

QD-0440 v.01.0 - Product Specification Sheet of ISS AC-575- EN

Product Description

The ISS AC-575 Integrated Sterilizer & Shredder (hereafter ISS AC-575) is a steam sterilizer with an integrated shredder, intended for the treatment of biological hazardous waste.

The ISS AC-575 performs both shredding and waste steam sterilization in a single vessel. The vessel is equipped with a motor-driven shaft, with powerful shredding/crushing blades which can rotate in two directions inside the vessel to reduce the size and volume of the waste.

ISS AC-575 includes the following features:

- Large capacity sterilization chamber
- Built-in steam generator
- Powerful vacuum pump for evacuation of the air from the waste for better steam penetration
- Automatic pneumatic door locking and door opening mechanism
- Drain box for evacuation of sterilized liquids
- Water separator system to prevent return of used water from the machine to the water source
- All the gases from the contaminated chamber (before sterilization) will be evacuated via 0.01 micron bio filter
- 2 temperature sensors, one in the bio filter and one in the chamber

Application

Celitron's compact medical hazardous waste solution, the Integrated Sterilizer & Shredder, is a steam sterilizer with an integrated shredder, designed for on-site conversion of biohazardous waste in hospitals and clinics, complying with the EU and WHO recommendations.

Dimensions

Chamber inner dia. x depth: 500 x 800 mm
 Chamber volume, net.: 150 litres
 External W x H x D: 1290 x 2150 x 2039 mm

Configuration and Options

Model	Heating	Doors
ISS AC-575	Electric, 380-400V, AC	Single

Available Accessories:

Standard:

- Built-in steam generator (18 kW)
- RS 232 communication port
- Integrated impact printer
- Reverse-Osmosis system (100 GPD)
- Unloading tray with holder for waste
- Waste bag ring with holder
- SD card slot with 2 GB SD card & reader

Optional:

- HMI PC software
- Air compressor



Languages

The operator panel is set up with following standard languages (maximum 8 languages per unit), more available upon request:

English Russian Spanish French
 Arabic Portuguese Lithuanian Finnish

Standards

ISS AC-575 complies with the following standards and codes:

- Machinery Directive- 2006/42/EC;
- Pressure Equipment Directive- PED 97/23/EC;
- 2006/95/EC Low Voltage Equipment Directive;
- EMC Directive 2004/108/EC Article 7 (1)
- RoHS II Directive 2011/65/EU
- EN 60204-1 - Safety of machinery - Electrical equipment of machines - Part 1: General requirements.
- The CE mark was first applied in: 2010.

The company's quality management system meets the following quality standards:

- ISO 9001 – Quality Management System – Requirements.
- ISO 13485 – Quality Systems – Medical devices – Particular requirements for the application of ISO 9001

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Standard features

- MICROPROCESSOR CONTROLLED** - The control system of the sterilizer is based on state of the art microcomputer technology, ensuring a highly reliable and safe operation. The computerized control unit ensures a fully automatic operation through the entire cycle; hence after setting the pre-selected data and starting the operation, no further intervention is necessary. The selected program, the main phases of the cycle and the status of the machine are controlled and displayed on digital readouts.
- DESIGN AND CONSTRUCTION** - The ISS meets the highest standards requirements for quality, safety and operation. Stainless steel pressure vessels 316L conforms to the Pressure Equipment Directive (PED). The chamber and door are designed for a maximum working pressure of 2.76 bar and full vacuum.
- CHAMBER** - The device is constructed of durable stainless steel 316L and is pre-heated by electrical silicone heaters. All metal parts in the inner surfaces are made of stainless steel. The vessel is supported by two arms which are also used to rotate the vessel for loading (45°), treatment (0°) and unloading (150°) positions. The vessel is turned by a motor, and the positions are indicated by magnetic sensor. The chamber is constructed with an internal sprinkler for the automatic cleaning process.
- DOOR** - The sterilizer's chamber is equipped with one door, provided with an automatic locking mechanism, activated by compressed air, preventing the opening of the door by a safety lock.
- BLADES** - The vessel is equipped with a multipurpose shredder/crusher blade on the bottom, to ensure use of the full volume of the vessel. It is regulated by an electric motor which drives the knife shaft through a tooth belt. The patented shaft connects the knife to the motor through the sealed bearing house. The 15 kW motor is sufficient to rotate the shaft with an RPM of 400-1700 for various operations. The blades are mounted on the shaft and are designed to shred waste such as sharps, dialyzers, syringes, papers, cloth, plastic and glass. The blade is made of high carbon steel with hardened cutting edges.
- GASKET** - The sealing of the chamber is made by utilizing a heat-resistant silicone rubber gasket.
- ENERGY SAVING MODE** - The ISS is equipped with an Energy Saving Mode which is activated when the unit is not used after a certain period of time. This mode saves energy and ensures safety of operation and is thus environmentally friendly.



