

# BIOPHARMACEUTICAL MICROFLUIDICS PROCESSORS



## M-700 Biopharmaceutical Machines

### Features:

- Operating pressures up to 690 bar (10,000 psi), 1379 bar (20,000 psi) and 2068 bar (30,000 psi)
- Low product hold up volume of <1 liter
- Minimum batch size of 12 liters
- Product contact surfaces are sanitary grade BPE compliant
- Ultra Clean In Place (UCIP) with diaphragm valves using supplied feed pump or customer's CIP system pump
- Instruments and valves are sanitary grade, BPE compliant
- CE compliant
- On-site startup assistance, operator and maintenance training
- Proprietary high pressure diaphragm priming valve
- Mechanical stroke counter (optional on Basic)
- Validatable under 21 CFR to cGMP - Enhanced & Aseptic
- IQOQ package and Documentation package
- Labeling for English (std), French, German, Italian, Spanish and others



## M-110EH-30 Biopharmaceutical Microfluidizer® Processors

### Features:

- Operating pressures up to 2068 bar (30,000 psi)
- Low product hold up volume of <180 ml on PHB, PHE, and PHA, 108 mL on standard model
- Minimum batch size of 200 mL on PHB, PHE, and PHA, 120ml on standard model
- Product contact surfaces are sanitary grade BPE compliant on PHB, PHE and PHA
- Instruments and valves are BPE compliant on PHB, PHE and PHA
- CE compliant
- Validatable under 21 CFR to cGMP on PHB, PHE and PHA
- Standard and PH Basic model dimensions: 150 cm (59") H x 79 cm (31") W x 71 cm (28") D and weigh 205 kg (450 lb)
- Enhanced and Aseptic models include a larger skid : 213 cm (84") H x 155 cm (60") W x 109 cm (43") D and weigh 430 kg (950 lb)
- Labeling for English (std), French, German, Italian, Spanish and others

