Xmatrx® Infinity

Automated Staining System for IHC, ISH, SS and FISH

OPERATOR'S MANUAL

Cat. No.: AS4000RX

CE

FOR RESEARCH USE ONLY

BioGenex

Doc. No: 953-0035.0 Rev. L. ECO: 734-SEZ

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IMPORTANT:

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

The material in this manual is subject to change without notice. There may be revisions in new editions of this manual, please contact BioGenex Customer Service to inquire about the current edition of this manual or to purchase a copy.

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Overview of the *Xmatrx*® *Infinity* Automated Staining System
Software Version 2.5R01b

BioGenex *Xmatrx*® 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*® 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 *Xmatrx*® *Infinity* 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	6520-60104	1
3.	Pipette Tip Waste Box	6520-17701C	1
4.	Reagent Vial 17 ml -	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 Xmatrx Elite and Infinity	XT148-YCDE	1
16.	Assembly Calibration Disk	6520-30753	1
17.	Software Distribution Package for Xmatrx Infinity	4812-00115	1
18.	Xmatrx 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 Xmatrx Infinity System (Auto executable CD)	4812-00119	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, ¼" 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

Xmatrx Infinity									
Sl.No	Item		Catalog No.	Qty	No of Tests	IHC	ISH	SS	*FISH
1	IHC Xflex Ultra Consumable Kit contains below items)		XT148-YCDE	1 kit	200	✓	NA	NA	NA
	1a	BARRIER SLIDE 25 X 40MM	XT151-SL	3	200			✓	✓
	1b	COVERSLIPS 25 X 40MM	XT118-YRK	2				✓	✓
	1c	PIPETTE TIPS	XT146-01X	1				✓	✓
	1d	PIPETTE TIPS	XT153-02X	2				✓	✓
2	ISH Consumable kit- Xmatrx (Contains Below items)		XT144-YAD	1 kit	100	NA	✓	NA	NA
	1a	BARRIER SLIDES 25 X 25MM	XT108-SL	2	100			NA	✓
	1b	COVERSLIPS 25 X 25MM	XT122-YQK	2				NA	✓
	1c	PIPETTE TIPS	XT146-01X	1				NA	✓
	1d	PIPETTE TIPS	XT153-02X	2				NA	✓
3	Xviz Detection kit		QD550-YCDE	1 kit	200	✓	NA	NA	NA
4	XISH One step Polymer HRP ISH Detection kit		DF400-YADE	1 kit	100	NA	✓	NA	NA
5	Super Sensitive Wash buffer (500ml. Conc.)		HK583-5KE	1 kit	100	✓	✓	✓	✓
6	EZ Dewax/ X-Dewax		HK584-5KE / HX016-XAK	1 kit	40	✓	✓	✓	✓
7	Antibodies*		refer catalog	1 vial	50/200	✓	NA	NA	NA
8	ISH Probes*		refer catalog	1 vial	25	--	✓	NA	NA
9	Special Staining Kit*		Refer catalog for required stain	1	50	NA	NA	✓	NA
10	eFISH Histo kit / eFISH Cyto kit		DF500-20XE / DF510-20XE	1	20	NA	NA	NA	✓
11	Barrier Slides 18x18 mm		XT114-SL	1	70	NA	NA	NA	✓
12	Cover Slips 18x18mm		XT121-YBX	1	20 approx	NA	NA	NA	✓
13	DAPI		HK606-10K	1	10 tests	NA	NA	NA	✓
14	eFISH probes		Refer Catalog	1	10/20 tests	NA	NA	NA	✓
15	Optimiser Reagent vials 20ml unlabelled , White/Brown		XT026-V24 / XT101-24X	1	24 Vials	NA	NA	NA	✓
16	XMount™ for Xmatrx® Infinity		HX035-10x	1	200	✓	✓	✓	NA
17	Vial Insert - 2ml 24 per pack		XT149-v24	1	NA	✓	✓	✓	✓
18	Brown Vial without neck 24 per pack		XT126-24V	1	NA	✓	✓	✓	NA
19	Unlabeled Xmatrx infinity 17ml white vial		XT154-v24	1	NA	✓	✓	✓	NA

20	Unlabeled Xmatrx infinity 17ml brown vials	XT155-v24	1	NA	✓	✓	✓	NA
21	Reagent Tray for FISH (30 Position)	6520-37404B	1	NA	NA	NA	NA	✓

NOTE: 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:

- There are no user serviceable parts in the Xmatrx® system. When any service is needed, please consult BioGenex Laboratories, Inc. at 1-800-421-4149 (for USA and Canada only), or 510-824-1400 for all repairs.
- To order consumables or reagents, please contact BioGenex Laboratories, Inc. For detailed contact information, see page IV of this manual.

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SECTION 1

INTRODUCTION TO *Xmatrx*®

I. Intended Use:

Xmatrx® Automated Slide Staining System is for Research Use Only. This system performs Immunohistochemistry (IHC), *In Situ* Hybridization (ISH), Special Stains (SS) tissue staining, FISH and many more techniques.

The Xmatrx® system must be used and handled by skilled and trained personnel. All personnel 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. This system does not provide interpretation of any staining results. Such interpretation is solely the responsibility of the user.

II. 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 multifunctional 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 coverslips at any step.

The computer is for running the *Xmatrx*® System, and should not be used for any other purpose.

III. Transportation and Storage of the Workstation

New and disinfected workstation(s) may be transported on any commercial vehicle suitable for the purpose, with adequate protective packaging provided by the original shipping crate. If the workstation is to be stored for an extended period of time, the original shipping crate must be used. The storage environment should be indoors, dry and protected from freezing temperatures, insects and rodents.

IV. Specifications

Item	Specification	Item	Specification
Total Slide Capacity	4 removable slide carriers x 10 slides per carrier = 40 slides	**Evaporation Control**	Oil sealing
Reagent Capacity	1 Reagent Tray with up to 49 vials of reagents	**Bulk Fluids**	7 User Defined Buffers (including DeWax and Alcohol)
Reagent Dispense Volumes	10-850 µl	**Staining Operation**	Multiple protocols can run simultaneously Multiple parameters within a single run
Reagent Dispenser	Standard 1 ml disposable tips - for macro reagents Standard 200 µl disposable tips – for micro reagents	**Weight**	400 lb/182 Kg
Pipette Tip Trays	Four trays: Two 96-tip disposable trays for 1 ml tips Two 96-tip disposable trays for 200 µl tips	**Electrical Specifications**	115V 60Hz 900W 230V 50Hz 900W
Slide Temperature	25°C to 105°C Each slide individually temperature controlled	**Ambient Operating Temperature**	15-30°C (59-86°F) Humidity 15%-55% RH
Integrated Cover-slipper	Places and removes individual coverslips Two coverslip boxes each for: ▪ 25 x 40 mm ▪ 25 x 25 mm ▪ 18 x 18 mm	**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/7/8/9/10IOT)

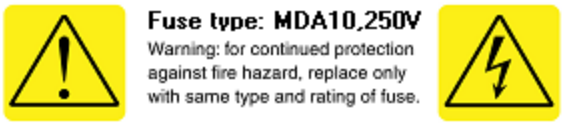
SECTION 2

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 Laboratories, Inc. assumes no liability for the user's failure to comply with these requirements.

I. Precautions and Warning

Xmatrx® 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 accessory list.



1.1 Do not operate the system in an environment where flammable vapors may be present. Operating AC-line-powered equipment in such an environment may cause an explosion.

1.2 When replacing fuses on the automated staining system, make sure that the correct fuse is used. Using the wrong fuse may lead to fire or instrument failure.

1.3 The AC-line cord provided with the staining system is intended to ground the chassis to help prevent shock and injury to personnel. *Xmatrx*® 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.

1.4 Be aware that during or shortly after a high temperature step on the workstation, touching the hot Heater Top(s) may cause burns.

1.5 Use of *Xmatrx*® may require 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.

1.6 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.

1.7 Liquids used on *Xmatrx*® 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.

1.8 Liquid waste produced from running the *Xmatrx*® system may be hazardous and should be disposed off properly according to local regulations.

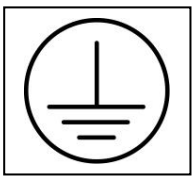
1.9 Excessive jarring of the workstation while the housing is open may cause the housing to close unexpectedly.

1.10 Test for ground continuity between the system chassis and adjacent equipment or metal plumbing to ensure that the operator cannot 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

1.11 Do not service the system while power is ON. Refer all servicing to a qualified technician.

1.12 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.

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



1.14 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.

II. Disclaimer Regarding Staining Results

Xmatrx® Staining System may be used only for Research 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.

III. Precautions Regarding Biohazardous Materials and Waste

Do NOT dispose of 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 of in the proper manner.

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 *Xmatrx*® to determine whether their waste is considered hazardous or not.

For the purpose of the above disclaimer, biohazardous 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 biohazardous 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 biohazardous waste generated on this instrument.

SECTION 3

ON-SITE INSTALLATION

I. Installation Requirements

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

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

a) Locate the *Xmatrx*® within three (3) feet of a suitable grounded electrical outlet.

b) The *Xmatrx*® 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 allow disconnecting 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 *Xmatrx*® that may obstruct access to the main switch or power cord.

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

c) It is not recommended that the *Xmatrx*® be located on a carpeted floor.

d) When selecting a location, be aware not to place a load upon any floor of the premises exceeding the floor load per square foot area, which such floor was designed to carry. Point loading must also be considered. The leveling pads of the *Xmatrx*® can apply a point load of approximately 55 lb/in^2.

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

II. Installation of Buffer Carboys to the Liquid Panel.
There are 7 carboys each(4L), one for IHC application and the other for FISH application.

The complete set of carboys consists of nine (9) Carboys (Figure 6): Two (2) 15L carboys are used for collecting the waste generated, and seven (7) 4L Carboys for seven (7) different solutions. The colored liquid sockets on this panel are presented in this order:

- Red
- Blue
- Orange
- Yellow
- Green
- White
- Black

The corresponding seven (7) buffer carboys for IHC are labeled as:

- IHC (red)
- SS (blue)
- ISH (orange)
- DEPC (yellow)
- DI-Water (green)
- Alcohol (white)
- Dewax (black)

The corresponding seven (7) buffer carboys for FISH are labeled as:

- Buffer-1 (red)
- Buffer-2 (blue)
- Buffer-3 (orange)
- Buffer-4 (yellow)
- DI-Water (green)
- Alcohol (white)
- DeWax (black)

Before attaching the buffer carboys, make sure the caps are secured tightly to the carboys. Make sure that the carboys caps are not over tightened also. Over tightening may result in cracking of the caps.

Set of 7 Buffer Carboys

The list of carboys for IHC and FISH are listed in the **Table 1a and 1b** respectively. There are seven (7) pairs of sockets on the Liquid Panel. Each pair consists of a white connector for air tubing, and a colored connector for liquid tubing connection (Figure 1a & 1b). When connecting carboy to liquid panel, be sure to match the color of a carboy connector with the color of a connector on this liquid panel. Please connect the carboys as described in **Table 1a and 1b**.

Figure 1a: **"**Liquid Panel" of the Workstation

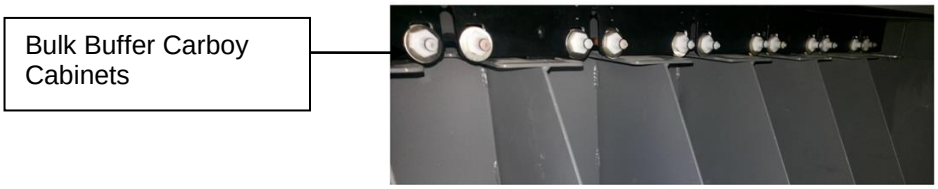


Figure 1b: **"**Liquid Panel" of the Workstation

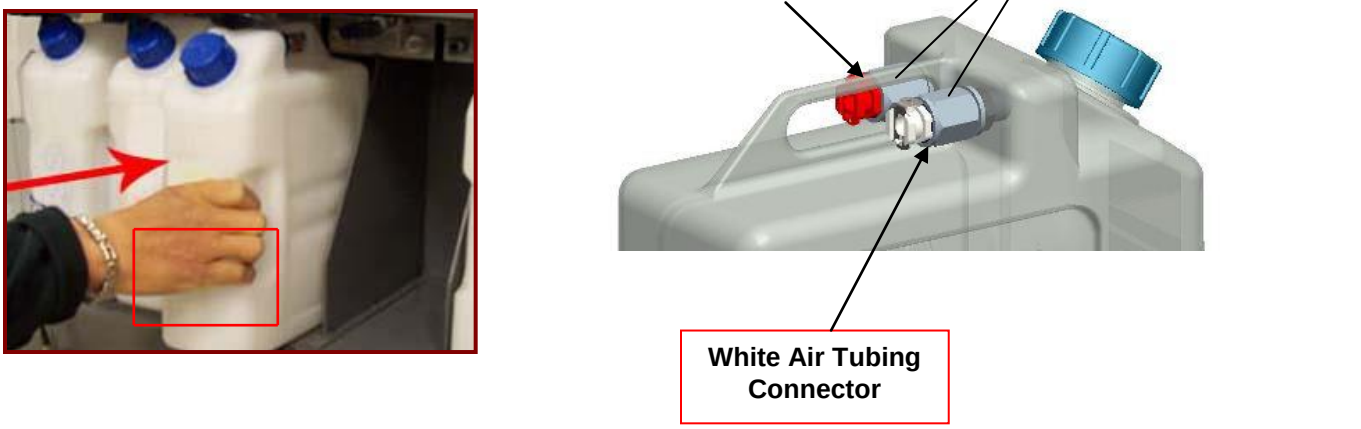


Fig 03: Loading/Unloading a Carboy

To install Carboys:

***Xmatrx*® Seven Liter (7L) Carboy Installation Instructions**

The 1st step to insert a carboy and lock with locate . Fig.3. press the tab to release the carboy form lock. Insert carboys according to the color labels by sliding carboy into the appropriate position. Push into position until locked into the connectors (Fig.2). Ensure the pressure returns to >5.0 on the pressure display (Fig.4).

Figure 2: Loading Carboys

Figure 4: Pressure Gauge

To release carboys for filling or cleaning, pull the release handle above the carboy (Fig.3). Pressure and lock will release and carboy can be removed (Fig.5).

Figure 5: Remove Carboy

Please connect the carboys as described in Table.1a for IHC run and 1b for FISH run.

Table 1a: Connection Method of 7 Carboys to the Workstation for IHC

Carboy Order in the Shelf (From Left to Right)	Connector Color of Carboy	Type Of Tubing	Socket Color on Manifold
IHC Wash	Red	Black Viton®	Red
SS Wash	Blue	Black Viton®	Blue
ISH Wash	Orange	Black Viton®	Orange
DEPC Water	Yellow	Black Viton®	Yellow
DI Water	Green	Black Viton®	Green
Alcohol	White	Black Viton®	White
DeWax	Black	Black Viton®	Black

Table 1b: Connection Method of 7 Carboys to the Workstation for FISH

Carboy Order in the Shelf (From Left to Right)	Connector Color of Carboy	Type Of Tubing	Socket Color on Manifold
Buffer-1	Red	Black Viton®	Red
Buffer-2	Blue	Black Viton®	Blue
Buffer-3	Orange	Black Viton®	Orange
Buffer-4	Yellow	Black Viton®	Yellow
DI Water	Green	Black Viton®	Green
Alcohol	White	Black Viton®	White
DeWax	Black	Black Viton®	Black

NOTE: When connecting, insert the 4L Carboy into matching color slot, push until connectors are seated firmly into manifold. Repeat the same for other Carboys. Two (2) waste bottles are placed on the lower deck in the front cabinet of the cart.

CAUTION

Xmatrx® Staining System should be installed by authorized BioGenex service personnel. Once installed and tested on site, the system is intended to remain in that location. If it is necessary to relocate the staining system, contact BioGenex to prepare the system for transport and reinstallation.

Failure to properly prepare the system for transport may result in damage to the automated mechanisms of the system.

This symbol alerts the user that appropriate precautions must be followed when connecting carboys to the cart. Be sure to match the color of each carboy connector with the color of the corresponding socket in the manifold when plugging in the connectors.

Part 2: Priming of Second 2X SSC Carboy During Run Initiation

After initiating a run on the Xmatrx system, the Verifying Consumables and Prime Screens will be displayed. At the "Prime Solutions" screen (**Figure 11**), the Buf. 3-(Orange) box will not be checked. In order to prime the second 2X SSC solution in the carboys, the operator must manually place a check mark in the box next to the "Buf. 3-(Orange)" (**Figure 12**) and continue.

Figure 11: Prime Solutions Screen

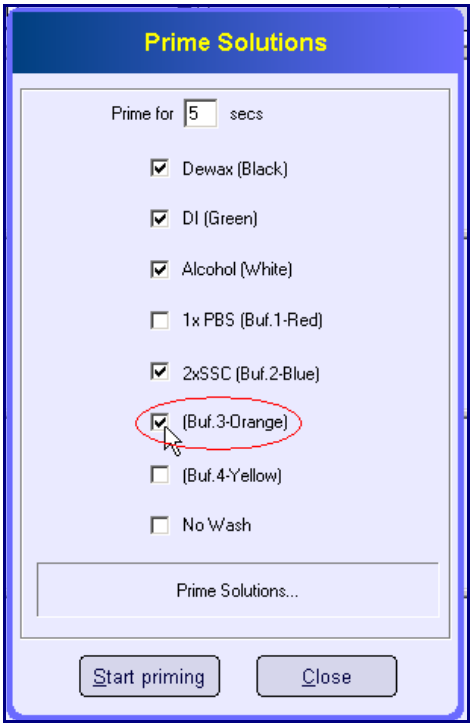


Figure 12: Prime Solutions Screen with Buf. 3-Orange checked for priming

III. Waste Carboy Connection

Install the Waste Carboys by attaching the volume sensors and waste tubing. When the waste tubing is connected to the waste carboy, make sure that the connector snaps into the mating 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.

Figure 13a: Waste Carboys

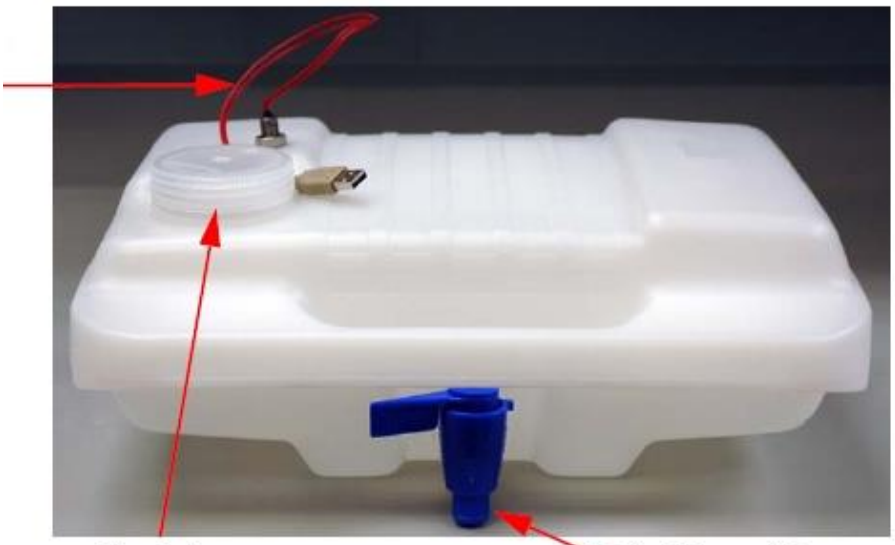


Figure 13b: Waste Carboys

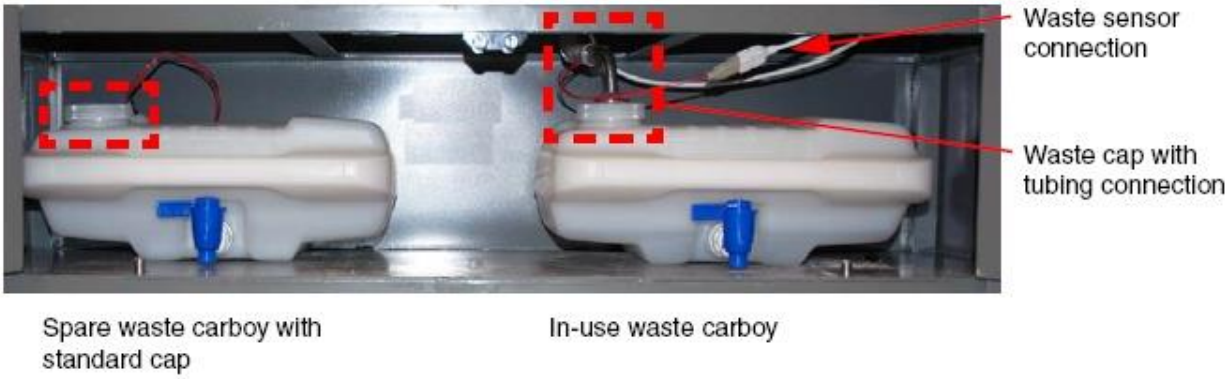


Figure 13c: Waste Carboys

Figure 14: Volume Sensor

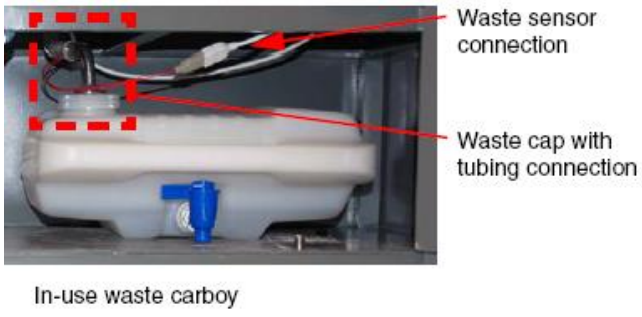


Figure 15: Waste Tubing

IV. Glossary

Term	Definition/Description
Bulk Bottles	Carboy for containing special liquids such as buffer and DI water. A complete set of buffer carboys for one (1) workstation consists of seven (7) buffer carboys.
Coverslip Mechanism	A combination of the Coverslip (CS) Box and the coverslip tray. The box is the CS container, and the tray holds the boxes in place. There are six (6) CS boxes in three (3) pairs of different sizes (18x18, 25x25, 25x40 mm) in a workstation.
E-Stop Button	Emergency stop button, located at the front of the *Xmatrx*® 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 *Xmatrx*® workstation and its accessories. The entire workstation sits on top a 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 pipette tips (1 ml each).
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	Oil bottle mounted on the robotic arm.
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 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 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.

Term	Definition/Description
Reagent Tray	A compartment in the front left corner of the workstation for holding reagent vial(s). Up to 49 reagent vials can be accommodated.
Robotic Arm	XYZ robotic arm allowing tri-axial movement with a unique multifunctional staining head that can pick up and discard pipette tips, apply reagent to tissue sections, rinse the slide(s), and blow the excess buffer off slide(s) at the end of a wash step. The Suction Cup, Robotic Head, Oil Pen, and Pipette Adapter are mounted on the robotic arm.
Robotic Head	Function module attached to the Z-Head that sprays liquid onto a slide and/or blow away liquid from a slide.
Slide Block	The largest separated space on the processing platform inside the workstation. A total of four (4) Slide Carriers are placed in this room, and each of the Slide Carriers contains ten (10) Slide Holders. Therefore, it allows up to 40 slides to be processed per run.
Slide Carrier	A long and rectangular compartment that holds ten (10) Slide Holders.
Slide Holder	A rectangular compartment on a Slide Carrier.
Small Pipette Tip Tray	Blue removable tray with 96 slots for a total of 96 BioGenex supplied white pipette tips (200 µl each).
Suction Cup	Translucent rubber cup for picking up Coverslips from a Cover-Slip Holder, or from a slide. The Suction Cup is attached to the lower back end of the Z-Head.
Waste Carboys	Two (2) carboys of 15 liter capacity each are stored in the cabinet at the base of the system for waste reagent from the system.
Waste Coverslip Box	Stainless steel box that collects used Coverslips.
Waste Pipette Tray	Removable tray, placed under the Pipette Well, for holding the used pipette tip(s) discarded by the Z-Head during operation.

