EtO Sterilisation

Ethylene Oxide (EtO) Sterilisation Process

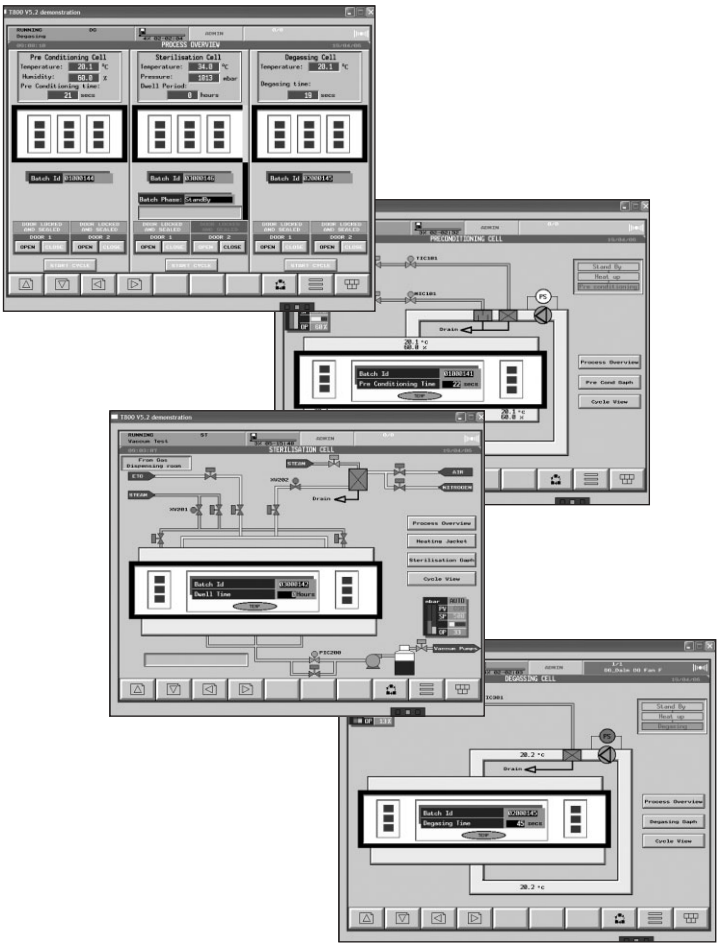
Application Note

Ethylene Oxide (EtO) sterilisation is mainly used to sterilise medical and pharmaceutical products that cannot support conventional high temperature steam sterilisation - such as devices that incorporate electronic components, plastic packaging or plastic containers.

EtO gas infiltrates packages as well as products themselves to kill micro organisms that are left during production or packaging processes. This gas, mixed with air at a ratio of at least 3% EtO gas, forms an explosive mixture. Pure EtO gas boiling point is 10.73 °C at atmospheric pressure. Most of the time, it is mixed with Nitrogen or CO2. This explosive condition requires Intrinsic Safe material (ATEX) zoning, for security of people as well as security of the process itself.

Safety of personnel is an important issue due to the harmful effect of EtO on humans. Polluted areas need to be alarmed using gas detectors set up at different locations to monitor any leak. Visual and audio alarm systems need to be provided. The system must inform any operator when a sterilisation cell contains EtO.

When this toxic gas is removed from the room it needs to be treated using thermal burners, scrubbers or oxidation for environmental protection or be transported to an alternate facility for treatment.



- **Recipe downloads**
- **Safety interlocks**
- **Autobatch release**
- **Temperature control**
- **Vacuum control**
- **21 CFR Part 11**

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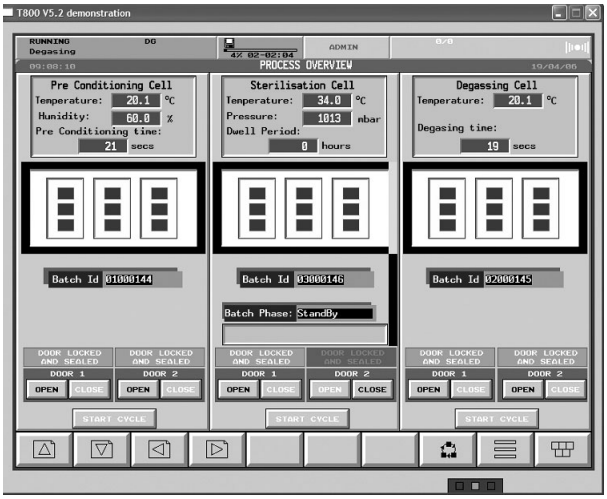
EtO Sterilisation process:

Most EtO sterilisation lines involve three different stages. These can be separated into three different cells depending on the size or amount of devices to treat:

- **PRE CONDITIONING**
- **STERILISER**
- **DEGASSER**

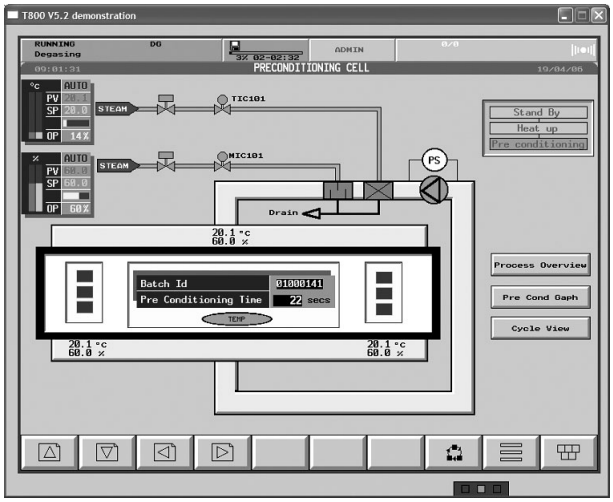


When cells are separated, automated loading/unloading systems are required. These save operator time as well as giving protection from exposure to a polluted environment, which could be detrimental to health.

PRE CONDITIONING STAGE

First, products need to go through a pre conditioning phase to make micro organisms grow. The batch load goes through a dwell time under a controlled environment of:

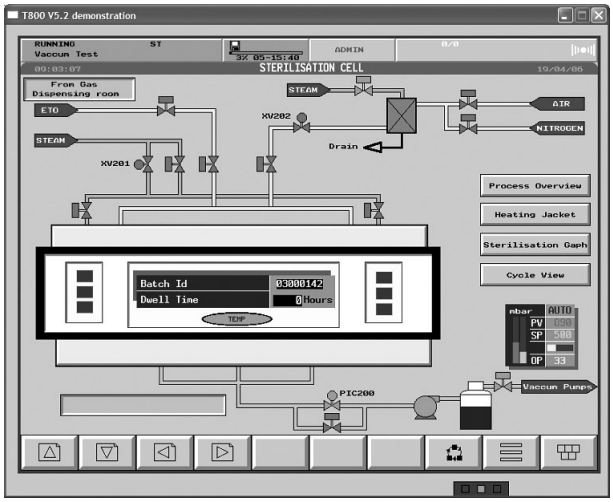
- **Temperature**
- **Humidity**



STERILISER STAGE

Then the load goes through a long and complex sterilisation cycle. Requirements of such a system are:

- **Accurate temperature control.**
- **Availability of the control system.**
- **Accurate pressure and vacuum control.**
- **Easy displays of process phases**
- **Dedicated customer recipes.**
- **Auto batching release through tolerance tests.**
- **Reporting.**
- **Security interlocks between actuators.**
- **Alarming.**
- **Shut down strategies.**
- **Audit Trail facilities – Trending.**
- **21CFR Part11.**



During this cycle, accurate temperature control is important and a heating jacket is used. As the overall duration of this cycle is around 60 hours, high availability of the system is vital and system redundancy is required. Doubling sensors, actuators and controllers as well as changeover facilities on these components, helps to ensure the product is sterilised even on hardware or software failure.

After the doors have been shut down and sealed correctly, the cycle can be started either manually or automatically. If any problem with door sealing is detected the cycle is interlocked and cannot start. Security interlocks are also used between air and EtO valves.

Once the cycle is started, easy to use displays are required to show:

- **The actual phase of sterilisation**
- **All the key set points and tolerances as loaded by the recipe**
- **All the key process values for the auto batch release facility**

Control of vacuum and pressure is also required. Due to the toxic effect of EtO, water ring rotary pumps are used. The vacuum process needs to perform the emergency evacuation phase for a fast evacuation of gas.

The sterilisation phases are:

- **Cycle start delay to enable the system to start in stable conditions**
- **General cell temperature check**
- **Initial vacuum phase**
- **Leak rate test**
- **First flush**
- **Second flush**
- **DEC (Dynamic Environmental Conditioning)**
- **EtO gas injection**
- **Sterilisation dwell time period under EtO**
- **Post dwell vacuum level**
- **First wash**
- **Second wash**
- **Final air admission**
- **Final chamber re-evacuation delay**

During execution of these phases a batch report is generated. This report will include: tolerance checks, phase changes, alarms, events and critical process values. A key feature of the system is “auto batch” release. During the sterilisation cycle if any abnormal condition occurs, the batch will be automatically stopped and condition(s) causing the stoppage will be identified. With this “auto batch” release facility operators do not have to wait until the end of the cycle and spend time going through the batch report to understand why it went wrong. With this feature, provided that batch is completed satisfactory it will be automatically forwarded to the degassing room without human check of tolerance, process values and alarms.

