

Maintaining of sterilization for products that are ETO sterilized

20% Ethylene Oxide C₂H₄O and 80% Carbon de Oxide (CO₂) is used as sterilization gas.

The U.S. F.D.A and the CE Authorities have approved the ETO sterilization process and tests. Validation was conducted according to AAMI standards and I.S.O 11135.

Procedure:

Packs are placed in a sealed gas autoclave cabin, and acclimatized to a temperature of 30°C, with moisture of 40% - 70%.

After remaining under these conditions for 18 hours, the temperature is raised to 32°C for a further 2 hours. Later slow vacuum is created in intervals of 10 PSI until a vacuum of 0.325 Bar is achieved.

Additional moisture to achieve 40% - 70% is inserted. Vacuum is maintained in the cabin for 90 minutes.

Ethylene Oxide mixture is inserted by pressure, in intervals of 10 PSI, until pressure exceeds 1.45 Bar. Contact remains for 18 hours.

After full contact of 18 hours, at a temperature of 32°C, and at pressure of 1.45 Bar, a vacuum is created by removing the Ethylene Oxide, in intervals of 10 PSI, until a vacuum of 0.325 Bar is reached.

Filtered air is inserted into the autoclave until atmospheric pressure is reached. Vacuum is again applied, at intervals of 10 PSI, and after inserting filtered air once again, the procedure is repeated 7 times consecutively. For ventilation, before the chamber is opened 1 additional smaller cycle is performed to remove ETO residues.

Validation of sterilization results for each sterilization process

Conformity Tests:

During the process of loading the autoclave, the following is loaded as well:

One sealed pack, same as the other packs to be sterilized but which also includes an electronic data collector to record the humidity and temperature during the sterilization process. The data is recorded and kept with the other batch data.

12 packs of pre-designed tubes containing suitable bacteria and spores are placed in 12 designated positions in the autoclave, according to our autoclave validation. These spores are tested for efficiency of sterilization. Results are obtained after 48 hours.

12 other packs, without spores and bacteria are placed in pre-determined and fixed positions and again tested for sterilization efficiency (Gram-

positive bacteria and Gram-negative bacteria). Results are obtained after 14 days.

In addition to microbial tests, 12 chemical detectors are also placed in pre-determined and fixed positions, to show efficiency of the gas.

Remaining Gas (ETO residues):

The AAMI recommendations for ETO residue levels after sterilization and BS EN ISO 10993-7 1996 have been adopted. Tests have been conducted in order to compare the Residue in PPM of Ethylene Oxide, Ethylene Chlorohydrin, and Ethylene Glycol that remain on the device after ETO sterilization.

Enclosed the following requested residue limits, test limits and results:-

	Required	Test	Result	
	<u>Limits of AAMI</u>	<u>Limit</u>	<u>Limit</u>	
Ethylene Oxide		25	15	not detectable
Ethylene Chlorohydrin		250	30	not detectable
Ethylene Glycol		500	150	not detectable

These results are similar to the tests that have randomly been conducted on similar dressing materials and packs, and on which residues were also undetected in the above test limits.

Re-validation:

According to ISO 11135, once a year a review of the validation system is performed, to see if there were any changes that require a new validation.

The review contains:

1. Are there any changes in the chamber?
2. Are there any changes in the procedure?
3. Are there any changes in the line of products?
4. Are there any changes in the formula of the Gas?
5. Since the last checkup, were there more than three consecutive failures?
6. When reviewing the Sterilization Reports, is there any sign indicating that a new validation should be performed?

If all the responses are negative, the validation is approved for another period.

