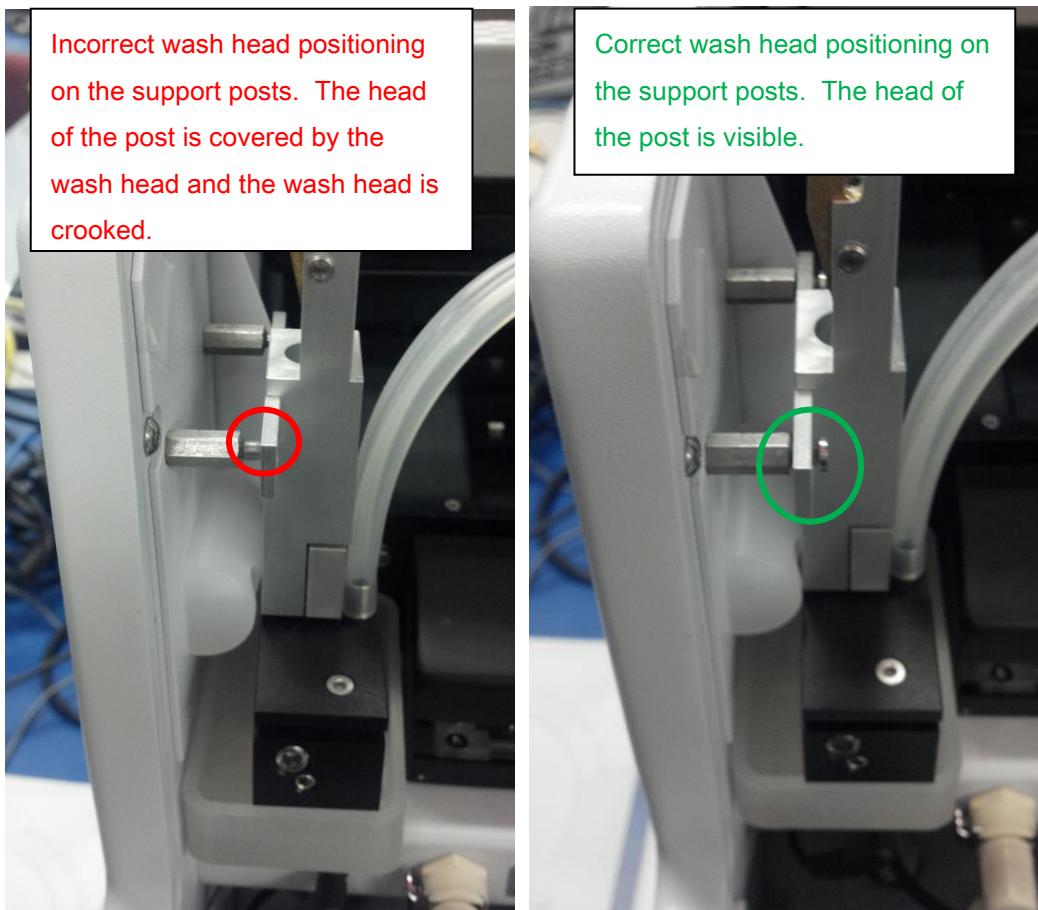
This calibration position is for the **wash head pick up position**.

Calibrate this position if the wash head is not being picked up successfully, or is not being released successfully.

If this position does not require calibration, click **next**.

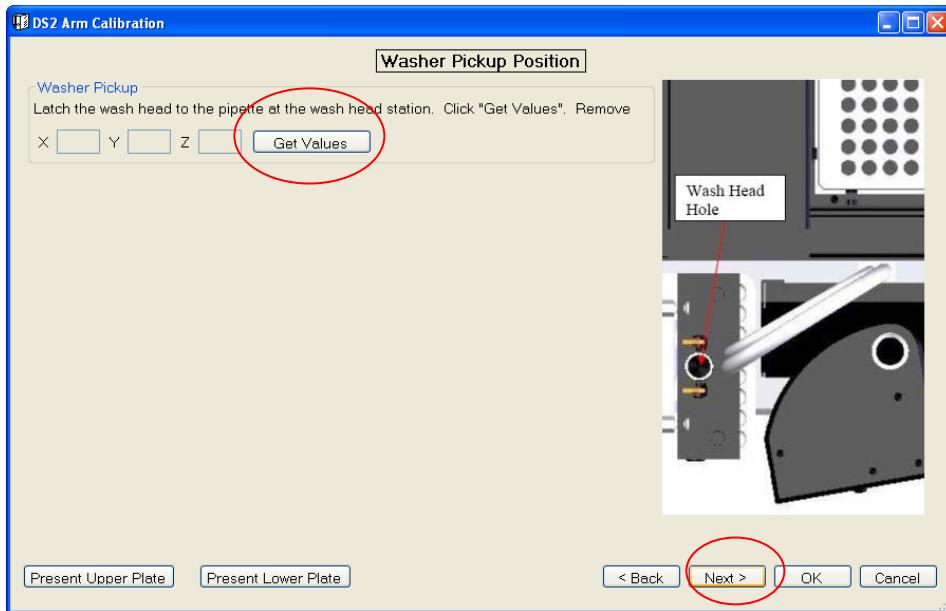
Technical Tips:

1. Make sure the wash head is positioned correctly on the support posts prior to calibrating this position. Incorrect positioning of the wash head will cause incorrect calibration.

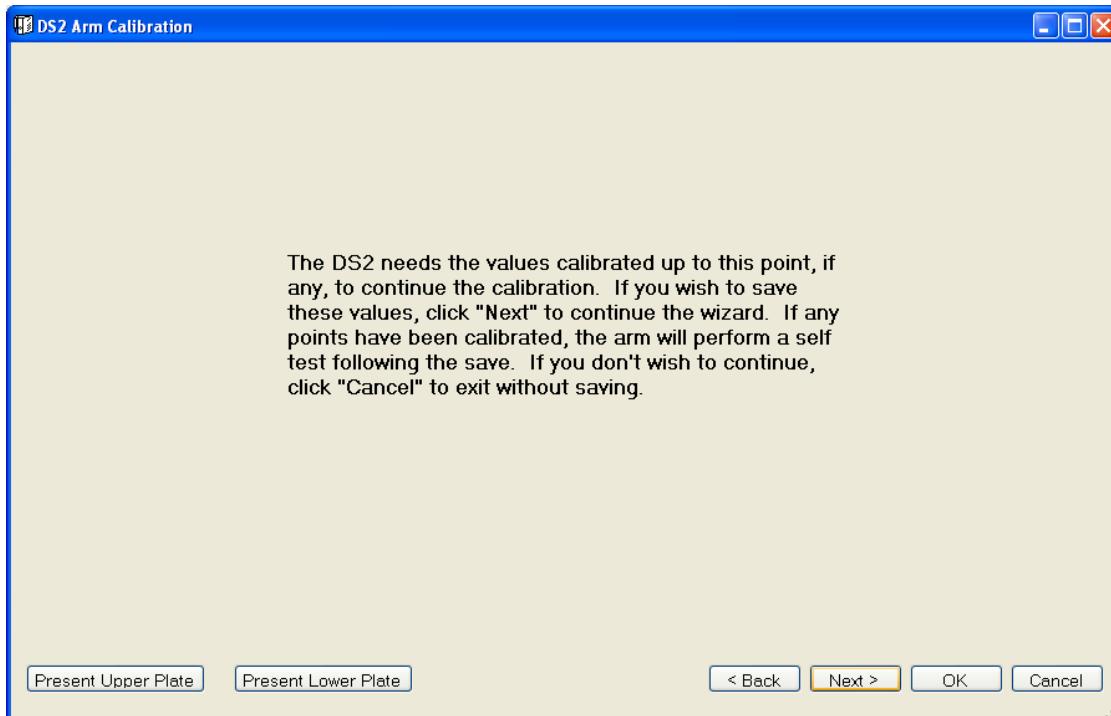


To calibrate this position, make sure the wash head is seated correctly (see technical tips above), follow the instructions on the screen and click **Get Values**. Once the X, Y, and Z values for all 6 positions are populated with values, click **Next**.

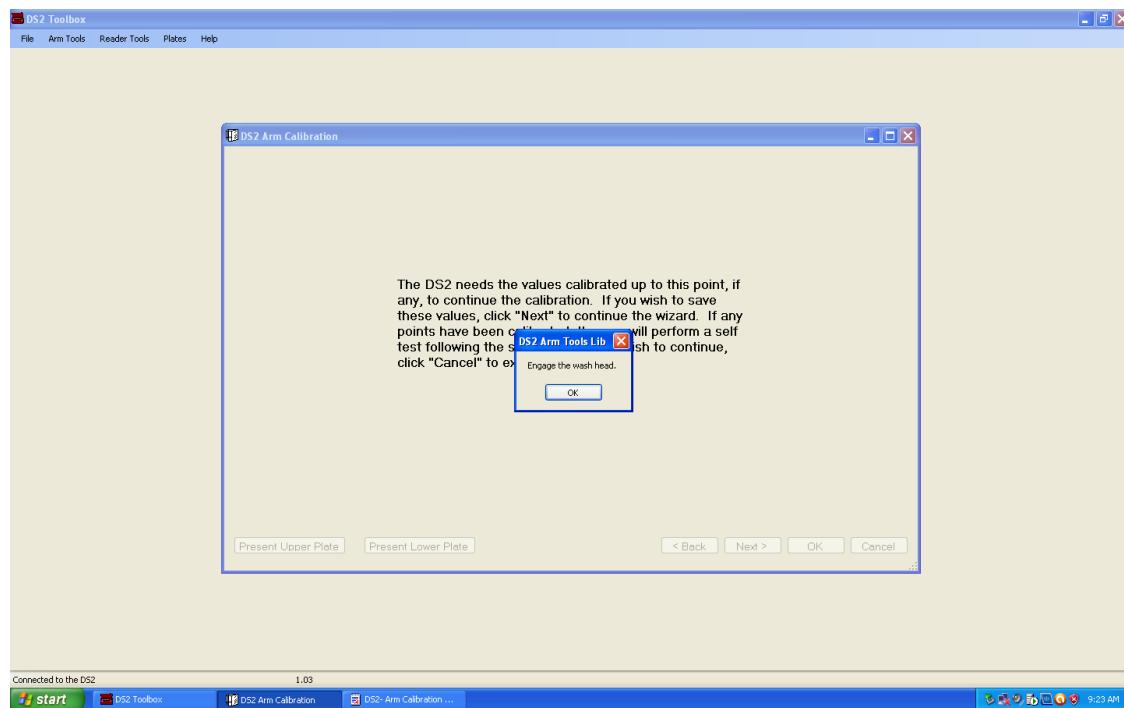
Appendix A Arm Calibration



When this screen appears, the DS2 is halfway through the calibration wizard. To save any new calibration points, or to continue the wizard to the desired calibration screen, click next.



Engage the wash head when instructed to do so, then click ok.



This calibration position is for the **wash head pin positions in the plate**.

Calibrate this position if the wash head pins are not centered, if the wash head is scratching the bottom of the plate during aspiration, if wash solution is dispensing outside of the plate, if incomplete aspiration is occurring, or if results indicate a washing issue.

If this position does not require calibration, click **next**.

Technical Tips:

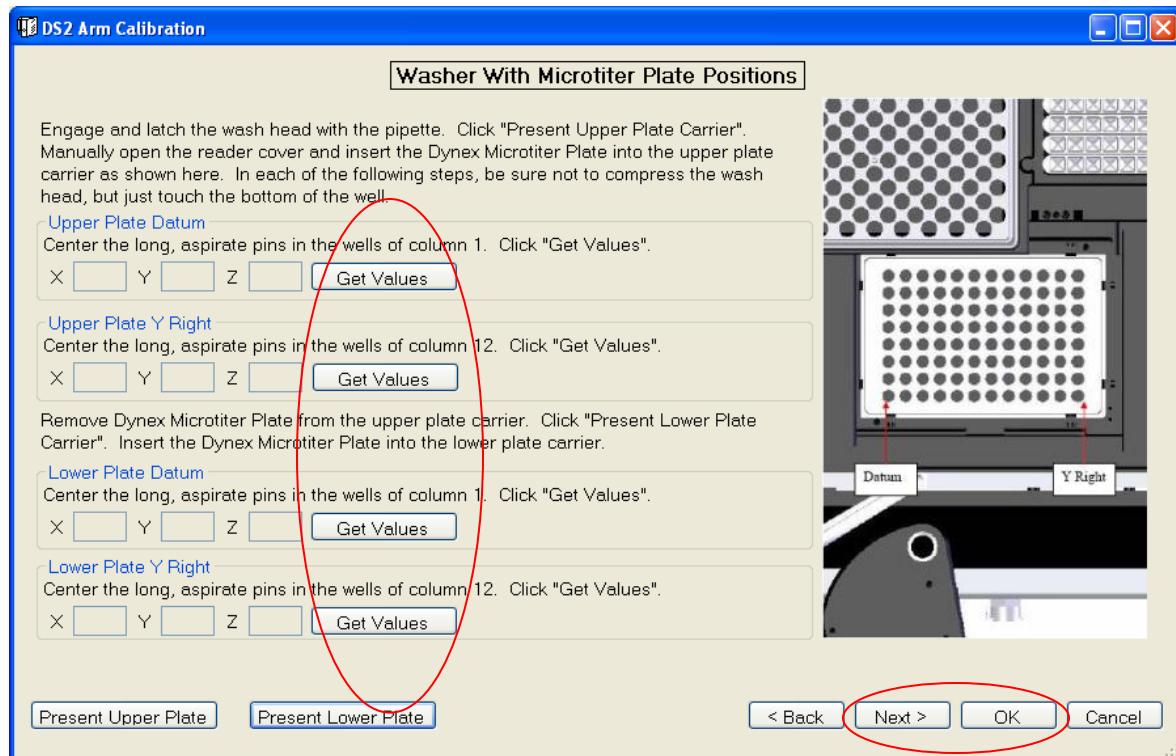
1. The spring gap must be kept open when calibrating the wash head positions in the plate. Put sample tips in the spring gap to keep the gap from closing. This will allow the aspiration pins to come in contact with the plate bottom, without compressing the spring. See picture below.



