*i*6000™ Diagnostics Automated Staining System

Barcode Enabled IHC Staining System

OPERATOR'S MANUAL

***i*6000™ Diagnostics Automated Staining System (Software Version 4.3d)**

CE

IVD For *in vitro* Diagnostics Use .

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***i*6000™ Diagnostics Automated Staining System**

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1.1 The Instrument

1.1.1 Intended Use

The i6000™ Automated Staining System is intended for *in vitro* diagnostic use for Immunohistochemistry (IHC), In Situ Hybridization (ISH)*, Special Stains* and other histological and histochemical staining procedures. The results must be interpreted by a qualified pathologist.

1.1.2 Automated Universal Staining

The i6000™ Automated Staining System is a complete and reliable system used for histochemical, immunohistochemical, and immunocytochemical staining in addition to certain in situ hybridization protocols. This fully automated, walk-away system provides excellent consistency of staining results between assays along with staining runs of up to 60 slides. The quick and efficient robotic execution of protocols saves time, money, and labor thereby allowing laboratory workers to perform other tasks. The i6000™ Automated Staining System combines BioGenex' superior primary antibodies, reagents and detection systems with a cutting-edge system automation and the user-friendly i6000™ Windows XP/7 Software. BioGenex Laboratories provides a complete set of reagents, buffers, hardware, and software, optimized for inter-assay consistency and accuracy of staining. The i6000™ system operates in an automated barcode-controlled operation mode. The built in 'Factory protocols' are standardized to produce reliable and consistent results. It also allows the user to modify these protocols to a limited extent in order to fine tune the process as per the requirements.

1.2 General Principles of Operation

The i6000 ™Automated Staining System consists of an XYZ robotic arm with a unique staining head that picks up and discards standard disposable pipette tips, and precisely applies reagents to tissue sections thereby eliminating the possibility of cross-contamination. The integrated wash and blow head rinses the slides after each reagent-incubation and blows off the excess buffer from the slides at the end of the rinsing step. It is designed to produce maximal spreading of reagents on tissue sections when used in conjunction with BioGenex immunostaining reagents. A barcode reader is provided for complete automation of the staining process. The i6000™ Automated Staining System is designed to complete a staining run of 60 slides in less than three and half-hours.

***Please contact BioGenex Technical Support for enabling Special stains and ISH applications.**

1.3 Precautions and Warning

The i6000™ Automated 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. The i6000™ Automated Staining System presents no hazards to operators if operated according to the instructions in this manual. Read the following safety precautions before applying power to the instrument.

The i6000™ Automated Staining System may be used only for the *in vitro* Diagnostic uses specified in this manual and for appropriate user defined purposes. Any other use is prohibited. Clinical interpretation of any staining results from the i6000™ Automated Staining System operation is solely the responsibility of the user.

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

Do not operate the i6000™ Automated Staining System in an environment where flammable vapors may be present. Operating AC-line-powered equipment in such an environment may cause an explosion.

Fuse type: GDB5A, 250V

Warning: For continued protection against fire hazard, replace only with same type and rating of fuse

When replacing any fuse on the i6000™ Automated Staining System, make sure that a fuse of the same type and rating is used. Using the wrong fuse may lead to fire or instrument failure.
The AC-line cord provided with the i6000™ Automated Staining System is intended to ground the chassis to help prevent shock and injury to personnel. The i6000™ Automated Staining System meets all national and local electrical codes that 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.

The barcode option of the i6000™ system uses a barcode reader that has been approved by the FDA for Class II use in a laboratory environment. However, as with any laser, it is advised that the operators not place their hand under the barcode reader when it is scanning or searching for barcodes. Also, in order to protect the operator's eyes, never place any reflective device under the barcode reader when it is running.

Use of the i6000™ Automated Staining System may require the use of hazardous chemicals. Please refer to the reagent manufacturer's instructions and be sure to follow all applicable local regulations

for the use, handling, storage, and disposal of any hazardous chemicals and waste. Liquids used on the i6000™ Automated Staining System may present a slip hazard if spilled on the floor. Excessive jarring of the instrument while the lid is open may cause the lid to close unexpectedly.

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.

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

Accessing the i6000™ Automated Staining System while the robotics are in motion, may cause bodily injury. Ensure that the run is paused prior to accessing the working space.

The i6000™ Automated Staining System is equipped with a door switch which when open will stop the movement of the robotic arm.

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

Warning Instructions

Power outlet should be near the equipment and it is easily accessible for easy disconnection of power from the equipment in case of fault.

Important safety instructions: Misuse of electrical components of i6000™ can cause electrocution, burns, fire and other Hazards.

Read this before using the i6000™

- Connection to MAINS supply: Where protective earthing is required, plug the i6000™ into a supply Qualified electrician or authorized service engineer.
- Use the i6000™ only for the purpose described in the instructions for use.
- Do not use accessories which are not supplied or recommended by BioGenex.
- Do not use the i6000™ if it is not working properly, or if it has suffered any damage.
- Do not let the i6000™ or its flexible cord come into contact with surfaces which are too hot to touch.
- Do not block air openings nor place i6000™ on a soft surface which might block them, and keep air openings free from lint, hair, fluff, etc.
- Do not place anything on top of the i6000™.
- Unless specifically instructed to do so by the instructions for use do not drop or put anything into any opening in the i6000™, or into any hose or coupling.
- Do not use the i6000™ out of doors.

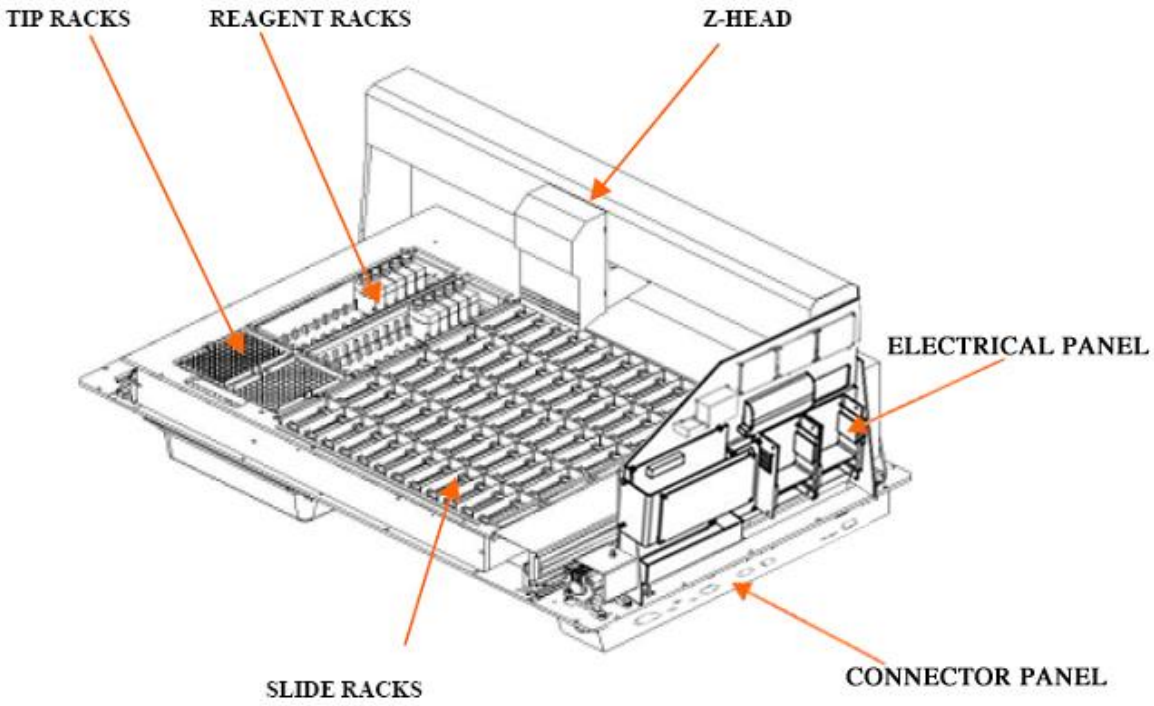
For any support, troubleshooting and repair contact BioGenex Technical Support.

For Installation pre-requisite, please refer to Appendix-7.

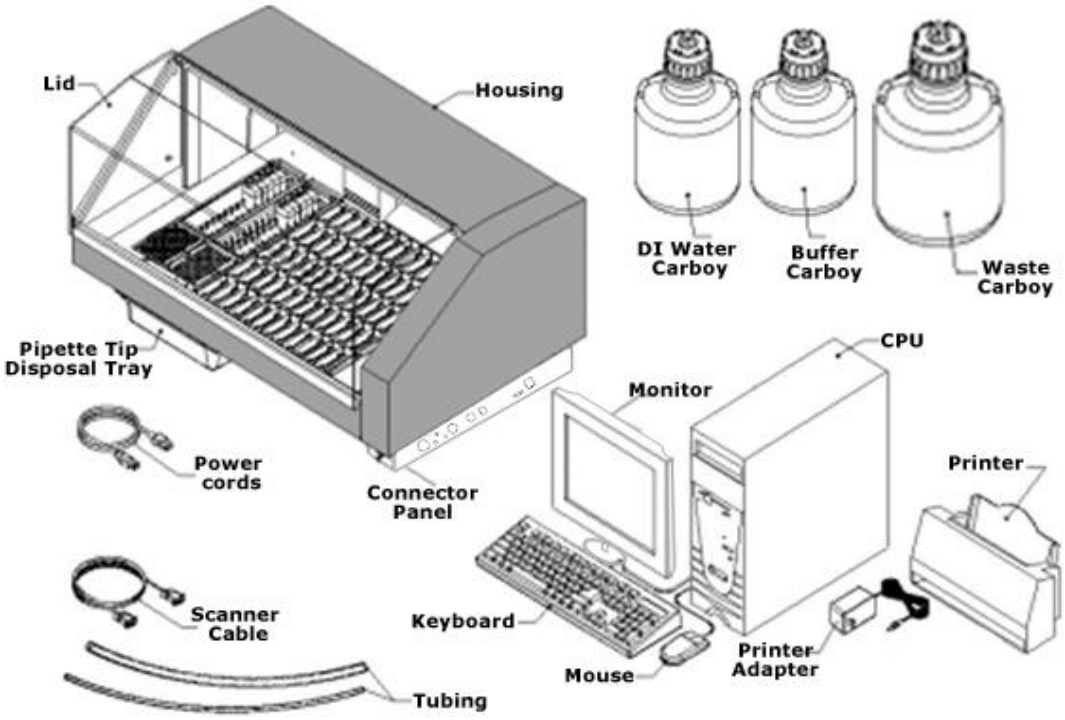
2.0 Instrument Overview

i6000™ Diagnostics

The BioGenex i6000™ Automated Staining System is a combination of hardware and software integrated with special reagents to automate IHC and special stain methods. This section describes the hardware and software specifications and the accessories provided with the system.



SLIDE RACKS: Consists of 5 racks where each rack can hold up to 12 slides, total 60 slides per run.
TIP RACKS: Consists of 2 racks where each can hold up to 96 tips, total 192 tips in each run. To run the system, use only BioGenex tips.
REAGENT RACKS: Consists of 2 reagent racks, each can hold up to 30 vials, total 60 vials in each run.
Z HEAD: An XYZ robot arm with a unique staining head that picks up and discards standard pipette tips, and precisely applies reagents to tissue sections eliminating any possibility of cross-contamination. The integrated wash and blow head rinses the slides after each reagent incubation and blows the excess buffer from the slide at the end of the rinsing step.
Y-AXIS MECHANISM: This will move the Z Head from front to back positions.
X-AXIS MECHANISM: This will move the Z Head from the left to right positions.
Z-AXIS MECHANISM: This will move the Z Head from the up to down positions.



i6000™ Diagnostics Accessories

2.1 Accessory Kit

BioGenex provides the following accessories along with the i6000™ Automated Staining System.

1.	**i6000™ Instrument**	01
2.	**Carboy and Tubing**	
	Air Tubing	01
	Waste Carboy Cap/20L Waste Carboy/Tubing/Label	01
	DI Water Carboy Cap/ Tubing/Label	01
	Buffer Carboy Cap/Tubing/Label	01
	SS Buffer Carboy Cap / Tubing/ label	01
	10 L carboy	01**
	10L Carboy	02
3.	**Power Cord**	01
4.	**Computer Accessories**	
	Computer	01
	Monitor	01
	Keyboard	01
	Mouse	01
	Barcode Scanner Cable	01
	Printer	01*
	Printer Cable	01*
	(*order separately)	

** - Needs to order Separately only when SS application is enabled.

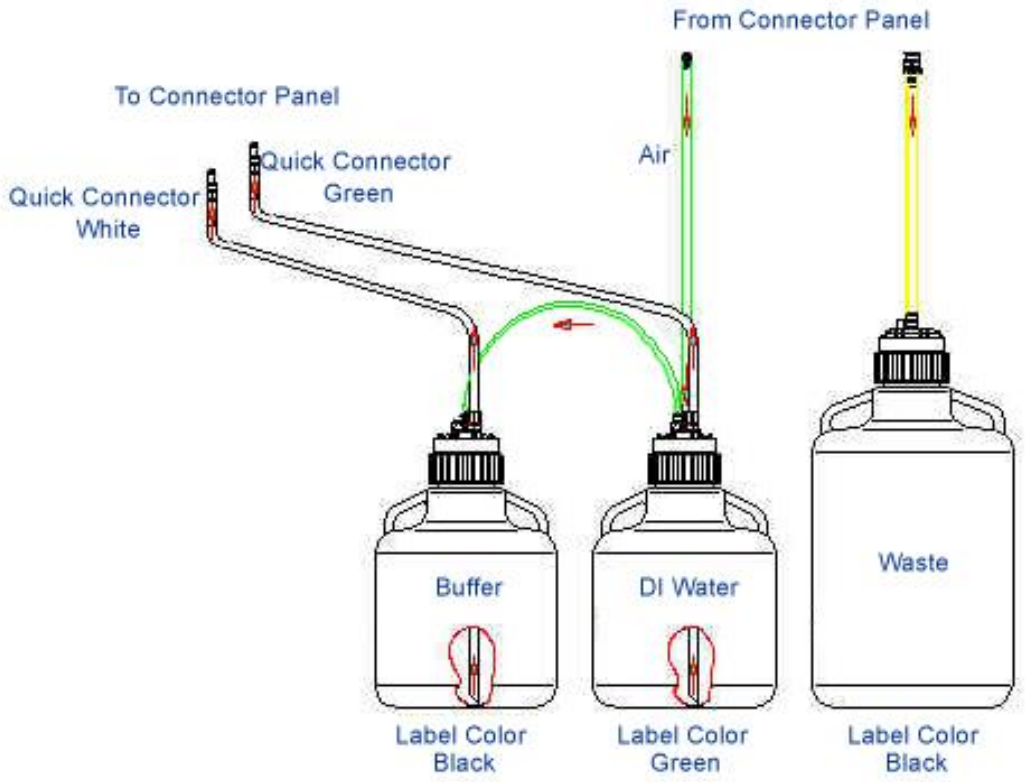
2.2 Instrument Setup

The i6000™ Diagnostics Automated Staining System is 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 i6000™ Diagnostics Automated Staining System to another site, contact BioGenex to prepare the system for transport and reinstallation. Failure to properly prepare the system for transport can result in damage to the automated mechanisms.

To use the system, check that the Buffer Carboy is full, and ensure that the tubing from the Buffer Carboy is securely connected to the instrument. An IHC staining run of 60 slides with a factory protocol will use approximately 7.3 liters of buffer.

Note: For best results, be sure to use Super Sensitive Wash Buffer (Cat No. HK583-5K). This buffer has been optimized to maximize the spreading of reagents on the tissue sections.

Make sure the cap O-rings (circular black rubber washers used to prevent air leakage from the carboys) are in place and that the caps are secured tightly to the carboys.

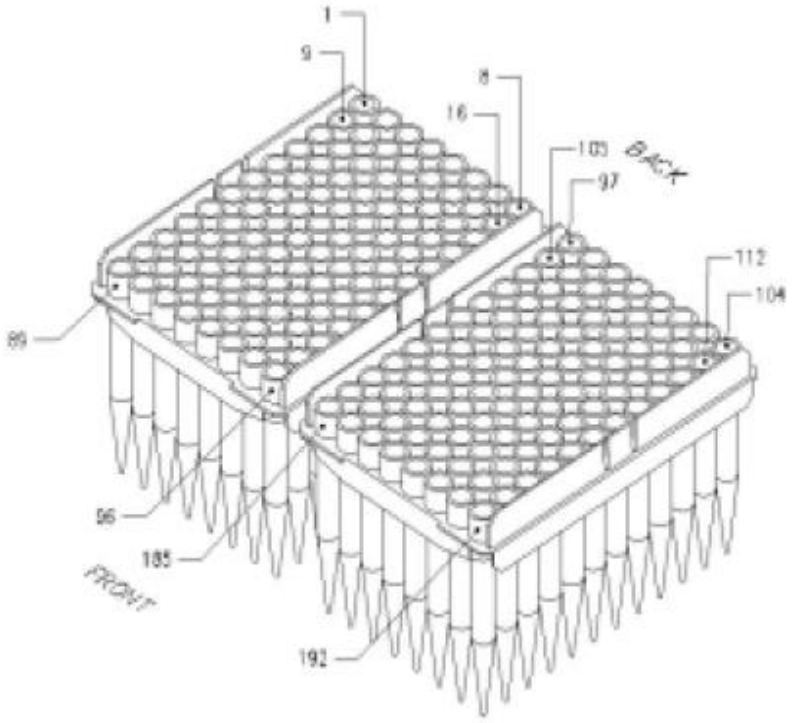


Ensure that the waste carboy is connected to the waste outlet on the side towards the front of the instrument and that the drain line is not kinked.

Make sure the pipette tip disposal tray is in place in the waste tray drawer under the left side of the instrument.

To install a tray of pipette tips in the unit, first place the front edge of the tip tray into position, then press the back side tray down into position. Make sure that the tray is pressed all the way down into

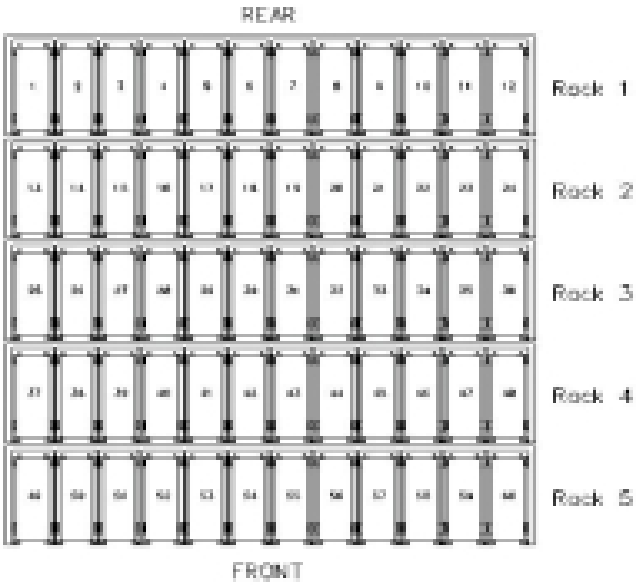
the recess. The tip adapter on the Z-head will pick up the first tip at the rear left-hand corner of the tray.

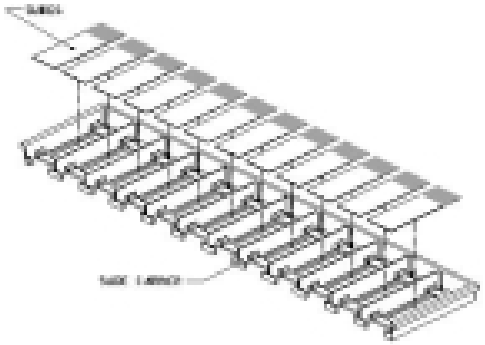


2.2.1 Loading the Slides

Slides can be loaded into the slide racks while they are in the instrument, or the racks can be removed from the System to make loading easier. If you remove the racks, it is recommended that you keep them properly oriented with respect to the instrument, i.e., with the open side towards the front.

For a barcode run, place the barcode labeled slides in the racks in any order. The location of each slide is recorded when the slides are scanned. Slide Racks have one completely open side for easy loading and one notched side. The frosted end of the slide should be placed at the closed side of the Slide Rack.





If a rack was removed from the instrument for slide loading, return it to its proper position in the system. The slides must lie flat in the carriers, i.e. the bottom of the slide against the positioning knobs, not on them. When placed in the system, the open side of the Slide Carrier should face the front of the instrument. Cover the slides with buffer to prevent them from drying out.

2. 2.2 Loading Reagents

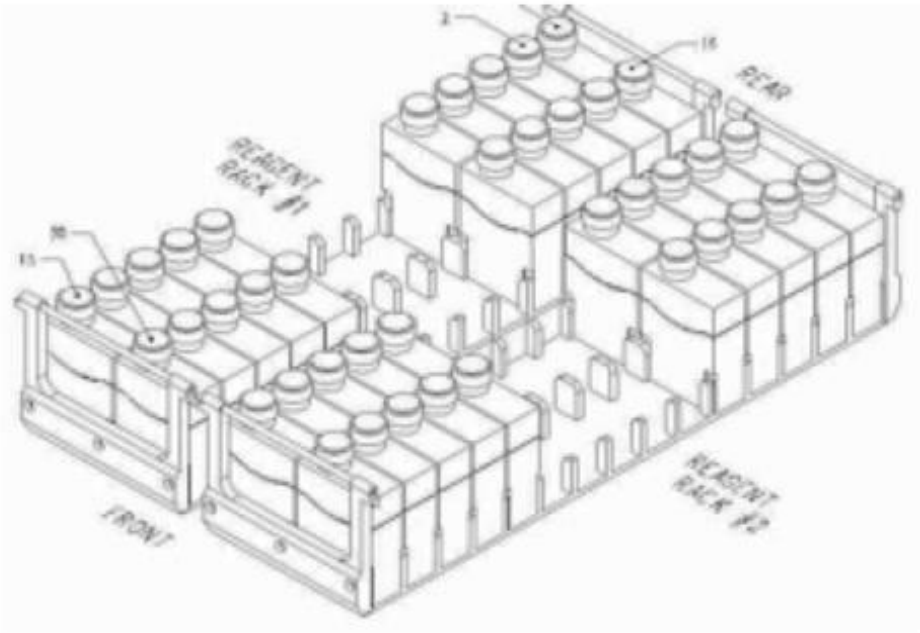
The i6000™ Automated Staining System can hold up to 60 different reagents. There are two removable reagent racks. Each can hold 30 vials. The left-hand rack holds vials 1-30 while the right-hand rack holds vials 31-60. Remove the reagent racks from the System to make vial loading easier.