SECTION 4

STARTING THE SYSTEM

I. Loading Consumables

Step	What to Load	Where to Load	How to Load	Precautions
4.1.1	**Slide**(s) with specimen. Up to 40 Slides may be loaded in a single run.	Slide Holders in the 4 Slide Carriers in the Slide Block	a) **Lift** the latch of the Slide Holder. b) **Tilt up** the open end of the frame of the Slide Holder with your fingers. c) **Insert** a Slide into the groove of the Slide Holder. Be sure to place the frosted end of the slide upwards. d) **Press** the frame into place, and push the Lock button forward to lock slide. e) **Repeat** the above steps to load other slides into the Slide Carrier(s) as needed. **NOTE**: Alternatively the slides may be loaded by: 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)	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. Ensure slide is loaded sample side up.
4.1.2	**Coverslip**(s)	Up to 6 Cover-Slip Boxes at the back left corner of the workstation	1. Load coverslips into coverslip boxes. 2. Attach the coverslip boxes to the coverslip tray in their respective magnetic grooves.	The Cover-Slip(s) should be stacked and loaded in the appropriate tray. Ensure open ends are to the front and back of system, not to the sides.

Step	What to Load	Where to Load	How to Load	Precautions
4.1.3	**Reagent**(s)	49 Reagents Vials are loaded into the Reagent Tray accordingly	**Place** vials, one by one into the Reagent Tray without removing the tray from the workstation. **NOTE:** Always place the top opening of every vial toward the left wall of the Reagent Tray. **NOTE**: Alternatively the reagent tray can be loaded by: 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.

Step	What to Load	Where to Load	How to Load	Precautions
4.1.4	**Pipette Tips** of different volumes (1 ml & 200 μl)	Up to 4 Pipette Trays of 96 slots in each tray. There are 2 types of Pipette Trays.	a) **Pull up** the blue Large Pipette Tray by grasping its two flaps. Remove it from the workstation. b) **Fill in** or replace with new box of blue pipette tips (1 ml/each tip). c) **Place** the Large Pipette Tray back and press it down firmly into its position in the workstation. d) **Repeat** above three steps to load the second Large Pipette Tray. e) **Remove** a black metal frame of small pipette tray from workstation. f) **Insert** a whole box of the white Small Pipette Tray with white pipette tips (200 μl/each tip) in it. g) **Place** the black metal frame of small pipette tray back into its position in workstation. h) **Repeat** above three steps to load the second Small Pipette Tray.	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 Service to fill oil bottle	

Fig: A Coverslips Loading

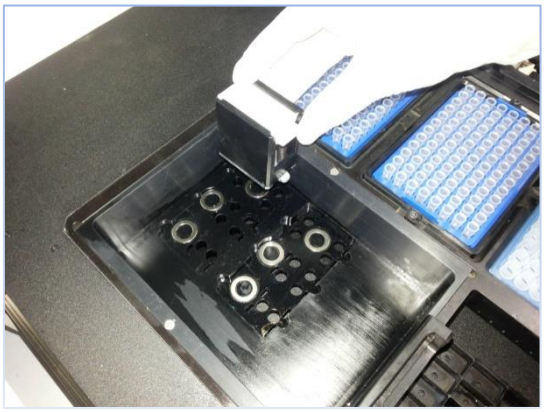


Fig: B Coverslip stack placing in to respective grooves

Figure C Working Plat Form

II. Starting the System Flowchart

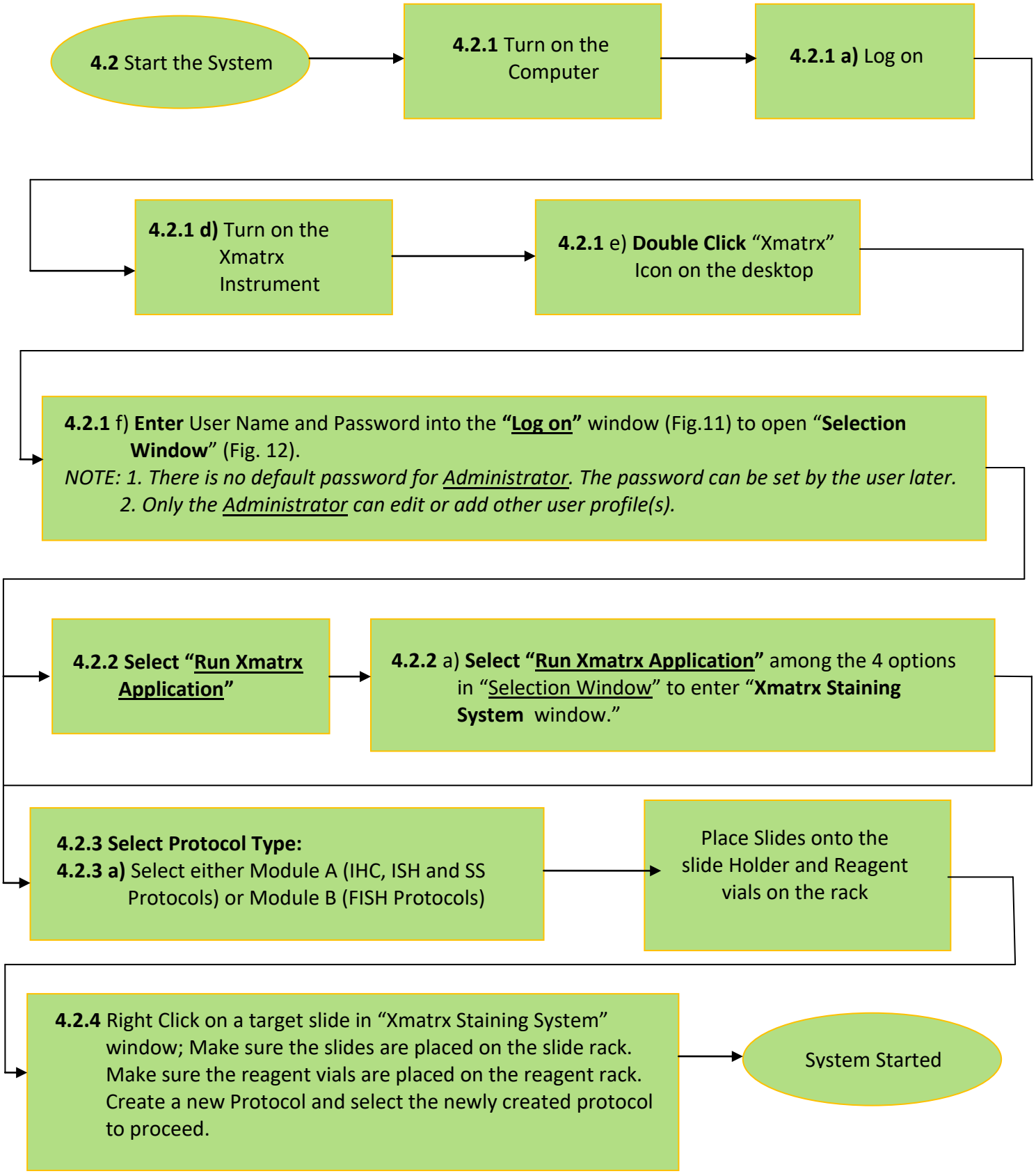


Fig 16: Workstation

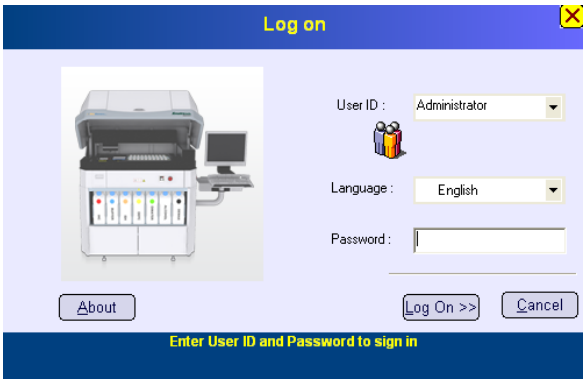


Figure 17: Select Username and enter Password in the "Log on" window. There is no password for the Administrator account by default. A password can be set later for this account.

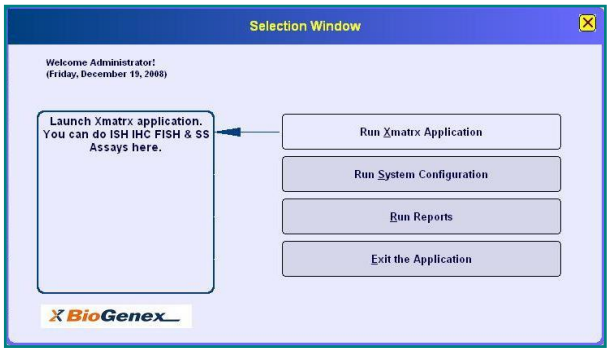


Figure 18a: Selection **Window** offers four options. Select the **"Run Xmatrx Application'** option.

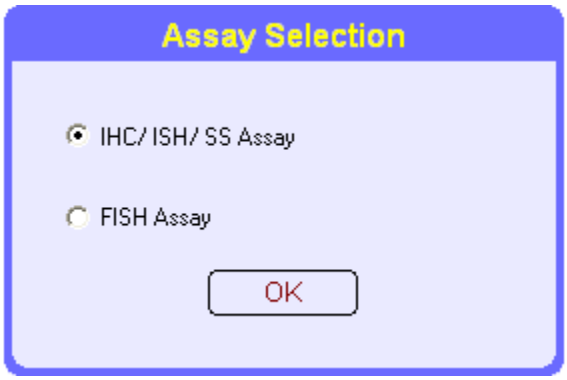


Figure 18b: Selection **Window** offers two options.
Module A: IHC/ ISH/ SS Protocols, Module B: FISH Protocols

- *Make sure the slides are loaded onto the slide platform.*
- *Make sure the necessary reagent vials are placed on the reagent rack.*

Note: From here onwards Module A refers to IHC, ISH and SS Protocols and Module B refers to FISH Protocols in this manual

SECTION 5

MODULE A – IHC, ISH & SS Protocols

CONFIGURATION SETTINGS

To properly manage a run, and to 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, which will be explained in this section.

I. Maintaining User Profiles

When the *Xmatrx*® 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 (Figure 20).

1. Select **<Run System Configuration**> from the Xmatrx **<Selection Window>**
2. The **<Xmatrx System Configuration & Calibration>** window appears.
3. To access the **<User Manager>** window, click on the **<Configuration>** bar and select **<User Manager>** from the dropdown menu.
4. The **<User Manager>** window will appear.

In the **<User Manager>** window, the *Administrator* can create, modify, or delete a user profile. Related items are User ID, Name, 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 dropdown menu from the **<Edit>** bar in the **<Xmatrx: Staining System>** window.

1. Select the **<Change Password>** option from the **<Edit>** dropdown menu.
2. The **<Change Password>** box (Fig.13a) appears and changes may be made.

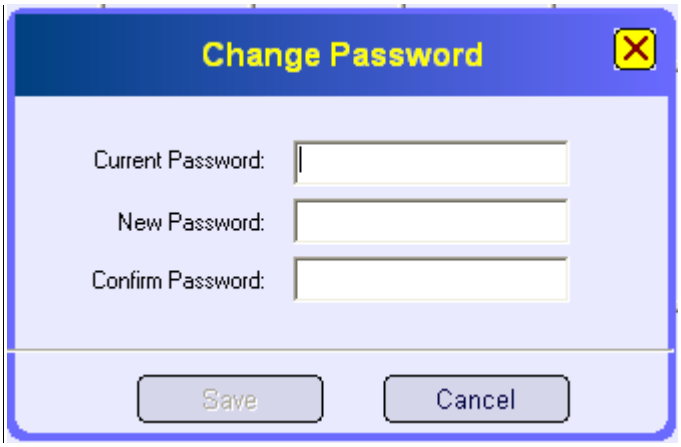


Figure 19 : <Change Password> Window

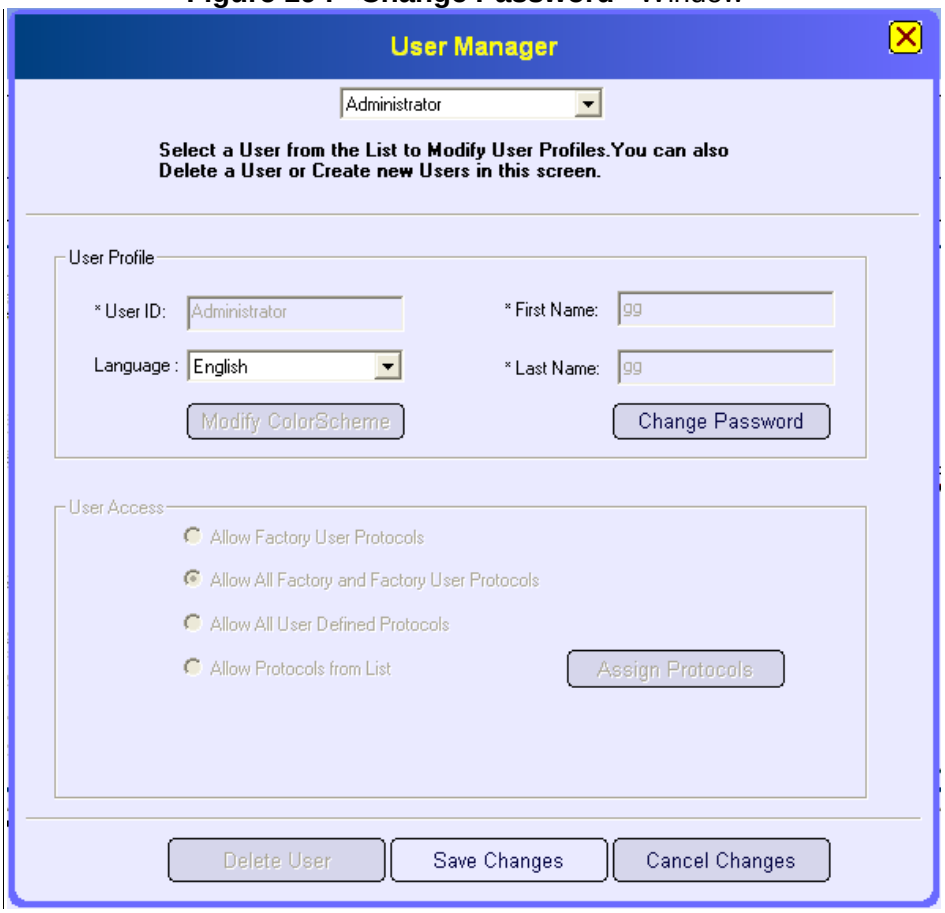


Figure 20: <User Manager> Window

Xmatrx® permits the selection of different colors, to identify different types of objects in the system, such as Caption Bar and Caption Text, or to identify different status of the same object such as SlideHeat, SlideCool and SlidePause. This rich color scheme helps the user to recognize and distinguish different objects correctly and easily in the course of a run. After entering the required information, click on **<Save Changes>** to save the input to the user database.

II. Specimen Name

Any slide-specific data entered via the **<Specimen Entry Form>** window in the system will be accessible in the **<Slide Editor>** window (Figure 21).

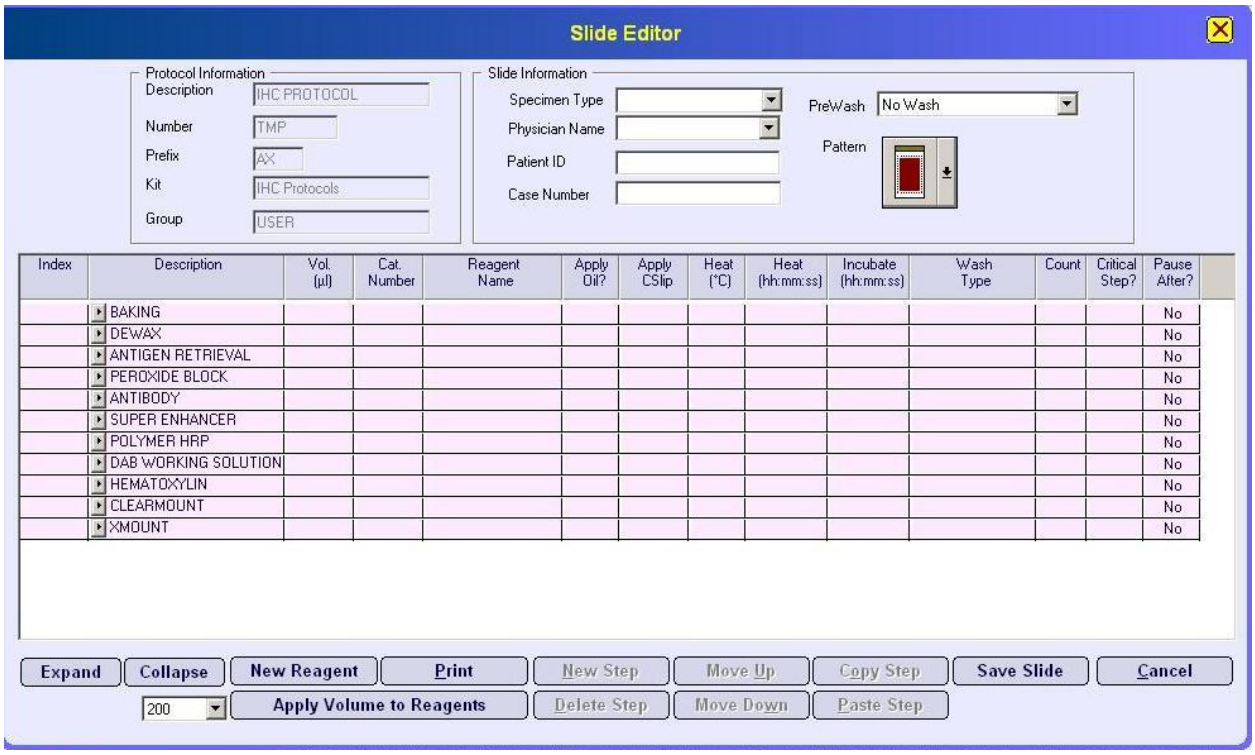


Figure 21: **<Slide Editor>** Window

To input specimen names into the system, use the **<Specimen Entry Form>** window (Figure 16a).

To open the **<Specimen Entry Form>** window:

1. From the **<Xmatrx System Configuration & Calibration>** window, select **<Specimen Names>** in the dropdown menu under the **<Configuration>** bar.

2. The **<Specimen Entry Form>** window (Figure 22) will appear.

To input a specimen name:

1. Type in a specimen name into the **<Name>** field. Specimen name field has a limit of 20 characters

2. Select **<Add>**.

3. The name will be listed in the name box below the **<Name>** field of the **<Specimen Entry Form>** window.

4. Select **<Done>** to close the window.

To delete a specimen name:

1. Click to highlight the target name in the name box of the window
2. Select **<Delete>**. The name will disappear.
3. Select **<Done>** to close the window.

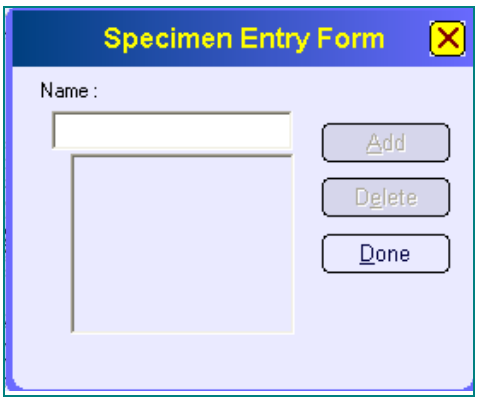


Figure 22: **<Specimen Entry Form>** Window

MODULE B – FISH Protocols

CONFIGURATION SETTINGS

To properly manage a run, and to 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 three (3) items within the Configuration module, which will be explained in this section.

Maintaining User Profiles

When the Xmatrx® 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 (Figure 24).

5. Select **<Run System Configuration**> from the Xmatrx **<Selection Window>**
6. The **<Xmatrx System Configuration & Calibration>** window appears.
7. To access the **<User Manager>** window, click on the **<Configuration>** bar and select **<User Manager>** from the dropdown menu.
8. The **<User Manager>** window will appear.

In the **<User Manager>** window, the *Administrator* can create, modify, or delete a user profile. Related items are User ID, Name, 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 dropdown menu from the **<Edit>** bar in the **<Xmatrx: Staining System>** window.

3. Select the **<Change Password>** option from the **<Edit>** dropdown menu.
4. The **<Change Password>** box appears and changes may be made.

Figure 23: <Change Password> Window

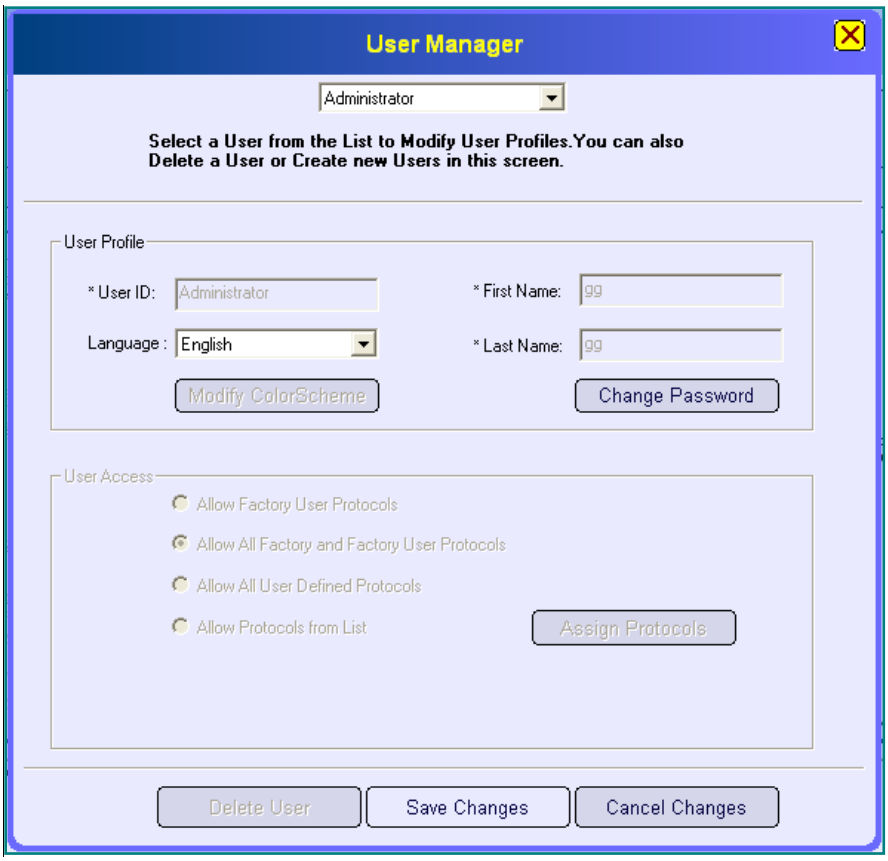


Figure 24: <User Manager> Window

Xmatrx® permits the selection of different colors, to identify different types of objects in the system, such as Caption Bar and Caption Text, or to identify different status of the same object such as SlideHeat, SlideCool and SlidePause. This rich color scheme helps the user to recognize and distinguish different objects correctly and easily in the course of a run. After entering the required information, click on **<Save Changes>** to save the input to the user database.

Specimen Name

Any slide-specific data entered via the **<Specimen Entry Form>** window in the system will be accessible in the **<Slide Editor>** window (Figure 25).

