

Project Specifications Report

1. Introduction

1.1 Description

The purpose of this project is to design and develop a web-based medical support system that integrates advanced artificial intelligence technologies to assist both healthcare professionals and patients. The system aims to enhance diagnostic accuracy, accelerate clinical decision-making processes, and support the early detection of critical diseases through AI-driven analysis tools.

At its core, the platform functions as a diagnostic assistant for physicians by providing in-depth analysis of medical images such as X-rays, CT scans, MRIs, and ultrasound images using state-of-the-art computer vision techniques. In parallel, the system offers a simplified and ethically controlled interface for patients, where symptom descriptions are interpreted using large language models (LLMs) to generate limited, context-aware suggestions accompanied by clear medical disclaimers emphasizing the necessity of professional consultation.

This dual-structured design is motivated by the growing challenges faced in modern healthcare environments, where increasing workloads, limited resources, and time constraints can negatively impact early diagnosis and effective triage. By integrating image-based and language-based diagnostic pathways within a single intelligent platform, the proposed system aims to reduce diagnostic oversights, support clinical workflows, and contribute to safer and more scalable healthcare delivery—while strictly preserving the central role of medical professionals in the final decision-making process.

1.2 Constraints

The proposed system is subject to a set of strict design, performance, security, and reliability constraints to ensure safe, ethical, and effective operation within a healthcare context.

First, the system must comply with all relevant data protection regulations, including GDPR, KVKK, and HIPAA. All patient-related data stored within the system shall be fully encrypted, ensuring that 100% of stored records are protected against unauthorized access. Compliance will be verified through regular security audits and database scans.

Second, all outputs presented in the patient-facing interface must include a clear legal and medical disclaimer. This requirement is mandatory for every patient-visible result, ensuring that users are continuously informed that the system does not provide a medical diagnosis.

and does not replace professional consultation. Disclaimer coverage must reach 100%, and compliance will be verified through black-box testing and user interface inspections.

From image upload to result display. Similarly, symptom-based suggestions generated for patients must be returned within 5 seconds (5,000 ms) after form submission. These constraints are intended to support efficient clinical workflows and timely user feedback, and they will be validated through system performance testing.

In terms of diagnostic reliability, the system must maintain a False Negative Rate (FNR) of no more than 5% for critical illnesses. This constraint is particularly important to minimize the risk of missing serious medical conditions. In addition, the overall diagnostic accuracy of the AI models must be at least 90%, as measured on an independent test dataset. Model performance will be evaluated using standard classification metrics derived from confusion matrix analysis.

To ensure ethical data usage, at least 95% of users must view the informed consent form before submitting any personal or medical data to the system. This constraint guarantees transparency and user awareness regarding data processing practices and will be verified through user interaction log analysis.

Finally, the system must demonstrate high availability and operational reliability. Monthly system downtime must not exceed 0.5%, corresponding to a minimum uptime of 99.5%. Server availability will be monitored and verified using automated uptime reporting tools such as cloud infrastructure monitoring services.

Together, these constraints define the minimum acceptable operational, ethical, and technical standards for the proposed AI-based medical support system and serve as objective criteria for system verification and acceptance.

1.3 Professional and Ethical Issues

The use of artificial intelligence in healthcare introduces important professional and ethical challenges due to the direct impact of system outputs on human health and the sensitive nature of medical data. This project addresses these challenges by adopting a responsible AI design approach that prioritizes patient safety, data privacy, and professional accountability.

One of the primary ethical issues is the risk that incorrect or misunderstood AI-generated outputs may negatively affect health outcomes. To mitigate this risk, the system is explicitly designed as a medical decision-support tool rather than an autonomous diagnostic system. Clear medical disclaimers are included in all patient-facing outputs, emphasizing that AI-generated insights are intended to support, not replace, professional medical judgment. This approach helps prevent overreliance on AI and reduces the risk of misinterpretation, particularly among non-expert users.

Data privacy and security represent another critical ethical and professional concern. Medical data is highly sensitive and must be protected against unauthorized access, misuse, or data breaches. The system enforces strict data protection measures, including encryption of data at rest and in transit, secure authentication mechanisms, and role-based access control (RBAC). In addition, personal identifiers are removed through anonymization techniques, and only the minimum necessary data is collected and processed, in accordance with GDPR, KVKK, and HIPAA regulations.