Caution: Use only BioGenex supplied 20ml vials. Improper fluid detection could occur with incorrect vials.

In the diagnostics version, the system will detect the location of the vials. However, orient the vials with the opening facing the left side.

It is very important to place enough reagents into each assigned position and load them in the exact order shown in the reagent map.

When the Reagent Rack is filled, place it in the instrument. Make sure that the rack is oriented properly, i.e. vial position 1 and 31 are installed towards the rear of the instrument. Make sure that the rack is firmly secured in place.

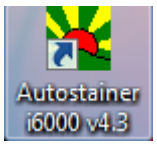


3.0 Getting Started
i6000™ Diagnostics

3.1 Logging On

The i6000™ software runs on the Windows XP® operating system. It was designed to provide the user, a very simple-to-use interface. This section will provide the details of the basic controls used to operate the i6000™ System.

- Switch-on the instrument and the computer.
- 'AutoStainer' is the default user name and enter 'optimax' as password to log on. Password is case sensitive. Use only lower case.
- Make sure that no error messages are displayed as Windows XP/7 starts.
- The Windows® XP desktop will be displayed.
- Double click the i6000™ icon on the desktop.



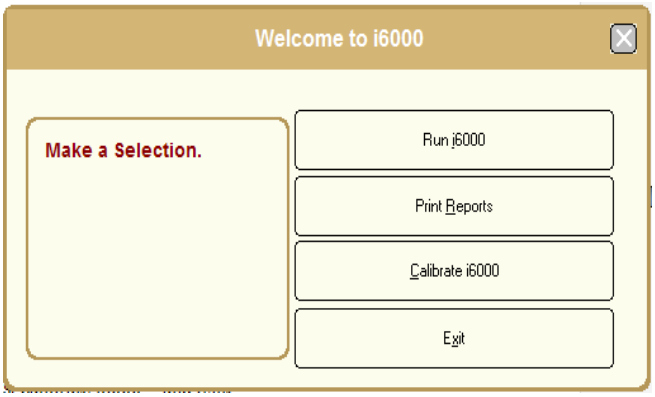
When the Log on to i6000™ window is displayed, type in the user name and the password. Choose a language of operation from the drop down menu.

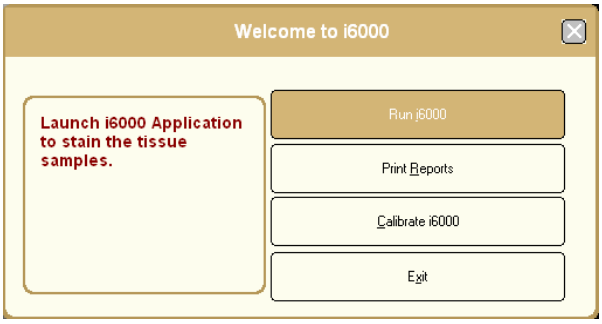
The default password for the Administrator is **'BioGenex**'. The password is not case sensitive. Once logged in as the Administrator, additional user profiles can be created. Users other than the administrator will have only limited access as defined by the Administrator.

The <**Welcome to the i6000**> System dialogue box will appear. There are four options: Run i6000™, Print Reports, Calibrate i6000™ and Exit.

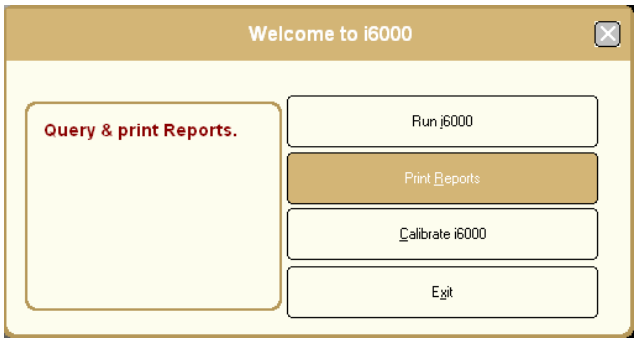
Click on:

- **Run i6000™** option to run the instrument and compose runs.
- **Print Reports** to print run reports.
- **Calibrate i6000™** to calibrate the instrument and
- **Exit** to exit the i6000™ application.



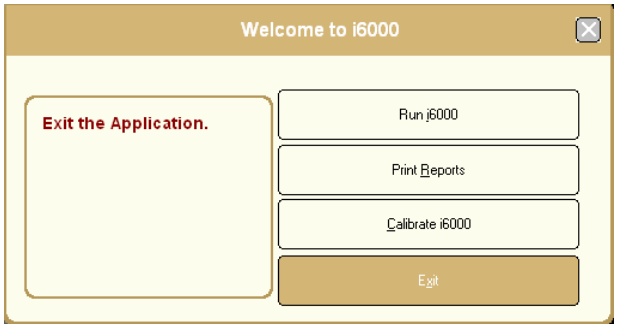


Click on the **Run i6000**™ button to open the **<Selection of Assay>** dialog box



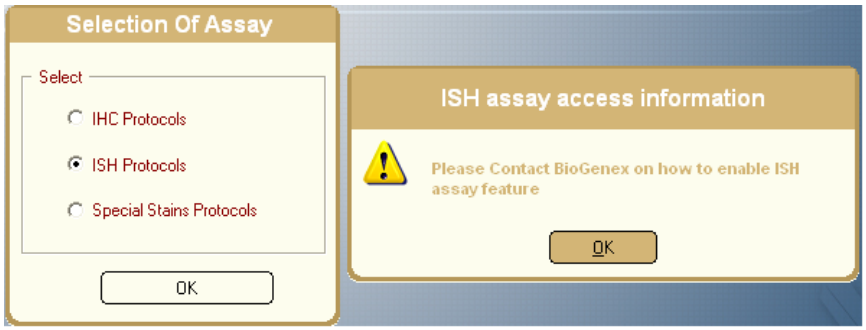
Click on the **Print Reports** button to open the **<Welcome to Reports i6000>** dialog box

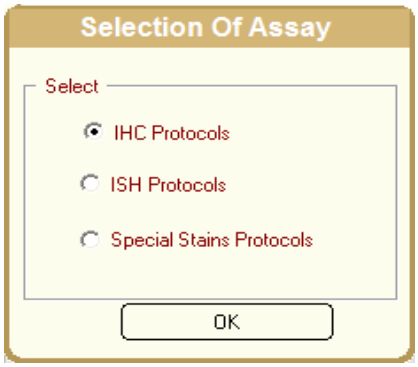
Click on the **Calibrate i6000** button to open the **< i6000 Calibration & Diagnostic Tool>** dialog box



Click on the **Exit** button to close the application.

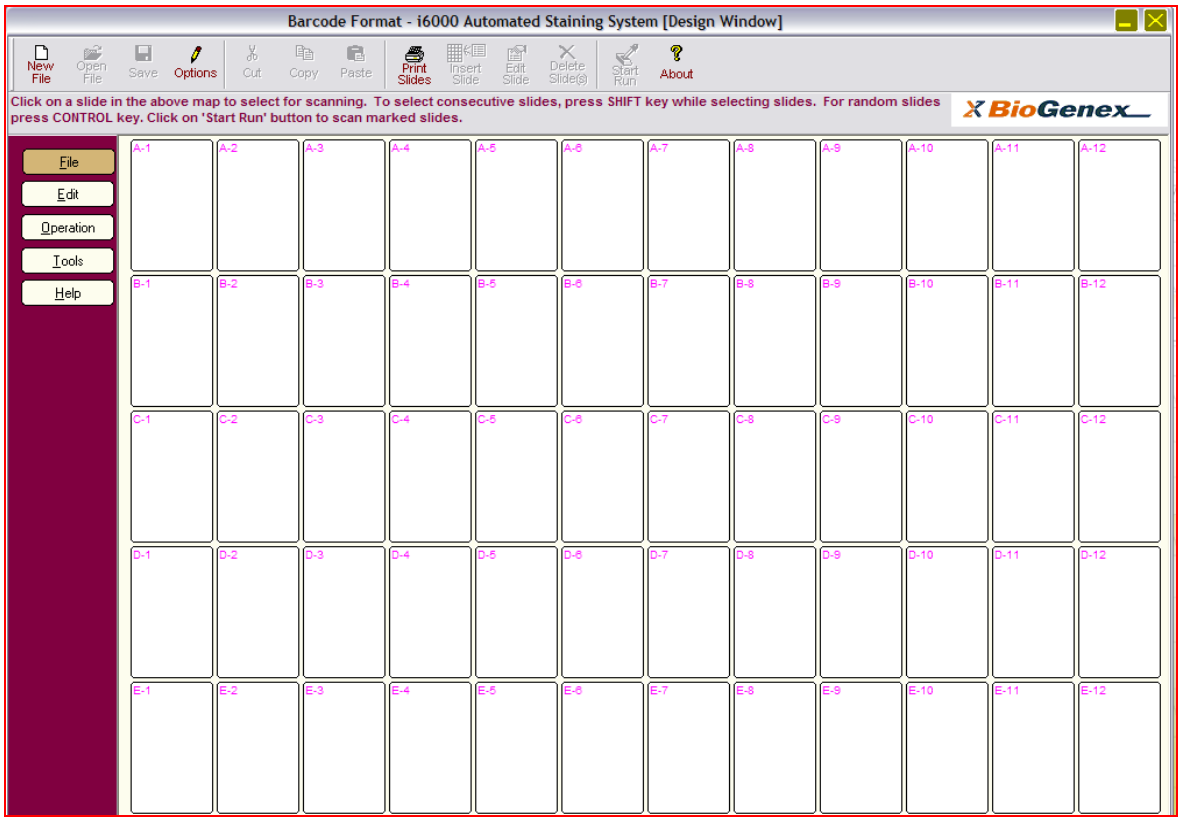
Select the assay of interest from the three options available – IHC Protocols, ISH Protocols* and Special Stains Protocols*.





Click **'OK'** button to open the **Barcode Format – i6000 Automated Staining System** [Design Window]

***Please contact BioGenex Technical Support for enabling Special stains and ISH applications.**



4.0 Tool Bars and Menu

4.1 Tool Bar

The Barcode format i6000™ [Design Window] tool bar has the following options

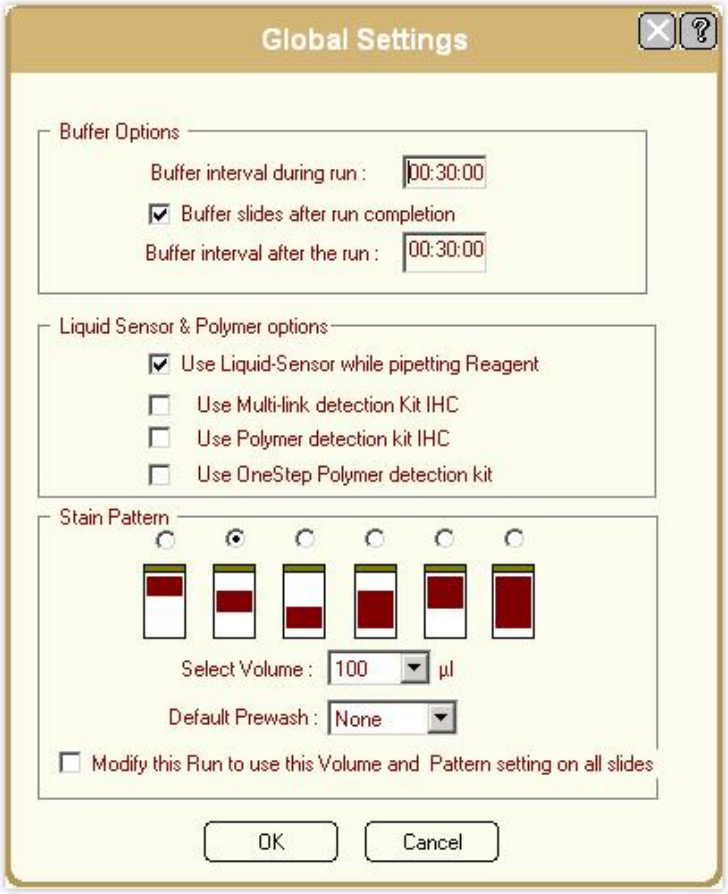
Icon	Function
	**New File -** Use this button to create a new staining run.
	**Options-** Use this button to display the Global setting screen.
	**Print Slides** – Use this button to print the slide map

	**Start -** Use this button once you have completed the slide setup and would like to start the run.
	**About –** Use this button to display the About screen. This screen contains the software version of the i6000™ software, and current user information. The user can view the software key by clicking on Show SW Key.

4.2 Global Settings

The user has the option to make various choices before the run starts. These choices will be used as the default settings for all slides within a run unless otherwise indicated.

Click on the **'Options'** button from the tool bar to open the **'Global Settings'** dialog box.



The following settings can be altered from this dialog box:

4.2.1 Buffer Options: The user can set a time to ensure that the instrument buffers the slide once within the chosen time interval during a run or after run completion.

4.2.2 Liquid Sensor Option: The user can run with or without the liquid level sensor.

4.2.3 Use Polymer Detection Kit for IHC: The user can choose polymer detection kit and protocol for IHC

4.2.4 Stain Pattern: The user can choose the staining pattern and default volume for all slides. Check the box on to the left side of the message "Modify this Run to use this volume & pattern settings on all slides", to override all previous settings by the global settings.

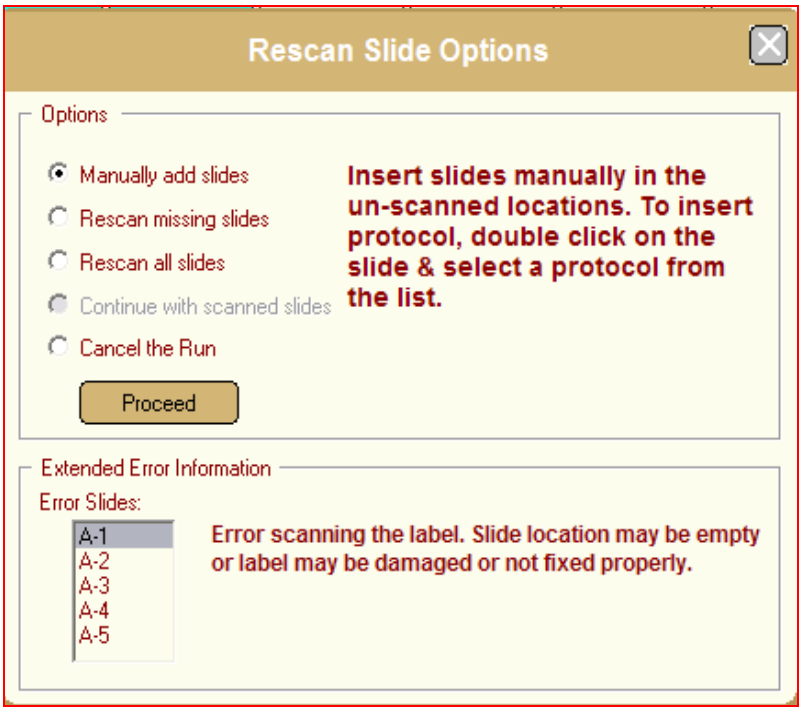
5.0 Executing a Run

5.1 Scanning Slides

Place the barcode labeled slides on the rack and select the corresponding slide positions, then click on the Start button. The following dialogue boxes will be displayed sequentially.

Note: The slides need not be placed in consecutive order and make sure to place correctly labeled slides for that particular run. Example: Slides labeled with IHC protocols for IHC run.

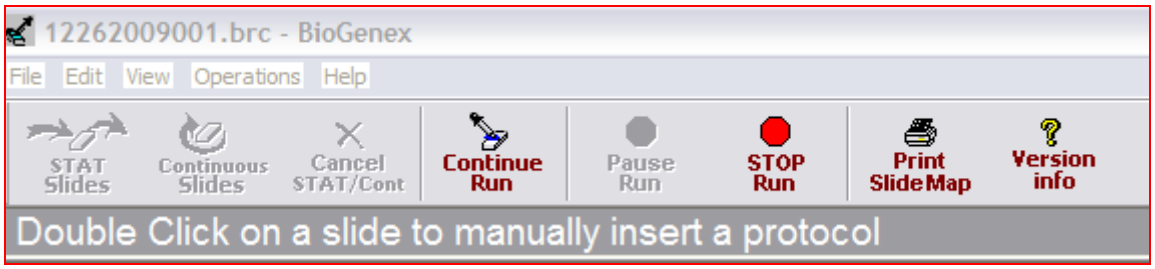
Click **'OK'** to continue. The Z-head will scan the selected slide positions. If the slide barcodes are not read properly, the Rescan Slide Options dialogue will be displayed.



The user can choose from the following options available:

- To rescan all the slides in the run, choose '**Rescan all slides'** and click on Proceed. This will take you back to the run window and it will erase all previously scanned slides and start over.
- To rescan only the unread slides, choose '**Rescan missing slides'** and click on Proceed. The instrument will rescan the slides that failed initially.

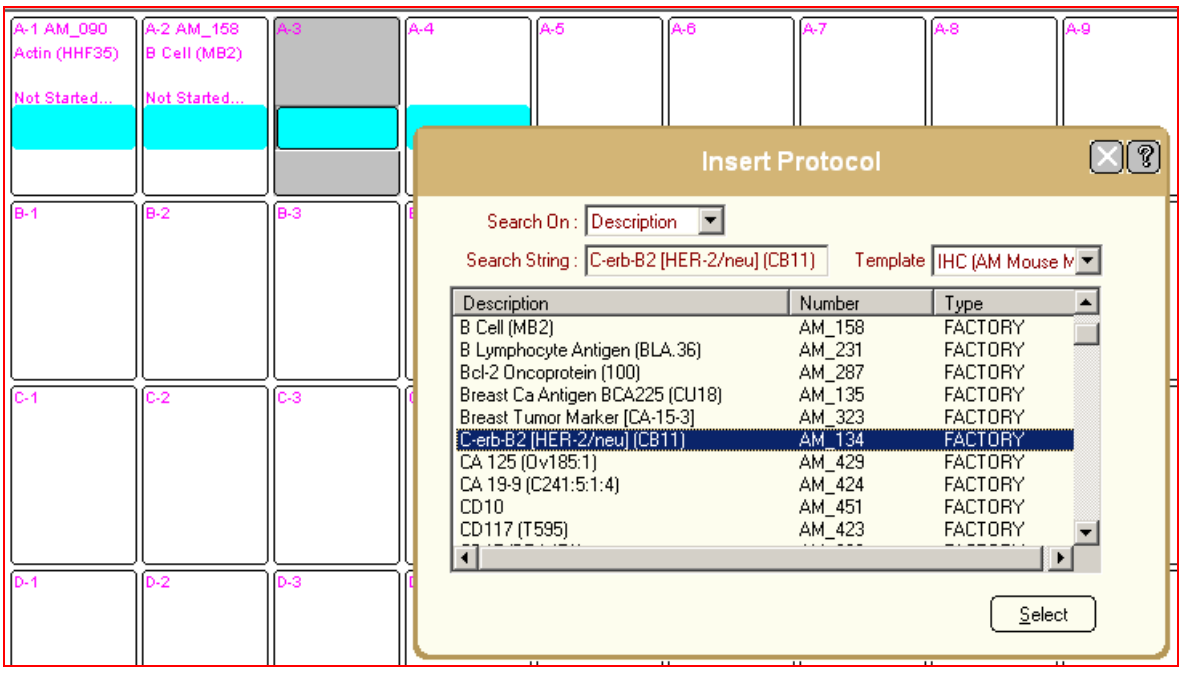
- If the scanning fails, the user can enter the slide information manually. Choose '**manually add slides'** and click on Proceed. A '**Run Window'** will open with a different tool bar and the file name displayed on top.



- '**Continue with scanned slides'**. Choose Cancel the Run to cancel the run.

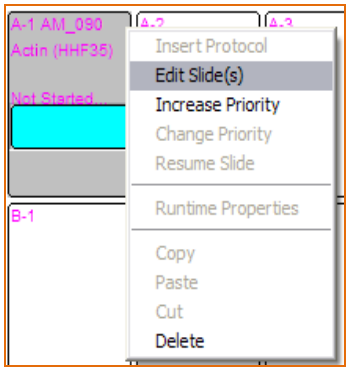
5.2 Insert Protocol

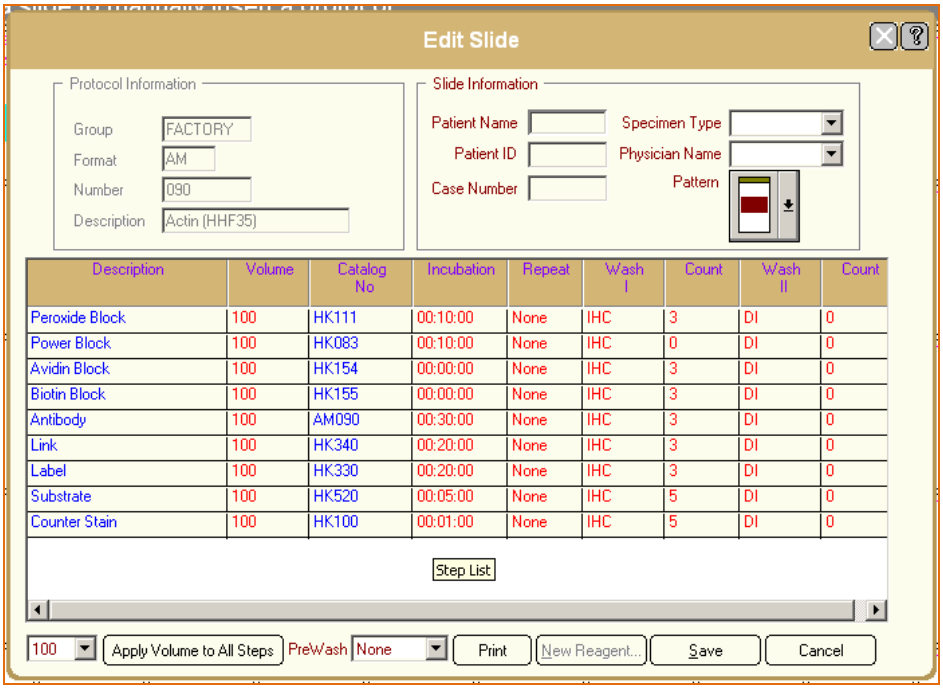
- Double click on the desired slide position to open the **Insert Protocol** window. Select the protocol of interest from the list available and click '**Select'** button to insert the protocol into the slide.


