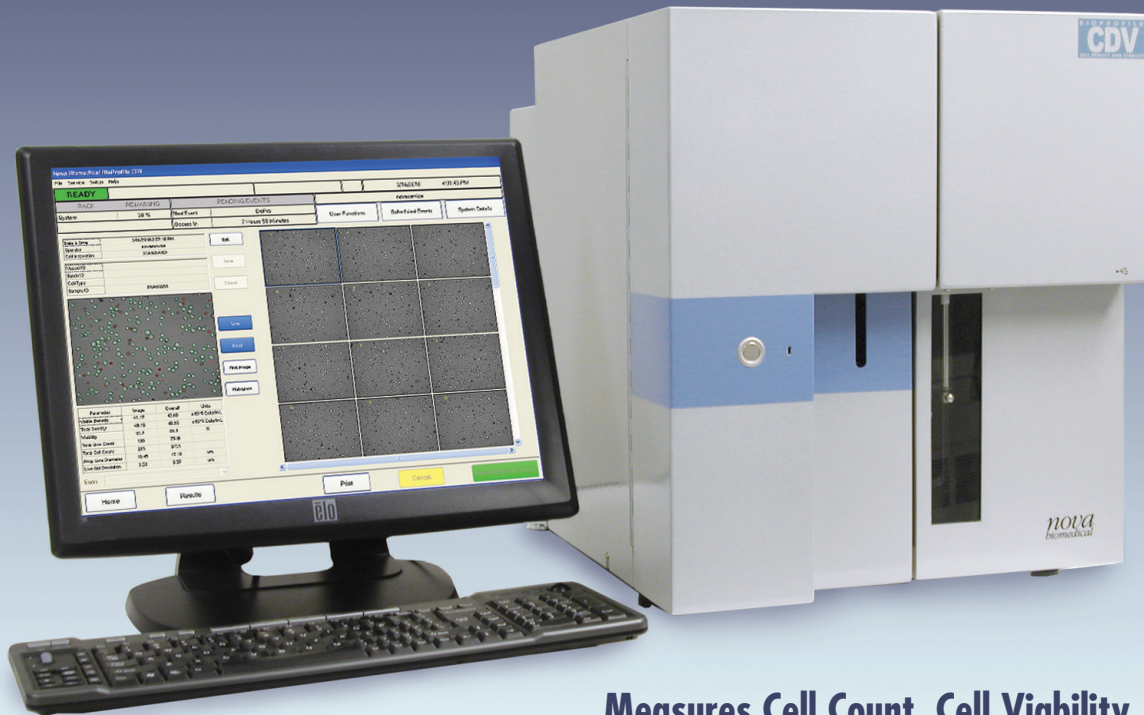


BIOPROFILE[®]
CDV

Advanced Technology, Automated Cell Density/Viability Analyzer



Measures Cell Count, Cell Viability, Cell Size

**High Resolution
Automated Trypan Blue Exclusion Assay at the
Cost of Low Resolution Assays**

Fast Counts, Less than 2.5 Minutes

**Wide Measurement Range, Up to
80 Million Cells per ml**

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Specifications

Principle of Operation:

BioProfile CDV utilizes the industry standard Trypan Blue Exclusion Assay. The cell sample is allowed to settle on a proprietary flowcell that is incrementally moved past the microscope objective (10x). The high powered Vision System, using proprietary detection algorithms, processes the result.

Measured Parameters:

Total Cell Density
Viable Cell Density
% Viability
Live Cell Diameter
Live Cell Standard Deviation/Histogram

Detectable Cell Density Ranges (utilizing selectable on-board dilution)

Dilution Ratio: 1:1
Density Range 100,000–20,000,000 cells/mL
Dilution Ratio: 1:2
Up to 40,000,000 cells/mL
Dilution Ratio: 1:4
Up to 80,000,000 cells/mL

Detectable Cell Diameter Range:

4 – 70 microns

Viability:

0 – 100%

Sample Volume:

less than 300 μ L of aspirated volume

Sampling Options:

Individual via syringe/cup
Automated batch using 20-position sampling tray

Analysis Times:

Less than 2.5 minutes
for manually introduced samples
Less than 3.0 minutes
for tray samples

Accuracy: Correlation Coefficient (R) of 0.97 to the BioProfile FLEX over the operating range

Dimensions:

16" W x 18.5" H x 20" D
(40.6cm W x 47.0cm H x 50.8cm D)

Weight:

Less than 50 pounds (22.7 Kg)

Reagent Pack Description:

2 Pack System with integral waste bag, on-board system diluent, and deproteinization solution.
300+ Samples/pack

Operating Temperature Range:

15-40°C (59-104°F)

User Interaction

17" Touch Screen
Keyboard
Mouse
Printer Support (USB or Network printer)
Barcode Reader
Simple, intuitive User Interface

Data Transfer/Communication:

USB Thumb Drive
Ethernet (RJ45 Connector)

Safety Certifications:

TUV, IEC 61010-1:2001

Quality Systems Certification: TUV: ISO 9001:2000

FDA Registered, OPC Compliant, PAT Compatible, 21 CFR Part 11 Compliant

21CFR Part 11 Compliant

FDA-regulated Good Laboratory Practice (GLP) and current Good Manufacturing Practice (cGMP) sites that utilize computers for instrument control, data acquisition, data transfer and archiving must follow 21CFR Part 11 requirements for electronic records and signatures.

BioProfile CDV provides comprehensive features to assist with meeting these requirements

- **Limited Access:** Administrative password configuration tools limit access to BioProfile CDV electronic records through password privilege levels. Automatic log-off and password de-activation features are also available to prevent unauthorized access.
- **Electronic Record Retention and Retrieval:** All data are securely and confidentially retained through password access control in both human readable and electronic form.
- **Audit Trails:** Time stamped audit trails record the date and time of operator entries of actions that create, modify, or delete electronic records. Records are maintained in original and audited form.

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