

200 EVO

cGMP Compact Part Washer

Thorough, efficient washing and drying of various components, materials and accessories commonly used in the biotech and pharmaceutical manufacturing process industries, such as filling lines, tableting machine parts, drums, containers, miscellaneous glassware and plasticware.

The 200EVO series washer is the outcome of 30 years of experience in designing, manufacturing and validating washing equipment according to the latest best practices and standards to support customers in exceeding the current GMP requirements. 200EVO Series represents the answer to those seeking for high flexibility, high throughput combined with the lowest running costs as well as minimum footprint requirements.

Each unit can be either steam or electrical heated and it comes with a single or double door for pass through applications. In case of double door configuration, an air-tight separation system is available on the clean side end of the washer. The unit can be equipped with a setup composed by sanitary ball valves or diaphragm valves accordingly to the user requirement specifications.



MODEL	Nominal Chamber Dimensions [mm – inch]	Nominal Chamber Volume [l – gal]
W200E-060	729 x 783 x 1089 28.7 x 30.8 x 42.9	622 - 164
W200E-100	959 x 1013 x 1089 37.8 x 39.9 x 42.9	1058 - 279
W200E-140	1129 x 1183 x 1089 44.4 x 46.6 x 42.9	1454 - 384

MAIN FEATURES

CLEANING PERFORMANCE

Washing and rinse are guaranteed thanks to rotary spraying arms mounted on top and bottom of the chamber. Arms are fully inspectable and feature calibrated orifices engineered to ensure the perfect coverage of the load.

Pressure of recirculated water is constantly monitored and rotation of the arms can be controlled via dedicated sensors.

In addition to the rotating arms, on purpose engineered washing patterns are equipped on tailored loading racks which connect to the main water manifold via a patented quick lock system.

FLEXIBILITY

Unlimited washing solutions are available thanks to the patented quick lock system which allow introduction of a limitless number of different tailored loading systems, each one engineered around the parts to clean with the aim to achieve the best performance in processing various size and shape components and parts meeting any specific demand. Up to 30 customizable washing programs with up to 20 phases each can be personalized to fulfil the most stringent cleaning requirements.

HIGH QUALITY CONSTRUCTION

According to the cGMP guidelines, all the wetted parts of the washing chamber are entirely made of stainless steel AISI316L featuring rounded corners with a minimum radius $R= 20$ mm, sloped surfaces with a minimum inclination toward the drain of 2 degrees. All the components in contact with the water are sanitary grade, FDA and 3.1 certified. The piping features a fall to drain, no dead legs (3D rule) nor dirt traps as well as absence of exposed threaded parts inside the wash chamber. All welds are performed according to the latest ASME-BPE sect. IX standards (WPS & WPQR) and inspected by certified operators (ASNT SNT-TC-1A) following ASME-BPE acceptance criteria.

A full cGMP compliant documentation package is also provided along with the machine.

An UPS connected with the control system and operator interface guarantee the data integrity (finalize printing of reports, safely close the audit trail registers and eventually shut down PLC and HMI).

All these features are trademarks of the IWT quality and attention to details around the international regulatory standards.

CONSTRUCTION MATERIALS

The construction, as well as the final assembly, are carried out paying the utmost attention to the details from the selection of the raw materials all the way through the testing, the qualification and the traceability of the components/materials.

List of the main construction materials:

AISI316L	All the wetted parts/components (chamber, piping, pump, valves, loading baskets) and drying system downstream the HEPA filter
AISI304	All the parts not in contact with the processing fluids (protection panelling as well as the transport trolleys and the frame of the machine) and drying system upstream the HEPA filter
PTFE	Membrane of the valves, gasket of the tri-clamps, parts of the loading baskets
EXPANDED MELAMINE	Thermal and acoustic insulation of the wash chamber and heat exchanger
ARMAFLEX	Insulation of the hot piping lines (asbestos free)
SILICONE	Inflatable gaskets (FDA compliant)

List of the average roughness of the washing chamber and the component in use:

$Ra \leq 0,51 \mu\text{m}$	ASME BPE SF5 Ball valves and ASME BPE SF1 Diaphragm valves (optional)
$Ra \leq 0,5 \mu\text{m}$	Internal surfaces of the washing chamber (mechanical polish) and passivated
$Ra \leq 0,51 \mu\text{m}$	Piping ASME BPE SF1 internally passivated
$Ra \leq 0,8 \mu\text{m}$	Standard washing pump, steam heating coil and heating elements

EASE OF MAINTENANCE

Daily maintenance is limited to the visual inspection of the static filters and it can easily be performed by the operator without any tool.

In case of routine maintenance or calibration, protection panels covering the technical compartments are hinged to allow easy and ergonomic access to the components for ease of service. In case of need panels are completely removable.

The main process pump is hinged for ease of approach avoiding any hazardous heavy lifting procedures, this also improves accessibility to other components.

Routine maintenance is performed by trained and qualified service technicians at regular intervals according to different agreements and service contract in place.

