SUNCOMBE

CIP & PROCESS ENGINEERS

BioWaste Effluent Decontamination Systems

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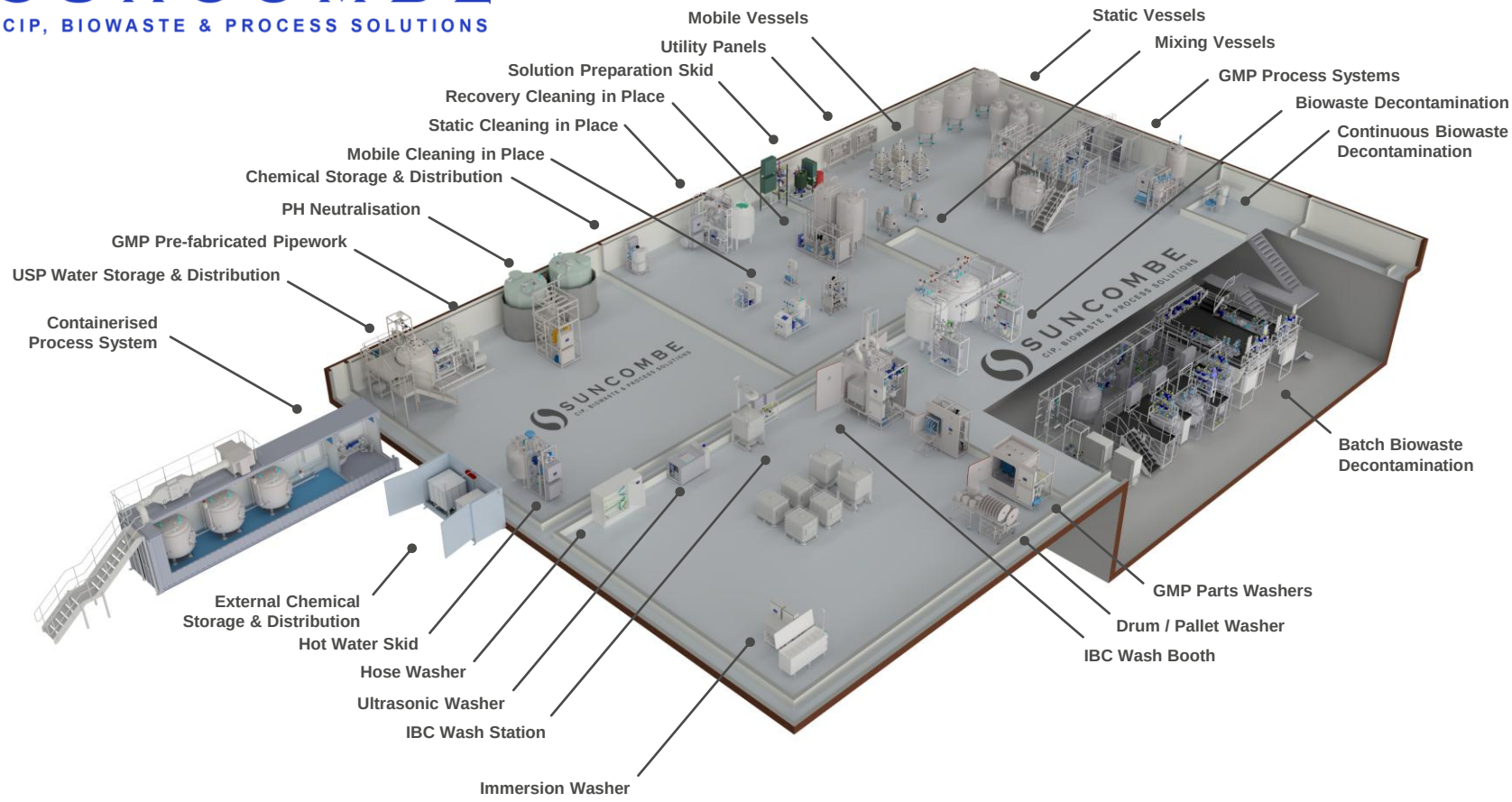
SUNCOMBE
CIP, BIOWASTE & PROCESS SOLUTIONS



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.

