Affymetrix®

User Guide

Affymetrix® GeneChip® System 3000Dx v.2

IVD

For in vitro diagnostic use.

P/N 08-0261 Rev. D

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Contents

Welcome to AMDS

Introduction

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

The AMDS User's Guide provides details concerning both the workflow and administrative functions of AMDS as part of the Affymetrix GeneChip® System 3000Dx v.2 (GCS 3000Dx v.2). For a system description, see *Affymetrix GeneChip® System 3000Dx v.2 System Overview* on page 13.

This manual explains how to use the AMDS to:

- Create and process test requests and generate test results
- Perform administrative tasks such as:
  - Viewing logs
  - Managing assays
  - Managing users
  - Maintaining the system
- Troubleshoot the system

The appendices also provide information for using the GeneChip® Fluidics Station 450Dx as well as the GeneChip® Scanner 3000Dx with AutoLoaderDx.

Intended Use

Indication(s) for Use

The Affymetrix GeneChip® Microarray Instrumentation System consisting of GeneChip® 3000Dx scanner with autoloader, FS450Dx fluidics station and GCOSDx/AMDS software is intended to measure fluorescence signals of labeled DNA and RNA target hybridized to GeneChip® arrays.

Special Condition for Use Statement

For use only with separately cleared GeneChip microarray assays.

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

Other Documentation

The Affymetrix® Molecular Diagnostic Software—AMDS Quick Reference Card is available (Part Number 08-0271).

The AMDS software also has online help.

Tooltip help is available for many interface elements—just hover over an interface element to view a description of the item or to view truncated data.

About Online Help

While the online help system is designed to provide content sensitive help, you can access the complete content of the user guide as well.

When you click **Help**, the cursor displays as a question mark as seen in Figure 1.1 on page 9. Clicking in various regions of the screen with the cursor will cause the associated help topic to display in the lower half of the center panel.

Figure 1.1 Online Help Button and Cursor

Accessing Context Sensitive Help

Context sensitive help provides both general information about the user interface as well as detailed information about specific tasks.

General User Interface Help

After you click **Help**, the cursor will turn into a question mark. Use this question mark to click on a pane in the left or right interface panels to get general information about:

- Workflow Pane
- Administrator Pane
- User Details Pane
- Device Status Pane
- Alerts and Alert Details Panes

A help topic related to your selection displays.

Task-Oriented Help

Getting help for a specific task is slightly different. For example:

1. On the **Workflow** pane or **Administrator** pane, click on the button related to activity you need help with.
   - If you clicked on a Workflow button, the related worklist displays in the center panel.
   - If you clicked on an Administrator pane button, the related administration screen displays.
2. Click **Help**.
3. Click on the center panel.

A help topic related to your selection displays.

Accessing the Complete Help System

To view the complete help system:

1. Click **Help** and then click anywhere on the AMDS interface.
   Context Sensitive Help displays.
2. Click **Show Navigation** (Figure 1.2 on page 10) on the Help toolbar.
   The entire help system displays, including navigation buttons, a navigation tree, and a help topic.
3. Click on the navigation buttons to locate your desired help topic. You can:
   - Click through the Contents list.
   - Select a topic from the Index.
   - Search for a topic.
   - Select a topic from your Favorites list.

Figure 1.2 Show Navigation Button on Help Screen Toolbar

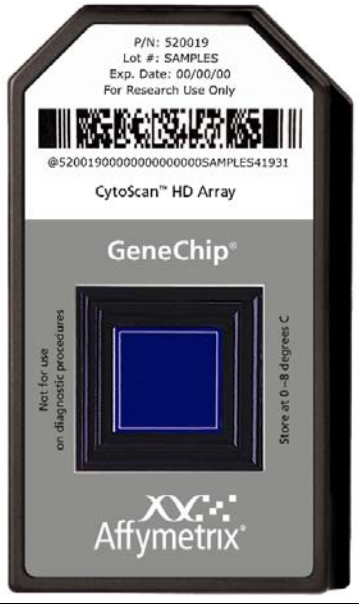
Terminology

These are key terms related to the Affymetrix GeneChip® System 3000Dx v.2:

- **Test Request**—a unique record of an assay performed on a particular specimen. Repeated runs of the same specimen would be represented by multiple test requests. Each test request is associated with a specific array cartridge.
- **Assay Software Module or ASM**—the software package that enables processing of a particular assay on a GCS3000Dx v2 system. Each ASM is supplied by Affymetrix or authorized partners in the form of a CD.
- **Assay**—the procedure that processes the specimen to produce the result. This would include the lab work and processing through the GCS3000Dx v2 workflow. In this manual, the term "assay" typically refers to the Assay Software Module.
- **Array**—the microarray, a glass substrate with oligonucleotide probes. A plastic cartridge surrounds and protects the array and forms the array cartridge. (Figure 1.3 on page 10) We often use the term "array" to refer to the array cartridge.

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 scanner or GCS 3000Dx.

Figure 1.3 Affymetrix GeneChip® Array Cartridges



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: Notes present 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.

Technical Support

Please consult your user manual, online help, and especially their troubleshooting sections before contacting Affymetrix technical support. If you are unable to resolve issues related to your GCS3000Dx v.2 system, please contact Affymetrix technical support.

If you are experiencing fluidics station or scanner 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, after service or calibration, the instrument does not perform to the specifications stated in *The FS450Dx Instrument Specifications* on page 96 or *GCS3000Dx Specifications* on page 119.

IMPORTANT: Make sure you have the model and serial number available when you make this call.

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Affymetrix GeneChip® System 3000Dx v.2 System Overview

The Affymetrix GeneChip® System 3000Dx v.2 consists of the hardware and software components that are required to process microarray based on assay parameters and to manage assay workflows.

This section describes the system hardware components and explores the AMDS User Interface.

Hardware Components

The Affymetrix GeneChip® System 3000Dx v.2 Instrument System includes standard hardware components that are delivered with all systems, required components that may be purchased directly from Affymetrix or purchased separately, and optional hardware components.

Standard Hardware Components

The Affymetrix GeneChip® System 3000Dx v.2 comes with these standard hardware components:

- A system workstation (Figure 2.1 on page 13)
- GeneChip® Fluidics Station 450Dx (Figure 2.2 on page 14)
- GeneChip® Scanner 3000Dx with AutoLoaderDx (Figure 2.3 on page 15)
- A barcode reader (Figure 2.4 on page 15)
- A hardware firewall (Figure 2.5 on page 16)

System Workstation, Monitor, and Soundbar

The system workstation (Figure 2.1 on page 13) hosts the AMDS software and provides the hardware interface to other system components. The workstation is a dedicated system for running AMDS and supporting the instruments of the GeneChip® System 3000Dx v.2. As a result, it is locked down to prevent other uses.

A monitor and sound bar (not pictured) are part of the workstation system.

Figure 2.1 System Workstation

GeneChip® Fluidics Station 450Dx

The Fluidics Station 450Dx (Figure 2.2 on page 14) is an instrument consisting of four modules installed in a single Station or housing. Each module holds a single GeneChip® microarray and performs functions required for hybridization, washing, and staining of that array. Up to 8 stations communicate with a single workstation. Each module controls the addition of target and staining fluids to the array cartridge and subsequent washing of the array. The module contains a pump, valve, thermo-electric system, and LCD that are controlled by scripts provided in the assay software module and automatically downloaded to each module, then stored in the module's electronic memory.

For more information, see *GeneChip® Fluidics Station FS450Dx* on page 66.

NOTE: Throughout this manual, the images of the fluidics station are pictures of the RUO version of the product. The Fluidics Station 450Dx differs from RUO version of the product in labeling, color of the levers, and the presence of a barcode next to the LCD screen for each module.

Figure 2.2 GeneChip® Fluidics Station FS450

GeneChip® Scanner 3000Dx with AutoLoaderDx

The GeneChip® Scanner 3000Dx with AutoLoaderDx (Figure 2.3 on page 15) is a wide-field, epifluorescent, confocal, scanning laser microscope which scans the chip after the staining process performed by the Fluidics Station. Array cartridges are loaded into the scanner by an automatic handler (the AutoLoaderDx) prior to scanning, and returned to the handler after scanning is complete.

NOTE: Throughout this manual, the images of the scanner are pictures of the RUO version of the product. The GeneChip® Scanner 3000Dx with AutoLoaderDx differs from RUO version of the product in labeling and skin color.

Figure 2.3 GCS 3000 with AutoLoader

Barcode Reader

Use the barcode reader (Figure 2.4 on page 15) to enter barcode-encoded information found on the following items: the GeneChip® array cartridge, the fluidics station, the specimen identification, the reagent lot number and other identification information.

Figure 2.4 Barcode Reader

Hardware Firewall

The hardware firewall (Figure 2.5 on page 16) protects against unauthorized access to the workstation.

Figure 2.5 Hardware Firewall

Additional Optional Hardware Components

You must purchase a data transfer server from Affymetrix if you are going to transfer data out of AMDS for downstream analysis. If you are going to use an uninterruptible power supply, you must buy it from Affymetrix. The printer you purchase must meet Affymetrix specifications.

In each case, contact Affymetrix for information about the component you wish to buy.

Optional Hybridization Oven

Depending on the type of assay, you may need a hybridization oven to prepare arrays for testing. Since you may already have a hybridization oven, its purchase is optional.

The GeneChip® Hybridization Oven 645 (Figure 2.6 on page 16) provides precise temperature and rotation control to ensure the successful hybridization of as many as 64 GeneChip®-brand cartridges at one time. It can be linked to the instrument system, enabling you to monitor and log temperature and rotation speed. You may also use the older model Affymetrix® GeneChip® Hybridization Oven 640. The Hybridization Oven 640 does not offer the same level of integration as the Affymetrix® GeneChip® Hybridization Oven 645 and may not support all assays (i.e. CytoScan HD is not supported by the 640).

Figure 2.6 Affymetrix® GeneChip® Hybridization Oven 645

Software Components

The Affymetrix GeneChip® System 3000Dx v.2 contains two types of software components:

- Affymetrix® Molecular Diagnostic Software (AMDS)
- Assay software modules

AMDS Software Component

AMDS provides the interface between the user and instrument systems. It provides control over the instruments, assay software modules, and the processes for data collection and management. Upon completion of scanning of the array, data is passed through AMDS to the assay software module that contains the algorithms and reporting functions to produce the clinical result specified by the assay software module.

AMDS provides tools to:

- Control assay workflows and view test results
- Perform administrative functions
- Troubleshoot the system

For information how to conduct workflows, see *Test Request Processing* on page 30. For information how to administer the system, see *AMDS Administrative Features* on page 44.

Assay Software Modules

Assay software modules provide all of the parameters necessary to process a specific Affymetrix GeneChip® array through its entire workflow. AMDS identifies a particular assay by its assay name. AMDS assists you in installing, and deactivating an assay. Assay management is explained in *Managing Assays* on page 47.

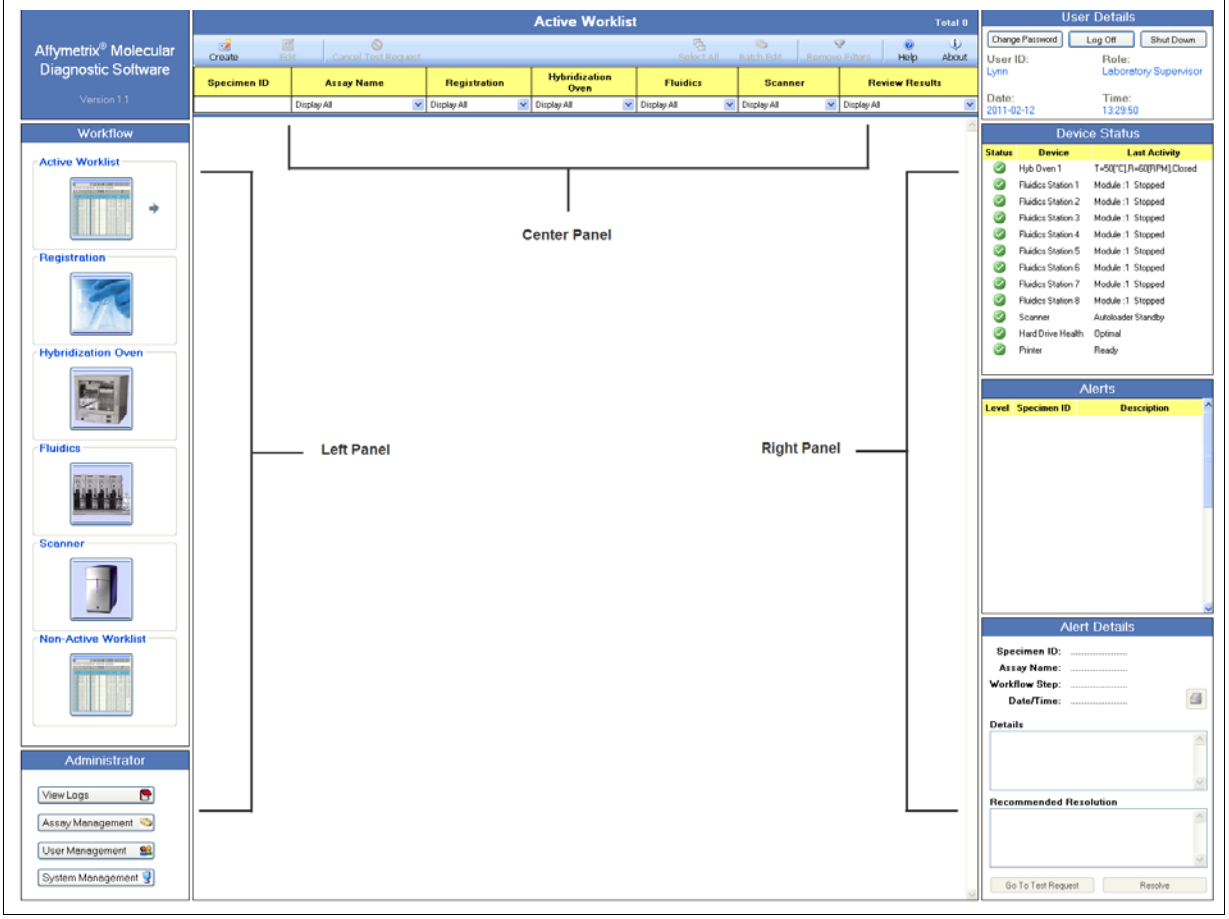
Assay software module manuals provides further instructions that are unique to specific assays.

AMDS User Interface

The AMDS user interface consists of three regions (Figure 2.7 on page 18):

- **Left Panel—**contains the **Workflow** and **Administration** panes, each of which contains several buttons.
- **Center Panel**—displays information related to the button you click on in the left pane. Online help also displays in the center panel.
- **Right Panel**—consists of the **User Details**, **Device Status, Alert**, and **Alert Details** panes.

Figure 2.7 AMDS User Interface



Workflow Pane

In the left panel, you see the **Workflow Pane,** which contains six buttons:

- Active Worklist
- Registration
- Hybridization Oven
- Fluidics
- Scanner
- Non-Active Worklist

When you click on a button in this pane, a worklist corresponding to the button you clicked displays in the center panel. A blue arrow also displays next to the button you have clicked. Click the next button in the pane to view the next step in a workflow.

Each button on the **Workflow** pane is defined below. Instructions for completing a workflow appear in *Test Request Processing* on page 30.

Active Worklist

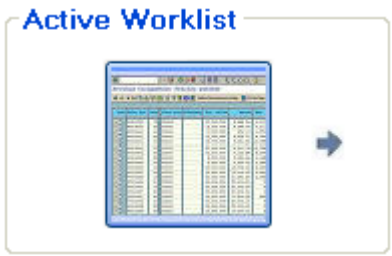
A test request is active until it has completed processing or has been canceled. While a test request is active, you can view its status by clicking **Active Worklist**. Data associated with that test request only appears on the Active Worklist and the test request's current stage in the workflow.

Click **Active Worklist** (Figure 2.8 on page 19) to:

- View the current status of all active test requests.
- Create new test requests.
- View and approve test results.

You cannot edit information that is displayed in the Active Worklist; rather, AMDS automatically maintains and updates the list. For more information, see *Active Worklist—Entering, Editing, or Canceling Test Requests* on page 30.

Figure 2.8 Active Worklist Button



Registration Worklist

After you create the test request, click **Registration Worklist** (Figure 2.9 on page 19) to associate a test request with a single array cartridge and to add the target preparation reagent kit lot numbers, if it supported by the assay software module.

For more information, see *Registration—Registering Test Requests* on page 34.

Figure 2.9 Registration Button

Hybridization Oven Worklist

Click **Hybridization Worklist** (Figure 2.10 on page 20) to enter data related to oven hybridization and to process the array in the hybridization oven.

Some assays do not use the hybridization oven; they perform hybridization on the fluidics station.Test requests that are associated with these assays skip this step and proceed to fluidics.

For more information, see *Hybridization Oven—Hybridizing Arrays in the Hybridization Oven* on page 35.

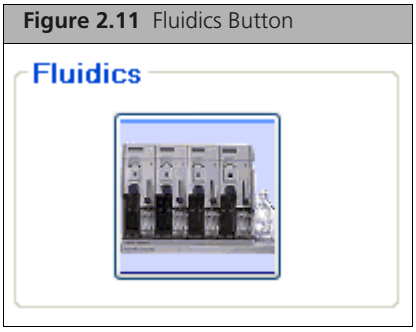
Figure 2.10 Hybridization Oven Button

Fluidics Worklist

Click **Fluidics** (Figure 2.11 on page 20) to associate a test request with a fluidics station and module and to run the associated fluidics script. The selected station and module will wash and stain the array.

For more information, see *Fluidics—Washing and Staining Arrays in the Fluidics Station* on page 38. See also *GeneChip® Fluidics Station FS450Dx* on page 66.

Figure 2.11 Fluidics Button

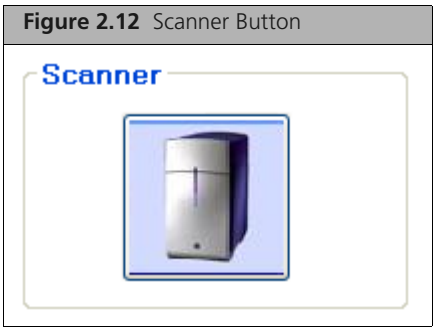


Scanner Worklist

After the array has been processed on the fluidics station, click **Scanner** (Figure 2.12 on page 20) to view the Scanner Worklist. AMDS automates control of the scanner and uses the assay information provided by the assay software module to manage the scanner settings for each type of array. The software enables you to scan the arrays on the scanner. AMDS then automatically grids the image, computes the intensities, and runs the analysis algorithm associated with the assay to generate a result.

For more information, see *Scanner—Scanning Arrays* on page 40. Also see *GeneChip® Scanner 3000Dx with AutoLoaderDx* on page 101.

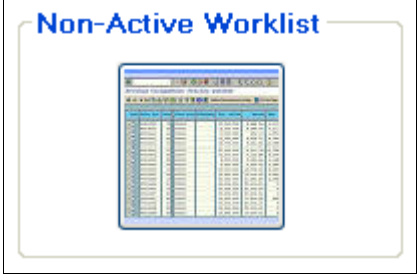
Figure 2.12 Scanner Button



Non-Active Worklist

Click **Non-Active Worklist** (Figure 2.13 on page 21) to display non-active test requests. The system moves test requests to the Non-Active Worklist when they have completed processing in AMDS, e.g. when the results have been viewed and approved, or when you cancel them.

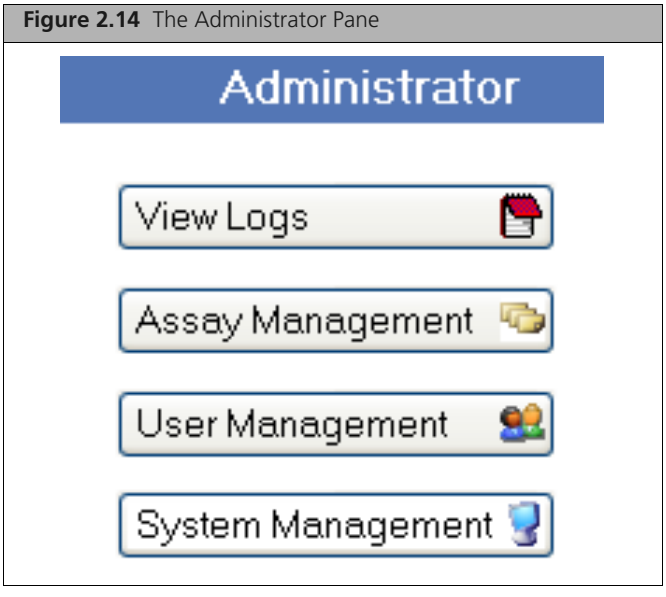
Figure 2.13 Non-Active Worklist Button



Administrator Pane

The **Administrator Pane** (Figure 2.14 on page 21) is located below the **Workflow Pane**. While the **Administrator Pane** is visible to everyone, only Laboratory Supervisors and System Maintainers are able to interact with its features.

Figure 2.14 The Administrator Pane



The **Administrator Pane** contains these buttons:

- View Logs
- Assay Management
- User Management
- System Management.

Clicking on one of these buttons displays related data in the center panel.

For more information, see *AMDS Administrative Features* on page 44.

User and System Information Panes

The right panel of the user interface has four panes that give you up-to-date information related to user details and device status.

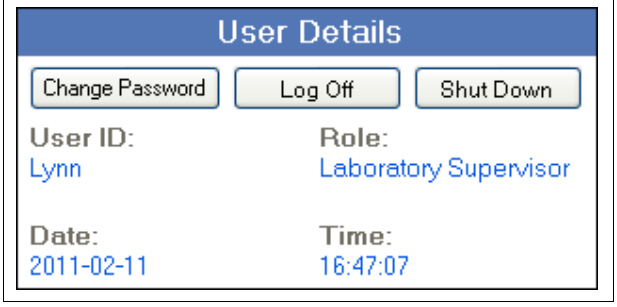
User Details Pane

You can view the User Details pane (Figure 2.15 on page 22) in the upper portion of the right panel. You can:

- Log off
- See who is logged in and their role
- See system time and date
- Change passwords
- Shut down the system.

For more information, see *Managing Users* on page 49.

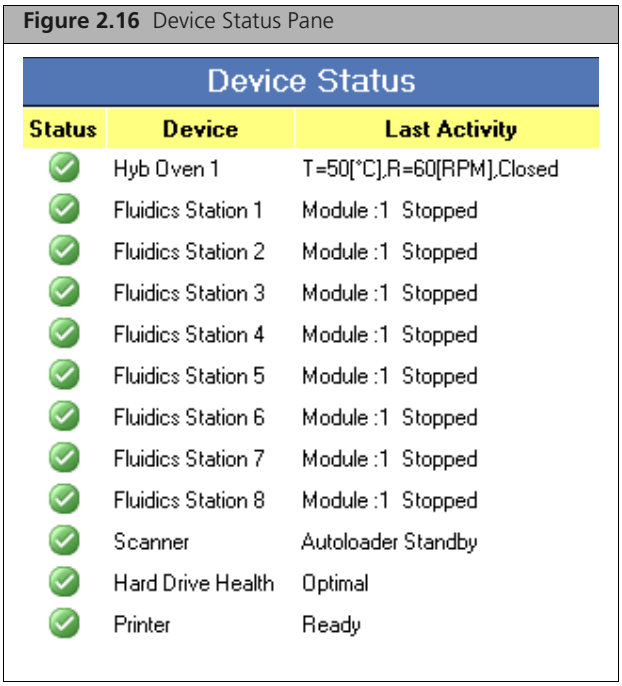
Figure 2.15 User Details Pane



Device Status Pane

Located just below the **User Details** pane is the **Device Status** pane (Figure 2.16 on page 22).

