

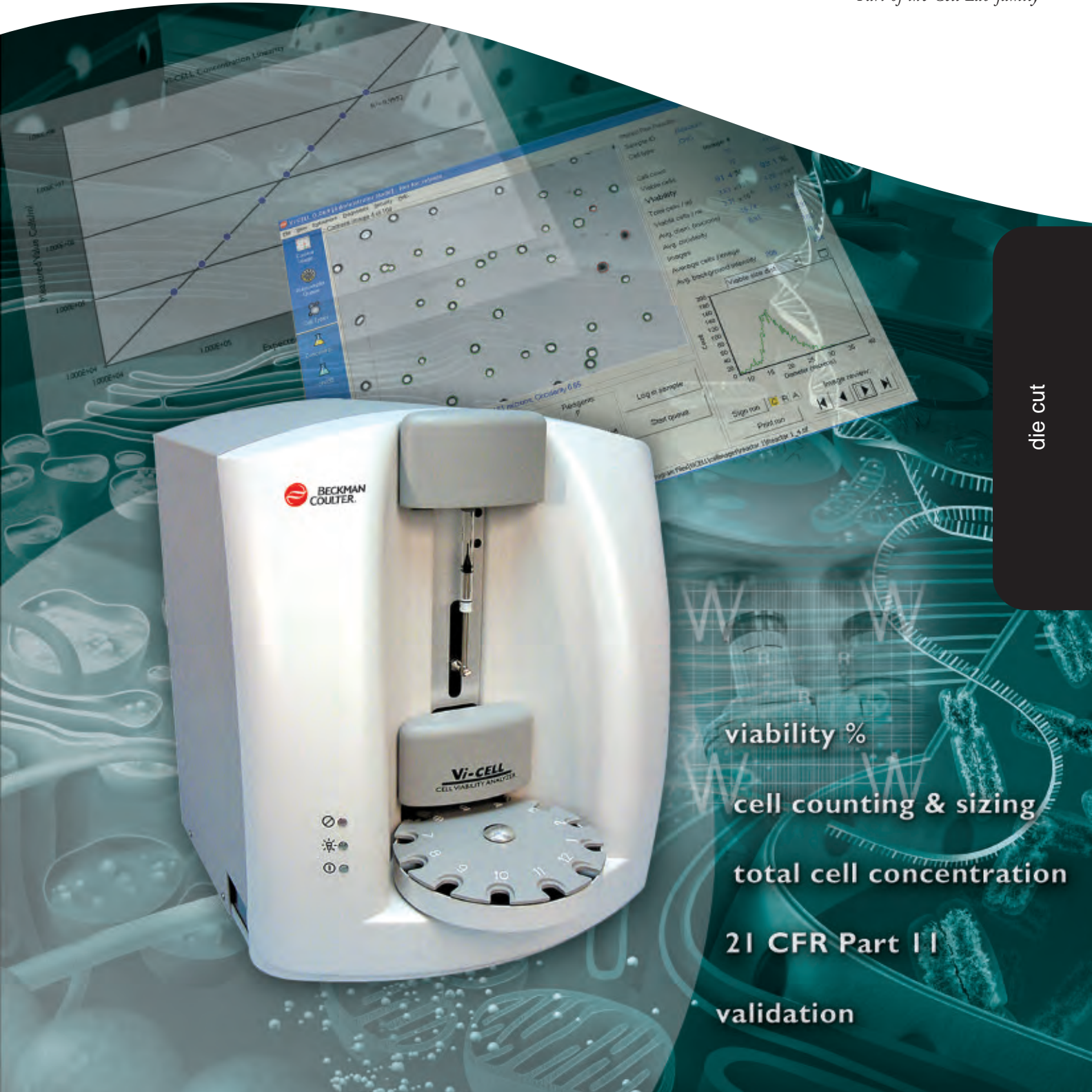


Automated viability solutions

VI-CELL™ SERIES

CELL VIABILITY ANALYZERS

Part of the Cell Lab family



die cut

viability %

cell counting & sizing

total cell concentration

21 CFR Part II

validation



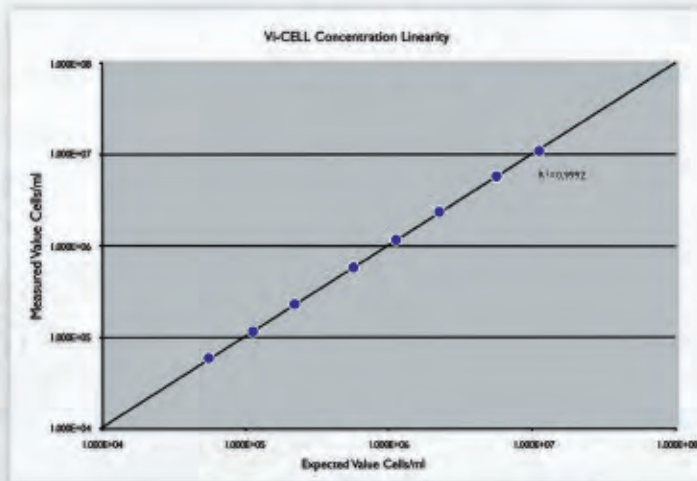
VI-CELL SERIES

Cell Viability Analyzers

The Beckman Coulter Vi-CELL automates the widely accepted trypan blue dye exclusion method for cell viability that has historically been performed manually with a light microscope and hemacytometer. In minutes, the Vi-CELL system measures 15 to 30 times the volume of the hemacytometer method with a more comprehensive number of parameters enhancing statistical reliability of the results.

The Vi-CELL Series features the following key benefits:

- Automated viability analysis using the trypan blue standard.
- Rapid, reliable and objective results over manual hemacytometer methods.
- Cell Imaging provides critical information not available using conventional methods.
- Enhanced Image resolution provides cellular detail 10x better than other image viability analyzers.



The Vi-CELL demonstrates excellent concentration linearity over a wide range.

Theory and Function

TRYPAN BLUE DYE EXCLUSION METHOD

The Vi-CELL utilizes the widely accepted trypan blue dye exclusion method to determine cellular viability. When cells die their membranes become permeable, thus allowing for the uptake of the trypan blue dye. As a result, the dead or non-viable cells become darker than the viable cells. It is this contrast that is measured to determine viability.

INSTRUMENT OPERATION

