Application Note

Using Flow Measurement Monitoring of Pharmaceutical Water for Injection (WFI) Production Process

WFI systems are used to produce high purity water for a variety of bio-processes including production of APIs and intermediates to final cleaning of equipment before a process run. Quality is of utmost importance in any pharmaceutical product, including WFI. A WFI production process is required to meet the strict standards of the United States Pharmacopoeia. The system is designed to rid the water of any pyrogens as well as to eliminate dead zones to avoid bacterial growth. Depending on the level of stringency used in the production process, different grades of WFI can be obtained. An elaborate and stringent qualification protocol (IQ/OQ/PQ) is therefore a must before initiating use of any WFI system. Regulatory standards require, amongst other tests, Operational Qualification to study the most critical aspects of the WFI system.

These include:
1. Verification of pump functioning
2. Ensuring the absence of back flow from the inlet
3. Confirming continuous flow through the WFI system
4. Verification of delivery rates

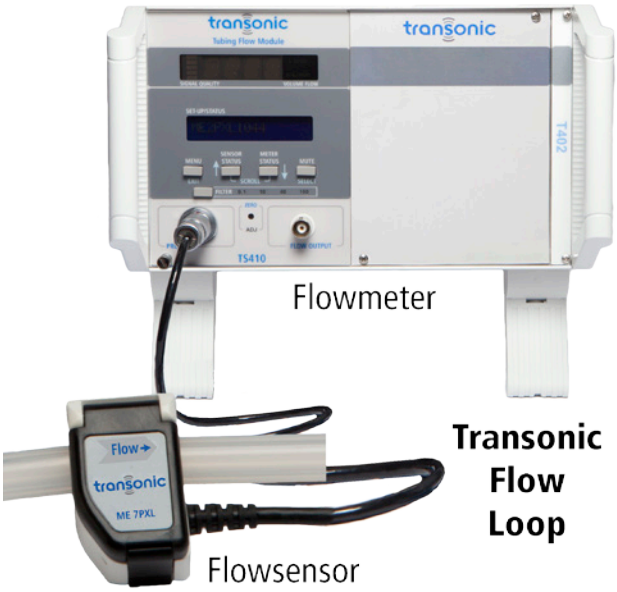

Fig. 1: Transonic Flow Loop consists of non-invasive Clamp-on Tubing Flowsensor and Flowmeter.

Most bioprocess facilities have multiple systems drawing from the same WFI system. Since these systems may draw water simultaneously, maintaining and monitoring the presence of a continuous flow in all sections of the WFI loop is imperative.

TRANSONIC FLOW LOOP (Fig. 1)

The "Flow Loop" consists of the MEPXL FlowEDGE™ Flowsensor which connects to a TS410 Flowmeter.

ME-PXL CLAMP-ON TUBING FLOWSENSORS

Transonic® ME-PXL Clamp-on Tubing Flowsensors are easy to use, accurate and reliable. They apply ultrasound energy through standard flexible tubing to monitor instantaneous and average volume flow of nutrients, cell culture media, saline, buffer or other liquid media. Clamp-on Tubing Flowsensors maintain total physical and electrical isolation between the sensor and the liquid being measured. In a WFI system, the Flowsensor should be installed at the return of the WFI loop (as it returns to the supply tank). This gives the most conservative estimate of the flow rates in the WFI distribution loop.

TS410 TUBING FLOWMETER

The modular TS410 allows life science operators to configure multiple-channel Flowmeters with mix and match capabilities to fit individual application requirements. 410-Series Flowmeter modules use enhanced transit-time ultrasound to measure liquid flow largely independent of flow velocity profile and turbulence.

FLOWEDGE™ ADVANTAGES

- Quick and easy clamp-on, clamp-off installation
- Use with flexible tubing of any material
- No fluid contact ensures ZERO risk of contamination
- No pressure drop
- Unaffected by turbulence in flow path
- Sensors available to fit tubing sizes from 1/8" OD to 1 1/4" OD
- Programmable alarms: low/high flow; received signal threshold alarm
- Easy-to-read numeric LED displays set-up/system status
- Analog signal easily integrated into control systems
- IP21 rating enclosure

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