Affymetrix® Molecular Diagnostic Software User's Guide

CE

IVD

For in vitro diagnostic use.

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CONTENTS

Chapter 1 Welcome to AMDS 7

Introduction 7

Intended Use 7

System Description 8

Terminology 11

How This Guide Is Organized 13

Conventions Used in This Guide 13

Resources 15

Other Documentation 15

Technical Support 16

Chapter 2 AMDS Overview 19

Introduction 19

Assay Workflow 20

Description of Assay Workflow Steps 21

Preparing The Target Sample 22

Creating, Editing and Deleting the Test Request 22

Registering the Test Request 22

Hybridizing the Test Request Assay 23

Washing and Staining the Array in the Fluidics Station 24

Scanning the Test Request Assay—the AutoLoaderDx 25

Computing Cell Intensities 25

Displaying and Archiving Test Results 26

Chapter 3 AMDS User Interface and Workflow 27

Introduction 27

The AMDS Application 28

The AMDS User Interface 28
Workflows and Worklists 29
The Left Panel—The Workflow 29
The Center Panel—The Worklists 31
Active Worklist 32
Registration Worklist 33
Hybridization Worklist 34
Fluidics Worklist 35
Scanner Worklist 36
Reviewing Test Results 37
Non-Active Worklist 38
The Right Panel—User and Instrument Details 39
User Details 40
Device Status 40
Alerts 42
Alert Details and Recommended Resolution 42
Roles and Privileges 42
The Administrator Panel 43
Administrator Functions 44

Chapter 4 Test Request Processing 45

Introduction 45
AMDS Quick Reference Guide 45
Using the Barcode Reader 51
Handling the Array Cartridge 52
Starting AMDS 54
Turning on the System 54
Changing Your Password 57
Logging Off 58
Shutting Down 59
Managing Test Requests 60
Creating, Editing and Cancelling Test Requests—The Active Worklist 60
Creating the Test Request 61

Editing Test Requests 65
Deleting Test Requests 67
Cancelling Test Requests 68
Associating Reagent Lot Numbers to Multiple Test Requests—Assay Batch 70
Registering a Test Request 71
Processing Test Requests 75
Hybridizing an Array 76
Washing and Staining an Array in the Fluidics Station 81
Scanning an Array 85
Scanning the Array in Normal Operational Mode 86
Scanning Arrays in Manual Mode—Manual Scan 87
Stopping a Scan 88
Adding Arrays During a Scanning Run 88
Reviewing Test Results 89
Batch Analysis Assay 92

Chapter 5 The AMDS Administrative Features 95

Quick Reference Guide 95
Viewing Logs 102
System Logs 102
Audit Logs 103
Managing the Assay 105
Installing an Assay 105
Installing a Certificate 106
Deactivating an Assay 107
Managing the Users 109
Adding a User 109
Editing a User 111
Managing the System 113
Changing the Instrument Settings 113
Managing the Fluidics Station 114
Managing the Workstation 116
Managing the Printer 117

Managing the Firewall Settings 119
Viewing Instrument Service Logs 120
Archiving Test Requests 121
Setting the General Configuration 122

Chapter 6 AMDS Troubleshooting 127

Introduction 127
First Type of Problem—Resolving Instrument Related Errors 128
Second Type of Problem—Resolving Individual Test Requests Errors 129
Third Type of Problem—Resolving Operational and Data Input Errors 129
Resolving Alerts 130
Resolving Alerts Procedure 131
Instrument Troubleshooting 132
Fluidics Station 133
AutoLoader 133

Appendix A The Fluidics Station 450Dx 135

Introduction 135
Warnings and Precautions 136
Instrument Components 138
Using the Fluidics Station 450Dx 141
Assay Documentation 141
Using the Barcode Reader with the Fluidics Station 142
The Fluidics Station 450Dx Protocols 142
Setting Up an Assay 143
Sample Hybridization Protocol Using the Fluidics Station 143
Sample Staining Protocol 144
Operating the Fluidics Station 145
Starting the Fluidics Station 145
Running a Fluidics Station Protocol 146
Shutting Down 156
Fluidics StationDx Care and Maintenance 160
Introduction 160

Instrument Care 160
Fluidics Station Bleach Protocol 160
The Bleach Cycle 161
The Rinse Cycle 166
Peristaltic Tubing Maintenance 169
Setting the Peristaltic Tubing Maintenance Parameters 169
Replacing the Peristaltic Tubing Procedure 171
Fluidics Station Troubleshooting and Assistance 173
Troubleshooting Decision Tree 173
Problems and Solutions 176
Meaning of Error Messages 180
Other Problems and Solutions 182
FS450Dx LCD Messages 184
The FS450Dx Instrument Specifications 187
Regulatory Compliance 188
CE Mark Declaration of Conformity 188
Regulatory 189
China RoHS Restriction of Hazardous Substances Compliance 190
SJ/T11364-2006 电子信息产品污染控制标识要求 192

Appendix B The Scanner 3000Dx with AutoLoaderDx 195

Introduction 195
Safe Operation 196
When to Contact Affymetrix 197
Laser Safety 197
Electrical Safety 199
Workstation - AutoLoader Connections 200
Connecting the Barcode Reader 203
AutoLoaderDx Indicator Lights and On/Off Button 204
Scanning Arrays 207
Using Tough-Spots™ to Prevent Leaks 207
Loading Arrays into the Carousel 208
Loading the Carousel into the AutoLoaderDx 210
Starting the AutoLoaderDx 212
Shutting Down the AutoLoaderDx 212

Cleaning and Maintenance 213

Configuring the AutoLoaderDx 213

Troubleshooting 214

Troubleshooting the AutoLoaderDx 214
Issues Relating to the AutoLoaderDx's Operation 215
Troubleshooting the AutoLoaderDx 217
AutoLoaderDx Error Messages 218
Manually Removing a Lodged Array Cartridge 220

The AutoLoaderDx Specifications 224

Regulatory Compliance 225

CE Mark Declaration of Conformity 225
Regulatory 227
China RoHS Restriction of Hazardous Substances Compliance 228
SJ/T11364-2006 电子信息产品污染控制标识要求 231

Index 235

Chapter 1 WELCOME TO AMDS

Introduction

Welcome to the Affymetrix® Molecular Diagnostic Software (AMDS) User's Guide.

The AMDS User's Guide provides details concerning both the workflow and administrator functions of the AMDS part of the Affymetrix Microarray Instrumentation System. AMDS Quick Reference Card (p/n 08-0262) is a complement to this user guide and provides an overview of AMDS.

This manual explains how to use the AMDS to:

- Create and process test requests and generate test results
- Perform administrative tasks such as:

  Managing user properties

  Performing systems management

  Installing, activating, and deactivating assays

  Viewing and archiving logs and records

Intended Use

The Affymetrix GeneChip® Microarray Instrumentation System, consisting of the GeneChip 3000Dx v.2 scanner with AutoLoaderDx, FS450Dx v.2 fluidics station and the Affymetrix Molecular Diagnostics Software, is intended to measure fluorescence signals of labeled DNA target hybridized to GeneChip arrays.

WARNING: Operators are responsible for following internal security policies to ensure security of patient data.

System Description

AMDS controls the assay work flow process of the Affymetrix Microarray Instrumentation System. The goal of the Microarray Instrumentation System is to produce a final test result based on the Affymetrix GeneChip® array technology. At the end of assay process, the software provides this test result in the form of a report that you can print and which the software archives as a file for further analysis.

AMDS is part of the larger Microarray Instrumentation System application suite. This suite consists three parts:

1. Affymetrix Software Developer's Kit (ASDK)—this provides the assay developer with all the tools necessary for the creation of a specific assay sofware module for use on the AMDS system.
2. Assay Software Module— this provides all the parameters necessary to process a specific Affymetrix® GeneChip® array from hybridization through fluidics to scanning to create a meaningful test result. AMDS identifies a particular assay software module by the Assay Name.
3. AMDS—this guides the user through all the steps necessary to process a GeneChip® array as a Test Request that uses the Assay Name as the blueprint to control the various array processes from hybridization though fluidics, scanning, log keeping and result printing and archiving.

NOTE: This user's guide deals only with the AMDS application.

AMDS is part of the Affymetrix® GeneChip® array laboratory system and works in connection with the following hardware (Figure 1.1 and Figure 1.2).

- A workstation equipped with a hardware firewall and installed with AMDS
- The Affymetrix® GeneChip® Fluidics Station 450Dx v.2 (aka the fluidics station)

- For more detailed information about the fluidics station, see the appendix, *The Fluidics Station 450Dx, on page 135*

- The Affymetrix® GCS3000 Scanner with AutoLoaderDx
  - For more detailed information about the scanner-AutoLoaderDx, see the appendix, *The Scanner 3000Dx with AutoLoaderDx, on page 195*.
- A printer
- A barcode reader
- An uninterruptible power supply

IMPORTANT: Depending on the particular assay, the system may also require a hybridization, or incubation, oven to aid in hybridizing the specimen to the array. This item is not part of the Microarray Instrumentation System.

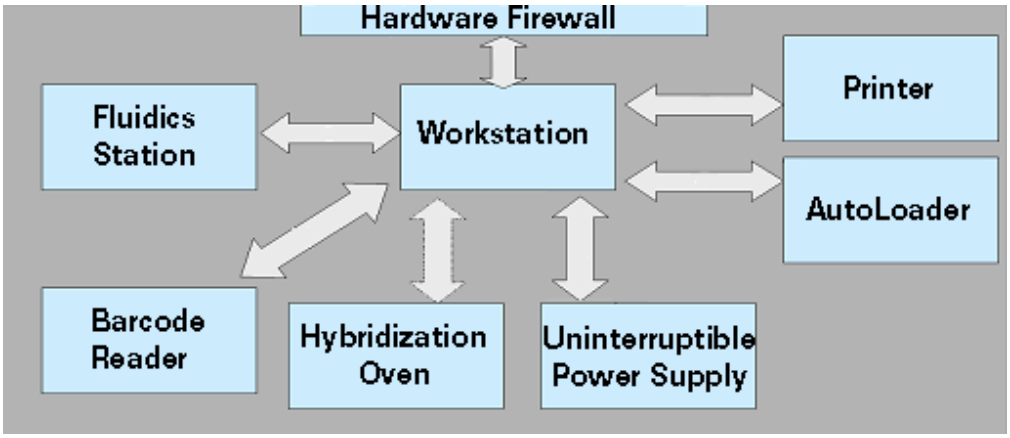

Figure 1.1 Schematic of the Microarray Instrumentation System hardware

Figure 1.2 The Microarray Instrumentation System major hardware components: Fluidics Station 450Dx, workstation terminal and GCS3000 Scanner with AutoLoaderDx

You can also use a barcode reader to enter barcode information such as that found on the following items: the GeneChip array cartridge, the fluidics station, the specimen identification, the reagent lot number and other identification information. (Figure 1.3).

See the section, *Using the Barcode Reader, on page 51* for more information on using the barcode reader.

Figure 1.3 The barcode reader

You may use your own hybridization oven. Affymetrix uses a new model oven, the Hybridization Oven 645 (Figure 1.4).

If you are using the GeneChip® Hybridization Oven 645, refer to the *GeneChip® Hybridization Oven 645*, P/N 08-0255, for detailed instructions.

Figure 1.4 The Affymetrix GeneChip® Hybridization 640 (left) and 645 (right)

Terminology

This user guide makes a distinction among the terms test request, assay, array and array cartridge although many users of the AMDS system employ these terms interchangeably.

The "test request" is a database record of the specimen identification (Specimen ID), the assay parameters (Assay Name) and a unique array cartridge identification number (Array ID), as well as supplementary specimen information. You set this up when you create, or enter, a test request.

The specimen "assay," which the partner has designed using the assay software module, employs the Affymetrix® GeneChip® array or the partner manufactured microarray to process the specimen and generate test results. An assay is a procedure, i.e., a collection of steps based on the assay parameters that tell AMDS how to process an array. AMDS also refers to the nucleic acid test sample as the "target."

An array is the physical microarray component that technicians created based on the specimen type and assay parameters. This consists of a glass substrate on which was placed oligonucleotide sequences. A plastic cartridge surrounds and protects the array and forms the array cartridge. We use the term "array" mainly to refer to the array itself and what AMDS does to the array based on the assay parameters. For example AMDS hybridizes, washes and scans an array based on the assay parameters.

We use the term "array cartridge" to refer to the physical array unit that you handle. The array cartridge is the plastic enclosure (Figure 1.5) that supports and protects the array on the glass chip as it proceeds through the AMDS workflow. For example you carry an array cartridge to a hybridization oven, insert an array cartridge into a fluidics station, or insert an array cartridge into the AutoLoaderDx.

For convenience, we also refer to the GeneChip Fluidics Station 450Dx as the fluidics station or as the FS450Dx and the GeneChip Scanner 3000Dx with AutoLoaderDx as the AutoLoaderDx.

Figure 1.5 Affymetrix GeneChip® array cartridges

How This Guide Is Organized

Chapter 1 deals with the introduction to the AMDS system.

Chapter 2 deals with a more detailed AMDS overview and the concept of workflow.

Chapter 3 introduces the AMDS graphic user interface (GUI) and the concept of roles and privileges.

Chapter 4 shows you in detail how to process a specimen sample through the AMDS workflow. This is the most important chapter for technicians who will directly run the samples.

Chapter 5 introduces you to the AMDS administrative features. This chapter is for those who have administrative privileges.

Chapter 6 is a brief chapter on the printing of results and logs.

Chapter 7 shows you how to perform basic troubleshooting.

Appendix A describes in detail how the Fluidics Station 450Dx works and how to perform basic maintenance. You must read and understand this chapter before attempting to process arrays.

Appendix B describes in detail how the AutoLoaderDx works and how to perform basic maintenance. You must read and understand this chapter before attempting to process arrays.

Conventions Used in This Guide

This manual provides a detailed outline for all tasks associated with AMDS. Various conventions are used throughout the manual to help illustrate the procedures described. Explanations of these conventions are provided below.

Instructions for procedures are written in a step format. Immediately following the step number is the action to be performed.

Following the response, additional information pertaining to the step may be found and is presented in paragraph format. For example:

> Click **Yes** to continue.
>
> The task proceeds.

Text Alerts

Text alerts will draw your attention to a particular piece of information. There are five types of text alerts: Note, Tip, Important, Caution and Warning.

NOTE: **The Note format presents important information pertaining to the text or procedure being outlined.**

TIP: **Information presented in Tips provide helpful advice or shortcuts for completing a task.**

IMPORTANT: **Important notes alert you to information important to the understanding or implication of the procedure or text.**

CAUTION: **Caution notes advise you that the consequence(s) of an action may be irreversible and/or result in lost data.**

WARNING: **Warnings alert you to situations where physical harm to person or damage to hardware is possible.**

Resources

Other Documentation

The following quick reference cards are available in various languages.

Part Number	Quick Reference Card Title
08-0262	Affymetrix® Molecular Diagnostic Software—AMDS Quick Reference Card, English
08-0270	Affymetrix® Molecular Diagnostic Software—AMDS Quick Reference Card, French
08-0271	Affymetrix® Molecular Diagnostic Software—AMDS Quick Reference Card, German
08-0272	Affymetrix® Molecular Diagnostic Software—AMDS Quick Reference Card, Italian
08-0273	Affymetrix® Molecular Diagnostic Software—AMDS Quick Reference Card, Spanish
08-0274	Affymetrix® Molecular Diagnostic Software—AMDS Quick Reference Card, Portuguese
08-0275	Affymetrix® Molecular Diagnostic Software—AMDS Quick Reference Card, Dutch
08-0276	Affymetrix® Molecular Diagnostic Software—AMDS Quick Reference Card, Danish
08-0277	Affymetrix® Molecular Diagnostic Software—AMDS Quick Reference Card, Swedish
08-0278	Affymetrix® Molecular Diagnostic Software—AMDS Quick Reference Card, Greek
08-0284	Affymetrix® Molecular Diagnostic Software—AMDS Quick Reference Card, Japanese

Technical Support

If you have questions or require technical support, please contact Affymetrix technical support.

If you are experiencing instrument (FS450Dx or AutoLoaderDx) problems, especially under any of the following conditions, unplug the instrument from the power source and contact Affymetrix Technical Support:

- when the power cord is damaged or frayed;
- if any liquid has penetrated the instrument;
- if, after service or calibration, the instrument does not perform to the specifications stated in the section, *The FS450Dx Instrument Specifications* *on page 187* or the section, *The AutoLoaderDx Specifications* *on page 224*.

If the instrument must be returned for repair, call Affymetrix technical support.

!

IMPORTANT: Make sure you have the model and serial number.

Affymetrix, Inc.

3420 Central Expressway
Santa Clara, CA 95051
USA
www.affymetrix.com

E-mail: support@affymetrix.com
Tel: 1-888-362-2447 (1-888-DNA-CHIP)
Fax: 1-408-731-5441

Affymetrix UK Ltd. EC REP

Voyager, Mercury Park,
Wycombe Lane, Wooburn Green,
High Wycombe HP10 0HH
United Kingdom

Tel: +44 (0) 1628 552550
Fax: +44 (0) 1628 552585
France Tel. +33 800919505
Germany Tel. +49 1803001334
supporteurope@affymetrix.com

Affymetrix Pte. Ltd. (Singapore)
7 Gul Circle
Keppel Logistics Building, Level 2M
Singapore
Tel: (65) 6395 7200
Fax: (65) 6395 7300

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Chapter 2 AMDS Overview

Introduction

AMDS provides the ability to process a microarray based on assay parameters. This includes:

- processing test requests through the AMDS application workflow
- creating test requests
- registering test requests
- hybridizing the array
- washing and staining the array in a fluidics station
- scanning the array in the GeneChip® AutoLoaderDX
- creating a test report

AMDS also manages the assay workflow: The system provides for:

- **Viewing Logs:** the system provides the ability to view logs, both audit and system logs, which record activities performed on the system. See *Viewing Logs, on page 102*.
- **Assay Management:** the system provides the ability to install and deactivate assays. The software manages assays through the worklist management function. See *Managing the Assay, on page 105*.
- **User Management:** this includes creating users and passwords, activating and deactivating users. The system also provides the ability to manage access to the system by associating users with groups. A group defines roles and permissions that control what system functions AMDS allows the user to perform. AMDS can also associate users with assays that AMDS allows them to run. See *Managing the Users, on page 109*.

- **System Management:** the system provides the ability to maintain the system, including performing regular maintenance, and performing regular systems checks. See *Managing the System, on page 113*.

Assay Workflow

The AMDS automates instrument control and provides a central infrastructure to acquire and track test requests. However, AMDS does not control target preparation. You must refer to the relevant Affymetrix package inserts and other documentation available for specimen handling and target preparation.

Table 2.1 shows the major steps and software functions in an assay.

Table 2.1 AMDS workflow quick reference guide

Assay Step	Output	Software Function
Prepare the target	Prepared sample that you can place onto an array.	Performed outside of the AMDS system control.
Target registration	Associate the target specimen with a unique array type and with reagent lot numbers.	AMDS associates the sample with the reagent used in preparation of the sample as well as with the Array ID. AMDS will then track the test request processing through the workflow to generation of a test report.
Hybridize, wash, and stain the array.	Hybridized, washed, and stained target specimen.	AMDS tracks the hybridization of the target specimen, which may be performed in a hybridization oven or on the fluidics station, depending on the assay parameters. The system also controls the washing and staining of the target specimen in the fluidics station as defined in the fluidics scripts associated with a particular assay type.

Table 2.1 AMDS workflow quick reference guide (Continued)

Assay Step	Output	Software Function
Scan	Image data (cell intensity data, .cel file)	AMDS automates control of the scanner, acquires and saves the scan data. The system automatically computes and saves the cell intensities from the image data as a .cel file. The system tracks the image and cell intensity data.
Run Test Report	Test report	An Affymetrix or partner created assay module generates test results.

AMDS provides a workflow-based tracking system for the data. The worklist manager (see the section, *Workflows and Worklists, on page 29*) tracks test request status through a series of steps that includes:

- Registration
- Hybridization
- Fluidics washing
- Scanning
- Test report generation

You can easily confirm the status of a test request that has not been purged from the system. See the section, *Archiving Test Requests, on page 121* for information on archiving and purging test requests. Active test requests, those that have not completed all steps of processing, will appear in the Active Worklist. See the section, *Active Worklist, on page 32* for more information on Active Worklists. Completed or cancelled test requests that have not yet been purged from the system, will appear on the Non-Active Worklist (See the section, *Non-Active Worklist, on page 38* for more information on Non-Active Worklists).

Description of Assay Workflow Steps

AMDS controls the processing of arrays through a series of workflow steps. This section provides a brief outline of the workflow steps.

Preparing The Target Sample

Refer to the appropriate assay package insert for documentation relevant to preparing your particular specimen for placement on the specific array that contains the assay.

Creating, Editing and Deleting the Test Request

Before you can process a specimen on AMDS, you must create a test request (TR) in the system. You manually create the test request using the Create Test Request function within the Active Worklist in AMDS.

The test request will have a Specimen ID, which identifies the patient's specimen, and the name of the assay type that AMDS will process (Assay Name). AMDS will create a TestRequestID and manage the assay using this ID. You can view, but not edit, the TestRequestID.

Before you submit the test request to the registration workflow you will have the opportunity to edit or discard the test request. However, after you have created the test request, you will have the opportunity to edit or cancel it.

See the section, *Creating, Editing and Cancelling Test Requests—The Active Worklist, on page 60* for more information on creating, editing and cancelling test requests.

Registering the Test Request

Once you have created a test request, the next step in the workflow is registration. The registration step is where you associate the test request with a specific and unique array cartridge (Array ID). The array ID identifies the unique ID of a physical array that comprises the array cartridge.

You can use an array cartridge only once for each assay since you can only apply one specimen to a particular array cartridge.

As mentioned earlier, you must load, or place, the patient's specimen (called the target) onto the array cartridge, and this occurs outside of AMDS. You can record the placement of the target onto the array cartridge in the registration step. You can also record the Target Preparation Reagent Lot Number used in preparing the target.

The assay type will determine if the system requires the reagent lot number. If the system requires the reagent lot number, you must enter it in addition to the array ID in order to progress to the hybridization step. The registration process associates the specimen's unique ID (Specimen ID) and the unique array ID (Array ID). From that point on, AMDS tracks the specimen using the Array ID throughout the remaining workflow.

The assay type, identified by the Assay Name, determines the assay specific steps through which AMDS processes the target (e.g. hybridization, fluidics, scanning, assay reporting), as well as the specific protocols to be used in the individual steps.

The target will usually have a barcode associated with it, in which case you can identify the sample by scanning the target barcode. Alternatively, you can enter manually the identifiers for the target, reagent, and array.

The test request that you create now contains all the information for processing the specimen on the array.

See the section, *Registering a Test Request, on page 71* for more information on registering test requests.

Hybridizing the Test Request Assay

You can hybridize the array that contains the assay specimen in a incubation, or hybridization, oven or on the fluidics station depending on the specifications of the assay (contained in the Assay Name) being performed.

During hybridization, you incubate the array with a hybridization cocktail containing the labeled target (the specimen sample) and control oligonucleotides in a buffer optimized for each type of assay performed (refer to the appropriate array package insert for details on the buffers).

If you perform hybridization in an Affymetrix hybridization oven, you must place the arrays in a tray (a maximum of 8 arrays to a tray) and load the tray in the hybridization oven at the temperature and for the duration specified by the assay being performed. AMDS manages the hybridization in the hybridization oven by using a separate workflow step with a separate worklist.

When the system completes the assay, you can remove the array to the fluidics station for washing and staining.

If your system is connected to the new Affymetrix Hybridization Oven 645, the system monitors the oven temperature and duration during the hybridization process.

For detailed information on using the Affymetrix Hybridization Oven 645, see the Affymetrix Hybridization Oven 645 User's Guide, P/N 08-0255 and the Affymetrix Hybridization Oven 645 Quick Reference Card, P/N 08-0256.

If you carry out hybridization in the fluidics station, the fluidics station repeatedly fills and drains the array with the hybridization cocktail.

See the section, *Hybridizing an Array, on page 76* for more information on hybridizing test requests.

Washing and Staining the Array in the Fluidics Station

After hybridization, the array undergoes a series of stringent washes (specifically optimized for each type of assay in the fluidics station). If you had labeled the target with a fluorescent tag, you can scan the array at this point using the Affymetrix® GeneChip® AutoLoaderDx.

AMDS controls the fluidics station using pre-programmed fluidics protocols, called *scripts*, for hybridizing (if necessary), washing, and staining the arrays. A fluidics station contains four modules and each module can process an array using different fluidics protocols.

However, each array within a particular fluidics station must be of the same assay type, i.e., the assay should have the same Assay Name. This is because the arrays of the same assay type use the same materials with which the fluidics station has been configured and primed.

See the section, *Washing and Staining an Array in the Fluidics Station, on page 81* for more information on washing and staining arrays.

See also the appendix, *The Fluidics Station 450Dx, on page 135* for details on fluidics station use.

Scanning the Test Request Assay—the AutoLoaderDx

After you have hybridized, washed, and/or stained an array, you can now scan the array that contains the assay. AMDS automates control of the AutoLoaderDx and uses the assay information (stored in the Assay Name file) to manage the scanner settings for each type of assay. The software enables you to start a scan and collect intensity data. After the AutoLoaderDx completes the scan, AMDS creates the raw data for computing intensities.

See the section, *Scanning an Array, on page 85* for more information on scanning arrays.

See also the appendix, *The Scanner 3000Dx with AutoLoaderDx, on page 195* for details on the AutoLoaderDx use.

If you have **administrative privileges**, you can use the AutoLoaderDx in three modes:

- Automode–allows you to automate the scanning of arrays by placing up to 48 arrays in a carousel. This is the default operating mode. See the section, *Configuring the AutoLoaderDx, on page 213*.
- Manual Mode–if you want to disable the automated feature of the AutoLoaderDx (Automode) and scan arrays one by one. See the section, *Enable Manual Mode, on page 214*.
- AutoLoaderDx Disabled–allows you to use the software alone without the presence of the AutoLoaderDx. See the section, *Disable AutoLoaderDx, on page 214*.

Computing Cell Intensities

After the AutoLoaderDx completes the scan, AMDS calculates intensities and produces an array image file, called the .cel file.

The strongest hybridization occurs between the particular array oligonucleotide sequence in the specimen target that is most nearly complementary to the immobilized oligonucleotide probe sequence. This produces the strongest fluorescence intensity.

The software represents the fluorescence intensity values from each pixel on the array in a grayscale or pseudo-color mode and superimposes a grid on the image to delineate the probe cells (features).

AMDS automatically:

- Analyzes the image data and computes a single intensity value for each probe cell on an array.
- Saves the cell intensity data as a.cel file.
- Outputs the .cel file to an archive folder.

Displaying and Archiving Test Results

At the end of the assay procedure, you can see the results by clicking the Awaiting Review hyperlink in the Review Results field in the Active Worklist window.

A window will appear that allows you to review and either accept the results or, if there is an obvious error, reject the results.

The particular format of the test results will depend on the design of the partner's results display.

See the section, *Reviewing Test Results, on page 89* for more in formation on viewing results.

Chapter 3 AMDS User Interface and Workflow

Introduction

This chapter explains the AMDS user interface and workflow concept of AMDS.

The workflow of AMDS starts with the creation of a test request and ends with the production and communication of a test result.

NOTE: The particular form of the communication of the test result will depend on the design of the partner's assay and software application.

This chapter also introduces you to running an assay in AMDS. This means creating and processing test requests. AMDS maintains worklists to track all test requests in the system. Once you enter test requests into the system and associate them with arrays, the system processes the arrays through the various workflow steps, such as target registration, hybridization, fluidics, scanning, and assay report generation, in order to generate test results.

The AMDS Application

Worklists comprise the AMDS application. Worklists provide control for the various functions: test request creation, editing and registration, as well as array hybridization, washing and staining, and scanning.

AMDS also includes several other essential functions such as logging, system management, and system maintenance. In summary, the AMDS application provides you with the following functions:

System Access
- Log On
- User Interface
- Log Off

Worklist Management
- Active Worklist
- Enter Test Request
- Non-Active Worklist

Test Request Management
- Edit Test Request
- Cancel Test Request

Workflow Processing
- Registration
- Hybridization Oven
- Fluidics
- Scanner
- Review Results

Administrator
- User Management
- System Management
- Assay Management
- View Logs

The AMDS User Interface

After you successfully log on, the main AMDS user interface appears. Three regions comprise this main interface:

- **Left hand region**—provides workflow and worklist navigation and administrator features.
- **Center region**—displays lists of test requests that AMDS is running. Thus, for example, when AMDS performs a fluidics protocol the center region displays a list test requests that are at the fluidics stage of their processing.
- **Right hand region**—contains user and instrument status information.

Figure 3.1 shows the functionality provided by each region.

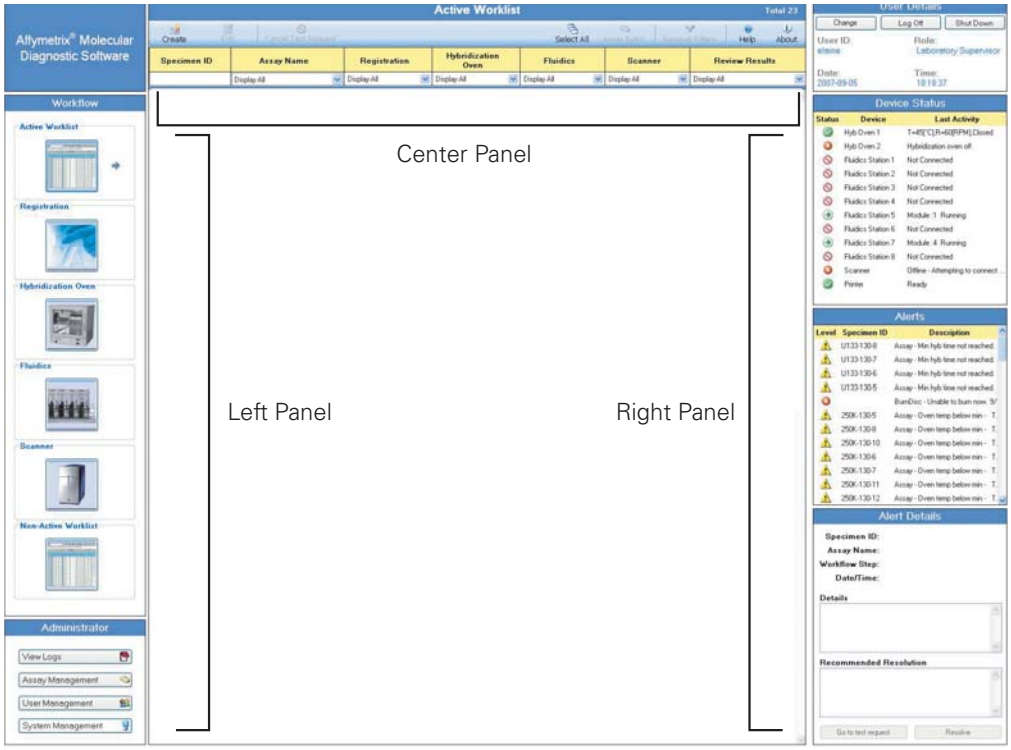


Figure 3.1 The AMDS user interface

Workflows and Worklists

The worklists manage test requests in the workflows. The Active Worklist and Non-Active Worklist monitor the flow of the test request through the AMDS system. Various menus display the status of each test request.

Worklist functions include the ability to view the Active worklists and to enter new test requests manually.

The Left Panel—The Workflow

The left panel is the workflow panel. The workflow panel provides icons that allow you to navigate through the workflow steps for processing a test request and array. The left panel provides access to both the workflow and administrator functions (Figure 3.2).

Figure 3.2 Workflow management pane

The Center Panel—The Worklists

The center region contains a worklist panel which lists, within the system, all the test requests that meet the criteria for that test. This region displays a worklist that is relevant to the function invoked.

- Active Worklist—all test requests that are active and waiting for you to further process them
- Registration Worklist—all test requests for which you have associated an array ID
- Hybridization Worklist—all test requests that are undergoing or about to undergo hybridization
- Fluidics Worklist—all test requests that are undergoing or about to undergo hybridization, washing and/or staining in the fluidics station
- Scanner Worklist—all test requests that are undergoing or about to undergo scanning in the AutoLoaderDx
- Non-Active Worklist—all test request that you have completed or cancelled

Active Worklist

The active worklist (Figure 3.3) displays all test requests the AMDS is currently processing. The worklist indicates the current stage in the workflow for each active test request. You cannot directly edit this list; rather the system maintains and updates this list.

See the section, *Managing Test Requests, on page 60* for more details about the active worklist and creating test requests.

Figure 3.3 The Active Worklist button

Registration Worklist

The registration worklist (Figure 3.4) allows you to associate a single array cartridge with the test request and add, if necessary, target preparation reagent lot numbers as well as add any comments.

See the section, *Processing Test Requests, on page 75* for more details about registration.

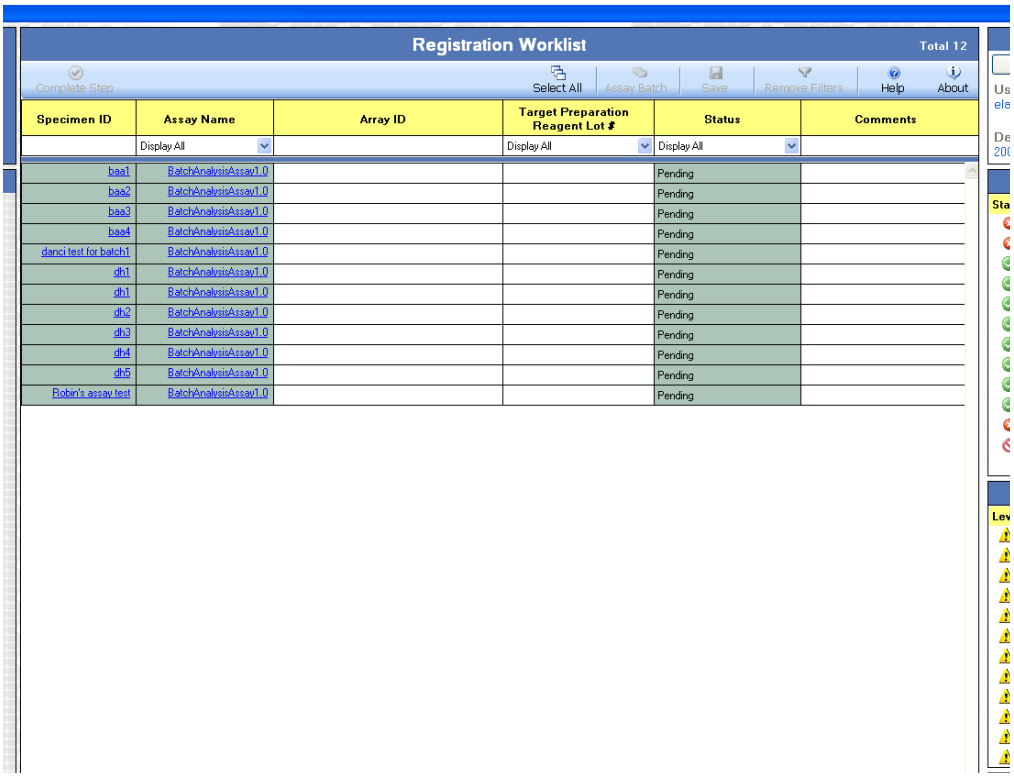


Figure 3.4 The Registration Worklist window

Hybridization Worklist

The hybridization worklist (Figure 3.5) allows you to associate hybridization oven information with the test request and add any comments desired.

See the section, *Hybridizing an Array, on page 76* for more details about hybridization.

You can supply your own oven. If you are using the GeneChip Hybridization Oven 645, refer to the *Hybridization Oven 645 User's Guide* (P/N 08-0255).

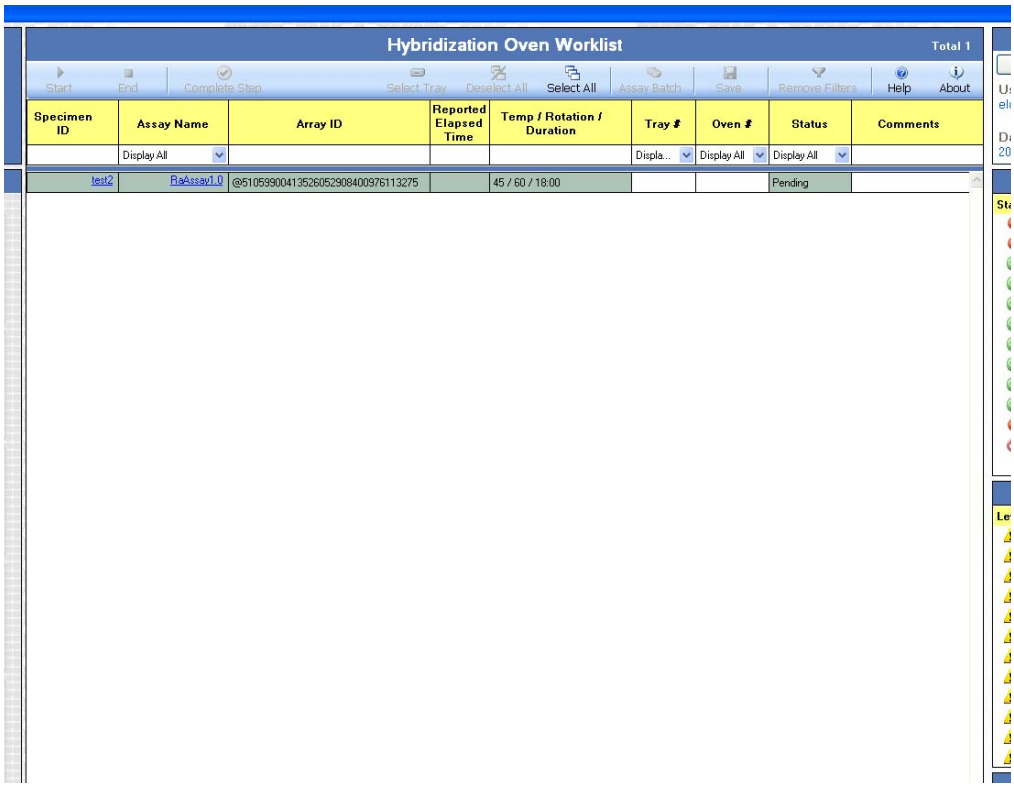


Figure 3.5 The Hybridization Worklist

Fluidics Worklist

The fluidics worklist (Figure 3.6) allows you to associate a fluidics station and module with the test request. This particular fluidics station will be the one that will wash and stain the array. You may add comments. The fluidics worklist window will appear the same whether the system processes a test request using the hybridization oven or the fluidics station.

See the section, *Washing and Staining an Array in the Fluidics Station, on page 81* and the appendix, *The Fluidics Station 450Dx, on page 135* for more details on using the Fluidics Station 450Dx.

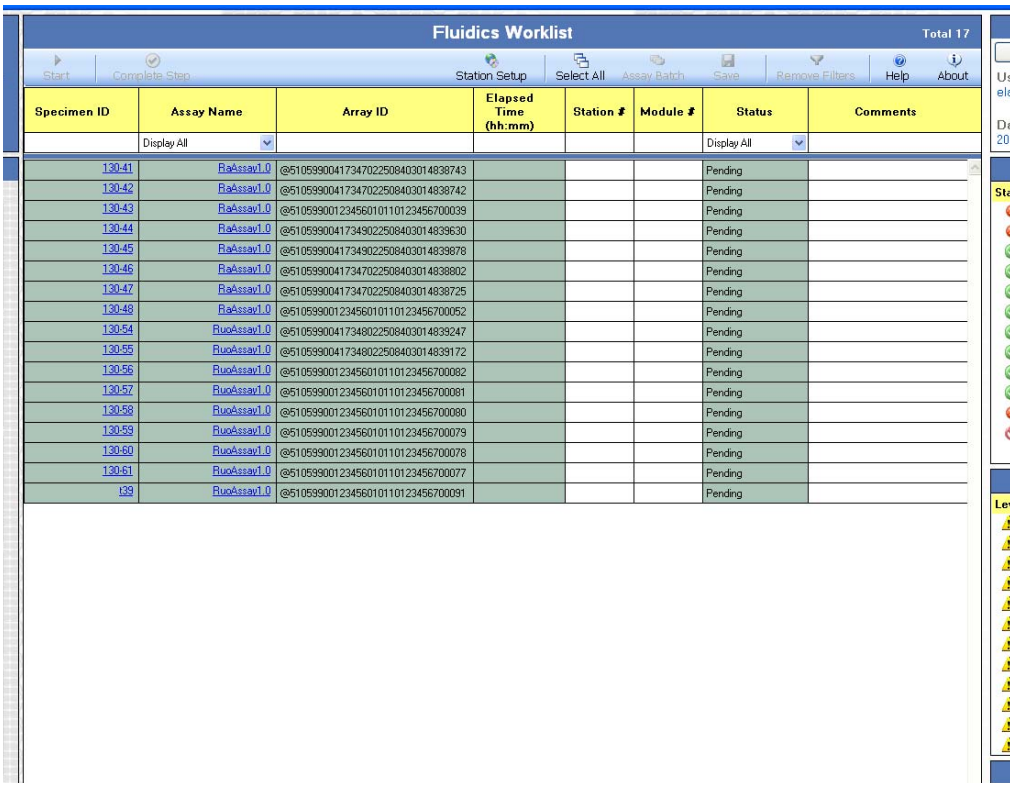


Figure 3.6 The Fluidics Worklist

Scanner Worklist

The scanner worklist (Figure 3.7) allows you to associate a test request with the AutoLoaderDx for the scanning of the array. You may add comments.

See the section, *Scanning an Array, on page 85* and the appendix, *The Scanner 3000Dx with AutoLoaderDx, on page 195* for details on scanning using the AutoLoaderDx.

