



UserGuide

GeneChip® System 3000Dx v.2

Instrument Operation and Use

 For In Vitro Diagnostic Use. 

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Chapter 1

Introduction

This User Guide gives an overview of the system operation of the GeneChip® System 3000Dx v.2 (GCS 3000Dx v.2) and detailed information for use of the instrument components.

In this chapter:

- *Indications for Use*
- *Instrument Usage Information*
- *Other Documentation*
- *Context-Sensitive Help*
- *Complete Help System*
- *Terminology*
- *Text Alerts*
- *Technical Support*
- *European Representative*

Indications for Use

GCS 3000Dx v.2 is intended to measure fluorescence signals of labeled DNA and RNA targets hybridized to Affymetrix arrays.

Instrument Usage Information

The expected life of the GCS 3000Dx v.2 system is at least 8 years, provided the system is used and maintained according to manufacturer's recommendations. For optimal operational performance, please follow recommended maintenance and service schedules and permit only qualified service personnel to replace parts when required.

Other Documentation

- Affymetrix® Molecular Diagnostic Software (AMDS) User Guide
- Affymetrix® Molecular Diagnostic Software (AMDS) Quick Reference Card
- Tooltip help¹
- Online Help²

Context-Sensitive Help

The Affymetrix® Molecular Diagnostic Software (AMDS) is the operating software for the GCS 3000Dx v.2. The AMDS online help system provides content-sensitive help.

1. Click **Help**.
2. Use the question mark cursor  to click on parts of the window. The help topic associated with the selected area is shown in the lower half of the center panel and includes information about the:
 - Workflow Pane
 - Administrator Pane

¹ To use this feature, place mouse cursor over an interface component to view its description or un-truncate truncated data.

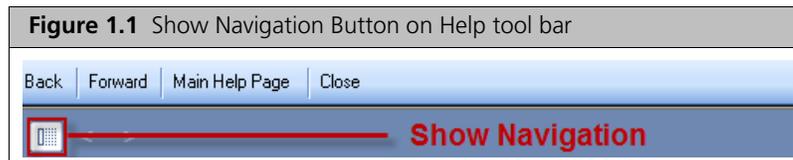
² To access, click:  Help

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

Complete Help System

To view:

1. Click **Help**
2. Click anywhere on the AMDS interface.
3. On the Help toolbar, click **Show Navigation** (Figure 1.1) to see the complete help system.
4. Use the navigation buttons to search for and select help topics.



Terminology

- **Test Request**—Unique record of an assay performed on a specimen. Repeated runs of the same specimen are represented by multiple test requests. Each test request is associated with a specific array cartridge.
- **Assay Software Module (ASM)**—The software package that runs an assay. ASMs are supplied by Affymetrix or authorized partners in the form of a CD.
- **Assay**—Procedure that processes the specimen to produce a result, includes bench work and running through the GCS3000Dx v2 workflow. In this manual, assay refers to the ASM.
- **Array**—A microarray is a glass substrate with oligonucleotide probes. A plastic cartridge surrounds and protects the array and forms the array cartridge. Array also typically refers to the array cartridge.
- **Fluidics station or FS450Dx**—GeneChip® Fluidics Station 450Dx v.2.
- **Scanner**—GeneChip® Scanner 3000Dx v.2 with AutoLoaderDx v.2.

Text Alerts

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

 **NOTE:** Information that may be of interest or of help to a user but is not critical to the primary purpose of the text.

 **IMPORTANT:** Information that is essential to the successful use of a product or the completion of a procedure and is not safety related.

 **CAUTION:** An alert to the user of hazards that, if not avoided, can cause minor or moderate personal bodily injury and/or damage to an instrument or loss of data.

 **WARNING:** Alerts the user to hazards that, if not avoided, can cause serious bodily injury or death, or produce potentially incorrect data that could cause harm to a patient.

 **DANGER:** Dangers alert the user to an imminent hazard that, if not avoided, will cause serious bodily injury or death, or will produce a result that could cause serious harm to a patient.

Technical Support

Consult this user manual and online help and review the troubleshooting sections before you contact Affymetrix technical support for unresolved issues.

For problems with the fluidics station or scanner, especially under any of the following conditions, **unplug the instrument** from the power source and contact Affymetrix technical support.

- Power cord is damaged or frayed
- The instrument does not perform to the specifications in *Table 4.5 on page 49* after service or calibration.

For complete contact information and specific regional support contact information, go to www.affymetrix.com/browse/contactUs.jsp. Have the model and serial number available when you call technical support.

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Chapter 2

System Overview

The GeneChip® System 3000Dx v.2 (GCS 3000Dx v.2) consists of hardware and software components for processing microarrays based on assay parameters. The Affymetrix Molecular Diagnostic Software (AMDS) manages assay workflows.

In this chapter:

- *Hardware*
- *Software*
- *AMDS User Interface*

Hardware

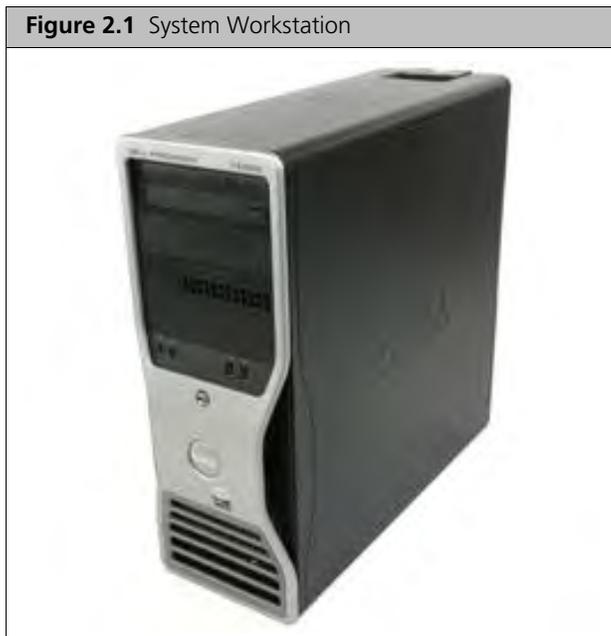
Standard Hardware Components

The GCS 3000Dx v.2 comes with these standard hardware components:

- System Workstation
- GeneChip® Fluidics Station 450Dx v.2 (fluidics station)
- GeneChip® Scanner 3000Dx v.2 (scanner) with AutoLoaderDx v.2
- Barcode Reader
- Hardware Firewall

System Workstation, Monitor, and Soundbar

Figure 2.1 System Workstation



AMDS is loaded on the workstation (Figure 2.1). It provides the hardware interface to other system components. Because the workstation is a dedicated system, it is locked down to prevent other uses. A monitor and soundbar (not pictured) are part of the workstation system.

Fluidics Station 450Dx v.2

Figure 2.2 Fluidics Station 450Dx v.2



The Fluidics Station 450Dx v.2 (Figure 2.2) consists of four modules installed in a single housing. Each module holds a single array and performs the hybridization, washing, and staining functions for that array. Up to eight stations can communicate with one system workstation.

Each module controls the addition of target and staining fluids to the array cartridge and array washing. Each module contains a pump, valve, thermo-electric system, and LCD that are controlled by scripts provided in the Assay Software Module (ASM). These scripts are automatically downloaded to each module and stored in its electronic memory.

Scanner 3000Dx v.2 with AutoLoaderDx v.2

Figure 2.3 Scanner 3000Dx v.2 with AutoLoaderDx v.2



The Scanner 3000Dx v.2 with AutoLoaderDx v.2 (Figure 2.3) is a wide-field, epifluorescent, confocal, scanning laser microscope. It scans the chip after staining on the Fluidics Station 450Dx v.2. Array cartridges are loaded into the scanner by the AutoLoaderDx v.2 (an automatic handler) before scanning and returned to the AutoLoaderDx v.2 when scanning finishes.

Barcode Reader

Figure 2.4 Barcode Reader



The barcode reader (Figure 2.4) is used to enter barcode-encoded information from:

- Array cartridge
- Fluidics station
- Specimen identification
- Reagent lot number
- Other identification information

Hardware Firewall

Figure 2.5 Hardware Firewall



The hardware firewall (Figure 2.5) protects against unauthorized access to the workstation. It is a required component of the system.

Optional Hardware Components

Additional components are:

- Uninterruptible power supply (UPS)
- Printer

Contact Affymetrix for optional hardware requirements.

Optional Hybridization Oven

Depending on the type of assay, you may need a hybridization oven to prepare arrays for testing. Requirements for a hybridization oven that connects to AMDS are:

Input Voltage	100–120 VAC, 5 A maximum or 220–240 VAC, 2.5 A maximum 50–60 Hz
Rotisserie Rotation Speed	10–80 RPM, programmable to 1 RPM
Oven Temperature Set Point Programmable Range	30–70 °C, programmable to 0.1°C
Time to Temperature	30 minutes from ambient to 60°C
Oven Temperature Accuracy	±1.0°C from 35–60°C
Communications	Nine-pin RS-232 port, 9600 Baud rate Monitors and reports oven temperature, rotisserie rotation rate, and oven status

Requirements for a hybridization oven that does not connect to AMDS are:

Input Voltage	100–120 VAC, 5 A maximum or 220–240 VAC, 2.5 A maximum 50–60 Hz
---------------	--

Rotisserie Rotation Speed	10–80 RPM, programmable to 1 RPM
Oven Temperature Set Point Programmable Range	30–70°C, programmable to 0.1°C
Time to Temperature	30 minutes from ambient to 60°C
Oven Temperature Accuracy	±1.0°C from 35–60°C
Communications	NA

Software

There are two types of software:

- Affymetrix® Molecular Diagnostic Software (AMDS)
- Assay Software Modules (ASM)

AMDS

AMDS is the user interface for the system. It provides control of the instruments, assay workflow, and the data collection and management processes. When array scanning finishes, data is passed through AMDS to the ASM. Alternatively, AMDS transfers the data to a network location for downstream analysis. AMDS also assists you in installing and deactivating an ASM.

AMDS tools:

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

ASM

ASMs provide the necessary parameters for processing an array through its entire workflow. ASMs contain the algorithms and reporting functions to produce the clinical result specific to that ASM. ASM user manuals give detailed instructions that are unique to specific assays.



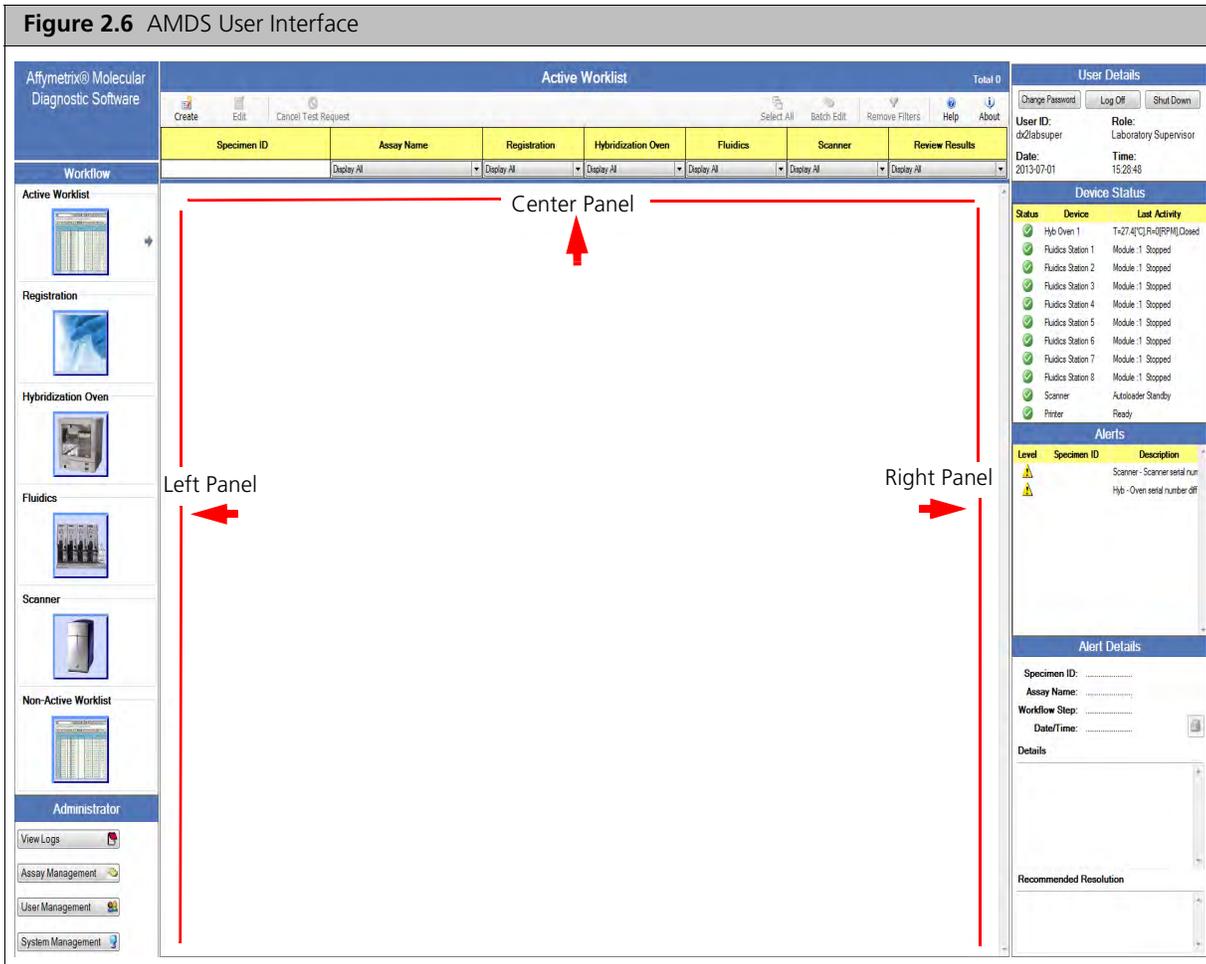
NOTE: For ASMs that allow auto-transfer of data, AMDS auto-transfers data (including DAT and CEL files) to your network where it is available for downstream analysis. Your network location must have ample storage and the correct access permissions for this auto-transfer feature to work.

