

Xmatrix[®] ELITE

Automated Staining System for IHC, ISH and SS

OPERATOR'S MANUAL

Cat. No.: AS4040B

FOR *IN VITRO* DIAGNOSTIC USE ONLY



Doc. No. 953-0058.0, Rev. L
ECO-734-SEZ

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IMPORTANT:

The *Xmatrix*[®] *Elite* Automated Staining System must be unpacked, inspected, and installed by an authorized BioGenex representative.

Read and understand all the safety and operation instructions contained in this manual before you attempt to use this system.

Section 2 (Safety Precautions) of this manual expounds more specifically to the safety instructions that must be followed to ensure safe operation and to maintain the *Xmatrix*.

Elite Diagnostics Automated staining system in safe condition. BioGenex Laboratories, Inc. assumes no liability for the user's failure to comply with those safety precautions.

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Elite Software Version 1.4 and Above

Overview of the *Xmatrx*[®] Elite Automated Staining System



BioGenex*Xmatrx*[®] Elite Automated Staining System is an array of reliable and efficient equipment that robotically executes any slide-based staining protocol with excellent consistency and accuracy. It precisely controls and regulates the temperature of 40 slides individually in a single run.

In this manual, the entire combination of the *Xmatrx*[®] Elite workstation, the computer system, and the bulk fluids are referred to as “BioGenex*Xmatrx*[®] Automated Staining System”, or simply “the system”. The mechanical mainframe that directly performs automated staining is referred to as “*Xmatrx*[®] workstation”, or simply “the workstation”, and occasionally “the instrument”.

Checklist of Xmatrix® Elite Automated Slide Staining System with Accessories

S.No.	Description of Item	Part Number	Qty
1.	Slide Carrier	6520-30704	4
2.	Reagent 49 Vial Tray - Diagnostics	6520-60104	1
3.	Pipette Tip Waste Box	6520-17701C	1
4.	Reagent Vial 17 ml - Diagnostics	6520-37836	6
5.	Cover-slip boxes/stacks (18x18mm)	6520-37981	3
6.	Cover-slip boxes/stack (25x25mm)	6520-37980	3
7.	Cover-slip boxes/stack (25x40mm)	6520-37979	3
8.	Cover-slip Disposal Box	6520-17705B	1
9.	Computer/CPU with Software Loaded	4270-00112	1
10.	Flat Monitor	4270-00113	1
11.	Printer For (IND Domestic Only)	4270-00122	1
12.	i 500 BLS-500	BLS500	1
13.	Printer Table/Stand	6520-37807	1
14.	Leveler	6520-04116	1
15.	IHC Xflex Consumable kit for Xmatrix Diagnostics and Research	XT148-YCDE	1
16.	Assembly Calibration Disk	6520-30753	1
17.	Software Distribution Package for Xmatrix Elite Diagnostics	4812-00131	1
18.	Xmatrix Series Instrument Installation Check List	951-6122.1	1
19.	UPS (For U.S Domestic Only)	4290-04029	1
20.	Assy Carboy 4L, IHC Buffer	6520-30715	1
21.	Assy Carboy 4L, SS Buffer	6520-30716	1
22.	Assy Carboy 4L, ISH Buffer	6520-30717	1
23.	Assy Carboy 4L, DEPC Buffer	6520-30718	1
24.	Assy Carboy 4L, DI Water	6520-30719	1
25.	Assy Carboy 4L, Alcohol	6520-30720	1
26.	Assy Carboy 4L, Dewax	6520-30721	1
27.	Acrylic Sheet	6520-20472	1
28.	Assy., Heater wiring	4501-27401	2
29.	2ml vial Fixture bottle	4911 02826	1
30.	2ml vial Graduated	4911 00024	1
31.	Fuse, 10AMP, Type MDA	4280-02245	2
32.	Operator's Manual package for Xmatrix Elite Diagnostics System (Auto executable CD)	4812-00132	1
33.	Power Cord for China	1650-02985	01
34.	Power Cord, G, 10A/250V, Italy	1650-02965	01

35.	Power Cord, K, 10A/250V, UK	1650-02966	01
36.	Power Cord, C, 10A/250V, Europe	1650-02967	01
37.	Power Cord, E, 10A/250V, Australia	1650-02968	01
38.	Power Cord, A, 10A/250V, USA	1650-02970	01
39.	Power Cord, H, 10A/250V, Israrel	1650-02971	01
40.	Power Cord, B, 10A/250V, Japan	1650-02972	01
41.	Power Cord, I, 10A/250V, India/South Africa	1650-02973	01
42.	Power Cord, F, 10A/250V, Denmark	1650-02974	01
43.	Power Cord, D, 10A/250V, Switzerland	1650-02967	01
44.	Acrylic Sheet	6520-20472	01
45.	Screws 8-32, 1/4" FHP	4510-08324-13	07
46.	Assay, Heater Wiring	4501-27401	02

NOTE: One line item from the following power cord list(Item# 33 to 43, depending on the country of destination

Listof Consumables,Reagents and Detection Kits.

S. No	Description of Item	Part Number	Qty	No. of Tests	IHC	ISH	SS	*FISH
	IHC Xflex Consumable Kit contains below items)	XT148-YCDE	1 Kit	200			NA	NA
1a	BARRIER SLIDE 25 X 40MM			200	✓	NA	✓	✓
1b	COVERSLIPS 25 X 40MM						✓	✓
1c	PIPETTE TIPS						✓	✓

1d	PIPETTE TIPS						✓	✓
	ISH Consumable kit-Xmatrix (Contains Below items)	XT144-YAD	1 Kit	100			NA	NA
2a	BARRIER SLIDES 25 X 25MM						NA	✓
2b	COVERSLIPS 25 X 25MM			100	NA	✓	NA	✓
2c	PIPETTE TIPS						NA	✓

2d	PIPETTE TIPS						NA	✓
	Xviz Detection kit	QD550-YCDE	1 kit	200		NA	NA	NA
	XISH One step Polymer HRP ISH Detection kit	DF400-YADE	1 kit	100	NA		NA	NA
	Super Sensitive Wash buffer (500ml. Conc.)	HK583-5KE	1 kit	100				
	EZ Dewax/ X-Dewax	HK584-5KE / HX016-XAK	1 kit	40				
	Antibodies*	refer catalog	1 vial	50/200		NA	NA	NA
	Resin Ribbon	XT034-XEX	1 roll	1000 Slides				NA
	Label Roll	XT035-XBX	1 roll	1000 Slides				NA
	ISH Probes*	refer catalog	1 vial	25	NA		NA	NA
	Special Staining Kit*	Refercatalog og forrequire d stain	1	50	NA	NA		NA
	eFISHHisto kit / eFISHCyto kit	DF500-20XE / DF510-20XE	1	20	NA	NA	NA	
	Barrier Slides 18x18 mm for Xmatrx	XT114-SL	1	70	NA	NA	NA	

	Cover Slips 18x18mm	XT121-YBX	1	20 Approx	NA	NA	NA	
	DAPI	HK606- 10K	1	10 tests	NA	NA	NA	
	eFISH probes	Refer Catalog	1	24 Vials	NA	NA	NA	
	Optimizer Reagent vials 20ml unlabelled,W hite/Brown	XT026- V24/ XT101-24X	1	NA	NA	NA	NA	
	User defined Empty barcode labeled vials- Two step IHC	XT077- AX0601 to XT077- AX0800	1	200		NA	NA	NA
	XMount™ for Xmatrx® Elite (barcode)	HX035- YCD	1	NA				NA
	i500 Plus LIS enabled barcode label printer	BLS500	1	NA				NA
	Vial Insert - 2ml 24 per pack	XT149-v24	1	NA	NA	NA	NA	
	Brown Vial without neck 24 per pack	XT126-24V	1	NA	NA	NA	NA	
	Reagent Tray for FISH (30 Position)				NA			

NOTE 1:

1. * IF FISH IS REQUIRED, NEED TO ORDER THE INSTRUMENT AS COMBO SOFTWARE I.E XMATRX ELITE WITH FISH.
2. ALL THE ABOVE MENTIONED (CONSUMABLES, REAGENTS AND DETECTION KITS) ARE NOT SUPPLIED ALONG WITH THE INSTRUMENT, NEED TO ORDER AS PER THE REQUIREMENT OF THE APPLICATION.

NOTE 2:

1. There are no user serviceable parts in the Xmatrx® Elite system. When any service is needed, please consult BioGenex Laboratories, Inc. at 1-800-421-4149 (for USA and Canada only) For support outside USA and Canada, please contact your local distributor.
2. To order consumables or reagents; please contact BioGenex Laboratories, Inc. For detailed contact information, see page 2 of this manual.

TABLE OF CONTENTS

S. No.	Chapter	Page No.
1.0	Introduction to Xmatrx®	14
	1. Intended Use ...	14
	1.1 Work Principles of the Workstation ...	14
1.3	Transportation and Storage of Workstation	15
1.4	Specifications	15
2.0	Safety Precautions	16
2.1	Precautions and Warning	16
2.2	Disclaimer Regarding Staining Results	19
2.3	Precautions Regarding Bio-hazardous Materials and Waste	19
3.0	On-site Installation	20
3.1	Installation Requirements	20
3.2	Installation of Buffer Carboys to the liquid panel	23
3.3	Waste Carboy Connection	24
3.4	Glossary	25
4.0	Starting The System	27
4.1	Loading Consumables	27
4.2	Executing a Run Flow Chart	32
4.3	Assay Selection	33
5.0	Configuration Settings	35

5.1	Maintaining User Profiles	...	35
5.2	Specimen Name	...	37
5.3	Buffer Lines	...	39
5.4	Changing System Clock for Day Light Saving Time	...	39
6.0	Building And Inserting Protocols		41
6.1	Protocol Types	...	41
6.2	Default Slide Pattern	...	41
6.3	Staining Steps	...	41
6.4	Building Protocols	...	42
6.5	Inserting a Protocol	...	42
6.6	Editing Protocols	...	46
6.6.1	Edit Protocol for a single slide	...	46
6.6.2	Editing user defined protocols	...	48
6.7	Adding Slides After a Run Has Begun through Continuous / Stat Mode	...	52
6.7.1	Inserting the slides to Run through Continuous Mode	...	52
6.7.2	Inserting the slides to Run through STAT Mode	...	56
7.0	Using Protocol / Slide Editor Windows		60
7.1	Editor Windows	...	60
7.2	Working in the <Protocol Editor> Window	...	60
7.2.1	Opening the Window	...	61
7.2.2	Operating the <Protocol Editor> Window		61
7.2.3	Button Options in the Editor Windows	...	63
7.2.4	Button Options in the Insert/Edit Protocol Windows	...	63
7.2.5	Slide Information Area	...	64
7.2.6	Protocol Information Area	...	65
8.0	Executing a Run		65
8.1	Initiating a Staining Run	...	65
8.2	Monitoring a Run	...	72
8.3	Pausing a Run	...	74
8.4	Checking the availability of buffer	...	74
8.5	Stopping a Run	...	75
8.6	Emergency Stop	...	77
8.7	Typical Error Message	...	77
9.0	Generating Reports		79
9.1	Launching the Reports Module	...	79
9.2	Default Report types	...	80
9.3	Previewing and Printing a Report	...	80
9.4	Exiting the Reports Module	...	81
10.0	Troubleshooting		82
10.1	Typical Error Message		82
10.2	Slide Heating Error	...	83
10.3	Errors at Pipette Tray	...	84
10.4	Pipette Drop Error	...	85

10.5	Pipette Disposing Error	...	87
10.6	Empty Coverslip Box Error	...	88
10.7	Coverslip Placement/Pickup Error	...	88
10.8	Error at DAB Mixing Step		89
10.9	Error at Xmount Step		92
10.10	Basic Troubleshooting	...	93
11.0	Routine Maintenance		95
11.1	Daily Cleaning	...	95
11.2	Monthly Maintenance Schedule	...	98
11.3	Half-yearly Maintenance Arrangement	...	100
APPENDIX 1	Service Plan	...	101
APPENDIX 2	Preventive Maintenance Checklist for Xmatrx[®] system	...	106
APPENDIX 3	Software License (BioGenex Software)	...	106
APPENDIX 4	Software License Agreement (Microsoft Software)	...	108
APPENDIX 5	Xmatrx Maintenance Schedule	...	117

INTRODUCTION TO XMATRX[®] ELITE

1.1. Intended Use:

Xmatrx® Elite Automated Slide Staining System is for diagnostic use only. The system performs and supports Immunohistochemistry (IHC), *InSitu* Hybridization (ISH) and Special Staining applications.

The system is enabled with the technology of processing multiple assays of IHC, ISH and SS in a single run. It is featured with real time Buffer level Monitoring and Automated on-board DAB working solution preparation. Protocol for different assays is selected via barcode reader built in the instrument, barcode label are pasted on the each slide and the system will read each slide and select the protocol automatically.

It has got BARCODE for updating the reagent volume during the run and displays reagent volume updation in terms of number of tests as well. Real time buffer level monitoring for wash buffers are enabled in the application window which displays the level of buffer volume in loaded carboys. This product uses 17mL reagent capacity vial with 49 nos. of reagent vials positions on the reagent rack. The software used is of closed mode with limited options for user defined protocol settings.

The *Xmatrx® Elite* system must be used and handled by trained personnel. All technicians who will be using the system must be trained. Failure to comply could result in damage to the instrument and injury to the user.

A qualified pathologist must interpret the staining results. The system does not provide interpretation of any staining results. Such interpretation is solely the responsibility of the user.

1.2. Work Principles of the Workstation

The workstation has an XYZ robotic arm that picks up standard disposable pipette tips, aspirates and dispenses reagents on specimens on the slide(s) placed in the workstation, and discards the pipette tips, thereby eliminating the possibility of cross-contamination.

The integrated multiple-functional Z-Head rinses slide after each incubation and blows excess buffer from the slides at the end of each wash step. The system regulates the incubation time and temperature of the slide(s) and controls evaporation by covering the specimen with cover slips in the steps involving micro reagents.

The computer is for running the *Xmatrx® Elite* system, and should not be used for any other purposes.

1.3. Transportation and Storage of the Workstation

New and disinfected workstation(s) can be transported on any commercial vehicle suitable for the purpose, with adequate protective packaging as

provided by the original shipping crate. If the workstation is to be stored for an extended period of time, ensure that the original shipping crate is used. The storage environment should be indoors, dry and protected from freezing temperatures, insects and rodents.

1.4 Specifications

Item	Specifications
Total Slide Capacity	4 removable slide carriers; 10 slides per carrier = 40 slides
Reagent Capacity	1 'Reagent Tray' with up to 49 vials for IHC/ISH/SS
Reagent Dispense Volumes	10-850 μ l
Reagent Dispenser	Standard 1 ml disposable pipette tips Standard 200 μ l disposable pipette tips
Pipette Tip Trays 1 ml tips (2 x 96) 200 μ l tips (2 x 96)	Four trays: Two 96-tip disposable trays for 1 ml tips Two 96-tip disposable trays for 200 μ l tips
Slide Temperature	25°C to 105°C Each slide with individual temperature control.
Integrated Cover-slipper	Places and removes individual coverslips Two coverslip stacks each for: <ul style="list-style-type: none"> ▪ 25 x 40 mm ▪ 25 x 25 mm ▪ 18 x 18 mm
Optimum Pressure for functioning of Instrument	5.5+/- 0.5 PSI
Evaporation Control	Oil sealing
Bulk Fluids	7 User Defined Buffers (including EZ-DeWax™ and Alcohol)
Staining Operation	Multiple protocols can be run simultaneously Multiple parameters within a single run
Weight	400 lb/182 Kg

Electrical Specifications	115V 60Hz 900W 230V 50Hz 900W
Ambient Operating Temperature	15-30°C (59-86°F) Humidity 15%-55%
Dimensions	Depth: 29"/73.7 cm Width: 46"/116.8 cm Height: 59"/149.9 cm
Software	Proprietary BioGenex software running on Microsoft® Windows xp/7/8/10 IOT

SECTION 2.0

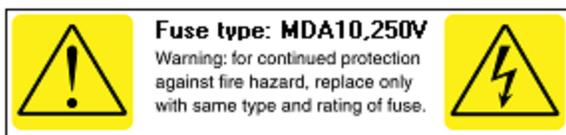
SAFETY PRECAUTIONS

The following general precautions must be observed during all phases of operation, service, and repair of this automated staining system. Failure to comply with these precautions or with specific warnings elsewhere in this manual violates the safety standards of the design, manufacturing, and intended use of this system. BioGenex assumes no liability for the user's failure to comply with these requirements.

Safety precautions

The following general precautions must be observed during all phases of operation, service, and repair of this automated staining system. Failure to comply with these precautions or with specific warnings elsewhere in this manual violates the safety standards of the design, manufacturing, and intended use of this system. BioGenex assumes no liability for the user's failure to comply with these requirements.

2.1. Xmatrx® Elite Staining System must be unpacked, inspected and installed by an Authorized BioGenex Representative. The serial number should be recorded and the Accessories checked against the list.



- i. **DO NOT** operate the system in an environment where flammable vapors are present. Operating AC-line-powered equipment in such an environment may cause an explosion.
- ii. When replacing fuses on the system, make sure that the correct fuse is used. Using the wrong fuse may lead to fire or instrument failure.
- iii. The AC-line cord provided with the staining system is intended to ground the chassis to help prevent shock and injury to lab staff. *Xmatrx® Elite* meets all

national and local electrical codes, which require a three-conductor AC outlet that connects the third wire of the line cord to the earth ground. Do not in any way defeat the grounding connection of this instrument.

- iv. Be aware that during or shortly after a high temperature step on the workstation, touching the hot Heater Top(s) may cause burns.
- v. The barcode option of the system uses a barcode scanner that has been approved by the FDA for Class II use in a laboratory environment. However, as with any laser, it is advised that the operators not place their hand under the barcode scanner when it is scanning or searching for barcodes. Also, in order to protect the operator's eyes, never place any reflective device under the barcode scanner when it is running. This instrument is also equipped with a second laser system beaming forward. Therefore do not operate the instrument when the 'Main Housing' is removed.



- vi. Be aware that, during the normal operation of the instrument the LASER radiation causes damage to the eye and skin if it exposed on the eye or skin.

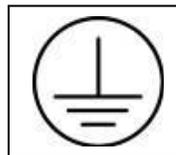


- vii. During the initial start of the run, LASER radiation will fall on the slide for scanning the barcode. Do not stare the beam for more than 0.25 Sec, since it is a visible LASER and starring in to beam more than 0.25 sec, cause damage to eyes.
- viii. Use of *Xmatrix® Elite* requires the use of hazardous chemicals. Please refer to the reagent manufacturer's instructions and be sure to follow all applicable regulations for the use, handling, storage, and disposal of any hazardous chemicals.
- ix. Appropriate safety precautions should be exercised to protect instrument operators from the risk of biological hazards. At a minimum, gloves should be worn during the operation of the instrument. Gloves, however, may not be sufficient personal protection in all cases. It is the operator's responsibility to confirm with their safety officer what precautions are required.

-
- x. Liquids used on *Xmatrix® Elite system* may present a slip hazard if spilled on the floor. Please ensure that all the bulk fluidics and waste containers are placed in a secondary containment.
 - xi. Liquid waste produced from running the *Xmatrix® Elite system* can be hazardous and should be disposed off properly as per the local regulations.
 - xii. Excessive jarring of the workstation while the housing is open may cause the housing to close unexpectedly.
 - xiii. Test for ground continuity between the system chassis and adjacent equipment or metal plumbing to ensure that the user
 - xiv. will not become a conductor between power ground and building ground. Never tamper with the 3-pin power plug. A GFI AC plug receptacle is highly recommended
 - xv. Do not service the system while power is ON. Refer all servicing to a qualified Service Staff or Technician.
 - xvi. Accessing the work platform of the workstation while the robotic arm is in motion may cause bodily injury. Ensure that the run is paused prior to accessing the work platform. The workstation is equipped with a door switch which, when open, will stop the movement of the robotic arm.



- xvii. This symbol identifies the location of the earth grounding point on the instrument.



- xviii. This symbol identifies the connection for liquid port or socket.



- xix. This symbol identifies the connection for air port or socket.



xx. This symbol identifies the maximum air pressure of the system.



xxi. This symbol alerts the user that infectious or biological hazardous materials may be present in the instrument and the appropriate precautions must be followed before handling the contents of the instrument or disposing of waste materials.



2.2. Disclaimer Regarding Staining Results

Xmatrix® Elite Automated Slide Staining System is used for Diagnostic Use only as specified in this manual and for appropriate user-defined purposes. Any other use is prohibited.

Interpretation of any staining results from the operation of the system is solely the responsibility of the user.

2.3. Precautions Regarding Bio-hazardous Materials and Waste

DO NOT dispose off hazardous waste down the sink, sanitary sewer, a rainwater runoff or storm drain. Dispose in accordance with local, state and federal regulations. Should the waste carboy become unusable, it too must be disposed-off appropriately.

Any business or industrial facility, including research and academic laboratories, that generate hazardous waste are required to comply with EPA hazardous waste regulations that are contained in Title 40 Code of Federal Regulations (CFR) Parts 190-399. It is ultimately the responsibility of the end user of *Xmatrix® Elite* to determine whether the waste is hazardous or not.

For the purpose of the above disclaimer, *bio-hazardous waste* is broadly defined as all biologically contaminated waste that could have the potential to cause harm to humans, domestic or wild animals, or plants. Specific examples of bio-hazardous

waste include human/human tissues, blood, or fluids; cell cultures; or human/animal tissues containing infectious agents or recombinant DNA.

Federal and state laws stipulate that each individual who generates hazardous waste is personally liable and is responsible for assuring compliance with regulations and proper hazardous waste management. Please contact your Biological Safety Management Office to obtain full information on your respective procedures to ensure precautions when handling biohazard materials and all bio-hazardous waste generated on this instrument.

SECTION 3.0

ON-SITE INSTALLATION

3.1. Installation Requirements

- *Xmatrix® Elite* system is available as 115V (60Hz, 900 Watts) model and 230V (50Hz) model.
- Make sure to connect the instrument to the appropriate power source while installing or operating it.
- Check the voltage setting on the back of the internal computer inside each *Xmatrix® Elite* Staining System to confirm that the setting (115V or 230V) matches the local voltage supply.

i. Installation Personnel

A BioGenex representative or an authorized technician will install the *Xmatrix® Elite*. All required assembly and connections will be performed at the time of installation.

ii. Installation Site

The installation site must provide adequate access, ventilation, floor loading and power for the *Xmatrix® Elite*. These requirements are specified below and in other locations of this manual. If in the future it becomes necessary to move the *Xmatrix® Elite* to another location the following requirements must be considered:

- a. Locate the *Xmatrix® Elite* within three (3) feet of a suitable grounded electrical outlet.
- b. The *Xmatrix® Elite* requires a minimum clearance of 18" on either side and 6" clearance in the rear to allow adequate ventilation and access to the main System ON/OFF switch.

WARNING:



This access is important in case of an emergency to disconnect the instrument either by use of the main switch, or by the removal of the power cord either from the power inlet on the instrument or from the power supply on the wall. DO NOT place anything next to the *Xmatrix® Elite* that may obstruct access to the main switch or the power cord.

NOTE

The *Xmatrx® Elite* is not routinely turned ON and OFF by using the main power switch. The instrument and computer can be turned ON and OFF independently

etted and flexible floor is not recommended for the installation of *Xmatrx® Elite*

- d. While selecting a location, point loading must be considered. Make sure *that the floor* is even and possesses sufficient load bearing capacity. The leveling pads of the *Xmatrx® Elite* can apply a point load of approximately 55 lb/in².

