**SELECTION**

**Chamber useful dimension (average)**
- B0111-100 - 406 x 406 x 630 mm
- B0111-210 - 408 x 408 x 1285 mm
- B0111-300 - 605 x 605 x 880 mm
- B0111-500 - 605 x 605 x 1285 mm

**Application**
- General
- Lactary
- Special cycles

**Control Sensor**
- Sensors with RBC calibration certificate

**Electric Supply Power**
- 220 V 50 Hz
- 380 V 60 Hz

**Door Configuration**
- One door
- Two doors for pass-through installation

**Anti-crushing System**
- With anti-crushing system

**Steam Supply**
- Direct steam (Standard)
- Switch (direct steam more steam generator)
- Steam Generator 18 kW / 30 Kg/h
- Steam Generator 36 kW / 60 Kg/h
- Steam Generator 44 kW / 73 Kg/h
- Steam Generator 52 kW / 86 Kg/h

**Vacuum System**
- Liquid ring vacuum pump 1.5 hp
- Liquid ring vacuum pump 3.0 hp

**Front Cabinet**
- Painted finish (standard)
- Stainless steel

**Lateral closing**
- Without closing (standard)
- Painted finish
- Stainless steel

**Back Closing**
- Without closing (standard)
- Painted finish
- Stainless steel

**Tightness**
- Hospital - Painted

**STIC**

**Air Compressor**
- Network compressed air (standard)
- R0100-040 Compressor (built-in the equipment)
- R0100-170 Compressor (separately)

**Accessories**
- Load rack
- Rack trolleys
- Wire mesh baskets
- Floor support
- Wall support
- Tray support (100/210 models)

**Installation Components**
- Network steam rack
- Steam sanitary filter
- Water valve
- Water treatment
- Compressed air valve

**Services**
- Points installation
- Replacement Parts Kit
- Validation
- Preventive Maintenance
- Training
- Extended Warranty
- Qualification
- Gamp 5 Documentation Folder

**APPLICATION**
Sterilizer designed to meet the most critical sterilization parameters and normative parameters of manufacture and security, being able to sterilizer and dry materials of density such as surgical fields and clothes, packed or unpacked instruments and tools, glasses, gloves, syringes, rubbers, liquids in open vials with $F_0$ calculation, mainly necessary in quality control laboratory with specific program for Bowie & Dick Test and Leak Test. Recommended for use in hospitals, emergency rooms and outpatient care centers, medical clinics, medical analyses laboratories and quality control laboratories.

It uses saturated steam from pressurized water with load conditioning phase with air removal through vacuum pulses, steam pressure and vacuum drying.

**MODELS AND CAPACITIES**
The HI SPEED II family is composed by small, medium and large sterilizers.

- B0111-100 – Capacity approximately of 100 l
- B0111-210 – Capacity approximately of 210 l
- B0111-300 – Capacity approximately of 300 l
- B0111-500 – Capacity approximately of 500 l
**STEAM STERILIZER HI SPEED II**

**MAIN CHARACTERISTICS**

**User setting:** The HI SPEED II family allows the equipment to be set at the purchase, searching for the best adequacy of the equipment to each user's needs.

**User accessible programming:** User-configurable parameters through command interface by password.

**Door:** Guillotine type door, with vertical movement, manually driven with no physical effort. The equipment can be set with single door or double door for pass-through installation.

**Chamber:** built with double wall and isolation in Bidim.

**Pipeline:** Existing pipeline welded in the chamber, in AISI 316 stainless steel.

**Air-tightness:** hospital detachable, facilitating the transportation through narrow corridors during the transportation and installation process.

**Validation:** The equipment is validated according to the procedures of Standard NBR ISO 17665-1.

**STANDARDS**

The projects, materials and construction of the equipment are in accordance with the specifications of the following entities:

- **NBR 11816:2003** – Steam sterilizer with vacuum, for medical devices;
- **NBR ISO 17665-1** – Sterilization of health care products - Steam Part 1: Requirements for development, validation and routine control of the sterilization processes for medical devices;
- **IEC 61010-1:2001** – Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements;
- **IEC 61010-2-040:2005** – Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2 – 040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials;
- **IEC 61326-1:2005** – Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements;
- **EN 980:2003** – Graphical symbols for use in the labeling of medical devices;
- **EN 554:1994** – Sterilization of medical devices – validation and routine control of sterilization by moist heat;
- **ISO 14971:2007** – Medical devices - Application of risk management to medical device;
- **ISO 7000:2004** – Graphical symbols for use on equipment;
- **EN ISO 13845:2003** – Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003);
- **EN ISO 9001:2000** – Quality management systems - Requirements;
- **IEC 60878:2005** – Graphical symbols for electrical equipment in medical practice;
- **EN ISO 15223:2000** – Symbols to be used with medical labels, labeling and information to be supplied;
- **ASME, Section VIII, Division I** – ASME Boiler and Pressure Vessel Code, Section VIII;
- **NBR 5601:1998** – Stainless Steel;
- **NBR 5410:2004** – Low-voltage electrical installations;
- **NBR 5419:2005** – Structure protection against atmospheric discharges.

**REGULATORY PARTS**

- **RDC No 56:2001** – Minimum requirements to prove the safety and efficacy of the medical products;
- **RDC No 59:2000** – Good Manufacturing Practices for Medical Products;
- **NR 13:1997** – Boilers and Pressure Vessels;

**COMMAND, CONTROL AND INSTRUMENTATION**

**Command panel:** Located at a height to facilitate the visualization and operation on the loading side of the sterilizer, containing micro-processed command interface, on/off power switch, start button, manovacuometer for vacuum and inner chamber pressure reading, manovacuometer for external chamber pressure reading, all of them with glycerin to allow stable readings and emergency button. The panel also has an optional printer.

**Secondary panel:** On the unloading side, in the case of double-door equipment, it has indicative lamps, manovacuometer with glycerin for inner chamber vacuum and pressure reading, selector switch to open the door and emergency button.

**Electric panel:** located on the side of the equipment and of easy access for maintenance.

**Feeding Source:** Stabilized and with low voltage output system (24 VCC).

**Electronic command:** Automatic, micro-processed with color touch screen that enables the full parameterization of sterilization cycle phases according to the user's real needs, with possibility of registering up to nine cycles and F parameterization, connection, programming and maintenance. The routines are indicated directly on the screen. It enables real-time visualization of the process parameters and cycle phases monitoring, the interface language configuration by the user with options in Portuguese, English and Spanish. Other languages may be optionally configured by the manufacturer upon request. Command allows, in the operation module:

- **Choice of the sterilization cycle.**
- **Digital reading of the temperature in the chamber.**
- **Digital reading of the inner chamber pressure (only Program “B”).**
- **Digital reading of the outer chamber pressure (only Program “B”).**
- **Digital reading of the descending sterilization time during the sterilization phase.**
- **Digital reading of the descending drying time during the drying phase.**
- **Display of cycle status messages.**
- **Real-time graphic visualization of the temperature and pressure sensors data (only Program “B”).**

**Multifunctional keyboard:** Interface through virtual keyboard on the Touch Screen to select the process parameters and enter cycles programming data.

The command enables the cycle parameters configuration through password within the safety range defined in the design.

**Printer:** The printer can be optionally installed on the frontal panel of the sterilizer and it enables to document the process by registering the time of the beginning of the process, time, temperature and pressure data of the inner chamber during the sterilization process, beginning of the cycle, cycle phases, beginning and end of exposure phase and indication of signature place of operator and supervisor's unit.

The printer consists of a plastic body and a lid that covers the paper reel. It has a thermal print mechanism and uses paper reel of 58 mm wide to print.

**Temperature Control:** electronic temperature control system in the inner chamber through PT-100 class A platinum thermal resistor located at the inner chamber condensate discharge drain. In Program “B”, a second PT-100 sensor can be located in the load to be processed. In this case, the controller will enable you to define if this sensor or the one placed next to the drain is the responsible for the cycle control. This measurement system and the temperature control meet the requirement of standard “ANSI/AAMI ST 8.2001 - Hospital Steam Sterilizers and ruling GMP-212.73.”

Inner and outer chamber pressure control (only in Program “B”): it is executed by electronic pressure transducers manufactured in AISI 316 stainless steel, with electronic temperature compensation and absolute pressure reading, independent on the atmospheric pressure of the location where the equipment is installed. The pressure transducers have from 4 to 20 mA output signal and accuracy of 0.5% full scale (0.5% FE). This system was designed according to standard AAMI ST 45:1992 and rule GMP-212.73 item C. The indications are collected digitally through the panels on the load side, in thousands or hundreds bars.

**Command valves:** They control the steam inlet into the inner chamber and the drain outlet; they are independent and of pneumatic start-up, built in brass.
controlled by compressed air solenoids valves. Electric solenoids valves for control of other supply lines.

CONSTRUCTION
Chamber: Cylindrical, built in double wall. Inner chamber: Built in AISI 316L stainless steel with sanitary polish. Outer chamber: Built in AISI 316L stainless steel. The chamber is tested with hydrostatic pressure equal to 1.5 times the design pressure. Externally, a layer of Bidim minimizes the steam condensation and the heat irradiation.

The set is dimensioned to support the following pressures, according to standard ASME, section VIII, division 1:
- Operational pressure up to 3.0 kgf/cm²;
- Hydrostatic test pressure of 4.5 kgf/cm², for both chambers.

Pipeline: Built in brass/bronze.

Chamber support structure: Built in carbon steel with anti-corrosive treatment. Adjustable casters for system leveling.

One independent validation inlet: located on the lateral side of the chamber, allowing the introduction of sensors to collect process temperature data. It consists of:
- Access by 1” diameter pipe.
- BSP thread.

Inner chamber drain: protected with 1” diameter filter in perforated stainless steel plate. It is located at 300 mm from the door flange on the non-sterile side.

Frontal cabinet of sterilizer: built in carbon steel plate with corrosion protection and painting. Optionally, the cabinet can be supplied in stainless steel plate with brushed finish.

Side closing (optional): The equipment can be supplied with no sides for installation between a double pass-through, enabling free access for maintenance; and optionally with sides in stainless steel plates or in carbon steel plates, with corrosive protection and painting.

Doors: Guillotine type door, with vertical movement, automatic start-up through selecting panel on the command panel. The doors move by the action of a pneumatic cylinder without counterweight, with anti-crushing system (optional) and calibrated closing effort. The door has internal side face built in AISI 316L stainless steel with sanitary polished finish, structural reinforcement in steel gusset, internal insulation with rock wool blanket, asbestos and chloroide free, which ensure external door temperature lower than 50°C, and external surface in carbon steel plate with corrosive protection and painting. Optionally, in AISI 304 stainless steel plate with brushed finish.

The equipment can be provided with single door or double door for sanitary pass-through installation.

A microswitch placed over the door enables the control system to determine when the door is closed. The pneumatic locking system prevents the opening of the door when the sterilizer is in operation.

Silicone gasket: round, activated by compressed air pressure that maintains the tightness of the door during the sterilization process. The gasket, located inside a gasket slot around the rectified door for better adjustment, is activated by the compressed air pressure in the closing and by the vacuum activation when opening the door.

STERILIZATION CYCLES:
The sterilizer has three options of programs available:

- **Program “A”** – Sterilizer provided with nine cycles:
  - Four cycles – Profile for Packages / Instrumentation / Headers;
  - Four cycles – Profile for Latex;
  - One cycle - Bowie & Dick Test.

- **Program “L”** – Sterilizer supplied with nine sterilization cycles specific for Lactary:
  - Four cycles – Profile for Lactary;
  - Three cycles – Profile for Liquids;
  - Two cycles – Profile for Latex.

- **Program “B”** – Sterilizer supplied with nine cycles:
  - Two cycles – Profile for Packages / Instrumentation / Headers;
  - One cycle – Profile for Latex;
  - Four cycles – Profile for Liquids;
  - One cycle - Bowie & Dick Test;
  - One cycle – Leak Test.

- **Packages Cycle**: Indicated for sterilization of textile materials and dense materials. The cycle profile presents the conditioning load phase through vacuum and steam pulses; exposure phase at 134°C and drying phase with mechanical vacuum. All parameters such as the vacuum depth, number of pulses, sterilization temperature and time of each phase are user-configurable through a password.

- **Latex Cycle**: Indicated for sterilization of diverse heat-sensitive materials, such as bungs, polypropylene vials, surgical gloves, silicone tubes, among others. The cycle profile presents the conditioning load phase through vacuum and steam pulses; exposure phase at 121°C and drying phase with mechanical vacuum. All parameters such as the vacuum depth, number of pulses, sterilization temperature and time of each phase are user-configurable through a password.

- **Lactary Cycle –** Cycle for sterilization of milk formulas at 110°C. Cycle for terminal sterilization of nursing bottle. The milk does not resist to high temperatures or long exposure to the heat. Therefore, the cycle only enables the terminal sterilization of the formulas, which must be prepared with aseptic procedures. The cycle profile presents the conditioning phase through single steam pulse; exposure phase at 110°C with time set by user, normally 10 minutes, and slow cooling phase.

- **Instrumentation and Glassware Cycle**: Indicated for sterilization of surgical instrumentation and stainless steel material, or other surface material such as glassware, bowls, tanks and stainless steel tools, and others. The cycle profile presents the conditioning load phase through vacuum and steam pulses; exposure phase at 134°C and drying phase with mechanical vacuum. All parameters such as the vacuum depth, number of pulses, sterilization temperature and time of each phase are user-configurable through a password.

- **Liquid Cycle (Flasks and Culture Medium)**: Indicated for liquids in non-hermetic packages. The cycle profile presents the conditioning phase through single steam pulse, scanning; exposure phase at 121°C and slow cooling phase with end of cycle defined by temperature. In this profile, the user can define the vacuum depth at the initial pulse limited by software in order to avoid the liquid outflow, the scanning phase time, the process temperature and the chamber or liquid temperature to end the cycle. The process can be calculated by F0 value; and calculation based on the temperatures measured by load sensor, when existing, placed in a control vial.

- **Bowie & Dick Test Cycle**: Indicated to determine the equipment ability in promoting the air removal and the steam penetration in the load to be sterilized. Cycle time of 210 seconds and temperature at 134°C, fixed values according to specific regulation definition (GMP). The number of pulses in the conditioning phase, as well as the vacuum depth and steam pressure, can be modified by user in order to adjust it to the profile selected for the sterilization cycles of dense material.

- **Leak Test Cycle**: Indicated to verify the air-tightness of the sterilization chamber. The cycle consists of vacuum pulse, accommodation time and leak verification time. The parameters are factory-set and unchangeable.

- **Flexible programming**: The cycles allow the programming by the user through password. The parameters can be set in the following range:
  - Process temperature between 101°C and 135°C, with degree to degree variation (Program “B”);
  - Number of vacuum and steam pulses between 1
Steam Sterilizer HI Speed II

COMPONENTS AND ACCESSORIES
Configurable for all models of HI Speed II family.
Vacuum system: Through a vacuum pump, unibody type, with water ring. The system is responsible for the vacuum pulses in the initial conditioning of the load and in the final drying. Dimensioned to meet the standard ABNT NBR 11816.
The component can be set at the moment of the order with pump options of 1.5 hp and 3.0 hp.
Steam supply: Equipment with possibility of double steam supply, with supply through central boiler and commutation for supply through incorporated electric generator, when required. Commutation of steam supply between central boiler and electric generator, controlled by IEM.
Steam generator: Optional, the generator is built in AISI 316L stainless steel, with automatic supply through water centrifugal pump. The generator has thermal insulation through rock wool blanket which is protected by a safety valve calibrated and sealed in the operational pressure. The water level is controlled by a float valve, regulated to indicate high or low levels which control the water feed and the safety level, cutting off the power supply of the resistances in case of lack of water. It is built in accordance with standards ASME – section VIII, division I and ABNT NBR 11816. The generator is provided with resistor shielded with electropolished AISI 316 stainless steel. The equipment has standard connection for the direct inlet of the network steam and the steam generation system is optional.
The resistors can be set at the moment of the order, with power options of 18kW, 24kW, 36 kW, 44 kW and 52 kW, with steam production capacity of 30kg/h, 40kg/h, 60 Kg/h, 73 Kg/h and 86 Kg/h, respectively.
Air compressor: Optional item, assembled outside the equipment structure. The compressor has a reservoir with 25 liters of capacity and provides 170 liters/minute of compressed air and pressure of 7.0 kgf/cm².

Electric supply voltage of 220 V – 50/60 Hz.

Clean air inlet for vacuum break: Through bacteriological, hydrophobic filter with efficiency of 99.9997% of 0.22 μm, replaceable, according to NBR ISO 17665-1.

Electric power supply: Three-phase, 220 or 380V, 50/60 Hz.

SAFETY
The equipment presents the following safety items:
- In case of lack of electric power the steam inlet is closed;
- In case of excess pressure the steam duct is closed;
- Safety valve normalized and calibrated at 3.0 kgf/cm², with cleaning and operational inspection device;
- Cycle starts only when there is steam pressure in the generator or in the supply line;
- Automatic door movement system with calibrate operational pressure, for operator protection;
- Impossibility of opening the doors after cycle begins and when there is steam pressure in the inner chamber;
- Impossibility of opening both doors simultaneously by the operator (in case of pass-through sterilizers);
- Blocking of exposure time count, in the lack of temperature defined for the cycle in the inner chamber;
- Safety thermostat for protection of electrical resistances;
- Emergency routine in case of lack of power which keeps the locking of the doors and release steam pressure from the inner chamber;
- Alarm system when water, steam and compressed air feeding fail;
- Emergency button on the equipment display to shut down sterilizer and depressurization in sterilizing chamber;
- Mechanic locking that does not allow opening doors when sterilizer is working.

NOTES
- The total width of the unpacked equipment is indicated in the engineering data table. To make the circulation of equipment inside the building easier, the frontal part can be disassembled, reducing the width. It is important to check the route that will be covered by the sterilizer in the building for the verification of bottlenecks. The release of these points is the buyer's responsibility;
- The gauges connections and supply lines indicated in the technical data table refer to the point of connection to sterilizer. The pipes that carry these supplies to installation sites must be calculated by third-parties and the dimensioning depends on the distance, supply pressures and necessary flows.
- The electric supply power must be supplied from a switchboard, with the protections listed in the technical data table. The switchboard must be installed near the sterilizer;
- Although it is possible to install the equipment with its right side (looking at the sterilizer load front) leaning on the wall, the ideal is to have free access all around the equipment;
- Workspaces are needed in front of the doors, on the side of loading and unloading equipment.

ENGINEERING DATA
Drain (i): The drainage line must be independent from the building sewerage and connected to an external pass-through. When connecting the equipment to the building sewerage line, a sealed connection is not possible and steam will be released in the area.
Electricity (c): the electric panel must have protection by circuit breakers for each load element independently. The panel must be close to the equipment. The feeding voltage must not vary ± 5%.
Water (I1): For the vacuum pump feeding, the water must be supplied at temperatures between 5°C and 15°C. Higher temperatures will make the drying process more difficult. It is recommended water with total CaCO₃ hardness below 170 mg/l, total CaCO₃ alkalinity up to 180 mg/l, total dissolved solids up to 300 mg/l and pH between 6.5 and 8.0. It is recommended the installation of 5 micra filter and manometer to read the pressure in the supply line.
Water (I2): for steam generation the water supplied must meet the requirements of standard NBR ISO 17665-1. A previous water treatment by deionization or reverse osmosis system is necessary.
Steam (h): It must be supplied with pressure between 2.5 and 3.0 bar, with titer above 95% (between 0.95 and 1.0) and free from contaminants and particulate material. A sanitary filter installation is recommended.
Compressed Air (j): It has to have the provision of the filter, pressure regulator and moisture eliminator in the supply line.
### TABLE: ENGINEERING DATA

<table>
<thead>
<tr>
<th></th>
<th>B0111-100</th>
<th>B0111-100P</th>
<th>B0111-210</th>
<th>B0111-210P</th>
<th>B0111-300</th>
<th>B0111-300P</th>
<th>B0111-500</th>
<th>B0111-500P</th>
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<tbody>
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<td><strong>Door</strong></td>
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<td><strong>Filtered water (f1)</strong></td>
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<td><strong>Vacuum Pump of Simple Action Liquid Ring</strong></td>
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<tr>
<td>Average/peak consumption (l/h)</td>
<td>93/200</td>
<td>125/250</td>
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<td>Pressure (bar)</td>
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<td><strong>Deionized water (f2)</strong></td>
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<td>Average/peak consumption (l/h)</td>
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<td>17/35</td>
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<td>Pressure (bar)</td>
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<td><strong>Steam (h)</strong></td>
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<td>Average/peak consumption (kg/h)</td>
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<td><strong>Compressed air (i)</strong></td>
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<td>Average/peak consumption (l/h)</td>
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<td><strong>With generator</strong></td>
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<td>Frequency (Hz)</td>
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<td><strong>Without generator</strong></td>
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<td><strong>Dimensional</strong></td>
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<tr>
<td>Chamber's sizes (mm)</td>
<td>408 x 408 x 630</td>
<td>408 x 408 x 1285</td>
<td>605 x 605 x 880</td>
<td>605 x 605 x 1285</td>
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<tr>
<td>Capacity (l)</td>
<td>100</td>
<td>210</td>
<td>300</td>
<td>500</td>
<td></td>
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</tr>
<tr>
<td>Number of baskets ISO</td>
<td>2</td>
<td>4</td>
<td>6</td>
<td>9</td>
<td></td>
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</tr>
<tr>
<td>External sizes (WxLxH cm)</td>
<td>92.0x98.5x171</td>
<td>92.0x158.5x171</td>
<td>119.5x118x188</td>
<td>119.5x158.5x188</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Package (cm)</td>
<td>108x119x200</td>
<td>108x178.5x200</td>
<td>135.5x118x188</td>
<td>135.5x178.5x217</td>
<td></td>
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</tr>
<tr>
<td>Volume (m³)</td>
<td>2.55</td>
<td>3.85</td>
<td>4.05</td>
<td>5.24</td>
<td></td>
<td></td>
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<tr>
<td><strong>Released heat (BTU)</strong></td>
<td>1500</td>
<td>2000</td>
<td>3000</td>
<td>3500</td>
<td></td>
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<td></td>
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<tr>
<td><strong>Sewer</strong></td>
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<td></td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Drain (i) Ø</td>
<td>1&quot;</td>
<td>1&quot;</td>
<td>1&quot;</td>
<td>1&quot;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Net</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Weight (kg) + load</td>
<td>390</td>
<td>855</td>
<td>885</td>
<td>925</td>
<td></td>
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</tr>
<tr>
<td>Weight (kg)</td>
<td>350</td>
<td>830</td>
<td>850</td>
<td>875</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Gross (kg)</td>
<td>500</td>
<td>960</td>
<td>990</td>
<td>1075</td>
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<tr>
<td><strong>Software Touch Screen</strong></td>
<td>Software “A”</td>
<td>HSA_CLP_1.000 / HSA_IHM_1.000</td>
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<tr>
<td></td>
<td>Software “B”</td>
<td>HSB_CLP_1.000 / HSB_IHM_1.000</td>
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<tr>
<td></td>
<td>Software “L”</td>
<td>HSL_CLP_1.000 / HSL_IHM_1.000</td>
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</tr>
</tbody>
</table>

**Note:**

(*1) The drain must be connected to the drainage line independently from the building sewerage.

(*2) The gauges displayed are those of the equipment connections. The dimensions of the supply piping must be sized by third parties.