Automated Cell Culture Analyzers

Multiple test menus for cell therapy, gene therapy, vaccine development, and alternative foods

BIOPROFILE® FLEX2 BASIC

BioProfile FLEX2 Basic A

pH, PCO_2, PO_2, Gluc, Lac, Na^+, K^+, Ca^{++}, Gln, Glu, NH_4^+
(With automatic dilutions and extended ranges)

BioProfile FLEX2 Basic B

pH, PCO_2, PO_2, Gluc, Lac, Na^+, K^+, Ca^{++}, Gln, Glu, NH_4^+
(With standard ranges)

BioProfile FLEX2 Basic C

pH, PCO_2, PO_2, Gluc, Lac, Na^+, K^+, Ca^{++}



nova® biomedical

BIOPROFILE® FLEX2 BASIC

Automated Cell Culture Analyzers with Maint

FLEX2 Basic analyzers utilize Nova's groundbreaking MicroSensor Card™ technology to provide a fully automated cell culture analyzer that eliminates biosensor maintenance, increases analyzer speed, and reduces sample volume.

FLEX2 Basic A, full 11-test menu with automatic dilutions and extended ranges:
pH, PCO_2, PO_2, Gluc, Lac, Na^+, K^+, Ca^{++}, Gln, Glu, NH_4^+

FLEX2 Basic B, 11-test menu with standard ranges:
pH, PCO_2, PO_2, Gluc, Lac, Na^+, K^+, Ca^{++}, Gln, Glu, NH_4^+

FLEX2 Basic C, 8-test menu:
pH, PCO_2, PO_2, Gluc, Lac, Na^+, K^+, Ca^{+++}



Maintenance-free sensors

All test sensors are combined in the credit-card-sized MicroSensor Card, which uses proven Nova biosensor technology that has been validated in thousands of cell culture processes. Cards are maintenance free, and are replaceable in seconds.

Fast analysis time

Test results for the complete menu are available in less than two minutes. This is the highest throughput of any cell culture analyzer and allows for a fully automated batch analysis of a 96-well microtiter plate in just over three hours. FLEX2 Basic analyzers have a maximum daily throughput of over 700 samples per day.

Small sample volume

Sample volume is 265 µL for a full 11-test profile, enabling chemistry testing from virtually all sizes of cell culture systems.

Onboard automated quality control

Onboard liquid QC provides true verification of performance and saves hours of labor each week compared to manual QC testing. QC cartridges contain up to a 30-day supply of QC material. Controls are run automatically at user-selected intervals.



enance-Free Sensors



Intuitive user interface with touchscreen display

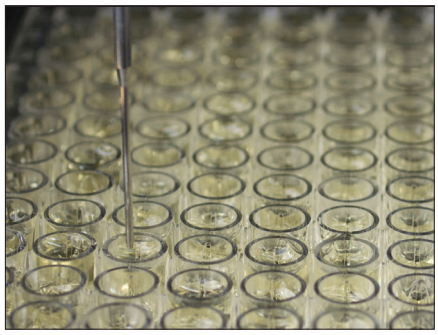
- The color touchscreen is easily operated with intuitive prompts and requires minimal training.
- The most commonly used function screens can be navigated with a single click.
- Batch assignment of sample information and test panels makes programming 96-well plates and sample trays fast and eliminates errors in setup.

Cartridge-based reagent management system (RMS)

RMS reagent cartridges provide several advantages:

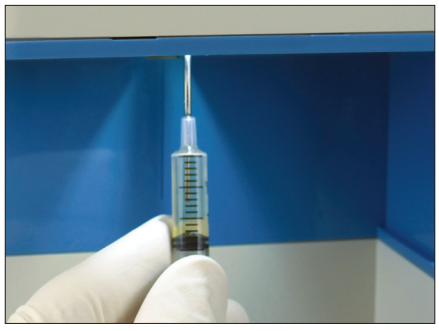
- Cartridge installation date, time, and lot number data are automatically recorded.
- Reagent usage and expiration are monitored.
- A self-contained, closed waste receptacle within the cartridge eliminates direct handling of waste and contact with hazardous biological materials. Other systems can pose significant waste handling hazards to operators.

