

# M815 Microfluidizer™ Pilot Scale Biopharma Processor Series

## M815 Biopharma Microfluidizer™ For Processing Clinical and Production cGMP Batches

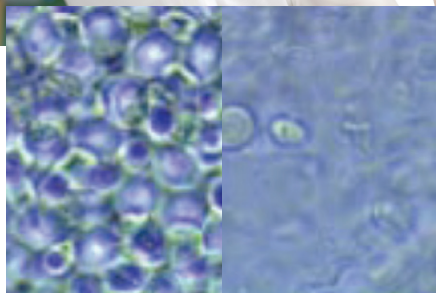
**Microfluidizer™** technology converts fluid pressure more efficiently into shear forces, leading industry performance standards in high pressure homogenization.

A unique solution to maintaining consistent process pressure, ensures 100% of your material gets exactly the same treatment. Whether you are working with small samples or production volumes, Microfluidizer™ technology is unmatched in submicron size reduction/disruption, product yield, and guaranteed process scale-up.

### Recommended Uses

Non-sterile processing of:

- Cell Disruption
- Nanoemulsions (with/without API)
- Nanodispersions
- Microencapsulation
- Deagglomeration



Before Processing

After Processing

*Along with other uses, the patented Microfluidizer™ can also be used for fine particle deagglomeration.*



Model shown is subject to change depending on options selected

### Unique Benefits of the M815

- Produces product flow rates up to 1200 mL/min at 689 – 2068 bar (10,000 – 30,000 psi)
- Has small batch capability; handles a minimum sample size of 1L
- Features a low product hold-up volume (800 mL)
- Is CIP process capable
- Integral feed pump and heat exchanger
- Lockable casters, standard door width for easy mobility
- Meets CE compliance standards
- Standard with 7" touchscreen HMI
- Allows monitoring of key process parameters
- Facilitates non-destructive processing of heat-sensitive materials
- Assures batch-to-batch process repeatability
- Features sanitary-grade and BPE-compliant product paths, instruments and valves
- Offers process pressure and temperature monitoring with local display and signal transfer to customer's data acquisition system
- Includes a complete document turnover package for validation support, including IQ/OQ, material certifications and calibrations
- Factory Acceptance Testing (FAT)
- Includes on-site start-up assistance, operator and maintenance training, SAT and IQ/OQ execution by our technical staff
- Enhanced version available with 15" industrial personal computer (IPC) that is able to validate under 21 CFR to cGMP with purchase of data logging option



**Microfluidizer™**

## Operating Principle

Like all Microfluidizer™ processors, the M815 utilizes the fixed-geometry interaction chamber and constant pressure pumping system. This technology allows users to achieve smaller particle sizes — with more uniform distribution and scale-up guaranteed (both from lab scale and to larger scale units) — than can be obtained with other methods.

The M815 models were designed to bridge the gap between the biopharma lab scale (M-110EH) and production scale (M-700 Series) models, and they are ideal for manufacturing batches in the range of 100L–300L, which are necessary for PHII and PHIII clinical trials.

## Standard Features

- Product feed pump, pharmaceutical grade with pressure gauge and purge valve
- Diamond interaction chamber
- Ceramic Auxiliary Processing Module (APM)
- Ceramic (Zirconia) plunger and seal quench for extended seal life
- Pharma grade heat exchanger
- Stainless steel enclosure
- Gauges for measuring hydraulic drive pressure, hydraulic oil level and temperature
- Self-contained unit, mounted on locking casters for portability, standard door width
- Feed temperature range 2°C – 75°C (35°F – 165°F)
- TEFC (totally enclosed fan-cooled) motor – starter optional
- Sanitary flush diaphragm pressure transducer with digital readout
- Class IV seals and gaskets certified
- 2 RTD temperature sensors

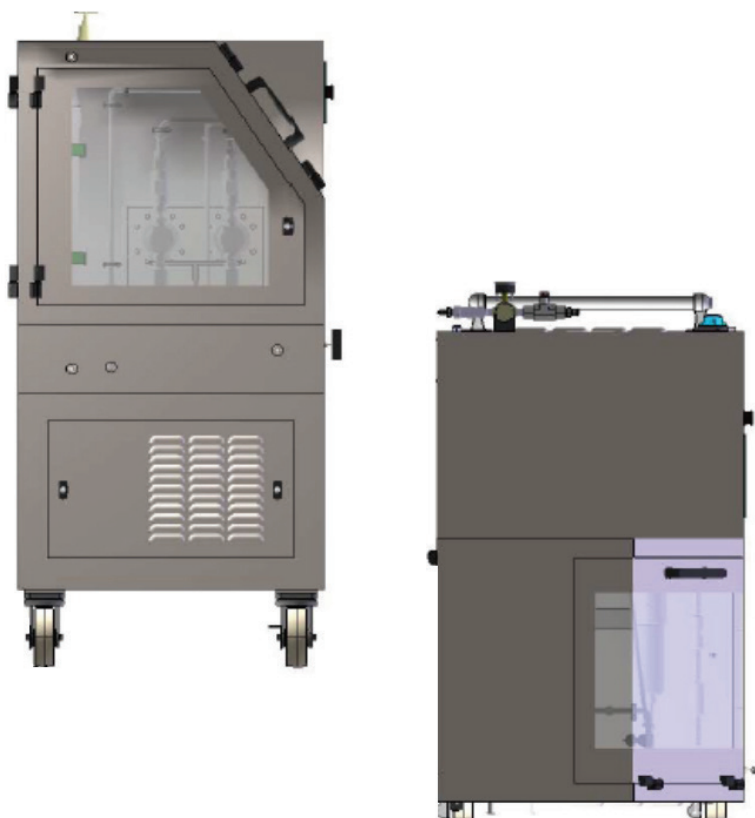
## Options

- Motor starter
- Additional RTD temperature sensor
- Steam-In-Place
- Heat exchange temperature control

## Specifications

Pressure Range	Up to 30,000 psi (2068 bar)
Flowrate Range	1.0–1.2 L/min
Dimensions	59"L x 34"W x 79"H (150cm x 86cm x 201cm)
Weight	1950 lbs (886 kg) With Oil 1800 lbs (818 kg) Without Oil

Note: Some options may change overall dimensions and weight of the machine.



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