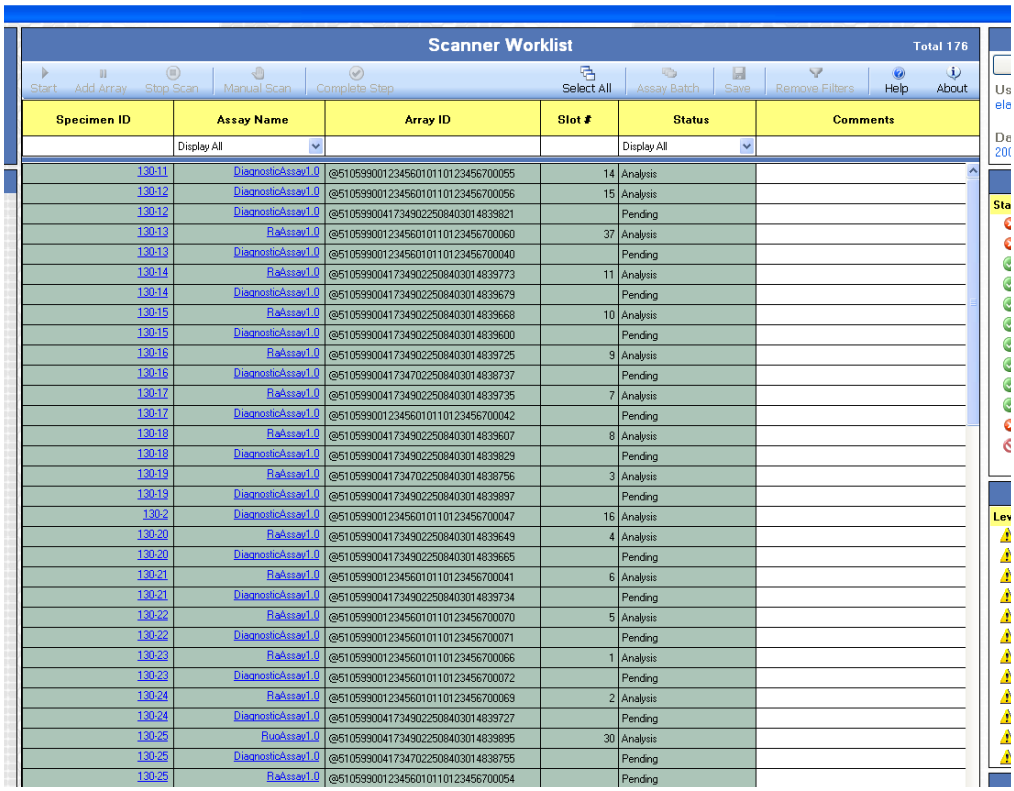


Figure 3.7 The Scanner Worklist

Reviewing Test Results

The review results display (Figure 3.8) allows you to review and approve or reject the results of the assay that AMDS just processed. You can access a report by clicking on the hyperlink, Awaiting Review, on the Active Worklist, Review Results field.

See the section, *Reviewing Test Results, on page 89* for details on viewing test results.

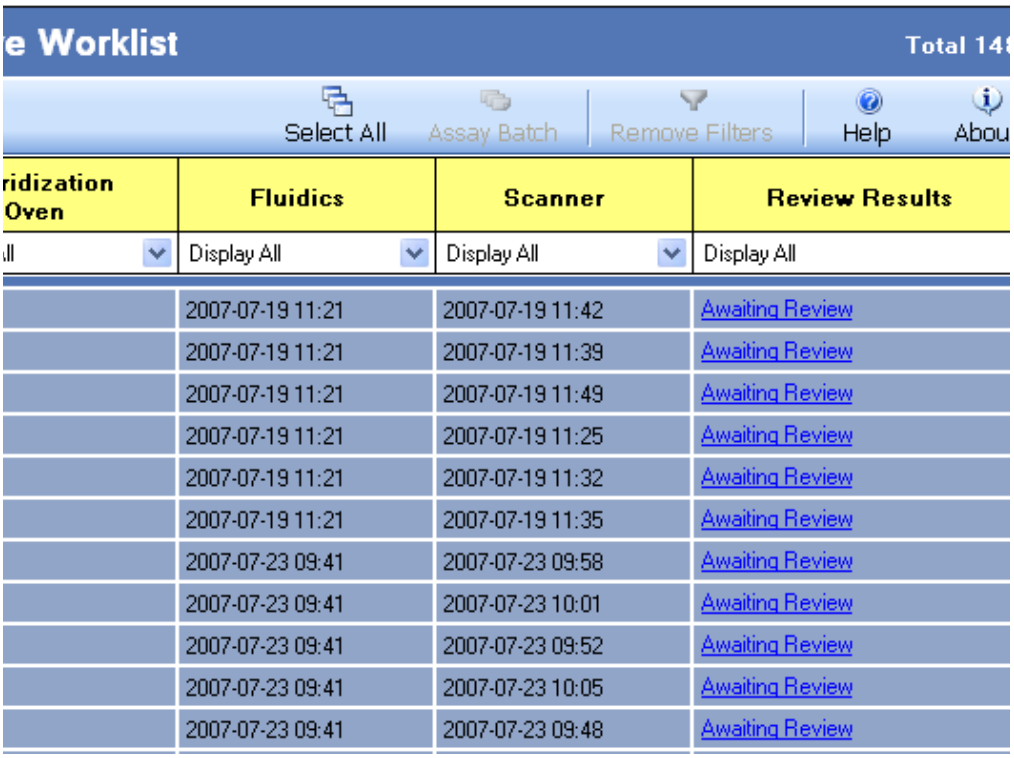


Figure 3.8 The Review Results Function

Non-Active Worklist

This non-active worklist (Figure 3.9) displays the non-active test requests in the system. The system moves test requests to the Non-Active Worklist either when you cancel them, or when you view them in the Review Results step.

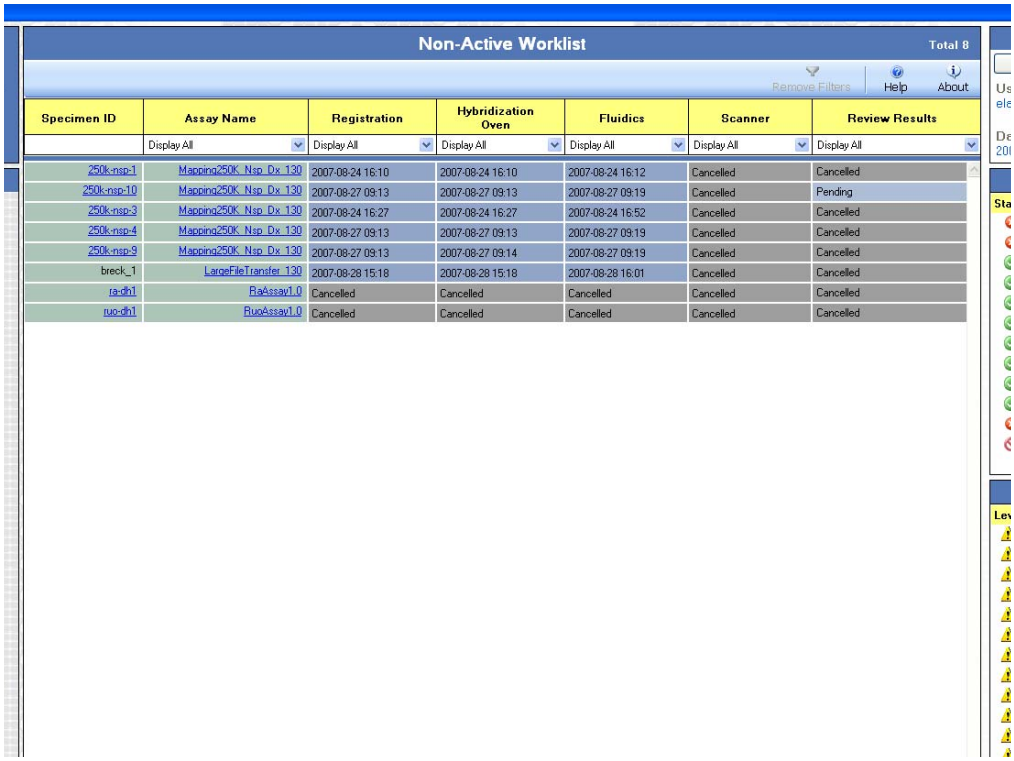


Figure 3.9 The Non–Active Worklist

The Right Panel—User and Instrument Details

The right panel, or region (Figure 3.10), provides important details necessary to monitor the user and instrument operation.

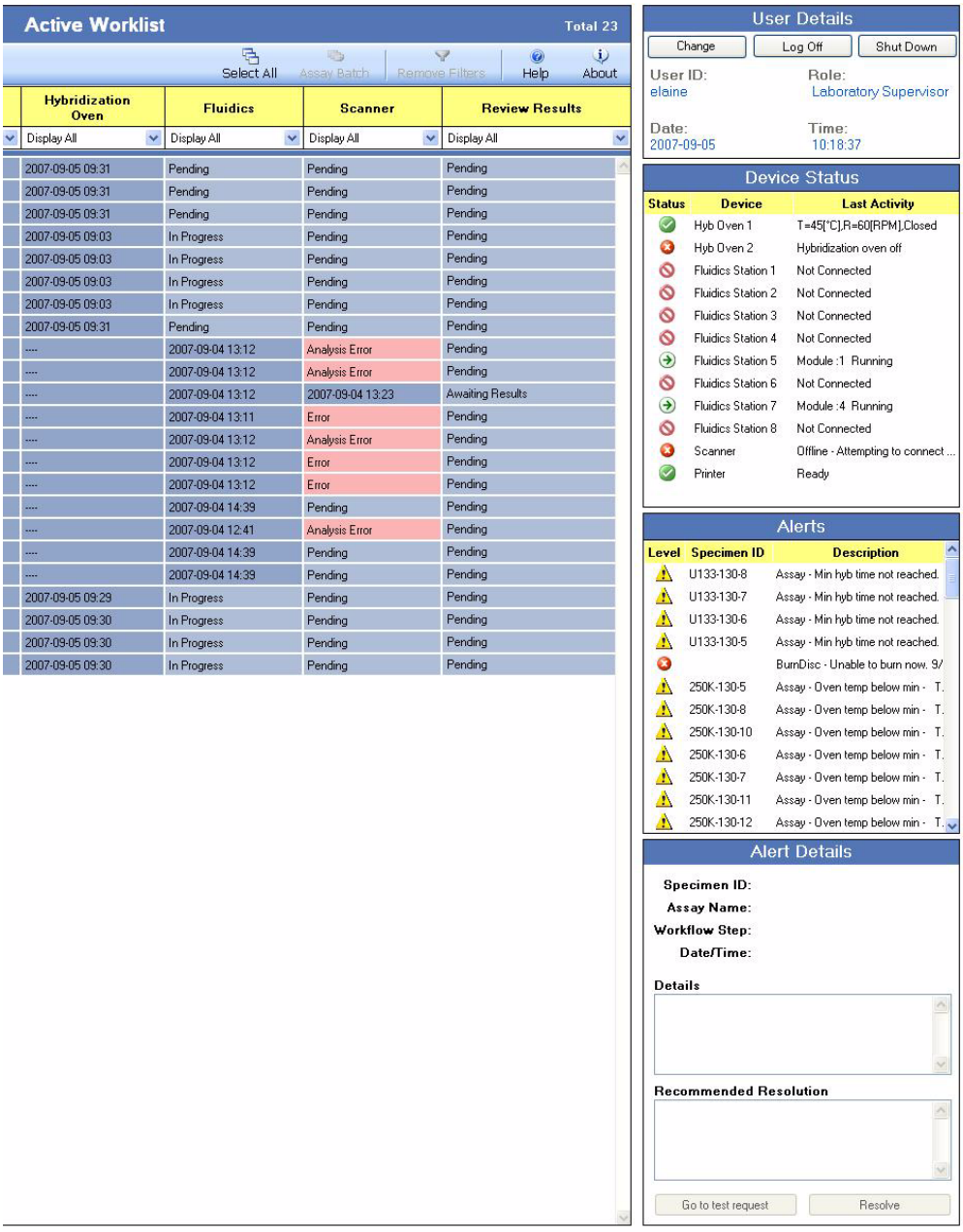


Figure 3.10 The right panel pane

User Details

The upper portion of the right hand region contains the User Details panel (Figure 3.11). This panel displays information regarding the user that is currently logged on to the AMDS. It also provides the means for logging off of the AMDS, and shutting down the system.

Figure 3.11 The User Details panel

Device Status

Below the User Details panel is the Device Status panel (Figure 3.12). This panel displays information regarding the status of the instruments in the form of a dashboard.

- green indicates that the instrument is operating normally
- yellow indicates that AMDS detects an abnormal condition and has raised an alert that needs attention
- red indicates a failure for that instrument

AMDS will monitor and report the status of the Hybridization Oven 645 (if connected), the fluidics station, the printer and AutoLoaderDx.

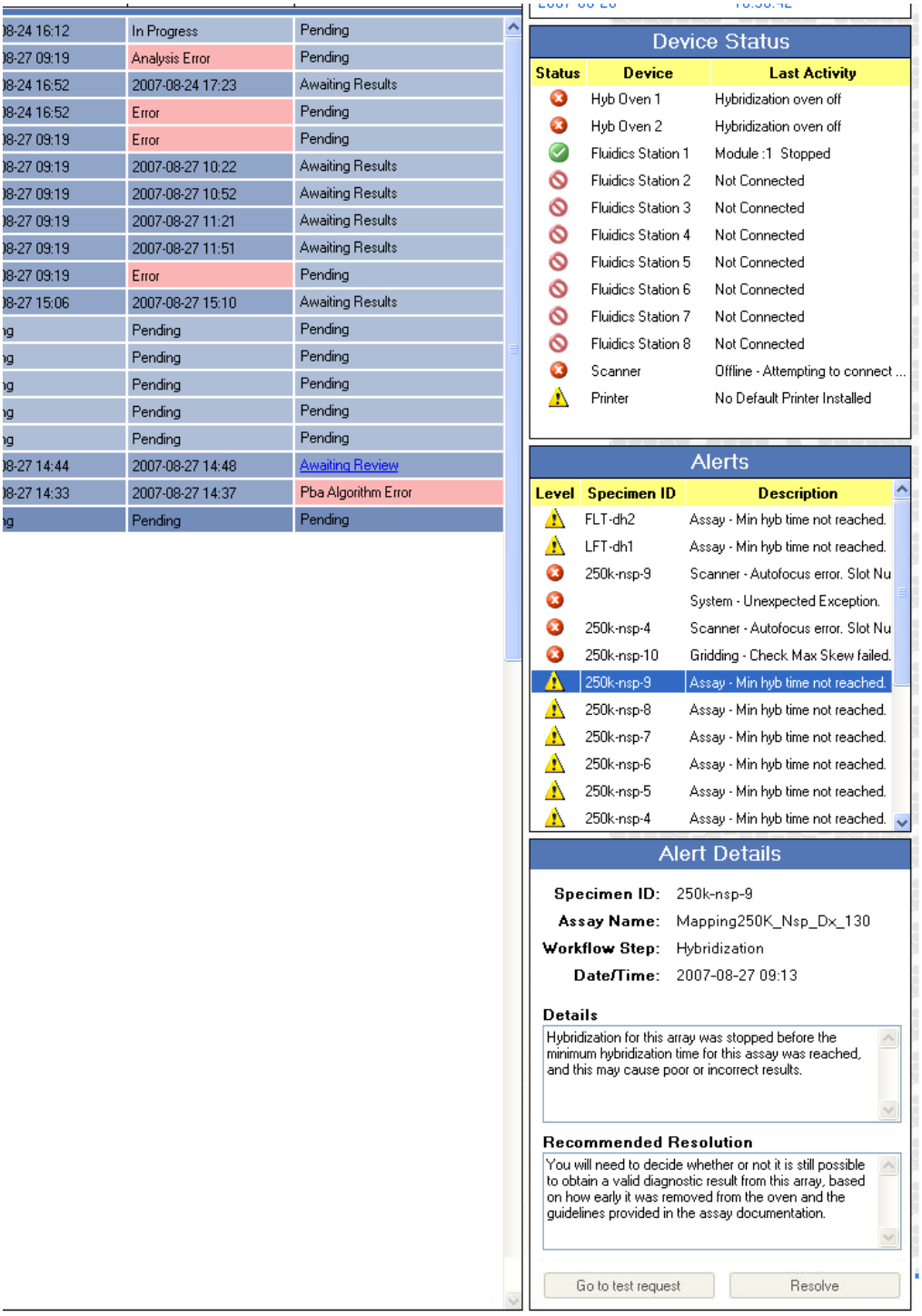


Figure 3.12 Device Status, Alerts, Alert Details panels

Alerts

Below the Device Status panel is the Current Alerts panel, which displays all system alerts (Figure 3.12). This may include notification that a problem occurred in processing which needs attention (e.g. the fluidics station is out of wash buffer).

Alert Details and Recommended Resolution

This panel gives you details of the particular alert and suggestions on dealing with that alert (Figure 3.12). Since the alert details can change based on the version of AMDS, it is not possible to list all the various messages that comprise the individual alert details. If an alert occurs you should read the detailed description and follow the recommended solution. See also the chapter, *AMDS Troubleshooting, on page 127* for details on device troubleshooting.

Roles and Privileges

AMDS provides users with various levels of control. The laboratory supervisor or system maintainer can assign these roles to the users. This section provides a brief summary of the various roles and privileges.

Everybody can at the minimal level of privileges:

- Log on
- Log off
- Change their password
- View all worklists
- View Assay Management screen

Guests also can do this minimal level.

Technicians can do the minimal level and, and in addition, can also, for all approved and registered assays:

- Enter/Edit/Cancel test requests
- Process test requests through the workflow (stopping short of approving/rejecting the result)
- View assay GUI
- Resolve alerts

- View System Logs

A Technologist have the ability to:

- Shut down the system
- Approve/Reject results (for all approved and registered assays)

The System Maintainers can:

- Perform user management
- Perform assay management
- Archive and purge data
- Perform user service on the instruments
- Perform general configuration of the system

The laboratory supervisor can do anything that the technologist can do in addition to anything the system maintainer can do.

The Administrator Panel

The lower section of the left hand region contains the Administrator panel (Figure 3.13). See the chapter, *The AMDS Administrative Features, on page 95* for details on using the administrator functions. The Administrator buttons give you the capabilities to view system and audit logs (View Logs), install and deactivate assay modules (Assay Management), add and manage users of the system (User Management), and manage instrument and other aspects of the system (System Management). This chapter describes each of these functions.

Administrator Functions

When you click on an administrative function (Figure 3.13), the center window will open and display additional detail regarding the selected administrative function. If you do not have administrative permissions, you will not see the Administrator panel.

Figure 3.13 Administrative function buttons

- View Logs—select a system log or an audit log to filter, view, print, or export. The audit logs can be a workflow step (hybridization, fluidics, scan) or report type (information or error type) or user type. See the section, *Viewing Logs, on page 102*.
- Assay Management—select an assay to install, activate or deactivate. See the section, *Managing the Assay, on page 105*.
- User Management—add or remove users or select a user to change the user's permissions or passwords. See the section, *Managing the Users, on page 109*.
- System Management—gain access to the In-House Services function to make changes to the Fluidics Station and workstation settings, archive test requests, view instrument service logs, and set the general configuration. See the section, *Managing the System, on page 113*.

Chapter 4 TEST REQUEST PROCESSING

Introduction

This chapter shows you how to process test requests through the various steps of the workflow in AMDS.

IMPORTANT: Before attempting any assay runs, you must be familiar with the operation of the fluidics station (see the appendix, *The Fluidics Station 450Dx*, *on page 135*) and the operation of the AutoLoaderDx (see the appendix, *The Scanner 3000Dx with AutoLoaderDx*, *on page 195*).

AMDS Quick Reference Guide

The AMDS quick reference guide summarizes the various tasks and how to perform them in the various worklist panels (Table 4.1).

Table 4.1 AMDS Quick Reference Guide for the Workflow

If you want to:	Then do this in a Worklist panel:
Create a test request	1. If not already in the Active Worklist window, click the **Active Worklist** button. 2. Click the **Create** button. 3. Complete the required fields. • Specimen ID • Assay Name 4. Click the **Submit** button.

Table 4.1 AMDS Quick Reference Guide for the Workflow (Continued)

If you want to:	Then do this in a Worklist panel:
Delete a new test request (if you have not yet submitted a test request)	1. If not already in the Active Worklist window, click the **Active Worklist** button to open the Active Worklist window. 2. Click the **Create** button. 3. Select the test request that you have just entered but have not yet submitted. 4. Click the **Delete** button. Note: you cannot delete the request after you have clicked the Submit button; you must cancel test request.
Edit a test request	1. If not already in the Active Worklist window, click the **Active Worklist** button. 2. Select the test request. 3. Click the **Edit** button. 4. Change the following fields • Specimen ID • Assay Name 5. Click the **Save** button.
Cancel a test request (after you have submitted that test request)	1. If not already in the Active Worklist window, click the **Active Worklist** button. 2. Select the test request. 3. Click the **Cancel Test Request** button.
Associate various reagent lot numbers to a batch of test requests—assay batch	1. In any worklist, select one or several Target Request records WITH THE SAME ASSAY NAME. 2. Click the **Assay Batch** button. 3. Fill in (if necessary) the Target Prep Reagent Lot Number. 4. Fill in (if necessary) the Reagent Lot Number. 5. Fill in (if necessary) the Hybridization Reagent Lot Number. 6. Click **OK**. 7. Confirm Step: enter your user name and password. 8. Click **OK**.

Table 4.1 AMDS Quick Reference Guide for the Workflow (Continued)

If you want to:	Then do this in a Worklist panel:
Register a test request	1. Click the **Registration** button to open the Registration worklist. 2. Select the test request. 3. Complete the following fields • Array ID (scan the cartridge array barcode or enter manually) • Reagent Lot Number—optional (scan the barcode of the reagent kit or enter manually) 4. Click the **Save** button. 5. Click the **Complete Step** button.
Set up test requests for hybridization	1. Click the **Hybridization Oven** button to open the Hybridization Worklist. 2. Select the test requests. 3. (Optional: Click the **Select Tray** button and enter the **oven number** or **E** if you are using an external, or unconnected, oven). 4. Associate the test requests with that tray. 5. Click the **Start** button. 6. Click the **End** button (when hybridization is complete). 7. Click the **Complete Step** button.

Table 4.1 AMDS Quick Reference Guide for the Workflow (Continued)

If you want to:	Then do this in a Worklist panel:
Set up a fluidics station or shut down a fluidics station	1. Click the **Fluidics** button to open the Fluidics Worklist. 2. Click the **Fluidics Station Setup** button. 3. Select the assay for a particular Fluidics Station number 4. Enter the particular Wash A and Wash B for each fluidics station. 5. Select the modules to run the fluidics station protocols. 6. Add comments. 7. Click the **Close** button if you want to reject the changes. 8. Click the **Save** button if you want to accept the changes. 9. Click the **Shut Down** button to shut down the Fluidics Station.
Prime a fluidics station	1. Add the proper reagent wash buffers and 1.5 mL vials in accordance with the assay protocol instructions. 1. Click the **Fluidics** button to open the Fluidics Worklist. 2. Click the **Station Setup** button to go to the setup window. 3. Select the row containing the fluidics station to prime. 4. Click the **Prime Fluidics Station** button. 5. Enter the Fluidics Station: • Number • Module 6. Click the **Start** button.

Table 4.1 AMDS Quick Reference Guide for the Workflow (Continued)

If you want to:	Then do this in a Worklist panel:
Set up test requests for a fluidics protocol	1. Click the **Fluidics** button to open the Fluidics Worklist. 2. VIEW THE PROMPTS ON THE FLUIDICS STATION LCD FOR INSTRUCTIONS: Add the proper reagent wash buffers and 1.5 mL vials in accordance with the assay protocol instructions. 3. VIEW THE PROMPTS ON THE FLUIDICS STATION LCD FOR INSTRUCTIONS: Insert the arrays into the fluidics station modules. 4. If you do not have a barcode reader: a. Select the test requests b. Enter the Station # c. Enter the Module # 5. If you have a barcode reader: a. Scan the array barcode b. Scan the fluidics module barcode 6. Click the **Start** button. 7. Click the **Complete Step** button (when the fluidics protocol is complete).
Set up test requests for scanning	1. Insert your arrays into the AutoLoaderDx 2. Click the **Scanner** button to open the Scanner Worklist. 3. Click the **Scan** button (no need to select arrays). 4. Click the **Complete Step** button (when the scan is complete).

Table 4.1 AMDS Quick Reference Guide for the Workflow (Continued)

If you want to:	Then do this in a Worklist panel:
Scan arrays in the Manual Scan mode	1. Insert the array into slot #1 of the AutoLoaderDx carousel. 2. Click the **Scanner** button to open the Scanner Worklist. 3. Select the test request. 4. Add identifying information for each test request if necessary. 5. Click the **Manual Scan** button. 6. Click the **Complete Step** button (when the scan is complete).
Review results	1. Click the **Active Worklist** button. 2. Click the **Awaiting Review** hyperlink. 3. View the Test Results Report. 4. Add comments. 5. Click the **Print** button if you want to print the report. 6. Click the **Approve** button to approve the report. 7. Click the **Reject** button to reject the results. 8. Fill in your user name and password.

Using the Barcode Reader

You can use the barcode reader to:

- Enter a specimen ID for a test request
- Associate a test request with an array ID
- Associate a test request with reagent lot numbers
- Associate multiple test requests with a reagent lot number (assay batch)
- Associate an array with a fluidics station and fluidics station module that is performing the run.

As an example, in the AMDS Registration window, for each test request, you can associate the Specimen ID, Array ID, and Reagent Lot # together by scanning the barcodes affixed to each item.

In the fluidics station, you do not need to select manually test requests prior to running a fluidics protocol. Just scan the array barcode then immediately scan the fluidics station module barcode. AMDS will automatically place the information in the proper test results fields (Figure 4.1).

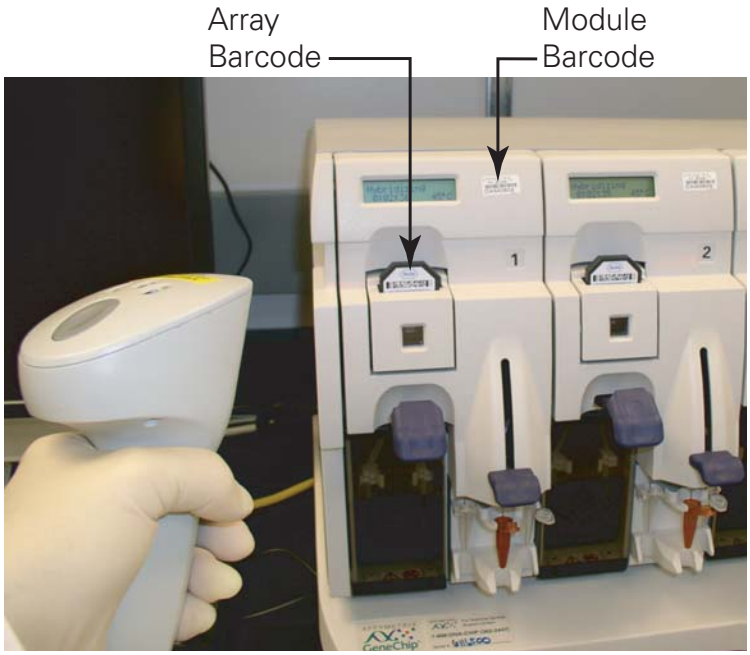


Figure 4.1 Using the barcode reader to scan an array barcode and a module barcode

See the section, *Using the Barcode Reader with the Fluidics Station, on page 142* for more information on using the barcode reader with the fluidics station.

The following additional examples will help familiarize you with how to use the barcode reader in AMDS:

- Within the Registration Worklist screen, highlight the desired test request record and use the barcode reader to read the barcode affixed to the **array cartridge**. AMDS will locate the proper field and automatically fill it in with the proper identification number.

For information regarding connecting the barcode reader, see the section, *Connecting the Barcode Reader, on page 203*.

NOTE: Note: Alternatively, if the barcode on any item is not readable for any reason, you can manually enter the ID by typing the number into the field after positioning the cursor in that field, rather than scanning the barcode.

Handling the Array Cartridge

The array comes mounted in a plastic package to form an array cartridge (Figure 4.2). The array contains a collection of oligonucleotide probes that have been arrayed on the inner glass surface. A chamber in the plastic package directly under the chip acts as a reservoir where hybridization and washing/staining occur.

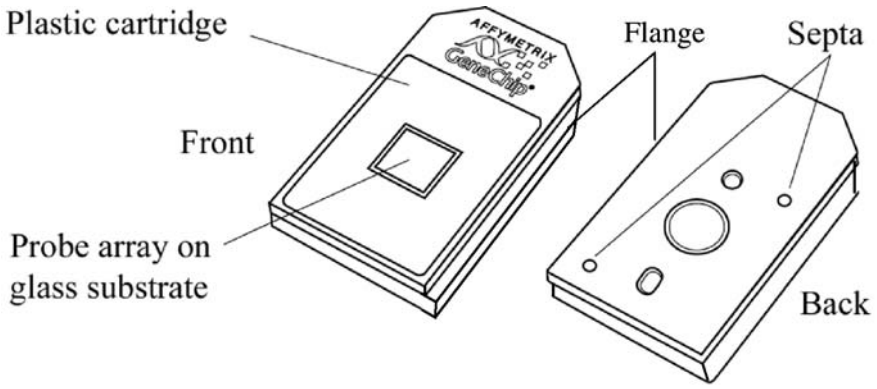


Figure 4.2 The array cartridge

Although the inner glass surface is protected, any contamination or scratches on the outer surface of the glass can compromise the integrity of the scan. **Avoid touching the surface of the chip with your fingers.** Skin oils and other substances, such as lotions or ink, can fluoresce. If the surface of the array chip is noticeably dirty, you should carefully clean the chip with a nonabrasive laboratory tissue.

Starting AMDS

IMPORTANT: Shutting down the AutoLoaderDx: to preserve the lifetime of the scanner's internal laser we recommend that you turn the AutoLoader OFF when it is not in use for any extended period of time such as overnight or a weekend.

Turning on the System

1. Turn on the computer workstation to launch AMDS.

   If you had administrator privileges, and had earlier selected the option "Turn AutoLoaderDx on at AMDS launch," then the laser will start to warm up when you launch AMDS.

   If you have administrator privileges, see the section, *Managing the AutoLoaderDx, on page 124* for instructions on how to do this.

   AMDS will perform a system self test to confirm the operational status of the system and ensure that all components are connected and operating properly.

2. Once AMDS completes a self test, the AMDS User Logon screen will appear (Figure 4.3).

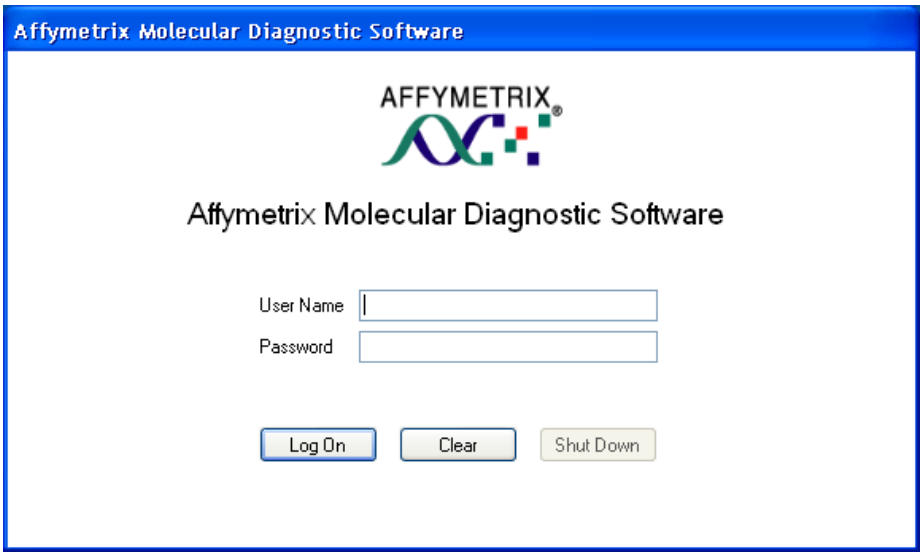


Figure 4.3 User Logon Screen

3. Log on to AMDS by entering your User Name and Password (provided by the Affymetrix service technician who installed AMDS or your system administrator) and click the **Log On** button.

   AMDS will authenticate your user name and password provided and present the initial system screen, shown in the following section: AMDS user interface. The system will provide access to the appropriate system functionality based on your user group with which you are associated. For details on user groups and permissions refer to the section, *The AMDS Administrative Features, on page 95*.

4. Turn on the AutoLoaderDx (for more detail on starting the AutoLoaderDx, see the section, *Starting the AutoLoaderDx, on page 212*).

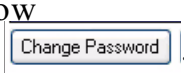
5. Turn on the Affymetrix® Fluidics Station 450Dx (for more detail on starting the fluidics station, see the section, *Operating the Fluidics Station, on page 145*).

WARNING:  **Laser in use during scanning.**

NOTE: The scanner laser should be turned on and warmed up for at least 10 minutes.

Changing Your Password

You can change your password from any workflow window.

1. In the User Details panel on any workflow window (Figure 4.4), click the **Change Password** button 

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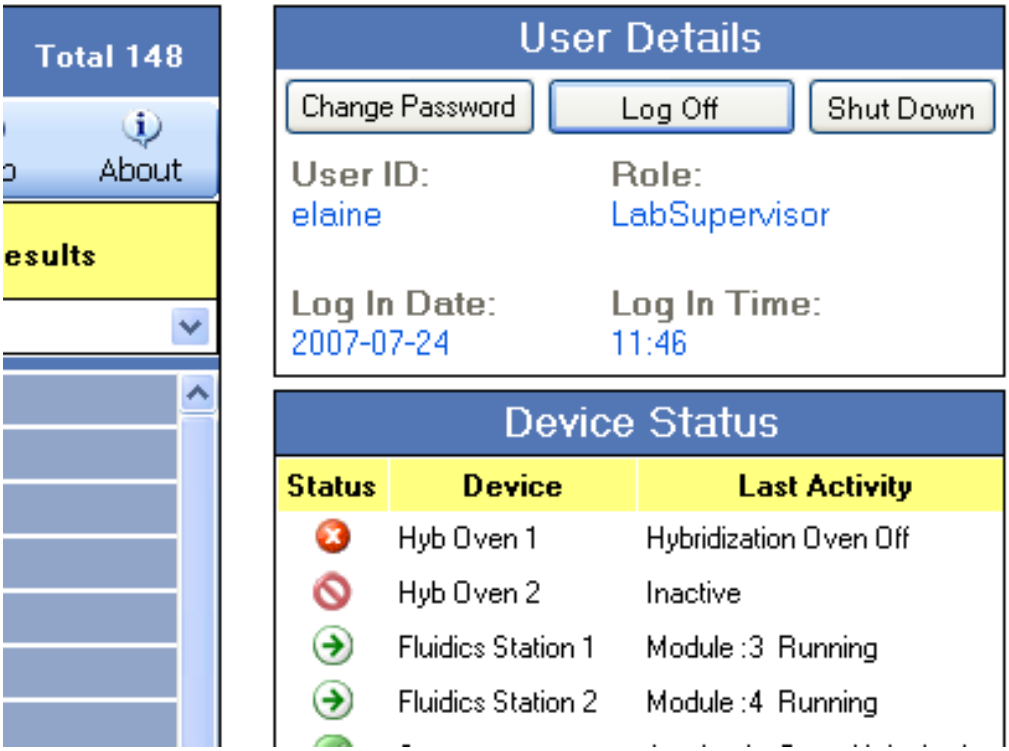


Figure 4.4 The User Details panel

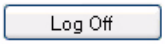
The Change Password dialog box opens (Figure 4.5).

Figure 4.5 The Change Password dialog box

2. Enter you old password.
3. Enter your new password.
4. Confirm you new password by entering it again.
5. Once you enter your information, click the **OK** button to apply the change.

Logging Off

This function allows you to log off of the AMDS. The log off functionality is available at all times.

1. In the User Details panel on any workflow window (Figure 4.4), click the **Log Off** button 

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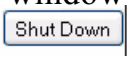
   Logging off will not terminate the active workflow processes. If there are test requests in hybridization, fluidics or scanning, AMDS will continue to process them.

Shutting Down

This function allows you to shut down AMDS. The shut down functionality is available at all times.

1. In the User Details panel on any workflow window (Figure 4.4), click the **Shut Down** button 

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   A System Shutdown message appears asking if you are sure you want to shut down. Click **Yes** or **No**.

2. A confirm window appears. Fill in your user name and password. Click **Yes**.

   The system will wait until AMDS completes all currently running test requests and then shut down.

   The system will not shut down if there are test requests in progress or complete on any worklist. In this situation, either wait for the test requests to finish or cancel the test requests.

Managing Test Requests

This section shows you how to enter, edit and cancel a test request using the AMDS workflow. This involves using the active worklist to create or edit the test request data and the registration worklist to associate the test request with a unique, physical, array cartridge ID.

Creating, Editing and Cancelling Test Requests—The Active Worklist

You can create, edit and cancel test requests. In addition, you can also filter, select all or assay batch the worklists. The Active Worklist panel provides these functions (Figure 4.6).

The following flow chart summarizes the steps required in creating or editing a test request.

Active Worklist → Create → Add Specimen ID & Assay Name → Enter Assay Batch information for a number of related test requests → Submit

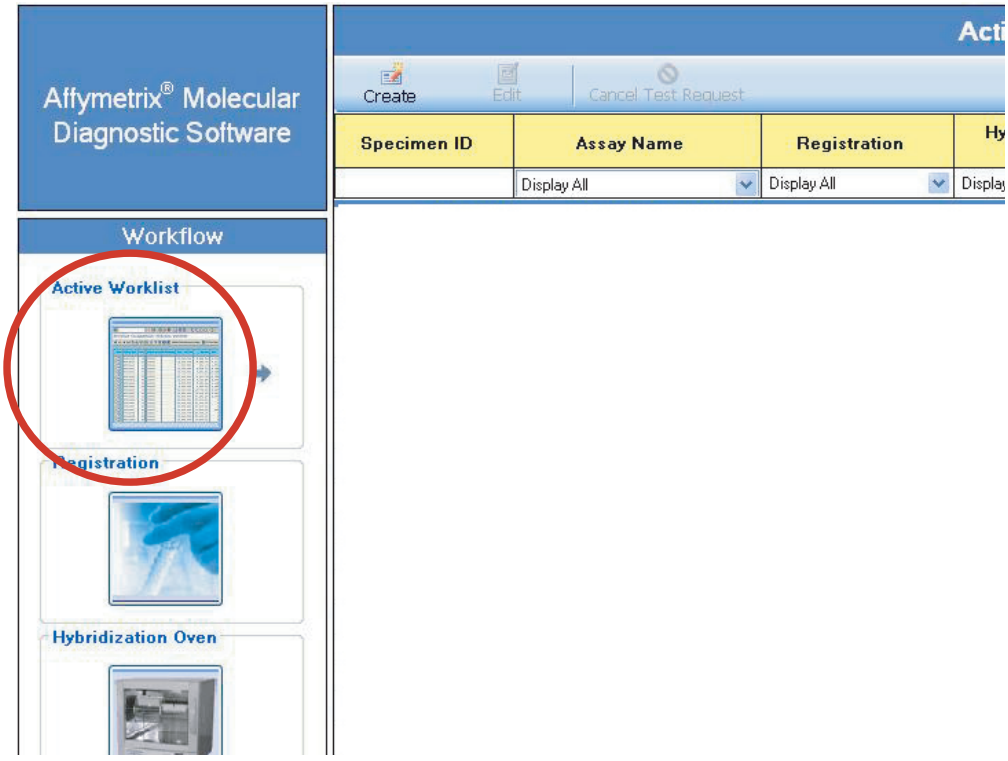


Figure 4.6 The Active Worklist button

Creating the Test Request

1. If you are not already in the Active Worklist window, select **Active Worklist** from the left pane (Figure 4.6).

   The Active Worklist panel opens (Figure 4.7).

Figure 4.7 The Active Worklist

2. Click the **Create** button  on the toolbar of the Active Worklist.

   The Enter Test Request Screen will appear (Figure 4.8).

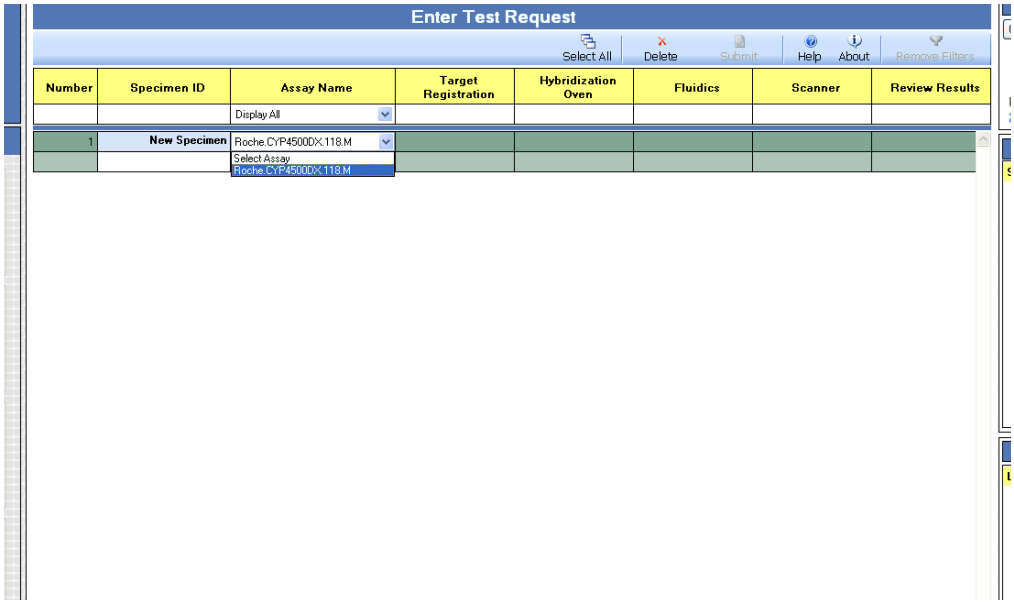


Figure 4.8 The Enter Test Request window

3. Enter one or more **Specimen ID** and **Assay Name** combinations.
4. Once you have made the entries, click the **Submit** button and the Enter Test Request screen closes.

Adding Additional Information to the Specimen ID

After you add a specimen, and return to the Active Worklist window, you can add certain types of pertinent information about the specimen. You can also add this information at a later date in other worklist windows.

