Functional Specification
Solution Manufacturing System
Pharmaceutical Factory Inyaung

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Software Class Functional Specification - Equipment Modules

Document Approval

Completion of the following signature blocks signifies the approver has reviewed this data and confirms all information is correct.

Approved by:

Name	Position	Signature	Date

Approved by:

Name	Position	Signature	Date

Revision History

Version	Changed by	Date	Change No.	Reason
2	David Paspa	15-02-2018	NA	Final EM structure
1	David Paspa	13-11-2017	NA	Initial Design

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Index List

Class	Description	Hygiene
AI	Analog Input	@@HYGIENE@@
AO	Analog Output	@@HYGIENE@@
CPU	Siemens S7-1500 CPU	@@HYGIENE@@
DI	Digital Input	@@HYGIENE@@
DI1	General alarm single digital input	@@HYGIENE@@
DI2	General alarm software module without field input	@@HYGIENE@@
DO	Digital Output	@@HYGIENE@@
EMA1	Manufacturing vessel agitator	@@HYGIENE@@
EMC1	Vessel LP CA and HP CA supply, Vacuum and Vent	@@HYGIENE@@
EMC2	WFI, PS(WFI) supply and PW, PS(PW) supply to manufacturing vessel	@@HYGIENE@@
EMC3	WFI, PS(WFI) supply and PW, PS(PW) supply to storage vessel	@@HYGIENE@@
EMG1	Vessel gas filter heating element and temperature indicator, drain valve and filter outlet line temperature indicator	@@HYGIENE@@
EMM1	Manufacturing vessel load cell	@@HYGIENE@@
EMS1	Main Unit ESTOP and Air pressure low switch	@@HYGIENE@@
EMS2	Auxiliary Unit ESTOP	@@HYGIENE@@
EMT1	Manufacturing filtration line heat exchanger cooling control	@@HYGIENE@@
EMV1	Vessels manway, bursting disc, bottom outlet valve and temperature alarms and interlocks	@@HYGIENE@@
EMV2	Vessel Inlet Sprayball Valves	@@HYGIENE@@
EMX1	Manufacturing vessel filtration line MMFLx	@@HYGIENE@@
EMX2	Shared Vessels Transfer Lines	@@HYGIENE@@
EMX4	CIP & SIP Drain	@@HYGIENE@@
EMX5	BFS Inlet Filling Line	@@HYGIENE@@
EMX6	Shared Filtration line SMFLx to Vessels Transfer Lines	@@HYGIENE@@
HE1	Vessel vent filter Electric Heating Element	@@HYGIENE@@
IL	Critical Interlock Calculation with up to 15 inputs	@@HYGIENE@@
IL	Non-Critical Interlock Calculation with up to 15 inputs	@@HYGIENE@@
MI1	Load cell mass indicator	@@HYGIENE@@
MOD1	Modulating control valve	@@HYGIENE@@
MOT1	Vacuum pump motor	@@HYGIENE@@
MX	Manufacturing Vessel and associated equipment	@@HYGIENE@@
PAI	Profinet Analog Input	@@HYGIENE@@
PAO	Profinet Analog Output	@@HYGIENE@@
PC1	Vessel ON/OFF pressure control loop with output valve selection	@@HYGIENE@@
PCMX	Mixing Vessel System Process Cell	@@HYGIENE@@
PCSY	Storage Vessel System Process Cell	@@HYGIENE@@
PDI	Profinet Digital Input	@@HYGIENE@@
PDO	Profinet Digital Output	@@HYGIENE@@
PI1	Vessel Pressure Indictor	@@HYGIENE@@

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POS1	On/Off valve with single output and no feedback	@@HYGIENE@@
POS2	On/Off valve with single output and closed position feedback	@@HYGIENE@@
POS3	On/Off valve with single output and opened position feedback	@@HYGIENE@@
POS4	On/Off valve with single output and both opened and closed feedback	@@HYGIENE@@
SIC1	Agitator speed control	@@HYGIENE@@
SY	Storage Vessel and associated equipment	@@HYGIENE@@SY
TC1	Heat exchanger cooling only temperature controller	@@HYGIENE@@
TI1	Vessel temperature Indicator with alarms and interlocks	@@HYGIENE@@
TI2	Line mounted temperature indicator	@@HYGIENE@@
VS1	Vacuum system	@@HYGIENE@@
ZSC1	Manway closed indication and alarm	@@HYGIENE@@
ZSC2	Flow path connection indication	@@HYGIENE@@

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Class	Description
EMC1	**Vessel LP CA and HP CA supply, Vacuum and Vent**

Scope

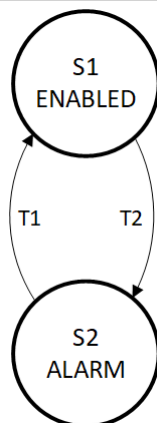| **Module Scope** |
|---|
| Applies to the compressed air, vent and vacuum lines of each manufacturing and storage vessel. |

Functional Requirements

Req Ref	Requirement
F1	The EM shall be able to be run in an On/Off Pressure Control state to pressurise the vessel head space with either HPCA or LPCA to a predefined pressure setpoint until commanded to stop.
F2	In the Pressure Control state the vessel head space pressure shall be maintained between low and high hysteresis values.
F3	In the Pressure Control state the vent valve shall open to relieve high pressure above the high hysteresis value and close again when the pressure drops below the target pressure setpoint.
F4	In the Pressure Control state the selected gas supply valve shall open to increase pressure when below the low hysteresis value and close again when the pressure rises above the target pressure setpoint.
F5	In the pressure control state there shall be a timeout and alarm if the pressure does not reach the setpoint within a certain time period.
F6	The EM shall be able to run in a valve fully opened state which which bypasses the pressure controller and simply opens the selected gas inlet valve to provide maximum supply pressure to the vessel until commanded to stop.
F7	The EM shall be able to vent the vessel by opening the vent valve until commanded to close.
F8	The EM shall be able to evacuate the vessel via the vacuum pump until commanded to stop.
F9	The drain line steam trap valve shall be able to be opened during SIP.

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State Diagram

States

State	Alarm State	State Description	SFC
PRESSURE	No	Blanketing and charging air to vessel	None
VALVE	No	Opened Selected Valve (Vent, LPCA, HPCA, Vacuum, Drain)	None

Child Device Initial States

State	Child Alias	Class	Description	Initial State
PRESSURE	PCn103	PC1	Vessel Pressure Controller	PRESSURE
PRESSURE	PIn103	PI1	Vessel Pressure Indictor	ENABLE
PRESSURE	DVn101	POS2	Vessel Vent Valve	CLOSE
PRESSURE	DVn103	POS2	Vessel HP CA Supply Valve	CLOSE
PRESSURE	DVn105	POS2	Vessel LP CA Supply Valve	CLOSE
PRESSURE	DVn107	POS2	Vessel Vacuum valve	CLOSE
PRESSURE	BAVn139	POS4	Vessel Vent line drain valve	CLOSE
VALVE	PCn103	PC1	Vessel Pressure Controller	VALVE
VALVE	PIn103	PI1	Vessel Pressure Indictor	ENABLE
VALVE	DVn101	POS2	Vessel Vent Valve	If VALVE = VENT Then OPEN Else CLOSE
VALVE	DVn103	POS2	Vessel HP CA Supply Valve	If VALVE = HPCA Then OPEN Else CLOSE
VALVE	DVn105	POS2	Vessel LP CA Supply Valve	If VALVE = LPCA Then OPEN Else CLOSE
VALVE	DVn107	POS2	Vessel Vacuum valve	If VALVE = VACUUM Then OPEN Else CLOSE
VALVE	BAVn139	POS4	Vessel Vent line drain valve	If VALVE = DRAIN Then OPEN Else CLOSE

Transitions

Transition	Description

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Parameters

Parameter	Description	Min	Max	Default	Unit
SETPOINT	Pressure Control setpoint	-0.05	5.0	1.0	@@UOM@@
P_BAND_HI	High pressure hysteresis value	0.0	2.0	0.1	@@UOM@@
P_BAND_LO	Low pressure hysteresis value	0.0	2.0	0.1	@@UOM@@
TIMEOUT	Time out period for pressure not reached alarm	0.0	10800.0	500.0	@@UOM@@
VALVE	Selected valve to be opened		1=HPCA, 2=LPCA, 3=VENT, 4=VACUUM, 5=DRAIN	0.0	@@UOM@@

Alarms

Alarm	Condition	Priority	Message
TIMEOUT	Timeout waiting to achieve pressure setpoint	M	Vessel (Mx/Sy) taking excessive time to achieve pressure setpoint

I/O

Physical I/O and ProfiNET I/O prefixed with a "P".

