LABORATORY DIVISION

cGLP Laboratory equipment

Glassware Washer and Dryer AQUA

Automatic cleaning solutions in QC labs

APPLICATION

Washers **AQUA** are particularly designed for process cleaning-disinfection and complete drying of materials used in the QC laboratories such as glassware, metal parts, plastic and rubber components.

The model type **AQUA** represent a reliable automatic washer disinfectors that perfectly combine wash time and water temperature with effective mechanical action and specific detergents for outstanding cleaning results.

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CONSTRUCTION DESIGN

- Square or rectangular cross section chambers of single-wall made by 316L stainless steel
- All internal corners are rounded to guarantee a perfect cleaning
- Single or double door for a pass through configuration
- Manual hinged or automatic vertical/side sliding type doors
- Automatic loading/unloading external conveyors
- Door frame made of 316L stainless steel with tempered glass window for internal visual inspection
- Chamber-door sealing by silicone gasket (double lips)

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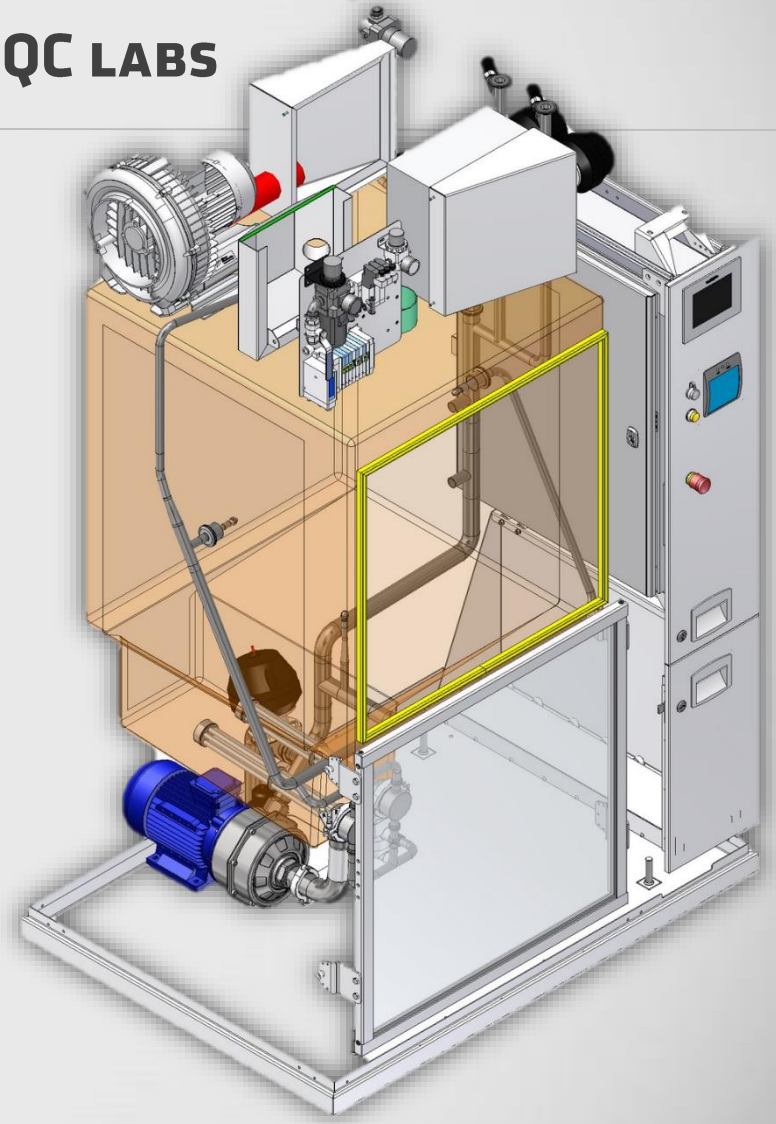
- Areas separation by means of bio-seal frame
- Piping completely made in flexible silicone/EPDM tubing or 316L SS
- Air ducts completely made in 316L SS with sanitary fittings
- 3 degree piping slopping to the floor drain
- Elastomeric rubber-based EPDM (Ethylene-Propylene Diene Monomer), to reduce heat loss and noise, properly insulates chamber, piping, components and instruments
- Product contact surfaces mechanically polished to a degree of roughness below 1 micron
- Wide range of accessories dedicated to customizable injection carts/baskets



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Components

- Components and instruments made of 316L SS and FDA approved polymers/elastomer

Working Programs

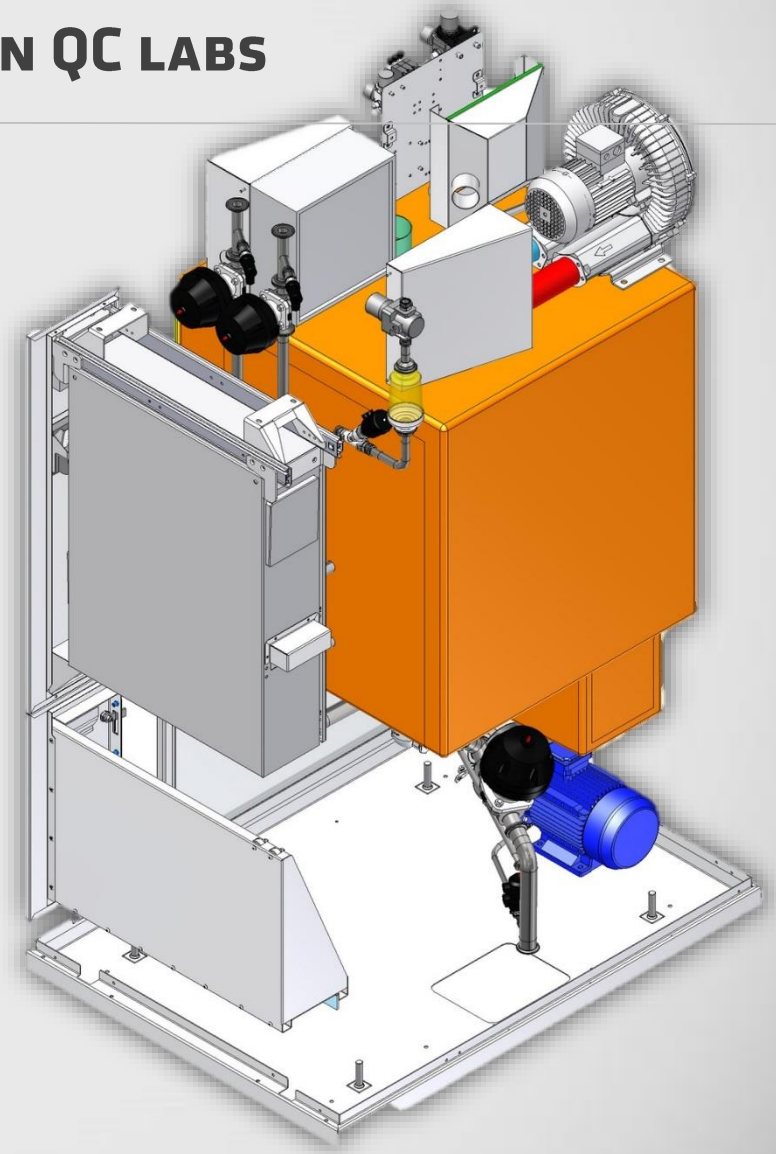
- PLC pre-installed programs + 100 additional custom programs
- Adjustable pre-wash, wash and final rinse water temperature up to 95 °C