A-1 AM_090
Actin (HHF35)
Not Started...
A-2 AM_158
B Cell (MB2)
Not Started...
A-3
A-4
A-5
A-6
A-7
A-8
A-9
B-1
B-2
B-3
C-1
C-2
C-3
D-1
D-2
D-3
Insert Protocol
Search On : Description
Search String : C-erb-B2 [HER-2/neu] (CB11)
Template IHC (AM Mouse M
Description
Number
Type
B Cell (MB2) AM_158 FACTORY
B Lymphocyte Antigen (BLA.36) AM_231 FACTORY
Bcl-2 Oncoprotein (100) AM_287 FACTORY
Breast Ca Antigen BCA225 (CU18) AM_135 FACTORY
Breast Tumor Marker [CA-15-3] AM_323 FACTORY
C-erb-B2 [HER-2/neu] (CB11) AM_134 FACTORY
CA 125 (Ov185:1) AM_429 FACTORY
CA 19-9 (C241:5:1:4) AM_424 FACTORY
CD10 AM_451 FACTORY
CD117 (T595) AM_423 FACTORY
Select

5.3 Edit Slide Parameters

Once the protocols are inserted into the slides, the user can edit the slide parameters as required. In order to edit, click once on the slide for its selection, and then right click on the same position to choose '**Edit Slide'** from the drop down list. The **Edit Slide** window opens. (Refer to section 6.1).

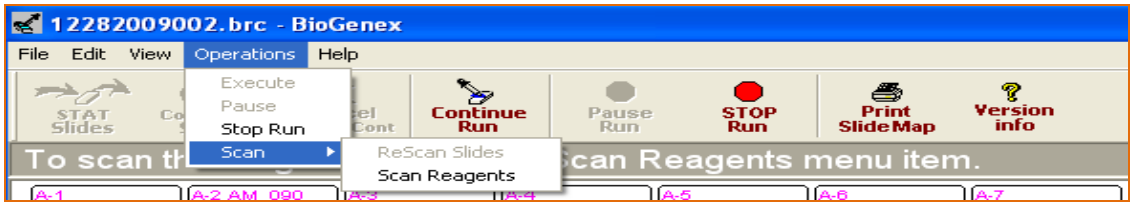


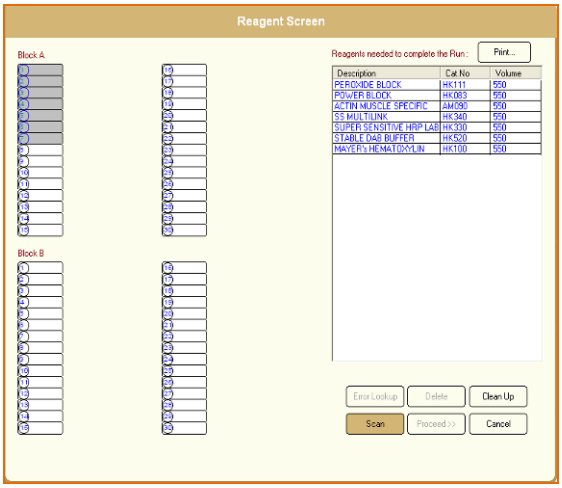


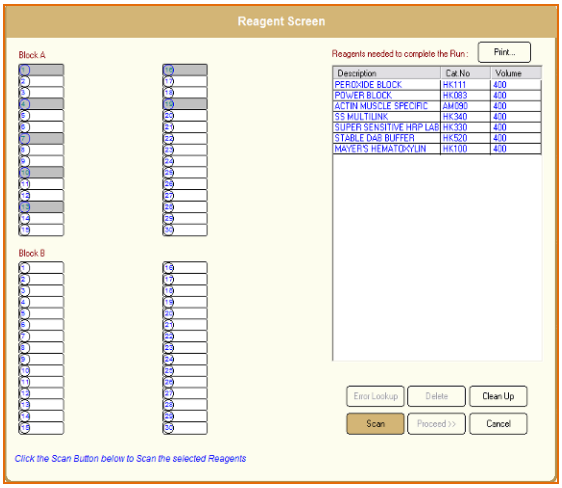
Once the necessary changes are made, click on '**Save'**. Click on '**Cancel'** to return to the run window without saving any changes. To continue with the run, click on the '**Continue Run'** button.

5.4 Scanning Reagents:

After inserting the protocols, click on **'Continue Run'** to open the **'Reagent Screen'** window. Reagent screen can also be opened through **'Scan Reagents'** under the **'Operations'** menu.

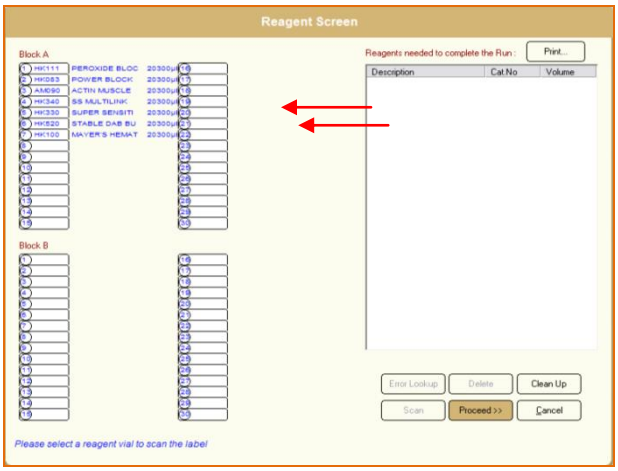


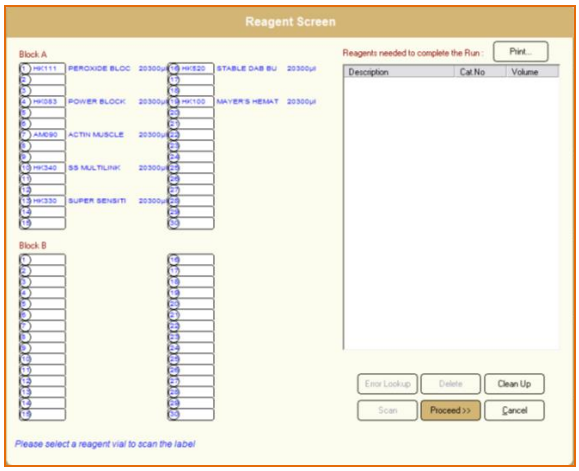




Default positions for reagent vials **Manually selected positions for reagent vials**

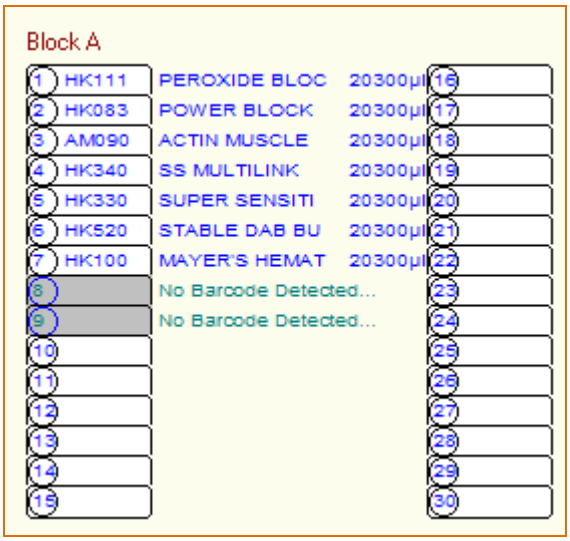
- The reagent map will be displayed with a list of reagents needed for completing the run. The vial positions highlighted are the consecutive default positions.
- If the reagents are not placed in these positions, select the desired positions by holding the 'Ctrl' key and click on the positions of your choice and click on Scan.
- As the instrument scans the reagents, the reagents will move from the reagent list to their corresponding vial numbers.

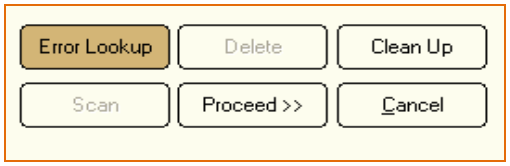


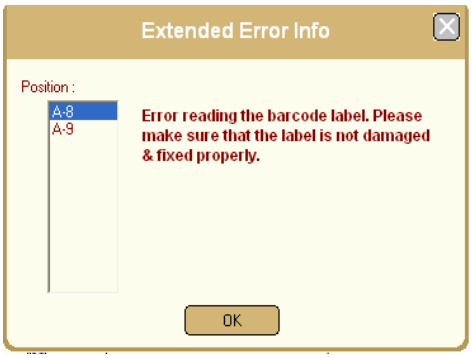


If an error occurs while scanning the reagents, a message will appear next to the vial number.

- Click on the '**Error Lookup**' to display detailed error information.
- A reading error such as the one displayed on vial A-8 (fig. below) can result from damaged or improperly fixed barcode label.
- A validation error such as the one displayed on vial A-9 can result from using an expired reagent or an improper lot number.
- Check the vial and replace it.
- To rescan the vials, select the vials by clicking on them and click on Scan. The instrument will rescan the selected reagents.

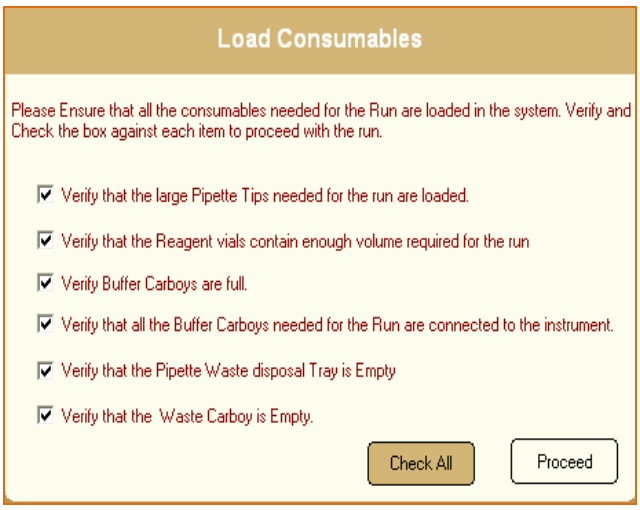


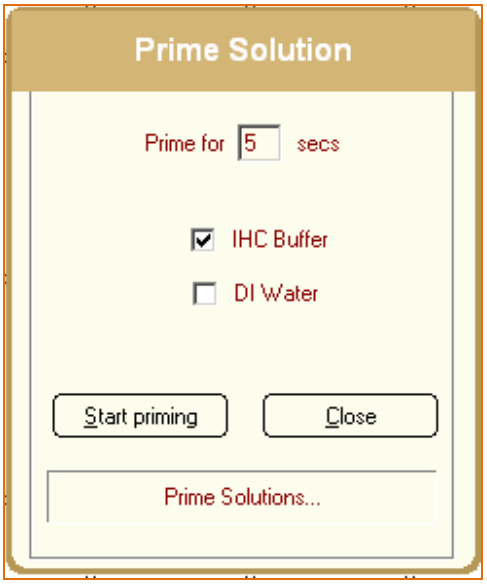


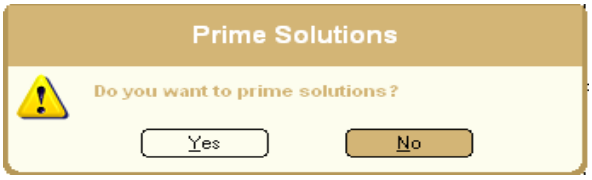


5.5 Starting the Run

Once the reagent scan is complete, click on '**Proceed'** button to open the '**Load Consumables'** dialogue box. Ensure that all the consumables needed for the run are loaded in the system. Verify and check the box against each item before proceeding ahead with the run.







Click on **'Proceed'** button to open **'Prime Solutions'** dialogue box. Select **'Yes'** and specify the time in the **'Prime for --- Sec'** box and click on **'Start Priming'**. After priming is done, select **'Close'.** The system prompts the user to **specify the Pipette Position.** The user can opt for one of the following:

- Start with left Box
- Start with Right Box
- Start from last used position
- Specify new start position --

Click **'Continue'**

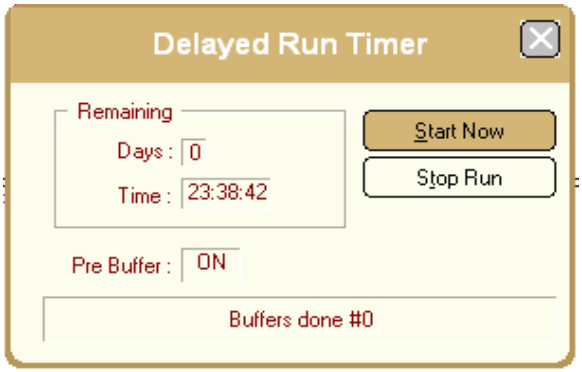
5.6 Delayed Run

The system again prompts the user whether to start a '**Delayed Run'** or not? Click **'No'** to start the run right away. To start a delayed run, click '**Yes**'. The following screen will be displayed.

The current date and time are the default entries. Enter the date and time when the run is scheduled to start (maximum delay is 3 days). The calendar can be accessed by clicking on the arrow to the right of the date. Note that the time is entered in 24-hour format.

While the run is yet to start, the slides can be buffered by selecting the '**Buffer Slide during waiting'** option. The frequency of buffering is set in the global settings.

Click **Start Delayed Run** to accept the time entered. Clicking Cancel will start the run without delay. The Delayed Run Timer window will be displayed.



In this window, the user can choose to cancel the run by clicking on the **Stop Run button**, or start the run immediately by clicking on the **Start now button**.

The number of buffering applied on each slide is displayed on this window during the waiting period. When the countdown is completed, the run will begin.

Leave the system on and the program running. Closing the program will cancel the programmed delayed run even if the program is restarted before the selected start date and time. There is a countdown window that will appear until the run begins.

5.7 Slide Information

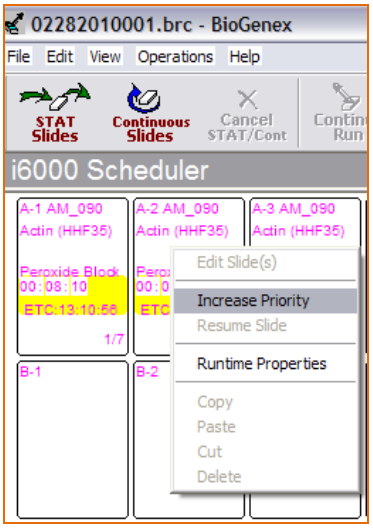
The following information will be displayed for each slide:

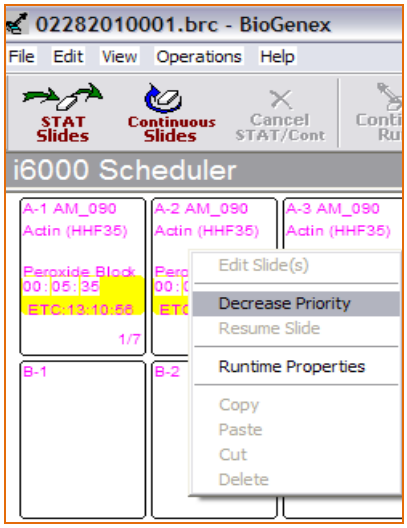
- Slide position
- Antibody number
- Antibody description
- Protocol Step that is currently being performed
- Remaining Time for that Step (countdown)
- Staining Pattern (colored area)
- Current step number and total steps of the protocol

5.8 Slide Priority

There are two priority settings for any slide position, 'Normal' and 'High'. Initially all the slides are at normal priority by default. The user can prioritize the slides as required in order to process them on a higher priority than the remaining slides in that run.

- To increase the priority of a slide, right click on the desired slide position and from the drop down list, select **'Increase Priority'**. This option is available only for normal priority slide(s)
- To decrease the priority, right click on the same position and select **'Decrease Priority'** from the drop down list. This option is available only for high priority slide(s).

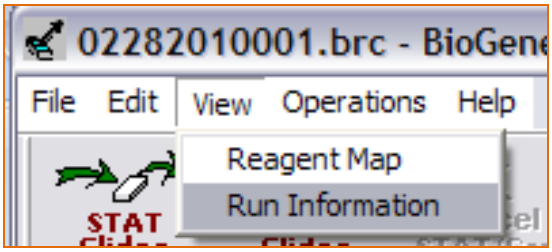


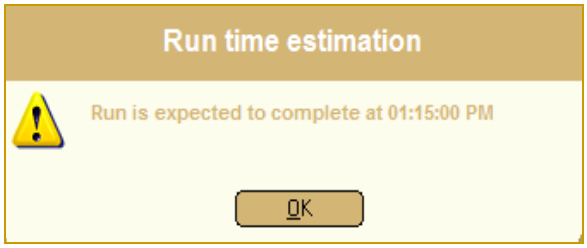


5.9 Run Information

The user can view the estimated time for completion of an ongoing run. The run completion time can be influenced by a number of factors like buffering cycle, addition of STAT or continuous slides, fixing errors like dropped pipette tip or lack of reagents. The system recalculates the run completion time after each of these steps.

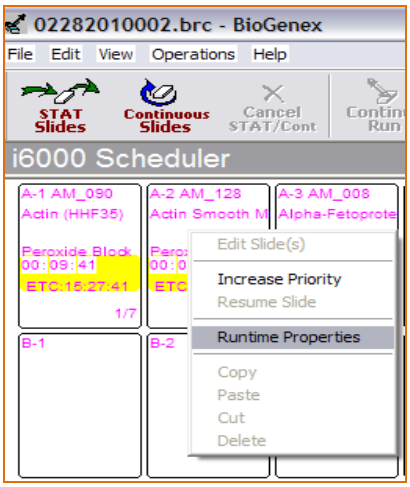
To view the run completion time, select the '**View > Run Information'** to open the **'Run time estimation'** Dialog box with a message "Run is expected to complete at ---".

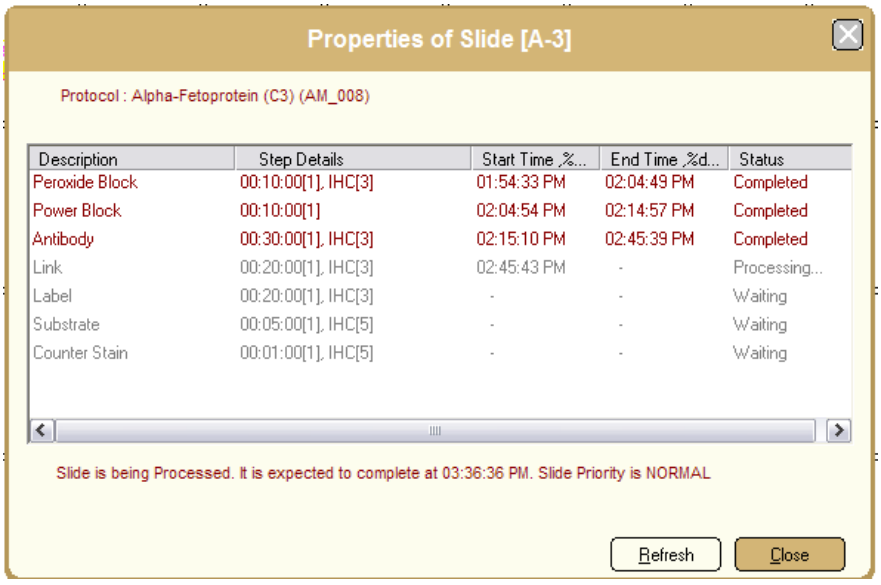




5.10 Runtime Properties

The status of each slide can be easily tracked from the information displayed on the respective positions. More detailed information can be obtained from the '**Runtime Properties'**. To find out individual slide progress, right click on the slide and select **'Runtime Properties'** from the drop down list to open the **'Properties of Slide [-]'** window. It displays the information on the steps that are ongoing, completed or yet to begin.