The Vi-CELL, while simple to use, represents the very latest in cutting edge image analysis technology and fluidics management. At the heart of the Vi-CELL is our customized liquid handling system. This system, which allows sample aspiration, reagent handling, and subsequent instrument cleaning, is fully automated. Once the cellular suspension has been aspirated and mixed with the trypan blue, it is pumped to the flow cell for imaging.

The Vi-CELL will analyze up to 100 images for a determination of cellular viability. This whole process and the subsequent cleaning cycle takes approximately 2.5 minutes.

IMAGING TECHNOLOGY

In the Vi-CELL system a proprietary algorithm is utilized to determine which cells have absorbed the trypan blue dye and which have not.

The first step is to digitize the collected video image and transform this from a continuous smooth image into an array of distinct elements or pixels. The Vi-CELL provides enhanced magnification and an effective pixel area size resulting in superior image resolution. Each element is assigned a "gray level" or brightness value from 0 (black) to 255 (white).

Thresholds within the software then determine which cells have absorbed trypan blue dye and which have not. Those cells that have lower gray values appear "dark" and are determined to be non-viable. Those with high "gray levels" are determined to be viable.

Sample Analysis

*has never been so simple,
it's as easy as ...*



STEP 1:
Load your sample.

STEP 2:
Log-in your sample.

Log in sample

Position	2
Sample ID	Reactor 1
Cell type	CHO
Dilution factor	1.0
Date	4/24/2002
Time	12:42:14 PM
Comment	Antibody Monoclonal # 285

Save images Print results

OK

STEP 3:
View your results.

