BioWaste Effluent Decontamination Systems
Features of Suncombe Range of BioWaste Effluent Treatment Systems

Suncombe and BioWaste
Suncombe Batch BioWaste decontamination systems are available for both thermal, thermochemical and chemical inactivation. Thermal inactivation can be performed using steam, super heated water or an established licensed electrical heating technique which minimises time and space.

- First System installed in 1990s
- 50+ years of design experience.
- Suitable for full validation.

BioWaste Levels
Bio-waste can be classified by the relative danger to the surrounding environment as biological safety levels (BSL). There are four safety levels. These are level 1 through level 4. Higher numbers indicate a greater risk to the external environment.

Manufacturing Standards
- 316 stainless steel product contact parts, 304 non-contact parts, Hastelloy and Duplex Stainless
- ASME BPE, 3A, cGMP standards, fully drainable, crevice free.
- TIG Welding; using an argon gas purge, using a computer controlled enclosed head orbital welding plant, carried out by technicians coded to EN 287, ie Suncombe procedures coded to EN ISO 15609, tested to EN ISO 15614 Part 1.
- ASME BPE standard Pipework, fully annealed, chemistry to ASTM A-269, manufactured to ASTM A-270, and 3A Standard.

Inactivation Systems
- Dual Redundancy
- Each section of the plant can be Cleaned (CIP) and sterilized (SIP)
- Dual Redundancy
- 316 stainless steel product contact parts, 304 non-contact parts, Hastelloy and Duplex Stainless
- SME BPE, 3A, cGMP standards, fully drainable, crevice free.
- SME BPE standard Pipework, fully annealed, chemistry to ASTM A-269, manufactured to ASTM A-270, and 3A Standard.

Risk Assessments
Suncombe Bio-Waste Inactivation Systems are individually subject to risk assessments throughout the design, development and build process.

Safety Integrity Level
The Critical processes within BioWaste systems should be designed to Safety Integrity Level as defined within IEC 61508. In cooperation with site personnel, a SIL assessment, calculation and report would be carried out on the critical processes.

Automation System
The Integrated Biosuite™ automation packages are designed to be operator friendly and simple to use whilst providing flexibility and optimisation. Reliable and robust, they have been developed over the last 10 years in co-ordination with clients operations staff, engineers and validation staff. They encompass all elements required to provide a controlled, repeatable automatic system.

A range of automation levels are available, starting from low level semi-automated systems, through low and mid level PLC and HMI versions, to advanced SCADA based systems. All levels are designed with the facilities required to provide a repeatable automated cycle.

Totally Integrated Automation
Pressure Relief
Complying with worldwide regulations, the pressure relief requirements are considered for each project individually. Detailed design activities provide the relieving requirements ranging from the removal of relief to double redundant bursting disc and pressure safety valves. Pressure relieving is also fitted to incoming services to ensure a positive pressure is always applied to the containment envelope.

Suncombe Process Development
Suncombe process engineers are qualified, experienced designers who are dedicated to serving the critical process sectors. With vast experience in BioWaste processing, we will apply leverage to all design methodologies, to ensure a smooth, reliable, robust Effluent Treatment project is completed.

Thermal Mapping
Thermal mapping studies are carried out to provide thermal models of process

Cameras
Options for PTZ cameras for area monitoring

Instrumentation
High quality analytical and process instrumentation.

Process Valves
Sanitary and sterile process routing valves providing reliable, robust routing.

Maintainability
The schemes are designed to ensure 100% safe and straightforward maintenance and service operations.

Validation/Documentation
The lifecycle approach is adopted (DQ, FDS, HDS, SDS, FAT, SAT, IQ & OQ) with validation being key to every stage of the development process, including Factory Acceptance Testing (FAT), SAT and Qualification.

