Standard Operating Procedure **SOP054**

Title: USE AND MAINTENANCE OF THE SYSTEC DX90 AUTOCLAVE

Location: CBE Tissue Engineering Laboratory (T208B)

1. PURPOSE

To describe the procedures for the use and maintenance of the Systec DX90 Autoclave.

2. SCOPE

This SOP applies to operational procedures for using the Systec DX90 Series autoclave in the CBE Tissue Engineering Laboratory (T208B) for (i) steam sterilization and safe disposal of solid biological waste that may contain biological agents, as defined in the CBE Code of Practice, where solid waste may include solid culture and stocks of infectious material, culture dishes, flasks and related devices, sharps bins, contaminated solid items such as paper towels, plastic pipettes, pipette tips, vials and gloves; (ii) steam sterilization of aqueous solutions and media for use in culture applications; (iii) sterilization of reusable equipment as well as bottles, beakers, pipettes, forceps; tubing etc. The procedure described in this SOP for solid waste treatment has been validated, based on typical waste loads described in Annex 1.

Important Restrictions: This autoclave cycles have been validated.

3. RESPONSIBILITES

CBE Laboratory Users

(i) Authorised users should check that the autoclave is in service . Autoclaves are inspected annually and certified by the service engineer or designate. The inspection, service and repair records are maintained as per University Safety Policy. 'Next service' date and 'next validation' date should be posted on / near the autoclave.

(ii) All users MUST ensure that all operational cycle runs, maintenance or testing procedures are be recorded and retained.

Responsible Person (RP)/Laboratory Manager (LM)

(iii) The Laboratory Manager or designated Responsible Person MUST ensure that the University Estates and Buildings Department is notified of all autoclave installation. They will inspect the autoclave at the statutorily required interval. Notification of such items should be made through the Departmental Safety Officer (DSO) and the Wolfson School Facilities Manager.

(iv) Notification of newly acquired equipment is required before it is brought into use, to ensure compliance with the Pressure Systems Regulations.

(v) The Laboratory Manager or designated Responsible Person is responsible for checking the usage log to ensure that the autoclave is serviced correctly; either on its annual 'due date' or when it has reached its 500 cycle limit.

(vi) The Systec DX series autoclave pressure vessel is serviced bi-annually by the Systec engineers as part of the service contract. It is the Laboratory Managers or designated Responsible Person duty to ensure that the Insurance inspection is performed with the Systec engineer present and the inspection certificate is lodged with the Technical Resources Manager in the Wolfson School.

(vii) Principal investigators/supervisor's MUST ensure that his/her employees are trained before operating any autoclave unit. All operators (regardless of experience) must have successfully completed an authorized training session on the safe operating procedures of autoclaves. Users must be instructed on the operation and safety regulations and, if required, to repeat this instruction at regular intervals

(viii) Maintenance of autoclaves should not commence without a 'Decontamination Certificate' (a proforma can be obtained from the CBE website).

4. SPECIAL NOTES: HEALTH & SAFETY

4.1. Risks to the operator

The autoclave is built according to standard safety regulations. Nevertheless, the danger of death or injury to the user or a third party, or damage to the autoclave or other material assets, can arise when using the appliance. For this reason, the autoclave is only to be used as it is intended to be used and in a faultless condition with regard to safety. **NOTE: Faults that could impact on safety must be resolved immediately.** The following residual risks result from the function of the autoclave, and must be considered at all times:

(i) **Crushing and or amputation hazards** - There is a danger of crushing or amputation of hands or fingers between the edge of the door and the edge of the container if closing of the door is no longer damped by spring or hydraulics.

(ii) **Burn and scald hazards** when unloading the autoclave (for some designated cycles) from (1) hot vessels or liquid escape from vessels leaking (2) hot surfaces inside the container or near the sterilisation substance. Hot surfaces of the door and chamber (3) escape of hot clouds of steam on opening the door (4) unathorised or improper programing of parameters (5) unrecognised errors and defects or poor maintenance procedures.

(iii) **Heavy Load hazards** - fully loaded baskets can be too heavy to lift manually when putting them in or taking them out of the autoclave. If this is the case, the baskets or fillers should be partially unloaded beforehand (max 35kg inclusive of basket or fillers).