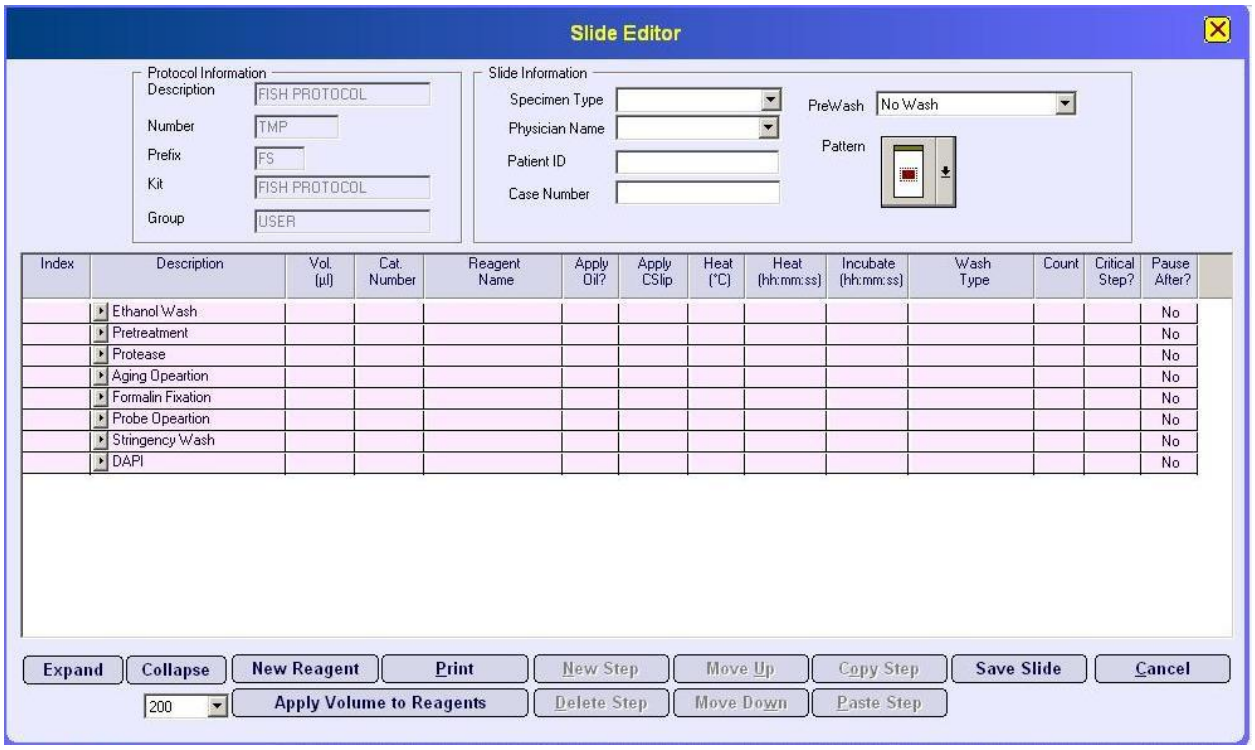


Figure 25: **<Slide Editor> Window**

To input specimen names into the system, use the **<Specimen Entry Form>** window (Figure 16).

To open the **<Specimen Entry Form>** window:

3. From the **<Xmatrx System Configuration & Calibration>** window, select **<Specimen Names>** in the dropdown menu under the **<Configuration>** bar.

4. The **<Specimen Entry Form>** window (Figure 26) will appear.

To input a specimen name:

5. Type in a specimen name into the **<Name>** field.

6. Specimen **<Name>** field has a character limit of 20 characters.

7. Select **<Add>**.

8. The name will be listed in the name box below the **<Name>** field of the **<Specimen Entry Form>** window.

9. Select **<Done>** to close the window.

To delete a specimen name:

4. Click to highlight the target name in the name box of the window
5. Select **<Delete>**. The name will disappear.
6. Select **<Done>** to close the window.

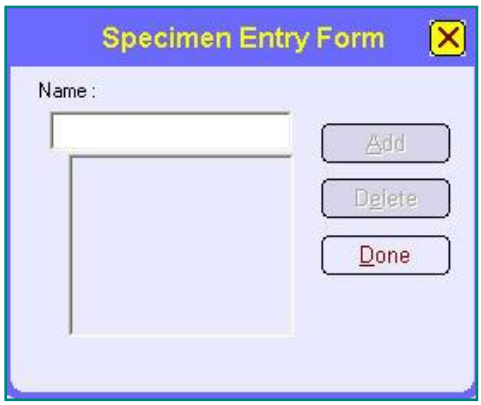


Figure 26: <Specimen Entry Form> Window

Changing System Clock for Daylight Saving Time (DST)

In August 2005, The United States Congress passed the Energy Policy Act, which changes the start and end dates of daylight savings time. This law goes into effect in 2007. DST will start three (3) week earlier (2:00AM on Sunday March 11) and will end one week later (2:00AM on Sunday November 4). Congress will evaluate the impact on energy consumption in the United States to determine if the new DST will continue beyond 2007.

The Xmatrx® system automatically manages DST settings, but management is based on the DST dates prior to 2007 and controlled by the operating system software. Some releases of system software do not contain the necessary information to autocorrect for the policy changes. Therefore, the automatic management of DST will be disabled, and it will be necessary to manually change the time on the date region that has been set DST to begin and end.

NOTE: Time will need to be changed two (2) times per year until software is upgraded.

Procedure:

1. Double click the time displayed in the Task Bar.
2. Set the correct time from the **<Date & Time>** screen. Press **<Apply>**, followed by **<OK>**.
3. Verify the time is correct.

SECTION 6

MODULE A

BUILDING and INSERTING PROTOCOLS

I. Protocol Types

There is a protocol template available in the protocol database.

Protocol template:	This protocol exists in the protocol database. This has all the steps included for a typical IHC staining run. User can edit/ modify the protocol parameters. User can also create a new protocol taking this as a template. User can also add or delete the steps in the protocol.

II. Staining Steps

On the *Xmatrx*® 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	Pauses staining run on the target slide(s) for a specified period of time.
Buffer Slide	Allows buffer to be dispensed onto the particular slide(s) 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 80-850 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.

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

- Apply Reagent
- Apply Micro reagent

The *Xmatrx*® System will not allow coverslipping for any operation that contains an "Apply Reagent" step.

III. Building Protocols

Open the "*Xmatrx*®**: Staining System**" window by selecting the "Run Xmatrx Application" bar in the "Selection Window"

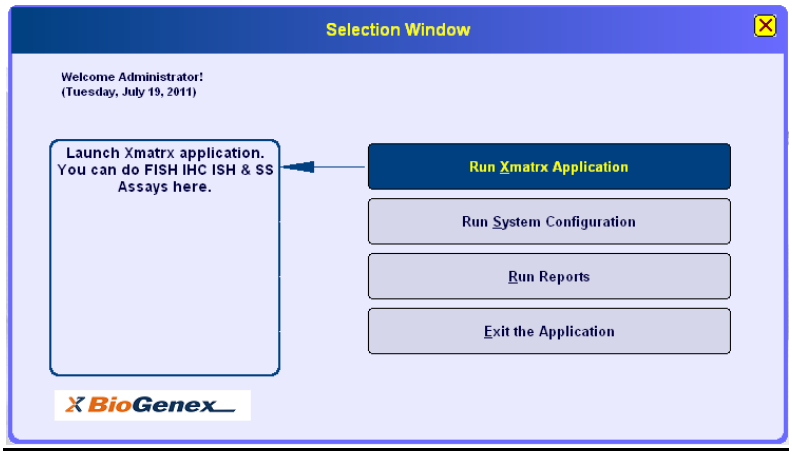


Figure 27: Selection Window

1. Click on the "**Edit**" bar in the "**Xmatrx: Staining System**" window and select **Edit Protocol Database** that leads to **Edit Protocols** window. Click **New** button in this window**.**

2. In the subsequent window, **New Protocol Editor (Fig.28)** Create a new protocol with the available template**.** Name the protocol and save it.

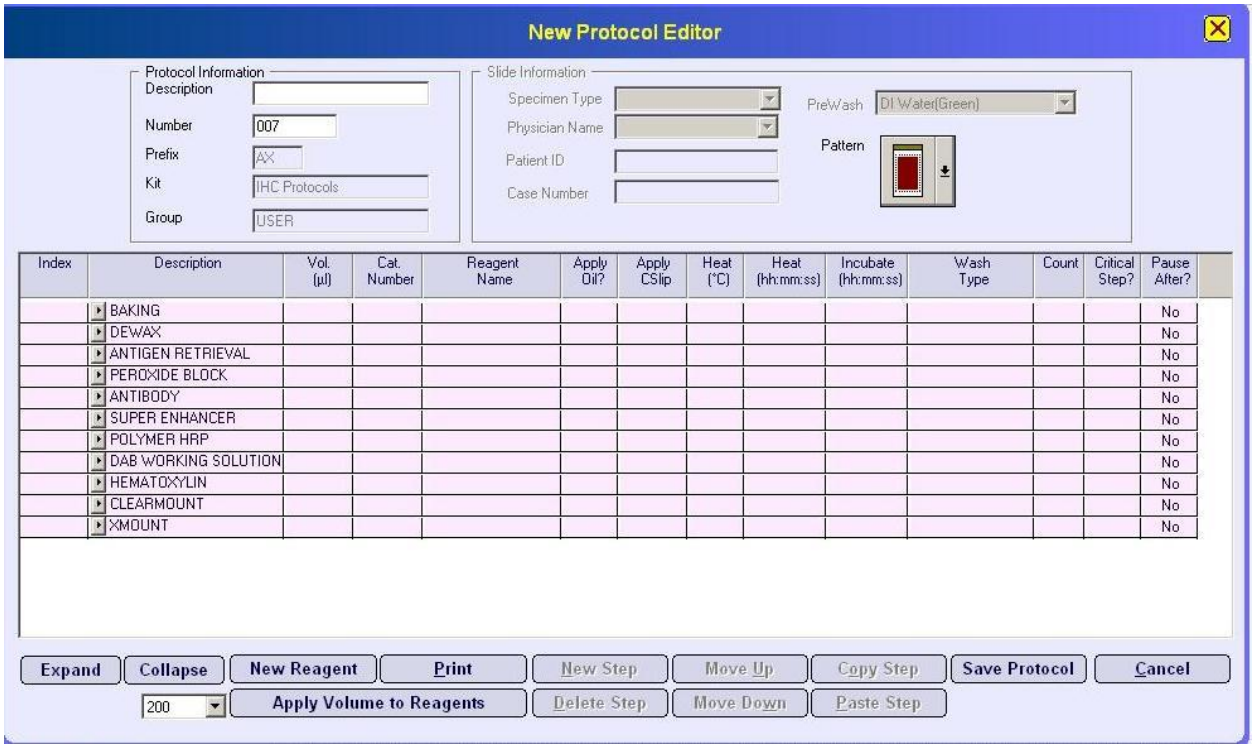


Figure 28: New Protocol Editor Window

IV. Inserting a Protocol

Click on a slide position to select it. The selected slide position will be highlighted. To insert a protocol, click on the **Edit** bar in the **Xmatrx Staining System** window and select '**Select Protocol'** or Right Click the mouse and **Select Protocol**.

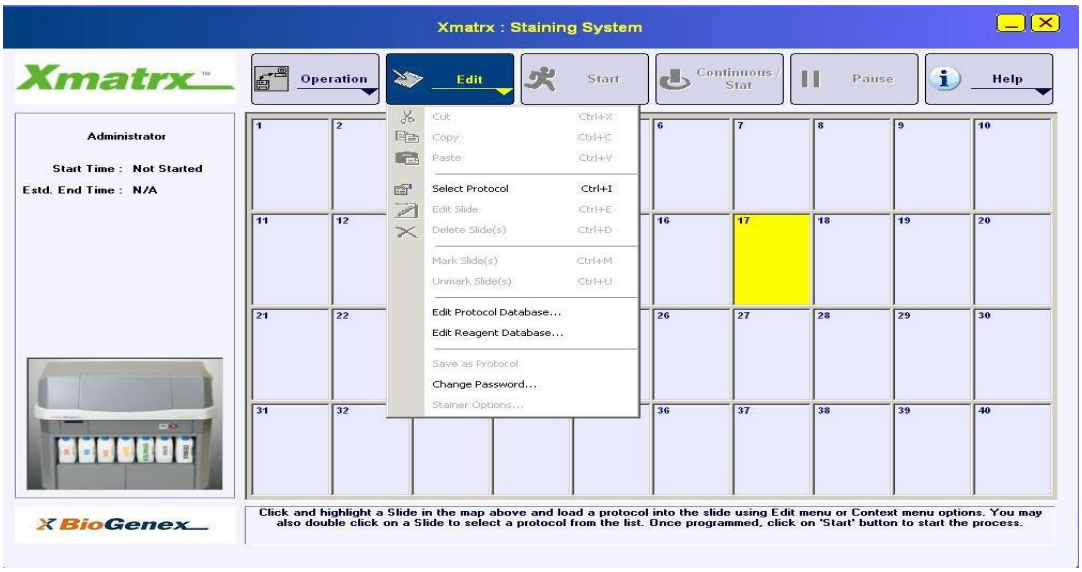


Figure 29: Inserting a protocol using the **Edit** bar

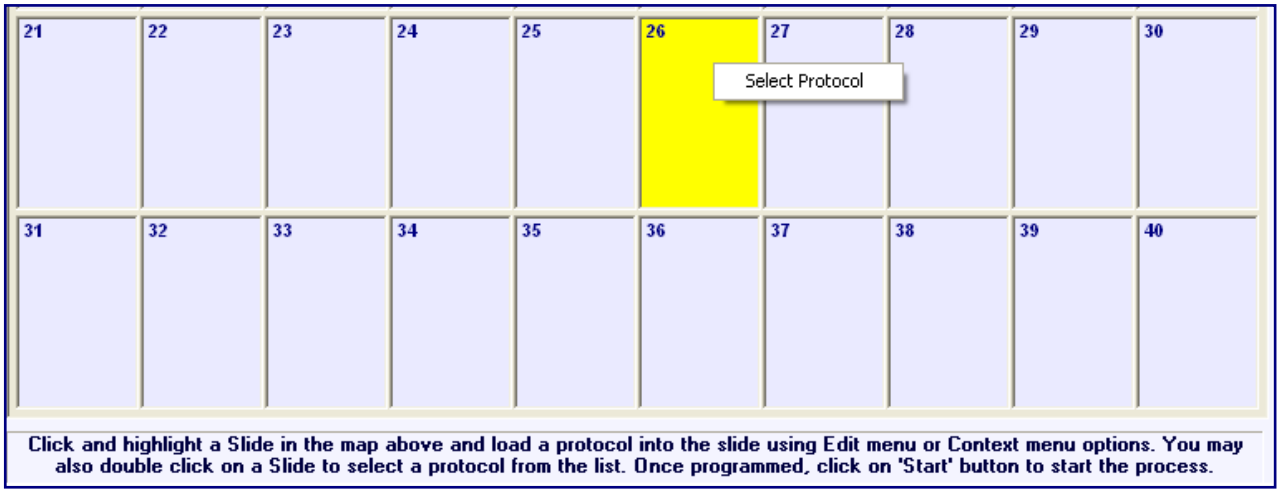


Figure 30: Inserting a protocol using the select '**Select Protocol' command**

NOTE: The protocol template currently listed in the software is 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.

V. Editing Protocols

Only the *Administrator* can edit the default protocol template and other user created protocols, and users can create User Protocols using the <**Copy**> option.

1. From the **<Edit Protocol>** window (Figure 31), highlight Protocol template and select the **<Edit>** button.

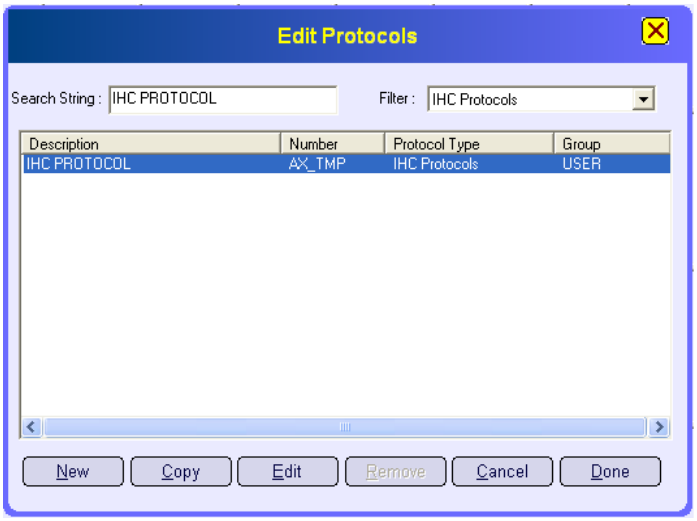


Figure 31: <Edit Protocol> Window

2. The **<Protocol Editor>** screen is displayed (Figure 32). For instructions on using the **<Protocol Editor>** window, refer to ***Section 7: Using Protocol/Slide Editor Windows***.

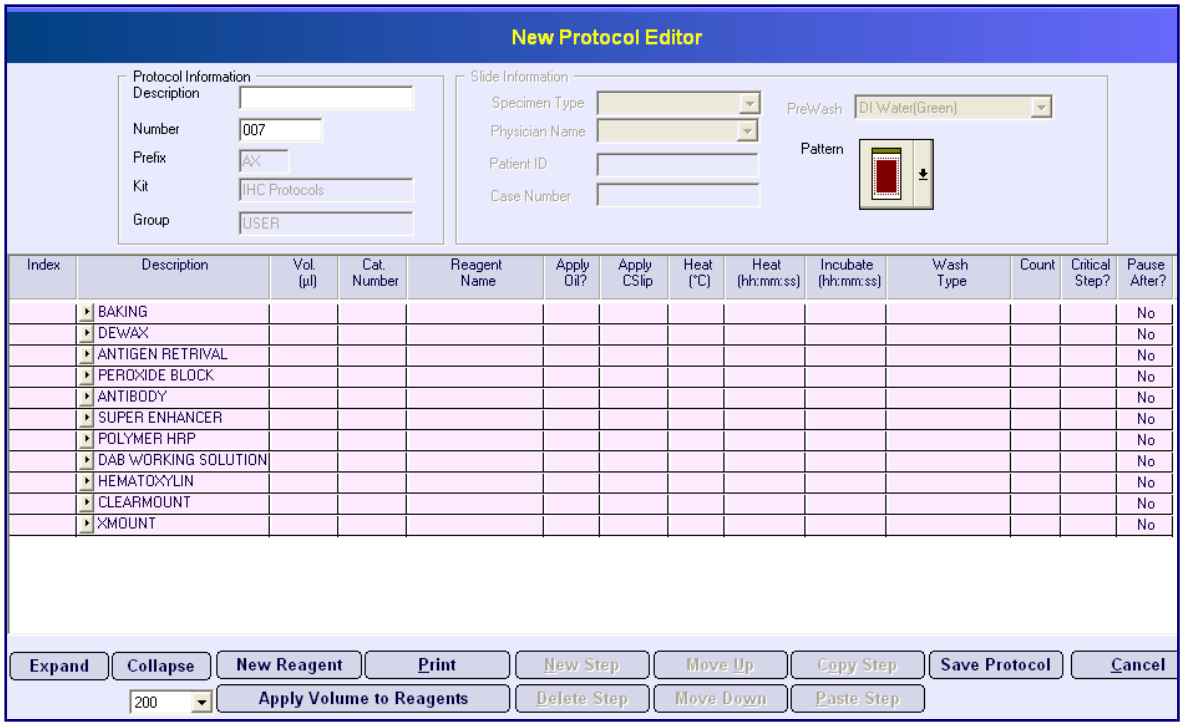


Figure 32: <Protocol Editor> Window

Copy and Create a new Protocol:

1. From the **<Insert Protocol>** window (Figure 33), select the desired protocol to copy and select the **<Copy>** button to open the **<New Protocol Editor>** window (Figure 34).

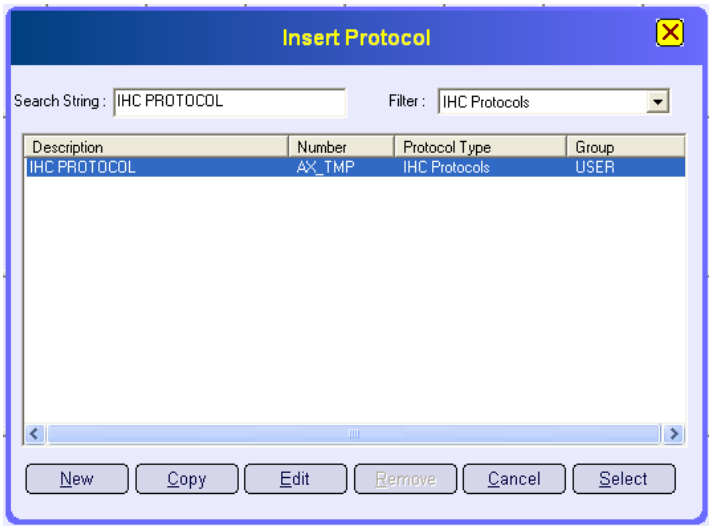


Figure 33: <Insert Protocol> <Copy> Window

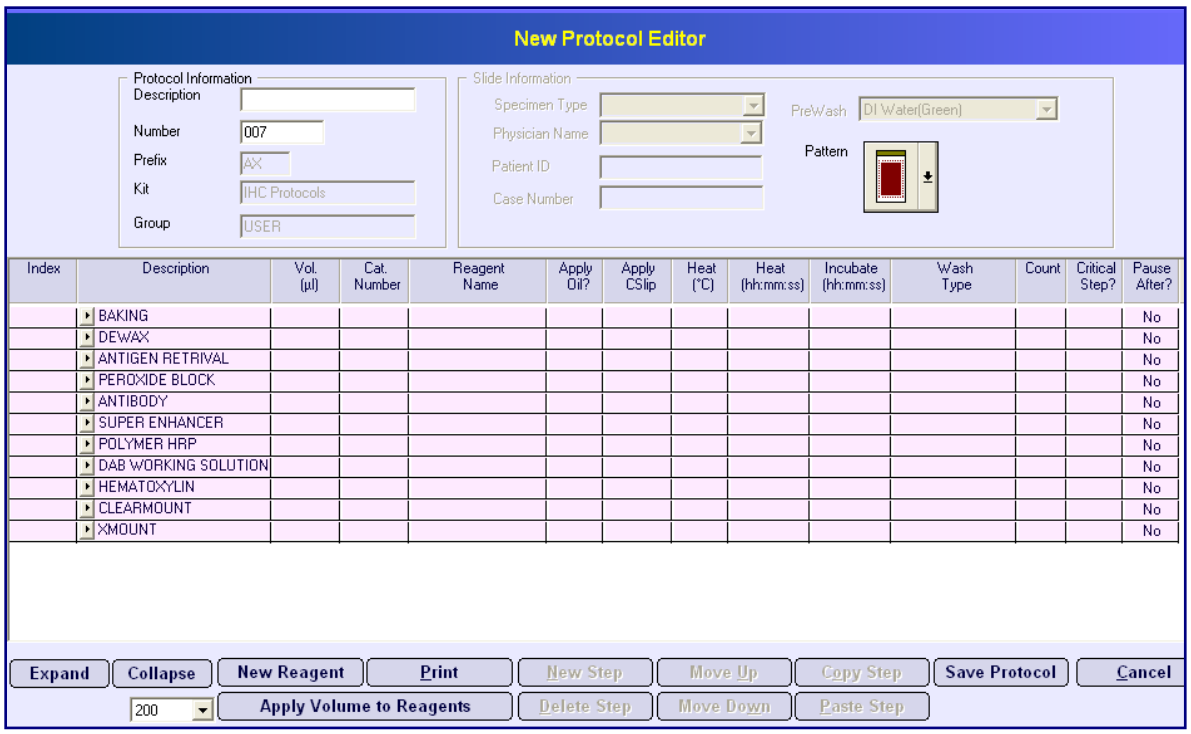


Figure 34: <New Protocol Editor> Window

2. After completing the design of a new protocol, click on the <**Save Protocol**> button to save the copied protocol.

Create a New Protocol from an Existing Protocol:

1. From the **<Insert Protocol>** window (Figure 35), select the desired protocol to copy and select the **<New>** button to open the **<New Protocol Editor>** window (Figure 36). For instructions on using the **<New Protocol Editor>** windows, refer to ***Section 7: Using Protocol/Slide Editor Window***.

