

# PRODUCT CATALOGUE

**Complete Process & Equipment Solutions for Cleaning (CIP/COP)  
and Sterilization (SIP) to the highly regulated Life Science Industries**



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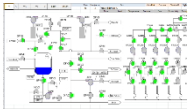


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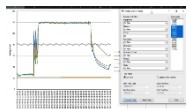
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## The McFlusion Difference

### Process comes first...always!

Analyze and establish critical process cleaning & sterilization parameters (TACCT) for effective in-situ cleaning (CIP), sanitization and sterilization (SIP) of manufacturing equipment

Process  
Knowledge &  
Expertise



Modular  
Equipment  
and  
Life-cycle Services

Hardware  
& Software  
Integration

### Process Integration

Ensure successful implementation and use...

- \* Software integration & full control, monitoring and reporting of processes
- \* Hardware integration - CIP/SIP adapters and spray devices

### Modular process cleaning (CIP/COP) and sterilization (SIP) equipment

Meet and surpass process cleaning & sterilization requirements...

- \* Portable CIP and CIP/SIP units
- \* Fixed CIP/SIP systems
- \* CIP and CIP/SIP utility systems and satellites
- \* Specialty parts washers (COP) and cleaning racks
- \* Upfront engineering/assessments/audits
- \* CIP/SIP tests (bench to full scale)
- \* CIP/SIP equipment rental & support
- \* Complete qualification program (CD, BD, DQ, FAT, SAT and IQQ)
- \* Support (remote or on-site support, spare parts, preventive maintenance, training and educational seminars)



## The McFlusion Difference

In McFlusion, we are subject matter experts within process cleaning, sanitization and sterilization and are renowned for our targeted problem-solving, pragmatic & consultative approach – and – not to forget our extensive equipment program, software and life cycle services.

### **Process comes first.....always!**

We offer a range of CIP consulting services that are based upon our well-proven, pragmatic (to-the-point) methodology that will establish the best possible (effective, reproducible, lean and compliant) cleaning, sanitization and sterilization solution(s) for our clients – whether dealing with a new or legacy facility.

#### • **CIP/SIP assessment**

- Theoretical review of process and equipment drawings; product(s) manufactured; cleaning validation program; existing (if any) cleaning equipment, operations and/or SOPs; facility layout & infrastructure; utility systems; historical data and observations; regulatory and/or audit observations, etc.
- Detailed on-site walk-down and inspection of processes and equipment; facility & infrastructure; Q&A sessions with QA, validation, operations, engineering & management, etc.
- Assessment summary report with observations/findings and recommendations – available on multiple levels ranging from conceptual to detailed design w/implementation details and planning.

#### • **Cleaning studies & tests**

- Bench scale (laboratory) cleaning tests on pre-soiled SS coupons – often working closely with the client and client's preferred chemical provider – to establish preliminary TACCT parameters.
- Off-site, full-scale, cleaning, sanitization and sterilization testing on pre-soiled equipment in our fully equipped test center to further develop and establish TACCT parameters in a CIP and/or SIP setting.

Photos:  
McFlusion test center



- On-site, full-scale, cleaning, sanitation and sterilization testing on the client's equipment & products – using McFlusion CIP/SIP rental equipment including accessories (adapters, spray devices, flex hoses, etc.

Photos:  
On-site cleaning test –  
using McFlusion equipment



- Cleaning test summary report with observations, scientific data supporting recommended TACCT parameters, CIP zones with flow/pressure calculations, recipes, etc.

## Portable CIP and CIP/SIP Units

McFlusion provides modular to fully customized process cleaning (CIP) and sterilization (SIP) units that are specifically designed and manufactured to meet the most stringent process and regulatory requirements within the highly regulated life science, biopharma, and vaccine industries.

McFlusion CIP and CIP/SIP units are perfectly suited for 'dedicated' process cleaning (CIP) and sterilization (SIP), where the portable units, locally, are dedicated to and integrated with the process equipment to-be-cleaned and/or sterilized.

This concept time and again offers huge advantages over traditional centralized installations and should be used, whenever possible, to increase process performance, flexibility and control as well as to increase effectiveness, reproducibility and to support leaner operations.

The CIP and CIP/SIP units are based on McFlusion's advanced, modular, hardware and software technology platform that facilitates full use and tight control, monitoring, and reporting of all critical parameters (TACCT) for in-situ cleaning (CIP) and sterilization (SIP) operations on applications, such as:

- Homogenizers
- Aseptic fill lines with isolator technology
- Filter stations
- Formulation & holding vessels
- Bio reactors
- Ultra filtration skids
- Freeze dryers
- Glove box isolators

Our CIP and CIP/SIP units for the life science, biopharma and vaccine industries are equipped with our Process Builder Design (PBD)<sup>™</sup> that secures an error-free, fast and effective integration with and execution of the cleaning and/or sterilization processes on the production equipment.

The PBD<sup>™</sup> secures an efficient cleaning and sterilization process with full data and process supervision.

All our CIP and CIP/SIP units are available and can be equipped with the optional 2-tier Data Collection System (DCS), as follows:

- Tier 1 – "DCS TECH" collects process technical data that can be applied for process analytics, trouble shooting, cleaning validation activities, etc.
- Tier 2 – "DCS GMP" adds collection of GMP data for audit trail, historian and reporting.

Our automation platform is prepared for multi-level integration & communication with site control systems, such as DeltaV.



## Portable CIP and CIP/SIP Units

Formulation & Holding vessels

Bio reactors



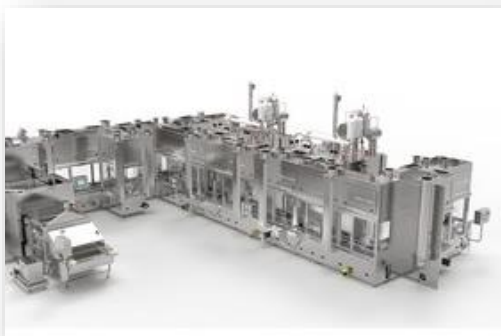
Centrifuges



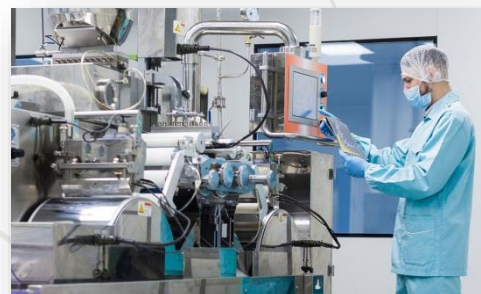
Parts Washers (COP)



Spray Dryers



Aseptic Fill Lines



Packaging lines



## Portable CIP Unit [CS25]



- ✓ Compact frame in AISI 304 stainless steel with wheels (or legs) and removable covers
  - ✓ Easy to maneuver
  - ✓ Easy to service
- ✓ Modular hardware and software platform – multiple configurations available.
- ✓ Integrated electrical panel with AB Compact Logix PLC and PC based touch screen HMI
  - ✓ Full recipe editor, alarm handling and cycle reporting to PDF
  - ✓ Process Builder Design (PBD)™
  - ✓ AutoTune™
  - ✓ Data Collection System (DCS) with TECH and GMP features
- ✓ Full TACCT cleaning performance and flexibility
  - ✓ Adjustable pressures
  - ✓ Adjustable flow rates
  - ✓ Adjustable temperatures
  - ✓ Adjustable concentrations
- ✓ Full instrumentation package, including level, pressure, flow, temperature and conductivity (low and high)
- ✓ Full system design and QA documentation

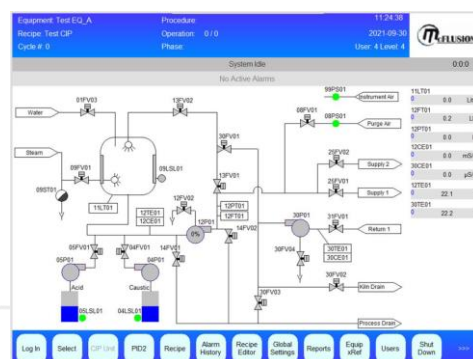
Technical Data	Unit	CS25
Buffer tank	Gallon	40
Supply pressure	PSI	<150
Supply flow	GPM	<45
Temperature, 2 x 10 kW or steam	°F	<200
Chemistry	mS/cm	<200

### Controls:

Allen Bradley compact Logix PLC	✓ Yes	
12" PC touch screen HMI	✓ Yes	
Allen Bradley software	✓ Yes	
McFlusion Process Builder Design™	✓ Yes	
McFlusion AutoTune™	✓ Yes	
Data Collection System (DCS)	Optional	TECH & GMP

### Size:

Dimensions (LxWxH)	Inch	53 x 26 x 55 (69)
Weight, dry	Lbs	~700



HMI interface: P&ID

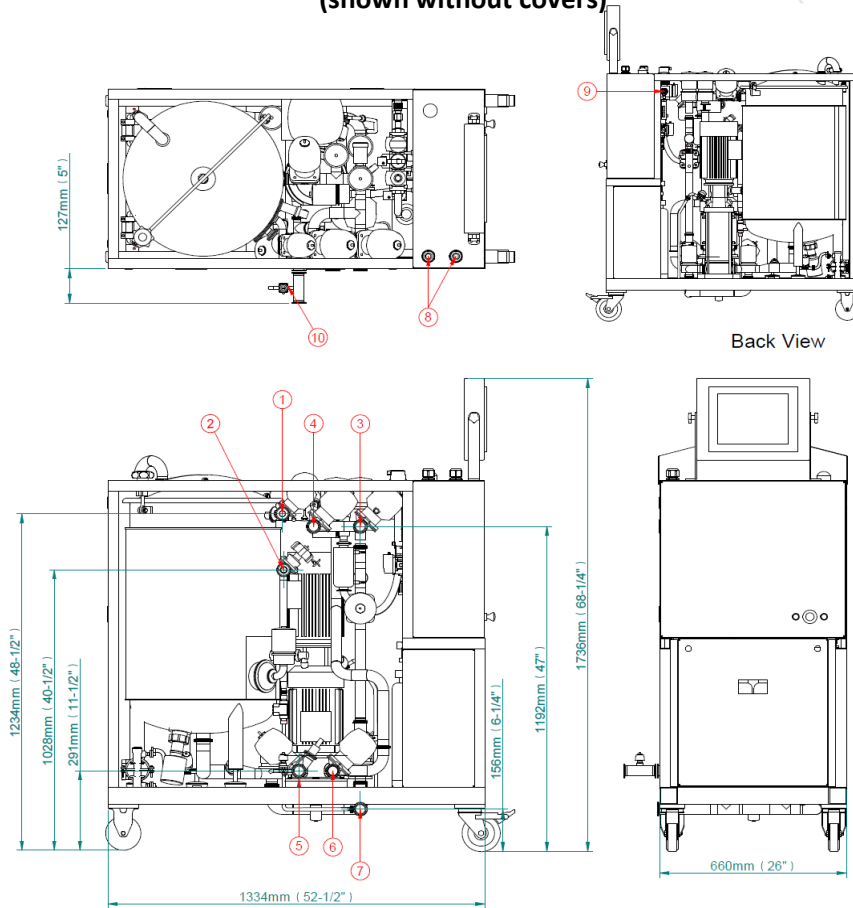
- ✓ Real time component status
- ✓ Real time instrument readings



Item Number	Description	Accessories
UP9001	CIP unit [CS25]	Please contact us

## Portable CIP Unit [CS25]

General layout & tie-in schematic  
(shown without covers)



#	Designation	Connection	Sizing	Expected setup
1	Water #1 (PW)	1½" Tri clamp	1" (25 mm)	< 20 gpm @ 20 psi
N/A	Water #2 (not shown)	1½" Tri clamp	1" (25 mm)	< 20 gpm @ 20 psi
2	Steam (for heating and/or SIP)	1½" Tri clamp	1½" (38 mm)	<300 lbs/hour @ 35
3	CIP supply 1	1½" Tri clamp	1½" (38 mm)	< 45 gpm @ 150 psi
4	CIP supply 2	1½" Tri clamp	1½" (38 mm)	< 45 gpm @ 150 psi
5	CIP return 1	1½" Tri clamp	1½" (38 mm)	< 45 gpm @ 30 psi
6	<b>Optional:</b> "Kiln" drain	1½" Tri clamp	1½" (38 mm)	< 45 gpm @ 30 psi
7	Process drain	1½" Tri clamp	1½" (38 mm)	< 45 gpm @ 20 psi
8	Electrical	Plug	3x480V, ground 40A	Plug
9	Compressed air	½" NPT or TC	1" (25 mm)	Nominal cfm @ 90 psi < 30 cfm @ < 30 psi (purge)
10	<b>Optional:</b> sampling adapter	½" Tri-clamp	½" (12.7 mm)	N/A

Item Number	Description	Accessories
UP9001	CIP unit [CS25]	Please contact us



## Portable CIP Unit [CS35]

- ✓ Compact frame in AISI 304 stainless steel with wheels (or legs) and removable covers
  - ✓ Easy to maneuver
  - ✓ Easy to service
- ✓ Modular hardware and software platform – multiple configurations available.
- ✓ Integrated electrical panel with AB Compact Logix PLC and PC based touch screen HMI
  - ✓ Full recipe editor, alarm handling and cycle reporting to PDF
  - ✓ Process Builder Design (PBD)<sup>™</sup>
  - ✓ AutoTune<sup>™</sup>
  - ✓ Data Collection System (DCS) with TECH and GMP features
- ✓ Full TACCT cleaning performance and flexibility
  - ✓ Adjustable pressures
  - ✓ Adjustable flow rates
  - ✓ Adjustable temperatures
  - ✓ Adjustable concentrations
- ✓ Full instrumentation package, including level, pressure, flow, temperature and conductivity (low and high)
- ✓ Full system design and QA documentation



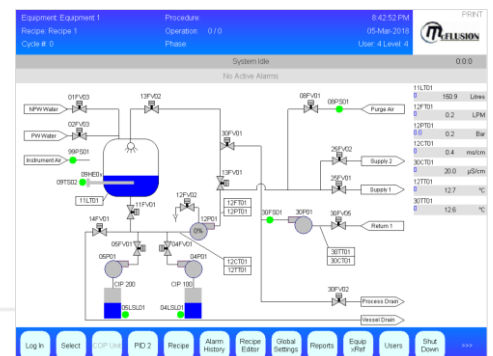
Technical Data	Unit	CS35
Buffer tank	Gallon	100
Supply pressure	PSI	<150
Supply flow	GPM	<75
Temperature, 3 x 10 kW or steam	°F	<200
Chemistry	mS/cm	<200

### Controls:

Allen Bradley compact Logix PLC	✓ Yes	
12" PC touch screen HMI	✓ Yes	
Allen Bradley software	✓ Yes	
McFlusion Process Builder Design ™	✓ Yes	
McFlusion AutoTune ™	✓ Yes	
Data Collection System (DCS)	Optional	TECH & GMP

### Size:

Dimensions (LxWxH)	Inch	65 x 34 x 71
Weight, dry	Lbs	~900



HMI interface: P&ID

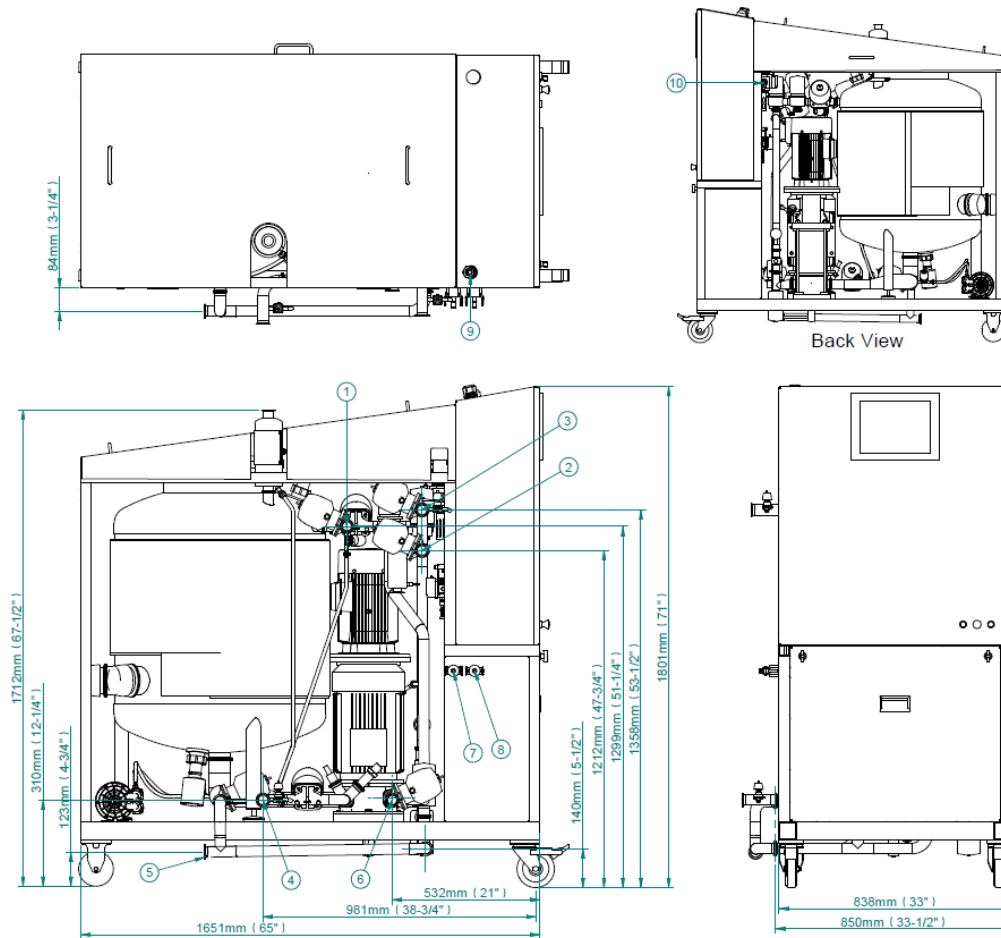
- ✓ Real time component status
- ✓ Real time instrument readings



