NanoVIP®

Automated Staining System

OPERATOR'S MANUAL

Cat. No.: AS1020

CE-IVD FOR *RESEARCH* USE ONLY

Doc No. 953-0060.0, Rev. D, ECO: 330-SEZ

BioGenex

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IMPORTANT:

NanoVIP® 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 *NanoVIP*® *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 described here 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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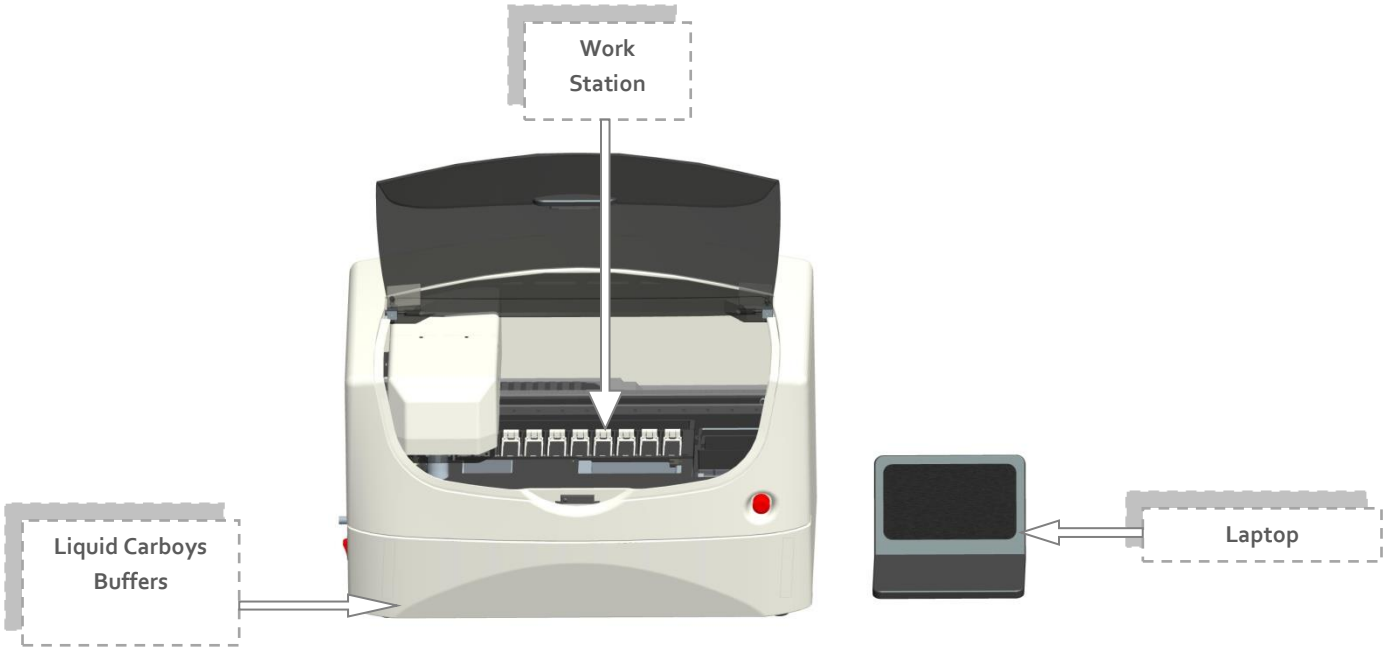
NanoVIP® Software Version **2.0**

Overview of the *NanoVIP*® *InVitro Diagnostics*Automated Staining System



BioGenex NanoVIP® 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 10 slides individually in a single run.

In this manual, the entire combination of the *NanoVIP*® workstation, the Laptop, and the bulk fluids are referred to as "BioGenex NanoVIP® System", or simply "the system".

The mechanical mainframe that directly performs automated staining is referred to as "NanoVIP® workstation", or simply "the workstation", and "the instrument."

Checklist of *Nano VIP*® Automated Slide Staining System with Accessories

No.	Description of Item	Part Number	Qty	Notes
1	Slide Rack	6520-30759	1	
2	Coverslip Stack 18 X 18	6520-37981	2	
3	Coverslip Stack 25 X 25	6520-37980	2	
4	Coverslip Stack 25 X 40	6520-60348	2	
5	Coverslips 18 X 18	XT121-YBX	1 Box	
6	Coverslips 25 X 25	XT122-90X	1 Box	
7	Coverslips 25 X 40	XT118	1 Box	
8	Slide 18X18	XT128-SL	1 Box	
9	Slide 25 X 25	XT108-SL	1 Box	
10	Slide 25 X 40	XT134-SL	1 Box	
11	Pipette tips small 200µl	XT146-01X	1 Box	
12	Tray-Cover Slip Disposal	6520-40811	1	
13	Waste Carboy	6520-37988	1	
14	Tip disposal tray	6520-17835	1	
15	Waste Carboy Tube	4460-02508	5 feet	
16	Assy.24 Vial tray	6520-60234	1	
17	Funnel	4300-41020	2	
18	Laptop and charger	4270-00147	1	
19	Laptop Communication cord	4270-04127	2	
20	Instrument Installation Check List-Nano VIP	951-6168.1	1	
21	Bull's Eye	6520-04116	1	
22	Nylon tie cable 200 mm	4508-10005	5	
23	Oil Bottle cap removal-Wrench	6520-10059	1	
24	10 ml Vials	6520-41714	6	
25	One line item from the following list, depending on the country of destination			
25.a	Power Cord for China	1650-02985	2	
25.b	Power Cord, G, 10A/250V, Italy	1650-02965	2	
25.c	Power Cord, K, 10A/250V, UK	1650-02966	2	
25.d	Power Cord, C, 10A/250V, Europe	1650-02967	2	
25.e	Power Cord, E, 10A/250V, Australia	1650-02968	2	
25.f	Power Cord, A, 10A/125V, USA	1650-02970	2	
25.g	Power Cord, H, 10A/250V, Israel	1650-02971	2	
25.h	Power Cord, B, 12A/125V, Japan	1650-02972	2	
25.i	Power Cord, I, 10A/250V, India/South Africa	1650-02973	1	

25.j	Power Cord, F, 10A/250V, Denmark	1650-02974	2	
25.k	Power Cord, D, Switzerland	1650-02977	2	
26	Power Cord Adapter, C14 to C5-10A, 250V	1650-10011	1	
27	FAB, OIL NEEDLE BASE	6520-41199	1	
28	ASSY HEATER WIRING	4501-17812	2	

* To be procured locally

NOTE:

1. There are no user serviceable parts in the ***NanoVIP®*** system. When any service is needed, please consult BioGenex Laboratories, Inc. at 1-800-421-4149 (for USA and Canada only)
   For support outside USA and Canada, please contact your local distributor.
2. To order consumables or reagents; please contact BioGenex Laboratories, Inc. For detailed contact information, see page 5 of this manual.

3. **One line item from the following power cord list (Item# 28a to28k, depending on the country of destination).**

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INTRODUCTION TO NANO VIP®

1.1. INTENDED USE

NanoVIP®Automated Slide Staining System is CE-IVD for research use only. It is suitable for IHC, Fluorescent *In-Situ* hybridization (FISH),ISH

The NanoVIP® 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. NanoVIP is easy to install and configure to initiate the runs Its Plug and play type of instrument for ease of use.

A qualified pathologist must interpret the results. This system does not provide clinical interpretation of any assay based processed staining results. Such interpretation is solely the responsibility of the user.

The clinical interpretation of any positive signal or its absence in developed slides should be evaluated within the context of clinical presentation, morphology, and other pathological criteria. The clinical interpretation of any positive signal or its absence should be complemented by using proper positive and negative internal and external controls, as well as other diagnostic tests.

WORK PRINCIPLES OF THE WORKSTATION

The workstation has an XYZ robotic arm.

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

The Laptop is for running the NanoVIP® system, and should not be used for any other purposes.

TRANSPORTATION AND STORAGE OF THE WORKSTATION

New 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-**30˚C to + 60˚C**, insects and rodents.

1.2. INSTRUMENT SPECIFICATIONS

Item	Specifications
Total Slide Capacity	10 slides (1 removable slide carriers; 10 slides per carrier).
Reagent capacity	1 Reagent Tray 24 vials (IHC/ISH/FISH)
Reagent Vial capacity	10ml

Reagent dispense Volumes	10-180µl (IHC/ISH/FISH)
Reagent Dispenser	Standard 200µl disposable tips
Pipette Tip Trays	Two 96-tip disposable tray for 200µl tips
Slide Temperature	25°C to 105°C (77°F-221 °F) Each slide individually temperature controlled
Integrated Cover-slipper	Places and removes individual coverslips. Integrated coverslip holder for: ▪ 18 x 18 mm ▪ 25 x 25 mm ▪ 25 x 40 mm
Evaporation Control	Oil sealing

Item	Specifications
Bulk Fluids	5 different wash Buffers
Staining Operation	Multiple protocol for all 10 slides with single slide pattern
Weight	106Lb/48Kg.
Electrical Specifications	110V 60Hz ; 230V 50HZ (380W)
Ambient Operating Temperature	15-30°C (59-86°F) Humidity 15%-55% RH
Dimensions	Depth: 53 cm/21" Width: 79 cm/31" Height: 53 cm/21"
Software	BioGenex software Microsoft® Windows 10 IOT (1809 build)

SAFETY PRECAUTIONS

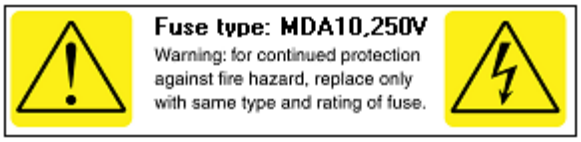
The following general precautions must be observed during all phases of operation, service, and repair of this automated staining system. Failure to comply with these precautions or with specific warnings elsewhere in this manual violates the safety standards of the design, manufacturing, and intended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

2.1. PRECAUTIONS AND WARNING

NanoVIP®Staining System must be unpacked, inspected and installed by an authorized BioGenex representative. The serial number should be recorded and the accessories should be checked against the accessory list.

i. **DO NOT** operates the system in an environment where flammable vapors are present. Operating AC-line-powered equipment in such an environment may cause an explosion.

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



iii. The AC-line cord provided with the staining system is intended to ground the chassis to help prevent shock and injury to lab staff. *NanoVIP®* meets all national and local electrical codes, which require a three-conductor AC outlet that connects the third wire of the line cord to the earth ground. Do not in any way defeat the grounding connection of this instrument.

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

v. Use of *NanoVIP®* requires the use of hazardous chemicals. Please refer to the reagent manufacturer's instructions and be sure to follow all applicable regulations for the use, handling, storage, and disposal of any hazardous chemicals.

vi. 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.

vii. Liquids used on *NanoVIP®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.

viii. Liquid waste produced from running the *NanoVIP® system* can be hazardous and should be disposed of properly as per the local regulations.

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

x. Test for ground continuity between the system chassis and adjacent equipment or metal plumbing to ensure that the user will not become a conductor between power ground and building ground. Never tamper with the 3-pin power plug. A GFI AC plug receptacle is highly recommended

xi. Do not service the system while power is ON. Refer all servicing to a qualified Service Staff or Technician.

xii. Accessing the work platform of the ***WORK STATION*** 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.

xiii. Lid should be always in closed condition during run mode.

xiv. During run mode lid should not be opened under UV light.

xv. To unlock carboy tray, press latch on either sides and pull gently.

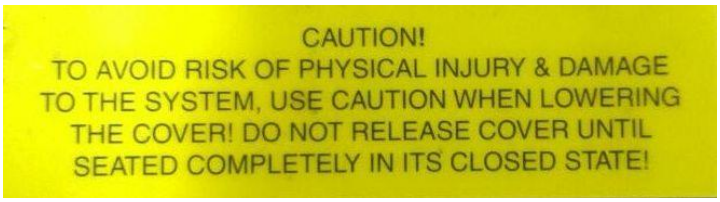
xvi. Check flow of liquid waste before starting the run. Empty waste carboy before starting each run.

xvii. The operator shall be trained and received adequate training in carrying out the procedures in the safest possible manner.

xviii. This symbol identifies the location of hot surface area

xix. This symbol identifies sharp point location.

xx. This label gives caution about closing the lid.



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

xxii. 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.

xxiii. This label gives caution before opening the lid.

2.2. Disclaimer Regarding Staining Results

Nano VIP® *fully-Automated* Slide Staining System is used for ResearchUse only as specified in this manual and for appropriate user-defined purposes. Any other use is prohibited.
Interpretation of any staining results from the operation of the system is solely the responsibility of the user.

2.3. PRECAUTIONS REGARDING BIO-HAZARDOUS MATERIALS AND WASTE

DO NOT dispose 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-off appropriately.

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

For the purpose of the above disclaimer, *bio-hazardous waste* is broadly defined as all biologically contaminated waste that could have the potential to cause harm to humans, domestic or wild animals, or plants. Specific examples of bio-hazardous waste include human/human tissues, blood, or fluids; cell cultures; or human/animal tissues containing infectious agents or recombinant DNA.

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

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ON-SITE INSTALLATION

3.1 INSTALLATION REQUIREMENTS

i. INSTALLATION PERSONNEL

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

ii. INSTALLATION SITE

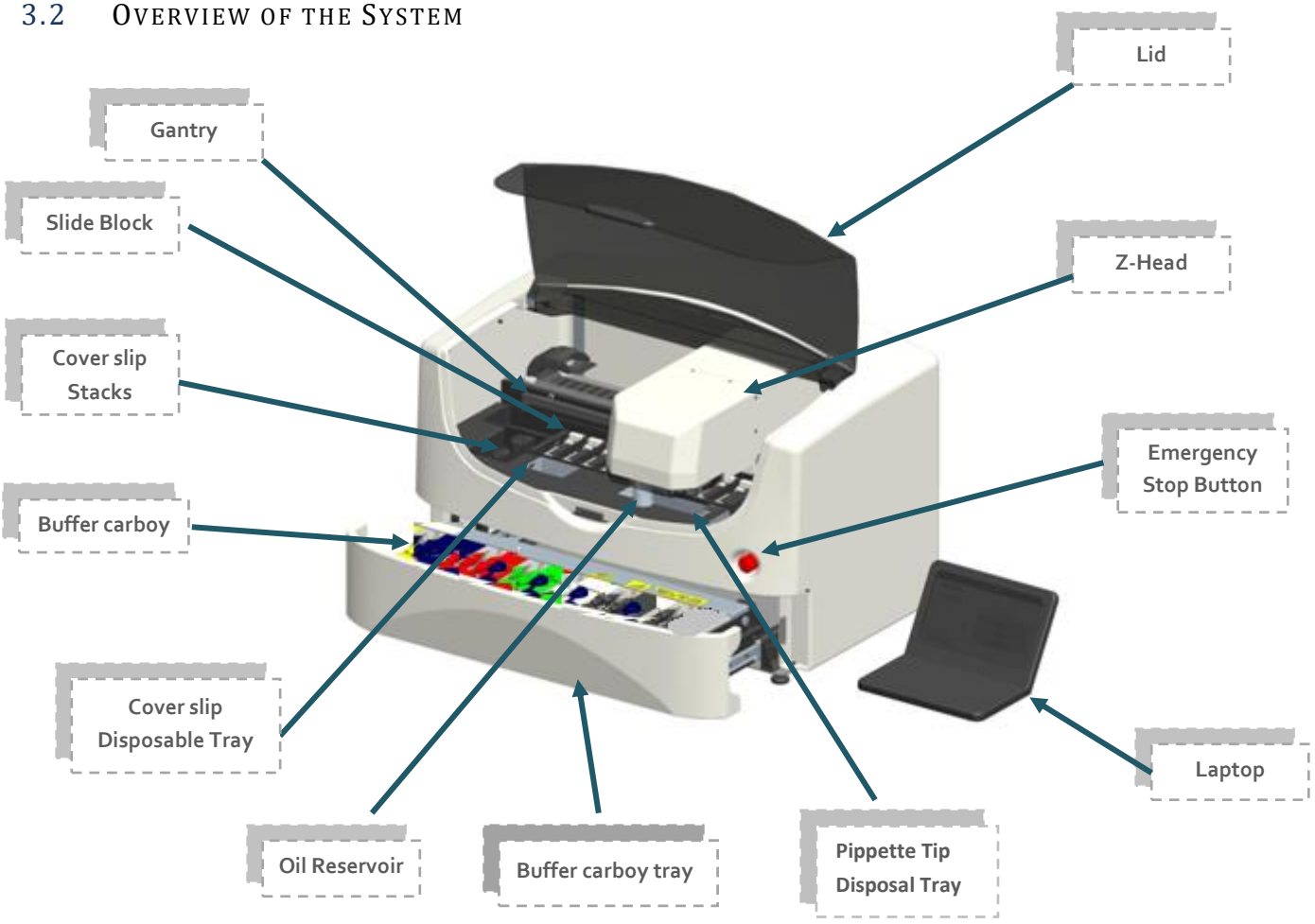
The installation site must provide adequate access, ventilation and power for the NanoVIP® instrument. These requirements are specified below and in other locations of this manual. If in the future it becomes necessary to move the NanoVIP® instrument to another location the following requirements must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

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

b. The NanoVIP® instrument shall be located on a test bench in the laboratoryby giving support from the bottom of the instrument.

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

3.2 OVERVIEW OF THE SYSTEM



3.3 Installation of Port

The USB A connector from the instrument should be inserted in the appropriate port as shown in the figure.

NOTE:

- Change in port will lead to malfunction.
- Do not use storage devices at any time in the laptop.

