

# Get Control in GMP Environments

Centrifugation that supports compliance and eliminates hassle.

Floor-standing ultracentrifuges and high-performance centrifuges are vital to many bioproduction processes. Instruments are run in Good Manufacturing Practice (GMP) environments, and must support compliance with these regulations. Innovative features built into Optima XPN and Avanti JXN Series centrifuges support GMP compliance while eliminating much of the administrative work of other systems.

## User Management

Controlling access to equipment within a GMP environment is critical. The Optima XPN and Avanti JXN Series centrifuges feature password protection for up to 50 unique user profiles. Users can be classified by one of three available security levels—Administrator, Super User, or Operator. Security levels provide the ability to control the level of access each user has to the centrifuge according to the permissions below.

User Level	Permission
Administrator	Unlimited access.
Super User	Can run all programs, manage users, assign programs, manage the rotor library.*
Operator	Can run assigned programs and change user options.

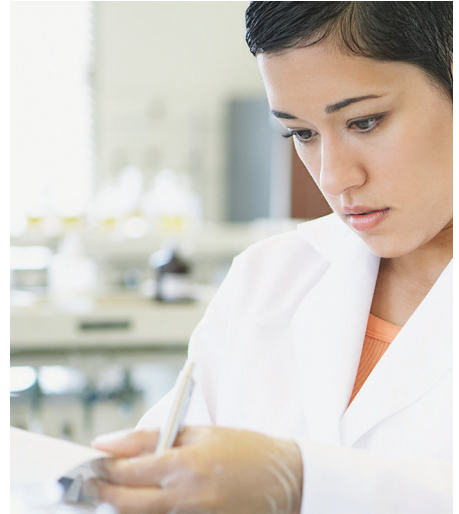
\*Available on Optima XPN Series only.

Administrators can require log-in before anyone can use the centrifuge. In addition, you can restrict operators to run only certain pre-defined programs, limiting the potential for errors. The Optima XPN and Avanti JXN Series centrifuges offer the option of establishing a PIN expiration date for optimum security.

## Data Logging

The Optima XPN and Avanti JXN Series allow for detailed run tracking that builds an archive of each run that includes the following:

- User information
- Start date and time of the run
- End date and time of the run
- Rotor type
- Program name
- Acceleration and deceleration parameters
- Before run comment
- After run comment
- Detailed information about each step in a run (speed, RCF, time, temp,  $\omega^2t$ )
- Any diagnostics that occurred during the run
- Graph of the run (speed and temperature)
- Electronic signature (if enabled)



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These data are stored and can be viewed on the centrifuge itself, or exported to a USB drive, network drive, or printer for archiving. This powerful tracking capability helps maintain an audit trail of centrifuge activities by ensuring that data from each and every run is recorded and linked to a specific user.

### System Logging

System log is a list of the dates and responsible users for each system option modified. Program log contains the history of changes to a particular run program including the date/time and user responsible for each of the program modifications.

### Run Comments

In addition to the standard centrifuge run parameters, it is also possible to capture user comments entered before or after a run in the run log history. These comment fields can include batch numbers, the name of the product being produced, anything out of the ordinary that occurred during the run, or anything else related to the run that would be useful to store in the log for future reference. The Optima XPN and Avanti JXN Series centrifuges allow you to add free-form comments before and after the run using the on-screen keyboard.

### Electronic Signature

In addition to capturing and storing run data, the Optima XPN and Avanti JXN Series centrifuges also offer electronic signature capability. Once a centrifuge run is complete, an electronic signature representing the run log's author, reviewer, or approver can be applied to the record. The electronic signature includes the user's name, date and time stamp, the instrument serial number, and any notes that were entered at the time of signature.

### User-Defined Programs

The Optima XPN and Avanti JXN Series centrifuges allow up to 1,000 user-defined programs consisting of up to 30 steps each, ensuring that virtually any protocol can be set up and stored for future use. Program names can consist of up to 64 characters (any combination of letters, numbers, or symbols), so they can be assigned meaningful names that allow for easy recall. Once established, user-defined programs can be assigned to specific operators, limiting the number of users with access to the protocol. Setting up and using user-defined protocols helps ensure consistency from run-to-run and minimizes user error during run setup.

### Real-Time Run Graphing

The Optima XPN and Avanti JXN Series centrifuges feature real-time run graphing that plots actual speed and temperature during the centrifuge run and stores it in the run log for future reference. The run graph offers a visual way to track and record run progress and quickly identifies any variation in speed or temperature.

### Rotor Tracking by Serial Number

The Optima XPN and Avanti JXN Series centrifuges are also able to track the number of cycles accumulated on specific rotors. Once set up, users can choose rotors by serial number from an on-screen rotor library. The centrifuge tracks the number of cycles, so the life of the rotor can be precisely tracked and retired before it becomes unsafe and potentially causes damage to the centrifuge. This detailed tracking information is also valuable input for Beckman Coulter Field Service Engineers performing rotor inspections as part of the Field Rotor Inspection Program (FRIP). These data help maintain laboratory safety and maximize instrument uptime.

### Remote Monitoring and Control

Most bioproduction facilities contain more than one centrifuge. The remote monitoring and control capabilities of the Optima XPN and Avanti JXN Series centrifuges make monitoring multiple instruments easy. Users can check the status of all instruments from virtually anywhere via personal computer using Virtual Network Computing (VNC) software, or mobile device using the custom MobileFuge application available for iOS and Android™ devices. The VNC software allows users to operate the centrifuge from a PC just as if they were standing in front of it. The MobileFuge mobile application lets users monitor up to 16 centrifuges at any one time and allows control of basic centrifuge functions from a mobile device. These remote monitoring and control features keep you updated on the status of your centrifuges, while also allowing you the freedom to complete other activities at the same time.

### Email Diagnostic Alerts

Using the email diagnostic alerts feature on the Optima XPN and Avanti JXN Series centrifuges, production managers can be notified whenever there is an issue with a centrifuge. Users enter the email address(es) where the notifications will be sent, then if a diagnostic issue occurs, the centrifuge will send a notification to everyone on the list alerting them to the problem. Regardless of where you are, you will immediately be notified of any pending issues with the centrifuge so you can take the appropriate action.



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For Beckman Coulter's worldwide office locations and phone numbers, please visit "Contact Us" at [www.beckmancoulter.com](http://www.beckmancoulter.com)

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