Item Number	Description	Accessories
UP9002	CIP unit [CS35]	Please contact us

## Portable CIP Unit [CS35]

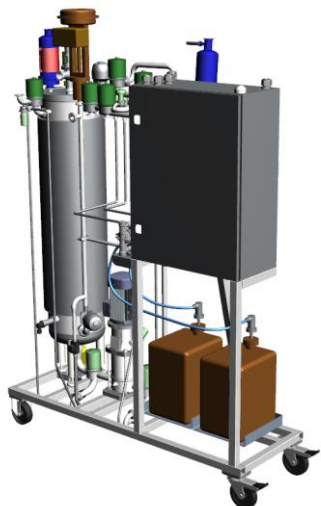
### General layout & tie-in schematic



#	Designation	Connection	Sizing	Expected setup
1	Water #1 (PW)	1½" Tri clamp	1" (25 mm)	< 20 gpm @ 45 psi
N/A	Water #2 (not shown)	1½" Tri clamp	1" (25 mm)	< 20 gpm @ 45 psi
2	CIP supply 1	1½" Tri clamp	1½" (38 mm)	< 75 gpm @ 150 psi
3	CIP supply 2	1½" Tri clamp	1½" (38 mm)	< 75 gpm @ 150 psi
4	CIP return	1½" Tri clamp	1½" (38 mm)	< 70 gpm @ 35 psi
5	Gravity drain (special)	1½" Tri clamp	1½" (38 mm)	~ 1-2 gallon
6	Process drain	1½" Tri clamp	1½" (38 mm)	< 75 gpm @ < 35 psi
7	<b>Optional:</b> Detergent refill #1	½" quick con.	TBD	N/A
8	<b>Optional:</b> Detergent refill #2	½" quick con.	TBD	N/A
9	Electrical	Plug	3x480V, 60 hz, 60A	N/A
10	Compressed air	¾" quick con. or Tri clamp	1" (25 mm)	Nominal cfm @ 90 psi < 45 cfm @ < 45 psi (purge)

Item Number	Description	Accessories
UP9002	CIP unit [CS35]	Please contact us

## Portable CIP/SIP Unit [CS10-S]



- ✓ Compact frame in AISI 304 stainless steel with wheels (or legs) and optional covers
  - ✓ Easy to maneuver
  - ✓ Easy to service
- ✓ Modular hardware and software platform – multiple configurations available.
- ✓ Integrated electrical panel with AB Compact Logix PLC and PC based touch screen HMI
  - ✓ Full CIP and SIP recipe editor, alarm handling and cycle reporting to PDF
  - ✓ Process Builder Design (PBD)<sup>™</sup>
  - ✓ AutoTune<sup>™</sup>
  - ✓ Data Collection System (DCS) with TECH and GMP features
- ✓ Full TACCT cleaning and sterilization performance and flexibility
  - ✓ Adjustable pressures & flows
  - ✓ Adjustable timers (CIP/SIP)
  - ✓ Adjustable temperatures
  - ✓ Adjustable concentrations
- ✓ Full instrumentation package, including level, pressure, flow, temperature and conductivity (low and high)
- ✓ Full system design and QA documentation

Technical Data - CIP	Unit	CS10-S	Technical Data - SIP	Unit	CS10-S
Buffer tank	Gallon	22	SIP supply pressure	PSI	<60
Supply pressure	PSI	<120	SIP supply temperature	°F	<302
Supply flow	GPM	<25	Optional: Modulating steam valve	mA	4-20
Temperature, 3 x 10 kW or steam	°F	<200	SIP return pressure/vacuum	PSI	-14.5 – 90
Chemistry	mS/cm	<200	SIP return temperature	°F	<302

### Controls:

Allen Bradley compact Logix PLC	✓ Yes
12" PC touch screen HMI	✓ Yes
Allen Bradley software	✓ Yes
McFlusion Process Builder Design <sup>™</sup>	✓ Yes CIP & SIP
McFlusion AutoTune <sup>™</sup>	✓ Yes
Data Collection System (DCS)	Optional TECH & GMP

### Size:

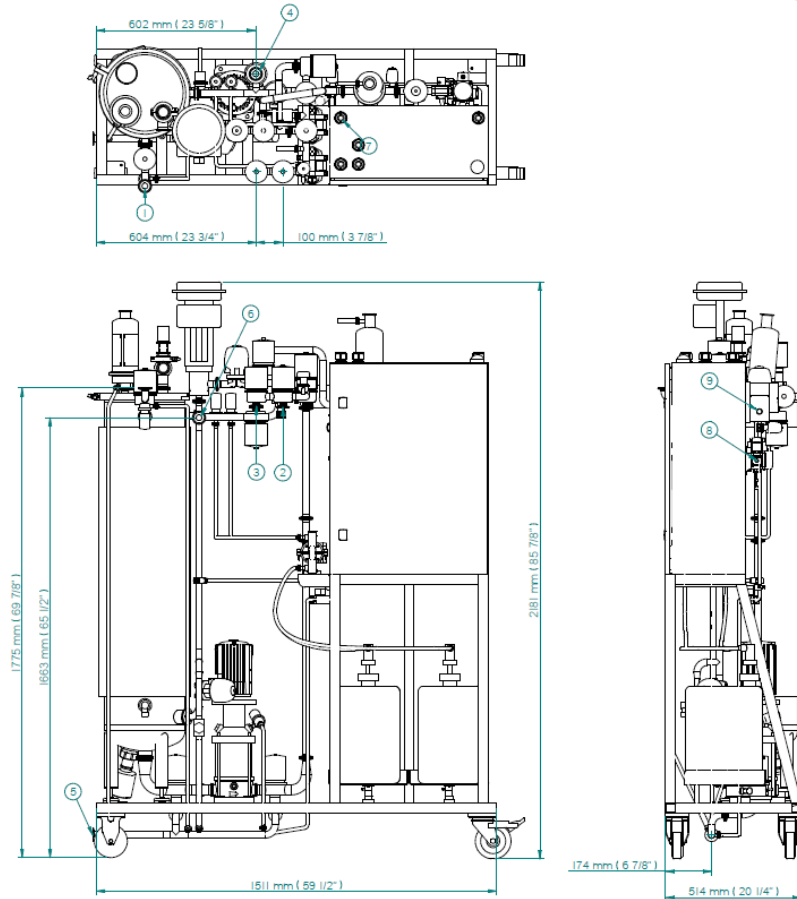
Dimensions (LxWxH)	Inch	60 x 21 x 85
Weight, dry	Lbs	~600



Item Number	Description	Accessories
UP9000	CIP/SIP unit [CS10-S]	Please contact us

## Portable CIP/SIP Unit [CS10-S]

### General layout & tie-in schematic



#	Designation	Connection	Sizing	Expected setup, CIP	Expected setup, SIP
1	Water #1 (PW)	1½" Tri clamp	1" (25 mm)	< 15 gpm @ 35 psi	N/A
N/A	Water #2 (not shown)	1½" Tri clamp	1" (25 mm)	< 15 gpm @ 35 psi	N/A
2	CIP/SIP supply 1-3	1½" Tri clamp	1" (25 mm)	< 25 gpm @ 120 psi	<60 psi
3	CIP/SIP supply 4	1½" Tri clamp	1" (25 mm)	< 25 gpm @ 120 psi	<60 psi
4	CIP/SIP return	1½" Tri clamp	1" (25 mm)	< 25 gpm @ 35 psi	-14.5 – 90 psi
5	Drain	1½" Tri clamp	1" (25 mm)	< 25 gpm @ 120 psi	N/A
6	Clean steam	1½" Tri clamp	1" (25 mm)	N/A	< 110 lbs/hr @ 30 psi
7	Electrical	Plug	3x480V, 60 hz, 20A	N/A	N/A
8	Compressed air	½" quick con. or Tri clamp	½"	Nominal cfm @ 90 psi	
9	Compressed clean air or Nitrogen	½" quick con. or Tri clamp	½"	< 35 cfm @ 40-110 psi (purge)	

Item Number	Description	Accessories
UP9000	CIP/SIP unit [CS10-S]	Please contact us

## Portable CIP/SIP Unit [CS25-S]



- ✓ Compact frame in AISI 304 stainless steel with wheels and removable covers
  - ✓ Easy to maneuver
  - ✓ Easy to service
- ✓ Modular hardware and software platform – multiple configurations available.
- ✓ Integrated electrical panel with AB Compact Logix PLC and PC based touch screen HMI
  - ✓ Full CIP and SIP recipe editor, alarm handling and cycle reporting to PDF
  - ✓ Process Builder Design (PBD)<sup>™</sup>
  - ✓ AutoTune<sup>™</sup>
  - ✓ Data Collection System (DCS) with TECH and GMP features
- ✓ Full TACCT cleaning and sterilization performance and flexibility
  - ✓ Adjustable pressures & flows
  - ✓ Adjustable timers (CIP/SIP)
  - ✓ Adjustable temperatures
  - ✓ Adjustable concentrations
- ✓ Full instrumentation package, including level, pressure, flow, temperature and conductivity (low and high)
- ✓ Full system design and QA documentation

Technical Data - CIP	Unit	CS25-S	Technical Data - SIP	Unit	CS25-S
Buffer tank	Gallon	40	SIP supply pressure	PSI	<60
Supply pressure	PSI	<150	SIP supply temperature	°F	<302
Supply flow	GPM	<45	Optional Modulating steam valve	mA	4-20
Temperature, 2 x 10 kW or steam	°F	<200	SIP return pressure/vacuum	PSI	-14.5 – 90
Chemistry	mS/cm	<200	SIP return temperature	°F	<302

### Controls:

Allen Bradley compact Logix PLC	✓ Yes	
12" PC touch screen HMI	✓ Yes	
Allen Bradley software	✓ Yes	
McFlusion Process Builder Design <sup>™</sup>	✓ Yes	CIP & SIP
McFlusion AutoTune <sup>™</sup>	✓ Yes	
Data Collection System (DCS)	✓ Yes	TECH & GMP

### Size:

Dimensions (LxWxH)	Inch	60 x 26 x 70
Weight, dry	Lbs	~750



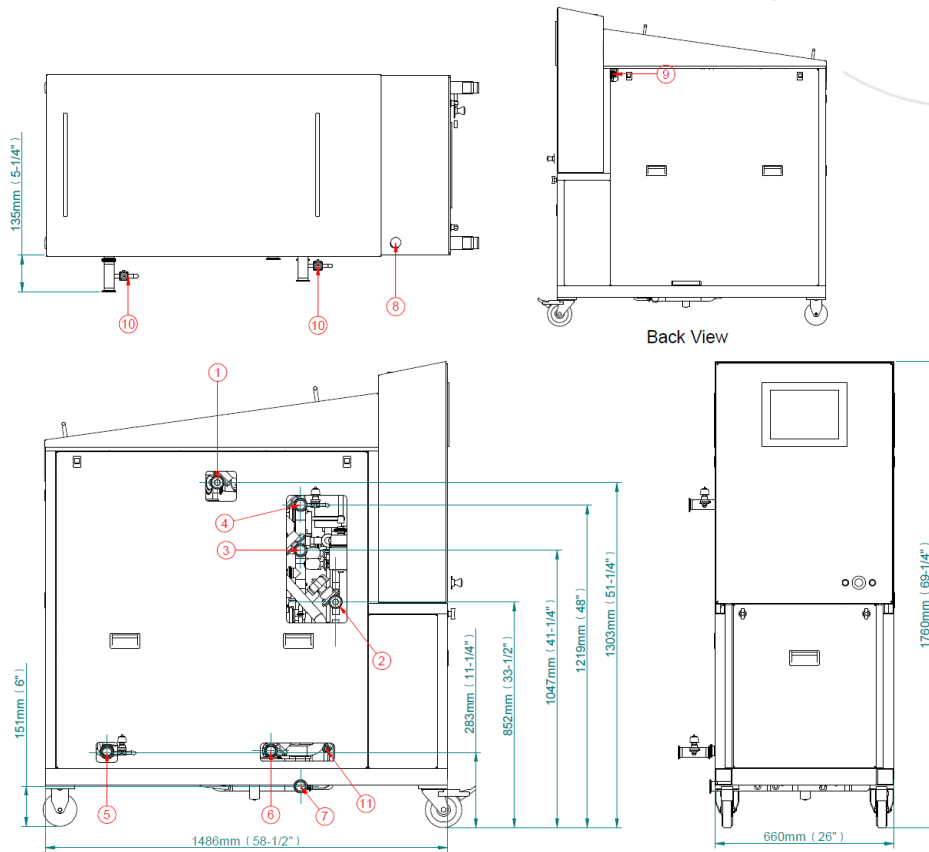
**Portable CIP/SIP unit [CS25-S]**  
(show without covers)

Item Number	Description	Accessories
UP9003	CIP/SIP unit [CS25-S]	Please contact us



## Portable CIP/SIP Unit [CS25-S]

### General layout & tie-in schematic



#	Designation	Connection	Sizing	Expected setup, CIP	Expected setup, SIP
1	Water #1 (PW)	1½" Tri clamp	1" (25 mm)	< 20 gpm @ 45 psi	N/A
N/A	Water #2 (not shown)	1½" Tri clamp	1" (25 mm)	< 20 gpm @ 45 psi	N/A
2	Clean steam	1½" Tri clamp	1" (25 mm)	N/A	< 250 lbs/hour @ 35 psi
3	CIP/SIP supply 1	1½" Tri clamp	1½" (38 mm)	< 45 gpm @ 150 psi	<60 psi
4	CIP/SIP supply 2	1½" Tri clamp	1½" (38 mm)	< 45 gpm @ 150 psi	<60 psi
5	CIP/SIP return	1½" Tri clamp	1½" (38 mm)	< 45 gpm @ 35 psi	-14.5 – 90 psi
6	Optional 'Kiln' drain	1½" Tri clamp	1½" (38 mm)	< 75 gpm @ < 150 psi	N/A
7	Process Drain	1½" Tri clamp	1½" (38 mm)	< 45 gpm @ 35 psi	N/A
8	Electrical	Plug	3x480V, 60 hz, 40A	N/A	
9	Compressed air	½" quick con. or Tri clamp	1" (25 mm)	Nominal cfm @ 90 psi < 35 cfm @ < 35 psi (purge)	
10	Optional: Sampling	½" Tri clamp	½" (12.7 mm)	N/A	
11	Optional: cooling	½" tri-clamp	½" (12.7 mm)	N/A	

## Portable CIP/SIP Unit [CS35-S]



- ✓ Compact frame in AISI 304 stainless steel with wheels and covers
  - ✓ Easy to maneuver
  - ✓ Easy to service
- ✓ Modular hardware and software platform – multiple configurations available.
- ✓ Integrated electrical panel with AB Compact Logix PLC and PC based touch screen HMI
  - ✓ Full CIP and SIP recipe editor, alarm handling and cycle reporting to PDF
  - ✓ Process Builder Design (PBD)<sup>™</sup>
  - ✓ AutoTune<sup>™</sup>
  - ✓ Data Collection System (DCS) with TECH and GMP features
- ✓ Full TACCT cleaning and sterilization performance and flexibility
  - ✓ Adjustable pressures & flows
  - ✓ Adjustable timers (CIP/SIP)
  - ✓ Adjustable temperatures
  - ✓ Adjustable concentrations
- ✓ Full instrumentation package, including level, pressure, flow, temperature and conductivity (low and high)
- ✓ Full system design and QA documentation

Technical Data - CIP	Unit	CS35-S	Technical Data - SIP	Unit	CS35-S
Buffer tank	Gallon	100	SIP supply pressure	PSI	<60
Supply pressure	PSI	<150	SIP supply temperature	°F	<302
Supply flow	GPM	<75	Optional: Modulating steam valve	mA	4-20
Temperature, 2 x 10 kW or steam	°F	<200	SIP return pressure/vacuum	PSI	-14.5 – 90
Chemistry	mS/cm	<200	SIP return temperature	°F	<302

### Controls:

Allen Bradley compact Logix PLC	✓ Yes	
12" PC touch screen HMI	✓ Yes	
Allen Bradley software	✓ Yes	
McFlusion Process Builder Design <sup>™</sup>	✓ Yes	CIP & SIP
McFlusion AutoTune <sup>™</sup>	✓ Yes	
Data Collection System (DCS)	Optional	TECH & GMP

