Functional Specification

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1 Introduction

Getinge Life Science is a division of the Getinge group of companies. Group products are used in the pharmaceutical, scientific, and health care industries in over 120 countries spanning five continents. Getinge Life Science manufactures ”industry standard” and custom designed sterilization equipment in its' modern facility in Getinge Sweden. Our production facilities are available for inspection at any stage of a project. In particular, we recommend visits during initial discussions and witnessing final testing at our facility.

1.1 This Functional Specification

1.1.1 Who made this document

A representative at Getinge Sterilization makes this document. The specification will formally be handled and revised by the regional sales manager.

1.1.2 Authority

The responsibility for this Functional Specification and the content is at:

- Getinge Sterilization AB, when the order is accepted by the manufacturer.

Any kind of questions or viewpoints about the content shall be appealed to those authorities.

1.1.3 Purpose

The Functional Specification is made in order to describe the functions to meet the user requirements.

This document is divided into major sections. The first section, OVERVIEW, is a general description of the objectives and the equipment being offered. The following sections, presents specific facts on the design and functions of the equipment. It is intended for design, qualification and to answer more detailed questions that are often raised by engineers, as well as operating and service personnel. A table of contents is provided for quick access to the information contained within.

1.2 Contractual status:

The User shall approve this document. This document will gain contractual status when the signatories in the front page are processed.

2 Overview

2.1 Key objectives and benefits:

2.1.1 Confidence

We respect our client's requests to protect information relating to particular operations and products. We request that similar confidentiality be extended to us and ask that this document and related information is not copied to third parties without our permission.

2.1.2 The Sterilizer Objective

This specification describes a high performance Getinge ventilator sterilizer. The sterilization process is an automatic batch process performed in a closed chamber (pressure vessel). Each process recipe is optimized for a product group and controlled by a control system (a PLC). The apparatus is specifically designed for sterilization of products that are pressure sensitive e.g. liquids in sealed glass or plastic containers. The ventilator system also makes it possible to rapidly cool and dry the product after sterilization. The product is counter balanced with air to ensure that the product is not damaged from internal or external pressures during the process. A fan system mixes the air and steam to provide a homogenous environment. The temperature distribution during sterilization is well within the accepted industry norm of one-degree C between the coldest and highest temperature within the chamber. Cooling of the product is achieved through passing cool water through heat exchangers installed inside the chamber. Compressed air is added to the chamber to prevents boiling or expansion of the product (counter balance). The fan system circulates the chamber environment across the heat exchangers rapidly cooling and removing moisture from the environment. No cross contamination can occur between the cooling media and the product. An inner liner (shroud) ensures that the airflow within the chamber is consistent and even.

2.1.3 GMP Impact

2.1.3.1 Design approach

The design and construction of the sterilization equipment minimizes the risk for errors, dangerous situations and product contamination through:

- The use of non-corrosive and non-toxic material in direct or indirect product contact.
- The use of a design that enables drain-ability and avoids dead legs.
- The uses of accurate and verified control system measure circuits, normally temperature & pressure.
- The use of design and process which enables uniform temperature distribution.
- The use of process alarms which detects unexpected and potentially critical conditions.
- The use of verified processes that assure product sterility and reproducible result.
- The use of a design, which permits effective cleaning, and maintenance in order to avoid cross contamination, builds up of dust and dirt, and in general adverse conditions that could affect the product quality.
- The use of safety analysis as a tool to assure safety for personnel and property.
- An ergonomic design approach, e.g. the equipment shall not exceed a noise level above 70dB(a) measured 1 meter from the user interface.

2.1.3.2 Risk analysis based classification of requirements

The requirements and functions are classified in categories depending of the risk.

- GMP critical requirements referenced may be exposed to “on site” qualification practices.

- Non GMP critical requirements referenced is tested and verified in accordance with Getinge Quality and Management System [4].
- Information regarding non-critical features and attributes referenced are neither tested nor verified.
- Non-critical information and attributes are included only to improve equipment understanding for the user.
- The FS is regarded as one of the most important documents for test reference during subsequent qualification, e.g. IQ, OQ, etc.
- The categories are used in this document on individual requirements or on entire sections.

2.1.3.3 Rationale for classification

In order to judge how to classify individual requirements Getinge Sterilization AB is using a GMP Impact Assessment Rationale [3]. The rationale is available for user audit at Getinge Sterilization AB.

2.1.3.4 Ready "off the shelf" components qualified in development projects

- Some hardware and software components are qualified in development projects and are then maintained in a validated state.
- The components are subject to project change control when they are maintained and updated.
- Qualified components are normally not subject to testing and verification in this specific project.
- Referenced qualified components in the specification which is used in this project are available for user audit from this description.
- The associated qualification activities in a development projects varies, refer to the Getinge Validation Policy [6] for a definition.

2.1.4 Important issues during and after delivery

The listed activities / issues are covered in the NON-FUNCTIONAL ATTRIBUTES section.

- Maintainability
- Service
- Testing and Qualification
- Shipping
- Documentation
- Installation
- Training

2.2 Reference to GxP regulations and other directives

2.2.1 Guidelines

The project is performed in accordance with:

ISPE GAMP4

ISPE Baseline

FDA, General principles of software validation, Final guidance, 2002

2.2.2 GxP regulations

FDA, 21 CFR Part 211 (Finished Pharmaceuticals)

FDA, 21 CFR Part 210 (General)

2.2.3 Directives & Regulations

Underwriters Laboratories (UL), Factory Mutual (FM) and Electrical Testing Laboratories (ETL) are independent test institutes (NRTL [9]) in USA and testing products regarding personal safety. Their equivalence in Sweden is ETL SEMKO.

The equipment is ETL-labeled - designed, manufactured and tested for compliance with:

2.2.3.1 Safety standards

The marking ETLc (for Canada) means compliance to:

- CAN/CSA STD.C22.2 No.1010.1

The marking ETLu (for USA) means compliance to "UL/IEC Harmonized Standard for safety":

- UL 61010-1 "Electrical Equipment For Laboratory Use; Part 1: General Requirements" (B)
- UL 61010-2-041 "Electrical Equipment for Laboratory Use; Part 2: Particular Requirements for Autoclaves Using Steam for the Treatment of Medical Materials and for Laboratory Processes" (B)
- UL 61010-2-042 "Electrical Equipment for Laboratory Use; Part 2: Particular Requirements for Autoclaves and Sterilizers Using Toxic Gas for the Treatment of Medical Materials, and for Laboratory Processes" (C)

2.2.3.2 Electrical Codes

NFPA 70 - National Electrical Code (NEC), in applicable parts (e.g. article 670, etc.)

NFPA 79 - Electrical Standards for Industrial Machinery

2.2.3.3 Pressure Vessel Code - American Society of Mechanical Engineers(ASME) New York

ASME Code Section VIII Div. 1 and Section I

Remark: The pressure testing is audited by a notified body for regulatory compliance.

2.2.4 Quality Certification

Getinge Sterilization is qualified and works according to ISO 9000:2000.

2.3 High level description

The Sterilizer is an integrated system that consists of the pressure vessel, piping system, frame, fascia and a control system (a PLC) with instruments and operator interfaces. This description contains general features and subsections for Control System, Mechanical System and Electrical System.

2.3.1 GMP Features

Getinge has incorporated features in the sterilizer to meet or exceed current Good Manufacturing Practices (cGMP). The features provide even temperature distribution once stabilization is achieved. Secondary temperature verification is furnished by including one additional temperature sensor located in close proximity to the drain temperature sensor. Digital read-out of the secondary temperature sensor is provided to the operator. A condensate level sensor is installed down stream from the drain temperature sensor. This ensures that the drain line temperature sensor is unaffected and that condensate does not come into contact with the product being sterilized. The process-wetted indicators described above conform to cGMP standards for hygiene, accuracy, scale and readability. Process piping is designed and constructed to minimize dead legs. A chamber port is provided to accommodate temperature sensors for validation.

2.3.2 Control system PACS 3000

The PACS 3000 programmable logic control system was designed, built, and tested according to the GAMP guideline and ISO 9001 quality system. The PACS 3000 system includes all aspects of control; accuracy, reproducibility, documentation, analysis, monitoring, multi level password security, alarming, programming, maintenance, and human-machine interface of the apparatus data and processes. It is a modular system and comprises sufficient I/O for the chosen process.

An on/off power switch, an emergency stop push button, a door blockage key and a user interface panel are provided on the control side of the sterilizer.

The user interface panel is a OP30 [5.7”] color screen which provides the display of current cycle selection, remaining cycle time, current phase name of the process, trend graph of the process, real time data, parameter settings, and maintenance functions. Process selection, process parameters, operator names, and other necessary alphanumeric information can be entered via the OP30 panel.

The OP30 operator interface has supervisor, operator, and maintenance functions with password protection profiles for individual users. The OP30 provides independent indicators for cycle status, door status, availability of steam, and alarm status at all times. Direct access keys for the most commonly chosen processes are provided as well as arrow keys for full navigation of the data tree. A ”start” button is provided to initiate the process. Open and close door buttons are provided to operate the control side door. The button portion of the control panel is completely sealed to allow for easy cleaning.

Audible and visual indicated alarms are provided to detect unexpected or critical situations. A failed process will be highlighted on the process report through a specific text when the situation occurs, the process will be labeled with ”PROCESS FAILURE” in the end of the report.

The PACS Supervisor is a separate system for process monitoring that replaces an independent recorder and produces, on a single page in real time, both the apparatus data and the data from it's independent sensors. This eliminates the arduous task of analyzing the apparatus data and the independent recording device by operating personnel after the process has ended. Process data is captured and stored within the PACS Supervisor controller and can be repeatedly printed out until the start of the next process. This ”emergency printout” is most commonly used when a printer has failed (i.e., paper jam or empty cartridge). Additional printing modes are available such as printing the logged data and the cycle graph simultaneously on the same page.

A thirty two- (32) column thermal Cobex printer is provided with the apparatus to document the process. It is mounted into the fascia of the apparatus. Process documentation (logging) includes a header that contains the date and time of the process selected, process start, process parameter values, batch information, and the machine counter (number of processes started). Process phase changes are logged with the name of the event along with a log of process data. A printing log rate determines the duration between logging samples during the start and the completion of a process. System alarms are printed during the process with the alarm name and a single log of data. A signature line is provided for a supervisor or operator signature.

The control system including operator controls, instruments, report, process and alarm features is described in accordance with the GAMP guideline in the FUNCTIONS, DATA and INTERFACES sections.

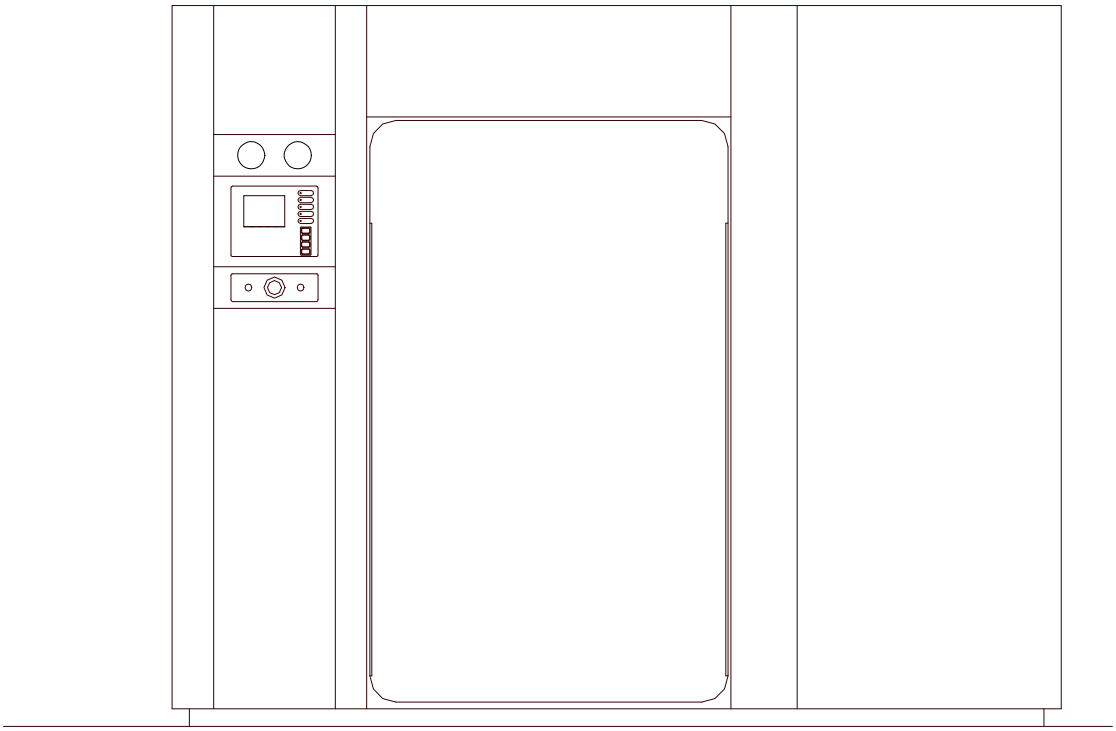
2.3.3 Mechanical system

The mechanical system covers the mechanical enclosure, pressure vessel, piping, electrical system and loading equipment if included.

2.3.3.1 Mechanical Enclosure

Stainless steel fascia panels are provided to separate the apparatus from the operator areas and make cleaning easy. The endurable fascia panels surrounds the apparatus in a so-called cabinet. The fascia panels are supported by a stainless frame structure. Certain selected fascia panels are hinged and snap secured for service access to the apparatus. All instruments are positioned to provide easy access and visibility for the operator.

NOTE: The sketch below is generic and used for improved understanding. The exact configuration may be different, refer to relevant sections for valid data regarding chamber dimension, user interfaces and indicators.