Example Electronic Data
Systems provide electronic data of critical parameters for each cycle

System Equipment
Best quality sterile suitable equipment
Suncombe Batch BioWaste Effluent Decontamination System 39260 Single Tank

The Batch BioWaste Effluent Decontamination System 39260 Single Tank is used for Biological Hazardous Effluent Decontamination and Growth Media Sterilisation. It is a custom designed system incorporating a single treatment vessel. The single vessel can also be used for collection or a separate collection vessel can be used. A range of capacities are available to suit the waste volume. The systems are supplied with controls and interlocking functionality to ensure containment is always maintained and there is always a positive release prior to discharge of treated waste.

Primarily used for thermal inactivation, they can also include back-up or alternative chemical and thermochemical facility. Thermal inactivation can be performed using steam, superheated water or electricity.

Batch BioWaste 39260 system Advantages

- Small footprint - Batch BioWaste 39260 are designed with an optimum small footprint
- pH Neutralisation - Batch BioWaste 39260 system can include pH Neutralisation
- Anti-foam - Batch BioWaste 39260 system can include the controlled addition of anti-foam
- Self-CIP - Batch BioWaste 39260 system provides the ability for self-CIP
- Up-time - using batch technology ensures a large % of uptime, compared to in-line technologies
- Positive Release - treated waste can be positively released manually or automatically
- Validatable Records - Electronic records are provided of all treatment parameters
- Chemical Treatment - The Batch BioWaste 39260 system can also be used optionally for chemical treatment or thermochemical treatment
- Containerised Versions - The Batch BioWaste 39260 system can also be supplied pre-constructed inside a shipping container

Batch BioWaste 39260 system with CHO Cells, GMO, and GMM

Extensively used in biopharmaceutical processing, genetically modified Chinese hamster ovary (CHO) cells are classed as genetically modified microorganisms (GMM) and regulations call for waste containing Class 2 to 4 GMM to be inactivated prior to release. The Batch BioWaste 39260 system addresses this requirement for GMM/GMO inactivation by providing multiple inactivation functions including variable temperature thermal kill, thermo-chemical kill and chemical kill.

BioSuite®3000 Automation System

The BioSuite®3000 Control System was specifically developed by Suncombe for BioWaste treatment duties. Designed to GAMP guidelines, the software is produced in house by qualified software engineers to standards including TickIT, GAMP and IEE recommendations.

- Operator configurable cycles
- User configurable Interlocks
- Audit Trail
- No flanges on waste stream—flanges or no use on the waste stream
- Sanitary valves with no product hold up, to ensure no untreated waste is present at any times—particularly relevant during maintenance periods.
- Printed Reports and Trends
- Repeatable automatic cycles
- User control with passwords
- Minimised dead legs to ensure that no untreated waste is present at any times—particularly relevant during maintenance periods.
- Alarm monitoring
- In built diagnostic ability
- Printed Reports and Trends
- Operator configurable cycles
- User configurable Interlocks
- Audit Trail
- Sanitary valves with no product hold up, to ensure no untreated waste is present at any times—particularly relevant during maintenance periods.
- Minimised dead legs to ensure that no untreated waste is present at any times—particularly relevant during maintenance periods.
- Alarm monitoring
- In built diagnostic ability
- Printed Reports and Trends
- Operator configurable cycles
- User configurable Interlocks
- Audit Trail

Separate Collection Tank

The Batch BioWaste 39260 system can be used with a separate collection tank. These are available as atmospheric or pressure types in various capacities and various materials dependent on the full requirement.

For further information please contact a Suncombe engineer.

Containerised Versions - The systems are available in containerised form. Containerised units can improve space utilization and reduce the commissioning, validation and maintenance durations as the modular equipment is supplied in a “ready to operate” state, needing only utility connections on site. Containerised units can speed up projects and substantially reduce capital costs, by minimising the infrastructure requirements, whilst they also allow relocation in the case of changing operations.

Heating

Alternate heating methods are available including:

- VenturiHeat™ - direct cross flow steam injection, using the venturi effect to minimise noise whilst providing turbulence to prevent layering and negate the requirements for mixing.
- OilHeat - secondary heating using an oil source for two degrees of separation between contaminated waste and the environment.
- Steam Heat - indirect usage of steam through plate or shell and tube heat exchangers to gently heat the fluid whilst recirculating.

