

iLine F PRO LIVE CELL ANALYZER

Optimize your bioprocess efficiency through real-time cell monitoring





Shed light on your cells

The Ovizio iLine F PRO provides you with improved insight into your cell-based processes by bringing real-time monitoring of Cell Quality Attributes (CQA's).

Based on label-free analysis, our analyzer ensures continuous monitoring of your cells status' without the manual handling usually required.

Secured connection to your bioreactor is ensured by our BioConnect, a **closed-loop cartridge** system that reduces the risk of contamination and further reduces manual handling.

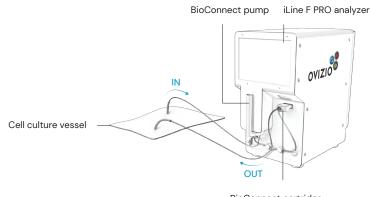
Cell detection is made possible through machine-learning algorithms, enabling continuous tracking of multiple parameters such as viability, bead count, cell activation profile, cell infection status, etc.

Our user-friendly software integrates remote-monitoring and automation features for improved cell-monitoring.

Our solution has followed numerous regulatory controls for **cGMP compliance readiness**, making it the ideal candidate for bioprocessing applications in cell & gene therapy applications.

The result:

- · Real-time information on cell culture status
- Drastically reduced hands-on time
- Maximized availability of biological sample
- Accelerated development of cell-based process



BioConnect cartridge

Features		Benefits
	Automated analyzer Closed-loop system	Achieve continuous cell monitoring Drastically reduce handling operations Drastically reduce risk of external contamination Eliminate wasted biological material
	Machine Learning algorithms	Achieve reproducible measurements Identify multiple Cell Quality Attributes (CQAs) Customize your cell classification
	Remote monitoring	Continuous cell monitoring Early detection of cell-growth issues Alert triggering options
OPC	Open platform communication	Optimize your bioprocesses & feeding strategy Reduce time-to-harvest

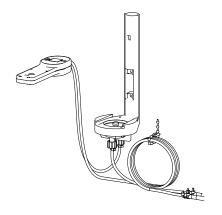
iLine F PRO

The iLine F PRO enables label-free cell analysis through holographic imaging. The analyzer is easy to use and only features one button for on/off operations. It is equipped with a built-in computer and and a 7 inch touchscreen display to enable continuous display of the ongoing cell monitoring.

Data can easily be backed up through a built-in USB port or sent to a dedicated server through the integrated ethernet port. An integrated QR code reader enables BioConnect identification for improved traceability.



BioConnect



Our BioConnect enables **closed-loop connection** between the iLine F PRO analyzer and the bioreactor. Through Luer lock or welding, it can connect with all common types of bioreactors, such as rocking-motion bags, re-usable and disposable benchtop bioreactors or stainless-steel bioreactors. Its assembly meets many ISO and FDA norms such as ISO 10 993, ISO 14 644, CFR 21 210 and CFR 21 211. It has been designed to be cGMP compliant ready for manufacturing vaccines or cell- & gene-therapies.

Machine Learning Algorithm

Our machine learning algorithm will scan each image and identify all visible objects, such as cells and beads. For each of these objects, it will measure multiple features and combine them into a biological signature.

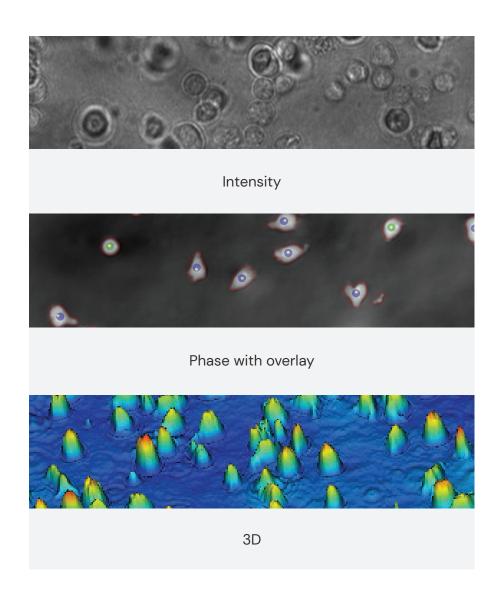
This signature will be utilized for cell classification and enables identification of different cell culture parameters such as:

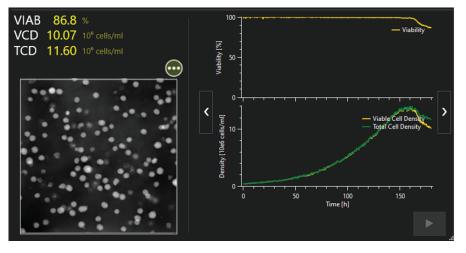
- · Cell viability
- · Cell count
- Magnetic bead count
- Morphological changes



Our software uses machine learning to identify object features and classify cells accordingly Situation A Situation B **Object Features** Diameter 10 Circularity 10 Membrane Regularity 10 Biological Classifier: (10,10,0,...) (7,8,1,...)

OsOne Software





Example of CHO Cells cultivated in Dasgib bioreactor for 7 days.

The OsOne software is at the center of Ovizio's analyzers. Designed to deliver an attractive user experience, OsOne is built for easy data acquisition and thorough quantitative data analysis of suspension cell cultures. The intuitive interface and wizard enable a rapid understanding and navigation through the app. Improved user traceability has been integrated to ensure compliance with FDA norm CFR21/11.

Specifications

Ovizio reader				
Туре	iLine F holographic transmission microscope			
Light source	Partially coherent monochromatic LED 630 nm (red)			
Sensor	C-MOS camera 2456 (H) x 2058 (V) – 8 bits			
Analyzer objective	Olympus LUCPLFLN2OX analyzer objective 20x – 0.45 NA			
Total magnification	22.2X			
Horizontal resolution	1.5 µm			
Field of view	318 µm x 318 µm			
Acquisition rate	15 fps max			
Data volume	128 Mb per measurement point. Note: volume may vary depending on selected cell line			
Input Power	100-240 V AC ~ 47-63 Hz – 45 W Typical, 90 W Max			
Integration capabilities				
Device	400 (15.7" - L) x 223 (9.2" - W) x 423 (16.7" - H) mm - 21 kg			
Shipment box	515 x 320 x 550 mm			
OsOne specifications				
OPC ready, automation via RESTful web services				
Compliant with CFR21/11 regulations				

Data output: ob	iect count, viabilit	y, viable cell dens	ity, total cell density

BioConnect		
Cell concentration range	Cell counting range of 0.5 to 10 Mcells/mL The device provides a ± 10% cell density variation	
Typical flow rate	From 4 to 12 mL/min	
Cell travel time	5 to 25 min. Varies according to specific setup (pump profile, total)	
Tubing length	180 cm of silicon 1 x 3 mm + 2 * 40 cm of PVC 3.1 x 4.2 mm	
Welding interface	PVC tubing (3.1 x 4.2 mm ID x OD)	
Adressable bioreactor volume ¹	From 300 mLto 10.0 L total process	
Retention volume	4.8 mL to 8.3 mL Note: Retention volume of BioConnect only, other tubing added between vessel and BioConnect will increase these values	
Sterilization	Gamma irradiation (25 kGy) and individual packaging	
Flow cell channel height	Between 150 and 200 µm	
Hygrometry	20-80% - non-condensing	
Temperature	15-25°C	
Shelf life	6 months at storage temperature from 15 to 30°C	
Bioreactor inner pressure limitation	Max 7.25 [500] psig [mbarg]	
Regulatory compliance	All fluid-contact materials have passed current USP Biological Test or ISO 10993 certification	

Note: these specifications may change without notice.

¹Tested range for efficient pumping and monitoring