2.3.3.2 Pressure Vessel

The pressure vessel is a welded and internally grounded chamber of high-grade stainless steel with ports for media, drains, sensors and validation equipment. Robotic manufacturing eliminates defects associated with manual techniques and provides an extremely high level of consistency. The pressure vessel has a jacket and automatic horizontal door assembly(ies).

The jacket enables functionality for steam heating. The heating reduces the process steam demand of the chamber while in process thereby producing a more efficient and effective process. The heated jacket will also reduce the amount of condensate formed within the chamber.

Construction of the door(s) consist of stainless steel plate reinforced on the external surface and is held in place during operation by retainers welded to the pressure vessel. The door(s) is(are) suspended on sealed bearings and a simple pneumatic motor operates the(any) door. The pneumatic motor is designed to operate with a minimal amount of force allowing for intrinsically safe personnel protection. The door(s) is(are) sealed by an active silicon rubber ”O” ring gasket, and is(are) fitted in the stainless steel groove of the respective chamber head ring. Mechanical and electrical devices prevent the user from opening the(any) door while the process is running.

The chamber and door(s) are insulated. The insulation is contained in a sheet metal casing. The chamber and jacket are designed to operate at full vacuum and up to the maximum allowable pressure.

Safety relief devices for both the chamber and jacket are supplied when required in accordance with applicable code requirements.

2.3.3.3 Loading Equipment

If loading equipment is included, it is specified in the contract between the Getinge Sales Company and the User.

2.3.3.4 Loading Equipment

The equipment includes loading trolleys with shelves for smooth load handling through the sterilizer. The trolleys are provided with hooking and latching devices. The chamber floor and adjacent external floor are provided with rails for guidance.

2.3.3.5 Process Piping

The process piping includes all internal chamber components and media lines to the chamber including isolating valves to non-process piping. The definition of where the process piping in the media line for process air starts is at the downstream side of the sterile air filter. Valves and major components are arranged to be easily accessible or removable for servicing and replacement.

The equipment is provided with a sterile air filter and housing, to provide sterile filtered compressed air when support pressure is needed in the process. Functions for automatic in situ integrity test (Water Intrusion Test, WIT) are provided.

2.3.3.6 Non Process Piping

The non-process piping includes piping that is not directly in contact with the product, process steam or sterile air such as the jacket piping, door gasket piping and drain system piping. Valves and major components are arranged to be easily accessible or removable for servicing and replacement.

The equipment will be furnished with recirculation utility connections for the cooling water. The cooling water recirculation loop is used to cool the effluent of the apparatus drain and it reduces the consumption of potable water that is necessary to run the equipment. This option may be connected to the user's cooling water return system while installing the equipment.

The door gasket piping will be supplied with sterile filtered air during process and in stand-by. But steam is supplied to the door gasket during the filter program(s) as an extra precaution to prevent cross contamination

The drain system is designed with a liquid ring mechanical pump that creates vacuum in the chamber and door gasket. Getinge's unique water conservation system is used to limit the consumption of the city water by 50% during the process, while guaranteeing maximum efficiency of the vacuum pump.

A pneumatic system is provided to control the operation of the air operated components of the apparatus. The tubing is assembled to present a neat mechanical space. Tubing is tagged along with the connection point to assure proper replacement during servicing.

2.3.3.7 Steam supply

A stainless steel shell and tube heat exchanger is provided to generate steam from a clean water source (i.e. WFI). Plant steam is applied to the shell of the heat exchanger, generating steam from the clean water inside the tubes. The system is integrated with the sterilizer and sized so that the customer does not have to provide the process steam utility.

2.3.4 Electrical system

The electrical system is designed and built to harmonize with national and local electrical codes for the installation site, refer to the *Directives and Regulation* section. The entire electrical system is provided with circuit protection to protect it from voltage surges. Motors are equipped with starters and appropriate circuit protection. All wires and their connection points are individually marked and noted on the electrical drawings. Wires are installed in open wire conduits where practical, with high voltage wires routed separately. Wiring for field devices located outside the enclosure utilize multiple conductor insulated cord and are sealed with water tight connections.

2.4 Main interfaces from the system to other systems or the environment

2.4.1 Control system interfaces:

- User Interface (Operating panels & controls)
- Inputs & Outputs
- Process printers
- Power supply

2.4.2 Mechanical system interfaces:

- Utilities
- Drains
- Loading equipment

2.5 Assumptions

2.5.0.0.1 The apparatus is only used for sterilization of material or equipment in accordance with PROCESS PROGRAM COMBINATION.

2.5.0.0.2 Utilities are provided according to the Technical Data Sheet [10].

2.5.0.0.3 The installation is performed according to the pre installation instructions [11] and the subsequent “installation instructions” in the service manual.

3 Functions

3.1 Door functions:

3.1.0.0.1 The open button is located near the door [hardware function]

3.1.0.0.2 The close button is located near the door [hardware function]

3.1.0.0.3 The door force will not exceed 150N if obstructed [hardware function]

3.1.0.0.4 Media cannot enter the chamber unless the door is closed [hardware function]

3.1.0.0.5 The door opens entirely through a single button press [software function]

3.1.0.0.6 The door closes upon continuous button press i.e. dead mans thumb [software function]

3.1.0.0.7 The door is retracted if an obstacle prevents closing [software function]

3.1.0.0.8 The door(s) will not be able to open during process [software and hardware function]

3.1.0.0.9 The door will not be able to open if chamber pressure is above atmospheric, refer to Media to chamber interlock and Door Opening Interlock in the SAFETY AND SECURITY section

3.1.0.0.10 The door shall not be able to open if the liquid temperature in a closed container exceeds 80°C, refer to Media to chamber interlock and Door Opening Interlock in the SAFETY AND SECURITY section

3.2 Process Program Selection

3.2.0.0.1 A new program is selected via the operating panel

3.2.0.0.2 A new program can only be selected when a program is not running

3.3 Process Start

3.3.0.0.1 A process is started through a start button press [software function]

3.3.0.0.2 A process cannot be started unless the door(s) are closed [software function]

3.3.0.0.3 A process cannot be started if a process alarm is active [software function]

3.3.0.0.4 A process can only be started if the process printer is not active or 15 minutes after previous process end [software function]

3.4 Process Program Combination V3110

The program combination has been designed for sterilization of a variety of items such as utensils, textiles, filters, liquids in sealed plastic and glass containers. All programs are initiated from a non-process state as indicated on the operator interface. A program may not be started unless the sterilizer door(s) is completely closed and no alarm conditions exist. Jacket heating to a temperature close to sterilization is used where appropriate, in the vacuum programs, in order to reduce steam consumption and achieve homogenous temperature distribution. In programs for sterilization of sealed plastic or glass containers an internal fan improves heat exchange, during both heating and cooling, and the containers structure is supported by sterile-filtered compressed air. In vacuum programs, the fan runs on low speed.

The program combination includes different recipes according to table below.

Table 1:

Program no.	Recipe name	Process type
P1	Utensils, glassware, textiles, plastic and rubber products	Vacuum cycle
P2	Filter, utensils	Vacuum cycle, ramped
P3	Liquid in sealed plastic or flexible containers	Ventilator cycle, flexible containers
P4	Liquid in sealed glass or rigid containers	Ventilator cycle, rigid containers
P6	Cold leak test	Leak rate test, cold
P7	Filter Sterilization	In-situ filter sterilization
P8	Filter test	In-situ filter intergraty test

3.4.1 Vacuum cycle

The process has been designed for sterilization of a variety of items. The recipes to the program may be for items such as normal utensils and non-liquid components, rubber stoppers and non-liquid components or equivalent applications.

The included post pulsing improves drying of components that is difficult to dry or components with particular need for final dryness.

3.4.1.0.1 Jacket heating is on through the entire program

3.4.1.0.2 The process logging is started

3.4.1.0.3 Air is removed in the chamber atmosphere and load through repeated evacuation and steam injection to a pressure just above atmospheric. The fan starts and runs in low speed mode. The dilution continues for an adjustable number of pulses

3.4.1.0.4 Steam is injected and condenses removed in order to heat up the chamber atmosphere and load to homogeneous sterilization temperature. The process continues to sterilization when all sensors have met sterile temperature

3.4.1.0.5 Physical sterilization is controlled at a selected hold temperature for a pre-determined time

3.4.1.0.6 Load drying is performed at a pressure below 0,1 bar (a) / 10 kPa (a) / 1,45 PSIA through evacuation. The drying shall continue for an adjustable time

3.4.1.0.7 Admit air in the chamber and evacuate repeatedly for an adjustable number of pulses

3.4.1.0.8 The fan is stopped. The chamber pressure is adjusted close to atmospheric

3.4.1.0.9 The process logging is stopped

3.4.1.0.10 The sterilizer is ready for opening of the door(s)

3.4.2 Vacuum cycle, ramped

The process is intended for steam sterilization of filters and delicate non-liquid components. The components are protected from rapid pressure and temperature changes through the use of ramp controllers.

3.4.2.0.1 Jacket heating is on through the entire program

3.4.2.0.2 The process logging is started

3.4.2.0.3 Air is removed in the chamber atmosphere and load through repeated evacuation and steam injection to a pressure just above atmospheric. The fan starts and runs in low speed mode. The dilution continues for an adjustable number of pulses. The pressure change rate is controlled not to exceed an adjustable value

3.4.2.0.4 Steam is injected and condenses removed in order to heat up the chamber atmosphere and load to homogeneous sterilization temperature. The process continues to sterilization when all sensors have met sterile temperature. The pressure change rate is controlled not to exceed an adjustable value

3.4.2.0.5 Physical sterilization is controlled at a selected hold temperature for a pre-determined time

3.4.2.0.6 Load drying is performed at a pressure below 0,1 bar (a) / 10 kPa (a) / 1,45 PSIA through evacuation. The drying shall continue for an adjustable time. The pressure change rate is controlled not to exceed an adjustable value

3.4.2.0.7 The fan is stopped. The chamber pressure is adjusted close to atmospheric. The pressure change rate is controlled not to exceed an adjustable value

3.4.2.0.8 The process logging is stopped

3.4.2.0.9 The sterilizer is ready for opening of the door(s)

3.4.3 Ventilator cycle, flexible containers

The process is intended for steam sterilization of liquid in sealed plastic or flexible containers. The containers must be possible to keep intact by supporting their internal pressure with an elevated chamber pressure. The support pressure is controlled to support the internal pressure changes in the products to protect the load.

3.4.3.0.1 The process logging is started

3.4.3.0.2 Steam is injected into the chamber from the top and the chamber drain is opened to remove air and condensate. The ventilator fan starts and runs in low speed mode. When the temperature reach a pre-determined limit the support pressure is started and the chamber drain closes. Though, the chamber drain bypass is still open. The process continues to sterilization when all sensors are above sterile temperature or if sufficient F0 value is attained at all load sensors

3.4.3.0.3 Physical sterilization is controlled at a selected hold temperature for a pre-determined time or if desired F0 value is attained at all load sensors

3.4.3.0.4 The fan is not used during the first part of the cooling, when the steam atmosphere collapses. After a few minutes the ventilator fan starts. The internal heat exchangers is cooled with water, which then cools the fan-distributed air. The heat energy is removed from the load by the forced airflow. The pressure will decrease during the cooling and hence must the support pressure be reduced simultaneously to protect the load

3.4.3.0.5 The chamber pressure is adjusted close to atmospheric

3.4.3.0.6 The process logging is stopped

3.4.3.0.7 The sterilizer is ready for opening of the door(s)

3.4.4 Ventilator cycle, rigid containers

The process is intended for steam sterilization of liquid in sealed glass or rigid containers. The containers must be possible to keep intact by supporting their internal pressure with an elevated chamber pressure.

3.4.4.0.1 The process logging is started

3.4.4.0.2 Steam is injected into the chamber from the top and the chamber drain is opened to remove air and condensate. The ventilator fan starts and runs in low speed mode. When the temperature reach a pre-determined limit the support pressure is started and the chamber drain closes. Though, the chamber drain bypass is still open. The process continues to sterilization when all sensors are above sterile temperature or if sufficient F0 value is attained at all load sensors

3.4.4.0.3 Physical sterilization is controlled at a selected hold temperature for a pre-determined time or if desired F0 value is attained at all load sensors

3.4.4.0.4 The fan is not used during the first part of the cooling, when the steam atmosphere collapses. After a few minutes the ventilator fan starts. The internal heat exchangers is cooled with water, which then cools the fan-distributed air. The heat energy is removed from the load by the forced airflow. Now, the support pressure is controlled at a fixed high pressure, since it makes the air atmosphere denser and a better heat conductor

3.4.4.0.5 The chamber pressure is adjusted close to atmospheric

3.4.4.0.6 The process logging is stopped

3.4.4.0.7 The sterilizer is ready for opening of the door(s)

3.4.5 Leak rate test, cold

The process is intended for verification of a process vessel not exceeding a leak rate affecting a sterile result. The actual leak rate test will be performed subsequent to an included normal utensil program.

3.4.5.0.1 The process logging is started

3.4.5.0.2 Air is removed in the chamber through vacuum pump evacuation down to 0,07 bar (a) / 7 kPa (a) / 1,0 PSIA

3.4.5.0.3 Allow the pressure to stabilize during 10 minutes before comparison

3.4.5.0.4 Compare the pressure rise during the next 10 minutes with the acceptance criteria 0,013 bar (a) / 1,3 kPa (a) / 0,19 PSIA. The pressure must not exceed the criteria for a ”Process OK”

3.4.5.0.5 The chamber pressure is adjusted close to atmospheric

3.4.5.0.6 The process logging is stopped

3.4.5.0.7 The sterilizer is ready for opening of the door(s)

3.4.6 Program for in situ air filter sterilization - Sterilization in-place (SIP)

An automatic process is provided for regular in situ sterilization of the sterile grade gas filter, to minimize the risk of bacterial grow-through. The process will be documented with the normal process report functions included.