AMDS User Interface

The AMDS user interface consists of three sections (Figure 2.6):

- **Left Panel**—Workflow and Administration panes
- **Center Panel**—Gives information based on your selection in the left pane; also shows online help when selected
- **Right Panel**—User Details, Device Status, Alert, and Alert Details panes

Figure 2.6 AMDS User Interface



Workflow Pane

Buttons are:

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

When you select an item, the associated worklist opens in the center panel. A blue arrow next to the selected item shows that it has been selected.

Active Worklist

A test request is active until processing finishes or it is canceled. While a test request is active, you can view its status by clicking **Active Worklist**. Data associated with a test request appear only on the Active Worklist and the current workflow stage of the test request. Active Worklist enables you to:

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

You cannot edit information in the Active Worklist. This worklist is maintained and updated by AMDS.

Registration Worklist

The Registration Worklist is the next step in the workflow. This step allows you to associate a test request with an array cartridge and adds the target preparation reagent kit lot numbers (if these are supported by the ASM).

Hybridization Oven Worklist

The Hybridization Worklist step allows you to enter oven hybridization data and processes the array in the hybridization oven.

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

Fluidics Worklist

The Fluidics step allows you to associate a test request with a fluidics station and module and runs the associated fluidics script. The selected station and module wash and stain the array.

Scanner Worklist

The Scanner selection opens the Scanner Worklist. AMDS automates control of the scanner and uses the assay information provided by the ASM to manage the scanner settings for each type of array. After scanning, AMDS automatically grids the image, computes intensities, and either runs an ASM-specific analysis algorithm to generate a result or transfers the files to data storage.

Non-Active Worklist

The Non-Active Worklist selection shows non-active test requests. The system moves test requests to the Non-Active Worklist when processing in AMDS finishes.

Administrator Pane

The Administrator Pane ([Figure 2.7](#)) is below the Workflow Pane. It is visible to everyone, but only Laboratory Supervisors and System Maintainers use it.



User and System Information Panes

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

User Details Pane

The User Details pane ([Figure 2.8](#)) is in the top portion of the right panel. Here you can:

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

- Shut down the system



Device Status Pane

The Device Status pane is just below the User Details pane (Figure 2.9).

Figure 2.9 Device Status Pane

The screenshot shows a 'Device Status' pane with a blue header. Below the header is a table with three columns: 'Status', 'Device', and 'Last Activity'. All status icons are green, indicating normal operation.

Status	Device	Last Activity
✓	Hyb Oven 1	T=27.4[°C],R=0[RPM],Closed
✓	Fluidics Station 1	Module :1 Stopped
✓	Fluidics Station 2	Module :1 Stopped
✓	Fluidics Station 3	Module :1 Stopped
✓	Fluidics Station 4	Module :1 Stopped
✓	Fluidics Station 5	Module :1 Stopped
✓	Fluidics Station 6	Module :1 Stopped
✓	Fluidics Station 7	Module :1 Stopped
✓	Fluidics Station 8	Module :1 Stopped
✓	Scanner	Autoloader Standby
✓	Printer	Ready

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

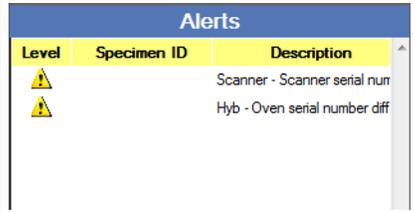
- **Green**—Device is operating normally
- **Yellow**—Abnormal condition detected
- **Red**—Communications issue or a device failure

AMDS provides status for the fluidics station, scanner, and printer, and for hybridization oven, only if connected.

Alert and Alert Details Panes

The Alert pane (Figure 2.10) provides alerts if a component or process is not operating as expected.

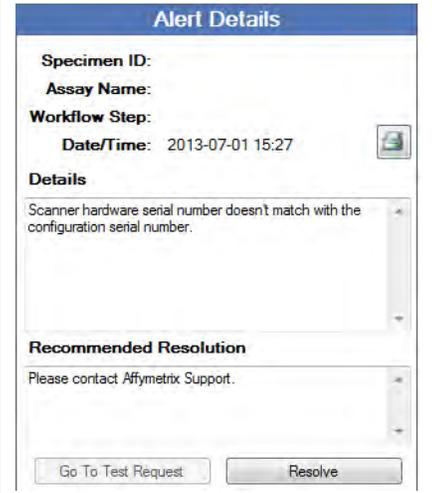
Figure 2.10 Alerts panes



Level	Specimen ID	Description
⚠		Scanner - Scanner serial num
⚠		Hyb - Oven serial number diff

When you click on an alert in this pane, information about the alert is shown in the Alert Details pane (Figure 2.11).

Figure 2.11 Alerts Details panes



Alert Details

Specimen ID:

Assay Name:

Workflow Step:

Date/Time: 2013-07-01 15:27

Details

Scanner hardware serial number doesn't match with the configuration serial number.

Recommended Resolution

Please contact Affymetrix Support.

Go To Test Request Resolve

Alert information may contain:

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

Chapter 3

System Operation Basics

In this chapter:

- *Before you Begin*
- *Start and Shut Down the System*
- *Change Password*
- *Using the Barcode Reader*
- *Edit Multiple Fields in AMDS*
- *How to Hold Array Cartridges*
- *E-Signatures*

Before you Begin

Read this entire manual and familiarize yourself with the instrument, software, and procedure.

Start and Shut Down the System

Start the Workstation

Turn on the computer workstation to launch the Affymetrix® Molecular Diagnostic Software (AMDS). AMDS performs:

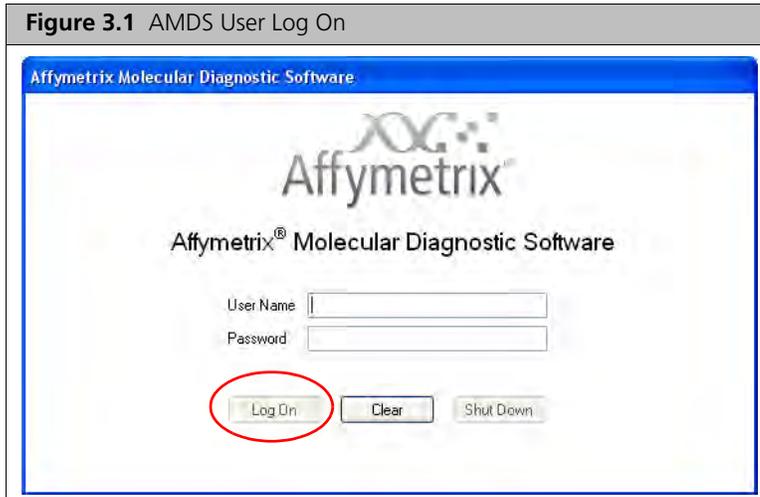
- A system self-test to confirm the operational status of the system and ensure that all components are connected and operating correctly
- Housekeeping tasks to ensure that all test requests are in known states and can be processed

When AMDS completes the self-test, the AMDS User Logon window opens.

Log onto AMDS

1. Obtain your User Name and Password from your Affymetrix service engineer or your system administrator.
2. Login ([Figure 3.1](#)):
 - A. Enter your **User Name**.
 - B. Enter your **Password**.

- c. Click Log On.



AMDS authenticates your credentials and provides functionality based on your user role.

Start the GeneChip® Fluidics Station 450Dx v.2 and Scanner 3000Dx v.2

When your test requests have reached the associated worklists, turn on the fluidics station and scanner. Scanner laser takes about 10 minutes to warm up.

▲ WARNING:  Laser in use during scanning.

! IMPORTANT: To preserve the lifetime of the scanner laser, turn off the scanner when it is not in use for an extended period of time, such as overnight or a weekend.

CAUTION: AutoLoaderDx v.2 carousel is in motion during start-up sequence.

Log Off

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

1. Go to User Details pane (Figure 3.2)



2. Click Log Off.

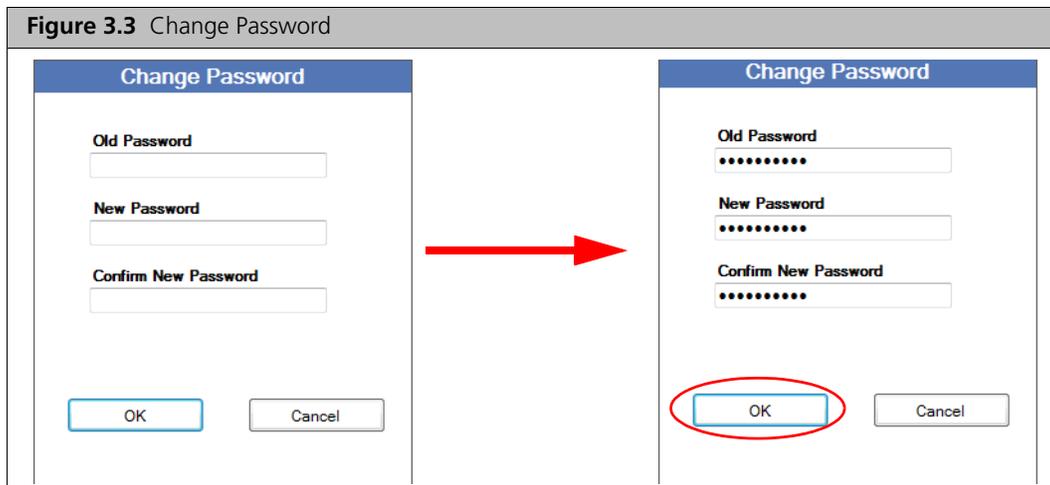
Shut Down

1. Go to User Details pane.
2. Click Shut Down.
3. Turn off instrumentation.

! **IMPORTANT:** If there are test requests in progress, a confirmation dialog box opens. Click Yes to initiate an orderly shutdown of the system. All tests requests that are "In Progress" go into an error state and must be re-run.

Change Password

1. Go to User Details pane.
2. Click Change Password.
3. In the Change Password dialog box, enter your old password [Appendix 3](#).



4. Enter and confirm your new password.
5. Click OK.

Using the Barcode Reader

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

Edit Multiple Fields in AMDS

Contiguous Select and Enter

1. Click on first row of your selection.
2. Press and hold Shift key.
3. Click on last row of your selection.
4. Press and hold Ctrl key and:
 - Select from drop-down in last row

or

- Click in field in last row and scan barcode

or

- Click in field in the last row, release the **Ctrl** key, and enter value

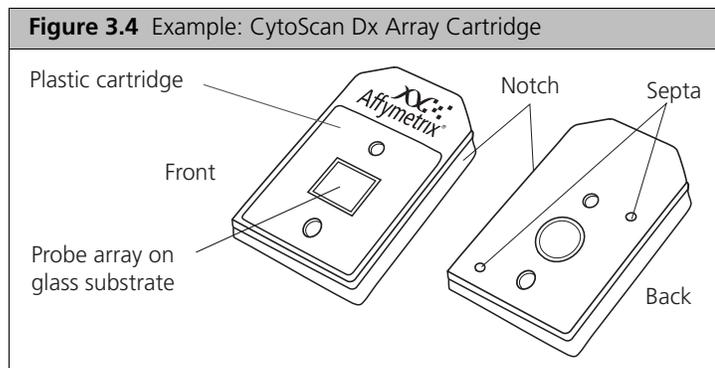
5. Click outside of field.

Non-Contiguous Select and Enter

1. Click on first row of your selection.
2. Press and hold **Ctrl** key.
3. Individually select each row.
4. While holding **Ctrl** key:
 - Select from drop-down in last row
 or
 - Click in field in last row and scan barcode
 or
 - Click in field in last row, release **Ctrl** key, and enter value
5. Click outside of field.

How to Hold Array Cartridges

Arrays come mounted in a plastic package to form an array cartridge (Figure 3.4). The array contains oligonucleotide probes on the inner glass surface. A chamber in the plastic package directly under the chip acts as a reservoir where hybridization and washing and staining occur.



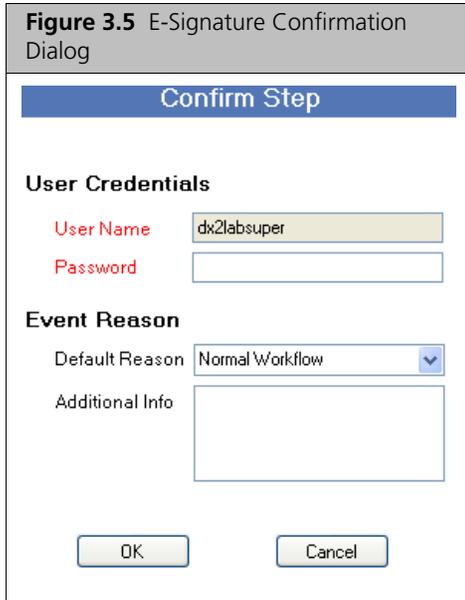
Although the inner glass surface is protected, any contamination or scratches on the outer surface of the glass can compromise the integrity of the scan.

! **IMPORTANT:** Do not touch the surface of the glass with your fingers. Skin oils and other substances, such as lotions or ink, can fluoresce. If the array surface is dirty, carefully clean it with a nonabrasive laboratory tissue.

E-Signatures

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

Figure 3.5 E-Signature Confirmation Dialog



The dialog box is titled "Confirm Step" in a blue header bar. It is divided into two main sections: "User Credentials" and "Event Reason". Under "User Credentials", there is a "User Name" field with the text "dx2labsuper" and an empty "Password" field. Under "Event Reason", there is a "Default Reason" dropdown menu currently showing "Normal Workflow" and a larger "Additional Info" text area. At the bottom of the dialog are two buttons: "OK" and "Cancel".

