BioProfile[®] Automated Chemistry Analyzers For Cell Culture and Fermentation



Simultaneous Analyses of up to 13 Key Chemistries

Reduced Testing Time and Cost

On-line automated sampling option

Five models and test menus for cell culture or fermentation



Glu



Multi-Test Analyzers Provide Fast, Easy Measurements

Nova's BioProfile Analyzers include five models of fully automated, multi-test systems designed for rapid, simultaneous analysis from 3 to 13 key measurements of nutrients, metabolites, and gases in cell culture and fermentation media. BioProfile features include:

- All results available in 3 minutes or less
- Automatic, one-button operation
- 40-position batch processing capability
- Automatic analyzer calibration
- No external sample preparation steps (except BioProfile 300)
- No gas tanks required

BioProfile Analyzers for Mammalian Cell Culture

Nova offers three BioProfile Analyzers with test menus specifically designed for mammalian cell culture.

- BioProfile 100 Plus offers eight measured tests including glutamine, glutamate, glucose, lactate, ammonium, pH, sodium, potassium, an calculated osmolality.
- BioProfile 400 adds PO₂ and PCO₂ for a total of ten measured tests, plus calculated air saturation and CO₂ saturation, and bicarbonate (HCO₃⁻).
- BioProfile Basic offers all of the advanced features of our more comprehensive BioProfile Analyzers and measures glutamine, glutamate, glucose, and lactate at a modest price.

BioProfile Basic Test Menu Nutrients/Metabolites Glutamine Glutamate Glucose Lactate

BioProfile 100 Plus Test Menu

	Nutrients/Metabolites	Acid/Base Status	Electrolytes	Calculated Parameter
	Glutamine	pН	Sodium	Osmolality
	Glutamate		Potassium	
	Glucose			
	Lactate			
	Ammonium			

BioProfile 400 Test Menu Nutrients/Metabolites **Calculated Parameters** pH/Gases Electrolytes Glutamine pН Sodium Osmolality Glutamate PO_2 Potassium Air Saturation Glucose PCO_2 CO₂ Saturation HCO₃⁻ Lactate Ammonium

BioProfile Analyzers for Bacterial Fermentation

BioProfile 300 offers a total of nine measured tests, including glucose, lactate, phosphate, glycerol, acetate, ammonium, pH, sodium, and potassium, plus calculated osmolality. The analyzer is offered in two versions: BioProfile 300A, without glycerol, and BioProfile

300B, without phosphate. These systems offer measurement ranges specifically suited to monitor bacterial cultures. A conversion kit is available for easy interchange between the A and B versions.

BioProfile 300 Test Menus								
	Nutrients/Metabolites		Acid/Base Status		Electrolytes		Calculated Parameter	
	Glucose	A/B	pН	A/B	Sodium	A/B	Osmolality	A/B
	Lactate	A/B			Potassium	A/B		
	Ammonium	A/B						
	Acetate	A/B						
	Phosphate	А						
2000000000000	Glycerol	В						

BioProfile 300A: Acetate, phosphate*, glucose, lactate, ammonium, pH, sodium, potassium, osmolality BioProfile 300B: Acetate, glucose, glycerol, lactate, ammonium, pH, sodium, potassium, osmolality *Also reports phosphorus.

BioProfile pHOx

BioProfile pHOx is designed to specifically measure the acid/base and respiratory parameters from cell culture and fermentation media. This compact, easy-to-use

analyzer provides rapid, accurate measurement of pH, PO₂, and PCO₂ in the most appropriate ranges for cell culture and fermentation. In addition, the

analyzer provides calculated values for total CO_2 (TCO₂) and bicarbonate (HCO₃⁻), CO₂ Saturation, and Air Saturation (Dissolved Oxygen).

BioProfile pHOx features a compact, lightweight chassis with an automated on-board quality control system to dramatically reduce operator involvement and maintenance. An all-liquid, fully automatic calibration system eliminates gas tanks, regulators, and tubing lines.