3.4.6.0.1 The process logging is started

3.4.6.0.2 The pressure in the filter piping system is adjusted close to atmospheric

3.4.6.0.3 Steam is injected into the filter piping system and the drain is opened to remove air and condensate. The process continues to sterilization when the sensor is above sterile temperature

3.4.6.0.4 Physical sterilization is controlled at a selected hold temperature for a pre-determined time

3.4.6.0.5 The filter is gently cooled until a pre-determined temperature is reached, since a warm filter is sensitive to high differential pressure

3.4.6.0.6 The process logging is stopped

3.4.7 Program for in situ air filter integrity test - Water Intrusion Test (WIT)

An automatic process is provided for regular in situ integrity test of the sterile grade air filter, to assure the sterility and function of the filter. Removal of the filter housing or any associated piping is not required, nor is there any need for the end user to perform an independent test. The process will be documented with the normal process report functions included. Water is needed to be able to perform the test. We recommend to use at least dionized water. As an option, it is possible to connect to a water pipeline of e.g. cooled WFI.

3.4.7.0.1 The process logging is started

3.4.7.0.2 If the temperature in the filter piping system is above 30º C a cooling phase is started to achieve a stabilized temperature below that limit

3.4.7.0.3 The pressure in the filter piping system is adjusted close to atmospheric

3.4.7.0.4 A water tank becomes filled with water, either from a manually filled water bottle or the optional alternative of filling from a pressurized water pipeline

3.4.7.0.5 The water tank becomes pressurized and this pressure is then used to fill the filter housing with water. After a while, the measuring point in the top of the filter housing becomes pressurized

3.4.7.0.6 A period of stabilization is needed, i.e. by pulsing a valve when necessary the test pressure is kept

3.4.7.0.7 The water integrity test starts. If the test fails the operator may choose between doing a re test or continue. The test result is logged

3.4.7.0.8 After the test the water is drained. The filter is then dried enough for being able to work according to its specifications. This means that all moisture is not gone, but enough. The drying time is an adjustable parameter though

3.4.7.0.9 The process logging is stopped

3.5 Alarms & Messages

3.5.1 Failure Alarms

3.5.1.1 If failure alarm occurs

3.5.1.1.1 The process stops when the alarm condition occurs

3.5.1.1.2 Valves and motors are put in a safe condition

3.5.1.1.3 The alarm is highlighted with an audible signal and a visual flashing indication

3.5.1.1.4 A specific alarm text will be printed in the process report

3.5.1.1.5 The last 20 alarms are stored in the control system memory, which is possible to access through a user interface

3.5.1.1.6 Interlock alarms shall not stop an ongoing process but prevent start of a new

3.5.1.2 After a failure alarm

3.5.1.2.1 The audible signal is muted and the flashing indication changes into a fixed light indication through a button press on the operator interface

3.5.1.2.2 The program is aborted and taken to a safe ending through a start button press

3.5.1.2.3 If the authorization key is activated the process can either be restarted (through start button) or stepped

3.5.1.2.4 Stepping through critical or potentially dangerous conditions must not be possible to do without meeting the critical condition

3.5.1.2.5 A stepped, restarted or aborted process is regarded as failed in the process report

3.5.1.2.6 The alarm is reset and the visual indication is turned off through a button press when the program is back in stand-by

3.5.1.2.7 Interlock alarms shall only be able to reset by authorized persons with activated authorization key

3.5.1.2.8 ”Process Failure” is printed in the end of the process report

3.5.1.3 Failure Alarm List

3.5.1.3.1 Power Failure [the alarm is set if power returns after a loss with duration above 10 seconds]

3.5.1.3.2 I/O Fault Alarm [the communication between the CPU and a I/O board is lost]

3.5.1.3.3 Emergency Stop Alarm [the emergency stop is activated]

3.5.1.3.4 Analogue Input Failure Alarm [this type of alarm is set if an analogue sensor is broken or out of range; the alarm text is associated with the faulty sensor e.g. AI-Fail Pressure, AI-Fail Jacket]

3.5.1.3.5 Steam Generator Error [the water level is low or the steam generator is malfunctioning]

3.5.1.3.6 Door Failure [the alarm is set if a door is not indicated to be closed during process]

3.5.1.3.7 Door Seal Failure [the alarm is set if a door seal is not indicated to be pressurized during process]

3.5.1.3.8 Pressure Timeout [[this type of alarm is set if pressure increase in process exceeds a reasonable maximum time]

3.5.1.3.9 Sterile Timeout [the alarm is set if the sterile timer has been halted for more than 5 min., due to low temperature]

3.5.1.3.10 Vacuum Timeout [the alarm is set if evacuation in a process exceeds a reasonable maximal time]

3.5.1.3.11 Door Interlock [is set if a hard wire door switch has a status other than expected]

3.5.1.3.12 Door Seal Interlock [is set if a hard wire door seal pressure switch has a status other than expected]

3.5.1.3.13 Pressure Interlock [is set if a hard wire chamber pressure switch has a status other than expected]

3.5.1.3.14 Temperature Interlock [is set if an independent load temperature interlock relay has a status other than expected]

3.5.1.3.15 Vacuum Pump Failure [the alarm is set if the vacuum pump is not working]

3.5.1.3.16 Fan Failure Alarm [the alarm is set if the fan is not working]

3.5.1.3.17 Fan Seal Alarm [the alarm is set if the fan seal is leaking]

3.5.1.3.18 Low Temperature [the control temperature is lower than the sterile temperature set point during sterilization]

3.5.1.3.19 High Temperature [the controller input temp. is higher than sterile temperature set point + 3° in sterile or 4° in kill]

3.5.1.3.20 Jacket Temperature High [the jacket has exceeded sterilization temperature+4° during process]

3.5.1.3.21 High Pressure [the actual pressure is higher than the calculated saturation pressure + a margin during sterilization]

3.5.1.3.22 Leak Rate Test Failure [the pressure increase exceeds 13 mbar/10 minutes during leak rate test]

3.5.1.3.23 Massive Leak [the leak test is aborted due to a leak resulting in a pressure above 0,5 bar(a) during stabilizing]

3.5.1.3.24 Bursting disc [is set if the bursting disc is broken]

3.5.2 Warning messages

3.5.2.1 Features of warning messages

3.5.2.1.1 Warning messages are used on a cycle in progress to indicate an override condition

3.5.2.1.2 An override condition requires an active authorization key

3.5.2.1.3 A warning messages has no audible indication

3.5.2.1.4 A specific text will be printed in the process report when the condition occurs

3.5.2.1.5 A specific text will be displayed on the user interface when the condition occurs

3.5.2.1.6 Warning messages affects the door control, refer to DOOR FUNCTIONS

3.5.2.1.7 Stepping through critical or potentially dangerous conditions must not be possible without meeting the critical condition

3.5.2.2 After a warning message

3.5.2.2.1 The cycle will proceed normally

3.5.2.2.2 The “Process Complete” light is red, at the end of the process, instead of green to indicate a failed process

3.5.2.2.3 ”Process Failure” is printed in the end of the process report

3.5.2.2.4 The warning message does not require any reset procedure

3.5.2.3 Warning message list

3.5.2.3.1 Sequence hold [a warning for a process hold at the next main condition through an activated authorization key. The process continues from the held condition to the next main condition upon a button press]

3.5.2.3.2 Step [a printed (only) warning for a process stepped without meeting a condition]

3.5.2.3.3 High condensate level [a warning for too high condensate level in the drain]

3.5.3 Information messages

3.5.3.1 General features for information messages

3.5.3.1.1 An information text function has no audible indication

3.5.3.1.2 An information text function don't affect the door control, refer to DOOR FUNCTIONS

3.5.3.1.3 A specific text shall highlight a certain condition that will prevent the machine from starting a cycle, i.e. “Prevented-start messages”, or is used to show conditions that are not sufficient to cause a failure of the cycle, i.e. “Service messages”, “Process report messages” and “Process information messages”

3.5.3.1.4 The function does not require any reset procedure, it disappears when the fault condition is gone

3.5.3.1.5 The cycle response is non-GMP critical resulting in a ”Process OK” printout on the report

3.5.3.2 Specific features for Prevented-start messages

3.5.3.2.1 The messages are associated with conditions that will prevent a cycle from starting

3.5.3.2.2 The start button indication-light will not be activated

3.5.3.2.3 Messages are displayed during five (5) seconds upon start trials on the operator panels when start button is pressed

3.5.3.3 List of Prevented-start messages

3.5.3.3.1 Steam Generator Error [prevents start and is shown during 5 seconds]

3.5.3.3.2 Step Key Is On [prevents start and is shown during 5 seconds]

3.5.3.3.3 Printer Active [a printing process printer prevents start for 15 minutes and is shown during 5 seconds]

3.5.3.3.4 Active Alarms [still active alarms prevents start and is shown during 5 seconds]

3.5.3.3.5 Door Seal Pressure [faulty status prevents start and is shown during 5 seconds]

3.5.3.3.6 Door not closed [prevents start and is shown during 5 seconds]

3.5.3.3.7 Door Key Switch [a door interlocked for closing prevents start and is shown during 5 seconds]

3.5.3.3.8 Jacket Temp Low [If the jacket temperature is too low compared with the jacket control temperature]

3.5.3.3.9 Jacket Temp High [If the jacket temperature is too high compared with the jacket control temperature]

3.5.3.3.10 Bursting Disc [If the bursting disc is leaking or broken]

3.5.3.4 Specific features for Service messages

3.5.3.4.1 The messages are constantly active in standby when the condition is active

3.5.3.4.2 The messages do not prohibit the start of a process

3.5.3.5 List of Service messages

3.5.3.5.1 Battery Error [is always on when the conditions occurs, does not affect the process at all]

3.5.3.5.2 Manual Outputs [is always on when a DO or AO is manually set and does not affect the process]

3.5.3.6 Specific features for Process report messages

3.5.3.6.1 The messages are only recorded on the process report

3.5.3.7 List of Process report messages

3.5.3.7.1 Process OK [is set upon a successful process]

3.5.3.7.2 Safety Interlock [is set if the monitoring relay system is not corresponding with the control system; the recorded texts are identical to the failure alarms, e.g. "door interlock", "gasket interlock"]

3.5.3.8 Specific features for Process information messages

3.5.3.8.1 The messages are only displayed on the operating panel

3.5.3.9 List of Process information messages

3.5.3.9.1 Equalize Manually [displayed when a manual equalization by user is expected, holds the process]

3.5.3.9.2 Step Manually [displayed when a manual step by the user is expected, holds the process]

3.6 GMP Functions

Getinge Sterilization AB has incorporated features in the sterilization equipment to meet or exceed current Good Manufacturing Practices (cGMP). In GmP Impact Assessment Rationale [3], which is available for user audit at Getinge Sterilization AB, further information of the rationale to the features in this section.

3.6.1 Temperature Distribution

The temperature distribution within the chamber has a maximum variation of plus or minus (+/-) 0.5°C from the mean chamber temperature, during a measured time period, once stabilization is achieved.

3.6.2 Secondary Drain Temperature

Secondary drain temperature verification is furnished by including one additional temperature sensor located in close proximity to the drain temperature sensor and it is monitored by a independent system. Digital read-out of the secondary temperature sensor is provided to the operator.

3.6.3 Condensate Level Sensor

A condensate level sensor is installed down stream from the drain temperature sensor. This ensures that the drain line temperature sensor is unaffected and that condensate does not come into contact with the product being sterilized. An alarm will sound if condensate is detected in the drain line.

3.6.4 Secondary Chamber Pressure

Secondary pressure verification is furnished by including one additional pressure sensor located in close proximity to the chamber pressure sensor and it is monitored by a independent system. Digital read-out of the secondary temperature sensor is provided to the operator.

3.6.5 Secondary Load Temperature

Secondary load temperature verification is furnished by including one additional temperature sensor located in close proximity to the load temperature sensor and it is monitored by a independent system. Digital read-out of the secondary temperature sensor is provided to the operator.

