Transient Overheating in Empty Autoclave Chambers

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ABSTRACT: *The transient overheat in empty autoclave chambers is a phenomenon that frequently occurs during validation studies. This article by Italian sterilization practitioner Vittorio Mascherpa investigates the main causes of it and suggests some methods to prevent it or to cope with it. The article also includes a useful table of superheating effects due to adiabatic isenthalpic expansion of saturated steam (i.e. in ideal conditions).*

KEYWORDS: moist-heat sterilization, steam sterilization of blood bags, pressure compensation, steam penetration, autoclaving, autoclave, single or double autoclaving

Final in-chamber drying of many sterilized items is an essential step for preserving the condition of sterility after their removal from the autoclave. Most of the energy required for drying comes by contact from the body of the sterilized items, a minor part from the chamber walls, mainly by radiation. These contributions may be sufficient or not, firstly depending on the amount of water condensed on the surface of, or inside the items.

In-chamber preheating of the items reduces the steam condensation on the load during the air removal steps, both by steam injection (continuous progressive dilution of residual air after the initial vacuum pull) and steam-vacuum pulses (alternate dilution by steam supply and vacuum pull, the so called ‘fractionated vacuum’). The air removal effect of fractionated vacuum depends only on high to low pressure ratio of the pulses, regardless to the saturation or superheating condition of the steam. Anymore, a superheated condition of the steam reduces the amount of it condensing on the load, that usually is still much colder than the saturation temperature.

For the above reasons the autoclave jacket is usually heated both during cycle preparation and during all the cycle at a constant temperature, the set point being only a few degrees lower than the sterilization temperature. This choice prevents any superheating effect during the exposure period, but not during the phases prior to it. In fact, during these phases the chamber is usually at a low pressure and the supplied steam:

a) receives energy from the autoclave walls maintained at a temperature higher than the saturation one;
b) superheats due to the quasi-adiabatic expansion through inlet valves and downstream of inlet nozzles.[*]

Both these effects are counterbalanced by heat dispersion and the presence of a certain amount of condensate in the steam.

In Fedegari Pure Saturated Steam Autoclaves the supply of the steam into the chamber is controlled by the pressure: the temperature set point is converted into a pressure set point according to the well known one-to-one correspondence between pressure and temperature of pure substances in saturation conditions (*Phases' Rule*). Thus, the compliance of actual temperature with temperature set point requires a steam saturation condition inside the autoclave. If the superheat condition caused by heat transmission from the autoclave walls and / or by adiabatic expansion of the steam entering into the chamber has not been completely compensated by heat dispersion and /or *by the transfer of energy to the load* during the final heating, a transient overheat condition might occur at the beginning of the exposure phase. This phenomenon would not be caused by a defective operation of the steam supply control, but by a still incomplete compensation of steam superheat created during the air removal phases.

On the contrary, an overheat occurring with load inside the chamber might damage the load and is to be prevented by a suitable design of the phases prior to exposure.

[*] The table in the next page provides data for steam superheating.