Risk Assessments

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

Safety Integrity Level

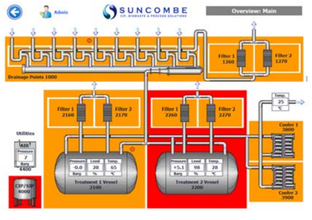
The Critical processes within BioWaste systems should be designed to Safety Integrity Level as defined within IEC 61508. In cooperation with site personnel, a SIL assessment, calculation and report would be carried out on the critical processes.

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 controllable, 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.

PLC Control Equipment



Advanced HMI System

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.
- T.I.G. Welding; using an argon gas purge, using a computer controlled enclosed head orbital welding plant, carried out by technicians coded to EN 287, to 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.

ASME SETTING THE STANDARD

ASME BPE An International Code for BioProcessing Equipment

GOOD MANUFACTURING PRACTICE GMP

PD 5500

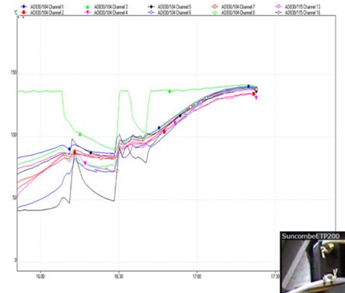
Totally Integrated Automation

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.



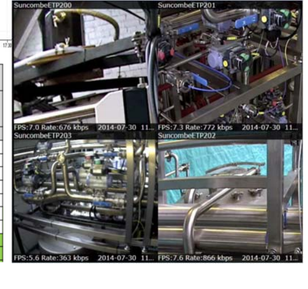
Time	Manway	AV2205	AV2204	AV2277
	Channel 1	Channel 2	Channel 3	Channel 4
	°C	°C	°C	°C
16:52:51	116.45	109.87	137.39	111.06
16:53:51	117.98	111.03	137.61	112.01
16:54:51	119.48	112.94	137.43	114.36
16:55:51	120.95	114.43	137.16	116.07
16:56:51	122.44	115.21	137.39	116.89
16:57:51	123.89	117.44	137.77	118.75
16:58:51	125.3	119.2	138.09	120.67
16:59:51	126.67	120.63	138.27	122.14
17:00:51	127.97	121.25	138.12	121.82

Thermal Mapping

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

Cameras

Options for PTZ cameras for area monitoring



Dual Redundancy

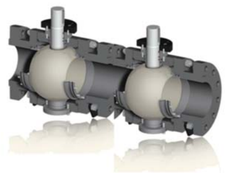
Each section of the plant can be Cleaned (CIP) and sterilized (SIP) with a double valve arrangement in place thereby ensuring operator safety and maintenance of containment. This facility provides secondary containment with the inter-valve space decontaminated on every cycle.

Instrumentation

High quality analytical and process instrumentation.

Process Valves

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



Maintainability

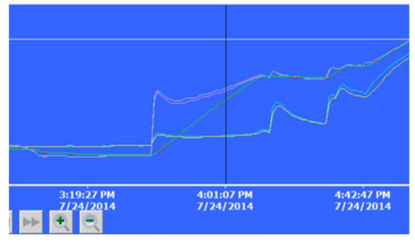
The schemes are designed to ensure 100% safe and straightforward maintenance and service operations.

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, super heated 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

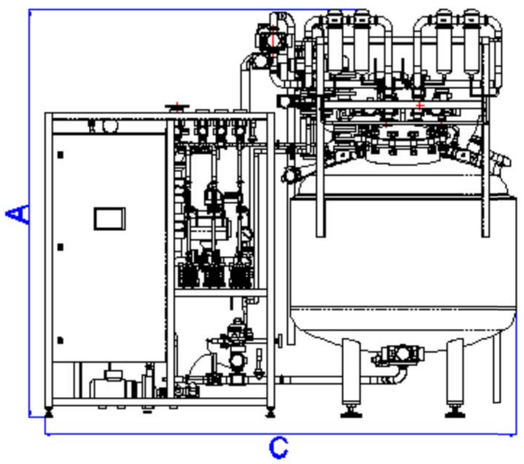
Extensively used in biopharmaceutical processing, genetically modified Chinese hamster ovary (CHO) cells are classed as genetically modified microorganisms (GMM) and regulations call for waste containing Class 2 to 4 GMM to be inactivated prior to release. The ***Batch BioWaste 39260 system*** addresses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

