

# SteriSense®



*The Ultimate  
Electronic  
Bowie Dick Test*

# The Ultimate Electronic Bowie Dick Test

ISO 11140-4  
Compliant

Tested by 3rd Party  
Test Institute



## 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 with audit trails – simple and easy!

## 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

*Verification of  
critical sterilization  
parameters  
beyond traditional  
methods*

## 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

### **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. 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).

#### **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-manufacturers, is referred to as a Bowie Dick Test Program.

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 3<sup>rd</sup> generation of the well-known TrackSense® Pro data loggers.

#### **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 3<sup>rd</sup> generation of the TrackSense Pro reader stations, which enables fast and secure data transmissions.



*Save time by  
changing the  
PCD between  
your test cycles*

# 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)

## How to use the SteriSense® System

- Step 1** Place the SteriSense measuring device in the reader station and open the SteriSense Software
- Step 2** Start the logger by clicking on "Start" and edit the sample number if necessary
- Step 3** Place the SteriSense measuring device inside the steam sterilizer and start the Bowie Dick Test Program
- Step 4** After the test program has 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. The test results will be stored in the software and be included in an automatically generated PDF report.

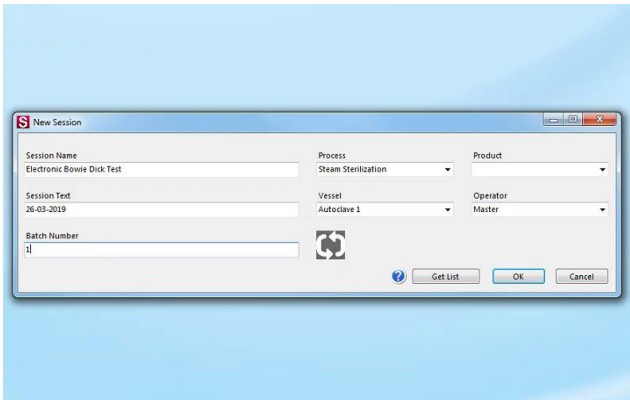
## Utilize the full Potential of SteriSense®

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

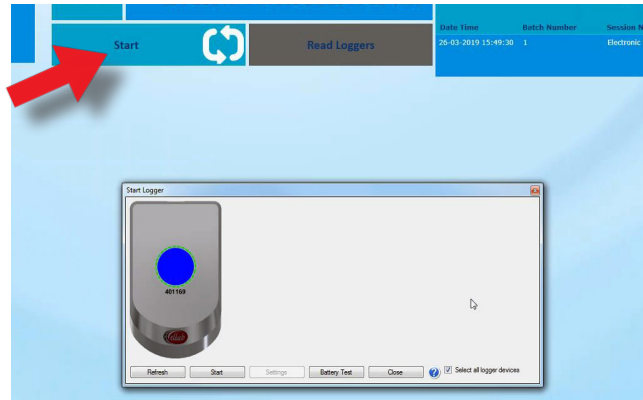
- Be part of validation studies with Ellab Track-Sense Data loggers\*
- Use for batch control during sterilization processes\*
- Perform a vacuum leak test\*
- Perform a check after the sterilizer has undergone service

*The software  
is almost  
autonomous*

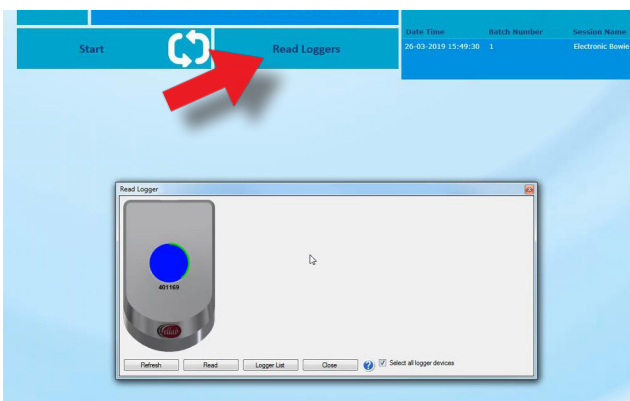
*\*Will require the software package ValSuite® Medical*



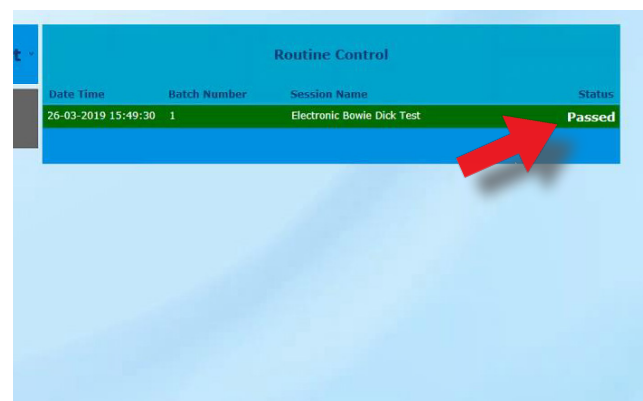
Place the SteriSense measuring device in the reader station and open the SteriSense Software. Define a unique Session Name.