### Size:

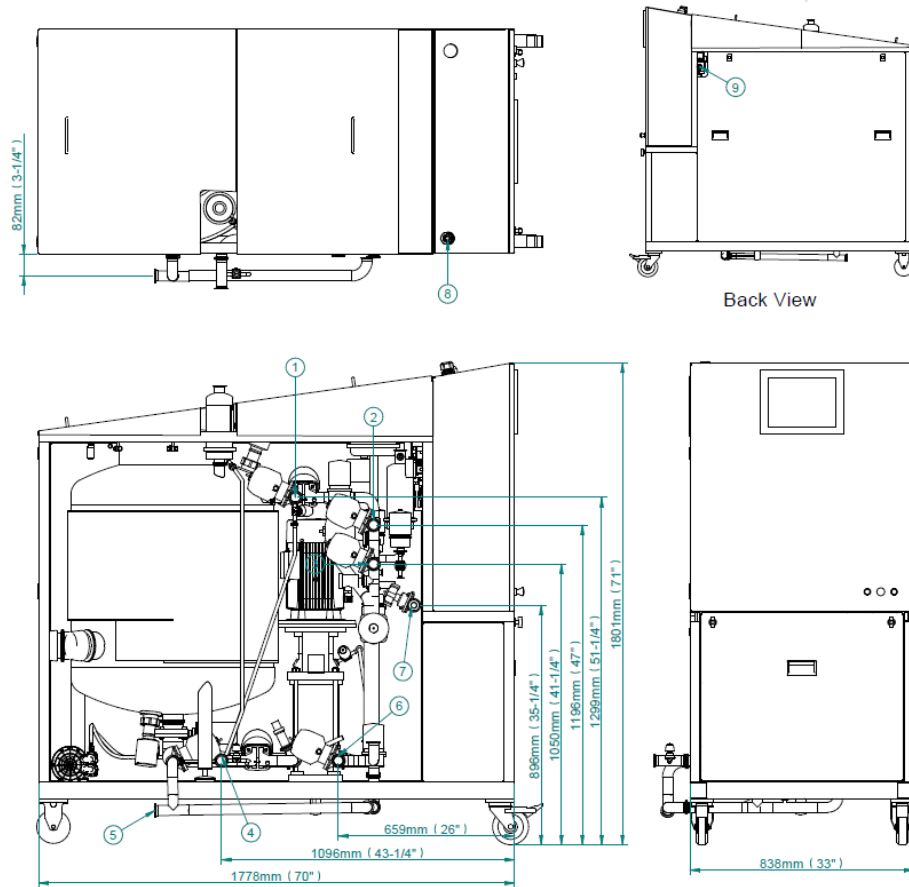
Dimensions (LxWxH)	Inch	65 x 34 x 71
Weight, dry	Lbs	~1,100



Item Number	Description	Accessories
UP9004	CIP/SIP unit [CS35-S]	Please contact us

## Portable CIP/SIP Unit [CS35-S]

### General layout & tie-in schematic



#	Designation	Connection	Sizing	Expected setup, CIP	Expected setup, SIP
1	Water #1 (PW)	1½" Tri clamp	1" (25 mm)	< 20 gpm @ 45 psi	N/A
2	Water #2 (WFI)	1½" Tri clamp	1" (25 mm)	< 20 gpm @ 45 psi	N/A
3	Clean steam	1½" Tri clamp	1" (25 mm)	N/A	< 250 lbs/hour @ 35 psi
4	CIP/SIP supply 1	1½" Tri clamp	1½" (38 mm)	< 75 gpm @ 150 psi	<60 psi
5	CIP/SIP supply 2	1½" Tri clamp	1½" (38 mm)	< 75 gpm @ 150 psi	<60 psi
6	CIP/SIP return	1½" Tri clamp	1½" (38 mm)	< 70 gpm @ 35 psi	-14.5 – 90 psi
7	Optional 'Kiln' drain	1½" Tri clamp	1½" (38 mm)	< 70 gpm @ < 150 psi	N/A
8	Process Drain	1½" Tri clamp	1½" (38 mm)	< 45 gpm @ 35 psi	N/A
9	Electrical	Plug	3x480V, 60 hz, 60A	N/A	
10	Compressed air	½" quick con. or Tri clamp	1" (25 mm)	Nominal cfm @ 90 psi < 45 cfm @ < 35 psi (purge)	
11	Optional: Sampling	½" Tri clamp	½" (12.7 mm)	N/A	
12	Optional: cooling	½" tri-clamp	½" (12.7 mm)	N/A	

Item Number	Description	Accessories
UP9004	CIP/SIP unit [CS35-S]	Please contact us

## Portable SIP Unit [SS]



- ✓ Compact frame in AISI 304 stainless steel with wheels and removable covers
  - ✓ Easy to maneuver
  - ✓ Easy to service
- ✓ Modular hardware and software platform – multiple configurations available.
- ✓ Integrated electrical panel with AB Compact Logix PLC and PC based touch screen HMI
  - ✓ Full SIP recipe editor, alarm handling and cycle reporting to PDF
  - ✓ Process Builder Design (PBD)<sup>™</sup>
  - ✓ 4-20 mA modulating valve
  - ✓ Data Collection System (DCS) with TECH and GMP features
- ✓ Full TACCT sterilization performance and flexibility
  - ✓ Adjustable pressures
  - ✓ Adjustable timers
  - ✓ Adjustable temperatures
  - ✓ Adjustable F0 set points (pass/fail)
- ✓ Full instrumentation package, including pressure and temperature on supply and return (cold spot)
- ✓ Full system design and QA documentation

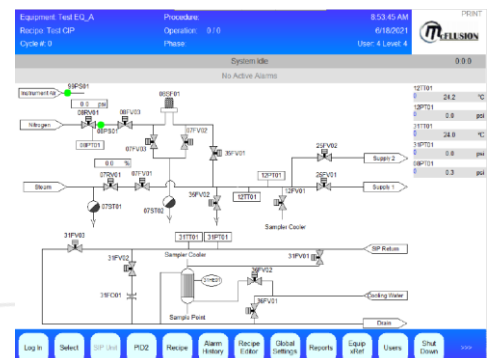
Technical Data - SIP	Unit	SS
SIP supply pressure	PSI	<60
SIP supply temperature	°F	<302
<b>Optional</b> Modulating steam valve	mA	4-20
SIP return pressure/vacuum	PSI	-14.5 – 90
SIP return temperature	°F	<302

### Controls:

Allen Bradley compact Logix PLC	✓ Yes	
12" PC touch screen HMI	✓ Yes	
Allen Bradley software	✓ Yes	
McFlusion Process Builder Design <sup>™</sup>	✓ Yes	SIP
McFlusion AutoTune <sup>™</sup>	✓ Yes	
Data Collection System (DCS)	Optional	TECH & GMP

### Size:

Dimensions (LxWxH)	Inch	60 x 26 x 70
Weight, dry	Lbs	~750



### HMI interface: P&ID

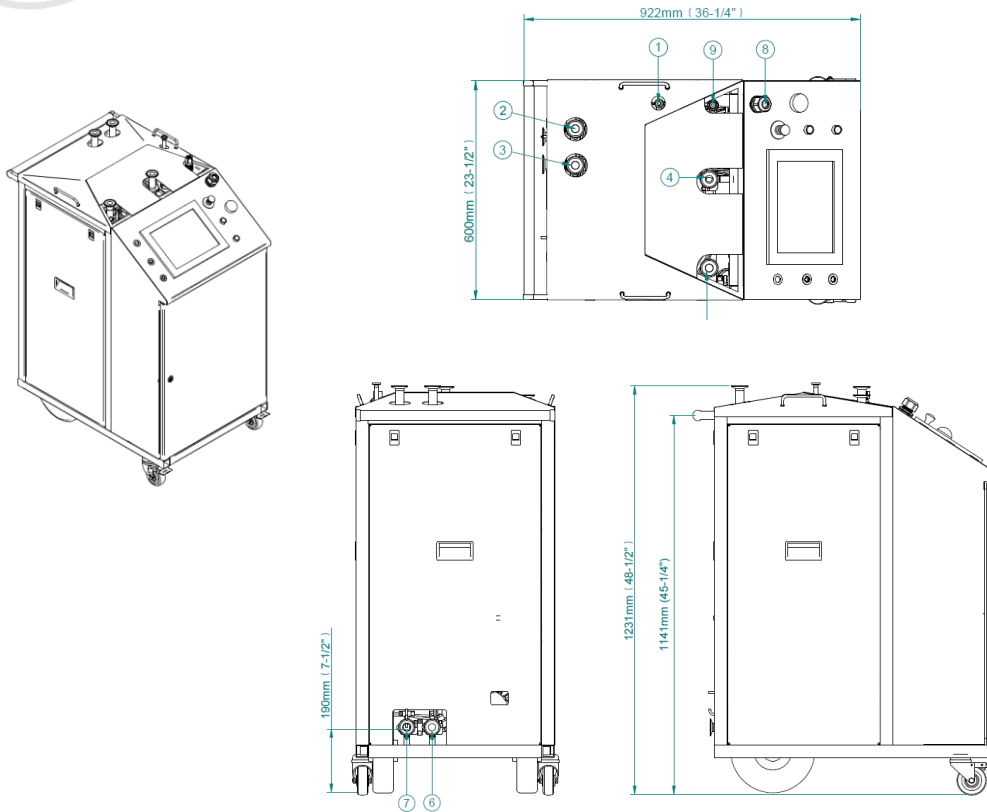
- ✓ Real time component status
- ✓ Real time instrument readings



Item Number	Description	Accessories
UP9005	SIP unit [SS]	Please contact us

## Portable SIP Unit [SS]

### General layout & tie-in schematic



#	Designation	Connection	Sizing	Expected setup
1	Cooling water	½" tri-clamp	½" (12.7 mm)	< 10 gpm @ <25 psi
2	SIP supply 1	1½" Tri clamp	1" (25 mm)	<250 lbs/hour @ <25 psi
3	SIP supply 2	1½" Tri clamp	1" (25 mm)	<250 lbs/hour @ <25 psi
4	Nitrogen	1½" Tri clamp	1" (25 mm)	< 50 cfm @ <45 psi
5	Steam	1½" Tri clamp	1" (25 mm)	<250 lbs/hour @ <30 psi
6	SIP return	1½" Tri clamp	1" (25 mm)	<25 lpm @ <25 psi
7	Drain	1½" Tri clamp	1" (25 mm)	TBD
8	Electrical	Plug	1x120V, 60 hz, 10A	N/A
9	Compressed air	½" quick con. or Tri clamp	1" (25 mm)	Nominal cfm @ 90 psi < 25 cfm @ < 35 psi (purge)

Item Number	Description	Accessories
UP9005	SIP unit [SS]	Please contact us



## CIP and CIP/SIP Systems

McFlusion provides modular to fully customized process cleaning (CIP) and sterilization (SIP) systems that are specifically designed and manufactured to meet the most stringent process and regulatory requirements within the highly regulated life science, biopharma, and vaccine industries.

These high performing and flexible CIP and CIP/SIP systems are based on McFlusion's advanced, modular, hardware and software technology platform – prepared for full integration with the process equipment and facility systems as well as local, dedicated, CIP satellites – using our Process Builder Design (PBD)<sup>™</sup>.

Our technology platform facilitates full use and tight control, monitoring, and reporting of all critical parameters (TACCT) for in-situ cleaning (CIP) and sterilization (SIP) operations on applications, such as:

- Aseptic fill lines with isolator technology
- Filter stations
- Formulation vessels
- Transfer lines
- Storage and holding tanks
- Bio reactors
- Ultra filtration skids
- Centrifuges
- Homogenizers
- Freeze dryers
- Glove box isolators
- Spray dryers

Our CIP and CIP/SIP systems for the life science, biopharma and vaccine industries are equipped with our Process Builder Design (PBD)<sup>™</sup> that secures an error-free, fast and effective software integration with and execution of the cleaning and/or sterilization processes on the production equipment.

The PBD<sup>™</sup> secures an efficient cleaning and sterilization process with full data and process supervision.

All our CIP and CIP/SIP systems are available and can be equipped with the optional 2-tier Data Collection System (DCS), as follows:

- Tier 1 – “DCS TECH” collects process technical data that can be applied for process analytics, trouble shooting, cleaning validation activities, etc.
- Tier 2 – “DCS GMP” adds collection of GMP data for audit trail, historian and reporting.

Our automation platform is prepared for multi-level integration & communication with site control systems, such as DeltaV.



## CIP and CIP/SIP Systems

Formulation & Holding vessels

Bio reactors



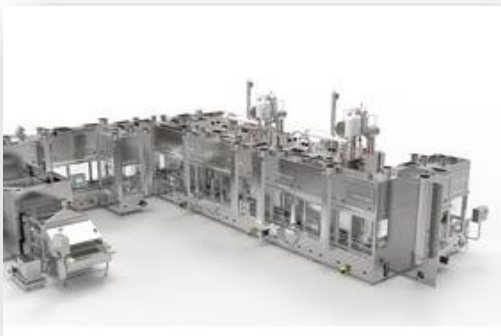
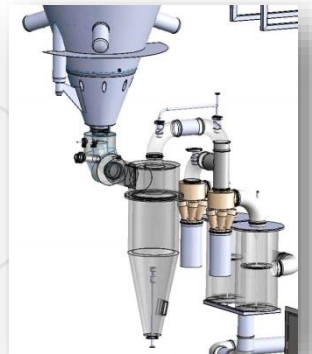
Centrifuges



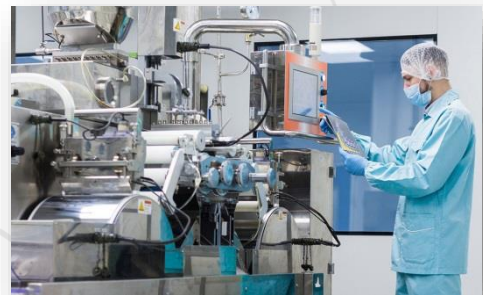
Parts Washers (COP)



Spray Dryers



Aseptic Fill Lines



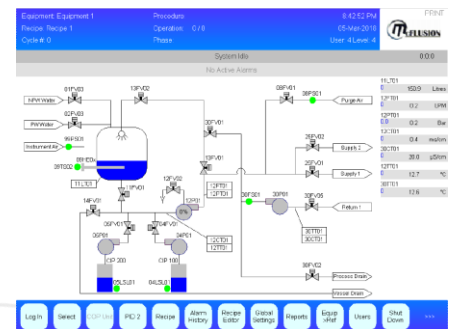
Packaging lines

## CIP System [CSV-1]

- ✓ Open frame in AISI 304 stainless steel with adjusted feet (optional covers)
  - ✓ Remote or integrated CIP return pump
  - ✓ Remote HMI station
- ✓ Modular hardware and software platform – multiple configurations available.
- ✓ Integrated electrical panel with AB Compact Logix PLC and PC based touch screen HMI
  - ✓ Full recipe editor, alarm handling and cycle reporting to PDF
  - ✓ Process Builder Design (PBD)<sup>™</sup> for full integration with process equipment and facility systems
  - ✓ AutoTune<sup>™</sup> for accurate control and supervision of supply zones (flow paths)
  - ✓ Data Collection System (DCS) with TECH and GMP features
- ✓ Full TACCT cleaning performance and flexibility
  - ✓ Adjustable pressures
  - ✓ Adjustable flow rates
  - ✓ Adjustable temperatures
  - ✓ Adjustable concentrations
- ✓ Full instrumentation package, including level, pressure, flow, temperature and conductivity (low and high)
- ✓ Full system design and QA documentation



Technical Data	Unit	CSV-1
Buffer tank	Gallon	150
Supply pressure	PSI	<150
Supply flow	GPM	<80
Temperature, Steam jacket	°F	<300
Chemistry	mS/cm	<200



### HMI interface: P&ID

- ✓ Real time component status
- ✓ Real time instrument readings

Controls:		
Allen Bradley compact Logix PLC	✓ Yes	
12" PC touch screen HMI	✓ Yes	
Allen Bradley software	✓ Yes	
McFlusion Process Builder Design <sup>™</sup>	✓ Yes	CIP
McFlusion AutoTune <sup>™</sup>	✓ Yes	
Data Collection System (DCS)	Optional	TECH & GMP

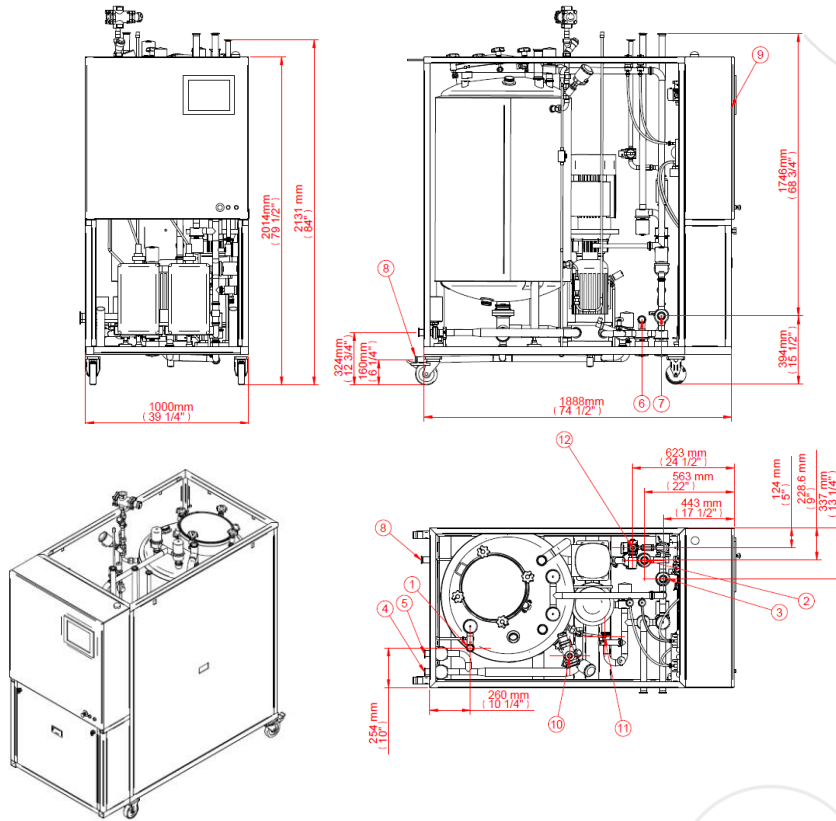
Size:		
Dimensions (LxWxH)	Inch	80 x 40 x 76
Weight, dry	Lbs	~1,500