Confirm Step

User Credentials

User Name dx2labsuper

Password

Event Reason

Default Reason Normal Workflow

Additional Info

OK Cancel

Chapter 4

GeneChip® Fluidics Station FS450Dx v.2

In this chapter:

- *Before You Begin*
- *Warnings and Precautions*
- *About the Instrument*
- *Using the Fluidics Station 450Dx v.2*
- *Fluidics Station Operation*
- *Fluidics Station Care and Maintenance*
- *Fluidics Station Bleach Protocol*
- *Peristaltic Tubing Maintenance*
- *Fluidics Station Troubleshooting and Assistance*
- *Fluidics Station LCD Messages*

Before You Begin

Familiarize yourself with the Affymetrix® Molecular Diagnostic Software (AMDS) interface before operating the Fluidics Station 450Dx v.2 (see [Chapter 2, System Overview](#)). Also refer to the *Affymetrix® Molecular Diagnostic Software User Guide*.

! **IMPORTANT:** You must read and understand the contents of this manual before operating the Fluidics Station 450Dx v.2 (fluidics station).

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.
- Ensure fluidics station is positioned on a sturdy, level bench and away from extremes in temperature and moving air.
- Follow Universal Precautions.
- Use a surge protector on the power line to the fluidics station.
- Disconnect the power cord of the fluidics station before replacing fuses.
- Always run a Shutdown protocol before turning off or not using instrument overnight or longer to prevent build-up of salt crystals.
- When not using instrument, leave sample needles in lowered position such that each needle extends into an empty vial to protect from damage.
- Always use deionized water to prevent line contamination.
- Use freshly prepared buffer to change buffers at each system startup.
- Do not send your instrument elsewhere for service or attempt to service it yourself. To protect your warranty and ensure safe operation, have instrument serviced only by Affymetrix or its representatives. If the instrument is not working correctly, contact Affymetrix technical support.
- 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 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.
- If any unintended or unexpected event occurs or is observed, shut down the instrument and notify Affymetrix technical support.

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.

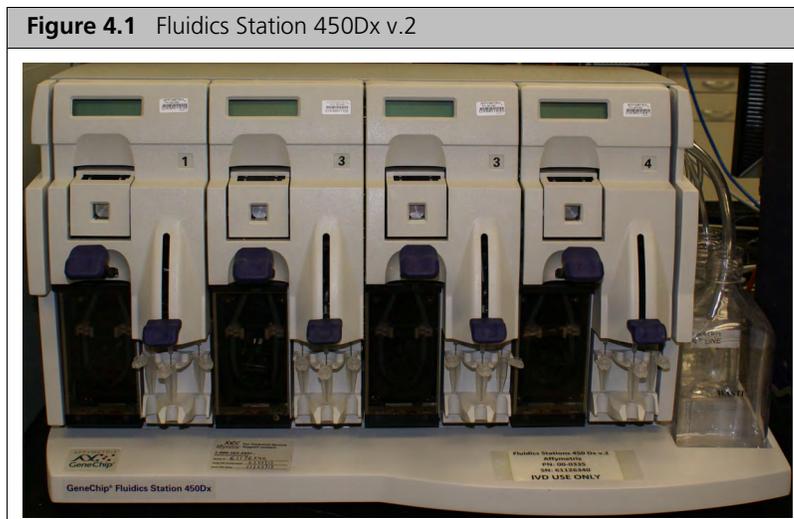
When to Contact Affymetrix

If any of the following occur, unplug the instrument and contact Technical Support.

- Power cord damaged or frayed.
- Liquid spilled onto instrument, or liquid has penetrated instrument.
- Instrument does not perform to the specifications in *Table 4.5 on page 49* after service or calibration.
- Instrument has been dropped or otherwise damaged.

About the Instrument

The Fluidics Station 450Dx v.2 ([Figure 4.1](#)) is part of the GeneChip® System 3000Dx v.2 (GCS 3000Dx v.2).



Modules

The fluidics station contains four modules. The software and computer workstation control each of the four modules independently of the others.

- Each module holds one array cartridge and up to three vials
- All modules are primed as a unit
- Only one assay is 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)

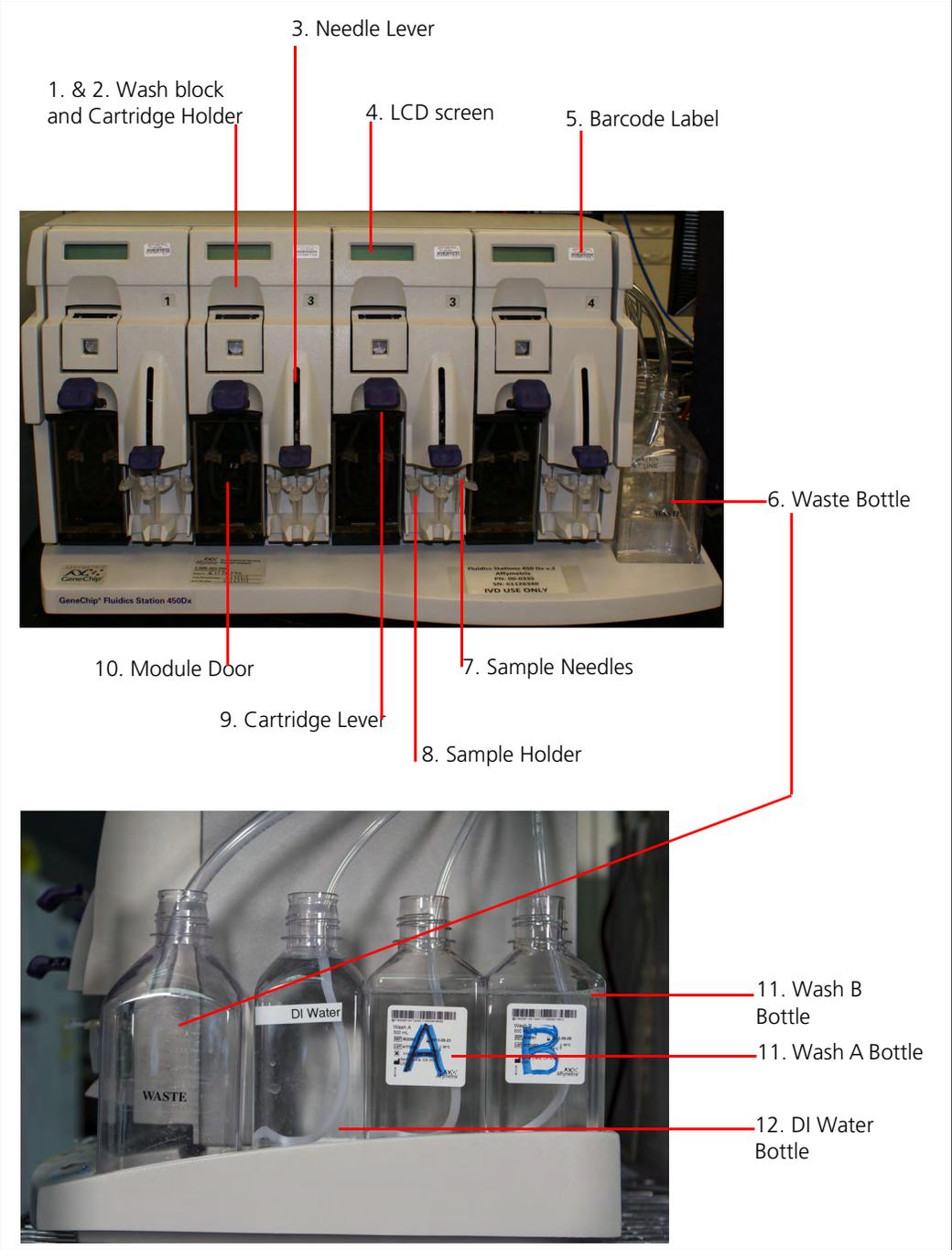
Components

! **IMPORTANT: Do not change fluidics station connections—permit only a qualified Affymetrix field service engineer to service this instrument.**

The fluidics station components are (Figure 4.2):

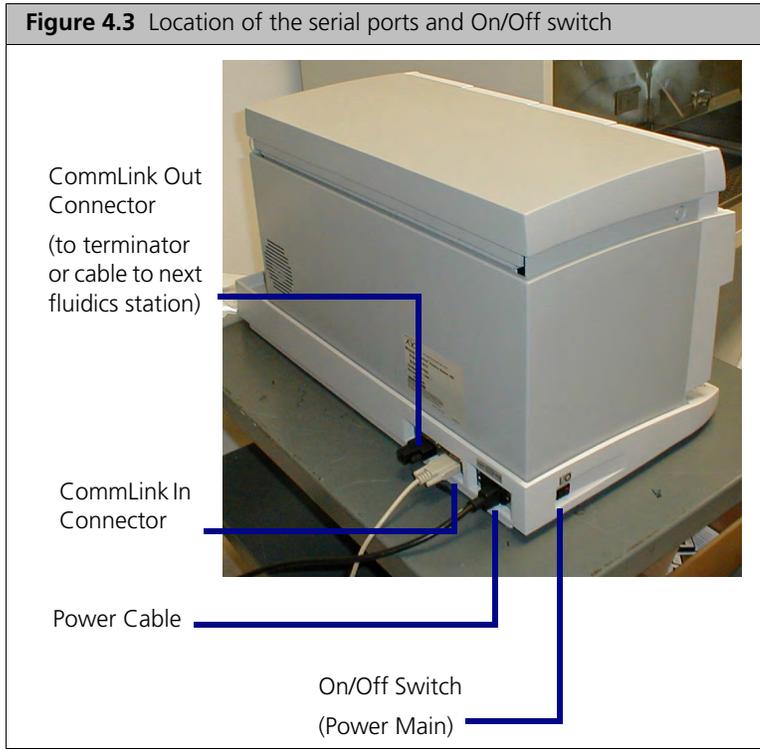
1. **Washblock**—Part of the cartridge holder that completes the fluid path when a cartridge is not in place (used for cleaning out or draining the fluidics station)
2. **Cartridge Holder**—Holds cartridge during fluidics operation
3. **Needle Lever**—Inserts needles into sample vials
4. **LCD Screen**—Shows messages during processes
5. **Barcode Label**—Module barcode identifier
6. **Waste Bottle**—Collects waste from hybridizations and washes
7. **Sample or Vial Needles**—Extend into the sample vials and draw fluid
8. **Sample Holders**—Hold up to three sample vials
9. **Cartridge Lever**—Engages or releases the cartridge holder
10. **Module Door**—Protective cover for peristaltic pump on module
11. **Wash Bottles**—Two, hold wash buffers and tubing that draws buffer through system
12. **DI Water Bottle**—Holds deionized water and tubing that draws water through system

Figure 4.2 Fluidics Station 450Dx v.2 and components



Connections

Communications connections are shown in [Figure 4.3](#).



Using the Fluidics Station 450Dx v.2

Assay Documentation

You must configure the fluidics station for the type of assay you run.

The partner who provides the assay determines the assay type and provides the relevant documentation that describes the fluidics station configuration requirements for that assay. The fluidics station must be correctly configured for the assay.

Barcode Reader Usage

1. In the Workflow panel of the AMDS interface, click **Fluidics** (Figure 4.4).



2. Hold the array or insert the array into the fluidics station module.
3. Use barcode reader to read array barcode. AMDS auto-selects the test request associated with your scanned barcode.
4. Use barcode reader to read fluidics module barcode. AMDS adds station and module numbers to the correct test request.

Barcode responds with one of three sound signals:

- **Good**–Detected correct test request
- **Double good**–Detected and confirmed valid association between test request and fluidics module
- **Bad**–Detected an error; check for on-screen error message with error-specific information.

Fluidics Station 450Dx v.2 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.

Fluidics Station Operation

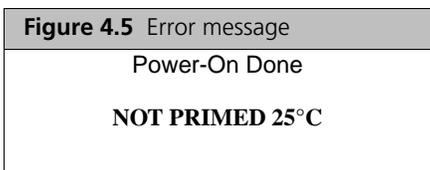
The information in this section is general because the number and types of steps required to process an array vary, as does the specific design of the assay and the contents of its array.

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

Start Fluidics Station

1. Make sure fluidics station is plugged in to power.
2. Make sure fluidics station is connected to the workstation (Figure 4.5).
3. Turn fluidics station switch **On** (left side of fluidics station).

The LCD screen message opens.



Prime Fluidics Station

! **IMPORTANT:** You must prime the fluidics station before you run assay protocols.

You must prime the fluidics station:

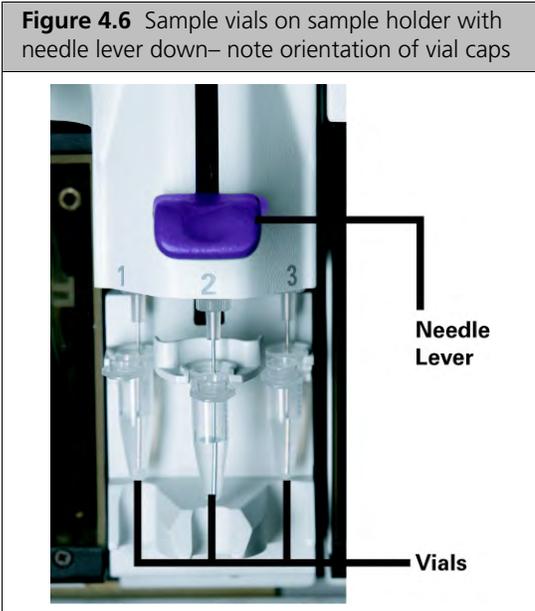
- When you first start it
- Before you process a cartridge
- When you change wash buffers
- When you change the assay associated with a fluidics station
- If LCD screen or any alert instructs you to run a prime protocol

Prime Fluidics Station

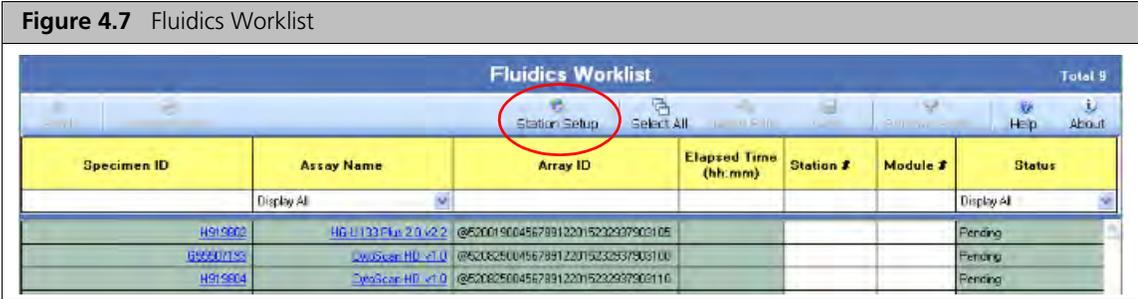
1. Make sure all wash lines are in correct wash bottles.