3.2. Installation of Buffer Carboys to the Liquid Panel.

- There 7 carboys each, one for IHC/ISH/SS application
- The complete set of carboys consists of nine (9) Carboys(Figure 1); Two 8L carboys are used for collecting the waste generated, and seven 4L Carboys for seven (7) different solutions. The colored liquid sockets on this panel are presented in this order:

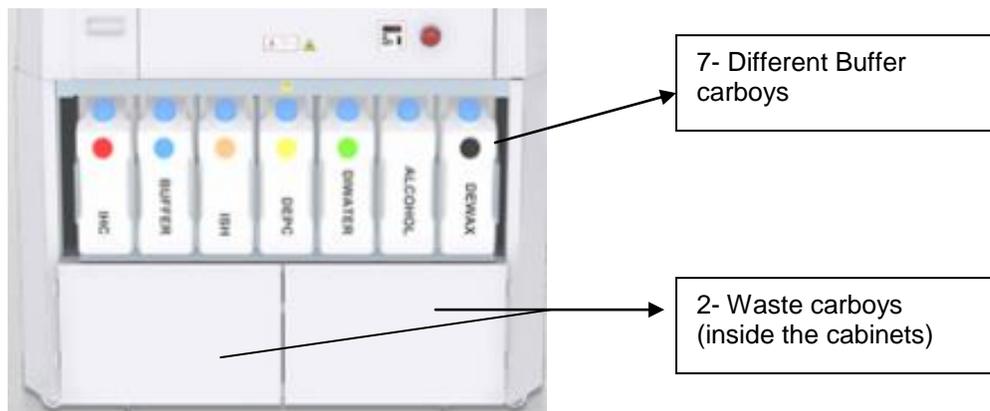


Fig: 1 Buffer carboys

The corresponding seven buffer carboys for IHC/ISH/SS are labeled as Table: 1a

	IHC/ISH/SS Bulk Carboys	Corresponding Color code for seven buffer carboys
1	IHC	Red
2	SS Buffer	Blue
3	ISH	Orange
4	DEPC	Yellow

5	DI Water	Green
6	Alcohol	Almond
7	Dewax	Black

NO

Note:

When connecting, insert the Carboy into matching color slot, push until connectors are seated firmly into manifold. Repeat the same for the remaining Carboys. Two (2) waste carboys are placed on the lower deck in the front cabinet of the cart

Before attaching the buffer carboys,

- Make sure the carboys are secured tightly but at the same time not overly tightened. Over tightening may result in cracking of the caps.
- The list of carboys for IHC/ISH/SS are listed in the **Table 1a**.
- There are seven (7) pairs of sockets on the Liquid Panel. Each pair consists of a white connector for air tubing and for liquid tubing connection (**Fig. 1**).
- When connecting carboy to liquid panel, be sure to match the color of a carboy in the respective cabinet. Please connect the carboys as described in **Table 1a**.
- Ensure that the System shall map the buffer volume requirement prior to the run and alerts the user to fill with the required quantity

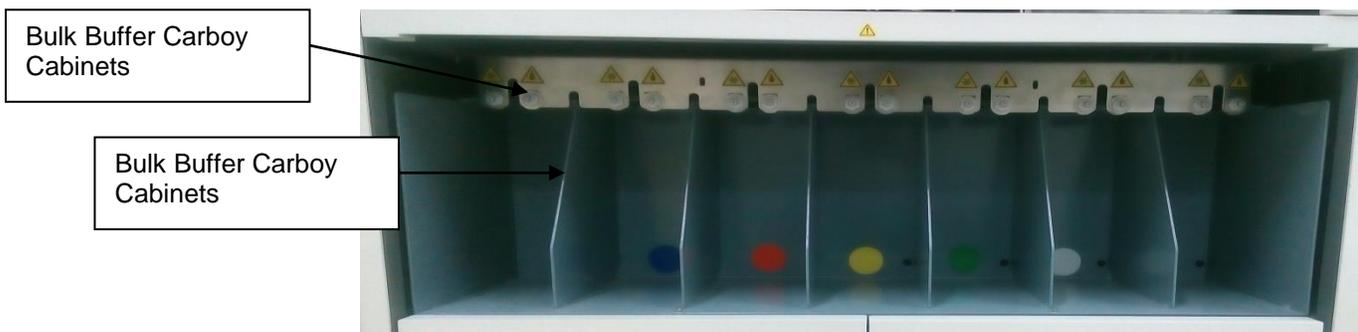


Fig. 2: "Liquid Panel" of the Workstation

To install Carboys:

1. To insert a carboy, push the carboy into a position until it locked into the connectors (**Fig.2**).
2. Insert carboys according to the color labels by pushing carboy into the appropriate position. (**Fig.2**).



CarboyCap

Color-Coded Label

3. Ensure the pressure returns to 5.5Psi on the pressure display

4. To release carboys for filling or cleaning, press the two knobs together at a time to release the carboy from the connectors (**Fig.4**).

5. Once the lock is released, the pressure will also come down and the carboy can be removed.

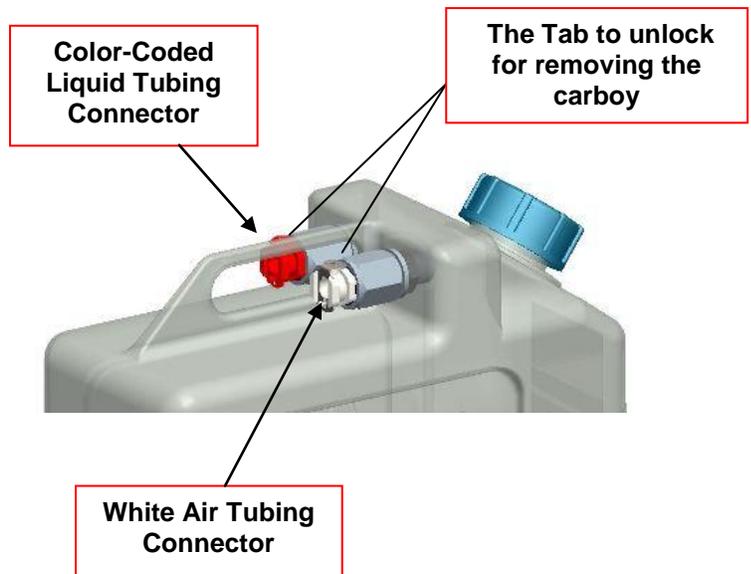


Fig 3: Color coded Buffer Carboy

Fig: 4: The Tab to release carboy

NOTE: When connecting, insert the Carboy into matching color cabinet, push until connectors are seated firmly into manifold. Repeat the same for the remaining Carboys. Two (2) waste carboys are placed on the lower deck in the front cabinet of the cart

3.3 Waste Carboy Connection

Install the Waste Carboys by attaching the volume sensors (Fig: 5) and waste tubing.

When the waste tubing is connected to the waste carboy, make sure that the Connector snaps into the matching connector on the waste carboy. Failure to do so may result in the waste backup in the tubing and may cause flooding of the instrument platform.

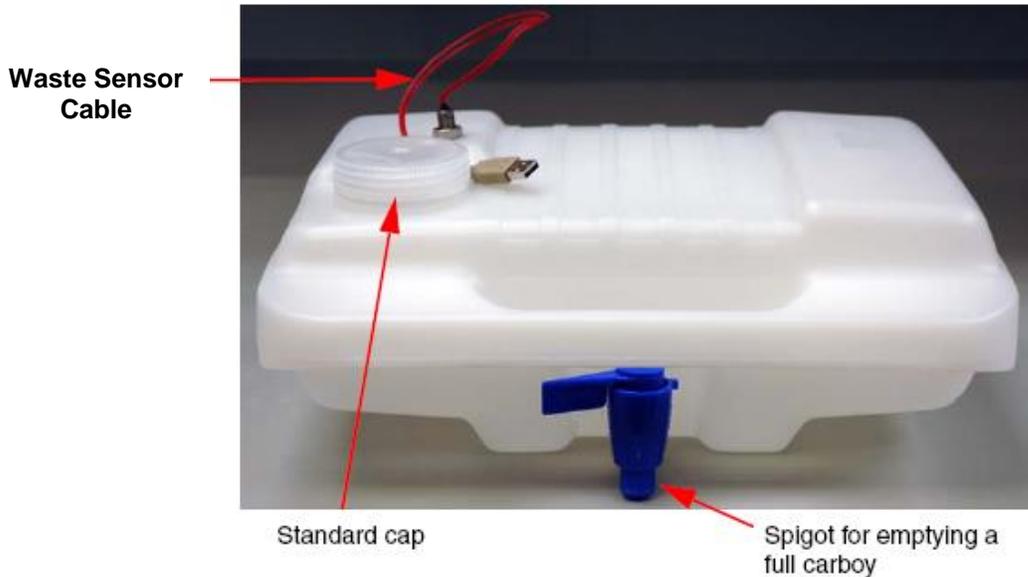


Fig:5 Waste Carboy with waste sensor cable

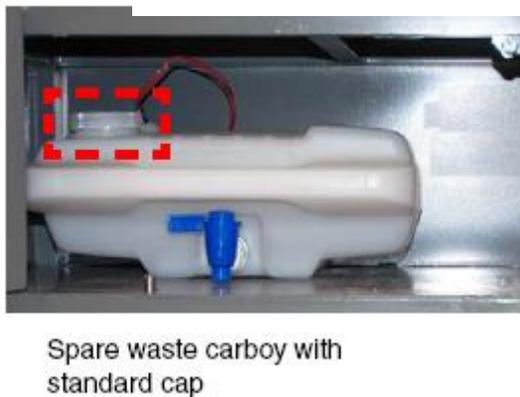
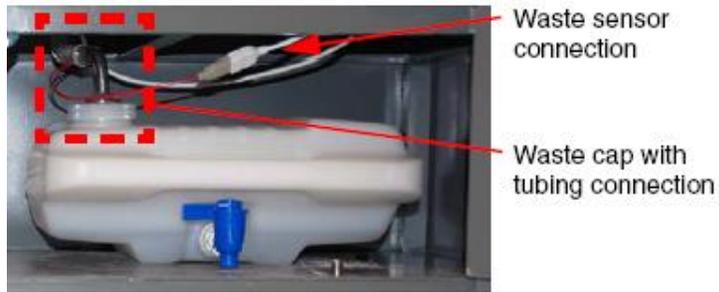


Fig. 6: Waste Carboys



Fig. 7: Volume Sensor



In-use waste carboy

Fig. 8: Volume Sensor

3.4 Glossary

Term	Definition/Description
Bulk Bottles	Carboy for containing special liquids such as buffer and DI water. A complete set of carboys for one (1) workstation consists of seven (7) carboys.
Coverslip Mechanism	A combination of the Coverslip (CS) stack and the Coverslip tray. The box is the CS stack, and the tray holds the boxes in place. There are six (6) CS stack in three (3) pairs of different sizes (18x18, 25x25, 25x40 mm) in a workstation.
Automated on-board DAB working solution preparation (optional)	Auto DAB function enables on-board mixing of DAB Chromogen and Buffer. Before starting the actual run, system calculates required quantity as per the number of slides selected to be processed.
Fixture bottles for ISH Probes	Specifically for ISH Probes use: 2ml graduated probe vial is inserted into 17ml vial Fixture bottle part No: 4911-02826.
E-Stop Button	Emergency stop button, located onto the front side of the <i>Xmatrix® Elite</i> workstation.
Gantry	Moving mechanical stand to which the robotic arm is attached and moves back and forth over the working platform.
Housing & Cabinet	Metal hood that encloses the entire <i>Xmatrix® Elite</i> workstation and its accessories. The entire workstation sits on top of the cabinet. All buffer carboys and waste carboys fit in the cabinet. The

	cabinet can be moved around on wheels, which lock into position once the unit position is fixed.
Large Pipette Tip Tray	Blue removable tray with 96 slots for a total of 96. BioGenex supplied blue 1ml pipette tips
Small pipette tip tray	Removable small pipette tip racks with 96 slots.
Liquid Panel	Connection panel visible on the front side of the cabinet. The Liquid Panel is loaded with seven (7) connection sockets for connecting buffer carboys to the workstation.
Oil Bottle	A plastic oil container mounted on the Z-head with level detection capability
Oil Pen (Oil Needle)	Slender syringe attached to the lower end of the robotic arm. The Oil Pen applies oil around the slide barrier. The size of the region bounded by oil is determined by the choice of cover slip size.
Pipette Adapter	Pipette tip adapter on the Z-Head is used to pick up, transport and discard a pipette tip.
Pipette Well	Vertical opening, surrounded by four (4) walls, at the front left part of the work base. A Waste Pipette tip tray should be placed under the Pipette Well for receiving the used pipette tip(s) discarded by the Z-Head.
Pressure Gauge	Displays the present air pressure and vacuum pressure in the workstation. The gauge is located at the right end of the Liquid Panel.

SECTION 4.0

STARTING THE SYSTEM

4.1. Loading Consumables

Step	What to load?	Where to load?	How to load?	Precautions
4.1.1	<p>Slide(s) with specimen . Up to <u>40 Slides</u> may be loaded in a single run.</p>	<p><u>Slide Holders</u> in the 4 Slide Carriers in the Slide Block</p>	<p>a) Lift the latch of the 'Slide Holder'.</p> <p>b) Tilt up the open end of the frame of the 'Slide Holder' with your fingers.</p> <p>c) Insert a Slide into the groove of the 'Slide Holder'. Be sure to place the frosted end of the slide upwards.</p> <p>d) Press the frame into place, and push the lock button forward to lock slide.</p> <p>e) Repeat the above steps to load other slides into the Slide Carrier(s) as needed.</p> <p>NOTE: Alternatively the slides may be loaded by:</p> <ol style="list-style-type: none"> 1. Removing the 'Slide Carrier(s)' from Slide Block 2. Loading slide(s) 3. Placing the 'Slide Carrier(s)' back into the Slide Block 4. Turn holder tabs on system to secure 'Slide Carrier(s)' 	<p>Make sure the marked end, i.e., the end with the word "BioGenex", of the slide is placed toward the rear of the workstation when you load a slide into the Slide Holder.</p> <p>Ensure slide is loaded sample side up.</p>

4.1.2	Coverslip(s)	Up to 6 Coverslip stacks for various Coverslip sizes at the back left corner of the workstation	<ol style="list-style-type: none"> 1. Cover-slip stacks are loaded with coverslips by pressing the white Coverslip feeder down which is spring and load the coverslips.(Fig: A) 2. The Loaded Cover-slip stacks are placed on respective grooves. Magnetic latches hold the coverslip rack in place.(Fig:B) 	<p>The Coverslip(s) should be stacked and loaded in the appropriate tray.</p> <p>Ensure open ends are to the front and back of system, not to the sides.</p>
4.1.3	Reagent	For IHC/ISH/SS up to 49 Reagent Vials can be loaded into the 'Reagent Tray'.	<p>Place vials, one by one into the 'Reagent Tray' without removing the tray from the workstation.</p> <p>DAB Mixing Vial must be placed with other reagent vials for Auto DAB function to take place.</p> <p>NOTE: Always place the top opening of every vial toward the left wall of the 'Reagent Tray'.</p> <p>NOTE: Alternatively the 'Reagent Tray' can be loaded by:</p> <ol style="list-style-type: none"> 1. Pulling up the 'Reagent Tray' from its seat in the workstation 2. Placing the vials into the 'Reagent Tray' 3. Returning the tray to its seat in the workstation 	Use only BioGenex reagent vials. Incorrect vials could result in fluid detection errors.

4.1.4	Pipette Tips of different volumes (1 ml & 200 µl)	<p>. Four trays</p> <ul style="list-style-type: none"> • two trays of 96 1-mL tips • two trays of 96 200-µL tips 	<p>a) Pull up the blue Large Pipette tip tray by grasping its two flaps. Remove it from the workstation.</p> <p>b) Fill in or replace with new box of blue pipette tips (1 ml/each tip).</p> <p>c) Place the large pipette tip tray back and press it down firmly into its position in the workstation.</p> <p>d) Repeat above three steps to load the second large pipette tip tray.</p> <p>e) Remove the small pipette tip racks from the workstation.</p> <p>f) Insert a full 200 µL pipette tip tray into each rack.</p> <p>g) Return each rack to its position on the workstation.</p> <p>h) Repeat above three steps to load the second Small pipette tip tray.</p>	Use only BioGenex supplied pipette tips. Other pipette tips may cause malfunction of the workstation.
4.1.5	Mineral Oil	Mineral Oil Reservoir on robotic head	Call BioGenex Customer Support to fill oil bottle.	



Fig: A Coverslips Loading

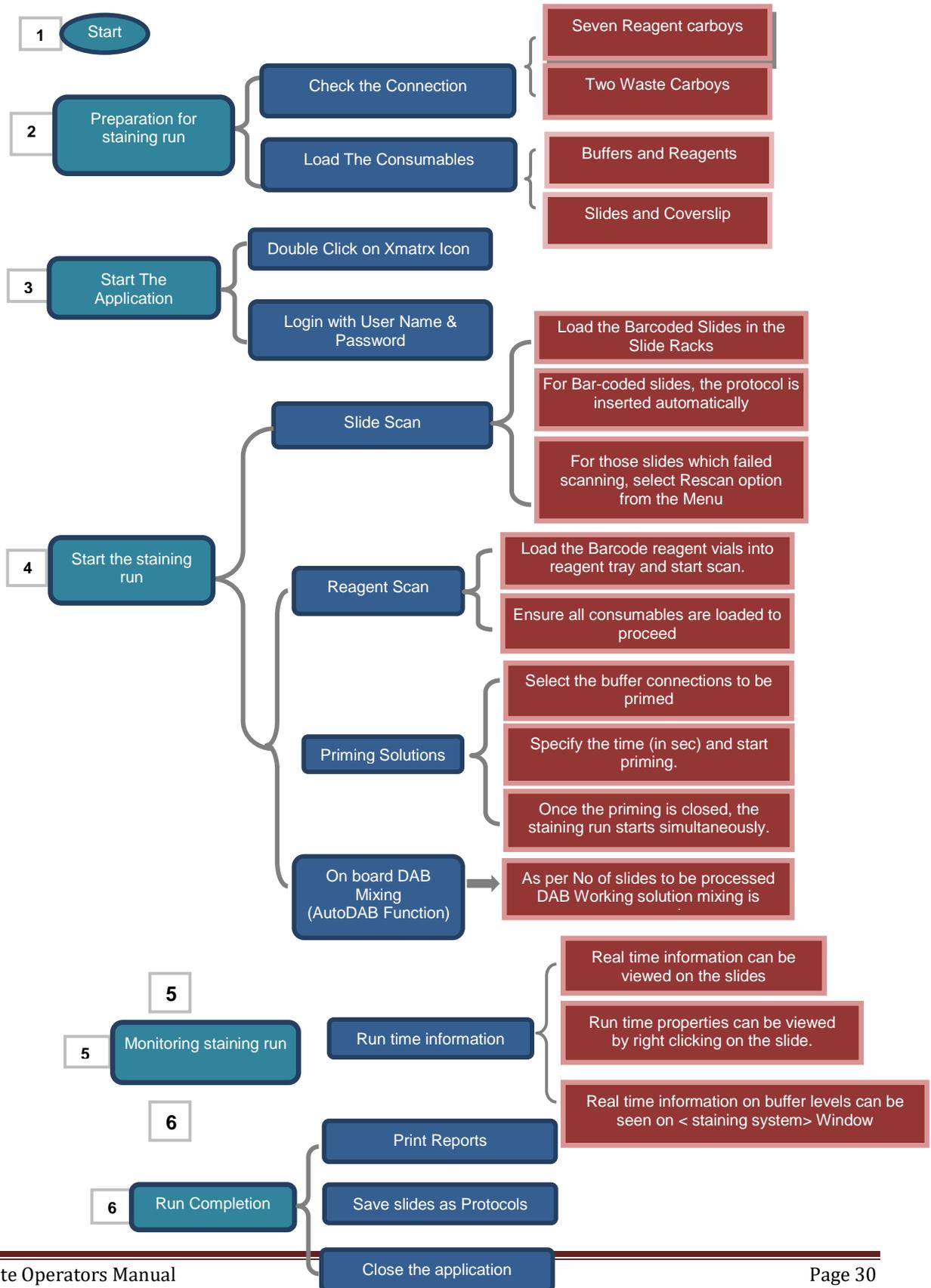


Fig: B Coverslip stack placing in to respective grooves



Figure: 9 Working Plat Form

4.2. EXECUTING A RUN FLOW CHART



4.3. LOGON on to XMATRIX Elite Application

1. Power ON the instrument and computer. At the <Log on to Windows> screen, <Biogenex> will automatically be selected. Enter the password “**optimax**” to access the desktop.
2. Double-click the <Xmatrix> icon on the desktop.



3. Enter the User ID and Password in the “Log on” window. There is no password for the Administrator account by default. A password can be set later for this account (Refer to ‘**Maintaining User Profiles**’ in Section 5).

Auto DAB and Continuous/status optional features and If this features is required, click on Enable Auto DAB and Enable Cont/STAT in the “Log on” window



Fig. 10“Log on “window

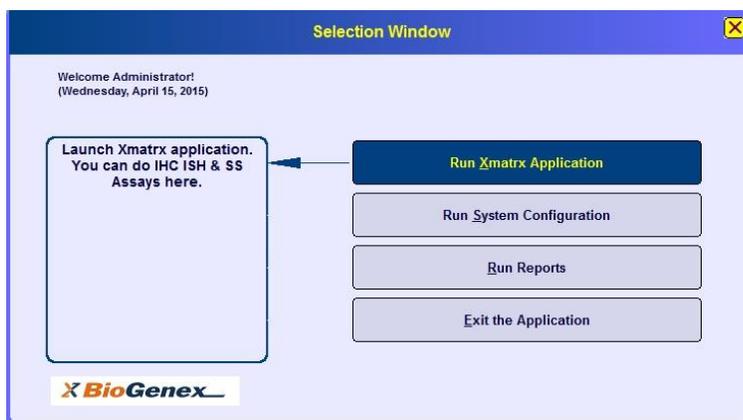


Fig 11: Selection Window

4. Selection **Window** offers four options. Click on the **<Run Xmatrx Application>** option to open the **<Xmatrx staining system>** window.
5. Elite Diagnostic system having multiple assay selection IHC, ISH and SS assays by bar code reader (for inserting the protocol refer section 6.5)

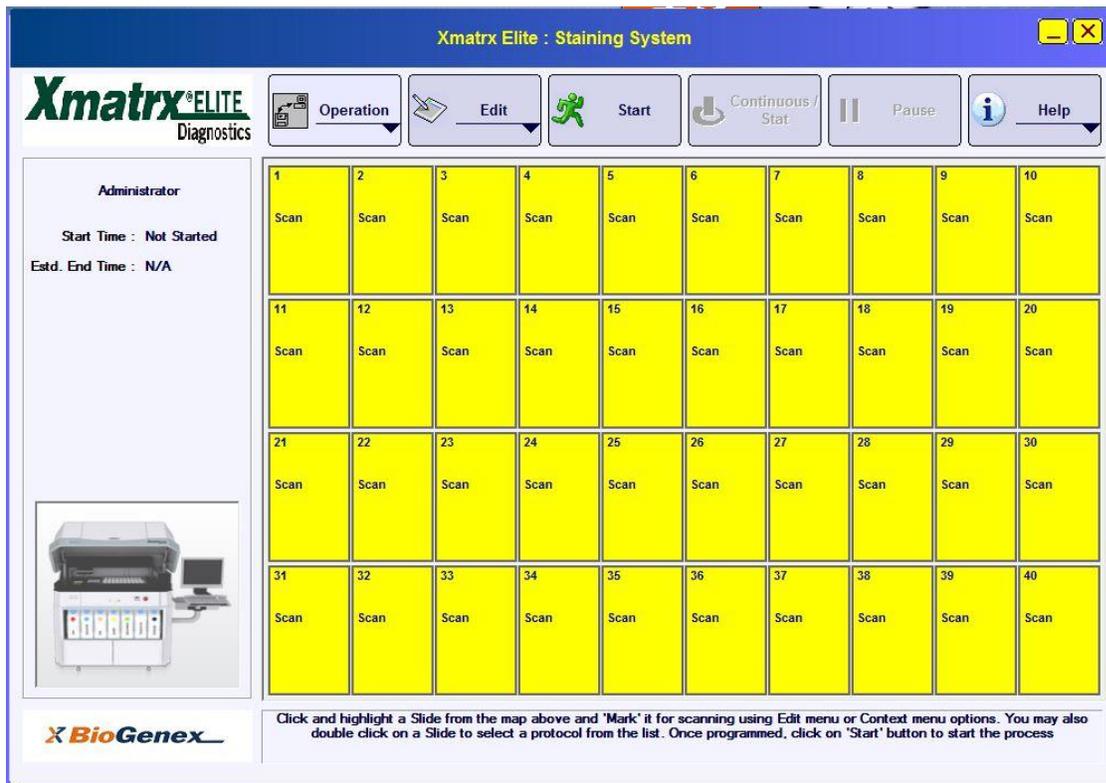


Figure 12 <Xmatrx: Staining System> window

- *Make sure the slides are loaded onto the slide platform.*
- *Make sure the necessary reagent vials are placed on the reagent rack along with DAB Mixing Vial.*

Section 5.0

CONFIGURATION SETTINGS

To manage a run and accurately collect information about the run, a series of configuration settings must be set by the *Administrator* prior to executing the staining run. There are four (4) items within the configuration module (common for any run), which will be explained in this section.

