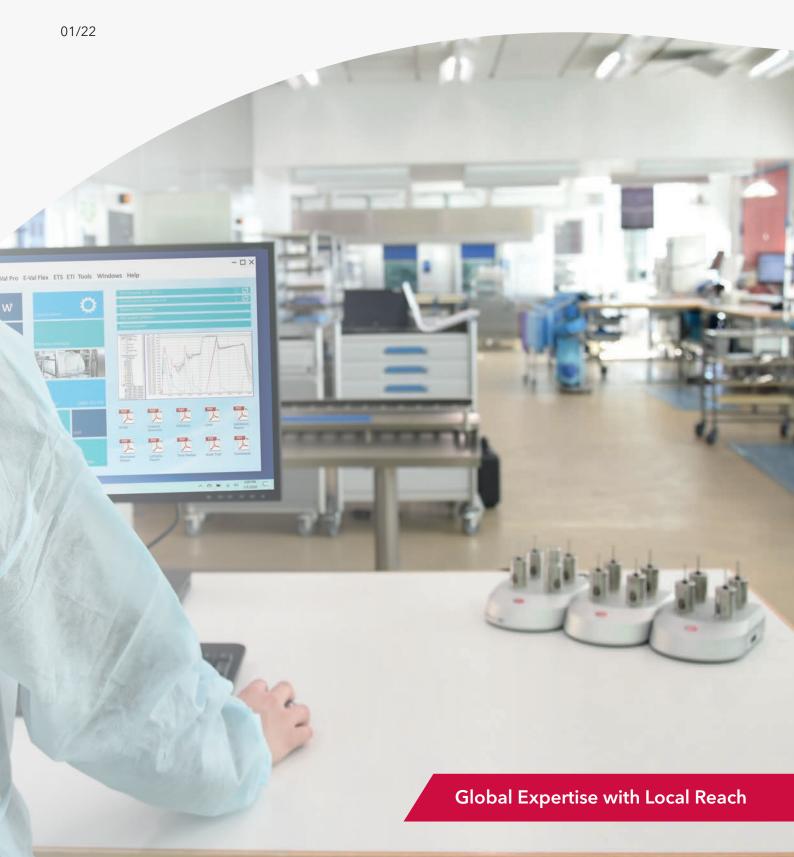
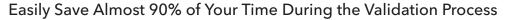
WHITE PAPER



# Easily Save Almost 90% of Your Time During the Validation Process



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#### Abstract/Summary

The saying "time is money" rang truer than ever during our time-saving study between wireless data loggers and cabled thermocouple systems. The study took <u>Ellab's wireless data loggers (TrackSense® Pro)</u> and a third-party cable system from the competitive market and compared operating times and costs. The two systems had an even amount of sensors and had to perform the exact same study.

The results of the study showed staggering timesaving opportunities when using wireless data loggers compared to cable systems, as well as far better return on investment and payback periods. When combined with the superior flexibility and technology, the study showed a clear conclusion in favor of wireless data loggers.







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### Why Should You Consider Switching to Wireless Data Loggers?

When it comes to the choice between wireless data loggers and thermocouple systems, there's always been a few advantages and disadvantages to either solution - but these have shifted over the years, as technology became more advanced.

#### Live Data is no Longer an Issue

What often excluded wireless data loggers from consideration in the past was their lack of real-time data. This point has since become mute, as advanced wireless data loggers have had the option of using live data for over a decade now. This feature provides operators with the best of both worlds in all the benefits of wireless data loggers, while simultaneously allowing them to monitor their processes in real-time.

#### SOP's have Evolved

Another aspect that initially tipped the scale in favor of cable systems were SOP's that historically would mention cable systems specifically. However, wireless data loggers have long since become accepted methods, and most SOP's have evolved to include them - in some cases, even exclusively.

#### The Difference in Equipment Cost isn't Everything

A final crucial hurdle that wireless data loggers faced were the costs surrounding purchasing a system. Cable systems were, and are to this day, somewhat cheaper at first glance when comparing initial investment costs.

However, it is worth mentioning that while wireless data loggers and thermocouple systems serve a similar purpose, operating costs are wildly different. For instance, the study in question compared the costs of wireless data loggers to cable systems over a year, which showed that while wireless data loggers had **41.5% higher** initial investment costs, they also had **86.2% lower** operating costs.

