

Diabetic Retinopathy ML Pipeline System Requirements

Citation

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1. Introduction

This document outlines the system requirements for a machine learning pipeline designed to predict diabetic retinopathy from retinal photographs. The system serves medical doctors and hospital administrators by providing automated screening capabilities for diabetic retinopathy detection.

2. Functional Requirements

2.1 Data Management

FR-001: WHEN a user uploads retinal photographs, the system SHALL validate image format (JPEG, PNG, TIFF) and minimum resolution (1024x1024 pixels).

FR-002: WHEN retinal images are ingested, the system SHALL automatically apply standardized preprocessing including noise reduction, contrast enhancement, and normalization.

FR-003: WHEN training data is provided, the system SHALL support annotations for diabetic retinopathy severity levels (No DR, Mild, Moderate, Severe, Proliferative).

FR-004: WHEN images contain patient metadata, the system SHALL store and associate DICOM-compliant metadata with corresponding images.

FR-005: WHERE data privacy regulations apply, the system SHALL support automated de-identification of patient information while preserving clinical relevance.

2.2 Model Training

FR-006: WHEN initiating model training, the system SHALL support configurable deep learning architectures (CNN, Vision Transformers, EfficientNet variants).

FR-007: WHEN training models, the system SHALL implement data augmentation techniques including rotation, flipping, brightness adjustment, and zoom.

FR-008: WHEN training is in progress, the system SHALL provide real-time monitoring of training metrics (loss, accuracy, AUC, sensitivity, specificity).

FR-009: WHEN training completes, the system SHALL generate comprehensive model performance reports including confusion matrices, ROC curves, and confidence intervals.

FR-010: WHEN multiple models are trained, the system SHALL support model versioning with metadata tracking (training date, dataset version, hyperparameters).

FR-011: WHERE clinical validation is required, the system SHALL support k-fold cross-validation and stratified sampling to ensure balanced representation across severity levels.

2.3 Single Image Inference

FR-012: WHEN a doctor uploads a single retinal image, the system SHALL return a prediction within 10 seconds.

FR-013: WHEN processing single images, the system SHALL provide diabetic retinopathy classification with confidence scores for each severity level.

FR-014: WHEN generating predictions, the system SHALL include visual attention maps highlighting regions of interest used in the classification decision.

FR-015: WHEN predictions are made, the system SHALL display historical comparison IF previous images from the same patient are available.

FR-016: WHERE prediction confidence is below a configurable threshold, the system SHALL flag the case for manual review.

2.4 Batch Image Processing

FR-017: WHEN processing image batches, the system SHALL support concurrent processing of up to 1000 images per batch.

FR-018: WHEN batch processing is initiated, the system SHALL provide progress tracking with estimated completion time.

FR-019: WHEN batch processing completes, the system SHALL generate summary reports with distribution statistics and flagged cases requiring urgent attention.

FR-020: WHEN processing large batches, the system SHALL support pause/resume functionality.

FR-021: WHERE batch results are ready, the system SHALL provide downloadable CSV reports with patient IDs, predictions, confidence scores, and recommendations.

2.5 Clinical Integration

FR-022: WHEN predictions indicate severe or proliferative diabetic retinopathy, the system SHALL automatically generate alerts for immediate clinical attention.

FR-023: WHEN doctors review predictions, the system SHALL provide clinical decision support including treatment recommendations based on severity classification.

FR-024: WHERE integration with Electronic Health Records is available, the system SHALL export results in HL7 FHIR format.

FR-025: WHEN generating reports for hospital administrators, the system SHALL provide population-level statistics and screening program metrics.

2.6 Quality Assurance

FR-026: WHEN image quality is insufficient for reliable prediction, the system SHALL reject the image with specific feedback on quality issues.

FR-027: WHEN predictions are made, the system SHALL log all processing steps for audit trail purposes.

FR-028: WHERE model drift is detected, the system SHALL alert administrators and recommend model retraining.

3. Non-Functional Requirements

3.1 Performance Requirements

NFR-001: WHEN processing single images, the system SHALL respond within 10 seconds for 95% of requests.

NFR-002: WHEN handling concurrent users, the system SHALL support at least 50 simultaneous prediction requests without performance degradation.

