



SUNCOMBE
CIP, BIOWASTE & PROCESS SOLUTIONS

PureVessel™ Sanitary - Sterile Vessels



Suncombe Ltd, Jade House, Lockfield Avenue, Brimsdown, Enfield, Middlesex, EN37JY, United Kingdom

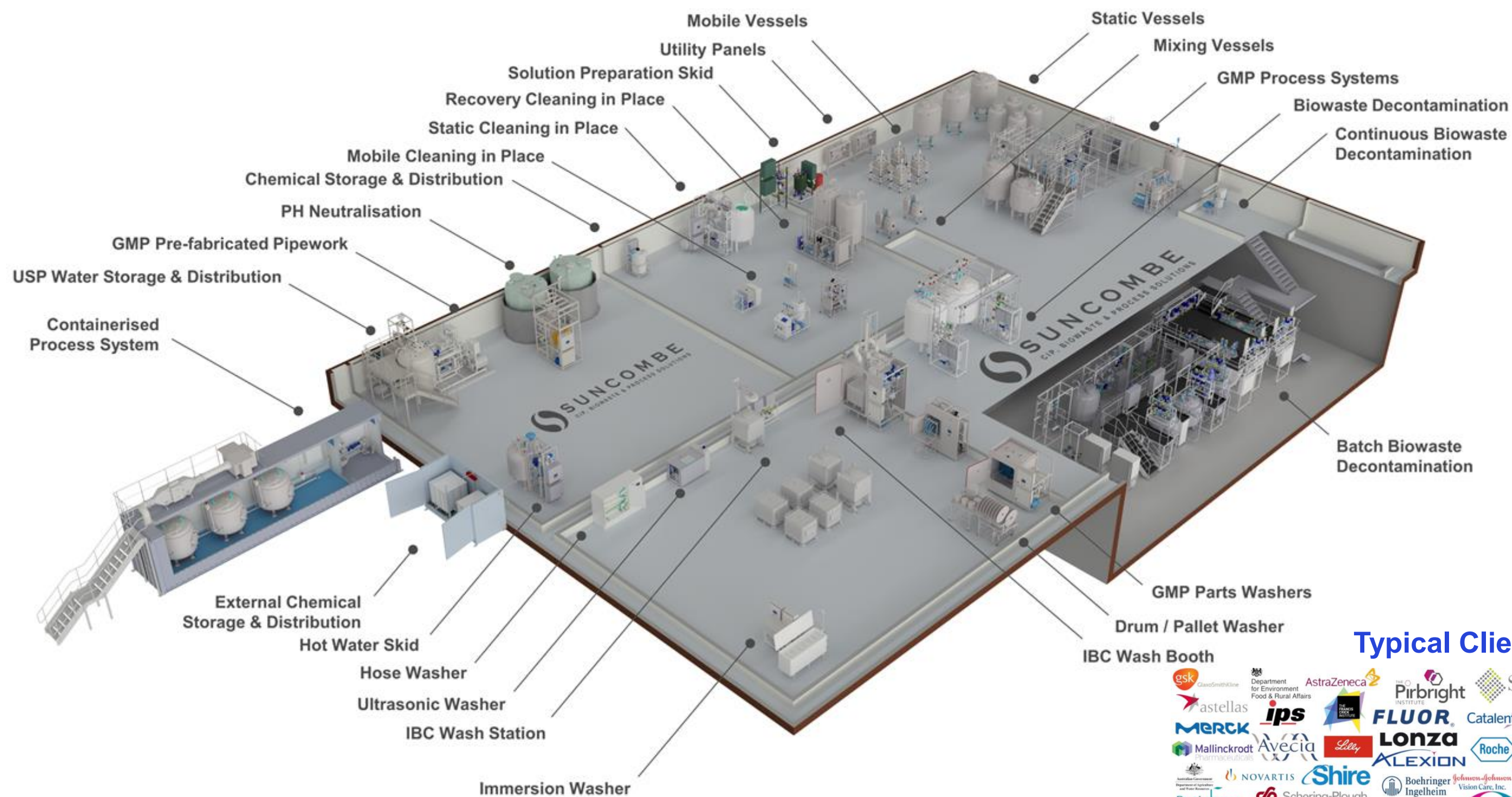
T +44(0)20-8443-3454 F +44(0)20-8443-3969 E info@suncombe.com W www.suncombe.com