3.7 Process Report Functions

3.7.0.0.1 The process report consists of pre log data, event logging, intermediate data and post logging

3.7.0.0.2 Important batch and machine information will be printed in the pre log data

3.7.0.0.3 Major process changes such as phase shifts and process limits results in event logging printouts

3.7.0.0.4 Additional low-speed event printouts will be made during pre- and post-treatment, refer to Functions which are configurative and their limits

3.7.0.0.5 Additional high-speed event printouts will be made during the hold period, refer to Functions which are configurative and their limits

3.7.0.0.6 Process alarms will be printed out as intermediate data when they happen

3.7.0.0.7 Process holds or manual steps will be printed out as intermediate data when they happen

3.7.0.0.8 A stepped, held or faulty process will be printed ”PROCESS FAILURE” in the post logging

3.7.0.0.9 A successful process will be printed ”PROCESS OK” in the post logging

3.8 Performance

3.8.1 Response time

Process controllers, inputs and outputs are updated every 250 milliseconds

3.8.2 Temperature resolution and accuracy

3.8.2.0.1 Temperature measure circuits, which include sensors and AI cards, have 0.1°C resolution

3.8.2.0.2 Inaccuracy is less than ±0.1°C

3.8.2.0.3 Temperature resolution and inaccuracy also applies to PACS Supervisor

3.8.3 Pressure resolution and accuracy

3.8.3.0.1 Pressure measure circuits have 0.001 bar (0.1 kPa) resolution or 0.01 PSI for English units

3.8.3.0.2 Inaccuracy below ±0.01bar /±1 kPa /±0.145 PSI in range 0-1bar(a) /0-100 kPa(a) /0-14.5 PSIA

3.8.3.0.3 Inaccuracy less than ±1% of actual value in range 1-5 bar(a) /100-500 kPa(a) /14.5-72 PSIA

3.8.3.0.4 Pressure resolution and inaccuracy also applies to PACS Supervisor

3.8.4 Timer accuracy

3.8.4.0.1 Timer inaccuracy is less than 10 seconds per 3 hours (approximately 1/1000)

3.8.4.0.2 Timer inaccuracy also applies to PACS Supervisor

3.9 Safety and security

3.9.1 Operator safety

3.9.1.1 Emergency Stop

3.9.1.1.1 An emergency stop button with an associated signal to the control system and an independent hard wire circuit to media supply valves is provided. Refer to INTERFACE section for a description

3.9.1.2 Media to Chamber Interlock

3.9.1.2.1 A door locked switch signal to the control system and an independent hard wire circuit to the supply valves is provided. Supply media can not enter the chamber unless the door is closed & locked

3.9.1.2.2 A door seal pressure signal to the control system and an independent hard wire circuit to the supply valves is provided. Supply media can not enter the chamber unless the door seal pressure is applied

3.9.1.2.3 An emergency stop signal to the control system and an independent hard wire circuit to supply valves are provided. Supply media can not enter the chamber when the emergency stop is activated

3.9.1.3 Door Opening Interlock

3.9.1.3.1 An emergency stop signal to the control system and an independent hard wire circuit to supply valves are provided. The door can not be opened when the emergency stop is activated

3.9.1.3.2 The control system monitors the chamber pressure and the equipment is provided with independent pressure interlock circuits to the door seal drain and door opening valves

3.9.1.3.3 The control system monitors the load temperature and the equipment is provided with independent temperature interlock circuits to the door seal drain and door opening valves

3.9.1.3.4 The door seal pressure can not be relived or the door opened if the chamber pressure is above or below atmospheric. The control system will only leave equlization when the pressure is at atmospheric ±0.05 bar / ±5 kPa / ±0.7 PSI. The independent system will not supply control voltage when the pressure exceeds 1.2 bar (a) / 120 kPa (a) / 17.5 PSIA

3.9.1.3.5 This interlock applies to a cooling process with support pressure for liquid in closed containers: The cooling can not be terminated and the door subsequent opened if the temperature exceeds 80°C during end of process

3.9.1.4 Self Checks

A self-check of the hard wire door interlock system will be performed to assure a working system that prevents the door from being opened or media being entered unless safety is guaranteed.

3.9.1.4.1 The control system monitors the independent interlock circuit and checks for the expected status at known process checkpoints

3.9.1.4.2 All included switching interlock contacts shall monitor in their both positions to assure working non-glued contacts. Some of those checkpoints may be a part of the normal operating sequence. The others are separately monitored to reveal a failed contact status that otherwise had remained undetected. Refer to process alarms for included interlock alarms

3.9.1.5 Redundancy

3.9.1.5.1 The control system and a hard wired independent system control the door interlock, refer to MEDIA TO CHAMBER INTERLOCK and DOOR OPENING INTERLOCK above for a description of the safety system

3.9.2 Data integrity

3.9.2.1 Power failure

3.9.2.1.1 The control system RAM memory has battery backup so data will not be lost during power failure

3.9.2.1.2 A battery with low voltage will be indicated with an information alarm, refer to PROCESS ALARMS, information alarms

3.9.2.1.3 A power failure exceeding 10 seconds will result in a failure alarm when the power returns

3.9.2.1.4 A power failure less than 10 seconds will continue the process when the power returns

3.9.2.1.5 The doors remain closed and locked during power failures

3.9.2.2 Backup and recovery

3.9.2.2.1 **Application software backup** to file requires a PC with a Getinge programming tool

3.9.2.2.2 **Application software backup** into a PROM on the main-board is made through an operating panel or programming tool

3.9.2.2.3 **Application software recovery** is performed from PROM or through a backup file with the programming tool to the main-board RAM

3.9.2.2.4 When **application software recovery** is performed from a PROM it requires a cold-start of the system

3.9.2.2.5 **Application software recovery**; the manufacturer (Getinge) keeps a copy of the application software - as delivered

3.9.2.2.6 **System software backup**; the control system operating system is executed directly in the system PROM's and will thus not be lost due to power failure or similar causes

3.9.2.2.7 **System software backup**; the control system has no facilities for system software backup

3.9.2.2.8 **System software recovery**; if the system fails for any reason, Getinge can provide replacement PROM's, which when they are installed recovers the system

3.9.2.3 Disaster recovery

3.9.2.3.1 If power and backup battery failure happens simultaneously is the **application software** in RAM lost

3.9.2.3.2 Recovery is performed according to, **Application software recovery** above

3.9.2.3.3 Note! Calibrations and changes to the **application software**, performed after the application software was backed up are lost

3.9.2.3.4 System software; Getinge can provide replacement Prom's, which when they are installed recovers the system

3.9.3 System security

3.9.3.1 Input Value Checking

Adjustable process parameters are configured for a specific range. An entered value below or above the range will not be accepted by the control system. The accepted maximum and minimum level is shown in the proximity of the operator interface input field. For a description of adjustable parameters, refer to FUNCTIONS WHICH ARE CONFIGURATIVE AND THEIR LIMITS, Adjustable Process Parameters sections below

3.9.3.2 Access Restrictions

3.9.3.2.1 The following protected areas is supported by the control system:

A = Parameter Settings

B = Time settings

C = Calibration

D = Boolean Password 1 (e.g. used for pin code protected maintenance programs)

E = Service

F = Dip switches (soft switches e.g. used for media monitoring)

G = Non process critical configuration (e.g. graphs, printer log etc.)

H = Process critical configuration (e.g. AI, DI, DO, F0 etc.)

I = Boolean Code (Application Software Code Programming)

J = Password Setup

K = Documentation

L = Boolean Password 2 (available for use in application software)

3.9.3.2.2 The following roles will be configured as standard :

Table 2:

Role	Access Areas
Operator 1	D
Parameter	A,D
Supervisor	A,B,D,G,J,K
Service	A,B,C,D,E,F,G,H,J,K
Programming	A,B,C,D,E,F,G,H,I,J,K,L
Calibration	C

3.9.3.2.3 Up to 50 unique users may be defined

3.9.3.2.4 Each user consists of a user name with maximum16 characters

3.9.3.2.5 Password may be both numerical and alphanumerical

3.9.3.2.6 The minimum number of characters in a password is 3 and the maximum is 6

3.9.3.2.7 The password is not case sensitive

3.9.3.2.8 Access areas give the user access to different areas of the CS1000 and operator interfaces

3.10 Configurative functions and their limits

3.10.1 Adjustable Process Parameters

The table(s) in this section present(s) the adjustable process parameters and their limits for each process type. The process equipment are delivered with default settings, in the recipe(s), of these parameters according to the specified program combination. See the program combination in appendix A for further information.

3.10.1.1 Vacuum cycle

Table 3:

	Parameter	Range
3.10.1.1.1	Pre Pulse Vacuum:	1-99
3.10.1.1.2	Sterilizing Temperature:	105 - 135°C

Table 3:

3.10.1.1.3	Sterilizing Time:	3 minutes - 9 hours
3.10.1.1.4	Drying Vacuum Time:	0 minutes - 9 hours
3.10.1.1.5	Drying pulses	0-10

3.10.1.2 Vacuum cycle, ramped

Table 4:

	Parameter	**Range**
3.10.1.2.1	Pre Pulse Vacuum:	1-99
3.10.1.2.2	Sterilizing Temperature:	105 - 135°C
3.10.1.2.3	Sterilizing Time:	3 minutes - 9 hours
3.10.1.2.4	Drying vacuum time:	0 minutes - 9 hours
3.10.1.2.5	Ramps (decrease/increase rate):	0,1-1,0 [bar/min.] / 10-100 [kPa/min.] / 1,45-14,5 [PSI/min.]

3.10.1.3 Ventilator cycle, flexible containers

Table 5:

	Parameter	**Range**
3.10.1.3.1	Sterilizing Temperature:	105 - 124°C
3.10.1.3.2	Sterilizing Time:	3 minutes - 9 hours
3.10.1.3.3	Support Pressure:	0-1,5 [bar(a)] / 0-150 [kPa(a)] / 0-21,8 [PSIA]
3.10.1.3.4	Cooling Pressure:	1-3,5 [bar(a)] / 100-350 [kPa(a)] / 14,5-50,8 [PSIA]
3.10.1.3.5	Cooling Temperature:	20-80°C

3.10.1.4 Ventilator cycle, rigid containers

Table 6:

	Parameter	**Range**

Table 6:

3.10.1.4.1	Sterilizing Temperature:	105 - 124°C
3.10.1.4.2	Overshoot Temperature:	0-4°C
3.10.1.4.3	Sterilizing Time:	3 minutes - 9 hours
3.10.1.4.4	Support Pressure:	0-1,5 [bar(a)] / 0-150 [kPa(a)] / 0-21,8 [PSIA]
3.10.1.4.5	Cooling Pressure:	1-3,5 [bar(a)] / 100-350 [kPa(a)] / 14,5-50,8 [PSIA]
3.10.1.4.6	Cooling Temperature:	20-80°C

3.10.1.5 Leak rate test, cold

Table 7:

	Parameter	**Range**
3.10.1.5.1	Max accepted leak rate:	0,013 [bar(a)/10 min] / 1,3 [kPa(a)/10 min] / 0,19 [PSIA/10 min]

3.10.1.6 Maintenance program for in situ air filter sterilization (SIP)

Table 8:

	Parameter	**Range**
3.10.1.6.1	Sterilizing Temperature:	105 - 135°C
3.10.1.6.2	Sterilizing Time:	3 minutes - 9 hours

3.10.1.7 Maintenance program for in situ air filter integrity test (WIT)

Table 9:

	Parameter	**Range**
3.10.1.7.1	Test Time:	10 minutes
3.10.1.7.2	Drying Time:	3 minutes - 9 hours

3.10.2 System Configuration

3.10.2.1 Activated jacket heating

The jacket heating may be adjusted to operate when a process is not active. The function provides an ”easy up” process start. The availability requires some steam and gives residual heat.

3.10.2.1.1 The jacket heating is activated through a soft-switch in the system program

3.10.2.1.2 The jacket temperature is targeting 100°C when jacket heating is on during idling

3.10.2.1.3 Jacket heating will always be off, when programs that not require heating are chosen

3.10.2.2 Steam generator monitoring

3.10.2.2.1 The equipment is prepared for steam generator monitoring. A dedicated digital input is monitored and it is supplied with a jumper at delivery. The equipment must be provided with a cable connection to the steam generator in order to utilize the function

3.10.2.2.2 An open circuit indicate steam generator malfunction, refer to PROCESS ALARMS, Failure alarm list

3.10.2.3 Low-speed printout interval

3.10.2.3.1 Is by default 1 minute and maybe configured within the range 1 second-99 minutes. Refer to Configuration, ACCESS RESTRICTIONS

3.10.2.3.2 A value faster than the process printer capacity maybe selected but not executed

3.10.2.4 High-speed printout interval

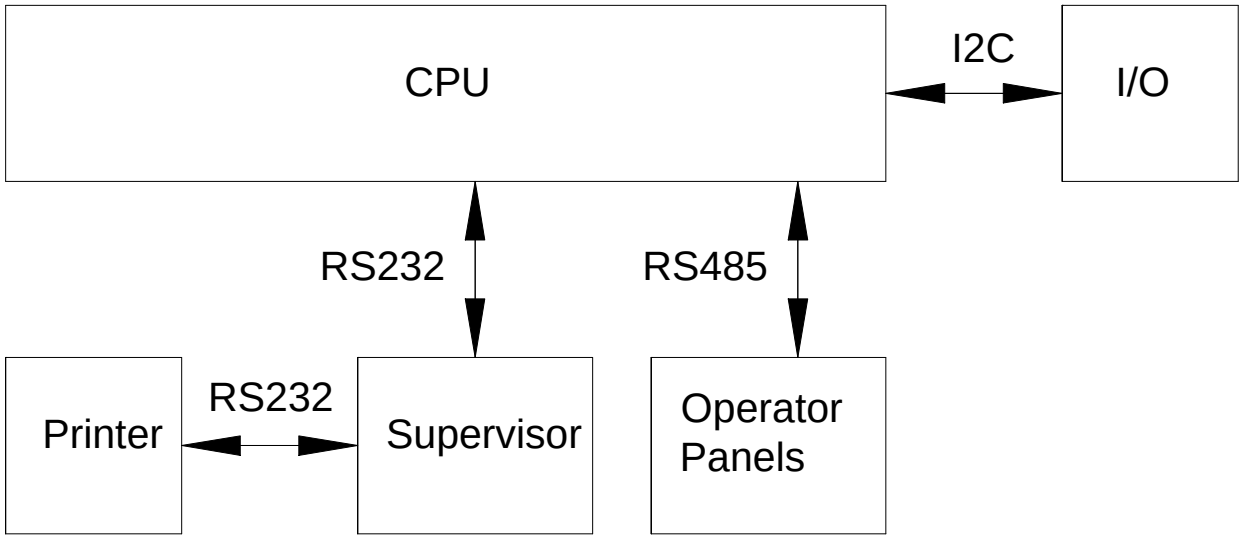
3.10.2.4.1 Is by default 30 seconds and maybe configured within the range 1 second-99 minutes. Refer to Configuration, ACCESS RESTRICTIONS

3.10.2.4.2 A value faster than the process printer capacity maybe selected but not executed

4 Data

4.1 PACS3000 data flow general layout

A brief description of the control system data flow is provided in this document. The PACS3000 general data flow architecture is designed in the development of the control system. Refer to the development project, QAPP: 565 11 94 issue 4, for more detailed documentation. The referred documents are available for audit at Getinge Sterilization AB Sweden.