Regeneration Heat - using thermal regeneration to recover the thermal energy in the treated waste for heating up the intreated waste, whilst ensuring two degrees of separation between the waste streams.

Equipment Standard

We treat the decontamination of bio-effluent as a critical duty and adhere to industry guidelines for hygienic and sanitary processing, including:

- 316L or higher alloys supplied with 3.1 material certificates to ensure material is correct for the duty
- Minimised dead legs to ensure that no untreated waste is present at any times—particularly relevant during maintenance periods.
- Sanitary valves with no product hold up, to ensure no untreated waste is present at any times—particularly relevant during maintenance periods.
- Guaranteed Surface Finish—To guarantee the efficacy of cleaning and sanitation.
- No flanges on waste stream—flanges or not use on the waste stream as flanges are non-sanitary and cannot be guaranteed to be fully cleaned prior to disc-connection.

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<table>
<thead>
<tr>
<th>Part #</th>
<th>Treatment litres per day</th>
<th>Dimensions m</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>A</td>
</tr>
<tr>
<td>39260 200/1 Tank</td>
<td>200</td>
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<td>2.5</td>
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<td>2.8</td>
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<td>3.3</td>
</tr>
<tr>
<td>39260 5000/1 Tank</td>
<td>5000</td>
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</tbody>
</table>
Suncombe Batch BioWaste Effluent Decontamination System 39220 with Combined Collection/Treatment Tanks

The Batch BioWaste Effluent Decontamination System with Combined Collection/Treatment Tanks is used for Biological Hazardous Effluent Decontamination and Growth Media Sterilisation. It is a custom designed system incorporating one or two vessels, which are used for both collection and treatment. With capacities to suit the waste volume, the systems are supplied with controls and interlocking functionality to ensure containment is always maintained and there is always a positive release prior to discharge of treated waste.

Primarily used for thermal inactivation, they also offer a back-up or alternative chemical and thermochemical facility. Thermal inactivation can be performed using steam, superheated water or electricity.

**Batch BioWaste 39220 system Advantages**
- **Dual Redundancy** - using a two tank Batch BioWaste 39220 system allows dual redundancy if one tank or system needs maintenance.
- **pH Neutralisation** - using a one or two tank Batch BioWaste 39220 system can include pH Neutralisation.
- **Anti-foam** - using a one or two tank Batch BioWaste 39220 system can include the controlled addition of anti-foam.
- **Self CIP** - using a one or two tank Batch BioWaste 39220 system provides the ability for self CIP.
- **Up-time** - using batch technology ensures a large % of uptime, compared to on-line technologies.
- **Positive Release** - treated waste can be positively released manually or automatically.
- **Validatable Records** - Electronic records are provided of all treatment parameters.
- **Chemical Treatment** - The Batch BioWaste 39220 system can also be used for chemical treatment or thermochemical treatment.
- **Containerised Versions** - The Batch BioWaste 39220 system can also be supplied pre-constructed inside a shipping container.

**Batch BioWaste 39220 system with CHO Cells, GMO and GMM**
Extensively used in biopharmaceutical processing, genetically modified Chinese hamster ovary (CHO) cells are classed as genetically modified microorganisms (GMM) and regulations call for waste containing Class 2 to 4 GMM to be inactivated prior to release. The Batch BioWaste 39220 system addresses this requirement for GMM/GMO inactivation by providing multiple inactivation functions including variable temperature thermal kill, thermo-chemical kill and chemical kill.