5.1 Maintaining User Profiles

When the *Xmatrix® Elite* system is started for the first time, an authorized *Administrator* will be the only person who can access the software and operate the system. Any other user, who expects to operate the system, must have his/her profile added into the system beforehand by the authorized *Administrator* via the **<User Manager>** window

1. Select **<Run System Configuration>** from the Xmatrix® Elite **<Selection Window>** (Figure 11)
2. The **<Xmatrix System Configuration & Calibration>** window appears (Fig: 13).



Figure 13: XMATRIX SYSTEM CONFIGURATION & CALIBRATION WINDOW

3. To access the **<User Manager>** window, click on the **<Configuration>** bar and select **<User Manager>** from the drop-down menu.
4. The **<User Manager>** window will appear (Fig: 14Error! Reference source not found.).
5. In the **<User Manager>** window, the *Administrator* can create, modify, or delete a user profile. Related items are User ID, Password, and desired language. The *Administrator* may also limit the protocol type(s) for a user account.



NOTE:
The password may also be changed by using the drop-down menu from the **<Edit>** bar in the **<Xmatrx: Staining System>** window.

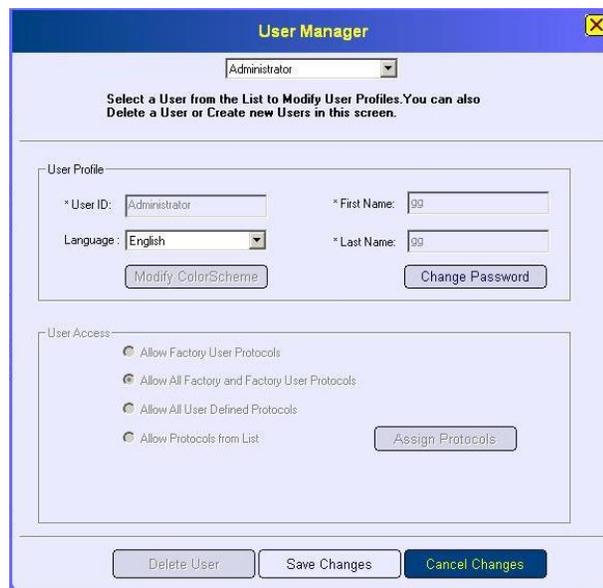


Figure 14:User Manager

- i. Select the **<Change Password>** option from the **<Edit>** drop-down menu.
- ii. The **<Change Password>** box appears



<Change Password> box and changes may be made.(Fig:15)



SECTION 6.0

BUILDING AND INSERTING PROTOCOLS

6.1. Protocols - IHC (One Step & Two Steps)/ISH/SS. Protocol Types

There are three types of protocols available in any staining run.

Factory Protocol	Factory defined and can only be partially modified directly by the user. Such protocols can be saved as Factory-User Protocol.
Factory-User Protocol	Derived protocol by editing a Factory Protocol. Factory-User Protocol is partially editable, and can be reverted to the original Factory Protocol in an editor window. These protocols can only be created and reverted by the <i>Administrator</i> .
User-Defined Protocol	A template, meant for using 3 rd party antibodies with Empty BARCODE tagged Vials, wherein user can modify volume of antigen retrieval and antibody solution, temperature, incubation time, wash type and number of washes.

6.2. Default Slide Pattern

IHC (One Step & Two Step Protocols)	25 x 40 mm
Special Stain Protocols	25 x 40 mm
Double stains	25 x 40 mm
ISH Protocols	25 x 25 mm

6.3. Staining Steps

On the *Xmatrix® Elite* system, any staining protocol is a combination of part or all of the following basic staining steps:

Blow	Blows a jet of air over the slide to remove the liquid from the slide.
Incubate	Allows the reagent to stay on the target slide(s) for a specified period of time.
Buffer Slide	Allows buffer to be dispensed onto the particular slide(s) as per the applied protocol.

Apply Oil	Applies oil onto the specified slide and seals the four (4) edge lines of a Coverslip on the slide.
Apply Coverslip	Delivers a Coverslip onto a slide position in the Slide Block.
Remove Coverslip	Removes a Coverslip from the target slide and discards the used Coverslip.
Heat	Heats up or cools down a slide to the temperature level pre-set in the applied protocol, and maintains the slide at the designated temperature for a specified time.
Repeat	Demands repetition of an existing step or an operation. When this step is present or added, all the other preceding steps listed above within the same operation block in a protocol/slide editor window will be repeated by the specified number of cycles.
Apply Reagent	Uses a 1000 µl pipette tip to apply reagent in volume of 100-850 µl to a target slide.
Apply Micro reagent	Uses a 200 µl pipette tip to apply probe in volume of 10-80 µl to a target slide.

Combination of staining steps is referred to as *Operations* in the *Xmatrx® Elite* system. Combination of different operations can be used to construct a protocol. An Operation can include only one (1) of the following steps:

- Apply Reagent
- Apply Micro reagent

The *Xmatrx® Elite* system will not allow Coverslip for any operation that contains an “Apply Reagent” step.

6.4. Building Protocols

Since its in the closed mode, the user will not be able to create any new protocols. However the **FACTORY** Protocols can be edited to a limited extent, which can then be saved as **FACTORY_USER** Protocols.

6.5. Inserting a Protocol

1. Ensure that bar-coded slides are loaded onto the slide racks.

Note:

1. Ensure that the correct bar-code is used IHC bar-code should not be used for ISH assay and vice versa. Also either One Step or Two step protocol to be used is determined on the Barcode itself. Suffix S on the barcode represents selection of One step Protocols.
2. Selection of multiple protocols can be limited to 5 different protocols of ISH & SS each (irrespective of number of slides selected) and number of protocols for IHC assay shall be determined according to the number of available reagent vial positions.
3. Software shall alert the user by providing pop-up window when the multiple protocol selection could not accommodate the number of vial positions
4. To insert User defined protocols also, User needs to give specific Barcode to the slide, same no. of which can be used to edit protocol from database.

- a. All slide positions are selected by default (Figure 19) after scanning is done protocol on the Barcode is recognized and marked on the respective slide position or
- b. To select the slide, click on the corresponding position on the slide map. Multiple slide positions can be selected by holding the **shift key** in the keyboard and click on the corresponding positions. The selected slide position is highlighted in yellow.

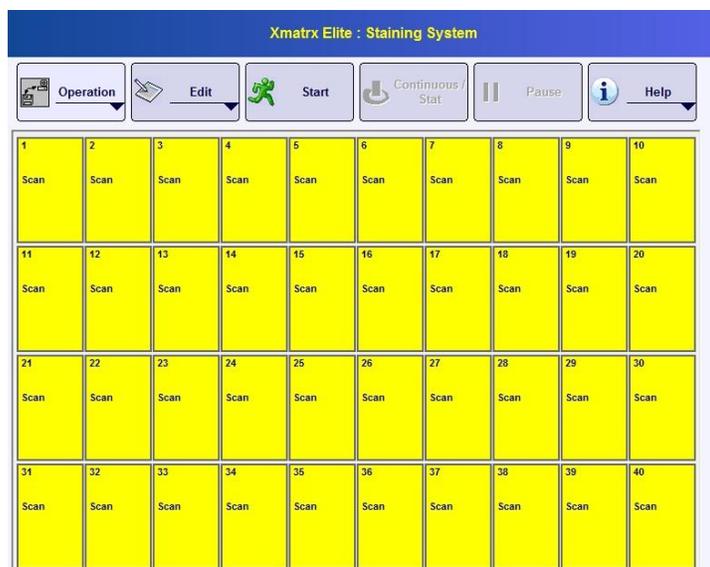


Figure 19: Default Selection of slide Positions for scanning

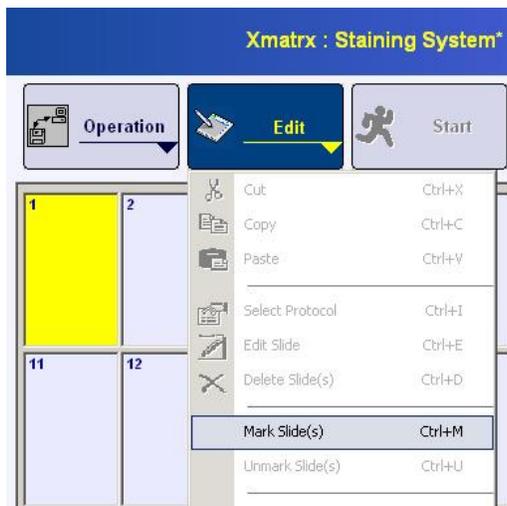


Fig. 20a: Mark slide using the **Edit** tab

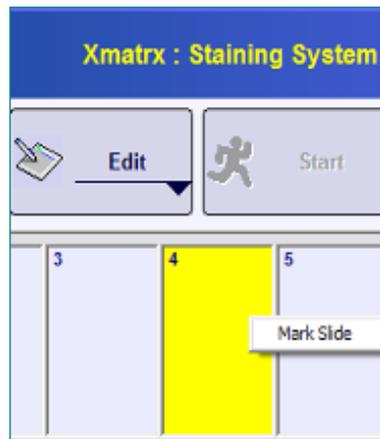


Fig. 20b: Mark slide using **Mouse** (Right Click) on target Slides

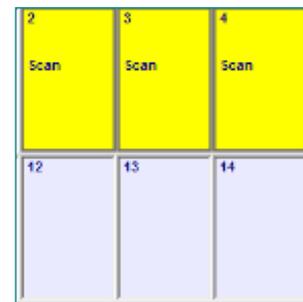


Fig. 20c: Marked Slides

2. After selecting/marking the slides for scan, Click on Start. The system will start scanning the slides.
3. Improper pasting or damaged labels can cause an **Error** while scanning the slides. Wait for the **<Rescan Options>** window to open (Figure 21). The user can select an appropriate option from the following:
 - a. Rescan the slides that were not successfully scanned.
 - b. Start the run with currently scanned slides. Discard the un-successful ones from this run.
 - c. Cancel the Run.

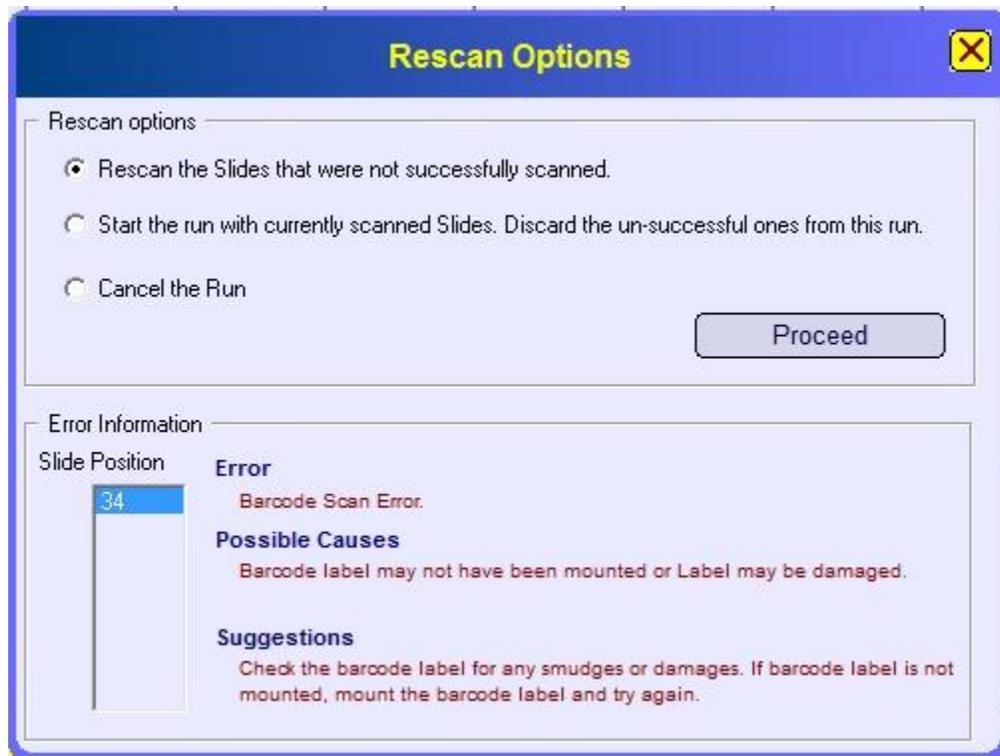


Figure 21 :< Rescan Options> window

4. Click on '**Proceed**' button.
5. Once scanning is completed window will appear and Protocols are assigned as per barcodes to each slide.
6. To edit the protocols selected automatically, go to '**Edit**' menu or '**Right Click**' on the target slide. From the drop down list, go to '**Select Protocol**' to open the **<Edit Protocol>**window.



NOTE:

- A. The antibody protocols currently listed in the software are provided as a reference for use with BioGenex primary antibodies, probes and detection reagents only, and are subject to change. Please consult the appropriate BioGenex product inserts for the most current information before setting up a staining run.
- B. Refer to section 7 for the button functions in Insert protocol window.

6.6. Editing Protocols

Factory Protocols can be edited to Factory-User Protocols from Protocol database, before scanning the slide; and only by *Administrator*.

- i. From the “**Edit**” menu in the “**Xmatrix: Staining System**” window select **Edit Protocol Database** from the drop down menu (Figure 22: <Edit protocol database>) <**Edit Protocols**> window opens
- ii. Select any **FACTORY** Protocol of interest from the list available and **Click on <Edit>**

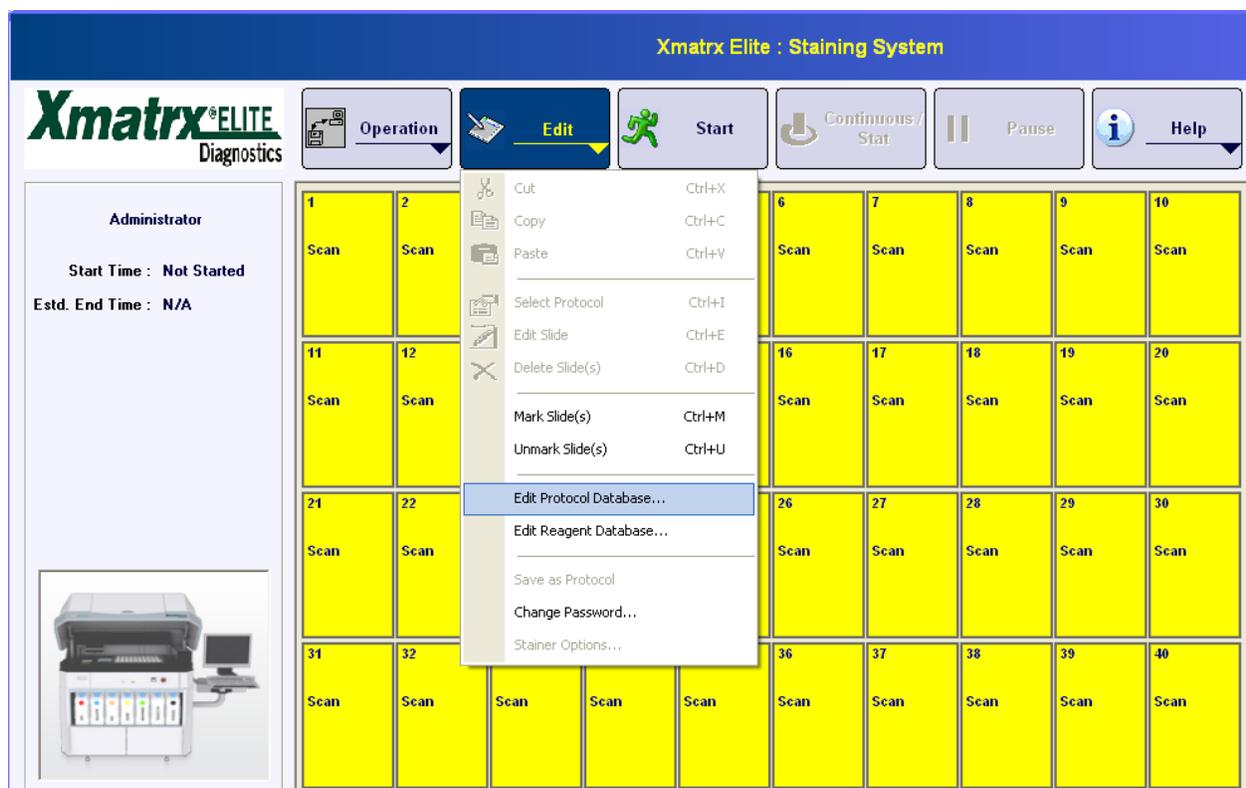


Figure 22: <Edit protocol database>

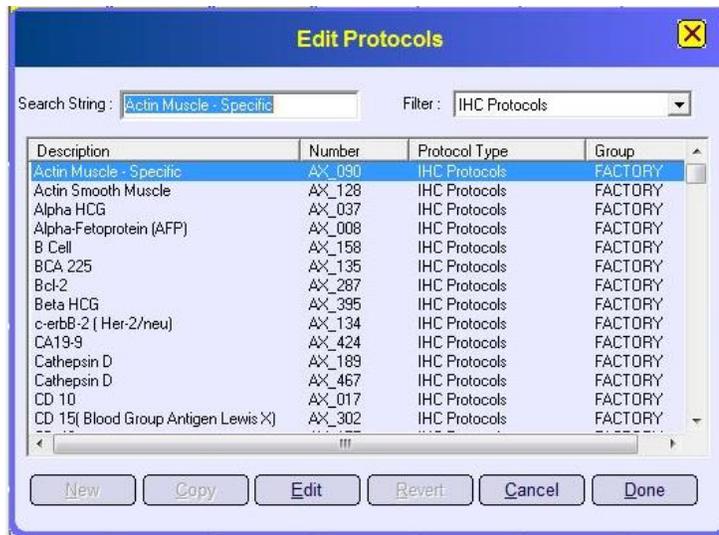


Figure 23: Edit Protocols

iii. A warning will be displayed stating the following: <Editing a FACTORY protocol will result in a FACTORY- USER protocol. Do you wish to continue?>

iv.

v.

vi. **Figure 24).** Select <Yes> to create a Factory-User Protocol.



Figure 24:Xmatrx Application Warning

vii. The <Protocol Editor> screen is .For instructions on using the <Protocol Editor> window, refer to **Section 7: Using Protocol/Slide Editor Windows.**

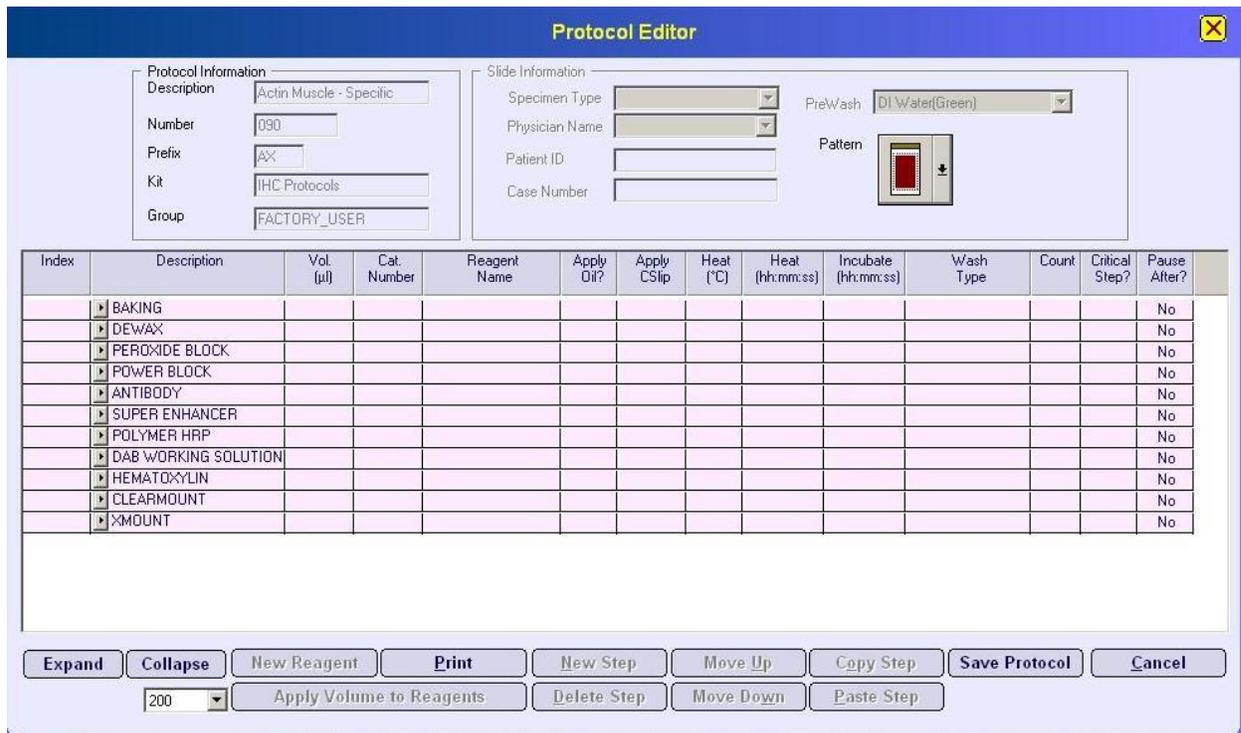


Figure25: <Protocol Editor> Window

6.6.1. Edit Protocol for a single slide:

Once a protocol has been assigned to a slide, the user has the option to edit the protocol before starting the actual run. The changes are applicable only to the current run and the slide(s) selected. This option helps in standardizing various parameters in a single run. After scanning is completed successfully, a <Select Operation> window will appear (Figure 26)



Figure 26: <Select Operation> Window after completing Scanning Successfully

- i. Select option (Figure 27) to edit the protocol.

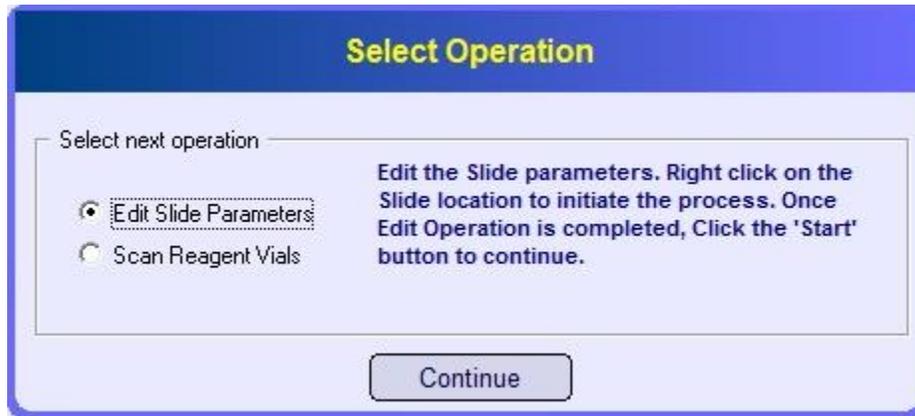


Figure 27: <Edit Slide Parameter> option on Slide operation Window

- ii. Go to a target slide and go to 'Edit' menu or 'Right Click' on the slide (Figure 28)



Figure 28: Edit single Slide: <Edit> Option or <Edit slide > option

- iii. Select 'Edit Slide' from the drop down menu to open the <Slide Editor> window (Figure 29).