Figure 2.16 Device Status Pane



This pane is an instrument status dashboard, providing color-coded status for each system device.

- Green indicates the device is operating normally.
- Yellow indicates that AMDS detected an abnormal condition that requires attention.
- Red indicates a communications issue or a device failure.

AMDS provides status for the hybridization oven, the fluidics station, the scanner, the printer, and the workstation hard drive.

For more information, see *AMDS Troubleshooting* on page 61.

NOTE: Older models of the workstation will not give Hard Drive Health status in the Device Status pane.

Alert Pane and Alert Details Pane

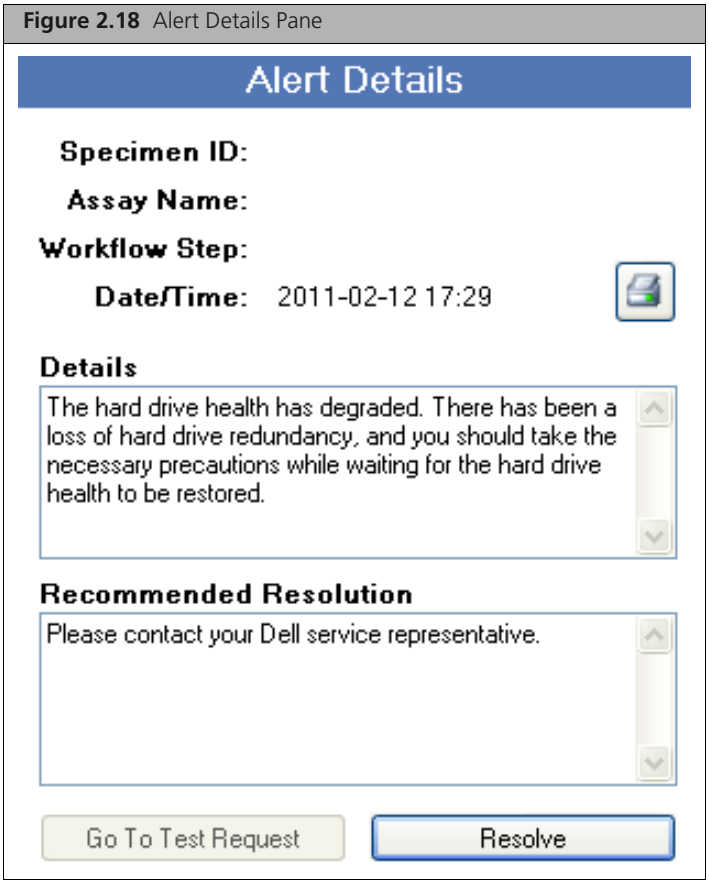
The **Alert pane** (Figure 2.17 on page 23) provides alerts if a component or process is not operating as expected. By clicking on a specific alert, information about the alert displays in the **Alert Details** pane (Figure 2.18 on page 24). Depending on the type of alert, you may see information related to:

- Specimen ID
- Assay Name
- Workflow Step
- Date/Time
- Alert details
- Recommended resolution

See *Device Status and Alert Icons* on page 62 for more information about different types and levels of alerts.

Figure 2.17 Alerts Pane

Figure 2.18 Alert Details Pane



Affymetrix GeneChip® System 3000Dx v.2 Operation Basics

Introduction

This section shows you how to:

- Start the system, including:
  - Starting the workstation
  - Logging on and off of the system
  - Starting the fluidics station and scanner
- Shut down the system
- Change your password
- Use the barcode reader
- Handle array cartridges

IMPORTANT: **Before attempting any assay runs, you must be familiar with the operation of the fluidics station (see the appendix, *GeneChip® Fluidics Station FS450Dx* on page 66) and the operation of the scanner (see the appendix, *GeneChip® Scanner 3000Dx with AutoLoaderDx* on page 101).**

Starting and Shutting Down the System

Before you process test requests, you need to start the workstation and follow instructions for starting the instrumentation.

Starting the Workstation

Turn on the computer workstation to launch AMDS.

- If the option "Turn on Laser" has been selected, the scanner laser will start to warm up when you launch AMDS.
- If you have administrator privileges, see *Configuring Scanner Settings* on page 60 for instructions on how to have the scanner laser warm up when AMDS launches.
- 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.
- AMDS will also perform some housekeeping tasks to ensure that all test requests are in known states and can be processed.

Once AMDS completes its self test, the AMDS User Logon screen displays (Figure 3.1 on page 26).

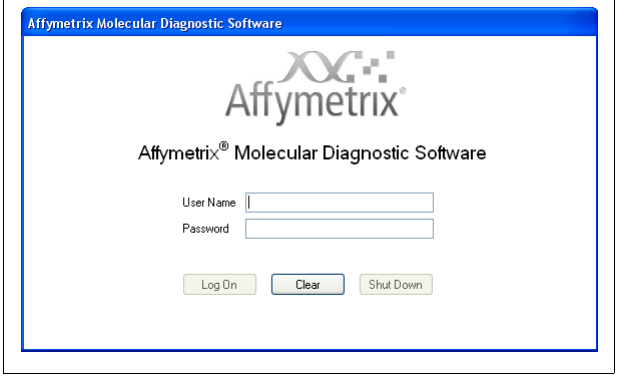
Logging onto AMDS

After you start the workstation and the User Logon screen displays (Figure 3.1 on page 26), enter your User Name and Password and click **Log On.**

- The Affymetrix service engineer who installed AMDS or your system administrator will have provided User IDs and Passwords.
- After authenticating your credentials, AMDS provides functionality based on your user role.

For more information about user roles, see *About User Roles* on page 50.

Figure 3.1 AMDS User Log On Screen



Starting the Fluidics Station and Scanner

Turn on the fluidics station and scanner when your test requests have reached the associated worklists.

For related information, see:

- *Operating the Fluidics Station* on page 70
- *Starting the Scanner* on page 113

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

NOTE: **The scanner laser requires about 10 minutes to warm up.**

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

Logging Off

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

1. In the User Details pane (Figure 3.2 on page 27), click **Log Off**.

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 to users with permission to shut down.

In the User Details pane (Figure 3.2 on page 27), click **Shut Down.**

IMPORTANT: If there are test requests in progress, the system asks for confirmation before shutting down. Clicking "Yes" to confirm the shut down will begin an orderly shut down of the system and cause all tests requests with a state of "In Progress" to go into an error state.

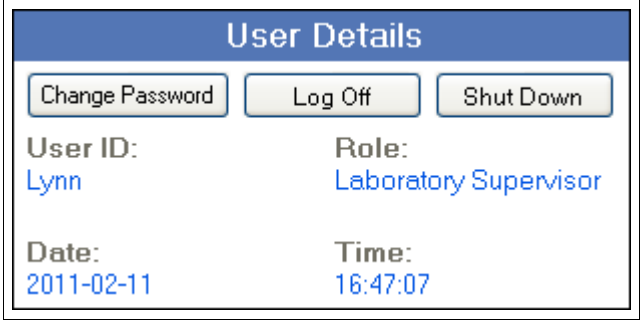
NOTE: When you shut down the workstation, the instrumentation does not shut down automatically. You will need to shut them down separately.

Changing Your Password

You can change your password at any time while you are logged onto the system.

1. In the User Details pane (Figure 3.2 on page 27), click **Change Password**.

Figure 3.2 The User Details Pane



2. After the **Change Password** dialog displays, enter your old password.
3. Enter and confirm your new password.

Click **OK** to apply the change.

Using the Barcode Reader

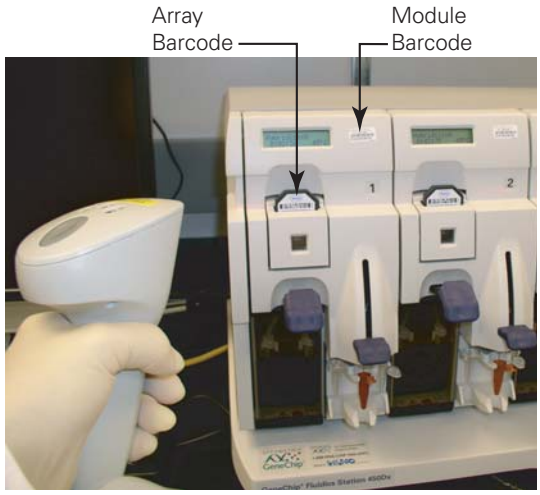
You can use the barcode reader to:

- 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 an array with a fluidics station and module.

As an example, in the AMDS Registration Worklist, for each test request, you can scan the barcode for the Specimen ID to select the associated test request. Then scan the Array ID barcode to associate a specific array with a test request.

In the Fluidics Worklist, scan the array barcode to select the associated test request and then immediately scan the fluidics station module barcode. AMDS will automatically place the fluidics station and module identifiers in the proper fields (Figure 3.3 on page 28).

Figure 3.3 Using the barcode reader to scan an array barcode and a module barcode



See *Using the Barcode Reader with the Fluidics Station* on page 69 for more information on using the barcode reader with the fluidics station.

Instructions for when to use the barcode reader are embedded in procedures throughout *Test Request Processing* on page 30.

NOTE: If the barcode on any item is not readable for any reason, you can manually enter the ID by positioning the cursor in that field and typing the information into the field. The recommended method is to always use the barcode reader when possible.

Editing Multiple Fields in AMDS

You may, at times, want to enter the same value into multiple data fields at once. For instance, if you are preparing a tray of 10 arrays for oven hybridization, instead of entering the tray number for each array separately, you can add the tray number to all ten arrays at once.

Contiguous Select and Enter

1. Click on the first row of the desired selection.
2. Hold down the **Shift** key.
3. Click on the last row of the desired selection.
4. Hold down the **Ctrl** key and:
   - A. Select from the drop-down in the last row. OR
   - B. Click in the field in the last row and scan the barcode. OR
   - C. Click in the field in the last row, release the **Ctrl** key, and enter the value.
5. Click out of the field or press the **Enter** key.

Non-Contiguous Select and Enter

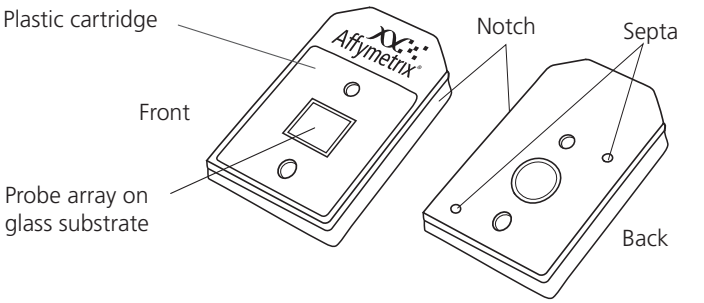
1. Click on the first row of the desired selection.
2. Hold down the **Ctrl** key
3. Select each desired row individually.

4. While still holding the **Ctrl key:**
   - **A.** Select from the drop-down in the last row. OR
   - **B.** Click in the field in the last row and scan the barcode. Or
   - **C.** Click in the field in the last row, release the **Ctrl** key, and enter the value.
5. Click out of the field or press the **Enter** key.

Handling the Array Cartridge

The array comes mounted in a plastic package to form an array cartridge (Figure 3.4 on page 29). 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 3.4 The Array Cartridge

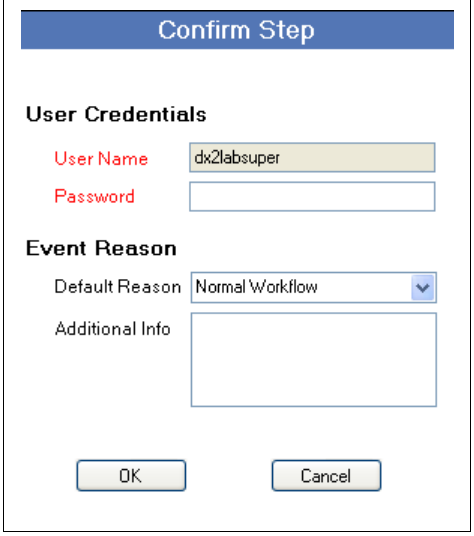


Although the inner glass surface is protected, any contamination or scratches on the outer surface of the glass can compromise the integrity of the scan. **Avoid touching the surface of the glass with your fingers.** Skin oils and other substances, such as lotions or ink, can fluoresce. If the surface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

E-Signatures

At times after completing procedures in AMDS, you will be prompted to confirm a change with your password and the reason for the change. These e-signatures help track user activity on the system.

Figure 3.5 E-Signature Confirmation Dialog



Test Request Processing

Introduction

A test request is a unique record of an assay performed on a particular specimen. Repeated runs of the same specimen would be represented by multiple test requests. Each test request is associated with a specific array cartridge.

To process test requests, follow these steps that correspond to the buttons in the workflow pane:

1. **Create test requests**—See *Active Worklist—Entering, Editing, or Canceling Test Requests* on page 30.
2. **Register test requests**—See *Registration—Registering Test Requests* on page 34
3. **Hybridize tests requests**—See *Hybridization Oven—Hybridizing Arrays in the Hybridization Oven* on page 35.
   - Some assays perform hybridization in an oven; other perform it on the fluidics station.
   - Consult your assay software module manual for more information on this step.
4. **Wash and stain test requests**—See *Fluidics—Washing and Staining Arrays in the Fluidics Station* on page 38.
5. **Scan arrays**—See *Scanner—Scanning Arrays* on page 40.
6. **Approve or reject results—**See *Post-Scan Processing* on page 42

   Consult your assay software module manual for information on this step.
7. **View non-active test requests**—See *Non-Active Worklist—Viewing Non-Active Test Requests* on page 43

Before you begin, familiarize yourself with:

- *Terminology* on page 10
- *Affymetrix GeneChip® System 3000Dx v.2 System Overview* on page 13
- *Affymetrix GeneChip® System 3000Dx v.2 Operation Basics* on page 25, including *Using the Barcode Reader* on page 27
- *GeneChip® Fluidics Station FS450Dx* on page 66
- *GeneChip® Scanner 3000Dx with AutoLoaderDx* on page 101

IMPORTANT: **Before attempting any assay runs, you must be familiar with the operation of the fluidics station (see the appendix, *GeneChip® Fluidics Station FS450Dx* on page 66) and the operation of the scanner (see the appendix, *GeneChip® Scanner 3000Dx with AutoLoaderDx* on page 101).**

NOTE: **Throughout test request processing, you will need to enter data related to the test request. Whenever possible, use the barcode reader rather than entering data by hand.**

Active Worklist—Entering, Editing, or Canceling Test Requests

Click on the **Active Worklist** button (Figure 4.1 on page 31) in the Workflow pane to create, edit, and cancel test requests.

The Active Worklist contains all active test requests, regardless of which step they are in the workflow. After all steps of the workflow are complete, you can approve or reject test request results from the Active Worklist. Once approved, rejected, or canceled, test requests appear on the Non-Active Worklist.

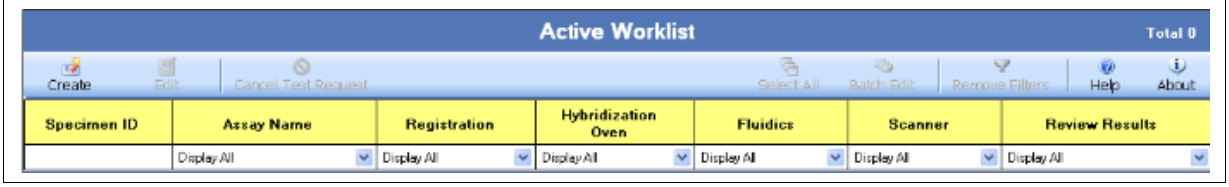
Figure 4.1 Active Worklist Button

Entering Test Requests

To create a test request:

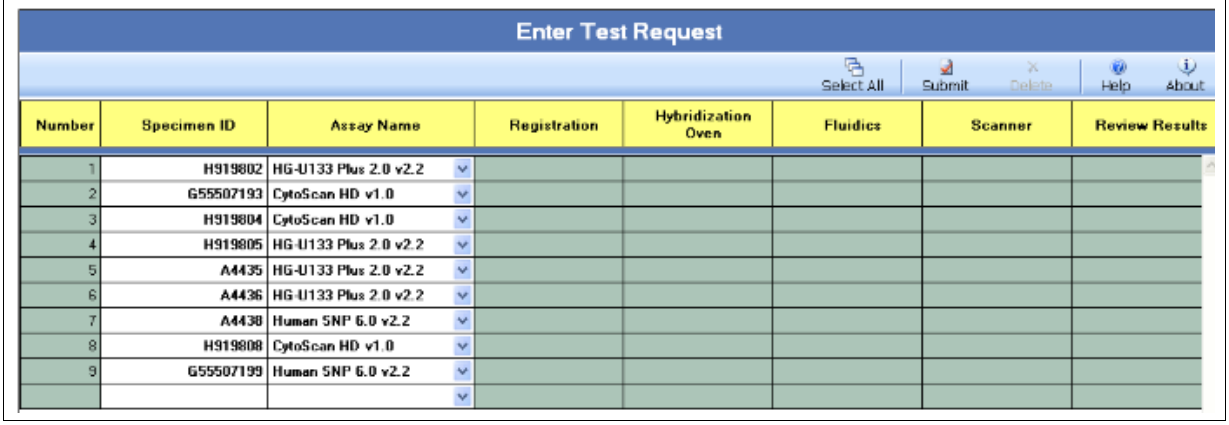
1. Click **Active Worklist**.
   The Active Worklist displays (Figure 4.2 on page 31) active test requests.

Figure 4.2 The Active Worklist



2. Click **Create**.
   - The Enter Test Request Screen displays (Figure 4.3 on page 31).
   - You can create more than one test request at a time.

Figure 4.3 The Enter Test Request screen



3. Enter the Specimen ID.
   - Use your barcode reader to enter the Specimen ID barcode.
   - If your specimen doesn't have a barcode, enter the name of the Specimen ID by hand in the Specimen ID field.
   - Specimen IDs do not need to be unique.
   - Specimen IDs can have up to 40 characters.
4. In the Assay name column, select the required Assay Name from the drop down list.

5. Click **Submit** or **Delete**.
   - You can submit one or more test requests at the same time once the Specimen ID and the assay name is selected.
   - Submitting your test request will create it and make it active.
   - If you delete your test request before submitting, no test request will be created.
   - In either case, the Enter Test Request screen closes.
   - You can identify your newly created test request in the Active Worklist based on the Specimen ID, Assay Name, and current status.

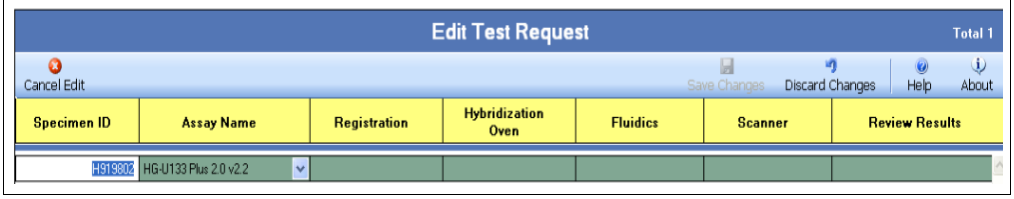
Editing Test Requests

You can edit the Specimen ID for a test request if you have not yet completed its registration. Once you register a test request, you cannot edit it.

To edit a test request:

1. From the Active Worklist, select a test request to be edited.
   The edit button displays on the Active Worklist toolbar.
2. Click **Edit**.
   The Edit Test Request pane displays (Figure 4.4 on page 32).

Figure 4.4 The Edit Test Request screen



3. Modify the **Specimen ID**.
   - This is the only field you can edit.
   - Click anywhere on the tool bar or Specimen ID row to indicate you have finished changing the ID.
   - You can now choose to save changes, discard changes, or cancel edit to continue.
4. To save your changes, click **Save Changes**.
   - When the Confirm Step dialog displays, enter your password and the reason for the change.
   - Click **OK**.
   - The modified Specimen ID appears on the Active Worklist.
5. To discard your changes, click **Discard Changes.**
   - The Confirm Step dialog box displays.
   - After you click **Yes**, you remain on the Edit Test Request Screen and can continue editing the Specimen ID.
6. To cancel all edits and to leave the Edit Test Request Screen, click **Cancel Edit.**

Canceling a Test Request

After you have submitted a test request, you cannot delete it, but you can cancel it and send it to the Non-Active Worklist. You can only cancel one test request at a time. You can cancel it during processing up until the point of generating results.

To cancel a test request:

1. From the Active Worklist, select the test request you would like to cancel.

2. Click **Cancel Test Request** on the Active Worklist toolbar.
   The **Confirm Step** dialog box displays.
3. Enter your password.
4. Select a reason for canceling from the list.
5. Enter any other necessary information.
6. Click **OK** to confirm cancelation.

AMDS moves the test request to the Non-Active Worklist.

Adding Additional Information to a Test Request

NOTE: See your assay software module manual for more details.

After you create a test request, and any time before the array associated with it begins scanning, you can add data to it.

The dialog box for adding this information will vary, depending on the assay software module. New fields cannot be added.

To add additional information to a test request:

1. From any worklist, click on the desired Specimen ID hyperlink.
   - The Additional Information dialog box displays.
   - This dialog will look different for different assay software modules.
   - Add information in the provided fields.
   - See your assay software module manual for details.

Viewing Assay Information

You can retrieve the information related to specific assays by opening the Assay Home screen.

1. From any worklist, click on the assay name hyperlink.
   - The Assay Home screen displays.
   - See your assay software module manual for more details.

Batch Editing Test Requests

IMPORTANT: Batch editing is only possible with test requests that use the same assay software module. The Batch Edit button will only work if none of the arrays associated with the selected test requests have started scanning.

You can use the Batch Edit command to associate information with multiple test request records.

To batch edit test requests:

1. From any worklist, select one or more test requests associated with a single assay software module and click **Batch Edit.**
   - The **Assay Batch Information** dialog box displays.
   - See your assay software module manual for more details.

Registration—Registering Test Requests

Click on the **Registration** button (Figure 4.5 on page 34) in the Workflow pane to view the Registration Worklist.

Figure 4.5 The Registration Button

Associating Test Requests, Arrays, and Reagent Kit IDs during Registration

NOTE: Not all assays require the use of a Target Preparation Reagent Lot ID. For some assays, you'll need to enter reagent data via the Reagent Information tab of the Assay Home Screen. See your assay software module manual for more details.