(iv) **Hazardous substances** - Infectious aerosol hazards from (1) failed exhaust filter cartridges or their improper disposal (2) non-sterile condensate left behind in the chamber if the sterilisation process is not successfully completed

(v) **Fire or explosion hazards** from (1) misuse of sterilisation cycles ie sterilisation of liquids using solid cycles (2) sterilisation of liquids in tightly closed containers (3) unathorised or improper programing of parameters.

(vi) **Operational hazards** - After using the autoclave, it must be ensured that the appliance is properly switched off by means of the main switch

(vii) **Risks due to wear** - The autoclave must be serviced at the regular intervals as specified in the servicing regulations (at least once a year or after 500 cycles).

(viii) **Specific risks of individual sterilization procedures** - Additional specific risks can arise when using particular sterilization cycles. Specific instructions regarding these risks and how to avoid are detailed in the operating manual.

(ix) **Incorrect use of the cycles for solids** - When sterilizing liquids in glass containers with the cycle for solids, the boiling process can be delayed and the glass container can shatter.

4.2. Safe Working Practices

In addition to the basic and specific safety instructions, risks can arise through dangerous working procedures. **NOTE: Detailed information on laboratory autoclaves can be found in British Standard BS2646 'Autoclaves for sterilisation in laboratories', in the HSE publication PM73, 'Safety at autoclaves' and in the local Code of Practice.**

(i) The operator MUST ensure that the item to be sterilized is suitable for steam sterilization in the autoclave with the options installed.

(ii) The operator MUST ensure that the maximum load capacity for the autoclave is never exceeded (refer to Operators Manual for specifications).

(iii) Hazardous chemicals or materials contaminated with them MUST NOT be autoclaved.

(iv) Materials contaminated with Virkon are NOT to be autoclaved.

(v) Any strong oxidizing material i.e. dry hypo chlorite's, MUST NOT be autoclaved with organic materials such as paper, cloth or oil.

(vi) While contaminated solid biohazardous waste, reusable equipment or aqueous solutions may be sterilized in the same autoclave, they MUST NOT be mixed or loaded together during the same cycle.

(vii) The main switch switches the power supply to the autoclave on and off. ALWAYS switch off the autoclave at the main switch if some danger has been detected in the autoclave.

(viii) The preset cycles of the autoclave can be changed significantly using the operational parameters described in the manual, and this may result in danger for the operating personnel or impair the sterilization result. Changes MUST only be made by trained personnel and MUST be documented in the appliance log book.

Note: Currently no CBE user is trained in the making the changes. All changes must be made by DW Scientific trained engineers.

4.3. Information and Training

(i) Only persons who have received the appropriate training are permitted to use autoclaves. The names of the authorised users should be posted on or nearby the autoclave.

(ii) All operators MUST observe all safety regulations and guidelines applying to the autoclave and the environment in which it is operated

(iii) All operators MUST read this SOP and confirm with their signature that they have understood both documents. A signed Training Agreement should be retained in the individual's Training Record.

(iv) All operators MUST use the prescribed PPE; heat resistant gloves, eye protection and an impervious apron (SOP037)

(v) All operators MUST keep the autoclave in a faultless condition with regard to safety.

(vi) All operators MUST stop using the autoclave as soon as any safety deficiency is detected. Operators MUST inform the Laboratory Manager or Responsible Person.

(vii) Autoclaved items should be stored separately from non-sterilised items. There should be designated laboratory areas for storage of items related to their contamination status and prior / intended use e.g. clean equipment for autoclaving, autoclaved equipment, and -contaminated used equipment for cleaning, contaminated used equipment for disinfection. All laboratory users should be aware of the system to ensure mix-ups do not occur (refer to SOP003).

5. EQUIPMENT AND MATERIALS

i. The Systec DX-90 Autoclave
ii. De-ionised water vessel
iii. Autoclave Basket
iv. Autoclave Log Sheets
v. Autoclave bags (Fisherbrand, polypropylene or HDPE)
vi. Autoclave Indicator Tape
vii. Polypropylene or stainless steels tubs as secondary containment
viii. Sharpsafe one Sharps autoclavable containers (nominal volume – 1L).

