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Design and supply of 3000 litre fully automatic autoclave for the pharmaceutical industry

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- At about 45% of the project life, the design work should be 75% complete, all the orders should be placed, construction work should begin and the budget should be finalised.

These figures vary from project to project and are dependent on the nature of the project. It is essential at the start of any project to define similar milestones to those outlined above. Progress and performance of the project team will then be measured against such a schedule.

13.8 Controls

For all projects it is essential for the project manager to set up appropriate and effective systems for the control of cost and performance.

Effective control systems also assist the project manager in maintaining an effective grasp on the project.

For a project of the size in this report the following control systems are effective:

(i) Variance analysis

A budget is drawn up and an estimated cost allocated to each activity in the budget. At regular intervals the actual amount spent on each activity is compared to the estimated cost for that period. All variances which then arise are then analysed and corrective measures are then taken.

(ii) Performance analysis

With this system of analysis, three elements of performance are measured. They are:

- The budgeted cost of work scheduled.
- The budgeted cost of work performed.
- The actual cost of work performed.

The analysis and comparison of these elements then provides data for effective performance controls.

(iii) Project reports and meetings

Regular project reports and meetings between all concerned parties are essential to communicate information on progress, to identify problems and to outline steps taken to overcome such problems.

13.9 Motivation

It is essential with every project to establish correct and effective motivational methods for the complete workforce in the interests of ensuring high productivity and good performance.

In this project, in order to ensure that the workforce were motivated to perform to the best of their ability, the following motivational factors were taken into account by management:

(i) Correct wages were paid.

(ii) Working conditions were always safe and suitable.

(iii) Direct involvement existed between the engineers and the workers.

(iv) The workers were always informed as to the progress of the work and the feedback of this information was always accurate and quick.

(v) Recommendations of improvements to the design and construction phases of the project by the workers were encouraged by management. These recommendations were always studied and where viable they were implemented with the full knowledge of all involved.

With this project it was found that the major factor influencing labour productivity was the project team's basic attitude to the work.

In order to maintain and even improve this attitude, it was necessary for the project leader to concentrate on the following three aspects:

(i) The elimination of the industrial relation problems such as those described above, which were related to:

- Earnings.
- Work conditions.
- Fringe benefits.
- Accurate job descriptions.

(ii) The establishment of a competent managerial team, which would earn the respect of the work force. This was essential, as without this confidence in the ability of management, it would have been impossible to maintain an acceptable level of productivity.

Reasons for loss of confidence generally resulted from:

- Unavailability of drawings and information when required.
- Differing versions of the same instructions to different people.
- Frequent changes to instructions.
- Delays in deliveries of materials and equipment.
- Frequent alterations for completed work.
- Poor site management.

(iii) The effective planning of manpower requirements to ensure that:

- No overloading of people on jobs occurred.

- Sufficient workers were utilised on jobs to obtain optimum output without increasing costs.
- Overtime work was kept to a minimal.

13.10 Backup Systems

It is essential with every project to ensure all essential backup systems exist. These systems include:

(i) A commissioning service where required.

In certain cases the contractor is required to handover to the client a plant which is completely tested and operational. In other cases the client undertakes to participate or even take charge of the commissioning stage of a project. This requirement should be defined in the contract stage of a project.

(ii) Manuals and operation instructions.

After completion of a project it is the contractor's responsibility to supply the client with an operation manual which includes:

- Operation instructions.
- Equipment details.
- Maintenance details.
- Spare parts recommendations.
- All approved engineering drawings.
- All inspection certificates.

(iii) After sales service.

For plant and equipment of specialised design, the contractor should ensure that the client has a readily available source of advice and service should the need arise.

ENQUIRY ISSUED BY CLIENT

PROPOSED TENDER SPECIFICATIONS PERTAINING TO AUTOCLAVE FOR THE TERMINAL STERILIZATION OF PRODUCTS FILLED IN GLASS CONTAINERS, AND FOR EQUIPMENT USED IN THE MANUFACTURE OF PARENTRAL PRODUCTS.