Mnemonic	Description	DI	DO	AI	AO	PDI	PDO	PAI	PAO

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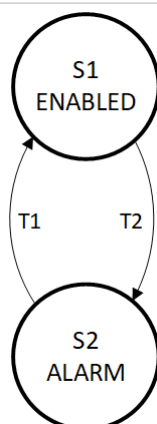| Class	Description
EMC2	**WFI, PS(WFI) supply and PW, PS(PW) supply to manufacturing vessel**

Scope

Module Scope
Applies to the WFI, PW and PS supply system to the Manufacturing vessel M1 and M2.

Functional Requirements

Req Ref	Requirement
F1	The EM shall charge PW or WFI to a predefined mass endpoint.
F2	The EM shall flush any of PW, PS(PW), WFI or PS(WFI) for a predefined time.
F3	The EM shall flush any of PW, PS(PW), WFI or PS(WFI) indefinitely until commanded to stop.
F4	The EM shall be able to have the operator setup the manual hose connection flowpath for the required addition prior to charging or flushing with steam or water.
F5	Once the flowpath is setup, low level interlocks shall continue to monitor the position of the manual hose connection and asynchronously close all steam and water supply valves should the flowpath no longer be integral.
F6	The EM shall be able to have the operator isolate the water and steam inlet manifold from the vessel by ensuring the flowpath proximity switches are not in place.
F7	There shall be a time-out alarm when charging to a predefined mass endpoint if the mass in the vessel does not increase within a reasonable time period.

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State Diagram

States

State	Alarm State	State Description	SFC
CHARGE	No	Preset weight charging to Manufacturing Vessel	PH_EMC2_CHARGE
FLUSH	No	Timed Filling of PW/WFI to Manufacturing Vessel	PH_EMC2_FLUSH
ISOLATE	No	Disconnect WFI/PW to Manufacturing Vessel	PH_EMC2_ISOLATE
SETUP	No	WFI/PW Setup for Manufacturing Vessel	PH_EMC2_SETUP

Child Device Initial States

State	Child Alias	Class	Description	Initial State
CHARGE	DVn109	POS2	Mx PS Supply for WFI Loop	CLOSE
CHARGE	DVn115	POS2	Mx PS Supply for PW Loop	CLOSE
CHARGE	DVn111	POS4	Mx WFI Supply Valve	CLOSE
CHARGE	DVn113	POS4	Mx PW Supply Valve	CLOSE
CHARGE	ZSCn103	ZSC2	Mx WFI Supply Flowpath Indicator	If MEDIUM = WFI Then IN Else OUT
CHARGE	ZSCn105	ZSC2	Mx PW Supply Flowpath Indicator	If MEDIUM = PW Then IN Else OUT
CHARGE	ZSCn107	ZSC2	Mx inlet line Flowpath Indicator	IN
FLUSH	DVn109	POS2	Mx PS Supply for WFI Loop	CLOSE
FLUSH	DVn109	POS2	Mx PS Supply for WFI Loop	CLOSE
FLUSH	DVn115	POS2	Mx PS Supply for PW Loop	CLOSE
FLUSH	DVn115	POS2	Mx PS Supply for PW Loop	CLOSE
FLUSH	DVn111	POS4	Mx WFI Supply Valve	CLOSE
FLUSH	DVn111	POS4	Mx WFI Supply Valve	CLOSE
FLUSH	DVn113	POS4	Mx PW Supply Valve	CLOSE
FLUSH	DVn113	POS4	Mx PW Supply Valve	CLOSE
FLUSH	ZSCn103	ZSC2	Mx WFI Supply Flowpath Indicator	If (MEDIUM = WFI OR MEDIUM = PS(WFI)) Then IN Else OUT
FLUSH	ZSCn103	ZSC2	Mx WFI Supply Flowpath Indicator	If (MEDIUM = WFI OR MEDIUM = PS(WFI)) Then IN Else OUT
FLUSH	ZSCn105	ZSC2	Mx PW Supply Flowpath Indicator	If (MEDIUM = PW OR

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				MEDIUM = PS(PW)) Then IN Else OUT
FLUSH	ZSCn105	ZSC2	Mx PW Supply Flowpath Indicator	If (MEDIUM = PW OR MEDIUM = PS(PW)) Then IN Else OUT
FLUSH	ZSCn107	ZSC2	Mx inlet line Flowpath Indicator	IN
FLUSH	ZSCn107	ZSC2	Mx inlet line Flowpath Indicator	IN
ISOLATE	DVn109	POS2	Mx PS Supply for WFI Loop	CLOSE
ISOLATE	DVn109	POS2	Mx PS Supply for WFI Loop	CLOSE
ISOLATE	DVn115	POS2	Mx PS Supply for PW Loop	CLOSE
ISOLATE	DVn115	POS2	Mx PS Supply for PW Loop	CLOSE
ISOLATE	DVn111	POS4	Mx WFI Supply Valve	CLOSE
ISOLATE	DVn111	POS4	Mx WFI Supply Valve	CLOSE
ISOLATE	DVn113	POS4	Mx PW Supply Valve	CLOSE
ISOLATE	DVn113	POS4	Mx PW Supply Valve	CLOSE
ISOLATE	ZSCn103	ZSC2	Mx WFI Supply Flowpath Indicator	OUT
ISOLATE	ZSCn103	ZSC2	Mx WFI Supply Flowpath Indicator	OUT
ISOLATE	ZSCn105	ZSC2	Mx PW Supply Flowpath Indicator	OUT
ISOLATE	ZSCn105	ZSC2	Mx PW Supply Flowpath Indicator	OUT
ISOLATE	ZSCn107	ZSC2	Mx inlet line Flowpath Indicator	OUT
ISOLATE	ZSCn107	ZSC2	Mx inlet line Flowpath Indicator	OUT
SETUP	DVn109	POS2	Mx PS Supply for WFI Loop	CLOSE
SETUP	DVn109	POS2	Mx PS Supply for WFI Loop	CLOSE
SETUP	DVn115	POS2	Mx PS Supply for PW Loop	CLOSE
SETUP	DVn115	POS2	Mx PS Supply for PW Loop	CLOSE
SETUP	DVn111	POS4	Mx WFI Supply Valve	CLOSE
SETUP	DVn111	POS4	Mx WFI Supply Valve	CLOSE
SETUP	DVn113	POS4	Mx PW Supply Valve	CLOSE
SETUP	DVn113	POS4	Mx PW Supply Valve	CLOSE
SETUP	ZSCn103	ZSC2	Mx WFI Supply Flowpath Indicator	If (MEDIUM = WFI OR MEDIUM = PS(WFI)) Then IN Else OUT
SETUP	ZSCn103	ZSC2	Mx WFI Supply Flowpath Indicator	If MEDIUM = WFI Then IN Else OUT
SETUP	ZSCn105	ZSC2	Mx PW Supply Flowpath Indicator	If (MEDIUM = PW OR MEDIUM = PS(PW)) Then IN Else OUT
SETUP	ZSCn105	ZSC2	Mx PW Supply Flowpath Indicator	If MEDIUM = PW Then IN Else OUT
SETUP	ZSCn107	ZSC2	Mx inlet line Flowpath Indicator	IN
SETUP	ZSCn107	ZSC2	Mx inlet line Flowpath Indicator	IN

Transitions

Transition	Description

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Parameters

Parameter	Description	Min	Max	Default	Unit
MEDIUM	Selected medium to be added		1=WFI, 2=PW, 3=PS(WFI), 4=PS(PW)	0.0	@@UOM @@
MASS	Mass of Medium to be charged	0.0	15000.0	0.0	@@UOM @@
TIMEOUT	Timeout period for mass charging	0.0	59.0	0.0	@@UOM @@
MEDIUM	Selected medium to be added		1=WFI, 2=PW, 3=PS(WFI), 4=PS(PW)	0.0	@@UOM @@
TIME_FLUSH	Time to flush for or zero to flush forever			0.0	@@UOM @@

Alarms

Alarm	Condition	Priority	Message
FLOWPATH	Flow path device, keypiece or valve, no longer setup	H	Flow path is no longer setup
TIMEOUT	Timeout waiting to achieve mass setpoint	M	Vessel Mx taking excessive time to achieve mass setpoint

I/O

Physical I/O and ProfiNET I/O prefixed with a "P".