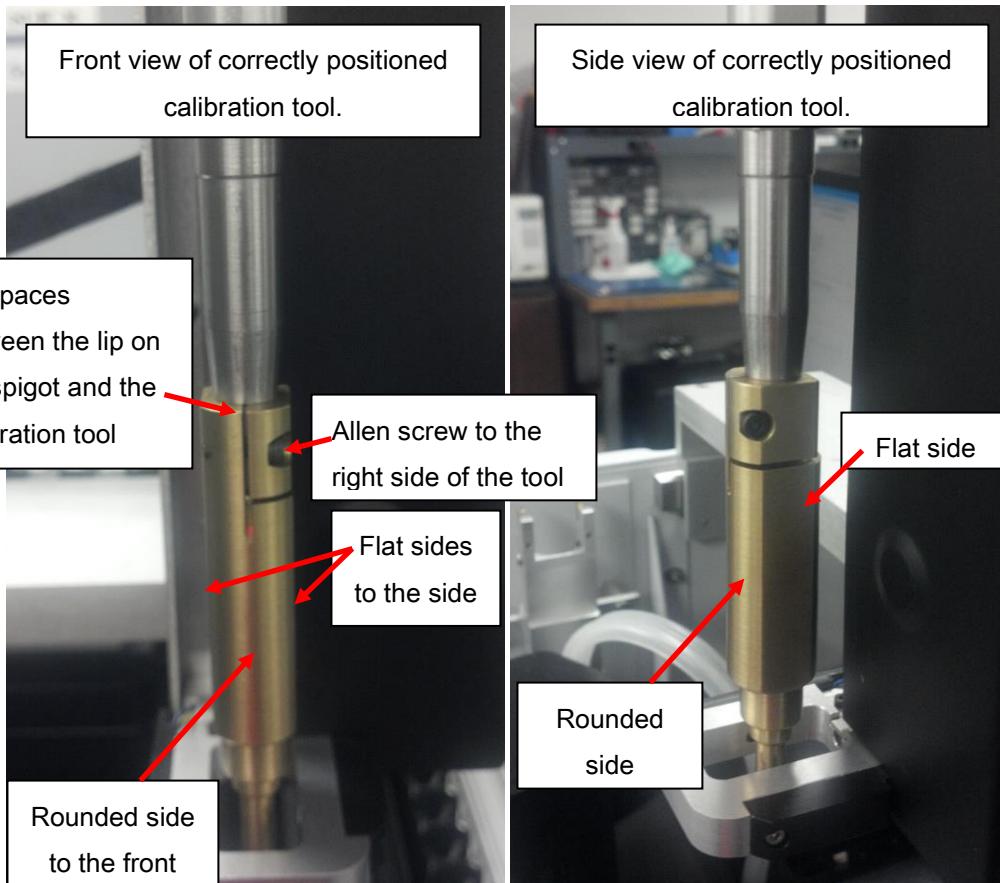
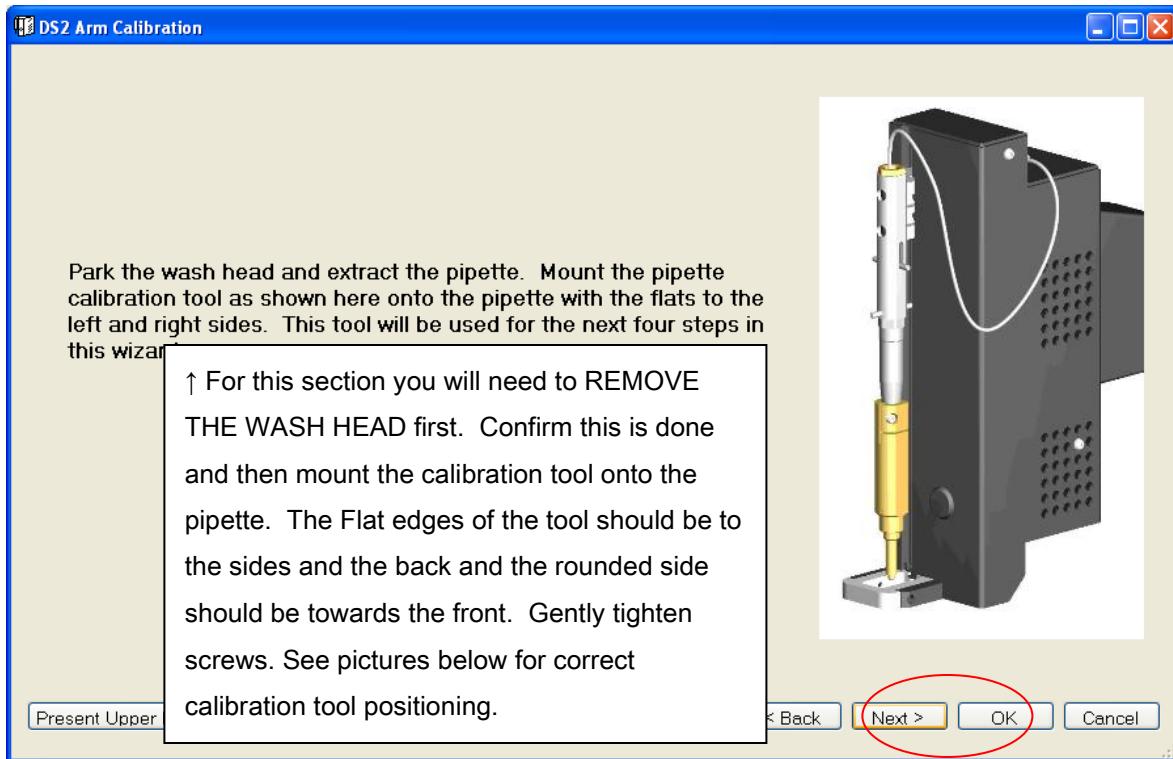
2. Please note: The plate carriers will move if you apply too much force while performing the calibration. Be gentle when inserting the aspiration pins into the white well inserts in the plate, taking care not to move the plate carrier around. If the plate carrier is moved, calibration values will be incorrect.
3. Be very careful when clicking “get values”. Make sure that the plate is in the plate carrier corresponding to the “get values” you are clicking. For example, when clicking “Get Values” for Upper Plate Datum, make sure the plate is actually in the Upper Plate carrier.

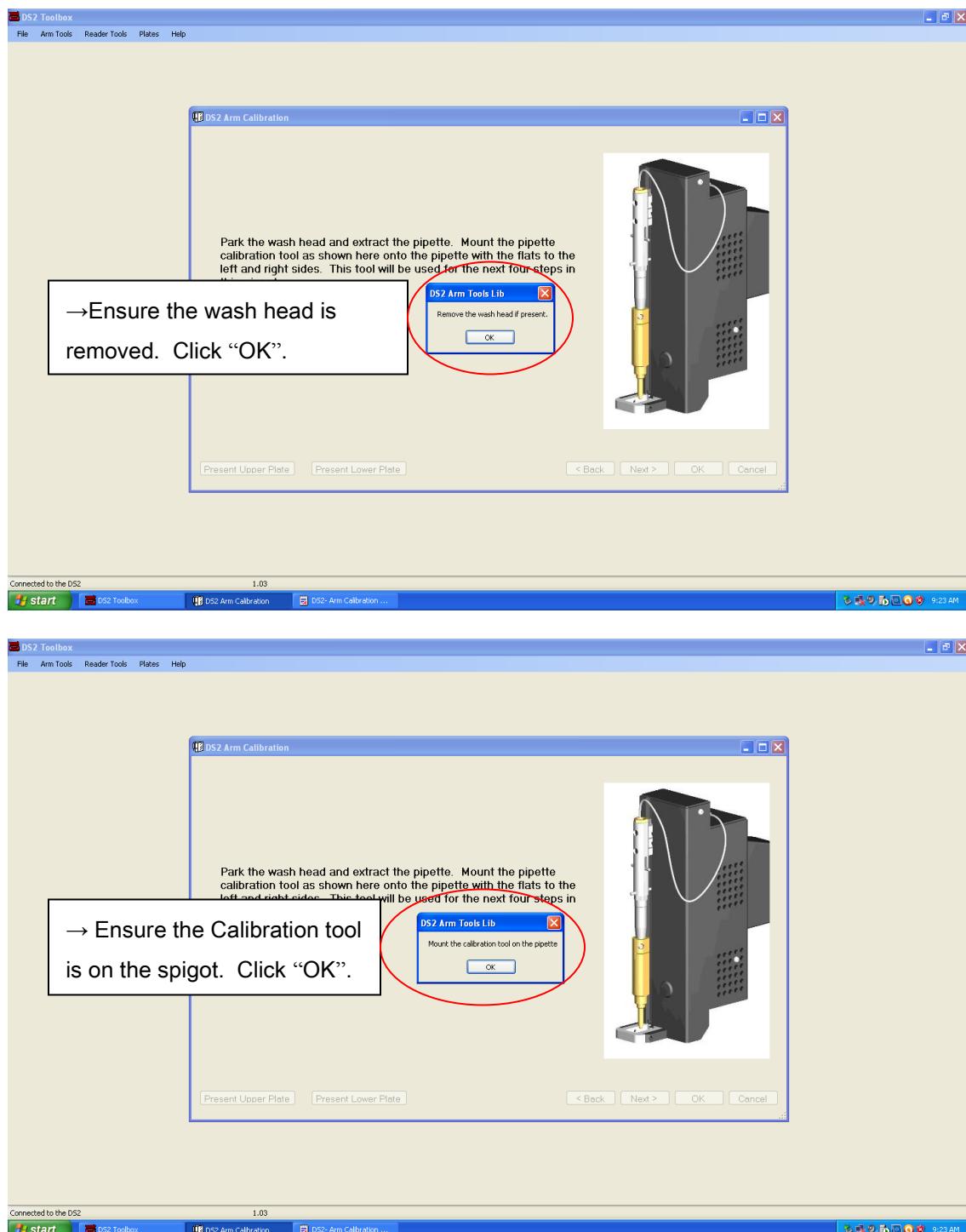
To calibrate this position, use the DS2 Calibration plate. Follow the instructions on the screen and the Technical Tips above when calibrating. Click **Get Values** for the Datum and Y Right positions in the upper plate carrier. Remove the DS2 Calibration plate from the plate carrier and make sure the wash head and pipette are off to the side. Click “Present Lower Plate” at the bottom of the screen. Insert the DS2 Calibration Plate when prompted, taking care not to move the plate carrier. Click “OK” prior to putting the wash head in the plate to avoid damaging the instrument. Click **Get Values** for the Datum and Y Right positions in the lower

plate carrier. Once the X, Y, and Z values for all 4 positions are populated with values, click **Next**.



To park the wash head, move the wash head back over and place it on the support posts. Remove the spigot from the wash head by pulling upwards until the pins on the spigot come out of the clamps on the wash head. Once the spigot is removed from the wash head, ensure the wash head is still correctly positioned on the support posts, so there are not wash head pick up issues later on. Reference page 13 of this guide for a picture of correct wash head placement on the support posts.





This calibration position is for the **sample and reagent tip positions when dispensing fluid to the plate.**

Calibrate this position if the sample/reagent tip is not centered in the well, if fluid is being dispensed outside the well, if the tip is dragging across the top of the well as it dispenses reagent, if the air gap pulled up between wells is not clean (fluid is pulled up instead of air).

If this position does not require calibration, click **next**.

Technical Tips:

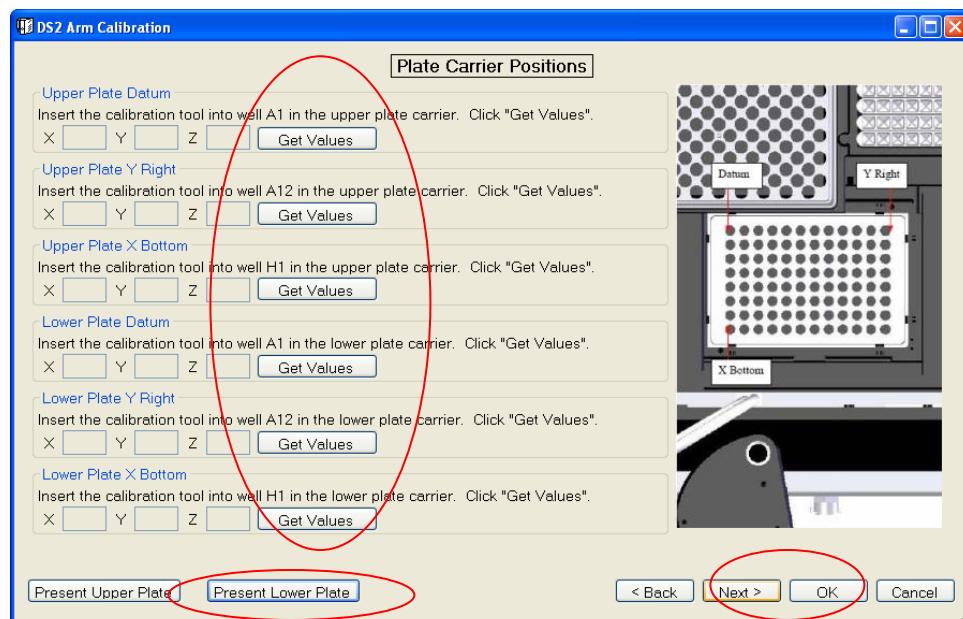
1. Please note: The plate carriers will move if you apply too much force while performing the calibration. Be gentle when inserting the calibration tool into the wells in the DS2 Calibration Plate, taking care not to move the plate carrier around. If the plate carrier is moved, calibration values will be incorrect. Make sure the calibration tool is in contact with the bottom of the well for each of the calibration positions.

2. Be very careful when clicking "get values". Make sure that the plate is in the plate carrier corresponding to the "get values" you are clicking. For example, when clicking "Get Values" for Upper Plate Datum, make sure the plate is actually in the Upper Plate carrier.

To calibrate this position, use the DS2 Calibration plate. Remove the DS2 Calibration plate from the instrument, Click "Present Upper Plate", Insert the plate in the upper plate carrier and Click OK.

Follow the instructions on the screen and the Technical Tips above when calibrating. Click **Get Values** for the Datum, Y Right, and X Bottom positions in the upper plate carrier.

Remove the DS2 Calibration plate from the plate carrier and make sure the calibration tool and pipette are off to the side and clear of the plate carrier. Click "Present Lower Plate" at the bottom of the screen. Insert the DS2 Calibration Plate when prompted, taking care not to move the plate carrier. Click "OK" prior to putting the calibration tool in the plate to avoid damaging the instrument. Click **Get Values** for the Datum, Y Right, and X Bottom positions in the lower plate carrier. Once the X, Y, and Z values for all 6 positions are populated with values, click **Next**.



This calibration position is for the **sample tube positions**.

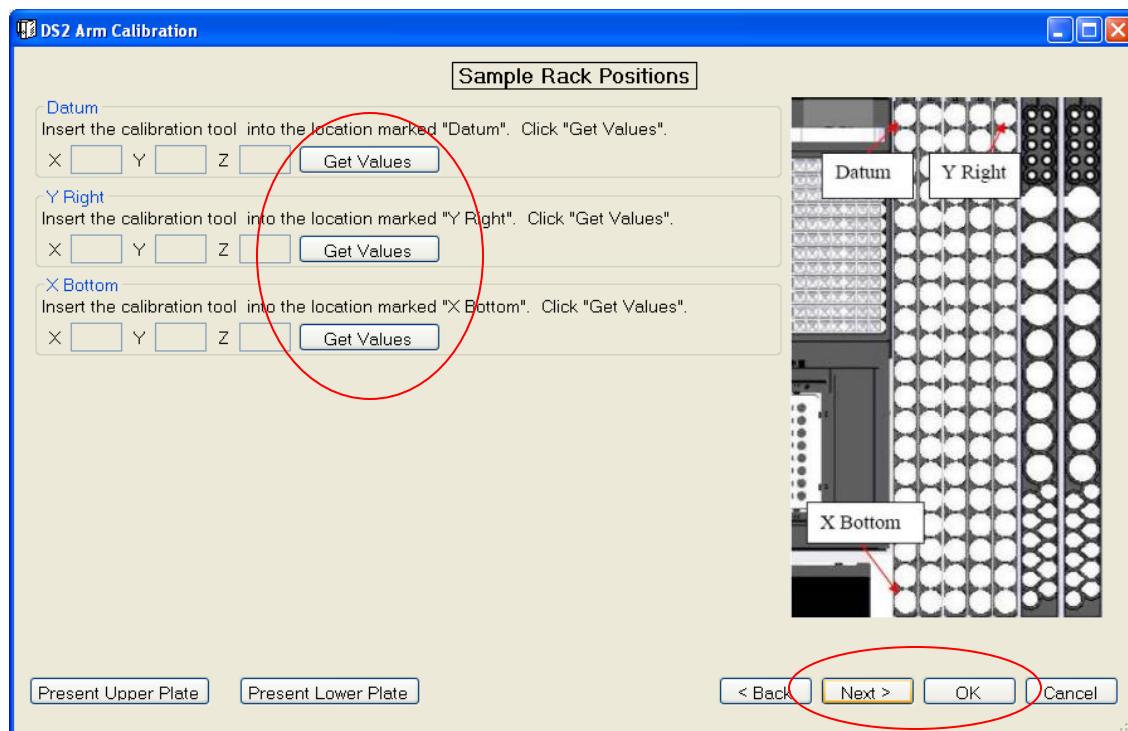
Calibrate this position if you suspect the system is not tracking fluid correctly in the sample tubes.

If this position does not require calibration, click **next**.

Technical Tips:

1. Please note: Make sure the calibration tool is touching the bottom of the rack. The lip of the tool can catch on the sample holder and feel like it is down all the way, when actually it is not.
2. Make sure the sample racks are pushed in all the way. If the racks are not positioned correctly, the calibration points will be incorrect. The racks should not move/tilt to the left or right when inserting the tool.

Follow the instructions on the screen and the Technical Tips above when calibrating. Click **Get Values** for the Datum, Y Right, and X Bottom positions. Once the X, Y, and Z values for all 3 positions are populated with values, click **Next**.