6. PROCEDURE

The following describes procedures for (i) steam sterilization of solid form biological waste that may contain biological agents, (ii) The sterilization of reusable equipment and (iii) the sterilization of liquids, aqueous solutions and media for use in culture applications (ie not waste disposal).

Before proceeding all operators must don

- Full length apron (green)
- Eye protection (safety goggles or full face visor)
- Specialised Heat Resistant (Orange) Gloves

6.1 Opening the Autoclave Door

(i) Turn on the power for the autoclave

(ii) **CAUTION:** Before opening the door check the log to see if the autoclave has recently performed a sterilisation cycle. If so the surfaces of the door and the autoclave chamber will be hot and on opening, hot clouds of steam can escape and lead to scalding.

(iii) To open the door, press the “Open” button displayed on the front panel. The autoclave will alarm for 30 seconds to warn the operator to move back. The door is unlocked and automatically opens slightly. The operator should stand clear and wait 1 minute before opening the door fully.

(iv) Wearing the appropriate PPE, lift the door until it reaches the horizontal stop. DO NOT pull the door from the front,

(v) Ensure that the flexible temperature sensor (PT100) is placed in the holder in the door when the door is opened. HINT: It is a good idea to put it in a coil, so that it does not trap in the seal of the autoclave.

(vi) **NOTE:** Before using the autoclave, ensure that the distilled water reservoir is filled to the marked level.

6.2 Selecting the Sterilisation Cycle

Depending on the item being sterilized, you MUST select an appropriate sterilization procedure in order to:

- eliminate risks to personnel and to the laboratory
- Guarantee a successful sterilization result.

A suitable sterilization procedure is selected using the arrow keys on the control unit. The corresponding cycle number, the name of the cycle and the pictogram for the temperature sensor used appears in the display.

Only three of these cycles are authorised for routine sterilisation as detailed in the following sections of this SOP (see Table 1). The use of any other cycle is prohibited unless authorised by the Laboratory Manager or Responsible Person.

Table 1: Preset Parameters for Sterilisation Cycles

Item being Sterilized	Sterilization Temp	Sterilization Time	Unloading Temp	Cycle No.	In Combination with:	Validated (Yes/No)
Solids, instruments	121 °C	20 min.	120 °C	1	N/A	NO
Solid Laboratory waste (non melting items) in Bags in the basket	121 °C	15 min.	99°C	4	N/A	NO
Liquids for cell culture applications (in bottles; max 5L)	121 °C	15 min.	80°C	6	N/A	NO

CAUTION: While contaminated solid biohazardous waste, reusable equipment or liquid may be sterilized in the same autoclave, DO NOT mix them together during the same cycle.

6.2.1. Cycle Selection

a. **CYCLE 1 (Solids, instruments)** must be used for steam sterilisation of solid equipment at 121°C for 20 min.

b. **CYCLE 4 (Solid waste in bags)** MUST be used for the sterilization of normal laboratory waste in bags (solid waste with low liquid content). The operating cycle, fixed at 121°C and 20 minutes, MUST be used for sterilisation of all solid biohazardous waste

c. CYCLE 6 (liquids for culture applications) MUST be used for sterilisation of liquids intended for culture applications. Autoclavable liquid container MUST NOT be tightly sealed. A Reference volume (blank) containing the same amount of distilled water should be kept open and the load-probe placed in the blank bottle.

6.3. Loading the Autoclave

6.3.1 Sterilisation & Disposal of Solid Form Waste with low liquid content and low propensity to melt: CYCLE 4

Waste for this cycle includes solid form waste which has low propensity to melt or has a low liquid content. Examples of such waste is given in Annex 1.

(i) ALWAYS wear appropriate PPE as described in SOP 037, Use of Personal Protective Equipment (PPE).

(ii) Use CBE approved transparent autoclave bags. DO NOT use any other bags!

(iii) Label the bags to identify the laboratory area from which it came

(iv) Ensure that the solid form waste is free from excess liquids and sharp objects that could puncture the waste bag. **CAUTION:** Sharps MUST be autoclaved separately using Cycle 4.

(v) **CAUTION:** DO NOT place sealed containers in the autoclave.