All utilities connection (water for washing, water for the final rinse, electricity, steam, condense return, compressed air and vapour exhaust) are entering the technical area from above.

PERSONNEL SAFETY

All service panels features special key lockers in order to allow the opening only by trained and authorized personnel. The electrical cabinet (IP55) is entirely made of stainless steel AISI 304 inclusive of lockable power disconnect switch. Emergency push-buttons aim to stop the machine at once whenever pressed, they are positioned next to unloading door for pass through configuration and on the main electrical cabinet on loading side. Opening of the unloading doors is only enabled when the temperature of the chamber is below a safety limit set by the manager under protected password.

STANDARD TECHNICAL DETAILS

DOORS

The IWT 200EVO features manually operated hinged doors, structure is AISI 304 construction with glass window to allow the monitoring of the cleaning processes and simplify communication through barriers. The glass is tempered, stratified and double glazed to reduce the heat transfer to the exterior during the high temperature washing and drying processes.

Opening and closing of the doors is manually managed by operator pressing the relevant lock / unlock pushbutton. The door is perfectly sealed by an inflatable gasket made of FDA compliant silicone for a perfect water and air tightness.

PROCESSING CHAMBER & SUMP

	W200E-060	W200E-100	W200E-140
Max load weight [kg – lbs]	200 – 440	300 - 660	400 - 880
Sump nominal volume [l – gal]	75 – 19.8	90 – 23.8	110 – 29.1
Sump min working volume [l – gal]	36 – 9.5	50 – 13.2	71 – 18.8

The washing chamber is designed to maximise the loading capacity either from a volume and a payload points of view. A clever level switch allows a variable filling volume of the sump to adjust the water quantity to the exact load requirements, this is resulting in water, detergent, energy and time savings.

PROCESS PUMP

The machine features a sanitary grade stainless steel centrifugal pump, installed in vertical position, ensuring a constant flow of water over the load. The pump dimensioning vary from 5.5kW to 7.5kW accordingly to

the unit size generating up to 3 bar (45 PSI). The water sprayed through the arms ensures both, perfect coverage as well as mechanical removal of the contaminant.

The correct functioning of the pump is constantly monitored by a pressure gauge directly connected to the unit controller. The pump, at the end of each stage of the cycle is duly drained.

A static filter, easily accessible and removable for cleaning purposes, is located inside the wash chamber to protect the pump itself from accidental objects that might fall.

CHEMICAL DOSING SYSTEM

A peristaltic pump for detergent dosage is located in the technical area of the machine to provide controlled and accurate dosage of the detergents into the washing tank. A flow meter measures the accurate quantity of solution dispensed.

A suction lance (425 mm – 16.7 inch draws the chemical from the drum while a floating switch sensor detects the actual level and sets an alarm displayed on the screen when it is nearly empty. If the detergent is not sufficient to achieve the set concentration, the washing cycle is disabled.

From two per 10 kg to three per 25 Kg drums can be hosted in the technical compartment of the machine accordingly to the selected unit size. Drums are located onto a stainless-steel basin to collect any unexpected spillage of chemicals.

EXHAUST SYSTEM

Vapour and condensate generated by washing and rinse at high temperatures can be exhausted from the chamber via dedicated thimble connected to the building HVAC system.

A butterfly valve duly isolates the chamber from the exhaust line and a dedicated drain is located in the lowest point to prevent any condense return.

The chamber is always kept in positive pressure by mean of HEPA filtered air coming from the drying side channel blower, this to prevent any possible cross contamination whenever the dumper valve is opened.

CONTROL SYSTEM

Two standard hardware and software configurations are available:

	SIEMENS	ALLEN-BRADLEY
PLC	1200 Series	CompactLogix 5370
HMI	7" TP700 Comfort Panel	6.5" PanelView 7

Controller code is developed in house according to the latest GAMP5 guidelines inclusive of CFR 21 Part 11 for Audit trail compliancy.

The system allows different password levels (ERES conform) for Operator identification (log-in) of users, supervisor, maintenance (to activate the manual functions) and system administrator.

The cycle parameters, password protected, can be set by the supervisor according to the different loads to process and with the expected level of cleaning to achieve.

All the data are displayed in real time on the screen and stored in an electronic format to comply with the regulatory standards. An easy access USB port allows data transfer of batch report in electronic format and PDF reports download (Siemens setup only).

DRYING SYSTEM

The drying system configuration includes:

- ▶ A pre-filter (3µm with 99.9% filtration efficiency on 5µm particles) located in the unit technical area
- ▶ A side channel compressor (up to 380 m3/h airflow based on unit size) for air flushing under inverter management for energy efficiency and process flexibility
- ▶ A heat exchanger either electrical or steam heated accordingly to the machine setup selected
- ▶ An HEPA H14 filtration system to supply sterile air to the chamber and load.

A pressure sensor monitors the air flow in real time sending a warning message in case of discrepancy of the values from the set-point.

