Tec4med Cryoport Systems CRYOGENE

Software Supported Warehouse & Freezer Mapping Services

Temperature mapping for warehouses, cold rooms and freezers

Tec4med · Cryoport Systems · Cryogene



Why temperature mapping is essential



WHY MAPPING MATTERS

Prove the space is controlled

- Map each storage area or freezer before use and repeat the study at defined intervals to demonstrate temperature uniformity.
- Use the results to identify hot and cold spots and select the right locations for continuous monitoring.
- Define logger quantity, placement, study duration, operating conditions and acceptance criteria in an approved protocol.



WHAT AUDIT READINESS REQUIRES

Make every decision traceable

- Apply a risk-based approach aligned with the relevant GxP requirements and the intended use of the area.
- Deploy calibrated data loggers and capture critical events such as door openings, loading and defrost cycles.
- Monitor the study as it runs so deviations can be investigated before time and data are lost.
- Deliver traceable data, documented deviations and a clear qualification report that is ready for audit.

Demonstrate temperature uniformity • identify hot and cold spots • document deviations and qualification results

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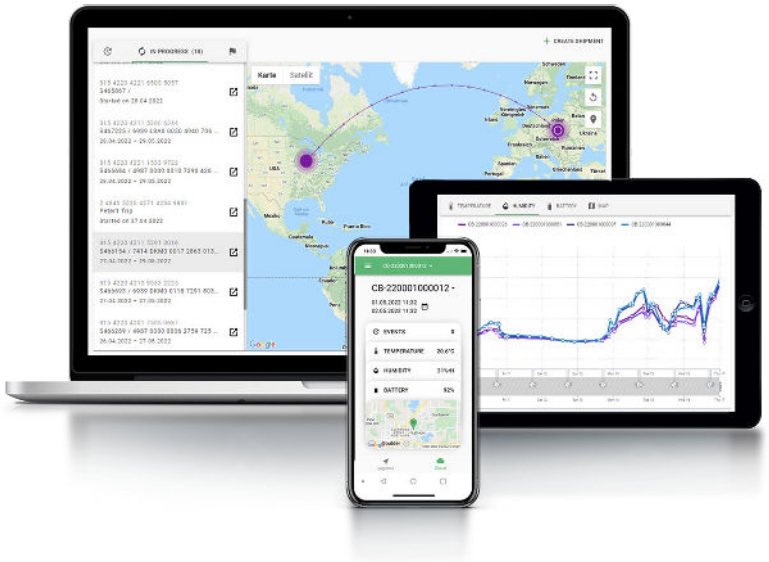
Tec4med as part of Cryoport

Member of the Cryoport Inc. since 2023



- Tec4med is a provider of supply chain visibility and cold chain solutions.
- We serve the biopharma, animal health, and reproductive medicine industries.
- Our systems include IoT sensor technology, supply chain visibility software, connected shippers and extended services.
- Tec4med operates in accordance with recognized frameworks for data integrity and quality assurance, including GxP, 21 CFR Part 11, GAMP 5, ISO/IEC 17025, and the ALCOA+ principles. Tec4med is ISO 9001 certified.
- Tec4med is part of Cryoport Systems, supporting the global life sciences.