(vi) **NOTE:** Not all plastics can be autoclaved. If unsure about a new container, place it in an autoclave-safe container the first time it is used.

(vii) **CAUTION:** Do not combine strong oxidizing material (such as dry hypochlorite's) with organic materials (such as paper, cloth, or oil). **Do not autoclave liquids containing chemical disinfectants**

(viii) Do not fill bags more than ½ full. DO NOT seal the bags. If the tops are taped or tied they MUST be opened loosely to ensure effective steam penetration.

(ix) Place bags in a secondary container – Use the wire mesh baskets provided! Wire mesh baskets may prevent the autoclave becoming dirty or damaged due to leaks in rubbish bags or other containers. Examine the secondary container for damage before using. DO NOT use any secondary container other than those designated for the purpose.

(x) DO NOT place the flexible temperature sensor in the item being autoclaved (ie the item may melt!). The temperature sensor should be placed in the holder provided for it in the sterilization chamber, or else left freely in the chamber. The coil for the probe must be positioned so that it does not block the seal.

(xi) DO NOT overload the autoclave. Overloading the autoclave can lead to insufficient ventilation of the autoclave and may cause faults to occur. For an optimal result, the steam must reach all parts of the item being sterilized.

(xii) Place autoclave indicator tape (white/green banded tape) on outside of the autoclave bag.

(xiii) DO NOT leave bags for autoclaving in the autoclave overnight. Autoclave the load as soon as possible after preparation.

(xiv) After autoclaving is complete bags must be removed from the autoclave and checked to see sterilisation has been effective (indicator tape). These are then transferred using secondary containment to holding area in waste collection point near Wolfson Goods Inwards before being transferred to the CBE for external collection.

6.3.2. Sterilisation & Disposal of Sharps Bins: CYCLE 4

(i) ALWAYS wear appropriate PPE as described in SOP 037, Use of Personal Protective Equipment (PPE).

(ii) **CAUTION:** Sharps MUST be placed in the approved, autoclavable sharps bins provided, as described in the Equipment and Materials List in Section 5.

(iii) Seal the sharps bin following the instructions on the side of the container

(iv) Place autoclave indicator tape across the top of the sharps container and place in autoclave basket.

(v) DO NOT autoclave cytotoxic (purple) sharps containers.

(vi) DO NOT place the flexible temperature sensor in the item being autoclaved (ie the item may melt!). The temperature sensor should be placed in the holder provided for it in the sterilization chamber, or else freely in the chamber. The coil for the probe must be positioned so that it does not block the seal.

(vii) DO NOT overload the autoclave. Overloading the autoclave can lead to insufficient ventilation of the autoclave and may cause faults to occur. For an optimal result, the steam must reach all parts of the item being sterilized.

(viii) Autoclave the load as soon as possible after preparation.

(ix) After autoclaving is over sharps bins must be removed from the autoclave and checked to see sterilisation has been effective (indicator tape). These are then transferred using secondary containment to holding area in waste collection point near Wolfson Goods Inwards before being transferred to to the CBE for external collection..

6.3.3. Sterilisation of solid form reusable equipment, instruments and vessels - Non-validated Cycle: CYCLE 1

6.3.3.1. Cycle Selection

(i) **CYCLE 1 (Solids)** MUST be used for the sterilization of all kinds of solids, such as instruments, glass and other materials for which the manufacturer recommends sterilization in the autoclave. **CAUTION:** Make sure that the solid items such as reusable equipment are suitable for autoclaving.

(ii) The operating cycle fixed at 121°C and 20 minutes MUST be used for sterilisation of all solids (except solid waste in bags). This cycle has NOT been validated. **NOTE:** If solid items are to be used in critical or costly experimental procedures it is recommended that this cycle is validated

6.3.3.2. Loading the autoclave with solid form reusable items: Starting the Cycle

(i) ALWAYS wear appropriate PPE as described in SOP 037, Use of Personal Protective Equipment (PPE).

(ii) Ensure that all solid items are suitable for steam sterilization at temperatures >121 °C or >134 °C and ensure that any packaging used is permeable to steam.

(iii) Inspect all solid vessels and other items for damage. DO NOT autoclave damaged items; consult the Laboratory Manager or Responsible Person.

