SUNCOMBE

Introduction to Washers

Cleaning and Hygienic Processing Solutions Since 1961

www.suncombe.com

Introduction to Suncombe

- 1961 -2011 - 50 years of Engineering Excellence
- Pioneers of Hygienic Processing, Washing and Cleaning
- Located in London, United Kingdom
- Worldwide network of sales and service agents
- UK Design and Manufacture to CE, cGMP, ASME BPE, EHEDG, GAMP, ATEX
- In-house personnel for all disciplines
- Motivated, dedicated and experienced Long Term Workforce
- Single point of contact for all aspects of a Project
- Validated Production including full documentation and testing
- Research and development for special requirements

Topics to be Covered

1. What is Washing?
2. What is Contamination?
3. Result of Washing
4. What is SIP?
5. Chemical SIP
6. Thermal SIP
7. How Washing Works
8. Washing Energy Sources
9. Washer Techniques
10. Types of Washers
11. Manufacturing
12. Automation
13. Validation

What is Washing?

The definition of washing is “to clean with water and, typically, soap or detergent and clean as free from dirt, marks, or stains. The definition of cleaning is “to expunge all residue of prior materials” or more informally “the removal of contaminants”.

What is Contamination?

Contamination is the presence of particles, chemicals, and other undesirable substances. It can take on many different forms, each of which may requires a specific cleaning mechanism for effective removal. In addition to considering the actual contamination we also need to consider the size, shape, thickness, adherence, positioning and many other factors, which may also have an effect on the selection of cleaning mechanism.

Result of Washing

Washing results in the equipment being chemically clean. This is defined as

"the removal of all residues of soil and all washing agents so that contact with the cleaned surface does not result in physical contamination".

If the equipment being cleaned needs to be micro-biologically clean then an additional process can be carried out. This process is called SIP.

What is SIP?

SIP or in its full form, Sterilising In Place is the generic term for sanitizing, disinfecting or sterilizing equipment normally after washing.

SIP results in the removal of microbiological contamination.

Chemical SIP

Sanitizing (or disinfecting) results in the removal of many of the remaining microbiological contamination. Sanitation or Disinfection is normally applied after washing. It can be achieved by many different methods depending on the application. Typical sanitizing methodologies include; Chemical sanitiser or disinfectant, steam, hot water, ozone, VHP etc.

Thermal SIP

Thermal sterilisation is achieved by the application of steam or hot water at a suitable temperature for a suitable time. It results in the removal of remaining microbiological contamination.

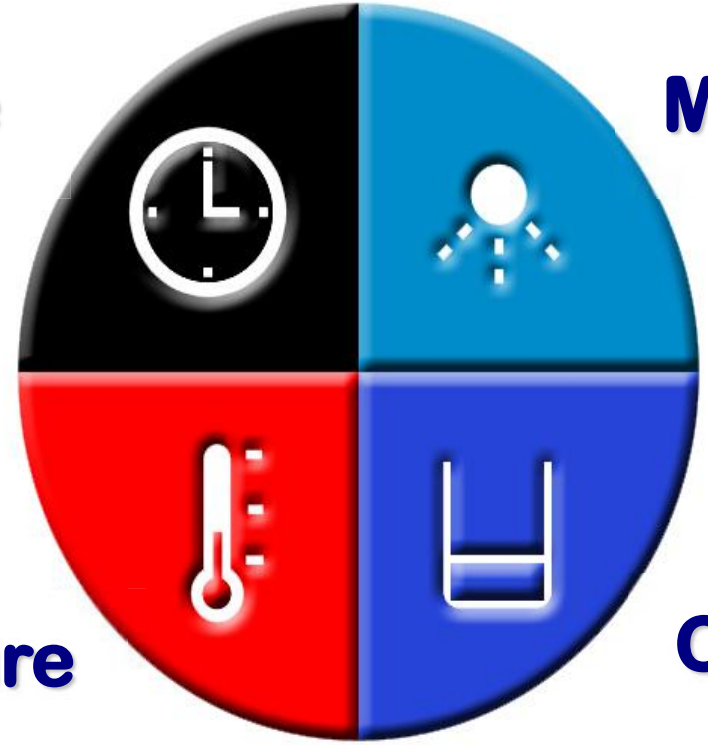
How Washing Works

The science of washing is based on applying the required amount of energy to the equipment to ensure that it is cleaned. The energy is primarily provided by the solution temperature (thermal energy), the use of detergent or solvent (chemical energy) and the application of kinetic energy for a defined time period.

Washing Energy Sources

Time

Mechanical



Temperature

Chemical

Temperature

Effect on cleaning operation:

Soil	Effect
Proteins	medium
Fats	good
Sugars	good
Salts	good

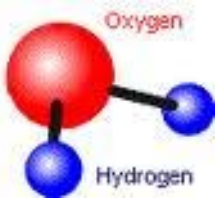
Note : ***Generally a 10°C temperature increase will improve cleaning efficiency by 50% (above 30°C)***

Chemical (Detergent)

Effect on cleaning operation:

Soil	Water	Alkali	Acid
Proteins	poor	good	medium
Fats	poor	good	medium
Sugars	good	--	--
Salts	medium	medium	good

Note : ***required concentrations depend on soil level, processes used, working time, temperature, ….***



Water Used for Cleaning Process

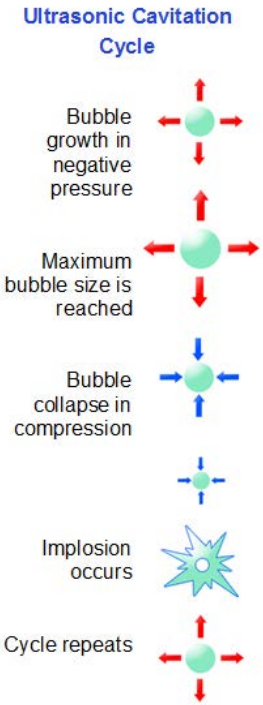
- Quality of Water used for aqueous cleaning is critical for performance:
  - Chemical properties (pH, hardness, etc.)
  - Biological properties (bioburden, endotoxins)

Mechanical

Effect on cleaning operation:

Most washing processes require mechanical energy in addition to the other energy sources.

