



**SUNCOMBE**  
CIP, BIOWASTE & PROCESS SOLUTIONS

**PureVessel™**  
**Sanitary - Sterile Vessels**



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

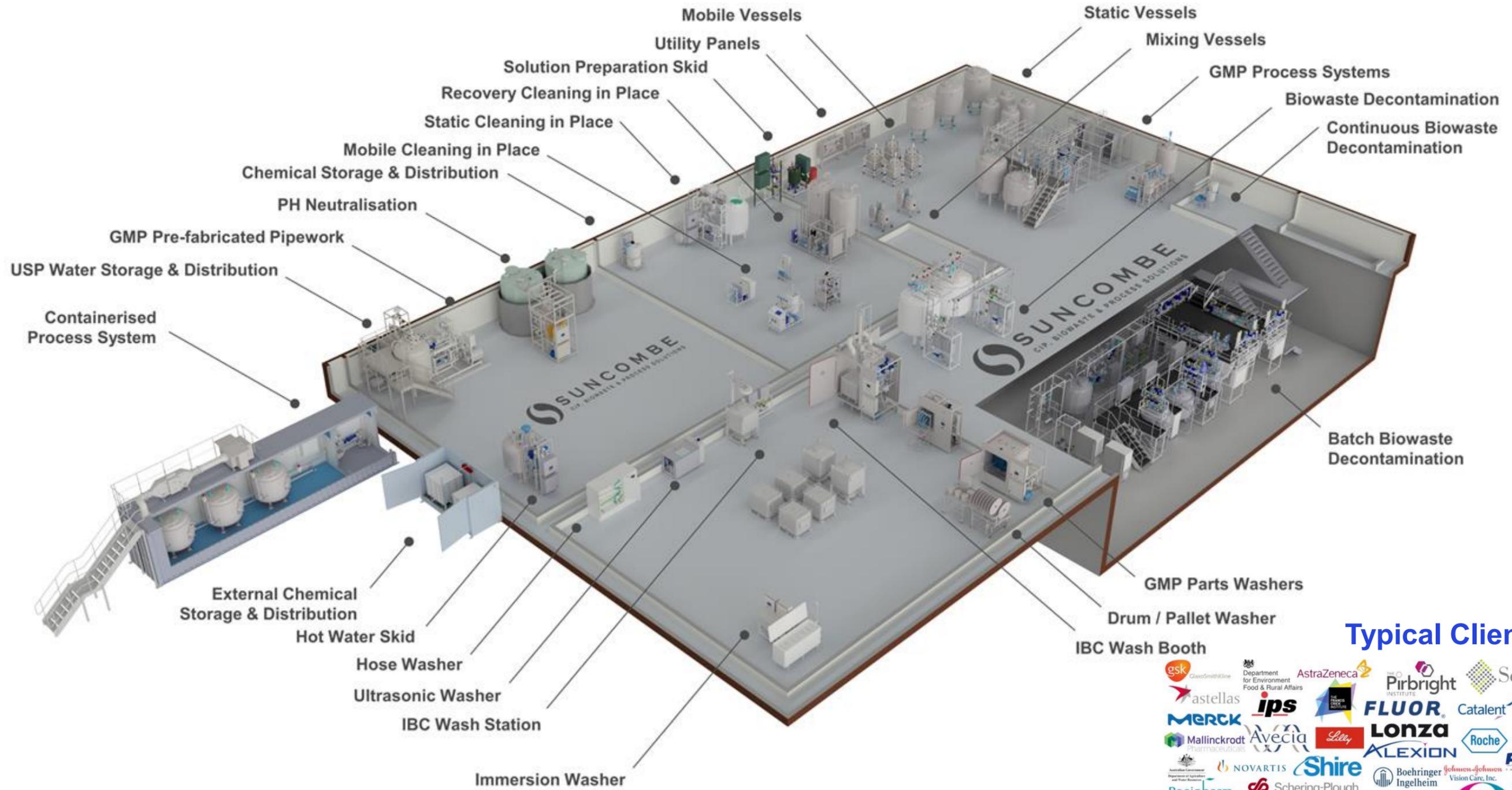
T +44(0)20-8443-3454 F +44(0)20-8443-3969 E [info@suncombe.com](mailto:info@suncombe.com) W [www.suncombe.com](http://www.suncombe.com)



