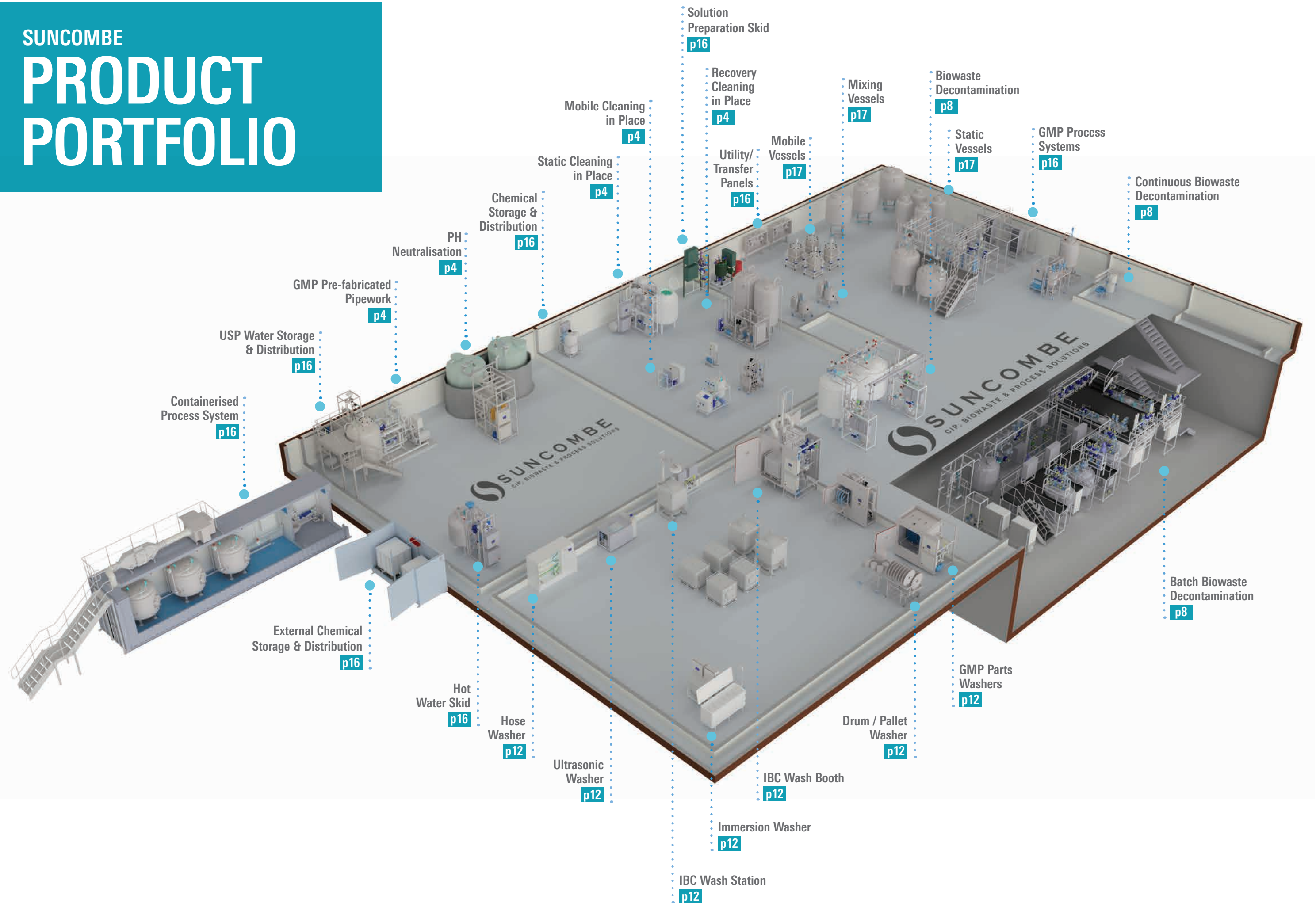


CIP, BIOWASTE & PROCESS SOLUTIONS

SUNCOMBE

PRODUCT PORTFOLIO



Message from the Chairman

Our company was created over 50 years ago specifically to supply a high quality range of hygienic processing, cleaning and decontamination systems. To continually achieve our goals, we use the most up-to-date facilities and employ the best-qualified and experienced staff.

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ALL ABOUT US

Guarantee

Suncombe Limited guarantees that all of the systems we supply would operate in accordance with your stated requirements and our design solutions included in our proposals.