Figure 1 Laptop

Figure 1 Port to be installed

3.4 Installation of Oil Reservoir:

1. Using Phillip screw driver, remove the front part of Z-head cover.

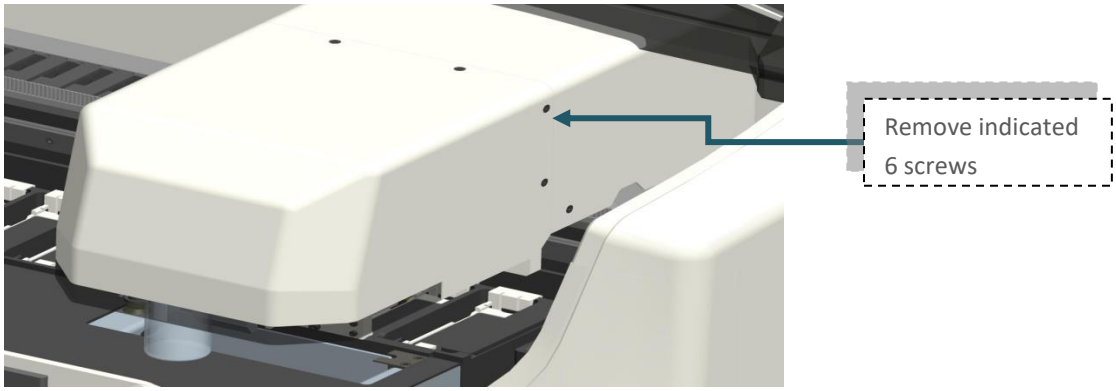


Figure 2 Removing Z head Cover

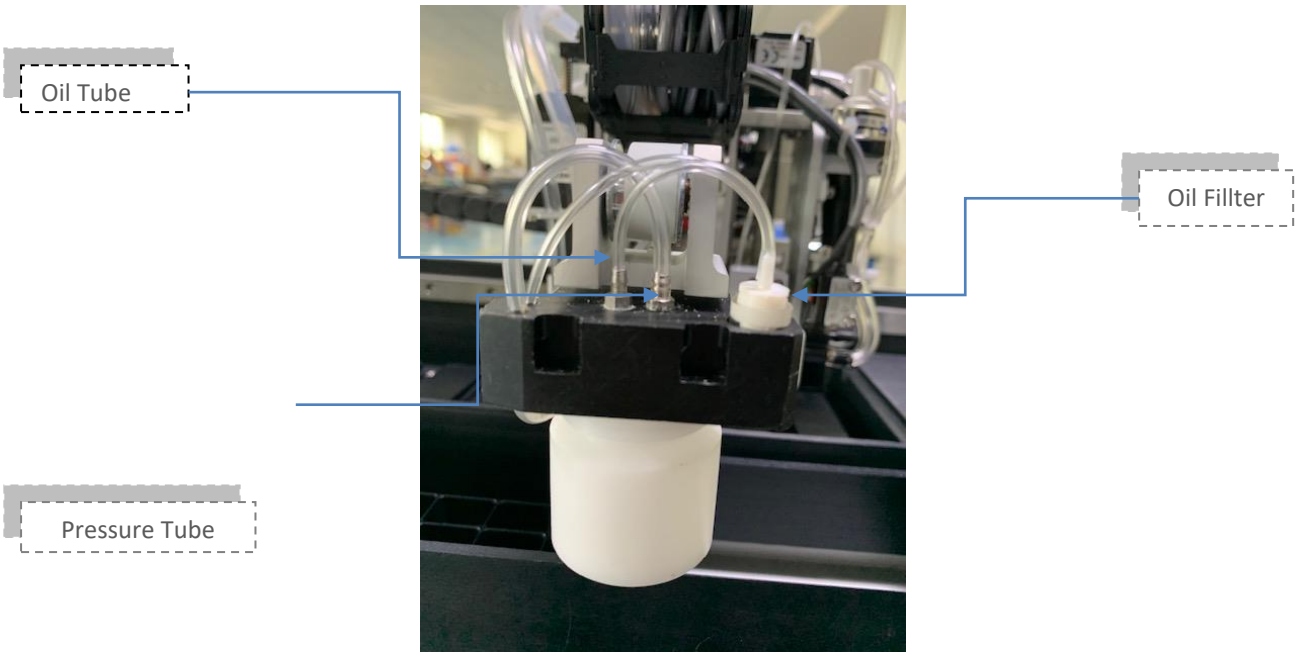


FIGURE 3 INSIDE VIEW

2. Remove the bottle inserted by moving anti-clockwise to open with help of Oil bottle removing tool(6520-10059) from cap.

3. Insert the pressure tube to the oil bottle and rotate the bottle clockwise to fix it in the position.
4. Close the z-head with the cover.

3.4 INSTALLATION OF BUFFER CARBOYS TO THE LIQUID PANEL.

There are five (5) pairs of sockets in Carboy Tray. Each pair consists of two connector's one tubing as inlet and other (Figure 4) as outlet for peristaltic pump. When connecting carboy in the Carboy tray, make sure to match the position of the carboy with the color of the peristaltic pump mounted in the Carboy Tray.

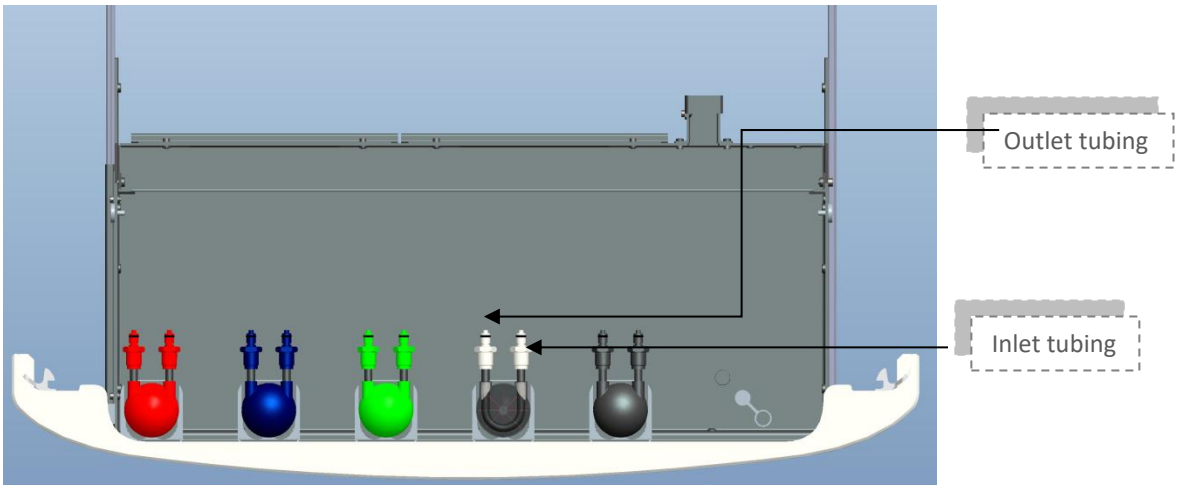


FIGURE 4: CARBOY TRAY IN THE INSTRUMENT

To install Carboys:

1. The first step is to place the carboys in the carboy tray and lock the quick connectors.
2. Insert Carboys according to peristaltic pump color into the appropriate position as shown in Figure .

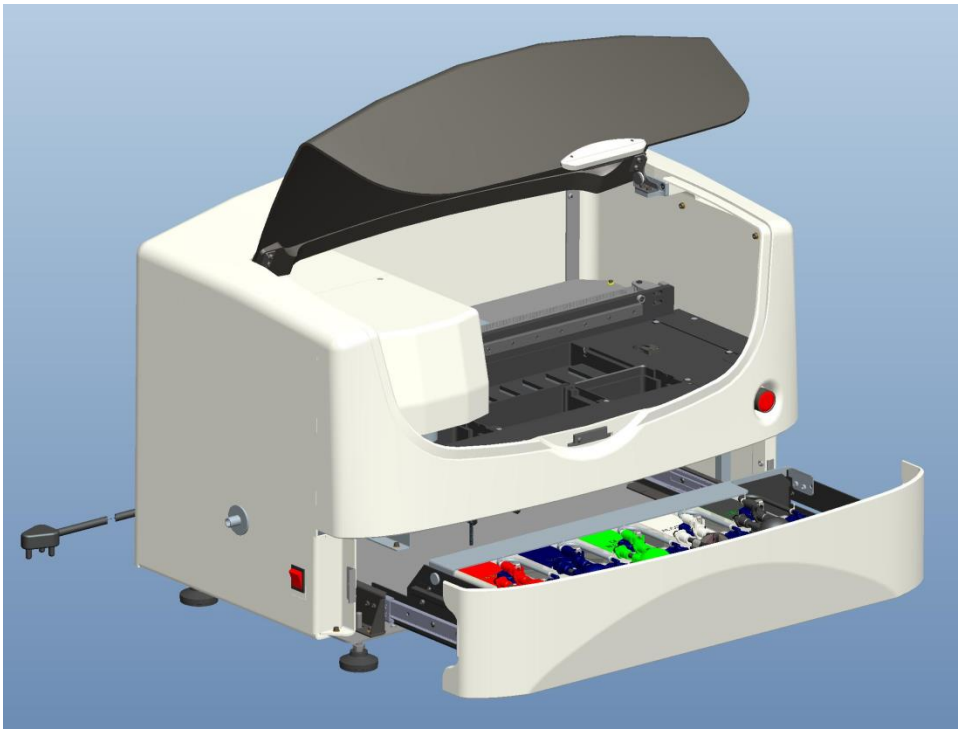


FIGURE 8 PLACING CARBOYS

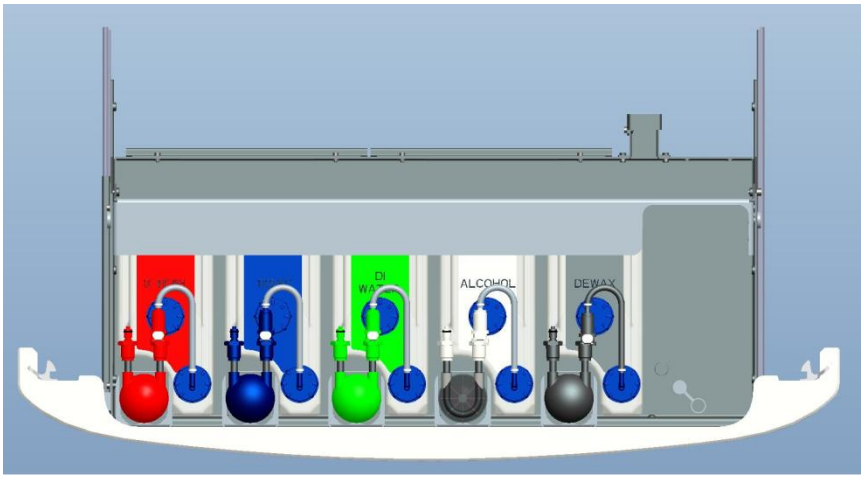


FIGURE 9: CARBOY TRAY IN THE INSTRUMENT WITH CARBOYS

3. Connect the Quick connectors as shown in Figure 5.

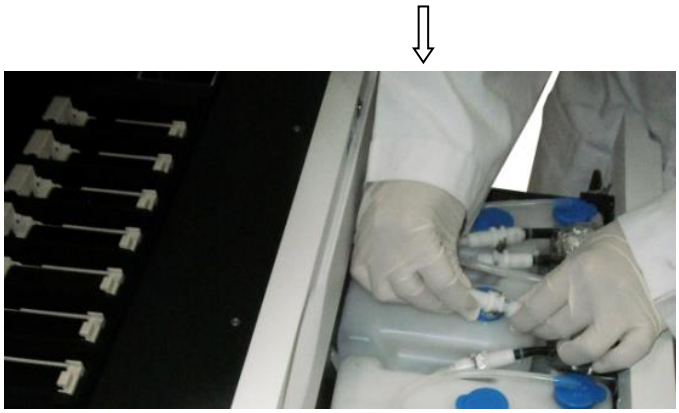


FIGURE 5CONNECTING QUICK CONNECTORS

4. Fix the carboy locking bracket by knob screw as shown in Figure 6

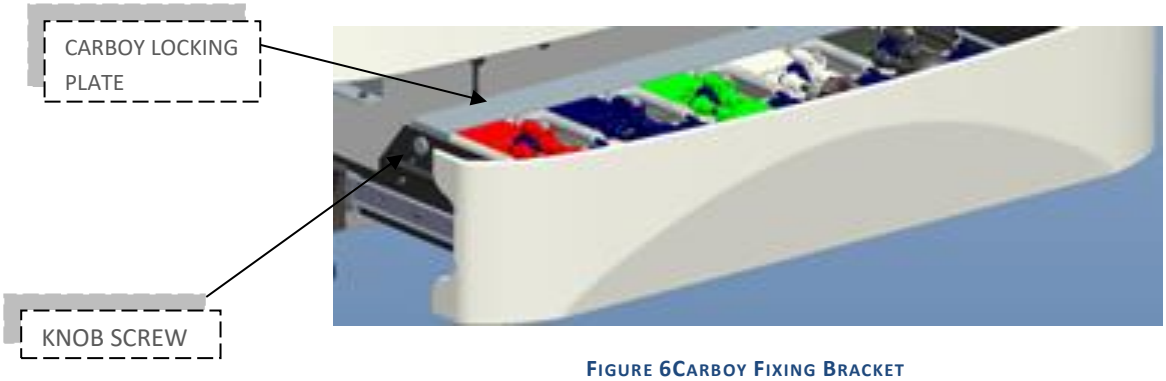


FIGURE 6CARBOY FIXING BRACKET

5. Carboys can be refilled by removing the cap and using funnel as shown in Figure 7.

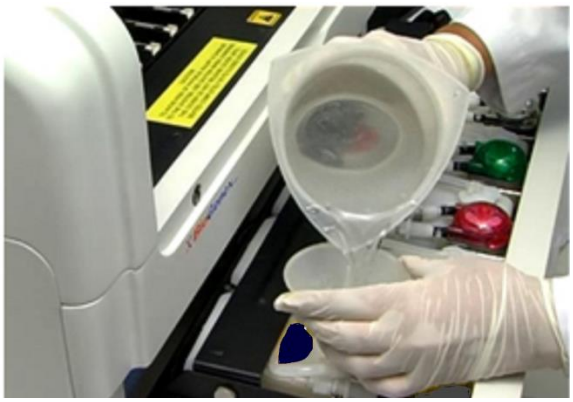


FIGURE 7 REFILLING CARBOYS

6. To remove Carboys for cleaning, pull the quick connectors as shown in Figure 8.

FIGURE 8 REMOVE CARBOYS

Please connect the Carboys as described in **Table 1**

Carboy Order in the Shelf (From Left to Right)	Peristaltic Pump Color	Type Of Internal Tubing for Peristaltic pump	Type Of External Tubing	Color on Carboy
DeWax	Black	Fluran F-5500A OR W Tube (ID 4mm)	Black Viton	Black
Alcohol	White	W Tube (ID 4mm)	White Silicone	White
DI Water	Green	W tube (ID 4mm)	Clear Tygon	Green
Buffer-1	Red	W tube (ID 4mm)	Clear Tygon	Red
Buffer-2	Blue	W tube (ID 4mm)	Clear Tygon	Blue

TABLE 1CONNECTION METHOD OF 6 CARBOYS TO INSTRUMENT

The complete set of carboys consists of five(5) Carboys (Figure 9): One 5L carboy is used for the waste generated, and five (5) 1L Carboys for five(5) different bulk reagents. The colored peristaltic pumps in the panel are presented in this order:

- Black
- White
- Green
- Red
- Blue

The corresponding six (6) buffer carboys are labeled as:

- DeWax(black)
- Alcohol (white)
- DI-Water (green)
- Buffer-1 (red)
- Buffer-2 (Blue)

Before attaching the buffer carboys, make sure the caps are secured tightly to the carboys.

FIGURE 9 SET OF 5 BUFFER CARBOYS

This symbol alerts the user that appropriate precautions must be followed when connecting carboys in the instrument. Be sure to match the position of each carboy with the color of the corresponding peristaltic pump when plugging in the connectors

3.5 WASTE CARBOY CONNECTION

When the waste tubing is connected to the waste carboy kept outside the instrument. Make sure that the waste tubing is fixed firmly with a cable tie both at the instrument end as well as waste carboy end. Failure to do so may cause flooding inside and near the instrument.

FIGURE 10 WASTE CARBOY WITH TUBING FIGURE 11 WASTE CARBOY CAP FIXATION

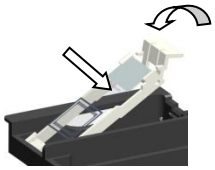
3.6 Glossary

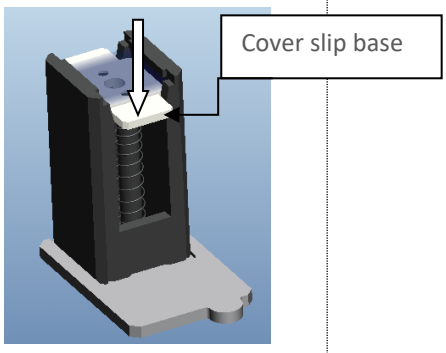
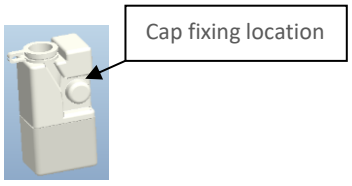
Term	Definition/Description
Bulk Bottles	Carboy for containing special liquids such as buffers, DI water, De-wax and Alcohol. A complete set of buffer carboys for one (1) instrument consists of five (5) buffer carboys.
Coverslip Mechanism	There are two cover slip bases available in the instrument to hold 18 x18 mm,25X25 mm and 25x40mm cover slips stacks. There is one CS box of size (18x18 mm,25x25 mm& 25x40mm) each with an instrument.
E-Stop Button	Emergency stop button, located in the front of the Nano VIP® Instrument.
Gantry	Moving mechanical stand to which the robotic arm is attached.
Housing & Cabinet	Metal hood that encloses the entire NanoVIP® instrument and its accessories. All buffer carboys are fitted in the instrument. Waste carboy is kept outside the instrument.
Carboy Tray	Carboy Tray is accessible from the front side of the instrument. The Carboy Tray is loaded with five (5) carboys with quick connectors and peristaltic pumps with tubing.
Oil Bottle	Oil bottle mounted on the robotic arm.
Oil Pen	Slender Pen attached to 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 Slide pattern and cover slip size.
Robotic Arm	XYZ robotic arm allowing tri-axial movement with a unique multifunctional staining head that can wash and blow the slide(s). The Suction Cup and Oil Pen are mounted on the robotic arm.