Which meant that within a year, the wireless data logger system would almost have returned its initial investment **twice** when compared to a third-party cable system.



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### How did the two Systems Perform in the Time-Saving Study?

The time-saving study compared two separate systems:

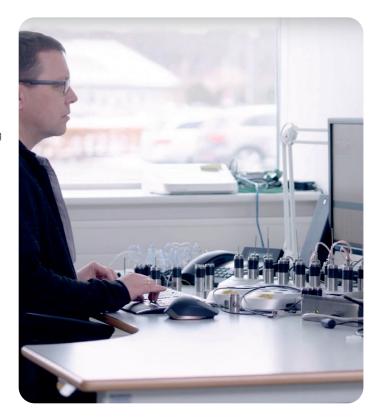
- Ellab's wireless data loggers (TrackSense Pro)
- A third-party cable system from the competitive market

#### **Time-saving Study Setup**

Both systems used 16 temperature sensors and a single pressure sensor and had to solve the same task of qualifying a pharmaceutical steam sterilizer. The study was broken down into 5 critical steps:

- 1. Preparing the study and calibrating test equipment
- 2. Assembling the qualification setup and initiating the process
- 3. Disassembling the qualification setup
- 4. Retrieving data from test equipment, performing data analysis and generating a report
- 5. Recalibrating test equipment

For each task covered by the various steps, the better performing piece of equipment was marked green, while the worse performing piece of equipment was marked red.



#### Step 1

	Preparing the study and calibrating test equipment			
Task no.	Tasks required for TrackSense Pro	Time hh:mm:ss	11.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1	
1	Preparing the study incl. Pass/Fail criteria and battery check	00:20:00	Preparing the study incl. Pass/Fail criteria	00:20:00
2	Calibration setup and calibration start	00:20:00	Preparing modules for calibration incl. checking thermocouples and replacing them where appropriate  Calibration setup and calibration start	03:30:00
3	Printing out data and results  Disassembling calibration setup	00:10:00	Printing out data and results  Disassembling calibration setup	01:30:00
4	Preparing database	00:05:00	N/A	00:00:00

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#### Step 2

Preparing the study and calibrating test equipment				
Task no.	Task no. Tasks required for TrackSense Pro Time Tasks required for hh:mm:ss third-party cable system		Time hh:mm:ss	
5	N/A	00:00:00	Configurating cable system and feeding thermocouples into the autoclave	00:20:00
6	Positioning data loggers and documenting the positions with photos	01:30:00	Positioning thermocouples and documenting the positions with photos	03:30:00
7	Starting data loggers	00:05:00	Starting cable system	00:05:00

#### Step 3

	Disassembling the qualification setup				
Task no.	Task no. Tasks required for TrackSense Pro Time Tasks required for hh:mm:ss third-party cable system		Time hh:mm:ss		
8	Removing data loggers from test objects	00:20:00	Removing thermocouples from test objects	00:45:00	
9	N/A	00:00:00	Removing thermocouples from the autoclave, incl. detangling thermocouples for transportation	01:00:00	

#### Step 4

	Retrieving data from test equipment, performing data analysis and generate report				
Task no.	Task no. Tasks required for TrackSense Pro hh:mm:ss third-party cable sys		Tasks required for third-party cable system	Time hh:mm:ss	
10	Retrieving data from data loggers and placing time markers	00:05:00	Retrieving data from the cable system	00:20:00	
11	Performing data analysis and determining whether Pass/Fail criteria were met	00:05:00	Performing data analysis and determining whether Pass/ Fail criteria were met	05:00:00	
12	Documenting data logger positions using photos from task 6	00:10:00	Documenting thermocouple positions using photos from task 6	01:30:00	
13	Printing and approving/signing report	00:03:00	Printing and approving/signing report	00:03:00	

Tasks 11 and 13 were repeated 3 times

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#### Step 5

Recalibrating test equipment				
Task no Tasks required for TrackSense Pro		Time hh:mm:ss		
14	Preparing, starting and disassembling calibration setup	00:30:00	Preparing, starting and disassembling calibration setup	01:30:00
15	Printing and approving/signing report	00:03:00	Printing and approving/signing report	00:03:00