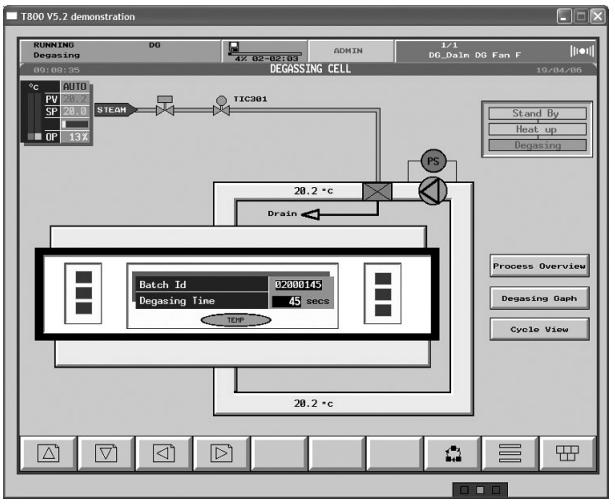
For each batch the operator selects appropriate product recipe. After recipe has been downloaded, the operator is given the opportunity to check if values are correct for this particular batch before starting the cycle.

When the batch is over an automatic print of the report can be performed. Batch logged files are also archived electronically for future review. Batch logged files could be searched by the following:

- **Batch ID**
- **Customer name**
- **Recipe**
- **Product type**
- **Start and stop time**

DEGASSER STAGE

Finally, products need to go through a degassing phase to remove any particle of EtO. The batch load goes over a dwell time under a temperature controlled environment



Eurotherm T800 Visual Supervisor

The Eurotherm Visual Supervisor is ideal for EtO steriliser applications because it combines all these key features into a single compact unit:

- **Batch control and reporting**
- **Powerful loop & sequence control**
- **Alarm management**
- **Recipe management**
- **Flexible graphics**
- **Audit trail**
- **SVGA touch screen display IP65**
- **Secure data logging and trending**
- **Access control and electronic signatures**

21 CFR Part 11 Ready

Sterilisation plants are 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 fermenters, freeze dryers, autoclaves, reactors, 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 tamperproof format**
- **Audit trail recording actions and changes to process parameters**
- **Electronic signatures**

With the Auditor features, electronic signature is configurable for all actions that may be performed from the Visual Supervisor display including the customised display, standard features such as batch management, recipe changes, access control changes, etc.

Scalable Architecture:

The Eurotherm Programmable Automation Controller T2550 is ideal for EtO steriliser applications combined with T800, because it offers all these key features:

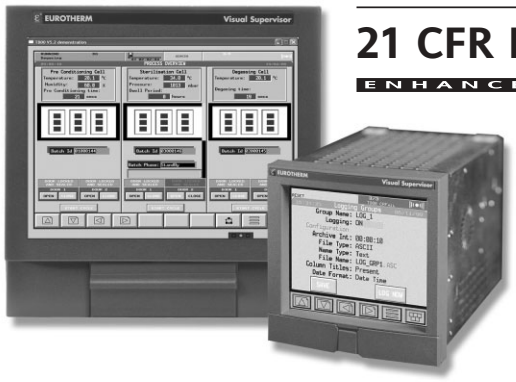
- **Powerful strategy engine**
- **Multitasking for rapid shutdown strategies**
- **Native redundancy features on critical strategy**
- **Calibration facilities**
- **Powerful loop & sequence control**
- **Scalable by adding slot of I/Os as required**

A range of I/O modules cater for the various interfaces required:

- **Analogue inputs: Temperature, Humidity, Pressure etc.**
- **Additional measurements: Gas level probes.**
- **Analogue outputs: Steam/Water/Gas control valves, fan speed**
- **Digital inputs: Doors, gas valves and motor status, pallet positions and numbers, etc.**
- **Digital outputs: Valve control solenoids, Pump control, etc.**

System Building Blocks:

- **Single steriliser (single T800)**
- **Degassing/Pre-conditioning cells**
- **Multiple units with Supervisory Workstations(s)**



21 CFR Part 11
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