

High-Temperature High-Pressure

GPS

Sterilizers



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HISAKA WORKS, LTD., Process Engineering
Division is both ISO9001 and ISO14001 certified.

HISAKA WORKS, LTD., Ikoma Plant is
ISO45001 certified.

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with hopeful technology
HISAKA

Fully automated operation ensures consistent sterilization and reduced staffing.

This system can operate under precise programs that allow stable sterilization after simply setting the optimum temperature and pressure for the product.
It is fully automatic with operation initiated at the touch of a button.
Hisaka's sterilizers allow you to minimize labor, improve efficiency, and reduce costs.



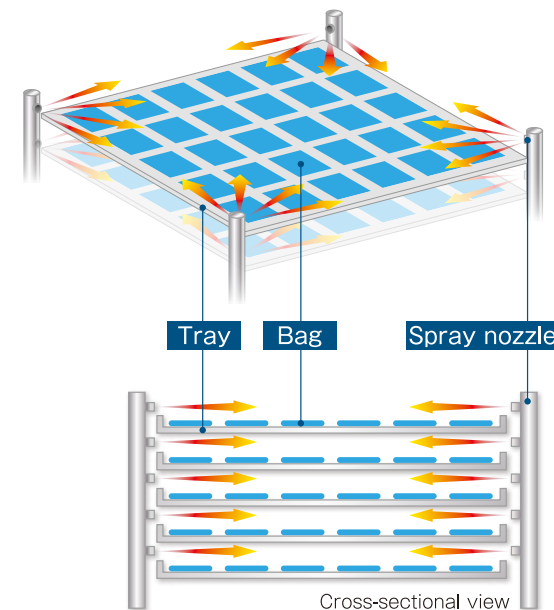
When installing the equipment, our highly specialized technicians will provide comprehensive on-site support, from Installation and Operational Qualification (IQ/OQ) to management of appropriate sterilization conditions.

The hot water spray type focuses on uniform dispersion of circulating water

The hot water spray type sterilizer is perfect for sterilizing soft bags and plastic bottles. The spray nozzles powerfully spray Four-way spray nozzle on all-stage of trays. This achieves an extremely uniform temperature distribution, resulting in minimal variation of F_0 values. The use of indirect heating and cooling eliminates the risk of steam contamination in the sterilization tank, and precise pressure control prevents the product containers from deforming. This makes the system the perfect choice for cGMP-compliant pharmaceutical manufacturing.



Inside the spray type sterilization tank



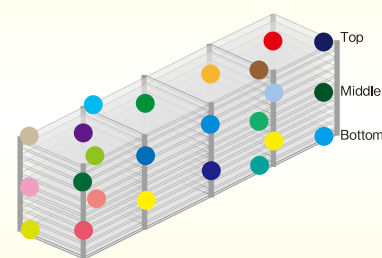
- Applications**
- Sterilization of infusion bags and bottles
 - Sterilization of pre-filled syringes
 - Sterilization of ampules and vials
 - Sterilization of hygienic cotton products
 - Sterilization of enteral/oral preparation
 - Sterilization of catheters
 - Sterilization of extracorporeal blood tubing and dialysis solution bags
 - Sterilization of dialyzers



Uniform temperature distribution

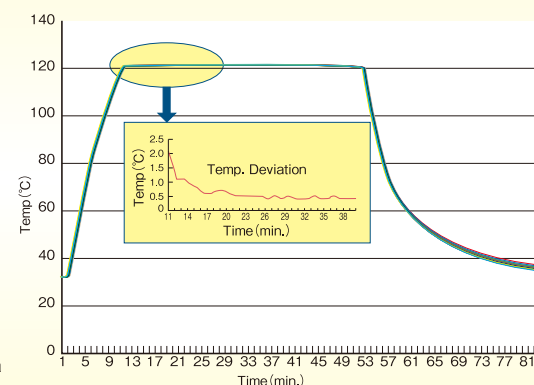
Verification of uniform temperature distribution with a full load of products

Sensors are placed at the center and at one corner of each tray stacked on the top, middle, and bottom layers. As the tank can accommodate four tray baskets, the temperature is measured at a total of 24 points. This allows you to have a temperature that is so uniform, the temperature curves almost perfectly overlap.



Measurement example: When sterilizing four tray baskets, measurement is performed at a total of 24 points, six for each tray basket.

