TOSCA Implementation Status & Readiness Tiers

Architecture Diagrams

Document Version: 1.2 **Last Updated:** 2025-11-05 **Current Version:** v0.9.13-alpha **Purpose:** Clear categorization of what's implemented vs what's required for different use cases

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Overview

This document categorizes TOSCA features into **readiness tiers** based on what's needed for different stages of development and deployment.

Tier Classification

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1. **TIER 1** - Lab/Experimentation (CURRENT - Phase 5)
2. **[DONE] Implemented - Safe for R&D with test data**
3. **Need to add**
4. **TIER 2** - Pre-Clinical Validation (Phase 6)
5. **WARNING** - Partially Planned - Required for cadaver/bench testing
6. **Need to add**
7. **TIER 3** - Clinical Trials (Phase 7)
8. **[FAILED] Not Started - Required for human testing (IRB approval)**
9. **Need to add**
10. **TIER 4** - FDA Submission/Production (Phase 8+)
11. **[FAILED] Not Started - Required for commercial deployment**
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TIER 1: Lab/Experimentation ([DONE] CURRENT STATUS)

What You Can Do: - [DONE] Internal R&D and proof-of-concept testing - [DONE] Algorithm development and optimization - [DONE] Bench testing with test patterns (no real patients) - [DONE] Software development and debugging - [DONE] Unit and integration testing - [DONE] Team training and familiarization

What You CANNOT Do: - [FAILED] Clinical trials with humans - [FAILED] Animal testing (requires validation) - [FAILED] Store real patient data (no encryption) - [FAILED] Production deployment - [FAILED] FDA submission

Implemented Features (Phase 5)

Feature	Status	Document
Core Treatment Logic		
Laser power control (5W)	[DONE] Working	01_system_overview.md
Actuator position control (45mm)	[DONE] Working	01_system_overview.md
Protocol execution engine	[DONE] Working	06_protocol_builder.md
Treatment session management	[DONE] Working	-
Safety Systems		
7 independent interlocks	[DONE] Working	03_safety_system.md
Selective shutdown (laser only)	[DONE] Working	SAFETY_SHUTDOWN_POLICY.md
Emergency stop handling	[DONE] Working	03_safety_system.md
Safety watchdog (500ms heartbeat)	[DONE] Working	07_safety_watchdog.md
GPIO monitoring (Arduino Nano)	[DONE] Working	03_safety_system.md
Camera & Image Processing		
Real-time streaming (30 FPS)	[DONE] Working	-
Allied Vision API integration	[DONE] Working	camera_controller.py
Thread-safe camera controls	[DONE] Working	camera_controller.py
Exposure/gain hardware feedback	[DONE] Working	camera_widget.py
Pixel format auto-detection	[DONE] Working	camera_controller.py
Ring detection	[DONE] Working	05_image_processing.md
Focus measurement	[DONE] Working	05_image_processing.md
Recording		
Video recording (MP4, unencrypted)	[DONE] Working	12_recording_manager.md
Data Management		
SQLite database (unencrypted)	[DONE] Working	02_database_schema.md
Session tracking	[DONE] Working	-
Treatment event logging	[DONE] Working	11_event_logging.md
Two-tier logging (JSONL + DB)	[DONE] Working	11_event_logging.md
Testing Infrastructure		
MockHardwareBase pattern	[DONE] Working	09_test_architecture.md
30+ test files	[DONE] Working	09_test_architecture.md
~85% code coverage	[DONE] Working	-
Threading		
Camera streaming thread	[DONE] Working	10_concurrency_model.md
Safety watchdog timer	[DONE] Working	10_concurrency_model.md
PyQt6 signal/slot communication	[DONE] Working	10_concurrency_model.md

Tier 1 Summary: 27 features implemented [DONE] (4 new camera features added Oct 2025)

TIER 2: Pre-Clinical Validation (WARNING: PLANNED - Phase 6)

What This Enables: - WARNING: Cadaver testing (dead tissue, no live patients) - WARNING: Bench validation with calibrated equipment - WARNING: Performance verification against specifications - WARNING: Safety system validation testing - WARNING: Pre-clinical animal testing (if applicable)

Still Cannot Do: - [FAILED] Human clinical trials (Tier 3 required) - [FAILED] FDA submission (Tier 4

required)