BioProfile pHOx Test Menu				
	pH/ Gases	Calculated Parameters		
	рН	CO ₂ Saturation		
	PO ₂	Air Saturation		
	PCO ₂	HCO ₃ -		
		Total CO ₂		
-		Total CO ₂		

BioProfile Applications

BioProfile Analyzers provide those assays necessary to address the testing requirements from small to large scale bioprocessing, encompassing:

- Research and Development
- Process Development
- Pilot Plant
- Production

Applications of the BioProfile include:

- Monitoring the progress of bioreactor runs
- Determining the consumption and production of key metabolites
- Identification of growth-limiting nutrients
- Design of feeding strategies
- Calibration of bioreactor probes
- Measurement of cellular respiration
- · Balancing media electrolytes
- Control levels of waste products

Fully Automated Testing

BioProfile Analyzers are fully automated and designed for easy use by any operator. After the "ANALYZE" key is pressed, the sample is automatically aspirated, and the analysis is performed without further operator intervention. With the exception of fermentation media, it is not necessary to prefilter the sample prior to testing.

An on-board computer monitors the analysis cycle from sample aspiration to results presentation. The operational status of the BioProfile Analyzer is continuously displayed; any deviation from normal operation is promptly reported to the operator, with any suspect data flagged.



Fast Analysis Time at Reduced Cost

BioProfile's comprehensive test menus allow consolidation of testing on a single analyzer. This results in significant time and labor savings, as well as real-time process control capabilities.

BioProfile's fast analysis time and consolidated testing also offer other advantages:

- Eliminate the requirement for taking multiple samples and large sample volumes from reactor vessels
- Provide real-time access to test results, enabling realtime process control
- · Decrease labor, capital equipment, and reagent costs
- Improve the ability to effectively monitor and control bioreactor processes
- Improve process reliability and reproducibility
- Speed optimization of feeding strategies
- · Improve manufacturing yield and quality



Presentation of Test Results

BioProfile Analyzers report test results on a CRT or monochrome display and a built-in printer. The analyzer can be programmed to alert the operator automatically when test data are outside predetermined normal ranges and critical limits. Out-of-range test samples are flagged on all data printouts.

All results can be stored for review individually or for trend analysis using the optional BioProfile Data Management (BDM) system or via an external computer with appropriate data communications software.

BioProfile 300 A 💳 17 Jul 04 10:57 Analyzer 1 Operator 123 Sample # 89652 Sample ID 17 Jul 04 10:52 Time of Analysis Sample Temperature 37.0 C L I N I H Corrected to 37.0 C 7.481 pН Ι 7.95 g/L 10.5 mmol/L * Gluc * I I. Ace 1.15 mmol/L PO_4 | <u>*</u> | Na+ 135 mmol/L 4.0 mmol/L 1 * 1 K+ NH_4^+ 6.54 mmól/L | * | 2.56 g/L Lac | * | 452.8 m0sm/kg 0sm | * |

Measuring Technologies

Potentiometric Electrodes pH, PCO₂, NH₄⁺, Na⁺, K⁺, Ace

Potentiometric-based electrodes measure charged ions and have a sensing membrane that is selective to the ion being measured. The membrane potential is directly proportional to the logarithm of the concentration of the ion being measured. The potential can be described by the Nernst equation:

$$E_{m} = E_{o} + 2.303 \quad \frac{RT}{nF} \quad \log a_{o}$$

Photometry

PO₄, Gly

BioProfile's photometric assay for phosphate measures the rate of change in light transmission through a sample mixture to calculate the analyte concentration in the sample.

The phosphate assay is based on reaction of phosphate ions with ammonium molybdate to form ammonium phosphomolybdate complex, which is converted to a blue dye using a reducing agent. The rate of change of absorbance of blue dye at 660 nm is proportional to the phosphate concentration.

The glycerol assay is based on oxidation of glycerol into formaldehyde using sodium meta-periodate in buffered solution. Formaldehyde further reacts with acetylacetone in the presence of ammonium salt to form a yellow dihydrolutidine derivative. The rate of change in absorbance of the yellow dye at 430 nm is proportional to the glycerol concentration.

