

Microfluidics™, division of MFIC
New “Level II” Steam-in-Place Option
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NEW “LEVEL II” STEAM-IN-PLACE OPTION NOW AVAILABLE ON MICROFLUIDICS™ MICROFLUIDIZER® FLUID PROCESSORS

**New Sterilizable, High-Pressure Valve Ensures the Most Challenging Regulatory Requirements Are Met for
Injectable Drug Formulations.**

Microfluidics has introduced a proprietary steam-sterilizable high-pressure diaphragm needle valve that operates at pressures up to 40,000 psi. This breakthrough allows the introduction of a “Level II” steam-in-place (SIP) option that is designed to meet the most challenging regulatory requirements for eliminating microbiological contaminants for injectable pharmaceutical formulations in cGMP manufacturing environments. Level II is in addition to the existing “Basic” and “Level I” SIP options for the Microfluidizer high-shear fluid processor (manufactured by Microfluidics, a division of MFIC Corporation, Newton, MA). Each SIP option is designed to meet the specific regulatory requirements of the pharmaceutical industry for the sterile processing of immiscible liquid emulsions and solids in liquid suspensions.

Level II is designed with single point inlets and outlets in the welded manifold for clean-in-place fluids, steam and purge air. A Ruttan drainable valve is used at each inlet and outlet (six total) to enhance condensate drainage. The proprietary high-pressure steam-sterilizable diaphragm needle valve ensures that the valve stem remains sterile as the valve opens and closes. It replaces the Microfluidizer processor’s standard needle valve used for system priming and for the two interconnecting bypass point valves on the Ultra-Clean-in-Place (UCIP) feature, which is standard with Level II. All material and welding are certified on Level II units.

The “Basic” option is offered only with the M210 series units and is the most economical steam option offering flexibility for the user. Mechanical pressure gauges are replaced with sanitary flush diaphragm pressure transducers. Four RTDs (or thermocouples) are installed in the product piping and steam lines to help researchers and process engineers monitor temperatures throughout the wet end of the system.

“Level I” is a mid-priced steam option that is offered on both the M-210 and the M-700 series systems. LEVEL I is also designed to enhance drainability. It includes the UCIP feature and two sanitary pressure transducers with flush diaphragm in place of the standard infeed and product pressure gauges. Six RTDs (or thermocouples) provide an increased number of temperature readouts in the product piping and steam lines.

All SIP options can be ordered to include digital temperature readouts (M2 Mod.JA) or with an indicator panel for pressure display mounting and temperature displays (M2 Mod. IP).

Microfluidizer processors’ patented technology reduces particles or droplets to submicron sizes by producing the highest shear rates available. The process uniformly deagglomerates, disperses and distributes the particles to create very stable emulsions and suspensions.

For more information on the appropriate Microfluidizer processor steam-in-place option for your application, call Microfluidics, a division of MFIC Corporation at 800.370.5452; e-mail mixinginfo@mfics.com; or visit www.microfluidicscorp.com. Free laboratory batch testing is available upon request.