

Calibration, Temperature Mapping and Qualification services

Calibration services

1040 / 1041

Our calibration services

ICU Scandinavia performs qualified calibration services for temperatures in laboratories and restaurants. We provide in-system calibration at your own premises, documented with complete calibration protocols for full traceability. When calibrating your temperature sensors in Boomerang, you ensure that all data is adjusted and show the actual value, in Boomerang 3.0 you have instant access to calibration certificates.

Our calibration personnel are trained and certified by our partner Pentronic, accredited laboratory AKL0076, being accredited according to ISO/IEC 17025.

Traceability

On a yearly basis, our temperature references are calibrated at accredited laboratories against ITS-90. This procedure meets the requirements of traceability stated in ISO/IEC 17025.

What is calibration ?

To calibrate; is to find out the deviation between true temperature (ITS-90) and the temperature measured.

Do you need calibration ?

Most temperature monitoring equipment are manufactured according to norms or standards that have very tight tolerances, this allows for temperature measurements with good results - even without calibration.

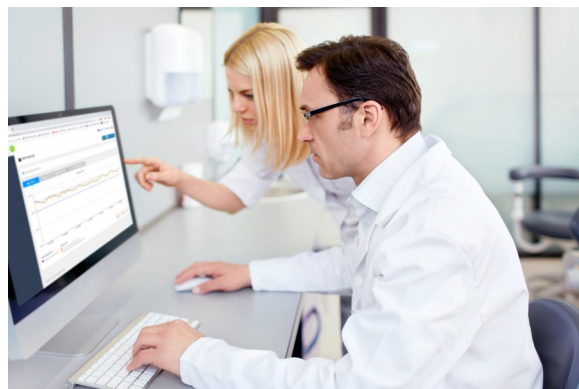
Today many operations experience increasing demands on traceability in terms of quality assurance, environmental demands, new regulations etc., in order to fulfil these kinds of requirements and to obtain complete documentation on your systems, qualified calibration of your system is the only solution.

Qualified calibration of your measurement equipment leads to less uncertainty in your measurements. Your measurement accuracy will be assured by calibration protocol and certificates for full traceability.



Contact

Please contact your Boomerang sales for any calibration questions and for a detailed business proposal performing an in-system calibration at your own premises.



Temperature mapping services

I055 / I056

Our temperature mapping services

ICU Scandinavia performs qualified Temperature Mapping services for refrigerators, freezers and cold storage rooms, documented with complete mapping protocols for full traceability.

Traceability

On a yearly basis, our temperature references are calibrated at accredited laboratories against ITS-90. This procedure meets the requirements of traceability stated in ISO/IEC 17025.

What is Temperature Mapping?

A temperature mapping study is the activity to measure and document the temperature distribution within a room or a chamber by locating the hottest and coldest spot.

WHO states the importance of temperature mapping:

Temperature mapping is the process of recording and mapping temperatures within three-dimensional (3D) spaces, such as cold and freezer rooms, dry storage areas, and refrigerator and freezer units.

Temperatures will not be the same everywhere within the storage area. Whether in a small refrigerator, a well-designed cold or freezer room, or, particularly, in a large warehouse, temperatures can vary much. Temperatures in the corners will most likely be different from those measured in the centre or close to cooling units. For example, temperature will be at its coldest next to the cooling fans and likely to be at its warmest close to the doors.

Temperature mapping and temperature monitoring are integral to the appropriate storage conditions for pharmaceuticals.

Good manufacturing practice (GMP) for pharmaceuticals recommend regular temperature mapping in all types of cold storage, and especially before you start to use new cold storage equipment.

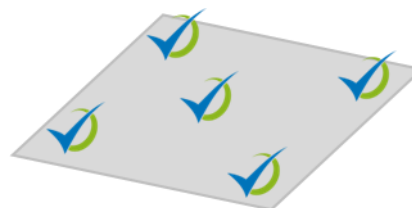
Our standard mapping options

I055 5-point mapping on each shelf in ultra-low freezer.

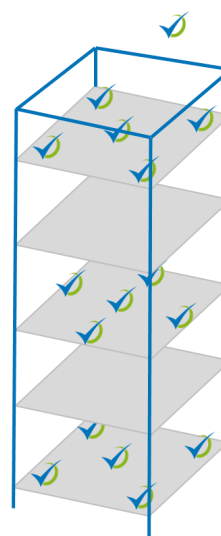
I056 15+1 point mapping in refrigerator or freezer (down to -30°C)
(for other specific requirements please contact your Boomerang sales representative)

Contact

Please contact your Boomerang sales for Temperature Mapping questions and for a detailed business proposal performing a mapping in your own premises.



Example: sensor placing for mapping on one (1) shelf



Example: 15+1 point mapping



Installation & Operational Qualification

1043 / 1044 IQ & OQ

Our qualification services

ICU Scandinavia performs qualification services for Boomerang customers that wants to validate their operations.

What is IQ & OQ ?

Installation Qualification (IQ) verifies that the system being qualified have been delivered, installed and configured in accordance with the customer's order.

An IQ from ICU Scandinavia includes:

- Verification that all equipment is installed according to the customer's specification. e.g. all sensors are installed in the correct equipment etc.
- Verification that the server/pc meets the requirements for the Boomerang system
- Verification that all Software is installed in a correct way
- Verification that the system is configured according to the customer's specification. e.g. Log time, alarms, distribution of alarms, backup settings etc.

The Operational Qualification (OQ) ensure that the system operates according to the configuration of the system. Installation qualification (IQ) shall be approved before an OQ can be made.

An OQ from ICU Scandinavia includes:

- Verification that the systems sensors measure the values correctly e.g. that all sensors are calibrated
- Verification that the alarm function is working correctly
- Verification that the alarm distribution is working correctly
- Verification of traceability
- Verification the reports and export of data can be made
- Verification that the backup function is working correctly
- Verification that the Boomerang application is working correctly

Do you need IQ & OQ ?

It is important to understand the difference between "Validation" and "Qualification".

Validation - refers to the total life cycle of a product or process, through development, through use and maintenance. The Owner is responsible for validating their processes (personnel, equipment, methods, SOPs) to ensure compliance with regulations (GMP/GLP/etc.)

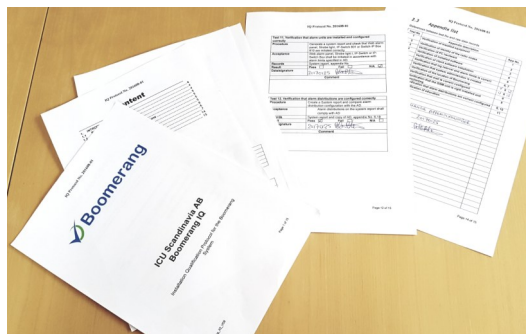
Qualification - is a part of the validation process which verifies module and system functional performance prior to being placed on-line and thereafter according to a standard operating procedure.

Boomerang customers requiring IQ & OQ are typically production sites, eg. pharmaceutical producing sites, very often there are cleanrooms involved. Accredited laboratories ask for IQ & OQ.

In general, anyone who wants to validate their operations can consider making Installation Qualification and Operational Qualification on their Boomerang installation. IQ and OQ will establish documented evidence which provide a high degree of assurance that the process meets the predetermined specifications and quality attributes.

Contact

Please contact your Boomerang sales for any IQ/OQ questions and for a detailed business proposal.



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