4.1.1 I/O data

All I/O data is updated 4 times a second in the CPU RAM.

4.1.1.1 Digital input

The current statuses for digital inputs are read in to the I/O database part of the CPU RAM.

4.1.1.2 Digital output

The digital output statuses are stored in the I/O database part of the CPU RAM. The system and application software updates the status in the I/O database upon execution in the processor.

4.1.1.3 Analogue input

The analogue value from each sensor is converted to a digital ”raw-value” in the A/D-converter.

The ”raw” data value is converted by the CPU to the correct physical units and is made linear and filtered and calibrated. The values are stored in the I/O database part of the CPU RAM.

4.1.1.4 Analogue output

The analogue output values are stored in the I/O database part of the CPU RAM. The system and application software updates the values in the I/O database upon execution in the processor.

4.1.2 Program data

The system software resides in the system prom and the application software resides in the program database part of the CPU RAM. The processor executes the software and is constantly reading and writing data in the RAM databases.

4.1.3 Operator Panel data

Operating panels and program tools are communicating with the control system through serial interfaces. Data is both received and transmitted between the operator interface and the control system.

4.1.4 Supervisor data

The PACS control system software reads the process values in the RAM and formats it to text strings. The text strings is transferred to the process printer over a RS232 serial interface

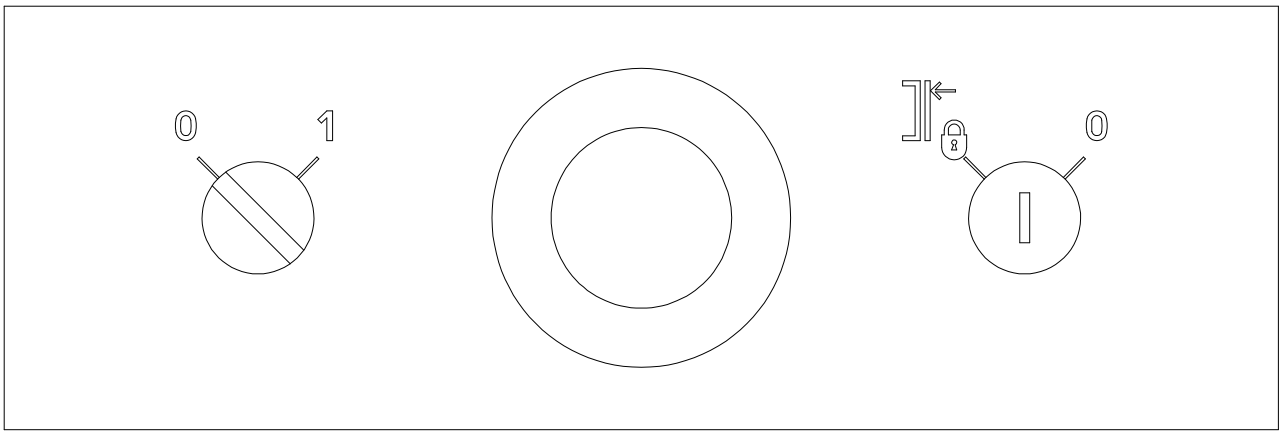
The Supervisor reads and calls for process values through a RS232 serial interface. The Supervisor has no access to internal data in the control system. Refer to the INTERFACE section for a more detailed description.

4.1.5 Process report data

The Supervisor system software reads the process values in the RAM and formats it to text strings. The text strings is transferred to the process printer over a RS232 serial interface. The application software calls for printout at temperature and pressure limits, upon process phase shifts and at periodical occasions. Refer to the INTERFACE section for a more detailed description.

5 Interfaces

5.1 Control Side Operator Switches



The operator controls consist of a control system power switch, an emergency stop switch and a door blockage key. The switches are located in the loading door proximity at an ergonomically correct height below the operating panel.

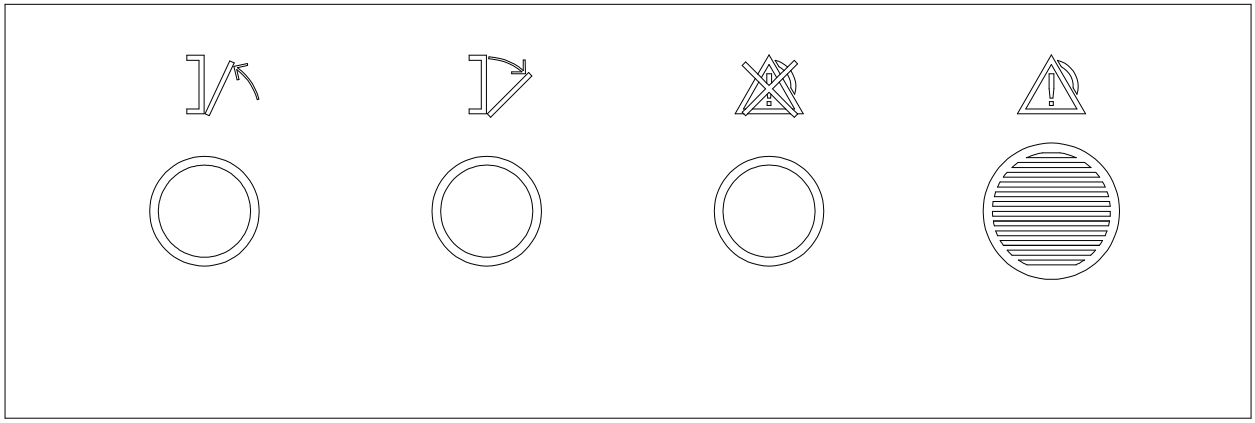
5.1.1 Switch description

5.1.1.0.1 The control system power switch TO THE LEFT is used to turn off and on the control system power & electrical devices connected to the control system transformer such as printers, pilot valves and instruments

5.1.1.0.2 The emergency stop IN THE MIDDLE is used to stop the process and shut down pumps, motors and incoming media. Two switch contacts are used for redundancy, one to a control system digital input and another hard wired to media supply pilot valves. The emergency stop activates a process alarm when used during process, refer to the PROCESS ALARM section for a description of the continued process

5.1.1.0.3 The door blockage key TO THE RIGHT is used for personal safety to prevent door closing and process start during loading or chamber cleaning. Two switch contacts are used for redundancy, one to a control system digital input and another hard wired to the door closing supply valve

5.2 Control side operator switches, second row



The operator controls on the second row consists of door open and close switches, a combined alarm switch/indicator and an alarm buzzer.

5.2.1 Switch description

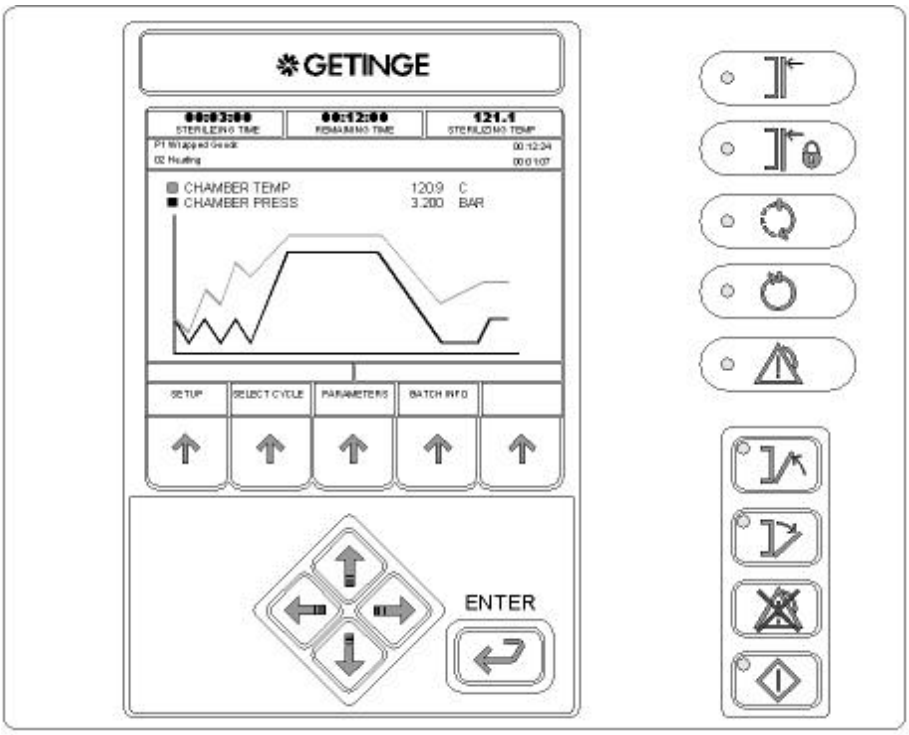
5.2.1.0.1 The door close switch located TO THE FAR LEFT is used to close the chamber door

5.2.1.0.2 The door open switch located BESIDE THE DOOR CLOSE SWITCH is used to open the chamber door

5.2.1.0.3 The alarm buzzer is located TO THE FAR RIGHT and is used for audible alarm indication by the control system

5.2.1.0.4 The alarm button/indicator located BESIDE THE BUZZER is used for alarm reset by the operator and visible alarm indication by the control system

5.3 User Interface OP30



The OP30 user interface consists of a 320x240 color LCD and a membrane keyboard with integrated LED's. Refer to the development project (with URS: 565 15 53, issue J and HDS: 565 15 55) for more information. The referred documents are available for audit at Getinge Sterilization AB, Sweden.

5.3.1 Description of buttons and LED's

5.3.1.0.1 The keyboard is provided with five soft-key buttons located below the display. The soft-key function available in a certain menu for a button will be described by a text on screen.

5.3.1.0.2 The keyboard is provided with four navigator buttons. The buttons will be used for selection in drop down menus and alphanumerical palettes available on screen.

5.3.1.0.3 The keyboard is provided with an enter button, e.g. used for choice of a selected menu / function in a list.

5.3.1.0.4 A button is provided for door opening.

5.3.1.0.5 A button is provided for door closing.

5.3.1.0.6 A button is provided for alarm mute and alarm reset. The button is also used for program stepping. The stepping function is only available during process when the authorization key is activated.

5.3.1.0.7 A button is provided for process start.

5.3.1.0.8 A yellow LED indication is provided for closed doors.

5.3.1.0.9 A yellow LED indication is provided for closed and locked doors.

5.3.1.0.10 A yellow LED indication is provided for a process cycle in progress.

5.3.1.0.11 A multicolor LED indication is provided for a completed process. The light is illuminated green for a successful process and red for a failed, stepped or held process.

5.3.1.0.12 A red LED indication is provided for a process failure alarm.

5.3.1.0.13 A yellow LED indication is provided for a closed door or a door moving towards closed position. The LED is integrated in the door close button.

5.3.1.0.14 A yellow LED indication is provided for an open door or a door moving towards open position. The LED is integrated in the door open button.

5.3.1.0.15 A yellow LED is provided to indicate ”ready to be started”. The LED is integrated in the start button.

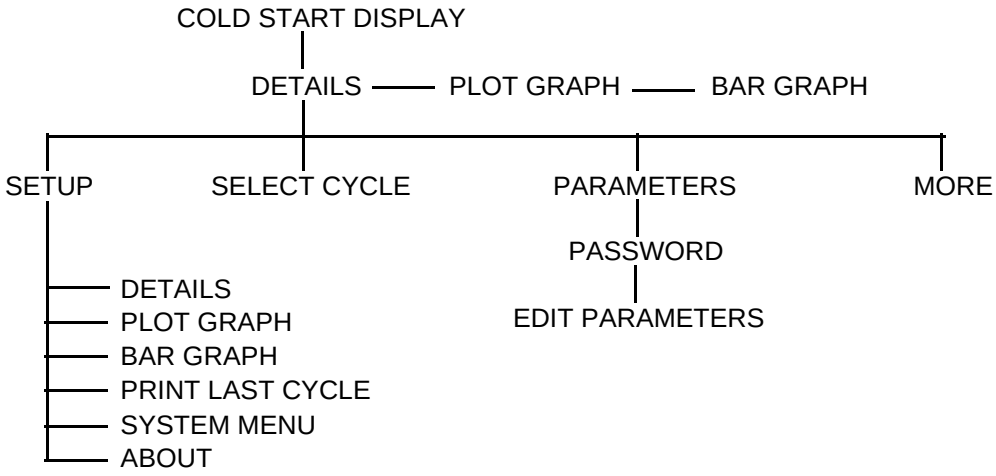
5.3.2 Definition of user roles

5.3.2.0.1 All roles defined in section FUNCTION, Safety and Security, Access Restrictions apply to the OP30 with one exception described below.

5.3.2.0.2 Programming of Boolean code can not be made (access area I)

5.3.3 Functions available

5.3.3.1 Operator functions



Most of the operator functions are unrestricted and do not require a specific area access.

NOTE: Area D access will be prompted during execution of programs or process functions with pin code protection.

5.3.3.1.1 Texts and menus are provided in English.

5.3.3.1.2 The **”set up”** drop down menu give access to the **”details”**, the **”plot graph”**, the **”bar graph”**, the **”print last cycle”**, the **”system”** and the **”about”** menus described below.

5.3.3.1.3 The **”details”** screen shows a scrollable list containing the displayable parameters. This menu is showed after a cold start and is also accessible through the ”setup” drop down menu.

5.3.3.1.4 The **”plot graph”** screen shows a graph of two predefined parameters as growing curves. This menu is accessed through the ”setup” drop down menu.

5.3.3.1.5 The **”bar graph”** screen shows two predefined parameters as vertical bars. This menu is accessed through the ”setup” drop down menu.

5.3.3.1.6 The **”print last cycle”** menu reprints the last process report. The option is only available when no process is ongoing. This menu is accessed through the ”setup” drop down menu.

