



LABORATORY RESEARCH CED SYSTEM



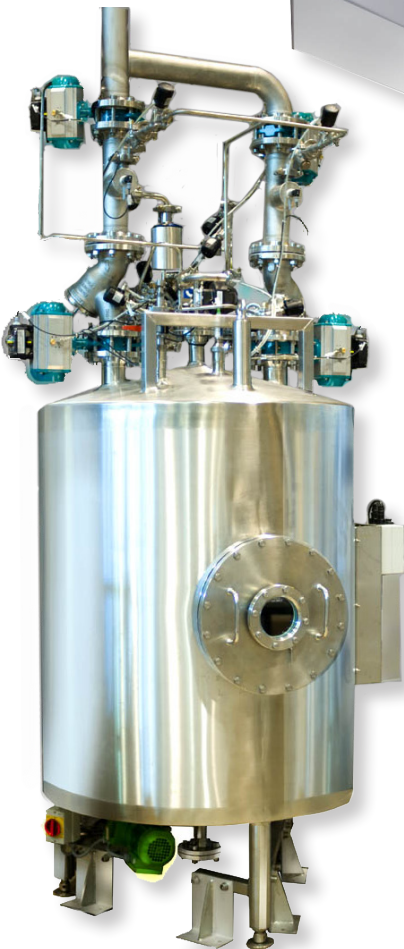
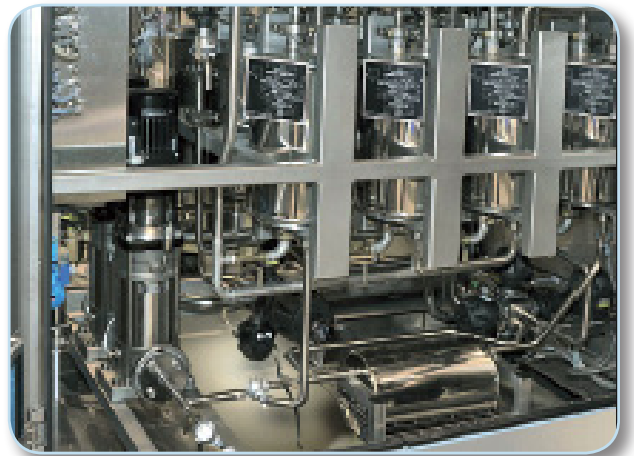
FOR HIGH CONTAINMENT APPLICATIONS BSL-2, BSL-3, BSL-4

