SUNCOMBE
CIP, BIOWASTE & PROCESS SOLUTIONS

MobileCIP®

CLEANING IN PLACE (CIP) SYSTEMS

The Mobile Biotech, Pharma and Critical Application cGMP Validatable Total Loss Cleaning In Place System

Overview

These mobile skid mounted systems provide a robust and repeatable method of cleaning process equipment with temperature controlled solutions and added chemicals.

Skids comprise all the necessary water storage tanks, heaters, pumps, valves, pipework and related components and instrumentation to deliver the required CIP cycle. 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 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

- ✓ Cleaning of Tanks
- ✓ Vessels Intermediate Bulk Containers (IBCs)
- ✓ Vats, Fermenters
- ✓ Mixers Processors
- ✓ Pipework Flexibles
- ✓ Transfer Line Valves
- ✓ Fluid Bed Dryers Mills
- ✓ Coaters Filters
- ✓ Pumps
- ✓ Dryers Tumblers
- ✓ Fillers
- ✓ and many more in Pharmaceutical, Biotech and other Critical process industries.

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

MobileCIP® DATASHEET
VERSION 3.13

Welcome

Since our foundation in 1961, Suncombe has pioneered the development of innovative solutions for cleaning in place, GMP Washers, skids, tanks and vessels and bio-waste decontamination. 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 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.
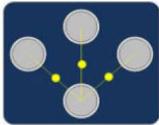
Our Clientele

Our Equipment
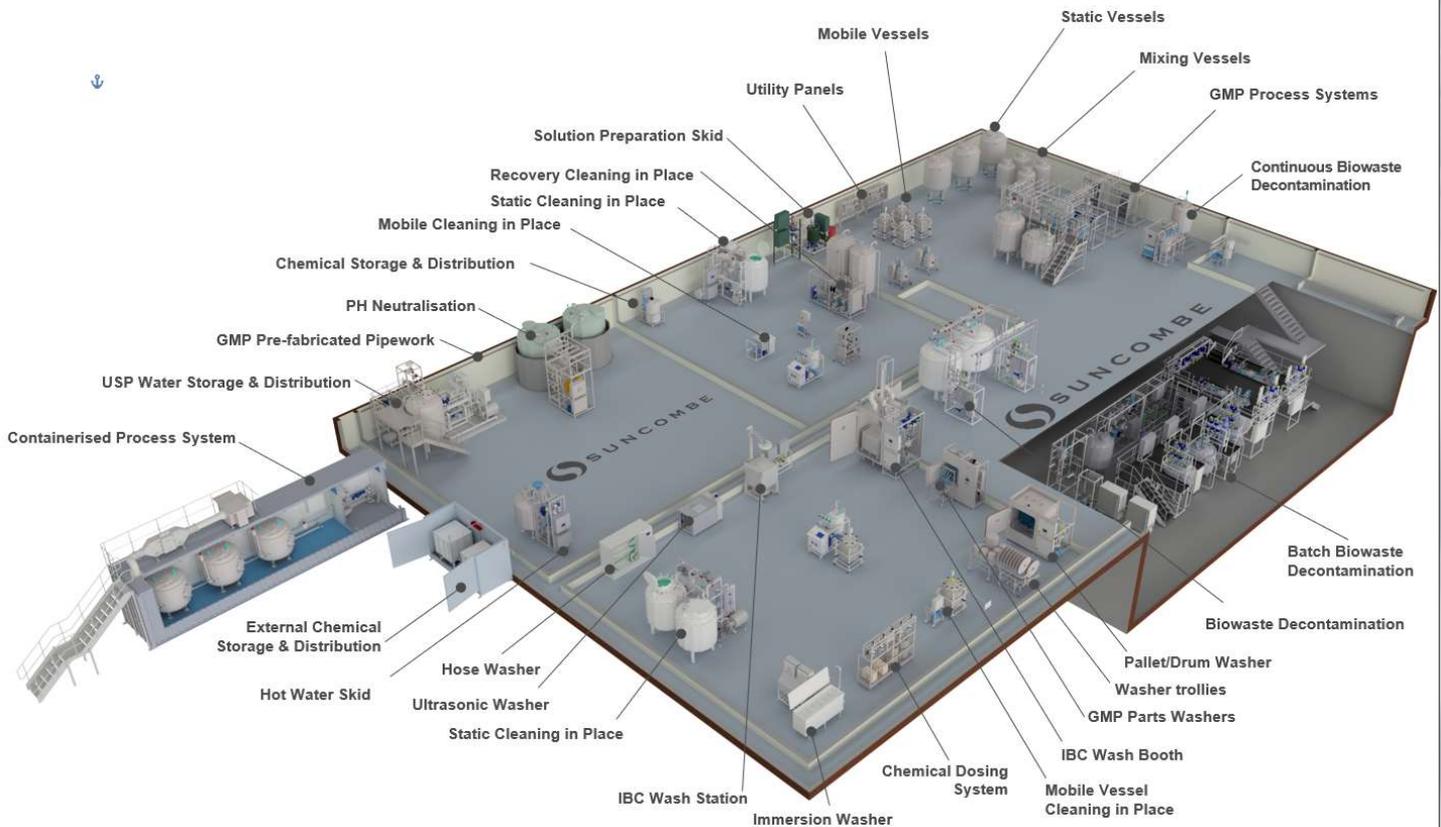
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Key Features	Benefits
Sanitary 316L stainless steel construction and components	CIP fluids are maintained at the highest sanitary standards complying with ASME BPE offering guaranteed surface finishes with diaphragm valves, full material traceability, weld maps and tables and welding dossier.
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
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 SmartCIP™ software	Control software specification has been developed and proven over many years for CIP applications 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.
CIP Vessel	316L Stainless Steel Pressure vessel with heated 0.2μm Vent Filter, bursting disc, sanitary construction with riboflavin tests.
Single-pass or Recirculation options	CIP fluids can be immediately discarded to waste after use ("Single Pass") or may be recirculated to reduce overall water and energy consumption.
Electrical or Steam water heating options	Heating energy may be derived from most convenient and cost-effective source available.
Heated Solution Preparation	Heated solutions are batch made up in CIP Vessel. Option for In-Line Heating validated method
USP Water	Can be used with Soft Water, Purified Water and Water for Injection. Facilities for two waters. Water can either fill vessel or bypass vessel.
Continuous monitoring of key parameters	CIP process is highly repeatable and validatable.
Chemical Addition	Space on the unit for 2 x client supplied chemical drums. Option for additional chemicals.
In-line or batch chemical dosing	Chemical solutions can be batch made up in CIP vessel/s or using optional In-Line Dilution validated method with flowmeter. Option for conductivity concentration verification.
Scavenge/Return Pump	Skid includes air handling scavenge pump to return CIP liquid
Plug 'n' Play	Fully integrated with comprehensive in-house testing to ensure fast start up on site
Skid is on castors ("mobile")	Location and relocation of CIP system is very flexible either by hand or using for forklift or pallet truck
CIP Distribution	A single CIP outlet is included. Options available for up to 10 separate CIP outlets for feeding to different items to be CIP'ed. Each outlet can be a single or double valve for CIP isolation. Distribution can also be via flowplate/splitter panel.
Covers	The systems are also available with stainless steel or thermoplastic covers
Air Purge	Includes air purge facility to evacuate all water from the CIP pipework
Fully Drainable	Automatic valves to fully drain entire skid including pump casing
Instruments	Sanitary instruments of Endress and Hauser/Mettler Toledo or equivalent with full material and calibration certification.
Final Rinse Confirmation	Final Rinse Conductivity to confirm completion of Cycle
Sterilise In Place (SIP) Option	Also available with Sterilise In Place (SIP) Option to provide validatable SIP cycles either following a CIP cycle or as a separate operation

