Life Sciences

INDUSTRY

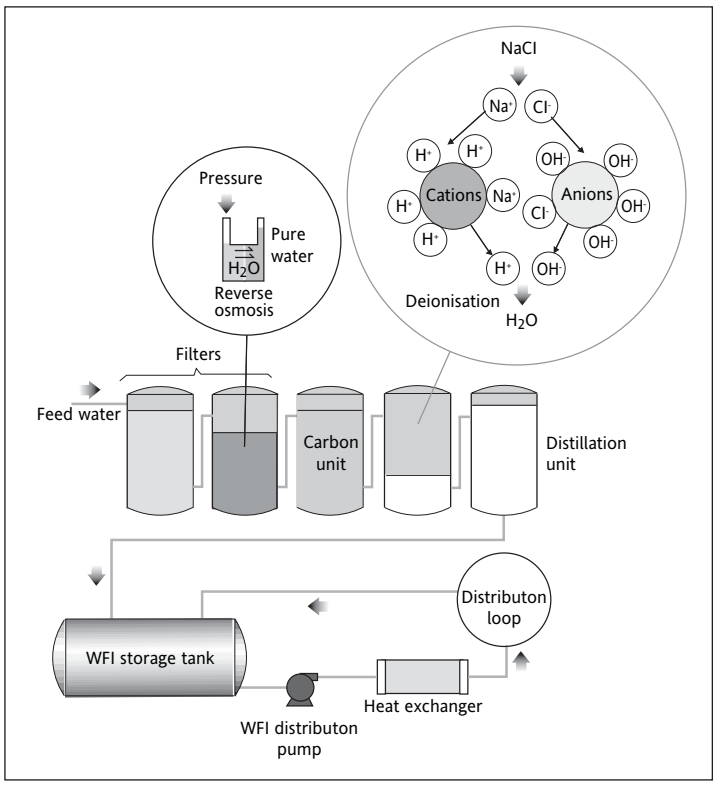
- **Control and sequencing**
- **Recipes**
- **Batch control and reporting**
- **Setpoint programming**
- **Bespoke displays**
- **Alarm management**
- **21 CFR Part 11**

The Water Purification Process

Application Note

Water purity is extremely important to pharmaceutical and biochemical industries. Suspended or dissolved particles, organic compounds, impurities and other contaminants prohibit the usage of tap water in laboratory applications and scientific research.

Parameters such as resistivity, conductivity, size of particulate matter and concentration of micro-organisms are used to categorise water quality and, therefore, specify intended uses for water. Some applications can tolerate the presence of specific impurities in the water, but others, such as High Performance Liquid Chromatography (HPLC) require removal of the majority of contaminants.



Contaminants

Water is an excellent solvent and can be sourced from almost anywhere on Earth. This property makes it prone to all kinds of contamination.

- Particulates: Silt and debris which can be removed by passing water through a 10 to 20 micron filter (or less if necessary).
- Micro-organisms: Bacterial agents constitute a real challenge for water purification systems. Their growth rate, size and robustness require an efficient design (detection, removal from water inlet, inhibition of growth, etc.). Bacteria are measured in colony forming units per millilitre and can be killed with disinfectants. As a result, their secretions and cellular fragments must also be removed to avoid contamination.
- Endotoxins, pyrogens, DNA and RNA: Cellular fragments and bacterial by-products. Harmful to tissue cultures. Can be detected with a Limus Amoebocyte Lysate (LAL) test.

