

GMP Water Heating Skids

The Biotech, Pharma and Critical Application cGMP Validatable Water Heating Skids



Overview

These skid mounted systems provide a robust and repeatable method of heating, storing and distributing hot water under cGMP auspices.

The skids comprise all the necessary water storage tanks, heaters, pumps, valves, pipework and related components and instrumentation to deliver the required hot water. Type, quantity and physical sizes of components are determined during the design phase of each project to suit the required application.

System construction and components are suitable for cGMP sanitary use in pharmaceutical, biotech and other hygienic applications.

Systems include a user-configurable recipe based control system to suit a wide range of applications and are pre-assembled and fully tested with operating utility supplies in our works to minimise risk and optimise installation and validation time on-site.

Systems comply with all applicable regulatory standards and are accompanied by a comprehensive suite of documentation covering all aspects of installation, operation and maintenance. Extended documentation packages can be supplied to meet specific validation needs.

Constructed to cGMP, a 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. All functions of the equipment would be fully wet and dry tested and test results would be documented in the FAT protocol.

Applications

- ✓ Cold Water Heating
- ✓ Hot Water Temperature Maintenance
- ✓ Storage of temperature Controlled Water
- ✓ Distribution of Temperature Controlled Water
- ✓ and many more in Pharmaceutical, Biotech and other Critical process industries.

Sustainability

- ✓ Available with steam or electrical heating components
- ✓ Options for heat recovery and reclaim
- ✓ Options for inclusions of heat pump technology

GMP Construction

- ✓ FDA approved components with no threads and triclamp connections
- ✓ ASME BPE 316L no dead legs, fully drainable, material & weld traceability
- ✓ Control and instrumentation to GAMP5
- ✓ Repeatable, validatable client configurable sequences
- ✓ Riboflavin proof of coverage

GMP Water Heating Skids DATASHEET

VERSION 1.9



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, just off the M25 in north London.

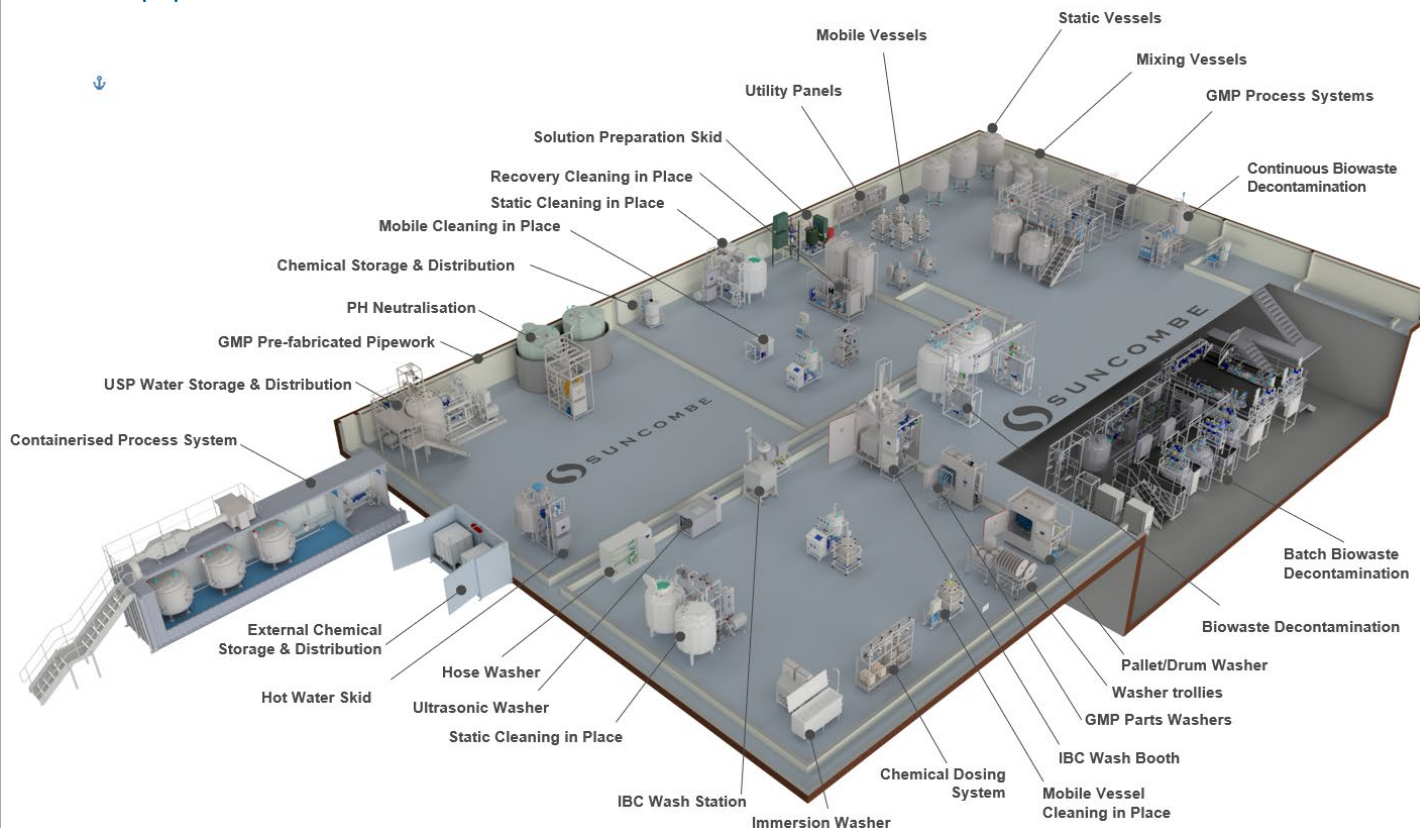
The team employ the very latest techniques, standards and best in class solutions. Having such a strong team allows us to offer the ability to carry out all of our work in-house, under our direct control

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 3.1/2.2 material traceability and welding dossier. This ensures a fully validatable and cleanable treatment environment.
Variable Duty Delivery Pump	316L Stainless Steel Heavy Duty Sanitary Delivery Pump with Variable Speed Drive to allow speed control to vary the delivery flowrate and pressure from the recipe, complete with PID loop and automatic impellor casing drain valve
Static/Distributed/Mobile Systems	Systems available as static, distributed in a number of pieces or mobile configuration
Siemens PLC and 12" colour HMI with options for additional 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. Versions also available with remote I/O for control by clients control system.
Suncombe ControlSuite™ software	Control software specification has been developed and proven over many years and includes a wide range of user or administrator configurable parameters to enable customised cleaning recipes, including water flow, pressure, time, temperature, chemical concentration and many more. User passwords, Active Directory, Audit Trails, Electronic CIP 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.
Storage Vessel/s	316L Stainless Steel Pressure vessel with heated 0.2µm Vent Filter, bursting disc, sanitary construction with riboflavin tests. Water storage or chemical make-up vessels.
Fully automated batch report	Electronic pdf reporting included – printed report optional
Steam, hot water/oil or electric water heating options	Heating energy may be derived from most convenient and cost-effective source available.
Heated Solution Preparation	Heated solutions can be batch made up in Storage Vessel /s or using In-Line Heating validated method
Continuous monitoring of key parameters	Decontamination 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 standard modules, we can supply individual units custom designed for your specific requirement.

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

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Capacity Table

Part #	Flowrate (litres per minute)	Storage Capacity (litres)	Pipe Size	Dimensions		
				Width (mm)	Depth (mm)	Height (mm)
0.5/N	5 - 15	None	0.5"	1,200	840	1,200
1.0/N	15 - 50	None	1"	1,200	840	1,200
1.5/N	50 - 110	None	1.5"	1,200	840	1,200
0.5/150	5 - 15	150	0.5"	1,600	840	1,850
1.0/500	15 - 50	500	1"	2,200	1,200	2,300
1.5/1000	50 - 110	1000	1.5"	2,500	1,400	2,800
2.0/2000	110 - 200	2000	2"	2,500	1,400	3,400
2.5/3000	200 - 330	3000	2.5"	3,000	2,000	3,400
3.0/5000	330 - 500	5000	3"	3,500	2,500	3,800
4.0/10000	500 - 1000	10000	4"	Please enquire		

Larger and alternate system capacities available – please enquire for details

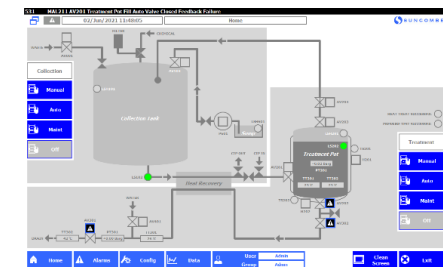
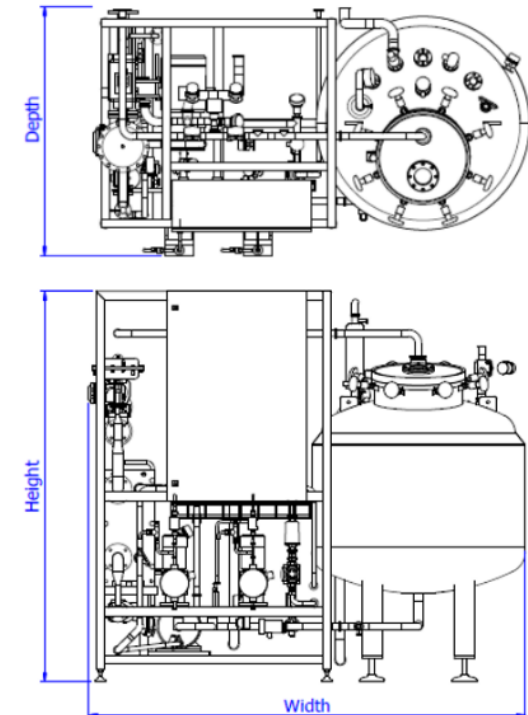
Dimensions are for vertical storage vessels. Horizontal storage vessels also available.

Please contact us for final equipment dimensions

Options

Material of Construction	Duplex, Hastelloy and thermoplastic materials available
Operating Voltage	Various to suit local utility
Heating	Electrical, steam, hot oil and recovery heating available
Covers	Thermoplastic or stainless steel covers
Non GMP	Non GMP versions available

Layout



Typical HMI