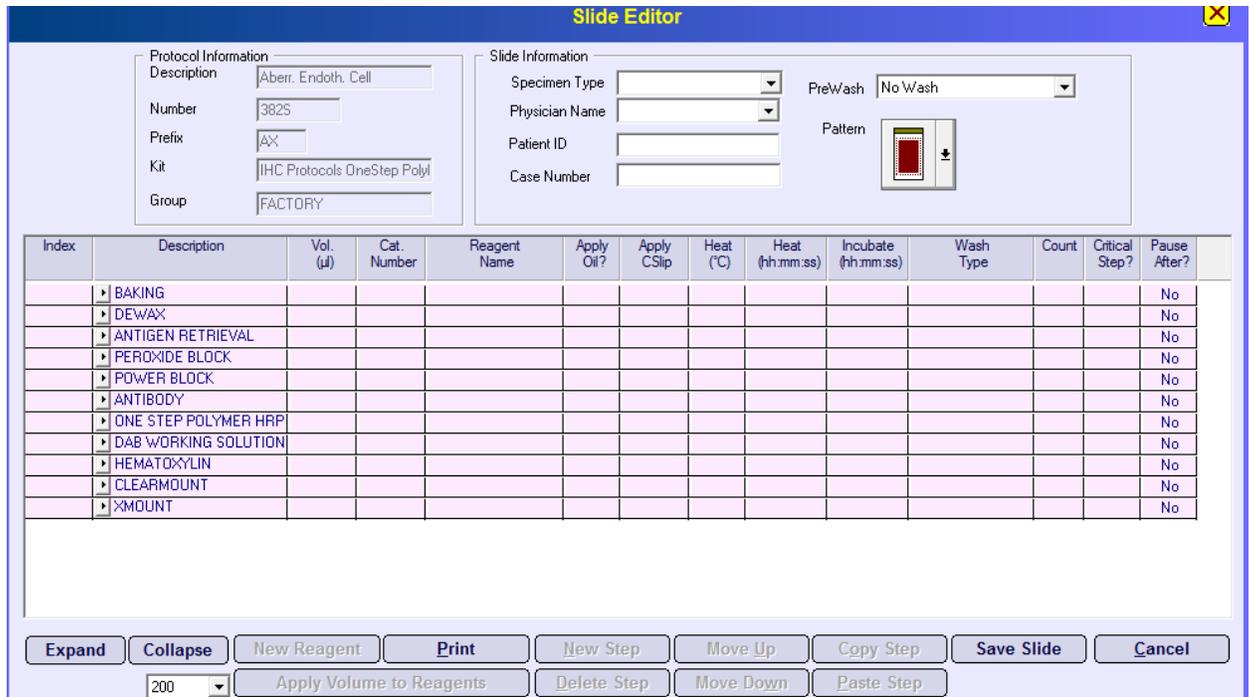


Figure 29: <Slide Editor> Window

- iv. Make the appropriate changes and click **'Save Slide'** button to apply in the current run.

6.6.2 Editing User Defined Protocols

This feature allows User to use third party antibody on Xmatrix EliteInstrument.

- i. From the **"Edit"** menu in the **"Xmatrix: Staining System"** window select **Edit Protocol Database** from the drop down menu **Figure 22: <Edit protocol database> <Edit Protocols>** window opens
- ii. On the upper right hand side there is dropdown list, from which User can select the desired protocol he wish to add to the particular slide

Figure 30)

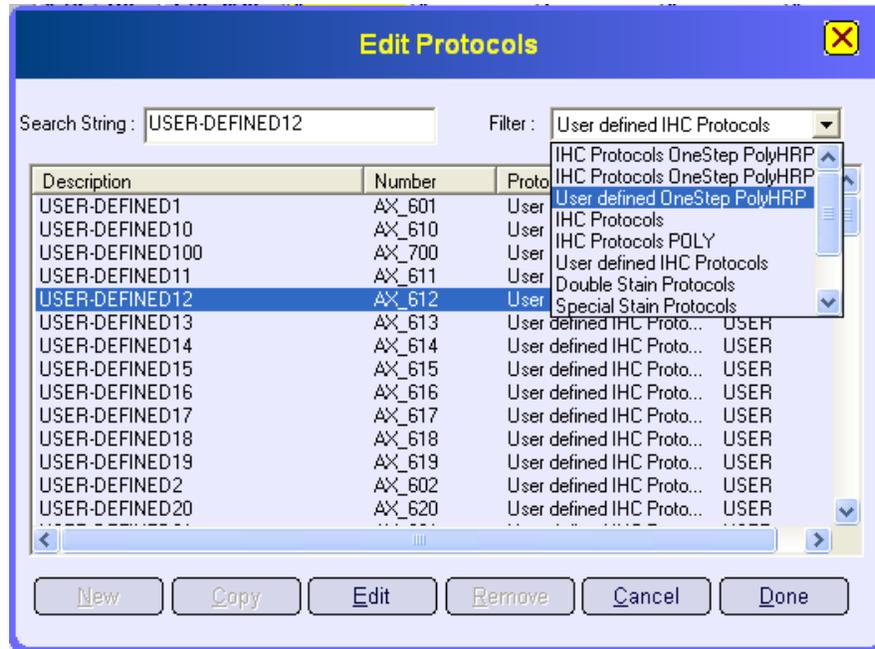
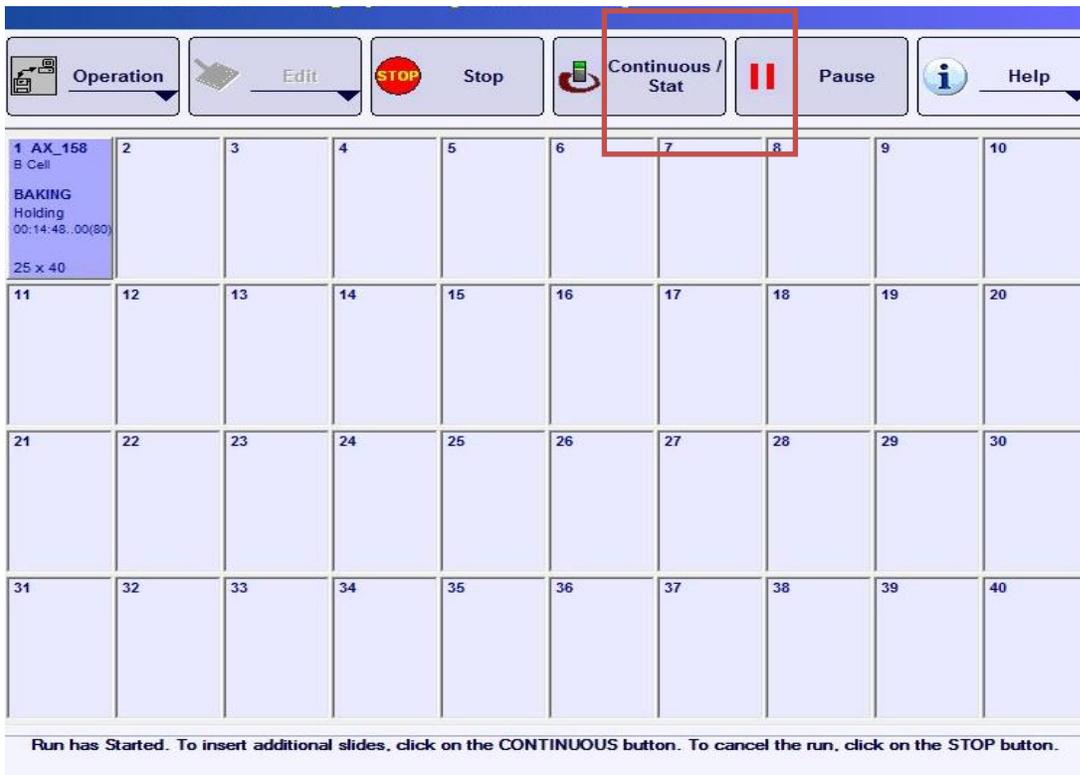


Figure 30: Dropdown list to select User defined Vial option with Choice of Protocols to be used

- i. Once desired protocol is selected, User will be directed to the **<Protocol Editor>** window or User can click on **<Edit>** to go to the **<Protocol Editor>** window .For instructions on using the **<Protocol Editor>** window refer to **Section 7: Using Protocol/Slide Editor Windows.**
- ii. Or once the slide is scanned and a user defined protocol is assigned to the slide, single slide can be edited as mentioned in Section 6.6.1 Step ii to step iv.
- iii. User defined protocol description can be changed; and the edited description will be saved and will be used for further reference of the edited protocol with the saved name.

6.7.0 Adding Slides after a Run Has Begun through Continuous / Stat Mode

Once the system has started processing a run, it is possible to insert more slides if needed (and if positions are available on the slide deck) using the <Continuous/stat> function button (Figure 31). (Note: This button will be in disable mode if you have not click on Enable Cont/Stat button in Log in window (Figure 3110)).



Figure

31 <Continuous / stat> button



IMPORTANT: If it is known before the run that this function is likely to be used during the run, the operator should load the reagent carboys to their full capacity, and prime the carboys that are expected to be used prior to starting the run

6.7.1 Inserting slides to the Run through Continuous Mode

To use this function:

- Select the <Continuous / stat > button at the top of the <Xmatrx: Staining System > window (Figure 31)
- By Default, Insert Continuous Slides is Checked. Inserting Continuous Slides Option process the slides with Normal Priority

- iii. The system will pause to allow insertion of new slides once the current operation has completed. This might take some time depending on the step that is being processed when the **<Continuous>** function was selected.

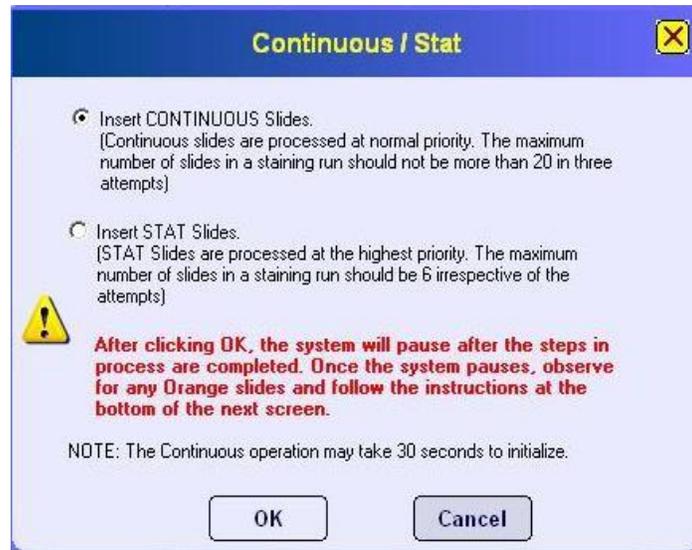


Figure 32: Continuous prompt

- iv. Read the instructions on the prompt that follows and then select **<OK>**.

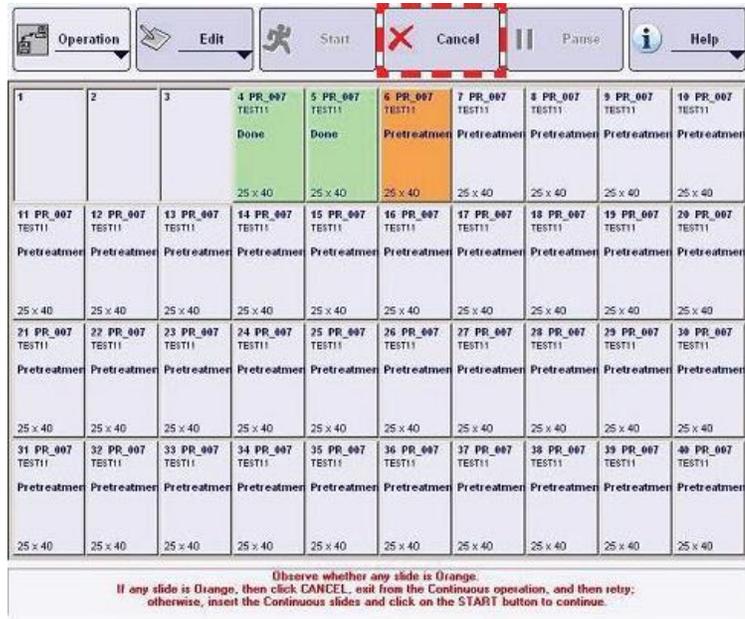


NOTE:

1. The Maximum Number of slides in a staining run should not be more than 20 in Numbers and in two attempts only. Since, the Reagent vial positions may not be sufficient.
2. Three attempt can be done when the assay is with SS assay alone.
3. Continuous Option Operation may take 30 seconds to Initiate.

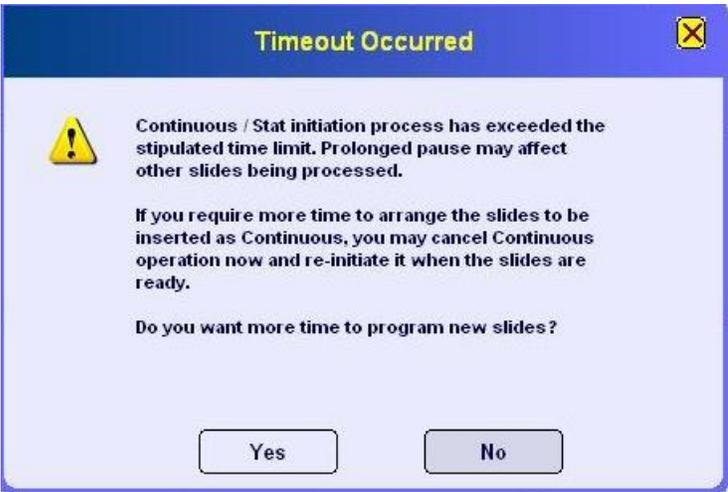


CAUTION: After the system pauses, look at the slide map. If any slide is ORANGE (processing) do not proceed! Select the **<Cancel>** button at the top of the **<Xmatrx: Staining System>** window, and then **<Yes>** to confirm the cancellation on the prompt that follows.



NOTE:
After cancelling, the operator can retry the <Continuous> option immediately.

- v. Once the system has paused, and the operator has verified that no current slides on the slide map are ORANGE, the lid lock will be released to open the lid and the new slide(s) may be positioned on the slide deck.
NOTE: A <Timeout Occurred> message will appear if <Start> is not selected within 60 seconds.



- vi. Selecting <Yes> on the prompt will allow the operator to continue setting up the new slide(s);
- vii. However, processing of the existing slides will be delayed until <Start> is selected.

-
- viii. Return to the on-screen slide map and right-click on a new slide position to open the **<Edit Protocol>** window.

NOTE: Multiple slides can be highlighted by using the following Windows options:

1. Highlight the first slide in a string, hold the <Shift> key, and click the mouse on the last slide in the string.
2. Highlight a slide, hold the <Ctrl> key, and click the mouse on any other slides desired.

- ix. On the **<Insert Protocol>** window, click on the **<Filter>** drop-down menu and select **<Show all Protocols>**.
- x. Highlight a protocol on the displayed list if one is acceptable for the current run. At this stage, the user also has the **<Edit>** to modify an existing protocol as Factory _ user Protocol screen will Pop up. to create Click **< yes>**.



IMPORTANT:

Keep in mind that processing of the existing slides will be delayed until <Start> is selected for the new slide(s).

- xi. When the desired protocol is highlighted, click **<Select>**.
- xii. If the protocol is acceptable, proceed to 'Step xv' below.
- xiii. If the protocol needs to be edited, open the **<Slide Editor>** by double-clicking on a single slide. Refer to Working in the Editor Windows on page 48 for instructions on making and saving edits.
- xiv. Verify the slide positions match the slide map and the protocol names and that the correct protocol is chosen for each new slide.
- xv. Select **<Start>**. The **<Reagent Map>** window will appear. The reagent Map may show that it requires extra reagents to load like Antibody, Reagents and DAB - (DAB buffer/DAB Chromogen/DAB Mixture vial Refer (Fig: 33) to be added, if the kept reagents are not sufficient to start the Continuous run.
- xvi. Follow all on-screen instructions and load all required reagents as directed.

- xvii. Click the '**Scan**' button to start the reagent scanning.
- xviii. After Scan, click **<proceed>** the following dialog will appear showing the required volume configurations of wash buffers. If the required volume of wash buffer is needed for the run, the operator should load the bulk reagent carboys to their full capacity.
- xix. Ensure the System pressure to 5.5 psi, when the bulk buffer carboy are removed from the liquid panel in Continuous /STAT mode.

6.7.2 Inserting slides to the Run through STAT Mode

To use this function:

- I. Select the **<Continuous / stat >** button at the top of the **<Xmatrx: Staining System >** window (Figure 31).
- II. Enable the Insert STAT slides Option and Click **<OK>**.

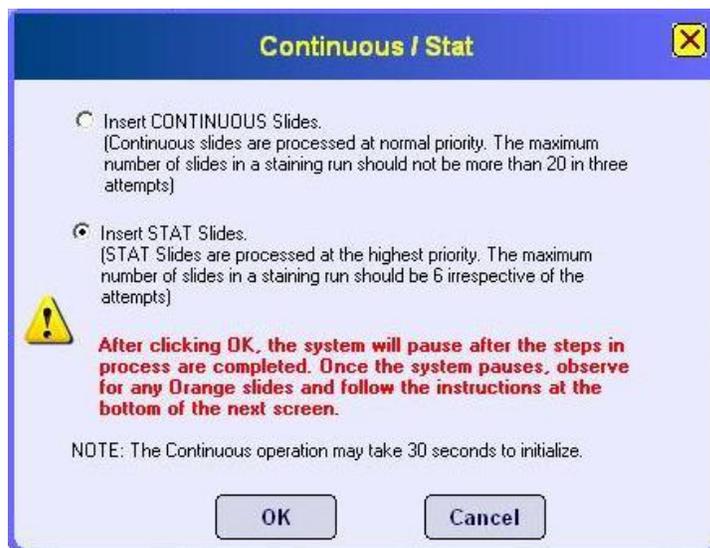


FIGURE 33: CONTINUOUS / STAT OPTION WINDOW

- III. Insert the slides on to the Available positions in Slide Deck. and click **<Start>**.
- IV. The system will pause to allow insertion of new slides once the current operation has completed. This might take some time depending on the step that is being processed when the **<STAT>** function was selected.
- V. Once the system has paused, and the operator has verified that no current slides on the slide map are ORANGE in color, the hood will be disabled to open, and the new slide(s) shall be positioned on the slide deck.



NOTE:

- a. STAT slides are Processed at the highest priority.
- b. STAT Option Operation may take 30 seconds to Initiate.
- c. The maximum Number of Slides in a staining Run should not be more than 6 in Number and in two attempts only. Since, the Reagent vial positions are not sufficient. Three attempt can be done when its performed with SS assay alone
- d. Inserted Slides through STAT mode are highlighted with different color.



NOTE:

A **<Timeout Occurred>** message will appear if **<Start>** is not selected within 60 seconds (**Fig : 34**)

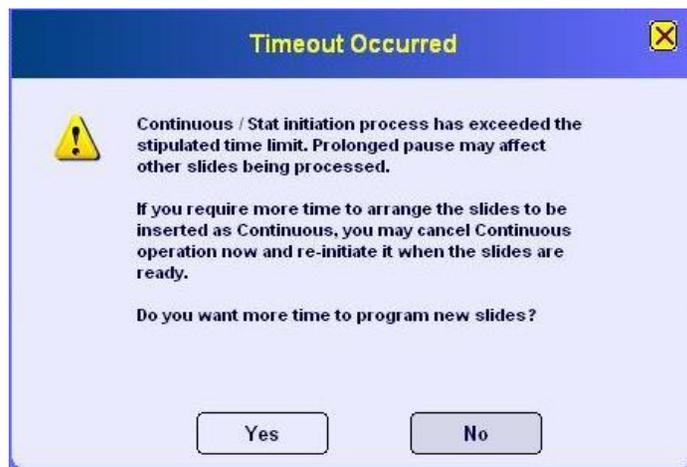


Fig: 34 Time occurred

- VI. Selecting **<Yes>** on the prompt will allow the operator to continue setting up the new slide(s);
- VII. However, processing of the existing slides will be delayed until **<Start>** is selected.
- VIII. Return to the on-screen slide map and right-click on a new slide position to open the **<Insert Protocol>** window.

NOTE: Multiple slides can be highlighted by using the following Windows options:

- Highlight the first slide in a string, hold the <Shift> key, and click the mouse on the last slide in the string.
- Highlight a slide, hold the <Ctrl> key, and click the mouse on any other slides desired.

- IX. On the <Insert Protocol> window, click on the <Filter> drop-down menu and select <Show all Protocols>
- X. Highlight a protocol on the displayed list if one is acceptable for the current run. At this stage, the user also has the <Edit> to modify an existing protocol as Factory _ user Protocol screen will pop up. To create Click < yes>. For instructions on these options, refer to one of the following:

<Edit>: Editing Protocols (Creating Factory User Protocols) on page



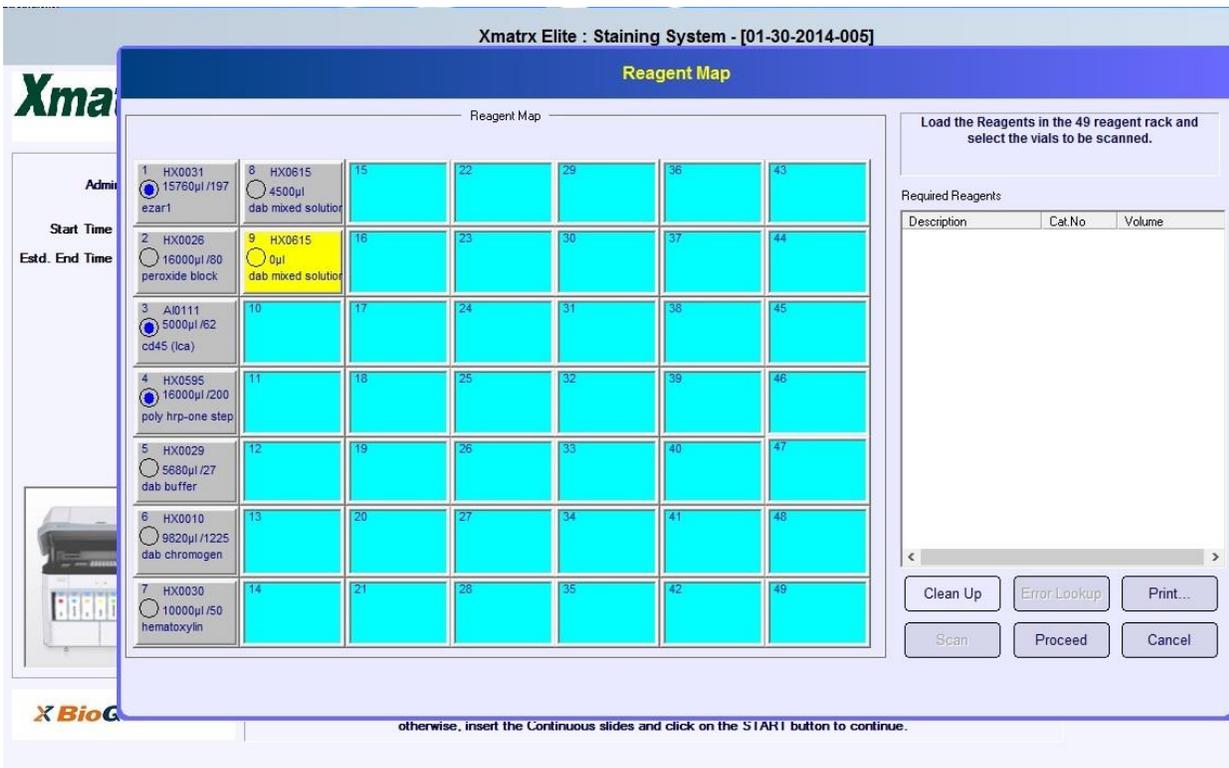
IMPORTANT: Keep in mind that processing of the existing slides will be delayed until <Start> is selected for the new slide(s).