OUTLINE

It is intended that this autoclave be utilized for the Terminal Sterilization of Parentral Products, filled in Glass Containers, and for the Sterilization of equipment such as receptor vessels, filter housings and machine parts, prior to the use of such equipment.

Ease of operation, safety, and control accuracy are of prime importance.

This specification is to be read in conjunction with Drawing AI 4/18.

PHYSICAL APPEARANCE & DIMENSIONS

The autoclave will be rectangular in construction of stainless steel, having loading doors at each end. The usable volume of the chamber is to be 3000L, having internal dimensions of not less than 1000mm wide x 1500mm high x 2000mm long.

An external jacket of stainless steel is to be fitted to the chamber.

All contact parts are to be of 316 stainless steel finished to 180 grit, except in the case of the valves, which shall be of 304 stainless steel, and the cladding, which is to be of 304 stainless steel, with welds made good and finished to 180 grit, and the jacket which is to be of 304 stainless steel.

The chamber and doors are to be designed to withstand both pressure and vacuum and the jacket is to be designed for both steam and cooling water.

The vessel is to be constructed in accordance with the ASME 8 code, and generally accepted Sound Engineering Practice, and comply with the Rules pertaining to the Design and Construction of Pressure Vessels as prescribed in the Factories Act. (Act 22 of 1941, as ammended)

Initial certification of the vessels is the responsibility of the supplier, and such Test Certificates will be supplied at the time of installation.

MATERIALS OF CONSTRUCTION

Inner Chamber, including inside of doors ; 316 Stainless Steel

Jacket, cladding, and outside of doors ; 304 Stainless Steel

Thermowells, including loose probe and attached wires ; 316 Stainless Steel

Insulation ; Mineral wool

Gland packings & Gaskets ; Food grade material, with no extractables at elevated temperatures.

Valves ; To be ball-type throughout, with contact parts of 304 Stainless Steel.

Heat exchanger ; To be plate type - 304 Stainless Steel contact parts, food grade gaskets.

Guages ; Analogue or digital type, oil filled in the case of analogue pressure guages.

Steam filter ; Sintered Stainless Steel

Switches ; All switches to be splash proof, or covered with a perspex cover.

MODE OF OPERATION

In broad outline, the autoclave is to be micro-processor controlled by a stepping controller.

It is to be capable of in-house re-programming.

It has to be capable of carrying out a number of sterilizing cycles which will basically consist of the following steps, but which may be altered later.

Once these parameters have been set, they are to be key-isolated, and the whole cycle is to be initiated by a single switch.

a) PRE-VACUUM CYCLE:-

Take the load to the Sterilizing Temperature, with the chamber being evacuated to an 80% vacuum three times, before the final Sterilization Temperature is reached, and the Sterilization cycle commences.

b) STERILIZATION CYCLE

The Sterilization Temperature, (which can be altered by means of a thumb-wheel type switch between 115°C and 130°C), to be held for a time and input to the microprocessor by means of a thumb-wheel type switch.

c) COOLING CYCLE

The vacuum is to be broken through a vent filter (0,3um supplied by the supplier of the steam filter to allow for standardization), and the temperature to be reduced by cooling the jacket with recycled water from a Hold Tank via the Heat Exchanger until the temperature is $\pm$ 60°C. Cooling water (at the temperature of the load) is then to be introduced to the chamber via spray devices to

ensure uniform spread of the cooling water, and evacuated via two drains situated at either end of the bottom of the chamber. Once the temperature of the load is 40°C the chamber is to be drained, the cooling water is to be pumped to the Hold Tank.

NOTE

It might become necessary to maintain a constant pressure in the chamber during the phase, and this should be accomplished by using filtered, compressed air in the ulluge space.

d) DYE TESTING

A Test Dye solution is to be introduced from a Holding Tank via the bottom of the chamber. The level of this dye stuff should be such that an ulluge space of ± 5% of the volume of the chamber remains.

