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Analytical Device for Continuous Monitoring of Bacteria in Pharmaceutical Grade Water



The Perfect Solution for:

- Continuous monitoring of bacterial cells in pharmaceutical grade water
- Measurement of grab samples
- Detection of biofouling and microbial excursions
- Verification of sanitization effects
- Reducing downtime after rebuilding measures and maintenance

Key Features:

- Robust, scientific method:
 - unaffected by fluctuations in pressure, temperature and flow rate
 - clear distinction between particles and bacteria
- Can be controlled by the PLC via Modbus or DI/DO
- Highly user-friendly and intuitive HMI with exceptional data export function
- Cartridge containing all necessary chemicals: no chemical or waste handling needed
- Sampling device is fully heat and ozone sanitizable
- FDA 21 CFR Part 11 compliant
- Certified under the IECEE CB Scheme and compliant with UL and FCC guidelines

Product Description:

The BWT AQU@Sense MB is an automated flow cytometer specifically adapted for the continuous monitoring of bacteria in low nutrient purified water (PW, WFI). The BWT AQU@Sense MB improves safety and promotes process control and understanding compared to the traditional plate counting.

Flow cytometry is a batch process in which the sample is mixed with a DNS specific fluorescent stain. After an incubation period the sample flows through a thin capillary where a laser induces fluorescence in the DNS bound stain. The fluorescent activity and the side scatter (SSC) are recorded for each cell and particle. Inorganic particles are not counted, as no fluorescent stain is bound to them.

The BWT AQU@Sense MB lowers cost by reducing cost-intensive plate counting to a minimum. Plate counting may be replaced fully after a validation of the BWT AQU@Sense MB according to USP <1223> or Ph. Eur. 5.1.6. Further financial saving can be obtained by re-evaluating the temperature and interval of hot water sanitization.

All necessary chemicals are contained in a securely sealed cartridge. The replacement of the refillable cartridge is quick and clean and no handling of hazardous chemicals is required. A service of the cartridge is included in every refill.

The measured sample and all chemicals used are directed back into the cartridge. Therefore, no contaminated wastewater is generated on-site. Each measurement is followed by a cleaning step to prevent biofouling and secure high-quality results.

Major time-savings can be achieved compared to plate counting, as the time-to-result is only 20min. The measuring interval can be adjusted manually from 30min to 6h, or may be controlled automated by the PLC of the BWT generation plant.

The BWT AQU@Sense MB reduces the error potential of manual sampling significantly. Grab samples are measured straight out of a screw-on, sterilized sampling tube and repeated measurement of the same sample can be automated.

BWT AQUA AG

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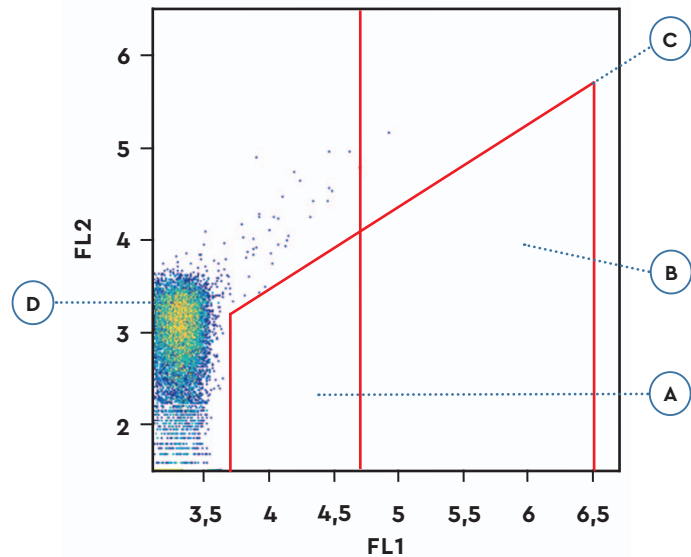
Included Documents:

- Operation manual
- EU declaration of conformity
- IQ-OQ documentation
- Validation confirmation
- Data sheet
- Safety data sheets (for the chemicals of the cartridge)

Measurement Results:

Example of graphical output for pharmaceutical grade water. The fluorescence of each cell is measured at 525nm (FL1) and 715nm (FL2).
A and B combined are ICC (intact cell count).

- A:** Small bacteria (LNA: low nucleic acid)
- B:** Large bacteria (HNA: high nucleic acid)
- C:** Gates for cell counting
- D:** Noise of detector



Technical Data:

General:	
Measuring principle	Flow cytometry
Protection degree	IP65
Ambient temperature	+5°C ... +35°C
Ambient humidity	10 ... 90% RH
Dimensions (WxDxH)	350 × 240 × 373mm
Weight	14kg
Connections:	
Outputs	4 digital outputs and 2 × 4 ... 20mA analog outputs, freely configurable
Inputs	4 digital inputs
Input sampling device	¼" Swagelok pipe screwing male
Output sampling device	¼" Swagelok pipe screwing male
Power supply	100 ... 240 VAC, 50/60 Hz, 1.4 A, max. 20W
Memory card	32 GB
Data export	USB and Ethernet
Measurement:	
Sampling volume	90µl
Sampling mode	Continuous or manual
Measurement interval	30min to 6h
Time-to-result	20min
Cartridge capacity	Max. 1000 measurements
Sample flow	200–400ml/min
Max. sample temperature	40°C
Sanitation conditions	Ozone up to 100ppb / hot water up to 85°C (without a running measurement)

Service and Maintenance:

It is recommended to carry out service by our professional BWT service technicians twice a year.

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