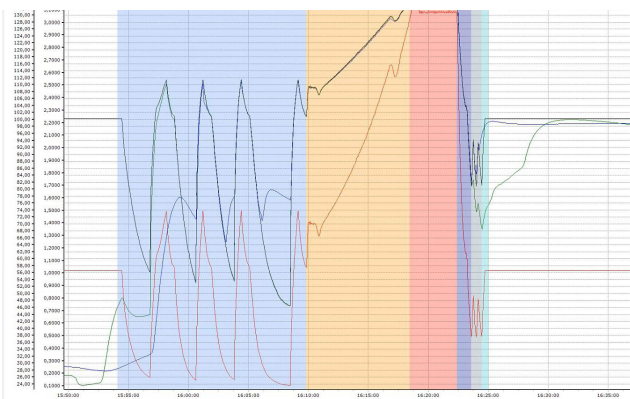
Press Start to activate the SteriSense measuring device, and place the device inside the steam sterilizer.



After the test program has 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.

Operator:	Master		
Process:	Steam Sterilization		
Product:	N/A		
Vessel:	Autoclave 1		
Session Start:	26-03-2019 15:49:38	Session Stop:	26-03-2019 16:41:34
Session Name:	Electronic Bowie Dick Test		
Session Text:	26-03-2019		



ISO 11140-4/17665 Electronic Bowie & Dick	
Name	ISO 11140-4/17665 Electronic Bowie & Dick Test 1
Description	Description
Batch Number	1
ISO standard status	ISO 17665 compliant
<b>Total Test Result</b>	<b>Passed</b>

Input parameters	
Process Start	26-03-2019 15:49:38
Process Stop	26-03-2019 16:41:34
Sterilizer size	60 Liters
Equipment Type	TS-Pro
Data series	Pressure, PCD Core, Ambient

Plateau phase	
Sterilization validation method	Original sample values
Sterilization temperature setpoint	134.00 °C
Upper Offset	3.00 K
Maximum temperature difference	2.00 K
Maximum temperature difference first 60 sec.	5.00 K
Minimum sterilization duration	00:03:00

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

# Designed With Your Needs in Mind



## Purchase or Subscription?

We know our customers have different needs, which is why we have made three 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.

### 3. Subscription Plan\*

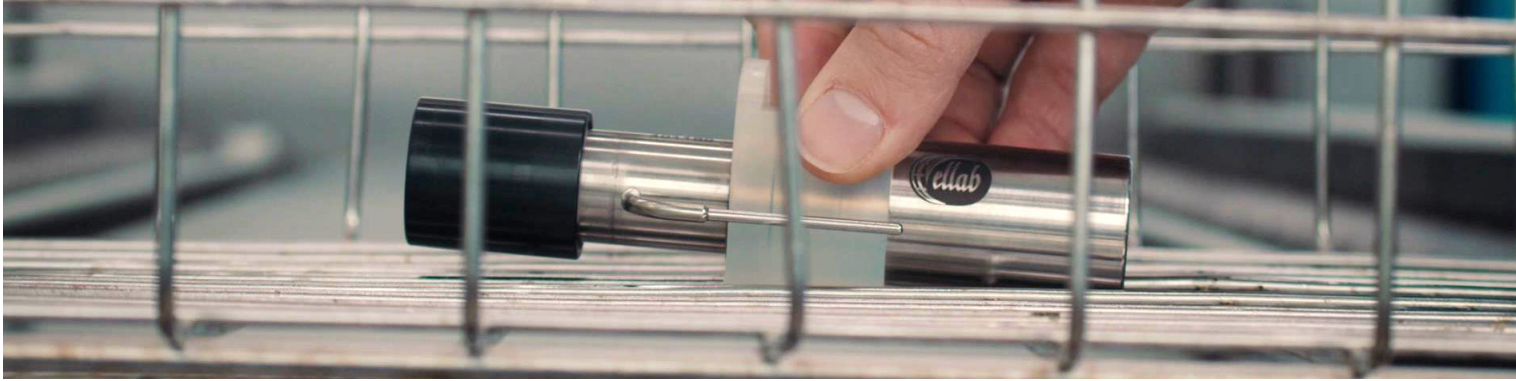
If you prefer complete peace of mind and wish to avoid an up-front investment, this is the perfect plan. You only need to focus on testing. Just before 12 months or 1,000 test cycles of use, Ellab will send you a pre-qualified replacement device with updated calibrations and a new battery. With this plan, you have access to a fully functional device all 365 days of the year.

*\*The Subscription Plan is not available in all countries*

	① Purchase excl. Service Plan	② Purchase incl. Service Plan	③ Subscription 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	1,000

*Different solutions  
for different  
customer needs*

# Technical Specifications



## SteriSense Unit

ISO Standard Compliance:	11140-4:2007, 134°C
3rd Party Test Institute:	SAL GmbH
Type of Sterilizers:	Steam Sterilizers / Autoclaves qualified for sterilization at +134 °C
Measuring Principle:	Piezoresistive / Electrical Resistance
Sensor Type:	Strain Gauge / Pt1000
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)

*Up to 1,000 test cycles between each calibration*

# Ellab



Ellab has been your validation partner since 1949, offering wireless data loggers and thermocouple systems for thermal validation processes.

We serve both small and large companies within the Pharmaceutical, Medical and Food industries. We have solutions for many applications such as sterilization, freeze drying, heat tunnels, pasteurization 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 that are supported by a responsive and competent service team.

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

Ellab A/S is ISO 9001 & ATEX IEC 80079-34 certified. Our calibration laboratories are accredited according to ISO 17025 by DANAK under registration no. 520.



Validation Solutions

**Ellab A/S**  
Trollesmindealle 25  
DK-3400 Hilleroed  
Denmark

contact@ellab.com  
www.ellab.com