Water connections

- Cold and warm RO/softened water + demineralized/purified water

Water recirculation pump

- High-power water recirculation pump made of 316L SS



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Spray System

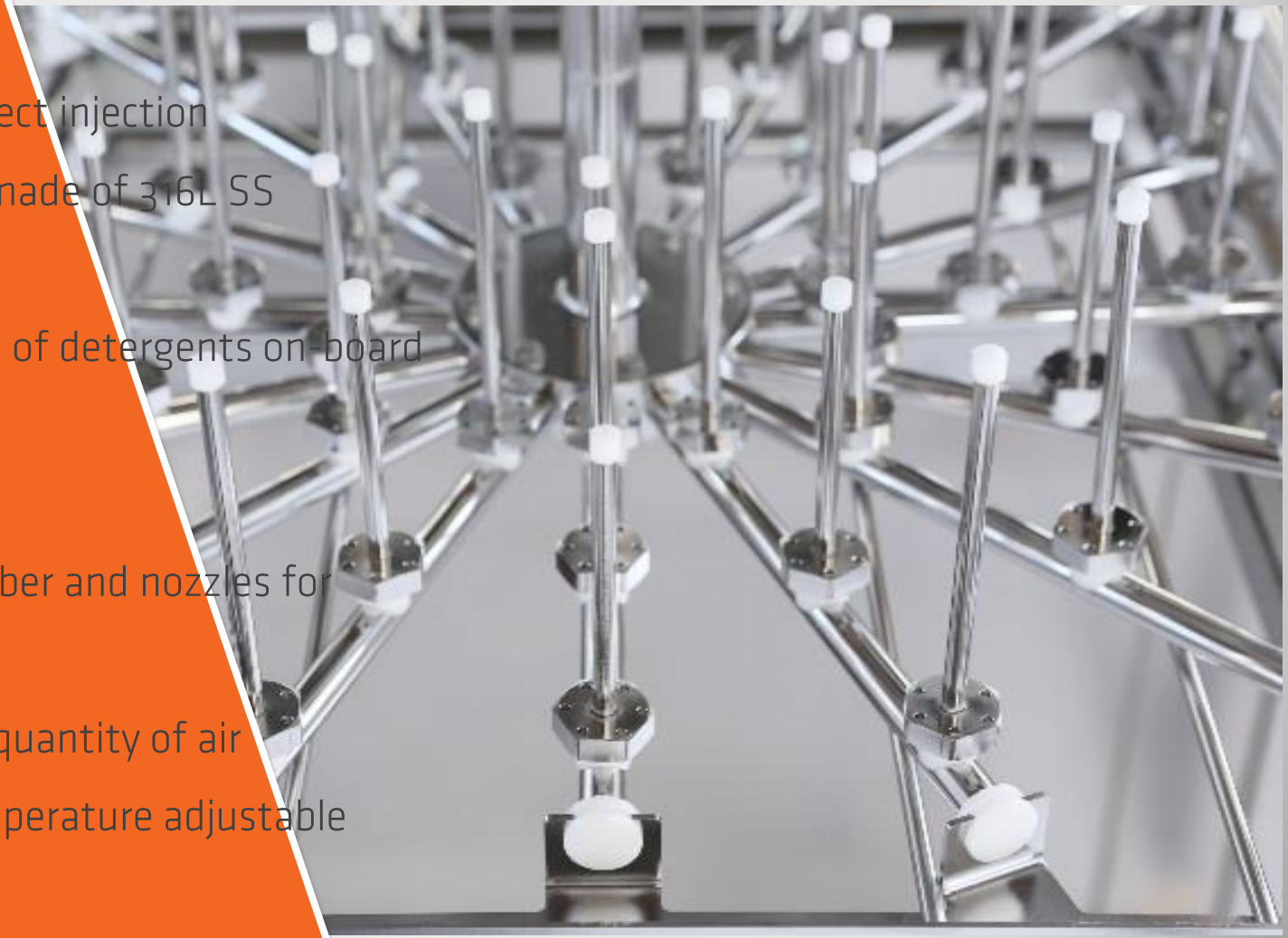
- Fully customizable nozzles configurations for direct injection
- Rotary spray arms in accordance to wash levels made of 316L SS

Dosing pump

- Up to 4 automatic high level accuracy dispensing of detergents on-board

Drying System

- HEPA-filtered forced air-drying system
- Electrical fans blow heated air through the chamber and nozzles for direct injection
- AC driver installed on the blower modulates the quantity of air
- Heating elements and blower provide drying temperature adjustable between 80°C and 130°C



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Controls

- PLC Siemens S7-1200
- HMI brand ASEM, Siemens, Allen-Bradley
- Paper-less recorder (optional) for real-time recording (FDA 21 CFR part 11)

Communication and connectivity

- USB, Ethernet, SCADA

Documentation

- Extensive project documentation: GANTT, GAD, P&ID, Utility interface agreement (UIA), Electrical diagram (ED), Pneumatic diagram (PD), Bill of materials (BOM), installation, user and maintenance manual, FAT, SAT, IQ/OQ

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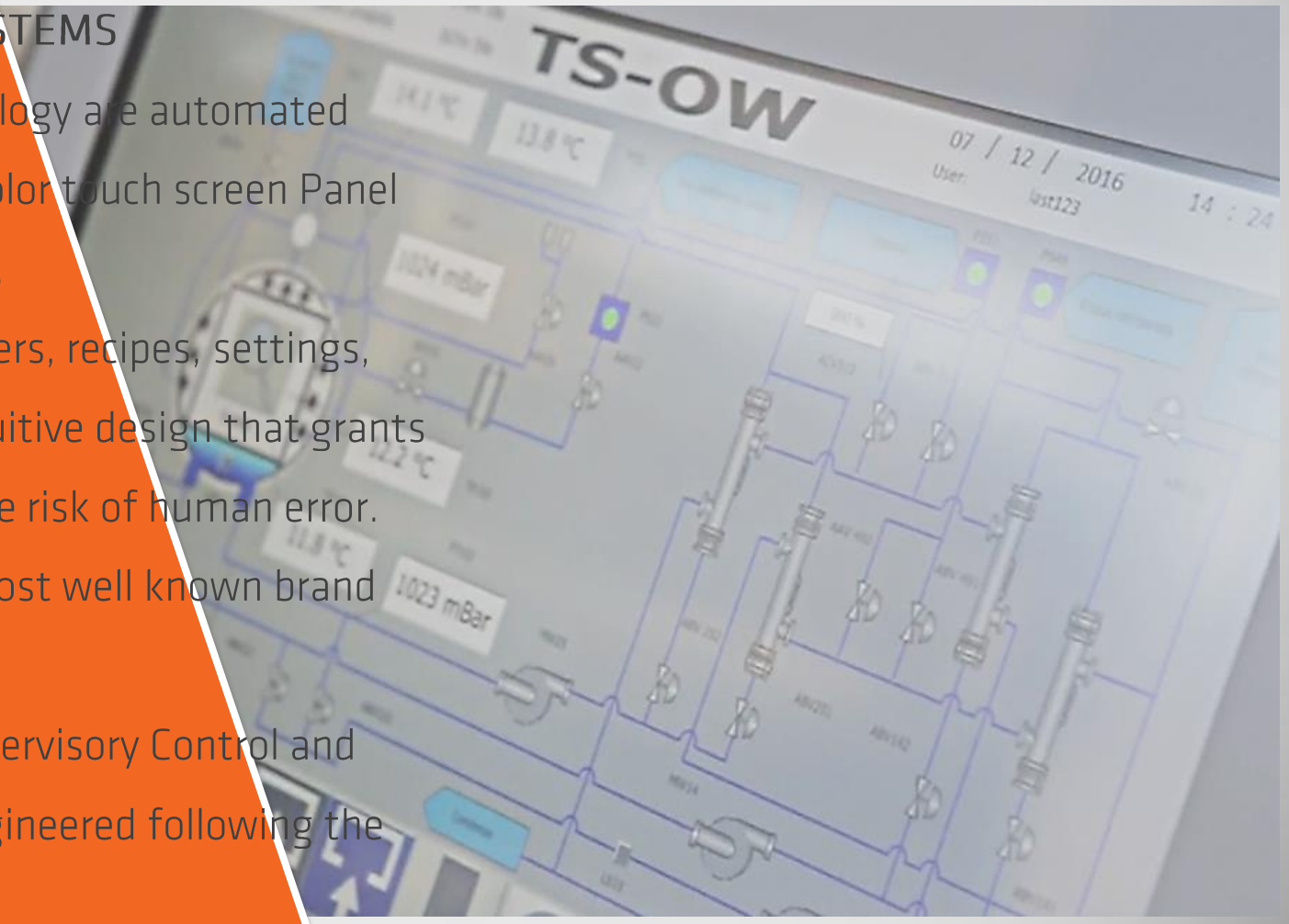
SUPERVISORY, TRACEABILITY AND CONTROL SYSTEMS

All laboratory equipment engineered by LAST Technology are automated through a Programmable Logic Controllers (PLC). A color touch screen Panel PC (IPC) performs as Human Machine Interface (HMI).

