BIOPROFILE® FAST CDV

FAST

Fully Automated Cell Density/Viability Analyzer

- Over 45 samples/hr throughput, nearly twice as fast as other analyzers
- Small, 100 µL samples
- Automated cell counts to 140e^6 vc/mL
- 32-position carousel tray and 96 well plate sampling options
- 90-day consumable use life
- 21 CFR Part 11 compliant software

nova® biomedical

FASTEST Fully Automated Cell Density/Via

BioProfile *FAST CDV* is a fully automated analyzer designed to meet the needs of cell culture scientists requiring high throughput, rapid and extremely accurate cell density and cell viability measurements. Utilizing trypan blue dye exclusion methodology with the industry's most innovative and automated sampling preparation, results are available in just one minute while eliminating virtually all manual sample prep procedures. Two precision syringe pumps perform all necessary dilution steps enabling fully automated cell counts to 140e^6 vc/mL. *FAST CDV* requires just 100 µL of sample volume which can be analyzed using Nova's proprietary sample cups designed specifically to eliminate adherence of cells to the cup walls and to enhance mixing of high cell density cultures.

FASTEST throughput

FAST CDV is the fastest cell density and cell viability analyzer utilizing trypan blue dye methodology. An innovative flow path, counting chamber, and automated sample prep sequences allow throughput of 45 samples per hour, nearly double the throughput of other cell density and cell viability analyzers. Two separate precision syringe pumps and sample processing systems enable interleaving of analysis sequences — the high-resolution image processing system can analyze one sample while the next sample is mixed and diluted in preparation for analysis.

Automated cell counts to 140e^6 cells/mL

The precision syringe pumps perform all sample prep steps and can analyze cell densities as low as 5e^4 cells/mL to as high as 140e^6 cells/mL without any manual or external dilutions. With advancements in cell line development and screening, virtually all cell culture processes exceed 15e^6 cells/mL, the upper limit of other automated cell counters. Onboard automated dilutions save labor and eliminate the need for diluents, additional pipets and tubes, while also eliminating errors commonly caused by manual dilutions.

In addition, automated dilutions eliminate cell lysis caused by batch pre-dilution of samples if the diluent is not matched to the osmolality of the sample.

Studies have shown cell viability can fall as much as 20% over the course of 20 minutes with samples that have been batch pre-diluted. *FAST CDV* samples are diluted and then immediately analyzed, eliminating adverse impacts by the diluent.

bility Analyzer

Sampling options

Sampling options include a 32-position carousel tray with true load-and-go functionality and a 96-well motorized tray. With the carousel tray, samples can be continuously loaded without having to remove spent cups, providing maximum workflow efficiency. An onboard waste receptacle has a storage capacity of 300 cups. The 96 well tray accepts standard 96 well plates for processing.

