

How to sterilize with the equipment

Preparing the lots to be sterilized

In order to make a better and economical use of the sterilizer, to reduce the environmental pollution, to reduce the number of medical items in store and to increase their availability, many factors should be born in mind.

When preparing the materials to be sterilized these following criteria should be taken into account:

- The exposure time required and necessary temperature according to the type of material the devices to be sterilized are made of, the capacity of those items to resist high temperatures and their permeability to the ethylene oxide gas.
- The aeration time required for those devices which will depend on the permeability capacity of each material.
- The frequency of use of those materials and the required availability for them.

Remind: the the forced ventilation reduces the aeration time.

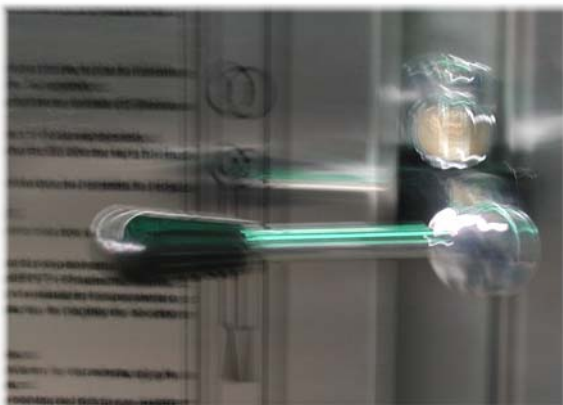
Recuerde: when the load consists of elements made of different kind of material, the following factors should be taken into account: the maximum temperature the elements can resist, the maximum exposure time requested, and the maximum aeration time requested.

Preparing and loading the elements.

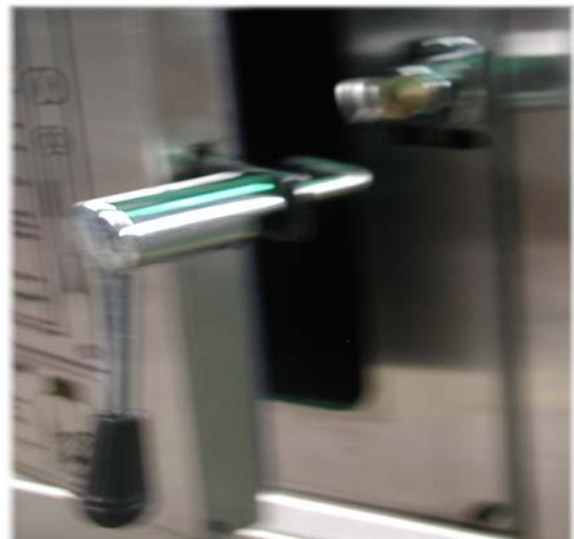
Follow the instructions on this booklet carefully.

Wrap all the items to be sterilized, once cleaned and free from liquid water, use the appropriate wrapping materials. We recommend using **Biolene's wrapping materials** to that purpose.

