

Batch Control Guidelines for Steam Sterilization



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Achieving sterility is a critical quality characteristic for all sterile items, products and containers. Sterility, however, cannot simply be assured through testing, but requires suitably designed, validated and controlled manufacturing processes. In other words, one cannot assume that sterilization has been achieved without first having the appropriate validation and qualification procedures in place. But in order to ensure and prove that a batch is valid, time, temperature, and in some cases, pressure, must be measured with automatic monitoring devices like the [TrackSense®](#) or [SteriSense®](#) wireless data loggers.

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Performance Tests for Steam Sterilizers

In order to ensure patient safety, different mandatory measures must be undertaken to establish appropriate sterilization. These measures are critical for safeguarding the medicines, surgical instruments, supplies, equipment and medical devices used for pharmaceutical and health-care procedures.

Prior to use, the overall functionality of the sterilizer must be checked. This process is called Qualification and involves the following steps:

- **Commissioning:** Consist of the Installation Qualification (IQ) and Operational Qualification (OQ) of the process equipment
- **Performance Qualification (PQ):** Is the physical qualification of the entire process
- **Validation Report:** Finally, a validation report that provides a summary of the performance





Daily Leak Rate- and Bowie Dick Tests

Steam sterilizers, particularly those capable of running vacuum cycles, are complex machines. It is therefore important to closely monitor the sterilization process to ensure the process has met all parameters. Which consequently means that the products can be defined as sterile.

A range of tests must be carried out on an autoclave prior to commencing the first daily sterilizing cycle. These tests include:

- **Leak Rate Test:** A leak rate test should be run every morning to test whether the machine's seals are secured
- **Air Removal and Steam Penetration Test:** The Bowie Dick test was previously performed by using Chemical Indicators, but more advanced and detailed test are available today through [electronic test devices](#). This test must be performed before the first sterilizing cycle of the day in order to determine whether the steam sterilizer is operating correctly.

Batch Control Through Parametric Release

In addition to performing daily routine tests of autoclaves, checking every batch prior to its release is also required. Historically, biological indicators (spore tests) or chemical indicators were used to perform batch control, but more advanced [electronic Bowie Dick test methods](#) have since become available.

Some sterilization processes already incorporate safety margins that can be considered for parametric release, as each process provides a Safety Assurance Level (SAL) of 10⁻⁶ or better. But in order for these processes to be considered for parametric release, they must be adequately validated initially and revalidated at least once per year. The aforementioned [electronic Bowie Dick test methods](#), that perform routine monitoring of the sterilizer, can consequently be used to demonstrate the necessary validated conditions. Thereby achieving the required SAL levels – allowing for a combined Bowie Dick test and batch control solution all in one device.

Measure Data, not Color - the Modern Bowie Dick Test

How do Chemical Indicators Work?

Chemical indicators contain chemicals that are affected by high heat and therefore change their color when exposed to specific sterilizing parameters. The chemical indicators are either single-parameter temperature-specific, affected only by heat, or multi-parameter chemical indicators that respond to a combination of conditions, such as time, temperature, moisture, gas concentration and humidity.

Chemical indicators do provide immediate verification that items have been processed as soon as they are removed from the sterilizer, but the reading of the result is highly subjective (uneven color change) and often rather challenging.



How do Biological Indicators Work?

Biological indicators are used for routine monitoring, qualification and load monitoring of a steam sterilizer. They are therefore designed to test and demonstrate whether the conditions during a steam (autoclave) cycle were adequate enough to achieve a defined level of microbial inactivation.

The process challenge device (PCD) containing the biological indicator, should be placed in the most challenging location in the chamber. In a steam sterilizer, this is typically on the bottom shelf near the drain. After the sterilization process, the vial is activated, allowing the spores to mix with the growth medium and be incubated for spore growth. This will usually take several hours, or in some cases even days, before a result is provided.



How do Electronic Bowie Dick Tests Work?

[Electronic Bowie Dick tests](#) do not have to rely on a slight change in color nor wait for several hours or days before producing a result. The data gathered by electronic Bowie Dick test devices can calculate whether steam sterilizers work as intended almost instantaneously.

Furthermore, some [advanced electronic Bowie Dick tests](#) have the added benefit of identifying the equilibration time and holding time, calculating a dilution factor or performing leak tests.

Why use Electronic Bowie Dick Tests for Routine Control?

In recent years, it has been standard operational procedure in hospitals to use biological indicators to monitor sterilization cycles. And even though these procedures are quite tricky and time consuming to operate, they have previously been considered to provide the only true answer as “dead bacteria don’t lie”.

However, with modern technology being as advanced as it is, it seems strange to still rely on a bacteria count in order to release a batch that finished several hours or days prior. A more rational and practical solution would be to ensure that your sterilizer is qualified and your sterilization process is validated. As doing so on a regular basis would allow for parametric release of your batch.

This modern approach is supported by the fact that the FDA has allowed for this solution to be used for products that are sterilized by steam – mainly due to the fact that parametric release uses physical data obtained from specific load configurations.



