

Product Spotlight

SteriSense® - Electronic Bowie Dick Test



In this Product Spotlight we will go through the importance of high quality steam sterilization and the advantages of using Ellab's Electronic Bowie Dick testing device, SteriSense to achieve ultimate peace of mind.

Creating the Ultimate Electronic Bowie Dick Test

Steam sterilization is a highly critical process in which surgical instruments, procedural tools and other hospital equipment are completely cleaned to the point of being sterile. Autoclaves, or steam sterilizers, are used for this important task – and therefore require daily tests to ensure that they sterilize as intended. One of the most common tests performed in this regard is the Bowie Dick test, in which an autoclave's steam penetration ability is evaluated prior to use. To perform this test, third party Bowie Dick test methods are required to provide an objective result on whether or not an autoclave functions as intended. SteriSense, Ellab's electronic Bowie Dick testing device, is the newest and most advanced solution for the job.

SteriSense was developed upon discovering how some chemical indicators could be misread or occasionally provide false positives – as they would almost never fail an autoclave, even when the reference method would. This automatically put the safety of patients on the line, as insufficiently sterilized products could get through this loophole and make their way into hospitals where patients and staff would be exposed to them.

SteriSense was therefore developed with one ultimate goal in mind: **ensuring patient safety**. SteriSense offers the following key benefits, providing the complete solution for the healthcare and medical industry:

· Easy to use:

The plug-and-play solution is easy to setup and use. With its simple interface and clear pass/fail results, Central Sterile Service Departments (CSSD) can quickly conduct and finish important tests

· Highly accurate:

The SteriSense device is among, if not the most, accurate device available on the market, ensuring that your data is highly reliable, objective and repeatable

· Complies with current norms:

In order to provide safe results, SteriSense complies with EN ISO 11140-4 and EN ISO 17665 standards – ensuring that no faulty autoclave passes inspection. In addition to this, the system lives up to the EN 285 and EN ISO 13060 standards to provide further analyses of critical parameters

· Innovative:

SteriSense was designed to be the most compact solution on the market while also being equipped with a unique replaceable Process Challenge Device (PCD) concept. Allowing you to run a test, quickly replace the PCD with a spare and run a second test – reducing downtime by eliminating the need for cooling the device

• Price competitive:

As the most reliable replacement for older methods like chemical and biological indicators, SteriSense is price competitive. Whereas traditional indicators have to be thrown out after every use, SteriSense can continuously be used over and over – accumulating fewer resources in the long run while simultaneously taking up no storage space

• Extremely versatile:

In addition to simply passing or failing an autoclave, SteriSense is the complete and ultimate solution. The device can check and pinpoint exactly where errors occur and be used for additional tests like leak tests and batch control





User-Friendly Device with an Outstanding Performance

SteriSense is extremely easy to use and requires next to no training. With just one click, the extremely compact device begins to measure and save data. After completing the Bowie Dick test program, the device is simply placed in the reader station. From here, the software automatically evaluates the data and presents the test result as passed or failed.

All analyzes and results are saved electronically in the MSQL database, from where they can be presented in reports with full documentation for potential audits.

Compliant and Comprehensive Software

When compared to traditional chemical indicator methods, SteriSense provides far better insight into the critical sterilization parameters than previously possible.

The standard Bowie Dick test report, generated by the SteriSense software, showcases the results of the predefined "checks" selected by the operator. The software also initiates a routine check in accordance with EN ISO 17665 when performing a standardized test.

In addition to this, the SteriSense software can also be used for a complete evaluation of the autoclave's performance. This is done by running any of the following qualifications – all in accordance with EN 285, EN ISO 17665, EN ISO 13060 and EN ISO 11140-4:

- · Detection of the holding phase
- · Temperature holding time
- · Temperature equilibration time
- · Air removal phase
- · Steam admission phase
- · Heating phase
- Drying phase
- · Calculation of the dilution factor

The SteriSense software has been independently tested by a thirdparty test institute in accordance with the reference method originally developed by Bowie and Dick, using the test procedures (cycles B1, B2 & B3) described in EN ISO 11140-4.

The Most Innovative Electronic Bowie Dick Test

SteriSense is by far the most compact Bowie Dick electronic test system on the market – and perfectly reflects the original reference method developed by Bowie and Dick in the 1960's. This is achieved through SteriSense's replaceable PCD, which purpose is to challenge, or simulate, the steam penetration in accordance with EN ISO 11140-4.

