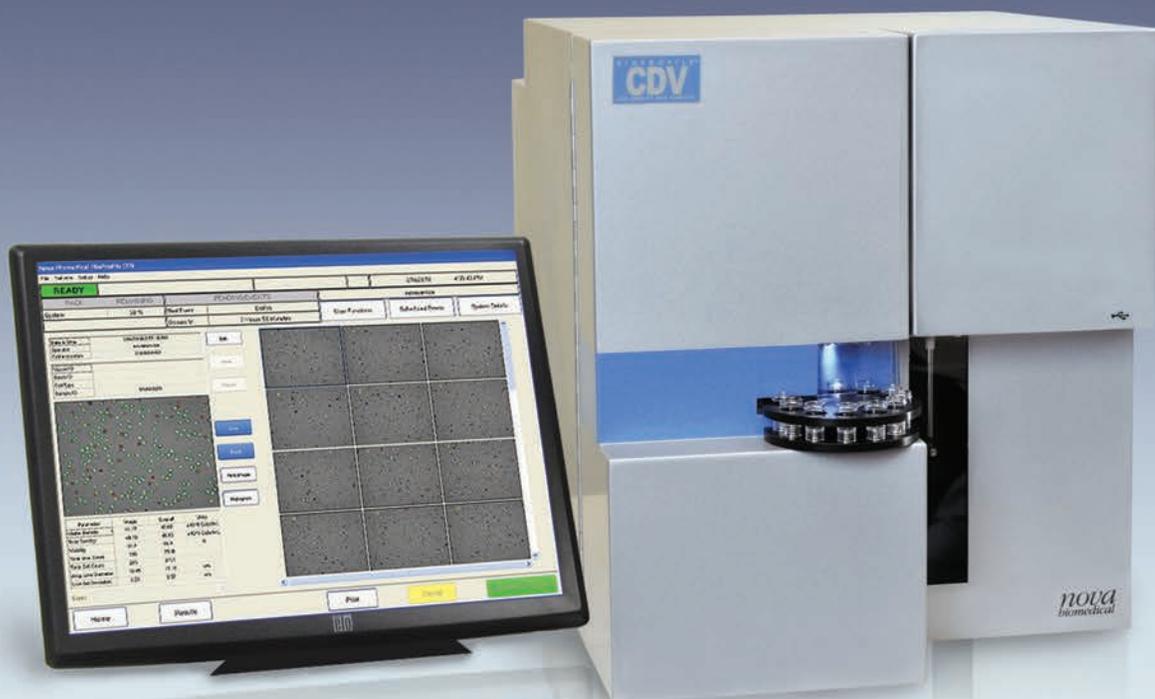


# BioProfile<sup>®</sup> CDV

## Instructions for Use Manual



*nova*<sup>®</sup>  
biomedical



# NOVA BIOMEDICAL SYMBOL DIRECTORY



*In vitro* diagnostic medical device



Discard 90 days after opening



Operator (By)



Product fulfills the requirements of Directive 98/79 EC (IVDD)



Do not use 30 days after opening



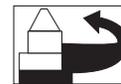
Date Opened (Test Strip Vial)



Caution, consult accompanying documents



Contents



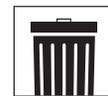
Date Opened (Control and Linearity Solution Vial)



Consult instructions for use



Manufactured by



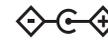
Discard Date



Biological risk



Control



Polarity



**Xi**

Irritant



Solution



On/Off



Catalog number



Level



Indoor, Dry Location Only



Batch code



This Side Up



Double Insulated



Serial Number



Fragile, Handle With Care



Ethernet Network



Temperature limitation



Keep Dry



AC (alternating current)



Upper Limit of Temperature



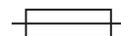
Authorized Representative in the European Community



DC (direct current)



Use by (last day of the month)



Fuse

YYYY - MM



### BioProfile® CDV Instructions for Use Manual

---

#### Part Number and Ordering Information

The BioProfile® CDV Instructions for Use Manual can be ordered from Nova Biomedical Order Services. Write or call:

Nova Biomedical Corporation	Telephone: 1-800-458-5813
200 Prospect Street	FAX: 1-781-893-6998 (in the U.S.A.) or
Waltham, MA 02454 U.S.A.	+1-781-899-0417 (outside the U.S.A.)
www.novabiomedical.com	

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#### Technical Assistance

For technical assistance inside the United States and Canada, call Nova Biomedical Technical Services at:

U.S.A.:	1-800-545-NOVA	1-781-894-0800	or FAX: 1-781-894-0585
Canada:	1-800-263-5999		

For technical assistance outside the United States and Canada, call your local Nova subsidiary or authorized distributor.

---

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BioProfile® is a registered trademark of Nova Biomedical Corporation.

The BioProfile CDV Analyzer is covered by the following patents:

U.S. Pat.No.4,686,479; U.S. Pat.No.4,759,828; U.S. Pat.No.5,352,348; U.S. Pat. No. 5,350,518.

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# BioProfile CDV Instructions for Use Manual

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# BioProfile CDV

---

## 1 Introduction

This manual provides all necessary instructions for the routine operation and maintenance of the BioProfile CDV Analyzer. Please read this manual carefully. It has been prepared to help you attain optimum performance from your analyzer.



**WARNING:** *Cell culture samples are potential sources of infectious agents. Handle all sample and flowpath components with care. Gloves and protective clothing are recommended.*

This section introduces the analyzer and covers requirements, tests performed, procedural limitations, and sample handling.

Also, this section covers the installation requirements and assembly procedures for the BioProfile CDV Analyzer.

**NOTE:** *Under the BioProfile Warranty, a Nova field service specialist will install this equipment for you.*

---

### 1.1 About This Manual

This manual is for the Nova Biomedical BioProfile CDV Analyzer.

**Throughout this manual:**

**NOTE** indicates especially important information.

**CAUTION** indicates information that is critical to avoid instrument damage or incorrect results.

**WARNING** indicates possible hazard to the operator.

## 1.2 Safety

Personnel operating this analyzer must be proficient in the operating and maintenance procedures of the analyzer. The following safety procedures must be followed.

### General Safety

1. Read the safety and operating instructions before operating the analyzer.
2. Retain the safety and operating instructions for future reference.
3. Observe all warnings on the analyzer and in the operating instructions.
4. Follow all operating and use instructions.
5. Do not install the analyzer within 5 feet of a water source.
6. Use only on a bench or stand that is recommended by the manufacturer.
7. Place the analyzer so that its location or position does not interfere with its proper ventilation.
8. Place the analyzer away from heat sources.
9. Connect the analyzer to a power supply only of the type described in the operating instructions or marked on the analyzer.
10. Do not defeat the safety purpose of the polarized or grounding type plug.
11. Route power cords so that they are not likely to be walked on or pinched by items placed upon or against them, paying particular attention to cords at plugs, power sockets, and at the point where they exit from the analyzer.
12. The analyzer should be cleaned only as recommended by the manufacturer.
13. Take care not to let objects or liquids fall into the analyzer.
14. The analyzer should be serviced only by qualified service personnel.
15. Do not attempt to service the analyzer beyond that described in the operating instructions. All other servicing should be referred to qualified service personnel.
16. Do not attempt to override the door latch safety switch unless instructed by a trained Nova Representative.

### Electrical Requirements:

- A grounded, 3-wire receptacle within 5 feet of the system is required for operation. The U.S. models require a 120 Volt AC line at 50/60 Hz frequency. The analyzer can be operated at 100-120, 220-240 Volt AC 50/60 Hz.
- It is recommended that the CDV Analyzer, computer, and monitor are connected to a 1100-1200VA Universal Power Supply to maintain the power load in the event of a power outage.

## Fuse requirements:

- 4 Amp Time Delay (SB 4A or T4A/250V) at 100-120, 220-240 Volt AC line

## Electrical Safety

1. To reduce the risk of electric shock, do not remove the cover.
2. There are **NO** operator serviceable parts inside the analyzer.
3. Servicing must be done only by qualified service personnel.
4. Before changing the fuse, unplug the power cord.
5. Replace the fuse with only the same type and rating.
6. To reduce the risk of fire or electric shock, do not expose the analyzer to water.
7. The analyzer is supplied with a main, non-rewireable plug for the intended country.
8. Ensure that the wall outlet receptacle is properly wired and earth grounded.
9. DO NOT use a 3-to-2 wire plug adapter.
10. DO NOT use a 2-wire extension cord or a 2-wire multiple-outlet power strip.

## Chemical and Biological Safety

1. Observe all precautionary information printed on the original solution containers.
2. Operate the analyzer in the appropriate environment.
3. Take all necessary precautions when using toxic materials to prevent the generation of aerosols.
4. Wear appropriate laboratory attire, e.g., safety glasses, gloves, lab coat, and breathing apparatus, when working with hazardous materials.
5. Dispose of all waste solutions according to company standard operating procedures.

## Environmental

- Indoor use at temperature between 15°C and 40°C (59°F and 104°F)
- Altitude up to 2,500 meters
- Relative Humidity of 0-85% (noncondensing)
- Installation category (II)
- Pollution degree (2)

# BioProfile CDV

---

## Dimensions:

Height:	18.5 in (47.0 cm)
Width:	16.0 in (40.6 cm)
Depth:	20.0 in (50.8 cm)

## Weight:

54.5 lb (24.72 kg) without reagent packs
59.0 lb (26.76 kg) with reagent packs

## Lifting the Analyzer:

1. Two people are needed to lift the analyzer.

**CAUTION:** *Never use the control panel or doors (open or closed) to assist you in lifting the analyzer. They cannot support the weight of the analyzer.*

2. From the left side, Person #1 places right-hand and left-hand fingertips under the finger ridge.
3. Tilt the analyzer so that both hands (one at a time) can grip under the analyzer (approximately 4 centimeters in from the front and back).
4. From the right side, Person #2 places right hand on the back of the machine to steady it as Person #1 tilts the analyzer backward.
5. Person #2 can now grip under the analyzer (approximately 4 centimeters in from the front) with the left hand. Then remove right hand from the back and grip under the analyzer (approximately 4 centimeters in from the back).
6. The analyzer now can be lifted from floor or bench and moved to a new location. If on the floor, position the analyzer to lift with your legs and not your back.
7. Reverse the directions to place the analyzer back down.

---

## 1.3 Intended Use and Tests Performed

### Intended Use

The BioProfile CDV is intended for the quantitative determination of cell density and cell viability.

---

## 1.4 The Sample

This section covers sample requirements and reference values for the Nova Bio-Profile CDV.

---

### 1.4.1 Handling Requirements

Ensure that all samples have been obtained and stored following accepted protocols. It is particularly important to ensure that samples are well mixed before introduction into the analyzer. Nova Biomedical recommends that you analyze the sample immediately to prevent changes in viability.

---

### 1.4.2 Dilution of Cell Density/Viability Samples Above the Measurement Range

If an operator is running a sample that may generate Cell Density/Viability results above the published measurement range, the BioProfile CDV can be programmed to make an increased dilution of the sample. This dilution increases the operating range of the CDV for this parameter.

- From within the Home screen in the Sample Information Section, change the Cell Density Configuration Dilution Ratio to 1:2 or 1:4 to accommodate the sample.
- When a dilution ratio is selected, the BioProfile CDV performs the dilution of the sample. No pre-dilution is required.
- A pre-dilution multiplier feature allows an operator to enter a dilution factor if the sample has been diluted externally before being analyzed by the BioProfile CDV. At the end of the sample analysis, the BioProfile CDV will factor any pre-dilution multiplier value into reported results.

# BioProfile CDV

---

## 1.5 Operation Overview

The BioProfile CDV Analyzer uses a touch screen monitor, keyboard, and mouse for menu navigation and data entry. The Home screen has mouse selectable buttons on the bottom bar: Home, Results, QC, Calibration, Maintenance, and Analyze.

The upper left-hand corner of the Home Screen reflects the state of the analyzer:

- READY (green)
- NOT READY (yellow)
- BUSY (blinking green)

The status of the reagent packs and information regarding the timing of upcoming events can be found across the top of the screen. There are 12 positions on the sample carousel. Eight samples can be loaded as 4 positions are not accessible due to proximity to the probe.

Sample specifics, including sample ID, vessel ID, etc., can be entered to distinguish the samples being analyzed. After all sample analysis specifics have been chosen and specific information relating to the dilution ratio, number of images, and the cell inspection type are entered for each sample location on the carousel, the CDV sample analysis can begin with the simple touch of the "Analyze" button found on the bottom right hand of the Home screen.

## 1.6 User Interface

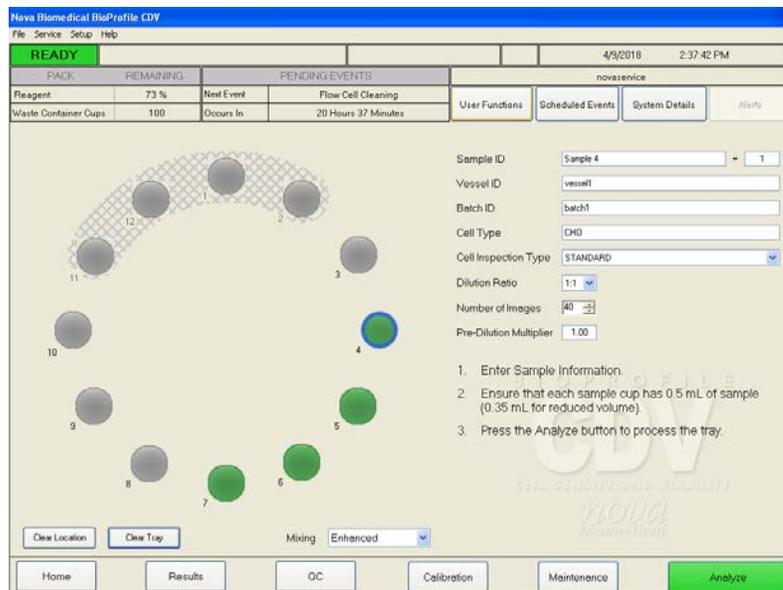


Figure 1.1 User Interface Screen

The analyzer status information is displayed at the top of every screen within the BioProfile CDV software and includes the following:

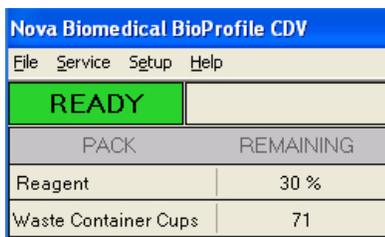


Figure 1.2 Status Box

**Analyzer Status** – The upper left-hand side of the screen shows a colored box displaying “READY” (green) or “NOT READY” (yellow), or “BUSY” (flashing green). If the system is “NOT READY,” text regarding the current state of the instrument can be found directly to the right of the status box. When Busy, the type of activity that makes the BioProfile CDV busy (calibration, maintenance, sample analysis) appears in the box to the right.

# BioProfile CDV

---

**Date and Time** – The current date and time are displayed in the upper right corner of the User Interface.



*Figure 1.3 Date and Time*

**Pack Remaining** – Displays the percent (%) fluid remaining for the reagent pack.

**CDV Reagent Pack:** Information is displayed as percent remaining for the reagent pack. The CDV pack expires for whichever comes first: the shelf-life date is reached, the 60-day use-life day is reached, or up to 500 samples have been analyzed. The CDV System reagent pack actually consists of 2 separate packs that are installed on the system at the same time.

**Waste Container Cups** – Displays how many cups the waste container can hold before emptying is required; the container can hold 100 cups.

PACK	REMAINING
Reagent	30 %
Waste Container Cups	100

*Figure 1.4 Pack Status*

**Pending Events** – The pending events section displays the next event scheduled to take place and when the event is scheduled to occur.

PENDING EVENTS	
Next Event	DePro
Occurs In	7 Hours 59 Minutes

*Figure 1.5 Pending Events*

**Current User** – Displays the ID of the user currently logged in to the BioProfile CDV system.



*Figure 1.6 Current User*

**User Functions** – Selecting this button displays the following options:

**Change Password:** This option allows the currently logged in user to change his/her password.



Figure 1.7 Change Password Dialog Box Screen

**View Privileges:** The privilege level set for the user currently logged into the system is displayed.

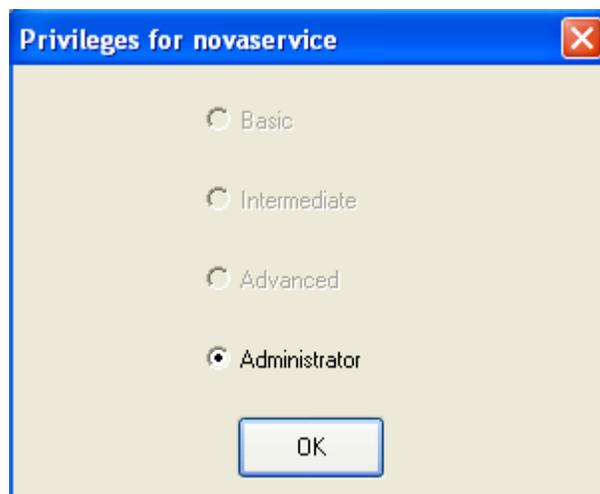
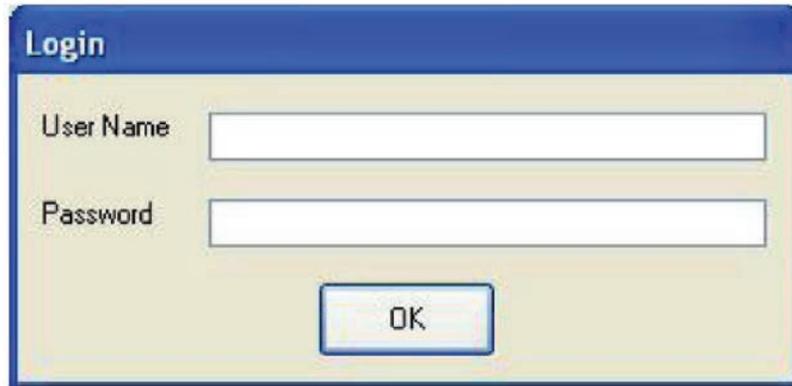


Figure 1.8 Privileges Screen

# BioProfile CDV

---

**Log out:** Selecting this item allows the user to log out of the CDV application. The Login dialog box will then appear for the next user to log in.



The image shows a 'Login' dialog box with a blue title bar. Inside the dialog, there are two input fields: 'User Name' and 'Password'. Below these fields is an 'OK' button.

*Figure 1.9 Login Dialog Box Screen*

**System Details** – Selecting System Details allows the user to check the analyzer status. Information available from within the System Details screen includes:

- Module Status (Exposure Time, Intensity)
- Well Status
- Air Detector Status
- Flow Times (Last Analysis and Calibration)

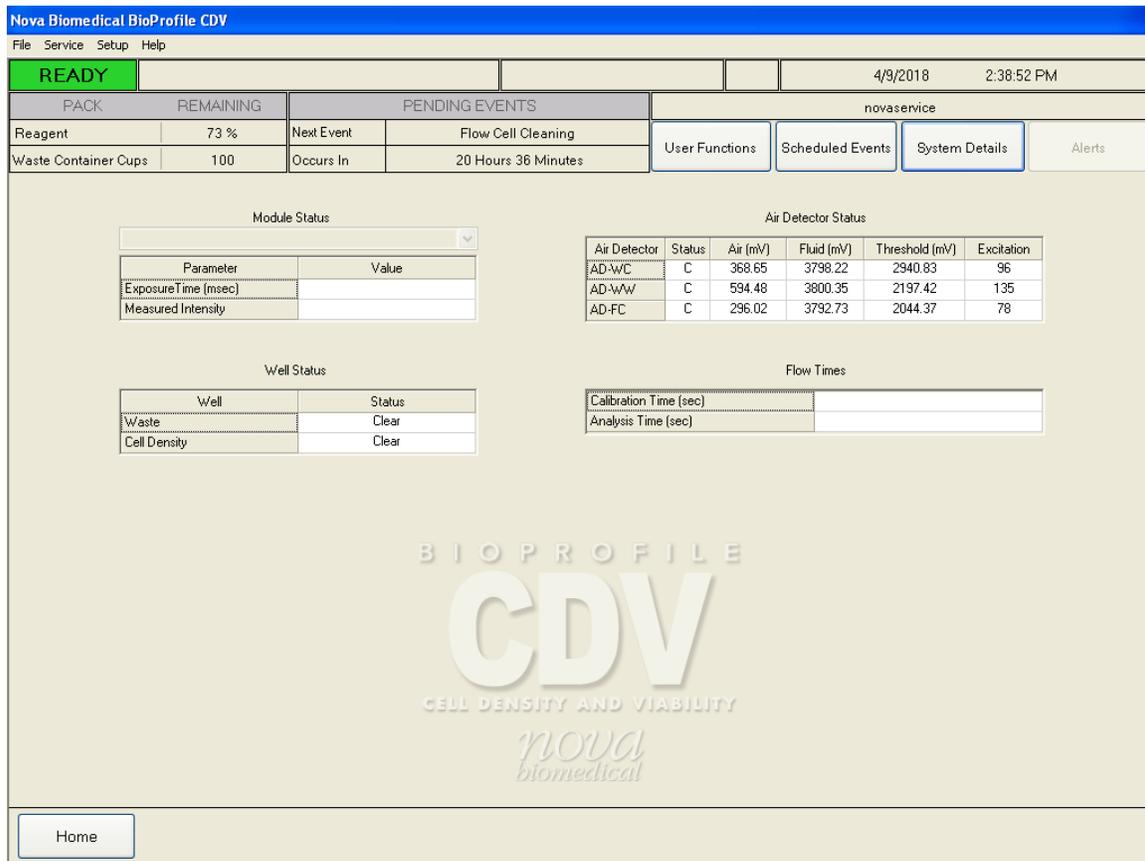


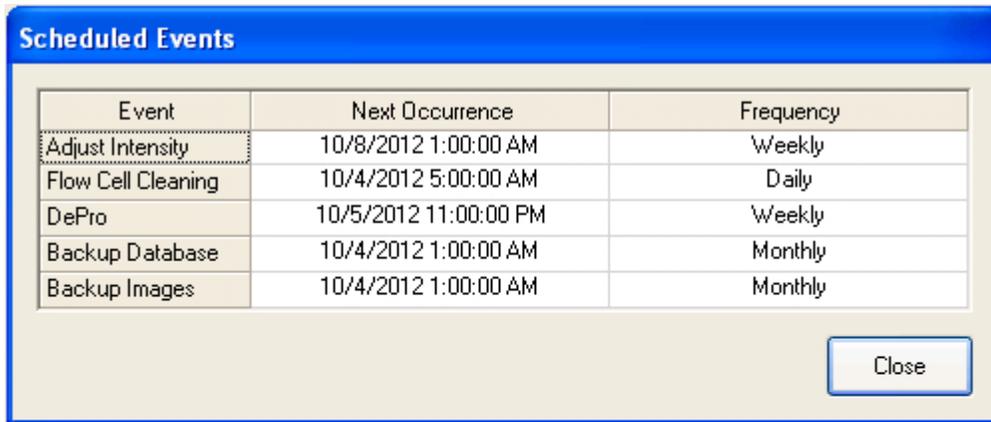
Figure 1.10 System Details Screen

# BioProfile CDV

---

**Scheduled Events** – By selecting the Scheduled Events button, a pop-up is displayed that allows the user to view the Scheduled Events screen, which contains information on upcoming events. This screen can display the following scheduled events:

- Adjust Intensity
- Flow Cell Cleaning
- DePro
- Backup Database
- Backup Images



Event	Next Occurrence	Frequency
Adjust Intensity	10/8/2012 1:00:00 AM	Weekly
Flow Cell Cleaning	10/4/2012 5:00:00 AM	Daily
DePro	10/5/2012 11:00:00 PM	Weekly
Backup Database	10/4/2012 1:00:00 AM	Monthly
Backup Images	10/4/2012 1:00:00 AM	Monthly

Figure 1.11 Scheduled Events Screen

**Alerts** – This function will alert the Administrator account that another user has unsuccessfully attempted to log in. If another user incorrectly logs in and exceeds the number of login attempts, the Alerts button will turn red, and a pop-up window will appear.