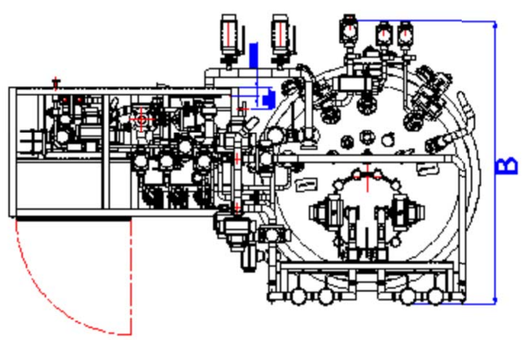
BioSuite#3000 Automation System

The BioSuite#3™ 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.
y control systems, change control during and post development, development to a software life cycle etc.
features include:

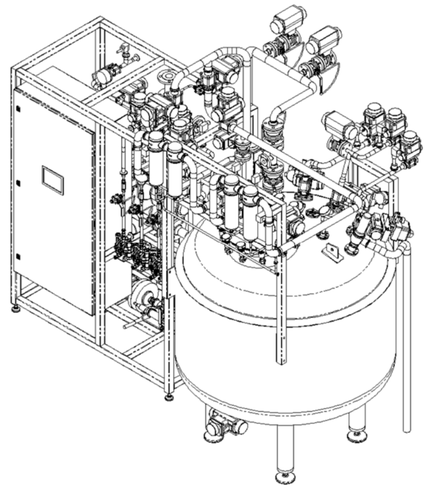
- ***Mimic Diagrams***
- ***Repeatable automatic cycles***
- ***Operator configurable cycles***
- ***User control with passwords***
- ***In built diagnostic ability***
- ***Printed Reports and Trends***
- ***Alarm monitoring***
- ***User configurable Interlocks***
- ***Audit Trail***

Drawing





3D Model



Dimensions

Part #	Treatment litres per day	Dimensions m		
		A	B	C
39260 200/1 Tank	200	1.9	1.4	2.7
39260 500/1 Tank	500	2.1	1.7	3.0
39260 1000/1 Tank	1000	2.5	1.8	3.2
39260 1500/1 Tank	1500	2.8	2.0	3.3
39260 2000/1 Tank	2000	3.0	2.2	3.5
39260 3000/1 Tank	3000	3.3	2.4	3.7
39260 5000/1 Tank	5000	3.6	2.8	4.0

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:

- VenturHeat™ - 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 conriminated 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 ensuting two degeree 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 certificiates 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 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, super heated 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

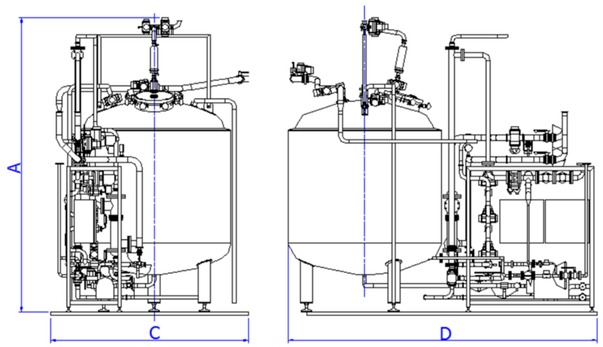
Extensively used in biopharmaceutical processing, genetically modified Chinese hamster ovary (CHO) cells are classed as genetically modified microorganisms (GMM) and regulations call for waste containing Class 2 to 4 GMM to be inactivated prior to release. The ***Batch BioWaste 39220 system*** addresses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