(iv) Place the items either on the perforated bottom plate or in the designated wire-mesh basket. DO NOT use tubs or similar vessels – the items could be damp or even wet when being taken out. DO NOT use any secondary container other than those designated for the purpose.

(v) Label the bags or secondary containers to identify the user and laboratory area from which it came.

(vi) Cap medium/solution bottles loosely or cover with aluminium foil. **CAUTION:** DO NOT

place sealed containers in the autoclave. Tightly capped medium/solution bottles may explode due to expansion.

(vii) Cover bottles that are not made of safety glass with aluminium foil.

(viii) Place small items such as scissors, forceps, tubing, tube connectors into an autoclave paper bag.

(ix) Place autoclave tape on the top of the free-standing vessels such as glass ware, pipette tip boxes or the paper bags and label it with your name.

(x) Place the flexible temperature probe in the holder provided for it on the lid. The coil for the probe must be positioned so that it does not block the seal.

6.3.4. Sterilisation of Liquids in Open Vessels (NOT liquid waste!)–Non-validated Cycle:CYCLE 6

NOTE: The sterilisation of liquid waste in bottles or vessels has NOT been validated. If liquid waste is generated, users MUST consult the Laboratory Manager or Responsible Person before proceeding.

6.3.4.1. Cycle Selection

WARNING: The sterilization of liquids in solids cycles is highly dangerous through boiling delays or exploding vessels and can result in serious injuries. For this reason, liquids may only be sterilized using the Cycle No 6. which is designed for this purpose!

NOTE: This cycle have NOT been validated. If liquid items are to be used in critical or costly experimental procedures it is recommended that this cycle is validated**.**

(i) **CYCLE 6 (Liquids),** with an operating cycle fixed at 121°C and 15 minutes, MUST be used for the sterilisation of liquids in suitable OPEN vessels. DO NOT USE FOR STERILISATION OF LIQUIDS IN TIGHTLY-SHUT VESSELS!

(ii) The autoclave is fitted with a temperature dependent door lock. For sterilisation of liquids, the flexible temperature sensor MUST therefore be placed in the liquid or in a reference vessel. The reference vessel should have the same size and fill volume as the vessel containing the liquid to be sterilized.

(iii) Use a stainless steel basket as a secondary container for autoclaving vessels containing culture medium/solutions.

(iv) CAUTION: DO NOT place sealed containers in the autoclave. Cap medium/solution bottles loosely – whether empty or full – to prevent explosions due to expansion.

(v) CAUTION: Vessels or containers containing liquid solutions should NOT be more than half filled.

(vi) CAUTION: Do not autoclave medium/solutions containing high concentrations of volatile or corrosive chemicals. Seek advice from the Laboratory Manager or Responsible Person.

6.4. Closing the Autoclave Door

(i) Once the autoclave has been loaded in accordance with instructions, close the autoclave door by holding firmly shut until the door lock engages.

(ii) The 'Ready' message in the display tells you that the door is completely locked.

6.5. Starting the cycle

(i) Once the door is securely locked, select the **correct cycle** by pressing the menu key. When the menu displays "Select Cycle" press the "Set" key. The list of cycles will then be displayed. **Choose Cycle 1, 4 or 6** using the arrow keys and then press the "Set" key.

(ii) In the equipment cycles (e.g., 1), no liquids may be sterilized. The sterilization of liquids in solids cycles causes danger through boiling delays or exploding vessels and can result in serious injuries. To prevent liquids mistakenly being autoclaved in a solids cycle, a safety query is performed after the Start display key is pressed. The message '**No Liquids!!!'** informs you that the cycle is not suitable for the sterilization of liquids. When you are sure that no liquids are in the autoclave, confirm the query by entering the code of your access level.

NOTE: Liquids MUST only be sterilized using the cycle No 6, which is designed for this purpose.

(iii) From this point on, the controller takes over the entire procedure. In the display you will see a plain text report about the first phase of the sterilization program. **NOTE:** The printer automatically logs the entire cycle procedure from the start of the cycle.

