

BioProfile® Automated Chemistry Analyzers For Cell Culture and Fermentation

Six models, simultaneous analysis of up to 13 key chemistries

Gluc Lac Gln Glu NH₄⁺ Osm pH
PO₂ PCO₂ Na⁺ K⁺ Ace PO₄ Gly

Fully automated testing

Direct sampling or batch processing with 40-position sample tray

Fast analysis time and reduced cost



nova[®]
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Multi-Test Analyzers Provide Fast, Easy Measurements



Nova's BioProfile Analyzers include six models of fully automated, multi-test systems designed for rapid, simultaneous analysis of 2 to 13 key nutrients, metabolites, and gases in cell culture and fermentation processes. BioProfile features include:

- Results in 3 minutes or less
- Automatic, one-button operation
- 40-position batch processing capability
- Automatic analyzer calibration
- No sample preparation
- No gas tanks required

BioProfile Analyzers for Cell Culture

Nova offers 4 models of BioProfile Analyzers with test menus specifically designed for mammalian cell culture.

- BioProfile Basic 2 measures glucose and lactate.
- BioProfile Basic 4 measures glucose, lactate, glutamine, and glutamate.
- BioProfile 100 Plus offers eight measured tests including glucose, lactate, glutamine, glutamate, ammonium, pH, sodium, potassium, and calculated osmolality.
- BioProfile 400 adds PO₂ and PCO₂ to the BioProfile 100 Plus test menu, and also calculated air saturation (dissolved oxygen), CO₂ saturation, and bicarbonate (HCO₃⁻).

BioProfile Analyzers for Fermentation

BioProfile 300 series analyzers offer a total of nine measured tests, including glucose, lactate, phosphate or glycerol, acetate, ammonium, pH, sodium, and potassium, plus calculated osmolality. The analyzer is offered in two versions: the BioProfile 300A which includes a phosphate assay, and the BioProfile 300B with glycerol testing. These systems offer measurement ranges specifically suited to monitor bacterial and yeast cultures. A conversion kit is available for easy interchange between the 300 A and B versions.

BioProfile pH0x

BioProfile pH0x 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 CO₂ (TCO₂), bicarbonate (HCO₃⁻), CO₂ saturation, and air saturation (dissolved oxygen).

BioProfile pH0x features a compact, lightweight chassis with an automated on-board quality control system to dramatically reduce operator involvement and maintenance.

BioProfile System Selection Guide

| | Glc | Lac | Glu | Gln | NH ₄ | pH | PCO ₂ | PO ₂ | Na | K | Ca | OSM | CD | CV | CDi | IgG | Ace | PO ₄ | Gly |
|----------------------------|-----|-----|-----|-----|-----------------|----|------------------|-----------------|----|---|----|-----|----|----|-----|-----|-----|-----------------|-----|
| BioProfile 400 | X | X | X | X | X | X | X | X | X | X | | | | | | | | | |
| BioProfile 100 Plus | X | X | X | X | X | X | | | X | X | | | | | | | | | |
| BioProfile Basic 4 | X | X | X | X | | | | | | | | | | | | | | | |
| BioProfile Basic 2 | X | X | | | | | | | | | | | | | | | | | |
| BioProfile 300A | X | X | | | X | X | | | | | | | | | | | X | X | |
| BioProfile 300B | X | X | | | X | X | | | | | | | | | | | X | | X |
| BioProfile pH0x | | | | | | X | X | X | | | | | | | | | | | |
| BioProfile FLEX | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | | X | |
| BioProfile CDV | | | | | | | | | | | | | X | X | | | | | |

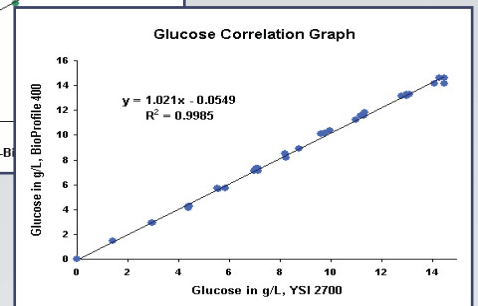
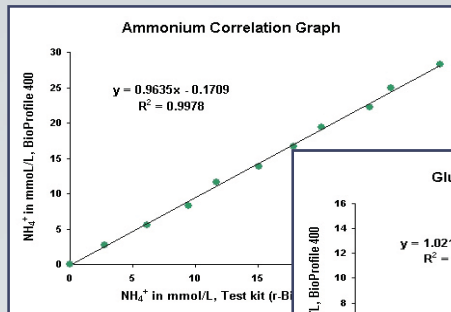
Fully Automated Testing