# 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

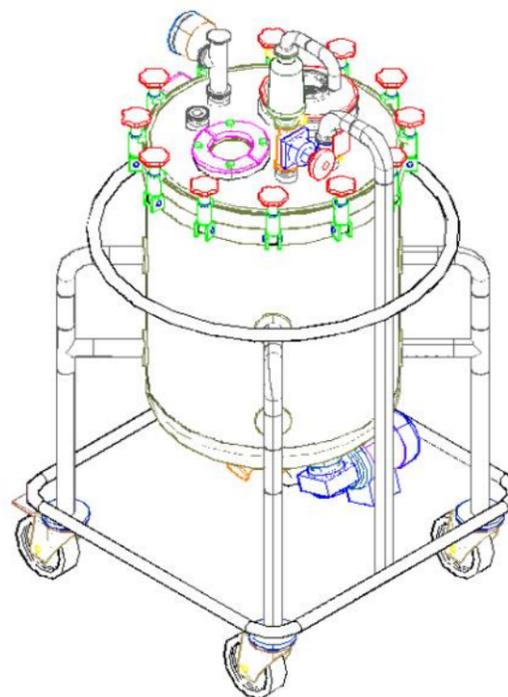
All functions of the equipment would be fully wet and dry tested and test results would be documented in the 'Pre-Factory Acceptance Test' (FAT) protocol. Following successful completion of this protocol, the client is invited to the FAT test, where all tests can be repeated or the pre-FAT tests results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

## Validation

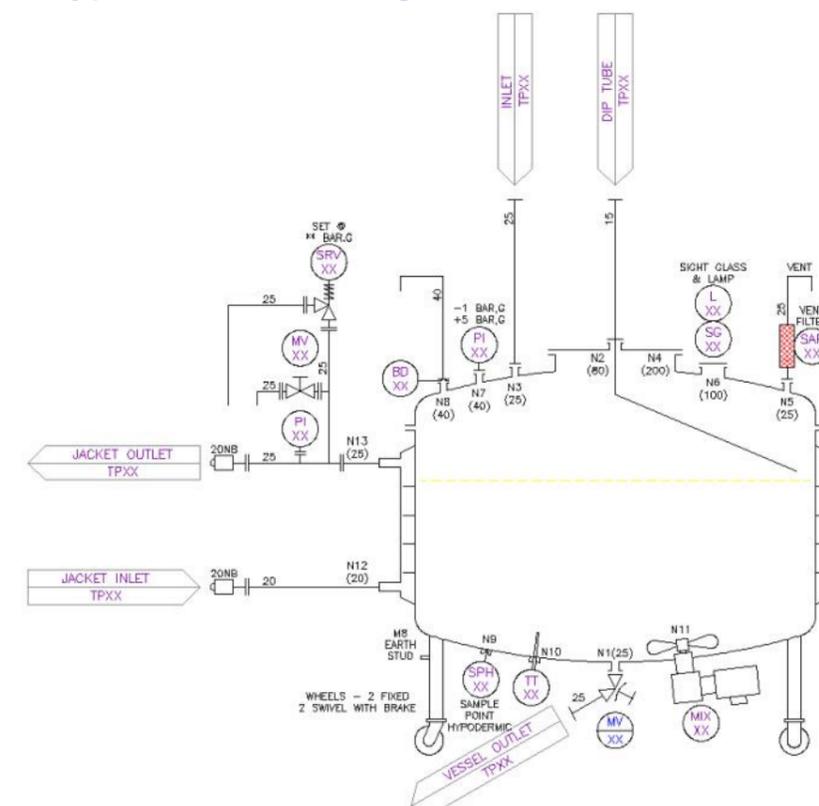
The PureVessel™ was developed to operate with the Suncombe PureCIP™, to provide a pre-validated Cleaning In Place and Sterilising In Place cycle. The pre-validated cycles are integrated into the PureCIP™ control system and an electronic batch record, secured to 21CFR part11, would be provided following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