Stored Run Results		
Sample ID	15mIBIIC	
Cell type	CHO	
	Image 4	Total
Cell count	34	4032
Viable cells	32	3768
Viability	94.1 %	93.5 %
Total cells / ml	2.71×10^6	3.23×10^6
Viable cells / ml	2.55×10^6	3.02×10^6

Software

*with power, flexibility,
and simplicity*

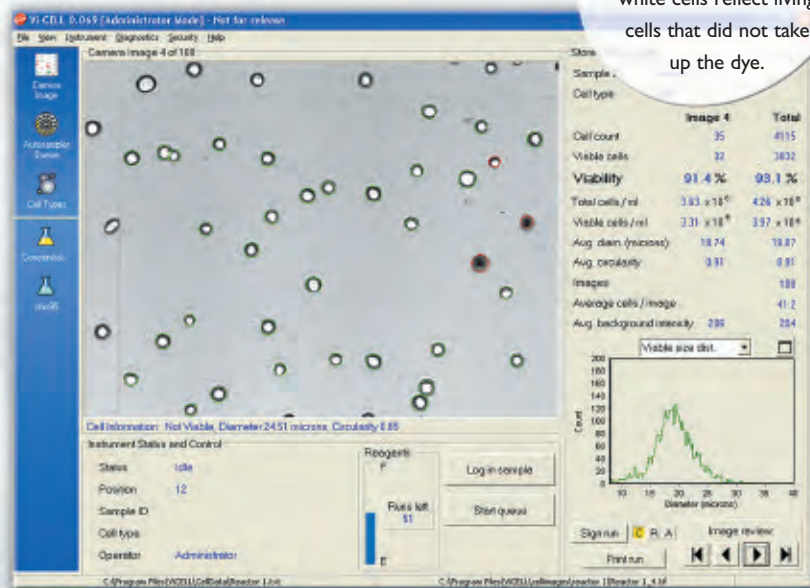
POWER AND FLEXIBILITY FOR R&D, QC AND MANUFACTURING APPLICATIONS – AT YOUR FINGERTIPS

The Vi-CELL software interface has been designed to be simple to use, yet offers numerous innovative features for those users demanding the maximum flexibility.

For many users the main screen may be the only one they need. Everything the user requires to log in samples and view results is right there. All of the available graphs, including Viability %, Viable size distribution, and Total cells/mL are easily selectable via the drop-down menu.

The bioprocess tracking, auto-sampler queue and control monitoring features are easily accessed via the novel navigation bar on the left side of the screen.

Real-time cellular imaging provides additional information not available using standard aperture cell counting methods. This image enhances the results, combining cellular detail with viability, size and concentration.

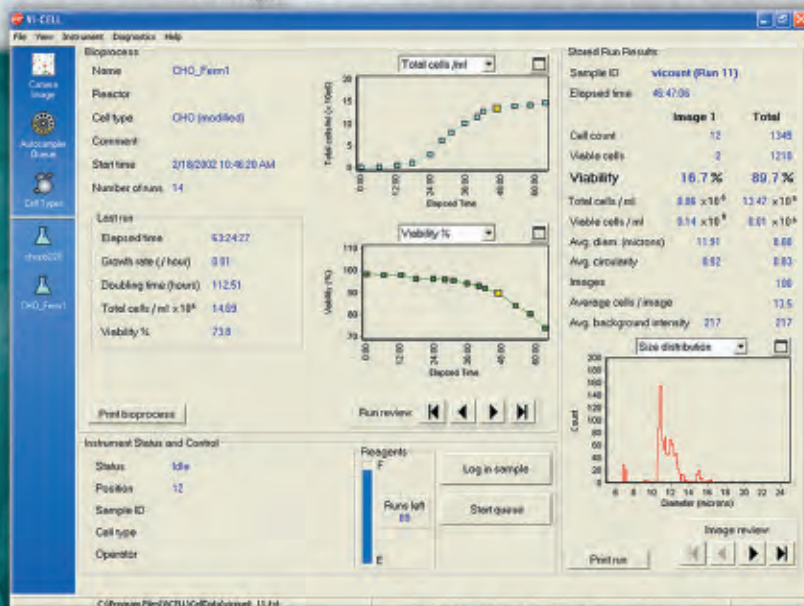


The trypan blue dye uptake by the dark cells here indicate they are dead, whereas the white cells reflect living cells that did not take up the dye.

*Real-time cellular imaging
enhances results*

Optimize your bioreactor data

Monitor your culture over time



BIOPROCESS-TRACKING

The Vi-CELL bioprocess-tracking feature allows convenient, automated tracking of your cell culture parameters, essential for optimum bioreactor productivity. Data points of total cell counts and viability percent are electronically recorded and stored, eliminating potential errors in manual recording. Thus, the bioprocess-tracking feature offers the complete solution for your bioreactor's cellular growth cycle.