Total Responsibility

Our business philosophy is to carry out all aspect of a project with long term employed permanent staff. This allows us to take total control of all projects and guarantee the quality of all aspects of the project. We feel that this is critical in regard to Software, Instrumentation, Fabrication and Electrical works. This policy also allows us to give full support for all aspects for the lifetime of the equipment. We currently still support and maintain our equipment from 1961, the time of our company formation.

Our Values

- We act with integrity and show respect
- We are passionate about our business and our products
- We aim for engineering excellence
- We offer value for money
- We pride ourselves on innovative design
- We offer quality in everything that we do
- We use robust health and safety guidelines
- We strive to continuously increase our knowledge
- We promote environmentally responsible practices

Quality Statement

We define our approach to quality as meeting or exceeding our customer's requirements for products and services. Our criteria include Satisfaction of Customers requirements, Zero Defects, On-Time delivery and Continued Product Support. All company functions are executed in accordance with our quality assurance system. We have a company-wide commitment to quality, which is integral to our business culture. Quality will remain our top priority and we will strive to provide quality in all aspects of our products and services.

Our Business

- Established in 1961 - serving industry for over 50 years
- Pioneers of hygienic processing, effluent treatment, washing, cleaning and sterilising
- Worldwide network of sales and service agents
- UK design and manufacture to CE, cGMP, ASME BPE, GAMP, ATEX
- In-house personnel for all disciplines
- Motivated, dedicated and experienced long term workforce
- Single point of contact for all aspects of a project

Validation Documentation

Typical documents packages include Document Index, Quality Plan, GANTT Programme, FDS, HDS, SDS, P&ID Drawings, GA Drawings, Equipment List, Instrument List, Circuit Drawings, Software Code and Test Protocols.

Validation Lifecycle

Our products follow the GAMP Validation Life Cycle with documentary evidence of procedures and processes during design, development, preconstruction, construction and commissioning.

Customer Care

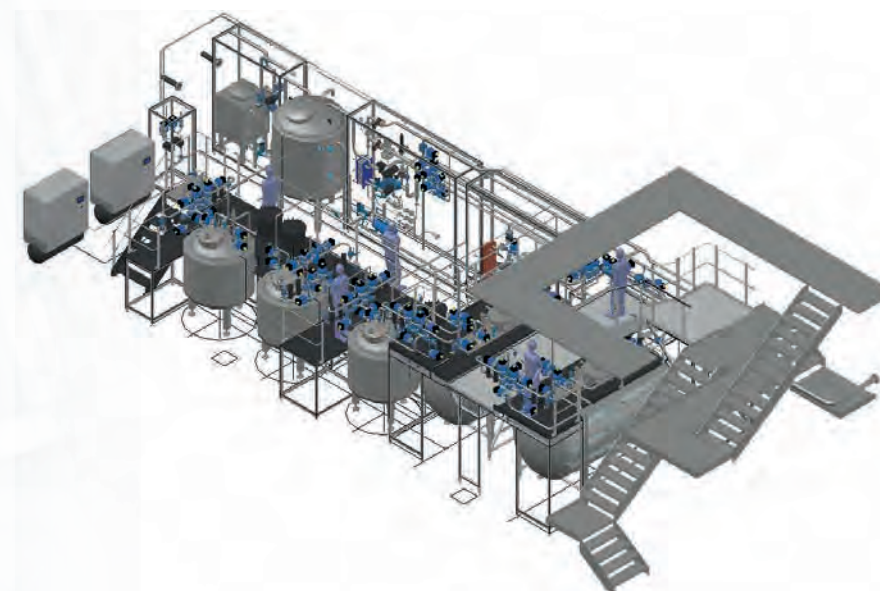
The Suncombe Customer Care department's obligation is to provide total customer support. This support starts at the proposal stage, continues throughout the contract and thereafter. A personal customer care agent will be assigned to you at quotation stage and will support you throughout.

Project Management

Individual Project Teams are selected for every project, with a Project Manager or Project Director as a single point of contact and a single point of responsibility.

Our Design

- PFD, P&ID, Schematics and Circuit Diagrams in ACAD
- Autodesk Inventor 3D Modelling is employed throughout the design process.