Slide Block	The largest separated space on the processing platform inside the workstation. Only one Slide Carrier is placed in this room, containing ten (10) Slide Holders. Therefore, it allows up to 10 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.
Suction Cup	Translucent rubber cup for picking up Coverslips from a Cover-Slip stack or from a slide. The Suction Cup is attached to the lower back end of the Z-Head.
Waste Carboy	One (1) carboy kept outside the instrument for collecting the waste from the instrument.
Waste Coverslip try	ABS Box that collects used Coverslips.
Pipette tip rack	Rack that is used to stack the small Pipette tip (200 µl). And the capacity of that rack is 96 Pipette tips.
Pipette tip disposal tray	Tray that is used to collect the used Pipette tips.
Reagent vial tray	Tray that is used to hold the reagent vials (24 Vial tray).

STARTING THE SYSTEM

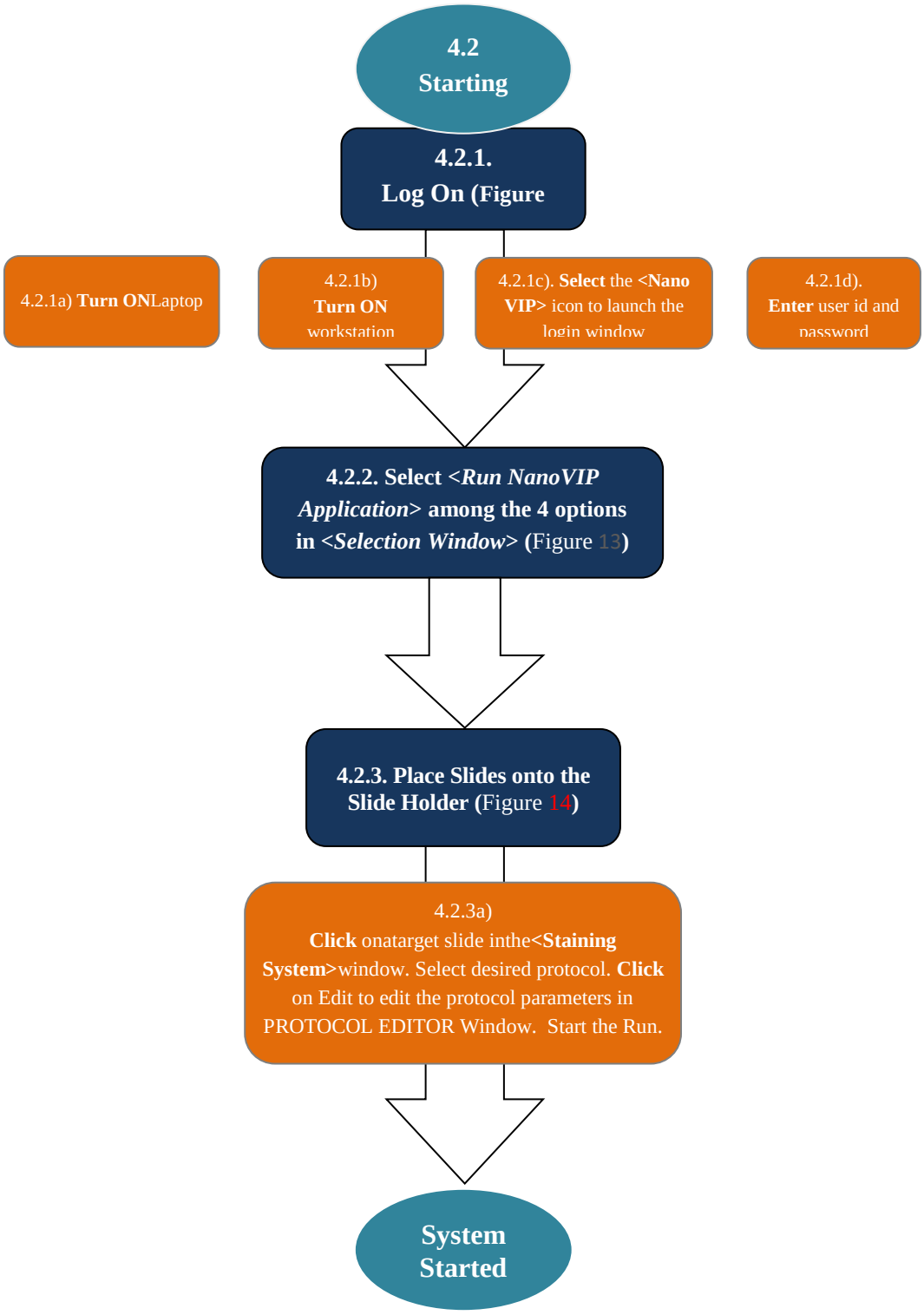
4.1. LOADING CONSUMABLES

Step	What to load?	Where to load?	How to load?	Precautions
4.1.1	**Slide**(s) with specimen. Up to 10 Slides may be loaded in a single run.	Slide Holders in the Slide Carriers in the Slide Block	a) **Lift** the Slide Holder by holding it on either side within cutout provided. As shown below.  b) **Tilt up** the open end of the frame of the Slide Holder with your fingers. As shown below.  c) **Insert** a Slide into the groove of the Slide Holder. Be sure to place the frosted end of the slide upwards and tilt down the frame. As shown below.  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 as needed.	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 with sample side up. Load slide according to Slide Map.

4.1.2	**Coverslip**(s)	Two (18X18mm ,25x25mm &25x40mm) Coverslip stacks which are available at the left side of the work station.	Load cover slips into coverslip as per the below note. a).Press the cover slip base downward with one hand as shown below.  b).Take the cover slips bunch with another hand and place on the cover slip base (while placing CS bunch need to tilt, for easy access to place).	The Cover-Slip(s) should be stacked and loaded in the appropriate stack.
4.1.3	**Mineral Oil**	Mineral Oil Reservoir on robotic head	a) Call Field Service to fill oil reservoir. b) Oil will last up to 3000 (approx.) oil sealing operations.	
4.1.4	**Pipette tips**	Pipette tip tray available at the right side top corner of the work station	Place all pipette tips in the tray.	a).Please use fresh pipette tips and it should be supplied by the BioGenex. Otherwise result may vary. b).Ensure continuity while placing pipette tips in the tray.
4.1.5	**Reagent Vials**	Reagent Vial tray available at the right side bottom corner of the work station.	Insert vials in 24 vial tray, no of vials depends on the requirement& ensure all inserted vials filled with required reagents. 	a).All vials need to be in same direction. As shown in the fig which is in side column. b). Ensure all cap need to be in open and it is fixed to vial as shown in fig. 

Note: Expiry date for these consumables is NOT APPLICABLE as they are supplied separately.

.4.2 STARTING THE SYSTEM



NOTE:

1. The instrument supports multiple protocols for all 10 slides with in a run.
2. The user is suggested to use all consumables from BioGenex. Failure to use correct consumables may cause system failure.

FIGURE 12ENTER USERNAME & PASSWORD IN THE <LOG ON> WINDOW. (SEE STEP 4.2.1(D))

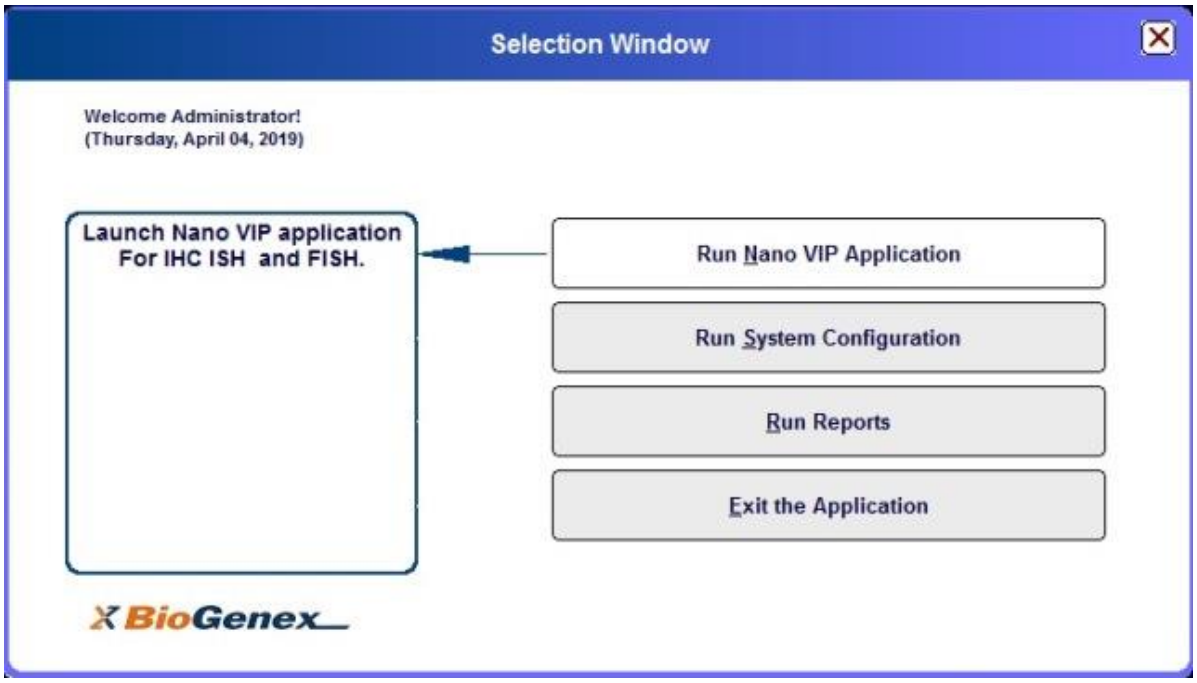


FIGURE 13<SELECTION WINDOW> OFFERS FOUR OPTIONS. SELECT THE <RUN> OPTION

FIGURE 14 SLIDES PLACED ON SLIDE HOLDER

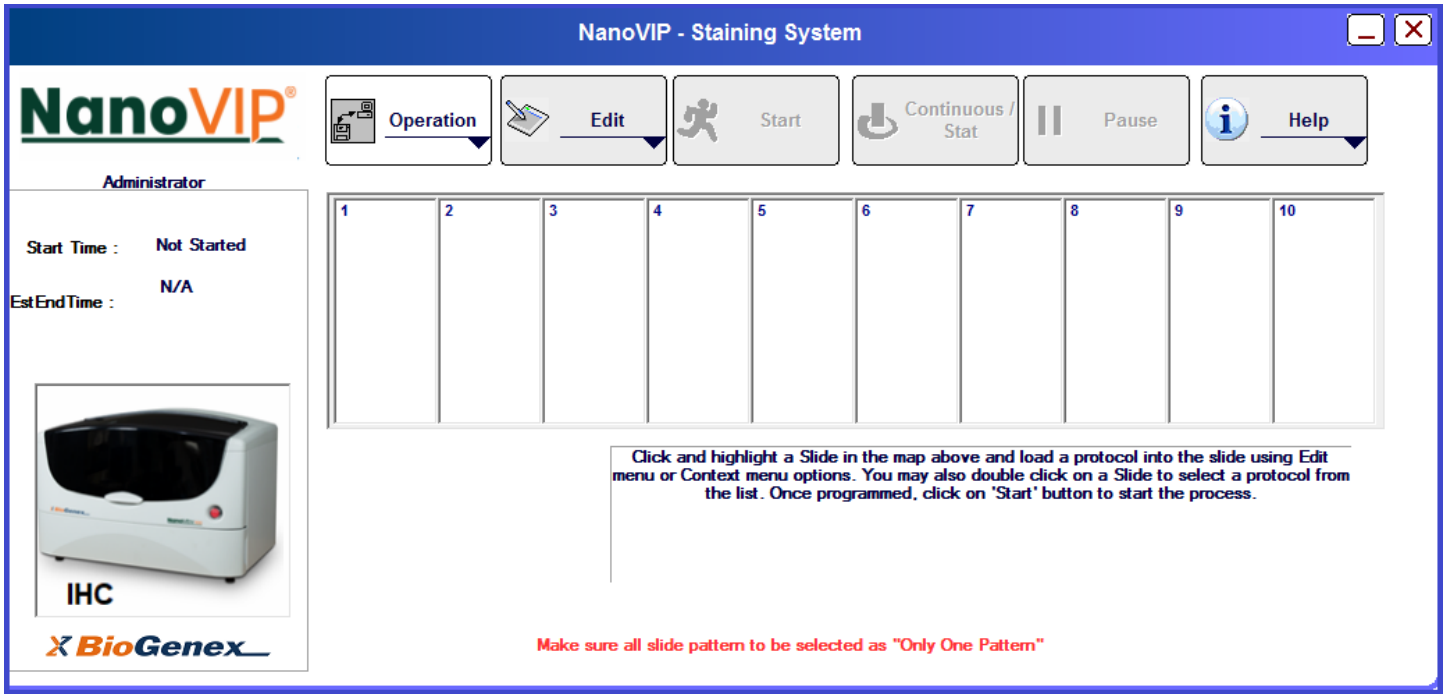


FIGURE 15:< SLIDE EDITOR> WINDOW

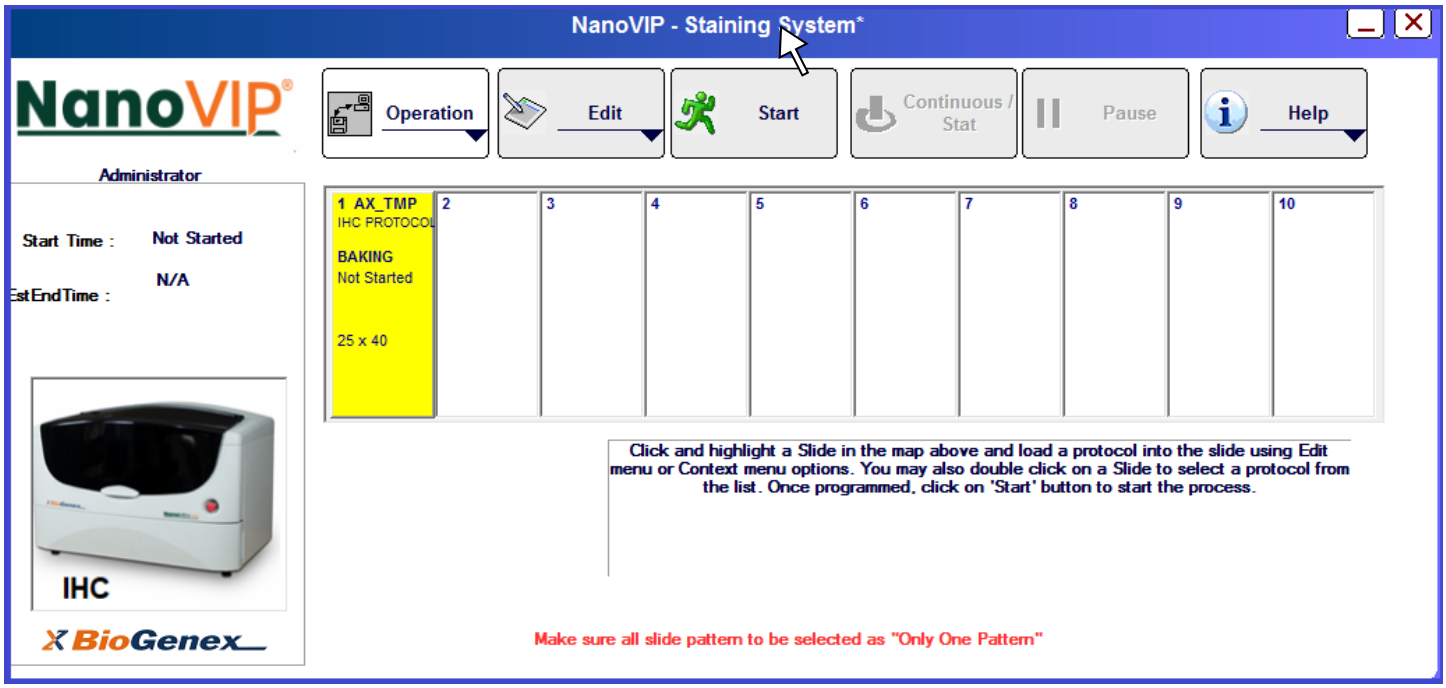


FIGURE 16 STARTING THE RUN AFTER SELECTING PROTOCOL
(FOR DETAILED PROCEDURE REFER TO *SECTION 6 BUILDING AND INSERTING PROTOCOL*)

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.

5.1 MAINTAINING USER PROFILE

When the NanoVIP® 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 19).

To access the **<User Manager>** window, follow the steps explained below:

1. Select **< Run System Configuration** > from **<Selection Window> (**Figure 13**)**
2. The **<System Configuration & Calibration>** window appears.

FIGURE 17<NANO VIP®> SYSTEM CONFIGURATION AND CALIBRATION

3. Click on the **<configuration>** option and select **<User Manager>** from the dropdown menu.

FIGURE 18: DROPDOWN MENU FOR USER MANAGER

4. The **<User Manager>** window will appear.

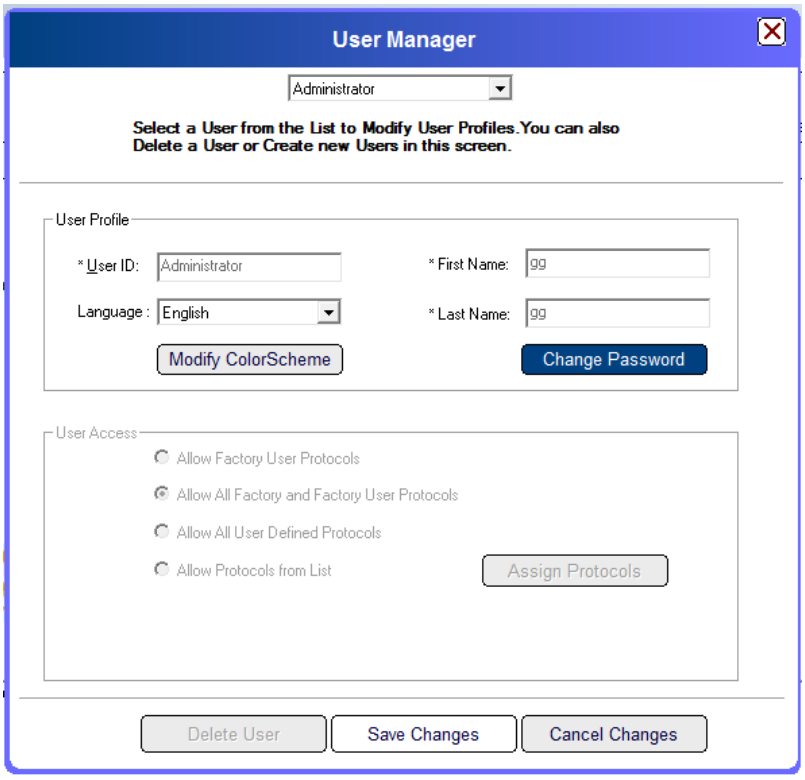


FIGURE 19:<USER MANAGER>WINDOW

In the **<User Manager>** window, the *Administrator* can create, modify, or delete a user profile. Related items are User ID, Password, and desired language (the current system supports English only). The *Administrator* may also limit the protocol type(s) for a user account.

