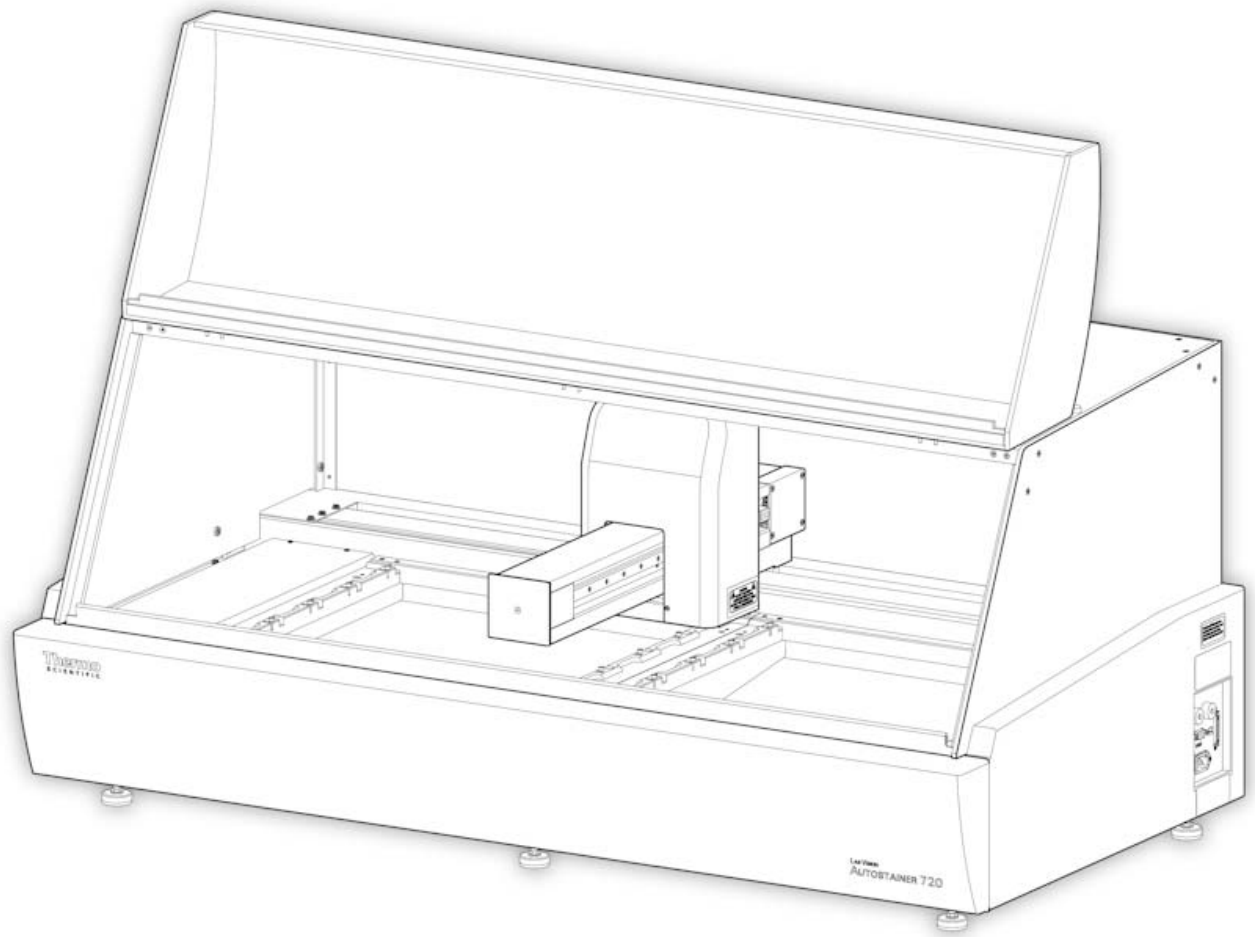
Thermo Scientific
Autostainer
Operator Guide
A80510100 Issue 5



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Standards

The Thermo Scientific Autostainer meets the following CE Mark requirements:

In Vitro Diagnostic Directive 98/79/EC

Low Voltage Directive 2006/95/EC, as amended by 93/68/EEC

Symbols

The following symbols and conventions may be used throughout this document and on the instrument:

This symbol is used on the equipment, or in a document, to indicate that instructions must be followed for safe and correct operation. If this symbol appears on the instrument, always refer to the Operator Guide.

This symbol is used on the equipment, or in a document, to indicate that there may be a biohazard associated with the instrument. Always act with common sense and be aware of the samples used. Take suitable precautions.

This symbol is used on the equipment, or in a document, to indicate that harmful chemicals are used. Refer to the Material Safety Data Sheets for the chemicals used. Always act with common sense and be aware of local laboratory procedures. Take suitable precautions.

This symbol is used on the equipment, or in a document to indicate that there is a possible danger from laser radiation either direct or scattered. Always act with common sense and never look directly into the laser beam.

A WARNING IS GIVEN IN THE DOCUMENTATION IF THERE IS A DANGER OF PERSONAL INJURY OR DAMAGE TO THE EQUIPMENT OR SAMPLES.

Note

Notes give additional information about a job or instruction, but do not form part of the instruction.

Other Symbols

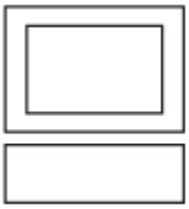
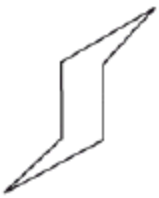
	This symbol and the associated LED are used on the equipment to indicate whether the computer is connected to the Autostainer unit. When the LED is illuminated, the unit has detected the computer connection.
	This symbol and the associated LED are used on the equipment to indicate whether there is power to the Autostainer unit. When the LED is illuminated, the unit is powered.

Table of Contents

Safety Information

Introduction

Thermo Fisher Scientific products are designed for convenient and reliable service; however, incorrect actions by a user may damage the equipment, or cause a hazard to health.

The following sections contain important information for the safe setup and use of the instrument.

All users must read and understand the following sections before using the instrument.

General Safety

This instrument, as supplied, conforms with IEC61010-1 and IEC61010-2-100; however, the addition of chemicals introduces potential hazards.

As with all scientific equipment, due care and good laboratory practice must be employed when dealing with these chemicals, and consideration must be given to the potential for hazard when dealing with particular chemicals.

Be aware that many of the reagents used with this instrument may be flammable. Do not introduce any source of ignition into, or near, the instrument once it has been loaded with reagents.

Do not remove any panels or covers. The instrument does not have any user serviceable parts.

The instrument must be properly connected to a good earth (ground) via the Mains input supply.

Position the instrument such that it is possible to interrupt the Mains supply at the source by removing the plug from the socket.

If the equipment is used in a manner not specified by Thermo Fisher Scientific , the protection offered by the equipment may be impaired.

Make sure that there is at least 100mm (4in) clearance around any fan inlets on the instrument.

In compliance with statutory requirements all our equipment is designed to accepted standards of safety. Its use does not entail any hazard if operated in accordance with the instructions given in the documentation. However, the following safety precautions must be obeyed:

- All users must have read and understood the Operator Guide and these safety instructions; and only operate the unit in accordance with the instructions.
- Potentially lethal voltages above 110V a.c. or 50V d.c. are present inside the instrument. Do not remove any access covers unless specifically instructed to do so.
- It is important that normal standards of safety and good laboratory practices are employed. Always use common sense when operating the instrument.
- Any problems and queries should be referred to your Thermo Fisher Scientific supplier.
- Correct maintenance procedures are essential for consistent performance. It is recommended that a Maintenance Contract is taken with our Service Department.
- Use only factory approved accessories or replacement parts with this instrument.
- Only use reagents recommended in the Operator Guide.

Disposal of Sealed Lead Acid Batteries

In cases where there are two back-up batteries, these should always be replaced as a pair at the recommended service interval.

If the instrument has mainly been operated in very low temperatures, or has been exposed to frequent mains failures, the batteries should be replaced every year.

The battery manufacturers advise their customers to comply with the relevant regulations within their particular country regarding disposal of this type of battery.

The batteries used within this instrument are valve regulated sealed lead-acid type rechargeable batteries; the specific details of which can be found in the Operator Guide.

Chemical Safety

THE INTRODUCTION OF CHEMICALS CREATES POTENTIAL HAZARDS AND THERMO FISHER SCIENTIFIC HAS ADOPTED THE FOLLOWING POSITION WITH REGARD TO THE SUBJECT OF VOLATILE CHEMICALS USED IN MEDICAL LABORATORIES:

- Non-specified chemicals are used in the instrument at the customers own risk.
- All the chemicals recommended by Thermo Fisher Scientific have auto-ignition temperatures considerably above any surface temperature that can be reached during a single fault failure on the instrument. Small quantities of paraffin wax present will not reach a temperature that will produce flammable vapour.
- The instrument contains no source of ignition in any areas of the instrument where chemicals are stored, or are likely to leak into in a single fault condition.
- The operator is fully aware of the contents of the specification documents detailing the properties of the chemicals they are using.
- The operator has carried out any legally required assessment of chemicals used and is using good laboratory practice.

Some chemicals which may be used during operation are flammable - do not use sources of ignition in the vicinity of the instrument when it is loaded with reagents.

Harmful chemical vapours such as xylene and toluene may be emitted during the normal operation of some instruments, and the operator should be aware of suitable precautions and safety measures.

Environment

This product is required to comply with the European Union's Waste Electrical and Electronic Equipment (WEEE) Directive 2002/96/EC. It is marked with the following symbol:

Thermo Fisher Scientific has contracted with one or more recycling / disposal companies in each EU Member State, and this product should be disposed of or recycled through them.

Further information on Thermo Fisher Scientific 's compliance with these Directives, the recyclers in your country, and information on Thermo Fisher Scientific products which may assist the detection of substances subject to the RoHS Directive are available at:

www.thermo.com/WEEERoHS

Warranty Statement

We at Thermo Fisher Scientific are proud of our quality, reliability and of our after-sales service. We continuously strive to improve our service to our customers.

Please ask your distributor or Thermo Fisher Scientific representative about Service Contracts which can keep your purchase in peak condition for many years to come.

Warranty provisions necessarily vary to comply with differences in national and regional legislation. Specific details can be found in the delivery documentation or from your dealer or representative.

Please note that your warranty may be invalidated if:

- This instrument is modified in any way.
- Accessories and reagents which have not been approved by Thermo Fisher Scientific are used.
- The instrument is not operated or maintained in accordance with the instructions in the Operator Guide.

Product Return Safety Declaration

Thermo SCIENTIFIC

PRODUCT RETURN SAFETY DECLARATION

Part 1 Decontamination Certificate

Any instrument or part of any instrument must be clean before being returned, and where necessary accompanied by a completed Decontamination Certificate. Should the instrument or any part of it be received in an unclean condition, or Thermo Fisher Scientific consider it to be a hazard, the instrument or part will be returned unrepaired at the expense of the customer.

It is important that the certificate is forwarded by post or fax, and a copy attached to the exterior of the container. Containers will not be opened until the company is in possession of the required certificate.

This form MUST be completed by the customer and NOT by a Thermo Fisher or distributor employee.

If an instrument or part is to be returned to Thermo Fisher Scientific, please note the following:

1 If the instrument or any part of it has been exposed to, or been in contact with potential pathogenic or radioactive material, it is essential that it is decontaminated.

2 Set procedures are laid down in the European Health and Safety Directives for decontamination. To avoid any misunderstanding, we request that all instruments or parts returned to us must be accompanied by a certificate stating the following:

We certify that this (Model)..... Serial No.....

- has not been exposed to pathogenic, radioactive or other hazardous material and has been cleaned

OR

- has been decontaminated and cleaned (if exposed to the above) according to approved procedures following exposure to:

- Has the instrument been used for work with human or animal Transmissible Spongiform Encephalopathies, e.g. Creutzfeld-Jacob disease, Scrapie or BSE?
  YES / NO
  If yes, please contact Thermo Fisher Service before taking any further action.

Signed ..... Position .....

Name (Block Capitals) .....

Company or Organisation .....

Full Address .....

.....

Part 2 Guidelines for Returning Instruments

Please use the checklist below to ensure that the instrument being returned is ready for collection.

- All reagents / wax removed from instrument, including vapour traps (if applicable)..... ☐
- Accessories are secured / itemised ..... ☐
- Instrument has had transit clamps fitted as per Operator Guide (if applicable)..... ☐
- Instrument is packed in original packaging..... YES / NO

RMA NUMBER .....

CARRIER .....

FOR ATTENTION OF .....

Laser Radiation

Symbols

LASER RADIATION - DO NOT VIEW DIRECTLY WITH OPTICAL INSTRUMENTS - CLASS 1M LASER PRODUCT.

LED LIGHT - DO NOT VIEW DIRECTLY WITH OPTICAL INSTRUMENTS.

CAUTION - USE OF CONTROLS OR ADJUSTMENTS OR PERFORMANCE OF PROCEDURE OTHER THAN THOSE SPECIFIED HEREIN MAY RESULT IN HAZARDOUS RADIATION EXPOSURE.

VIEWING THE LASER OUTPUT WITH CERTAIN OPTICAL INSTRUMENTS (FOR EXAMPLE, EYE LOUPES, MAGNIFIERS AND MICROSCOPES) WITHIN A DISTANCE OF 100MM MAY POSE AN EYE HAZARD.

POSSIBLE EXPOSURE TO CLASS 1M LASER RADIATION WHEN THE FRONT COVER OF THE INSTRUMENT IS OPEN OR IF THE Z-HEAD COVER IS REMOVED.

CLASS 1M LASER RADIATION WHEN OPEN

DO NOT VIEW DIRECTLY WITH OPTICAL INSTRUMENTS

Laser and LED Specification

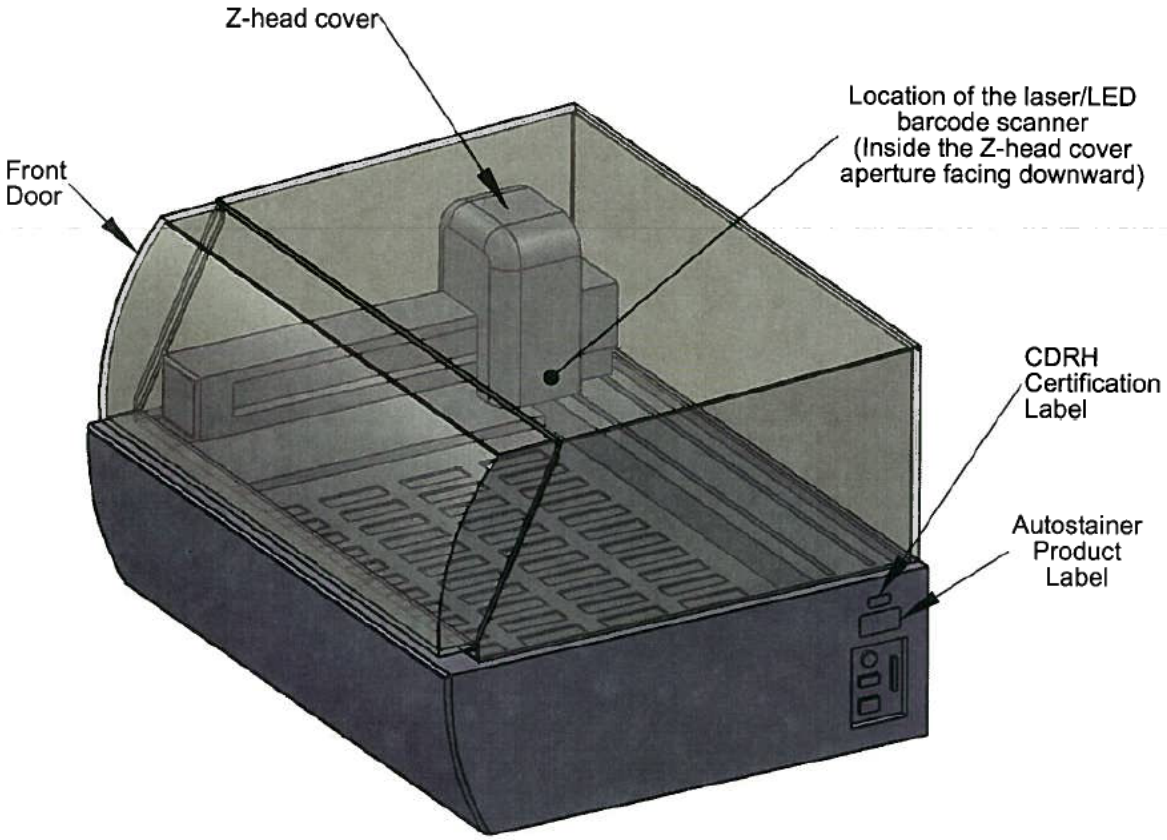
Property	Value
Laser Wavelength	652 nm
Laser Maximum Output	163.425 µW
Laser Pulse Duration	30 Hz with 20.4 ms 'on' time
LED Wavelength	630 nm
LED Maximum Output	12.723 µW
LED Pulse Duration	30 Hz with 11.2 ms 'on' time

Laser Label on Instrument

The following label appears on the Autostainer instrument.

