SYSTEC HX-580

New Generation: Laboratory autoclaves Systec H- Series are characterized by their modern design, user-friendly functions and state-of-the-art technology

- ✓ New design, fully revamped interior and a completely new touchscreen control
- ✓ Shorter and more efficient process times
- ✓ Process optimization fitted to requirements
- ✓ Safe, fast, accurate and validatable sterilization processes

STANDARD FEATURES

- Advanced HMI and PLC with touch-screen control
- Optimized HMI allows quick navigation and customization of processes and settings
- Newly developed autoclave system software (PLC)
- Code-secured access rights for changing parameters and further safety-relevant intervention
- Internal memory capacity for storing minimum 10 years of documentation data
- Timer for programmable start time
- Calculation of F0 value
- Adjustable automatic opening of door at end of program
- Network (Ethernet) and USB ports for external data transfer
- Text input for batch information (up to 20 characters)
- Integrated feature for comprehensive batch documentation, with export as PDF and CSV either on a USB-Stick or into the Ethernet network
- Backup feature allows to backup and restore the complete autoclave software including sterilization programs, individual settings and parameters
- Time synchronization with time server via network or internet
- Integrated steam generator separated from the chamber
- Housing, support frame and pressure chamber, made of corrosion-resistant stainless steel
- The pressure vessel of the autoclave is made of corrosion-resistant stainless steel 1.4404 (AISI 316L) and is electro-polished for ease of cleaning
- Ring-lock system for safe locking of the pressure vessel door
- All connections on the pressure vessel are designed as Tri-Clamp
- Temperature and pressure range up to 140 °C, 4 bar absolute pressure, optionally extendable to 150°C, 5 bar
- Up to 100 sterilization programs, sterilization programs and program list fully customizable
- 2x flexible PT-100 temperature sensors (Class A) in the autoclave chamber
- Additional temperature sensor in condensate exhaust
- Water-cooled waste water exhaust, thermostatically controlled
- Validation port for introducing external measuring equipment

TECHNICAL DATA

Outer dimensions	
• Width (mm)	1290
• Height (mm)	2030
• Depth (mm)	1350
Total chamber volume (liter)	735
Nominal chamber volume (liter)	580
Chamber dimensions, Ø x depth (mm)	1000x750
Heat capacity (kW)	36
Operating temperature (°C)	140
Operating pressure (bar, absolute pressure)	4
Optional 150 °C, 5 bar (absolute pressure)	
Please consider the below indications with regards to weight and	

installation surface. A check of the installation place by a structural engineer regarding the floor load might be needed prior to installation and start-up of the autoclave.	
Net weight (kg)	1190
Number of feet	4

*Please see dimensions on separate drawing.

MEDIA CONNECTIONS

Electrical connection Other voltage / amperage available on request.	380-400 V, Three-phase, 50/60 Hz (CEE socket, 63 A)
Demineralized water Only for steam generation. If a central demineralized water supply is not available, a demineralization cartridge can be used or demineralized water for steam generation can be taken from an external tank.	¾” male thread for tube connection, 1 - 5 bar pressure
Process water (tap water) For exhaust condensation, optional water - cooling system and optional vacuum system.	¾” male thread for tube connection, 1 - 5 bar pressure
Compressed air Mandatory to operate pneumatic valves and for optional water-cooling system with support air pressure. If a central compressed air supply is not available, a small and silent compressor can be offered.	DN 7.2 mm quick release connector. 270 l/min at 5 bar. Quality ≤ class 4 according to DIN ISO 8573
Drain	1” male thread for tube connection. Max. height of the siphon is 400 mm.

Adhere to the water quality thresholds!

The quality of the demineralized water and the process water (unprocessed water) used has a considerable influence on the performance and service life of the device.

DOOR AND LOCKING SYSTEM

The lid is insulated and covered by heat resistant polyurethane which protects the operator from contact and possible injury by hot components. It also incorporates the touch-screen control system. By default, the lid is hinged on the left-hand side but can also be hinged on the right-hand side on request.

The innovative ring-lock closure in combination with a robust lip seal made of silicone ensures that the autoclave lid is hermetically sealed and hence safe. The lip seal is additionally compressed as a result of the steam pressure; thus, additional compressed air is unnecessary. Locking takes place automatically when the lid is closed.

