NEW AUTESTER FDA/GMP

REGULATIONS:

EU GMP – ANNEX 1:	STERILE MANUFACTURING, ENVIRONMENTAL CONTROL AND RISK MANAGEMENT.
EU GMP – ANNEX 15:	QUALIFICATION & VALIDATION (IQ/OQ/PQ)
ISO 17665-1 / 17665-2:	STEAM STERILIZATION – PROCESS VALIDATION AND CONTROL
EN 285:	REQUIREMENTS FOR LARGE STEAM STERILIZERS
ISO 13485:	QUALITY MANAGEMENT SYSTEMS FOR MEDICAL DEVICES
21 CFR PART 11:	DATA INTEGRITY AND SECURITY (FOR EQUIPMENT WITH DIGITAL RECORDING)
GAMP 5:	SOFTWARE AND AUTOMATION LIFECYCLE MANAGEMENT

BLOCKCHAIN SECURITY

CLOUD CONNECTIVITY

CER.21 - APAR.11

DESIGNED ACCORDING TO THE MOST DEMANDING INTERNATIONAL STANDARDS

OUR AUTOCLAVES ARE DESIGNED TO MEET THE KEY REGULATORY REQUIREMENTS OF THE PHARMACEUTICAL INDUSTRY, ENSURING FULLY TRACEABLE, REPEATABLE, AND VALIDATABLE PROCESSES IN ACCORDANCE WITH INTERNATIONAL STANDARDS.

Each unit is delivered with complete technical documentation to facilitate audits and IQ/OQ/PQ validations if required, ensuring that the process is fully demonstrable.

SATURATED STEAM TECHNOLOGY FOR A FULLY VALIDATABLE STERILIZATION PROCESS

SELECTA autoclaves use pressurized saturated steam as the sterilizing agent, combining precise control of temperature, pressure, and exposure time to ensure the destruction of resistant microorganisms, with automatic monitoring of the F_0 value.

PRINCIPLES OF PROCESS OPERATION

- Internal or external steam generation
- PID control of temperature and pressure
- Independent probe for cycle verification
- Programmable cycles according to load type, including liquids
- Vacuum systems for optimal steam penetration
- Drying by vacuum, filtered air, and radiation
- Automatic parameter recording

ADVANTAGES FOR PHARMACEUTICAL APPLICATIONS:

- Full alignment with EU GMP, FDA, and quality audits
- Digital recording compliant with 21 CFR Part 11
- Hygienic design in AISI 316L stainless steel
- Process repeatability under audit conditions
- Full support for IQ/OQ/PQ validations
- Load (core) probe for real product temperature control

THE SAME MODELS ARE AVAILABLE WITHOUT GMP CONNECTION

Autoclaves for sterilization “Autester ST DRY GMP-S / USB-S”

PROCESS CONTROL BY PLC.
AUTOMATIC DRYING AND PURGING SYSTEM BY FRACTIONATED VACUUM.
FOR ADJUSTABLE TEMPERATURES FROM 105°C TO 134°C (0.21 TO 2 BAR). MAXIMUM PRESSURE: 2.5 BAR.
COMPLIANT WITH PRESSURE EQUIPMENT DIRECTIVE 2014/68/EU.
VERTICAL MODEL. CAPACITIES: 50, 80, AND 150 LITERS.
GMP-S MODELS WITH GMP CONNECTION AND USB MODELS WITHOUT GMP CONNECTION.

NEW

EU GMP Annex 11

FDA 21 CFR Part 11

Fo

Wi Fi

USB

CONFORMITY	
EN 61010-1	SAFETY REQUIREMENTS FOR LABORATORY EQUIPMENT.
EN 61010-2-040	SAFETY FOR STERILIZER EQUIPMENT FOR LABORATORY USE
EN 61326-1	ELECTROMAGNETIC COMPATIBILITY FOR EQUIPMENT FOR LABORATORY USE.
AD2000	MERKBLATTER PRESSURE EQUIPMENT DESIGN CODE.

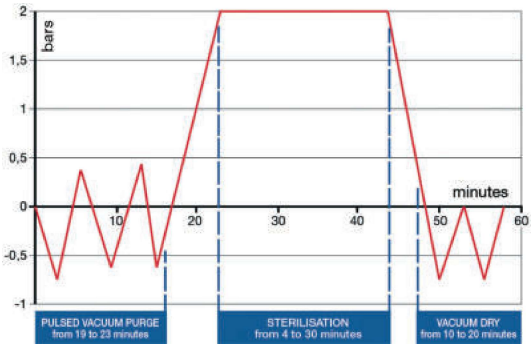
FEATURES

Exterior cabinet and countertop in stainless steel.
Tank and lid in stainless steel (AISI 316L).
Purging by fractionated vacuum and atmospheric pump.
Steam generator.
Water tank to supply the boiler.
Possibility to supply the boiler from an external water source.
6 operating modes.
Connection for a second control probe.
10 fully configurable user programs.
Lateral port for external probe (except for 150-liter autoclave).
Internal memory for storing 200 cycles.

