GXP MENTOR · TEMPERATURE MONITORING SYSTEM

Data Sheet and Product Specification

Cloud-based environmental monitoring and compliance reporting platform for pharma, healthcare and food and beverage industries. All your IOT sensors in a validated, live web dashboard with automated scheduled reports and FDA CFR 21 Part 11 compliance.

GAMP 5 Cat 5 | 21 CFR Part 11 | PIC/S Annex 11 | ALCOA+ | ICH Q1A(R2) | USP <1079.2>

The TMS Data Visualisation and GxP Compliance Reporting Platform is a validated, multi-tenant Software-as-a-Service application. It turns your IOT sensors into a full GxP compliance-ready dashboard and reporting system with: fleet health at a glance, drill-in charts and smart insights per sensor, on demand and scheduled PDF reports with every regulator-expected metric (MKT, MKH, OOS, Time-in-Range, and more) plus sign-off and comments. Every change is logged in our FDA CFR 21 Part 11 audit trail.

KEY FEATURES

Real-Time Monitoring
A single Health Score summarises fleet status, backed by KPI tiles and a 24-hour heat map. Every sensor page carries a Smart Analysis panel that spots trends and gaps automatically.

Battery + Signal at a Glance
Battery and signal show on every screen. Mains-powered sensors are labelled automatically. Weak-signal units are flagged before they drop offline.

Five Report Types
Sensor, Gateway, Battery, Signal, and Trend Analysis (with MKT and Time-in-Range). Each can carry a sign-off block plus an optional Comments section. PDF or CSV.

Flexible Scheduler
Schedule reports weekly or monthly at any hour. Daylight-saving is handled automatically. A reconciler retries any missed run within 15 minutes without ever double-sending.

Pharma Regulation Built-In
GAMP 5 Category 5. Every change writes a before-and-after entry to the audit trail. Two-tier login lockout with admin unlock. Distributed rate limits on sensitive endpoints. Deactivated accounts stay for retention.

Multi-Tenant Admin
Each client organisation gets its own view. Admins control report access per org and page access per user. New users are welcomed by email and set their password on first sign-in.

Gateway Workspace
iMonnit gateways get their own list and detail. Every sensor connected to a gateway shows in one table, with battery, signal and last reading rolled up.

API Failover
Each iMonnit integration supports up to three API keys. If one is rate-limited or fails, the next is tried automatically. Repeated auth failures are audited.

ENHANCED SECURITY · MULTI-LAYER ENFORCEMENT · STANDARDS-ALIGNED

NIST SP 800-63B | OWASP ASVS | OWASP Top 10 | GAMP 5 (2nd ed) | ISO/IEC 27001 | PIC/S PI 006-4 | CIS AWS Foundations | 21 CFR Part 11 | W3C CSP L3

CURRENTLY SUPPORTED SENSOR TYPES

Type	Metrics	Unit
Temperature	Min, Max, Avg, MKT, % In Spec	°C
Temperature & Humidity	Dual KPIs: temp + humidity, each with spec	°C / %rh
Low Temperature	Min, Max, Avg, MKT, % In Spec	°C
Voltage Monitor	% On, Count On/Off	State
Dry Contact	Custom labels (Door/Smoke/Motion/Leak…)	State
Three Phase Current	Phase 1/2/3 Min/Avg/Max (incl. AppID 109)	Amperes
CO2	Min, Max, Avg + optional 8h TWA	ppm

TECHNICAL SPECIFICATIONS

Platform	**Web-based, tms.gxpmentor.com**
Validation	**GAMP 5 Cat 5, VC-08 signed 26 Aug 2026 (CQ-05 closure)**
Sensor provider	**iMonnit, multi-vendor on roadmap**
API resilience	**Three-key failover pool per integration, auto on rate limit or timeout**
Scheduler	**Per-org firing hour, weekly or monthly, DST-safe, 15-min reconciler**
Reports	**5 report types with sign-off + optional Comments, PDF or CSV**
Data export	**Per-sensor ZIP (raw CSV + PDF), per-report CSV**
Audit trail	**ALCOA+, before-and-after values, user + timestamp on every change**
Session security	**15-min idle timeout; two-tier lockout (5 fails/15 min + 10 fails/24 h, admin unlock)**
Infrastructure	**Vercel, Supabase (Postgres + RLS), Resend, AWS S3 (PAB on)**