This calibration position is for the **reagent tube positions**.

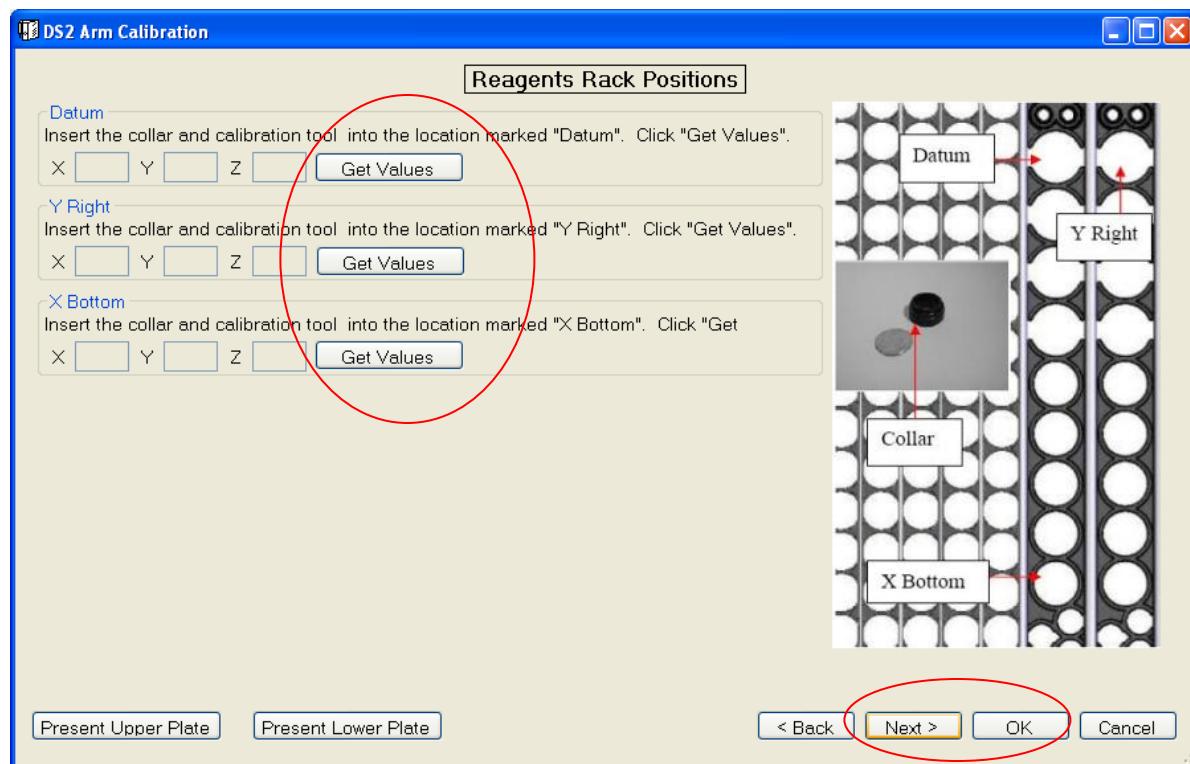
Calibrate this position if you suspect the system is not tracking fluid correctly in the reagent tubes.

If this position does not require calibration, click **next**.

Technical Tips:

1. Please note: This calibration uses the calibration collar. Make sure the calibration collar is inserted and pushed down as far as it will go into the correct reagent tube position.
2. Please note: Make sure the calibration tool is touching the bottom of the rack.
3. Make sure the reagent racks are pushed in all the way. If the racks are not positioned correctly, the calibration points will be incorrect. The racks should not move/tilt to the left or right when inserting the tool.

Follow the instructions on the screen and the Technical Tips above when calibrating. Click **Get Values** for the Datum, Y Right, and X Bottom positions. Once the X, Y, and Z values for all 3 positions are populated with values, click **Next**.



This calibration position is for the **control tube positions**.

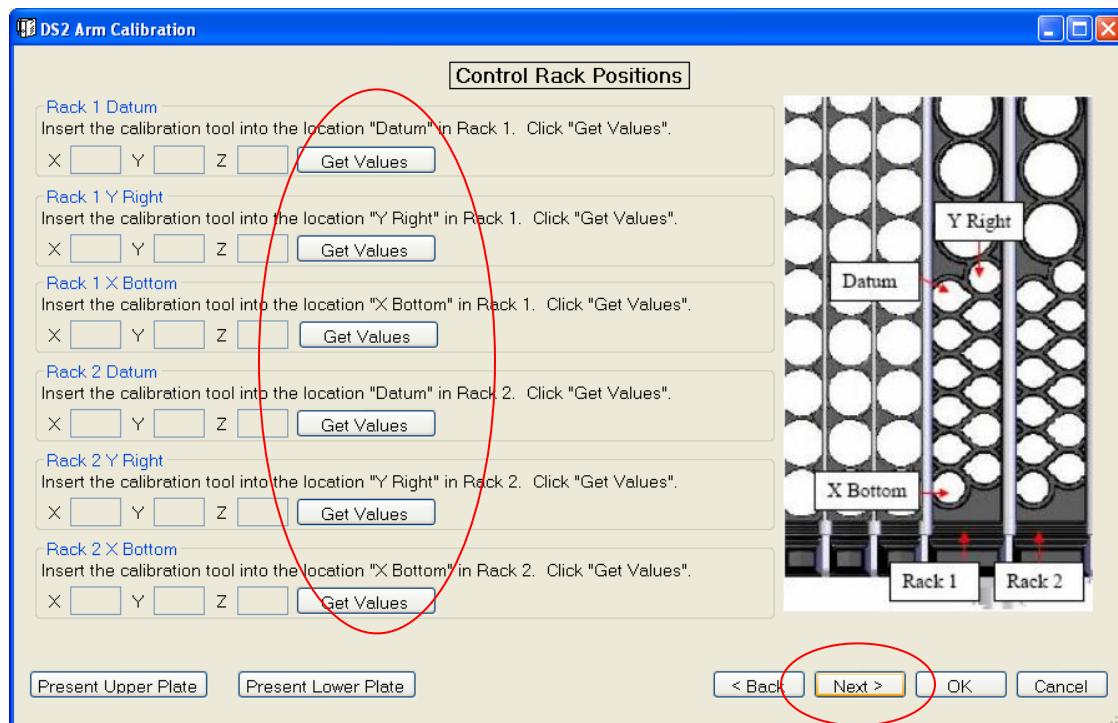
Calibrate this position if you suspect the system is not tracking fluid correctly in the control tubes or if the sample tip is not centered in the control tube.

If this position does not require calibration, click **next**.

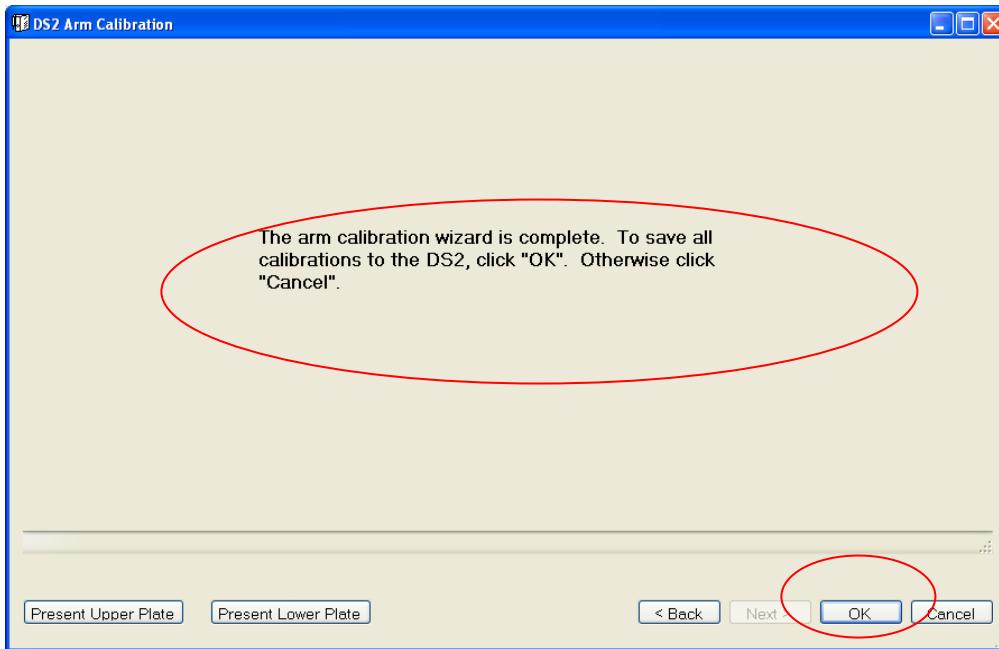
Technical Tips:

1. Please note: Make sure the calibration tool is touching the bottom of the rack.
2. Make sure the reagent racks are pushed in all the way. If the racks are not positioned correctly, the calibration points will be incorrect. The racks should not move/tilt to the left or right when inserting the tool.

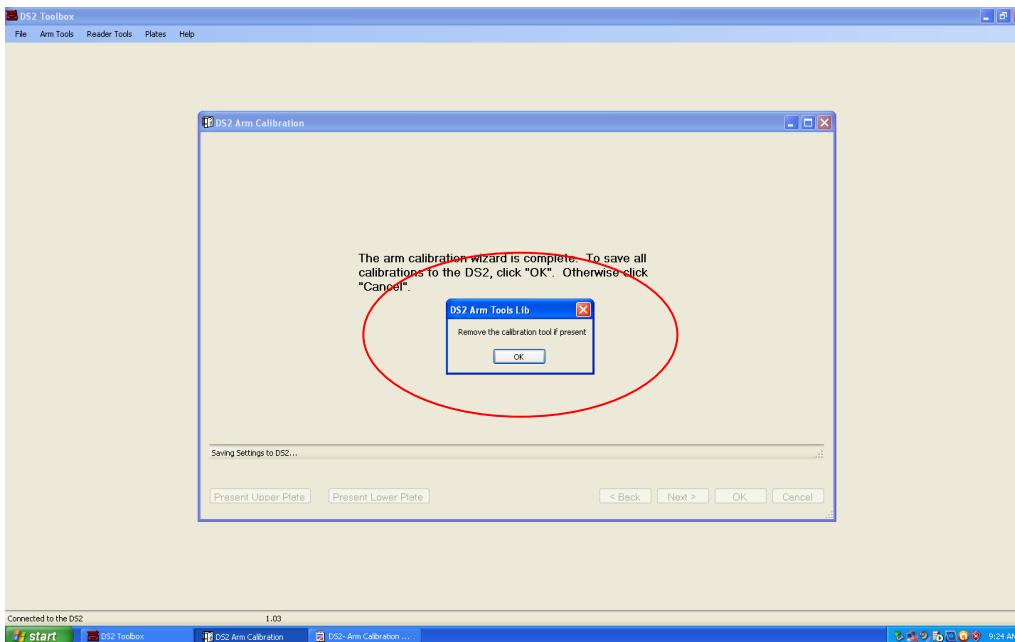
Follow the instructions on the screen and the Technical Tips above when calibrating. Click **Get Values** for the Datum, Y Right, and X Bottom positions for rack 1 and rack 2. Once the X, Y, and Z values for all 6 positions are populated with values, click **Next**.



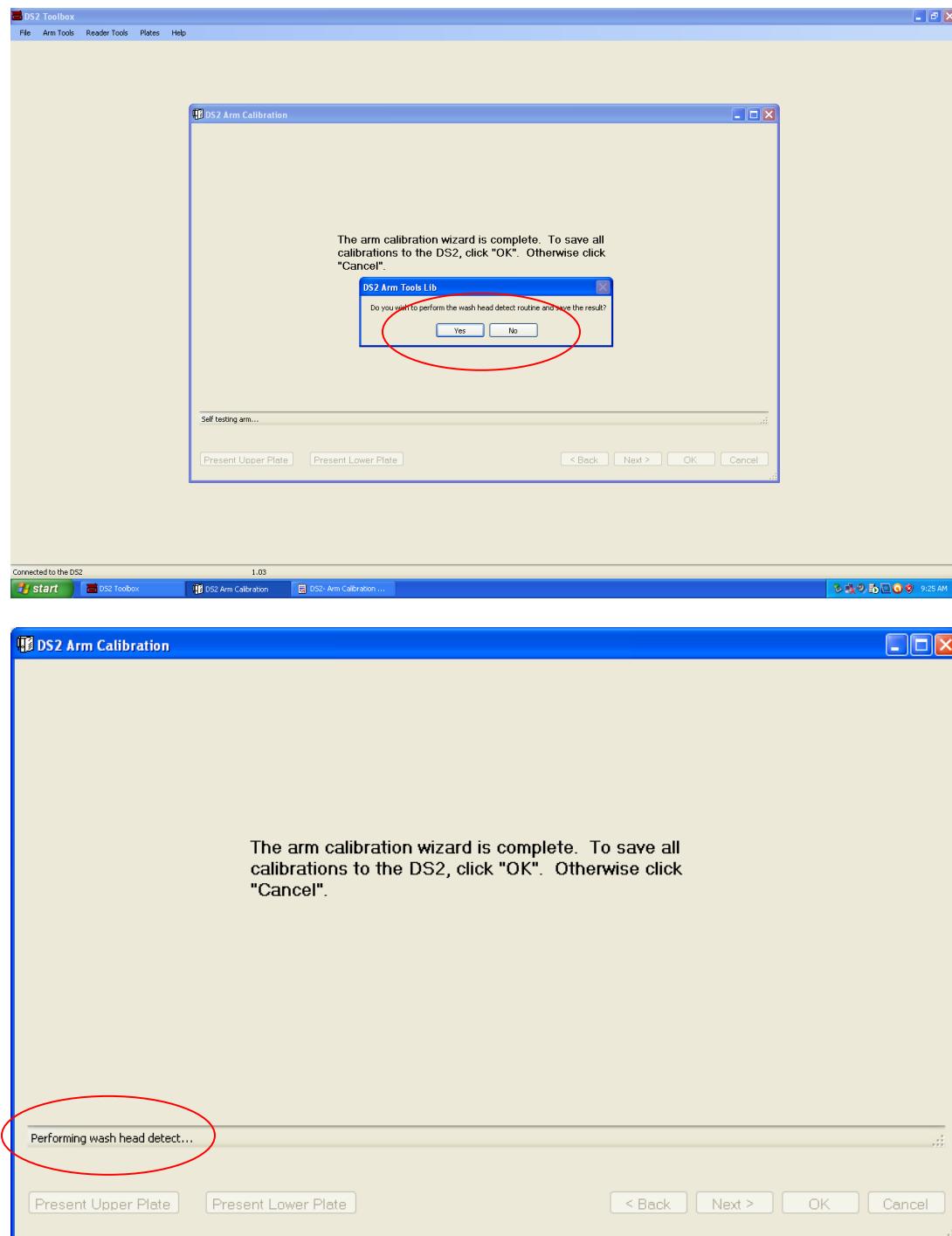
Appendix A Arm Calibration



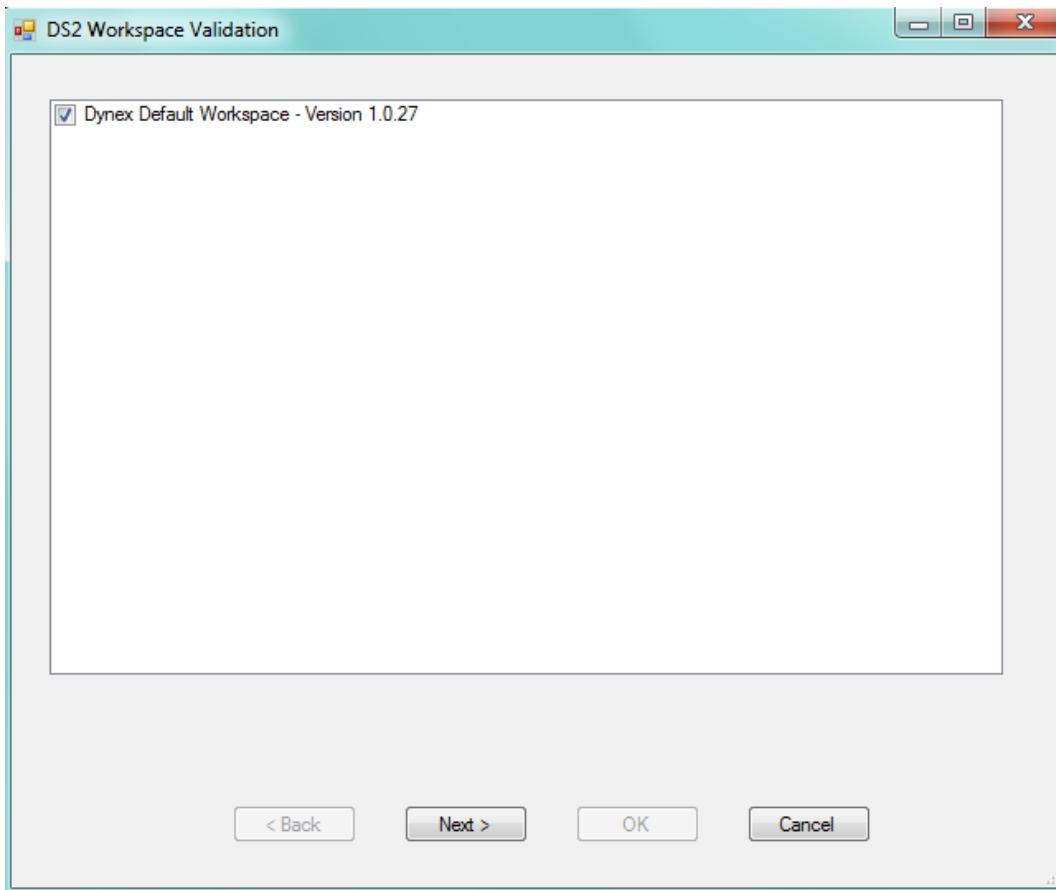
Remove the Calibration tool using the allen wrench. Click OK when done.