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Summary of 2 sterilization runs for ETO sterilization Validation (translation from Hebrew version dated 25 March 2001)

1. General

- 1.1. Introduction of 20 temperature sensors and 12 humidity sensors of validation KAYE into the sterilizer by means of sealed "Terri Clamp" connectors, through the 1.5" opening in the sterilizer, - see attached photograph.
- 1.2. Sterilizer loaded with 168 containers that contain products for sterilization. Each container is made from plastic material, packed in blister pack, not ventilated – see attached diagram. These containers are loaded onto 6 carriages, each carriage holds 28 containers, - see diagram no. 2 attached.
- 1.3. 19 temperature sensors - numbered from 1 – 19 are placed into 19 blister- packs, close to the components within the pack, each temperature sensor with the above blister pack placed in the center of each container, labeled in diagram no. 2.
11 humidity sensors numbered from 1- 11 are placed in the center of each container – labeled in diagram no. 2. Temperature sensor no. 20 and humidity sensor no. 12 are placed outside the container, in the center of the sterilizer container, at a distance of 20 cm from the ceiling.
Due to limited length of the sensor wires, temperature sensors were not placed in carriage no. 1, and humidity sensors were not placed in carriage numbers 1-2. (See diagram no. 2). The temperature sensor of the sterilizer was placed between carriage no. 3 and 4, at a distance of 30 cm. from the base of the carriages.
- 1.4. Measurements: Distance between the rows of containers and the side walls of the sterilization walls = 10 cm, Distance between the top layers of containers to the ceiling = 60 cm. Distance between the rows of containers = 5 cm.
- 1.5. Each carriage of 8 containers was covered with nylon and wrapped with shrink, - see attached photograph.
- 1.6. Outside temperature = 15 degrees centigrade, Outside Humidity = 63%.

2. First Run

- 2.1. Commencement of sterilization cycle on 18.2.01 at 15.35 hours, according to standard sterilization conditions for releasing ETO. Instead of ETO release, clean air was released.
- 2.2. Validator KAYE was activated for measuring and registering temperature and humidity in the sterilizer.

- 2.3. Completion of procedure on 20.2.01 at 20.00 hours.
- 2.4. Notes:
 - 2.4.1. Difference in temperature of 4 deg. Centigrade was noted between the temperature of KAYE validator and temperature sensor in the sterilizer. Calibration of this sensor was performed by a member of staff, at temperature of 11 degrees centigrade and 30 degrees centigrade.
 - 2.4.2. When the door of the sterilizer was opened, drops of water were noted on the goods, and dampness on the walls and ceiling of the sterilizer.