SUNCOMBE

CIP, BIOWASTE & PROCESS SOLUTIONS

Product Portfolio



Typical Clientele



PureVessel™ Sanitary - Sterile Vessel 10 to 750 Litre Capacity

Introduction

Developed over the last 60 years, The Suncombe PureVessel™s are fully sanitary - Sterile pressure vessels, available with capacities from 10 to 750 litres. Designed in a modular manner, the vessels can be equipped with top entry agitators, bottom mounted magnetic mixers, heating and cooling jackets, mounted on load cells, spray devices and instruments with the option of custom design and manufacture for your particular requirement. They are high specification units constructed from 316 stainless steel and optionally Hastelloy for chlorine resistance built to comply with ASME BPE Bioprocessing Equipment guidelines.

Typical Manufacturing Standards

- ASME BPE Construction, fully drainable, crevice free.
- cGMP, GAMP

Typical Equipment

- 316L stainless steel contact parts, 304 non-contact parts
- Sanitary Valves, manual and air operated
- Calibrated Instruments

Automation System

A range of automation levels are available, starting from entry level, through mid level PLC and HMI versions, to advanced validateable systems. All levels provide a repeatable automated cycle.

Equipment Lifecycle

The validation 'V' model 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.

Testing

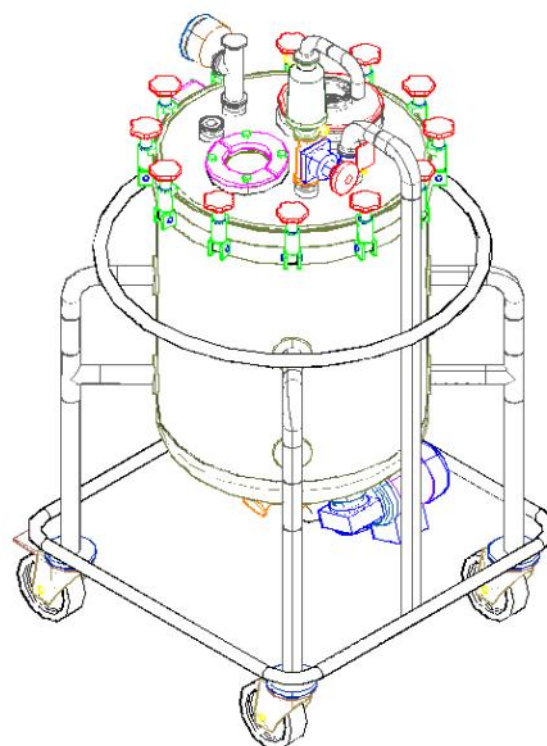
All functions of the equipment would be fully wet and dry tested and test results would be documented in the 'Pre-Factory Acceptance Test' (FAT) protocol. Following successful completion of this protocol, the client is invited to the FAT test, where all tests can be repeated or the pre-FAT tests results can be used for leverage.