Mnemonic	Description	DI	DO	AI	AO	PDI	PDO	PAI	PAO

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Class	Description
EMC3	**WFI, PS(WFI) supply and PW, PS(PW) supply to storage vessel**

Scope

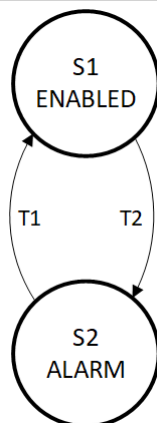| Module Scope |
|---|
| Applies to Storage vessels S1, S2, S3 and S4.
This EM class is similar to EMC2 except the storage vessels do not have load cells and hence there can be no charging to a mass endpoint. |

Functional Requirements

Req Ref	Requirement
F1	The EM shall flush any of PW, PS(PW), WFI or PS(WFI) for a predefined time.
F2	The EM shall flush any of PW, PS(PW), WFI or PS(WFI) indefinitely until commanded to stop.
F3	The EM shall be able to have the operator setup the manual hose connection flowpath for the required addition prior to charging or flushing with steam or water.
F4	Once the flowpath is setup, low level interlocks shall continue to monitor the position of the manual hose connection and asynchronously close all steam and water supply valves should the flowpath no longer be integral.
F5	The EM shall be able to have the operator isolate the water and steam inlet manifold from the vessel by ensuring the flowpath proximity switches are not in place.

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State Diagram

States

State	Alarm State	State Description	SFC
FLUSH	No	Timed Filling of PW/WFI to Storage Vessel	PH_EMC3_FLUSH
ISOLATE	No	Disconnect WFI/PW to Storage Vessel	PH_EMC3_ISOLATE
SETUP	No	WFI/PW Setup for Storage Vessel	PH_EMC3_SETUP

Child Device Initial States

State	Child Alias	Class	Description	Initial State
CHARGE	DVn109	POS2	Sy PS Supply for WFI Loop	CLOSE
CHARGE	DVn115	POS2	Sy PS Supply for PW Loop	CLOSE
CHARGE	DVn111	POS4	Sy WFI Supply Valve	CLOSE
CHARGE	DVn113	POS4	Sy PW Supply Valve	CLOSE
CHARGE	ZSCn103	ZSC2	Sy WFI Supply Flowpath Indicator	If MEDIUM = WFI Then IN Else OUT
CHARGE	ZSCn105	ZSC2	Sy PW Supply Flowpath Indicator	If MEDIUM = PW Then IN Else OUT
CHARGE	ZSCn107	ZSC2	Sy Inlet line Flowpath Indicator	IN
FLUSH	DVn109	POS2	Sy PS Supply for WFI Loop	CLOSE
FLUSH	DVn109	POS2	Sy PS Supply for WFI Loop	CLOSE
FLUSH	DVn115	POS2	Sy PS Supply for PW Loop	CLOSE
FLUSH	DVn115	POS2	Sy PS Supply for PW Loop	CLOSE
FLUSH	DVn111	POS4	Sy WFI Supply Valve	CLOSE
FLUSH	DVn111	POS4	Sy WFI Supply Valve	CLOSE
FLUSH	DVn113	POS4	Sy PW Supply Valve	CLOSE
FLUSH	DVn113	POS4	Sy PW Supply Valve	CLOSE
FLUSH	ZSCn103	ZSC2	Sy WFI Supply Flowpath Indicator	If (MEDIUM = WFI OR MEDIUM = PS(WFI)) Then IN Else OUT
FLUSH	ZSCn103	ZSC2	Sy WFI Supply Flowpath Indicator	If (MEDIUM = WFI OR MEDIUM = PS(WFI)) Then IN Else OUT
FLUSH	ZSCn105	ZSC2	Sy PW Supply Flowpath Indicator	If (MEDIUM = PW OR MEDIUM = PS(PW)) Then IN Else OUT

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FLUSH	ZSCn105	ZSC2	Sy PW Supply Flowpath Indicator	If (MEDIUM = PW OR MEDIUM = PS(PW)) Then IN Else OUT
FLUSH	ZSCn107	ZSC2	Sy Inlet line Flowpath Indicator	IN
FLUSH	ZSCn107	ZSC2	Sy Inlet line Flowpath Indicator	IN
ISOLATE	DVn109	POS2	Sy PS Supply for WFI Loop	CLOSE
ISOLATE	DVn109	POS2	Sy PS Supply for WFI Loop	CLOSE
ISOLATE	DVn115	POS2	Sy PS Supply for PW Loop	CLOSE
ISOLATE	DVn115	POS2	Sy PS Supply for PW Loop	CLOSE
ISOLATE	DVn111	POS4	Sy WFI Supply Valve	CLOSE
ISOLATE	DVn111	POS4	Sy WFI Supply Valve	CLOSE
ISOLATE	DVn113	POS4	Sy PW Supply Valve	CLOSE
ISOLATE	DVn113	POS4	Sy PW Supply Valve	CLOSE
ISOLATE	ZSCn103	ZSC2	Sy WFI Supply Flowpath Indicator	OUT
ISOLATE	ZSCn103	ZSC2	Sy WFI Supply Flowpath Indicator	OUT
ISOLATE	ZSCn105	ZSC2	Sy PW Supply Flowpath Indicator	OUT
ISOLATE	ZSCn105	ZSC2	Sy PW Supply Flowpath Indicator	OUT
ISOLATE	ZSCn107	ZSC2	Sy Inlet line Flowpath Indicator	OUT
ISOLATE	ZSCn107	ZSC2	Sy Inlet line Flowpath Indicator	OUT
SETUP	DVn109	POS2	Sy PS Supply for WFI Loop	CLOSE
SETUP	DVn109	POS2	Sy PS Supply for WFI Loop	CLOSE
SETUP	DVn115	POS2	Sy PS Supply for PW Loop	CLOSE
SETUP	DVn115	POS2	Sy PS Supply for PW Loop	CLOSE
SETUP	DVn111	POS4	Sy WFI Supply Valve	CLOSE
SETUP	DVn111	POS4	Sy WFI Supply Valve	CLOSE
SETUP	DVn113	POS4	Sy PW Supply Valve	CLOSE
SETUP	DVn113	POS4	Sy PW Supply Valve	CLOSE
SETUP	ZSCn103	ZSC2	Sy WFI Supply Flowpath Indicator	If (MEDIUM = WFI OR MEDIUM = PS(WFI)) Then IN Else OUT
SETUP	ZSCn103	ZSC2	Sy WFI Supply Flowpath Indicator	If MEDIUM = WFI Then IN Else OUT
SETUP	ZSCn105	ZSC2	Sy PW Supply Flowpath Indicator	If (MEDIUM = PW OR MEDIUM = PS(PW)) Then IN Else OUT
SETUP	ZSCn105	ZSC2	Sy PW Supply Flowpath Indicator	If MEDIUM = PW Then IN Else OUT
SETUP	ZSCn107	ZSC2	Sy Inlet line Flowpath Indicator	IN
SETUP	ZSCn107	ZSC2	Sy Inlet line Flowpath Indicator	IN

Transitions

Transition	Description

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Parameters

Parameter	Description	Min	Max	Default	Unit
MEDIUM	Selected medium to be added		1=WFI, 2=PW, 3=PS(WFI), 4=PS(PW)	0.0	@@UOM @@
RUN_TO_TIME	Flag indicating if flush to preset time	0 = FALSE	1 = TRUE	0.0	@@UOM @@

Alarms

Alarm	Condition	Priority	Message
FLOWPATH	Flow path device, keypiece or valve, no longer setup	H	Flow path is no longer setup

I/O

Physical I/O and ProfiNET I/O prefixed with a "P".

Mnemonic	Description	DI	DO	AI	AO	PDI	PDO	PAI	PAO

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Class	Description
EMG1	**Vessel gas filter heating element and temperature indicator, drain valve and filter outlet line temperature indicator**

Scope

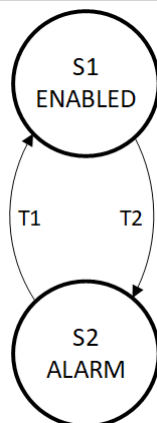| Module Scope |
|---|
| Applies to all manufacturing and storage vessels. |

Functional Requirements

Req Ref	Requirement
F1	Filter state, which is the normal operational state of the EM. In this state the SIP condensate line valve shall be closed.
F2	SIP state, in which the SIP condensate line valve shall be opened.
F3	In both states the filter housing heater element shall only turn on when the vessel temperature is above a preset value.
F4	Once the vessel temperature drops below that value less a deadband parameter the heater shall be turned off a set time later.