Registration consists of associating a test request with the array to be used for the test request. Depending on the assay, the target preparation reagent kit information may also be collected during this step.

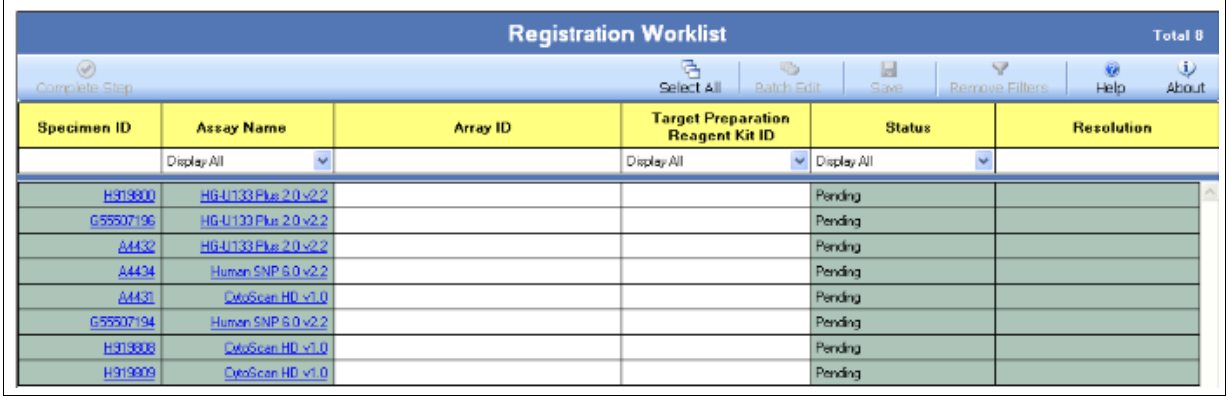
To register a test request:

1. Click **Registration**.

   The Registration Worklist displays (Figure 4.6 on page 34).

2. Scan the Specimen ID barcode.
   - AMDS will select the test request associated with this Specimen ID.
   - You can also select the Specimen ID from the list.
3. Scan the array barcode from the array cartridge.
   - AMDS will populate the Array ID field.
   - AMDS will warn you if you have already used this Array ID, if the array is expired, or if the array type is not compatible with the assay type.
   - You can enter this information by hand, too.

Figure 4.6 The Registration Worklist



4. Optional: Enter the Target Preparation Reagent Kit ID.
   - Target Preparation Reagent Kit IDs may be entered with the barcode reader or by hand.
   - See your assay software module manual for more information about how to enter the Reagent information for your specific assay.
5. Click **Save** to save your registration information and remain in the Registration Worklist.

   This step allows you to save your work and pause before proceeding with the workflow.
6. Click **Complete Step.**

This step will complete registration and move the test requests to the next step in the workflow, which will depend on the type of assay you are using. Consult your assay software module manual for more information.

Troubleshooting Registration

AMDS will check your data as you enter Array IDs and Reagent Kit IDs. You must correct the data if you get a message regarding one of the following errors:

- The Array ID already exists.
- You have entered an invalid Array ID.
- The array is expired.
- The Reagent Kit ID entry is disabled for this assay.
- The Reagent Kit ID entered is invalid for this assay.

Until you correct the error, you cannot complete registration.

Hybridization Oven—Hybridizing Arrays in the Hybridization Oven

IMPORTANT: **Make sure you understand how to operate your hybridization oven. 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.**

Click the **Hybridization Oven** button (Figure 4.7 on page 35) in the Workflow pane to view the Hybridization Oven Worklist.

Figure 4.7 Hybridization Oven Button

Oven hybridization consists of multiple steps:

1. Entering oven information.
2. Starting and monitoring the oven hybridization process.
3. Ending oven hybridization and removing the arrays from the oven.

Hybridizing in an Oven vs. Hybridization on a Fluidics Station

Depending on the assay, hybridization can be performed in a hybridization oven or on the fluidics station. If your assay does not perform oven hybridization, your test requests will appear on the Fluidics Worklist at this time. Consult your assay software module manual for more information.

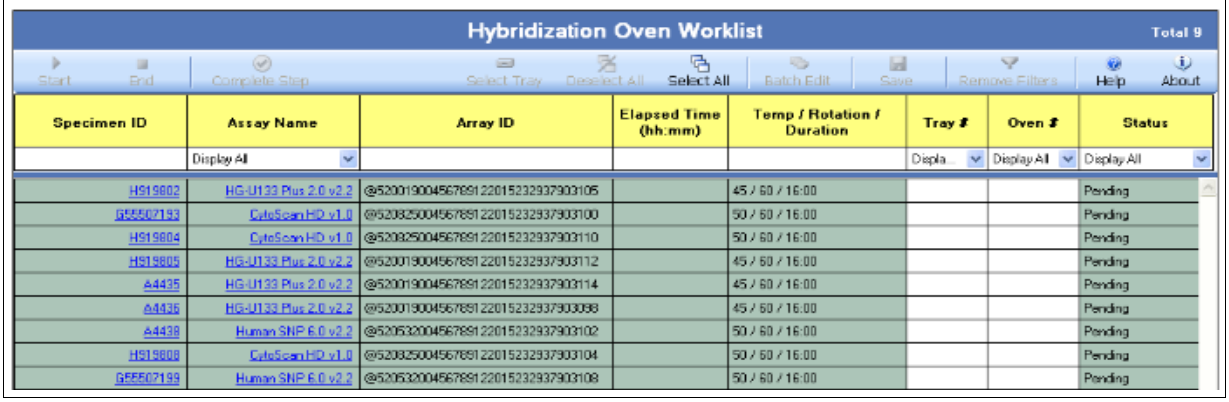
Entering Oven Data

NOTE: You cannot change any parameter in the Time/Rotation/Duration field displayed on the Hybridization Oven Worklist. These values inform you of the optimal hybridization parameters for the assay.

To enter oven information:

1. Click **Hybridization Oven** (Figure 4.7 on page 35).
   The Hybridization Oven Worklist displays. (Figure 4.8 on page 36).

Figure 4.8 The Hybridization Oven Worklist



2. Associate test requests with a particular oven tray.
   - Follow these steps only if you are using an oven tray.
   - You may want to perform this task for multiple test requests at a time. For more information, see *Editing Multiple Fields in AMDS* on page 28.

   A. To enter the tray ID with the barcode reader:

   1) Scan the barcodes of the arrays you will be placing in the tray.
   This will select the test requests.

   2) Scan the tray's barcode.

   B. To enter the tray number by hand:

   1) Select the test requests.

   2) Enter a tray ID.

3. Associate test requests with a particular oven:

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

1) Select all test requests for the arrays you will place into the oven.
If you have entered tray numbers for your test requests, you can select all the test requests for a particular tray by selecting one of the test requests and clicking **Select Tray**.

2) Click and hold the **Ctrl** key.
3) Place the cursor into a selected oven number field.
4) Release the **Ctrl** key.
5) Enter the oven number.

   For the GeneChip® Hybridization Oven 645, the value will be either "1" or "2," depending on your oven setup.
6) Click **Enter**.

   AMDS populates the oven number for all selected Specimen IDs.

You can also enter the oven number by hand for each test request.

Starting and Monitoring Oven Hybridization

IMPORTANT: The background color of the Reported Elapsed Hybridization Time cell will be yellow when the time is less than the minimum time required by the assay parameters, green when it falls within the acceptable range, and red when it exceeds the maximum allowable time.

You can place your arrays into an oven that is hybridizing other sets of arrays, as long as the oven temperature and rotation speed are correct for your arrays. Monitor your arrays using data from AMDS.

To start and monitor oven hybridization:

1. Turn on the oven and wait for it to reach the correct hybridization temperature.
2. Place the array cartridges into trays.
3. Place the trays into the hybridization oven.
4. Select the test request(s) in the Hybridization Oven Worklist and click **Start** on the toolbar**.**
5. Monitor the hybridization process.
   - You can monitor elapsed time for all oven hybridization processes on the Hybridization Oven Worklist.
   - If you are using a GeneChip® Hybridization Oven 645, you can monitor the temperature, rotation speed, and oven door status in the **Device Status** pane. Alerts related to your process display in the **Alerts** pane and **Alerts Details** pane.
   - For more information about device status and alerts, see *AMDS Troubleshooting* on page 61.

Ending Oven Hybridization

To end oven hybridization:

1. When the correct amount of time has elapsed, remove the arrays from the oven.
2. Select the test requests associated with the arrays and click **End**.
3. Click **Complete Step.**

This completes oven hybridization and moves the test requests to the Fluidics Worklist.

Troubleshooting Oven Hybridization

AMDS will check your data as you enter Tray and Oven information. You must correct the issue if you get a message regarding one of the following errors:

- Arrays are not compatible for inclusion on same tray.
- Arrays are not compatible for current temperature and rotation speed of oven.

Fluidics—Washing and Staining Arrays in the Fluidics Station

IMPORTANT: Make sure you know how to operate the fluidics station. See *GeneChip® Fluidics Station FS450Dx* on page 66.

Click on the **Fluidics** button (Figure 4.9 on page 38) in the Workflow pane to view the Fluidics Worklist.

Figure 4.9 The Fluidics Button

AMDS provides the tools to set up the fluidics station and then to complete washing and staining of the arrays.

You can monitor the fluidics station and the washing and staining process on the:

- LCD on the fluidics station
- Fluidics Worklist
- Device Status pane
- Alerts and Alert Details panes

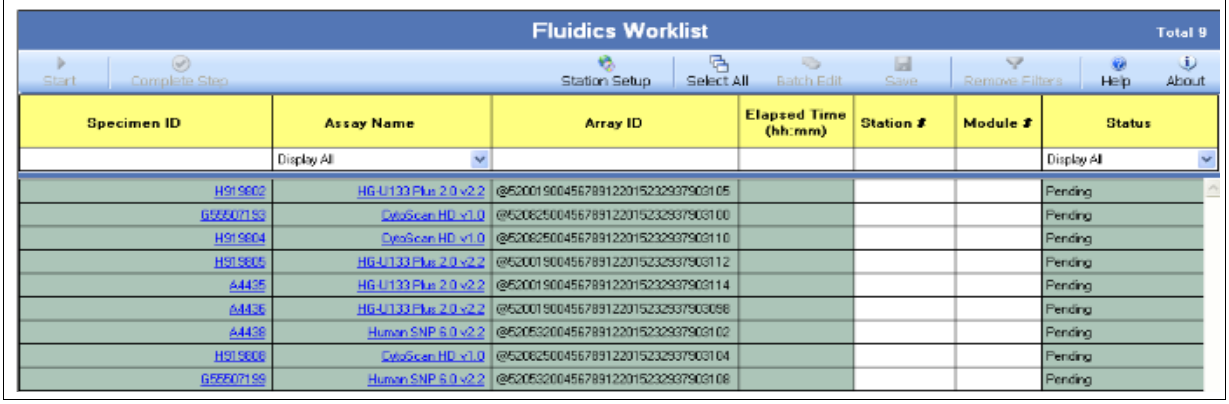
Consult *AMDS Troubleshooting* on page 61 for information regarding alerts and instrument error messages.

Setting Up the Fluidics Station

To set up the fluidics station:

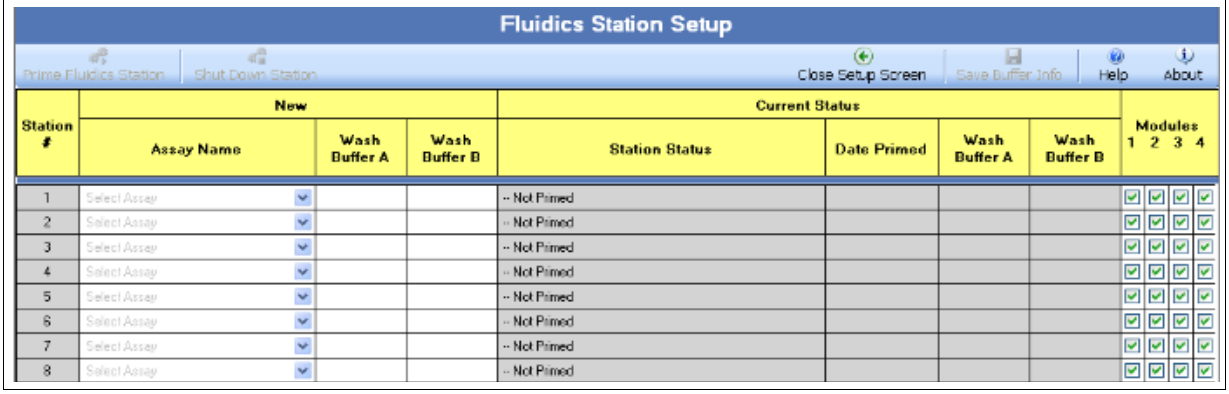
1. Click **Fluidics**.
   The Fluidics Worklist displays (Figure 4.10 on page 38).

Figure 4.10 The Fluidics Worklist



2. Click **Station Setup**.
   The Fluidics Station Setup screen displays (Figure 4.11 on page 39).

Figure 4.11 The Fluidics Station Setup screen



3. Select the desired assay from the Assay Name field for each of the fluidics stations that will be used at this time.
4. If required, enter Wash Buffer A and Wash buffer B lot numbers.
   Information entered in these fields will be saved into the logs for test requests.

NOTE: You need to use the module check boxes only if the fluidic station contains faulty modules. Unchecking a fluidics module will cause that module to be skipped and it won't be available for processing arrays.

5. Select the fluidics station(s) and click **Prime**.
   See *Priming the Fluidics Station* on page 75 for details.
6. Click **Close Setup** on the toolbar.

IMPORTANT: You must prime the fluidics station: when you first start the fluidics station, when you change the wash buffers, if you have performed a shutdown on the station since it was last used, or if resolution to an alert tells you to prime. You DO NOT need to reprime the fluidics station when using assays that use the same wash buffers.

Associating Test Requests with Fluidics Stations

To associate test requests with a fluidics station:

1. Click **Fluidics**.
   The Fluidics Worklist displays. (Figure 4.10 on page 38).
2. Place the array in the fluidics station module.
   Do not load the cartridge at this time.
3. Associate the test request with a fluidics station module:
   A. If you are using a barcode reader, repeat the following steps for each array you wish to process:
      1) Scan the array barcode.
         AMDS selects the array associated with the test request.
         You will hear a single "ding" sound.
      2) Scan the barcode for the fluidics station module that will process the array.
         The fluidics station and module information will be entered for the test request.
         You will hear a double "ding" sound.

B. If you are entering the information manually:

1) Select a test request record with the desired Array ID.

2) Enter the fluidics station number in the Station # field and module number in the Module # field.

You are ready start the fluidics run.

Starting the Fluidics Run

To start the fluidics run:

1. Select the test requests on the Fluidics Worklist.
2. Click **Start** on the toolbar of the Fluidics Worklist.
3. Follow the instructions on the fluidics station LCD.
4. After you remove the arrays from the fluidics station, click **Complete Step**.

This step completes washing and staining arrays with the fluidics station and moves the test request(s) to the Scanner Worklist.

The fluidics stations will continue running for a few minutes after you remove the arrays.

If you are done processing arrays for this assay, or won't be processing any more arrays on this fluidics station for several hours, perform the shut down procedure. See *Shutting Down the Fluidics Station* on page 75.

Scanner—Scanning Arrays

IMPORTANT: Make sure you know how to operate the scanner. See ***GeneChip® Scanner 3000Dx with AutoLoaderDx* on page 101**.

NOTE: For certain assays, as determined by the assay manufacturer, the system may require additional information for each test request in order for that test request to run successfully. Failure to enter the additional information prior to starting to scan the array will cause a failure when attempting to execute the analysis algorithm following the scanning step. See your assay software module manual for details.

Click on the **Scanner** button (Figure 4.12 on page 40) in the Workflow pane to view the Scanner Worklist.

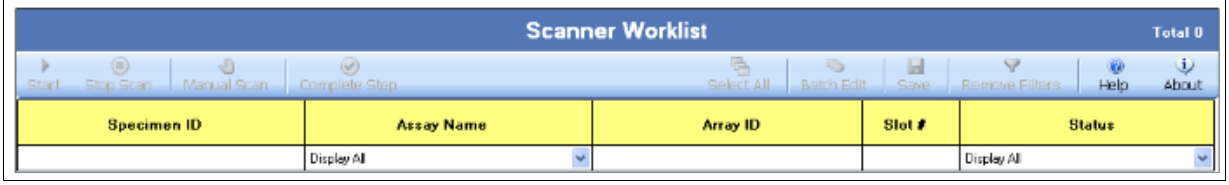
Figure 4.12 The Scanner Worklist Button

Scanning Arrays in Normal Operational Mode

To scan an array in normal operational mode:

1. Click **Scanner** (Figure 4.12 on page 40).
   The Scanner Worklist displays (Figure 4.13 on page 41).

Figure 4.13 The Scanner Worklist



2. Load the array cartridges into the AutoLoaderDx starting with slot 1.

NOTE: During a scanner run, always start with the array in slot 1. It is most efficient to remove all scanned arrays and shift any unscanned arrays in the carousel to slot 1 so there are no empty slots.

3. Add any additional arrays in the remaining slots in a contiguous manner.
4. Click **Start**.
   As each array is encountered, the scanner will pass the Array ID to AMDS. AMDS will find the associated test request.
5. When the scan completes, as indicated by the status for the test request showing complete, click **Complete Step**.

This step completes scanning in normal operational mode and removes the test request(s) from the Scanner Worklist.

Scanning Arrays in Manual Mode

You can scan one array at a time using the manual scan function. Use this function to scan arrays that have illegible or missing barcode labels. AMDS will attempt to scan the barcode and, if it can, will validate that the selected test request is correct.

To scan arrays in manual mode:

1. Click **Scanner**.
   The Scanner Worklist displays (Figure 4.13 on page 41).
2. Open the AutoLoaderDx door.
3. Insert the array into the AutoLoaderDx carousel at slot 1.
4. Close the door.
5. Select the correct test request on the worklist.
   The **Manual Scan** button is enabled.
6. Click **Manual Scan**.
   The door locks and scan begins. After the scan is complete, the door unlocks. Open the door and remove the array.
7. Click **Complete Step**.

This step completes scanning in manual mode. After post-scan processing is complete, you can review, approve, or reject the test results on the Active Worklist. For more information, see *Post-Scan Processing* on page 42.

Stopping an Scanner Run

If you want to add arrays to the carousel or if issues occur, you can stop the scanner in the middle of a scanner run.

To stop a scanner run:

1. Click **Stop Scan**.
   The scanner will finish scanning the current array and then stop and unlock the door.
2. Optional: Add an array to the scanner.
3. Optional: Click **Start** to resume scanning with the array in slot 1.

NOTE: The scanner will not rescan any previously scanned arrays and will always start its run with the array in slot 1.

Post-Scan Processing

Once the scan is complete, AMDS will:

- Take the resulting DAT file
- Apply a grid to it
- Generate intensity data
- Generate a CEL file

The CEL file will then be analyzed in the manner specified by the assay software module. When this processing is complete, an Awaiting Review hyperlink (Figure 4.14 on page 42) displays in the Review Results column of the Active Worklist. At this time, the results are ready to be reviewed.

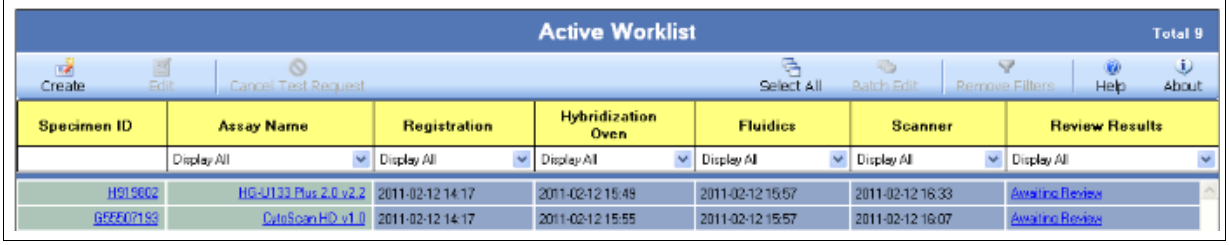
Reviewing Test Results

The workflow for reviewing and processing test results is assay dependent. See your assay software module manual for specific instructions.

To review test results:

1. Click **Active Worklist**.
2. Click on the **Awaiting Review** hyperlink for your test request.

Figure 4.14 The Review Results Function



The assay software displays a Results screen for your particular assay. See your assay software module manual for instructions on how to finalize the test request.

You may want to view log files or generate archives related to test requests. For more information, see *Viewing Logs* on page 44 and *Archiving and Purging Test Requests* on page 57.

After you accept or reject a test request, you can view it on the Non-Active Worklist.

Non-Active Worklist—Viewing Non-Active Test Requests

You can view test requests on the Non-Active Worklist when:

- You have canceled them before test request processing is complete.
- After you approve test requests and before they have been archived and purged.

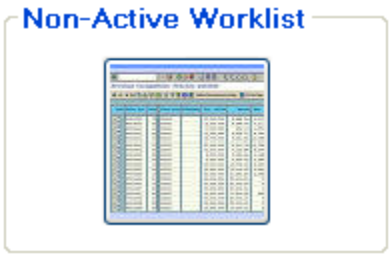
Once you archive and purge a test request, you can only view it from CD/DVD or network location where you created the archive. For more information, see *Archiving and Purging Test Requests* on page 57

After you approve test requests and before you archive them, you can view test requests on the Non-Active Worklist (Figure 4.15 on page 43) to display non-active test requests. The system moves test requests to the Non-Active Worklist when they have completed processing in AMDS, e.g. when the results have been viewed and approved, or when you cancel them.

To view test requests on the Non-Active Worklist:

1. Click the **Non-Active Worklist** button (Figure 4.15 on page 43) on the Administrator pane.

Figure 4.15 Non-Active Worklist Button



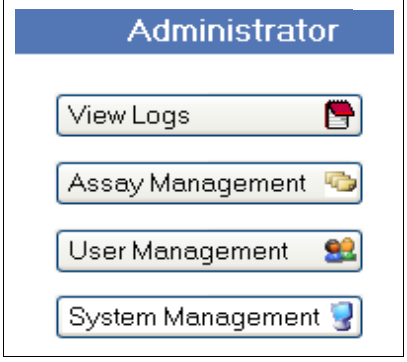
AMDS Administrative Features

AMDS supports the following administrative features:

- Viewing logs
- Managing assays
- Managing users
- Managing the system

To access these features, click on the corresponding buttons in the Administrator pane (Figure 5.1 on page 44). If a button is disabled, you do not have access to that feature. Your user privileges are defined by your user role. For information about user roles, see *About User Roles* on page 50.

Figure 5.1 Administrator Pane



Viewing Logs

The View Logs function allows you to:

- View system logs and audit logs.
- Filter logs according to specific criteria.
- Export and burn logs files to CDs or DVDs for troubleshooting or retention.

System Logs

System logs contain system level algorithm and computer messages as well as recorded parameters of completed assays, such as date and time, the component, type, user, etc.