**Batch BioWaste 39220 system One Tank Layout**

**Batch BioWaste 39220 system Dual Redundant Two Tank Layout**

**Batch BioWaste 39220 system One Tank Dimensions**

<table>
<thead>
<tr>
<th>Part #</th>
<th>Treatment litres per day</th>
<th>Dimensions m</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td>39220 200/1 Tank</td>
<td>200</td>
<td>2.0</td>
</tr>
<tr>
<td>39220 500/1 Tank</td>
<td>500</td>
<td>2.2</td>
</tr>
<tr>
<td>39220 1000/1 Tank</td>
<td>1000</td>
<td>2.5</td>
</tr>
<tr>
<td>39220 1500/1 Tank</td>
<td>1500</td>
<td>3.0</td>
</tr>
<tr>
<td>39220 2000/1 Tank</td>
<td>2000</td>
<td>3.5</td>
</tr>
<tr>
<td>39220 3000/1 Tank</td>
<td>3000</td>
<td>4.0</td>
</tr>
<tr>
<td>39220 5000/1 Tank</td>
<td>5000</td>
<td>5.0</td>
</tr>
</tbody>
</table>

**Batch BioWaste 39220 system Dual Redundant Two Tank Dimensions**

<table>
<thead>
<tr>
<th>Part #</th>
<th>Treatment litres per day</th>
<th>Dimensions m</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td>39220 200/2 Tank</td>
<td>800</td>
<td>2.0</td>
</tr>
<tr>
<td>39220 500/2 Tank</td>
<td>2000</td>
<td>2.2</td>
</tr>
<tr>
<td>39220 1000/2 Tank</td>
<td>4000</td>
<td>2.5</td>
</tr>
<tr>
<td>39220 1500/2 Tank</td>
<td>6000</td>
<td>3.0</td>
</tr>
<tr>
<td>39220 2000/2 Tank</td>
<td>8000</td>
<td>3.5</td>
</tr>
<tr>
<td>39220 3000/2 Tank</td>
<td>12000</td>
<td>4.0</td>
</tr>
<tr>
<td>39220 5000/2 Tank</td>
<td>20000</td>
<td>5.0</td>
</tr>
</tbody>
</table>

**Single or Dual Redundant**
The Batch BioWaste 39220 systems are available in a single tank or two tank dual redundant configuration. The single tank variant collects throughout the day and then treats out of hours. The two tank variant can collect and treat 24/7 and also provide dual redundancy.

**Containerised Versions** - The systems are available in containerised form. Containerised units can improve space utilization and reduce the commissioning, validation and maintenance durations as the modular equipment is supplied in a ‘ready to operate’ state, needing only utility connections on site. Containerised units can speed up projects and substantially reduce capital costs, by minimising the infrastructure requirements, whilst they also allow relocation in the case of changing operations.

**Heating**
Alternate heating methods are available including:
- VenturiHeat™ - direct cross flow steam injection, using the venturi effect to minimise noise whilst providing turbulence to prevent layering and negate the requirements for mixing.
- OilHeat - secondary heating using an oil source for two degrees of separation between contaminated waste and the environment.
- Steam Heat - indirect usage of steam through plate or shell and tube heat exchangers to gently heat the fluid whilst recirculating.
- Regeneration Heat - using thermal regeneration to recover the thermal energy in the treated waste for heating up the intreated waste, whilst ensuring two degree os separation between the waste streams.

**Equipment Standard**
We treat the decontamination of bio-effluent as a critical duty and adhere to industry guidelines for hygienic and sanitary processing, including:
- 316L or higher alloys supplied with 3.1 material certificates to ensure material is correct for the duty.
- Minimised dead legs to ensure that no untreated waste is present at any times—particularly relevant during maintenance periods.
- Sanitary valves with no product hold up, to ensure no untreated waste is present at any times—particularly relevant during maintenance periods.
- Guaranteed Surface Finish—to guarantee the efficacy of cleaning and sanitation.
- No flanges on waste stream—flanges or not use don the waste stream as flanges are non-sanitary and cannot be guaranteed to be fully cleaned prior to disc-connection.
Suncombe Batch BioWaste Effluent Decontamination System 39290 with Separate Collection and Treatment Tanks

The Batch BioWaste Effluent Decontamination System with Collection and Treatment Tanks is used for Biological Hazardous Effluent Decontamination and Growth Media Sterilisation. It is a custom designed system incorporating separate vessels for collection and treatment. With capacities to suit the waste volume, the systems are supplied with controls and interlocking functionality to ensure containment is always maintained and there is always a positive release prior to discharge of treated waste.