A P&ID control interface manage all process parameters, recipes, settings, sequence of operations and their storage with an intuitive design that grants an easily accessing to the information, minimizing the risk of human error.

Hardware and software are provided only from the most well known brand such as Siemens, Allen Bradley, ASEM, Rockwell.

In compliance to the 21 CFR Part 11 LAST install a Supervisory Control and Data Acquisition (SCADA) system, developed and engineered following the Good Automated Manufacturing Practices (GAMP 5).



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PRODUCT HANDLING CONFIGURATION

- Ergonomic design for manual or full-automatic procedures
- Racks/baskets completely made by AISI 316L stainless steel with PEEK/PTFE Mainframe made by round and rectangular tubing
- Multi level system with a dedicated spray arm for each level
- Racks/baskets with fine finish to a degree of roughness 0.5 micron (20 micro inches), electro-polished and submitted to a final passivation treatment
- Cart connection with self-ducting and self-disconnection system
- Use of 316L stainless steel combined with FDA approved elastomers
- Tailor-made solutions available for any type of load

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ACCESSORIES

In combination with the washing machine AQUA are available a wide and complete range of racks, inserts, trays, accessories and washing carts including: nozzles for glassware or vials and injection washing for pipettes.

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NORMS & STANDARDS

Quality Management (ISO 9001:2015)
Current Good Laboratory Practice (cGLP)
US Food and drug Administration (FDA)
Code of Federal Regulation Title 21 (FDA 21 CFR part 211 and 212)
Code of Federal Regulation Title 21 (FDA 21 CFR part 11)
Washer-disinfectors-general requirements, terms and definition (ISO 15883-1:2006 and BS EN ISO 15883-2:2009)
Safety Requirements for Electrical Equipment (IEC 61010-1:2010)
Safety Requirements for Electrical Equipment (IEC 61010-2-040:2015)
EMC Directive (IEC 61326-1:2013)
Governing directives for affixing the CE mark – machinery directive (2006/42/EC)
Underwriters Laboratories (UL)
Canadian Standards Association (CSA)
Occupational Health and Safety management systems (ISO 45001:2018)

Ente Certificazione Macchine srl

CERTIFICATO n. PGH-2018-LTUT91

CERTIFICATE No. PGH-2018-LTUT91 rev.1

Ente Certificazione Macchine srl Certifica che l'Organizzazione / Certify that the Organization

Last Technology SRL

Via Sagree, 9 33080 Prata Di Pordenone (PN) I

Per il seguente campo di attività / For the following of activities

Progettazione, costruzione, commercializzazione, i
servizi di supporto alla qualifica per macchine c
sterilizzazione, decontaminazione, disinfezione ed

Design, construction, commercialization, instal
qualification services for washing, sterilization, dec
disinfection, and drying machineries.

Ha implementato e mantiene un / Has implemented and maintains a

Sistema di Gestione per la Qu / Quality Management System

che soddisfa i requisiti delle seguenti norme / which fulfils the requirements of the following standard

UNI CEI EN ISO 9001:2015

Data di prima emissione / Date of first issue 04/05/2018

Data di emissione / Date of issue

Data di revisione / Date of revision 17/04/2019

Data di scadenza / Expiry date

Rev.5 29/10/2018

Cer_01 Certificato SGQ

Firma auto / Authorized s

(Antonio Bedonni – Legal

Ente Certificazione Macchine srl

Via Ca' Bella 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO)

☎ +39 0516705141 🖷 +39 0516705156 ✉ ecm@entecerma.it www.entecer

kiwa

CERTIFICATO

Reg. Number 18641 – I Valid From: 2020-02-28

First issue date 2016-06-08 Last change date 2020-02-28

Valid Until 2022-06-07 IAF Sector 18

Occupational Health and Safety Management System Certificate
ISO 45001:2018

We certify that the Occupational Health and Safety Management System of the Organization:

LAST TECHNOLOGY S.r.l.

Is in compliance with the standard UNI ISO 45001:2018 for the following products/services:

Design, construction and installation of washing, sterilization, decontamination, disinfection and drying machines.

Chief Operating Officer
Giampiero Belcredi

The maintaining of the certification is subject to annual surveillance and dependent on the observance of Kiwa Cermet Italia contractual requirements.
This certificate is composed of 1 page.
The date of issuance of this certificate is the date of first issue by another accredited body

LAST TECHNOLOGY S.r.l.
Registered Headquarters
- Via Sagree,9 33080 Prata di Pordenone (PN) Italia

Certified sites
- Via Sagree,9 33080 Prata di Pordenone (PN) Italia

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
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E-mail info@kiwacermet.it
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CERMET

IAF

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SCR N° 013F

Glassware Washer and Dryer AQUA

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THE RANGE

Type	Chamber dimensions (mm / inches)			Capacity (litres / cu.ft.)	Overall dimensions (mm / inches)		
	Width	Height	Lenght		Width	Height	Lenght
AQUA 250	585 / 23	700 / 27.5	617 / 24.5	250 / 8.5	1050 / 41	2090 / 82	765 / 30
AQUA 350	735 / 29	700 / 27.5	817 / 32	400 / 14	1200 / 47	2090 / 82	965 / 38
AQUA 500	685 / 27	700 / 27.5	997 / 39	500 / 17.5	1150 / 45	2090 / 82	1145 / 45
AQUA 1000	1000 / 39.5	1000 / 39.5	1000 /39.5	1000 / 35.5	2400 / 94.5	2800 / 110	1215 / 48
AQUA 1250	1000 / 39.5	1250 / 49	1000 / 39.5	1250 / 44.5	2400 / 94.5	2800 / 110	1215 / 48
AQUA 1500	1250 / 49	1000 / 39.5	1250 / 49	1500 / 53	2600 / 102	2800 / 110	1585 / 62.5
AQUA 4000	1400 / 55	1900 / 75	1500 / 59	4000 / 142	2600 / 102	2800 / 110	1670 / 66

Upon request LAST Technology is able to provide customized chamber sizes up to 5 m3

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PROCESS SEQUENCES DESCRIPTION

The process consists of combined phases to provide maximum process flexibility. The choice of times and temperatures makes it possible to obtain the most appropriate cycle for the characteristics of the material to be processed.

The machine process is developed in accordance to the current codes, standards and type of product to be processed.

From dirty to product ready to be sterilized; passing through a pre-washing, washing with chemicals, rinsing and final hot air drying. Keeping under control the water the conductivity, T.O.C. level and the PH.