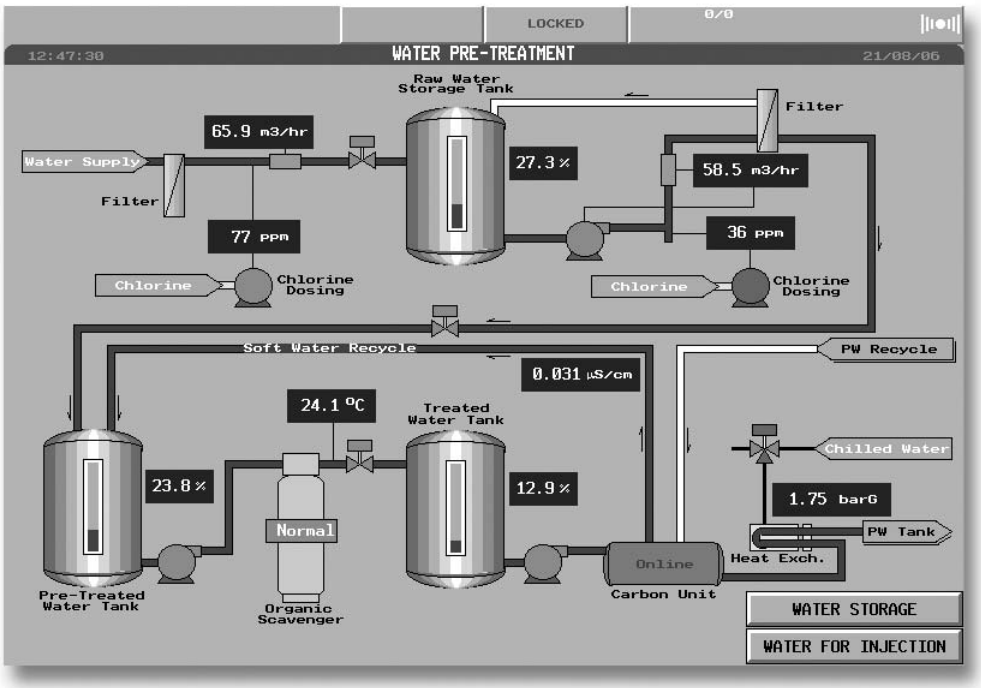
- Dissolved inorganic elements: Include phosphates, nitrates, calcium and magnesium, carbon dioxide, silicates, iron, chloride, fluoride, and any other natural or man-made chemicals resulting from exposure to the environment. Electrical conductivity (µSiemens/cm) is used to monitor high concentration of ions, while resistivity (MΩcm) is used to identify ions if present in small concentrations. These contaminants affect water hardness and alkalinity/acidity.
- Dissolved organic elements: Pesticides, plant and animal remains or fragments. Total Organic Carbon (TOC) analysers are used to measure CO2 emitted by organics subjected to oxidisation. Organic-free water is mainly used in applications where analysis of organic substances is carried out (e.g. HPLC, chromatography and mass spectrometry).

Scientific applications require elimination of certain types of contaminants. On the other hand, pharmaceutical productions require, in most cases, near-total removal of impurities (criteria dictated by specific standards or local/international regulatory bodies).

Purification process

There are a number of methods commonly used to purify water. Their effectiveness is linked to the type of contaminant being treated and the type of application the water will be used for.

- Filtration: This process can take the form of any of the following:
  - Coarse filtration: Also called particle filtration, it can utilise anything from a 1 mm sand filter, to a 1 micron cartridge filter.
  - Microfiltration: Uses 1 to 0.1 micron devices to filter out bacteria. A typical implementation of this technique can be found in the brewing process.
  - Ultrafiltration: Removes pyrogens, endotoxins, DNA and RNA fragments.
  - Reverse osmosis: Often referred to as RO, reverse osmosis is the most refined degree of liquid filtration. Instead of a filter, it uses a porous material acting as a unidirectional sieve that can separate molecular-sized particles.
- Distillation: Oldest method of purification. Inexpensive but cannot be used for an on-demand process. Water must be distilled and then stored for later use, making it again prone to contamination if not stored properly.
- Activated carbon adsorption: Operates like a magnet on chlorine and organic compounds.
- Ultraviolet radiation: At a certain wavelength, this might cause bacteria to be sterilised and other micro organics to be broken down.
- Deionisation: Also known as ion exchange, it is used for producing purified water on-demand, by passing water through resin beds. Negatively charged (cationic) resin removes positive ions, while positively charged one (anionic) removes negative ions. Continuous monitoring and maintenance of the cartridges can produce the purest water.