- XI. When the desired protocol is highlighted, click **<Select>**.
- XII. If the protocol is acceptable as is, proceed to Step 15 below.
- XIII. If the protocol needs to be edited, open the **<Slide Editor>** by double-clicking on a single slide. Refer to Working in the Editor Windows on page 48 for instructions on making and saving edits.
- XIV. Verify the slide positions match the slide map and the protocol names and that the correct protocol is chosen for each new slide.
- XV. Select **<Start>**. The <Reagent Map> window will appear. Select **<Start>**. The **<Reagent Map>** window will appear. The reagent Map may show that it requires extra reagents to load like Antibody, Reagents and DAB - (DAB buffer/DAB Chromogen/DAB Mixture vial Refer **(Fig: 33)** to be added, if the kept reagents are not sufficient to start the Continuous run.
- XVI. Follow all on-screen instructions and load all required reagents as directed.

- XVII. Click the '**Scan**' button to start the reagent scanning.
- XVIII. After Scan, click **<proceed>** the following dialog will appear showing the required volume configurations of wash buffers. If the required volume of wash buffer is needed for the run, the operator should load the bulk reagent carboys to their full capacity.
- XIX. Ensure the System pressure to 5.5 psi, when the bulk buffer carboy are removed from the liquid panel in Continuous /STAT mode.

Note: 1. DAB mixture vial needs to be added compulsory in Continuous/STAT mode
 2. Reagent volume updation in terms of number of tests cannot be displayed when the Xmatrx performs multiple assays.

Fig:33 Reagent Map showing that it requires extra DAB Mixture vial in Cont/STAT Mode.



Section 7.0

USING PROTOCOL/SLIDE EDITOR WINDOWS

7.1 Editor Windows

There are two editor windows:

Protocol Editor	Appears when <Edit Protocol Database> is selected by clicking the Edit button in the <Xmatrx-Staining System> window.
Slide Editor	Appears in the <Xmatrx-Staining System> window by right-clicking the position of the successfully scanned bar-coded slide.

The layout for both the Editor windows is as follows:

Protocol Information	Upper left area of the editor window contains information about the current protocol.
Slide Information	Upper right area which contains information about the current slide (when in the <Slide Editor> window).
Protocol	Central area which contains the operations and steps of the protocol.

The bottom area contains buttons to edit the protocol. The significance of these windows is as follows:

- i. The **<Protocol Editor>** window allows the user to edit the existing protocol. However, the protocol description in the **Protocol Information** and the **Slide Information** are as parts of factory default options and cannot be changed.



NOTE:

For USER_DEFINED Protocols, Description of antibody or Probe can be modified for User's ready reference.

- ii. The **<Slide Editor>** window allows the user to change the information in the **Slide Information** area, but none of the information in the **Protocol Information** area. This window is used to edit single slide only.

The protocol area and the button area are functionally identical in both the editor windows.

7.2 Working in the <Protocol Editor> Window

The information below describes how to edit a protocol with the < Protocol Editor> window. Except wherever indicated, the options used can also be applied to the <Slide Editor> window as well.

7.2.1 To open the window:

From the <Edit Protocol> window, click the 'Edit' button (Figure: 34a) to open the <Protocol Editor> window.(Figure:34b)

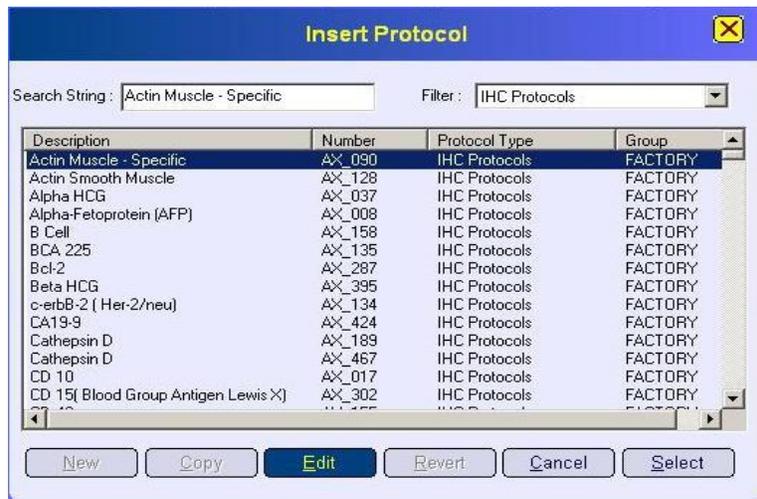


Fig:34a<Edit Protocol>

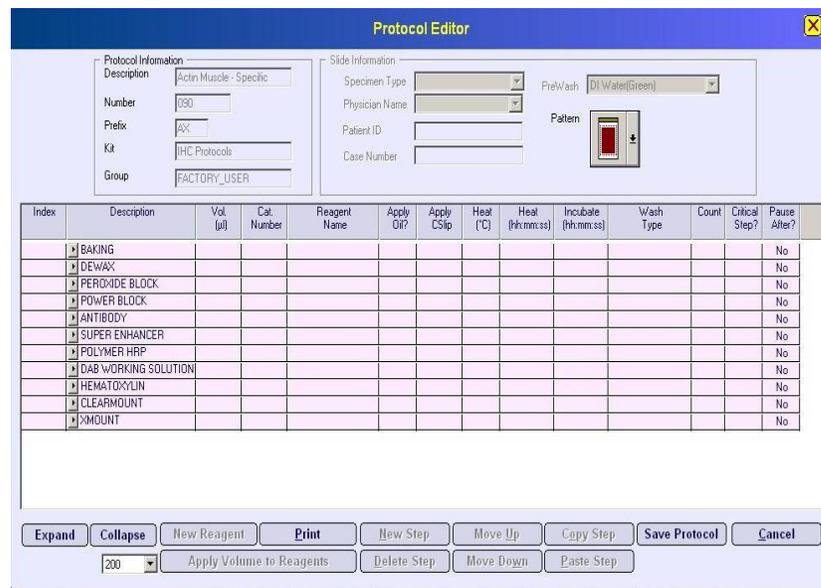


Fig: 34 b <Protocol Editor>

7.2.2 Operating the <Protocol Editor> Window

A protocol consists of operations, which in turn have steps. An operation is represented by a row with pink cells, and a step is represented by a row with grey cells.

Initially, only the operations are visible. To see the steps of a particular operation:

1. Click on the arrow to the left of the operation name.
2. Click the arrow again to collapse the rows.
3. To see all steps for all operations of a protocol, click the **<Expand>** button (Figure).
4. To hide all steps for all operations, click the **<Collapse>** button. (Figure).

The screenshot shows the 'Slide Editor' window. It has two main sections: 'Protocol Information' and 'Slide Information'. Below these is a table of steps. The table has columns for Index, Description, Vol. (µl), Cat. Number, Reagent Name, Apply Oil?, Apply CSlip, Heat (°C), Heat (hh:mm:ss), Incubate (hh:mm:ss), Wash Type, Count, Critical Step?, and Pause After?. The 'BAKING' operation is expanded, showing 'Heat Slide' steps. The 'DEWAX' operation is collapsed, showing a 'Wash Slide' step. The 'ANTIGEN RETRIEVAL' operation is collapsed, showing a 'PEROXIDE BLOCK' step. The 'POWER BLOCK' operation is collapsed, showing an 'Apply Reagent' step. The 'ANTIBODY' operation is collapsed, showing an 'Incubate Slide' step. At the bottom, there are buttons for 'Expand', 'Collapse', 'New Reagent', 'Print', 'New Step', 'Move Up', 'Copy Step', 'Save Slide', 'Cancel', 'Apply Volume to Reagents', 'Delete Step', and 'Move Down'.

Index	Description	Vol. (µl)	Cat. Number	Reagent Name	Apply Oil?	Apply CSlip	Heat (°C)	Heat (hh:mm:ss)	Incubate (hh:mm:ss)	Wash Type	Count	Critical Step?	Pause After?
▼	BAKING												No
	Heat Slide						80	00:15:00				No	
	Heat Slide						26	00:01:00				No	
▼	DEWAX												No
	Wash Slide								00:03:00	XDewax (Black)	1	No	
	Wash Slide								00:03:00	XDewax (Black)	1	No	
	Wash Slide								00:00:10	D1 Water(Green)	1	No	
	Wash Slide								00:00:10	D1 Water(Green)	1	No	
	Wash Slide								00:00:10	IHC Wash(Red)	1	No	
▶	ANTIGEN RETRIEVAL												No
▶	PEROXIDE BLOCK												No
▼	POWER BLOCK												No
	Apply Reagent	200	HX0083	Power Block					00:00:00			No	
	Incubate Slide								00:00:00			No	
▶	ANTIBODY												No

Figure 35a Expand and Collapse steps of an operation



NOTE:

In the <Slide Editor> window, the save button is called <Save Slide> and will save the changes only for that slide.

The cells of all the parameters that can be edited are in light blue color. Others in pink and grey shades cannot be changed

5. A down arrow will be displayed when the light blue cells are clicked. Click again on the arrow to select from the drop down list (Figure).

6. Select the appropriate option to assign it to the corresponding step and list is closed.

		00:00:05
85	00:02:00	
100	00:15:00	
		00:01:00
		00:00:10

		00:00:05
85	00:02:00	
100	00:15:00	
		00:01:00
		00:00:10

		00:00:05
85	00:02:00	
100	00:15:00	
		00:01:00
		00:00:10

		00:00:05
91	00:02:00	
100	00:15:00	
		00:01:00
		00:00:10

Figure 35b: Changing the Step parameters from Dropdown menu

7. Incubation and heating Time can be changed directly by double clicking on the light blue cells. (Figure 36)

		00:00:05
91	00:02:00	
100	00:15:00	
		00:01:00
		00:00:10

		00:00:05
91	00:05:10	
100	00:15:00	
		00:01:00
		00:00:10

Figure 36: Direct Parameter editing

8. After making the necessary changes, click on the **'Save Protocol'** button to save the changes.

7.2.3 Button Options in the Editor Windows

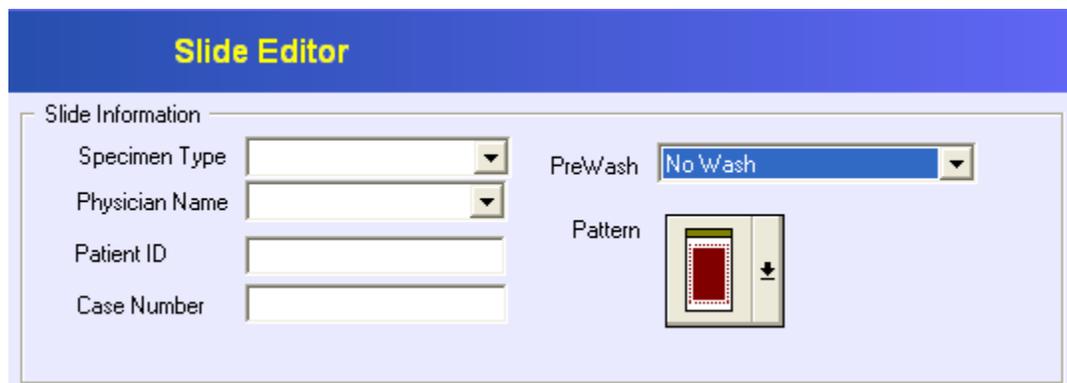
Expand	Click this button to display all the steps for all operations on the screen.
Collapse	Click this button to close all the steps for all operations on the screen.
Print	Click this button to print the protocol displayed in the window.
Save Protocol	Click this button to save a new protocol after the new protocol has been designed.
Cancel	Click this button to cancel all the previous changes made in the window.

7.2.4 Button Options in the Insert/Edit Protocol Windows

Edit	Click this button to open the Protocol Editor window
Revert	Click this button to undo all the changes and restore the original Factory protocol. It is active when Factory-User protocols are selected.(Allowed in Administrator login alone)
Cancel	Click this button to close the window without assigning any protocol to the slides
Select	Click this button to assign the protocol to the marked slide.
Done	After editing/reverting a protocol, click this button to close the window

7.2.5 Slide Information Area

- i. The **Slide Information** area (**Error! Reference source not found.**)is open for changes only when working in the **<Slide Editor>** window to edit a single inserted slide. While in the **<New Protocol Editor>** or the **<Protocol Editor>** window, this area is inactive.
- ii. When the **<Slide Editor>** window is open, **<Prewash>** can be selected by clicking on the arrow to activate the drop-down menu.
- iii. **<Specimen Type>**settings can be selected by clicking on the arrow to activate the respective drop-down menus. In order to have these settings available in this window, the specimen types must be entered in advance by the Administrator, through the configuration module (refer to **Section5.2 SPECIMEN NAME**).



The screenshot shows the 'Slide Editor' window with a blue header. Below the header is a 'Slide Information' section containing four input fields: 'Specimen Type' (a dropdown menu), 'Physician Name' (a dropdown menu), 'Patient ID' (a text box), and 'Case Number' (a text box). To the right of these fields are two more options: 'PreWash' (a dropdown menu currently showing 'No Wash') and 'Pattern' (a small icon of a slide with a red area and a downward arrow).

Figure 37: <Slide Editor> Window

7.2.6 Protocol Information Area

- i. The **<Description>** field (Figure) is used to enter a title for the new protocol. The **<Description>** field must be filled in before the Protocol is saved.

The **<Number>**, **<Prefix>**, **<Kit>**, and **<Group>** fields are automatically filled with relevant information when the window opens. The information in these fields cannot be edited by directly working in these fields

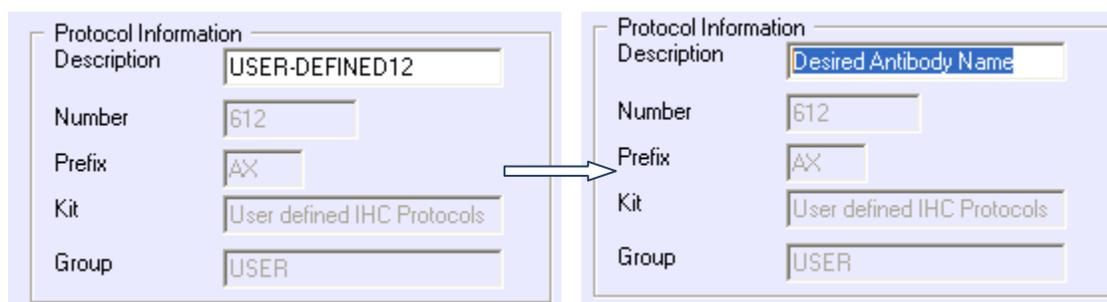


Figure 38: <Protocol Information> Area

SECTION 8.0

EXECUTING A RUN

The user must ensure that all preparatory steps are completed, such as loading of consumables and reagents. Confirm that all the required buffer carboys are filled with sufficient volume of appropriate solutions. Ensure the waste carboy is empty. (Refer to **Section 3: On-Site Installation**).

Prior to starting a run, the operator should re-verify the following:

- a. Required slide positions are selected.
- b. The slides are properly placed on the slide racks.
- c. Reagents vials are available for the run. Remove the caps of the reagent vials and load them on the reagent rack with the vial opening on the left. Ensure that the caps are not interchanged when placing them back on the vials.
- d. Required Buffer Carboys are filled and connected to the respective tubing connector.

8.1. Initiating a staining run:

1. Once the slides are loaded and protocols inserted, select **<Start>** from the menu bar of the **<Xmatrix: Staining System>** window.
2. The **<Reagent Map>** window (**Fig.39**) will appear with a list of **required reagents** in the panel on the right. Load the reagent racks with the

BARCODE reagent vials and click the **'Scan'** button to start the reagent vial scanning.

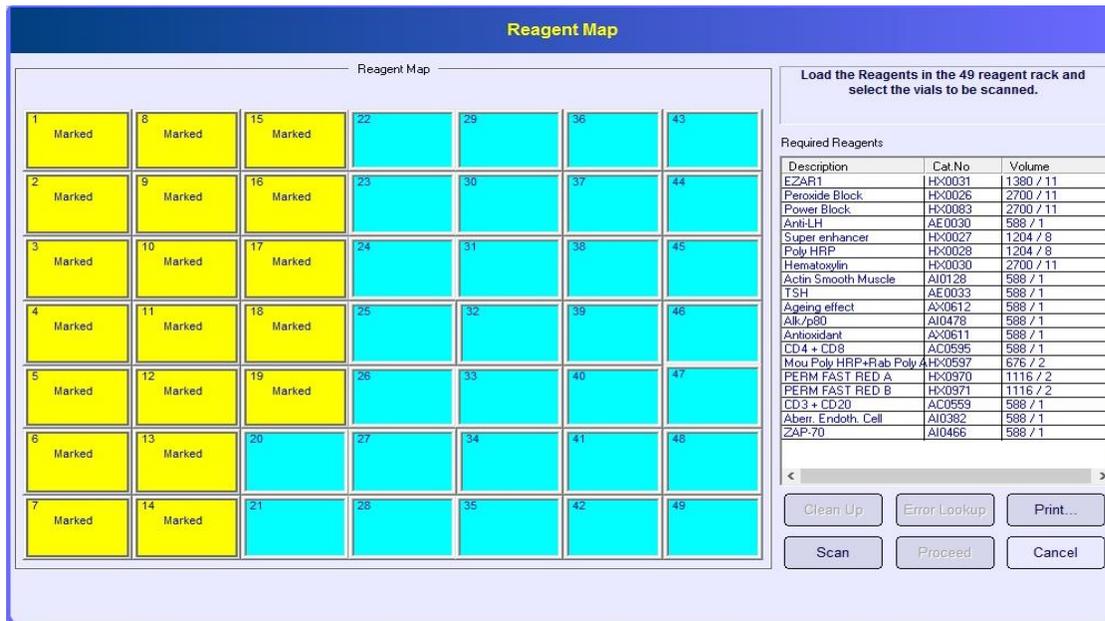


Figure: 39<Reagent Map>

3. Load the reagent racks with the BARCODE reagent vials, Make sure that the Empty BARCODE vial is inserted along with DAB buffer and DAB chromogen vials with sufficient volume available for no. of tests to be performed and click the **'Scan'** button to start the reagent scanning.
4. The BARCODE labels are scanned automatically and the corresponding positions in the reagent map are highlighted (Figure).
5. Reagent map displays required reagents volume for a run with number of tests. Number of tests calculation shall be with respect to the volume of dispensing on each slide.

7. This dialog shows the existing volumes and Required volumes for Wash Buffers.
8. Required Volumes and Add-on volumes are calculated based on existing and required volumes.



NOTE:

For Wash buffer Extra 400 ml volume needs to be added apart from required volume.

9. Add-on Volume fields are made editable so that user fill any volume and update in those fields.
10. User can reset the Buffer Volumes by clicking corresponding Reset Buttons.
11. Once the user clicks the Update Volumes Button, Existing volumes will be added with Add-on Volumes and will be updated.
12. Wait for the workstation to pressurize. The Pressure Gauge at the lower right end of the workstation should display **>5.5**
13. If required, select **<Print>** in the **<Reagent Map>** window to print the reagent map for future reference.
14. Select **<Proceed>** to close the **<Reagent Map>** window. The **<Load Consumables>** window (Fig. 42) will appear. Check all consumables and then click **<Proceed>**.

A screenshot of a software dialog box titled "Load Consumables". The title bar is blue with the text "Load Consumables" in yellow. The main area has a light blue background and contains a bold instruction: "Please Ensure that all the consumables needed for the Run are loaded in the system. Verify and Check the box against each item to proceed with the run." Below this are seven checklist items, each with an unchecked checkbox: "Verify that the large Pipette Tips needed for the run are loaded.", "Verify that the Small Pipette Tips needed for the run are loaded.", "Verify that the Coverslips needed for the run are loaded.", "Verify that all the Buffer Carboys needed for the Run are connected to the instrument.", "Verify that the Pipette Waste disposal Tray is Empty", "Verify that the Coverslip Waste disposal Tray is Empty", and "Verify that the Waste Carboy is Empty." At the bottom right, there are two buttons: "Check All" and "Proceed".

Fig. 42<Load Consumables>checklist

15. Make the intended selections in the **<Select Pipette Positions>** window (Fig.43) for the pipette tip start positions in the two large pipette tip boxes and two small pipette tip boxes respectively (front, back or last used position).

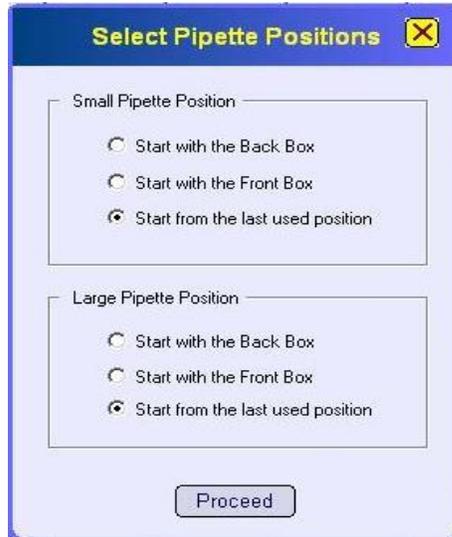


Figure 43<Select Pipette Positions> Window

16. Select **<Proceed>** to quit this window. The **<Prime Solutions>** box (Fig. 44) will appear in order to select the solution(s) that need to be primed.



Figure 44<Prime Solutions> Window

17. Buffer lines that are required for the new run will be automatically selected.

-
18. Enter the digit(s) into the **<Prime for __secs>** field to set the prime time (in seconds) (five (5) seconds is the default).
 19. Select **<Start Priming>**. The workstation will start priming.
 20. If priming is not required, select **<Close>** to move-over and the staining run will start.
 21. At the end of priming, the **<Prime Again>** button will become active.
 22. If any of the buffer lines is not primed sufficiently (no free flow of buffer from the wash-blow head), select **<Prime Again>** again to re-prime solution(s).
OR
Select **<Close>** to proceed to the next step. The **<Prime Solutions>** box will close.

Note:

Aspirations and mixing of Chromogen will be done with Large Tip and follows non contamination path during the travel from Chromogen buffer to DAB Buffer.

23. After the priming is done, Auto DAB mixing will be carried out. Required Volume of DAB Buffer and Chromogen will be mixed into an Empty Vial, which will then have DAB working Solution.

Note:

Aspirations and mixing of Chromogen will be done with Large Tip and follows non contamination path during the travel from Chromogen and DAB buffer to DAB mixer vial

24. Once mixing is completed, the actual staining process will begin.

25. Delayed run

- a. The Delayed Run screen (Fig: 45) will be displayed after clicking on **<close>** on above Screen. If you want to start right away, click **No**.



Figure: 45 Delayed Run

- b. To start a delayed run, click **yes**. The following screen will be displayed.(Fig 46) The system shall ask for time to start processing the slides.



Figure: 46Delayed Run window to set Time and Date

- c. The window will appear to set the time to start the run, and the system shall be able to understand the time set by the user is ahead (later than the current time) and pop up a message to the user when the set time is prior to the current time which is incorrect. Time shall be displayed in 24 Hours format
- d. You must leave the system on and the program running. Closing the program will cancel the programmed delayed start run even if the program is restarted before the selected start date and time.
- e. There is a countdown window that appears until the run begins.
- f. When cancellation of run is selected by the user, system shall ask for a confirmation to cancel to the run.
- g. Once the set time reaches, system shall start processing the slides without any further response from the user.
- 26.**An audio-alert will indicate the completion of the process.
- 27.**When the staining run is completed, the **<Run Completed successfully>** dialog box (**Fig. 47**) will appear for further action.



