



Requirements for laboratory control systems:

Have you thought about what type of temperature logging you need for your operation?

Different operations need different solutions

Different operations have different requirements in terms of the type of check that should be in place and the documentation that should be generated. When you look at temperature logging, there are various options, depending on the scope that you are considering and your budget.

There is much to gain by implementing the right type of solution. However, it is important that your requirements give rise to the correct solution, depending on the following factors:

- Is your operation a large one or a small one?
- Do you need the option to expand the system with more measurement points or multiple labs?
- Is it just temperatures that you need to log, or do you need more sensor types?
- Does the system need to be able to sound an alarm and send messages to various people in the event of any deviations?

There are many questions to which answers need to be found before you find the correct system for your precise operation.

Here, we will attempt to provide a summary of the most common options from which to choose. Do a little investigation into the benefits and drawbacks of the various options so that as laboratory manager or quality manager you are able to choose the option that best suits you and your operation.

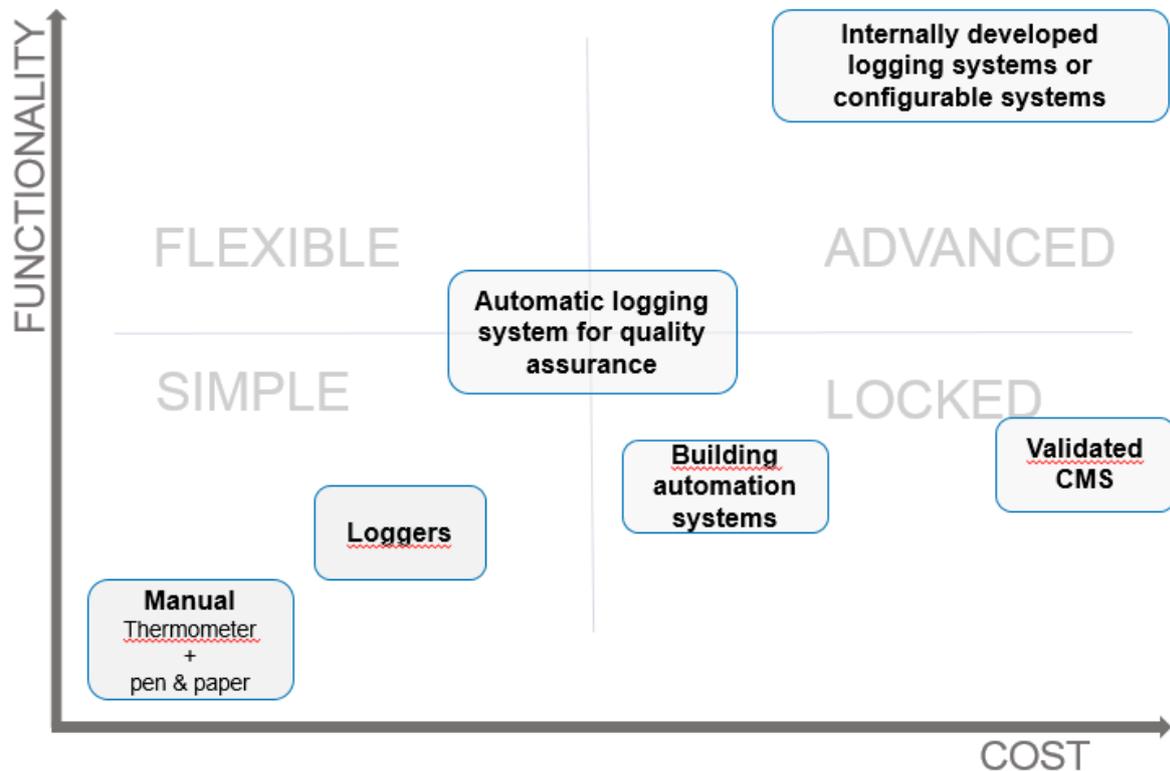
The choice on offer may seem like a jungle of various options, but when you look at the various solutions and map them to your own requirements, it tends to be fairly clear in the end which solution is right for you.

Below, we describe the options in somewhat general terms, as well as their pros and cons.





Categorisation of temperature logging options



Manual temperature reading:

- little (or no) investment
- work-intensive (expensive in terms of work time)
- performed far too infrequently (typically once per day)
- high risk of missing/making an error (the human factor)

Loggers:

- record the temperature continuously
- have to export to a computer (be emptied of data)
- trigger no alarm in the event of any deviations

Property systems:

- record the temperature continuously
- may trigger an alarm in the event of any deviations
- very little flexibility
- expensive to install
- do not satisfy laboratory requirements such as calibration and traceability





Validated CMS (continuous monitoring systems):

- log the temperature continuously and trigger an alarm in the event of any deviations
- satisfy all the mandatory requirements for quality assurance in production and laboratories, particularly in terms of documentation
- very expensive and time-consuming to buy and install
- very little flexibility (or none at all)
- minimal functionality; only the essentials
- expensive to maintain

Internally-developed or configurable logging systems:

- tailor-made; meet the exact specifications that you set up as requirements, neither more nor less
- flexibility: can be modified at any time as the requirements of the operation change
- require in-house (or hired) engineering resources
- usually require a significant investment initially
- often take a long time to develop and, above all, to test/verify
- sufficient knowledge required in order to write a requirements specification

Automatic systems for continuous logging:

- control of logging 24/7 and every day of the year
- complete traceability
- support for advanced functions such as report generator, alarm distribution, calibration, etc.
- flexibility: can be extended as the requirements of the operation change
- access to support and service organisation
- often require an initial investment or hire contract, as well as a licence fee
- certain desired specialist functions may be missing.