- CONTROL SYSTEM** - A microprocessor based control system, state of the art "Freescale" technology, automatically controls all programs including the sterilization cycle. The system includes a 5.7" digital touch-screen graphic display, communication, self and remote diagnosis and PC connection for external documentation and printing. It ensures a reliable, safe and user-friendly operation. The displayed information is available for users in a variety of languages. During the sterilization cycle the control system measures, controls and shows in digital display: the time, chamber temperature, chamber pressure and sterilization status. While the power is off, the non-volatile memory keeps the status of the sterilizer, and the real-time clock, driven by its own back-up battery, keeps running the date and time.



- ALARMS** - Depending on the state of the input and of the installed accessories, the controller is capable of displaying and/or printing several alarms, including:
 - Door Unlock
 - Temperature/ Pressure Error
 - Low/High Temperature
 - Low/High Pressure
 - and more.
- CYCLE DOCUMENTATION** - For a clear and concise documentation of processes, the control unit is provided with a 24 character per line printer, connected to the processing unit. This releases a hard copy printing of the relevant information regarding operation during the cycle, such as temperature, pressure, sterilization and number of cycles, etc. In case of an uncompleted cycle, the print-out indicates the cycle failure and the cause of the failure.
- STEAM GENERATOR** - The steam generation takes place in a vessel which is completely separated from the sterilization chamber (i.e. no heating elements inside the chamber itself). The steam generator (18 kW) is built-in into the housing and automatically controlled by the electronic system. The steam capacity is 56 lbs/h.



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Options and Accessories

STANDARD

- REVERSE-OSMOSIS (water softener)**

A Reverse-Osmosis system shall be used to improve the quality of the water used to generate steam in the electric steam generator. The use of mineral-free water will contribute to better performance and longer life of the autoclave's chamber. The water purification system uses a high quality booster pump which can provide 6.8 bar water pressure to pass through the membrane even under low water pressure area. The booster pump prevents damage, prolongs the life of the membrane and improves the TDS rejection of 26.4 or 52.8 liter per day. It is capable of removing over 96% of total dissolved solids +99% of all organics +99% of all bacteria.



- DATA COLLECTION**

Sterilization cycles' data can be collected online on a SD card through an SD card slot, and can be downloaded into a computer equipped with proprietary PC software. 2 GB SD card collects up to 40 years logging data, including: the selected cycle, start time, cycle stages, temperature/pressure, end time, cycle graph, cycle status (pass/ fail), etc. All collected data can be printed via PC.



- WASTE TROLLEY**

Waste trolley for handling and transporting the filled waste bag easier.



- WASTE BAG RING WITH STAND**

Waste bag ring with special design for unloading the treated waste. It can be connected with the chamber's flange and while the chamber is turning to the unloading position the waste can be easily discharged without any interruption.

Waste bag ring stand to hold waste bag ring, when placing the waste bag on it or when it is not in use.



- POLIETILEN WASTE BAGS**

Polyethylene waste bags in two sizes. One for the waste trolley (1400 x 900 x 0.08mm) and one for the waste ring (1850 x 895 x 0.08mm - Ø=550 mm).



OPTIONAL

- MONITORING AND DOCUMENTATION SOFTWARE (HMI SOFTWARE)**

Powerful PC Windows based software is available for monitoring, logging, control and service.