Air temperature set-point is according to the customer needs and the max set value 120°C – 248°F

At the end of the drying stage of the cycle, a cool down

stage is performed to achieve a settable chamber temperature value below the safety limits, usually ranging between 40°C and 50°C – 104° and 122°F.

HEPA H14 filtration is equipped with DOP test connections and differential pressure monitoring system to detect filter clogging level.

WASHING RACKS

A comprehensive set of loading racks, standardize or tailored, are available to meet specific requirement in term of throughput, stock density and batch optimizations. Racks are designed and manufactured to ensure a complete repeatability in the positioning of the different contact parts to be processed, this ensures the best exposure to the automatic cleaning procedure and dripping of surfaces for perfect drying results. Racks are equipped with quick-lock port to connect it with the unit main process water line, they feature free-rolling wheels for ease of loading / unloading and locking system for safe stock and manoeuvring on transport trolleys.

WORKING PRINCIPLES

Items to be washed are loaded into the appropriate loading rack purposely design and built.

The rack is handled via a transport trolley featuring two pivoting caster wheels with brake and two fixed wheels, a recovery shelf prevents liquids/powders from falling onto the floor.

The transport trolley is positioned in front of the duly opened loading door, a locking mechanism safely anchors the trolley to the unit itself to perfectly match the internal rails. Rack is then easily and ergonomically pushed into the washing chamber by the operator.

The door is then manually closed and locked. The operator after log-in selects the suitable washing cycle and initiates it by pressing the start button on the control panel. The unit proceeds through the selected washing programme and automatically stops on completion of all the phases or whenever an alarm occur.

When cycle is positively accomplished visual and audible signals warn the operator and the machine enable the release of the unloading door. Operator presses the door opening button on the control panel to unlock it and then manually open it.

The wash cycle is fully customizable to meet different needs in terms of cleaning, available phases are Wash, Rinse, Drying and Extraction.

Washing water, final rinse water, detergent and energy consumption can be optimized to minimize running costs and maximize efficacy.

	SIEMENS	ALLEN-BRADLEY
CYCLEs	30 cycles	
PHASEs	up to 20 phases	up to 10 phases
PARAMETERs	Time, Temperature, Detergent concentration	

WASH

Washing represents one of the main phases of the cycle, the time allocated to this phase is strictly related to the level of contamination of the components to wash and the consequent level of cleaning to achieve.

Washing is carried out using the preferred type of water (softened, RO, purified, WFI...) refilled in the process tank via the dedicated incoming line inclusive of air-gap.

Tank is filled to the volume set in the washing program, main pump is activated to recirculate the solution and heating system is switched on. Average washing temperature can range from 20 to 85 °C (68 to 185°F).

Detergent is injected via peristaltic dosing pump in the recirculation line and accurate volume control is monitored by a flow meter, the controller allows dosing the chemical above a specific water temperature as set in the machine parameters.

Once water level, chemical concentration, temperatures and recirculation pressure are according to the settings the phase countdown starts. Once phase expires the solution is totally drained from chamber, sump and piping in preparation of the upcoming step.

Should a fault occur, the cycle is stopped at once, the alarm message is displayed on the screen, recorded and printed. In this condition, the unloading door remain closed and locked, the cycle has to be restarted from the beginning.

Multiple wash phases with different water inlets or detergents can be programmed in a cycle.

RINSE

During rinse phase the selected water type (softened, RO, purified, WFI...) is refilled in the process tank via the dedicated incoming line inclusive of air-gap, it is warmed up and then sprayed over the load to allow the complete removal of the detergent from the washed items. Average temperature set-point can range from 20 to 85 °C (68 to 185°F). Once the temperature set-point is achieved, the phase countdown can start for a set time according to the needs and then the solution is totally drained from chamber, sump and piping in preparation of the upcoming step.

The rinse efficacy can be assessed by means of an optional conductivity probe with a minimum reading

range of 0,02 µS/cm and temperature compensated. At the end of the rinse phase, the conductivity is verified and if no traces of detergent left onto the washed items are detected then the rinse cycle is considered accomplished. On the opposite if the conductivity is out of the pre-set range the final rinse will be repeated up to a maximum of three times.

Should a fault occur, the cycle is stopped at once, the alarm message is displayed on the screen, recorded and printed. In this condition, the unloading door remain closed and locked, the cycle has to be restarted from the beginning.

Several rinse phases with different water inlets can be programmed in a cycle.

DRYING

At the end of the wet phases the drying takes place to perfectly dry the washed items as well as the chamber, processing piping and components. Intake air is pre-filtered and warmed up (temperature set point can be as high as 120 °C – 248°F, hot air is then blown by mean of the side channel compressor, through HEPA filter, inside the chamber to dry all external surfaces, inside the loading rack, through the process piping and main pump to guarantee complete dryness.

Upon completion of the drying phase of the cycle, a minimum cool down time minimize heat exposure during unloading operations.

Should a fault occur, the cycle is stopped at once, the alarm message is displayed on the screen, recorded and printed. In this condition, the unloading door remain closed and locked, the cycle has to be restarted from the beginning.

