SUNCOMBE
CIP, BIOWASTE & PROCESS SOLUTIONS

HTST Skid

High-Temperature Short Time (HTST) Systems

The Validatable HTST systems for the Biotech sector

Electrical heating now available throughout the range

Overview

The Suncombe High-temperature short-time treatment systems (also known as HTST or flash pasteurization), are quickly becoming an integral part of many biopharmaceutical companies' viral risk-mitigation strategies for bioburden reduction and viral inactivation.

The systems are configured to rapidly heat the material from ambient, to a pre-determined temperature and then subsequently hold the material at this temperature to reduce or eliminate viable microorganisms and viruses in a liquid under continuous flow conditions, prior to applying cooling to reduce the temperature for process use.

The Suncombe HTST systems have been specifically develop, using robust, proven design principles, the systems are designed around the requirements of the ASME Bioprocessing Equipment standard to ensure that your product is HTST treated in a reliable, repeatable, validatable and auditable manner. Facilities can be incorporated for in built cleaning in place (CIP) and sterilising in place (SIP).

ASME
SETTING THE STANDARD

ASME
BPE

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Welcome

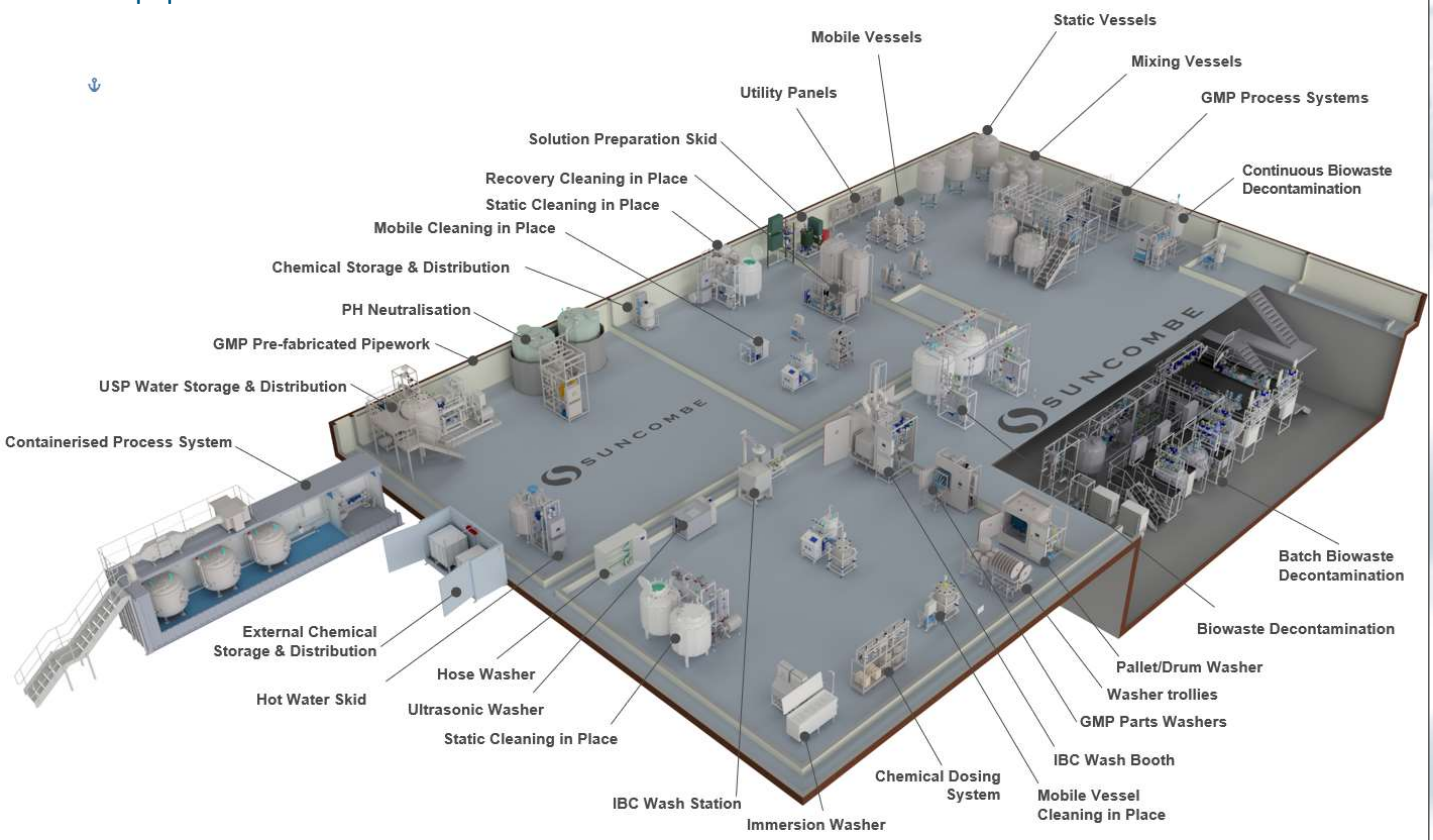
Since our foundation in 1961, Suncombe has pioneered the development of innovative solutions for cleaning in place, bio-waste decontamination, GMP Washers, sanitary skids and vessel skids. The business continues to be privately owned and managed day to day by Dave Adams and Steve Overton.