1. Click on the desired Specimen ID

   The Additional Information dialog box opens (Figure 4.9).
2. Add the following information. This this information includes:
   - Patient First Name
   - Patient Last Name
   - Patient ID
   - Specimen Type - Tissue
   - Specimen Type - Tissue Subtype

- Specimen Type - Collection
- Specimen Type - Storage Processing
- Special Specimen Type
- Collection Date
- Collection Time
- Requesting Physician First Name
- Requesting Physician Last Name
- Requesting Institution

3. When you have completed adding the information, click **Save and Close** or just **Close** to exit without saving.

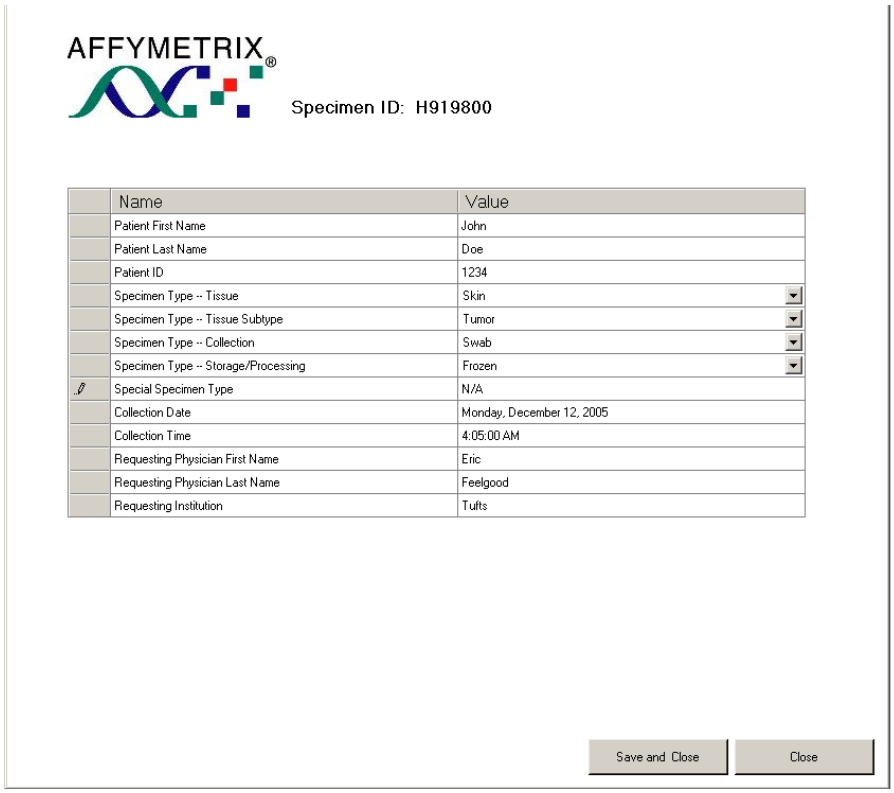


Figure 4.9 The Specimen ID additional information dialog box

Retrieving Additional Information and Viewing Test Request Logs

You can retrieve a summary of all the specimen information and test request logs for particular assay type.

1. In the **Assay Name** field, click on the **Assay Name**.

   The Assay Home (aka Assay Landing) window appears (Figure 4.11).

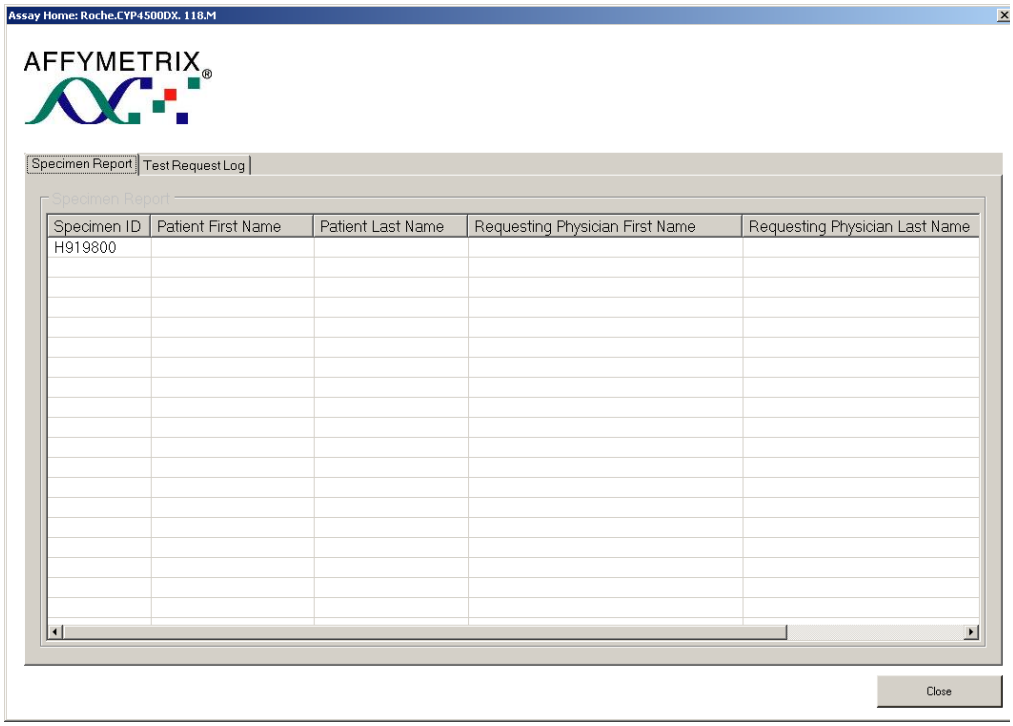


Figure 4.10 The Test Request Log tab

2. Click on the **Specimen Report** tab to view all the specimen IDs associated with that assay type.
3. Click on the **Test Request Log** tab (Figure 4.11) to view all the test requests associated with that assay type. Each test request will include information on its:
   - Date
   - Time
   - User
   - Type
   - Sub System
   - Short Message

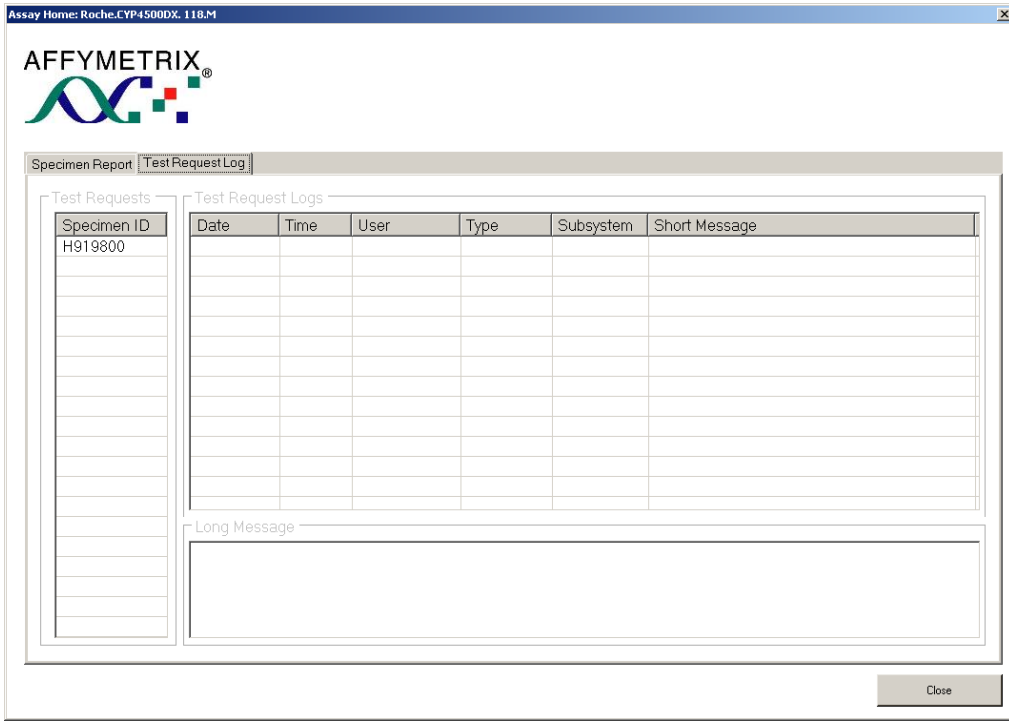


Figure 4.11 The Test Request Log tab

Editing Test Requests

This function allows you to edit a test request. You can edit test requests before you submit them, that is, before they enter the registration stage. You cannot edit test requests after the system completes registration.

Editing the Test Request Procedure

1. From the Active Worklist, select a test request to be edited.
2. Click the **Edit** button 

on the toolbar of the Active Worklist panel.

   The Edit Test Request panel will appear (Figure 4.12).

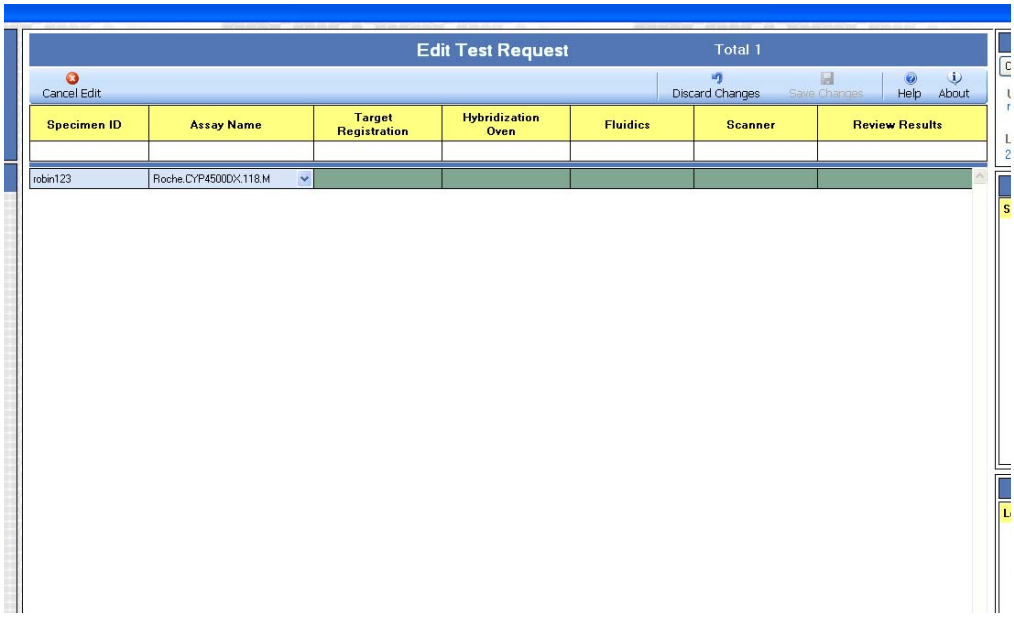
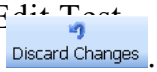


Figure 4.12 The Edit Test Request window

3. Modify either the **Specimen ID** or **Assay Name** (these are the only two fields that you can edit).
4. Click the **Save** button.
5. The Confirm Step dialog box appears (Figure 4.13).
6. Enter your User Name and Password and an Event Reason as well as any other information in the Additional Info box.
7. If you want to cancel the edit and return to the Active Worklist, click the **Cancel Edit** button 

.
8. If you want to discard the edits but remain in the Edit Test Request screen, click the **Discard Changes** button 

.

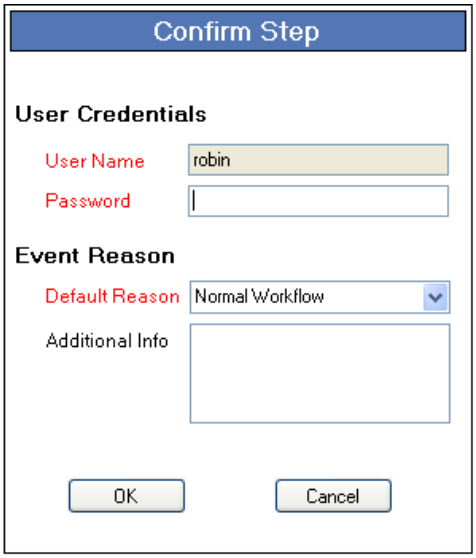


Figure 4.13 The Confirm Step dialog box

Deleting Test Requests

You can delete a test request if you have not yet submitted it to the worklist.

1. If you are not already in the Active Worklist window, select **Active Worklist** from the left pane (Figure 4.6).

   The Active Worklist panel opens (Figure 4.7).

2. Click the **Create** button 

on the toolbar of the Active Worklist.

   The Enter Test Request Screen will appear (Figure 4.8).

3. Select the test 

that you want to delete and click the **Delete** button .

   AMDS will immediately delete the contents of the test request record.

Cancelling Test Requests

After you have submitted a test request, you cannot delete it, but you can cancel it and send it to the Non-Active Worklist.

1. From the **Active Worklist**, select the test request you would like to cancel.
2. Click the **Cancel Test Request** button 

on the toolbar of the Active Worklist panel.

   The Confirm Step dialog box appears (Figure 4.14).
3. Enter your User Name and Password and an Event Reason as well as any other information in the Additional Info box.

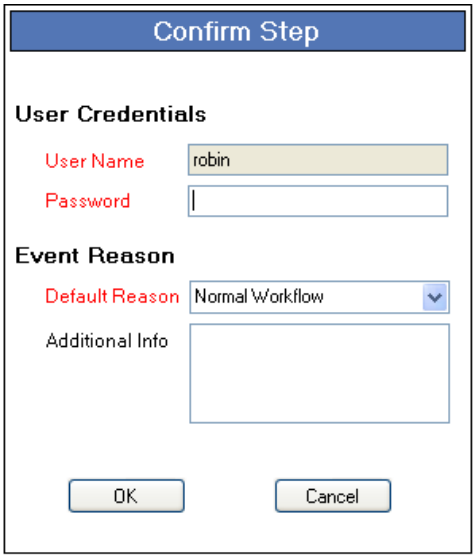


Figure 4.14 The Confirm Step dialog box

4. AMDS will transfer the test request to the Non-Active Worklist (Figure 4.15).

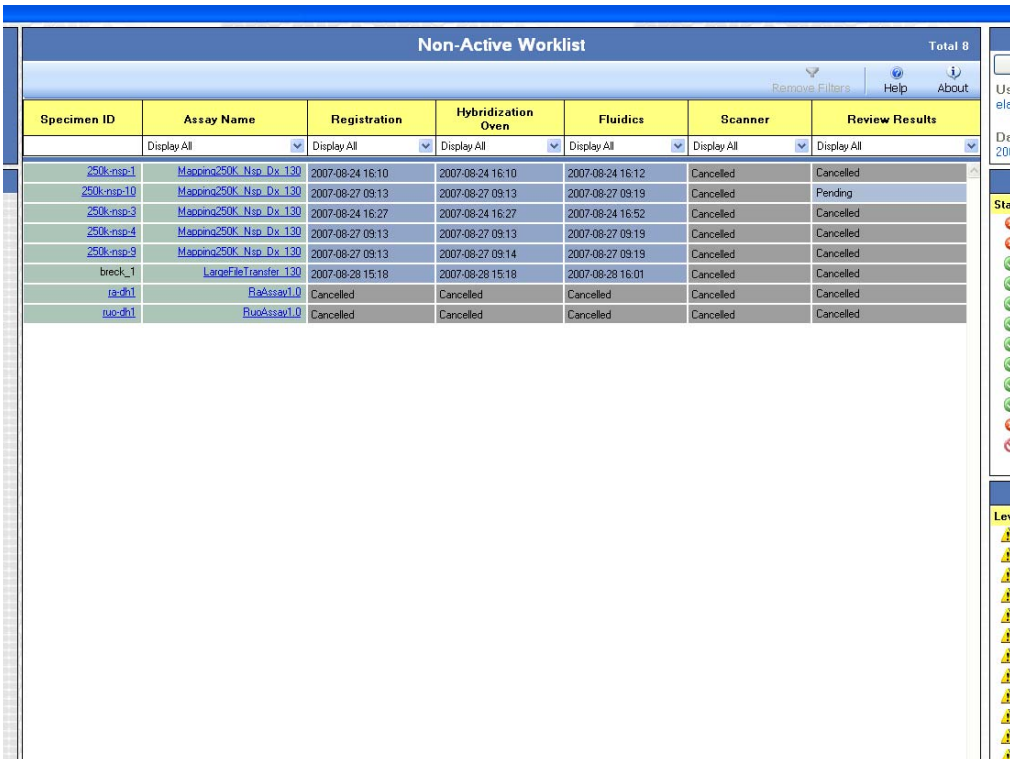


Figure 4.15 The Non–Active Worklist

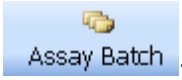
Associating Reagent Lot Numbers to Multiple Test Requests—Assay Batch

You can use the Assay Batch command to associate certain reagent lot numbers to multiple test request records. These lot numbers include target preparation reagent lot numbers, stain reagent lot numbers and hybridization reagent lot numbers.

1. From the **Active Worklist** or **Registration Worklist**, select one or more test requests or, if all the test re[illegible]e same Assay Name, click the **Select All** button 

to select all the listed test requests.

IMPORTANT: **The Select All button will only work if all the test requests are associated with one Assay Name.**

2. Click the **Assay Batch** button 

.

   The Assay Batch Information dialog box appears (Figure 4.16)

   The right column lists the selected Specimen IDs

   The left dialog box allows you to enter:

   - Target Prep Reagent Lot Number
   - Stain Reagent Lot Number
   - Hybridization Reagent Lot Number

3. Click the **Save and Close** button to save and close, or the **Close** button to close without saving.

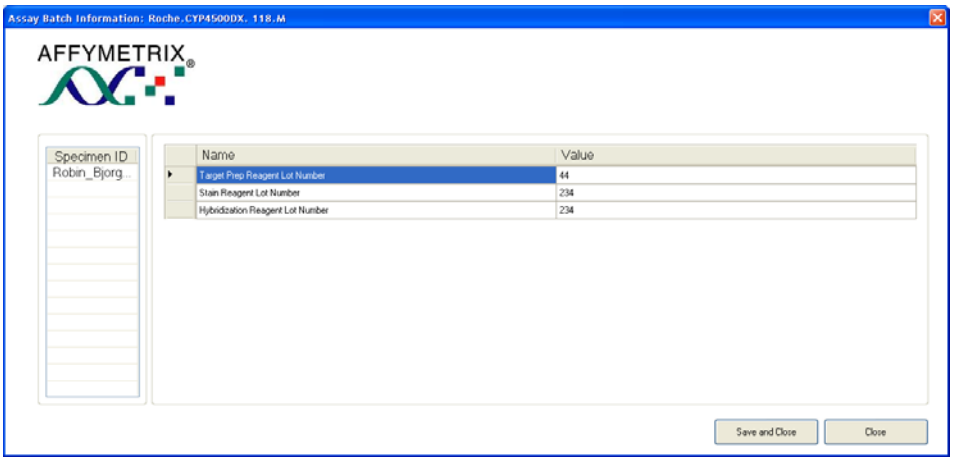


Figure 4.16 The Assay Batch Information dialog box

Registering a Test Request

The following flow chart summarizes the steps required in registering a test request. The steps in bold are those relevant to the registration procedure.

Active Worklist → Create → Add Specimen ID & Assay Name → Submit → **Register** → **Add Array ID (and Reagent Lot Number)** → **Save** → **Complete Step**

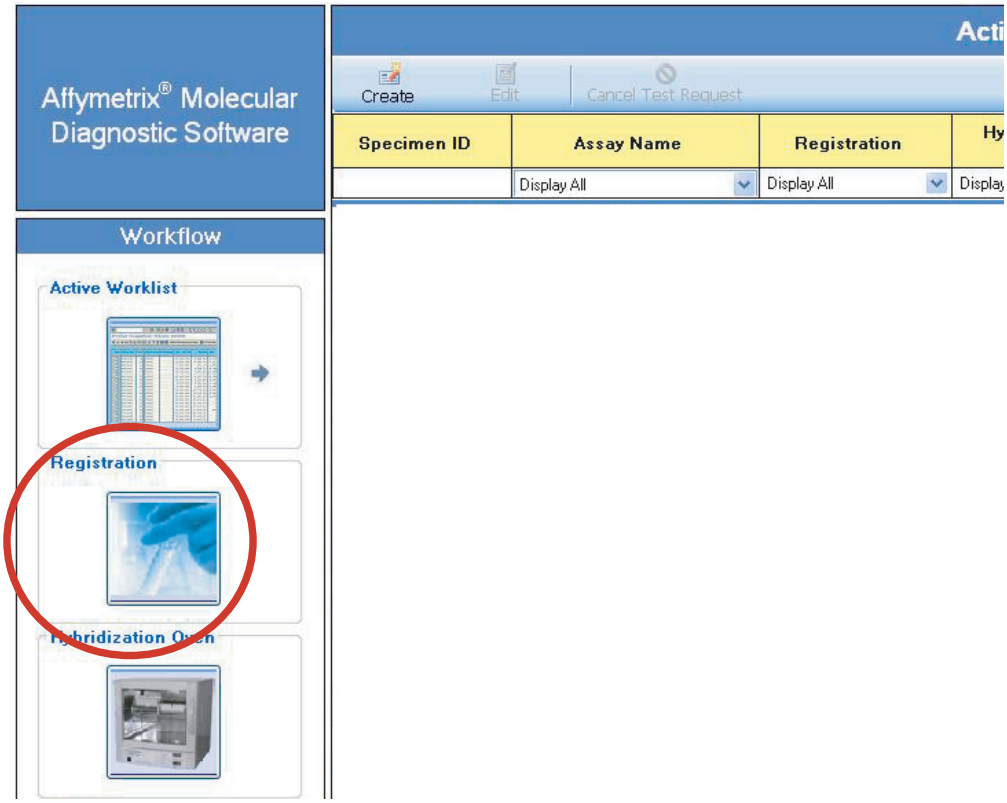


Figure 4.17 The Registration Worklist button

Registration Procedure

1. Click the **Registration** button from the workflow window (Figure 4.17). The Registration Worklist will appear in the center panel (Figure 4.18).

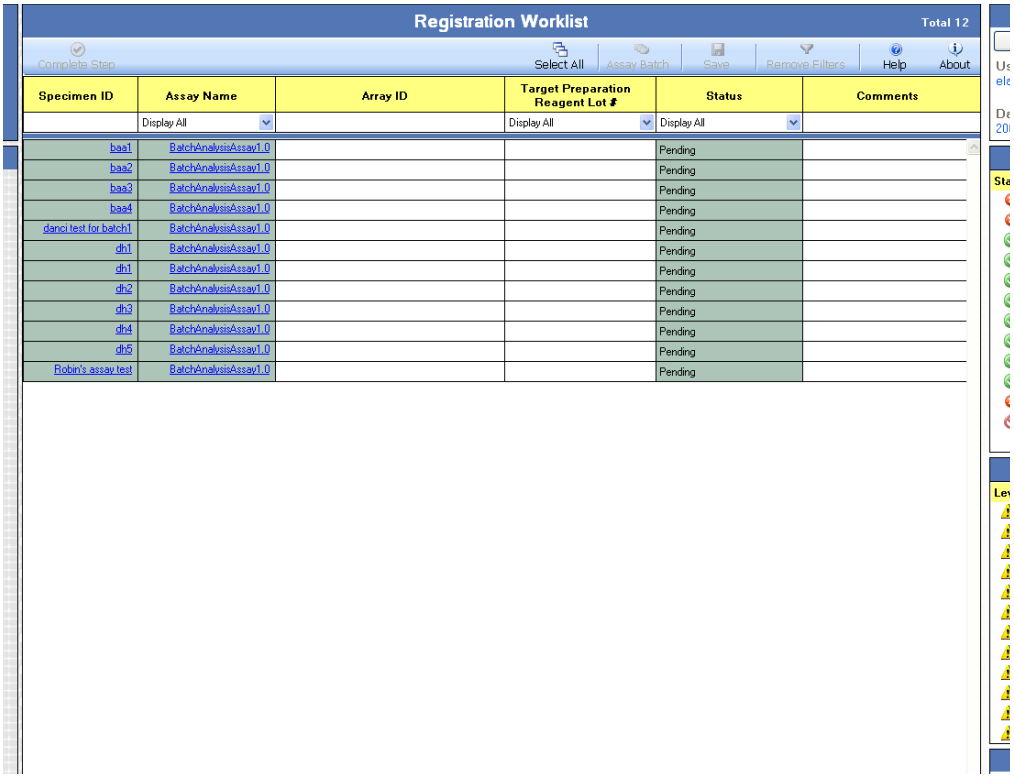


Figure 4.18 The Registration Worklist window

2. Highlight the desired test request record and scan the barcode on the array cartridge.

   Or scan the specimen ID barcode and then scan the barcode on the array cartridge.

   The AMDS will locate the proper field and add the info.

   If you are manually entering information, click in the **Array ID** field and manually enter the appropriate array ID barcode the array.

3. Optional: If you want to enter reagent lot numbers: Select one or more test requests and enter the same reagent lot number for all these test requests by scanning the barcode on the reagent kit.

   If you are manually entering information, Shift-click and select all the test requests. Select one **Reagent Lot Number** field of a test request, enter the value manually, click **Enter** and AMDS will fill in all the selected test requests.

4. When you enter text information in the field in question (Array ID and Reagent Lot Number) AMDS will check your information. If a problem exists, you will get one of the following error messages. You must correct the error before AMDS will proceed.
   - If that Array ID already exists, AMDS will alert you with an error message.
   - If you have entered an invalid part number, AMDS will alert you with an error message.
   - If the array has expired, AMDS will alert you with a warning message.
   - If any test requests have an invalid array ID, AMDS will alert you with an error message.
5. Click **Save** button to save your registration and remain in the registration field.
6. Click the **Complete Step** button 

to move the test requests with complete information from the Target Registration Worklist to the next step in the workflow. The particular assay being run will determine the next step. This may be the Hybridization Oven step or the Fluidics step.

Processing Test Requests

From this point on, you will be processing an array. This section describes the physical steps involved in processing an array, from hybridizing the array to producing a test report. The particular assay that you are running determines the specific sequence of steps required to process the array. For example, an assay may specify that the you must hybridize an array in a hybridization oven. In this case, the system will process the array through the hybridization oven step.

Alternatively, the assay may call for AMDS to hybridize an array in the fluidics station. In this case, the system will bypass the hybridization oven step and process the array in the fluidics station after you have registered the sample. See the section, *Washing and Staining an Array in the Fluidics Station**, on page 81* and the appendix, *The Fluidics Station 450Dx**, on page 135*.

The workflow processing described in this chapter presents the possible steps in which an assay may participate and does not imply that a particular assay will participate in all of the steps.

Hybridizing an Array

The following flow chart summarizes the steps required to process an array from test request creation to the end of the array hybridization protocol. The steps in bold are those relevant to the hybridization procedure. This procedure assumes that your workstation is connected to the Affymetrix Hybridization Oven 645.

Active Worklist → Create → Add Specimen ID & Assay Name → Submit → Register → Add Array ID → Save → Complete Step → **Hybridization → Select Tray # (optional) & Select Oven #Start → End → Complete Step**

If you are using the GeneChip® Hybridization Oven 640, refer to the *GeneChip Hybridization Oven 640 User's Guide*, P/N 700281, for detailed instructions. If you are using the GeneChip® Hybridization Oven 645, refer to the *GeneChip® Hybridization Oven 645*, P/N 08-0255, for detailed instructions.

IMPORTANT: **If you are using the Hybridization Oven 645, you must manually enter the oven number. If you are not using or connected to the Hybridization Oven 645, you should also manually enter the Tray # (optional) and Oven # before starting the hybridization incubation.**

Figure 4.19 The Hybridization Worklist button

Hybridization Oven Procedure

1. Click the **Hybridization Oven** button from the workflow (Figure 4.19).

   The Hybridization Oven Worklist appears. (Figure 4.20).

NOTE: You cannot change any parameter in the Time/Rotation/Duration field. Technicians set these when they originally designed the particular assay.

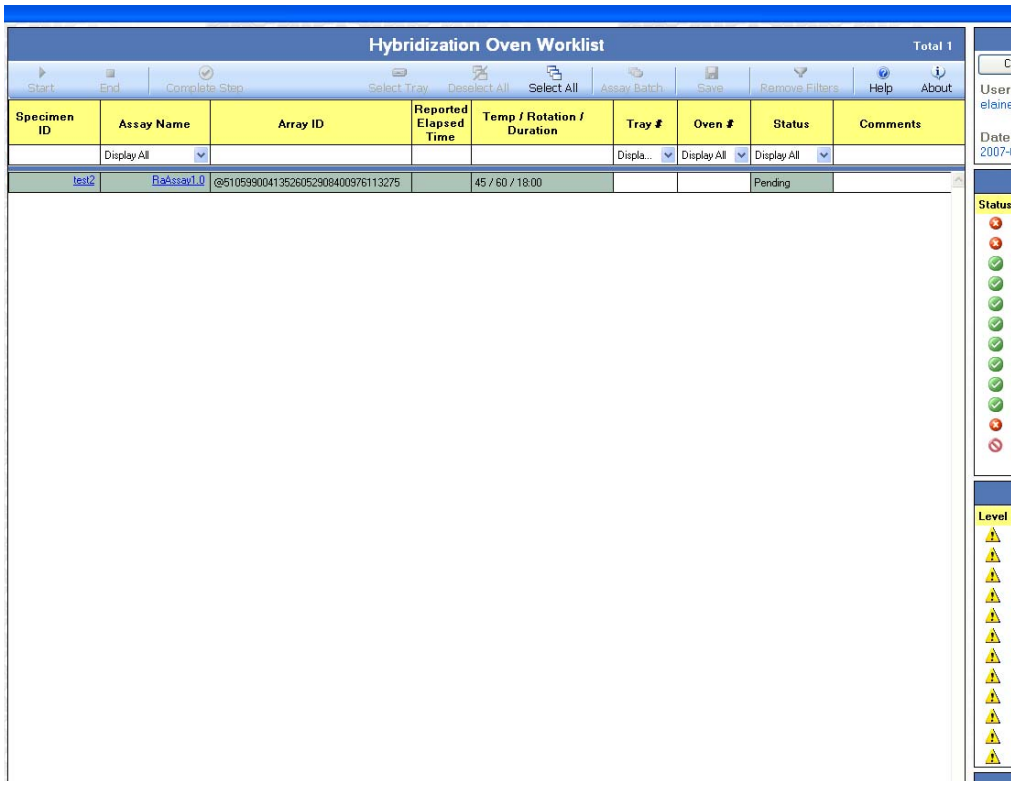


Figure 4.20 The Hybridization Worklist

2. Associate test requests with a particular tray.
   a. Shft-click or Ctl-click to select several test requests
   b. Ctl-click in the tray# field.
   c. Enter the tray number.
   d. Press **Enter**. AMDS will associate all the selected test requests with the tray number.
   e. If you want to select all the test requests that were earlier associated with a particular tray, select one test request with the newly added tray number and click the **Select Tray** button. All the test requests associated with that tray will be selected.
3. Associate test requests with a particular oven.
   a. Shft-click or Ctl-click to select several test requests
   b. Ctl-click in the oven# field.

c. Enter the oven number. If you are using the Hybridization Oven 645, this number may be either 1 or 2 depending on your oven configuration.

d. Press **Enter**. AMDS will associate all the selected test requests with the oven number.

NOTE: If you are using a third party oven or the GeneChip® Hybridization 640, enter "E" for external in the Oven # field.

4. Select one or more test requests.

   All test requests run at the same time in the same oven must have the same required temperature, rotation and duration).

5. Place the array cartridges in the in the tray then in the oven. Refer to your oven documentation for detailed instructions for doing this. If you are using the GeneChip® Hybridization Oven 645, see the GeneChip® Hybridization Oven 645 User's Guide, P/N 08-0255.

6. Click the **Start** button from the Hybridization Oven panel toolbar.

   If you are using the GeneChip® Hybridization Oven 645, AMDS will constantly display the status of the oven in the Device Status panel on the right side of the worklist (Figure 4.20).

7. Once the hybridization is complete, select the specimens that have completed hybridization and click the **End** button from the Hybridization Oven Worklist toolbar.

IMPORTANT: The color of the reported elapsed hybridization time will be yellow if the time is less than the minimum time required by the assay parameters. If the elapsed time falls within the acceptable range (determined by the assay), the color will be green. If the elapsed time is greater than that required by the assay parameters, the color will be red.

8. Select **Complete Step** from the Hybridization Oven Worklist toolbar to advance the test request to the next step in the workflow.

Washing and Staining an Array in the Fluidics Station

The following flow chart summarizes the steps required to process a an array from test request creation to the end of the fluidics protocol. The steps in bold are those relevant to the fluidics protocol. This procedure assumes that your workstation is connected to the Affymetrix Fluidics Station 450Dx.

Active Worklist → Create → Add Specimen ID & Assay Name → Submit → Register → Add Array ID → Save → Complete Step → Hybridization → Select Tray #; Select Oven # → Start → End → Complete Step → **Fluidics** → **(add your arrays to modules)** → **Scan Barcode of Array and associated module (or select and fill in Select Module # & Select Station #)** → **Start** → **Complete Step**

For more detail on the operation of the fluidics station, see the appendix, *The Fluidics Station 450Dx*, *on page 135*.

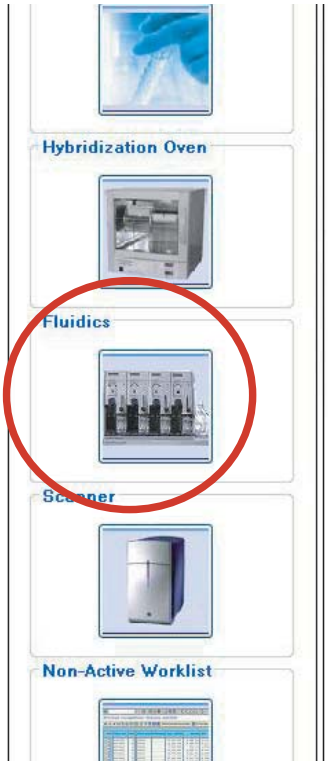


Figure 4.21 The Fluidics Worklist button

Setting Up the Fluidics Station

1. Click the **Fluidics** button from the workflow (Figure 4.21).
   The Fluidics Worklist appears. (Figure 4.22).

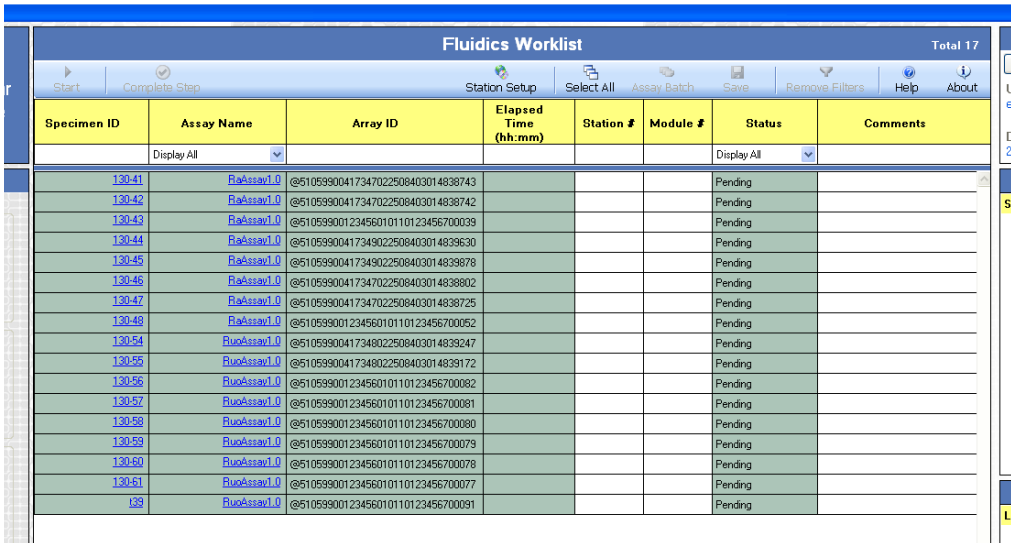


Figure 4.22 The Fluidics Worklist

2. Click the **Station Setup** button 

   The Fluidics Station Setup window appears (Figure 4.23).

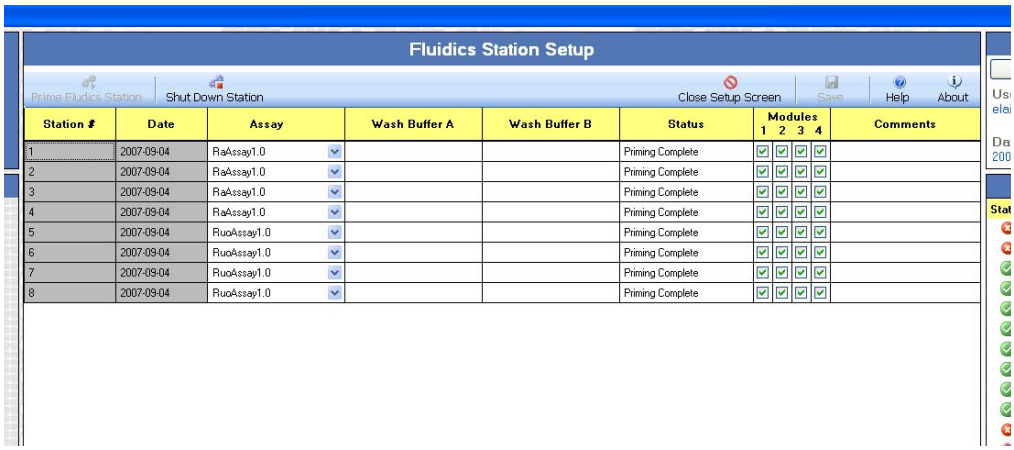


Figure 4.23 The Fluidics Worklist

3. Select the desired assay from the Assay field for each of the fluidics stations.

4. If the assay module instructions for a particular fluidics station (Station #) require a specific buffer (Wash Buffer A and Wash Buffer B), add the buffers to the fluidics station and enter the wash buffer names or IDs in the Wash Buffer A and Wash Buffer B fields.

NOTE: You need to use the module check boxes only if the fluidic station contains faulty modules.

5. Click the **Close Setup Screen** 

to return to the Fluidics Worklist.

Priming the Fluidics Station

If you have not yet primed the fluidics station, see the chapter, *Priming the Fluidics Station, on page 157* for details on priming the fluidics station.

IMPORTANT: You must prime the fluidics station: when you first start the fluidics station, when you change the wash solutions, before processing a cartridge, if you have performed a shutdown on any module, and if the LCD window instructs you to run a prime protocol.

Using the Fluidics Station

Once you have set up and primed the fluidics station, you can now proceed to use the fluidics station in your assay.

1. Click the **Fluidics** button from the Workflow (Figure 4.21).
   The Fluidics Worklist appears. (Figure 4.22).
2. If you are entering the information manually, select a test request record with the desired array ID and enter the fluidics station number in the Station # field and module number in the Module # field for the test request.

3. Insert the arrays into the fluidics station modules.
4. If you are using a barcode reader, scan each array then immediately scan the fluidics station module that will process the array. The array ID on the array will identify the proper test request registered to that array ID. See the section, *Using the Barcode Reader, on page 51* for instructions on using the barcode reader.

   The status of the test request will change to ready.
5. Select the test requests.
6. Click the **Start** button on the toolbar of the Fluidics Worklist panel.
7. When the status indicates complete, click the **Complete Step** button 

to advance the test request to the next workflow step.
8. To shut down the fluidics station, click the **Station Setup** button 

. When the Station Setup window appears (Figure 4.23), click the **Shutdown Station** button 

.

Scanning an Array

The following flow chart summarizes the steps required to process an array from test request creation to the end of the scanning procedure. The steps in bold are relevant to the scanning procedure. This procedure assumes that your workstation is connected to the Affymetrix AutoLoaderDx.

Active Worklist → Create → Add Specimen ID & Assay Name → Submit → Register → Add Array ID → Save → Complete Step → Hybridization → Select Tray #; Select Oven # → Start → End → Complete Step → Fluidics → (Add Arrays to modules) → (Scan Barcode of Array and associated module or Select Module # and Select Station #) → Start → Complete Step → **Scanner** → **(Add Arrays)** → **Start** → **Complete Step**

For more details on scanning and running the AutoLoaderDx, see the appendix, *The Scanner 3000Dx with AutoLoaderDx, on page 195*.

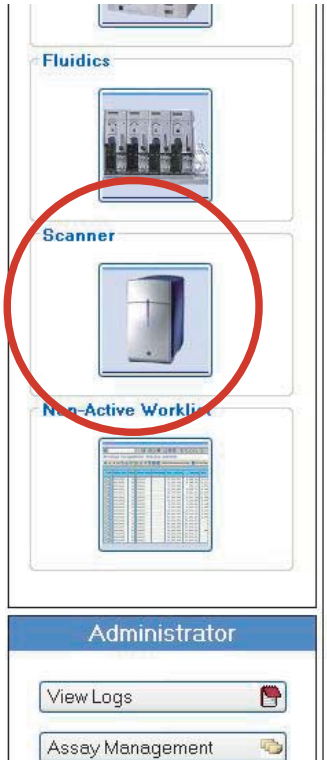


Figure 4.24 The Scanner Worklist button

Scanning the Array in Normal Operational Mode

1. Select **Scanner** from the Workflow (Figure 4.24).

   The Scanner Worklist in the center panel will appear (Figure 4.25).

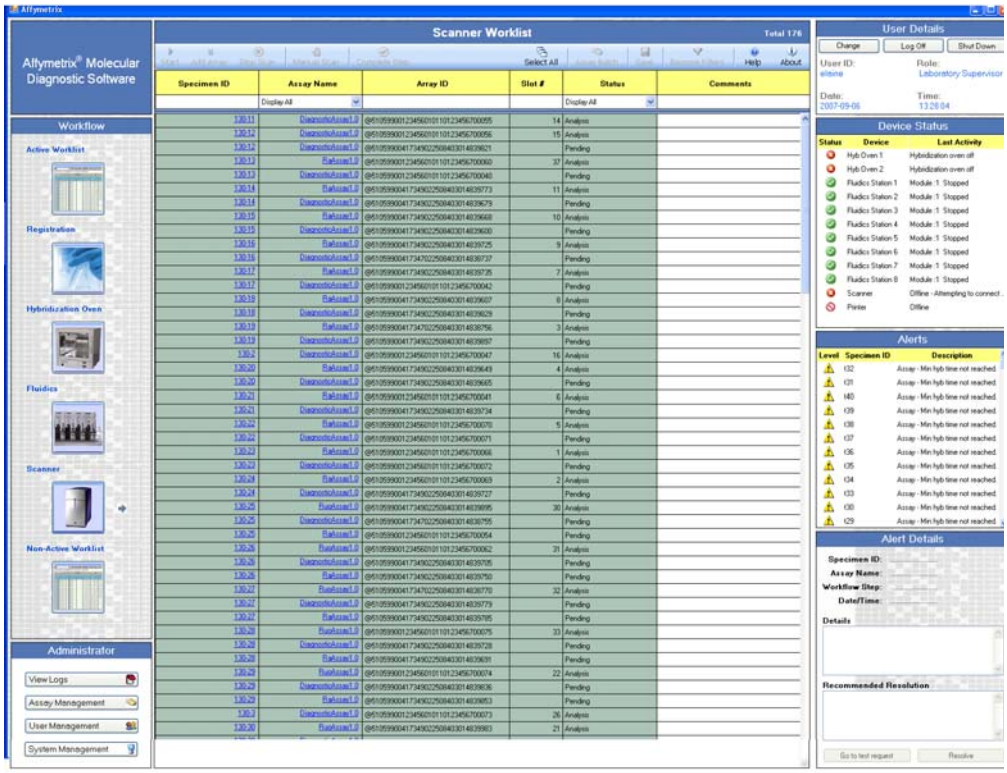


Figure 4.25 The Scanner Worklist

2. Load the array cartridges into the AutoLoaderDx.
3. Click the **Start** button from the toolbar of the Scanner Worklist panel.