Single or Dual Redundant

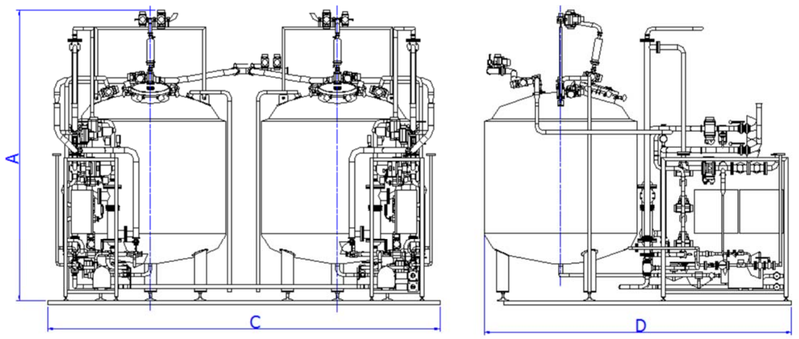
The ***Batch BioWaste 39220*** systems are available in a single tank or two tank dual redundant configuration. The single tank variant collects throughout the day and then treats out of hours. The two tank variant can collect and treat 24/7 and also provide dual redundancy.

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.

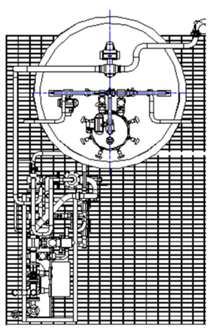
Batch BioWaste 39220 system One Tank Layout



Batch BioWaste 39220 system Dual Redundant Two Tank Layout

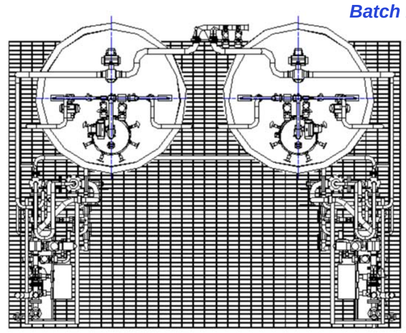


Batch BioWaste 39220 system One Tank Dimensions



Part #	Treatment litres per day	Dimensions m		
		A	D	C
39220 200/1 Tank	200	2.0	3.0	1.2
39220 500/1 Tank	500	2.2	3.2	1.4
39220 1000/1 Tank	1000	2.5	3.2	1.6
39220 1500/1 Tank	1500	3.0	3.4	1.8
39220 2000/1 Tank	2000	3.5	3.5	2.0
39220 3000/1 Tank	3000	4.0	4.0	2.0
39220 5000/1 Tank	5000	5.0	4.2	2.4

Batch BioWaste 39220 system Dual Redundant Two Tank Dimensions



Part #	Treatment litres per day	Dimensions m		
		A	D	C
39220 200/2 Tank	800	2.0	3.0	2.4
39220 500/2 Tank	2000	2.2	3.2	2.8
39220 1000/2 Tank	4000	2.5	3.2	3.2
39220 1500/2 Tank	6000	3.0	3.4	3.6
39220 2000/2 Tank	8000	3.5	3.5	4.0
39220 3000/2 Tank	12000	4.0	4.0	4.0
39220 5000/2 Tank	20000	5.0	4.2	4.4

Heating

Alternate heating methods are available including:

- VenturHeat™ - 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 conriminated 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 ensuting two degeree 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 certificiates 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.

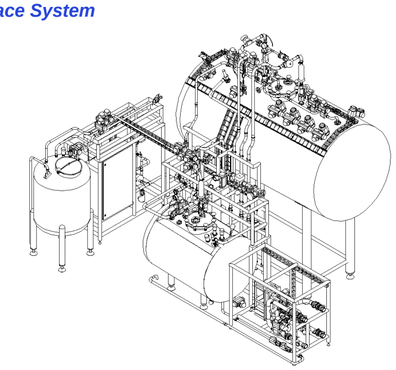
Batch BioWaste 39290 system ***Advantages***