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Diagram
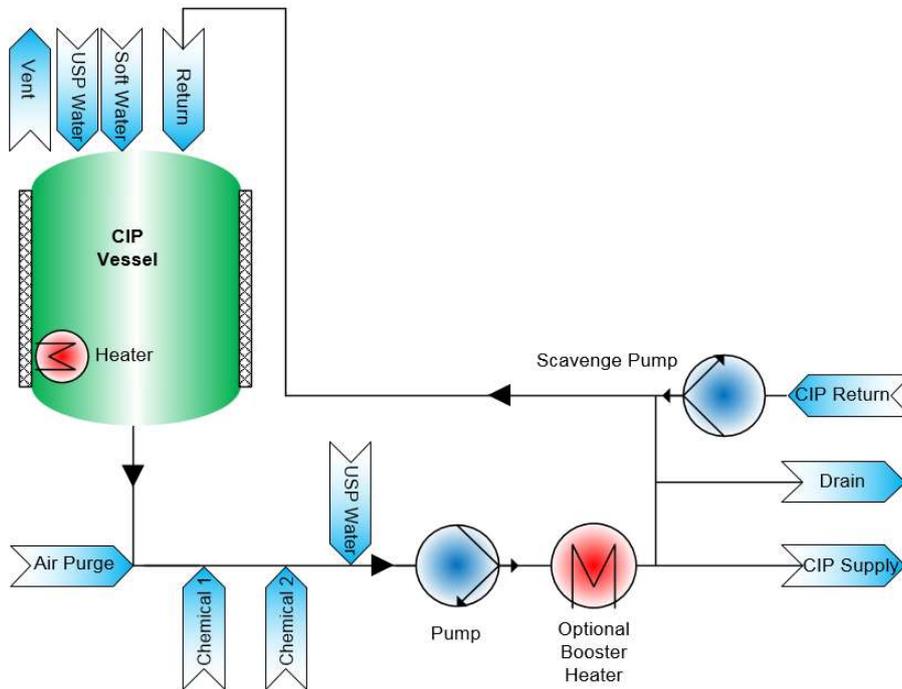
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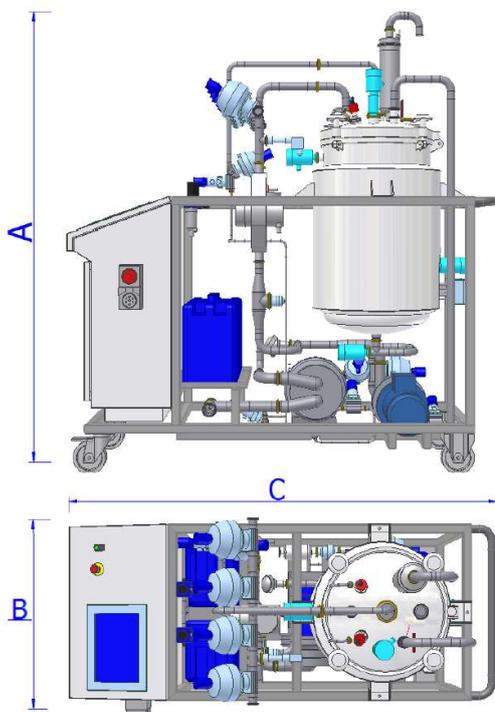
Dimensions