The View System Logs screen (Figure 5.2 on page 45) displays the system log in the upper half of the View Logs screen.

See also *Exporting and Burning Log Files to CD or DVD* on page 46.

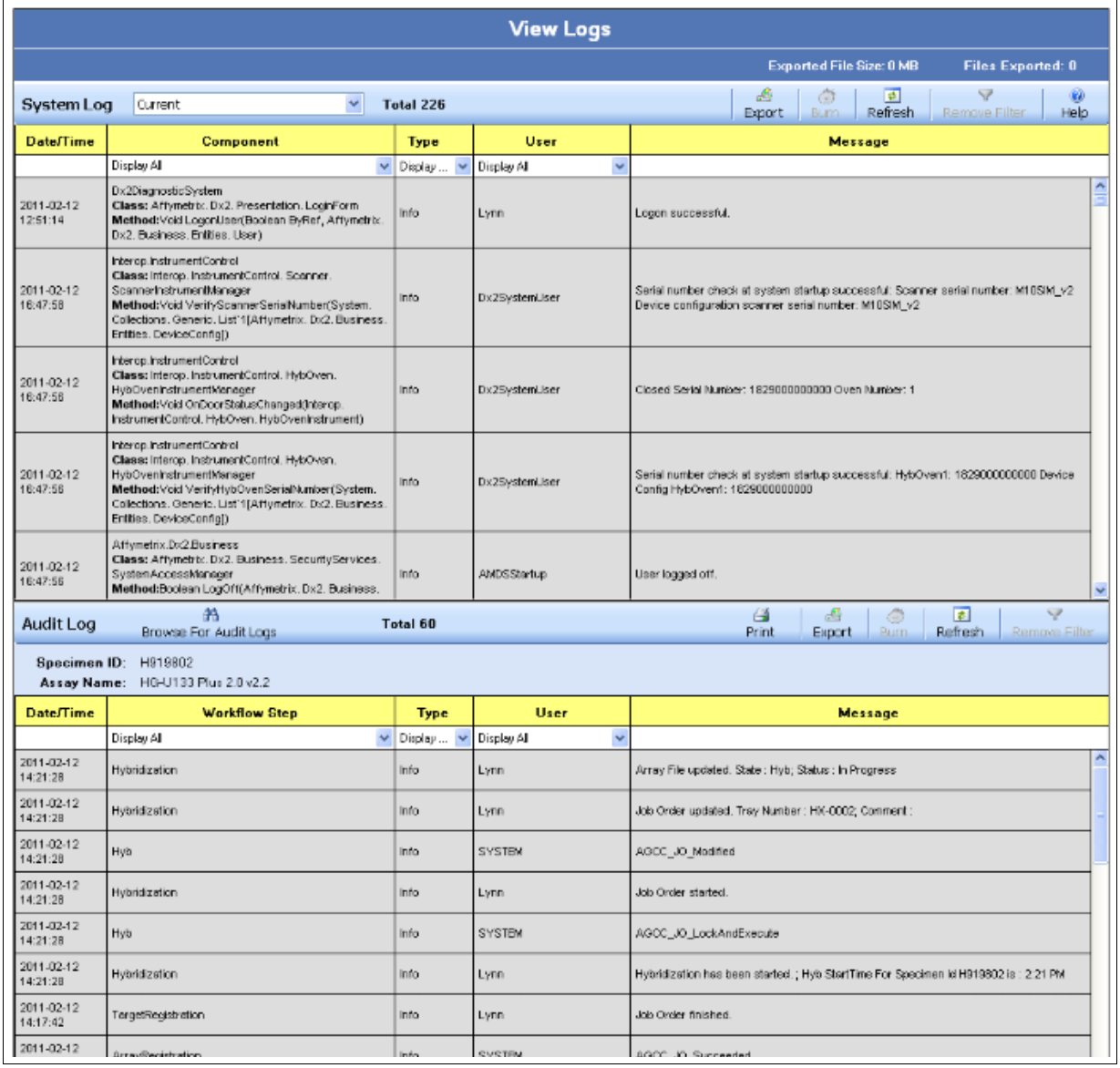
To view a system log:

1. Click the **View Logs** button (Figure 5.1 on page 44) in the Administrator pane.

   The log view displays the current system log.

2. Optional: If you wish to view a system log other than the current one, select one from the System Log list.

Figure 5.2 View Logs Screen



Filtering the System Log

To filter log entries:

1. After selecting a system log, enter filter criteria in the row that is just below the system log column headers.

   You can filter the log according to:

   - Date/Time
   - System component
   - Log message type
   - User

2. Click **Remove Filter** to display all log entries.

Audit Logs

Audit logs contain information, messages, and parameters related to a specific test request for each step of the workflow.

See also *Exporting and Burning Log Files to CD or DVD* on page 46.

Viewing Audit Logs

To view an audit log:

1. Click the **View Logs** button (Figure 5.1 on page 44) on the Administrator pane.
   The Audit Log displays in the lower half of the View Logs screen.
2. In the Audit Logs toolbar, click **Browse for Audit Logs** to locate a specific test request's log.
3. Select the test request you want to view.
4. Click **Display**.

Filtering Audit Logs

To view audit log entries related to specific types of information:

1. After selecting an audit log, enter filter criteria in the row that is just below the audit log column headers.
   You can filter the log according to:
   - Date/Time
   - Workflow step
   - Log message type
   - User

Printing Audit Logs

To print an audit log:

1. Select the audit log for printing.
2. Click **Print**.

Exporting and Burning Log Files to CD or DVD

NOTE: You can burn logs only to the workstation's internal CD/DVD drive.

At any time while viewing either a system or audit log, you can click **Export** to send the entire log file to the export queue. The View Logs toolbar shows the total size and number of logs in the queue.

To export log files:

1. For each system and audit file you want to export,
   - Select the file.
   - Click **Export.**

   The View Logs toolbar increases the number of exported files by 1.
   The entire unfiltered log file is exported.

To burn the log file to CD or DVD:

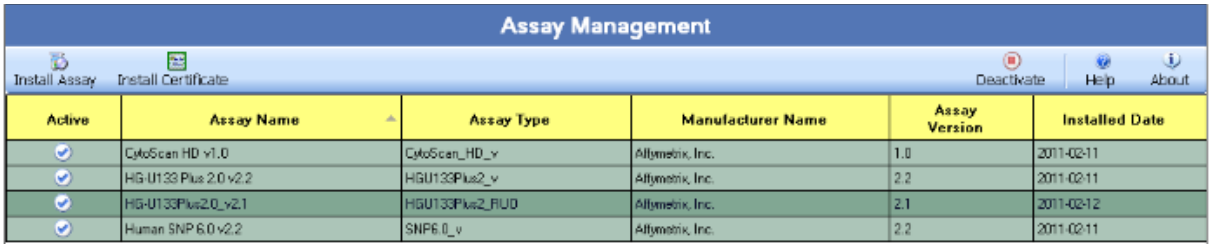
1. Click **Burn** to export the current list to the workstation's CD/DVD drive.
   - All queued log files burn to the disc drive.
   - Whether you click the System Log **Burn** button or the Audit Log **Burn** button, all exported log files, regardless of log type, burn to CD/DVD.

Managing Assays

The Assay Management function provides the capability to install, repair, deactivate assays, or deactivate SSL certificates.

Installing Assays

Figure 5.3 The Assay Management screen



NOTE: If the assay communicates with a remote server and the certificate for that server has not been installed on AMDS, you need to install the server certificate first. See your assay software module manual to determine if you need to install the certificate. See also *Installing a Certificate* on page 48.

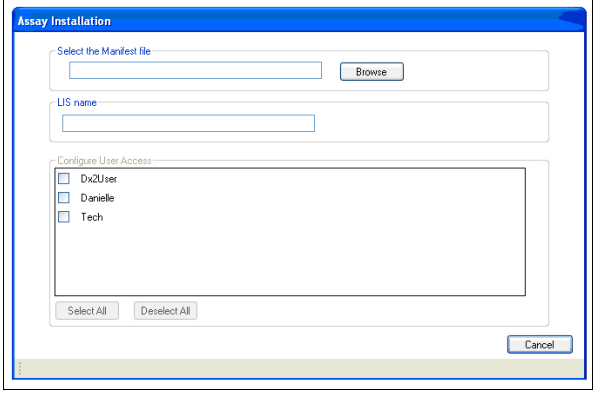
NOTE: In most cases, an Affymetrix field service engineer will install the certificate and assay.

In order to install an assay, you must have the assay's installation bundle, which is typically provided on a CD.

To install the assay:

1. Click the **Assay Management** button (Figure 5.1 on page 44) in the Administrator pane.
   The **Assay Management** screen displays (Figure 5.3 on page 47).
2. Place the cd containing the assay software module installation bundle into the workstation's internal CD/DVD drive.
3. On the Assay Management toolbar, click **Install Assay**.
   The **Assay Installation Dialog** displays (Figure 5.4 on page 48).
4. In the **Select the Manifest** file box, enter or browse to the manifest file.
   The assay manufacturer provide the manifest file as part of the assay installation bundle.
5. Select the users who should be permitted to run this assay.
   - Click **Select All** to select all the users.
   - Click **Deselect All** to deselect all the users.
6. When the **Install** button displays, click **Install**.

Figure 5.4 The Assay Installation Function



Deactivating an Assay

You can deactivate an assay if you no longer use this assay and do not want it to appear as a selection in the AMDS application. There is no mechanism to uninstall an assay.

1. Select an assay from the Assay Management screen (Figure 5.3 on page 47).
2. Click **Deactivate** on the Assay Management toolbar.

Once you deactivate an assay, you can still complete the workflow for any active test requests for this assay. The assay will no longer be available for entering new test requests.

Repairing or Reactivating an Assay

To repair or reactivate an assay, reinstall the assay as if it were a new install. See *Installing Assays* on page 47.

Installing a Certificate

NOTE: You must be logged in as a Laboratory Supervisor or System Maintainer to install a certificate.

Some assays may require the transfer of data to a remote system during the analysis phase of the workflow. This transfer requires the installation of a server certificate to enable AMDS to trust the server through https protocols.

As a security measure, AMDS requires that you or the Affymetrix field service technician install a SSL server certificate installed on your local workstation in order for your workstation to communicate with the remote server. This is required for the transfer of the Gene Profiling cGMP v1.1 Assay test request data to the data transfer server.

You should have the certificate installed before installing the assay. The Affymetrix service technician should have installed a certificate at the time of the system's installation. If for some reason the service technician did not install a certificate or if the server has changed after the system's initial installation, you must install a certificate.

If a proper certificate has not been installed, you can still install the assay and process test requests; however, you will have no permission to access the remote server, and you cannot transfer test request data to the remote server. If you cannot access the remote server and have already installed a certificate, contact Affymetrix technical support.

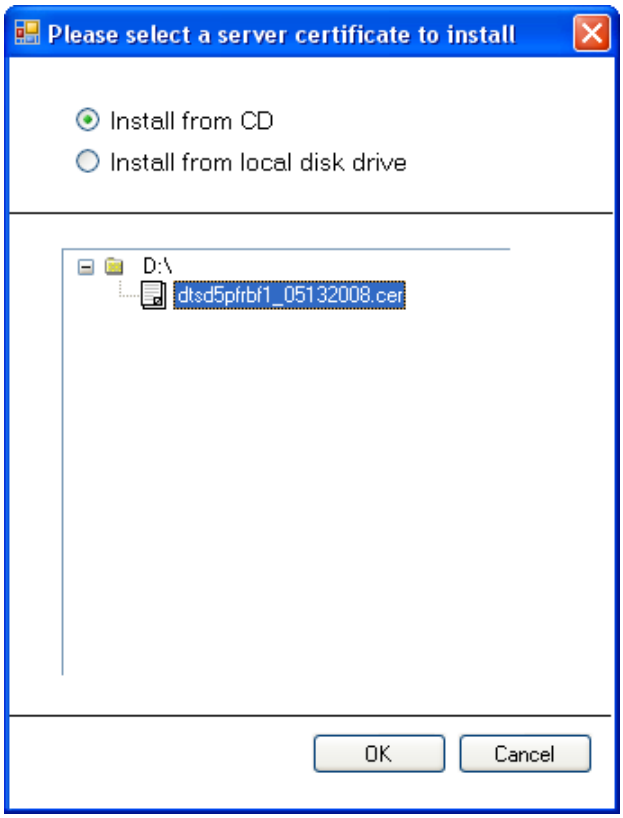
To install a certificate:

1. Click the **Assay Management** button (Figure 5.1 on page 44) on the Administrator pane.
2. Click **Install Certificate.**

   The Server Certificate dialog appears (Figure 5.5 on page 49).
3. Select either **Install from CD** or **Install from local disk drive.**
4. Browse for and select the desired .cer file.

   The certificate you want to install has a .cer extension.
5. Click **OK** to continue or **Cancel** to end the installation.
   - If the installation is successful, you will receive the message, "You have successfully added the server certificate 'x.cer' to the AMDS trusted certificate store."
   - If the installation fails, AMDS will notify you with a particular algorithm message. The software will prevent you from accessing the server and from transferring data without the proper certificate installed.
6. Click **OK** to dismiss the message and return to the Assay Management screen.

Figure 5.5 Server Certificate Dialog



Managing Users

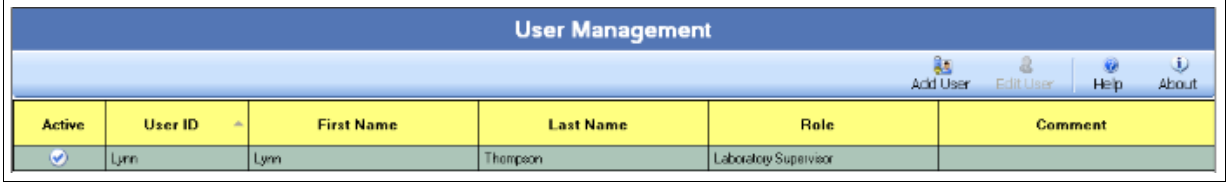
The **User Management** button allows you to add users or to change user privileges.

To open the User Management screen:

1. Click the **User Management** button (Figure 5.1 on page 44) on the Administrator pane.

   The **User Management** screen displays (Figure 5.6 on page 50).

Figure 5.6 User Management screen



About User Roles

Each user has a defined role that specifies the actions the user is allowed to perform on the system:

- **Guest**—Users with this role are allowed to view non-patient information on the system and are not allowed to perform any of the processing steps for a test request. When assigning the Guest role to a user, we recommend not assigning them access to any assay software modules.
- **Technician** —A user with a Technician role can create test requests and process them through the workflow. A technician cannot approve or reject the results for test requests.
- **Technologist**—Users with the role of Technologist can create and process test requests through the workflow, and can approve or reject results.
- **System Maintainer**—A user with a System Maintainer role can access all the System Management screens, and perform tasks like archiving test requests, maintaining the instruments, and general system configuration. This user cannot perform any of the processing steps for a test request and cannot view any patient data. When assigning the System Maintainer role to a user, we recommend not assigning them access to any assay software modules.
- **Laboratory Supervisor**—A user with a Laboratory Supervisor role can perform all of the tasks associated with the Technologist role and all of the tasks associated with the System Maintainer role.

Adding a User

Before adding a user, you should review the different AMDS user roles in *About User Roles* on page 50.

If there are no assays installed on the system, you do not have the option of granting assay access to a user.

Guests and system maintainers should not be granted access to assays.

To add a user:

1. In the **User Management** toolbar, click **Add User**.
   The **Add User** screen displays (Figure 5.7 on page 51).
2. Establish the following characteristics of the new user.
   - Select the **Active** box to make the user currently active or deselect the **Active** box to create a user without granting immediate access to the system.
   - Enter a user ID.
   - Enter the user's first and last name.
   - Optional: Enter a comment.
   - Create and confirm a password.
     - The password must have a minimum of 8 characters, 1 uppercase and 1 lowercase character, two special characters, and two numerics.
     - The numerics and the special characters may repeat.
   - Select the user's role.
   - Select the assay groups you want for the user.
3. Click **Save Changes**.

AMDS commits the information and creates the user in the system with the associated roles and permissions.

Editing a User

You can change any user attribute other than the user ID.

1. In the User Management screen (Figure 5.6 on page 50), select a user.
2. Click **Edit User**.

   The **Edit User** screen displays.

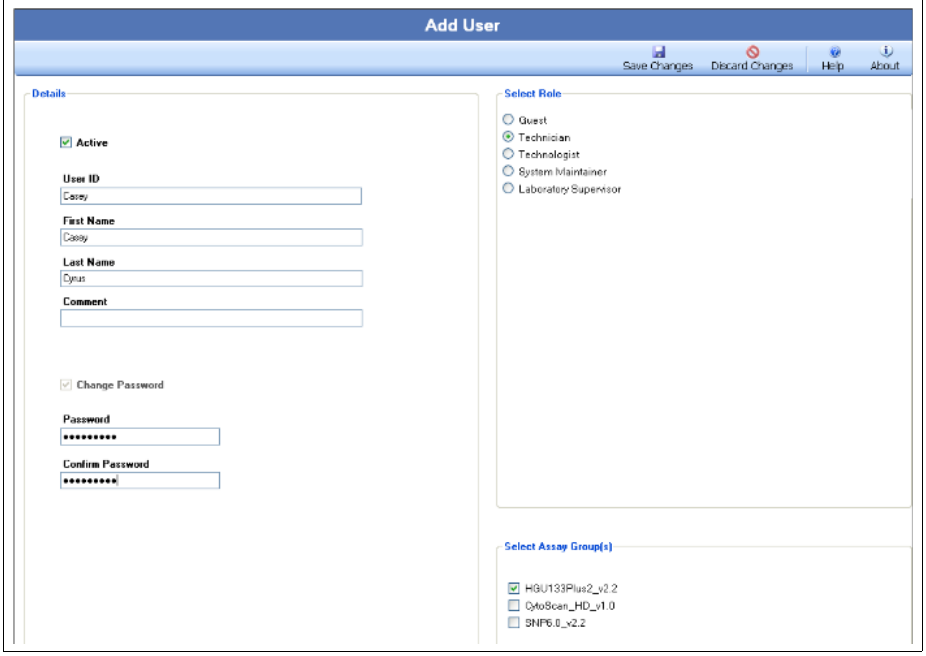
   The Edit User screen looks like the Add User screen (Figure 5.7 on page 51), displaying the user's current data and disabling the User ID field.
3. You can:
   - Select **Active** to activate or deselect to deactivate the user.
   - Edit the user's first and last name.
   - Enter or edit a comment.
   - Change a password by selecting the **Change Password** box and then entering and confirming the new password in the **Confirm Password** dialog box.
   - Change the user's role.
   - Change the assays groups to which the user has access.
4. Click **Save Changes**.

   AMDS commits the information and change the associated roles and permissions of the user.

Deactivating a User

To deactivate a user, uncheck the **Active** box on the Edit User screen. You can reactivate the account at a later date.

Figure 5.7 The Add User screen



Managing the System

Click the **System Management** button (Figure 5.1 on page 44) on the Administrator pane to access these system management functions:

- **User Performed Service**—view the system's configuration—i.e., the device and instrument settings—and manage the fluidics station, workstation, scanner, printer and firewall.
- **Service Logs**—view logs detailing user performed services.
- **Archive Test Request**—archive and then purge test request data.
- **General Configuration**—change the time and time zone settings for your particular location, change the configuration flags for your instruments, and set up network archive location.

Each of these functions has a separate screen. To switch screens, follow the instructions in *Changing System Management Screens* on page 52.

Changing System Management Screens

The System Management Menu, located on the System Management toolbar, allows you to switch between system management screens. When you click on the **System Management** button in the Administrator pane, the default screen is the User Performed Service screen *User Performed Service Screen* on page 53.

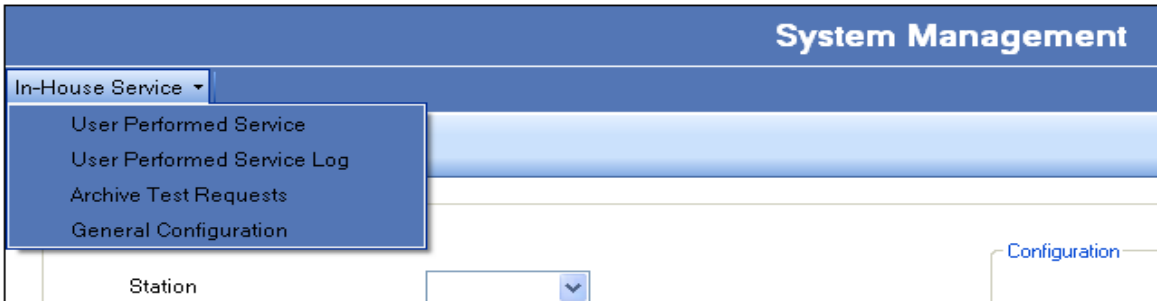
To change system management screens:

1. Click the **System Management** button (Figure 5.1 on page 44)on the Administrator pane.
2. From the System Management menu (Figure 5.8 on page 52), select one of the following:

- User Performed Services
- User Performed Service Log
- Archive Test Requests
- General Configuration

The selected screen displays.