The mechanical energy is determined by the type of washer selected, and can include spray, agitation, turbulation, cavitation and ultrasonic.



Time (Duration)

The duration of each washing step is to be optimised according to the main following parameters :

- Type of Equipment
- Type of Wash Carried Out
- Cleaning solution temperature
- Chemical concentration
- Mechanical Energy Process

Washers Techniques

- Immersion
- Immersion with Agitation
- Immersion with Turbulation
- Spray Cleaning
- Fogging
- Ultrasonic Cleaning
- Air Purging
- Drying and Cooling

Types of Washers

- Enclosed Cabinet Washers
- Spray Washers
- Combined Washers
- Immersion Tanks

PureKleen™ Parts Washer
Fold Down Door

Validated Spray Cleaning and Drying, Single Fold Down Door or Pass Through, Full Containment, Bespoke Trolley Designs, Special Chamber Sizes

PureKleen™ Parts Washer
Sliding Door

Validated Spray Cleaning and Drying, Single Slide Down Door or Pass Through, Full Containment, Bespoke Trolley Designs, Special Chamber Sizes

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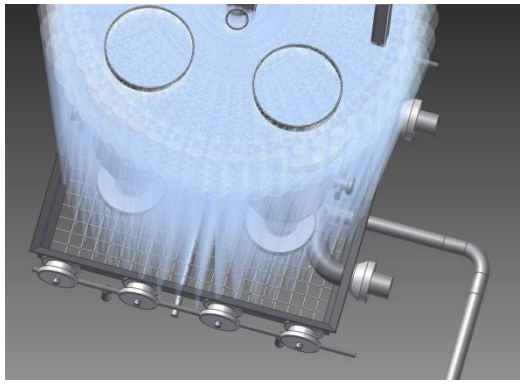
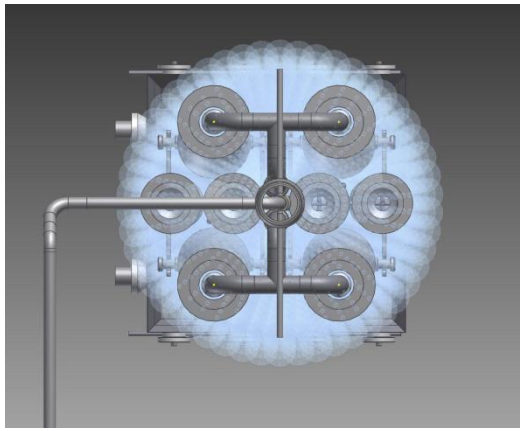
PureKleen™ Parts Washer with Side Access

PureKleen™ Parts Washer with Side Access in production (note stainless steel sheet is still covered with plastic protective sheet)

PureKleen™ Parts Washer Spray Visualisation





3D Modeling of Spray for validated Cleaning and Drying

SteriWasher™ Parts Washer

Validated Spray Cleaning and Drying, Single Hinged Door or Pass Through, Full Containment, Bespoke Trolley Designs, Special Chamber Sizes

SonoKleen™ Parts Washer

Combination PartsWasher for Spray Cleaning, Turbulation, Flood Cleaning, Ultrasonic and Drying, Custom Chamber Sizes and Designs, Single Door or Pass Through

IBC Washbooth

Validated Internal and External Spray Cleaning and Drying, Full Containment, Single Door or Pass Through, Floor or Pit Mounted, Cone or Split Valve Operation

General Purpose Washbooth

Loading Trolley

Validated Spray Cleaning and Drying, Full Containment, Single Door or Pass Through, Floor or Pit Mounted, Custom Trolleys for cleaning components

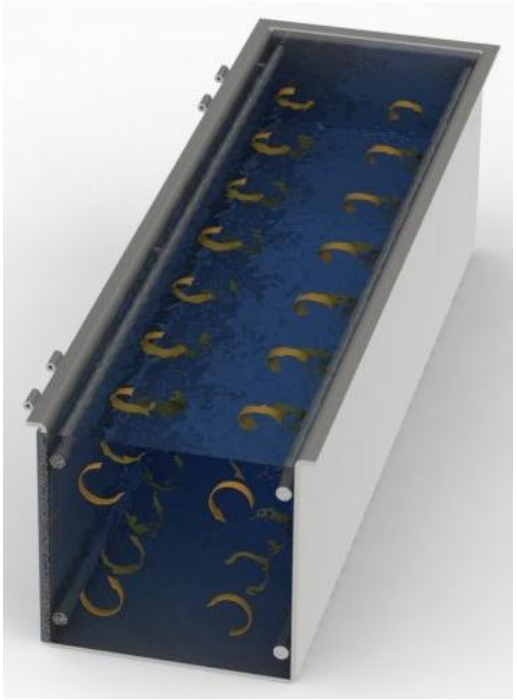
DrumWasher™

Spray Cleaning and Drying, Hinged or Fold Down Doors, Custom Chamber Sizes and Designs, Single Door or Pass Through