The wash head detect routine calibrates the wash head magnet and sensor positions. Always say "Yes" to perform the wash head detect routine.



Depending on the version of the DS2 toolbox you are running, you may or may not see the following screen after performing the wash head detect routine (Toolbox 1.03 will show this screen):



If you do see this screen, click the “Next” Button. If it result says “Pass”, the calibration is complete. If it the workspace validation fails, click OK to view the report and repeat the arm calibration for any positions detailed in the report. Please note, this workspace validation is only checking for impossible values (like negative numbers); it is not checking that the values are correct or within average expected ranges. If you calibrated the upper plate instead of the lower plate, this validation will pass, but your values for those calibration points will still be incorrect.

Once calibration is complete, save the arm calibration values again following the instructions on page 2. Make sure to use a unique identifier for the file name in addition to the date so the file will not overwrite.

After the arm calibration values have been saved, exit the DS2 Toolbox Software and **open the DS-Matrix software and run the assay from your list of assays called “Installation Assay”**. Choose to run 2 or 3 samples and when the system requests fluids, simply load bottles containing water. Load the plate used for startup when the software asks for a plate to be loaded on the system. This assay will check the movement of the arm following the calibration. Pay special attention to any positions calibrated while the assay is running to confirm the problem requiring calibration has been resolved.

Appendix B Labware Specifications

B.1 Specifications

Type	Max Volume mL	Height mm	Internal Diameter mm	External Diameter mm	Bottom Shape
Controls & Standards Vial	2000	44.45	8.69	10.3	V
Deep Well Strip	2000	39.8	7.4	8	V
Large Reagent Tube	25000	89.2	22.45	25.4	V
Small Reagent Tube	15000	75.9	17.6	20.5	V
12x75 Sample Test Tube	4000	74.4	9.7	11.9	U

B.2 Consumables & Accessories Ordering Information

Item Number	Description	Unit
65910	Blue Sample Tips, 300 µL, 108/box	4 box pack
65921	White Reagent Pipette Tips, 108/box	4 box pack
62910	Deep Well Strips, 250/box	Box
62920	Reagent Tubes, 25 mL, 10/pack	Pack
62930	Small Reagent Tubes, 15 mL, 10/pack	Pack
65940	Control/Standards Vials w. Caps, 33/pack	Pack
394000100	Purge Tray, Microplate Form	3 Pack

Note: Only DYNEX accessories and consumables have been used in support of CE marking 98/79/EC in-Vitro Diagnostic Directive. The sample and the reagent pipette tips have been defined as accessories as only these tips have been found to meet the stated precision and accuracy specifications

B.3 Microplate Ordering Information

Item Number	Description	Quantity / Box
1000	Immilon® Medium binding, untreated polystyrene, 96-well flat bottom immunoassay plates	40
1010	Immilon® 2HB, High binding, treated polystyrene, 96-well flat-bottom immunoassay plates	40
1011	Immilon® 2HB, High binding, treated polystyrene, 96-well "U"-bottom plates	40

Appendix C Curve Fit Equations

DS-Matrix allows the user to select from nine mathematical relationships to determine the concentration of the compound of interest. In this appendix, each of the curve fits is defined.

C.1 Linear Regression

A **Linear Regression** is used to put a "best fit" straight line through a set of data points. **Equation C-1** describes a linear relationship between the measured variable and the concentration of the compound of interest:

$$Y = mX + b \quad \text{C-1}$$

where: **m** = the slope

b = the y-intercept defining the line

X = the value for the concentration

Y = the value for measured variable (O.D.)

The linear regression formulae for determining the best straight line through a series of data points are provided in **Equations C-2** and **C-3**:

$$m = \frac{N\sum x_i y_i - \sum x_i \sum y_i}{N\sum x_i^2 - (\sum x_i)^2} \quad \text{C-2}$$

$$b = Y_{\text{mean}} - m (X_{\text{mean}}) \quad \text{C-3}$$

The linear regression coefficient, R, is defined by **Equation C-4**:

$$R = \frac{(N\sum x_i y_i - \sum x_i \sum y_i)^2}{(N\sum x_i^2 - (\sum x_i)^2)(N\sum y_i^2 - (\sum y_i)^2)} \quad \text{C-4}$$

The linear correlation coefficient (R) is used to determine how well the line fits through the points of the graph. Since the linear correlation coefficient can be either positive or negative, the value of R^2 is normally reported. When comparing two sets of data (fits), the fit with the larger value for R^2 is a better fit for the data set; if $R^2=1$, all data points lie along the line of best fit and if $R^2=0$, the data points are highly scattered and there is a poor correlation.

Once the linear relationship best fit has been established for a set of known standards, the concentration of an unknown sample can be determined via equation C-1.

An example of a linear relationship is presented in Figure C-1.

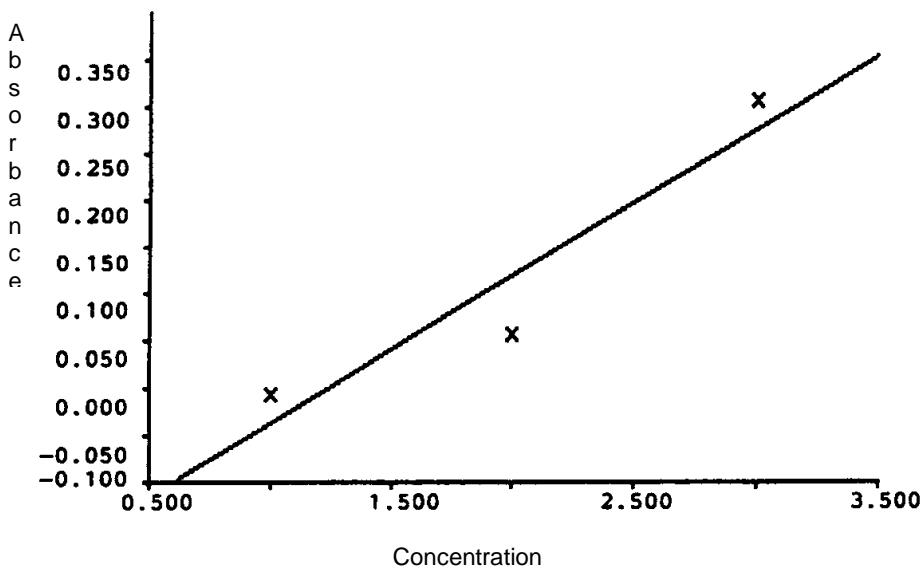


Figure C-1: Linear Regression Fit

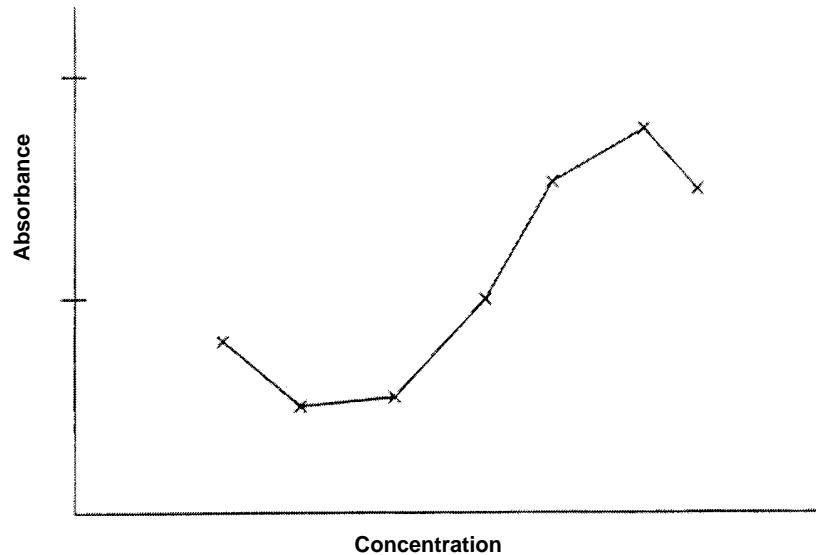


Figure C-2: Polygon Fit

C.2 Polygon Fit (Point to Point Fit)

A **Polygon Fit** of the data involves joining successive data points using straight lines in a connect-the-dots fashion as shown in Figure C-2.

C.3 Quadratic, Cubic and Quartic Regression

Polynomial regressions are similar to a linear regression (equation C-1), but use quadratic, cubic and quartic equations to relate the observed OD to the concentration.

Equation C-5 is a quadratic equation, **Equation C-6** is a cubic equation, and **Equation C-7** is a quartic equation.

$$\text{Quadratic Equation: } Y = a + bX + cX^2 \quad \text{C-5}$$

$$\text{Cubic Equation: } Y = a + bX + cX^2 + dX^3 \quad \text{C-6}$$

$$\text{Quartic Equation: } Y = a + bX + cX^2 + dX^3 + eX^4 \quad \text{C-7}$$

The procedures used to fit these functions to experimental data are similar to that for linear regression and have a similar mathematical derivation. A polynomial regression tends to minimize the deviations of the data points from the polynomial equation. The squaring (cubing, etc.) of the deviations tends to minimize them since positive and negative deviations tend to cancel out.

The regression coefficient is handled in a similar manner as with a linear relationship. When $R^2 = 1$, all the data points have been fitted to the curve, when $R^2 = 0$, the data points are scattered.

Examples of Quadratic and Quartic fits are shown in Figure C-3 and C-4 respectively.

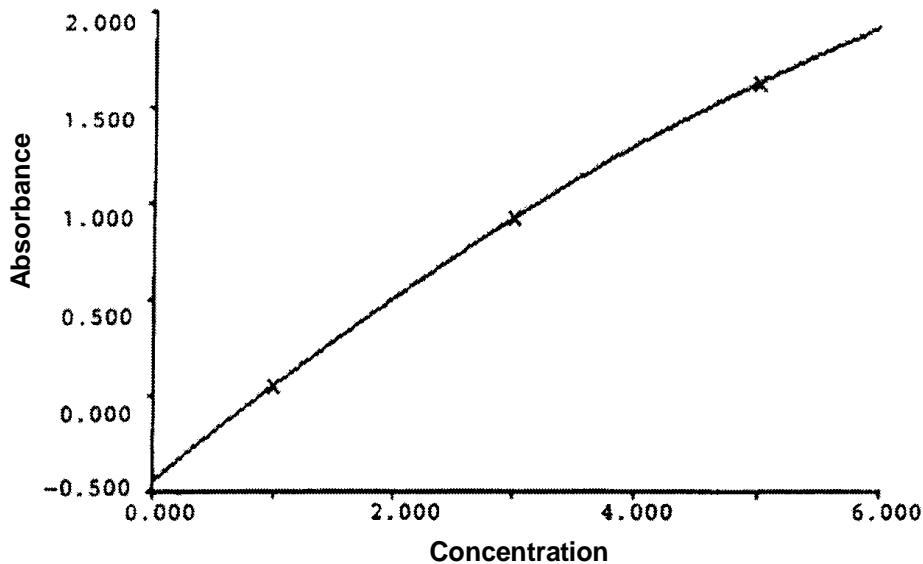


Figure C-3: Quadratic Fit

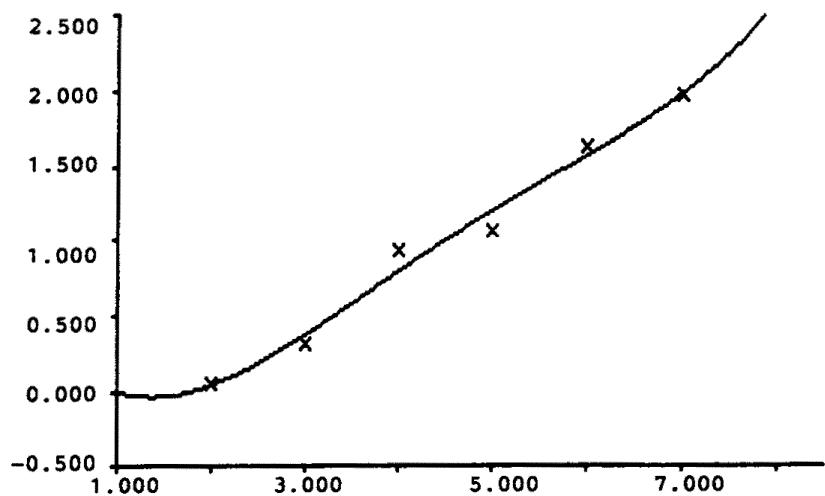


Figure C-4: Quartic Fit

C.4 Cubic Spline Curve Fitting

When a **Cubic Spline Curve fit** is used, a curve is passed through all the data points and a smoothing function is applied. **Equations C-8** to **C-10** are then used to determine the concentration of the sample.

$$y = a_0 + a_1 x + \sum_{i=1}^{n-2} b_i \Phi_i(x) \quad \text{C-8}$$

$$\Phi_i(x) = \varnothing_i(x) - \left(\frac{x_n - x_i}{x_n - x_{n-1}} \right) \varnothing_{n-1}(x) + \left(\frac{x_{n-1} - x_i}{x_n - x_{n-1}} \right) \varnothing_n(x) \quad \text{C-9}$$

$$\varnothing_i(x) = \begin{cases} 0 & x < x_i \\ (x - x_i)^3 & x \geq x_i \end{cases} \quad \text{C-10}$$

The Cubic Spline Curve Fit is not a best fit algorithm as it assumes that each data point is correct. If the data is erratic, if it is known that the data has significant errors or if the concentration/absorbance has many inflection points, this method can lead to significant errors in the reported concentration.

At high concentrations, the Cubic Spline Curve Fit may break up (Figure C-5). In some cases, a semi-log or log-log axis (instead of a linear fit) will improve the quality of the data.