Our Facilities

- 8,000 sq.ft freehold owned primary manufacturing facility in London, United Kingdom.
- 12,000 sq.ft leasehold secondary manufacturing facility in close locality to primary facility with additional storage space as required.
- 40 core long term permanent staff, with length of service of up to 40 years.
- Approved sub-contract temporary staff for larger projects
- Independent private company with same ownership since 1961.
- Typical projects from €75,000 to €5,000,000

Our Manufacturing

Welding

- Welding would be of T.I.G. (Tungsten Inert Gas) method; using an internal and external argon gas purge, using a computer controlled welding plant

Equipment Standard

- 316L Stainless Steel, Duplex Stainless and Hastelloy materials Surface RA 0.5um or better
- ASME BPE standard Pipework, fully annealed, chemistry to ASTM A-269, manufactured to ASTM A-270, and 3A Standard.



Our Clientele

- 3M Pharmaceuticals
- WS Atkins
- Astellas Pharma
- AstraZeneca
- Avecia
- Avon
- Bausch+Ströebel
- BCM Boots
- Catalent
- DPS Engineering
- Eisal Pharmaceuticals
- Foster Wheeler Energy
- Fournier Pharma
- Fluor
- GlaxoSmithKline
- Health Protection Agency
- Ipsen
- Intervet
- JE Jacobs
- Johnson & Johnson
- Lonza Group
- Matcon IDEX
- Merck & Co.
- Medimmune, Inc
- National Health Service
- Novartis
- Oystar Manesty
- Patheon
- Pfizer
- Roche
- Schering-Plough
- Laboratories Servier
- Sigma-Aldrich
- Solvay
- Sanofi Aventis
- UCB Pharma
- Unilever
- Wyeth Pharmaceuticals

Our Sectors

- Pharmaceutical
- Biotechnology
- Research
- Cosmetics
- Toiletries
- Healthcare
- Medical
- Food
- Beverage and other hygienic and critical processing industries

INTRODUCING CLEANING IN PLACE (CIP)

CIP or in its full form, Cleaning In Place, is defined as **techniques to clean process equipment without dismantling and with minimal operator involvement.**

Suncombe and CIP

Suncombe pioneered the technology of CIP in the 1950's. Suncombe CIP Systems have been supplied for over 50 years and are used throughout the world in many different industries and sectors.

- First System installed in 1961
- 1,000s of System used throughout the world.
- 50+ years of design experience.
- Developed with major clientele to meet their requirements.
- Suitable for full validation.



Static CIP

Permanently installed unit with pipework and CIP routing used to transfer CIP fluids to the equipment being cleaned.

CIP - Using Energy for Cleaning

Cleaning uses a combination of thermal, chemical and kinetic energy applied for a set time. CIP allows higher thermal, chemical energies to be used for set times, thereby providing guaranteed repeatable cleaning.

Benefits of CIP

The benefits of CIP over other cleaning methods include:

- Automated, repeatable, reliable and validatable
- Improved Health and Safety
- No/minimal equipment dismantling required
- Often improves cleaning times and reduces labour costs
- More effective using higher temperatures, stronger chemicals



Mobile CIP

Plug and Play CIP system that is moved to point of use and connected via flexibles.

CLEANING IN PLACE CIP SYSTEMS



PureCIP™

The PureCIP™ is a Total Loss Cleaning In Place system supplied worldwide to the Biotech, Pharmaceutical, Medical, Healthcare, Personal Care and other critical processing industries. Complying with ASME BPE, GAMP, ISPE and 21CFR11. Built to hygienic and sanitary standards the PureCIP™ incorporates a number of CIP buffer vessels for storing, batching and delivering CIP fluids. It also includes heating facilities, detergent dosing facilities, valving, pumps, instrumentation and an in-built control system.



CIP+Plus™

The original Suncombe CIP+Plus™ systems were introduced in 1963. Since this time they have been continuously developed to provide a technologically advanced and robust, reliable means of supplying repeatable, validateable, controllable CIP cleaning. Used throughout the world in the Dairy, Food, Beverage, Cosmetics, Personal Care and other Industries, the CIP+Plus™ is available as a full or partial recovery system, which allow the recovery and reuse of the detergents used for CIP saving utilities and energy and subsequently costs.



MobileCIP™

The MobileCIP™ is a Total Loss Cleaning In Place system supplied worldwide to the BioPharma, Healthcare, Cosmetics, Personal Care, Food, Dairy, Beverage and other Processing Industries. Designed and developed to be mobile to allow the entire system to be moved to its point of use. Manual or automatically operated, the systems can be used for cleaning processing equipment including Tanks, Vessels, Vats, Fermenters, Mixers, Processors, Pipework, Valves, Isolators, Mills, Coaters, Filters, Pumps, Dryers and Fillers.