UltraWasher™

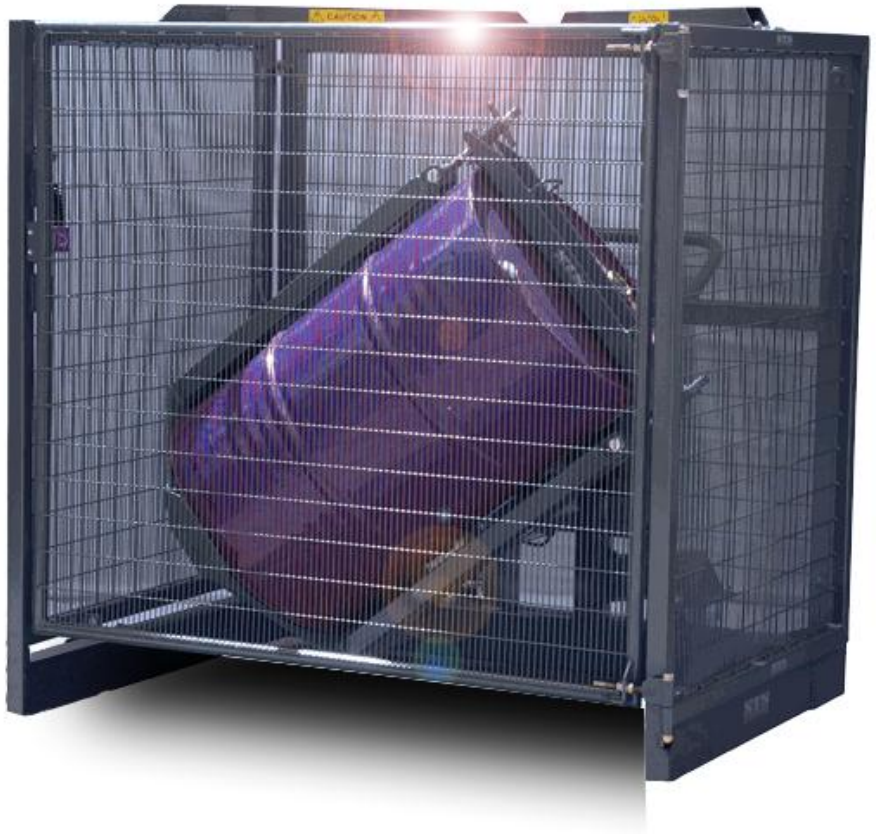
Internal and External Spray Cleaning and Drying, Open Bottomed, Single Door or Pass Through, IBC Inverter Option

ImmersionWasher™



Immersion, agitation, turbulation and spray cleaning for parts and hoses

DrumRoll™



Internal and External Spray Cleaning, Drum Loader and Inverter, Single or Multiple Drum Mounting,

MediWasher™

MediWasher™ are front loading or pass-through large washer/disinfectors, which are designed for the cleaning of Bed frames, Trolleys, Commodes, Furniture, Operating Tables

IBC WashStation

Validated Internal Spray Cleaning and Drying of IBCs

www.suncombe.com

CIP Washing

CIP or in its full form, Cleaning In Place,
is defined as

”Equipment and techniques to allow cleaning of process equipment without dismantling or manual cleaning with minimal operator involvement”.

CIP Washing Equipment

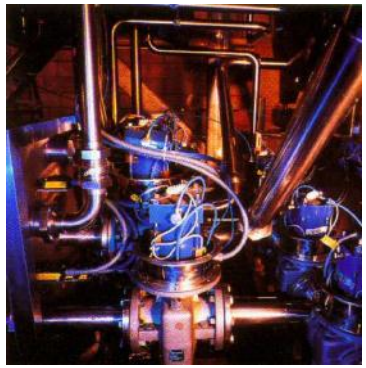
We offer a separate full range of equipment for Cleaning In Place

Typical Static CIP System

Typical Mobile CIP System

Manufacturing

- 316L Stainless Steel, Duplex Stainless and Hastelloy materials.
- Stainless fully welded supports and framework
- Enclosed head orbital Welding Equipment
- Crevice free sanitary construction



Sanitary Standard

- Materials: Wetted parts 316 stainless steel, non wetted parts 304 stainless steel
- Finishes: wetted parts surface descaled and bead removed, non wetted parts satin polished
- Pipework Material: Welded 316 Stainless Steel tubing, fully annealed, chemistry to ASTM A-269, manufactured to ASTM A-270. Descaled bore, bead removed internally, polish 150 grit O.D.
- Pipework Standard: Configured to Good Manufacturing and Engineering Practices (cGMP). Designed to hygienic specifications. Free draining.
- Welding: Welding would be of T.I.G. (Tungsten Inert Gas) method; using an internal and external 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 EN288.

- Weld finishing: Pipework welds, externally cleaned, fabrication welds cleaned and buffed
- Inspection: 100% visual, Hydrostatic Testing
- Material Documentation: 2.2 certificates of conformity, generic welder certificates, generic welding machine certificates, generic welding procedures, no weld logs or weld maps
- Process fittings Triclamp, Service fittings BSP or Flanged

- Process valves: Hygienic specification butterfly valves, 316 stainless steel, EPDM gaskets
- Service valves yellow metal gate type
- Documentation: Certificate of conformance, GA Drawing, P&ID, Electrical Drawings, Operation manual, Visual inspection report