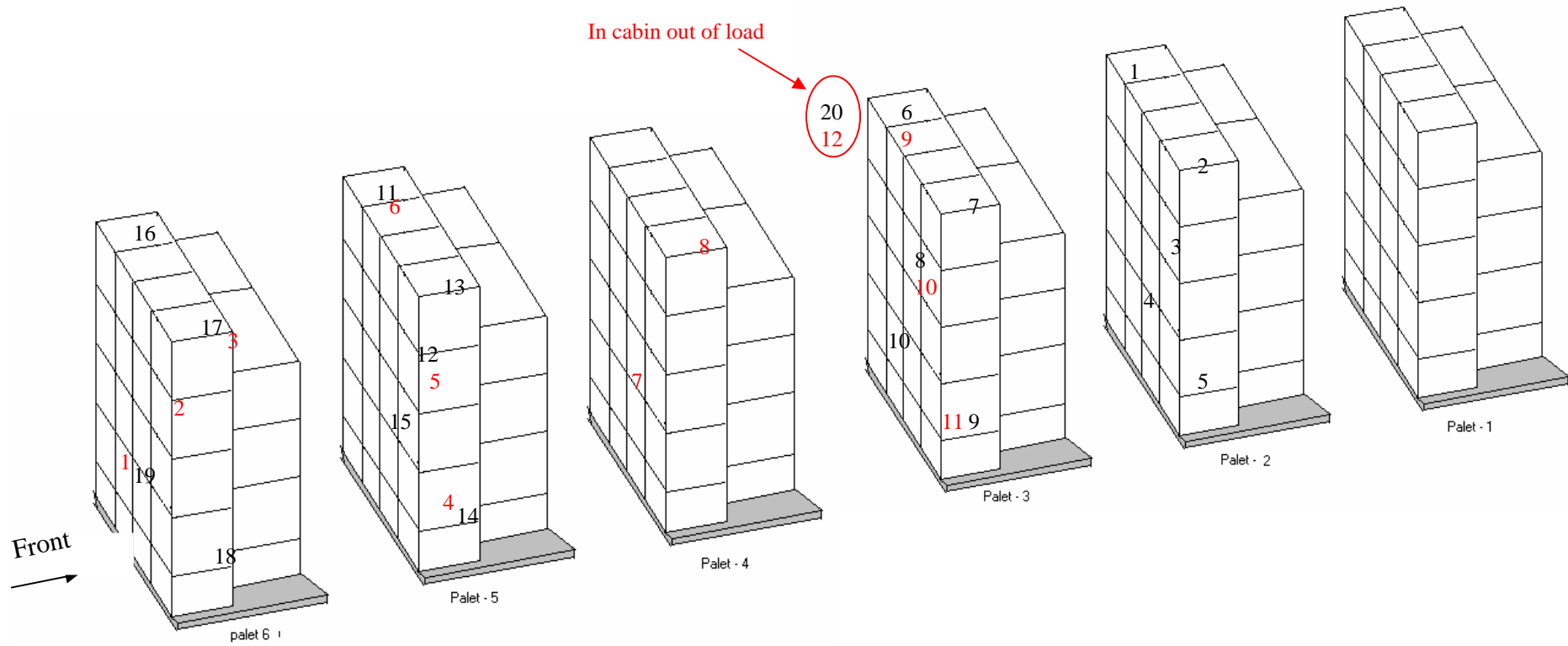
3. Second Run

- 3.1. The container carriages were not removed from the sterilizer after Run no. 1.
- 3.2. Distribution of temperature and humidity sensors were the same as in Run no. 1, except for Temperature sensor no. 20 and humidity sensor no. 12 that were placed together with the Sterilization sensor, between carriage no. 3 and 4, at a distance of 1 meter from the ceiling of the sterilizer.
- 3.3. Outside temperature = 11 deg. Centigrade. Outside humidity = 75%.
- 3.4. Procedure commenced on 21.2.01 at 11.20 hours. This procedure was stopped manually before the release of gas due to shortage of time.
- 3.5. Notes:
 - 3.5.1. At the beginning of the run, the electronic controller stopped at the stage of humidity measurement, and was re-set manually by the operator.
 - 3.5.2. During run no. 2 the temperature printout page jammed, and part of the climatic registration was not printed.
 - 3.5.3. According to the printout, it appears that the problem occurred when the stage of vacuum (-700 mbar) was reached, and pressure started increasing in the sterilizer.