Isometric View



Typical PFD Drawing

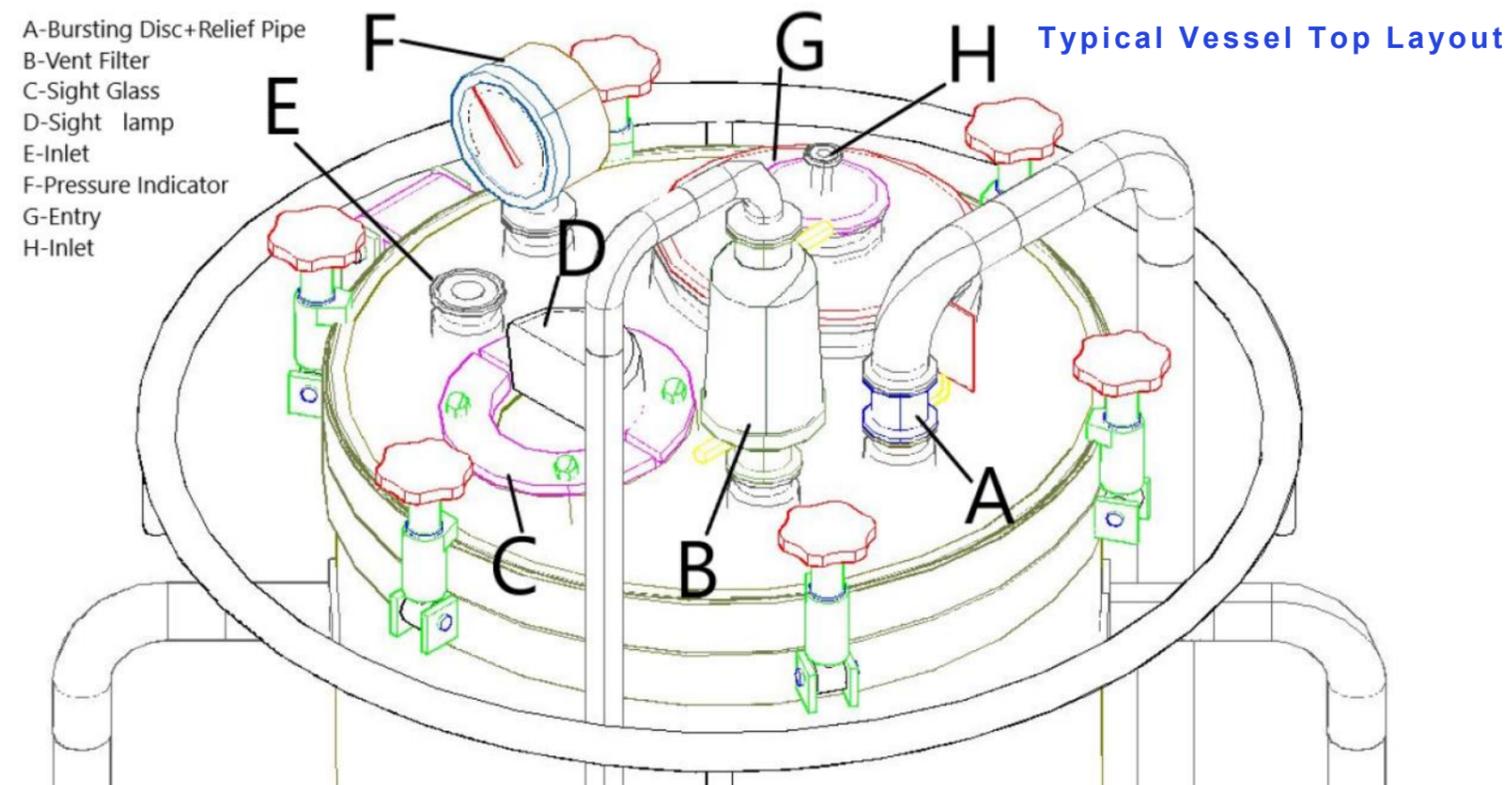
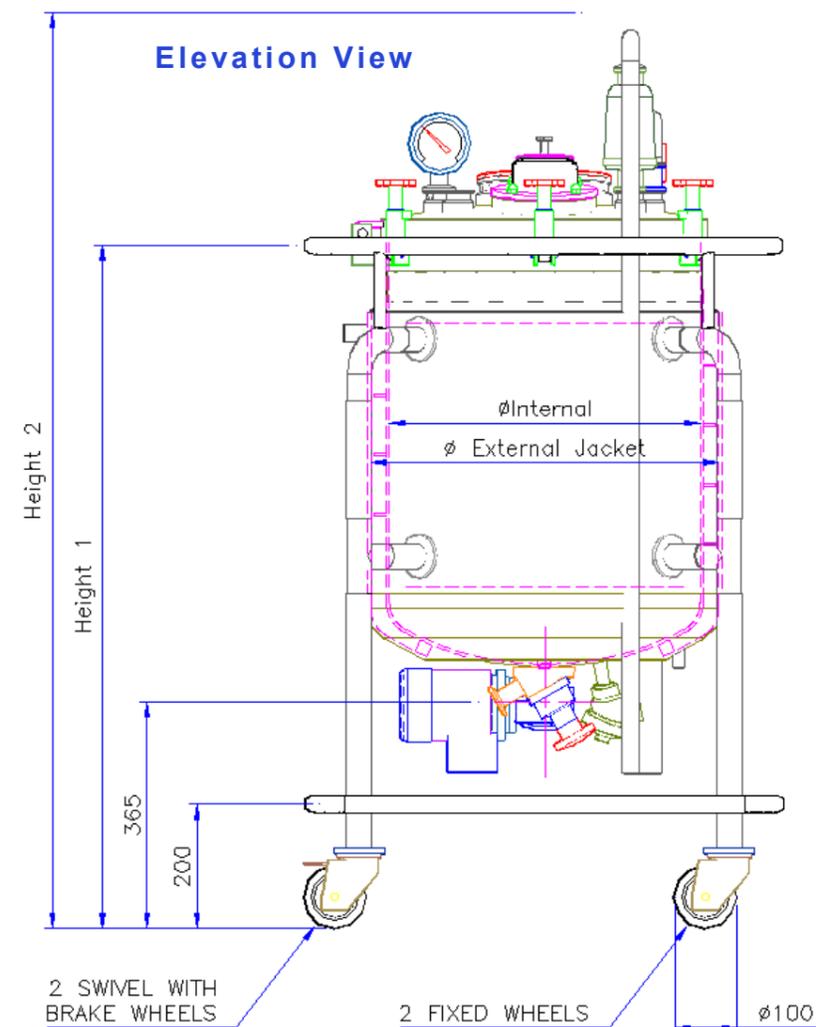