   It is not necessary to select test requests or enter any information or read any barcode. The AutoLoaderDx uses a built-in barcode reader to identify the array ID and thus the test request that you had earlier registered with this array ID.

4. When the scan completes, as indicated by the status for the test request showing complete, click the **Complete Step** button to advance the test request to the next step in the workflow.

NOTE: For certain assays, as determined by the assay manufacturer, the system may require certain additional information for each test request in order for that test request to run successfully. Failure to enter the additional information prior to completion of the scanning step will cause a failure while attempting to execute the analysis algorithm following the scanning step. The assay manufacturer should provide this information as part of the assay documentation.

To enter additional information for a test request:

1. Click on the **Specimen ID** hyperlink in the Active Worklist for a particular specimen.
    - The Additional Info window will appear (see the section, *Adding Additional Information to the Specimen ID, on page 62*).
2. Enter requested information then, to save, click the **Save and Close** button.

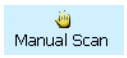
Scanning Arrays in Manual Mode—Manual Scan

You can scan one array at a time using the manual scan function. You can use this function to scan arrays that have illegible or missing barcode labels.

Do not confuse this with the manual mode that the system administrator can access by clicking the System Management button in the Administrator panel of the worklist. For more detail on this function, see the section, *Enable Manual Mode, on page 214*.

1. Select **Scanner** from the Workflow (Figure 4.24).

   The Scanner Worklist in the center panel will appear (Figure 4.25).
2. Select a test request.

   The Manual Scan button becomes available.
3. Add some identifying information about the array in the Array ID field.
4. Click the **Manual Scan** button 

.

5. Open the AutoLoaderDx door. Insert the array into the AutoLoaderDx carousel at **Slot #1**. Close the door.
6. Click the **Start** button.

   The door will lock and the scan will begin. When the scan has completed, the door will unlock. Open the door and remove the array.

Stopping a Scan

You can stop the AutoLoaderDx in the middle of a scanning run

1. Click the **Stop Scan** button.

   The AutoLoaderDx will continue with the current array scan then stop and unlock the door.

Adding Arrays During a Scanning Run

You can stop the AutoLoaderDx in the middle of a scanning run to add arrays.

1. Click the **Add Array** button.

   The AutoLoaderDx will continue with the current array scan then stop and unlock the door.
2. Add your arrays.
3. Click the **Start** button to resume.

NOTE: The AutoLoaderDx will not rescan any previously scanned array.

Reviewing Test Results

The following flow chart summarizes the steps necessary to review and process the results of an assay.

Active Worklist → (in Review Results field) Awaiting Results → (view test results window) → (add comments–required) → (complete user name and password) → Accept/Reject

Figure 4.26 The Review Results Function

Reviewing Results Procedure

1. On the Active Worklist and in the Review Results field (Figure 4.26), select the **Awaiting Review** hyperlink for any of the completed test requests on the Active Worklist to view the Assay Report.

   The partner designed software will create a particular Results window that is tailored for your particular assay. Each partner created software may display different Results windows.

In this example (Figure 4.27), a Test Results View window appears. This contains summary information on the assay.

In the this example, the information includes but not limited to:

- Upload URL—the location in the workstation of the uploaded file
- Upload Time—the time and date of the upload
- Specimen ID
- Patient Name
- Target Preparation Date—when a technician prepared the target from the specimen
- Test Date—when the technician performed the AMDS assay
- Array ID—the ID of the specific GeneChip array that AMDS used to perform the assay
- Uploaded Files—the .cel, .dat and audit files that AMDS created from the assay

NOTE: This example is only for illustrative purposes. The actual Test Results View will be different for each partner assay. The Additional Info, the Assay Batch and the Assay Home (Assay Landing) windows may also be different. For information on the particular Test Results View for your test result, see the partner assay documentation for your assay.

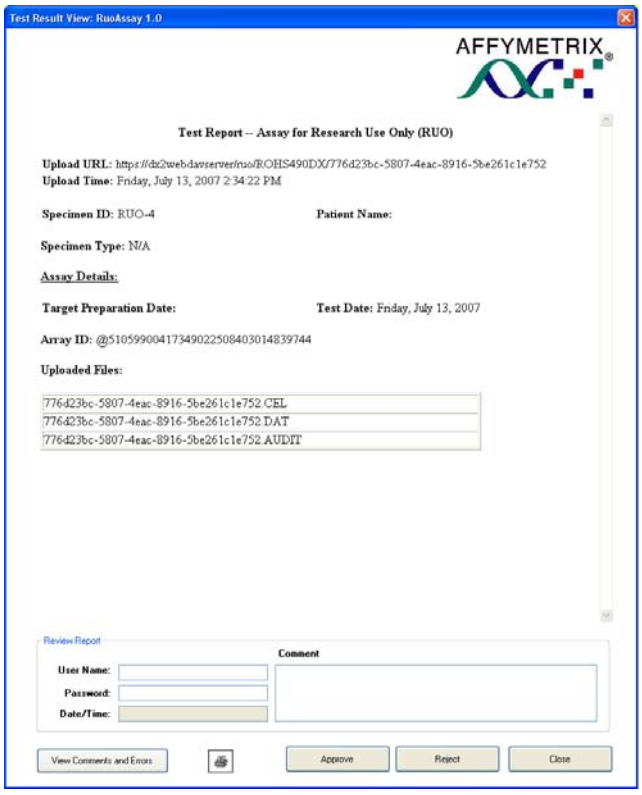


Figure 4.27 The Test Results View window—your particular window will display results different from this

2. Click the **View Comments and Errors** button to see any added information regarding the assay (Figure 4.28).

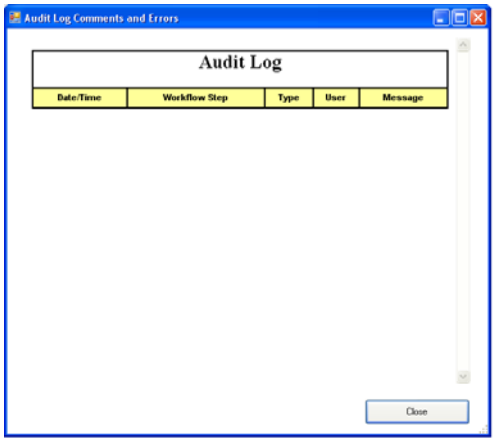


Figure 4.28 The Audit Log Comments and Errors window

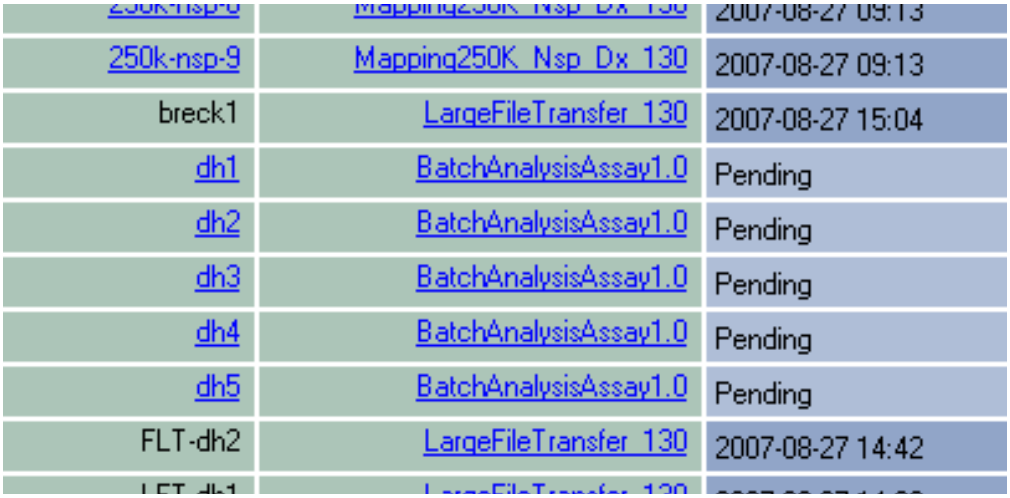
3. Click the **Close** button.
4. In the Test Results View window, Comments field, add any relevant comments regarding this assay. AMDS requires this to complete the review.
5. Fill in your user name and password.
6. Click the **Print** button if you want to print the report.
7. Click **Accept**, **Reject**. (click **Close** if you would like to exit without completing the review).

   AMDS will move the completed assay test request to the Non-Active Worklist and archive the assay results in a folder on the workstation.

Batch Analysis Assay

A special assay type, BatchAnalysisAssay, provides batch analysis functions (Figure 4.29).

IMPORTANT: **Do not confuse this function with the Assay Batch command to associate reagent lot numbers and test requests. See the section, *Associating Reagent Lot Numbers to Multiple Test Requests—Assay Batch*, *on page 70* for information on the Assay Batch command.**



250k-nsp-9	Mapping250K_Nsp_Dx_130	2007-08-27 09:13
breck1	LargeFileTransfer_130	2007-08-27 15:04
dh1	BatchAnalysisAssay1.0	Pending
dh2	BatchAnalysisAssay1.0	Pending
dh3	BatchAnalysisAssay1.0	Pending
dh4	BatchAnalysisAssay1.0	Pending
dh5	BatchAnalysisAssay1.0	Pending
FLT-dh2	LargeFileTransfer_130	2007-08-27 14:42

Figure 4.29 BatchAnalysisAssay in the Assay Name field

See the batch assay manual for details on the specific implementation of the Assay Batch Analysis. For test requests associated with an assay of the Batch Assay Analysis type, you will not be able to assign an array ID in the registration step until you have associated that test request with a batch via the Assay Landing screen. Note that the partner creates the Assay Landing screen.

Batch analysis occurs only after AMDS completes the assay run and has created the .cel files for those test requests that you have associated with a particular batch. The .cel files should be ready for analysis at this point at the completion of the run.

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Chapter 5 THE AMDS ADMINISTRATIVE FEATURES

Quick Reference Guide

Figure 5.1 and Table 5.1 summarize the functions of the Administrator feature.

Figure 5.1 Administrative function buttons

Table 5.1 AMDS Quick Reference Guide for administrators

If you want to:	Then do this in the Administrator panel:
View your system and audit logs	1. Click the **View Logs** button. 2. Select your log.
Export your system and audit logs to a CD or DVD	1. Click the **View Logs** button. 2. Select your log. 3. Click the **Export** button. 4. Click the **Burn** button.

Table 5.1 AMDS Quick Reference Guide for administrators (Continued)

If you want to:	Then do this in the Administrator panel:
Install an assay	1. Click **Assay Management** 2. Click the **Install** button. 3. Select the Manifest File for an assay. 4. Select the users to whom you want access to this particular assay. 5. Click the **Install** button again.
Deactivate an assay	1. Click **Assay Management** 2. Select the Assay. 3. Click the **Deactivate** button.
Activate an assay	1. Perform the "install an assay" procedure again on the deactivated assay.
Add a user	1. Click **User Management** 2. Click the **Add User** button. 3. Fill in the user's details • User ID, • First Name • Last Name • Comment • Password 4. Select the user's role • Guest • Technician • Technologist • SystemMaintainer • LabSupervisor 5. Select the assay groups associated with this user. 6. Click the **Discard Changes** or **Save Changes** button.

Table 5.1 AMDS Quick Reference Guide for administrators (Continued)

If you want to:	Then do this in the Administrator panel:
Edit a user	1. Click **User Management** 2. Select the user. 3. Click the **Edit User** button. 4. Change the user's details • User ID, • First Name • Last Name • Comment • Password 5. Change the user's role • Guest • Technician • Technologist • SystemMaintainer • LabSupervisor 6. Change the assay groups associated with this user. 7. Click the **Discard Changes** or **Save Changes** button.
Activate or deactivate a user	1. Click **User Management** 2. Click the **Edit User** button. 3. Check or uncheck **Active**. 4. Click the **Discard Changes** or **Save Changes** button
Change a user's password	1. Click **User Management** 2. Click the **Edit User** button. 3. Check **Change Password Confirm Password** 4. Change the password 5. Confirm the changed password 6. Click the **Discard Changes** or **Save Changes** button. or, if you want to change your own password: In the **User Details** panel, click **Change Password,** change the password, click **OK**.

Table 5.1 AMDS Quick Reference Guide for administrators (Continued)

If you want to:	Then do this in the Administrator panel:
Change the fluidics station settings	Click **System Management** → **In-House Service** → **User Performed Service** and in the Fluidics Station panel change: 1. the FS450Dx Station (select **Select Station**) 2. the warning notification to perform a bleach protocol (in the Configuration panel, select and change **Bleach Interval Warning Limit**). To accept, click the **Save** button, or if you leave the User Services window and a window appears asking you to accept or reject the changes, click **Yes**, or if you want to reject the changes, click **No** or **Cancel** • Note: the warning limit must be less than the alert limit. 3. the alert that is the time interval between performing a bleach protocol has passed (in the Configuration panel, select and change **Bleach Interval Alert Limit**) 4. the warning notification to change the peristaltic tubing (in the Configuration panel, select and update **Change Tubing Warning Limit**) • Note: the warning limit must be less than the alert limit. 5. the alert notification that the time interval between changing the peristaltic tubing has passed (in the Configuration panel, select and update **Change Tubing Alert Limit**)
Perform a Home, Bleach or Change Tubing procedure	Click **System Management** → **In-House Service** → **User Performed Service** and in the Fluidics Station panel: 1. select **Procedure (Beach, Home, Change Tubing)** 2. click **Perform**
Monitor the workstation hard disk volume	Click **System Management** → **In-House Service** → **User Performed Service** and in the System panel view **HDD Space Available**.

Table 5.1 AMDS Quick Reference Guide for administrators (Continued)

If you want to:	Then do this in the Administrator panel:
View the size of the data file to be exported	Click **System Management** → **In-House Service** → **User Performed Service** and in the System panel view **Export File Size**.
Change the warning that the workstation hard disk is reaching its space capacity	Click **System Management** → **In-House Service** → **User Performed Service** and in the System panel, Configuration view, change **HDD Space Warning Limit**. • Note: the warning limit must be greater than the alert limit.
Change the alert that the workstation hard disk has reached its space capacity	Click **System Management** → **In-House Service** → **User Performed Service** and in the System panel, Configuration view, change **HDD Space Alert Limit**. • Note: the warning limit must be greater than the alert limit.
Perform a self test to determine the health of the system—confirm that services are running and check instrument communication	Click **System Management** → **In-House Service** → **User Performed Service** → **System Self-Test** (in the System panel)
View the instrument service logs	Click **System Management** → **In-House Service** → **Service Logs**
Archive test request data	Click **System Management** → **In-House Service** → **Archive Test Requests** select test request record, insert blank CD disc, click **Archive**

Table 5.1 AMDS Quick Reference Guide for administrators (Continued)

If you want to:	Then do this in the Administrator panel:
Change local time, time zone, day light saving	1. Click **System Management** → **In-House Service** → **General Configuration** 2. In the Time Zone Editable panel, check **Editable Local Time** and change the local time 3. In the Time Zone Editable panel, check **Time Zone** and change the time zone and day light saving status. 4. In the Time Zone Editable panel, check **Day Light Saving** and select **Yes** or **No**. 5. Click the **Save** button or the **Discard Changes** button.
Turn the scanner laser on if the laser was off at system start up	1. Click **System Management** → **In-House Service** → **General Configuration** 2. In the System Configuration Flags panel, check the **Turn On Laser** box. 3. Click the **Save** button or the **Discard Changes** button.
Disable the AutoLoader	1. Click **System Management** → **In-House Service** → **General Configuration** 2. In the System Configuration Flags panel, check the **Disable AutoLoader** box. 3. Click the **Save** button or the **Discard Changes** button.
Force the AutoLoader to warm up the array cartridges at positions 1 to 4 in the AutoLoader carousel when starting a scan	1. Click **System Management** → **In-House Service** → **General Configuration** 2. In the System Configuration Flags panel, check the **Force Array Warm Up** box. 3. Click the **Save** button or the **Discard Changes** button.
Approve or reject analysis results, once available, before proceeding	1. Click **System Management** → **In-House Service** → **General Configuration** 2. In the System Configuration Flags panel, check the **Require User Approval** box. 3. Click the **Save** button or the **Discard Changes** button.

Table 5.1 AMDS Quick Reference Guide for administrators (Continued)

If you want to:	Then do this in the Administrator panel:
Identify the printer (Printer Name)	Click **System Management** → **In-House Service** → **User Performed Service** → **Printer Name** (view the printer name; you cannot change the printer)
Transfer from online (server network) to offline status.	Click **System Management** → **In-House Service** → **User Performed Service** → **Online/Offline** (Select one in the Printer panel)
Identify the number of jobs in the queue	Click **System Management** → **In-House Service** → **User Performed Service** → **Number of Jobs in the Queue** (View in the Printer panel)
Purge all the jobs in the queue	Click **System Management** → **In-House Service** → **User Performed Service** → **Purge All** (in the Printer panel)
Resume all printing jobs	Click **System Management** → **In-House Service** → **User Performed Service** → **Resume All** (in the Printer panel)
Backup your firewall settings (not used in IVD systems)	Click **System Management** → **In-House Service** → **User Performed Service** → **Last Backup** → **Backup** (in the Firewall panel)
Restore your firewall settings (not used in IVD systems)	Click **System Management** → **In-House Service** → **User Performed Service** → **Last Backup** → **Restore** (in the Firewall panel)

Viewing Logs

The View Logs function 

allows you to view the system and audit logs for your test requests. View Logs window contains an upper region, or System Log, and lower region, or Audit Log.

NOTE: Do not confuse Viewing Logs with the instrument service logs that you can view in System Management → In-House Service → Service Logs (see the section, *Viewing Instrument Service Logs, on page 120*).

System Logs

System logs record various algorithm and computer messages and recorded parameters of the completed assays such as the date/time, the component (i.e., the AMDS Business, Interop, Instrument Control), type (i.e. Error, Info, Comment) or User, etc.

NOTE: The system and audit logs may be very big. Take this into consideration before you print.

1. Click the **View Logs** button 

.

   The View Logs window appears (Figure 5.2).

   The upper region displays the system log information.
2. The current system log is the default window.
3. In the **System Log** dropdown list, select a system log for a previous period for display.
4. Filter the system log view by date/time, component, type, user, etc.
5. Click the **Print** button to print the System Log.

To export System Log files:

1. Select your file (only one at a time).

2. Click the **Export** button.

   AMDS formats and stages the selected files for export, and alerts you when the files are ready to burn.

3. Click the **Burn** button to export the current list to the workstation's CD or DVD.

Audit Logs

Audit logs various messages and parameters for each of the workflow steps such as the Date/Time, the Workflow Step (i.e. Hybridization, Fluidics, Scan, Report), Type (e.g. Info, Error) or User, etc.

1. Click the **View Logs** button 

.

   The View Logs window appears (Figure 5.2).

   The lower region displays the audit log. AMDS associates audit logs with a test requests.

2. Click on **Browse for Audit Logs** button to select a test request for which to view audit log details.

3. Filter the audit log by Date/Time, Workflow Step (i.e. Hybridization, Fluidics, Scan, Report, Type (e.g. Info, Error) or User, etc.

4. Click the **Print** button to print the Audit Logs.

To export Audit Log files:

1. Select your file (only one at a time).

2. Click the **Export**.

   AMDS formats and stages the selected files for export, and alerts you when the files are ready to burn.

3. Click the **Burn** button to export the current list to the workstation's CD or DVD.

NOTE: You cannot select an additional or external CD or DVD player. AMDS automatically exports the logs to the workstation's single internal player.

Figure 5.2 The View Logs window: the upper pane contains the System Log; the lower pane contains the Audit Log.

Managing the Assay

The Assay Management function 

provides the capability to install or deactivate assays.

1. Click the **Assay Management** button 

.

   The Assay Management window appears (Figure 5.3).

Figure 5.3 The Assay Management window

Installing an Assay

In order to install an assay, you must have a valid manifest file. The install assay function allows you to browse to the manifest file and install the assay. The install assay function also requires an LIS Name (LIS—Laboratory Information System) and identifies the users who should have access to the assay.

1. Click the **Install Assay** button 

.

   The Assay Installation Dialog appears (Figure 5.4).

2. In the Select the Manifest file box, enter or browse to the Manifest file name and directory location. (Note: the assay manufacturer will provide the manifest file).
3. In the LIS name box, enter a unique LIS name for the assay. (This is required even if your current system is not connected to an LIS.)
4. Select the users who should be permitted to run this assay. Click the **Select All** button to select all the users.

   Click the **Deselect All** button to deselect all the users.
5. When the Install button appears, click the **Install** button.

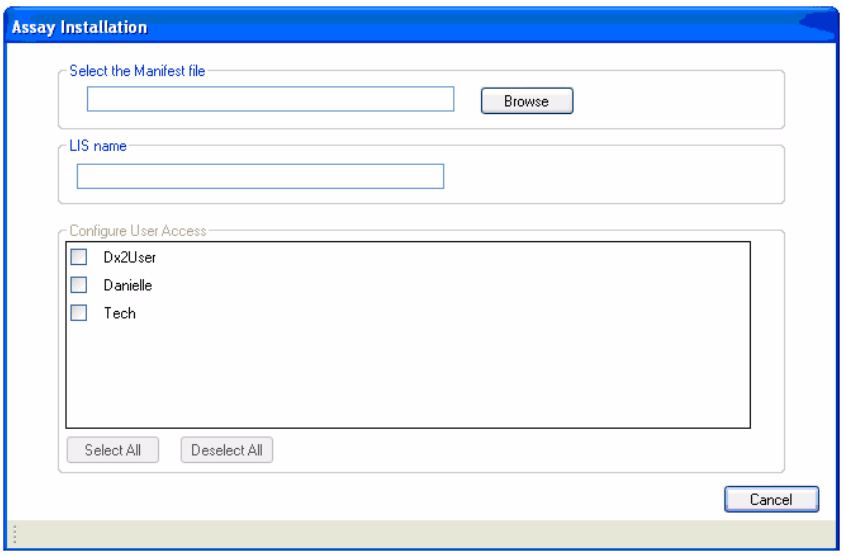


Figure 5.4 The Assay Installation Function

Installing a Certificate

The AMDS IVD application does not use certificates. The AMDS RUO (Research Use Only) version handles server certificates to enable the AMDS system to trust the RUO Server through https protocols.

AMDS assays that perform their analysis on the local workstation do not use certificates. This is known as Local Analysis assays (LA assays).

AMDS assays that do not perform local analysis and do not return an analysis report require a certificate. This is known as No Analysis assays (NA assays).

The setup technician will generate a certificate on the RUO Server at set-up time.

Deactivating an Assay

The deactivate assay function allows you to deactivate an assay if you no longer use this assay and do not want it to appear as a selection in the AMDS application.

1. Select an assay from the Assay Management panel (Figure 5.3).
2. Click the **Deactivate** button (Figure 5.5).

   AMDS moves the target request to the Non-Active Worklist window.

NOTE: If you want to activate or re-activate an assay, you must re-install the assay from a separate CD/DVD that contains the assay in question.

Figure 5.5 The Deactivate Assay function

Managing the Users

The User Management button 

allows you to add or to change the characteristics of users.

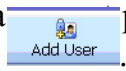
1. Click the **User Management** button 

.

   The User Management window appears(Figure 5.6). This screen shows the list of current users and provides buttons for adding or editing users.

Figure 5.6 User Management Function

Adding a User

1. In the User Mana 

panel toolbar (Figure 5.6), click the **Add User** button .

   The Add User window appears (Figure 5.7).

2. Establish the following characteristics of the new user.

   - Select the **Active** box to make the user currently active.

- Deselect the **Active** box to deactivate a user.
- Enter a user ID.
- Enter the user's first and last name.
- Enter a comment (optional).
- Create and confirm a password.
- Select the user's role.
- Select the type of assay groups to which you want the user to have access.

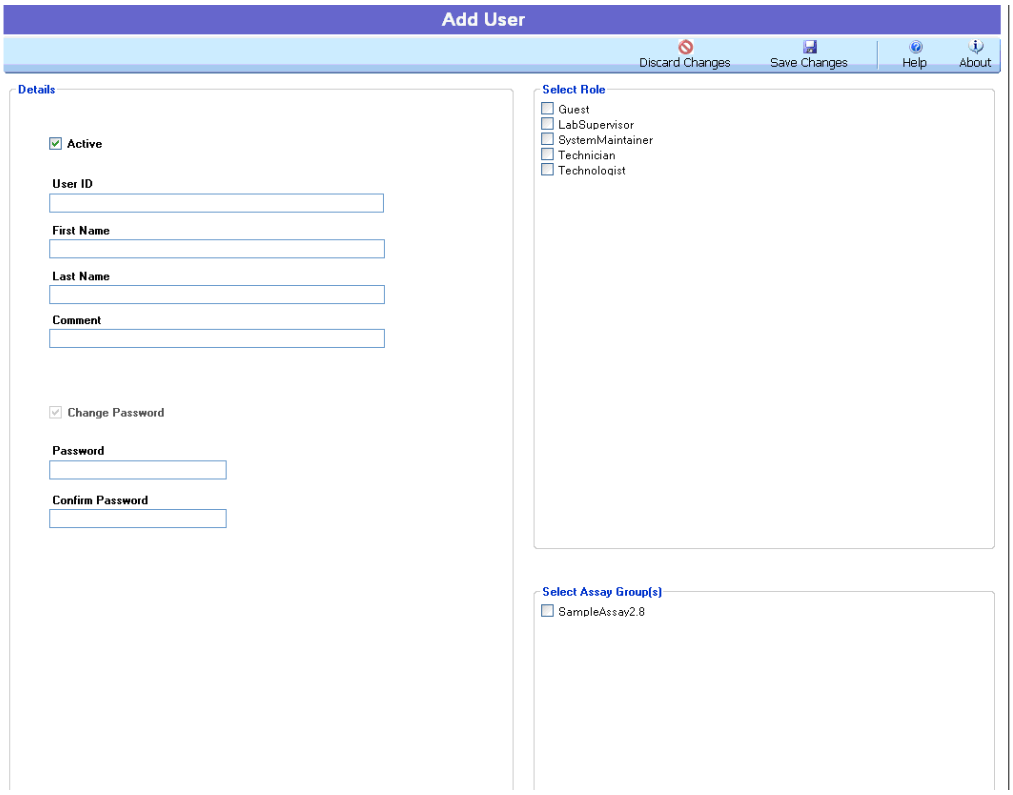


Figure 5.7 The Add User Function

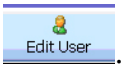
3. Click the **Save Changes** button.

   AMDS will commit the information and create the user in the system with the associated roles and permissions.

   Click the **Discard Changes** button if you do not want to add the user.

Editing a User

You can change any attribute other than the user name.

1. In the User Management panel toolbar (Figure 5.7), select a user.
2. Click the **Edit User** button 

.

   The Edit User window appears (Figure 5.8).
3. Change to the characteristics of a current user.
   - Select the **Active** box to make the user currently active.
   - Deselect the **Active** box to deactivate a user.
   - Enter a user ID
   - Enter the user's first and last name.
   - Enter a comment.
   - Create or change a password. If you want to change a password, select the **Change Password** box, enter the new password. Enter the password again in the **Confirm Password** dialog box.
   - Select the user's role.
   - Select those assays groups to which you want the user to have access.

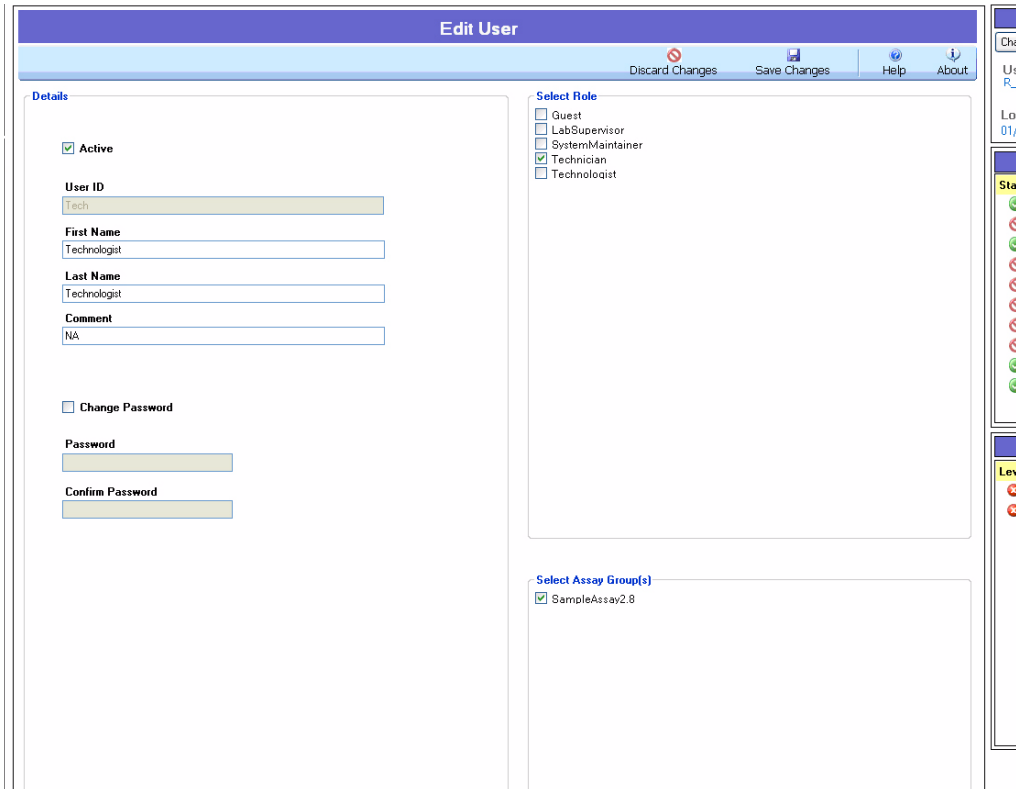


Figure 5.8 The Edit User Function

4. Click the **Save Changes** button.

   AMDS will commit the information and change the associated roles and permissions of the user.

   Click the **Discard Changes** button if you want to cancel and lose the changes.

Managing the System

System management function 

enables you to perform various types of simple service on AMDS.

When you click on the System Management window, the In-House Services function becomes available. Note that the default window will be the User Performed Service function.

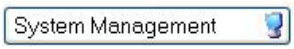
The System Management function allows you access to the following functions.

- User Performed Service—This is the default widow of the System Management function. You can view the system's configuration, i.e., the device and instrument settings, and make minor changes to the fluidics station, workstation, scanner, printer and firewall settings.
- View Service Logs—view your device, or instrument, service logs

NOTE: Do not confuse the View Service Log function with the View System and Audit logs in the section, ***Viewing Logs, on page 102*****.**

- Archive Test Requests—save test data to a hard drive or CD.
- General Configuration—change the time and time zone settings for your particular location and change the configuration flags for your instruments.

Changing the Instrument Settings

1. Click the **System Management** button 

.
2. The System Management window appears and displays the In-House Service dropdown list (Figure 5.9).

   If you are not already on the default User Performed Service window, select **In-House Service** → **User Performed Service**.

Managing the Fluidics Station

The appendix, *The Fluidics Station 450Dx, on page 135* provides greater detail on using and maintaining the fluidics station.

1. Click the **System Management** button 

.
2. The System Management window appears and displays the In-House Service dropdown list (Figure 5.9).

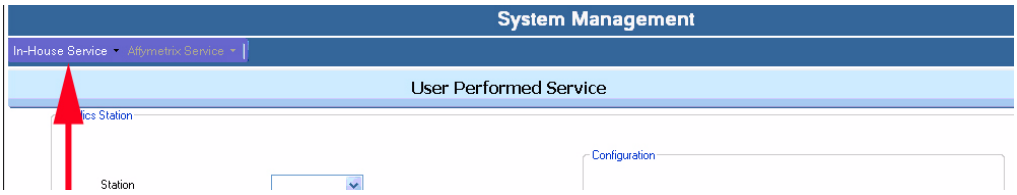


Figure 5.9 The In-House Services function

If you are not already in the default User Performed Service window (Figure 5.10), select **In-House Service** → **User Performed Service**.

View the Fluidics Station panel (Figure 5.10).

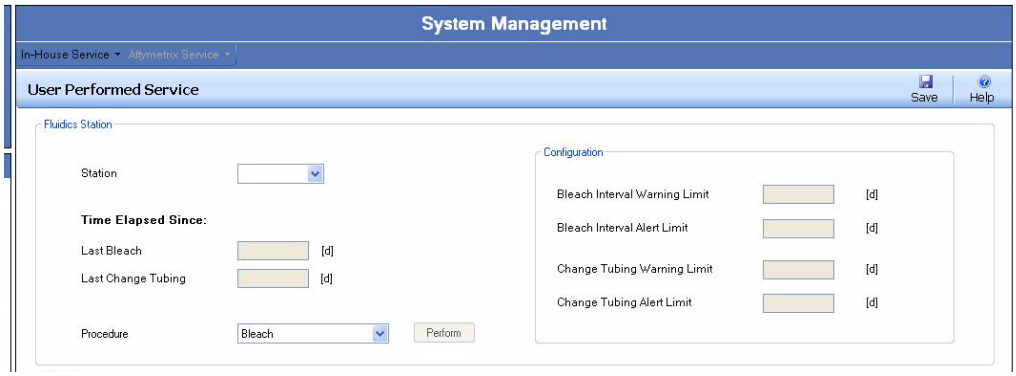


Figure 5.10 The management functions for the fluidics station

3. Select a station number from the drop down list. The system will show the last bleach and peristaltic tube change.
4. If you want to perform a bleach protocol, select **Bleach** in the Procedure dialog box and see the section, *The Bleach Cycle, on page 161* for details on using the bleach protocol.

5. If you want to change the tubing, select **Change Tubing** in the Procedure dialog box and see the section, *Peristaltic Tubing Maintenance, on page 169* for more details on changing the peristaltic tubes.
6. If you are having problems communicating with the fluidics station or just want to test the communications, select **Home** in the Procedure dialog box and click the **Perform** button.

   The Confirm Step dialog box appears. Enter your password and the Event Reason. Click **OK**.

   AMDS will instruct the fluidics station to home the valves. If successful, the LCD on the fluidics station will inform you. If homing fails, the Device Status panel on a worklist window will alert you. If you fail after several unsuccessful tries to home the fluidics station, turn off then turn on the fluidics station. If these failures continue, call Affymetrix technical support.
7. In the Configuration panel, set the **Bleach Interval Warning Limit**, **Bleach Interval Alert Limit**.
8. Click the **Save** button.
9. The Confirm Step dialog box appears. Enter your password and the Event Reason. Click **OK**.
10. In the Configuration panel, set the **Change Tubing Warning Limit** and **Change Tubing Alert Limit**.

NOTE: The warning limit times must be less than the alert limit times.

11. Click the **Save** button.
12. The Confirm Step dialog box appears. Enter your password and the Event Reason. Click the **OK** button.

Managing the Workstation

You can monitor the amount of space on the workstation's hard disk and the size of the data file size that you export.

1. Click the **System Management** button 

.
2. The System Management window appears and displays the In-House Service dropdown list (Figure 5.11).

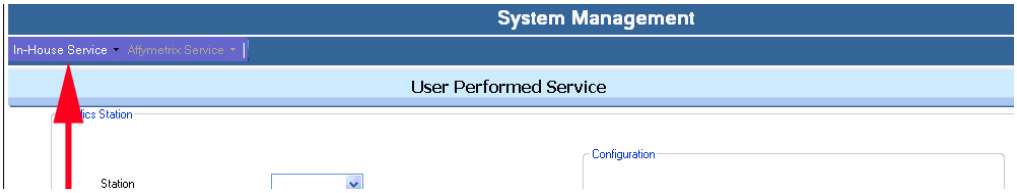


Figure 5.11 The In-House Services function

If you are not already on the default User Performed Service window, select **In-House Service** → **User Performed Service**.

View the System panel (Figure 5.12).

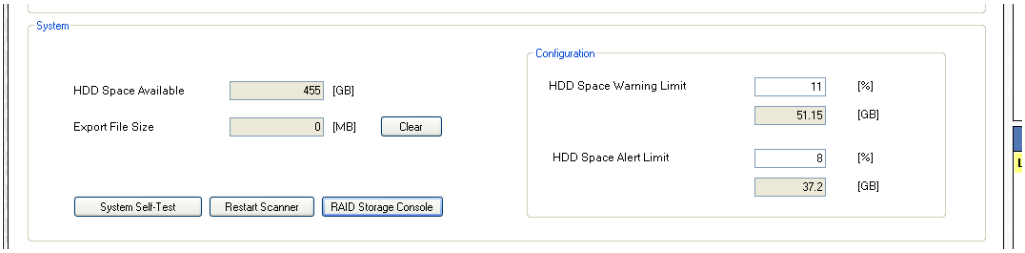


Figure 5.12 The management functions for the workstation

3. To view the hard drive space available and the size of the data file for saving to the hard drive click the **System Self-Test** button to perform a system self test.
4. To restart the AutoLoaderDx, click the **Restart Scanner** button.

   Use this function if you are experiencing problems connecting to the AutoLoaderDx. Clicking this button will attempt to restart AutoLoaderDx and establish communication between the workstation and the AutoLoaderDx.
5. To view and manage the Intel® RAID Matrix volumes and to check the health of your hard drives, click the **RAID Storage Console** button.

The Intel® Matrix Storage Console window appears and displays information on your hard drives (Figure 5.13).

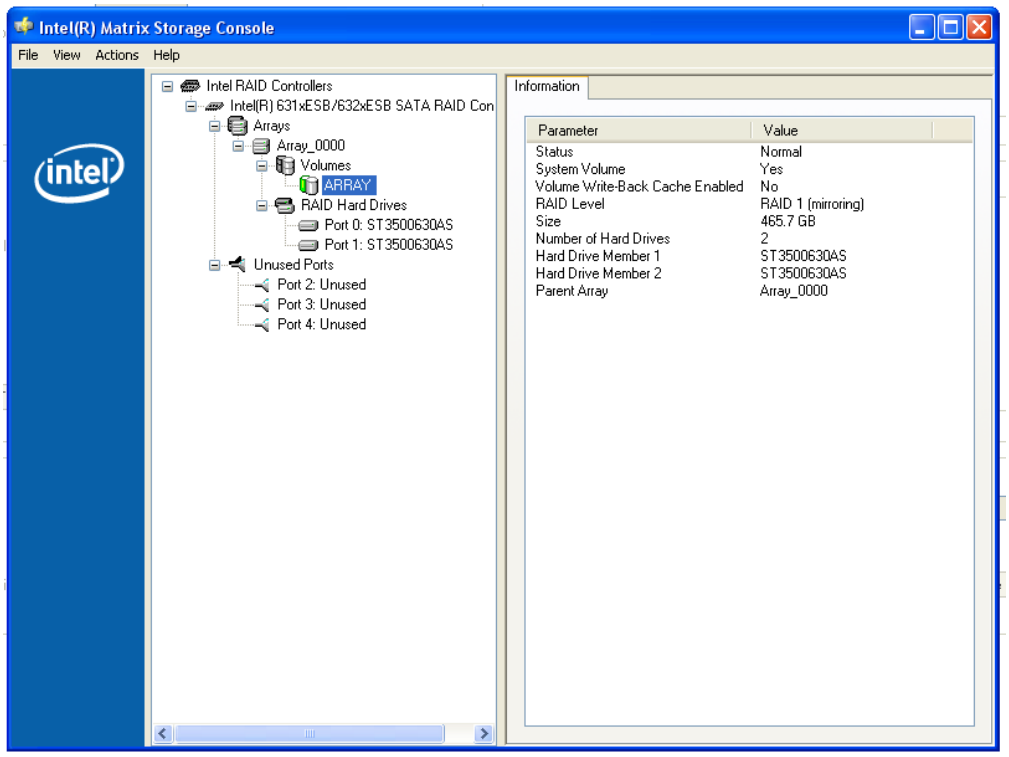


Figure 5.13 The RAID Matrix Storage Console window

6. To set a warning and alert that informs you that you are reaching the capacity limit of your hard disc drive, in the Configuration panel, set the **HDD Space Warning Limit**, **HDD Space Alert Limit**. Click the **Save** button.

NOTE: The warning limit times must be less than the alert limit times.

Managing the Printer

You can perform several printer maintenance functions. You can:

- Transfer from online to offline status.
- Identify the number of jobs in the queue

- Purge all the jobs in the queue
- Resume printing

1. Click the **System Management** button 

.
2. The System Management window appears and displays the In-House Service dropdown list (Figure 5.14).

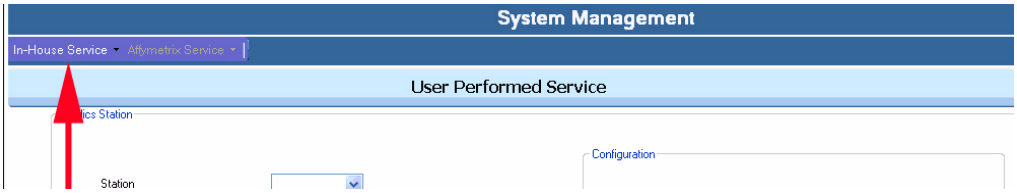


Figure 5.14 The In-House Services function

If you are not already on the default User Performed Service window, select **In-House Service** → **User Performed Service**.

View the Printer panel (Figure 5.15).

NOTE: You cannot change the printer. The Affymetrix service technician set up the printer when he installed the AMDS system.

Figure 5.15 The management functions for the printer

3. View the printer name.
4. To send the printer offline (for printer maintenance, etc.) and stop the printing of the job queue, select **Offline**.
5. To bring the printer online, select **Online**. The Print button in the workflows will become enabled.