Figure 1.12 Invalid Entry Pop-up



Figure 1.13 Red Alerts Button

If the Administrator logs in, they select the red Alerts button to view the message. In addition, the incorrect user's account will become deactivated until the Administrator reactivates it. This action will be recorded in the Audit log.

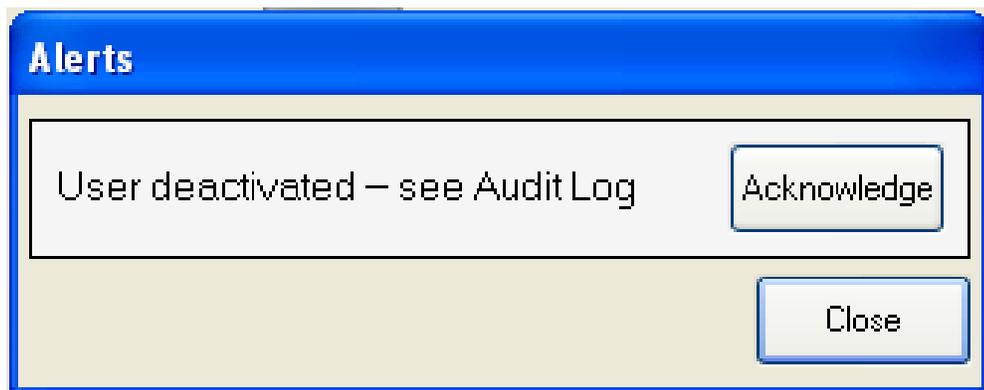


Figure 1.14 Administrator Message Pop-up

# BioProfile CDV

---

## 2 Main Menu Bar

This section describes how to set up the analyzer to analyze different types of samples. Use the Main Menu Bar to adapt the analyzer to your requirements.

The following section describes the items in the Main Menu Bar, which is present at the top of all screens and contains the following options:

- File
- Service
- Setup
- Help

An operator is able to select items in the Main Menu Bar any time that the system is not BUSY. If the system is busy, an operator can view items in the Main Menu Bar, but will not be able to select any of these items with the exception of the Help menu.

---

### 2.1 File

Selecting File displays the following pull-down menu:

- Database Management
  - Backup Database
- Audit Log
- Install Host Software
- Install Analyzer Software
- Print Screen
- Shut Down Host Computer

## 2.1.1 Database Management

Highlighting "Database Management" displays the following submenu.

- Backup Database
  - Selecting this option allows a user with appropriate privileges to backup the current database.
    - The database will be backed up to the Bridge Computer.
    - Database consists of data, images, setup information, calibration information, etc.

2.1.2 Audit Log

The Audit Log serves as an electronic trail of the changes and/or updates made to the setup of your BioProfile CDV. The Audit Log documents the date/time, user, and action performed. A list of all the actions recorded in the Audit Log can be found in Section 5.4. To view the audit log, select **Audit Log** from the File pull-down menu. From the drop-down calendar, select the date range for the Audit Log items you wish to view. The operator cannot delete or modify entries captured in the Audit Log. Notations in the Audit Log can be sorted by Date and Time or User by selecting the header of the desired column.

- **Export** the Audit Log
  - Exports a copy of the selected portion of the Audit Log to a USB drive or export folder on the Bridge Computer
  - Can be viewed in any spreadsheet program
- **Close** the Audit Log
  - Closes the Audit Log dialog box

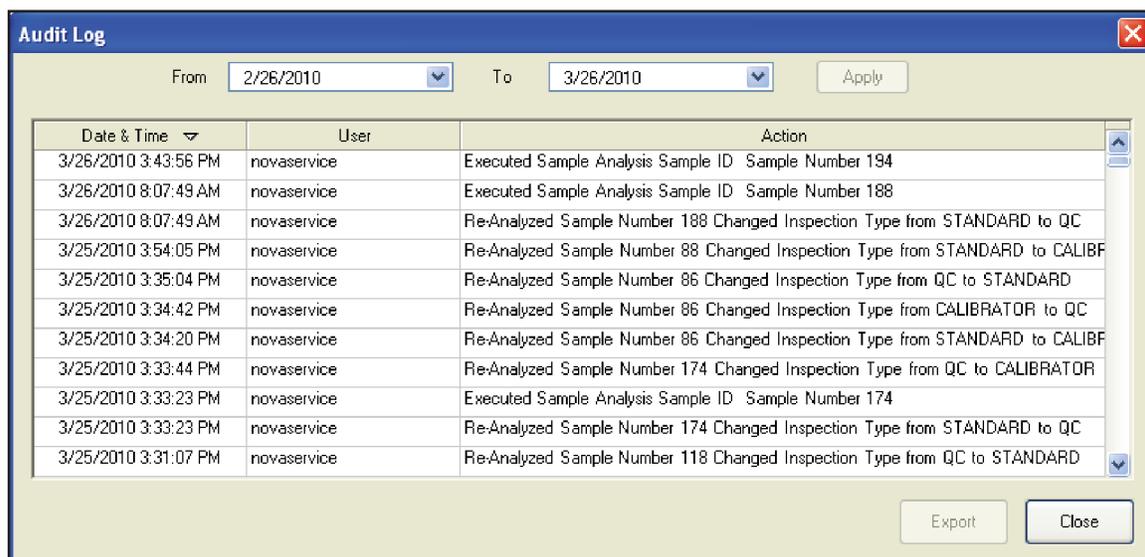


Figure 2.1 Audit Log

# BioProfile CDV

---

## 2.1.3 Install Software

An operator with the appropriate privileges is able to install software by selecting the **Install Software** function (Host or Analyzer).

**NOTE:** *Only BioProfile CDV related software can be installed on the BioProfile CDV Analyzer. No other software will be allowed. Software can only be installed by qualified service personnel*

---

## 2.1.4 Print Screen

An operator will be able to export a screen shot to the Bridge Computer or external drive.

---

## 2.1.5 Shut Down Host Computer

To shut down the Host Computer, select **Shut Down Host Computer**. This initiates a proper shutdown of the software and hardware within the host computer. Shutting down the Host Computer does not change the state of the BioProfile CDV Analyzer: it will stay in Calibration.

---

## 2.2 Service

Select **Service** to display the following pull-down menu:

- System Test
- Error Log

## 2.2.1 System Test

The System Test is a service program. **The System Test Menu should only be accessed by qualified Nova representatives.**



Figure 2.2 System Test Log In

## 2.2.2 Error Log

To view the Error Log, select **Error Log** from the Service pull-down menu. From the drop-down calendar, select the date range for the Error Log items you wish to view. Messages in the Error Log can be sorted by Date and Time or Description by selecting the column header. The operator cannot delete or modify the Error Log.

- **Export** the Error Log.
  - Exports a copy of the selected portion of the error log to a USB drive or export folder on the Bridge Computer.
  - Exported items can be viewed in any spreadsheet program.
- **Close** the Error Log.
  - Closes the error log dialog box

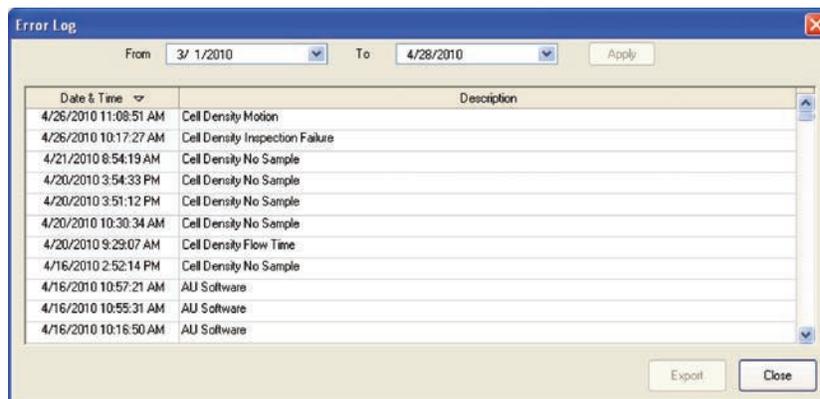


Figure 2.3 Error Log

## 2.3 Setup

Select Setup to display the following pull-down menu:

- Create/Edit Users
- Analyzer Information
- Units of Measure
- Cell Inspections
- Scheduled Maintenance
- Scheduled Backups
- QC Levels
- Auto Complete
- Auto Export
- Date and Time
- Auto Logout
- Results Screen Image Layout
  - 3 images wide by 4 images high
  - 4 images wide by 5 images high

## 2.3.1 Create/Edit Users

An operator with appropriate privileges is able to do the following:

- Create/deactivate a user
- Change Password
- Apply/Add privileges to a user

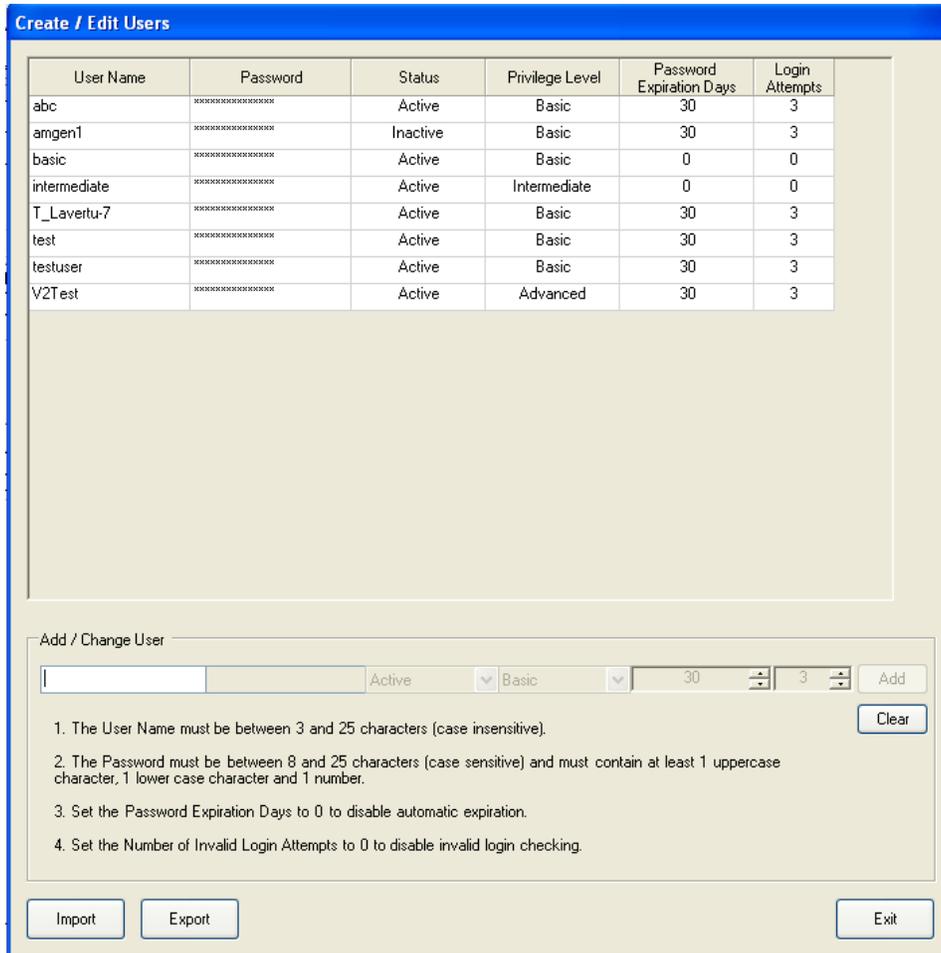


Figure 2.4 Edit Users Screen

From within the Setup pull-down menu, select **Create/Edit Users**.

To create a new user:

- Enter a User Name. The User Name must be 3 - 25 characters. User names are not case-sensitive. User names cannot begin or end with a blank space and cannot contain special characters.

# BioProfile CDV

- Enter a password for this user that contains at least one upper case alpha character, one lower alpha character, and one numeric value. Passwords must be 8 - 25 characters.
- In the dropdown, select the User Status (active or inactive).

**NOTE:** *Inactive User Accounts cannot log in to the system.*

- In the next dropdown box, select the Privilege Level (Basic, Intermediate, Advanced, Administrator) for the User Account.
- The available functions for each privilege level are outlined in the table that follows.

Privilege Level Table					
	Basic Privilege	Intermediate Privilege	Advanced Privilege	Admin. Privilege	Admin. Account
<b>File</b>					
View Audit Log	X	X	X	X	X
Export Audit Log Entries	X	X	X	X	X
Export Print Screen Images	X	X	X	X	X
Shut Down Host Computer	X	X	X	X	X
Backup The Database		X	X	X	X
Install Host Software*				X	X
Install Analyzer Software*				X	X
<b>Service</b>					
View Error Log		X	X	X	X
Export Error Log		X	X	X	X
<b>Setup</b>					
Change Result Screen Image Layout	X	X	X	X	X
View/Edit Analyzer Information			X	X	X
Configure Units of Measure			X	X	X
View/Edit/Configure Cell Inspection Types			X	X	X
Configure Scheduled Maintenance			X	X	X
Configure Scheduled Database/Image Backups			X	X	X
Configure QC Levels			X	X	X
Configure Auto Completion (Sample Indexing)			X	X	X
Configure Auto Export			X	X	X
Configure Date & Time			X	X	X
Configure Auto Logout			X	X	X
Create/Edit Users				X	X
<b>Help</b>					
View Support Info	X	X	X	X	X
Export Diagnostic Logs			X	X	X

	Basic Privilege	Intermediate Privilege	Advanced Privilege	Admin. Privilege	Admin. Account
<b>User Functions</b>					
Change Personal Password	X	X	X	X	X
View Privilege Level	X	X	X	X	X
Log Out	X	X	X	X	X
View Scheduled Events	X	X	X	X	X
View System Details	X	X	X	X	X
<b>Analyze</b>					
Configure & Run a Sample Analysis	X	X	X	X	X
<b>Results</b>					
View Results & Images	X	X	X	X	X
Export/Print Results & Images	X	X	X	X	X
Export Histogram	X	X	X	X	X
View/Export Growth Calculations	X	X	X	X	X
Edit Sample Information		X	X	X	X
Re-Analyze A Sample		X	X	X	X
<b>QC</b>					
Run QC Analysis	X	X	X	X	X
View/Export/Print QC Results	X	X	X	X	X
<b>Calibration</b>					
Perform Module Calibration	X	X	X	X	X
Perform Air Detector Calibration	X	X	X	X	X
<b>Maintenance</b>					
Install Reagent Pack	X	X	X	X	X
Prime Flow Cell	X	X	X	X	X
Clear Wells	X	X	X	X	X
Analyzer Shut Down Procedure	X	X	X	X	X
Initialize the Tray (Carousel)	X	X	X	X	X
Flow Cell Cleaning		X	X	X	X
Intensive Cleaning		X	X	X	X
Adjust Intensity		X	X	X	X
DePro		X	X	X	X
<b>*Procedures should only be performed by trained Nova Service Personnel</b>					

- Set the number of days after which the password will expire. Setting this number to 0 gives the password no expiration.
- Set the number of failed login attempts that a user can try before the account is made inactive, Setting this number to 0 means there is no limit to the number of failed logins. It can only be made active again by a user with Administrator privileges.
- Select the "Add" button to save the user account.

# BioProfile CDV

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## **To Change a User Account:**

- Select the User Account from the list at the top of the menu.
- Edit the Password, Status, Privilege Level, Expiration Days, or Login Attempts.
- Select the "Change" button to save the changes
- Select Exit to exit the Create/Edit Users Menu.

## **User Privilege Levels:**

The system will support user privilege levels including basic, intermediate, advanced, administrator privilege, and administrator account.

### **Basic Privilege:**

Users with basic privileges shall have access to the basic functions of the analyzer including calibration, perform QC analysis, and run samples.

### **Intermediate Privilege:**

Users with the Intermediate Privilege shall be able to perform all functions that can be done by a user with the basic privileges plus have the ability to edit sample information, export error logs, and perform additional maintenance.

### **Advanced Privilege:**

Users with the Advanced Privilege shall be able to perform all functions that can be done by a user with the Intermediate Privileges plus configure scheduled events and access/edit quality control levels and cell inspection types.

### **Administrator Privilege:**

Users with the Administrator Privilege shall be able to perform all functions that can be done by a user with the Advanced Privileges. Additionally, an administrator can create and edit user accounts.

### **Administrator Account:**

The system shall support an account with the username Administrator which will have all administrator privileges. This account cannot be deactivated or exported.

### **Account Status:**

The system shall support 2 levels of account status, active, and interactive.

- A system Administrator shall be able to manually deactivate a user either at the Create/Edit Users Screen directly or by file importation.
- A system Administrator shall be able to manually re-activate a user either at the Create/Edit Users Screen directly or by file importation.

### **Password Expiration:**

The administrator can set the number of days a password is active.

### Login Attempts:

The administrator shall be able to set the number of invalid login attempts (incorrect password for an established user) before the user account is deactivated.

### Exporting and Importing User Accounts:

An end user with appropriate privileges can export and import User Accounts and settings from one system to another.

- Insert a USB drive into an available USB port on the analyzer.
- In the Create/Edit Users Menu, select the Export button, then select the USB drive that the file will be exported to.
- Insert the USB drive on another system. From the Create/Edit Users Menu, select the Import button and the appropriate USB drive location to import the user account settings.

## 2.3.2 Analyzer Information

Analyzer information (Analyzer ID, Location, and Serial Number) can be configured in order to identify your BioProfile CDV Analyzer. The analyzer information will be included on every printed report and appended on exported files.



Figure 2.5 Analyzer Information Screen

## 2.3.3 Cell Inspections

### Assay Description

Cell Density and/or Cell Viability (CDV) is the measurement of the total number of cells in suspension and a proportional determination of live and dead cells. To best understand how results are calculated and the parameters that affect CDV measurement, it helps to have an overview of how the analyzer works.

1. A sample is aspirated by the sample probe and dispensed into the analysis well.

## BioProfile CDV

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2. The sample is mixed with Trypan Blue and advanced to the imaging cuvette where the cells are allowed to settle.
3. The imaging cuvette is indexed up to 40 locations for analysis.
4. The sample is discarded as waste. The analysis well, tubing lines, and imaging cuvette are cleaned in preparation for the next sample.
5. The analysis is performed by the onboard imaging system, and the raw images are stored uncompressed on the operating system computer hard drive for potential re-analysis. Compressed images are also saved for later viewing.
6. At the completion of the imaging process, the BioProfile CDV displays virtual slides that can be enlarged by the user for closer inspection.

These images are subjected to analysis using the Cell Density Inspection Type Parameters. As digital images, they are not subject to degradation and can be re-analyzed with new parameters at any time within 60 calendar days of imaging. The BioProfile CDV applies the parameters to the images and presents the user with both a graphical and numerical representation of the results. Ten separate parameters can be configured including brightness thresholds, size, focus, and settling time.

**NOTE:** *After 60 days, uncompressed bitmaps are deleted. Compressed JPEGs are present in a database at the completion of the analysis. The images are stored and can be viewed but once compressed, the images can no longer be reanalyzed.*

---

### 2.3.3.1 Live and Dead Cell Identification

#### **Trypan Blue Exclusion**

The Trypan Blue Exclusion test is used to determine the number of viable cells present in a cell suspension. It is based on the principle in which, unlike dead cells, live cells possess intact cellular membranes that exclude Trypan Blue dye. A cell suspension mixed appropriately with Trypan can be visually examined to determine whether individual cells take up or exclude dye. Viable cells have clear cytoplasm whereas nonviable cells have blue cytoplasm.

#### **Programmed Cell Death**

Apoptosis is typically a passive, degenerative process, which is characteristically different from cell necrosis in morphology and biochemistry. Apoptosis results in the condensation of the nucleus and decrease in cellular volume, eventually leading to the fragmentation and blebbing of the cell. These smaller constituents (apoptotic bodies) may be confused for individual small dead or live cells. The life cycle within a properly maintained cell culture typically follows natural cell growth and death via apoptosis. Observable cellular morphology coupled with Trypan exclusion allows the CDV to correctly ascertain the differences between live and dead cells.

## 2.3.3.2 Configuring the Cell Density Module

### Cell Inspection

The CDV allows you to configure 10 parameters that can affect how the sample is read and interpreted. These parameters include: Live Cell Brightness Threshold, Live Cell Minimum Size, Dead Cell Brightness Threshold, Dead Cell Minimum Size, Average Dead Cell Diameter, Dead Cell Aggregate Area, Debris Size Threshold, Focus Offset, Settling Time, and Cell Density Multiplier. All parameters except for Focus Offset and Settling Time can be readjusted and used to reanalyze prior images to allow for optimum cell inspection configuration. It is important to note that although the Focus Offset and Settling Time can be adjusted at any time, these changes are not applied until a new sample is physically run.

To review or edit an existing Cell Inspection Type or to create a new one:

1. From the Home screen select **Setup** from the menu bar.
2. Select the **Cell Inspections** menu.
3. With the proper user privileges, all of these inspection types can be modified except "Standard." The Focus Offset Parameter for the inspection type labeled "QC" and "Standard CHO" can be modified if needed.

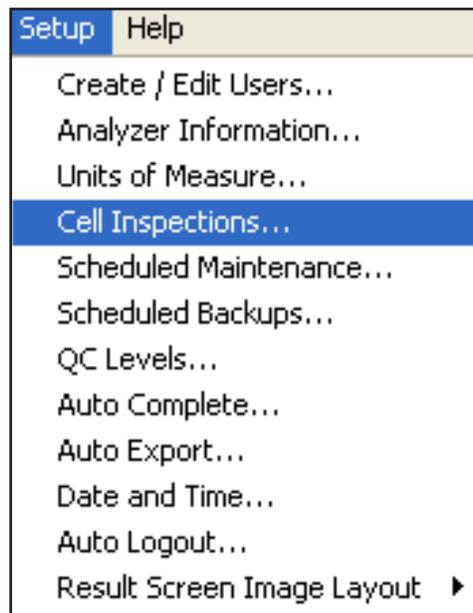


Figure 2.6 Cell Inspections Drop-Down Menu

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4. New inspection types can be created by checking the box next to “Create new cell inspection type.” You may base your new inspection type on any existing type by selecting **Based on** and choosing the appropriate inspection type in the drop down menu.

Configure Cell Inspections

Inspection Type: CHO-2 [Deactivate]

Create new cell inspection type

Based on: STANDARD

Inspection Data

Parameter	Value	Units	Lower Limit	Upper Limit
Live Cell Brightness Threshold	160		0	255
Live Cell Minimum Size (Diameter)	4.00	um	0.00	100.00
Dead Cell Brightness Threshold	80		0	255
Dead Cell Minimum Size (Diameter)	8.00	um	0.00	100.00
Dead Cell Aggregate Area	600	um <sup>2</sup>	0	100000
Average Dead Cell Diameter	20.00	um	0.00	100.00
Debris Size Threshold	2500	um <sup>2</sup>	0	100000
Focus Offset	-12		-50	50
Settling Time	60	sec	15	240
Cell Density Multiplier	1.000		0.700	1.300

[OK] [Apply] [Cancel]

Figure 2.7 Configure Cell Inspections Screen

## 5. Cell Inspection Parameters

The “Standard” and “Standard CHO” cell inspection types were based on numerous cell lines tested at Nova Biomedical. While this is a good starting point, they are not intended as a final inspection type. Customization of an inspection type will greatly improve the accuracy of your cell count.

### a. Live Cell Brightness Threshold

- i. Live Cell Brightness is measured from 0 to 255 on a scale where zero is black and 255 is white. The normal background of a Trypan stained slide is around 127.
- ii. Changing this parameter results in changes to the minimum allowable threshold of a live cell. For example, a slightly dark live cell may not be counted at a setting of 200 but is counted correctly at a setting of 180.