# PureVessel™ Sanitary - Sterile Vessel 10 to 750 Litre Capacity

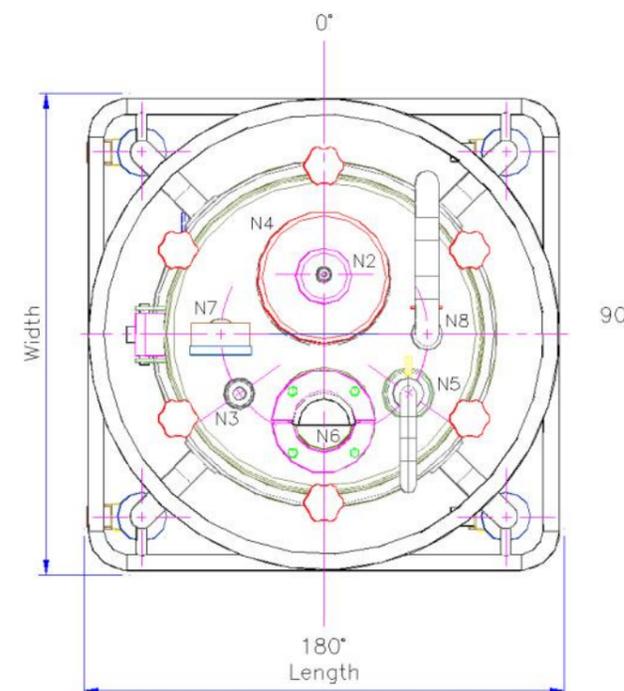
## Dimensions

| Part #<br><br>PureVessel™ | Dimensions             |                      |                      |                |                |          |           |
|---------------------------|------------------------|----------------------|----------------------|----------------|----------------|----------|-----------|
|                           | 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



