FLEX2 integration with Sartorius ambr® 15



BioProfile FLEX2

Provides comprehensive analysis of 16 key cell culture measurements including: Gluc, Lac, Gln, Glu, NH_4^+, Na^+, K^+, iCa, pH, PCO_2, PO_2, total cell density, viable cell density, viability, cell diameter, osmolality. With the addition of the BioProfile External Sampling Module (ESM), FLEX2 automatically samples and analyzes from the Sartorius ambr 15 cell culture system to provide complete walkaway operation.

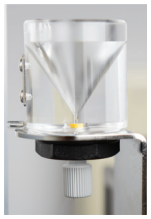
System Components

External Sampling Module (ESM)



- Enables sample transfer from ambr 15 to FLEX2 and from FLEX2 to waste.
- The reagent cartridge contains reagents for fluid path flushing, cleaning, and deproteinizing, and a self-contained, internal waste receptacle.
- ESM requires minimal bench space, 7" x 8" x 18" (H x W x D) or 17.8cm x 20.3cm x 45.7cm (H x W x D).

Fluid connections and sampling cup



- An acrylic sampling cup installed on the ambr 15 deck provides a sample transfer point for ESM to access ambr 15 cell culture samples.
- Sample residence time in the sampling cup is less than 10 seconds, minimizing O_2 consumption and CO_2 production during sample transfer.
- Gas-impermeable tubing transfers culture samples from the sampling cup to the FLEX2 analyzer and minimizes equilibration of the sample with atmospheric gases.

Sample Scheduling and Configuration

- Scheduling of FLEX2 analyses and test selection is done on the ambr 15 software user interface.
- After analysis, data is transmitted to the ambr 15 database.
- Feedback control, parameter adjustments, and other control schemes based on FLEX2 results are managed in the ambr 15 software suite.

Integrated Operation

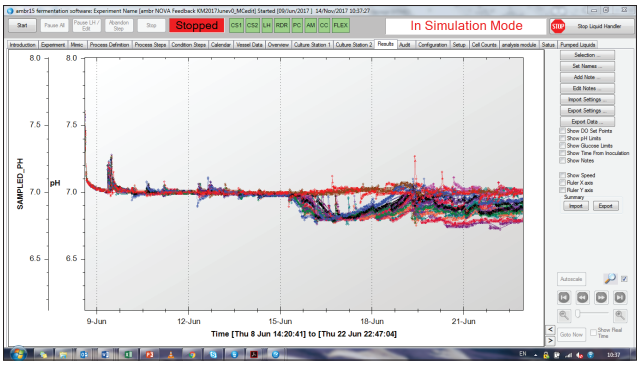
1. ambr 15 draws a sample from one of its bioreactors and dispenses into the sampling cup.
2. ESM moves the sample from the cup to FLEX2 for analysis.
3. After analysis, FLEX2 immediately transmits all measured and calculated data to the ambr 15 software.
4. The sample moves to the ESM sample waste container.
5. ESM purges and cleans the fluid path.

Benefits of FLEX2 Integration

Fast Cycle Time, Low Sample Volume

- Cycle time is 6-7 minutes depending on the configuration of selected tests.
- Total sample volume for a complete 16-test panel is 400-500 µL.

Comprehensive Data Management

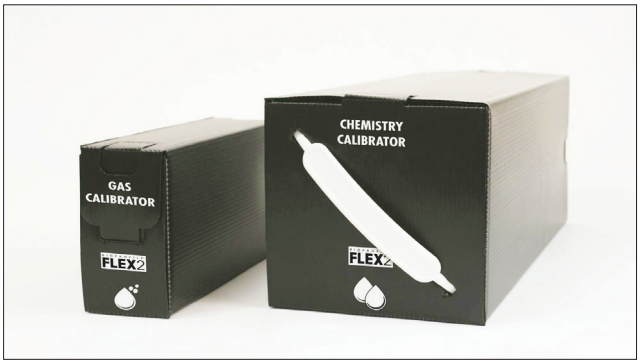


- FLEX2 data is incorporated and displayed on all relevant ambr 15 graphs.
- The data is also stored within the FLEX2 database.
- OPC enables real-time data transmission to OPC compliant historians and LIMS.
- FLEX2 auto-exports data (.csv file) onto a network folder, which enables easy retrieval from any network computer and provides a remote location for data backup.

Automated Fluid Path Cleaning

- Each sample transfer is followed by a full fluid path cleaning using solutions contained within the ESM reagent pack, eliminating sample-to-sample carryover.
- An automated deproteinization cycle follows sampling to disinfect the fluid path and eliminate protein buildup.

Reagent Management



- FLEX2's Reagent Management System continuously monitors the status of all reagents and sensors and reports remaining quantity of tests available.
- Prior to sampling, the ambr 15 system checks all FLEX2 reagents and MicroSensor cards to ensure there are sufficient reagents remaining to complete all scheduled analyses for that day.

Other Features

- Allows users to define which tests are critical for analysis.
- Constantly monitors the status of ALL parameters and pauses sampling if one or more critical parameters becomes unavailable, preserving culture volume.

Long-Term Automated Sampling and Analysis

- FLEX2/ambr 15 integration provides comprehensive, automated monitoring of key cell culture attributes using minimal sample volume.
- FLEX2's reagent capacity enables walkaway, automated sampling and analysis for more than a week.
- FLEX2's onboard, automated quality control provides automated daily instrument qualification.
- FLEX2 configured, with a 48 position osmometer and integrated with a 48 bioreactor ambr 15, allows for automated osmolality results with no need for interim consumable replacement.

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