6. Click the **Purge All** button to cancel all the jobs in the print queue.
7. To print all the jobs in the queue, click the **Resume All** button to continue printing the job queue.

Managing the Firewall Settings

The AMDS firewall monitors incoming and outgoing messages from the workstation and protects the workstation from malicious intrusion (Figure 5.16). Users can backup and restore firewall settings.

Figure 5.16 The user maintenance functions for the printer

Viewing Instrument Service Logs

You can open and view the service logs for the instruments.

1. Click the **System Management** button 

.
2. Select **In-House Service** → **Service Log** (Figure 5.17).

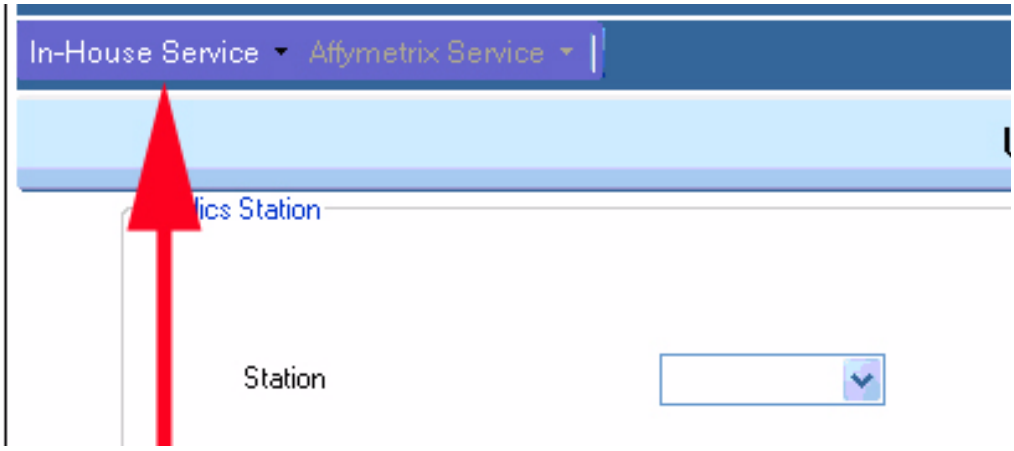


Figure 5.17 The In-House Service tab

The User Performed Service Log screen will appear in the center panel. You can filter the log by Date/Time, Procedure, User or Device (Figure 5.18).

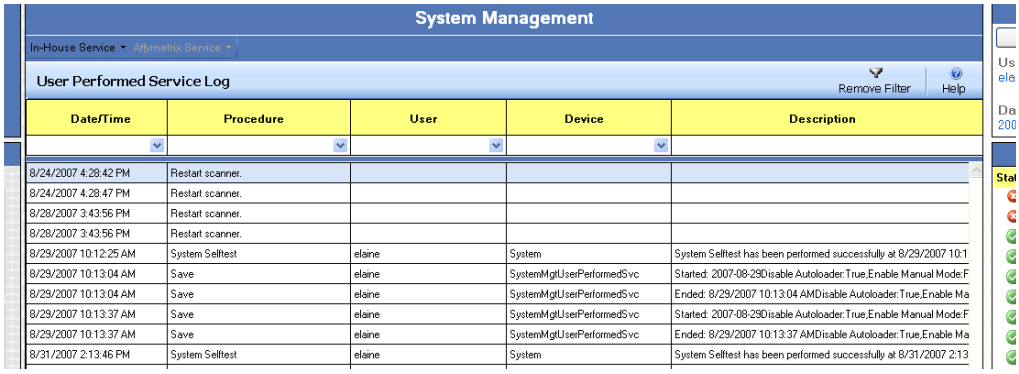


Figure 5.18 The User Performed Service Logs window

Archiving Test Requests

1. Click on the **System Management** button 

.
2. Select **In-House Service** → **Archive Test Requests** (Figure 5.19).

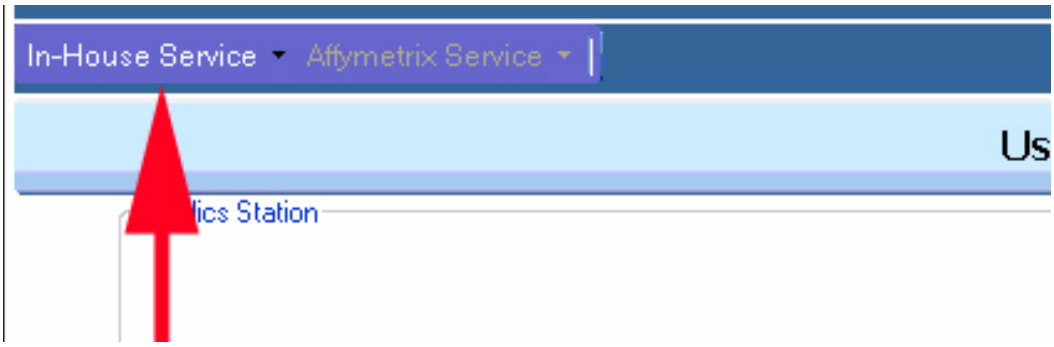


Figure 5.19 The In-House Service tab

The System Management Archiving screen will appear in the center panel (Figure 5.20).

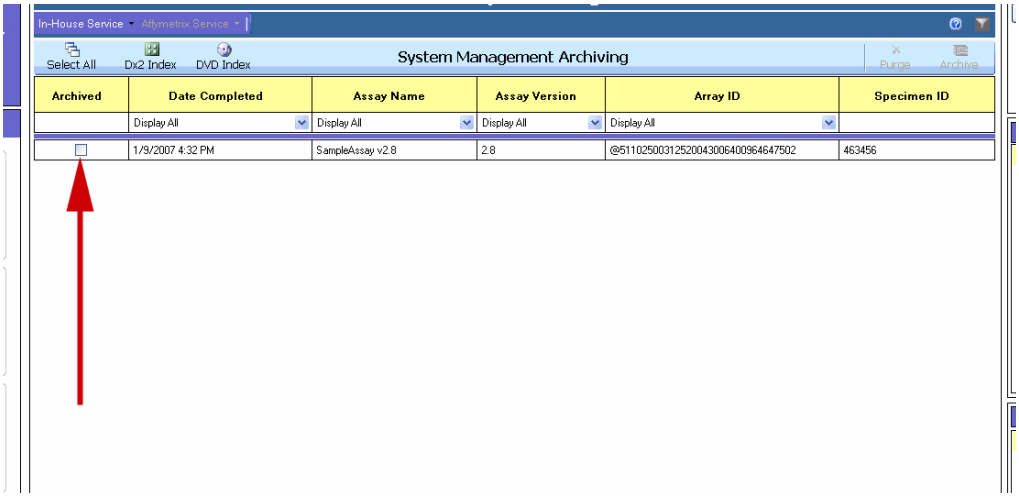


Figure 5.20 The System Management Archiving window

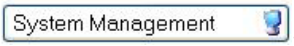
1. Filter the log by Date Completed, Assay Name, Assay Version, or Array ID.
2. Select those test requests you wish to archive.
3. Click the **Archive** button to archive the test request records

4. After you have archived the test request records, you can click the **Purge** button if you want to delete the archived test request records from the system.

IMPORTANT: **You can only purge a test request record after you have archived it. Once you purge a test request record, you cannot recover it.**

Setting the General Configuration

In the General Configuration window you can view and set the time zone and set several system configuration flags.

1. Click on the **System Management** button 

.
2. Select **In-House Service** → **General Configuration** (Figure 5.21).

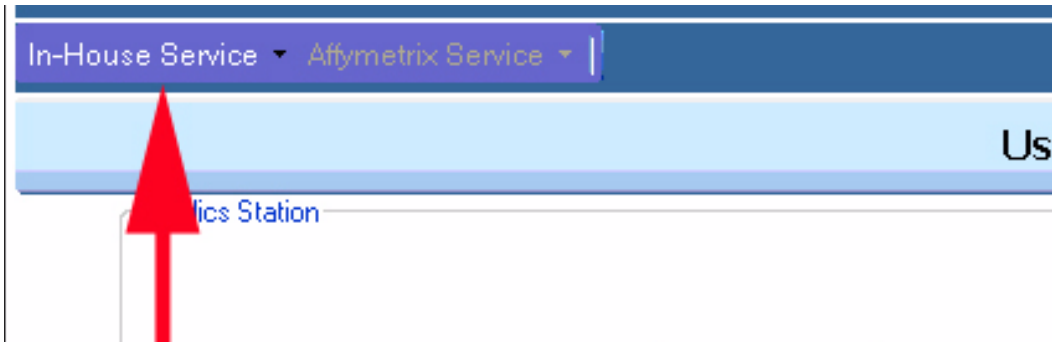


Figure 5.21 The In-House Service tab

The General Configuration window appears (Figure 5.22).

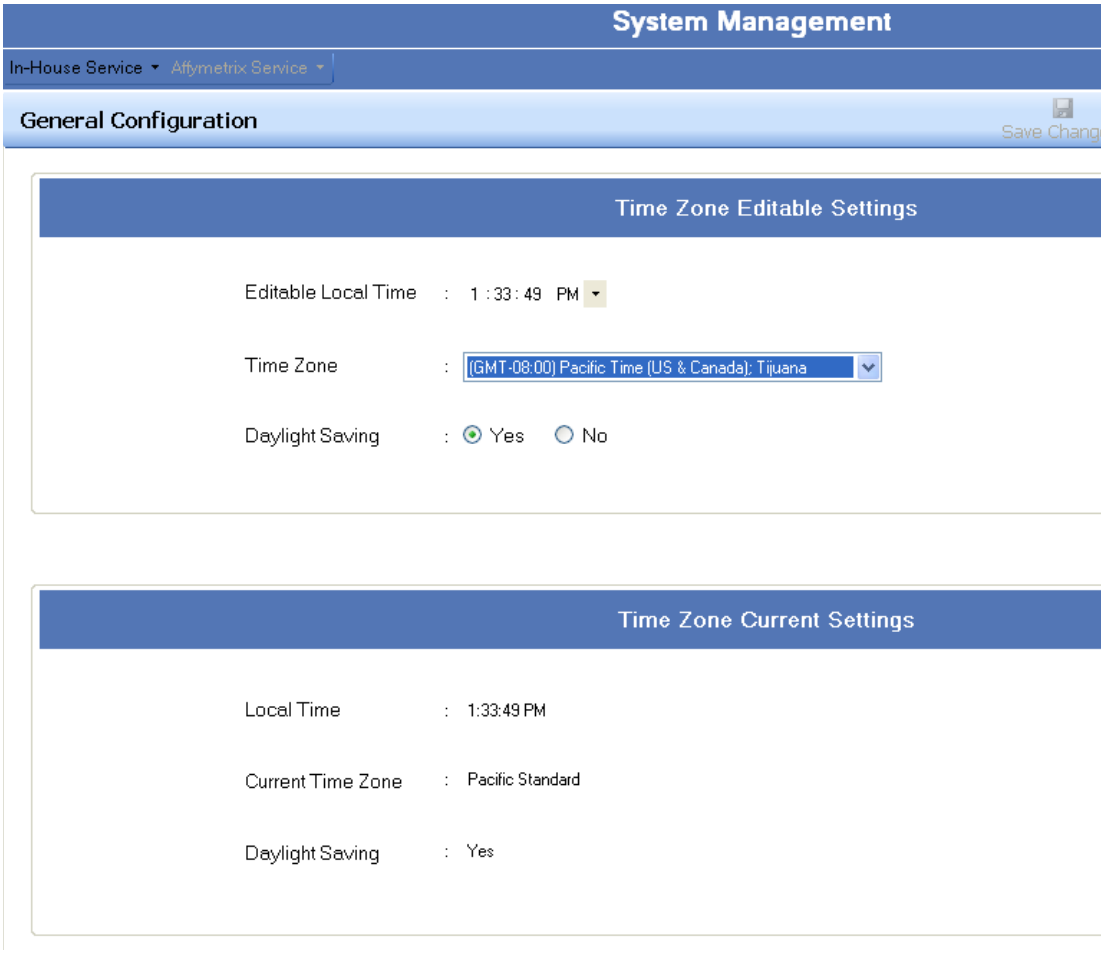


Figure 5.22 The General Configuration window

Setting and Viewing Date and Time

You can set the local time, time zone, and savings time. In the **Time Zone Editable Settings** panel:

1. In **Editable Local** time, set the local time.
2. In **Time Zone**, set your local time zone.
3. In **Daylight Savings**, select **Yes** or **No**.

In the **Time Zone Current Settings** panel, view the local time, time zone, and savings time.

Managing the AutoLoaderDx

In the System Configuration Flags window, you can control three functions of the AutoLoaderDx and require user approval (Figure 5.23).

You can control the following three functions of the AutoLoaderDx:

- Turn on scanner every time you launch AMDS.
- Disable the AutoLoaderDx to run only the software.
- Force arrays 1 to 4 to warm up when you start scanning a run to speed up the run. This is faster than warming each array one at a time.

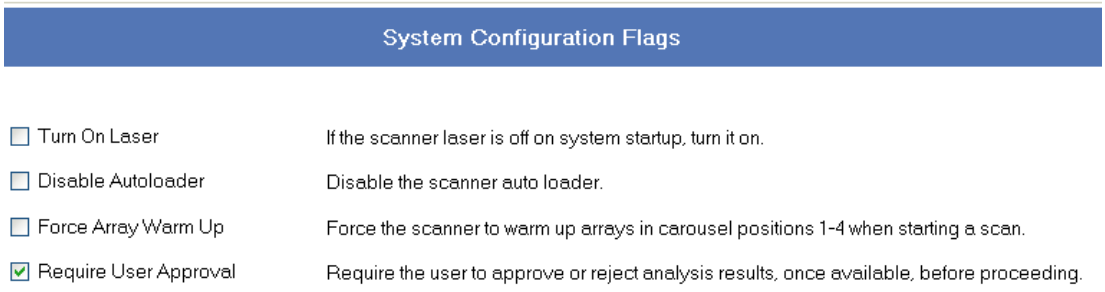


Figure 5.23 The System Configuration Flags window

In the **System Configuration Flags** window:

1. Select **Turn on Laser** to turn on the AutoLoaderDx laser automatically when you launch the AMDS application.
2. Select **Disable AutoLoader** box to disable the AutoLoaderDx and use just the AMDS application without the AutoLoaderDx.
3. Select **Force Array Warm Up** if the arrays are not already at room temperature, and you want raise the temperature of the arrays in carousel positions 1 to 4 before scanning.

Requiring User Approval for the Analysis Results

Select **Require User Approval** to require the technician to approve or reject the analysis results as they become available after an assay run (Figure 5.23). This flag is meaningful only if your AMDS system is connected to a laboratory information system (LIS) network. Selecting this box when you are connected to a LIS allows you to make a final determination as to whether or not the test request assay run is complete before the software uploads the test request results to the LIS.

NOTE: If you are not connected to a LIS, you must select this box so that the technician will have a method of approving or rejecting the results.

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Chapter 6 AMDS TROUBLESHOOTING

Introduction

There are generally three categories of problems that can cause trouble when executing test requests:

- Instrument related problems, such as problems with the Hybridization Oven, problems with a fluidics station or module, or problems with the scanner.
- Problems with a particular test request, for example the bar code of the array associated with a test request could not be read, or gridding fails for a test request.
- Operational errors, including data input errors.

The system tracks and reports on all three categories of problems mentioned above. This section provides information as to how to identify that a problem has occurred, and provides some general guidance as to how to try to resolve a problem.

First Type of Problem—Resolving Instrument Related Errors

The status of the various instruments are displayed in the Device Status panel (Figure 6.1).

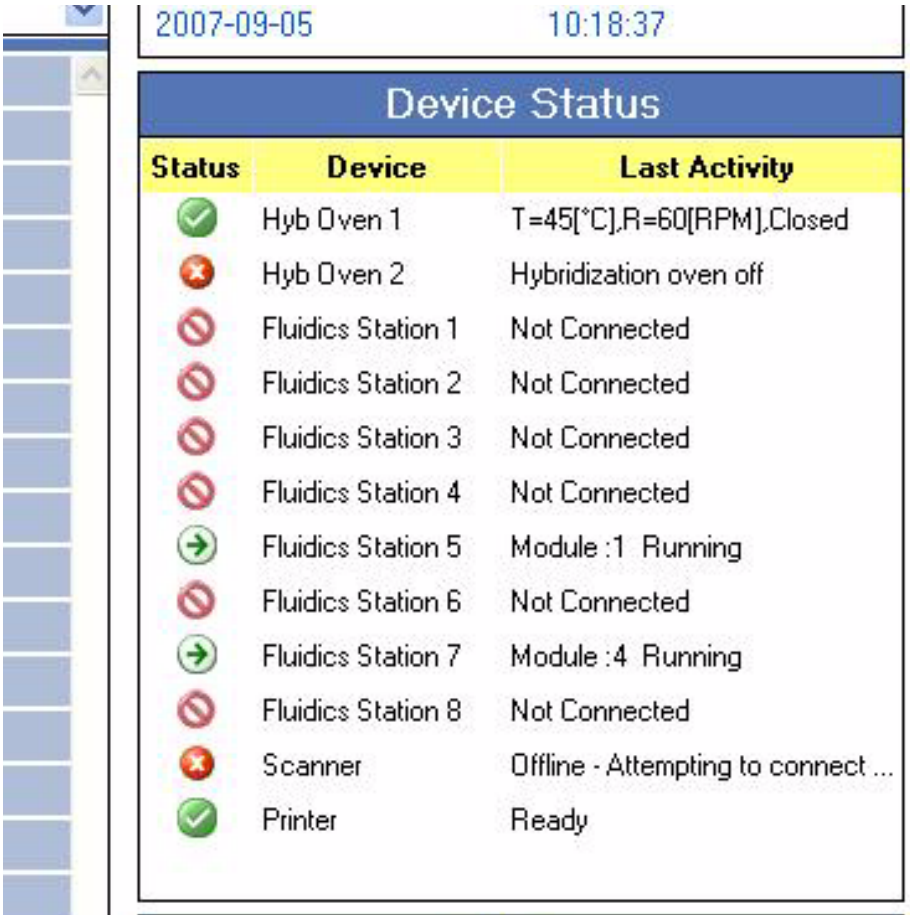

Figure 6.1 The Device Status Panel

Generally if an instrument, such as the Hybridization Oven 645, fluidics station or scanner functions properly, the Status column displays a Green icon next to the instrument name. This is the first place to look if you suspect trouble with an instrument. If a problem arises in an instrument, AMDS will raise an alert. Alerts inform you of the problem that occurred and provides suggestions as to how to resolve the alert.

If the device status screen indicates a problem with an instrument, examine the alerts list for additional detail (Figure 6.2). To address the problem, open the alert to receive additional information on the alert, and follow the suggested resolution to resolve the problem. Once resolved, clear the alert by following the "Resolving Alerts" procedure below.

In many cases, you may not be able to resolve an instrument problem. In these cases, call an Affymetrix service technician to resolve the problem. You should not attempt to correct this kind of problem yourself.

Second Type of Problem—Resolving Individual Test Requests Errors

The second category of troubleshooting relates to problems with an individual test request. You can resolve several errors that can occur relating to a test request, these include:

- Scanner could not read the bar code.
- Autofocus error.
- Gridding error.
- Analysis algorithm error as a result of missing information.

As with the instrument errors, the test requests errors will raise an alert. Refer to the individual alert for additional information and a suggested course of action for resolving the error. Once you have resolved the error, AMDS can proceed with the assay run.

Third Type of Problem—Resolving Operational and Data Input Errors

The third and final category of error consists of operational or data input errors. These type of errors are relatively easy to detect and correct as the User Interface is designed to provide immediate feedback and prevent incorrect operation and/or data input. Some examples of incorrect operation or data input include:

- Entry of an invalid Array Barcode.
- Selection of an assay type that has not been installed on the system.

- Batching of arrays that require different hybridization temperatures.
- Loading of an array into a fluidics station that is not primed.
- Loading of an array into a fluidics station that is configured for a different assay type.
- Starting a workflow step on an array before it has completed the required prerequisite workflow steps, for example, scanning an array while AMDS is still processing that array's test request in the fluidics worklist.

In each of these cases, AMDS will immediately display an error message that informs you the action or data entered is inappropriate and prevents you from proceeding.

Resolving Alerts

During the processing of test requests through the workflow, any issues encountered by the system will be communicated to the user through the Alerts panel. You can clear these alerts (Figure 6.2).

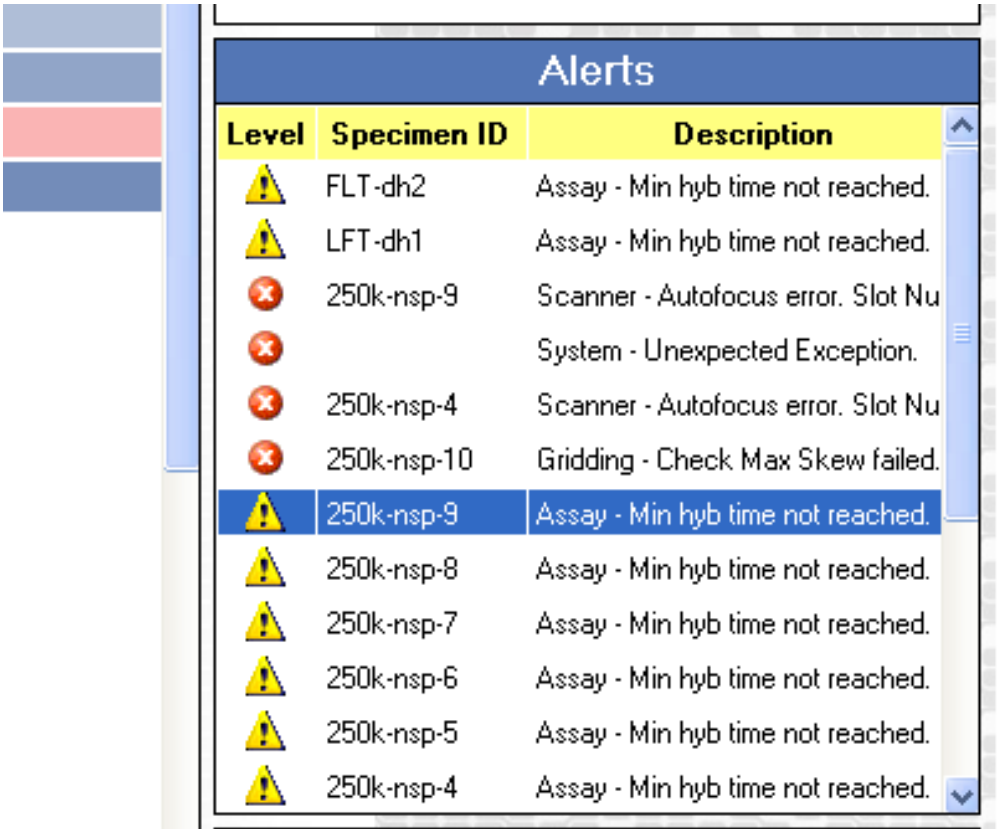

Figure 6.2 User Alert Function

Resolving Alerts Procedure

1. From any workflow window, double-click on an alert in the Alerts panel. The Alert Details panel will appear in the lower-right corner of the screen (Figure 6.3).

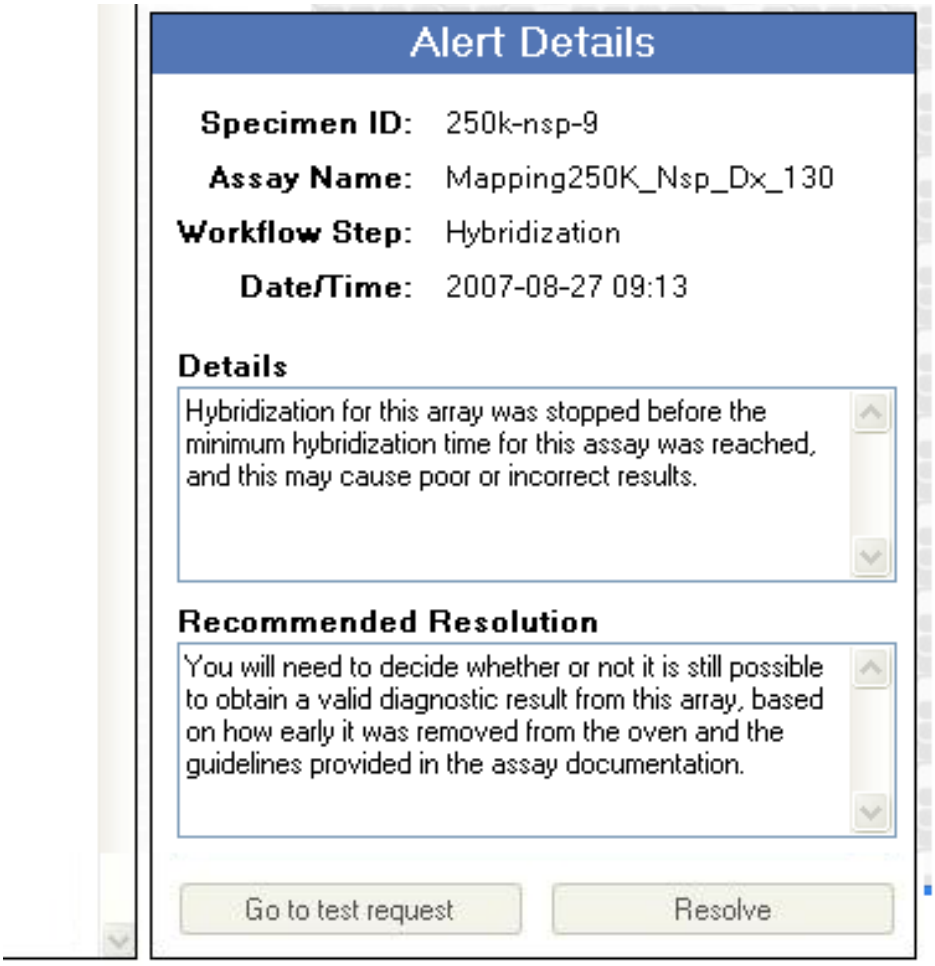

Figure 6.3 User Alert Function

2. If the Alert has a Specimen ID associated with it, use the **Go To test request** button to select the row in the current worklist that contains the related test request.
3. After resolving the issue, click the **Resolve** button and enter an e-Signature to continue processing the test request.

Instrument Troubleshooting

Many instrument errors will require the attention of a qualified Affymetrix field service engineer. However, there are some errors that can be resolved and are listed here.

Fluidics Station

- **The station is not primed:** You can access the fluidics setup window to prime the fluidics station for the selected assay class. See the section, *Priming the Fluidics Station, on page 157*.
- **Fluidics station configured for a different assay:** Open the fluidics station set up window to reconfigure the station for the correct assay type. You can also use a fluidics station that already has the correct assay type selected. See the section, *Setting Up the Fluidics Station, on page 82* for details on changing the assay type.
- **Missing fluid error:** You can supply the necessary fluid, clear the alert and resume the fluidics run. You can change the fluids and prime the fluidics station. If you continue to see this error, it may indicate a system failure. Call Affymetrix technical support. See the section, *Fluidics Station Troubleshooting and Assistance, on page 173*.

AutoLoader

- **Autofocus error:** This error generally occurs if the probe cartridge glass substrate is smudged or dirty, usually with a thumb print. Clean the array, clear the alert and retry.
- **Barcode could not be read:** Retrieve the array and process using the manual scan procedure. See the section, *Scanning Arrays in Manual Mode—Manual Scan, on page 87*.
- For more information on AutoLoaderDx troubleshooting, see the section, *Troubleshooting, on page 214*.

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Appendix A

THE FLUIDICS STATION 450DX

Introduction

This chapter introduces the Affymetrix® GeneChip® Fluidics Station 450Dx (aka the fluidics station) and its components, gives an overview of how the fluidics station works, and covers the safe use of the fluidics station.

The fluidics station is part of the AMDS that includes the GeneChip® AutoLoaderDx.

Warnings and Precautions

- Installation and de-installation of the system must be done by a trained Affymetrix representative. The system warranty may be voided if used in a manner not specified by the manufacturer.
- Exercise the normal precautions that are required for handling all laboratory reagents.
- Wear gloves when using the fluidics station.
- Exercise standard precautions when obtaining, handling, and disposing of potentially carcinogenic reagents.
- Do not send your instrument elsewhere for service or attempt to service it yourself. To protect your warranty and ensure safe operation, the instrument should be serviced only by Affymetrix or its representatives. If the instrument is not working correctly, please contact your Affymetrix Technical Support representative.
- Do not use the fluidics station in ways not specified by Affymetrix. Doing so may impair the protections provided by the fluidics station.

▲

WARNING: Do not place hands or fingers inside the cartridge holder. Under electrical load conditions, the area behind the cartridge holder can have temperatures that rise to 100°C or higher.

- The fluidics station requires two people to lift and handle it safely. Each person should firmly grasp the base of the instrument at the end opposite the other to lift. Use OSHA standards for lifting techniques.
- The instrument must be surrounded by adequate airspace. Slots and openings in the instrument and the electronics compartment covers are for ventilation. Do not block or cover them.
- Never push an object into the instrument ventilation slots; equipment damage or injury may result. Do not set liquids on top of the instrument.
- The FS450Dx is intended for indoor, laboratory use in a controlled environment.

Caution Notices:

CAUTION

You must have read and understood the contents of this manual before attempting to operate this fluidics station.

CAUTION

The power supply cord is used as the main disconnect device. Ensure that the socket outlet is located and installed near the equipment and is easily accessible.

Instrument Components

The GeneChip® Fluidics Station 450Dx (aka the fluidics station) contains four modules. Each module can hold one GeneChip® array cartridge and up to three vials. The software and computer workstation can control each of the four modules independently of the others. You can use any or all of the modules at the same time. The modules are numbered 1 through 4 near the LCD window.

Figure A.1 and Figure A.2 show the components and cable connections of the fluidics station. See Figure B.2 on page 201 for the cable connection to the AutoLoaderDx. This is for reference only. Affymetrix recommends that only a qualified service technician attempt to service this instrument or change these connections.

The GeneChip Fluidics Station 450Dx includes the following components.

1. Sample Holders — holds up to three sample vials
2. Module Door — protective cover for the peristaltic pump on the module
3. Cartridge Holder — holds the cartridge during fluidics operation
4. Washblock — part of the cartridge holder that completes the fluid path when a cartridge is not in place (used for cleaning out or draining the fluidics station)
5. Cartridge Lever — engages or releases the cartridge holder
6. Needle Lever — inserts the needles into the sample vials
7. LCD Window — displays messages during processes
8. Lid Release Buttons — one on each side (on older fluidics station models. New models open merely by lifting the lid.)
9. Wash Bottles (2) — hold wash buffers and tubing that draws buffer through system
10. DI Water Bottle — holds deionized water and tubing that draws water through system
11. Waste Bottle — collects waste from hybridizations and washes

12. Sample or Vial Needles — extend into the sample vials and draw fluid.

13. Barcode Label—each module has an associated barcode to identify the module that is used by the worklist.

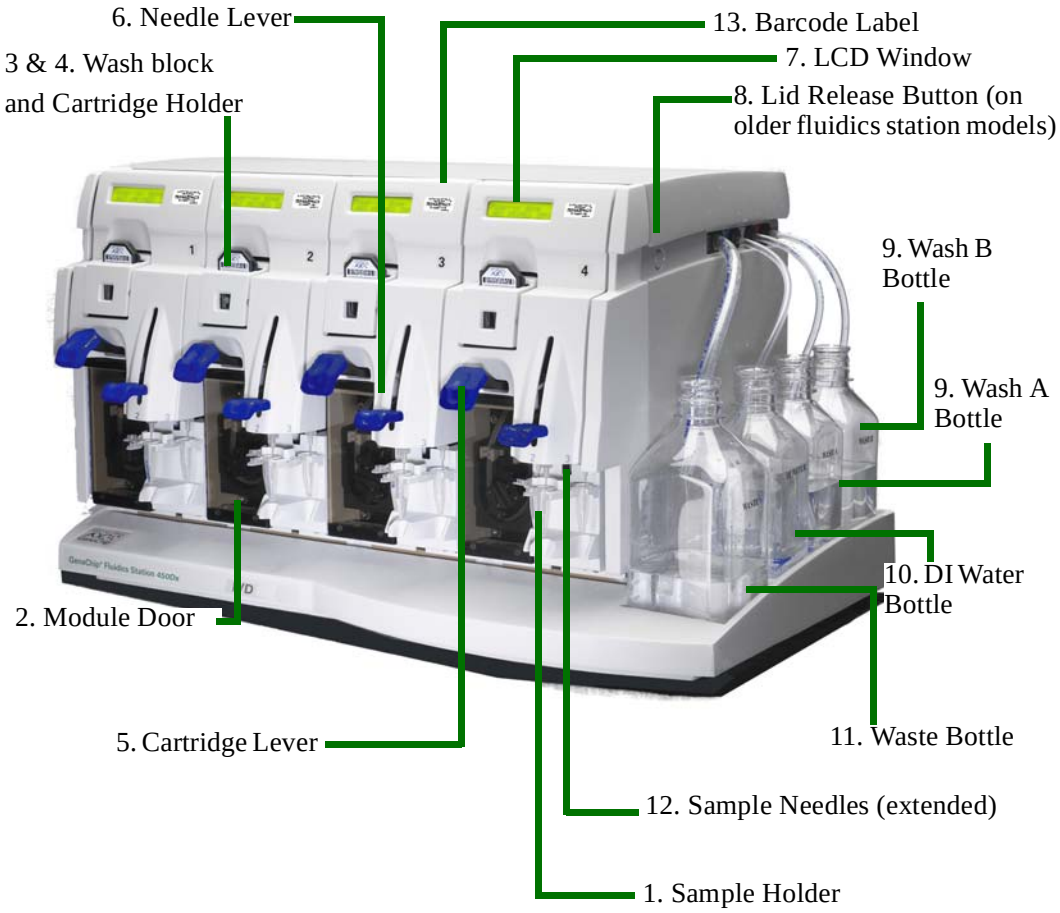

Figure A.1 The GeneChip® Fluidics Station 450Dx and components

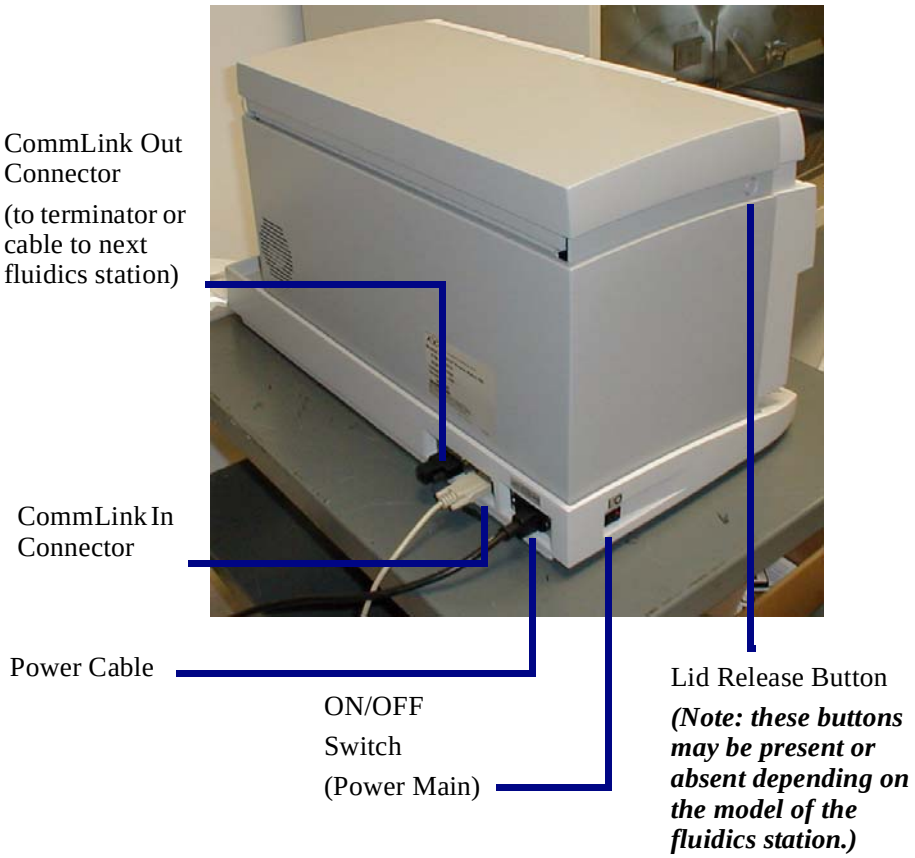

Figure A.2 Location of the serial ports and ON/OFF switch

Using the Fluidics Station 450Dx

This section shows you how to run the fluidics station.

Assay Documentation

You must configure the fluidics station for the type of assay that you will run on the fluidics station. The partner who provides the assay will determine the assay type and will provide the relevant documentation in the form of a package insert or other type of document.

Each assay package insert, or assay document, will describe the fluidics station configuration requirements for that assay. The system will ensure that the fluidics station is configured properly for the assay being run. If the station is not configured properly for the assay, you will be notified. You may then configure the station for that assay, or run the test request on a fluidics station that is correctly configured for that assay.

Using the Barcode Reader with the Fluidics Station

1. Open the Fluidics Worklist.
2. Hold the array or insert the array into the fluidics station module.
3. Aim the barcode reader at the barcode of the array and record the barcode number.
4. Aim the barcode reader at the barcode of the fluidics module and record the barcode number. The AMDS software will locate the appropriate fields in the Fluidics Worklist and add the numbers.

   The barcode reader emits three distinct sounds depending on the sound's function.

   a. A "good" sound that indicates that the barcode reader recorded the correct test request

   b. A "double good" sound that indicates that the barcode reader confirms a valid association

   c. A "bad" sound that indicates that the barcode reader detects an error. Check the relevant AMDS window for information on the error.

See the section, *Using the Barcode Reader, on page 51* for more information on using the barcode reader.

See the section, *Connecting the Barcode Reader, on page 203* for information on connecting the barcode reader to the workstation.

The Fluidics Station 450Dx Protocols

This section describes in summary detail how to use the Fluidics Station 450Dx with sample protocols. See the section, *Washing and Staining an Array in the Fluidics Station, on page 81* for details on using the fluidics station to process arrays.

NOTE: These instructions are for use with the AMDS software. Please consult partner assay instructions for use as needed. For more specific information on hybridizing the target to the array cartridge, refer to the appropriate package insert.

Setting Up an Assay

Before running a protocol on the fluidics station, you must first define an assay in the AMDS software. For information on defining an assay, refer to the assay instructions or to the appropriate package insert. See also the chapter, *Creating, Editing and Cancelling Test Requests—The Active Worklist, on page 60*.

Sample Hybridization Protocol Using the Fluidics Station

If you are to hybridize an array on the fluidics station, the following steps briefly illustrate the protocol.

1. Start from the fluidics worklist and use the applicable assay product insert or partner's documentation to start the fluidics station protocol.
2. Place a new assay-specific array cartridge containing the specimen sample into the cartridge holder on the selected module of the fluidics station. Gently pull up on the cartridge lever to close the washblock and engage the array.
3. Depending on the assay instructions, place appropriately prepared sample vials in the sample vial holders as indicated on the fluidics station LCD. Please note that the indicated position may be different depending on the particular assay protocol used.
4. The fluidics station will perform the following actions to hybridize the bound target to the probe on the cartridge and prepare it for washing. The fluidics station will:

- draw hybridization cocktail from the vial into the cartridge and mix it by alternately draining and filling the cartridge at a selected temperature for the time set by the assay manufacturer;
- expel the hybridization cocktail back into the sample tube, or into the waste line, at the end of the hybridization step, depending on the assay manufacturer's specifications;
- clean the module tubing and needles for the next cartridge to be processed.

Sample Staining Protocol

If you will be staining an array, the following steps illustrate the protocol.

1. Start from the fluidics worklist and use the applicable assay product insert or partner's documentation to start the fluidics station protocol.
2. After the hybridization of the array, the array remains in the cartridge holder. If you have removed the array for any reason, replace the same array cartridge into the cartridge holder on the selected module of the fluidics station. Gently flip the cartridge lever to close the washblock and engage the array.
3. Depending on the assay instructions, place appropriately prepared vials in the sample vial holders as indicated on the fluidics station LCD. Please note that the indicated position may be different depending on the particular assay protocol used.
4. The fluidics station will perform the following actions to stain the bound target on the cartridge and prepare it for scanning. The fluidics station will:
    - wash the cartridge with wash solution (or solutions) at a selected temperature;
    - draw staining solution from the vial into the cartridge and mix it by alternately draining and filling the cartridge at a selected temperature;
    - expel the staining solution to the waste line;

- fill the cartridge with wash solution for scanning;
- clean the module tubing and needles for the next cartridge to be processed.
- After staining and washing, the AutoLoaderDx scans the cartridge by laser light to obtain fluorescence intensity data. For information on using the scanner, see the section, *Scanning an Array, on page 85*.

Operating the Fluidics Station

This section illustrates how to operate the fluidics station to process assays. This discussion must be general since the number and type of steps required to process your specific array will be different depending on the specific design of the assay that the array contains.

IMPORTANT: **Do not lower needles or engage the washblock until prompted by the fluidics station LCD.**

Starting the Fluidics Station

1. Check to ensure that the fluidics station is connected to the power main through the power cord provided.
2. Check to ensure that the fluidics station is connected to the workstation. CommLink connections are located on the back of the fluidics station. See Figure A.2 on page 140.
3. Flip the **ON/OFF** switch for the fluidics station to the **ON** position. The switch is located on the left side of the fluidics station. See Figure A.2 on page 140. The LCD window should display the following:

Power-On Done
NOT PRIMED 25°C

4. If you have not done so already, turn on the computer workstation. The AMDS software will automatically open.

Running a Fluidics Station Protocol

The following steps represent a general procedure. Your specific protocol may indicate steps different from these outlined below.

1. Check to ensure that all the wash lines are in the appropriate wash bottles. Please consult the array package insert that came with the cartridge kit for the appropriate wash buffer solutions, or contact your Affymetrix technical support representative.
2. If you have not yet primed the fluidics station for the new assay, prime the fluidics station now. See the section, *Priming the Fluidics Station, on page 157*.
3. Load three standard 1.5 mL vials in the sample holders of each module that is to be primed (Figure A.7).
4. In the Active Worklist main window (Figure A.3). Click the **Fluidics** icon button.