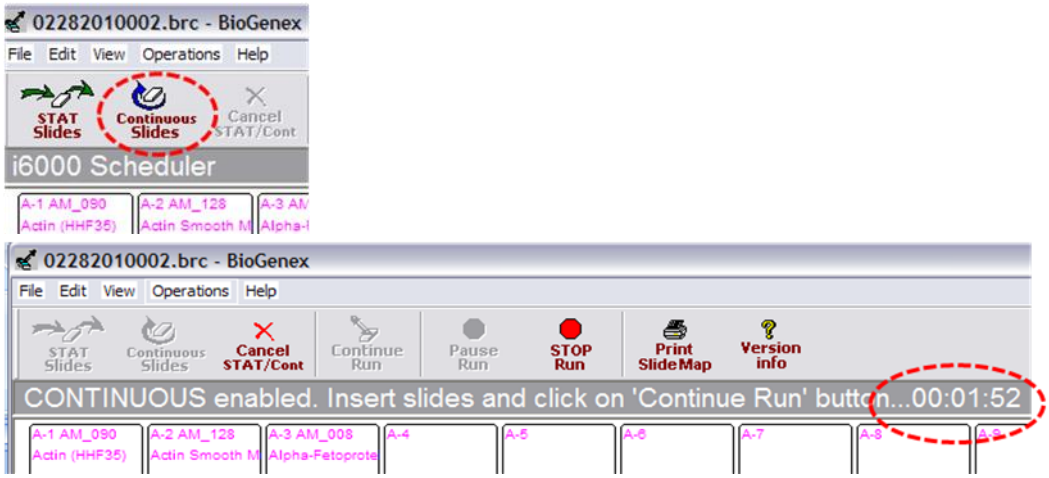




5.11 Inserting Continuous Slides

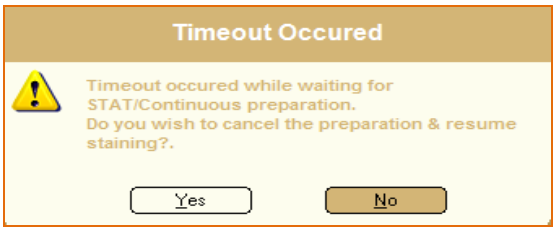
Initiating a Continuous Run - The i6000™ system facilitates optimal workflow through the continuous access. Depending on the availability of free racks, the user can add extra slides (a maximum of 30) to an ongoing run, increase priority and save time.

- To start a continuous run, click on the **'Continuous Slides'** button.
- The ongoing run is paused for 2min with a message "**CONTINUOUS enabled. Insert slides and click on 'Continue Run' button...**" and a **'2 min Timer'** displayed below the tool bar



- Insert the Barcoded new slide(s) into the vacant positions available and click on **'Continue Run'** to start the slide scan. If the scanning fails, insert the slides manually as described previously
- Click on 'Continue Run' again to proceed ahead. If the reagents for the new slide(s) are already available with the system, a message stating the same will be displayed. Click '**OK'** to continue with the run.

- If additional reagents are required, the 'Reagent Screen' will appear. Load the reagents and click on 'Scan' to start the reagent scan. Once the reagent scanning is complete, click on 'Proceed' to continue the run.
- A delay exceeding 2min. in initiating a continuous run sets off a system alarm along with a warning message <**Timeout Occurred**> displayed on the screen.
- Click 'No' to reset the timer and continue setting up the continuous run. Click '**Yes**' to cancel the continuous run.

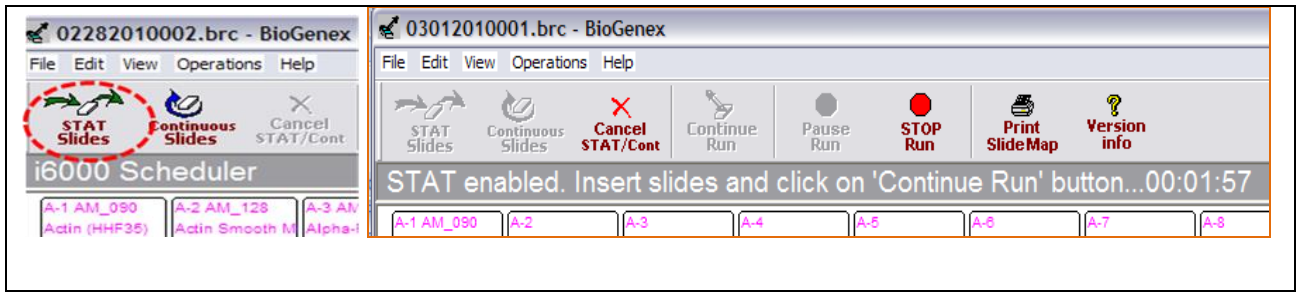


It is advisable to have all the reagents and consumables ready before initiating a continuous run.

5.12 Inserting STAT Slides

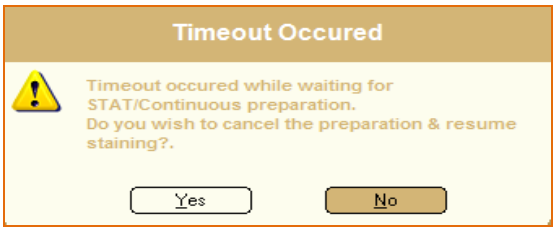
STAT access is a very handy feature that allows the user to add a maximum of six slides to an ongoing run (depending on the availability), which are processed at a higher priority than normal.

- Click on the <**STAT Slides**> button in the tool bar to start the STAT run.



- The ongoing run is paused for 2min with a message "**STAT enabled. Insert slides and click on 'Continue Run' button...**" and a **'2 min Timer'** displayed below the tool bar.
- Insert the Barcoded new slide(s) into the vacant positions available and click on **'Continue Run'** to start the slide scan. If the scanning fails, insert the slides manually as described previously
- Click on 'Continue Run' again to proceed ahead. If the reagents for the new slide(s) are already available with the system, a message stating the same will be displayed. Click '**OK'** to continue with the run.

- If additional reagents are required, the 'Reagent Screen' will appear. Load the reagents and click on 'Scan' to start the reagent scan. Once the reagent scanning is complete, click on 'Proceed' to continue the run.
- A delay exceeding 2min. in initiating a STAT run sets off a system alarm along with a warning message <**Timeout Occurred**> displayed on the screen.
- Click 'No' to reset the timer and continue setting up the STAT run. Click '**Yes**' to cancel the STAT run.



It is advisable to have all the reagents and consumables ready before initiating a continuous run.

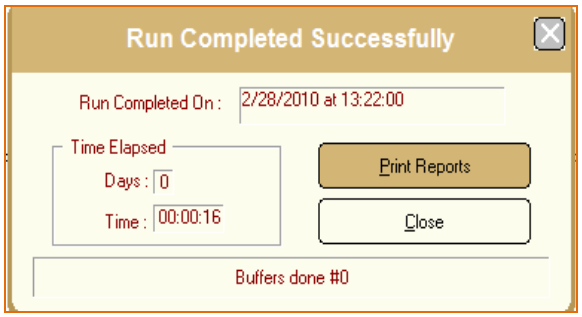
5.13 Run Completion

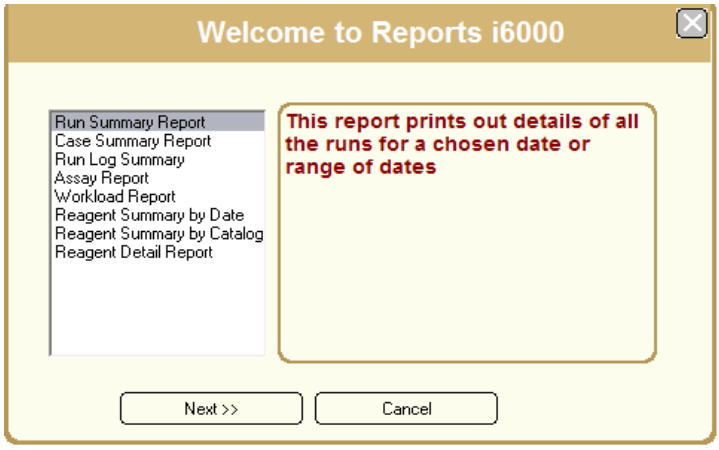
At the end of the run, the **'Run Completed successfully'** dialog box is displayed along with the following information

I. The time of run completion
II. How long ago the run completed
III. The number of buffering cycles applied since the run ended

- Click on 'Print Reports' button to open the 'Welcome to Reports i6000' dialog box.
- On the left panel of this dialog box, following options are available:

- Run Summary Report
- Case Summary Report
- Run Log Summary
- Assay Report
- Reagent Summary by Date
- Reagent Summary by Catalog
- Reagent Detail Report





Once an option is selected, a brief description of its function is displayed on the right panel. Select an option and click '**Next'** button to open the report in a new window in a preset format.

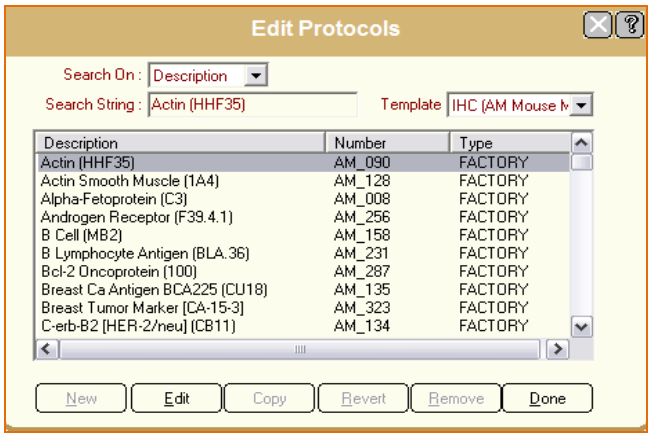
6.0 Protocols

A protocol is a set of operations performed sequentially under defined conditions. The i6000™ diagnostics system comes along with '**FACTORY'** protocols that are optimized to deliver consistent and reliable results when using BioGenex reagents. However, the user can modify the factory protocol to a limited extent as per the requirements.

6.1 Edit Protocol

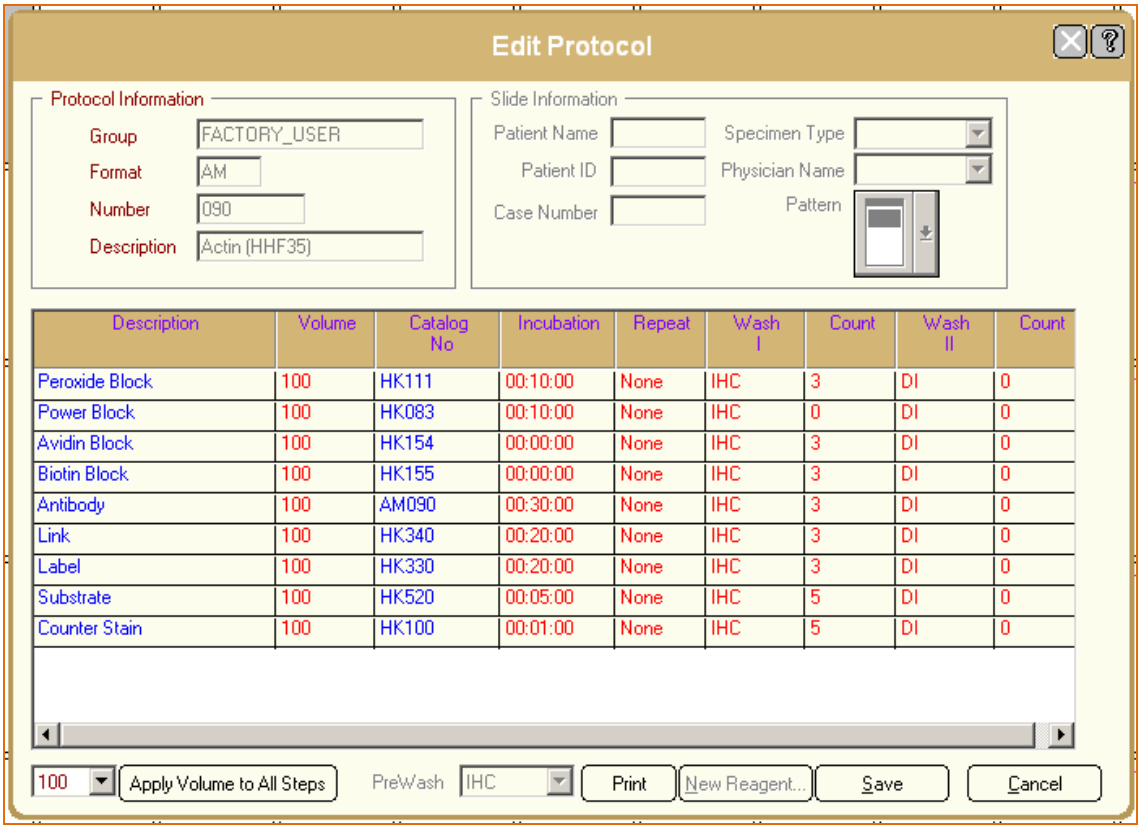
A 'FACTORY' protocol when edited, changes to a **'FACTORY_USER'** protocol. Only the Administrator is authorized to edit a FACTORY protocol. To edit a Factory protocol:

- Open the 'i6000 Automated Staining System [Design Window]'
- Click on the **'Operation'** menu and select **'Edit Protocols'** from the drop down list.

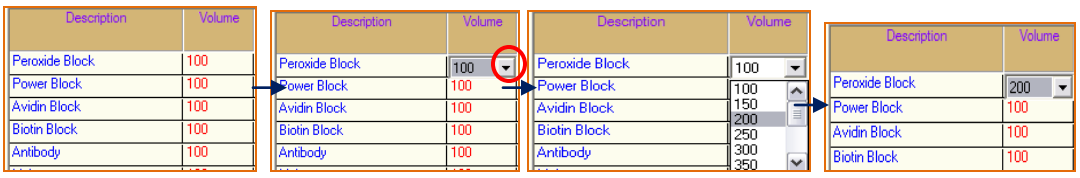


- The **'Edit Protocols'** window will open. Select the protocol of interest from the list available, by clicking on it.
- Click the **'Edit'** button, or double click on the highlighted protocol.
- A warning message "Editing a FACTORY protocol will result in a FACTORY_USER protocol. Do you wish to continue?" will appear on the screen.

- Click **'Yes'** or press **'Enter'** key to open the **'Edit Protocol'** window. Click **'No'** to return to **'Edit Protocols'** window



- All the parameters can be edited except for those items in blue.
- To edit a parameter, click on the corresponding cell to visualize an **'Arrow'** button by the side of it.
- Click the arrow to select from the drop down list. Click on the appropriate value to assign it to the cell.

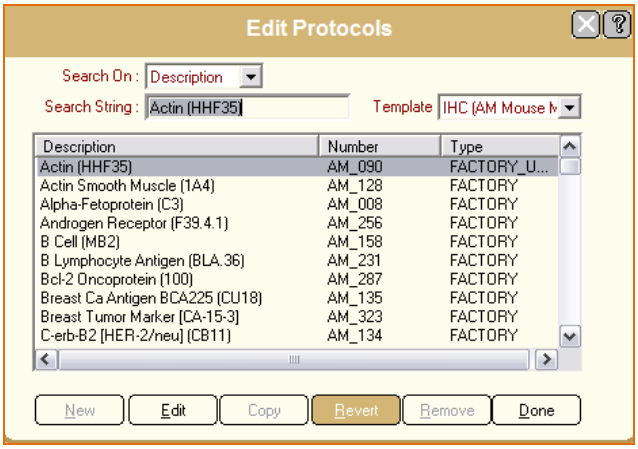


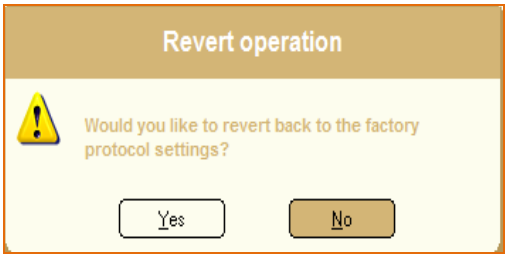
- Click **'Save'** button to save the changes as **FACTORY_USER** Protocol. This will be highlighted when you return to the '**Edit Protocols'** screen.
- Click **'Cancel'** button to undo all the modifications and return to the **'Edit Protocols'** screen.

6.2 Revert Protocol

A FACTORY_USER Protocol can always be reverted back to the original FACTORY protocol settings from which it is derived. Only the Administrator is authorized to revert back a FACTORY_USER protocol to a FACTORY protocol. To revert a FACTORY_USER protocol

- From the Operation menu click on 'Edit Protocol' to open the Edit Protocols window.
- Select the FACTORY_USER protocol that needs to be reverted. Once selected, the Revert button is activated.
- Click the Revert button. A 'Revert Operation' dialog box is displayed on the screen.





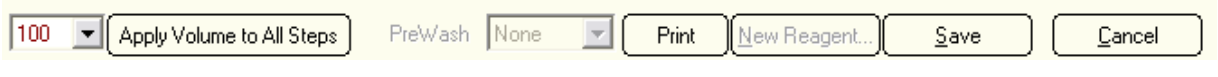
- Click 'Yes' to restore the Factory Protocol settings. Once restored the 'Edit Protocols' window will be displayed again.
- Click 'No' to retain the FACTORY_USER protocol.

Button Functions in **'Edit Protocols'** window

Edit:	Click this button to open the 'Edit Protocol' window
Revert:	Click this button to undo all the changes in a FACTORY_USER protocol and restore the original FACTORY protocol. This button is active only when a FACTORY_USER protocol is selected
Done:	Click this button to close the 'Edit Protocol' window

Note: In the Barcode format, the **'New', 'Copy' and 'Remove'** buttons are inactive.

Button Functions in **'Edit Protocol'** window



Apply Volume to All Steps:	Click this button to apply the volume specified in the adjacent box to all the steps in the protocol. To set the volume, click the arrow button and select an appropriate value from the drop down list.
Print:	Click this button to print the protocol.
Save:	Click this button the save the changes made to the protocol.
Cancel:	Click this button to close the window without saving the changes.

Note: In the Barcode format, the **'PreWash'** and **'New Reagent'** options are inactive.

7.0 Reagents

7.1 Edit reagent description

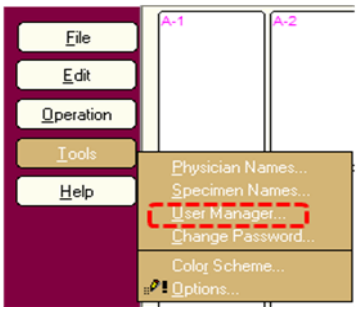
In the diagnostics system, the reagent description cannot be edited

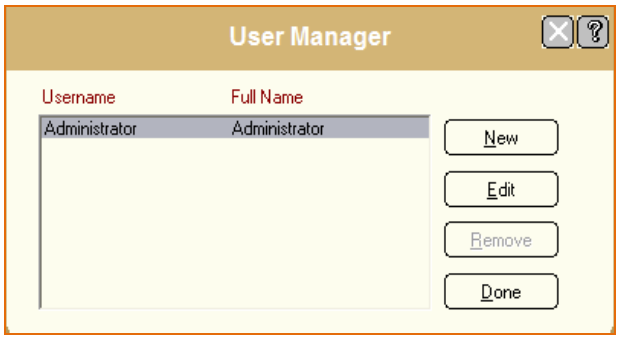
8.0 Global Settings and Other Tools

8.1 User Manager

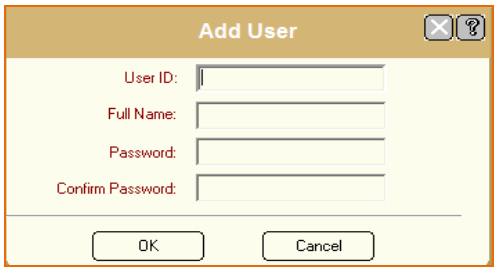
When the software is first installed, it can be accessed only by the Administrator. The 'User Profiles' need to be added by the administrator. To access the User Manager:

- Select the **Tools** menu and click on **User Manager** from the drop down list. The User Manager screen will be displayed.



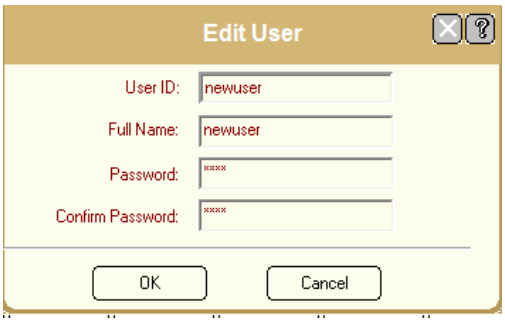


- Click the 'New' button to display the 'New User' window
- Enter a User ID, the full Name, Password, and Confirm Password. The entry made in 'Confirm Password' should match exactly with that of the 'Password'.
- Press 'OK' to save the new user and the user will be added to the user database.



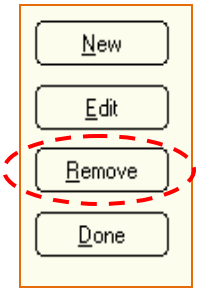
8.2 Edit User Profiles

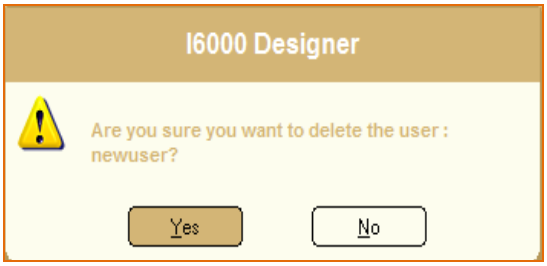
- Select a user from the User Manager window and click the Edit button.
- The **'Edit User'** window will be displayed.
- Make the necessary changes and click **'OK'** to save.



8.3 Delete User Profile

- Open the User Manager window and select the user profile to be deleted. The 'Remove' button gets activated only when a user profile other than the Administrator is selected
- Click **'Remove'** button to open a confirmation message.





- Click 'Yes' to delete the user profile from the database. The user will no longer have any access to the system.
  Note: Administrator profile cannot be deleted.

8.4 Change Password

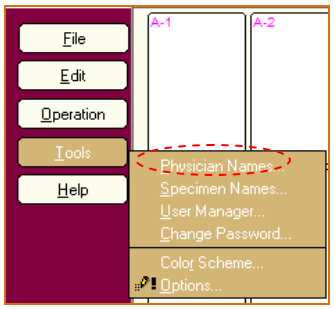
While creating a user profile, the Administrator will assign a password. The user can log in using this password. However, it can be changed if the user intends to do so.

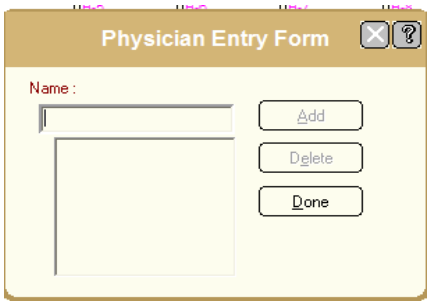
- From the ‘Tools’ menu, click on ‘Change Password’.
- The ‘Change Password’ window will be displayed.
- Enter the new password and retype the same in ‘Confirm Password’ field.
- Click ‘OK’ to save the new password. Clicking cancel will close the window without saving the changes.