The ring-lock is released by pressing the related button on the touchscreen, whereby the lid opens automatically. Opening of the door can also be set for each program individually to be opened automatically at the end of a sterilization cycle. The seal is made of heat-resistant silicone and is very durable.

Temperature- and pressure-controlled door-lock

Systec H-series autoclaves are fitted ex-factory with a pressure- and temperature-controlled door lock according to Pressure Vessel Regulations and according to ISO/DIN regulations. The door of the autoclave remains locked as long as the pressure or temperature is too high inside the autoclave (or inside the product in case of liquid sterilization).

STEAM GENERATOR

Steam generation takes place in a steam generator that is completely separated from the sterilization chamber (i.e. no heating elements in the chamber itself). The steam generator integrated into the autoclave housing. As the generator is separated from the chamber, it does not need be cooled during the cool-down-phase of the autoclave but can remain in standby to provide steam for the next cycle in place.

Advantages:

- No used (dirty) water inside the chamber
- Easier cleaning as there are no heating elements inside the chamber
- More rapid cooling
- Less cooling water required
- Steam is immediately available for the next cycle after cooling, as the steam generator does not need to be cooled down.

The steam generator incorporates all the necessary control functions, valves and pumps for automatic filling with demineralized water. A low- and high-water detection system is incorporated into the steam generator to protect the heating elements in case there is not enough water supplied.

PRESSURE VESSEL AND SAFETY INSTALLATIONS

The pressure vessel of the autoclave is made of corrosion-resistant stainless steel 1.4404 (AISI 316L) and is electro-polished for ease of cleaning.

Safety valve and over-temperature cut-off

Should the pressure exceed a maximum level, a type approved safety valve is activated and releases the pressure from the chamber. An over-temperature cut-off protects against excess temperature. In both cases, the cycle will be interrupted, and an alarm is given.

CONTROL MECHANISM

A microprocessor controls all functions of the autoclave. These include steam pressure, temperature, sterilization time as well as the optional functions of rapid cooling, pre- and post-vacuum and drying. In cases of deviation from the set values, a corresponding alarm is displayed in plain text.

The control panel is ergonomically integrated into the lid cover of the autoclave.

The 5.7-inch touchscreen incorporates 7 programs as standard. Up to 100 programs can easily be added by the operator. Each program has a fixed name which refers to the user's manual and may have an individual description given by the operator.

Program parameters such as temperature and time can be set and saved for each of the programs individually. The touchscreen displays temperature and pressure numerically or as a graph, respectively, in real-time.

Program 1	Fast cycle for solids, instruments, apparatus and plastic items, with rapid steam exhaust (or fractionated pre- and post-vacuum with optional vacuum system and drying with optional Superdry)
Program 2	For waste material in waste destruction bags with pulsed heat-up phase for improved air removal out of the destruction bags (or fractionated pre- and post-vacuum with optional vacuum system)
Program 3	For sterilization of liquid waste material with slow steam exhaust (or optional rapid water cooling)
Program 4	For liquids with subsequent controlled steam exhaust and self-cooling (or optional rapid water cooling)
Program 5	Cleaning program with rapid steam exhaust
Program 6	Vacuum Test (Requires optional vacuum system)
Program 7	Bowie-Dick Test (Requires optional vacuum system)

Program variations and programs for special applications are available on request.

The programs run fully automatically. Temperature measurement is done in the sterilization chamber or in a reference vessel (on liquid sterilization) via a flexible temperature sensor and by a second fixed sensor at the coldest spot in the condensate exhaust. Both temperature sensors need to measure the required temperature during the sterilization phase. A lower temperature will cause a failure message.

The control mechanism consists of combined temperature and pressure regulation which allows the set steam pressure on liquid cycles to be exceeded by up to 0.3 bar during the heat-up phase without allowing the product temperature to be exceeded. This means that the heat-up phase can be shortened by about 50 % compared to simple temperature regulation.

STEAM EXHAUST CONDENSER

The exhausted steam vapor generated during the cycle is automatically cooled and thus condensed. This exhaust condensation process prevents the release of unpleasant odors and protects waste-water piping that may be made of plastic from overheating (maximum temperature for condensate to be drained is adjustable). The process is thermostatically regulated via a PT-100 temperature sensor to save cooling water.