Item Number	Description	Accessories
UP9007	CIP sysem [CSV-1]	Please contact us

## CIP System [CSV-1]

### General layout & tie-in schematic



#	Designation	Connection	Sizing	Expected setup
1	Water #1	1½" Tri clamp	1" (25 mm)	< 50 gpm @ 30 psi
N/A	<b>Optional:</b> Water #2 (not shown)	1½" Tri clamp	1" (25 mm)	< 30 gpm @ 20 psi
2	CIP supply 1	1½" Tri clamp	1½" (38 mm)	< 80 gpm @ < 150 psi
3	CIP supply 2	1½" Tri clamp	1½" (38 mm)	< 80 gpm @ < 150 psi
4	CIP return 1	1½" Tri clamp	1½" (38 mm)	< 80 gpm @ 35 psi
5	CIP return 2	1½" Tri clamp	1½" (38 mm)	< 80 gpm @ 35 psi
6	Optional: Ozone in	1½" Tri clamp	1½" (38 mm)	< 70 gpm @ < 40 psi
7	Optional: Ozone out	1½" Tri clamp	1½" (38 mm)	< 70 gpm @ < 40 psi
8	Process Drain	1½" Tri clamp	1½" (38 mm)	< 80 gpm @ < 35 psi
9	Electrical	Plug	3x480V, 60hz, 60A	N/A
10	Steam (for heating)	1" NPT	1" (25 mm)	< 300 lbs/hour @ 35 psi
11	Condensate	½" NPT	½" (12 mm)	N/A
12	Compressed air	1" Tri clamp	1" (25 mm)	Nominal cfm @ 90 psi < 45 cfm @ < 45 psi (purge)

Item Number	Description	Accessories
UP9007	CIP system [CSV-1]	Please contact us

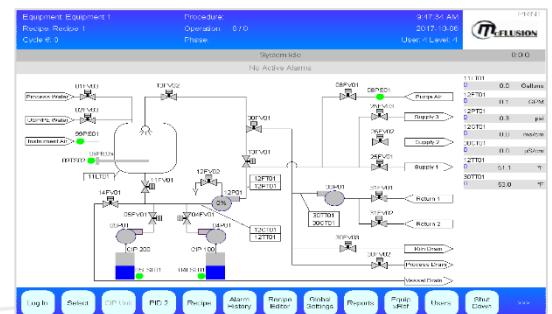


## CIP System [CSV-2]

- ✓ Open frame in AISI 304 stainless steel with adjusted feet (optional covers)
  - ✓ Remote or integrated CIP return pump
  - ✓ Remote HMI station
- ✓ Modular hardware and software platform – multiple configurations available.
- ✓ Integrated electrical panel with AB Compact Logix PLC and PC based touch screen HMI
  - ✓ Full recipe editor, alarm handling and cycle reporting to PDF
  - ✓ Process Builder Design (PBD)™ for full integration with process equipment and facility systems
  - ✓ AutoTune™ for accurate control and supervision of supply zones (flow paths)
  - ✓ Data Collection System (DCS) with TECH and GMP features
- ✓ Full TACCT cleaning performance and flexibility
  - ✓ Adjustable pressures
  - ✓ Adjustable flow rates
  - ✓ Adjustable temperatures
  - ✓ Adjustable concentrations
- ✓ Full instrumentation package, including level, pressure, flow, temperature and conductivity (low and high)
- ✓ Full system design and QA documentation



Technical Data	Unit	CSV-2
Buffer tank	Gallon	250
Supply pressure	PSI	<175
Supply flow	GPM	<120
Temperature, Steam jacket	°F	<300
Chemistry	mS/cm	<200



HMI interface: P&ID

- ✓ Real time component status
- ✓ Real time instrument readings

### Controls:

Allen Bradley compact Logix PLC	✓ Yes	
12" PC touch screen HMI	✓ Yes	
Allen Bradley software	✓ Yes	
McFlusion Process Builder Design™	✓ Yes	CIP
McFlusion AutoTune™	✓ Yes	
Data Collection System (DCS)	Optional	TECH & GMP

### Size:

Dimensions (LxWxH)	Inch	80 x 40 x 80
Weight, dry	Lbs	~1,750

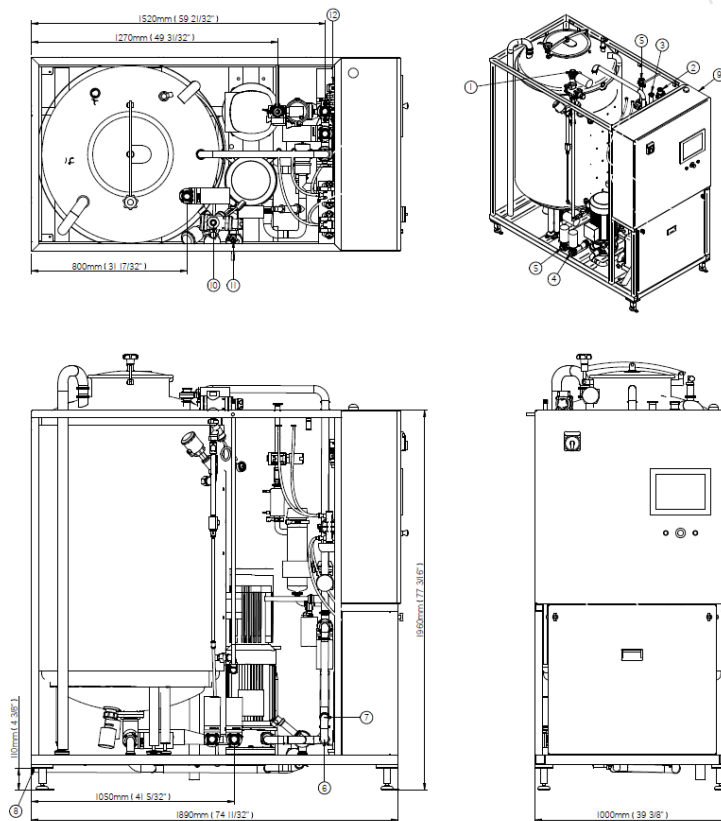


Item Number	Description	Accessories
UP9008	CIP system [CSV-2]	Please contact us



## CIP System [CSV-2]

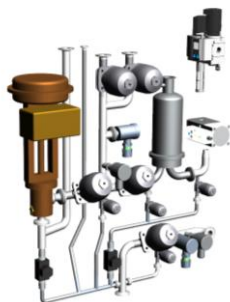
### General layout & tie-in schematic



#	Designation	Connection	Sizing	Expected setup
1	Water #1	1½" Tri clamp	1" (25 mm)	< 50 gpm @ 30 psi
N/A	<b>Optional:</b> Water #2 (not shown)	1½" Tri clamp	1" (25 mm)	< 30 gpm @ 20 psi
2	CIP supply 1	1½" Tri clamp	1½" (38 mm)	< 120 gpm @ < 175 psi
3	CIP supply 2	1½" Tri clamp	1½" (38 mm)	< 120 gpm @ < 175 psi
4	CIP return 1	1½" Tri clamp	1½" (38 mm)	< 120 gpm @ 35 psi
5	CIP return 2	1½" Tri clamp	1½" (38 mm)	< 120 gpm @ 35 psi
6	<b>Optional:</b> Ozone in	1½" Tri clamp	1½" (38 mm)	< 70 gpm @ < 40 psi
7	<b>Optional:</b> Ozone out	1½" Tri clamp	1½" (38 mm)	< 70 gpm @ < 40 psi
8	Process Drain	1½" Tri clamp	1½" (38 mm)	< 120 gpm @ < 35 psi
9	Electrical	Plug	3x480V, 60hz, 60A	N/A
10	Steam (for heating)	1" NPT	1" (25 mm)	< 300 lbs/hour @ 35 psi
11	Condensate	½" NPT	½" (12 mm)	N/A
12	Compressed air	1" Tri clamp	1" (25 mm)	Nominal cfm @ 90 psi < 45 cfm @ < 45 psi (purge)

Item Number	Description	Accessories
UP9008	CIP system [CSV-2]	Please contact us

## Wall-mounted SIP System [SS]



- ✓ Wall mount SIP installation (frame and covers not shown)
  - ✓ Service-able from front
  - ✓ Integrated or remote HMI station
- ✓ Modular hardware and software platform – multiple configurations available.
- ✓ Integrated or remote electrical panel with AB Compact Logix PLC with PC based HMI station
  - ✓ Full SIP recipe editor, alarm handling and cycle reporting to PDF
  - ✓ Process Builder Design (PBD)<sup>™</sup>
  - ✓ AutoTune<sup>™</sup>
  - ✓ Data Collection System (DCS) with TECH and GMP features
- ✓ Full TACCT sterilization performance and flexibility
  - ✓ Adjustable pressures
  - ✓ Adjustable timers
  - ✓ Adjustable temperatures
  - ✓ Adjustable F0 set points (pass/fail)
- ✓ Full instrumentation package, including pressure and temperature on supply and return (cold spot)
- ✓ Full system design and QA documentation

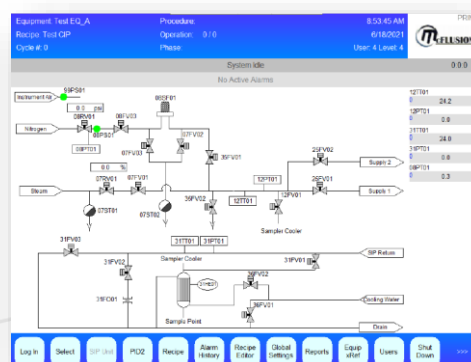
Technical Data - SIP	Unit	SS
SIP supply pressure	PSI	<60
SIP supply temperature	°F	<302
Optional: Modulating steam valve	mA	4-20
SIP return pressure/vacuum	PSI	-14.5 – 90
SIP return temperature	°F	<302

### Controls:

Allen Bradley compact Logix PLC	✓ Yes	
12" PC touch screen HMI	✓ Yes	
Allen Bradley software	✓ Yes	
McFlusion Process Builder Design <sup>™</sup>	✓ Yes	SIP
McFlusion AutoTune <sup>™</sup>	✓ Yes	
Data Collection System (DCS)	Optional	TECH & GMP

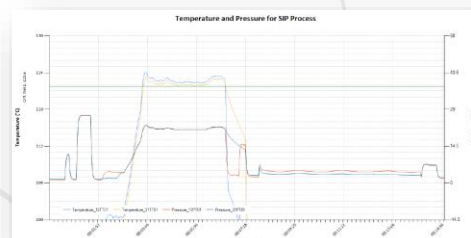
### Size:

Dimensions (WxDxH)	Inch	28 x 10 x 40
Weight, dry	Lbs	~225



HMI interface: P&ID

- ✓ Real time component status
- ✓ Real time instrument readings



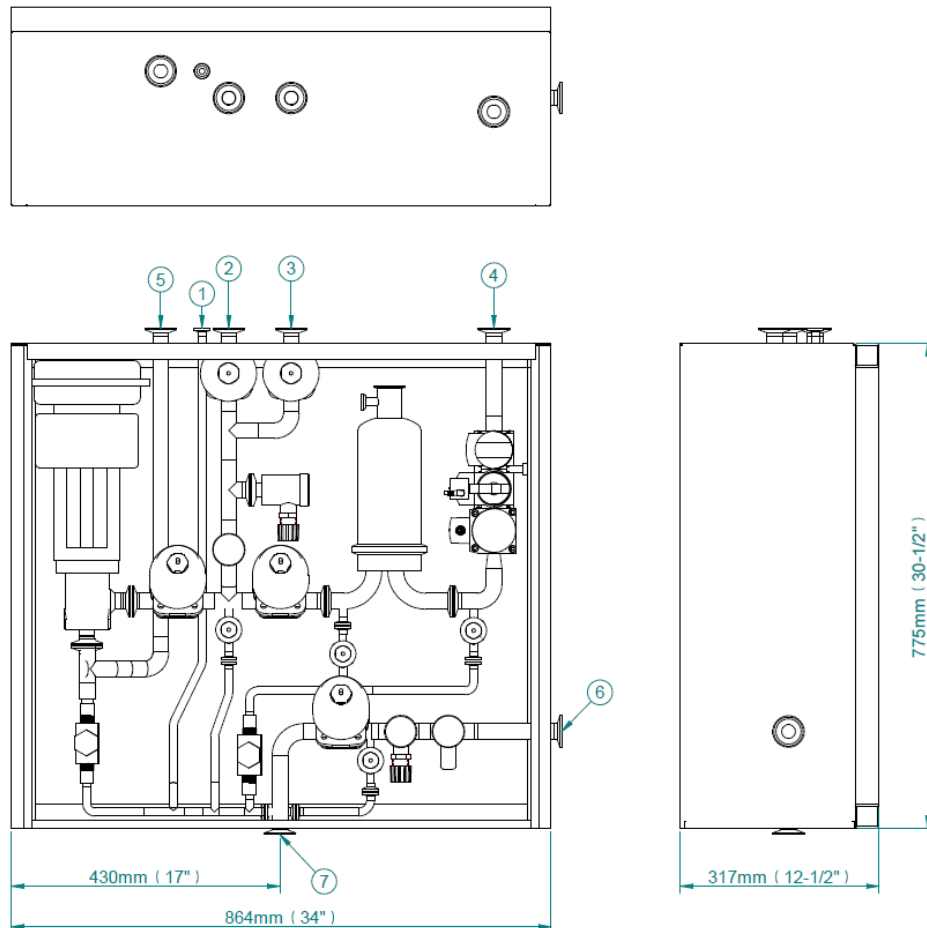
SIP report

- ✓ Temperature curves
- ✓ Pressure curves

Item Number	Description	Accessories
UP9006	SIP system [SS]	Please contact us

## Wall-mounted SIP System [SS]

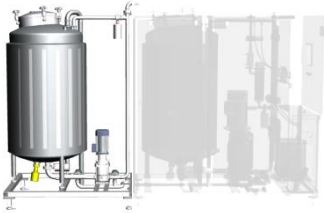
### General layout & tie-in schematic



#	Designation	Connection	Sizing	Expected setup
1	Cooling water	½" tri-clamp	½" (12.7 mm)	< 10 gpm @ <25 psi
2	SIP supply 1	1½" Tri clamp	1" (25 mm)	<250 lbs/hour @ <25 psi
3	SIP supply 2	1½" Tri clamp	1" (25 mm)	<250 lbs/hour @ <25 psi
4	Nitrogen	1½" Tri clamp	1" (25 mm)	< 50 cfm @ <45 psi
5	Steam	1½" Tri clamp	1" (25 mm)	<250 lbs/hour @ <30 psi
6	SIP return	1½" Tri clamp	1" (25 mm)	<25 lpm @ <25 psi
7	Drain	1½" Tri clamp	1" (25 mm)	TBD
8	Electrical	Plug	1x120V, 60 hz, 10A	N/A
9	Compressed air	½" quick con. or Tri clamp	1" (25 mm)	Nominal cfm @ 90 psi < 25 cfm @ < 35 psi (purge)

Item Number	Description	Accessories
UP9006	SIP system [SS]	Please contact us

## 150 and 250 Gallon Add-on Buffer Tank Systems for CIP and CIP/SIP systems



- ✓ Compact platform in AISI 304 stainless steel with four (4) adjustable feet
- ✓ 150 gallon or 250 gallon atmospheric buffer vessel (optional vent filter)
- ✓ Level and temperature control & monitoring
- ✓ Integrated heating module (electric or steam)
- ✓ Integrated circulation and transfer pump
- ✓ Wetted parts and components in AISI316L SS, diaphragm valves, etc.
- ✓ Electrical panel with remote I/Os for full integration to McFlusion CIP and CIP/SIP equipment
- ✓ System is designed for full internal cleaning, sanitization and purge.

Technical Data	Unit	150 gallon Buffer tank	250 gallon Buffer tank
Buffer tank	Gallon	150	250
Supply pressure	PSI	<45	<45
Temperature, Electric (steam jacket)	°F	<200 (<300)	<200 (<300)

### Controls:

Remote I/O - integrated with and controlled by CIP or CIP/SIP equipment	✓ Yes	✓ Yes
McFlusion Process Builder Design <sup>™</sup>	✓ Yes	✓ Yes

### Size:

Dimensions (LxWxH)	Inch	63 x 40 x 85	63 x 40 x 85
Weight, dry	Lbs	750	850

Item Number	Description	Accessories
MP7000	150 Gal add-on buffer tank	Please contact us
MP7001	250 Gal add-on buffer tank	

## 250 Gallon Stand-alone Hot Water Tank System



- ✓ Open frame in AISI 304 stainless steel with adjusted feet
- ✓ 250 gallon atmospheric buffer tank
  - ✓ Optional vent filter arrangement w/rupture disc including upgrade to differential pressure transmitters for accurate level control.
- ✓ Integrated electrical panel with AB Compact Logix PLC
  - ✓ Full integration with McFlusion CIP or CIP/SIP equipment
- ✓ Instrumentation package, including level and temperature
- ✓ Circulation and transfer pump
- ✓ Integrated heating module (electric or steam)
- ✓ Wetted surfaces in AISI 316L stainless steel, diaphragm valves, etc.
- ✓ Full system design and QA documentation
- ✓ System is designed for full internal cleaning, sanitization and purge. System is prepared for integration with Ozone skid.

