# Universal Software-Driven Constraint Tracking Form

Purpose:

- This document captures constraints that originate from software itself, including architectural decisions, performance targets, concurrency limits, interface restrictions, and memory behavior.  
- These constraints apply across various software domains (embedded, cloud, web, mobile, hybrid).

- Traceability to IEEE 29148 (SRS), ISO 26262 (safety), DO-178C (avionics), IEC 62304 (medical), and other domain-specific standards is enabled where required.

| **Constraint ID** | **Category** | **Constraint Description** | **Design Rationale** | **Owner** | **Impacted Requirements** | **Domain Application(s)** | **Impacted Components** | **Associated Standard(s)** | **Verification Method** | **Risk Impact** | **Status** |
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| SWC-01 | Performance | Real-time data visualization latency shall not exceed 1 second between acquisition and display. | Ensures clinicians can make timely decisions based on real-time NICU signals. | Merve İçkilli | REQ-PRF-001, REQ-DSP-002 | Web Dashboard, IoMT Middleware | Backend API, WebSocket Interface | ISO/IEC 25010 (Performance Efficiency) | System latency test (1000 samples) | High | Active |
| SWC-02 | Security & Privacy | All patient data must be encrypted at rest and in transit (AES-256 + HTTPS/TLS 1.3). | To comply with HIPAA/GDPR data protection standards and prevent unauthorized access. | Merve İçkilli / Sena Filiz | REQ-SEC-004, REQ-INT-006 | Cloud, Hospital Network | Database, API Gateway | IEC 62443, GDPR, HIPAA | Static code review, penetration testing | High | Active |
| SWC-03 | Reliability | System uptime shall be at least 99% during testing phase. | Critical for continuous NICU signal monitoring without data loss. | İrem Onaran | REQ-RLB-003 | Web, Cloud | Backend Services, Data Stream Processor | ISO/IEC 25010 (Reliability) | Stress testing and uptime logs | Medium | Proposed |
| SWC-04 | Timing | AI inference for neonatal distress prediction must execute within ≤ 3 seconds per sample. | Ensures predictions are clinically actionable without user delay. | Neva Varol | REQ-AI-005 | AI Module | ML Inference Engine | ISO/IEC 62304 (Medical Software Lifecycle) | Performance profiling | High | Active |
| SWC-05 | Network & I/O | Support for minimum 10 concurrent device streams via MQTT protocol. | Guarantees scalability and multi-device NICU monitoring. | Sena Filiz | REQ-NET-010 | IoMT Gateway | MQTT Broker, Stream Manager | IEEE 29148 (Interface Constraints) | Load test with 10 simulated devices | Medium | Active |
| SWC-06 | Data Integrity | Incoming data packets must be verified using CRC or checksum validation before storage. | Prevents corrupted physiological data from being analyzed or visualized. | Merve İçkilli | REQ-INT-007 | Backend Data Handler | Data Validator Module | ISO/IEC 25010 (Data Integrity) | Validation during ingestion test | High | Active |
| SWC-07 | Usability / Human Factors | All UI alert notifications must appear within ≤ 2 seconds and be color-coded for severity. | Improves clinician response time and reduces cognitive overload. | Şevval Neva Varol | REQ-UI-003 | Web Dashboard | Alert Manager, UI Layer | ISO 9241-210 (Ergonomics of Interaction) | Usability testing with mock users | Medium | Proposed |
| SWC-08 | Resource / Platform | AI model memory footprint shall not exceed 2 GB RAM during runtime. | Ensures compatibility with hospital-grade servers and local deployment constraints. | Sena Filiz | REQ-RES-004 | AI Module | Model Runtime | ISO/IEC 25010 (Resource Utilization) | Profiling using memory monitor tools | Medium | Active |
| SWC-09 | Compliance | Software design and documentation must adhere to IEEE 1058 and ISO/IEC 12207 lifecycle standards. | Required for academic and industrial compliance evaluation. | İrem Onaran | REQ-QMS-001 | All | Documentation, Process | IEEE 1058, ISO/IEC 12207 | Document audit & peer review | Low | Active |
| SWC-10 | Ethical / Legal | Use of real patient data requires anonymization and ethics board approval. | Ensures full compliance with ethical research regulations. | İrem Onaran / Merve İçkilli | REQ-ETH-002 | AI Module, Database | Data Management Layer | GDPR, TOBB ETÜ Ethics Guidelines | Audit of data source and anonymization logs | High | Proposed |

Approval & Control

| Role | Name | Signature | Date |
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