FEDEGARI BIER DEVICE

PRINCIPLE AND PERFORMANCES

Validation and routine control of the sterilization processes are based on the monitoring and verification of physical quantities characterizing the process, such as temperature, pressure and exposure time in the case of a moist heat sterilization. Moreover the process is challenged against test devices containing a known and defined number of viable micro-organisms that have a known resistance to the sterilization method that they are used for. This type of microbiological challenge devices are called *Biological Indicators*.

Depending on the approach followed for the validation of the sterilization treatment, product release can be based on one of the two systems (physical or microbiological) or both.

If Biological Indicators (BIs) are used for the product release, user shall or should determine the resistance characteristics of the BIs. In particular the users shall execute the BIs resistance determination if BIs are prepared by the user themselves; they should execute that determination if commercial BIs are used.

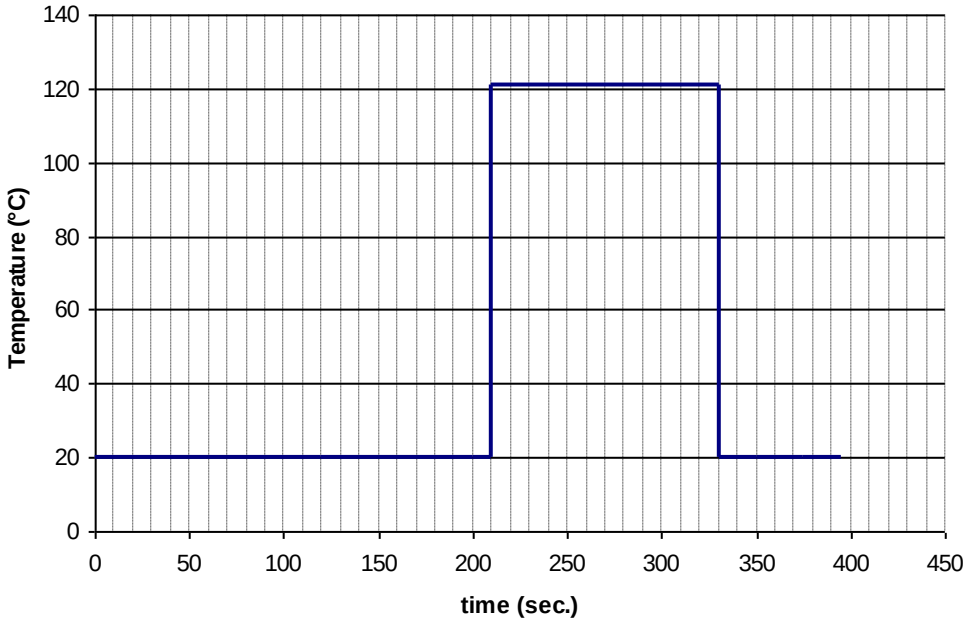
The BIs resistance characterization exercises are usually carried out in a dedicated sterilizer called B.I.E.R. (Biological Indicator Evaluator Resistometer) or in “homemade” systems if the inoculation media of the viable micro-organism is suitable.

For the moist heat sterilization the method consists of the exposition, for a established time, of the selected bioburden to the preset temperature at the saturated steam conditions. The support of the bioburden is also important.

Three main causes of error are present in these exercises: the calibration of the measuring instruments; the delay in reaching and interrupting the steady state at which the bioburden has to be exposed; the not homogeneous temperature distribution throughout the BIs support.

The error due to the calibration can be “easily” reduced but the others are more difficult even using a dedicated equipment.
The Fedegari BIER device (patent pending) contributes to reduce these two endemic errors in the BIs characterization (calibration should be executed on regular bases usually) and gives the advantage that the sterilizer can be used also for the common microbiological laboratory activities.