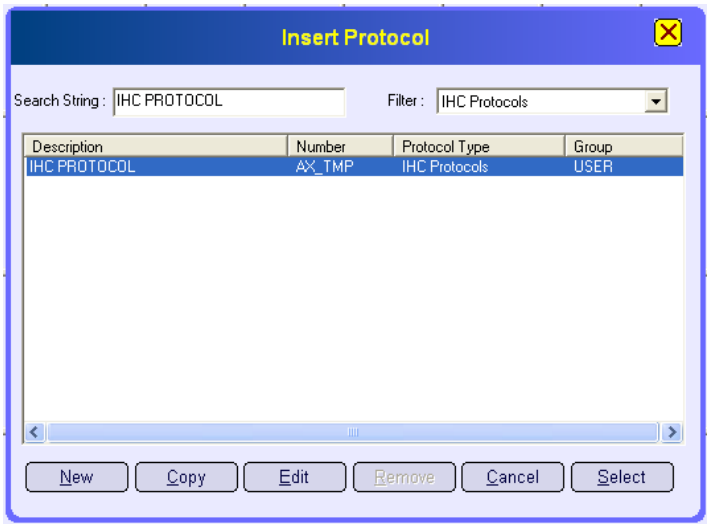


Figure 35: <Insert Protocol> <New> Window

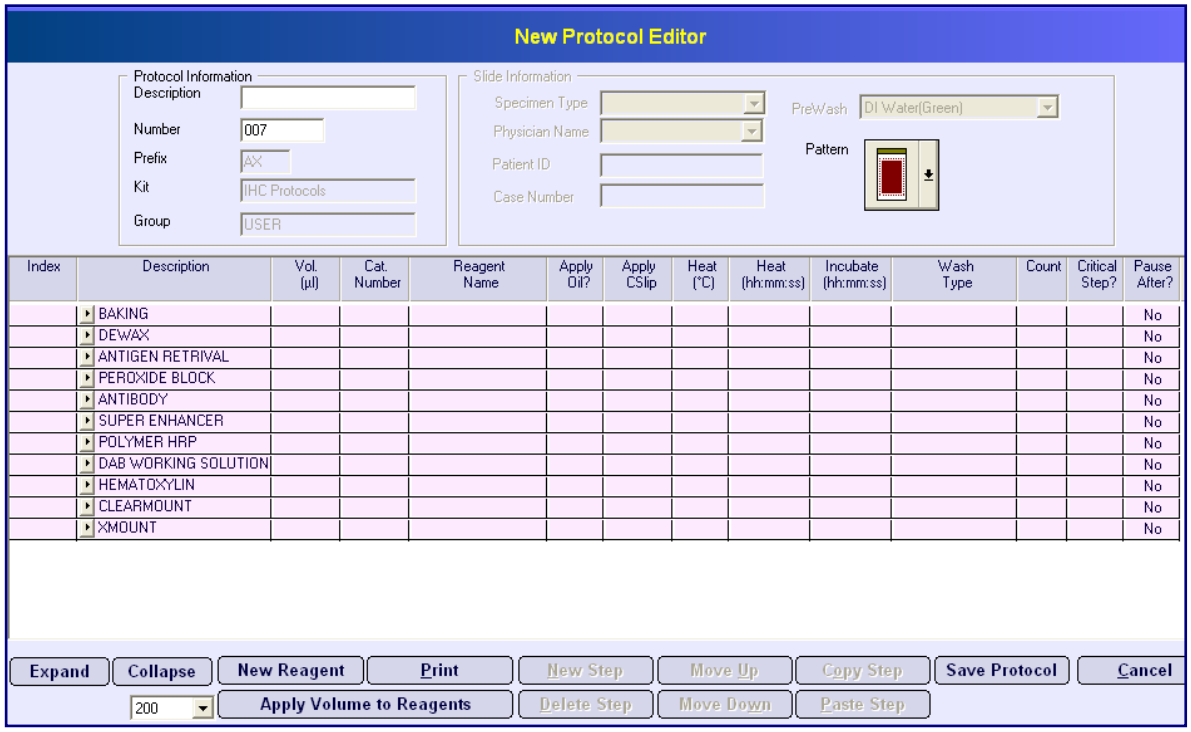


Figure 36: <New Protocol Editor> Window

2. To save the Protocol, select **<Save Protocol>**. The Protocol can be retrieved later in the **<Insert Protocol>** window.

MODULE B

BUILDING and INSERTING PROTOCOLS

The user can select any of the options of protocol available for staining runs in the FISH module. The protocol available to the user is,

Default Protocol Template	Default protocol template is given in the software. The user can customize the individual steps/operations in the protocol as per the requirement. This protocol is fully editable and can be created by any user with the permission of creating new protocols.

Staining Steps

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

Blow Slide	Blows a jet of air over the slide to remove the liquid from the slide.
Incubate Slide	Pauses a staining run on the target slide(s) for a specified period of time.
Wash Slide	Allows buffer to be dispensed onto the particular slide(s) per the applied protocol.
Apply Oil	Applies oil onto the four (4) edge lines of a coverslip on the slide.
Apply Coverslip	Picks up a coverslip from the appropriate coverslip box and applies a coverslip onto a slide.
Remove Coverslip	Removes a coverslip from the target slide and discards the used coverslip into the coverslip dispose box.
Heat Slide	Heats up or cools down a slide to the temperature level specified in the step, and maintains the set temperature on a slide for a time duration specified in the step.
Repeat Step	This step is used in repeating an existing step(s) within the same operation block. In the same operation block, any step(s) listed above this step will be repeated for a number of cycle(s) specified in this step. If there are two repeat steps present within the same operation block, then any step(s) before the first repeat step will be repeated for the number of cycle(s) specified in the first repeat step, and then for the second repeat step, any step(s) between the first and second repeat steps will be repeated for the number of cycle(s) specified in the second repeat step.
Apply Reagent	Uses a 1000 µl pipette tip to apply reagent in volume of 80-850 µl to a target slide.

Apply Probe	Uses a 200 µl pipette tip to apply probe in volume of 10-80 µl to a target slide.

Combinations of staining steps are referred to as *Operations* in the Xmatrx™ system. Combinations of different operations may be used to construct a protocol. An Operation can include only one (1) of the following steps:

- Apply Reagent
- Apply Probe

The Xmatrx® System will not allow coverslipping for any operation that contains an "Apply Reagent" step.

Create a New Protocol:

1. From the **<Insert Protocol>** window (Figure 37), select the desired protocol and select the **<New>** button to open the **<New Protocol Editor>** window (Figure 38). For instructions on using the **<New Protocol Editor>** windows, refer to ***Section 7: Using Protocol/Slide Editor Window***.

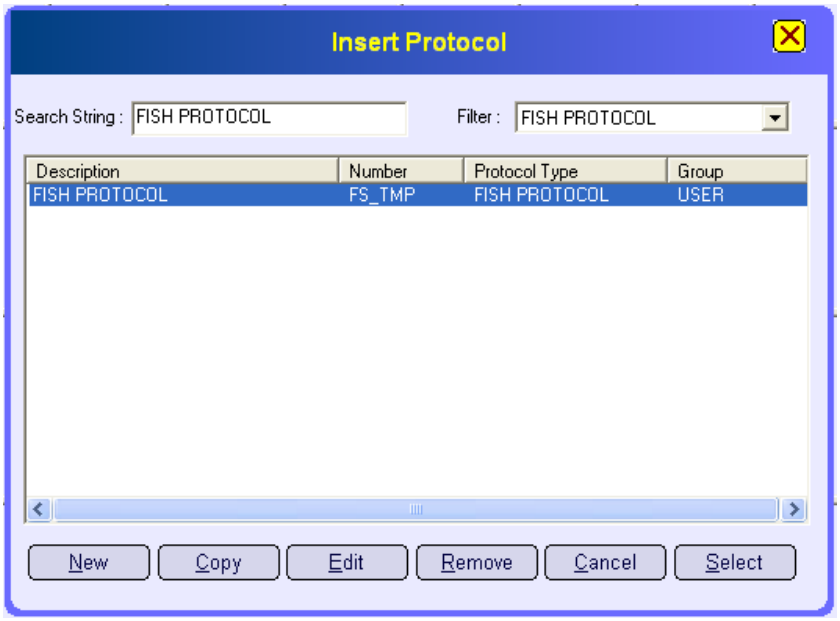


Figure 37: <Insert Protocol> <New> Window

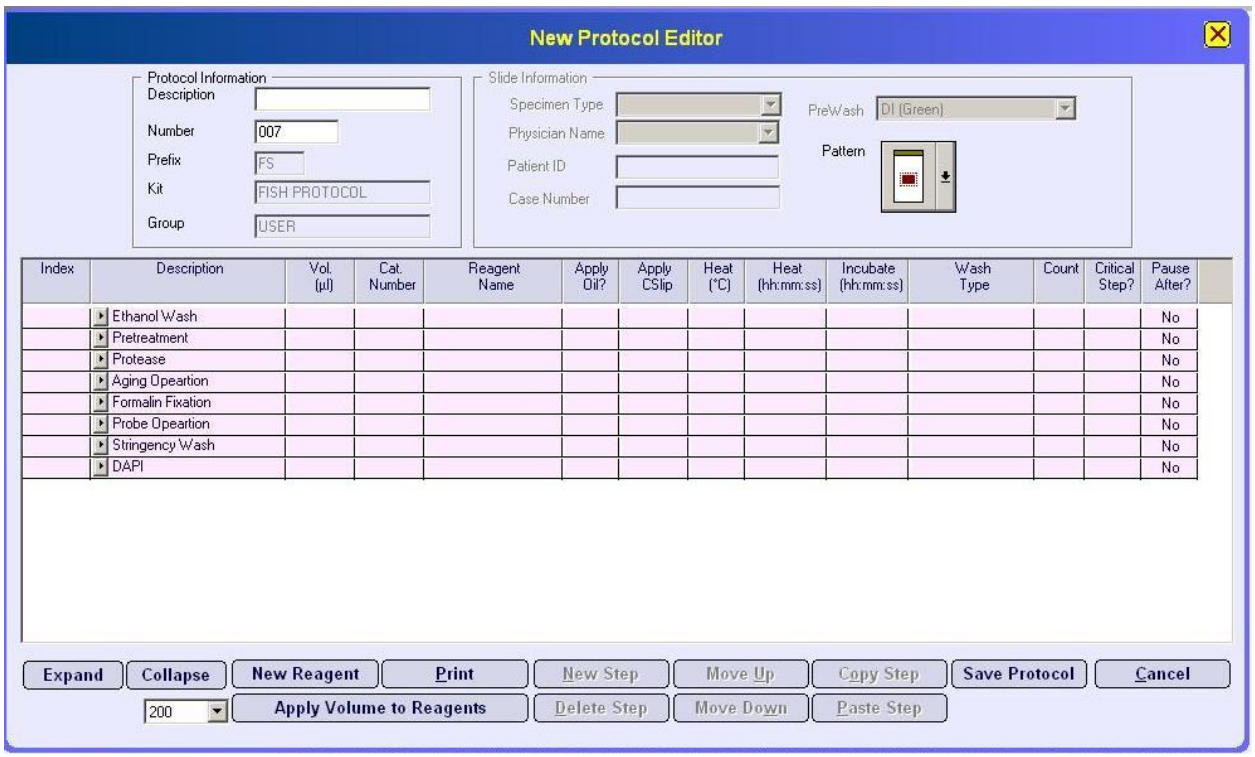


Figure 38: <New Protocol Editor> Window

2. To save the Protocol, select **<Save Protocol>**. The Protocol can be retrieved later in the **<Insert Protocol>** window.

SECTION 7

MODULE A

USING PROTOCOL/SLIDE EDITOR WINDOWS

I. Editor Windows

When building or editing a protocol or editing a slide, refer to ***Section 6: Building and Inserting Protocols***. There are three types of editor windows available:

New Protocol Editor	Appears when **<New>** or <**Copy**> is selected in the <**Edit Protocols**> window.
Protocol Editor	Appears when **<Edit Protocol Database>** is selected by clicking the Edit button in the **<Xmatrx-Staining System>** window.
Slide Editor	Appears by double-clicking on an inserted slide in the <Xmatrx-Staining System> window, or by right-clicking on an inserted slide and choosing the <Edit Slide> option.

The layout of each of these three (3) windows is the same.

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 that enable creation or editing of the protocol. Important differences between the three (3) editor windows are:

1. The **<New Protocol Editor>** window allows the user to change the protocol description and number in the **Protocol Information** area, but not the information in the **Slide Information** area. This window allows the user to build a protocol or save a copied protocol.

2. The **<Protocol Editor>** window allows the user to change only the protocol description in the **Protocol Information** area, but none of the information in the **Slide Information** area. This window is used to edit an existing protocol.

3. 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 buttons area function identically in all three (3) editor windows.

II. Opening and Closing the <New Protocol Editor> Window

The following information describes how to create a new protocol with the **<New Protocol Editor>** window. Except where indicated, the techniques used can also be applied to the **<Protocol Editor>** and the **<Slide Editor>** windows.

To open the window:

1. From the **<Edit Protocol >** window (Figure 39), click the **<New>** button to open the **<New Protocol Editor>** window (Figure 40).

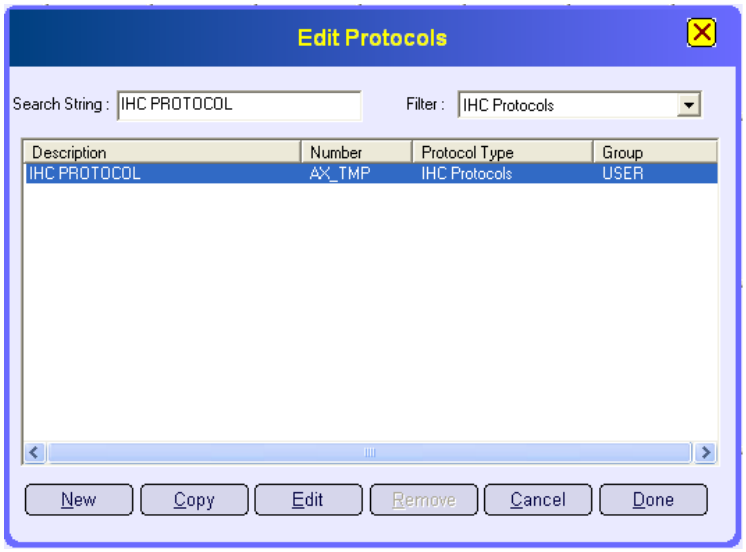


Fig 39: Edit Protocol Window

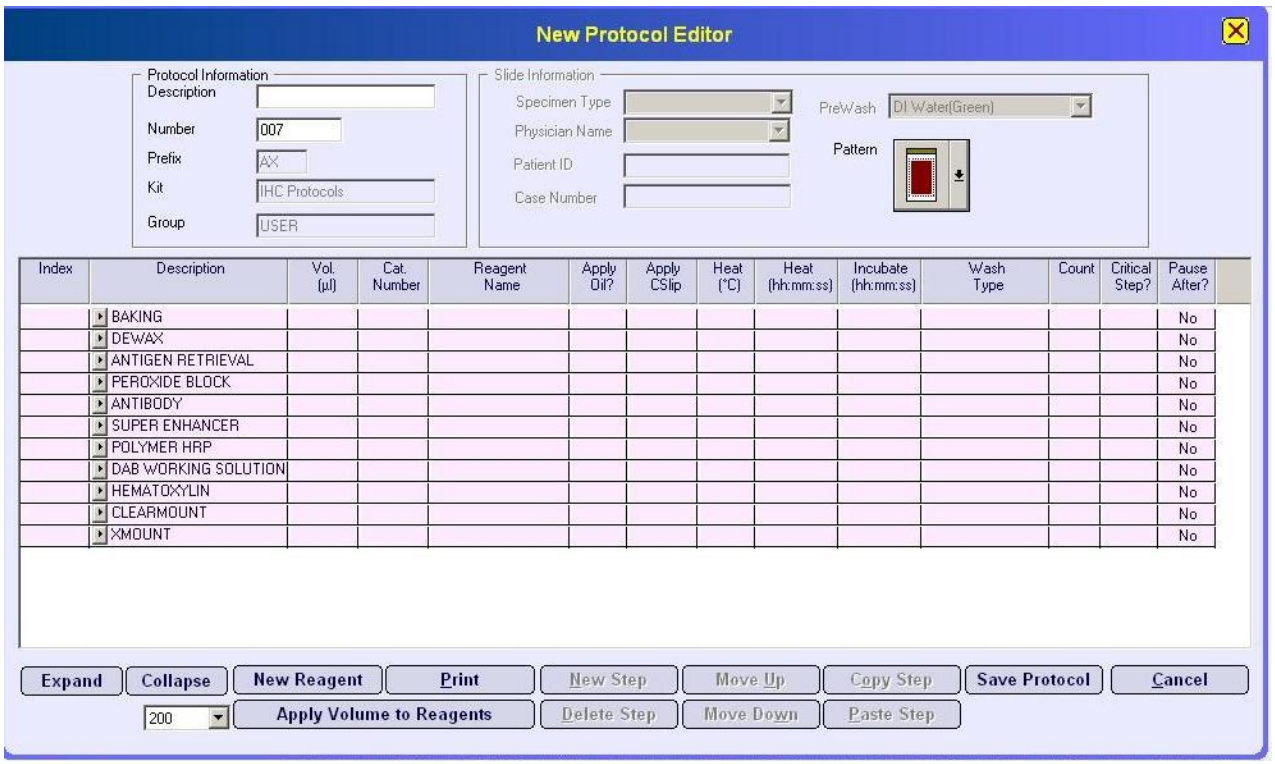


Fig 40: New Protocol Editor Window

2. In the ***Protocol Information*** area, a protocol number is automatically generated for a new protocol. It can be changed to any three (3) digit number. The description field is blank and must be filled out before the window is closed.

To close the window:

1. After completing the building of a new protocol, click on the button **<Save Protocol>** to save the new protocol and exit the window.

III. Working in the <New Protocol Editor> Window

A protocol is made up of operations, which in turn are made up of steps. An operation is represented by a row with pink cells, and a step is represented by a row with blue cells.

Initially, only the operations are visible.

1. To see the steps of a particular operation, 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 34a) from the buttons area.

4. To hide all steps for all operations, click the **<Collapse>** button.

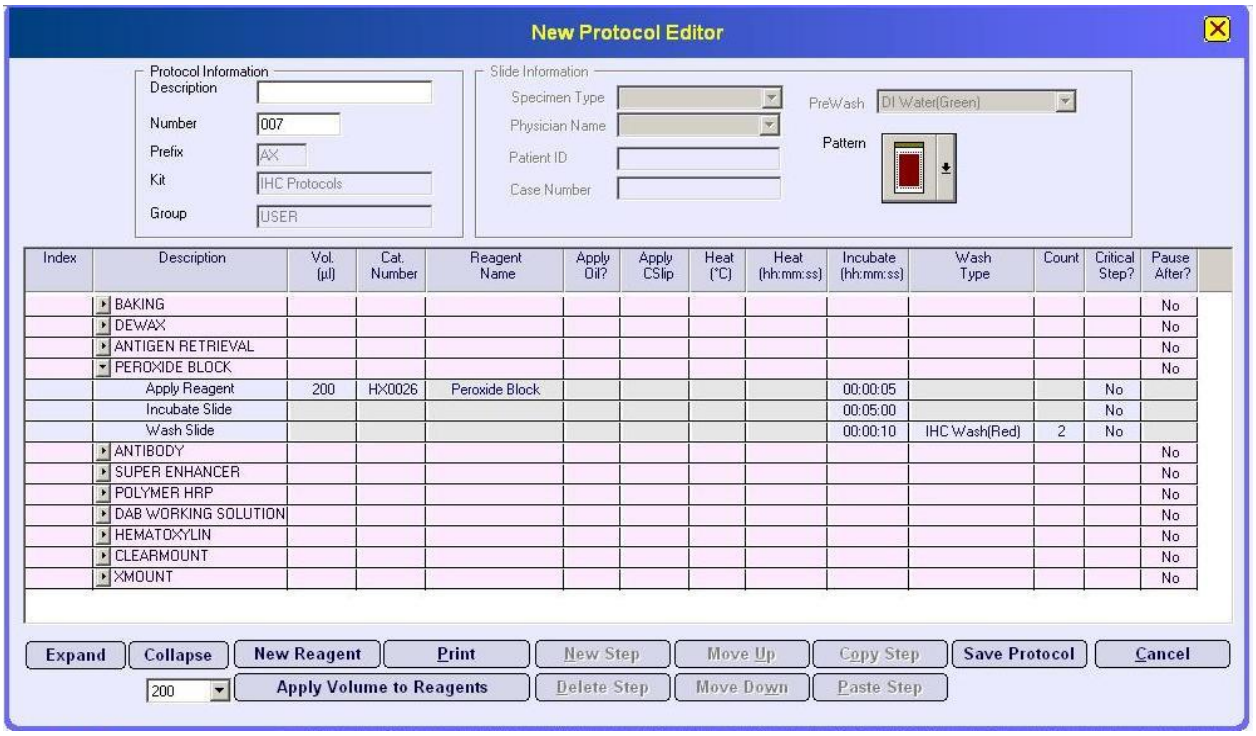


Figure 41: <**New Protocol Editor>** window

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

5. After designing a new protocol:

   A. Name the Protocol in the description.

   B. Select **<Save Protocol>** to save the new protocol.

   C. The **<New Protocol Editor>** window will close.

   D. The **<Insert Protocol>** window will become active, with the name of the new protocol highlighted.

   E. By selecting the **<Select>** button, the **<Insert Protocol>** window will close. The new protocol will be applied to the Slide Map of the **<Xmatrx: Staining System>** window.

IV. Button Options in the Editor Windows

Expand	Clicking on this button will display all the steps for all operations on the screen.
Collapse	Clicking on this button will close all the steps for all operations on the screen.

Apply Volume to Reagents	After selecting the volume in the field at the left of this button, click on this button to set the reagent volume in all the **<Apply Reagent>** steps in the protocol. The reagent volume should not be less than 100 µl. For example, if the selected volume is 95 µl, the selection will not come into effect. An alternative method for specifying the reagent volume in the particular reagent step is to highlight the step and click the cell in the **<Vol.>** column. User can select the reagent volume from the drop-down menu. The available range for reagent volume selection is 80 to 850 µl. When the **<Apply Volume to Reagents>** button is clicked, the volume appearing in its filed will replace the volume in all the **<Apply Reagent>** steps.
Apply Volume to Probe	When the selected volume in the related field is 45 or less, the **<Apply Volume to Reagents>** button will change to **<Apply Volume to Probe>**. When the **<Apply Volume to Probe>** button is clicked, the volume appearing in its field will replace the volume in all the **<Apply Probe>** steps in the protocol. When selecting a number directly in the **<Vol.>** column, the available volume range for **<Probe Step>** is 10 to 80 µl.
Print	Clicking on this button will print the protocol displayed in the window.
Save Protocol	Clicking on this button will 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.

V. Slide Information Area

The **Slide Information** area (Figure 35) is open for changes only when working in the **<Slide Editor>** window to edit a single inserted slide. When in the **<New Protocol Editor>** or the **<Protocol Editor>** window, this area is inactive.

When in the **<Slide Editor>** window, the type **<PreWash>** can be selected by clicking on the arrow to activate the dropdown menu.

<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 an Administrator from the configuration module (see Section 5).
.

Figure 42: **<Slide Information>** Area

VI. Protocol Information Area

The **<Description>** field (Figure 43) 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 except **<Number>** cannot be edited by directly working in these fields.

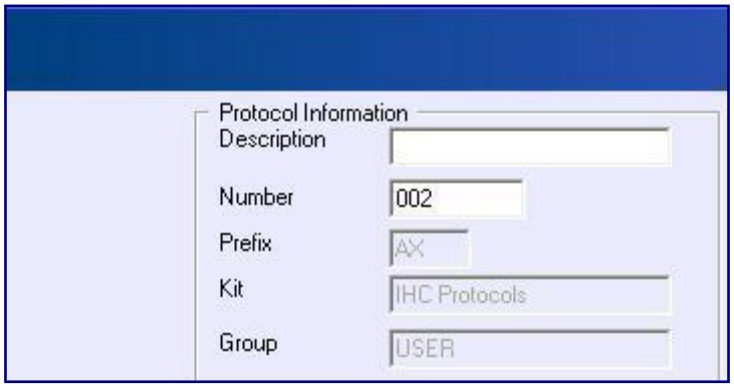


Figure 43: **<Protocol Information>** Area

VII. Insert Slides After a Run Has Begun through Continuous / Stat Mode

During preliminary login user has an option to use continuous/ stat mode with a check box, As shown in the below Fig CON/STAT log in window. This option need to be selected before starting the run.