Figure 47<Run Completed Successfully>Window

28. Once mixing is completed users may:

- **<Print Reports>** from the run (refer to **Section 9: Generating Reports** for details of printing)
- **<Close>** the run

29. If the user selects **<Close>**, a **<Completed>** dialog box appears (**Fig. 48**).



Figure 48<Completed> Confirmation Box

30. Select **<OK>** to close the box and the **<Exit the Application>** bar to exit the subsequent **<Selection Window>**. The operation is now complete.

8.2. Monitoring a Run

Real time information of a staining run can be viewed in the **<Xmatrx: Staining System>** window. The slide map in the window always presents the real time information for each slide being processed. The color scheme together with text on the slide(s) helps the user to easily identify the current step in progress on any slide. For detailed information on an individual slide:

1. Right click the slide to view the drop-down menu (**Fig. 49**).

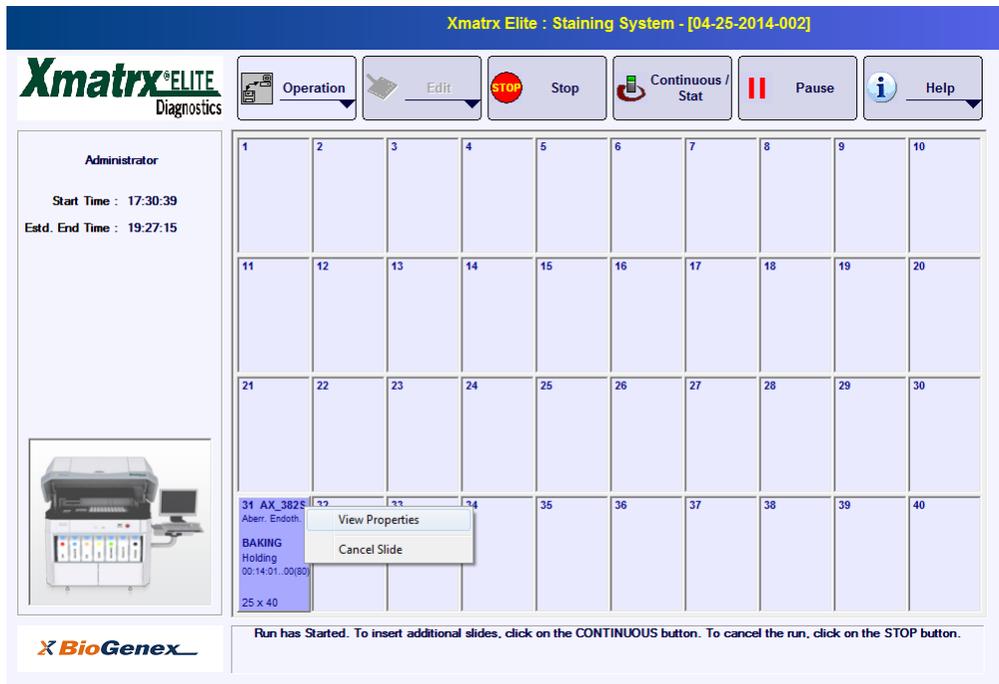


Figure 49<View Properties> Menu

2. Select **<View Properties>** option to open a **<Runtime Properties>** window (Fig. 50).



Figure 50<Runtime Properties> Window for IHC

3. The staining progress for a single slide is displayed in the **<Runtime Properties>** window. Information concerning the current step on a slide as well as the remaining time is indicated for quick reference.

NOTE: Estimates for the time remaining displayed on the run time properties window are approximate.

8.3. Pausing a Run

To pause a run at any time:

1. Select **<Pause>** at the top of the **<Xmatrix: Staining System>** window. The **<System Paused>** message box (Fig. 51) will be displayed.

NOTE: The system will not pause until linked steps are completed.

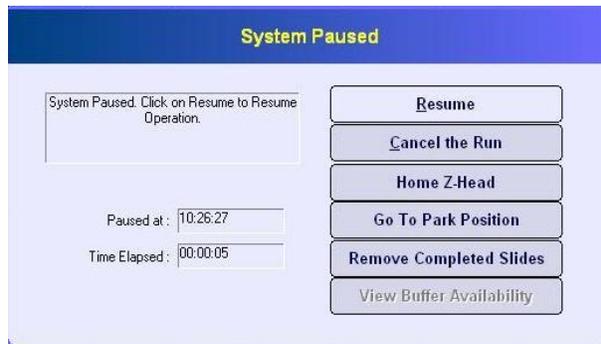


Figure 51 <System Paused> Message Box

2. Either click on the **<Resume>** bar in the **<System Paused>** message box, or press the **<Enter>** key on the keyboard to resume the paused staining run.
3. To terminate the run, select **<Cancel the Run>** in the message box.
4. To return the Robotic-head to its home position, select **<Home Z-Head>**.
5. To park the Z-head, select **<Go To Park Position>**.
6. To remove completed slides if any, select **<Remove Completed Slides>**.
7. After approximately 45 seconds a **<Confirm>** window will display. If **<Pause>** is not confirmed, the run will resume in 60 seconds.

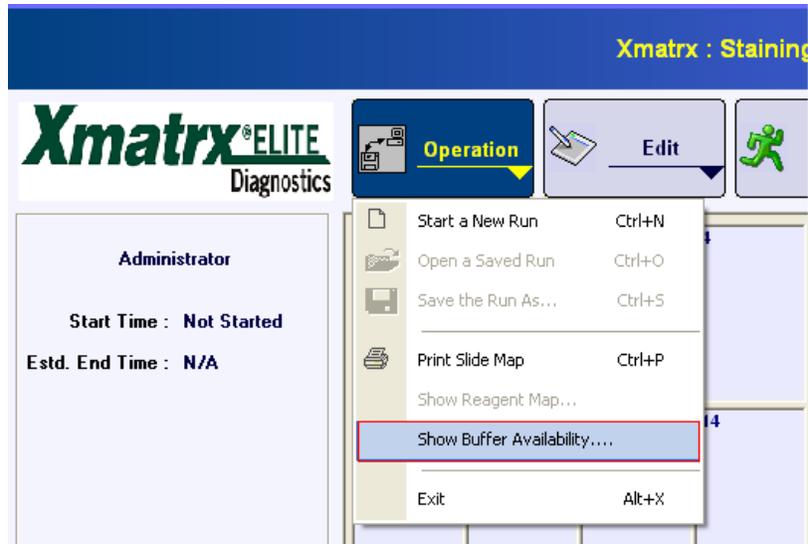


CAUTION: Prolonged pause during a staining run may lead to invalid test results due to the extended incubation time over the affected staining step(s)

8.4 Checking the Availability of Buffers

To check the availability of the buffers during the run:

1. Go to **Operation** in the stainer module



2. Click on Show Buffer Availability, the available volumes are displayed as below:

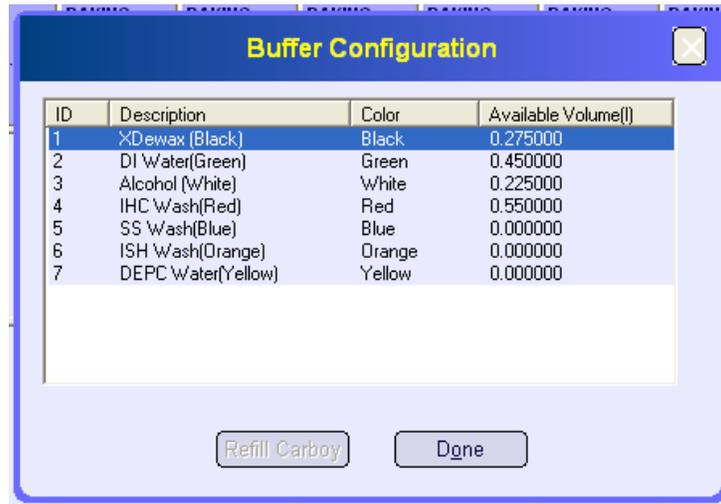


Figure 52: Bufferconfiguration

8.5. Stopping a Run

To stop a run in progress:

1. Select **<Stop>** at the top of the **<Xmatrx: Staining System>** window.

-OR-

Click on the **<Operation>** bar to display a drop-down menu. Select **<Exit>** (**Fig. 53**) from the menu.

2. The stop confirmation message box **<Confirm>** will be displayed.



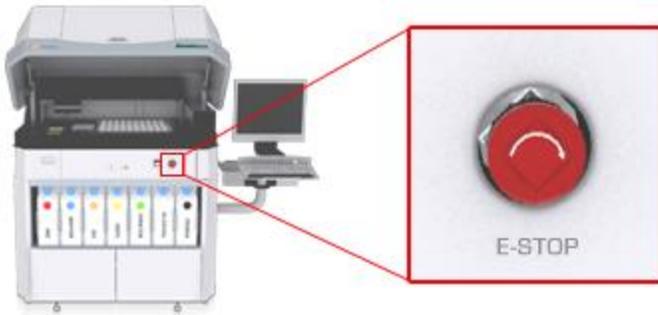
Figure 53 **<Exit>** option

3. To continue the staining run, click on the **<No>** button. To terminate the current run, click on the **<Yes>** button.

4. Once the **<Yes>** button in the **<Confirm>** box has been clicked, the run will be terminated, and return to the **<Selection Window>** screen.

8.6. Emergency Stop

The **<E-Stop>** (Emergency Stop) button is located at the lower right end of the workstation. Pushing this emergency stop button will stop the robotic arm immediately. This is used in case of an emergency.



IMPORTANT:

Once the E-Stop button is pressed, the run in progress is cancelled and cannot be resumed.

8.7 Typical Error Message

1. When the **<E-Stop>** button is pressed while the Z-Head is in motion, it stops moving, the system will set off an alarm, and a system error message (**Fig. 54**) will be displayed on the screen. The run in progress is cancelled and cannot be resumed.
2. After clearing the emergency situation, release the **<E-Stop>** button by rotating it in clockwise direction.

Click the **<Close>** button in the system error message window to exit the **<Xmatrix: Staining System>** window. The **<Selection Window>** will be displayed.

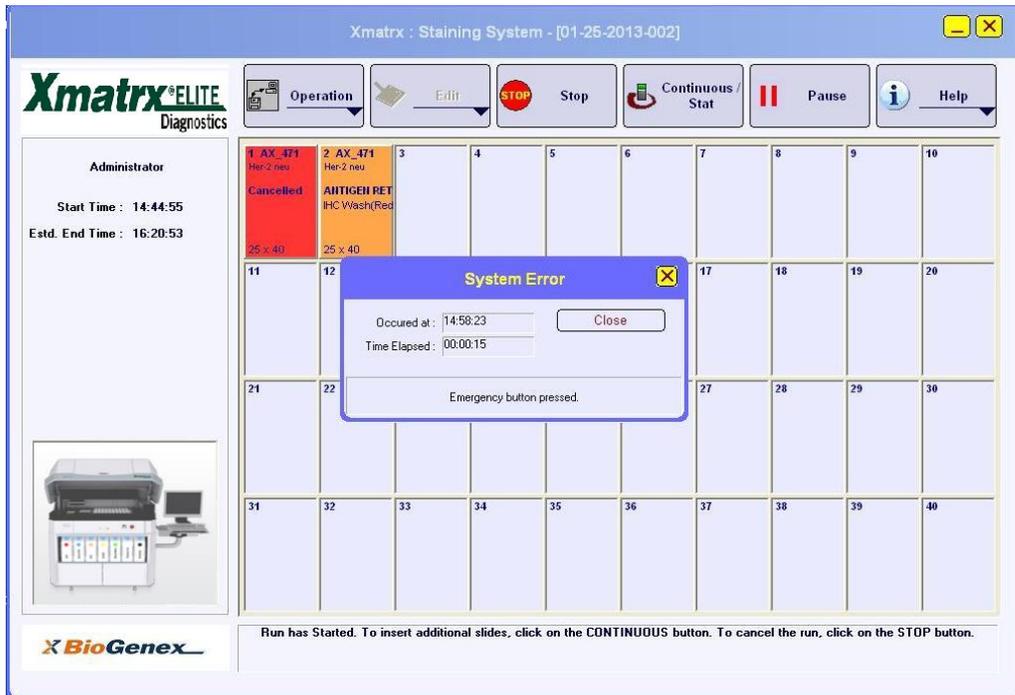


Figure52<System Error> Message

When emergency-stop is pressed, while the Z-head is with add-ons (pipette tip or coverslip) then after exiting from the application when try to re-login into the staining application, the software doesn't allow proceeding until the add-on's (pipette tip or coverslip) are manually removed.

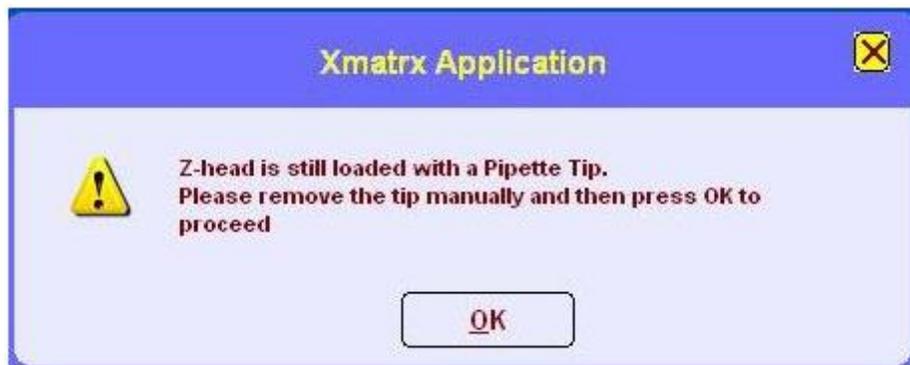


Figure53: Warning Message

SECTION 9.0

GENERATING REPORTS

9.1. Launching the Reports Module

There are two (2) ways to access the 'Reports Module' after a staining run is completed:

1. Click the bar **<Run Reports>** in the main dialog window **<Selection Window>** (Fig. 11),
2. Click on the **<Print Reports>** option in the **<Run Completed successfully>** window (Fig. 56a).



Figure 56 : <Run Completed Successfully> window

Either way, the **<Welcome to Reports Module>** window (Fig. 56b) will appear. This window is the main interface for printing.

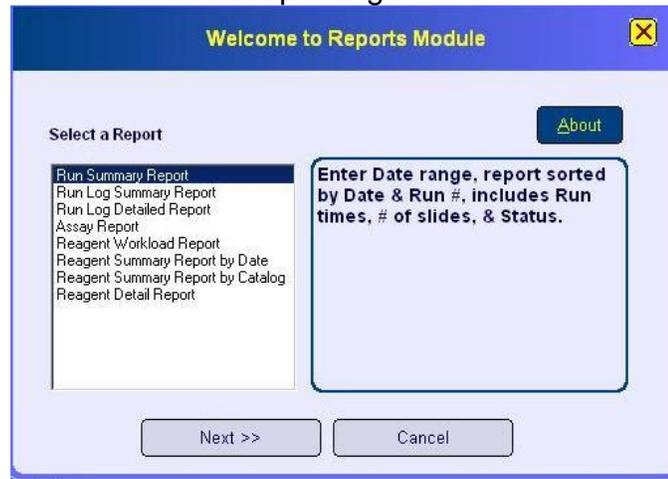


Figure 56b: Report module

9.2. Default Report Types

The *Xmatrx® Elite* software provides the user with eight (8) types of default report formats. These reports will summarize the staining data for reference. The **<Welcome to Reports Module>** window (Fig. 57) displays the various types of reports in the left column. Selecting a report type will display a short description in the box on the right. In addition, the users may customize reports to meet their own individual needs.



Figure 59<Welcome to Reports Module>window

1. Select the report-type in the **<Select a Report>** dialog box. Select **<Next>** in the **<Welcome to Reports Module>** window, which will open the **<Select Parameters for Run Summary Report>** window (Fig. 58).



Figure 58<Select parameters for Run Summary Report> Window

2. Select the date (or date range), run number or catalog number of the report.

9.3. Previewing and Printing a Report

Once the selections are made in the **<Select parameters for Run Summary Report>** window:

1. Select **<Preview & Print Report>** to open the **<Reports>** screen.
2. The **<Reports>** screen displays the report for preview (Fig.59).

Reagent Workload Report



Summary of Reagents used in the Run : 11-18-2013-001

Print Date/Time: 11/18/2013 - 11:41:51

Run Start Time : 10:30:24

Run End Time : 11:33:13

Serial # : AS40342

Run Start Date : 11/18/2013

Run End Date : 11/18/2013

User : Administrator

Catalog Number	Description	Vol Used / Tests	Vol Avail / Tests	Lot #	Expiry Date	Serial #	Type
HX0031	EZAR1	800 µl / 10	15,200µl / 183	1212	1214	3651	Probe Vial
HX0026	Peroxide Block	2,000 µl / 10	14,000µl / 67	1212	1214	3652	Reagent Vial
HX0083	Power Block	2,000 µl / 10	14,000µl / 67	1212	1214	3653	Reagent Vial
AE0030	Anti-LH	80 µl / 1	4,920µl / 55	1212	1214	3654	Probe Vial
HX0027	Super enhancer	640 µl / 8	15,360µl / 185	1212	1214	3655	Probe Vial
HX0028	Poly HRP	640 µl / 8	15,360µl / 185	1212	1214	3656	Probe Vial
HX0030	Hematoxylin	2,000 µl / 10	14,000µl / 67	1212	1214	3657	Reagent Vial
AE0033	TSH	80 µl / 1	4,920µl / 55	1212	1214	1237	Probe Vial
AX0612	Ageing effect	80 µl / 1	4,920µl / 55	1212	1214	3658	Probe Vial
AI0128	Actin Smooth Muscle	80 µl / 1	4,920µl / 55	1212	1214	2587	Probe Vial
AI0478	Alk/p80	80 µl / 1	4,920µl / 55	1212	1214	3659	Probe Vial
AC0595	CD4 + CD8	80 µl / 1	4,920µl / 55	1212	1214	3661	Probe Vial
HX0597	Mou Poly HRP+Rab Poly A	160 µl / 2	13,840µl / 166	1212	1214	3662	Probe Vial
HX0970	PERM FAST RED A	560 µl / 2	13,440µl / 46	1212	1214	3663	Probe Vial
HX0971	PERM FAST RED B	560 µl / 2	13,440µl / 46	1212	1214	3664	Probe Vial
AC0559	CD3 + CD20	80 µl / 1	4,920µl / 55	1212	1214	3665	Probe Vial
AI0382	Aberr. Endoth. Cell	80 µl / 1	4,920µl / 55	1212	1214	3666	Probe Vial
AI0466	ZAP-70	80 µl / 1	4,920µl / 55	1212	1214	3667	Probe Vial
AX0611	Antioxidant	80 µl / 1	4,920µl / 55	1212	1214	2588	Probe Vial

Total Reagents Used : 19

Comments :

Figure 59<RUN SUMMARY REPORT> Preview



3. To print the report, click on the printer icon  at the top of the <Reports> screen.

9.4. Exiting the Reports Module

To exit the 'Reports Module':

1. Select the <X> button on the title bar of the <Reports>screen and return to the <Welcome to Reports Module> window.
2. Select <Cancel> to quit the window, then select <Exit the Application> in the <Selection Window> to quit *Xmatrx® Elite*.

SECTION 10.0

TROUBLESHOOTING

This section lists the possible *Xmatrix® Elite* malfunctions and errors with appropriate corrective actions. More complicated malfunctions or errors may be referred to BioGenex Customer Support.

10.1 TYPICAL ERROR MESSAGES

For most detectable malfunctions in the system, there is a corresponding error message that is displayed on the screen once the malfunction occurs.

The table below lists some typical errors. The method of clearing an error message is presented along with the error message in the same message window.

No	Error Message	Corrective Action
1	Pipette tip boxes for large pipette tips are empty	Please Load new boxes and resume the staining run
2	Pipette Boxes for small pipette tips are empty	Please Load new boxes and resume the staining run
3	Error picking a small pipette tip from the pipette box	Ensure that tips are available at the desired location and the pipette box is not empty
4	Error picking a large pipette tip from the tip box	Ensure that pipette tips are available at the desired location and the pipette tip box is full
5	Pipette tip sensor indicates that there is no tip on the Z Head.	Pick up a pipette tip and try again
6	Pipette tip fell in the middle of an operation	Remove the pipette tip and resume operation
7	Pipette tip dropped in slide area	Remove the pipette tip and resume staining
8	Pipette tip has dropped in the reagent rack area	Remove the dropped pipette tip and resume operation
9	Pipette tip is dropped	Remove the fallen pipette tip and resume the operation
10	Unable to dispose pipette tip	Remove the pipette manually and click <OK>to

		continue
11	There is not enough reagent available in the reagent vial	Replace the vial
12	Error sensing the liquid in reagent vial	Make sure enough reagent is available in the vial.
13	The requested pattern is not supported for this operation	Modify the selection of the pattern
14	Large coverslip stack are empty	Load Coverslips and resume staining on affected slides
15	Error placing the coverslip on the slide	Dispose the coverslip, and place a new coverslip on slide
16	Error disposing the coverslip into the coverslip disposal	Check the calibration and try again. Manually dispose off coverslip.
17	Emergency button is pressed	Click on 'close' to terminate the application.
18	Sensor indicates that the oil bottle is empty.	Please contact BioGenex Customer Support.

10.2. Slide Heating Error

If the system encounters a problem while heating the slide, the process on the specific slide will stop and the slide will be marked as **<Error>** and highlighted in red on the Slide Map screen (**Fig. 60**).

1 AX_007 Bel-2 BAKING Holding 00:14:04..00(70) 25 x 40	2 AX_007 Bel-2 BAKING Holding 00:14:04..00(70) 25 x 40	3 AX_007 Bel-2 BAKING Holding 00:14:04..00(70) 25 x 40	4 AX_1118 Bel-2 PRG7262.00 BAKING Error	5
11	12	13	14	15

Figure 60 Slide Map: Heating Errors

Corrective Action(s)

1. To view the error message, right click on the failed slide and then click on the **<View Properties>** from the drop-down menu. The **<Runtime**

Properties>window will be displayed with the error message at the bottom of the screen in blue (**Fig. 61**).

2. From the Slide Map, resume the failed slide by right clicking on the slide and selecting **<Resume Operation>** from the right click menu. The system will retry the heating step on the affected slide and proceed to the next step if the heating step is successfully completed.
3. If the problem persists, discontinue using the failed slide position and contact BioGenex Customer Support.

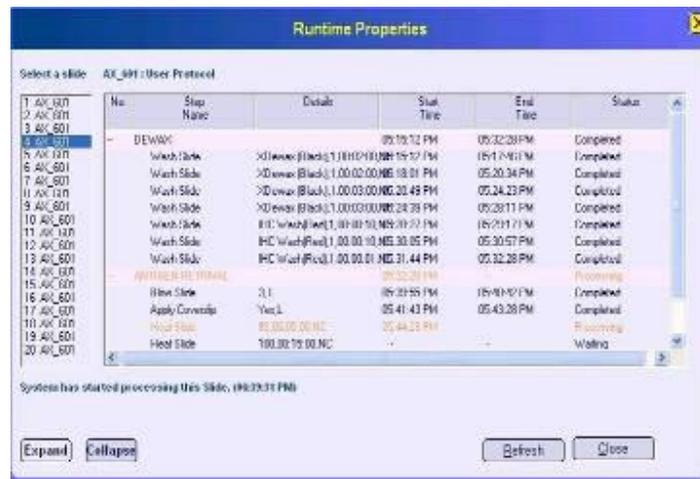


Figure 61: Runtime Properties screen

10.3. Errors at Pipette tip tray

If the Z-Head pipette tip adapter fails to pick up a pipette tip from a pipette tip tray during an operation, or if the pipette tip trays are sensed empty, the system alarm is set off. It is followed by the error message **<System Error>** displayed for 10 to 15 seconds (**Fig. 62a**). Once the **<System Error>** clears, the affected slides are marked with an **<Error>** and highlighted in red in the Slide Map (**Fig. 62b**). A **<Fix Errors>** button displays on the left side of the screen. The following steps describe how to overcome this error.

