



SUNCOMBE

CIP, BIOWASTE & PROCESS SOLUTIONS

IsolatorCIP™



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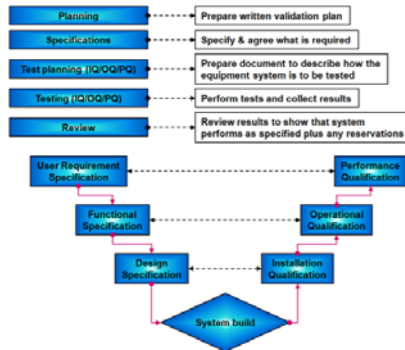
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IsolatorCIP™

Incorporating, innovative and novel methodologies, the **IsolatorCIP™** was developed following industry demands, to provide a standard and customisable system, allowing reliable, repeatable and validatable CIP and WIP of Isolators and Gloveboxes. Designed for aqueous, detergent and/or solvent cleaning, the **IsolatorCIP™** was developed to incorporate "Lean Manufacturing Principles" ensuring that waste is minimised and efficiency is maximised. Utilising variable duty configurations, the **IsolatorCIP™** can also be used to effectively clean processing equipment enclosed in the isolator or fitted onto the in-feed or discharge. Incorporating replaceable modules, the base unit is a fully hygienic version, with optional modules for sterile use including sanitising and sterilising configurations.

Validation/ Documentation

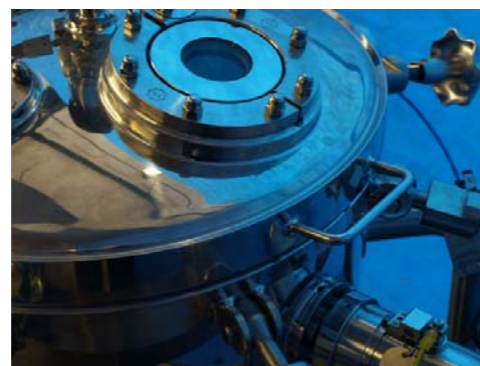
The lifecycle approach is adopted (DQ, FDS, HDS, SDS, FAT, SAT, IQ & OQ) with validation being key to every stage of the development process, including Factory Acceptance Testing (FAT), SAT and Qualification.



CIP Vessels or In-line Systems

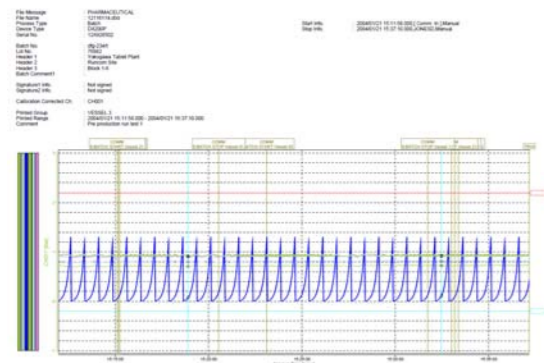
Dependant on utilities available the **Isolator-CIP™** is available with:

- 316L stainless steel atmospheric tanks
- 316L stainless steel pressure vessels
- In-line versions without a vessel



CIPSuite™ Batch Records

Hard copy printed records or Electronically recorded Batch records.



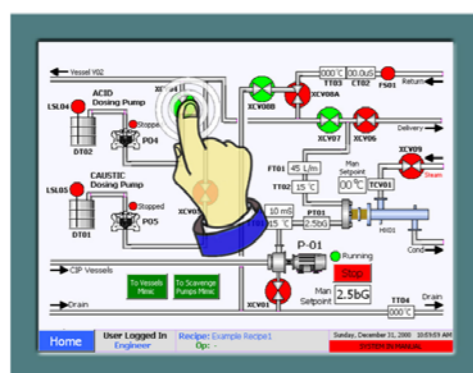
Automation System

The Integrated CIPSuite™ automation packages are designed to be operator friendly and simple to use whilst providing flexibility and optimisation. Reliable and robust, they have been developed over the last 10 years in co-ordination with clients operations staff, engineers and validation staff. They encompass all elements required to provide a controllable, repeatable automatic system.

A range of automation levels are available, starting from low level semi-automated systems, through low and mid level PLC and HMI versions, to advanced SCADA based systems. All levels are designed with the facilities required to provide a repeatable automated cycle.



Level 1000 Basic System



Level 3000 Advanced System

Manufacturing Standards

- 316 stainless steel product contact parts, 304 non-contact parts, Hastelloy and Duplex Stainless
- ASME BPE, 3A, cGMP standards, fully drainable, crevice free.
- T.I.G. Welding; using an argon gas purge, using a computer controlled enclosed head orbital welding plant, carried out by technicians coded to EN 287, to Suncombe procedures coded to EN ISO 15609, tested to EN ISO 15614 Part 1.
- ASME BPE standard Pipework, fully annealed, chemistry to ASTM A-269, manufactured to ASTM A-270, and 3A Standard.



Instrumentation

High quality analytical and process instrumentation.



Process Valves

Sanitary and sterile process routing valves providing mixproof, dead leg free routing.



Sanitary Pump

In built Sanitary Centrifugal feed and liquid ring return pumps

ASME BPE Pipework and Triclamp Fittings



CIPSuite4™ Intelligent Options

The CIPSuite™ automation packages have options for:

- Historical Archiving
- Trending
- Web Access
- 21CFR11 Compliance
- Server/Client Architecture
- Networking
- OPC, SQL, ODBC, OLE-DB Integration
- Downtime Monitor (for OEE)

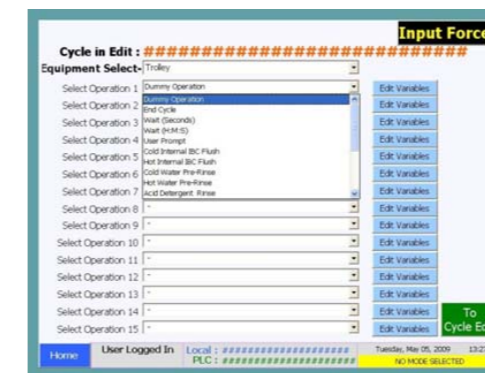


Totally Integrated Automation

CIPSuite™ 2 to 4 Versatile Recipe Control

Build your own recipe/operational method from sequences, including:

- Flush to drain
- Pre-rinse
- Chemical make-up
- Recirculation Cleaning
- Single Pass Cleaning
- Final rinse
- Drain
- Air Purge
- Self CIP



LEAN Technology

Adopting LEAN principles, all Suncombe products are developed to ensure they minimise utilities and time, whilst ensuring the safety of the operators and the efficiency of the processing. Utilising innovative concepts, they incorporate a combination of traditional and new technologies to provide an environmentally friendly, low utility and energy usage facility that is safe and ergonomic for the operators. Our automated systems are configured to incorporate LEAN principles including Overall Equipment Effectiveness, Energy Lean, downtime maintenance and other procedures.