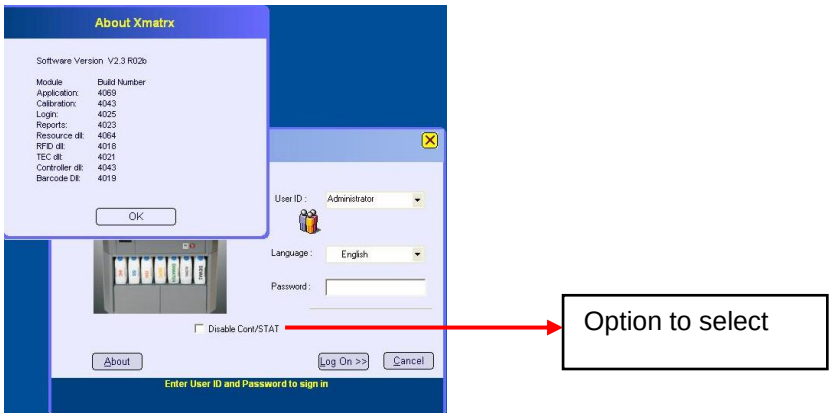


FIG: CON/STAT

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.

Note: The Continuous / stat function is available in both Module A / Module B.

slides to the Run through Continuous Mode

Figure 44: <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.

To use this function:

1.Select the <Continuous / stat > button at the top of the <Xmatrx: Staining System > window.

2. By Default, Insert Continuous Slides is Checked. Inserting Continuous Slides Option

process the slides with Normal Priority .

3. 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.

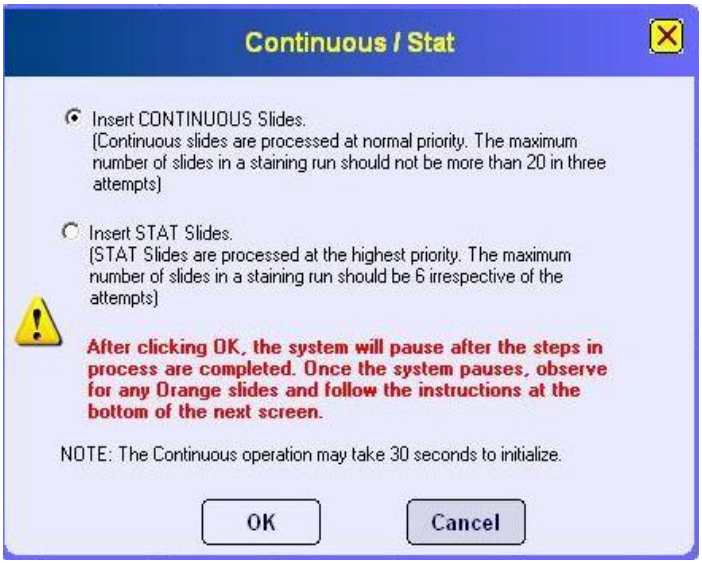


Figure 45: Continuous prompt.

4. 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 three attempts only.

2. 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.

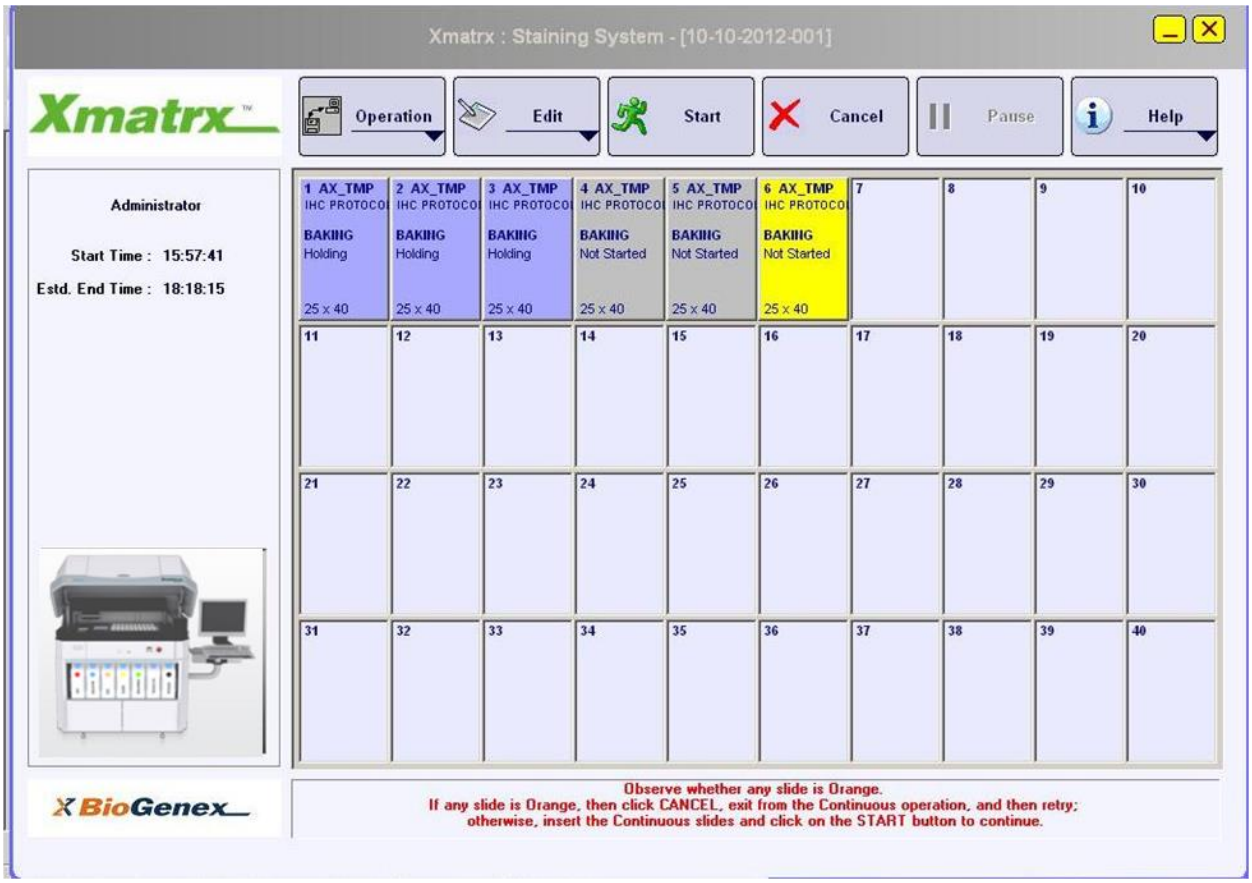


Figure 46 : <Continuous / stat> button

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

5. Once the system has paused, and the operator has verified that no current slides on the slide map are ORANGE, the hood may be opened, 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.

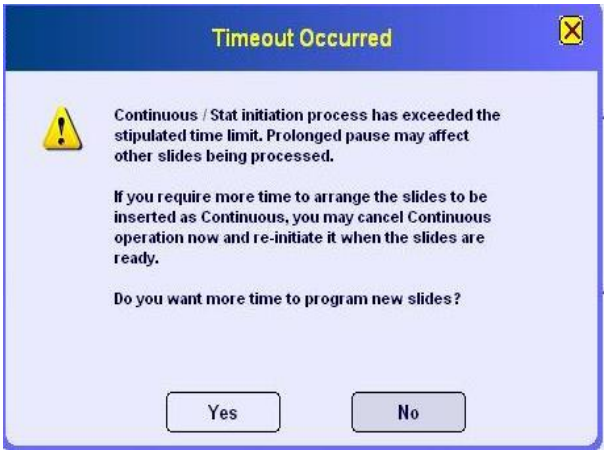


Figure 47: Timeout Prompt

6 Selecting <Yes> on the prompt will allow the operator to continue setting up the new slide(s);

7. However, processing of the existing slides will be delayed until <Start> is selected.

8. 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

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

9. When the desired protocol is highlighted, click <Select>.

10. If the protocol is acceptable as is, proceed to Step 15 below.

11 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 5–25 for instructions on making and saving edits.

12.Verify the slide positions match the slide map and the protocol names and that the correct protocol is chosen for each new slide.

13..Select <Start>. The <Reagent Map> window will appear.

Follow all on-screen instructions and load all required reagents as directed.

VIII. Inserting slides to the Run through Stat Mode.

Figure 48: Continuous / Stat

To use this function:

1.Select the <Continuous / stat > button at the top of the <Xmatrx: Staining System > window.

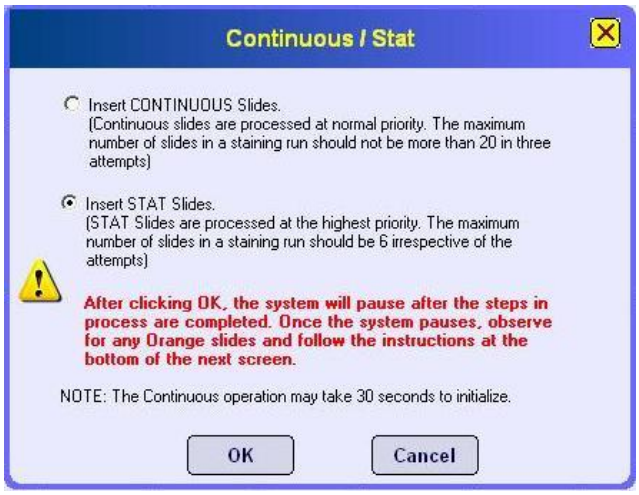


Figure 49: Continuous / Stat

	NOTE: Stat Slides highlighted with Separate color.

NOTE:

1. STAT slides are Processed at the highest priority.

2. STAT Option Operation may take 30 seconds to Initiate.

3. The maximum Number of Slides in a staining Run should be 6 in Number irrespective of the attempts for STAT.

4. Inserted Slides through STAT mode are highlighted with different color.

2. Enable the Insert STAT slides Option and Click <OK>.

3. Insert the slides on to the Available positions in Slide Deck.and click <start>.

4. 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.

5.Once the system has paused, and the operator has verified that no current slides on the slide map are ORANGE, the hood may be opened, and the new slide(s) may be positioned on the slide deck.

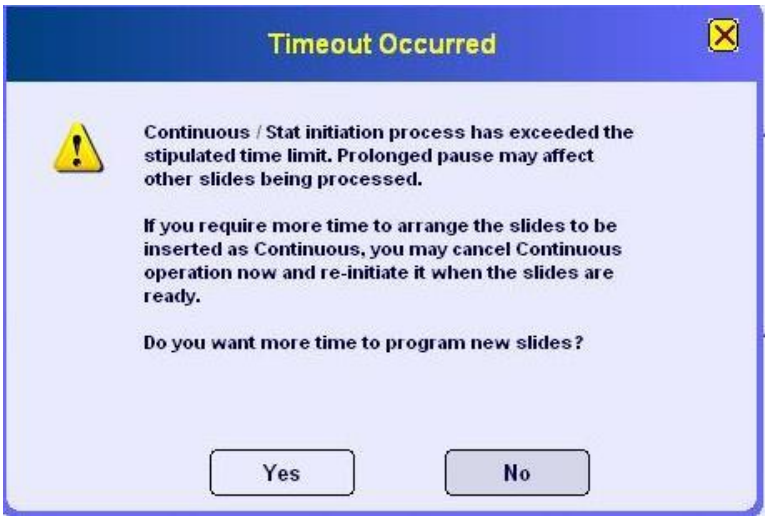


Figure 50: Timeout

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

6. Selecting <Yes> on the prompt will allow the operator to continue setting up the new slide(s);

7. However, processing of the existing slides will be delayed until <Start> is selected.

8. 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

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

9. When the desired protocol is highlighted, click <Select>.

10. If the protocol is acceptable as is, proceed to Step 15 below.

11. 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 5–25 for instructions on making and saving edits.

12. Verify the slide positions match the slide map and the protocol names and that the correct protocol is chosen for each new slide.

13. Select <Start>. The <Reagent Map> window will appear.

Follow all on-screen instructions and load all required reagents as directed.

MODULE B

USING PROTOCOL/SLIDE EDITOR WINDOWS

Editor Windows

When designing or editing a protocol or a slide from the <Insert Protocol> window, refer to ***Section 6: Building and Inserting Protocols***. There are three types of editor windows available:

New Protocol Editor	Appears when **<New>** or <**Copy**> is selected in the <**Edit Protocols**> and <**Insert Protocols**> windows.
Protocol Editor	Appears when **<Edit>** in the **<Insert Protocol>** window is selected.
Slide Editor	

The layout of each of these three (3) windows is the same.

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 that enable creation or editing of the protocol. Important differences between the three (3) editor windows are:

- The **<New Protocol Editor>** window allows the user to change the protocol description and number in the **Protocol Information** area, but not the information in the **Slide Information** area. This window allows the user to design a protocol or save a copied protocol.

- The **<Protocol Editor>** window allows the user to change only the protocol description in the **Protocol Information** area, but none of the information in the **Slide Information** area. This window is used to edit an existing protocol and to modify the staining pattern.

- 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 buttons area function identically in all three (3) editor windows.

Opening and Closing the <New Protocol Editor> Window

The following information describes how to create a new protocol with the **<New Protocol Editor>** window. Except where indicated, the techniques used can also be applied to the **<Protocol Editor>** and the **<Slide Editor>** windows.

To open the window:

- From the **<Insert Protocol>** window, select the desired protocol and click the **<New>** button to open the **<New Protocol Editor>** window (Figure 51).

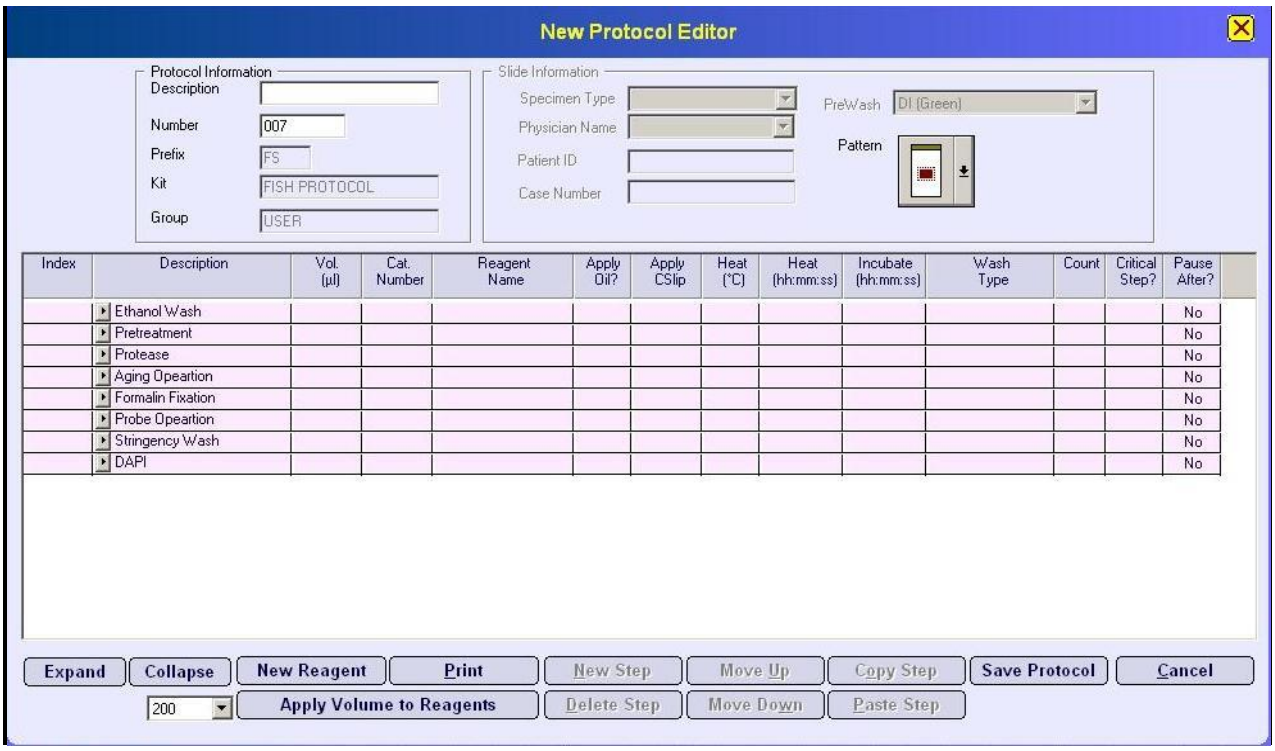


Figure 51: **<New Protocol Editor> Window**

- In the ***Protocol Information*** area, a protocol number is automatically generated for a new protocol. It can be changed to any three (3) digit number. The description field is blank and must be filled out before the window is closed.

To close the window:

- After completing the design of a new protocol, click on the button **<Save Protocol>** to save the new protocol and exit the window.

Working in the <New Protocol Editor> Window

A protocol is made up of operations, which in turn are made up of steps. An operation is represented by a row with pink cells, and a step is represented by a row with blue cells.

Initially, only the operations are visible.

- To see the steps of a particular operation, click on the arrow to the left of the operation name.
- Click the arrow again to collapse the rows.
- To see all steps for all operations of a protocol, click the **<Expand>** button (Figure 52) from the buttons area.
- To hide all steps for all operations, click the **<Collapse>** button.

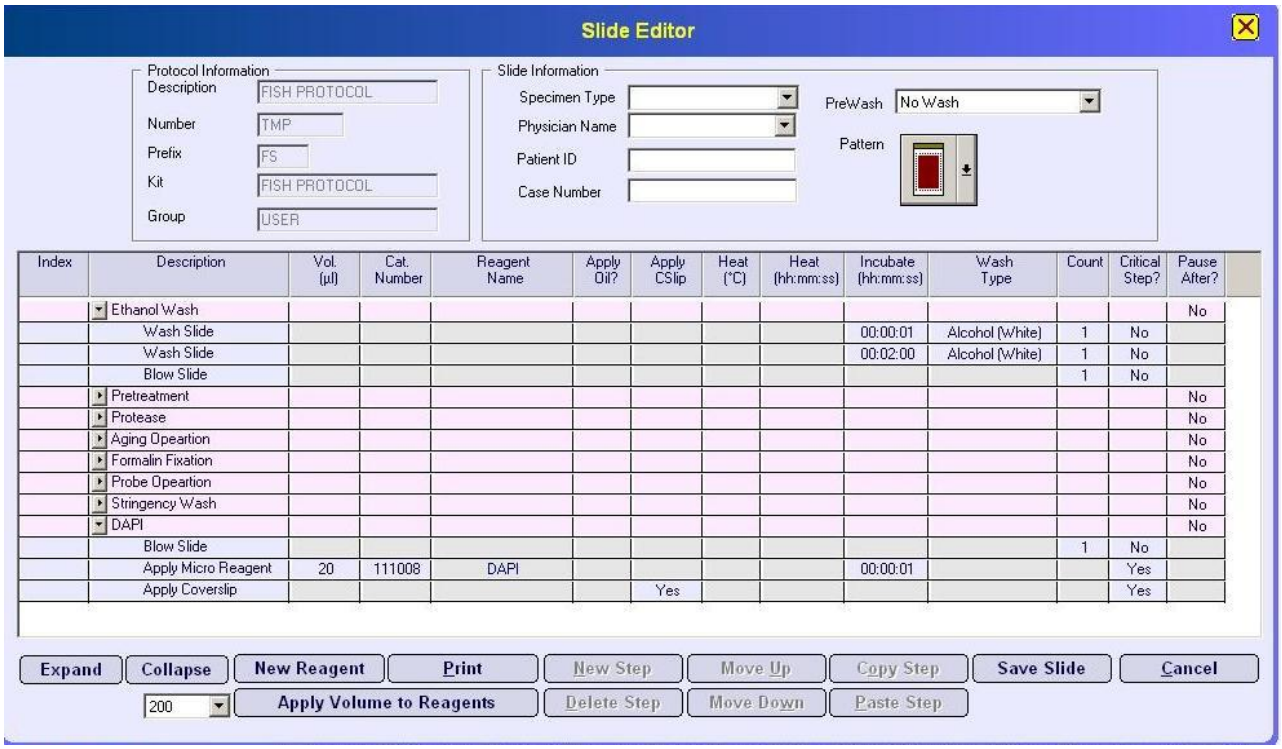


Figure 52: <**New Protocol Editor> Window**

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

- After designing a new protocol:
  - Name the Protocol in the description.
  - Select **<Save Protocol>** to save the new protocol.
  - The **<New Protocol Editor>** window will close.
  - The **<Insert Protocol>** window will become active, with the name of the new protocol highlighted.
  - By selecting the **<Select>** button, the **<Insert Protocol>** window will close. The new protocol will be applied to the Slide Map of the **<Xmatrx: Staining System>** window.

Button Options in the Editor Windows

Expand	Clicking on this button will display all the steps for all operations on the screen.
Collapse	Clicking on this button will close all the steps for all operations on the screen.
Apply Volume to Reagents	After selecting the volume in the field to the left of this button, click on this button to set the reagent volume in all the **<Apply Reagent>** steps in the protocol. The reagent volume should not be less than 100 µL. For example, if the selected volume is 95, the selection will not come into effect. An alternative method for specifying the reagent volume in the particular reagent step is to highlight the step and click the cell in the **<Vol.>** column**.** An arrow will display to allow the user to select the reagent volume from the drop-down. The available range for reagent volume selection is 80 to 850 µL. When the **<Apply Volume to Reagents>** button is clicked, the volume appearing in its field will replace the volume in all the **<Apply Reagent>** steps.
Apply Volume to Probe	When the selected volume in the related field is 45 or less, the **<Apply Volume to Reagents>** button will change to **<Apply Volume to Probe>.** When the **<Apply Volume to Probe>** button is clicked, the volume appearing in its field will replace the volume in all the **<Apply Probe>** steps in the protocol. When selecting a number directly in the **<Vol.>** column, the available volume range for **<Probe Step>** is 10 to 80 µL.
Print	Clicking on this button will print the protocol displayed in the window.
Save Protocol	Clicking on this button will 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.

Slide Information Area

The **Slide Information** area (Figure 53) is open for changes only when working in the **<Slide Editor>** window to edit a single inserted slide. When in the **<New Protocol Editor>** or the **<Protocol Editor>** window, this area is inactive.

When in the **<Slide Editor>** window, the **<PreWash>** and **<Pattern>** settings can be selected by clicking on the arrow to activate the respective dropdown menus.

<Specimen Type> setting can be selected by clicking on the arrow to activate the drop-down menu. In order to have this setting available, the specimen types must be entered in advance by an Administrator from the configuration module.

If desired, the **<Case Number>** may be entered in the appropriate field.

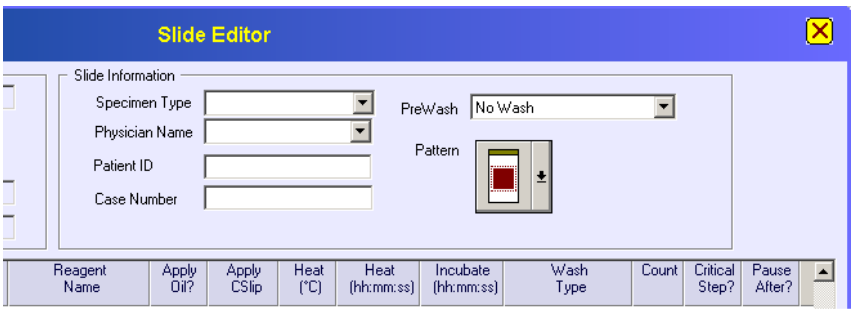


Figure 53: **<Slide Information> Area**

Protocol Information Area

The **<Description>** field (Figure 54) 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.