Primarily used for thermal inactivation, they also offer a back-up or alternative chemical and thermochemical facility. Thermal inactivation can be performed using steam, super heated water or electricity.

**Batch BioWaste 39290 system Advantages**

- **Separate Collection** - a single collection tank provides a buffer to collect the waste
- **Separate Treatment** - a single treatment tank is filled from the collection tank (either by gravity, pumped or vacuum) to treat the waste
- **Treatment Tank Decontaminate In Place** - the treatment tank can be decontaminated in place
- **Cleaning In Place** - the entire system can be Cleaned In Place
- **Up-time** - using batch technology ensures a large % of uptime, compared to on-line technologies
- **Positive Release** - treated waste can be positively released manually or automatically
- **Validatable Records** - Electronic records are provided of all treatment parameters
- **Chemical Treatment** - The system can also be used for chemical treatment or thermochemical treatment
- **Containerised Versions** - The system can also be supplied pre-constructed inside a shipping container
- **Dual Redundancy** - using a two tank system allows dual redundancy if one tank or system needs maintenance
- **pH Neutralisation** - using a one or two tank system can include pH Neutralisation
- **Anti-foam** - using a one or two tank system can include the controlled addition of anti-foam

**Batch BioWaste 39290 with CHO Cells, GMO and GMM**

Extensively used in biopharmaceutical processing, genetically modified Chinese hamster ovary (CHO) cells are classified as genetically modified microorganisms (GMM) and regulations call for waste containing Class 2 to 4 GMM to be inactivated prior to release. The system addresses this requirement for GMM/GMO inactivation by providing multiple inactivation functions including variable temperature thermal kill, thermo-chemical kill and chemical kill.

**Alternative Configurations**

Alternate layouts are available to suit site locations.

**Vertical/Horizontal Tanks**

The configurations shown detail horizontal collection tanks. These are also available as vertical cylindrical tanks if preferred.

**Batch BioWaste 39290 Square Configuration System Dimensions**

<table>
<thead>
<tr>
<th>Part #</th>
<th>Collection (litres per day)</th>
<th>Treatment (litres per day)</th>
<th>Dimensions (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>39290 In Line 1000</td>
<td>1000</td>
<td>5.0</td>
<td>1.5</td>
</tr>
<tr>
<td>39290 Square 1000</td>
<td>1000</td>
<td>6.0</td>
<td>4.2</td>
</tr>
<tr>
<td>39290 In Line 3000</td>
<td>3000</td>
<td>6.0</td>
<td>3.1</td>
</tr>
<tr>
<td>39290 Square 3000</td>
<td>3000</td>
<td>4.0</td>
<td>3.7</td>
</tr>
<tr>
<td>39290 In Line 5000*</td>
<td>5000</td>
<td>7.0</td>
<td>3.6</td>
</tr>
<tr>
<td>39290 Square 5000</td>
<td>5000</td>
<td>4.5</td>
<td>4.2</td>
</tr>
<tr>
<td>39290 In Line 10000</td>
<td>10000</td>
<td>8.5</td>
<td>3.9</td>
</tr>
<tr>
<td>39290 Square 10000*</td>
<td>10000</td>
<td>5.0</td>
<td>4.5</td>
</tr>
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</tr>
<tr>
<td>39290 Square 15000</td>
<td>15000</td>
<td>6.0</td>
<td>4.5</td>
</tr>
</tbody>
</table>

**Heating**

Alternate heating methods are available including:

- **VenturiHeat™** - direct cross flow steam injection, using the venturi effect to minimise noise whilst providing turbulence to prevent layering and negate the requirements for mixing.
- **OilHeat** - secondary heating using an oil source for two degrees of separation between contaminated waste and the environment.
- **Steam Heat** - indirect usage of steam through plate or shell and tube heat exchangers to gently heat the fluid whilst recirculating
- **Regeneration Heat** - using thermal regeneration to recover the thermal energy in the treated waste for heating up the intreated waste, whilst ensuring two degrees of separation between the waste streams.