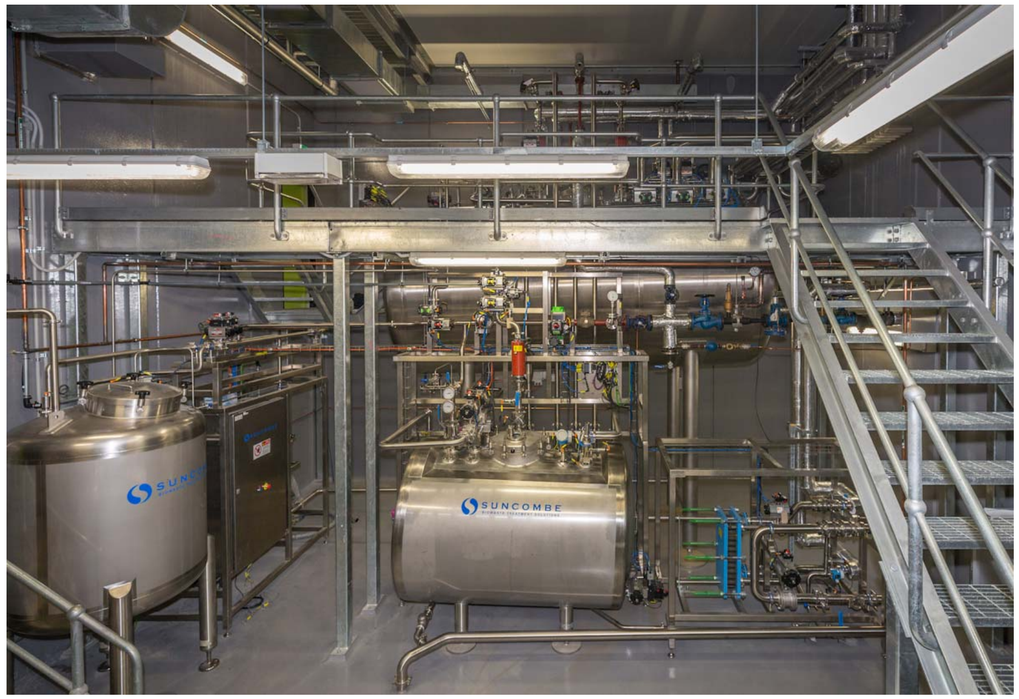
- ***Separate Collection*** **-** a single collection tank provides a buffer to collect the waste
- ***Separate Treatment*** **-** a single treatment tank is filled from the collection tank (either by gravity, pumped or vacuum) to treat the waste
- ***Treatment Tank Decontaminate In Place -*** the treatment 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 system with CHO Cells, GMO and GMM

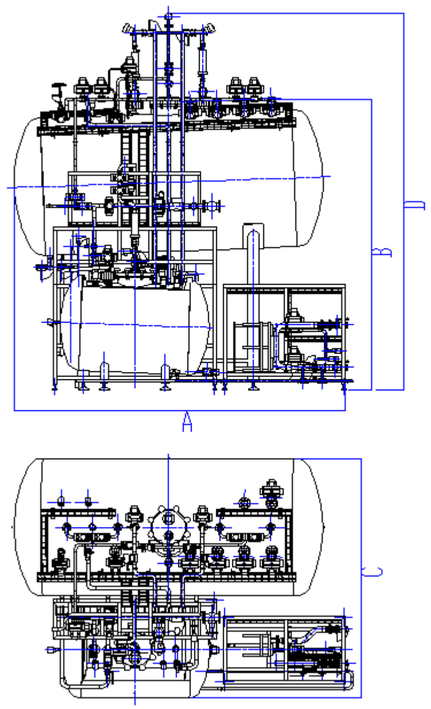
Extensively used in biopharmaceutical processing, genetically modified Chinese hamster ovary (CHO) cells are classed as genetically modified microorganisms (GMM) and regulations call for waste containing Class 2 to 4 GMM to be inactivated prior to release. The system addresses this requirement for GMM/GMO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