32-position carousel tray with over 45 samples per hour throughput

96-well plate sampling options

Low sample volume requirements

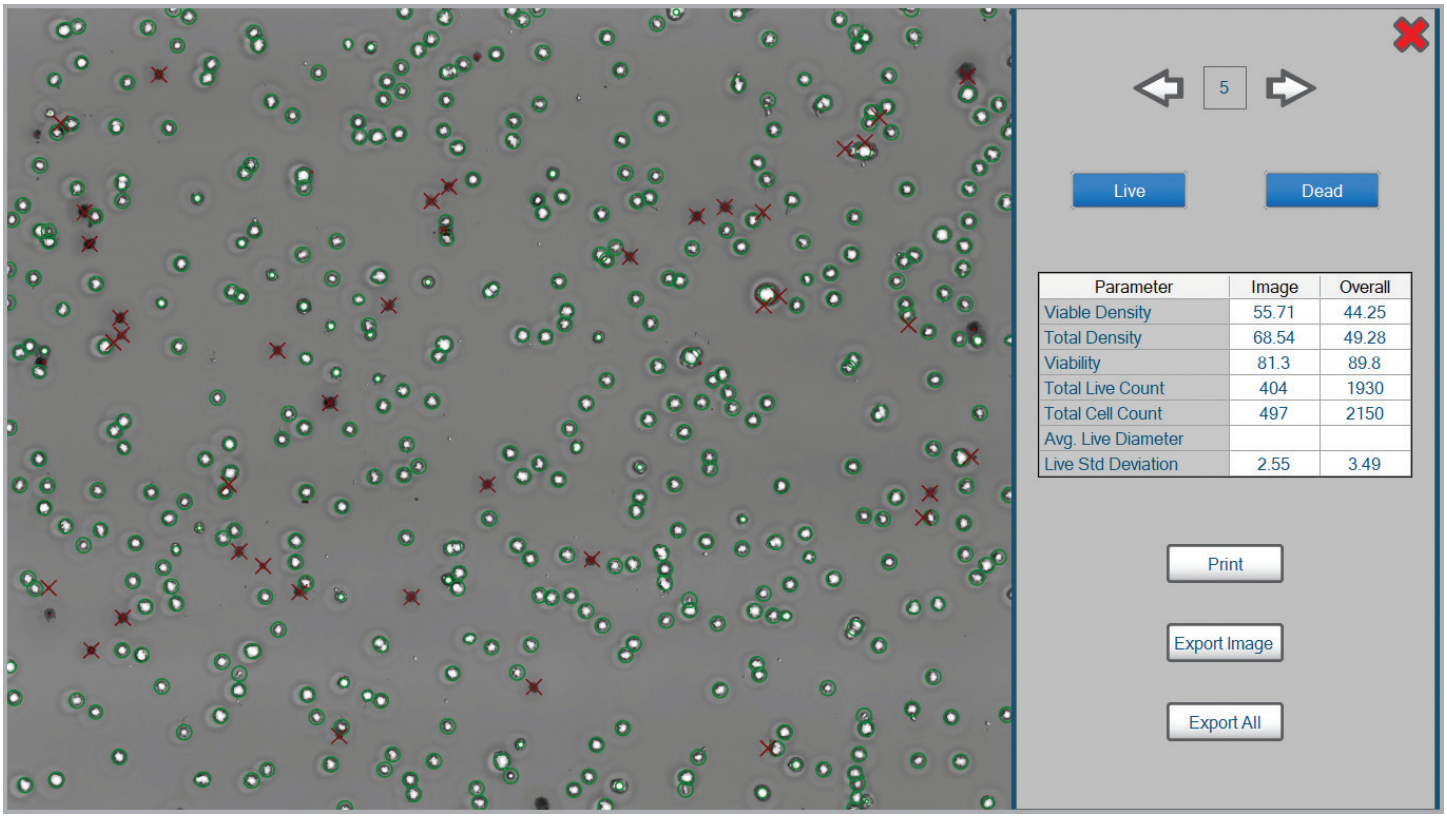
Cell culture continues to advance toward small volume culture systems, and BioProfile *FAST CDV* requires just 100µL of sample to provide accurate analysis of total cell density, viable cell density, cell diameter, and percent aggregate.

21 CFR Part 11 Compliant Software

FAST CDV complies with FDA's GMP electronic records guidance document 21 CFR Part 11. Its software architecture applies the strictest standards to electronic record retention and retrieval, audit trails, user privileges and access, and network security. Nova reviews all updates to FDA's guidance and makes continuous improvements to the software to ensure compliance.

Comparable to BioProfile FLEX2 CDV results

The trypan blue dye technology and algorithms developed for *FAST CDV* were derived from the Nova BioProfile FLEX2 CDV module so there is excellent correlation of *FAST CDV* to FLEX2 data. For customers using other automated cell counters, cell inspection criteria can be customized to ensure results are comparable to virtually any cell counter.

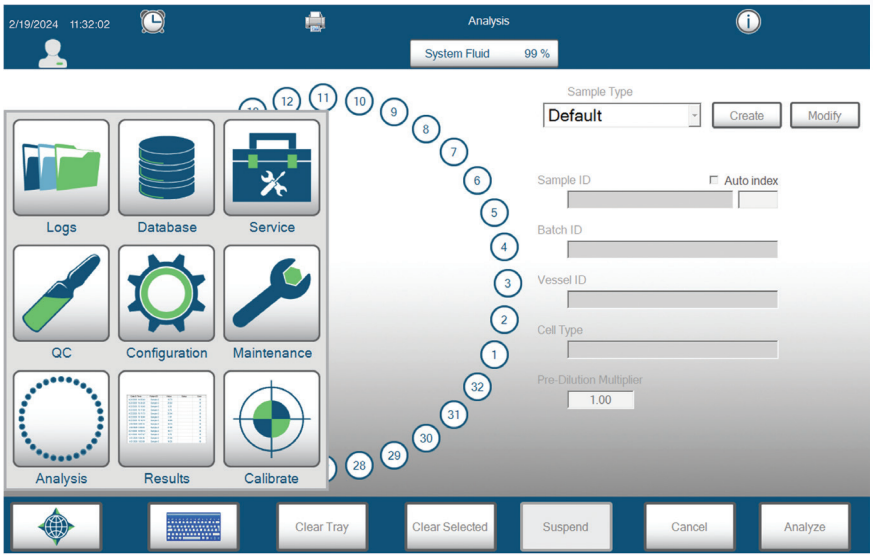


Highest Resolution Image Processing

FAST CDV's high-resolution digital optics and advanced software algorithms, combined with the large number of cells counted, optimize cell counting accuracy and precision.