**Equipment Standard**

We treat the decontamination of bio-effluent as a critical duty and adhere to industry guidelines for hygienic and sanitary processing, including:

- 316L or higher alloys supplied with 3.1 material certificates to ensure material is correct for the duty
- Minimised dead legs to ensure that no untreated waste is present at any times—particularly relevant during maintenance periods.
- Sanitary valves with no product hold up, to ensure no untreated waste is present at any times—particularly relevant during maintenance periods.
- Guaranteed Surface Finish—to guarantee the efficacy of cleaning and sanitation.
- No flanges on waste stream—flanges or not used on the waste stream as flanges are non-sanitary and cannot be guaranteed to be fully cleaned prior to disc-connection.
Suncombe Batch BioWaste Effluent Decontamination Systems—Custom Designs

Custom Configurations
The Suncombe Batch effluent decontamination systems are available as custom designs for your specific requirement.

Dual Redundant Level 4 Decontamination System
System incorporating separate Collection and Treatment Tanks, including Dual Redundant Collection Tanks, Treatment Tanks, Air Compressors, Outlet Cooling Systems, control logic and processors, for Level 4 pathogens, with containment guarantee and full traceable audit reports and Safety Integrity Level 3 compliance.

Dual Redundant Level 4 Decontamination System
System incorporating combined Collection and Treatment Tanks, including Dual Redundant Tanks, Air Compressors, Outlet Cooling Systems, control logic and processors, for Level 4 pathogens, with containment guarantee and full traceable audit reports and Safety Integrity Level 3 compliance. Including DIP, CIP and SIP on the contained drain paths.
Suncombe Batch BioWaste Effluent Decontamination Systems

Custom Collection and Treatment Vessel Combinations

Custom Collection Vessel and Treatment Vessel Configurations

The Suncombe Batch effluent decontamination systems can be configured with custom Collection Vessel and Treatment Vessel Combinations to reflect any BioWaste Decontamination capacity Requirement.

**Capacity:** Collection or Reception Vessels are available from 200 litre capacity to 20,000 litre capacity or larger.

**Number:** Collection or Reception Vessels can be supplied as single vessels to hold the entire waste storage capacity or in quantities of 2, 3 or more vessels to provide different processing waste storage requirements and/or dual redundancy.

**Decontamination In Place:** Collection or Reception Vessels can be supplied with specific requirements for Decontamination In Place (DIP), which can alter the design of the Vessels from simple atmospheric sealed vessels to full pressure vessels suitable for thermal sterilisation. Configurations can also include full Cleaning In Place (CIP) and chemical treatment, as well as pH control.

**Materials of Construction:** Typically Collection or Reception Vessels are manufactured from 316L Stainless Steel Vessels. This material is often used as the process at this point tends to be at lower temperatures. Varied duplex stainless steels and hastelloy are also available for extended corrosion resistance. The Collection or Reception Vessels typically are fully sanitary design to ensure all parts can be CIPed and DIPed and if included Sterilised In Place (SIP). For specific client situations thermo-plastic vessels can also be used.

**Geometry:** The geometry of Collection or Reception Vessels depends somewhat on the available location and available envelope. Typically most smaller capacities (up to 1,000 litre) are vertical cylindrical vessels, medium capacities (1,000—5,000 litre) are typically either vertical or horizontal and most vessels over 5,000 litre capacity are horizontal.

**Collection or Reception Vessels Transfer Methodology:** The optimum transfer methodology is to use gravity transfer and to enable this the Collection or Reception Vessels are located at a higher elevation to allow gravity drainage to the treatment vessels. However due to space constraints and equipment layouts, this is not always possible and alternative transfer options are available using pumped systems and/or vacuum transfer. All transfer arrangements are configured so as to allow CIP, Dip and SIP and dual redundancy as required.