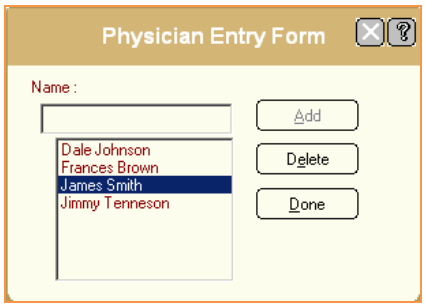
8.5 Physician Names

A list of Physicians Names can be maintained for easy entry in the **Edit Slide** window. Each name entered will be available in a drop down list in the Slide Information area of ‘Edit Slide’ Window. To enter Physician names:

- From the **‘Tools’** menu, click on the **‘Physician Names’** to open the **‘Physician Entry Form’**
- Type the name in the **Name** field and click **Add.** The name will appear on the list below.
- To delete a name from the list, select the name and click **Delete.**



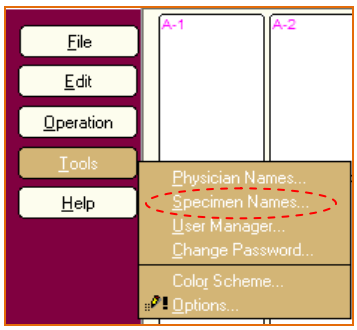


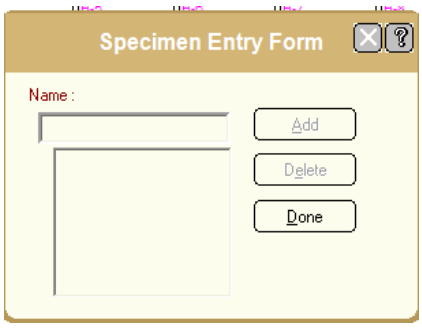


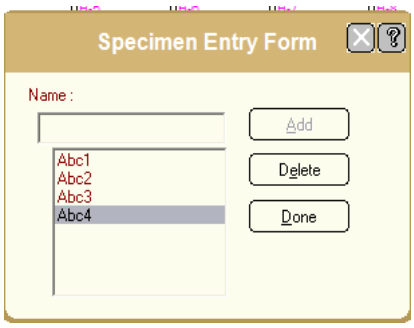
8.6 Specimen Types

A list of specimen types can be maintained for easy entry in the ‘Edit Slide’ window. Each name entered will be available in the drop down list in the Slide Information area of ‘Edit Slide’ Window. To add the specimen names:

- From the ‘**Tools’** menu, click on the **Specimen Names** to open the **‘Specimen Entry Form’**
- Type the name in the **Name** field and click **Add.** The name will appear on the list below.
- To delete a name from the list, select the name and click **Delete.**





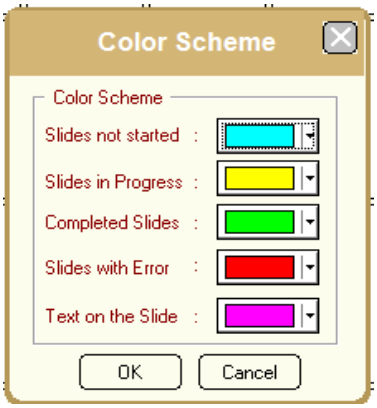


8.7 Color Scheme

The color scheme is meant for representing the status of the following:

- Slides not started
- Slides in progress
- Completed slides
- Slides with Error
- Text on the slide

From the **'Tools'** menu, select **'Color Scheme'** to open the **'Color Scheme'** window

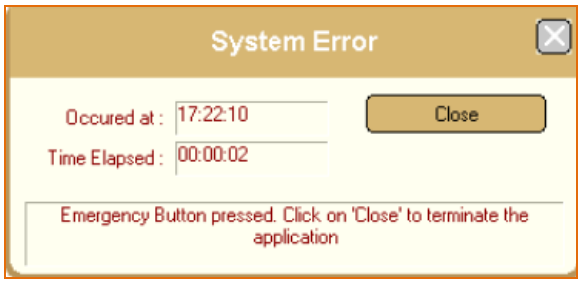


9.0 Pause or Stop Function

Prolonged pause during a staining run may cause invalid test results due to extended incubation time for the affected step and the slide(s).

9.1 Emergency Stop

The automated system has an Emergency off Switch, located on the front side of the instrument in the lower-right hand corner. When pressed, the 'System Error' screen is displayed.

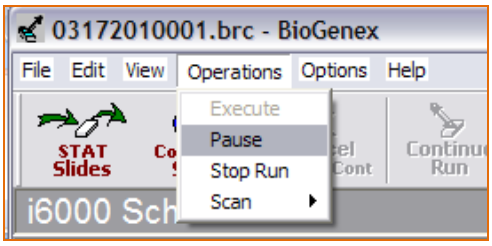


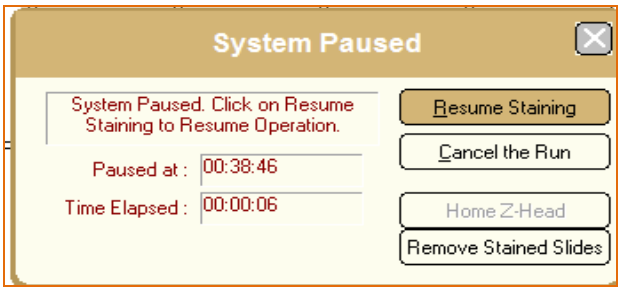
To continue, close the application by clicking on the **Close** button, turn back the Emergency stop and start a new run.

9.2 Software Pause

To pause a run at any time

- Click on the **'Operations'** button in the menu bar and select **'Pause'** from the drop down list.

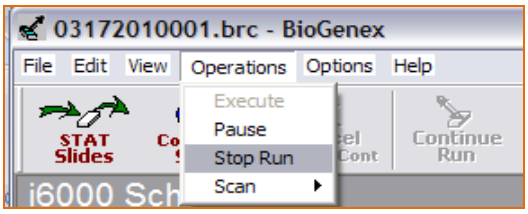


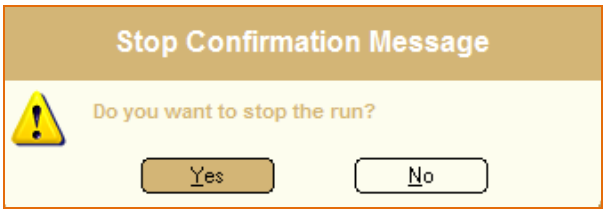


- Click the '**Resume Staining'** button or press '**Enter'** key to continue the staining run.
- Click '**Cancel the Run'** to cancel the run
- Click '**Home Z-Head'** to return the Z-head to the home position
- Click '**Remove Stained Slides'** to remove the completed slides from the slide map.

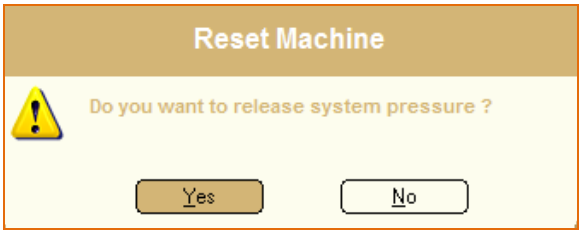
9.3 Software Stop

- To stop a current run, click on the red **Stop button,** or select 'Stop Run' from the **Operations** menu.
- The '**Stop Confirmation Message'** will be displayed





- Click '**No'** to return to the staining run.
- Click '**Yes'** to terminate the current run. The **Reset Machine** dialog box will be displayed
- To keep the instrument pressurized, click on the 'No' button. To release the system pressure, click on the 'Yes' button.



10.0 Reports

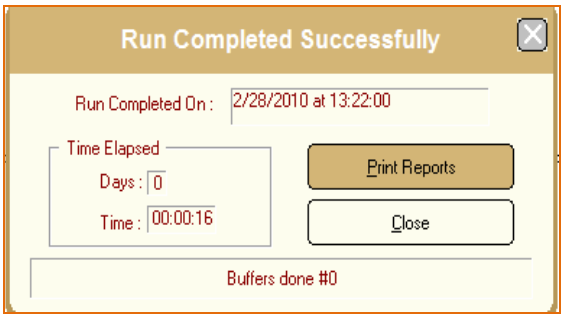
The i6000™ software provides the user with an array of reports summarizing data for easy reference. Users can design and customize new reports.

10.1 Starting the Reports Module:

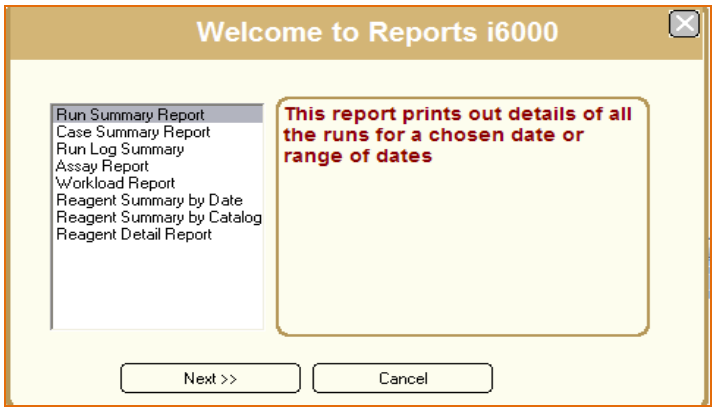
There are two ways to launch the Reports module –

1) Print Reports from main log in screen- **"Print Reports"** window
2) Once the staining run is completed- **"Run Completed Successfully"** window

- Click '**Print Reports**' from the main log in 'Welcome to i6000' screen OR the 'Run Completed Successfully' window



- The **'Welcome to Reports i6000'** window is displayed



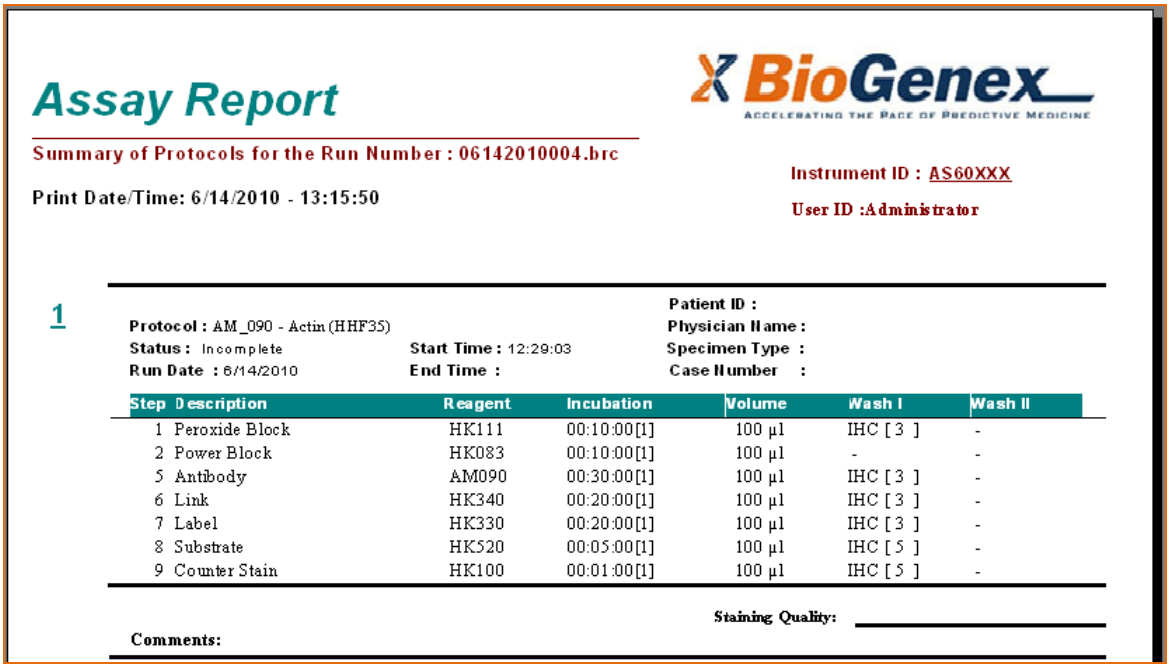
- Select a report format from the list available by clicking on it. A brief description of the report format selected will be displayed on the panel onto the right.
- Select a report format of interest and click '**Next'** to proceed ahead with the print.
- Click '**Cancel'** to go back to the main log in window.

Report	**Function**
Run Summary Report	This report prints out details of all the runs for a chosen date or range of dates
Case Summary Report	This report prints out all the slides that were composed for a specific case number
Run Log Summary	This report prints out the details for a specific run
Assay Report	This report prints out protocol details of all slides for a specific run
Workload Report	This report lists out all the reagents used in a specific run
Reagent Summary by Date	This report prints all the reagents used in a range of dates. Report is grouped by date.
Reagent Summary by Catalog	This report prints all the reagents used in a range of dates. Report is grouped by Catalog number
Reagent Detail Report	This report prints out the detailed usage of a specific catalog

- After selecting a report format, clicking on the 'Next' button would open a dialog box that can be used to set the parameters like date, run number, assay etc.
- For each report the desired parameters can be selected from the drop down list displayed by clicking the arrow button adjacent to the fields.

- Once the parameters are set, click on **'Preview & Print Report'** button.

- The chosen report will be displayed on the screen. Click on the printer icon 



Assay Report

BioGenex
ACCELERATING THE PACE OF PREDICTIVE MEDICINE

Summary of Protocols for the Run Number : 06142010004.brc

Print Date/Time: 6/14/2010 - 13:15:50

Instrument ID : AS60XXX

User ID :Administrator

1

Protocol : AM_090 - Actin (HHF35)
Status : Incomplete
Run Date : 6/14/2010
Start Time : 12:29:03
End Time :
Patient ID :
Physician Name :
Specimen Type :
Case Number :

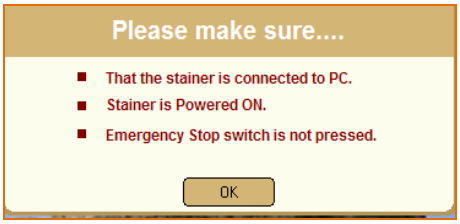
Step	Description	Reagent	Incubation	Volume	Wash I	Wash II
1	Peroxide Block	HK111	00:10:00[1]	100 µl	IHC [3]	-
2	Power Block	HK083	00:10:00[1]	100 µl	-	-
5	Antibody	AM090	00:30:00[1]	100 µl	IHC [3]	-
6	Link	HK340	00:20:00[1]	100 µl	IHC [3]	-
7	Label	HK330	00:20:00[1]	100 µl	IHC [3]	-
8	Substrate	HK520	00:05:00[1]	100 µl	IHC [5]	-
9	Counter Stain	HK100	00:01:00[1]	100 µl	IHC [5]	-

Staining Quality: _____

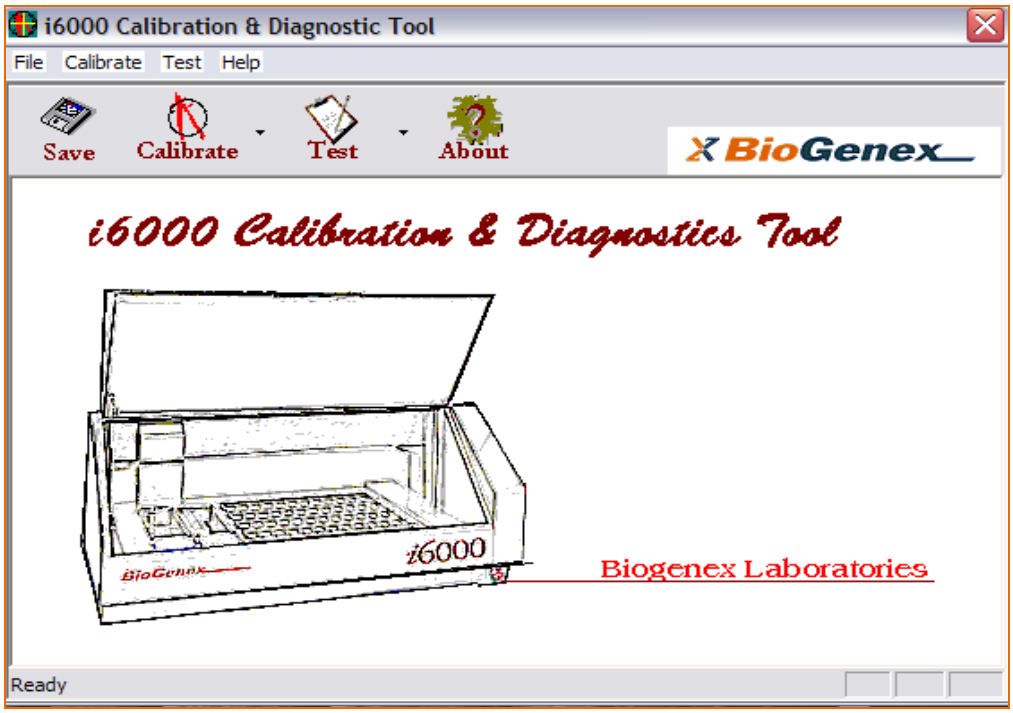
Comments:

11.0 Calibration and Diagnostics

To start the calibration program, click 'Calibrate **i6000'** button from the 'Welcome to i6000' window. The 'Please make sure…' dialog box will be opened.



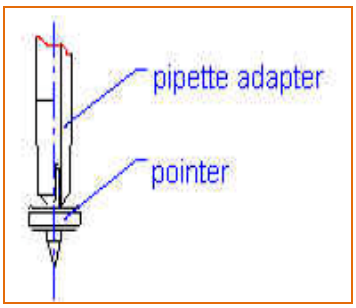
Press 'OK' to display the **'i6000 Calibration & Diagnostics Tool'** window.



11.1 One Point Calibration

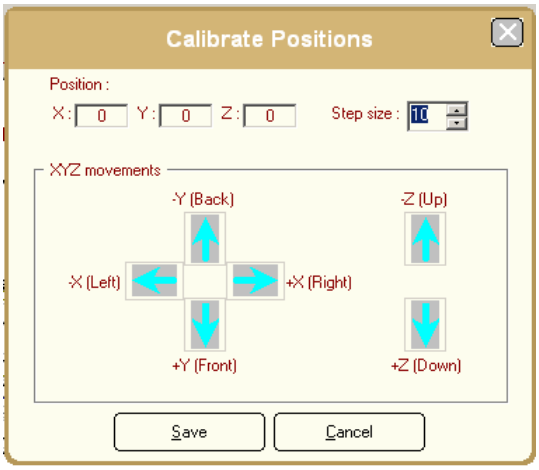
The i6000™ Automated Staining System **'1 Point Calibration'** is made possible by the use of a one piece-working base. This base provides consistent spacing between functional locations of the system, i.e., the pipette tips, reagent racks, and slide racks are in fixed locations

- Select **'1 Point Calibration'** from the Calibrate menu.
- Insert the calibration pointer into the pipette tip adapter.
- The flat end of the pointer goes into the orifice at the bottom of the adapter. The pointer must be inserted completely; make sure that the flat disk portion of the pointer is touching the tip adapter.



Caution: Do not move the Z-head when installing the pointer as this will cause inaccurate calibration.

- Once the pointer is installed, click 'OK' to display the **'Calibrate Positions'** window.



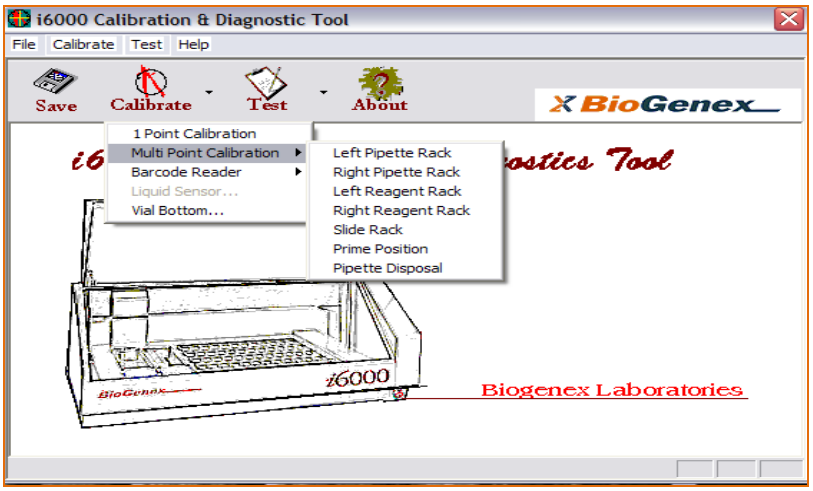
- Set the **Step Size** to 10.
- Use the arrow buttons or the keyboard to move the Z-head to a position just above the calibration target.
- Set the step size to 3
- Lower the Z-head until the pointer is close to the center point of the calibration target. Adjust the X and Y positions again if needed.

  Caution: Do not overdrive the pointer into the target. If you force the motor to 'skip', the calibration will be incorrect. Click **'Cancel'** and start the calibration all over again.
- Click on Save to move the Z-head from the target. Remove the calibration pointer to complete the One Point Calibration.

11.2 Multi Point Calibration

The tasks involved in this must be completed in the order they are presented in the Multi-point Calibration menu.

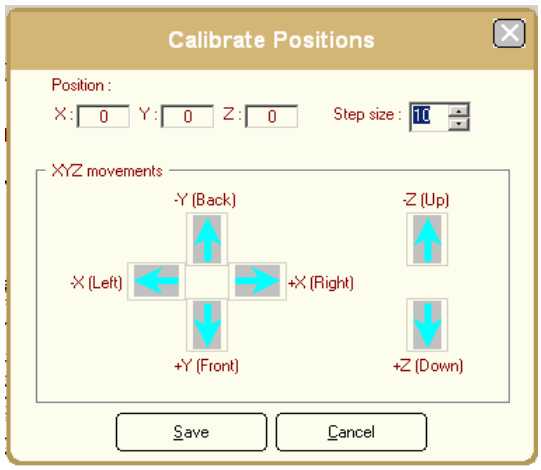
- Select Calibrate from the i6000™ Calibration & Diagnostic Tool menu. Choose **'Multi Point Calibration'** from the drop down menu.