IsolatorCIP™

Incorporating, innovative and novel methodologies, the IsolatorCIP™ provides reliable, repeatable and validateable CIP and WIP of Isolators and Gloveboxes. Designed for aqueous, detergent and/or solvent cleaning, the IsolatorCIP™ was developed to incorporate "Lean Manufacturing Principles" ensuring that waste is minimised and efficiency is maximised. The IsolatorCIP™ can also be used to effectively clean processing equipment enclosed in the isolator or fitted onto the in-feed or discharge. Incorporating replaceable modules, the base unit is a fully hygienic version, with optional modules for sterile use including sanitising and sterilising configurations.



CIPOne™

Utilising standard pre-approved modules, the CIPOne™ is a fully modularised system that offers an economic solution to CIP whilst maintaining the quality of build and operation. The system is available in mobile or static versions and is built from a selection of modules, allowing configuration of the system that you require whilst also affording full future proofing by either exchanging or adding modules at any time. The CIPOne™ can be supplied with no water storage or with the facility to store 500, 1,000 or 1,500 litres of cold water and deliver this water in a controlled manner to the equipment to be cleaned.



pH Control & Dosing

Suncombe pH Neutralisation Systems incorporate robust control systems and instrumentation to ensure 100% neutralisation. Available as stand-alone units or as part of our integrated process stream. Chemical Storage and Dosing systems provide internal or external, local or remote chemical storage with dosing systems for point of use or distributed chemical dosing.



INTRODUCING BIOWASTE EFFLUENT TREATMENT SYSTEMS

Suncombe BioWaste Effluent Treatment Systems **decontaminate liquid hazardous infectious waste streams for research, production, laboratory and bio-containment environments.**

Suncombe and Biowaste

Suncombe offer Batch BioWaste decontamination and treatment systems. Our systems are available for both thermal and thermochemical 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.

Treatment Excellence

Using robust, proven design principles, the systems deal with Biowaste Level 1 to 4 and take into account two main areas of concern. Firstly the systems effectively sterilise or inactivate any harmful pathogens in the waste stream and secondly total containment must be assured at all times.

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.

Large BioWaste Decontamination Systems

- **BioWasteBatch™**
For any volume from CL1 to CL4
- **EDS+™**
For any volume from CL1 to CL3

Small Scale BioWaste Decontamination Systems

- **BioWasteMicro™ and BioWasteSink™**
For volumes from 30 to 500 litres per day + from CL1 to CL3



BIOWASTE

EFFLUENT TREATMENT SYSTEMS



All waste levels up to BSL4



Effluent Decontamination System BioWasteBatch™ with separate collection and treatment tanks

The BioWasteBatch™ effluent treatment systems are used throughout the world for the most critical of biowaste treatment facilities and are custom designed systems which provide any number of collection and treatment tanks. Typically these separate tank systems are used for facilities which have a large throughput of waste and subsequently store the waste for gradual treatment. They are available using the traditional method of heating and cooling in the treatment vessels or our new hybrid technology of heating in the treatment vessel and cooling on the discharge. BSL4 systems incorporate multiple dual redundant safety features to ensure 100% containment both into and out of the system to guarantee that there is no possibility of untreated waste being inadvertently discharged. Our BioWasteBatch™ effluent treatment systems provide a 100% positive release of treated waste.

Effluent Decontamination System BioWasteBatch™ with Combined collection and treatment tanks

Including all of the facilities of the BioWasteBatch™ effluent treatment systems with separate collection and treatment tanks, these systems are developed to utilise combined collection and treatment tanks. Minimising the inter-system transfers and transport systems this methodology lessens the reliance on pumping and transfer components. Used throughout the world in BSL4 facilities, it is primarily used for applications where facilities have typically lower peak flowrates and those when downtime periods are available in the working day. Also suitable for both traditional and our new hybrid cooling technology the BSL4 systems incorporate multiple dual redundant safety features to ensure 100% containment both into and out of the system to guarantee that there is no possibility of untreated waste being inadvertently discharged. Our BioWasteBatch™ effluent treatment systems provide a 100% positive release of treated waste.