VAPOUR EXTRACTION

Vapour extraction removes the highly moistened and humid air from the chamber. Extraction phase also accelerates the cool down of chamber and exhausts the heat emitted from chamber and load consequently the hot drying phase.

The exhaust time can be set according to the needs.

UTILITIES MANAGEMENT

Sterile air filter

An air filtration (0,22 µm) system can be provided to be installed on board of the unit to sterilize the incoming compressed air to be used for flushing and single pass rinse purposes

Exhaust fan

A dedicated exhaust fan (400m³/h – 235cfm min airflow) can be installed on top of thimble connection to integrate client's ductwork line. Extra height is required (400 mm – 15.7 inch)

Classified remotable pre-filter

An ePM10 (99%+ removal efficacy standard to 5 micron) can be equipped for side channel compressor air inlet. This option is also suitable in case of pre-filter remote installation requirements, extension piping is provided by others. A minimum extra unit height is required (250 mm – 9.8 inch).

Double drain

Two butterfly valves, installed downstream to main drain valve, can divert waste solution in different points. Selected drain type can be programmed per each wet phase of the cycle

Remote drain

A dedicated pump can be installed to remote drain location to a maximum distance of 10m – 32.8ft with up to 5m – 16.4ft of vertical extension. This feature is not compatible with double drain requirements

Drain cooling

Drain solution can be cooled during dumping operations via inline cold-water injection

WATER MANAGEMENT

Additional water inlet

Up to three water inlets, two on top of the standard one, can be equipped to tune the different cycle phases accordingly to the specific application needs. Ball valves or diaphragm valves can be selected.

Manual intercept valve

Water inlets can be equipped with manual intercept valves, either ball or diaphragm valves can be

selected. Extra unit height is required (25 mm – 1 inch).

Loop valve management

The possible loop valve connected to the unit can be directly controlled via a dedicated electrovalve managed by the unit PLC. Alternatively, an indirect management can be performed via signals exchange between unit and main loop controller. VFCs for process control (IN: loop ready, Valve Closed; OUT: water request) are included.

Loop water supply flushing

The loop water supply line can be flushed by mean of sterile compressed air via. Solution includes a dedicated connection and electrovalve managed by the unit PLC, it works in conjunction with the sterile air filter option.

Single pass rinse

A dedicated water line inlet can be boosted by sterile compressed air to rinse the load with single pass process. The system is inclusive of a diaphragm valve and a magnetic no-return sanitary valve. This feature works in conjunction with the sterile air filter option and it is suitable also for pre-wetting purposes.

Single pass pre-wetting

A dedicated water line inlet can be boosted by sterile compressed air to pre-wet the load with single pass process. The system is inclusive of a diaphragm valve and a no-return valve. This feature works in conjunction with the sterile air filter option.

Manual intercept valve for single pass processes

Water inlets for single pass processes can be equipped with manual intercept valves, either ball or diaphragm valves can be selected. Extra unit height is required (55 mm – 2.2 inch).

Inlet water sampling point

A manual inlet water sampling point featuring Block&Bleed diaphragm valve can be equipped per each water supply. Sampling points can be easily reached from the top loading front side of the unit accessing a hinged key-locked panel. Not suitable for sampling of single pass processes water.

Process water sampling point

A manual aseptic sampling valve can be installed on process pump intake line. Sampling points can be easily reached from the bottom loading front side of the unit accessing a hinged key-locked panel.

CHEMICALS MANAGEMENT

Additional chemical dosing system

Up to three chemical dosing system, two on top of the standard one, can be equipped to tune the different wash phases accordingly to the specific application needs. This feature includes a peristaltic dosing pump, a volumetric flow meter, suction lance (425mm – 16.7 inch) with min level sensor.

Day tank

A day tank can be equipped to integrate with third party remoted chemical dosing system. The solution is inclusive of a 5 litres (169 oz) reservoir with min-max level sensors and related signals exchange management via VFCs (IN: system ready; OUT: refill request) between the unit PLC and remote chemical dosing system

Chemical storage compartment

A dedicated chemical storage compartment is available to be positioned external to the unit, inclusive of lock keys and spillage containment tray. Suitable for up to three 25 litres – 6.5 gal chemical drums.

Remote chemical dosage pump

A kit inclusive of PTFE piping extension (15m – 49 ft long) and spare extra length suction lance (950 mm – 16.7 inch) to work in conjunction with bulky detergent containers. Maximum suitable distance is 10m – 32.8ft of horizontal run and 5m – 16.4ft of vertical one.