Regulatory Compliance

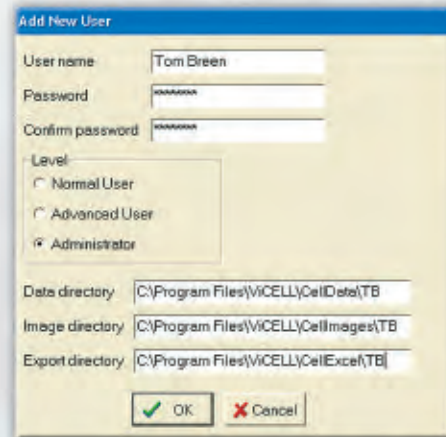
Establishing a strong partnership

21 CFR PART 11

The Electronic Records and Electronic Signatures Rule (21 CFR Part 11) was established by the FDA to define the requirements for submitting documentation in electronic form and the criteria for approved electronic signatures. Since analytical instrument systems such as the Vi-CELL generate electronic records, these systems must facilitate compliance with the Electronic Records Rule. By selecting the 21 CFR Part 11 option in the software, it automatically allows the user to configure the system for compliance.

The Vi-CELL features the following key system components to facilitate 21 CFR 11 compliance:

- Audit trail
- Electronic signature capability
- Secure user sign-on
- User level permissions
- Administrative configuration tools



V-CHECK PROGRAM

Beckman Coulter Inc. complies with current Good Manufacturing Practices (cGMP's). This gives Beckman Coulter a unique understanding of the strict requirements that users in regulated industries are subjected to. As a result, Beckman Coulter has established a comprehensive program to address all aspects of the instrument validation.

The V-Check program is a comprehensive package that addresses all appropriate aspects of a product's life cycle, from instrument development to ongoing performance verification (SQ, DQ, IQ, OQ, PQ). The V-Check program contains all the necessary documentation for instrument validation. This documentation is required to show auditors and investigators proof of proper instrument validation. It consists of a number of functional inter-linked components, which have been

designed to give the user assurance that the product is fit for the purpose that it has been designed for and will perform on a consistent basis for these tasks. Where other instrument manufacturers leave off, Beckman Coulter and the V-Check program assists with ongoing quality checks of the instrument (PQ). This demonstrates that it is important to consider products from a manufacturer that not only understands your needs, but is also willing to develop a Partnership for quality.



Vi-CELL Series

Solutions for low and high-throughput environments

THE VI-CELL S *(Single Position)*

Allows individual sample runs for most all cell types in the size range of 5 to 70 micron diameter.

THE VI-CELL AS *(Auto-Sampler)*

Offers identical capabilities with the added feature of a 12-position sample carousel for increased sample throughput and enhanced automation.

THE VI-CELL XR *(Extended Range)*

Offers additional benefits over the S and AS Models:

- Extended size range to 2 microns, allowing additional analyses of yeast, and smaller cells.
- Increased sample throughput with greater efficiency.
- Reduced sample volume results in less reagent use.
- Auto focus capability increases instrument ease of use.
- Variable aspiration and mixing cycles optimize results.
- Enhanced image magnification (6.75 \times), provides unparalleled cellular detail.
- Circularity measurement helps isolate debris from cells.



The 12-position 'continuous' auto-sampler for high-throughput environments eliminates the need to remove the carousel.



