

ControlSuite™ Automation System



Standalone and Integrated Automation Solutions for Suncombe Process Systems

Overview

Suncombe have been developing Automation systems for over 60 years and the ControlSuite™ is the latest version of the Suncombe Process automation system that has been developed over the last 60 years and uses a standard generic core, which is optimised for all Suncombe machines and processes. This commonality ensures ease of use, training and maintenance.

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.

Applications

- ✓ CIP/SIP/DIP and WIP Systems
- ✓ BioWaste Decontamination Systems
- ✓ GMP Washers
- ✓ High Purity Skids
- ✓ Utility Skids
- ✓ Solution, Buffer and Media Preparation systems
- ✓ USP Water Storage and High Purity Skids
- ✓ Custom applications
- ✓ Integrated Systems

Standards and Guidelines

- ✓ GAMP Guidelines
- ✓ 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

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DATASHEET

VERSION 1.4



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.

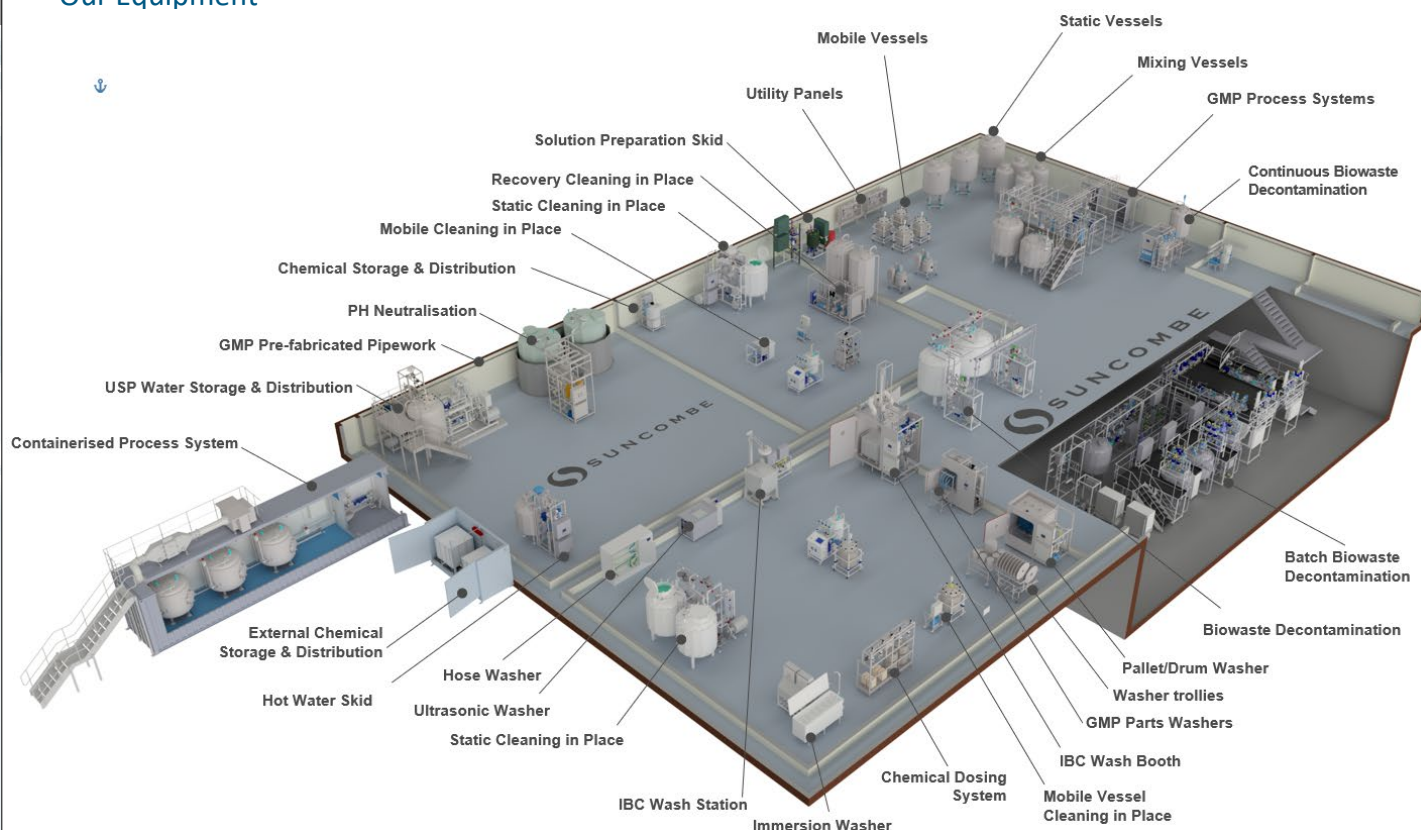
The team employ the very latest techniques, standards and best in class solutions. Having such a strong team allows us to offer the ability to carry out all of our work in-house, under our direct control