#### **Summary**

	Qualification Stage - and Total Qualification Labor Time				
Step no.	Step category	TrackSense Pro	Third-party cable system		
		Time hh:mm:ss	Time hh:mm:ss		
1	Preparing the study and calibrating test equipment	00:55:00	05:20:00		
2	Assembling the qualification setup and initiating the process	01:35:00	06:05:00		
3	Disassembling the qualification setup	00:20:00	01:45:00		
4	Retrieving data from test equipment, perform data analysis and generate report	00:39:00	16:59:00		
5	Recalibrating test equipment	00:33:00	01:33:00		
Summary	Total Labor Time	04:02:00	31:42:00		

#### What does this mean for the Bottom Line?

It is only fair to note that the study was conducted by Ellab personnel with a lot of experience conducting similar tests, particularly with Ellab solutions. However, given the drastic difference in labor time, it is safe to assume that the gap between the two solutions would remain large regardless of the operators.

#### So how much Time is Saved with Wireless Data Loggers?

When looking at the numbers acquired from the study, we can conclude: users of a third party cable system, could save up to **87.2% of their time** by switching to wireless data loggers - saving them a total of 27 hours and 40 minutes per study.



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#### Software had the Biggest Influence

The time it took to retrieve and analyze data was what resulted in the largest gap between the two tests. The tools and automation features, or lack thereof, found within the software were crucial aspects that determined whether the task became a breeze or a slow-moving affair.

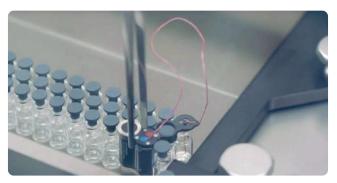
The manual labor and preparation required to obtain the appropriate data and generate the correct reports drastically set back the third-party cable system.

#### Time is Money

When these numbers are converted from time to currency, one can start to see one of the main benefits of running wireless data loggers over traditional cable systems - regardless of the initially higher investment costs.







Investment Costs			
Description	TrackSense Pro	Third-party cable system	
Capital Investment (net prices)	54.100 €	31.635€	

Fixed Costs			
Description	TrackSense Pro	Third-party cable system	
Depreciation over 10 years	5.410 €	3.163 €	
Interest rate 6%	1.623€	949 €	
Total fixed costs per year	7.033 €	4.112 €	

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## Validation & Monitoring Solutions

#### Easily Save Almost 90% of Your Time During the Validation Process

Variable Costs			
Description	TrackSense Pro	Third-party cable system	
Factory calibration of test equipment	2.164€	1.500 €	
Consumables	1.191 €	1.000 €	
Misc.	100€	100€	
Total variable cost per year	3.455 €	2.600 €	

Labor Costs			
Description	TrackSense Pro	Third-party cable system	
Total labor cost per hour	154€	154€	
Total labor time per qualification (hh:mm:ss)	04:22:00	31:42:00	
Time in hours	4,37	31,70	
Cost per cycle	674€	4.897 €	
Annual Number of Qualification- Cycles	25	25	
Total labor costs per year	16.850€	122.425€	
Savings on labor per year	105.575 €	0€	

Footnote: All data and prices are from 2014

Given these results, the difference in investment costs coming in at **22.465 EUR** pales in comparison to the **105.575 EUR** that is saved on an annual basis by switching to wireless data loggers. The drastic difference showcases the ability to almost provide a complete return on investment twice in the span of a single year. Not to mention all the time that is freed up to conduct more qualifications and validations when switching to a setup that is almost 8 times faster.



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#### **Bringing it all Together**

The time-saving study leaned heavily in favor of wireless data loggers for a faster and more efficient process. The reduction in labor costs meant the data loggers have a way shorter payback period that will often justify the higher investment costs.

For a pharmaceutical steam sterilizer, with the same amounts of sensors and measuring points, the study was able to save 87.2% of the time and 86.2% of the operating costs with wireless data loggers, for an initial one-time cost that was only 41.5% higher than cable systems.

While this study was of a steam sterilization process, the majority of the differences in time can be translated to other applications. Most of the issues were related to the software and handling of cables, which would apply to almost every scenario.

#### Cost Isn't Everything

In addition to the difference in labor intensity and costs, there are other areas where wireless data loggers outshine traditional cable methods - mainly due to the differences in technology. These areas include a higher accuracy, less drift-over-time and a faster response time.

#### **Higher Accuracy**

With wireless data loggers come one of the biggest benefits, RTD measuring elements. RTD's provide the highest accuracy possible and are often the go-to solution for applications that require accuracies around  $\pm$  0.05 to  $\pm$  0.1 °C.