A vacuum of -40 kPa is to be drawn on this ulluge space for a period input in the microprocessor after which the vacuum is to be broken via the Vent Filter.

The ulluge space should then be pressurised to +200 kPa using filtered compressed air. This pressure is to be maintained for a period input in the microprocessor.

The chamber should then be drained and the dye solution should then be pumped to a Holding Tank.

e) RINSING

Washing water containing a surfactant is to be pumped via the Spray Devices to the chamber of recycled for a time determined by a thumb wheel-type switch.

The chamber should be drained and the washing water should be pumped to drain.

f) DRYING

A vacuum of -50 kPa is to be drawn on the chamber and a temperature of +40°C is to be created within the chamber by pressuring the Jacket with Steam.
This vacuum and temperature are to be maintained for a length of time determined by a thumb-wheel type switch.

CONTROL

THEMO COUPLES

5 Themo couples are to be provided, and linked to a recorder, either digital or analogue, preferably with a strip-type chart, with graduations not exceeding 1°C. These themo couples are to be situated as follows- two at the top of the chamber, one at each end, two at the bottom of the chamber, one at each end, and one on a 3m "pig-tail" cable with braided heat resistant wire, to enable placing in the centre of the load. (Temperature throughout the chamber is not to differ by more than 1°C when loaded). A gland is to be provided to enable validation themo-couples to be introduced to the chamber. (See attached diagram)

CYCLE RECORDING

A two pen recorder to monitor temperature and pressure in the chamber is to be supplied. The chart diameter is to be at least 250mm or in the case of the strip-recorder, the chart to have a minimum width of 250mm.
Accuracy of 0,5% of scale is required.
An indicating themometer shall be provided. The sensing element of this themometer shall be corrosion resistant, and positioned to indicate the temperature in the chamber drain

PARAMETER MEASUREMENT

Temperature, Pressure, and Vacuum within the chamber are to be displayed using analogue or digital displays, and are to be installed in such a way as to allow calibration against a standard guage.

Accuracy of 1,5% of scale is required, and in the case of temperature indicators 0,5°C.

Pressure within the Jacket is to be displayed by means of an analogue or digital display.

CYCLE INDICATION

Each phase of the cycle is to be indicated by an illuminated light.

Cycle failure is to be indicated and an audio-alarm sounded in this condition, and when the cycle was completed, if the cycle should fail, the cycle timer should resent to zero.

In addition to the process indicators fitted at the operating and of the Autoclave, the following should be fitted at the opposite end;

i) Chamber pressure guage

ii) Chamber vacuum guage (this may be combined with the pressure guage)

iii) An illuminated light indicating cycle in progress

iv) An illuminated light and audio-alarm indication cycle failure

v) An illuminated light and audio-alarm indicating cycle complete

SAFETY

INTERLOCK

The autoclave shall be equipped with a automatic interlock machanism designed in such a way that steam cannot enter the chamber, under normal operating conditions, when either door is unlocked.

DOORS

All chamber doors shall incorporate a mechanism that automatically prevents the opening of the doors when a pressure greater then 27 kPa exists in the sterilizer chamber. It shall in addition, not be possible to open both doors together, except when a manual override is operated.

HANDLES

The temperature of all handwheels, handles, or similar devices used by the operator during normal operation of the sterilizer, shall not exceed 50^{o}C (122^{o}F), if metal, or 60^{o}C (140^{o}F), if non-metal.

ON/OFF SWITCH

Means of switching off the power shall be located within easy reach of the operator and shall be clearly labelled.

THERMAL INSULATION

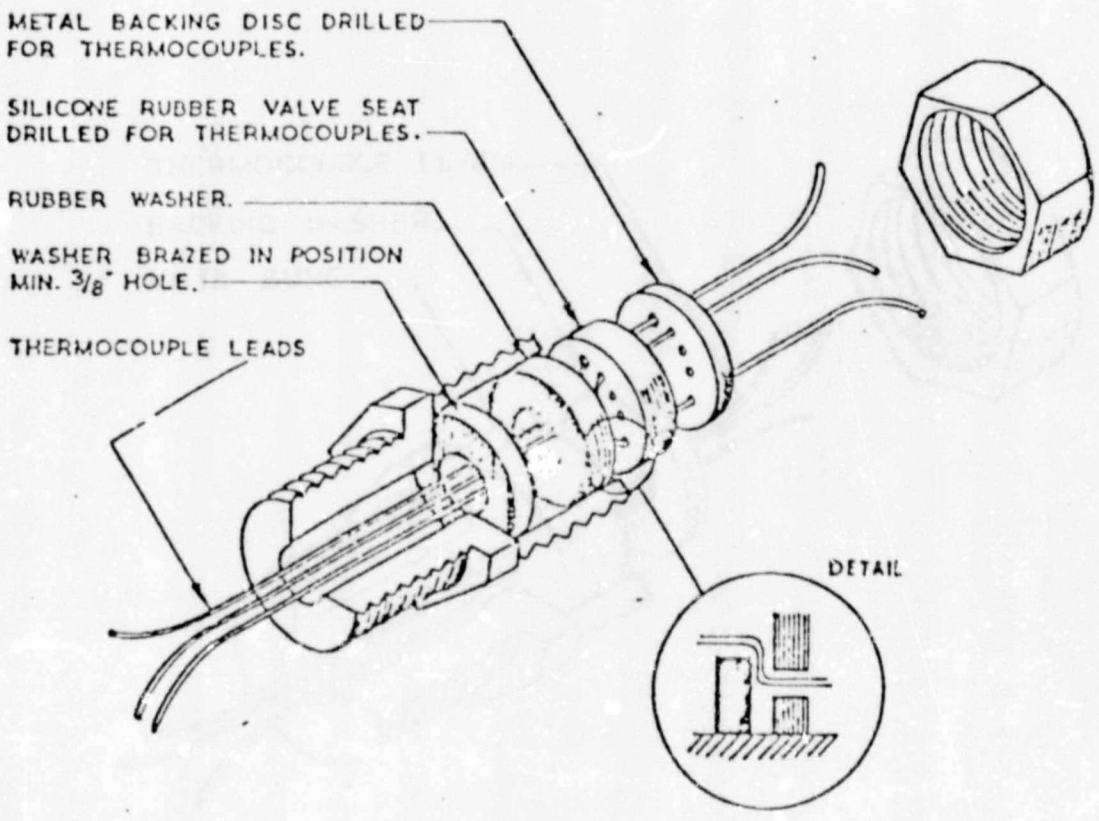
Thermal insulation shall be provided. The insulation shall be non-hygroscopic and shall be suitably attached to the sterilizer, so as to minimize thermal losses and maintain temperature uniformity in the chamber.

VACUUM BREAK VALVE

A manually operated Vacuum Break Valve is to be supplied.

Figure A2.1

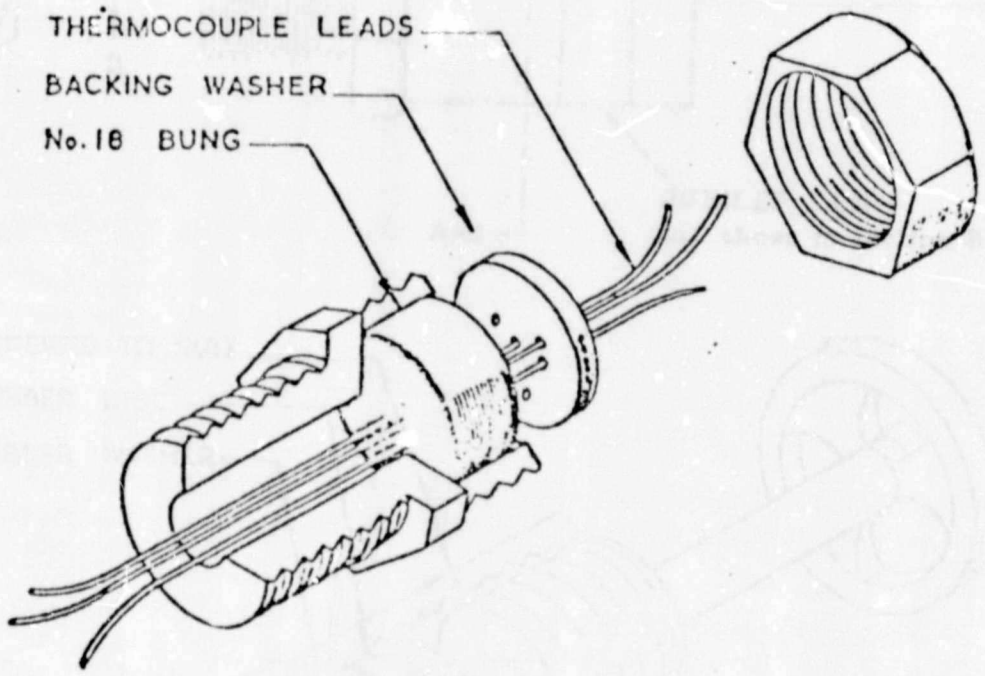
METHOD OF INTRODUCING THERMOCOUPLES INTO STERILIZER CHAMBER



3/4" B.S.P. x 22 mm. COPPER COMPRESSION FITTING (YORKSHIRE 611LB 22mm x 3/4" M1).
SUITABLE FOR UP TO 12 TWIN CORE THERMOCOUPLES.

Figure A2.2

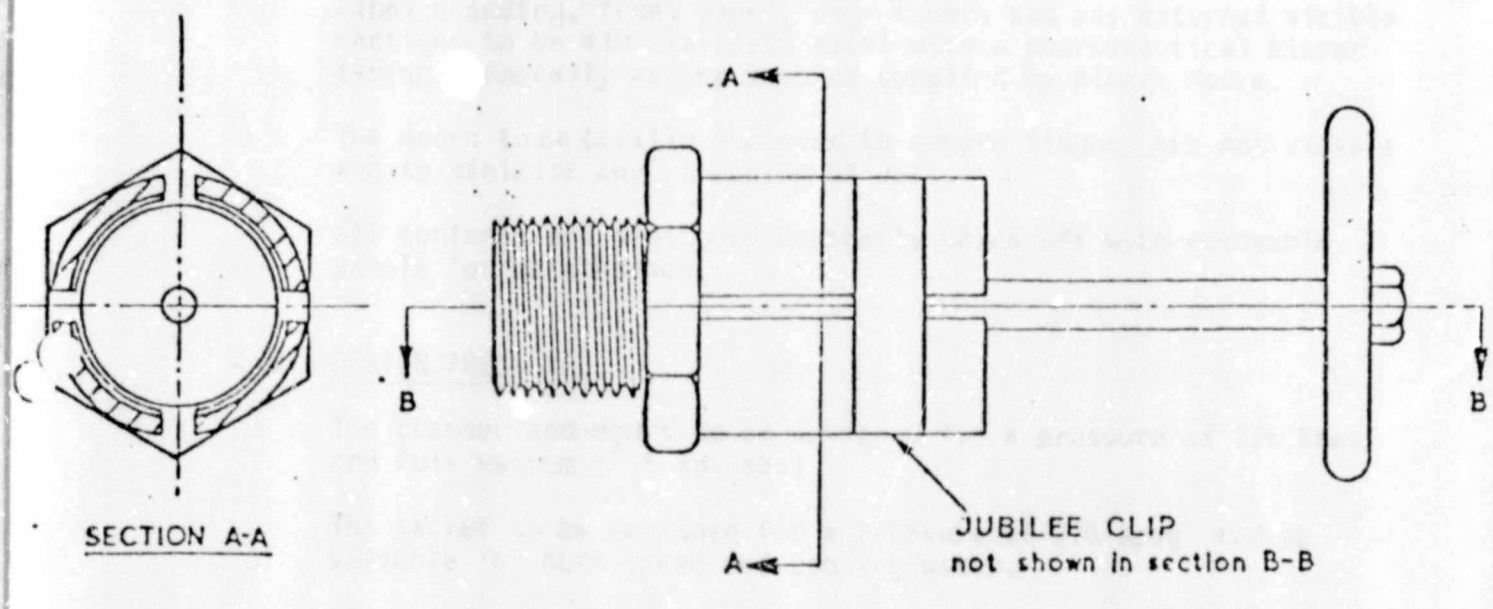
METHOD OF INTRODUCING THERMOCOUPLES INTO STERILIZER CHAMBER

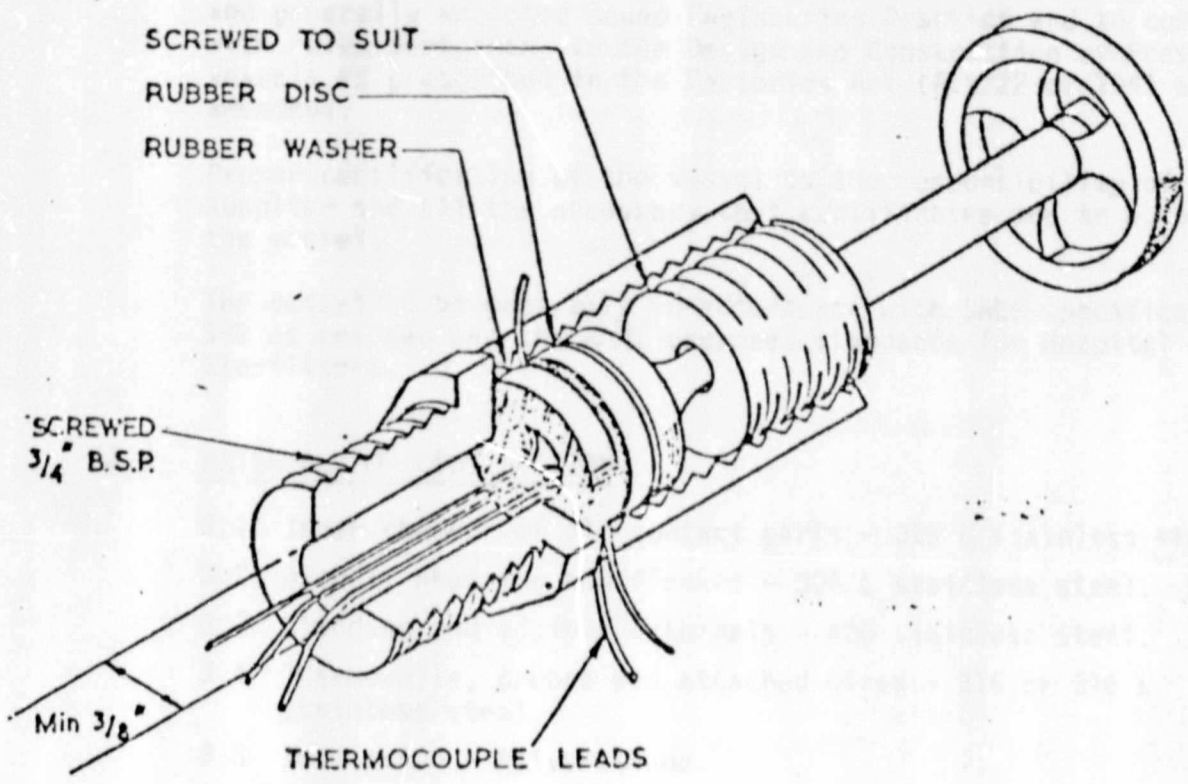


3/4" B.S.P. x 22mm COPPER COMPRESSION FITTING (YORKSHIRE 611LB 22mm x 3/4" M.I.) FITTED WITH No. 18 RUBBER BUNG CUT TO LENGTH AND SUITABLE BACKING WASHER.
SUITABLE FOR UP TO 6 TWIN CORE THERMOCOUPLES.
FOR 12 THERMOCOUPLES USE TWO GLANDS ON A 'Y' BRANCH.

Figure A2.3

METHOD OF INTRODUCING THERMOCOUPLES INTO STERILIZER CHAMBER





SECTION B-B

SUITABLE FOR UP TO 12 THERMOCOUPLES OF EITHER TWIN OR SINGLE CORE WIRE

1.0 FINISH

All contact parts to be 316 L stainless steel with a 180 grit finish, generally as per samples supplied by Albert Moore.

Jacket, headring, fingers and external welds to be 304 L stainless steel with a pharmaceutical mirror finish, generally as per samples supplied by Albert Moore.

Final cladding, front panel, door covers and any external visible sections to be 430 stainless steel with a pharmaceutical mirror finish, generally as per samples supplied by Albert Moore.

The doors to be totally enclosed to ensure fingers are not visible and to minimise any trapping of dust.

All controls and piping to be neatly boxed off with removable panels for maintenance.

2.0 DESIGN PRESSURES

The chamber and doors to be designed for a pressure of 276 Kpag and full vacuum ($\pm$ 5 Kpa abs)

The jacket to be designed for a pressure of 276 Kpag and be suitable for both steam and cooling water.

The vessel to be constructed in accordance with ASME VIII code and generally accepted Sound Engineering Practice and to comply with rules pertaining to the Design and Construction of Pressure Vessels as prescribed in the Factories Act (Act 22 of 1941 as amended).

Proper certification of the vessel is the responsibility of the supplier and all the necessary test certificates are to accompany the vessel.

The vessel to be generally in accordance with SABS specification 982 as revised and the AAMI proposed standards for Hospital Steam Sterilisers.

3.0 MATERIALS OF CONSTRUCTION

3.1 Inner chamber of all contact parts - 316 L stainless steel.

3.2 Jacket, headring and fingers - 304 L stainless steel.

3.3 Cladding and visible externals - 430 stainless steel.

3.4 Thermowells, probes and attached wires - 316 or 316 L stainless steel.

3.5 Insulation - Polyurethane.

3.6 Gaskets - Silicone

3.7 Valves - Asco regulators
NDE isolating valves
ASCO control valves

Before final installation of valves, supplier to submit a list of valves to be used for approval by client.

3.8 Heat Excnanger/Condensor - Coil type of 316 L stainless steel construction.

3.9 Guages - Analogue vapour proof type.

3.10 Vent filters - Millipore Type CVGB 71 TP1

3.11 Limit switches - To be drip proof.

4.0 MODE OF OPERATION

The Autoclave tc be a micro-processor controlled by a sequence controller which is programmed for 4 cycles as described below. The pre-selected cycle to be initiated by a single switch. (Preference is to be given to Kaye Digistrip Model 4 controller)

4.1 Cycle 1 - Dressing Type (No liquids)

4.1.1 Pulse cycle - The chamber pressure is evacuated to 20 Kpa abs. The chamber pressure is then returned to atmospheric pressure by the inlet of steam. The process continues for a pre-set number of times and periods.

4.1.2 Sterilising cycle - The chamber pressure is raised to a maximum of $\pm$ 240 Kpag (a pre-selected level set on the temperature controller). When the correct temperature is reached the sterilising temperature will be held for a pre-set time.

4.1.3 Drying cycle - The chamber pressure is reduced to approximately 5 Kpa absolute, after which vacuum drying occurs for a pre-set period.

4.1.4 Vacuum break - The chamber pressure is returned to atmospheric pressure by the inlet of filtered air via a bacterial filter.

