

# 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. So whether you are working with small lab samples or production volumes, the Microfluidizer™ is unmatched in submicron size reduction/disruption, product yield, and guaranteed process scale-up.

### Recommended Uses

Non-sterile processing of:

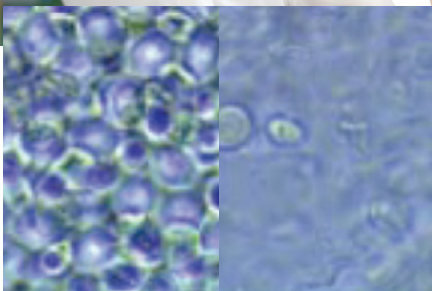
- Nanoemulsions (with/without API)
- Nanodispersions
- Microencapsulation
- Deagglomeration
- Cell Disruption



Model shown is subject to change depending on options selected

### Unique Benefits of the M815

- Has small batch capability; handles a minimum sample size of 200 ml\*
- Achieves processing pressures up to 2068 bar (30,000 psi)
- Produces product flow rates up to 1000 mL/min at 689 - 2068 bar (10,000 - 30,000 psi)
- Is able to validate under 21 CFR to cGMP
- Meets CE compliance standards
- Standard with 7" touchscreen HMI
- Features accessible maintenance points for easy maintenance
- Allows monitoring of key process parameters
- Facilitates safe processing of thermally sensitive materials
- Has cost-effective production capability
- Assures batch-to-batch process repeatability
- Features a low product hold-up volume (180 ml\*)
- 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
- Is CIP process capable
- Includes a complete document turnover package for validation support, including IQ/OQ, material certifications and calibrations
- Comes with Factory Acceptance Testing (FAT)
- Includes on-site start-up assistance, operator and maintenance training, SAT and IQ/OQ execution by our technical staff



Before Processing

After Processing

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

## 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
- Stainless steel enclosure
- Gauges for measuring hydraulic drive pressure, hydraulic oil level and temperature
- Self-contained unit, mounted on locking casters for portability
- Feed temperature range 16°C – 75°C (35°F – 165°F)
- TEFC (totally enclosed fan-cooled) motor, starter, controls and power cord
- Sanitary flush diaphragm pressure transducer with digital readout
- Class IV seals and gaskets certified (enhanced and aseptic models *only*)

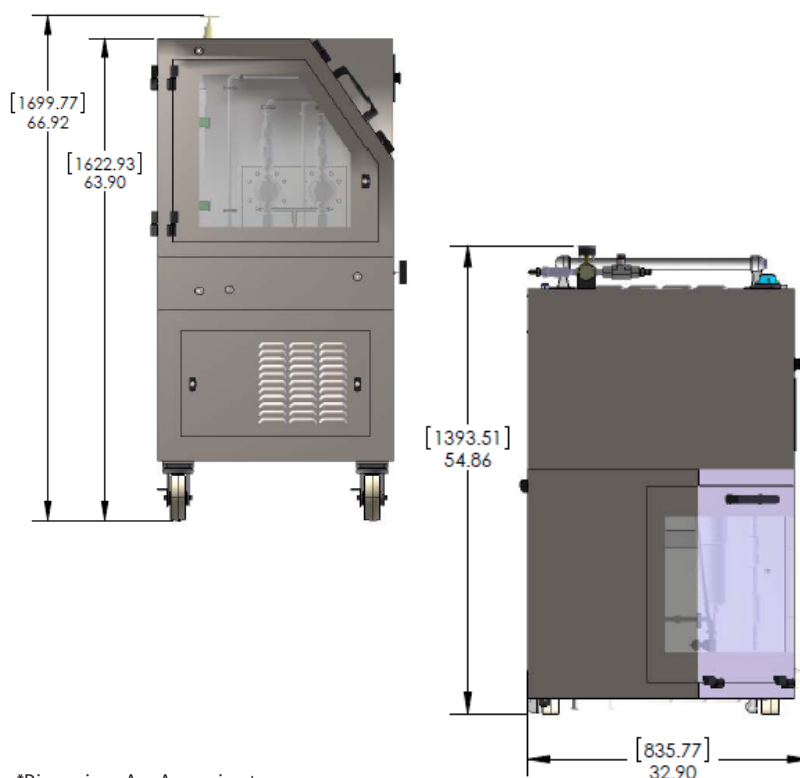
## Options

- 2 liter reservoir, pharmaceutical grade
- Filtered hydraulic oil
- On-board air compressor for air switch activation
- Product coolant temperature control, automatic (enhanced model *only*)

## Specifications

Pressure Range	Up to 30,000 psi (2068 bar)
Flowrate Range	1.0-1.2 L/min
Dimensions	57"L x 34"W x 72"H (145cm x 86cm x 183cm)
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.



\*Dimensions Are Approximate



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