Complies with FDA performance standards for laser products except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.

CDRH Certification label located on outer cover.



Autostainer showing position of labels.

Storage and Handling

Reagents

Reagents used on the Autostainer include various salt buffers, protein solutions (antibodies and detection systems), chromogenic chemicals (DAB, AEC, Fast Red, etc.) and tissue dyes. Sterile procedures, containers, and probes should be used when opening, diluting, and decanting all solutions to prevent contamination with bacteria. Each of these materials must be stored at 4°C when not in use to prevent microbial growth. If any solution becomes cloudy, it should be considered contaminated and should not be used. The manufacturer's use instructions should be followed for all reagents.

FOLLOW GOOD LABORATORY PRACTICE AND WEAR GLOVES WHEN HANDLING HAZARDOUS SUBSTANCES, SUCH AS DAB

Instrument

General

- The Autostainer must only be operated using the authorized program on the computer (accessed by clicking the Autostainer icon).
- Do not use the CD-ROM drive port and other applications while the Autostainer is operating.
- Do not switch off power until the program is properly closed down on the computer as indicated by the green computer LED on the front right of the Autostainer.
- The front lid of the Autostainer must be closed during operation for safety.
- Before opening the lid check on screen to see if the Autostainer is still in operation.
- The instrument may not operate properly if exposed to direct sunlight.
- The buffer and water bottles must be kept at floor level to ensure proper operation.
- Buffer must contain surfactant to ensure good spreading of reagents on slides (e.g. Tween 20 at 0.05% v/v).

Programming, Reagent Arrangement and Barcode Labelling

CARE MUST BE TAKEN WHEN PROGRAMMING PROTOCOLS, ARRANGING REAGENTS AND LABELLING SLIDES, AS MISTAKES MAY RESULT IN FALSE POSITIVE OR FALSE NEGATIVE RESULTS.

Chapter 1

Introduction to Autostainer

Theory and Intended Purpose

The Autostainer is intended to be used by laboratory professionals who are trained in immunohistochemistry. The Autostainer is intended to facilitate procedures used in immunohistochemistry – the application of immuno-reagents (antibodies) to tissue sections, cell cultures, cytospins, cytology ThinPrep© or smears on glass microscope slides.

The Autostainer allows the automation of immunohistochemistry procedures by providing:

- Slide racks.
- Reagent racks.
- A delivery system to put the reagents on the slides.
- An interface to program the computer, in order to assign reagents to the slides in the proper sequence, and to allow the proper timing of each step.

Description, purpose, and principle of working

The Autostainer is an automated, computer-driven liquid handling system, compatible with all currently available reagents for immunohistochemistry, and related applications. The instrument is designed to perform highly consistent automated immunostaining, in a way that closely mimics the manual methods used in most laboratories. This enables the easy transfer of established manual methods to an automated instrument, without any changes to the reagents used.

Note

The Autostainer should be placed in a location that avoids direct sunlight and an environment away from extreme heat or cold.

Note

The "~" symbol on the rating plate indicates that this instrument operates on an alternating current (a.c.) supply.

Note

Maximum supply voltage fluctuations must not exceed 10% of nominal voltage.

Note

The unit must be connected to an effectively earthed (grounded) outlet

Note

This instrument requires surge protection.

Note

Performance may deteriorate if operated outside of the recommended operating temperature range.

System Specification

	Autostainer 360	Autostainer 480S	Autostainer 720
Placement	For Indoor Use Only		
Instrument Dimensions (WxDxH)	76 x 67 x 58 cm	91 x 67 x 58 cm	128 x 67 x 58 cm
Minimum Required Space (WxDxH) (not inc. Computer and Printers)	85 x 60 x 95 cm	100 x 60 x 95 cm	135 x 60 x 95 cm
Voltage Rating	100-120 VAC, 50/60Hz 220-240 VAC, 50/60Hz		
Current Rating	4A MAX at 120 Vac		
	2A MAX at 240 Vac		
Weight	55kg	65kg	80kg
Temperature (Recommended Operating)	+15°C to +30°C (+59°F to +86°F)		
Temperature (Operating Limits)	+5°C to +40°C (+41°F to +104°F)		
Temperature (Transport and Storage)	-25°C to +55°C (-13°F to 131°F) +70°C (+158°F) for short exposure		
Maximum relative humidity	80% for temperatures up to 31°C (86°F), decreasing linearly to 50% at 40°C (104°F). (no condensation)		
Altitude	Up to 2,000 m (6,500 ft)		
Pollution Degree	2		
Over Voltage Category	II		
Slide Capacity	36	48	72
Reagent Capacity	40	49	84
Reagent Dispense Volumes (µl)	100, 150, 200, 400, 600 minimum 2x100/150 (drop 25µl)		
Pipette Capacity	1.6 ml		
Reagent Carryover Via Pipette	<10-6		
Dispense Locations on Slides	Top - Middle - Bottom		

Note

The Autostainer should be placed in a location that avoids direct sunlight and an environment away from extreme heat or cold.

The "~" symbol on the rating plate indicates that this instrument operates on an alternating current (AC) supply.

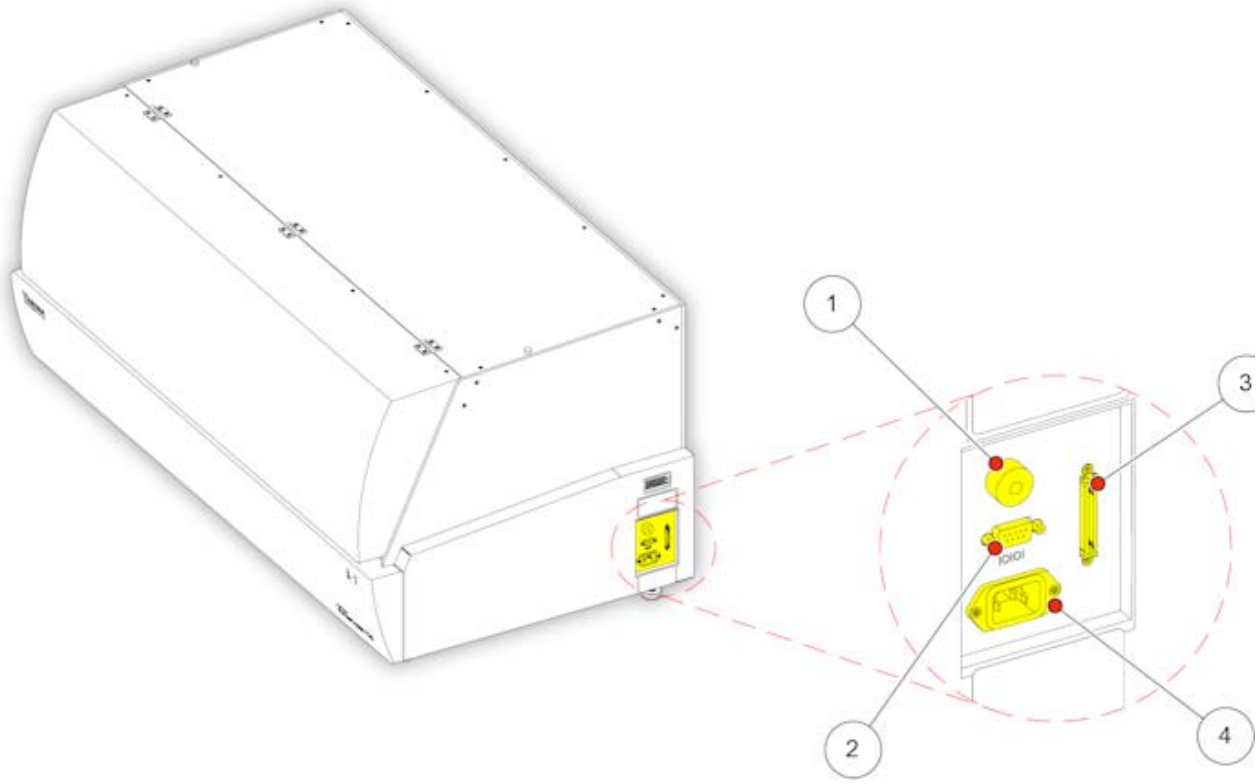
Maximum supply voltage fluctuations must not exceed 10% of nominal voltage.

The unit must be connected to an effectively earthed (grounded) outlet

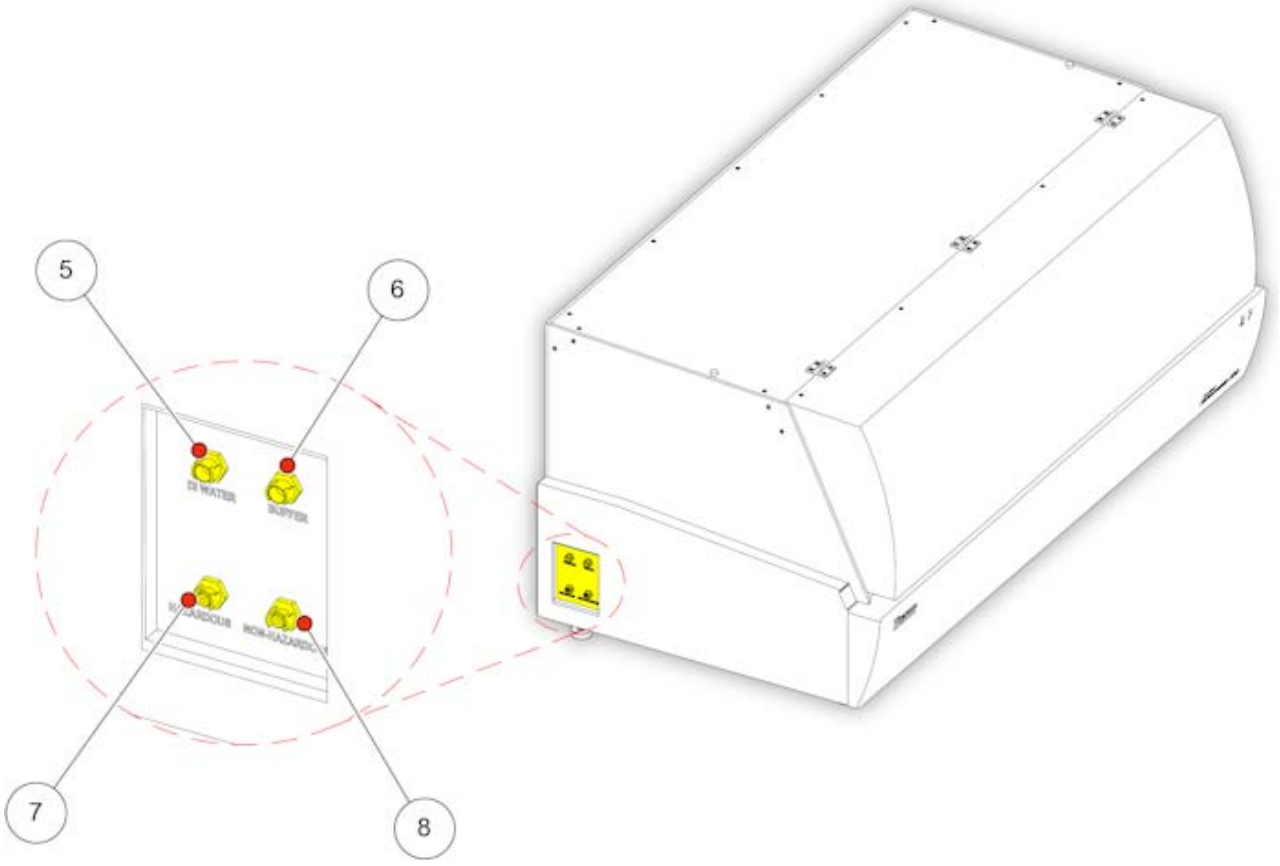
This instrument requires surge protection.

Performance may deteriorate if operated outside of the recommended operating temperature range.

Identification of Parts

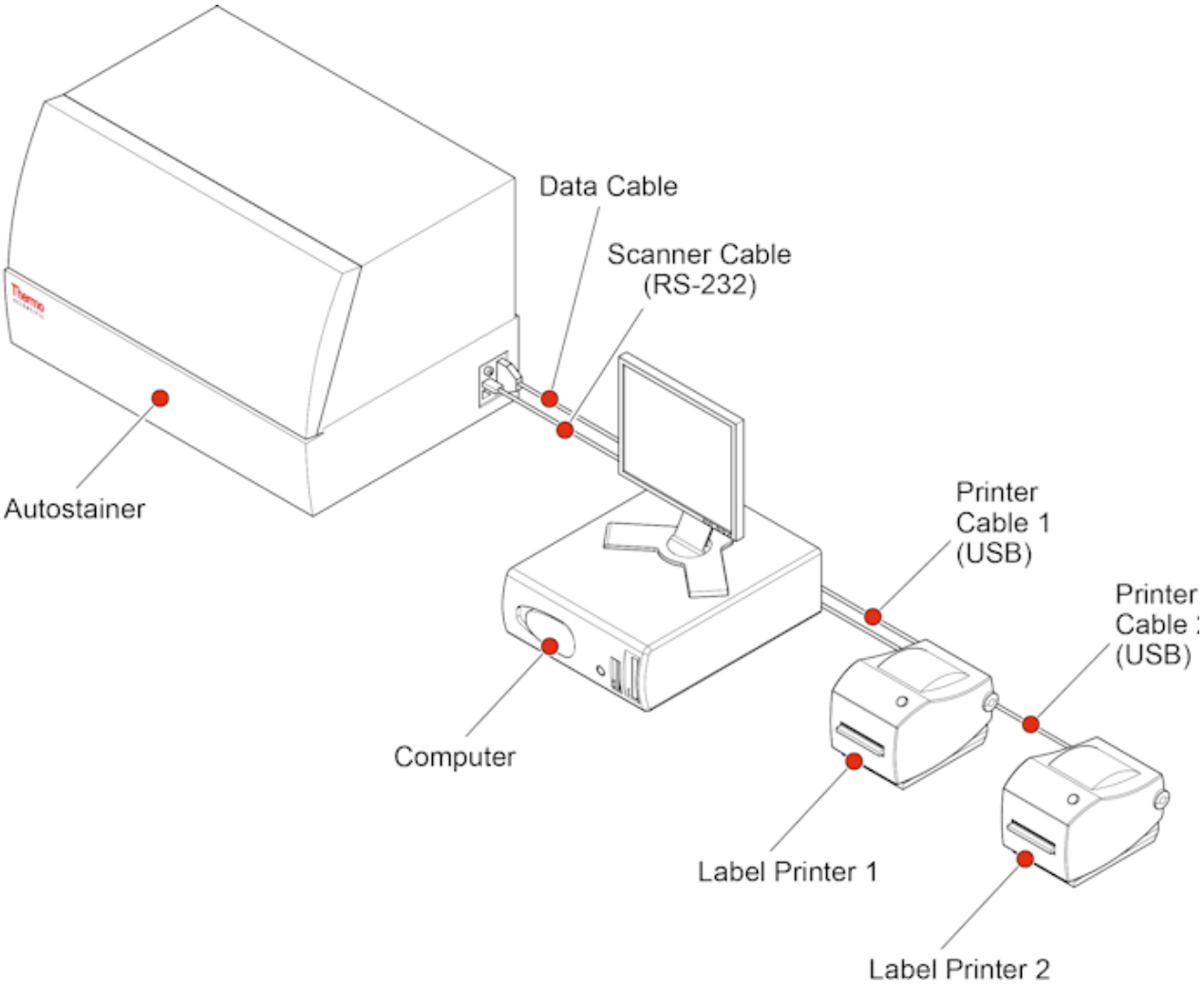


View on right-hand side of Autostainer showing electrical connections and circuit-breaker reset.