Note : The jacket is filled with steam prior to use. The pressure is maintained.

4.2 Cycle 2 - Ampoule cycle with water cooling.

4.2.1 Pre-vacuum - The chamber pressure is reduced to 5 Kpa absolute. The process continues for a pre-set number of times and periods whilst the temperature is raised to the sterilizing temperature. However, check with normally accepted ampoule cycles to avoid unnecessary boiling of solutions.

4.2.2 Sterilising - The chamber pressure is raised to a pre-set temperature and held for a pre-set time.

4.2.3 Spray cooling - The contents of the chamber are then cooled by spray cooling. The water is re-circulated to the jacket via a heat exchanger to $\pm$ 40°C after which the cycle is completed. At all stages ensure differential temperature does not exceed $\pm$ 5°C per minute.

4.3 Cycle 3 - Ampoule Cycle with no water cooling.

4.3.1 Pre-vacuum - The chamber pressure is reduced to 5 Kpa abs.

The process continues for a pre-set number of times and periods whilst the temperature is raised to the sterilising temperature.

However, check with normally accepted ampoule cycles to avoid boiling of solutions being sterilised.

4.3.2 Sterilising - The chamber pressure is raised to a pre-set temperature and held for a pre-set time.

4.3.3 Cooling - Contents to be allowed to cool down naturally to a temperature of $\pm$ 40^{0}C after which cycle is completed.

4.4 Cycle 4 - Equipment Cycle.

4.4.1 This cycle is identical to cycle 2, however it is pre-set to operate for a different sterilising temperature and period.

5.0 CONTROLS

All starters, the 2 channel cycle temperature and pressure recorder, safety devices, instruments and local control cabinet to be supplied. All selection switches to be installed under lockable plastic covers. (Recommended controller and 6 channel recorder to be KAYE Digistrip Model 4.)

5.1 RTD's

6 RTD's to be provided and linked to a digital or analogue recorder (type to be approved by client), with a strip-type chart with graduations of maximum 1^{0}C.

The RTD's to be situated as follows:

2 at the top of the chamber, one at each end, one of which will control the cycle,
2 at the bottom of the chamber, one at each end,
1 on a 3 m "pig-tail" cable with braided heat resistant wire for placing in the centre of the load, and
one in the drain for recording of cycle.

The temperature throughout the chamber is not to differ by more than 1^{0}C when loaded.

A gland is to be provided to enable 12 validation RTD's to be introduced to the chamber (see attached diagram).

5.2 Cycle recording

A pressure recorder of 250mm width is to be supplied with an accuracy of 0,5%.

An indicating thermometer to be provided, Mercury in glass or similar.

The sensing element of the thermometer to be corrosion resistant and positioned so as to indicate temperature in the chamber top (and should be either Taylor or similar model).

5.3 Parameter measurement

Temperature, Pressure and Vacuum within the chamber are to be displayed using analogue displays, and are to be installed in such a way as to allow calibration against a standard guage.

Accuracy of 1,5% of scale is required, and in the case of temperature indicators, 0,5°C. Pressure within the jacket is to be displayed by means of an analogue display.

5.4 Cycle indication

Each phase of cycle is to be indicated by an illuminated light.

An audible and indicator alarm to be provided to highlight:

(a) Cycle failure
(b) Cycle complete
(c) Both doors open at the same time

This should have a key reset.

5.5 In addition to the process indicators fitted at the operating end of the Autoclave, the following should be fitted at the opposite end (clean side).

(i) Chamber pressure guage

(ii) Chamber vacuum guage (this may be combined with the pressure guage)

(iii) An illuminated light indicating cycle in progress

(iv) An illuminated light indicating cycle failure

(v) An illuminated light indicating cycle complete

(vi) An illuminated light indicating door open other end.

6.0 SAFETY

6.1 Interlock

The Autoclave shall be equipped with a automatic interlock mechanism designed in such a way that steam cannot enter the chamber, under normal operating conditions, when either door is unlocked.

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