Intuitive User Interface

An intuitive user interface, custom sample types, and intelligent sample sequencing make sample analysis as easy as two taps of the screen. Custom sample types allow users to save personal settings for automatic population of configuration information as well as preferred onboard dilutions and cell inspection settings. Intelligent sample sequencing automatically indexes and assigns a unique number to each sample. A 10.6 inch touchscreen display with onboard digital keyboard eliminates the need for additional peripherals. Quick navigation icons make it possible to reach the most common functions with a single touch of the screen. A notification header at the top of the user interface provides instant access to date and time, pending events, reagent status, and onboard training tutorials.



Automated maintenance

No maintenance is required beyond reagent pack replacements. All fluid path maintenance is performed automatically utilizing cleaning solutions contained within the reagent pack to ensure maximum uptime.

High-capacity, cartridge-based reagent management system

FAST CDV reagent cartridges incorporate RFID technology for auto-recognition of pack installation as well as logging the installation date, time, lot number, expiration date, and quantity of tests available. Reagent packs have a use life of more than 500 samples and up to 90 days once installed.

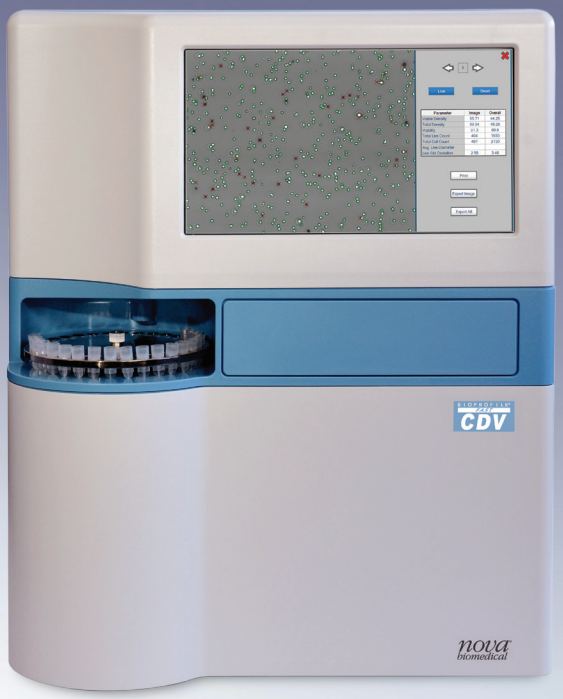
Full network capabilities

FAST CDV has a multitude of options for data transmission and IT data integrity. Both raw data and images can be sent to user-defined network locations on your existing network. As an OPC-compliant device, a custom OPC server coupled with *FAST CDV* can add an additional level of encryption while also enabling bi-directional communication.

Windows Active Directory is used to simplify user account management and user profiles.

Specifications

BIOPROFILE® FAST CDV



Physical Dimensions

Width: 17.5", Depth: 21.5", Height: 16.5"

Parameter Linear Range

Measurement range: 50,000 cells/mL to 140,000,000 cells/mL.
This range is accomplished by user-selectable onboard dilutions performed by the analyzer.
No external/manual dilutions are required. User selectable dilution ratios:

Ratio 1:1 0.05 to 35.00 million cells/mL
Ratio 1:2 0.10 to 70.00 million cells/mL
Ratio:1:4 0.20 to 140.00 million cells/mL

Viability Range

0 to 100%

Live Cell Diameter Range

4 to 70 µm

Accuracy Specifications Summary

Parameter	Reference Analyzer	R^2	Lower Slope Limit	Upper Slope Limit
Total Cell Density	BioProfile FLEX2	0.97	0.95	1.05
Viable Cell Density	BioProfile FLEX2	0.97	0.95	1.05
Viability (%)	BioProfile FLEX2	0.97	0.95	1.05
Live Cell Diameter	BioProfile FLEX2	0.97	0.95	1.05

Units of Measure and Resolution

Analyte	Resolution	Alternate Units
Viable Cell Density	0.01 e^6 cells/mL	0.01 e^5 cells/mL
Total Cell Density	0.01 e^6 cells/mL	0.01 e^5 cells/mL
Viability	0.1 %	
Cell Diameter	0.01 µm	
% Aggregate	0.1 %	

Analysis Time

Fast CDV utilizes a dual flow path, synchronized design to process samples.
Time to complete first sample: Less than 130 seconds
Time to process subsequent results (in queue samples): Less than 70 seconds

General Safety

IEC 61010-1:2001
EN 61000-4-2 Electrostatic Discharge
EN 61000-4-3 Radiated Immunity
EN 61000-4-8 Magnetic Field
21 CFR Part 11 Compliant

Though not a Medical Device, the *Fast CDV* is designed to maintain compliance with cybersecurity requirements outlined in Content for Premarket Submissions for Management of Cybersecurity in Medical Devices – Guidance for Industry and Food and Drug Administration Staff October 2, 2014.

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Specifications current as of revision date.

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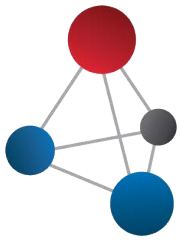
Notes:



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