View on left-hand side of Autostainer showing pipe couplings.

Item	Description
1	Circuit Breaker Reset Button
2	Barcode Scanner Connector
3	Computer Connector
4	Mains Input Socket
5	DI Water Inlet Coupling
6	Buffer Inlet Coupling
7	Hazardous Outlet Coupling
8	Non-Hazardous Outlet Coupling



Block diagram of instrument connection

Chapter 2

Installation and Setup

Transportation and Unpacking

- Unpacking and setup will be carried out by a factory-trained professional.
- The Autostainer must be placed on a solid, level, vibration-free laboratory bench.
- The instrument must be levelled.
- Two people are required to move the Autostainer.
- It is important that the arm is secured prior to moving the Autostainer.
- Keep the Autostainer level during transportation.

Preparation prior to operation

Instrument

The following preparations must be completed prior to operation:

- Make sure all waste bottles are empty.
- Make sure Buffer and DI Water bottles are filled with appropriate water or reagent.
- Put free end of DI Water inlet tube into the bottle labelled DI Water.
- Put free end of Buffer inlet tube into the bottle labelled Buffer.
- Put free end of Hazardous waste outlet tube into the bottle labelled Hazardous.
- Put free end of non-Hazardous waste outlet tube into the bottle labelled non-Hazardous.
- Make sure there are no obstructions to the movement of the robot arm.
- Ensure reagent rack(s) with vials is correctly loaded and pushed firmly down in the guide clips.
- The printer must be attached to the computer to print reports.
- The slide labeler must be attached to the computer to print labels.
- Barcoded labels must be attached to slides and reagents to use the barcode reading system.
- Turn the instrument on (via the computer interface).

Reagents

In order to operate the Autostainer for optimum results, all reagents must be prepared in a meticulous manner.

- All reagent volumes must be correct to ensure proper staining.
- Vials must be in their proper locations or bar-coded with reagent bar coding enabled.
- Antibody reagents must be correctly diluted.
- Buffer solutions and chromogen reagents must be fresh.
- Some reagents may need to be prepared immediately prior to use.

Special materials and equipment required in order to use the IVD instruments properly.

- The Autostainer will only accommodate reagent vials, vial racks, and slide racks designed specifically for the instrument. No other vials, vial racks, or slide racks may be substituted.
- The Autostainer is designed to hold and stain tissue sections or cell smears on glass microscope slides. Any special conditions of collection, pretreatment, and storage conditions for the tissue sections are variable and must be determined by the user.

Chapter 3

Basic Operation

The Autostainer is designed to hold and stain tissue sections or cell smears on glass microscope slides. Any special conditions of collection, pre-treatment, and storage conditions for the tissue sections are variable and must be determined by the user.

Start Up Procedure

Turning on the Autostainer and signing in:

- Turn on the computer and monitor and you will observe the Autostainer icon displayed in the typical Microsoft® Windows® user interface screen.
- Double click the Autostainer icon.

Autostainer icon

- The **Sign In** screen will appear with the cursor in the **Name Box**.
- Type in your name and press **Enter** – the cursor will move to the **Password Box**.
- Type in your password and press **Enter** – the **Main Menu** screen will appear.

At the Main Menu screen you can:

- Click on the **Program** button to program a run.
- Click on the **Initialize** button to set up the Autostainer or to edit any of the initialize information (institution information, staff names, default reagent volumes, frequency of the cleaning cycle, and other options).
- Click on the **Clean** button to get cleaning instructions ready to start a cleaning cycle.
- Click on the **Scan Slides** button to scan slides labeled with Auto program bar codes.
- Click on the **Sign Off** button to exit the Autostainer.
- Click on the **Reagent Tracking** button to review alphabetical list of reagents used.
- Click on the **Help** button to view information relevant to the **Main Menu** screen.
- Click on the **Prime Pump** button to ensure proper operation of the rinse mechanism.

Programming Methods

The Autostainer series has two configuration options linked to different methods of programming slides and printing barcoded labels. One configuration option is selected according to the user's needs during installation. The first configuration option (BarMeth 1) is primarily used in research settings that are using few protocols on large runs.

BarMeth 1 allow users to program directly from the grid and then print slide labels with barcodes that correspond to the programmed slides.

The second configuration option (BarMeth 2) is designed for routine clinical labs where primary antibodies are run often with few changes to the protocols once they have been established. This method allows the user to enter patient information and select which antibodies (Auto Programs) will be run on this patient’s slides.

The slide labels and barcodes are then printed with the correct slide information and bar code which directs the test that will be performed on the slide.

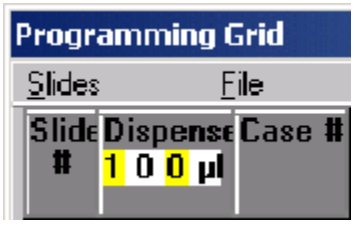
Typical Operation (Step by Step)

Programming on the main grid

Note

These steps can be taken if the configuration option BarMeth 0 or BarMeth 1 have been selected or after scanning slides with configuration option BarMeth 2)

- Press the **Enter** key or click on the **Program** button in the **Main Menu** screen.
- At this point the Program grid is not active until the user either enters information into the **Slide Information** screen or uses the **Slides** button, a slide count facility, to enter the number of slides to be tested without entering slide information.
- Access the **Slide Information** screen by pressing the **Enter** key or clicking the **Slide Info** button in the bottom left of the program grid.
- Select a protocol template for the current staining program via the **Protocol Template Design** screen, unless you are using the protocol template set as the default template which activates each time you open the software. (See section on **Protocol Templates**).
- Assign the required reagents to all slides in the **Programming Grid** screen.
- To change the Primary Antibody volume for all slides, click on the **µl** symbol in the first row in the **Dispense** column, and select the desired volume in the **All Slides Primary Volume** screen.



Changing the primary antibody volume.

- To change the volume for an individual slide, click on the µl symbol for that slide. Similarly, to change the reagent drop zone for all slides or one slide, viewing a slide with the label to the right, click on one of the three dispense locations (Yellow), or hold the **Control** key and click to select more than one.

Note

The dispense volume applies to each dispense location selected. E.g. volume set at 100 µl with two yellow bars = 200 µl (The software will compute dispensing of no more than 200 µl of any one reagent to a slide).

- Click **Next** to go to the **Assign Reagents to Vials** screen and select reagent rack choice, then click **OK**.
- A **Runtime** screen appears as a pre-warning of the time required. Click **OK**.
- A **Reagent Layout Map** screen appears to detail the volumes and locations of reagents in vial rack(s). This screen is often printed to provide total reagent, buffer, and water volume requirements.
- Click **Next** to go to **Slide Layout Map** – load **Slides** screen for on-screen guidance to correctly locate slides.
- Continue at **Starting the Staining Run**.

Scanning barcoded slides

Note

These steps can be taken if the configuration option has been selected to be BarMeth 0 or BarMeth 2.

1. If configuration option BarMeth 0 is selected, click the **Scan Slides** button; if BarMeth 2 is selected, click the **Program** button to display the **Load and Scan Slides** screen with a **Scan Slides Count** dialog on top of it.
2. If the slides to be stained are already labeled, enter the number of slides to be stained, click the **OK** button and continue at **Step 5**. If the slides are not yet labeled, click the **Print Labels** button to display the **Auto Program Labels** dialog and continue at **Step 3**.
3. Check the **Print Panels** option to print a label for each slide in multi-slide auto-programs or un-check the option to print only the first slide.
4. There is a choice of three possible ways to print new auto-program bar coded slide labels by entering data and selecting auto-programs and one way to print labels defined by an external system:
    - **Print Designed Labels** – select an auto-program from the list, enter a number of labels, and click Print to print the labels.
    - **Edit Label Text** – enter a number of labels and click **Edit** to display the **Edit Slide Label** dialogue. Check the **Edit** option next to the lines that will be different for each label and check the **Record** option after the lines that will be used to identify the slides when they are being stained (the **Edit** and **Record** options are retained). Enter the text to identify each slide and press **Enter** to advance to the next line. After the last edited line, select the auto-program for the slide and click the **OK** button to print the label. Click **Cancel** to return to the **Auto-program Labels** dialogue.
    - **Enter Label Slide Info** – click the **Enter** button to display the **Slide Information** dialogue. Enter the slide identifying information and select one or more auto-programs by scrolling the list to the desired auto-program name and pressing **Enter**. The labels to be printed will appear in the list box. If a list entry was added by mistake, click on it to display a deletion confirmation message. Check the **Delete Duplicate Antibodies** option to prevent the same antibody from different, multi-slide auto-programs from being selected. After all labels for a case (or block if **Block ID** is enabled) have been added, press **Tab** key to begin entering the next set of slide identifying information. When all labels have been entered, click the **Finish Entry** button to display the **Print Slide Labels** dialogue. Labels added by mistake can also be deleted from this list by clicking on them and responding to the deletion confirmation message. Click the **Print** button to begin printing all of the list labels. Clicking the **More Labels** or **Exit** button will interrupt printing. If printing is interrupted, returning to the **Print Slide Labels** dialogue will display the un-printed labels. Click **More Labels** to return to the Slide Information dialogue. Click **Exit** to return to the **Auto-program Labels** dialogue.
    - If configuration option Import 1 is selected, a **Label Import** button appears at the bottom of the **Auto-program Labels** dialogue. If a file named IMPORT.TXT has been placed in the program folder by a **Laboratory Information System**, clicking this button opens the file and prints a label using the data in each line of the file. Each line must include the name of an auto-program at the end of the line. Up to three text fields may precede the auto-program name. Each text field may be up to twenty characters followed by a **Tab**. The default label format prints each text field on the corresponding line. If configuration option DsgnImpt 1 is selected, the labels are printed according to the **Design Slide Label** specification. That specification must at least select SlideID/Text Line 1, Case#/Text Line 2, for as many text fields as there are in IMPORT.TXT in order to capture the supplied information.

From **Auto-program Labels** click **Cancel** to return to the **Scan Slide Count** dialogue and enter the number of slides to be stained.

5. If the reagent bar coding option is enabled, scanning of both slides and reagents can be initiated in one step by checking the **Scan Reagents and Slides** option. This option bypasses the **Programming Grid**, so there is no opportunity to makes changes or to save the program.
6. Load the slides into the slide racks and click the **Scan Slides** button. Click **OK** to the "**Is the arm clear to move?**" message to begin scanning the slides.
7. If the **Scan Reagents and Slides** option was not checked or there is any error in slide scanning, when all slides have been entered, click the **OK** button to display the **Programming Grid** with slides already programmed. Click the **Back to Grid** to discard any slide programming and display an empty **Programming Grid**.

Unused labels and reprint labels

The **Auto-program Labels** dialogue includes two buttons, **Unused Labels and Reprint Labels**, that provide access to lists of labels printed but not yet used in a complete staining run and labels already used.

Entries in the **Unused Labels** list can be deleted or copied to additional labels. The textual information in the **Unused Labels** list is used to fill in the identification of slides, for example, on the **Programming Grid**, when the slides are scanned. If the "**Auto-delete after n days**" is greater than zero, entries that are older than the specified interval will be deleted whenever the user accesses the list and exits by clicking **OK**. When labeled slides have been processed the corresponding entries are moved to the **Reprint Labels** list.

Entries in the **Reprint Labels** list can be copied to additional labels but cannot be changed except by specifying a number greater than zero in the "**Within n days**". Labels processed prior to that limit are not displayed but remain in the list indefinitely.

Copies of labels from either the **Unused Labels** or **Reprint Labels** list will be identical to the original labels except for the slide reference, which should be unique for each label.

Starting the Staining Run

- When ready click **Next** to go to the **Set Start Time** screen. If required, adjust the start time using the scroll bar. If active, make a note of the **Batch-Time** when an alarm will request addition of the labile substrate vial. Activate the **Check Volumes** facility then click **Start Run**.
- A **Run Program Now** warning will ask if the pathway is clear for the arm to move. Click **OK** if all racks are correctly positioned.
- A request for 0.1 or 0.2 litres of extra buffer will appear to account for probe washing during reagent checking. Click **OK**.
- The Autostainer will run to completion without further attention.

In preparation for a staining session, you should have the following items ready:

- A list of information, including patient details (Slide ID), case numbers and/or block numbers, on slides to be run and the requested antibody/protocol.
- De-paraffinised slides hydrated in buffer or water.

Note

Buffer used with the Autostainer must contain surfactant, such as 0.05% v/v Tween 20.

- The reagents required for the staining Program at ambient temperature, in vials and correctly located in a vial rack.
- Sufficient buffer and deionised or distilled water in containers connected to Autostainer.

Note

To ensure proper spreading of reagents on the slides, buffer must contain 0.05% v/v Tween 20.

- Waste containers (for hazardous and non-hazardous waste) large enough to accept the waste from the staining Program.

Slide Information

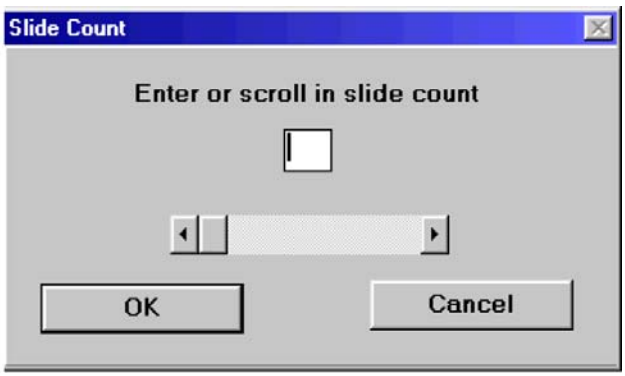
A **Programming Grid** remains inactive (reagents cannot be assigned to cells) until slide information is added to the system. After opening a new **Programming Grid**, the highlighted button would be "**Slide Info**"; therefore pressing the **Enter** key will take you to the **Slide Information** screen.

Alternatively, a Programming Grid can be activated by entering a number (slides) for the slide counter.

Entering slide count number only

This option activates a **Programming Grid** without columns for **Patient**, **Case** or **Block** details.