Validation

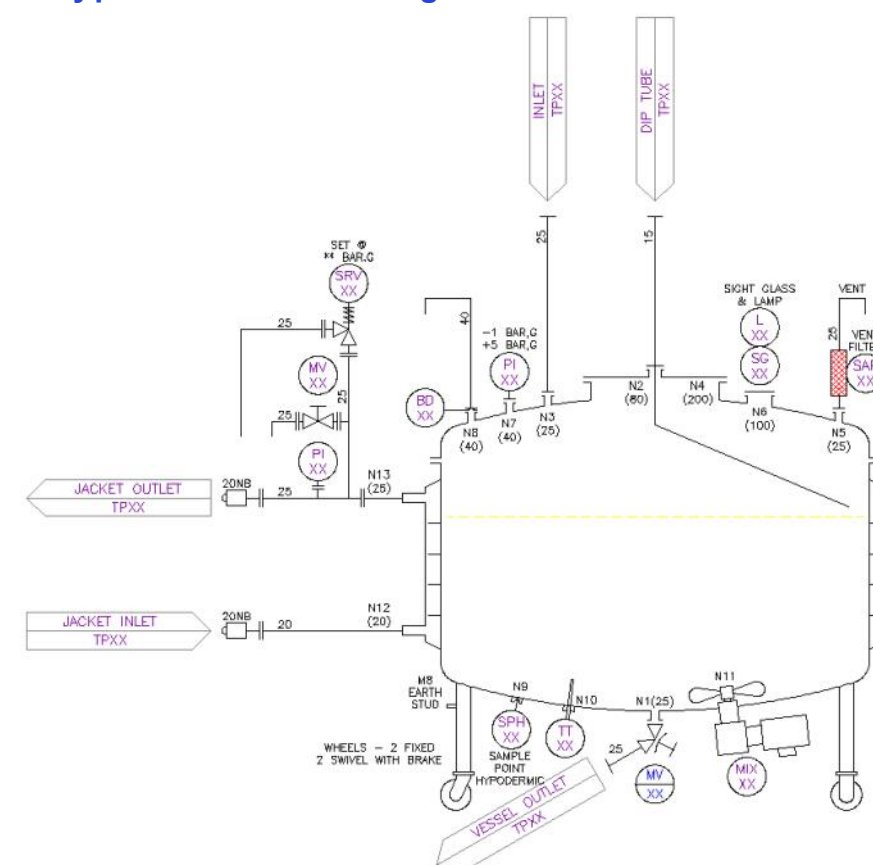
The PureVessel™ was developed to operate with the Suncombe PureCIP™, to provide a pre-validated Cleaning In Place and Sterilising In Place cycle. The pre-validated cycles are integrated into the PureCIP™ control system and an electronic batch record, secured to 21CFR part11, would be provided following every cycle, allowing total confidence in the CIP and SIP result.