## b. Live Cell Minimum Size (Diameter)

- i. Changing this parameter increases or decreases the minimum size allowable to distinguish a live cell.
- ii. Using your knowledge of your own cell lines, set this number to the size you feel is adequate for a small live cell. For example, if the average CHO cell is 12.5  $\mu\text{m}$ , you may find a setting of 8-9 may work best to include small viable cells while excluding smaller apoptotic bodies.
- iii. Decrease this number if live cells are bright, slightly small and not counted as live.

## c. Dead Cell Brightness Threshold

- i. Dead Cell Brightness is measured from 0 to 255 on a scale where zero is black and 255 is white. This setting sets the upper limit for dead cell brightness.
- ii. Increase this number if dead cells are light in color and are not counted as dead.

## d. Dead Cell Minimum Size (Diameter)

- i. This parameter sets the minimum size a cell needs to be in order to be distinguished as dead.
- ii. If debris from lysed cells are counted as dead cells, increasing this number excludes the smaller non-cell items.
- iii. Decrease this number if small dead cells are not counted.

## e. Average Dead Cell Diameter

- i. This number is used to calculate the number of dead cells in an aggregate clump.
- ii. Typically this number is 2-3  $\mu\text{m}$  smaller than the average live cell diameter.
- iii. Change this number if aggregate clumps of dead cells are not being counted correctly. For example, if you have a clump made up of what appears to be 10 dead cells, yet the orange aggregate count is 25 you need to increase the Average Dead Cell Diameter.

## f. Dead Cell Aggregate Area

- i. This parameter sets the minimum area the BioProfile CDV counts a clump as an aggregate of dead cells.
- ii. This number approximates the area taken by 2 or more dead cells in a clump ( $\mu\text{m}^2$ ).

## g. Debris Size Threshold

- i. This number sets the minimum area the BioProfile CDV counts as debris. An image with debris present is excluded from the analysis.
- ii. Increasing this number allows smaller debris to be present without excluding the image from the analysis.

## h. Focus Offset

- i. This parameter is the focus setting for the cell type.
- ii. Changing this number changes the distance between the objective lens and the cuvette stage.
- iii. A more positive number decreases the distance between the objective lens and the cuvette.
- iv. A properly focused image has all of the cells in that image in crisp focus with well defined nuclei and cell membranes.

## i. Settling Time

- i. This parameter changes the amount of time (in seconds) the cells are allowed to settle before beginning the imaging process.
- ii. Increase this number if cells appear in multiple planes when the images are captured.
- iii. The settling time clock is initiated once the entire sample has been pumped into the cuvette.

## j. Cell Density Multiplier

- i. This parameter allows the user to set a multiplier (0.700 - 1.300) that adjusts the total and viable densities when correlating to a reference analyzer.

6. After you have entered values in the inspection data, save your settings by selecting "Apply" or "OK."
7. Exit the configuration menu by clicking either OK or Cancel.

**NOTE:** Selecting **OK** saves the settings.

### 2.3.4 Configure Scheduled Maintenance

The BioProfile CDV allows you to schedule automated maintenance cycles. By selecting **Scheduled Maintenance**, the user is able to automate the Adjust Intensity, Flow Cell Cleaning and Depro sequences. These maintenance routines can all be performed manually as well through the Maintenance Screen.

#### Adjust Intensity

- The Adjust Intensity sequence is performed to confirm the concentration of Trypan Blue solution in the reagent pack. During this procedure, a sample of the Trypan solution is aspirated and analyzed for change in concentration based on reagent evaporation.
- It is recommended that the Adjust Intensity procedure is performed on a weekly basis or, if necessary, more frequently.
  - When programming your BioProfile CDV to perform automated Adjust Intensity cycles, select **Change Schedule**, select a start date, time, and select a frequency. Select **Activate Schedule** then select **OK**.

#### Flow Cell Cleaning

- The Flow Cell Cleaning sequence is a cleaning routine performed using the reagents contained in the CDV Reagent Pack. This cleaning can be performed as often as necessary.
- The Flow Cell Cleaning takes approximately 10 minutes to complete.
- It is recommended that the Flow Cell Cleaning be performed daily whenever cell samples are run.
  - When programming your BioProfile CDV to perform automated Flow Cell Cleaning cycles, select **Change Schedule**, select a start date and time, and select a frequency. Select **Activate Schedule** then select **OK**.

#### Depro

- The Depro sequence is a cleaning routine performed using the Deproteinizing solution found in the CDV Reagent Pack.
- It is recommended that the Depro sequence be performed weekly or, if necessary, more frequently.
  - When programming your BioProfile CDV to perform automated DePro cycles, select **Change Schedule**, select a start date and time, and select a frequency. Select **Activate Schedule** then select **OK**.

**Configure Scheduled Maintenance**

Adjust Intensity

Activate Schedule

Change Schedule

Start 9/17/2010 1:00:00 AM Frequency Weekly

Flow Cell Cleaning

Activate Schedule

Change Schedule

Start 9/17/2010 1:00:00 AM Frequency Weekly

DePro Module

Activate Schedule

Change Schedule

Start 10/ 1/2010 1:00:00 AM Frequency Monthly

OK Cancel

Figure 2.8 Configure Scheduled Maintenance Screen

## 2.3.5 Scheduled Backups

The Scheduled Backups feature allows the operator to program a scheduled frequency to automatically backup the database or backup CDV images to the export folder locations on the Bridge Computer.

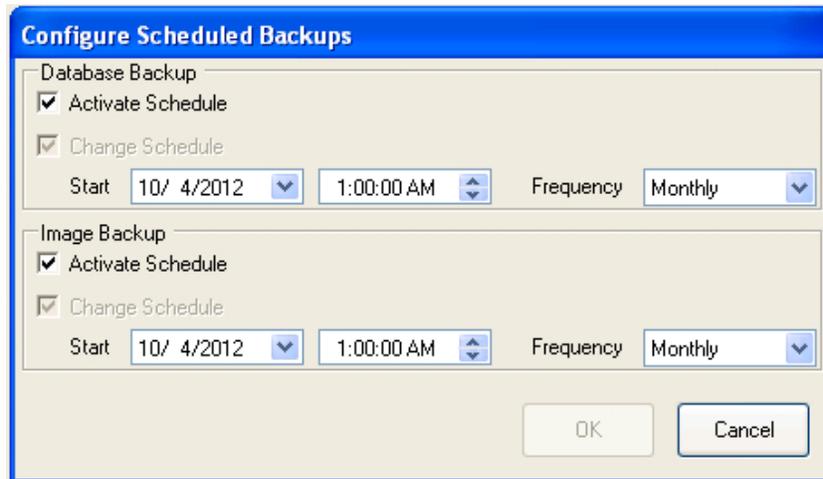


Figure 2.9 Configure Scheduled Backups Screen

## 2.3.6 QC Levels

Selecting the QC Levels menu allows an operator with sufficient privileges to setup Quality Control ranges for total density.

Available QC Control Levels for the BioProfile CDV are as follows:

Level 8: Cell Density (Low)

Level 9: Cell Density (High)

All of the information necessary to setup QC is provided on the insert sheets included with each box of quality control material. This information includes Lot Number, Expiration Date, Storage Conditions, and Reference Ranges for the BioProfile CDV.

# BioProfile CDV

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## 2.3.6.1 QC Setup

To setup QC ranges, first select **Setup** then **QC Levels**. This displays the Configure QC Levels screen. From the Configure QC Levels screen, select the Level of QC to be configured from the drop-down list.

**NOTE:** *If a QC level has never been configured it is displayed grayed out. Once the level has been configured, it is displayed in black text.*

Parameter	Lower Limit	Upper Limit	Units
Total Density	1.00	800.00	x10 <sup>5</sup> Parts/mL

Figure 2.10 Configure QC Levels Screen

- First, select the **Create new lot** check box.
- Enter the QC Lot Number in the space provided.
- Select the QC lot's Expiration Month from the drop-down list
- Select the QC lot's Expiration Year from the drop-down list.
- Select the Lower Limit field and enter the Lower Limit from the control's insert sheet.
- Press Tab or select the next field and enter the Upper Limit from the insert sheet.
- Select **OK** or **Apply** to save the programmed QC Level information.
- Select **OK** or **Cancel** to exit the Configure QC Levels menu.

**NOTE:** *The default Lower Limit and Upper Limit are the measurement range of the analyzer.*

## 2.3.7 Auto Complete

The Auto Complete Screen shows past Sample IDs, Batch IDs, Vessel IDs, and Cell Types that have been used. Each category in the dropdown box will contain the associated IDs. Past IDs can be deleted by selecting and clicking delete. Samples can be indexed by letter or number.

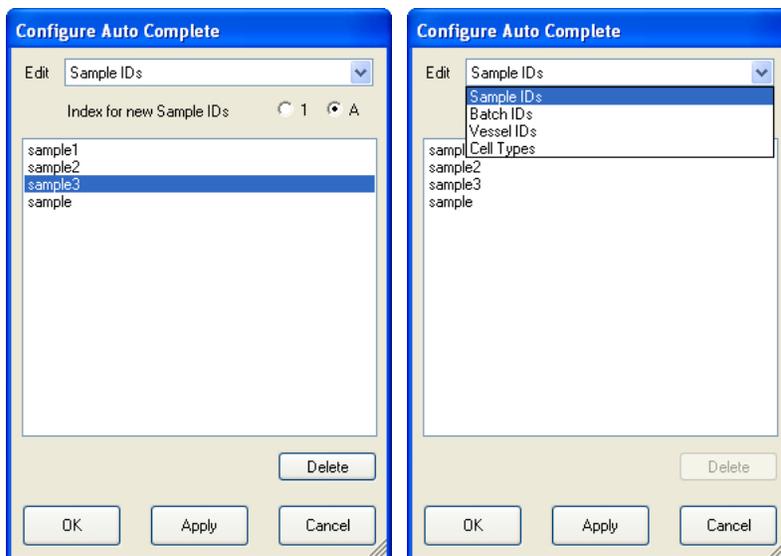


Figure 2.11 Configure Auto Complete Screen

## 2.3.8 Auto Export

By selecting Auto Export and by checking the sample results box, the data will be automatically exported to the bridge computer after each sample analysis.

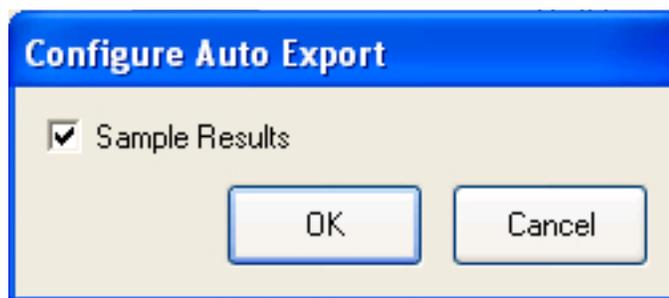


Figure 2.12 Configure Auto Export Screen

## Automatic Exporting of Sample Results

- This functionality is enabled in the Setup menu of the CDV User Interface.

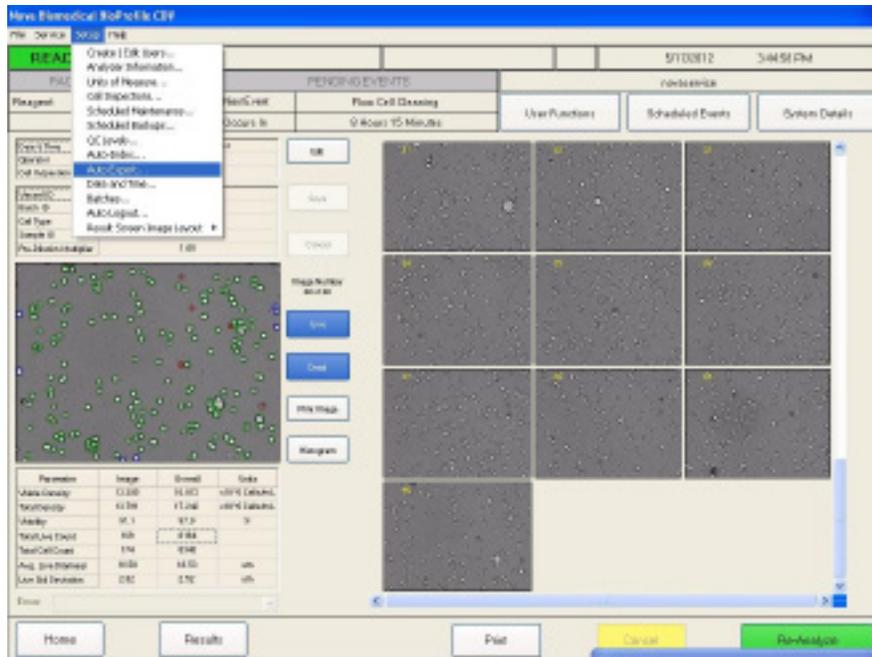


Figure 2.13 Auto Exporting of Sample Results Screen



Figure 2.14 Configure Auto Exporting of Sample Results: OK/Cancel Pop-up

- Data can be configured to export to the Bridge Computer after each sample analysis.
- Files are sent as .csv read-only files.
- Only sample data for samples analyzed after the feature is enabled will be exported. All samples analyzed prior to enabling of this feature will not be automatically exported. However, these samples can be manually exported.

- At the beginning of each month, a new file is created and named SampleResults<Year>-<Month>.csv.
- Each time a sample is analyzed, a new file is sent in its entirety to ensure that a communication error does not lose any of the previous data. The file is “closed” at the end of each month.
- The Files are placed in the Bridge Computer’s Export Results Folder.

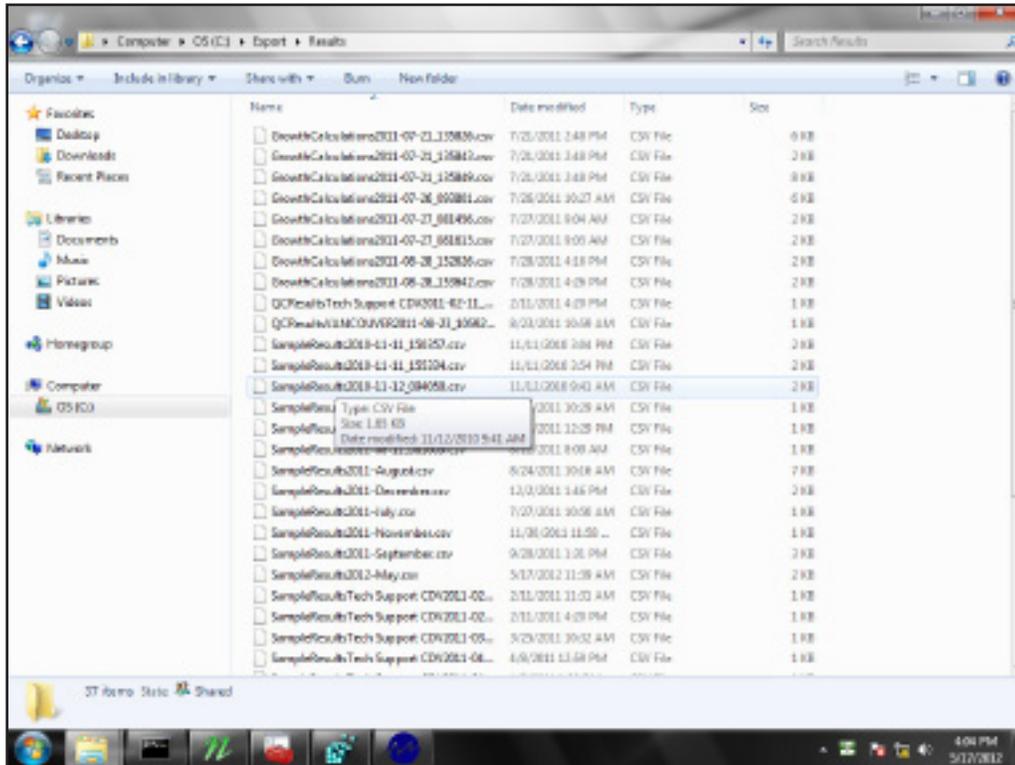


Figure 2.15 Bridge Computer's Export Results Screen

- The data on the Bridge Computer can be found within the C:\Export\Results folder.

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## 2.3.8.1 Scheduled Backups of Data to the Bridge Computer

- The BioProfile CDV database and sample images can be automatically exported to the Bridge Computer using the Scheduled Backups function.
- This functionality is accessed through the Setup menu (Scheduled Backups > Configure Scheduled Backups).

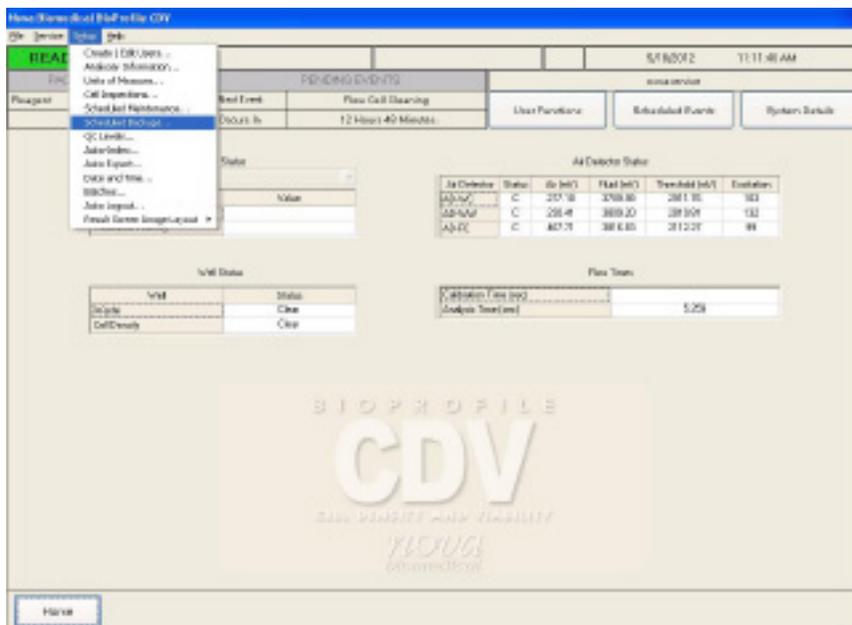


Figure 2.16 Scheduled Backups Screen

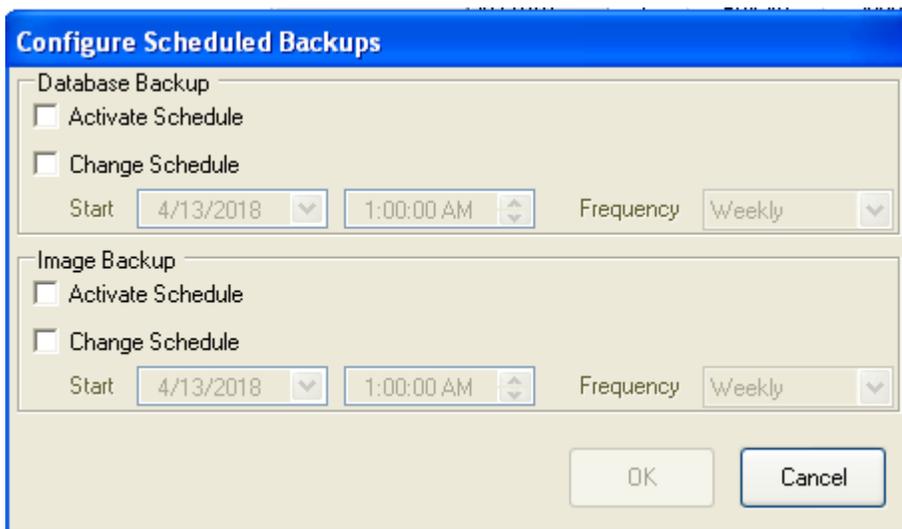


Figure 2.17 Configure Scheduled Backups

- When this function is configured, the files are exported to the C:\Export\Database\Backup and the C:\Export\Images folders respectively on the Bridge Computer.
- The database and individual sample images can also be exported manually (one at a time) to the Bridge Computer.
- Additional Manual Exports available include:
  1. Audit Log
  2. Error Log
  3. QC Results
  4. Growth Calculations
  5. User Interface Diagnostic Logs

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## 2.3.8.2 Connecting to Domains and Network Printers

- The Bridge Computer can be set up to allow individual user logins (on a specific domain). For specific instructions on how to set up User Logins on the Bridge Computer to a domain, please have your IT department contact Nova Technical Support.
- The BioProfile CDV Analyzer can be connected to a network printer through the Bridge Computer. This allows the operator to print results directly from the CDV User Interface.

# BioProfile CDV

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## 2.3.9 Date and Time

The Date and Time menu allows the operator to program the correct Date and Time for the BioProfile CDV analyzer. The Date and Time are recorded in the Sample Results each time a sample is analyzed.

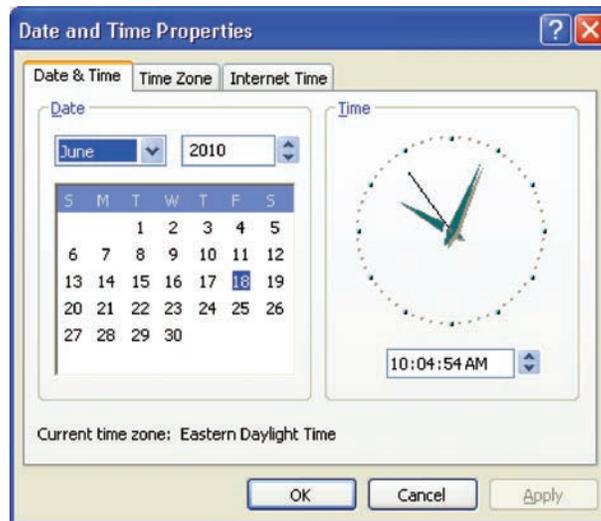


Figure 2.18 Date and Time Properties Screen

## 2.3.10 Auto Logout

This feature allows a user to set a scheduled Auto Logout time for the BioProfile CDV system.

### To set the Auto Logout feature

1. Select Auto Logout from the Setup menu.
2. Select the box marked “Enabled” in the Configure Auto Logout window.
3. Select the interval (minutes).
4. Select OK.

Once the Auto Logout feature is set and enabled, the system will automatically log the current user out if the analyzer detects no external activity for the set interval.

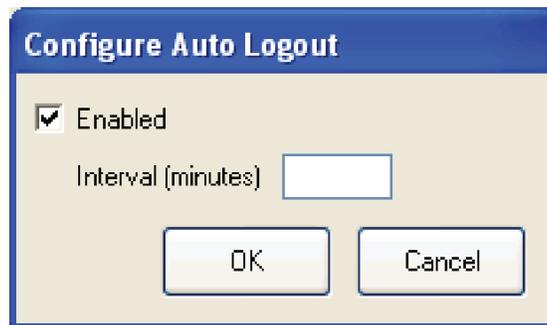


Figure 2.19 Configure Auto Logout Screen

## 2.3.11 Results Screen Image Layout

The Results Screen Image Layout lets the operator choose the format of how the sample result images will be displayed on the Results screen. The images are generated during an analysis and can be displayed as either 3 x 4 or 4 x 5.

# BioProfile CDV

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## 2.4 Help

Selecting the Help menu displays the following:

- About BioProfile CDV
  - If an operator selects this option, the About BioProfile CDV Host Computer System Screen is displayed. This screen displays the software running on the analyzer.