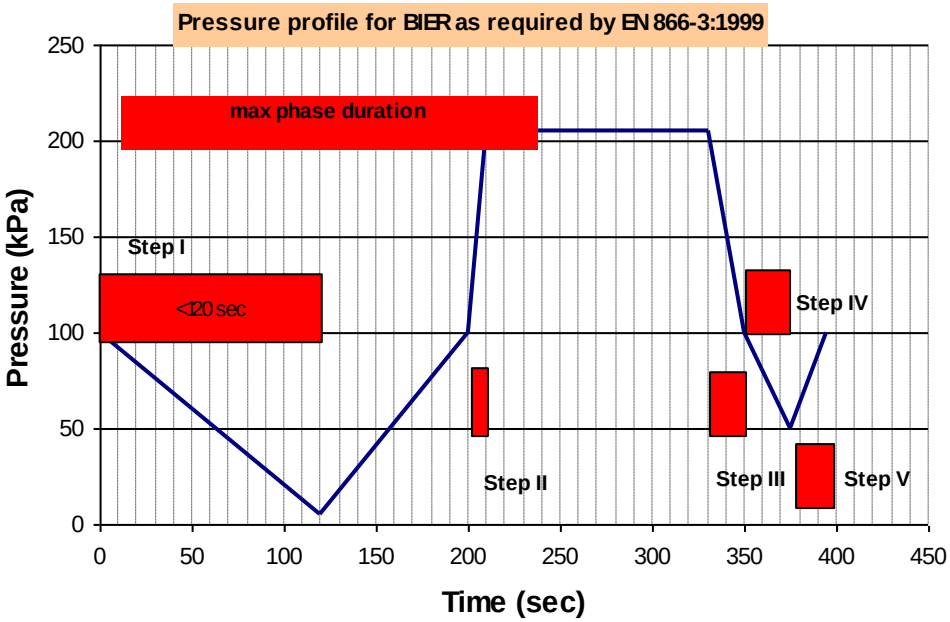
The principle of the Fedegari BIER device is based on the possibility to introduce the BIs to be analysed during the exposure phase of a saturated steam cycle. In this way the BIs are not exposed to the ancillary phases of the sterilization cycle as the vacuum step for air removal, the heating of the chamber, the final vacuum to steam removal, reducing the time spent outside from the steady state.
The ideal temperature profile for a BIER is the “square” wave reported below:



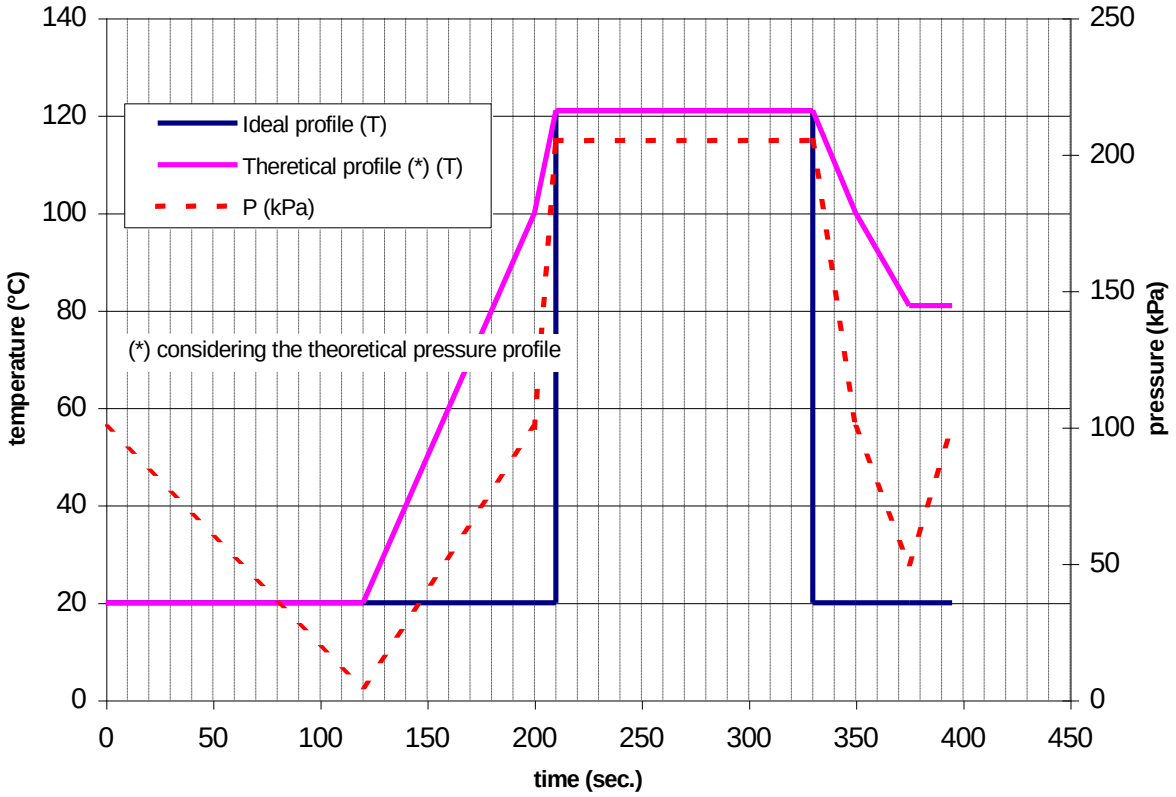
A BIER complying with the standard EN 866-3 (Biological systems for testing sterilizers and sterilization processes – Particular system for use in moist heat sterilization) as well as the ANSI/AAMI ST44:2002 (Resistometer used for characterizing the performance of biological and chemical indicators) must have the following performance:

1. Air removal
   from P_{amb} to 5 kPa in 2 minutes
   (air removal by gravity and steam pulses are not admitted for this phase)
2. Final heating
   from 100 kPa to Pste in 10 seconds
3. Steam discharge
   from Pste to 100 kPa in less than 20 seconds
4. Steam removal
   from 100 kPa to 5 kPa in less than 25 sec
5. Atmospheric balance
   from 5 kPa to Pamb in less than 20 sec

The theoretical profile is reported in the following graph.



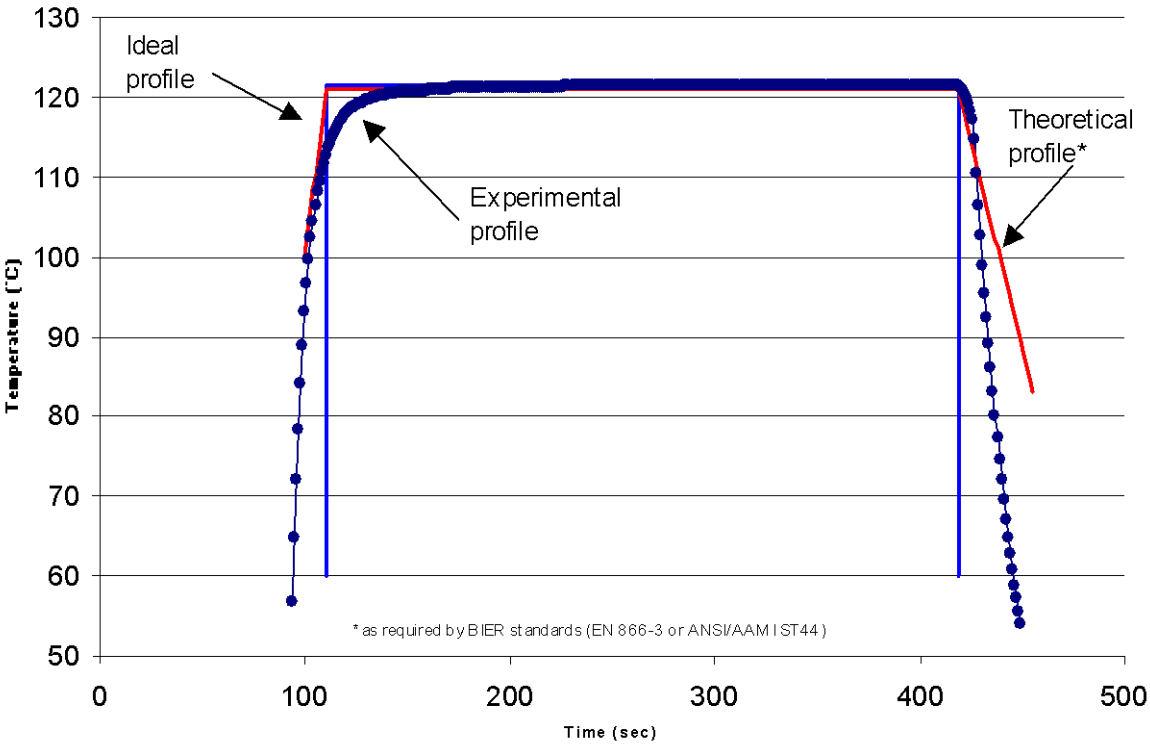
The pressure profile required by the standards (and defined here as “theoretical”) can be used to calculate the temperature profile for an environment where saturated steam conditions are obtained.
A comparison between the ideal and the “theoretical” temperature profile for the determination of the resistance values of BIs is reported below.