CONTINUOUS EFFLUENT DECONTAMINATION SYSTEM®

Safety Validation
Efficacy Reliability

Design in accordance with GAMP 5

THE CONTINUOUS FLOW APPROACH

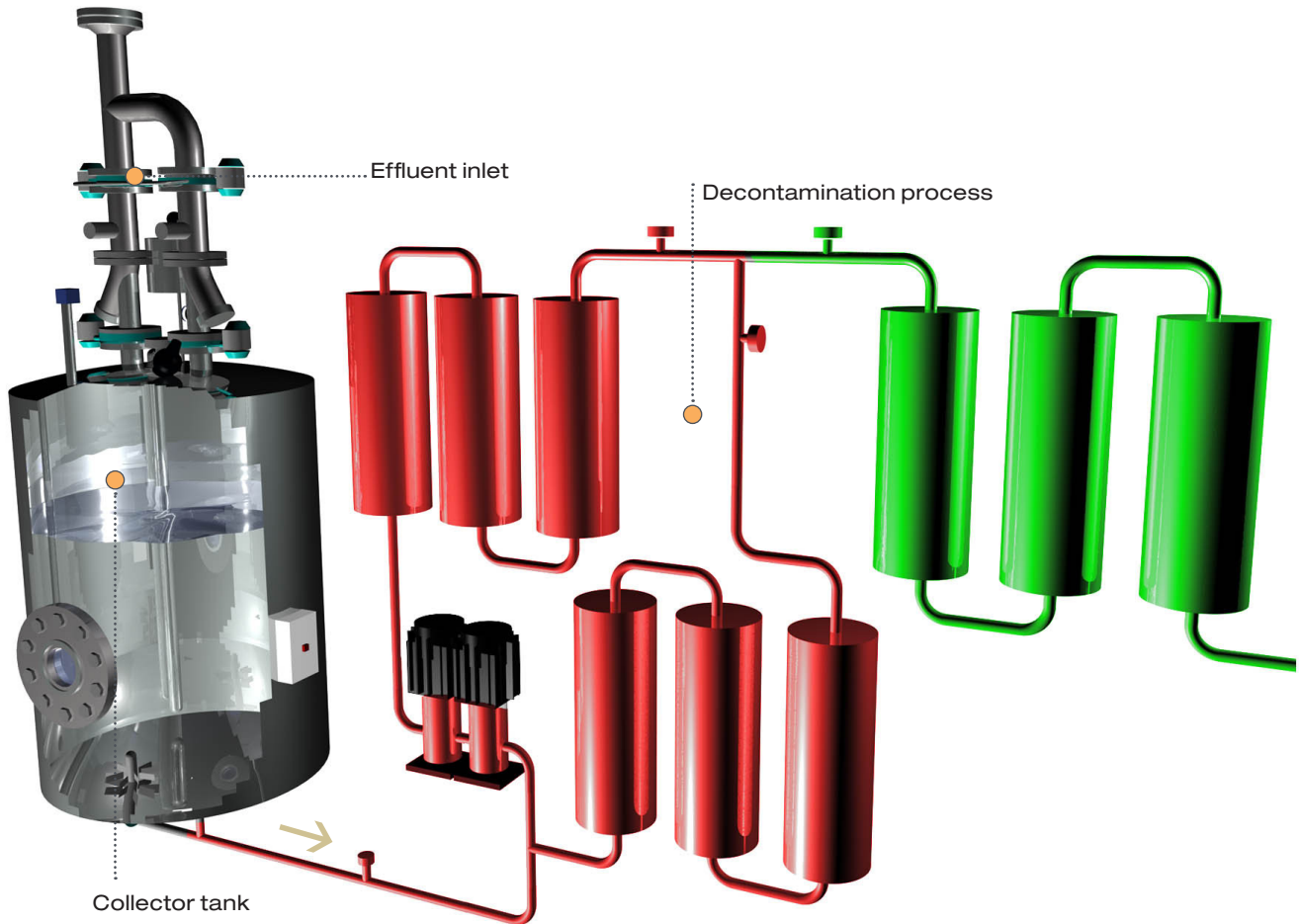


Due to increasing requirements, modern research facilities require safe, reliable and efficient processing systems which meet all environmental and technical requirements with proven efficacy and easy operation. Continuous pressure on lowering capital costs, minimizing operator intervention, lowering facility and operational costs demand such energy and space saving properties that cannot be met with conventional systems.

Increasing processing volumes and presence of bio-hazardous organisms create requirements that standard batch processing systems cannot meet.

STERIS's Continuous Effluent Decontamination System is designed to help meet or exceed the increasing requirements of pharmaceutical production facilities rated BSL-2, BSL-3 or BSL-4.

HOW THE CONTINUOUS EFFLUENT TECHNOLOGY WORKS



The effluent stream is gravity drained or pumped to a buffer tank. If present, solid particles are removed from the effluent stream and sterilized prior to entering the buffer tank. The decontamination unit starts and stops automatically, according to user-definable start and stop levels of the tank. Effluent is pressurized and pumped through plant steam heat exchangers to raise temperature to a minimum of $\geq 150\text{ }^{\circ}\text{C}$ with exposure to achieve decontamination efficiency equal to 45 minutes in a sterilizer, or higher. Effluent is cooled down to customer specific outlet temperature by using cooling water heat exchangers. Decontamination process and system status are continuously monitored and

recorded by the self-diagnostic automatic control system. Each startup features a short automatic closed loop heating up and tuning of the decontamination process before starting actual effluent processing. The safety features of the CED system prevent any cross-contamination to environment.

