



Validation & Monitoring
Solutions

| SteriSense®

The Ultimate Bowie Dick Test



**PATENT
PENDING**

Global Expertise with Local Reach

SteriSense®

The Ultimate Electronic Bowie Dick Test



Peace of Mind

SteriSense is a brand new and innovative device for Electronic Bowie Dick Tests that is unmatched in accuracy, performance and reliability.

SteriSense provides you with the ultimate peace of mind, by ensuring that your Steam Sterilizer functions in accordance with current norms and is sterilizing as expected.



User-friendly

SteriSense is extremely easy to use and requires only little training to operate. With just a single click in the software, the SteriSense measuring device will start to measure and record data.

Once the Bowie Dick Test Program has ended, the device is simply placed back in the reader station where the software automatically processes the data and provides a test result.

All test results are saved electronically and can be presented in accessible reports including audit trails – simple and easy!

Verification of critical sterilization parameters beyond traditional methods



ISO 11140-4 Compliant
Tested by 3rd Party
Test Institute



Why use SteriSense® Instead of Other Electronic Bowie Dick Test Devices?

SteriSense is by far the most compact Electronic Bowie Dick Test on the market. The Process Challenge Device (PCD) has the unique feature of being replaceable, which allows the user to run several test cycles in a sequence with very limited need for cooling. This reduces the amount of time and investments spent on unnecessary backup devices. The replaceable PCD feature is **patent pending**.

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



Why use SteriSense® Instead of Traditional Indicators?

Unlike traditional chemical indicators, where you subjectively decide according to a change in color, SteriSense provides a much more in-depth verification of critical sterilization parameters, eliminating any guess work. The SteriSense software also automatically generates and stores printable reports, ensuring electronic documentation of the process.

In summary, by using the SteriSense for full parametric release you gain the following advantages:

- Economically efficient with high test volumes
- Improved safety - 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 the need for guessing
- Time stamps included to increase reliability

SteriSense® Measuring Device

A Sterisense Measuring Device consists of Three Main Parts

Process Challenge Device (PCD)

The PCD has been 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.

SteriSense® Triple Sensor

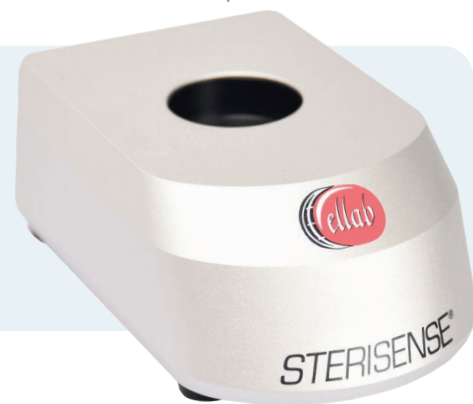
1. A temperature sensor that measures inside the PCD
2. A second temperature sensor that measures the ambient temperature in the sterilization chamber
3. A pressure sensor that measures the ambient pressure value within the chamber

SteriSense® Data Logger

The SteriSense data logger is designed to store data during the daily routine control of a steam sterilizer, which, by many sterilizer-manufactures, is referred to as a Bowie Dick Test Program.

SteriSense® Single Reader Station

The highly compact reader station is used to start and read the SteriSense data logger. Much like the data logger, the reader station is based on Ellab's 3rd generation of the TrackSense Pro reader stations, which enables fast and secure data transmissions.



Between tests, the PCD needs to be cooled down to ambient temperature (approx. 90 minutes), which is why it is a big advantage that the device can easily be disassembled from the body (logger) and be changed with a spare. Due to the PCD design, SteriSense is also able to check for the presence of non-condensable gases (NCG).

The data logger contains a battery with enough capacity to run 1,000 test cycles of 30 min. The data logger itself is based on Ellab's 3rd generation of the well-known TrackSense® Pro data loggers.

