



Integrated Inline
Viable Biomass
Measurement in
Rocking Motion
Bioreactors

Simplifying Progress

SARTORIUS

Single-Use Process Measurement and Control

The Biostat® Rocking Motion (RM) bioreactor system ensures optimal process control and cell growth for all single-use cell culture applications. Flexsafe® RM bags with single-use integrated analytics allows plug and play real-time monitoring of:

- pH: integrated pH patch
- DO: dissolved oxygen (DO) patch
- Viable cell volume (VCV): BioPAT® Viamass sensor disc

The data is fed directly into the local controller where oxygen transfer, liquid additions and mixing can be adjusted by wave-induced motion whereby bubble free overlay aeration protects cells from shear stress. This automated process control generates consistent process conditions and reliable electronic batch records while enabling automated substrate feed strategies based on VCV.

Additionally, harvest/transfer points and optimal time points for infection for viral production can be based on real-time VCV data for improved process and product consistency. The integrated single-use capacitance technology is available from 5 L to 100 L working volumes.

This makes the Biostat® RM system highly suitable for the rapid production of:

- monoclonal antibodies
- recombinant proteins
- antibody drug conjugates
- vaccines
- stem cells and T-cells





BioPAT[®] Viamass Technology

Capacitance measurement does not count the number of viable cells (i.e. density). It measures the polarization potential of all the viable cells in the field; thus

- more cells = higher signal
- bigger cells = higher signal

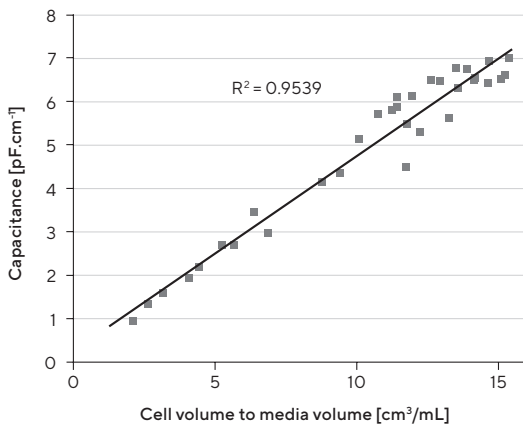
The BioPAT[®] Viamass signal plot aligns to the VCV and biomass.

Practical System Setup

- A stable capacitance signal is generated as the bioreactor rocking motion is compensated for
- Qualified sterile single-use bags with integrated sensor discs
- Aber hardware and control software integrated into Sartorius local controller and firmware multi-use flush probes



pH



Measurement

- All living cells polarized by the field from the sensor disc
- Measurement field up to 20–25 mm into bag volume
- Dead cells and protein invisible to measurement field

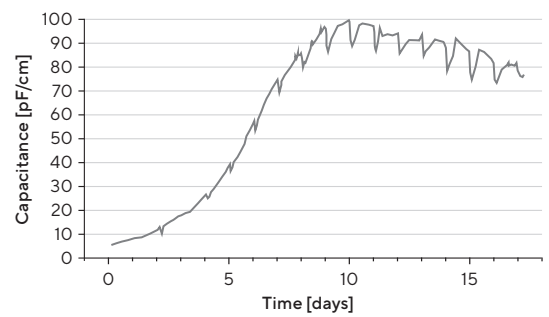


BioPAT® Viamass Sensor Disc

- Sartorius made and qualified high density polyethylene (HDPE) sensor disc
- 4 electrodes made of 100 % Platinum
- Identical geometry to Aber 25 mm multi-use flush probes



DO



Electronic Hardware

- Compact light weight system
- Rocker mounted with connection to the DCU tower
- Electrically grounded

Process Control Capabilities

- Automatically pause or switch feed on desired cell concentration
- Consistent seed transfer concentration
- Viable biomass based feed control
- Maintain perfusion cell concentration setpoint

What Are the Features of This Setup?