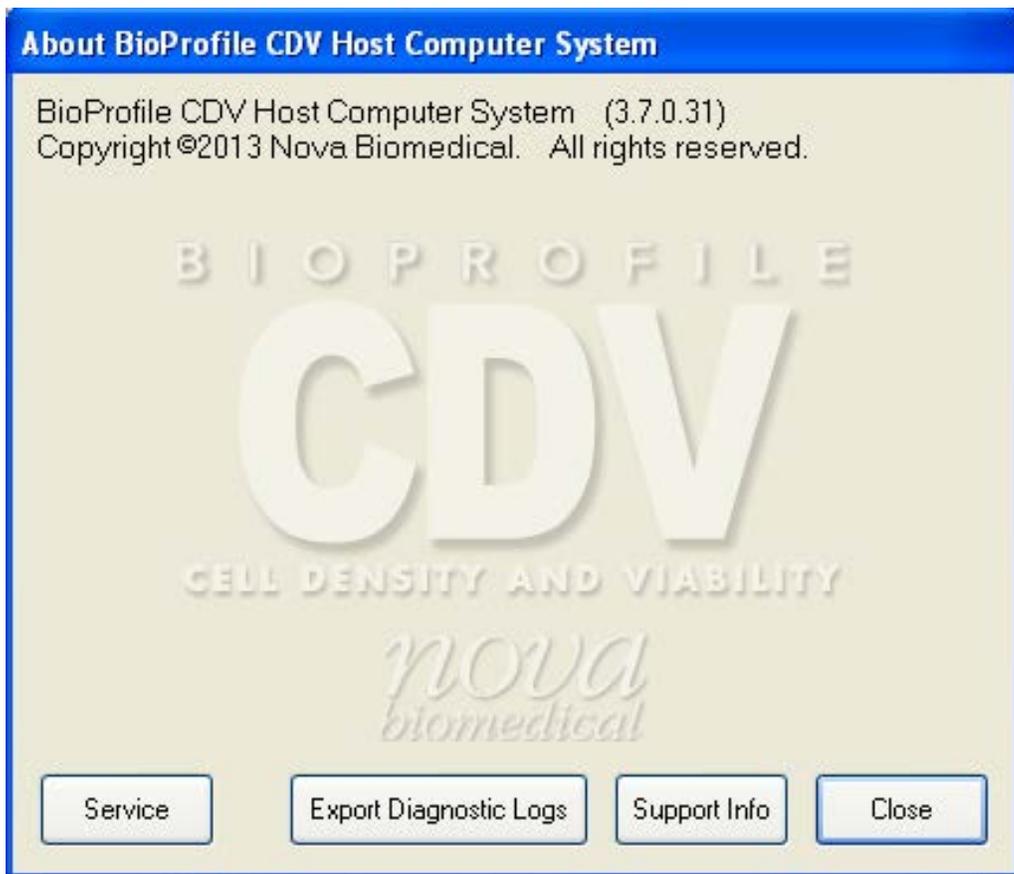


Figure 2.20 About BioProfile CDV Screen

Four Options can be selected from this Screen:

1. Service
  - The Service button is to be used by Nova Field Support Representatives only.
2. Export Diagnostic Logs Button
  - The BioProfile CDV Diagnostic Logs can be exported to a USB drive or to the Bridge Computer using this button.

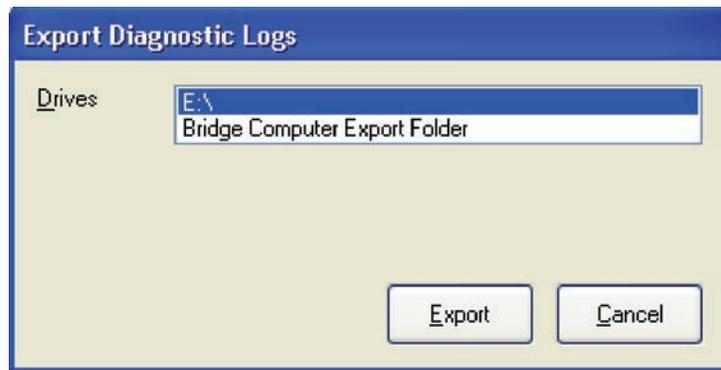


Figure 2.21 Export Diagnostic Logs

### 3. Support Info

- The Support Info button displays a screen that shows version information for the software programs running on the BioProfile CDV system.

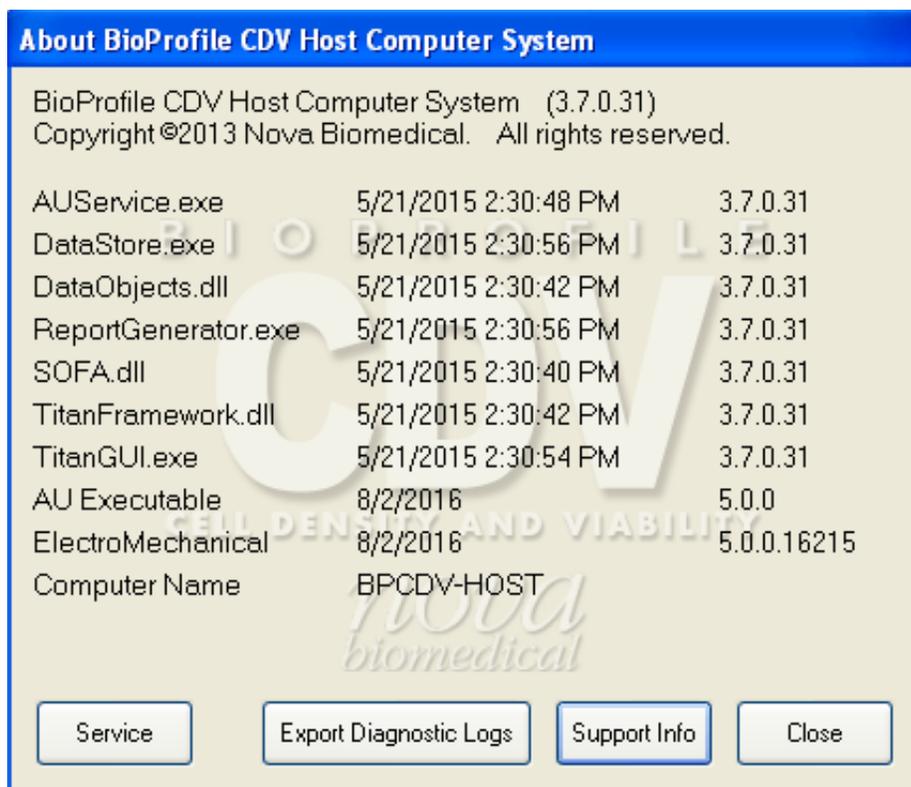


Figure 2.22 About BioProfile CDV Screen Support Info Button

### 4. Close

- The Close button closes the About BioProfile CDV window.

# BioProfile CDV

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## 3 Operation

This section describes how to operate the analyzer. The BioProfile CDV Components consists of the following items:

1. Computer Monitor, Keyboard, and Mouse
2. Bridge Computer
3. Customer Provided USB Printer (Not included/provided by Nova Biomedical)
4. Analytical Compartment
5. KVM switch to switch keyboard, monitor, and mouse between CDV User Interface and Bridge Computer Interface.

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### 3.1 Monitor, Keyboard and Mouse

The Computer Monitor displays information on system functions, how to access system functions, and output sample results. The operator has a keyboard and mouse to access control to the analyzer.

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### 3.2 Bridge Computer

The Bridge Computer serves as a bridge between the BioProfile CDV Analyzer and a customer network. It can be added to a network domain and BioProfile CDV data can be exported to it, making the data conveniently accessible.

The Bridge Computer runs the Microsoft® Windows 7™ operating system. Customer domain policies can be pushed to it and customer-required software (e.g. anti-virus software) can be installed on it.

The BioProfile CDV includes a KVM (Keyboard Video Mouse) switch that allows both the CDV User Interface and Bridge computers to be controlled by a single keyboard, video, and mouse set.

# BioProfile CDV

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## 3.3 Printer

The BioProfile CDV does not come with a printer. A USB printer can be installed by the operator.

**NOTE:** *If the printer driver is not recognized by the system, the appropriate drivers can be installed onto the Bridge Computer by the end user.*

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## 3.4 Pumps

A syringe pump is used to aspirate and mix the sample as well as move it through the analyzer.

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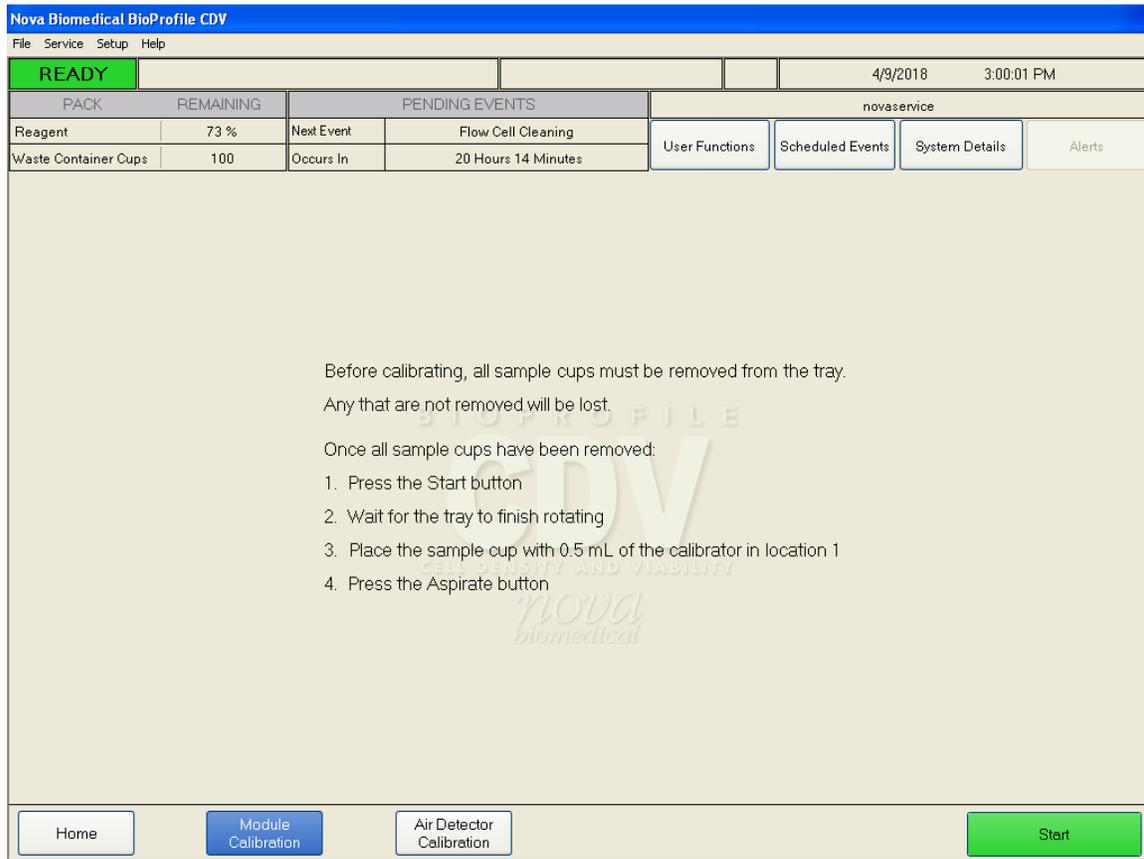
## 3.5 Reagent Packs

The reagent pack consists of 2 separate packs: the Reagent Cartridge and the reagent bottle pack. Both packs are installed as a pair.

- a. The reagent bottle pack contains 4 bottles necessary for cell density analysis.
- b. The bottle pack caps, but not seals, must be removed before installing the pack.
- c. A Reagent Management System (RMS) chip on the Reagent Cartridge stores pack information (Remaining Volume, pack Lot #, Install Date, Shelf-Life) and communicates the pack status to the analyzer.
- d. The pack can easily be disassembled for reagent disposal.

## 3.6 Calibration

Calibration options can be accessed by selecting the Calibration button at the bottom of the Home screen. The Calibration screen is displayed here.



3. Operation

Figure 3.1 Calibration Screen

After choosing either the Module or Air Detector Calibration button, select the green "Start" button in the lower right hand corner. Calibrations can be cancelled at any time by selecting the "Cancel" button. If a calibration is terminated, the module will return to an uncalibrated state.

## 3.6.1 Module Calibration

The Module calibration is used to calibrate the focus and intensity of the camera system. **It is not used to check cell counting accuracy.**

As the software establishes focal range, the bead images go in and out of focus. Optimal focus is established for each section of the Cell Density cuvette.

Total calibration time is approximately 10 minutes. To run the Module Calibration:

1. Select the Module Calibration button.
2. The Module Calibration is performed using an external calibration solution. It requires the use of Nova Cell Density Calibrator Solution (PN 43034). The Nova Cell Density Calibrator Solution should be vortexed at high speed for 10 seconds prior to pipetting into the sample cup. Avoid forming large bubbles within the ampule during vortexing. Select the “Start” button. After selecting the “Start” button:
  - a. The sample carousel tray will rotate.
  - b. Wait for the tray to finish rotating.
    - i. Dispense 0.5 mL of vortexed calibrator solution into Cup #1.
    - ii. Select “Aspirate” when ready.
  - c. Towards the end of the calibration countdown, the image gallery will start to populate. At this point, the user should examine all 45 images and can exclude up to 5 images that contain any debris or an undesirable background. The analyzer will automatically mark “suggested” images to exclude with a yellow “X.”
    - i. An image can be excluded by right clicking on the image. A red “X” appears on the image when selected for exclusion.
    - ii. When 5 images have been excluded, select the “Done” button in the lower right hand corner of the screen to complete the calibration.
    - iii. If no images are excluded by the operator, the last 5 images in the gallery are automatically excluded.

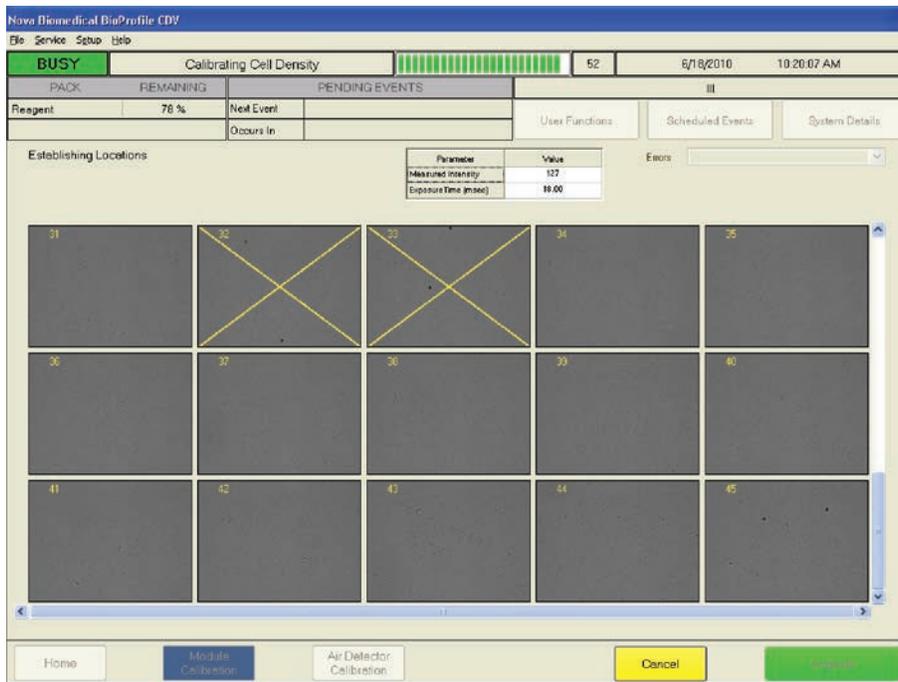


Figure 3.2 Analyzer Suggested Images to Exclude



Figure 3.3 Operator Excluded Images Screen

# BioProfile CDV

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## 3.7 Waste Container

After each analysis (QC, Calibration, and Sample Analysis), the spent cup is deposited into the waste container located behind the door. The waste container can hold up to 100 discarded cups. To empty, remove the container and discard the cups.

**WARNING: The cups are considered a biohazard and should be discarded in accordance with your institution's standard operating procedure.**

When the waste container is reinstalled, a prompt will ask if the waste container has been emptied. Selecting "Yes" will reset the waste container cups back to 100 remaining.

PACK	REMAINING
Reagent	30 %
Waste Container Cups	100

Figure 3.4 Waste Container Cups Reset to 100

## 3.8 Programming Quality Control Levels

Whenever a new lot of BioProfile External QC material is to be used, the information from the Control Level Assay Data Sheet must be entered into the BioProfile CDV prior to use. Configure the QC material using the following steps:

1. Select the “Setup” menu from the top tool bar.
2. Select the “QC Levels” option. This will display the “Configure QC Levels” window shown here.

Parameter	Lower Limit	Upper Limit	Units

Figure 3.5 Configure QC Levels

3. From the drop-down box, select the level of QC that you wish to enter.

Parameter	Lower Limit	Upper Limit	Units

Figure 3.6 Select QC Levels

## BioProfile CDV

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4. Select "Create New Lot."
5. Using the Assay Data Sheet included with the QC material, input the Lot Number, Expiration Month and Year, and the Lower and Upper Limit values.

**NOTE:** A minimum of 6 digits must be entered into the Lot Number field in order for the ranges to be applied.

Parameter	Lower Limit	Upper Limit	Units
Total Density	1.00	800.00	x10 <sup>5</sup> Parts/mL

Figure 3.7 Input QC Information

6. Once all of the QC information has been entered, select "Apply" to save the information and keep the window open or, select "OK" to save the information and close the window. The QC information for that specific Lot will now be programmed into the BioProfile CDV and will be available when testing that level of QC material.

## 3.9 Running Quality Control

To run Quality Control samples:

1. Select the **QC** button from the BioProfile CDV Home Screen. This will bring up the QC Screen.
2. Select the Level of Quality Control (Level 8 or 9) that will be tested.

**NOTE:** The Quality Control material must first be configured under the Setup menu.

3. Select the **Analyze** button to begin the Quality Control analysis. Deposit 0.5 mL of vortexed QC material into cup #1 using a pipette then select aspirate. Quality Control data will be populated in the QC Results screen. The QC screen will indicate whether the Level of Quality Control being tested passes or fails according to the information found in the Quality Control Insert Sheet.

**NOTE:** QC images can be viewed when the analysis has completed by right clicking on the image. Each bead within the image should have a green circle around the perimeter indicating it was counted.

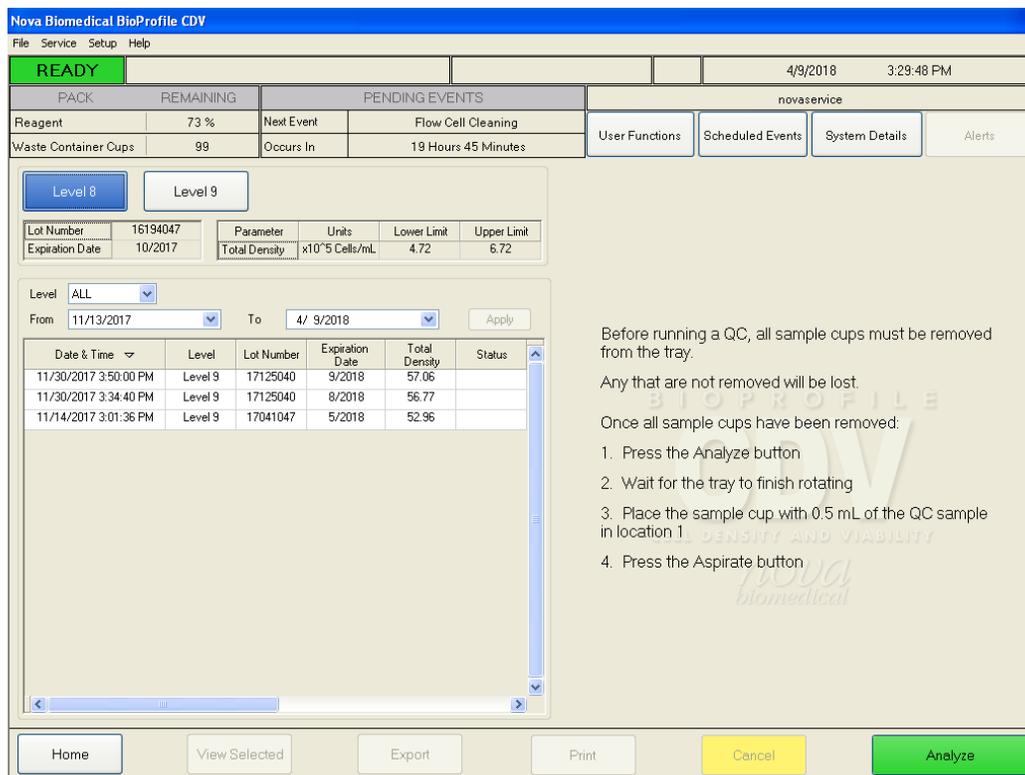


Figure 3.8 Quality Control Screen

# BioProfile CDV

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## 3.10 Running Sample Analysis

### Running a Sample Analysis

To run a sample on the BioProfile CDV, select a cup location. Input the Sample Information for the sample (Vessel ID, Batch ID, Cell Type, Sample ID). Be sure to select the appropriate Cell Inspection Type, Dilution Ratio, and Number of Images to be processed from within the Sample Information box. Each cup location must be individually programmed.

**NOTE:** The "Reduced Volume" mixing routine enables the end user to run tray samples using only 350  $\mu$ L of sample rather than 500  $\mu$ L when sample is limited. If pipetting 350  $\mu$ L of sample into the tray, the "Reduced Volume" mixing routine must be selected.

**NOTE:** Nova recommends the use of a vortex when mixing both samples and QC material. Follow the QC Insert Sheet for complete instructions when analyzing QC material.

The BioProfile CDV offers 3 dilution options (1:1, 1:2, and 1:4) for high-density cell culture samples. If a dilution is selected, the BioProfile CDV will perform the dilution and the results reported are calculated to correct for the dilution.

Choose the number of images you want to analyze. Each image represents a section of the cuvette. The analysis of more images provides greater precision of results. The minimum and maximum number of images that can be analyzed is 10 – 40.

Sample ID	sample	-	H
Vessel ID	vessel1		
Batch ID	batch1		
Cell Type	celltype1		
Cell Inspection Type	STANDARD CHO		▼
Dilution Ratio	1:1		▼
Number of Images	40		▲▼
Pre-Dilution Multiplier	1.00		

Figure 3.9 Sample Information Configuration

Please be aware of the following minimum sample volume requirements when preparing/presenting a sample:

- A minimum of 500  $\mu\text{L}$  is required.
- For Reduced Volume Tray Samples, 350  $\mu\text{L}$  is required.

The Home Screen will transition to the Results Screen. Upon completion of the sample analysis, the screen displays each image. Each image can be enlarged by first selecting it from the others and then selecting the image located in the results section to the left. Selecting an individual image to review presents you with information for that slide as well as the entire group of slides. Selecting the LIVE and/or DEAD buttons next to the preview visually identifies cells the BioProfile CDV has counted as live (green circle) or dead (red X) as well as clumps of dead cells (orange numbers) and blue circles for cells in which accurate diameter determinations cannot be made.

**NOTE:** Cells marked with blue circles will count towards viable density, total density, and viability but will not count towards average live diameter.