5.3.3.1.7 The **”system”** menu provides access to the system menu tree, refer to System functions. Any of the area passwords (B, C, E, F, G, H, J & K) is valid for access to the menu tree. The ”system” menu is accessible through the ”setup” drop down menu.

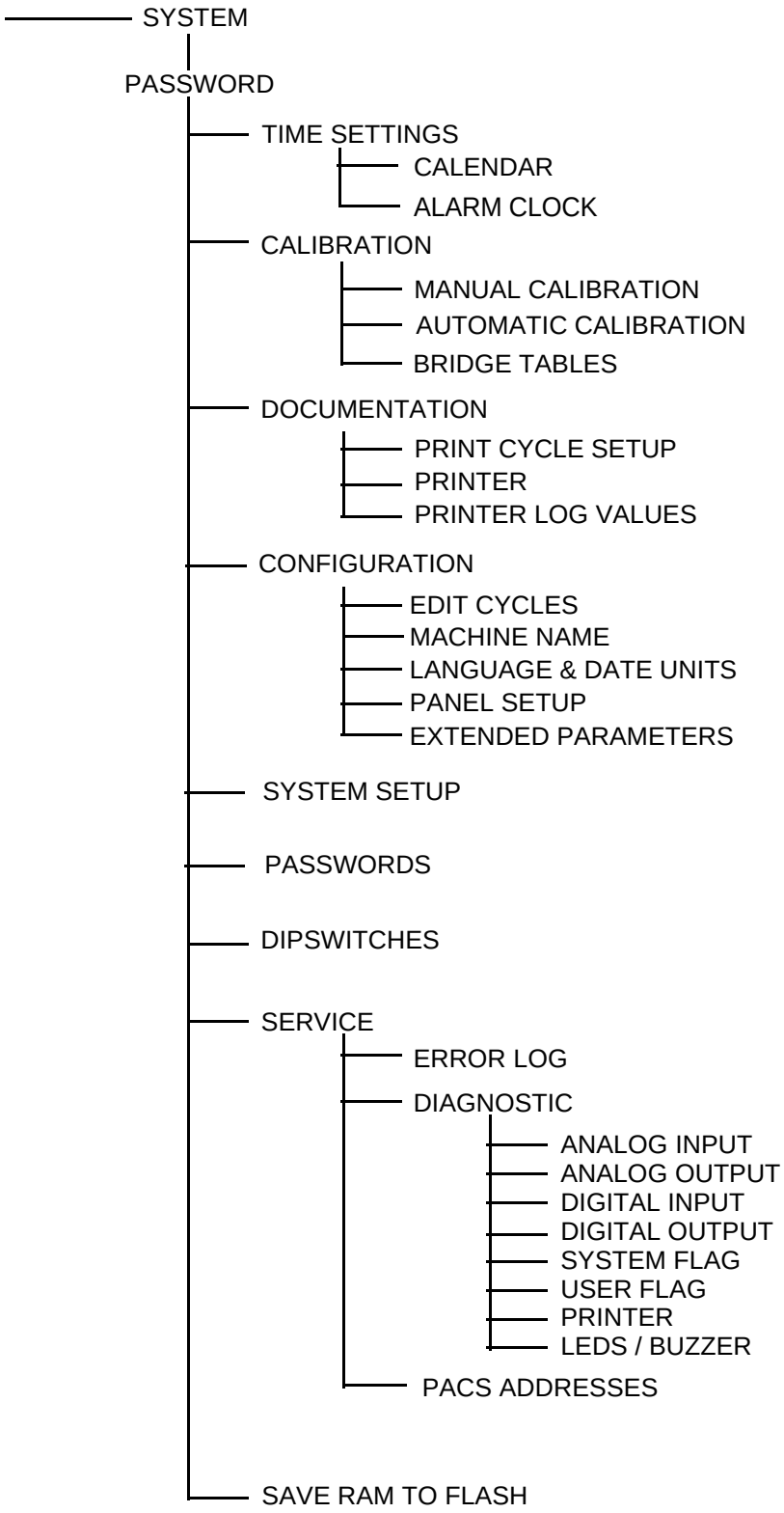
5.3.3.1.8 The **”about”** menu displays (among other things) the control system in the form of version information for the panel and the control system. The menu also provides functions for adjustment of the display brightness. The ”about” menu is accessible through the ”setup” drop down menu.

5.3.3.1.9 The **”select cycle”** menu provides selection of any available process program.

5.3.3.1.10 The **”parameters”** menu provides viewing and editing of non-critical adjustable process parameters for the selected program. Area password A is required for editing.

5.3.3.1.11 The **”more”** menu gives access to functions and menus that are initiated in the Boolean application software. If no such functions exist will this field be blank. If only one function is defined will the ”more” menu be replaced by the Boolean function.

5.3.3.2 System functions



All system functionality requires specific area access.

5.3.3.2.1 The **"time settings"** menu provides access to the **"calendar"** and the **"alarm clock"** menus. The function requires B area access.

5.3.3.2.2 The **"calendar"** menu provides updating of time & dates. The function requires B area access.

5.3.3.2.3 The **”alarm clock”** menu displays (if there is one) a list of events that can be started automatically at times set here. The function requires B area access.

5.3.3.2.4 The **”calibration”** menu provides access to the **”manual calibration”**, the **”automatic calibration”** and the **”bridge tables”** menus. The function requires C area access.

5.3.3.2.5 The **”manual calibration”** menu provides features for manual adjustment of the constants GAIN and OFFSET that is used for correction of analogue input signals. A calibration report may be directed to the process printer for documentation. All functions require C area access.

5.3.3.2.6 The **”automatic calibration”** menu provides features for automatic adjustment of the constants GAIN and OFFSET that is used for correction of analogue input signals. A calibration report may be directed to the process printer for documentation. All functions require C area access.

5.3.3.2.7 The **”bridge tables”** menu provides features for input of bridge compensation table data used for correction of a pressure transducer input signal. A report may be directed to the process printer for documentation. All functions require C area access.

5.3.3.2.8 The **”documentation”** menu provides access to the **”print cycle setup”**, the **”printer”** and **”printer log value”** menus. The function requires K area access.

5.3.3.2.9 In the **”print cycle setup”** menu you can choose to print out program documentation (phase list and parameter list) for chosen programs or for all programs. The function requires K area access.

5.3.3.2.10 The **”printer”** menu provides functions to adjust the type of presentation for the data to be printed out and the length of the logging interval. All functions requires K area access.

5.3.3.2.11 The **”printer log value”** 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. Three independent lists are available that is used for different programs. All functions requires K area access.

5.3.3.2.12 The **”configuration”** menu provides access to the **”edit cycles”**, the **”machine name”**, the **”language & date units”**, the **”panel setup”** and the **”extended parameters”** menus. The function requires G area access.

5.3.3.2.13 The **”edit cycles”** menu provides functions for editing the program number and name. When changing the name, an alphanumeric keyboard pops up. All functions requires G area access.

5.3.3.2.14 The **”machine name”** menu provides functions for updating the machine name used on screen and in process reports. When changing the data, an alphanumeric keyboard pops up. All functions requires G area access.

5.3.3.2.15 The **”language & date units”** menu provides functions for updating menu language, date format, units of pressure (Bar, PSI, kPa) and temperature (°C, °F). All functions requires G area access.

5.3.3.2.16 The **”panel setup”** menu provides (among other things) selection screen saver and of the type of basic menu to be displayed after booting up. All functions requires G area access.

5.3.3.2.17 The **”extended parameters”** menu provides functions for editing process P-parameters. All editing requires G area access.

5.3.3.2.18 The **”system setup”** menu provides functions for editing the machine node number. The menu also provides enabling or disabling of the print last cycle function and the cycle CHR function. All functions requires H area access.

5.3.3.2.19 The **”passwords”** menu provides functions for maintenance of users, passwords and area access for each user. The menu also provides support descriptions of the area access codes. All functions requires J area access.

5.3.3.2.20 The **”dipswitches”** menu provides enabling or disabling of soft switches affecting the behaviour of the application software, e.g. whether media switches should be monitored or not. All functions requires F area access.

5.3.3.2.21 The **”service”** menu provides access to the **”error log”**, the **”diagnostic”** and the **”PACS addresses”** menus. The function requires E area access.

5.3.3.2.22 The **”error log”** menu provides functions for viewing and printing the ”last 20” alarm list. The function requires E area access.

5.3.3.2.23 The **”diagnostic”** menu provides access to the **”analog input”**, the **”analog output”**, the **”digital input**”, the **”digital output”**, the **”system flag”**, the **”user flag”**, the **”printer”** and the **”led / buzzer”** menus. The function requires E area access.

5.3.3.2.24 The **”analog input”** menu provides viewing of the analog input values. The function is accessible through the menus ””service \diagnostics” and requires E area access.

5.3.3.2.25 The **”analog output”** menu provides viewing and manual control of the analog outputs. The function is accessible through the menus ”service \diagnostics” and requires E area access.

5.3.3.2.26 The **”digital input”** menu provides viewing of the digital input status. The function is accessible through the menus ”service \diagnostics” and requires E area access.

5.3.3.2.27 The **”digital output”** menu provides viewing and manual activation of the digital outputs. The function is accessible through the menus ”service \diagnostics” and requires E area access.

5.3.3.2.28 The **”system flag”** menu provides viewing of the system flag status. The function is accessible through the menus ”service \diagnostics” and requires E area access.

5.3.3.2.29 The **”user flag”** menu provides viewing of the user flag status. The function is accessible through the menus ”service \diagnostics” and requires E area access.

5.3.3.2.30 The **”printer”** menu sends and prints a test page on the process printer (if existing). The function is accessible through the menus ”service \diagnostics” and requires E area access.

5.3.3.2.31 The **”led / buzzer”** activates all existing LED's and the buzzer. The procedure reveals thus any audible or visible indicator malfunction. The function is accessible through the menus ”service \diagnostics” and requires E area access.

5.3.3.2.32 The **”PACS addresses”** menu is used for name definition of the PACS systems that are connected to the unit. The function requires E area access.

5.3.3.2.33 The **”save RAM to flash”** menu provides backup of the application software and the calibration values to the PROM. The function requires G area access.

5.3.4 Error handling and security

5.3.4.0.1 Power failure is not critical, nothing will be lost since all software is stored and executed directly in the operator interface PROM's.

5.3.4.0.2 A communication failure between the control system and the user interface board will be highlighted by a ”communication failure” pop up screen. The screen disappears once the communication is reestablished.

5.3.4.0.3 Backup and recovery is not applicable since all user interface software is stored and executed directly in the user interface PROM's. All critical data is stored in the control system not in the user interface

5.3.4.0.4 Disaster recovery, the user interface is normally replaced if it fails.

5.3.4.0.5 The use of RS422 communication protocol with flow control ensures a safe and reliable data transfer between the control system and the user interface.

5.3.4.0.6 The hardware and connections complies with the EMC-directives and the FCC-rules. The compliance assures integrity, low emissions and flicker absence.

5.4 Interface with equipment

5.4.1 Temperature sensors

The equipment is provided with necessary temperature sensors for all included functions.

5.4.1.1 Type

5.4.1.1.1 Pt100 Class A RTD-sensor with single or dual element and cable

5.4.1.1.2 The sensor wiring are either insulated with steam and heat resistant and pressure tight silicon rubber or insulated with non-heat-resistant PVC depending on application i.e. if the cable is inside the steam environment or not.

5.4.1.2 Manufacturer

5.4.1.2.1 Pentronic

5.4.1.3 Methods for measurement

5.4.1.3.1 A sensor element is used as a passive resistance emitter connected through a 4-wire cable to the control system.

5.4.1.3.2 The control system creates a current and monitors the voltage over the sensor.

5.4.1.3.3 Circuits and software to assure linear readings is included in the control system.

5.4.1.3.4 Functions for calibration and correction available from the operator interface are included in the control system system software.

5.4.1.4 Error handling, recovery, and reporting

5.4.1.4.1 A temperature sensor shall operate within a configured range.

5.4.1.4.2 A temperature sensor with a leakage current to the ground shall be detected.

5.4.1.4.3 A sensor out of range or with leakage current will result in a failure alarm. Refer to PROCESS ALARMS, failure alarms.

5.4.1.5 Security

5.4.1.5.1 Process sensors regarded as critical for safety or with GMP-impact are redundant and connected to the independent system - PACS Supervisor.

5.4.2 Pressure sensors

5.4.2.1 Type

5.4.2.1.1 Diaphragm sealed piezo-electric emitter

5.4.2.2 Manufacturer

5.4.2.2.1 Keller AG

5.4.2.3 Methods for measurement

5.4.2.3.1 The sensor is used as a passive emitter connected through a cable to the control system

5.4.2.3.2 The control system creates currents and monitors the voltage over the sensor

5.4.2.3.3 The sensor includes a temperature sensor and is temperature compensated by the control system

5.4.2.3.4 Circuits and machine ware for linearization is included in the control system

5.4.2.3.5 A unique Whetstone compensation bridge and a correction table are used in the control system for correction.

5.4.2.3.6 Functions for calibration and correction available from the operator interface are included in the control system system software

5.4.2.4 Error handling, recovery, and reporting

5.4.2.4.1 A pressure sensor shall operate within a configured range

5.4.2.4.2 A sensor out of range will result in a failure alarm. Refer to PROCESS ALARMS, failure alarms

5.4.2.5 Security

5.4.2.5.1 Process sensors regarded as critical for safety or with GMP-impact are redundant and connected to the independent system - PACS Supervisor.

5.5 The PACS Supervisor

Refer to the development project (with QAPP: 565 11 94, issue 4, titled “Quality and Project Plan P2000 CPU ver3”) for more information. The referred documents are available for audit at Getinge Sterilization AB, Sweden.