S **NOTE:** Refer to array package insert in cartridge kit for correct wash buffer solutions or contact Affymetrix technical support.

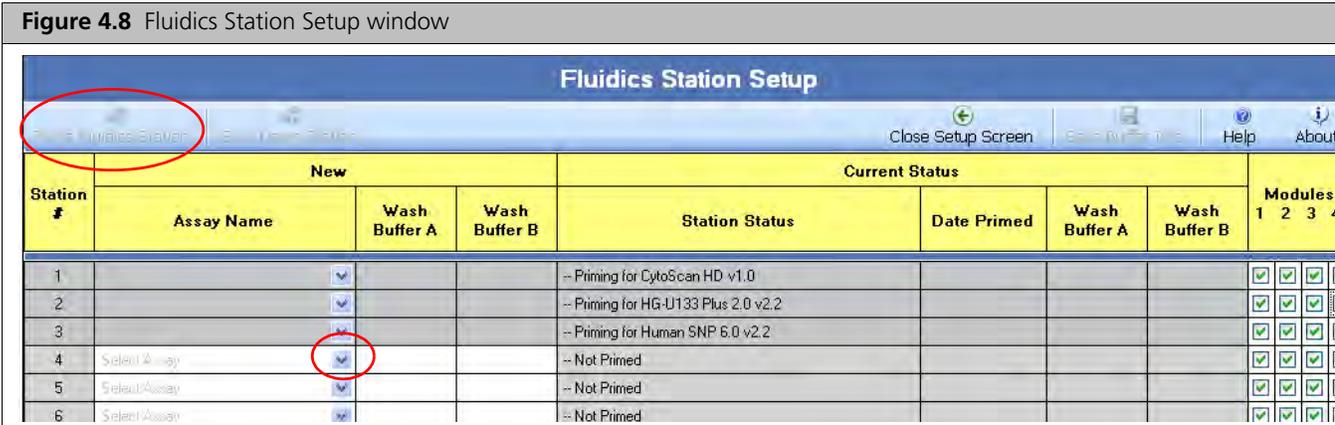
- 2. Load 3 1.5-mL tubes in sample holders for each module to be primed (Figure 4.6).



- 3. In Workflow panel, click Fluidics (Figure 4.7).
- 4. In Fluidics Worklist, click Station Setup (Figure 4.7).



- 5. In Fluidics Station Setup (Figure 4.8) under Assay Name, click the down-arrow and select an assay name from drop-down list for the station to be primed. You must select an assay name for each station to be primed.



6. Under **Station #**, select stations to be primed.
7. Click **Prime Fluidics Station**.
Priming message opens in the status field.
8. Follow instructions on fluidics station LCD screen.

Troubleshoot Fluidics Station Connection to Workstation

1. In User Performed Service window, go to Procedure section and select **Home**.
2. Click **Perform**.
3. In Confirm Step dialog box, enter your password and reason.
4. Click **OK**.

If homing:

- **Succeeds**—LCD on the fluidics station opens message
- **Fails**—Device Status region in worklist window shows message.

If several attempts fail, turn off the fluidics station. Then turn it back on and restart the AMDS workstation. If failures continue, call Affymetrix technical support.

Run a Fluidics Station Protocol

The following is a general procedure. Your protocol may be different.

1. Make sure all wash lines are in correct wash bottles. Refer to array package insert in cartridge kit for correct wash buffer solutions or contact Affymetrix technical support.
2. Prime fluidics station.
3. In Workflow panel, click **Fluidics**.
4. In Fluidics Worklist, associate test request(s) with fluidics station and module (Figure 4.9).

Figure 4.9 Fluidics Worklist

Specimen ID	Assay Name	Array ID	Elapsed Time (hh:mm)	Station #	Module #	Status
H919902	HG-U133 Plus 2.0 v2.2	@5200190045678912201523237902105				Pending
H919903	ChIPScan.HD.v1.0	@52008250045678912201523237903100				Pending
H919904	ChIPScan.HD.v1.0	@52008250045678912201523237903110				Pending

- A. Barcode reader.
 - a. Load array cartridge into module washblock. Do not engage the washblock until prompted by fluidics station LCD.
 - b. Scan barcode on array cartridge.
 - c. Scan barcode on fluidics station module.
- B. Manual.
 - a. In test request record with Specimen ID, place cursor Station # field and enter station number.
 - b. Place cursor in Module # field and enter module number.

- c. Place array cartridge in module washblock (Figure 4.10). Do not engage washblock until prompted by fluidics station LCD. This module must be the same as the module that you earlier associated with the array.

Figure 4.10 Inserting the cartridge into the cartridge holder - note orientation and array label



5. Select test request rows to process—rows show “Ready” in Status field.
6. Click Start.
7. Follow fluidics station LCD screen instructions.
8. Follow prompts.

If you are prompted to:

- **Load Vials**—Load 1.5-mL vials into sample holder of fluidics station.
- **Load Cartridge**—Flip cartridge lever up to engage cartridge septa needles into the septa (Figure 4.11). LCD screen indicates when cartridge engagement is correct.

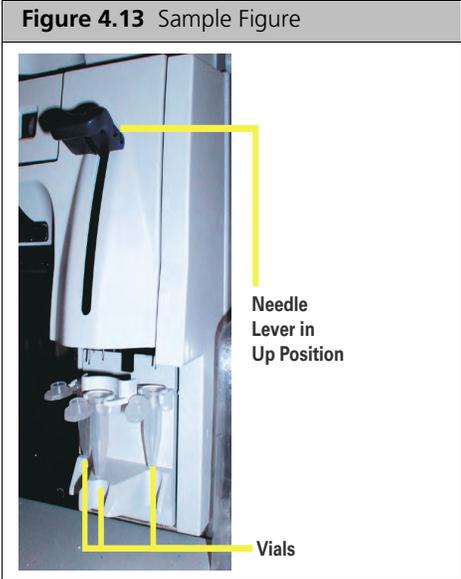
Figure 4.11 Flip the cartridge lever up to engage the cartridge septa needles into the septa.



NOTE: To minimize array damage, the door closure forces are controlled. If you cannot get proper engagement, press on the cartridge holder to complete the action (Figure 4.12). Do not force the cartridge lever up.



- **Load Vials 1-2-3**—Place 3 1.5-mL sample vials containing reagents into sample holders 1, 2 and 3 on fluidics station (Figure 4.13). When you place vials, orient vial caps toward you. Vials must seat snugly.

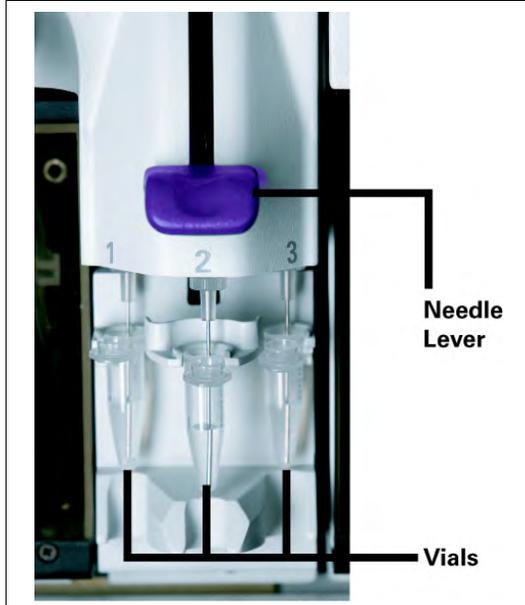


When vials are loaded, gently but firmly press down on needle lever to insert the needles into the vials. Run commences automatically (Figure 4.14 and Figure 4.15).

Figure 4.14 Press down on the needle levers to start the protocol.



Figure 4.15 The sample vials on the sample holder with the needle lever down — note the orientation of the vial caps.



- Eject Cartridge—Flip cartridge lever down and remove and inspect cartridge.

NOTE: If air bubbles are present in cartridge, return to cartridge holder. Load cartridge by pulling up on cartridge lever to closed position. Fluidics station drains cartridge and fills it with fresh volume of last-used wash buffer. When LCD screen indicates, eject cartridge and remove and inspect for bubbles. If no bubbles present, it is ready to scan. Engage washblock to continue.

- Engage Washblock—Flip cartridge up to re-engage washblock.
- Remove Vials—Lift up needle lever. Replace used vials with new, empty vials. Lower needle lever.

- As the run progresses, make sure cartridge is filling correctly and bubbles are not forming.

NOTE: If air bubbles are present in cartridge, return it to cartridge holder. Engage washblock by pulling up on cartridge lever to closed position. The fluidics station drains the cartridge and then fill it with a fresh volume of the last wash buffer used. If LCD screen displays eject cartridge again, remove cartridge and inspect for bubbles. If no bubbles are present, it is ready to scan.

When hybridization or washing and staining protocols finish, the LCD screen shows “EJECT CARTRIDGE.”

Shut Down Fluidics Station

Perform the Shutdown protocol at the end of a session.

- Place wash lines into a bottle filled with deionized water.
- In the Fluidics Station Setup window, run **Shutdown** protocol.
- Follow the instructions on LCD screen.
- When finished, turn switch to Off.

IMPORTANT: To maintain the cleanliness of the fluidics station and obtain the highest quality image and data possible, perform a weekly bleach protocol (see [Fluidics Station Bleach Protocol](#)).

Fluidics Station Care and Maintenance

Instrument Care

Follow these procedures:

- 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 is off, unused overnight, or longer. This prevents salt crystals from forming in the fluidics station.
- 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.
- Place the fluidics station on a sturdy, level bench away from extremes in temperature and away from moving air.

Fluidics Station Bleach Protocol

This protocol removes residual SAPE-antibody complex that may be present in the fluidics station tubing and needles. This protocol takes approximately one hour and forty minutes. Run this protocol weekly.

If you have AMDS administrator privileges, set the Bleach Interval Warning Limit and Bleach Interval Alert Limit.

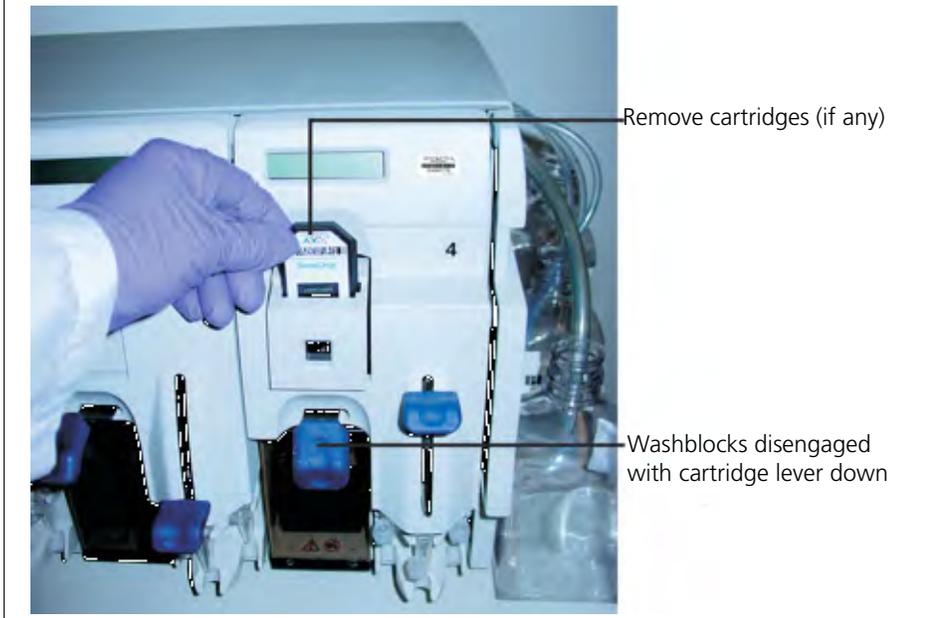
Use dedicated bottles for bleach and DI water to prevent cross-contamination.

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

Bleach Cycle

1. Disengage cartridge holder for each module by pressing down on the cartridge lever. Remove any array cartridges (Figure 4.16).

Figure 4.16 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.
 - A. In 1-liter graduated cylinder combine and mix well:
 - 43.75 mL commercial bleach (e.g., Clorox bleach, which is 6% hypochlorite)
 - 456.25 mL DI water
 - B. Pour solution into 500-mL plastic bottle.
 - C. Shake well.



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

3. Place plastic bottle on the fluidics station.



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

4. Place on fluidics station:
 - One empty 1-liter waste bottle
 - One 500-mL bottle of bleach solution from Step 2
 - One 1-liter bottle of DI water.

5. Insert waste line into the waste bottle (Figure 4.17).

Figure 4.17 Immerse the tubes into the 0.525% sodium hypochlorite solution. The waste line remains in the waste bottle.



6. Immerse all three wash and water lines of the fluidics station into the 500-mL bottle of bleach solution (Figure 4.17). Do not immerse waste line into bleach.

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

7. In the AMDS Administrator pane, click System Management (Figure 4.18).

Figure 4.18 Administrator Pane



8. In the System Management window the User Performed Service window opens. (If not, select **In-House Service** > **User Service**.) (Figure 4.19).