The password may be changed by entering new password in the *New Password* text box **<User Manager>** window.

- Click the **<Change Password>** button. This saves the password changes
- Click the **<Save changes>** button. This saves the changes
- Click the **<Cancel>** button. This cancels the previous profile changes
- Click the **<Delete User>** button. This deletes the user profile.

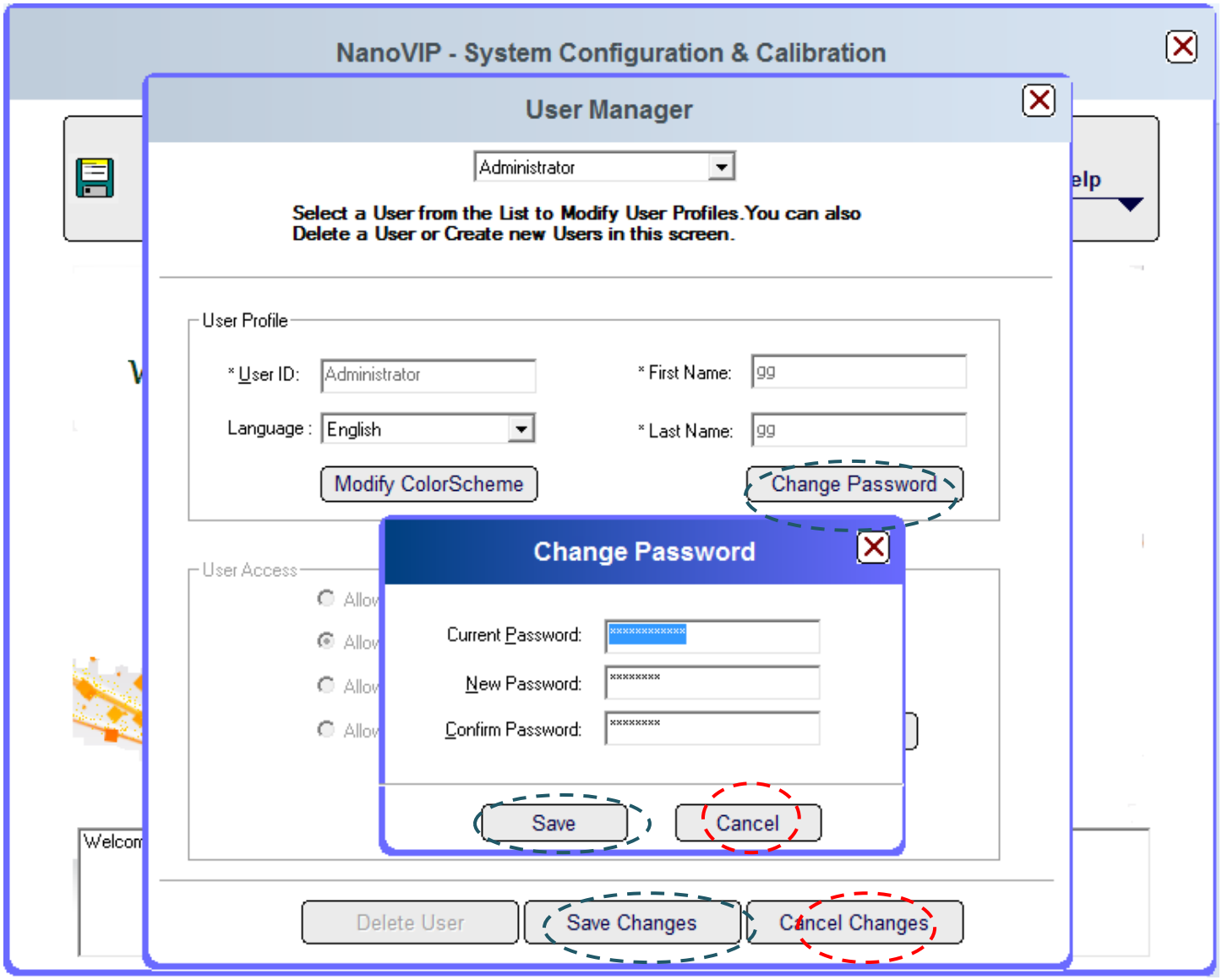


FIGURE 20 CHANGING PASSWORD <USER MANAGER> WINDOW

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

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

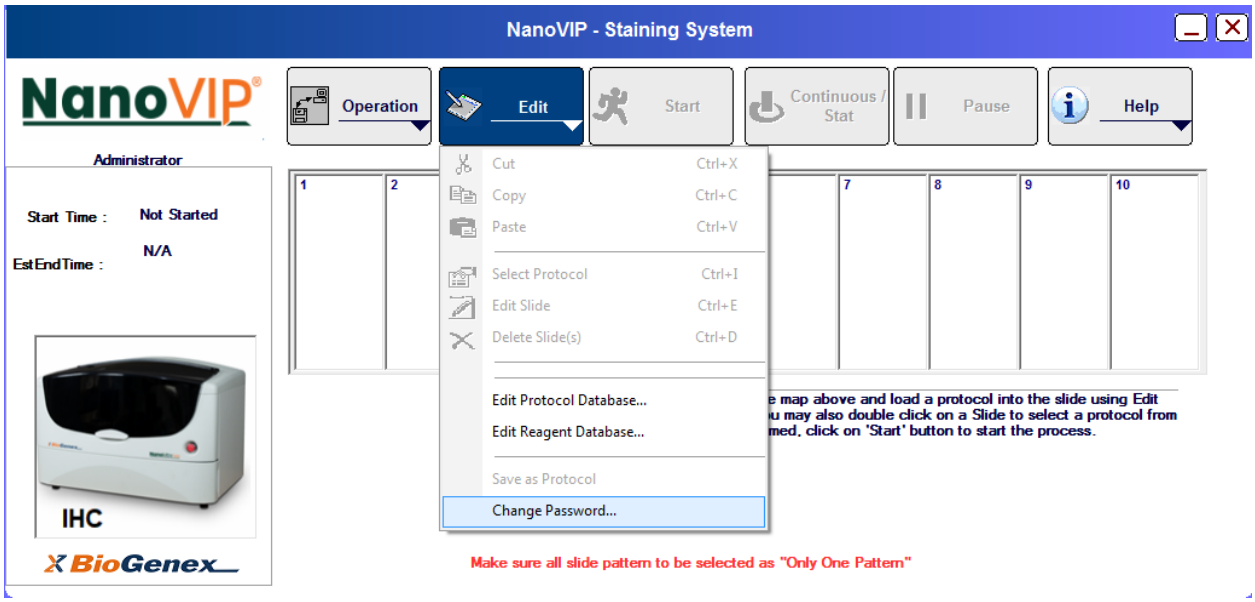


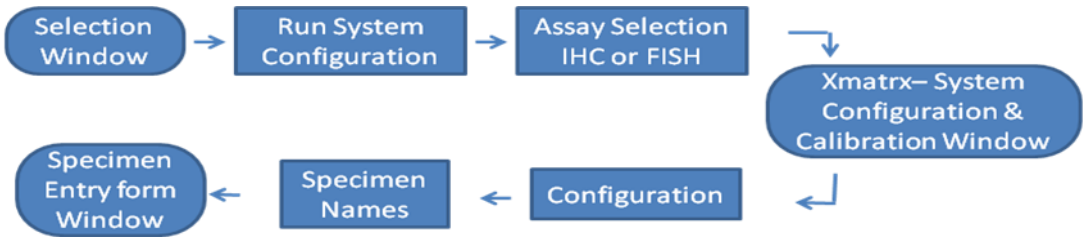
Figure 21 Changing Password from Edit dropdown menu on < NanoVIP®: Staining System> window.

ii. The **<Change Password>** box appears and changes may be made.

FIGURE 22<CHANGE PASSWORD> WINDOW

NanoVIP® 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 'Slide-Heat', 'Slide-Cool' and 'Slide-Pause'. This rich color scheme helps the user to recognize and distinguish different objects correctly and easily in the course of a run. Once the required information is entered, click on the **<Save Changes>**button to save the input to the user database.

5.2 SPECIMEN NAME



FLOWCHART 1 PATH TO <SPECIMEN ENTRY FORM> WINDOW

Specimen names can be added to the system using the **<Specimen Entry Form>** window. To open the **<Specimen Entry Form>** window: (Refer to the flowchart above)

From the **< NanoVIP® System Configuration & Calibration>** window (Figure 17), select **<Specimen Names>** in the drop-down menu under the **<Configuration>** tab (Figure 23). The **<Specimen Entry Form> window (**Figure 24**) will** appear.

Figure 23< Nano VIP® System Configuration & Calibration> window

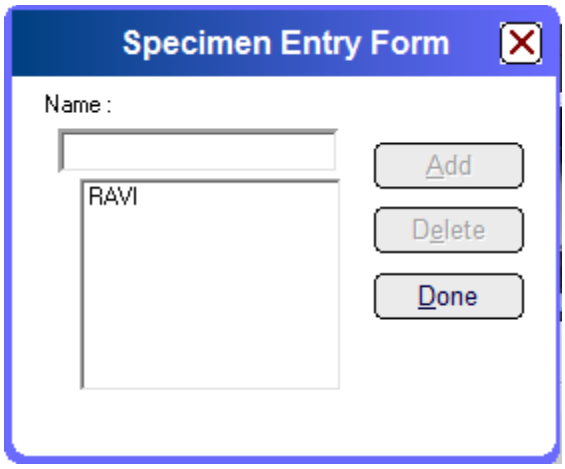


FIGURE 24<SPECIMEN ENTRY FORM> WINDOW

To add 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.

Any slide-specific data entered via the <**Specimen Entry Form**> window in the system will be accessible in the <**Slide Editor**> window (Figure 15).

5.3 BUFFER LINES

Among the five (5) buffer carboy connectors on the Liquid Panel of the workstation, three (3) of the five(5) are usually designated for DeWax, DI water and Alcohol, while the other two (2) buffer connectors are designated as wash buffers depending on the application requirement.

The description of buffer that passes through a particular liquid connector and its corresponding buffer line is set by default and cannot be changed. While refilling the buffer carboys, the operator has to be careful not to change the sequence (Refer to Section 3), as it will lead to erroneous results.

BUILDING AND INSERTING PROTOCOL

6.1. PROTOCOL

6.1.1. PROTOCOL TYPES.

There are three (3) types of protocols available in any staining run.

Factory Template Protocol	This is template protocol provided by company, which needs to be modified as per the requirement by User. This can be saved as Factory-User Protocol or User Protocol.
Factory-User Protocol	Derived protocol by editing allowed parameters in a Factory Protocol. Factory Protocol is partially editable and can be reverted to the original Factory settings in editor window. These protocols can only be edited and reverted by the *Administrator*
User Protocol	A new or copied protocol created by any user is saved as User protocol, for which the operations and steps are taken from Factory template and user can modify existing individual parameters independently or create new steps as required.

6.1.2. SLIDE PATTERNS AVAILABLE

Full test area	25 x 40 mm
Half test area	25 x 25 mm
One third test area	18 x 18 mm

From these options one pattern can be selected at a time for one Run, two patterns cannot be used in single run.

18 X 18 mm pattern is recommended for FISH Protocols.

25 X 25 mm pattern is recommended for ISH Protocols

25 X 40 mm pattern is recommended for IHC Protocols

6.1.3. STAINING STEPS

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

Blow	:	Blows a jet of air over the slide to remove the liquid from the slide.
Incubate	:	Allows the reagent to stay on the target slide(s) for a specified period of time.
Wash Slide	:	Allows buffer to be dispensed onto the particular slide(s) as per the applied protocol.
Apply Oil	:	Applies oil in the middle of double barrier of the 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 Slide	:	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.

Apply Micro Reagent: Uses a 200 µl pipette tip to apply probe in volume of 20-80 µl to a target slide.

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

- Apply Reagent
- Apply Probe

The NanoVIP® *system* will not allow coverslip for any operation that contains an "Apply Reagent" step.

6.1.4. Building Protocols

The **FACTORY** Protocols can be edited to a limited extent, which can then be saved as **FACTORY_USER** Protocols. And a protocol can be created and saved as **USER** Protocol, which will not have any limit for changing the parameters.

All these protocols can be seen in <**Edit Protocols**>Window.