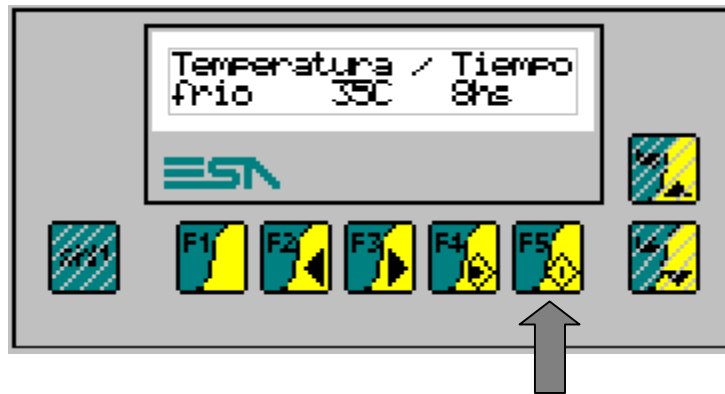
CLOSED DOOR



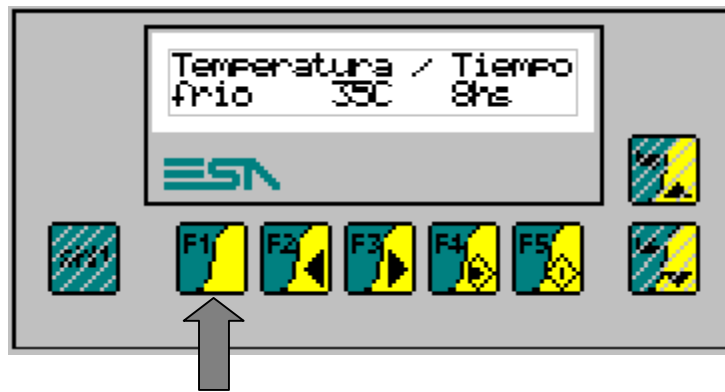
OPEN DOOR



Open the sterilizer door and place the basket containing the elements to be sterilized inside the chamber.
Advice:



Press the scape key to cancel any changes made.



Setting the aeration time

Press either the up or down button until the “aeration time” message is displayed. Then, follow the above detailed instructions to set the desired cycle.



(AERATION TIME)

Aborting the cycle

If you need to abort a cycle for any reason at any time, press either the up or down button until the “abort cycle” message is displayed.



Then press F5 to interrupt the cycle. Notice that “**shift**” and “**F5**” must be pressed simultaneously. Then, a message asking for confirmation (“confirm abort”) will appear.



(CONFIRM ABORT? F1 ABORT, F2 CONTINUE)

Then, in case you want to abort the cycle press again “**shift**” and “**F1**” buttons simultaneously or if you want to cancel the command or have pressed the abort command by mistake, just wait till the abort message disappears from the screen and the process will continue.

Once the interruption command is confirmed, the equipment will do each and every necessary step to end the process safely the soonest possible.

During the interruption process, the following message will be displayed (“aborting cycle”):



(ABORTING CYCLE...)

Notice that if the process is interrupted, all the materials inside the chamber will only be considered to be sterile providing they have already been aerated at the moment of the interruption. Otherwise, the aeration time required should be done outside the chamber. Whenever a cycle is interrupted, the materials inside the chamber should be handled with precaution. The personnel should wear gloves without exception. If the purge cycle has not been completed, that is to say, the aeration process had not run, and the gas released before the cycle was interrupted; then, there is likely to be ethylene oxide gas inside the chamber. Therefore, all the personnel should take additional safety measures. Once the abort process has ended, the machine will return to standby mode. The following message will appear:



(SELECT CYCLE PARAMETERS)

Starting the cycle

When all the sterilization parameters (temperature / sterilization time and aeration time) have been chosen; and all the before mentioned points have been checked, the operator can start a cycle. Press "up" and "down" buttons until the first message appears.



(F1 STARTING CYCLE – COLD, AERATION 2HS)

Verify that:

- **The cartridge has been placed correctly.**
- **There is enough distilled water in the bottle.**
- **The water reservoir is $\frac{3}{4}$ full.**
- **The door is tightly close and locked.**

The cycle will start after pressing simultaneously the “shift” and “F1” buttons.
If you forgot to lock the door, the following message will appear



Por Favor Trabe la
Puerta...

(PLEASE, LOCK THE DOOR)

Then you have to lock the door and enter the command to start the cycle again.

Then the following message will appear. The sterilizer will start to run a partial vacuum upto 100 mmHg in the chamber in order to check that the chamber is tightly closed and there is no leakage.



Succionando Puerta
Por favor espere...

(VACUUM IN PROCESS, PLEASE WAIT)

If the initial vacuum can not be reached, the following message will appear on the screen



Falla Vacio, verif.
Puerta y F. cartucho

(VACUUM FAILS, CHECK DOOR AND CARTRIDGEHOLDER)

Then check that the lid of the cartridgeholder is tightly closed and there are no package between the chamber wall and the door. Start the cycle again.

If this failure message reappears and it can not be worked out, call a technician.

When the vacuum pump goes off, the initial vacuum should be approximately 100 mmHg. (this value will decrease as the chamber heats up). At this moment the operator may leave the equipment unattended till the end of the cycle.