Isometric View



Typical PFD Drawing



PureVessel™ Sanitary - Sterile Vessel 10 to 750 Litre Capacity

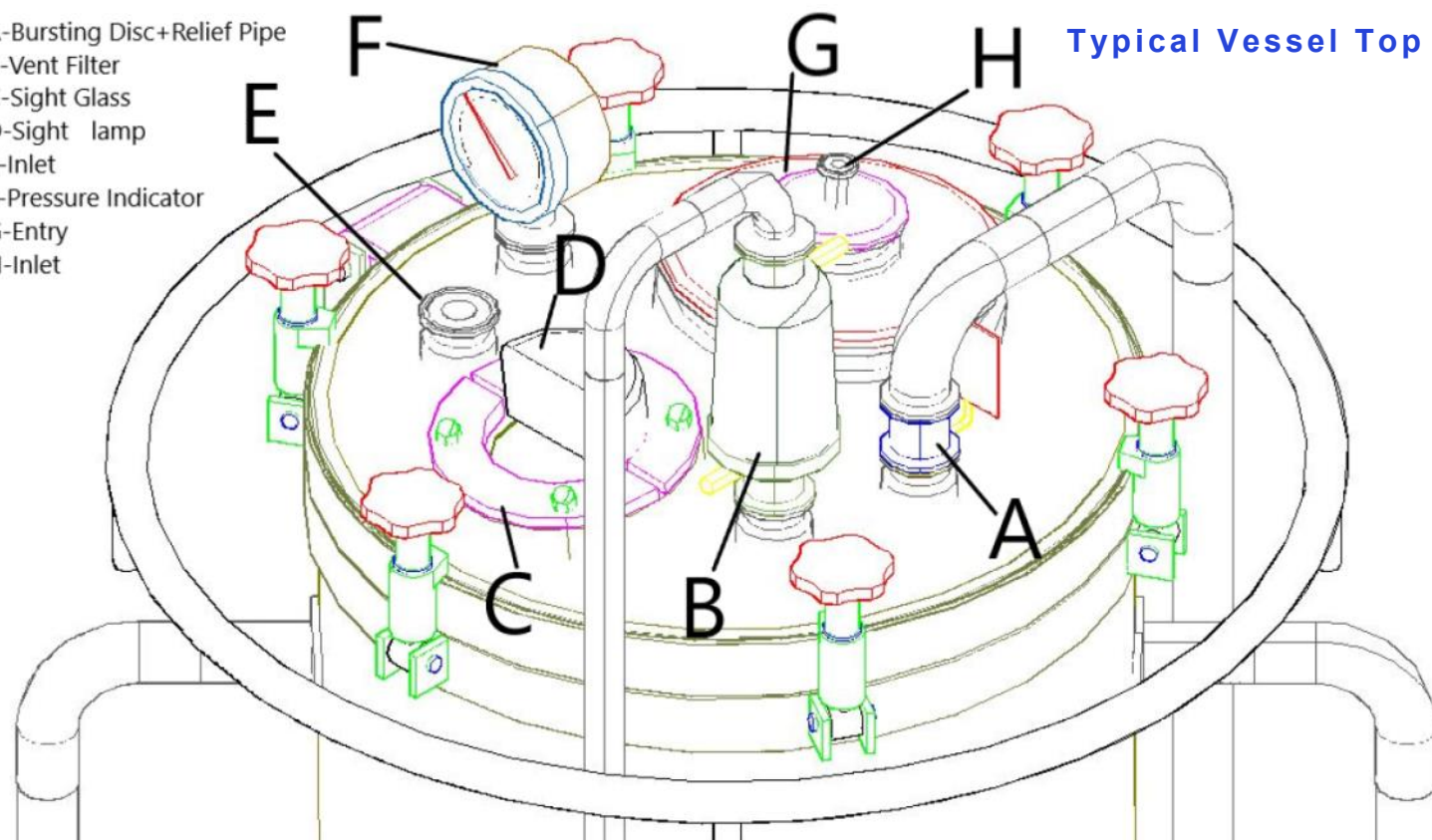
Dimensions

Part #	Dimensions						
PureVessel™	Vessel Capacity litres	Internal Diameter mm	External Diameter mm	Height 1 mm***	Height 2 mm***	Width mm	Length mm
39012-30	30	450	458	900	1300	740	740
39012-30J*	30	450	510	900	1300	740	740
39012-50	50	450	458	1000	1400	740	740
39012-50J*	50	450	510	1000	1400	740	740
39012-100	100	500	508	1100	1500	790	790
39012-100J*	100	500	560	1100	1500	790	790
39012-150	150	550	558	1250	1500	825	825