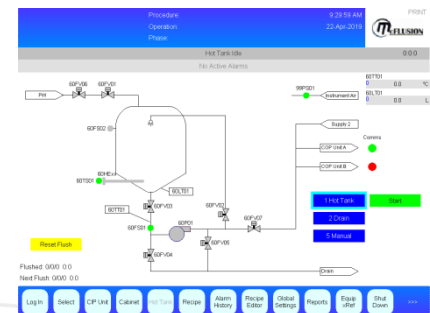
Technical Data	Unit	CSV-HWT
Buffer tank	Gallon	250
Supply pressure	PSI	<45
Temperature, Electric (Steam jacket)	°F	<200 (300)

### Controls:

Allen Bradley compact Logix PLC	✓ Yes
12" PC touch screen HMI	Optional
Allen Bradley software	✓ Yes
McFlusion Process Builder Design™	✓ Yes
Purge functionality	✓ Yes
Ozone	Optional
Data Collection System (DCS)	Optional

### Size:

Dimensions (LxWxH)	Inch	63 x 40 x 85
Weight, dry	Lbs	~850



### HMI interface: P&ID

- ✓ Real time component status
- ✓ Real time instrument readings

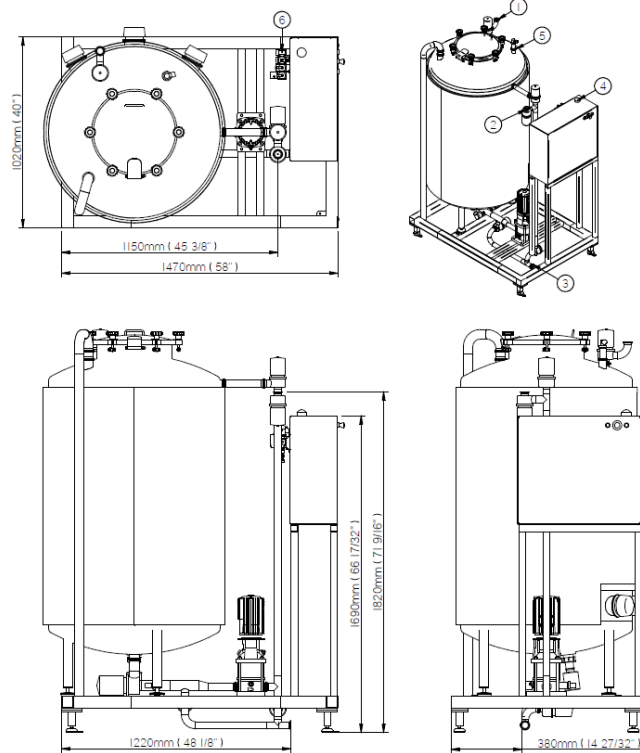


Item Number	Description	Accessories
UP6009	250 gal stand-alone hot water tank system [CSVHWT]	Please contact us



## 250 Gallon Stand-Alone Hot Water Tank System

### General layout & tie-in schematic



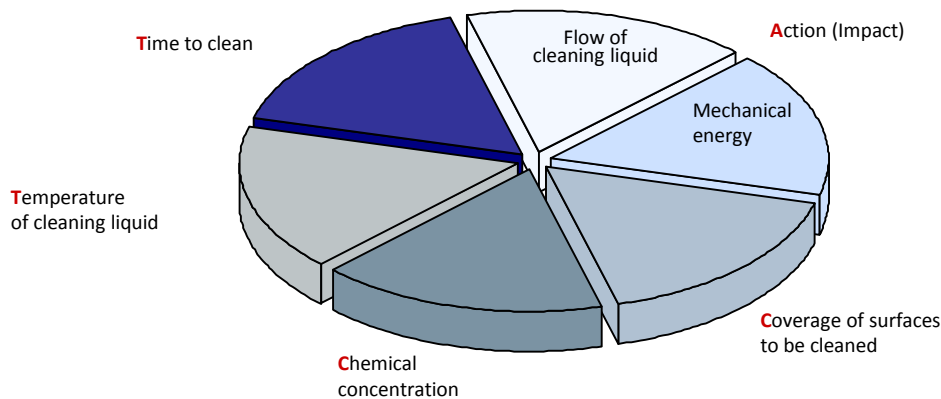
#	Designation	Connection	Sizing	Expected setup
1	Water #1	1½" Tri clamp	1½" (38 mm)	< 50 gpm @ 30 psi
2	Supply / transfer	1½" Tri clamp	1½" (38 mm)	< 45gpm @ < 35psi
3	Drain	1½" Tri clamp	1½" (38 mm)	< 30 gpm @ 20 psi
4	Electrical	Plug	60 Amps	3x480V, ground, 60 Hz, 60 Amps
5	High level switch	1½" Tri clamp	1" (25 mm)	N/A
6	Compressed air	¼" NPT	½" (4 mm)	Nominal cfm @ 90 psi

Item Number	Description	Accessories
UP6009	250 gal stand-alone hot water tank system [CSVHWT]	Please contact us

## Specialty Parts & IBC Washers

McFlusion designs and manufactures specialty Parts and IBC Washers for Cleaning-Out-of-Place (COP), sanitization and drying of disassembled parts, larger componentry and vessels (bins, drums and IBCs) within the highly regulated life science, biopharma, and vaccine industries.

The specialty Parts and IBC washers are based upon our modular hardware and software technology platform that facilitates full use and tight control, monitoring, and reporting of all critical parameters (TACCT) for cleaning (COP), sanitization and drying operations.



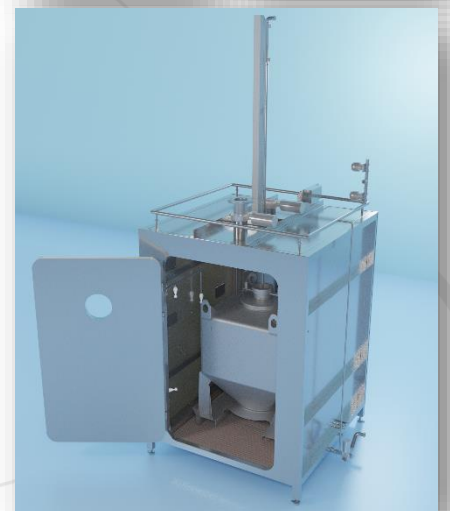
Each Parts and IBC Washer is designed using configurable equipment modules:

- Process cleaning unit (portable or fixed CIP);
- Single or double-door washing cabinet (configurable);
- Customized parts racks with multiple individual cleaning zones and/or cleaning adapters for drums/IBCs or other large equipment;
- Forced air drying module (portable or fixed);

Our specialty parts and IBC washers for the life science, biopharma and vaccine industries are equipped with our Process Builder Design (PBD)<sup>™</sup> that secures an efficient and validated cleaning process with full data and process supervision.

All our Parts and IBC washers are available and can be equipped with the optional 2-tier Data Collection System (DCS), as follows:

- Tier 1 – “DCS TECH” collects process technical data that can be applied for process analytics, trouble shooting, cleaning validation activities, etc.
- Tier 2 – “DCS GMP” adds collection of GMP data for audit trail, historian and reporting.



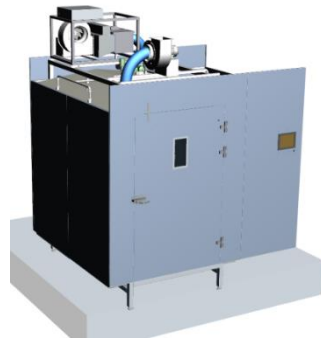
## Specialty Parts & IBC Washers

McFlusion's modular program for specialty Parts and IBC Washers includes the following main configurations:

1

### Complete Specialty Parts & IBC Washer

- Single or double door washing cabinet for portable parts racks or stand-alone larger equipment (IBCs, totes, etc.)
- Integrated process cleaning system
- Forced air drying module (integrated)
- Portable custom racks for disassembled parts and componentry



2

### Modular Specialty Parts & IBC Washer

- Stand-alone, portable or fixed, process cleaning system
- Single or double door washing cabinet for portable parts racks or stand-alone larger equipment (IBCs, totes, etc.)
- Stand-alone, portable or fixed (integrated), forced air drying module
- Portable custom racks for disassembled parts and componentry



- OR -



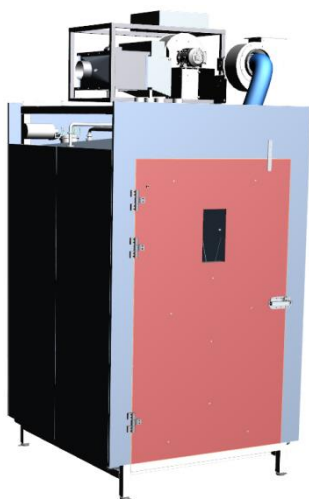
3

### Modular, Portable, Specialty Parts (COP) Washer System

- Stand-alone, portable or fixed, process cleaning unit
- Portable or fixed single door washing cabinet for smaller parts w/ single or multiple custom shelves for disassembled parts
- Stand-alone, portable or fixed, forced air drying module



## Specialty Parts & IBC Washing Cabinet [PW1]



- ✓ Multi-purpose washing cabinet for disassembled parts, portable IBCs, hoppers and other process equipment
- ✓ Single or double door washing cabinet in AISI 316 stainless steel with four (4) adjustable feet
- ✓ Perforated (drainable) floor with guide rails for process equipment and/or portable racks
- ✓ Sloped drain pan w/single low point for true single-pass-to-drain rinses and/or re-circulation.
- ✓ Configurable piping and spray device setup with multiple cleaning zones
- ✓ Full integration with McFlusion process cleaning (CIP) systems
  - ✓ Full recipe editor, alarm handling and cycle reporting to PDF
  - ✓ Process Builder Design (PBD)™ for full control and process supervision
  - ✓ AutoTune™ for accurate control and supervision of supply zones (flow paths)
  - ✓ Optional: Data Collection System (DCS) with TECH and GMP features
- ✓ Full TACCT cleaning performance and flexibility
  - ✓ Adjustable pressures
  - ✓ Adjustable flow rates
  - ✓ Adjustable temperatures
  - ✓ Adjustable concentrations

Technical Data	Unit	PW1
Outer chamber dimensions (LxWxH)	Inch	73 x 70 x 110
Inner chamber dimensions (LxWxH)	Inch	68 x 65 x 100
Drain pan dimensions (LxWxH)	Inch	68 x 65 x 15
Door size (WxH)	Inch	55 x 90
Weight	Lbs	2450



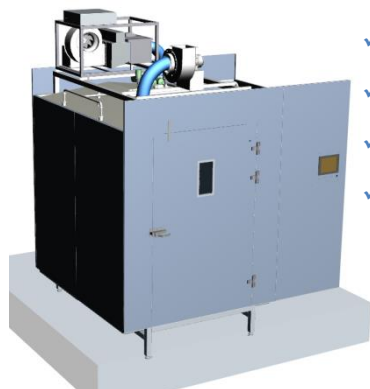
Controls:		
Full integration with and controlled by McFlusion CIP equipment	✓ Yes	Recipe editor, alarm handling and reporting
12" PC touch screen HMI	✓ Yes	Integrated or remote
Data Collection System (DCS)	Optional	TECH & GMP

Configurations and options		
Ceiling & wall mount rotary spray arms	✓ Yes	Full coverage, adjustable impact
Portable, customized, parts rack(s)	✓ Yes	Single to multi-zone racks
Forced air drying module	✓ Yes	Pre-filter, fan, heater HEPA filter
Exhaust fan	Optional	
McFlusion CIP	Required	Select portable or stationary CIP



Item Number	Description	Accessories
UP6050	Parts washing cabinet [PW1]	Please contact us

## Specialty Parts & IBC Washing Cabinet [PW2]



Washing cabinet shown with forced air-drying module and exhaust fan as well as fixed CIP system, fascia plates and HMI

- ✓ Multi-purpose washing cabinet for disassembled parts, portable IBCs, hoppers and other process equipment
- ✓ Single or double door washing cabinet in AISI 316 stainless steel with four (4) adjustable feet
- ✓ Perforated (drainable) floor with guide rails for process equipment and/or portable racks
- ✓ Sloped drain pan w/single low point for true single-pass-to-drain rinses and/or re-circulation.
- ✓ Configurable piping and spray device setup with multiple cleaning zones
- ✓ Full integration with McFlusion process cleaning (CIP) systems
  - ✓ Full recipe editor, alarm handling and cycle reporting to PDF
  - ✓ Process Builder Design (PBD)™ for full control and process supervision
  - ✓ AutoTune™ for accurate control and supervision of supply zones (flow paths)
  - ✓ Optional: Data Collection System (DCS) with TECH and GMP features
- ✓ Full TACCT cleaning performance and flexibility
  - ✓ Adjustable pressures
  - ✓ Adjustable flow rates
  - ✓ Adjustable temperatures
  - ✓ Adjustable concentrations

Technical Data	Unit	PW2
Outer chamber dimensions (LxWxH)	Inch	101 x 84 x 110
Inner chamber dimensions (LxWxH)	Inch	96 x 80 x 100
Drain pan dimensions (LxWxH)	Inch	96 x 80 x 15
Door size (WxH)	Inch	55 x 90
Weight	Lbs	2650

Controls:		
Full integration with and controlled by McFlusion CIP equipment	✓ Yes	Recipe editor, alarm handling and reporting
12" PC touch screen HMI	✓ Yes	Integrated or remote
Data Collection System (DCS)	Optional	TECH & GMP

Configurations and options		
Ceiling & wall mount rotary spray arms	✓ Yes	Full coverage, adjustable impact
Portable, customized, parts rack(s)	✓ Yes	Single to multi-zone racks
Forced air drying module	✓ Yes	Pre-filter, fan, heater HEPA filter
Exhaust fan	Optional	
McFlusion CIP	Required	Select portable or stationary CIP



Item Number	Description	Accessories
UP6051	Parts washing cabinet [PW2]	Please contact us



## Portable Parts Washing Cabinet [PW3]



- ✓ Multi-purpose washing cabinet for disassembled parts and accessories
- ✓ Single door washing cabinet in AISI 316 stainless steel with bottom frame and four (4) wheels
- ✓ Perforated (drainable) floor with guide rails for pull-out drawer
- ✓ Sloped drain pan w/single low point for true single-pass-to-drain rinses and/or re-circulation.
- ✓ Configurable piping and spray device setup with multiple cleaning zones
- ✓ Full integration with McFlusion process cleaning (CIP) systems
  - ✓ Full recipe editor, alarm handling and cycle reporting to PDF
  - ✓ Process Builder Design (PBD)™ for full control and process supervision
  - ✓ AutoTune™ for accurate control and supervision of supply zones (flow paths)
  - ✓ Optional: Data Collection System (DCS) with TECH and GMP features
- ✓ Full TACCT cleaning performance and flexibility
  - ✓ Adjustable pressures
  - ✓ Adjustable flow rates
  - ✓ Adjustable temperatures
  - ✓ Adjustable concentrations

Technical Data	Unit	PW3
Outer chamber dimensions (LxWxH)	Inch	40 (59) x 36 x 70
Inner chamber dimensions (LxWxH)	Inch	35 x 35 x 48
Drain pan dimensions (LxWxH)	Inch	35 x 35 x 12
Door size (WxH)	Inch	55 x 38
Weight	Lbs	375

### Controls:

Full integration with and controlled by McFlusion CIP equipment	✓ Yes	Recipe editor, alarm handling and reporting
12" PC touch screen HMI	✓ Yes	Remote (on CIP equipment)
Data Collection System (DCS)	Optional	TECH & GMP

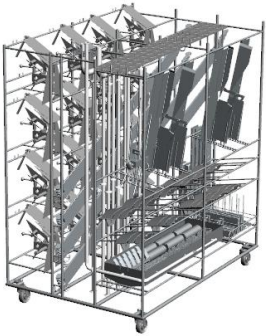
### Configurations and options

Ceiling & wall mount rotary spray arms	✓ Yes	Full coverage, adjustable impact
Drawer, customized	✓ Yes	Single to multi-zone racks
Forced air drying module	Optional	Pre-filter, fan, heater HEPA filter
Exhaust fan	Optional	
McFlusion CIP	Required	Select portable or stationary CIP



Item Number	Description	Accessories
UP6052	Parts washing cabinet [PW3]	Please contact us

## Portable Parts Rack, Size PW1



- ✓ Compact, open, frame in AISI 316 stainless – constructed in round tube/rods for full clean-ability and drainage
  - ✓ Four (4) wheels, antistatic
- ✓ Multi-level rack system to maximize parts load
  - ✓ Rack loadable from all four (4) sides
- ✓ Custom racks & shelves
  - ✓ Racks - including brackets, flow-thru boxes, etc. - are developed in 2D/3D with full parts load and cleaning simulation
- ✓ Single point TC connections for up to three (3) different flow paths (cleaning zones)
- ✓ Distribution piping in AISI 316 stainless steel for multiple zones
  - ✓ Integrated static spray nozzles and rotary spray arms
- ✓ Racks are self-cleaning and drain-able (gravity and purge)
- ✓ Cleaning, sanitization and purge process with individual control of each flow path (cleaning zone) is controlled by McFlusion recipe editor with AutoTune™ (patent pending) functionality

Technical Data	Unit	Rack
Dimensions (LxWxH)	Inch	41 x 43 x 75
Weight	Lbs	App. 240
Material of construction	N/A	AISI316L, EPDM, PTFE
Temperature	°F	<200
Chemistry	N/A	Compatible with standard chemicals

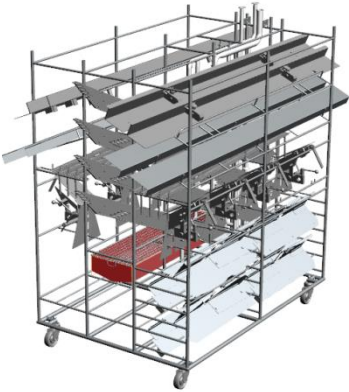
Configuration	
Single to multiple layer(s)	✓ Yes
Multiple cleaning zones (1-3)	✓ Yes
Static spray nozzles	✓ Yes
Rotary spray arms	✓ Yes
High impact spray devices	✓ Optional
Flow thru box	✓ Optional



Item Number	Description	Accessories
MP7011	Portable parts rack	Please contact us

## Portable Parts Rack, Size PW 2

- ✓ Compact, open, frame in AISI 316 stainless – constructed in round tube/rods for full clean-ability and drainage
  - ✓ Four (4) wheels, antistatic
- ✓ Multi-level rack system to maximize parts load
  - ✓ Rack loadable from all four (4) sides
- ✓ Custom racks & shelves
  - ✓ Racks - including brackets, flow-thru boxes, etc. - are developed in 2D/3D with full parts load and cleaning simulation
- ✓ Single point TC connections for up to three (3) different flow paths (cleaning zones)
- ✓ Distribution piping in AISI 316 stainless steel for multiple zones
  - ✓ Integrated static spray nozzles and rotary spray arms
- ✓ Racks are self-cleaning and drain-able (gravity and purge)
- ✓ Cleaning, sanitization and purge process with individual control of each flow path (cleaning zone) is controlled by McFlusion recipe editor with AutoTune™ (patent pending) functionality



Technical Data	Unit	Rack
Dimensions (LxWxH)	Inch	41 x 60 x <75
Weight	Lbs	App. 275
Material of construction	N/A	AISI316L, EPDM, PTFE
Temperature	°F	<200
Chemistry	N/A	Compatible with standard chemicals



Configuration	
Single to multiple layer(s)	✓ Yes
Multiple cleaning zones (1-3)	✓ Yes
Static spray nozzles	✓ Yes
Rotary spray arms	✓ Yes
High impact spray devices	✓ Optional
Flow thru box	✓ Optional



Item Number	Description	Accessories
MP7012	Portable parts rack	Please contact us

## Hardware Integration Modules

McFlusion has a diverse range of products for hardware Integration – applicable for Pilot Plants to Large Scale Manufacturing facilities.