SAFETY

Device that prevents the lid from opening while the chamber is under pressure.
Safety valve. Prevents the pressure from exceeding the maximum limit.
Safety pressure switch. Disconnects the heating in case of overpressure.
Thermal protective cover for the lid.
Closed-door detection sensor.
Atomatic generation of reports in PDF and CSV.

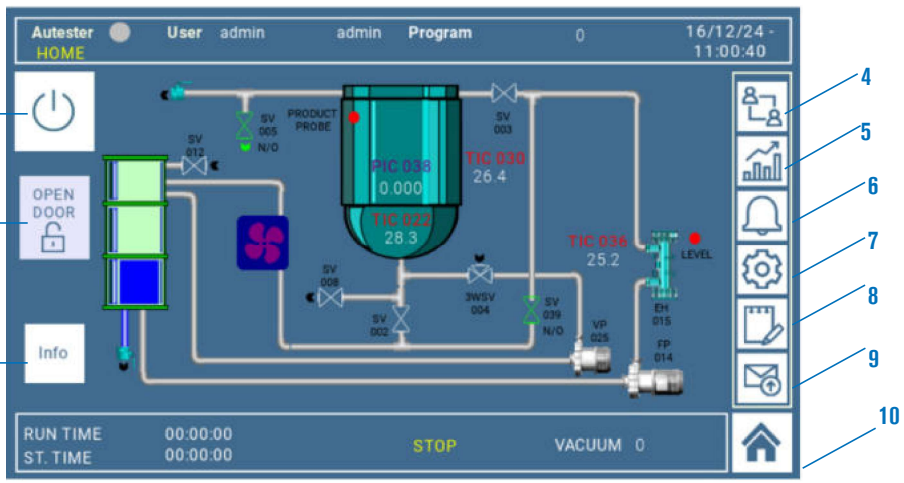
DIAGRAM SHOWING THE FUNCTION CYCLE AUTESTER ST DRY-S



CONTROL PANEL

TFT touch screen with virtual buttons. TFT 7” - HMI.

1. Start button.
2. Manual lid opening.
3. Information.
4. User Change menu.
5. Trend menu.
6. Alarms menu.
7. Configuration menu.
8. Recipes menu.
9. FTP transfer menu.
10. Home.



PLC FUNCTIONS

The microprocessor controls the performing of the air extraction process, sterilizing and drying, executing the selected procedures and commands by the user, adjusting the following parameters:

- Sterilization temperature from 105°C up to 134°C.
- Sterilization time from 3' to 59'.
- Drying time from 20' to 60'.
- Up to 10 user-configurable programs.
- Six operating modes:
- Solid 1 - Solid 2 fractions. - Solid 3 fractions
- Drying - Liquids - Liquids 2 probes
- Verification test
- Vacuum - Bowie Dick.
- Settings:
- Units – languages (Spanish, English, French).
- Printer module On/Off. - Clock: date/time.
- External water: on/off.
- Password for configuration.
- Calibration (adjustment offset)
- Temperature probe 1 - Temperature probe 2
- Water dosing. - Pressure
- Audible and visual alarm for overtemperature and insufficient temperature.
- Network failures detection and memorization
- Safety therrmostat by software
- Sterilization cycles data logging with capacity for over 500 cycles.
- Internal cleaning program
- Graphical representation of real time process

Error messages of functions and program execution are displayed and an acoustic alarm sounds. The vapour generator automatically cuts out.

MODELS	Code	Connection GMP	Drying	Capacity liters	Ø / Height (usable) cm	Height / Width / Depth (external) cm	Temp. ° C	Tank Capacity	Basket Capacity	Consumption W	Weigth Kg
AUTESTER ST DRY USB-S 50	4002521	NO	YES	50	30 63	117 48 62	105 a 134	10	3	4850	108
AUTESTER ST DRY USB-S 80	4002522	NO	YES	80	40 60	119 58 72	105 a 134	10	2	4850	136
AUTESTER ST DRY USB-S 150*	4002523	NO	YES	150	50 76	118 80 95	105 a 134	20	3	14000*	250
AUTESTER ST DRY GMP-S 50	4002524	YES	YES	50	30 63	117 48 62	105 a 134	10	3	4850	108
AUTESTER ST DRY GMP-S 80	4002525	YES	YES	80	40 60	119 58 72	105 to 134	10	2	4850	136
AUTESTER ST DRY GMP-S 150*	4002526	YES	YES	150	50 76	118 80 95	105 to 134	20	3	14000*	250

They are supplied without baskets and without drums. * Code 4002526 and 4002523 due to its power consumption, is manufactured for three-phase current at 230 V or 400 V, to be specified.