39012-150J*	150	550	610	1250	1600	825	825
39012-200	200	600	608	1250	1650	890	890
39012-200J*	200	600	660	1250	1650	890	890
39012-300	300	650	658	1450	1850	940	940
39012-300J*	300	650	710	1450	1850	940	940
39012-500	500	820	828	1600	1950	975	975
39012-500J*	500	820	880	1600	1950	975	975
39012-600	600	820	828	1700	2050	975	975
39012-600J*	600	820	880	1700	2050	975	975
39012-750	750	1000	1008	1660	2100	1200	1500**
39012-750J*	750	1000	1080	1660	2100	1200	1500**

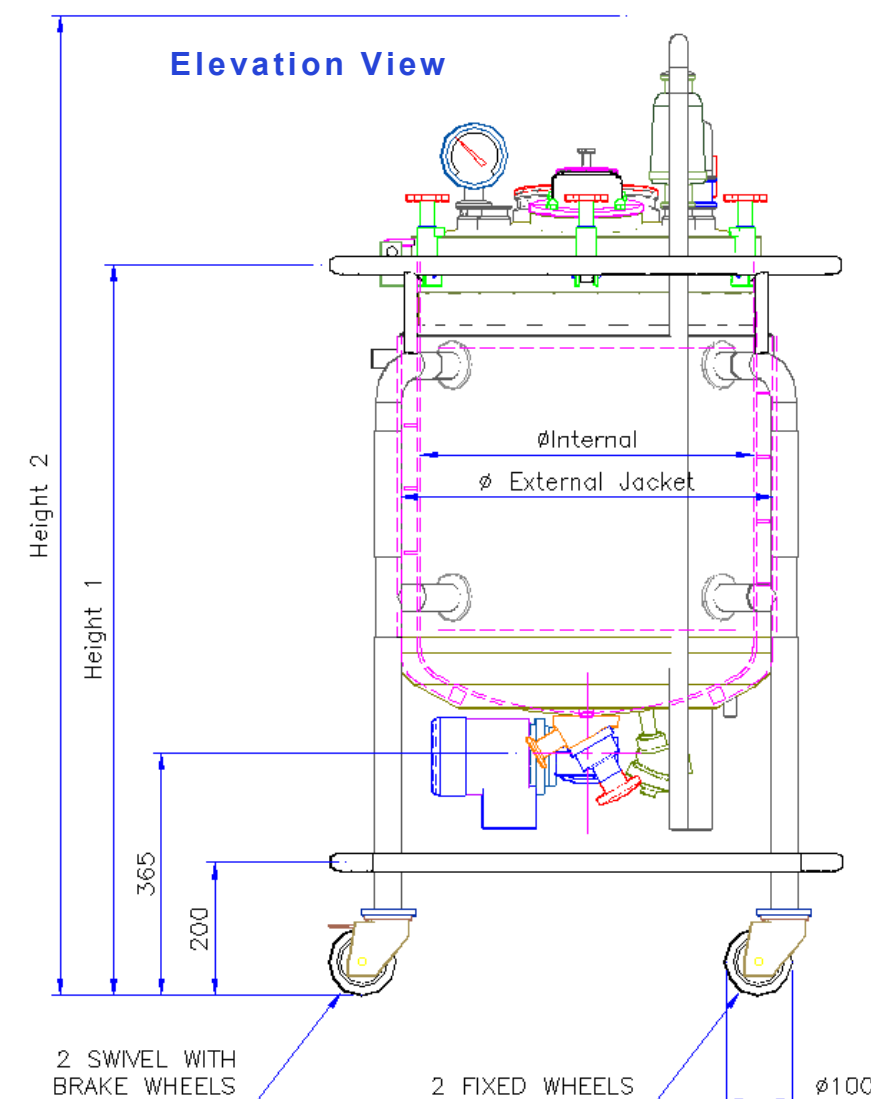
* Jacketed version **Including Push Handle ***Height can be reduced by reducing leg length—please enquire for details