Supporting Dave and Steve is a close-knit, dedicated, highly motivated and long-standing team encompassing a wealth of technical experience and knowledge in all relevant disciplines, including design, manufacture, testing, installation, validation, documentation and after-sales support. All of our work is carried out across our own facilities north of London near Stansted Airport.

The team employ the very latesttechniques, standards and best in class solutions. Having such a strong team allows us to offer the ability to carry out all of our work in-house, under our direct control and quality management system. It also ensures that we own and preserve all the knowledge and experience gained with every project and allows us to offer continued support for all our installed systems throughout their lifetime.

Our Clientele

Our Equipment



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Key Features	Benefits
Sanitary 316L stainless steel construction and components	Systems are constructed to the highest sanitary standards with 3.1 material traceability and welding dossier. This ensures a fully validatable and sterilisable, cleanable environment.
Static/Mobile	Static and Mobile versions available.
Treatment Parameters	Variable flowrates, treatment temperature, holding time, outlet temperature. Preset and variable configuration to provide Temperature/Time, f0 or log kill requirements. Temperatures up to 136°C or greater if required.
Siemens PLC and 12" colour HMI with options for larger HMIs	Control hardware is industry standard and supported worldwide by Siemens. Ethernet interface included for transfer of critical operating variables to other systems. Designed to enable integration to third party equipment or higher level control system. Option for Rockwell Allen Bradley.
Suncombe BioSuite software	Control software specification has been developed and proven over many years for HTST applications and includes a wide range of user or administrator configurable parameters to enable customised decontamination profiles. User passwords, Active Directory, Audit Trails, Electronic batch reports for local or network storage are possible. User interface screens and process visualisation is simple, intuitive, clear and comprehensive. Remote access options are possible if required. Software complies with FDA 21CFR and EU GMP regulations.
Fully automated processing	The system provides continuous operation and Suncombe's BioSuite software enables fully automated treatment.
Fully automated reporting	Electronic pdf reporting included – printed report optional
Automatic Operation	Automatic Liquid Inlet Automatic Liquid treatment Automatic Liquid Discharge Automatic Alarms and Warnings
Utility Requirements	Systems only require compressed air, water, steam, coolant and electrical utility connections.
Heating Options	Direct steam, indirect steam or low temperature hot water heating for delicate liquids. Options for oil and electrical heating.
Sustainability	Designed for sustainability, options for regenerated and sustainable energy usage.
Continuous monitoring of key parameters	HTST process is highly repeatable and validatable.
Safety	Alarms, interlocks and fail-safe design prevent waste discharge in the event of an unsuccessful treatment. This encompasses scenarios such as power loss and under-temperature events.
Plug 'n' Play	Comprehensive in-house testing to ensure fast start up on site.
Covers	The systems are also available with stainless steel or thermoplastic covers
Compact design	Designed to fit into new facilities or to be retrofitted into existing facilities with limited available space.
Configurable	Based on generic standard modules, we can supply individual units custom designed for your specific requirement.
Cleaning In Place and Sterilising In Place	Prepared for CIP and SIP with optional CIP/SIP System