24-point temperature measurement data

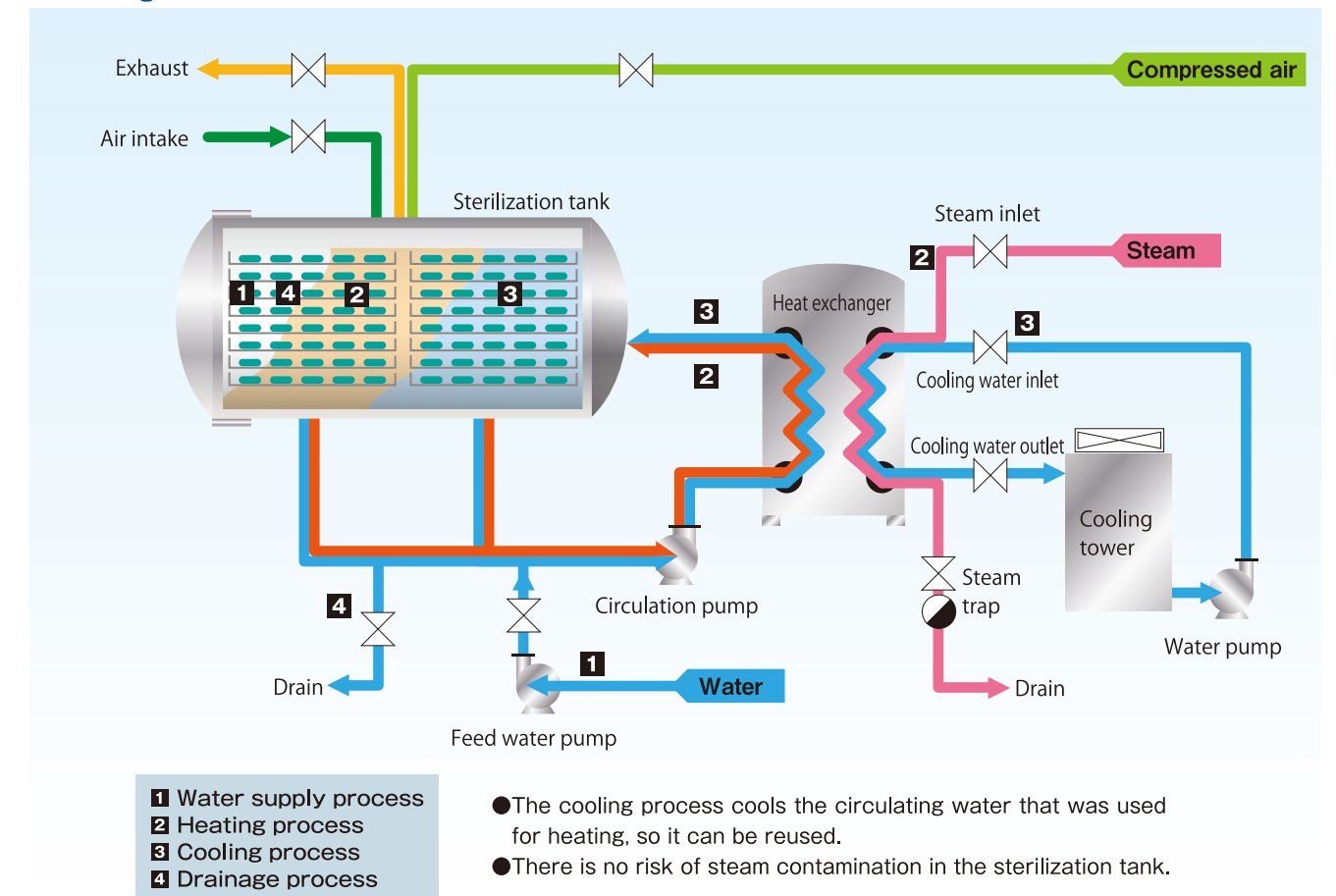


* This graph indicates the temperature deviation at each measurement point.

Highly economical due to using less energy and water

- Having only a small amount of water in the sterilization tank allows for a more rapid start-up and reduces costs when using purified water.
- Large-scale equipment can install purified water recovery tanks and hot water recovery tanks, which also save energy.
- Indirect heating and cooling using a plate heat exchanger allows you to use cooling tower water as the coolant, further helping to conserve water.

Flow diagram



Control technology based on years of experience

- The air-containing container processing system prevents the containers from deforming.
- The system is also compatible with plastic bottles and vials.
- No influence of water pressure due to buoyancy or liquid depth, sterilization can be performed without any risk of the bottles deforming. It also allows the pressure to be precisely controlled, even in Large-scale equipment.
- Fully-automatic control allows the temperature and pressure to be freely set to the desired values.
- Sterilization conditions can be easily set via the touch screen.

Suitable for Sterile Products

- Enables sterile drying within the sterilization tank and then direct transfer to a cleanroom.

Hisaka's novel technology* enables rapid drying and cooling

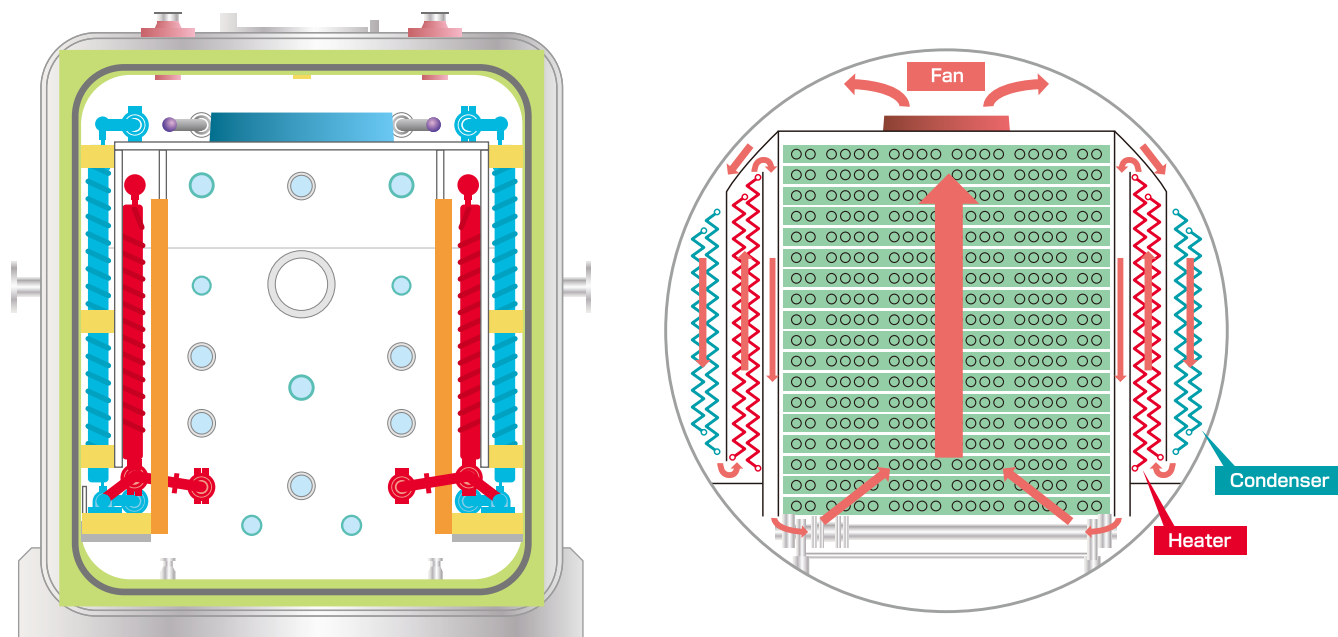
* Patent obtained. (Patent No. 7680890)