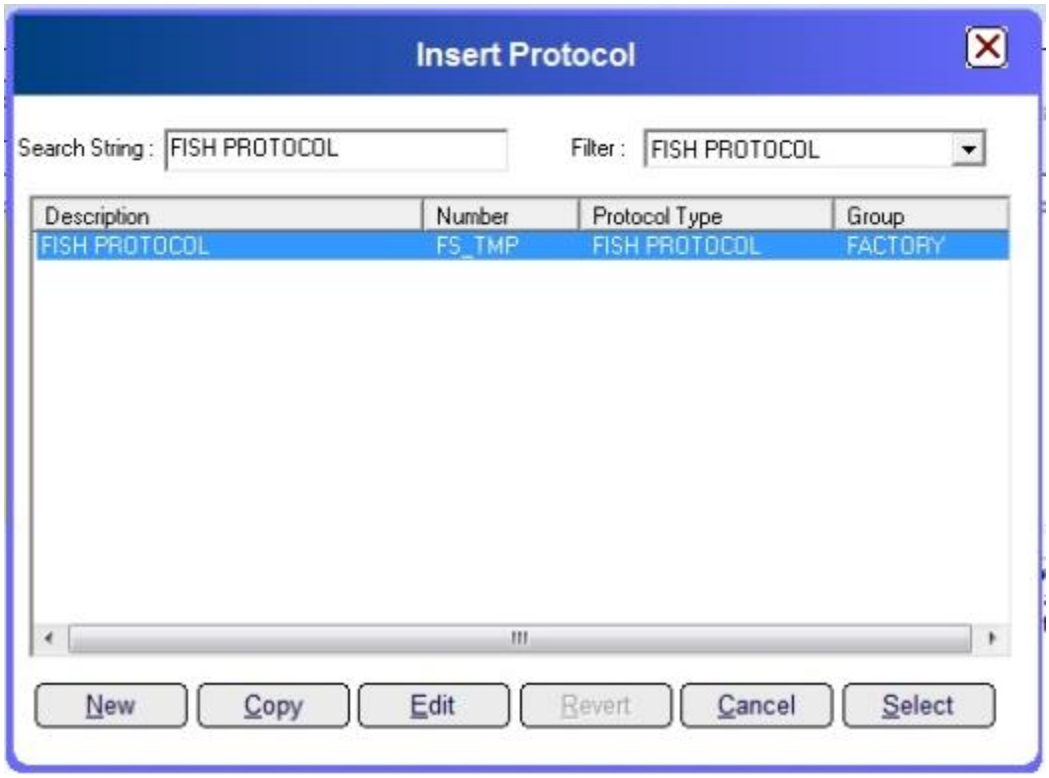


Figure 25<Edit Protocols> window

6.2 Using Factory Protocols

6.2.1 Inserting a Factory Protocol

To insert a Factory Protocol

1. From the <Selection Window> select <Run> (Figure 13) to open the <Staining System> window (Figure 26).

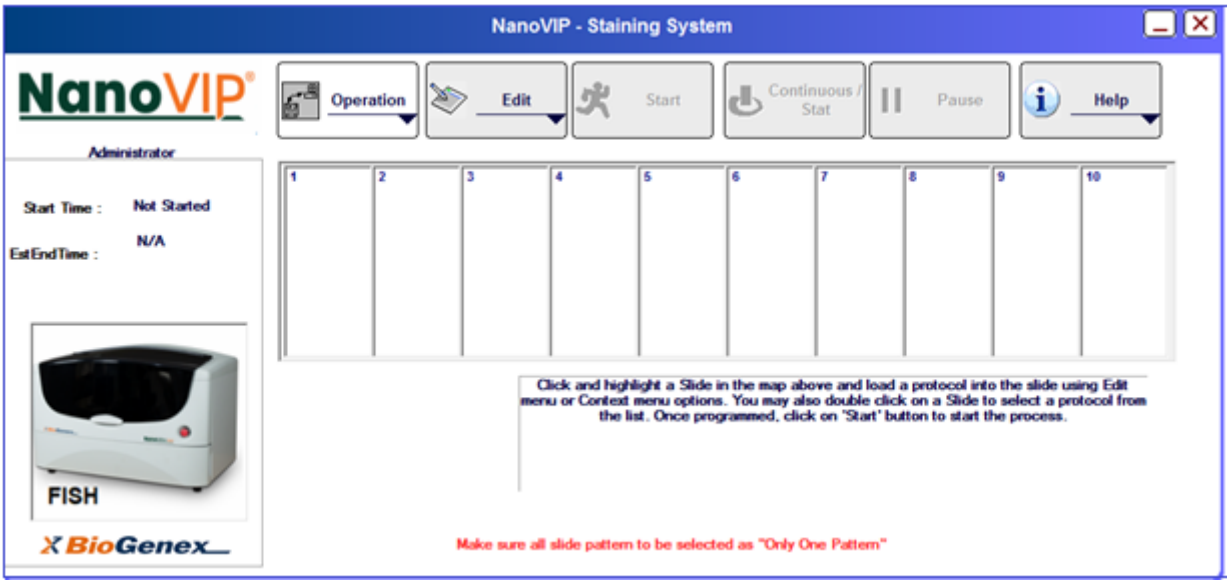


FIGURE 26:<STAINING SYSTEM> WINDOW

2. Right Click on the slide position to open the **<Select Protocol>** window (Figure 27).

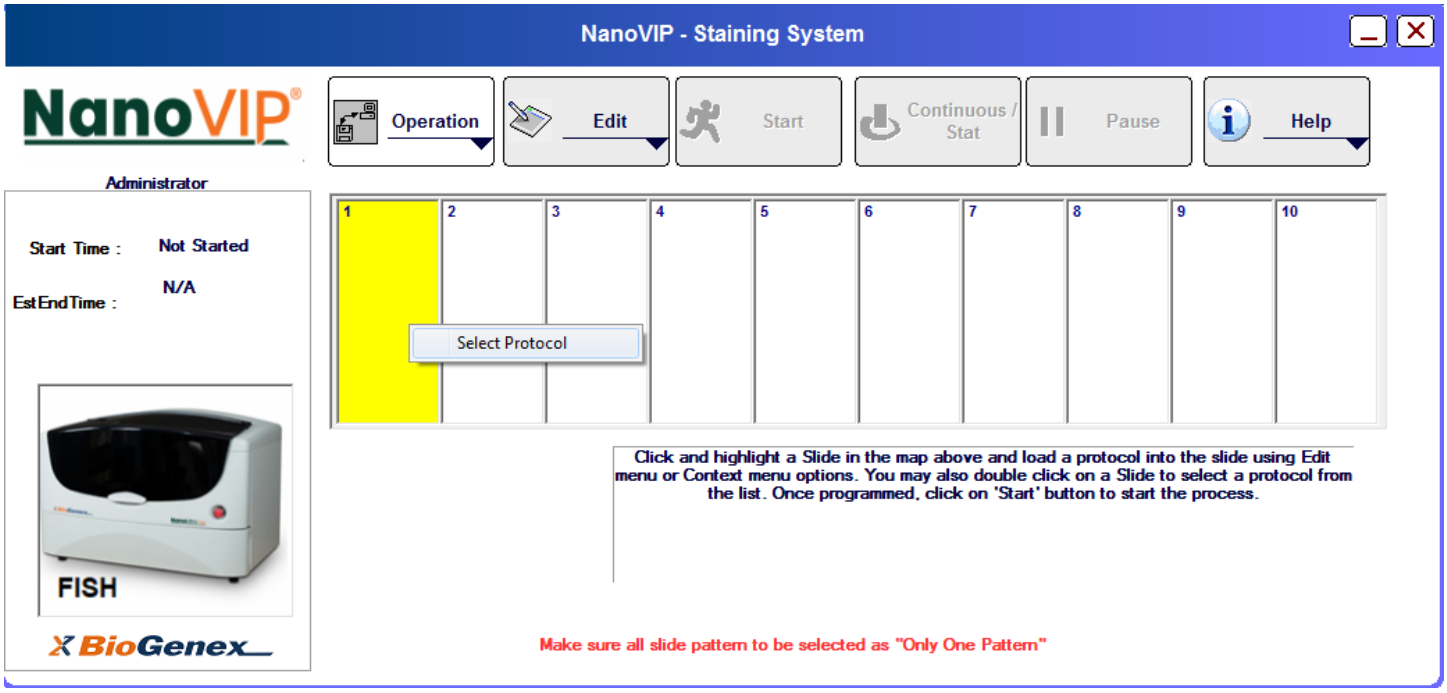


FIGURE 27 STAINING SYSTEM SELECT PROTOCOL

3. The < **Edit Protocols** > window (Figure 25) will appear.
4. Select the desired Protocol from the Protocol list and click on the <Select> button.

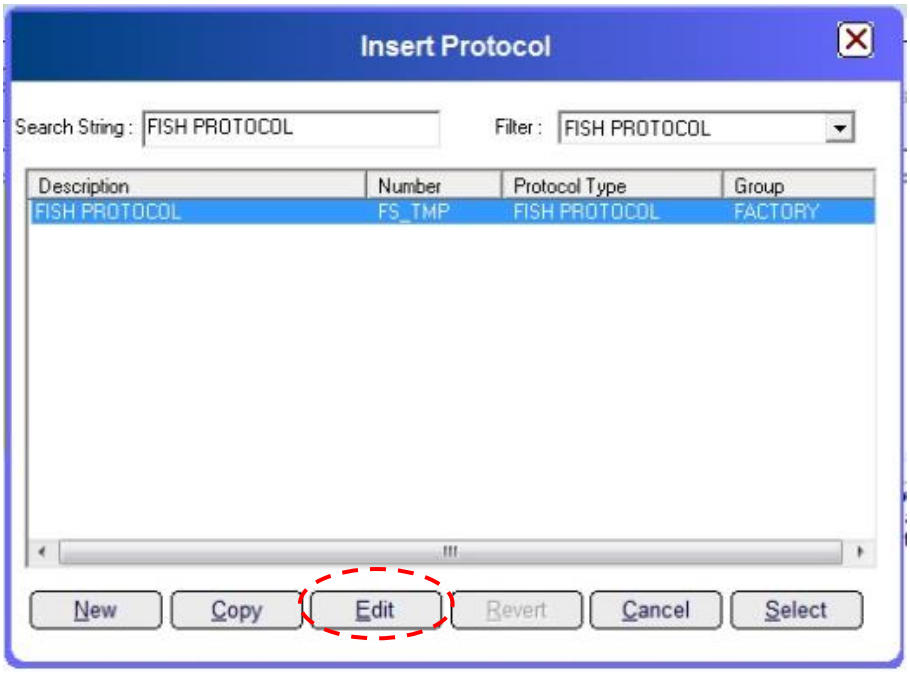


FIGURE 28 SELECT FACTORY PROTOCOL

5. Repeat the above steps for the other slide positions as needed.

6.3 EDITING PROTOCOLS

From Factory Protocols, only the *Administrator* can create Factory-User Protocols, and users can create User Protocols by modifying the Factory Defined Protocols or newly created protocol.

1. From the **<Edit Protocols>** window (Figure 25), highlight Factory Protocol and select the **<Edit>** button (Figure 33).

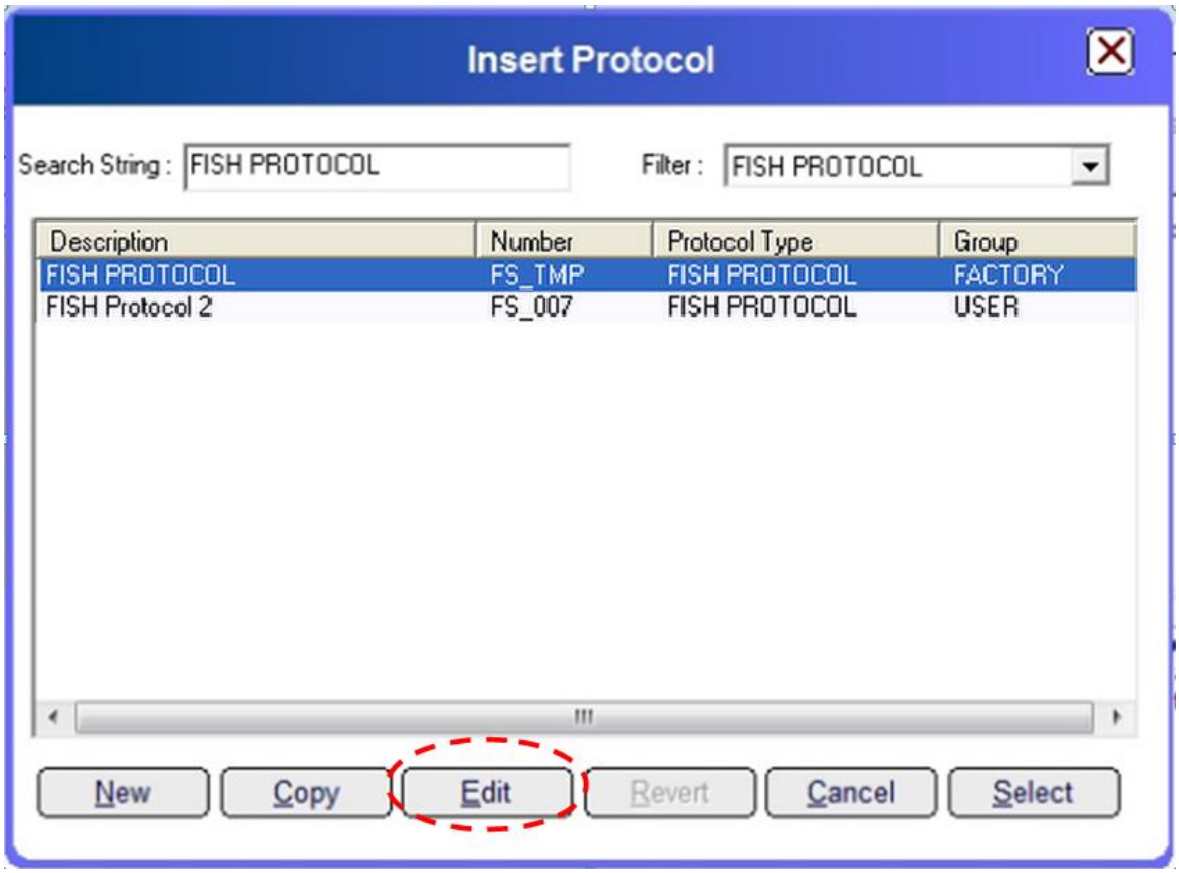


FIGURE 29<EDIT PROTOCOLS> WINDOW

2. The < **Protocol Editor** > window is displayed (Figure 31)
(For instructions on using the < **Protocols Editor**> window refer to ***Section 7:*** ***Using Protocol/Slide Editor Windows***)

6.4 COPY AND CREATE A USER PROTOCOL

1. From the <**Edit Protocol**> window (Figure 25), select the desired protocol to copy and select the <**Copy**> button (Figure 30) to open the < **Protocol Editor**> window (Figure 31).

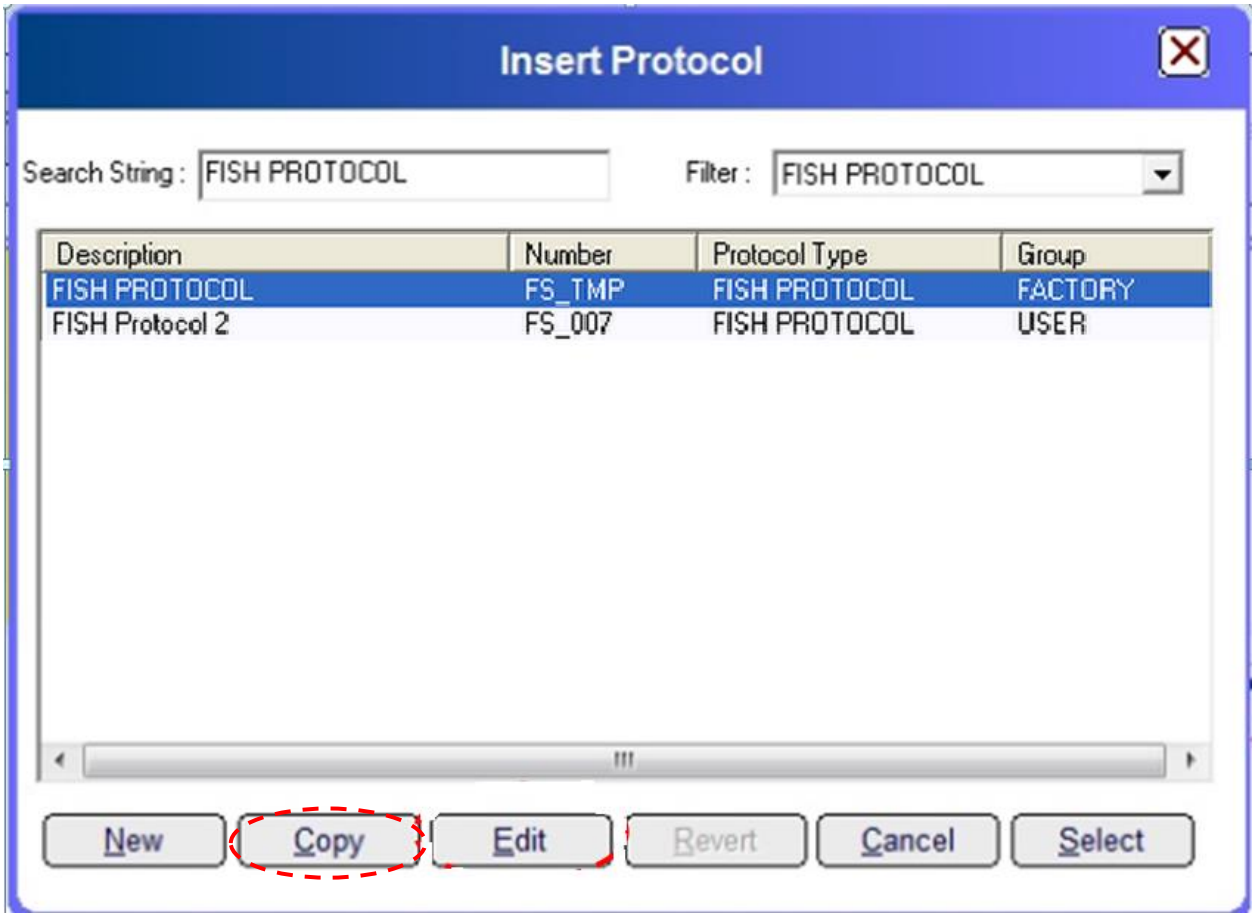


FIGURE 30<COPY>OPTION ON INSERT PROTOCOL WINDOW

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

6.5 CREATE A NEW USER PROTOCOL FROM AN EXISTING PROTOCOL

1. From the **<Edit Protocol>** window (Figure 25), select the desired protocol and select the **<Edit>** button (Figure 29) to open the **<Protocol Editor>** window (Figure 31).
   (For instructions on using the **<Protocol Editor>** windows, refer to ***Section 7: Using Protocol/Slide Editor Windows.)***
2. After completing the design of a new protocol, click on the <**Save Protocol**> button to save the copied protocol.

6.6 CREATE A NEW USER PROTOCOL FROM AN EXISTING PROTOCOL

1. From the **<Edit Protocol>** window (Figure 25), select the desired protocol and select the **<Edit>** button (Figure 29) to open the **<Protocol Editor>** window (Figure 31).
   (For instructions on using the **<Protocol Editor>** windows, refer to ***Section 7: Using Protocol/Slide Editor Windows*.**)
2. To save the Protocol, select **<Save Protocol>**. The Protocol can be retrieved later in the **<Edit Protocol>** window.

USING PROTOCOL/SLIDE EDITOR WINDOWS

7.1 PROTOCOL EDITOR WINDOW

A <**Protocol Editor**> window is will be displayed when **Edit** is clicked from <**Edit protocol**> or **<insert protocol>** window (for details refer to ***Section 6: Building and inserting Protocol***). There is only one type of editor window available. Editing a protocol or slide in a **<Protocol editor>** window is explained in this section.

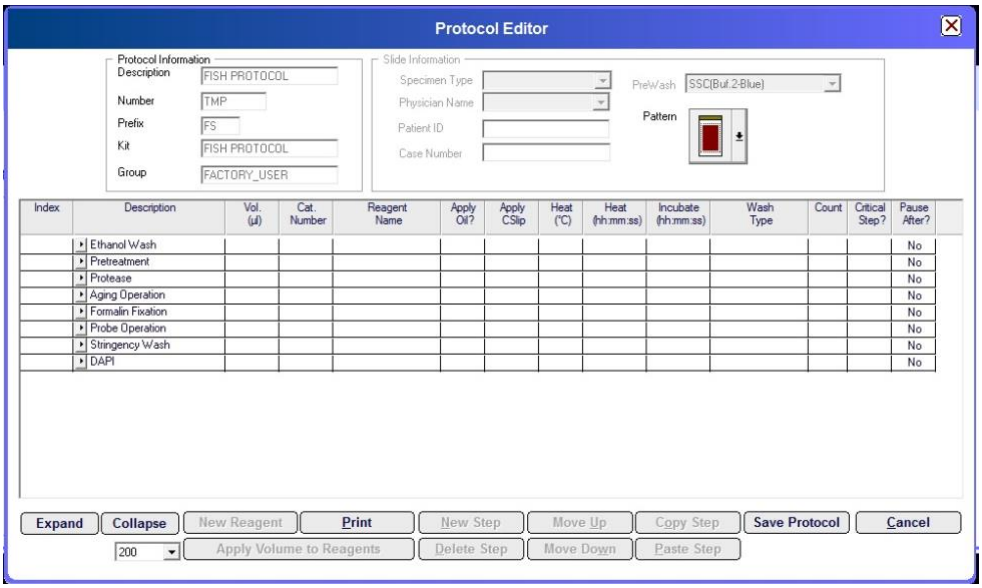


FIGURE 31< PROTOCOL EDITOR>WINDOW

7.2 LAYOUT OF <PROTOCOL EDITOR> WINDOW

7.2.1 PROTOCOL INFORMATION.

Upper left area of the editor window contains information about the current protocol.

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

- A protocol number is automatically generated for a new protocol. It can be changed to any four (4) digit number.
- The description field is blank and must be filled out before the window is closed.

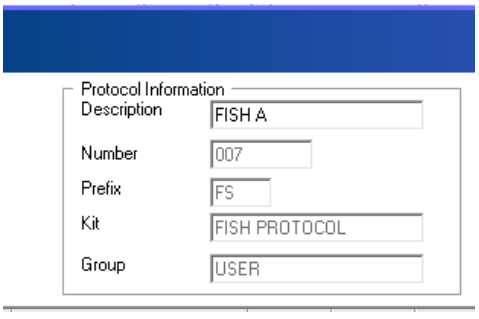


FIGURE 32PROTOCOL INFORMATION AREA

7.2.2 SLIDE INFORMATION AREA

Upper Right area of the window contains information about slide being processed. The **Slide Information** area (Figure 34) is open for changes only when working in the <**Protocol Editor**> window, after selecting a protocol. Once protocol is selected, right click on slide, select <**Edit Slide**> option from dropdown menu.