A-Bursting Disc+Relief Pipe
B-Vent Filter
C-Sight Glass
D-Sight lamp
E-Inlet
F-Pressure Indicator
G-Entry
H-Inlet

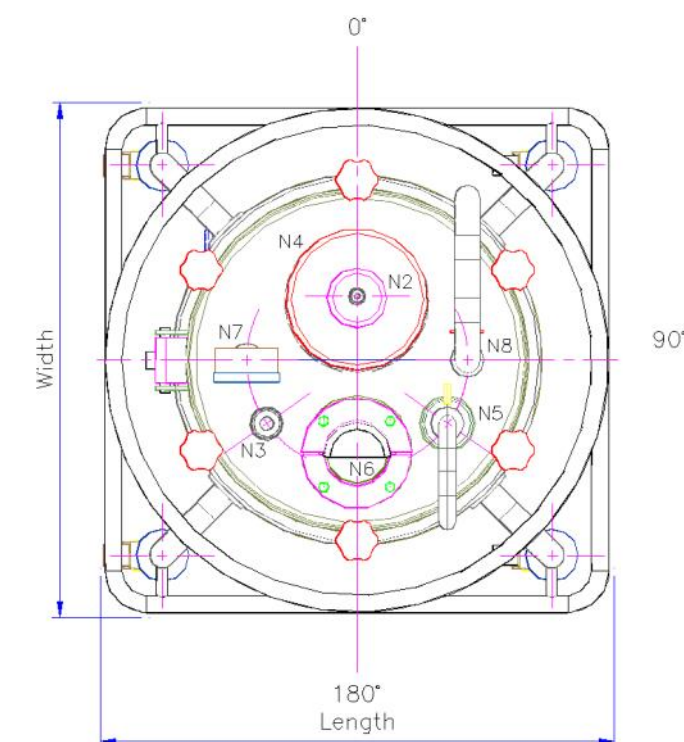
Typical Vessel Top Layout



Elevation View



Plan View



PureVessel™ Sanitary - Sterile Vessel 10 to 750 Litre Capacity

Specification and Options

Description	Included	Optional
Construction		
Materials of Construction - Wetted Parts	316L Stainless Steel	C22 Hastelloy
Materials of Construction - Non-wetted Parts	304 Stainless Steel	304 Stainless Steel
Capacity (litres)	30, 50, 100, 150, 200, 300, 500, 600, 750	Other capacities available
Fittings	Triclamp	Other connections available
PED Cat	As required	-
Third party	As required	-
Mobile/Static	Mobile	Static
Jacketed (Spiral)	Available	-
Insulation and clad	Available	-
Vessel pressure design	3bar/FV	Other pressures available
Jacket Pressure design	3bar/FV	Other pressures available
Vessel pressure working	As required	-
Jacket Pressure working	As required	-
Vessel temperature design	0/150°C	Other temperatures available
Vessel temperature working	<150°C	-
Jacket temperature design	0/150°C	Other temperatures available
Jacket temperature working	<150°C	-
Internal finish	0.76µmRa	0.38, 0.51 µmRa
Electropolishing	Available	-
External finish	1.2µmRa	Other finishes available
100% visual NDT external	Yes	-
100% Dye Penetrant NDT	Yes	-
PD 5500	Yes	Other codes available
Hydraulic test Pressure	Yes	To Code
Tag method	Stainless Steel Disc	Other methods available
Passivation	Available	-
ASME BPE Design	Y	-
Steam sterilisable	Y	-
Nozzles and Ancillaries		
Inlet 1 Size with/without dip tube	25 on 80 nozzle	Other sizes available
Inlet 2 Size	25	Other sizes available
Inlet 3 Size	N/A	Other sizes available
Spray Head assembly	Available	-
Spray ball nozzle size	80 in lid Typical	-
Vessel Spray head type	Rotating	Fixed
Vent Diameter	25	Other sizes available
Vessel Vent Filter Heated	Available	-
Vessel Vent Filter Non-Heated Disposable	Available	-
Sightglass/Sight Lamp	Available	-
Vessel earth stud	Y	-
Vessel name plate	Y	-

Description	Included	Optional
Valves		
Flush Mount Diaphragm Outlet Valves	Manual	Automatic
Flush Mount Diaphragm Inlet Valves	N	Available
Diaphragm Inlet Valves	N	Available
Sample point - Hypodermic	Available	Other sizes and types available
Mixer/Agitator		
Magnetic Mixer	Available	-
Top Entry Mixer	Available	-
Mixer Speed Monitor	Available	-
Instruments		
Top Entry Temperature transmitter	Available	-
Bottom Entry Temperature transmitter in Thermowell	Available	-
Pressure	Indicator	Transmitter
Level/Volume	Switch	Transmitter
Weight/Volume (Load cells)	Available	-
Conductivity	Available	-
pH	Available	-
TOC	Available	-
Burst Disc Diameter	40	-
Burst Disc Rating	4 Bar	Other pressures available
Burst disc sensors	Available	-
Jacket Ancillaries		
Manual jacket air vent	Available	-
Jacket pressure relief	Available	-
QR jacket connections	Available	-
Jacket Pressure indicator	Available	-
Automation		
Chart recorder—electronic	Available	-
Junction box—for remote connections	Available	-
Control panel - for local connections	Available	-
Control panel with local HMI & PLC	Vessel Mounted	Wal Mounted
Records and Validation		
Batch Records compliant with 21CFR11	Available	-
Audit Trail compliant with 21CFR11	Available	-
Windows Domain Users compliant with 21CFR11	Available	-
CIP/SIP Integration		
Integration with PureCIP™ for Vessel CIP	Available	-
Integration with PureCIP™ for Vessel SIP	Available	-
Integration with PureCIP™ for Vessel CIP & SIP	Available	-
Integration with MobileCIP® for Vessel CIP	Available	-
Integration with MobileCIP® for Vessel SIP	Available	-
Integration with MobileCIP® for Vessel CIP & SIP	Available	-
Integration with COPStation™ for Vessel CIP & SIP in enclosed location		

PureVessel™ & PureCIP™ Cleaning In Place and Sterilising In Place

PureVessel™ and PureCIP™ Cleaning In Place and Sterilising In Place

The PureVessel™ was developed to operate with the Suncombe PureCIP™ and MobileCIP®, to provide a pre-validated Cleaning In Place and Sterilising In Place cycle. The pre-validated cycles are integrated into the PureCIP™ control system and an electronic batch record, secured to 21CFR part11, would be provided following every cycle, allowing total confidence in the CIP and SIP result.

PureVessel™ and Hybrid Single Use (SUT) Systems

The terminology Hybrid bioprocessing is typically used to describe a bio processing facility which employs a combination of single use technologies (SUT) and stainless steel repeat use equipment.

One of the main drivers for the use of single use methodologies is the complexity of the clean in place and sterilise in place operations, to ensure that there is no cross contamination and all work is developed in a sterile state.

There are many advantages in employing re-usable stainless steel equipment and in order to ensure that this usage is more practical, we have developed a pre-validated combination of PureVessel™s and PureCIP™.