TRIMs & PANELs

Angle trim for barrier separation on loading side

An angle trim to facilitate the flush alignment between machine and separation walls

Angle trim for barrier separation on unloading side

An angle trim to facilitate the flush alignment between machine and separation walls

Air-tight barrier separation for unloading side

An air-tight barrier separation to complete the on-board sealing of the unit in presence of a separation walls

Floor coving connection profiles

A profile to facilitate the flush alignment between machine bottom frame and flooring

OPERATOR INTERFACE & DATA MANAGEMENT

SIEMENS SETUP

7" HMI on unloading side: an additional operator interface (Comfort Panel TP700 Series) is available to be installed on the unloading side end of the unit

12" HMI on loading side: alternatively to the standard solution is available a larger size operator interface (Comfort Panel TP1200 Series) to be installed on the loading side end of the unit

12" PanelPC on loading side with connectivity with customer network: a PanelPC package (IPC427E & IFP1200 Series) is available to be installed on the loading side end of the unit and main electrical box. It includes:

- ▶ PLC to OPC Server connection to retrieve batch information and machine status. Client's OPC server, provided by others, reads data from a communication data block arranged on the machine PLC
- ▶ HMI to Server connection to allow remote user management and HMI data backup (Audit trail, alarm and cycle log)
- ▶ Multiple remote printers management (pdf or A4)
- ▶ Last cycle trends visualization

TeleService: a dedicated software upgrade can be integrated for service and maintenance purposes. Include UBIQUITY platform for remote connectivity to PLC and HMI via secure VPN connection IEC 62443-3 certified

Printer Server: a printer server installed onboard of the electrical cabinet can enable the management of an additional printer (pdf or A4)

On-board Printer: a compact, paper roll format, printer can be installed in proximity of operator interface on loading side of the unit. If the printer functioning is eventually enabled, the process parameters as well as alarms are automatically printed at the end of each cycle

A4 Printer: a remote printer can be linked via pier-to-pier connection with the main controller for A4 format reports printing. Printer and cabling to be provided by others, printer drivers compliancy to be verified and agreed. If the remote printer functioning is eventually enabled, the process parameters as well as alarms are automatically printed at the end of each cycle.

ALLEN-BRADLEY SETUP

6.5" HMI on unloading side: An additional operator interface (Panel View Plus 7) is available to be installed on the unloading side end of the unit

TeleService: a dedicate software upgrade can be integrated for service and maintenance purposes. Include UBIQUITY platform for remote connectivity to PLC and HMI via secure VPN connection IEC 62443-3 certified

Printer Server: a printer server installed onboard of the electrical cabinet can enable the management of an additional printer (pdf or A4). It includes PDF reports downloadable from a dedicated 2nd USB port installed in the proximity of HMI on loading side of the unit

On-board Printer: a compact, paper roll format, printer can be installed in proximity of operator interface on loading side of the unit. If the printer functioning is eventually enabled, the process parameters as well as alarms are automatically printed at the end of each cycle

A4 Printer: a remote printer can be linked via pier-to-pier connection with the main controller for A4 format reports printing. Printer and cabling to be provided by others, printer drivers compliancy to be verified and agreed. If the remote printer functioning is eventually enabled, the process parameters as well as alarms are automatically printed at the end of each cycle

PROCESS MONITORING

Rinse and chemical conductivity probe

A conductivity probe, featuring two-electrode system for low/high reading range (0,02-50000 $\mu\text{S}/\text{cm}$) and temperature compensated, can be equipped to control rinse water quality prior to drain and detergent concentration in the process tank.

Arms rotation monitoring system

Dedicated sensors can be installed to monitor, not count, the actual rotation of the arms during the cleaning processes

OTHER OPTIONS

Additional filtration system

An additional filter (mesh 16) can be installed upstream the process pump intake to protect from accidental fine objects that might fall. Options strongly suggested in case of glassware processing

Spillage tray

Aspillage tray inclusive of warning sensor can be included underneath the unit

Semaphore light and buzzer

Multi-colour semaphore light and buzzer can be installed on both loading and unloading sides of the unit. 5 colours available (green, red, yellow, blue and orange) with a maximum of 3 active simultaneously

Automation system under external UPS

The main electrical cabinet can be upgraded to connect the automation system with an external UPS. Predisposition includes an additional 24V transformer and a redundancy module. Single-phase utility connection under UPS line to be provided by others

Volt Free Contact

Multiple VFC can be equipped and programmed for simple signal exchange purposes

DOCUMENTATION

The 200EVO is provided with the following standard documentation:

- ▶ EC Declaration
- ▶ User & Maintenance Manual
- ▶ P&ID
- ▶ Electrical Wiring Diagram
- ▶ Pneumatic Diagram
- ▶ Customized Layout
- ▶ Spare Parts List

QUALIFICATION & VALIDATION PACKAGES (OPTIONAL)

Basic Specifications Package - It includes the following standard documents related to the machine configuration selected:

- ▶ Mechanical Design Specifications
- ▶ Hardware Design Specifications
- ▶ Software Design Specifications
- ▶ Functional Design Specifications (flow-charts in full optional design with indications of actual configuration)

Design Qualification - It includes the following documents reviewed according to the URS:

- ▶ Mechanical Design Specifications
- ▶ Hardware Design Specifications
- ▶ Software Design Specifications
- ▶ Functional Design Specifications
- ▶ P&ID, Pneumatic & Electrical wiring diagrams

Requirements Traceability Matrix - RTM includes all references between IWT DQ documentation and URS in a matricial format to track the completeness of the relationship

FAT Factory Acceptance Test - It includes FAT protocol, execution and first calibrations certifications

Riboflavin test during FAT - It includes the Riboflavin Test protocol, its execution on machine chamber and relevant test report

On-site Qualification Package - It includes the following documents:

- ▶ SAT Site Acceptance Test
- ▶ IQ Installation qualification
- ▶ OQ Operational Qualification (Only GMP critical alarms simulation included)

Alarms qualification - It includes the OQA Operational qualifications for all alarms.