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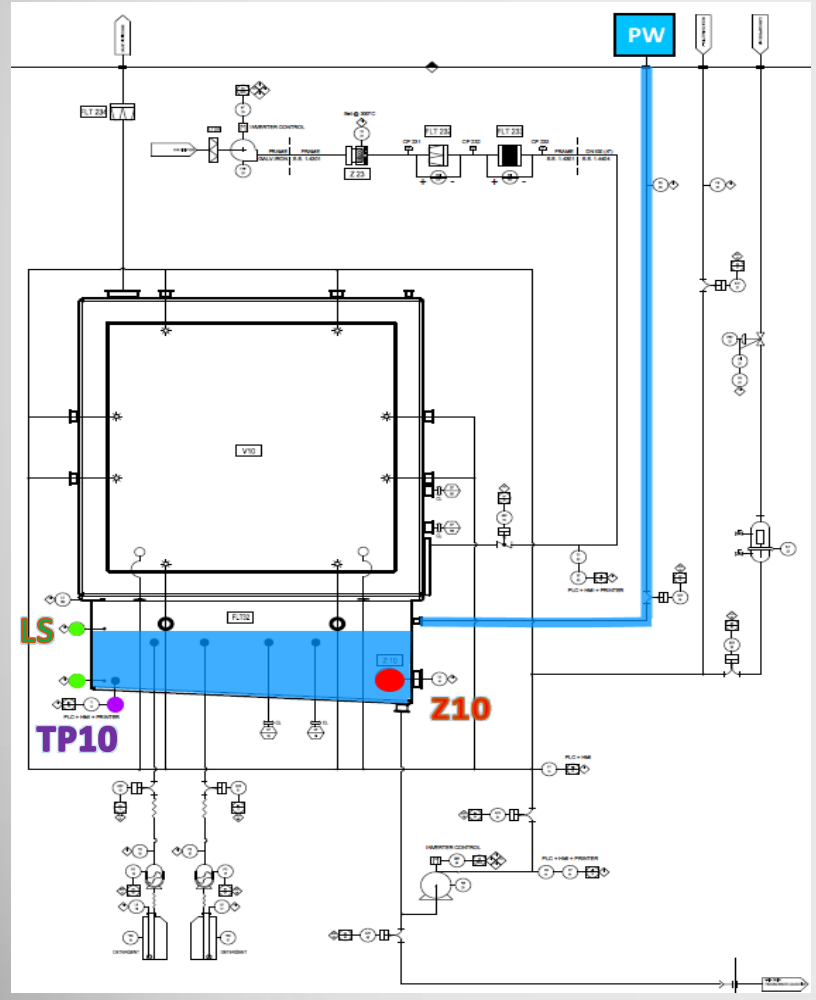

AUTOMATED WASHING PROCESS DESCRIPTION

WORKING PHASE

A) one phase of product pre-washing

B) one phase of product washing

- Water loading - The RO/Softened water is loaded in the tank below the chamber, until the level sensor LS101 give the signal.
- Water heating - Only if the pre-washing has to be done with hot water, the water is heated in the tank by the heating elements Z10, until the temperature set point is reached. The temperature is controlled by the probe TP10.

Glassware Washer and Dryer AQUA

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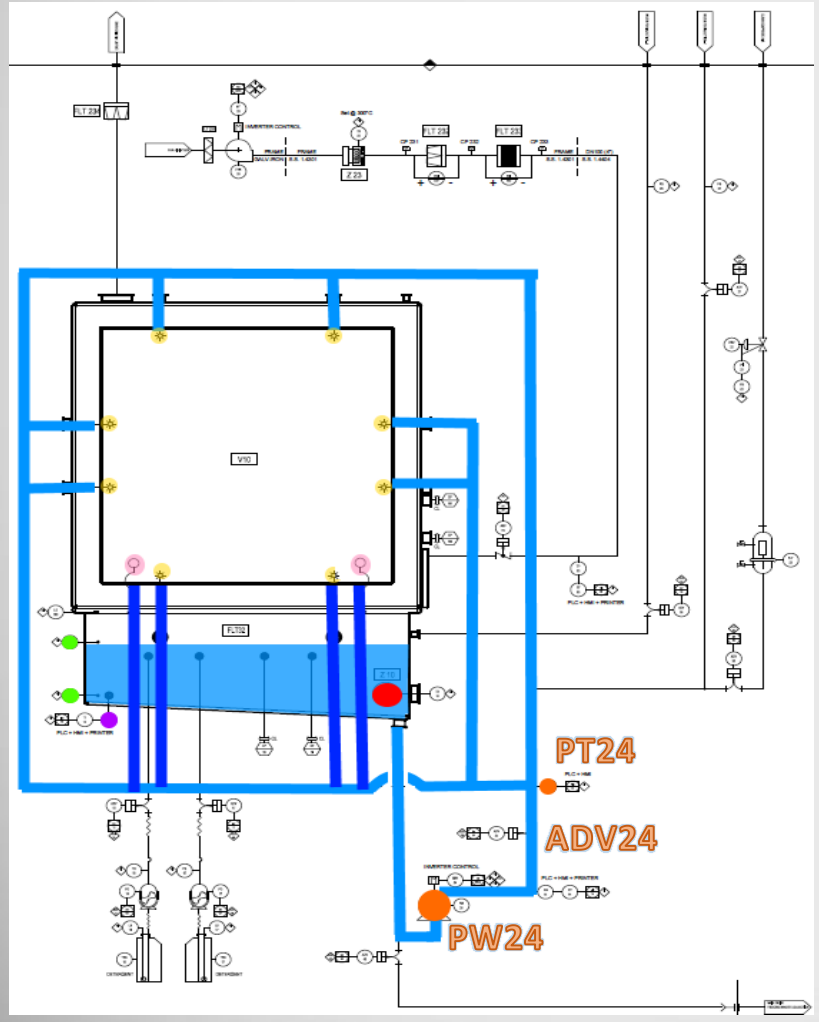

A) One phase of product pre-washing

- Water recirculation pump PW24 start
- Valve ADV24 is opened
- Pressure switch PT24 acquire the signal that the pump is running
- Water goes into the chamber by the spray-ball and into the trolley through fast connections

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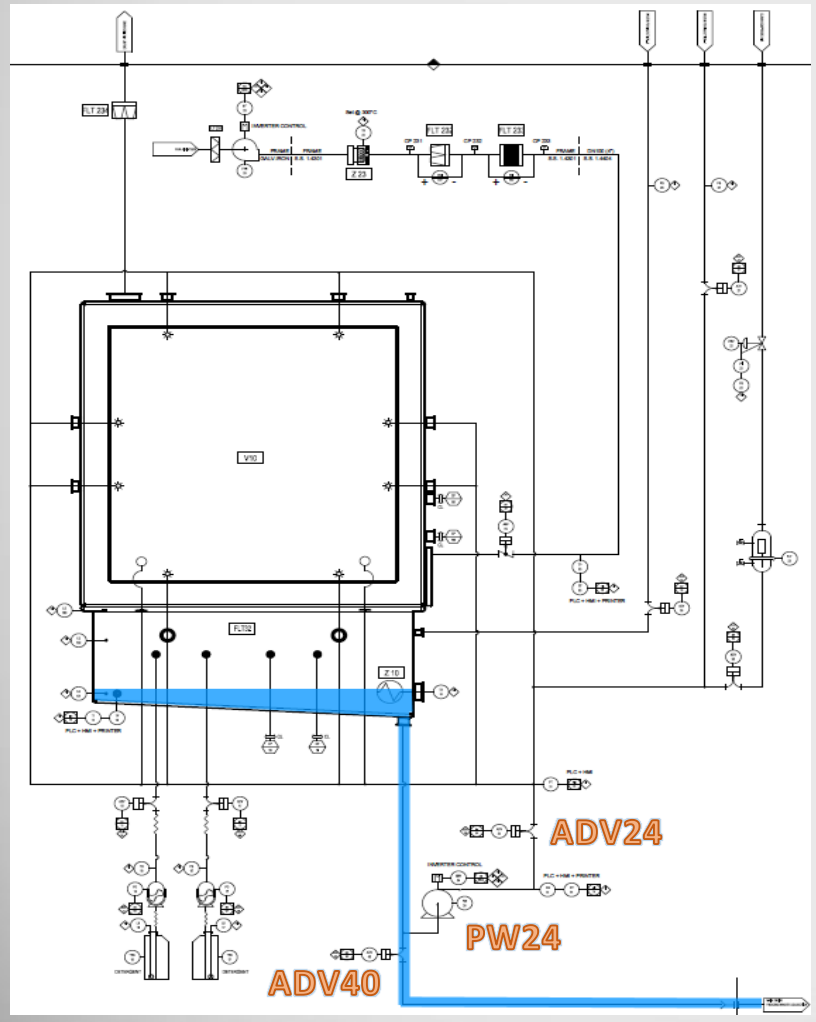

- Water recirculation pump PW24 stops
- Valve ADV24 and ADV40 are opened
- Water is drained from chamber
- After the drain phase the rinsing phase could be repeated many times as for the recipe settings.