POSSIBILITIES FOR DOCUMENTATION

STANDARD: Internal memory
The internal memory for process data uses the internal storage; this is part of the Systec PLC. The capacity is sufficient to store process data over an average period of minimum 10 years.

STANDARD: Electronic data output
The integrated documentation feature is used for comprehensive batch documentation and for exporting the electronic data as PDF or CSV via network interface* or USB. The essential values of the individual program phases and process parameters are presented in a tabular overview, followed by a graph and a numerical table of the program sequence.

*The network interface requires the optional “Save to Folder” feature for downloading the file to an FTP/SFTP server.

STANDARD: Backup Feature
The backup function (via USB) enables the user to save and restore:

- program lists and their parameters,
- complete backups of the device with the current device software and its databases.

The backup file is encrypted and thus protected against manipulation.

STANDARD: Real-time clock
The device has a real-time clock with automatic changeover to daylight savings time. Time, date, and time zone can be set manually via the touch screen, the web server, or automatically via the internet. A time server and an internet connection are required to automatically set the time.

- Automatic summer/wintertime
- Automatic leap year detection

OPTIONAL: Save to Folder
The „Save to Folder“ function automatically exports the current process log to a computer or server in the same network by either FTP, SFTP or FTPS after the cycle has been finished.

OPTIONAL: SCADA connection
All relevant information (current values of defined analogue and digital inputs and outputs of a device, current process status, alarms) is transmitted by the autoclave using the OPC-UA protocol.

OPTIONAL: Printer
An integrated printer is optionally available for documenting the program type, batch number, date, and time. The printout contains the essential information of a program cycle. It shows the basic parameter settings and the success or failure of a program cycle.

The printout is created in the language that has been selected on the device.

OPTIONAL: Advanced CFR 21 Part 11 solution
All data can be downloaded from the autoclave as PDF and/or CSV (Excel) files*, using the USB or network interface**. Both the PDF and CSV files are electronically signed by the autoclave. This electronic signature is clearly assigned to the respective autoclave. It also indicates whether the exported files are valid or not. Any attempt of manipulation will result in the file being marked as invalid.

The advanced CFR 21 Part 11 solution also includes

- Extended user account control. This includes an individual or global program list for each user, the assignment of the user to an individually created group (e.g. user, supervisor, administrator, cleaner, etc.) which has customizable rights.
- AuditTrail: All executed actions (e.g. changing parameters, starting or stopping sterilization programs) are documented and can be traced back to the respective user and time stamp (date/time).
- There are up to five fields for electronic signatures. These are used to sign the exported PDF or CSV files on a PC (or any other device with the functionality to sign documents electronically). The electronic signatures are not included in this option.

* The network interface requires the optional “Save to Folder” feature for downloading the file to an FTP/SFTP server.
** only cycle data can be transferred via the network interface.

FURTHER OPTIONS AND ACCESSORIES AVAILABLE

Systec autoclaves are built in a modular design and therefore can be fitted to meet specific requirements. Options for process optimization are available for:

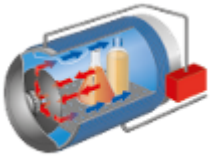
- Sterilization of liquids (culture media)
- Sterilization of solids
- Sterilization of liquids or solid waste
- Sterilization of biohazard materials

Sterilization of liquids

OPTIONAL: Quick cooling with/without support air pressure

Quick cooling with cooling water, for open or burst proof hermetically closed vessels.

- No loss of liquid due to boiling of the culture media
- Improved productivity from reduced cycle times and the full utilization of the filling volume in each bottle
- Prevention of delayed and over-boiling
- Prevention of the risk of bottles bursting during or after sterilization
- Prevention of re-contamination by the use of hermetically sealed bottles during sterilization
- Reduction of cooling time by up to 60 %



OPTIONAL: Radial ventilator
In conjunction with optional jacket cooling with cooling water and support pressure, the radial ventilator ensures accelerated removal of heat from the sterilization items to the cooled chamber jacket (cooling coil). The radial ventilator is located in the lid of the chamber (no reduction of chamber depth!) and is driven by a magnetic motor which is installed externally, under the door cover.