Unit capacities range from 300 to 3,000 liters per hour, and product range consists of five main unit sizes (300/500/1,000/2,000/3,000 l/h) and standard 1,000L vertical collector tanks. Simple customization of capacities and tank sizes/orientations help to guarantee the most suitable and optimal system for your application.

Ease of Use

Automated operation and self-diagnostics.

Productivity

Up to 24 hours of continuous uptime.

Cost Savings

Heat recovery option reduces energy consumption

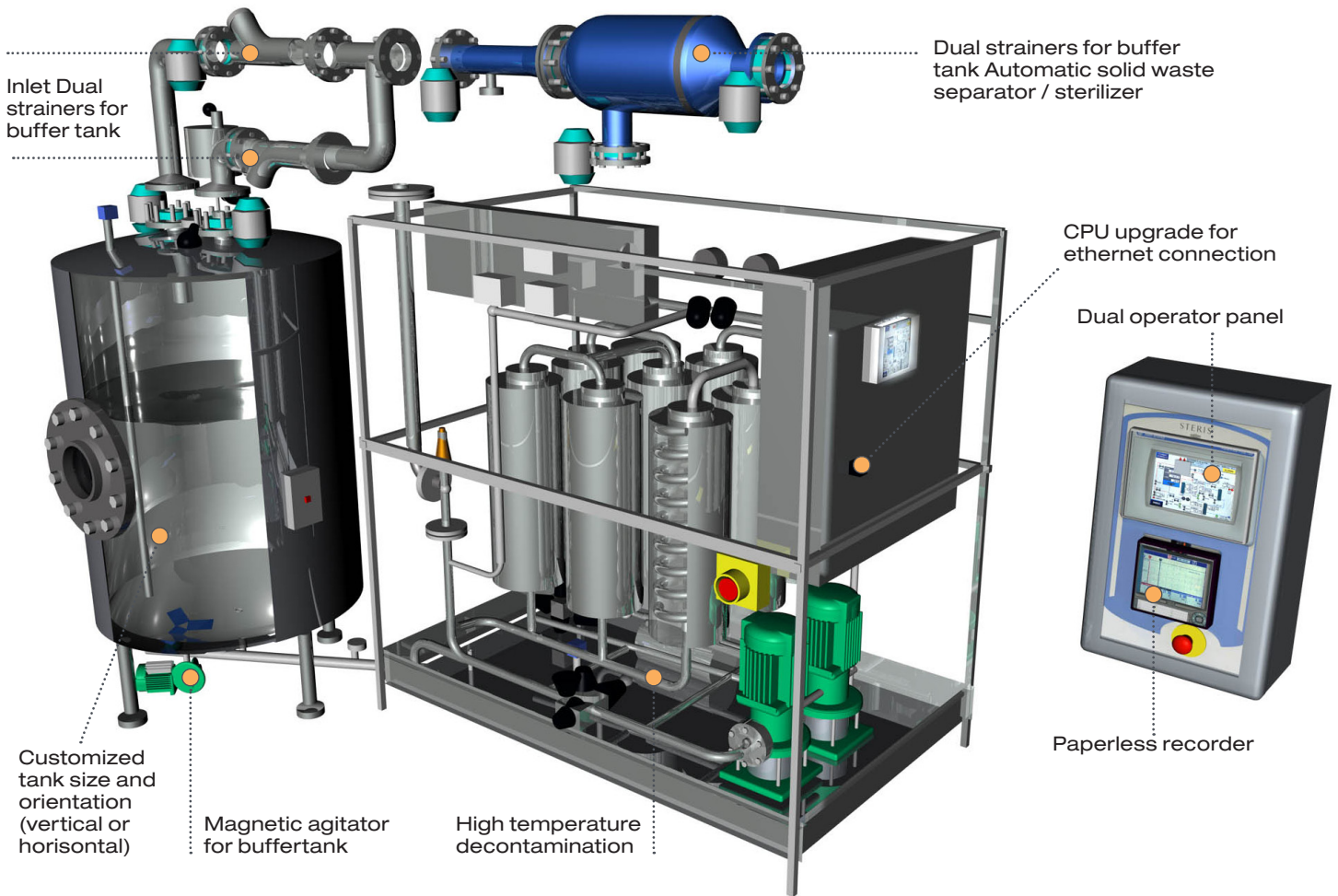
Flexibility

Requires considerably less room space than traditional kill tanks.

Easy to Validate

Documentation includes full protocols and methods to meet highest industry requirements.

OPTIONAL FEATURES



Inlet Dual strainers for buffer tank

Dual strainers for buffer tank Automatic solid waste separator / sterilizer

CPU upgrade for ethernet connection

Dual operator panel

Paperless recorder

Customized tank size and orientation (vertical or horizontal)

Magnetic agitator for buffertank

High temperature decontamination