MATERIALS & COMPONENTS CERTIFICATIONS (OPTIONAL)

Basic certification Package - it includes the following documents:

- ▶ 3.1 Certificates or declaration of the supplier of all the materials in contact with process fluid
- ▶ Data sheets of the components listed in the P&ID
- ▶ FDA certificates of all the parts in contact with process fluid

Full certification Package -it includes the following documents:

- ▶ 3.1 Certificates or declaration of the supplier of all the materials in contact with process fluid
- ▶ Data sheets of the components listed in the P&ID
- ▶ FDA certificates of all the parts in contact with process fluid
- ▶ Data sheets of all the electrical components included in the wiring diagram
- ▶ Traceability of the 3.1 Certificates or declaration of the supplier and cross reference with drawings of all the parts

Welding book - it includes the following documents for all the parts in contact with process fluid:

- ▶ Copy of the internal WPS and WPQR
- ▶ Copy of the approval test certificate of each welder who worked on the manufacturing of the parts

Welding book and traceability - it includes the following documents for all the parts in contact with process fluid:

- ▶ Copy of the internal WPS and WPQR
- ▶ Copy of the approval test certificate of each welder who worked on the manufacturing of the parts
- ▶ Welding Log & Inspection book duly filled and signed by both certificated welder and qualified operator (ASNT SNT-TC-1A) on:
 - 20% of the orbital welds in contact with the process fluid
 - 100% of the manual welds in contact with the process fluid
- ▶ Traceability of the welds by mean of drawing maps (on manual and orbital welds) and indelible tagging (on orbital welds)

Endoscopic Visual Piping welding inspection - inspection performed by qualified operator (ASNT SNT-TC-1A) on 100% of the orbital welds in contact with the process fluid. Video or pictures included

Orbital welds samples - collection of the samples of orbital welds per every tool start-up and WPS change

RX analysis of weld samples - RX analysis of all pipe orbital weld samples.

EQUIPMENT CONFIGURATION

SIZE

200EVO-060

200EVO-100

200EVO-140

DOORS

ONE DOOR

TWO DOORS

HARDWARE

SIEMENS

ALLEN BRADLEY

HYDRAULIC CIRCUIT

SANITARY BALL VALVES

DIAPHRAGM VALVES

HEATING METHOD

STEAM

ELECTRICAL

POWER

400V-50Hz

380V-60Hz

480V-60Hz

Others

TECHNICAL COMPARTMENT (as seen from loading side)

LEFT-HAND

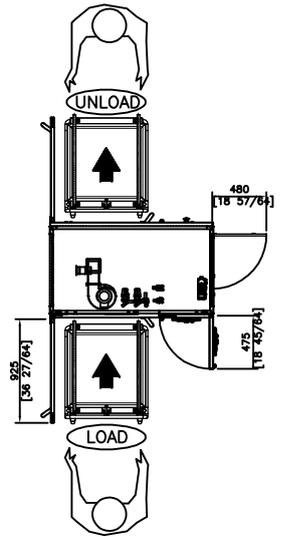
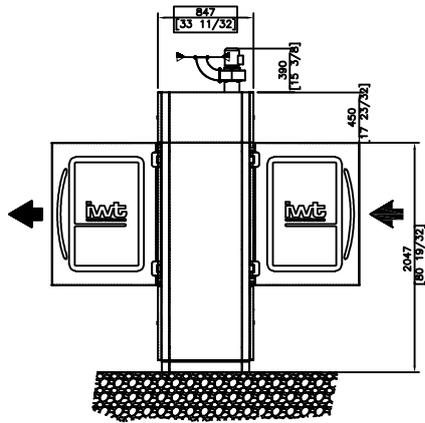
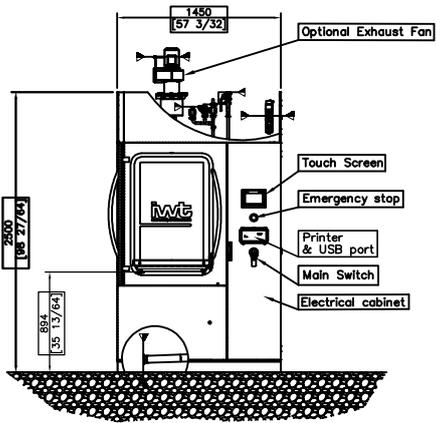
RIGHT-HAND