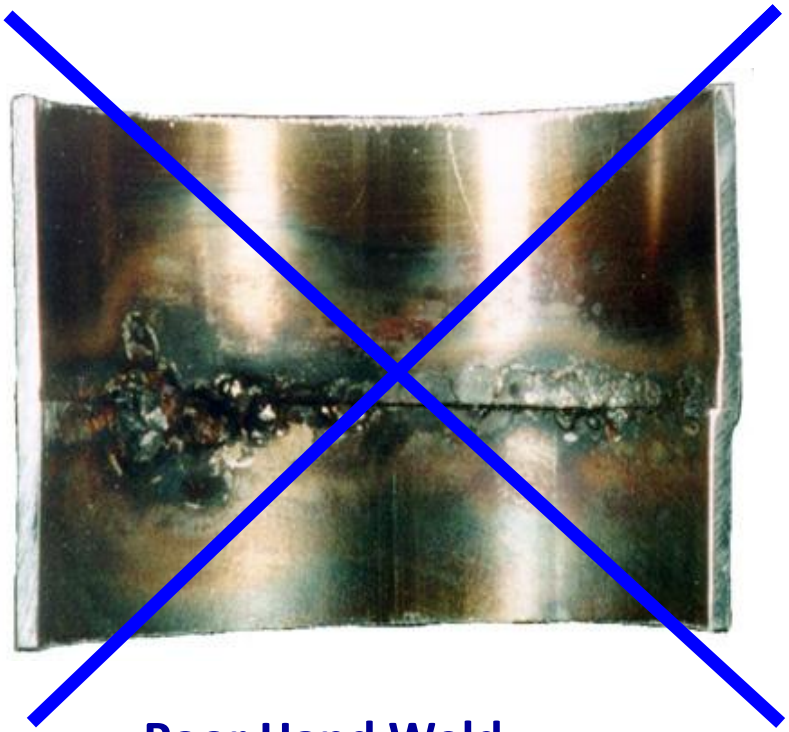
ASME BPE Standard

- Materials: Wetted parts 316L stainless steel, non wetted parts 304 stainless steel
- Finishes: wetted parts surface RA 0.5um max, non wetted parts RA 0.9um max
- Pipework Material: ASME BPE standard, Welded 316L Stainless Steel Bio-pharmaceutical specification tubing, fully annealed, chemistry to ASTM A-269, manufactured to ASTM A-270, and 3A Standard.
- Pipework Standard: Configured to Good Manufacturing and Engineering Practices (cGMP). Designed to ASME BPE specifications. Free draining.
- Welding: Welding would be of T.I.G. (Tungsten Inert Gas) method; using an internal and external 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 EN288.

- Inspection: 100% visual external, 100% Dye-penetrant , 20% Boroscope
- Material Documentation: 3.1b material certificates linked to each part, weld maps, weld logs, welder certificates, welding machine certificates, welding procedures. Welding profiles and maps will be compiled for all welds.
- Process fittings Triclamp, Service fittings BSP or Flanged
- Process valves: Pharmaceutical specification diaphragm valves, 316 stainless steel, 0.5um max, internal finish, fully certified and documented, PTFE sandwich gaskets (FDA compliant material).

- Service valves yellow metal gate type
- Documentation: Full documentation package as per enquiry pack.

Welding Techniques



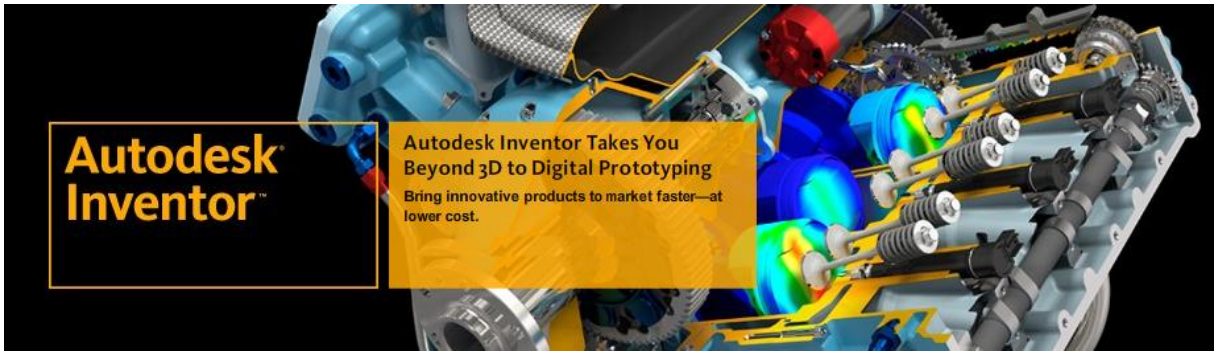
Poor Hand Weld

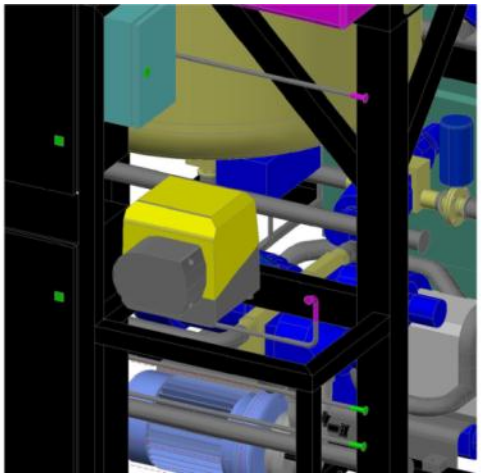
- Difficult to clean
- Drainage problems
- Corrosion