SUPPLEMENTS for vertical autoclaves

Pt 100 probe. For temperature reading. In order to ensure that the time and temperature parameters are met under all circumstances, the autoclaves have a connector to install a temperature probe either inside a culture flask, waste packages, etc. and thus ensure that the time spent at a temperature is actually the programmed one.
When the external probe is connected, the controller must be selected in settings and the values detected by the probe appear on the display and in the recorder.
Note: For Presoclave Plus autoclaves, the probe is only used to read the temperature by means of an external thermometer or recorder.
Code 4001219

Loading and unloading crane.
Basket lifter for loading and unloading of 50, 80 and 150L autoclaves.
With adapter for handling baskets without deforming them.
Axial rotation to unload the baskets to a transport trolley.
Total height of the elevator: 2.35 m (mounted on the autoclave).
Epoxy coated steel lower part and stainless steel upper part.
Maximum load of the elevator: 40Kg.
Power supply: 230V 300W
UP/DOWN push button.
Code: 1002426

Ink printer (see page 64)
Code: 4120113

ACCESSORIES:

Wire baskets in stainless steel. AISI 304.
For **St Dry GMP-S / St Dry USB-S**, 50.
Capacity, 3 baskets Ø 25,5 and 20 cm high.
Code: 1000495
For **St Dry GMP-S / St Dry USB-S** 80.
Capacity, 2 baskets Ø 36 and 28 cm high.
Code: 1000496
For **St Dry GMP-S / St Dry USB-S** 150.
Capacity, 3 baskets Ø 44,5 and 22 cm high.
Code: 1000780

Drums sterilization in stainless steel. AISI 304.
For **St Dry GMP-S / St Dry USB-S** 50.
Capacity, 3 drums Ø 25,5 and 20 cm high.
Code: 1002418
For **St Dry GMP-S / St Dry USB-S** 80.
Capacity, 2 drums Ø 35 and 27 cm high.
Code: 1002419

Detergent Bio-Sel. (see page 64)
Water distillation unit especially for autoclaves. (see page 64).
Purge microfilter. Part No. 4001221
Installation and start-up.
(Only in Spain)
Code 1003001

OPTIONS: for vertical autoclaves, need to be factory fitted.

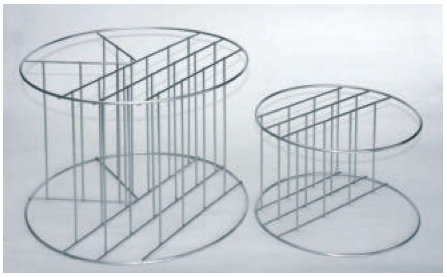
Pt 100 Sensor. 2nd Probe for reading sample temperature.
To guarantee in all circumstances that the system has completed the cycle to the set time and temperature parameters, the Autester ST DRY PV III autoclave can be installed with a temperature probe that can be placed within the culture flask, residual packets etc.
When the probe is connected to the controller of the autoclave, it must be selected in settings, whereby the real time temperature values detected by the probe, are displayed and printed.
For autoclaves PRESOCLAVE III and PRESOCLAVE PLUS this Pt100 sensor only reads the temperature with an external thermometer.
Part No. 4001219

ACCESSORIES FOR VERTICAL AUTOCLAVES

AISI 304 stainless steel wire baskets.

Part No.	Ø cm	Height cm	Suitable for autoclaves Part No.	Number of baskets
1004771	22	14	4001745	1
1004772	22	24	4001756	1
1004773	23	17	4001757	2
1000495	26	19	4001770 - 4002521 - 4002524	3
1000496	36	28	4002525 - 4001771 - 4002522 -4002442-4002444	2
1000780	47	22	4002526 - 4001772 - 4002523-4002443-4002445	3
1000490*	26	19	4001770 - 4002521 - 4002524	3
1000491*	36	26	4002525 - 4001771 - 4002522-4002442-4002444	2
1000492*	47	20	4002526 - 4001772 - 4002523-4002443-4002445	3

*AISI 304 stainless steel blind baskets.



AISI 316 stainless steel wire dividers for autoclave baskets.
Part No.
1001217 4 divider compartments for basket part no. 1000495.
1001218 6 divider compartments for basket part no. 1000496.
1001222 7 divider compartments for basket part no. 1000780.

Sterilization Drums.

Código	Ø	Height cm	Suitable for autoclaves Part No.	Capacity Drums
1002418	25	18	4001770 - 4002521 - 4002524	3
1002419	35	27	4002526-4001771-4002523-4002442-4002444	2
1002420	28	18	Not suitable for our autoclaves.	

Water distiller, specially for autoclaves "DEST-4".
Distillation capacity: 1.2 litres/hour. Internal capacity 4 litres.
Case made from thermo resistant plastic.
Internal stainless steel.
Cooling by forced air though a condenser. Without glass heater elements.
Easy to use. Safety cut out system if over temperature due to insufficient water.
Comes complete with a 4 litre three way dispenser plastic bottle with filter.
Note: for daily use it is recommended to change the filter every 3 months.

No external additional water required

Part No.	Capacity Distillation litre/Hour	Conductivity µs/cm	Ø cm	Height cm	Power W	Weight Kg
4001729	1.2	5	29	39	750	3.5

Spare: Dispenser spout with filter. Part No. 4001730

Detergent "BIO-SEL"
We recommend the use of BIO-Sel detergent for cleaning, it is also biodegradable and free from Phosphates.
Part No.
1000025 Capacity 1 litre.
1000026 Capacity 4 litres.
1000852 Box of 12 x 1 litre flasks.
1000853 Box of 4 x 4 litre flasks.