How to check the parameters during the cycle

By pressing the up and down vertical buttons (▲▼) all relevant parameters of each process are displayed. The “manual abort” message can also be displayed on the screen.



(PRE-CONDITIONING. HEATING UP)

What is the sterilizer doing?

After the cycle has started, the sterilizer will automatically and successively run the following processes.

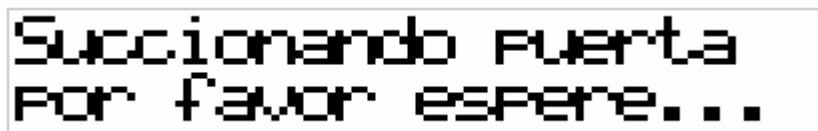
Positioning of the valves for sterilization

On switching on, if there is no cycle running, the sterilizer turns the chamber valves into aeration position assuring, in this way, that there is no pressure or vacuum inside the chamber due to changes in room temperature.

Therefore, whenever a cycle starts the valves turn into sterilization position.

Initial vacuum; hermetic control

Once the valves have been closed, the sterilizer runs a quick vacuum process of 100 mmHg to hermetically close the door and prevent the chamber to raise pressure as it heats up. The vacuum also ensures that there are no significant leakages due to an inadequate locking of the door or a loosely closure of the cartridgeholder cap.



(VACUUM IN PROCESS, PLEASE WAIT...)

Pre-heating

The chamber and the materials inside are warmed up slowly according to the programmed temperature. Once the programmed temperature is reached, it is held for a while to ensure that the temperature level is homogeneous inside the chamber.

From that moment, the control system will maintain the temperature close to the programmed temperature during all the process up to the final cooling.

```
Preacond. Calef.  
Temp: ##.# C Set: ##
```

(PRECONDITIONING – HEATING / TEMPERATURE)

The present temperature and the set value are displayed.

```
Preacond. Calef.  
Vacio: ### mmHg
```

(PRECONDITIONING – HEATING / VACUUM)

The present vacuum value is displayed.

```
Preacond. Calef.  
F5 Aborta Ciclo
```

(PRECONDITIONING – HEATING / TEMPERATURE)

From this moment the cycle can be interrupted.

Vacuum

The vacuum pump takes out the air inside the chamber till a vacuum of 560 mmHg is reached (approx 0,75 bar).

```
Preacond. Vacio  
Temp: ##.# C set:##
```

```
Preacond. Vacio  
Vacio: ### mmHg
```

```
Preacond. Vacio  
F5 Aborta Ciclo
```

Humidification

Small amounts of water vapour are pumped into the chamber. This water goes previously through a heater so that the water is sprayed into the chamber as steam to humidify it.

A calculated amount is pumped in order to assure a proper humidification of the chamber. The amount of water is calculated according to the model of equipment (size of the chamber) and the temperature of the chose cycle.

After these pumps, the sterilizers remains still for a few minutes so as to let the chamber homogenize the humidity inside.

```
Preacond. Humidif.  
Temp: ##.# C Set:##
```

```
Preacond. Humidif.  
Vacio: ### mmHg
```

```
Preacond. Humidif.  
F5 Aborta Ciclo
```

Puncture of the cartridge and gas intake

The cartridge is punctured. Then the sterilizer remains still for a few minutes in order to let the gas go in the chamber.

```
Ingreso de Gas a la  
Camara ...
```

Esterilización

It will take as long as the programmed time

```
Esterilizando  
Temp: ##.# C set:##
```

```
Esterilizando  
Vacio: ### mmHg
```

```
Esterilizando  
Resta: ## hs. ## m
```

```
Esterilizando  
F5 Aborta Ciclo
```

Gas purge

The gas purge process is carried out 14 times. It consists of an inlet of air upto 100 mmHg. Then the sterilizer remains still to help the diffusion. There follows a vacuum of upto 460 mmHg. After that follows another still time to help difussion.

Finally after these cycles have been done, air enters so as to even out the values of both chamber and room pressure.

```
Barrido del Gas  
Temp: ##.# C set:##
```

```
Barrido del Gas  
Vacio: ### mmHg
```

```
Barrido del Gas  
F5 Aborta Ciclo
```

Positioning of the valves for aeration

The valves are moved to turn the chamber into aeration mode.