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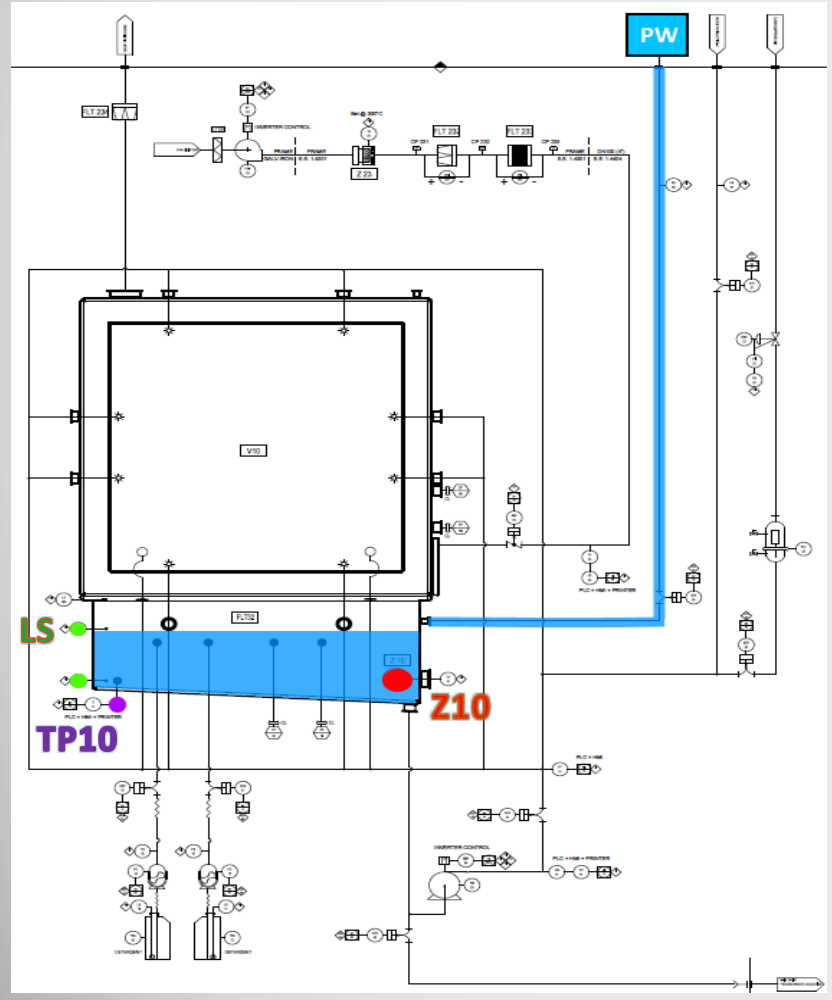

- Water loading - The RO/Softened water is loaded in the tank below the chamber, until the level sensor LS101 give the signal.
- Water heating - Only if the pre-washing has to be done with hot water, the water is heated in the tank by the heating elements Z10, until the temperature set point is reached. The temperature is controlled by the probe TP10.

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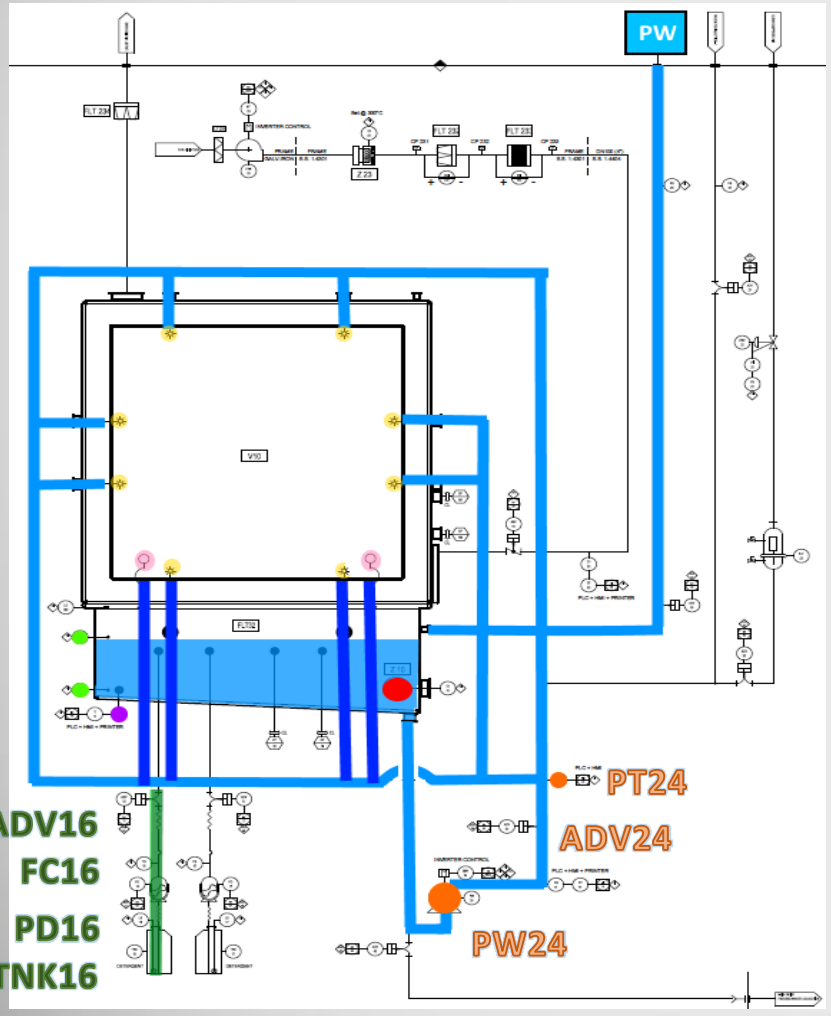

B) One phase of product washing

- Water recirculation pump PW24 start
- Valve ADV24 is opened
- Pressure switch PT24 acquire the signal that the pump is running
- Water goes into the chamber by the spray-ball and into the trolley through fast connections
- Once-though water spraying to the load
- Detergent dosing – The detergent is taken from tank TNK16 (or TNK17), with the pump PD16 (or PD17). The valves ADV16 (or ADV17) is open and the flow is controlled by FC16 (or FC17). Detergent can be loaded in the chamber's tank or can sent be directly in the pipes.