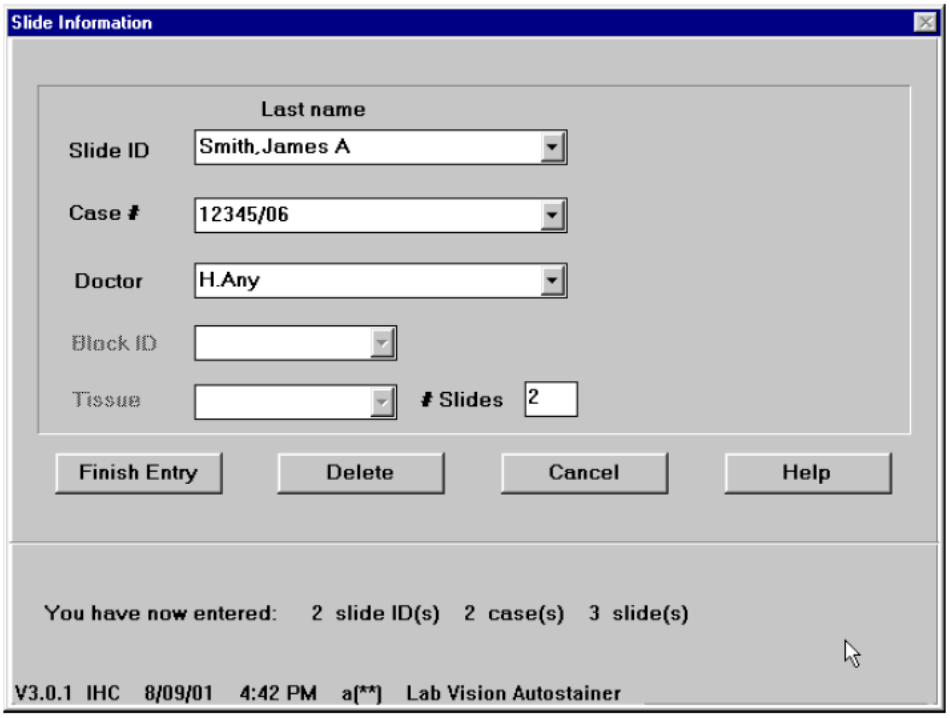
1. Before any slide information has been entered, press the '**S**' key, or click on the **Slides** heading at the top left of the **Programming Grid** screen – the **Slide Count** dialogue will display.
2. Type in, or scroll, the number of slides for the **Program** within the **Slide Count** box. A click in the arrow increases the count by one. A click in the bar, right or left of the scroll block adds or removes multiples of 12 slides. When the count is correct press **Enter** or click **OK**.



Slide count dialogue box.

Entering slide information

1. Click the **Slide Info** button in the **Programming Grid** screen to display the **Slide Information** screen. The cursor will be in the **Slide ID** box (If the **Slide ID** option was not enabled in the **Initialize/Options** screen, the cursor will start in the **Case** # box. Go to **Step 5**).



Slide information screen.

2. Type in the patient's last name or any other identifying information. Press **Enter** and a box for the **First Name** will appear with the cursor in it.
3. Type in the patient's first name, or other slide identification, or nothing and press **Enter** and a **MI (middle initial)** box will appear with the cursor in it.
4. Type in the middle, initial or nothing and press **Enter** to move the cursor to the **Case** # box.

Note

Steps 2-4 can also be accomplished by entering all the following information into the Slide ID box: patient's last name, comma, first name, space, and middle initial. Press Enter – the cursor will move directly to the Case # box.

5. Type in the **Case** # and press **Enter** – the cursor will move to the next field that is enabled.
6. If **Doctor** is enabled, press the up/down arrow key(s) to select from the list of doctors already entered, or type in any other doctor's name. Press **Enter** to advance to the next enabled field.
7. If **Block ID** is enabled, type in the **Block ID** and press **Enter**.
8. If **Tissue** is enabled, select from the list of tissues already entered or type in another tissue. Then press **Enter**.
9. In the # **Slides** box, type in the number of slides you will run for that case and press **Enter** – the cursor will now move back to the last enabled box.

Note

Up to 36/48/84slides can be entered per staining Program. If the number of slides exceeds 36/48/84, a warning message will appear telling you how many excess slides have been entered. A summary display at the bottom of the screen shows the numbers of slide IDs, Cases, and slides currently entered. This status line updates as new slide information is added providing a useful reference while programming.

10. If **Block ID** is enabled and there are more slides for the same **Case Number**, enter the next **Block ID**, and continue at **Step 8**. Otherwise, press **Enter** to move to the next **Case** #.
11. Continue at **Step 5**. When you have entered the last, or only **Case** # for a patient, press **Enter** to move the cursor from Case back to the **Slide ID** box. If necessary, repeat from **Step 2** or with the cursor in the blank **Slide ID** box, press **Enter** to highlight the **Finish Entry** button. With the **Finish Entry** button highlighted, press **Enter** to exit the **Slide Information** screen and return to the **Programming Grid** screen.

Note

If you want to omit information for any of the fields in the Slide Information screen, simply press the space bar once followed by Enter to move the cursor to the next field. The only field, which MUST contain an entry, is the # Slides box.)

Deleting slide information

There are several ways to delete slides and associated information:

- Deleting a **Slide ID**: Deletes all slides associated with the selected **Slide ID**.

Note

As a slide is deleted, all subsequent slides move up in the Programming Grid.

- Deleting a **Case** #: Deletes all slides associated with the selected **Case** #.
- Deleting a **Block ID**: Deletes all slides associated with the selected **Block**.
- Reducing the number of slides for a **Block ID** or **Case** #: This can only be done in the **Slide Information** screen if the slides to be subtracted have not already been programmed with reagents. Otherwise, you will be warned to return to the **Programming Grid** to delete slides.
- Deleting a specific slide: Erases one slide at a time and it must be done in the **Programming Grid** screen.

Deleting a slide ID

1. Click on the **Slide Info** button in the **Programming Grid** screen to display the **Slide Information** screen.
2. Press the down arrow key on your keyboard until the desired **Slide ID** appears highlighted.
3. Press **Enter** – the selected **Slide ID** will show in the **Slide ID** box and the cursor will move to the **Case** # box.
4. Click the **Delete** button – you will be asked if you want to delete the **Slide ID**.
5. Click on the **Yes** button – the recorded **Slide ID**, all its **Case** #s, and associated slides will be deleted from the program and the cursor will be positioned in the **Slide ID** box (Click **Cancel** if you wish to undo any changes and return to the **Programming Grid**).
6. Press **Enter** to go to the **Finish Entry** button.
7. Press **Enter** to return to the **Programming Grid** screen.

Deleting a Case

1. Click on the **Slide Info** button in the **Programming Grid** screen to display the **Slide Information** screen.
2. If **Slide ID** is enabled, press the down arrow key on your keyboard until the desired **Slide ID** is highlighted and press **Enter**. The selected **Slide ID** will show in the **Slide ID** box and the cursor will move to the **Case** # box.
3. Press the down arrow key until the desired **Case** # appears highlighted in the **Case** # box.
4. Click **Delete** and you will be asked you if you want to delete the selected **Case** #.
5. Click **Yes** and the selected **Case** # and all its slides will be deleted from the program. The cursor will return to the **Slide ID** box (Click **Cancel** if you wish to undo any changes and return to the **Programming Grid**).
6. Press **Enter** to go to the **Finish Entry** button.
7. Press **Enter** to return to the **Programming Grid** screen.

Deleting a Block ID

1. Click on the **Slide Info** button in the **Programming Grid** screen to display the **Slide Information** screen.
2. If **Slide ID** is enabled, press the down arrow key on your keyboard until the desired **Slide ID** is highlighted and press **Enter**. The selected **Slide ID** will show in the **Slide ID** box and the cursor will move to the **Case** # box.
3. Press the down arrow key until the desired **Case** # appears highlighted in the Case # box. Press **Enter** to move onto the **Block ID** box.
4. Press the down arrow key until the desired **Block** appears highlighted in the **Block ID** box – the complete record, depending on which boxes are active should now be displayed (**Slide ID, Case** #, **Doctor**, etc).
5. Click **Delete** and you will be asked if you want to delete the selected **Block ID**.
6. Click **Yes** and the selected **Block ID** and all slides associated with it will be deleted from the program. The cursor will be positioned in the **Case** # (Click **Cancel** if you wish to undo any changes and return to the **Programming Grid**).
7. Press **Enter** to go to the **Finish Entry** button.
8. Press **Enter** to return to the **Programming Grid** screen.

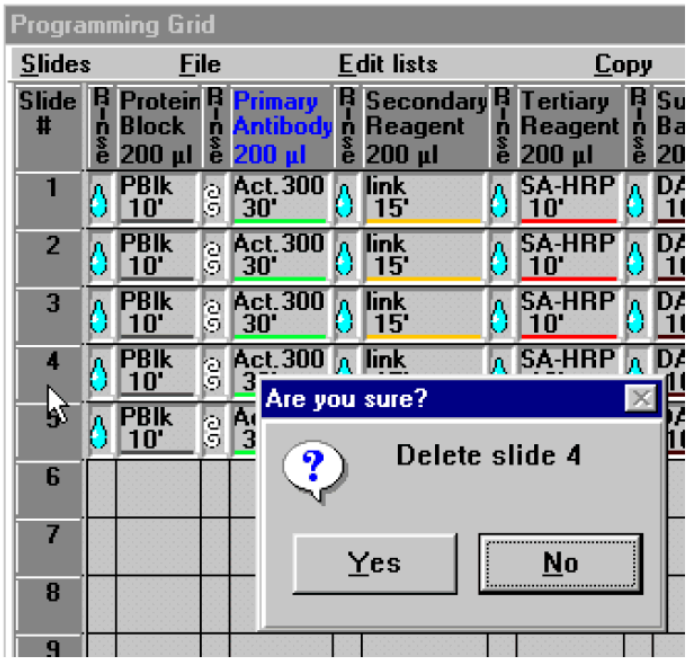
Reducing the Number of Slides

This can be performed in the **Slide Information** screen only if slides have not been programmed with reagents.

1. Click on the **Slide Info** button in the **Programming Grid** screen to display the **Slide Information** screen.
2. Select the **Slide ID**, **Case** #, and **Block ID** of the slide you want to remove.
3. In the # **Slide** box, reduce the number to the required amount and press **Enter**.

Deleting a Slide

1. In the **Programming Grid** left mouse click on either the **Slide Number** column, or the **Slide Information** column, for the row representing the slide to be deleted. A dialog box will appear enabling you to confirm deletion of the selected slide.



Deleting a slide.

2. Click **Yes** and the selected slide will be deleted from the program.

Note

It is only possible to delete one slide at a time by this method.

Editing Individual Slides

1. The **Edit Individual Slide** function can be used to edit any reagent cell for any slide in the current Program without making changes to the entry in the reagent list. A change of reagent or the incubation time will only show in the relevant reagent cell.
2. In the **Programming Grid** screen, click on the reagent cell where a change is to be made. The reagent list for the relevant reagent category will display.
3. At the top of the reagent list, click on [edit slide] – an **Edit Individual Slide** screen will display with reagent details relating to the cell.
4. Edit any of the active fields displayed. Use the up/down arrow keys to select a different reagent or use the **Tab** key to move within the screen, e.g. to get to **Time** (min). Make the required changes by selecting a reagent or highlighting and typing over original entry.
5. Press **OK** when finished and the cell in the **Programming Grid** screen will display the newly entered information.

Note

The changes made to the reagent file by this method apply only to the altered slide in the current program. Permanent changes can be made to the reagent file via the Edit List facility (See Editing Reagent Lists).

Negative and Positive Control Slides

In the **Programming Grid** if there is spare slide capacity (i.e. fewer than 36|48|84slides programmed), as a primary antibody is assigned to a slide, two buttons will appear in the top right corner of the **Programming Grid** labeled **Neg.Ctl** and **Pos.Ctl**. Clicking either button will add a slide just after the slide to which a primary antibody was last added or changed. Clicking **Pos.Ctl** will add another slide with all of the same reagents and the letters, PC, with the slide number. Clicking **Neg.Ctl** will initiate a search for an appropriate negative control antibody according to the following rules:

1. If there is a reagent in the primary antibody reagent list with the first three characters being "**_NC**" and the remainder of the name identical to the primary antibody on the original slide, that reagent is automatically assigned.
2. If there is a reagent in the list that begins with "**_NC**" where the remainder of the name does not match any other primary antibody name, and if the first character of the compatibility code matches the first compatibility character of the primary antibody assigned to the slide, the message "**Missing Negative Control**" will appear asking if you want to assign that reagent. If you click **Yes** or press **Y**, that reagent will be assigned. If you click **No** or press the **N** key, no slide will be added. See the note below on how to establish species-related negative controls.

Note

Primary antibodies can be assigned compatibility codes, usually based on their species origin. It is assumed that if there is more than one character in a code, the first code indicates the species. To support a generic negative control antibody for all primary antibodies from the same species, add to the primary antibody reagent list an antibody listing that begins with "_NC" followed by the species name (e.g. rabbit) and set the compatibility code to the code for that species.

Displaying the Full Reagent Name

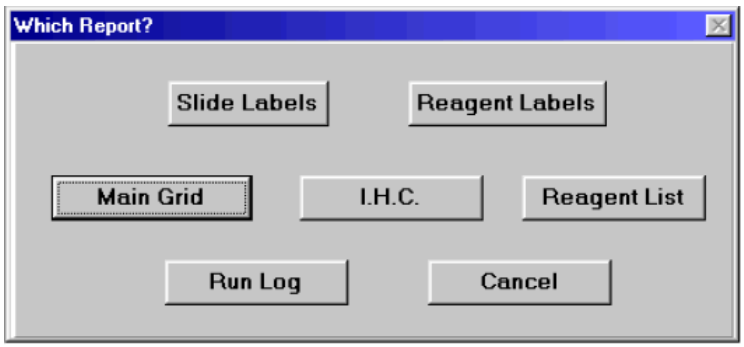
Right click on a reagent short name in the **Main Grid** to display a small adjacent box showing the full reagent name.

Labels

If your system includes a **Slide Label** printer connected to the **Autostainer PC**, you can print labels for all of the slides in the current or previous programs or a subset of them. The same printer can also be used to print labels for all, or a subset, of the reagents in the current program or from the full list of reagents.

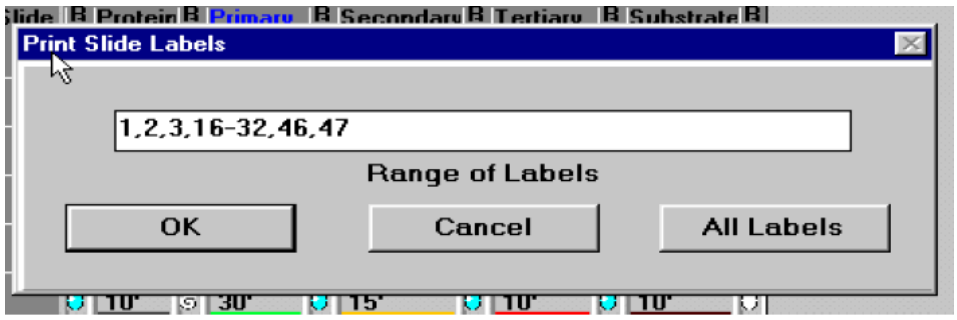
Slide Labels Printing

1. In the **Programming Grid** screen click the **Print** button – the **Which Report** dialogue box will be displayed.



Which report dialogue box.

2. Click the **Slide Labels** button – if there are slides in the current program, the **Print Slide Labels** dialogue will be displayed.



Print slide labels dialogue box.