Amperometric Electrodes Glu, Gln, Gluc, Lac, PO,

The basic amperometric electrode is the oxygen electrode, which consists of an oxygen-permeable membrane covering a platinum cathode. This cathode is kept at constant potential. As the sample oxygen diffuses through the membrane, it is reduced at the cathode, consuming electrons. This change in current flow is directly proportional to the oxygen concentration in the sample.

Glutamine, glutamate, glucose, and lactate biosensors are amperometric electrodes that have immobilized enzymes in their membranes. In the presence of oxygen and the substrate being measured, these enzyme membranes produce hydrogen peroxide (H_2O_2), which is then oxidized at a platinum anode held at constant potential (see equations below). The resulting flow of electrons and current change is proportional to the sample concentration.



Analytical Performance

Correlation Data Analyte	Correlation Coefficient (R ²)	Comparison Analyzer/Method
Glutamine	0.99	YSI 2700 Select Dual Channel Analyzer
Glutamate	0.99	YSI 2700 Select Dual Channel Analyzer
Glucose	0.99	YSI 2700 Select Dual Channel Analyzer
Lactate	0.99	YSI 2700 Select Dual Channel Analyzer
Ammonium	0.99	R-Biopharm Ammonium Test Kit (Boehringer Mannheim)
Osmolality	0.99	Precision Systems Inc., Multi-Osmette Model 2430
pН	0.99	Chiron/Bayer 248
PO ₂	0.98	Chiron/Bayer 248
PCO ₂	0.98	Chiron/Bayer 248
Acetate	0.99	Boehringer Mannheim Acetate Kit
Phosphate	0.99	Ortho Ektachem DT 60
Glycerol	0.99	Ortho Ektachem DT 60

Results obtained from BioProfile Analyzers are compared to those obtained using conventional techniques; correlation data are summarized in the accompanying table. Correlation graphs for ammonium and acetate are shown below. A complete set of correlation graphs is displayed on the Nova web site (www.novabiomedical.com).





Ammonium Correlation ($R^2=0.99$)

Acetate Correlation ($R^2=0.99$)

Direct, Batch, or Automated Sampling

BioProfile Analyzers offer the flexibility of sampling in the following modes:

- Direct Sampling test tube, syringe, pipette, flask
- Batch processing 40-position tray with full walkaway automation
- Optional On-Line Autosampler connects up to 4 bioreactors for direct, automated sampling



Mobile Workstation Cart



Mobile workstation carts with a UPS power supply are available for all BioProfile models. These carts allow transport of the analyzer to any location.

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Compact cart (*BioProfile pHOx*)

Automated Sampling

The BioProfile On-Line Autosampler connects up to four bioreactors or fermentation vessels to a BioProfile Analyzer for direct, automated sampling. Sampling frequency is programmed into the BioProfile Data Management System (BDM) by the user for data storage and/or review and trend analysis. The BDM is included with the On-Line Autosampler.





Feedback Control System

A Feedback Control System, available as an option to the On-Line Autosampler, allows automated introduction of nutrients when preset limits are reached. Addition of nutrients is signaled by the BDM when a specified parameter measures outside the programmed range. As many as eight feedback loops can be configured.



Data courtesy of Cytomatrix, Woburn, MA

OPC Server

Nova's OPC Server software allows the BioProfile Analyzer to transfer analytical data on key chemistries to any bioreactor controlling software that is OPC compliant. This critical data allows the controller to initiate real time feedback control to optimize the bioprocess. The OPC Server software can be installed on the Nova BioProfile Data Manager (BDM) or on an ancillary computer.

