



Vacuum Leak Test

(Ref. [SOP VAL-175](#))

1. Procedure

A Vacuum Leak Test is performed to test the integrity of the autoclave. This form must be printed for each consecutive test.

1.1 Vacuum Leak Test Performance

- 1.1.1 Synchronise the time of the Graphic Recorder (Eurotherm Chessell 6000 Multichannel Graphic Recorder) to within 1 minute of the autoclave. **Sign/Date**
- 1.1.2 With the autoclave in standby state and the side door slightly open, install the test equipment (thermocouple harness, independent pressure measurement device) onto the autoclave validation port(s) located on the side of the autoclave. **Sign/Date**
- 1.1.3 Perform a Vacuum Leak Test and record cycle number. **Cycle Number**
- Was test conducted successfully without alarm? **Yes/No**
- If no, fill out Vacuum Leak Test Summary table in Autoclave Validation Protocol (Form-780 Autoclave Validation Protocol), record deviation number and repeat test again (Note: upon retest print off this form **Deviation Number**
- If yes, continue to point 1.1.4.
- 1.1.4 Retrieve the autoclave printout(s) and chart recorder trace, sign all printouts and attach to this document. **Sign/Date**

2. Completion

Upon completion of this test attach document to the Autoclave Validation Report.

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Table 1. Vacuum Leak Test Parameters

Actions	Expected Results	Actual Results		Acceptance Criteria Met (Yes/No)	Sign/Date	
Verify the autoclave Vacuum Leak Test Cycle parameters.	The Vacuum Leak Test Cycle parameters from the autoclave are verified.	Verify parameters	Yes/No			
Start Vacuum Leak Test Cycle.	Autoclave cycle starts and information is documented in the spaces provided	Test Date				
		Cycle Number				
		Time of Run				
Observe and record the initial Vacuum Test Chamber Pressure (<i>1st recorded print of the Vacuum Hold Phase</i>).	Initial Vacuum Test Chamber Pressure is recorded at start of Vacuum Hold Phase and is: ≈15kPa	Initial Pressure Value (kPa)				
Once evacuated, the chamber holds the established vacuum level for 30 minutes without further action from the vacuum pump	The chamber holds the established vacuum level for 30 minutes .	Start Time				
		End Time				
		Total Time (min)				
Observe and record the final Vacuum Test Chamber Pressure (<i>last recorded print of the Vacuum Hold Phase</i>).	Final Vacuum Test Chamber Pressure is recorded at end of Vacuum Hold phase.	Final Pressure Value (kPa)				
Calculate the ΔP for the Vacuum Hold Phase.	$\Delta P = \text{Final Vacuum} - (\text{Pressure} - \text{Initial Vacuum Pressure})$. ΔP is ≤ 3.5 kPa	$\Delta P =$				
Retrieve the autoclave printout and chart recorder chart, label and attach as specified in the test procedure.	The cycle is completed with NO alarm conditions.	The cycle completed with no alarm conditions.	Yes/No			
		The autoclave printout displays a reading of "CYCLE COMPLETED".	The autoclave recorded a reading of 'Cycle Completed'.			Printo
	The printout and chart recorder chart are stamped and attached.	The printout and chart recorder are stamped and attached.	The printout and chart recorder are stamped and attached.			Chart