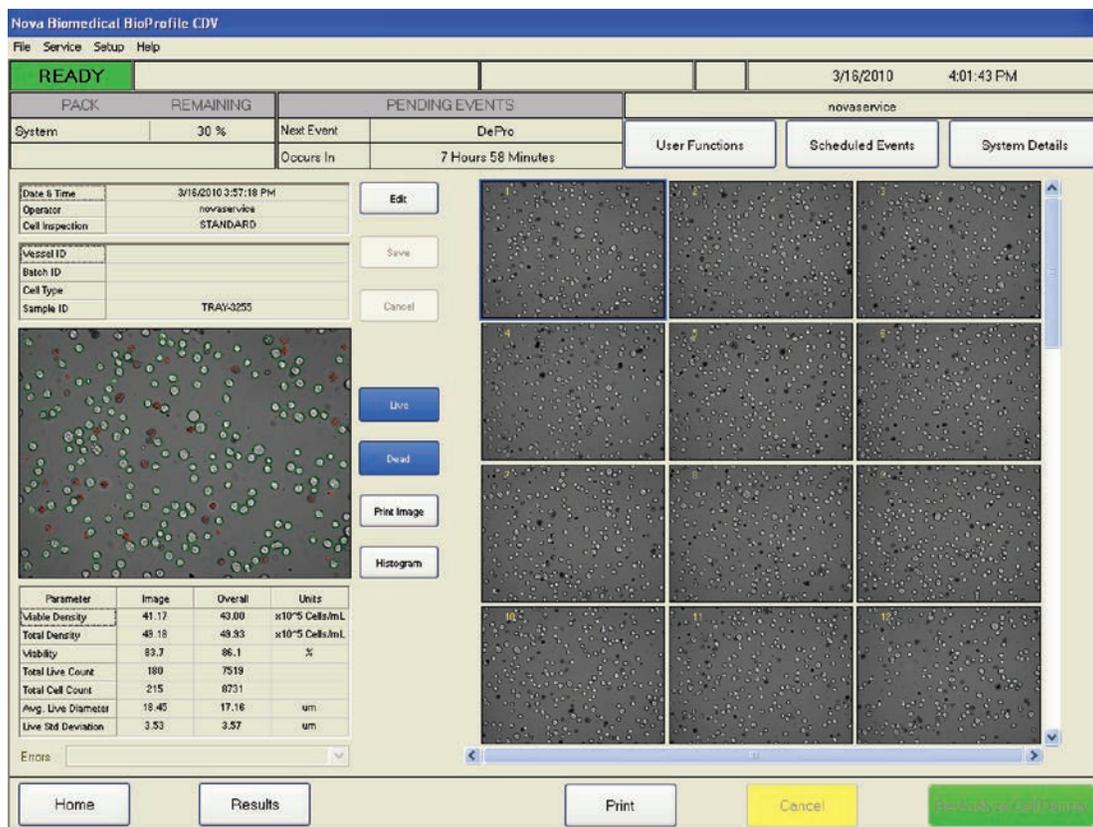


Figure 3.10 Sample Image Results

**NOTE:** Additional samples can be added to the carousel during an analysis from the Home Screen.

# BioProfile CDV

## Suspending Carousel to Add Samples

The CDV analyzer allows for continuous loading of the carousel. As a sample is being analyzed, more samples can be configured by suspending the carousel.

To add more samples, from the current sample analysis screen, press the Home button at the bottom left corner.

Select the carousel positions and configure the sample information. The carousel will be suspended, shown with a yellow circle, until Resume is pressed at the bottom right corner.

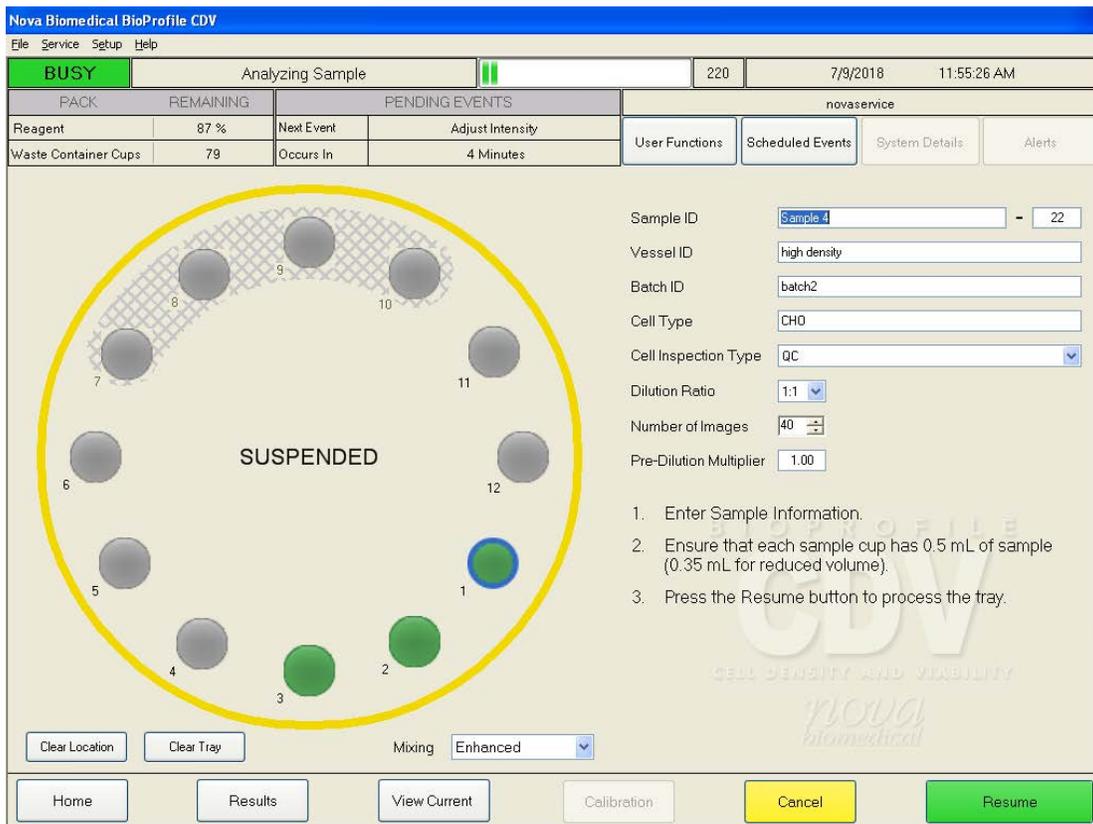


Figure 3.11 Suspended Carousel

## Reviewing Cell Density Data

- Viable Density – The total number of live cells in suspension expressed in cells per milliliter (cells/mL).
- Total Density – The total number of cells in suspension expressed in cells per milliliter (cells/mL).
- Viability – The percentage of total cells in the suspension that are viable. (e.g. 850 live cells in suspension containing 1000 cells are calculated to have a viability of 85%.)

- Total Live Count – The total number of live cells counted during the analysis.
- Total Cell Count – This is the total number of live and dead cells counted during the analysis.
- Average Live Diameter – The average diameter of live cells measured in micrometers (µm).
- Live Standard Deviation – A calculation of the SD of live cell diameter is measured over the entire sample and for each slide individually.

Parameter	Image	Overall	Units
Viable Density	41.17	43.00	$\times 10^5$ Cells/mL
Total Density	49.18	49.93	$\times 10^5$ Cells/mL
Viability	83.7	86.1	%
Total Live Count	180	7519	
Total Cell Count	215	8731	
Avg. Live Diameter	18.45	17.16	µm
Live Std Deviation	3.53	3.57	µm

Errors

Figure 3.12 Cell Density Data from a Sample Result

## Reanalyzing CDV Data

CDV samples run in the last 60 days may be reanalyzed using alternative cell inspection types. To reanalyze, follow these steps:

1. From the Recall Results screen select the sample you wish to reanalyze.
2. Select View Selected.
3. Select Reanalyze and choose the Cell Inspection Type from the resulting drop-down menu.
4. Select Start.

**NOTE:** New values in the Focus Offset and Settling Time parameters will not be applied to reanalyzed samples. Changes in these values will apply only when samples are presented to the analyzer.

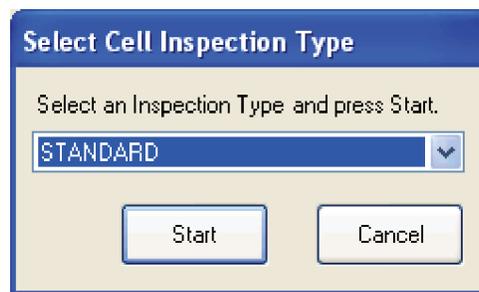


Figure 3.13 Reanalyze Menu

## 3.10.1 Entering Sample Information

Sample Information is not required in order to run an analysis but can be inserted for identification purposes. The sample information can include the following:

- a. **Vessel ID** – any combination of alphanumeric characters (25 Maximum)
- b. **Batch ID** – any combination of alphanumeric characters (25 Maximum)
- c. **Cell Type** – any combination of alphanumeric characters (25 Maximum)
- d. **Sample ID** – any combination of alphanumeric characters (25 Maximum)

**NOTE:** *Sample information can be input using alphanumeric characters plus underscore, dash and space. As information is entered, previously used ID's autopopulate in the selected field.*

### Module Configuration

In order to run an analysis, the following 3 options must be specified:

1. **Cell Inspection Type** – Select the down arrow to choose from any of the available cell inspection types. These inspection types are programmed from within the Setup menu. Once an inspection type is selected, it will be used for subsequent samples unless a new inspection type is selected. The default inspection type is "STANDARD."
2. **Dilution Ratio** – Select the down arrow to choose from the available dilution ratios. If your sample is expected to contain a total density of cells above 20 million cells/mL, the image may be overcrowded, which reduces counting accuracy and slows processing time. Selecting the correct/appropriate dilution ratio may improve module performance when cell densities are above the default range. Use the guidelines below to select the appropriate dilution range:

Dilution	Total Density
1:1	0.1 - 20 million cells/mL
1:2	0.2 - 40 million cells/mL
1:4	0.4 - 80 million cells/mL

**NOTE:** *The reported result accounts for the dilution; no additional calculation is necessary.*

3. **Number of Images** – You can select between 10 to 40 images to be processed for a sample. The default number of images is 40. Allowing more images to process provides for greater precision of results, but does increase analysis time.

## 3.11 Reviewing Results

1. After the "Aspirate" button is selected, the results screen is displayed.

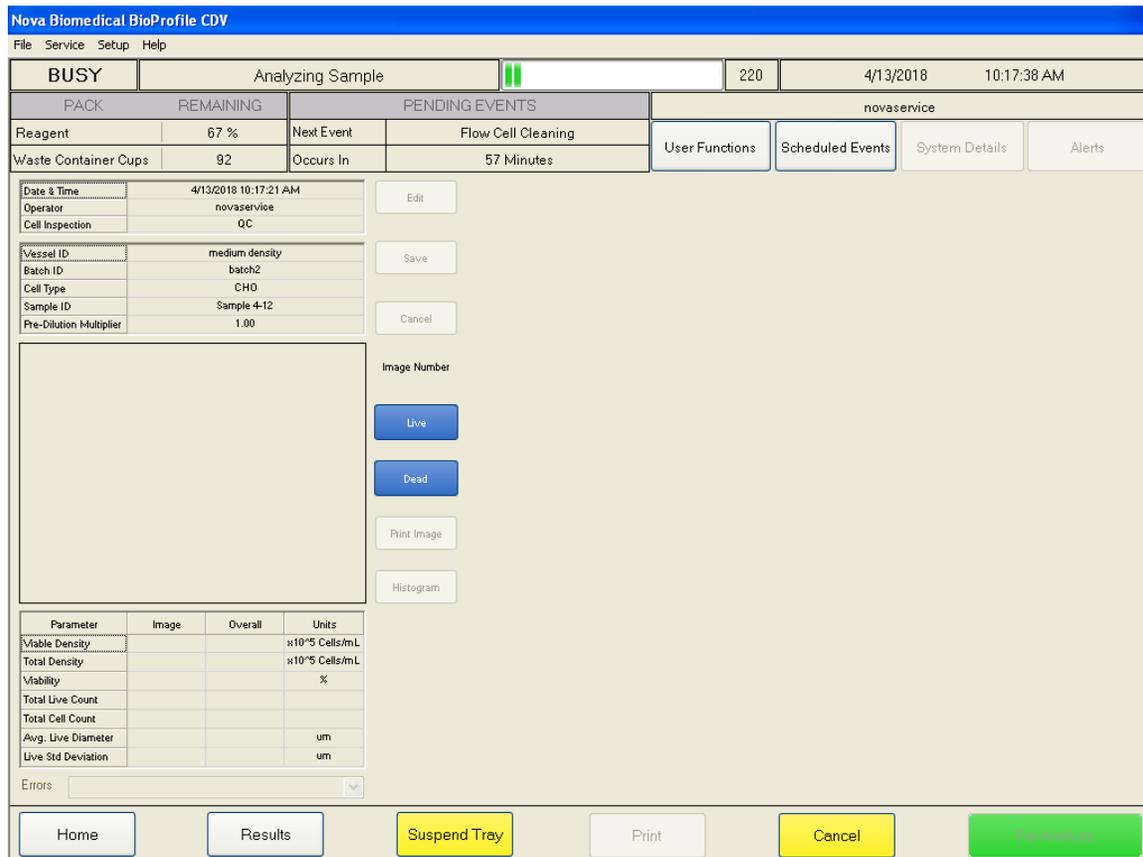


Figure 3.14 Current Sample Results Screen

2. A small status bar appears in the top center of the results screen. The status bar moves towards the right of the status area as the analysis progresses. Just to the right of the small status area is a countdown of how many seconds are left for the analysis.
3. The Results Screen is divided into different sections for a sample analysis.
  - a. **Sample Information** –Includes the date and time of the analysis, the operator who was logged in at the time of the sample analysis, and any other Sample Information entered. To the right of the Sample Information section there are 3 buttons. They are as follows:

**Edit** – Allows you to either edit the sample information that was entered previously or enter sample information that was originally left out. All Sample Information changes are tracked in the Audit Log (Sample Results can not be changed or edited).

## BioProfile CDV

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**NOTE:** *When changes are made to the sample information, the sample gets re-saved in the database with the date and time that the sample was edited. However, the original sample time is conserved and listed on the results tab as "sample time."*

**Save** – Saves the edited sample information.

**Cancel** – Cancels any modifications to the sample information.

- b. **Results** – includes the following information:
1. **Most recent image** – as the analyzer collects sample images from the Cell Density/Viability Module, this image changes accordingly. Sample analysis must be completely finished before you can browse the images.
    - a. Right clicking on the image enlarges the image.
    - b. At the bottom of an enlarged image are 3 buttons:
      - i. **Print Image** - prints the enlarged image.
      - ii. **Export** - Exports the image as a bmp file to a USB drive (user provided) or the shared drive.
      - iii. **Close** - Closes the enlarged image window.
  2. **Live button** – selecting this option highlights the live cells (as determined by the inspection software) in a green outline. Selecting this option again eliminates the green outlines.
  3. **Dead button** – selecting this option highlights the dead cells (as determined by the inspection software) with a red "X." If a clump of dead cells is detected, the number (orange) of dead cells within that clump is displayed instead of the "X."
  4. **Print Image button** – selecting this button prints the selected image.
  5. **Histogram button** – selecting this button displays a histogram showing a comparison of Total Live Cell Count versus Live Cell Diameter.
  6. **Growth Calculations** - Displays plots of various cell parameters from samples with the same batch ID.
  7. **Cell Inspection Type** – this type is selected from the sample information grid just prior to running the analysis.
  8. **Image Number** – displays the sequential number of the image being displayed in this section as well as the total number of available images.

9. **Additional Information** – displays and splits into 3 columns labeled "Image" (currently displayed image), "Overall," and "Units"

- Viability Density
- Total Density
- Viability (%)
- Total Live Count
- Total Cell Count
- Avg. Live Diameter ( $\mu\text{m}$ )
- Live Std Deviation

- c. **Image Gallery** – displays thumbnails of the images collected from the most recent sample. The number of images displayed in this section is selected from within the Sample Information screen. Selecting any one of these thumbnails automatically displays a larger version of the image under the results section. The image number value displayed within this section changes accordingly, as does the information displayed under the "Image" column.

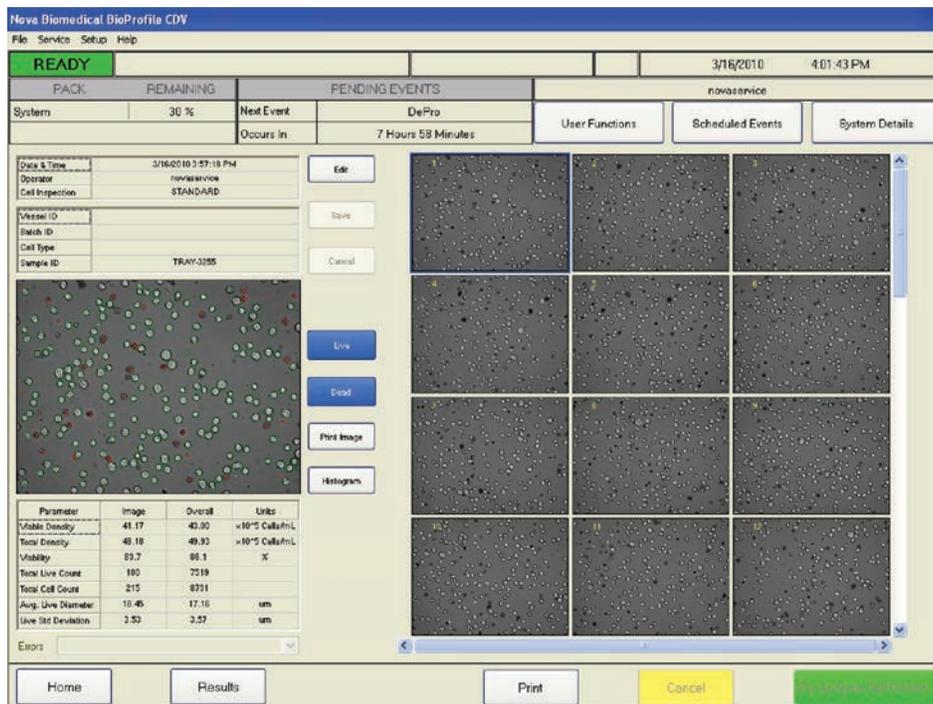


Figure 3.15 Completed Sample Analysis Results Screen

# BioProfile CDV

- On the bottom right, the Aspirate button now displays “Re-Analyze.” Selecting this button allows an operator to apply an alternate cell inspection type for the most recent sample. Once an alternate cell inspection type and the “Start” button are selected, the BioProfile CDV re-analyzes and redisplayes the most current cell density images using the new criteria.

## 3.12 Results Recall

To access the sample results stored within the Bioprofile CDV software, select the "Results" button at the bottom of the Home screen. The results are organized by date and time in reverse chronological order (top to bottom). The most recent sample being displayed at the top. To organize the data alphabetically or sequentially, click on the column header to display how you would like the data sorted. Use the scroll bar at the right to scroll through all the results. Use the scroll bar at the bottom to view additional sample information.

**Nova Biomedical BioProfile CDV**  
File Service Setup Help

**READY** 4/9/2018 3:31:03 PM

PACK REMAINING PENDING EVENTS novaservice

Reagent 73 % Next Event Flow Cell Cleaning User Functions Scheduled Events System Details Alerts

Waste Container Cups 99 Occurs In 19 Hours 43 Minutes

**Recall Results** From 8/ 1/2016 To 4/ 9/2018 Apply

Date & Time	Sample ID	Total Density	Viable Density	Viability	Avg. Live Diameter	Total Live Count	Total Cell Count	Live Std Deviation	Cell Inspection Type	Number of Images	Live Cell Cou Std Deviation
3/30/2018 11:45:58 AM	test JF-1	38.64	0.02	0.1	25.10	2	3880	0.00	AmgenCHO	40	0.2
10/17/2017 10:13:07 AM	QC9Test-JT-1	46.14	46.14	100.0	10.48	4401	4401	0.92	QC	40	10.8
10/16/2017 5:08:13 PM	CalbTest-JT-3	24.63	24.63	100.0	10.38	2350	2350	0.76	QC	40	7.9
10/16/2017 12:16:58 PM	CalbTest-JT-2	19.67	19.67	100.0	10.42	1876	1876	0.95	QC	40	8.1
10/16/2017 12:08:59 PM	CalbTest-JT-1								QC	40	
8/25/2017 3:41:15 PM	Lv 9 17125040-4	521.84	521.84	100.0	10.54	4978	4978	0.84	QC	40	10.6
8/25/2017 3:39:02 PM	Lv 9 17125040-3								QC	40	
8/25/2017 3:05:11 PM	Lv 9 17125040-2	412.71	412.71	100.0	10.50	3937	3937	0.91	QC	40	47.5
8/25/2017 2:53:05 PM	Lv 9 17125040-1	551.50	551.50	100.0	10.57	2762	2762	0.86	QC	40	66.1
8/25/2017 2:45:42 PM	Lv 8 17020041-1	66.69	66.69	100.0	10.32	334	334	0.71	QC	40	8.7
6/28/2017 10:23:44 AM	test-7	618.60	618.60	100.0	10.41	5901	5901	0.78	QC	40	11.4
6/28/2017 10:18:15 AM	test-6	602.14	602.14	100.0	10.54	5744	5744	0.90	QC	40	12.5
6/28/2017 7:44:02 AM	test-5								QC	40	
6/23/2017 11:22:31 AM	test-3								QC	40	
6/19/2017 2:05:04 PM	test-1	564.19	564.19	100.0	10.86	5382	5382	0.91	QC	40	9.3
5/8/2017 11:50:53 AM	Pre-Dil test-19	0.00	0.00	0.0	0.00	0	0	0.00	QC	40	0.0
5/8/2017 11:46:53 AM	Pre-Dil test-18	0.00	0.00	0.0	0.00	0	0	0.00	QC	40	0.0
5/8/2017 11:42:53 AM	Pre-Dil test-17	0.10	0.10	100.0	10.21	1	1	0.00	QC	40	0.2
5/8/2017 11:38:51 AM	Pre-Dil test-16	589.14	589.14	100.0	10.42	5620	5620	0.81	QC	40	11.1
5/8/2017 11:34:52 AM	Pre-Dil test-15	586.84	586.84	100.0	10.41	5598	5598	0.83	QC	40	9.9
5/8/2017 11:30:51 AM	Pre-Dil test-14	608.12	608.12	100.0	10.50	5801	5801	0.87	QC	40	10.7
3/22/2017 2:20:10 PM	Pre-Dil test	6225.61	6225.61	100.0	10.88	14847	14847	1.17	QC	40	17.8
3/22/2017 1:41:32 PM	Test1-29	57.55	57.55	100.0	9.87	549	549	0.54	QC	40	3.6

Home View Selected Export Print Export Histogram Growth Calculations

Figure 3.16 Recall Results Screen

A specific time period of samples can be displayed by designating dates within the "From" and "To" boxes above the results table. Selecting the down arrow within these boxes displays a calendar. Choose the desired month first, then the day. Once the day is selected, the desired date (month and day) is displayed in the box.

Once the "From" and "To" time period is selected, select the Apply button next to the date boxes to display the desired data.

The screenshot shows the Nova Biomedical BioProfile CDV software interface. At the top, there is a status bar with 'READY' and the date '4/9/2018 3:31:16 PM'. Below this is a navigation bar with 'File Service Setup Help'. The main interface is divided into several sections: 'PACK' (READY), 'REMAINING' (73%), 'PENDING EVENTS' (Next Event: Flow Cell Cleaning, Occurs In: 19 Hours 43 Minutes), and 'novaservice' (User Functions, Scheduled Events, System Details, Alerts). The 'Recall Results' section is active, showing a table of results with columns for Date & Time, Sample ID, Viability, Avg. Live Diameter, Total Live Count, Total Cell Count, Live Std Deviation, Cell Inspection Type, Number of Images, and Live Cell Count Std Deviation. A drop-down calendar is open over the table, showing the month of August 2016. The calendar has a red box around the date '4/9/2018' and a red box around the 'Today' label. At the bottom of the screen, there are six buttons: Home, View Selected, Export, Print, Export Histogram, and Growth Calculations.

Figure 3.17 Results Recall Drop-Down Calendar Screen

On the bottom of the Recall Results screen are 6 buttons:

1. **Home** - takes you back to the Home screen.
2. **View Selected** – if selected, allows an operator to view the details of a selected sample. Unless a single entry is selected, this button is disabled.
  - a. To view the details of a particular sample, select one of the sample rows displayed. The row will be highlighted. The View Selected button should now be activated. Only one sample can be chosen at a time.