These are typical only and should be confirmed.

Part #	Vessel Capacity litres	Flowrate Litres per minute	Length mm	Width mm	Height mm
MobileCIP® 60	150	0-60	1,750	850	2,000
MobileCIP® 100	250	0-100	1,950	1,050	2,150
MobileCIP® 150	350	0-150	1,950	1,050	2,450

Most common versions shown above. Other sizes are available.
All Systems also available with 0, 1 or 2 vessels.

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Typical MobileCIP®

IBC Washing Variant – With built in automatic lid positioning for Intermediate Bulk Containers (IBCs)
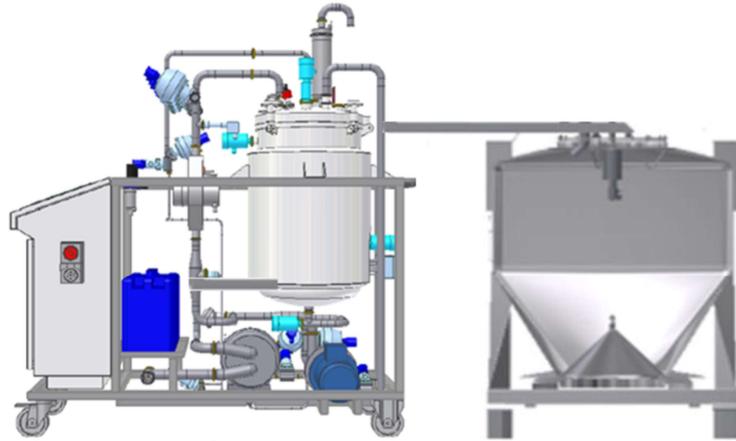
Typical MobileCIP®
Operator Interface HMI
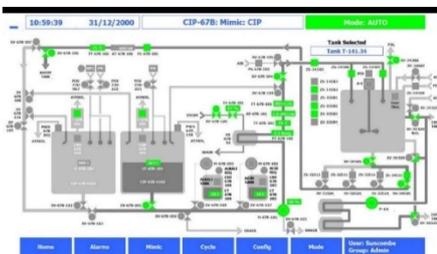
Typical MobileCIP® Operator Interface
HMI Recipe Configuration
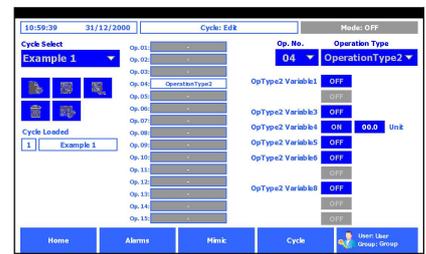
Utilities

Water (Soft, USP, PW, WFI - 1, 2 or 3 waters)	20 – 150 litres/min @ 1 bar (ideally as per system flowrate)
Compressed Air (internal regulator)	Minimal use @ 7bar
Air Purge (internal regulator and HEPA filter)	700 Slpm
Electricity	>12 kW 400Vac 3ph+n 50hz. Other voltages available to order
Heating	Electrical or steam - utility dependant on system duty
Drain	20 - 150 litres/min @ 1 bar (as per system flowrate)

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.

Typical Operator Interface

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

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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.