Figure 4.19 User Performed Service window - User Maintenance Area

The screenshot shows the 'User Performed Service' window. On the left, there is a 'Station' dropdown menu set to '1'. Below it, the 'Time Elapsed Since:' section shows 'Last Bleach' and 'Last Change Tubing' both set to '105 [d]'. At the bottom left, the 'Procedure' dropdown is set to 'Bleach' and a 'Perform' button is visible. On the right, the 'Configuration' section contains four rows of settings: 'Bleach Interval Warning Limit' (10 [d]), 'Bleach Interval Alert Limit' (100 [d]), 'Change Tubing Warning Limit' (10 [d]), and 'Change Tubing Alert Limit' (100 [d]).

9. From **Station** drop-down list, select a station number.
10. Select **Bleach** from procedure list
11. Click **Perform**.
12. In Confirm Step dialog box, enter your password and event reason.

 **CAUTION: Temperature ramps up to 50°C.**

13. You are prompted to press down the needle levers (Figure 4.20).



The fluidics station begins the protocol. After approximately 30 minutes, the LCD prompts you when the bleach cycle is over and the rinse cycle is about to begin.

14. Continue to follow prompts on LCD screen.

Rinse Cycle

The rinse cycle is essential to remove all traces of bleach from the system. *Failure to complete this step can result in damaged arrays.*

1. When prompted on the LCD for each module, lift up on the needle levers and remove the bleach vials.
2. Load clean, empty vials onto each module.
3. Remove the three wash and water lines from the bleach bottle and transfer them to the DI water bottle (Figure 4.21).

Figure 4.21 Immerse the three wash and water lines in the DI water bottle. The waste line remains in the waste bottle.



4. Press down on the needle levers to begin the rinse cycle.

When the rinse is completed (approximately 1 hour), the fluidics station brings the temperature back to 25°C and drains the lines with air. The LCD display reads “CLEANING DONE.”

5. Discard the vials used for the bleach protocol.
6. Follow instructions in Table 4.1 after bleach protocol finishes.

Table 4.1 Use of fluidics station after a bleach protocol

If you are:	Then do this:
Planning to use the system immediately	When bleach protocol finishes, remove DI water supply used in rinse phase and install appropriate reagents for use in your next staining and washing protocol (including fresh DI water). <i>Perform a prime protocol before loading arrays.</i> Failure to run prime protocol results in irreparable damage to the loaded hybridized arrays.
Not planning to use the system immediately	System is already well purged with water, so you do not need to run an additional shutdown protocol. Remove old DI water bottle and replace with fresh bottle.
Not planning to use the system for an extended period of time (>1 week)	Remove DI water and perform a “dry” protocol shutdown. This removes most of the water from the system and prevents unwanted microbial growth in the supply lines. Also, remove pump tubing from peristaltic pump rollers.

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 and use the following procedure when needed.

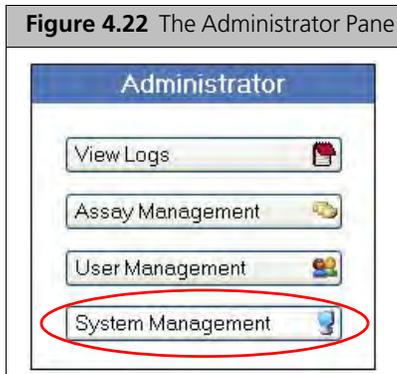
CAUTION: Wear gloves when changing tubing. Do not allow fluid from old tubing to spill onto surfaces.

IMPORTANT: For systems in routine use, replace silicone peristaltic tubing monthly (PN 400110). To ensure proper performance, use only Affymetrix tubing.

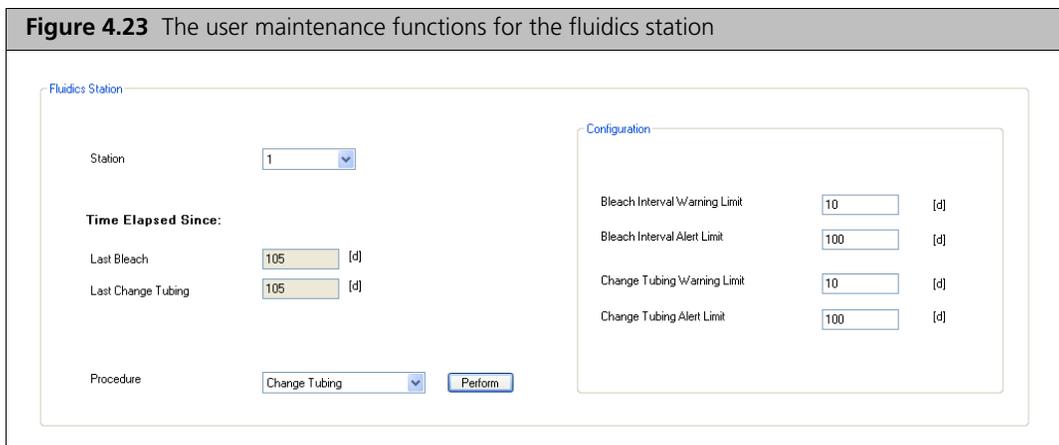
Set Peristaltic Tubing Maintenance Parameters

Set the peristaltic tubing maintenance parameters upon first setup or after peristaltic tubing is replaced.

1. In the Administrator pane, click **System Management** (Figure 4.22).



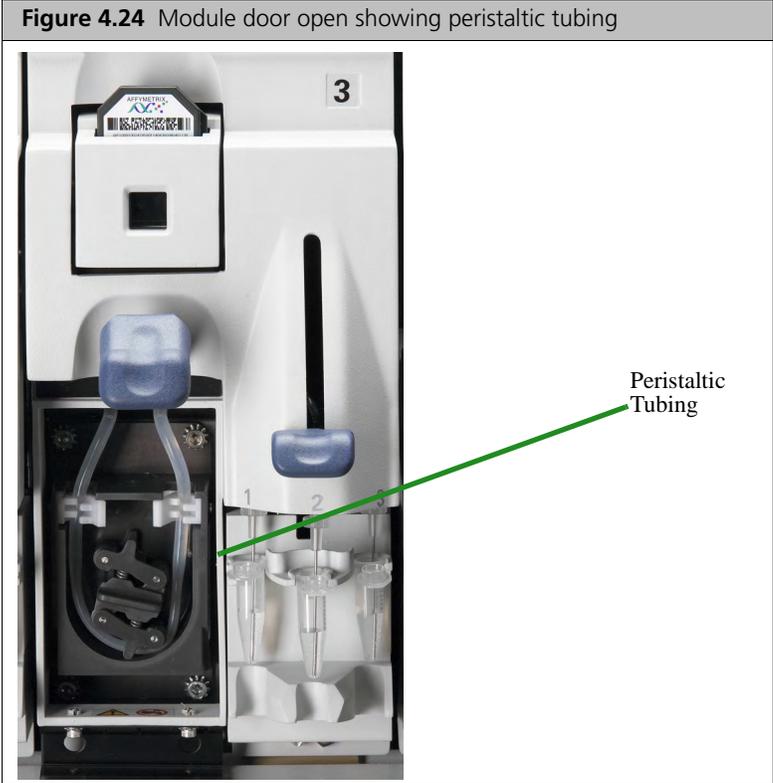
2. In the fluidics station maintenance section (Figure 4.23) go to **Station** drop-down list and select a station number.



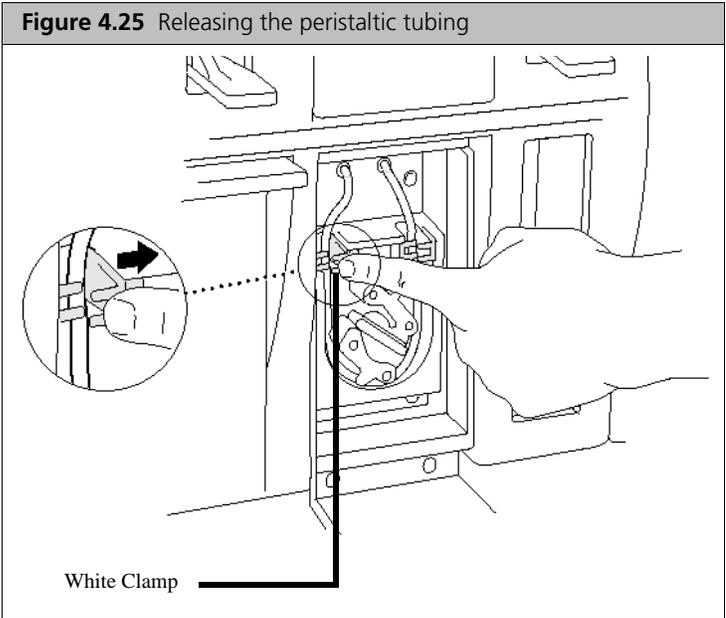
3. From **Procedure** list, select **Change Tubing**.
4. Click **Perform**.
5. In **Confirm Step** dialog box, enter your password and event reason.
6. Click **OK**.

Replace Peristaltic Tubing

- 1. Open module door (see [Figure 4.24](#) and [Figure 4.25](#)).



- 2. Open the white clamps to release tubing on both sides ([Figure 4.25](#)).



! **IMPORTANT:** Do not remove the module. Do not attempt to replace tubing where the module has been removed from the fluidics station case—this can damage the motor driver circuitry.

3. Pull tubing off while gently turning the peristaltic pump head and discard old tubing.
4. Replace tubing with new peristaltic tubing from accessory kit.
 - A. Attach one end of new tubing to fitting at top right of pump enclosure.
 - B. Insert tubing into 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 tubing into the pump head while slowly turning the pump.
 - D. Insert free end of tubing into other clamp and attach to other fitting.
5. Close the drop-down module door.



NOTE: Order more replacement tubing (PN 400110).

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

Use the following flowcharts ([Figure 4.26](#) and [Figure 4.27](#)) to begin troubleshooting the fluidics station for a Missing Fluid Error (MFE).

Figure 4.26 Troubleshooting decision tree, page 1

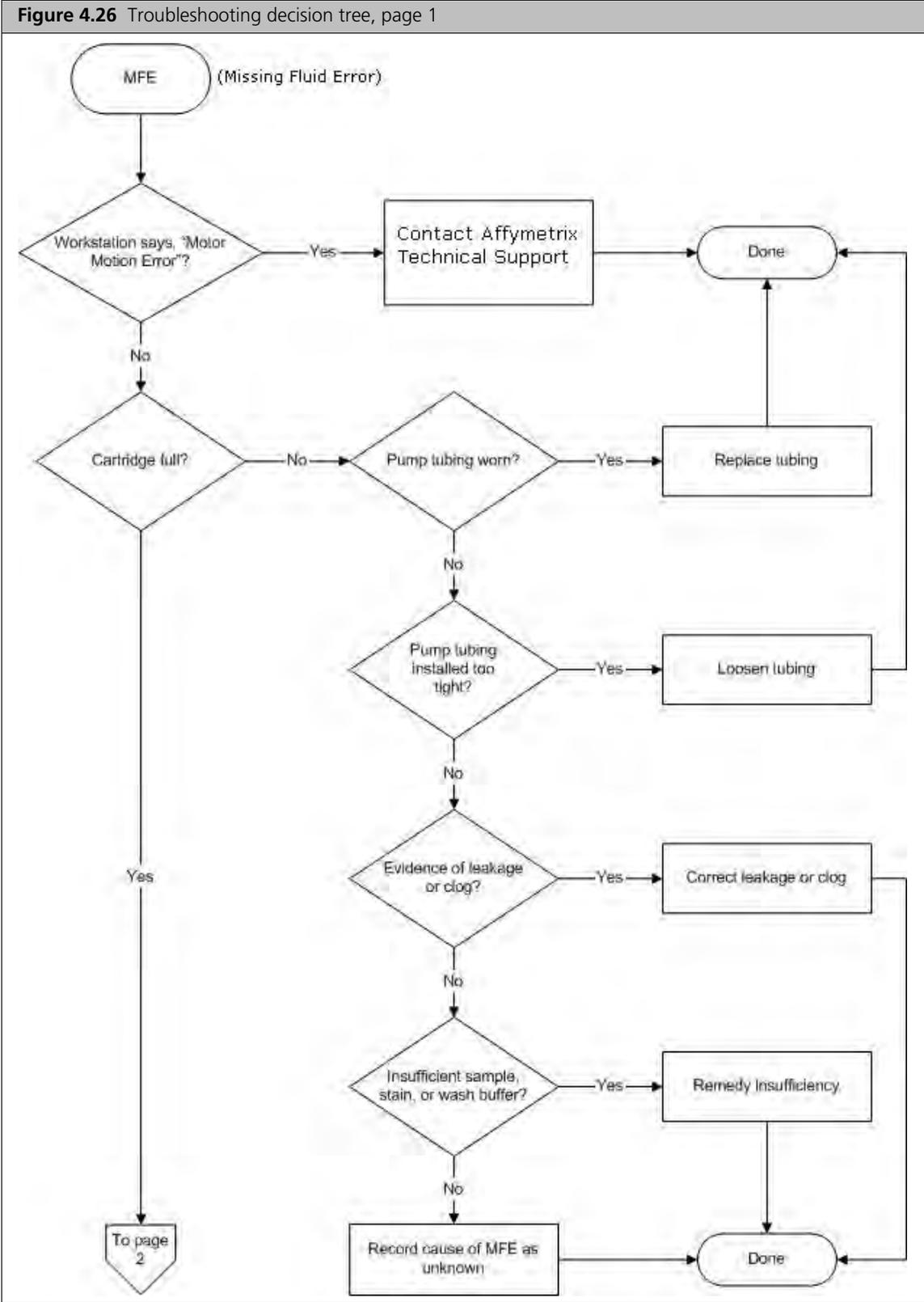
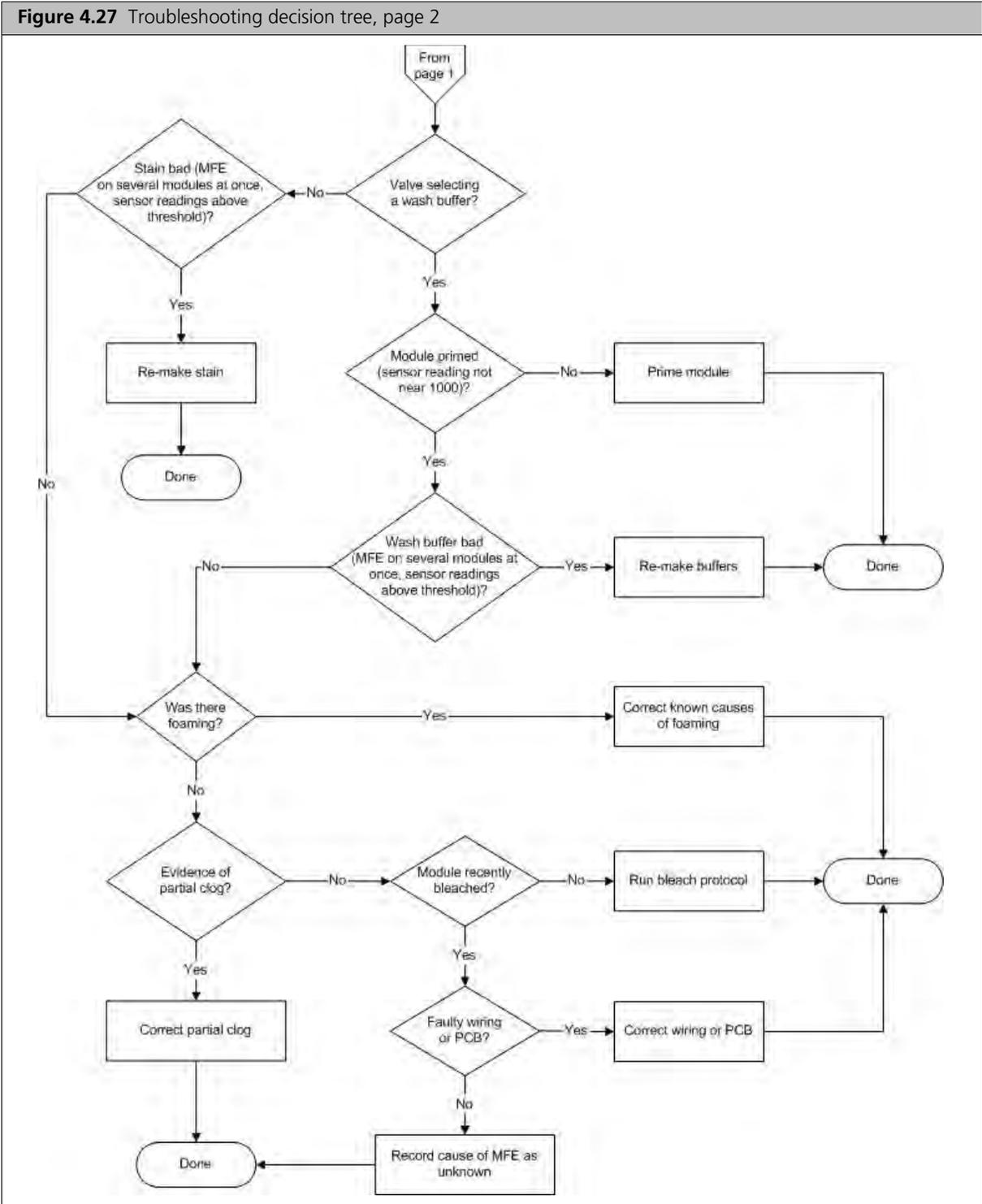