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State Diagram

States

State	Alarm State	State Description	SFC
FILTER	No	Gas Filtration for Vessel	None
SIP	No	SIP of Gas Filter	None

Child Device Initial States

State	Child Alias	Class	Description	Initial State
FILTER	HEn101	HE1	Mx Electric Heating Element	ENABLE
FILTER	BAVn141	POS4	Mx Vent Filter AF1101 Drain valve	CLOSE
FILTER	TIn101	TI2	Mx Vent Filter Temperature Indicator	ENABLE
FILTER	TIn103	TI2	Mx Vent Filter top outlet temperature	ENABLE
SIP	HEn101	HE1	Mx Electric Heating Element	ENABLE
SIP	BAVn141	POS4	Mx Vent Filter AF1101 Drain valve	OPEN
SIP	TIn101	TI2	Mx Vent Filter Temperature Indicator	ENABLE
SIP	TIn103	TI2	Mx Vent Filter top outlet temperature	ENABLE

Transitions

Transition	Description

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Parameters

Parameter	Description	Min	Max	Default	Unit
FILT_TEMP	PV from filter temperature CM	0.0	150.0	PV	@@UOM @@
SIP_TEMP	PV from SIP temperature CM	0.0	150.0	PV	@@UOM @@
CUTIN_TEMP	Vessel temperature at which to turn on the filter housing heater	0.0	150.0	40.0	@@UOM @@
CUTIN_DB	Deadband value for cutin temperature hysteresis	0.0	150.0	2.0	@@UOM @@
CUTOUT_TIME	Time to turn off filter housing heater once temperature reduces below cut-in temperature less deadband	0.0	150.0	1.0	@@UOM @@

Alarms

Alarm	Condition	Priority	Message

I/O

Physical I/O and ProfiNET I/O prefixed with a "P".

Mnemonic	Description	DI	DO	AI	AO	PDI	PDO	PAI	PAO

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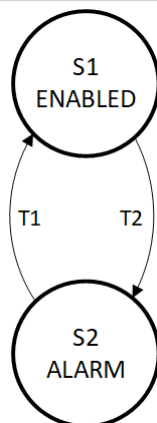| Class	Description
EMM1	**Manufacturing vessel load cell**

Scope

Module Scope
Applies to the load cells in the manufacturing vessels M1 and M2.

Functional Requirements

Req Ref	Requirement
F1	Provides a more accurate measurement of the vessel mass by allowing it to settle without agitation.
F2	Users of the vessel mass shall first check the EM Substate completion flag before using the measured value provided by the EM.
F3	Current mass (measured value from MI1 CM). This is the same as the Gross mass.
F4	Tare mass (MI1 value saved when vessel empty).
F5	Net mass (Current mass - Tare mass).

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State Diagram

States

State	Alarm State	State Description	SFC
MEASURE	No	Measure the mass of Manufacturing Vessel	PH_EMM1_MEASURE
TARE	No	Tare mass measurement of Manufacturing Vessel	PH_EMM1_TARE

Child Device Initial States

State	Child Alias	Class	Description	Initial State
MEASURE	MIn101	MI1	Mx Mass Indicator	ENABLE
TARE	MIn101	MI1	Mx Mass Indicator	ENABLE

Transitions

Transition	Description

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Parameters

Parameter	Description	Min	Max	Default	Unit
MASS_CURRENT	Current settled and more accurate vessel gross mass.	0.0	15000.0	PV	@@UOM @@
MASS_TARE	Saved Tare mass value	0.0	15000.0	0.0	@@UOM @@
MASS_NETT	Calculated Nett mass value = Current mass - Tare mass	0.0	15000.0	0.0	@@UOM @@

Alarms

Alarm	Condition	Priority	Message

I/O

Physical I/O and ProfiNET I/O prefixed with a "P".

Mnemonic	Description	DI	DO	AI	AO	PDI	PDO	PAI	PAO

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Class	Description
EMS1	**Main Unit ESTOP and Air pressure low switch**

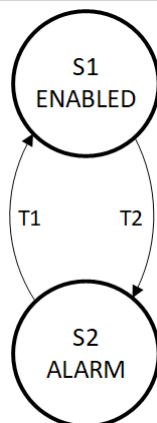## Scope

Module Scope
Unit Emergency stop placeholder EM.

Functional Requirements

Req Ref	Requirement
F1	This is an S88 placeholder only. The E-Stop DI1 CM shall be interlocked with all functions and hardwired with all associated motors.

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State Diagram

States

State	Alarm State	State Description	SFC
ENABLED	No	Main Unit Emergency stop EM placeholder	None

Child Device Initial States

State	Child Alias	Class	Description	Initial State
ENABLED	ASLn000	DI1	Instrument air pressure low	ENABLE
ENABLED	ESn100	DI1	Emergency Stop	ENABLE

Transitions

Transition	Description

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Parameters

Parameter	Description	Min	Max	Default	Unit

Alarms

Alarm	Condition	Priority	Message

I/O

Physical I/O and ProfiNET I/O prefixed with a "P".

Mnemonic	Description	DI	DO	AI	AO	PDI	PDO	PAI	PAO

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Class	Description
EMS2	**Auxiliary Unit ESTOP**

Scope

Module Scope

Functional Requirements

Req Ref	Requirement

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State Diagram
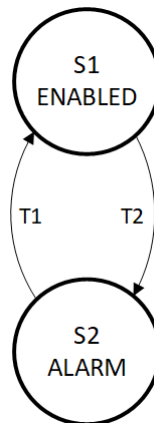
States

State	Alarm State	State Description	SFC
ENABLED	No	Auxiliary Unit Emergency stop EM placeholder	None

Child Device Initial States

State	Child Alias	Class	Description	Initial State
ENABLED	ESnnnn	DI1	Emergency Stop	ENABLE

Transitions

Transition	Description

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Parameters

Parameter	Description	Min	Max	Default	Unit

Alarms

Alarm	Condition	Priority	Message

I/O

Physical I/O and ProfiNET I/O prefixed with a "P".

Mnemonic	Description	DI	DO	AI	AO	PDI	PDO	PAI	PAO

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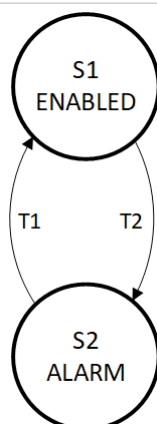| Class	Description
EMT1	**Manufacturing filtration line heat exchanger cooling control**

Scope

Module Scope
Applies to Manufacturing Filtration Line heat exchanger cooling control.

Functional Requirements

Req Ref	Requirement
F1	Perform PID controlled cooling of the filtration line heat exhanger to a defined product temperature setpoint measured in the filtration line at the outlet of the heat exchanger.
F2	Perform pre-cooling of the heat exchanger prior to product flow through it. In this case cooling is achieved by setting the cooling water temperature control valve to its fixed output position.

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State Diagram

States

State	Alarm State	State Description	SFC
COOL	No	Cooling of Product in Heat Exchanger	None
DRAIN	No	Draining of Heat Exchanger Jacket	PH_EMT1_DRAIN
PREEMPT	No	Preemptive cooling of Heat Exchanger	None

Child Device Initial States

State	Child Alias	Class	Description	Initial State
COOL	TCVn157	MOD1	Mx cooling water supply valve	REMOTE
COOL	BAVn167	POS4	MMFLx Cooling Water Supply Drain Valve	CLOSE
COOL	BAVn169	POS4	MMFLx Cooling Water Return Drain Valve	CLOSE
COOL	BVn151	POS4	Mx Cooling Water Supply Valve	OPEN
COOL	BVn153	POS4	Mx Cooling Water Return Valve	OPEN
COOL	TCn109	TC1	Mx Inline Heat Exchanger Temperature Controller	ENABLE
COOL	TIn109	TI1	Mx Inline Heat Exchanger Temperature Indictor	ENABLE
DRAIN	TCVn157	MOD1	Mx cooling water supply valve	CLOSE
DRAIN	BAVn167	POS4	MMFLx Cooling Water Supply Drain Valve	OPEN
DRAIN	BAVn169	POS4	MMFLx Cooling Water Return Drain Valve	OPEN
DRAIN	BVn151	POS4	Mx Cooling Water Supply Valve	CLOSE
DRAIN	BVn153	POS4	Mx Cooling Water Return Valve	CLOSE
DRAIN	TCn109	TC1	Mx Inline Heat Exchanger Temperature Controller	DISABLE
DRAIN	TIn109	TI1	Mx Inline Heat Exchanger Temperature Indictor	ENABLE
PREEMPT	TCVn157	MOD1	Mx cooling water supply valve	LOCAL
PREEMPT	BAVn167	POS4	MMFLx Cooling Water Supply Drain Valve	CLOSE
PREEMPT	BAVn169	POS4	MMFLx Cooling Water Return Drain Valve	CLOSE
PREEMPT	BVn151	POS4	Mx Cooling Water Supply Valve	OPEN
PREEMPT	BVn153	POS4	Mx Cooling Water Return Valve	OPEN
PREEMPT	TCn109	TC1	Mx Inline Heat Exchanger Temperature	DISABLE

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			Controller	
PREEMPT	TIn109	TI1	Mx Inline Heat Exchanger Temperature Indictor	ENABLE

Transitions

Transition	Description

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Parameters

Parameter	Description	Min	Max	Default	Unit
SETPOINT	PID setpoint	0.0	150.0	Calling	@@UOM@@
MEASURE	PV from transfer line temperature probe	0.0	150.0	PV	@@UOM@@

Alarms

Alarm	Condition	Priority	Message
TIMEOUT	Timeout waiting to achieve temperature setpoint	M	Vessel (Mx/Sy) taking excessive time to cool

I/O

Physical I/O and ProfiNET I/O prefixed with a "P".