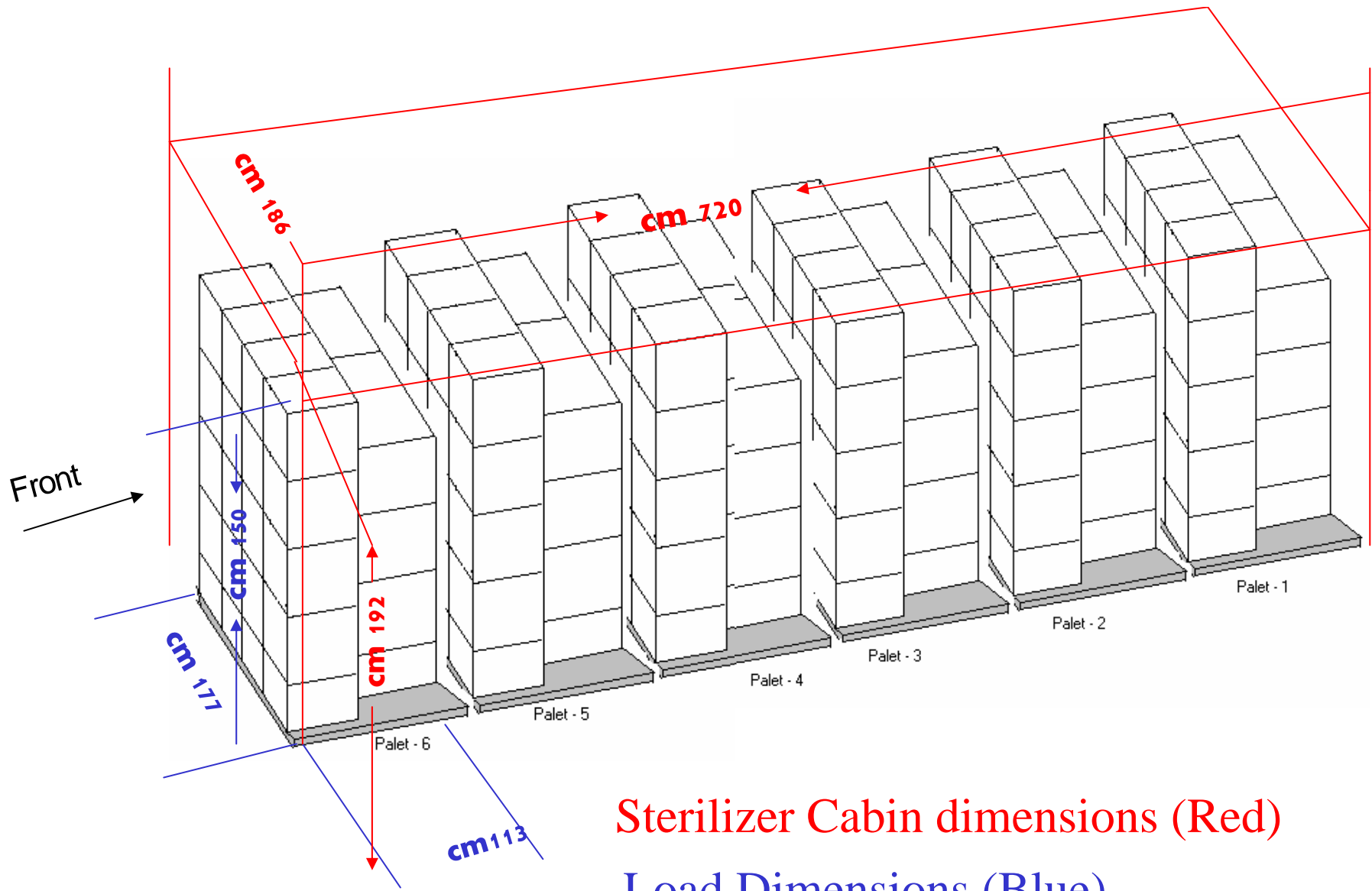
Summary:

- 1. The average humidity within the container and within the products was within the accepted limits. After five hours, the climatic humidity stabilized, and equalized in relation to temperatures in all samples, and ranged between 55% to 60% within the container.
- 2. The temperature stabilized after three hours of climatisation, and the heating device that was activated, maintained the temperature between 28^oC and 37^o C in peaks.