3. Either click the **All Labels** button to print a label for each slide in the program, or type in the numbers of the slides for the labels to be printed and click **OK**. Individual slide numbers may be entered with a combination of numbers separated by commas and/or ranges of numbers separated by a hyphen. For example, "1,3,5-10,20,25-48" (do not include quotation marks, do not use any spaces or any other punctuation) would print labels for slides 1, 3, 5, 6, 7, 8, 9, 10, 20, and 25 to 48.

4. You may continue using the Autostainer program while labels are being printed – including printing other reports – but any other sets of labels (slides or reagents) cannot be selected until printing of the first set is complete. Clicking on the Cancel button of the **Which Report** dialogue, or exiting from the **Programming Grid** to the **Main Menu** will stop any label printing.

5. If a printer error such as running out of labels occurs, a message box will be displayed. Examine the printer to determine what has happened. If the problem can be corrected and the printer resumes printing labels, the message box will disappear automatically. If the problem cannot be corrected, click the **Cancel** button to abandon label printing, deal with the label printer, and then send a new print command.

Reagent Labels Printing

1. In the **Programming Grid** screen click the **Print** button – the **Which Report** dialogue will be displayed.
2. Click the **Reagent Labels** button – the **Print Reagent Labels** dialogue will be displayed.
3. If reagents have been entered in the current program, they will be listed.
4. You may select from the list of current reagents by clicking on each reagent name for which a label is needed. Then click **OK**. To print labels for all of the currently used reagents, click **Print All**.
5. To print labels for reagents other than those in the current program, click **Other Reagents**. The complete alphabetical list of all your reagents will be listed. You may select from the list by clicking relevant names, or **Print All**.
6. If you wish to print more than one set or series of labels please read **Steps 4-5** under **Slide Label Printing**.

Barcode Reagent Labels Printing

1. Select the **Enable Barcode Reading / Reagents** option in the **Options** screen.
2. Assign a unique bar code to every reagent in the **Edit Reagent List** screens.
3. You may print bar coded reagent labels by clicking the **Print** button on the **Main Grid** and then the **Reagent Labels** button as described above.
4. You can also print labels for new vials during the set up of a staining run. The labels are read before each run. **Reagent Volumes** can be checked at the same time or at the beginning of the run. If a reagent requires more than one vial, volume checking before the run cannot be disabled.
5. If the configuration Rgt Xpdt 1 has been selected and a reagent has an expiry date, the date will be appended to the bar code and checked for expiration when the bar code is read.
6. If the configuration Rgt BLot 1 has been selected and the reagent has a lot number, the lot will be appended and captured when the bar code is read for reporting in the IHC Report.

Reagents

Programming Reagents

Before being able to assign specific reagents to slides in a program you should enter, slide information (patient, case, block etc.), and choose or modify a protocol template. The **Programming Grid** screen then displays and is ready to be completed. The first cell to be programmed will be flashing and the appropriate reagent list will be displayed.

1. Click on the reagent of your choice in the reagent list displayed – a window will ask if you want to assign the same reagent to the remainder of the slides.

Note

This message will appear for all reagent categories in the protocol with the exception of the Primary Antibody and Pre-treatment columns.

2. If all or most of the slides in the program are to undergo the same treatment for that part of the protocol, click Yes. The software will "**fill down**" the chosen reagent for the current step to all unprogrammed slides. If the majority of the slides require individual reagents, click the **No** button. The cursor automatically moves horizontally to flash in the next unprogrammed cell. A new list of reagents opens for the reagent category appropriate for the next protocol step.
3. Repeat **Steps 1-2** until the **Programming Grid** is filled and every slide has a complete set of common reagents assigned to it.
4. The flashing cursor moves next to the cell for the primary antibody for slide 2, then 3, then 4 etc. until all cells have been programmed.

Note

Each programmed cell displays the abbreviated name and the incubation time for the selected reagent. If a recommended pre-treatment for particular antibodies has been entered in the reagent list it will automatically appear in the Pre-treatment Column provided pretreatment has been activated in the protocol template.

Making Amendments

1. To change any reagent displayed in a cell, click on the cell to display the list of reagents corresponding to the protocol step.
2. Use alphabetical keyboard entries to find the correct reagent, or click on the relevant listing – your selection will then replace the old information and appear in the cell.
3. To change the incubation time for a reagent in any single cell, click on the cell to display the list of reagents. At the top of the list, select **Edit Slide**. In the **Edit Individual Slide Reagent** box press **Tab** or move the cursor to the time box. Enter the new incubation time and press **Enter** to return to the **Programming Grid**.

Loading Reagents

1. After finishing assigning all reagents in the **Programming Grid** screen, click **Next** to get to the **Slide Layout Map – Program Slides** screen.
2. Make any changes to the dispense locations or volumes and click **Next** again to select whether to re-use the reagent rack(s) from previous staining **Programs**.
3. Click "**Re-use One Reagent Rack**" to refill/relocate the reagent vials to original rack locations, or
4. Click "**Re-use Two Reagent Racks**" if you wish to maintain positions for more reagents than fit a single rack, even though the number of reagents in the current program does not exceed the number of reagents that would fit one rack. The Autostainer software will then calculate and display the run time.
5. Click **OK** to advance to the **Reagent Layout Map** screen showing where to "**load reagents**." Place the filled reagent vials in the racks according to the reagent map displayed on screen. The reagent map shows the location of the reagent vial, the minimum volume of reagent needed for the program, including the automatically programmed "**dead**" volume (200 µl). If you elected to re-use one or both reagent racks, some of the circles showing vial locations may be blinking. A blinking vial indicates a new or different reagent, or that the same reagent from a different lot is to be loaded. As you add or replace these reagents, you may click on each vial to turn off the blinking (optional). Vial locations used previously but not in the current program will appear with the reagent name grayed and no volume displayed.

Note

Make sure that enough reagents are in the vials to complete the programmed run and that the reagent rack is properly seated in its correct location and orientation.

6. To view a detailed listing of the reagents used in the current program, click on the **Reagent List** button in the **Reagent Layout Map** screen. Press **OK** in the **Reagent List** screen to return to the **Reagent Layout Map** screen.

Calculate Dilutions

If you need to prepare a dilution, the Autostainer software can assist your calculations. To use this function, click on **Dilutions** button in the **Reagent Layout Map** screen.

1. In the **Calculate Dilutions** screen, enter the volume of reagent needed for the **Program** in the appropriate box. (The required reagent volumes are shown in the **Reagent Layout Map** screen.)

Note

The calculator will only operate with volumes of 1.0 ml or more. This is to avoid it calculating a need to probe a volume of reagent less than 1 µl to make the dilution.

2. After you have entered the volume needed, enter the dilution ratio for that reagent. The first ratio number will default to one, but can be changed if necessary. Press **Enter** and type in the remainder of the dilution ratio.
3. When volume and dilution factors are entered, click on **Calculate**, and the software will display the volumes of concentrated reagent and of diluent required to make the correct dilution for that reagent.
4. Click **OK** to make another dilution calculation or **Back** to return to the **Reagent Layout Map** screen to continue setting up the program.

Copying Reagents from Slide to Slide(s)

The **Copy** command is a useful tool to speed up programming. It can be used to copy single cells or multiple rows/columns of cells.

1. Click on **Copy** at the top of the **Programming Grid** screen – the word "**Copy**" changes to "**Select**."
2. Position the mouse cursor over the left uppermost cell to be copied, press and hold the left mouse button.
3. Drag the mouse to the right and down until all the target cells to be copied have been selected. DO NOT RELEASE THE MOUSE BUTTON UNTIL YOU HAVE SELECTED ALL THE CELLS TO BE COPIED. The chosen cells will become highlighted (white) as they are selected.
4. When you have highlighted the cells to be copied, release the left mouse button. The word "**Select**" at the top changes to "**Paste**."
5. To "**Paste**", move the mouse cursor to the cell where you want the copied cells to be pasted and click. The copied cells will be pasted to the appropriate cells.
6. You can continue with multiple "**Paste**" clicks if required, or click anywhere outside the programmed cells to turn off the copy facility. The word "**Paste**" changes back to "**Copy**."

Note

If a collection of rows is copied, select the paste destination by clicking on the uppermost target row. The highlighted cells CAN be pasted to areas already programmed. In this case, the software will ask if you want to "Copy over steps already programmed." Click Yes.

Editing Reagent Lists

The **Edit Reagent Lists** function can be used to make changes to all reagent related information such as reagent name, lot No, expiry date, and incubation times, which are contained in the reagents file.

1. In the **Programming Grid** screen open, the **Edit** lists menu by clicking Edit list in the menu bar to display the list of reagent categories.
2. Click on the name of reagent category to be modified and the corresponding **Edit Reagent List** screen will open.
3. To display a specific reagent, place the cursor in the upper box for the reagent name and press the down arrow key or the **Page Down Key** to scroll. Scroll until the required reagent appears highlighted in the **Reagent Name** box. Alternatively, click on the **Reagent Name** box arrow and type the first characters of the reagent to be found until it appears at the top of the scroll list. Press **Enter** to display the current information for that reagent which can then be edited (reagent full name, short name, compatibility code, incubation time, lot No, and expiry date).

Note

Editing a reagent full name will result in a second complete entry for that reagent. If a simple change to the full name is required, it is better to delete the incorrect entry and reenter all information.

4. Edit any of the visible boxes by moving the cursor (use **Tab** or mouse) to the targeted information and type to replace or modify details. To delete the reagent, click the **Delete** button. A window will ask you to confirm that you want to delete the reagent. Click **Yes**.
5. After editing the reagent list click **OK** in the **Edit Reagent List** screen – a window will appear asking if you want to save the changes made.
6. Click **Yes** to save the changes or **No** to cancel them. The **Programming Grid** screen will be display again. If you respond **Yes** to changes made to the reagent file using the **Edit Reagent Lists**, the changes are fixed until next changed and will be reflected in the reagent information displayed in subsequent programming sessions.

Adding Reagents to the Reagents List

1. In the **Programming Grid** screen, open the **Edit Lists** menu by clicking **Edit List** in the menu bar to display the list of reagent categories.
2. Click on the reagent category to be added to and the corresponding **Edit Reagent List** screen will display with the cursor flashing in the **Reagent Name** box.
3. Type in the full name of the reagent you want to add to the list and press **Tab** or **Enter** – the cursor will move to the **Short Name** box.
4. Enter an abbreviated name, up to 10 characters long and press **Tab** or **Enter** – the cursor will move to the **Compatibility** box or, if reagent bar coding is enabled, the **Barcode** box.

Note

The abbreviated name cannot exceed 10 alphanumeric characters. The "short name" is the information that will appear in the Programming Grid and reagent vial map, therefore it is convenient to incorporate dilution factors into the 10-character name, e.g. "Actin.250" where the dilution factor is 1:250.

5. If reagent bar coding is enabled, a bar code must be entered for every reagent. The selection of bar codes may be automated by selecting the configuration option AutoBcd 1. The suggested bar code may be changed. If configuration option AutoBcd 2 is specified, the bar code will be entered automatically.
6. Enter the correct compatibility code (optional) and press **Tab** or **Enter** – the cursor will move to the **Lot No** box.
7. Enter the reagent's lot number (optional) and/or press **Tab** or **Enter** – the cursor will move to the **Expiry Date** box

Note

The lot number cannot exceed 8 characters.

8. If the lot number of an existing reagent is changed, both the existing lot and new lot are maintained. In order to change a reagent lot number without creating a new one, click the **Change** button after entering the new lot. **Lot** numbers are not copied to auto-programs unless the configuration option AutoLot 1 has been selected, in which case only one lot will be recognized for any reagent and the **Change** button will not appear. With configuration option AutoLot 1, any change causes all Auto Programs to be examined and the reagents therein updated to the current lot numbers.
9. Enter the reagent's expiry date (optional) and press **Tab** or **Enter** – the cursor will move to the **Incubation Time** box.

Note

Reagent expiry date, if entered, must be in the form of MM/YY where the M's are numerical characters symbolizing a month and Y's the last two digits of the year. The year cannot be more than 10 years in the future.

10. Enter the reagent's incubation time and click **OK** – a dialog box will appear asking if you want to save the changes to the reagent list.
11. Click the **Yes** button – the newly entered reagent details are fixed, until next changed, and will be added to the reagent list and be reflected in the **Programming Grid** screen display.

Deleting Reagents from the Reagents List

1. In the **Programming Grid** screen, open the **Edit Lists Menu** by clicking on the menu title – all available reagent lists will be displayed.
2. Click on the reagent category of interest – the corresponding **Edit Reagent List** screen will display and the cursor will be flashing in the **Reagent Name** box.
3. To display the reagent you want to delete: click in the **Reagent Name** box and press the down arrow key until the target reagent appears highlighted in the **Reagent Name** box. Alternatively, click on the **Reagent Name** box arrow, type the first characters of the reagent of choice until it appears at the top of the list, and press **Enter**. All information which can be edited (reagent's full name, short name, compatibility code, incubation time, lot No, and expiry date) will be displayed.
4. Click the **Delete** button in the **Edit Reagent List** screen – a dialogue box will appear asking if you want to delete the selected reagent.
5. Click the **Yes** button – the **Edit Reagent List** screen will appear.
6. Click the **OK** button – a dialogue box asking if you want to save the changes made to the reagents' file to disk will appear.
7. Click on the **Yes** button – the **Programming Grid** screen will appear.

Editing Primary Antibodies

Editing primary antibodies is very similar to editing other reagents with the following additional features:

1. If a pretreatment is required for an antibody, it must be edited on the same screen. If the pretreatment is to be performed prior to placing the slide on the instrument, such as **Heat-Induced Epitope Retrieval**, check the **Manual Step** option for the pretreatment.
2. Multiple entries for an antibody with a variation such as dilution ratios can be added at the same time by entering a **Qualifier**. Doing so will open two addition sets of boxes for further qualifier additions. They will all be assigned the same incubation times, but this setting can be changed later by editing the qualified antibodies individually.
3. An auto-program can be created directly from the antibody edit screen by clicking on the drop down list below the **Auto-program** button, selecting from the list of predefined auto-programs with unprogrammed antibody steps, and clicking the **Auto-program** button. The antibody will be inserted in the selected auto-program and the new auto-program will be assigned the short name of the antibody. You can create multiple auto-programs for the same antibody by changing the short name each time.

Reagent Tracking

This feature is particularly useful for a quick review of reagent usage. Additionally, if expiry dates and lot numbers have been entered into the reagent lists (Edit lists) they will appear in this file and can be checked regularly to note forthcoming expiry dates. At the end of every staining program, whether or not the program is completed, the reagents used during that program are cumulatively recorded into the total volume(s) and number of slides treated with each reagent.

The totals are kept in a data file from which you can review, print, and reset any or all reagents.

Reviewing reagent usage

- From the **Main Menu** screen, click the **Reagent Tracking** button to display the **Reagent Tracking** screen.
- After a pause while the file is retrieved the reagents data list will be displayed in a scrollable list.

Printing all reagent usage

- In the **Reagent Tracking** screen, click the **Print All** button.

Printing selected reagent usage

- In the **Reagent Tracking** screen click on each of the reagents, you want to print.
- Click the **Print Selected** button.

Resetting all reagent usage

- In the **Reagent Tracking** screen, click the **Reset All** button.

Resetting selected reagent usage

- In the **Reagent Tracking** screen click on each of the reagents, you want to reset.
- Click the **Reset Selected** button.