Hot water sanitisation

Sanitisation of water purification equipment with hot water is achieved via an appropriate combination of exposure time and temperature. A primary use for this process is to deactivate viable microbes. It is worth mentioning that Endotoxin reduction is not achieved as a direct result of the hot water sanitisation process.

Based on the feed water source, system operating conditions and the end-user's operating and maintenance procedures, traditional chemical cleaning processes may still be required.

Sanitisation using hot water involves incorporating heat exchangers into the traditional clean in place (CIP) system to gradually heat and cool water circulating through the reverse osmosis membrane system. Membrane manufacturers commonly stipulate a controlled heating and cooling rate to protect against irreversible damage to the membrane and ensure the system's long-term performance.

A typical hot water sanitisation sequence would consist of the following phases:

- Initialisation (conditions checking)
- Heating
- Holding
- Cooling

A control system must therefore provide flexibility in the way in which accurate and repeatable control of the sterilisation is achieved and will include the following features:

- Precise loop control with setpoint profile programming
- Sequential control for sanitation/sterilisation
- Onscreen operator messaging
- Duty standby pump control
- Secure collection of on-line data from the purified water system for analysis and evidence
- Local operator display with clear graphics and controlled access to parameters

Eurotherm Eycon™ Visual Supervisor

The Eurotherm visual supervisor is ideal for autoclave applications because it combines all these key features into a single compact unit:

- **Powerful loop and sequence control**
- **Flexible graphics**
- **Setpoint programmer**
- **Batch control and reporting**
- **Audit trail**
- **XGA touchscreen display to IP65**
- **Secure data logging and trending**
- **Recipe management**
- **Alarm management**
- **Access control and electronic signatures**

21 CFR Part 11 - 'Ready to use!'

Water purification plants are used in industries likely to require validation to the requirements of the FDA, EMEA or other applicable regulatory body. The visual supervisor has been widely used in validated processes including freeze dryers, autoclaves, reactors, fermenters, purified water systems, tablet coating machines, etc.

The Auditor feature on the visual supervisor has been specifically designed to meet the requirement of the FDA's 21 CFR Part 11 including:

- Controlled user access
- Secure data logging in tamper resistant format
- Audit trail recording user actions and changes to process parameter
- Electronic signature

21 CFR Part 11
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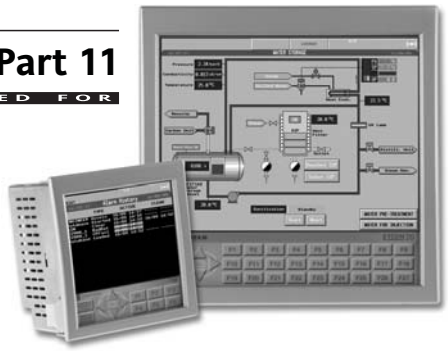

With the Auditor feature, Electronic signature is configurable for all actions which may be performed from the visual supervisor display including the customised display and standard features such as batch, recipe changes, access control changes, etc.

Scalable architecture

A complete system can be created in combination with T2550 DIN rail I/O bases. Connection is via ELIN and I/O is scalable by adding 4. 8 or 16 slot bases as required. A range of I/O modules caters for the various interfaces required:

Analogue inputs	Temperature, water flow, line pressures, level, pH, conductivity, chlorine and carbon measurements, etc.
Analogue outputs	Control valves, flow/pressure regulators, pumps speed
Digital inputs	Bursting discs, conductivity and other analytical measurements alarms, valves and pumps statues, etc.
Digital outputs	Valve control solenoids, pump control etc.

System building blocks:

- Pre-treated water system (single Eycon)
- Water for injection and distribution system (single Eycon)
- Complete system with supervisory workstation(s)

Eurotherm: International sales and service

Understanding and providing local support is a key part of Eurotherm's business. Complementing worldwide Eurotherm offices are a whole range of partners and a comprehensive technical support team... to ensure you get a service you will want to go back to.

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