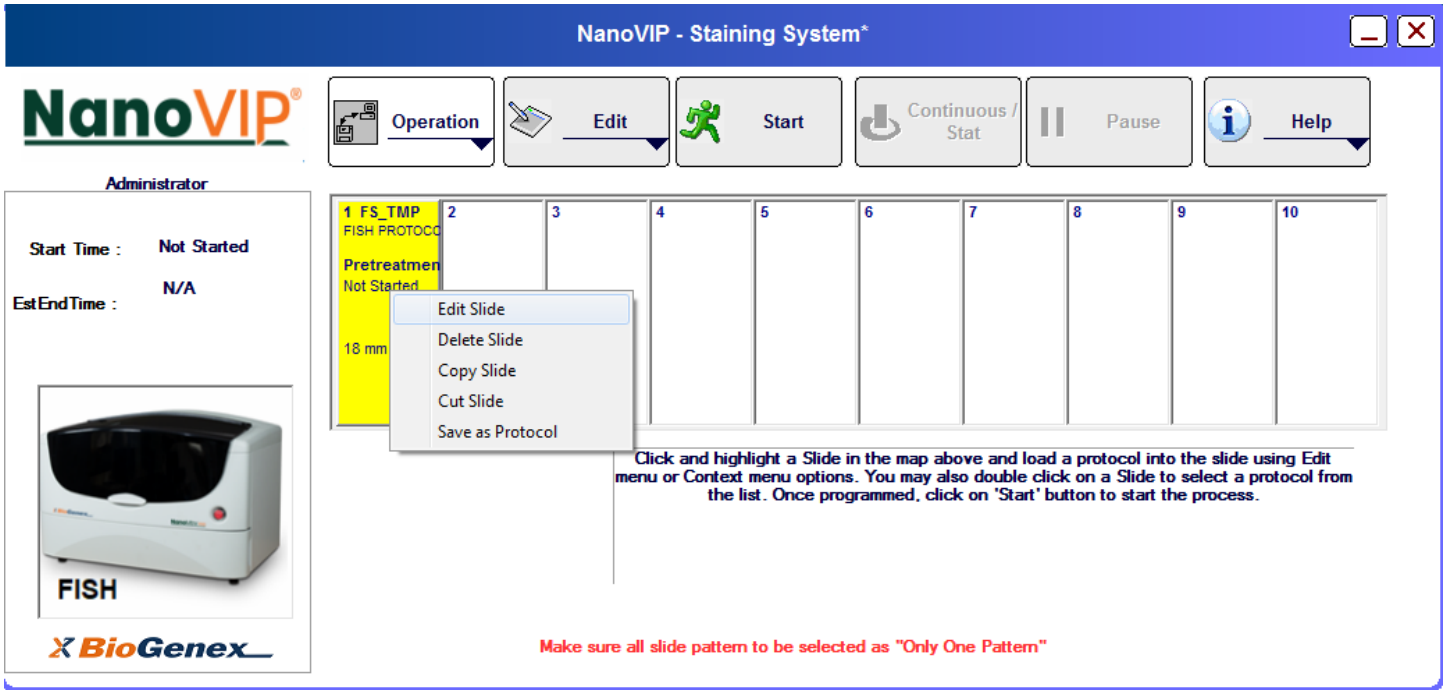


FIGURE 33<EDIT SLIDE> OPTION AFTER SELECTING PROTOCOL

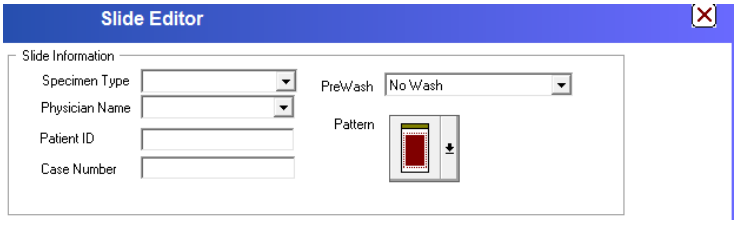


FIGURE 34<SLIDE INFORMATION AREA>

- <**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 (see Section *5.2 Specimen Name*).
- If desired, the <**Case Number**> may be entered in the appropriate field.
- Slide Pattern can be selected from given three options.

7.2.3 PROTOCOL

This area contains the operations and steps of the protocol.

- An operation and its Steps can be viewed and closed using Expand and Collapse Command buttons at the bottom.

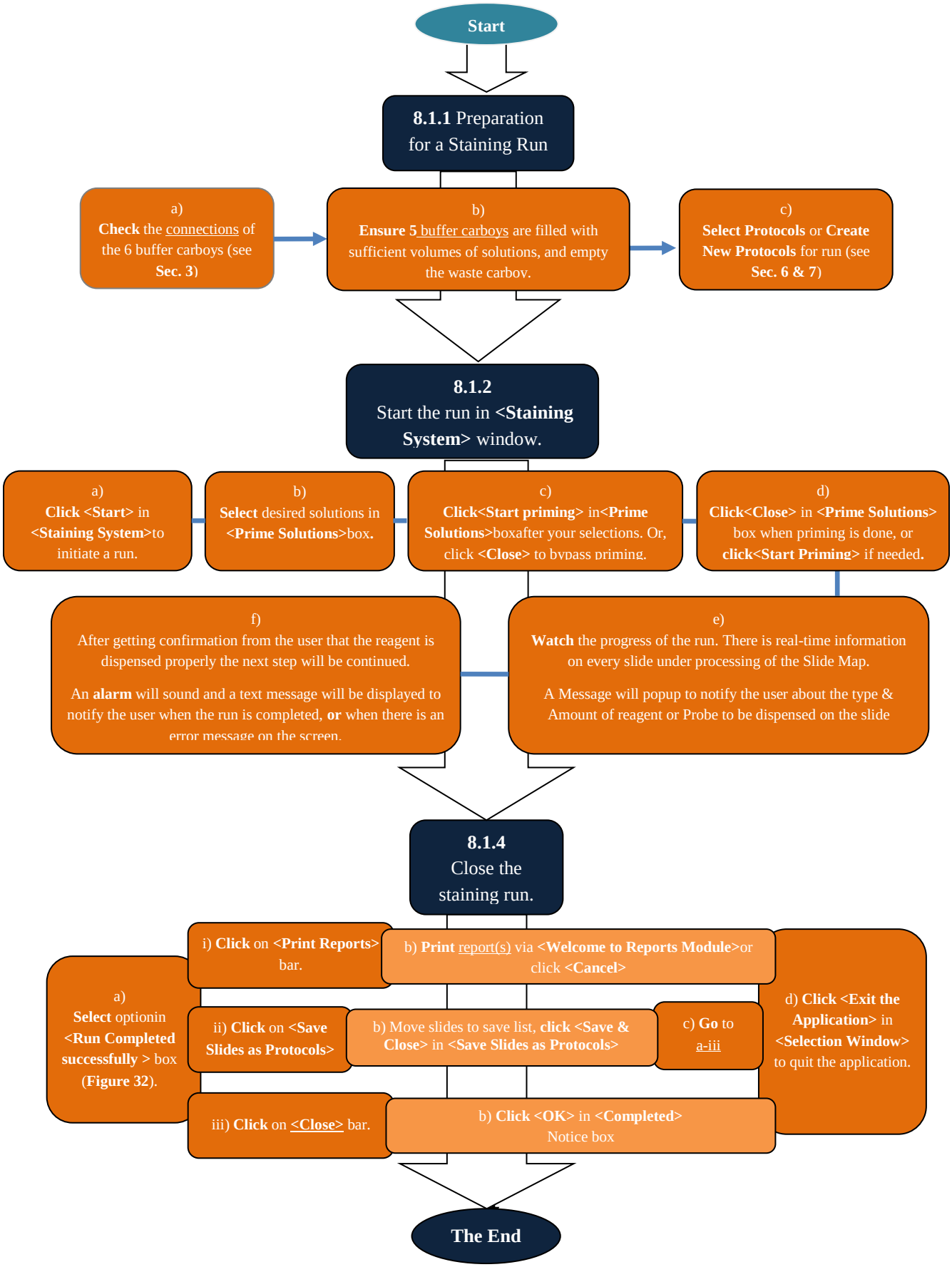
- Steps and its parameters can be edited, added, deleted, copied as per the requirement and saved by clicking on <Save Protocol> command at the bottom.

7.2.4 COMMANDS

The bottom area contains buttons for giving commands like

Expand	**:**	Expands all operations and shows detailed information of each step.
Collapse	**:**	Closes all details and returns back to view of Major steps in a protocol.
New step	**:**	For Creating New Step
Delete Step	**:**	For Deleting Step
Move up and Move down	**:**	Can be used to move across the steps of a protocol.
Copy Step and Paste Step	**:**	Allows copying and pasting selected steps
Save	**:**	Saves the protocol with changes made as **<FACTORY_USER >**or **< USER >**
Cancel	**:**	Cancels the changes made in protocol.
Print	**:**	Enables printing of protocol.

EXECUTING A RUN



8.1 Preparation for Executing Run

The user must ensure that all preparation steps are completed, such as programming protocols and editing slides for the new run. Confirm that all the required buffer Carboys are filled with sufficient volume of appropriate solutions and Coverslip stack with sufficient number of cover-slips. Ensure the waste carboy is empty. (Refer to ***Section 3:** On-Site Installation*).

The **<Staining System>** window is the main interface for building protocols and applying slide settings.

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

1. Correct protocol with the right coverslip pattern is chosen for each slide loaded on NanoVIP® instrument.
2. Buffer Carboy levels are sufficient for the run
3. Coverslip Stack with sufficient Coverslips.

8.2 Initiating A Staining Run

1. Select **<Start>** in the **<Staining System>** window. (Figure 16)
2. The **<Load Consumables>**window (Figure 35) will appear in order to confirm all the loaded consumables, after confirming click “check all” and then “Proceed”.

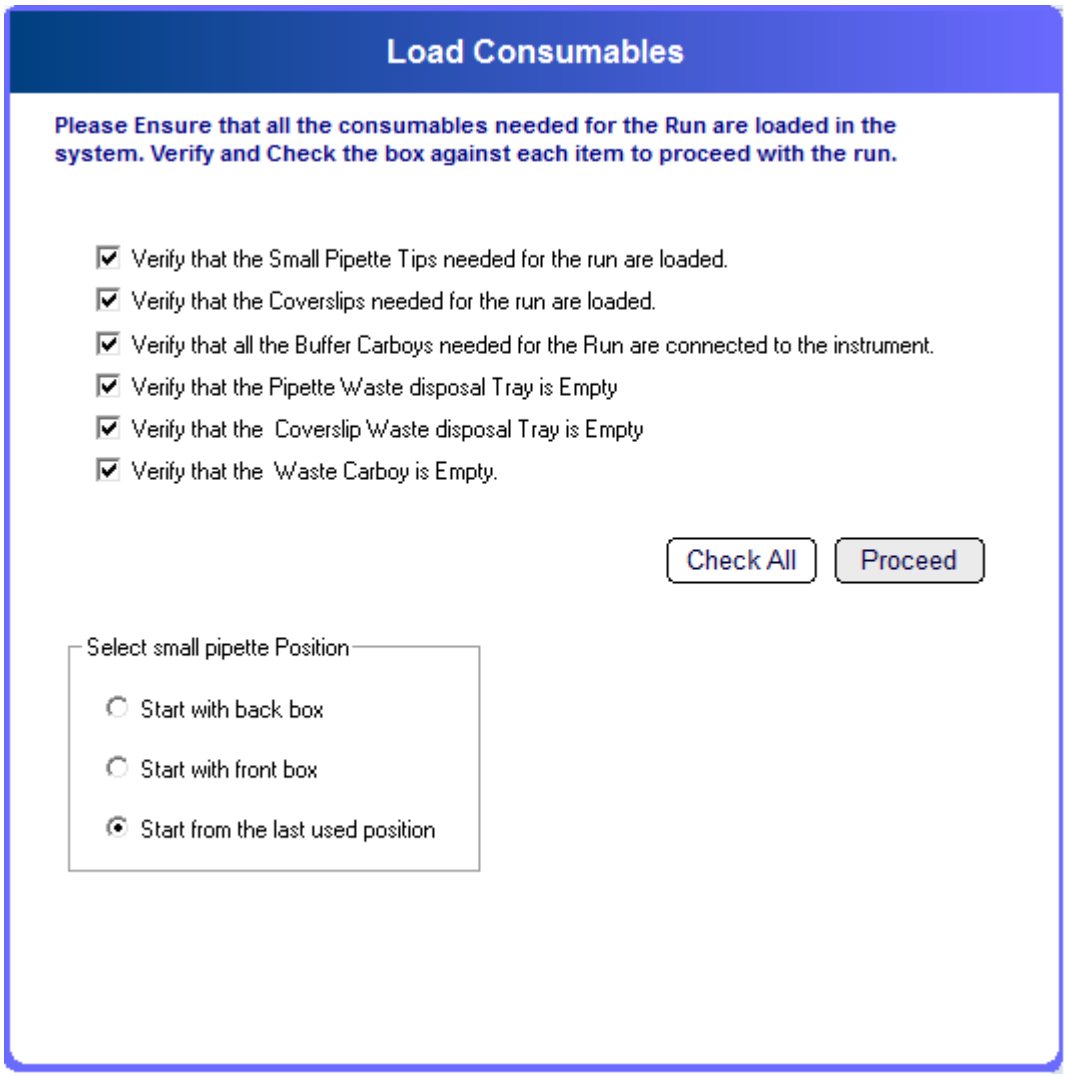


Figure 35Load Consumables Screen

3. The<**Prime Solutions**> window (Figure 36) will appear in order to select the solution(s) that need to be primed.

   To Prime Solutions is one of the important steps in a run. In solution priming, air gaps, if any, are removed in the tubing and nozzles connected to buffer carboys thus making it ready to dispense exact amount of solution as fed in the protocol. This avoids erroneous results due to insufficient dispensing of solutions.

   Buffer carboys can be primed before selecting a protocol also (For detailed information see section 11.2 Prime Solutions)

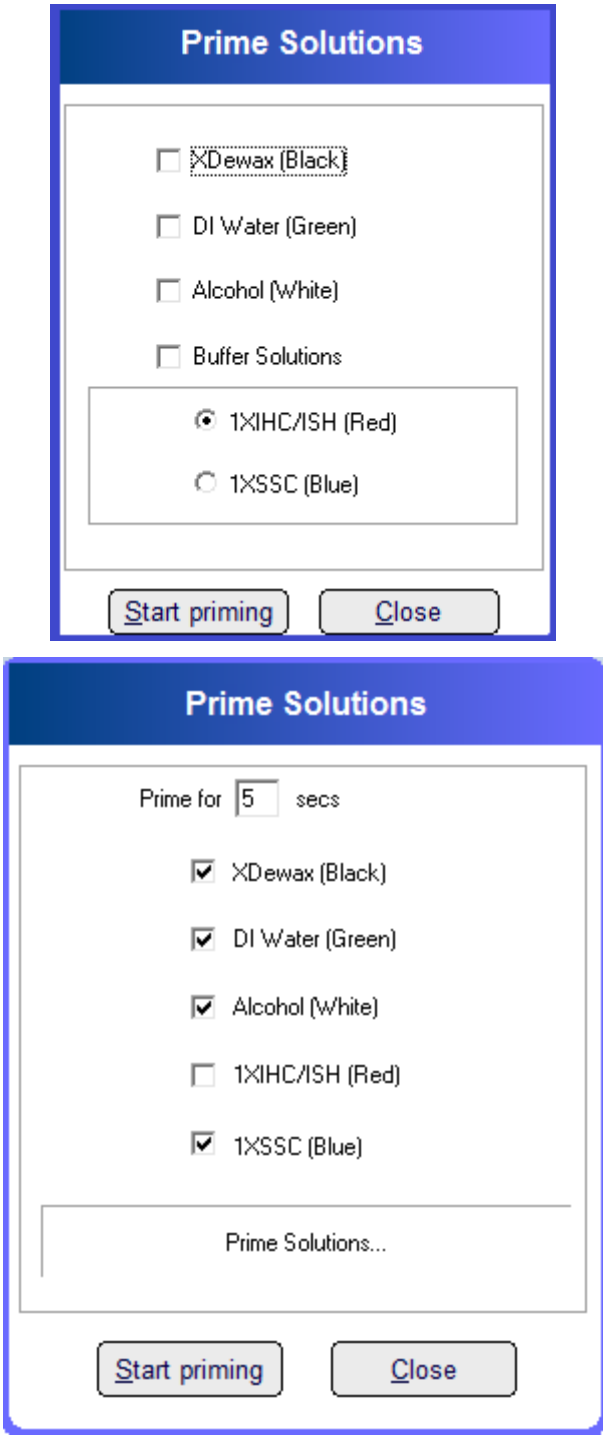


FIGURE 36PRIME SOLUTIONS SCREEN

4. Buffer lines that are required for the new run will be automatically selected.
5. Here priming is automated function.

6. Select <**Start Priming**>. The workstation will start priming.
7. If priming is not required, select <**Close**> to bypass and the staining run will start.
8. At the end of priming, the <**Prime Again**> button will become active.
9. If any of the buffer lines has not been primed sufficiently, select < **Prime Again**> to re-prime solution(s). Or select <**Close**> to proceed to the next step. The <**Prime Solutions**> window will close.
10. The actual staining process will begin. When the process is completed, an alarm will sound.
11. When the staining run is completed, the <**Run Completed successfully**> dialog box (Figure 37) will appear for further action.

FIGURE 37<RUN COMPLETED SUCCESSFULLY> WINDOW

12. Once the run is completed successfully, the user may:
    i. <**Print Reports**>of the run (refer to ***Section 9:*** *Generating Reports* for printing operation details)
    ii. <**Close**> the run.

<Save Slides as Protocols>Window

13. If the user selects <**Close**>, a <**Completed**> dialog box appears (Figure 38).

FIGURE 38<COMPLETED> CONFIRMATION BOX

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

8.3 MONITORING A RUN

Real time information of a staining run may be viewed in the <**Staining System**> window. The slide map in the window always presents the real time information for each slide being processed. The color scheme assigned in advance to represent different types of objects and different status of the same object, together with text on the slide(s), help the user to easily recognize, which particular phase of the protocol an individual slide is involved in.

8.3.1 RUNTIME PROPERTIES

All the details of a run can be monitored from properties window of slide.