Figure 5.8 The System Management Menu

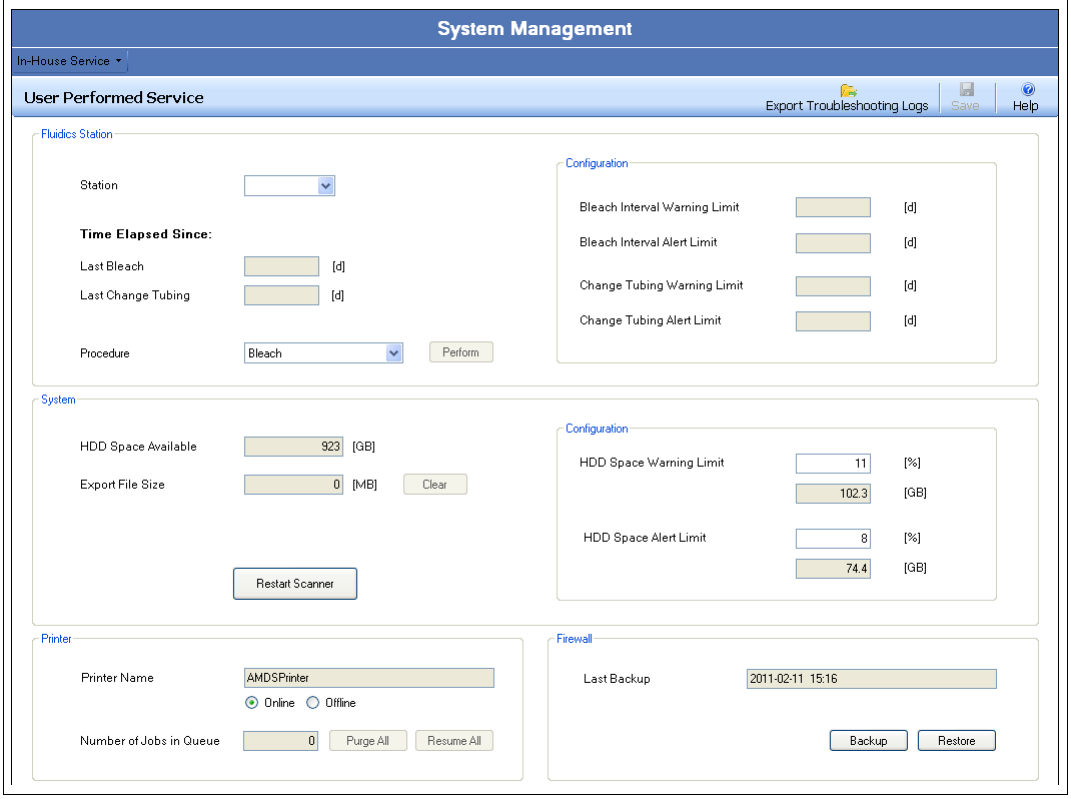


Managing Instrument Settings on the User Performed Service Screen

This screen provides controls to manage the following:

- Fluidics stations
- System hard drive
- Scanner
- RAID settings (not applicable to all systems)
- Printer
- Firewall

Figure 5.9 User Performed Service Screen



Managing Fluidics Stations

IMPORTANT: **When performing fluidics management procedures, make sure you select a fluidics station first.**

NOTE: **For greater detail on using, troubleshooting, and maintaining fluidics stations, see *GeneChip® Fluidics Station FS450Dx* on page 66**

On the Fluidics Station region of the User Performed Services screen (Figure 5.10 on page 54), you can:

- In the Elapsed Time fields, see how many days have elapsed since the last bleach or tube change took place for the selected fluidics station.
- Perform a bleach protocol:
  - **A.** Select Bleach in the Procedure dialog box.
  - **B.** Follow the procedures provided in *The Bleach Cycle* on page 78.
  - **C.** Click **Perform**.
- Change the tubing:
  - **A.** Select Change Tubing in the Procedure dialog box.
  - **B.** Follow the procedures provided in *Peristaltic Tubing Maintenance* on page 83.
  - **C.** Click **Perform**.
- Troubleshoot or test communication between the workstation and the fluidics station:
  - **A.** Select **Home** in the Procedure dialog box.

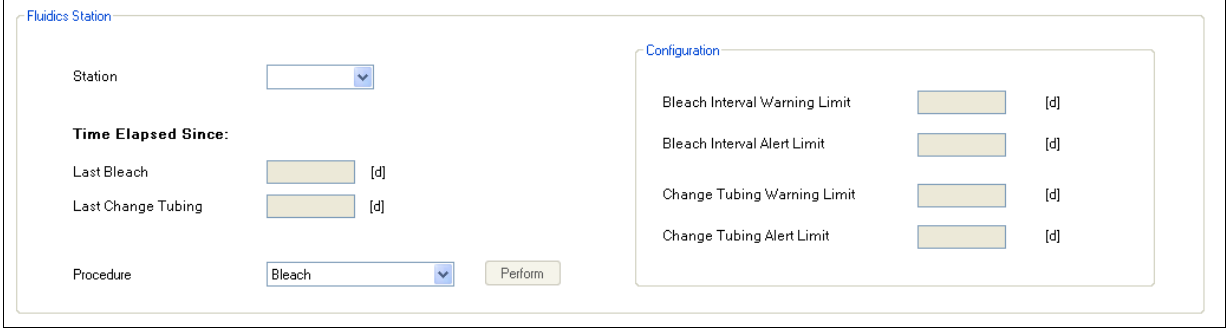
B. Click **Perform**.

If the operation is unsuccessful, see *Troubleshooting the Fluidics Station Connection to the Workstation* on page 70.

- View or change the Bleach Interval Warning Limit and Bleach Interval Alert Limit:
  - The bleach reminder is preconfigured on to a schedule recommended by Affymetrix.
  - Set these limits in the Fluidics Station Configuration region.
  - The warning times must be less than the alert times.
  - It is recommended to change the alert first and then the warning.
  - Click **Save** after you have changed the values.
- View or change the Change Tubing Warning Limit and Change Tubing Interval Alert Limit:
  - The change tubing reminder is preconfigured on to a schedule recommended by Affymetrix.
  - Set these limits in the Fluidics Station Configuration region.
  - The warning times must be less than the alert times.
  - It is recommended to change the alert first and then the warning.
  - Click **Save** after you have changed the values.

After each of these changes, the Confirm Step dialog box displays. Confirm the change with your password and the reason for you performed the action.

Figure 5.10 The Fluidics Station region of the User Performed Services screen



Managing the Workstation Hard Disk

On the System region of the User Performed Services screen (Figure 5.11 on page 55) you can:

- View how much space is available on the workstation hard disk.
- View the size of the current export files.
- Clear the exported file list.
  - Clearing this list removes all exported logs from the system without burning them to disc.
  - Next to the Export File Size field, click **Clear**.
- View or change the HDD Space Warning Limit or HDD Space Alert Limit:

NOTE: These warnings and alerts notify you when the workstation hard drive is nearing capacity. You should archive and purge data before you reach your limit. Once AMDS hits the alert limit, you will no longer be able to scan any arrays until you have archived and purged enough data to stay below your limit.

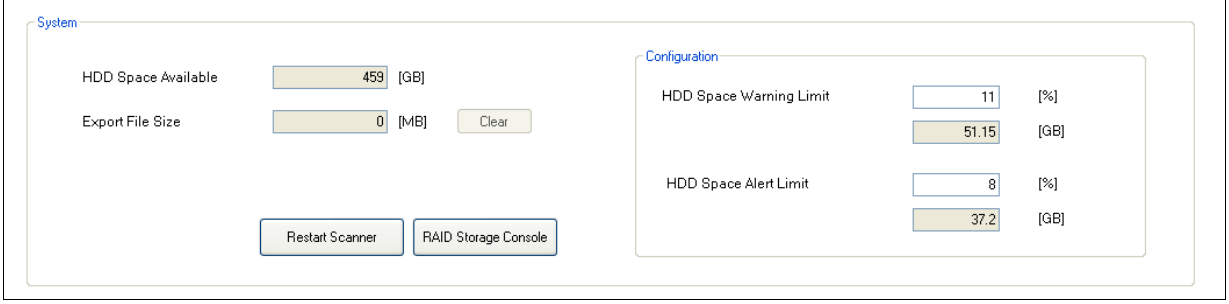
  - Set these values in the System region.
  - The space alert limit must be less than the warning alert limit.
  - It is recommended to change the alert first and then the warning.
  - Your system will prevent you from setting the alert below a certain percentage.

- View and configure RAID storage settings.

  For more information, see *Viewing RAID Storage Status* on page 55.

After each of these procedures, click **Save**. When the Confirm Step dialog box displays, you need to confirm the change with your password and the reason for the change.

Figure 5.11 The System Region of the User Performed Services Screen



Restarting the Scanner

Clicking this button will attempt to restart the scanner and establish communication between the workstation and the scanner. Perform this function if you are experiencing problems connecting to the scanner.

1. On the System region of the User Performed Services screen, click **Restart Scanner** to restart the scanner.

For complete instructions related to the scanner, see *GeneChip® Scanner 3000Dx with AutoLoaderDx* on page 101.

Viewing RAID Storage Status

Depending on your AMDS workstation model, you may have a **RAID Storage Console** button on the User Performed Service System region.

If your system displays this button, you can click on it to view the RAID Matrix volumes and check the health of your hard drive. Consult your RAID console documentation for more information.

If your system does not display this button, check the hard drive status on the Device Status pane. In either case, if the hard drive status is not optimal, contact Affymetrix support.

Managing the Printer

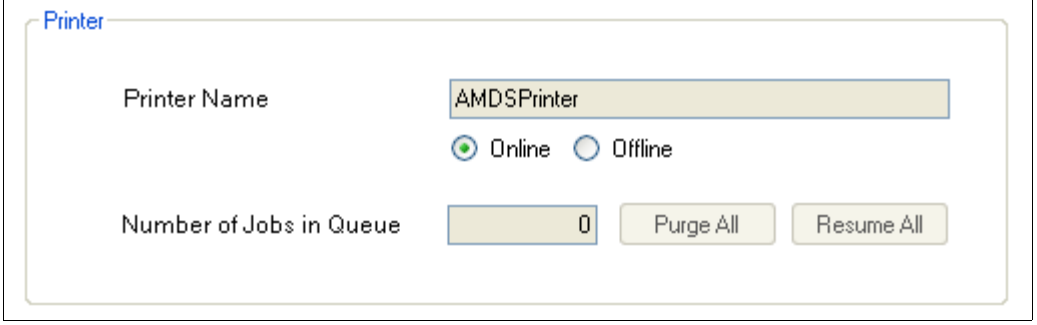
On the Printer region of the User Performed Services screen (Figure 5.12 on page 56), you can:

- View the printer name.
- View the number of jobs in queue.
- Change the printer's online/offline status:
  - Taking the printer offline disables the print button on screens where it is available. Bringing the printer online enables the print button.
  - To take the printer offline (for printer maintenance, etc.) and stop printing jobs in queue, select **Offline**.
  - To bring the printer online, select **Online**.
- Purge all print jobs.

  Click **Purge All** to remove all the jobs from the print queue.
- Resume all queued print jobs.

  To resume jobs in the queue, click **Resume All**.

Figure 5.12 The Printer region of the User Performed Services screen



NOTE: You cannot change the printer. An Affymetrix service engineer sets up the printer as part of the AMDS installation process.

Backing Up and Restoring Firewall Settings

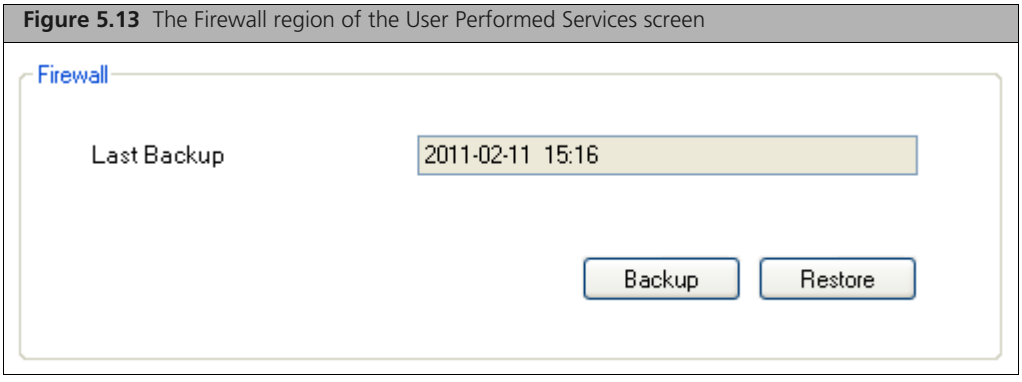
The AMDS firewall monitors incoming and outgoing messages from the workstation and protects the workstation from malicious intrusion (Figure 5.13 on page 56).

On the Firewall region of the User Performed Services screen, you can:

- View the last firewall backup.
- Backup current firewall settings.
- Restore firewall settings from the last backup.

Some assays access servers on an intranet or on the internet. When these assay software modules are installed, a rule is written to the firewall. This rule permits communication between the AMDS workstation and the remote server. Restoring firewall settings may overwrite these rules and prevent AMDS from communicating with the server. In this case, reinstall any assay software modules that communicate with remote servers in order to restore communication between the workstation and server.

Figure 5.13 The Firewall region of the User Performed Services screen



Viewing User Performed Service Logs

NOTE: Do not confuse the View Service Log function with the View System and Audit logs that are described in the section *Viewing Logs* on page 44.

A User Performed Service Log entry will be created for most of the actions you perform on the User Performed Services screen. You can open and view the service logs for user performed services.

To view and filter user performed service logs:

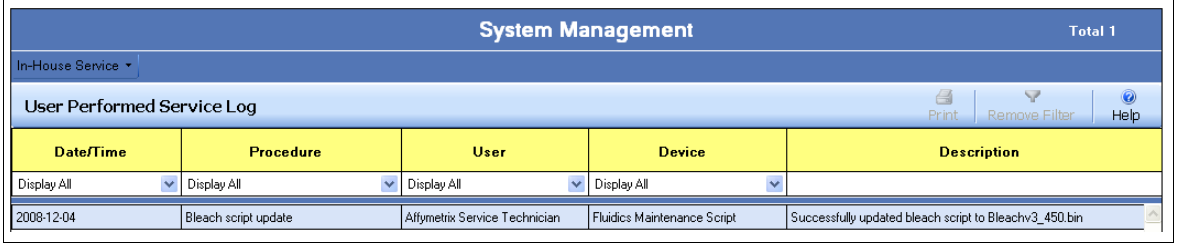
1. From the System Management menu, select **User Performed Service Logs**. (See *Changing System Management Screens* on page 52).

   The User Performed Service Logs screen displays.

2. You can filter the log by:
   - Date/Time
   - Procedure
   - User
   - Device
   - Description
3. Click **Remove Filter** to view all log entries.

You can also print the user performed service log.

Figure 5.14 View User Performed Service Log



Archiving and Purging Test Requests

AMDS allows for test requests to be archived, and subsequently purged, in order to conserve space on the hard drive. Test requests can be archived multiple times before they are purged.

NOTE: Once test requests are purged, there is no way to restore the archived test requests to AMDS. The only place test request data exists is on the CD/DVD containing the archive, any print outs, or similar material.

On the Archive Test Requests screen, you can:

- View test requests:
  - That are within AMDS, ready to be archived.
  - On a CD/DVD containing an archive.
- Filter the archive.
- Archive test requests to CD/DVD or network location.
- Purge selected test requests.

Viewing and Filtering Test Request Archives

You can view test requests that are in AMDS that are ready to be archived or those that have already been archived to a CD/DVD.

To view test request archives:

1. From the System Management menu, select **Archive Test Requests**. (See *Changing System Management Screens* on page 52).
   - The Archive Test Request screen displays (Figure 5.15 on page 58).

- If a test request has a green checkmark in the Archived DVD or Network column, it has been successfully archived.
- The System Management toolbar displays the total number of tests that are ready to be archived.

2. Click **AMDS Index** to view test requests in AMDS that are ready to be archived.
3. Click **DVD Index** to view test requests from an archive CD/DVD.
   The disc must be in the workstation disc drive.
4. You can filter the index by:
   - Date completed
   - Assay name
   - Array ID

Archiving Test Requests

Archiving is not the same process as exporting logs. When you archive to CD or DVD, you only archive the selected test requests. Exported log files are not burned to a disc when archiving test requests.

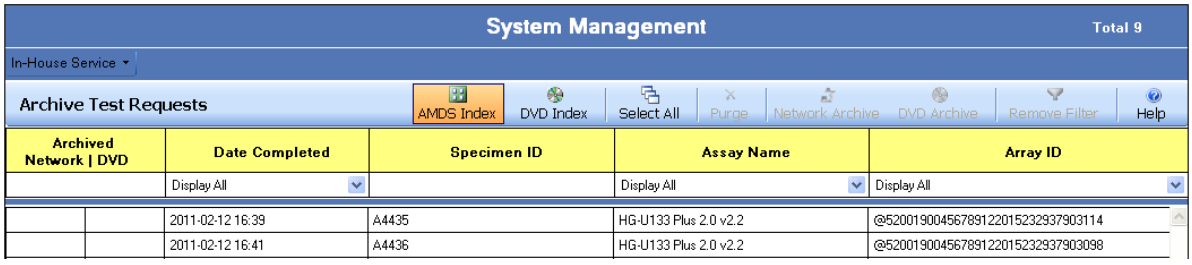
You can archive test requests to:

- A network drive (See *Configuring Network Archive Storage* on page 60).
- A DVD or CD

To archive test requests:

1. If necessary, use filters to locate the test requests you want to archive.
2. Select the test requests.
   - You can use **Select All** if you want to archive all of the displayed test requests.
   - When you select test requests, you see the number of selected test requests on the toolbar.
3. Click **DVD Archive** to burn the selected test requests to CD or DVD.
4. Click **Network Archive** to archive to a remote drive.
   - The network drive must be configured for this feature to be available.
   - For more information, see *Configuring Network Archive Storage* on page 60.

Figure 5.15 The Archive Test Requests Screen



Purging Test Requests

You can only purge a test request record after it has been archived.

Once the test requests have been purged, they are no longer available on the AMDS system.

- You can view test requests that have been archived to CD/DVD by using the DVD Index button.
- You can view test requests archived to either CD/DVD or a network location from a non-AMDS workstation.

To purge test requests:

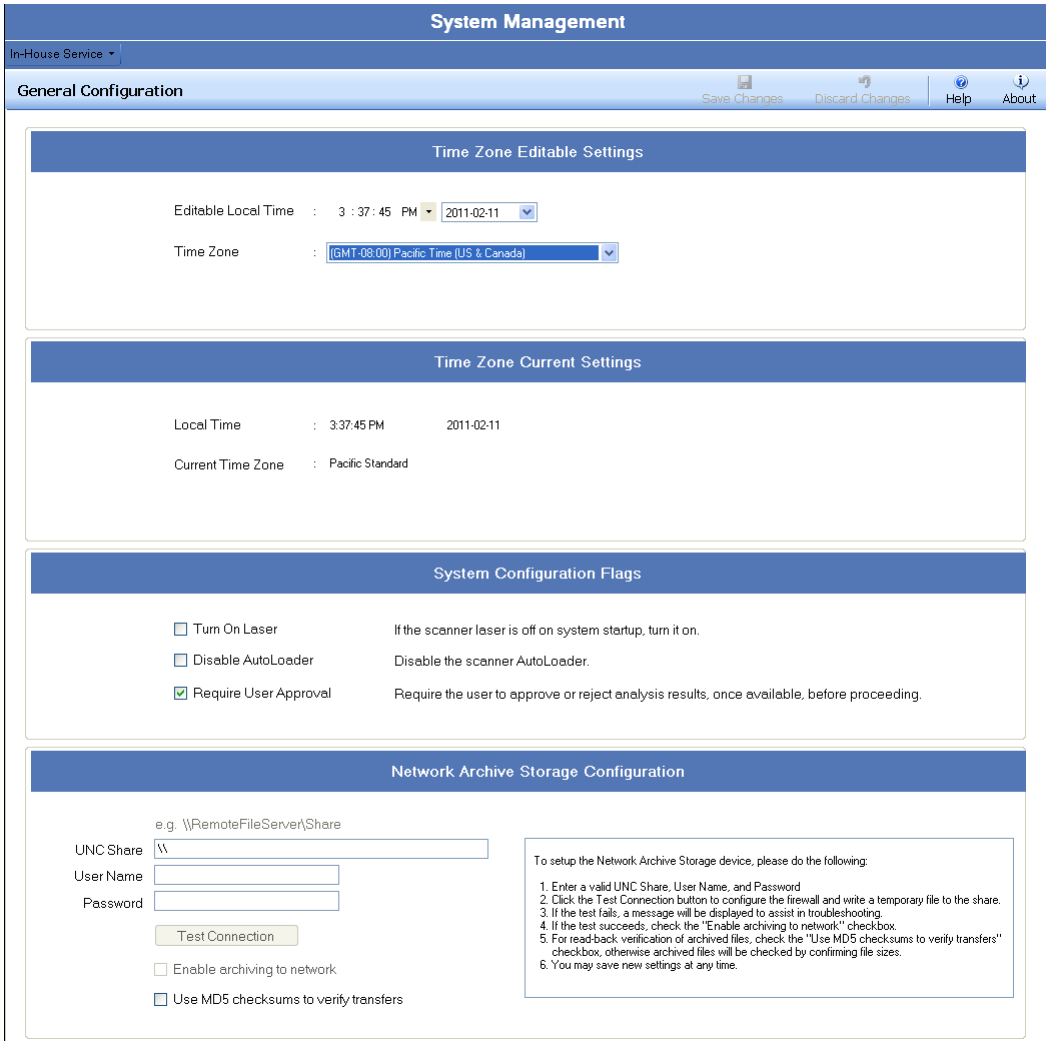
1. Select the test requests you wish to purge.
2. Click **Purge**.

Setting General Configurations

In the General Configuration screen you can:

- View and configure time and time zone settings.
- Configure scanner settings.
- Require users to approve or reject analysis results before proceeding.
- Configure network archive location settings.

Figure 5.16 The System Configuration Flags screen



Viewing and Configuring Time Zone Setting

NOTE: Do not change the local time or time zone if there are any test requests in progress on any worklist.

To view time zone current settings:

1. From the System Management menu, select **General Configuration**. (See *Changing System Management Screens* on page 52).
2. On the General Configuration screen, view the Time Zone Current Settings region (Figure 5.16 on page 59).

To configure time zone settings:

1. On the **Time Zone Editable Settings** region:
   A. In **Editable Local** time, set the local time.
   B. In **Time Zone**, set your local time zone.
2. Click **Save Changes**.

Configuring Scanner Settings

In the **System Configuration Flags** screen (Figure 5.16 on page 59): you can configure the scanner to:

1. Select **Turn on Laser** to turn on the scanner laser automatically when you launch the AMDS application.
2. Select **Disable AutoLoader** box to disable the scanner and manually load/unload arrays from the scanner.

   This should only be used on systems where the AutoLoader has failed and there are arrays that need to be scanned immediately.

   For complete instructions, see *Disabling the AutoLoaderDx* on page 113.
3. Click **Save Changes**.

Requiring User Approval for the Analysis Results

In the **System Configuration Flags** screen, select **Require User Approval** to require the technician to approve or reject the analysis results as they become available after an assay run (Figure 5.16 on page 59).

This flag is meaningful only if you do not wish to have the opportunity to approve or reject the results on the AMDS system. Deselecting this box will cause the test requests to immediately move to the Non-Active Worklist upon completion of the analysis algorithm. The user will not be able to view the results through the Active Worklist.

NOTE: This checkbox is intended for use in conjunction with an LIS. If you check this box, you will need to review the results for each test request. If the box is unchecked, the test requests disappear from the Active Worklist upon completion of the workflow and reappear on the Non-Active Worklist without user intervention.

Configuring Network Archive Storage

To setup the Network Archive Storage device:

1. On the General Configuration screen, view the **Network Archive Storage Configuration** region (Figure 5.16 on page 59).
2. Enter a valid:
   - UNC Share
   - User Name
   - Password
3. Click **Test Connection** to configure the firewall and write a temporary file to share.
   - If the test fails, an error message provides assistance troubleshooting the problem.
   - If the test succeeds, check **Enable archiving to network.**
4. For read-feedback verification of archived files, check **Use MD5 checksums to verify transfers**.
5. Click **Save Changes**.

AMDS Troubleshooting

Introduction

There are generally three categories of problems that can be encountered when executing test requests:

- Instrument related errors, such as communications issues 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. 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.