An acronym for "OLE for Process Control," OPC is a published industrial standard for system interconnectivity that provides a standards-based infrastructure for the exchange of process control data. It uses Microsoft COM and DCOM technology to enable applications to exchange data on one or more computers using client server architecture. OPC defines a common set of interfaces so that each application retrieves data in exactly the same format, regardless of the data source. Using OPC standards, data can be transmitted from any data source to any OPC-compliant application including HMI/SCADA, data historians, spreadsheets, and databases. The result is a complete, out-of-the-box, plug and play communication solution.

True interoperability reduces implementation costs and builds a fully scaleable system to accommodate your current and future bioprocessing requirements.



21 CFR Part 11 Compliance

21 CFR Part 11 describes regulatory requirements governing electronic signatures and records that assure the integrity of data within a diagnostic instrument such as the BioProfile Analyzer.

The BioProfile Data Management System (BDM) incorporates effective archival and restorative

mechanisms as well as adequate security features and audit trails to automatically monitor the creation, modification, and deletion of electronic records. These features create full compliance with 21 CFR Part 11 requirements.

In-Depth Customer Support

Nova provides a variety of in-depth programs to assist in the technical support, training, service, and validation of our BioProfile Analyzers. Our large internal support staff and 40 person domestic field support group can execute timely and efficient installation, training, instrument qualification, instrument qualifications validation, and field service to keep Nova's systems functional. This capability sets Nova apart from our competition.

Professional Installation

Nova customer support begins with professional installation of the BioProfile Analyzer by a qualified Nova service technician who is trained on a host of biotechnology applications. Nova's well developed and established organization has provided service to our customers for more than 25 years, and can be integral to the success of your bioprocess monitoring program.

Comprehensive Training Programs

Upon installation, the service representative will provide onsite training, focusing on operation, troubleshooting, and maintenance issues. This training will allow your group of primary users to become familiar with the system and allow any applicationspecific issues to be resolved.

An optional advanced training program for the key operator, held at Nova's headquarters facility in Waltham, MA, is also available. The factory training is a three-day course covering all technical aspects of the systems from measurement theory to troubleshooting. A certificate is provided for documentation in your company training records. In addition, ongoing customized training programs are available for user groups either onsite or at Nova's headquarters.

Technical and Applications Support

Technical and applications support is provided by Nova's Biotechnology Applications Support Specialists. Should onsite service be required, a trained service technician will be dispatched to your facility, following notification of a problem.

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The BioProfile Instrumentation Qualification (IQ) protocol provides comprehensive information to assist you in validating your BioProfile Analyzer for use in your bioprocess. The IQ protocol includes:

- System documentation
- Pre-installation checks
- Installation procedure checks
- Installation performance qualification
- Instrument/system control verification

The BioProfile Instrumentation Qualification/ Operation Qualification (IQ/OQ) service includes all Installation Qualification procedures outlined above plus:

- Performance of IQ/OQ procedures
- All required NIST traceable standard materials
- Statistical analysis and final report

These optional services can be performed either during installation or at a later date.

Correlation, Recovery, and Precision Studies

Nova has performed a series of correlation, weigh-in recovery, and precision studies to assist customers with validation of our BioProfile Analyzers. The correlation studies demonstrate the comparability between BioProfile Analyzers for each of the analytes measured by the BioProfile Analyzer versus competitive instrumentation. The weigh-in recovery studies provide a clear-cut indication of measurement accuracy, while precision studies assure consistent performance for each measured parameter.