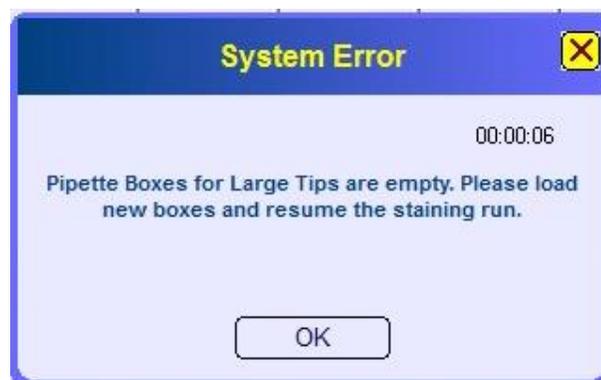


Figure 62a System Error



Figure 62b Corrective Action(s)

1. Click the **<Fix Errors>** button in the window. The Z-Head will stop proceeding and the **<Fix Errors>** window will appear with the description of the error condition and the appropriate instruction to address the problem (**Fig. 65**).



<Description> - Pipette tip boxes for large pipette tips are empty. Please load new boxes and resume the staining run.

<Fix> - Refill/replace the empty pipette tip boxes and resume operation.

Fig. 63: <Fix Errors> window

2. Perform the action as instructed on the **<Fix Errors>** screen to clear the error condition. In this case, refill the pipette tip tray, or replace the pipette tip tray with a new tray of pipette tips. Make sure that the new pipette tip tray is firmly seated and that there is no obstruction along the path of the Z-Head movement.
3. In the **<Fix Errors>** window, click the **<Fix Errors>** button.
4. Click on the **<Close>** button to exit from the **<Fix Errors>** window. The system will automatically resume the run as soon as the **<Close>** button is selected.
5. If the problem persists, contact BioGenex Customer Support.

10.4 Pipette Drop Error

If the Z-Head pipette **tip adapter** drops a pipette tip during an operation, system alarm is set off and a **<System Error>** pop-up is displayed on the screen with count down of 10sec. Once the **<System Error>** clears, the slide that encountered the

<Pipette Dropped> error will be marked as <Error> and highlighted in red on the Slide Map. The <Fix Error> button will appear on the left side of the screen.

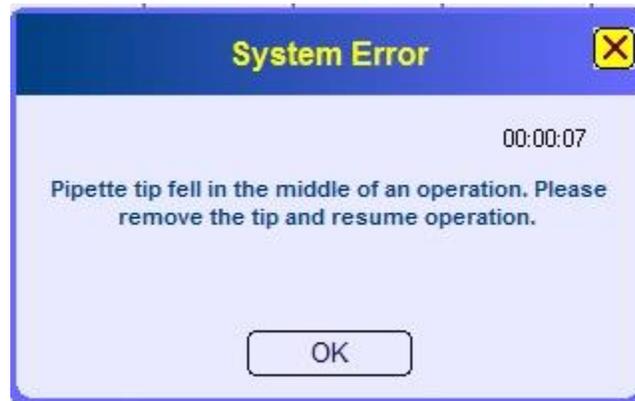


Figure 64 System Error: Pipette Dropped

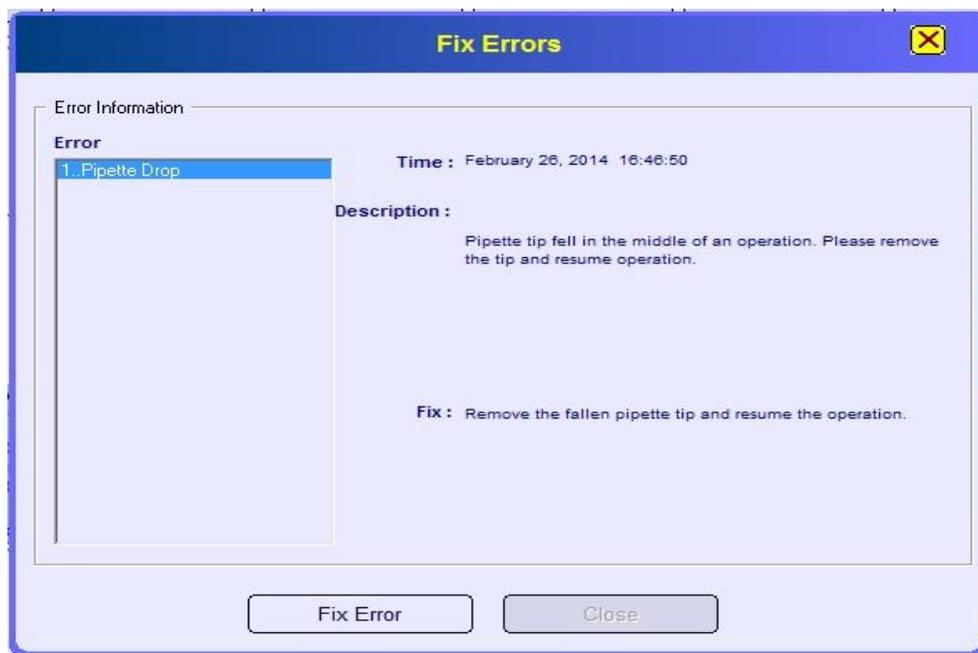


Figure 65: Fix Error



Corrective Action(s)

1. Click the **<Fix Errors>** button in the window. The Z-Head will stop proceeding and the **<Fix Errors>** box will display with the description on the error condition and the appropriate instruction to correct the problem
 - **<Description>** - pipette tip dropped during an operation. Please remove the tip and resume operation.
 - **<Fix>** - Remove the fallen pipette tip and resume the operation.

Perform the action as instructed on the **<Fix Errors>** screen. In this case, remove the dropped pipette tip from the system and make sure that all the 'Slide Carriers' are positioned properly and there is no obstruction to the free movement of the Z-Head over the Slide Block.

2. In the **<Fix Errors>** window, click on the **<Fix Error>** button and then click on the **<Close>** button to exit the **<Fix Errors>** window.
3. Go to High Lighted with Red in color Slide, Right click on the slide. select<Resume Slide>. from Selection , Repeat this step for all the slides to Resume the slides.
4. If the problem persists, contact BioGenex Customer Support.

10.5. Pipette Disposing Error

After attempting allowable retries, if the Z-Head pipette tip adapter fails to eject a used pipette tip into the pipette disposal tray, an alarm will sound and the error message **<System Error>** will appear on the screen.. Once the pop-up message clears, the Z-Head will try again to dispose off the used pipette tip into the pipette disposal tray. If the failure recurs (after attempting the allowable retries), system alarm sets off and the error message **<System Error>** is displayed on the screen.

The system will continue to try and dispose of the pipette tip until the error condition is cleared. If the condition is cleared, the system will normally proceed to the next step. Follow the steps below if the system is unable to clear the error condition on its own.

1. Manually remove the pipette tip from the pipette tip adapter before the Z-Head starts to move. Once the **<System Error>** is cleared, the system will automatically proceed to the next step.
2. If the problem persists, discontinue the run and contact your BioGenex Customer Support.



CAUTION: User Intervention would be required to remove the pipette tip from the Tip adopter Until unless the tip is ejected from pipette tip adopter the Run will not resume.

10.6. Empty Coverslip stack Error

If the Z-Head suction cup fails to pick up a coverslip while in operation, or if the coverslip stack are sensed as empty, the slides will be marked as **<Error>** and highlighted in red on the Slide Map screen . The **<Fix Error>** button will be displayed on the left side of the window.

Before to the display of FIX ERR at LHS, an indication message with count down of approx. 10sec will be displayed with the statement “the large/medium/small coverslips stack is empty. Please load the coverslips in order to resume the staining run”. Please provide the screenshots.

Corrective Action(s)

1. Click the **<Fix Errors>** button in the window. The Z-Head will stop proceeding and the **<Fix Errors>** window will appear with the description of the error condition and the appropriate instruction to correct the problem.
 - **<Description>** - Coverslip stack is empty. Small coverslip stack are empty. Load coverslips and resume staining on affected slides.
 - **<Fix>** - Refill/replace the empty coverslip stack and resume operation.

Perform the action as instructed on the **<Fix Errors>** screen to clear the error condition. Ensure the coverslip boxes are placed in the **'CORRECT'** orientation and the coverslips are properly seated in the coverslip stack.

2. In the **<Fix Errors>** window, click on the **<Fix Error>** button and then click on the **<Close>** button to exit the **<Fix Errors>** window. The system will automatically resume the run as soon as the **<Close>** button is selected.
3. If the problem persists, contact BioGenex Customer Support.

10.7. Coverslip Placement / Pickup Error

During the staining operation, if the Z-Head suction cup fails to place a coverslip onto the slide, or fails to pick up a coverslip from the slide, or if it drops a coverslip in the middle of an operation, the slide that is in process will be marked as **<Error>** and highlighted in red on the 'Slide Map' screen.

1. To view the error message, right click on the failed slide and click on the **<View Properties>** from the drop-down menu. The **<Runtime Properties>** window will appear with the error message displayed on the bottom of the screen in blue. One of the two possible error messages (**Fig.66&67**) could be encountered.
2. From the 'Slide Map', resume the failed slide by right clicking on the slide and selecting **<Resume Operation>** from the right click menu. Repeat the step for all other affected slides in the run. The system will retry the Coverslip operation on the affected slide and proceed to the next step if it is successfully completed.
3. If the problem persists, contact BioGenex Customer Support.

Runtime Properties

Select a slide: AX_001 / User Protocol

No.	Step Name	Details	Start Time	End Time	Status
1	APPLY DAB MIXING		05:02:14 PM		Processing
2	Apply Coverslip	Yes/L	05:02:14 PM	05:03:49 PM	Completed
3	Remove Coverslip	Yes/L	05:02:20 PM		Processing
4	Wash Slide	IHC WashProd,3.00.00.10.NC			Waiting
5	SUPER ENHANCER				Waiting
6	POLYMER HRP				Waiting
7	DAB WORKING SOLUTION				Waiting
8	HENATOLOLIN				Waiting
9	CLEARMOUNT				Waiting
10	MOUNT				Waiting

System has started processing this Slide. IHC3207 PMS

Expand Collapse Refresh Close

Figure 66: Coverslip Placement Errors

Runtime Properties

Select a slide: AX_001 / User Protocol

No.	Step Name	Details	Start Time	End Time	Status
1	APPLY DAB MIXING		08:43:57 PM		Processing
2	Apply Coverslip	Yes/L	08:43:57 PM		Processing
3	Remove Coverslip	Yes/L			Waiting
4	Wash Slide	IHC WashProd,3.00.00.10.NC			Waiting
5	SUPER ENHANCER				Waiting
6	POLYMER HRP				Waiting
7	DAB WORKING SOLUTION				Waiting
8	HENATOLOLIN				Waiting
9	CLEARMOUNT				Waiting
10	MOUNT				Waiting

System encountered error while processing this Slide. Error placing the coverslip on the slide.

Expand Collapse Refresh Close

Figure 67: Coverslip Pickup Errors

10.8 Error at DAB mixing step

AutoDAB mixing can fail due to following three reasons:

AutoDAB mechanism uses 3 vials.

- i. A vial for chromogen
- ii. A vial for buffer
- iii. And a vial for mixing



Note:

Do not reuse the mixing vial and always use a fresh mixing vial.

1. Mixture Vial Not Placed

During the scanning operation, if DAB mixing vial is not placed <Mixer vial> error (Figure 68) will pop up on <Reagent Map> Window.



Figure 68: Mixer Vial Error

2. Errors at Pipette tip tray

AutoDAB function can fail due to Errors at pipette tip tray as empty and it will be provided with an alert message as pipette tip box is empty

3. Pipette Drop Error

If the Z-Head pipette tip adapter drops a pipette tip during any stage of DAB mixing operation, system alarm is set off and a respective <System Error> pop-up is displayed on the screen with countdown of 10sec.

a. Pipette dropped in DAB Buffer during aspiration (Figure 69:)

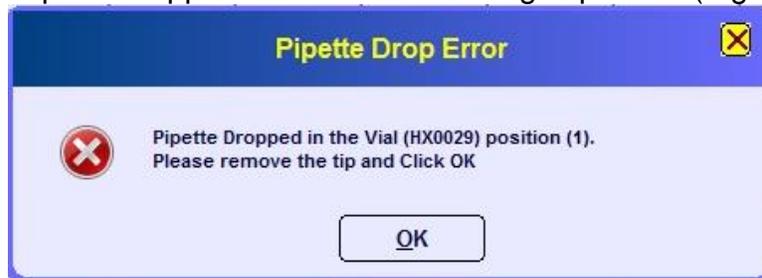


Figure 69: System Error when Pipette dropped in DAB Buffer during aspiration

b. Pipette dropped in DAB Chromogen Vial during aspiration (Figure70)

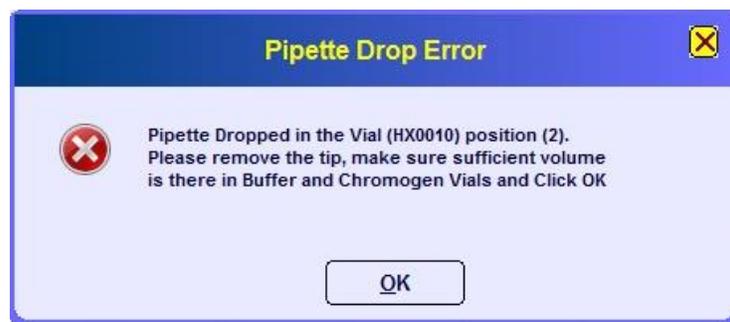


Figure70: System Error when Pipette dropped in DAB Chromogen during aspiration

-
- c. Pipette dropped in mixer vial during Mixing (Figure 71:)



Figure 71: System Error when Pipette dropped in DAB Mixer Vial during dispensing buffer/chromogen reagents into mixer vial

- d. Pipette dropped into the mixer vial during dispensing buffer/Chromogen

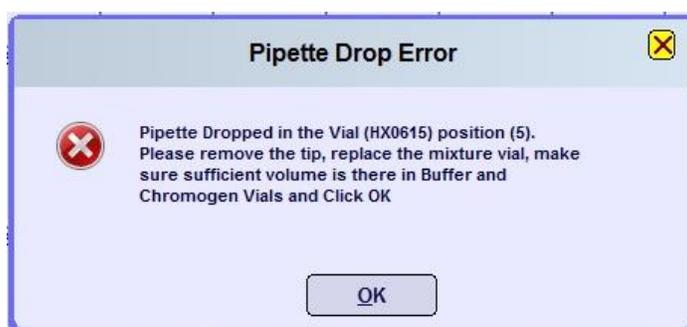


Figure 72: System Error when Pipette dropped in DAB Mixer Vial during Dispensing

4. Pipette Disposing Error

Please refer to **6.5** for more information.

5. Auto DAB function error

AutoDAB function entails the use of 3 vials, one vial each for chromogen, buffer and mixing vial. If a minimum of 5 slides are not selected the system displays a “BarCode Scan error”

After the display of error message, the system exits and mandates to select a minimum of 5 slides from the stainer window

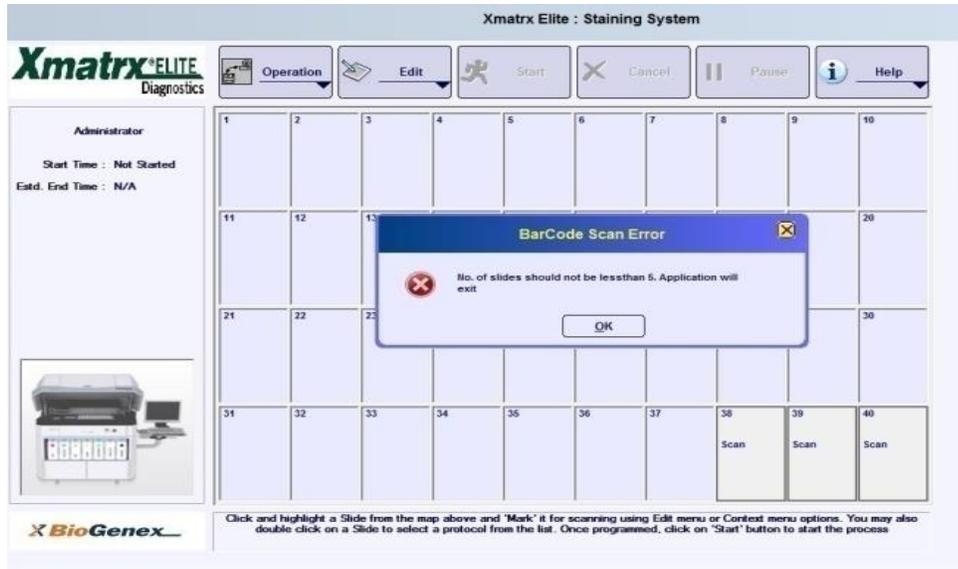


Figure 73: Barcode scan error

10.9 Error at Xmount Step

Coverslipping after applying Xmount is essential step to avoid drying of applied Xmount. Software is designed such that Xmount application is stopped if system encounters Empty Coverslip box at the time of applying Xmount or any step before.

When system encounters, there is empty coverslip in the box, after applying Xmount on the first slide of processing lot, it shows it in red color with error and stops further application of Xmount to next slides after blowing step.

- When system has encountered Empty Coverslip Box error at any step before the step of applying Xmount and proceeded without corrective actions, Blowing step before the application of Xmount are carried out and further operation is stopped over there showing error on the slides.

In both the cases, same corrective actions are to be followed.

Corrective action:

To resume the operation of applying Xmount, follow the steps mentioned in *Section* after which User needs to go to individual slide, right click it and select the <Resume Operation> from the dropdown list.

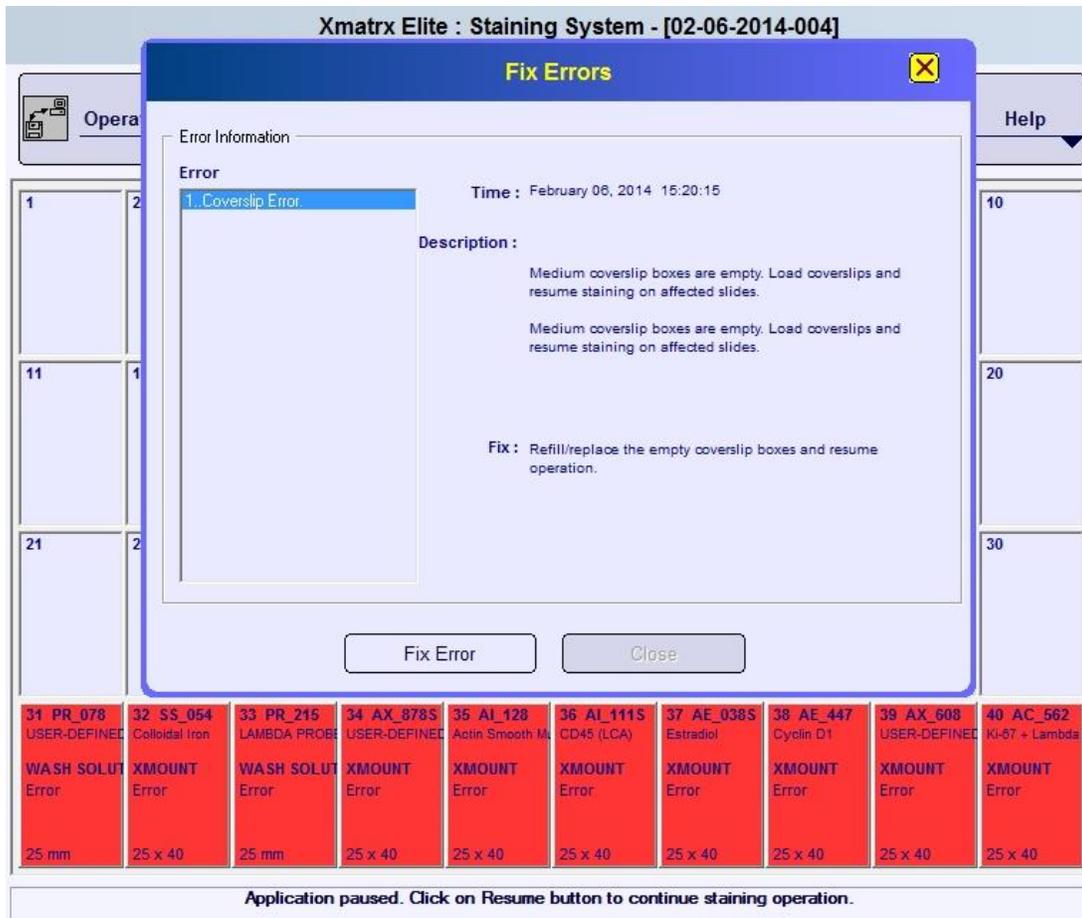


FIGURE 74: No coverslip ErrorAtXmount step

10.10. Basic Troubleshooting

No	Symptom	Possible Cause(s)	Corrective Action(s)
1	There is no power to the workstation	<ul style="list-style-type: none"> UPS may not be plugged in Power cord may not be plugged in Power switch not turned ON. No power to the receptacle Safety fuse may 	<ol style="list-style-type: none"> 1. Plug the UPS power cord into an appropriately grounded power source. 2. Plug the power cord into the UPS. 3. Find the power switch on the right side of the workstation, turn it ON. 4. Ensure that the power source has power supply. 5. Request authorized service

		be blown	personnel to check and replace the fuse.
2	Buffers are not primed.	<ul style="list-style-type: none"> Air leakage Air pressure may not be strong enough 	<ol style="list-style-type: none"> 1. Check carboy caps and gaskets, and ensure that they are tightly secured. Also check the connectors on Liquid Panel. 2. Check the Pressure Gauge, and ensure the pressure on the gauge is between 5.2 - 5.7 while priming. 3. If the problem still persists, please call BioGenex Customer Support
3	Failure in Coverslip pick up	<ul style="list-style-type: none"> Related CS stack is empty Vacuum pressure of Suction Cup is not strong enough Suction Cup may not have arrived at the correct position over the CS stack 	<ol style="list-style-type: none"> 1. Check the CS stack and fill in Coverslips as necessary. 2. Ensure there are no leakages in the tubing. 3. Suction Cup could have micro-tear. Call Service to replace the Suction Cup. 4. Request service personnel to calibrate Suction Cup with the CS stack
4	Failure in pipette tip pick up	<ul style="list-style-type: none"> Target pipette tip box is empty Pipette tip adapter cannot fit into a pipette properly 	<ol style="list-style-type: none"> 1. Fill in the Pipette Box, or replace it with a new box full of the correct size pipette tips. 2. Request service personnel to calibrate the Pipette Adapter with the pipette box.
5	Failure in pipette tip disposing	<ul style="list-style-type: none"> Stopping position of pipette tip adapter at pipette tip ejector is not correct 	Request service personnel to calibrate the disposal position of pipette tip adapter at the Pipette tip ejector.

SECTION 11.0

ROUTINE MAINTENANCE

The *Xmatrix® Elite system* requires minimal routine cleaning and sanitizing. Regular preventive maintenance ensures reliable and consistent staining and helps to eliminate any potential contamination.

11.1. Daily Cleaning

Daily cleaning needs to be performed after the last run of the day. It is recommended that the operator wear gloves.