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



Suncombe Ltd

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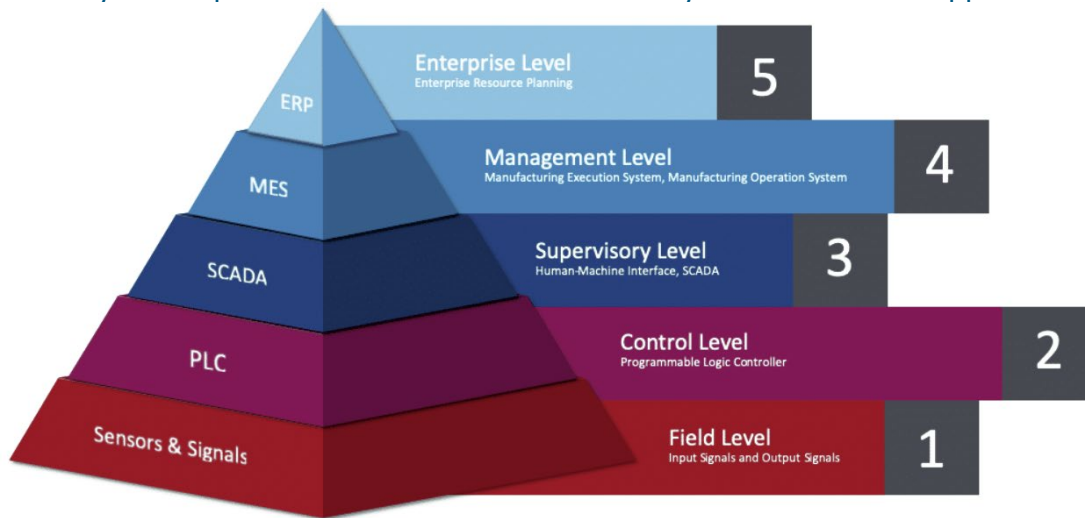
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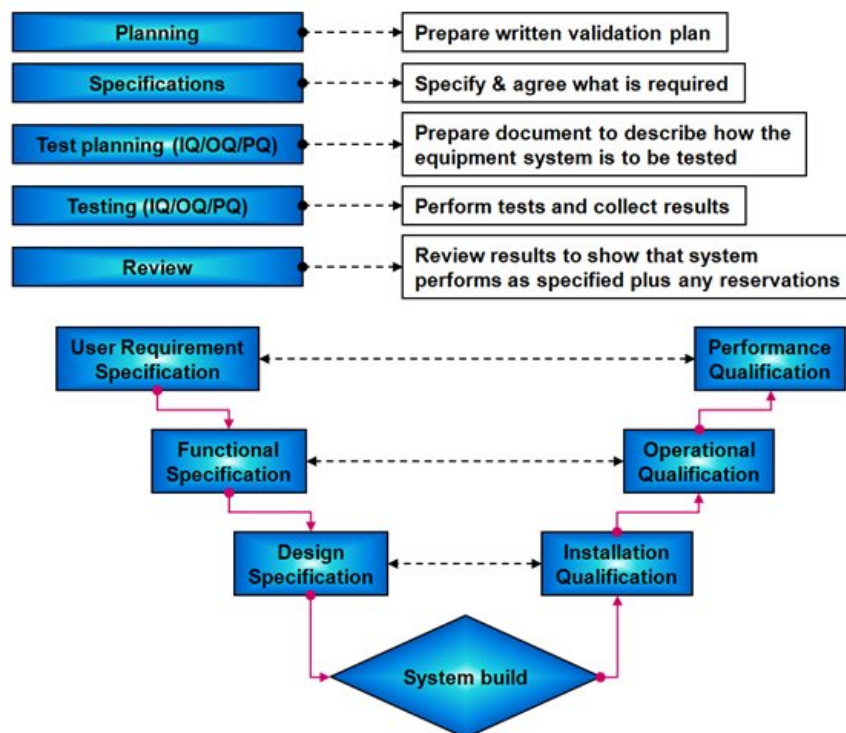
The layer model of technology and business process for manufacturing enterprises.