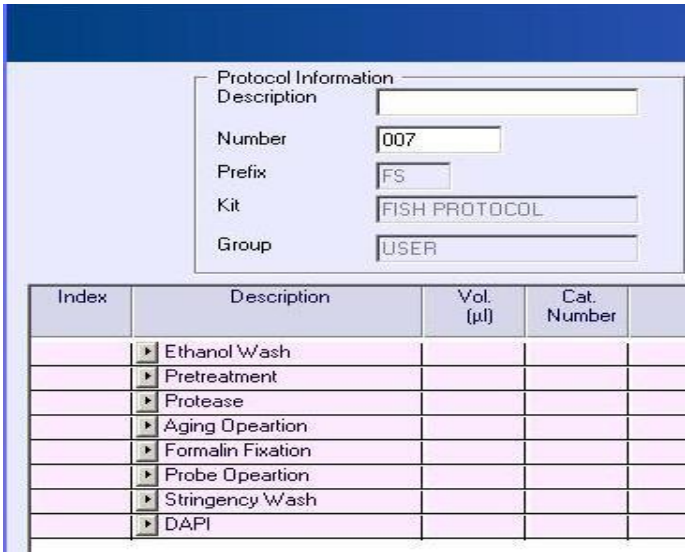


Figure 54: **<Protocol Information> Area**

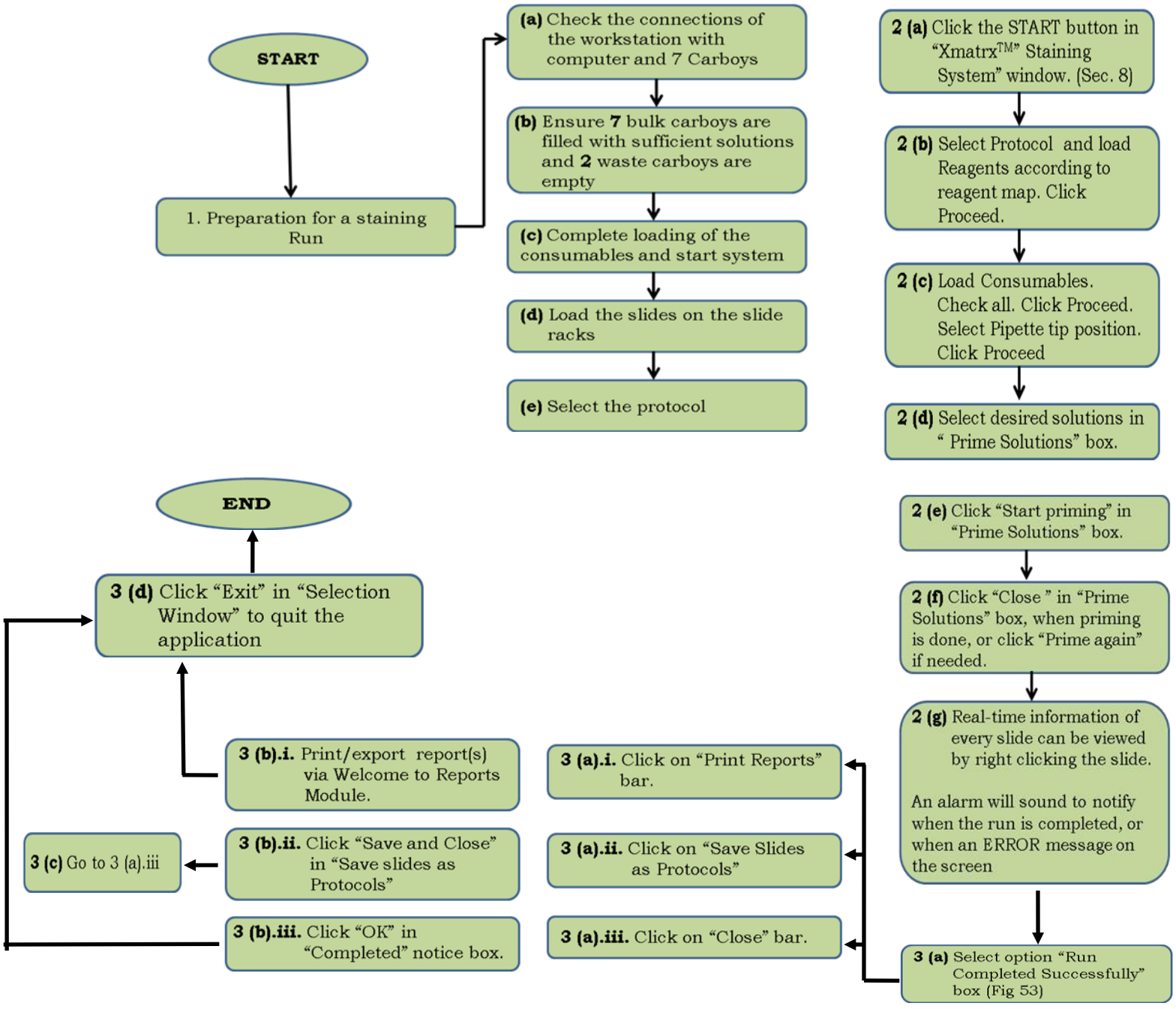
NOTE:

Inserting the slides to the Run through Continuous / stat function is similar to Module A. In Module B.

SECTION 8

EXECUTING A RUN

I. Understanding a Run



II. Executing a staining 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 staining run, the operator should re-verify the following:

1. The slides are properly placed on the slide racks.
2. Required Slide positions are selected.
3. 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.
4. Buffer Carboy levels are sufficient for the run.

Initiating a staining run:

1. Select the slide. Right click/ click twice on the slide to insert the protocol. Click on **<Start>** to start the run.
2. The **<Reagent Screen>** window (Figure 55) will appear. Insert the reagents to be used for the run and click **<Proceed>**.

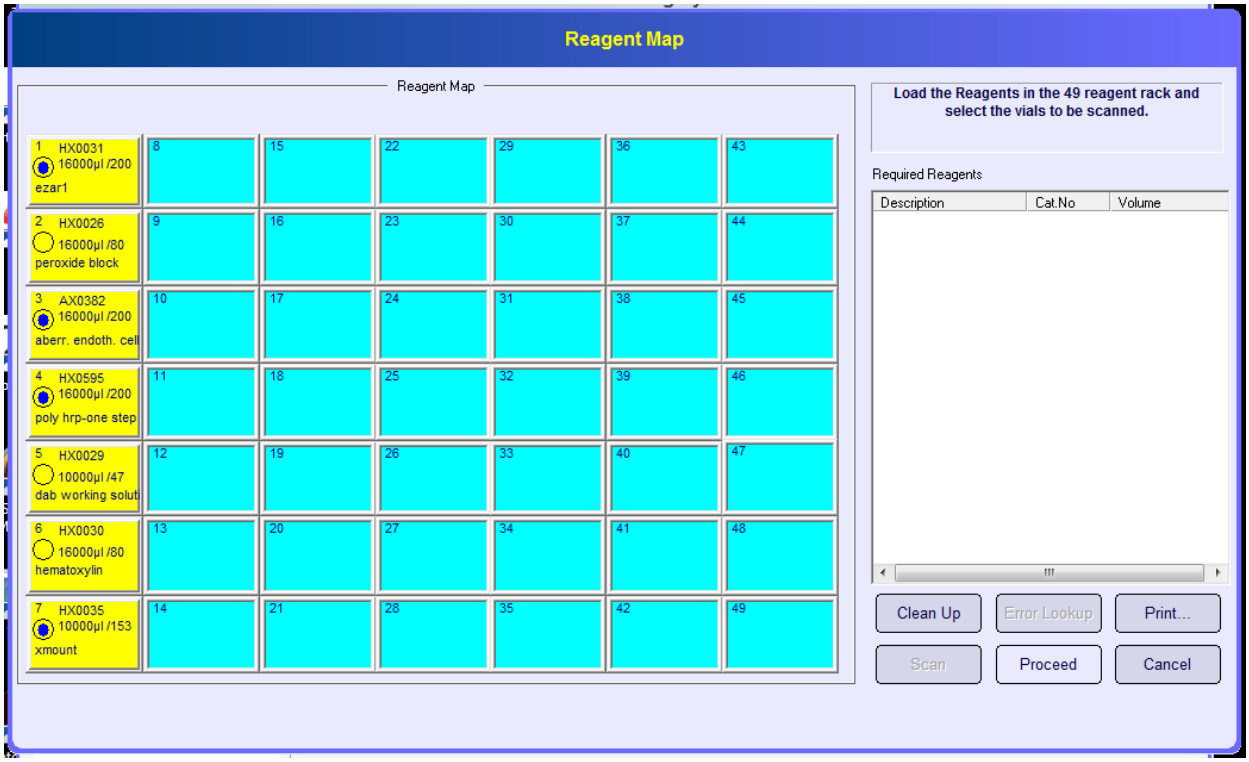


Figure 55: The **Reagent Map** Window

3. If required, select **<Print>** in the **<Reagent Map>** window to print the reagent map for future reference.
4. Wait for the workstation to pressurize. The Pressure Gauge at the lower right end of the workstation should display **>5.0**

5. The **<Load Consumables>** window (Figure 56) will appear. Check all consumables and then click **<Proceed>**.

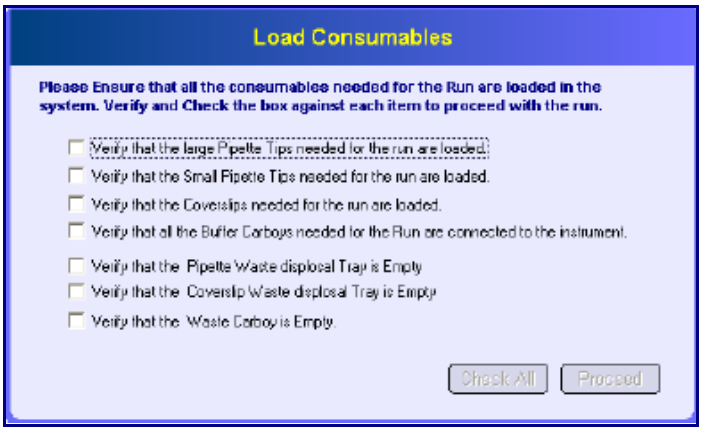


Figure 56: <Load Consumables> checklist

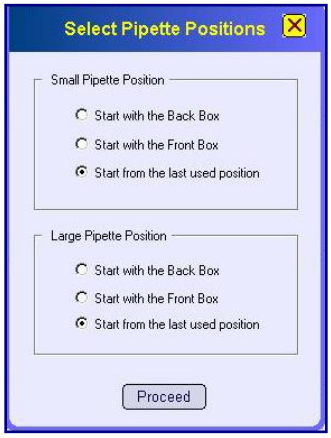


Figure 57: **<Select Pipette Positions>** Window

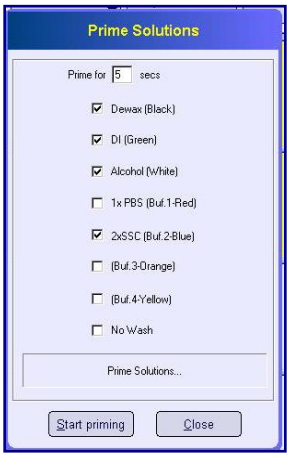


Figure 58: **<Prime Solutions>** Window

6. Make the intended selections in the **<Select Pipette Positions>** window (Figure 57) for the pipette-picking start positions in the two (2) large pipette boxes and two (2) small pipette boxes respectively (front, back or last used position).

7. Select **<Proceed>** to quit this window. The **<Prime Solutions>** box (Figure 58) will appear in order to select the solution(s) that need to be primed.

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

9. Enter the digit(s) into the **<Prime for __ secs>** field to set the prime time (in seconds) (five (5) seconds is the default).

10. Select **<Start Priming>**. The workstation will start priming.

11. If priming is not required, select **<Close>** to bypass and the staining run will start.

12. At the end of priming, the **<Prime Again>** button will become active.

13. If any of the buffer lines has not been 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. The actual staining process will begin. When the process is completed, an alarm will sound.

14. 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.**

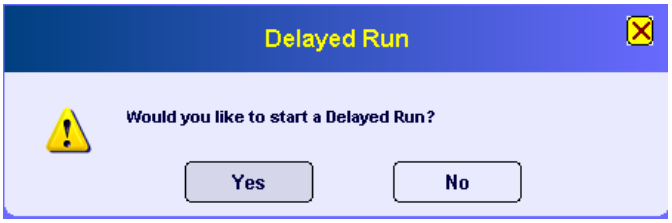


Figure: 45 Delayed Run

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:46 Delayed 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.

15. When the staining run is completed, the **<Run Completed Successfully>** dialog box (Figure 59) will appear for further action.

Figure 59: **<Run Completed Successfully>** Window

16. Once the run is completed successfully, the user may:

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

17. If the user selects **<Close>**, a **<Completed>** dialog box appears (Figure 60).

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

Figure 60: **<Completed>** Confirmation Box

III. Monitoring a Run

Real time information of a staining run may 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 dropdown menu (Figure 61).

2. Select **<View Properties>** option (Figure 54) to open a **<Runtime Properties>** window (Figure 62).

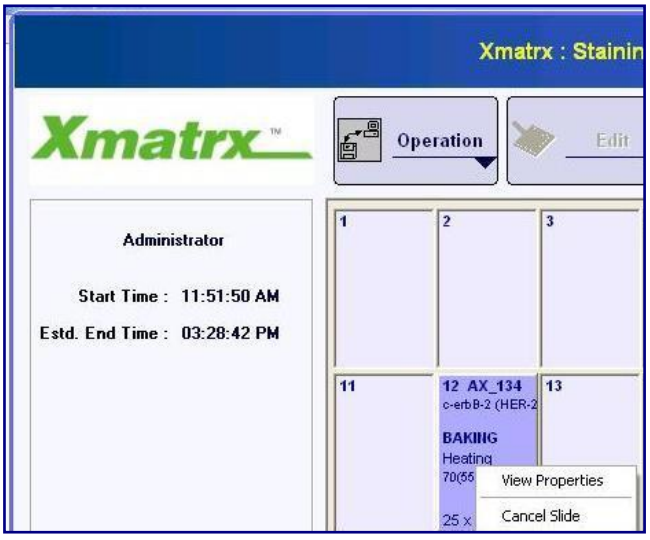


Figure 61: **<View Properties>** Menu

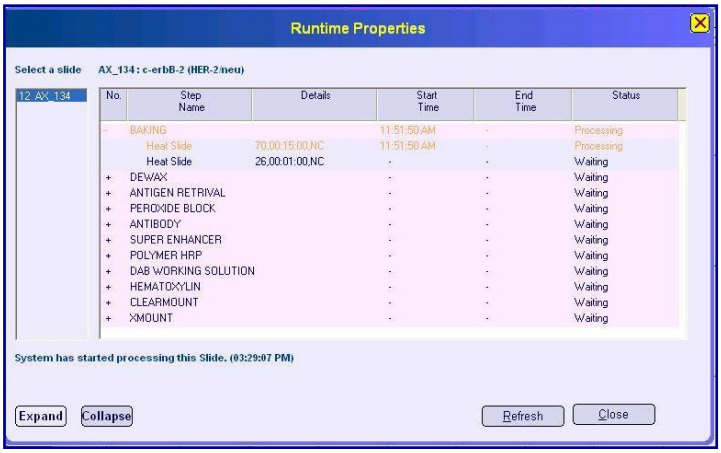


Figure 62: **<Runtime Properties>** Window for IHC

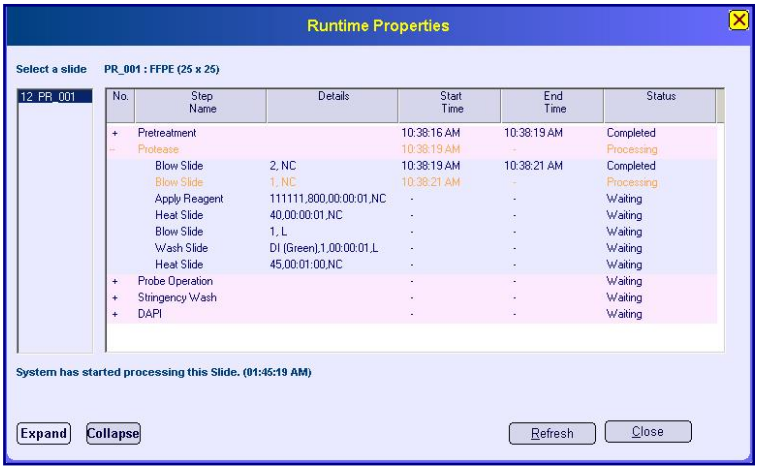


Figure 63: **<Runtime Properties>** Window for FISH

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

NOTE: Estimates of remaining time displayed on the Run time properties window are approximate.

IV. Pausing a Run

To pause a run at any time:

1. Select **<Pause>** at the top of the **<Xmatrx: Staining System>** window. The **<System Paused>** message box (Figure 64) will be displayed.

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

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 any completed slides, select **<Remove Completed Slides>**.

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

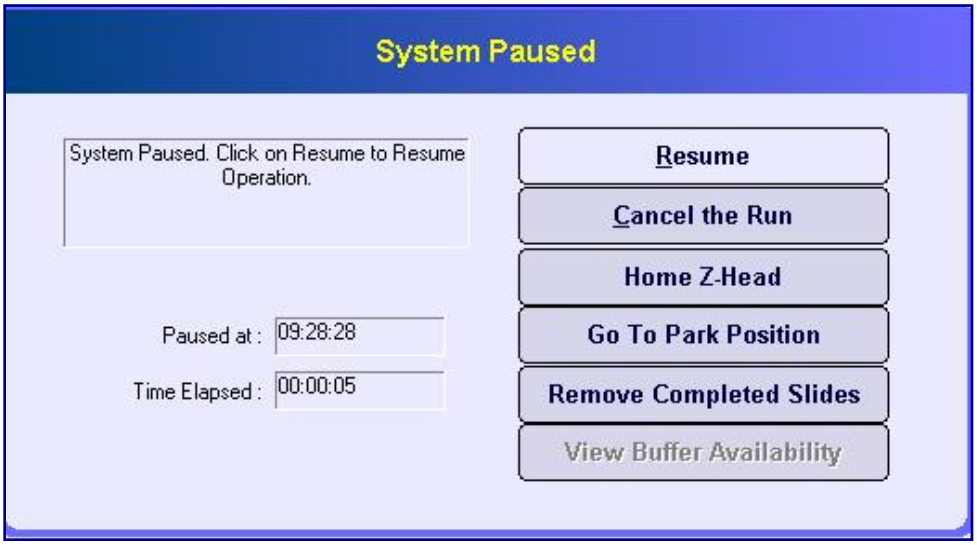


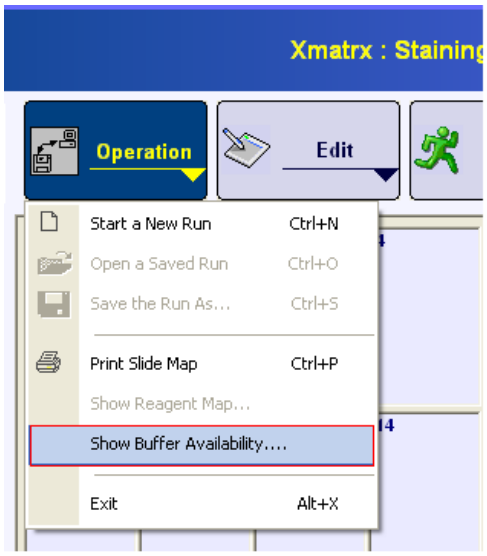
Figure 64: **<System Paused>** Message Box

7. After approximately 60 seconds a **<Confirm>** window will be displayed. If **<Pause>** is not confirmed, the run will resume in 60 seconds.

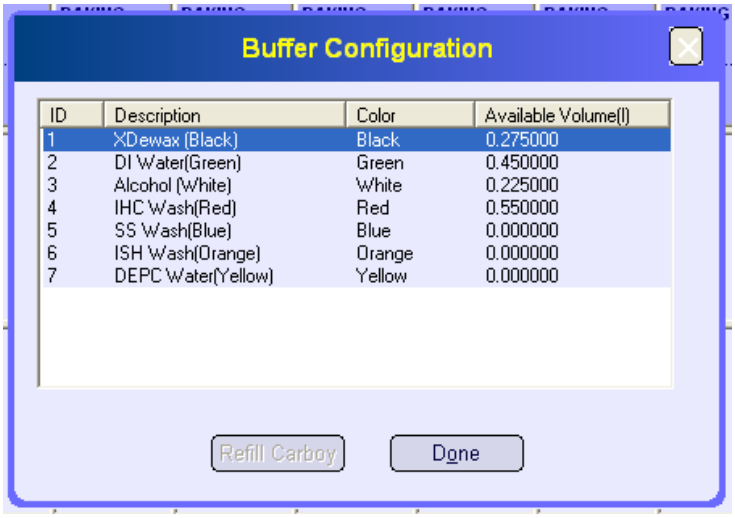
V. Checking the Availability of Buffers

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:



In addition to this, real time monitoring of Buffer level is made available in Bar chart form to the right hand side of <Xmatrx Staining system window>

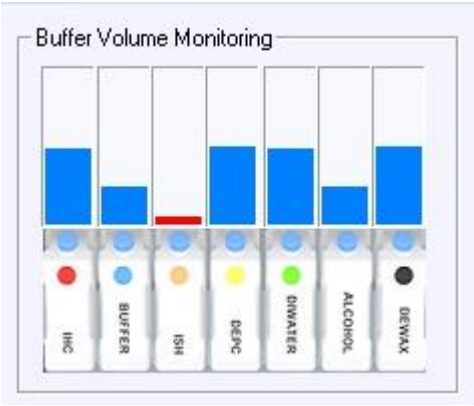


Figure 52: Real Time Buffer Level Monitoring

In this small Bar Chart, Blue and Red levels show actual carboy level filled.
Although buffer levels are calculated and filled as per the requirement, this provides additional information on Live status of Buffer levels. When any level reaches to red color it is indication of buffer has reached to its dead volume level.

VI. Stopping a Run

To stop a run in progress:

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

-OR-

2. Click on the **<Operation>** bar to display a dropdown menu. Select **<Exit>** (Figure 65) from the menu.

Figure 65: **<Exit>** option

3. The stop confirmation message box **<Confirm> (**Figure 66) will be displayed.

Figure 66: **<Confirm>** Stop Message Box

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

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

VII. 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. When the **<E-Stop>** button is pressed while the Z-Head is in motion, it stops moving, the system alarm will sound, and a system error message (Figure 67) will be displayed on the screen. Once the **<E-Stop>** button is pressed, the run in progress is cancelled and cannot be resumed.

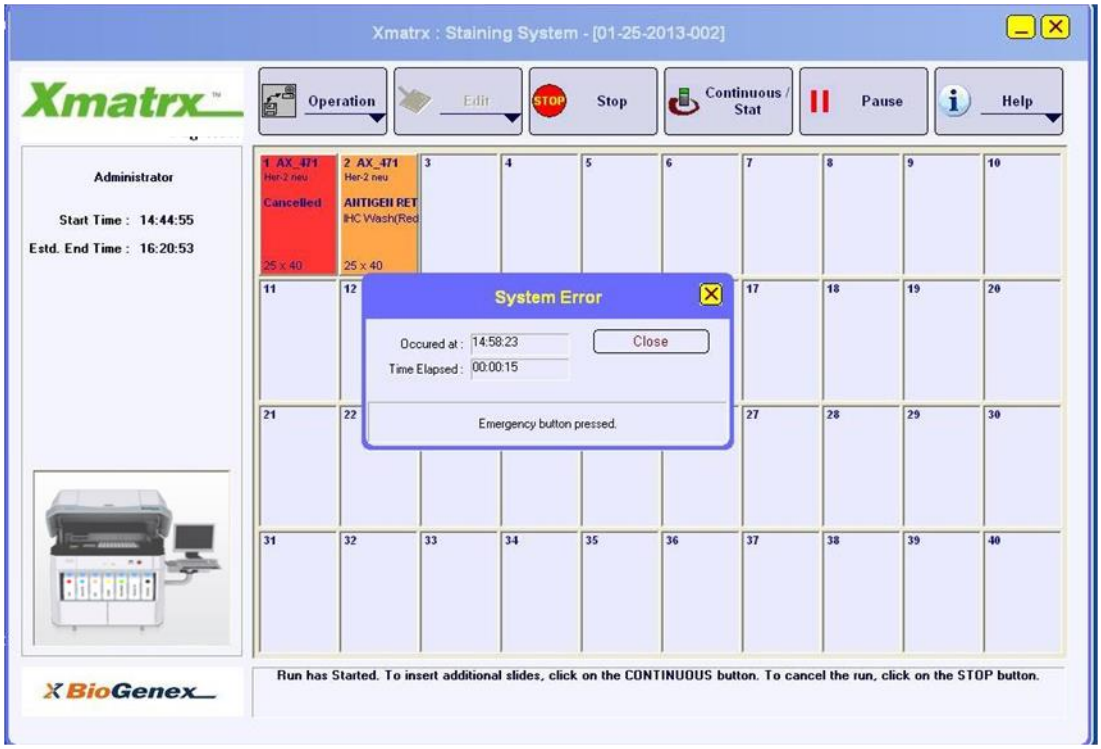


Figure 67: **<System Error Message>** Screen

After clearing the emergency situation, release the **<E-Stop>** button that stops the system alarm. Click the **<Close>** button in the system error message window to exit the **<Xmatrx: Staining System>** window. The **<Selection Window>** will be displayed.