11.3 Left Pipette Rack

- From the **'Calibrate'** menu, select the **'Multi Point Calibration'**
- Select **'Left Pipette Rack'** from the drop down list.
- The Z-head will move to position one of the left pipette tip box. The following screen will be displayed

- Make sure the Z-head is empty and place a pipette tip in position one in the left pipette box. Click 'OK' to continue.
- The Z-head will drop to pipette position one to pick up the pipette tip. The Calibrate Positions window is displayed on the screen



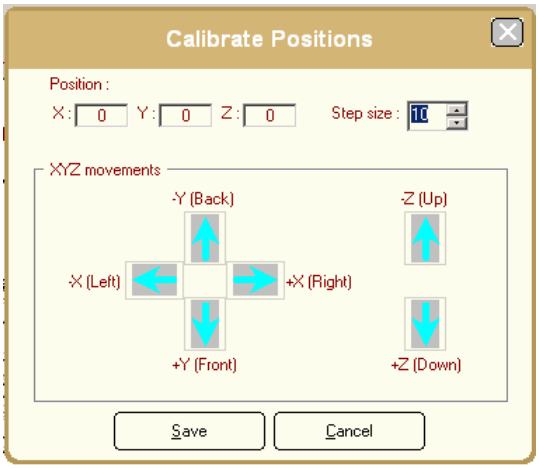
- Adjust the Z-head using the arrow keys as needed. Click '**Save'** to complete calibration.

To test the calibration for accuracy, use the diagnostics to pick up pipettes from positions 1, 8, 89, 96 and 45. To pass the test, pipette tips from all the positions should be picked up and be discarded in a single attempt.

11.4 Right Pipette Rack

- From the **'Calibrate'** menu, select the **'Multi Point Calibration'**
- Select **'Right Pipette Rack'** from the drop down list.
- The Z-head will move to position one of the right pipette tip box. The following screen will be displayed

- Make sure the Z-head is empty and place a pipette tip in position one in the right pipette tip box. Click 'OK' to continue.
- The Z-head will drop to pipette position one to pick up the pipette tip. The 'Calibrate Positions' window is displayed.



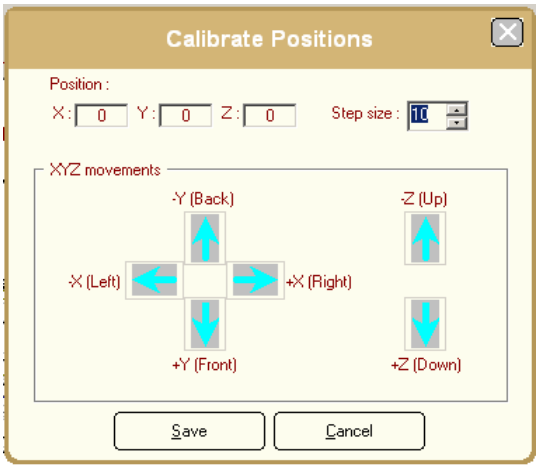
- Adjust the Z-head using the arrow keys as needed. Click '**Save'** to complete calibration.

To test the calibration for accuracy, use the diagnostics to pick up pipettes from positions 97, 104, 141, 185 and 192. To pass the test, pipette tips from all the positions should be picked up and be discarded in a single attempt.

11.5 Left Reagent Rack

- Place a bar-coded vial in position one of the left reagent rack.

- Select 'Left Reagent Rack' from the 'Multi Point Calibration' drop down menu. The 'Calibrate Positions' window is displayed.



- Center the pipette tip adaptor over the reagent vial by using the X-Y axis control.
- Use the Z control to lower the pipette tip adaptor close to the vial to determine the center position. Click 'Save'

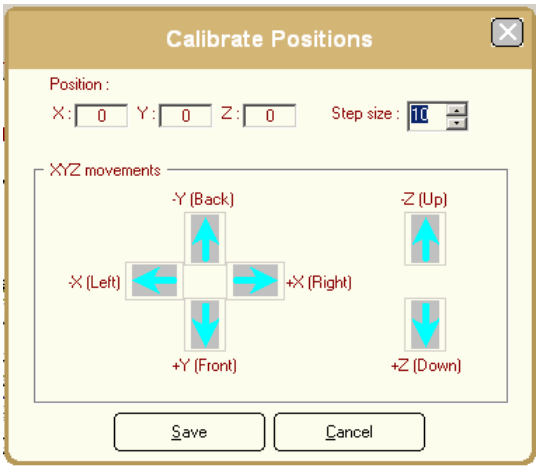
11.6 Right Reagent Rack

- Place a bar-coded vial in position one of the right reagent rack.
- Select 'Right Reagent Rack' from the 'Multi Point Calibration' drop down menu. The 'Calibrate Positions' window is displayed.
- Center the pipette tip adaptor over the reagent vial by using the X-Y axis control.
- Use the Z control to lower the pipette tip adaptor close to the vial to determine the center position. Click 'Save'

11.7 Slide Rack

- Select '**Slide Rack'** from the **'Multi Point Calibration'** drop down menu.
- The Z-head will move towards slide position one. The following screen will be displayed.

- Make sure the Z-head is empty and click 'OK' to continue. The **'Calibrate Positions'** window is displayed.



- Adjust the Z-head using the arrow key to ensure that the blow head is centered on the slide and located right after the label.
- Click '**Save'** to complete calibration.
  To test the calibration for accuracy, use the diagnostics to blow and wash the slide. Make sure that the volume used covers the slide properly.

11.8 Prime Position

- Select Prime Position from the 'Multi Point Calibration' drop down menu.
- The Z-head will move forward to the front of the instrument.
- Adjust the Z-head position using the arrow key to ensure that the Z-head is far enough forward to allow the unit to prime the solutions without splashing the liquid on the slides. Save the settings.

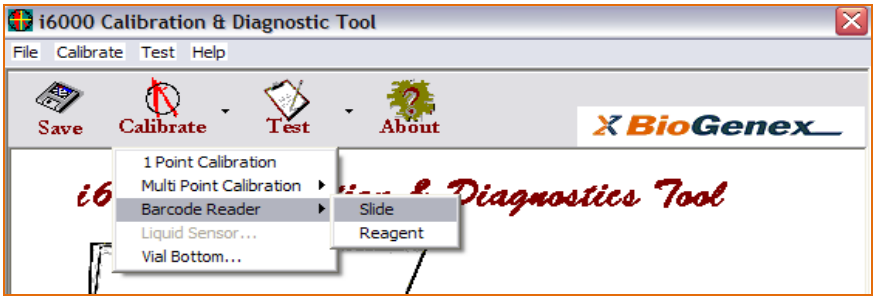
11.9 Pipette Tip Disposal

- Select **'Pipette Disposal'** from the '**Multi Point Calibration'** drop down menu.
- The Z-head will move to a position above the pipette tip disposal area.
- Adjust the Z-head position using the arrow key so that the pipette tip can be dropped directly into the center of the disposal area. Save the settings.

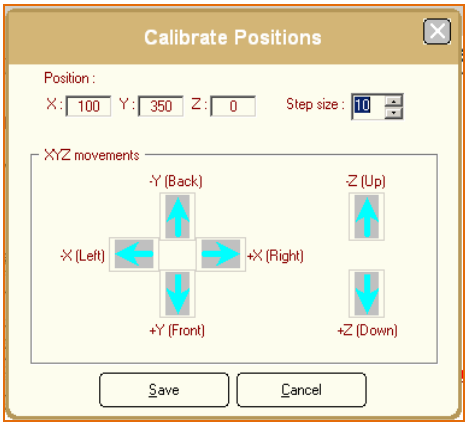
11.10 Barcode Reader Calibration

11.10.1 Slide Position

- From the Calibrate menu, select 'Barcode Reader'.
- Click on the 'Slide' from the drop down list.



- The Z-head will move to slide one position. Make sure the Z-head is empty and click 'OK'. To display **'Calibrate Positions'** window.



- Use the arrow buttons or the keyboard to move the Z-head, ensuring that the red beam is centered on the barcode and on the slide, and is at the top edge of the barcode. Click on **'Save'**

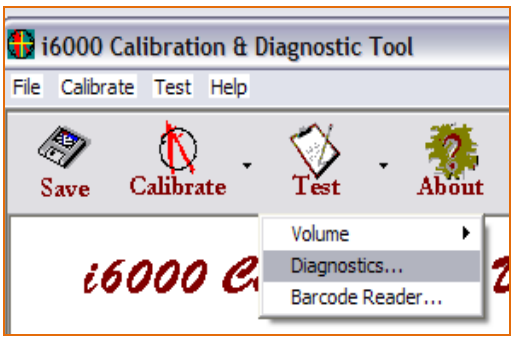
11.10.2 Reagent Position

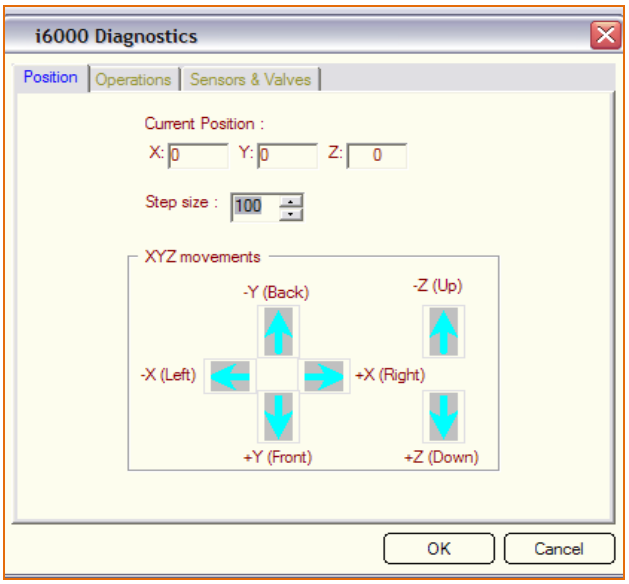
- To calibrate the reagent vial, select Barcode Reader, and click on 'Reagent'.
- The Z-head will move to reagent vial one. The 'Calibrate Positions' window is displayed.
- Use the arrow buttons or the keyboard to move the Z-head, ensuring that the red beam is to the edge of the bottle just above the barcode label.
- The left end of the beam should be midway over the opening of the vial. Click on 'Save'

11.11 Vial Bottom Calibration

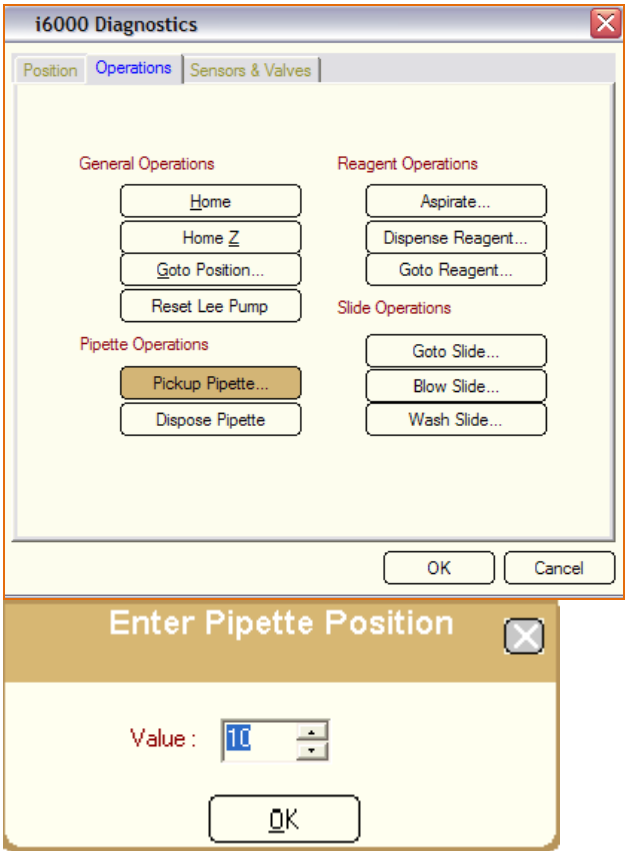
Using a micro pipette, fill an OptiMiser™ Vial with 3000 µl of liquid and place the vial at position one. Be sure that the vial and rack are seated completely.

Select **'Test'** from the i6000™ Calibration & Diagnostic Window and then click on **'Diagnostics'** from the drop down list. The **'i6000 Diagnostics'** window is displayed.





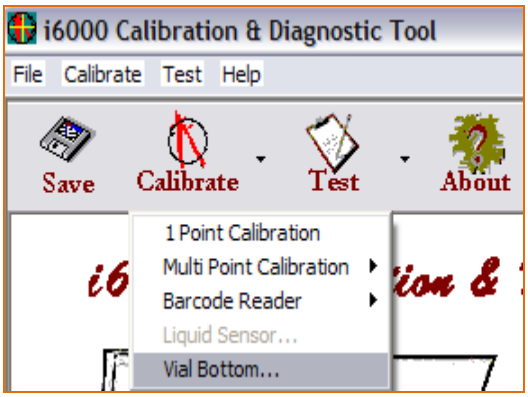
Click on the **'Operations'** and select **'Pickup Pipette'** from the options available.

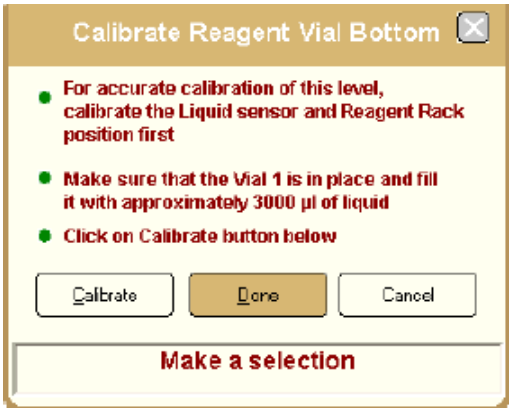


Enter a pipette position value and click **'OK'**. The Z-head will move forward to the pipette tray and pick up the pipette from the desired position. When the operation is done, close the **'Diagnostics'** window.

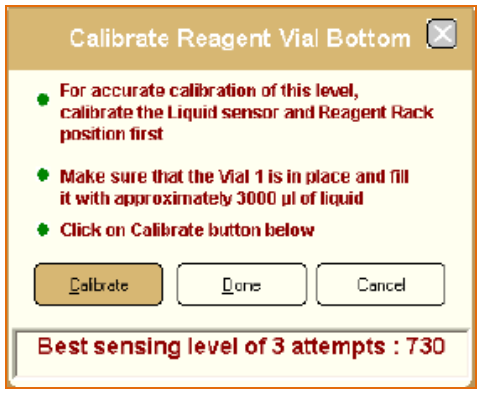
Open the 'i6000™ Calibration and Diagnostic tool' window, and select **'Vial Bottom'** from the '**Calibrate'** menu.

- From the **'Calibrate'** menu, click on Vial Bottom from the drop down list.
- The Calibrate Reagent Vial Bottom dialog box will be displayed.





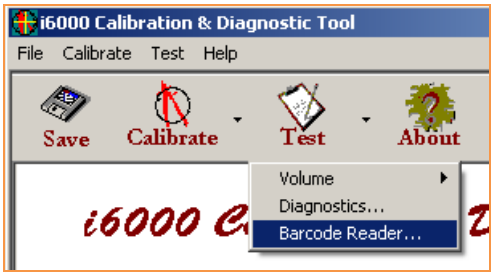
- The instrument will sense the liquid three times and display the value reading each time. After three attempts, the best sensing level is displayed

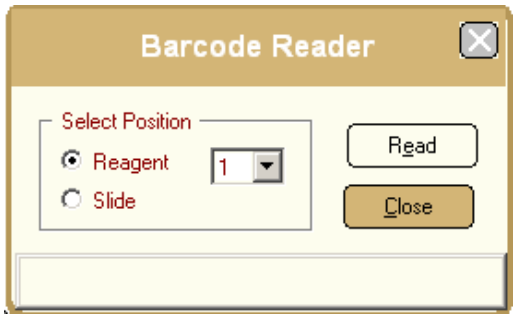


- Continue to click on **'Calibrate'** until a consistent reading is obtained three times in a row.
- Once a consistent reading is obtained, click on the "Done" button to save the value in the registry.
- If a one-point calibration is performed, then the bottom vial calibration will need to be repeated.

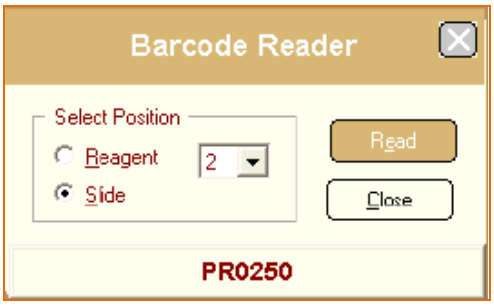
11.12 Test the Barcode Calibration Accuracy

Test the calibration for Barcode accuracy. Choose Test from the i6000™ Calibration & Diagnostics window, and then select Barcode Reader. The following windows will be displayed.

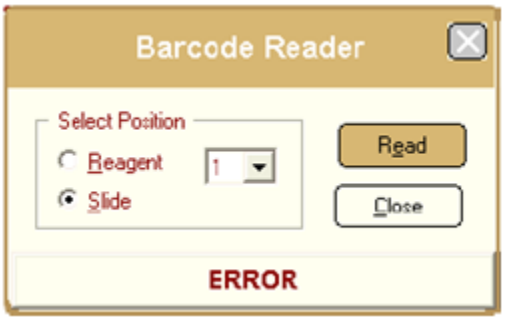




- Select either Reagent or Slide and choose a position from the box.
- Place a barcode on the reagent or slide and place them in the chosen location. Click on '**Read'**.



- If the reagent or the slide is read successfully, the calibration is effective.
- If there is any problem in reading a Slide or Reagent, an 'Error' will be displayed. Recalibration is required.

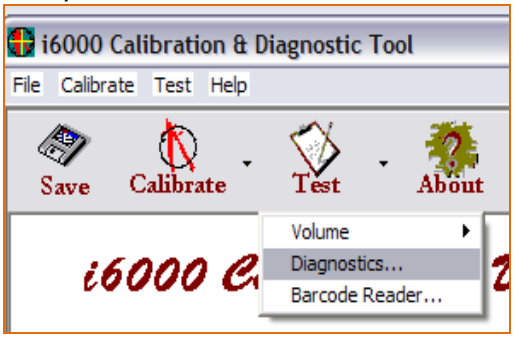


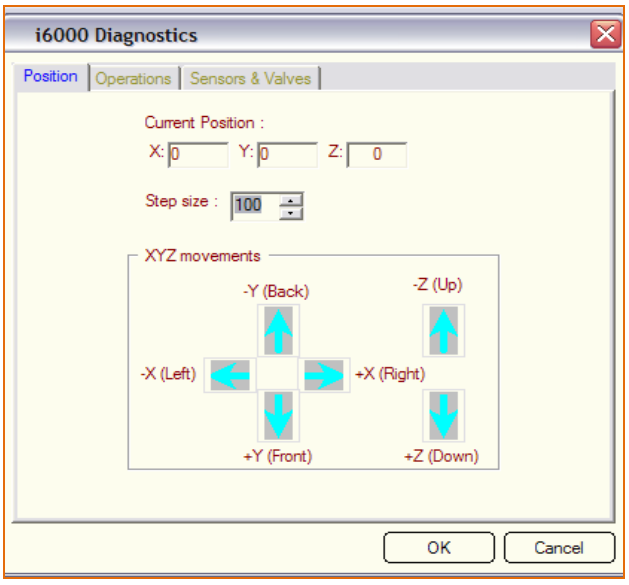
11.13 Diagnostics

The i6000™ Automated Staining System diagnostics feature is a powerful tool designed to assist you in checking the components for proper function. This program provides a method for you to test the motors, valves and pumps used in the system. The ability to test these devices can greatly reduce the time taken to identify failures.

- Open the 'i6000™ Calibration and Diagnostic tool' window, and select **'Diagnostics'** from the 'Test' menu.

The Diagnostics screen will be displayed, providing you with complete control of the system from one convenient screen.



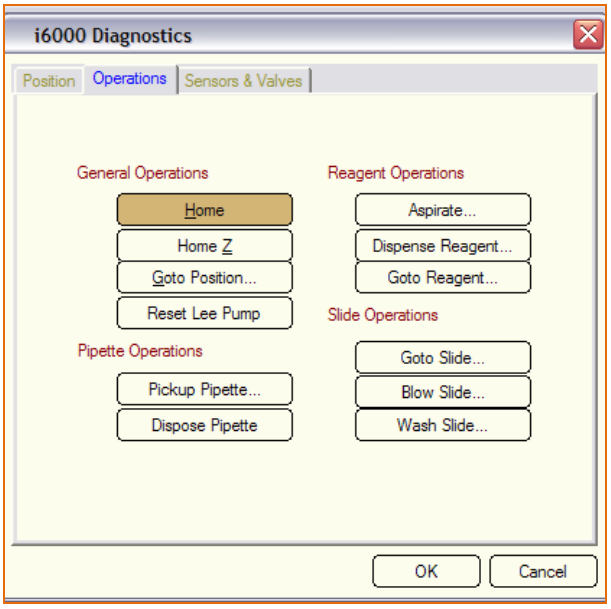


- The Diagnostic screen contains 3 main sections: Position, Operations and Sensors & Valves.

11.14 Position

- This section enables you to move the Z-head in any direction in the specified step size (1-1000).
- The step size determines how far the Z-head will move in the selected direction. Type in the step size then click on the arrow corresponding to the direction that you want to move.
- You can also use the 'Arrow Keys' on keyboard to move the Z-head.
- This section also displays the Current Position (expressed in number of steps from home) of the Z-head.