For more specific troubleshooting information related to the fluidics station and the scanner, see:

- *Fluidics Station Troubleshooting and Assistance* on page 86
- *Troubleshooting the Scanner* on page 114

Instrument Related Errors

If you suspect an issue with an instrument, check the Device Status pane as seen in (Figure 6.1 on page 62). The pane provides you with three pieces of information:

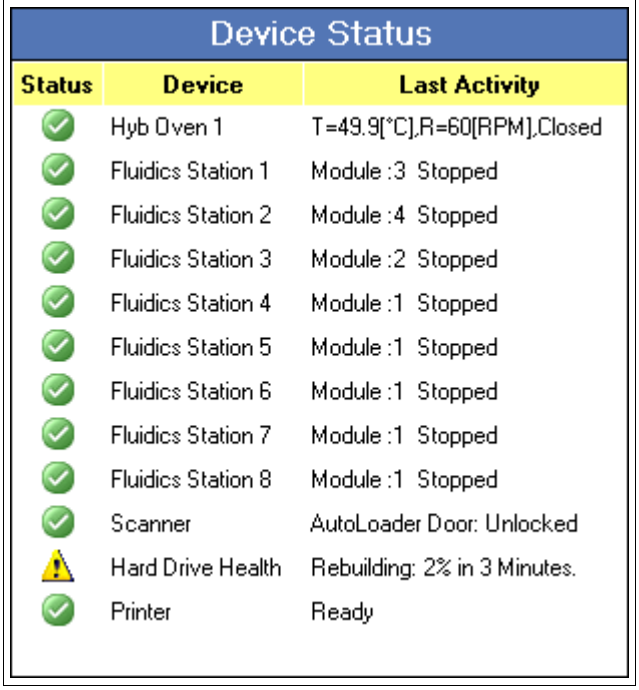
- The device name
- The device status
- Last activity

Check the device status icons to see if there are instrument errors. In (Figure 6.1 on page 62), for instance, all devices have green status, but the hard drive health has a yellow triangle, indicating that the hard drive is rebuilding. For more information, see *Device Status and Alert Icons* on page 62 and *Viewing Alerts and Alert Details* on page 62.

NOTE: **Occasionally an instrument issue occurs and no alert is evident in AMDS. One example is a leaking fluidics module. If you are not sure how to handle an issue and there is no alert with a recommended resolution, turn off the instrument and contact Affymetrix support.**

NOTE: **In some cases you may not be able to resolve an instrument problem. You will be directed to contact Affymetrix support to resolve the problem. You should not attempt to correct this kind of problem yourself.**

Figure 6.1 Device Status Pane



Device Status and Alert Icons

On the Device Status pane, check the device status icon to check device status.

These are the Device Status icons:

- **Green check mark**—the device is ready
- **White circle with green arrow**—the device is running properly
- **Yellow triangle**—check the Alert and Alert Details panes
- **Red circle with slash**—the device is not connected
- **Red circle with white x**—the device is turned off or attempting to connect

Viewing Alerts and Alert Details

The Alerts pane (Figure 6.2 on page 63) provides a short description of an error and the Alerts Details pane (Figure 6.3 on page 63) provides a full description and suggests corrective action.

Click on the alert in the Alerts Pane and view the corresponding alerts details on the Alerts Details pane. Then follow the procedures described in *Resolving Alerts* on page 64.

Figure 6.2 Alerts Pane

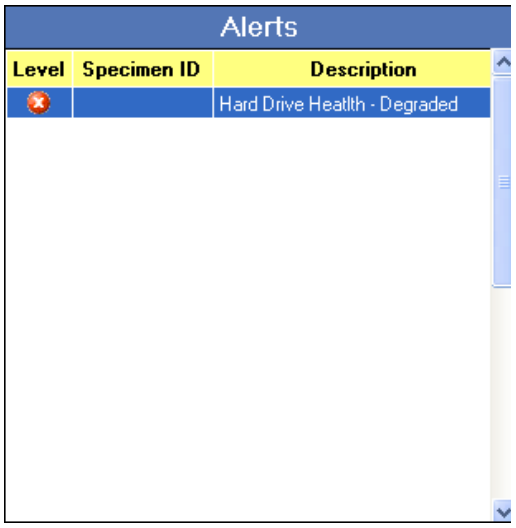
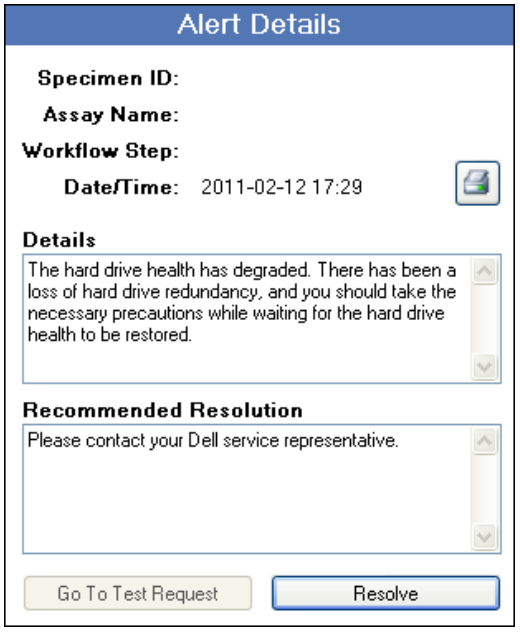


Figure 6.3 Alert Details



Individual Test Request Errors

The second category of troubleshooting relates to problems with an individual test request. These issues generate an alert with an associated Specimen ID and module.

Potential alerts include:

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

Refer to the individual alert for additional information and a suggested course of action for resolving the error. For more information, see *Resolving Alerts* on page 64

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.
- 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.
- Scanning an array that array's test request is still displayed in the Fluidics Worklist.

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

Resolving Alerts

To resolve an alert:

1. Click on the Alert in the Alerts pane (Figure 6.2 on page 63).
   The alert details display (Figure 6.3 on page 63).
2. Follow the suggested resolution procedure.
   - The resolution procedure varies depending on the alert.
   - If the alert is associated with a Specimen ID, use the **Go to test request** button to select the row in the worklist that contains the related test request.
3. After resolving the issue, click **Resolve**.
4. At the prompt, enter your password and additional information and click **OK** to remove the alert from the list.

NOTE: If after completing the recommended resolution procedure you are unable to resolve the error, call Affymetrix support.

Instrument Troubleshooting

Many instrument errors require the attention of a qualified Affymetrix field service engineer. However, there are some errors related to the fluidics station and scanner that can be resolved.

Troubleshooting the Fluidics Station

There are several fluidics station errors you can correct.

Fluidics Station is Not Primed

You can access the fluidics setup pane to prime the fluidics station for the selected assay class. See the section, *Priming the Fluidics Station* on page 75.

Fluidics Station Configured for a Different Assay

Open the Fluidics Station Setup screen to prime the station for the correct assay type or determine which fluidics station is configured for the assay type. See *Setting Up the Fluidics Station* on page 38 for details on changing the assay type.

Missing Fluid Error

The error generally occurs if there insufficient quantities of fluids are provided, or if the wrong fluids are provided. You can:

- Determine the source of the problems on the station LCD.
- Follow the resolution procedure in the alert details.
- Clear the alert, and continue the fluidics run.

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 86.

Troubleshooting the Scanner

There are several autoloader errors you can correct.

Autofocus Error

This error generally occurs if the array cartridge glass substrate is smudged or dirty, usually from 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 *Scanning Arrays in Manual Mode* on page 41.

GeneChip® Fluidics Station FS450Dx

Introduction

Figure A.1 Affymetrix® GeneChip® Fluidics Station 450

This section 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 GCS3000DX v.2 that includes the GeneChip® 3000Dx Scanner with AutoLoaderDx.

NOTE: Throughout this manual, the images of the fluidics station are pictures of the RUO version of the product. The Fluidics Station 450Dx differs from RUO version of the product in labeling, color of the levers, and the presence of a barcode next to the LCD screen for each module.

IMPORTANT: Make sure you familiarize yourself with the AMDS software interface before operating the Fluidics station. See *AMDS User Interface* on page 17

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 fluidics station 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.

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.

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. All modules are primed as a unit. Only one assay can be associated with a fluidics station at a time. You can use any or all of the modules at the same time. The modules are numbered 1 through 4 near the LCD screen.

Figure A.2 on page 68 and Figure A.3 on page 69 show the components and cable connections of the fluidics station. See Figure B.2 on page 105 for the cable connection to the scanner. This is for reference only. Affymetrix recommends that only a qualified service engineer 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 screen — 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.2 The GeneChip® Fluidics Station 450 and components

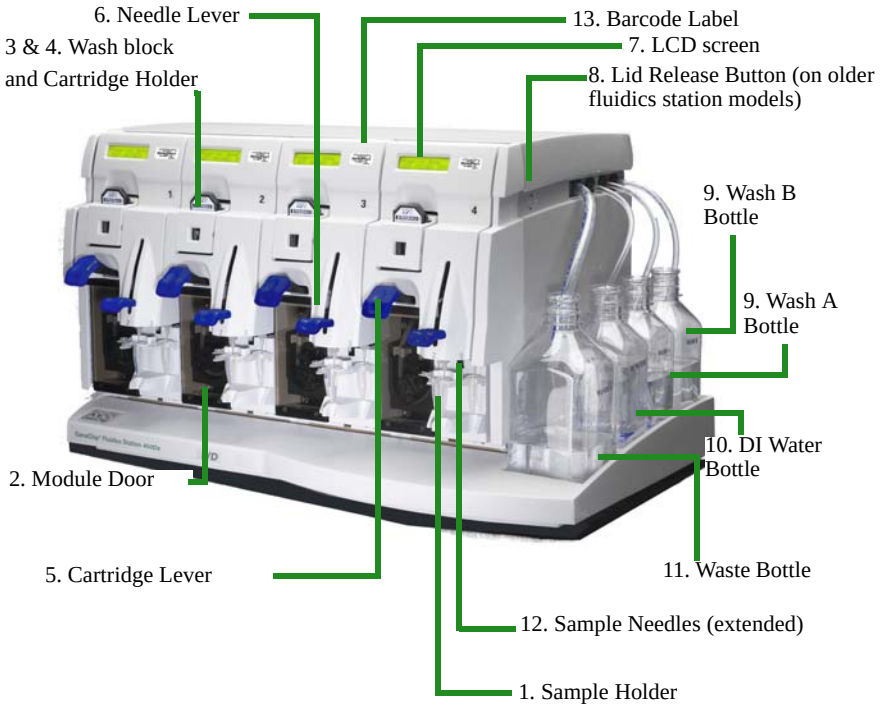
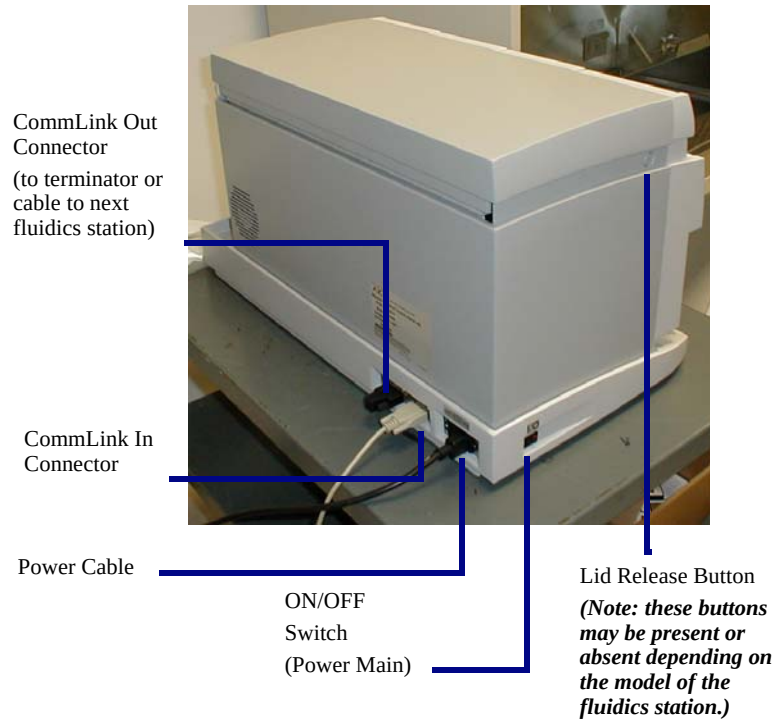


Figure A.3 Location of the serial ports and ON/OFF switch



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 want to run on the fluidics station. The partner who provides the assay determines the assay type and provides the relevant documentation in the form of a package insert or other type of document.

Each assay package insert, or assay document, describes the fluidics station configuration requirements for that assay. The system ensures 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. AMDS locates 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 selected the correct test request

b. A “double good” sound that indicates that the barcode reader confirms a valid association between the test request and the fluidics module.

c. A “bad” sound that indicates that the barcode reader detects an error. Check the Device Status and Alerts panes for information related to the error.

See the section, *Starting and Shutting Down the System* on page 25 for more information.

See the section, *Scanner Indicator Lights and On/Off Button* on page 106 for information on connecting the barcode reader to the workstation.

Fluidics Station 450Dx Protocols

Each assay software module contains a fluidics protocol which provides processing instructions to the fluidics station. AMDS automatically selects the correct protocol for each test request.

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.3 on page 69.
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. The LCD screen should display the following:

Power-On Done
NOT PRIMED 25°C

4. If you have not done so already, turn on the workstation and log onto AMDS.

Troubleshooting the Fluidics Station Connection to the Workstation

To troubleshoot or test communication between the workstation and fluidics stations:

1. Select **Home** in the Procedure dialog box and click **Perform**.
   The **Confirm Step** dialog box displays.
2. Enter your password and the Event Reason.
3. Click **OK**.
   - AMDS instructs the fluidics station to home the valves.
   - If successful, the LCD on the fluidics station informs you.
   - If homing fails, the Device Status region on a worklist screen alerts you.
   - If you fail after several unsuccessful tries to home the fluidics station, turn off the fluidics station. Then turn the fluidics station back on and restart the AMDS workstation.
   - If these failures continue, call Affymetrix technical support.

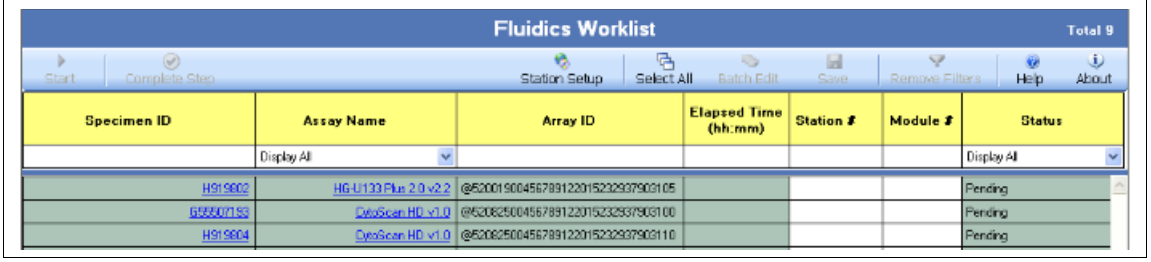
Running a Fluidics Station Protocol

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 75.
3. In the Active Worklist pane click **Fluidics**.

   The Fluidics Worklist displays (Figure A.4 on page 71).

Figure A.4 Fluidics Worklist



4. If you using a barcode reader to associate a test request with a fluidics station and module do the following (See *Using the Barcode Reader with the Fluidics Station* on page 69):
   a. Load the array cartridge into the module washblock. Do not engage the washload until prompted by the fluidics station LCD.
   b. Scan the barcode on the array cartridge.
   c. Scan the barcode on the fluidics station module.
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 on page 72). 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.
6. Select the test request rows that you would like to start processing on the fluidics station. These rows should indicate **Ready** in the Status field.
7. Click **Start** to begin the fluidics protocol.

   The LCD screen **on the fluidics station** and the AMDS Status field in the Fluidics Worklist indicates the status of the protocol as it progresses.
8. Follow the instructions on the fluidics station LCD screen. (See also the section, *Fluidics Station LCD Messages* on page 94 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.

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

- 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 on page 72).

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.

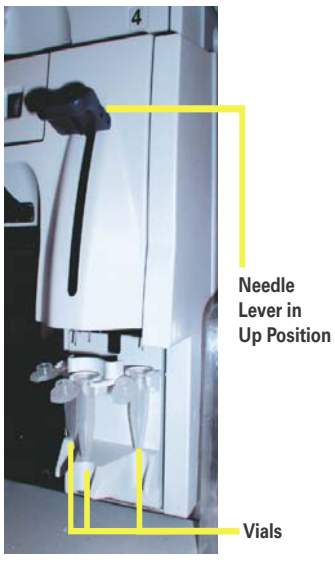
DO NOT FORCE UP THE CARTRIDGE LEVER.

9. 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 on page 73).

Figure A.7 Sample Figure

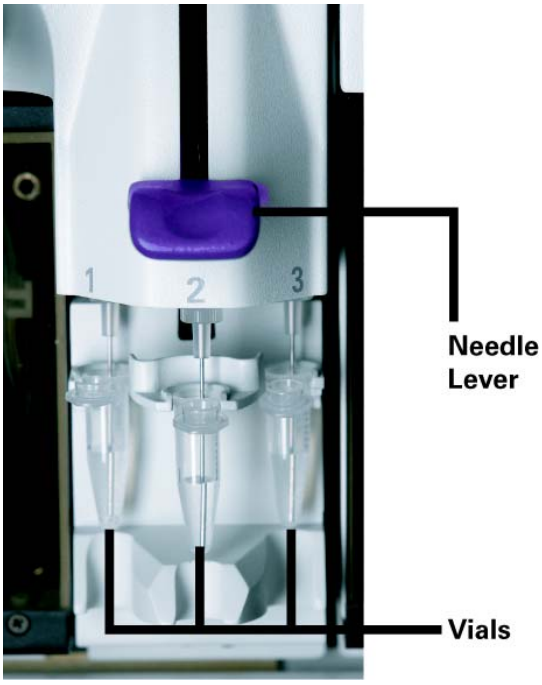


NOTE: When you place the vials into the holders, orient the vial caps toward you so that the vials seat snugly into their respective holders.

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 commences 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 section.

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

EJECT CARTRIDGE

11. Eject and remove the cartridge by pushing down on the cartridge lever. The LCD screen 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 drains the cartridge and then fill it with a fresh volume of the last wash buffer used. When it is finished, if the LCD screen 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.**

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

    The fluidics station automatically performs a Cleanout protocol. The LCD screen indicates the progress of the Cleanout protocol. When the Cleanout protocol is complete, the LCD screen should display the following:

REMOVE VIALS

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

Shutting Down the Fluidics Station

You should perform the Shutdown protocol at the end of a session. Run the shutdown protocol any time you will not use the fluidics station within the next twelve hours.

1. The shutdown protocol requires three 1.5 mL sample vials for each module.
2. Place the wash lines into a bottle filled with deionized water.
3. Run the **Shutdown** protocol and follow the instructions on the LCD screen.
4. 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 78 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 before you can use it to run assay protocols.

You should prime the fluidics station:

- When you first start the fluidics station,
- Before you process a cartridge

- When you change the wash buffers,
- When you change the assay associated with a fluidics station.
- If the LCD screen instructs you to run a prime protocol.

If any alert instructs you to run a prime protocol.

To prime the fluidics station:

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.9 on page 74).
3. In the Active Worklist pane, click **Fluidics** (Figure A.10 on page 76).

Figure A.10 Fluidics Button

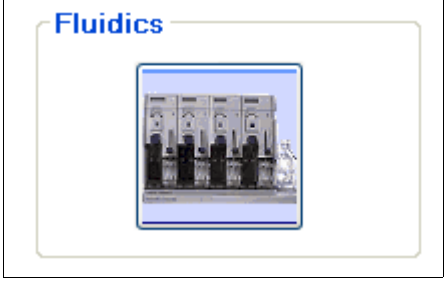
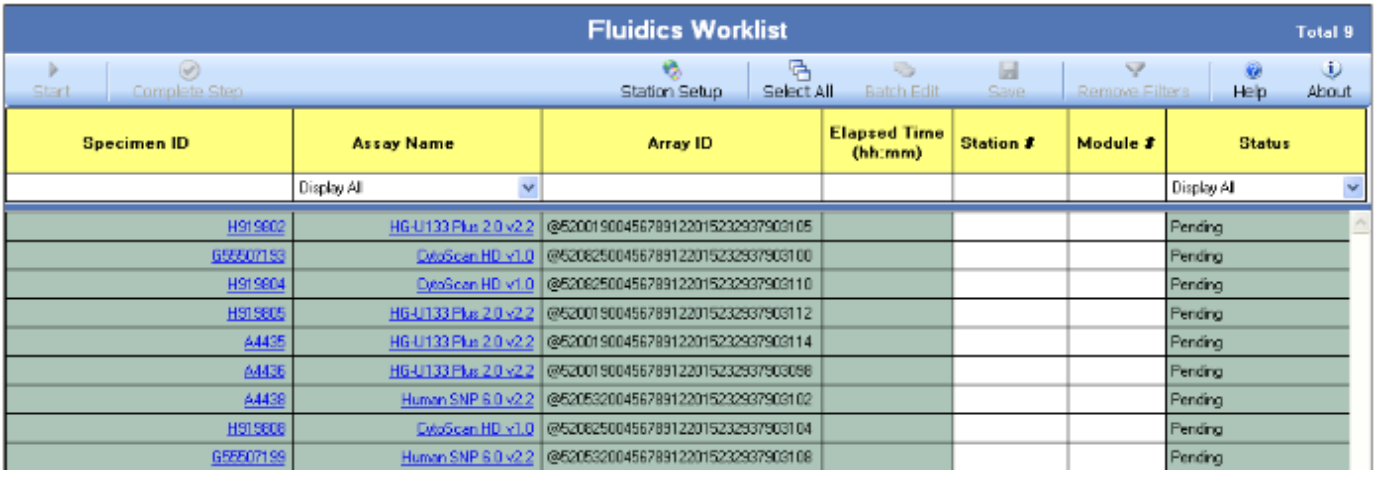


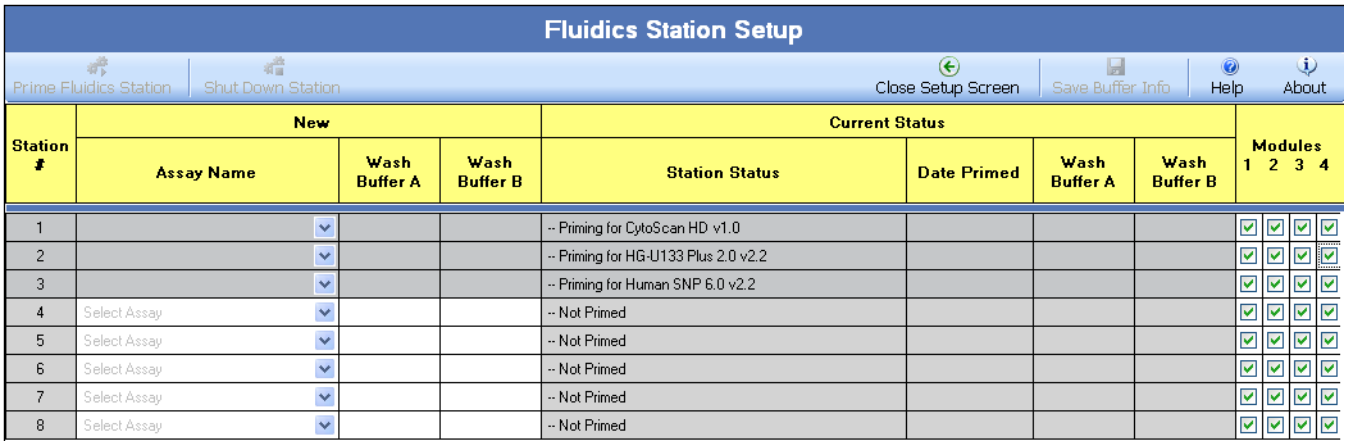
Figure A.11 The Fluidics Worklist



The Fluidics Worklist displays (Figure A.11 on page 76).