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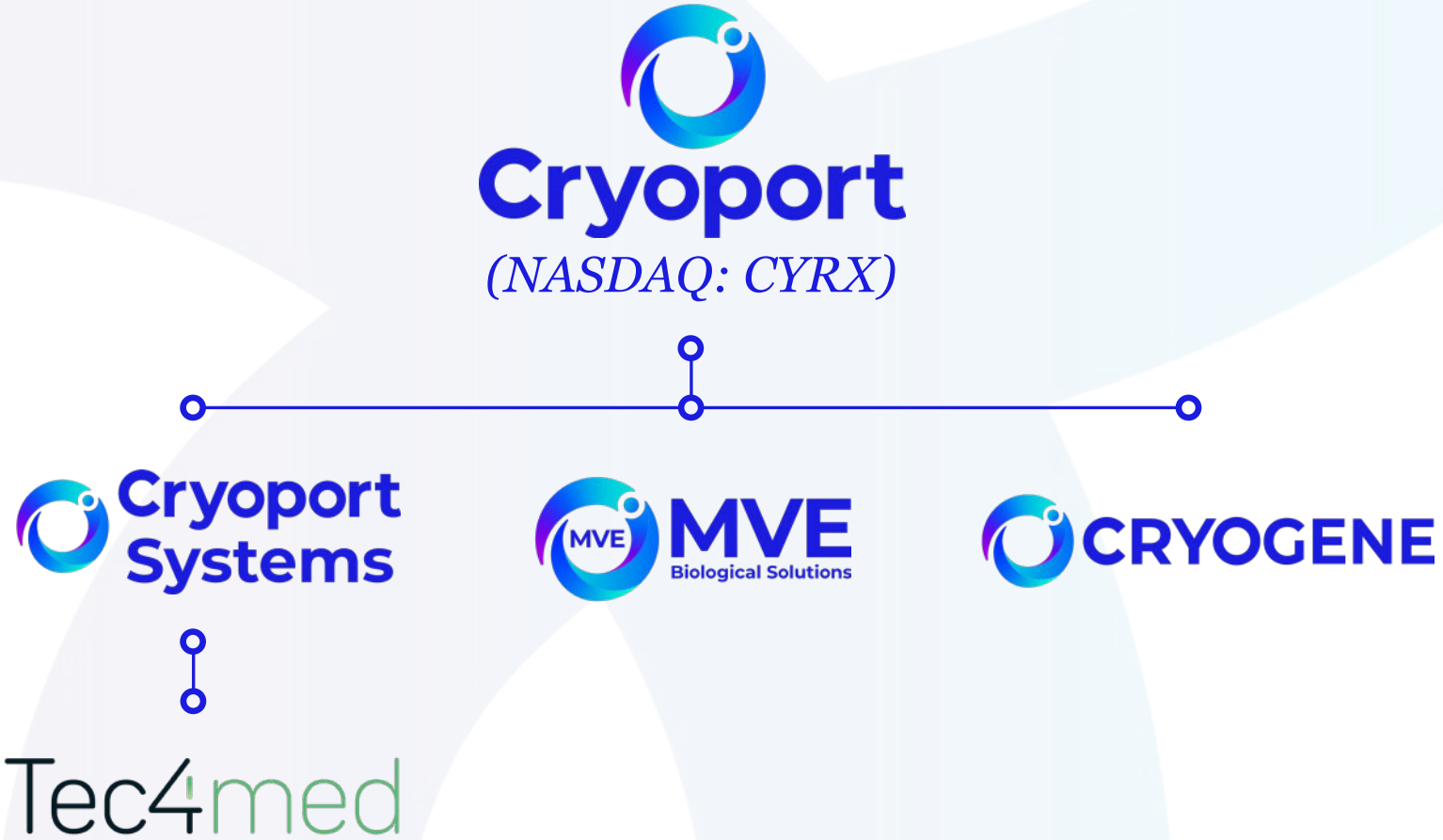
Cryoport, Inc. Organization



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On-Site Mapping & Monitoring Services

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Software-enabled mapping services