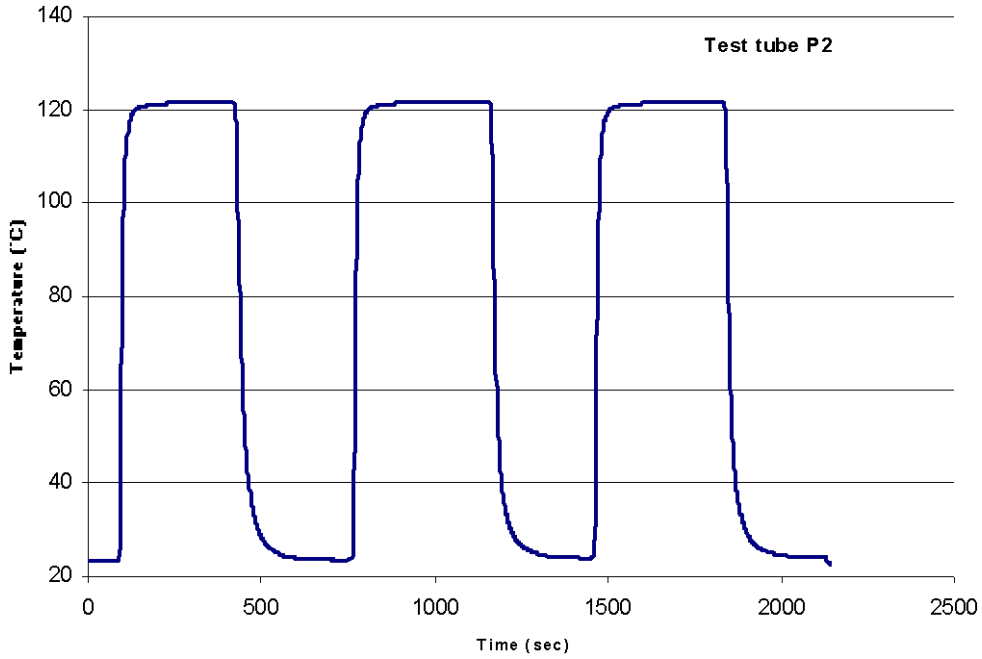
From this graph is evident that also following the requirements expressed in the standards, the determination of the BIs resistance implies an error. Its amount can be estimated to be about 5 seconds for a bioburden population with a z-value equal to 10 and supposing an instantaneous heating of the bioburden population and its support.

Under the same assumptions relevant to the instantaneous heating of the product, the error of the Fedegari BIER device is about 2 seconds, time that corresponds to the introduction and the extraction of the sample from the testing chamber.

From the experimental point of view, that of course takes into account also the heat transfer delay from the chamber to the product, the temperature profile obtained for a stainless-steel test-tube with a internal volume of 3 ml is reported below. The temperature was recorded with a wireless sensor (Datatrace of Mesalab). This kind of sensor is not particularly appropriate for such a measurement, as for its response time as for its mass.



Another example of temperature profile relevant to a different stainless-steel test-tube with a volume of 2 ml is reported in the following picture.



An investigation about the microbiological performances of the device has been carried out together with Dr. G.R. Gillis, president of the SGMBiotech, leader in the commercial BIs production. During this co-operation Fedegari BIER device was used for the determination of the performances of the BIs produced by SGMBiotech and these results were compared with those ones obtained with the traditional BIER sterilizers used in SGM premises. Comparable results were obtained (to be published).

CONCLUSIONS

Not considering the heating transfer from the environment to the product (common problem for the traditional and the Fedegari approach) the characteristics of the two systems are:

BIER Autoclave

- The traditional BIER autoclaves introduce an error if compared with the ideal temperature profile for the determination of the performances of a Biological Indicator
- This error is related to the air and steam removal from the chamber before and after the exposure phase

Fedegari BIER Device

- Sample is inserted in the sterilizing chamber only after that the exposure conditions have been reached
- Sample is extracted from the testing chamber when the process condition are still maintained in the chamber itself
- The duration of the introduction and the extraction is less than 2 seconds
- This period can be considered as the deviation from the ideal behaviour.