4. Click **Station Setup**.
   The Fluidics Station Setup widow displays (Figure A.12 on page 77).

Figure A.12 The Fluidics Station Setup screen



5. In the Fluidics Station Setup screen, select:
   - The Station #
   - The Assay to be primed from the drop-down
6. Highlight the stations to be primed.

   This step enables the **Prime Station** button on the toolbar.
7. Click **Prime Station**.

   The status field displays the priming message (Figure A.12 on page 77).
8. Follow the instructions in the LCD screen **on the fluidics station** as the prime protocol progresses. The LCD screen on the fluidics station and the fluidics station dialog box 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

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

Instrument Care

- Disconnect the power cord of Fluidics Station before replacing fuses.
- 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 prevents 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 protects 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 Fluidics Stations* on page 53.

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.13 on page 78).

Figure A.13 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 solution and a one liter bottle of DI water. Insert the waste line into the waste bottle (Figure A.14 on page 79).
4. Immerse all three wash and water lines of the fluidics station into the 500 mL of bleach solution (Figure A.14 on page 79). **DO NOT IMMERSE THE WASTE LINE INTO THE BLEACH.**

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

Figure A.14 Immerse the tubes into the 0.525% sodium hypochlorite solution. The waste line remains in the waste bottle.

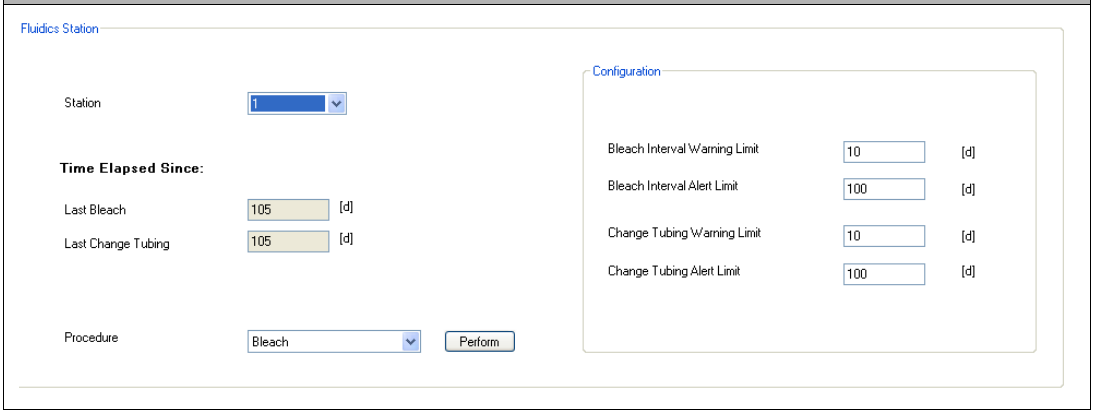
5. Click the **System Management** button (Figure A.15 on page 80) on the Administrator pane.

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

Figure A.15 Sample Figure

6. The System Management screen displays. The User Performed Service screen should be the default screen. If not, select **In-House Service** > **User Service**. The User Performed Service screen displays. Note the fluidics station maintenance area (Figure A.16 on page 80).

Figure A.16 Sample Figure



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

   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.

Figure A.17 Press down on the needle levers to start the bleach protocol

10. The fluidics station begins the protocol and begins to empty the lines and perform the cleaning cycles using bleach solution.
11. 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.18 on page 82). At this step, you need not be concerned regarding the bleach that remains in the lines.

Figure A.18 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 empties the lines and rinses 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 fluidics station 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 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 Fluidics Stations* on page 53.

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. Click the **System Management** (Figure A.19) button on the Administrator pane.

Figure A.19 The Administrator Pane

2. The System Management screen displays. The User Performed Service screen should be the default screen. If not, select **In-House Service** > **User Service**. The User Performed Service screen displays. Note the fluidics station maintenance area (Figure A.20).

Figure A.20 The user maintenance functions for the fluidics station

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

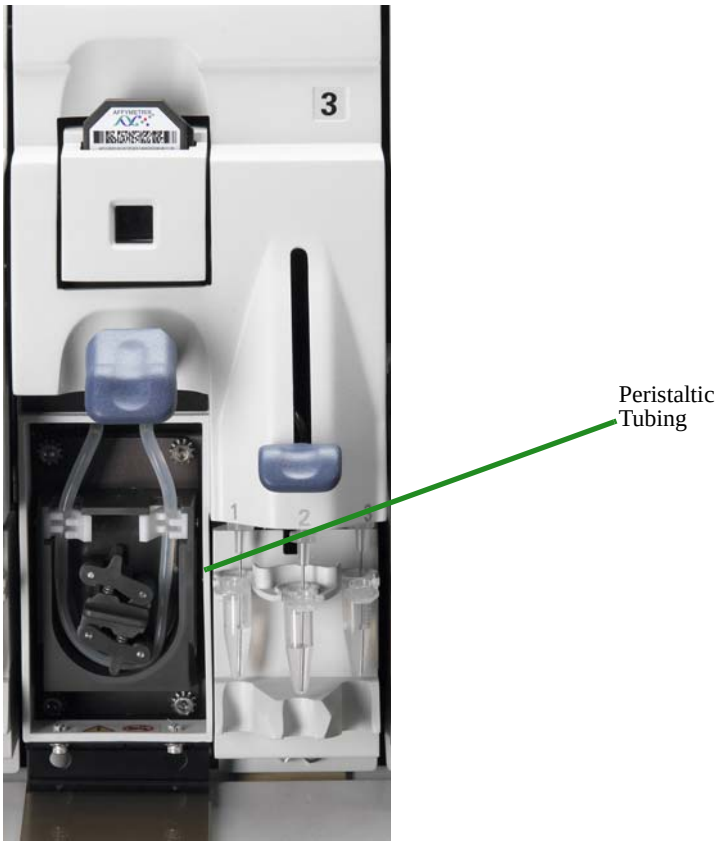
   The Confirm Step dialog box opens. Enter your password and event reason.

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

Replacing the Peristaltic Tubing Procedure

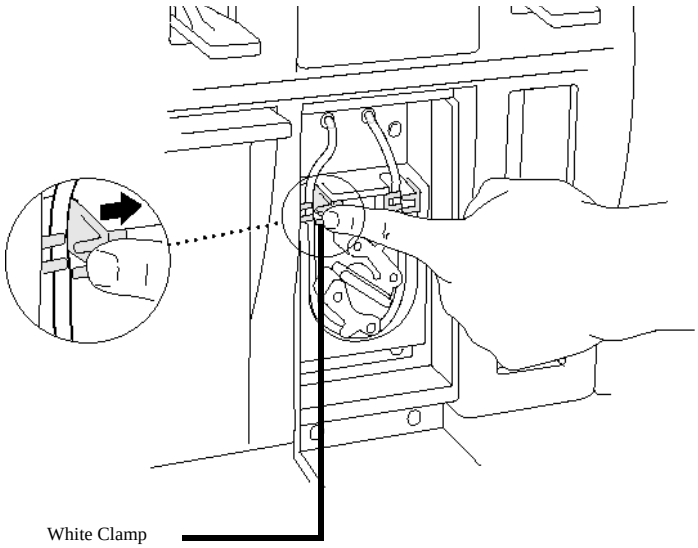
1. Open the module door. See Figure A.21 on page 85 (component number 2) and Figure A.22.

Figure A.21 Module door open showing peristaltic tubing



2. Open the white clamps to release tubing on both sides. See Figure A.21.

Figure A.22 releasing the peristaltic tubing



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.**

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.23 and Figure A.24) show you how to begin troubleshooting the fluidics station for a Missing Fluid Error (MFE).

Figure A.23 Troubleshooting decision tree, page 1

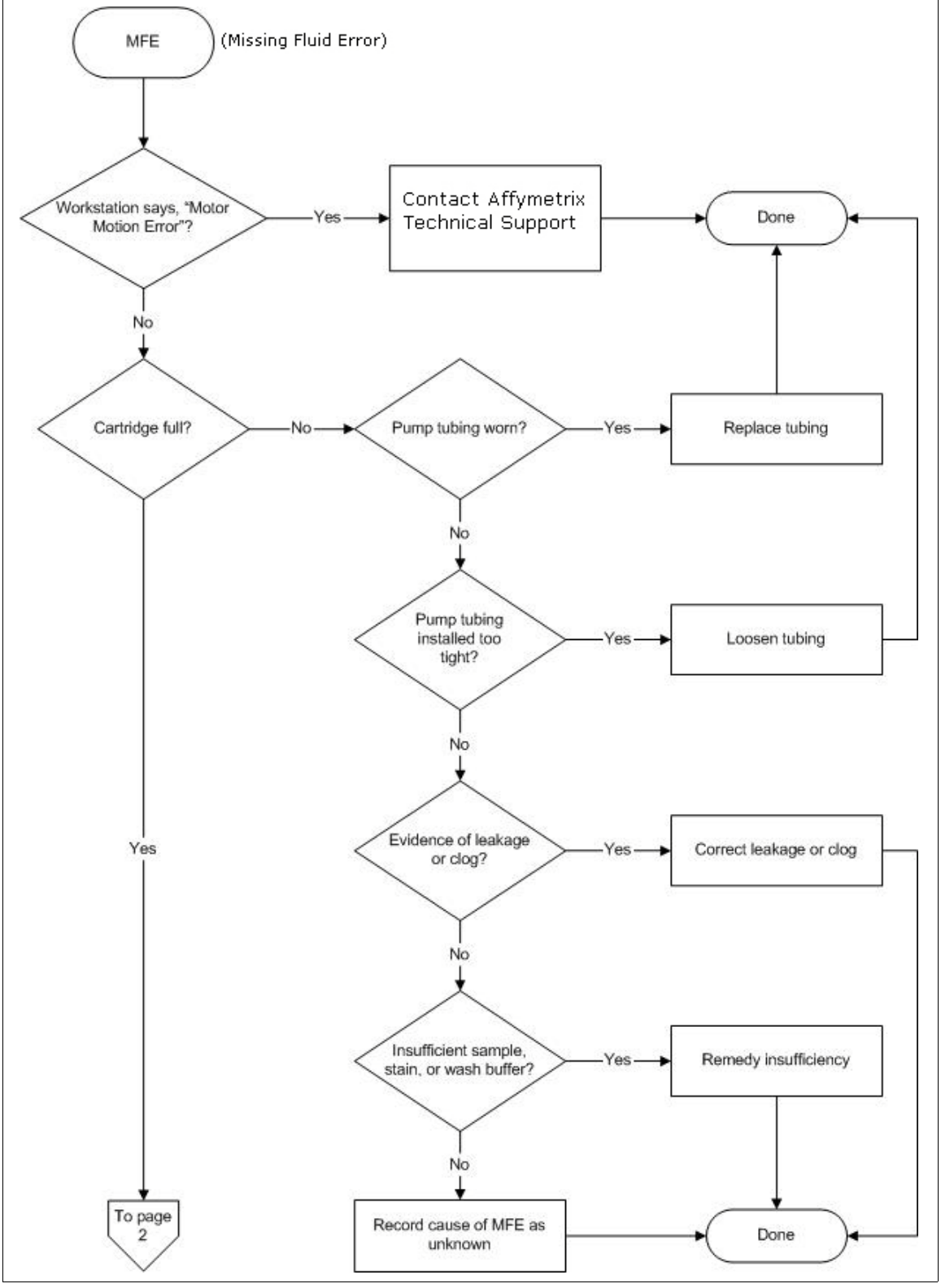
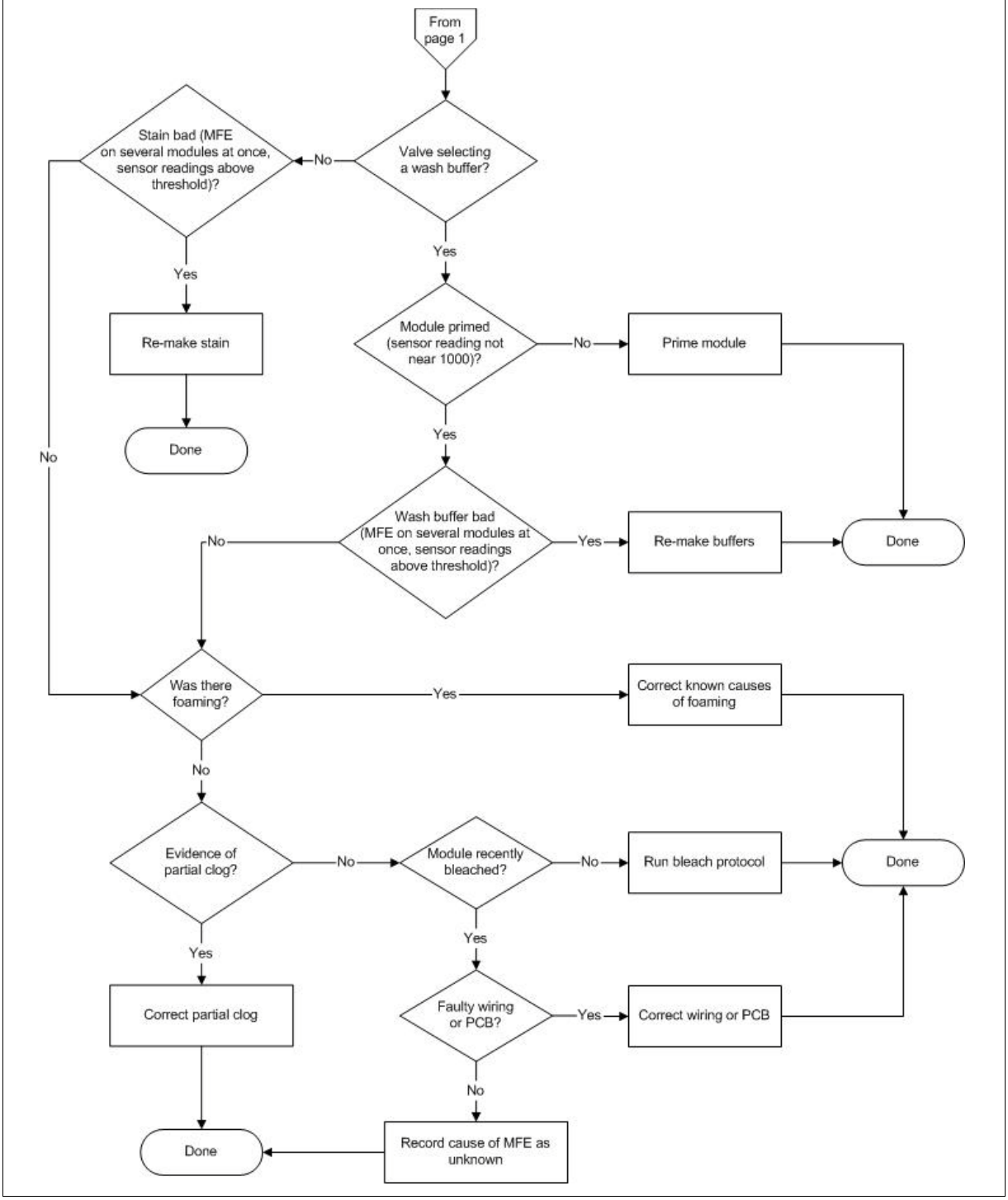


Figure A.24 Troubleshooting decision tree, page 2



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 screen on the alert pane.

Table A.2 Problems and Solutions

Error Message	Problem	Possible Cause	Possible Solution (Follow the recommended resolution in the current Worklist screen on the alert pane.)
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. Sample or staining solution not in place properly.	In the current Worklist screen on the alert pane, follow the recommended resolution. In the current Worklist screen on the alert pane, follow the recommended resolution. Make sure sample or stain vial is in the sample holder. In the current Worklist screen on the alert pane, 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 screen on the alert pane, follow the recommended resolution. You may need to loosen the tubing clamps, allow tubing to relax, close the clamps.
		Insufficient volume of sample or staining solution (500 µL). Blocked sampling tube or line of the fluidics station.	In the current Worklist screen on the alert pane, follow the recommended resolution. You may need to run a **Shutdown** 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 screen on the alert pane, 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 screen on the alert pane.)
Missing Fluid Error (continued)	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.	Turn fluidics station power on, and then try to connect again.
		Loose cables.	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 screen on the alert pane, follow the recommended resolution.
Error While Draining **Error While Filling**	Cartridge is not filling or draining properly.	Defective septa in cartridge.	In the current Worklist screen on the alert pane, follow the recommended resolution. You may need to use a new cartridge.
		Insufficient sample or stain volume.	Add more sample solution to sample vial.
		Excessive bubbling in cartridge.	Change the buffer, reduce detergent
		Buffer conductivity too low.	Use fresh buffer
		Failure of one of the fluid sensors.	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 screen on the alert pane, 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 screen on the alert pane.)
Invalid Command	Communication error detected Note where in protocol error occurred.		In the current Worklist screen on the alert pane, follow the recommended resolution. You may need to: Identify if chip is filled. Contact Affymetrix for service.
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.
Valve Motion Error			In the current Worklist screen on the alert pane, follow the recommended resolution. If problem persists, contact Affymetrix for service.
Valve Not Homed			In the current Worklist screen on the alert pane, follow the recommended resolution. If problem persists, contact Affymetrix for service.
Valve Out of Position			In the current Worklist screen on the alert pane, 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 screen on the alert pane.

Table A.3 Error Messages

Error Message	Meaning (Follow the recommended resolution in the current Worklist screen on the alert pane.)
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.
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 screen on the alert pane.

IMPORTANT: NEVER run the prime script with anything but the correct buffers.

Table A.4 Other Problems and Solutions

Problem	Possible Cause	Possible Solution (Follow the recommended resolution on the alerts pane.)
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. Washblock requires replacement. Salt buildup in the lines of the fluidics station.	Call Affymetrix technical support for service. Call Affymetrix technical support for service. Run the **Shutdown** 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. Extra flashing on the cartridge. Salt buildup on the cartridge needles. Cartridge holder aligned and attached to the fluidics station improperly. Cartridge holder not properly engaged to the fluidics station.	Use another cartridge. Use another cartridge, or call Affymetrix technical support for service. Run the **Shutdown** script with fresh DI water to flush out salt blockage. Clean cartridge needles with a wet cotton swab. Call Affymetrix technical support for service. Place the cartridge into the cartridge holder. Push the holder door shut, and firmly lift the lever to engage the cartridge needles.
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.

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.

Fluidics Station 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.
Draw 2nd Stain	Empty, draw sample to both sensors.
Draw 3rd Stain	Empty, draw sample to both sensors.

Table A.5 LDC Messages (Continued)

Message	Meaning
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.
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.
3420 Central Expressway
Santa Clara, CA 95051

Declare under sole responsibility that the Affymetrix® Fluidics Station model FS450Dx v.2 conforms to the relevant provisions of the following standards of safety & 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 managements systems - requirements for regulatory purposes

Electromagnetic Compatibility (EMC) Directive 2004/108/EC:

EN 61326-1, 2006	Electrical equipment for measurement, control, and laboratory use – EMC requirements
EN 55011: 2007; Amendment A2: 2007	Class A Radiated and Conducted Emissions
EN 61000-4-2: 1995; Amendment 2: 2001	Electrostatic Discharge
EN 61000-4-3: 2006; Amendment 1: 2008	Radiated Immunity
EN 61000-4-4: 2004	Electrical Fast Transient / Burst Immunity
EN 61000-4-5: 2006	Surge Immunity
EN 61000-4-6: 2007	Conducted Immunity
EN 61000-4-8: 1993; Amendment 1: 2001	Magnetic Field Immunity
EN 61000-4-11: 2004	Voltage Dips and Interrupts
EN 61000-3-2: 2006	Class A Harmonic Current Emissions
EN 61000-3-3: 1995, Amendment 2: 2006	Limits; Voltage Changes, Fluctuations, and Flicker

EU Low Voltage Directive 2006/95/EC:

IEC 61010-1: 2001	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
IEC 61010-2-101/A1: 2003	Safety requirements for electrical equipments for measurement, control and laboratory use. Particular requirements for in vitro diagnostic medical equipment
EN 61010-1: 2001	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements

EN 61010-2-081/A1: 2003	Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
EN 61010-2-101: 2002	Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for in vitro diagnostic (IVD) medical equipment
UL 61010-1/R: 2005-07	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
CAN/CSA C22.2 No. 61010-1:2004	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
CAN/CSA C22.2 No. 61010-2-101: 2004	Safety requirements for electrical equipments for measurement, control and laboratory use. Particular requirements for in vitro diagnostic medical equipment
CAN/CSA C22.2 No.61010-2-081: 2004	Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes

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* 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
Internal Power Supplies	X	O	X	O	O	O
Motors and Pumps	O	O	O	O	O	O

**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

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 有毒有害物质或元素名称及含量* 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
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
马达和喇叭	O	O	O	O	O	O

*X：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。

O：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

GeneChip® Scanner 3000Dx with AutoLoaderDx

Introduction

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

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

Figure B.1 GeneChip® Scanner 3000Dx with AutoLoaderDx

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

WARNING: ONLY authorized personnel may service this equipment. The GCS3000 Scanner contains an incorporated Class 3B laser. Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

WARNING: The GCS3000 Scanner contains an incorporated Class 3B laser with the following specifications: Wavelength = 532nm +/- 1 nm; Beam Divergence (full angle) = <8mrad; Output Duration = Continuous Wave; Maximum Power Output = 500mW.

Safe Operation

To ensure safe operation of the scanner:

IMPORTANT: Shutting down the scanner: 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 scanner.

- 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 scanner 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 scanner 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 scanner-workstation. The proper scanner connection is located near the top of the workstation.

CAUTION: This 10/100 Base T Ethernet communications port is dedicated to the scanner-workstation interface. You cannot connect the scanner 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 on page 105 and Figure B.3 on page 106 show the cable connections of the workstation and the AutoLoader. This is for reference only. Affymetrix recommends that only a qualified service engineer attempt to service or change these connections.