Save time by changing the PCD between your test cycles



Protective Adaptor for Electronic Bowie Dick Test Devices

Ellab has developed a Protective Adaptor for SteriSense and the TrackSense Pro Bowie Dick sensor. The main purpose of this adaptor is to protect the ambient temperature sensor. This is especially crucial when utilizing the exchangeability of the PCD by screwing it on and off.

The Protective Adaptor improves the robustness of the SteriSense unit.

It is easily mounted in 3 steps:

- Unscrew the PCD - no tools required
- Insert the SteriSense or Bowie Dick sensor unit into the Protective Adaptor with the ambient sensor sliding into the slot. Ensure that it goes all the way up to the fixating o-ring.
- Mount the PCD again without overtightening - no tools required



Utilize the Full Potential of SteriSense®

You have the option of utilizing SteriSense to perform even more complex analysis than a simple routine control, such as:

- Be part of validation studies with Ellab TrackSense Data loggers*
- Use for batch control during sterilization processes*
- Perform a vacuum leak test*
- Perform a check after the sterilizer has undergone service

**Will require the software package ValSuite® Medical or ValSuite® Plus*

ValSuite®





The software
is almost
autonomous

User-friendly & Comprehensive Software Package

Absolute Compliance

When compared to traditional methods, the SteriSense 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.

SteriSense has been tested by a 3rd party certified test institute to comply with the reference method originally developed by Dr. J. Bowie and J. Dick, using a test procedure described in EN ISO 11140-4.

When analyzing data, the SteriSense software can perform the following "checks":

EN ISO 17665

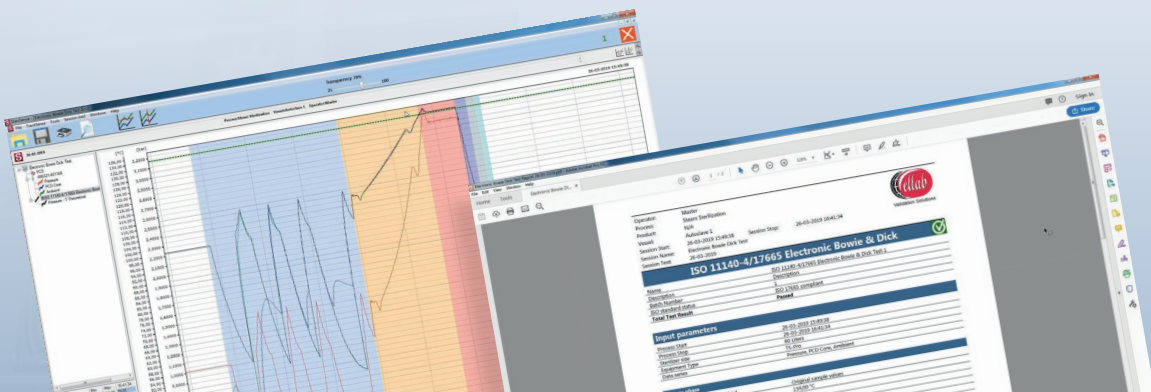
1. Phase detection (default)
2. Holding time (default)
3. Equilibration time (default)
4. Maximum temperature deviation (default)

EN ISO 11140-4

5. Air removal phase (optional)
6. Heating phase (optional)
7. Drying phase (optional)

Advanced Check

8. Dilution factor calculation (optional)



Different
solutions for
different
customer
needs

Pick the SteriSense Solution Ideal for You

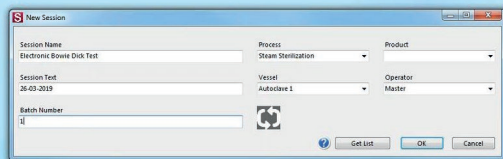
SteriSense offers two different software version: one for simpler use and one with added features called SteriSense Pro. The Pro version offers the following additional features:

- A Database Management System - allowing you to operate and access multiple databases.
- Generate and store XML files to be used as e.g. an interface for reporting when certain conditions are met - allowing you to release a unit for routine operation
- A cloud based data logger list that allows you to operate the system from various remote positions within the same organization/network

How to Use the SteriSense® System

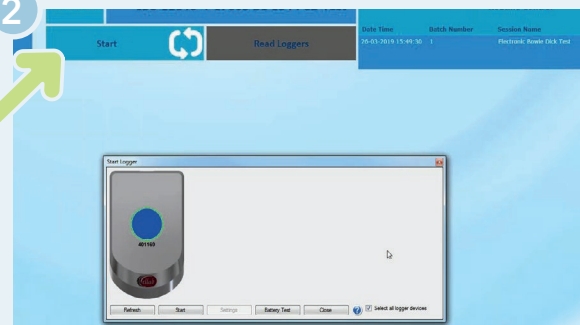
See the step-by-step instructions below, illustrating exactly how easy and intuitive the SteriSense operating system really is:

1

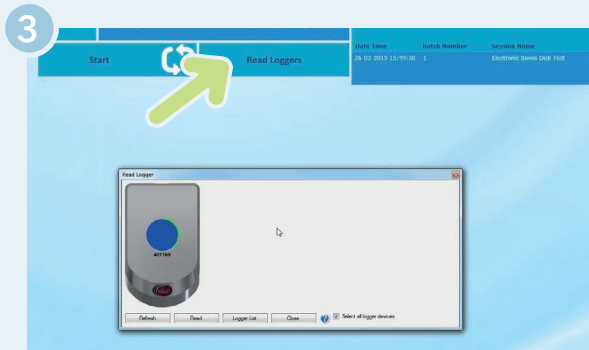


Place the SteriSense measuring device in the reader station and open the SteriSense Software. Define a unique Session Name.

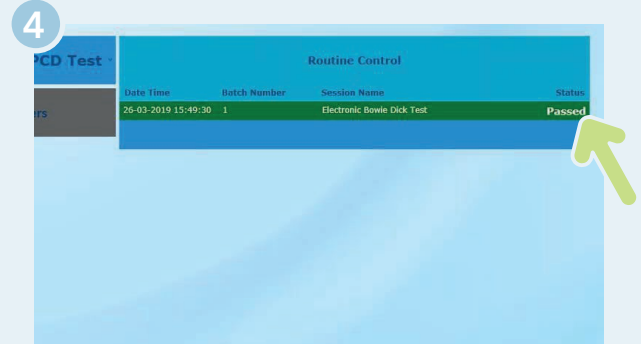
2



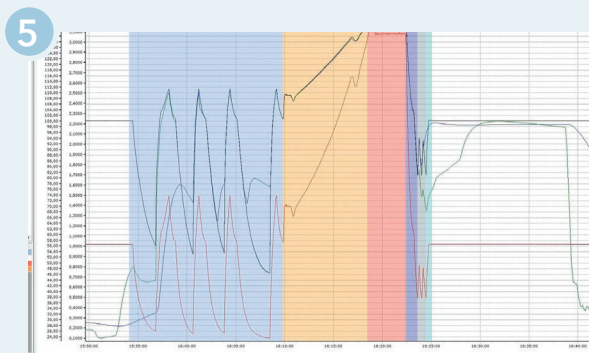
Press **Start** to activate the SteriSense measuring device, and place the device inside the steam sterilizer.



After the test program is completed, place the SteriSense measuring device back 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.



Detailed performance information and time stamps are included to increase reliability.



The test results will be stored in the software and be included in an automatically generated PDF report.

In addition to the steps mentioned above, the SteriSense software offers an Advanced Trending Report to compare the measured values from the defined vessel (sterilizer) over time. This allows you to know in advance if any changes might jeopardize the performance, and thereby avoid down time - ultimately providing Pre Maintenance Warnings.