5.5.0.1 Functions

5.5.0.1.1 The PACS Supervisor is an independent monitoring and documentation system that receives process readings from the control system and compares them with own independent sensors.

5.5.0.1.2 The system is connected to the report interface and prints all process data on one process report.

5.5.0.1.3 Refer to FUNCTIONS-Process report functions and INTERFACES-Report Functions for a description of the process printer functions used by the supervisor.

5.5.0.1.4 The PACS Supervisor utilize the same user interface as the control system. Refer to USER INTERFACE, Functions available, Operator functions, Select PACS.

5.5.0.1.5 The Supervisor is used as an independent

5.5.0.2 Performance

5.5.0.2.1 The Supervisor is based on identical hardware as the control system

5.5.0.2.2 Timer inaccuracy is identical to the control system

5.5.0.2.3 Temperature resolution and inaccuracy is identical to the control system

5.5.0.2.4 Pressure resolution and inaccuracy is identical to the control system

5.5.0.3 Data transmitted and received

5.5.0.3.1 The Supervisor reads start and stop requests for printing in the control system

5.5.0.3.2 The Supervisor reads slow or fast printing requests in the control system

5.5.0.3.3 The Supervisor reads event-printing requests in the control system

5.5.0.3.4 Status information is transmitted to the control system for 5 dedicated system flags

5.5.0.3.5 Process data is received from the control system

5.5.0.4 Data format and interruption

5.5.0.4.1 Comli language is used in communication with the control system for questions and status information

5.5.0.4.2 Master [Supervisor] - Slave [control system]

5.5.0.5 Timing

5.5.0.5.1 Requests are transmitted every second to the control system

5.5.0.5.2 Data is received from the control system when the control system decides to answer

5.5.0.6 Protocol and rate of data transfer

5.5.0.6.1 RS232 Serial Interface

5.5.0.6.2 57600 bits/second

5.5.0.7 Communication between Supervisor and control system

5.5.0.7.1 The Supervisor uses the control system serial interface buffer for all communication.

5.5.0.7.2 The Supervisor has no access to internal data in the control system

5.5.0.8 Error handling

5.5.0.8.1 All sensors shall operate within a configured range

5.5.0.8.2 A pressure sensor out of range is presented and printed 9,999

5.5.0.8.3 A temperature sensor out of range or with leakage current is presented and printed 999,9

5.5.0.9 Safety & Security

5.5.0.9.1 The Supervisor is based on identical hardware as the control system so the SAFETY & SECURITY-power failure, backup & recovery and disaster recovery sections applies to PACS Supervisor

5.6 Report interface Cobex thermal printer

5.6.0.0.1 Type: thermal printer

5.6.0.0.2 Location: panel mounted

5.6.0.0.3	Paper supply:	paper roll
5.6.0.0.4	Paper width:	2-3/8” (60 mm)
5.6.0.0.5	Paper roll length:	75ft (22.86 m)
5.6.0.0.6	Print speed:	1 Line per second
5.6.0.0.7	Printer buffer:	8151 characters
5.6.0.0.8	Power supply:	supplied from the control system transformer
5.6.0.0.9	Power consumption	up to 48 watts
5.6.0.0.10	Communication:	serial.RS232 interface (baud rate 9600 bps)

6 Mechanical Design Specification

6.1 Mechanical Enclosure

6.1.1 Fascia Panels

6.1.1.0.1	Material	Stainless steel 1.4301 (304)
6.1.1.0.2	Front surface texture	Tetra polished Ra< 1,2 micrometer
6.1.1.0.3	Thickness	1.5 mm [0.06”]
6.1.1.0.4	Fascia panel design	Double folded, partially welded 33 mm [1 ¼”]
6.1.1.0.5	Panel Support	30 mm [1 ¼”] squared hollow bar with screw joints
6.1.1.0.6	Construction	Recessed installation with 33 mm panels mounted in front of the walls with overlap

6.1.2 Instrument Column

The side mounted instrument column consists of modular extruded aluminum sections in order to house all selected instruments and controls. The top and bottom sections are anodized in a dark blue color and the intermediate sections are powder coated in a light blue color.

6.1.2.1 Location

6.1.2.1.1	Control side	Beside the chamber door

6.1.2.2 Top & Bottom Section

6.1.2.2.1	Material	Extruded aluminum profile
6.1.2.2.2	Surface	Anodized
6.1.2.2.3	Color	NCS S 4550-R80B [Dark Blue]

6.1.2.3 Instrument Sections

6.1.2.3.1	Material	Extruded aluminum profile
6.1.2.3.2	Surface	Powder Coated Polyester Paint
6.1.2.3.3	Color	NCS S 2060-R80B [Light Blue]

6.1.3 Piping Skid

6.1.3.0.1	Design	Rectangular profile
6.1.3.0.2	Material	Stainless steel 1.4301 (304)
6.1.3.0.3	Surface finish	Mechanically polished
6.1.3.0.4	Feet	Adjustable [threaded]

6.2 Pressure Vessel

6.2.1 Chamber Configuration

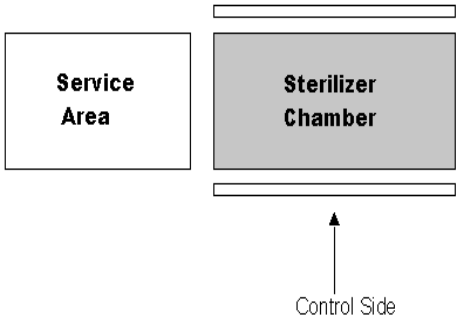
6.2.1.0.1	Loading Height	Loading Height 600 mm [24”]

6.2.2 Installation

6.2.2.0.1	Type	A stainless steel cabinet will surround the apparatus

6.2.3 Service Area Location

6.2.3.0.1	Location	Left side
6.2.3.0.2	Reference	The from above sketch below show how the service area are located regarded to the sterilizer chamber and doors. The control side is shown for reference.



6.2.4 Chamber Internal Dimensions

6.2.4.0.1	Chamber width	720 mm [28 ”]
6.2.4.0.2	Chamber height	1050 mm [41 ”]
6.2.4.0.3	Chamber depth	1350 mm [53 ”]
6.2.4.0.4	Useable width	660 mm [26 ”]
6.2.4.0.5	Useable height	990 mm [39 ”]
6.2.4.0.6	Useable depth	1350 mm [53 ”]
6.2.4.0.7	Usable chamber volume	0,88 m3 [31 ft3]

6.2.5 Chamber Construction

6.2.5.0.1	Cross section	Rectangular
6.2.5.0.2	Internal corners	Radius 75 mm [3”]
6.2.5.0.3	Material	AISI 316Ti acid proof stainless steel
6.2.5.0.4	Design pressure	3 bar (g) [45 psig] & full vacuum
6.2.5.0.5	Welds	Robotic or semi-automatic whenever possible

6.2.6 Internal Chamber and Ports Finish

6.2.6.0.1	Internal surface	Ground and polished to a high luster
6.2.6.0.2	Internal Ra value	0,5 microns ± 0,13 [20 micro inches ± 5]
6.2.6.0.3	Internal door surface	Ground and polished to a high luster

6.2.6.0.4	Internal door surface Ra value	0,5 microns ± 0,13 [20 micro inches ± 5]

6.2.7 Chamber Ports

6.2.7.0.1	Construction	Pressure vessel piping welded to the chamber
6.2.7.0.2	Quantity	According to Getinge QMS design standard [K048 GE Sterilizer/ K049 GEV Sterilizer/ K050 GEC Sterilizer]
6.2.7.0.3	Material	Equal to the grade of the chamber material
6.2.7.0.4	Connections	Tri-clamp 2”
6.2.7.0.5	Slope	Greater than 2 %
6.2.7.0.6	Maximum deadleg	6x the pipe diameter

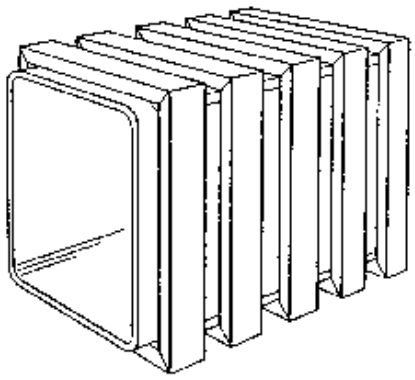
6.2.8 Validation Port

6.2.8.0.1	Construction	Pressure vessel piping welded to the chamber
6.2.8.0.2	Quantity	One [1]
6.2.8.0.3	Size	Tri-clamp 2”
6.2.8.0.4	Material	Gr 316L
6.2.8.0.5	Connections	Tri-clamp, capped
6.2.8.0.6	Slope	Greater than 2 %

6.2.9 Jacket

The jacket is a series of ”U” channels continuously welded to the chamber. The sectional jacket design adds the structural rigidity while eliminating the need for any external carbon steel supports of the chamber and allows visual inspection of all welds.

NOTE: The sketch below is generic with few details and intended for improved understanding. The exact chamber configuration may be different, refer to relevant sections for valid data regarding chamber dimension.



6.2.9.0.1	Jacket design	Sectional 'U' formed profiles welded around the chamber
6.2.9.0.2	Jacket material	AISI 316Ti (1.4571) stainless steel
6.2.9.0.3	Design pressure	3,0 bar(g) [45 PSIG]
6.2.9.0.4	Jacket connections	Threaded

6.2.10 Doors

6.2.10.0.1	Quantity	1

6.2.11 Door

6.2.11.0.1	Design	Fully automatic, horizontally sliding
6.2.11.0.2	Opening and closing	Automatic button controlled
6.2.11.0.3	Door operation	Pneumatic motor
6.2.11.0.4	Door safety	Stops if obstructed
6.2.11.0.5	Internal door surface	AISI 316Ti stainless steel
6.2.11.0.6	Door reinforcements	SA516 Gr60 corrosion protected carbon steel
6.2.11.0.7	Door retainers	SA516 Gr60 corrosion protected carbon steel
6.2.11.0.8	Door pins	AISI 316 stainless steel

6.2.12 Door gasket

6.2.12.0.1	Design	Seamless hollow gasket (o-ring) of heat resistant silicon rubber
6.2.12.0.2	Operation	The gasket is mounted in a groove that runs around the chamber opening. When the groove is pressurized, the gasket is pushed out against the door surface to seal the door to the chamber. When the groove is under vacuum the gasket is retracted. This prevents damage to the gasket during loading and unloading
6.2.12.0.3	Gasket sealing media	Compressed air during sterilization. Process steam during in- line filter sterilization cycle to sterilize the gasket groove
6.2.12.0.4	Gasket retraction	Liquid ring vacuum pump

6.2.13 Inner lining

6.2.13.0.1	Design	Ensures that the airflow within the chamber is consistent and even.
6.2.13.0.2	Material	AISI 316L stainless steel.

6.2.14 Ventilator System

6.2.14.0.1	Quantity of fans	1
6.2.14.0.2	Motor design	2 speed
6.2.14.0.3	Motor manufacturer	ABB with custom shaft
6.2.14.0.4	Motor shaft material	Duplex stainless steel corresponding to AISI 329
6.2.14.0.5	Motor shaft seal type	Pressurized mechanical seal using condensed steam to seal
6.2.14.0.6	Mounting	Flange mounted through the top of the chamber
6.2.14.0.7	Fan blade design	Radial, centrifugal
6.2.14.0.8	Fan material	Acid proof stainless steel, corresponding to AISI 316

6.2.15 Heat Exchanger for Cooling

6.2.15.0.1	Material	AISI 316Ti stainless steel tube, corresponding to Wnr 1.4571
6.2.15.0.2	Location	Inside the chamber between the chamber wall and inner liner.
6.2.15.0.3	Fitted	Continuos stainless steel tube which is passed through a chamber port and sealed on the external side of the tube. This prevents any cross contamination of cooling media and the chamber environment.
6.2.15.0.4	Cooling media	Cooling water

6.2.16 Chamber Insulation & Cladding

6.2.16.0.1	Material	Non corrosive glass wool fulfilling requirements in ASTM 795.
6.2.16.0.2	Cladding material	Aluminum sheet metal
6.2.16.0.3	Cladding thickness	1.5 mm [0.06 ”]
6.2.16.0.4	Cladding texture	Stucco
6.2.16.0.5	Cladding assembly	The aluminum sheets are joined together around the chamber, with all openings capped, to prevent shedding of the insulation material

6.3 Steam supply

6.3.1 Clean steam generator

6.3.1.0.1	Type	Steam heated
6.3.1.0.2	Heat exchanger	Double tube plate
6.3.1.0.3	Material	AISI 316L

6.3.1.1 Feed water pump material

6.3.1.1.1	Casing	Wnr. 1.4581 Stainless steel.
6.3.1.1.2	Wheel	Wnr. 1.4571 Stainless steel
6.3.1.1.3	Sealing	SiC/A- Carbon- Viton
6.3.1.1.4	Feed water isolation valve	Gemu diaphragm

6.3.1.2 Clean steam generator size

6.3.1.2.1	Maximum steam output	200 lbs/hr

6.4 Media Connections

6.4.0.0.1	Common Steam	External Steam Supply
6.4.0.0.2	Process Air	External Air Supply
6.4.0.0.3	Instrument Air	External Air Supply
6.4.0.0.4	Pump water	External Water Supply

6.4.0.0.5	Circ. Cooling water	External Water Supply
6.4.0.0.6	Circ. Cooling water return	External Return
6.4.0.0.7	Condensate return	

6.5 Process Piping

6.5.0.0.1	Material Certificate	Included, refer to the ORDER DELIVERABLES sheet for definition of all included test reports.
6.5.0.0.2	Type	3.1.B for welded componets and other components when available. Type 2.2 for all other process wetted parts.

6.5.1 Piping Design

All process piping components are constructed of high grade stainless steel. Stainless steel piping in contact with clean steam and sterile air are orbital welded pipes with tri-clamp connectors.

6.5.1.0.1	Pipe standard	US O.D.
6.5.1.0.2	Material	AISI 316L stainless steel tube
6.5.1.0.3	Internal surface finish	0.5 micrometer [12.7 micro inches]
6.5.1.0.4	Welding	Automatic orbital machine welds
6.5.1.0.5	Joints equal or smaller than 3”	Tri-clamp
6.5.1.0.6	Joints larger than 3”	Stainless steel flange
6.5.1.0.7	Maximum deadleg	6x the pipe diameter
6.5.1.0.8	Minimum slope towards drain	1%
6.5.1.0.9	Insulation	Hot and cold pipes

6.5.2 Valve Design

6.5.2.0.1	Valve manufacturer(s)	Gemü, ASCO
6.5.2.0.2	Body material	Stainless steel 316L
6.5.2.0.3	Gemu valve type	Globe piston
6.5.2.0.4	Asco valve type	Solenoid

6.5.3 Chamber Safety Valve

6.5.3.0.1	Material	Brass
6.5.3.0.2	Regulatory	Meets or exceeds the standards for the country of destination

6.5.4 Chamber Bursting Disc

6.5.4.0.1	Manufacturer	BS&B
6.5.4.0.2	Material	AISI 316L
6.5.4.0.3	Certification	ASME coded, UD stamped

6.5.4.0.4	Sensor (”tell tale”)	External pressure switch
6.5.4.0.5	Sensor mounting	Between the rupture disk and safety valve

6.5.5 Pressure Switches

6.5.5.0.1	Manufacturer	TECSIS
6.5.5.0.2	Type	Diaphragm isolated
6.5.5.0.3	Wetted material	AISI 316L
6.5.5.0.4	Connector	Tri Clover

6.5.6 Sterile Air Filter

6.5.6.0.1	Manufacturer	Sartorius
6.5.6.0.2	Type	0.2-micron hydrophobic gas filter
6.5.6.0.3	Filter material	PTFE
6.5.6.0.4	Housing material	Electro-polished AISI 316L stainless steel housing

6.5.7 Automatic In- Situ Sterilisation

6.5.7.0.1	Function	Automatic in situ filter sterilization. All necessary piping and valves will be provided for sterilization and cooling of the filter. A pre-programmed process will ensure and document that the filter is sterilized and ready for use. It is possible to remove the filter housing.
6.5.7.0.2	Process Piping	AISI 316L
6.5.7.0.3	Connections before the filter	Compression fittings
6.5.7.0.4	Connections after the filter	Tri-clamp sanitary
6.5.7.0.5	Welding (after the filter)	Automatic tube welded

6.5.8 Automatic integrity test, W.I.T

6.5.8.0.1	Function	Automatic in situ testing of the filter’s integrity. The process is controlled and documented by the sterilization equipment’s control system. Removal of the filter housing or any associated piping is not required, nor is there any need for the end user to perform an independent test.
6.5.8.0.2	Testing media	Water

6.5.9 Process Pressure Indicator, Control Side

6.5.9.1 The control side will be provided with indicators for chamber, jacket and incoming steam pressure.

6.5.9.2 Chamber Pressure Indicator, Control Side

6.5.9.2.1	Manufacturer	WIKA
6.5.9.2.2	Type	Bourdon tube with diaphragm isolation

6.5.9.2.3	Process wetted material	AISI 316L
6.5.9.2.4	Dial	-1/+5 Barg [0-30 inchHg / 0-45 PSIG]
6.5.9.2.5	Connection	TriClover

6.5.9.3 Steam Pressure Indicator, Control Side

6.5.9.3.1	Manufacturer	WIKA
6.5.9.3.2	Type	Bourdon tube with diaphragm isolation
6.5.9.3.3	Process wetted material	AISI 316L
6.5.9.3.4	Dial	-1/+5 Barg [0-30 inchHg / 0-45 PSIG]
6.5.9.3.5	Connection	TriClover

6.6 Non Process Piping

All non-process piping components are constructed of copper / brass / bronze / stainless. All piping are brazed or welded with flanged or threaded connections.

6.6.1 Jacket Piping

6.6.1.1 Pipe Design

6.6.1.1.1	Pipe standard	Metric
6.6.1.1.2	Material	Copper, Cu
6.6.1.1.3	Joints	Threaded or flanged
6.6.1.1.4	Maximum deadleg	N/A
6.6.1.1.5	Insulation	Hot and cold pipes

6.6.1.2 Valve Design

6.6.1.2.1	Valve manufacturer(s)	Gemü, ASCO
6.6.1.2.2	Body material	Brass
6.6.1.2.3	Gemü valve type	Globe piston
6.6.1.2.4	ASCO valve type	Solenoid

6.6.1.3 Jacket Safety Valve

6.6.1.3.1	Material	Brass
6.6.1.3.2	Regulatory	Meets or exceeds the standards for the country of destination

6.6.1.4 Pressure Switches

6.6.1.4.1	Manufacturer	Bailey Mackay
6.6.1.4.2	Type	Capillary tube
6.6.1.4.3	Wetted material	Copper, brass, bronze

6.6.1.4.4	Connector	Tri Clover

6.6.2 Door Gasket Piping

6.6.2.1 Pipe Design

6.6.2.1.1	Pipe standard	Metric or US O.D.
6.6.2.1.2	Pipe material	Stainless Steel 316L
6.6.2.1.3	Joints	Threaded, flanged or compression coupling
6.6.2.1.4	Insulation	Hot pipes

6.6.2.2 Valve Design

6.6.2.2.1	Manufacturer	Gemü
6.6.2.2.2	Body material	316L stainless steel
6.6.2.2.3	Type	Globe piston

6.6.2.3 Pressure Switches

6.6.2.3.1	Manufacturer	Bailey & Mackey
6.6.2.3.2	Type	Diaphragm copper
6.6.2.3.3	Wetted material	Brass
6.6.2.3.4	Connector	Threaded

6.6.3 Drain System Piping

6.6.3.1 Pipe Design

6.6.3.1.1	Pipe standard	Metric
6.6.3.1.2	Material	Copper, Brass, Bronze
6.6.3.1.3	Joints	Threaded or flanged
6.6.3.1.4	Insulation	Hot and cold pipes

6.6.3.2 Valve Design

6.6.3.2.1	Manufacturer	Gemü
6.6.3.2.2	Body material	Brass, Bronze
6.6.3.2.3	Type	Globe Piston

6.6.3.3 Pump Specification

6.6.3.3.1	Manufacturer	SIHI
6.6.3.3.2	Type	Liquid ring pump
6.6.3.3.3	Case material	Cast Iron
6.6.3.3.4	Impeller material	Brass

6.6.3.3.5	Capacity	Chamber dry-air evacuation to 0,4 Bars (a) [6 PSIA] in less than 60 seconds

6.6.3.4 Cooling Condensor

6.6.3.4.1	Manufacturer	Cetetherm
6.6.3.4.2	Type	Plate heat exchanger
6.6.3.4.3	Material	Stainless steel plates brazed with copper

6.6.4 Pneumatic System Piping

6.6.4.0.1	Tube standard	Metric
6.6.4.0.2	Tube material	Plastic, Polyurethane C98A
6.6.4.0.3	Connection	Rapid fittings or compression couplings

6.6.5 Non-Process Pressure Indicators

6.6.5.1 Jacket Pressure Indicator, Control Side

6.6.5.1.1	Manufacturer	WIKA
6.6.5.1.2	Type	Bourdon tube
6.6.5.1.3	Material	Copper / Brass
6.6.5.1.4	Scale	-1/+5 Barg [0-30 inchHg / 0-45 PSIG]
6.6.5.1.5	Connection	Threaded

6.7 Electrical System

6.7.1 Voltage & Frequency Requirements

6.7.1.0.1	Voltage	460 Volts
6.7.1.0.2	Phases	3
6.7.1.0.3	Frequency	60 Hertz

6.7.2 Grounding & Connections

6.7.2.0.1	Connection wires necessary	4 [3 phases and a ground wire]
6.7.2.0.2	Compatible to system type	TN-S, TN-C or IT system

6.7.3 Wiring

6.7.3.0.1	Markers	Wires are marked using non-smearing, heat resistant markers. Wire numbers will be documented on the electrical schematics. All terminal blocks are clearly marked.
6.7.3.0.2	Color standard	NFPA 14.2.4

6.7.4 Components

6.7.4.0.1	Motor starter manufacturer	Telemechanique
6.7.4.0.2	Power disconnect manufacturer	Telemechanique
6.7.4.0.3	Circuit breaker manufacturer	ABB

6.7.5 Conduits

6.7.5.0.1	Type	Open wire ways
6.7.5.0.2	Material	Plastic

6.7.6 Enclosures

6.7.6.0.1	Enclosure material	Painted steel
6.7.6.0.2	Rating	Min. IP 55 [NEMA 12]
6.7.6.0.3	Manufacturer	Rittal or NPP
6.7.6.0.4	Service Clearance	Forward 1 m [3 1/2 ft]
6.7.6.0.5	Internal light	Included
6.7.6.0.6	External Power Outlet	European Standard Included
6.7.6.0.7	PC connection	9 pin D-Sub
6.7.6.0.8	Authorization Key	Side mounted

6.8 Customized alarm

6.8.1 High level alarm

6.8.1.0.1 Getinge will add an extra alarm for high level off external tank. Tank is delivered by customer.

6.8.2 Proximity switch

6.8.2.0.1 Getinge will add an extra alarm for external tank in position. Sensor is provided by customer

7 Non-functional attributes

7.1 Availability

7.1.1 Reliability

7.1.1.0.1 Service intervals in the manuals are calculated for normal operation, which is defined in section Life-time in MAINTAINABILITY below

7.1.1.0.2 The equipment is designed for normal operation

7.1.1.0.3 Spare parts are available for at least 10 years after delivery

7.1.2 Redundancy

No arrangements for redundant availability are provided

7.1.3 Error checking

No arrangements for error checking with concern to availability are provided

7.1.4 Stand-by operation

The equipment may be operated from cold or 100°C Jacket temperature, the availability for operation is improved with hot jacket, refer to CONFIGURATIVE FUNCTIONS AND THEIR LIMITS, System configuration sections above

7.2 Maintainability

7.2.1 Service Access

7.2.1.0.1 Refer to PRESSURE VESSEL, Chamber Configuration section above for information about service area location

7.2.1.0.2 Refer to MECHANICAL ENCLOSURE, Service Door section above for information about access

7.2.2 Expansion & enhancement possibilities

7.2.2.0.1 The control system support expansion up to 64 digital inputs with opto-coupler isolation and internal 24 Volt DC supply

7.2.2.0.2 The control system support expansion up to 64 digital outputs with normally open relay contacts

7.2.2.0.3 The control system support expansion up to 24 analog inputs with temperature, pressure or general purpose interface

7.2.2.0.4 The control system support expansion up to 8 analog general purpose outputs

7.2.3 Spare capacity

In general is 10% input and output capacity provided

7.2.4 Likely changes in environment

No arrangements for environmental changes are provided

7.2.5 Lifetime

7.2.5.0.1 The equipment is designed for normal operation during at least 10 years.

7.2.5.0.2 Normal operation is defined as 8 hours a day during 220 days per year.

7.3 Functional Testing

Functional testing is always included and is ruled through procedures in the Getinge QMS [4].

7.4 Factory Acceptance Test

Included acceptance test activities are specified in the contract between the Getinge Sales Company and the User.

7.5 Shipping & Crating

Preparing the equipment for shipment and crating will be completed at the factory in Sweden. Getinge has a long history of shipping equipment globally and will pack and crate the equipment so that it will arrive safely at your facility.

Depending on the agreed shipment methods will one of the following packages be used:

7.5.0.0.1 Ground or air: The equipment will be hedged.

7.5.0.0.2 Sea: The equipment will be crated and water protected with a plastic cover.

7.6 Documentation

7.6.0.0.1 Included documentation and number of copies for e.g. manuals, drawings and test reports are specified in the contract between the Getinge Sales Company and the User.

7.6.0.0.2 Manuals are provided in English

7.7 Installation

7.7.0.0.1 A general pre-installation instruction is sent to the user prior to delivery, to aid the site preparation.

7.7.0.0.2 The apparatus is shipped fully tested and ready for installation.

7.7.0.0.3 Drawings and technical data sheets are provided for specifics of the apparatus installation.

7.7.0.0.4 A customized installation manual and operating instructions are also provided with the apparatus.

7.7.0.0.5 The responsibility for and extent of included work during installation is specified in the contract between the Getinge Sales Company and the User.

7.8 Training

Included training activities are specified in the contract between the Getinge Sales Company and the User.

7.9 Qualification

Included qualification activities are specified in the contract between the Getinge Sales Company and the User.

7.10 Service

Included service activities are specified in the contract between the Getinge Sales Company and the User.

8 Glossary

PACS	Programmable Autoclave Control System
GMP	Good Manufacturing Practice
cGMP	Current Good Manufacturing Practice
GAMP	Good Automated Manufacturing Practice
QMS	Getinge Quality Management System

9 References

[3] GMP Impact Assessment Rationale, available at Getinge Sterilization AB

[4] Getinge Quality Management System (QMS)QMS 2000 Public 5.0

[6] Getinge Validation Policy, document 01.27.00 in QMS 2000 Public 5.0

[9] Nationally Recognized Testing Laboratory

[10] Technical Data Sheet, separate document

[11] Pre installation instruction, separate document

[12] The program combination, separate document

10 Document history

Date	Version	Description	Prepared by
2004-08-24	A	First draft	SN
2005-01-21	B	Voltage changed in section 6.7.1. Condensate return added in section 6.4. High level alarm added in section 6.8.1. Proximity switch added in section 6.8.2	HE