To access properties,

1. Right click on the slide to be monitored.

2. From dropdown menu select <**view properties**> option.
3. <**Runtime properties**> window will open.
   This window shows all information about steps in an operation, time spent, and status of the step.

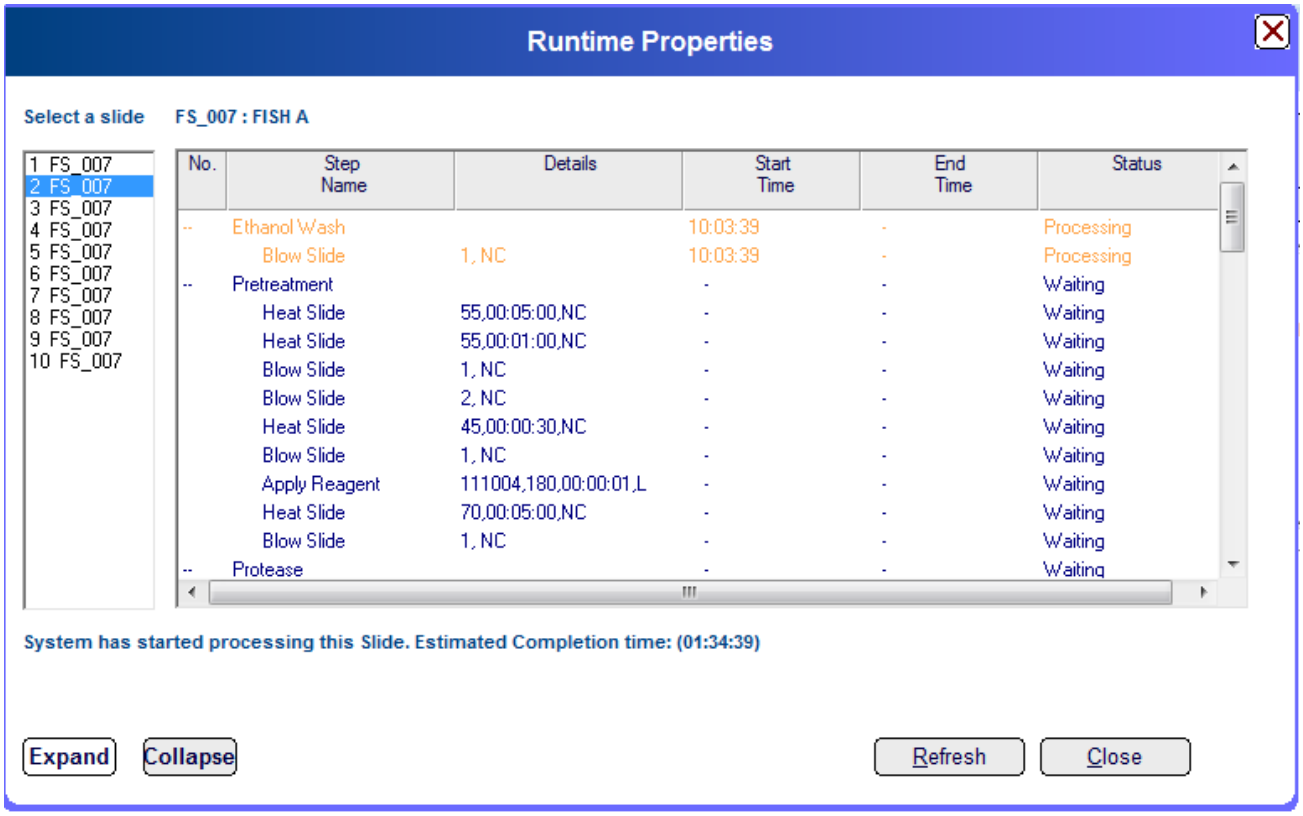


FIGURE 39<RUNTIME PROPERTIES> WINDOW

8.4 Stop a Run

To stop a run in progress:

1. Select **<Stop>** at the bottom of the **<Staining System>** window.(Figure 26)
2. The stop <**Application Stopped**> message box will be displayed.

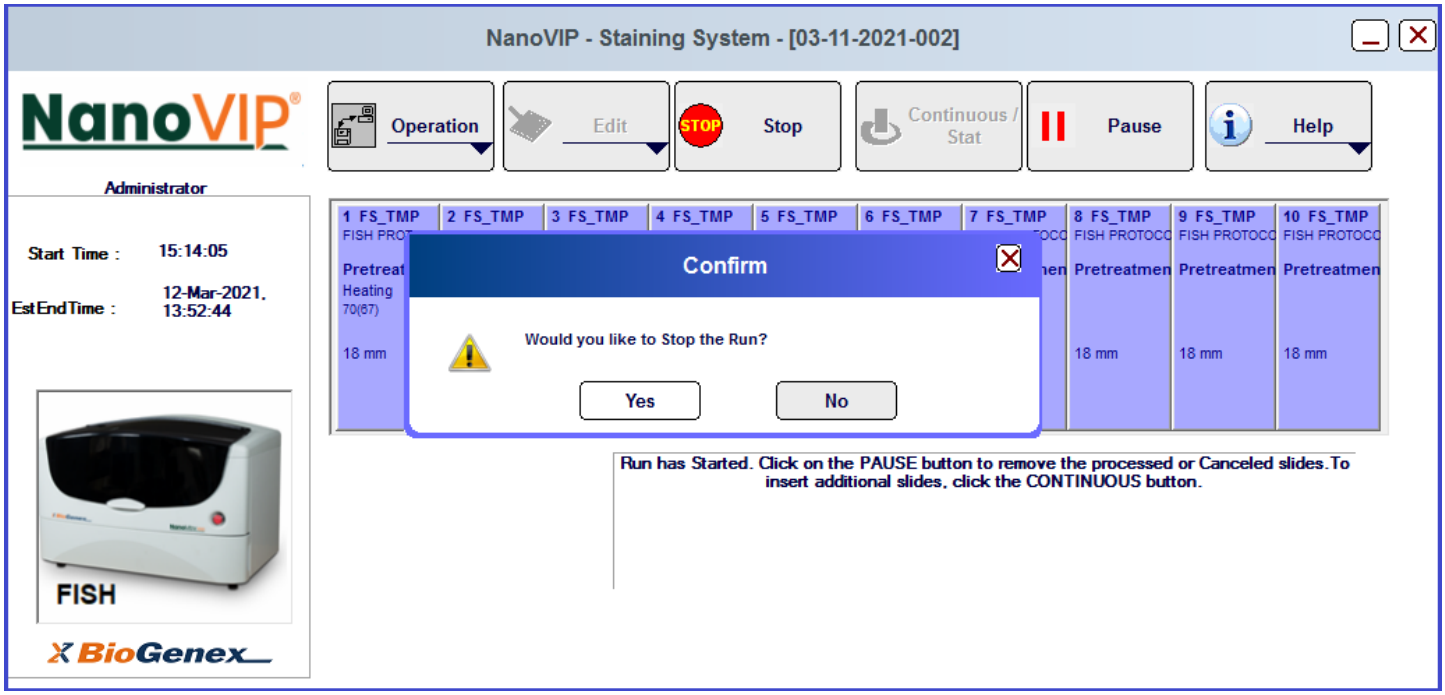


FIGURE 40<APPLICATION STOPPED> STOP MESSAGE BOX

3. Click on the <Yes> button. To terminate the current run.

8.5 Emergency Stop

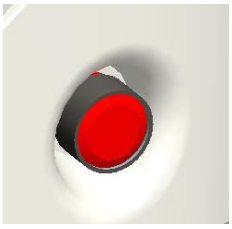


FIGURE 41EMERGENCY STOP BUTTON

The **<E-Stop>** (Emergency Stop) (Figure 41) button is located at the lower right end of the Instrument. Pushing this emergency stop button will stop a staining run immediately. This is used in case of an emergency. When the **<E-Stop>** button is pressed while the Z-Head is in motion, the instrument will stop running, the system alarm will sound, and a system error message (Figure 42) will be displayed on the screen. Once the **<E-Stop>** button is pressed, the run in progress is cancelled and cannot be resumed.

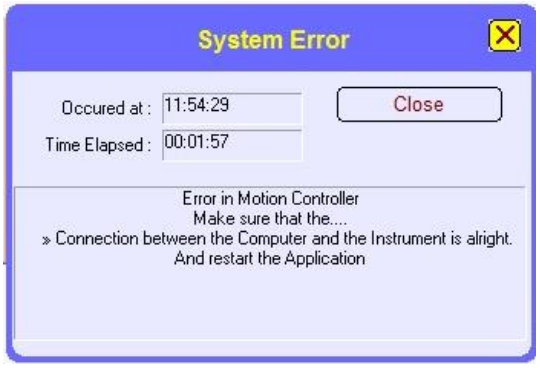


FIGURE 42<SYSTEM ERROR MESSAGE> SCREEN

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

8.6 TYPICAL ERROR MESSAGES

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

The main objects that tend to incur error messages are:

- Robotic Head
- Oil-Pen
- E-Stop button
- Communication failures arising due to Power failures, Voltage Fluctuations.

The table below lists some typical error messages that might appear with higher frequency when the instrument is in use.

The method of clearing an error message is presented along with the error message in the same message window.

Sr. No	Error Message	Corrective Action
1	**Coverslip boxes are empty**	Load Coverslips and resume staining on affected slides
2	**Error placing the coverslip on the slide**	Dispose the coverslip, and place a new coverslip on slide
3	**Unable to dispose the coverslip into the coverslip disposal**	Check the calibration and try again. Manually dispose of coverslip.
4	**Emergency button is pressed**	Operation cannot be performed. Clear the error, then re-start the operation.
5	**Error if vacuum is not created**	Operation cannot be performed. Clear the error and re-start the operation.
6	**Coverslip removal error**	This might occur due to following: 1. Cover slip might be broken: in this case remove it manually and then click fix errors.

Sr. No	Error Message	Corrective Action
		2. If it occurs due to any other cause: contact BioGenex services.
7	**Heater failure**	Contact BioGenex services.
8	**Error in Motion Controller**	This might occur due to the following reasons. 1. Power Failures 2. Voltage Fluctuations Operation cannot be performed. Clear the error and then restart the run with fresh new samples.

GENERATING REPORTS

9.1. LAUNCHING THE REPORTS MODULE

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

1. Click the bar **<Run Reports>** (Figure 43) in the main dialog window **<Selection Window>**,

   OR

2. Click on the **<Print Reports>** option in the **<Run Completed successfully>** window (Figure 44).

Either way, the **<Welcome to Reports Module>** window (Figure 45) will appear. This window is the main interface for printing.

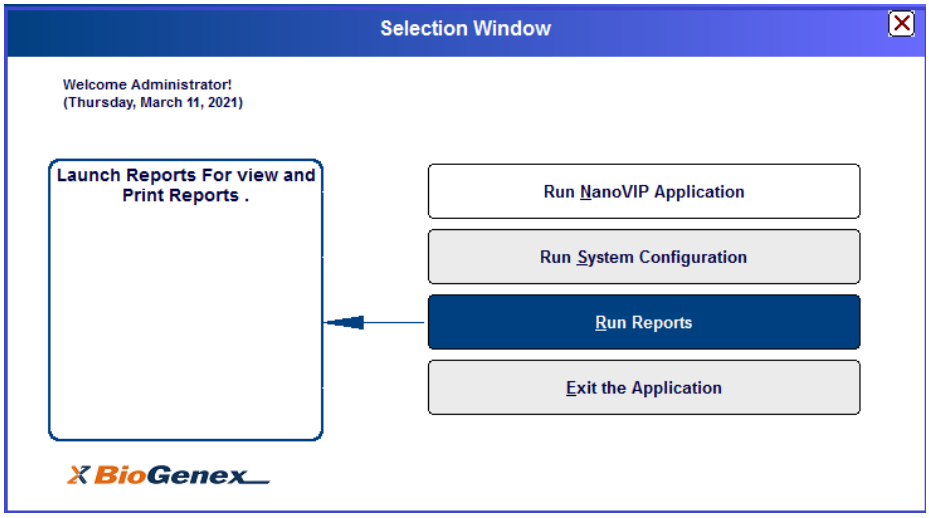


FIGURE 43<RUN REPORTS> OPTION ON <SELECTION WINDOW>

FIGURE 44<RUN COMPLETED SUCCESSFULLY> WINDOW

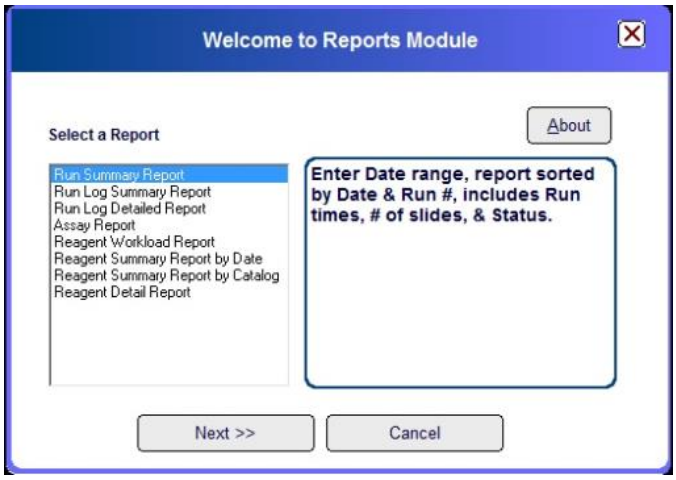


FIGURE 45<WELCOME TO REPORTS MODULE> WINDOW

9.2. DEFAULT REPORT TYPES

The *NanoVIP*® software provides the user with four (4) types of default report formats. These reports will summarize the staining data for reference. The **<Welcome to Reports Module>** window (Figure 45) displays the various types of reports in the drop down list. Selecting a report type will display the corresponding report. In addition, users may customize reports to meet their own individual needs.

1. Select the report-type in the **<Select a Report>** dialog box. Select **<Next>** in the **<Welcome to Reports Module>** window, which will open the **<Select Parameters for Run Summary Report>** window (Figure 46).

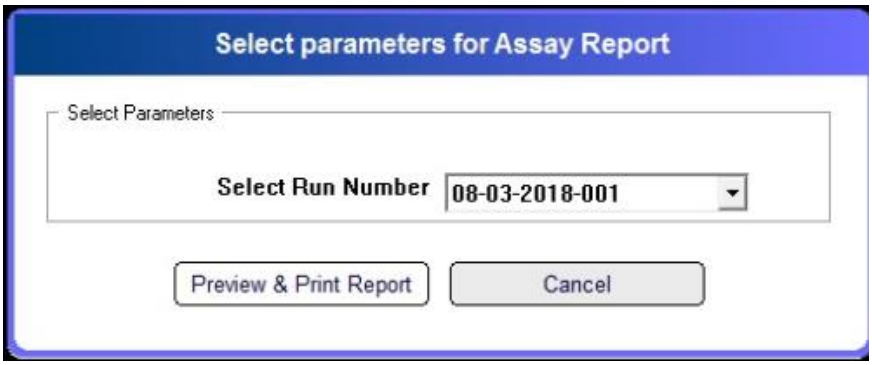


FIGURE 46<SELECT PARAMETERS FOR RUN SUMMARY REPORT> WINDOW

2. Select the date (or date range), run number or catalog number of the report. (Figure 46)

9.3 PREVIEWING AND PRINTING A REPORT

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

1. Select **<Preview & Print Report>** to open the **<Reports>** screen.
2. The **<Reports>** screen displays the report for preview (
3. Figure 47).

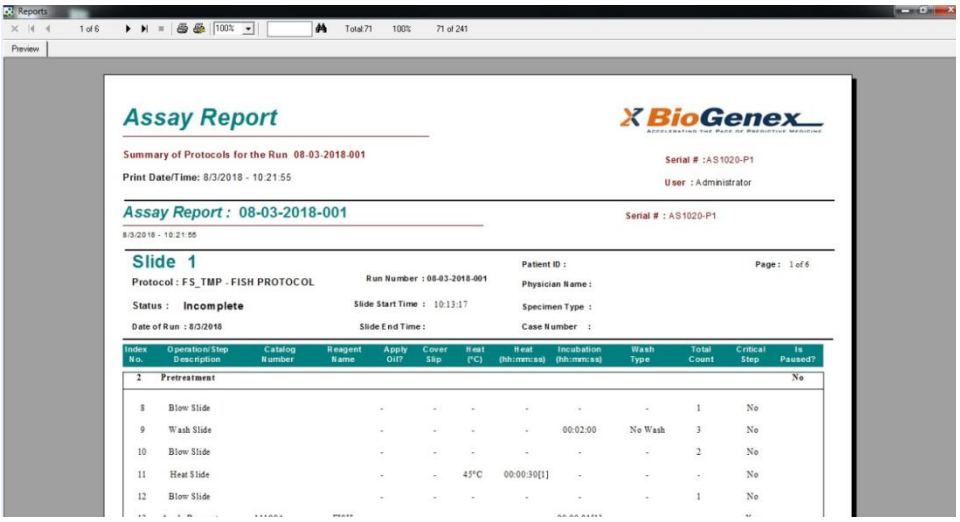


FIGURE 47< PRINT PREVIEW> SCREEN.

4. To print the report, click on the printer icon 

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

9.4. EXITING THE REPORTS MODULE

To exit the 'Reports Module':

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

TROUBLESHOOTING

Observed problems with the NanoVIP® System are characterized by symptoms. Troubleshooting tools, references, and suggested techniques are provided to help the operator trace the symptom(s) to one or more root causes. With this information, the operator can perform corrective actions necessary to resolve the problem.

Information in this section lists possible NanoVIP® malfunctions and errors. The operator has access rights to correct some problems or errors. When this type of error occurs, appropriate corrective actions are described.

Correction of more complicated malfunctions or errors is usually performed by a BioGenex Representative.

Customer Support

If you have questions, please contact your BioGenex Technical Service.

10.1 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.