Different types of lab described

In a small laboratory with just two or three refrigerators or freezers, manual temperature reading may suffice. These can be written down together with the date, time and signature and then the documentation can be stored in binders. Of course, this is only an option if it is felt that there is no need for an alarm in the event of a deviation as the samples stored are not of any great financial value, or there are other reasons why no alarm is required in the event of a deviation.

Laboratories with a limited number of measurement points and no requirement for an alarm in the event of a deviation may instead choose to install Temperature Loggers in their freezers. With these, the temperature is logged several times a day, depending on the chosen logging interval. Depending on the data storage possibilities (memory capacity) in these Loggers, the data must be exported from the Logger to a computer at regular intervals, for example every week or fortnight. Documentation on variations in temperature over time is then stored on the computer, which means that reports and quality audits can be created. However, the main purpose of so-called Temperature Loggers is to log the temperature in transit, when it is a matter of maintaining an uninterrupted refrigeration chain when transporting refrigerated items from A to B.

However, most laboratories require logging in real time, i.e. continuous logging of temperatures that also triggers a warning or alarm in the event of any deviations from normal values.

The simplest automatic temperature measurement system is formed by connecting temperature sensors to existing property systems. Such a system often requires fairly extensive installation work, whereby cables are run from the property's "engine room" to all the refrigerators and freezers in the lab. As well as the high cost of the installation work, the system also offers very little flexibility. Adding new measurement points or moving refrigerators and freezers around the lab is both difficult and expensive. Care also needs to be taken to ensure that the measured values are documented. Does the property system really satisfy the quality requirements for traceability, calibration and data integrity imposed by the laboratory's quality procedures? A property system is of course primarily for the property: keeping track of water, heating, cooling and ventilation.

If your operation is the "production" of, for example, pharmaceuticals and you would like a turnkey system complete with all the documentation required for certification and accreditation in accordance with your quality standards, then a "Validated CMS" may be worth considering. Here, the system is supplied with complete quality documentation, and everything is validated and ready immediately following installation. However, the price tag on these systems is many times greater than for other logging systems – often by a factor of ten or twenty. You should also be prepared for the fact that these systems may not be as flexible and modern as other logging systems, as every function is verified and validated. The validation documents are very comprehensive and therefore expensive to produce, which of course means that suppliers of such systems have to limit functionality and the intervals at which the systems are updated for reasons of both cost and quality.





Laboratories with very specific requirements for special functionality may perhaps consider developing their own systems of continuous logging. This will obviously provide a very flexible system, and one that will hopefully offer the specific functionality that is being sought. If you are considering developing a system yourself, you should have a very good idea of the functions and requirements of the system. You need to be prepared for the fact that it takes time to develop products and systems. It may make things easier if you have your own development engineers who specialise in electronics and programming. If not, you will need to engage consultants for the development. However, ultimately it is only those with “extremely specific (and almost impossible) requirements for functions” who choose to develop systems themselves; most projects never get off the ground because of the waiting time or the cost of development. The future maintenance of the system also needs to be taken into account. It is always difficult to predict what new functions and requirements will emerge in the future. Do you really have the resources to administer a system that is such an important part of your quality assurance work?

However, the vast majority of laboratories are somewhere in the middle in terms of requirements, not out in the extremities of functionality or specifications. There are clear requirements for security, traceability and efficiency. It is important to satisfy the procedural requirements for quality assurance in laboratories, but flexibility is also important – the ability to log many different types of sensor. You may wish to connect a number of different laboratories within a hospital or company to the same system in order to provide a good overview of the quality of the operation. It is also important for the system to be scalable, i.e. that you can begin on a small scale and then expand:

- with more measurement points
- with more departments
- by giving more users access to log into the system
- etc.

It is important that the system is always able to keep up with developments in computers and operating systems, and for new versions of the system software to be released that will support new sensors and new accessories such as tablets, smartphones, etc. An automatic system of continuous temperature logging satisfies the vast majority of regulatory requirements for quality assurance in laboratories. This is a system that has been developed for logging and quality assurance purposes, which guarantees that it has the functions that most labs expect and need.





Summary

The most flexible solution is also the one that is suitable for most types of operation. When choosing, you obviously need to review your own requirements for functionality, security, resource needs, flexibility and costs.

What should I do now?

Once you have found out which solution is best for your own lab's logging requirements, you need to find out how much such a solution may cost.

We have produced a guide that will help you to find out what investments you need to consider when you wish to secure quality in your lab.

Please feel free to click on "Investments in control systems".

My name is Per Hammargren and I am the Sales and Marketing Manager at ICU Scandinavia and the author of this document. I am one of the founders of ICU Scandinavia and I have an IT background. Since the start back in 1992, we at ICU Scandinavia have helped thousands of laboratories, hospitals, private clinics, pharmaceutical companies, logistics companies, fertility clinics, etc., worldwide by providing automatic temperature monitoring systems.

ICU Scandinavia AB is a leader in automatic systems for monitoring, log and quality assurance in laboratories and for food safety. Our systems, Boomerang and Coolguard, meet the regulatory requirements for logging and documentation for laboratories, cold storage facilities and food safety. In 1998 we were pioneers in automatic temperature monitoring and log. Today our experience within the field is unbeatable and we work together with world leading customers and partners, in order to assure quality and security in laboratories and restaurants all over the world. ICU Scandinavia holds offices in three countries: Poland, Switzerland and in Sweden where our headquarters is located. www.icuscandinavia.com