(iv) **Preselectable starting time:** If the parameter StartByTime is set to "1" in the cycle selected, the current time and the current date appear after the Start display button is pressed. You can use the arrow keys to set the desired start time and press the Start display button to enter this time. Instead of the current time, the time remaining until the start is displayed.

6.6. End of cycle

After the completion of an autoclave cycle, an acoustic signal sounds and the message 'Cycle ended' appears in the display. The autoclave procedure is completed and the item being sterilized can be taken

out and used in accordance with the prescribed procedure, as described in the sections “Opening the door” and “Taking out the autoclaved item”.

6.6.1. Stopping the cycle

If you wish to end a cycle prematurely, you must stop the procedure in progress.

- Press the Stop display key. Display message ‘Manual Stop’ after user stops cycle
- Confirm the error message by pressing the Quit display key and entering the code for the access level. After a manual stop, the interrupted autoclave process cannot be continued, but must be started again if desired.

(i) **Items possibly not completely sterilized!**

- Depending on the point at which the sterilization process is interrupted, the sterilization may be incomplete. An interruption in the warm-up or sterilization phase causes the cycle to pass directly to the cool-down phase. In this case, to guarantee complete sterilization you must repeat the entire sterilization process!
- By interrupting the process in the cooling-down phase, for example, you do not speed up the process. Please consider that the door can only be opened when the unloading temperature has been reached and atmospheric conditions prevail inside the chamber.

(ii) **Cycle error**

If an error occurs, the “ERROR” LED lights up and a corresponding error message appears in the display.

- Press the Quit display button and enter the code for the corresponding access level.
- Press the Set display key to confirm the error message.

(iii) **Items possibly not completely sterilized!**

Depending on the point at which the sterilization process is interrupted, the sterilization may be incomplete. An interruption in the warm-up or sterilization phase causes the cycle to pass directly to the cool-down phase. In this case, to guarantee complete sterilization you must repeat the entire sterilization process!

If you are not clear about the meaning of an error message and how to resolve the problem, consult chapter 8: “Description of errors” of the Equipment manual.

6.7. Opening the door

(i) When the sterilization process is completely finished and the specified unloading temperature and atmospheric conditions have been reached, the message 'Opening Door' appears in the display. The door can now be opened see (ii).

NOTE: If the sterilization process is stopped prematurely, the error message 'Manual Stop Fail' appears in the display. After you press the Quit display button and enter the code for the corresponding access level, the door can be opened (after the unloading temperature and atmospheric conditions set have been reached).

(ii) **CAUTION:** Before opening the door check the log to see if the autoclave has recently performed a sterilisation cycle. If so the surfaces of the door and the autoclave chamber will be hot and on opening, hot clouds of steam can escape and lead to scalding.

(iii) To open the door, press the "Open" button displayed on the front panel. The autoclave will alarm for 30 seconds to warn the operator to move back. The operator should stand clear. The door is unlocked and automatically opens slightly. The operator should stand clear and wait 1 minute before opening the door fully.

(iv) Wearing the appropriate PPE, lift the door using the grip handles on the side until it reaches the horizontal stop. DO NOT pull the door from the front.

(v) Ensure that the flexible temperature sensor (PT100) is placed in the holder in the door when the door is opened.

6.8. Unloading the Autoclave: Taking out the autoclaved item

When the autoclave procedure has ended and the once door has been opened, adhere to all safety precautions when removing an autoclaved item from the autoclave (Refer to the special notes on health and safety). The following steps must be taken:

(i) If the load inside the autoclave is not yours, check the log and ask the owner to remove the load. DO NOT remove a load with which you are unfamiliar with its contents.

(ii) ALWAYS wear appropriate protective clothing when unloading the autoclave to avoid being burned or scalded.

CAUTION: There is danger of crushing and or amputation between the door and the edge of the autoclave chamber if the door has not been completely opened.

(iii) If required, remove the flexible temperature sensor from the autoclaved item (or reference vessel) and fix it to the holder provided for it in the door.

(iv) Remove the basket, tub or item from the autoclave chamber and check the indicator tape:

- Totally black lines indicates that steam exposure was effective
- Not totally black lines indicate failure during the discard cycle. Re-autoclave the waste by loading with sterilisation indicators and record the results in the User Log
- If it is fails again, report the problem to the responsible person or laboratory manager

6.9. Switching off the autoclave

(i) After use, switch off the autoclave at the main switch located at the side of the autoclave

(ii) If some danger has been detected in the autoclave switch off the autoclave at the main switch.