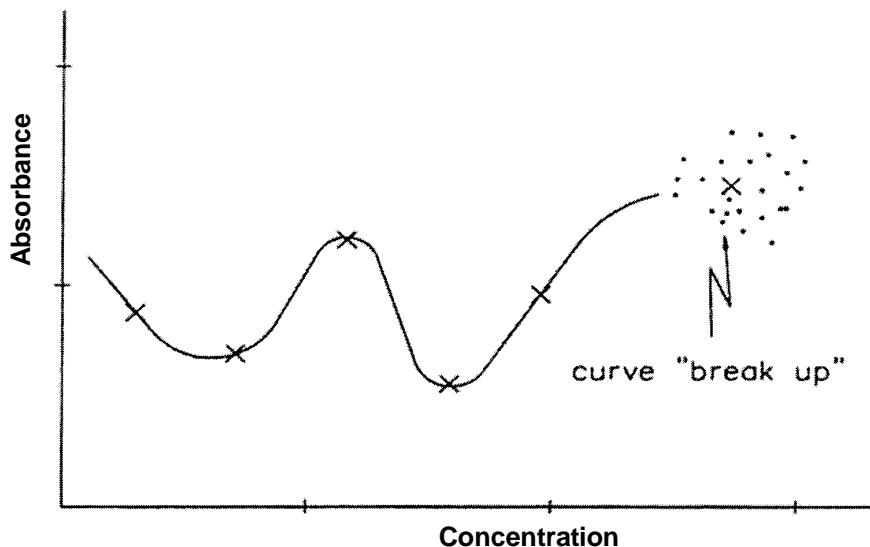


Figure C-5: Cubic Spline Curve Fit

C.5 Akima Fit

The Akima fit constructs a smooth curve through the data points. The fitted curve appears smooth and approximates a manually drawn curve (Figure C-6).

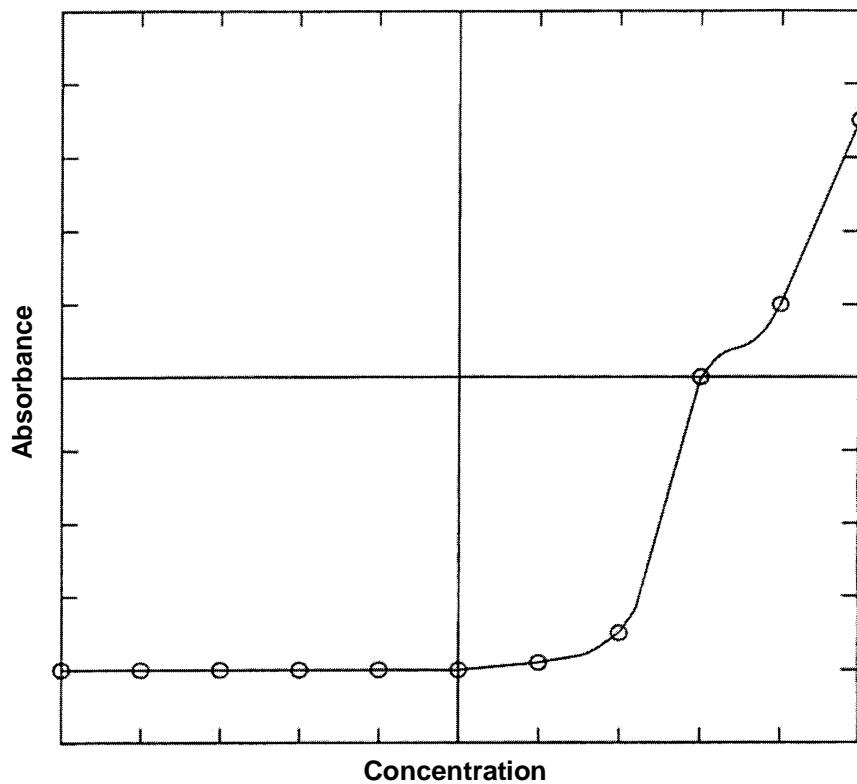


Figure C-6: Akima Fit

The Akima Curve Fit involves applying a set of polynomials to the data points, which determines the slope of the curve at each point .The Akima Fit is based on the assumption that each data point is determined by five points, the point of interest and two points on either side of it.

C.6 Extrapolation of Non-Linear Curves

In many instances, a data point is observed outside the range of the curve that is used to determine the concentration. The analyst should note that some curve fit functions may not behave as expected if they are extrapolated beyond the range defined by the data points.

For example, the readings for a set of Standards increase in a non-linear fashion with increasing concentration for a given test (right side of curve in Figure C-7) and the user determines that a quadratic curve fit might give the best fit for such data. However, at concentrations lower than the concentration of the lowest Standard, the curve may turn sharply upwards as shown in the left side of the curve.

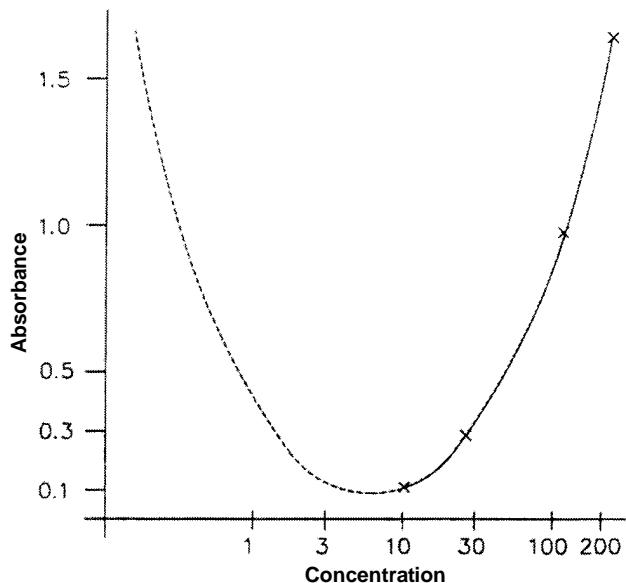


Figure C-7: Non-Linear Curve Fit

C.7 Sigmoid Fit (4PL Fit)

Many immunoassays are characterized by an S-shaped or sigmoid curve fit (Figure C-8).

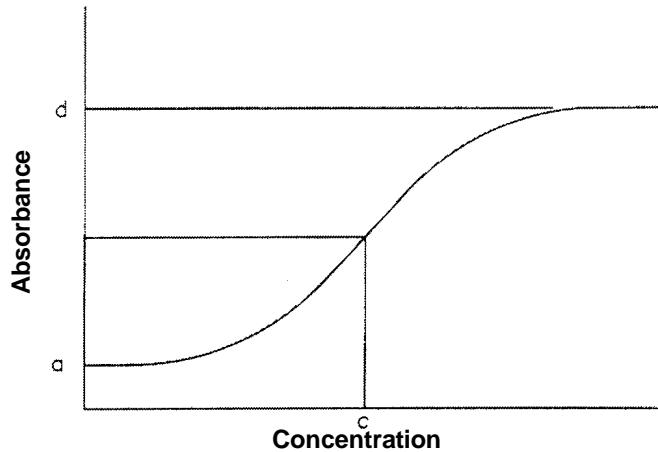


Figure C-8: Sigmoid Curve

The sigmoid curve is described by equation C-11:

$$Y = \frac{[a-d]}{1 + \left(\frac{X}{c}\right)^b} + d \quad \text{C-11}$$

where:
a is the minimum response
b is the shape factor (determines the gradient of the curve)
c is the response midway between the maximum (d) and the minimum response
d is the maximum response

The above definition assumes that **b** has a positive value. If **b** is negative, the definition of parameters **a** and **d** are reversed.

Matrix uses an algorithm for estimating the four parameters and determining the best fit for the sigmoid curve. The curve requires at least four standards (data points), one for each of the four parameters. It is recommended that at least eight Standards are defined on a plate to ensure satisfactory statistical significance.

The Sigmoid Curve Fit algorithm is iterative, requiring many complex calculations. Matrix may take some time to process the results. If the curve cannot be drawn or data cannot be processed, a Windows® “Illegal Operation – Shut Down” error message will occur. If this happens, examine your data carefully to determine if the number of Standards should be altered or a different type of curve fit should be used.

C.8 Log – Logit Curve Fit

The Log – Logit Curve Fit is the **Rodbard's Four Parameter** fit, similar to the Sigmoidal fit. It also uses auto- or manually-assigned parameters to calculate the graph.

Standard curves commonly display a pronounced sigmoidal shape when plotted on an OD versus log dilution scale. The logit function adopts the same general shape and is a reasonable relationship to use in modeling standard curves. It is described as:

$$\text{OD} = d + \{(a - d)/[1 + (\text{dilution}/c)^b]\}$$

Parameters a and d represent the upper and lower asymptotes, respectively, of the curve and correspond to the theoretical OD of the assay at infinite and zero concentrations, respectively. The value c is the dilution associated with the point of symmetry of the sigmoid and is located at the midpoint of the assay found at the inflection point of the curve. The value b is a curvature parameter and is related to the slope of the curve.

C.9 Using Logarithmic Axes Fitting

In most instances, linear scales are used to plot the concentration (**X axis**) and the OD measured variable (**Y axis**). Alternatively, a semi-log fit or a log-log axes fit can be used. The following example equations relate to linear regression fits, but Semi-Log and Log-Log Axes fits may be used with all the other selectable curve fits.

C.9.1 Semi-Log Fit

When a semi-log fit is used, the **X axis** presents log (power of 10) concentration. To obtain the concentration of a sample, equation C-12 is used.

$$\text{Concentration} = \text{antilog } (y-c)/m \quad \text{C-12}$$

C.9.2 Log-Log Fit

When a log-log fit is used, the **X axis** represents the log of the concentration (concentrations in powers of 10) and the **Y axis** represents log of the OD (measured variable). To obtain the concentration of a sample, equation C-13 is used.

$$\text{antilog Concentration} = \text{antilog } (y-c)/m \quad \text{C-13}$$

Appendix D Equation Functions

D.1 Entries for Quality Control Equations

SYMBOL	FUNCTION	COMMENT
0-9	Numeric entry	
+	Addition	Standard Arithmetic operator
-	Subtraction	Standard Arithmetic operator
/	Divide	Standard Arithmetic operator
*	Multiplication	Standard Arithmetic operator
**	To the power of	Standard Arithmetic operator
(())	Parenthesis	Max 6 levels
Log	Base 10 logarithm	
Ln	Natural logarithm	
Exp	Inverse natural logarithm	
CV(<i>well type</i>)	Coefficient of variation	
SD(<i>well type</i>)	Standard deviation	
Median©	Median	If all values in a group are listed, the median is the value in the middle of the list. If the list contains an even number of values, the median is the mean of the middle two. The group of values may be a well type, or a sample, if it contains replicates.
Custom Variable		Can be used to prompt for entry of a variable number at run time
>	Greater than	
<	Less than	
>=	Greater than or equal to	
<=	Less than or equal to	
==	Must be equal to	
MIN or MAX		Represents the highest or lowest value on the plate or within a group of values. The group may be a well type or a sample if it contains replicates. EX: MIN(PC)= the lowest value of all the Positive Control samples MIN= the lowest value on the plate

SYMBOL	FUNCTION	COMMENT
T,T1,T1.1	Referenced Well Types	<p>T represents the mean of all the Test values</p> <p>T1 represents the mean of the replicates of Test1</p> <p>T1.1 is the value of the first replicate of Test 1</p> <p>T1.2 is the value of the second replicate if Test 1</p>
I	Each sample of a well type	<p>EX: $0.74^{\circ}\text{C} < \text{Ci} < 1.25^{\circ}\text{C}$ means each Control sample must be within 25% of the mean of the Controls or that well is removed from the calculations. Should be accompanied by a <i>Valid</i> statement</p>
Valid()		<p>A <i>Valid()</i> expression indicates that a specified number of values within a group must pass other QC equations otherwise the data fails QC. The group of values may be a Well Type or a sample with replicates.</p> <p>EX: <i>valid(PC)>=3</i> means the number of valid Positive Controls must be greater than or equal to three or QC is failed.</p>
=	Assignment	<p>An assignment expression indicates that, depending on certain criteria, a well type, sample or replicate should be assigned a value.</p> <p>EX: If $\text{NCi} < 0.0$ then $\text{NCi}=0.0$</p> <p>Thus, if every NC value is less than 0.0, then let every NC be assigned a value of 0.0</p>
If {condition} then {expression} else {expression}	Conditional Requirement	<p>EX: If $\text{PC} < 0.2$ then $\text{NC} > 0.5$ else $\text{NC} > 0.1$</p> <p>Means If the average PC value is less than 0.2 then the average NC value must be more than 0.5 else the average NC value must be more than 0.1.</p> <p>If these conditions are not met, the data fails QC</p>

SYMBOL	FUNCTION	COMMENT
Verify (value, limit, mode)	Expression	<p>Indicates that a specified number of values within a group must be within specified limits or the data fails QC.</p> <p>Value represents a well type checked for the number of verified samples within that group or number of verified replicates within a specified sample.</p> <p>Limit determines the range into which values must fall in order to be verified.</p> <p>A limit may be a number.</p> <p><i>EX:</i> If the value is PC, the mode is 0 and the limit is 0.2, so that every PC sample is within 0.2 of the average of all the group values.</p> <p>A limit may be a percentage.</p> <p><i>EX:</i> If the value is PC, the mode is 0 and the limit is 20%, then every PC sample must be within 20% of the average of all the group values.</p> <p>A Limit may be a standard deviation.</p> <p><i>EX:</i> If the value is PC, the mode is 0 and the limit is 1.5SD, then the standard deviation of all the PC samples must be within 1.5 SD.</p> <p><i>EX:</i> Verify(T,10%,2>=3</p> <p>Means the number of verified Test samples must be greater than or equal to 3. A verified Test sample falls within 10% of the mean of all other Test samples.</p>

SYMBOL	FUNCTION	COMMENT
<i>Following Threshold</i>		
POS / NEG	Well Label	The user can require that a specific (default or user defined) threshold Well Type be labeled All samples within the Well Type must fall into the required result range or the Well Type will fail QC and a warning will be displayed in the results.
<i>Following Curve Fit</i>		
Min R-squared		R-squared may be used to determine how closely the standards fit a linear regression curve fit. QC may fail if they R-squared is below a specified value.
Min Slope		
Max Slope		
Min Y-Intercept		
Max Y-intercept		Min slope / Max slope may be used to define the change in Y over the change in X within a certain range
		Min Y-intercept / Max Y-intercept may be used to keep the data on the y-axis in the correct place or else the curve fit fails, meaning there is not enough discrimination in response.

D.2 Entries for Ratio and Threshold Equations

SYMBOL	FUNCTION	COMMENT
Sample	Value of every well on the plate	Represents the value of every well on the plate regardless of Well Type <i>EX: sample/10</i>
0-9	Numeric entry	
+	Addition	Standard arithmetic operator
-	Subtraction	Standard arithmetic operator
/	Divide	Standard arithmetic operator
*	Multiplication	Standard arithmetic operator
**	To the power of	Standard arithmetic operator
(())	Parenthesis	Max 6 levels
Log	Base 10 logarithm	
Ln	Natural logarithm	
Exp	Inverse natural logarithm	
MIN or MAX		Represents the highest or lowest value on the plate or within a group of values. The group may be a well type or a sample if it contains replicates. <i>EX: MIN(PC)= the lowest value of all the Positive Control samples</i> MIN= the lowest value on the plate
CV(well type)	Coefficient of variation	
SD(well type)	Standard deviation	
Median()	Median	If all values in a group are listed, the median is the value in the middle of the list. If the list contains an even number of values, the median is the mean of the middle two. The group of values may be a well type, or a sample, if it contains replicates.
Custom Variable		User defined variable name
VariableX		Different variable to use each time run is done

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Appendix E Tube Definition

Custom bottle definitions can be created in the DS-Matrix software by following the instructions below. A ruler capable of measuring in mm increments or a micrometer is required for accurate measurements. A bottle definition may be entered into the bottle database, but it may not be used until it has been calibrated.

Calibration of a bottle (referred to as Fluid Level Tracking in the DS-Matrix software) requires an accurate laboratory grade balance with precision to 1mg (0.001gm). A custom bottle definition must be calibrated before it will appear for use in drop down lists in the DS-Matrix software. Newly defined and calibrated bottles should be tested and validated before incorporating them into customer assays.



Warning: *Improper bottle definition and calibration can lead to incorrect results!*

1. Select the **Tools** menu.
2. Select **Database Maintenance...** from the drop down menu.
3. Select **Bottle Type** as the Database Type.
4. Click the **Add Consumable** button.