01 **Intake & site survey**



02 **Mapping protocol**



03 **Sensor plan & calibration**



04 **Field engineers on site**



05 **Live mapping**



06 **Report & QA approval**



Scope & constraints

Protocol & criteria

Placement & traceability

Controlled installation

Live data & intervention

Report, review & approval

ONE CONNECTED EVIDENCE CHAIN AND SOFTWARE PROCESS

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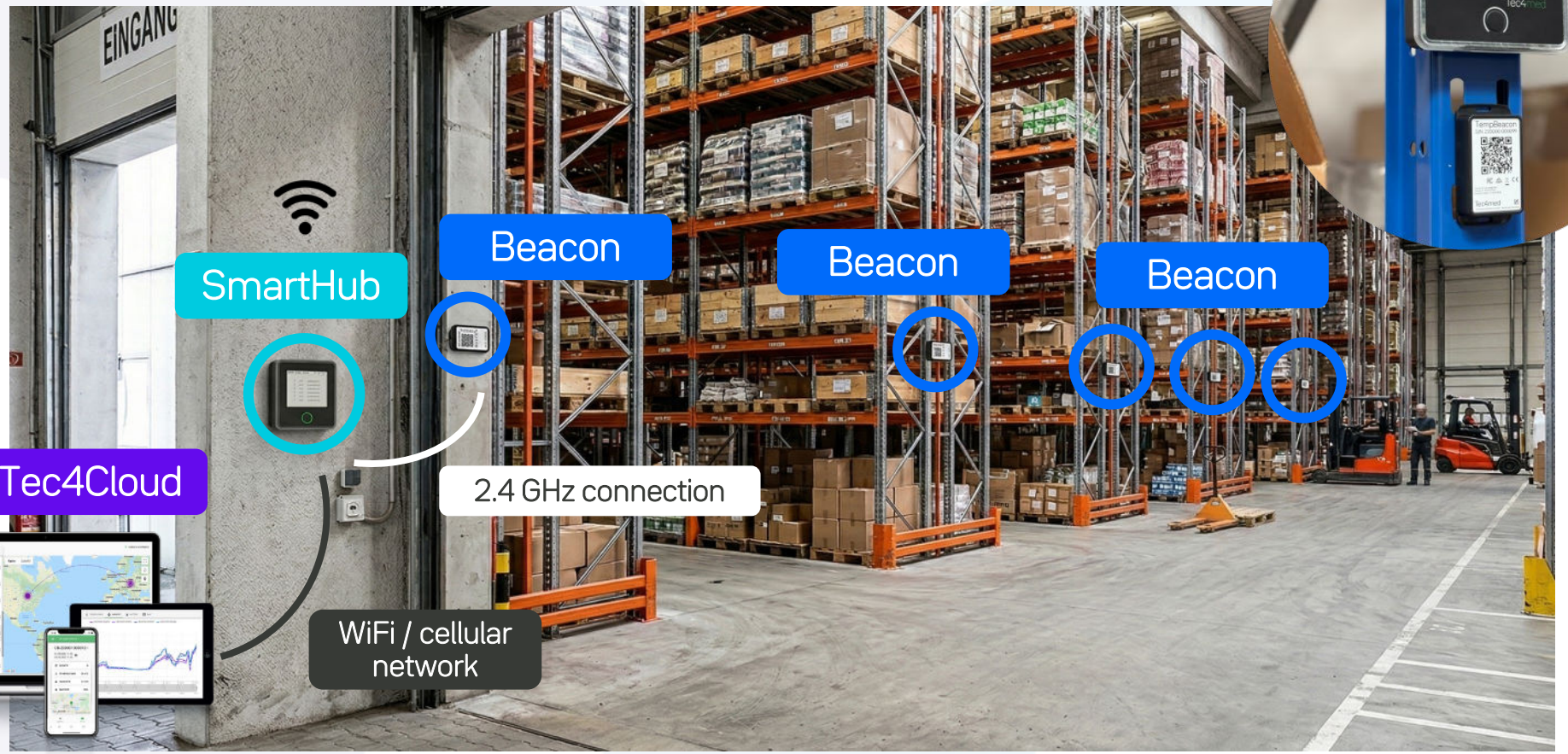
Our On-Site Mapping for Warehouses

- Beacon measure temperature **at various cold and hotspots** and humidity at given setpoints
- SmartHub acts as a **gateway** and sends data from the Beacons to Tec4Cloud
- Tec4Cloud provides **digital mapping protocol, live mapping** services + **reporting**