Designed with Your Needs in Mind

Purchase with or without Service Plan

We know our customers have different needs, which is why we have made two options available to choose from when investing in a SteriSense system.

1. Purchase Excl. Service Plan

This is the most straight forward option. You buy the equipment and get full ownership and control of when to calibrate and conduct service. Ellab recommends a maximum of 1,000 test cycles or 12 months between each calibration (whichever comes first).

2. Purchase Incl. Service Plan

In addition to buying the equipment with full ownership, this option includes an all-inclusive service plan. The service plan ensures that Ellab performs calibration and service after 1,000 test cycles or after 12 months of use (whichever comes first). The factory warranty is also extended as part of this service plan.

	1	2
	Purchase excl. Service Plan	Purchase incl. Service Plan
Ownership of equipment	✓	✓
Calibration and battery change	Ad hoc	✓
Service and Repairs	Ad hoc	✓
Maximum number of test cycles between calibration	1,000 (recommended)	1,000

Up to 1,000 test cycles between each calibration



SteriSense Unit Technical Specifications

ISO Standard Compliance: 11140-4:2007 type B1, B2 and B3, 134 °C

3rd Party Test Institute:	SAL GmbH
Type of Sterilizers:	Steam Sterilizers / Autoclaves qualified for sterilization at +134 °C according to EN 285 (volume larger than 60 L) and EN ISO 17665 (moist heat autoclaves)
Measuring Principle:	Piezoresistive / Electrical Resistance
Sensor Type:	Strain Gauge / Pt1000 Temperature
Temperature Measuring Range:	0 to +140 °C (Calibrated +25 to +140 °C)
Temperature Accuracy: +25 to +140 °C:	± 0.05 °C
Pressure Measuring Range:	10 mBar to 6 Bar
Accuracy:	± 0.25% Full Scale (± 15 mBar)
Logger Housing Material:	316L Stainless Steel
PCD Housing Material:	PEEK
Operating Temperature:	-20 to +150 °C
Operating Pressure:	0.001 mBar to 10 Bar ABS
Diameter:	25 mm
Length:	125 mm including PCD (30 mm)
Weight with Battery:	240 g
Memory Capacity:	40,000 Data Points / 10,000 Samples
Minimum Sample Rate:	1 Second
Maximum Sample Rate:	24 Hours
Intrinsically Safe:	Ex II1GD ia IIC T3 Ga, -55 °C ≤ Tamb ≤ +105 °C
Time Accuracy:	± 5 Seconds per 24 Hours
Battery:	TSP 150L Battery
Expected Battery Lifetime:	1,000 Tests / 500 Hours (at +134 °C with Sample Rate of 1 Sec)



Validation & Monitoring
Solutions

Global Expertise with Local Reach

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Ellab has been your validation and monitoring partner since 1949, offering both validation equipment and validation services as well as environmental wireless monitoring solutions.

We serve both small and large companies within the Life Science and Food industries and have solutions for almost all applications such as sterilization, freeze drying, environmental chamber testing, depyrogenation, warehouse mapping, pasteurization, controlled temperature units (CTU) and many more.

Ellab develops unique and innovative solutions based on input from close interactions and dialogues with our customers. Our goal is to help our customers overcome challenges and increase their productivity by providing reliable and efficient solutions.

Ellab also offers complete turn-key or supplemental rental solutions, equipment qualification and validation services and our specialized training courses within Ellab Academy.


Ellab has a long tradition and dedication for delivering the highest performance and quality in our industry. Our user friendly and flexible validation and monitoring solutions are recognized and used by thousands of customers worldwide.

Ellab A/S in Denmark is ISO 9001, ISO 14001 & ATEX IEC 80079-34 certified. Ellab A/S Calibration facilities are accredited according to ISO 17025 by DANAK under registration no. 520 and our affiliates in UK, Germany and Italy also carry the ISO 17025 accreditation executed by local authorities.

For further information all certificates for the Ellab Group can be found [here](#).



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