1

### Remote HMI Panels

- Wall mounted panels
- Built-in (embedded into wall) with flush front

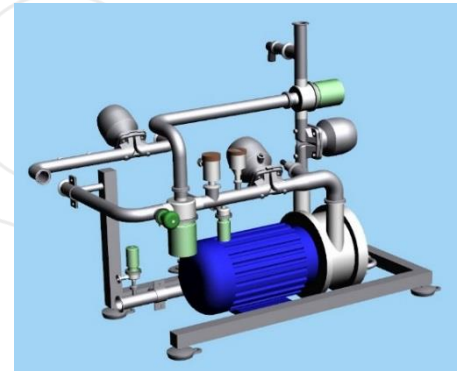
- Front or back access to panels
- AISI304 / 316 stainless steel
- NEMA4X / IP65
- 12" Windows 10 panels – standard program



2

### Remote CIP and CIP/SIP Return Pump Modules

- Stand-alone, portable or fixed, CIP or CIP/SIP return pump modules.
- Configurable with local valve manifold for single-pass-to-drain and/or re-circulation operations, condensate & waste-water cooling and local instrumentation, such as final rinse conductivity, pH, pressure and temperature transmitters.
- Integrated with and controlled by McFlusion CIP or CIP/SIP units via standard Ethernet/IP



3

### Vacuum Pump Modules

- Stand-alone or integrated vacuum pump modules
- Portable or fixed skid with single or double liquid ring vacuum pump
- Exhaust with housing, drain w/ optional cooling, process connections with pneumatic valves.
- Integrated with and controlled by McFlusion CIP or CIP/SIP units via standard Ethernet/IP





## Hardware Integration Modules - continued

McFlusion has a diverse range of products for hardware Integration – applicable for Pilot Plants to Large Scale Manufacturing facilities.

4

### CIP and CIP/SIP Docking Stations

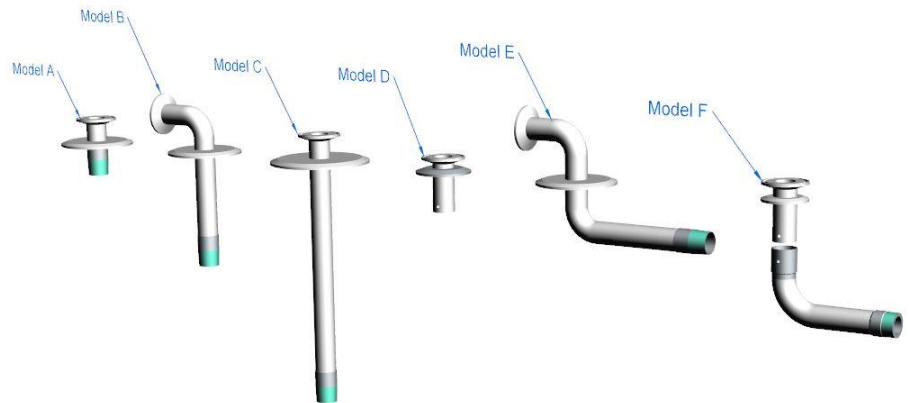
- Docking station(s) for portable tank(s) and other portable equipment.
- Docking station can be equipped with single or multiple CIP and/or SIP process connections – reflecting the complexity of the process vessel.
- Docking station(s) are typically equipped with 'remote' HMI panels with 12" Win 10 touch screen panel, stack-light and E-stop as well as USP and Ethernet ports for communication with the process vessel's TCU, mixer and valves
- Integrated with and controlled by McFlusion CIP or CIP/SIP units via standard Ethernet/IP



5

### CIP Adapters

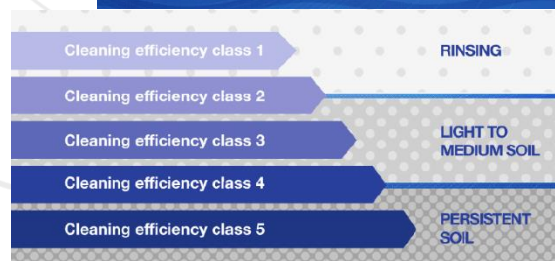
- Double tri clamp adapters
- Aux. lengths and sizes (ASME BPE tubing)
- Connections with NPT, BSP, split, TC
- Fully sanitary connections with O-rings and/or gaskets
- AISI316
- Ra < 15, EP



6

### Spray Devices

- Selection of spray device(s) is based upon the equipment to-be-cleaned as well as the product soils to-be-removed.
- Full program of spray devices – ranging from static spray balls for light soils, single-axis rotary spray devices for medium soils to double-axis high impact spray devices for the very difficult-to-clean applications.





## Automation and Data Management Platform

All McFlusion process cleaning (CIP/COP), sanitization and sterilization (SIP) equipment are equipped with a standardized and modular control platform that applies for all automation software and hardware, that is pneumatic, electrical, instrumentation and automation installations.

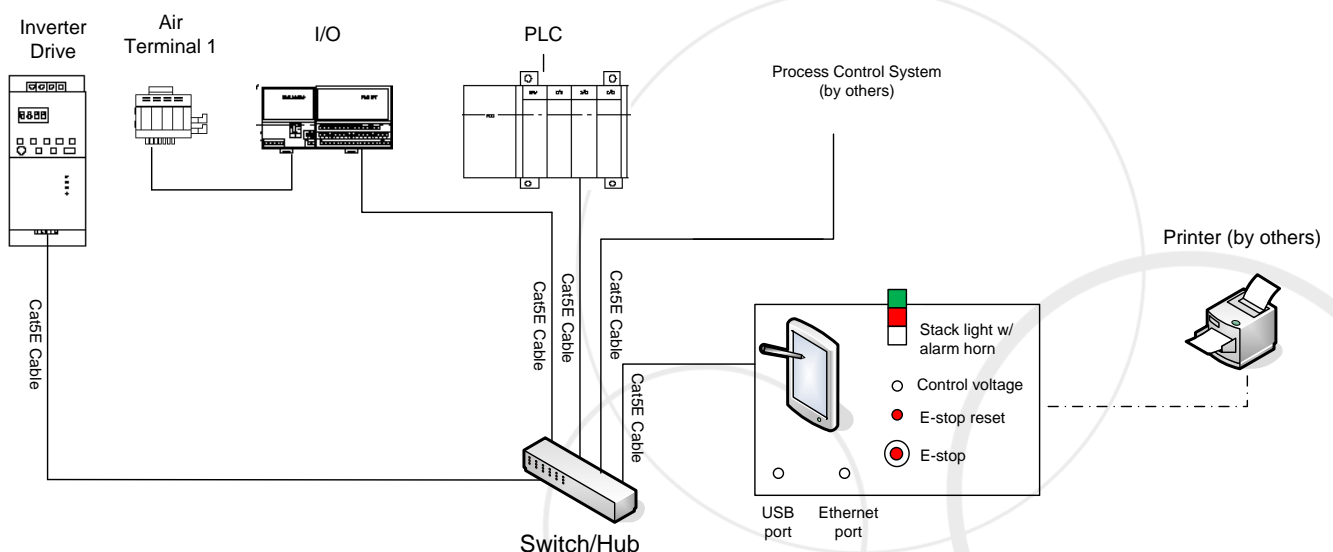
The baseline automation platform is based upon Allen Bradley PLC's, programmed in RS Logix 5000, with a 12" PC based touch screen operator panel, running either Rockwell Factory Talk View or a Windows 10 integrated HMI software, with full recipe editor, alarm handling and cycle reporting to PDF (USB).

The baseline automation platform is based on ISA S88 Batch Model and is 21CFR part 11 compliant (with Electronic Records and Electronic Signatures as add-on modules to the basic platform).

This automation platform includes McFlusion's **AutoTune™** (patent pending) software that detects process deviations in pressure and flow, as well as cleaning device performance automatically. AutoTune™ establishes the baseline for a cleaning procedure and monitors process flow paths used in cleaning, sanitization, and sterilization with automated alarms and interlocks if a validated process is changing over time. AutoTune™ protects your process equipment and ensures that your cleaning process is consistent and reliable over time.

In addition, the automation platform is prepared for the add-on McFlusion **Process Builder Design™** (patent pending) process integration that communicates with and integrates all relevant componentry on the process equipment to ensure that cleaning and/or sterilization processes are not only easily and correctly set up and configured but also allows accurate adjustment and monitoring (e.g. during CIP/SIP cycle development, validation and daily operation).

Example: Automation Hardware (network) setup.



## Process Builder Design (PBD)

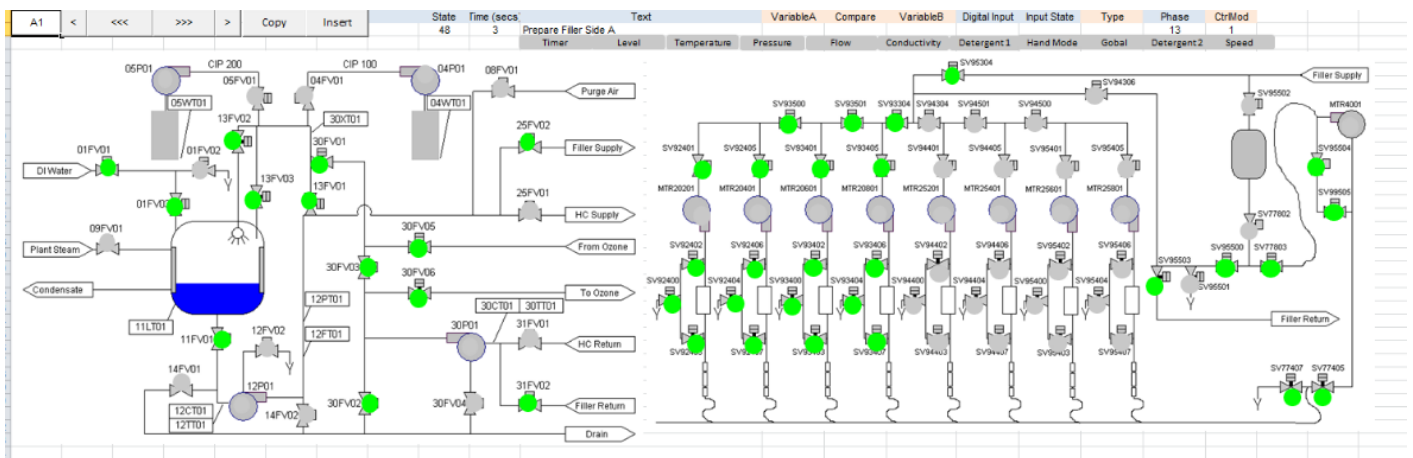
For all our Process cleaning (CIP) equipment we have an add-on CIP Process Integrated platform for all process equipment that we are cleaning.

We will control the CIP/SIP sequences from the CIP plc – and integrate with the process equipment plc through a simple I/O mapping between the plc’s – without changing the process equipment plc software. Any interlocks or other conditions for the process equipment will be unchanged.

As such – we can create an efficient cleaning process with full data and process supervision of all elements of the process equipment we are cleaning.

And – we will develop and validate the CIP process in a fraction of time otherwise needed.

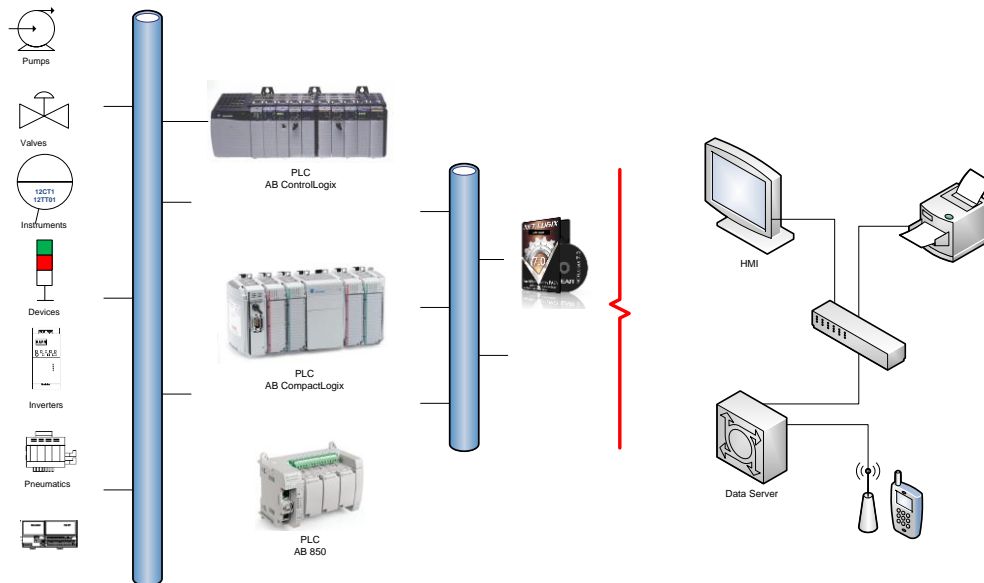
Ask for our “Process Builder Design” software platform to be included in any cleaning project.



Item Number	Description
MP9014	<p>Process Builder Design (PBD) is an add-on to McFlusion's CIP/SIP systems.</p> <p>Process Builder Design – add on</p> <p>PBS is used for control and monitoring of process equipment being cleaned and/or sterilized - using an integrated PLC-to-PLC tool based on direct I/O control (without changing the PLC controls of the process equipment).</p>

## Data Collection System (DCS)

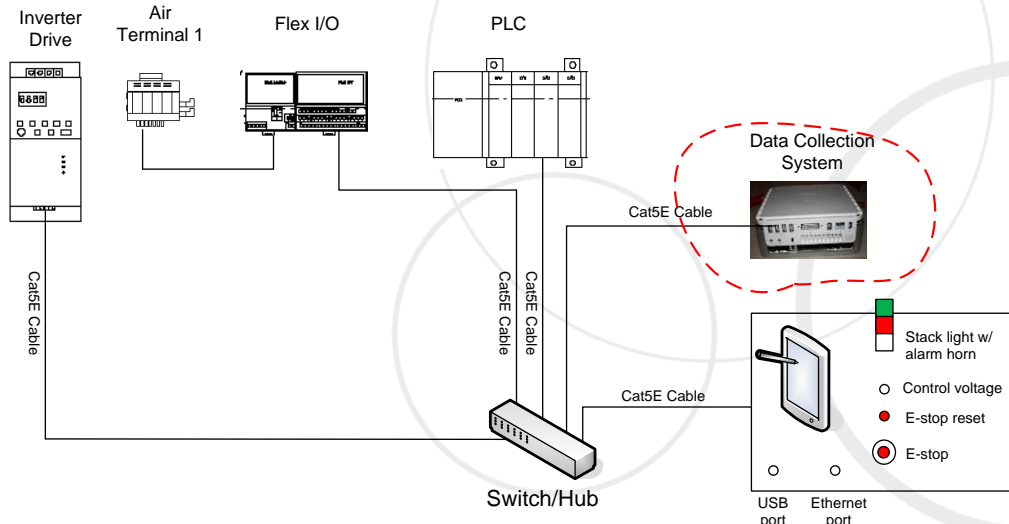
The DCS hardware platform is based on a stand-alone Win10 Pro computer that will be installed permanently in the electrical panel of the CIP equipment, where it will be set up to pull data from the PLC by means of Ethernet.



The Win10 Pro Computer will have the following basic software installed:

- Communication software (.NET OPC) to connect the DCS software to the Allen Bradley Compact Logix PLC
- Data Collection Server and Client software – developed in C# – using a SQL database to store all data and a Microsoft Excel developed application for viewing and analyzing process technical data. A SQL database only is used for all GMP defined data and reports:
- Windows RDP communication to computer to eliminate the need for and use of keyboard, monitor and mouse

The schematic below shows an example of the automation hardware (network) setup with DCS.



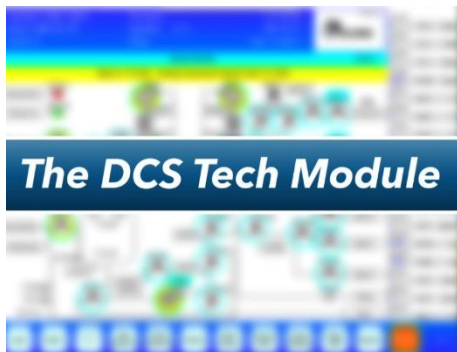
## Data Collection System (DCS)

All our process cleaning (CIP/COP) equipment are available and can be delivered with the optional 2-tier Data Collection System (DCS).