Suncombe systems operate at levels 1 to 3 with the ability to interface and support the higher levels.



Automation Lifecycle

Suncombe systems are 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.



Date Report Printed	Time Report is Printed	Cycle Report	SUNCOMBE
Cycle Started	Date/Time Cycle Started		
Cycle Started By	User that Initiated Cycle		
Cycle Number	Cycle Number	Cycle Name	
Batch Number	Batch Number [8 Alphanumeric]		
Operation 01	Operation Type	Total Time	
Operation 02	Operation Type	Total Time	
Operation 03	Operation Type	Total Time	
Operation 04	Operation Type	Total Time	
Operation 05	Operation Type	Total Time	
Operation 06	Operation Type	Total Time	
Operation 07	Operation Type	Total Time	
Operation 08	Operation Type	Total Time	
Operation 09	Operation Type	Total Time	
Operation 10	Operation Type	Total Time	
Operation 11	Operation Type	Total Time	
Operation 12	Operation Type	Total Time	
Operation 13	Operation Type	Total Time	
Operation 14	Operation Type	Total Time	
Operation 15	Operation Type	Total Time	
Cycle Total Time	Cycle Total Time		
Cycle Finished Time	Date/Time Cycle Finished		

Quality Components

Suncombe automation systems integrate quality components from first class manufacturers.



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Key Features	Benefits
Custom Design	All design and manufacture carried out by Suncombe personnel, based on a generic core, customised for every client's specific application.
Automation Layers	<p>The layer model of technology and business process for manufacturing enterprises identifies automation levels. These levels are:</p> <ul style="list-style-type: none"> • Level 0 Defines the actual physical processes. • Level 1 Defines the activities involved in sensing and manipulating the physical processes. • Level 2 Defines the activities of monitoring and controlling the physical processes. • Level 3 Defines the activities of workflow to produce the desired end products. • Level 4 Defines the business-related activities needed to manage a manufacturing operation. <p>Suncombe systems operate at levels 1 to 3 with the ability to interface and support the higher levels.</p>
In-House Personnel & Responsibility	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.
Data Interface	A Data Interface is provided for remote system interface.
Engineering Variables	Global variables are included in the system as Engineering Variables.
General Alarm	A volt-free fail-safe alarm contact is included.
Audible and Visual Alarm	The HMI is used to provide an audible and visual alarm.
Alarms	All alarms would be displayed on the HMI and need to be acknowledged before being reset in the alarm list.
Record Storage	All records are stored to the HMI storage media and can also be copied onto a site network.
Heartbeat	A communication alarm (heartbeat) is included for confirmation of communication.
Audit trail / Electronic records	An Electronic record of actions performed on the system will be retained of data with a secure date/time stamp, as defined in the FDS.
Active Directory	User rights and access can be controlled through the clients existing Active Directory.
Electronic Signatures	Electronic signature features are included compliant with 21CFR11.
System Clock	System Clock Date/Time can be derived via automatic synchronization from a certifiable source.
Back-up and Restore	A backup and restore procedure is provided to allow full backup and restore of the PLC and HMI data.
Licenses	Licenses are included for the runtime version of all of the software products incorporated on the system.
Software Commenting	All software code would be commented to allow comprehension.

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ControlSuite™ Operator Interface Images