# BioProfile CDV

Nova Biomedical BioProfile CDV  
File Service Setup Help

**READY** 4/9/2018 3:31:03 PM

PACK REMAINING PENDING EVENTS novaservice

Reagent 73 % Next Event Flow Cell Cleaning  
Waste Container Cups 99 Occurs In 19 Hours 43 Minutes

User Functions Scheduled Events System Details Alerts

Recall Results From 8/ 1/2016 To 4/ 9/2018 Apply

Date & Time	Sample ID	Total Density	Viable Density	Viability	Avg. Live Diameter	Total Live Count	Total Cell Count	Live Std Deviation	Cell Inspection Type	Number of Images	Live Cell Cou Std Deviatio
3/20/2018 11:45:58 AM	test_JF-1	38.84	0.02	0.1	25.10	2	3880	0.00	AmgenCHO	40	0.2
10/17/2017 10:13:07 AM	QC9Test-JT-1	46.14	46.14	100.0	10.48	4401	4401	0.32	QC	40	10.8
10/16/2017 5:08:13 PM	CalibTest-JT-3	24.63	24.63	100.0	10.38	2350	2350	0.76	QC	40	7.9
10/16/2017 12:16:58 PM	CalibTest-JT-2	19.67	19.67	100.0	10.42	1876	1876	0.95	QC	40	8.1
10/16/2017 12:08:59 PM	CalibTest-JT-1								QC	40	
8/25/2017 3:41:15 PM	Lv 9 17125040-4	521.84	521.84	100.0	10.54	4978	4978	0.84	QC	40	10.6
8/25/2017 3:39:02 PM	Lv 9 17125040-3								QC	40	
8/25/2017 3:05:11 PM	Lv 9 17125040-2	412.71	412.71	100.0	10.50	3937	3937	0.91	QC	40	47.5
8/25/2017 2:53:05 PM	Lv 9 17125040-1	551.50	551.50	100.0	10.57	2762	2762	0.86	QC	40	66.1
8/25/2017 2:45:42 PM	Lv 8 17020041-1	66.69	66.69	100.0	10.32	334	334	0.71	QC	40	8.7
6/28/2017 10:23:44 AM	test-7	618.60	618.60	100.0	10.41	5901	5901	0.78	QC	40	11.4
6/28/2017 10:18:15 AM	test-6	602.14	602.14	100.0	10.54	5744	5744	0.90	QC	40	12.5
6/28/2017 7:44:02 AM	test-5								QC	40	
6/23/2017 11:22:31 AM	test-3								QC	40	
6/19/2017 2:05:04 PM	test-1	564.19	564.19	100.0	10.86	5382	5382	0.91	QC	40	9.3
5/8/2017 11:50:53 AM	Pre-Dil test-19	0.00	0.00	0.0	0.00	0	0	0.00	QC	40	0.0
5/8/2017 11:46:53 AM	Pre-Dil test-18	0.00	0.00	0.0	0.00	0	0	0.00	QC	40	0.0
5/8/2017 11:42:53 AM	Pre-Dil test-17	0.10	0.10	100.0	10.21	1	1	0.00	QC	40	0.2
5/8/2017 11:38:51 AM	Pre-Dil test-16	589.14	589.14	100.0	10.42	5620	5620	0.81	QC	40	11.1
5/8/2017 11:34:52 AM	Pre-Dil test-15	586.84	586.84	100.0	10.41	5598	5598	0.83	QC	40	9.9
5/8/2017 11:30:51 AM	Pre-Dil test-14	608.12	608.12	100.0	10.50	5801	5801	0.87	QC	40	10.7
3/22/2017 2:20:10 PM	Pre-Dil test	6225.61	6225.61	100.0	10.88	14847	14847	1.17	QC	40	17.8
3/22/2017 1:41:32 PM	Test1-29	57.55	57.55	100.0	9.87	549	549	0.54	QC	40	3.6

Home View Selected Export Print Export Histogram Growth Calculations

Figure 3.18 View Selected Activated Screen

- b. Select the View button to see sample details. Results, sample information, and cell density images are displayed.
  - c. This detailed information can be printed externally by selecting the "Print" button displayed at the bottom of the screen.
  - d. Selecting the "Results" button at the bottom of the screen takes you back to the Results Recall screen.
3. **Export** – transfers (exports) data in a form that is available to another software program such as a spreadsheet.
    - a. To export sample data, select the row(s) of data that you wish to export. The Export button should now be active.
    - b. Select the "Export" button. The Export Results dialog box displays. The BioProfile CDV software will export data to a USB device or the Export folder of the Bridge Computer. The file name is created by the BioProfile CDV software and cannot be changed. The file name is always in the format yyyy-mm-dd\_hhmmss.csv.

- c. All available locations are displayed in the box next to "Drives." Select the location where you want to export.
- d. Select the Export button. The data are written to the selected device. The data will be in comma-delimited format for easy import into a spreadsheet.
- e. After the data has been exported, the "Safely Remove Hardware" program will be displayed(unless you are exporting to the Bridge Computer). Choose the drive you want to stop and select "Close."

**NOTE:** Individual cell images can only be exported within 60 days from the original date of analysis.

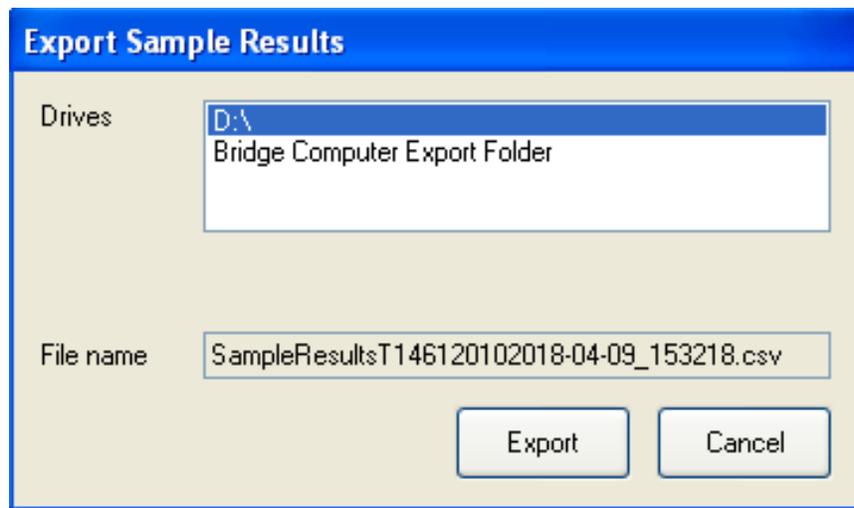


Figure 3.19 Export Sample Results Screen

#### 4. Print

- a. Using the cursor, several rows of sample data can be selected simultaneously for printing. The printed format is similar to the format the data is displayed in on this screen.

#### 5. Export Histogram

- a. In order to graphically view the live cell diameter data from a CDV sample, data can be selected and then analyzed using the "Export Histogram" function.
- b. The data is exported as a .CSV file. The file can be opened using any program that can access .CSV files.
- c. The .CSV file can be opened and plotted using any standard graphing technique.

## 6. Growth Calculations

In addition to the Histogram, the analyzer can also display growth calculations for a range of samples configured with the same Batch ID. By selecting the Results button from the home screen, the Growth Calculations button becomes available. The user can then choose the Batch ID name from the dropdown, and the applicable samples are listed.

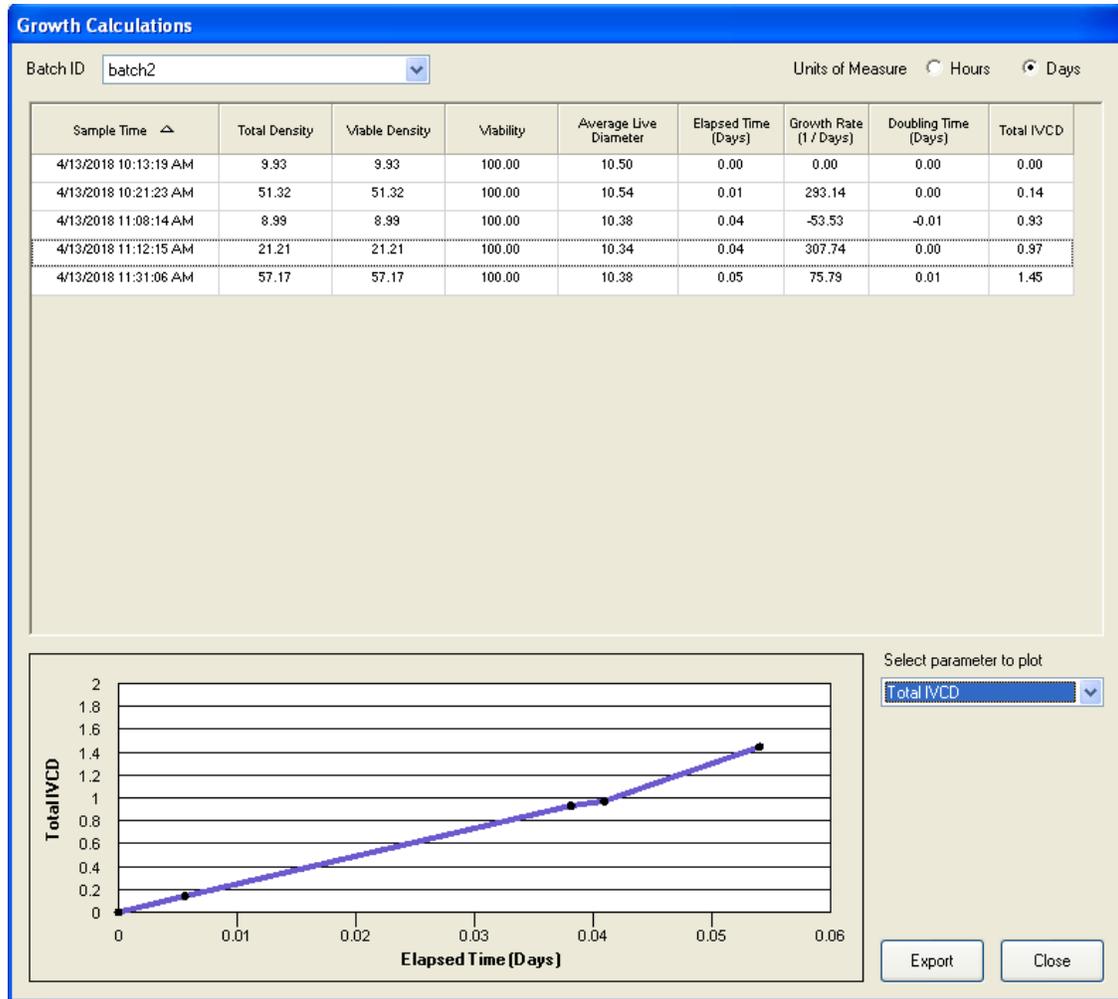


Figure 3.20 Growth Calculation Selected

The results are shown in a graph, which can be changed by selecting an option from the dropdown list in the bottom right.

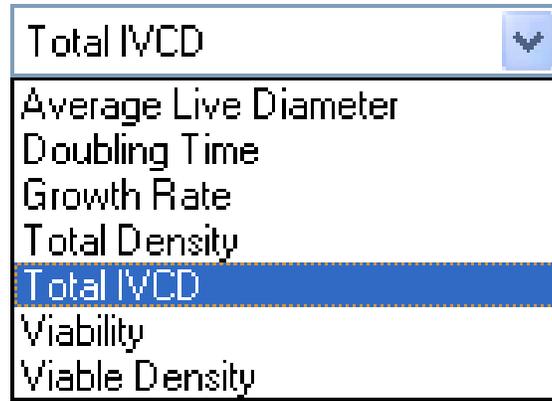


Figure 3.21 Plot Dropdown

Growth Calculations can be exported by the user by selecting the Export button, then the destination. Growth calculations are exported as .CSV files, which can be plotted using any standard graphing technique.

### 3.13 Exporting Data to the Bridge Computer Export Folder

- The BioProfile CDV CPU offers a shared folder that may be accessed from another computer over a TCP/IP network connection. When the Export feature is used, an option to export the data to a shared folder is provided.
- Data must be exported before it becomes accessible from a networked computer.
- If the shared folder is used heavily, the shared folder should be purged occasionally through normal Windows procedure. This is especially true if bitmap images are exported to the shared folder.
- The shared folder may be accessed from computers that are part of a domain and computers that are not part of a domain.

**NOTE:** *The end user should consult their IT personnel when attempting to put the Bridge Computer on a domain.*

# BioProfile CDV

---

4 Maintenance

The following sections provide detailed information and directions to operate and to maintain the BioProfile CDV Analyzer. From the Home screen, select "Maintenance."



**WARNING:** Cell culture samples are potential sources of infectious agents. Handle all sample and flowpath components with care. Gloves and protective clothing are recommended.

It is important to perform preventive maintenance as scheduled.

**NOTE:** All maintenance functions are performed from within the Maintenance Screen. The options in the Maintenance Screen are accessed by selecting the "Maintenance" button at the bottom of the Home Screen.

4. Maint

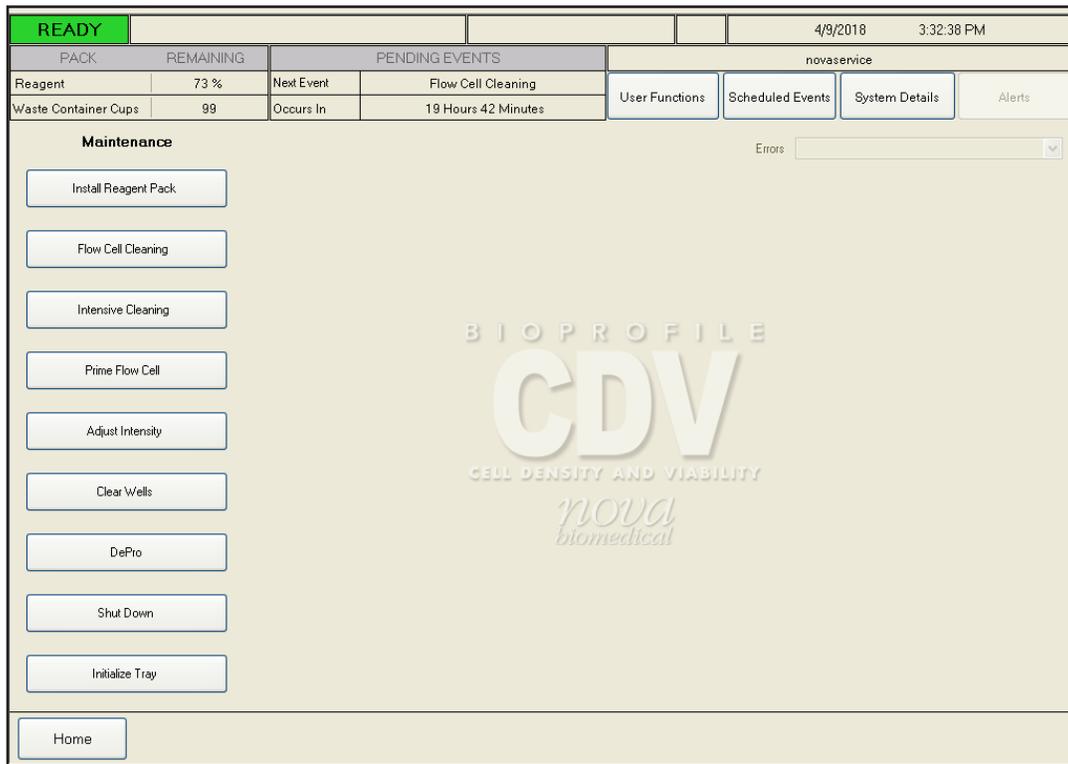


Figure 4.1 Maintenance Screen

## 4.1 Install Reagent Pack

1. Select the **Install Reagent Pack** button.

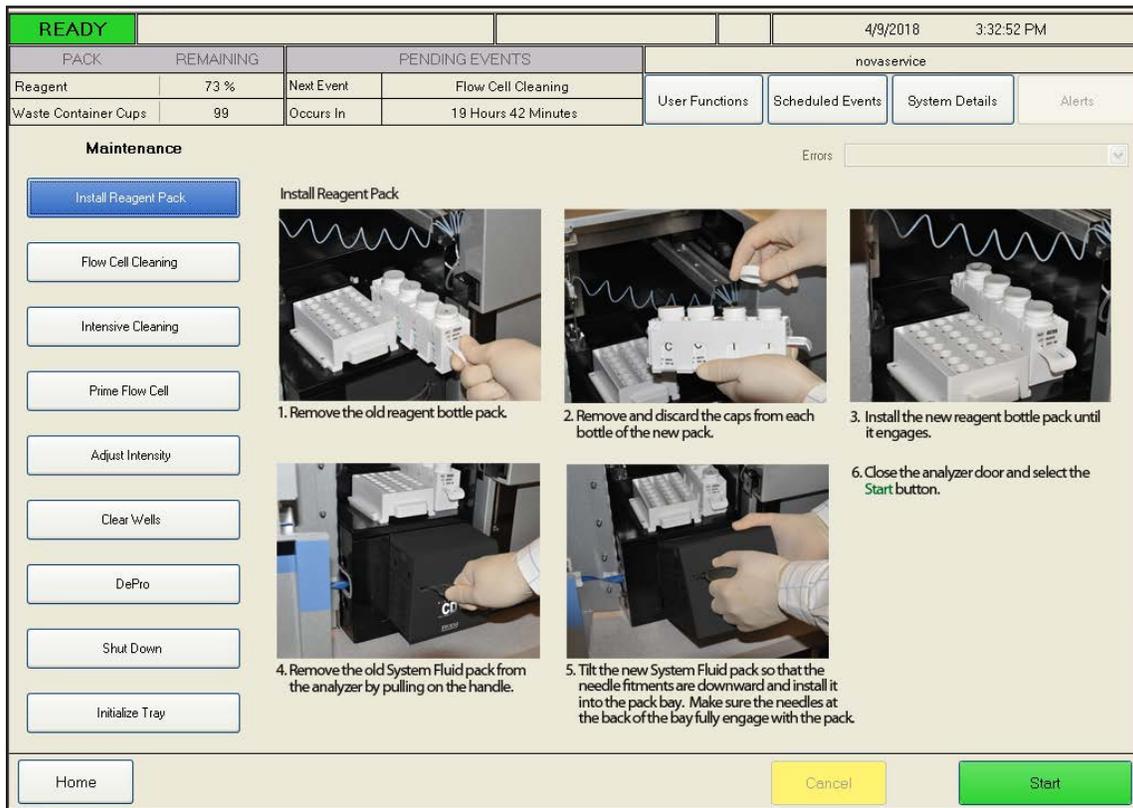


Figure 4.2 Install Reagent Pack Screen

**WARNING: Trypan Blue is a known carcinogen. Handle with care.**

2. Follow the instructions displayed on the screen:
  - a. Remove the old BioProfile CDV Reagent Bottle Pack.
  - b. Remove and discard the caps from each bottle of the new pack.
  - c. Install the new reagent bottle pack until it engages.
  - d. Remove the old System Fluid pack from the analyzer by pulling on the handle.
  - e. Tilt the new System Fluid pack so that the needle fitments are downward and install it into the pack bay. Make sure the needles at the back of the bay fully engage with the pack.
  - f. Close the analyzer door and select the Start button.

**NOTE:** *The BioProfile CDV Bottle Pack “T” bottles contain Trypan Blue. These bottles can easily be removed from the pack by bending out the two tabs while holding the bottle in place. In addition, all BioProfile CDV waste empties into the System Fluids pack. Therefore, the System Fluids pack will also contain Trypan Blue when removed from the system. The pack can be easily disassembled and the waste pouch can be removed for disposal.*

**CAUTION:** *Failure to remove the bottle caps will result in damage to the system probe.*

**NOTE:** *The analyzer automatically adjusts the background color intensity when a new BioProfile CDV Reagent Pack is installed.*

# BioProfile CDV

## 4.2 Maintenance

### 4.2.1 Flow Cell Cleaning

Flow Cell cleaning is a procedure to perform a quick cleaning of the cell density flow path and cuvette. This procedure can be used if the CDV images show signs of debris, residue, artifacts, etc. that are not cleaned out during normal sample analysis. Flow Cell Cleaning can be performed daily when cells are run as preventative maintenance.

1. Select the Flow Cell Cleaning button.

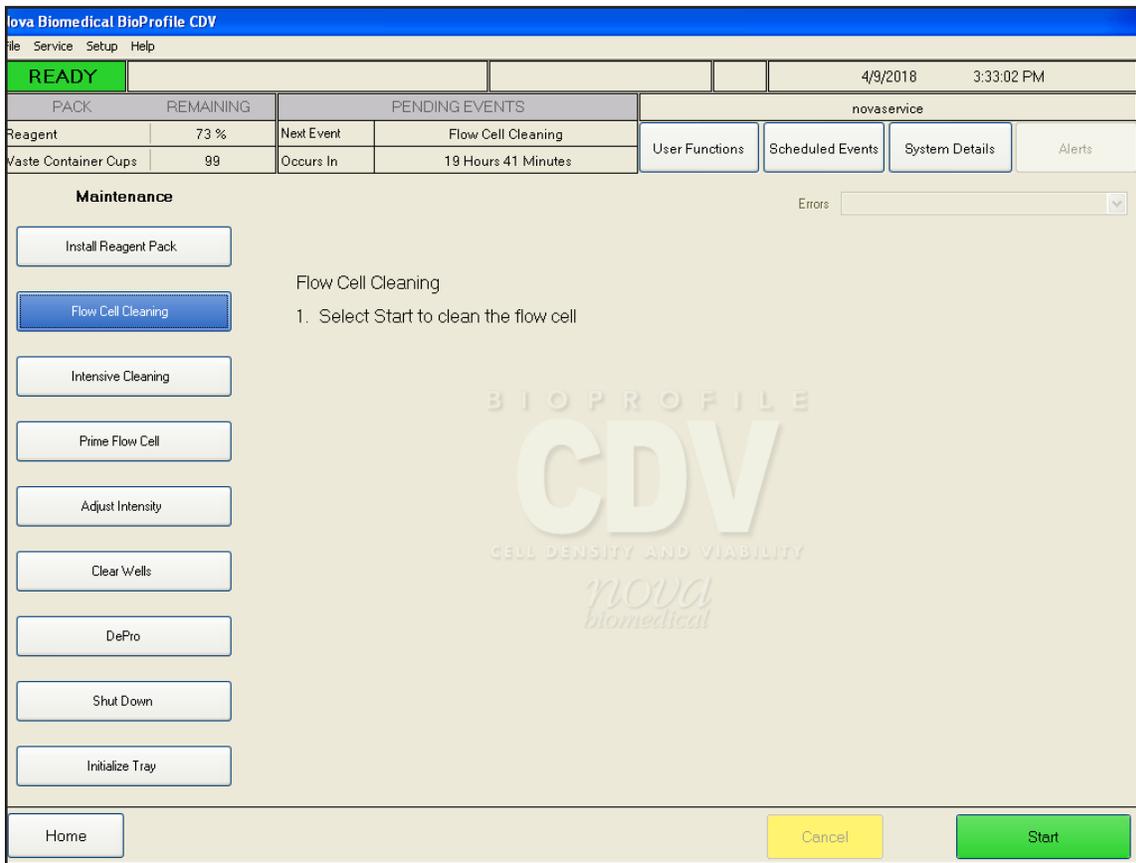
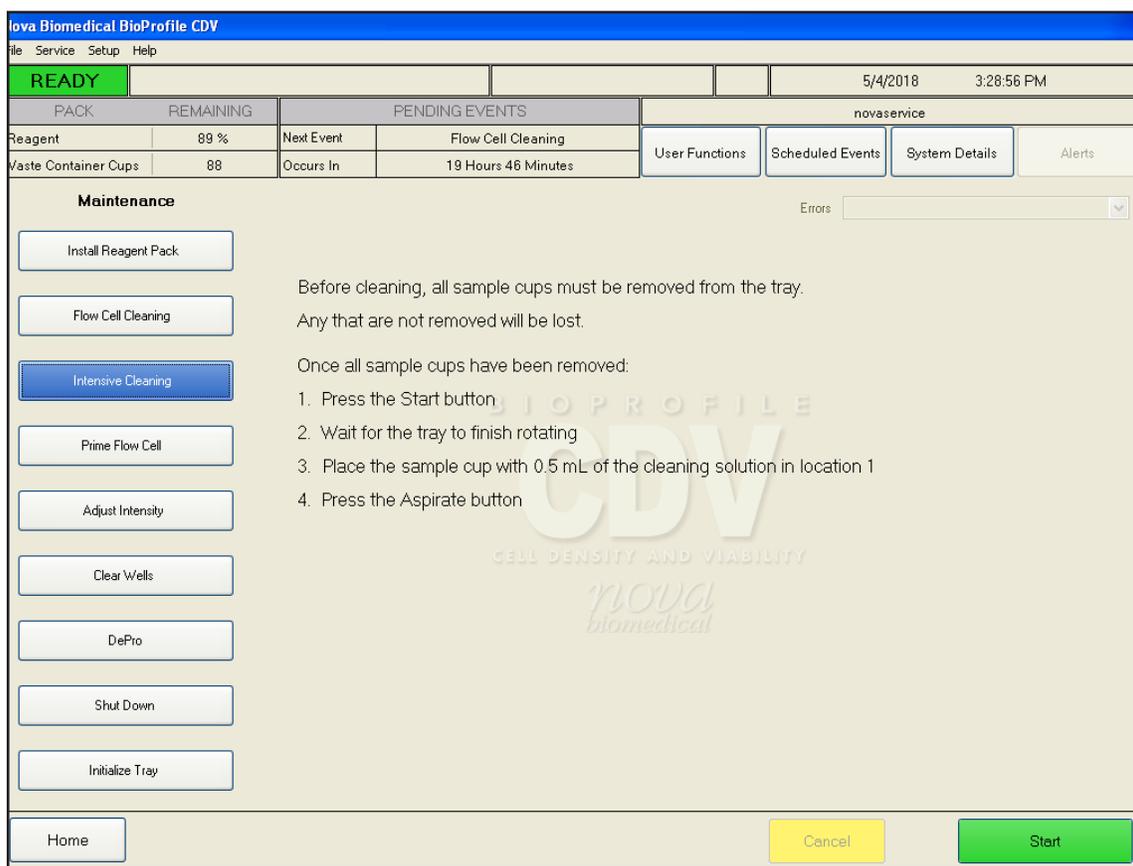


Figure 4.3 Flow Cell Cleaning Screen

2. Select the green Start button in the lower right corner of the screen. This procedure takes approximately 10 minutes to complete. Forty-five images will appear on the screen. Use these images to check for the effectiveness of the Fast Cleaning procedure. The operator can exclude up to 5 image locations, if necessary, by right clicking on the image thumbnails. The Fast Cell Cleaning procedure can be run as often as necessary.