The fan mounted at the top of the chamber provides forced air agitation, and condensers and heater heat exchangers mounted on the chamber's inner surface allow highly efficient drying and cooling.

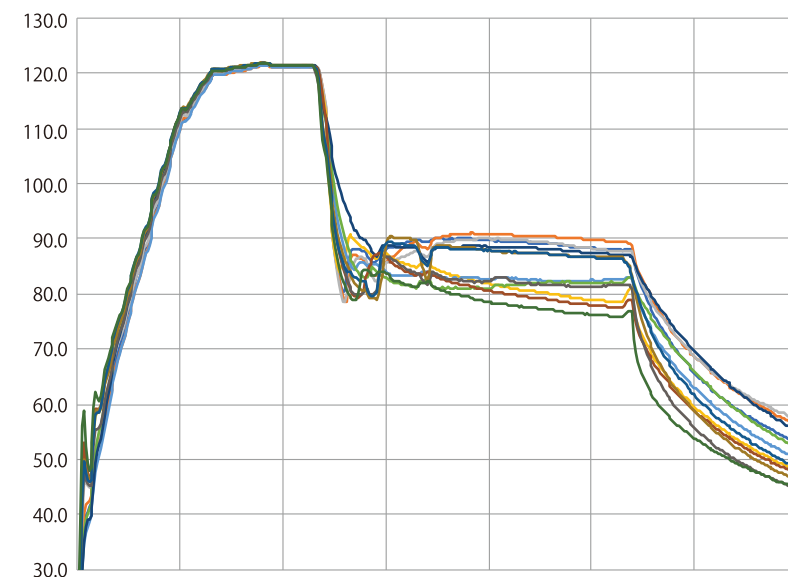
Applications

- Sterilization of pre-filled syringes
- Sterilization of ampoules and vials

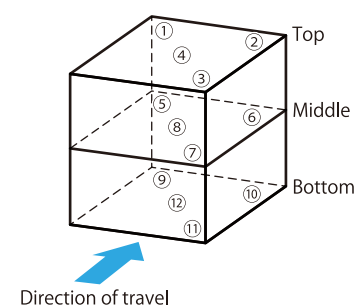
Image of the configuration inside the chamber



Reference data for a single complete cycle



Using our testing equipment, temperature data was measured at a total of 12 points during the sterilization process with a full load of baskets. The drying and cooling time has been shortened by 30% compared to conventional methods, and complete drying is possible.



Improved durability due to no requirement to have a jacket

Hisaka's novel technology enables drying and removal without the need to install a jacket. This greatly reduces the risk of cracking due to differences in size between the chamber and jacket as they expand and contract.

* Jackets may be selected as an optional extra.

Drying and cooling time is 30% shorter than the conventional method* (based on our independent comparison)

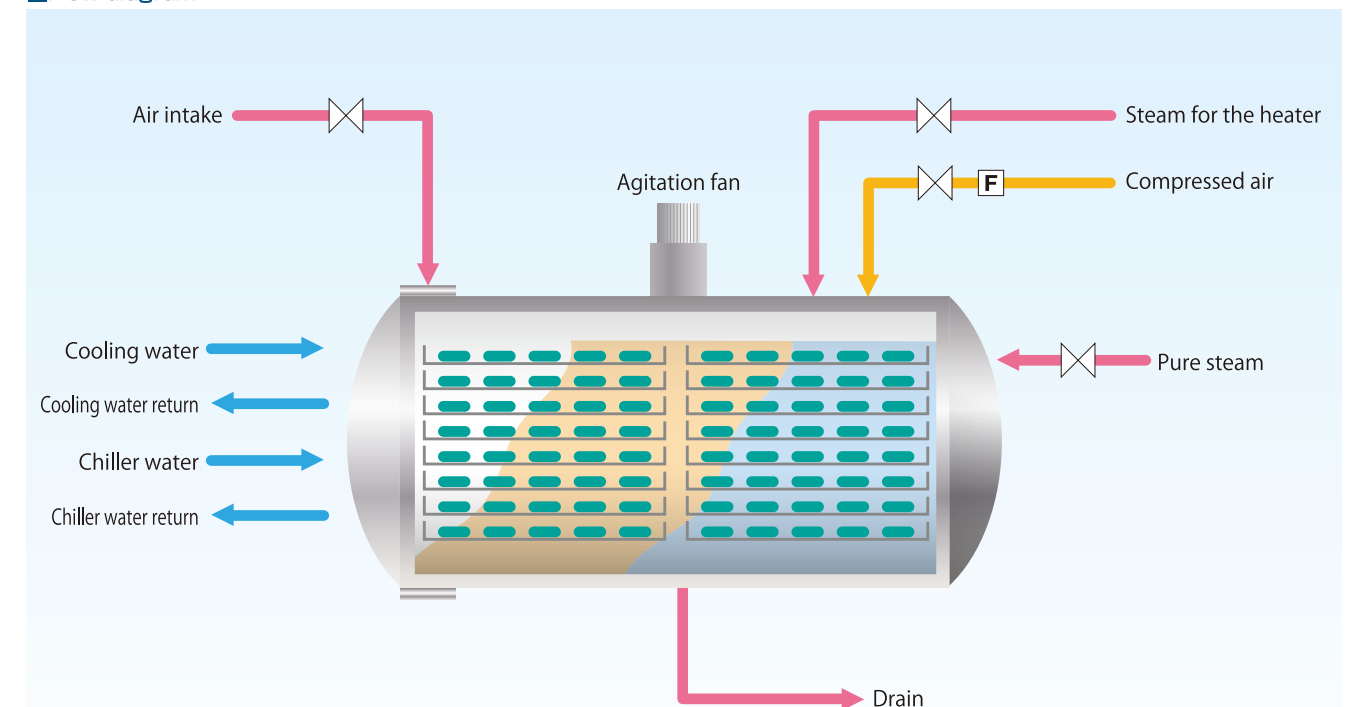
By co-locating the condenser and heater within the equipment as heat exchangers, we have achieved reduced drying and cooling times through improved heat exchange efficiency.