Pre-Validation Testing

The pre-validation of the clean in place and sterilise in place operations is demonstrated at Factory Acceptance Testing (FAT), SAT and Qualification. All functions of the In Place and Sterilising In Place would be fully wet and dry tested and test results would be documented in the **'Pre-Factory Acceptance Test' (FAT)** protocol. Following successful completion of this protocol, the client will be invited to the FAT test, where all tests can be repeated or the pre-FAT tests results can be used.

PureCIP™ for Bioprocessing Upstream and Downstream

The PureCIP™ has been developed to provide a single Cleaning In Place facility that can be shared by multiple CIP clients in the Bioprocessing Upstream and Downstream process. Typical clients can include:

- PureVessel™
- Solution Preparation
- Media Preparation
- Bioreactor
- Ultrafiltration
- DepthFiltration
- TFF Filtration
- Centrifuges

PureCIP™ and MobileCIP® Cleaning In Place and Sterilising In Place System

The Suncombe PureCIP™ and MobileCIP® are The Biotech, Pharma and Critical Application cGMP Validatable Total Loss Cleaning In Place System and have been supplied to many biopharma organisations around the world over the last 50 years.

PureCIP™ Introduction

These 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.



Static PureCIP™



MobileCIP®

PureVessel™ & PureCIP™ Site Location and Layout

PureVessel™ and PureCIP™ Site Layout

As part of the project, consideration need to be given to the possible locations for the cleaning and the cleaning in place system. Depending on the layout of the facility there are a number of different methodologies that can be adopted. Suncombe engineers are able to advise the optimum selection for your specific requirement.

Suncombe COPStation™

The Suncombe COPStation™s have been supplied for over 55 years for providing a controlled location for cleaning mobile tanks, vessels, flexibles, hoses, change parts and process equipment. These units are used with a Cleaning in Place (CIP) system to provide the cleaning media and the control.

Developed to provide a permanent location for cleaning allowing the equipment to be connected in the same manner for each use. Once closed the COPStation™s provide an enclosed environment which minimises noise and provides a protective environment in case of any leaks of high temperature water or chemicals. Normally combined with one of our CIP systems, the COPStation™s are seamlessly integrated into the CIP systems control suite, which provides all safeguards, interlocks and a safety facilities.

Every COPStation™ is specifically designed for its particular application and is developed by Suncombe CIP engineers together with the client personnel to provide the optimum solution.