Aeration

The aeration fan keeps working during the whole programmed time.

```
Ventilacion  
Temp: ##.# C set:##
```

(AERATION)

```
Ventilacion  
Resta: ## hs. ## m
```

(AERATION – REMAINING TIME: ... HS ... MINUTES)

```
Ventilacion  
F5 Aborta Ciclo
```

(AERATION – F5 ABORT CYCLE)

Cooling

The temperature is no longer controlled. Therefore the temperature in the chamber, which is ventilating, decreases to allow the operator to handle the materials immediately.

```
Ventilacion  
Enfriando...
```

(AERATION – COOLING THE CHAMBER)

Ending of cycle

When the cycle ends, a beep alarm will sound to indicate that the cycle has finished. On the display, the end of cycle message will appear.

Ciclo Finalizado
F1 Impr. F5 Termina

(END OF CYCLE – F1 PRINT, F5 FINISH)

End of cycle and report printing

When the cycle has ended, a record of the sterilization parameters can be printed out as many times as necessary by pressing the buttons “shift” and “F1” simultaneously since the records are kept in memory until a new cycle is started. The record of the sterilization parameters can be printed each time the cycle ends.

Consequently, before a new cycle is started the last cycle done can be printed. To do so search the following message on the display by pressing the up/down buttons.

F1 Imprime datos del
ultimo Ciclo

To start a new cycle, search the message “Start cycle” and then press the buttons “shift” and “F5” simultaneously.

Reminder: once a new cycle is started, all previous records are erased.

Reading the record

Following there is a sample of a printout.

Biomédica S. R. L.

FIME 2002

Ethylene oxide Sterilizer BM-2

Software version 1.1

Sterilization Lot Nr: 1234567890

Cycle: Normal (55 C, 4 hs.)

Aeration: 12 hs.

Cycle Start:

19/07/2001-11:18 13,8 C 000 mmHg

Preacondicioning: Heating

19/07/2001-11:48 55,9 C 040 mmHg

Preacondicioning: Vacuum of the Chamber

19/07/2001-11:58 54,3 C 460 mmHg

Preacondicioning: Humidification

19/07/2001-12:10 55,1 C 440 mmHg

Gas injection in the Chamber:
 19/07/2001-12:15 56,8 C 310 mmHg
 Sterilization:
 19/07/2001-12:20 53.1 C 305 mmHg
 19/07/2001-12:25 55,8 C 319 mmHg
 19/07/2001-12:30 54,3 C 307 mmHg
 Temperature Range
 19/07/2001-13:50 52.9 C Minimum
 19/07/2001-15:50 56.9 C Maximum
 Pressure Range
 19/07/2001-15:20 Minimum 180 mmHg
 19/07/2001-15:35 Maximum 319 mmHg
 Purges:
 19/07/2001-17:18 54,8 C 000 mmHg
 Aeration:
 20/07/2001-05:18 53,8 C 000 mmHg
 Completing Cycle
 20/07/2001-05:30 25,7 C 000 mmHg
 End of cycle

Following the report is explained in detail. The date and time of each event is recorded when it is finished with the following format: dd/mm/aaaa-HH:MM

The temperature is expressed in Celsius grades and the vacuums in mercury milimeters.

Biomedica S. R. L.

FIME 2002

- This introduction can be customized with the user's information.

Esterilizador por Oxido de Etileno BM-2
 Versión de software 1.1

- Model and version of the equipment software

Lot nr N: 1234567890
 Cycle: Normal (55 C, 4 hs.)
 Aeration: 12 hs.

- Cycle information. Lot number, which increases one number after the other with each cycle, and the chosen values for the relation temperature - sterilization time - aeration time.

Cycle start:
 19/07/2001-11:18 13,8 C 000 mmHg

The cycle starts at this moment. The initial temperature conditions are showed.