The CED system includes optional features to help meet any requirements depending on needs of the application, facility planning, data transfer and additional safety & redundancy features. For other requirements, please consult our engineering for customized solutions.

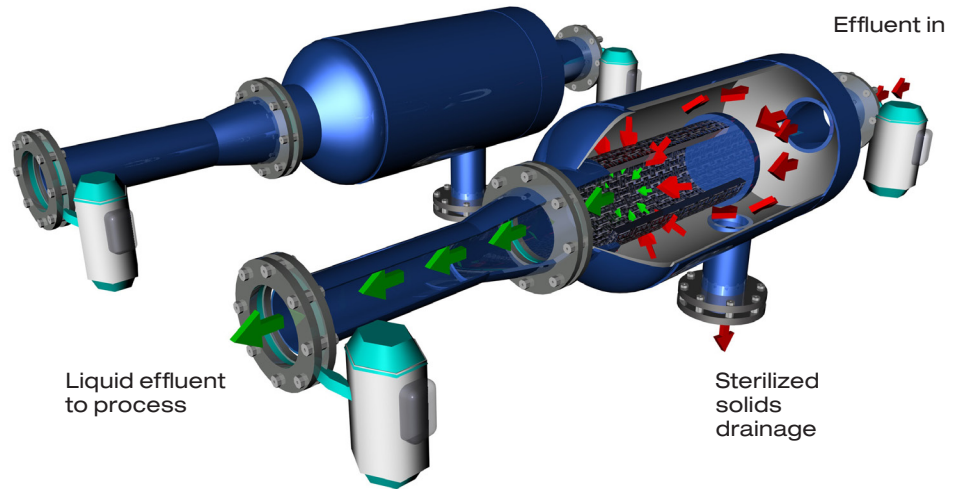
- Magnetic Agitator for Buffer Tank
- Dual Inlet Strainers for Buffer Tank
- Six Channel Paperless Recorder
- Automatic Solid Waste Separator
- Dual Automatic Solid Waste Separators
- High Temperature Decontamination (max. +163 °C)
- CPU Upgrade for Ethernet Connection
- Dual Operator Panels
- Tank Size Upgrade 1000L => 2000L
- Tank Size Upgrade 1000L => 3000L
- Room leak indicator and alarm
- Mobile CIP skid for CED Cleaning In Place
- Safe Heat Recovery System
- Alkaline Batch Decontamination + High Temperature Decontamination (max. +163 °C) for treatment of prions
- Uninterruptible Power Supply (UPS) for Control Voltage (24 VDC)
- Paper printer
- Control Cabinet Accessories Upgrade
- Ground Fault Circuit Interrupt (GFI)