Figure 4.27 Troubleshooting decision tree, page 2



Problems and Solutions

This section lists alert messages. To resolve these alerts, follow the recommended resolution in the current Worklist screen on the alert pane (Table 4.2).

Table 4.2 Problems and Solutions

Error Message	Problem	Possible Cause	Possible Solution
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.
		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.	Fill buffer bottles.
	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.
	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	Fluidics Station does not respond.	Power not switched on at the fluidics station. Loose cables.	Turn fluidics station power on, and then try to connect again. 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.

Table 4.2 Problems and Solutions (Continued)

Error Message	Problem	Possible Cause	Possible Solution
Error While Draining Error While Filling	Cartridge is not filling or draining properly.	Defective septa in cartridge. Insufficient sample or stain volume. Excessive bubbling in cartridge. Buffer conductivity too low. Failure of one of the fluid sensors.	In the current Worklist screen on the alert pane, follow the recommended resolution. You may need to use a new cartridge. Add more sample solution to sample vial. Change the buffer, reduce detergent Use fresh buffer 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.
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

This section lists common error messages and meanings. To resolve these alerts, follow the recommended resolution in the current Worklist screen on the alert pane (Table 4.3).

Table 4.3 Error Messages

Error Message	Meaning
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 its HOME position.
Valve Motion Error	The Valve command did not result in the valve reaching its 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"	<p>"Stage C" "WashA" "Sense/Threshold" "960/890"</p> <p>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.</p> <p>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.</p> <p>For example: Missing Fluid Error for 4 seconds Stage A valvePos WashA for 4 seconds Sense/Threshold 820/600for 4 seconds</p>

Other Problems and Solutions

This section lists other problems and their solutions. Follow the recommended resolution in the current worklist screen on the Alert pane (Table 4.4).

Table 4.4 Other Problems and Solutions

Problem	Possible Cause	Possible Solution
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 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 lists common messages that appear on the fluidics station LCD during fluidics station operation (Table 4.5).

Table 4.5 LCD 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.
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.

Table 4.5 LCD Messages (Continued)

Message	Meaning
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.

Chapter 5

GeneChip® Scanner 3000Dx v.2 with AutoLoaderDx v.2

In this chapter:

- *Before You Begin*
- *About the Instrument*
- *Safe Operation*
- *Scanning Arrays*
- *Cleaning and Maintenance*
- *Configure Scanner*
- *Troubleshooting*

Before You Begin

Familiarize yourself with the Affymetrix® Molecular Diagnostic Software (AMDS) interface (see [Chapter 2, System Overview](#)) before operating the GeneChip® Scanner 3000Dx v.2 (Scanner 3000Dx v.2). Also refer to the *Affymetrix® Molecular Diagnostic Software User Guide*.

! **IMPORTANT:** You must read and understand the contents of this manual before operating the scanner.

About the Instrument

The Scanner 3000Dx v.2 with AutoLoaderDx v.2 (scanner) (Figure 5.1) is designed expressly for scanning multiple array cartridges. The scanner can scan up to 48 arrays automatically without operator presence.

Figure 5.1 Scanner 3000Dx with AutoLoaderDx v.2



Safe Operation

- ▲ WARNING:**   Do not remove the external case or skin or scanner cover of the AutoLoaderDx v.2. Use the scanner only as instructed in this manual. 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 are permitted to service this equipment. The Scanner 3000Dx v.2 contains an incorporated Class 3B laser. Use of controls or adjustments or performance of procedures other than those specified may result in hazardous radiation exposure.
- ! IMPORTANT:** To preserve the lifetime of the internal laser, turn the scanner *Off* when it is not in use for any extended period of time, such as overnight or a weekend.

Precautions

- 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 100 pounds (45.4 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.

 **CAUTION: Never push an object into the instrument ventilation slots—equipment damage or personal 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. Do not compromise this safety feature. If the instrument AC plug does not mate with the available power source receptacle, consult a licensed electrician to install a correct plug.

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. The scanner is a Class 1 laser product when the laser is enclosed in scanner case. The laser itself is a Class 3B 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.

 **IMPORTANT:** Scanner is a Class 1 laser product when the laser is enclosed in the scanner case. The laser itself is a Class 3B laser product.

 **CAUTION:**  Use laser safety glasses when servicing. *Do Not Stare Into Laser Beam*

Class 1 Laser Product

The green laser is a 532-nm solid-state laser. This is a Class 3b laser and has visible outputs greater than 5 mw but not more than 500 mw. 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 guide and when all covers are in place, the AutoLoaderDx v.2 is classified as a Class 1 Laser. This device complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.

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

Electrical Safety

The scanner is designed for input voltage from 100 to 240 VAC nominal, 50 to 60 Hz.



NOTE: The scanner power supply auto-detects input voltage and configures 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:  Do not use the scanner in a manner not specified in this manual. To do so may impair the protection provided by the equipment.



IMPORTANT: Do not confuse your company network connections with the dedicated ethernet port of the scanner-workstation. The correct scanner connection is located near the top of the workstation. This 10/100 Base T Ethernet communications port is dedicated to the scanner-workstation interface. You cannot connect the scanner to your company ethernet communications network.



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

Workstation-AutoLoaderDx v.2 Connections

! **IMPORTANT:** Permit only an Affymetrix service engineer to service or change the instrument cable connections (see [Figure 5.2](#) and [Figure 5.3](#)).

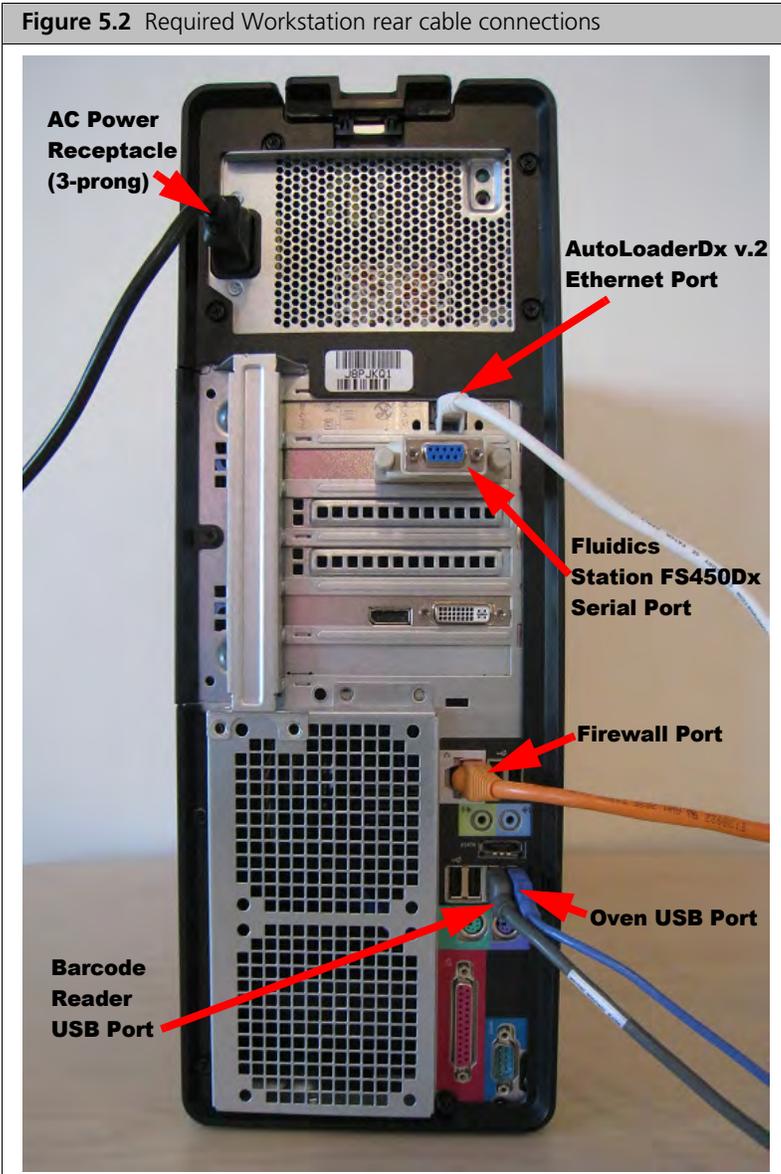
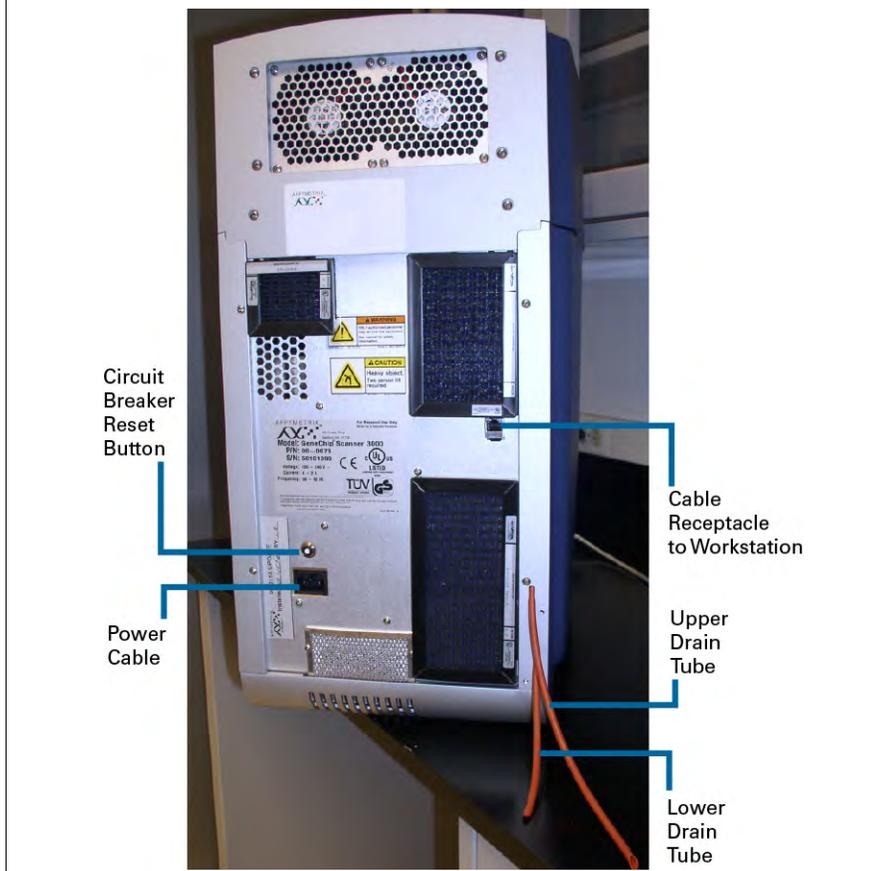
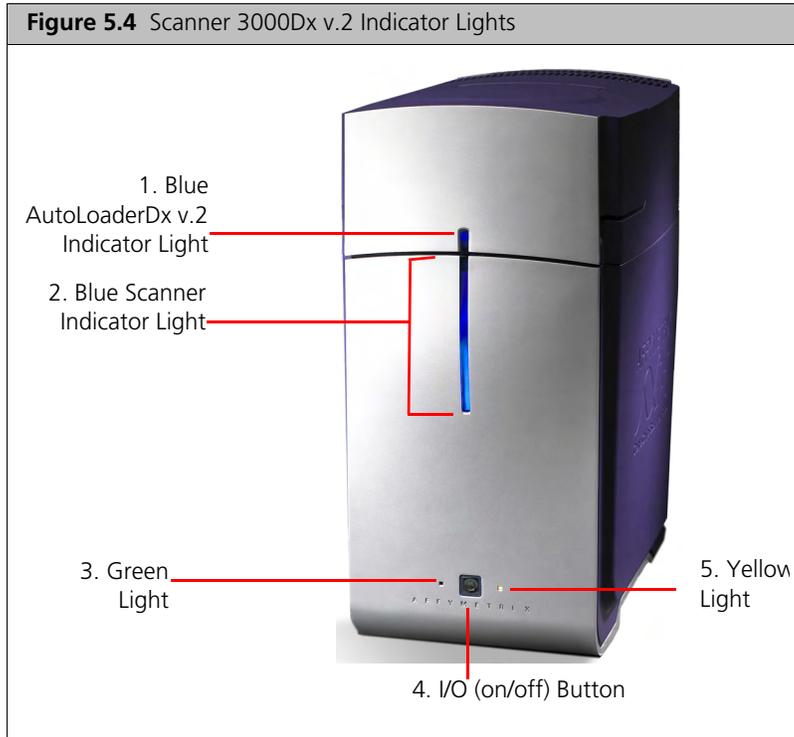