BioProfile Models and Test Menus

BioProfile pH	Ox	Tact		
Parameters	eters Methodology		Measuring Range	Imprecision +/-
pН		Ion Selective Electrode	5.00-8.00 pH units	0.01
PO ₂		Membrane Amperometric	0-800 mmHg	5.0%
PCO ₂		Membrane Potentiometric	3-200 mmHg	5.0%
- Drofile De				
BioProfile Ba	SIC	Test		
Parameters		Methodology	Measuring Range	Imprecision +/-
Glutamine		Enzyme/Amperometric	0.2-6.0 mmol/L	5.0%
Glutamate		Enzyme/Amperometric	0.2-6.0 mmol/L	5.0%
Glucose		Enzyme/Amperometric	0.2-15.0 g/L	5.0%
Lactate		Enzyme/Amperometric	0.2-5.0 g/L	5.0%
BioProfile 10	0 Plus			
Parameters		lest Methodology	Measuring Range	mprecision +/-
Glutamine		Enzyme/Amperometric	0.2-6.0 mmol/L	5.0%
Glutamate		Enzyme/Amperometric	0.2-6.0 mmol/L	5.0%
Glucose		Enzyme/Amperometric	0.2-15.0 g/L	5.0%
Lactate		Enzyme/Amperometric	0.2-5.0 g/L	5.0%
Ammonium		Ion Selective Electrode	0.2-25.0 mmol/L	5.0%
pH		Ion Selective Electrode	5.00-8.00 pH units	0.01
Na ⁺		Ion Selective Electrode	40-220 mmol/L	1.5%
K ⁺		Ion Selective Electrode	1.0-25.0 mmol/L	3.0%
Die Drefile 20				
BioProfile 30	U A7 B	Test		
Parameters		Wiethodology		
Giucose	A/B	Enzyme/Amperometric	0.0-30.0 g/L	5.0%
Lactate	A/B	Enzyme/Amperometric	0.0-8.0 g/L	5.0%
Ammonium	A/B	Ion Selective Electrode	0.2-200.0 mmol/L	5.0%
pH	A/B	Ion Selective Electrode	4.00-8.00 pH units	0.01
Na⊤	A/B	Ion Selective Electrode	40-220 mmol/L	3.0%
K ⁺	A/B	Ion Selective Electrode	1.0-25.0 mmol/L	3.0%
Acetate	A/B	Membrane Potentiometric	2.0-200.0 mmol/L (0.12 - 11.80 g/l	.) 6.0%
Phosphate*	Α	Photometric, Light Transmission	0.0-2.0 mmol/L	0.1
Glycerol	B	Photometric, Light Transmission	0.0-10.0 g/L	6.0%
*Also reports phospi	norus. Measu	uring range 0-60 mg/L.		
BioProfile 40	0	Test		
Parameters		Methodology	Measuring Range	Imprecision +/-
Glutamine		Enzyme/Amperometric	0.2-6.0 mmol/L	5.0%
Glutamate		Enzyme/Amperometric	0.2-6.0 mmol/L	5.0%
Glucose		Enzyme/Amperometric	0.2-15.0 g/L	5.0%
Lactate		Enzyme/Amperometric	0.2-5.0 g/I	5.0%

Glucose Enzyme/Amperometric 0.2-15.0 g/L 5.0%	
Lactate Enzyme/Amperometric 0.2-5.0 g/L 5.0%	
AmmoniumIon Selective Electrode0.2-25.0 mmol/L5.0%	
pH Ion Selective Electrode 5.00-8.00 pH units 0.01	
PO ₂ Membrane Amperometric 0-800 mmHg 5.0%	
PCO ₂ Membrane Potentiometric 3-200 mmHg 5.0%	
Na ⁺ Ion Selective Electrode 40-220 mmol/L 1.5%	
K+Ion Selective Electrode1.0-25.0 mmol/L3.0%	

BioProfile Specifications

BioProfile pHOx

Measured Parameters: pH, PO₂, PCO₂

Calculated Parameters: Total CO₂, HCO₃⁻, Air Sat, CO₂ Sat Sample Analysis Time: 45 seconds

Sample Size: Minimum 0.3 mL

Sample Containers: Test tube, syringe, pipette, flask

Calibration:

User-selectable, fully-automatic two-point calibration every 2, 4 or 6 hours; user-selectable single-point calibration every 30 or 45 minutes, independent of sample or with each sample; manual calibration at any time

Data Transmission Ports: RS-232 serial, ASTM protocol

Electrical Requirements: 100-120; 220-240 VAC, 50/60 Hz, 130W System Printer: 29-column thermal