Preconditioning: Heating
 19/07/2001-11:48 55,9 C 040 mmHg

When the heating process ends, which made the temperature homogenous, a little vacuum will be noticed. This is due to the initial vacuum the sterilizer does at the beginning of the cycle (approx. value: 100 mmHg). However, when the chamber is heated the vacuum decreases a little.

Preconditioning Chamber Vaccum
 19/07/2001-11:58 54,3 C 460 mmHg

It shows when the vaccum is reached.

Preaconditcioning: Humidification

19/07/2001-12:10 55,1 C 440 mmHg

The injection of water vapours has been completed and the time needed for the humidity to be homogeneous has elapsed.

Notice that the vacuum may decrease because of the injection of vapour.

Gas injection in the chamber:

19/07/2001-12:15 56,8 C 310 mmHg

This event is recorded a few minutes after the cartridge is punctured. At this part of the process, the vacuum inside the chamber will also decrease a little because of the gas. If the vacuum value does not decrease it means that the cartridges was not punctured and the cycle have to be aborted.

Sterilization:

19/07/2001-12:20 53.1 C 305 mmHg

19/07/2001-12:25 55,8 C 319 mmHg

19/07/2001-12:30 54,3 C 307 mmHg

During the programmed sterilization time the values of the parameters are recorded every 5 minutes. Notice that in case of a power outage, the record timing will be altered. And if there is a sharp decline in the temperature values the cycle should be aborted.

Moreover, if the record shows a that the value of vacuum has decreased, be aware that little fluctuations in the vacuum values may occur which are given rise by the fluctuation of the temperature in the chamber.

If the vacuum goes down to a value under 200 mmHg and the situation continues along the process, call a technician.

If the vacuum goes down to a value under 100 mmHg do not use the sterilizer since there may be leakages into the sterilization room.

Temperature range

19/07/2001-13:50 52.9 C Minimum

19/07/2001-15:50 56.9 C Maximum

Pressure range

19/07/2001-15:20 Minimum 180 mmHg

19/07/2001-15:35 Maximum 319 mmHg

The record of each event not only shows the values at the time of recording but also the maximum and minimum values registered from the last record to assure the operator that the sterilization values have been within the acceptable values.

Purges:

19/07/2001-17:18 54,8 C 000 mmHg

the record of the values is done at the end of the purge cycle.

Aeration:

20/07/2001-05:18 53,8 C 000 mmHg

The record of the values is done when the forced aeration finishes and the temperature of the chamber is no longer controlled.

Completing the Cycle

20/07/2001-05:30 25,7 C 000 mmHg

End of cycle

This record is done when the fan is turned off and the chamber temperature is rather cold.

- Do not load the chamber full. The gas will not penetrate well into packages thus affecting the efficacy of the ethylene oxide sterilization.
- Use at least one biological indicator with each sterilization process. This biological indicator should be placed right in the middle of the pile of packages inside the chamber.
- Make sure that there is no package blocking the chamber's inner holes, specially the vacuum pump hole. (This will certainly not happen if the basket is used correctly)
- When closing the door, make sure nothing is in between the front panel of the chamber and the door. The vacuum required may not be reached.
- Close the door, lock it and take the key away.

Preliminary checking.



Turn the general switch on and after a few minutes check whether any of the following statements appear on the display:

Seleccione Param. de
operacion

(SELECT CYCLE PARAMETERS)

Temperatura / Tiempo
frio 35C 8hs

(TEMPERATURE / TIME – COLD 35° C , 8 HS)

```
Tiempo de Ventilado  
2 hs.
```

(AERATION TIME – 2 HS)

```
F1 Inicia Ciclo  
frio      Vent 2 hs.
```

(F1 TO START CYCLE – COLD , AERATION 2HS)

```
F1 Imprime datos del  
ultimo Ciclo
```

(F1 TO PRINT LAST CYCLE PARAMETERS)

```
Ciclo Finalizado  
F1 Impr.  F5 Termina
```

(END OF CYCLE – F1 TO PRINT. F5 TO END)

When the later message is on the screen, “Ciclo finalizado/(End of cycle)”, by pressing “F5” you will end the process. Notice that for the command to be accepted, “shift” and the function key (F5, in this case) should be pressed simultaneously.