	M-110EH-30				M-700 Series			
Biopharmaceutical Features:	Standard	Basic	Enhanced	Aseptic	Standard	Basic	Enhanced	Aseptic
Stainless steel frame and enclosure	Incl.	Incl.	N/A	N/A	Incl.	Incl.	N/A	N/A
Stainless steel skid with additional frame for accessory mounting	N/A	N/A	Incl.	Incl.	N/A	N/A	Incl.	Incl.
Motor starter	Incl.	Incl.	N/A	N/A	Opt.	N/A	N/A	N/A
Motor starter panel and process interlocks	N/A	N/A	Incl.	Incl.	Opt.	Opt.	Incl.	Incl.
Flushed diaphragm sanitary product pressure transducer with digital display in freestanding enclosure	Opt.	N/A	N/A	N/A	Opt.	N/A	N/A	N/A
Flushed diaphragm sanitary product pressure transducer with digital display in freestanding enclosure and calibration	N/A	Incl.	N/A	N/A	Opt.	Opt.	N/A	N/A
Flushed diaphragm sanitary product pressure transducer with calibration and integrated to Yokagawa process monitor	N/A	N/A	Incl.	Incl.	N/A	N/A	Incl.	Incl.
Class VI seals and gaskets certified	N/A	Incl.	Incl.	Incl.	N/A	Incl.	Incl.	Incl.
Seal Quench	Opt.	Incl.	Incl.	Incl.	Incl.	Incl.	Incl.	Incl.
Product contact surface finished to < 20Ra and electropolished ( where possible), all surfaces passivated	N/A	Incl.	Incl.	Incl.	N/A	N/A	N/A	N/A
Product contact surfaces finished to < 20Ra, all surfaces electropolished and passivated	N/A	N/A	N/A	N/A	N/A	Incl.	Incl.	Incl.
Manual CIP	N/A	Incl.	Incl.	N/A	N/A	N/A	N/A	N/A
Ultra Clean In Place (UCIP)	N/A	N/A	N/A	Incl.	Opt.	Incl.	Incl.	Incl.
Sanitary product heat exchanger: Straight through double tubesheet with relief valve for safety and return line for product recirculation	N/A	Incl.	Incl.	N/A	N/A	N/A	N/A	N/A
Sanitary product heat exchanger: Straight through double tubesheet with rupture disc for safety and return line for product recirculation	N/A	N/A	N/A	Incl.	N/A	N/A	N/A	N/A
Sanitary product heat exchanger: Straight through double tubesheet with relief valve for safety	N/A	N/A	N/A	N/A	N/A	Opt.	Incl.	Incl.
Product heat exchanger coolant flow modulation control	N/A	N/A	Opt.	Incl.	N/A	N/A	Incl.	Incl.
Product temperature monitoring assembly including: Two type T thermocouples, dual digital displays and calibrations	Opt.	Incl.	N/A	N/A	Opt.	N/A	N/A	N/A
Product temperature monitoring assembly including: One or two RTD's with digital displays and calibrations	N/A	N/A	N/A	N/A	N/A	Opt.	N/A	N/A
Process Monitoring via Yokagawa display and HMI panel with RTD temperature sensors and calibration to comply with 21 CFR part 11 electronic signature and batch record keeping	N/A	N/A	Incl.	Incl.	N/A	N/A	Incl.	Incl.
Feed pump, pharmaceutical grade double diaphragm air pump mounted on machine with sanitary feed pressure gage	N/A	Opt.	N/A	N/A	N/A	Incl.	N/A	N/A
Feed pump, pharmaceutical grade double diaphragm air pump mounted on machine with flushed diaphragm sanitary transducer with calibration and integration with Yokagawa Process Monitor	N/A	N/A	Opt.	Opt.	N/A	N/A	Incl.	Incl.
Flow totalizer, to measure product and CIP flow rates with integration to Yokagawa Process Monitor	N/A	N/A	Incl.	Incl.	N/A	N/A	Incl.	Incl.
Stroke counter, mechanical	Opt.	Opt.	N/A	N/A	Opt.	Opt.	N/A	N/A
Steam In Place allows complete steam sterilization of product contact surfaces including: Diaphragm priming valve, diaphragm valves in piping, six RTDs, steam traps, steam regulator, certifications,	N/A	N/A	N/A	Incl.	N/A	N/A	N/A	Incl.
Product Inlet Strainer	N/A	N/A	N/A	N/A	Opt.	Opt.	Opt.	Opt.
Inlet Reservoir, 300 ml glass with adapter	Opt.	Opt.	Opt.	Opt.	N/A	N/A	N/A	N/A
2 Liter open 316 stainless steel reservoir, pharmaceutical grade, <20 Ra, jacketed for cooling or heating product feed materials, jacket fluids operating range: -10°C to 90°C @ 5.83 bar (70 psi) maximum	Opt.	Opt.	Opt.	Opt.	N/A	N/A	N/A	N/A
2 Liter open 316 stainless steel reservoir, pharmaceutical grade, <20 Ra, electropolished and passivated	N/A	Opt.	Opt.	Opt.	N/A	N/A	N/A	N/A
Air Compressor for motion switches	Opt.	Opt.	Opt.	Opt.	Opt.	N/A	N/A	N/A
IQ/OQ package: Installation and Operation Qualification document on CD	Opt.	Incl.	Incl.	Incl.	Opt.	Incl.	Incl.	Incl.
Turn-Over Package: Complete document package including manuals, drawings, materials certifications and calibrations on CD	N/A	Incl.	Incl.	Incl.	N/A	Incl.	Incl.	Incl.
FAT: Factory Acceptance Test to standard Microfluidics protocol with deionized water as processed fluid	Opt. 1 day	2 days	2 days	3 days	Opt. 1 day	Opt. 2 days	2 days	3 days
SAT and IQ/OQ execution: Includes two days on site by factory technician	Opt. 2 days	2 days	2 days	2 days	Opt. 2 days	Opt. 2 days	2 days	3 days
Start-up and training: Includes factory technician on site for start-up and maintenance training	Opt. 1 day	1 day	2 days	2 days	Opt. 1 day	1 day	2 days	3 days
Extended Warranty 1 year	Opt.	Opt.	Opt.	Opt.	Opt.	N/A	N/A	N/A
Preventive Maintenance Service	Opt.	Opt.	Opt.	Opt.	Opt.	N/A	N/A	N/A
Hydraulic Oil	Opt. 10 gal	Opt. 10 gal	Opt. 10 gal	Opt. 10 gal	Opt. 35 gal	Opt. 35 gal	Opt. 35 gal	Opt. 35 gal
Safeguard Spares	Opt.	Opt.	Opt.	Opt.	Opt.	Opt.	Opt.	Opt.
Seal quench fluid recirculation system	N/A	N/A	N/A	N/A	Opt.	Opt.	Opt.	Opt.