Cable systems, however, use thermocouples which have rather poor accuracy when compared to RTD's. These accuracies typically fall between  $\pm$  0.2 to  $\pm$  0.5 °C, up to 5 times worse than wireless data loggers.

#### Less Drift-Over-Time

Due to the design of the RTD sensors, they have a very small drift-over-time. This means that they can produce stable readings for longer, without the need for constant calibrations.

Thermocouples have a relatively high drift-over-time, as they are more susceptible to heat- and chemical exposure as well as mechanical damage, all of which can cause inhomogeneity in the conductor wires, thereby making readings unreliable. To counter this problem, thermocouples must be calibrated and adjusted frequently, which spawned the original need for pre- and post-calibrations.

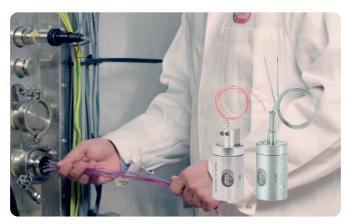
#### **Faster Response Times**

RTD sensors generally have a faster response time. This is mainly due to the placement of the sensor element being closer to the tip, and the surrounding metal material that easily conducts heat.

Thermocouple sensors on the other hand generally have a slower response time due to the time it takes to reach thermal equilibrium. Additionally, the material surrounding the sensor tip on thermocouples is typically made of plastic, which is far less effective at conducting heat.

For thermocouples to reach a higher response time than RTD sensors, they would need to be equipped with a "naked tip" - thereby stripping the sensor of its protective layer. While naked tip sensors are valid and useful in certain scenarios, these sensors are at higher risk of drift. There are also certain applications that would cause damage to equipment if naked tips were to be used, such as steam sterilization or other processes with high differentials in pressure or vacuum.

**Footnote:** Read more in Ellab's <u>6 key Differences Between RTD's</u> <u>and Thermocouples</u> white paper



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#### **Getting the Best Tools for the Job**

The wireless data loggers used in the time-saving study were Ellab's very own TrackSense® Pro. Flexible and reliable, TrackSense Pro have high quality data loggers for all applications and situations. The system is equipped with interchangeable sensors and the option for real-time data.

With immensely accurate measurements and fast response times, the TrackSense Pro family of wireless data loggers is the go-to solution for all qualification and validation needs.

#### Interchangeable Sensors

Whether temperature, relative humidity, pressure, conductivity, CO2 or vacuum measurements are required, TrackSense Pro has a sensor that does the job. All TrackSense Pro sensors are <u>interchangeable</u>, meaning they can be unscrewed and changed whenever necessary. A data logger that initially came with a temperature sensor can be equipped with a pressure sensor, and vice versa - all while maintaining complete traceability, as all information is stored within the sensor.

#### Leading Validation and Calibration Software

The biggest difference between the two systems in the study was due to the software. Ellab's ValSuite® software is fully optimized for ease-of-use, flexibility and to reduce the amount of manual labor required for accurate results. The system is FDA 21 CFR Part 11 compliant and can effortlessly generate the required reports with pass/fail results. Other features include:

- One software platform for all Ellab qualification, validation and calibration equipment
- Data analysis and calculation tools
- Complete data integrity
- Can run from a stand-alone PC or through a network
- Windows security option
- And much, much more...

#### Still in Favor of Cable Systems?

If thermocouples are required for a specific process due to their high measuring range or pin-point sensor tip placements, Ellab has the most versatile cable system available. The E-Val™ Pro is a light and portable thermocouple system with a touch-display – ready to take on any thermal process.



The E-Val Pro thermocouples are equipped with USB connectors, allowing them to be effortlessly plugged in to- and removed from the system. The module can function as a stand-alone unit or in a large network, all password protected and clean-room compliant. And unlike most other cable systems, the E-Val Pro can even be equipped with sensors to measure other parameters like relative humidity, pressure, CO2 and much more.

However, what really sets E-Val Pro apart from the competition is the <u>ValSuite software</u>. Much like <u>TrackSense</u> <u>Pro</u>, the E-Val Pro uses the same software and has just as easy a time analyzing, processing and reporting on valuable data. This also means that the difference in labor time between TrackSense Pro and E-Val Pro is far smaller than when compared to third-party cable systems, as a significant amount of the time saved was a direct result of the ValSuite software.



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