BioProfile Analyzers are fully automated and designed for ease of use. 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 pre-filter the sample prior to testing. An on-board computer monitors the analysis cycle from sample aspiration to results presentation. Any deviation from normal operation is detected and any suspect data flagged.



Accurate Analytical Performance

BioProfile Analyzers use a combination of measuring technologies, including amperometric and potentiometric sensors and photometric sensors, to provide accurate test results. As shown in these correlation graphs for ammonium and glucose, results obtained from BioProfile Analyzers are accurate throughout a wide measurement range. A complete set of correlation graphs is displayed on the Nova web site (www.novabiomedical.com).

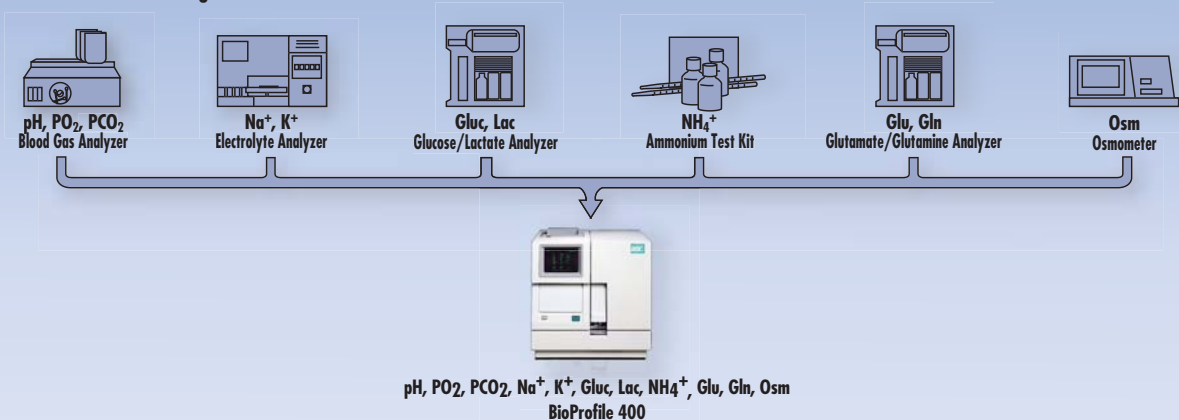


Fast Analysis Time at Reduced Cost

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:

- Eliminates the requirement for taking multiple samples and large sample volumes from reactor vessels
- Provides real-time access to test results, enabling real-time process control
- Improves data analysis with a single data stream and OPC capability
- Decreases labor, capital equipment, and reagent costs
- Improves the ability to effectively monitor and control bioreactor processes
- Improves process reliability and reproducibility
- Speeds optimization of feeding strategies
- Improves manufacturing yield and quality

BioProfile 400 Time and Labor Savings



Direct or Batch Sampling

BioProfile Analyzers offer the flexibility of direct sampling from tubes, syringes, and flasks, or batch processing with the 40-position tray allowing full walk-away automation.



Presentation of Test Results

BioProfile Analyzers report test results on a display and a built-in printer. The analyzer can be programmed to automatically alert the operator 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.