Chapter 4

Creating a new staining program

1. Press **Enter** or click the **Program** button in the **Main Menu** screen – the **Programming Grid** screen will appear displaying an empty grid with the default protocol template on the x-axis.
2. Press **Enter** or click the **Slide Info** button, which brings up the **Slide Information** screen and continue with **Step 3**. Alternatively, press the "**S**" key or click on **Slides** (top left) to bring up the **Slide Count** box. Scroll or type to enter the required number of slides, and continue at **Step 5**.
3. Enter slide information for all the slides to be run in the current staining program (Please refer to the **Slide Information** section)
4. Return to the **Programming Grid** screen by clicking on the **Finish Entry** button in the **Slide Information** screen.
5. To create a new **Protocol** template or to select an existing one, click on the **Protocol Template** button in the **Programming Grid** screen – the **Protocol Template Design** screen will appear (Please refer to the **Protocol Template** section "**Creating/Editing**").
6. Return to the **Programming Grid** screen by clicking on the **Use Template** or **Cancel** buttons in the **Protocol Template Design** screen.

Note

At this time the Programming Grid should be visible displaying the patient information for the slides in the current program and the selected protocol template as a header on the x-axis. The first cell to be programmed will be flashing and the appropriate reagent list will be displayed. The specific reagents to be applied to each slide in the current staining program can now be selected. See Reagents Section.

Using an Existing Staining Program

1. Click on the **Program** button in the **Main Menu** screen – the **Programming Grid** screen will appear displaying an empty grid with the default protocol template on the x-axis at the head of the columns.
2. Click on the **File Menu** at the top of the screen – a drop-down menu including **Open**, as well as a list of the last 5 staining programs used, will appear.
3. Click on the relevant listed program in the drop-down menu (The **Programming Grid** screen will appear displaying a programmed grid). Alternatively select **Open** – the **Load Program from Disk** screen will appear displaying a list of all stored programs.
4. Select the program you want by clicking on it – the selected program will appear highlighted in the box and remain in the list.
5. Click **OK**. The **Programming Grid** screen will appear displaying a programmed grid.
6. To edit the slide information, click on the **Slide Info** button – the **Slide Information** screen will appear.
7. Edit slide information as necessary for any of the slides already entered, or that have been added to the current program (Please refer to the Slide Information section).
8. Return to the **Programming Grid** screen by clicking **Finish Entry** in the **Slide Information** screen.
9. To edit the current protocol template, click on the **Protocol Template** button in the **Programming Grid** screen to access the **Protocol Template Design** screen (Please refer to the **Creating/Editing a Protocol Template** section).
10. Return to the **Programming Grid** screen by clicking **Use Template** or **Cancel** in the **Protocol Template Design** screen.

Note

At this time the Programming Grid should be visible displaying the patient information for the slides in the program and the selected protocol template heading columns on the x-axis. The specific reagents for the current staining program can be edited.

Deleting an Existing Staining Program

- Click on the **Program** button in the **Main Menu** screen – the **Programming Grid** screen will appear displaying an empty grid with the default protocol template on the x-axis at the head of the columns.
- Click on **File** at the top of the screen – the drop-down menu will include **Open**.
- Select **Open** to access the **Load Program From Disk** screen will appear displaying the list of stored programs.
- Select the program to be deleted by clicking on it – the selected program will appear highlighted in the box and remain in the list.
- Click **Delete** in the **Load Program From Disk** screen – a dialogue box will appear asking if you want to delete the selected staining program.
- Click **Yes** and the selected staining program will be permanently deleted and the **Load Program From Disk** screen will be displayed.
- Return to the **Programming Grid** screen by clicking **Cancel** in the **Load Program From Disk** screen.

Starting a Staining Program

Click **Next** in the **Reagent Layout Map** screen – the **Slide Layout Map** screen will appear again, this time with the heading **Load Slides**.

The slides can be loaded at the Autostainer site or at any location convenient to you. If loading at the Autostainer, it is possible to simply tilt the slide racks by slotting the slide rack tabs (on the back of the racks) into the slots in front of the rack-locating studs before placing the slides in position. If you prefer to load the slides away from the Autostainer, remove the slide racks and take them to the loading location. It is useful to have a supply of buffer available (squeeze bottle) to flood slides to prevent drying as each rack of 12 slides is loaded.

To load a slide, hold it with your thumb and forefinger on each side of the slide close to the opposite end from the frosted section.

Place the frosted end of the slide horizontally on the lower (middle) of the position studs and push it gently into place under the two (upper) securing clips.

Repeat this procedure to load all slides in their correct positions while referring to the slide layout map to confirm correct positioning.

It is advisable to go through the following checklist, before starting the staining program:

Reagents

- Should be at room temperature.
- Should be loaded in vials with sufficient to ensure completion of the staining program.
- Should be loaded in the correct locations in the reagents racks and the racks correctly positioned.

Buffer

- The buffer reservoir must contain enough buffer to complete the staining program.
- Pump should be primed to ensure proper buffer flow through buffer tubing.

Slides

- Should be loaded in correct positions in the slide racks.
- Slide racks must be properly seated on their studs on the slide rack frame.
- Click Next to display the Set Start Time dialogue. You can delay the start time of the staining program by up to {24 hours minus the total run time}. As you increase the delay, the volume of rinse solution will increase to allow for the extra idle rinses required to prevent the slides from drying out. If a new buffer or water reservoir has been installed, it is advisable to click the appropriate Prime Pump button. The Autostainer will start and initialize (go the home position).
- The pump will run and turn off automatically after ten seconds. Alternatively, you may turn it off by clicking the same button again. To ensure correct priming the Prime Pump button can be clicked again if necessary.
- To be sure that there is sufficient reagent in all vials, click **Check Volumes** to allow the instrument to go to each vial to verify that the liquid levels in all vials are sufficient. This process will be repeated if you have programmed "**Substrate-Batch**" reagents. When you respond to the alarm to add Substrate and click **OK**, the instrument will check the fluid level before proceeding. This feature enables you to walkaway with complete confidence that the instrument has adequate reagents for the program. If you do not enable **Check** volumes, there could be insufficient reagent during the run. If this happens, a message will be displayed showing the reagent, location, and the required volume. The dialogue reporting not enough reagents to continue includes an "**Override**" button to continue the run immediately.

- Click the **Start Run** button when the instrument is fully prepared. The **Run Program Now** message will be displayed to remind you of the needed volumes of rinse solution and other preparations. At this time it is important to check that reagent vials/racks are correctly located and that all slide racks are located horizontally on their positioning studs. Click **OK** to turn on the instrument and begin the staining program. After the instrument has initialized itself to the "**Home**" position, (right rear corner) the **Run Log** screen will appear and the Autostainer will start the programmed staining run. The **Elapsed Time, Remaining Time**, and **Total Time** for the current staining program will be displayed in the upper right hand corner of the **Run Log** screen.

The **Start Time, Current Time**, and **Complete Time** will be displayed directly underneath.

Note

If the Current Time (as determined by the computer clock) is not accurate, DO NOT CHANGE IT DURING THE PROGRAM. Wait until the program is completed before adjusting the time.

Note

The Run Log screen will be visible while the Autostainer is in operation. The Autostainer's steps will be displayed in detail throughout the program.

IF YOU NEED TO REVIEW THE LOG RUN WHILE THE AUTOSTAINER IS OPERATING DO NOT CLICK HOLD – DRAG WITH THE MOUSE BUTTON. USE THE PAGE UP/PAGE DOWN OR THE UP AND DOWN ARROW KEYS.

- The complete run log can be stored and/or printed at the end of the staining procedure.

Emergency Stop

The **Emergency Stop** button on the **Run Log** screen can be used to stop the program at any time during the operation of the Autostainer. The program cannot be re-started from its existing position once stopped.

Click on the **Emergency Stop** button in the **Run Log** screen – a dialogue box will be displayed asking if you want to stop the program.

Use the mouse to click **Yes** to stop the program

Note

This is not a keyboard operated command.

The Autostainer will abort the program and a dialogue box will appear asking if you want to save the run log.

If you do not want to abort the program, click **No** so the Autostainer can resume the staining program.

Note

When a program is aborted, the Autostainer will not stop immediately. It will first complete the function it was performing when the program was ended. If the probe has not been cleaned since it last held reagent, a message will ask if you want to clean the probe. If you click Yes, the instrument will re-initialize itself to the "Home" position before cleaning the probe. If you think a serious malfunction has occurred, do not click Yes to the clean probe enquiry.

IF A SERIOUS MALFUNCTION OCCURS, DISCONNECT THE POWER CORD FROM THE MAINS SUPPLY AND CONTACT THE THERMO FISHER SCIENTIFIC SERVICE DEPARTMENT.

Programming During a Run

The **Run Log** screen contains three buttons, **Emergency Stop, New Program** and **Review Program**. By clicking **New Program**, you open a clean **Programming Grid** and can perform all of the steps to create a new program, or load and modify another existing program up to the point of viewing the Reagent Layout Map.

When you click **Next** on that screen, or click **Next** or **Exit** on the **Programming Grid**, you will return to the **Run Log** screen of the program in progress.

The same multiprogramming capability is available during a cleaning program (See **Maintenance**).

Clicking the **Review Program** button will allow you to examine the current **Programming Grid** for the program in progress. You cannot make any changes to it.

Completing a Staining Run

At the end of the staining program the Run Log screen will display the message “End Program Run” and the computer will beep every few seconds indicating that the Autostainer’s program has been completed (See Precautions Ending a Program below).

TAKE CARE TO ACTIVATE END PROGRAM RUN AND ALLOW THE OPERATING ARM TO PARK BEFORE REMOVING SLIDES.

1. Click **OK** in the **Run Log** screen. A window will appear asking if you want to save the run log.
2. Click **Yes** to save the run log. A window will appear offering the program name as a suitable name for the log run. Click **OK** and the Log run will be saved and the program will end. Alternatively, click **No** to return to the **Main Menu** screen without saving the Log run.
3. Click **Sign Off** – the **Exit** screen will appear.
4. Click **Yes** – the **Windows**™ screen will appear.
5. Click **Start** on the **Task Bar** and a pop-up menu list with choices will appear.
6. Click **Shut Down** and the **Shut Down Windows** dialogue will appear.
7. Click **OK** to **Shut Down** and allow the computer to shut down.
8. Switch off the computer if it does not auto stop.

Note

The Autostainer unit does not need to be switched off. It can be left with the single “power” green LED displaying.

Auto Programming

Auto programming offers the opportunity to "**copy**" any row of programmed reagents and their incubation times. The "**copy**" is then stored for re-use as an auto program.

Auto programming provides a very fast and highly recommended programming method. It is important to remember that auto programs are computer files that directly match a corresponding protocol template. If you change the protocol template, the auto program will no longer "**match**" the template.

1. In the **Programming Grid** screen, with one or more slides already programmed, click on the **Auto** button in the menu bar. The drop-down menu options will be **Program** and **Setup**.
2. Click **Setup** to create a new auto program. The menu bar text will change to **Setup**.
3. Move the mouse cursor to any reagent cell on the chosen slide. Click and hold the left mouse button. Drag to highlight the slide and release. When you release the mouse button the **Save Auto Program** screen will appear.
4. Enter a name for the auto program (usually matching the primary antibody name) and click **OK**. This saves the protocol template and all the programmed reagents for the selected slides.
5. Repeat from **Step 3** for the next slide. You can repeat dragging across multiple slides, or the entire program grid.
6. **Setup** mode remains active so you can create multiple auto programs during one session, until you click on **Setup** on the menu bar.
7. To deactivate setup, click **Setup** in the menu bar and it will revert to **Auto**.

Re-using an Auto Program

Create a new staining program or edit an existing program.

Click the **Auto** button in the menu bar. From the drop down list, click **Program**. The primary antibody cell of the first slide with no reagents programmed will be blinking and a list of auto programs that match the current protocol template will appear in place of the normal reagent lists.

Note

Only auto programs that have identical protocol and rinse steps in exactly the same sequence as the current protocol (unaffected by different volumes) will be listed.

Keyboard enter alphabetically or click to the desired auto program in the displayed list.

The number of slides that each auto program will load is displayed in brackets after the auto-program name. That number of consecutive slides will be programmed regardless of any prior programming.

You may also select for re-programming any slide that is already programmed by clicking on the primary antibody cell. **Program** mode of the auto-program facility remains active until you click on **Program** on the menu bar.

Note

If an auto-program includes more than one slide and the following slides have already been assigned reagents, there is a message box asking whether to copy over the programmed slides. If the answer is “No,” programmed slides are skipped and the auto programming is applied to the next unprogrammed slides.

Shut-Down Procedure

Switching OFF

To turn off the Autostainer, simply go back to the **Main Menu** screen of the Autostainer program and click on the **Sign Off** button to exit out the Autostainer program.

Taking Out of Operation

In case the Autostainer needs to be taking out of operation, shut-down the computer first and unplug all connected cables.

Refer to the Safety and Warranty Booklet for decontamination instruction.

Internal Quality Control

Checking the function of the IVD instrument

If the instrument has not been used recently or otherwise might not have rinse solution in the input tubing, the user has the option to perform a Prime Pump step one or more times until the rinse solutions flow properly. During mechanical start up, before moving on either horizontal axis, the instrument attempts to move both Z-axes to the home positions. If that is successful, it attempts to move to the Y-axis home position.

If successful, it moves to home on the X-axis. In order to ensure that buffer can be dispensed during the run, the instrument moves to an unobstructed position over the sink and runs the pump for ten seconds.

Verification of results

Verification of results obtained on the Autostainer is the responsibility of the user by including process and test controls as well as other confirmatory tests and clinical history.

Internal quality control of the entire in vitro diagnostic system

The user must provide quality control by any or all of the following methods:

Positive tissue control

Include a known positive tissue, preferably with variable levels of reactivity; it should test positive.

Negative Process Control

Replace primary antibody with buffer or nonsense antibody; it should test negative with no background.

Negative Tissue Control

Include a known negative tissue and apply primary antibody; it should test negative with no background.

Positive Process Control

Include more than one antibody and its control: If one is positive, the process worked.

Chapter 5

Cleaning and Maintenance

- Any general cleaning must be done when the Autostainer is not operating. For general cleaning, use a soft cloth with warm water and mild detergent.
- Only the metallic parts should be cleaned with alcohol.
- Do not remove the drain filter gauze from the sink unit. If the drain filter contains small fragments of debris, use a moistened paper towel to pick up and discard debris.

SOME SMALL GLASS SHARDS ORIGINATING FROM MICROSCOPE SLIDES MAY COLLECT AROUND THE DRAIN.

- The acrylic top part should be cleaned using a soft cloth, warm water, and mild detergent.

Note

The top acrylic part of the Autostainer may be cleaned using water or non-alcoholic detergent. Never use solvent based fluids on the acrylic or the surface may be damaged.

- Slide racks and reagent racks, as well as the sink in the Autostainer can be cleaned with water and mild detergent.

Automated Cleaning

The Autostainer keeps track of the number of slides stained in the **Main Menu** screen. It will notify you when you have completed the total number of slides pre-set in the **Runs/Cleaning** box in the **Initialize** screen.

A **Maintenance Message** will appear displaying how many slides have been done on the Autostainer since the last cleaning cycle.

- It is recommended that the Autostainer be cleaned every 240 slides, or at least weekly if you stain fewer than 240 slides per week.
- Click the **Clean** button in the **Main Menu** screen to display the **Instrument Maintenance** screen.
- Click the **Clean** button in the **Instrument Maintenance** screen to display the **Cleaning Instructions** dialogue box with detailed instructions on how to prepare the instrument for a cleaning/maintenance program.

Note

You will need the DAB Away kit (Code: TA-125-DA) to perform the cleaning program.

- The **DAB Away Kit** consists of the following:
  - DAB-Away 1 solution
  - DAB-Away 2 solution
  - Decolourising agent solution
- Load the cleaning reagents according to the on-screen instructions.

