Life Sciences

INDUSTRY

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

The Sterilisation Process (Autoclaves)

Application Note

Through history, humans have used fire to purify items. Heat generated through application of high temperatures acts by disrupting membranes and denaturing proteins and nucleic acids. Burning, however, is a bit excessive for everyday usage.

Transmissible agents (such as spores, bacteria and viruses) can be eliminated through sterilisation. This is different from disinfection, where only organisms that can cause disease are removed.
Some of the methods used to achieve sterilisation are:

- Autoclaves: Highly effective and inexpensive. Unsuitable for heat sensitive objects.
- Hot air ovens: Inefficient compared to autoclaves.
- Ethylene oxide: Suitable for heat sensitive items but leaves toxic residue on sterilised items.
- Low-temperature steam and formaldehyde: Effective for instruments with cavities or tubular openings.
- Sporicidal chemicals: Often used as disinfectants but can also sterilise instruments if used for prolonged periods.
- Irradiation: Gamma rays and accelerated electrons are excellent at sterilisation.
- Gas plasma.

The preferred principle for sterilisation is through heat, the autoclave being the most widely used method of achieving it.

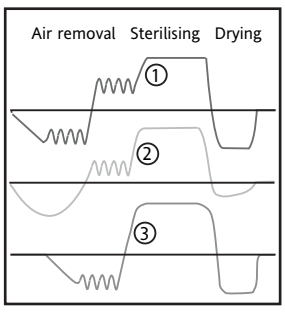
In a dry air oven, it takes two hours at 160°C to kill spores of the bacterium Clostridium botulinium (associated with canned food). Using saturated steam, the same spores are killed in just five minutes at 121°C, proving that moist heat is more effective than dry heat.

Autoclave design and control

To be effective against spore forming bacteria and viruses, autoclaves need to:

- Have steam in direct contact with the material being sterilised (i.e. loading of items is very important).
- Create vacuum in order to displace all the air initially present in the autoclave and replacing it with steam.
- Implement a well designed control scheme for steam evacuation and cooling so that the load does not perish.

The efficiency of the sterilisation process depends on two major factors. One of them is the thermal death time, i.e. the time microbes must be exposed to at a particular temperature before they are all dead. The second factor is the thermal death point or temperature at which all microbes in a sample are killed.



The steam and pressure ensure sufficient heat is transferred into the organism to kill them. A series of negative pressure pulses are used to vacuum all possible air pockets, while steam penetration is maximised by application of a succession of positive pulses.

Typical pressure cycles used in autoclaves are:
1. Cycle for fabrics, assembled filter units and discard loads.
2. Cycle for laboratory plastic and glassware.
3. Cycle mainly used for discard loads.

Process performance can be confirmed by monitoring colour changes on indicator tape often taped onto packages or products to be autoclaved. Biological indicators can also be used. These contain Bacillus Sterothermophilus spores, which are amongst the toughest organisms an autoclave will have to destroy. After a run in an autoclave, the internal glass in the vial is shattered, allowing the spores into a differential liquid medium. If the autoclave has destroyed the spores, the medium remains a blue colour. Otherwise, the spores will metabolise, causing a yellow colour change after two days of incubation at 56°C.
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
- Recipe Management System for easy parameterisation
- Sequential control for complex control strategies
- Secure collection of on-line data from the sterilisation 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!'

Autoclaves 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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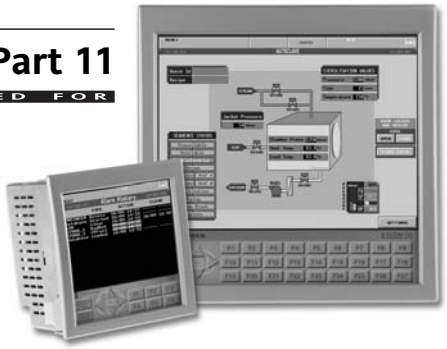

With the Auditor feature, Electronic signature is configurable for all actions which may be performed from the visual supervisor display including the customised display and standard features such as batch, recipe changes, access control changes, etc.

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	Jacket, chamber, drain, load probe, air detector and air filter temperatures, jacket and chamber pressures
Analogue outputs	Steam control valve, pressure regulator
Digital inputs	Door closed, locked, sealed; switches, emergency stop
Digital outputs	Valve control solenoids, pump/fan controls

System building blocks:

- Autoclave (single Eycon™ visual supervisor)
- Multiple autoclaves with supervisory workstation(s)

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