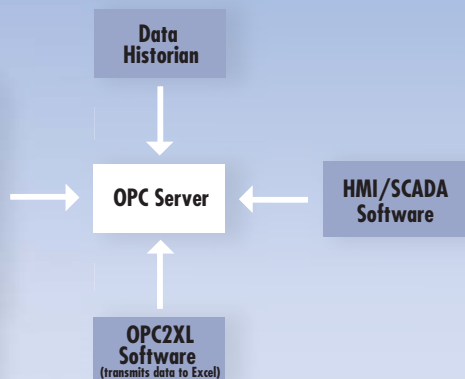
| BioProfile 300 A | | | | |
|------------------------------|-----------------|------------|---|---|
| Operator 123 | 17 Jul 03 10:57 | Analyzer 1 | | |
| Sample # | 1 | | | |
| Sample ID | 89652 | | | |
| Time of Analysis | 17 Jul 03 10:52 | | | |
| Sample Temperature | 37.0 C | | | |
| Corrected to 37.0 C | | L | N | H |
| pH | 7.481 | | * | |
| Gluc | 7.95 g/L | | * | |
| Ace | 10.5 mmol/L | | * | |
| PO ₄ | 1.15 mmol/L | | * | |
| Na ⁺ | 135 mmol/L | | * | |
| K ⁺ | 4.0 mmol/L | | * | |
| NH ₄ ⁺ | 6.54 mmol/L | | * | |
| Lac | 2.56 g/L | | * | |
| Osm | 452.8 mOsm/kg | | * | |

OPC Server

Nova's OPC Server software allows total system management of the BioProfile Analyzer including transfer of 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. The OPC Server software can be installed on the Nova BioProfile Data Manager (BDM) or on an ancillary computer.

Using OPC standards, BioProfile data can be transmitted 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.

Typical System Configuration



Comprehensive Customer Support



Professional Installation

Nova customer support begins with professional installation of the BioProfile Analyzer by a qualified Nova service technician. Installation consists of setting up the analyzer, verifying performance, and providing on-site training of operators.

Technical and Applications Support

Technical and applications support is provided by Nova's Biotechnology Applications Support Specialists. Our applications support personnel have extensive backgrounds in cell culture and fermentation processes.

IQ/OQ

The BioProfile Instrumentation Qualification (IQ) protocol provides assistance in validating your BioProfile Analyzer for use in bioprocesses. 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 quality control material
- Statistical analysis and final report

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

Other BioProfile Analyzers



BioProfile FLEX

BioProfile FLEX is an automated, modular, multi-test analyzer for fast, comprehensive cell culture analysis. The FLEX measures up to 16 key cell culture attributes from a small 1 ml sample. Results are available in 2-8 minutes, depending on tests selected. The modular design of BioProfile FLEX can be customized with one to four analytical modules:

- Chemistry/Electrolyte/Gas
- Cell Density, Cell Viability, Cell Diameter
- IgG/PO₄
- Osmolality



BioProfile CDV

BioProfile CDV incorporates advanced, state-of-the-art technology for rapid, high resolution measurement of cell density and cell viability at a moderate cost. It measures cell count, cell viability, and cell size using the high resolution automated trypan blue exclusion assay. It does this at the cost of low resolution assays. Counts are fast, less than 3 minutes and the wide measurement range is up to 80 million cells per ml.

BioProfile Specifications

BioProfile Basic 2/4

Measured Parameters

Basic 2: Gluc, Lac

Basic 4: Gluc, Lac, Gln, Glu

Sample Analysis Time: 2.0 minutes

BioProfile 100 Plus

Measured Parameters:

Gluc, Lac, Gln, Glu, NH_4^+ , pH, Na^+ , K^+

Calculated Parameter: Osm

Sample Analysis Time: 2.0 minutes

BioProfile 300 A/B

Measured Parameters

300A: Ace, PO_4 , Gluc, Lac, NH_4^+ , pH, Na^+ , K^+

300B: Ace, Gly, Gluc, Lac, NH_4^+ , pH, Na^+ , K^+

Calculated Parameter: Osm

Sample Analysis Time: 2.5 minutes

BioProfile 400

Measured Parameters:

Gluc, Lac, Gln, Glu, NH_4^+ , pH, PO_2 , PCO_2 , Na^+ , K^+

Calculated Parameters:

Osm, Air Sat, CO_2 Sat, HCO_3^-

Sample Analysis Time: 3.0 minutes

| Parameter | BP 2/4, 100, and 400 and pHox Measuring Range | BP 300 A/B Measuring Range |
|----------------|---|----------------------------|
| Glucose | 0.2-15.0 g/L | 0.0-30.0 g/L |
| Lactate | 0.2-5.0 g/L | 0.0-8.0 g/L |
| Glutamine | 0.2-6.0 mmol/L | - |
| Glutamate | 0.2-6.0 mmol/L | - |
| Ammonium | 0.2-25.0 mmol/L | 0.2-200.0 mmol/L |
| pH | 5.0-8.0 | 4.0-8.0 |
| PO_2 | 0-800 mmHg | - |
| PCO_2 | 3-200 mmHg | - |
| Na^+ | 40-220 mmol/L | 40-220 mmol/L |
| K^+ | 1.0-25.0 mmol/L | 1.0-25.0 mmol/L |
| Acetate | - | 2.0-200.0 mmol/L |
| Phosphate | - | 0.0-2.0 mmol/L |
| Glycerol | - | 0.0-10.0 g/L |

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-of-range flagging levels, quality control ranges

Sample Containers:

Test tube, syringe, pipette, flask, sample cup

Sample Size:

0.5mL

Data Transmission Ports:

RS-232 serial

Electrical Requirements:

90 to 230 Volts, 50/60 Hz

System Printer:

52-column thermal

System Size and Weight:

20.5 inches (52 cm) H x 19.2 inches (49 cm) W x

20.7 inches (53 cm) D x Weight: 90 lbs (41 kg)

Certifications:

ISO 9001, CSA, CE



BioProfile pHox

Measured Parameters:

pH, PO_2 , PCO_2

Calculated Parameters:

Total CO_2 , HCO_3^- , Air Sat,

CO_2 Sat

Sample Analysis Time:

45 seconds

Sample Size:

0.3mL

Size and Weight:

15 in H x 12 in W x 15 in D

(38.1 cm H x 30.5 cm W x 38.1 cm D)



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. An optional 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. 21 CFR Part 11 compliance is also achieved through OPC connectivity.

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NOVA BIOMEDICAL HEADQUARTERS: 200 Prospect Street, Waltham, MA 02454-9141 U.S.A. TEL: (781) 894-0800 (800) 458-5813 FAX: (781) 894-5915 Int'l FAX: (781) 899-0417
NOVA BIOMEDICAL AUSTRIA/EASTERN EUROPE/MIDDLE EAST: Laxenburger Strasse 33/6, A-1100 Vienna, Austria TEL: (43) 1-603 09 700 FAX: (43) 1-603 09 702 e-mail: office@novabio.at
NOVA BIOMEDICAL CANADA, LTD: 17 - 2900 Argentia Road, Mississauga, Ontario L5N 7X9 Canada TEL: (905) 567-7700 (800) 263-5999 FAX: (905) 567-5496 e-mail: info@novabio.ca
NOVA BIOMEDICAL FRANCE: Parc Technopolis - Bât. Sigma 3 Avenue du Canada 91940 Les Ulis Courtaboeuf, France TEL: (33) 1-64 86 11 74 FAX: (33) 1-64 46 24 03 e-mail: info@novabiomedical.fr
NOVA BIOMEDICAL GmbH: Messenhäuser Str.42, 63322 Rödermark, Germany TEL: (49) 6074-8448-0 FAX: (49) 6074-844833 e-mail: info@novabiomedical.de
NOVA BIOMEDICAL INDIA: 307, Apra Plaza II, Plot No.14, Sector - 10, Dwarka, New Delhi - 110 075 India TEL: +91-11-25085653 +91-11-25075653 FAX: +91-11-25085630 e-mail: novabio@nde.vsnl.net.in
NOVA BIOMEDICAL K.K.: Mita 43MT Building-7F, 13-16 Mita 3-chome, Minato-ku, Tokyo 108-0073, Japan TEL: (81) 3-5418-4141 FAX: (81) 3-5418-4676 e-mail: info@novabiomedical.co.jp
NOVA BIOMEDICAL U.K.: Innovation House, Aston Lane South, Runcorn, Cheshire WA7 3FY United Kingdom TEL: (44) 1928 704040 FAX: (44) 1928 796792 e-mail: info@novabiomedical.co.uk
IN THE U.S.A., call toll-free 800-458-5813 **IN CANADA,** call toll-free 800-263-5999
Internet address: www.novabiomedical.com e-mail: info@novabio.com