NOTE: When the power supply is switched off during operation, the current process is interrupted. The autoclave gradually returns to a depressurized state and low temperature, and can then be opened safely. After the power supply is interrupted and then switched on again, the autoclave returns to the state it was in before the power supply was interrupted. Any error messages that may have been displayed on the control panel before the interruption are displayed exactly as before. The pressure and temperature values displayed reflect the current state.

(iii) In case of emergency; to shut off the steam source switch the power off using the emergency safety switch located behind the autoclave). Leave the laboratory and prevent others from entering. Consult the Laboratory Manager or Responsible Person and contact the DSO.

6.10. Autoclave Load Testing and Recording

Autoclave runs used for waste management must be checked on each occasion by the use of recording strips and maintained so as to ensure effective functioning and data recording. Although autoclaves undergo annual performance and safety checks, autoclave cycles may be inconsistent due to the diversity of loads placed within them. Autoclaves which have a load temperature probe and printout of cycle parameters effectively monitor the sterilisation process.

(i) The operator MUST record details of each cycle run in the User Log each time the autoclave is used. This should include the following:

- Basic details such as operator name, date of use, cycle number should be recorded on the log sheet provided (Section 7).

(ii) Records must also be kept of all maintenance and service activities, reporting of incidents, accidents and/or faults. All failed tests must be reported to the Laboratory Manager.

(iii) The autoclave must be inspected annually and certified by the service engineer or designate. The inspection, service and repair records should be maintained in the Maintenance & Service Log (Section 7.)

6.11. Preventive Maintenance Measures

The maintenance and care tasks described in this section must be carried out at regular intervals. This guarantees that

- the good working order and reliability of the appliance is maintained
- errors and defects are recognised early
- the service life of the appliance is maximised

The prescribed tasks can be quickly and easily carried out by the user or by technical personnel.

CAUTION: Before every maintenance or care activity, ensure that the sterilization chamber is pressureless, and disconnect the autoclave from the mains supply.

6.11.1 Cleaning the autoclave

CAUTION: Do not use a corrosive cleaning agent! Never use steel wool or wire brushes for cleaning, as they scratch the surface and can do long-term damage to the autoclave. It is recommended that IMS (70%) as described in SOP004 is used as a cleaning agent.

(i) **Daily maintenance of the autoclave (or first user of the day)**

- Clean the gasket with a soft cloth.
- Clean the contact surfaces (collar on which the door closes, door) with a soft cloth.

(ii) **Weekly maintenance of the autoclave**

- Remove the baskets or other vessels from the autoclave. Clean the interior of the autoclave and the baskets with a mild cleaning agent and water. Use only a soft cloth or a sponge.
- Inspect the condition of the strainer and clean off any dirt immediately. The dirt strainer is located in the middle of the floor of the sterilisation chamber and can be taken out without using tools and then cleaned.

(iii) **Maintenance tasks to be carried out regularly**

- Always carry out the sterilization cycles in accordance with the operating manual.

- **Once a month:** Inspect the condition of the supply lines of the autoclave for cracks or possible mechanical damage. Report findings to the Laboratory Manager or Responsible Person

- The autoclave is equipped with 2 safety valves: one is located at the steam generator, the other at the sterilization chamber. As long as the autoclave is inspected regularly (every 500 cycles, or at least once a year) by an authorized customer service agent, preventive relieving of the valves is not necessary. If for any reason the need should arise, the casings of the autoclave should be taken off and the accessible safety valves should be relieved by turning the finger screws to the left. Afterwards, the finger screws should be screwed back in the opposite direction until tight. It is absolutely necessary to wear suitable protective clothing (safety goggles, thermal gloves, etc.). **CAUTION:** When the appliance is hot, there is a danger of scalding!

(iv) **Maintenance performed by technical customer service**

- In addition to all maintenance and care tasks carried out by the operator or user, the autoclave MUST be maintained by a technical customer service agent at regular intervals. This not only increases the reliability of the product, but you can also then be sure that the appliance has been tested for safety in keeping with all applying norms and guidelines.