Superheating effects of adiabatic isenthalpic expansion

P_i (abs bar)	T_i (°C)	$h_i = h_o$ (kcal / kg)	P_o (abs bar)	T_{sat} @ P_o (°C)	c_s @ P_o (kcal / kg °C)	ΔT superheat (°C)	T_o @ P_o & h_i (°C)
6.0	158.8	658.1	5.0	151.8	0.556	~ 3.4	~ 155.2
			4.0	143.6	0.553	~ 7.6	~ 151.2
			3.5	138.9	0.533	~ 10.7	~ 149.6
			3.0	133.5	0.525	~ 13.9	~ 147.4
			2.5	127.4	0.516	~ 18.0	~ 145.4
			2.0	120.2	0.506	~ 23.1	~ 143.3
			1.5	111.4	0.496	~ 29.8	~ 141.2
			1.0	99.6	0.484	~ 39.5	~ 139.1
			0.5	81.3	0.469	~ 55.7	~ 137.0
5.0	151.8	656.2	4.0	143.6	0.553	~ 4.2	~ 147.8
			3.5	138.9	0.533	~ 7.1	~ 146.0
			3.0	133.5	0.525	~ 10.3	~ 143.8
			2.5	127.4	0.516	~ 14.3	~ 141.7
			2.0	120.2	0.506	~ 19.4	~ 139.6
			1.5	111.4	0.496	~ 26.0	~ 137.4
			1.0	99.6	0.484	~ 35.5	~135.1
			0.5	81.3	0.469	~ 51.6	~ 132.9
4.0	143.6	653.9	3.5	138.9	0.533	~ 2.8	~ 141.7
			3.0	133.5	0.525	~ 5.9	~ 139.4
			2.5	127.4	0.516	~ 9.9	~ 137.3
			2.0	120.2	0.506	~ 14.8	~ 135.0
			1.5	111.4	0.496	~ 21.4	~ 132.8
			1.0	99.6	0.484	~ 30.8	~ 130.4
			0.5	81.3	0.469	~ 46.7	~ 128.0
3.5	138.9	652.4	3.0	133.5	0.525	~ 3.0	~ 136.5
			2.5	127.4	0.516	~ 7.0	~ 134.4
			2.0	120.2	0.506	~ 11.9	~ 132.1
			1.5	111.4	0.496	~ 18.3	~ 129.7
			1.0	99.6	0.484	~ 27.7	~ 127.3
			0.5	81.3	0.469	~ 43.5	~ 124.8
3.0	133.5	650.8	2.5	127.4	0.516	~ 3.9	~ 131.3
			2.0	120.2	0.506	~ 8.7	~ 128.9
			1.5	111.4	0.496	~ 15.1	~ 126.5
			1.0	99.6	0.484	~ 24.4	~ 124.0
			0.5	81.3	0.469	~ 40.1	~ 121.4
2.5	127.4	648.8	2.0	120.2	0.506	~ 4.7	~ 124.9
			1.5	111.4	0.496	~ 11.1	~ 122.5
			1.0	99.6	0.484	~ 20.2	~ 119.8
			0.5	81.3	0.469	~ 35.8	~ 117.1
2.0	120.2	646.4	1.5	111.4	0.496	~ 6.2	~ 117.2
			1.0	99.6	0.484	~ 15.3	~ 114.9
			0.5	81.3	0.469	~ 30.7	~ 112.0
1.5	111.4	643.3	1.0	99.6	0.484	~ 8.9	~ 108.5
			0.5	81.3	0.469	~ 24.1	~ 105.4
1.0	99.6	639.0	0.5	81.3	0.469	~ 14.9	~ 96.2
-	-	632.0	0.5	81.3	-	-	-

Note

Superheat calculations by Fedegari from physical raw data at www.engineeringtoolbox.com/saturated -steam-properties-d_457

Superheating during real expansion is in fact less intense than in the ideal case, thanks to the non-reversibility of the process, to heat dispersion and to the presence in the steam of a certain amount of condensate (the titre of saturated steam is always lower than 1).

A potentially different behaviour between small load testing and full load testing is foreseen by standards as EN 285 and HTM 2010. When testing small loads, a transient overheat as big as + 5 °C in comparison with the minimum sterilization temperature is admitted for a maximum time of 60 s after beginning of the so called holding period. The same is not admitted if full loads are tested.

If testing with reduced loads allows for transient overheat, even more so will happen in empty chambers. It is also obvious that the presence of any material in the chamber reduces the amount of this overheat. Thus, a correct validation approach should include:

- study of a cycle suitable for obtaining finally dry products without overheating at the beginning of the exposure phase;
- evaluation of the overheat that occurs in empty chamber at the beginning of the exposure phase;
- trials to reduce the overheat in empty chamber by changes in the preheating phases of the cycle, provided that these changes do not affect the final dryness of the product; form this point of view, any internal material as trolleys and trays is compatible with the concept of empty chamber and may contribute to reduce, or even may eliminate the transient overheat;
- specification in the validation rationale of the maximum overheat that might occur with empty chamber (or in the chamber without load) at the beginning of the exposure phase;
- performance and verification of test runs.

An obvious preliminary condition for the above validation exercise is the use of steam of good and repeatable quality. This includes that the steam be not superheated upstream of the control valves and that the upstream pressure be not to high and cause an non-compensable excess of overheat in the chamber (see also table in Page 2).