- AIR COMPRESSOR**

The series of FIAC silent piston compressors are the outcome of recent technological research and design. The Compact model features a special soundproofing system made up of a metal soundproof panel, painted with epoxy paint, which guarantees remarkably low noise levels plus the total elimination of vibrations.
(Acoustic pressure < 70 dB).



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Cycle description

ISS AC-575 offers 4 sterilization cycles, 1 test cycle and 1 cleaning cycle.

The recommended load volume is minimum the half of the chamber's useful volume in order to reach optimized shredding result.

1. Waste Sterilization

- Sterilization temperature: 273°F (134°C), 0°F +5.4°F (0°C +3°C)
- Sterilization time: 5 minutes.
- Dry Time: 5 minutes.
- Vacuum pulses: 1.
- Average cycle time: 25-35 minutes.



Cycle Sequence

- **Loading the waste:** Waste is loaded into the chamber. The door closes and the chamber rotates to the operating position (fully vertical). The waste cycle can be started with pressing one button on the full color touch-screen display.
- **Vacuum stage:** The air is being removed from the chamber through the biohazard filter with the help of the powerful vacuum pump.
- **Heating stage:** Steam is introduced into the chamber until the sterilization temperature is reached 273°F (134°C) and pressure of 45,25 psi (312kPa).



Shredding:

The shredder starts working during the heating stage in different speeds, as required and continues working until the end of the cycle.

- **Sterilization stage:** The unit starts sterilizing at 273°F (134°C), 45,25 psi (312 kPa) for at least 3 minutes (can be extended in case of need).
- **Exhaust stage:** The shredder starts working in low speed. Cold water is injected to the chamber to reduce pressure down to 32 psi (220 kPa). When pressure is lower than 32 psi (220 kPa), the fast exhaust valve opens.
- **Drying stage:** Pushing air into the chamber for approximately 5 seconds (till around 17,4 psi (120 kPa)) and releasing it through the fast exhaust valve.
- **Unloading:** The chamber rotates to the unloading position and the waste is evacuated to the bin.



2. Textiles no cut cycle

This cycle is especially for textile waste load without shredding.

- Sterilization temperature: 134°C (273°F), -0°C +3°C, (-0°F +5.4°F)
- Sterilization time: 5 minutes.
- Dry Time: 5 minutes.
- Vacuum pulses: 1.
- Average cycle time: 25-35 minutes.

3. Special Waste Cycle

Special Waste Cycle parameters might differ from the original values in the Waste Cycle, as it can be customized by a local technician, according to the type of the medical waste.

4. Glass Cycle

Glass Cycle parameters differ from the regular Waste Cycle, due to the reduced shredding time (30 sec.) and minimized water injection into the chamber. When Glass Cycle is selected, only glass waste is allowed to be loaded into the vessel.

5. Dynamic test

The purpose of this test is to detect leakages under pressure.

Operations Sequence

- The shredder is operated to create a vortex.
- Vacuum created up to 5 psi (35 kPa).
- Sterilization time: 3.5 minutes.
- No drying stage.
- During periodic Maintenance, or if a leak has been detected during this test, a technician may use leak detection foam to detect the source of leakages during this test.

6. Cleaning cycle

Operations Sequence

- Water and steam are introduced into the EMPTY chamber; steam is introduced to the filter to clean any remaining residues.
- The system holds a temperature of 60°C in the chamber for 5 minutes, while the shredder is working at high speed.
- Drainage of the water and residue into the drain box via the Fast Exhaust valve.
- Adding Water for 2 minutes. The shredder's motor is stopped.
- Pressurizing the chamber to 16 psi (110 kPa) with steam and compressed air.
- Drainage of the water into the drain box via the Fast Exhaust valve.

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Waste Collection and Segregation

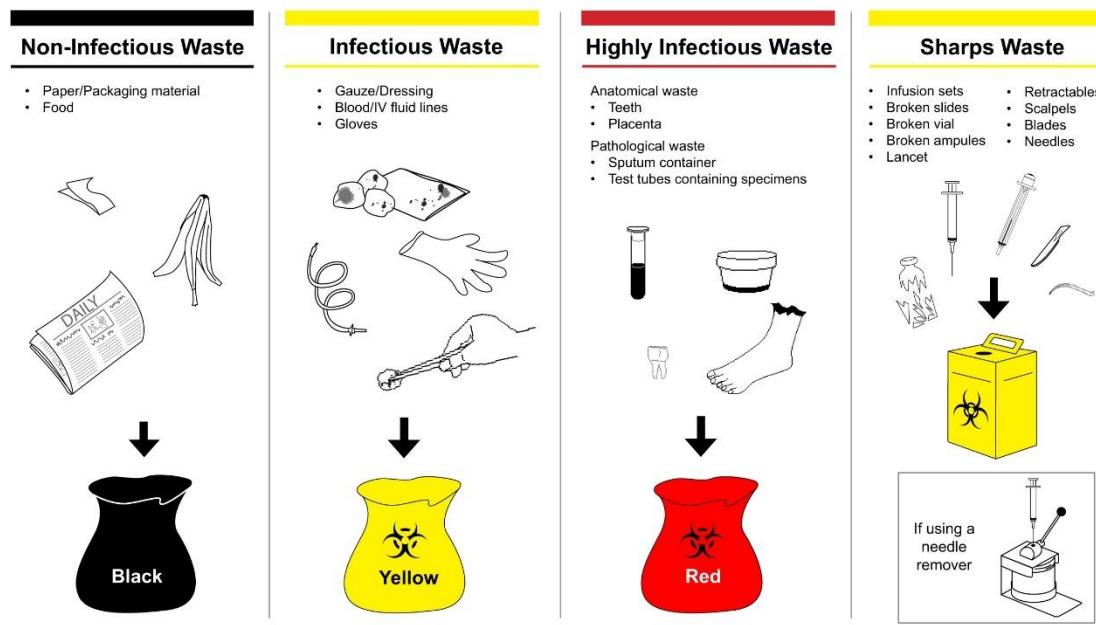
Many countries have national legislation that prescribes the waste sorting categories to be used and a colour-coding system for waste containers. Where there is no national legislation, the World Health Organization (WHO) system is available (see table below. Source: WHO, Safe management of wastes from health-care activities, 2nd edition). Colour-coding makes it easier for medical and hospital staff to place waste in the correct container and to maintain waste segregation during transport, storage, handling, and disposal. Colour-coding also provides a visual indication of the potential risk posed by the waste in a given container.

Type of waste	Colour of container and markings ^a	Type of container
Highly infectious waste	Yellow, marked "HIGHLY INFECTIOUS", with biohazard symbol	Strong, leak-proof plastic bag, or container capable of being autoclaved
Other infectious waste, pathological and anatomical waste	Yellow with biohazard symbol	Leak-proof plastic bag or container
Sharps	Yellow, marked "SHARPS", with biohazard symbol	Puncture-proof container
Chemical and pharmaceutical waste	Brown, labelled with appropriate hazard symbol	Plastic bag or rigid container
Radioactive waste ^b	Labelled with radiation symbol	Lead box
General health-care waste	Black	Plastic bag

The treatment in the ISS requires that different kinds of waste shall be worked upon separately. This requires responsibility of all involved employees at the hospital, so that the segregation of waste is done at the stage of waste generation.

Follow the below recommendations for waste segregation:

Segregation of Medical Waste - Four Categories



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Note: Highly infectious waste (red bags) shall be treated in this machine according to local rules and regulations.

Any segregation method to be implemented shall be in compliance with local rules and regulations.

The Manufacturer's recommendations concerning the sterilization of each type of material/item shall be taken into consideration.

THE FOLLOWING TYPES OF WASTE CAN BE PROCESSED IN THE ISS:

- Sharps Wastes including glass waste (**max. 5-10% / load**)
- Dressing, textiles, gloves (**including diapers, max. 15-20 % / load**)
- Plastic (**up to 90% per load**)
- Paper, packaging material (max. 15-20 % per load)
- Food Waste from healthcare facilities*

Note:: It is forbidden to put into the loads any metal wires and big metal parts, because they can cause malfunctions or damage to the machine.

* The food waste to be sterilized and shredded by ISS shall consist of leftovers from the patients' meals, not of remaining debris from the kitchen, for what other regulations may be applicable.

RECOMMENDED WASTE SEGREGATION FOR THE ISS AC-575

It is highly recommended for hospitals and clinics, producing large amount of textiles (such as infected linens or blankets) and glass to segregate at the point of generation separately from other infectious wastes. This requires responsibility of all involved employees at the hospital. The operator can use the dedicated Textile No Cut, Special Waste and Glass Cycles to treat the segregated hazardous waste.

CONDITIONS

- This device is for indoor use only!
- The sterilizer should be loaded only with the material as described above.
- The environment shall not exceed an ambient temperature of 40°C and a relative humidity of 85% respectively.
- The operation altitude shall not be over 2000 meters (ambient pressure shall not be lower than 80 kPa (11.6 psi)).

REQUIRED UTILITIES

- Electrical: 380-400VAC, 3 Phases, 50Hz, 36kW
- Optional- External Steam: 6kg /hr. at 6 bar
- Water: 30 l/min. cold water, $\frac{3}{4}$ " connection
- Drain connection: Dia. 110 mm
- Compressed Air: 6 bar
- HVAC: Standard computer environment, 10 air exchanges/hour in room, machine connection to outside vent.

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Technical Data	Integrated Sterilizer & Shredder ISS AC-575
External dimensions W x H x D	1290 x 2150 x 2039 mm (50.8 x 84.7 x 80.3 inch)
Maximum depth (door open)	2740 mm (107.87 inch)
Chamber volume, net.	150 liters. (39.6 gal)
Chamber shape	Cylindrical 316L welded, electro polished
Chamber dimensions, inner dia. x depth	500 x 800 mm (19.7 x 31.5 inch)
Approximate weight	880 kg (1940.0 lb.)
Approximate shipping weight with housing	1150 kg (2535.3 lb.)
Shipping dimensions W x H x D for the unit	1160 x 1950 x 1460 mm (45.7 x 76.8 x 57.5 inch)
Shipping dimensions W x H x D for the frame, housing and steam generator	1160 x 1460 x 2220 mm (45.7 x 57.5 x 87.4 inch)
Average water consumption during the cycle	50-75 liters
Average mineral free water consumption during the cycle	6 liters
Max. working pressure	2.7 bar (39 psi)
Min. working pressure	-0.9 bar (-13.5 psi)
Steam source	Saturated steam - 25.4 kg/h steam capacity
Steam pressure (relative)	2.5 bar (36.3 psi)
Compressed air pressure	6.0-8.0 bar (87.0-116.0 psi)
Water source	Filtered tap water
Water pressure	1.0-6.0 bar (14.5-87 psi)
Heaters power	17.4 kW
Peak sound level	86 dB
Average power consumption per cycle	7- 9 kWh
Max electric power	36 kW, 3 phase, 380-400V – 3 x 63A, 50 Hz
Voltage fluctuation	±10%
Operation	Electronic with microprocessor
Controls	Digital
Display	LCD color display, resistive touch screen
Integrated ink printer	Yes (Standard)
Connection to PC	RS232 (Standard)
Unloading accessories	Waste trolley with tray, waste bag ring with stand, polyethylene bags and hook
Maximum solid load	up to 67 kg (148 lb.)
Maximum textile load for waste cycle	20% of the total load
Maximum textile load for textile no cut cycle	10 kg
Minimum recommended load volume	half of the chamber's useful volume
Number of sterilization cycles	4 cycles -1 waste cycle, 1 textiles no cut cycle, 1 special waste cycle, 1 glass cycle
Number of cleaning and test cycles	2 cycles - 1 dynamic test cycle and 1 cleaning cycle
Sterilization temperature	134°C

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Technical Data	Integrated Sterilizer & Shredder ISS AC-575
Air removal	Fractionated vacuum
Drying system	Vacuum/Compressed air
Suggested cycle time (minutes)	Total time: Sterilization waste, textiles no cut, special waste and glass cycles 25-35 min, Cleaning cycle 15 min
Stand-by	Yes
Automatic switch-off protections (night cycle)	Yes
Appearance of face	Painted/Glass
Type of closure	Painted
Automatic water filling	Standard
Automatic water draining	Standard
Manual water filling and draining	No
Door locking device	Fully automatic chamber door locking device with pneumatic system. Cabinet door with safety switch.

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