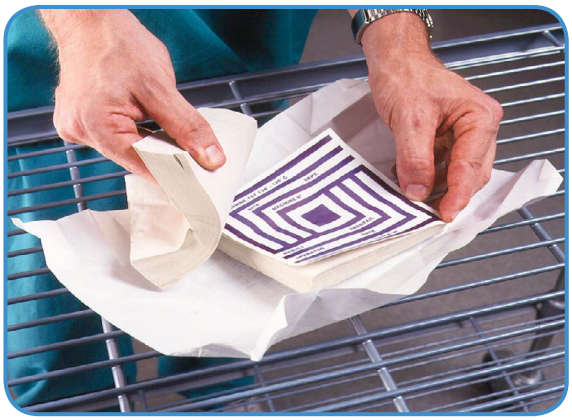
# HOW TO: Understanding the Complementary Roles of Air Removal (Bowie-Dick), Leak and Biological Testing in Steam Sterilization

## Introduction

Air… It's the enemy of steam sterilization, potentially preventing steam contact with the load items intended to be sterilized. Air leaks and/or failure to remove all the air trapped in the chamber and load can play a significant role in sterilization failure. Steam sterilizers come equipped with diagnostic tests such as the air removal (Bowie-Dick) and leak test to help ensure the integrity of the plumbing and vacuum system and verify that most if not all air has been removed. These diagnostic tests are intended to complement one another and play an important role along with biological indicators to ensure an efficacious steam sterilization process.



## Air Removal (Bowie-Dick) Testing

The air removal test, also known as the **Bowie-Dick test** indicates whether the vacuum system is operating properly so that the sterilizer can be used for prevacuum cycles. It identifies the presence of air in the chamber after the conditioning phase. Operators are instructed not to use a prevacuum cycle if the unit will not pass the Bowie-Dick test. However, the unit can still be used for a Gravity or Steam Flush Pressure Pulse (SFPP) cycle, which do not draw a vacuum during conditioning. Some causes of Bowie-Dick test failure are poor air removal, poor steam quality and super heat conditions. Leaks in the piping can also be a source of failure.

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=== L E A K   T E S T ==
======================
CYCLE START AT 11:17:12A
            ON  4/29/11

CYCLE COUNT          273
OPERATOR _____________
STERILIZER    VAC 00
SERIAL # 1000000-00


                   V=inHg
- TIME      T= F  P=psig
----------------------
C 11:17:29A 180.5   0.4P
C 11:18:30A 255.5  12.0P
C 11:19:41A 171.0  23.4V
C 11:20:13A 266.3  26.2P
C 11:21:34A 201.1  27.5V
L 11:22:13A 272.7  22.6P
L 11:32:32A 194.2  27.9V
L 11:34:32A 193.2  27.9V
L 11:44:32A 189.1  27.8V
LEAK RATE IS:
 0.2 mmHg/min

L 11:44:33A 189.1  27.8V
E 11:44:33A 189.1  27.8V
Z 11:45:12A 191.0   1.9V

LOAD             042905

TOTAL CYCLE =27:43

PRINTOUT CHECKED BY:

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* NOT READY    11:58:23A
DOOR OPEN
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## Leak Testing

A **leak test** is used to verify the integrity of the sterilizer pressure vessel and its plumbing. A perfectly sealed vessel with perfectly sealed plumbing components will have no leaks, but to permit for reasonable wear and tear on equipment the industry standard for sterilizers is to allow up to a 1.0 mm Hg per minute leak rate average over a specified time period, usually 10 minutes.

Operator manuals recommend that the leak test be performed on a daily or weekly basis. The intention of this test is to allow the user to check the integrity of the unit between service visits to see if some component may be failing. This is best determined by keeping a log of the test results to see if there has been either a gradual or a more radical change in the leak rate, and this will allow the user to contact the service provider to schedule a repair before the leak causes a problem with Bowie-Dick tests, biological indicators or internal indicator strips.

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## The Importance of the Warm up Cycle

A **warm up cycle** should be run prior to both Bowie-Dick and leak testing. Sterilizers that have been turned off overnight, or have been in the idle mode (jacket warm, but cycle not run since the day before) should always have a short cycle run prior to the diagnostic test to warm up the unit. Check valves may leak slightly when not hot and this can contribute to an increase in the leak rate. By running the warm up cycle, these components reach their operating temperature and tend to stay consistent in operation for that day. Running a warm-up cycle may prevent failure of the leak test in cases where cold components are contributing to air leakage.

## Leak Rates Exceeding Specified Limits

Sterilizer operators may question what actions are necessary when the leak rate exceeds the specified limit of 1.0 mm Hg per minute. AAMI and the operator manual recommend immediate shutdown of the sterilizer until the unit can be serviced. Since the Bowie-Dick test has limited sensitivity by comparison, the leak test can act as an early indicator of problems with inadequate air removal.

It is important to consider the history of leak test results for the sterilizer. If in the past the sterilizer had very low leak rates, such as 0.2 or 0.3 mm Hg on a routine basis, and the leak rate suddenly increases to 1.1 or 1.3 mmHg, this indicates that a component is probably failing fairly rapidly and service should be called immediately.

However, if the test has been close, but not over, such as 0.7 or 0.8 mm Hg per minute readings, then the increase in leak rate is fairly gradual and a service visit can be scheduled on a non-emergency basis. The operator should continue to monitor the leak rate, by running the leak test daily, and take immediate action if it rises above the acceptable limit.

## Biological Indicators

A **biological indicator** (BI) is a device that provides a defined resistance to the sterilization process. BI results must be acceptable in order for an operator to use the sterilizer to produce sterile goods. AAMI recommends running a biological a minimum of once per week but many facilities run one every day. A biological should be run with all loads containing an implantable device. Biologicals may also be adversely affected by air leaks and air that the vacuum system has failed to remove.

STERIS University Key Learning Objective ➔ Air removal, leak and biological tests all play a unique and complementary role in assuring the sterility of processed goods. The air removal test verifies if the vacuum system is removing air adequately while the leak test determines whether or not air is entering the sterilizer chamber through leaks in the piping. The biological test indicates if sterilization parameters have been met (but does not guarantee that all items in the load have been properly exposed). All three tests are necessary to provide the appropriate confidence level in the sterility of the processed goods and should not be considered as substitutes for one another.



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