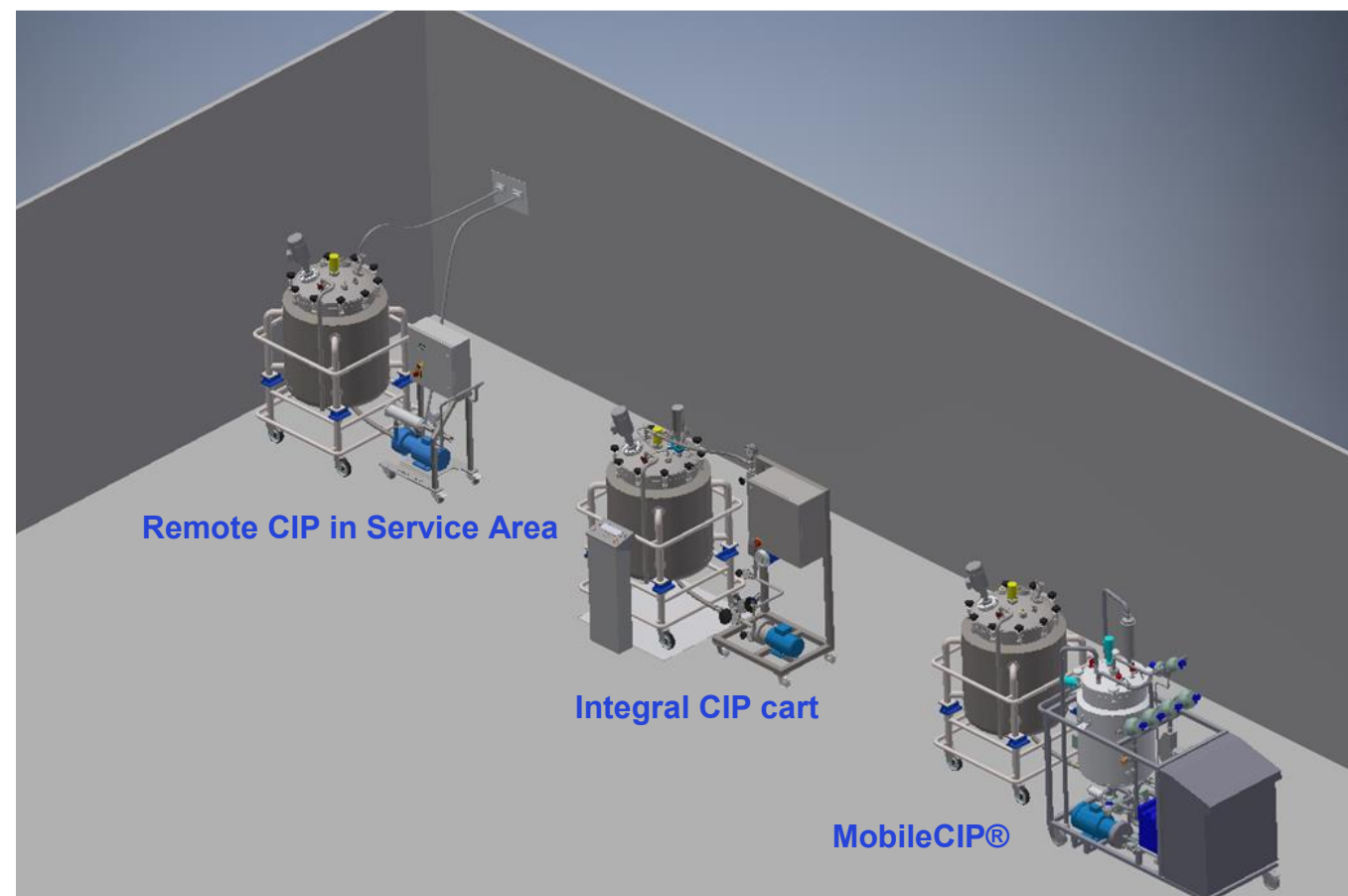
Suncombe COPStation™

Other CIP Methodologies

There are a number of other methodologies that can be adopted for CIP distribution to PureVessel™s. Suncombe engineers are able to advise the optimum selection for your specific requirement. The diagram below shows some typical options, as follows:

1. Remote CIP in Service Area - the CIP is remotely located and entry and exit of CIP/SIP solutions to and from the are id via a wall plate or utility panel.
2. Integral CIP cart - an Integral CIP cart is supplied with each vessel to enable CIP wherever the vessel is moved to. This version is un-common.
3. MobileCIP® - a MobileCIP® is taken into the area where the vessel is located and connected for local CIP/SIP.

Other CIP Methodologies



Smart Automation - The 'heartbeat' behind every Suncombe system

Automation Background

When it comes to reliable automation systems, Suncombe has been one of industry's manufacturers of choice for generations. With over 50 years of experience in the development, manufacture and validation of our versatile automation systems, we have many systems that are 20, 30 and 40 years old, still in operation around the world

Integrated Automation

Complimenting the great attention to detail paid to all of our systems, a detailed automation suite sits behind each one. Incorporating robust, proven hardware and software concepts, the systems have been extensively developed for the optimum process automation allowing straightforward integration into your facility.

In-House Personnel

With dedicated in-house automation personnel for electrical design, instrumentation and software, Suncombe engineers have tremendous experience in incorporating a broad range of control solutions to suit your specific control requirements.

Development

Suncombe offer a complete package, from the initial idea phase, though conceptual design and the detailed design all backed by our over 60 years as an independent company and with all of the required in depth technical knowledge and support, to guarantee the success of your project.

Advantages

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.

Example Standards and Guidelines

- GAMP Guidelines
- EU Machinery Directive
- EU Low Voltage Directive
- EU cGMP Guidelines
- EU EMC Electromagnetic Compatibility Directive
- EN 60204 Safety of machinery

PureVessel™ and PureCIP™ Integrated Automation

For CIP and SIP each PureVessel™ can individually 'plug' into the automation system, allowing the CIP/SIP to recognise the PureVessel™ being cleaned and select the optimum cycle for this vessel. On cycle completion an electronic and/or paper batch report is generated to accompany the clean/sterile vessel.

The automation system can incorporate an automated, screen based Standard Operating Procedure (SOP) which allows the system to be operated, under 21CFR part11, to maintain a full validatable batch record. This automated SOP can be expanded to cover the production operations as well.



Typical Operator Interface Graphics