BioProfile Basic

Measured Parameters: Glu, Gln, Gluc, Lac

Sample Analysis Time: 3.0 minutes

BioProfile 100 Plus

Measured Parameters: Glu, Gln, Gluc, Lac, NH4+, pH, Na+, K+ **Calculated Parameter:** Osm

Sample Analysis Time: 2.0 minutes

BioProfile 300 A/B

Measured Parameters (300A): Ace, PO₄, Gluc, Lac, NH₄⁺, pH, Na⁺, K⁺ **Measured Parameters (300B):**

Ace, Gluc, Lac, Gly, NH₄⁺, pH, Na⁺, K⁺ Calculated Parameter: Osm

Sample Analysis Time: 2.5 minutes

BioProfile 400

Measured Parameters: Glu, Gln, Gluc, Lac, NH₄⁺, pH, PO₂, PCO₂, Na⁺, K⁺ **Calculated Parameters:** Osm, Air Sat, CO₂ Sat, HCO₃ Sample Analysis Time: 3.0 minutes

Available on All Analyzers

Optional Accessories: Bar code reader (sample identification) Mobile workstation cart with UPS power supply (BioProfile Basic, 100 Plus, 300, 400) Compact cart with UPS power supply (BioProfile pHOx)

User-Definable Features: Parameters to be reported, offset range, units of measure, auto or manual data presentation, date and time, out-ofrange flagging levels, alert range flagging levels, quality control ranges, quality control reminder ON/OFF interval, mandatory control reminder ON/OFF interval

System Size and Weight: **Height:** 15.0 in (38.1 cm) Width: 12.0 in (30.5 cm) Depth: 15.0 in (38.1 cm) Weight: 18 lbs (8.2 kg) without reagent pack

Certifications: ISO 9001, CSA, TÜV, CE

Sample Size: Minimum 0.5 mL **Calibration:**

Fully-automatic two-point calibration; single-point calibration with each sample

User-Definable Features: Parameters to be reported, offset range, units of measure, auto or manual data presentation, date and time, user passwords, out-ofrange flagging levels, quality control ranges

Sample Containers: Test tube, syringe, pipette, flask

Data Transmission Ports: RS-232 serial

Electrical Requirements: 90 to 230 Volts, 50/60 Hz

System Printer: 52 column thermal

System Size and Weight: Height: 20.5 inches (52 cm) Width: 19.2 inches (49 cm) Depth: 20.7 inches (53 cm) **Weight:** 90 lbs (41 kg)

Certifications: ISO 9001, CSA, TÜV, CE

- On-Line Autosampler (Except BioProfile pHOx) Connects up to four bioreactors or fermentation vessels to a single analyzer
- Feedback Control System (option to On-Line Autosampler) Allows automated introduction of nutrients when preset limits are reached





World Leader in Biosensor Technology

Nova Biomedical is the world leader in the development of biosensor technology for the measurement of metabolites, nutrients, electrolytes, and gases in complex physiological solutions.

Over twenty-five years, Nova's technology has been proven accurate and reliable in thousands of hospitals and laboratories that use our biosensor-based analyzers.



Nova Biomedical Firsts

- 1978 First practical biosensor for Ionized Calcium
- 1980 First biosensor to measure Chloride in blood
- 1984 First biosensor to measure Total Calcium
- 1985 First biosensor to measure Hematocrit by ISE/Conductivity
- 1987 First biosensor to measure Lithium
- 1988 First biosensor to directly measure whole blood Glucose

- 1990 First biosensor to measure BUN (urea)
- 1992 First biosensor to directly measure whole blood Lactate
- 1994 First biosensor to measure Ionized Magnesium
- **1996** First biosensor to measure Total CO₂ in whole blood
- 1996 First biosensor to measure Creatinine
- **1997** First fiber-optic SO₂% assay

- 1998 First nonlysing optical Hemoglobin assay
- 1998 First Ammonium biosensor
- 1999 First non-diluting direct Glutamine biosensor
- 1999 First non-diluting direct Glutamate biosensor
- 2001 First Acetate biosensor



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