INTEGRATED, VALIDATED REAGENT SOLUTIONS

- Color coded packs
- Quick & easy installation
- Validated reproducibility

Vi-CELL XR Vi-CELL AS Vi-CELL S

Benefits

Part Number	383556	6605769	383080	
Auto Sampler	Yes	Yes	No	Eliminates need to remove carousel
Size Range (µm)	2-70	5-70		Improved measuring range for small cells and yeast
Sample Volume (mL)	0.5	1		Reduced reagent consumption, nearly double the sample runs
Analysis Time (min.)	2.5	3.5		Time savings, increased throughput
Imaging Technology <ul style="list-style-type: none"> • Camera Focus • Image Collection • Camera 	Auto Firewire 1394x1040 CCD	Manual Image Frame Grabber 640x480 CCD		Resolution increased 2x, providing for better analysis of small cells and yeast. Higher resolution improves identification of clustered cells for optimum analysis
Image Zoom	Yes	No		Helps identify and optimize cell types and cell clustering
Aspiration and Trypan Blue Mixing	Variable	Fixed		Helps optimize cell types, such as fragile cell lines. Added mixing helps separate sticky cells before analysis, improving results.
Out of Range Concentration Flag	Yes	No		Automatically keeps operator informed
Filled Dispense Tray Flag	Yes	No		Automatically keeps operator informed
Bioprocess 3D, Rotatable Plotting	Yes	No		Visually see trend changes
Export Multi-run Files to MS Excel	Yes	No		Facilitates Data Handling
Upgraded Audit Trail	Yes	No		Assists in system validation requirements
Non-viable Cell Declustering User-defineable Declustering Options	Yes	No		Helps in optimizing cell types, such as “sticky cell lines” and helps number cells in clusters
Added Preferences for Secured Users	Yes	None		Assists in system validation requirements
Enhanced Circularity Measurement	Yes	No		Helps in isolating debris from sample

CELL LAB

DELIVERING CONTEXTUAL BIOLOGY.

Prepare

Identify

Probe

Sort

Evaluate

Diagnose

Prepare



Identify



Probe



Sort



Evaluate



Diagnose



- Automated liquid handling
- Automated lysing
- General purpose centrifugation
- High performance centrifugation
- Ultracentrifugation

- Automated fluorescence microscopy
- Cell counting
- Cell markers
- Cell viability analysis
- Flow cytometry
- Monoclonal antibodies

- Automated liquid handling
- Flow cytometry
- Microarray technology
- Monoclonal antibodies
- Signal transduction assays

- Cell sorters
- Micro-piezo electric tips
- Reagents (various)

- Monoclonal antibodies
- Multi-mode plate reading
- Genomics solutions
- Proteomics solutions
- Software informatics

- Automated liquid handling
- Flow cytometry
- Immunassays
- Monoclonal antibodies
- Software algorithms

Technical Specifications

Instrument Function:

Concentration Range5×10⁴ to 1×10⁷ cells/mL
*Counting Accuracy: ± 6%**

Operating SystemWindows® 98, Windows® 2000, Windows® XP

Instrument TypeVideo imaging through a quartz flow cell

Power RequirementsPower 50 watts (65 Watts Max.)
Voltages 100V, 120V, 220V
or 240V 50/60 Hz

Temperature10° to 40° C (50° to 104° F)

Weight11.3kg (25lb)

Unit Dimensions (H×W×D)44.5cm (17.5") × 38cm (15") × 41cm (16")

Ordering Information

PART NUMBER		AUTO SAMPLE	SIZE RANGE (µM)	SAMPLE VOLUME (ML)	CYCLE TIME (MIN)	VIABILITY RANGE	IMAGING TECHNOLOGY
383556	Vi-CELL XR	Yes	2-70	0.5	<2.5	0-100	Auto-focus routine Firewire Camera 1394 × 1040 CCD array
6605769	Vi-CELL AS	Yes	5-70	1.0	<3.5	0-100	See VI-CELL S
383080	Vi-CELL S	No	5-70	1.0	<3.5	0-100	Manual focus routine Image frame grabber 640 × 480 CCD array
383722	Vi-CELL XR Quad Pack						
383198	Vi-CELL AS, S Quad Pack						
175478	Vi-CELL Concentration Control						
175474	Vi-CELL Focus Control						

The Vi-CELL Series – and all our Cell Lab offerings – are an important part of a broad continuum of Beckman Coulter products, including automated liquid handling, capillary electrophoresis, centrifugation, ultracentrifugation, DNA sequencing, electrochemistry, flow cytometry, fragment analysis, HPLC, integrated core systems, microarrays, particle characterization, scintillation counting, and spectrophotometry.

For information on our comprehensive line of systems, please contact your local Beckman Coulter representative or visit our web site at

www.beckmancoulter.com/cell.lab

* Against the Coulter Counter® reference method



Developing innovative solutions in Systems Biology.

Innovate **Automate**
SIMPLIFY

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