1. Remove and empty the Waste Pipette tip tray from the workstation at the end of every workday. Dispose the used pipette tips and rinse the Waste Pipette tip tray with DI water. Place the Waste Pipette tip tray back into its position in the workstation after cleaning.
2. Use a soft and damp cloth or lint-free paper to wipe out any dirt from all four (4) of the pipette tip trays (the trays only, not the tips) if necessary.
3. Remove all reagent vials from the Reagent Rack. Remove the Reagent racks and rinse with DI water. Return onto the instrument after drying.
4. Remove and empty the Waste Coverslip Box. Rinse with DI water and dry.
5. Remove all slides from the slide racks. Remove all four (4) of the slide carriers and soak them in DI water to remove all traces of residue. Dry them with a cloth. Return them to their position.
6. Run System Clean-up (Log in as System Administrator):
 - a. From the **<Selection Window>**, select **<Run System Configuration>** to open the **<Xmatrix – System Configuration & Calibration>** window. Click on the **<Test>** and select **<System Cleanup>** from the drop-down menu (**Fig. 75**).

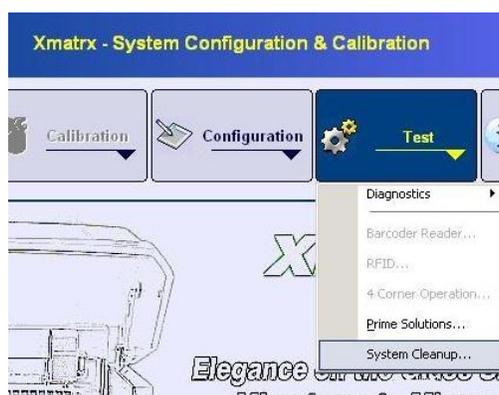


Figure 75:<Test> drop down list

- b. Make sure that the DI water and ethanol carboys contain an appropriate volume to perform the maintenance.

-
- c. The <System Cleanup> window will appear. Click <Start>(Figure 75a)
NOTE: System Cleanup will complete in approximately 30 minutes. It will utilize the water and ethanol carboys

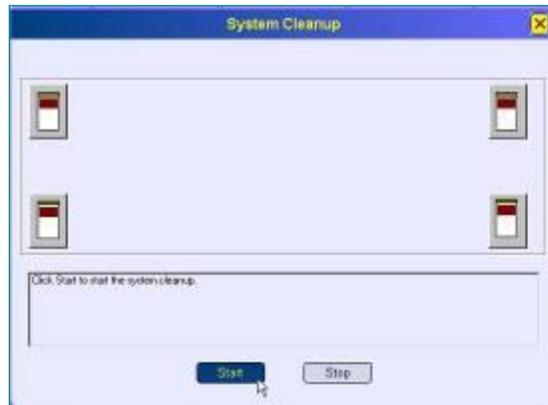


Figure 75a: System Clean Up

- d. After System Clean-up is completed, click on the <X> in the upper right hand corner of the screen to close the window
7. Use a soft and damp cloth to wipe off all of the visible interior and exterior surfaces of the instrument.



CAUTION:

It is not recommended to wash or rinse any area or surface of the instrument, especially the electrical components and circuits that sit above the Heater Base or under the Inspection Plate of the Housing. This could damage the instrument, causing an electrical short.

8. Use a clean and soft cloth to dry off all the surfaces of the instrument.
9. Clean the area surrounding the *Xmatrx® Elite* system.

Prime Solutions

Double-click on **Xmatrx** icon on the computer screen to open **<Log on>** window

As Administrator, click on **<Log on>** button in **<Log on>** window to open **<Selection Window>**, then click on **<Run System Configuration>** bar to open the **<Xmatrx – System Configuration & Calibration>** window

Click **<Test>** button in **<Xmatrx – System Configuration & Calibration>** to display a drop-down menu, select the option **<Prime Solutions>** to open the **<Prime Solutions>** window.

Operate in **<Prime Solutions>** window:

1. Click in the top four (4) squares to select all (i.e., Dewax, DI water, Alcohol, and Buffer Solutions).
2. Click to select one (1) of the four (4) Buffer Lines (repeat this selection with the remaining four (4) Buffer Lines after each round of priming, but deselect the Dewax, DI water, and alcohol after the first pass).
3. Click **<Start Priming>** button to start priming. Repeat the priming twice with a single buffer line. Click **<Close>** button to end priming with this particular buffer line.
4. Repeat above operation to complete the priming with all four (4) buffer lines.
5. Connect the alcohol carboy to Dewax line and perform priming. Connect the DI water carboy to all buffer lines except Dewax and Alcohol one after the other and perform priming. Example: Remove the IHC buffer carboy, connect the DI water carboy to the IHC buffer line and perform priming of IHC line. This ensures DI water is run through the IHC line. Repeat this for remaining buffer lines.
6. After priming every buffer line with DI water, click **<Close>** button to end priming.

Click the **<X>** button to close **<Xmatrx – System Configuration & Calibration>**, and click **<Exit the Application>** bar to exit **<Selection Window>**. The priming operation is done.

Follow the guidelines to operate in the **<Prime Solutions>** window:

11.2. Monthly Maintenance Schedule

The purpose of monthly maintenance is not only to clean the instrument, but also to prevent the growth of bacteria or mold within the tubing, bulk bottles, and in some areas of the instrument. This procedure should also be followed for disinfecting the instrument prior to transport or storage of the instrument.

1. Perform the daily clean-up procedure.
2. Move the Robotic-Head to the position above the drain hole of the Slide Block. There are three ways to do this:
 - i. Open the **<Prime Solutions>** window in the **<Xmatrx-System Configuration & Calibration>** module (see details in the flowchart under 'Prime Solutions' on the previous page). The Robotic-Head will move over the drain hole in the Slide Room automatically.
 - ii. Turn OFF the power to the workstation. Slide the gantry forward until the Robotic-Head points to the drain hole of the base plate.



CAUTION:

The computer can still be powered ON while the instrument is powered OFF. Never turn OFF the computer while the instrument is ON.

- iii. From **<Xmatrx-System Configuration & Calibration>** select **<Test>**. Click on **<Diagnostics>** from the drop-down menu to open **<Diagnostics – Motion>** window (Fig. 76). In the **<Diagnostics – Motion>** window, use the X/Y arrows to bring the Z-Head to the correct position directly above the drain hole of the instrument.

OR

Enter the X 1000 / Y 2100 / Z 0 coordinates in the X, Y, Z fields under **<Current Position>**, then click on the **<Go to Position>** button. The Z-Head will move to the specified position.

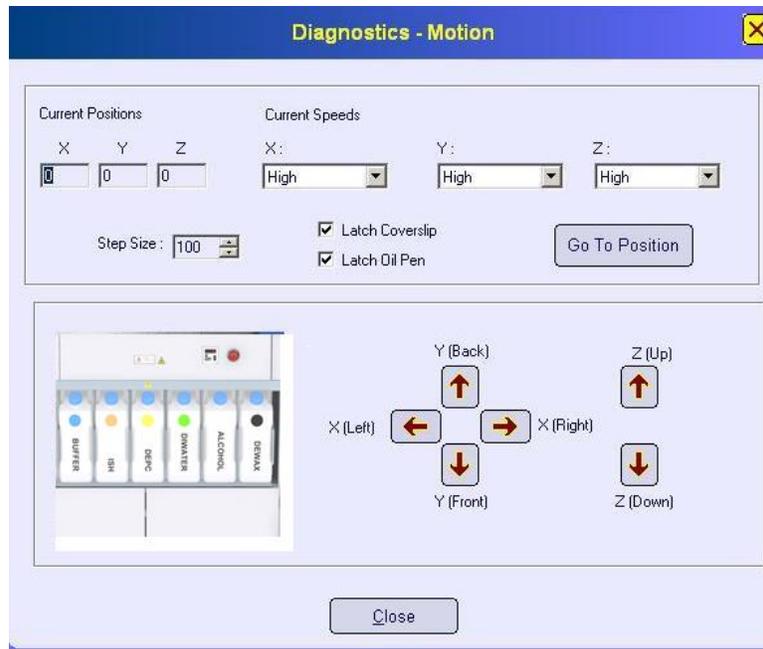


Fig. 76: <Diagnostics – Motion> window

3. Clear off DeWax residue from Dewax line: If Dewax solution has been used through the Dewax line, empty the Dewax carboy; fill it with 100 ml of alcohol. Prime Dewax line three (3) times with the alcohol. Let it sit for ten (10) minutes after the final priming. The alcohol should be rinsed away from Dewax line later. (See below).



NOTE:

Skip the above step if the Dewax feature was not utilized during any staining operations prior to this monthly maintenance schedule.

4. Rinse all the buffer carboys with DI-water: Disconnect all seven (7) buffer carboys from the instrument. Remove the caps from the buffer carboys and empty each carboy. Fill in each bottle with one gallon of DI-water and add a capful of chlorine bleach. Shake the bleach solution thoroughly in every carboy. Empty the bleach solution from the buffer carboys.



WARNING:

Before rinsing the Waste Carboy, turn it in to your Biological Safety Management Office for a proper treatment in accordance with EPA hazardous waste regulations and other local, state, and federal regulations.

-
5. Prepare fresh cleaning solution for each buffer carboy: Empty the buffer carboys, and use one carboy to dilute 150 ml of Professional Lysol Deodorizing cleaner (the active ingredient: alkyl dimethyl benzyl ammonium chlorides) to 3,600 ml with distilled water.
 6. First rinse the liquid transportation system with Lysol deodorizing cleaning solution: Recap each carboy filled with the above cleaning solution; re-attach them to their appropriate ports on the Liquid Panel. Prime their liquid lines three times. Wait for ten minutes after the final priming. Empty the Carboys.
 7. Second rinse of the Carboys with DI-water: Fill each of the seven (7) Carboys with 3 to 4 liters of DI-water only. Re-attach the buffer carboys (i.e., including Waste Carboy) to their appropriate connectors on the instrument. Rinse their liquid lines by priming three (3) times. Empty the Carboys store them upside down and allow drying.
 8. Clean the drainage tray (i.e., the base of the instrument) with powdered cleanser (i.e., bleach) and a soft plastic brush. Rinse and dry the tray. Ensure that the waste liquid can be drained properly. Check and adjust the drainage tubing as necessary.
 9. Dry the interior of the instrument by wiping all surfaces with a clean soft cloth.
 10. Leave the 'Housing Cover' open and let the instrument for an overnight drying.

11.3. Half Yearly Maintenance Arrangement

Only a trained service technician, or BioGenex service staff, can perform this preventive maintenance every six (6) months. For documentation purposes, it is required that the maintenance report with the instrument serial number, and the maintenance date be clearly filled out.

See Appendix 2 for PM checklist

APPENDIX 1

SERVICE PLAN

For a period of one year from the date of installation ("Service Period"), BioGenex Laboratories, Inc. ("BioGenex") will provide the following services for maintenance and repair of the *Xmatrix® Elite Automated Staining System* ("System") purchased, leased or rented by the Customer ("Services"):

1. Preventative Maintenance Service
2. Emergency Repair Service
3. Software Upgrades

I. Customer Responsibilities

Customer must

1. Maintain the installation site and its environment in a condition suitable for operation of the System, and
2. Maintain the System under the daily/monthly routine maintenance schedule as provided in the System User's Manual.

II. Service Charges

BioGenex may charge the customers its standard service rates or may decline to provide the services required to correct a malfunction caused by Customer's failure to fulfill its responsibilities hereunder: the failure of anyone other than BioGenex or its service contractor to comply with its written instructions or recommendations, the combination of the System with an incompatible third party product, the alteration or improper storage, handling, use or maintenance of any part of the System by anyone other than BioGenex or its service contractor, any factor external to the System or beyond BioGenex reasonable control.

III. Additional Terms

Services will be provided during regular business hours. BioGenex may subcontract with service contractors any of the service obligations to Customer. No such subcontract will release BioGenex from its obligations to Customer. In lieu of repair, BioGenex may elect to replace the System or any part thereof, or refund the portion of the Purchase Price paid by Customer. Replacement parts will be provided on an exchange (refurbished) or new part basis, at BioGenex's option. Labor to install replacement parts is included. Replaced parts become BioGenex's property. Components of the System covered by a third party warranty are subject to the limitations contained in that warranty. The Services are due only if the System remains at the Installation Site. Rigging or facility services, accessory, consumable and supply items are charged separately. The Services provided under this Service Plan are performed under the terms and conditions of the Standard System Purchase and License Agreement or Lease and Reagent Purchase Agreement between BioGenex and Customer, as applicable, which are incorporated herein by reference.

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V. Diagnostics and Calibration

BioGenex service personnel or an authorized technician will perform any service, including calibration. An operator should not conduct calibration with this system. When in need, please call BioGenex Customer Support.

The administrator can make a good use of the diagnostics feature of the *Xmatrix® Elite Diagnostics system* to test the functioning of the system, or to locate the problem with the system. In the *Xmatrix® Elitesystem*, there is a diagnostics program ready for use. The most basic module in diagnostic program is the <Test> function. The future **<Diagnostics>**, in which the **<Operation>** screen is an all-inclusive window for testing any of the visible mechanical performances of the Z-Head assembly. Specifically the following operations can be tested:

- Slide operations
- Pipette operations
- General operations
- Reagent operations
- Coverslip operations

To enter **<Operations>** window:

1. Double-click on the **<Xmatrix>** icon on the computer screen to open the **<Log on>** window.
2. Enter as Administrator and enter the password, and select **<Log on>** to open the **<Selection Window>**
3. Select **<Run System Configuration>**. The **<Xmatrix – System Configuration & Calibration>** window appears.
4. Select **<Test>** to open a drop-down menu.
5. Select the option **<Diagnostics>** in the drop-down menu to open a sub-menu.
6. Select **<Operation>** in the submenu. The **<Operations>** screen (**Fig. 77**) will appear.

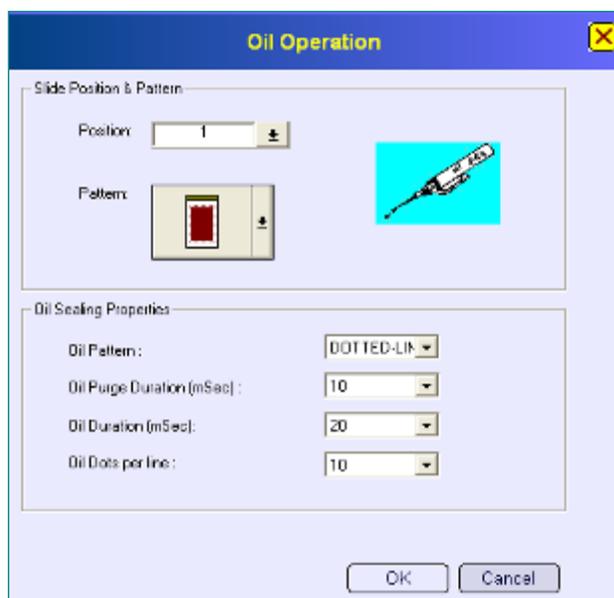


Fig. 77: <Operations> Window

The <Operations> window has five modules, namely – Slide Operations; Pipette Operations; Reagent Operations; Coverslip Operations and General Operations.

By clicking on any button under a module, an operation window will open to work in. Follow the instructions in the window to proceed.

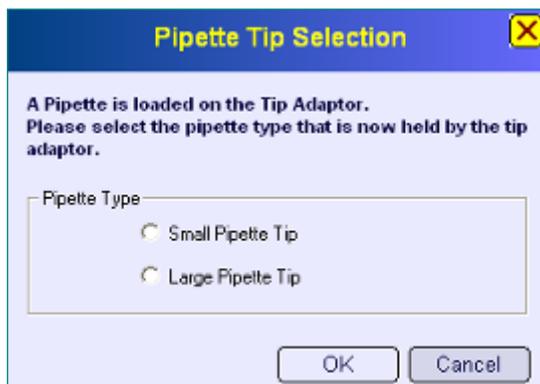
Slide Operations



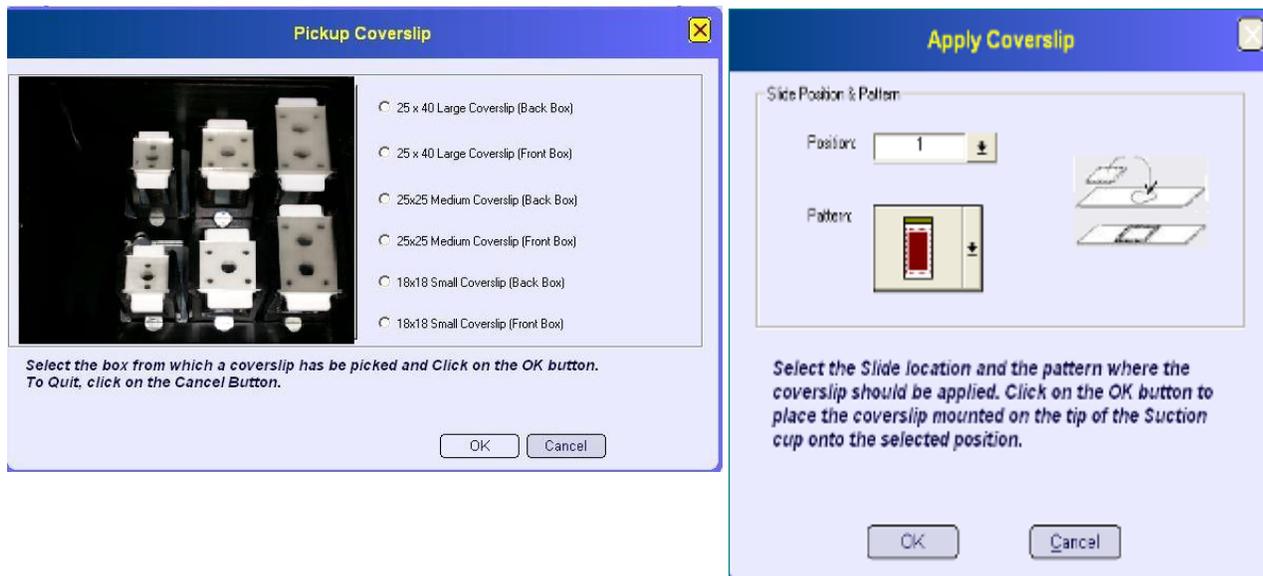
Pipette Operations



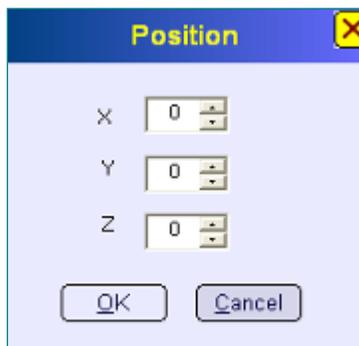
Reagent Operations



Coverslip Operations



General Operations



Under the <Diagnostics> drop-down menu, there are tests for <Sensors & Latches>, <Temperature>, and <Motion>.

Service personnel will guide the user through these tests, if necessary.

APPENDIX 2:**PREVENTIVE MAINTENANCE CHECKLIST FOR (for Service Personnel)**

Sr. No.	Items to check	Result (Circle as appropriate)		Note
1.	Monitor display is very clear to	Yes	No	
2.	Keyboard functions well	Yes	No	
3.	Run the “Check Disk C:” feature	Done	No	
4.	Clear previous data of staining runs from computer	Done	No	
5.	Check and update software version of Xmatrx	Done	No	Save data to diskettes if necessary
6.	Check connection of quick connectors and valves on Liquid Panel	Done	No	
7.	Check the overall condition of Z-Head assembly, and tighten the screws	Done	No	
8.	Check Housing Cover Switch and E-Stop switch	Done	No	
9.	Check the connection of all cables and wires to the Electrical Panel	Done	No	
10.	Calibrate Z-Head movement and test Tip Sensor, etc.	Done	No	
11.	Use “Calibration” screen to calibrate Z-Head assembly	Done	No	
12.	Calibrate Barcode Scanner performance	Done	No	
13.	Test functionality of Z-Head assembly by Diagnostics	Done	No	
14.	Conduct “Temp Switching Test”, “Peak Temp Test”, and “Temp	Done	No	

Durability Test"				
15.	Follow monthly maintenance schedule to complete cleaning work with workstation, carboys and liquid lines	Done	No	Gaskets/O Rings of the caps O.K?
16.	Check the Viton tubing in the carboys and replace if necessary.	Done	No	
17.	Check the gas spring of the lid	Yes	No	
18.	Replace the Assy Carboy 4L Dewax (Part # 65020-30713) with new one	Yes	No	
19.	Check visually for proper oil dispense. Replace oil needle if needed	Yes	No	
20.	Check visually for accurate coverslip positioning	Yes	No	
21.	Check for any shearing or loosening of the Z Head solenoid shafts	Yes	No	
22.	Check for proper operation of the anti-drip valves	Yes	No	No leakage when OFF No blockage when ON
23.	Check the oil tubing (PVC) and replace if necessary.			
24.	BARCODE reader calibration	Done	No	
Comment				

Maintenance Performed by: _____

Date: _____

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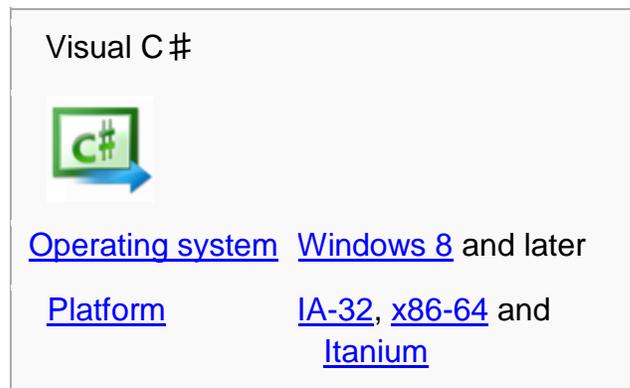
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7. Microsoft Visual C# is Microsoft's implementation of the C# specification, included in the Microsoft Visual Studio suite of products. It is based on the ECMA/ISO specification of the C# language, which Microsoft also created. While multiple implementations of the specification exist, Visual C# is by far the one most commonly used] In most contexts, an unqualified reference to "C#" is taken to mean "Visual C#

The term Visual denotes a brand-name relationship with other Microsoft programming languages such as Visual Basic, Visual FoxPro, Visual J# and Visual C++. All of these products are packaged with a graphical IDE and support rapid application development of Windows-based applications.

Visual C# is also heavily used by ASP.NET web sites and standalone applications based on the .NET Framework.



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APPENDIX 5



Xmatrx Maintenance Schedule

Xmatrx Diagnostics System requires minimal routine cleaning and Sanitizing. Regular maintenance ensures reliable and consistent staining and helps to eliminate any potential contamination.

The below mentioned cleaning procedure needs to be performed after the last run of the day. It is recommended that the operator wear gloves before starting the cleaning.

Sl.No	Activity	Daily	Weekly	Monthly	Remarks
1	Waste Tip Disposal	✓	✓	✓	NA
2	Waste Coverslip disposal	✓	✓	✓	NA
3	Empty the Waste carboy	✓	✓	✓	NA
4	System Clean up	✓	✓	✓	Select System Clean Up in Run System Configuration
5	Heater Flat form cleaning	X	✓	✓	NA
6	IHC Carboy Cleaning	X	✓	✓	With DI Water or Chlorine bleach
7	DI-Water Carboy Cleaning	X	✓	✓	With DI Water or Chlorine bleach
8	De-Wax Carboy cleaning	X	✓	✓	With Alcohol
9	Priming IHC line	X	X	✓	With DI Water
10	Priming DI Water line	X	X	✓	With DI Water
11	Priming De-wax line	X	X	✓	Remove Dewax Carboy and prime with Alcohol
12	Clean Slide racks	X	X	✓	With DI Water
13	Clean Waste cover slip Box	X	X	✓	With DI Water
14	Clean Pipette disposal Box	X	X	✓	With DI Water
15	Clean the Reagent tray	X	X	✓	With DI Water
16	Clean the Waste Carboys	X	X	✓	With Chlorine bleach and again with DI Water
17	Clean the instrument inside and outside with Soft Damp cloth	X	✓	✓	NA

Lab Technician: _____

Lab In charge: _____