Required Features (Not Yet Implemented)

Feature	Status	Priority	Document
Security (Critical)			
Database encryption (SQLCipher AES-256)	WARNING: Planned	P0	08_security_architecture.md
Video file encryption (AES-256-GCM)	WARNING: Planned	P0	12_recording_manager.md
Configuration file encryption	WARNING: Planned	P1	08_security_architecture.md
Key derivation (PBKDF2)	WARNING: Planned	P0	08_security_architecture.md
Calibration (Critical)			
Photodiode calibration workflow	WARNING: Planned	P0	13_calibration_procedures.md
Actuator position calibration	WARNING: Planned	P0	13_calibration_procedures.md
Camera pixel calibration	WARNING: Planned	P1	13_calibration_procedures.md
Calibration database & records	WARNING: Planned	P0	13_calibration_procedures.md
NIST-traceable certificates	WARNING: Planned	P0	13_calibration_procedures.md
Audit Trail Integrity			
HMAC signatures per event	WARNING: Planned	P1	11_event_logging.md
Cryptographic event chain	WARNING: Planned	P2	11_event_logging.md
Audit verification tool	WARNING: Planned	P1	11_event_logging.md
Performance			
Database query threading	WARNING: Planned	P2	10_concurrency_model.md

Tier 2 Summary: 13 features planned WARNING: (0 implemented)

Estimated Effort: 3-4 months (Phase 6)

TIER 3: Clinical Trials ([FAILED] NOT STARTED - Phase 7)

What This Enables: - Clinical trials with human subjects (IRB approval) - Real patient data collection - Treatment outcome tracking - Adverse event reporting

Requirements:

Feature	Status	Priority	Notes
User Authentication			
Login system (username/password)	[FAILED] Not started	P0	08_security_architecture.md
Password hashing (Argon2)	[FAILED] Not started	P0	08_security_architecture.md
Session management	[FAILED] Not started	P0	-

Password policy enforcement	[FAILED] Not started	P1	08_security_architecture.md
Access Control			
Role-based permissions	[FAILED] Not started	P0	08_security_architecture.md
Operator vs Administrator roles	[FAILED] Not started	P0	08_security_architecture.md
Audit trail for user actions	[FAILED] Not started	P0	Already implemented [DONE]
Compliance			
HIPAA compliance validation	[FAILED] Not started	P0	External audit
IRB documentation package	[FAILED] Not started	P0	Clinical team
Informed consent tracking	[FAILED] Not started	P0	New feature
Adverse event reporting	[FAILED] Not started	P0	New feature
Data Protection			
PHI anonymization tools	[FAILED] Not started	P1	New feature
Data export for analysis	[FAILED] Not started	P1	New feature
Patient data retention policy	[FAILED] Not started	P0	Policy document

Tier 3 Summary: 12 features required [FAILED] (0 started)

Estimated Effort: 4-6 months (Phase 7)

TIER 4: FDA Submission/Production ([FAILED] NOT STARTED - Phase 8+)

What This Enables: - FDA 510(k) or PMA submission - Commercial production deployment - Clinical use outside of trials - Regulatory compliance across all jurisdictions

Requirements:

Feature	Status	Priority	Notes
Design Controls			
Complete Design History File (DHF)	[FAILED] Not started	P0	FDA requirement
Risk management file (ISO 14971)	[FAILED] Not started	P0	FDA requirement
Traceability matrix (requirements ↔ tests)	[FAILED] Not started	P0	09_test_architecture.md
Design verification report	[FAILED] Not started	P0	Test results summary
Design validation report	[FAILED] Not started	P0	Clinical validation
Software Validation			
Software validation plan	[FAILED] Not started	P0	IEC 62304
Unit test documentation	[DONE] Implemented	-	09_test_architecture.md
Integration test documentation	WARNING: Partial	P0	Needs formal docs
System test documentation	[FAILED] Not started	P0	End-to-end testing