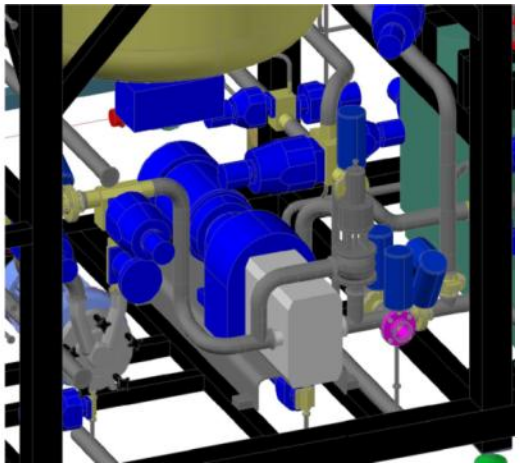
Orbital Weld

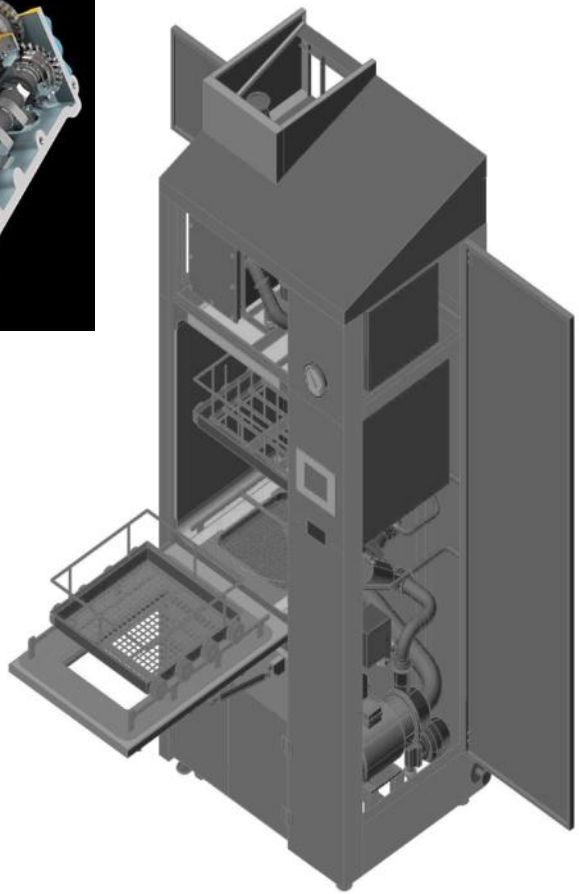
3D Modelling

- Autodesk Inventor 3D Modelling is employed throughout the design process









Automation Systems

- PLC Based Siemens or Allen Bradley Recipe Control Systems
- 4” – 15” HMI or Industrial PC Operator Interface
- Designed to GAMP guidelines and produced in house

Automation Systems

CIPSuite#1™ & ControlSuite#1™

- PLC Based **Suite#1™** - 1 Recipe basic Control Systems
- PLC Based **Suite#1-6™** - 6 Recipe basic Control Systems
- Hard Coded fixed Recipes with variable time parameters
- Designed to GAMP guidelines and produced in house

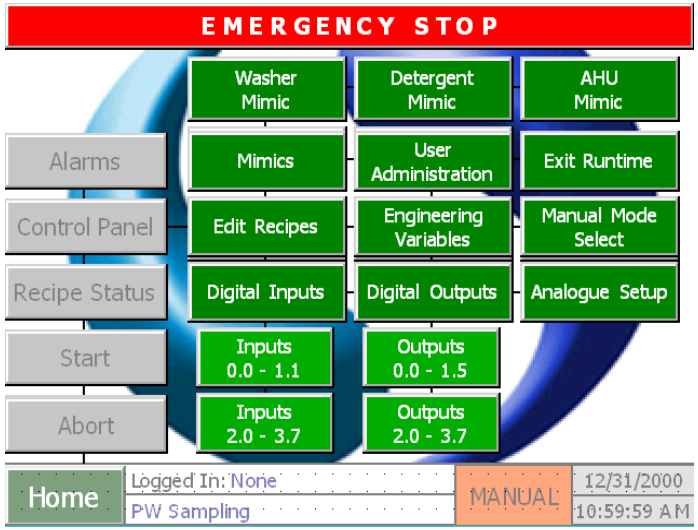
CIPSuite#1™

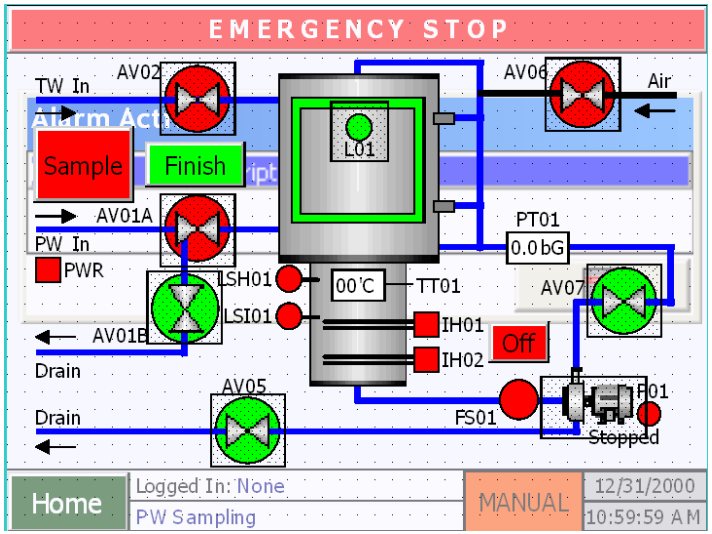
CIPSuite#1-6™

Automation Systems

CIPSuite#2™ & ControlSuite#2™

- PLC Based **Suite#2™** 100 Recipe mid-level Control Systems
- 10 Steps per recipe, 10 variables per step
- 6” Full Colour HMI with option for printout, Interface support, no networking