Figure 5.3 Scanner 3000Dx v.2 Rear Connections



Scanner Indicator Lights and On/Off Button

The front panel buttons and indicators as shown in [Figure 5.4](#).



Buttons and Indicators

1. **Blue AutoLoaderDx v.2 Indicator Light**—On AutoLoaderDx v.2, running vertical at front center. When on, indicates that AutoLoaderDx v.2 door is closed and locked. It turns 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**—
 - On—System is ready to scan (yellow off)
 - Flashing—Scan is in progress
4. **I/O (On/Off) Button**—In the center. When yellow light is:
 - On—Idle, laser is warming up (laser not ready, green off)
 - Off—System ready, no errors (green on)
 - Flashing—error
5. **Yellow Light**

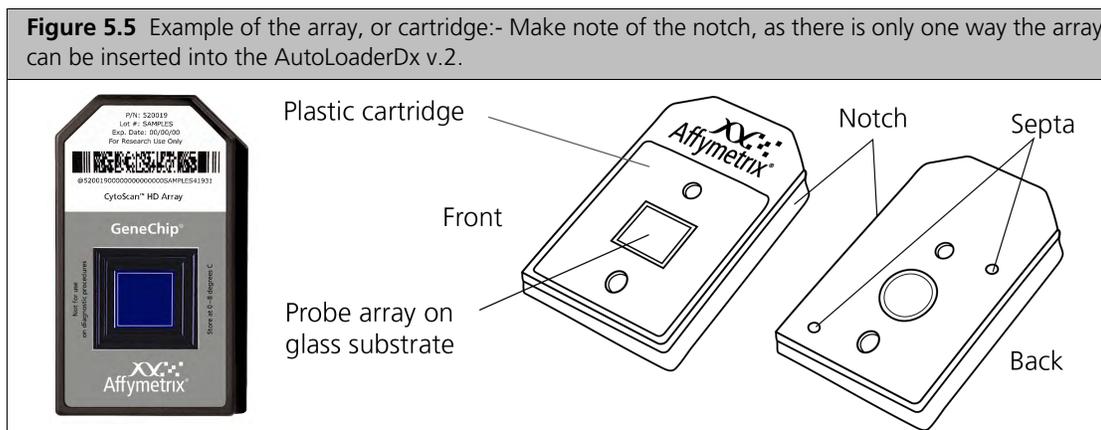
Indicator Lights Summary Table

Table 5.1 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 v.2. The arrays are similar to those in [Figure 5.5](#).

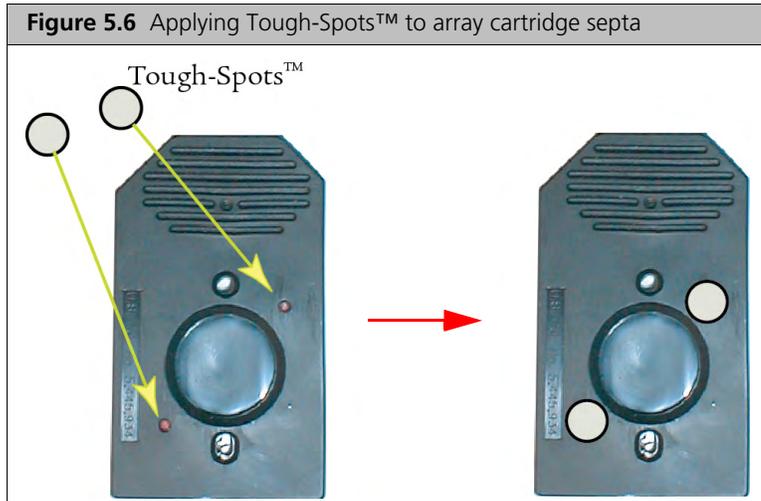


Use of Tough-Spots™ to Prevent Leaks

Tough-Spots™ are chemically inert polyvinyl labels that adhere to all plastics. Use 3/8-inch circle diameter Tough-Spots (Affymetrix PN 64-0158 or USA Scientific PN 9185-0000) to prevent leakage from the array cartridge septa.

Before you load the array cartridge in the scanner, remove old Tough-Spots and apply new as follows.

1. On back of array cartridge, clean excess fluid from around septa (Figure 5.6).



2. Carefully apply one Tough-Spot over each of the two septa and press to ensure that the spots remain flat.

NOTE: If a Tough-Spot does not apply smoothly and there are bumps, bubbles, tears, or curled edges, do not attempt to smooth them out. Remove the spot and apply a new one.

Load Arrays into Carousel

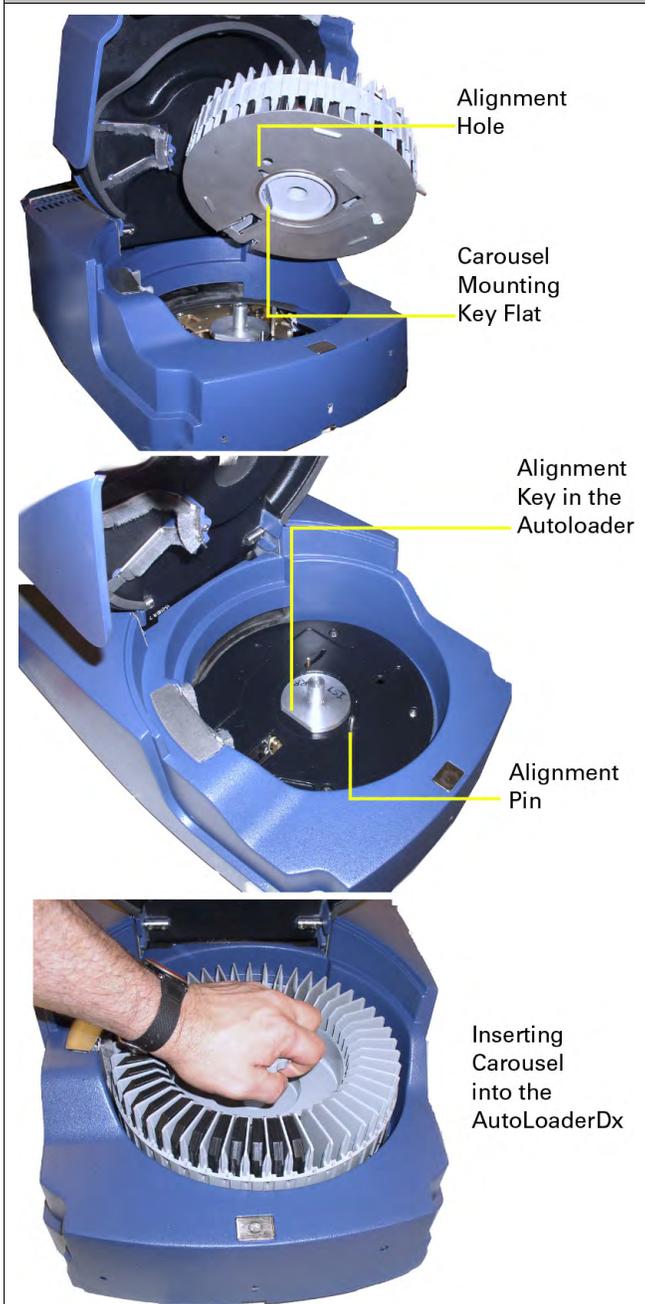
1. Load up to 48 arrays into the carousel, starting with slot 1 (Figure 5.7).



- Always start processing with array in slot 1.

- Maximize scanner performance—remove scanned arrays and place an unscanned array in slot 1. Avoid empty slots.
2. Load Carousel into AutoLoaderDx v.2 and turn carousel until alignment pin seats into alignment hole (Figure 5.8).

Figure 5.8 Loading the carousel into the AutoLoaderDx v.2



3. Turn carousel clockwise until carousel mounting key flat seats gently into the AutoLoaderDx v.2 alignment key (Figure 5.9) and close AutoLoaderDx v.2 door.

Figure 5.9 Inserting and turning the carousel; the carousel should be seated and flush with housing.



NOTE: You may have to turn the carousel several times before it seats into the alignment pin and alignment key. When seated properly, the carousel is flush with the AutoLoaderDx v.2 housing. The seating of the key flat is confirmed by a gentle falling of the carousel into the key.

CAUTION: AutoLoaderDx v.2 door does not remain open unassisted. When opening door, do not release until hands and fingers are clear.

Start Scanner

1. Press the I/O button on the front panel.
2. Wait 10 minutes for the scanner to warm up.

Shut Down Scanner

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

IMPORTANT: Request a professional service call for maintenance at least twice a year. Contact Affymetrix technical support for details.

Disable the AutoLoaderDx v.2

If you have a problem with the AutoLoaderDx v.2, you can scan arrays with the AutoLoaderDx v.2 disabled by following this procedure.

1. Make sure AutoLoaderDx v.2 is in “ready” state (green light solid, yellow light off).
2. Go to General Configuration window and select **Disable AutoloaderDx**.
3. Click **Save Changes**.

4. In the Confirm Step dialog box, enter your password and reason and click **OK**.
5. In reboot scanner dialog box, click **OK**.
6. When you see “Autoloader Mode has changed” in Device Status pane, turn scanner **off**.
7. Wait 1 minute, then turn scanner on.
The scanner boots up and goes through laser warm-up. The connection between the scanner and AMDS is established soon after laser warm-up starts.
8. When you see “Autoloader Standby” in Device Status pane, restart the workstation.
9. Remove carousel from Autoloader.
10. Drop an array into the slot.
11. In Scanner Worklist, click **Manual Scan** to scan array. Autofocus begins in about 90 seconds.

Cleaning and Maintenance

Keep the scanner 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.

! **IMPORTANT:** The GCS3000Dx v.2 requires calibration and maintenance twice a year by authorized Affymetrix personal to ensure system performance. Failure to maintain the system as recommended may result in the failure of the system to perform in accordance with specifications.

Configure 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 v.2 so you can continue processing arrays if the AutoLoaderDx v.2 fails.

Troubleshooting

Scanner Troubleshooting Table

Table 5.2 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.

Scanner Operation Issues Table

Table 5.3 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)	<p>AMDS notes the failure and opens an alert that says “Cannot connect to scanner” or something similar. However, there are two issues to note. First, AMDS reports such a failure only after a network time-out of about 30 seconds.</p> <p>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.</p> <p>To restore proper operation, verify that the scanner is on and that communication cables are properly connected.</p> <p>See the section, <i>Managing Instrument Settings on the User Performed Service Screen</i> in the <i>Affymetrix® Molecular Diagnostic Software User Guide</i>. Click Restart Scanner to restart the scanner.</p> <p>You may need to close AMDS and restart the scanner, 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.</p>
Laser warm-up lasts for ten minutes, during which time the “Turn Laser On” button remains unchanged and AMDS displays the status message “Warm-up”.	Simply note that this is normal operation.
Autofocus fails if salt deposits accumulate on the array.	Use Tough-Spots to prevent leaks in the array. See the quick reference card, PN 08-0076, or the section, <i>Use of Tough-Spots™ to Prevent Leaks</i> on page 58.

Scanner Diagnostic Table

Table 5.4 Scanner Diagnostic Table

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	<ul style="list-style-type: none"> ■ 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. 	
Carousel does not rotate	<ul style="list-style-type: none"> ■ 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 v.2 misses next array	Array UP sensor not working, call technical support.	
Stuck array		See the section, Manual Removal of Lodged Array Cartridge on page 66
AutoLoaderDx v.2 freezes up	Door is open or ajar	
Scanner overheats	<ul style="list-style-type: none"> ■ Heater Failure ■ TE failure ■ TE hot fans vent blocked 	<p>Call technical support.</p> <p>Call technical support.</p>
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 array. See the quick reference card, PN 08-0076, or Use of Tough-Spots™ to Prevent Leaks on page 58 .
The array does not descend into scanner.	<ul style="list-style-type: none"> ■ Carousel not seated correctly ■ Door is open or ajar ■ Heater is waiting until array is at temperature. 	