To best perform the regular tests that allow for parametric release, we once again turn our attention to the electronic Bowie Dick test. The typical parameters evaluated through these tests are temperature and pressure, but these alone are not enough. A process challenge device is also necessary in order to properly challenge the steam penetration ability of the autoclave.

Another benefit of prioritizing the use of electronic Bowie Dick test methods is the software that comes with it. Some more [advanced Bowie Dick test software](#) can calculate the theoretical temperature based on the pressure, as well as include this temperature in calculations in order to prove that saturated steam is available. Furthermore, the dilution factor can be calculated to check whether appropriate vacuum is achieved – providing a quick indication of how well the heat penetration function works and how efficient the steam is introduced into the chamber - and air evacuated.

Overall, the electronic Bowie Dick test devices and software provide a very thorough evaluation of the presence of air or non-condensable gasses, as well as inadequate steam. Combine this with parametric release, electronic reporting and clear results, and you have a complete FDA approved solution that ensures patient safety.

Historically, arguments that were typically presented against electronic Bowie Dick test devices have long since been solved. As newer electronic tests are designed specifically to address those concerns by allowing for further in-depth evaluations of the process. And due to some [electronic Bowie Dick test](#) devices now being even smaller than biological indicators, they can easily be positioned throughout the load and located in areas where sterilization is least likely to occur – thereby testing and ensuing sterility of worst case scenarios.

SteriSense®

- the Ultimate Electronic Bowie Dick Test

[SteriSense](#) is Ellab's answer to every challenge presented by chemical indicators, biological indicators and even older electronic methods, all in one. The electronic Bowie Dick device consists of various parts, namely:

- Process Challenge Device (PCD) to challenge steam penetration
- Triple sensor for temperature and pressure measurements
- Data logger with large battery capacity
- Reader station for quick and easy readings
- Software for calculations, clear pass/fail result and reporting

Process Challenge Device (PCD):

The PCD was specially designed to reflect the reference method originally developed by Dr. J. Bowie and J. Dick in the 1960's. The function of the PCD is to "challenge" the steam penetration of a steam sterilizer in accordance with EN ISO 11140-4. Between tests, the PCD needs to be cooled down to ambient temperature (approx. 90 minutes), which is why Ellab designed it to easily be detached from the data logger body and be changed with a spare. An additional feature of the PCD design, is SteriSense's ability to check for the presence of non-condensable gases.

It is worth mentioning that the interchangeable PCD is patent pending.



Triple Sensor:

The pre-calibrated sensors, due to their Pirani and RTD technology, offer highly stable performances, even for intensive daily use. The triple sensor module of SteriSense consists of the following individual sensors:

- A temperature sensor that measures inside the PCD
- A second temperature sensor that measures the ambient temperature in the sterilization chamber
- A pressure sensor that measures the ambient pressure value within the chamber

When combined, the three sensors provide a complete overview of what occurs within the autoclave, as well as comparable data used to calculate the steam's penetration ability.

Data Logger:

The SteriSense data logger can store data during the process and contains a battery with enough capacity to run multiple cycles. The design and functionality is based on Ellab's 3rd generation of the tried and tested [TrackSense® Pro data loggers](#).

Single Reader Station:

The highly compact reader station is used to start and read the logger. It enables fast and secure data transmissions through plug-and-play USB connection.

SteriSense® Software:

The SteriSense software is what ties everything together, providing a complete overview of the test, results and cycles through clear pass/fail results, graphs and reports. The reports can be stored electronically, or alternatively, be printed for potential audits.

Using the SteriSense Pro software it is now possible to set up a client/server solution with remote access.

How to use the SteriSense® System (1-2-3-GO!)

Electronic Bowie Dick tests have never been easier than with SteriSense, as the user-friendly system is operated through three easy steps:

Step 1: Place the SteriSense measuring device in the reader station and open the SteriSense Software.

Step 2: Start the device by clicking on “Start” and place it inside the steam sterilizer close to the identified cold spot (zone).

Step 3: Once the sterilization program is complete, place the SteriSense in the reader station to read the data. The result of the test will either pass or fail, which will appear on the screen shortly after the data has been processed. The test results will be stored in the software and be included in an automatically generated PDF report.

To repeat the test, simply unscrew the PCD and replace it with a cold spare to repeat the process without having to wait for the original to cool down.

When compared to traditional methods, the SteriSense solution provides far more insight into critical sterilization parameters than previously possible. The standard report showcases all the results from the optional ‘checks’ performed by the software. When using the standard settings, a routine control test will be performed in accordance with EN ISO 17665 (moist heat autoclaving).

SteriSense has been tested by a 3rd party certified test institute to comply with the reference method described in EN ISO 11140-4.



Bringing it all Together...

When taking everything into consideration, using biological indicators for batch control quickly becomes obsolete. As long as your steam supply is clean, the acts of monitoring and releasing products solely based on physical data collected from sterilization cycles pose no risk – in fact, there are only benefits to be gained.

*By using modern FDA approved electronic methods like [SteriSense](#), that ensure sterility and allow for parametric release, your process becomes much easier. The clear pass/fail result is immediately obtained, **saving valuable time** and **ensuring patient safety**.*