The small PCD has the unique feature of being interchangeable, which allows for several test cycles to be run in a sequence without the need for cooling. This is highly beneficial for operators, as the standard recommendation for PCD type measuring devices states that the unit should normally be cooled down to ambient temperature between tests in order to avoid false readings (about 90 minutes). However, seeing as the SteriSense PCD can easily be removed from the logger body and replaced by a cold spare, this waiting time is now obsolete. This naturally reduces the overall process time dramatically and saves resources as back-up devices are no longer required.

In addition to the PCD, the SteriSense triple sensor design is rather unique in its own way. The two temperature sensors measure the temperature inside the PCD as well as the ambient temperature in the sterilization chamber. While simultaneously, the pressure sensor measures the ambient pressure within the chamber, detecting vacuum pulses, calculating the theoretical ambient temperature and locating possible super-heated steam. Based on this principle, SteriSense is able to check for the presence of non-condensable gases (NCG) by analyzing the steam's capability to heat the core inside the PCD.

Using SteriSense for daily Bowie Dick tests provide the following benefits when compared to other electronic challenge devices:

- · Ultra-compact size
- · Highly user-friendly software
- · Advanced sterilization analysis
- Up to 1,000 test cycles between each calibration





More Accurate and Reliable Bowie Dick Testing

When compared to traditional chemical indicators, SteriSense stands out as a more secure, user-friendly and affordable choice. As previously mentioned, patient safety is of utmost importance and should never be taken lightly, which is why a reliable device like SteriSense is necessary to avoid false positives and inaccurate, subjective readings. Ellab's electronic Bowie Dick test is also the more environmental-friendly choice, as it produces next to no waste or chemicals and does not need to be discarded after every use.

The intuitive software immediately informs operators whether the test was successful or not, and automatically generates and stores printable reports, providing precise and easily accessible documentation of the process.

Using SteriSense for daily Bowie Dick tests provide the following benefits when compared to traditional chemical indicators:

- · Economically efficient with high test volumes
- Improved patient safety through objective results that eliminate the risk of false or grey zone readings
- Additional critical information checks performed according to ISO 17665
- Easy to store, retrieve and compare the data from a database convenient and safe method that eliminates any guesswork
- · Time stamps included to increase reliability
- Friendlier towards the environment with next to no waste product

A Solution for any Budget

As different users have various needs, the SteriSense system has been made available as three different options:

Purchase excl. service plan:

SteriSense is bought with full ownership and control over when to calibrate and conduct service. A maximum of 1,000 test cycles or 12 month intervals between each calibration is highly recommended

• Purchase incl. service plan:

Gain full ownership of the device and retrieve an all-inclusive service plan. The plan ensures that Ellab performs calibration and service after every 1,000 test cycles or 12 month intervals (whichever comes first). The factory warranty is also extended as part of this service plan

Utilize the High Versatility of SteriSense®

In addition to completing daily Bowie Dick tests, the SteriSense system can also be used to control each batch and perform a so called "parametric release".

To control a batch, a validation study must first take place involving the SteriSense unit. Once validated, any future batches within the autoclave can be controlled by only using the SteriSense measuring system – resulting in a clear pass/fail result. In order to continue this process however, the autoclave must be validated annually with a SteriSense unit involved.

Parametric release is based on the measurements of critical physical parameters by an independent electronic device. This release process is not only more accurate, but also much faster than biological indicators, which can take up to several days before providing a result. The SteriSense test results are immediately available after the process has finished and data is read.

Additional features:

- Validation studies in combination with <u>TrackSense</u>® data loggers
- · Vacuum leak tests
- · Simple post-service checks of sterilizers

These features require ValSuite® Medical or Plus

The Reliable Choice for Testing Autoclaves

SteriSense provides the simplest user experience, while remaining the most advanced electronic Bowie Dick testing system available today. The software complies with current norms and regulations, ensuring that the highly accurate measuring device provides clear and reliable results – thereby eliminating any risk to patient safety.

The intuitive replaceable PCD solution and ultra-compact design, also ensures a smooth and optimized experience when approving autoclaves on a daily basis. While the various budgeting options makes the highly versatile system accessible to every need.



on <u>SteriSense</u>® or to find the right solution please contact: