

GE 6913 AR-2
ANIMAL SCIENCE GROUP



5102112-010-01

Reporting an accident or incident



Use this information when reporting incidents and accidents involving the unit.

If an accident or an incident associated with the occurs, this must be reported immediately in writing to the address below. The report must be used to identify the cause of the accident or incident and to what extent the occurrence was due to the unit

The unit is a product in the Getinge range.

The unit may also be a sterilizer that is a medical engineering product and which conforms to the EU medical devices directive, or which is constructed in a similar way to a medical device. Under the medical devices directive, the manufacturer must investigate the cause of accidents/incidents that occur and report them to the authorities concerned.

The investigation may lead to changes in new or already delivered devices or in instructions and guidance.

The following circumstances must be reported:

1. circumstances that caused the death of a patient, user or someone else, or that caused serious deterioration in the health of a patient, user or someone else.
2. circumstances that might have caused, the death of a patient, user or someone else, or that might have caused serious deterioration in the health of a patient, user or someone else.

The following information is required:

The manufacturing number of the unit (on a label in the electrical cabinet), Date/time of event, Description of event, Consequences of event.

Contact: Name, Phone number, Address:, E-mail:

The information must be sent by letter or fax to:

GETINGE STERILIZATION AB

For the attention of: Quality Manager

Box 69

31044 GETINGE

Sweden

Fax: +46 (0)35 549 52

Attention symbols

Some of the warnings, instructions and advice in this manual are so important that we used the following special symbols to draw attention to them. The symbols used are as follows:

Warnings



This symbol indicates a warning in the text of the manual. The nature of what the warning relates to is such that it may result in more or less severe injury and in certain cases mortal danger. The symbol is also used to highlight safety components, etc. See “Safety devices - an overview” under “Introduction” in the DESCRIPTION OF OPERATION or under “Maintenance” in the SERVICE MANUAL.

Instructions



This symbol highlights instructions that are important for avoiding damage to the unit and/or load, among other things.

Advice



This symbol indicates important advice and hints that make it easier to work with the unit.

Symbols on the unit

Hot surface

This symbol gives warning of a hot surface.



SERVICEMANUAL

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INSTALLATION

This pre-installation instruction covers the information needed to prepare the installation site, before delivery of the unit.

With the delivery of the machine a specific installation instruction will be enclosed. A copy of the specific instruction is also enclosed in the manual.

The specific instruction may also cover details such as:

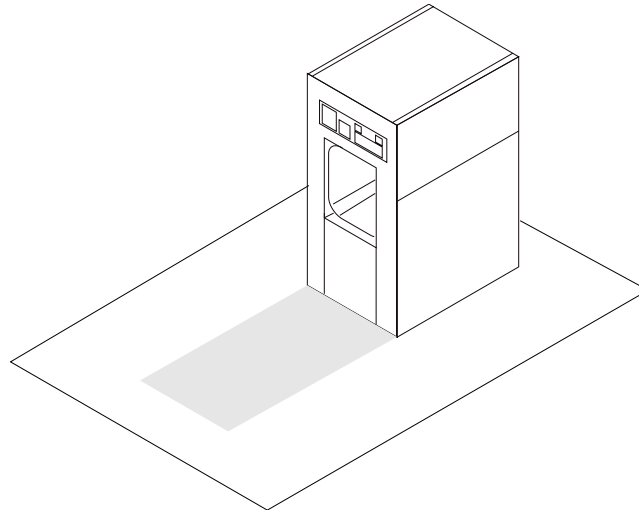
- Unpacking
- Rigging and transportation within the facility
- Reassembly of the dismantled equipment
- Functional test prior to use.

General requirements to be met by the installation location

Use Getinge Sterilization AB's installation drawings for design and building purposes when determining the necessary dimensions and design. Experience has shown that particular attention should be paid to the following points.

- The ceiling height in the service room must be sufficient to allow space for all equipment according to the installation drawing.
- The service room must have good lighting and be ventilated. For requirements regarding ventilation, see the special section on this topic in this instruction manual.
- All dimensions relating to foundations, floor pits, wall openings, etc. refer to finished dimensions. These dimensions must be complied with when floor, wall and ceiling linings have been installed.
- When choosing the wall covering in the service room it should be kept in mind that the room may be filled with steam the event of a failure.
- The equipment must be set up so that the distance to the nearest workplace or treatment position is more than 1.5 meters (5 foot).
- The floor in front of the door(s) of the sterilizer must be flat and level within in a zone as shown in the diagram below. When installing several sterilizers that are to be served by a common loader, the width of this area must be the same as that of the entire installation.

These requirements, and others such as those relating to floor loading, are specified in more detail on the installation drawing.



Installing a sterilizer in a wall opening

- There must be no trim, baseboards or similar objects within approximately 5 centimeters (2 inch) from the edge of the opening next to the wall opening for building in the sterilizer.
- Sterilizers installed in wall openings should be sealed to the wall in order to separate the sterile and non-sterile sides. The edges of the wall opening and the transition between the front plates of the sterilizer and the wall should be finished in a properly hygienic manner.
- **Sterilizers with vertically-operating doors:** These models have a generous gap between the front plates of the sterilizer and the wall opening. The gap must be covered with suitable fitting pieces. Getinge sells an add-on system for this purpose.
- **Sterilizers with horizontally-operating doors** There are two variants: either the front plates are designed to lie outside and overlap the wall, or a gap is left between the wall and the plates. The version with the gap must be sealed with silicone compound or similar. The outside of the front plates meets the wall in this version so that a smooth transition is obtained. The installation drawing shows the specific installation method for a particular sterilizer.



Find out the central point of gravity when lifting and transporting a packed or not packed sterilizer thereby avoiding serious accidents.

Unpacking

- Check when unpacking the equipment that the order No. of its data plate conforms with the ordering No. of the documents.
- Check that the sterilizer is faultless. Any transportation damage should be reported within seven days to the transport company that was responsible for delivery.
- Do not remove the protective plastic film from stainless steel panels until the installation is completed.
- There is certain equipment such as expendable items, control unit, operating instruction and list of programs by-packed the sterilizer inside the chamber. The two latter are to be posted where easily observed by the operator at work.



Please note that those articles are adapted for each sterilizer. When unpacking more than one sterilizer the articles are not to be interchanged.

Internal transport

It is recommended that a transport firm experienced in dealing with heavy lifting should be appointed when the autoclave is to be transported to its intended position.

The autoclave must if possible be lifted by the lifting eyes on the top of the chamber. Where this is not possible, it may be lifted with a jack using the four brackets welded into the sides of the chamber slightly above the bottom of the chamber. The autoclave is transported by placing 'roller-skates' underneath the chamber legs and rolling the autoclave into position.

If the door lintel at the time of delivery is fitted on the chamber and has to be disassembled for internal transport, this can be done as follows:

- Loosen the four retaining screws underneath the door lintel.
- Pull the door lintel sideways out of the ball bushings in which the door is suspended.

When the autoclave is in position, re-fit the door lintel in the reverse sequence.

Storage

The unit must be stored in a temperature between 2 and 40°C (35 and 105°F) and at a maximum relative humidity 95% (non-condensing).

Installation

- Observe national and local regulations concerning service space.
- Make sure that the clearance distances required by health and safety regulations are provided.
- Place the sterilizer close to but never over a drain. Make sure there is sufficiently wide workable space on the service side. Take into consideration the requirement for a clearance distance to an electric cabinet, normally 0,7-1 meters (27-40 inch) depending on specific standard. The rear (single-door sterilizer) and the other long side can be positioned alongside a wall, but there should preferably be working space here too. See also diagrams and drawings.
- Replace the bolts that served as feet during transport with the feet supplied with the unit (delivered in the chamber).
- Adjust the legs so that the chamber side is vertical and the chamber floor is horizontal in depth, while checking that the prescribed loader height is maintained. See also the instructions on the installation drawing for the particular sterilizer concerned.

Connection



Certain types of installation work, water and electrical, for example, should be done by authorized technicians. If the work is not done properly, injury and damage may result.

Faulty installation work invalidates the warranty on the product supplied.

Pipework and electrical wiring should be done in a professional manner so that the service compartment looks workmanlike and provides a practical workplace which minimizes the risk of accidents.

- Find out the connection points and connection data of the equipment by studying the installation drawings.
- Pay attention to local regulations.
- Remove debris by flushing or blowing through all pipes that will be connected.

- Insulate hot and very cold pipes.
- Mark pipes and electrical wiring.



Install shut-off devices in the media supply lines near each unit, so that the operator can use them without passing through a risk area. The inner part of the service compartment is not a suitable place for this.

Refitting the door

It is important that the sterilizer chamber is first correctly installed and aligned in accordance with the applicable installation instructions before work starts on refitting the door parts.

For various reasons: packing material, method of transport, intake dimensions at the user etc., the door parts may be delivered dismantled to a greater or lesser extent.

Because of the low propulsion force imposed for safety reasons, the door must be correctly hung so that it runs between its end positions with no friction other than that caused by the ball bushing.

When the lintel has been removed.

The descriptions of installation of the lintel refer to the two illustrations A and B which follow the text. Note that references in the description for the aluminum door bar (type A) also refer to the more complete illustration on the right (type B).

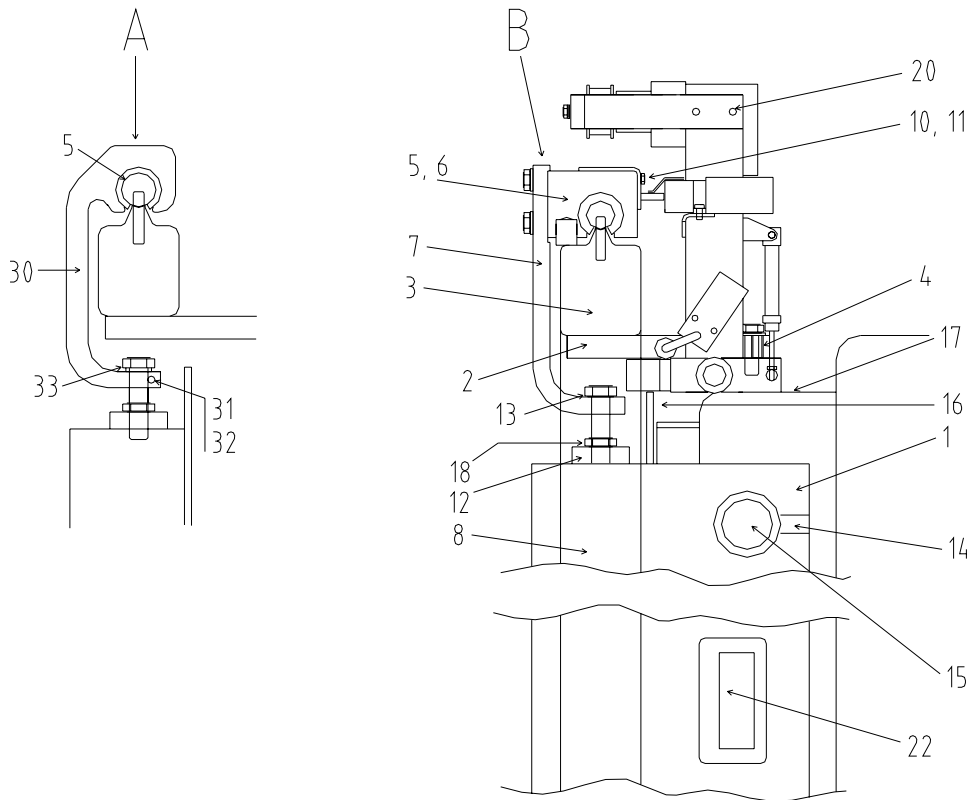
Smaller sterilizers with aluminum door bar (type A):

- Lift up the lintel unit (3) on the lintel brackets (2) and make sure that the suspension screws with washer (33) under the screw heads are positioned in the slot in the door bars.
- Secure the lintel with screws and install locking screws (32) with locknuts (31) in the door bars.

Larger sterilizers with stainless steel door bar (type B):

- Lift the lintel unit (3) on to the lintel brackets (2) and fix it with the screws.

- Attach the support brackets (7) in the bushing housing (6). Make sure that the upper fixed shoulder of the suspension brackets make contact with the machined upper faces to the bearing housing.



This applies to all types:

- In the standard version, sterilizers with door openings larger than 672 x 920 mm are fitted with a side pillar for the projecting part of the door lintel. Install the support pillar under the lintel and adjust it so that it neither hangs loosely nor is under such strain that the door lintel is deformed. If the lintel is deformed, and not horizontal, the door will move more stiffly in one direction on opening, and this will interfere with the door or prevent it opening.

When door motor has been removed.

- Install the motor unit with the screws (20). Positioning as shown on drawing above.
- Secure the toothed belt at both ends of the bearing connection. The toothed belt must be slightly slack so that the pneumatic motor can overcome its friction at rest on starting, without having to pull the door. For further information, see under *Changing the toothed belt* in the DOOR chapter.

Transport lock and general checks

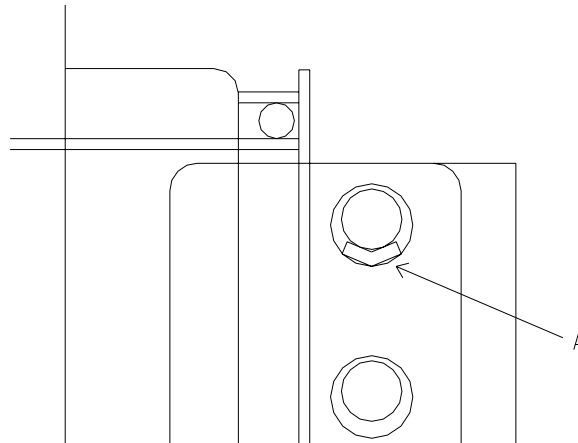


DO NOT REMOVE the piece of metal that locks the door for transport until the steps described in the section “When the lintel has been removed” above have been done and checked.

- Remove the transport locking device at the side of the door.

Sterilizers with moving door seal:

- Lift the door to remove the transport supports (A) located under/above some of the bolt pins.



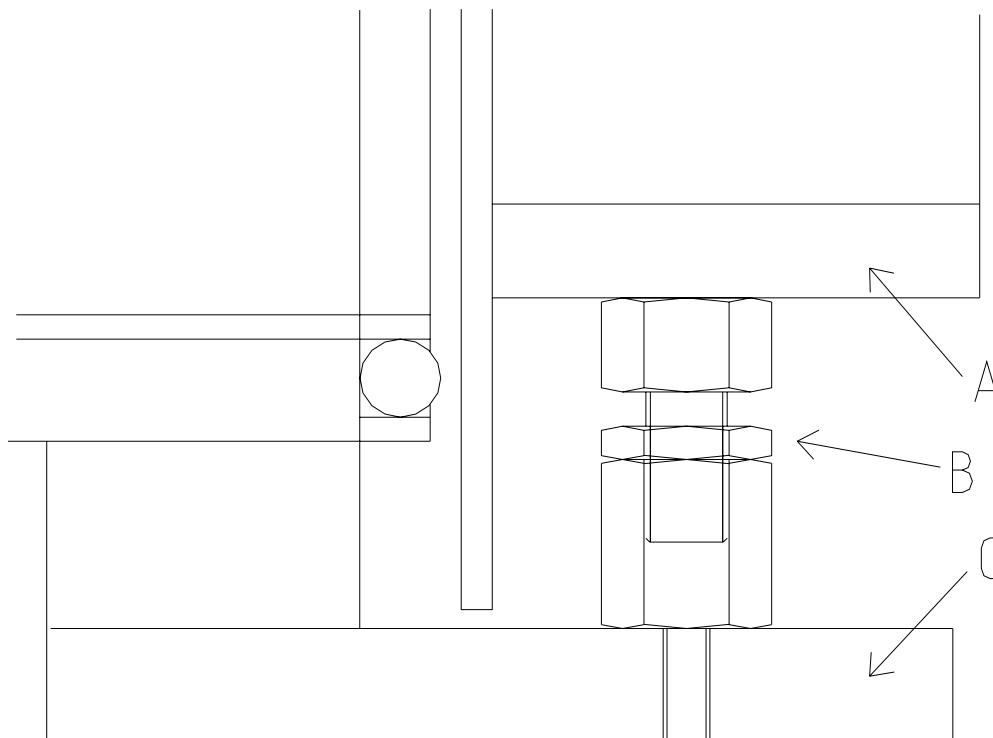
- This can be done with a large screwdriver or crowbar inserted in a bolt hole. If the doors are heavy, a jack can be used to lift them.



Never lift the door by the suspension screws (13) as this will affect the height setting.

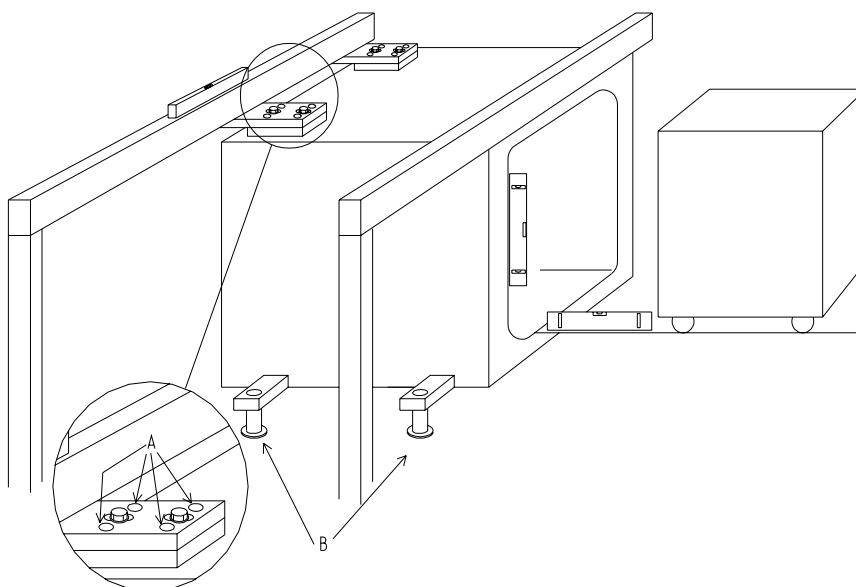
Sterilizers with fixed door seal:

- Remove the transport supports (B) located between the bottom edge (A) of the door and the door threshold fixing brackets (C).



- Use the built-in thread mechanism of the transport supports to lower and release the door.

Leveling the chamber



- Check at several points along the top of the lintels that they are horizontal. Use an accurate spirit level when doing this check.

- If the lintel is not horizontal the chamber might not be correctly leveled. If necessary, adjust the feet / support points (B) of the chamber so that the lintels are horizontal.



Leave the adjusting screws (A) of the lintel fixings alone. The adjustment must be done with the support points of the chamber (B).

- Check that the seal plane of the chamber coincides with the plumb line and that the distance between the door plane and the seal groove is more or less the same all round the door. If it is not, the chamber might not have been properly leveled. HINT: A long spirit level and spacers of equal thickness can be used when checking.
- Check also that the chamber floor fits the load equipment.
- Correct the chamber by adjusting the support points if necessary.



Note that the seal planes of large chambers are not entirely parallel, because of the limited manufacturing tolerances that can be achieved on such large welded constructions.

If possible, any deviation from the vertical should be distributed between the sides during assembly at the factory, and this also applies to erection at the user's premises.

This applies to all types:

- Carry out all checks in accordance with sections of the type *Checking and adjusting the ... of the door* in the DOOR chapter.
- Pneumatic motor:
The closing force according to the applicable standard (IEC 1010-2-41) must not exceed 150 N. At the time of delivery, Getinge's door system agrees with this regulation.
- Carry out function checks on the door before taking the sterilizer into service, as described under FUNCTION CHECK.

Electrical



Before welding on or near the sterilizer, ALL plug-in leads must be disconnected from ALL the PCBs of the control system.

Components in the control system of the installation and other electrical components tolerate supply voltage variations of -10/+5 %. If greater voltage variations are likely, a mains voltage stabilizer will have to be provided between the mains circuit breaker of the installation and the control equipment. As the equipment will present an inductive load to the stabilizer, the stabilizer should be well oversized (at least 500 VA). Permitted frequency deviation $\pm 1\%$.

- Check that all terminal screws are tight..



General: Connect the equipment through a nearby multi-pole lockable, safety-marked switch to a three-phase supply with non-disconnectible protective earth conductor.

In the planning phase: Concerning voltage and frequency, mains circuit breaker ratings and wiring sizes, see the document "Technical data".

When connecting the equipment: connect as shown on the wiring diagram. The drawing number is given in the documentation of the equipment.

- If the building where the equipment is installed has a separate equipotential bonding system, a wire must be run from this to the earthing (grounding) terminal of the surge protection. The surge protection is located in the terminal box. See the wiring diagram.
- If the control system of the equipment is to be connected to a standalone computer, the power supply to the computer should be taken from the the same distribution board as the equipment is connected to. Common supply is important in order to avoid potential differences and therefore the risk of damage to the electronic circuits of the equipment.
- A printer used to print from the equipment must be connected in accordance with the wiring diagram. Normally it will take its supply directly from the electrical system of the equipment. Some equipment has sockets for a printer. If so, these are marked with the symbol for heavy current and the text **E 110** and **230 V**. The signal cable is connected to a multipole socket marked **E 110**.



- A printer used elsewhere must be powered from the same distribution board as the equipment. Common supply is important in order to avoid potential differences and therefore the risk of damage to the electronic circuits of the equipment.
- The supply cable to the sterilizer should be run so that the temperature rise in the cable due to its insulation and ambient temperature remains within permissible limits.
- The routing and overcurrent protection of the supply cable must be such that the sterilizer cannot be subjected to short-circuit currents exceeding 6 kA.
- The following requirement is applicable in countries where IEC 61000-3-3 applies: Equipment with a current less than 16 Amps on each phase which is supplied from a public power distribution system applies to the directive. The public power distribution system must at least be capable to provide 100 Amps on each phase or have an impedance of $Z[\text{ohm}] = 0,15 + 0,15 \cdot i$.
- Load-breaking switches in accordance with IEC 898, with B or C characteristic, are recommended for circuit protection. If such switches are not available, protection can be provided by IEC 269-1 fuses, characteristics gG or gM.
- Vacuum pumps, fans, pumps and motors located in separate rooms away from the common service area of the installation must have their own individual multi-pole, lockable, safety-marked switches. A switch of this description must always be installed close to the motor.
- **Vacuum pumps and pumps for liquids:** First make sure that the feedwater tanks and pipework are filled with water. Then check that the direction of rotation of the pump is correct by **briefly** operating the pump contactor by hand. Correct this as shown in the drawing below.



Running the shaft seal dry could destroy it in just a few seconds.

- **Fans and three-phase motors:** check that the direction of rotation is correct by **briefly** operating the motor contactor by hand. Correct this as shown in the drawing below.
- **Correcting the direction of rotation:** Swap two of the phase wires in the supply cable between the motor and the contactor. For some equipment the “contactor” may take form of a frequency converter or soft-starter.
- It is recommended that the three-phase supply should be protected by an earth leakage circuit breaker with a 300 mA trip current.

ESD (Electrostatic discharge)



ESD damage in installation and servicing may destroy the electronic equipment. Read the instructions below BEFORE starting work.

ESD damage

ESD is an overall term describing how electronic circuits are damaged by the static charging to which they are exposed when they come into contact with electrically charged objects. Virtually all non-earthed objects in the world around us have a static charge. Equipment and people are imperceptibly charged by friction in the air or between shoes and floor in ordinary walking. This charge is transferred to the electronic circuits when they are touched.

Any damage that occurs to the electronics may be difficult to detect and trace. It varies from immediate destruction of a circuit so that it no longer works at all to insidiously affecting operation so that performance is not maintained. The circuits may even appear to be undamaged and then later disintegrate inexplicably.

Most replacements of electronic boards where the fault cannot be explained and is blamed on uneven quality are probably due to ESD damage.

Requirements for protection in installation and servicing

GETINGE has ESD protection integrated into the production and testing of electronic equipment and also requires ESD protection to be used after delivery for the warranty to apply.

Damage usually occurs after delivery if electronic boards are stored in non-ESD-approved packs, if electronic boards are placed on non-ESD-protected work surfaces or if people not wearing ESD protection touch them. Simple equipment can be obtained for all these situations which prevents charging and therefore ESD damage. Contact your local distributor of ESD protective equipment or GETINGE After Sales.

Practical requirements

- Keep electronic boards only in screened and ESD-approved (marked) bags.
- Use ESD pads connected to earth in accordance with the manufacturer's instructions to hold disassembled or new electronic boards during assembly work.

- Do not touch electronic boards with tools that may be charged, e.g. screwdrivers with a plastic or wooden handle. Use earthed tools if necessary.
- Always use an ESD wrist band connected to earth in accordance with the manufacturer's instructions when working in the electronic enclosure or when handling boards.
- Never keep foreign objects such as drawings or plastic pockets inside the electronic box.
- Test the ESD protective equipment regularly.

Incoming media

General safety requirements for supply lines

The document Technical Data states permitted pressure levels for all incoming media.

If the stated pressure of the medium does not exceed the design pressure of the pressure vessel, the equipment does not normally have protection against excessive pressure for that medium.

Where the supply medium pressure (as stated in Technical Data) exceeds the design pressure of the pressure vessel, the equipment is protected against excessive pressure for a well-defined inflow rate of that medium. The protection takes the form of a specific safety valve and suitable designed restrictions and valves in the internal pipework.

To ensure that the equipment is only supplied at the permitted pressure levels, the user must accept liability for fitting the supply lines with reducing valves and safety valves in accordance with the regulations.



Whether or not the sterilizer is equipped with a safety valve, the user must install correctly dimensioned safety valves in the supply lines for incoming media.

Note that the pressure vessel safety systems cease to operate if the pressure of any medium exceeds the range stated in Connection data. This results in a RISK OF BURSTING.



Note that this is a general document which describes many different grades of media and methods of connection for a large number of variants of Getinge products.

For more specific information, see the document “Technical Data” and the other specifications of the appliance.

Waterquality

Driving liquid for the vacuum system

TEMPERATURE

The highest water temperature for maximum performance for the vacuum system is 15 °C (60 °F). This temperature may be exceeded by 5 °C (10 °F) if reduced depth of evacuation and capacity can be accepted. This applies primarily to sterilizers of the EN model, i.e. designed for the European market.

Certain models intended primarily for tropical climates can easily be modified for use with water temperatures up to 35 °C (95 °F). This topic is covered under "Connection and pressures" in this section and in the section headed "Customer-programmable functions" in the SERVICE MANUAL.

HARDNESS

To minimise sterilizer service and maintenance costs, the water hardness should not exceed 4dH (0.7mmol/l). A water softener is recommended where the water is harder than this.

Cooling water for heat exchangers

TEMPERATURE

The highest water temperature for satisfactory performance is 15°C (60°F). This temperature may be exceeded by 5°C (10°F) if reduced performance is acceptable.

WATER QUALITY

To minimise service and maintenance costs, the water hardness should not exceed 4dH / (0.7mmol/l) / (70 ppm). A water softener is recommended where the water is harder than this. The cooling water must not be corrosive, nor must it contain substances that are abrasive or which form deposits. The water salt content should not be so high as to cause scaling as a result of the temperature.

Connecting water

Common water supply

Some equipment in the basic version is supplied with water from a single common connection to the sterilizer. This means that the water temperature and hardness are the same for all the water-using equipment.

The water must always be colorless, with no solid contaminants such as sand, flakes of rust, graphite, etc. The content of other substances

may vary, as previously mentioned, and the temperature should be suited to the requirements of the vacuum pump sealing water. If the sterilizer is connected to the drinking water supply, requirements for Back flow prevention must be observed; see *Connecting with reverse siphon protection*.

Separate supply of cooling water from a closed cooling system

If the equipment has been ordered with a separate cooling water circuit for connection to a closed-circuit cooling system, the cooling water circuit will have its own connection point. Back flow prevention can be provided in the closed circuit if it is considered appropriate, see *Connecting with reverse siphon protection*.

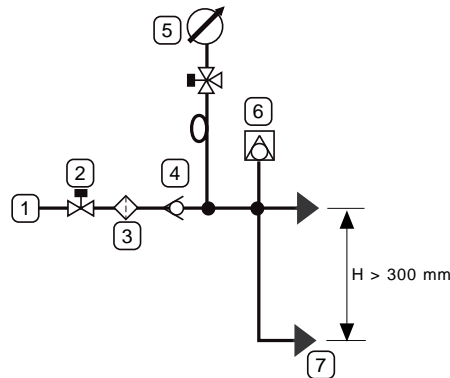
Connection with reverse siphon protection

Any connections made to a drinking water supply must comply with national and local regulations. In countries where EU regulations apply, the national requirements will gradually be complemented by harmonised EN standards, regulating the connection and prescribing equipment for such purposes as reverse siphon protection.

Reverse siphon protection

When the equipment is installed, an approved (and, in certain cases, type-tested) reverse-siphon protection device must be fitted in the supply line. Details of the particular types of reverse siphon protection devices that must be used, and how they must be installed, are regulated by the responsible authorities in each country.

- In the absence of specific rules for connection, we recommend that a connection to the drinking water supply should be arranged as follows:



| | | | |
|---|---|---|---------------------------|
| 1 | Main supply line | 2 | Shut-off valve |
| 3 | Filter | 4 | Non-return valve |
| 5 | Pressure gauge, including water pockets and isolating valve | 6 | Reverse siphon protection |
| | | 7 | Connection to sterilizer |

- The above components should be supplied by the customer unless the contract states otherwise.

Pressure

- **For service water systems:** Normally the equipment is supplied via a shutoff valve to a water pipe system with a positive pressure of 3.5 to 6 bar(e), equivalent to 350 to 600 kpa(e) or 50 to 90 psig. Models for certain markets and models that can be converted for tropical conditions can be connected to pipe systems with a pressure as low as 1.0 bar(e), equivalent to 100 kpa(e) or 15 psig. Precise information about pressures, temperatures, consumption rates and connection size for each medium is given in the Technical Data document. In case of doubt, Technical Data always takes precedence.
- **For closed systems:** Normally the equipment is supplied via a shutoff valve to a circulating system with a positive pressure of 3.5 to 6 bar(e), equivalent to 350 to 600 kpa(e) or 50 to 90 psig. Note that the pressure in the return line must normally be at least 1.0 bar lower, equivalent to 100 kpa lower or 15 psi lower. Precise information about pressures, temperatures, consumption rates and connection

size for each medium is given in the Technical Data document. In case of doubt, Technical Data always takes precedence.



The Technical Data document states a permitted pressure range for all incoming media. Always check that the equipment is connected to supply lines in which the pressure is within the correct range.

Note that the pressure vessel safety systems cease to operate if the pressure of any medium exceeds the range stated in Technical Data. This results in a RISK OF BURSTING!

Steam

The result of a sterilization is very dependent on the nature of the steam used. The steam must therefore meet certain quality requirements.

Steam generators based upon evaporation from high pressure hot water should not be used since the steam produced is of inferior quality for sterilization purposes.

Minimum cleanness requirements

The following are minimum cleanness requirements, but may be regarded as normal requirements to be met by steam for heating in heat exchangers and jackets. It is the user's responsibility to choose the steam quality for sterilization, taking account of local regulations and official requirements.

1. Solid particles such as welding pellets, graphite, rust flakes, sand etc must not occur, since the steam comes into physical contact with the goods to be sterilized. These impurities may also block steam traps and chokes.
2. For the same reason, liquids must not occur, except very small amounts of water.
3. Gases will prevent close contact between the steam and the micro-organisms to be killed. They must be kept below the proportions below.
 - Hydrazine (N₂H₄) max 0.11 mg/kg (ppm) steam.
 - Ammonia (NH₃) max 5 mg/kg (ppm) steam.
 - Air and/or non-condensable gases max 7 ml (0.25 oz) per 200 ml (6.75 oz) condensate, formed by the steam-air/gas mixture.

4. Other chemicals such as softener residue and similar substances must not occur in sterilizing steam.
 - Salt content max 1 mg/kg (ppm) steam.

Analysis of condensate

An analysis of the condensate from the steam gives an idea of its cleanness as regards other substances. These substance should not occur in concentrations exceeding the values given in mg/kg condensate in the table below.

Evaporation residues 1.0 mg/l (ppm), of which:

| | |
|---|-------------------|
| Silicon in the form of SiO ₂ | 0.01 mg/kg (ppm) |
| Iron | 0.1 mg/kg (ppm) |
| Cadmium | 0.005 mg/kg (ppm) |
| Lead | 0.05 mg/kg (ppm) |
| Other heavy metals | 0.1 mg/kg (ppm) |
| Chlorides | 0.1 mg/kg (ppm) |
| Phosphates | 0 mg/kg (ppm) |

Recommended pH = 5 - 7

Suitable conductivity < 3 µS/cm [at 20 °C (68°F)]

Suitable hardness ≤ 0.1 dH (1.8 ppm)

Steam of the quality specified below under Process steam is recommended for the sterilization of products that come into direct or indirect contact with the human blood circulation, where there are very stringent requirements for cleanness.

Process steam

In accordance with cGMP, the chemical content of the steam must conform to the requirements for WFI of the European Pharmacopoeia (EP) 3rd edition 1997, United States Pharmacopoeia (USP XXIII) and/or another local pharmacopoeia.

Alternatively, steam with a chemical content equivalent to clean steam for sterilization as per HTM 2031 may be used if the user's local regulations and official requirements allow it.

Pressure

- A See the document “Technical Data” for correct information about steam pressure.



If the steam supply line pressure exceeds the steam pressure stated in Connection data, the user must install a pressure reduction unit with a suitable safety valve which has sufficient blow-off capacity for the amount of steam supplied.

- B Permitted pressure variations max ± 0.1 bar (equivalent to ± 10.0 kPa or ± 1.5 psi).

Moisture content

Sterilizers should be supplied with dry saturated steam. The ideal physical state “dry saturated” is difficult to maintain in a practical application, and measurement/control of the moisture content of the steam is tricky .

Applying the advice given below, which is based upon practical experience, will generally result in steam with a satisfactory moisture content. This means that it is not superheated either. Superheating of the steam is highly undesirable in connection with sterilization because it does not contribute the humidification necessary to kill micro-organisms.

Methods and values for determining the quality of the steam and the degree of superheating are described in standard EN285, for instance.

Practical arrangements

1. Connect the equipment to a line in which steam is consumed continuously. Long branch connections should be avoided.
2. Choose the appropriate pipe size from the table below. If more than one piece of equipment is connected to the same line, a diversity factor of 0.8 or higher may be applied.

| Steam pressure | Highest design gas velocity |
|--------------------------|-----------------------------|
| 2.5 [bar (e)], 36 [psig] | 38 [m/s], 125 [feet/s] |
| 3 [bar (e)], 45 [psig] | 35 [m/s], 115 [feet/s] |
| 4.5 [bar (e)], 65 [psig] | 30 [m/s], 100 [feet/s] |
| 6 [bar (e)], 90 [psig] | 25 [m/s], 80 [feet/s] |

The specific steam pressure of the equipment is given in the document "Technical Data". If the installation is to be connected to a steam supply at a different pressure, the table can be used for guidance. If in doubt, contact Getinge Sterilization AB.

3. The steam supply pipes should have a fall of at least 1:50 (1/4 inch per foot) in the direction of flow.
4. Install reducing valve(s) in the supply line if the pressure is higher than that specified in Technical Data. The steam pressure upstream of the reducing valve should not fluctuate more than 10%.
Do not reduce the pressure by a factor smaller than 0.5 in one step. Use a second reducing valve for greater reduction ratio. Each reducing valve must be followed by a safety valve.



If the steam in the supply line is wet, include condensate removal as shown in Figure "A" just before the reducing valve, as shown in the sketches below.

The drain line of safety valves should have at least the same dimension as the valve blowoff opening and must not contain shut off devices or chokes. Water pockets formed in the piping, must be drained.

5. There must be no chokes or restrictions placed in horizontal pipes.
6. Fit the last reducing valve not more than 6 m (20 ft) pipe length away from the sterilizer, but not closer than 4 m (13 ft) if the maximum reduction ratio (2:1) is used.

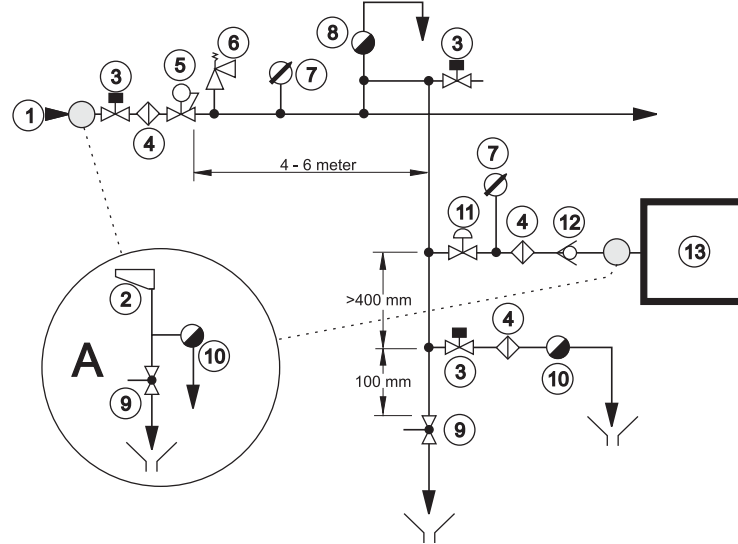


If the reducing valve is positioned much more than 6 meters (20 feet) from the sterilizer, include condensate removal as shown in Figure "A" just before the sterilizer.

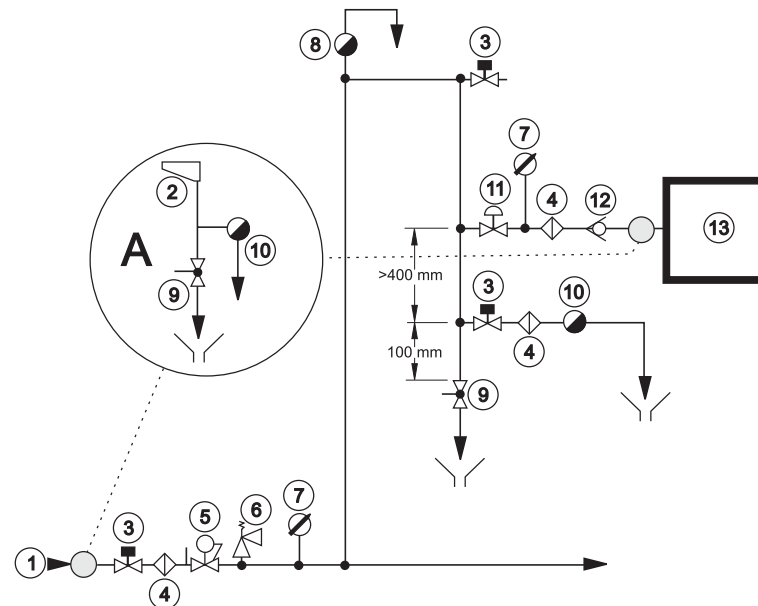
7. The last condensate removal device (see figure below) should not be placed more than 1 meter (3 feet) away from the sterilizer steam connection. If this is not possible for practical reasons, a steam dryer can be installed directly at the steam connection.
8. There should be no steam consumers other than sterilizers, steam converters or treatment stations (WSSD) connected downstream of the last reducing valve.
9. Branch pipes should be connected to the top of a horizontal main pipe.
10. A steam sampling point with shutoff valve should be provided between the reducing valve and the sterilizer so that the quality of the steam can be checked. The sampling point can also be used for blow-down in preparation for work that requires the steam system to be depressurized.

11. Because it is intended to be used daily, the shut off valve should be easy to operate, for instance a remote controlled ball valve.
12. Insulate steam pipes up to the sterilizer steam connection.

An arrangement as shown below normally satisfies the requirements for dewatering, filtration and monitoring facilities when supplying a sterilizer with steam from a main steam supply line.



Supply line in ceiling.



Supply line in floor or in the storey below.

| | | | |
|---|--------------------------------|----|-------------------------|
| 1 | High-pressure line | 8 | Vent |
| 2 | Labyrinth diverter / separator | 9 | Ball valve |
| 3 | Shut-off valve | 10 | Steam trap |
| 4 | Filter | 11 | Remote-controlled valve |

| | | | |
|---|----------------|----|-------------|
| 5 | Reducing valve | 12 | Check valve |
| 6 | Safety valve | 13 | Sterilizer |
| 7 | Pressure gauge | | |

Compressed air quality

Instrument air

To ensure long life and reliable operation, the pneumatic components of the equipment must be connected to a compressed air network that supplies dry air with a low content of particles and oil.

Modern compressed air components are lubricated for life, so there is no need for oil to be added to the instrument air. The air must obviously not contain any solvents or abrasive or corrosive foreign substances that may damage the pneumatic components.

According to international standards, air quality is divided into classes.

| ISO 8573-1 quality classes | | | | |
|----------------------------|---|----------------|--------------|-----------------|
| Quality class | Content of contaminants Size and max conc. | | Dewpoint | Oil content |
| | µm (µInch) | mg/m3 (ppm) | °C (°F) | mg/m3 (ppm) |
| 1 | 0,1 (4) | 0,1 (0,08) | -70 (-94) | 0,01 (0,008) |
| 2 | 1 (39) | 1 (0,8) | -40 (-40) | 0,1 (0,08) |
| 3 | 5 (197) | 5 (4) | -20 (-4) | 1,0 (0,8) |
| 4 | 15 (591) | 8 (6) | +3 (+37) | 5,0 (4) |
| 5 | 40 (1600) | 10 (8) | +7 (+45) | 25 (20) |
| 6 | - | - | +10 (+50) | - |

Where the equipment is connected to a common supply of process air and instrument air, the levels recommended below may be unacceptable for process air from a hygienic point of view.

Getinge recommends instrument air in the following classes:

- Contaminants content Class 3 or better.
- Dew point Class 4 or better.

- Oil content Class 3 or better.

Air connection

Instrument air only

Some equipment in its basic version has only instrument air. Refer to the practical arrangements below. Any non-return valves, filters, etc. are supplied by the purchaser, unless the contract states otherwise.

Common supply

If the user's requirements for air quality and the compressed air network can meet the peak loading of the equipment without the pressure dropping below 6 bar(g) / 600 kPa(g) / 85 psig, process air and instrument air can be connected to the same compressed air network. A check valve and sterile air filter, if required, should be supplied by the customer unless otherwise stated in the contract. See "Technical data" for details of peak consumption, etc.

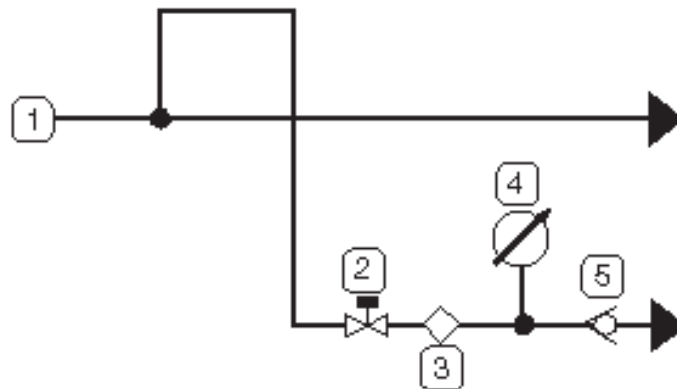
Separate supply

Some equipment with a high peak process air loading is intended to be supplied separately with process air and instrument air. The equipment may not operate properly and may be unsafe if the pressure in the instrument air supply falls because of high process air consumption. Any check valves, filters, etc. must be supplied by the customer unless the contract states otherwise. See "Technical data" for details of peak consumption, pressure, etc.

Practical arrangements

Connect the air connections of the equipment via a shutoff valve to a compressed air network with a pressure of at least 6 bar(g) / 600 kPa(g) / 85 psig and no more than 8 bar(g) / 800 kPa(g) / 115 psig. See also the

document “Technical data”. Where information is contradictory, “Technical data” always takes precedence.



- | | | | |
|---|------------------|---|----------------|
| 1 | Main supply line | 2 | Shut-off valve |
| 3 | Filter | 4 | Pressure gauge |

Drain

Waste pipes must be piped to the floor drain without restriction or back-pressure. Drains coming from different parts of the equipment must not be combined (when existing).

Comply with local regulations relating to waste water (addition of formalin, temperature restrictions, etc.).

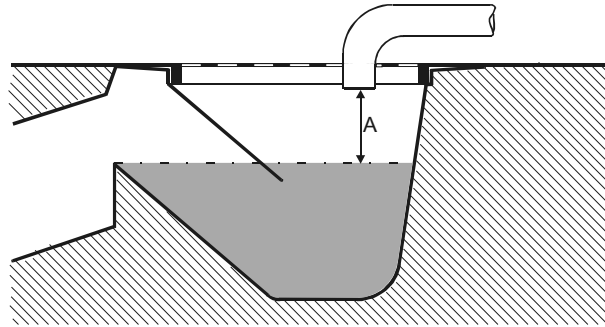
Drains from the equipment are run through separate pipes, for contaminated and non-contaminated water respectively. The contaminated water must always run directly to waste.



The non-contaminated water - mainly used as cooling water - can also be recycled and, after cooling if necessary, can be re-used as cooling water. See also above under “Cooling water for heat exchangers”.

- Run the drain pipe(s) with a fall towards the floor drain, where it/they must terminate at a distance of at least two pipe diameters above the highest water level of the water trap, but at least 20 mm (1”) above

the water level (dimension A). Pipes less than 1.5 m (5 ft) long require only a minimal fall.



- Design the waste pipes for short duration temperatures of about 100°C (212°F)..



Plastic waste pipes should be avoided, as a loss of cooling medium may result in the outlet being exposed to waste water at 100°C (212°F) for a long time.

- The capacity of the waste water system must comply with current regulations. The technical data of the equipment states starting values for the calculation of standard flow in hospital and industrial environments. These calculations must be made in accordance with national regulations. Normally, after calculation of the design flow rate, the system capacity must be increased by an additional 50 %.
- The size and number of floor drains must match the size and number of the connections on the equipment; see Technical data. The floor drain opening should be at least 200 mm (8").



WARNING: The outlet of the safety valve must always be connected to a pipe which runs to a safe place.

Ventilation

All types of apparatus

On the basis of the values specified under technical data, the ambient temperature of the unit must be controlled to 15 - 35°C (60 to 95 °F) by suitable adaptation of the ventilation. If possible, relative humidity should not exceed 85%.

These requirements apply not only to the service area of the apparatus but also to the operator zones.

All sterilizers

Bear in mind the heat added from the load when unloading and in storage after a process.



Note that the load supplies a considerable amount of additional heat in the operator area when it is unloaded after completion of the process. This heat emission is not stated in the document “Technical data”.



Note: To ensure that air can circulate around the sterilizer, the sterilizer must be positioned so that there is a clear space of at least 10 cm (about 4 inches) all round.

Sterilizers with cabinet

On machines with a cabinet, the space between the floor and the cabinet plates (about 10 cm) must be open so that cooling air can circulate around the sterilizer chamber.

Sterilizers with vertically-operating door.

Some sterilizers are fitted with a ventilation connector at each door, to be connected to the ventilation system. This provides an efficient barrier to prevent excessive surplus moisture and heat finding their way into the operator's zone.

Ventilation

All types of equipment

On the basis of the values for heat dissipation given in the technical data, the ambient temperature around the equipment must be regulated to 15 to 35°C (60 to 95°F) by means of a suitable ventilation system. If possible, relative humidity should not exceed 85 %.

These requirements apply not only to the service area of the equipment but also to the operator areas.

All sterilizers

Bear in mind the heat contribution of the load when unloading and when storing after the process.



The load contributes a significant amount of heat to the operator area when the load is unloaded on completion of the process. This heat emission is not stated in the technical specification.

Sterilizers with a vertically-operating door:

Each sterilizer door is fitted with a ventilation stub, which must be connected to the ventilation system. This provides an efficient barrier to prevent excessive surplus moisture and heat finding their way into the operator area.

Inspection by authorities

The user of the equipment must, upon installation of the unit, inform the appropriate authorities that this has been done and also comply with local restrictions governing the connection of water, drainage and ventilation. There are often local restrictions on connection to the drinking-water mains, on how wastewater is to be treated and how ventilation is to be arranged. This is particularly important when installing sterilizers for formalin sterilization or ethylene oxide sterilization as limit values for emissions may have to be complied with.



The owner of the equipment must find out whether a pressure vessel authority inspection must be carried out prior to use.

Responsibility for pressure vessel and safety valves

Pressure vessels subjected to cyclic loads must according to pressure vessel regulations be inspected periodically.

The end-user is responsible to arrange inspections of pressure vessels and checks of safety valves in accordance with requirements from notified bodies in each country.

All equipment with safety valves: If the equipment is provided with one or more safety valves, a description of a check is to be found in the section *Check of safety valve* in the chapter GENERAL ADVICE.

All equipment with bursting disc: A description for assembly of bursting discs is to be found at *Assembly of bursting disc* in chapter COMPONENTS.

Pressure vessel with door(s): If the equipment is provided with pressure vessel doors, a description of a safety check is to be found in the DOOR chapter.

Only for equipment according to the European pressure vessel directive: The first inspection must be carried out at the latest upon a number of cycles given by the manufacturer on the pressure vessel EEC declaration of conformity. Further inspections is stated by the notified body, normally at the first inspection.

Functional check-up prior to use

- This function check must be carried out by a skilled technician. See chapter FUNCTIONAL CHECK for further information.
- For sterilizers that are to be validated under European Standards, the function check must be based on instructions according to EN554.
- For sterilizers that are to be validated under Australian Standards, the function check must be based on instructions according to AS/NZS 4187:2003.
- The user should set up a routine for continuous tests of the equipment.

FUNCTION CHECK

Before use



Read all the documentation and check that all supply media are correctly connected to the connection points.

- Correction of Supervisor at high installation altitude:



If the sterilizer has been installed at a very high altitude, it will be necessary to adjust certain pressure limits in order to maintain independent monitoring of door safety.

The reason for the adjustment is that the independent pressure reading is related to absolute pressure; in other words, the setting is always calculated from absolute vacuum.

This means that the independent pressure window of the duplicated door safety function and the self-monitoring of its operation, may be too high in relation to the prevailing atmospheric pressure.

Adjustment should be considered if the average atmospheric pressure at the installation site is below 925 mbar(a). **Contact Getinge for more information.**

- Check that the guidelines of the installation instructions about the connection of supply media are followed: electric power, water, compressed air, steam, etc.
- Check also that the guidelines for waste and ventilation have been met.
- Check that the operating instructions are displayed at the unit.
- Carry out any customisations of the unit (where applicable). See the section headed “Functions which can be programmed by the user” in the chapter on ADVICE AND INSTRUCTIONS.
- Check that all the connecting screws belonging to electric cables are sufficiently tightened. Pay particular attention to power wiring.
- Open the valves for all supply media.
- Check that the separator tank water level is just below the overflow.
- If water needs to be added, follow the instructions under “Vacuum system”- starting and checking, in the chapter MAINTENANCE.

- When the separator water tank is full of water, check the direction of rotation of the pump by briefly pressing the pump contactor button. The direction of rotation of the pump must agree with the arrow on the pump housing. To reverse the direction of rotation, follow the instructions under *Electrical* in the chapter INSTALLATION.
- Check that the pump draws sealing water by briefly pressing the motor contactor. When running down, the pump must be braked by the resistance of the water. If the pump takes a long time to stop, the liquid ring is not sufficient. If water needs to be added, follow the instructions under “Vacuum system”- starting and checking, in the chapter MAINTENANCE.



Do not let the pump run dry for more than a few seconds.

- If the vacuum pump has jammed, pull off the pump impeller according to the instructions in the COMPONENTS chapter of this manual.
- Perform all safety checks as described in the GENERAL ADVICE and The Door chapters.
- Check and, if necessary, adjust the supply of sealing water and leak air to the vacuum pump. See the “Vacuum pump” section in the COMPONENTS chapter.

Note that the end user is responsible for ensuring that pressure vessels are inspected and safety valves are checked in accordance with the requirements of the supervisory authority in each country. See also *Responsibility for pressure vessels and safety valves* at the end of the INSTALLATION chapter.

- Methods for checking safety valves (where applicable) are described under *Checking safety valves* in the ADVICE AND INSTRUCTIONS chapter.
- Instructions for fitting bursting disks (where applicable) are given under *Installing bursting disks* in the COMPONENTS chapter.
- Do a leakage check on the installation and the sterilizer. Covered-in equipment and cabinet models must be checked with the cladding plates removed.
- Run all processes while checking pressure, temperature, times and the operation of the indicator lamps. Set points will be found in the phase list. File the test run printouts.
Note that the basic version of some equipment, and apparatus connected to higher-level systems, may not have special provision for process printout.

MAINTENANCE

To be done by trained technicians only

ESD (Electrostatic discharge)



ESD damage in installation and servicing may destroy the electronic equipment. Read the instructions in the ESD section in the INSTALLATION chapter BEFORE starting work.

Overview of safety devices



Cladding and front panels must prevent access to the parts of the installation that are normally accessible only to trained personnel.

General access to an installation supplied without cladding, which should normally only be maintained by trained personnel must be prevented. A convenient way of preventing access is to install the equipment in a lockable area.

The cladding panels of the unit, or if none are fitted, the room in which the unit is installed, must ensure that only authorised and specially trained personnel can have access to the internal parts of the installation.

Safety components

Every unit is equipped with a number of components with the specific purpose of ensuring the safety of personnel. These items are marked with the a warning triangle below in the following documents:



- electrical diagrams
- pipework diagrams
- spare parts lists

These components have undergone special tests before being accepted as safety components. For this reason, they must not be replaced with components of any make or design that has not been approved by GETINGE AB. It is of the highest importance that the operational reliability of these components is continuously upheld during the entire service life of the installation. The signs [tecknen??] are used not only to indicate important components, but also to draw attention to other safety factors that call for special attention, such as dimensions, tolerances, materials, etc.

Independent process monitoring (supervision)

Besides the PACS 3000 control system, the autoclave is equipped with a PACS Supervisor.

The Supervisor uses an independent pressure transducer to monitor the chamber pressure. The supervisor will block the door from opening should the pressure in the chamber be too high.

The general features of this system are described in the chapter on the CONTROL UNIT PACS 3000, with pressure monitoring described under the "Safety interlocking of door opening" heading in the DOOR chapter.

General requirements



When working behind panels, be aware of the risks of injury by crushing, cutting and burning, and of the risks of live electrical equipment.

The need for maintenance depends chiefly on the extent to which the unit is used. The frequency of preventive measures will therefore vary from case to case. If the sterilizer is used to its full capacity, and/or the quality of the media is poor, more maintenance may be required.

Note that the end user is responsible for ensuring that pressure vessels are inspected and safety valves are checked in accordance with the requirements of the supervisory authority in each country; see also *Responsibility for pressure vessels and safety valves* at the end of the INSTALLATION chapter.

Methods for checking safety valves (where applicable) are described under *Checking safety valves* in the ADVICE AND INSTRUCTIONS chapter.

Instructions for fitting bursting disks (where applicable) are given under *Installing bursting disks* in the COMPONENTS chapter.

Getinge AB will only accept responsibility for product safety and, where applicable, for CE marking, if the following minimum requirements are met by the user.

- The sterilizer has been installed in accordance with Getinge's instructions and drawings.
- Operators and maintenance personnel have been trained for their tasks. Getinge AB can offer such training.
- Consumables, spare parts and accessories used must be approved by Getinge AB.
- Equipment must be maintained in accordance with the maintenance chart in the SERVICE MANUAL or more often.
- Any modifications must be approved and documented by Getinge AB and be done by authorized personnel.

After commissioning

When the sterilizer has been in service for one month, deposits and particles from new pipes will have collected in filters and sensitive components. If these deposits are not dealt with they will cause malfunctions, leakage and reduced performance.

- Clean all dirt filters and restrictors.
- Clean all steam traps. Remove deposits on their seats and floats.
- Check that the pipework of the installation and unit is leaktight.
- Check that all the electrical connection screws on power, earth and neutral cables are tight.
- Perform a leaktightness test by running the Leakage test process. See Leakage test in the OPERATOR MANUAL under *The process*.

After a long idle period

After the sterilizer has been idle for a long time, it is advisable to carry out the actions below. A long idle period may be a shutdown or a holiday.

During the idle period

- If possible, the unit should be started and operated once a week.

On starting after the idle period:

- Run an approved leakage test.

Maintenance plan

Replacing the sterile filter

Depending on use, number and size, the filter should be replaced, in the event of a breakdown or according to local regulations, but in any event at least once a year.

The integrity of the filter should be checked in accordance with local regulations or every week in continuous operation.

General guidelines for periodic maintenance

In many cases, maintenance specified under *weekly* and *monthly* can be done by an authorized user trained in performing the stated tasks. The slightly more demanding maintenance tasks under *quarterly*, *six-monthly*, *etc.* must be done by trained technical maintenance personnel. Local and national safety regulations must always be followed.

Once a week

Monthly

- Carry out safety checks as described under *Crush protection* in the DOOR chapter.

Quarterly

- Carry out the maintenance under “Monthly”.
- Check the door seal. If necessary, lubricate or replace the seal. See the section on DOOR. Note that special operating conditions and/or media quality may require shorter or longer intervals.
- Perform a leaktightness test by running the Leakage test process. See Leakage test in the OPERATOR MANUAL.

Every six months

- Perform the maintenance operations as described under "Every month" up to and including "Every three months".
- Clean all dirt filters and restrictors.
- Clean all steam traps. Remove deposits on their seats and floats.
- Check that the pipework of the installation and unit is leaktight. Seal all leaks. Replace any leaking gaskets.

- Check that all the electrical connection screws on power, earth and neutral cables are tight.
- Check that the door motor is firmly secured.
- Check that the V-belt is free from defects. Replace it if necessary.
- Perform the following maintenance operations, which are described in more detail under DOOR:
 - Check the door position vertically, laterally and backward/forward.
 - Checking the operation of door seal and seal groove valves.
 - Lubricate or replace the door seal if necessary.
 - Perform safety checks as described in “Door safety devices”.
 - Perform safety checks as described in “Interlocking the start function”.
 - Safety checks as described in “Blocking of chamber media supply”.
 - Safety checks as described in “Safety blocking of door opening”.
- Check the lead seals on all safety valves.
- If the seal is not intact, the valve must be replaced. Alternatively, an authorized person from the pressure vessel authority can be called to re-inspect and re-seal the valve.



**If the seal of a safety valve has been broken, the opening pressure may have been changed.
Units with broken safety valve-seals must not be used.**

- Check that none of the safety valves is leaking water or steam.
- The feedwater tank for integral or external steam generators for process steam must be regularly cleaned to prevent the growth of algae and bacteria. Observe local restrictions and the recommendations of hygienists. Note that bacteria and algae that find their way into the steam generator may form pyrogens that end up on and in the sterile goods.
- Clean the holes and nipples described under “Vacuum pump”, “Cavitation protection” in the COMPONENTS chapter. With the sterilizer in service, check that air is drawn into the pump.
- Print out the list of the twenty most recent faults (see the CONTROL UNIT chapter) and assess whether these indicate faults in components or incorrect settings.
- Check the operation of the operator panel display, any LEDs and printer, if any. See the CONTROL UNIT chapter.

Yearly

- Perform the maintenance operations described under “Monthly” up to and including “Six monthly”.
- Temperature sensors and pressure sensors connected to the control system must be checked against an independent system with documented accuracy, traceable to a national standard. Note that the measurement error of the reference instrument must not exceed one-third of the measurement inaccuracy to be achieved. National standards and local regulations must be complied with.

Temperature check: We recommend doing the check in ice water at 0 °C (32 °F) and in an oil bath at process temperature, eg 121 °C (250 °F). It is very important to allow the sensors to stabilise in the baths before doing the check. An ice bath must be filled with crushed ice and be properly stirred.

The temperature measuring error must not exceed 0.5 °C (0.9 °F).
Calibration of temperature sensors, see CONTROL UNIT.

Pressure check: A reference instrument for pressure checking is usually combined with equipment for raising and lowering the pressure. If this is not the case, the check can often be done by connecting the reference instrument directly to the unit and using the built-in features to alter the pressure. Note that the pressure measuring system of the unit can detect pressure changes within ± 1 mbar / ± 0.1 kPa / ± 0.0145 psi and that the permitted measurement error below refers to absolute levels for the entire range.

The pressure measurement error must not exceed ± 8 mbar / ± 0.8 kPa / ± 0.115 psi within a range 0-1 bar(a) / 0-100 kPa(a) / 0-14.5 psia.
At pressures above 1 bar(a) / 100 kPa(a) / 14.5 psia, the difference must not be greater than $0.01 \times P(a)$. Calibration of pressure sensors, see CONTROL UNIT.



If the pressure sensor of the unit is removed, the gasket must be replaced with a genuine Getinge spare part.

- Clean the separator according to the instructions under “Vacuum system”.
- Before starting the installation, check that there is enough sealwater. The level must be just below the overflow.
- Check and adjust the amount of sealwater to the vacuum pump and where applicable its cavitation protection, according to the instructions under “Vacuum pump...” in the COMPONENTS chapter.

- Remove the diaphragm valves of the installation and check that no diaphragms are split or damaged. We recommend replacing all diaphragms yearly. This is especially important where the diaphragm is subjected to vacuum or high pressure.
- Run all processes while checking pressure, temperature, times and the operation of the indicator lamps. File the relevant process documentation such as recorders charts, process printouts or log files from the test runs.

Additional maintenance operations, every second year

- Perform the following operations, as described in the “Heat exchangers” section of the COMPONENTS chapter.
 - If the water is harder than 4 dH (70 ppm), clean all plate-type heat exchangers.
 - Pressure-test all the heat exchangers.
- Replace the humidity protection device in the control cabinet. Write the replacement date on a label and attach the label beside the humidity protection device.

Automatic filter sterilization with integrity test

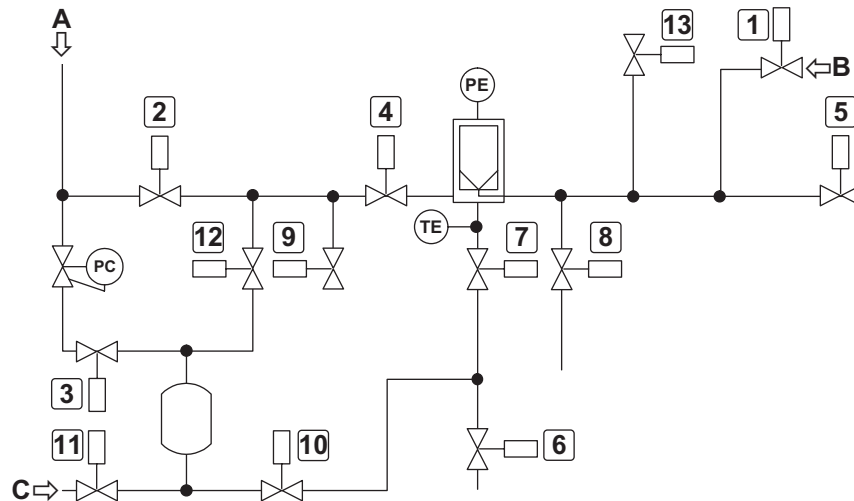
* This symbol indicates that the text applies only to sterilizers.

The unit has a program for sterilizing and testing air filters.

The programs (which are sometimes combined into one program) have the following steps:

- Sterilization
- Cooling
- Pressure equalization
- Filling with water
- Test (water intrusion test, WIT)
- Draining

- Drying



A = Compressed air

B = Steam

C = Water

When the filter is in normal use, valves (*2), 4 and (*13) are always open.



NOTE: The temperature in the service room and of the water used for the test should be between 20°C and 30°C for a reliable test.

Sterilization of the filter

Sterilization

1. The filter housing and water tank are depressurised by closing all valves except 4, 6, 7, 10 and 12, which are opened. When the pressure falls below 1.3 bar(a) / 130 kPa(a) / 19 psia, valve 6 closes and at the same time valve 9 is kept open for 30 seconds.
2. The filter housing, cartridge and water tank are heated by steam pulsed in from valve 1. The steam valve is controlled by the temperature in the drain of the filter housing. Valves 4, 6, 7, 8, 10 and 12 are open all the time during heating and sterilization. If the pressure goes above 2.5 bar(a) / 250 kPa(a) / 36 psia, heating stops temporarily. When the temperature sensor reaches 121 °C, heating changes to sterilization.
3. The filter is sterilized at 121 °C for 30 minutes. The system regulates to 122 °C. The sterilizing timer stops temporarily if the temperature falls below 121 °C.

Cooling

1. The filter is first cooled carefully with reduced compressed air. Valves 3, 4, 6, 7, 8, 10 and 12 are open during system cooling.

Where appropriate, valve 13 is kept open to supply compressed air to the door seal of the sterilizer. Cooling continues until the temperature has fallen to 60 °C. Where sterilization is to be followed by an integrity test, the program proceeds directly to pressure equalisation below.

2. Cooling ends and pressure is carefully built up again by closing valves 6, 7 and 8.
3. After 30 seconds, valves 3 and 12 also close and valve 2 opens.

Automatic integrity test

Cooling and pressure equalization before the test

1. The filter is cooled with reduced compressed air. Valves 3, 4, 6, 7, 8, 10 and 12 are open to carefully cool the system down to 80 °C. Valve 2 then opens and cooling continues down to 30 °C and for a further 20 minutes. Where appropriate, valve (*13) is kept open to supply compressed air to the door seal of the sterilizer.
2. The filter housing is depressurised again by all valves closing except 4, 6, 7, 10 and 12, which open. When the pressure falls below 1.3 bar(a) / 130 kPa(a) / 19 psia, valve 6 closes and at the same time as valve 9 opens. After 30 seconds, pressure equalisation stops.

Filling the water tank from a container (option 1)

1. All valves are closed except 4, 6, 7, 9, 11 and 12, which open, allowing water from the container to fill the water tank. Filling takes eight minutes.

Filling the water tank from a pipe (option 2)

1. All valves are closed except valve 11, which opens for two minutes, allowing water from the main supply to fill the water tank. The water pressure must not exceed 9 bar(e) / 900 kPa(e) / 130 psig.
2. All valves are closed except valves 9 and 12, which open for five seconds to release the cushion of compressed air above the water.
3. Valve 11 opens again for two minutes, allowing more water from the supply to fill the water tank.


Filling the filter housing with water

1. All valves are closed except 3, 7, 8, 9 and 10, which are open to carefully fill the filter housing with water. When the pressure exceeds 1.3 bar(a) / 130 kPa(a) / 19 psia, valve 8 closes.
2. When the pressure has reached 3.4 bar(a) / 340 kPa(a) / 50 psia, valve 10 closes. If that pressure is not reached within five minutes, the filter is assumed to be leaking and the system gives an alarm.

3. All valves are closed except 3, 7 and 9. Valve 10 opens in brief pulses to reach the test pressure of 3.5 bar(a) / 350 kPa(a) / 51 psia.
4. The pulses continue for 10 minutes, but only if the pressure is lower than 3.5 bar(a) / 350 kPa(a) / 51 psia. If the total number of pulses exceeds 15, an alarm is given.

Testing

1. The water tank and areas downstream and upstream of the filter are depressurized by keeping valves 8, 9, 10 and 12 open. The other valves are closed. After 60 seconds, valve 8 closes, to avoid exposing the sterile pipe system. At this stage an alarm is given if the pressure falls below 3.45 bar(a) / 345 kPa(a) / 50 psia.
1. The tests begin when the pressure is in the range 3.45-3.55 bar(a) / 345-355 kPa(a) / 50-51.5 psia.
2. The test period is 10 minutes. The permitted pressure drop depends on the volume of air in the filter housing. This air volume has been measured by Getinge Sterilization AB before delivery and the permitted pressure drop has been calculated. See separate report. The permitted pressure drop has been programmed into the control system.
3. If the pressure drop is excessive, an alarm is given and the program stops and waits for a signal from the operator:

Pressing  / [START] moves the process on to draining/drying.

Pressing **P1** / [TEST] instead performs the test by making the program jump back to the water filling stabilization period and starting the process from that point.

Draining

1. Draining by gravity starts with only valves 6, 7 and 9 open.
2. After 30 seconds, draining starts with reduced compressed air by valves 3, 4 and 12 also opening. This continues for three minutes.

Drying

1. Draining is changed to more powerful drying by valve 2 opening. The system waits for five seconds, then closes valve 3.
2. At the same time, valve 8 opens to drain any water downstream of the filter. The water tank is emptied by valve 10 opening. Where appropriate, valve (*13) is kept open to supply compressed air to the door seal of the sterilizer.
3. Drying continues for 15 minutes.
4. All valves close. Valves (*2) and 4 open.
5. The test is complete.

Cycle counter

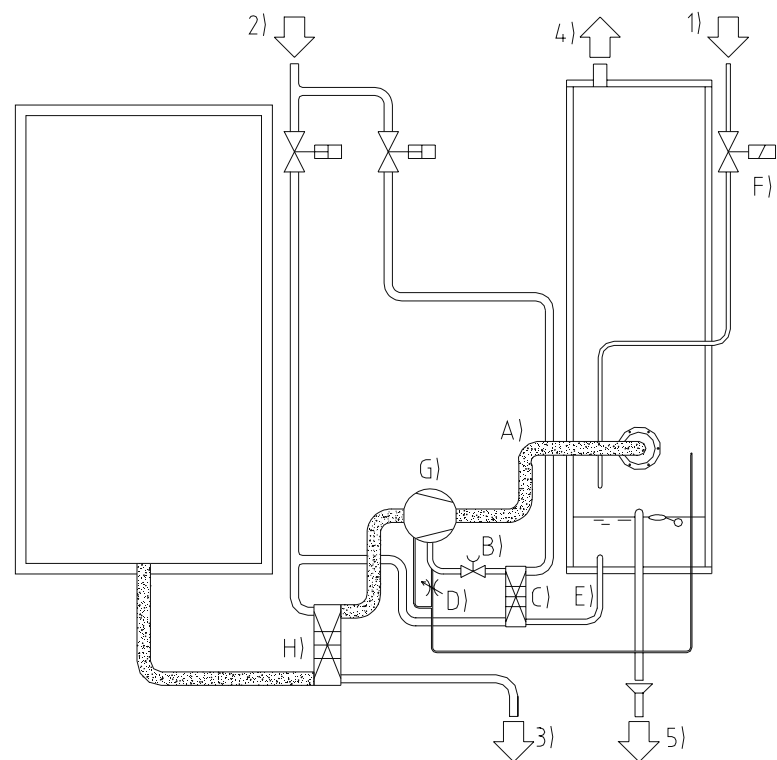
The PACS 3000 control system is fitted with a cycle counter. The cycle counter is printed out on each process log with Supervisor or an A4 printer connected to PACS 3000. On cold-start or replacement of CPU, this cycle counter will be reset to zero. The cycle counter can only be adjusted or read off using GETINGE CS 1000.

Vacuum system

The installation has a vacuum system consisting of a vacuum pump, a condenser and a combined silencer, separator and circulation container for sealing water.

The sealing water is recirculated to the vacuum pump. This means that water consumption is very low.

A plate-type heat exchanger continuously cools the sealing water, removing the heat generated by the vacuum pump.



A Vacuum
tube

B Ball valve

C Radiator

D Restrictor
valve

| | | | |
|----------------|-----------------------|------------------------|-----------------|
| E Suction pipe | F Filler valve | G Vacuum pump | H Condenser |
| 1 Cold water | 2 Cooling water inlet | 3 Cooling water outlet | 4 Air discharge |
| 5 Discharge | | | |

Cleaning the separator

Cleaning the ball valve for sealing water:

Ball valve B) must be cleaned at least once a year. Note or preferably mark the setting of the ball valve before removing it. When refitting, take care to set the opening angle of the ball valve as it was before removal.

Cleaning the filler valve for sealing water:

The filler valve must be cleaned at least once a year. Dismantle and clean valve F) and check that it is working. Then refit the valve.

Heat exchangers:

The plate heat exchangers must be cleaned at least once every two years. Clogging depends very much on the water quality, and particularly on the water hardness. Clogging mainly causes a deterioration in cooling capacity and longer processes.

At the time of cleaning, heat exchangers should be pressure-tested to check that no cracks have formed.

For cleaning, pressure testing and capacity testing, see the section on "Heat exchangers" in the chapter on COMPONENTS.

Cleaning the separator box

The box must be cleaned at least once a year.

VERSION WITH CENTRAL PUMP INLET ("large box"):

- Remove the ring and rubber sleeve on the box. Slacken the screws at the flange on the vacuum pump to vacuum pipe A). Twist out the actual pipe, so that the box can be rinsed and cleaned through the opening. Drain off the sealing water by removing the suction line marked E).

VERSION WITH PUMP INLET ON THE END ("small box"):

- Remove the access panel and gasket in the middle of the box.

APPLIES TO ALL VERSIONS:

- Drain off the sealing water by removing the suction line marked E).
- If a level switch is fitted, remove it so that it is not damaged during cleaning.
- Use a 60 mm (2.5") bottle brush with a flexible handle to clean mechanically, both upwards and downwards. It is an advantage if the brush has an end brush, so that the bottom can be cleaned better. A

brush can be ordered from GETINGE by quoting part number 400-100-000.

- If there are deposits in the box, suction connection E) can be plugged and a household detergent poured in and left to stand overnight, to dissolve the deposits.
- Rinse out the box thoroughly with hot water before refitting suction line E).
- Refit the suction line, level switch and ball valve. Open the ball valve fully (do not forget to mark the set opening position) and fill the box with water to the overflow. Refill for 5 minutes so that the vacuum pump definitely receives sufficient sealing water

VERSION WITH CENTRAL PUMP INLET (“large box”):

- Fit the vacuum pipe, sleeve, ring and associated screws. Tighten the screws of the ring to the flange at the vacuum pump to make it leaktight.

VERSION WITH PUMP INLET ON THE END (“small box”):

- Fit the access panel, gasket and associated screws. Tighten the screws so that the joint is leaktight.

APPLIES TO ALL VERSIONS:

- Return the ball valve to the original marked position. If there is no mark, set the pump to a basic setting by opening the valve 45°.

Start-up and check

Check that the pump draws sealing water by briefly pressing the motor contactor. When running down, the pump must be braked by the resistance of the water. If the pump takes a long time to stop, the liquid ring is not sufficient.

Only run the motor for short times when there is insufficient sealing water in the pump, otherwise the seal may be damaged.

Activate the filler valve manually to top up with sealing water (if there is a shortage). It may also be necessary to briefly fully open the pump throttle valve, in order to restore it to the correct position when the pump has started to draw water. The installation must not be put into service unless the service technician has determined that the pump is getting enough sealing water.



Make sure that the water level in the container is high enough. If the pump runs dry, the shaft seals may be damaged.

Recycling of cooling water

Connections 1) and 2) are normally connected together, but when the water in the cooling circuit is to be recycled, 1) and 2) are separated. Connection 1) is then used exclusively for sealing liquid for the vacuum pump.

2) and 3) are connected during installation to the special cooling water circuit for recycling. This is subject to the requirements of the document “Technical Data” and the INSTALLATION chapter.

Warranty

Warranty conditions and warranty period are described in the commercial documentation. See the order confirmation that governs the terms of delivery for this unit.

Service

Contact your local GETINGE representative
or
GETINGE Service Team
International dept.
Phone: +46 35-15 56 36
Fax: +46 35-583 08

Spare parts

Contact your local GETINGE representative
or
GETINGE
Spare parts dept.
Phone: +46 35-15 56 37
Fax: +46 35-15 56 60

ADVICE AND INSTRUCTIONS

Manual interventions in the process


When faults occur during a process because of interruptions in the supply of media or component faults, the process may, after an alarm has been triggered, get stuck in a phase from which the control equipment cannot proceed.

Various options are then open to the user. Options that do not involve a hazard to the user are described in the “Alarms” section of the OPERATOR MANUAL. If the operator’s options for action are not possible or do not solve the problem, a trained technician must be called to advance the program manually.



With the stepping option, a technician can under certain circumstances manually bypass built-in safety conditions.

Manual stepping with keyswitch

On manual stepping of a program with the  button or the “STEP” button after the keyswitch has been set to *Stepping/Authorized user*, all parameters are controlled by the automatic control equipment, so that hazardous situations cannot normally occur. With manual control, the program is stepped from one process phase to another without temperature, time or pressure conditions being met.

For safety reasons, the ability to step past critical process conditions is blocked. This applies to certain pressure, temperature and level conditions, *except where there is a fault in an analog sensor*. Stepping should be while the unit is still in the alarm phase.



When using this method, the blocks that prevent hazardous situations from arising are removed. The technician himself has to decide which operations are permitted.



The above method may only be used by technicians who are thoroughly familiar with the process, the properties of the goods and the functioning of the individual components.

Faulty analog sensor

If an analog pressure sensor or temperature sensor becomes faulty during a process, the process stops. The type of fault does not allow restarting of the process, since the sensor fault persists after acknowledgement, even if it is not indicated again. Another consequence of a faulty analog sensor is that no pressure or temperature controller becomes operative. This in turn means that neither temperature, pressure nor ramped temperature changes can be controlled.

With a pressure sensor fault, the operator must also step past the pressure conditions on post-vacuum, evacuation, emptying, self-cooling and pressure equalisation. With a temperature sensor fault, the operator must step past the corresponding temperature conditions.

Sensor fault, independent system

In case the process is stopped in a cooling- or door opening phase, due to failure of the independent sensors, the safety system can be by-passed by manual operation of the safety relays.



See the electric wiring diagram.


Pressure sensor fault

Process with drying vacuum, exiting the program:


In principle there are two ways of exiting from the process if a pressure sensor fault occurs, **A)** rapid exit or **B)** manual exit. For both methods, a technician must be called to activate the *Stepping/Authorized user* keyswitch in order to reach the standby phase. To avoid accidental stepping or holding of the process, the key must be reset between every stepping operation.


A) Rapid exit:

1. To make the process jump to post-treatment, press **[START]** / . **NOTE:** The process will be controlled with fast evacuation. The ramp regulator does not start. If a ramp is needed it must be controlled by manually operating the vacuum valve.
2. The operator panel shows “Step manually” to indicate that manual action is required. When the required vacuum has been reached, turn the keyswitch to *Stepping/Authorised user*.
3. Step past the limit value for vacuum in the drying phase by pressing **[STEP]** /  so that the program moves on to pressure equalization. The display shows the message “Equalize pressure manually”.

4. Equalise the chamber pressure to atmospheric pressure by opening the solenoid valve to the air intake filter or support pressure. Check the chamber pressure gauge.
5. Step out of the pressure equalization phase by pressing [STEP] /  .
(NOTE: This is only possible when there is a pressure sensor fault)

B) Manual exit:

1. Equalise the chamber pressure to atmospheric pressure by opening the solenoid valve to the outlet or to the air intake filter or support pressure. Check the chamber pressure gauge.
2. Turn the keyswitch to *Stepping/Authorised user*.
3. Then step out of the process by repeatedly pressing [STEP] /  ..


Note that attempting to start by pressing [START] /  when *Stepping/Authorised user* is active restarts the process from where it stopped. This gives new alarms and secondary errors when the pressure sensor is faulty.

Temperature sensor fault



Process with drying vacuum, exiting the program:


In principle there are two ways of exiting from the process if a temperature sensor fault occurs, **A)** automatic or **B)** manual exit. For method B), a technician must be called to activate the *Stepping/Authorized user* keyswitch in order to reach the standby phase.

A) Automatic exit:

1. Jump to post-treatment by pressing the [START] button /  .
2. Post-vacuum and pressure equalisation are done normally and the process is then exited.

B) Manual exit:

1. Turn the keyswitch to *Stepping/Authorised user*.
2. Then step the process to the post-treatment phase by repeatedly pressing [STEP] /  ..
3. Start post-treatment by pressing the [START] button/  . Post-vacuum and pressure equalisation are done normally and the process is then exited.

Note that attempting to start by pressing [START] /  when *Stepping/Authorised user* is active restarts the process from where it

stopped. This gives new alarms and secondary errors when the temperature sensor is faulty.

Manual control by manually actuating the control valves

The above method can be used to check the operation of individual components, for troubleshooting and with system faults that keep the process in the same phase.

When operating from menus on the operator panel or via a program tool, there are no software interlocks to prevent hazardous situations arising. See the CONTROL SYSTEM chapter for precise information about which menus are used at each interface.

When control valves are operated directly there are no interlocks at all. We advise against this form of control.

Note that when operating via the operator panel or programming tool, it is extremely important that all outputs are reset to auto mode when the work is complete. If this is not done, the safety and operation of the unit will be at risk during the remainder of the process.

Normally the operator is informed at the start of the next process if an output is set to manual mode. Despite this, the status must always be reset to auto mode immediately on completion of work.



When using this method, the blocks that prevent hazardous situations from arising are removed. The technician himself has to decide which operations are permitted.

External safety interlock fault

The sterilizer is equipped with an automatic monitoring system for those external components that serve as safety interlocks independently of the control system.

If the external components changed their position, or got stuck and are constantly indicating “safe position”, this would not normally have been noticed in service. It would only have been discovered when it was too late and the control system has also failed, ie when the external components were needed for safety purposes.

The purpose of the monitoring system is to ensure the operation of both the safety systems that allow media, among other things, to be admitted to the chamber or the door to be opened.

Monitoring is done by a system of relays which is in contact with the



external components and the control system. At certain predetermined places before and during the process, the control system checks by means of the relay monitoring that the respective external component has opened or closed its contacts as expected.

If the relay information does not agree with the control system's own information, the control system stores the discrepancy until the process has ended.

After the process, an alarm is activated and a message indicated what type of interlocking is present (see also "Fault codes" in the operation chapter of the OPERATION manual).

The alarm cannot be reset in the normal way, and as long as the alarm is activated, a new process cannot be started.

INTERLOCK FAULTS

1. Shut off the audible signal by pressing the  button or the [ALARM OK] button.
2. Rectify the faulty component.
3. Activate the stepping key and reset the alarm with the  button or the [ALARM OK] button.
4. Set up the component and do a safety check. The procedure is described in the DOOR chapter.
5. Check that interlock faults have not been activated after completion of a process.

Backup battery fault

If there is a fault in the control system backup battery, an alarm is triggered when the current process has ended and the control system has returned to the standby phase. In this mode, no parameters or program sequences have been lost. Data is only lost if the power to the control system is turned off with the main switch or if there is a power failure.

Before shutting down:

1. Save the program in the flash memory or in a file; see also the CONTROL SYSTEM chapter.
2. Make sure that the program has been saved, so that it can be reloaded.
3. Only turn off the operating current when you quite certain that the program has been saved.

Replace battery

The battery cannot be replaced. Instead, order an replacement CPU board if a new battery is needed.



WARNING!

Lithium battery. Explosion hazard.

**We advise against any attempt to replace the battery!
If a new battery is needed, order a replacement card.**

Never replace the battery with a type other than that supplied.

When operating voltage is lost:

If the backup battery voltage is low at the same time as a power failure occurs during a process, all software is lost.

The control system can no longer check the process, and the unit must be brought to a safe mode by manual control. See the description of the menus for testing digital outputs in the chapter CONTROL UNIT PACS3000.



When using this method, the blocks that prevent hazardous situations from arising are removed. The technician himself has to decide which operations are permitted.



The above method may only be used by technicians who are thoroughly familiar with the process, the properties of the load and the functioning of the individual components.



Note: If the control unit PROM is to be used to restore the software by a “cold start”, when the unit has been brought to a safe mode, all changes made and calibrations done since delivery are deleted.

Restoring software from E-PROM (cold start)



Cold start may only be done with the unit in a safe mode and by a technician who is thoroughly familiar with the process.

Read the warning below and then the cold-starting instructions in the chapter CONTROL UNIT.

Warning

When programs are loaded from a PC or on cold starting from a PROM, the system goes to standby phase; this means that risky situations may occur.

Before loading/cold start, the unit must first be brought to the standby phase or brought manually to a non-hazardous phase where the vessel contains no water and/or condensate, is depressurised and any liquid loads have cooled. See also the separate instructions for manual handling in this chapter.

A cold start from the PROM means that old values will appear for settings that have been changed in the RAM.

In a similar way saved, old values are loaded from PC. This makes it necessary to update any changes and calibration values. Calibration values from the latest calibration for analog sensors must also be entered.

Manual door opening



The following important steps must be taken into consideration before a door is opened after manual intervention.

- Identify the valve that is to be operated, to be sure that it **really is the proper valve**.
- Manually open a drain valve, to drain the chamber of liquids.
- Depressurise the chamber by opening the drain valve.
- If the load consists of liquid, the door must not be opened until the temperature of the liquid is well below its boiling point.

User-programmable functions

Barring codes

In the control system there are four different types of code, permitting four different types of action. The purpose of these codes is to prevent people who do not have sufficient knowledge or authority from accessing, intentionally or accidentally, actions whose consequences they cannot foresee.

It is important that these codes are communicated only to people who need them in their work and who have the necessary expertise / authority.

1. Operator code

This code prevent the starting of programs that are intended as test programs, emergency programs or programs for the sterilization of liquids. It is a common feature of these programs that they need not be validated for routine sterilization.

On some autoclaves the authorization code also prevents the door being opened after an incorrect process.

2. Parameter code

This code prevents unintentional alteration of adjustable parameters. Adjustable parameters and the ranges within which they can be set are evident from the program combination. The program combination also shows which values are stored in the control system EPROM on delivery.

3. Team leader code

The code prevents a change to the control system calendar being made unintentionally. The team leader is also authorised to create new codes at operator and parameter level and to print out program documentation.

4. Service code

This code prevents access to menus offering settings and tests that require an authorized technician.

5. Programming code

This code prevents access to the menus that can be used to change the sequence program.

This code is used only in exceptional cases by users, since this level of authorization calls for very detailed knowledge of the control system programming and the design and operation of the autoclave.

6. Calibration code

The code prevents calibration happening unintentionally.

On delivery, the autoclave control system has four different codes. These are described in a separate document in a sealed envelope. The

codes can be changed by the user. A brief description of the procedure for this is included in the sealed document.

Changing the program description parameters

The parameters that are most likely to need changing during programming at the user's premises are listed in the programming combination.

The ability to change parameters in a program combination varies from one apparatus to another. Some equipment has a very large number of selectable parameters; other equipment has few or none. The degree of possible adaptation depends on the user's requirements and official demands within the application, and on the level of training of the operators.

As well as parameters for sterilizing temperature and time it is sometimes possible to adapt the post-treatment of the processes to achieve maximum dryness of goods that are difficult to dry, to set the desired liquid temperature, or to protect the goods from over-rapid changes of pressure and temperature.

See also the section on setting the parameter values in the CONTROL SYSTEM chapter. Suitable settings for steam sterilizers with different types of goods are described in the separate Getinge guide STERILIZATION WITH STEAM.

Changing the door function

On sterilizers with two doors, the unloading door opens automatically after a process. After processes intended only for testing or maintenance, the door normally only opens when the door button is pressed.

The door function can be changed individually for each program by changing the value of a parameter. To make this change it is essential to have access to the programming code.

Parameter values

0= A door does not open until a door pushbutton is pressed.

1= The unloading door opens automatically on successful completion of a process.

Maintenance codes

Time-based or cycle-based intervals can be programmed so that the unit keeps track of when maintenance is needed. A number of intervals are already programmed on delivery, in accordance with the recommendations in the MAINTENANCE chapter. If the DIP switch for maintenance message is activated, the end of a service interval will trigger a "MAINTENANCE" message.

This function is not enabled on delivery, since not all users have the CS1000 tool which is needed to reset an active message. The maintenance menus are updated in the background even if the DIP switch is disabled, and can be used, for example, when a service technician with the CS1000 tool happens to be visiting.

See also “Service indicator” in the MAINTENANCE chapter.

Date and time

The service code gives access to menus where the date and time can be changed. See the CONTROL UNIT chapter.

Calibration

Analogue sensors/transducers must be calibrated, for example when replaced. The calibration menu becomes available with the service code. See the calibration menus section in the PACS 3000 CONTROL UNIT chapter

When using an oil bath, note the following points:

- A Accuracy must meet the requirements of EN285 (AS 1410 for Australia and New Zealand)
- B Compounds or condensation in the oil may cause coatings and thus severely reduced the accuracy of measurement. Change the oil at regular intervals.
- C Use an oil bath with a large capacity, preferably more than five litres.
- D Allow the measuring instrument to stabilize for one to two hours after the bath has reached the set temperature.
- E Allow the oil bath to stabilize for at least 30 minutes after the sensors are lowered into the bath and the bath has regained its set temperature.
- F Clean the sensors thoroughly to remove the oil after calibration.



Note: If the EPROM in the control unit is to be used to restore the software by means of a cold start, after the autoclave has been brought to a safe state, all changes and calibrations performed after delivery will be erased.

Setting the autoclave number

The autoclave number is an identification of a particular autoclave which is used in communication between operator control panels or GETINGE programs. The number, which must be in the range 1 - 99,

also serves as an identification on printed listings of process data and thus makes the lists traceable.

The programming proceeds as follows:

- Go to menu Configuration – Pacs address.
- Enter the autoclave number in accordance with the instructions for this menu as given in the PACS 3000 CONTROL UNIT chapter.
- Exit from the menu.

Log interval for process data

The log interval can be changed so that more or less measurement data is printed out. Logging during the sterile phase is controlled by the value "Short interval", whilst printout of data during the remaining parts of the process is controlled by the value "Long interval". On delivery, both these values are set to 59 min. 59 sec. Usually this setting only gives printout of data when the sub-process changes.

See also the "Printer" section in the OPERATION chapter of the INSTRUCTION MANUAL or, if the equipment includes Supervisor, the "Documentation of the process" section in the PROCESS chapter.

The programming proceeds as follows:

- Go to menu Configuration – Printer log values.
- Set the required long logging interval in accordance with the instructions for this menu in the PACS 3000 CONTROL UNIT chapter.
- Exit from the menu.

Safety valve check

Raising the pressure and checking the unit

The following pressure testing of safety valves can be done on equipment supplied with incoming media at a pressure above the opening pressure of the safety valve. Checking of safety valves on equipment with a lower pressure or safety valves combined with a bursting disk is described below under *Testing in a test rig*.

Identify the opening pressure of the safety valve by reading off the pressure on the valve itself. Note that the design pressure of the pressure vessel may be higher than the opening pressure of the safety valve. The pipework diagram of the unit may also be useful for identification purposes.



Wear safety gloves when checking a safety valve. Escaping steam and water and hot pipe components may cause burns.

Check the operation of all safety valves as follows.

- Start a process and when it has started, stop it with the emergency stop.
- Reset the emergency stop and acknowledge any alarms.
- Manually operate the pilot valve of the incoming media valve (air or steam) to the pressure vessel and observe the pressure rise on the pressure gauge. Blow-off should begin at “Normal opening pressure” according to the table below. At full blow-off, the pressure should never exceed the “Max permitted test pressure” in the table below.

Any safety valve that does not meet these conditions must be replaced.



Immediately restore the pilot valve to the service position if the safety valve does not open or for some other reason the pressure tends to exceed “Max permitted test pressure”.

- Return the pilot valve to its normal operating position and terminate the process.

| Normal opening pressure | Max permitted test pressure |
|-------------------------|-----------------------------|
| 3.0±0.15 bar(e) | 3.3 bar(e) |

| | |
|-----------------------------|------------------------------|
| 310±16 kPa(e) / 45±2 psig | 340 kPa(e) / 50 psig |
| 3.5±0.18 bar(e) | 3.85 bar(e) |
| Rated pressure of valve ±5% | Rated pressure of valve +10% |

Testing in test rig

Equipment supplied with media at a pressure below the opening pressure or equipment fitted with a bursting disk in combination with a safety valve cannot be pressure-tested on the unit.



Take care when removing and pressure-testing safety valves. Make sure that pressure vessels and pipework systems are depressurised before removing the valve. Escaping steam and water and hot pipe components may cause burns.

Check the operation of all safety valves as follows:

- Remove the valve and pressure-test it in a test rig.
- Identify the opening pressure of the safety valve by reading off the pressure on the valve itself. Note that the design pressure of the pressure vessel may be higher than the opening pressure of the safety valve. The pipework diagram of the unit may also be useful for identification purposes.
- The opening pressure must never exceed the “Max permitted test pressure” in the table above.

Any safety valve that does not meet these requirements must be replaced.

THE DOOR

General

The horizontally moving sliding door is suspended in two ball bushings travelling on a supporting steel rod. This is attached to a rigid bar above the door. The lower part of the door is guided by rollers on each side of the thick plate forming the door surface.

The opening and closing motion of the door is executed by a pneumatic motor, equipped with a timing belt pulley working on a timing belt attached to the door. The door motion speed is controlled by a fixed chokes in the motor air inlet connection. As an additional safety measure there is a load sensor fitted on the pneumatic motor, to sense any bigger object obstructing the door closing. The load sensor stops the door-motion before a squeeze-situation occurs, thereby avoiding personal and material damage.

When the door is completely closed, it is locked mechanically. This lock activates a limit switch which makes it possible to pressurize the door seal.

During a process and in the event of media failure (electric power, steam or compressed air) the doors are kept locked by the automatic control equipment and the door lock described above. The doors cannot be opened until the condition "chamber pressure = zero (± 100 mbar)" is met, not even if an electrical fault results in an opening command.



The door closing system is made up of a number of components. Their interaction has been carefully tested to give the necessary safety in terms of damage to equipment and injury to people. These parts must not be subjected to violence or incorrect operation that may alter their original function.



Adjustments to doors and associated equipment may only be made by authorized personnel.

Seal between door and chamber

The seal between the door and chamber is formed by a rubber gasket which can move in a groove around the opening of the chamber.

The moving door seal is pressed against the door by steam, compressed air or an inert gas. The media used depends on the type of unit. The door seal is released when the pressure medium is evacuated.

Some special types of sterilizer are fitted with double door seals. Where two door seals are used on a negative pressure sterilizer, only the outer seal can move.

Media to the chamber

Before media can be admitted to the chamber, all the requirements below must be met:

- A Emergency stop not activated
- B Door(s) closed.
- C Door seal pressurized.
- D Control system giving a control signal to open the media valves.

Checking and adjusting the door position

Important preparations

Several of the checks below depend on how the sterilizer is installed at the user's premises. It is extremely important that the chamber is first set up and aligned in accordance with the installation instructions provided. These can be found in the INSTALLATION chapter of this manual. The settings described are often done at the factory, but always after the chamber and door lintels have been leveled.

The lintels on larger chambers are usually removed before dispatch, to allow the sterilizer to be transported and moved into place. Normally there should be no need to change the settings already done at the factory if the chamber is correctly leveled on installation at the user's premises. This also assumes that the door lintel is refitted with no alteration of the adjustable fixings. The chamber is regarded as correctly leveled when the top is horizontal and when the seal place of the chamber coincides with the vertical.

Because the door propulsion force is relatively low for safety reasons, operation of the door is highly dependent on correct leveling so that the door can run between its end positions without any upward gradient and with no friction other than that caused by the ball bushing.

Action is only required if problems arise with the movement or leaktightness of the door. Do not do any of the adjustment operations

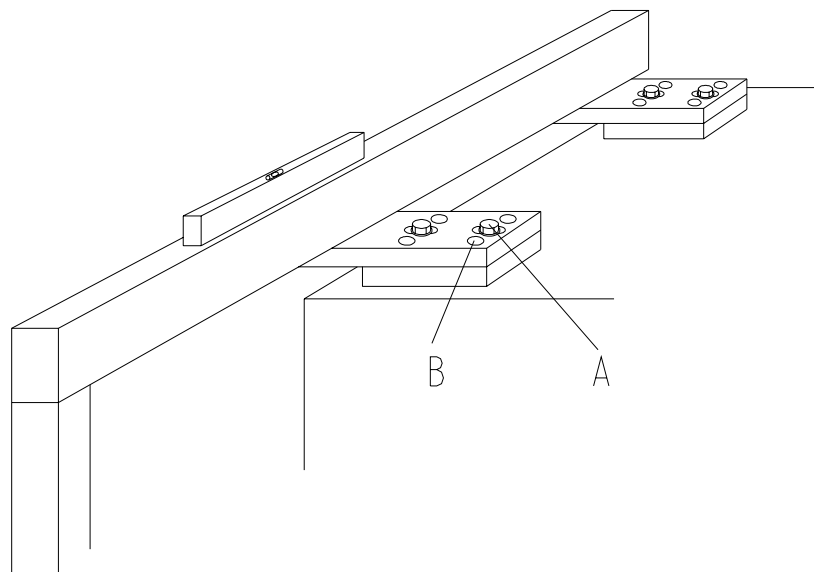
below until the sterilizer has been installed in accordance with applicable installation instructions.

Checking the leveling of the chamber

Check that the chamber is correctly adjusted before starting any of the checks below. See “Leveling the chamber” under *Refitting the door* in the chapter INSTALLATION.

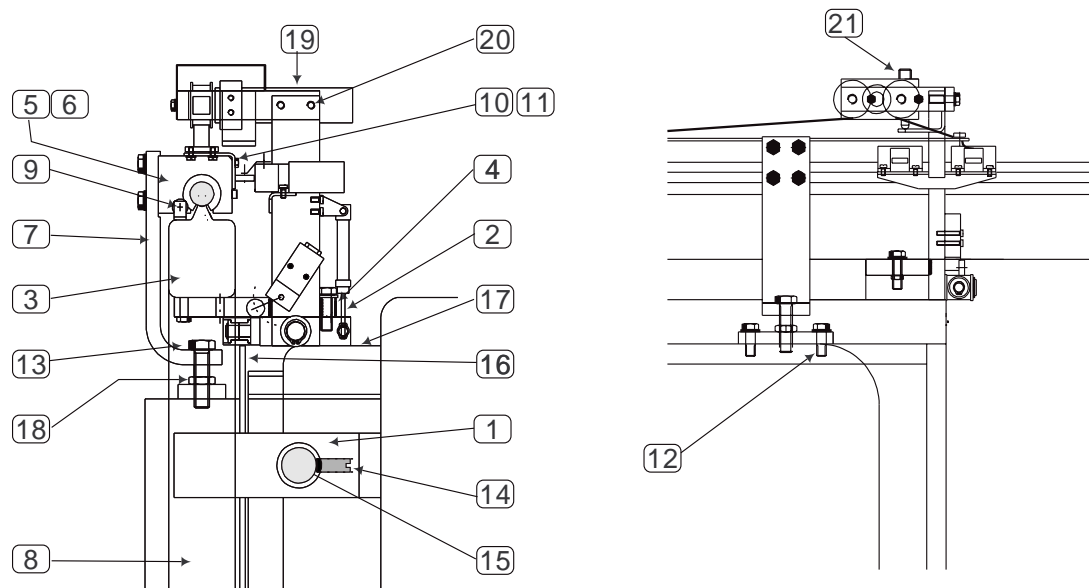
Lintel slope

Normally the lintels only need to be adjusted at the factory. Check first that the chamber has been correctly leveled before starting any individual adjustment of the lintels.



Adjusting the slope of the lintel:

The level of the lintel can be adjusted with the adjusting screws (B). Before adjusting, reduce the load on the lintel by lifting the door. While adjusting, check carefully that the lintel does not move in any unwanted direction.



Vertical setting of the door

When the setting is correct, the door bolt adjusting screws (14) should line up centrally with the bolts (15). Adjust with screws (13) if necessary.

Plumb adjustment of the door

- The door is set centrally between the seal groove and the setting screws so that it moves freely.
- The door can be adjusted by slackening the door holder screws (12) so that the door holder can be moved in the slotted holes until the door hangs vertically. The door cover plate must be in place during the adjustment.
- Tighten the fixing screws.

Adjusting the door clearance

- Always check first that the door is not binding because the seal gasket is projecting.
- Close the door until the bolt pins are just outside their holes in the chamber bolts.
- Loosen the rollers that guide the lower part of the door, so that the door hangs freely.

- Check that the distance between the door and the seal groove is as shown in the table below (when the door is pushed away from the chamber).

| Seal groove | Door clearance | Comments |
|------------------------------|----------------|--------------------------|
| Groove width 14 mm | 3-(5) mm | One or two moving seals. |
| Groove width 18-26 mm | 5-(7) mm | One or two moving seals. |
| Two seal grooves (one fixed) | 3-(5) mm *) | GEE, negative pressure |

*) Note that, on a gas sterilizer with negative pressure program, the door clearance is calculated from the fixed seal.

Note that the larger door clearance stated in brackets should not normally be complied with. In cases where manufacturing tolerances, flatness and the size of the door are an unfavorable combination, such that the door tends to bind, the larger clearance (shown in brackets) may be permitted.

Having a larger clearance increases risk of a characteristic “clunk” when the door is pulled back against the chamber during the vacuum phases of the process. The sound is not harmful, but should be avoided for aesthetic reasons.

If the lower part of the door is too near or too far away from the seal groove:

- Go back to *Plumb adjustment of the door* above.

Set the bolt bracket adjusting screw as follows:

1. Slacken all locking screws and back off the adjusting screws a few turns.
2. Close the door completely and insert sheet metal strips of the thickness (door clearance) stated in the table, at each corner, between the door and the seal groove.
3. Tighten all adjusting screws until the metal strips are gripped very lightly.
4. Lock the adjusting screws and remove the metal strips.



All locking screws must be properly tightened, as they form an integral part of the pressure vessel.

Checking the clearance between door and chamber

When the door is hanging freely, the clearance must be half the table figure (door clearance). With the described procedure, the distance between bolt and adjusting screw will then be equal.

- Slacken the screws (4) and if necessary move the entire door suspension beam (3) with the two brackets, which have slotted holes.



Leave the adjusting screws of the lintel fixings alone.

- Adjust and tighten the guide rollers at the bottom edge of the door.

The door seal

The door seal is that part of the pressure vessel that is most exposed to wear and tear. The composition of the material, the design of the seal, its fitting and care are of extreme importance for reliable operation and long life of the seal. GETINGE's door seal consists of a special silicone material, and its physical design is intended to make best use of its special characteristics.



Use only genuine GETINGE door seals. Remember that each seal is an integral part of the pressure vessel.

Care

There are several negative factors that adversely affect the life of the door seal. By avoiding them as far as possible, the life of the seal can be considerably extended.

- Avoid leaving the sterilizer switched on in the stand-by mode during the night. Although the door seal material can withstand continuous temperatures of more than 200 °C, it slowly degrades where it is in contact with the seal groove. Leaving the sterilizer continuously energised will shorten the life of the seal by about 60%.
- If the sterilizer has a steam generator, the generator must be drained at the prescribed intervals. Any feed water other than de-ionised feed water will gradually build up a concentration of minerals and other substances. At high concentrations, several of these substances are carried over with the steam and precipitated on the seal as weak acids.
- If the sterilizer is connected to a central steam system, the quality of the steam is decisive in determining the life of the seal. Chemicals are often added to the feed water for such purposes as protecting pipes against corrosion. Undesirable chemical characteristics of the steam include high hydrazine or carbon dioxide contents.
- Keep the seal lubricating layer intact and the sealing groove clean. The lubricating layer not only assists the seal in sliding, but is also an effective barrier against long-term chemical breakdown. See also under the “Lubrication of the door seal” heading.

Checking the operation of the door seal and seal groove valves.

Carry out a leakage test in accordance with the description in the PROCESS chapter in the OPERATING MANUAL. If no malfunctions occur during the test, the valves referred to above are working.

- If the valve for pressurizing the seal groove does not open, the leakage test cannot be done.

- If the valve for pressurising the seal groove does not close or if the seal groove drain valve does not open, the door cannot be opened when the test is complete, because of friction against the door seal. The same thing applies if the seal has hardened or if the lack of a lubricating layer causes it to stick in the seal groove.
- If a pressure rise occurs during the leak test, this may be due to a leaky steam valve to the chamber or to a worn seal. Leakage of this type also makes it difficult to maintain an even temperature in the chamber.
- If a similar pressure is noted during the plateau period of sterilization or disinfection programs, this is a sign that the door seal is worn.

Removal and cleaning

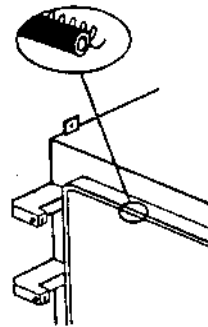
1. Remove the gasket from the groove. Be careful with the seal and the groove.
2. Carefully clean the seal groove.
 - First remove any coatings of hardened lubricant with a very fine emery cloth (no coarser than 320 grit)
 - Then wash the groove with a soap solution and wipe dry with clean paper.
 - Wash again until the paper is clean after wiping.

When relubricating an old seal

1. Clean the seal with alcohol until its surface feels absolutely smooth.
2. Inspect the seal where it has been in contact with the seal groove. If the material has started to perish, the seal should be replaced.
3. Spray the entire seal with a thin coat of anti-friction lacquer. (ordering. no. 4666695-01)

On fitting

1. Check that the spring is at place at the bottom of the groove.

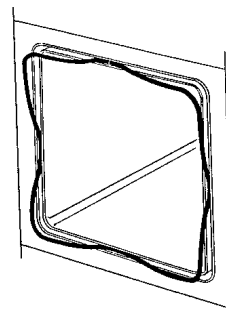


Relubricated seal

2. Fit the seal as before. Centre the corners so that they are positioned exactly as before.

New seal

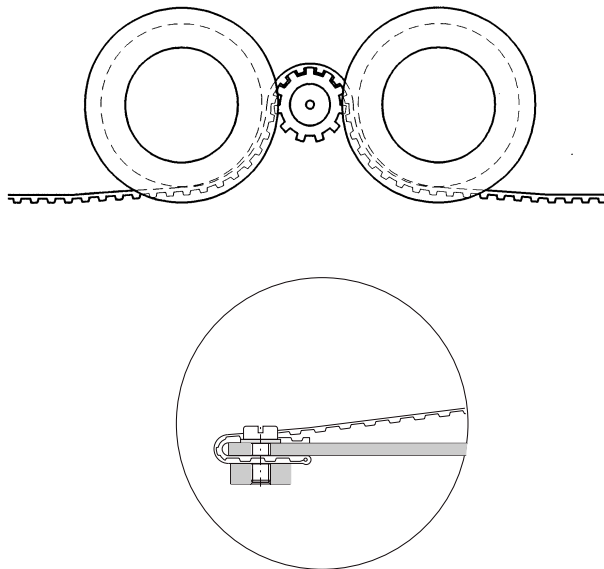
3. When fitting a new seal, it is extremely important that the excess length is distributed correctly. It helps to have the assistance of a second person.
4. Press the seal join into the middle of the upper horizontal part of the groove.
5. Secure the seal in the middle of the straight parts of groove so that its excess length is equally distributed between the fixing points.



6. Press in the seal between the previous fixing points, dividing the sections into smaller and smaller parts so that the entire excess length is equally distributed over the entire length.
7. Work some of the surplus towards the corners so that the seal can properly fill the width of the groove at the radii.
8. Finally press the entire seal into place so that it is inside the edge of the groove.

Changing the toothed belt

Fit the new toothed belt with some slack, so that the pneumatic can overcome its own static friction on starting, without having to move the heavy door. Two wheels press the belt against the driving sprocket of the toothed belt to compensate for the extra play in the toothed belt.



The belt is folded double to achieve a smoother bending radius and to reduce the risk of wear.

Door safety devices

Crush protection

The speed and crush force of the door are controlled by throttles inside the pneumatic motor. According to the applicable standard (IEC 1010-2-41) the force must not exceed 150 N.

The pneumatic motor has a built-in pressure sensor. The air supply is cut off before the force exceeds 150 N, stopping the motion of the door. On closing, a pressure sensor interrupts the closing command from the control system and reverses the door. The breaking force of the sensor is adjusted at the factory and cannot normally be adjusted or altered.

Safety check

1. Check that the door runs freely. For adjustment, see ADJUSTING DOOR POSITION above.
2. Check that the motion is smooth and jerk-free and that the closing and opening force does not exceed 150 N when the rotary motion of the door motor is blocked.
3. Check that the built-in force sensors work properly when the motor rotates, so that the air supply and therefore the motion of the door are stopped at a force lower than 150 N. Do this check in both directions.

Action if there is a fault: A door motor that fails the safety check above must be replaced.



NOTE: If the breaking force of the force sensors is too low the door will stop unnecessarily.

4. Check that the pressure switch which is connected to the control system works. The digital input (see electrical diagram, “door not stopped” input) which is connected to the pressure switch must be inactivated (the LED goes out) when the door closing motion is blocked. The check is carried out where appropriate on the pressure switches of both doors.

Emergency stop

When the emergency stop button is pressed, the motion of the door is blocked and control system goes to alarm mode.

Safety check

1. Open the door. Press the emergency stop button while door is moving. The door must stop and the control system must give an

alarm. Reset the alarm and the emergency stop button, and give another door opening command.

2. Close the door and repeat the function check during the closing motion.



If the above functions do not work, immediately call a trained sterilizer technician to check and adjust the sterilizer.

Interlocking of the start function

The horizontally sliding sterilizer door is only able to resist chamber pressure when the door is completely closed so that the door bolts are fully engaged. When the door is completely closed, it is mechanically locked by a spring-loaded latch which drops down behind the edge of the door. The latch operates an electrical limit switch which prevents the process starting if the door is not completely closed.

Safety check

1. On double-ended sterilizers, all checks must be done separately on each door.
2. Check that all components are securely attached.
3. By actuating the cylinder, check that the roller of the door lock lifts 1-2 mm above the top of the door. This can be adjusted by the threaded piston of the cylinder.
4. Close the door. Check that the roller of the lock rolls smoothly on top of the door. Also check that the latch drops down easily behind the door. The distance between door and roller must be 1 to 2 mm when the door is closed.
5. Check the condition of the electrical limit switch. Lift the door latch arm lock and let it drop back. The arm of the limit switch must follow the motion of the lock with no friction.
6. Check that the contacts of the electrical limit switch change over before the middle of the door latch roller (starting from the latched position) comes level with top of the door.
7. Keep the door lock in its upper position and try to start a process. The process must not be able to start.

Blocking the media supply to the chamber

Media supply to the chamber requires several safety systems to be intact. The systems are all independent of the control system and cut off the electric power supply to the media valves.

Limit switches

A limit switch senses that the door is fully closed before the signal is passed to the media valve.

Adjustment

For safety reasons, the limit switch cannot be adjusted.

Safety check

1. Switch on the operating current with the doors closed and check that there is voltage at the *GASKET* terminal.
2. Open the door on one side and check that the voltage disappears from the *GASKET* terminal.
3. On double-ended sterilizers, do the same check on the door switch on the other side as well, possibly after a process with opening restrictions on the door.

Emergency stop

An emergency stop button breaks the circuit when pressed.

Safety check

1. Start a process and check that there is voltage at the *MEDIA* terminal. Note: This check must not be done until after the seal has sealed.
2. Press the emergency stop button on the one side and check that there is no voltage at the *MEDIA* terminal. Reset the emergency stop button and check that there is voltage again at the *MEDIA* terminal.
3. Finish the process.
4. On a double-ended sterilizer, do the same check with the emergency stop button on the other side as well.

Door seal steam pressure switch

A pressure switch senses the pressure in the seal groove and cuts off the electric power supply to the chamber media valves at the same time as the input to the control system is cut off. This results in an alarm when the pressure falls below the prescribed level.

Normally, double-ended sterilizers have a single pressure switch for the seal grooves of both doors, since the seal grooves are supplied in

parallel. This is not the case with double-ended sterilizers with SPF function, nor with ethylene oxide sterilizers. On these, each door has its own pressure switch.

Identify the components involved by referring to the electrical and pipework diagrams of the sterilizer. The pressure switch operating pressure is shown on the pipework diagram.

Setting

1. With the sterilizer in standby mode, switch off the electric power with the control switch.
2. Shut off the incoming steam and air supplies.
3. Disconnect the connecting pipe and connect a reference instrument to the door seal pressure switch. Initially the pressure switch must be kept at atmospheric pressure.
4. Remove the cover from the pressure switch (to access the adjusting nut).
5. Adjust the pressure switch until the contact closes. For further information, see under *Pressure switch* in the COMPONENTS chapter.
6. Set the reference instrument to the pressure stated on the pipework diagram, normally 1.7 bar(e) / 170 kPa(e) / 25 psig. If there are conflicting data, the data on the pipework diagram take precedence.
7. Switch on the power with the control switch.
8. Slowly turn the setting nut on the pressure switch until the LED on the input of the control unit goes out.
9. Continue with the safety check below, from step 5).

Safety check

1. With the sterilizer in standby mode, switch off the electric power with the control switch.
2. Shut off the incoming steam and air supplies.
3. Disconnect the connecting pipe and connect a reference instrument to the door seal pressure switch.
4. Switch on the power with the control switch.
5. Close the sterilizer door(s), check that emergency stop buttons have been reset, and connect a test lamp or similar to terminal *MEDIA*.
6. Increase the pressure until the reference instrument shows 3 bar(e) / 300 kPa(e) / 45 psig. Check that the test lamp and the control unit LED are lit.
7. Slowly reduce the pressure with the reference instrument until the test lamp and the control unit LED go out. The pressure at changeover should be as stated on the pipework diagram, normally 1.7±0.1 bar(e) / 170±10 kPa(e) / 25±2 psig. If there are conflicting data, the data on the pipework diagram take precedence.

8. Remove the test lamp and the reference instrument.
9. Reconnect the pipe to the pressure switch and refit the pressure switch cover.
10. Open the incoming steam and air supplies.

Safety interlocking of the door opening

The safety interlocks to prevent the door opening are duplicated, split between the control system and an independent supervisory system. The safety criteria of both systems must be fulfilled before the door can be opened.

Independent pressure switch

Adjustment

Adjust the pressure switch with the sterilizer in the stand-by mode. The pressure switch for chamber pressure is easy to identify on the electrical circuit diagram sheet for safety interlocks, where the external interlock is routed through auxiliary relay 1.

1. Turn on the control power supply and check whether terminal *OPEN* is live. If it is, screw in (clockwise) the adjusting nut for the pressure switch group 1 until the terminal is de-energised.
2. Slowly screw out (anticlockwise) the adjusting nut until terminal *OPEN* is again energised, and then turn the nut through a further quarter turn anticlockwise.

Safety check

1. Start a process.
2. Check that terminal *OPEN* is de-energised before the chamber pressure has reached 0.2 bar(e).

Supervisor

Setting

The Supervisor safety blocking is not adjustable, as the temperature limits for releasing the door interlock are programmed into the software. Pressure is measured by a separate pressure transducer. However, a defective or incorrectly calibrated pressure transducer can jeopardise safety blocking.

Safety test

1. Start a process.
2. Check that terminal *OPEN* becomes non-live when the chamber pressure is higher than 1.2 bar (a). Read all the values on the control

system display panel, and not on the supervisory system control panel. If the values are taken from PACS Supervisor, it will not be possible to decide whether or not the system needs to be calibrated.

(NB: There may be a few seconds' delay in the readings between the PACS Supervisor and the PACS 3000 control system.)

Calibrate the supervisory system sensors if necessary.

The control system

Adjustment

The safety interlocking provided by the control system is not adjustable, since the pressure limits for allowing the door to open are programmed in the software. Pressure is measured with a dedicated pressure sensor and temperature with dedicated temperature sensors. A faulty or incorrectly calibrated temperature sensor can threaten the safety interlocking.

Safety check

Check the pressure and temperature sensors with a reference instrument. If an incorrect indication is found, replace faulty sensors and calibrate.

CONTROL UNIT PACS 3000

The letters **PACS** stand for **P**rogrammable **A**utoclave **C**ontrol **S**ystem.

The purpose of the control system is to issue orders and send them to the executive components of the unit so that a number of process steps are performed in accordance with a predetermined template. The order signals are worked out by the computer program of the control unit in conjunction with measurements of actual parameter values for the current program. These are usually times, temperatures and pressures.

Several different pieces of equipment can be connected to the control unit for programming, monitoring and documenting the processes.

The operator communicates with the control unit via a control panel or an ordinary PC. There are several versions of the operator-machine interface, from the simplest, which consists of two pushbuttons and eight LEDs to show that certain statuses have been reached, to the most advanced, which allow complete programming of the control system, among other things.

All operator panels can be used to monitor the processes, since they display all the set parameter values as well as actual values on request. All relevant data associated with a given process, such as batch number, operator number, date, etc., can be entered by the operator.

Programs, system definitions and process data can be documented by connecting a printer to the unit. A host computer can also be connected directly to the CPU of the control system.

If necessary, a measurement and monitoring system which is completely independent of the control system, can be set up by providing the equipment with a PACS SUPERVISOR. This contains a separate CPU and its own measurement and control cards. The SUPERVISOR performs its measurements by means of separate temperature and pressure sensors alongside those of the control unit. The system has links to the control unit CPU and can therefore use the shared operator panel, as well as adding the control unit readings to the process documentation. The SUPERVISOR can also be involved in independent interlocking of door opening, for example.

The computer contains programs for automatic calibration of the temperature and pressure sensors. Where alternative correction constants are known, they can be entered manually. The testing functions include means of activating analog and digital outputs and for monitoring analog and digital inputs.

The control unit hardware is divided, so that the operator panels can form small separate units that are easy to position at the most suitable location. CPU, measurement and control boards and the power supply are installed in separate electrical enclosures which are connected to the operator panels by shielded cables.

A number of special terms

STERILIZATION refers to the entire series of treatments that make up a process aimed at achieving the total killing of all living organisms. This applies to sterilizers and usually includes air removal, heat treatment and a drying phase.

STERILIZING refers to the actual killing part of the process, the heat treatment.

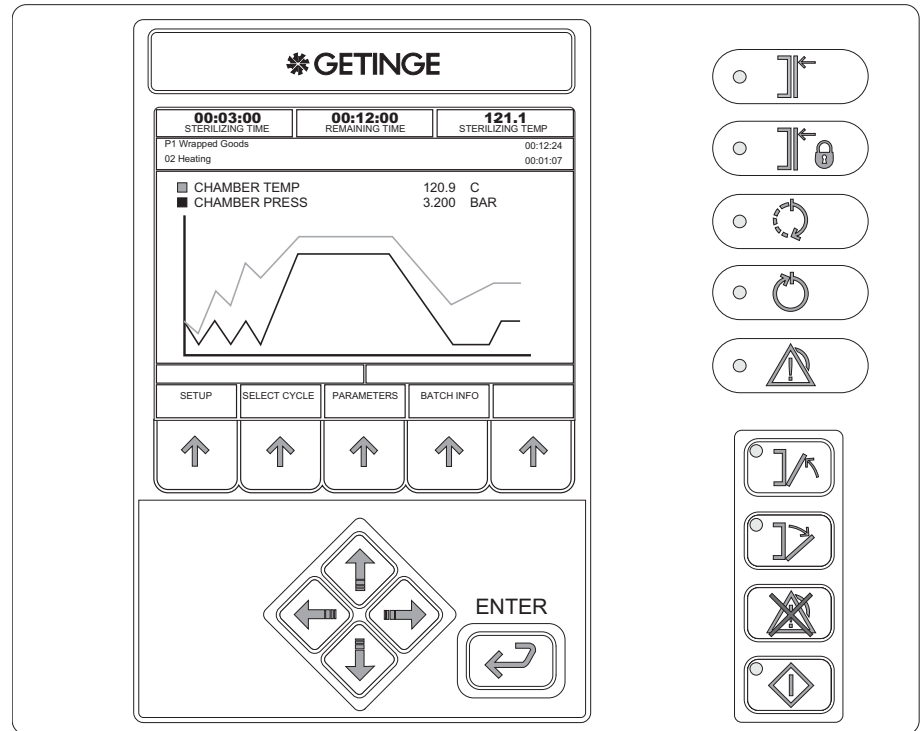
On the same basis as the two terms above, STERILIZATION TIME refers to the duration of the entire process from the start until the objects can be taken out of the sterilizer. The PROCESS TIME is the same as the sterilization time.

The STERILIZING TIME is only that part of the process for which the programmed STERILIZING TEMPERATURE exists in the chamber.



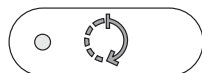
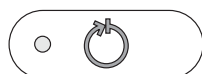


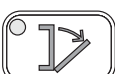
In this context, PARAMETERS means FACTORS THAT INFLUENCE THE sterilization process. Examples of parameters in the sterilization process are temperature, pressure, time, humidity, gas concentration, etc.


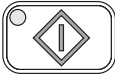
PARAMETER VALUES may be permanently set in the program, be adjusted by the operator, be included in selectable recipes or downloaded from a higher-level system.

Operating panel type OP 30



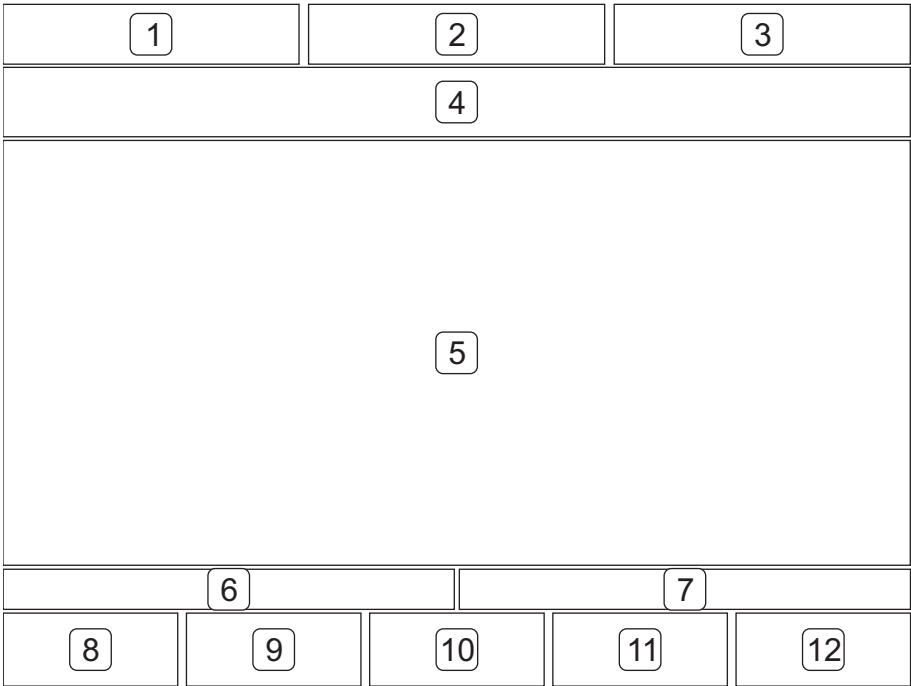
Indicators and controls

| | |
|---|---------------------------------------|
|  | The door(s) is/are closed. |
|  | The door(s) is/are closed and locked. |
|  | Process running |
|  | Process completed without errors |
|  | Defective process |
|  | Close door |
|  | Open door |

| | |
|---|------------------|
|  | Reset the alarm. |
|  | Startup |

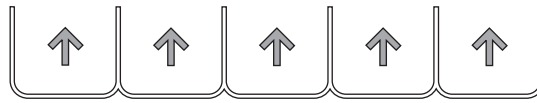
Display

The display is divided into a number of windows in which information about the process appears as described below.



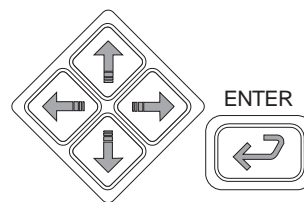
| | |
|---------------|--|
| Fields 1 - 3 | Process parameters |
| Field 4 | Program number, program name and process time Phase number, phase name and phase time |
| Field 5 | Process window |
| Field 6 | Alarm text (white on a red background) |
| Field 7 | Information text (white on a blue background) |
| Fields 8 - 12 | Key texts adapted to each menu |

Function keys



1. Five labels for the function keys appear at the bottom of the character window. The texts (max two lines of seven characters) are centred in a window.
2. The key texts always appear in the same place. Example: if the HOME function is active on any of the display, it always appears in key position two.

Cursor keys



There are five keys for navigation on the panel. These keys (which always have the same functions) are four arrow keys (up, down, left and right) to control the cursor and an ENTER key.

On the main process display the program keys are used to move around in the on-screen menu to choose a function.

Using the operator panel

General

1. The image is normally made up of different displays with different extra function choices, displays where data appears or displays with editable fields where data can be entered or changed.
2. The cursor keys are used to scroll through all the selectable fields on the current display. When you select a field, it is displayed reversed.
3. If there are more rows (list entries) than will fit into a single window (about ten) only the first ten are displayed, and a scrollbar appears on the right of the display.
4. You can scroll through the entire list with the aid of the arrow keys. When the cursor reaches the last displayed field of the list and there

are more fields below it, pressing the down key causes the list to scroll up one row at a time. The same applied when scrolling in the opposite direction.

5. All selectable list boxes and choices operate as rotating lists. This means that, if you press the down key when the last choice is selected (highlighted), the first choice in the list is selected. The rotating choice list operates regardless of the number of choices available.
6. The HOME key always uses key position 2 and returns you to the main menu and logs off the current user.
7. System messages on the panel, such as “System busy” etc appear as popup menus.

Screen display modes

A display can have up to three modes:

- A READ MODE – you can scroll between values
- B EDIT MODE – values can be changed
- C SAVE MODE – to save edited values

Editing fields

- When the display is in read mode, pressing ENTER causes the display to switch to edit mode and lets you edit the chosen field.
- Arrow keys are used to modify fields.
- When the screen display is in edit mode, pressing ENTER makes the display change to save mode.
- Arrow keys are used to choose another field.
- When the display is in save mode, pressing ENTER causes the display to switch to edit mode and lets you edit the chosen field.
- The SAVE key saves value in PACS and puts the display in read mode.

- **Editing numeric fields** – The first numeral flashes and the others are displayed in reverse. The flashing numeral can be increased/decreased with the up/down arrow keys. Pressing the left/right arrow keys choose the next numeral to the left/right, and makes it editable at the same time. If you press right-arrow key at the far right numeral, the cursor does not move to another numeral. The same applies to the far left numeral.

When you press ENTER after editing a numeric field, the system checks automatically that the new value is within the permitted range.

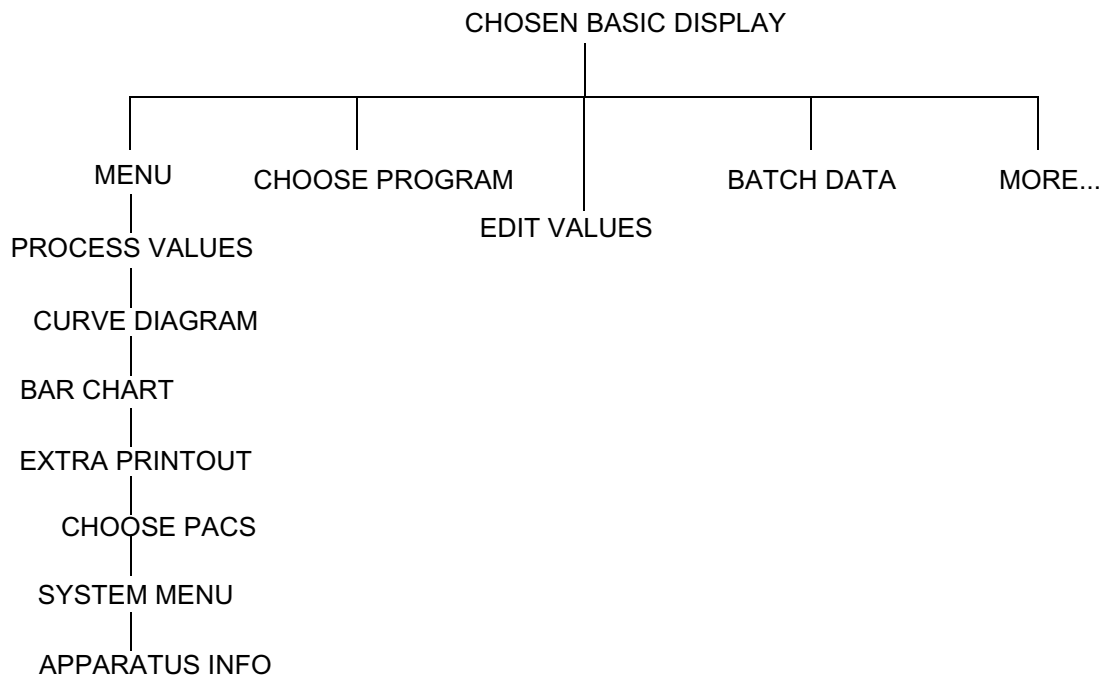
- **Editing option fields** – All numerals in the field flash. Pressing the up/down arrow keys changes the value of the field to the previous/next value in the list. If the field has the last value in the list, pressing the down key displays the first value. Likewise for the first value in the list when the up key is pressed.

- **Editing alphanumeric fields** – A keyboard is displayed above the current screen display. The keyboard is not transparent. A cursor appears where the field value is located. The field value is empty. The first key on the keyboard is selected. The arrow keys are used to access a character. Pressing ENTER places the chosen character in the field. The arrow keys and the ENTER key are used repeatedly to place characters in the field. The keyboard supports both upper and lower case (small and capital) letters. A program key labelled “SHIFT LOCK” toggles the display of characters on the keyboard between upper and lower case. Pressing the OK program key closes the popup menu and returns you to the previous display. Characters are entered into the chosen field.

The OK and CANCEL keys

- In READ MODE, the OK key returns you to the previous display
- The CANCEL function always uses key position 1 and is defined as follows:
 - In READ MODE
 - return to previous display. No confirmation is needed.
 - EDIT MODE, without popup
 - returns the original value of the field and changes the display to SAVE MODE.
 - EDIT MODE, with popup
 - returns the original value of the field, returns the previous display and changes it to SAVE MODE.
 - SAVE MODE
 - prompts for “Confirm cancel” (of this function has been chosen), returns all fields on the display to their original values and returns the previous display.
- If the option in the panel setting menu for confirmation of save and cancel is set to Yes, the prompt “CONFIRM SAVE?” appears when you press SAVE, letting you choose Yes or No. Yes saves the values on the display and lets you continue. No returns you to the display. This setting is made in the system menu and is described in the service manual.
- If the option in the panel setting menu for confirmation of save and cancel is set to Yes, the prompt “CONFIRM CANCEL?” appears when you press CANCEL, letting you choose Yes or No. Yes restores previous values and lets you continue. No returns you to the display. This setting is made in the system menu and is described in the service manual.

Operator menu tree



Description of operator menu tree

Chosen basic display

The control system has three ways of reporting on the process. The basic setting is defined in the system menu and is described in the service manual. These three possibilities are described under Settings, where the display mode can also be temporarily changed.

Menu

Process values

Shows a scrollable list containing the displayable parameters.

Curve diagram

Shows two predefined parameters as growing curves.

Bar chart

Shows two predefined parameters as vertical bars.

Extra printout

This option is only available when the control system is in the standby phase.

When the function has been chosen, a new display with the following options appears:

1. CANCEL – return to previous menu display
2. HOME – return to basic display
3. NO – return to previous menu display
4. YES – print out the latest process and return to the previous menu display

Choose PACS

This option only appears if the panel is connected to more than one PACS or if the sterilizer has a SUPERVISOR.

System menu

Described in the service manual. A password is required for access to this menu.

Apparatus info

Displays (among other things) the control system in the form of version information for the panel and the control system.

The brightness of the display can be increased or reduced with the number 2 function key (LESS BRIGHT) and the number 3 function key (BRIGHTER).

Choose a process

Displays a list of available processes. If there are more processes than will fit in a menu display, they are displayed in a scrollable list.

Parameters

Displays a list of parameters. An “A” before the parameter name means that the parameter can be adjusted (Adjustable).

Press EDIT to adjust a parameter. An alphanumeric keyboard now appears, with a prompt to enter a password. If you enter the wrong password, “WRONG CODE” appears. After a second or two, the password entry display re-appears.

When the correct password has been entered, a list of options appears. If the list is too long to fit into a display, it is scrollable.

Choose the selected parameter by pressing ENTER. An entry screen for the chosen parameter appears.

Edit the value and press ENTER. Provided that the chosen value is within the approved range, it will be transferred to the previous display. Press SAVE to save the value or CANCEL to restore previous values.

Batch

This option is only available if the function has been defined. A PC is required to define this function.

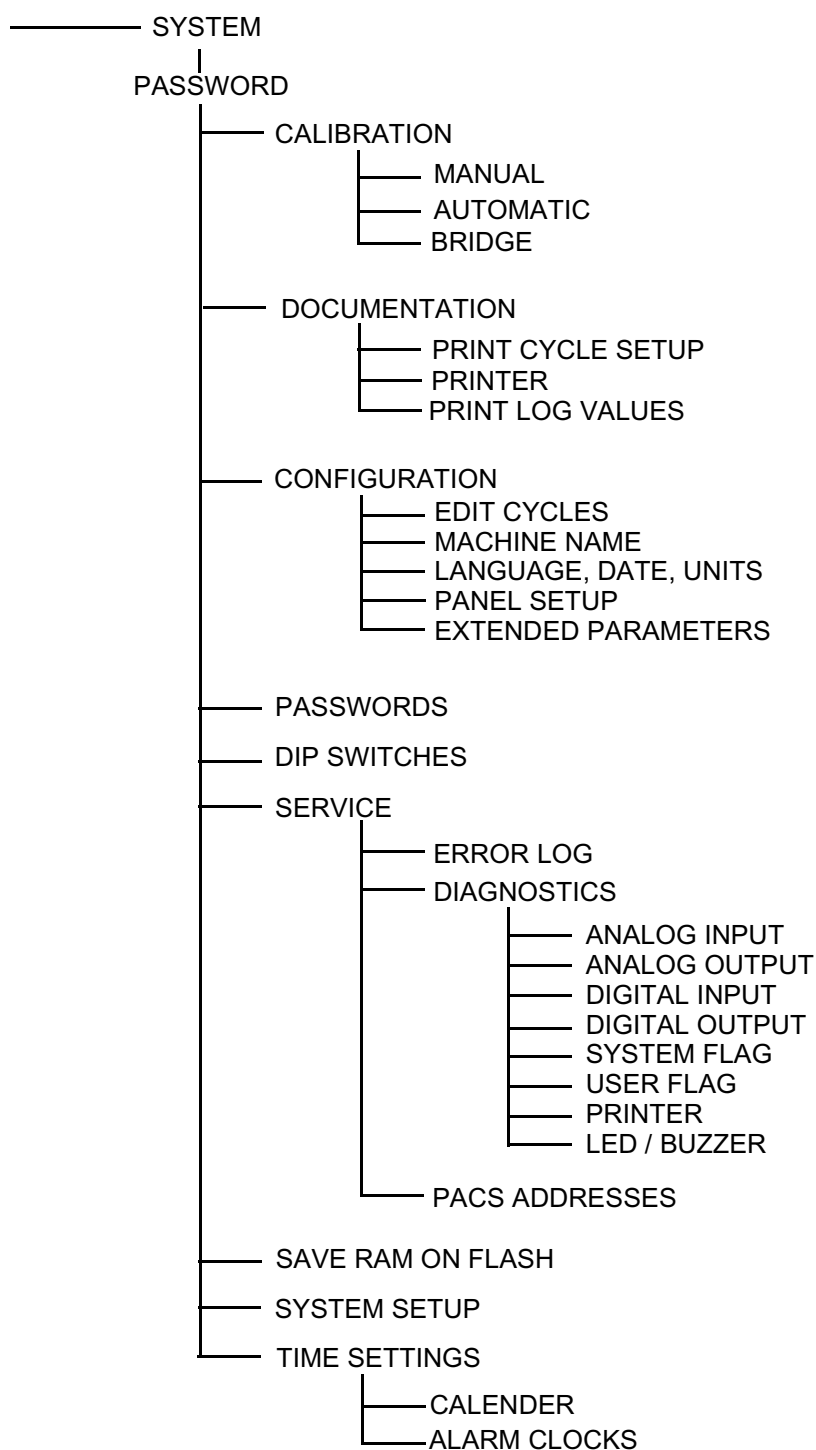
Entry of batch data

Defined values are entered with an alphanumeric keyboard.
Press SAVE to save entered data.

Menu

This function is only displayed in situations where one of the pre-programmed functions is active.

System menu



Enter password

An alphanumeric keyboard appears. Use the arrow keys to select the required character and choose it with ENTER. Press OK to enter the password. Delete incorrect characters with ERASE. Use CANCEL to quit the entry display.

If the wrong password is entered, a dialog box appears with the text “Wrong password. Try again” for about five seconds.

Calendar

Use the arrow keys to move the cursor to the task you want to change. Press ENTER to choose. Use up-arrow to increase the value and down-arrow to reduce it. Use the left and right arrow keys to move to the next digit/number.

When the changes are complete, press ENTER again.

Calibration

Manual calibration

The calibration constants GAIN and OFFSET for analog input signals are set in this menu. The inputs are displayed in a scrollable list. Select the required sensor with the up/down arrow keys. To jump between GAIN and OFFSET, use the right/left arrow keys.

Press ENTER to edit the value. Use the left/right arrow keys to move the cursor and the up/down arrow keys to increase/reduce the value. Use the “+/-” key to change the sign of the value. To quit editing, press ENTER.

Automatic calibration

In this menu, one or more sensors are chosen for automatic calibration. Use the up/down arrow keys to select the required sensor. To choose it, press ENTER. Use the up/down arrows to toggle “No”/“Yes”. The highlight changes between “Yes” and “No” for each keypress. Note that, if a temperature sensor is chosen, no pressure sensor can be chosen, and vice versa.

Confirm the choice with ENTER and continue to choose sensors, or press NEXT to continue. Enter the lowest reference value. The cursor is at the decimal position. To increase/reduce the value, use the up/down arrow keys. Move the cursor with the left arrow key. The number of integer positions increases for each press of the left arrow key.

Press LOW SAVE to proceed to enter the high reference value. When you press HIGH SAVE, the values are saved.

Bridge tables

The system contains four bridge compensation tables. Each table has seven lines of Rb, GAIN and OFFSET parameters. You can scroll through the list with the NEXT TABLE keys.

Rb is a value between 3000 and 4000 ohms.

Gain is a value between 0 and 999.9

Offset is a value between -999.9 and 999.9

Move the cursor to the required value with the arrow keys and press ENTER to open it for editing. Use the up/down arrow keys to change

the value. Press ENTER to proceed to the next value. Press SAVE or CANCEL to continue.

Press ID to name the sensor or to change its name. The display changes to an alphanumeric keyboard which the operator can use to enter a name. To quit, press ENTER. In the next menu display, choose SAVE or CANCEL.

Documentation

In this menu you can choose to print out program documentation (phase list and parameter list) for chosen programs or for all programs.

Configuration

Name and address

Use the up/down arrow keys to select the item to be edited. Press ENTER to confirm. When changing the name, an alphanumeric keyboard is displayed.

Language, date, units

Here you can choose language, date format, units of pressure and temperature. Move the cursor to the required unit with the up/down arrow keys and open it for editing by pressing ENTER. Browse through the available options with the up/down arrow keys. Press ENTER when the required unit appears.

Printer

In this menu you can determine the type of presentation for the data to be printed out and the length of the logging interval. Move the cursor to the required heading with the up/down arrow keys and open the value for editing by pressing ENTER. Use the up/down arrow keys to change the values. Press ENTER when the value has been corrected. Press SAVE or CANCEL to continue.

Printer log values

This menu lets you build up lists in which you define the parameters that are to be included in the printout. Each list lets you determine which parameters are to be included and in which order they will be arranged.

Select a line and press ENTER. A list of input and function types appears. Select a desired category. A list of all those defined in the system appears. To add the required parameter to the list, press ENTER.

Panel setting

Here you can choose (among other things) the type of basic menu to be displayed. Move the cursor to the required heading with the up/down arrow keys and open the option for editing by pressing ENTER. Browse through the available options with the up/down arrow keys. Press ENTER when the required unit appears.

Alarm clock

This menu displays (if there is one) a list of events that can be started automatically at times set here.

PACS addresses

In this menu you can define the names of the PACS systems that are connected to the unit.

Passwords

A list of names, valid passwords and access areas is displayed. Use the arrow keys to select the item to change and press ENTER to make it editable. Use the up/down arrow keys to change the value and press ENTER when the change is complete.

Note that you cannot change the password that you used to log in.

When you press ACCESS AREAS, a list which explains the meanings of the letters A - K appears.

DIP switches

This menu contains options for setting various functions. We advise against changing any of these settings, since this may adversely affect the operation of the sterilizer.

Service

Error log

The latest alarms are shown in a list. To see more information about a given alarm, select it and press MORE INFO.

Diagnostics

Analog input

This menu shows all defined analog inputs on the screen. Current values are continuously updated.

Analog output



**The operator disables the built in safety system by setting the mode to MANUAL,
Make absolutely sure that it is safe to set the output to manual mode before doing so.**

In AUTO mode the outputs are controlled by the PACS program.-

In MANUAL mode the output can be controlled to set, desired values.

The MODE column specifies whether the output is in AUTO or MANUAL mode. The values in these columns can be changed between the two options with the up/down arrow keys.

In the SET field the operator can specify the value to which the output should be set. The limits for the value field are 0.0 - 100.0%. Note that MANUAL mode must be selected, otherwise the value will be ignored..



Remember to reset the MODE to AUTO before quitting the menu.

Digital input

This menu shows all defined digital inputs on the screen. Current values are continuously updated.

Digital output



The operator disables the built in safety system by setting the mode to MANUAL, Make absolutely sure that it is safe to set the output to manual mode before doing so.

In this menu, digital outputs can be set to desired status. Current values are continuously updated.

In AUTO mode the outputs are controlled by the PACS program.-

In MANUAL mode the output can be set to the desired status.

The MODE column specifies whether the output is in AUTO or MANUAL mode. In these columns, the operator can change between the two options with the up/down arrow keys.

In the SET field the operator specifies the status of the output. The value alternates between 0 and 1 (off/on) every time the up/down arrow is pressed. Note that MANUAL mode must be selected, otherwise the value will be ignored.



Remember to reset the MODE to AUTO before quitting the menu.

System flags

This menu shows all defined user flags in a scrollable list on screen. Current values are continuously updated.

User flags

This menu shows all defined system flags in a scrollable list on screen. Current values are continuously updated.

Printer

When PRINTOUT pressed, a text string is sent to the connected printer.

LEDs and buzzer

When TEST is pressed, the LEDs light up and the buzzers sounds intermittently for five seconds.

Save RAM in Flash

With this function you can save the content of the RAM in a Flash memory if there is one.

I²C-link faults on PACS 3000 modules.

I²C stands for “Inter-IC” and is a link with two conductors for efficient inter-IC control.

I²C is the communication link between the PACS 3000 CPU and the modules (AI, AO, DI and DO) connected to the CPU. The I²C-link is serial. It begins with the CPU and end with the last module.

IO error alarm

When a communication error occurs between the CPU and an input or output module defined in the software, an alarm is given. The alarm is a sum alarm for all I²C communication.

Possible I²C faults:

1. The I²C component in a module is faulty.
A faulty I²C component or the lack of a power supply to the module may completely disable communication.
2. Cable break between the modules.
Because serial communication is used, a cable break anywhere along the chain causes a fault in the connection for all modules beyond the break.
3. The DIP-switch address settings are wrong.

DIP-switch settings on PACS 3000 modules

Every PACS 3000 input and output module has a four-pole DIP- switch for setting the IO-address of the module. The binary number system in the table below shows the module address number system.

Example:

| Module number | Digital | DIP settings DIP number 4. 3. 2. 1 | Calculation |
|---------------|---------|--|---------------------|
| 0 | 0000 | on on on on | $0 + 0 + 0 + 0 = 0$ |
| 1 | 0001 | on on on off | $0 + 0 + 0 + 1 = 1$ |
| 2 | 0010 | on on off on | $0 + 0 + 2 + 0 = 2$ |
| 3 | 0011 | on on off off | $0 + 0 + 2 + 1 = 3$ |
| 4 | 0100 | on off on on | $0 + 4 + 0 + 0 = 4$ |
| 5 | 0101 | on off on off | $0 + 4 + 0 + 1 = 5$ |
| 6 | 0110 | on off off on | $0 + 4 + 2 + 0 = 6$ |
| 7 | 0111 | on off off off | $0 + 4 + 2 + 1 = 7$ |

Each input and output module has a separate page in the electrical diagram. The page number is the same as the module number. The DIP-switch settings are shown on the corresponding page.

Note that each type of module has its own address series which begins with zero within its type. The system supports up to eight DI, eight DO, eight AI, and four AO modules. Independent process monitoring (Supervisor) limits the use of analog inputs because the Supervisor logs its own analog inputs and those of the control unit. Inputs from AI24 upwards are reserved for the Supervisor. This limits the number of analog inputs on the control unit to 24 (AI0-AI23). Normally this means max 4-6 analog input modules, depending on the number of inputs per chosen module.

Examples of addressing:

Digital input module 10 is on page 10 of the electrical diagram. The “0” in “10” stands for “ module 0” and the correct DIP-switch settings are:

1 = on (0)

2 = on (0)

3 = on (0)

4 = on (0)

Digital input module 11 is on page 11 (the second “1” stands for module 1) and has the following DIP-switch settings:

1 = off (1)

2 = on (0)

3 = on (0)

1 = off (1)

4 = on (0)

The same applies to digital outputs (DO) on pages that begin with “5”, for example 50 for DO module “0”, 51 for DO module “1”, etc.

If you look closely at the module you can see the word “ON” printed on the DIP-switch case. If the four DIP-switches are set to “ON”, the setting is 0000. The four DIP-switches are numbered 1, 2, 3 and 4 and the number is on the DIP-switch.

On new modules, the DIP-switches are normally set to address “0”.



NOTE:

Switch off the main power supply when setting DIP-switches. When the power is switched back on, the CPU reads the settings. If the DIP-switch settings are changed with the power on, the CPU does not read the changes.

Checking I²C faults with PC and CS1000

1. Start the PC
2. Start CS1000
3. Choose the “Diagnostic” menu
4. Choose the “System flag” menu
5. Enter the password “Enter Password” (service authorisation is required)
6. Status “0” indicates that there is no I²C communication fault in any module. **NOTE:: “0” also appears if the module has not been configured.**
“1” indicates that there is an I²C fault.
7. System flag SF00 indicates an internal I²C fault (sum alarm).
8. For faults on DO modules, check SF128-SF135.
9. For faults on DI modules, check SF136-SF143.
10. For faults on AO modules, check SF144-SF147.
11. For faults on AI modules, check SF152-SF159.
 (NOTE: SF160-SF161 are not used)

Manual check of I²C faults

Fault tracing:

1. Check that the I²C cables and the power supply AC1 - COM - AC2 – are correctly connected to all modules. The voltages AC1 and AC2 are 18 V to COM, ie 36 V between AC1 and AC2.
2. Prepare an I²C cable long enough to reach all modules from the CPU.
3. Switch off the power.
4. Disconnect the I²C cables between the modules.
5. Connect the prepared I²C cable to the last module in the chain (the CPU is the first).
NOTE: The last module is only connected to one I²C cable.
6. Switch on the power.
7. Start CS1000.
8. Check whether the I²C fault is present in the module by using the system identifiers in the CS1000 as described earlier.
9. If there is communication, switch off the power, disconnect the prepared I²C cable and connect the normal I²C cable between the last and the next-to-last module.
10. Connect the prepared I²C cable to the next-to-last module.
11. Switch on the power.
12. Start CS1000.
13. Check whether the I²C fault is present in the last two modules by using the system identifiers in the CS1000 as described earlier.

Check all cards by following the steps above until the cable break is located. If the cable is faulty, replace it. If the module is not working properly, replace the card.

NOTE: A CM1 card contains one analog input module, two digital input modules and two digital output modules. If the CM1 panel is not working properly, the entire CM1 card must be replaced.

Technical data, PACS 3000

| | |
|---|------------------------------|
| Adaptation to mains voltage by means of transformer | 2 * 18 ±10% V AC, 50 - 60 Hz |
| Power consumption depends on the size of the system | < 100 VA |
| Permitted ambient temperature in service | +10 — +60°C |
| Moisture resistance | 90% rel. |
| of control system | 100% rel. |
| front panel | |

| | | |
|---|----------------|--|
| Water and dust protection | control system | IP54 |
| | front panel | IP65 |
| Electromagnetic compatibility | | FCC 15 J, CIS PR22, EN 50081-1, EN 50082-1, IEC 801 |
| PCB design to | | CSA and UL |
| Maximum distance between control panel and control unit | | >1000 metres |
| System sampling rate for all inputs and outputs | | 4 Hz |
| Type of digital inputs supplied from system | | Opto-coupled 24 V DC |
| Number of digital input modules | | Maximum 8 |
| Number of inputs with each module | | 8 |
| Type of digital outputs | | Relays, contact rating 12 A |
| Number of digital output modules | | Maximum 8 |
| Number of digital outputs per module | | 8 |
| Number of analog input modules | | Maximum 10 |
| Number of analog inputs with PACS 3000 alone | | Maximum 32 |
| Number of analog inputs with PACS Supervisor connected | | Maximum 24 |
| Type and number of analog inputs per module: | AI1 | 3 RTD Pt100 1 pressure |
| Type and number of analog inputs per module: | AI2 | 3 thermocouples type K, T 1 pressure |
| Type and number of analog inputs per module: | AI3 | 6 RTD Pt100 |
| Type and number of analog inputs per module: | AI4 | 6 thermocouples type K, T |
| Type and number of analog inputs per module: | AI6 | 4 general purpose 0 - 20 mA 0 - 5 V 0 - 10 V 4 - 20 mA ^{*1} |

| | | |
|-----------------------|----------------|--|
| Type of analog input: | A. Temperature | |
| | Sensor | Pt 100 only four-wire |
| | Resolution | 0.1 °C |
| | Inaccuracy | ±0.1 °C |
| | Range | -5 - +150 °C |
| Type of analog input: | B. Temperature | |
| | Sensor | TC type K, Chromel-Alumel |
| | Resolution | 0.1 °C |
| | Inaccuracy | ±0.2 °C |
| | Range | -5 - +150 °C |
| Type of analog input: | C. Temperature | |
| | Sensor | TC type K, Chromel-Alumel |
| | Resolution | 0.2 °C |
| | Inaccuracy | ±0.4 °C |
| | Range | -5 - +800 °C |
| Type of analog input: | D. Temperature | |
| | Sensor | TC type T, Copper - Constantan |
| | Resolution | 0.1 °C |
| | Inaccuracy | ±0.2 °C |
| | Range | -5 - +150 °C |
| Type of analog input: | E. Pressure | |
| | Sensor | Wheatstone bridge 0 - 500 mV/v |
| | Resolution | 0.001 bar(a) |
| | Inaccuracy | ±0.01 bar(a) within 0 - 1 bar(a) ±1% of actual value within 1 - 5 bar(a) |
| | Range | 0 - 5 bar(a) |

| | | |
|-------------------------------------|--------------------|---|
| Type of analog input: | F. Pressure | |
| | Sensor | Wheatstone bridge |
| | | 0 - 300 mV/V |
| | Resolution | 0.001 bar(a) |
| | Inaccuracy | ±0.001 bar(a) |
| | Range | 0 - 1.5 bar(a) |
| Type of analog input: | G. General purpose | |
| | Sensor | 0 - 20 mA, 4 - 20 mA ^{*1} , 0 - 5 V, 0 - 10 V |
| | Inaccuracy | 0.1% of measuring range |
| | Range | as above |
| Analog outputs | | 0 - 20 mA, 4 - 20 mA, 0 - 5 V, 0 - 10 V Resolution 0.4% Activation rate 4 Hz |
| Number of analog output modules | | Maximum 4 |
| Number of analog outputs per module | | 2 |

*1. Where 4 - 20 mA is chosen, all four inputs are adapted to that working range.

PACS SUPERVISOR

The PACS SUPERVISOR is an instrument for independent monitoring and documentation of processes. The Supervisor measures the process parameters with its own sensors and other measuring equipment which is completely independent of the control unit's equipment.

Physically, the same types of components are used as in the control unit, so that description of operation and servicing instructions in the manual can be used for both.

The control unit also provides the Supervisor with information about batches, control unit sensor signals, phase designations, activated alarms, and logged-in operator codes.

Operator control panel

The Supervisor shares the operator panel with the control unit.

The operator panel is normally logged in to the control unit. Menus for the Supervisor are the same as for the control unit, but since the Supervisor has its own CPU (own PACS address) the operator must connect to the Supervisor (via the menu system) instead of to the sterilizer control unit. Normally it is only necessary to log on to the Supervisor when you need to access menus for programming, calibration, emergency printout, printout of calibration reports, or some other action. The function and position of the menus can be seen from the menu trees for the relevant type of operator panel.

Calibration

It is just as important to maintain the accuracy of the Supervisor sensors as that of the control unit sensors. Both sets of sensors should therefore be calibrated together.

Documentation

The SUPERVISOR has the important function of independently documenting the process by registering a large number of process parameters, partly from its own independent measuring system, and partly from that of the control system.

These process parameters can be printed out during a process or saved to a disk on a connected PC as log files.

The parameters that are normally recorded are pre-defined in the Supervisor when it is delivered from the factory. Up to 12 values on a line can be programmed using normal printout size. Compressing the printout size allows up to 20 values to be printed on a line.

The make-up and number of measured values can be changed with OP30, OP50 or a PC and the CS1000 application tool. Administrator

rights are needed to make changes. Changes from the operator panel are described generally above under the respective panel. Note that it is necessary to change byte “PACS address” from the sterilizer control unit to the Supervisor via the menu system.

Changing logged measured values in CS1000:

- Choose sterilizer number (PACS address) for Supervisor (numbers from 51 upwards) on starting or change to Supervisor via the menus:
 - "view"
 - "overview"
 - "select"
- Go to the “Settings” menu.
- Choose the “Printer log signal definition” menu.
- Enter the administrator password.
- Press “OK” to confirm.
- Make the required changes.
- Press “OK” to confirm and exit the menu.

Printout options

Printouts are available in the form of a report with all simultaneously measured values printed on one line, known as logging, and/or in the form of a graph. The exact composition of the printout can be determined with a “printout mode”, which can be chosen via the operator panel or CS1000.

Mode 1 printout

An introduction containing batch information is followed by logging during the process.

Mode 2 printout

As mode 1, but is supplemented afterwards by showing the process in the form of one or more consecutive graphs. The appearance of the graphs, the units used and the measured values can be defined from the operator panel or from CS1000.

Defining a graphical “process picture” in CS1000:

- Go to the “Settings” menu.
- Choose the “Process Screens” menu.
- Choose the “Graph Process Picture” menu.
- Enter the administrator password.
- Press “OK” to confirm.
- Make the required changes.

- Press “OK” to confirm and exit the menu.



If you choose to store the data on disk, storage of the graph(s) should be disabled.

If the graph(s) is/are to be stored as well, the logging time will be extended by at least 30 minutes. If a new process is started during this time, storage is aborted and the remaining measured values are lost.



Only Getinge personnel may program the system to disable graph storage.

Even after graph storage has been disabled as above, the graph(s) will still be printed out during the process.

Mode 3 printout

In this printout mode, an introduction in the form of batch information is followed by process details in the form of a graph. The graph is produced in real time, while the process is running, and is concluded at the same time as the process.

After the graph, and activated alarms are printed out, together with all measured values at the time of the alarm.

Storage on disk is not possible in mode 3.

Mode 4 printout

The process is drawn in the form of one or more graphs in parallel with logged measured values. In this mode the logging interval should be set to at least 30 seconds to allow time for the graph to be drawn.

Storage on disk is not possible in mode 4.

Emergency printout

If printout fails or is defective, an emergency printout of the last process performed can be made.

The emergency printout is ordered via the operator panel or CS1000. This cannot be done while the process is running.

The emergency printout can handle 600 logged values. If the completed process contains more than 600 logged values, the emergency printout omits every other reading.

Safety functions

The Supervisor, with its independent temperature and pressure sensors, is used in parallel to the control unit to achieve duplicated safety for

important monitoring functions. The approval of the Supervisor is therefore needed to terminate a liquid cooling process or to open the sterilizer door after a process.

Detailed information about these monitoring functions can be found under the heading “Independent process monitoring” in the MAINTENANCE chapter.

Connecting the printer

A printer is connected to the Supervisor, mainly to print process logs and/or graphs, but also calibration reports, for example.

In addition, the system is designed so that the control unit can also print to the Supervisor printer. This function may, for example, be used to print calibration reports or other program information.

Technical data

The SUPERVISOR is constructed with the same hardware as the control unit, so that its technical data are the same.

COMPONENTS

Illustration on drawings

- Electric wiring diagrams are drawn with power off.
- Apparatus and components are illustrated in their basic position.
- Pressure switches are illustrated in the position they take for atmospheric pressure.
- Thermal switches are illustrated in the position they take for room temperature.

Departures from these rules are indicated on the diagrams.

Lexmark printer, 570 33 30

Laser printers are products that are subject to frequent changes of model.

See the Lexmark manual for reliable and up-to-date information.



Warning! The printer must be supplied with power from the same distribution board as the power to the sterilizer; see also the chapter entitled "Installation". The printer cannot be connected to the socket outlet on the sterilizer.

Vacuum pump LEM 90

Varieties

| Item no. | Volt | Hz | kW | Notes |
|--------------|-----------------|----|-----|-------|
| 479 23 80-01 | 200-254/350-440 | 50 | 2,2 | |
| 479 23 80-02 | 200-254/350-440 | 60 | 3,6 | |
| 570 04 18-01 | 220-240/380-415 | 50 | 2,2 | |
| 570 04 18-02 | 220-240/380-400 | 60 | 3,6 | |

The direct-on-line starter cutout current should be set to the value stated on the motor data plate.

Sealing water: 1 litre / 6 sec.

Separator 565 39 24

See also “Cleaning the separator” in the MAINTENANCE chapter.

The installation also has a combined silencer, separator and circulation container for the seal water.

The separator is normally installed behind the electrical cabinet between the upright frame posts of the vacuum unit.

The seal water is recirculated to the vacuum pump. This means that water consumption is very low.

A plate-type heat exchanger continuously cools the seal water, removing the heat generated by the vacuum pump. It is very important that the cooling works properly if the vacuum unit is to have its full suction capacity.

To achieve the best operating economy, the installation should have a circulating cooling water system, so that the seal water is not cooled by water that is consumed.

If the water level in the container is low, it is topped up automatically. The seal water is continuously replaced as new condensate from the process is added. The water level in the container must be just below the overflow.

To avoid damage to the pump, it is important that the pipe connections are leaktight (especiallt the ones at the bottom of the separator so that

the water does not leak out. The water supply valve must operate reliably for the same reason.



Make sure that the water level in the container is high enough. If the pump runs dry, the shaft seals may be damaged.

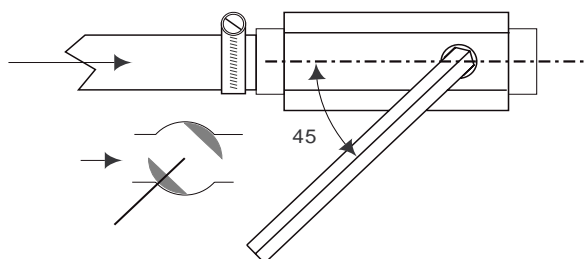
Seal water

See also “Sealing liquid for the vacuum pump” in the INSTALLATION INSTRUCTIONS chapter of the DESCRIPTION OF OPERATION manual.

Sealing water flow control

Method A requires some experience of vacuum pumps and is normally simple to perform. Method B is measurable, but slightly more complicated.

Make the adjustments below during the post-treatment phase when the vacuum pump is working under stable pressure conditions.



Set the pump to a basic setting first, by opening the ball valve slightly less than 45°.



Do not let the pump run with the ball valve closed. Within a few minutes the pump will be completely drained of water, and this may damage the shaft seals.

Method A:

1. Restrict the water as much as possible without the pump running unevenly, then open the valve slightly to ensure a sufficient flow of water.

If the pump gets too much water, cavitation will occur. If it does not get enough, its performance will drop and getting a deep vacuum may be difficult.

Method B:

1. Check that the consumption of seal water is stated under the heading “Vacuum pump”. If this information is not stated, use method A above.
2. Connect an external measuring glass via a T-piece and two valves (non-restricting) to the hose that supplies seal water from the tank to the pump, so that you can switch in service to applying suction only to the measuring glass. Make sure that all the water does not drain out and top up the tank/pump as necessary.
3. Fill the measuring glass with water and position it with the water surface approximately level with the pump shaft.
4. Start a process and switch to the measuring glass when the pump is working under post-vacuum in stable conditions.
5. Using a stopwatch, note how long it takes for the level to fall by an amount equivalent to one liter.
6. Adjust the ball valve setting so that the time taken is as shown in the specification under the heading “Vacuum pump”.

Anti-cavitation protection

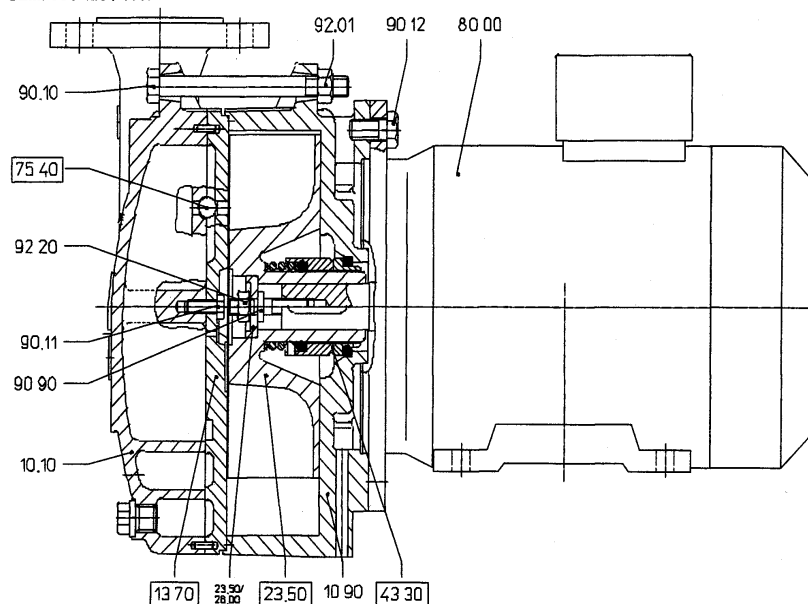
To counteract cavitation in the pump, small amounts of air are continuously supplied via the following three separate anti-cavitation functions:

- Addition of air via the built-in connection on the pump body. For practical reasons (to eliminate spillage), air at atmospheric pressure is taken by a hose from the feedwater tank or the circulation container.
- Addition of air into the suction line of the pump, with restricted feed from the compressed air supply via a solenoid valve. The anti-cavitation protection is only active at pressures above 150 mbar(a) / 15 kPa(a) / 2.5 psia. The restriction is opened three turns as a basic setting. Normally there is no need to change this.
- Addition of air into the pump sealing water, with restricted feed. For practical reasons (to eliminate spillage), air at atmospheric pressure is normally taken by a hose from the feedwater tank or the circulation container. The restriction is opened two to three turns as a basic setting. Normally there is no need to change this.

Servicing

The purpose of the following instructions is to make easier any form of work that involves dismantling the pump.

LEM. 90 / 125 / 150:



| | | | |
|-------|-----------------|-------|------------------------|
| 43.30 | Mechanical seal | 10.10 | Pump housing end plate |
| 90.90 | Adjusting nut | 13.70 | Guide plate |
| 23.50 | Impeller | 10.90 | Pump housing |
| 90.30 | Plug | 92.01 | Nut |
| 75.40 | Valve ball | 90.10 | Screw |
| 92.20 | Locknut | 90.11 | Screw |
| 80.00 | Motor | 90.12 | Screw |

Preparations



Switch off and lock the safety switch.

1. Disconnect all pipes connected to the pump.
2. Disconnect all electrical connections to the pump. Mark the cables with the correct phase sequence.
3. Remove the pump from the unit, or, if it is a standalone pump, from its stand.

Dismantling

1. Remove the hexagon screws in the pump housing end plate (90.10).
2. Separate the pump housing end plate (10.10) together with the guide plate (13.70) from the pump housing (10.90) by prising at the centering groove with a screwdriver, for instance. Take care of the plastic balls (75.40).
3. Unscrew the locknut (92.02) or (92.20) from the impeller. Hold the adjusting screw (90.90) securely with an Allen key.
4. Pull off the impeller (23.50) using one of the two methods below or a combination of them.
 - a. Unscrew the adjusting screw (90.90) from the motor shaft.
 - b. Remove the hexagon screws (90.12) in the motor flange. Prise off the pump housing (10.90) with symmetrically applied tools, so that it brings impeller with it. Use a puller if necessary.
5. Remove the parts of the mechanical seal (43.30).
6. Where there is a seal cover (47.10), remove it.
7. Where there is a motor adapter (72.30), remove it from the pump housing (10.90).
8. Where applicable, remove the screw that secures the guide plate to the pump housing end plate (90.11), (90.31 and 91.40) or (91.40), depending on pump model.
9. Separate the guide plate (13.70) from the pump housing end plate (10.10).

Assembling

Before reassembling, all parts should be thoroughly cleaned and inspected. In particular, inspect all sealing surfaces for wear and scoring.

If necessary, smooth the guide plate (13.70) against a surface plate with an emery cloth. Coat threaded parts, sliding surfaces and the “contact side” of the guide plate, towards the impeller, with Molycote anti-friction paste (except the sealing surfaces. Do not coat the mechanical shaft seal.

- Pump type with “0” at the end of the pump designation: Sealing surfaces on grey iron parts must be coated with a viscous, semi-drying sealing compound such as “Epple 33” or “Permatex”.
- Pump type with “4” or “9” at the end of the pump designation: Sealing surfaces on stainless steel parts must be coated with sealant such as “Silastik”.

Check that the key is in place in the keyway before assembly begins.



Take care to prevent dirt, foreign bodies and excess sealant getting into the pump housing.

The following general recommendation concerning tightening torques for screws and nuts must be observed.

| Thread: | M6 | M8 | M10 | M12 |
|---------|--------|-------|-------|-------|
| Torque: | 8.5 Nm | 12 Nm | 25 Nm | 40 Nm |

1. Press the fixed part of the shaft seal (43.30) into position in the pump housing (10.90).



Take care! The material of the sliding ring is brittle and it is easy to damage the O-ring.

2. Put the pump housing (10.90) into position, orienting it so that the offset of the pump chamber centre relative to the motor shaft is towards the motor fixing, and secure it to the motor flange with the screws.
3. If the adjusting screw (90.90) was removed from the impeller, screw it into the shaft thread.
4. Place the rotating part of the shaft seal (43.30) on the impeller hub. If necessary, secure the seal in accordance with its assembly drawing.
5. Slide the impeller (23.50) on to the motor shaft. Coat the impeller with sealant in such a way that the flange and the threads of the adjusting nut are sealed off.

| | |
|--------------------|---------------------------|
| LEM 90 / 125 / 150 | Clearance: 0.15-0.175 mm. |
|--------------------|---------------------------|

| | |
|---------------------|--------------------------|
| LEM 250 / 325 / 425 | Clearance: 0.15-0.20 mm. |
|---------------------|--------------------------|

Secure the impeller on the motor shaft with the adjusting nut (90.90) and the locknut (92.02) or (92.20). Make sure that a clearance as shown in the table above is obtained between the impeller and the mating face of the guide plate (13.70) on the pump housing (10.10). Re-check the clearance after tightening the locknut.

6. Place the valve balls (75.40) in their positions in the pump housing end plate (10.10) or on the guide plate (13.70).

7. Apply sealant as above to the sealing surfaces of the pump housing end plate (10.10). Assemble the pump housing endplate to the guide plate.
8. Apply sealant to the remainder of the sealing surfaces and tighten the pump housing end plate (10.10) and the guide plate to the pump housing (10.90) with the screws (90.10). Tighten the screws in opposite alternate pairs. Take care with the mounting position. The correct position is with the connections upwards when the pump is horizontal. The markings must line up.



Note: The shaft seal is easily damaged. Do not turn the pump shaft with no liquid in the pump.

Turn the shaft from the fan end, and check that it rotates soundlessly. If the shaft binds, this is usually because the impeller is wrongly adjusted relative to the guide plate.

See also the pump manufacturer's manual.

Loosening a seized pump shaft

It has been reported that the shaft of a vacuum- or feed water pump due to the fine clearances may become too tight after standing for a period without use. The motor will then not rotate when switched on. In this case, proceed as follows:



Switch off mains at the safety switch and lock.

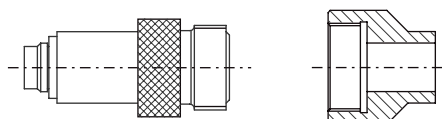
- Remove the fan hood of the pump motor.
- Pry off the fan with two symmetrically applied levers (for example large screw drivers).
- Protect the shaft with a folded piece of sheet metal when applying a pipe wrench. Twist in both directions to loosen.
- If this procedure fails to loosen the shaft then:
- Loosen the screws, holding the pump housing together, about one turn.
- Make another attempt to loosen the shaft.
- If required, tap carefully on the loosened housing.
- Tighten the screws, in rotation checking that the shaft is free to rotate.

Reset the lockable switch and check by brief manual operation of the contactor that the pump works normally.

Pressure transducer

The signal from the pressure transducer is used by the control unit and, where applicable, by the PACS Supervisor, to measure pressure. The pressure transducer itself does not have any means of calibration; instead this is done with the control system or the supervisor. The transducer must be calibrated regularly, as described in the MAINTENANCE chapter.

Carefully remove the pressure transducer, using hand force. If necessary, a polygrip tool may be used, in which case the tool must be applied to the knurled part and used with great care.



Sealing against the inner part of the pressure transducer and outwards towards the service space is provided by a small O-ring located between the diaphragm of the pressure transducer and the adapter mounted on the sterilizer chamber. When fitting the pressure transducer, screw it fully home into the adapter by hand, then carefully secure it with the polygrip tool applied to the knurled part.

Hand tightening is normally sufficient to provide a seal. Take great care when using the polygrip tool, to avoid subjecting the pressure transducer to stresses that might lead to incorrect indications.



Take care not to damage the diaphragm when assembling and dismantling. Never use tape, sealing compound etc. to seal the thread.

Always fit a new O-ring when the transducer is refitted.

Single circuit pressure switch 469 56 96

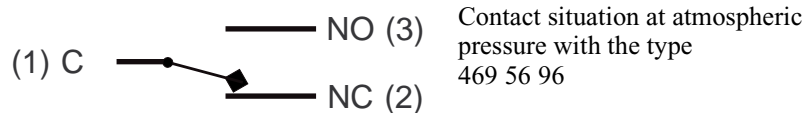
1 bar = 100 kPa = 14.504 psig

| Item number | Range bar | Switching difference | | Permissible pressure bar |
|--------------|--------------|----------------------|-------------------|--------------------------------|
| | | (fixed) bar | adjustable bar | |
| 469 56 96-01 | 0.14 - +4 | | 0.2 ±0.1 | 5.0 |
| 469 56 96-02 | -1 - +1 | | 0.15 ±0.05 | 4.0 |

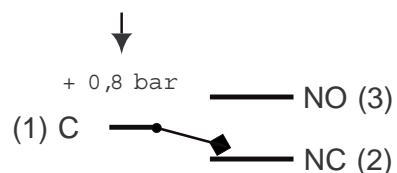
| | | | | |
|--------------|----------|----------|--|-------|
| 469 56 96-03 | 0.5 - 11 | 0.3 ±0.1 | | 13.75 |
| 469 56 96-08 | 0.5 - 11 | 0.3 ±0.1 | | 13.75 |

Temperature limits -20 - +70

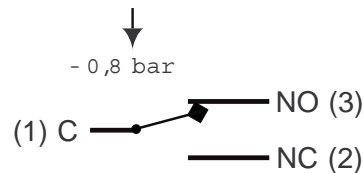
Contact ratings 5A / 250 V



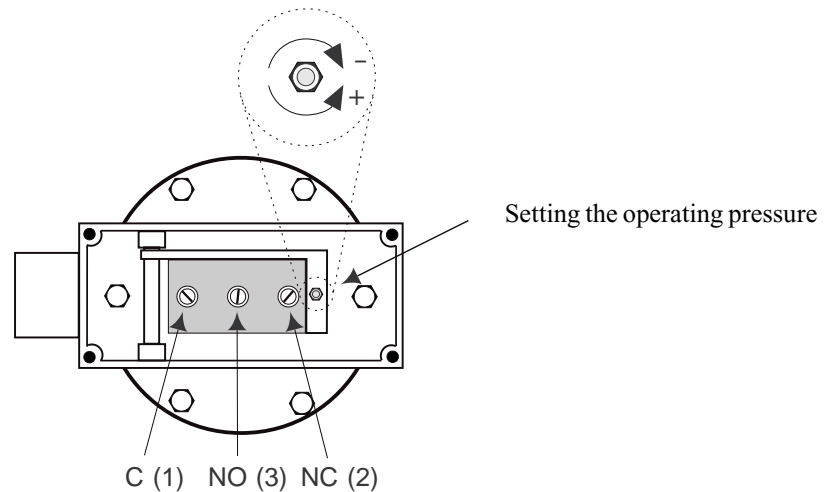
With type 02, the contact situation depends on whether the switch is set for change over at sub- or overatmospheric pressure. The figures below illustrate the contact position at atmospheric pressure.



Change over from C-NC to C-NO takes place at +0.8 bar, falling pressure.



Change over from C-NC to C-NO takes place at -0.8 bar, falling pressure.



The markings NC, NO and C (or 1, 3, 2) appear at the contacts of the pressure switch.



The adjusting screws are electrically live. To avoid short circuits, use insulated tools.

Level switch, Mini-Squing 570 10 75

Level switches of this type can be used to ensure that no condensate remains in the pipes on an autoclave or to indicate level in a steam generator. They are also used to detect the lower and upper levels in the pipe system/vessel during the process on a CPS.

The level switch has a fork which is inserted into the pipe system and connected by TC coupling or thread. The switch operates according to the principle that the fork is excited to vibrate at its natural frequency, which changes depending on the medium it is working in, so that the switch can detect a difference between liquid and air. The level switch does not need to be adjusted.

The level switch has two selectable and fundamentally different contact functions, fail-safe dry or fail-safe wet.

The switch can operate with liquids with densities between 0.6 and 2.0 kg/dm³ and viscosities between 0.2 and 10000 cP. The liquid temperature may be between -40°C and 150°C.

The contact function has a delay of 1 sec. The changeover point for water is 13 mm from the tip of the fork in vertical assembly and 3 mm above the centre-line of the fork in the case of horizontal assembly.

For further information, see the wiring diagram of the apparatus and the manufacturer's data sheet.

Solenoid valves

Hum from a solenoid valve may be a forewarning of overheating due to abnormally high electric current through the solenoid. Generally an alternating current rises when the circuit impedance decreases and this happens when the solenoid is no longer surrounded by a closed iron circuit. An air gap in the magnetic circuit could be caused by dirt preventing the armature from reaching its end position when the solenoid becomes energized.



The power shall be switched off at the isolator. The isolator shall be blocked in "off" position.

- Remedy the humming by cleaning the plunger and its housing.
- Replace the O-ring between solenoid and body when these items have been dismantled.

Certain types of solenoid valves take help from their working medium to close. These, called pilot controlled valves, are often equipped with an orifice in the diaphragm through which the working medium is admitted.

- Observe the location of the orifice while dismantling to enable for correct assembling.

Some solenoid valves have a preferred flow direction indicated by an arrow on the body. However, there are cases when the valve is fitted to face the flow, particularly where vacuum occurs.

- Therefore, check before removal, the way solenoid valves are directed in the piping system that they can be correctly refitted.



The rubber seal on solenoid valves operating in steam will age after a while. To avoid leakage it is recommended that the armature and the spring is replaced every second year.

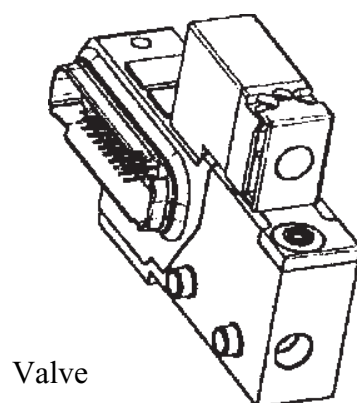
Pilot valve block 570 18 47

The pilot valve block is made up of a connection module with cable and connector and up to 16 valve modules. If there is a need for unique pneumatic supply of one or more valve modules, special intermediate

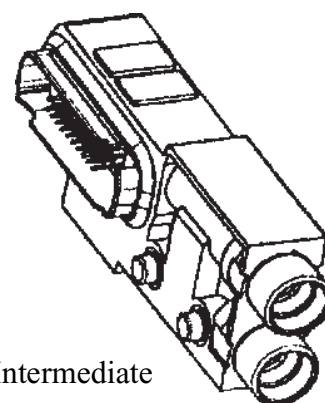
inlets are used; see Included parts below. There are five versions of the valve modules, designed for different types of current, hose dimensions and with normally close or normally open valve function:

1. Normally closed 24 V AC - 6 mm. Part no. 570 18 47-70
2. Normally closed 24 V AC - 4 mm. Part no. 570 18 47-71
3. Normally open 24 V AC - 4 mm. Part no. 570 18 47-72
4. Normally closed 24 V DC - 4 mm. Part no. 570 18 47-75
5. Normally open 24 V DC - 4 mm. Part no. 570 18 47-76

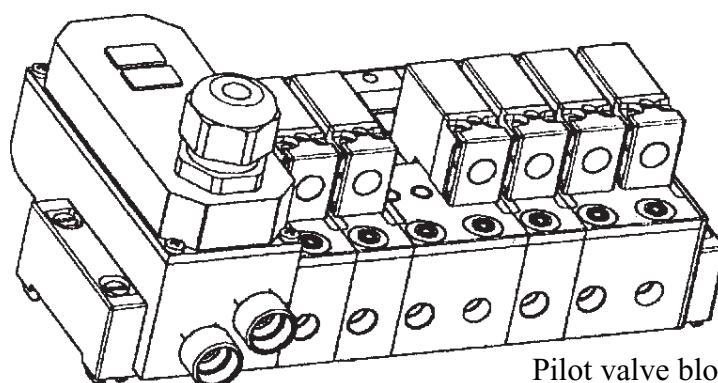
Note that the pins on the cable to the connection module are fitted uniquely in the male connector housing for each valve block. Every coloured cable core with a pin must be placed at a numbered position in the male connector housing, in accordance with a wiring list in the electrical diagram of the unit.



Valve



Intermediate



Pilot valve block

Included parts

| 3/2 valve with protection circuit | |
|-----------------------------------|---------------|
| NC 24 V AC - 6 mm | 570 18 47- 04 |
| NC 24 V AC - 4 mm | 570 18 47- 05 |
| NO 24 V AC - 4 mm | 570 18 47- 06 |
| NC 24 V DC - 4 mm | 570 18 47- 13 |
| NO 24 V DC - 4 mm | 570 18 47- 14 |

| Solenoid valve for 3/2 valve | |
|------------------------------|---------------|
| Solenoid valve (24 VAC) | 570 18 47- 07 |
| Solenoid valve (24 V DC) | 570 18 47- 15 |

| Other parts | |
|--|---------------|
| Connection module with 5 metres of cable and connector | 570 18 47- 73 |
| Connection module with 9.9 metres of cable and connector | 570 18 47- 74 |
| Intermediate inlet | 570 18 47- 08 |

The 3/2-valve with protection circuit

has a pneumatic indicator which is red on a normally closed module and yellow on a normally open one. The protection circuit has a signal light to indicate an electrical signal to the valve block.

The solenoid valve

has a knob for operating the valve manually. With the knob in positions marked “I” the valve is manually activated. In the “O” position it is controlled by the control system.

Removing and installing pilot valves

It is very important to exercise extreme cleanliness when working with pilot valves. Dirt, swarf or gasket residue must not get into the valve ducts. If in doubt, replace the valve.

Foreign particles in the valves may block the valve in the open position and cause leaky operation, so that open doors close or media valves accidentally open, for example.



Observe extreme cleanliness when working on control valves. Be aware of the risk of foreign particles in the valves, which may cause unintended operation. After working on the control valves, check that the doors do not close when they are not meant to.

After working on the control valves, always check that the doors do not close when closing is not activated. The compressed air must be turned on for this check.

Pt 100 sensor (RTD)

Metallic enclosure: Acid-proof stainless steel (AISA 316 or similar)

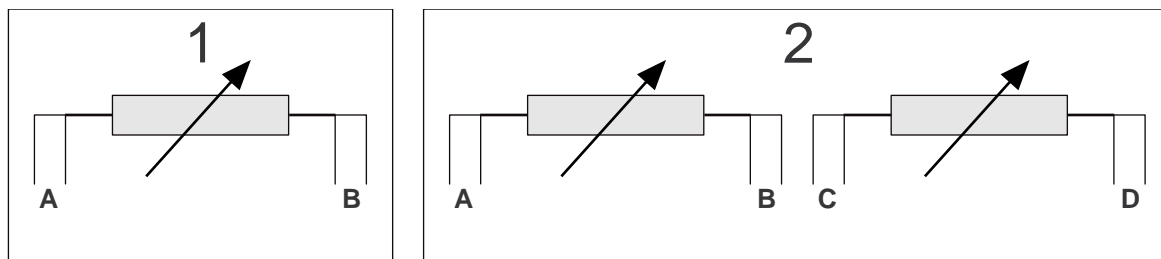
Temperature range: 0 to +140 °C

Working pressure: -1 to +3 bar

Standard: IEC 751-1983, Class A, four-wire.

| Model | Cable | | Type | Diagram | Metallic enclosure | | |
|----------------|-----------------|---------|--------|---------|--------------------|----------|----------|
| | Material | Length | | | Length | Diameter | Type |
| 470 11 44 - 01 | Silicone rubber | 8 m | Single | Fig 1 | 150 mm | 3 mm | Bent |
| 470 11 44 - 02 | Silicone rubber | 8 m | Single | Fig 1 | 150 mm | 3 mm | Straight |
| 470 80 21 - 01 | PVC | 3 m | Single | Fig 1 | 120 mm | 2.5 mm | Bent |
| 470 80 21 - 02 | PVC | 5 m | Single | Fig 1 | 350 mm | 3 mm | Bent |
| 470 80 21 - 03 | PVC | 5 m | Single | Fig 1 | 260 mm | 3 mm | Bent |
| 470 80 21 - 04 | PVC | 8 m | Single | Fig 1 | 120 mm | 3 mm | Bent |
| 570 03 09-02 | PVC | 8 m | Single | Fig 1 | 120 mm | 3 mm | Bent |
| 570 03 08-01 | Silicone rubber | 8 m | Double | Fig 2 | 150 mm | 3 mm | Bent |
| 570 00 15 - 01 | Silicone rubber | 8 m | Double | Fig 2 | 150 mm | 3 mm | Bent |
| 570 00 15 - 02 | PVC | 2 x 5 m | Double | Fig 1 | 120 mm | 3 mm | Straight |
| 570 00 15 - 03 | Silicone rubber | 8 m | Double | Fig 2 | 150 mm | 3 mm | Bent |

| Model | Cable | | Type | Diagram | Metallic enclosure | | |
|----------------|-----------------|---------|--------|---------|--------------------|----------|------|
| | Material | Length | | | Length | Diameter | Type |
| 570 00 15 - 04 | PVC | 2 x 5 m | Double | Fig 1 | 150 mm | 3 mm | Bent |
| 570 06 93-01 | Silicone rubber | 3 m | Double | Fig 2 | 195 mm | 4,5 mm | Bent |
| 570 06 93-02 | Silicone rubber | 3 m | Double | Fig 2 | 260 mm | 4,5 mm | Bent |



| | | | |
|-----------|---------|----------|------------|
| A = White | B = Red | C = Blue | D = Yellow |
|-----------|---------|----------|------------|

Piston valves

Piston valves are used for various media as shut-off valves or as control valves with an on/off function. Such valves are normally maintenance-free, and so any maintenance or replacement is determined by long-term wear or by seal damage.

- Wear and tear can give rise to leakage in the actuator seal, the sleeve seals of the stainless steel pipe or in the valve body stem seal. If the valve is otherwise in good condition, such leakage can be cured by a renovation set.



Always replace seals, including any face seals in connections when dismantling the valves.

- Wear and tear in the valve actuator will give rise to leakage of compressed air to the surroundings. Leakage into the valve body and its media is prevented by a vent hole in the stainless steel guide tube.
- Wear and tear of the stainless steel pipe sleeve couplings can give rise to leakage between that part of the valve body that is connected to the top of the valve stem and the vent hole in the stainless steel pipe sleeve. Depending on how the valve is connected, such leakage can be

detected by means of a leak test of the sterilizer or by leakage of media through the hole.

- Damage to, or dirt on, the valve body stem seal can cause leakage between the inlet and outlet sides of the valve. If the valve is connected to the sterilizer chamber, the easiest way to detect such leakage is by means of a leak test of the sterilizer.



Pressurise the actuator with compressed air when removing the valve body to replace the stem seal. This will compress the closing spring.



Beware of the risk of injury when removing the valve body or actuator, as both contain compressed springs.

Diaphragm valves

Diaphragm valves are used where the hygiene requirements for the pipework are especially strict. They are used for various media as shutoff valves or as a control valves with on/off function.

There are a number of different designs of valve, eg two-way valves and zero-deadleg valves. All designs are available with different actuators, eg normally open pneumatic actuators, normally closed pneumatic actuators or manual actuators.

The diaphragm in the valve is available in various materials, eg EPDM or PTFE in an EPDM frame. The diaphragm ages and can suffer fatigue damage if it is subjected to heat, liquid gases, liquids or steam, and should normally be checked quarterly and replaced if necessary.

The wear is greatest on a valve that is sometimes subjected to steam on one side and full vacuum on the other side, or if the valve is used as a control valve and is therefore subjected to a large number of load changes all the time.

- Wear may lead to leakage through the sealing grooves of the diaphragm, or through the diaphragm to the surrounding environment. If the valve is otherwise in good condition, the leakage can be cured by renewing the diaphragm.



Always renew the diaphragm when removing, repairing and refitting the actuator.

- If there is wear damage on the valve actuator, compressed air will leak into the environment. Leakage into the valve body and its media is prevented by a vent hole in the stainless steel connection sleeve..
- Troubleshooting with ear damage and valve diaphragm leakage: Depending on how the valve is connected, such leakage can be detected by means of a leak test of the sterilizer or by leakage of media through the hole.

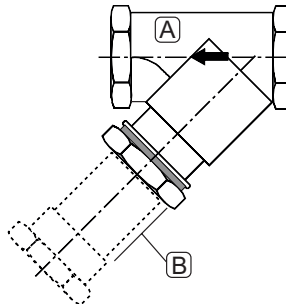


When removing the valve body to renew the diaphragm, pressurise the actuator with compressed air. This will compress the closing spring. Note: This only applies to normally closed valves.



Bear in mind the risk of injury when removing a valve body or actuator, since the actuator contains a closing spring under tension.

Filters and strainers




A = filter housing B = filter element

Cleaning

- Unscrew the filter element and clean the strainer thoroughly.
- Flush out the filter housing.
- Refit the filter element.

Restrictors

Locate the restrictors by finding the -symbol on the P&I diagram. The diameter of the restrictor is stated beside the symbol or on the parts list that belongs to the diagram.

Cleaning

Remove the restrictor and clean it with a wire of suitable gauge. In an emergency a drill with the same diameter as the bore of the restrictor may be used. Note that the drill must only be rotated by hand. Do not use a power drill, since the diameter of the restrictor may be altered if drill does not go in straight.

Soldered plate-type heat exchangers

The operation of the heat exchangers is crucial for the general performance of the unit as well as for process times and the ability to achieve deep vacuum. Note that there is a risk that validated results may no longer be achieved if the heat exchanger leaks or is clogged.

Normally, plate-type heat exchangers need no maintenance, but they do require descaling approximately every other year. If the water hardness exceeds 4 dH, it may be necessary to clean them more often.

Limescale generally tends to obstruct the cooling water inlet of the final heat exchanger first. Inspection there therefore provides a good indication of the condition of the cooling system. Even if the heat exchanger is not clogged, even moderate deposits affect the efficiency of the heat transfer surfaces, so regular cleaning is recommended in any event.

After cleaning, heat exchangers should also be pressure-tested. In normal operation the condensate circuit is not under pressure, but the cooling circuit is. Pressure testing will reveal any leakage.

Cleaning

Our first recommendation for cleaning is an environment-friendly and harmless cleaning agent produced specially for GETINGE plate-type heat exchangers. The agent, trade mark “Limeclean” contains special ingredients. It should not be confused with similar products available on the open market.

Clean the heat exchangers as follows:

- Remove the heat exchanger.
- Read the instructions for using the cleaner and dilute it as instructed.
- The cleaning solution should be heated to about 55 °C for best effect. Alternatively, the heat exchanger can be filled with the cleaner and then heated up.
- Fill the heat exchanger with the diluted (and possibly heated) cleaning solution.
- Allow the solution to act for a few minutes if there is limescale to be removed.

- Follow all other parts of the instructions for the cleaner, covering handling, waiting time, emptying and rinsing.

In an emergency, an alternative method can be used:

- Remove the heat exchanger.
- Place the heat exchanger in a cleaning bath containing one of the acids listed. Instead, the heat exchanger can be filled with one of the acids below, if the position of the connections, etc, makes this possible.
 - 5% phosphoric acid
 - 5% oxalic acid
 - 10% citric acid



Do not use other acids or other concentrations than those listed above.



Working with acids may be dangerous. Follow the instructions and safety regulations of the chemical suppliers.

- Make sure that the heat exchanger is filled completely with liquid and leave the unit in the bath for about one hour.
- Empty the heat exchanger and immediately rinse it thoroughly with water.
- If the heat exchanger is heavily scaled, the treatment may need to be repeated. If this happens, consider reducing the time between descaling operations.



After disconnecting the heat exchanger connections, always fit new gaskets to avoid leakage.

Pressure testing

- Pressure-test the heat exchanger with water at 3 - 6 bar(e). Pressure-test one side and check that water does not leak from the connections on the other side, or through the soldering.



Use only water for pressure testing and do not exceed 10 bar(e).

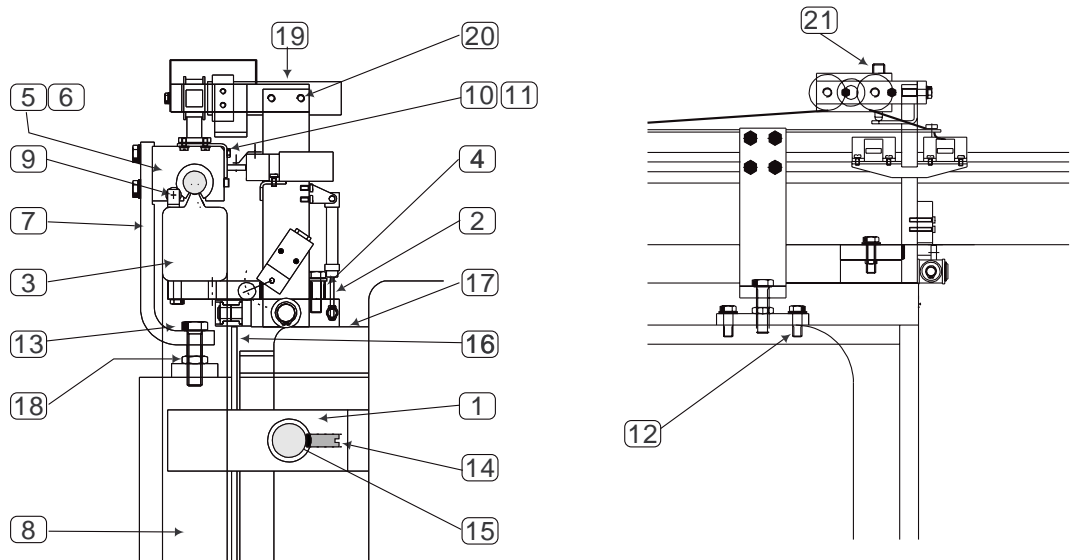
SCRAPPING INSTRUCTION

- When taking apart compressed air controlled piston valves, compressed air must be used due to the spring load in the actuator.



When dismantling doors and chamber care has to be taken due to the weight of the items.

- The special lifting eyes on the top of the chamber should be used when lifting the chamber.
- For door removal, see the instructions below:



- Loosen the locknut (18).



Note that there are different versions of sterilizers and that the above picture is a general one, so your sterilizer may not look exactly like the one in picture.

- Lower the door by turning the suspension screws (13) until the door hangs on the bolts.
- Unscrew the suspension screws.
- Remove the lintel unit (3).
- Use the tapped holes for the suspension screws when lifting the door off the hinges.