Mnemonic	Description	DI	DO	AI	AO	PDI	PDO	PAI	PAO

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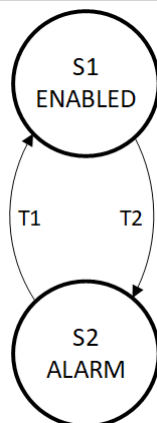| Class	Description
EMV1	**Vessels manway, bursting disc, bottom outlet valve and temperature alarms and interlocks**

Scope

Module Scope
Applies to all vessels in SMS1 and SMS2.

Functional Requirements

Req Ref	Requirement
F1	The EM shall discharge the vessel contents by opening the bottom outlet valve.
F2	The EM shall be able to disable the manway cover alarm so that the manway cover may be opened or closed by the operator without alarm for filling the vessel with solid compounds during batch manufacture. The alarm may be re-enabled after batch operations are complete.
F3	The EM shall also provide state of the manway proximity switch.
F4	The EM shall also provide the state of the vessel overpressure bursting disc.

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State Diagram

States

State	Alarm State	State Description	SFC
DISCHARGE	No	Tank outlet Discharge	None
ISOLATE	No	Vessel Isolated from Environment	None
MANWAY	No	Vessel Manway Opening	None

Child Device Initial States

State	Child Alias	Class	Description	Initial State
DISCHARGE	RDn101	DI1	Vessel Burst Disc	ENABLE
DISCHARGE	DVn121	POS2	Vessel Outlet Valve	OPEN
DISCHARGE	TIn105	TI1	Vessel Temperature Indicator	ENABLE
DISCHARGE	ZSCn101	ZSC1	Vessel Manway Position	CLOSE
ISOLATE	RDn101	DI1	Vessel Burst Disc	ENABLE
ISOLATE	DVn121	POS2	Vessel Outlet Valve	CLOSE
ISOLATE	TIn105	TI1	Vessel Temperature Indicator	ENABLE
ISOLATE	ZSCn101	ZSC1	Vessel Manway Position	CLOSE
MANWAY	RDn101	DI1	Vessel Burst Disc	ENABLE
MANWAY	DVn121	POS2	Vessel Outlet Valve	CLOSE
MANWAY	TIn105	TI1	Vessel Temperature Indicator	ENABLE
MANWAY	ZSCn101	ZSC1	Vessel Manway Position	OPEN

Transitions

Transition	Description

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Parameters

Parameter	Description	Min	Max	Default	Unit
ENAB_ALM	Enable or disable Manway Alarm	0 = FALSE	1 = TRUE	0.0	@@UOM@@

Alarms

Alarm	Condition	Priority	Message
FLOWPATH	Flow path device, keypiece or valve, no longer setup	H	Flow path is no longer setup

I/O

Physical I/O and ProfiNET I/O prefixed with a "P".

Mnemonic	Description	DI	DO	AI	AO	PDI	PDO	PAI	PAO

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Class	Description
EMV2	**Vessel Inlet Sprayball Valves**

Scope

Module Scope
Applies to all vessels in SMS1 and SMS2 and includes only the inlet spray ball valves.

Functional Requirements

Req Ref	Requirement
F1	The EM shall allow the two spray ball inlet valve on the top of each vessel to either both be opened, both be closed or operate in a "flip-flop" mode where each valve alternately opens and closes so that only one valve is opened at a time.

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State Diagram

States

State	Alarm State	State Description	SFC
CHARGE	No	Charging into Manufacturing Vessel through both sprayballs	None
PULSE	No	Sprayball inlet valves operate in flip-flop mode	PH_EMV2_PULSE

Child Device Initial States

State	Child Alias	Class	Description	Initial State
CHARGE	DVn117	POS2	Vessel Spray Ball 1 Valve	OPEN
CHARGE	DVn119	POS2	Vessel Spray Ball 2 Valve	OPEN
PULSE	DVn117	POS2	Vessel Spray Ball 1 Valve	OPEN
PULSE	DVn119	POS2	Vessel Spray Ball 2 Valve	OPEN

Transitions

Transition	Description

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Parameters

Parameter	Description	Min	Max	Default	Unit
TIME_OPENED	Required opened time for each sprayball inlet valve in flip-flop mode	0.0	300.0	5.0	@@UOM @@

Alarms

Alarm	Condition	Priority	Message

I/O

Physical I/O and ProfiNET I/O prefixed with a "P".

Mnemonic	Description	DI	DO	AI	AO	PDI	PDO	PAI	PAO

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Class	Description
EMX1	**Manufacturing vessel filtration line MMFLx**

Scope

Module Scope
Applies to Manufacturing vessels M1 and M2 filtration lines.

Functional Requirements

Req Ref	Requirement
F1	The EM shall transfer product from manufacturing vessel to the filter manufacturing filtration line.
F2	The EM shall CIP filtration transfer line from manufacturing vessel to CIP Wash Drain tundish.
F3	The EM shall SIP filtration transfer line from manufacturing vessel.
F4	The EM shall also make drain line SIP condensate temperature available to other user and/or other users can also access the CMs for these devices
F5	The EM shall indicate that the flowpath is setup correctly for the selected duty and shall provide an interlock flag for monitoring by other agents, such as the Unit.
F6	The flowpath interlock flag shall only be raised when a separate Interlock Armed flag is set, indicating that the flow path is now critical to product and operator safety. The Armed flag shall be set by a sequence once initial setup of the flowpath has been confirmed.

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State Diagram

States

State	Alarm State	State Description	SFC
CIP_MMFLX	No	CIP_MMFLx Operation for MMFLx	None
CIP_MX	No	CIP_Mx Operation for MMFLx	None
FILTER	No	Filtration Operation of MMFLx	None
SETUP_CIPSIP	No	Setup of CIPSIP for MMFLx	PH_EMX1_SETUP_CIPSIP
SETUP_FILTER	No	Setup of MMFLx for Filtration Operation	PH_EMX1_SETUP_FILTER
SIP	No	SIP Operation for MMFLx	None

Child Device Initial States

State	Child Alias	Class	Description	Initial State
CIP_MMFLX	DVn171	POS2	MMFLx Filtration Line filter inlet drain valve	CLOSE
CIP_MMFLX	DVn173	POS2	MMFLx Inline Heat Exchanger inlet valve	OPEN
CIP_MMFLX	ZSCn113	ZSC2	MMFLx Filtration Inlet Flowpath Indicator	OUT
CIP_MMFLX	ZSCn115	ZSC2	MMFLx Filtration Inlet CIP & SIP Flowpath Indicator	IN
CIP_MX	DVn171	POS2	MMFLx Filtration Line filter inlet drain valve	OPEN
CIP_MX	DVn173	POS2	MMFLx Inline Heat Exchanger inlet valve	CLOSE
CIP_MX	ZSCn113	ZSC2	MMFLx Filtration Inlet Flowpath Indicator	OUT
CIP_MX	ZSCn115	ZSC2	MMFLx Filtration Inlet CIP & SIP Flowpath Indicator	IN
CIP_SY	ZSCn113	ZSC2	MMFLx Filtration Inlet Flowpath Indicator	If MX = M2 Then IN Else OUT
CIP_SY	ZSCn115	ZSC2	MMFLx Filtration Inlet CIP & SIP Flowpath Indicator	If FLZ=FL1 Then IN Else OUT
FILL_MX	ZSCn113	ZSC2	MMFLx Filtration Inlet Flowpath Indicator	If MX = M2 Then IN Else OUT
FILL_MX	ZSCn115	ZSC2	MMFLx Filtration Inlet CIP & SIP Flowpath Indicator	If FLZ=FL1 Then IN Else OUT
FILL_SY	ZSCn113	ZSC2	MMFLx Filtration Inlet Flowpath Indicator	If MX = M2 Then IN Else OUT
FILL_SY	ZSCn115	ZSC2	MMFLx Filtration Inlet CIP & SIP Flowpath Indicator	If FLZ=FL1 Then IN Else OUT