## 4.2.2 Intensive Cleaning

An intensive cleaning sequence using Nova Depro Solution can help mitigate extreme circumstances where cuvettes become dirty with cellular debris.



4. Maint

Figure 4.4 Intensive Clean Screen

### Select Intensive Cleaning Button.

**Non-Carousel Analyzer:** Select "Start" at the bottom right of the screen. Present 1 mL of Depro Solution to the probe and press "Aspirate." The solution will soak for 30 minutes in the cuvette and fluidic lines.

**Carousel Analyzer:** Select "Start" at the bottom right of the screen. The carousel will move so that position 1 is facing the user. Place a sample cup into position 1 and fill with 1 mL of Depro Solution then select continue. The solution will soak for 30 minutes in the cuvette and fluidic lines.

# BioProfile CDV

## 4.2.3 Prime Flow Cell

The Prime Flow Cell procedure uses System Fluid to prime the CDV flow path and cuvette.

1. Select the Prime Flow Cell button.

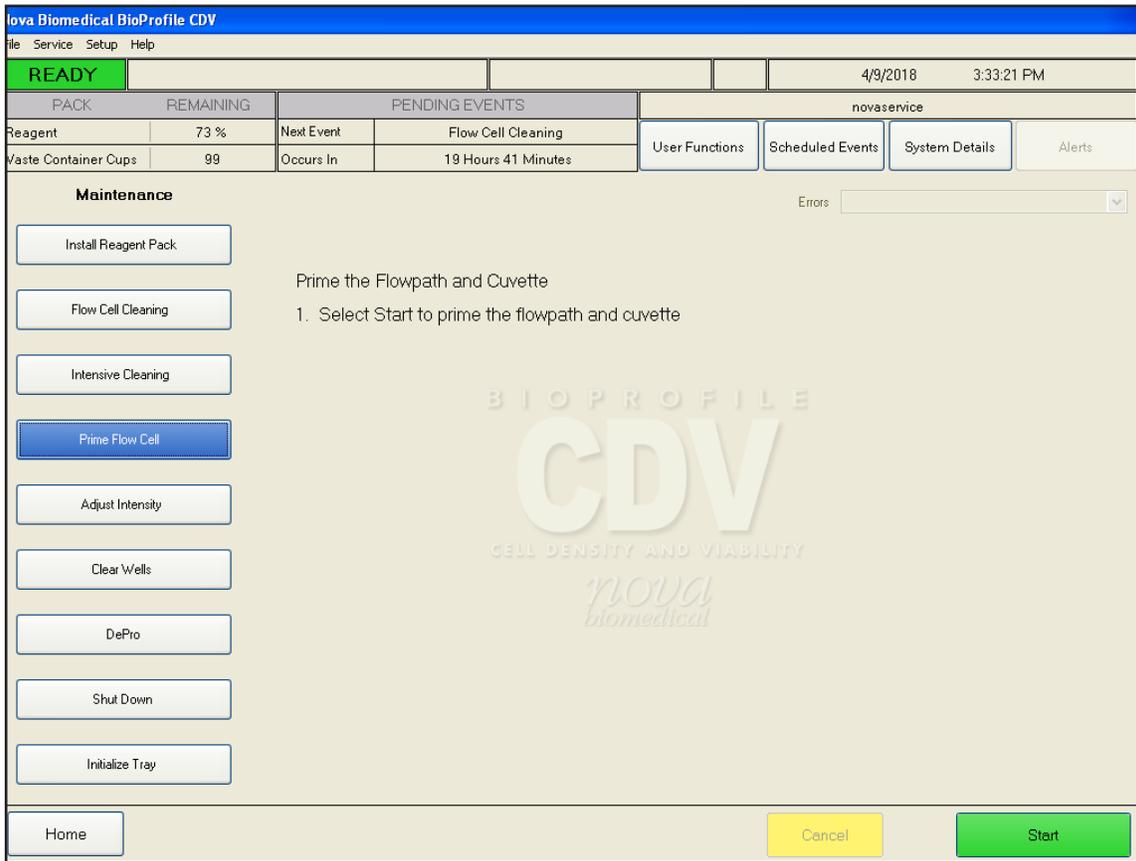


Figure 4.5 Prime Flow Cell Maintenance Screen

2. Select the green Start button located at the lower right corner of the screen.

4.2.4 Adjust Intensity

The BioProfile CDV uses the Trypan Blue solution in the reagent bottle pack to set the background value of the CDV cuvette. As the Trypan Blue reagent is consumed, the dye becomes more concentrated and the dye itself may actually become darker in color. To adjust for this change in the color of the dye, the light source for the cuvette can be increased or decreased (Adjust Intensity). The Adjust Intensity procedure should be run weekly at a minimum to correct for reagent evaporation/consumption.

1. Select the Adjust Intensity button.

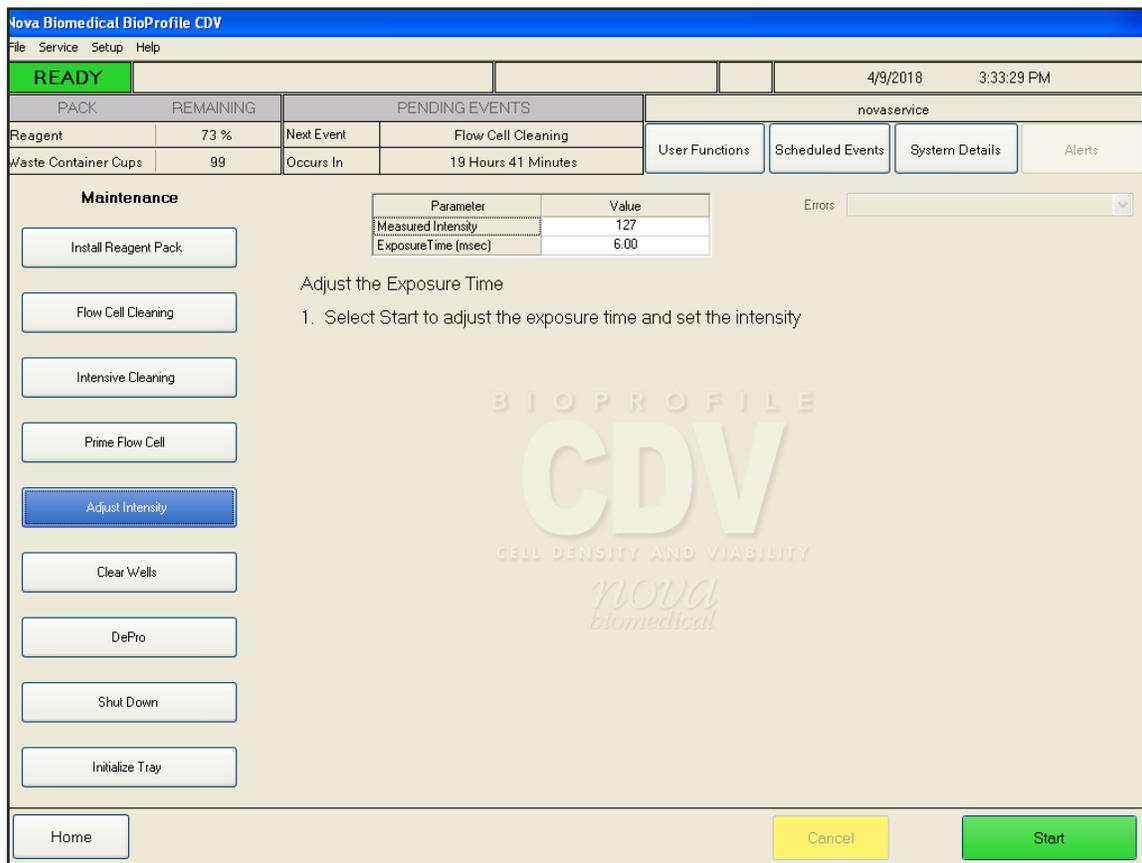


Figure 4.6 Adjust Intensity Screen

2. Select the Start button located at the lower right corner of the screen.
3. The Adjust Intensity procedure takes approximately 200 seconds to complete. During this time, the Measured Intensity and Exposure Time will be determined for the CDV imaging system.

4. Maint

# BioProfile CDV

## 4.2.5 Clear Wells

The Clear Wells function is used to check the proper operation of the Waste Well, Valves, and Flowpaths after a maintenance action is performed, such as the removal of an obstruction.

1. Select the Clear Wells button.

**NOTE:** System fluid is aspirated out of the System Fluids pack by the syringe pump. The fluid is then delivered to the Waste Well and CDV well and is pumped through each flow path.

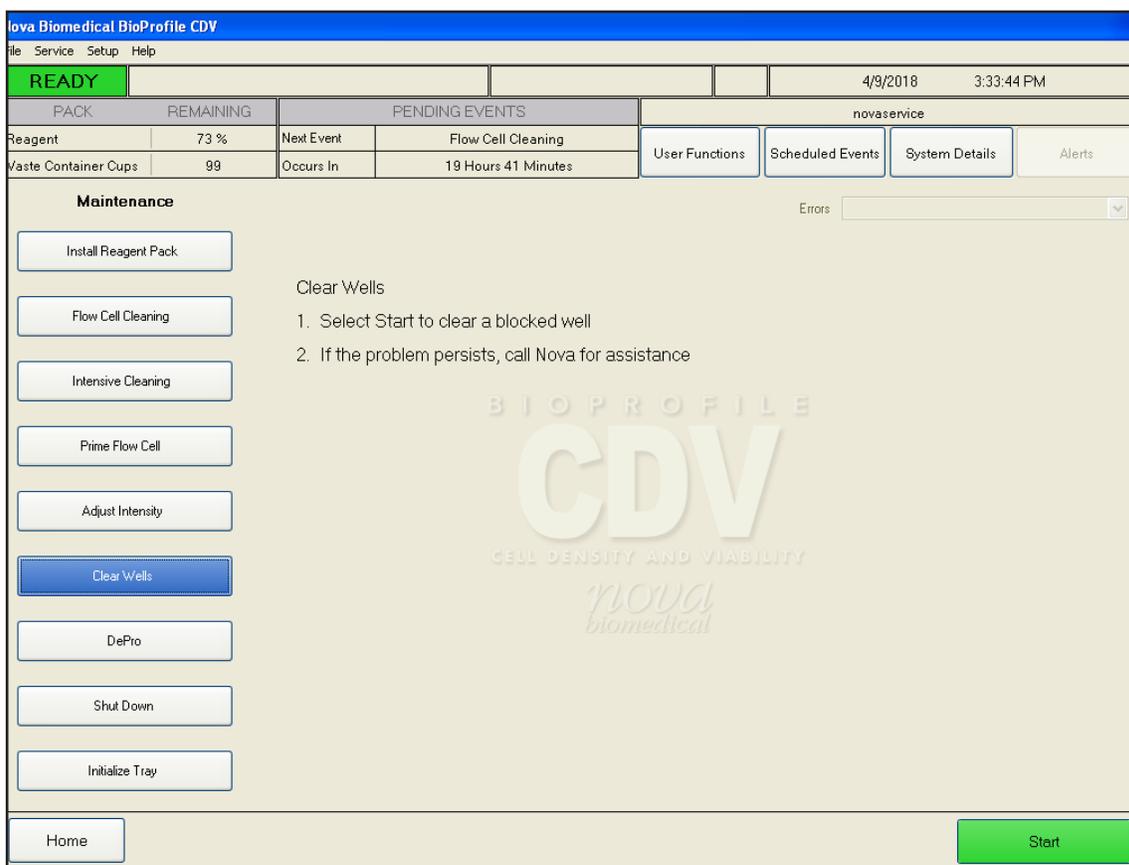
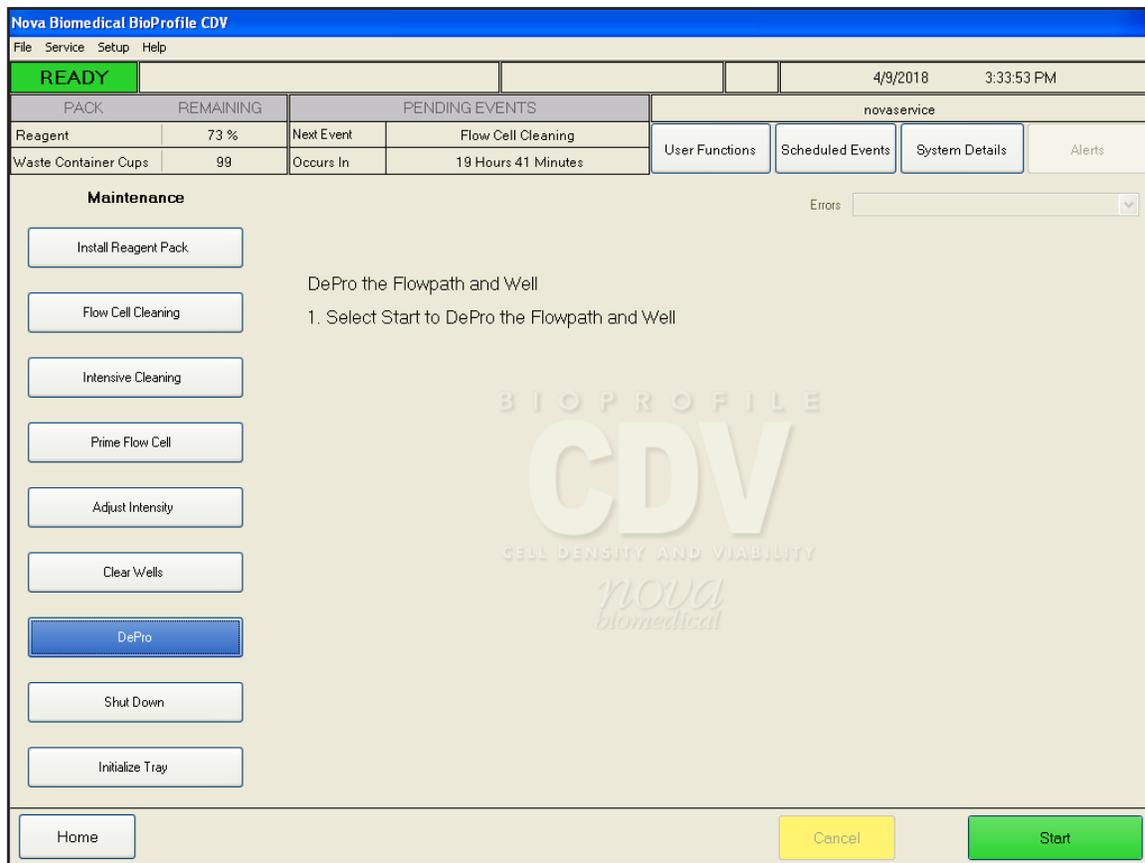


Figure 4.7 Clear Wells Maintenance Screen

## 4.2.6 DePro

The DePro maintenance function uses the Deproteinizing solution from the BioProfile CDV Reagent pack and delivers it to the Waste Well and CDV well. Once delivered to the wells, the DePro solution is allowed to soak in the well and fluidic lines for an extended period of time. The purpose of this procedure is to remove any protein build-up and/or blockages that may accumulate as samples are run. The BioProfile CDV system should be deproteinized weekly at a minimum.

1. Select the DePro button.



4. Maint

Figure 4.8 DePro Maintenance Screen

## 4.3 Shut Down Analyzer

The Shut Down Analyzer function should be used if the BioProfile CDV must be shut down for more than 48 hours. This procedure ensures that no reagents or fluids will remain in the fluid lines while the BioProfile CDV is powered down. By removing all reagents and fluids, salt build-up and blockages are less likely to form and cause damage to the analyzer.

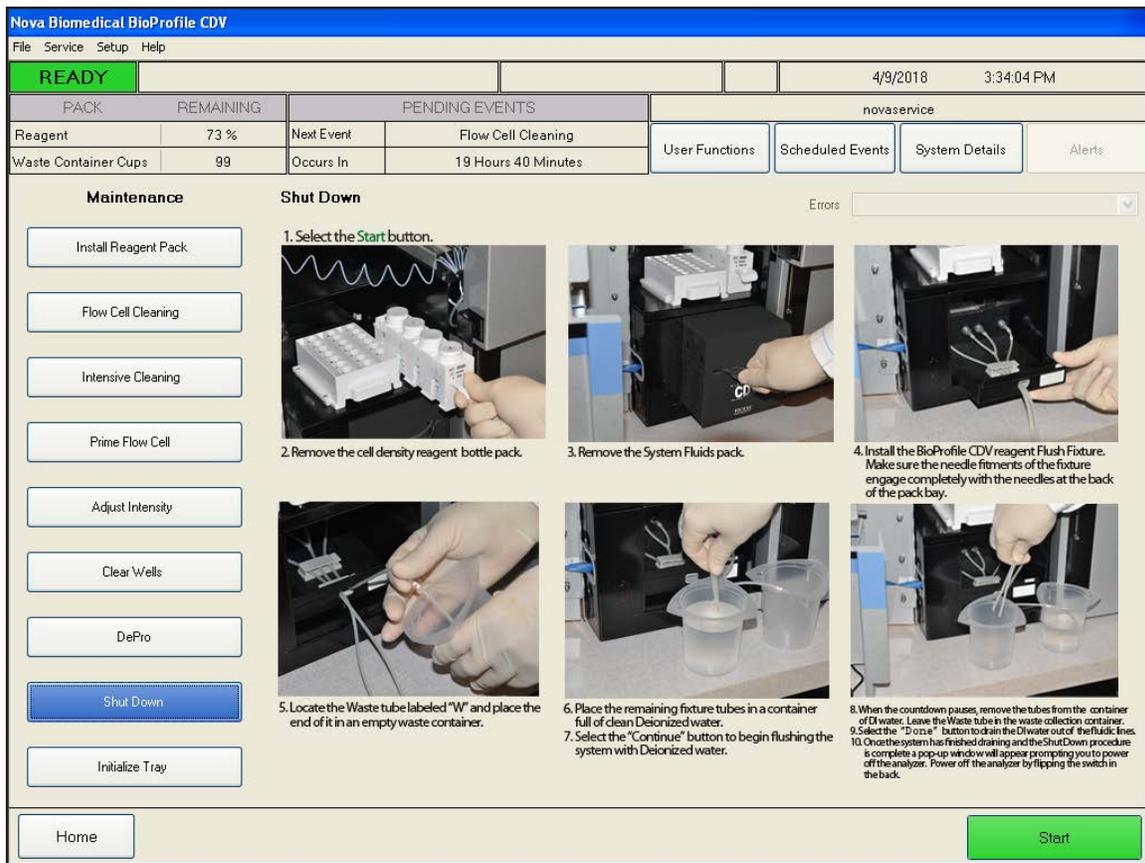


Figure 4.9 Shut Down Analyzer Screen

To properly shut down the analyzer, proceed as follows:

1. Select the Start button.
2. Remove the cell density reagent bottle pack.
3. Remove the Systems Fluid Pack.
4. Install the BioProfile CDV Reagent Flush Fixture. Make sure the needle fittings of the fixture engage completely with the needles at the back of the pack bay.
5. Locate the Waste Tube labeled "W" and place the end of it in an empty waste container.

6. Place the remaining fixture tubes in a container full of clean deionized water.
7. Select the "Continue" button to begin flushing the system with deionized water.
8. When the countdown pauses, remove the tubes from the container of DI water. Leave the waste tube in the waste collection container.
9. Select the "Done" button to drain the DI water from the fluidic lines.
10. Once the system has finished draining and the shut down procedure is complete, a pop-up window will appear prompting you to power off the analyzer. Power off the analyzer by flipping the switch in the back

---

## 4.3.1 Restarting BioProfile CDV After Long Term Shut Down

1. Replace the BioProfile CDV Reagent Pack (System Fluids and Bottle Pack).
2. Turn on the Analyzer and the Computer.
3. Wait for the Analyzer to initialize and load.
4. Initialize tray from the Maintenance Menu.
5. A Waste Well Blockage error will most likely occur upon start up. Go into the BioProfile CDV Maintenance screen.

**NOTE:** *Air detectors throughout the analyzer are expecting to detect fluid at certain times. Because the system was stored dry, there is currently no fluid in the lines for the air detectors to detect.*

6. Run the Clear Wells function about 3 to 4 times until an Air Detector calibration can be completed without producing any errors. This primes some lines with fluid, allowing the air detectors to work once again.
7. Calibrate the BioProfile CDV as needed.
8. Test Quality Control Levels 8 and 9 before sample testing.

---

## 4.4 Initialize Tray

Initialize Tray checks the tray and moves it so that position #1 is under the probe. This must be done when the instrument is first turned on.

# BioProfile CDV

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## 5 Troubleshooting

This section describes the error solutions and explains the troubleshooting procedures for the BioProfile CDV Analyzer.



*WARNING: Cell culture samples are potential sources of infectious agents. Handle all sample and flowpath components with care. Gloves and protective clothing are recommended.*

### 5.1 Troubleshooting Procedures

The recommended troubleshooting procedures use the most logical and direct steps to resolve the error code. The solutions are set up in a block format that lists groups of steps to perform in order to restore analyzer operation. The steps are also organized to prevent unnecessary parts replacement, such as sample probe and tubing, until the more common causes for an error have been checked.

If the recommendations given here do not resolve the problem, contact Nova Technical Support for troubleshooting assistance. When calling Technical Support, it is helpful to have written down the analyzer Serial Number, the error messages, and flow times.