Automated 96-well microtiter plate analysis



FLEX2 Basic analyzers are the only cell culture chemistry analyzers to offer automated sampling from 96-well plates. Plate configurations may be saved for efficient loading of future plates with the same configuration.

Syringe or cup sampling for critical analysis



Individual samples can also be analyzed directly from syringes or cups. Batch sampling of 96-well plates can be interrupted at any time to run critical samples.

Advanced Analytical Technology

The FLEX2 Basic test menus are configured with advanced chemistry and gas analysis technology that is integrated with robotics.

Chemistries

Glucose, lactate, glutamine, glutamate, ammonium, sodium, potassium, and calcium measurements are performed using electrochemical biosensors integrated into one credit-card-sized component.

Broad analytical range with improved low end accuracy

The lower analytical range has been extended to provide accurate results down to 0.10 g/L for glucose and lactate, and 0.10 mmol/L for glutamine and glutamate.

FLEX2 Basic A Onboard auto-dilutions

Robotic automation and a precise metering syringe perform all dilutions on board the Basic A, eliminating time-intensive manual dilutions and error associated with manual techniques. The use of onboard auto-dilutions on the FLEX2 Basic A provides the broadest analytical range of any cell culture analyzer.

Photometric detection methods used by other analyzers often require time-consuming, manual pre-dilution of high cell concentration samples to avoid poor measurement accuracy. FLEX2 Basic electrochemistry assays provide accurate results regardless of cell concentration.

Analyte specificity

Nova's biosensors are developed specifically for cell culture applications, where processes typically utilize extremely complex media formulations. These electrochemistry detection methods provide excellent specificity for the analyte of interest.

High throughput chemistry analysis

FLEX2 Basic analyzers are capable of analyzing a full chemistry panel using 135 µL of sample in 120 seconds, or a throughput of 30 samples per hour. Full 96-well plates can be analyzed in about three hours.

Gases

pH, PCO_2, and PO_2 measurements are performed by potentiometric and amperometric biosensors in the maintenance-free, disposable MicroSensor Card.

Improved accuracy

Unlike hospital blood gas analyzers, which are often used for cell culture analysis, Nova's algorithms for measuring pH, PCO_2, and PO_2 were specifically developed for cell culture applications. These algorithms are optimized for mammalian cultures that typically exhibit much higher oxygen consumption and carbon dioxide production rates compared to human blood cells. FLEX2 Basic analyzers ensure accurate pH and gas values even in cultures with high cell densities.

Chemistry, gas, and pH values available in manual and 96-well plate analysis modes

The user can configure FLEX2 Basic analyzers to provide chemistry, gas and pH results from both manual samples and 96-well microtiter plate samples.

Connectivity and Compliance

Advanced OPC connectivity

Nova's OPC connectivity integrates with any OPC-compliant devices, such as bioreactor controllers, data historians, laboratory information management systems (LIMS), and plant management systems. Nova's OPC connectivity features:

- Automated bidirectional data and control commands
- Data archiving
- Connection to any OPC-compliant device
- Connectivity verification
- Bioreactor feedback control
- Remote monitoring of status and data

USB and network printing

Sample data, quality control results, and audit and calibration logs can be sent to both external USB printers as well as network printers.

Compliance with 21 CFR Part 11

Limited access

User log-on is secured by both user ID and password. Automatic log-off prevents unauthorized access.

Electronic record retention and retrieval

- All data are securely retained through password access control in both human-readable and electronic forms.
- Records are readily retrievable throughout their retention period.

Audit trails

- Time-stamped audit trails record the date and time of operator entries and actions that create, modify, or delete electronic records.
- Record changes do not obscure previously recorded information.
- Records are maintained in original and audited form.

GMP compliance

All FLEX2 Basic analyzers meet GMP manufacturing requirements through installation qualification (IQ) and operational qualification (OQ) documentation and validation support from Nova specialists.

