

# BWT AQU@Sense MB

The RMM device for bioburden monitoring in pharmaceutical water

Data sheet EN 09/2024



## The perfect solution for:

- Continuous monitoring of bacterial cells in pharmaceutical grade water
- Measurement of grab samples (offline mode)
- Fast detection of biofouling and microbial excursions
- Verification of sanitization effects
- Reducing downtime after rebuilding measures and maintenance (e.g., fast OOS investigation)
- Enhanced data handling and trend analysis (CCS)

## Key features:

- Robust, scientific method: unaffected by fluctuations in pressure, temperature, and flow rate
  - » clear distinction between particles and bacteria
  - » single cell detection
  - » primary validated technology
- 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 Compliance
- Fully automated: TTR 20 minutes
- Electronic gapless documentation

## Product description

### Device

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.

### Method – distinction between live and dead cells

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

The implementation of AQU@Sense MB reduces the costs for water quality monitoring since plate counting can be completely replaced after validation of the BWT AQU@Sense MB according to USP <1223> or Ph. Eur. 5.1.6. Further financial savings can be achieved by optimizing the temperature and reducing the interval of hot water disinfection. The long-term benefits of qualifying and implementing AQU@Sense MB outweigh the short-term investment costs.

### ICC cartridge

All necessary chemicals are contained in a securely sealed cartridge. The replacement of the refillable cartridge is quick and clean, and no direct contact with hazardous chemicals is required. A complete 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.

### Further application benefits

Major time-savings can be achieved compared to plate counting, as the time-to-result is only 20 minutes. The measuring interval can be adjusted manually from 30 minutes up to 6 hours or may be controlled automatically by the PLC of the BWT water system. Improved data management and trend analysis play a crucial role in enhancing a comprehensive contamination control strategy (CCS).

The BWT AQU@Sense MB reduces the error potential of manual sampling significantly. Grab samples are taken directly from a sterilizable, screw-on sample tube and up to five technical replicates can be performed for each measurement. Which indeed decrease the need for re-sampling, retests, and OOS investigations.

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## Analytical device for continuous monitoring of bacteria in pharmaceutical grade water

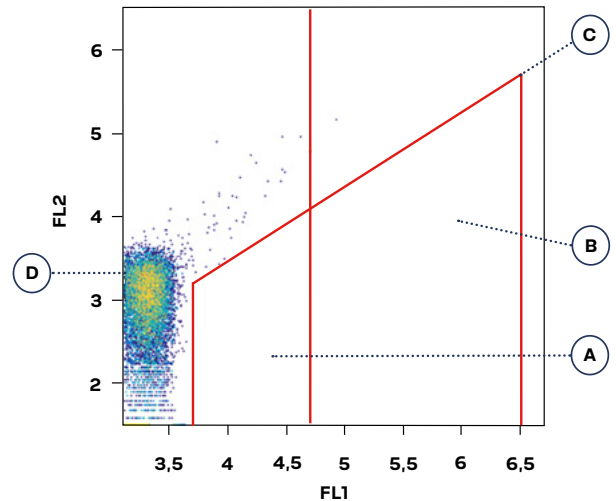
### Included documents:

- 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 525 nm (FL1) and 715 nm (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 × 373 mm
Weight	14 kg

### Connections:

Outputs	4 digital outputs and 2 × 4 ... 20mA analog outputs, freely configurable
Inputs	4 digital inputs
Input sampling device	1/4" Swagelok pipe screwing male or Serto (SO NV51A21 - 6,35)
Output sampling device	1/4" Swagelok pipe screwing male or Serto (SO NV51A21 - 6,35)
Power supply	100 ... 240 VAC, 50/60 Hz, 1.4 A, max. 20 W
Memory card	32 GB
Data export	USB and Ethernet

### Measurement:

Sampling volume	90 µl
Sampling mode	Continuous or manual
Measurement interval	30 min to 6 h
Time-to-result	20 min
Cartridge capacity	Max. 1000 measurements
Sample flow	200-400 ml/min
Max. sample temperature	40 °C
Sanitation conditions	Ozone up to 100ppb / hot water up to 85 °C (without a running measurement)
Max. Sample pressure	0.5 bar

## Service and Maintenance:

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

### BWT AQUA AG

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