   The Fluidics Worklist appears (Figure A.4).

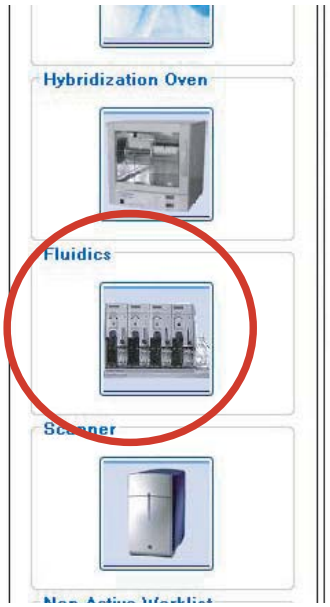

Figure A.3 Click the Fluidics icon to gain access to the fluidics control screen

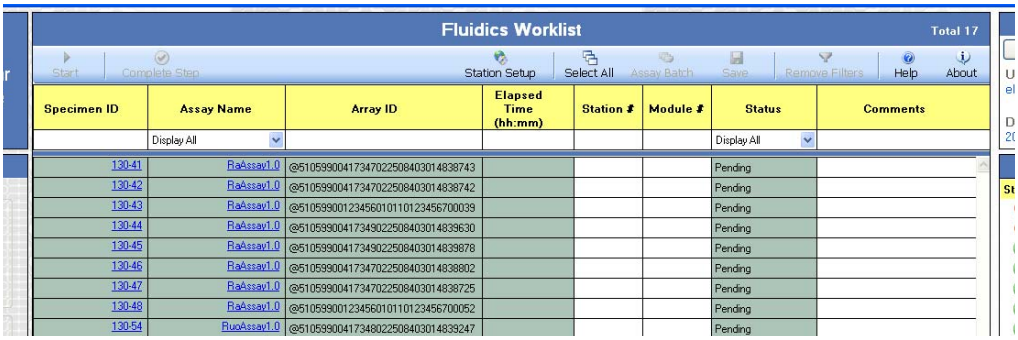

Figure A.4 The Fluidics Worklist

5. If you are manually associating a test request with a fluidics station and module do the following:

   a. In the test request record that contains the desired Specimen ID, place the cursor in the Station # field and enter the station number.

   b. Place the cursor in the Module # field and enter the module number.

   c. Place the array cartridge in the module washblock (Figure A.5). Do not engage the washblock until prompted by the fluidics station LCD. The module must be the same as the module that you earlier associated with the array(Figure A.5).

Figure A.5 Inserting the cartridge into the cartridge holder - note orientation and array label

6. If you using a barcode reader to associate a test request with a fluidics station and module do the following (See the section, *Using the Barcode Reader, on page 51*):

a. Load the array cartridge into the module washblock (Figure A.5). The module must be the same as the module that you earlier associated with the array.

b. Scan the barcode on the array cartridge.

c. Scan the barcode on the fluidics station module.

7. Select the test request rows that indicate **Ready** in the Status field.

8. Click the **Start** button to begin the fluidics protocol.

The LCD window **on the fluidics station** and the AMDS Status field in the Fluidics Worklist window will indicate the status of the protocol as it progresses.

9. Follow the instructions on the fluidics station LCD window or in the AMDS fluidics station field (see also the section, *FS450Dx LCD Messages, on page 184* for more LCD messages). A selection of the available prompts is given below as examples:

- If prompted to:

LOAD VIALS

load the 1.5 mL vials into the sample holder of the fluidics station.

- If prompted to:

LOAD CARTRIDGE

Since you earlier loaded an array cartridge into the fluidics station module, you must now engage the washblock.

Flip the cartridge lever up to engage the cartridge septa needles into the septa. Proper engagement of the washblock with the cartridge is indicated by a change in the message on the LCD (Figure A.6).

Figure A.6 Flip the cartridge lever up to engage the cartridge septa needles into the septa.

IMPORTANT: **To minimize damage to the array, the door closure forces are controlled. If you cannot get proper engagement, simply press on the washblock to complete the action. Do not force anything.**

Press on the washblock.

DO NOT FORCE UP THE CARTRIDGE LEVER.

10. If prompted to:

LOAD VIALS 1-2-3

place the three 1.5 mL sample vials containing reagents into the sample holders 1, 2 and 3 on the fluidics station in accordance with the assay instructions (Figure A.7).

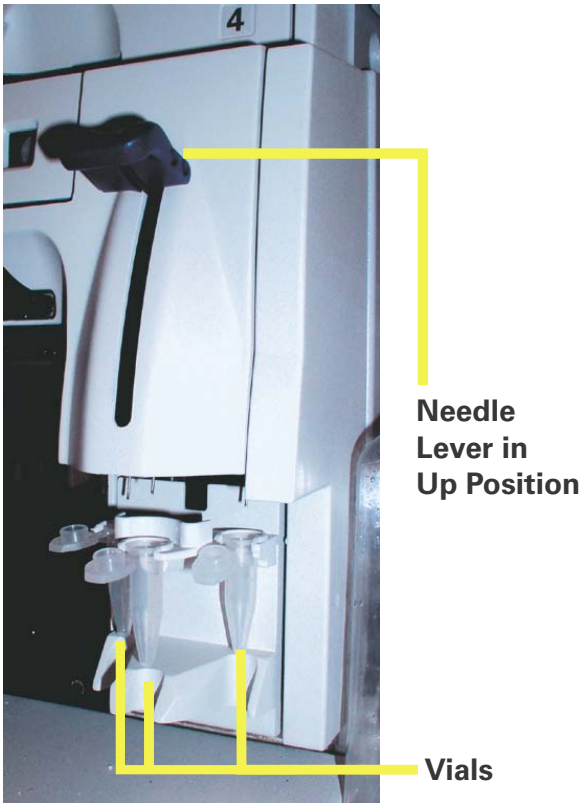

Figure A.7 The sample vials on the sample holder with the needle lever up — note the orientation of the vial caps.

NOTE: When you place the vials into the holders, orient the vial caps toward you so that the vials seat snugly into their respective holders.

d. When you have loaded the vials, gently but firmly press down on the needle lever to insert the needles into the vials. The run will commence automatically. See Figure A.8 and Figure A.9.

Figure A.8 Press down on the needle levers to start the protocol.

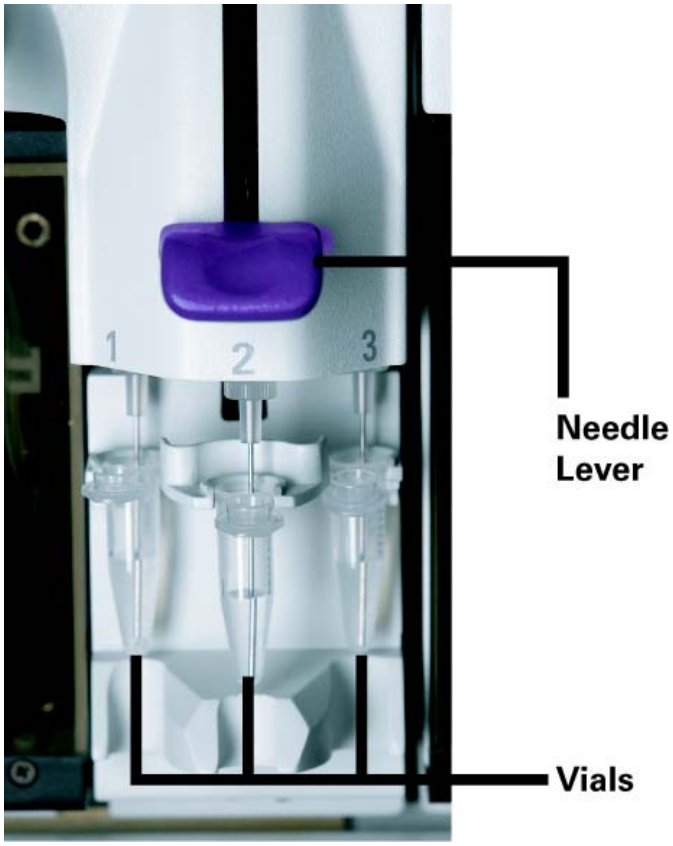

Figure A.9 The sample vials on the sample holder with the needle lever down — note the orientation of the vial caps.

As the run progresses, check to ensure that the cartridge is filling properly and that bubbles are not forming. If it is not filling properly, see the note below in this chapter.

11. When you have completed the hybridization, or washing and staining protocols, the LCD window should display the following:

EJECT CARTRIDGE

12. Eject and remove the cartridge by pushing down on the cartridge lever. The LCD window should display the following:

ENGAGE WASHBLOCK

NOTE: If air bubbles are present in the cartridge, return it to the cartridge holder. Engage the washblock by pulling up on the cartridge lever to the closed position. The fluidics station will drain the cartridge and then fill it with a fresh volume of the last wash buffer used. When it is finished, if the LCD window displays EJECT CARTRIDGE again, remove the cartridge and inspect it again for bubbles. If no bubbles are present, it is ready to scan; proceed to step 13.

13. Flip up the cartridge holder lever to re-engage the wash block.
14. Lift up on the needle lever to remove the needles from the vials.
15. Replace the used vials with new empty vials.
16. Press down on the needle lever.

    The fluidics station will automatically perform a Cleanout protocol. The LCD window will indicate the progress of the Cleanout protocol. When the Cleanout protocol is complete, the LCD window should display the following:

REMOVE VIALS

17. Lift the needle lever and remove the sample vials from the sample holder.

Shutting Down

You should perform the Shutdown protocol at the end of a session. Do not keep the fluidics station on if you will not use it again within the next 12 hours. This will reduce the risk of salt buildup in the instrument.

1. As with the prime protocol, the shutdown protocol requires three 1.5 mL sample vials for each module.
2. After removing an array from the array holder, the LCD window displays the message:

   ENGAGE WASHBLOCK

3. Engage the washblock by gently flipping up on the array cartridge lever to the up position.
4. Press down on the needle lever.

   The fluidics station automatically performs a Cleanout protocol. The LCD window indicates the progress of the Cleanout protocol.
5. When the fluidics station LCD window indicates:

   REMOVE VIALS

   the fluidics station has completed the Cleanout protocol.
6. Remove the sample vials from the sample holder.
7. If no other hybridizations are to be performed, place the wash lines into a bottle filled with deionized water.
8. Run the **Shutdown** protocol.
9. After the Shutdown protocol is complete, flip the **ON/OFF** switch to the **OFF** position.

IMPORTANT: **To maintain the cleanliness of the fluidics station and obtain the highest quality image and data possible, a weekly bleach protocol. Please refer to the section, *Fluidics Station Bleach Protocol, on page 160* for further details.**

Priming the Fluidics Station

Priming fills the fluidics station lines with wash buffers designed for that assay and deionized water. You must prime the Fluidics Station FS450Dx before you can use it to run assay protocols.

You should prime the fluidics station:

- when you first start the fluidics station,
- when you change the wash solutions,
- before processing a cartridge if you have performed a shutdown on any module, and
- if the LCD window instructs you to run a prime protocol.

1. Check to ensure that all the wash lines are in the appropriate wash bottles. Please consult the array package insert that came with the cartridge kit for the appropriate wash buffer solutions, or contact your Affymetrix technical support representative.
2. Load three standard 1.5 mL vials in the sample holders of each module that is to be primed (Figure A.7).
3. In the Active Worklist main window (Figure A.10). Click the **Fluidics** icon button.

   The Fluidics Worklist appears (Figure A.11).

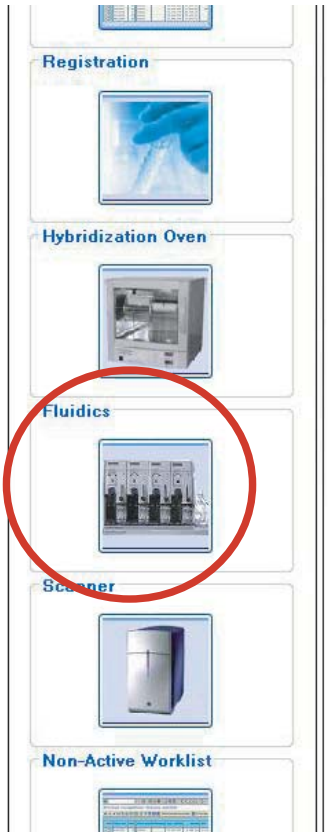

Figure A.10 Click the Fluidics icon to gain access to the fluidics control screen

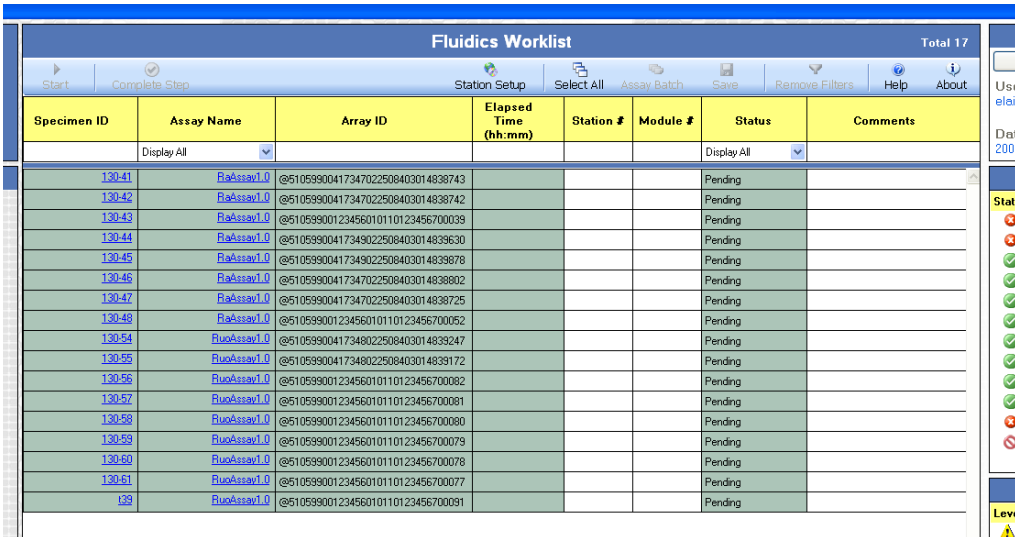

Figure A.11 The Fluidics Worklist

4. Click the **Station Setup** button 

.
5. The Fluidics Station Setup widow appears (Figure A.12).
6. In the Fluidics Station Setup window, select the Station #, the Assay and the Modules to be primed.
7. Click the **Prime Station** button 

.

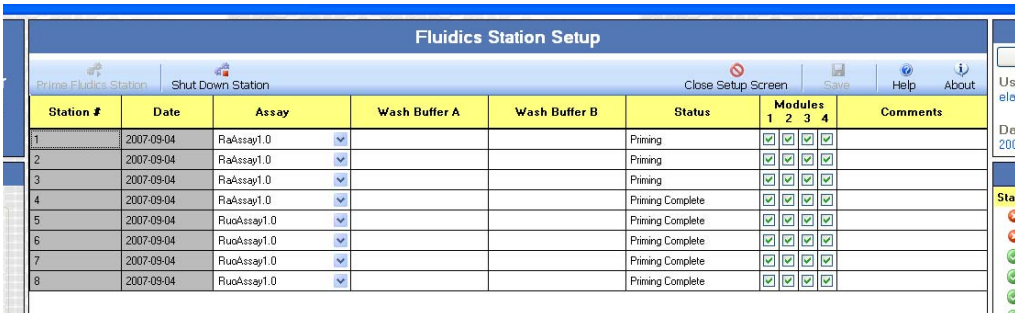

Figure A.12 The Fluidics Station setup window

The status field will display the priming message (Figure A.13).

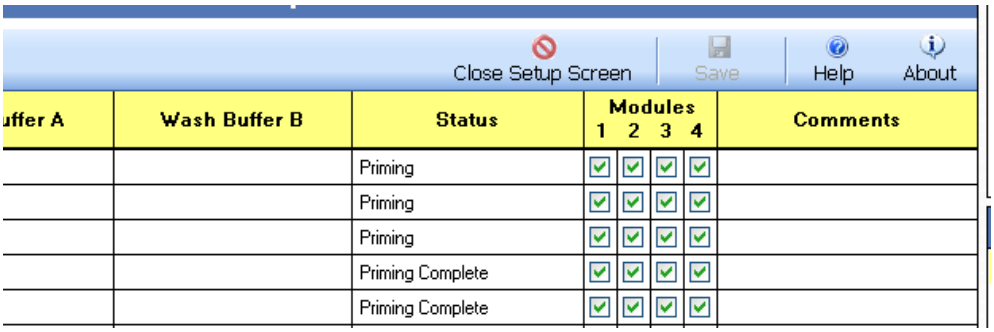

Figure A.13 The Priming Status field

8. Follow the instructions in the LCD window **on the fluidics station** as the prime protocol progresses. The LCD window on the fluidics station and the fluidics station dialog box will indicate the status of the prime and when AMDS has completed the priming protocol.

After you have primed the fluidics station, you are ready to hybridize or wash and stain a sample.

Fluidics StationDx Care and Maintenance

Introduction

This chapter provides instructions on caring for and maintaining the instrument, and on troubleshooting if problems arise.

Instrument Care

- Use a surge protector on the power line to the fluidics station.
- Always run a Shutdown protocol when the instrument will be off or unused overnight or longer. This will prevent salt crystals from forming within the fluidics system.
- When not using the instrument, leave the sample needles in the lowered position. Each needle should extend into an empty vial. This will protect them from accidental damage.
- Always use deionized water to prevent contamination of the lines. Change buffers with freshly prepared buffer at each system startup.
- The fluidics station should be positioned on a sturdy, level bench away from extremes in temperature and away from moving air.

Fluidics Station Bleach Protocol

This protocol is designed to eliminate any residual SAPE-antibody complex that may be present in the fluidics station tubing and needles. The protocol runs a bleach solution through the system followed by a rinse cycle with deionized (DI) water. This protocol takes approximately one hour and forty minutes to complete. Affymetrix recommends running this protocol weekly.

If you have AMDS administrator privileges, you can set the Bleach Interval Warning Limit and Bleach Interval Alert Limit. See the section, *Managing the Fluidics Station, on page 114*.

To avoid carryover, or cross contamination, from the bleach protocol, Affymetrix recommends the use of dedicated bottles for bleach and DI water. You can obtain additional bottles from Affymetrix.

Part Number	Description
400118	Media Bottle, SQ, 500mL
400119	Media Bottle, SQ, 1000mL

The Bleach Cycle

1. Disengage the washblock for each module by pressing down on the cartridge lever. Remove any array cartridge (Figure A.14).

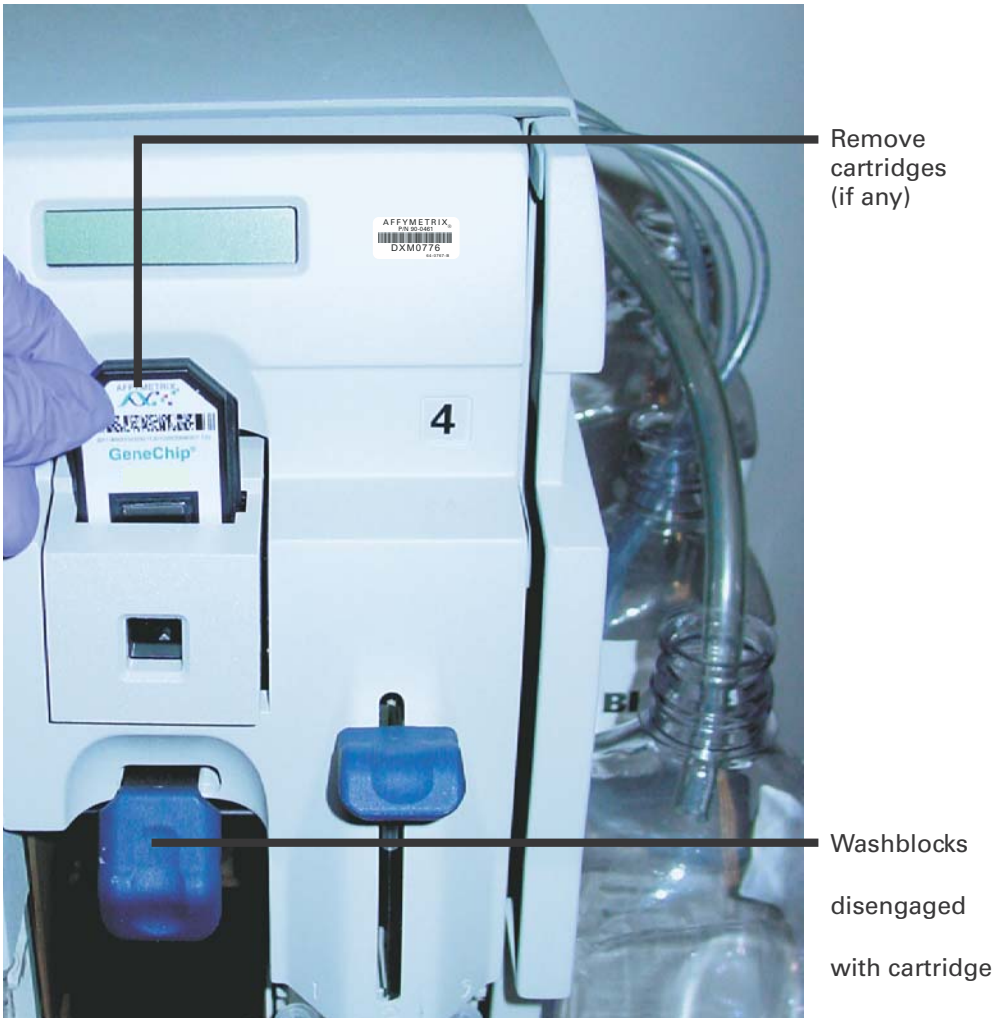

Figure A.14 Disengaged washblocks showing cartridge levers in the down position; remove any cartridges

2. Prepare 500 mL of 0.525% sodium hypochlorite solution using deionized water. Shake well.

   For example: follow these directions to make 500 mL of bleach.

   In a 1 liter plastic or glass graduated cylinder combine 43.75 mL of commercial bleach (such as Clorox® bleach[1], which is 6% sodium hypochlorite) with 456.25 mL of DI H_2O, mix well. Pour the solution into a 500 mL plastic bottle, and place the plastic bottle on the fluidics station.

IMPORTANT: **The shelf life of this solution is 24 hours. After this period, you must prepare a fresh solution.**

NOTE: **Each fluidics station with four modules requires 500 mL of the 0.525% sodium hypochlorite solution.**

3. Place on the fluidics station an empty one liter waste bottle, a 500 mL bottle of bleach and a one liter bottle of DI water. Insert the waste line into the waste bottle (Figure A.15).
4. Immerse all three wash and water lines of the fluidics station into the 500 mL of bleach solution (Figure A.15). **DO NOT IMMERSE THE WASTE LINE INTO THE BLEACH.**

IMPORTANT: **The bleach protocol requires approximately one liter of deionized water.**

[1]Affymetrix also recommends the new Clorox® Ultra Bleach (with 6.15% sodium hypochlorite) but your mixing calculations will be different.

Figure A.15 Immerse the tubes into the 0.525% sodium hypochlorite solution. The waste line remains in the waste bottle.

5. In the AMDS software, click the **System Management** button the menu (Figure A.16).

Figure A.16 Click the System Management button to gain access to maintenance functions.

6. The System Management window appears. The User Performed Service window should be the default window. If not, select **In-House Service → User Service**. The User Performed Service window appears. Note the fluidics station maintenance area (Figure A.17).

Figure A.17 The user maintenance functions for the fluidics station

7. From the dropdown list, select a station number. The system will show the last bleach and peristaltic tube change.
8. Select the **Bleach** procedure from the dropdown list and click the **Perform** button.

   The Confirm Step dialog box opens. Enter your password and event reason.

   AMDS enters the time and date information into the device log.

CAUTION: Temperature will ramp up to 50°C.

9. Follow the prompts on the LCD. Load three empty 1.5 mL vials onto each module if you have not already done so.
10. Press down on each of the needle levers to start the bleach protocol (Figure A.8).

Figure A.18 Press down on the needle levers to start the bleach protocol.

11. The fluidics station will begin the protocol and begin to empty the lines and perform the cleaning cycles using bleach solution.
12. After approximately 30 minutes, the LCD will prompt you when the bleach cycle is over and the rinse cycle about to begin.

The Rinse Cycle

Once the bleach cycle has finished, the second part of the protocol is a rinse step. This step is essential to remove all traces of bleach from the system. Failure to complete this step can result in damaged arrays.

1. Follow the prompts on the LCD for each module. Lift up on the needle levers and remove the bleach vials. Load clean, empty vials onto each module.
2. Remove the three wash and water lines from the bleach bottle and transfer them to the DI water bottle (Figure A.19). At this step, you need not be concerned regarding the bleach that remains in the lines.

Figure A.19 Immerse the three wash and water lines in the DI water bottle. The waste line remains in the waste bottle.

3. Press down on the needle levers to begin the rinse cycle. The fluidics station will empty the lines and rinse the needles.

4. When the rinse is completed after approximately one hour, the fluidics station will bring the temperature back to 25°C and drain the lines with air. The LCD display will read:

CLEANING DONE

5. Discard the vials employed for the bleach protocol.

6. Follow these suggestions in Table A.1 after you have completed the bleach protocol.

Table A.1 Suggestions on using the FS450Dx after a bleach protocol

If you are:	Then do this:
Planning to use the system immediately	After running the bleach protocol, remove the DI water supply used in the rinse phase and install the appropriate reagents for use in your next staining and washing protocol (including fresh DI water). • Perform a prime protocol without loading your arrays. **Failure to run a prime protocol will result in irreparable damage to the loaded hybridized arrays.**
Not planning to use the system immediately	Since the system is already well purged with water, you need not run an additional shutdown protocol. Just remove the old DI water bottle and replace it with a fresh bottle.
Not planning to use the system for an extended period of time (longer than one week)	Remove the DI water and perform a "dry" protocol shutdown. This will remove most of the water from the system and prevent unwanted microbial growth in the supply lines. Also, remove the pump tubing from the peristaltic pump rollers.

NOTE: After you have completed the bleach protocol, discard the vials.

NOTE: At this point you can, in the Configuration area, set the Bleach Interval Warning Limit and Bleach Interval Alert Limit. Click Save to save your configuration.

Peristaltic Tubing Maintenance

You must periodically replace the peristaltic tubing because of wear, contamination, or in order to avoid salt buildup. Inspect the tubing on a weekly basis, if you see evidence of these conditions, follow the procedure outlined below.

If you have AMDS administrator privileges, you can set the Change Tubing Warning Limit and Change Tubing Alert Limit. See the section, *Managing the Fluidics Station*, *on page 114*.

Wear gloves when changing tubing. Do not allow fluid from old tubing to spill onto surfaces.

IMPORTANT: **For systems in routine use, Affymetrix recommends monthly replacement of the silicone peristaltic tubing (part number 400110). To ensure proper performance, use only tubing available from Affymetrix. This tubing is manufactured to the required specifications to ensure proper fluid delivery and array performance. You can obtain additional tubing by ordering from Affymetrix:**

Setting the Peristaltic Tubing Maintenance Parameters

You should set the peristaltic tubing maintenance parameters when you or the service engineer originally set up the fluidics station or after you have replaced the peristaltic tubing.

1. In the AMDS software, click the **System Management** button the menu (Figure A.20).

Figure A.20 Click the System Management button to gain access to maintenance functions.

2. The System Management window appears. The User Performed Service window should be the default window. If not, select **In-House Service → User Service**. The User Performed Service window appears. Note the fluidics station maintenance area (Figure A.17).

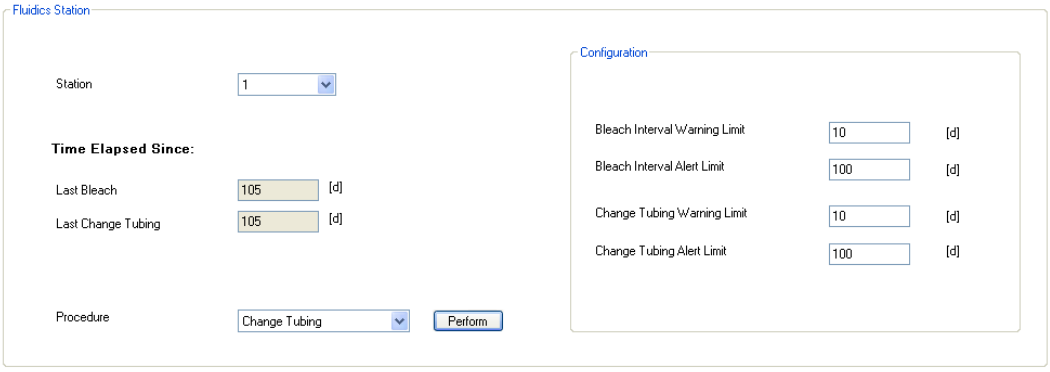

Figure A.21 The user maintenance functions for the fluidics station

3. From the dropdown list, select a station number. The system will show the last bleach and peristaltic tube change.
4. Select the **Change Tubing** procedure from the dropdown list and click the **Perform** button.

   The Confirm Step dialog box opens. Enter your password and event reason.

   AMDS enters the time and date information into the device log.

Replacing the Peristaltic Tubing Procedure

1. Open the module door. See Figure A.1 on page 139 (component number 2) and Figure A.22.

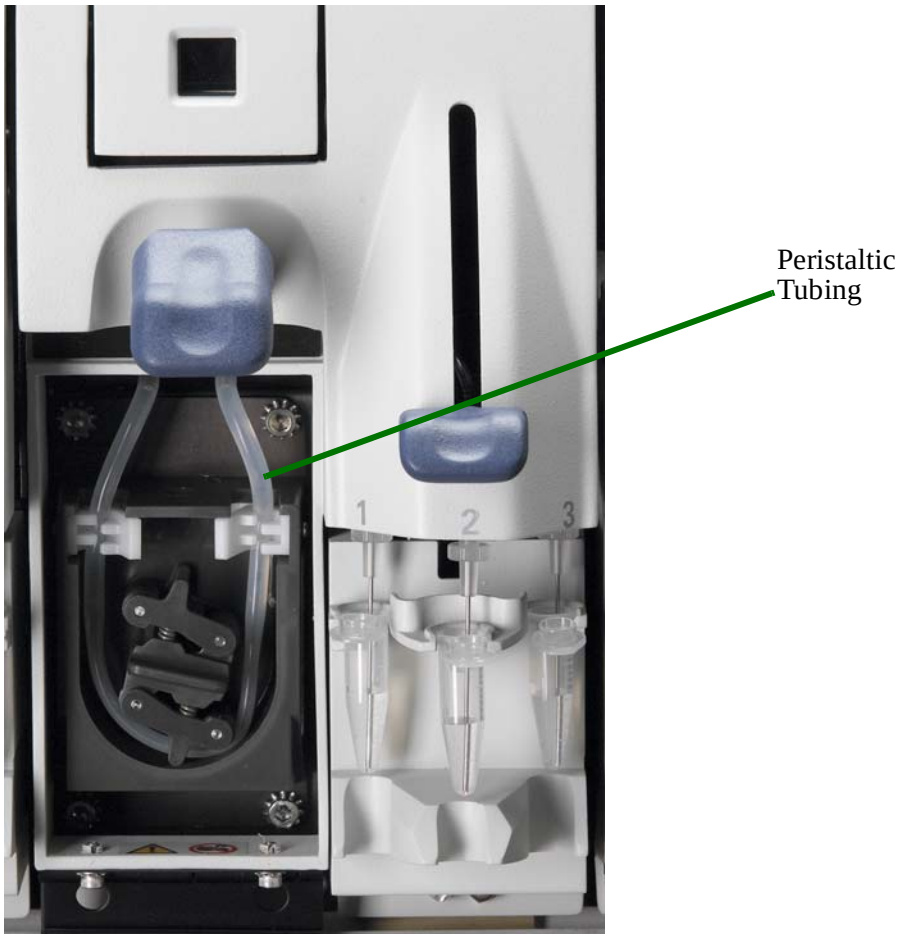

Figure A.22 Module door open showing peristaltic tubing

2. Open the white clamps to release tubing on both sides. See Figure A.23.

▲

WARNING: Do not remove the module. Do not attempt to replace the tubing on a module where the module has been removed from the case of the fluidics station. In this case, rotating the pump may damage the motor driver circuitry.

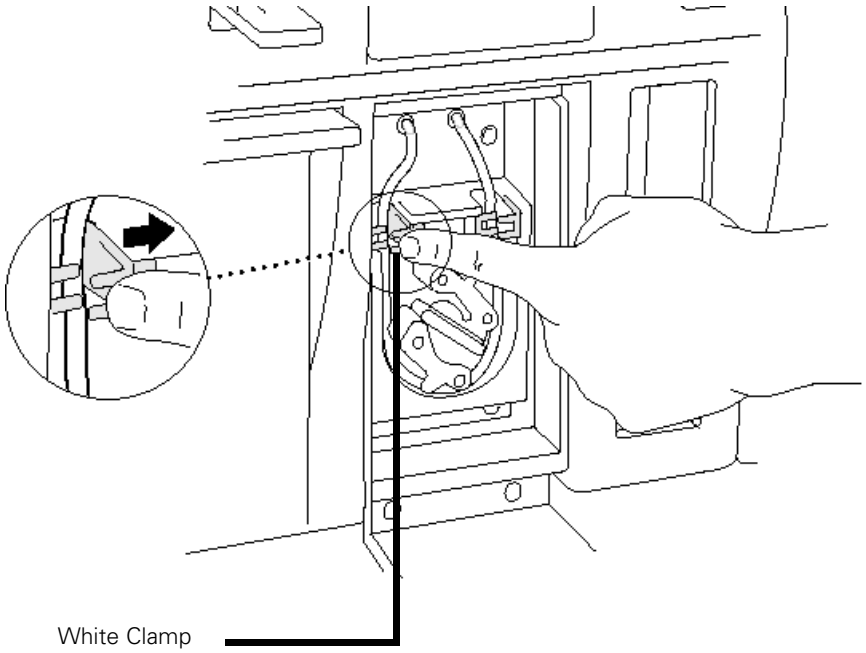

Figure A.23 Releasing the peristaltic tubing

3. Pull tubing off while gently turning the peristaltic pump head. Discard old tubing.
4. Replace tubing with new peristaltic tubing supplied with the accessory kit as described below:
   a. Attach one end of the new tubing to the fitting on the right at the top of the pump enclosure.

b. Insert the tubing into the clamp under the fitting without stretching the portion of the tubing between the fitting and the clamp. There should be a small amount of slack in that portion of the tubing.

c. Work the tubing into the pump head while slowly turning the pump.

d. Insert the free end of the tubing into the other clamp, and attach it to the other fitting.

5. Close the drop-down module door.

6. Order more replacement tubing (P/N 400110).

NOTE: At this point you can, in the Configuration area, set the Change Tubing Warning Limit and Change Tubing Alert Limit. Click Save to save your configuration.

Fluidics Station Troubleshooting and Assistance

If problems arise with the fluidics station, use the following tables to locate the description that matches the problem. If you cannot find a solution, call Affymetrix Technical Support for assistance.

Troubleshooting Decision Tree

The following simple flow charts (Figure A.24 and Figure A.25) show you how to begin troubleshooting the FS450Dx for a Missing Fluid Error (MFE).

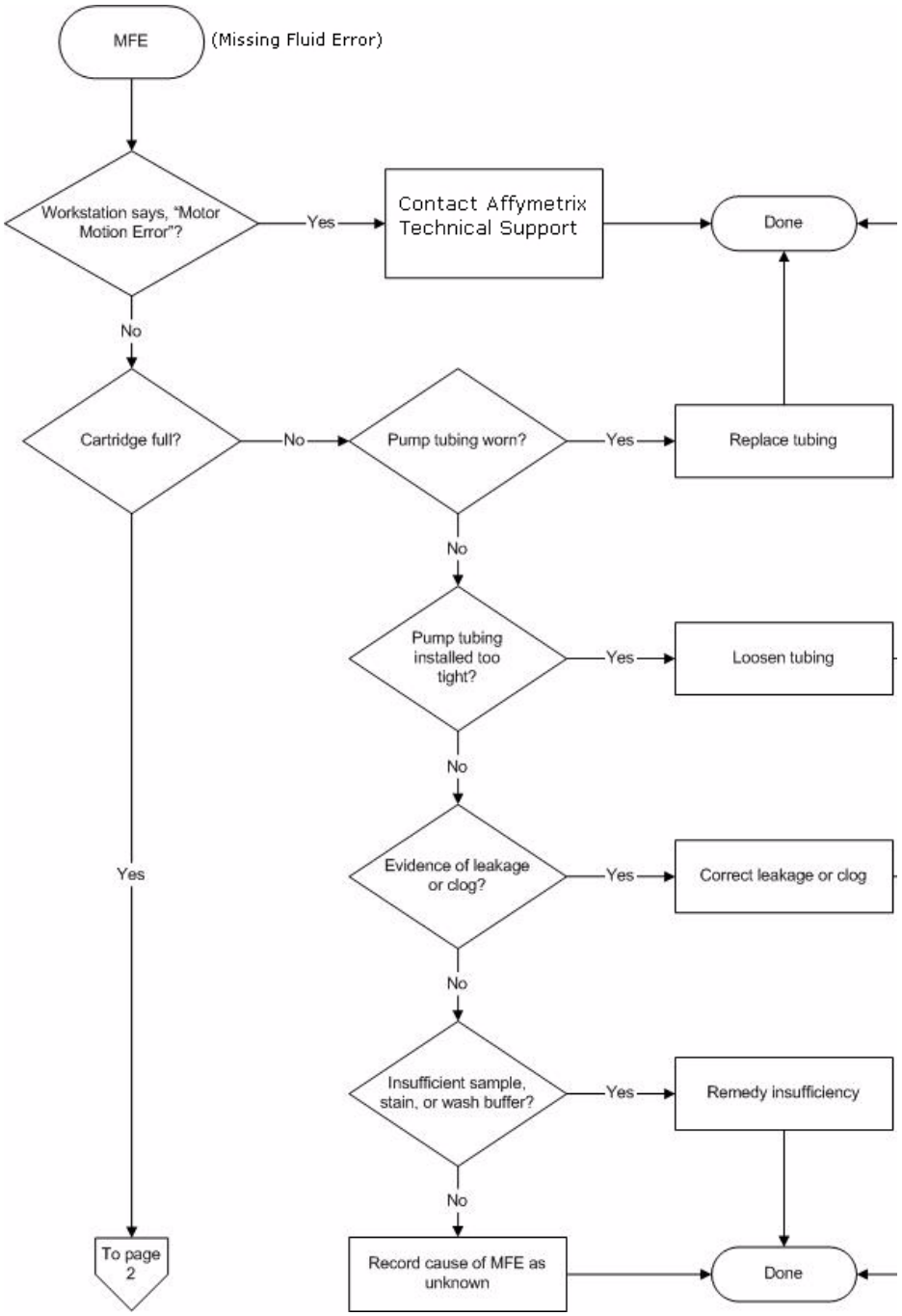

Figure A.24 Troubleshooting decision tree, page 1

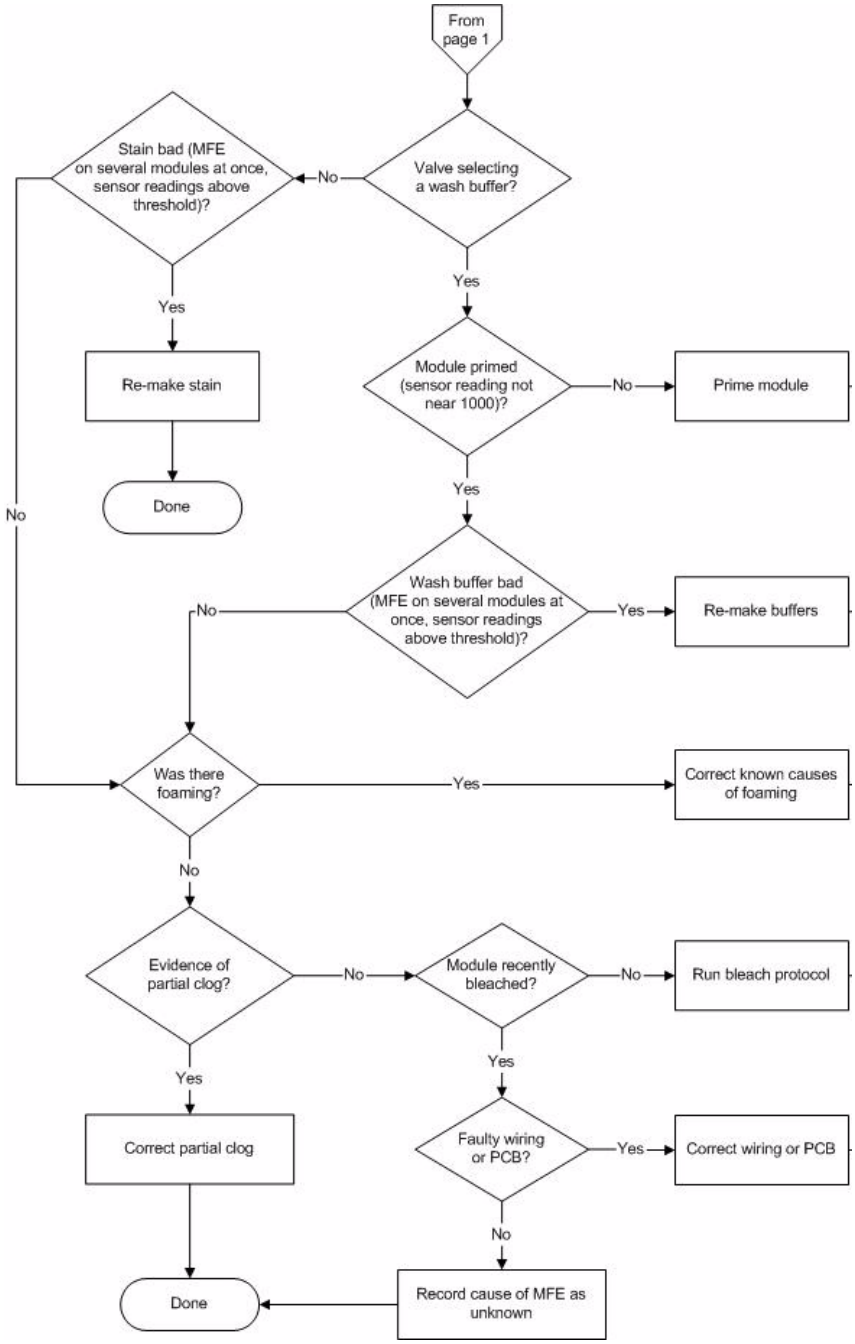

Figure A.25 Troubleshooting decision tree, page 2

Problems and Solutions

This section lists some alert messages, the possible causes and solutions (Table A.2). AMDS may display these as alerts. To resolve these alerts, follow the recommended resolution in the current Worklist window on the alert panel.