11.15 Operations



The following pre-programmed functions are available:

General Operations

- Home: Move Z-head to Home in all three directions X, Y, and Z.
- Home Z: Move the Z-head to home in the Z direction only.
- Go to Position: Allows you to enter the X, Y, and Z coordinates that you would like to move to.
- Reset Lee Pump: This is reserved for service personnel. It allows correct aspiration and dispensing of reagent.

Reagent Operations

- Aspirate: Move down in the current X and Y position until fluid is detected. Draw specified volume into pipette (1-1000).
- Dispense Reagent: In the current X, Y and Z position dispense specified volume (1-1000).
- Go to Reagent: Move to a specified reagent vial (1-60).

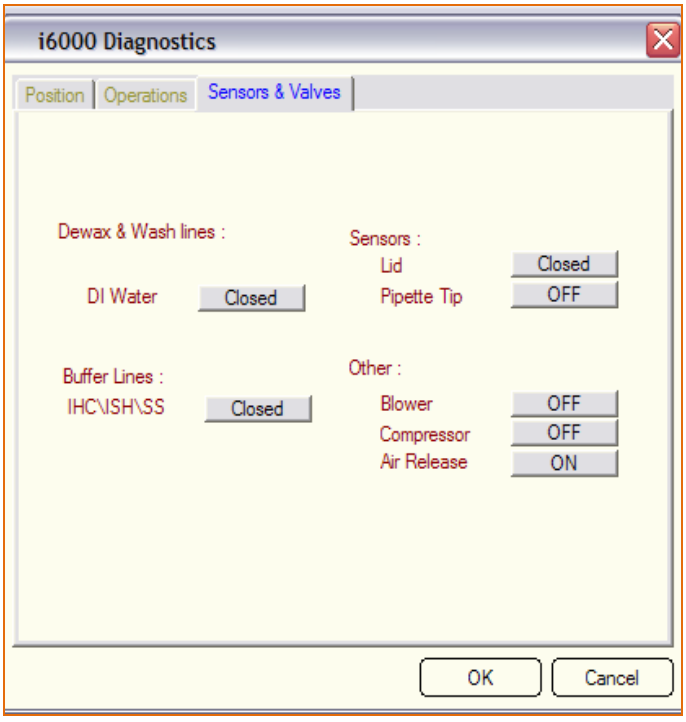
Pipette Operations

- Pickup Pipette: Pickup specified pipette tip. (1-192).
- Dispose Pipette: Move to the Disposal Position and eject tip from adapter.

Slide Operations

- Go to Slide: Move to a specified slide (1-60).
- Blow Slide: blow the slide
- Wash Slide: wash the slide

11.16 Sensors and Valves



This section enables you to control the state (on or off) of the fluid delivery valves, blower, compressor and the air release valve. It also displays the status of the lid and the pipette tip sensor.

To test the fluid delivery valves you must turn the air release valve off and the compressor on and allow the system to pressurize.

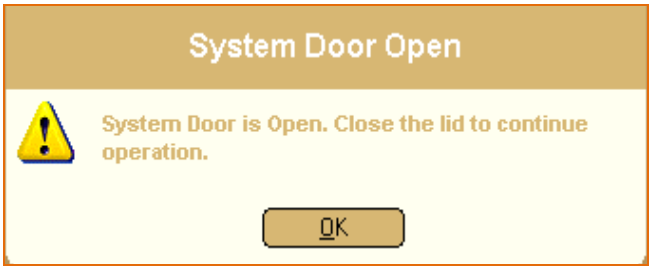
Make sure the Z-head is moved over to the Prime Position. Once pressurized open the fluid delivery valve to be tested. Fluid should now be dispensed from the wash head.

12.0 Error Conditions

This section describes some of the common error messages that might appear while using the i6000™ Automated Staining System.

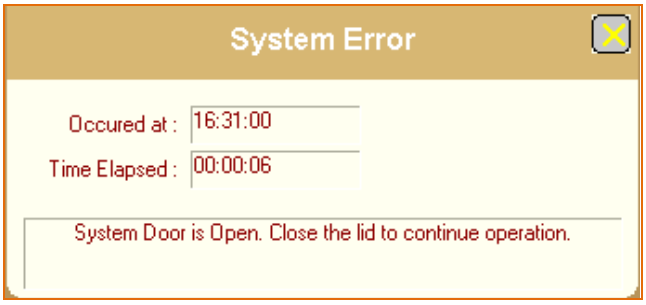
12.1 System Door Error

The instrument will not run with the door open. If the system door is open when starting the run, an error message will be displayed.



Close the system door and click **OK** to continue.

If at any time during the run, the system door is opened, the instrument will pause and an error message will be displayed.



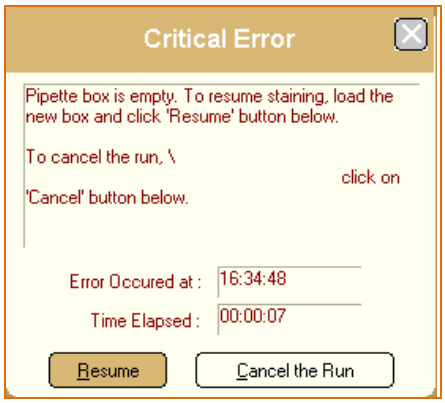
When the system door is closed the run will resume.

12.2 Pipette Errors

Pipette tip errors are divided into four basic groups: Tip Errors at Box, Tip Errors at Reagent, Tip Errors at Slide, and Tip Errors Post-Dispense. Each group provides a specific error message and requires a slightly different response.

12.2.1 Pipette Tip Errors at Box

- If the Z-head tip adapter fails to pick up a pipette tip from the box holder, or the pipette tip is missing, the system will re-attempt to pick up a tip.
- The Z-head goes to its home position, returns to the pipette tip it just failed to pick up, and tries to pick it up again.
- If it successfully picks up the tip on this second try at the same position, the staining run continues. If it fails to pick up the tip at the same position, it will attempt to pick up a tip in the next three positions.
- After eight consecutive failures, an audible alarm will sound and the following message will be displayed.

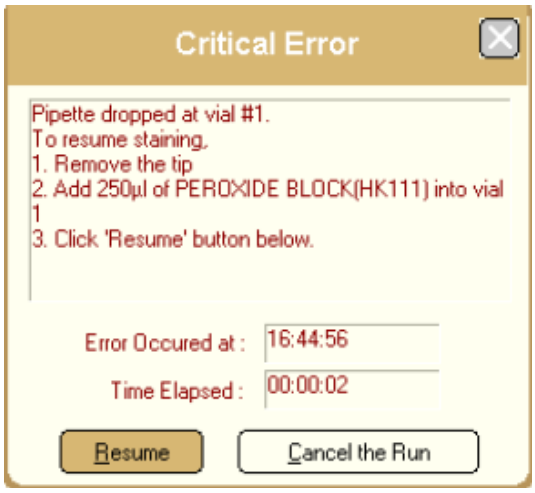


- Replace the box of pipette tips in the unit with a new full box.
- Make sure the tip box is well seated and that there is no obvious obstruction to the Z-head movement. Select Resume continuing.
- When Resume is selected, the Z-head will attempt to pick up the first tip in the new box. If it is successful, the staining run continues. If not, the cycle begins again.
- The Z-head will make four attempts to pick up a tip from the new box of pipette tips. If unsuccessful, the above error message will be displayed again.
- Click '**Cancel the Run'** to abort the run.

12.2.2 Pipette Tip Errors at Reagent

If the Z-head tip adapter drops a pipette tip after drawing reagent, but before moving to the slides, the Z-head will stop, an alarm sets off with the following message displayed on the screen.

A 10 sec. timer will start ticking. Remove the pipette tip and click '**OK'** to continue the run. If it takes more than 10 sec. to remove the tip, a 'Critical Error' message will be displayed on the screen.



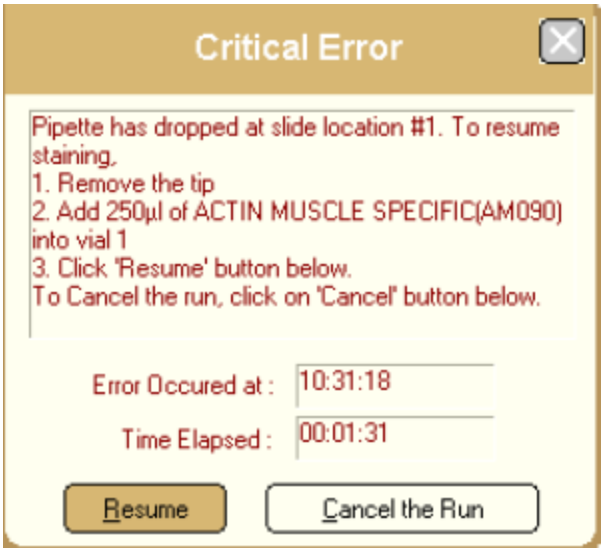
Make sure the reagent vial and the vial rack are positioned properly. Follow the instructions provided in the error message, and click **'Resume'**.

The Z-head will pick up a new pipette tip and move to the reagent vial to draw the reagent again and continue the run.

12.2.3 Pipette Tip Errors at Slide

If the Z-head tip adapter drops a pipette tip after moving to the slides but before completely dispensing the drawn reagent, the Z-head will stop, and an alarm sets off with the following message displayed on the screen.

If the error is not cleared within 10 sec. a 'Critical Error' message will be displayed on the screen.



Make sure the slide racks are positioned properly and there is no other obstruction to the free movement of the Z-head. Follow the instructions provided in the error message and click 'Resume'.

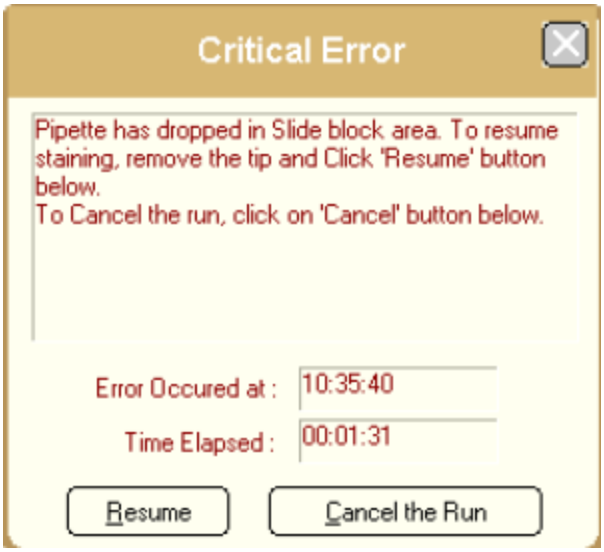
The Z-head will pick up a new pipette tip, to dispense the reagent on each of the affected slides listed in the error message.

12.2.4 Pipette Tip Errors Post Dispense

If the Z-head tip adapter drops a pipette tip after completely dispensing the reagent, but before the tip is ejected, the Z-head will stop.

An alarm sets off with the following message displayed on the screen.

If the error is not cleared within 10 sec. a 'Critical Error' message will be displayed.

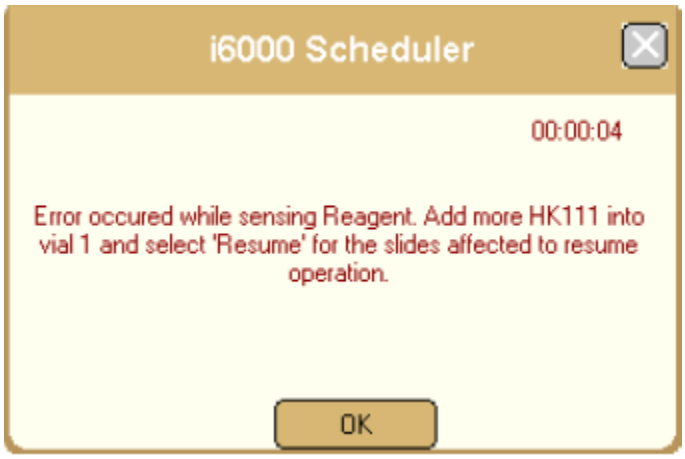


Remove the dropped tip and select Resume to continue the run.

12.3 Reagent Errors

Reagent Vial Empty or Missing Errors

If the reagent vial is either empty or does not contain the required amount of reagent, the liquid level sensor will detect and sets off an alarm with the following message displayed on the screen.



All the slides that are affected are highlighted in a different color (selected in the color scheme), and the staining is stopped at this point for the affected slides.

These slides will then be buffered periodically depending upon the time set in global settings for Buffer interval during run. To resume the staining, right click on the slide and select '**Resume staining'.**

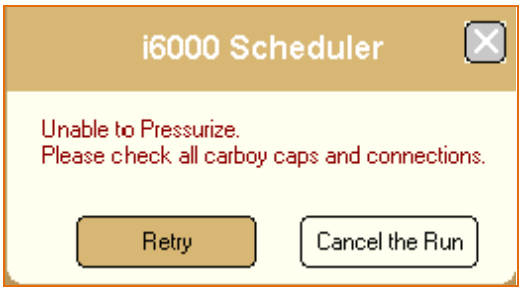
12.3.1 Insufficient Reagent Vials Error

If a run requires more than 60 reagents, including primary antibodies, links, labels, substrates, and counter-stains, clicking on **'Start'** will display the following message.

- Click '**OK'** to cancel the run.
- You can start over again or in the case of an open run, open the previous stored staining run and edit it.
- Edit/ Delete slides and/or protocols to bring down the total number of reagents required to 60 or less.

12.4 System Pressurization Errors

If the system is not pressurized within five minutes, the 'i6000 Scheduler' dialog box will be displayed.



Ensure that all carboy caps are securely tightened and click on the '**Retry'** button.

If pressurization continues to fail, click on the **'Cancel the Run'** button to exit. Check all carboy connections and secure them before restarting the run.

Appendix-1

System Specifications

- Dimensions:

  40.5” W x 24” D x 18.5” H (1028 mm W x 610 mm D x 470 mm H)

- Weight:

  130lbs

- Electrical Specifications:

  115/230VAC 50/60Hz

- Power Consumption:

  300 Watts

- Normal Operating Temperature:

  18-28.5 °C (64 – 80.5 °F)

- Slide Capacity:

  Total Capacity: 60 Slides, 5 racks (12 slides per rack)

- Reagent Capacity:

  Total Capacity: 60 Reagent vials, 2 racks (30 reagents vials per rack)

- Reagent Dispensing Volume:

  100 µl, 150 µl, 200 µl, 250 µl, 300 µl, 350 µl, 400 µl, 500 µl, 600 µl, 700 µl, 800 µl and 900 µl

- Reagent Dispensing Accuracy: ± 5 %

- Operating system: Windows® XP

- Buffer Containers: 10 Liters Each

- Waste Containers: 20 Liters Each

Performance Characteristics

The pattern and intensity of staining is highly consistent and reproducible when slides from the same run using identical specimen and protocols are compared. Similarly, slides using the same specimen and protocols stained on different instruments yielded highly consistent and reproducible results. In comparison to manual results, the instrument staining results are identical, if not indistinguishable. No variation was

found amongst the open format and the barcode format. Staining specifications were consistently achieved in STAT, continuous or batch run formats.

Appendix-2

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 *i*6000™ Automated Staining System purchased, leased or rented by the Customer ("Services"):

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

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.

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'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.

Warranty Disclaimer

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Software may not be uninterrupted or error free and that any warranty for Year 2000 compliance is made only to the extent provided in the software licenses contained in this Operating Manual.

Appendix-3

Software License
(BioGenex Software)
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Appendix-4

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If the SOFTWARE is provided by Manufacturer on media separate from the SYSTEM and is labeled "For Upgrade Purposes Only' ("Upgrade SOFTWARE"), you may install one copy of the Upgrade SOFTWARE onto the SYSTEM as a replacement copy for the SOFTWARE originally installed on the SYSTEM and use it in accordance with Section 1 of this EULA. You may also install additional copies of the Upgrade SOFTWARE as replacement copies onto additional SYSTEMS which are the same brand and model as the SYSTEM and contain a duly licensed copy of the same version and language release of the SOFTWARE ("ADDITIONAL SYSTEMS"), provided that (1) Manufacturer has supplied a corresponding serialized sticker for each additional copy of the Upgrade SOFTWARE, and (2) you affix a serialized sticker per Manufacturer's instructions for each unit of Upgrade SOFTWARE you install. If the SOFTWARE is provided by Manufacturer on separate media and labeled as "Recovery Media," you may not make a copy of the SOFTWARE as

described in Section 1 for archival purposes. Instead, you may use the Recovery Media solely to restore or reinstall the same version and language release of the SOFTWARE as originally installed on the SYSTEM and thereafter use the SOFTWARE as restored or reinstalled in accordance with Section 1 of this EULA. A single unit of Recovery Media may be used by you to restore or reinstall the SOFTWARE on ADDITIONAL SYSTEMS.

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Appendix-5

Daily /Monthly Cleaning

Daily Cleaning

The **i**6000™ Automated Staining System requires minor cleaning and sanitation to ensure consistent staining, eliminate potential contamination, and guarantee the longevity of the instrument. The following procedure should be performed after the last staining run of the day:

1. Remove the Pipette Tip Waste Tray. Discard tips and rinse tray with tap water.
2. Remove the tip boxes, reagent rack and slide racks from the instrument. Rinse the reagent rack and slide racks with tap water.
3. Disconnect the buffer carboy from the connector panel of the instrument.
4. Connect the DI Water Carboy to buffer quick coupling (White color) on the liquid panel of the instrument.
5. Prime the system with buffer. The **i**6000™ Automated Staining System will rinse the buffer line with the DI water. Repeat three times.
6. Now disconnect the DI Water carboy from the buffer quick coupling and connect it to the DI Water quick coupling (Green color) on the liquid panel.
7. Prime the system with DI Water. The **i**6000™ Automated Staining System will rinse the DI Water line with the DI water. Repeat three times.
8. After the priming cycle is finished, remove the rinse tubing and reconnect each carboy to its appropriate inlet port.
9. Wipe the working space of the instrument with a soft damp cloth. Dry the interior by wiping all surfaces with a clean soft cloth.

Monthly Cleaning

To prevent the growth of bacteria or mold in the tubing, carboys, and other areas, the following procedure should be preformed monthly. Wear gloves and eye protection while performing this procedure:

1. Remove the tip boxes, reagent rack and slide racks from the machine. Rinse the reagent rack and slide racks with tap water.
2. Rinse the tip adapter, tip ejector and the blow head with steady stream of DI water from a rinse bottle. Remove any salt accumulation.
3. Remove the carboys and caps from the system including the Waste carboy. Empty both the Buffer and DI Water carboys and rinse with DI Water. Fill each carboy with 1 Gallon of a 1% bleach solution. (30 - 40ml of bleach to 4 liters of DI Water). Secure the carboys with caps and roll the bleach solution thoroughly around the carboys.
4. Empty the bleach solution from each of the carboys and rinse with DI Water. Empty the carboys.
5. Store the Buffer and DI Water carboys upside down to let them dry.
6. In the DI Water carboy, prepare fresh cleaning solution by diluting 150 ml of Professional Lysol Deodorizing cleaner (active ingredient: alkyl dimethyl benzyl ammonium chlorides) to 3600 ml of distilled water. In Countries, where Professional Lysol is not available or is not allowed to be sold, use 4% Sodium Hypochlorite. Dilute 50ml of Sodium Hypochlorite in 950ml of DI Water.
7. Connect the Waste Carboy to the instrument.
8. Connect the DI Water Carboy filled with diluted solution to buffer quick coupling (White color) on the liquid panel of the instrument.
9. In prime solutions window, select the buffer line. The **i**6000™ Automated Staining System will rinse the buffer line. Repeat three times.
10. Now disconnect the DI Water carboy filled with the diluted solution to the buffer quick coupling and connect it to the DI Water quick coupling (Green color) on the liquid panel.
11. In prime solutions window, select the DI Water line. The **i**6000™ Automated Staining System will rinse the DI Water line. Repeat three times.
12. Wait for 10 minutes after the last prime is done.
13. Empty the DI Water carboy to discard any residual solution and rinse the carboy with DI Water.
14. Fill the DI Water carboy with DI and rinse both the lines by priming 3 times.
15. Empty the DI Water carboy and store it upside down and let it dry.
16. Clean the Drain Tray with powdered cleanser (Comet with bleach) and a soft plastic brush. Rinse and dry. Check that the waste drains properly. Adjust the drain tubing as necessary.
17. Clean the working space table with a soft damp cloth.
18. Dry the interior of the instrument by wiping all surfaces with a clean soft cloth.
19. Leave the lid open and let the instrument air dry overnight.

Appendix-6

Instrument Packaging Procedure for i6000™ Diagnostics/ Infinity Automated Staining System

1.0 **Purpose:**
1.1 This procedure describes the packing procedure for *i*6000™ Diagnostics/ Infinity shipment.

2.0 **Scope:**
2.1 This procedure applicable to the Systems Manufacturing Department.

3.0 **Definitions:**
3.1 QC: Quality Control

4.0 **Responsibility:**
4.1 It is the responsibility of Systems Manufacturing to oversee and enforce this procedure.

5.0 **Related Documents:**
5.1 Instrument Packaging Procedure Check list for Instrument Manufacturing Area doc no. 951-3320.1
5.2 Packing List for Accessories Box - i6000™ System (Doc. #951-3323.1)

6.0 **Packaging procedure for shipping an instrument without accessory kits follows**:
6.1 Two people are required when handling the instruments.
6.2 Inspect instrument to be sure it is undamaged and clean. All reagents, pipette tips, tip tray and slide carriers should be removed.
6.3 Place the instrument into a vapor bag (shrink-wrap is acceptable) and seal on the top.
6.4 Place the Cap (PN: 6100-20005) on the flat floor and place Fab, Bottom Buffer Left (PN: 6100-20004) and Fab, Bottom Buffer Right (PN: 6100-20003) inside the Cap carton (PN: 6100-20005) as shown in the photo1.