Plan View



# PureVessel™ Sanitary - Sterile Vessel 10 to 750 Litre Capacity

## Specification and Options

| Description                                  | Included                                  | Optional                     |
|--|---|------------------------------|
| <b>Construction</b>                          |   |                              |
| 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   | -                            |
| <b>Nozzles and Ancillaries</b>               |   |                              |
| 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                        |
|--|----------------|---------------------------------|
| <b>Valves</b>  |                |                                 |
| 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 |
| <b>Mixer/Agitator</b>  |                |                                 |
| Magnetic Mixer   | Available      | -                               |
| Top Entry Mixer  | Available      | -                               |
| Mixer Speed Monitor  | Available      | -                               |
| <b>Instruments</b>   |                |                                 |
| 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      | -                               |
| <b>Jacket Ancillaries</b>  |                |                                 |
| Manual jacket air vent   | Available      | -                               |
| Jacket pressure relief   | Available      | -                               |
| QR jacket connections  | Available      | -                               |
| Jacket Pressure indicator  | Available      | -                               |
| <b>Automation</b>  |                |                                 |
| 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                     |
| <b>Records and Validation</b>  |                |                                 |
| Batch Records compliant with 21CFR11                                   | Available      | -                               |
| Audit Trail compliant with 21CFR11                                     | Available      | -                               |
| Windows Domain Users compliant with 21CFR11                            | Available      | -                               |
| <b>CIP/SIP Integration</b>   |                |                                 |
| 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
- Depth Filtration
- 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.



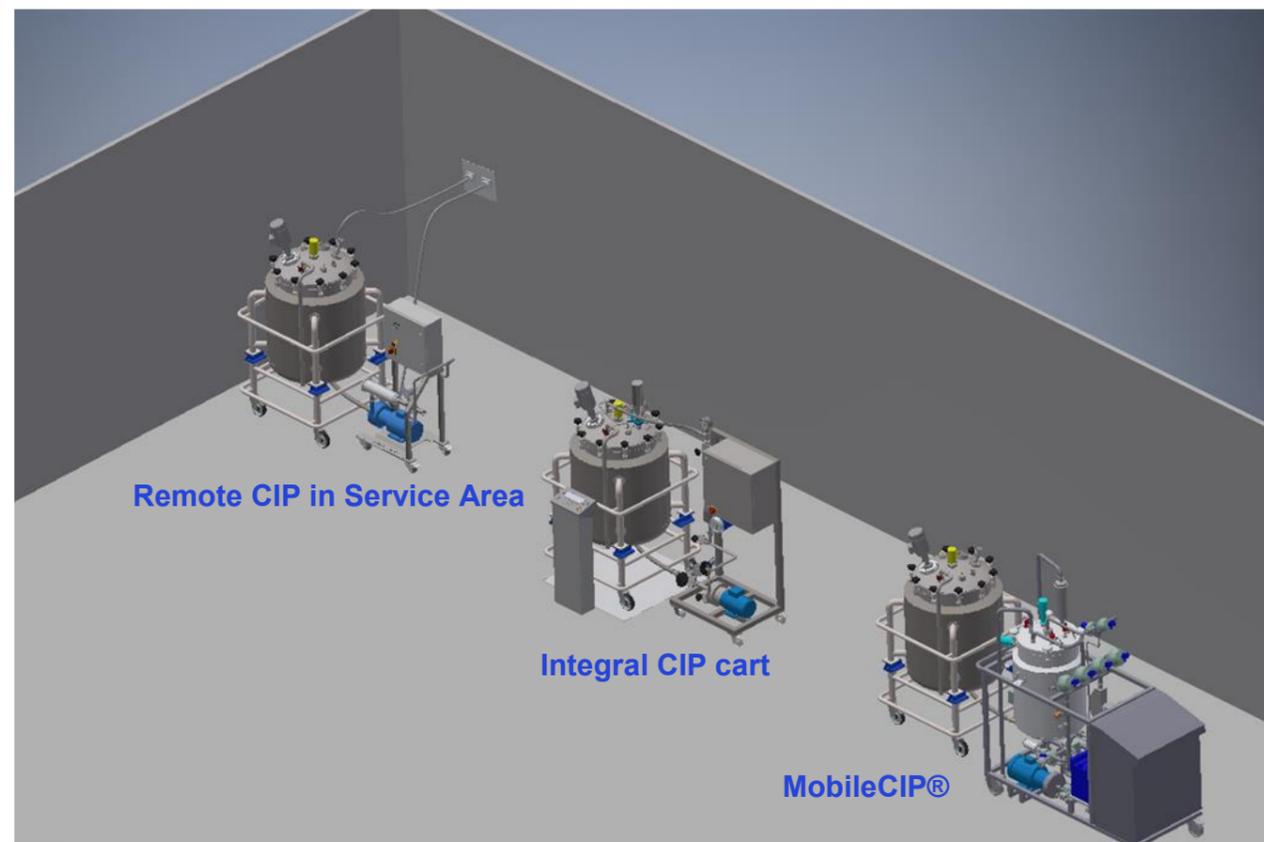
Suncombe COPStation™

### 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 area 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, through 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.

## 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.



## 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

## Typical Operator Interface Graphics