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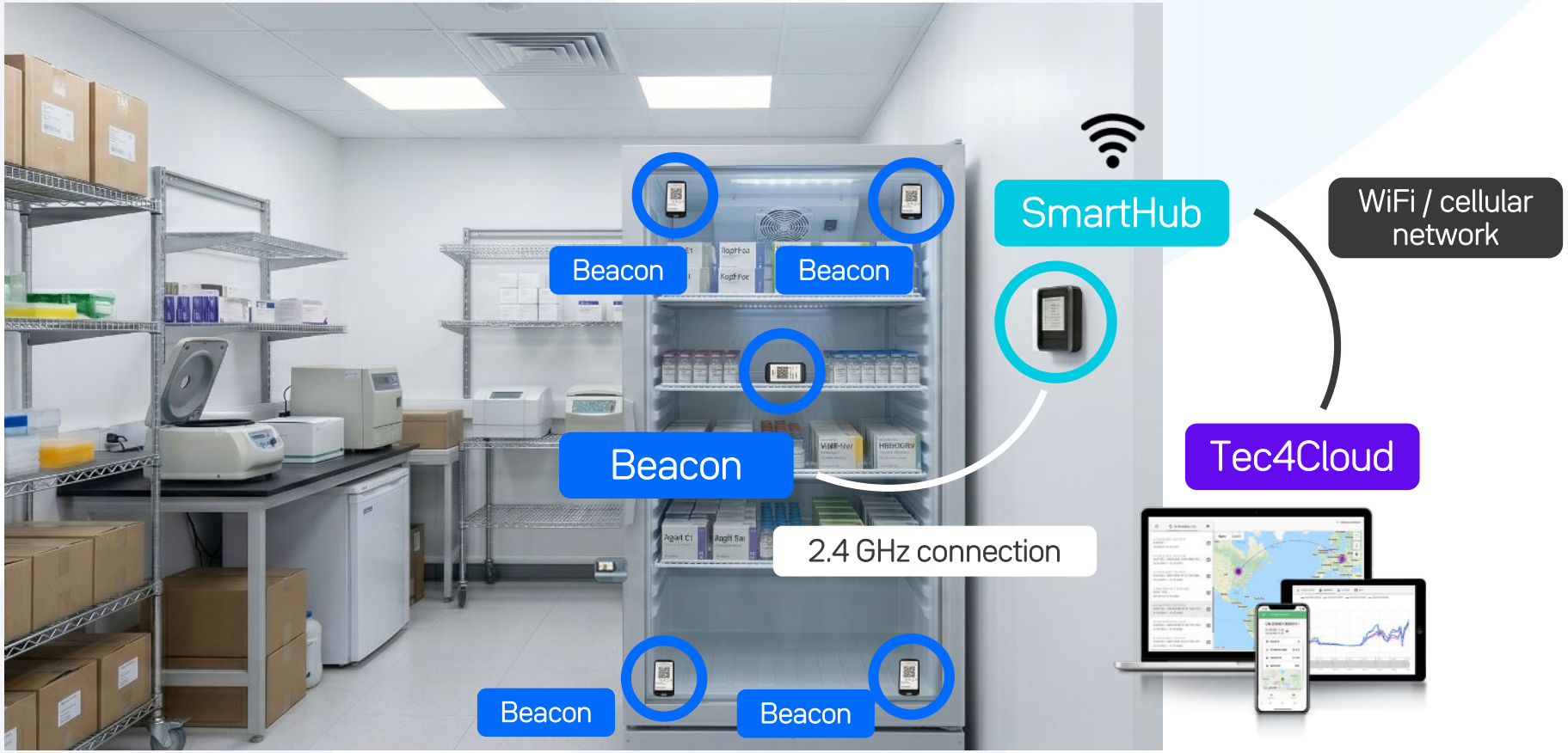

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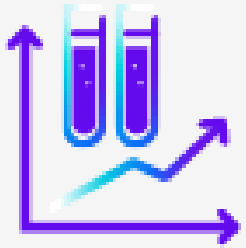
After the study: staying qualified



Requalification

Mapping is not a one-off.
Studies are repeated on a defined cycle, and again after any significant change to loading, airflow, refrigeration equipment or set-point. We schedule it, run it, and keep the evidence current.



Continuous mapping

The study shows where the hot and cold spots actually are. Tec4med sensors then stay at exactly those points, so routine monitoring watches the worst case rather than an average and the data keeps the qualified state alive between studies.

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Continuous mapping replaces periodic remapping with always-on evidence



Traditional mapping

100 deployed → 5 remain

Full-volume study → spot monitoring

FULL REMAP

All 100 loggers return on the defined cycle to re-establish the temperature profile - then the process repeats.

Periodic snapshots • repeated deployment
Recommendet for new facilities.



Continuous mapping

Risk first → 20 stay in place

Targeted mapping → continuous evidence

ALWAYS CURRENT

The same loggers continuously map and monitor the risk zones, keeping validation evidence alive between changes.

Living evidence • remap when operations change

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Advantages of Tec4med's software supported mapping services powered by Cryoport / Cryogene



Live mapping, intervene & adjust when required



ISO 17025 Calibrated sensors



Audit-ready



One vendor, multiple studies



Warehouse and freezer mapping



Field engineers on site



Full chain of compliance and audit trail



Fully digital mapping protocol, results within minutes



Human review

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Your Partner in Pharmaceutical Compliance

Tracking Eco-System:

- Tec4med operates in accordance with:
  - FDA 21 CFR Part 11
  - GAMP5
- Tec4med is DIN EN ISO 9001 certified
- We are focusing on the needs of the pharmaceutical industry and established a full Quality-Management-System (QMS).
- We run own laboratories for sensor calibration (operates in accordance with ISO 17025) and packaging validation that are based on DAkkS standards.

ISTA 7D/7E
AFNOR

FDA 21 CFR Part 11

DIN 58345
DIN 58371

FCC

EMV
RoHS

UL US
US CA

IEC 61010 / 9001
IEC 13485 / 62368

RCM Tick

UN3373

IATA

NIST

GDP

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Support & contact

Support whenever you need it.



Email: inquiry@tec4med.com

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