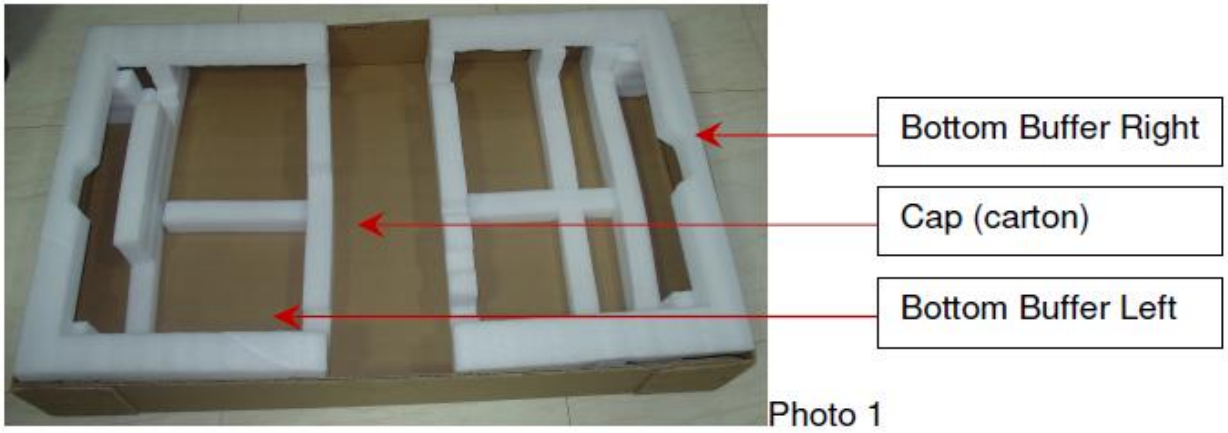

Photo 1

6.5 Place the i6000™ Autostainer instrument on the both the buffers and ensure that instrument has properly seated on the buffers. Place the Sleeve carton (PN: 6100-20005) from the top of the instrument as shown in the photo 2.

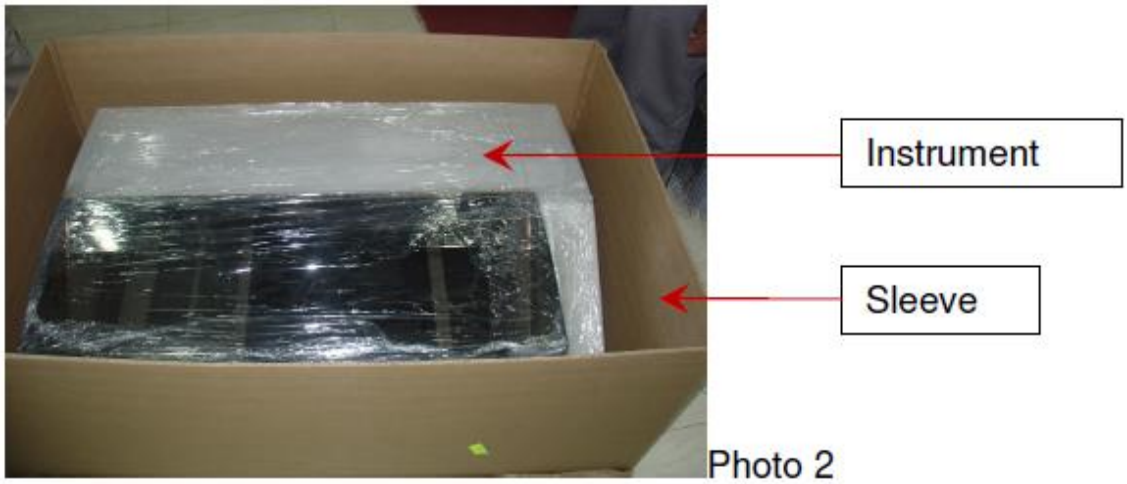

Photo 2

6.6 Place the Fab, Buffer Right (PN: 6100-20001) and Fab, Buffer Left (PN: 6100-2002) on the instrument as shown per the photo 3.

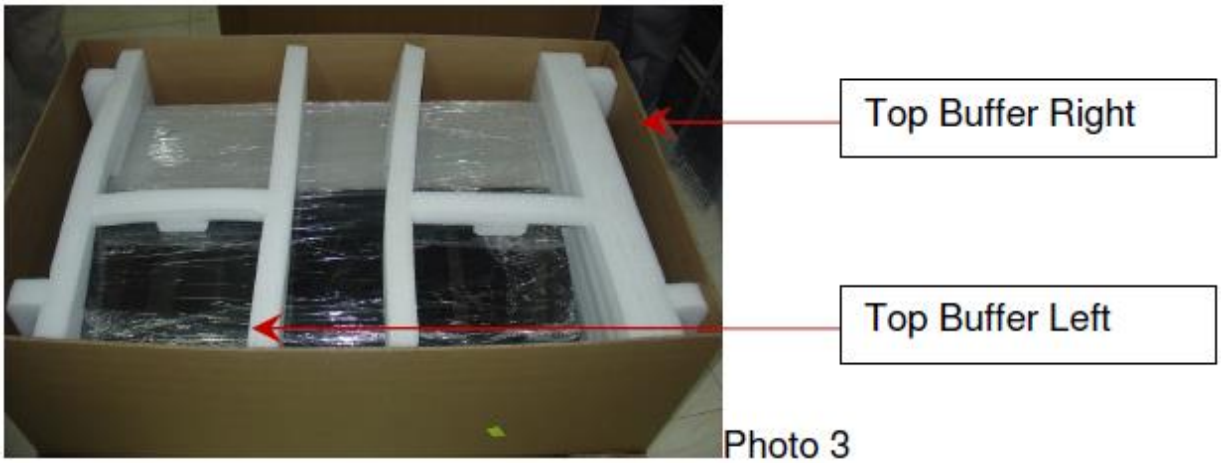

Photo 3

6.7 Place the Top Cap on the sleeve as shown in the photo 4.

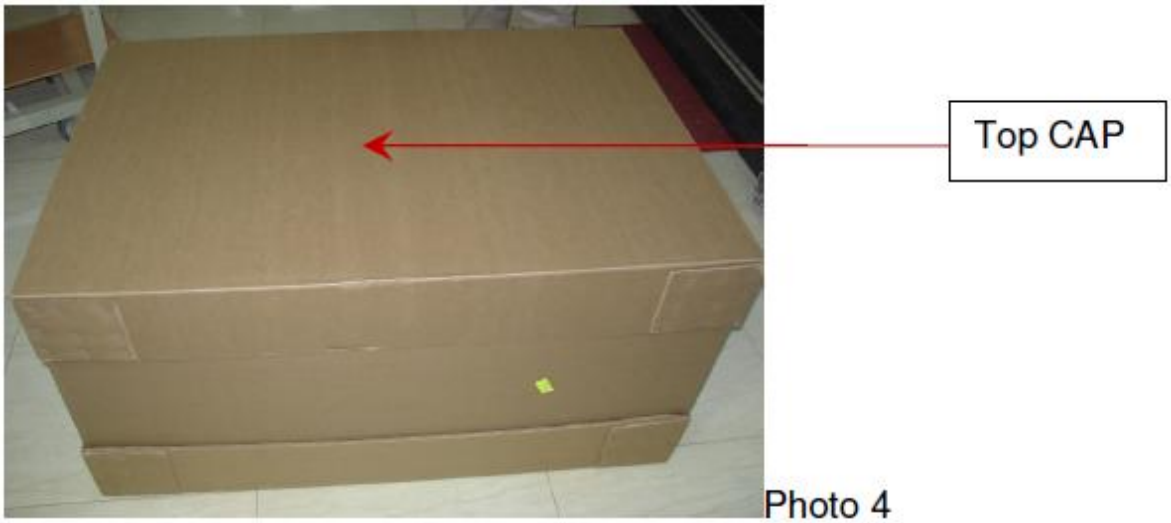

Photo 4

6.8 Wrap it with the nylon band strip using edge protectors. Push this setup into the Wooden Crate as shown in photo 5

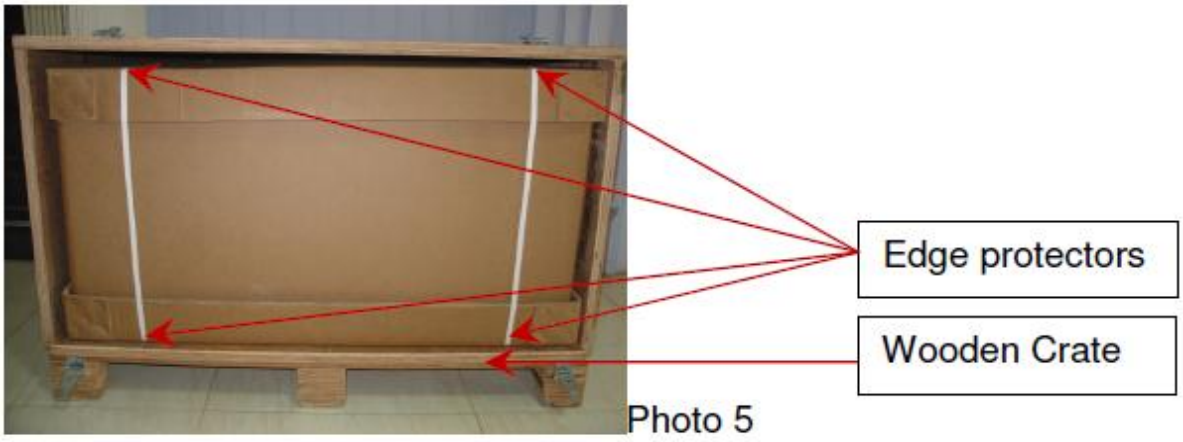

Photo 5

6.9 Close the Crate with the front door and lock latches. Strap the door with metal banding material and clips in no less than 2 locations. The bands should run from end to end parallel to the long side of the pallet (see reference drawing). This is important to make sure the bands are not broken by pallet jacks or forklifts during shipping. Bands must be tight enough to prevent the instrument box from moving on the pallet.

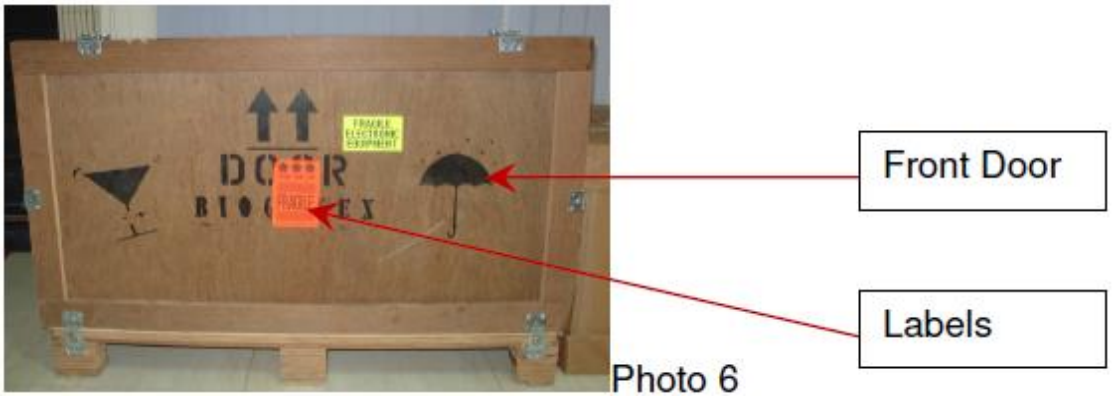

Photo 6

Apply appropriate container marking and labels as required by the Package Marking Procedure based on the shipments destination and mode of transportation.

7.0 **The following instructions apply if the instrument is to be shipped with an accessory kit**:
7.1 Two people are required when handling a loaded accessory kit box.
7.2 Verify the accessories in the Box per Doc.#951-3323.1
7.3 Include a copy of the Packing list 951-3320.1 in the Accessory kit box.
7.4 Seal the accessory kit box on top and bottom in the same manner as the instrument box.
7.5 Accessory box should be placed on the Wooden crate of the instrument and strap it to the instrument box at 2 locations from front to rear using the same approved metal banding materials as for the instrument box.
7.6 Apply labels shipping labels on the crate as shown in the photo6.

Appendix-7

Pre-Installation Checklist for i6000™ Systems

Instructions to the Sales Team

This document helps the Customer in understanding the requirements for installing i6000™ instrument in their laboratory. Being prepared with an understanding and compliance to these requirements will help the installation team to perform efficient and hassle-free installation and training at the Customer's site.

Please help the Customer fill out this checklist and check the boxes to show that the topic was discussed with the Customer and approved by them. Please complete this document with clear and legible notes of any special instructions or confirmation to the specifications. Please fax or send the completed document to Customer Support for approval, and leave a completed copy with the Customer.

Scheduling the installation and training can not take place if this document is not approved by all concerned.

BioGenex Representative: _____

Name of the Institution: _____

Institutional Contact:

Name: _____

Title: _____

Telephone: _____

Fax: _____

Email: _____

1. Delivery

- The Customer shall inspect all shipments upon delivery, for external damage. If there is evidence of external damage, BioGenex Customer Support shall be notified immediately.

- Dock working hours and access restrictions, if any.

- It may require at least two people to take the instrument out of the carton and carry it to its final install site.

- Appropriate cart for transport of accessories.

- Storage space for the empty carton/packaging material.

Recommendations / Customer comments:

_____

_____

2. Environmental Requirements

a. Space requirements

Minimum Table/Platform Size:

- Length = 72" (includes Instrument, Computer and Monitor)
- Width = 30"
- Sufficient to support 75kg
- Storage space to install the bulk reagent carboys beneath the table/platform
- Clearance of 6" is required from the rear wall.

Instrument Height = 20" (Lid Closed); 33" (Lid Open)

Recommendations / Customer comments:

_____

_____

b. Power requirement

- 230V, 50Hz, 15 Amps grounded wall socket for 1KVA Online UPS System that supports the Instrument, Computer and Monitor.

- UPS System shall be provided by the customer. The output of the UPS System shall have 3 sockets of 5A each.
- Additional wall socket for DeskJet Printer is required as the UPS rating do not include this printer.

Recommendations / Customer comments:

_____
_____

c. Room temperature requirement

- Ambient temperature range : 18ºC - 28.5 ºC

Recommendations / Customer comments:

_____
_____

d. DI Water

- The instrument requires DI water to be filled in the bulk reagent bottle.

Recommendations / Customer comments:

_____
_____

e. Waste Disposal

- The instrument has a built-in waste storage container and does not require connecting to a running drain. Local regulations with respect to waste storage and disposal should be observed by the customer.

Recommendations / Customer comments:

_____

_____

3. Training information

- Key Operator/s to be trained: _____
  - _____
  - _____

- Is/Are the Key Operator/s competent with using MS WINDOWS Operating system?

- Please have the expected Key Operator/s answer the following questions

  1. Describe the use of the right mouse button
  2. Use the "Start" button to start Windows Explorer
  3. Arrange the desktop alphabetically
  4. Use the Clock to set date and time
  5. Open "Windows Explorer" and open a directory on the "C:" drive.
  6. Copy a file from one directory to another, using "drag and drop"
  7. Use "My Computer" to select a printer and display its properties.
  8. Open the "Recycle Bin".

- If the Key Operator/s cannot answer six of the eight questions, formal training on MS WINDOWS must be accomplished by the customer prior to installation and training with the i6000™ instrument. The customer should acquire appropriate training documentation and fax the proof of training, when completed, to BioGenex Customer Support.

Recommendations / Customer comments:

_____

_____

Final Notes:

- The person assigned to training must be free from interruptions during the on-site training. It is preferable to train a "key" operator, and then let them train others as necessary.

- Inform the customer that they must be available on the days of installation. Complete installation of the instrument, calibration and training may take at least two days.

Recommendations / Customer comments:

_____

_____

Signatures

CUSTOMER: **BIOGENEX REPRESENTATIVE:**

_____ _____

Date: _____ Date: _____

Reviewed by BioGenex Customer Support: _____

Reviewer's Signature Date

Appendix-8

Instrument Installation Instructions for *i*6000™ Diagnostics/Infinity Automated Staining Systems

1. Purpose
1.1 To define the process for installation of i6000™ Diagnostics/Infinity systems quickly and efficiently.

2. Scope
2.1 This procedure applies to installation of the i6000™ Diagnostics/Infinity systems.

3. Definition: N/A

4. Responsibility
4.1 Field Service Engineers, Application Specialists or appropriately trained BioGenex personnel have to install the unit.
4.2 Installers have to fill out the Installation Checklist Document No. 951-6124.1 in duplicate.
4.2.1 Provide copy of the completed checklist to the customer.
4.2.2 Provide original of the completed checklist to BioGenex Customer Support.

5. Related Documents:
5.1 Packing List for Accessories Box - i6000™ Diagnostics/Infinity systems. (Doc# 951-3323.1)
5.2 Instrument Installation Checklist for i6000™ (Doc# 951-6124.1)
5.3 Operator's Manual i6000™ Diagnostics System Doc No.953-0048.0
5.4 Operator's Manual i6000™ Research System Doc No.953-0049.0

6. Procedure:
6.1 Verify the received accessories against the Packing Lists. Contact Customer Support in case of short shipment and await instructions.
6.2 Remove the i6000™ Diagnostics/Research system from its crate and place it in the Lab on a flat surface that has sturdy support.
6.3 Ensure that the instrument is located with 6" clearance from the rear wall for ventilation.
6.4 Open the housing cover and remove the packing material inside the instrument.

6.5 Remove the M3x16 SHCS screw fixed to the left of the Z Head cover. This screw is fixed at BioGenex to ensure that the pipette adapter is secured firmly during the shipment.
6.6 Unpack the Computer and the monitor.
6.7 Ensure that the 110/230 Voltage Selector Switch located on the rear side of the computer is set per the local Mains Power System.
6.8 Connect the video cable to the Computer and the Monitor.
6.9 Connect the Keyboard and Mouse to the Computer.
6.10 Connect the Ethernet Cable (4500-00132; Cable Ethernet Cross Over) from the Computer to the port marked "Ethernet" on the connector panel of i6000™.

6.11 Connect the 9-pin barcode cable to the COM port on the Computer and the port marked “Scanner” on the connector panel of i6000™ (Applicable to i6000™ Diagnostics Systems only).
6.12 Install the Slide Racks, Reagent Racks and Pipette tips.
6.13 Install the Pipette Tip Waste Tray.
6.14 Fill the DI Water and Buffer carboys with at least 2L of DI Water.
6.15 Attach the carboy caps to their respective carboys and connect them to the liquid panel per the color coding (Buffer: White; DI Water: Green)
6.16 Attach drain connector (Elbow Fitting) to one end of the large drain tubing. Plug the elbow fitting into the connector on the liquid panel and the other end of the drain tubing to the Waste Carboy Cap and secure with a cable tie.
6.17 Place 4 slides in positions 1, 12, 49 and 60 on the slide racks and level the instrument. Adjust the leveling screws as required with the help of Level (6520-04116) available in the accessories kit.
6.18 Connect the power cords of i6000™, Computer, Monitor, Printer* and i500* Labeling System to a UPS System* of appropriate rating.

* Wherever supplied.

NOTE: Perform the setup of Inkjet Printer and i500 Plus - LIS Enabled Barcode Printer wherever supplied with the i6000™ system.
6.19 Turn ON the Computer and Monitor.
6.20 Select the user”Autostainer”. Type in password “optimax”.
6.21 Check the date and time and make changes if necessary.
6.22 Turn ON the i6000™ Diagnostics/Research system. Ensure that the Emergency Stop switch is not pressed.
6.23 Perform the following calibrations per procedure explained in Section 11 of the Operator Manual 953-0048.0 and 953-0049.0
6.23.1 Multipoint Calibration
6.23.2 Barcode Reader (Slide and Reagent).
6.23.3 Vial Bottom
6.24 Prime the Buffer and DI Water lines to verify the liquid flow.
6.25 Check the drain flow and adjust the position of the Waste Carboy or the length of the drain tubing to enhance the flow.
6.26 Setup the Inkjet Printer per the following procedure.
6.26.1 Switch ON the printer.
6.26.2 Install the printer cartridges.
6.26.3 Connect the printer cable to the USB port of the Computer.
6.26.4 Insert the CD provided by the Printer Manufacturer in the CD-ROM of the computer to install the printer drivers.
6.26.5 Print a test page to ensure that the printer is ready.
6.27 Perform a 4 Corner plus 2 Test per procedure explained in Appendix 5 of the Operator Manual 953-0048.0
6.28 Drain out the left over DI water in the carboys, if any.
6.29 Install the i500 Plus - LIS Enabled Barcode Label Printer per the following procedure.
6.29.1 Connect the i500 Plus - LIS Enabled Barcode Label Printer to the USB port of the computer.
6.29.2 Connect the Power adapter of the i500 Plus - LIS Enabled Barcode Label Printer to the UPS System*
* Wherever supplied.
6.29.3 Insert the i500 Plus - LIS Enabled Barcode Label Printer CD in the CD-ROM of the computer to install the setup files.
6.29.4 Install the printer drivers available in the i500 Plus - LIS Enabled Barcode Label Printer CD
6.29.5 Restart the computer after the installation of drivers is complete.
6.29.6 Click “Barcode Labeler” icon on the desktop.

6.29.7 Select i6000™ Automated Stainer from the list of products.
6.29.8 Click “Sync” to synchronize the Labeler with i6000™ Diagnostics/Research system. Ensure that the i6000™ system is turned ON while performing synchronization.
6.30 Train the customer’s key operator on the staining and diagnostic functions of the instrument.
6.31 Peel off the white backing from the Lamination Holder and stick it on Fab. Side Housing next to the serial number label.
6.32 Insert the laminated Daily/Maintenance Scheduler in the Lamination Holder from the top.
6.33 Peel off the backing from the Business Cards Holder and stick it on Fab. Side Housing next to the Lamination Holder.
6.34 Insert the Business Cards of the FSE/AS/Sales in the Business Cards Holder.
6.35 Fill out the Installation Checklist document 951-6124.1 and file copies of Checklist as mentioned in Section 4.2.