Performance qualification (PQ)	[FAILED] Not started	P0	Bench testing
Manufacturing			
Installation qualification (IQ)	[FAILED] Not started	P0	Production units
Operational qualification (OQ)	[FAILED] Not started	P0	Production units
Software bill of materials (SBOM)	[FAILED] Not started	P0	Cybersecurity
Cybersecurity risk assessment	[FAILED] Not started	P0	FDA requirement
Regulatory Submissions			
510(k) pre-submission meeting	[FAILED] Not started	P0	FDA interaction
510(k) submission package	[FAILED] Not started	P0	Complete filing
Post-market surveillance plan	[FAILED] Not started	P0	FDA requirement
Quality System			
Quality manual (ISO 13485)	[FAILED] Not started	P0	QMS documentation
Standard operating procedures (SOPs)	[FAILED] Not started	P0	All processes
Change control procedures	[FAILED] Not started	P0	Version management
CAPA system (Corrective/Preventive Action)	[FAILED] Not started	P0	Quality system

Tier 4 Summary: 21 features required [FAILED] (1 partially implemented)

Estimated Effort: 12-18 months (Phase 8+)

Quick Reference: What Can I Do?

[DONE] Right Now (Tier 1 - Current)

YES: - Develop and test algorithms - Run unit and integration tests - Benchmark performance - Train team members - Refine protocols - Test with calibration targets - Use mock patient data - Software development

NO: - Clinical trials - Real patient data - Animal testing - FDA submission - Production deployment

WARNING: After Phase 6 (Tier 2 - Pre-Clinical)

Additional YES: - Cadaver testing - Bench validation - Calibration verification - Safety system qualification - Animal testing (if applicable)

Still NO: - Human clinical trials - FDA submission - Production deployment

After Phase 7 (Tier 3 - Clinical Trials)

Additional YES: - IRB-approved human trials - Real patient data collection - Outcome tracking - Adverse event reporting

Still NO: - FDA submission (need full validation) - Commercial deployment

After Phase 8+ (Tier 4 - FDA/Production)

Additional YES: - FDA 510(k) submission - Commercial deployment - Clinical use - Production units

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Development Roadmap

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CURRENT        Phase 6        Phase 7         Phase 8+
(Tier 1)       (Tier 2)       (Tier 3)        (Tier 4)

Lab Testing    Pre-Clinical   Clinical        FDA/Production
23 [DONE]          13 WARNING:          12 [FAILED]           21 ×
               +3-4 months    +4-6 months     +12-18 months
               Encryption     Authentication  Design Controls
               Calibration    Access Control  Validation Docs
               Audit Sigs     IRB Compliance  QMS Complete
```

Total Features: - [DONE] **27 implemented** (Tier 1 complete - updated Oct 2025) - WARNING: **13 planned** (Tier 2 - Phase 6) - [FAILED] **33 future** (Tiers 3 & 4 - Phases 7-8+) - **73 total features** across all tiers

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Risk Assessment by Tier

Tier	Risk if Used Prematurely	Mitigation
Tier 1 (Current)	Low - test data only	[DONE] No real patient exposure
Tier 2 (Phase 6)	Medium - unvalidated for humans	WARNING: Cadavers/bench only
Tier 3 (Phase 7)	High - regulatory violation	[FAILED] Need IRB approval
Tier 4 (Phase 8+)	Critical - illegal use	[FAILED] Need FDA clearance

CRITICAL WARNING: - Using Tier 1 system for Tier 3 work (clinical trials) = **HIPAA violation** + **IRB violation** + potential **FDA enforcement action** - Using Tier 1 system for Tier 4 work (production) = **Federal crime** (selling unapproved medical device)

Summary

Current Capabilities (Tier 1): - Fully functional for **lab experimentation and R&D** - **27 core features implemented and tested** (updated Oct 2025) - Safe for **development with test data only** - Production-ready camera implementation with Allied Vision API compliance

Next Milestone (Tier 2 - Phase 6): - **13 features to add** (encryption, calibration, audit integrity) - Estimated **3-4 months** development time - Enables **pre-clinical validation and bench testing**

Path to Clinical Use: - Tier 1 → Tier 2 → Tier 3 → Tier 4 - Total estimated time: **19-28 months** from current state - Total features to add: **46 features** across 3 phases

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Document Owner: Project Manager **Last Updated:** 2025-10-30 **Next Review:** Start of Phase 6

Recent Updates (2025-10-30): - Added 4 new camera features (Allied Vision API integration, thread safety, hardware feedback, pixel format auto-detection) - Updated feature count from 23 → 27 implemented features - Updated FPS specification from 60 → 30 FPS (hardware-controlled frame rate) - Version: 1.1