Tier 1 – “DCS TECH” collects process technical data that can be applied for process analytics , trouble shooting, cleaning validation activities, optimization etc.

Tier 2 – “DCS GMP” adds collection of GMP data for audit trail, historian and reporting.

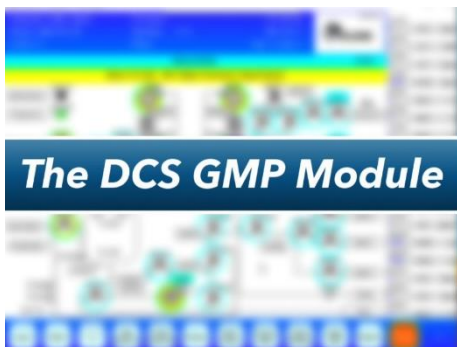
### Tier 1 Data Collection System (DCS) - TECH



#### DCS-TECH key features:

- Data collection from PLC every second, 24/7
- Raw data saved in Excel – structured in 24-hour files OR
- Raw data saved in SQL database
- Process Viewer with Playback Tool for full raw data and event data (Excel apps)
- Graphical Viewer for Analogue data (in Excel apps)
- Equipment Performance Report in PDF
- Alarm Reports in PDF
- Pro-active maintenance Reports in PDF

### Tier 2 Data Collection System (DCS) - GMP



#### DCS-GMP key features:

- Data for GMP Reports stored in separate SQL database

Reports are generated for:

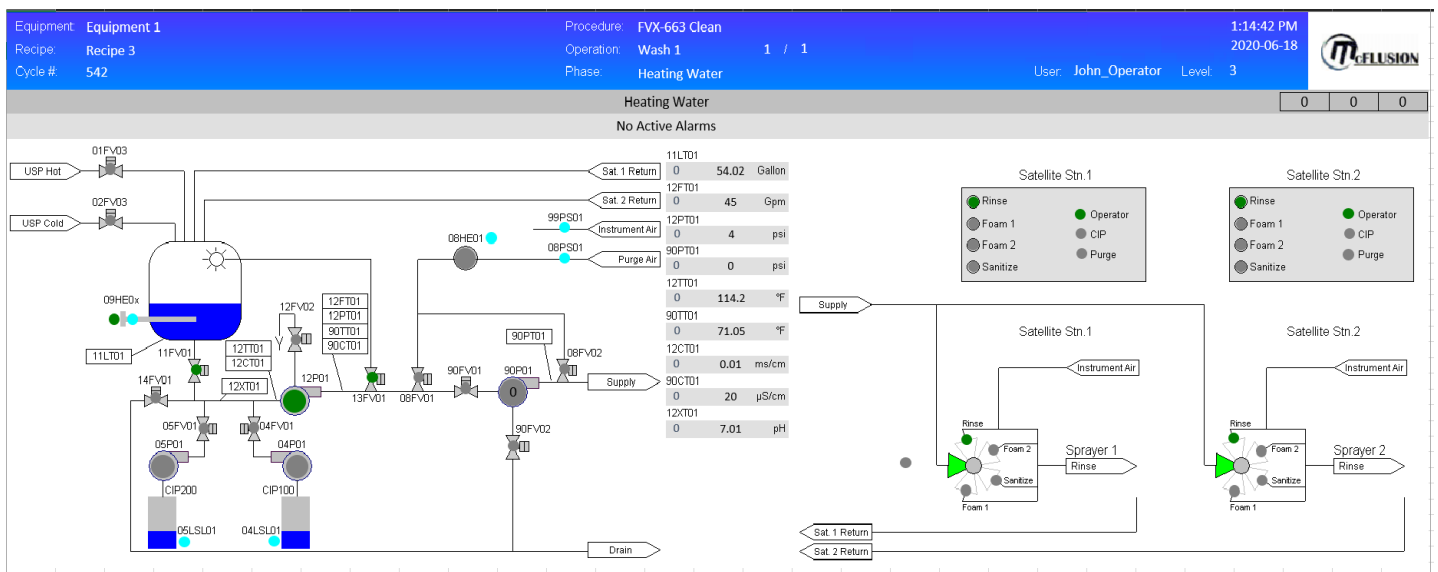
- Users
  - log in/log out, new users, user account changes before/after with time stamp
- CIP recipes
  - New recipes, recipe changes (old vs new comparison with yellow highlights to indicate changes)
- Global System parameters & timers
  - Shared timers and settings (old vs new comparison with yellow highlights to indicate changes)
- Alarm history events
  - Alarms activated/acknowledge with time stamp
- CIP Cycle reports – historic comparison

Item Number	Description	
MP9009	DCS TECH	GMP Data and Reports are - as standard - stored on the same computer that holds the technical data, viewer and reports.
MP9010	DCS GMP	As an option separate computers can be used for GMP and Technical data.

## Data Collection System (DCS) - TECH

## Data Collection System (DCS) – TECH

The DCS-TECH collects technical data and is equipped with our process analytics and trouble-shooting tool that uses an interactive Process Flow Diagram of the CIP and process equipment with visual component status – based upon events.



Technical data from the CIP equipment's PLC is collected every second, 24/7, which is saved, structured and presented in various reports – using the Win10 computer.

- The DCS software will collect the following data:
  - All analog and digital values will be logged every second  
This includes instrument readings, pumps, electrical heaters and valves.
  - All event data – Process info, User log in/log out and alarms will be logged.

The DCS-TECH system will automatically generate a pre-determined file, comprising the above data in an ODBC compliant, black box (unstructured data) format for every 24 hours.

The visualization of each component in the process analytics and trouble-shooting software tool is based upon all - or sorted events - to make it possible to focus on specific process information and issues.

Note:

This tool also allows McFlusion Process engineers to access and analyze the data from a remote location on an as-needed basis (requires service contract)

Item Number	Description
MP9009	DCS TECH GMP Data and Reports are - as standard - stored on the same computer that holds the technical data, viewer and reports.
MP9010	DCS GMP As an option separate computers can be used for GMP and Technical data.



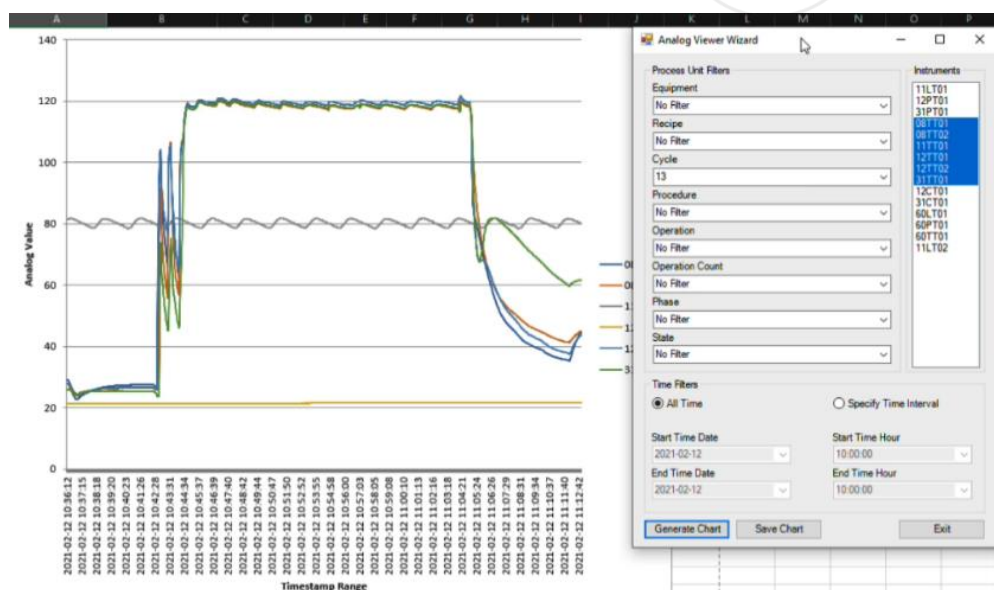
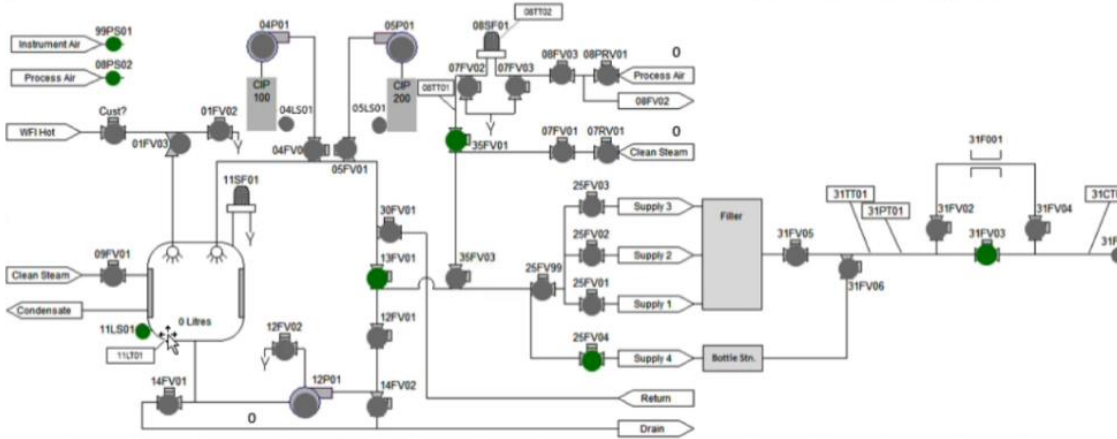
## Data Collection System (DCS) – TECH (continued)

Software tool for process trending graphics are also included.

The DCS-TECH system will automatically generate and save the following reports in PDF format:

- Performance reports
- Alarm reports
- Pro-active maintenance

Equipment:	Bottle_Station	Procedure:	SIP				2/12/2021
Recipe:	Bottle Stn CIP	Operation:	13 Sterilize	1	1		
Cycle #:	13	Phase:	26 Pressure Hold	User:	4	Level:	4
State 90 - Vent prior to Pressure Hold Test							
Alarm # 53 (M) - WFI Water Permission Signal Absent							



Item Number	Description	
MP9009	DCS TECH	GMP Data and Reports are - as standard - stored on the same computer that holds the technical data, viewer and reports.
MP9010	DCS GMP	As an option separate computers can be used for GMP and Technical data.

## Data Collection System (DCS) - GMP

### DCS-GMP Software for Audit Trail / CIP Cycle Historian

The data collection system (DCS-GMP) software for audit trail / CIP cycle historian will collect all GMP 21CFR Part 11 and Cleaning Validation relevant data.

The computer will collect all data and automatically save in a SQL database , white box (structured data) format every event and activity based.

The audit trail / historian data includes:

- Users
  - log in/log out, new users, user account changes before/after with time stamp
- CIP recipes
  - new recipes, recipe changes before/after with comparison with yellow highlights between versions)
- Global System parameters & timers
  - shared timers and settings (before and after with comparison with yellow highlights between versions)
- Alarm history events
  - alarms activated/acknowledge with time stamp
- CIP Cycle reports – historic comparison

## Recipe Report Comparison Report Version 2 vs. Version 1

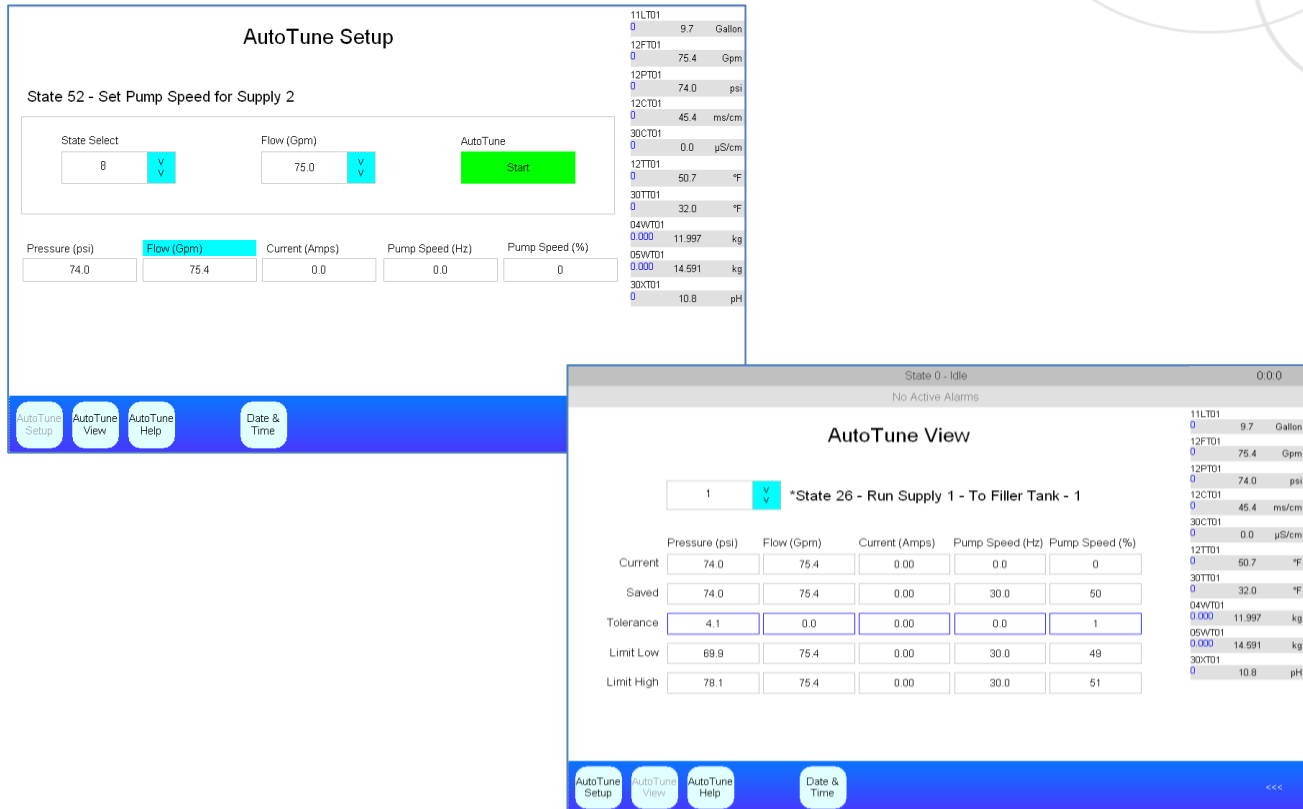
Equipment:	CIP#	Owner:	4	Equipment:	CIP#	Owner:	4
Recipe Name:	Recipe 1	Edit Date:	03-23-2020	Recipe Name:	Recipe 1	Edit Date:	03-23-2020
Recipe Number:	1	Edit Time:	19:32:31	Recipe Number:	1	Edit Time:	19:36:55
Version:	2			Version:	1		

Recipe Parameters 1/4										Pre Rinse 1	Pre Rinse 2	Wash 1	Post Rinse 1	Wash 2	Post Rinse 2	Post Rinse 3	Final Rinse				
Heuristics										1	1	0	0	1	1	0	0	1	1		
Supply Type: Recirculate										Rec	Rec	X	X	Rec	Rec	Rec	Rec	X	X	Rec	Rec
Draw after Supply: No / Yes										No	No	X	X	No	No	No	No	X	X	No	No
Purge after Drain: No / Yes										No	No	X	X	No	No	No	No	X	X	No	No
State 9 - Fill Buffer Tank	Gallons	30	30	0	0	30	30	30	30	30	30	30	30	30	30	30	0	0	30	30	
State 13 - Heat Water	°F	12	12	0	0	12	12	12	12	12	12	12	12	12	12	12	0	0	12	12	
State 18 / 18 - Add Detergent	ml/cm					50	100	100						50	100	50	100				
State 21 - Run Internal Circulation	min					60	60							60	60						
Recipe Parameters 2/4										Pre Rinse 1	Pre Rinse 2	Wash 1	Post Rinse 1	Wash 2	Post Rinse 2	Post Rinse 3	Final Rinse				
State 23 - Set Pump Speed for Supply	%	60	60	0	0	60	60	60	60	60	60	60	60	60	60	0	0	60	60		
State 28 - Run Supply	min	3600	3600	0	0	3600	3600	3600	3600	3600	3600	3600	3600	3600	3600	0	0	3600	3600		
State 37 - Return with Air	min					15	15							15	15						
Recipe Parameters 3/4										Pre Rinse 1	Pre Rinse 2	Wash 1	Post Rinse 1	Wash 2	Post Rinse 2	Post Rinse 3	Final Rinse				
State 41 - Purge Through Pump to Clean	min	15	15	0	0	15	15	15	15	15	15	15	15	15	15	0	0	15	15		
State 42 - Purge Lines	min	15	15	0	0	15	15	15	15	15	15	15	15	15	15	0	0	15	15		

#### Item Number Description

MP9009	DCS TECH	GMP Data and Reports are - as standard - stored on the same computer that holds the technical data, viewer and reports.
MP9010	DCS GMP	As an option separate computers can be used for GMP and Technical data.

## McFlusion's AutoTune™ Software (CIP Heartbeat™)



### AutoTune™

AutoTune™ is based on pressure, flow, amperage and pump frequency data, that will be used to determine a baseline CIP Heartbeat™ for each CIP route.

As such – we can determine minor changes to the performance of each CIP route – from e.g., minor changes like a few blocked holes in a spray ball, lack of CIP devices rotation to major events like leaking valves, hoses missing etc.

The CIP Heartbeat™ is developed based on Fluid Dynamics theories and empirical data for relevant properties.

