

## Sterilizing Autoclave Controller Retrofit

MAAK supplied a retrofit control system for an Amsco sterilizer to replace an existing Eagle 2200 Universal Steam Controller supplied with the system.

The scope of supply included: design, fabrication (control panels), instrumentation, software development, SCADA system, installation and commissioning, FAT and SAT. The system design adhered to the GAMP (Good Automated Manufacturing Practice) life-cycle approach to the validation of automated systems.



### Process Description

The autoclave chamber can be vacuumed as well as pressurized with clean steam. When the chamber is pressurized to the required sterilization temperature, the dwell period begins whereby the goods are sterilized. Depending on the type of goods the process can involve further steps including evacuation, drying and cooling.

Clean steam is introduced to the chamber via a modulating valve. The chamber is evacuated using a vacuum pump. Pressure in the chamber is released either via the vacuum pump (fast exhaust) or via a smaller drain valve (slow exhaust). Vacuum in the chamber is released either by injecting steam (during the start of a cycle) or by air through the sterile filter and vacuum breaker.

### Automation

The autoclave is controlled by an industrial PLC and the operators interact with the system via an OIT (touch screen as well as keypad). The PLC and OIT are programmed to allow the operator to select one of two main cycle types: Gravity and Pre-Vacuum. Within each type, the operator can select one of 10 pre-defined cycles. The operator can also perform a Vacuum Leak Test Cycle and a Vent Filter Sterilization Cycle. The operator, via a password controlled configuration screen, can edit the parameters for each specific cycle. The OIT displays pertinent process information to the operator such as current status, cycle, step, sub-step, hold time, recipe number, pressures, and temperatures. Critical information is also printed directly from the controller.

The controller also allows the user, via a password protected screen, to perform maintenance functions on the control system.

New regulatory guidelines (FDA, MCA) require the vessel drain temperature to be the key parameter. Special control algorithms were developed to provide fast, precise temperature

regulation of the drain temperature. For larger vessels where the delay effect on the drain temperature is even more pronounced, this scheme is of enormous benefit.