Figure B.2 Workstation rear cable connections

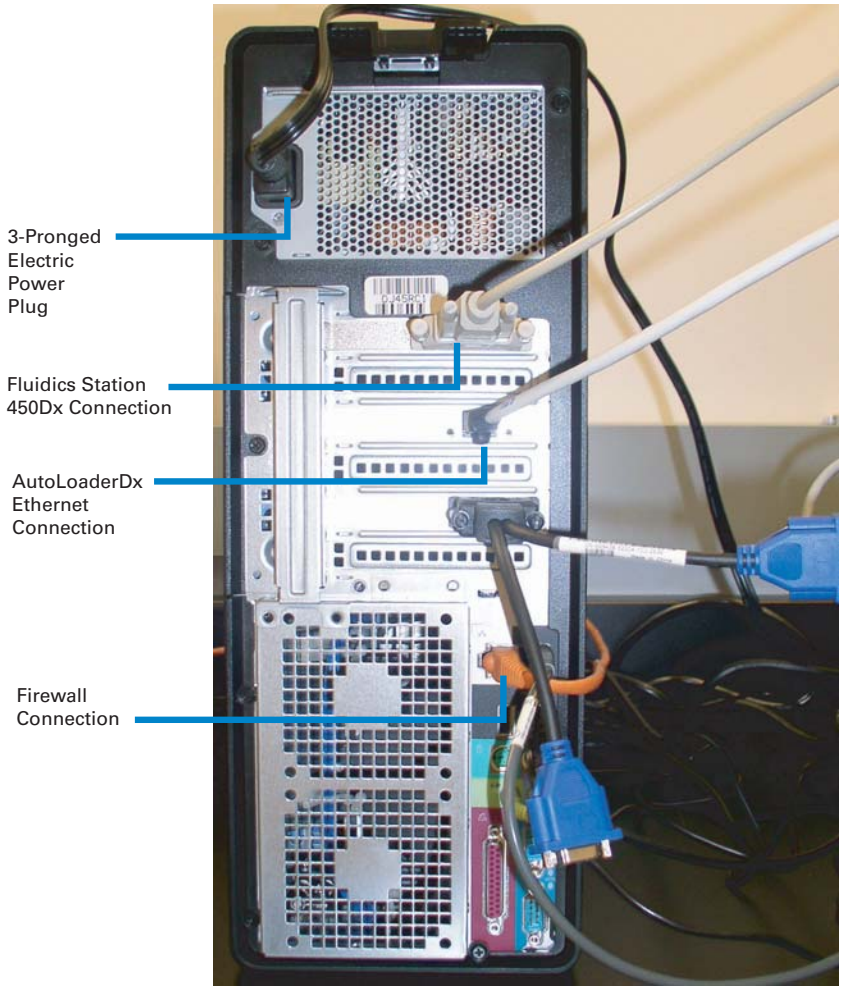
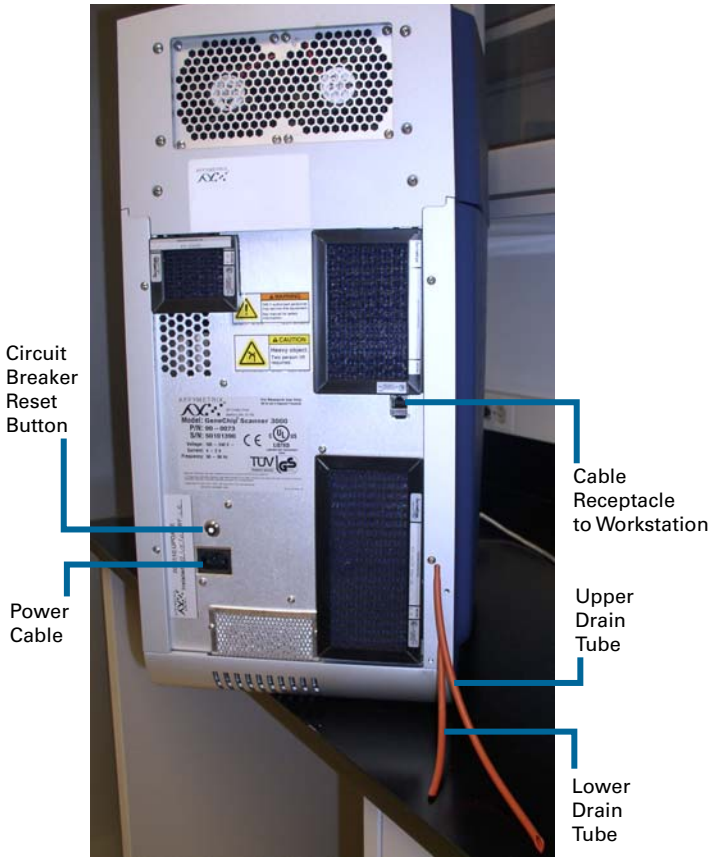


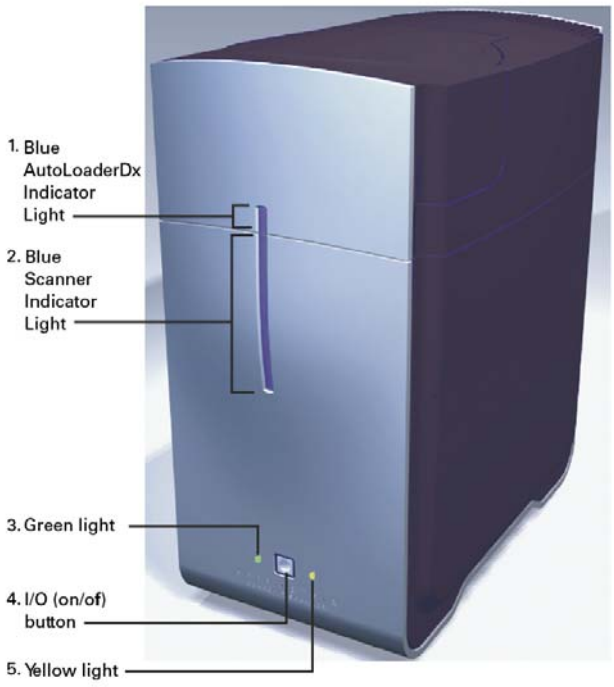
Figure B.3 Scanner Rear Connections



Scanner Indicator Lights and On/Off Button

The front panel has the following button and indicators (Figure B.4 on page 107).

Figure B.4 Scanner Indicator Lights



1. Blue 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. Blue scanner indicator light on the scanner body, running vertical at front center. This light extends to the bottom of the scanner 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

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

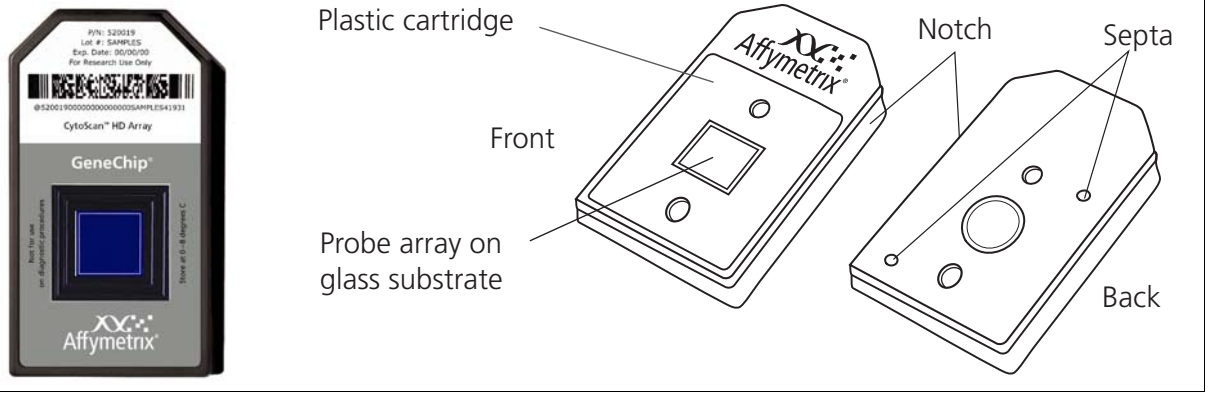
Table B.1 Light colors and meanings

Condition	Green Light	Yellow Light	Blue Scanner Indicator Light	Blue Scanner 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
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 scanner door is unlocked waiting to receive a carousel
Error	Off	Flashing	On	Off	Fatal error, reboot scanner and software, scanner door is unlocked to remove carousel if necessary
Scanning	Flashing	Off	On	On	Scanning is in progress and scanner door locked
Scanning	Flashing	Off	On	Off	Scanning is in progress and scanner 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.5.

Figure B.5 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 scanner, 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 scanner.

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

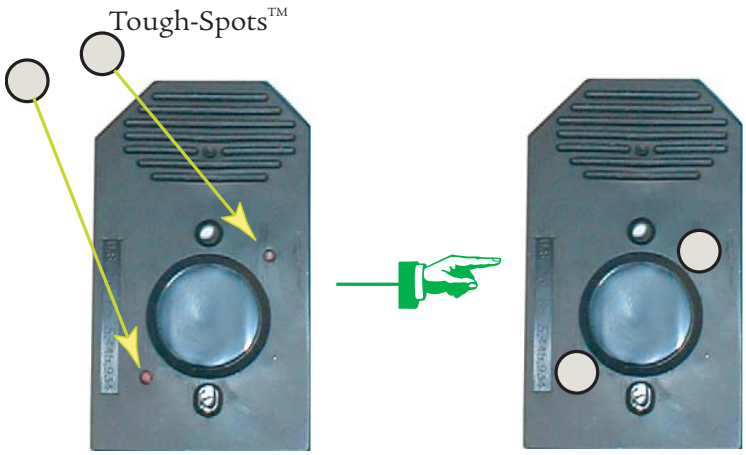
or from

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.6 on page 110).

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.6 on page 110).

Figure B.6 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.7 on page 111).

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

Figure B.7 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.7 on page 111).
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.9 on page 113).

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

Figure B.8 Loading the carousel into the AutoLoaderDx

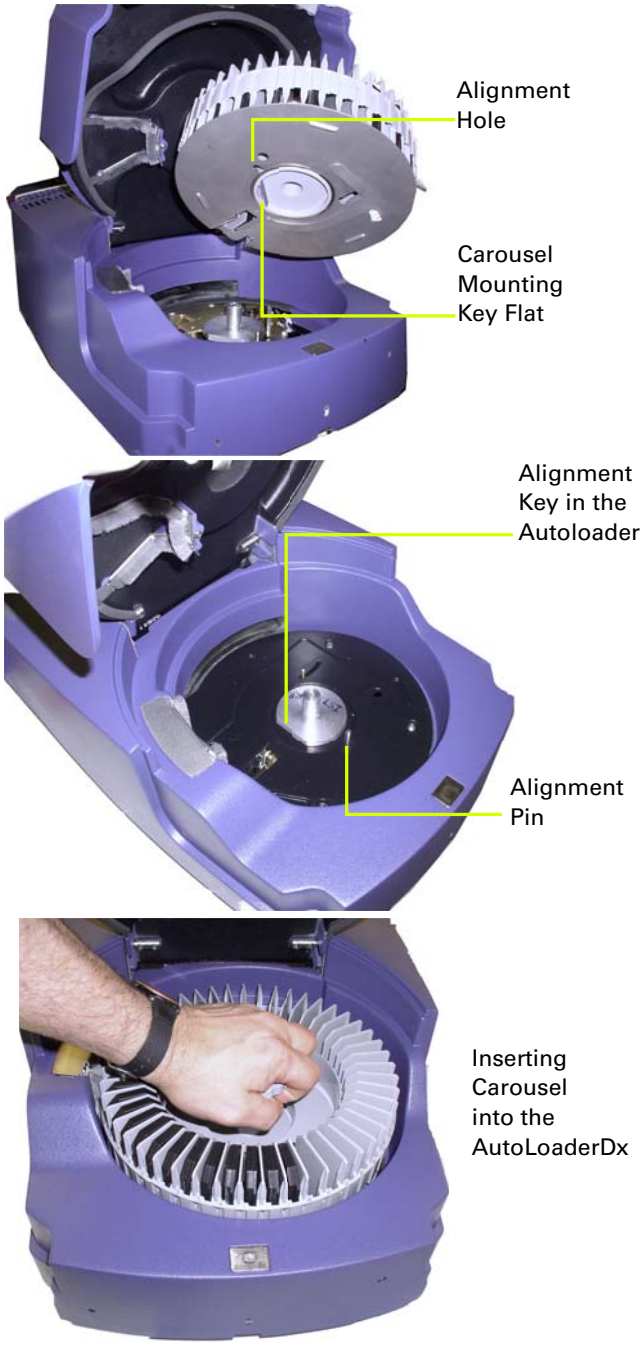


Figure B.9 Inserting and turning the carousel; the carousel should be seated and flush with housing.

Starting the Scanner

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

Shutting Down the Scanner

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.**

Disabling the AutoLoaderDx

If you are having issues with your AutoLoaderDx and need to scan arrays with the AutoLoaderDx disabled, follow these instructions exactly.

To disable the AutoLoaderDx:

1. With the AutoLoaderDx in "ready" state (green light solid, yellow light off), check Disable AutoLoaderDx on the General Configuration screen.
2. Click **Save Changes** button and enter your credentials in the Confirm Step dialog.
3. Click **OK** in the dialog that appears telling you to reboot the scanner.

4. At this time, the AutoLoaderDx status in the Device Status pane should appear as "AutoLoader Mode has changed." Turn the scanner off. Wait one minute, then turn it on again.
5. The scanner will boot up and go through laser warm-up. The connection between the scanner and AMDS should be established soon after laser warm-up starts. When the scanner status in the Device Pane is "AutoLoader Standby," then restart the workstation.
6. Remove the carousel from the AutoLoader, drop an array into the slot, and use Manual Scan from the Scanner Worklist to scan the array. Autofocus should begin about 90 seconds after you click **Manual Scan**.

Cleaning and Maintenance

The scanner 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 damage the exterior surfaces. Clean the carousel by hand using warm water and, if necessary, mild detergent.

The GCS3000Dx v.2 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 Scanner

If you are an administrator, you can configure two scanner functions:

- Set the scanner to turn on and warm up when AMDS launches.
- Disable the AutoLoaderDx so you can continue processing arrays if the AutoLoaderDx fails.

For instructions for these two functions, see *Configuring Scanner Settings* on page 60.

Troubleshooting

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

Troubleshooting the Scanner

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

Table B.2 Scanner 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.
Scanner fails with array inside	Power failure	Manually extract array. Check all connections to scanner. Turn scanner on, restart software.

Issues Relating to Scanner Operation

In using the scanner 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 scanner

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 scanner 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 scanner is on, that communication cables are properly connected. See the section, *Changing System Management Screens* on page 52. Click the **Restart Scanner** button to restart the scanner. You may need to close AMDS and restart screens then restart AMDS. If the system remains unresponsive, disconnect and reconnect power to the scanner, restart the scanner normally, close and restart screens and AMDS.
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.
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 109.

Troubleshooting the Scanner

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

Table B.4 Scanner 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 blue LED is off.	

Table B.4 Scanner Troubleshooting Guide (Continued)

Problem	Possible Cause	Corrective Action
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	
AutoLoaderDx misses next array	Array UP sensor not working, call technical support.	
Stuck array		See the section, *Manually Removing a Lodged Array Cartridge* on page 117
AutoLoaderDx freezes up	Door is open or ajar	
Scanner 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 109.
The array does not descend into scanner.	▪ Carousel not seated correctly ▪ Door is open or ajar ▪ Heater is waiting until array is at temperature.	

Scanner Error Messages

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

Table B.5 Scanner Error Messages

Message	Meaning
HEATER_LOW	"Warning: The warming chamber temperature is low. Refer to the troubleshooting guide."
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 scanner door to ensure that it is not open.
HEATER_HIGH	"Warning: The warming chamber temperature is high. Refer to the troubleshooting guide."

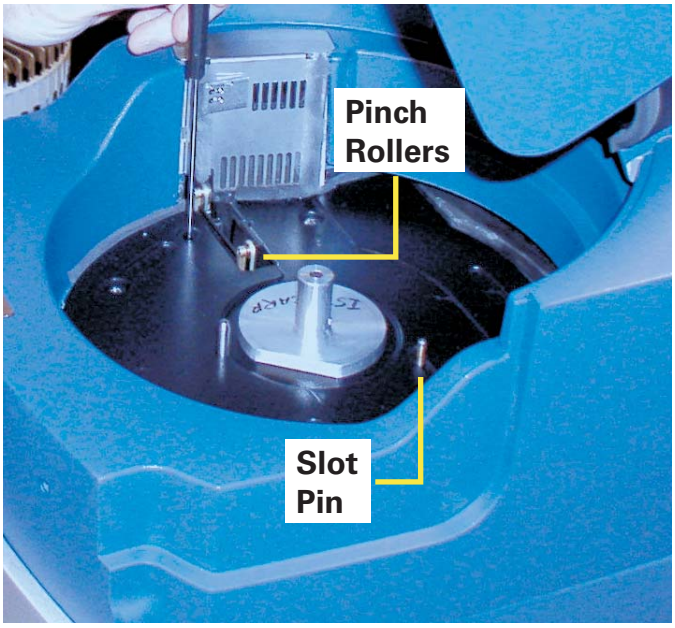
Manually Removing a Lodged Array Cartridge

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

1. Turn the scanner 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 scanner back in and turn it on.

17.Load the carousel after the scanner boots up.

18.If arrays continue to become lodged in the AutoLoaderDx, you should call technical support.

GCS3000Dx Specifications

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

Table B. Item	Table B. Parameter	Table B.9 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 Current Line Frequency.	100 - 240 V ~ 4 - 2 A 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.
3420 Central Expressway
Santa Clara, CA 95051

Declare under sole responsibility that the Affymetrix® GeneChip® Scanner model GCS3000Dx v.2 and its accessory Autoloader Dx conforms to 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 managements systems - requirements for regulatory purposes

Electromagnetic Compatibility (EMC) Directive 2004/108/EC:

EN 61326-1, 2006	Electrical equipment for measurement, control, and laboratory use - EMC requirements
EN 55011: 2007; Amendment A2: 2007 Class A	Radiated and Conducted Emissions
EN 61000-4-2: 1995; Amendment 2: 2001	Electrostatic Discharge
EN 61000-4-3: 2006; Amendment 1: 2008	Radiated Immunity
EN 61000-4-4: 2004	Electrical Fast Transient / Burst Immunity
EN 61000-4-5: 2006	Surge Immunity
EN 61000-4-6: 2007	Conducted Immunity
EN 61000-4-8: 1993; Amendment 1: 2001	Magnetic Field Immunity
EN 61000-4-11: 2004	Voltage Dips and Interrupts
EN 61000-3-2: 2006 Class A	Harmonic Current Emissions
EN 61000-3-3: 1995, Amendment 2: 2006	Limits; Voltage Changes, Fluctuations, and Flicker

EU Low Voltage Directive 2006/95/EC:

EN 60825-2:2004	Safety of laser products. Safety of optical fibre communication systems (OFCS)
IEC 61010-1: 2001	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements

IEC 61010-2-101/A1: 2003	Safety requirements for electrical equipments for measurement, control and laboratory use. Particular requirements for in vitro diagnostic medical equipment
EN 61010-1: 2001	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
EN 61010-2-081/A1: 2003	Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
EN 61010-2-101: 2002	Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for in vitro diagnostic (IVD) medical equipment
UL 61010-1/R: 2005-07	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
CAN/CSA C22.2 No. 61010-1:2004	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
CAN/CSA C22.2 No. 61010-2-101: 2004	Safety requirements for electrical equipments for measurement, control and laboratory use. Particular requirements for in vitro diagnostic medical equipment
CAN/CSA C22.2 No.61010-2-081: 2004	Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes

GCS 3000Dx v.2 GeneChip Instrument System

We,
Affymetrix, Inc.
3420 Central Expressway
Santa Clara, CA 95051

Declare under sole responsibility that the Affymetrix® GeneChip® GCS 3000Dx v.2 GeneChip Instrument System, including the Scanner GCS3000Dx v.2, the AutoloaderDx, the Fluidics Station FS450Dx v.2, and associated Workstations with Affymetrix Molecular Diagnostic Software (AMDS), 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 managements systems - requirements for regulatory purposes

Electromagnetic Compatibility (EMC) Directive 2004/108/EC:

EN 61326-1, 2006	Electrical equipment for measurement, control, and laboratory use - EMC requirements
EN 55011: 2007; Amendment A2: 2007 Class A	Radiated and Conducted Emissions
EN 61000-4-2: 1995; Amendment 2: 2001	Electrostatic Discharge
EN 61000-4-3: 2006; Amendment 1: 2008	Radiated Immunity
EN 61000-4-4: 2004	Electrical Fast Transient / Burst Immunity
EN 61000-4-5: 2006	Surge Immunity
EN 61000-4-6: 2007	Conducted Immunity
EN 61000-4-8: 1993; Amendment 1: 2001	Magnetic Field Immunity
EN 61000-4-11: 2004	Voltage Dips and Interrupts
EN 61000-3-2: 2006 Class A	Harmonic Current Emissions
EN 61000-3-3: 1995, Amendment 2: 2006	Limits; Voltage Changes, Fluctuations, and Flicker

EU Low Voltage Directive 2006/95/EC:

EN 60825-2:2004	Safety of laser products. Safety of optical fibre communication systems (OFCS)
IEC 61010-1: 2001	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
IEC 61010-2-101/A1: 2003	Safety requirements for electrical equipments for measurement, control and laboratory use. Particular requirements for in vitro diagnostic medical equipment

EN 61010-1: 2001	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
EN 61010-2-081/A1: 2003	Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
EN 61010-2-101: 2002	Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for in vitro diagnostic (IVD) medical equipment
UL 61010-1/R: 2005-07	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
CAN/CSA C22.2 No. 61010-1:2004	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
CAN/CSA C22.2 No. 61010-2-101: 2004	Safety requirements for electrical equipments for measurement, control and laboratory use. Particular requirements for in vitro diagnostic medical equipment
CAN/CSA C22.2 No.61010-2-081: 2004	Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes

Regulatory

This device complies with Part 15 of FCC Rules (Table B.10). 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.10 Regulatory Certifications

Regulatory Agency	Certification
CE	
Class I Laser Device	Complies with EN 60825-1:2007 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 60825-1:2007 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.11 and Table B.12 contain information identifying the specific hazardous material(s) and the components/parts in which they are found.

Table B.11 Table Containing Names and Contents of Toxic or Hazardous Materials* Instrument: Affymetrix GeneChip® GCS3000 ScannerDx with 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
Internal Power Supplies	O	O	O	O	O	O
Motors and Pumps	O	O	O	O	O	O

* *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.12 Table Containing Names and Contents of Toxic or Hazardous Materials* 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 Components	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
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

** 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*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
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

*×：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*

仪器：Affymetrix GeneChip GCS3000 ScannerDx

部件名称	铅（Pb）	汞（Mg）	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
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

*×：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

Labeling Symbols

Table B.13 Graphic Symbols for use in Labeling

Symbol / Label	Statement
	Part/Catalog Number
	Lot Number
	Expiration Date YYYY–MM Kit will expire on the last day of the month.
	Temperature Limitation
	Contains Sufficient for < n > Tests
Xi	Irritant
	Hazards
	Consult Instructions for Use
	Manufacturer
	*In vitro* Diagnostic Medical Device
	European Conformity
	Authorized Representative in the European Community

Index