* The conventional method consists of a condenser and jacket.

Achieving space-saving

The internal circulation type sterilizer has the drying unit mounted inside the chamber. Space savings of approximately half the area are possible.

Flow diagram



Efficient drying and cooling after sterilization

A heat exchanger and blower are installed on the circulation piping that is mounted outside the chamber, and forcibly agitating the air inside the chamber allows for more efficient drying and cooling.

Applications

- Sterilization of pre-filled syringes
- Sterilization of Infusion bags (double bags) and bottles

Various methods (hot water spray, shower, rotating types) can be combined

In addition to the use of pressurized steam, various other sterilization methods are available. We can tailor the best operating method for your particular formulations or packaging materials.

Drying and cooling time is 40% shorter than the conventional method* (based on our independent comparison)

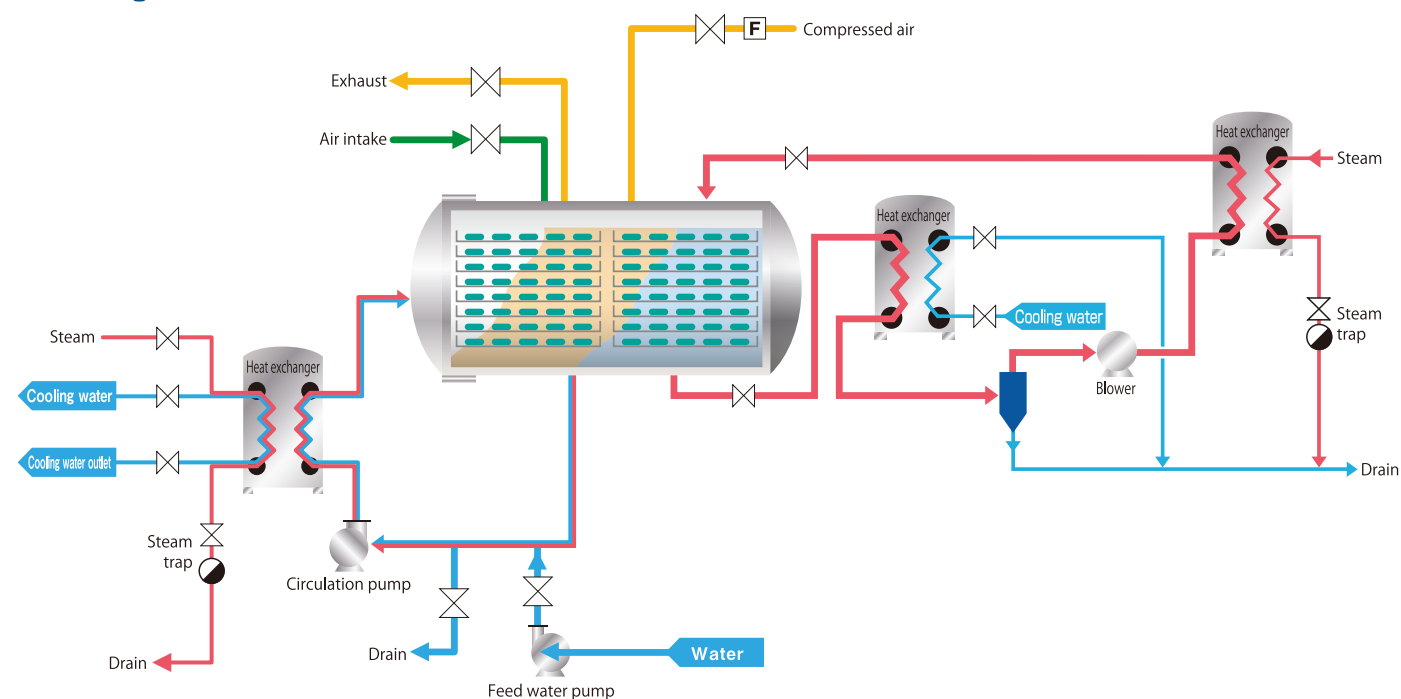
Equipped with Hisaka's highly efficient plate heat exchangers for rapid drying and cooling.

* The conventional method consists of a condenser and jacket.