- The radial ventilator is placed in the door of the sterilization chamber so that the usable space in the autoclave is not reduced.
- Ventilation performance: 250 m^3/h
- Reduction of cooling time by up to 70 %

OPTIONAL: Ultracooler
In conjunction with optional jacket cooling with cooling water, support pressure and radial ventilator, it is possible to significantly reduce the cooling time and the entire sterilization process by integrating the additional Ultracooler heat exchanger.

- The Ultracooler is also placed in the door of the sterilization chamber near the radial ventilator so that the usable space in the autoclave is not reduced. This way, the entire interior space can be used for full loading!
- Reduction of cooling time by up to 90 %
- Depending on the load, cooling times between 15 and 60 minutes can be achieved

Sterilization of solids and

Sterilization of waste in disposal bags

OPTIONAL: Vacuum system
Typical solids are pipette tips (in boxes), empty glassware and waste in bags as well as porous materials such as filters or fabrics. For this type of sterilization, it is important to remove all air from the products to be sterilized in order to ensure precise, reproducible and validatable sterilization results. The vacuum device effectively removes the air from solids, tubing, porous materials, fabrics and disposal bags, allowing the steam to penetrate completely. The process includes a fractionated pre-vacuum phase in combination with the standard steam generator. This is the only way to achieve validatable sterilization of porous materials, solids, fabrics, or waste in bags.

OPTIONAL: Superdry
This optional accessory increases the drying efficiency for solids and porous materials such as filters and fabrics. Heat energy from the standard steam generator is transferred to the heating coils around the body of the sterilization chamber and is used for drying. Deep-vacuum drying using the optional vacuum device in conjunction with Superdry avoids the necessity for subsequent drying in a separate drying cabinet.

Sterilization of hazardous biological substances

OPTIONAL: Exhaust air filtration with condensate inactivation
For the sterilization of hazardous biological substances, Systec autoclaves can be fitted with an optional air exhaust filtration system. The autoclavable sterile filter, consisting of a filter cartridge with a PTFE membrane of pore size 0.2 µm, is installed in a pressure-proof housing and can be quickly changed at any time. The filter is also automatically sterilized inline during the sterilization process, monitored by the PT-100 temperature sensor. The condensate is retained inside the pressure vessel during the heating and sterilization phases and is therefore also sterilized. By air exhaust filtration and condensate inactivation, it is ensured that no microorganisms can escape before the end of the sterilization phase. This ensures that all gases and liquids representing a hazard, are filtered and sterilized in-line, if they are to be released into the atmosphere.

FURTHER OPTIONS

- Extension of temperature and pressure ranges up to 150 °C / 5 bar (absolute pressure)
- Up to 5 additional PT-100 temperature sensors
- Available with stainless steel casing
- Feature for the integration into SCADA systems via OPC UA
- Keep-warm function for liquids after program has finished
- Potential-free contact: The potential-free contact can be used to establish an external potential-free connection to one or more digital outputs or device status lines. This potential-free contact helps to prevent malfunctions when switching external actuators (such as signal lamps, valves and pumps).
- Combined heating: The combined heating function supplements the built-in steam generator with an external steam heating option.

- Auxiliary steam heater: The auxiliary steam heater replaces the integrated steam generator for heating using on-site clean steam.
- Further options are available, such as a steam/air mixture, hot and cold-water sprinkling, pharmacopoeia programs, extended temperature holding times for the sterilization of microorganisms with higher temperature resistances or for material testing (stress tests) in industrial applications.
- Customer-specific process evaluation, special designs and development are available on request.
- FAT / SAT

OPTIONAL ACCESSORIES

- Easy load transport carts
- Transfer cart for Easy Load
- Loading shelves / trays
- Baskets / tubs (stainless steel)

QUALIFICATION AND VALIDATION

A validation port (Tri-Clamp DN25 A50.5 ISO) for validation with external data loggers is provided by default. GMP/GLP-compliant IQ/OQ/PQ documentation can be offered as an option (including implementation by a trained Systec service technician as necessary).

All the above options can also be retrospectively fitted to current Systec Autoclaves. The basic version includes all the connections necessary for any of the options.