Scanner Error Messages

The following error messages (Table 5.5) indicate a serious malfunction of the scanner. *Your arrays, or the data generated from them, may be at risk.* Shut down the scanner and remove the carousel. Do *not* continue to use the scanner in Automode. Call Affymetrix technical support.

Table 5.5 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.”

Manual Removal of Lodged Array Cartridge

1. Turn scanner off and remove power cord from back of the unit.
2. Open AutoLoaderDx v.2 door on top of unit.
3. Remove carousel. Keep arrays in carousel and at correct temperature while recovering the array still in the AutoLoaderDx v.2.
4. Remove hole plug, just in front of the array slot in the base piece of insulation (in [Figure 5.10](#), the screwdriver is inserted into this hole).

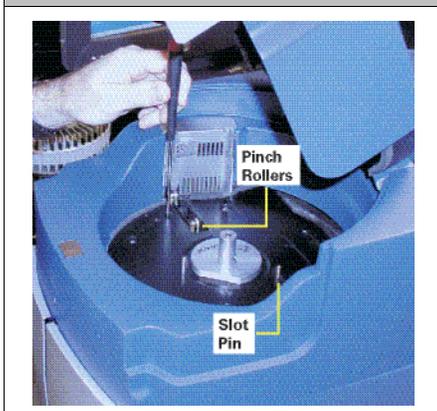
Figure 5.10 Hole plug



5. Use a standard, flat (-) screwdriver and 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 breaks the Y stage in the AutoLoaderDx v.2.* The Y stage has now ascended to its maximum position.

- 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 (Figure 5.11). You should see the little pinch rollers near the array slot close a little as you do this.

Figure 5.11 Slot pin and pinch rollers



- Insert a 3/16-inch hex driver into the hole that is located on the front of the AutoLoaderDx v.2 housing on the left. You should feel it engage a coupling.
- Turn the hex driver counterclockwise until you see the array appear through its opening (Figure 5.12). (The array should stay up if you stop turning the hex driver). If you do not see the array after turning the hex driver for 10 seconds go to step 11.

Figure 5.12 Hex driver



- 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.
- If you do not see the array after turning the hex driver for 10 seconds, stop.

12. Using tool (Figure 5.13) 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)

Figure 5.13 Tool,
Affymetrix PN 13-0256



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 using this procedure, call 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 v.2, call technical support.

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 specifications.
- If the instrument has been dropped or otherwise damaged.

If the instrument must be returned for repair, call Affymetrix Technical Support.

Appendix A

Specifications and Regulatory Information

Specifications

GeneChip® Fluidics Station 450Dx v.2

Table A.1 Fluidics Station 450Dx v.2 Specifications

Height	15.8 inches (40.2 cm)
Width	28 inches (71.1 cm)
Depth	16.1 inches (41 cm)
Weight	80 pounds (36.3 kg)
Voltage	100-240 VAC, 3 A; 300 watts
Operating Temperature Range	15 to 30°C
Operating Humidity Range	10 to 90% RH (non-condensing)
Operational	1 to 3 vials per module Auto-sampling up to 3 vials per module Configured with 2 or 4 modules

Scanner

▲ WARNING:  *The GeneChip® Scanner 3000Dx v.2 contains an incorporated Class 3B laser with these specifications:*
Wavelength=532 nm ±1 nm
Beam Divergence (full angle)=<8 mrad
Output Duration=Continuous Wave
Maximum Power Output=500 mW.

Table A.2 Scanner 3000Dx v.2 Specifications

Height without AutoLoaderDx v.2	31 inches (78.7 cm)
Height with AutoLoaderDx v.2 (door closed)	44.5 inches (113 cm)
Width	22.5 inches (57.2 cm)
Depth	31 inches (78.7 cm)
Weight without AutoLoaderDx v.2	70 pounds (31.8 kg)
Weight with AutoLoaderDx v.2 (fully loaded)	105 pounds (47.6 kg)
Line (Mains) Voltage	100-240 VAC, 50-60 Hz
Current	4-2 A
Excitation wavelength	532 nm (green) laser, 10 mW maximum

Table A.2 Scanner 3000Dx v.2 Specifications (Continued)

Emission Filter	570 nm, Long-Pass
Autoloader	48 microarrays per carousel
Cooled Environment	Average temperature = 15°C

Quick Reference Card

Table A.3 Part numbers

Item	Part Number
Affymetrix Molecular Diagnostic Software (AMDS) Quick Reference Card	English—08-0262
	Chinese—08-0262 CN
	Danish—08-0262 DA
	German—08-0262 DE
	Spanish—08-0262 ES
	French—08-0262 FR
	Greek—08-0262 GR
	Italian—08-0262 IT
	Japanese—08-0262 JP
	Dutch—08-0262 NL
	Portuguese—08-0262 PT
Swedish—08-0262 SE	

Labeling Symbols

Symbol / Label	Statement / Meaning
	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

Symbol / Label	Statement / Meaning
	Consult Instructions for Use
	Manufacturer
	<i>In vitro</i> Diagnostic Medical Device
	European Conformity
	Authorized Representative in the European Community

Regulatory Compliance–GeneChip® Fluidics Station 450Dx v.2

CE Mark Declaration of Conformity

Affymetrix, Inc.
3450 Central Expressway
Santa Clara, CA 95051 USA

Declare under sole responsibility that the GeneChip® Fluidics Station 450Dx v.2 meets the provision of the Council Directive 98/79/EC for In Vitro Diagnostic Medical Devices as transposed in the national laws of the Member States.

Table A.4

Referenced Standards	
Low Voltage Directive (LVD) 2006/95/EC	Electromagnetic Compatibility (EMC) Directive 2004/108/EC
Referenced Safety Standards	Referenced EMC Standards
IEC 61010-1:2001 IEC 61010-2-081:2001+A1:2003 IEC 61010-2-101:2002	EN 61326-1, 2006 CISPR 11:2003;Amendment 2, 2006, Class A EN 55011:2007;Amendment A2:2007, Class A
EN 61010-1:2001 EN 61010-2-081:2002+A1:2003 EN 61010-2-101:2002	IEC 61000-3-2:2005+A1:2008 IEC 61000-3-3:2008 IEC 61000-4-2:2008 IEC 61000-4-3:2008 IEC 61000-4-4:2007 IEC 61000-4-5:2005 IEC 61000-4-6:2008 IEC 61000-4-11:2004
CAN/CSA-C22.2 No. 61010-1/R:2009 CAN/CSA-C22.2 No. 61010-2-081:2004 CAN/CSA-C22.2 No. 61010-2-101:2004	
UL 61010-1/R:2008-10	EN 61000-3-2:2006, Class A EN 61000-3-3:1995, Amendment 2:2006 EN 61000-4-2:1995, Amendment 2, 2001 EN 61000-4-3:2006, Amendment 1, 2008 EN 61000-4-4:2004 EN 61000-4-5:2006 EN 61000-4-6:2007 EN 61000-4-11:2004

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 brouilleur du Canada.

Regulatory Agency	Certification
	
	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.5](#) contains information identifying the specific hazardous material(s) and the components/parts in which they are found.

Table A.5 Table Containing Names and Contents of Toxic or Hazardous Materials* Instrument: GeneChip® System 3000Dx v.2, Fluidics Station 450Dx v.2 (per Affymetrix specification 08-0264)

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

Table A.5 Table Containing Names and Contents of Toxic or Hazardous Materials* Instrument: GeneChip® System 3000Dx v.2, Fluidics Station 450Dx v.2 (per Affymetrix specification 08-0264)

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

*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 1）。

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
马达和线圈	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

Regulatory Compliance–GeneChip® Scanner 3000Dx v.2

CE Mark Declaration of Conformity

Affymetrix, Inc.
3450 Central Expressway
Santa Clara, CA 95051 USA

Declare under sole responsibility that the GeneChip® Scanner 3000Dx v.2 and its accessory AutoLoader Dx v.2 meet the provision of the Council Directive 98/79/EC for In Vitro Diagnostic Medical Devices as transposed in the national laws of the Member States.

Table A.6

Referenced Standards	
Low Voltage Directive (LVD) 2006/95/EC	Electromagnetic Compatibility (EMC) Directive 2004/108/EC
Referenced Safety Standards	Referenced EMC Standards
IEC 61010-1:2001 IEC 61010-2-081:2001+A1:2003 IEC 61010-2-101:2002 IEC 60825-1:2007	EN 61326-1, 2006 CISPR 11:2003;Amendment 2, 2006, Class A EN 55011:2007;Amendment A2:2007, Class A
EN 61010-1:2001 EN 61010-2-081:2002+A1:2003 EN 61010-2-101:2002 EN 60825-1:2007	IEC 61000-3-2:2005+A1:2008 IEC 61000-3-3:2008 IEC 61000-4-2:2008 IEC 61000-4-3:2008 IEC 61000-4-4:2007 IEC 61000-4-5:2005 IEC 61000-4-6:2008 IEC 61000-4-8: 2001 IEC 61000-4-11:2004
CAN/CSA-C22.2 No. 61010-1/R:2009 CAN/CSA-C22.2 No. 61010-2-081:2004 CAN/CSA-C22.2 No. 61010-2-101:2004	
UL 61010-1/R:2008-10	EN 61000-3-2:2006, Class A EN 61000-3-3:1995, Amendment 2:2006 EN 61000-4-2:1995, Amendment 2, 2001 EN 61000-4-3:2006, Amendment 1, 2008 EN 61000-4-4:2004 EN 61000-4-5:2006 EN 61000-4-6:2007 EN 61000-4-8: 1993; Amendment 1, 2001 EN 61000-4-11:2004

Table A.7

Conformity Assessment		
Device Classification	Route to Compliance	Standards Applied
Class: Self-Certify	Annex III of IVD 98/79/EC Council Directive	ISO 13485–Medical Devices–Quality Management Systems–Requirements for Regulatory Purposes

GeneChip® System 3000Dx v.2

Affymetrix, Inc.

3450 Central Expressway

Santa Clara, CA 95051 USA

Declare under sole responsibility that the GeneChip® System 3000Dx v.2, including the Scanner 3000Dx v.2, the AutoLoaderDx v.2, the Fluidics Station 450Dx v.2, and associated Workstations with Affymetrix® Molecular Diagnostic Software (AMDS) meet the provision of the Council Directive 98/79/EC for In Vitro Diagnostic Medical Devices as transposed in the national laws of the Member States.

Table A.8

Referenced Standards	
Low Voltage Directive (LVD) 2006/95/EC	Electromagnetic Compatibility (EMC) Directive 2004/108/EC
Referenced Safety Standards	Referenced EMC Standards
IEC 61010-1:2001 IEC 61010-2-081:2001+A1:2003 IEC 61010-2-101:2002 IEC 60825-1:2007	EN 61326-1, 2006 CISPR 11:2003;Amendment 2, 2006, Class A EN 55011:2007;Amendment A2:2007, Class A
EN 61010-1:2001 EN 61010-2-081:2002+A1:2003 EN 61010-2-101:2002 EN 60825-1:2007	IEC 61000-3-2:2005+A1:2008 IEC 61000-3-3:2008 IEC 61000-4-2:2008 IEC 61000-4-3:2008 IEC 61000-4-4:2007 IEC 61000-4-5:2005 IEC 61000-4-6:2008 IEC 61000-4-8: 2001 IEC 61000-4-11:2004
CAN/CSA-C22.2 No. 61010-1/R:2009 CAN/CSA-C22.2 No. 61010-2-081:2004 CAN/CSA-C22.2 No. 61010-2-101:2004	
UL 61010-1/R:2008-10	EN 61000-3-2:2006, Class A EN 61000-3-3:1995, Amendment 2:2006 EN 61000-4-2:1995, Amendment 2, 2001 EN 61000-4-3:2006, Amendment 1, 2008 EN 61000-4-4:2004 EN 61000-4-5:2006 EN 61000-4-6:2007 EN 61000-4-8: 1993; Amendment 1, 2001 EN 61000-4-11:2004

Table A.9

Conformity Assessment		
Device Classification	Route to Compliance	Standards Applied
Class: Self-Certify	Annex III of IVD 98/79/EC Council Directive	ISO 13485–Medical Devices–Quality Management Systems–Requirements for Regulatory Purposes

Regulatory

This device complies with Part 15 of FCC Rules ([Table A.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 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.

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 brouilleur du Canada.

Table A.10 Regulatory Certifications

Regulatory Agency	Certification
	
Class I Laser Device	Complies with EN 60825-1:2007 Complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007
Hand held barcode reader is a Class II laser device	Complies with EN 60825-1:2007 Complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007
	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.11](#) and [Table A.12](#) contain information identifying the specific hazardous material(s) and the components/parts in which they are found.

Table A.11 Table Containing Names and Contents of Toxic or Hazardous Materials* Instrument: GeneChip® System 3000Dx v.2, Scanner 3000Dx v.2 with AutoLoaderDx v.2 (per Affymetrix specification 08-0265)

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

Table A.11 Table Containing Names and Contents of Toxic or Hazardous Materials* Instrument: GeneChip® System 3000Dx v.2, Scanner 3000Dx v.2 with AutoLoaderDx v.2 (per Affymetrix specification 08-0265) (Continued)

Component/Part Categories	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent Chromium (Cr 6)	Polybrominated Biphenyls (PBBs)	Polybrominated Diphenyl Ethers (PBDEs)
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 A.12 Table Containing Names and Contents of Toxic or Hazardous Materials* Instrument: GeneChip® Scanner 3000Dx v.2

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

Table A.12 Table Containing Names and Contents of Toxic or Hazardous Materials* Instrument: GeneChip® Scanner 3000Dx v.2 (Continued)

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

*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.

Figure A.1 Scanner Chinese Text 1

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	Pb (ppm)	Hg (ppm)	Cd (ppm)	Cr(VI) (ppm)	PBB (ppm)	PBDE (ppm)
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

*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

Figure A.2 Scanner Chinese Text 2

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

*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

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