When the **<E-Stop>** button is pressed while the Z-Head is not in motion, the system alarm will sound, and the slides on the slide map turn red (Figure 67).

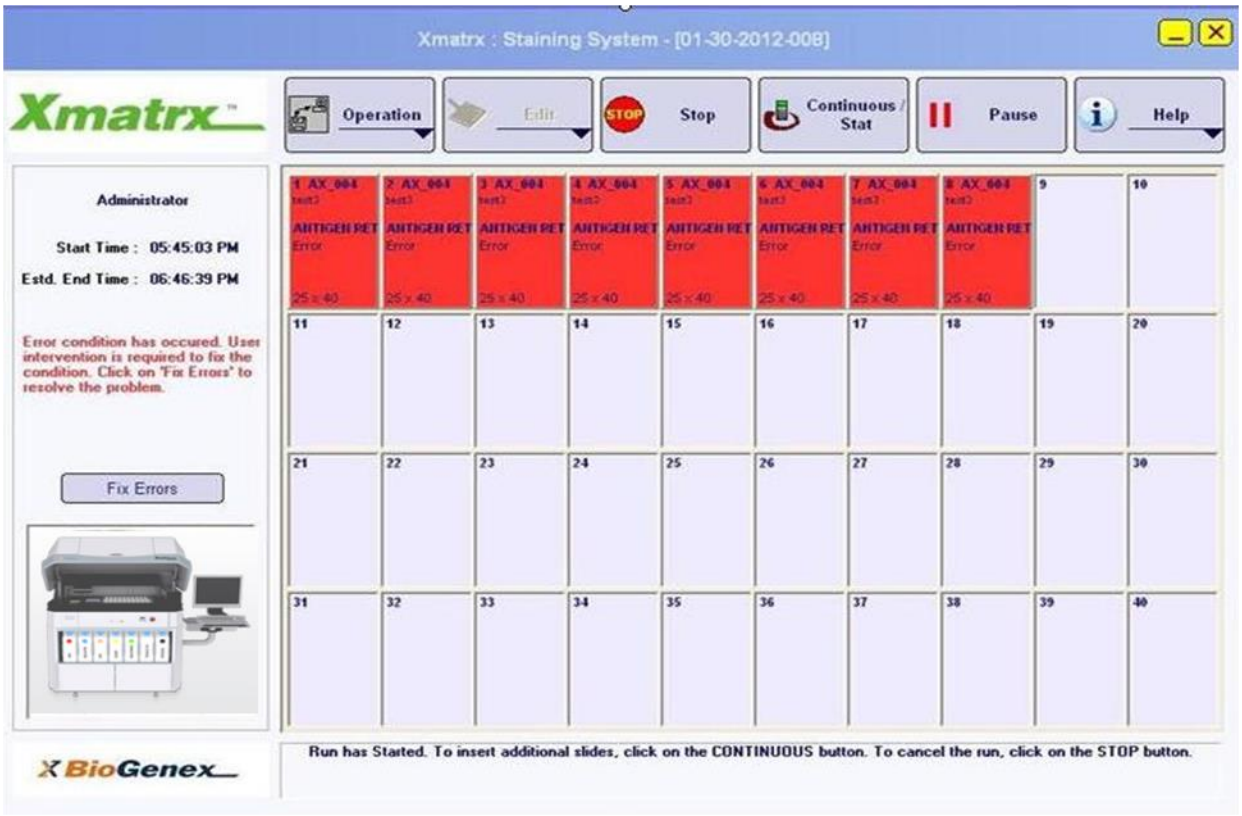


Figure 68: Error Screen

After clearing the emergency situation, release the **<E-Stop>** button to stop the system alarm. the software exits from the staining application; no need to click on stop button and exit)

VIII. The 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 Boxes for Large Tips are empty	Please Load new boxes and resume the staining run
2	Pipette Boxes for Small 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 pipette box	Ensure that tips are available at the desired location and the pipette box is not empty
5	Tip sensor indicates that there is no tip on the Z Head.	Pick up a pipette tip and try again
6	Pipette fell in the middle of an operation	Remove the tip and resume operation
7	Pipette dropped in Slide area	Remove the tip and resume staining
8	Pipette tip has dropped in the reagent rack area	Remove the dropped tip and resume operation
9	Pipette tip has dropped	Remove the fallen pipette tip and resume the operation
10	Unable to dispose pipette	Remove the pipette manually and click **<OK>** to continue
11	There is not enough reagent available in the reagent vial	Replace the vial or add reagent (enough volume) into 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 boxes 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 call BioGenex Customer Service.
19	Pipette Drop at reagent vial during aspiration.	Error message pops up and prompts for removing the pipette tip and Resume.
20	Pipette Drop at reagent vial after as aspiration	Error message pops up , Prompts for adding Reagent to the vial , click < Yes > to add

No	Error Message	Corrective Action
		reagent if needed. Click < No > . to skip and continue the run.

IMPORTANT: During the pipette tip drop at reagent vial after aspiration of the reagent, Pops up for adding reagent, click < Yes > for adding the reagent to the vial for which the Dispensing of volume is due. Click < NO > to cancel the effected slides.

IMPORTANT: Keep in mind that the Reagent Count down in the Registry takes place when you don't add Reagent to the Run, which may cause insufficient reagent for the run.

SECTION 9

GENERATING REPORTS

I. Launching the Reports Module

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

1. Click the bar **<Run Reports>** in the main dialog window **<Selection Window>** (Figure 69), or
2. Click on the **<Print Reports>** option in the **<Run Completed Successfully>** window (Figure 70).

Either way, the **<Welcome to Reports Module>** window (Figure 71) will appear. This window is the main interface for printing.

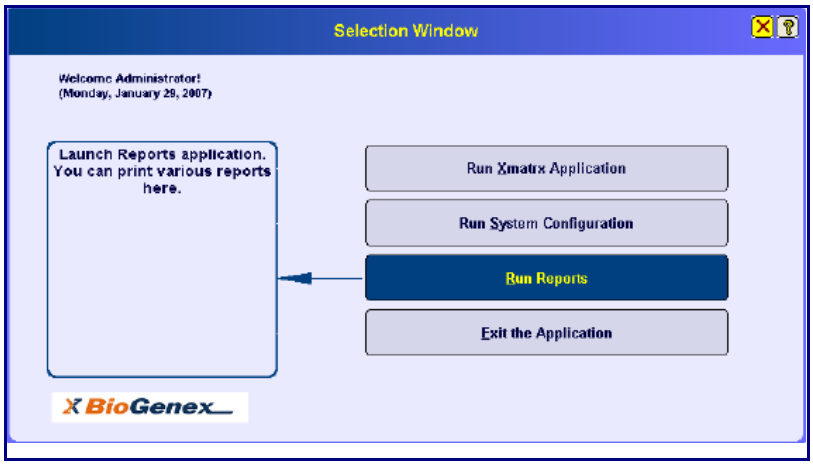


Figure 69: **<Selection Window>** window

Figure 70: **<Run Completed successfully>** window

II. Default Report Types

The *Xmatrx*® 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 (Figure 71) 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.

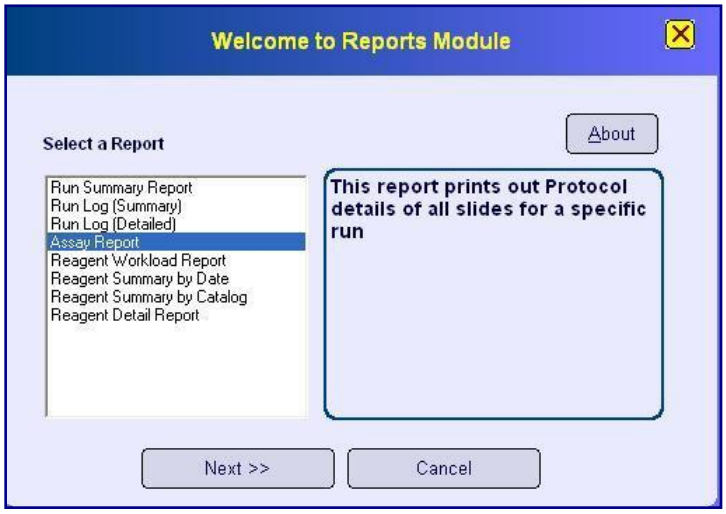


Figure 71: <Welcome to Reports Module> Window

1. Select the report-type in the **<Select a Report>** dialog. Click on **<Next>** in the **<Welcome to Reports Module>** window, which will open the **<Select Parameters for Run Summary Report>** window (Figure 72).

Figure 72: **<Select parameters for Run Summary Report>** Window

2. Select the date (or date range), run number, or catalog number of the report (Figure 73).

III. Previewing and Printing a Report

Once the selections have been 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.
3. To print the report, click on the printer icon 

at the top of the **<Reports>** screen.

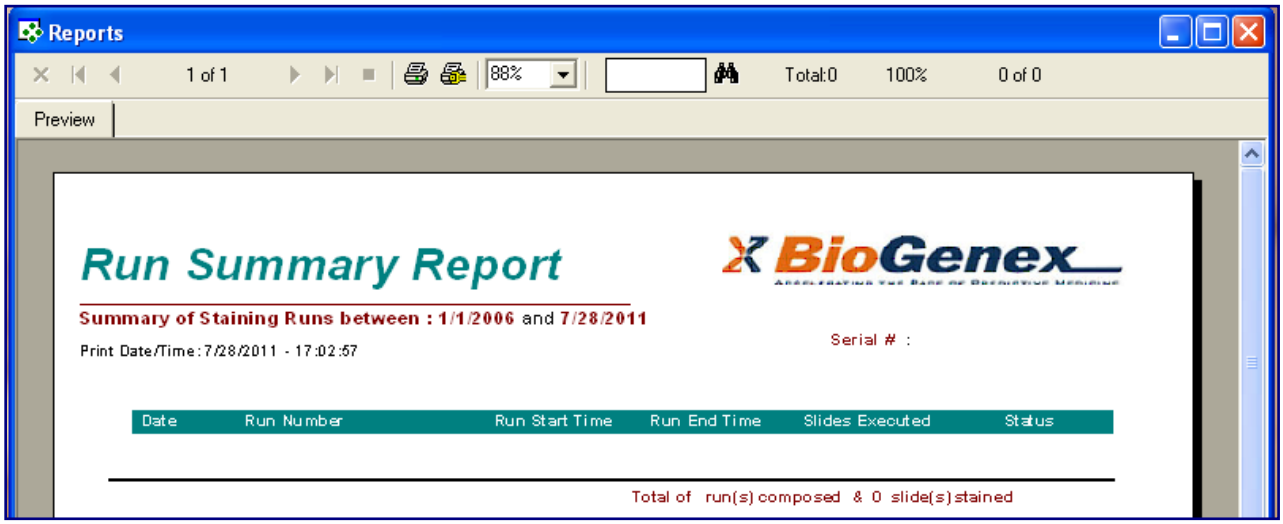


Figure 73: Run Summary Report print view

IV. Exiting the Reports Module

To exit the Reports Module:

1. Click on 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*®.

SECTION 10

TROUBLESHOOTING

Information in this section lists possible *Xmatrx*® malfunctions and errors appropriate corrective actions.

More complicated malfunctions or errors may be referred to BioGenex Customer Service.

I. 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.

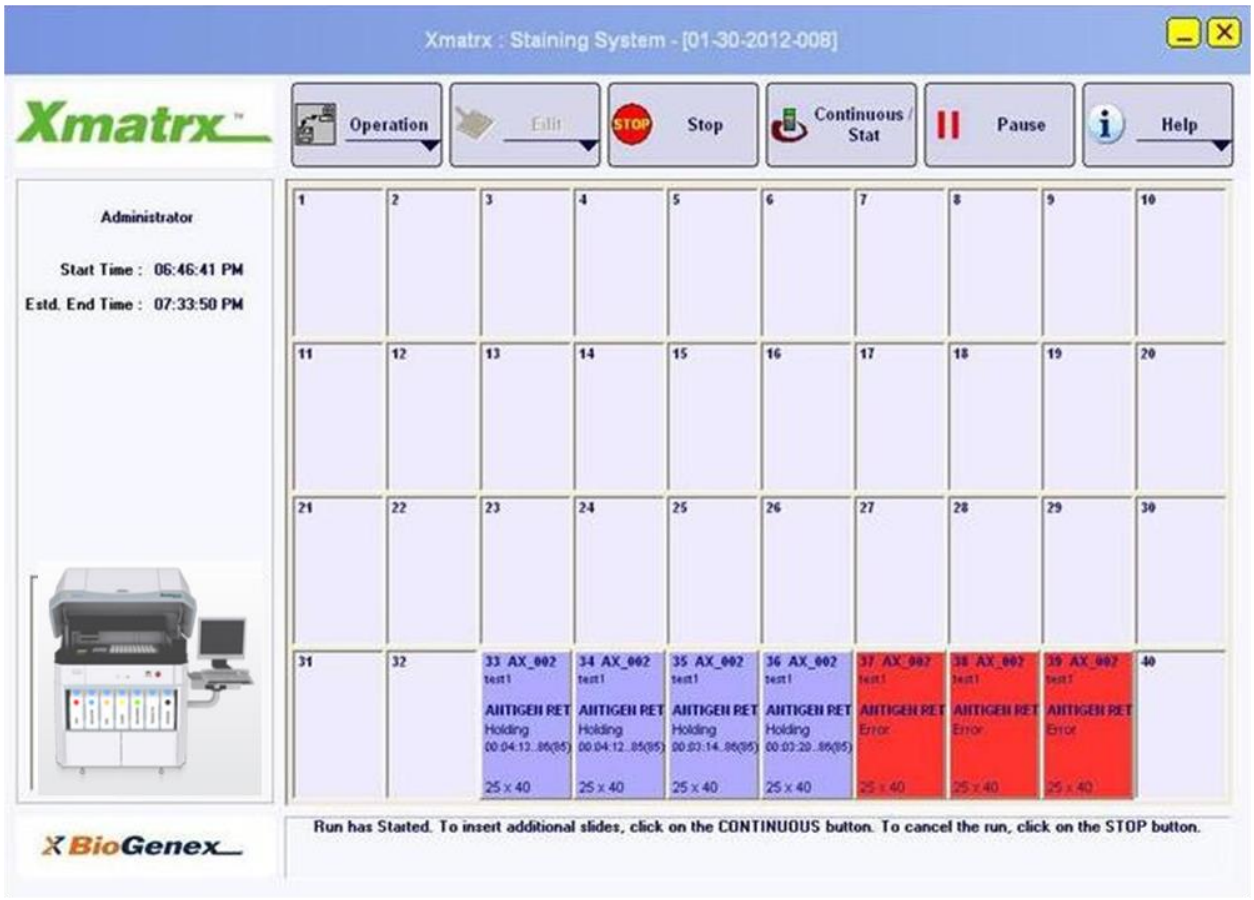


Figure 74: Slide Map: Heating Errors

Corrective Action(s)

1. To view the error message, right click on the failed slide and then click on the **<View Properties>** from the dropdown menu. The **<Runtime Properties>** window displays with the error message displayed on the bottom of the screen in blue.
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 Service.

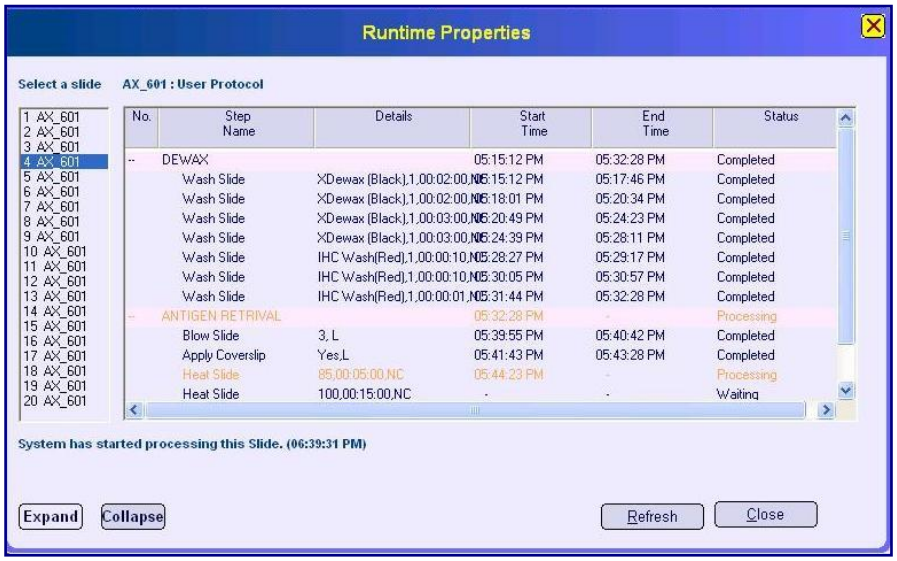


Figure 75: Runtime Properties screen

II. Errors at Pipette Tray

If the Z-Head Pipette Adapter fails to pick up a pipette tip from a Pipette Tray when in operation, or if the Pipette Trays are sensed empty, an alarm will sound and an error message **<System Error>** pop-up message will appear for approximately 10 to 15 seconds (Figure 76). Once the **<System Error>** clears, the affected slides are marked with an **<Error>** and highlighted in red in the Slide Map (Figure 77). A **<Fix Errors>** button displays on the left side of the screen. The following steps describe how to recover from this error.

Figure 76: System Error

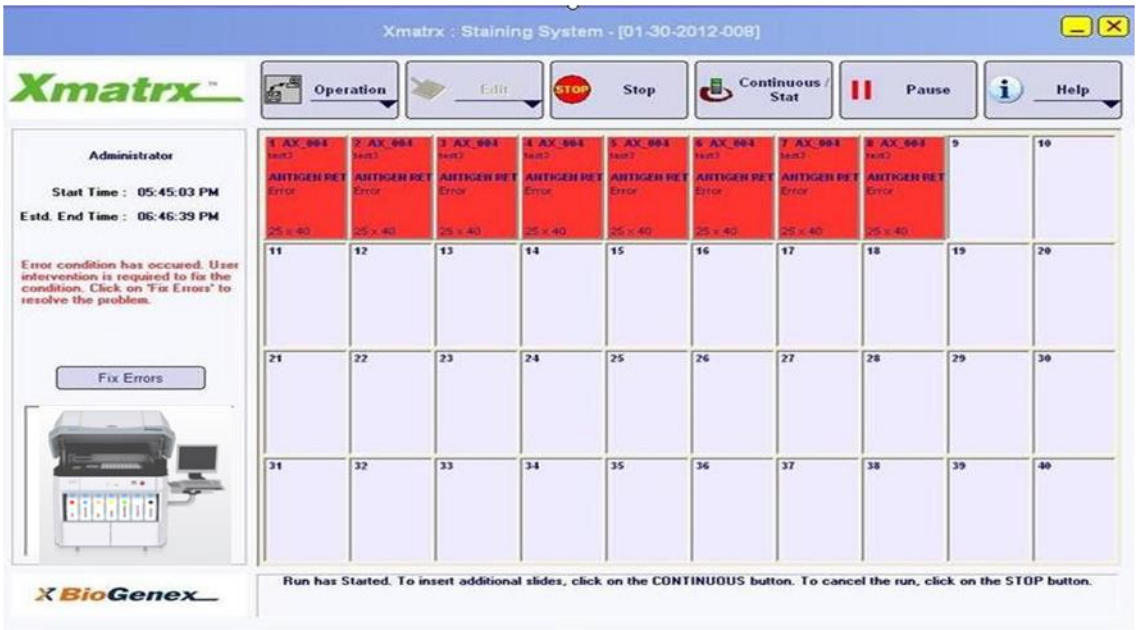


Figure 77: Fix Errors

Corrective Action(s)

1. Click on **<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 (Figure 78).

    - **<Description>** - Pipette Boxes for Large Tips are empty. Please load new boxes and resume the staining run.
    - **<Fix>** - Refill/replace the empty pipette tip boxes and resume operation.

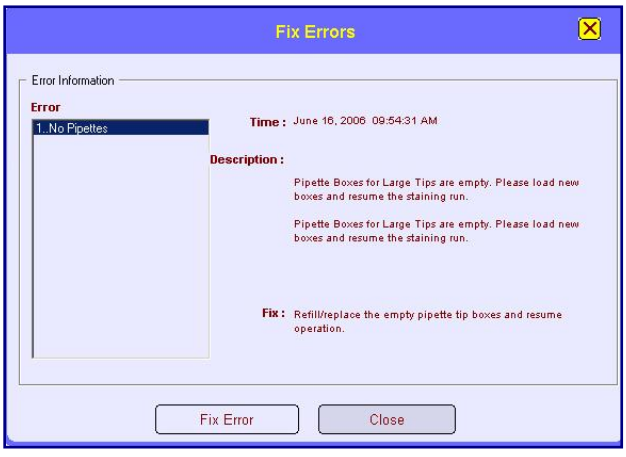


Figure 78: Fix Errors

2. Perform the action as instructed on the **<Fix Errors>** screen to clear the error condition. In this case, refill the pipette tray, or replace the pipette tip tray with a new tray of pipette

tips. Make sure that the new pipette 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 on 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 Service.

III.A Pipette Drop Error (Before Reagent Aspiration)

If the Z-Head Pipette Adapter drops a pipette tip in the middle of an operation, an alarm will sound and an error message **<System Error>** pop-up will appear on the screen (Figure 79-a)

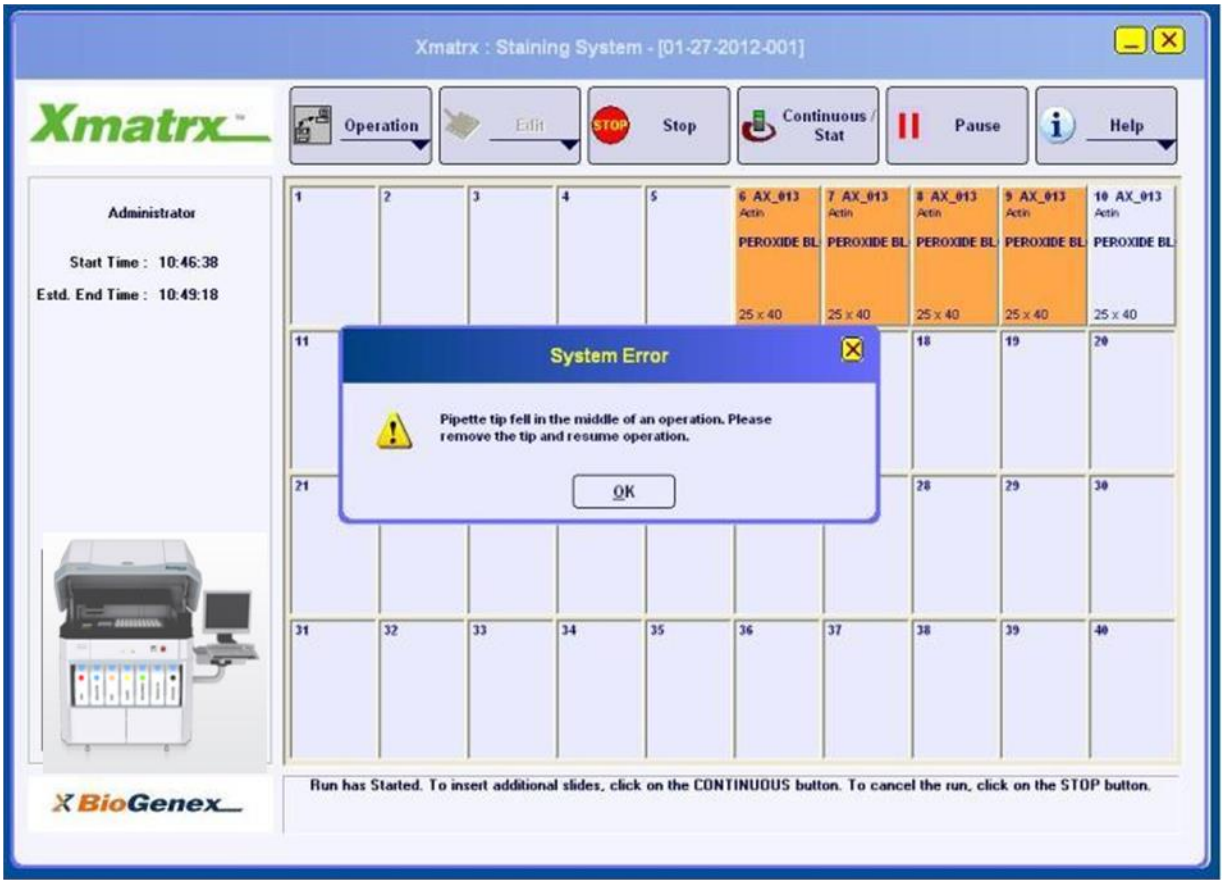


Figure 79-a: System Error: Pipette Dropped

. Once the **<System Error>** gets addressed by the user, the run will continue.