ADDITIONAL NOTES

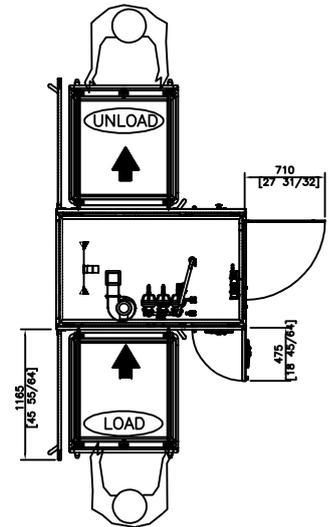
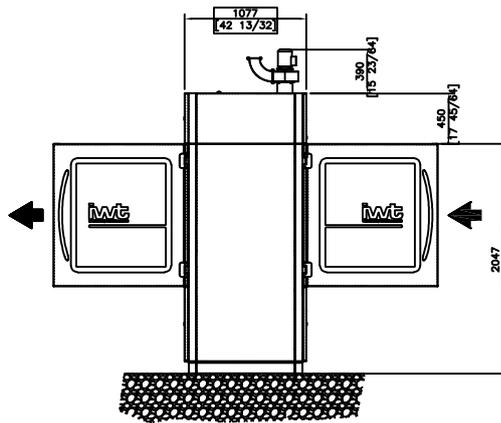
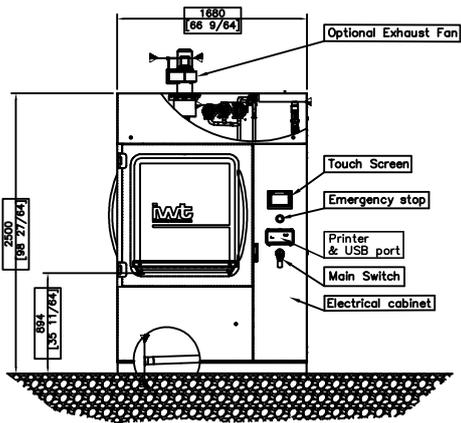
COMPLIANCE TO DIRECTIVES AND STANDARDS

cGMP	Current Good Manufacturing Practices
GAMP5	Good Automation Manufacturing Practices
ISPE Baseline Guides	International Society for Pharmaceutical Engineering
ASME-BPE	American Society of Mechanical Engineers - Bioprocessing Equipment
ASNT SNT-TC-1A	Personnel Qualification and Certification in Non-destructive Testing
CFR Title 21, Part 210	Current Good Manufacturing Practices in manufacturing, processing, packing, or holding of drugs
CFR Title 21, Part 211	Current Good Manufacturing Practices for finished Pharmaceuticals
CFR Title 21, Part 820	Quality System Regulation
CFR Title 21, Part 11	Electronic Records; Electronic Signature
2006/42/EC	Machinery Directive
2014/35/UE	Low Voltage Directive
2014/30/UE	EMC Directive
UNI EN ISO 12100	Safety of machinery - General principles for design. Risk assessment and risk reduction
CEI EN 60204-1	Safety of machinery - Electrical equipment of machines. General requirements
UNI EN ISO 13849-1	Safety of machinery - Safety-related parts of control systems - Part 1: General principles for design
UNI EN ISO 13732-1	Ergonomics of the thermal environment - Methods for the assessment of human responses to contact with surfaces - Part 1: Hot surfaces

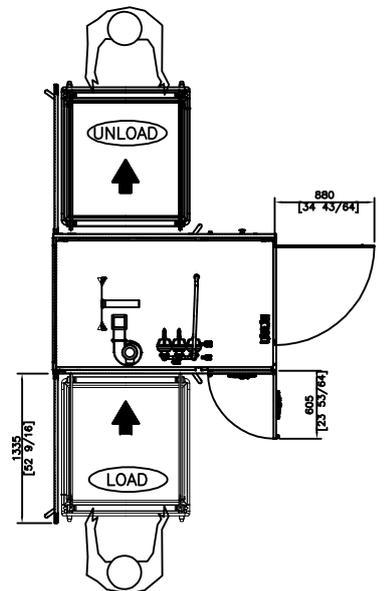
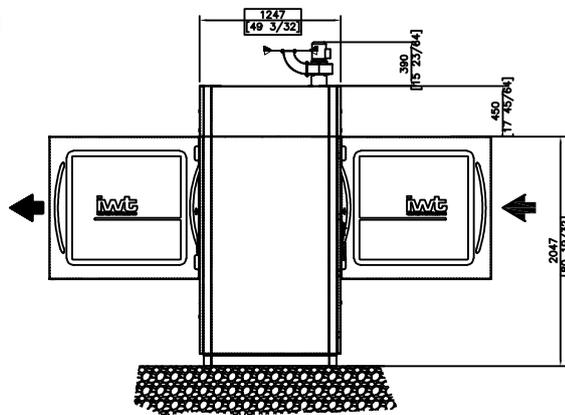
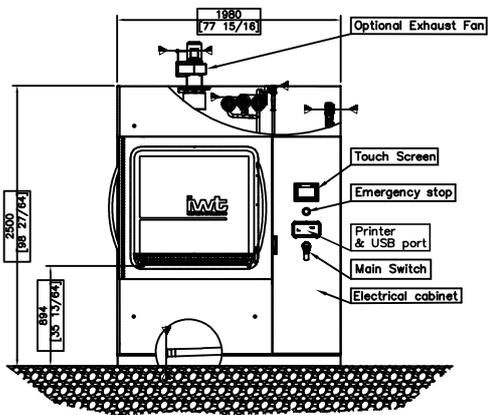
W200E-060