Note

The cleaning reagents must be located in the vial rack positions shown on the screen.

- Position them in the reagent rack and click **OK** in the **Cleaning Instructions** dialogue box – the Autostainer will find "**home**" position and start the cleaning program.

THE REAGENT PROBE WILL STOP AT THE LOWEST POSITION IN THE CLEANING REAGENT. THIS IS TO BE EXPECTED AND SHOULD NOT BE CONSIDERED TO BE AN ERROR.

- A **Run Log** will be displayed. If the configuration option DIWATER 0 has been selected or has not been defined, when the program is completed, a dialogue box indicating that the DI water should be replaced with buffer will appear. If so, replace DI water with buffer and click on the **OK** button in the **Maintenance** screen – the **Initialize** screen will be displayed.
- Click the **Sign Off** button – the **Exit Autostainer** screen will appear.
- Click the **Yes** button to exit the program or **No** to sign on again and continue using the Autostainer.
- The **Run Log** screen contains a **New Program** button. By clicking that button, you can perform all of the steps to prepare a new program, or load and modify an existing program to the point of viewing the **Reagent Layout Map**.
- When you click **Next** on that screen, click **Next**, or **Exit** on the **Programming Grid**, you will return to the **Run Log** screen. The cleaning cycle including the 30 minutes delay holding Acid-alcohol in the reservoir takes 50 minutes to complete from start.

Cleaning Log

Each time the Autostainer completes a cleaning program, or when the slide count is reset without cleaning, a record is added to the **Cleaning Log**.

To view and/or print the log:

- Click the **Clean** button in the **Main Menu** window - the **Maintenance** screen will be displayed.
- Click the **Cleaning Log** button in the **Maintenance** screen - a **Cleaning Log** dialogue will appear displaying the list cleaning or reset events with dates and times.
- To print the whole list, click the **Print All** button.
- To print a page of the list, scroll to the desired section and click the **Print Screen** button.

Disposal Information

SOME OF THE REAGENTS USED ON THE AUTOSTAINER MAY BE HAZARDOUS.

The user must determine from the MSDS sheet for a given reagent if a reagent is hazardous. If a reagent is determined to be hazardous, the user must determine proper disposal according to local regulations. The

Autostainer allows separation of waste streams for the chromogen step if a hazardous reagent, such as DAB, is used. The container used for this waste stream is marked “Hazardous Waste.” This container must only be used for hazardous waste in order to avoid increasing the volume of any hazardous waste unnecessarily. If a nonchromogen reagent known to be hazardous and is used in other parts of the method, the waste container that the reagent is directed to will be considered hazardous waste, whether or not it is marked as such, and must be disposed of according to local regulations.

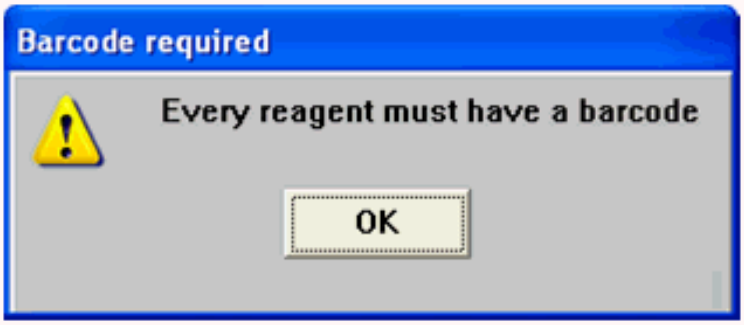
Sterilisation, Decontamination or Disinfection

THE AUTOSTAINER IS NOT DESIGNED TO STAIN FRESH (UNFIXED) TISSUE OR CELL SMEARS THAT MAY CONTAIN INFECTIOUS ORGANISMS. ONLY TISSUE SECTIONS OR CELL SMEARS THAT HAVE BEEN FIXED IN A MICROBICIDAL / VIRICIDAL FIXATIVE SHOULD BE USED.

Chapter 6

Troubleshooting

- The Autostainer program will report data entry errors in a small dialogue box similar to the Figure below.



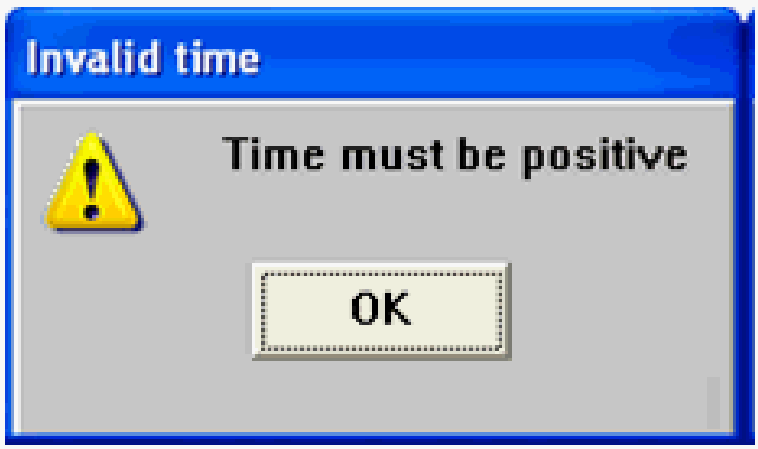
Data entry error dialog box.

- Clicking the OK button returns the user to the entry box where the error can be corrected.
- The Autostainer program report external device errors in a small dialogue box similar to the Figure below.

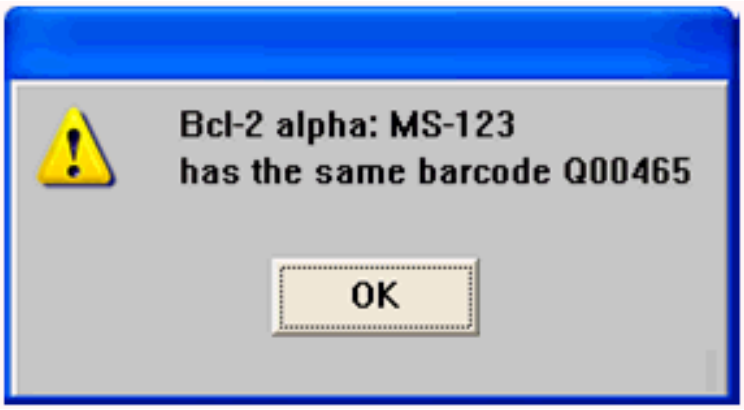
External device error dialogue box.

- Once the fault has been corrected, clicking the Retry button will attempt to carry out the failed command again.
- Clicking Cancel will abort the operation.

If in the test box time, no valid number is entered the following window appears. Please enter a positive number.



If this error message occurs, please change the text box entry for the barcode accordingly.



If this error message is displayed please make sure that:

- The printer is turned on
- The printer is installed properly

If the error persists please contact your local customer service representative.

Staining Performance

Please note that staining results are very much dependent on the quality of the tissue and the way it has been processed prior to staining. To rule out tissue related problems we suggest a comparison of staining results from manual staining performed in parallel with staining on the Autostainer.

Correction and elimination of error(s) by the user, or Technical Service for:

No staining/weak staining/false negatives

- Check the run log to see if any deviation from normal operation is reported.
- Check that the reagent vials contain sufficient reagent volumes.
- Check that the buffer and reagents were at room temperature at the start of the run.
- Check that the reagent vials are placed correctly in the reagent rack.
- Check that the slides were placed in the correct positions in the slide racks and that the instrument and all slides are horizontal (check with level gauge).
- Check the programming grid for possible errors in the protocol used.
- Verify that the reagent supplier's recommendations were followed.
- For AEC stains, the Tween content in the buffer may cause weak staining. Reduce Tween concentration to 0.05% and increase incubation time for the AEC – or split up the AEC incubation into two protocol steps of the same total incubation time – use blow step between AEC steps.

Background

- Check the buffer and water reservoirs – missing buffer or water could be the cause.
- Check that the protocol includes a "Rinse" step between all reagent steps.
- Check that the slides are horizontal using the level gauge.

Inconsistent staining

- Check that all slides are level when placed in the Autostainer – use level gauge on individual slides (difficult to check slides in the back of the instrument – use a mirror to get a vertical look at the gauge).
- Check the items listed above under No staining/weak staining/false negatives.
- Consider whether the programmed reagent volume and dispense location were adequate to cover the tissue sample.
- Check whether the buffer and reagents were at room temperature before the start of the staining run.

Slides dry out

- Check that all slides are level when placed in the Autostainer – use level gauge on individual slides (difficult to check slides in the back of the instrument – use a mirror to get a vertical look at the gauge).
- Note that longer incubation times require an increased volume of reagent dispensed on each slide. For incubation times of one hour or more, drying out may best be avoided by splitting up the protocol step into two consecutive steps with same reagent (to avoid that the total run time becomes extremely long in such case, apply an intermittent blow step).
- Check that there is enough buffer and deionised water in their respective containers.

Fluid Handling

Correction and elimination of error(s) by the user, or Technical Service for:

Buffer is not flowing at an optimal flow

Check that there is sufficient buffer. If not, then fill the container with buffer and prime the pump.

Buffer is not blown off completely before reagent is added to the slides

- Check that there is sufficient buffer. If not, then fill the container with buffer and prime the pump.
- Check that levelling is satisfactory.
- Check the Compressor - can you hear it operating?
- If the problem persists, call Technical Service.

Reagent dropped on slides appears to spread in an H-shape pattern

- Check that there is sufficient buffer. If not, then fill the container with buffer and prime the pump.
- Check how the slides are treated before staining to ensure that the surface of the slides are hydrophilic.
- Keep the slides immersed in buffer at least 15 minutes before placing them in the Autostainer.
- Check that the buffer contains “Tween 20” at the recommended concentration of 0.05% to 0.1%, which should not be exceeded.
- Check the de-waxing procedure for possible clues.
- Check that the slides are properly levelled.
- The air-sweep made by the buffer/air head immediately before reagent dispensing may be too weak – feel the airflow with a finger to judge this.
- Check for obstructions on the air blow outlet and try to rinse the air outlet nozzle with a small brush.
- Check compressor – can you hear it operating?
- If problem persists call Technical Service.

Buffer or deionised/distilled water does not flow out of the buffer head

- Check that there is sufficient buffer or water in the containers.
- Check that none of the tubing from the containers to the instrument are bent or damaged.
- Prime the tubing and pump for buffer or water (or both) by following the normal priming procedure (See Priming of Buffer and Deionised Water Pump).

Drops are formed on the tip of the reagent probe

Observe precisely where in the program this occurs:

- When probe moves from the wash station to the reagent vials.
- When probe moves from the wash station to the slide for rinse step.
- When probe moves from the reagent vials to slides.
- When probe moves from slide to slide.
- In addition, call Technical Service.

Dosage uneven, some slides receive too little or no reagent

- Check that the buffer contains Tween 20 in the prescribed concentration of 0.05%. If not, adjust the buffer, prime the buffer pump to assure the tubing contains buffer in the right concentration and try the run again.
- If the problem prevails, call Technical Service for help.
- When calling, please describe the symptom as precisely as possible, preferably with information including:
  - The protocol – possibly fax a copy of the program used.
  - The slides.
  - Whether the symptom appears in more than one run, etc.
- Also please check if the clear plastic tubing around the syringe (placed on the left side of the moving arm) contains air bubbles – if so removal of the bubbles may solve the problem. Technical Service might be able to guide you over the phone how to do this.
- You may also observe the syringe operating for possible clues to the cause. If any leaks can be observed inform Technical Service.

Probe moves to reagent vial, but does not go down into the vial or stops before reaching the surface

- Check that the instrument is properly grounded, i.e. connected to a power outlet with ground connection.
- To assure proper power cord connections switch off the instrument completely, pull out the power cord to the instrument, insert it again, switch on power, and restart the system.
- If the problem persists call Technical Service.

Waste backs up in the sink

Remove obstruction from the filter in the bottom of the sink.

Electrical

Correction and elimination of error(s) by the user, or Technical Service for:

- The right LED (green light) is not lit, indicating there is no power to the instrument.
- Check that the power cord is plugged into a working outlet via the surge control unit and that all circuit breakers between power outlet and instrument are switched on.
- Check the fuse on the right side of the instrument – if the white portion has popped out, reset by pushing it back.

Mechanical

Correction and elimination of error(s) by the user, or Technical Service for:

- Bent probe

  The probe tip may be bent if the caps are left on the reagent vials when a staining run is started.

  Call Technical Service and make sure to remove the caps before runs in the future.

- Both toxic and non-toxic wastes are pumped to the same external waste container

  One of the two waste pumps is broken – this will have an effect of the other pump taking over.

  Except for the inconvenience of the mixed waste streams the instrument will function as usual and can safely be operated in a normal fashion.

  Call Technical Service to have the pump changed.

- Waste is flowing out from the overflow tube (large diameter, clear tube)

  Both waste pumps have failed.

  Call Technical Service to have the pumps checked and possibly changed.

- The probe or wash-blow head is misaligned

  Call Technical Service to have the instrument calibrated.

Computer and Software

Correction and elimination of error(s) by the user, or Technical Service for:

The computer screen froze: no reaction to mouse or keyboard

- Regardless of whether the Autostainer is operating or not you can only do as follows, even though current run and unsaved data will be lost:
- Reboot the computer by simultaneously pressing the keys Ctrl Alt Delete keys twice. The computer will close all programs (unsaved data and the Log run for the program in progress will be lost). Shut down the computer and switch off power to the computer before restarting the computer again.
- If the computer does not even respond to the Ctrl Alt Delete, shut down the computer by holding on/off button in for more than 4 seconds, which will switch off the power.
- If the monitor blocks repeatedly, the computer may need servicing – call Technical Service for advice.
- The following error message may be displayed:

Appendices

THE FOLLOWING SECTIONS ARE INTENDED AS A QUICK REFERENCE GUIDE TO PERFORMING THE STATED OPERATIONS USING THE AUTOSTAINER. THEY ARE NOT INTENDED TO REPLACE THE MORE DETAILED INSTRUCTIONS CONTAINED IN THE MAIN BODY OF THIS DOCUMENT. USERS SHOULD BE FAMILIAR WITH THE FULL OPERATING PROCEDURE BEFORE ATTEMPTING TO RUN THE INSTRUMENT USING THE FOLLOWING GUIDES.