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FILTER	DVn171	POS2	MMFLx Filtration Line filter inlet drain valve	CLOSE
FILTER	DVn173	POS2	MMFLx Inline Heat Exchanger inlet valve	OPEN
FILTER	ZSCn113	ZSC2	MMFLx Filtration Inlet Flowpath Indicator	IN
FILTER	ZSCn113	ZSC2	MMFLx Filtration Inlet Flowpath Indicator	If MX = M2 Then IN Else OUT
FILTER	ZSCn115	ZSC2	MMFLx Filtration Inlet CIP & SIP Flowpath Indicator	If FLZ=FL1 Then IN Else OUT
FILTER	ZSCn115	ZSC2	MMFLx Filtration Inlet CIP & SIP Flowpath Indicator	OUT
ISOLATE	ZSCn113	ZSC2	MMFLx Filtration Inlet Flowpath Indicator	OUT
ISOLATE	ZSCn115	ZSC2	MMFLx Filtration Inlet CIP & SIP Flowpath Indicator	OUT
SETUP	ZSCn113	ZSC2	MMFLx Filtration Inlet Flowpath Indicator	If MX = M2 Then IN Else
SETUP	ZSCn115	ZSC2	MMFLx Filtration Inlet CIP & SIP Flowpath Indicator	If FLZ=FL1 Then IN Else OUT
SETUP_CIPSIP	DVn171	POS2	MMFLx Filtration Line filter inlet drain valve	CLOSE
SETUP_CIPSIP	DVn173	POS2	MMFLx Inline Heat Exchanger inlet valve	CLOSE
SETUP_CIPSIP	ZSCn113	ZSC2	MMFLx Filtration Inlet Flowpath Indicator	OUT
SETUP_CIPSIP	ZSCn115	ZSC2	MMFLx Filtration Inlet CIP & SIP Flowpath Indicator	IN
SETUP_FILTER	DVn171	POS2	MMFLx Filtration Line filter inlet drain valve	CLOSE
SETUP_FILTER	DVn173	POS2	MMFLx Inline Heat Exchanger inlet valve	CLOSE
SETUP_FILTER	ZSCn113	ZSC2	MMFLx Filtration Inlet Flowpath Indicator	IN
SETUP_FILTER	ZSCn115	ZSC2	MMFLx Filtration Inlet CIP & SIP Flowpath Indicator	OUT
SIP	DVn171	POS2	MMFLx Filtration Line filter inlet drain valve	OPEN
SIP	DVn173	POS2	MMFLx Inline Heat Exchanger inlet valve	OPEN
SIP	ZSCn113	ZSC2	MMFLx Filtration Inlet Flowpath Indicator	If MX = M2 Then IN Else OUT
SIP	ZSCn113	ZSC2	MMFLx Filtration Inlet Flowpath Indicator	OUT
SIP	ZSCn115	ZSC2	MMFLx Filtration Inlet CIP & SIP Flowpath Indicator	IN
SIP	ZSCn115	ZSC2	MMFLx Filtration Inlet CIP & SIP Flowpath Indicator	If FLZ=FL1 Then IN Else OUT

Transitions

Transition	Description

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Parameters

Parameter	Description	Min	Max	Default	Unit

Alarms

Alarm	Condition	Priority	Message
FLOWPATH	Flow path device, keypiece or valve, no longer setup	H	Flow path is no longer setup

I/O

Physical I/O and ProfiNET I/O prefixed with a "P".

Mnemonic	Description	DI	DO	AI	AO	PDI	PDO	PAI	PAO

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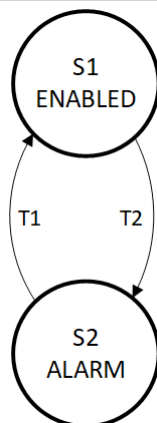| Class	Description
EMX2	**Shared Vessels Transfer Lines**

Scope

Module Scope
Applies to Storage vessels S1, S2, S3 and S4.

Functional Requirements

Req Ref	Requirement
F1	The EM shall be configured for the transfer path from manufacturing vessel to storage vessel via the heat exchanger and manufacturing filtration line. Both for product transfers as well as CIP and SIP.
F2	The EM shall be configured for transfer path from a storage vessel to filling line 1 or filling line 2.
F3	The EM shall be configured for transfer path to filling line 1 or filling line 2 directly from a manufacturing vessel.
F4	The EM shall configure SIP path with all valves opened.
F5	The EM shall post SIP CA pressurisation state where the terminal path valves are closed but other valves remain opened.
F6	Setup of the flow path for SIP shall also be used in the filtration operation as the flow path is the same.
F7	The EM shall also make sterile filter outlet pressure available to other user and/or other users can also access the CMs for these devices
F8	The EM shall indicate that the flowpath is setup correctly for the selected duty and shall provide an interlock flag for monitoring by other agents, such as the Unit.
F9	The flowpath interlock flag shall only be raised when a separate Interlock Armed flag is set, indicating that the flow path is now critical to product and operator safety. The Armed flag shall be set by a sequence once initial setup of the flowpath has been confirmed.

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State Diagram

States

State	Alarm State	State Description	SFC
CIP_SY	No	CIP of Storage Vessel Sy to Sy Drain	None
FILL_MX	No	Filling operation from Mixing Vessel Mx direct to Filling Machine FLz	None
FILL_SY	No	Filling operation from Storage Vessel Sy to Filling Machine FLz	None
FILTER	No	Filling operation from Mixing Vessel Mx to Storage Vessel Sy	None
ISOLATE	No	Isolate flowplate transfer path	PH_EMX2_ISOLATE
SETUP	No	Setup flowplate transfer path from source to destination	PH_EMX2_SETUP
SIP	No	SIP of Storage Vessel Sy to SMFLx	None

Child Device Initial States

State	Child Alias	Class	Description	Initial State
CIP	ZSCn111	ZSC2	SMFL1 to Sy/BFSy Flowpath Indicator	IN
CIP_MMFLX	ZSCn113	ZSC2	SMFL2 to Sy/BFSy Flowpath Indicator	OUT
CIP_MMFLX	ZSCn115	ZSC2	Sy to BFSy P1 Flowpath Indicator	IN
CIP_MX	ZSCn113	ZSC2	SMFL2 to Sy/BFSy Flowpath Indicator	OUT
CIP_MX	ZSCn115	ZSC2	Sy to BFSy P1 Flowpath Indicator	IN
CIP_SY	DVn123	POS2	Sy Transfer line valve from vessel	OPEN
CIP_SY	DVn125	POS2	Sy Transfer line valve from SMFL	CLOSE
CIP_SY	DVn127	POS2	Sy Transfer line valve to drain	OPEN
CIP_SY	DVn129	POS2	Sy Transfer line valve to filling	CLOSE
CIP_SY	ZSCn111	ZSC2	SMFL1 to Sy/BFSy Flowpath Indicator	If MX = M1 Then IN Else OUT
CIP_SY	ZSCn113	ZSC2	SMFL2 to Sy/BFSy Flowpath Indicator	If MX = M2 Then IN Else OUT
CIP_SY	ZSCn115	ZSC2	Sy to BFSy P1 Flowpath Indicator	If FLZ=FL1 Then IN Else OUT
CIP_SY	ZSCn117	ZSC2	Sy to BFS2 P1 Flowpath Indicator	If FLZ=FL2 Then IN Else OUT
FILL_MX	DVn123	POS2	Sy Transfer line valve from vessel	CLOSE