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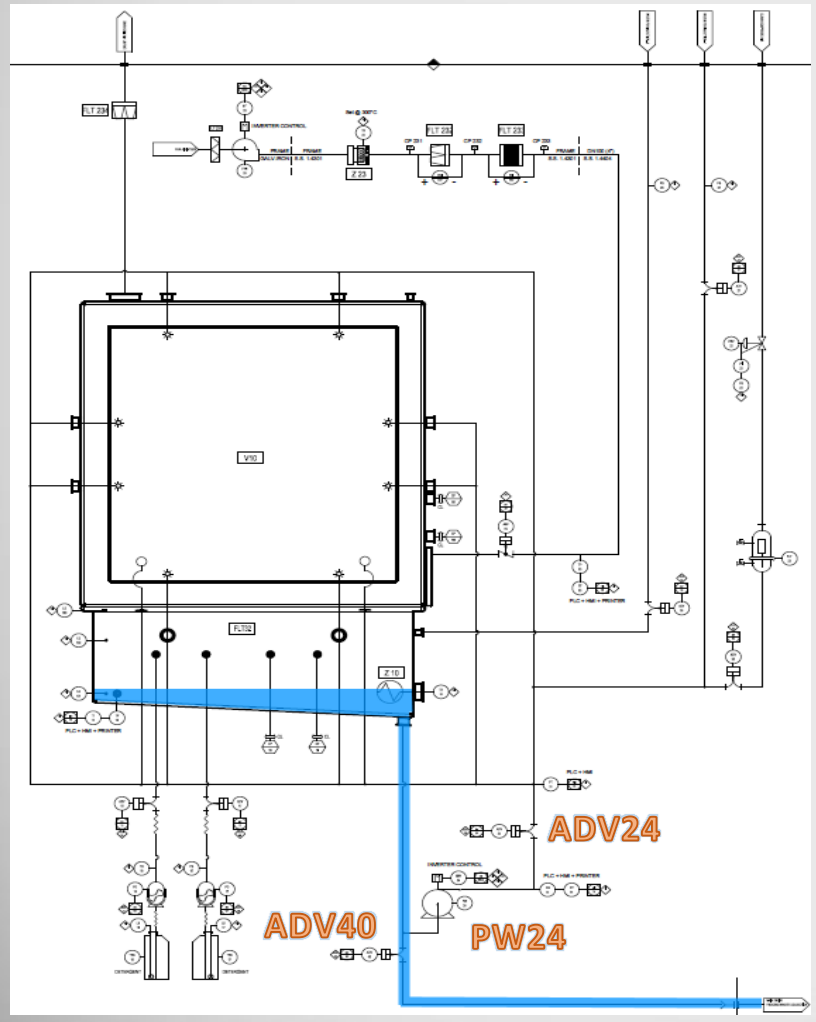

- Water recirculation pump PW24 stops
- Valve ADV24 and ADV40 are opened
- Water is drained from chamber
- After the drain phase the rinsing phase could be repeated many times as for the recipe settings.

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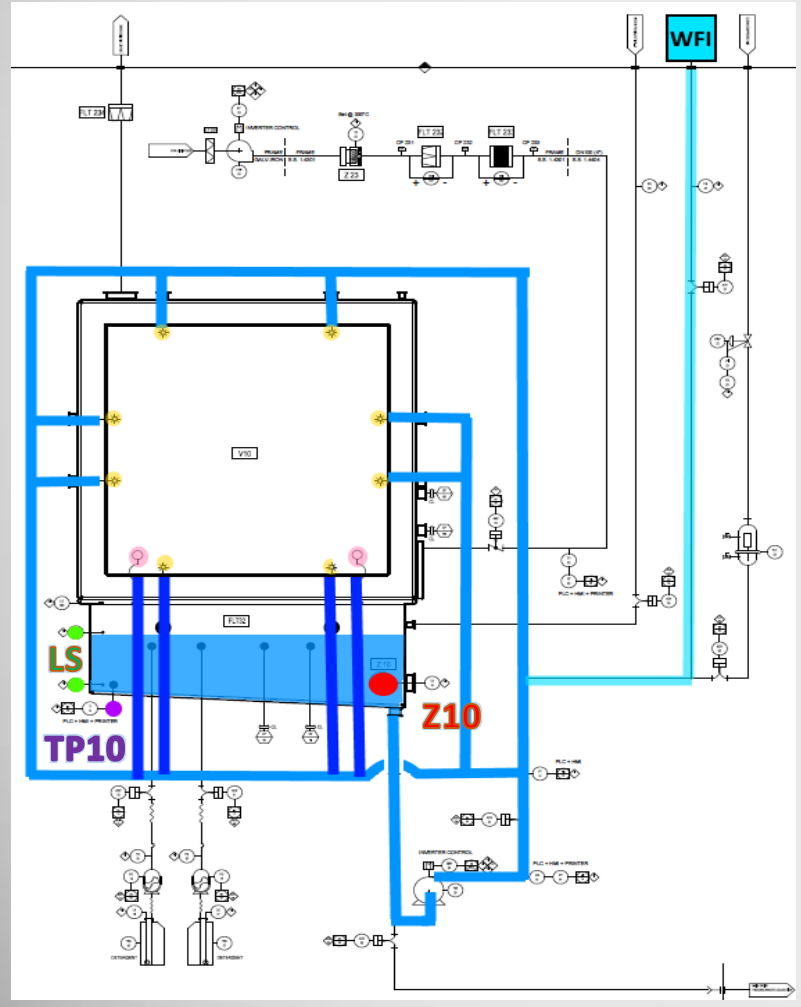

A) product rinsing with RO/PW

- The Demi/Purified water is loaded directly in the chamber until the level sensor LS101 in the chamber tank give the set point signal.
- Only if the rinsing has to be done with hot water, the water is heated in the tank by the heating elements Z10, until the temperature set point is reached. The temperature is controlled by the probe TP10.

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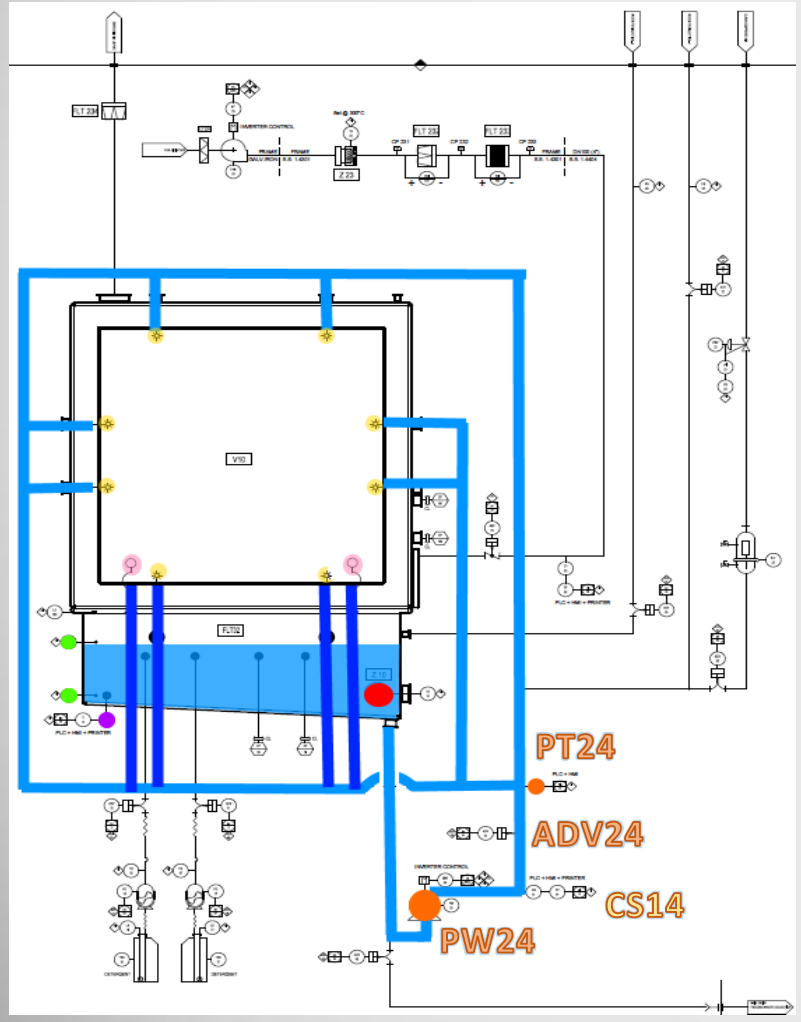

- Water recirculation pump PW24 start
- Valve ADV24 is opened
- Pressure switch PT24 acquire the signal that the pump is running
- Water goes into the chamber by the spray-ball and into the trolley through fast connections
- Once-though water spraying to the load
- Conductivity check - During the rinsing phase with Demi/PW the conductivity is checked by the probe CS14. The phase go ahead until the conductivity's value reach the exact set point. If the conductivity doesn't reach it, the phase may be repeated.