OPTIONAL FEATURES

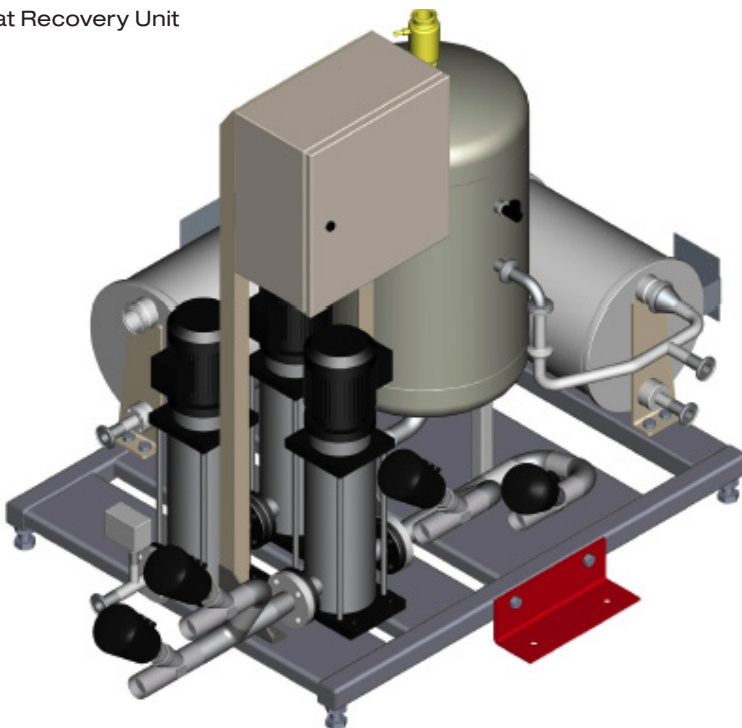
What is new?

Automatic Solid Waste Separation and Sterilization process for removing and handling solids separately from the liquid stream. Solids are screened out to separator vessel and liquid passes to the collector tank through a special strainer. When separator is full, automatic direct steam injection sterilizes the solid content of the separator vessel. After successful sterilization, the solids are cooled down and drained to common drainage system or collector vessel, aided by rinse water to clean and prepare the vessel for next use. Automatic screen back flush during operation prolongs the system uptime.

- reliable sterilization result
- minimizes system fouling & plugging
- eliminates system downtime
- dual separators configuration ensures fully continuous operation



Heat Recovery Unit



Safe heat recovery system

Direct heat transfer between decontaminated (hot) effluent and contaminated incoming (cold) effluent creates a risk of unhandled cross-contamination. The CED system can be equipped with the unique patent pending Safe Heat Recovery System.

This feature includes an internal pressure controlled heat transfer loop and additional heat exchangers to safely transfer heat from decontaminated effluent to incoming contaminated effluent without any risk of cross-contamination. This is achieved by ensuring positive pressure on the clean side at any situation.

The typical heat recovery ratio for saving heating energy (plant steam consumption) is -40% and for cooling energy (cooling water consumption) -50%.

PROCESS TESTING AND QUALIFICATION

In addition to standard Factory Acceptance Testing (FAT) and Site Acceptance Testing (SAT) the process and equipment qualification is extended to consist of full biological challenge testing of the entire processing system.

The CED process qualification testing uses *Geobacillus Stearothermophilus* spores at population of min. 106 CFU population in each test batch. At least 50% of test batch is sampled out of the process online decontamination result (overkill) verified by independent laboratory analysis. 3 consecutive test runs at decontamination set point qualifies the Performance Qualification tests (PQ) of the CED system. Also the service sterilization cycles of other parts of the process (filter, tank, etc.) have similar testing methods. CED system includes complete testing protocols.

CED performance qualification can be easily repeated, e.g. annually, semi-annually or even more frequently if required. This methodology and the testing protocols have widely been accepted by local authorities. These methods are unique due to the characteristics and specific patented design of the truly continuous effluent process.