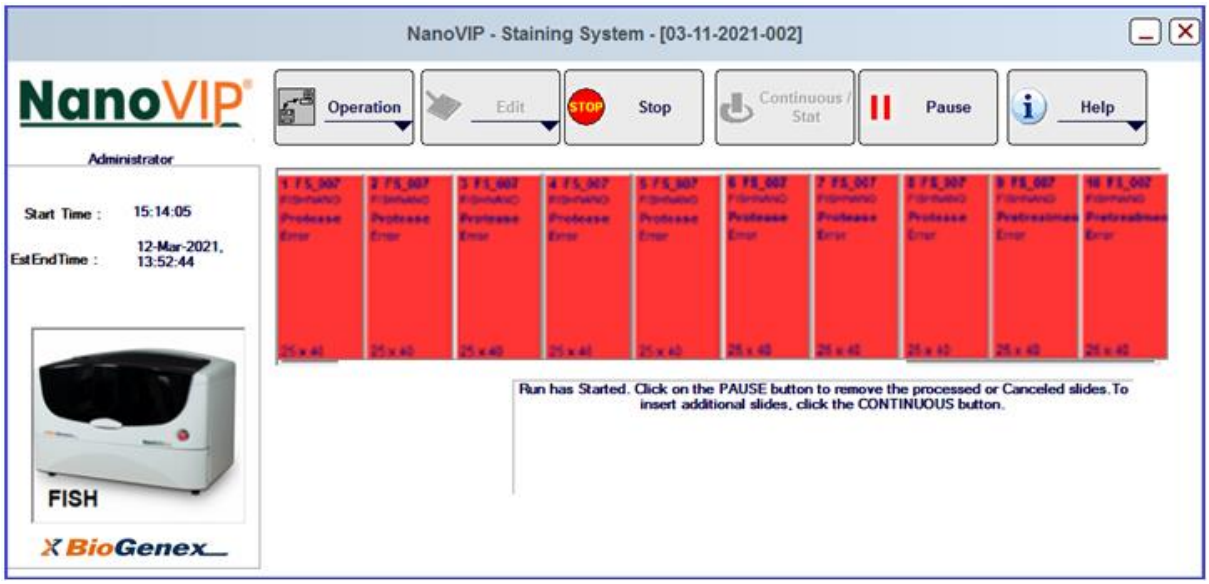


FIGURE 48SLIDE MAP: HEATING

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.

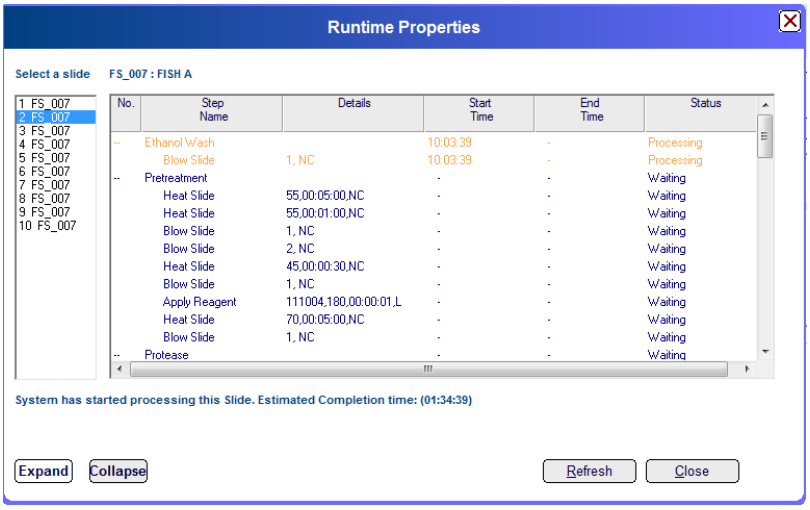


FIGURE 49RUNTIME PROPERTIES SCREEN

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 Technical Service.

10.2 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, 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 50FIX ERRORS: EMPTY COVERSLIP BOX

Corrective Action(s)

1. The Z-Head will stop proceeding and Error Message window will appear with the description of the error condition and the appropriate instruction to correct the problem.
   - **<Description>** - Coverslip box is 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.
3. Ensure the coverslip boxes are placed in the correct orientation and the Coverslips are properly seated in the coverslip box.

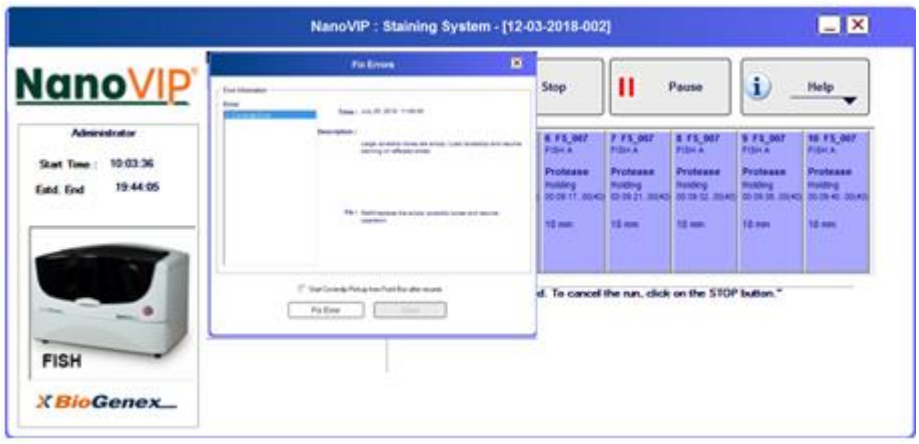


FIGURE 51FIX ERRORS: COVERSLIP BOX IS EMPTY

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

10.3 Coverslip Placement / Remove Error

During the staining operation, if the Z-Head suction cup fails to place a coverslip onto the slide, or fails to remove 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 Technical Service.

10.4 Basic Troubleshooting

Sr. No	Symptom	Possible Cause(s)	Corrective Action(s)
1	There is no power to the workstation	• Power cord may not be plugged in • Forgot to turn on power switch • No power to the receptacle • Safety fuse may be blown	1. Plug the power cord. 2. Find the power switch on the right side of the workstation, turn it ON. 3. Ensure that the power source has power supply. 4. Request authorized service personnel to check and replace the fuse.
2	The display on Laptop/Touch Panel PC is blank or incorrect after the power is turned ON	• Controller may need to be reset.	1. Turn OFF the Instrument and Laptop/Touch Panel PC. 2. Unplug the power cord. Wait ten (10) seconds, and plug back in. 3. Re-start the Laptop/Touch Panel PC and then turn ON the Instrument. 4. Request service personnel to check the Laptop/Touch Panel PC.
3	The instrument could not prime	• Not enough liquid in the carboy bottles • Peristaltic pump internal tubing might be pinched off • Unknown cause	1. Check carboy caps and O-rings, and ensure that they are secured. Also check the connectors on Liquid Panel. 2. Check the peristaltic pump internal tubing for any damage.
4	Failure in Cover-slip 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 no air is leaking from tubing. 3. Request service personnel to calibrate Suction Cup with the CS Box. 4. Suction Cup could have micro-tear. Call Service to replace the Suction Cup.

Sr. No	Symptom	Possible Cause(s)	Corrective Action(s)
5	Instrument Z-Head could not move to left or right	• Related to communication failure between X or Y motor	1. Plug out and plug in instrument communication port to laptop from the assigned communication USB port and restart the application. If still existing contact Field Service.

ROUTINE MAINTENANCE

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

11.1 DAILY CLEANING

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

Remove and empty the Waste Coverslip Box. Rinse with DI water and dry.

1. Remove the slides from the Slide rack. Remove the slide carrier and soak them in DI water to remove all traces of residue. Dry them with a cloth. Return them to their position.
2. 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 abo

3. Use a clean and soft cloth to dry off all the surfaces of the instrument.
4. Clean the area surrounding the NanoVIP® system.

11.2 PRIME SOLUTIONS

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

Figure 52 Nano VIP® –System Configuration and Calibration Window

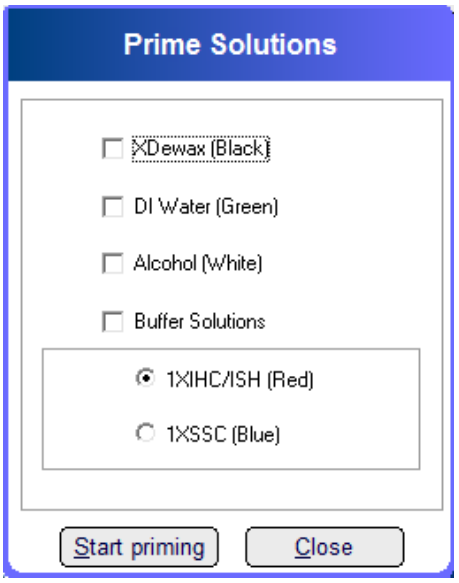


Figure 53 Prime Solutions Window

For information on what is priming of solution, refer to ***Section8.2*** ***Initiating A Staining Run***

In test mode, solution priming is not controlled automatically, whereas it is controlled manually; i.e. once started, it can be stopped whenever priming is done.

Double-click on NanoVIP® icon on the Laptop screen to open **<Log on>** window

↓

As Administrator, click on **<Log on>** button in **<Log on>** window to open **<Selection Window>**, then click on **<System Configuration & Calibration>** bar to open the **<System Configuration & Calibration>** window (Figure 17)

↓

Click **<Test>** button in **<System Configuration & Calibration>** to display a dropdown menu (**Error! Reference source not found.**), select the option **<Prime olutions>** to open the **<Prime Solutions>** window (Figure 52).

↓

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

1. Click in the top four (4) squares to select all (i.e., Dewax, DI water, Alcohol, and Buffer Solutions).
2. Click to select one (1) of the two (2) Buffer Lines (repeat this selection with the remaining two(2) Buffer Lines after each round of priming, but deselect the Dewax, DI water, and alcohol after the first pass).
3. Click **<Start Priming>** button to start priming. Repeat the priming twice with a single buffer line. Click **<Close>** button to end priming with this particular buffer line.
4. Repeat above operation to complete the priming with all two(2)buffer lines. Click **<Close>** button to end priming.

↓

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

11.3 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:

   a. Open the **<Prime Solutions>** window in the **<System Configuration & Calibration>** module (see details in the previous flowchart). The Robotic-Head will move over the drain hole in the Slide Room automatically.

   b. 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 Laptop can still be powered ON while the instrument is powered OFF. Never turn OFF the Laptop while the instrument is ON.

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 five (5) buffer Carboys from the instrument. Remove the caps from the buffer carboys and empty each carboy. Fill in each bottle with one gallon of DI-water and add a capful of chlorine bleach. Shake the bleach solution thoroughly in every carboy. Empty the bleach solution from the buffer carboys.

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

5. Prepare fresh cleaning solution for each buffer carboy: Empty the buffer carboys, and use one (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 cleaningsolution: 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 five (5) 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 drying.

8. Clean the drainage tray (i.e., the base of the instrument) with powdered cleanser (i.e., bleach) and a soft plastic brush. Rinse and dry the tray. Ensure that the waste liquid can be drained properly. Check and adjust the drainage tubing as necessary.

9. Dry the interior of the instrument by wiping all surfaces with a clean soft cloth.

10. Leave the Housing Cover open and let the instrument air-dry overnight.

11.4 Semi Annual Maintenance Arrangement

Only a trained service technician, or BioGenex service personnel, will perform this preventive maintenance every six(6) months. To contact BioGenex Technical Service, call 1-800-553-7042 (U.S.A. and Canada only). For documentation purposes, it is required that the maintenance report with the instrument serial number, and the maintenance date be clearly filled out.

APPENDIX I
SERVICE PLAN

For a period of one (1) year from the date of installation ("Service Period")*, BioGenex Laboratories, Inc. ("BioGenex") will provide the following services for maintenance and repair of the NanoVIP® Automated Staining System ("System") purchased, leased or rented by the Customer ("Services"):

3. Preventative Maintenance Service
4. Emergency Repair Service
5. Software Upgrades

CUSTOMER RESPONSIBILITIES

The customer must maintain the:

1. Installation site and its environment in a condition suitable for operation of the System
2. System under the daily/monthly routine maintenance schedule as provided in the NanoVIP® Operator's Manual.

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.

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 option. Labor to install replacement parts is included. Replaced parts become BioGenex 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.

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.

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 Technical Service at**1-800-421-4149.**

PREVENTIVE MAINTENANCE CHECKLIST FOR NANO VIP

Please check off these actions in the following order as they are performed.

SI.NO	Items to check	Result (Circle as appropriate)	Note / Remark
1.	Verify and tighten all the screws on the Z-head. Switch off the Nano VIP and check for free motions in X, Y directions, apply lubricant on X, Y rails and adjust belt tensions, if needed.	Yes No	
2.	Laptop functions well	Yes No	
3.	Check for any damages to vacuum pad & Replace the damaged vacuum pad (Part No: 4201-04155), if applicable. Clean the Fitting & tubing's connected Vacuum pad and replace the same, if required.	Yes No	
4.	Clean the Wash Head nozzles and check for any physical damages to the nozzles and replace the damaged wash head (Part No 6520-17881)	Yes No	
5.	Clean the Blow Head nozzles and check for any physical cracks / damages to the Air blower / nozzles / blow head and replace the damaged blow head (Part No 6520-40801)	Yes No	
6.	Physically check TEC heater for any bulges, Conduct "Temp Switching Test", "Peak Temp Test", and "Temp Durability Test" for 10TEC modules & Replace non-working / bulged Assy. TEC heater (Part #4501-17812), if needed	Yes No	
7.	Replace Pipette tip adopter. Test the pipette tip sensor and ensure it is working fine through the diagnostics/run mode.	Yes No	
8.	Check visually for proper oil dispense. Replace damaged oil needle (Part number#6520-41775), & damaged oil tubing's, if needed	Yes No NA	
9.	Check for proper operation of the non-drip valve IHC, DI water, Alcohol & De-wax, replace if found leakage	Yes No	
10.	Check and mention the earthling voltage between neutral and earth _____(less than 2 VAC) at output of UPS. Check UPS battery backup is working fine else replaces the UPS.	Done No	
11.	Educate the customer to release E-stop switch prior to use of Nano VIP Check & replace E-stop if required.	Yes No	

12.	Check for the leakages in Fitting frame quick connectors & if found any, kindly replace the quick connector Clean the filter in all 5 , 1L carboys Check and replace the damaged gasket carboy cap (Part No # 6520-41147) & 1L Carboy cap (Part No 6520-40879, 6520-40883) if needed.	Yes No	
13.	Train the customer on Nano VIP Do's and Don'ts Daily, Weekly & Monthly maintenance procedures & perform the same at site.	Yes No	
14.	Check for accurate positioning of coverslip and oil seal operation for 25 x40, 25 x25 & 18x18 coverslips onto respective barrier slides	Yes No NA	
15.	Take the backup of current software and upgrade the software to latest version and perform the calibration as per the respective document	Done No NA	status:
16.	Perform the mock run report and real run report to ensure run is completed without any errors and attach the report	Yes No	
	Comments:		

Maintenance Performed by: _____ Date: _____

List of the Spare Parts

No	Item Name	Specification	Qty	Part Number
1	Fuse	MDA10, 250V	2	4280-02249
2	Carboy	1 Liter	1	6520-40882
3	Peristaltic pump internal tubing	TUBING, FLURAN, 3/16 ID x 5/16 OD	2	4460-02542

NOTE:
There are no user serviceable parts with the NanoVIP® system. When any service is needed, please consult BioGenex for all repairs.

APPENDIX I
METHODOLOGICAL BACKGROUND

FLUORESCENT *IN-SITU* HYBRIDIZATION

FISH (Fluorescent *In-Situ* hybridization) is a technique which is used to detect and localize the presence or absence of specific DNA sequences on chromosomes. This technique uses fluorescently-labeled DNA molecules (probes) to detect other DNA molecules (chromosomes or genes) of complementary sequence that can be seen using fluorescent microscopes. FISH has employed *In-Situ* on whole cells, nuclei, or inter-phase and metaphase chromosomes.

Cells or tissue are placed on a slide and treated (fixed) to stabilize cellular structures. Chemical and enzymatic procedures are employed to remove membranes and cytoplasmic proteins that prevent access to the cells' DNA. Cellular DNA is exposed to high temperature in order to open it, making it accessible to fluorescently-labeled probe DNA. Probe is added to the sample and allowed to hybridize with complementary sequence of the target DNA. Excess probe is removed post-hybridization and a counterstain is applied to visualize the nuclei. Detection of the probe on the target DNA is based on the color that its fluorescent label emits. Based on the signal patterns, a technician or pathologist is able to interpret chromosomal and/or gene abnormalities.

APPENDIX III
SOFTWARE LICENSE

BIOGENEX SOFTWARE

This software license agreement is a legal agreement between you (either an individual or an entity) and BioGenex Laboratories, Inc. ("BioGenex"), manufacturer of the NanoVIP® Automated Staining System. This is a license and not an agreement for sale. You obtain no rights other than those granted to you under this BioGenex Software License ("License"). By using the NanoVIP® Automated Staining System on which BioGenex software program(s) have been preinstalled, you are agreeing to be bound by the terms of this license.

1. **LICENSE.**

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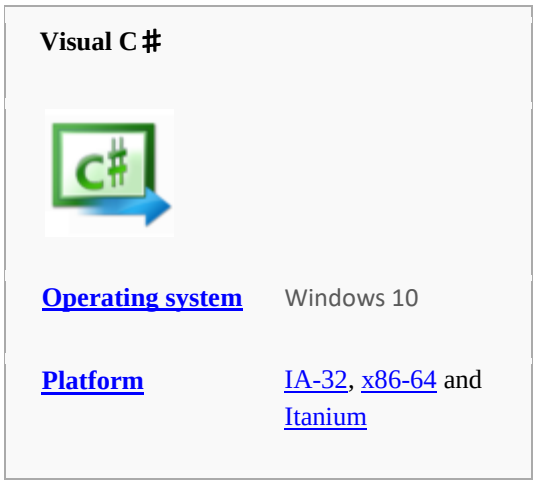

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APPENDIX IV
QUICK START GUIDE

The Quick Start Guide can be used as a tool to lead the operator through the basic steps to perform:

- Instrument Run Preparation
- Starting the Run
- Completing the Run
- Daily Maintenance

The Quick Start Guide does not reflect the same pagination and the Operator's Manual. It has been designed to be pulled from the Operator's Manual and used separately as a "Quick Start Guide." For any detailed information on procedures within the Quick Start Guide, refer to the appropriate section in this Operator's Manual.

DECOMMISSION.

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