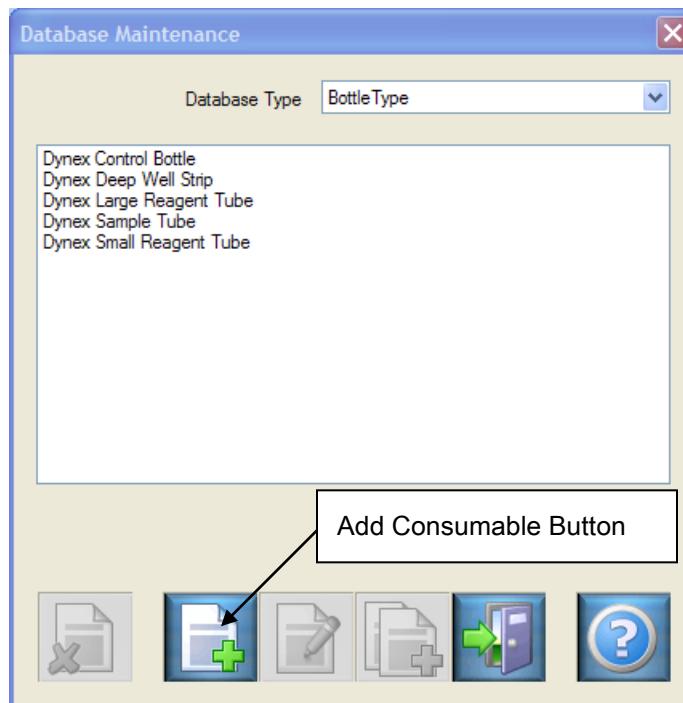


Figure E-1: Add Consumable Button

5. Enter a name for the new tube and click **OK**.

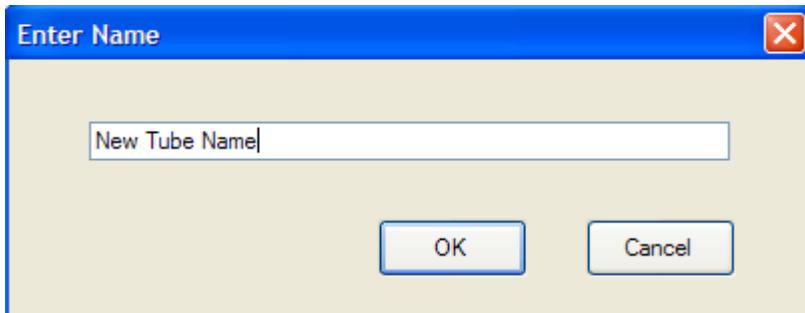


Figure E-2: Enter tube name

6. In the **Bottle** window enter in the following information:

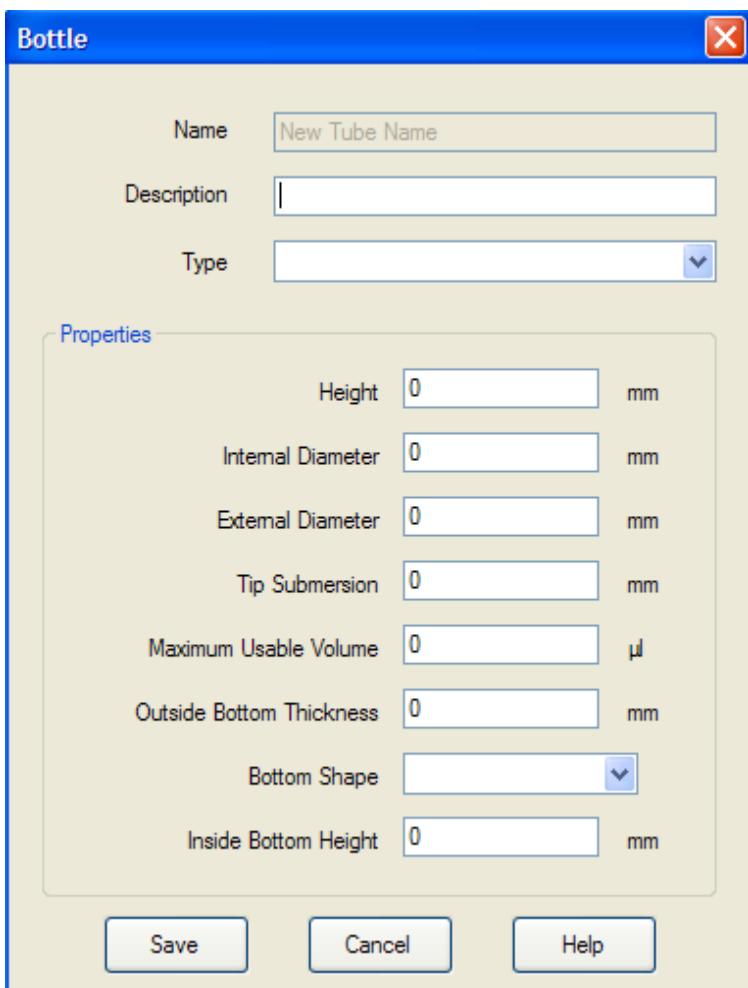


Figure E-3: Bottle Definition window

- a. Description: Description of the bottle (optional)
- b. Type: Select the tube type that best corresponds to the use of the new tube (For example: if the tube is used to hold test specimens, select Test Sample).
- c. Use a micrometer (preferred) or ruler to measure the tube:
 - i. Height: enter tube height (bottom to top) in mm.
 - ii. Internal Diameter: enter the diameter of the inside of the tube in mm (represented by the dotted line).

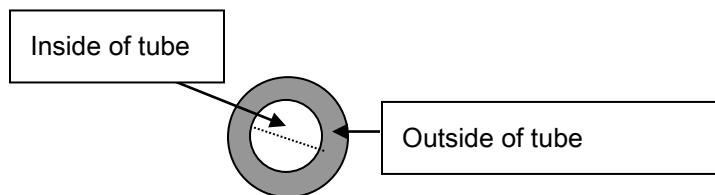


Figure E-4: Internal tube diameter

- iii. External Diameter: enter the diameter of the tube in mm (represented by the dotted line).

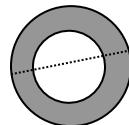


Figure E-5: External tube diameter

- iv. Tip Submersion: enter the number of mm the tip should submerge below the surface of the liquid while aspirating.
- v. Maximum usable volume: Enter the maximum useable volume in the tube in μL . The higher the maximum useable volume, the greater the dead volume required for the tube.
- vi. Outside bottom thickness and Inside Bottom Height: Enter both of these values in mm. Outside bottom thickness is the distance from where the fluid holding portion of the tube ends to the physical bottom of the tube. Inside Bottom Height is the distance from where the fluid holding portion of the tube begins to where the straight sides of the inside of the tube begin. See diagram below:

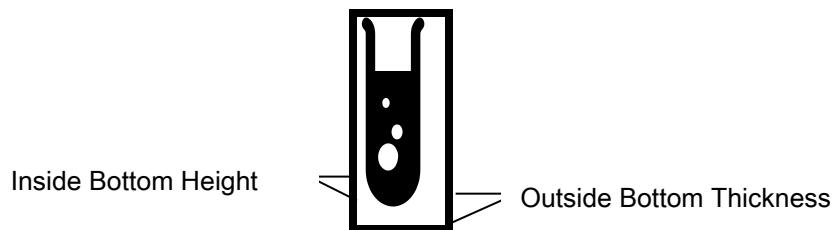


Figure E-6: Outside Bottom Thickness and Inside Bottom Height

- vii. Select a bottom shape from the drop down list.
 - viii. Click **Save** to save the settings.
7. Click the **Exit** button to leave the Database Maintenance window.

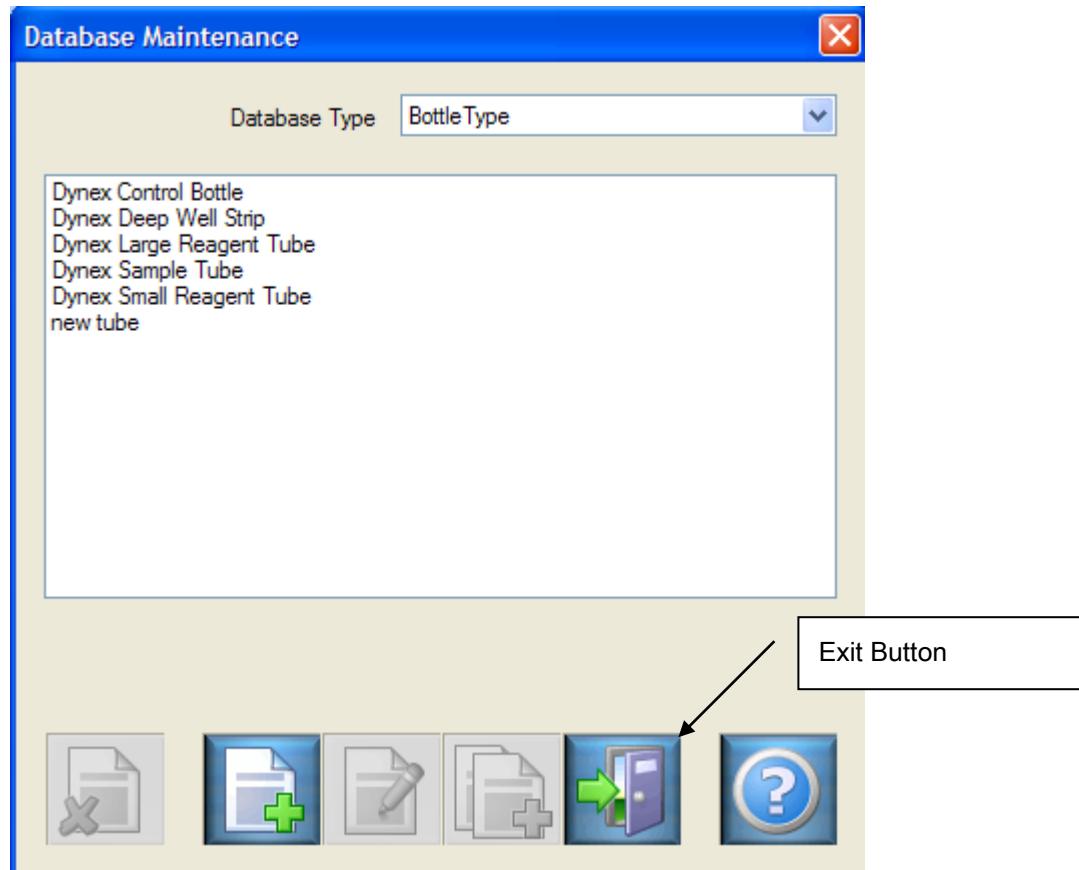


Figure E-7: Exiting the Database Maintenance Window

8. Select the **Tools** menu.
9. Select **Fluid Level Tracking**.
10. Select the newly created tube from the drop down list under **Selected Bottle Type**.

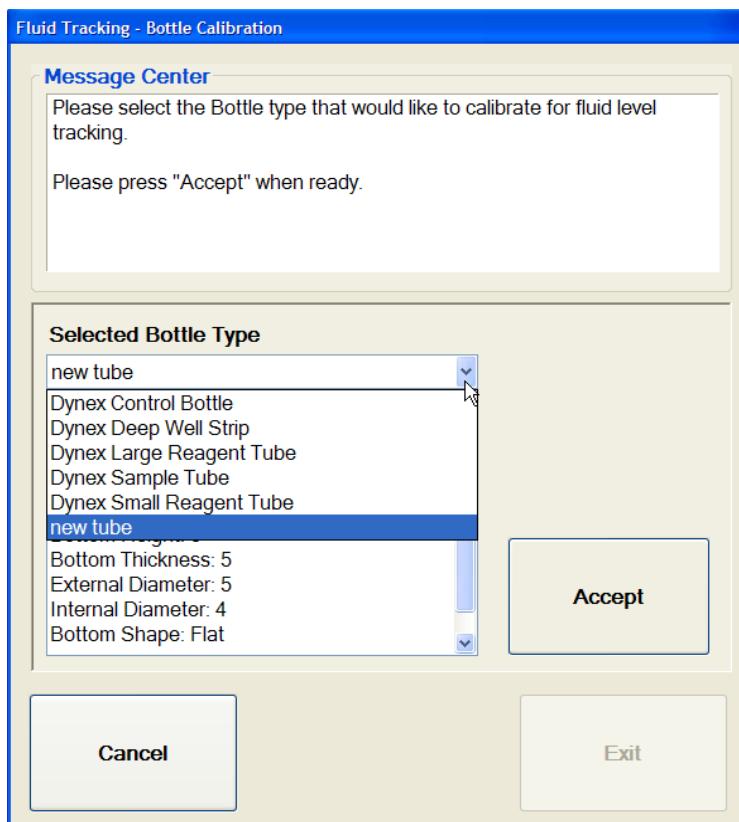


Figure E-8: Fluid Level Tracking Window

11. Follow the directions in the message center to calibrate the new tube. Once the tube has been calibrated using fluid level tracking, it is available for use on the DS2. **Do not use a new tube without performing fluid level tracking.**

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Appendix F Plate Definition

Custom plate definitions can be created in the DS-Matrix software by following the instructions below. A ruler capable of measuring in mm increments or a micrometer is required for accurate measurements.



Warning: *Improper plate definition can lead to incorrect results!*

1. Select the **Tools** menu.
2. Select **Database Maintenance...** from the drop down menu.
3. Select **Plate Type** as the Database Type.
4. Click the **Add Consumable** button:

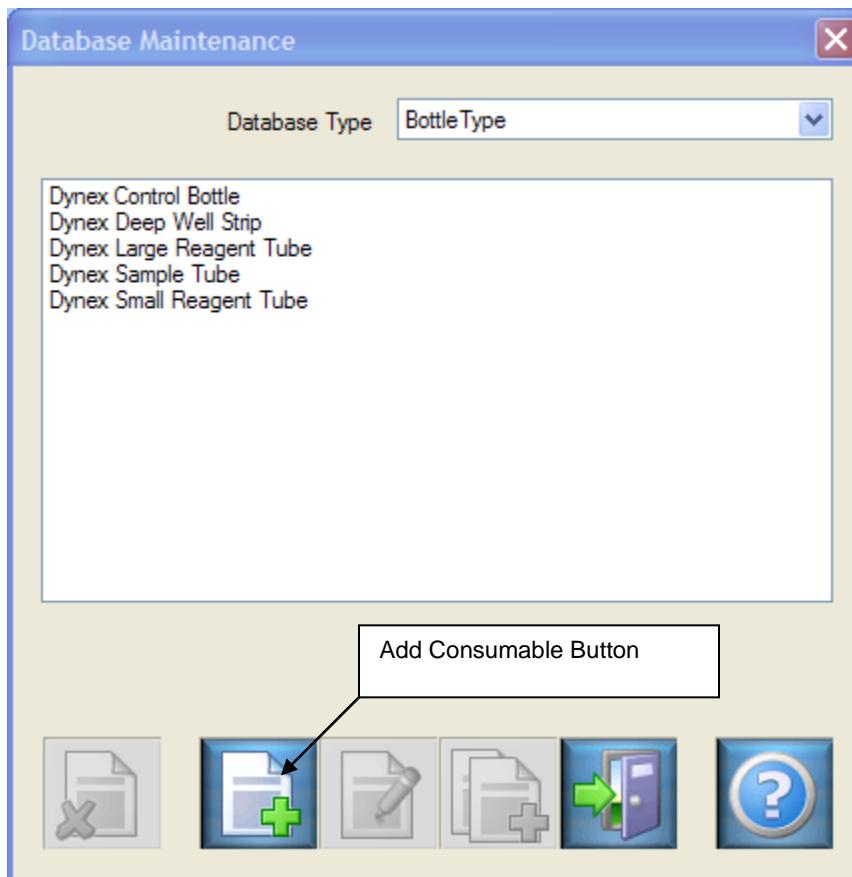


Figure F-1: Add Consumable button

5. Enter a name for the new plate and click **OK**.

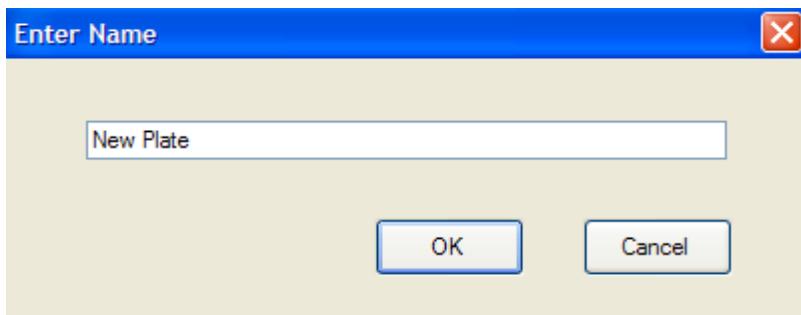


Figure F-2: Entering a new plate name

6. In the **Plate** window, enter the following information:

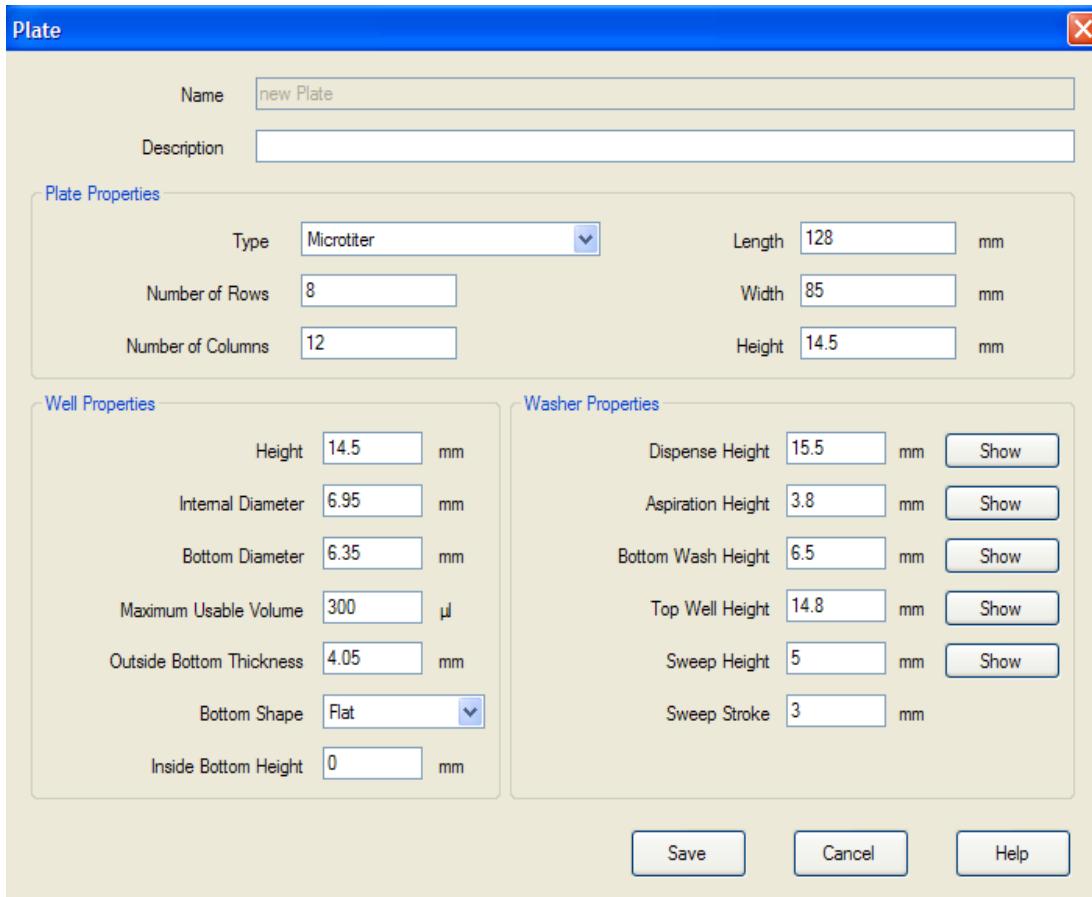


Figure F-3: Plate Definition Window

- Description: enter a description to clarify the plate name (Optional)
- In the **Plate Properties** area:

Plate Properties

Type	<input type="text" value="Microtiter"/>	Length	<input type="text" value="128"/>	mm
Number of Rows	<input type="text" value="8"/>	Width	<input type="text" value="85"/>	mm
Number of Columns	<input type="text" value="12"/>	Height	<input type="text" value="14.5"/>	mm

Figure F-4: Plate Properties Definition

- Select **Microtiter** as the plate **Type**.
- Enter the **Number of Rows** the plate contains.
- Enter the **Number of Columns** the plate contains.
- Enter the **Length** (longer side) of the plate in mm
- Enter the **Width** (shorter side) of the plate in mm
- Enter the **Height** of the plate in mm

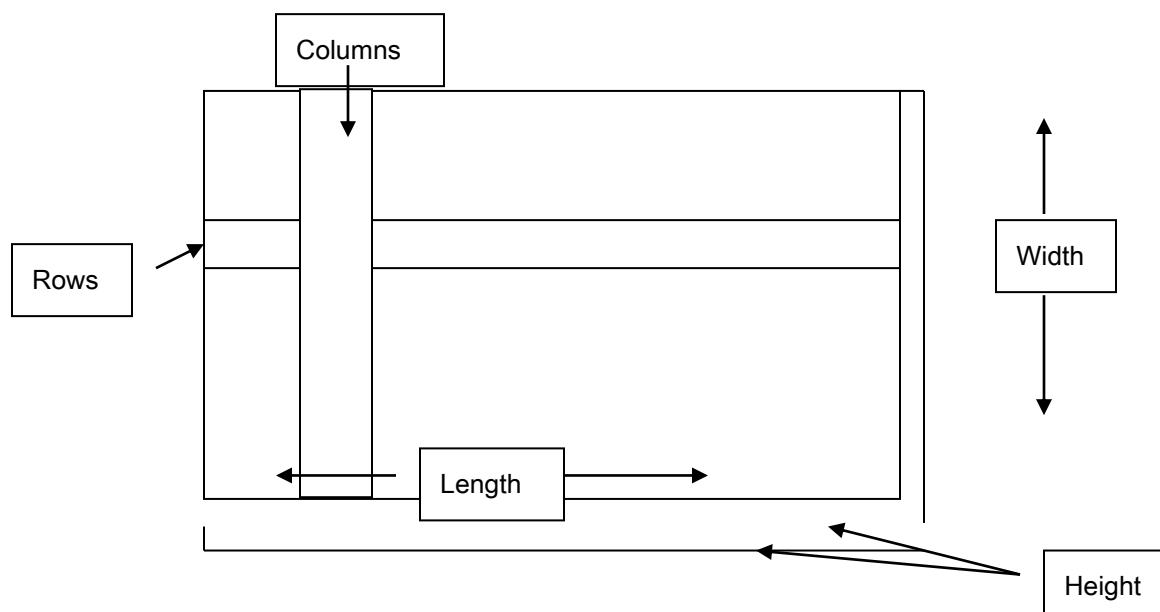


Figure F-5: Diagram Representation of Plate Properties

c. In the Well Properties area:

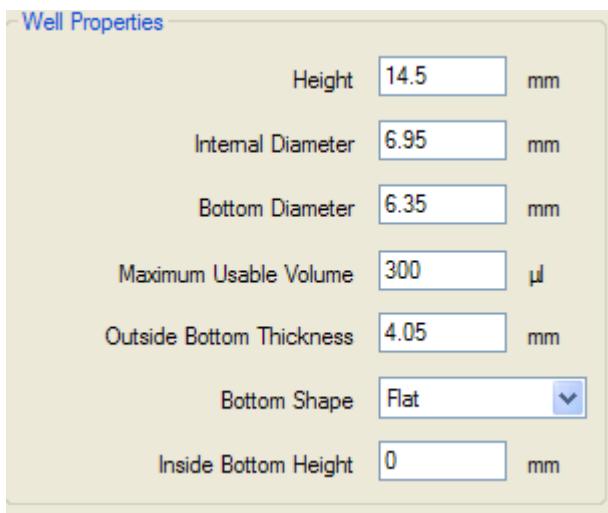


Figure F-6: Well properties definition

- i. Enter the well **Height**. The well height is measured from the outside of the bottom of the well to the outside of the top of the well.
- ii. Enter the **Internal Diameter**. The interior diameter is shown by the dotted line in the figure below. Interior diameter is measured near the top of the well.

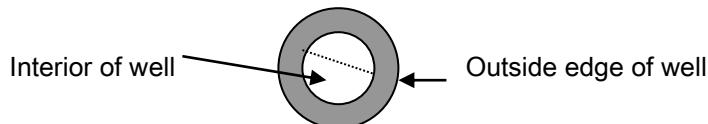


Figure F-7: Internal diameter of well

- iii. Enter the **Bottom Diameter**. The bottom diameter is the diameter of the well at the point closest to the bottom of the well.
- iv. Enter the **Maximum Usable Volume**. This is the volume of fluid that can safely be dispensed to the well without causing the well to overflow.
- v. Enter the **Outside Bottom Thickness**. The outside bottom thickness is equal to the internal well height minus the total well height (see step 6.c.i above for total well height).
- vi. Enter the **Bottom Shape**.

- vii. Enter the **Inside Bottom Height**. For flat bottom shaped microtiter plates, the Inside Bottom Height is always equal to zero. For "U" and "V" bottom plates, the inside bottom height is equal to the distance between the lowest point in the well and the point at which the sides of the well are straight.

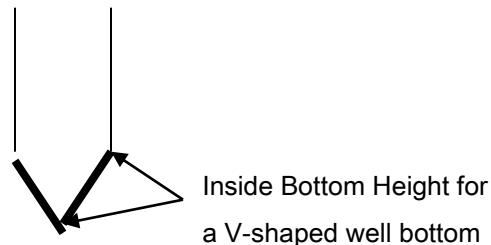


Figure F-8: Diagram of Inside Bottom Height

- d. In the Washer Properties area:

Washer Properties			
Dispense Height	<input type="text" value="15.5"/>	mm	Show
Aspiration Height	<input type="text" value="3.8"/>	mm	Show
Bottom Wash Height	<input type="text" value="6.5"/>	mm	Show
Top Well Height	<input type="text" value="14.8"/>	mm	Show
Sweep Height	<input type="text" value="5"/>	mm	Show
Sweep Stroke	<input type="text" value="3"/>	mm	

Figure F-9: Washer Properties Window

- **Note:** Insert a plate into the lower plate carrier. Clicking the **Show** button with a plate in the plate carrier moves the wash head assembly to the position associated with the Show button.

- i. Enter the **Dispense Height**. The Dispense Height is the level at which the wash head will dispense fluid into the well. At the Dispense Height, the aspirate pins (long pins) on the wash head should be just slightly higher than the top of the well (approximately 1 mm).
- ii. Enter the **Aspirate Height**. The aspirate height is positions the aspirate pins just above the bottom of the well. When the Show button is clicked the aspirate pins should not touch the bottom of the wells.
- iii. Enter the **Bottom Wash Height**. At the correct bottom wash height, the aspirate pins should be positioned in the approximate center of the well, a few mm above the aspirate height.
- iv. Enter the **Top Well Height**. At the correct top well height, the aspirate pins should be exactly even with the top of the well.
- v. Enter the **Sweep Height**. At the correct sweep height, the aspirate pins should be a millimeter or two higher than the aspiration height. The sweep height is the height the aspirate pins are lifted up off the bottom of the well to move to the sweep position. If well bottoms are scratched when washing the plate, the sweep height must be increased.
- vi. Enter the **Sweep Stroke**. The sweep stroke is the distance the aspirate pins move from the center of the well when operating in sweep mode or super sweep mode. The sweep stroke should be adjusted so that aspiration is optimized without scraping the sides of the wells.

Appendix G Multiple Tubes per Sample Feature

Multiple Tubes per Sample Feature

The multiple tubes/sample feature is a user configurable, “generic”, version of the existing spreadsheet Boolean Function feature. This feature cannot be accessed without the use of a licensing dongle available from Dynex Technologies.

This feature allows the assay programmer to:

- Specify the number of tubes assigned to one specimen.
- Specify the tube equation definitions (how the specimen result is calculated using multiple tubes), for example: TubeA = Tube A, TubeB_{final} = TubeB_{raw} – TubeA, etc.
- Specify the User specified evaluation equations. The evaluation equations are True/False in nature, for example: Tube A <= 8.0. The next evaluated equation depends on the answer to the True or False question.

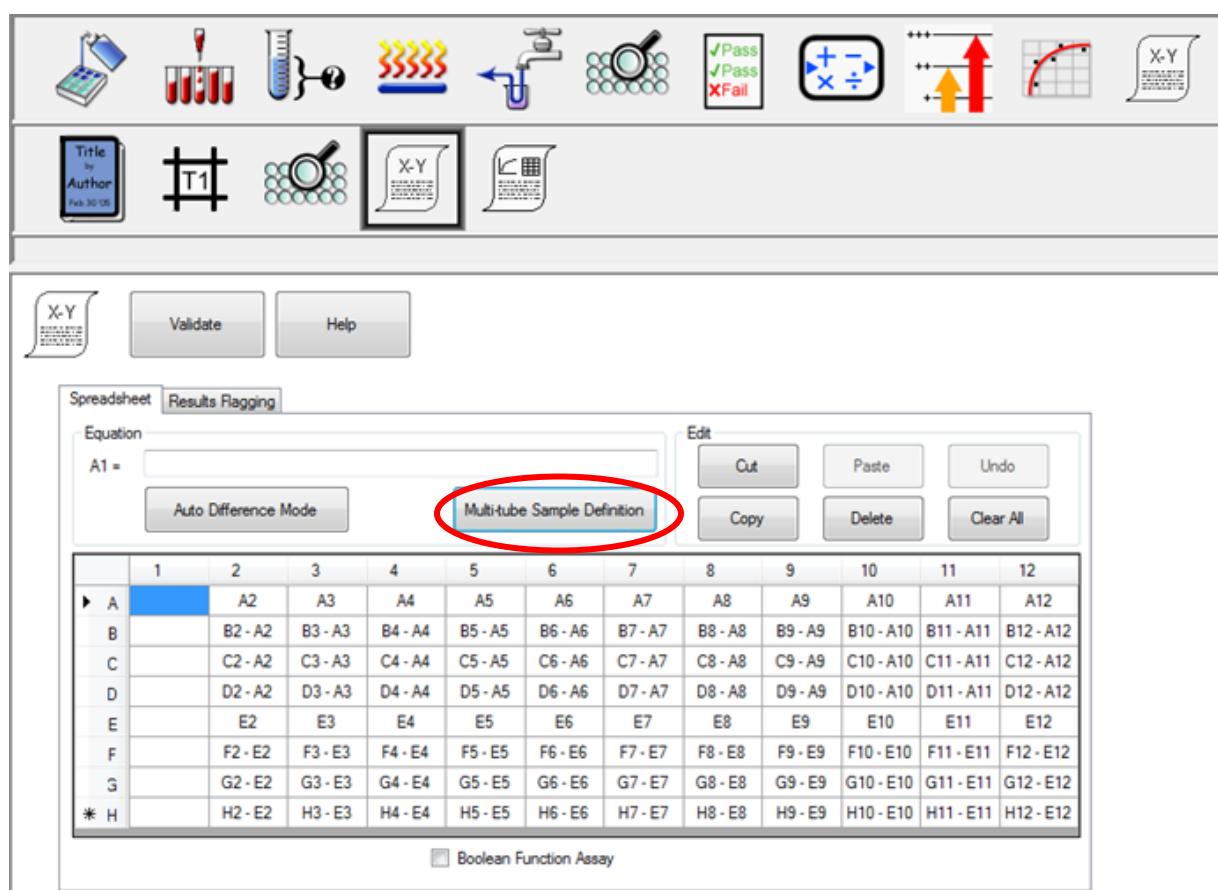


Figure 1. Multi-tube Sample Definition button (only visible when using licensing dongle)

To Program the Multiple Tube per Sample Feature in the Spreadsheet Operation:

- Click on the Multi-tube Sample Definition button (circled in red in Figure 1). The dialog shown in Figure 2 will appear (note: when writing a new program, text fields in this dialog will be empty):