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FILL_MX	DVn125	POS2	Sy Transfer line valve from SMFL	OPEN
FILL_MX	DVn127	POS2	Sy Transfer line valve to drain	CLOSE
FILL_MX	DVn129	POS2	Sy Transfer line valve to filling	OPEN
FILL_MX	ZSCn111	ZSC2	SMFL1 to Sy/BFSy Flowpath Indicator	If MX = M1 Then IN Else OUT
FILL_MX	ZSCn113	ZSC2	SMFL2 to Sy/BFSy Flowpath Indicator	If MX = M2 Then IN Else OUT
FILL_MX	ZSCn115	ZSC2	Sy to BFSy P1 Flowpath Indicator	If FLZ=FL1 Then IN Else OUT
FILL_MX	ZSCn117	ZSC2	Sy to BFS2 P1 Flowpath Indicator	If FLZ=FL2 Then IN Else OUT
FILL_SY	DVn123	POS2	Sy Transfer line valve from vessel	OPEN
FILL_SY	DVn125	POS2	Sy Transfer line valve from SMFL	CLOSE
FILL_SY	DVn127	POS2	Sy Transfer line valve to drain	CLOSE
FILL_SY	DVn129	POS2	Sy Transfer line valve to filling	OPEN
FILL_SY	ZSCn111	ZSC2	SMFL1 to Sy/BFSy Flowpath Indicator	If MX = M1 Then IN Else OUT
FILL_SY	ZSCn113	ZSC2	SMFL2 to Sy/BFSy Flowpath Indicator	If MX = M2 Then IN Else OUT
FILL_SY	ZSCn115	ZSC2	Sy to BFSy P1 Flowpath Indicator	If FLZ=FL1 Then IN Else OUT
FILL_SY	ZSCn117	ZSC2	Sy to BFS2 P1 Flowpath Indicator	If FLZ=FL2 Then IN Else OUT
FILTER	DVn123	POS2	Sy Transfer line valve from vessel	OPEN
FILTER	DVn125	POS2	Sy Transfer line valve from SMFL	OPEN
FILTER	DVn127	POS2	Sy Transfer line valve to drain	CLOSE
FILTER	DVn129	POS2	Sy Transfer line valve to filling	CLOSE
FILTER	ZSCn111	ZSC2	SMFL1 to Sy/BFSy Flowpath Indicator	If MX = M1 Then IN Else OUT
FILTER	ZSCn111	ZSC2	SMFL1 to Sy/BFSy Flowpath Indicator	OUT
FILTER	ZSCn113	ZSC2	SMFL2 to Sy/BFSy Flowpath Indicator	IN
FILTER	ZSCn113	ZSC2	SMFL2 to Sy/BFSy Flowpath Indicator	If MX = M2 Then IN Else OUT
FILTER	ZSCn115	ZSC2	Sy to BFSy P1 Flowpath Indicator	If FLZ=FL1 Then IN Else OUT
FILTER	ZSCn115	ZSC2	Sy to BFSy P1 Flowpath Indicator	OUT
FILTER	ZSCn117	ZSC2	Sy to BFS2 P1 Flowpath Indicator	If FLZ=FL2 Then IN Else OUT
FILTER_BLEED	ZSCn111	ZSC2	SMFL1 to Sy/BFSy Flowpath Indicator	OUT
ISOLATE	DVn123	POS2	Sy Transfer line valve from vessel	CLOSE
ISOLATE	DVn125	POS2	Sy Transfer line valve from SMFL	CLOSE
ISOLATE	DVn127	POS2	Sy Transfer line valve to drain	CLOSE
ISOLATE	DVn129	POS2	Sy Transfer line valve to filling	CLOSE
ISOLATE	ZSCn111	ZSC2	SMFL1 to Sy/BFSy Flowpath Indicator	OUT
ISOLATE	ZSCn113	ZSC2	SMFL2 to Sy/BFSy Flowpath Indicator	OUT
ISOLATE	ZSCn115	ZSC2	Sy to BFSy P1 Flowpath Indicator	OUT
ISOLATE	ZSCn117	ZSC2	Sy to BFS2 P1 Flowpath Indicator	OUT
SETUP	DVn123	POS2	Sy Transfer line valve from vessel	CLOSE

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SETUP	DVn125	POS2	Sy Transfer line valve from SMFL	CLOSE
SETUP	DVn127	POS2	Sy Transfer line valve to drain	IN
SETUP	DVn129	POS2	Sy Transfer line valve to filling	CLOSE
SETUP	ZSCn111	ZSC2	SMFL1 to Sy/BFSy Flowpath Indicator	If MX = M1 Then IN Else
SETUP	ZSCn113	ZSC2	SMFL2 to Sy/BFSy Flowpath Indicator	If MX = M2 Then IN Else
SETUP	ZSCn115	ZSC2	Sy to BFSy P1 Flowpath Indicator	If FLZ=FL1 Then IN Else OUT
SETUP	ZSCn117	ZSC2	Sy to BFS2 P1 Flowpath Indicator	If FLZ=FL2 Then IN Else OUT
SETUP_CIP	ZSCn111	ZSC2	SMFL1 to Sy/BFSy Flowpath Indicator	IN
SETUP_CIPSIP	ZSCn113	ZSC2	SMFL2 to Sy/BFSy Flowpath Indicator	OUT
SETUP_CIPSIP	ZSCn115	ZSC2	Sy to BFSy P1 Flowpath Indicator	IN
SETUP_FILTER	ZSCn113	ZSC2	SMFL2 to Sy/BFSy Flowpath Indicator	IN
SETUP_FILTER	ZSCn115	ZSC2	Sy to BFSy P1 Flowpath Indicator	OUT
SETUP_SIP	ZSCn111	ZSC2	SMFL1 to Sy/BFSy Flowpath Indicator	OUT
SIP	DVn123	POS2	Sy Transfer line valve from vessel	OPEN
SIP	DVn125	POS2	Sy Transfer line valve from SMFL	OPEN
SIP	DVn127	POS2	Sy Transfer line valve to drain	OPEN
SIP	DVn129	POS2	Sy Transfer line valve to filling	OPEN
SIP	ZSCn111	ZSC2	SMFL1 to Sy/BFSy Flowpath Indicator	If MX = M1 Then IN Else OUT
SIP	ZSCn111	ZSC2	SMFL1 to Sy/BFSy Flowpath Indicator	OUT
SIP	ZSCn113	ZSC2	SMFL2 to Sy/BFSy Flowpath Indicator	If MX = M2 Then IN Else OUT
SIP	ZSCn113	ZSC2	SMFL2 to Sy/BFSy Flowpath Indicator	OUT
SIP	ZSCn115	ZSC2	Sy to BFSy P1 Flowpath Indicator	IN
SIP	ZSCn115	ZSC2	Sy to BFSy P1 Flowpath Indicator	If FLZ=FL1 Then IN Else OUT
SIP	ZSCn117	ZSC2	Sy to BFS2 P1 Flowpath Indicator	If FLZ=FL2 Then IN Else OUT

Transitions

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Parameters

Parameter	Description	Min	Max	Default	Unit
MX	Manufacturing Vessel.		M1, M2		@@UOM@@

Alarms

Alarm	Condition	Priority	Message
FLOWPATH	Flow path device, keypiece or valve, no longer setup	H	Flow path is no longer setup

I/O

Physical I/O and ProfiNET I/O prefixed with a "P".

Mnemonic	Description	DI	DO	AI	AO	PDI	PDO	PAI	PAO

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Class	Description
EMX4	**CIP & SIP Drain**

Scope

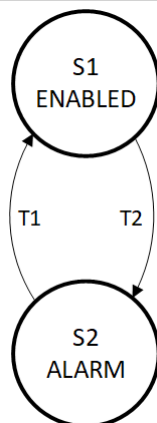| **Module Scope** |
|---|
| Applies to the arrangement of CIP and SIP drains throughout the manufacturing and filling systems. |

Functional Requirements

Req Ref	Requirement
F1	The EM shall arrange the valves for CIP, with the CIP drain valve opened and SIP drain valve closed.
F2	The EM shall arrange the valves for SIP, with the CIP drain valve closed and SIP drain valve opened.
F3	The EM shall also make drain line SIP condensate temperature available.
F4	The SIP drain valve shall have a pulse mode which periodically pulses the valve open and closed for predetermined opened and closed times.
F5	The EM shall indicate that the flowpath is setup correctly for the selected duty and shall provide an interlock flag for monitoring by other agents, such as the Unit.
F6	The flowpath interlock flag shall only be raised when a separate Interlock Armed flag is set, indicating that the flow path is now critical to product and operator safety. The Armed flag shall be set by a sequence once initial setup of the flowpath has been confirmed.