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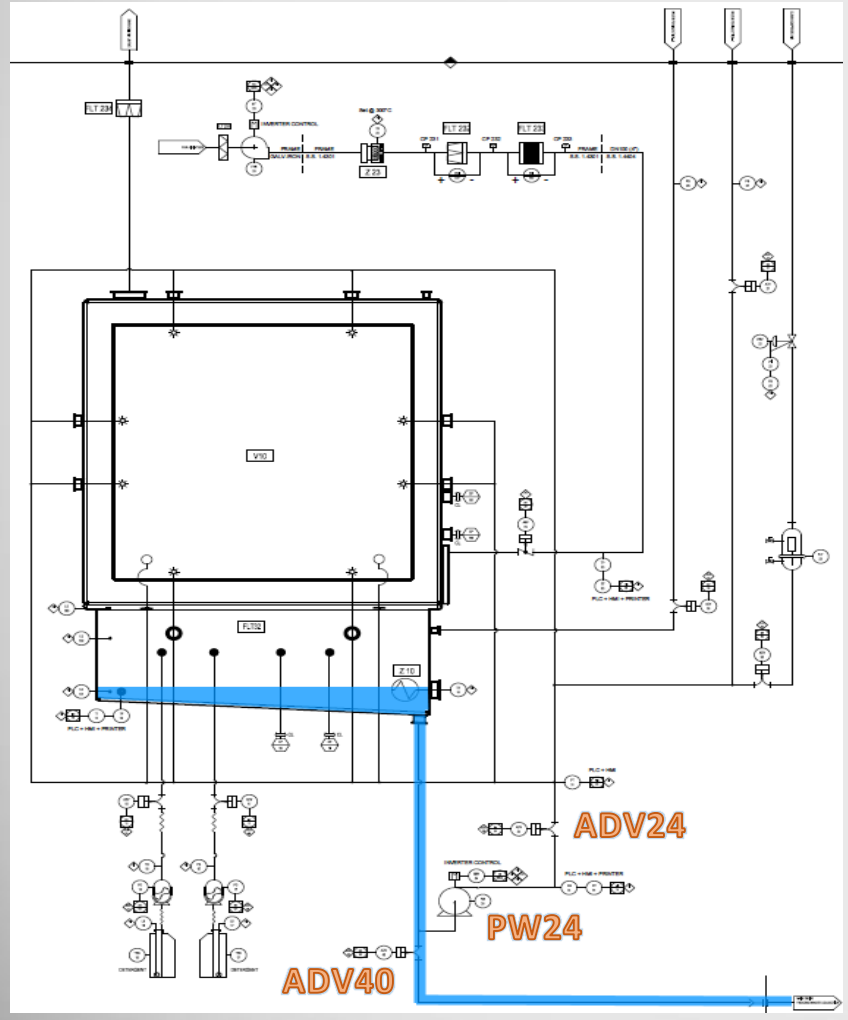

- Water recirculation pump PW24 stops
- Valve ADV24 and ADV40 are opened
- Water is drained from chamber
- After the drain phase the rinsing phase could be repeated many times as for the recipe settings.

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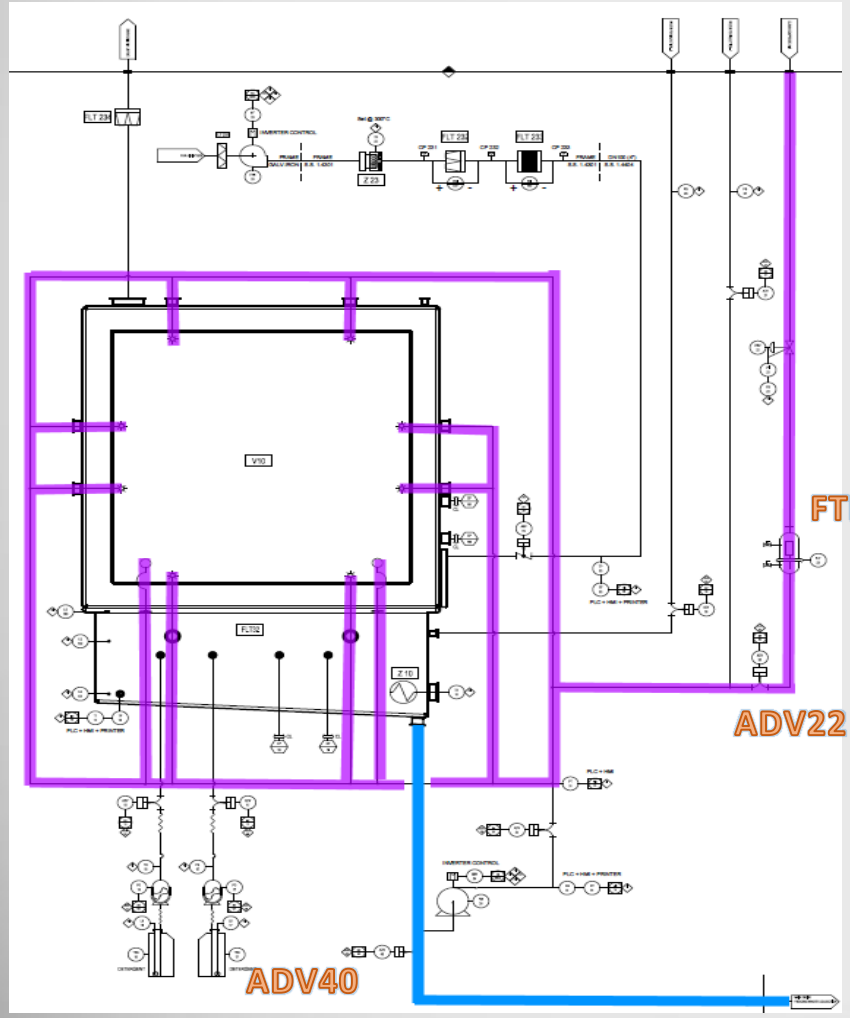

Product and machine drying

- Before the drying phase the machine piping and, the internal surfaces of product and the cart are dripped by the injection of cartridge filtered (FLT22) compressed air
- Valve ADV22 is opened and compressed air flow thru the pipes and cart
- ADV40 is opened and the dripped water is emptied from chamber to the drain.
- Exhaust of all the air

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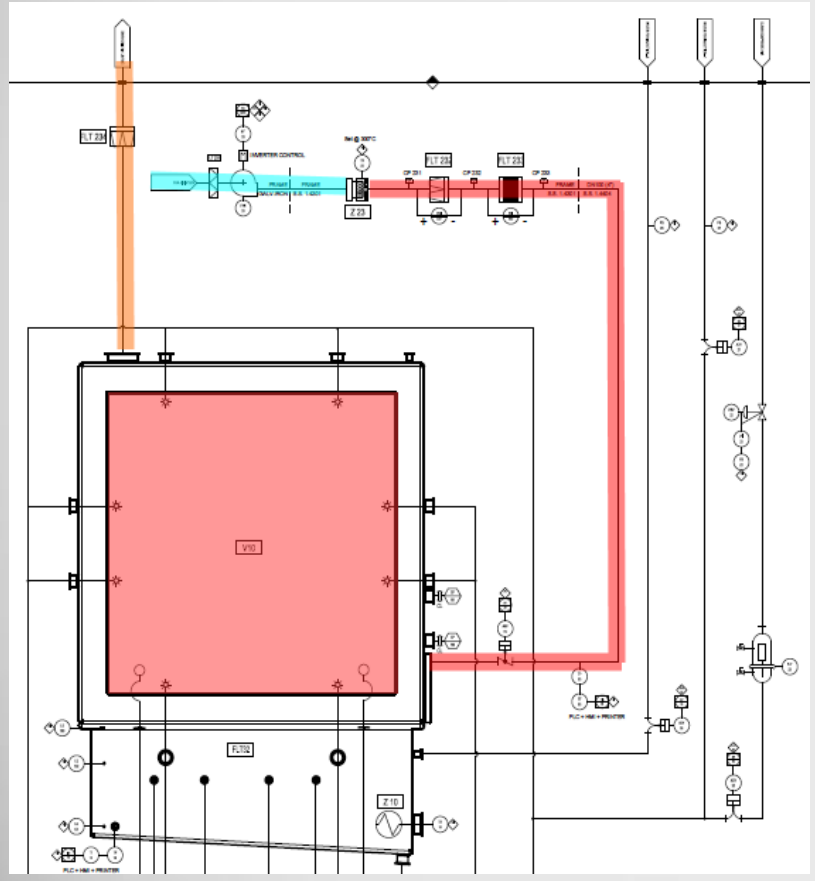
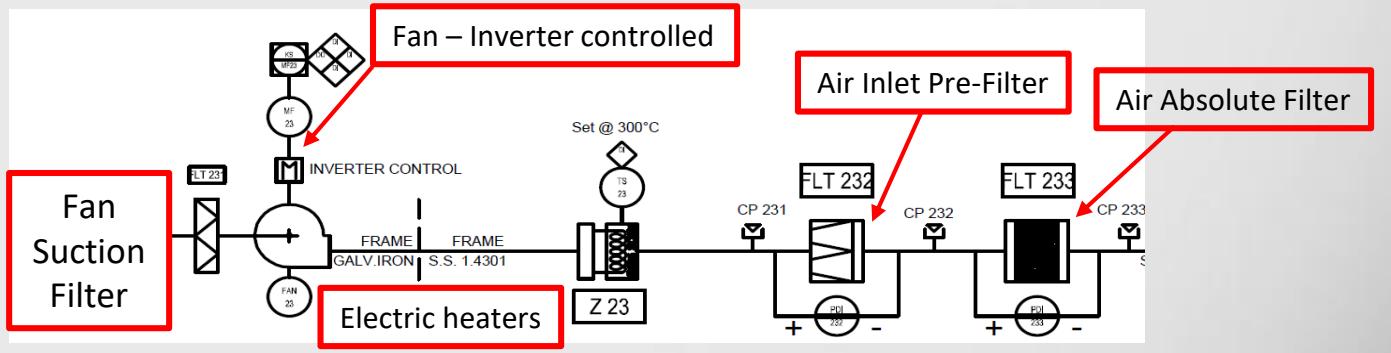