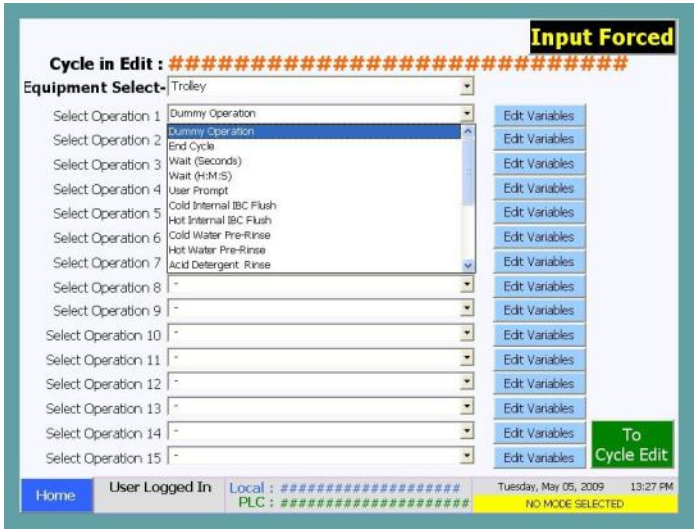


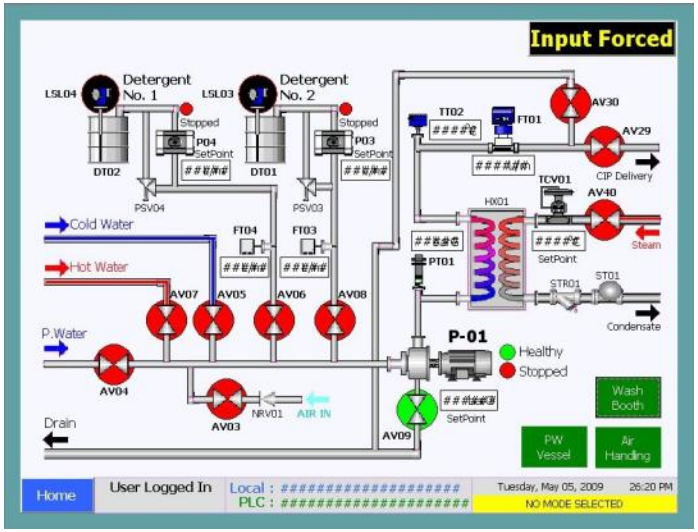


Automation Systems

CIPSuite#3™ & ControlSuite#3™

- PLC Based **Suite#3™** 100 Recipe advanced Control Systems
- 15 Steps per recipe, 15 variables per step
- 8” or 10” Full Colour HMI with printout
- Interface support, networking

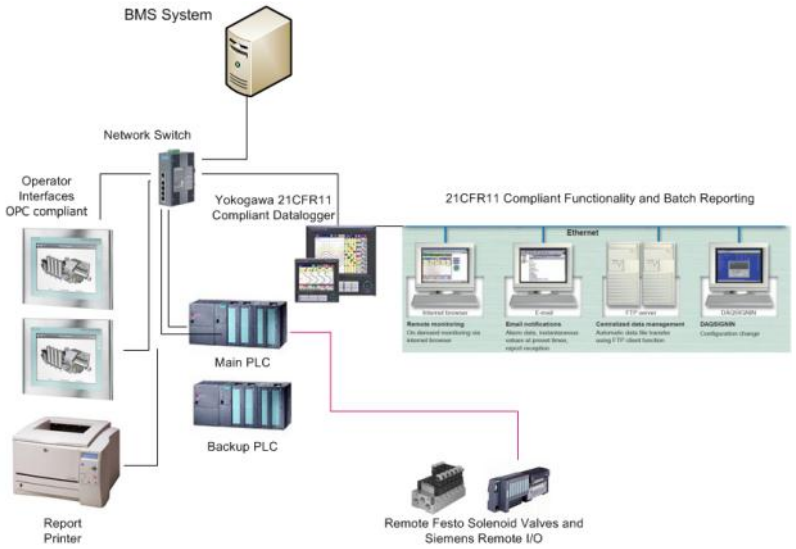


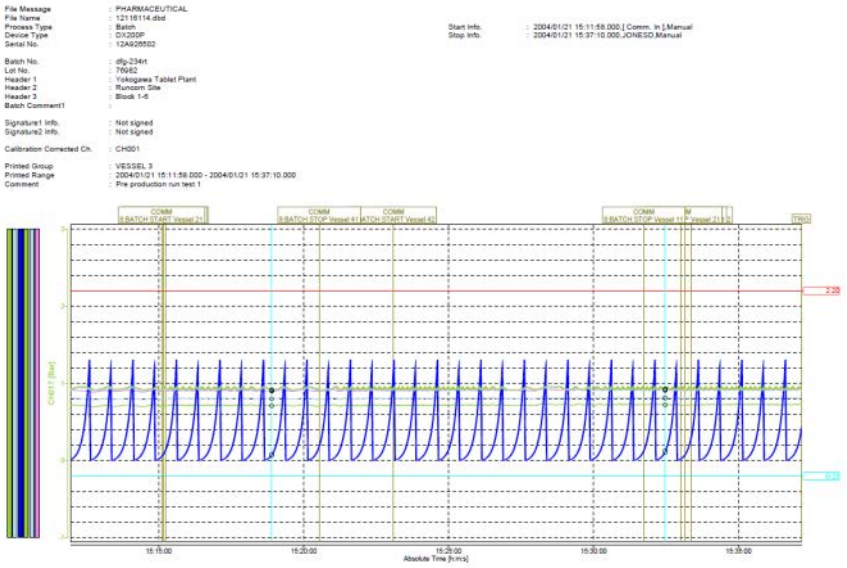


Automation Systems

Suite#3™ with 21CFR11 reporting

- PLC Based **Suite#3™** 100 Recipe advanced Control Systems
- 8” or 10” Full Colour HMI with printout, Interface support, networking
- 21CFR11 compliant Electronic records and Batch Reports



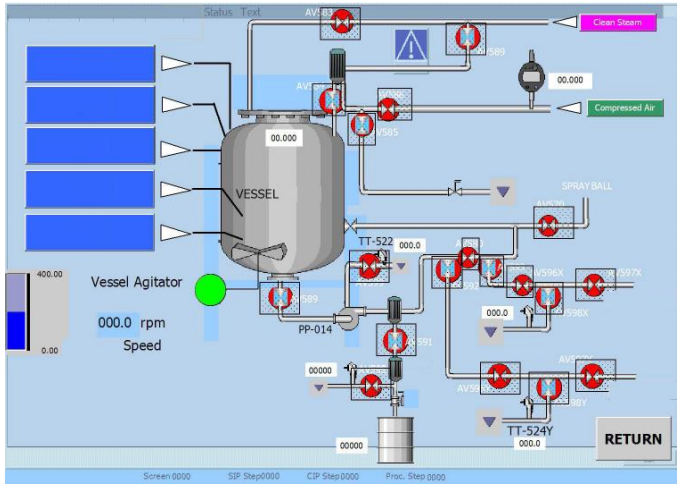


Automation Systems

CIPSuite#4™ & ControlSuite#4™

- PLC Based **Suite#4™** 100 Recipe high level Control Systems
- 15 Steps per recipe, 15 variables per step
- Electronic record storage facilities and batch reporting compliant with 21CFR11
- Industrial PC running iFIX or WINCC SCADA, full interfacing and networking

Batch Header Information	
Batch	FGHI1234
Start	04/09/2008 08:48:00
End	04/09/2008 08:51:00
Product	
Operator	
Desalt Solution (kg)	24.5
Purified Water (kg)	96.0

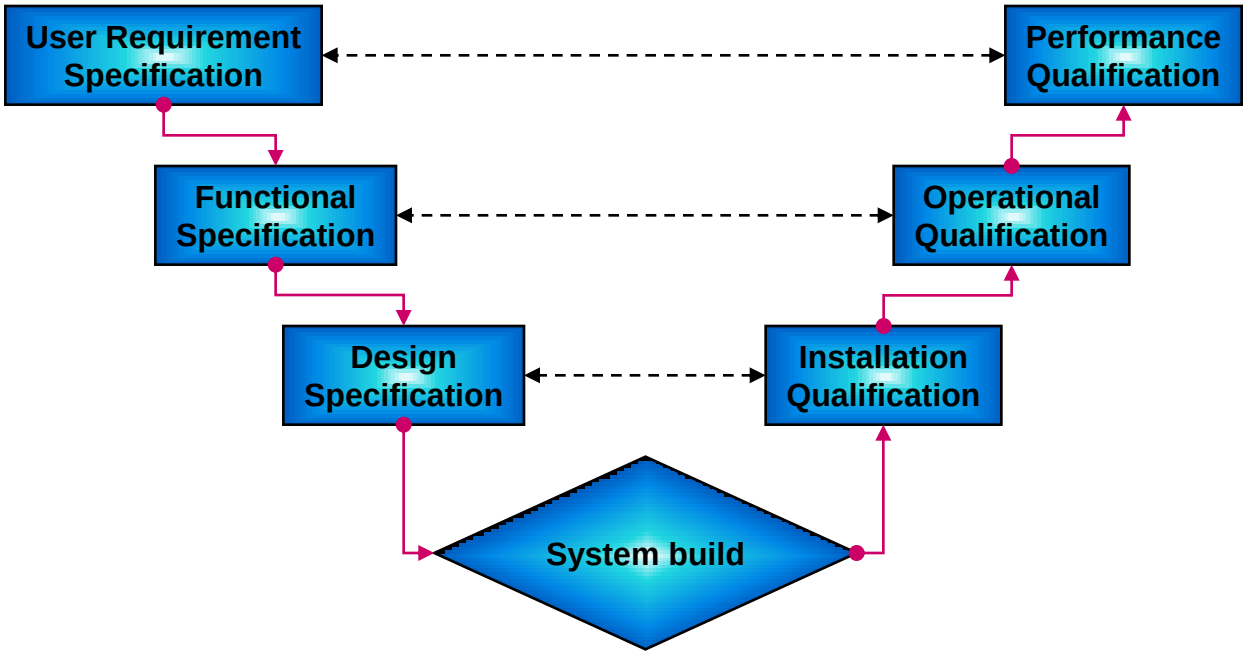


Washer Monitoring Systems

- **Conductivity** - To Monitor Strength
  To Separate Phases
- **Temperature** - To Control and Monitor
- **Flow** - To Control
- **Pressure** - For Agitation, Turbulation,
  Spray and Integrity Testing
- **Time** - From the Control System
- **Turbidity** - To Control

Validation

Planning	Prepare written validation plan
Specifications	Specify & agree what is required
Test planning (IQ/OQ/PQ)	Prepare document to describe how the equipment system is to be tested
Testing (IQ/OQ/PQ)	Perform tests and collect results
Review	Review results to show that system performs as specified plus any reservations



Validation

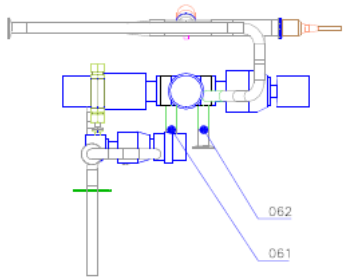
Our products follow the GAMP Validation Life Cycle with documentary evidence of procedures and processes during design, development, pre-construction, construction and commissioning . Typical documents packages include Quality Plan, FDS, HDS, SDS, Document Index, P*ID Drawings, GA Drawings, Equipment List, Instrument List, Circuit Drawings, Software Code and Test Protocols.

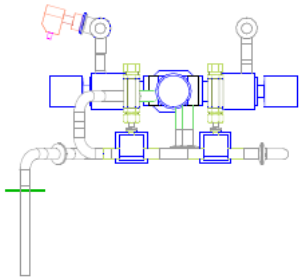
Typical Weld Map and Table

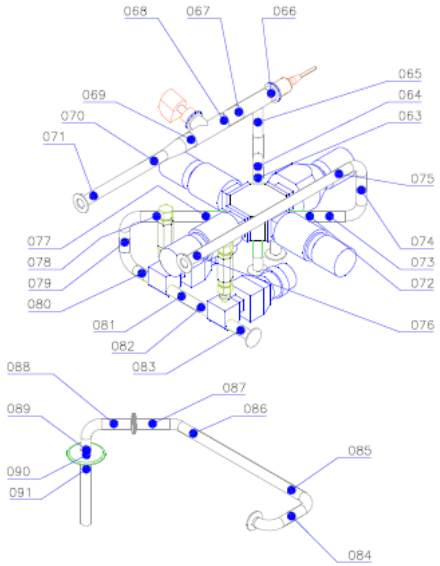
DO NOT SCALE – IF IN DOUBT ASK

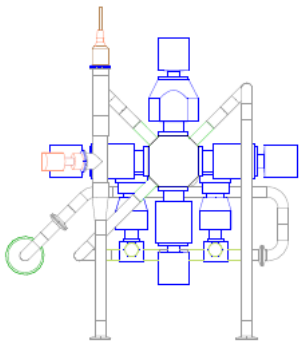
WELD TABLE

I.D. PROCEDURE DATE	WELD No.	SIZE/DESCRIPTION	HEAT No.
JOG 007 23 MAR 10	061	VALVE BLOCK XCV-140-005/007/008A/0089	SEE SECTION 6
		25 FERRULE	773102
JOG 007 23 MAR 10	062	VALVE BLOCK XCV-140-005/007/008A/0089	SEE SECTION 6
		25 FERRULE	773102
JOG 002 23 MAR 10	063	VALVE BLOCK XCV-140-005/007/008A/0089	SEE SECTION 6
JOG 002 23 MAR 10	064	25 TUBE	975244
		25 BEND 90°	70001
JOG 002 23 MAR 10	065	40 x 25 RED TEE	R367/70067
JOG 007 23 MAR 10	066	40 FERRULE	421150
JOG 002 23 MAR 10	067	40 x 25 RED TEE	R367/70067
JOG 002 23 MAR 10	068	40 TUBE	30845
		40 INSTRUMENT TEE	32NM8
JOG 002 23 MAR 10	069	40 x 25 CONC RED	S701005/70001
JOG 002 23 MAR 10	070	25 TUBE	975244
JOG 002 23 MAR 10	071	25 FERRULE	77102
JOG 002 23 MAR 10	072	VALVE BLOCK XCV-140-005/007/008A/0089	SEE SECTION 6
JOG 002 23 MAR 10	073	25 TUBE	975244
		25 BEND 90°	70001
JOG 002 23 MAR 10	074	25 BEND 90°	70001
JOG 002 23 MAR 10	075	25 TUBE	975244
JOG 002 23 MAR 10	076	25 FERRULE	773102
JOG 002 23 MAR 10	077	VALVE BLOCK XCV-140-005/007/008A/0089	SEE SECTION 6
JOG 002 23 MAR 10	078	25 TUBE	975244
		25 BEND 90°	70001
JOG 002 23 MAR 10	079	25 BEND 90°	70001
JOG 002 23 MAR 10	080	25 VALVE XCV-140-005	SEE SECTION 6
JOG 002 23 MAR 10	081	25 TUBE	975244
JOG 002 23 MAR 10	082	25 VALVE XCV-140-004	SEE SECTION 6
JOG 002 23 MAR 10	083	25 FERRULE	773102
JOG 002 23 MAR 10	084	25 FERRULED BEND 90°	F012113A/30441
		25 BEND 90°	R367
JOG 002 23 MAR 10	085	25 TUBE	975244
JOG 002 23 MAR 10	086	25 BEND 45°	70053
JOG 002 23 MAR 10	087	25 FERRULE	773102
JOG 002 23 MAR 10	088	25 FERRULE	773102
		25 BEND 90°	70053
JOG 007 01 APR 10	089	80 FERRULE BLANK	244578
JOG		25 BEND 90°	70053









PARTS LIST

ITEM	QTY	SIZE	DESCRIPTION
1	1	40	FLOW SWITCH
2	1	40	CONDUCTIVITY & TEMP TRANSMITTER
3	1	40	SPRAY NOZZLE
4	1	40	VALVE BLOCK XCV-140-005/007/008A/0089
5	2	40	VALVE BLOCK XCV-140-004/005
6	2	15	CHECK VALVE NRV-140-004/005
7	1	40	TUBE
8	1	25	TUBE
9	1	80	FERRULE BLANK
10	1	40	FERRULE
11	7	25	FERRULE
12	7	25	BEND 90°
13	1	25	BEND 90° WITH FERRULE
14	1	25	BEND 45°
15	1	40 x 25	RED TEE
16	1	40	INSTRUMENT TEE
17	1	40 x 25	CONCENTRIC REDUCER
18	1	80	SEAL
19	2	40	SEAL
20	4	25	SEAL
21	1	80	CLAMP
22	6	40/25	CLAMP

Suncombe Products

Static CIP Skids

PartsWashers

Mobile CIP skids

Tanks, Vessels and Mixers

IBC Wash Booths

Filter/Membrane Skids

Bio-Waste Inactivation Skids

Processing Skids

Solution Preparation Systems

www.suncombe.com

Typical Clientele
BioPharma/Medical/Chemical

Typical Clientele Personal Care

Typical Clientele Food and Beverage

Nestlé
Good Food, Good Life

Sara Lee

Choose Cadbury

Coca-Cola

Yoplait

Ribena

Northern Foods

Guinness

Dairy Crest

Fisherman's Friend

McDonald's

St Ivel

Fox's Biscuits

Associated British Foods plc

Thank you for your attention
For further information please contact:

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