Support Services

The purchase of a FLEX2 Basic analyzer is just the beginning of a long commitment from Nova to you. Nova offers an extensive array of support services to help maintain peak analyzer performance.

Installation

Performed by a Nova field specialist, installation consists of analyzer setup and performance verification.

Validation assistance

Nova installation staff can perform extended precision and reference analyzer correlation studies. Nova performs all tests and provides complete documentation to verify compliance with regulatory standards. In addition to IQ/OQ support, we can assist with performance qualification (PQ) protocol development and implementation.

Field service

On those occasions when service is needed, a team of field service representatives, located throughout the country, is available to provide on-site support, resolving issues with minimal downtime.

Comprehensive applications support

A knowledgeable applications staff with significant industry experience is available to help with custom optimizations, IQ/OQ, process automation support, and other site-specific needs.

Telephone assistance hotline

We maintain a highly skilled and experienced technical support staff available by phone or email. From basic questions to advanced troubleshooting, they are able to resolve most problems over the phone without requiring on-site support.

BioProfile FLEX2 Basic A, B, C Specifications

Sample Analysis Time:

2.0 minutes (Chemistry only), 2.0 minutes (Gas only), 2.0 minutes (All tests)
Operating Temperature Range 10–30oC (50–86oF)
Operating Relative Humidity Range 20–85%
Sample Size.....135 to 265 µL

Sample Options:

Individual via syringe/cup
Automated batch using 20-position tray or 96-well plates

Operating System .....Windows 10
Electrical Requirements ..... 90-264 VAC, 50 to 60 Hz
(Universal Power Supply)

System Size and Weight:

Height: 61 cm (24 in), Width: 43 cm (17 in),
Depth: 64 cm (25 in)
42.6 kg (94 lb) without reagent packs

Certifications:

IEC 61010-1:2010, Quality Systems Certification:
EN ISO 13485:2016, OPC Compliant, PAT Compatible,
21 CFR Part 11 Compliant



Test Menus and Ranges	BioProfile FLEX2 Basic A		BioProfile FLEX2 Basic B		BioProfile FLEX2 Basic C	
	Low	High	Low	High	Low	High
pH	5.000	8.000	5.000	8.000	5.000	8.000
pCO2 (mmHg)	3.0	300.0	3.0	300.0	3.0	300.0
pO2 (mmHg)	3.0	500.0	3.0	500.0	3.0	500.0
Glucose (g/L)	0.10	60.00	0.10	15.00	0.10	15.00
Lactate (g/L)	0.10	24.00	0.10	6.00	0.10	6.00
Sodium (mmol/L)	40.0	1200.0	40.0	300.0	40.0	300.0
Potassium (mmol/L)	1.00	400.00	1.00	100.00	1.00	100.00
ionized Calcium (mmol/L)	0.10	40.00	0.10	10.00	0.10	10.00
Glutamine (mmol/L)	0.10	24.00	0.10	6.00	–	–
Glutamate (mmol/L)	0.10	24.00	0.10	6.00	–	–
Ammonium (mmol/L)	0.20	100.00	0.20	25.00	–	–

All include calculated values for O_2 Saturation; CO_2 Saturation; HCO_3 -(bicarbonate), Temp. Corrected pH, PCO_2, PO_2
FLEX2 Basic A Ranges reflect user-selectable 1:4 dilution.

BioProfile FLEX2 16 Test Cell Culture Analyzer



FLEX2 is an automated comprehensive cell culture analysis system using MicroSensor Card technology, optical measurement, and freezing point osmometry. It requires minimal maintenance and delivers fast results, with a small sample volume. 16 important cell culture parameters can be analyzed in 4.5 minutes with a 265µL sample. On-line autosampling options are available.

Test Menu:

pH, PCO_2, PO_2, Gluc, Lac, Gln, Glu, NH_4^+, Na^+, K^+, Ca^{++}, total cell denisity, viable cell density, viability, cell diameter, osmolality

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Specifications current as of revision date. 474C V15 INT EN 11/9/23