Diagram No.2 Position of Temp. & Humidity Probes in Load



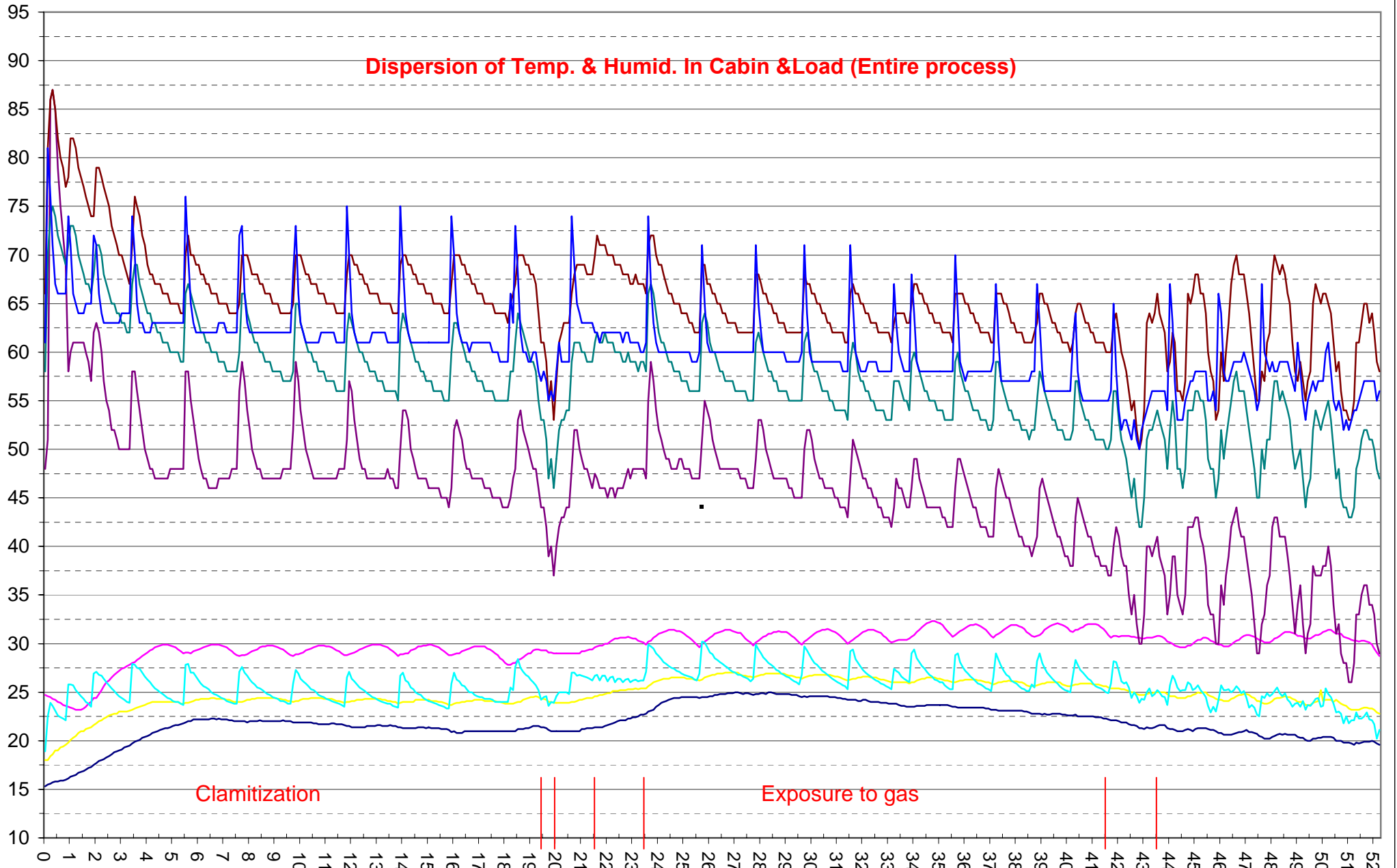
Humidity probes - in Red
Temp. Probes in Black



Sterilizer Cabin dimensions (Red)

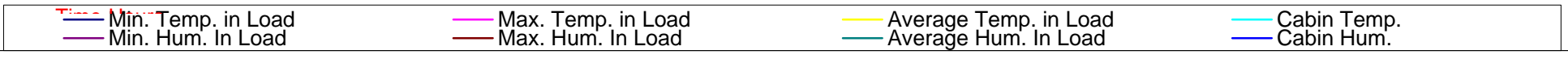
Load Dimensions (Blue)

Dispersion of Temp. & Humid. In Cabin & Load (Entire process)



Clamitization

Exposure to gas



Dispersion of Temp. & Humid. In Cabin & Load (Entire process)

