



EMPTY CHAMBER TEST FOR AUTOCLAVES

(Ref. SOP VAL-175)

1. Objective

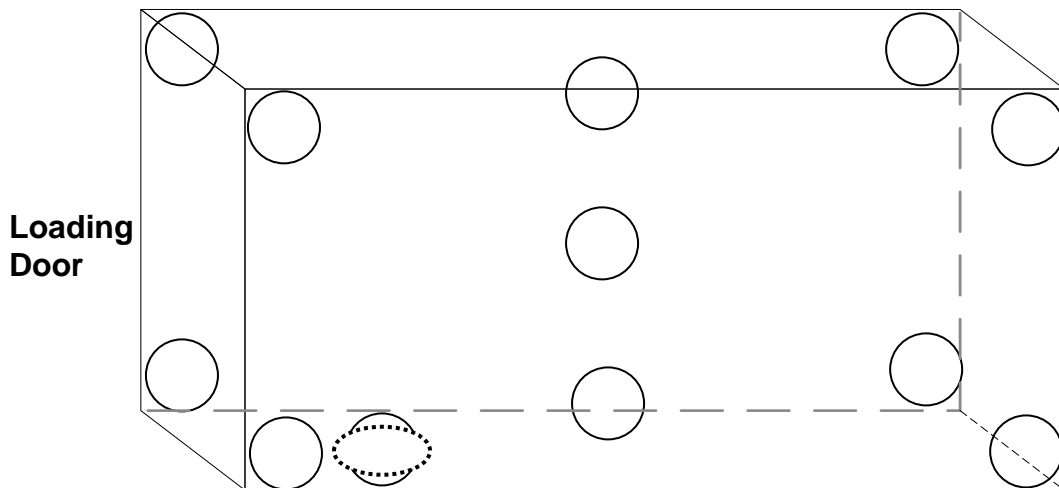
This test is to be completed in order to demonstrate that during the exposure phase of a standard cycle, the empty autoclave chamber is capable of providing a uniform temperature environment.



2. Procedure

2.1 Ensure that a Pressure Regulator Test has been successfully completed using Form-795. Sign/Date

2.2 Position the thermocouples through out the empty chamber of the autoclave; in all corners, top, bottom and middle of the chamber. Place one thermocouple in the drain next to the chamber probe. Record the thermocouple numbers in Figure 1. Strikeout any thermocouple positions that were not required. Sign/Date

Figure 1. Chamber - Thermocouple Distribution Configuration



 Drain  Thermocouple (Write the T/C number inside the circles)

2.3 Run the autoclave with an exposure time of 30 minutes according to Operating Instruction manual. Sign/Date

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2.3 Record the thermocouple temperature results in the table below.

Sign/Date

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Table 1. Thermocouple Temperature Results

Thermocouple #	Acceptance Criteria	Temperature (°C)	Pass / Fail
1	The average temperatures of the T/C's are within $\pm 1.8^{\circ}\text{C}$ of the mean chamber temperature during the exposure phase and the temperature averaged over the exposure period for each T/C is $\geq 121.1^{\circ}\text{C}$.		
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
Mean temperature			

2.4 Has the empty chamber test been successfully completed without any deviations.

Yes/No Dev #

Sign/Date

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2.5 Attach all printouts and charts to this form.

Sign/Date

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3. Completion

Upon completion of this test attach all documentation to the Validation Protocol (Form 780).