Product and machine cooling

- Blowing of HEPA filtered cold air for cooling the chamber and external surfaces of product
- The air inlet filters are provided with the connection for the differential pressure manometer, placed in the loading side, to perform the filter's integrity check.
- Air is heated by electric elements. Temperature is controlled by the probe TP23.
- Air enter in the chamber thru the valve ABV23 and is exhausted from the top of the chamber thru the filter FLT234.



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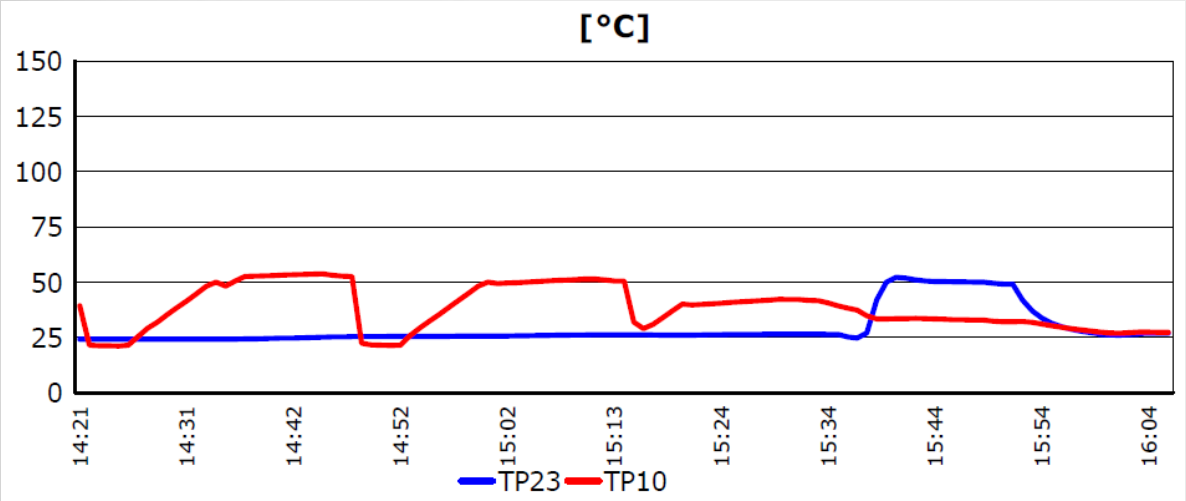

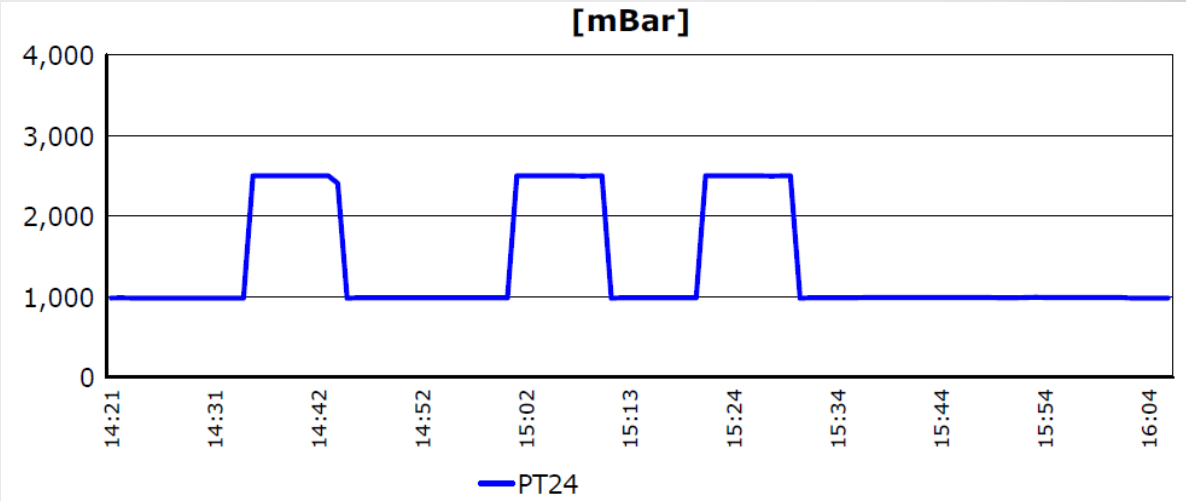

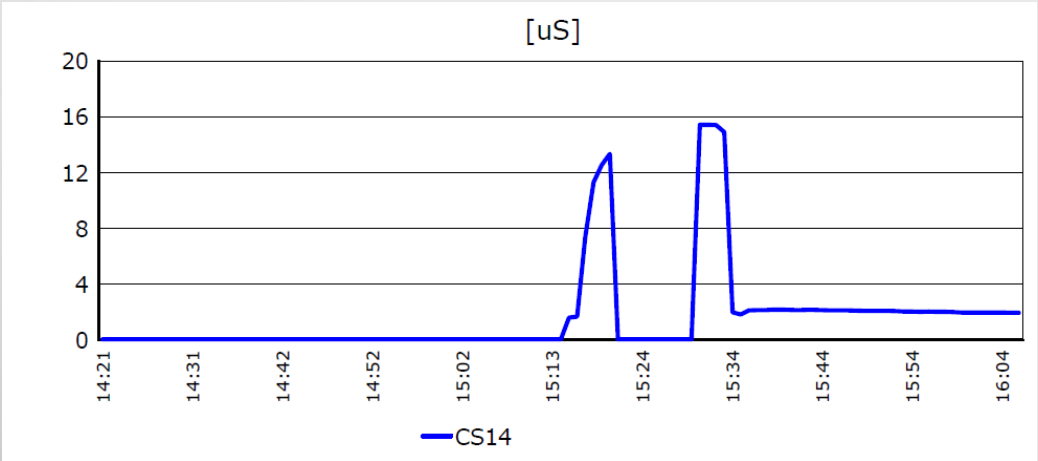

ADVANCED SOLUTIONS FOR INFECTION PREVENTION