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Designers, manufacturers & installers of quality, hygienic processing and cleaning systems and Equipment

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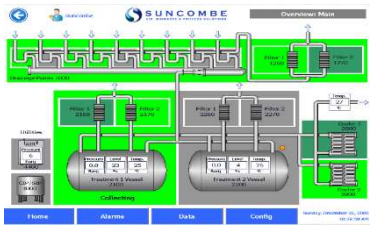
Control and Automation System

Renowned for their ease of operation and versatility, Suncombe systems are designed and manufactured for reliability, repeatability and longevity, whilst complying with the highest international regulatory standards. With dedicated in-house automation personnel for control design and software, Suncombe engineers have tremendous experience in incorporating a broad range of control solutions to suit your specific control requirements.

Developed to the GAMP 'V' model (Verification and Validation), system life cycle approach, which links the three main qualification activities (installation, operation and performance) back to the design process, the system software is produced in house by qualified software engineers, encompassing software development standards, quality control systems and change control during and post development.

Standards and Guidelines

- ✓ GAMP Guidelines
- ✓ FDA 21CFR11 Compliance
- ✓ ASME BPE
- ✓ EU Machinery Directive
- ✓ EU Low Voltage Directive
- ✓ EU cGMP Guidelines
- ✓ EU EMC Electromagnetic Compatibility Directive
- ✓ IEC 61131 for PLCs
- ✓ EN 60204 Safety of machinery
- ✓ EN 60439 Low Voltage Switchgear
- ✓ CE and UKCA Marks



Typical Operator Interface

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Our Sustainability Operations

Sustainability of Suncombe Equipment

As a company, we recognise the importance of sustainability and the need to minimise our environmental impact. All Suncombe equipment has been re-developed for sustainability purposes and incorporates techniques and methodologies to minimise impact on the environment, including technologies that reduce energy consumption, emissions, and waste, as well as adopting practices that promote sustainability and reduce the environmental impact of operations.

Social Responsibility

Our company philosophy is one of Social Responsibility and under this banner we are fully committed to the need to balance economic growth with environmental stewardship and social responsibility.

Overall, Suncombe demonstrates a commitment to sustainability and environmental responsibility in our operations and products. For further details Suncombe have produced Sustainability and Lifecycle White Papers available **on request**

Here are some of the ways we achieve this:

- ✓ Efficient use of resources: Suncombe uses energy-efficient technologies in our equipment, which helps to reduce energy consumption and carbon emissions.
- ✓ Waste reduction: Suncombe strives to reduce waste throughout our operations, from manufacturing to product disposal. We use sustainable materials and designs that minimise waste and maximise product lifespan.
- ✓ Recycling: Suncombe promotes recycling and reusing of materials to reduce waste. We also recycle our own equipment where possible.
- ✓ Compliance with regulations: Suncombe adheres to environmental regulations and standards set by governing bodies, ensuring that our operations do not harm the environment.
- ✓ Green initiatives: Suncombe invests in research and development of new, sustainable technologies and processes to further reduce our environmental impact.
- ✓ Lifecycle Considerations: The company emphasizes the entire lifecycle of our equipment, from design and manufacturing to use and disposal. We strive to select materials and components that are environmentally friendly and can be recycled or disposed of responsibly. Featuring design with margin, upgrading and future-proofing extends the equipment lifecycle.