W200E-100



W200E-140



SERVICE REQUIREMENTS

SERVICE	CONNECTION	SERVICE REQUIREMENTS		
			METRIC UNIT	US IMPERIAL UNIT
Electrical supply	Electrical cabinet 200EVO-060	Voltage and frequency: Type: Power required: Circuit Breaker: Line fuse:	400V 50Hz 3phases+neutral+earth 7 kW 32 A 40 A	480V 60Hz 3phases+earth 7 kW 25 A 30 A
	Electrical cabinet 200EVO-100	Voltage and frequency: Type: Power required: Circuit Breaker: Line fuse:	400V 50Hz 3phases+neutral+earth 8.5 kW 40 A 50 A	480V 60Hz 3phases+earth 8.4 kW 35 A 45 A
	Electrical cabinet 200EVO-140	Voltage and frequency: Type: Power required: Circuit Breaker: Line fuse:	400V 50Hz 3phases+neutral+earth 10.5 kW 50 A 63 A	480V 60Hz 3phases+earth 10.5 kW 40 A 45 A
Compressed air	¼" GAS (F) [¼" NPT (F)]	Dynamic pressure: Quality: Min flow rate:	6 bar filtered, dry and oil free 50 NI/min @ 6bar	87 psi filtered, dry and oil free 1.8 SCFM @ 87 psi
Water Supply	200EVO-060 ¾" Tri-Clamp ASME BPE 200EVO-100 200EVO-140 1" Tri-Clamp ASME BPE CLAMP BS4825	Dynamic pressure: Static pressure: Supply temperature: Supply flow rate: Max hardness	2-4 bar max 8 bar 15°C<T<85°C 3600 l/h (1 l/s) 100ppm of CaCO3	29-58 psi max 116 psi 60°F<T<185°F 950 gal/h (0.26 gal/s) 100ppm of CaCO3
Water Supply	200EVO-060 ¾" Tri-Clamp ASME BPE CLAMP BS4825 200EVO-100 200EVO-140 1" Tri-Clamp ASME BPE CLAMP BS4825	Dynamic pressure: Static pressure: Supply temperature: Supply flow rate: Max hardness	2-4 bar max 8 bar 15°C<T<85°C 3600 l/h (1 l/s) 100ppm of CaCO3	29-58 psi max 116 psi 60°F<T<185°F 950 gal/h (0.26 gal/s) 100ppm of CaCO3
Steam	¾" G (F) [¾" NPT (F)] DN20	Dynamic pressure: Static pressure: Quality: Min flow rate:	3-5 bar max 6 bar filtered, dry and saturated 110 kg/h	44-72 psi max 87 psi filtered, dry and saturated 242 lbs/h
Condense return	½" G (F) [½" NPT (F)] DN15	Min flow rate: Back pressure:	110 kg/h 1 bar	242 lbs/h 14 psi
Exhaust	Flange 128x128mm [5x5"]	Min flow: Static pressure: Max ductwork resistance:	300m³/h 250 Pa 250 Pa	177 CFM 250 Pa 250Pa
Floor Drain	2" ½ Tri-Clamp ASME BPE Pipe = Ø63.5mm [2"] Ferule = Ø77.4mm [3.05"] CLAMP BS4825	Min flow rate	2 l/s	0.5 gal/s
Data management	RJ45 Ethernet socket			

WEIGHT	200EVO-060	200EVO-100	200EVO-140
Empty	1010 kg – 2222 lbs	1140 kg – 2508 lbs	1260 kg – 2772 lbs
Operating	1285 kg – 2827 lbs	1530 kg – 3366 lbs	1770 kg – 3894 lbs
NOISE LEVEL			
At 1 meter – 3ft	< 70 dbA	< 70 dbA	< 70 dbA
APPROXIMATE HEAT LOSS			
	1400 kcal/h – 5550 BTU/h	1600 kcal/h – 6350 BTU/h	1800 kcal/h – 7140 BTU/h

Machine configuration:-two doors, Siemens setup, steam heated, diaphragm valves, technical compartment on right-hand side. Exhaust fan and water 2 inlet options.

Utility requirements may change depending on final product configuration. Please consult with your local representatives for further details

IWT is constantly reviewing its products for improvements. Consequently, the actual product may differ from the one described here.
200EVO_ProductProfile_rev.00_Mar2021