When the information displayed on the screen is not found among the above list, it means that there is a cycle in process, and so, you must wait till the cycle ends or in case you want to abort the process, you must follow the instructions in the section “Manual abort of cycle”.

- Check that the bottle for the distilled water is, at least, half filled with distilled water. If necessary fill the bottle full. The bottle is placed inside the storage cabinet.
- Check that the bottle for water is $\frac{3}{4}$ part filled with ordinary water. The bottle is placed inside the storage cabinet.

Notice: the equipment should not run either without these mentioned bottles or without enough water.




- Unscrew the lid of the cartridgeholder and insert a cartridge inside. Check that the rubber gasket of the cartridge holder’s lid is in good order and condition and firmly in place.

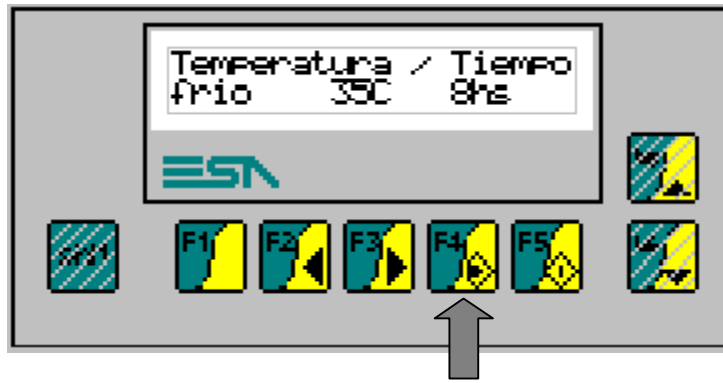


Selecting the sterilization parameters

Press either the up or down key and search for the following message (“time / temperature”):




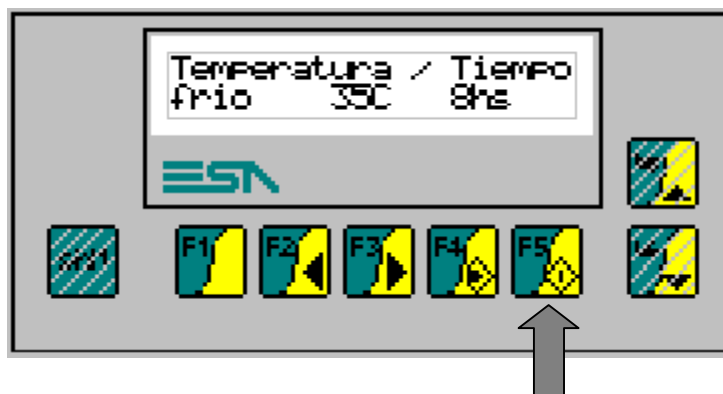
Once the message is displayed, the values of the temperature or the exposure time may be changed by pressing the selecting key 



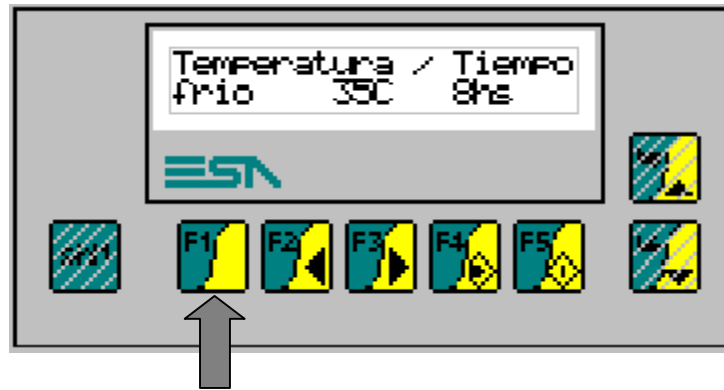
Choose the desired cycle (cold or normal) by pressing the up/down keys (▲▼)



Press the  key to confirm the change of parameters.



Press the scape key to cancel any changes made



Choosing the aeration time

Search the message “aeration time” on the screen and follow the above detailed instructions to choose a cycle.



Aborting a cycle manually

A cycle can be aborted at any time. Search the abort message by using the up and down buttons.