LABFISH
CLINICAL TRIAL SUPPLIES

WE ARE DEDICATED TO QUALITY – SUPPLIES FOR CLINICAL TRIALS

EXPLANATION SHEET

TOPIC

CONTINUOUS TEMPERATURE MONITORING (CTM)

Monitoring storage conditions of samples and Investigational Medicinal Products (IMP) **is a requirement in every clinical trial** for all kinds of storage environments from ultra-low freezers (-80°C), over general freezers (-20°C) and medical refrigerators (+2°C - +8°C) up to storage at ambient temperature (20°C).

It is still quite common to use min/max thermometers which are read out on a daily basis, though min/max thermometers are increasingly being replaced by the far more sophisticated **temperature data loggers** (or: Temperature Monitoring Devices - TMD).

BENEFITS OF DATA LOGGERS

Temperature data loggers **have many advantages over min/max thermometers** including:

- Automatic data collection in electronic format – simply connect the logger to a USB port and download the temperature data as PDF file.
- No more need for taking daily temperature readings and noting the values in handwritten lists.
- Data is recorded in **short intervals** of usually 5 to 15 minutes – **even outside working hours and at night.**
- In case of a temperature breach, **the logger records data documenting the complete event of the breach including the length as well as the temperature profile.** Min/max thermometers can only show the maximum or minimum value of the temperature breach and provide no information on the length and the temperature profile.

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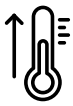
EXPLANATION SHEET - CONTINUOUS TEMPERATURE MONITORING (CTM)

CASE STUDY

SCENARIO MIN/MAX-THERMOMETER VS. TEMPERATURE DATA LOGGER

In this scenario, a high value Investigational Medical Product for a clinical trial is stored in a medical refrigerator at 5°C with permitted storage conditions ranging from 2°C – 8°C. The temperature is monitored every morning of each working day. It is Friday afternoon and a member of the staff needs to find a specific box in the refrigerator which takes longer than expected and the door is open for five minutes. During this time, warm air enters the refrigerator and the temperature probe of the min/max thermometer is in the

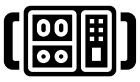


stream of the warm air and reacts fast – the temperature reading is already 15°C. The member of staff has found the medication, closes the door and eventually leaves for the weekend.

On Monday morning, the temperature is read out and shows a maximum temperature of 15°C, way outside the storage conditions. The site immediately contacts their monitor and asks what to do. The monitor asks for all available data which in result is: Between the readings on Friday

and Monday – full 3 days – the maximum storage temperature was 15°C. There is no further information so the worst case needs to be assumed: The medication was stored at a far too high temperature for 3 days. The sponsor's QA department is contacted and can only conclude that the medication needs to be destroyed

and replaced as the maximum storage time at this temperature is limited to 24 hours. Apart from the large financial loss, the replacement will take several weeks leading to delays in the trial.



Had a Temperature Monitoring Device been used, the outcome would have been far better: The temperature data would have shown that the temperature breach was only during a period of a few minutes while the door was open, after the door

was closed, the temperature returned to the correct storage temperature. The medication could still be used, a replacement would not be necessary. A large financial loss and a delay in the trial would have been avoided.

Similar scenarios - in many variations – still occur frequently during clinical trials. Resolving the issues usually involves several people both at the site as well as the sponsor costing valuable resources.

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EXPLANATION SHEET - CONTINUOUS TEMPERATURE MONITORING (CTM)

OUR SERVICES

⟶ LOGGER PROGRAMMING SERVICE

LABFISH programs the logger **according to your specifications** – simply forget about user training and any software issues!
Throughout the rental period LABFISH offers user support for any questions related to operating the logger or retrieving and storing data.

⟶ CALIBRATION OF TEMPERATURE DATA LOGGERs

Temperature Data Loggers should always have a valid calibration to ensure confidence in the data. After the initial calibration, a recalibration period of 1 year is a good and very common guideline to comply with FDA/EMA Good Clinical Practice (GCP) and Good Manufacturing Practice (GMP) guidelines. **LABFISH offers the full range of calibrations services for temperature data loggers for the temperature range from -80°C to +50°C in LABFISH's in house calibrations facility.**

⟶ reCAL EXCHANGE SERVICE

LABFISH offers the reCAL Exchange Service which is the most convenient way to always have a temperature data logger at the site with a valid calibration:

1. We keep track of the calibration expiration date,
2. Get in touch with the site in time
3. And provide a freshly calibrated instrument.
4. In exchange, we pick up the "old" instrument.

Keeping up with your calibrations has never been easier.

⟶ INSTALLATION SERVICE

Temperature data loggers for ultra-low freezers (-80°C) measure the temperature via an external temperature sensor that must be placed and fixed in the ultra-low freezer.
The temperature sensor is inserted through a port on the back of the ultra-low freezer.
LABFISH offers the correct mounting and positioning of the temperature sensor before delivery of the unit, so that the site can start measuring right away.

SUMMARY

⟶ GOOD ARGUMENTS FOR CONTINUOUS TEMPERATURE MONITORING

1. Min/Max thermometers are unreliable devices delivering limited information and are not state-of-the-art.
2. Temperature data loggers provide a detailed overview over temperature profiles.
3. Continuous temperature monitoring is the key to storing valuable medication as well as temperature sensitive PK samples and avoiding unnecessary workload as well as preventing trial delays.

RESOURCES

EMA (European Medicine Agency): ICH Guidelines for Good Clinical Practice E6(R2) Sections 5.18.4, 8.2.11, 8.2.12, 8.3.6, 8.3.7
1. EU GMP (Chapter 3)
2. FDA 21CFR606.60
3. FDA 21CFR820.72
4. FDA 21CFR211.68