Waste levels up to BSL3

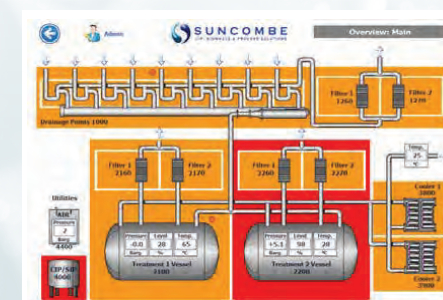


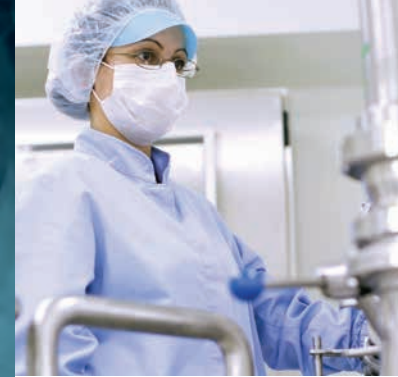
Effluent Decontamination System EDS+™ for BioSafety Level BSL1 - 3

The EDS+ system is a BioWaste Treatment System for biologically hazardous waste decontamination and growth media sterilisation. It is a predesigned system consisting of one or two vessel vessels, which are used for both collection and treatment. With a large range of 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. Our EDS+™ Bio-Waste Effluent Treatment Systems are available for both thermal and thermochemical inactivation. Thermal inactivation can be performed using steam, super heated water or an established licensed electrical heating technique which minimises time and space. The EDS+™ system is used throughout the world in BSL1 to BSL3 facilities and is available in single tank or two tank dual redundant systems.

Effluent Decontamination System BioWasteMicro™ for BioSafety Level BSL1 –3

The BioWasteMicro™ effluent treatment system is a pre-designed system which treats low volumes of effluent using an innovative batch process allowing positive release of all of your waste. A buffer vessel is used to provide a continuous collection facility and a set volume batch treatment facility is used. The BioWasteMicro™, uses SteriHeat™ established licensed electrical heating technology to treat the effluent in batches at variable f0 lethality settings. Using robust, proven design principles, the systems deal with CL BioSafety Waste Level 1 to 3 and take into account two main areas of concern. Firstly the systems effectively sterilise or inactivate any harmful pathogens in the waste stream and secondly total containment must be assured at all times. The unit can be fully chemical decontaminated.





INTRODUCING WASHERS

The **definition of washing** is “to clean with water and typically, soap or detergent and clean as free from dirt, marks, or stains”. The result of washing is “the removal of all residues of soil and all washing agents so that contact with the cleaned surface does not result in physical contamination”.

Suncombe and Washers

Suncombe washers have been supplied for over 50 years since the 1950's and encompass many different washing technologies to provide a full range of washing facilities. They are used throughout the world in many different industries and sectors.

- First System installed in 1961
- 1,000s of System used throughout the world.
- 50+ years of design experience.
- Developed with major clientele to meet their requirements.
- Suitable for full validation.

Washing Technologies

- Immersion
- Immersion with Agitation
- Immersion with Turbulation
- Spray Cleaning
- Fogging
- Ultrasonic Cleaning
- Air Purging
- Drying and Cooling



WASHERS



PureKleen™

PureKleen™ range of Parts Washers are front loading or pass through washer/disinfectors, supplied worldwide to the Biotech, Pharmaceutical, Medical, Healthcare, Personal Care and other critical processing industries. Built to hygienic and sanitary standards and complying with ASME BPE, GAMP, ISPE and 21CFR11, they are designed for the cleaning of critical components.



SonoKleen™ and ImmersionWasher

Built to hygienic and sanitary standards and complying with ASME BPE, GAMP, ISPE and 21CFR11, the SonoKleen™ PartsWashers employ a combination of ultrasonic, immersion, turbulence, recirculation and spray cleaning to provide the ultimate clean. They provide an environmentally friendly, low water and energy usage washing facility for parts washing.



BoothWasher™

The BoothWasher™ is a multi-purpose washer in single door or pass through versions, that offers a contained, validateable unit to clean and dry any combination of components.



IBCWashBooth™

The Suncombe IBCWashBooth™ is a high specification unit, using an innovative spray technique, that offers a contained, validateable unit to clean and dry Intermediate Bulk Containers (IBCs). Achieving excellent cleaning using high impact accurate spray targeting, they incorporate existing and new technologies to provide an environmentally friendly, low water and energy usage washing facility for IBC washing.