Corrective Action(s)

Remove the fallen tip and Click on **<OK >** button in the window. When clicked on OK button, then the slides get resumed and the run will continue.

III.B Pipette Drop Error (After Reagent Aspiration)

If the Z-Head Pipette Adapter drops a pipette tip in the middle of an operation after the reagent aspiration, an alarm will sound and an error message **<System Error>** pop-up will appear on the screen (Figure 79-b)

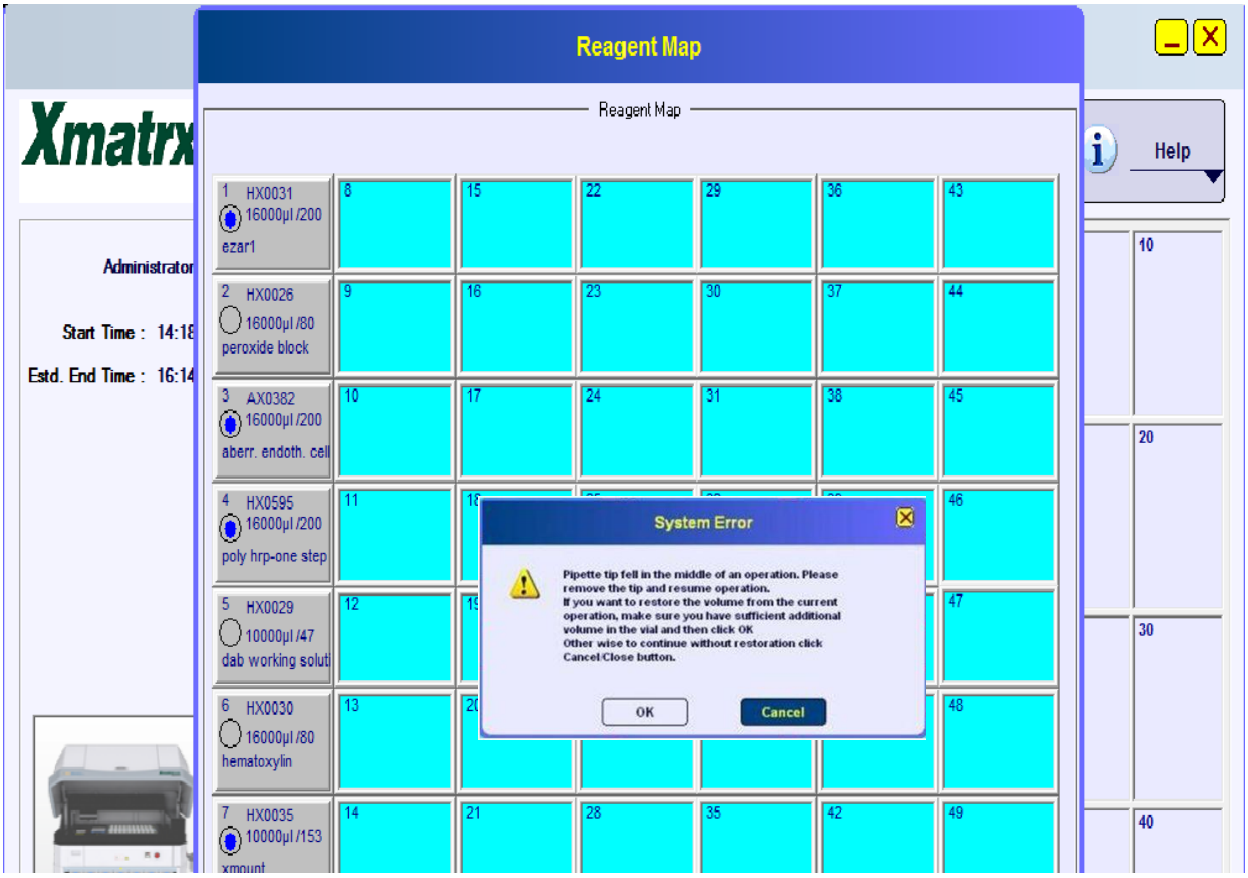


Figure 79-b: System Error: Pipette Dropped

Corrective Action(s)

1. Remove the fallen tip and Click on either **<OK> or <Cancel>** button in the window.
   - **1.1** When **<OK>** button is clicked, the lost reagent volume gets restored and the respective slides will be processed. **(Note: prior clicking on Ok button, add the respective volume in the vial manually as asked in the <system error> message displayed).**
   - **1.2** When **<Cancel>** button is clicked, the lost volume doesn't get restored back and the slides which are in error condition remains into error condition without being processed because of the volume insufficiency.

IV. Pipette Disposing Error

After attempting allowable retries, if the Z-Head Pipette 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 for approximately 10 to 15 seconds (Figure 82). Once the pop-up message clears, the Z-Head will try again to dispose of the used pipette tip into the Pipette Disposal Tray. If the failure recurs (after attempting the allowable retries), an alarm will sound and the error message **<System Error>** will display on the screen for approximately 10 to 15 seconds.

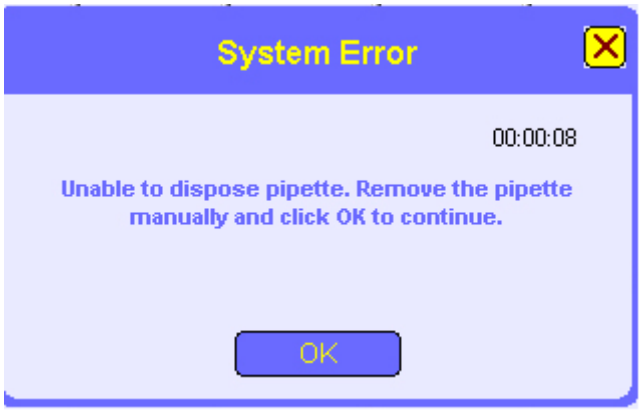


Figure 82: System Error: Pipette Disposing

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. Wait for the next **<System Error>** message pop-up to display. When the **<System Error>** message is counting down and before it expires, manually remove the pipette tip from the Pipette Adapter before the Z-Head starts to move. After the pipette tip is removed and the **<System Error>** is cleared, the system will normally proceed to the next step.

2. If the problem persists, discontinue the run and contact your BioGenex Customer Support.

V. Empty Coverslip Box Error

If the Z-Head suction cup fails to pick up a coverslip from a coverslip stack while in operation, or if the coverslip boxes are sensed as empty, An error message pops with a count down time of 10 sec , the slides in the Slide Map that are to be affected with the error will be marked as **<Error>** and highlighted in red on the Slide Map screen. A **<Fix Error>** button will display on the left side of the screen.

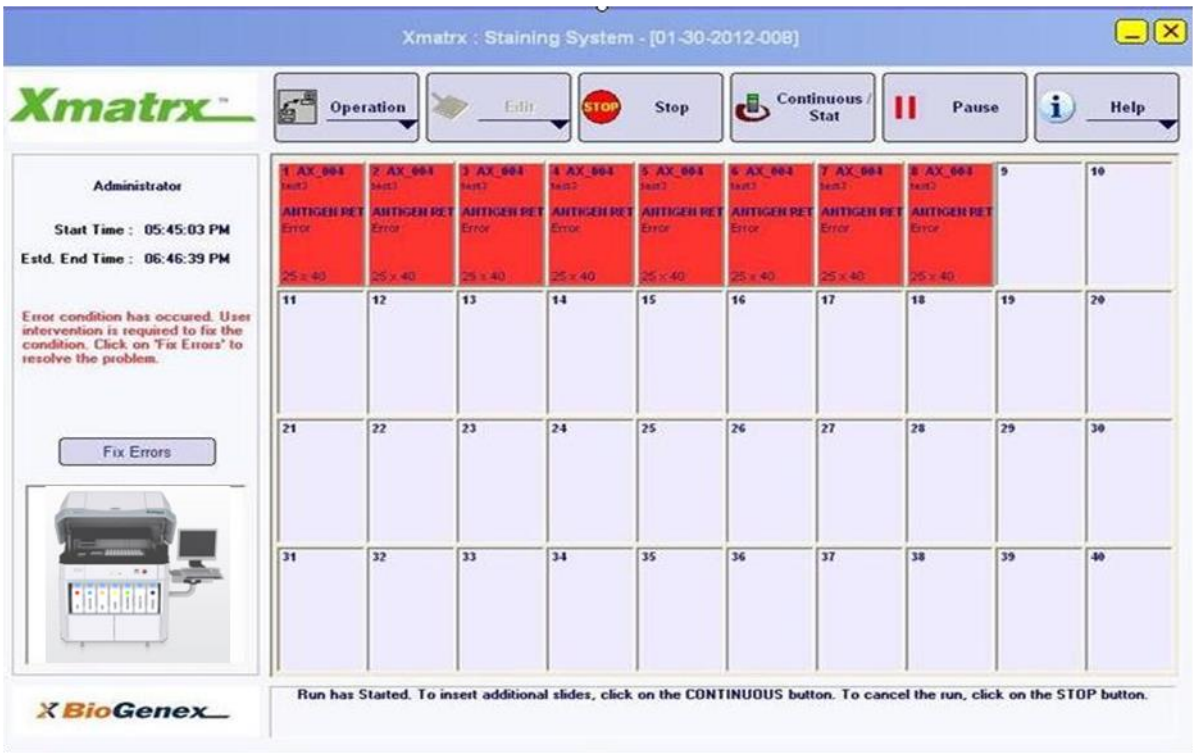


Figure 83: Fix Errors: Empty Coverslip Box

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 box is empty. Small coverslip boxes are empty. Load coverslips and resume staining on affected slides.
    - **<Fix>** - Refill/replace the empty coverslip boxes and resume operation.

2. 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 box.

3. 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.

4. If the problem persists, contact BioGenex Customer Service.

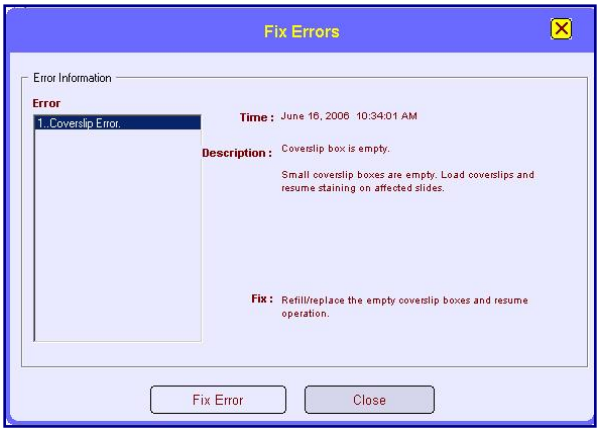


Figure 84: Fix Errors: Coverslip Box is Empty

VI. 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 dropdown menu. The **<Runtime Properties>** window will appear with the error message displayed on the bottom of the screen in blue. See the following two (2) figures for possible error messages.

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 Service.

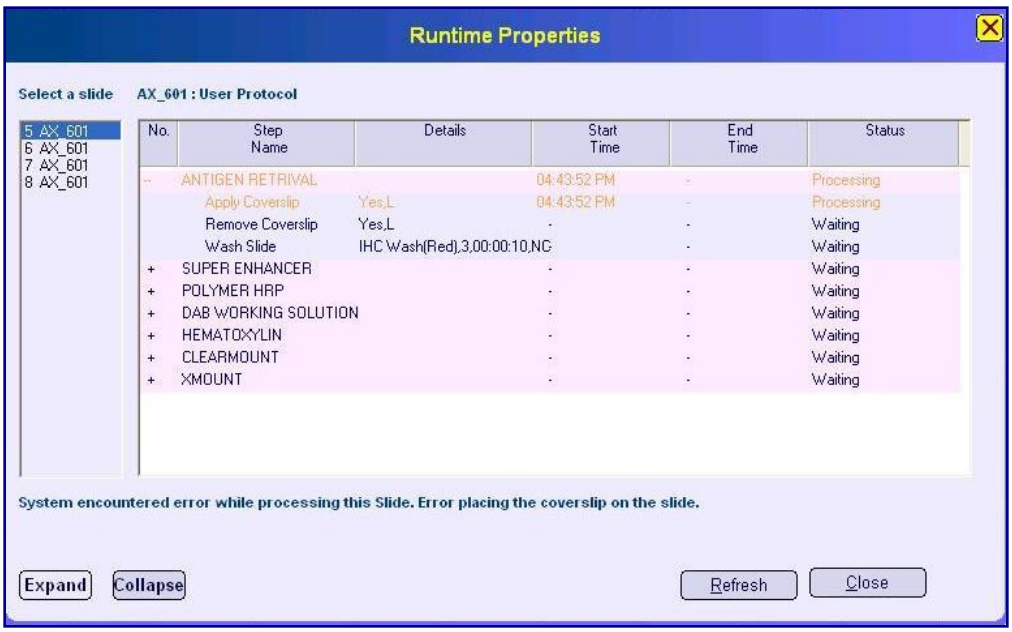


Figure 85: Coverslip Placement Errors

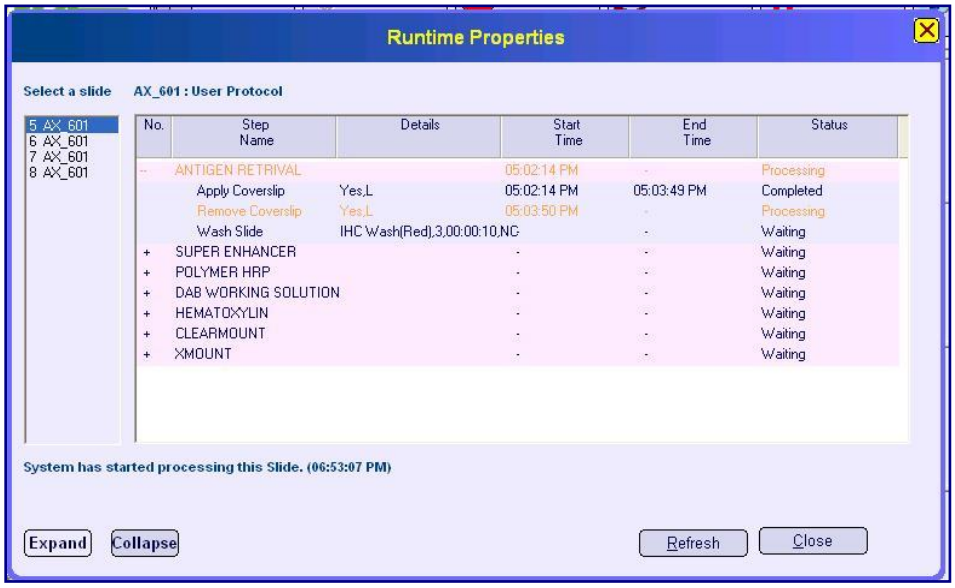


Figure 86: Coverslip Pickup Errors

VIII. Basic Troubleshooting

No	Symptom	Possible Cause(s)	Corrective Action(s)
1	There is no power to the workstation	• 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 be blown	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 personnel to check and replace the fuse.
2	Buffers are not primed.	• Air leakage • Air pressure may not be strong enough	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 when priming. 3. If the problem still persists, please call BioGenex Customer Service
3	Failure in Coverslip pick up	• Related CS Box is empty • Vacuum pressure of Suction Cup is not strong enough • Suction Cup could not arrive at the correct position over the CS Box	1. Check the CS Box, 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 Box.
4	Failure in pipette tip pick up	• Target pipette box is empty • Pipette Adapter can not fit into a pipette properly	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	• Stopping position of Pipette Adapter at Pipette Ejector is not correct	Request service personnel to calibrate the disposal position of Pipette Adapter at the Pipette Ejector.

SECTION 11

ROUTINE MAINTENANCE

The *Xmatrx*® System requires minimal routine cleaning and sanitizing. Regular preventive maintenance ensures dependable and consistent staining and helps to eliminate any potential contamination.

I. Daily Cleaning

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

1. Remove and empty the Waste Pipette Tray from the workstation at the end of every workday. Dispose the used pipette tips and rinse the Waste Pipette Tray with DI water. Place the Waste Pipette 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 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>**.

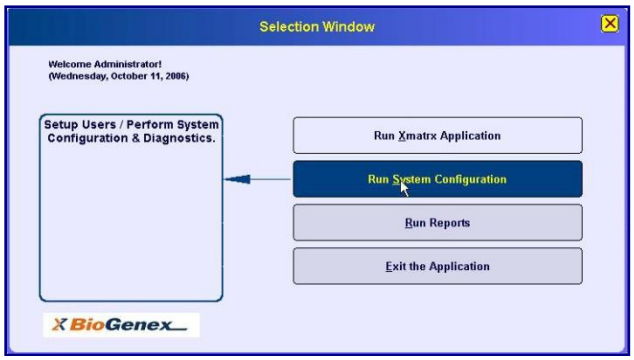


Figure 87: **<Run System Configuration>**

b. The **<Xmatrx – System Configuration & Calibration>** window will appear. Click on the **<Test>** menu.

Figure 88: **<Xmatrx – System Configuration & Calibration>**

c) In the **<Test>** menu, select **<System Cleanup>**.

Figure 89: **<System Cleanup>**

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

e) The **<System Cleanup>** window will appear. Click **<Start>**.

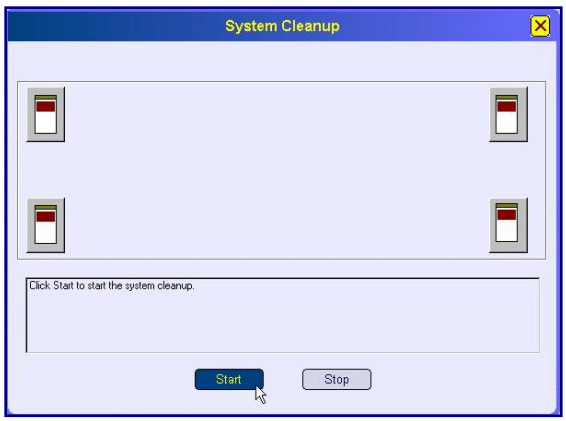


Figure 90: **<System Cleanup>**

NOTE: System Cleanup will complete in approximately 30 minutes. It will utilize the water and ethanol carboys.

f) After System Cleanup has completed, click on the **<X>** in the upper right hand corner or 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*® system.

Prime Solutions

The following are guidelines for operating in the **<Prime Solutions>** window:

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 dropdown menu, select the option **<Prime Solutions>** to open the **<Prime Solutions>** window.

⇩

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

- Click in the top four (4) squares to select all (i.e., Dewax, DI water, Alcohol, and Buffer Solutions).
- 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).
- 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.
- Repeat above operation to complete the priming with all four (4) buffer lines.
- 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.
- 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.

II. 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 cleaning 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 previous flowchart). 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>** then **<Diagnostics>**. The **<Diagnostics – Motion>** window will open (Figure 91).

   In the **<Diagnostics – Motion>** window, use the X/Y arrows to bring the Z-Head at 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.

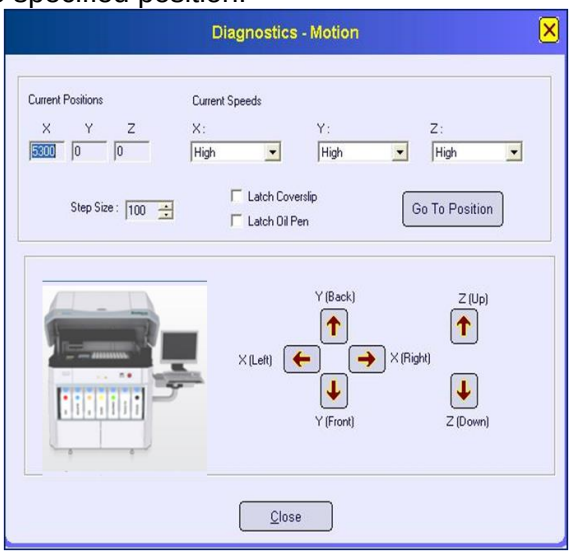


Figure 91: **<Diagnostics – Motion>** window

3. Clear off De-Wax residue from De-Wax line: If De-Wax solution has been used through the De-Wax line, empty the De-Wax carboy; fill it with 100 ml of alcohol. Prime De-Wax 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 De-wax line later. (See below).

   NOTE: Skip the above step if the De-Wax 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 Carboy 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 (1) 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; reattach them to their appropriate ports on the Liquid Panel. Prime their liquid lines three (3) times. Let sit for ten (10) 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 1 to 2 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 to dry.

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 air-dry overnight.

III. Half Yearly Maintenance Arrangement

Only a trained service technician, or BioGenex service personnel, will 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 *Xmatrx*® 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 Operating Manual.

II. Service Charges
BioGenex may charge 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.

IV. Warranty Disclaimer
The System, including all hardware, software, and parts are provided AS IS. BioGenex SPECIFICALLY DISCLAIMS ALL EXPRESS, STATUTORY OR IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO, IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT OF THIRD PARTY RIGHTS. Where disclaimer of implied warranties is prohibited by law, such warranties expire 90 days after the date of delivery of the System.

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 Service.

The administrator can make a good use of the diagnostics feature of the *Xmatrx*® system to test the functioning of the system, or to locate the problem with the system. In the *Xmatrx*® system, 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 **<Xmatrx>** icon on the computer screen to open the **<Log on>** window.
2. Enter as Administrator and enter password, and select **<Log on>** to open the **<Selection Window>**
3. Select **<Run System Configuration>**. The **<Xmatrx – System Configuration & Calibration>** window appears (Figure 93).
4. Select **<Test>** to open a dropdown menu.
5. Select the option **<Diagnostics>** in the dropdown menu to open a submenu.
6. Select **<Operation>** in the submenu. The **<Operations>** screen (Figure 94) will appear.

Upon entering the **<Operations>** window, five (5) modules will display. By clicking on any button under a module, an operation window will open to work in. Follow the instruction in the window to proceed.

Figure 92: **<Xmatrx – System Configuration & Calibration>** Window

Figure 93: <Operations> Window

Under the <Diagnostics> **dropdown 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 *Xmatrx*® System

S.No.	Items to check	Result (Circle as appropriate)	Note
1.	Monitor display is very clear to see	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.	Test functionality of Z-Head assembly by Diagnostics	Done No	
13.	Conduct "Temp Switching Test", "Peak Temp Test", and "Temp Durability Test"	Done No	
14.	Conduct a "4-Corner Test Run"	Done No	
15.	Follow monthly maintenance schedule to complete cleaning work	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
23.	Check the oil tubing (PVC) and replace if necessary.		
Comment			

Maintenance Performed by: Date:

APPENDIX 3

SOFTWARE LICENSE
(BioGenex Software)

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APPENDIX 4

IMPORTANT - READ CAREFULLY BEFORE USING THE *Xmatrx*® AUTOMATED STAINING SYSTEM WHICH CONTAINS MICROSOFT® SOFTWARE

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(Microsoft Software)

IMPORTANT-READ CAREFULLY: This End-User License Agreement (EULA) is a legal agreement between you (either an individual or a single entity) and the manufacturer (Manufacturer) of the special purpose computing device (SYSTEM) you acquired which includes certain Microsoft software product(s) installed on the SYSTEM (SOFTWARE PRODUCT or SOFTWARE). The SOFTWARE includes computer software, the associated media, any printed materials, and any online or electronic documentation. By installing, copying or otherwise using the SOFTWARE, you agree to be bound by the terms of this EULA. If you do not agree to the terms of this EULA, Manufacturer and Microsoft Corporation (Microsoft) are unwilling to license the SOFTWARE to you. In such event, you may not use or copy the SOFTWARE, and you should promptly contact Manufacturer for instructions on return of the unused product(s) for a refund.

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