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State Diagram

States

State	Alarm State	State Description	SFC
CIP	No	CIP Operation for Drain	None
SIP	No	SIP Operation for Drain	None
SIP_PULSE	No	SIP Pulse Mode Operation for Drain	PH_EMX4_SIP_PULSE

Child Device Initial States

State	Child Alias	Class	Description	Initial State
CIP	BAVCIP	POS4	Mx CIP Drain Valve	OPEN
CIP	BAVSIP	POS4	Mx SIP Condensate Drain Valve	CLOSE
CIP	TISIP	TI2	Mx Drain Temperature Indicator	ENABLE
SIP	BAVCIP	POS4	Mx CIP Drain Valve	CLOSE
SIP	BAVSIP	POS4	Mx SIP Condensate Drain Valve	OPEN
SIP	TISIP	TI2	Mx Drain Temperature Indicator	ENABLE
SIP_PULSE	BAVCIP	POS4	Mx CIP Drain Valve	CLOSE
SIP_PULSE	BAVSIP	POS4	Mx SIP Condensate Drain Valve	OPEN
SIP_PULSE	TISIP	TI2	Mx Drain Temperature Indicator	ENABLE

Transitions

Transition	Description

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Parameters

Parameter	Description	Min	Max	Default	Unit
SIP_TEMP	PV from Drain line temperature probe			Calling	@@UOM @@
TIME_OPENED	Required time to open the SIP valve in pulse mode	0.0	300.0	5.0	@@UOM @@
TIME_CLOSED	Required time to close the SIP valve in pulse mode	0.0	300.0	5.0	@@UOM @@

Alarms

Alarm	Condition	Priority	Message
FLOWPATH	Flow path device, keypiece or valve, no longer setup	H	Flow path is no longer setup

I/O

Physical I/O and ProfiNET I/O prefixed with a "P".

Mnemonic	Description	DI	DO	AI	AO	PDI	PDO	PAI	PAO

Class	Description
EMX5	**BFS Inlet Filling Line**

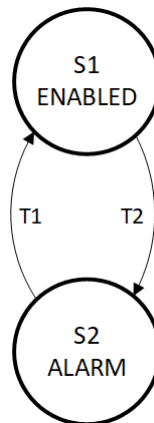## Scope

Module Scope
Applies to the filling inlet line to the BFS machine.

Functional Requirements

Req Ref	Requirement
F1	This EM is a placeholder for the filling pause push button and filling line temperature indicator.

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State Diagram

States

State	Alarm State	State Description	SFC
FILL	No	Fill Operation	None

Child Device Initial States

State	Child Alias	Class	Description	Initial State
FILL	PBn4101	DI2	BFSz Pause Push Button	ENABLE

Transitions

Transition	Description

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Parameters

Parameter	Description	Min	Max	Default	Unit
PAUSED	Filling is paused if push button activated.	0 = FALSE	1 = TRUE	0.0	@@UOM@@

Alarms

Alarm	Condition	Priority	Message
FLOWPATH	Flow path device, keypiece or valve, no longer setup	H	Flow path is no longer setup

I/O

Physical I/O and ProfiNET I/O prefixed with a "P".

Mnemonic	Description	DI	DO	AI	AO	PDI	PDO	PAI	PAO

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Class	Description
EMX6	**Shared Filtration line SMFLx to Vessels Transfer Lines**

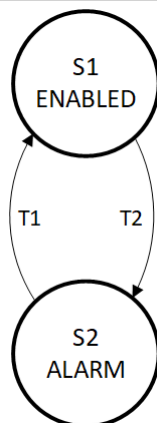## Scope

Module Scope
Applies to the storage vessel transfer line after the filters.

Functional Requirements

Req Ref	Requirement
F1	The EM shall CIP the storage vessel filtration transfer line to the CIP Wash Drain tundish.
F2	The EM shall SIP the storage vessel filtration transfer line.
F3	The EM shall also make drain line SIP condensate temperature available to other user and/or other users can also access the CMs for these devices
F4	The EM shall indicate that the flowpath is setup correctly for the selected duty and shall provide an interlock flag for monitoring by other agents, such as the Unit.
F5	The flowpath interlock flag shall only be raised when a separate Interlock Armed flag is set, indicating that the flow path is now critical to product and operator safety. The Armed flag shall be set by a sequence once initial setup of the flowpath has been confirmed.

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State Diagram

States

State	Alarm State	State Description	SFC
CIP	No	CIP Operation for SMFLx	None
FILTER	No	Filtration Operation of SMFLx	None
FILTER_BLEED	No	Filter Bleed Operation of SMFLx	PH_EMX6_FILTER_BLEED
SETUP_CIP	No	Setup of CIPSIP for SMFLx	PH_EMX6_SETUP_CIP
SETUP_SIP	No	Filtration Setup for SMFLx	PH_EMX6_SETUP_SIP
SIP	No	SIP Operation of SMFLx	None

Child Device Initial States

State	Child Alias	Class	Description	Initial State
CIP	DVn135	POS2	SMFLy Filtration Line filter outlet drain valve	OPEN
CIP	DVn137	POS2	SMFLy Filtration Line filter outlet valve	OPEN
CIP	ZSCn109	ZSC2	SMFLy Filtration Line outlet T-piece Flowpath Indicator	OUT
CIP	ZSCn111	ZSC2	SMFLy Filtration Outlet CIP Flowpath Indicator	IN
CIP_SY	ZSCn111	ZSC2	SMFLy Filtration Outlet CIP Flowpath Indicator	If MX = M1 Then IN Else OUT
FILL_MX	ZSCn111	ZSC2	SMFLy Filtration Outlet CIP Flowpath Indicator	If MX = M1 Then IN Else OUT
FILL_SY	ZSCn111	ZSC2	SMFLy Filtration Outlet CIP Flowpath Indicator	If MX = M1 Then IN Else OUT
FILTER	DVn135	POS2	SMFLy Filtration Line filter outlet drain valve	CLOSE
FILTER	DVn137	POS2	SMFLy Filtration Line filter outlet valve	OPEN
FILTER	ZSCn109	ZSC2	SMFLy Filtration Line outlet T-piece Flowpath Indicator	IN
FILTER	ZSCn111	ZSC2	SMFLy Filtration Outlet CIP Flowpath Indicator	If MX = M1 Then IN Else OUT
FILTER	ZSCn111	ZSC2	SMFLy Filtration Outlet CIP Flowpath Indicator	OUT
FILTER_BLEED	DVn135	POS2	SMFLy Filtration Line filter outlet drain valve	CLOSE
FILTER_BLEE	DVn137	POS2	SMFLy Filtration Line filter outlet valve	CLOSE

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D				
FILTER_BLEED	ZSCn109	ZSC2	SMFLy Filtration Line outlet T-piece Flowpath Indicator	IN
FILTER_BLEED	ZSCn111	ZSC2	SMFLy Filtration Outlet CIP Flowpath Indicator	OUT
ISOLATE	ZSCn111	ZSC2	SMFLy Filtration Outlet CIP Flowpath Indicator	OUT
SETUP	ZSCn111	ZSC2	SMFLy Filtration Outlet CIP Flowpath Indicator	If MX = M1 Then IN Else
SETUP_CIP	DVn135	POS2	SMFLy Filtration Line filter outlet drain valve	CLOSE
SETUP_CIP	DVn137	POS2	SMFLy Filtration Line filter outlet valve	CLOSE
SETUP_CIP	ZSCn109	ZSC2	SMFLy Filtration Line outlet T-piece Flowpath Indicator	OUT
SETUP_CIP	ZSCn111	ZSC2	SMFLy Filtration Outlet CIP Flowpath Indicator	IN
SETUP_SIP	DVn135	POS2	SMFLy Filtration Line filter outlet drain valve	CLOSE
SETUP_SIP	DVn137	POS2	SMFLy Filtration Line filter outlet valve	CLOSE
SETUP_SIP	ZSCn109	ZSC2	SMFLy Filtration Line outlet T-piece Flowpath Indicator	IN
SETUP_SIP	ZSCn111	ZSC2	SMFLy Filtration Outlet CIP Flowpath Indicator	OUT
SIP	DVn135	POS2	SMFLy Filtration Line filter outlet drain valve	OPEN
SIP	DVn137	POS2	SMFLy Filtration Line filter outlet valve	OPEN
SIP	ZSCn109	ZSC2	SMFLy Filtration Line outlet T-piece Flowpath Indicator	IN
SIP	ZSCn111	ZSC2	SMFLy Filtration Outlet CIP Flowpath Indicator	If MX = M1 Then IN Else OUT
SIP	ZSCn111	ZSC2	SMFLy Filtration Outlet CIP Flowpath Indicator	OUT

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Transition	Description

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Parameters

Parameter	Description	Min	Max	Default	Unit
SY	Storage Vessel Sy		1=S1, 2=S2, 3=S3, 4=S4	0.0	@@UOM @@

Alarms

Alarm	Condition	Priority	Message
FLOWPATH	Flow path device, keypiece or valve, no longer setup	H	Flow path is no longer setup

I/O

Physical I/O and ProfiNET I/O prefixed with a "P".

Mnemonic	Description	DI	DO	AI	AO	PDI	PDO	PAI	PAO