6.12. Spill Response

(i) Spills may occur from a boil over or breakage of containers. All spills MUST be cleaned up immediately.

(ii) Wait until the autoclave and materials have cooled to room temperature. Contain the spilled material using absorbent paper towels. Refer to SOP038 to determine the necessary protective equipment, spill cleanup, and disposal protocols.

(iii) Clean the equipment and work area in order to collect and remove all spilled materials. Dispose of the waste following the protocol appropriate for the material. If materials have been intermingled, follow the cleanup and disposal protocol for the most hazardous component of the mixture.

(iv) If required, carry out the cleaning cycle (Cycle 12) for cleaning the autoclave. To do this, the autoclave heats up to a temperature of 134 °C and sterilizes the interior for one minute. Record the cycle run in the autoclave log.

(v) Uncontaminated cracked glassware must be disposed of properly in the “Broken Glass” disposal bucket.

(vi) Record the spill and cleanup procedure in the Spill Record Log (Refer to SOP038).

6.13. Equipment Malfunction

(i) If the autoclave fails, malfunctions or does not operate as expected, **DO NOT** attempt to fix the problem. The user should contact the Laboratory Manager. With permission of the Laboratory Manager the user should consult the Operator Instruction Manuals to access fault finding, error displays and troubleshooting procedures.

(ii) If the equipment malfunction cannot be rectified according to troubleshooting procedures detailed in the Operator and Users Manuals the Laboratory Manager must be informed and a "Do Not Use" notice should be posted on the equipment. Contact the manufacturer for advice and coordinate with the Lab Manager for external maintenance and servicing.

(iii) **Autoclave repair MUST be performed by <u>qualified</u> persons only**.

(iv) External maintenance and servicing of the equipment can only be performed after it or its component part(s) has been suitably disinfected and free from hazardous substances (refer to SOP003 for further details) and a 'Decontamination Certificate' has been issued (a proforma can be obtained from the CBE website). **NOTE:** There may be cavities in the interior of the housing that are difficult to clean, and may contain remains of hazardous substances. The work should be carried out under a Permit to Work scheme.

(v) Record the problem and corrective actions in the Maintenance and Service Log (Section 7)

(vi) When a fault occurs during a make-safe cycle an assessment of risk should be made and appropriate action taken. It may be necessary to disinfect those chamber attachments on which engineering work is to be carried out. Chamber condensate for example should be considered to be contaminated with viable organisms

6.14. Decommissioning and Disposal of the Autoclave

The autoclave MUST only be decommissioned by trained personnel and the disposal of the machine MUST be carried out in accordance with the applicable laws and regulations. Refer to the operation manual for instructions.

7. <u>DOCUMENTATION</u>

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The following records are outputs of this SOP:
7.1 Autoclave Training Agreement
7.2 Autoclave Maintenance and Service Log
7.3 Autoclave User Log

These records will be filed in autoclave maintenance file in the CBE.

SOP Version History

Version Reviewed	Date Revised/ Reviewed	Revision Summary	New Version Number
1.0	25.03.10 E.Ratcliffe	Annual Review – following revision identified: 1. The use of this autoclave for waste treatment has been discontinued since the acquisition of two new autoclaves sited in the CBE laboratory Unit. Consequently the following has been revised since they refer to procedures that are redundant: 1a. Section 2. Removed "(iii) sterilization of solid biohazardous waste". 1b. Section 4.2. (iv) Removed reference to autoclaving solid biohazardous waste 1c. Section 7.1.3. Removed whole section on 'sterilisation of solid biohazardous waste'. 1d. Section 7.7 Validation section removed	2.0
2.0	23/02/2011 P.Hourd	Revised following transfer of equipment to the T208b Tissue Engineering Laboratory, located in the Wolfson School as part of the CBE.	3.0
3.0	**5th December 2019 by C.Kavanagh**	**New lean template Revised to update to current procedures. Removal of reference to BOSE equipment**	**4.0**
4.0	**8th February 2022 by C.Kavanagh**	**Minor editorials. Removed statement to say Autoclave cycles not validated.**	**4.0**