NFR-003: WHEN processing batch jobs, the system SHALL achieve throughput of at least 100 images per minute on standard hardware.

NFR-004: WHEN system load is high, the system SHALL maintain prediction accuracy within 2% of baseline performance.

3.2 Reliability Requirements

NFR-005: WHEN in production, the system SHALL maintain 99.5% uptime during business hours (8 AM - 8 PM local time).

NFR-006: WHEN system failures occur, the system SHALL automatically restart processing within 5 minutes.

NFR-007: WHEN data corruption is detected, the system SHALL implement automatic data integrity checks and recovery procedures.

NFR-008: WHERE backup systems are required, the system SHALL maintain real-time data replication to secondary systems.

3.3 Security Requirements

NFR-009: WHEN handling patient data, the system SHALL comply with HIPAA regulations and implement end-to-end encryption.

NFR-010: WHEN users access the system, the system SHALL require multi-factor authentication for all clinical users.

NFR-011: WHEN processing sensitive data, the system SHALL implement role-based access control with audit logging.

NFR-012: WHERE data transmission occurs, the system SHALL use TLS 1.3 or higher for all communications.

NFR-013: WHEN storing data, the system SHALL encrypt all patient information at rest using AES-256 encryption.

3.4 Scalability Requirements

NFR-014: WHEN user load increases, the system SHALL support horizontal scaling to handle 10x current capacity.

NFR-015: WHEN storage needs grow, the system SHALL support dynamic storage expansion without service interruption.

NFR-016: WHERE computational demands increase, the system SHALL support GPU scaling for training and inference workloads.

3.5 Usability Requirements

NFR-017: WHEN doctors use the interface, the system SHALL provide intuitive navigation requiring no more than 3 clicks to reach any primary function.

NFR-018: WHEN displaying results, the system SHALL present information in clinically relevant formats familiar to ophthalmologists.

NFR-019: WHEN errors occur, the system SHALL provide clear, actionable error messages in medical terminology.

NFR-020: WHERE accessibility is required, the system SHALL comply with WCAG 2.1 AA standards.

3.6 Accuracy and Clinical Requirements

NFR-021: WHEN making predictions, the system SHALL maintain minimum sensitivity of 90% for detecting referable diabetic retinopathy.

NFR-022: WHEN classifying severity levels, the system SHALL achieve specificity of at least 85% to minimize false positives.

NFR-023: WHEN compared to expert ophthalmologists, the system SHALL demonstrate substantial agreement ($\text{Kappa} > 0.6$).

NFR-024: WHERE clinical validation is performed, the system SHALL undergo annual recalibration against current clinical standards.

3.7 Regulatory and Compliance Requirements

NFR-025: WHEN deployed in clinical settings, the system SHALL maintain FDA Class II medical device compliance standards.

NFR-026: WHEN processing international data, the system SHALL comply with relevant data protection regulations (GDPR, local privacy laws).

NFR-027: WHEN generating clinical reports, the system SHALL maintain complete audit trails for regulatory inspection.

NFR-028: WHERE clinical claims are made, the system SHALL provide transparent model explainability and decision reasoning.

3.8 Maintenance and Support Requirements

NFR-029: WHEN models require updates, the system SHALL support zero-downtime model deployment.

NFR-030: WHEN system maintenance is needed, the system SHALL provide at least 24-hour advance notice to clinical users.

NFR-031: WHERE technical support is required, the system SHALL provide 24/7 support for critical clinical functions.

NFR-032: WHEN training new models, the system SHALL maintain backward compatibility with existing clinical workflows.

4. Constraints and Assumptions

4.1 Technical Constraints

- System must operate within existing hospital IT infrastructure
- Must integrate with common PACS (Picture Archiving and Communication Systems)
- Limited to commercially available GPU hardware for inference

4.2 Regulatory Constraints

- Must comply with local medical device regulations
- Subject to periodic clinical validation requirements
- Must maintain detailed documentation for regulatory audits

4.3 Assumptions

- Medical staff have basic computer literacy
- Hospital network provides adequate bandwidth for image transmission
- Regular model updates will be supported by clinical validation studies
- Training data will be continuously available for model improvements