Quick Operation of Autostainer (Basic)

1. Turn computer on: Black button at front of computer
2. Double click on Autostainer icon
3. Type in user name and password: press enter
4. Click **Program**
5. Click **Print Labels**
6. Enter patient info and choose antibodies and **Finish Entry**
7. Click **Print**
8. When finished click **Cancel**
9. Label slides and load them onto stainer racks
10. Enter slide count: click **OK** (scanning will begin shortly)
11. When scanning is complete click **OK**
12. **Main Grid** appears; make adjustments to drop zones or edit slides at this screen
13. Click **Next**
14. Reagent list appears; print labels if needed
15. Load and un-cap reagents, check for proper volumes
16. Click **Next**
17. Click **Scan Vials**
18. Click **Next**
19. **Save Program** box appears; click **Yes** to save run
20. Name program; click **OK**
21. **Start Run** screen appears. **Prime Pumps** is needed
22. Click **Start**
23. Dialogue box will appear asking to verify bulk fluid levels: click **OK**
24. When run is complete, alarm will sound
25. Click **Print IHC** and then **OK**
26. **Save Run Log** box appears: click **Yes** to save
27. **Print Run Log** box appears: click **No**

28. Remove slides and coverslip

Quick Operation of Autostainer (Sub-Batch)

1. Turn computer on: Black button at front of computer
2. Double click on Autostainer icon
3. Type in user name and password: press enter
4. Click **Program**
5. Click **Print Labels**
6. Enter patient info and choose antibodies and **Finish Entry**
7. Click **Print**
8. When finished click **Cancel**
9. Label slides and load them onto stainer racks
10. Enter slide count: click **OK** (scanning will begin shortly)
11. When scanning is complete click **OK**
12. **Main Grid** appears; make adjustments to drop zones or edit slides at this screen
13. Click **Next**
14. Reagent list appears; print labels if needed
15. Load and un-cap reagents, check for proper volumes
16. Click **Next**
17. Click **Scan Vials**
18. Click **Next**
19. **Save Program** box appears; click **Yes** to save run
20. Name program; click **OK**
21. **Start Run** screen appears. **Prime Pumps** is needed
22. Click **Start**
23. Dialogue box will appear asking to verify bulk fluid levels: click **OK**
24. An alarm sounds to mix the Substrate-batch
25. When mixed add to substrate batch to proper vial
26. Click **Scan Vials**
27. Stainer will continue to completion
28. When run is complete, alarm will sound
29. Click **Print IHC** and then **OK**
30. **Save Run Log** box appears: click **Yes** to save
31. **Print Run Log** box appears: click **No**
32. Remove slides and coverslip

Quick Operataion of Autostainer - Slide Info (Configuration Option BarMeth 1)

1. Turn the computer on: Black button at front of the computer.
2. Double click on Autostainer icon.
3. Type in user name and password: press **Enter**.
4. Click **Program**.
5. Click **Slide Info**.
6. Enter patient info and numbers of slides and Finish Entry.
7. Click **Auto** and **Select Program**.
8. Select correct protocols to match slide information on the left.
9. Click **Next**.
10. Click **All** to print all slide labels.
11. Label slides and load them onto Autostainer racks and begin any pre-treatment.
12. Reagent list appears; print labels if needed.
13. Load and un-cap reagents, check for proper volumes.
14. Click **Next**.
15. Set Start Time window appears (If not then check Scan Reagents and Slides).
16. Prime Pumps as needed.
17. Click **Start Run** – instrument will scan slides and reagents.
18. Dialogue box will appear asking to verify bulk fluid levels: click **OK**.

    If Substrate-Batch is used an alarm sounds to mix the Substrate-Batch

    When mixed add to Substrate-Batch to proper vial
19. Autostainer will continue to completion.
20. When run is complete, alarm will sound.
21. Click **Print IHC** and then **OK**.
22. Save / Print Run window will appear print and save files as necessary.
23. Remove slides and coverslip.

Quick Operation of Autostainer - Enter Tests (Configuration option BarMeth 1)

1. Turn the computer on: Black button at front of the computer.
2. Double click on Autostainer icon.
3. Type in user name and password: press **Enter**.
4. Click **Program**.
5. Click **Enter Tests**.
6. Enter patient info and choose antibodies and click **Finish Entry**.
7. Click **Next**.
8. Click **All** to print all slide labels.
9. Label slides and load them onto Autostainer racks and begin any pre-treatment.
10. Reagent list appears; print labels if needed.
11. Load and un-cap reagents, check for proper volumes.
12. Click **Next**.
13. Set Start Time window appears (If not then check Scan Reagents and Slides).
14. Prime Pumps as needed.
15. Click **Start Run** – instrument will scan slides and reagents.
16. Dialogue box will appear asking to verify bulk fluid levels: click OK.

    If Substrate-Batch is used an alarm sounds to mix the Substrate-Batch

    When mixed add to Substrate-Batch to proper vial
17. Autostainer will continue to completion.
18. When run is complete, alarm will sound.
19. Click Print IHC and then OK.
20. Save / Print Run window will appear print and save files as necessary.
21. Remove slides and coverslip.

Quick Operation of Autostainer - Label Printing

1. Enter Slide Info. 1st line is patient name
2. Tab to next line
3. Enter Case Number, this is your accession number
4. **Tab** to next line
5. Enter Doctor if desired
6. **Tab** to next line
7. Enter Block ID
8. **Tab** to next line
9. Enter Tissue if desired
10. **Tab** to Antibody List
11. Choose antibodies from drop down menu and click Enter, the chosen antibodies will appear in the box on the right. If you need to delete an antibody, click on the antibody and a dialogue box will appear asking if you want to delete it.
12. Use **Tab** to move back to the Slide ID to continue entering label information, until all labels are made.
13. When finished, click **Finish Entry** and then **Print.**

Appendix B - Spares and Accessories

Description	Part Number
Vials and Reagent Trays	
12ml Barcode Vials for 2-D Systems (pack of 100 vials)	A80510136
15ml Cylindrical Vials for the LV-1 or Dako Autostainer(pack of 100 vials)	S20002
Reagent Tray with Wash Station for Autostainer720 and 360 (holds 40 vials)	A00408
Reagent Tray for Autostainer480S (holds 49 vials)	A00380
2nd Reagent Tray for Autostainer720 with No Wash Station (holds 44 vials)	S00428
LV-1 Reagent Rack, Blue	S20005
LV-1 Reagent Rack, White	S20001
Tray for 40 Autostainer vials	S00140
Labels and Printers	
Reagent Barcode Label Kit, 3000 Labels and Ribbon Set	A80510134
Flap Slide Label Kit, 3000 Labels and Ribbon Set	A80510135
No Flap Slide Label, 3200 Labels and Ribbon Set	K21004
Label Printer Software (only for printers not connected to an Autostainer)	ZebraSW
Label Printer with Printer Cable, 220V	S19011
Accessory Reagents	
DAB-Away Kit for Automated Instrument Cleaning	TA-250-DA
Tween® 20, 125ml	TA-125-TW
Accessories	
PT Module Pump Kit (included in PT Module System)	A80410008
Autostainer Slide Rack	A80510139
Toxic Waste Tube	A80510140
Non-toxic Waste Tube	A00049
Buffer In-line Tubing	A80510077
DI Water In-line Tubing	A80510078
Reagent Rack	A80510050
Buffer Bottle	S20007
Carboy	AP15690

Carboy Lid	AP15691
Service Manual	S22031
User Guide Translations CD Including Safety Guide	A80510107-CD

Appendix C - Reagents List

UltraVision Quanto

Product Name	Kit Includes	Volume	No. of Tests	Part Number
HRP Systems				
UltraVision Quanto Detection System HRP	Ultra V Block, Primary Antibody Amplifier Quanto, HRP Polymer Quanto	60 ml	300-600	TL-060-QHL
UltraVision Quanto Detection System HRP	Ultra V Block, primary Antibody Amplifier Quanto, HRP Polymer Quanto	125 ml	625-1250	TL-125-QHL
UltraVision Quanto Detection System HRP DAB	Hydrogen Peroxidase Block, Ultra V Block, Primary Antibody Amplifier Quanto, HRP Polymer Quanto, DAB Quanto Substrate, DAB Quanto Chromogen	60 ml	300-600	TL-060-QHD
UltraVision Quanto Detection System HRP DAB	Hydrogen Peroxidase Block, Ultra V Block Primary Antibody Amplifier Quanto, HRP Polymer Quanto, DAB Quanto Substrate, DAB Quanto Chromogen	125 ml	625-1250	TL-125-QHD
Alkaline Phosphatase				
UltraVision Quanto Detection System AP	Ultra V Block, Primary Antibody Amplifier Quanto, AP Polymer Quanto	60 ml	300-600	TL-060-QAL
UltraVision Quanto Detection System AP	Ultra V Block, Primary Antibody Amplifier Quanto, AP Polymer Quanto	125 ml	625-1250	TL-125-QAL

UltraVision LP

Product Name	Kit Includes	Volume	No. of Tests	Part Number
HRP Systems				
UltraVision LP (HRP DAB)	Peroxide Block, Ultra-V-Block, Enhancer, Labelled Polymer, DAB Chromogen/Substrate	15 ml	75-150	TL-015-HD
UltraVision LP (HRP DAB)	Peroxide Block, Ultra-V-Block, Enhancer, Labelled Polymer, DAB Chromogen/Substrate	60 ml	300-600	TL-060-HD
UltraVision LP (HRP DAB)	Peroxide Block, Ultra-V-Block, Enhancer, Labelled Polymer, DAB Chromogen/Substrate	125 ml	625-1250	TL-0125-HD
UltraVision LP (HRP AEC)	Peroxide Block, Ultra-V-Block, Enhancer, Labelled Polymer, AEC Chromogen/Substrate	15 ml	75-150	TL-015-HA
Ultra Vision LP (HRP)	Ultra-V-Block, Enhancer, Labelled Polymer	60 ml	300-600	TL-060-HL
Ultra Vision LP (HRP)	Ultra-V-Block, Enhancer, Labelled Polymer	125 ml	625-1250	TL-125-HL
Alkaline Phosphatase				
UltraVision LP (AP Fast Red)	Ultra-V-Block, Enhancer, Labelled Polymer, Fast Red Chromogen/Substrate	15 ml	75-150	TL-015-AF
UltraVision LP (AP)	Ultra-V-Block, Enhancer, Labelled Polymer	60 ml	300-600	TL-060-AL
UltraVision LP (AP)	Ultra-V-Block, Enhancer, Labelled Polymer	125 ml	625-1250	TL-125-AL

UltraVision One

Product Name	Kit Includes	Volume	No. of Tests	Part Number
HRP Systems				
UltraVision LP (HRP DAB)	Peroxide Block, Ultra-V-Block, UV One Polymer, DAB Chromogen/Substrate	15 ml	75-150	TL-015-HDJ
UltraVision LP (HRP DAB)	Peroxide Block, Ultra-V-Block, UV One Polymer, DAB Chromogen/Substrate	60 ml	300-600	TL-060-HDJ
UltraVision LP (HRP DAB)	Peroxide Block, Ultra-V-Block, UV One Polymer, DAB Chromogen/Substrate	125 ml	625-1250	TL-0125-HDJ
UltraVision LP (HRP AEC)	Peroxide Block, Ultra-V-Block, UV One Polymer, AEC Chromogen/Substrate	15 ml	75-150	TL-015-HAJ
Ultra Vision LP (HRP)	Ultra-V-Block, UV One Polymer	60 ml	300-600	TL-060-HLJ
Ultra Vision LP (HRP)	Ultra-V-Block, UV One Polymer	125 ml	625-1250	TL-125-HLJ
Alkaline Phosphatase				
UltraVision LP (AP Fast Red)	Ultra-V-Block, UV One Polymer, Fast Red Chromogen/Substrate	15 ml	75-150	TL-015-AFJ
UltraVision LP (AP)	Ultra-V-Block, UV One Polymer	60 ml	300-600	TL-060-ALJ
UltraVision LP (AP)	Ultra-V-Block, UV One Polymer	125 ml	625-1250	TL-125-ALJ

Ultra Vision Plus

Product Name	Kit Includes	Volume	No. of Tests	Part Number
HRP Systems				
UltraVision Plus (HRP DAB)	Peroxide Block, Ultra-V-Block, Biotinylated Secondary, HRP Labelled Streptavidin, DAB Chromogen/Substrate	15 ml	75-150	TL-015-HDX
UltraVision Plus (HRP AEC)	Peroxide Block, Ultra-V-Block, Biotinylated Secondary, HRP Labelled Streptavidin, AEC Chromogen/Substrate	15 ml	75-150	TL-015-HAX
UltraVision Plus (HRP)	Ultra-V-Block, Biotinylated Secondary, HRP Labelled Streptavidin	60 ml	300-600	TL-060-HLX
UltraVision Plus (HRP)	Ultra-V-Block, Biotinylated Secondary, HRP Labelled Streptavidin	125 ml	625-1250	TL-125-HLX
Alkaline Phosphatase				
UltraVision LP (AP Fast Red)	Ultra-V-Block, Biotinylated Secondary, AP Labelled Streptavidin, Fast Red Chromogen/Substrate	15 ml	75-150	TL-015-AFX
UltraVision LP (AP)	Ultra-V-Block, Biotinylated Secondary, AP Labelled Streptavidin	60 ml	300-600	TL-060-ALX
UltraVision LP (AP)	Ultra-V-Block, Biotinylated Secondary, AP Labelled Streptavidin	125 ml	625-1250	TL-125-ALX

Chromogen Systems

Description	Additional information	Volume	No. of Tests	Part Number
DAB Plus Substrate System (HRP)	High sensitivity deep brown DAB chromogen	6 ml DAB Plus Chromogen + 60 ml Substrate	300-600	TA-060-HDX
DAB Plus Substrate System (HRP)	High sensitivity deep brown DAB chromogen	12 ml DAB Plus Chromogen + 125 ml Substrate	625-1250	TA-125-HDX
Liquid Fast-Red Substrate System (AP)	Solvent resistant fast red chromogen (can be permanently mounted)	1 ml Liquid Chromogen + 60 ml Substrate	300-600	TA-060-AL
Liquid Fast-Red Substrate System (AP)	Solvent resistant fast red chromogen (can be permanently mounted)	2 ml Liquid Chromogen + 125 ml Substrate	625-1250	TA-125-AL
Tablet Fast-Red Substrate System (AP)	Fast red chromogen (must be aqueously mounted)	12 Tablets + 60 ml Substrate	300-600	TA-060-AF
Tablet Fast-Red Substrate System (AP)	Fast red chromogen (must be aqueously mounted)	25 Tablets + 125 ml Substrate	625-1250	TA-125-AF
AEC (HRP ready to use)	Red AEC chromogen (must be aqueously mounted)	60 ml Single Solution	300-600	TA-060-SA
AEC (HRP ready to use)	Red AEC chromogen (must be aqueously mounted)	125 ml Single Solution	625-1250	TA-125-SA
DAB Quanto	High Sensitivity dark brown DAB chromogen with prolonged stability	2 ml DAB Quanto Chromogen + 60 ml DAB Quanto Substrate	600	TA-060-QHDX
DAB Quanto	High Sensitivity dark brown DAB chromogen with prolonged stability	4 ml DAB Quanto Chromogen+ 125 ml DAB Quanto Substrate	1250	TA-125-QHDX
Permanent Fast Red Quanto	High Sensitivity, Solvent resistance, on slide mixing	60 mL Substrate + 60 mL chromogen	600	TA-060-QAL
Permanent Fast Red Quanto	High Sensitivity, Solvent resistance, on slide mixing	125 mL Substrate + 60 mL chromogen	1250	TA-125-QAL

Wash Buffers and Dilutents

Description	Additional Information	Volume	No. of Tests	Part Number
Phosphate Buffered Saline (10X)	Makes 10L	Powered for 1L of 10X	Varies by application	AP-9009-10
Phosphate Buffered Saline (25X)	Makes 3125mL	125 ml	Varies by application	TA-125-PB
Tris Buffered Saline (25X)	Makes 3125 mL	125 ml	Varies by application	TA-125-TB
Tris Buffered Saline and Tween 20 (20X)	Makes 2500 mL	125 ml	Varies by application	TA-125-TT
Tris Buffered Saline and Tween 20 (20X)	Ideal for automated use; Makes 20 L	1000 ml	325-650 (automated)	TA-999-TT
Phosphate Buffered Saline and Tween 20 (20X)	Makes 2500 mL	125 ml	Varies by application	TA-125-PT
Phosphate Buffered Saline and Tween 20 (20X)	Ideal for automated use; Makes 20 L	1000 ml	325-600 (automated)	TA-999-PT
UltraClean Diluent	Diluent includes serum-free blocking	125 ml	Varies by application	TA-125-UC
Phosphate Buffered Saline and Tween 20 (20X)	Diluent without blocking solution	125 ml	Varies by application	TA-125-UDX
Phosphate Buffered Saline and Tween 20 (20X)	Diluent without blocking solution	125 ml	Varies by application	TA-125-UD

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