Table A.2 Problems and Solutions

Error Message	Problem	Possible Cause	Possible Solution (Follow the recommended resolution in the current Worklist window on the alert panel.)
Missing Fluid Error	Cartridge not filling completely with sample solution or buffer during initial stages of hybridization wash or staining protocol.	Possible holes in the septa of the cartridge.	In the current Worklist window on the alert panel, follow the recommended resolution.
		Sample or staining solution not in place properly.	In the current Worklist window on the alert panel, follow the recommended resolution. Make sure sample or stain vial is in the sample holder. In the current Worklist window on the alert panel, follow the recommended resolution. You may need to add more sample solution to the sample vial.
		Blocked sampling tube or line of the fluidics station. Failure of one of the fluidics sensors. Pump tubing stretched too tightly around the pump.	Call Affymetrix technical support for service. In the current Worklist window on the alert panel, follow the recommended resolution. You may need to loosen the tubing clamps, allow tubing to relax, close the clamps.

Table A.2 Problems and Solutions (Continued)

Error Message	Problem	Possible Cause	Possible Solution (Follow the recommended resolution in the current Worklist window on the alert panel.)
Missing Fluid Error (continued)		Insufficient volume of sample or staining solution (500 µL). Blocked sampling tube or line of the fluidics station.	In the current Worklist window on the alert panel, follow the recommended resolution. You may need to run a **Prime** script with fresh deionized (DI) water to flush out salt blockage.
	Cartridge not filling completely with buffer during wash script	Buffer bottle empty. Module not primed.	Fill buffer bottles. Prime module.
	System detects improper conditions while filling. Note where in protocol error occurred.	• Missing or insufficient stain or antibody in vial? • Wash empty? • Air bubbles in line? • Leaks?	In the current Worklist window on the alert panel, follow the recommended resolution.
	Recovered less sample than initial input during Recover script.	Loose tubing attachments inside the fluidics station.	Call Affymetrix technical support for service.
Fluidics Station X Does Not Respond		Power not switched on at the fluidics station. Incorrect fluidics station designated for communication. Loose cables.	Turn fluidics station power on, and then try to connect again. Designate correct fluidics station on workstation. Firmly connect cables to fluidics station.
Sensor Timeout	"Sensor Timeout" error message on workstation.	No user response to "Remove Vial" prompt or other prompt.	In the current Worklist window on the alert panel, follow the recommended resolution.

Table A.2 Problems and Solutions (Continued)

Error Message	Problem	Possible Cause	Possible Solution (Follow the recommended resolution in the current Worklist window on the alert panel.)
Error While Draining **Error While Filling**	Cartridge is not filling or draining properly.	Defective septa in cartridge. Insufficient sample or stain volume. Excessive bubbling in cartridge. Buffer conductivity too low. Failure of one of the fluid sensors.	In the current Worklist window on the alert panel, follow the recommended resolution. You may need to: Use a new cartridge. Add more sample solution to sample vial. Change the buffer: reduce detergent. Call Affymetrix technical support for service.
Error While Filling	System detects improper conditions while filling. Note where in protocol error occurred.	• Missing or insufficient stain or antibody in vial? • Wash or DI water empty? • Air bubbles in line? • Leaks?	Identify if chip is filled: In the current Worklist window on the alert panel, follow the recommended resolution.
Invalid Command	Communication error detected Note where in protocol error occurred.		In the current Worklist window on the alert panel, follow the recommended resolution. You may need to: Identify if chip is filled. Contact Affymetrix for service.

Table A.2 Problems and Solutions (Continued)

Error Message	Problem	Possible Cause	Possible Solution (Follow the recommended resolution in the current Worklist window on the alert panel.)
Temperature Timeout	Temperature does not reach specified temperature.	Temperature has not reached required level in expected time if ambient temperature is within operating specifications (15 to 30 degrees C).	Call Affymetrix technical support for service.
Improper Script	Script does not work.	User is attempting to run a FS400 or FS450 script on FS450Dx	In the current Worklist window on the alert panel, follow the recommended resolution. You may need to download proper FS450Dx script and continue.
Valve Motion Error			In the current Worklist window on the alert panel, follow the recommended resolution. If problem persists, contact Affymetrix for service.
Valve Not Homed			In the current Worklist window on the alert panel, follow the recommended resolution. If problem persists, contact Affymetrix for service.
Valve Out of Position			In the current Worklist window on the alert panel, follow the recommended resolution. If problem persists, contact Affymetrix for service.

Meaning of Error Messages

The following lists some of the common error messages and what they mean (Table A.3). AMDS may display these as alerts. To resolve these alerts, follow the recommended resolution in the current Worklist window on the alert panel.

Table A.3 Error Messages

Error Message	Meaning (Follow the recommended resolution in the current Worklist window on the alert panel.)
Invalid Command	The script contains a command that can not be executed because its command code is either undefined or has a format error.
Improper Script	The first command of the script is not the required FS450Dx command.
Temperature Timeout	The Re-attempt command timed out before the set point temperature was reached.
Sensor Timeout	The Await Sensors command timed out before the anticipated sensor pattern was seen.
Valve not Homed	The Home command did not result in the valve reaching it HOME position.
Valve Motion Error	The Valve command did not result in the valve reaching it target valve position.
Valve out of Position	According to the outer valve encoder, the valve did not reach a valid position when it was last rotated.
Error while Filling	While filling the cartridge, the AwaitMotor command terminated because of the step count not the expected sensor pattern, and that the same error had occurred several times consecutively.
Error while Draining	While draining the cartridge, the AwaitMotor command terminated because of the step count not the expected sensor pattern, and that the same error had occurred several times consecutively.

Table A.3 Error Messages (Continued)

Error Message	Meaning (Follow the recommended resolution in the current Worklist window on the alert panel.)
Missing Fluid Error Examples: "Stage C" "WashA" "Sense/Threshold" "960/890"	"Stage C" "WashA" "Sense/Threshold" "960/890" The Pump command completed its step count before the conductivity sensor determined that the cartridge contained a solution with conductivity below the set threshold value. The Missing Fluid Error (MFE) Display not only gives a visual notification of an error condition to the operator, but gives you information that enables you to determine the cause of the error. It does this by displaying information about the sensor value and the fluid that caused the error. It shows this internal information in a continuous loop until the machine is powered down or a script is started. For example: Missing Fluid Error for 4 seconds Stage A valvePos WashA for 4 seconds Sense/Threshold 820/600for 4 seconds

Other Problems and Solutions

Table A.4 lists uncommon problems and their solutions. AMDS may display these as alerts. To resolve these alerts, follow the recommended resolution in the current Worklist window on the alert panel.

Table A.4 Other Problems and Solutions

Problem	Possible Cause	Possible Solution (Follow the recommended resolution on the alerts panel.)
Air bubbles left in cartridge at the end of a hybridization-wash script.	Air bubble in wash line	You may need to perform a Cleanout procedure or a Priming procedure.
Buffer leaking inside the fluidics station.	Loose tubing attachments inside the fluidics station.	Call Affymetrix technical support for service.
	Washblock requires replacement.	Call Affymetrix technical support for service.
	Salt buildup in the lines of the fluidics station.	Run the **Prime** script with fresh DI water to flush out salt blockage.
Cartridge needles of the fluidics station not engaging with the cartridge.	Possible defective septa on the cartridge.	Use another cartridge.
	Extra flashing on the cartridge.	Use another cartridge, or call Affymetrix technical support for service.
	Salt buildup on the cartridge needles.	Run the **Prime** script with fresh DI water to flush out salt blockage. Clean cartridge needles with a wet cotton swab.
	Cartridge holder aligned and attached to the fluidics station improperly.	Call Affymetrix technical support for service.
	Cartridge holder not properly engaged to the fluidics station.	Place the cartridge into the cartridge holder. Push the holder door shut, and firmly lift the lever to engage the cartridge needles.

Table A.4 Other Problems and Solutions (Continued)

Problem	Possible Cause	Possible Solution (Follow the recommended resolution on the alerts panel.)
Sample needles do not properly enter vial.	Bent sample needle User may be pressing the needle lever down to quickly or with too much force.	Replace sample needle. Engage sample needle lever more slowly and/or with less force.

FS450Dx LCD Messages

This section describes the LCD script messages and their meaning (Table A.5). The following is a list of some of the common messages that appear on the fluidics station LCD throughout the course of the fluidics station operation. The actual list of messages on a particular fluidics station may include some that are not listed here (Table A.5).

Table A.5 LDC Messages

Message	Meaning
Changing –>	Wait for temperature to reach set point
Draining to Waste	Empties cartridge.
Purging with A	Purges chip with ~ 1mL of buffer A at 25°C from bottom to top then to waste.
Draining to Vial 1	Recovers stain to Vial #1 for reuse or disposal.
Draining to Vial 2	Recovers stain to Vial #2 for reuse or disposal.
Draining to Vial 3	Recovers stain to Vial #3 for reuse or disposal.
Filling with A or Filling with B	Drains and fills cartridge with last wash solution used, if any.
EJECT WASHBLOCK	Disengage washblock.
LOAD CARTRIDGE	Prompt for loading cartridge.
REMOVE PREVIOUS VIALS	Prompt to remove vials.
LOAD VIALS 1-2-3	Prompt for loading vials 1, 2, and 3.
LOAD VIALS 1& 2	Prompt for loading vials 1 and 2.
LOAD VIALS 1& 3	Prompt for loading vials 1 and 3.
LOAD VIAL 1	Prompt for loading vial 1.
LOAD VIAL 2	Prompt for loading vial 2.
LOAD VIAL 3	Prompt for loading vial 3.
Filling with A	Empty, fill with wash-A, mix by drain-and-fill, repeat, leave cell full.
Filling with B	Empty, fill with wash-B, mix by drain-and-fill, repeat, leave cell full.
Draw 1st Stain	Empty, draw sample to both sensors.

Table A.5 LDC Messages (Continued)

Message	Meaning
Draw 2nd Stain	Empty, draw sample to both sensors.
Draw 3rd Stain	Empty, draw sample to both sensors.
EJECT CARTRIDGE	Prompt for removal of cartridge.
ENGAGE WASHBLOCK	Prompt for engagement of washblock.
DO CLEAN CYCLE	Begin cleaning cycle.
REMOVE STAIN VIALS	Prompt to remove stain vials, if present.
LOAD 3 EMPTY VIALS	Prompt to load vials.
Purging with water	Purge with 5mL water to clean line.
Washing needle 1	Performing wash needle #1 procedure.
Purging with air	Purge with air.
Washing needle 2	Performing wash needle #2 procedure.
Washing needle 3	Performing wash needle #3 procedure.
Washing Lines	Wash tube from valve to waste.
Prime Lines	Equilibrate tube from valve to waste with wash A.
REMOVE ALL VIALS	Prompt to remove vials.
LOAD SAMPLE VIAL IN LOC 1	Prompt for loading sample vial in location 1.
Flushing with WashA	Flushing with wash solution A.
Filling with WashA	Empty, fill with wash-A, mix by drain-and-fill, repeat, leave cell full.
A washes D/F	Wash with A by mixing using drain-and-fill procedure.
Flushing with Wash	Flushing with wash solution B.
B washes D/F	Wash with B by mixing using the D/F (drain-and-fill) procedure.
REMOVE SAMPLE VIAL	Make sure sample vial is removed.
LOAD EMPTY VIAL IN LOC 1	Make sure empty vial is present.
Flushing with Wash	Flushing with wash solution B.

Table A.5 LDC Messages (Continued)

Message	Meaning
Draining to Waste	Drain waste.
needle 1 w/Wash	Flush needle 1 with Wash B.
Washing needle	Wash needle with water.
REMOVE VIAL	Prompt to remove vial.
Washing done	Completion of washing.
READY	System is ready.

The FS450Dx Instrument Specifications

Fluidics Station Dimensions:

(height, depth, width)
40.2 x 41.0 x 71.1 cm or 15 13/16 x 16 1/8 x 28 inches

Product Weight:

Approximately 80 pounds or 36.3 kg

Power Input:

100 to 240 V**~,** 3 A
300 watts or less

Main supply voltage fluctuations not to exceed 10% of the nominal supply voltage.

Temperature:

Operating: 15° to 30° C
Storage (non-operating):-10° to 60° C

Humidity:

Operating: 10-90% RH, non-condensing
Storage (non-operating):10% to 95% RH

Other:

Pollution degree, 2

Installation category, II

Electrical Supply

The electrical supply shall meet the input specified on the instrument label. Voltage fluctuations shall not exceed 10% nominal supply voltage.

Altitude

<2000m

Regulatory Compliance

CE Mark Declaration of Conformity

We,
Affymetrix, Inc.
890 Embarcadero Drive
West Sacramento, CA 95605

declare under sole responsibility that the Affymetrix® GeneChip® 3000Dx v.2, including Scanner model GCS 3000Dx, the AutoloaderDx, Fluidics Station FS450Dx, and associated Workstation with Molecular Diagnostic System software, is Manufactured in the United States of America, with U.S. and Non-U.S. components, and conforms with the relevant provisions of the following standard(s) of safety and compliance, and/or other normative document(s):

EU In-Vitro Diagnostic Medical Devices Directive 98/79/EC, Annex III CE Declaration:

ISO 13485:2003	Medical devices -- Quality management systems -- Requirements for regulatory purposes

EU EMC Directive 89/336/EEC:

EN 61326-1:1997+A2:2001	Equipment for Measurement Control and Laboratory Use
EN 55011:1998+A2:2002	Limits and methods of measurements of radio disturbance characteristics of industrial, scientific and medical (ISM) radio frequency equipment
EN 61000-3-2:2000	Limits for harmonic current emissions (equipment input < 16A per phase)
EN 61000-3-3:1995 +A1:2001	Limitation of voltage fluctuations and flicker in low voltage supply systems for equipment with rated current < 16A
EN 61000-4-2:1995	Electrostatic discharge immunity
EN 61000-4-3:1995	Radiated, radio frequency, electromagnetic field immunity
EN 61000-4-4:1995	Electrical fast transient/burst immunity
EN 61000-4-5:1995	Surge immunity
EN 61000-4-6:1996	Immunity to conducted disturbances, induced by radio frequency fields
EN 61000-4-11:1994	Voltage dips, short interruptions and voltage variations immunity

EU Low Voltage Directive 73/23/EEC:

EN 61010-2-101:2002	Safety requirements for electrical equipment for measurement, control and laboratory use, Particular requirements for in vitro diagnostic medical equipment
EN 60825-1:1994 +A2:2001	Safety of laser products—Part 1: Equipment classification, requirements and user's guide

Regulatory

This device complies with Part 15 of FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesired operation.

This Class A digital apparatus meets all requirements of the Canadian Interference-Causing Equipment Regulation.

Cet appareil numérique de la classe A respecte toutes les exigences du Règlement sur le matériel broullier du Canada.

Regulatory Agency	Certification
CE	
	Compliant with directive 2002/96/EC (WEEE)

China RoHS Restriction of Hazardous Substances Compliance

Manufacturers of Electronic Information products (EIPs) that are sold to the People's Republic of China, are required to provide information about lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyls and polybrominated diphenyl ethers contained within.

In accordance with the Chinese RoHS (Restriction of Hazardous Substances), Table A.6 contains information identifying the specific hazardous material(s) and the components/parts in which they are found.

Table A.6 Table Containing Names and Contents of Toxic or Hazardous Materials[a]

Instrument: Affymetrix GeneChip Fluidics Station 450Dx

Component /Part Categories	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent Chromium (Cr 6)	Polybrominated Biphenyls (PBBs)	Polybrominated Diphenyl Ethers (PBDEs)
Printed Circuit Boards	X	O	X	O	O	O
Rubber & Plastic Parts	O	O	O	O	O	O
Electrical Components	X	O	O	O	O	O
Internal Metal Parts	O	O	O	O	O	O
External Metal Parts	O	O	O	O	O	O
Labels	O	O	O	O	O	O
Packaging/ Shipping Materials	O	O	O	O	O	O
Internal Lasers, Optics & Sensors	O	O	O	O	O	O
Adhesives	O	O	O	O	O	O

Table A.6 Table Containing Names and Contents of Toxic or Hazardous Materials[a]

Instrument: Affymetrix GeneChip Fluidics Station 450Dx

Component /Part Categories	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent Chromium (Cr 6)	Polybrominated Biphenyls (PBBs)	Polybrominated Diphenyl Ethers (PBDEs)
Internal Power Supplies	X	O	X	O	O	O
Motors and Pumps	O	O	O	O	O	O

[a]X = Indicates that the toxic or hazardous substance contained is above the limit of 1000 ppm for lead and above 100 ppm for cadmium

O = Indicates that the toxic or hazardous substance contained is below the limit of 1000 ppm for lead, mercury, hexavalent chromium, polybrominated biphenyls and polybrominated diphenyl ethers; and below 100 ppm for cadmium.

SJ/T11364-2006 电子信息产品污染控制标识要求

目前许多电子信息产品由于功能、性能或生产技术的需要，仍含有大量如铅 （Pb）、汞 （Hg）、镉 （Cd）、六价铬 [Cr （VI）]、多溴联苯 （PBB）和多溴二苯醚 （PBDE）等有毒有害物质或元素。这些含有毒有害物质或元素的电子信息产品在废弃之后，如处置不当，不仅会对环境造成污染，也会造成资源的浪费。因此，为了达到节约资源、保护环境的目的，以有毒有害物质或元素的减量化、替代为主要任务的电子信息产品污染控制工作已经提到政府主管部门的议事日程。为此，信息产业部等七部委以“从源头抓起，立法先行”的思路和原则，制定了《电子信息产品污染控制管理办法》（信息产业部 39 号部长令，简称《管理办法》），以立法的形式，推动电子信息产品污染控制工作，旨在从电子信息产品的研发、设计、生产、销售、进口等环节限制或禁止使用上述六种有毒有害物质或元素。

为了进一步落实《管理办法》并达到限制有毒有害物质或元素在电子信息产品中使用的目标，必须有配套使用的统一的标识方法标准。因此，为了配合中华人民共和国《管理办法》的实施，同时也为中华人民共和国信息产业界对六种有毒有害物质或元素铅 （Pb）、汞 （Hg）、镉 （Cd）、六价铬 [Cr （VI）]、多溴联苯 （PBB）和多溴二苯醚 （PBDE）的测试提供一个统一的标识方法，特制定本标准（表 Table A.7）.

Table A.7 有毒有害物质或元素名称及含量[a]

仪器： Affymetrix GeneChip Fluidics Station 450Dx

部件名称	铅 （Pb）	汞 （Hg）	镉 （Cd）	六价铬 [Cr （VI）]	多溴联苯 （PBB）	多溴二苯醚 （PBDE）
印制电路板	X	O	X	O	O	O
橡胶和塑料元件	O	O	O	O	O	O
电子元件	O	O	O	O	O	O
内部金属零件	X	O	O	O	O	O
外部金属零件	O	O	O	O	O	O
标签	O	O	O	O	O	O
组装 / 装货资料	O	O	O	O	O	O

Table A.7 有毒有害物质或元素名称及含量[a]

仪器：Affymetrix GeneChip Fluidics Station 450Dx (Continued)

部件名称	铅（Pb）	汞（Hg）	镉（Cd）	六价铬 [Cr（VI）]	多溴联苯（PBB）	多溴二苯醚（PBDE）
内部激光，光学器件和传感器	O	O	O	O	O	O
胶粘剂	O	O	O	O	O	O
内部电源	X	O	X	O	O	O
马达和唧筒	O	O	O	O	O	O

[a] ×：表示该有毒有害物质至少在该部件的某一均质材料中的含量超出 1000 ppm 铅（Pb）100 ppm 镉（Cd）的标准规定的限量要求。

○：表示该有毒有害物质在该部件所有均质材料中的含量均在 1000 ppm 铅（Pb）汞（Hg），六价铬 [Cr（VI）]，多溴联苯（PBB），多溴二苯醚（PBDE），100 ppm 镉（Cd）的标准规定的限量要求以下。

电子信息产品污染控制标识要求 (Marking for Control of Pollution Caused by Electronic Information Products) SJ/T11364-2006

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Appendix B

THE SCANNER 3000DX WITH AUTOLOADERDX

Introduction

This chapter describes how to use the GeneChip® Scanner 3000Dx with AutoLoaderDx (aka the AutoLoaderDx). The AutoLoaderDx is used as part of the overall assay workflow.

Affymetrix has designed the AutoLoaderDx expressly for scanning multiple array cartridges. The AutoLoaderDx can scan up to 48 arrays automatically without operator presence.

Figure B.1 The Affymetrix® AutoLoaderDx

WARNING: **Do not remove the external case or skin or scanner cover of the AutoLoaderDx. Use the AutoLoaderDx only as instructed in this user guide. Do not attempt to service the instrument. Only qualified service technicians can open and service the AutoLoaderDx. There are no customer serviceable parts. Removing the case exposes the customer to laser and electrical shock hazards.**

Safe Operation

To ensure safe operation of the AutoLoaderDx:

IMPORTANT: **Shutting down the AutoLoaderDx: To preserve the lifetime of the scanner's internal laser we recommend that you turn the scanner OFF when it is not in use for any extended period of time, such as overnight or a weekend.**

- Read this section completely before operating the instrument.
- Do not attempt to service this instrument. Any attempt at unauthorized service may damage the instrument and/or void the warranty.
- The instrument weight is approximately 63 pounds (28.6 Kg). Do not place it on an unstable cart, stand, or table. Failure to properly support the instrument may cause serious damage or injury and may void the warranty.

CAUTION: **Heavy object. Two people are required to lift the AutoLoaderDx.**

- The instrument must be surrounded by adequate airspace. Slots and openings in the instrument and the electronics compartment covers are for ventilation. Do not block or cover them.

- Never push an object into the instrument ventilation slots; equipment damage or injury may result. Do not set liquids on top of the instrument.
- The instrument has an AC receptacle with a safety ground appropriate for the country of destination. The plug is designed to connect only to a 3-prong ground receptacle. This safety feature should not be compromised in any way. If the instrument AC plug does not mate with the available power source receptacle, consult a licensed electrician to install one that does.

When to Contact Affymetrix

Under any of the following conditions, unplug the instrument from the power source and contact technical Support:

- When the power cord is damaged or frayed.
- If any liquid has been spilled into the instrument.
- If the instrument has been penetrated by water.
- If, after service or calibration, the instrument does not perform in accordance with the capabilities stated in the specifications.
- If the instrument has been dropped or otherwise damaged.

If the instrument must be returned for repair, call Affymetrix technical support.

Laser Safety

The laser is equipped with an automatic shutter that inhibits its output beam and ensures safe operation under conditions encountered in normal operation. The instrument covers, the array access port, and protective shutters ensure that during instrument operation no directed or stray laser light leaves the instrument.

IMPORTANT: **The AutoLoaderDx is a Class I laser product when the laser is enclosed in scanner case. The laser itself is a Class IIIB laser product.**

DANGER

Laser radiation when open. Avoid direct exposure to laser beam.

The lasers can cause serious injury if the instrument is not operated in accordance with instructions in this user guide.

CAUTION

Use laser safety glasses when servicing
DO NOT STARE INTO LASER BEAM.

Class I Laser Product

The green laser is a 532nm solid-state laser. This is a Class IIIb laser and has visible outputs greater than 5mw but not more than 500mw. It must never be operated in an exposed manner. Any object in the direct path of the laser beam may be damaged. Eyes and skin can be seriously damaged by direct exposure to, specular reflections from, or diffuse reflections from this laser. If improperly used, a laser of this type can cause fires. When used according to the instructions in this manual and when all covers are in place, the GeneChip® AutoLoaderDx is classified as a Class I Laser Device per 21 CFR 1040.

Always take note of laser safety labels; they indicate areas where exposure to laser beams may be hazardous.

Electrical Safety

The scanner will automatically handle any input voltage from 100 to 240 VAC nominal, 50 to 60 Hz

NOTE: The scanner's power supply will autodetect the input voltage source and configure itself.

CAUTION

The power supply cord is used as the main disconnect device. Ensure that the socket outlet is located and installed near the equipment and is easily accessible.

CAUTION: If you use the AutoLoaderDx in a manner not specified in this user guide, you may impair the protection provided by the equipment.

CAUTION: Do not confuse your company's network connections with the dedicated Ethernet port of the AutoLoaderDx-workstation. The proper AutoLoaderDx connection is located near the top of the workstation.

CAUTION: This 10/100 Base T Ethernet communications port is dedicated to the AutoLoaderDx-workstation interface. You cannot connect the AutoLoaderDx to your company's Ethernet communications network.

IMPORTANT: **The reset button is the scanner's circuit breaker. The breaker switch will be tripped whenever the scanner experiences an electrical fault condition. Press to reset. If you cannot reset this switch, contact Affymetrix technical support.**

Workstation - AutoLoader Connections

Figure B.2 and Figure B.3 show the cable connections of the workstation and the AutoLoader. This is for reference only. Affymetrix recommends that only a qualified service technician attempt to service or change these connections.

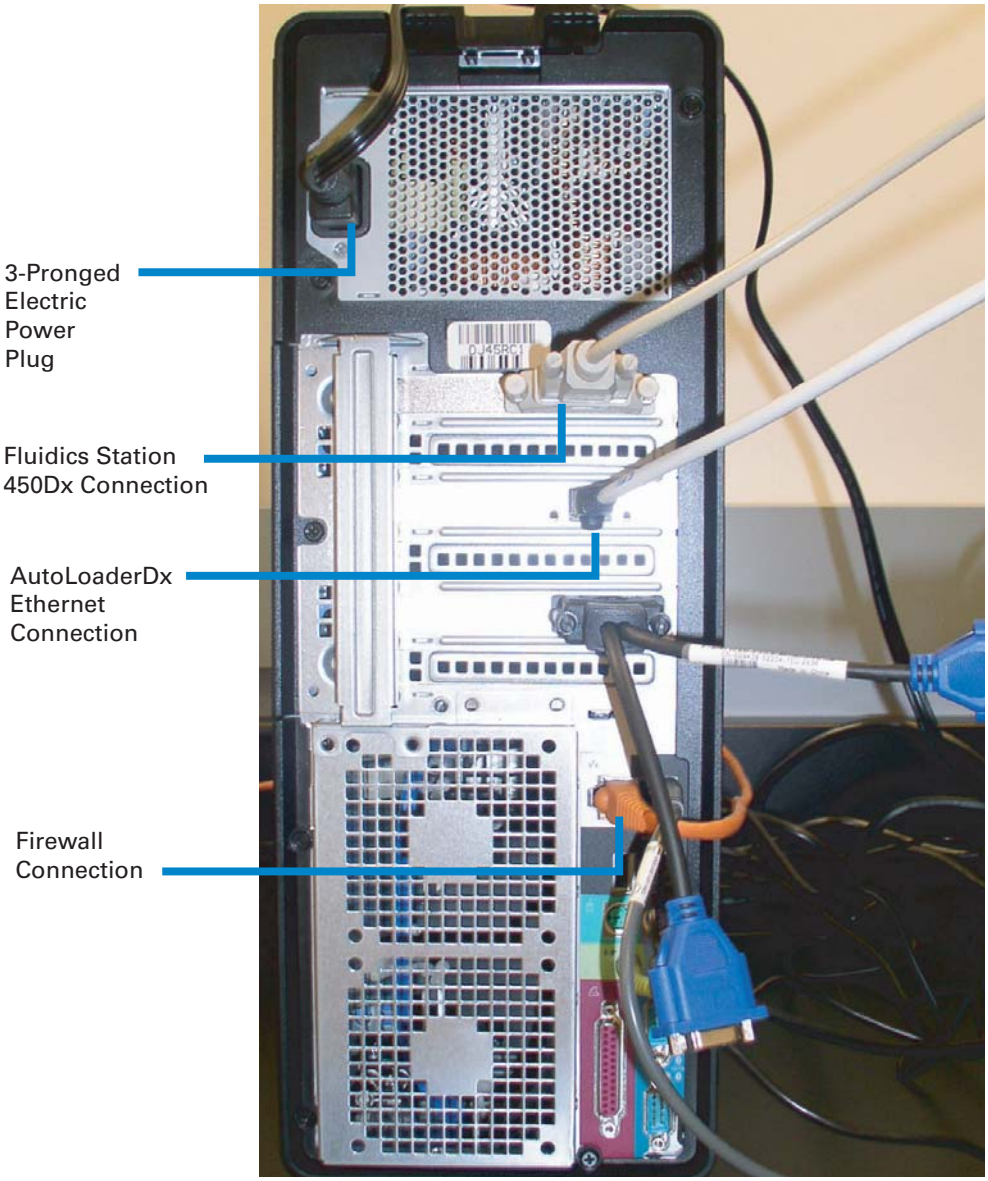


Figure B.2 Workstation rear cable connections

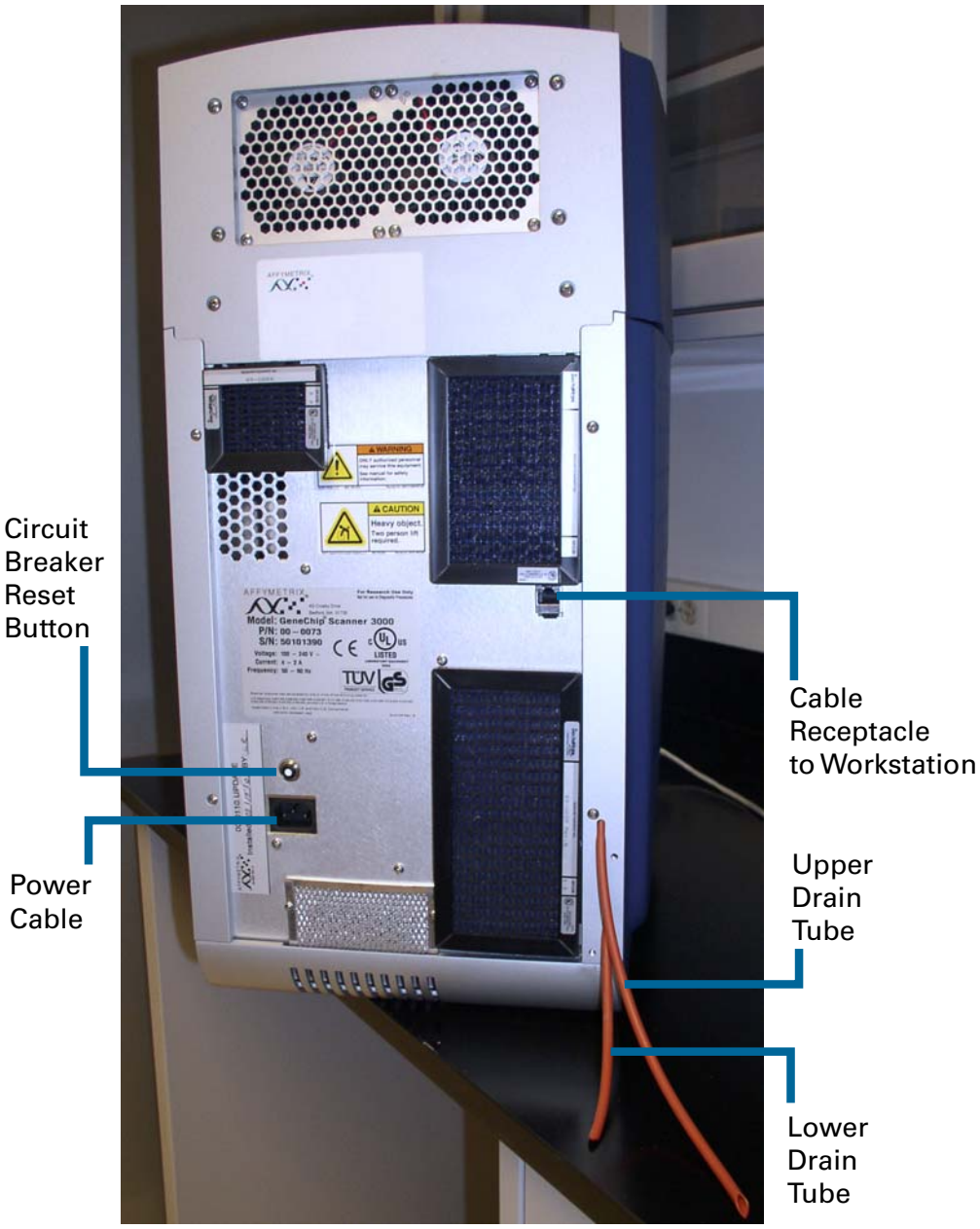


Figure B.3 AutoLoaderDx rear connections

Connecting the Barcode Reader

1. Connect the barcode reader carriage to the workstation's USB port (Figure B.4).
2. Connect the barcode reader carriage to the USB cable and power cable (Figure B.4).

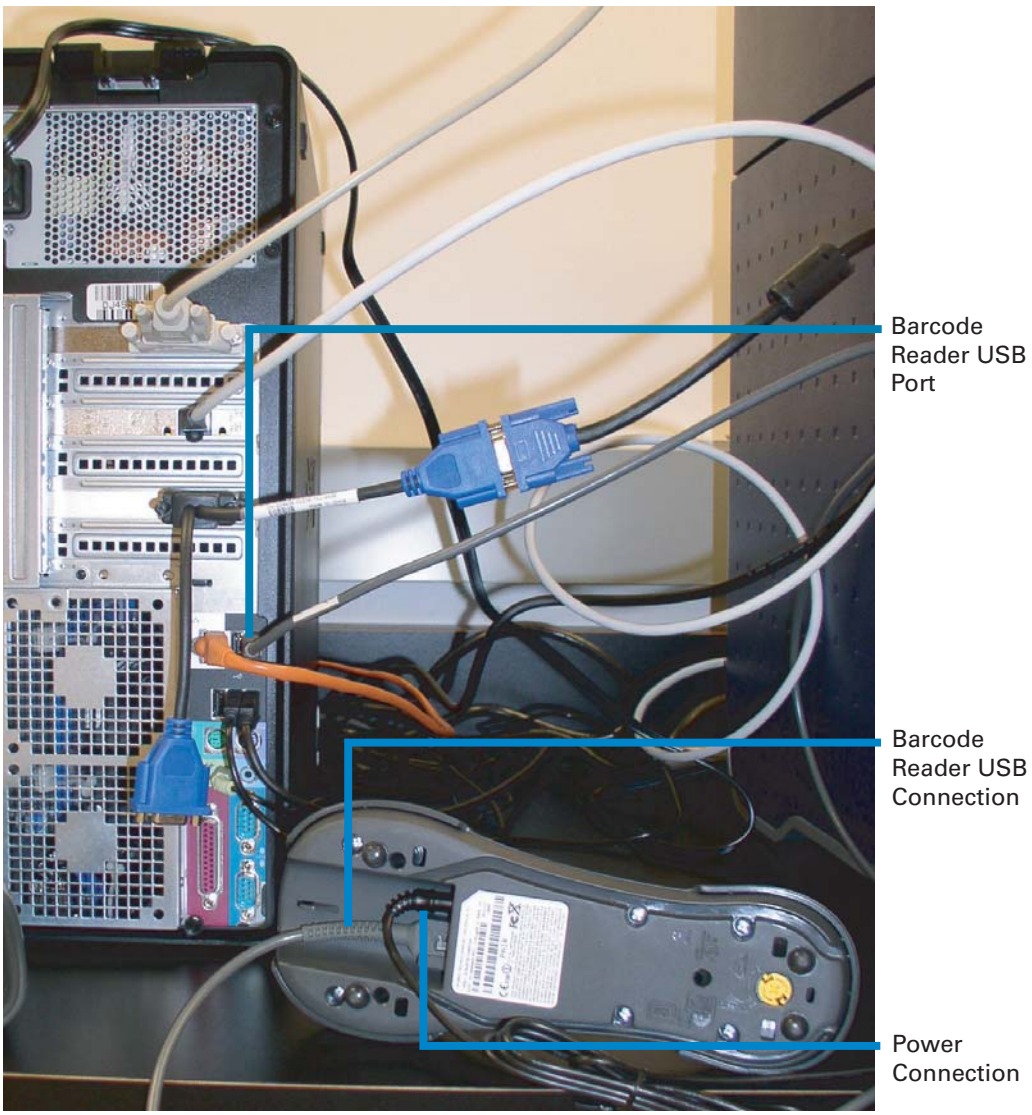


Figure B.4 Workstation and barcode reader connections

AutoLoaderDx Indicator Lights and On/Off Button

The front panel has the following button and indicators (Figure B.5).

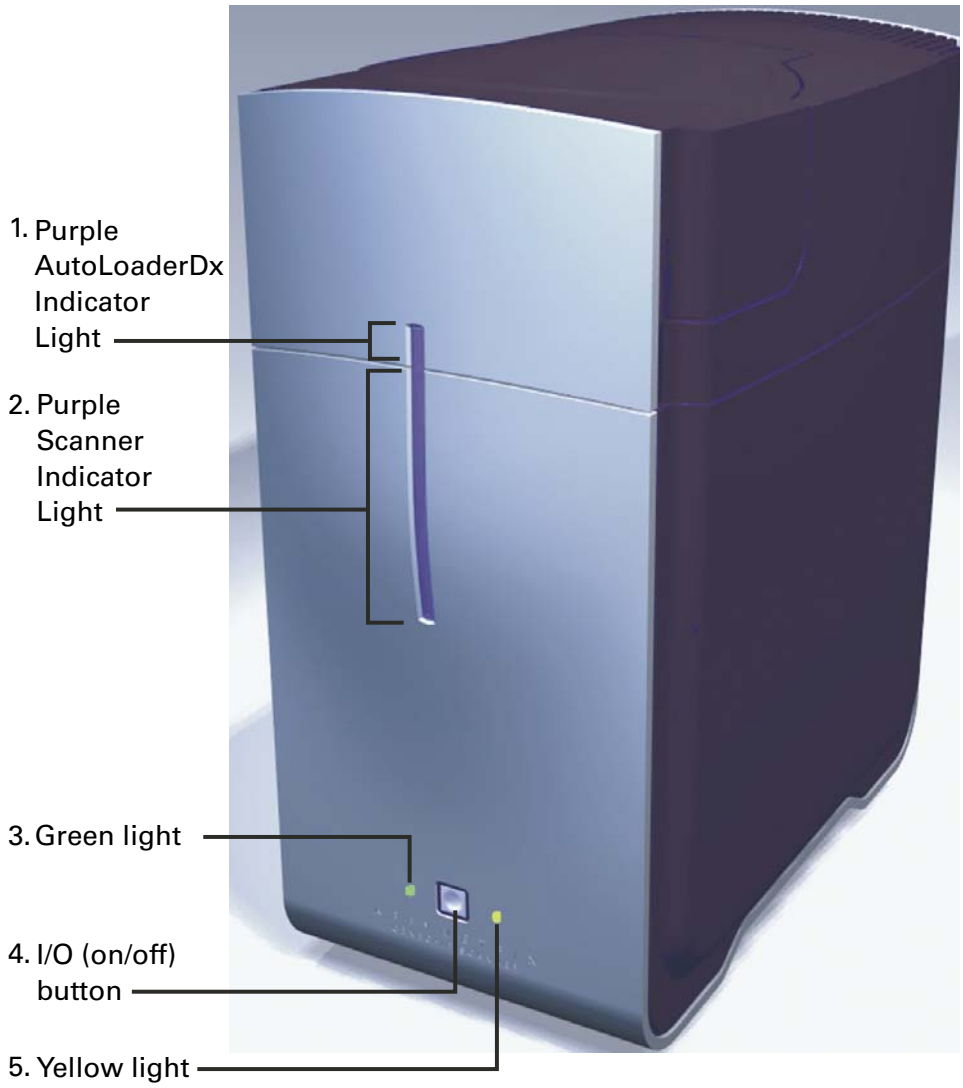


Figure B.5 The AutoLoaderDx indicator lights

1. Purple indicator light on AutoLoaderDx, running vertical at front center. This light appears to be merely an extension of the lower scanner light. However, when on, it indicates that the AutoLoaderDx door is closed and locked. It will turn off when the door is unlocked.

2. Purple scanner indicator light on the AutoLoaderDx body, running vertical at front center. This light extends to the bottom of the AutoLoaderDx and is always on when the scanner is on.
3. Green light
   a. On = System is ready to scan (yellow off)
   b. Flashing = Scan in progress
4. I/O (on/off) button in the center.
5. Yellow light
   a. On = Idle, laser is warming up (laser not ready, green off)
   b. Off = System ready, no errors (Green on)
   c. Flashing = Error

Summary of Indicator Lights

The table (Table B.1) below summarizes the light conditions and their meaning.

Table B.1 Light colors and meanings

Condition	Green Light	Yellow Light	Purple Scanner Indicator Light	Purple AutoLoaderDx Indicator Light	Meaning
Initial boot up	Off	Off	On	Off	Initial power up; embedded PC takes control
Scanner boot up	On	On	On	Off	Embedded PC takes control of scanner boot up

Table B.1 Light colors and meanings (Continued)

Condition	Green Light	Yellow Light	Purple Scanner Indicator Light	Purple AutoLoaderDx Indicator Light	Meaning
Laser warm up	Off	On	On	Off	Software enabled and laser is warming up
System ready	On	Off	On	Off	Scanner ready for use and AutoLoader Dx door is unlocked waiting to receive a carousel
Error	Off	Flashing	On	Off	Fatal error, reboot scanner and software, AutoLoader Dx door is unlocked to remove carousel if necessary
Scanning	Flashing	Off	On	On	Scanning is in progress and AutoLoader Dx door locked
Scanning	Flashing	Off	On	Off	Scanning is in progress and AutoLoader Dx door is unlocked

Scanning Arrays

This section shows you how to scan multiple arrays using the AutoLoaderDx. The GeneChip arrays are similar to those shown in Figure B.6.