IBCWashDock™

Supplied worldwide to the Food, Dairy, Beverage, Biotech, Pharmaceutical, Medical, Healthcare, Personal Care and other processing industries, the IBCWashDock™ provides internal IBC cleaning and drying, incorporating technologies to provide repeatable patterns to ensure total coverage of all internal surfaces.



SteriWasher™

The SteriWasher™ Parts Washer is an innovative new robust, heavy duty validateable Parts Washer, developed for use in the pharmaceutical, biotech, food, beverage, healthcare and other critical sectors. Accessed via a robust hinged door, the washing chamber is constructed from 316 stainless steel and is of hygienic construction. Employing a combination of specially developed variable duty spray technologies, the washer provides high energy impingement washing together with low energy flushing chosen by a simple recipe selection. The SteriWasher™ provides an environmentally friendly, low water and energy usage washing facility in production and research environments for equipment ranging from critical small parts and tools to large mixers, drums and containers.

Skid mounted, sanitary modular systems **helps simplify the installation of complicated processes** and are used throughout industry. Providing a controlled environment for manufacture, skid mounting allows in process inspection and factory acceptance testing prior to delivery.

INTRODUCING PROCESSING SKIDS, SUPER SKIDS & MODULES

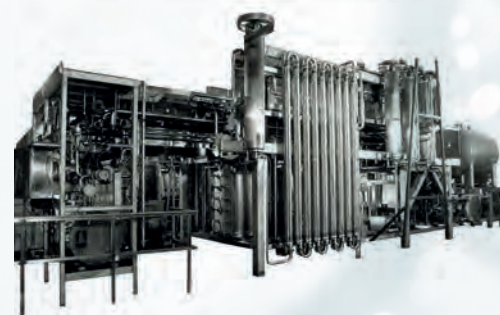


Advantages of Processing Skids/Modules

- Smart Project Management controlling all aspects of the Skid/Module with a single Project Manager/Director.
- All aspects of the project carried out with in-house staff including design, development, drawings, calculations, fabrication, finishing, piping, wiring, testing, automation, integration and testing.
- Skid/Module can be built and completed in parallel with the facility build of pre-built ready for a shutdown/changeover period.
- Pre-validated system allows full documentation and testing protocols to be performed prior to shipment.

Example Skids/Modules

- Solution Preparation
- Buffer and Media Preparation
- Final Formulation and Fill
- Process Utility Skids
- Temperature Control Systems
- Powder Incorporation
- Heating/Cooling Skids
- IBC Discharge Stations
- Neutralisation Skids
- SunFlo™ Utility Panels
- Transfer Panels & Flowplates
- Chemical Dosing Skids



Suncombe is a leading manufacturer of hygienic and sterile tanks, vessels, mixers and processors.

Scope of Supply

Suncombe offer a range of standard solutions, as well as custom vessels and pride ourselves on our ability to understand and meet our customers' particular needs by producing custom stainless steel vessels to match their precise requirements. Our pressure vessels are PED certified and conform to PD 5500, ASME VIII, EN13445 and other internationally recognised standards.



Micromix Vessels (3-100 litres)

Suncombe 'Micro-Mixers' are designed to provide a solution for mixing of small volumes of product, from 3 litres to 100 litres. Used in the biotech, healthcare, diagnostics, parenteral, food and pharmaceutical sectors, the vessels are available in standard versions or bespoke versions to suit your requirements. They are available with jackets, load cells, insulation, ATEX versions, SIP duties, skid mounted units and control systems and include the simple validation package which is a feature on all of our products, and include comprehensive databooks, processes, procedures and documentation.



PharmaVessel™

Suncombe PharmaVessels™ are a range of static and mobile pressure vessels developed for the biotech, pharmaceutical, healthcare, food and other critical processing industries. Supplied since the 1970's, these vessels are custom designed to incorporate the features required for each individual application. Available in 316L Stainless steel, duplex or Hastelloy preparation vessels, the vessels can incorporate any client required equipment.



SaniTank™

Suncombe SaniTank™ Liquid Storage and transport Tanks, available in capacities from 10 to 500 litres, are a range of fully sanitary atmospheric tanks available in 316 Stainless steel, duplex or Hastelloy materials, developed for the specific requirements of the biopharmaceutical, personal care, healthcare, food science and beverage sectors. With standard vessel internals they are available with different external layouts.

INTRODUCING TANKS VESSELS & MIXERS

Features

- Heating and Cooling Jackets
- Magnetic Mixers and Top Mount Mixers
- Powder Incorporation
- Mixing, blending, conditioning and transfer



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