Batch BioWaste 39290 Square Configuration with Integral Cleaning In Place System

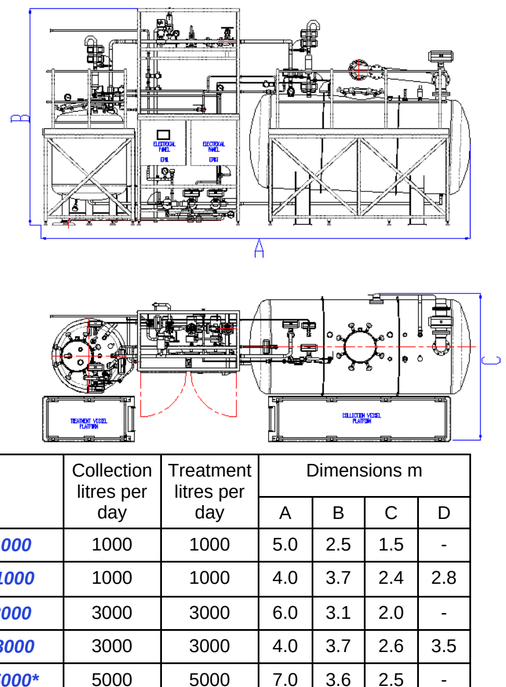




Batch BioWaste 39290 Square Configuration System Dimensions



Batch BioWaste 39290 In Line Configuration System Dimensions



Part #	Collection litres per day	Treatment litres per day	Dimensions m			
			A	B	C	D
39290 In Line 1000	1000	1000	5.0	2.5	1.5	-
39290 Square 1000	1000	1000	4.0	3.7	2.4	2.8
39290 In Line 3000	3000	3000	6.0	3.1	2.0	-
39290 Square 3000	3000	3000	4.0	3.7	2.6	3.5
39290 In Line 5000*	5000	5000	7.0	3.6	2.5	-
39290 Square 5000	5000	5000	4.5	4.2	3.0	4.6
39290 In Line 10000	10000	10000	8.5	3.9	3.5	-
39290 Square 10000*	10000	10000	5.0	4.5	3.2	5.2
39290 In Line 15000	15000	15000	9.5	4.2	3.8	-
39290 Square 15000	15000	15000	6.0	4.5	4.0	5.2

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.

Single or Dual Redundant

The ***Batch BioWaste 39290*** systems are available with a single or multiple collection and/or treatment tanks in a single tank or dual redundant configuration. The single redundant variant collects and treats throughout the day. The dual redundant variant can continue collecting and treating 24/7 in the event of equipment maintenance or failure.

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:

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Equipment Standard

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- 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.

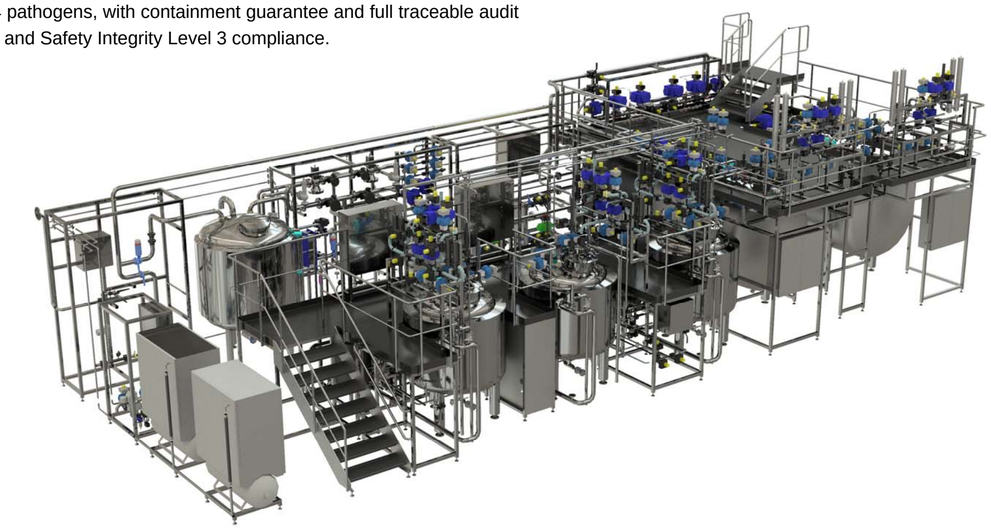
Suncombe Batch BioWaste Effluent Decontamination Systems—Custom Designs

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 vessel 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 CIP'ed and DIP'ed 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.