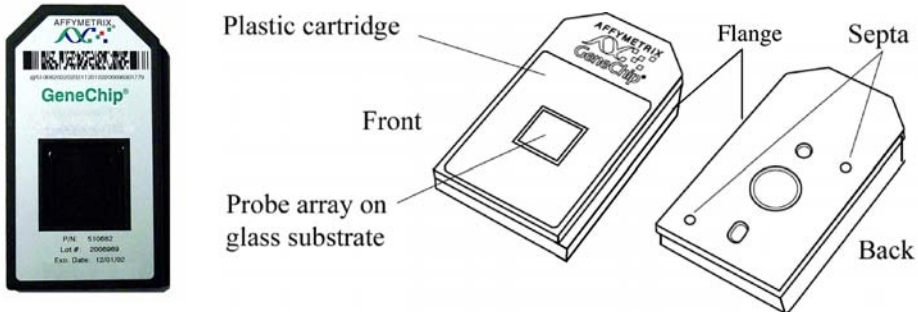


Figure B.6 The array, or cartridge: note the location of the flange. The AutoLoaderDx will accept the array in only one orientation.

Using Tough-Spots™ to Prevent Leaks

Tough-Spots™ are chemically inert polyvinyl labels that adhere to all plastics. Affymetrix recommends using 3/8-inch circle diameter Tough-Spots to prevent leakage from the array cartridge septa.

Before loading the array cartridge into the AutoLoaderDx, follow this procedure to prevent the leaking of fluids from the array during scanning.

Even if you have already applied Tough-Spots to the array prior to hybridization or after washing, you must remove the old Tough-Spots and apply new ones before you load them into the AutoLoaderDx.

Affymetrix recommends the use of Tough-Spots™ obtained from Affymetrix P/N 64-0158

or from

USA Scientific, Inc. P.O. Box 3565 Ocala, FL 34478 (800)LAB-TIPS P/N 9185-0000

1. On the back of the array cartridge, clean excess fluid from around septa (Figure B.7).

2. Carefully apply one Tough-Spot over each of the two septa. Press to ensure that the spots remain flat. If a Tough-Spot does not apply smoothly; that is, if you observe bumps, bubbles, tears or curled edges, do not attempt to smooth them out. Remove the spot and apply a new one (Figure B.7).

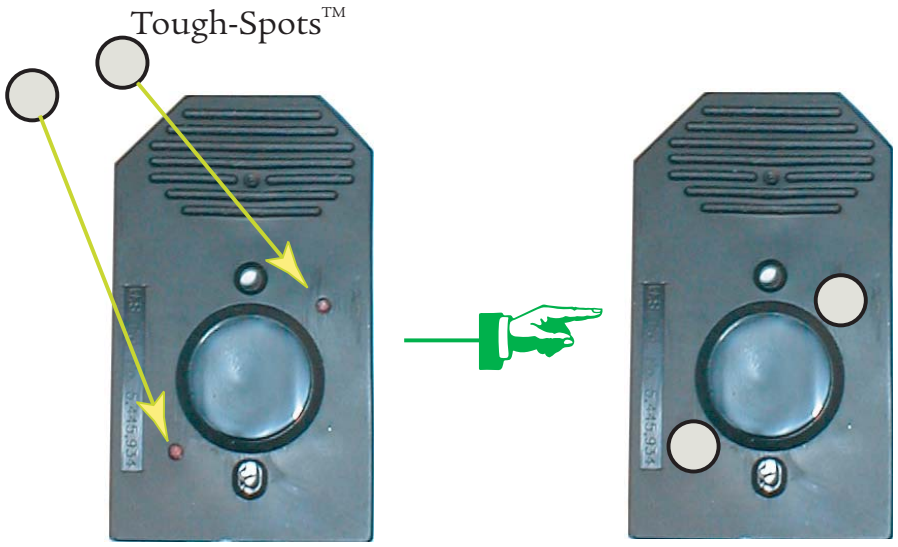


Figure B.7 Applying Tough-Spots™ to array cartridge septa

Loading Arrays into the Carousel

1. Load your arrays into the carousel (up to 48). Note that only one orientation is possible (Figure B.8).

   Arrays should be loaded into the carousel starting at position #1. Additional arrays need not be contiguous. The AutoLoaderDx will always scan and check all 48 slots starting a position #1.

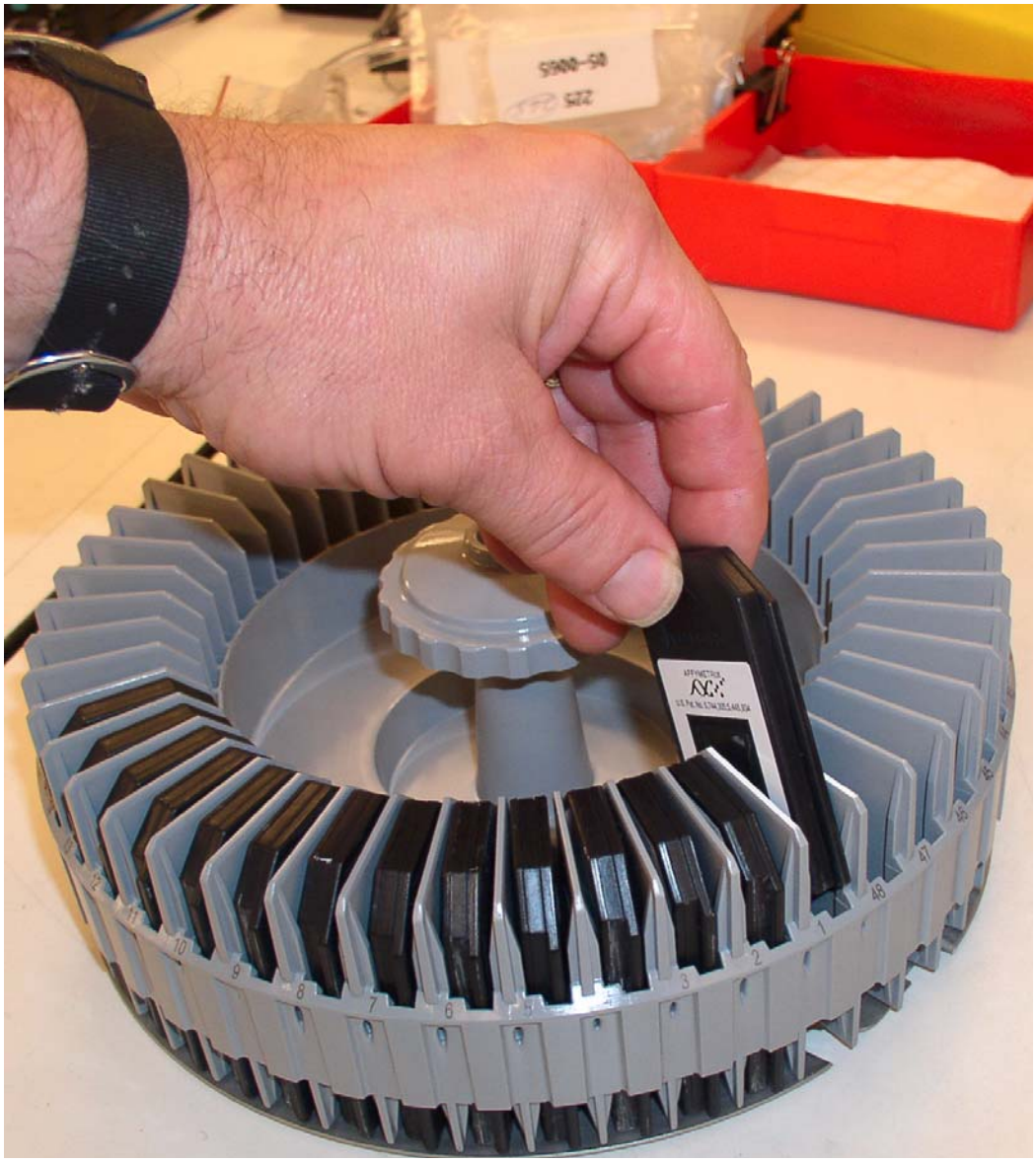


Figure B.8 Loading the arrays into the chip carousel, note that each slot is numbered 1 through 48, and each array can fit in only one orientation.

Loading the Carousel into the AutoLoaderDx

1. If you have previously removed the carousel from the AutoLoaderDx. Load the carousel into the AutoLoaderDx by inserting the carousel into the AutoLoaderDx and turning the carousel until the alignment pin seats into the alignment hole (Figure B.9).

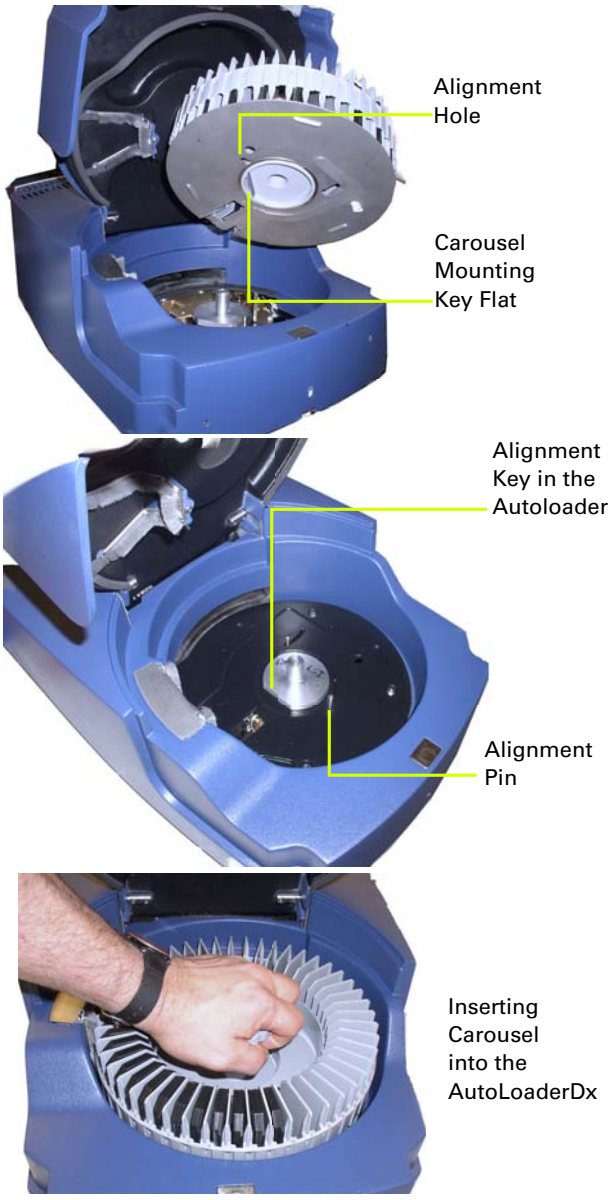


Figure B.9 Loading the carousel into the AutoLoaderDx

2. Turn the carousel clockwise until the carousel mounting key flat seats gently into the AutoLoaderDx alignment key. You may have to turn the carousel several times before it will seat into the alignment pin and alignment key. When seated properly, the carousel will be flush with the AutoLoaderDx housing. Close the AutoLoaderDx door (Figure B.10).

Figure B.10 Inserting and turning the carousel; the carousel should be seated and flush with housing.

NOTE: The seating of the key flat is confirmed by a gentle falling of the carousel into the key.

NOTE: AUTOROTATION

The AutoLoaderDx has a heater to warm up the arrays prior to scanning in order to reduce condensation and fogging of the array window. The AutoLoader uses a process called autorotation to maintain the temperature stability of the carousel.

The AutoLoaderDx spins the carousel around during the autorotation routine. This occurs only after the AutoLoaderDx run is complete or during a power failure as described below.

Autorotation occurs during a power failure only if the uninterrupted power supply (UPS) is included as an accessory. The UPS provides power to the AutoLoaderDx during a power failure. If the power fails during the scan of an array, that scan is completed and then the system turns off the heater and enters the autorotation mode to conserve power and cool the chips in the carousel.

During a scanning run, the carousel rotates to introduce the next array into the AutoLoaderDx, so autorotation is not needed. After the scanning run is complete, the AutoLoaderDx turns off the heater and rotates the carousel to get even cooling of the arrays.

Starting the AutoLoaderDx

1. Press the **I/O** button on the front panel to turn on the instrument.
2. Wait ten minutes for the AutoLoaderDx to warm up.

Shutting Down the AutoLoaderDx

1. Press the **I/O** button on the front panel to turn off the instrument.

IMPORTANT: **Affymetrix recommends a professional service call for maintenance at least twice a year. Please contact Affymetrix technical support for details.**

Cleaning and Maintenance

The AutoLoaderDx requires little in the way of customer maintenance. The instrument must be kept clean and free of dust. Dust buildup can degrade performance. Wipe the exterior surfaces clean using a mild dish detergent solution in water. Do not use ammonia based cleaners or organic solvents, such as alcohol or acetone, to clean the system because they may d213mamage the exterior surfaces. Clean the carousel by hand using warm water and, if necessary, mild detergent.

The Affymetrix Genechip Microarray Instrumentation System for IVD use requires calibration and maintenance twice a year by authorized Affymetrix personal to ensure the system performance. Failure to maintain the system as recommended may result in the failure of the system to perform in accordance with specifications published by Affymetrix.

Configuring the AutoLoaderDx

If you are an administrator, you can control three functions of the scanner (Figure B.11). You can:

- Turn on and warm up laser when you launch AMDS.
- Run the scanner one specimen at a time in manual mode.
- Disable the AutoLoaderDx to run only the software.

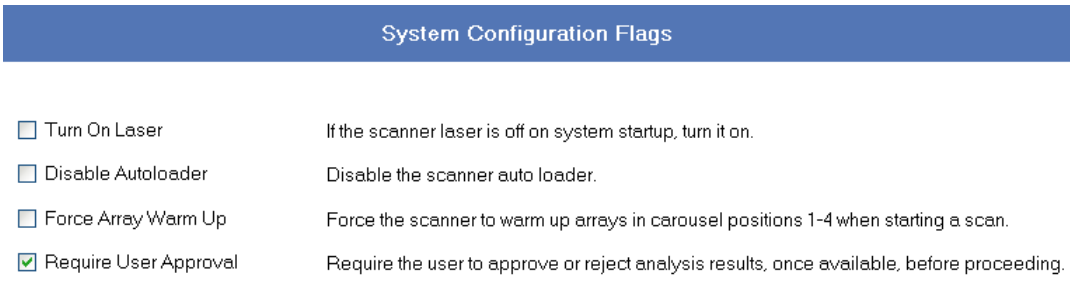


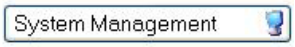
Figure B.11 The user maintenance functions for the AutoLoaderDx

Turn on Laser at Startup

1. Click on the **System Management** button 

.
2. Select **Turn on Laser at Startup** box (Figure B.11).

Enable Manual Mode

1. Click on the **System Management** button 

.
2. Select **Enable Manual Mode** box (Figure B.11).

Disable AutoLoaderDx

1. Click on the **System Management** button 

.
2. Select **Disable AutoLoader** box (Figure B.11).

Troubleshooting

This section deals with issues and problems that might occur with the AutoLoaderDx.

Troubleshooting the AutoLoaderDx

This section deals with issues relating primarily to the scanner part of the AutoLoaderDx especially when the AutoLoaderDx is in Manual Mode.

Table B.2 AutoLoaderDx Troubleshooting

Problem	Possible Cause	Corrective Action
No image when scanning	Power off or cable loose	Check all connections and power.
	Loss of laser power	Contact technical support.
Intermittent problems scanning	Loose cable	Check all rear connections.

Table B.2 AutoLoaderDx Troubleshooting

Problem	Possible Cause	Corrective Action
AutoLoaderDx fails with array inside	Power failure	Manually extract array. Check all connections to AutoLoaderDx. Turn AutoLoaderDx on, restart software.

Issues Relating to the AutoLoaderDx's Operation

In using the AutoLoaderDx you may encounter some issues, or problems, that may require your intervention. Below is a list of these issues.

Table B.3 Issues that may affect the AutoLoaderDx

Issue	Explanation
If communications are interrupted during a scan (by a faulty cable connection or power being lost at the scanner, for example)	AMDS will properly note the failure and present an alert that says "Cannot connect to Scanner" or something similar. However, there are two issues to note. first, AMDS will report such a failure only after a network time-out of about 30 seconds. Second, rarely, if communications have been lost, AMDS and the AutoLoaderDx may not be able to automatically restore communications once the problem is rectified, and both may become unresponsive. To restore proper operation, verify that the AutoLoaderDx is on, that communication cables are properly connected. See the section, *Changing the Instrument Settings, on page 113*. Click the **Restart Scanner** button to restart the AutoLoaderDx. You may need to close AMDS and restart Windows then restart AMDS. If the system remains unresponsive, disconnect and reconnect power to the scanner, restart the scanner normally, close and restart Windows and AMDS.

Table B.3 Issues that may affect the AutoLoaderDx (Continued)

Issue	Explanation
Repeated attempts to send commands (Start, Turn Laser On, etc.) from AMDS to the Scanner while AMDS is reporting the scanner "Offline" may result in AMDS becoming unresponsive until communications are restored	If communications cannot be re-established, follow the recommendations of item 1.
If the Scanner experiences multiple autofocus failures, the system may enter an unresponsive state.	Follow the recommendations of item 1 to restore communications and correct operation.
Laser warm-up lasts for ten minutes, during which time the "Turn Laser On" button will remain unchanged and AMDS will display the status message "Warm-up".	Simply note that this is normal operation.
If no array is inserted and a scan started.	The scanner will attempt go through the first parts of the auto-focus routine and then report "Failed to find chrome border."
Autofocus will fail if salt deposits accumulate on the array.	Use Tough-Spots to prevent leaks in the GeneChip array. See the quick reference card, p/n 08-0076, or the section, *Using Tough-Spots™ to Prevent Leaks* *on page 207*.

Troubleshooting the AutoLoaderDx

This section deals primarily with diagnosing problems that may occur to the AutoLoaderDx.

Table B.4 AutoLoaderDx Troubleshooting Guide

Problem	Possible Cause	Corrective Action
Intermittent problems scanning	Loose cable	Check all rear connections.
Scanner fails with array inside	Power failure	Manually extract array. Check all connections to scanner. Turn scanner on, restart software.
Carousel does not automatically home	• Check for stuck array • Carousel not seated on D ring • Alignment Pin not engaged in Carousel • Door is open or ajar • Door is open when purple LED is off.	
Carousel does not rotate	• Door is open or ajar • System is warming up, array in heater • Carousel not seated on D ring • Alignment Pin not engaged in Carousel • Laser in Scanner is warming up. AMDS has Start grayed out in this case	
Carousel misses next array	Array UP sensor not working, call technical support.	
Stuck array		See the section, *Manually Removing a Lodged Array Cartridge, on page 220*

Table B.4 AutoLoaderDx Troubleshooting Guide (Continued)

Problem	Possible Cause	Corrective Action
AutoLoaderDx freezes up	Door is open or ajar	
AutoLoaderDx overheats	• Heater Failure • TE failure • TE hot fans vent blocked	Call technical support. Call technical support.
Autofocus routine fails to conclude	Salt buildup on array cartridge substrate	Check for salt on chrome border. Use Tough-Spots to prevent leaks in the GeneChip array. See the quick reference card, p/n 08-0076, or *Using Tough-Spots™ to Prevent Leaks, on page 207*.
The array does not descend into scanner.	• Carousel not seated correctly • Door is open or ajar • Heater is waiting until array is at temperature.	

AutoLoaderDx Error Messages

The following error messages indicate a serious malfunction of the AutoLoaderDx. Your arrays, or the data generated from them, may be at risk. You should shut down the AutoLoaderDx and remove the carousel. Do not continue to use the AutoLoaderDx in Automode. Call Affymetrix Technical Support.

Table B.5 AutoLoaderDx Error Messages

Message	Meaning
HEATER_LOW	"Warning: The warming chamber temperature is low. Refer to the troubleshooting guide."

Table B.5 AutoLoaderDx Error Messages (Continued)

Message	Meaning
COLD_CHAMBER_LOW	"Warning: The cold chamber temperature is low. Refer to the troubleshooting guide."
COOL_HOTSIDE_HIGH	"Warning: The cooler hot-side temperature is high. Refer to the troubleshooting guide." Note: Before calling technical support, check around the ventilation vents to ensure that nothing is blocking them.
COLD_CHAMBER_HIGH	"Warning: The cold chamber temperature is high. Refer to the troubleshooting guide." Note: Before calling technical support, check the AutoLoaderDx door to ensure that it is not open.
HEATER_HIGH	"Warning: The warming chamber temperature is high. Refer to the troubleshooting guide."

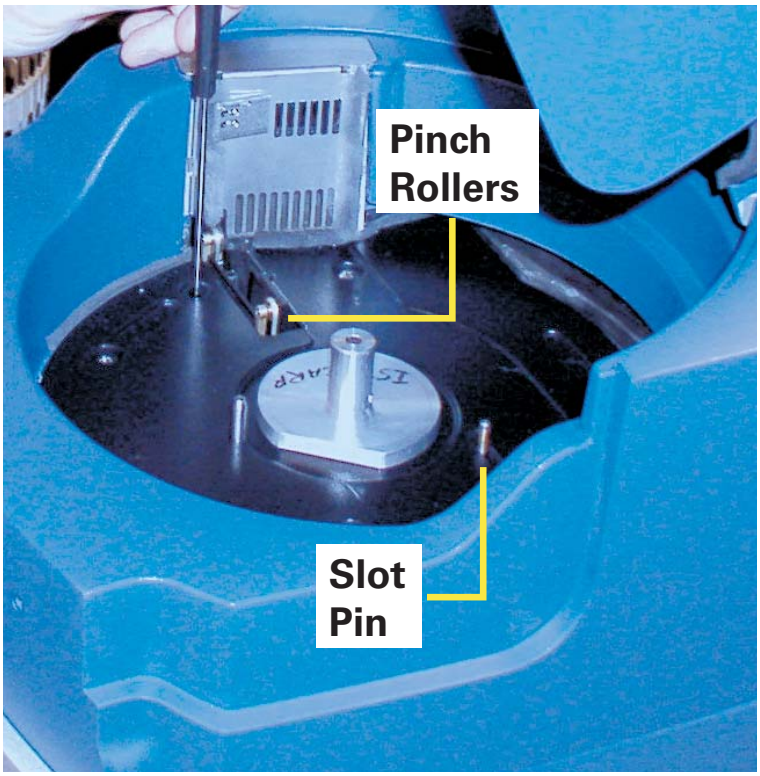
Manually Removing a Lodged Array Cartridge

In the event that a array becomes lodged in the array transport mechanism, follow the procedure outlined below.

1. Turn the AutoLoaderDx off and remove the power cord from the back of the unit.
2. Open the AutoLoaderDx door on top of the unit.
3. Remove the carousel from the system. (Keep the arrays in carousel and at the proper temperature while recovering the array still in the AutoLoaderDx).
4. Remove the hole plug, which is just in front of the array slot in the base piece of insulation. In the photo to the right, the screwdriver is inserted into this hole.

5. Using a standard, flat (-) screwdriver, (13-0257) gently slide it down through the hole making sure not to damage the shaft and spring that are protruding into the hole. When the screwdriver stops, it should be in contact with the scanner Y stage screw. Slowly turn the screwdriver until you feel it engaging the slot on the screw of the scanner Y stage.

6. Slowly turn the screw clockwise until it hits a hard stop and cannot turn further. (Do not try to turn it further or use excessive force because it will break the Y stage in the AutoLoaderDx). The Y stage has now ascended to its maximum position.
7. Using your fingers, slowly slide the slot pin, which is sticking through the slot in the base piece of insulation, to the right until it stops. You should see the little pinch rollers near the array slot close a little as you do this.



8. Insert a 3/16" hex driver (Affymetrix P/N 13-0255) into the hole that is located on the front of the AutoLoaderDx housing on the left. You should feel it engage a coupling.
9. Turn the hex driver counter clock wise until you see the array appear through its opening. (The array should stay up if you stop turning the hex driver). If you don't see the array after turning the hex driver ten seconds go to step 11.

10. Grab and hold the array with your fingers. Using your other hand slowly slide the slot pin (Step 7) back to the left. This should open up the pinch rollers. Pull the array out.

11. If you do not see the array after turning the hex driver for 10 seconds, stop.
12. Using tool (Affymetrix P/N 13-0256) with the hook down and toward the back, slide it vertically down against the front of the array opening, about 1.5 inches. (There is a small groove made for this tool in the middle of the front array guide)

13. Pull the top finger grip of the tool toward the front of the unit, and then pull it up while still putting pressure towards the front. The array should come up with the tool. When you see it, grab the array and pull it out of the unit.
14. If you cannot get the array out after doing this procedure, call for Affymetrix technical support.
15. Put the hole plug back into the hole in the base piece of insulation.
16. Plug the AutoLoaderDx back in and turn it on.
17. Load the carousel after the AutoLoaderDx boots up.
18. If arrays continue to become lodged in the AutoLoaderDx, you should call technical support.

The AutoLoaderDx Specifications

Table B.6 The Specifications of the Scanner 3000Dx with AutoLoaderDx

Item	Parameter	Value
Weight	Shipping	approx 115 pounds (52.2 Kg)
	Free-standing	approx 100 pounds (45.4 Kg)
Dimensions	Width	~13.25 in.
	Depth	~21.25 in.
	Height	~32 in.
Power	Voltage	100 - 240 V ~
	Current	4 - 2 A
	Line Frequency.	50 - 60 Hz
Working Environment	Temperature	59°F-85°F (15°C-30°C)
	Humidity	10-90% Non-condensing
	Clearance	2 in. (5 cm) on side, back
		12.5 in. on top
	Pollution Degree	2
	Installation Category	II
	Altitude	<2000m
Electrical Supply	Provide voltage, frequency or power rating per unit label	
Main Supply Voltage Fluctuations	Are not to exceed ±10% of the nominal supply voltage	

Regulatory Compliance

CE Mark Declaration of Conformity

We,
Affymetrix, Inc.
890 Embarcadero Drive
West Sacramento, CA 95605

declare under sole responsibility that the Affymetrix® GeneChip® 3000Dx v.2 Instrumentation, including the Scanner GCS 3000Dx, the AutoloaderDx, the Fluidics Station FS450Dx, and associated Workstation with Molecular Diagnostic Systems software, is Manufactured in the United States of America, with U.S. and Non-U.S. components, and conforms with the relevant provisions of the following standard(s) of safety and compliance, and/or other normative documents:

EU In-Vitro Diagnostic Medical Devices Directive 98/79/EC, Annex III CE Declaration:

ISO 13485:2003	Medical devices -- Quality management systems -- Requirements for regulatory purposes

EU EMC Directive 89/336/EEC:

EN61326-1:1997+A2:2001	Equipment for Measurement Control and Laboratory Use
EN 55011:1998+A2:2002	Limits and methods of measurements of radio disturbance characteristics of industrial, scientific and medical (ISM) radio frequency equipment
EN 61000-3-2:2000	Limits for harmonic current emissions (equipment input < 16A per phase)
EN 61000-3-3:1995 +A1:2001	Limitation of voltage fluctuations and flicker in low voltage supply systems for equipment with rated current < 16A
EN 61000-4-2:1995	Electrostatic discharge immunity

EN 61000-4-3:1995	Radiated, radio frequency, electromagnetic field immunity
EN 61000-4-4:1995	Electrical fast transient/burst immunity
EN 61000-4-5:1995	Surge immunity
EN 61000-4-6:1996	Immunity to conducted disturbances, induced by radio frequency fields
EN 61000-4-11:1994	Voltage dips, short interruptions and voltage variations immunity

EU Low Voltage Directive 73/23/EEC:

EN 61010-2-101:2002	Safety requirements for electrical equipment for measurement, control and laboratory use, Particular requirements for in vitro diagnostic medical equipment
EN 60825-1:1994 +A2:2001	Safety of laser products -- Part 1: Equipment classification, requirements and user's guide

Regulatory

This device complies with Part 15 of FCC Rules (Table B.7). Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesired operation.

This device complies with FDA performance standards for laser products except for deviations pursuant to Laser Notice No. 50, dated July 26, 2001.

This Class A digital apparatus meets all requirements of the Canadian Interference-Causing Equipment Regulation.

Cet appareil numérique de la classe A respecte toutes les exigences du Règlement sur le matériel broullier du Canada.

Table B.7 Regulatory Certifications

Regulatory Agency	Certification
CE	
Class I Laser Device	Complies with EN 60825-1:1994 + A2:2001. Complies with FDA performance standards for laser products except for deviations pursuant to Laser Notice No. 50, dated July 26, 2001
Hand held barcode reader is a Class II laser device	Complies with EN 60825-1:1994 + A2:2001. Complies with FDA performance standards for laser products except for deviations pursuant to Laser Notice No. 50, dated July 26, 2001
	Compliant with directive 2002/96/EC (WEEE)

China RoHS Restriction of Hazardous Substances Compliance

Manufacturers of Electronic Information products (EIPs) that are sold to the People's Republic of China, are required to provide information about lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyls and polybrominated diphenyl ethers contained within.

In accordance with the Chinese RoHS (Restriction of Hazardous Substances), Table B.8 and Table B.9 contain information identifying the specific hazardous material(s) and the components/parts in which they are found.

Table B.8 Table Containing Names and Contents of Toxic or Hazardous Materials[a]

Instrument: Affymetrix GeneChip GCS3000 AutoLoaderDx

Component/ Part Categories	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent Chromium (Cr 6)	Polybrominated Biphenyls (PBBs)	Polybrominated Diphenyl Ethers (PBDEs)
Printed Circuit Boards	X	O	X	O	O	O
Rubber & Plastic Parts	O	O	O	O	O	O
Electrical Components	X	O	O	O	O	O
Internal Metal Parts	O	O	O	O	O	O
External Metal Parts	O	O	O	O	O	O
Labels	O	O	O	O	O	O
Packaging/ Shipping Materials	O	O	O	O	O	O
Internal Lasers, Optics & Sensors	O	O	O	O	O	O
Adhesives	O	O	O	O	O	O

Table B.8 Table Containing Names and Contents of Toxic or Hazardous Materials[a]

Instrument: Affymetrix GeneChip GCS3000 AutoLoaderDx (Continued)

Component/ Part Categories	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent Chromium (Cr 6)	Polybrominated Biphenyls (PBBs)	Polybrominated Diphenyl Ethers (PBDEs)
Internal Power Supplies	O	O	O	O	O	O
Motors and Pumps	O	O	O	O	O	O

[a]X = Indicates that the toxic or hazardous substance contained is above the limit of 1000 ppm for lead and above 100 ppm for cadmium

O = Indicates that the toxic or hazardous substance contained is below the limit of 1000 ppm for lead, mercury, hexavalent chromium, polybrominated biphenyls and polybrominated diphenyl ethers; and below 100 ppm for cadmium.

Table B.9 Table Containing Names and Contents of Toxic or Hazardous Materials[a]

Instrument: Affymetrix GeneChip GCS3000 ScannerDx

Component /Part Categories	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent Chromium (Cr 6)	Polybrominated Biphenyls (PBBs)	Polybrominated Diphenyl Ethers (PBDEs)
Printed Circuit Boards	X	O	X	O	O	O
Rubber & Plastic Parts	O	O	O	O	O	O
Electrical Componen ts	O	O	X	O	O	O
Internal Metal Parts	X	O	O	O	O	O
External Metal Parts	O	O	O	O	O	O
Labels	O	O	O	O	O	O

Table B.9 Table Containing Names and Contents of Toxic or Hazardous Materials[a]

Instrument: Affymetrix GeneChip GCS3000 ScannerDx (Continued)

Component /Part Categories	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent Chromium (Cr 6)	Polybrominated Biphenyls (PBBs)	Polybrominated Diphenyl Ethers (PBDEs)
Packaging/ Shipping Materials	O	O	O	O	O	O
Internal Lasers, Optics & Sensors	X	O	X	O	O	O
Adhesives	O	O	O	O	O	O
Internal Power Supplies	X	O	X	O	O	O
Motors and Pumps	O	O	O	O	O	O

[a]X = Indicates that the toxic or hazardous substance contained is above the limit of 1000 ppm for lead and above 100 ppm for cadmium

O = Indicates that the toxic or hazardous substance contained is below the limit of 1000 ppm for lead, mercury, hexavalent chromium, polybrominated biphenyls and polybrominated diphenyl ethers; and below 100 ppm for cadmium.

SJ/T11364-2006 电子信息产品污染控制标识要求

目前许多电子信息产品由于功能、性能或生产技术的需要，仍含有大量如铅 （Pb）、汞 （Hg）、镉 （Cd）、六价铬 [Cr （VI）]、多溴联苯 （PBB）和多溴二苯醚 （PBDE）等有毒有害物质或元素。这些含有毒有害物质或元素的电子信息产品在废弃之后，如处置不当，不仅会对环境造成污染，也会造成资源的浪费。因此，为了达到节约资源、保护环境的目的，以有毒有害物质或元素的减量化、替代为主要任务的电子信息产品污染控制工作已经提到政府主管部门的议事日程。为此，信息产业部等七部委以“从源头抓起，立法先行”的思路和原则，制定了 《电子信息产品污染控制管理办法》（信息产业部 39 号部长令，简称 《管理办法》），以立法的形式，推动电子信息产品污染控制工作，旨在从电子信息产品的研发、设计、生产、销售、进口等环节限制或禁止使用上述六种有毒有害物质或元素。

为了进一步落实 《管理办法》并达到限制有毒有害物质或元素在电子信息产品中使用的目标，必须有配套使用的统一的标识方法标准。因此，为了配合中华人民共和国 《管理办法》的实施，同时也为中华人民共和国信息产业界对六种有毒有害物质或元素铅 （Pb）、汞 （Hg）、镉 （Cd）、六价铬 [Cr （VI）]、多溴联苯 （PBB）和多溴二苯醚 （PBDE）的测试提供一个统一的标识方法，特制定本标准（表 Table B.10 和 Table B.11）.

Table B.10 有毒有害物质或元素名称及含量[a]

仪器：Affymetrix GeneChip GCS3000 AutoLoaderDx

部件名称	铅 （Pb）	汞 （Hg）	镉 （Cd）	六价铬 [Cr （VI）]	多溴联苯 （PBB）	多溴二苯醚 （PBDE）
印制电路板	X	O	X	O	O	O
橡胶和塑料元件	O	O	O	O	O	O
电子元件	X	O	O	O	O	O
内部金属零件	O	O	O	O	O	O
外部金属零件	O	O	O	O	O	O
标签	O	O	O	O	O	O
组装 / 装货资料	O	O	O	O	O	O

Table B.10 有毒有害物质或元素名称及含量[a]

仪器：Affymetrix GeneChip GCS3000 AutoLoaderDx (Continued)

部件名称	铅（Pb）	汞（Hg）	镉（Cd）	六价铬[Cr（Ⅵ）]	多溴联苯（PBB）	多溴二苯醚（PBDE）
内部激光，光学器件和传感器	O	O	O	O	O	O
胶粘剂	O	O	O	O	O	O
内部电源	O	O	O	O	O	O
马达和唧筒	O	O	O	O	O	O

[a]×：表示该有毒有害物质至少在该部件的某一均质材料中的含量超出 1000 ppm 铅（Pb）100 ppm 镉（Cd）的标准规定的限量要求。

○：表示该有毒有害物质在该部件所有均质材料中的含量均在 1000 ppm 铅（Pb）汞（Hg），六价铬[Cr（Ⅵ）]，多溴联苯（PBB），多溴二苯醚（PBDE），100 ppm 镉（Cd）的标准规定的限量要求以下。

电子信息产品污染控制标识要求（Marking for Control of Pollution Caused by Electronic Information Products）SJ/T11364-2006

Table B.11 有毒有害物质或元素名称及含量[a]

仪器：Affymetrix GeneChip GCS3000 ScannerDx

部件名称	铅（Pb）	汞（Hg）	镉（Cd）	六价铬[Cr（Ⅵ）]	多溴联苯（PBB）	多溴二苯醚（PBDE）
印制电路板	X	O	X	O	O	O
橡胶和塑料元件	O	O	O	O	O	O
电子元件	O	O	X	O	O	O
内部金属零件	X	O	O	O	O	O
外部金属零件	O	O	O	O	O	O
标签	O	O	O	O	O	O
组装/装货资料	O	O	O	O	O	O

Table B.11 有毒有害物质或元素名称及含量[a]

仪器：Affymetrix GeneChip GCS3000 ScannerDx (Continued)

部件名称	铅（Pb）	汞（Hg）	镉（Cd）	六价铬[Cr（VI）]	多溴联苯（PBB）	多溴二苯醚（PBDE）
内部激光，光学器件和传感器	X	O	X	O	O	O
胶粘剂	O	O	O	O	O	O
内部电源	X	O	X	O	O	O
马达和唧筒	O	O	O	O	O	O

[a]×：表示该有毒有害物质至少在该部件的某一均质材料中的含量超出 1000 ppm 铅（Pb）100 ppm 镉（Cd）的标准规定的限量要求。

○：表示该有毒有害物质在该部件所有均质材料中的含量均在 1000 ppm 铅（Pb）汞（Hg），六价铬[Cr（VI）]，多溴联苯（PBB），多溴二苯醚（PBDE），100 ppm 镉（Cd）的标准规定的限量要求以下。

电子信息产品污染控制标识要求（Marking for Control of Pollution Caused by Electronic Information Products）SJ/T11364-2006

INDEX

Symbols

.cel files 25

A

Active worklist 32
Add user 109
Adding arrays during a scan 88
Administrative features 95
Administrator functions 44
Alerts 42
  resolving 130
AMDS 7, 8, 28
  quick reference guide 45
Array 75
  cartridge 52
  handling 52
  removing from AutoLoaderDx 220
  scanning 85
  scanning one array 87
Array cartridge 12
Arrays
  adding 88
  loading cartridges 208
  scanning 207
  stopping a scan 88
ASDK 8
Assay 11
  batch analysis 92
  deactivating 106
  installation 105
  scanning 85
  setting up 143
Assay batch 70
Assay home 64
Assay landing 64
Assay management 19
Assay management panel
  selecting assays 107
Assay parameters 11
Assay software module 8
Assay workflow 20, 21
Associating reagent lot numbers 70
AutoLoaderDx 195
  carousel 210
  China RoHS 228
  cleaning and maintenance 213
  configuring 213
  declaration of conformity 225
  dimensions 224
  disable 214
  disabled 25
  electrical safety 199
  electrical supply 224
  error messages 218
  issues 215
  laser safety 197
  manual mode 214
  regulatory 227
  safe operation 196
  setting up 199
  specifications 224
  troubleshooting 214, 217
  turn laser on at startup 214
  weight 224
  working environment 224
Automode 25

B

Barcode reader 10, 51
associate an array and fluidics station 142
Batch analysis assay 92
Bleach cycle 161
Bleach interval alert limit 115
Bleach interval warning 115
Bleach protocol 114
Bubbles 155

C

Cancelling
test requests 68
Carousel
loading 208
Cartridge septa 149
Cell intensities 25
China RoHS
AutoLoaderDx 228
fluidics station 190, 192
Configuration panel 115
Confirm step dialog box 68
Creating
test request 61

D

Deactivate assay 106
Declaration of conformity
AutoLoaderDx 225
Device status 40
Diagnostic assay 20
Diagnostic results 26
Documentation
conventions used 13
fluidics station assay 141
resources 15

E

Edit user 111
Error
error while draining 180
improper script 180
invalid command 180
missing fluid 176, 181
sensor timeout 177
Error messages
AutoLoaderDx 218
Errors
operational and data input 129
resolving device related 128
test requests 129

F

Fluidics station
assay documentation 141
bleach protocol 160
care and maintenance 160
China RoHS 192
components 138
dimensions 187
error messages 180
home procedure 115
homing 115
hybridization and wash protocol 143
installation category 187
modules 138
operating altitude 187
operating humidity 187
operating temperature 187
other problems and solutions 182
peristaltic tubing replacement 169
pollution degree 187
power input 187
power requirements 187
precautions 136
priming 83
problems and solutions 176
regulatory 189

rinse cycle 166
running a protocol 146
setting up 82
shutting down 156
starting 145
troubleshooting 173
using 83, 141
weight 187
Fluidics Station 450Dx 135
Fluidics station protocols 142
Fluorescence 26
Functions
administrator 44

G

GeneChip® 3000Dx AutoLoader-Dx 195
GeneChip® probe arrays 12
Getting started 27

H

Hard Disk Space 213
HDD space alert limit. 117
HDD space warning limit 117
Home procedure 115
Homing valves 115
Hybridization 23
Hybridizing 76

I

Image data 26
Indicator lights
AutoLoaderDx 205
Install assay 105
Instrument related errors
resolving 128
Instrument troubleshooting 132
Intended use 7

L

Laser safety 197
Leaks
preventing 207
LIS 105
Logging off 58
Logs
service 120
viewing 102

M

Management
AMDS 19
assay 19
system 20
user 19
viewing logs 19
Manual mode 25
Microarray 12
Missing fluid error 176
Molecular Diagnostic System
administrative features 95

N

Non-active worklist 29, 38
Normal operational scanning mode 86

O

Oligonucleotide sequence 25
Operational and data input errors
resolving 129

P

Peristaltic tubing change 115
Peristaltic tubing replacement 169
Priming the fluidics station 83
Printer management 117
Probe array handling 52

Problems and Solutions
fluidics station 173
Processing test requests 75
Protocol
bleach 160
hybridization 143
running on a fluidics station 146
staining 144
Protocols
fluidics station 142

Q

Quick reference cards 15

R

RAID storage console 116
Registration 22, 72
Resolving
alerts 130
test request errors 129
Resources 15
Restart scanner 116
Results 89
reviewing 37
Review results 89
Reviewing diagnostic results 37
Rinse cycle 166

S

Sample
staining protocol 144
Scanner
AutoLoaderDx 195
Scanning
arrays 207
normal operational mode 86
Scanning an array 25
Select 107
Service logs 120
Shutting down 59
Specifications
AutoLoaderDx 224
FS450Dx 187
Specimen ID
adding additional information 62
Staining 24
Staining protocol 144
Starting the fluidics station 145
Stopping a scan 88
System
logoff 58
shutting down 59
starting 54
System management 20
System self-test 116

T

Target 11
Target preparation 20, 22
Target registration 20
Technical support 16
Terminology 10
Test requests
additional information 62
archive 121
cancelling 68
creating 61
deleting 67
editing 65
processing 45, 75
registration 71
resolving errors 129
reviewing results 89
scanning 85
scanning one array 87
stopping a scan 88
washing and staining 81
Tough-Spots™ 207
Troubleshooting 127
AutoLoaderDx 214
fluidics station 173

instruments 132
Tubing change 115

U

User details 40
User interface 28
User management 19
add user 109
edit user 111

V

Vials 152
Viewing logs 19

W

Washblock 151
Washing and staining 24, 81
Workflows and worklists 29
Worklist
active 29, 32
hybridization 34
non-active 29, 38

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