Optimal pressure control for your particular product

Pressure control can be set according to the particular characteristics of each product. This eliminates the risk of container deformation or loosening of rubber stoppers.

Flow diagram



Rapid and efficient drying and cooling after sterilization

After sterilization, the product is dried and cooled so it can be removed without any adhesion of moisture.

Applications

- Sterilization of Medical equipment and devices, rubber stoppers, dust-free clothing
- Sterilization of Ampules and vials

Uniform sterilization

Degassing using a vacuum pump and pressurized steam ensures a uniform temperature distribution within the sterilization tank.

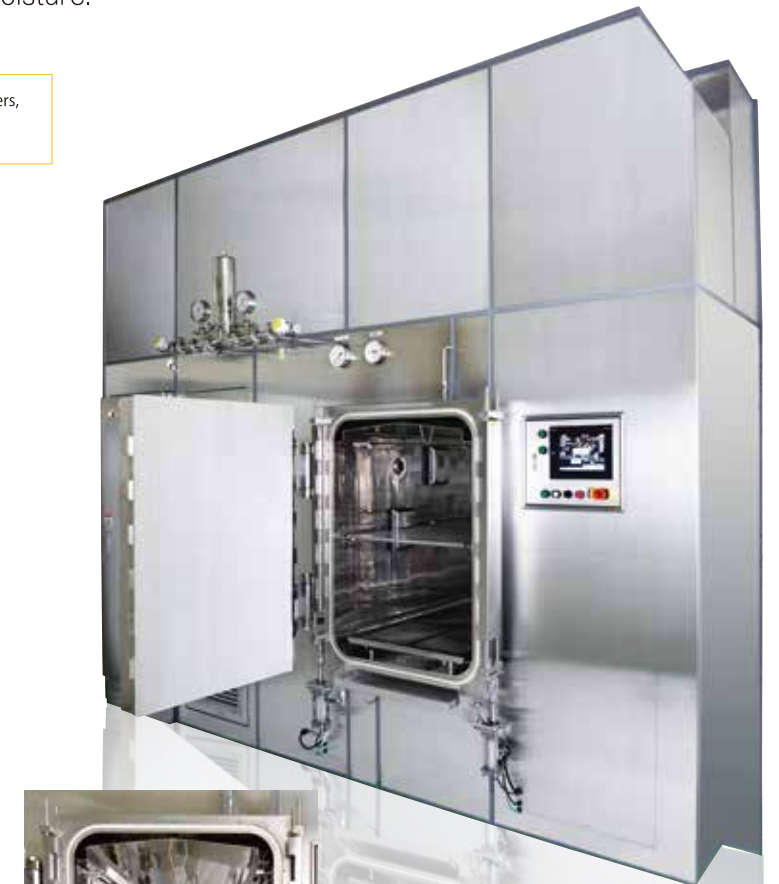
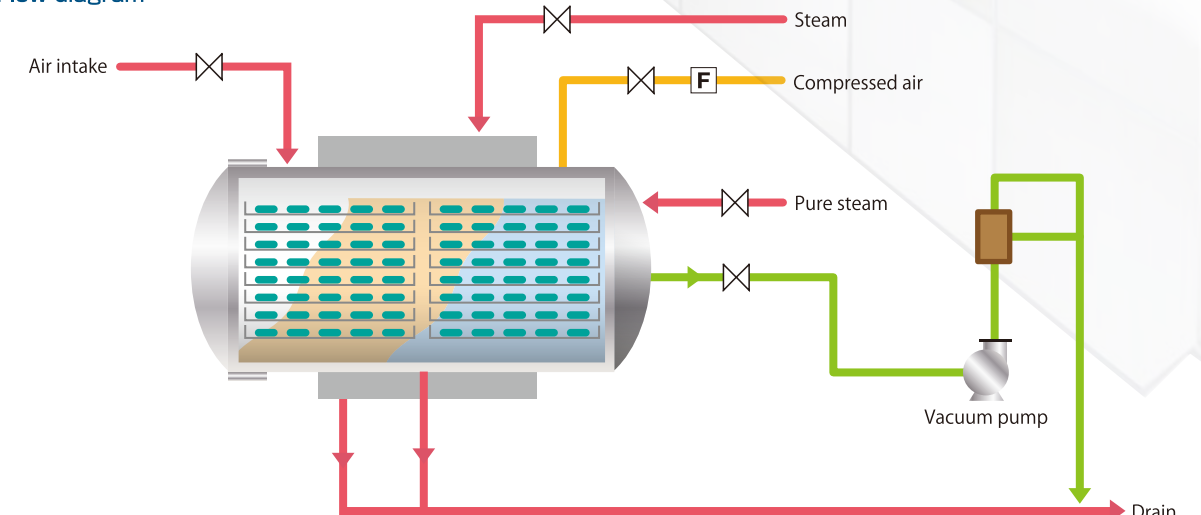
Installation space flexibility

We can design the layout based on your particular installation space, making it possible to use the equipment in limited spaces.

Setting optimal drying conditions

You can set various parameters such as the number of vacuum pulses and the amount of steam injected into the jacket. This enables optimal drying conditions for your product.

Flow diagram



The rotating type enables efficient and uniform sterilization all the way to the center of highly viscous products.

Active switching of the direction of water flow within the sterilization tank allows for uniform water flow in all directions. The rotational movement thoroughly mixes products even with high viscosity so that they are sterilized evenly and efficiently all the way to the center.

Applications

- Sterilization of Oral nutritional liquid
- Sterilization of Enteral nutrition formula

Uniform water flow dispersion (flow-switching method)

The direction of flow in the tank can be switched to achieve uniform water flow in all directions. This minimizes temperature variation and delivers uniform sterilization of all products in the tank.

High-temperature, rapid processing

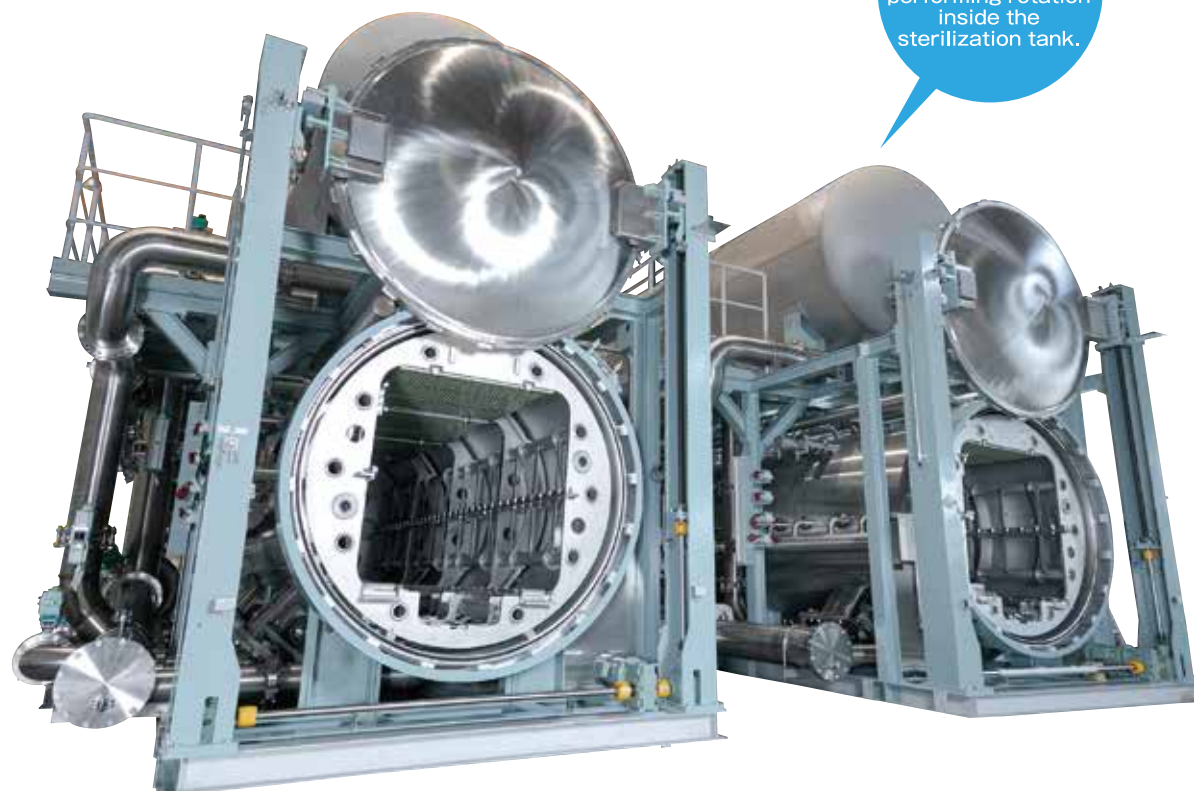
Utilizing advanced preparation of hot water in the hot water tank completely eliminates any wasted time. Therefore, the system can efficiently operate at a high temperature in a short time.

The rotating type is perfect for processing high-viscosity products

Rapid and precise sterilization is ensured by rotating inside the sterilization tank. Because it sterilizes uniformly with high precision, it is perfect for the sterilization of high-viscosity formulations.



Highly viscous liquid is rapidly sterilized by performing rotation inside the sterilization tank.



Safe and reliable batch type heat treatment equipment

This system performs thermal treatment to inactivate harmful microorganisms and viruses contained in wastewater (primarily from pharmaceutical plants). We will propose the optimal system tailored to your requirements.

Applications

- Inactivation of viruses and microorganisms contained in wastewater

Robust heat treatment

Multiple temperature sensors are installed to control and monitor the temperature inside the tank and ensure that it rises to the set value. A recorder can be used to log and manage operational data such as temperature and pressure.

Optimal system configuration

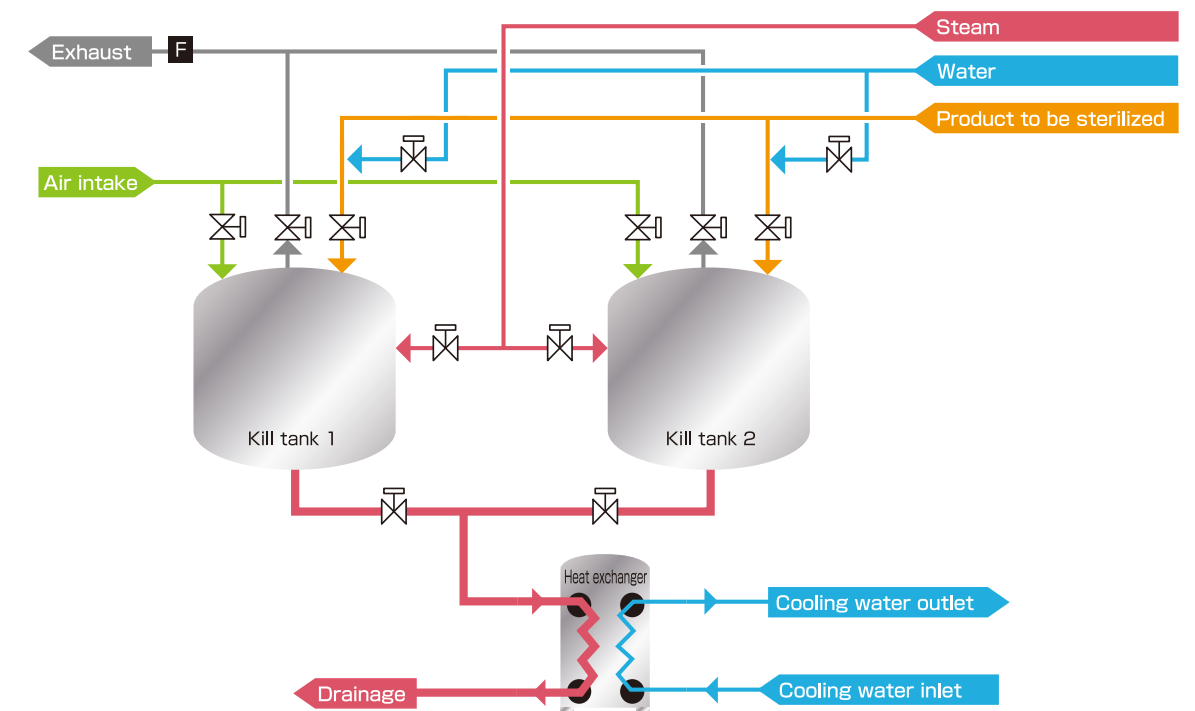
We design custom equipment configurations that satisfy your particular requirements, such as processing capacity, processing time, and installation dimensions. For example, we can provide indirect cooling to reduce cooling time.

Flexible control systems

You can utilize program control to automatically perform alternate switching between multiple tanks in accordance with the operation. It can also handle data communication and operation management with higher-level systems.



Flow diagram



Our Total Automation System Creates Efficient Production Lines

As a company that holds the top market share in the infusion sterilization industry, Hisaka has created a comprehensive operation system that efficiently handles production plans and ensures strict levels of hygiene for pharmaceutical factories that require a high level of cleanliness.

Loader Loads the product.

Unloader Unloads the product.

Stacker Stacks the trays.

Unstacker Unstacks the trays.

Flow of trays
Flow of product



The stacked empty trays are placed on the stock conveyor.

Stacker



The remaining empty trays are stacked.



The unloaded products are transferred to the next process.

Unloader



The products are removed from the tray.

Unstacker



The trays are placed in a single layer.

Unstacker



The trays are placed in a single layer.

Loader



The product is transferred by suction.

Loader



The trays are loaded.

Stacker



The trays are stacked.



The stacks are rotated on a rotating table.



The stacks are transferred into the sterilizer.

Reduced labor requirements

The system can be run completely automatically without the need for manual operation.

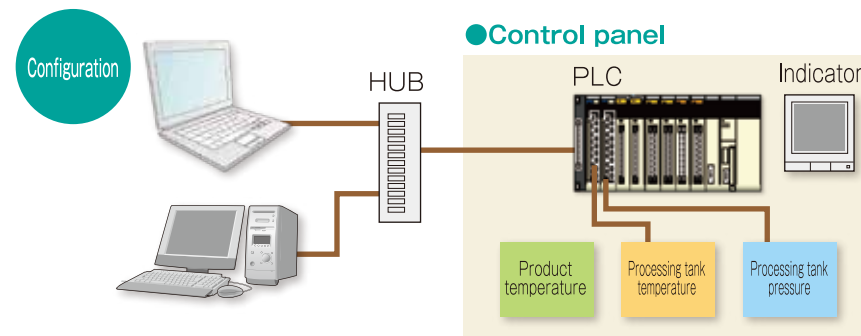
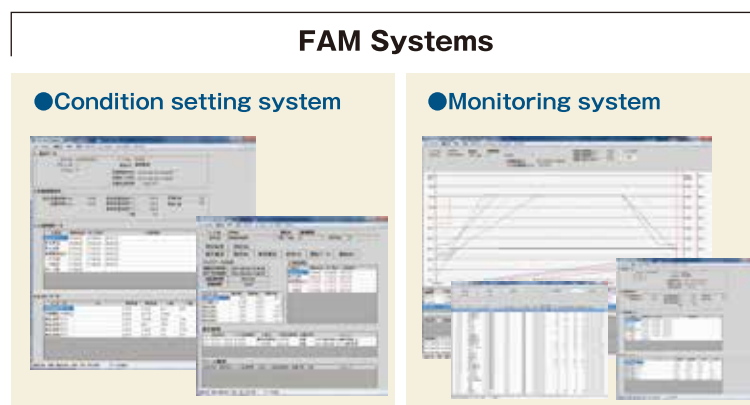
Reliability and record of performance

Hisaka has a solid track record of delivering various highly praised FA systems in the pharmaceutical industry, where advanced technology and reliability are critical requirements.

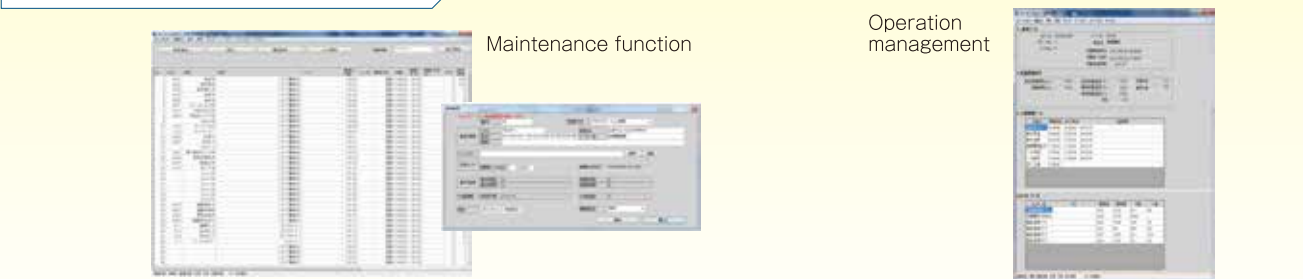
Improved productivity and creativity with guaranteed quality

This comprehensive system provides backup for everything from production management and quality control to operational data management and documentation for sterilization equipment. It also facilitates the development of sterilization conditions and the analysis and management of probability-based data, enabling more effective operation.

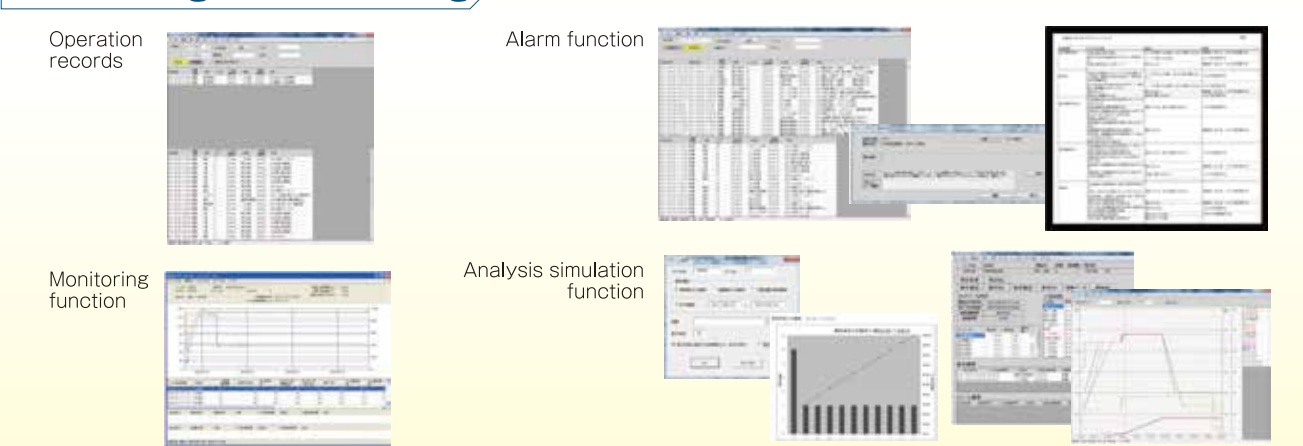
It is a comprehensive system consisting of a sub-system that collects, monitors, and reports operational data, and a sub-system that creates and manages programs to handle operating and control conditions.



Critical limit



Monitoring and recording



If you wish to implement a comprehensive plant system, it is necessary to have a reliable plant-wide control system and production management system.

This allows you to easily monitor the status of all equipment from every section.

A permanently installed system that can test samples to verify operating conditions

In addition to having a range of sterilization testing machines for confirmation and testing before system installation, we can also create systems with entirely custom specifications from the planning and development stage that are tailored to your particular product.

Model: GPS-40RTGN

Hot Water Storage Type Sterilization Testing Machine

Includes the Next-Generation Air-Containing Container Processing System (GGG) temperature and pressure control system (air-containing system).



Specifications

- Processing capacity: 10 kg
- Max. working pressure: 0.6 MPa
- Max. working temperature: 150°C
- Wetted part material: SU-S316
- Sterilization tank dimensions: Inner diameter = 400 mm, Length = 800 mm
- Effective liquid volume: 75 liters
- Heating method: Hot water heating, steam heating
- Cooling method: Replacement/recovery (1-stage and 2-stage cooling)
- Pressure control: Constant-pressure/air-containing
- Processing mechanism: Stationary and rotating type
- Heating capacity: 20 to 140°C, approx. 30 minutes
- Temperature distribution in tank: Within $\pm 0.5^{\circ}\text{C}$
- Rotational speed: 1 to 35 RPM
- Equipment dimensions: 1,610 mm (W) x 1,900 mm (L) x 1,970 mm (H)
- Equipment weight: 1,300 kg
- Utilities
 - Steam = 50 kg/h
 - Cooling water = 150 liters per cycle (6 m³/h)
 - Equipment power: 5 kW

Model: GPS-60SPXTG

Hot Water Spray Type Sterilization Testing Machine

Includes the Next-Generation Air-Containing Container Processing System (GGG) temperature and pressure control system (air-containing system).



Specifications

- Processing capacity: 20 kg
- Max. working pressure: 0.5 MPa
- Max. working temperature: 140°C
- Wetted part material: SUS-316
- Sterilization tank dimensions: Inner diameter = 600 mm, Length = 735 mm
- Effective liquid volume: 20 liters
- Heating method: Hot water spray heating
- Cooling method: Spray cooling
- Pressure control: Constant-pressure/air-containing
- Processing mechanism: Stationary type
- Heating capacity: 20 to 130°C, approx. 11 minutes
- Temperature distribution in tank: Within $\pm 0.5^{\circ}\text{C}$
- Equipment dimensions: 1,330 mm (W) x 2,130 mm (L) x 1,800 mm (H)
- Equipment weight: 1,600 kg
- Utilities
 - Steam = 150 kg/h
 - Cooling water = 360 liters per cycle (2 m³/h)
 - Equipment power: 5.4 kW