Complete integrated technology package from Sartorius

- Electronic and software control fully integrated to local controller
- One source of service and support
- Compensated for Rocking motion
- All SU material are qualified for GMP use



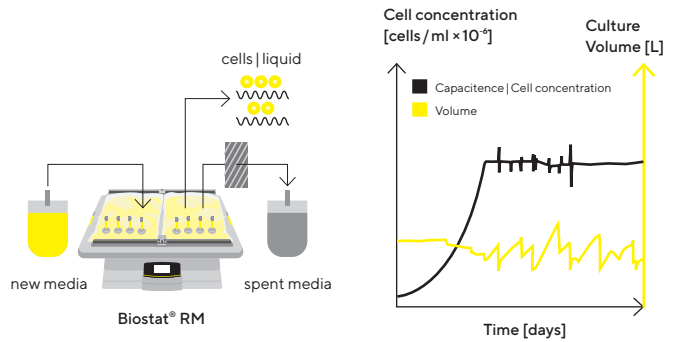
What Are the Benefits to This Setup?

- Easy to use plug and play operation for rapid cell expansion
- Lower risk of contamination due to lower sampling needs
- Reduced risk of unrepresentative samples from manual handling
- Decreased labor and laboratory costs for offline analysis
- Improved process consistency and data gathering

“BioPAT® Viamass tracks the real-time biomass changes throughout the duration of the process offering insights into growth rates, feed additions and maximum viable cell volume.”

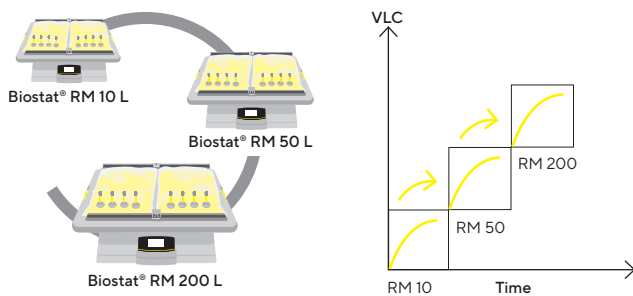
Perfusion Forward Feed | Bleed Control

- Biomass based feed | bleed Perfusion control
- More consistent output from biomass
- Reduced operator efforts



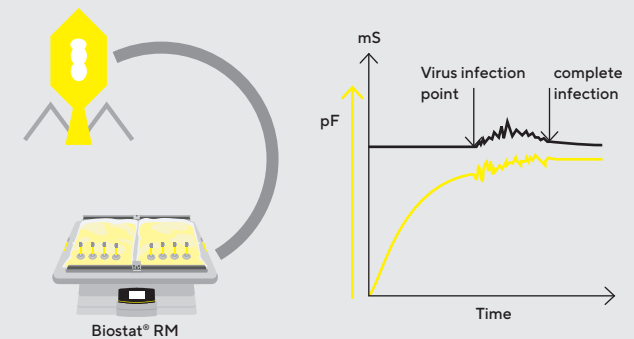
Seed Train Viable Biomass

- Consistent transfer of biomass from one vessel volume to the next
- Clearer process time planning
- Low manual sampling requirements



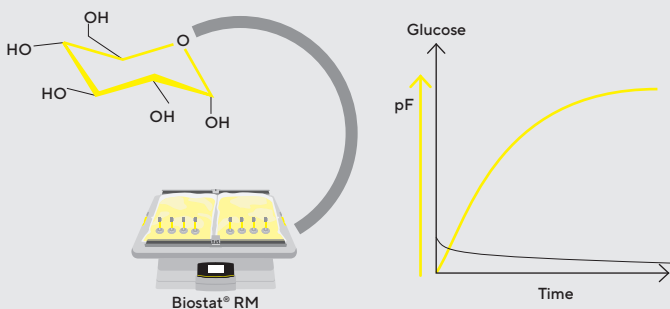
Virus Infection

- Consistent virus infection point based on cell parameter data, increase the virus output consistency



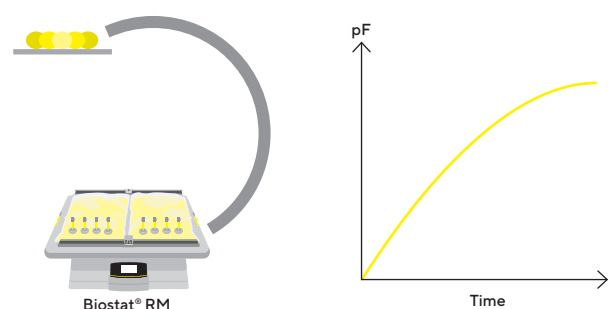
VCV Based Feed Control

- Dynamic feed control based on living cell volume
- Increased process control | quality | performance
- Reduced labor efforts



Microcarrier Cell Volume

- More accurate VCV | biomass measurement for microcarrier applications




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