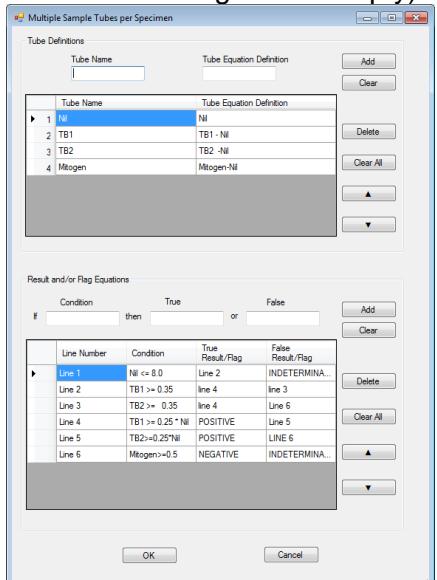


Figure 2. Multiple Sample Tubes per Specimen Dialog

- Enter the Tube Definitions

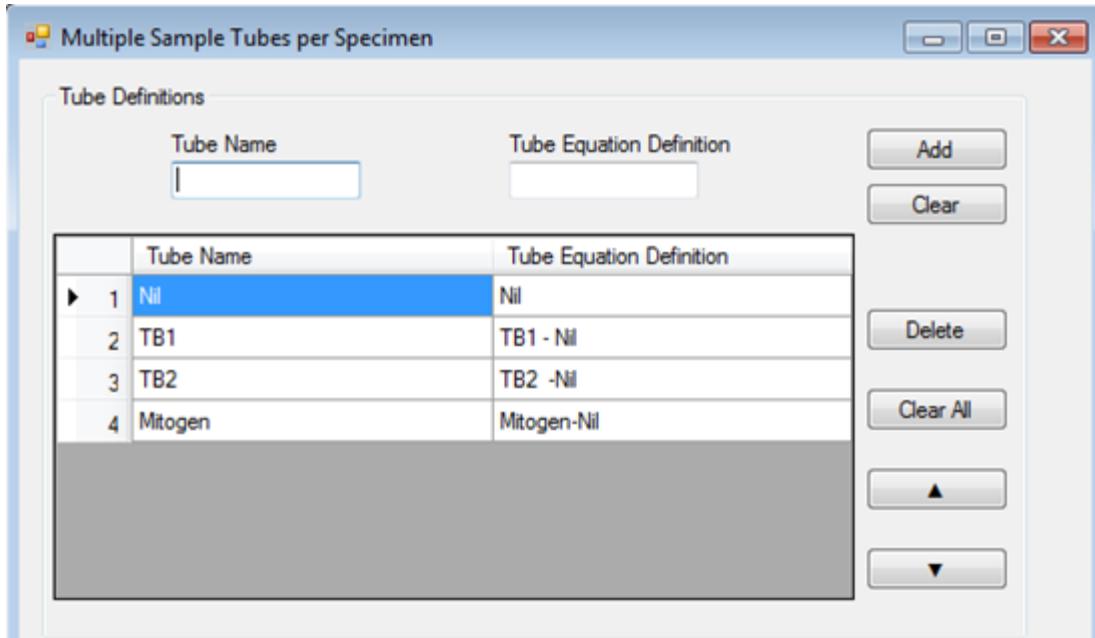


Figure 3. New Tube Definition

a. Defining a New Tube Definition

At the top of the Tube Definitions box are two text boxes: *Tube Name* and *Tube Equation Definition*. Enter in the tube name and definition from the assay package insert, and then select **Add**. The entered data will be added to the grid box below. The names entered in these boxes will also appear in the

report. Selecting **Clear** will clear the contents of the *Tube Name* and *Tube Equation Definition* text boxes.

b. Editing Existing Tube Definitions

Select a tube name by clicking on it. The desired text will auto populate the *Tube Name* and *Tube Equation Definition* text boxes. Edit the contents in the boxes or edit the data inside the grid cells. Selecting **Delete** will delete the selected tube. Selecting **Clear All** will delete all tubes. The **Up** or **Down** arrow will move the selected tube in the grid.

3. Enter the Result and/or Flag Equations

This section defines the Boolean (true/false) equations used to calculate sample results. Any sample result should eventually resolve to an output string (In the example in Figure 4 the output strings are: POSITIVE, NEGATIVE, or INDETERMINATE). Several equations may be needed to calculate the final result.

	Condition	True	False	Line Number	Condition	True Result/Flag	False Result/Flag
If	<input type="text"/>	<input type="text"/>	<input type="text"/>	Line 1	Nil <= 8.0	Line 2	INDETERMINATE...
	Line 2	TB1 >= 0.35	line 4	Line 3			
	Line 3	TB2 >= 0.35	line 4	Line 6			
	Line 4	TB1 >= 0.25 * Nil	POSITIVE	Line 5			
	Line 5	TB2 >= 0.25 * Nil	POSITIVE	LINE 6			
	Line 6	Mitogen >= 0.5	NEGATIVE	INDETERMINATE...			

Figure 4. Result and/or Flag Equations Entry

a. New Evaluation Rule

- At the top of the Result and/or Flag Equations box are three text boxes: Condition, True, and False. Enter in the desired data, and then select **Add**. The entered data will be added to the grid box below. A line number will automatically be assigned to the data. Selecting **Clear** will clear the contents of the Condition, True and False boxes.
- Condition is some equation that will evaluate to a true or false answer. The Condition text box permits the use of white space. The Condition text box requires an equation symbol (<, <=, ==, !=, >=, >) between the first and second tube equation definitions as show in Figure 4.
- True defines what happens when the Condition is true.
- False defines what happens when the Condition is false.
- True Result Flag and False Result Flag Column formatting
- Either the equation defines the final result or the next equation needs to be evaluated.

- If the cell does not contain the word LINE then it is the final result and sample evaluation is complete.
 - If the word LINE is found execution will continue at that grid line. While it is tolerant of capitalization a blank character is required between the word LINE and the number digit.
- b. Editing Evaluation Rules
- Select an entry by clicking on it. The contents will automatically populate the Condition, True and False boxes. You can edit the contents in the text boxes or you can edit the data inside the grid cells. Selecting Delete will delete the selected equation. Selecting Clear All will delete all equations. The Up or Down arrow will move the selected equation in the grid. When moving equations, ensure the references Line numbers in the True Result Flag and False Result Flag Columns are still accurate. Dynex recommends arranging the equation entries into the proper order prior to assigning line numbers to the True and False Result Flag Columns.
- c. How Rule Evaluation Works
- For each sample, evaluation begins with Line 1. For Example, in Figure 5-49, if Nil <= 8.0 is FALSE then the Result is INDETERMINATE and the sample evaluation is complete. Otherwise the software will perform the equation in Line 2.
 - The actual OD (or derived from OD) data is defined in the Tube Definition area and is automatically calculated by the standard spreadsheet operation. For example TB2 = TB2-Nil.
 - Lines 2 and 3 compare TB* to 0.35. In Line 2 if TB1 >= 0.35 the software will evaluate the result by comparing TB* to Nil (line 4). Otherwise the software will evaluate the data by the equation in Line 3 and compare TB2 to 0.35. If TB2 >= 0.35 the software will then compare TB* to Nil (line 4). Otherwise the software will evaluate the data in Line 6 and measure the Mitogen level.
4. When all tube definitions and assay equations are entered, select **OK** to return to the Assay Editor Spreadsheet Operation dialog. The Spreadsheet Operation dialog will update its cell definitions to match the tube definitions defined in the Multiple Sample Tubes per Specimen dialog.

Using the Multiple Tubes per Specimen Feature when Creating a Worklist:

When using the multiple tubes per sample feature, there may be 3 or 4 tubes per sample.

Load the sample tubes into the sample racks in the expected consecutive order.

For example:

Patient	Tube	Sample Rack Location
Amy	Tube A	01
	Tube B	02
	Tube C	03
	Tube D	04
Bob	Tube A	05
	Tube B	06
	Tube C	07

Patient	Tube	Sample Rack Location
	Tube D	08
Cindy	Tube A	09
	Tube B	10
	Tube C	11
	Tube D	12

Figure 5. Example of Loading Multiple Tubes per Sample in the Sample Racks

After loading the sample tubes into the sample racks in the correct order, barcode scan the sample tubes. In the event that each of the tubes for the specimen have the same barcode, the DS-Matrix software will issue a warning message and automatically append the duplicate IDs prior to proceeding. If the sample barcodes are already unique for each of the sample tubes the software will not issue a warning and will proceed directly to the assay selection screen.

When duplicate IDs are detected, the software will display the following dialog:

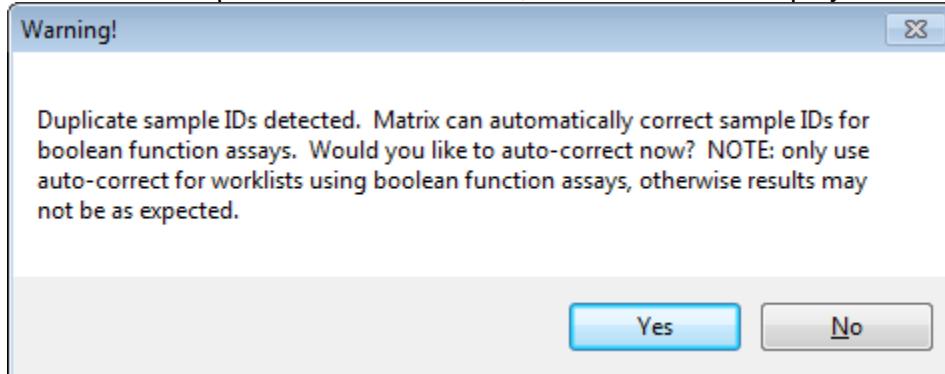


Figure 6. Warning to Auto-correct duplicate IDs

In order to proceed, the operator must choose “Yes” and allow the software to update the duplicate sample IDs. The first sample ID in the series will remain unchanged, and all subsequent tubes will be appended with a unique suffix. When “Yes” is selected, the assay selection screen will display for the operator to choose the assay for the worklist. The appended IDs are visible on the left side of the screen (Figure 8)

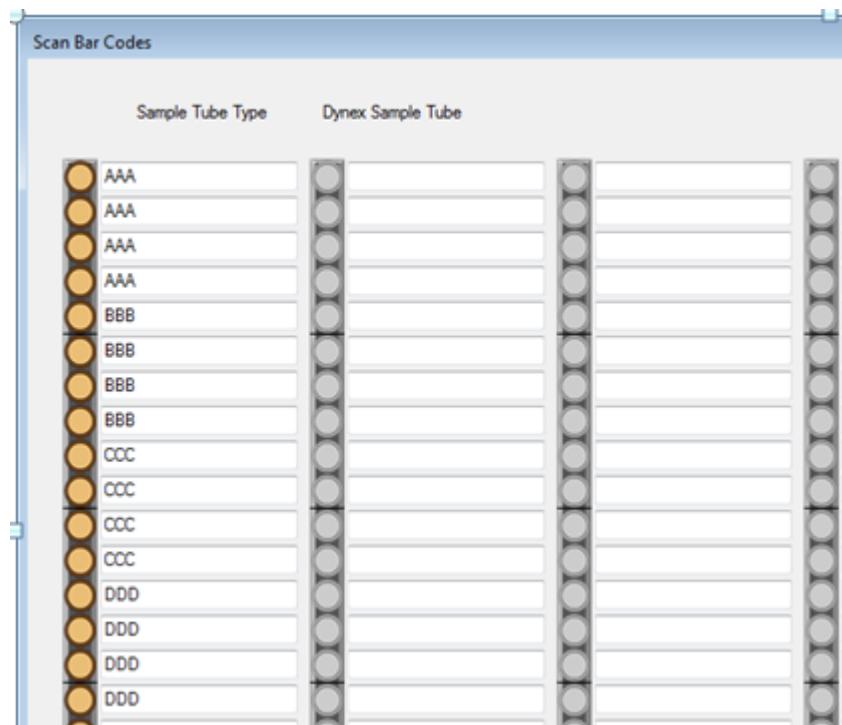


Figure 7. Barcode Scan IDs Prior to Appending

The DS2 detects the duplicate sample tube labels and asks the operator for permission to auto-adjust the sample IDs.

When “YES” is selected, the ID for the first tube (AAA in this example) is unchanged. The second tube AAA is appended with “-a”, The third tube AAA is appended with “-b”, and the fourth tube AAA is appended with “-c”. The software automatically displays the Assay Selection screen after appending the Sample IDs as shown in Figure 8.

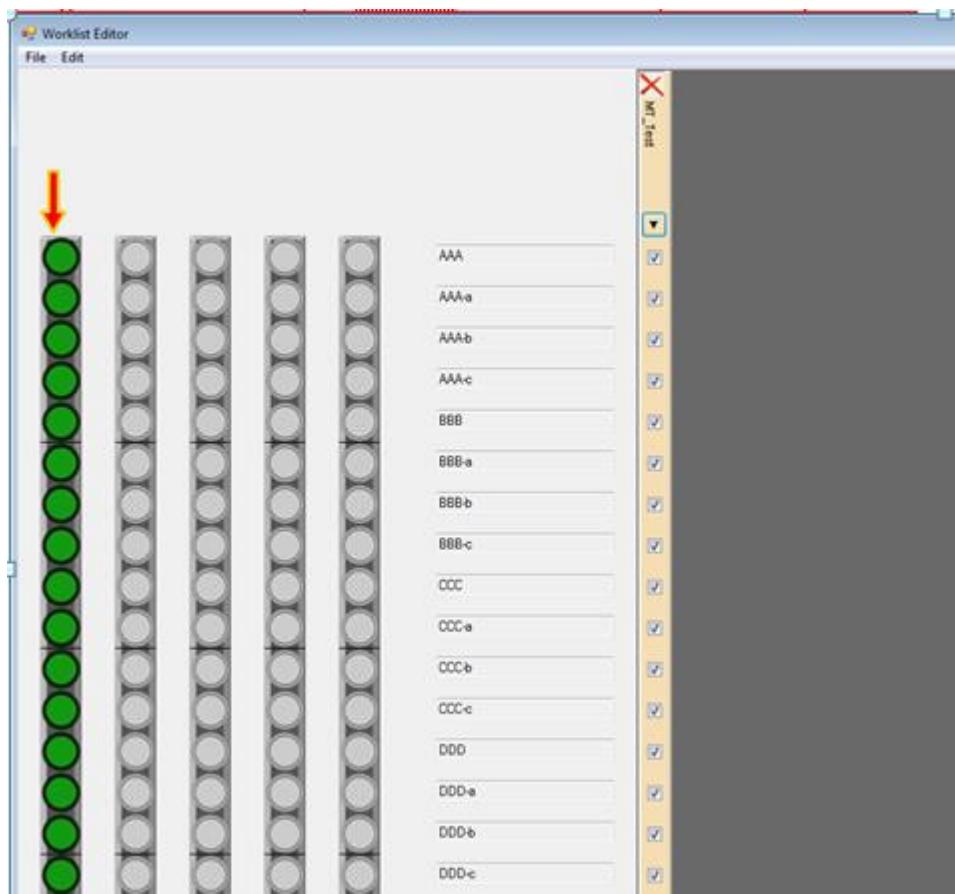


Figure 8. Auto-adjusted sample IDs in Assay Selection screen.

When the Green Check Mark button is selected, normal worklist execution begins. When executing the worklist, multiple tubes per sample assays follow the same sequence of events as single tube/sample assay programming. There is no difference in scheduling, fluid transfer, incubation or washing operations.

Reports with Multiple Tubes per Sample Results:

Under the Spreadsheet Results there is a MULTITUBE BOOLEAN FUNCTION RESULTS table section. It automatically sizes itself to the tube/sample count specified by the assay program. The column headings are derived from the assay tube definition created by the user in the Spreadsheet operation. There are columns for Sample Id, each Tube defined by the user (Nil, TB1, TB2, Mitogen), each compound tube (TB1-Nil, TB2-Nil, Mitogen-Nil), and the Result.

Using LIS-Link with the Multiple Tubes per Sample Feature:

To send multiple tubes/sample results to the LIS program it is necessary to use LIS-Link version 2.02.

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