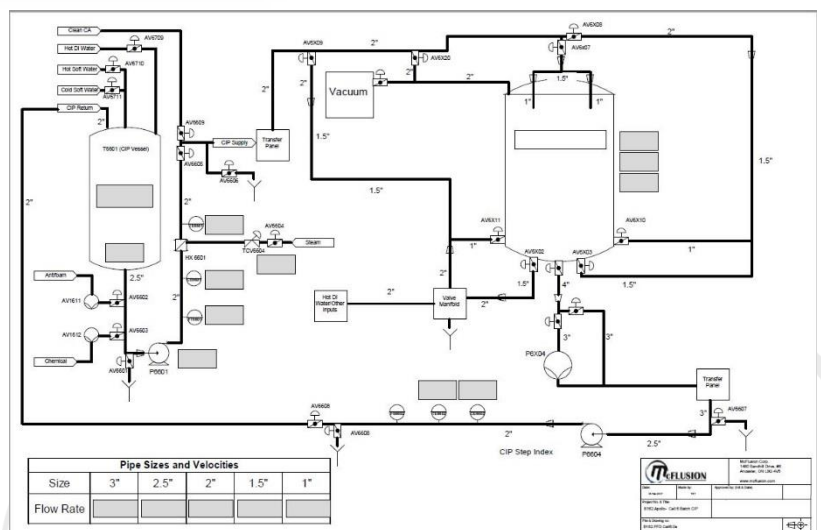
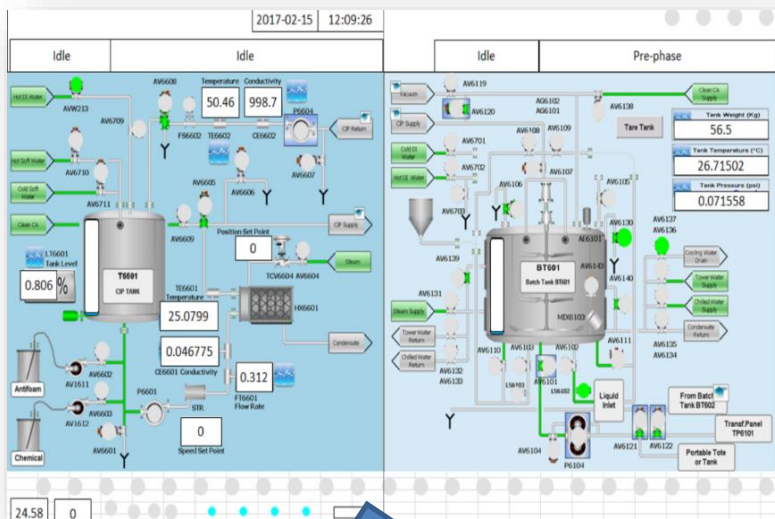
We have the possibility to add viscosity and density parameters as part of the CIP Heartbeat™ by adding relevant instrumentation to the CIP system.

## Data Collection Audit Tool (Technical) for Non-McFlusion CIP and/or Process systems

McFlusion has developed a simple and efficient Data Collection and Analytical Module designed for usage at existing installations of CIP and other process systems.

The module is using our DCS TECH software as foundation and can be used for Rockwell RS Logix plc's, Siemens S7 plc's as well as S88 based batch software (DeltaV, GE iFix, RS Batch)

We will be re-using the existing HMI screens as background "dummies" and create a read-only interface where the historical process data can be viewed and analyzed.



Item Number	Description
MP9015	DCS Audit Tool

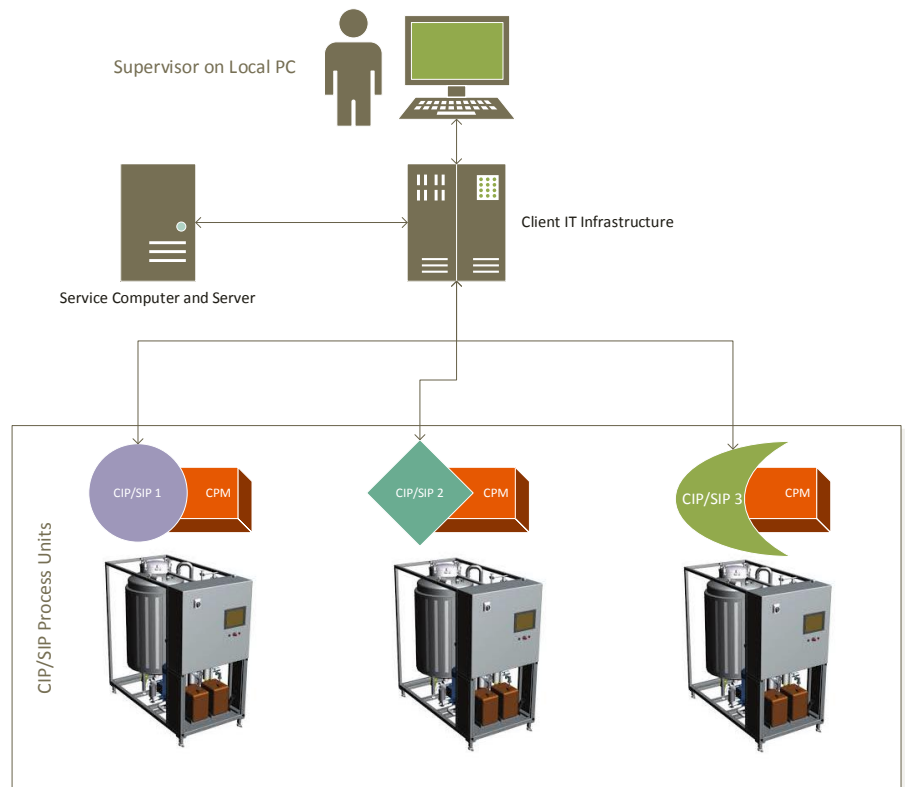
Contact us for further information.

## CIP / SIP Management System (CMS)


McFlusion's CIP/SIP Management System is an on-premises or Azure cloud-based supervisory module for monitoring and auditing the current and historical operational status of a CIP/SIP unit in real-time.

The CMS uses existing on-site infrastructure to network a single or multiple CIP/SIP process units to a centralized data collection server repository running Microsoft SQL Server. The CMS is interfaced with via a desktop dashboard application which provides supervisory analytics including:

- Current operational status of the process equipment
- Historical batch data for all process equipment including cycle reports and alarm histories
- *In situ* process monitoring of CIP/SIP units during cleaning procedures
- Data collection and analytics of critical process parameters
- Audit trail for CIP/SIP parameters, settings, and recipes.



McFlusion Dashboard



Current Status

Status: Running

Equipment: Filler 9

Recipe: CFBA-7

Cycle Started By: AlexP

Cycle Duration: 00:13:38









Weekly Cycle Summary

Cycle Number	Equipment	Recipe	Operator	Cycle Status
1	RFS2	CFBA-7	Op1	Pass
2	CIP4	CFSe-9	Op1	Pass
3	Filler6	CFBA-4	Spr4	Pass
4	CIP3	CFSf-8	Op1	Pass
5	RFS2	CFBA-7	Spr4	Fail
6	CIP4	CFSe-9	Spr4	Pass
7	Filler8	CFBA-5	Op2	Pass

Alarm History

#	Description	On	Off
33	Detergent too low for Wash 1	2021-Mar-13 14:45:02	2021-Mar-13 14:51:16
15	Minimum pressure for purge	2021-Mar-14 12:12:14	2021-Mar-14 12:12:18
127	Cycle Aborted	2021-Mar-14 12:14:42	2021-Mar-14 12:14:51
19	Water level too low for pump	2021-Mar-15 09:13:44	2021-Mar-15 09:21:10
12	Conductivity Low	2021-Mar-15 10:14:08	2021-Mar-15 10:16:26

Cycle Reports

#	Date	PDF Report
12	2021-Mar-08 07:15:26	
13	2021-Mar-09 08:11:38	
14	2021-Mar-13 06:14:27	
15	2021-Mar-14 06:24:36	
16	2021-Mar-16 07:10:16	
17	2021-Mar-17 08:17:43	
18	2021-Mar-21 14:15:26	
19	2021-Mar-23 16:36:22	

### Item Number Description

MP9011	CMS for one Unit	CMS includes a physical server based on MS SQL / Azure for integration with an on-site IT infrastructure as well as full cloud-based Microsoft Azure storage with either an existing Azure subscription or a McFlusion subscription
MP9012	CMS for multiple Units	



## Quality System

### McFlusion (Project) Quality System

McFlusion uses a Quality Manual, which is based upon cGMP requirements, to define quality activities – thereby that all our deliverables meet our internal quality standards and requirements as well as the specific requirements stipulated by our clients.

Our Quality Manual is structured in sections, which are divided into subsections. This structure allows the selection of activities that are relevant for the specific project.

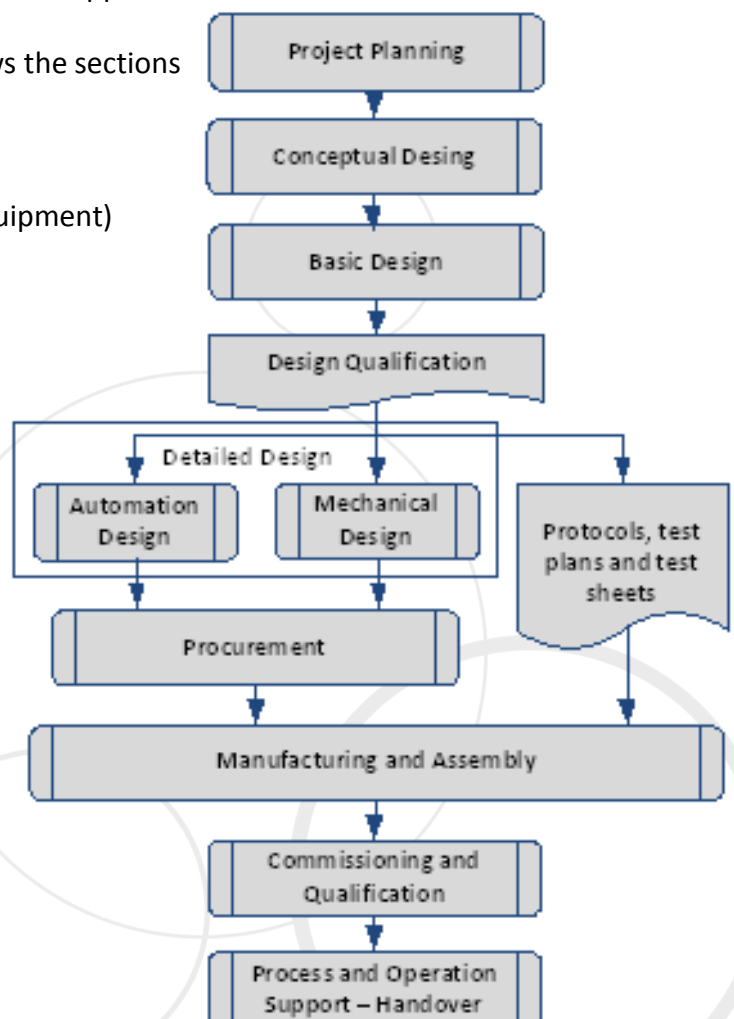
McFlusion can develop - or assist with the development of - User Requirement Specification (URS) and Requirement Traceability Matrix (RTM) that will be maintained throughout the qualification of the equipment.

After receipt of the PO, we will prepare a basic design package – comprising of P&ID, Layout drawing, component list, Software and Hardware Design Specification (SHDS) and a Project (Quality) Milestone Plan – that will be submitted to the client for review and approval.

The Project (Quality) Milestone Plan typically follows the sections (project phases), as listed below:

- Project and project planning in general
- Conceptual design (not required for standard equipment)
- Basic design
- DQ (design qualification and approval)
- Detailed design
- Protocols, test plans and sheets
- Procurement
- Manufacturing
- Assembly
- Commissioning and qualification
- Process and operation support - handover

Detailed information about McFlusion's Quality Manual will be provided upon request.



## Documentation

### System documentation package:

- P&ID
- Layout drawing
- Lead sheet
- Component list
- Software & Hardware Design Specification (SHDS) including attachments:
  - Electrical design (key diagrams)
  - PLC I/O list;
  - Instrument settings (Inst.set);
  - Process builder design (PBD) – CIP;
  - Process builder design (PBD) – SIP;
  - Recipe parameters (REC);
  - Alarm list (ALM);
  - Report (REP);
  - User interface screens (UID);
  - AutoTune (AT);
- User manual;
- PM list;
- Spare parts lists;
- Virtual archive with technical literature (manuals/data sheets, etc. for pumps, valves, instruments, etc.;

### GMP/QA documentation:

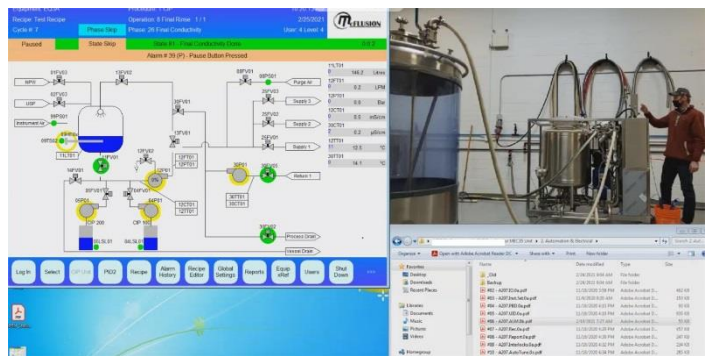
- General manufacturing certificate for welding, materials used & surface roughness;
- Cleaning and passivation certificate;
- Test and performance certificate;
- Factory calibration documentation;
- Material certificates for all materials in product contact;
- General surface roughness certification for  $Ra > 20$ ;
- Weld log – including logs to the individual welders, full internal inspection of welds;
- 100% Video Endoscope with recording of wetted welds;
- 21CFR part 177 and USP class VI compliance certificates for all wetted elastomers;
- Inspection and measurement of all possible dead legs;
- Inspection and measurement of slope and drain-ability;
- McFlusion FAT protocol – using PQ404 and 405 instructions and test scripts;
- FAT execution;

## GMP Services

McFlusion's GMP services are an integral part of our life-cycle approach for each of our process cleaning (CIP/COP), sanitization and sterilization (SIP) products.

The GMP services program focuses primarily on post-installation activities, such as:

- FAT (remote/virtual or in-person)
  - Protocol
  - Execution
- Equipment installation verification
- Equipment start-up
- Multi-level training programs
  - Operators
  - Maintenance staff
  - Validation
  - Administrator/Supervisor
- Commissioning/SAT
  - Protocols
  - On-site execution
- Qualification (IOQ)
  - Protocols
  - On-site execution
- CIP/SIP cycle development
- Validation support
- Educational seminars on CIP/SIP related topics



Virtual FAT with live feed from test center – including full sharing of HMI and documentation



FAT in our fully equipped test center - including full performance, operational and installation verification.



Commissioning/SAT and IOQ executed in our client's facility

## Materials of Construction and Manufacturing

McFlusion is providing process equipment – exclusively – for the life science and pharmaceutical industry segments. As such, our workshops and quality systems are designed for the highly regulated cGMP industry.

- All Non-Wetted (exterior) Surfaces:  
T304 Stainless Steel, mechanical polish with all weld discoloration removed, unless otherwise specified.
- Wetted Sanitary Surfaces and Tubing:  
T316L Stainless Steel, mechanical polish with various surface finishes as per ASME BPE standards, such as SF5: electropolished with RA < 20 µin (< 0.5 µm);
- Sanitary tube welding:  
All sanitary tube welding will be completed using an orbital welder, wherever possible.

The welding is performed in an argon gas purged atmosphere. The manual welds necessary on the unit to minimize dead-leg distances will be performed by highly skilled welders, who perform the welds without the need for extra ground flush or interior polishing, as requested by the ASME BPE standard.

Any weld – manual or orbital – not easily accessible will be inspected by a video boroscope. 100% of welds are inspected by McFlusion QA to determine, if the weld is acceptable or not.

Acceptance of welds is based on the ASME BPE 2012 color atlas and the FORCE institute standards.

Welds found unacceptable are documented as such and removed from the piping system. All orbital and manual welds are assigned a serial number and are documented in a weld log.

As an option, product contact welds can be 100% inspected and recorded by a third party (video boroscope inspection and recording).

- Elastomers:  
FDA approved EPDM are applied for gaskets, seals and diaphragms.

Note: FDA approved PTFE (EPDM core) for gaskets, seals and diaphragms for SIP.  
Elastomers: non-animal derived, USP class VI.

## About McFlusion

### Cleaning, Sanitization and Sterilization are at the core of what we do

We are subject matter experts within process cleaning, sanitization and sterilization and are renowned for our targeted problem-solving approach that provides our clients with the best possible process and equipment solution by using our process, technology and regulatory expertise to ensure that they can manufacture quality products.

McFlusion process cleaning (CIP/COP), sanitization and sterilization (SIP) equipment is designed for efficiency, lean operation and compliance - using all available TACCT parameters.

Our process cleaning (CIP/COP), sanitization and sterilization (SIP) products are perfectly suited for hard-to-remove product residuals as well as hard-to-clean applications, such as Oral (Solid and liquid) Dosage Form and OLC (ointment, liquid, creams) manufacturing facilities.

In all of the industries that we service our products outperform traditional cleaning and sterilization equipment.



### The McFlusion Group

The McFlusion Group consists of **McFlusion**, **Clean 3X** and **Morrflo**.

- **McFlusion** provides complete process and equipment solutions for cleaning (CIP/COP), sanitization and sterilization (SIP) to the highly regulated life science, pharmaceutical and medical device industries.
- **Clean3X** provides cleaning and sanitization products for cleaning (CIP) and sanitization to cosmetic/topical, medical marijuana, and nutritional industries.
- **Morrflo** provides complete fluid handling and chemical dosing systems for industrial applications, such as oil and gas.