FOR TECHNICAL ASSISTANCE, CALL TOLL FREE:

USA	1-800-545-NOVA (6682)
Canada	1-800-263-5999
Other Countries	Contact your local Nova Biomedical Sales Office or Authorized Nova Biomedical Distributor

## 5.2 Error Solutions

The following is a list with page reference for the Error Solutions.

### A

AD-FC Delta mV 5-3  
AD-FC Overload 5-3  
AD-FC Read Error 5-3  
AD-WC Delta mV 5-3  
AD-WC Overload 5-3  
AD-WC Read Error 5-3  
AD-WW Delta mV 5-4  
AD-WW Overload 5-4  
Audit Log Notations 5-10  
Auto Focus Failure 5-6  
Auto Intensity Failure 5-6

### C

Cell Density Flow Time 5-6  
Cell Density Motion 5-7

### I

Inspection Failure 5-6

### N

No Cell Density Reagent 1 5-4  
No Depro Solution 5-5  
No Mucosal 5-5  
No Sample 5-5  
No System Fluid 5-4

### S

Service Errors 5-9  
SRV Err 5-8  
Syringe Pump Error 5-8  
System Pack Empty 5-7  
System Pack Expired 5-7  
System Pack Not Present 5-7  
System Pack Not Valid 5-7

### W

Waste Well Flow Time 5-8

## AD-FC Delta mV

During the last calibration sequence, the measured difference between the 2 calibrators did not meet the minimum specifications for a properly performing Air Detector.

Recommended Solutions:

1. Verify that the System Fluid Pack is seated properly.
2. Recalibrate the Air Detectors.

## AD-FC Overload

During the last calibration sequence, the Air Detector reading was outside the software's limits.

Recommended Solutions:

1. Recalibrate the Air Detectors.
2. Call Nova Biomedical Technical Support.

## AD-FC Read Error

During the last calibration or analysis, the Air Detector failed to provide a reading.

Recommended Solutions:

1. Recalibrate the Air Detectors.
2. Call Nova Biomedical Technical Support.

## AD-WC Delta mV

During the last calibration sequence, the measured difference between the 2 calibrators did not meet the minimum specifications for a properly performing Air Detector.

Recommended Solutions:

1. Verify that the System Fluid Pack is seated properly.
2. Recalibrate the Air Detectors.

## AD-WC Overload

During the last calibration sequence, the measured difference between the 2 calibrators did not meet the minimum specifications for a properly performing Air Detector.

Recommended Solutions:

1. Verify that the System Fluid Pack is seated properly.
2. Recalibrate the Air Detectors.

## AD-WC Read Error

During the last calibration or analysis, the Air Detector failed to provide a reading.

Recommended Solutions:

1. Recalibrate the Air Detectors.
2. Call Nova Biomedical Technical Support.

# BioProfile CDV

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## AD-WW Delta mV

During the last calibration sequence, the measured difference between the 2 calibrators did not meet the minimum specifications for a properly performing Air Detector.

Recommended Solutions:

1. Verify that the System Fluid Pack is seated properly.
2. Recalibrate the Air Detectors.

## AD-WW Overload

During the last calibration sequence, the Air Detector reading was outside the software's limits.

Recommended Solutions:

1. Recalibrate the Air Detectors.
2. Call Nova Biomedical Technical Support.

## No System Fluid

During the last air detector calibration or analysis, system fluid was not detected.

Recommended Solutions:

1. Verify the percent remaining in the CDV Reagent pack. If there is less than 10% remaining, replace the pack.
2. Reseat the System fluid pack. Reinstall the pack and confirm fluid flow. Then recalibrate.
3. Verify that syringe pump is working properly.
4. Contact Nova Biomedical Technical Support.

## No Cell Density Reagent 1

During the last calibration, sample analysis, or maintenance sequence, Trypan Blue was not aspirated by the sample probe. Please note, no action is required if the message occurs infrequently.

Recommended Solutions:

1. Verify the percent remaining in the BioProfile CDV Reagent pack. If there is less than 10% remaining, replace the pack.
2. Contact Nova Biomedical Technical Support.

## No Sample

During the last calibration, sample analysis, or maintenance sequence, the cell density assay volume was not sufficient. Please note, no action is required if this message occurs infrequently.

1. Verify the percent remaining in the BioProfile Reagent pack. If there is less than 10% remaining, replace the pack.
2. Verify the percent remaining in the System Fluid Pack. If there is less than 10% remaining, replace the pack.
3. Open the front cover of the analyzer and verify that the cell density well is empty:
  - If the cell density well is not empty, remove the fluid with a pipet and verify that the cell density well is free of obstruction using a lint-free tissue.
  - If the cell density well is empty, recalibrate the air detectors.
4. Call Nova Biomedical Technical Support.

## No Depro Solution

During the last sequence, the analyzer failed to detect the presence of the Depro Solution.

Recommended Solutions:

1. Verify the System Pack is properly installed.
2. Recalibrate the Air Detectors.

## No Mucosol

During the last sequence, the analyzer failed to detect the presence of the Mucosol Solution.

Recommended Solutions:

1. Verify the bottle pack is properly installed.
2. Recalibrate the Air Detectors.

# BioProfile CDV

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## Cell Density Flow Time

During the last sample analysis, calibration, or maintenance sequence, the cell density flow time was outside the specified limits. Please note, no action is required if this message occurs infrequently.

Recommended Solutions:

1. Verify the percent remaining in the CDV Reagent Pack. If there is less than 10% remaining, replace the pack.
2. Open the front cover of the analyzer and verify that the cell density well is empty.
  - If the cell density well is not empty, remove the fluid with a pipet and verify that the cell density well is free of obstruction by wiping it clean with a lint-free tissue.
  - If the cell density well is empty, recalibrate the air detectors.
3. Run a Depro Maintenance Cycle.
4. Call Nova Biomedical Technical Support.

## Auto Focus Failure

During the last calibration, the auto focus sequence did not complete successfully.

Recommended Solutions:

1. If no other errors are present, repeat the calibration.
2. Call Nova Biomedical Technical Support.

## Auto Intensity Failure

During the last calibration or maintenance sequence, the intensity adjustment was outside the specifications.

Recommended Solutions:

1. Verify the percent remaining in the BioProfile CDV Reagent pack. If there is less than 10% remaining, replace the pack.
2. Call Nova Biomedical Technical Support.

## Inspection Failure

During the last analysis, the expected response was not received from the image processor.

Recommended Solutions:

1. Call Nova Biomedical Technical Support.

## Cell Density Motion

During the last sample analysis, calibration, or maintenance sequence, there was a mechanical error in the imaging system. Please note, no action is required if this message occurs infrequently.

Recommended Solutions:

1. Call Nova Biomedical Technical Support.

## System Fluid Pack Not Present

During the last sample analysis or calibration sequence, the system detected that the System Fluid Pack was not present.

Recommended Solutions:

1. Verify that the System Fluid Pack is correctly inserted into its bay.
2. Reinstall the System Fluid Pack using the maintenance menu screen.
3. Contact Nova Biomedical Technical Support.

## System Fluid Pack Not Valid

During the last sample analysis or calibration sequence, the system detected that the System Fluid Pack was not valid.

Recommended Solutions:

1. Verify that the System Fluid Pack is correctly inserted into its bay.
2. Reinstall the System Fluid Pack using the maintenance menu screen.
3. Contact Nova Biomedical Technical Support.

## System Fluid Pack Empty

During the last sample analysis or calibration sequence, the system detected that the System Fluid Pack was empty.

Recommended Solutions:

1. Reinstall the System Fluid Pack using the maintenance menu screen.
2. Contact Nova Biomedical Technical Support.

## System Fluid Pack Expired

During the last sample analysis or calibration sequence, the system detected that the System Fluid Pack was expired.

Recommended Solutions:

1. Install a new CDV Reagent Pack using the maintenance menu screen.
2. Contact Nova Biomedical Technical Support.

# BioProfile CDV

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## Syringe Pump Error

During a requested operation, the system syringe pump produced an error.

Recommended Solutions:

1. Contact Nova Technical Support.

## SRV Err

Recommended Solutions:

1. Contact Nova Technical Support.

## Waste Well Flow Time

During the last sample analysis, calibration, or maintenance sequence, the waste well flow time did not meet the specified limits.

Recommended Solutions:

1. Verify the percent remaining in the CDV Reagent Pack. If there is less than 10% remaining, replace the pack.
2. Open the front cover of the analyzer and verify that the waste well is empty.
  - If the waste well is not empty, remove the fluid with a pipet and verify that the well is free of obstruction by wiping it clean with a lint-free tissue.
3. Run the Clear Wells sequence from the Maintenance screen.
4. Call Nova Biomedical Technical Support.

## 5.3 Service Errors

The following is a list of Service Errors. If you experience any of the following errors, please contact Nova Biomedical Technical Support.

- Cell Density Interlock Failure
- Cell Density Fluid Sense
- Cell Density X Motor
- Cell Density Z Motor
- Door Latch Failure
- Host Communications Failure
- IPD Communications Failure
- Syringe Pump Action Failure
- Syringe Pump Communications Failure
- System Probe X Motor
- System Probe Y Motor
- System Probe Z Motor
- System Probe

## 5.4 Audit Log Notations

The following is a list of actions that are stored in the Audit Log if performed by a BioProfile CDV user.

- Archiving the Database
- Backing up the Database
- Canceling a QC Analysis
- Canceling a Sample Analysis
- Change Cell Density Multiplier
- Change Live Cell Brightness Threshold
- Change a QC Lower Limit
- Change a QC Upper Limit
- Change the Average Dead Cell Diameter
- Change Batch ID
- Change Dead Cell Aggregate Area
- Change Dead Cell Brightness Threshold
- Change Dead Cell Minimum Size
- Change Live Cell Minimum Size
- Change Sample ID
- Change Debris Size Threshold
- Change Focus Offset
- Change Sample Type
- Change Settling Time
- Change Vessel ID
- Finish Flow Path Service
- Installing Analyzer Software
- Installing Host Software
- Re-analyzing Cell Density Images
- Running a QC Analysis
- Running a Sample Analysis
- Start Flow Path Service
- Exceeding the number of login attempts

## 6 First Generation CDV

**NOTE:** *This section applies only to customers who purchased the analyzer before the carousel type tray was standard.*

### 6.1 First Generation Tray

#### Running a Sample

To run a sample on the BioProfile CDV, select a Sample Type (Manual or Tray). For a Manual analysis, input the Sample Information for the sample (Vessel ID, Batch ID, Cell Type, Sample ID). For Tray analyses, sample information can only be entered once a tray location has been selected. Be sure to select the appropriate Cell Inspection Type, Dilution Ratio, and Number of Images to be processed from within the Sample Information box. If the samples are being run from a tray, each tray location must be individually programmed.

**NOTE:** *If presenting a sample manually from a syringe or sample tube, be sure to mix the sample to prevent cell settling. Tray samples will be mixed using either the "Normal," "Enhanced," or "Reduced Volume" mixing routine options found on the tray sample diagram. The "Reduced Volume" mixing routine enables the end user to run tray samples using only 350 $\mu$ L of sample rather than 500 $\mu$ L when sample is limited. If pipetting 350 $\mu$ L of sample into the tray, the "Reduced Volume" mixing routine must be selected.*

**NOTE:** *Nova recommends the use of a vortex when mixing both samples and QC material. Follow the QC Insert Sheet for complete instructions when analyzing QC material.*

The BioProfile CDV offers 3 dilution options (1:1, 1:2, and 1:4) for high-density cell culture samples. If a dilution is selected, the BioProfile CDV will perform the dilution and the results reported are calculated to correct for the dilution. (See Section 3.7: Running an Analysis for specifics on choosing a dilution ratio.)

Choose the number of images you want to analyze. Each image represents a section of the cuvette. The analysis of more images provides more accurate results. The minimum and maximum number of images that can be analyzed is 10 – 40.

SAMPLE INFORMATION	
Vessel ID	
Batch ID	
Cell Type	
Sample ID	
Cell Inspection Type	STANDARD <input type="button" value="v"/>
Dilution Ratio	1:1 <input type="button" value="v"/>
Number of Images	40
Pre-Dilution Multiplier	1.00

Figure 6.1 Sample Information Configuration

Please be aware of the following minimum sample volume requirements when preparing/presenting a sample:

#### For Manual Samples

- A minimum of 300  $\mu$ L is required.

#### For Tray Samples (Normal or Enhanced Mixing)

- A minimum of 500  $\mu$ L is required.
- For Reduced Volume Tray Samples, 350  $\mu$ L is required.

#### Reanalyzing CDV Data

CDV samples run in the last 60 days may be reanalyzed using alternative cell inspection types. To reanalyze, follow these steps:

1. From the Recall Results screen select the sample you wish to reanalyze.
2. Select View Selected.
3. Select Reanalyze and choose the Cell Inspection Type from the resulting drop-down menu.
4. Select Start.

**NOTE:** *New values in the Focus Offset and Settling Time parameters will not be applied to reanalyzed samples. Changes in these values will apply only when samples are presented to the analyzer.*

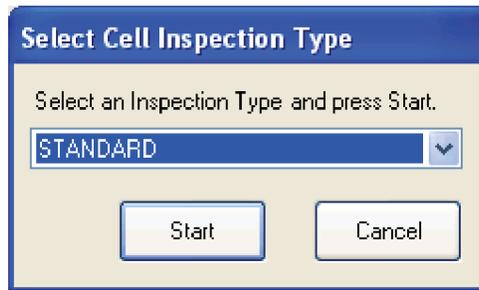


Figure 6.2 Reanalyze Menu

## 6.2 Select Sample Types

Verify that you are at the Main Menu by selecting the "Home" button at the bottom right hand corner of the screen.

1. When no sample type or parameter panel is selected, the "Analyze" button at the bottom right of the screen is disabled. If the Manual sample type is selected, the "Analyze" button turns green and becomes enabled. If the Tray sample type is selected, at least one tray location must be configured in order to analyze the tray.

# BioProfile CDV

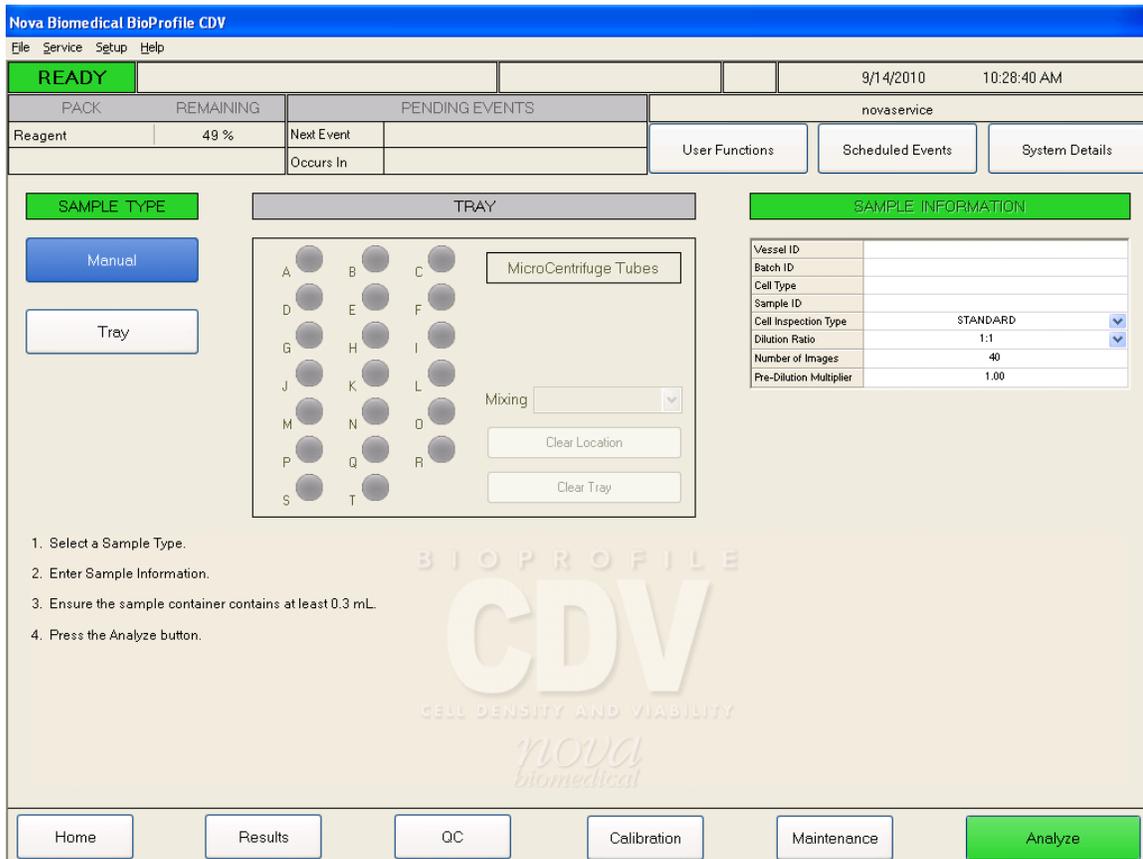


Figure 6.3 Manual Sample Type Screen

2. Choose the appropriate sample type for this sample by selecting "Manual" or "Tray". The Sample Type banner at the top of this selection changes from yellow to green once a selection is made.

If a Tray Sample is selected, a mixing routine can be specified for each sample.

- a. The Normal routine mixes each tray sample 3 times by aspirating, then dispensing the sample into the center of the cup before aspirating the sample for analysis. This routine works well with most cell lines.
- b. The Enhanced routine mixes each tray sample 3 times by aspirating, then dispensing the sample into the cup at 3 different positions around the cup before sample analysis. This allows the sample to be mixed from 3 different locations and significantly improves mixing of samples prone to clumping or sticking.

All Tray settings are retained until cleared by either pressing "Clear Tray" or "Clear Location." Once a sample is run, its location is displayed in red (spent).

**A Instrument Specifications**

This section includes instrument specifications for the Nova BioProfile CDV.

**A.1 Instrument Specifications**

Measurement Range: Cell Density(CD)100,000-80,000,000 cells/mL\*

**\*NOTE:** *The upper limit for CDV can be extended using one of the dilution options available for this parameter.*

*Extended CDV Measurable Range Using a Dilution:*

1:1	200.0 x 10 <sup>5</sup>
1:2	400.0 x 10 <sup>5</sup>
1:4	800.0 x 10 <sup>5</sup>

Analysis Rate:	Test Panel	Analysis Time
	CDV	150 Seconds

Sample Volume: 300 microliters Manual (Non-carousel Systems Only)  
 500 microliters Tray or Carousel  
 350 microliters Reduced Volume

Reagents: One BioProfile CDV Reagent Pack  
 Includes:  
 System Fluid Pack  
 Reagent Bottle Pack

Dimensions:	Height:	18.5 in (47.0 cm)
	Width:	16.0 in (40.6 cm)
	Depth:	20.0 in (50.8 cm)

Weight: 54.5 lb (24.72 kg) without calibrator packs

Power: 100-120, 220-240 VAC, 50/60 Hz, 700W

Cleaning the Cabinet: Clean the cabinet with a damp (not wet) lint-free cloth. Do not use aerosol sprays, solvents, or abrasives that might damage the finish.

# BioProfile CDV

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## A.2 Spare Parts and Supplies List

You can order the following parts and supplies from Nova Biomedical and its distributors.

<b>Description</b>	<b>Part Number</b>
BioProfile CDV Reagent Pack .....	48796
BioProfile CDV V2 Reagent Pack.....	58117
BioProfile Control Level 8.....	43472
BioProfile Control Level 9 .....	43473
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## A.3 Warranty

Subject to the exclusions and upon the conditions specified below, Nova Biomedical or the authorized Nova Biomedical distributor warrants that they will correct free of all charges including labor, either by repair, or at its election, by replacement, any part of an instrument which fails within one (1) year after delivery to the customer because of defective material or workmanship. This warranty does not include normal wear from use and excludes: (A) Service or parts required for repair to damage caused by conditions, electric current fluctuations, work performed by any party other than an authorized Nova representative or any force of nature; (B) Work which, in the sole and exclusive opinion of Nova, is impractical to perform because of location, alterations in the Nova equipment or connection of the Nova equipment to any other device; (C) Specification changes; (D) Service required to parts in the system contacted or otherwise affected by expendables or reagents not manufactured by Nova which caused shortened life, erratic behavior, damage or poor analytical performance; (E) Service required because of problems, which, in the sole and exclusive opinion of Nova, have been caused by any unauthorized third party; or (F) instrument refurbishing for cosmetic purposes. All parts replaced under the original instrument warranty will be warranted only until the end of the original instrument warranty. All requests for warranty replacement must be received by Nova or their authorized distributor within thirty (30) days after the component failure. Nova Biomedical reserves the right to change, alter, modify or improve any of its instruments without any obligation to make corresponding changes to any instrument previously sold or shipped. All service will be rendered during Nova's principal hours of operation. All requests for service outside of Nova's principal hours of operation will be rendered by the prevailing weekend/holiday rates after receipt of an authorized purchase order. Contact Nova for specific information.

The following exceptions apply:

1. Consumable items, including calibrator packs, tubing, and external standards are warranted to be free of defects at time of installation. The item must be placed into service prior to the expiration date printed on the packaging. All defects must be promptly reported to Nova Biomedical in writing. This warranty is invalid under the conditions specified after item 2.
2. Freight is paid by the customer.

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The warranties are invalid if:

1. The date printed on the package label has been exceeded.
2. Non-Nova Biomedical reagents or controls are used, as follows: Nova Biomedical will not be responsible for any warranties on consumables or other parts if these parts are used in conjunction with and are adversely affected by reagents, controls, or other material not manufactured by Nova but which contact or affect such parts. Reagent formulations not manufactured by Nova Biomedical may contain acids, concentrated salt solutions, and artificial preservatives that have been shown to cause problems such as shortened electrode life, electrode membrane damage, electrode drift, erratic analytical results, and inaccurate instrument performance.

THE FOREGOING OBLIGATIONS ARE IN LIEU OF ALL OTHER OBLIGATIONS AND LIABILITIES INCLUDING NEGLIGENCE AND ALL WARRANTIES, OF MERCHANTABILITY OR OTHERWISE, EXPRESSED OR IMPLIED IN FACT BY LAW AND STATE OUR ENTIRE AND EXCLUSIVE LIABILITY AND BUYER'S EXCLUSIVE REMEDY FOR ANY CLAIM OF DAMAGES IN CONNECTION WITH THE SALE OR FURNISHING OF GOODS OR PARTS, THEIR DESIGN, SUITABILITY FOR USE, INSTALLATION OR OPERATION. NOVA BIOMEDICAL WILL IN NO EVENT BE LIABLE FOR ANY SPECIAL OR CONSEQUENTIAL DAMAGES WHATSOEVER, AND OUR LIABILITY UNDER NO CIRCUMSTANCES WILL EXCEED THE CONTRACT PRICE FOR THE GOODS FOR WHICH THE LIABILITY IS CLAIMED. IN ORDER FOR THE WARRANTY TO BE EFFECTIVE, THE WARRANTY CARD MUST BE SENT TO NOVA BIOMEDICAL, 200 PROSPECT STREET, WALTHAM, MASSACHUSETTS, 02454, USA.

## B Theory

This section explains the instrument theory of the BioProfile CDV Analyzer.

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### B.1 Cell Density

The BioProfile CDV measures cell density and cell viability using the Trypan Blue Dye Exclusion method. Live cells with intact cell membranes are selective in the compounds that can pass through the membrane. In a viable cell, Trypan Blue is not absorbed, and the cells appear unstained. However, Trypan Blue traverses the membrane in a dead cell, and the cells stain a distinctive blue color.

The BioProfile CDV Analyzer automates the Trypan Blue Dye Exclusion method and acquires digital images at 10X optical magnification. The cells are counted, measured, and categorized as Live or Dead, using sophisticated image processing software.

# BioProfile CDV

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