From a professional responsibility perspective, the project also emphasizes transparency and accountability in AI-assisted decision-making. Model outputs provided to healthcare professionals are supported by confidence scores and explanatory indicators, enabling clinicians to critically assess AI suggestions rather than accepting them as definitive conclusions. This design choice aligns with ethical AI principles and supports trust, interpretability, and responsible system use in clinical settings.

Overall, by addressing ethical concerns related to incorrect predictions, data privacy, and professional responsibility, the project demonstrates a commitment to ethical AI deployment in healthcare. These measures ensure that the system supports medical professionals and patients in a safe, secure, and ethically sound manner while maintaining compliance with legal and professional standards.

2. Requirements

External Interface Requirements

User Interfaces

The system shall provide two distinct user roles: Doctor and Patient, each with a customized dashboard and role-specific functionalities.

The system shall allow doctors to:

- Upload medical images, including MRI, X-ray, CT, and ultrasound images.
- View AI-assisted diagnostic results supported by detailed visual and textual annotations.
- Review symptom-based analyses and laboratory result interpretations.

- Access and track previous patient interactions through a secure history interface.

The system shall allow patients to:

- Input symptoms in natural language through a simplified and user-friendly form.
- Receive AI-generated suggestions limited to common and low-risk conditions (e.g., cold, flu), accompanied by a clear medical disclaimer encouraging consultation with a licensed physician.
- Be protected from viewing medical terms or results that could cause unnecessary anxiety (e.g., “benign tumor”, “calcification”), unless explicitly deemed clinically significant.
- View non-technical explanations supported by intuitive visual content.

Hardware Interfaces

The system shall be hosted on cloud-based infrastructure with GPU support to enable fast and efficient inference of deep learning models.

The system shall support secure upload of diagnostic images from multiple devices, including hospital scanners, mobile phones, and personal computers.

Software Interfaces

The system shall integrate with:

- Large Language Models (LLMs), such as OpenAI APIs or Hugging Face models, for processing and interpreting symptom descriptions.
- Computer vision and deep learning libraries, including TensorFlow, PyTorch, and OpenCV, for medical image analysis tasks.

Communication Interfaces

- The system shall expose secure RESTful APIs to enable communication between the frontend, backend, and machine learning inference services.

- The system shall implement logging and monitoring mechanisms to securely trace model decisions, system events, and user interactions.

Functional Requirements

- The system shall allow doctors to upload and analyze medical images using task-specific deep learning models.
- The system shall allow doctors to override, annotate, or comment on AI-generated outputs with their own professional observations.
- The system shall allow patients to submit symptom descriptions in free-text format and receive a basic list of non-critical health possibilities.
- The system shall append a clear and visible medical disclaimer to every patient-facing output.
- The system shall prevent the display of technical, high-risk, or anxiety-inducing medical interpretations to patients unless the case is explicitly flagged by a physician.
- The system shall provide an early warning mechanism to assist doctors in identifying potentially missed conditions, such as early-stage lung cancer.
- The system shall support multi-modal diagnostic logic by combining image-based analysis and symptom-based interpretation when both inputs are available.

The system shall utilize separate deep learning models fine-tuned on task-specific datasets for:

- Lung X-ray analysis (pneumonia, tuberculosis, lung cancer).
- Brain CT analysis (tumor detection, stroke, Alzheimer's disease).
- General X-ray analysis (fractures, scoliosis).
- Ultrasound image analysis (thyroid nodules, fatty liver disease).
- Symptom-based diagnosis (cold, flu, COVID-19, migraine).
- Laboratory test interpretation (e.g., CBC, liver enzymes, glucose levels).

Performance and System Requirements

- The system shall deliver AI-based medical image analysis results to doctors within 10 seconds.
- The system shall generate symptom-based suggestions for patients within 5 seconds.
- The system shall support a minimum of 100 concurrent users with minimal performance degradation.
- The system shall ensure that all image-based and NLP-based models achieve and maintain:
 - Overall accuracy greater than 90% in internal validation,
 - False Negative Rate (FNR) lower than 5% for critical illnesses,
 - False Positive Rate (FPR) lower than 10% across all cases.
- The system shall support localization in at least Turkish and English, with 100% translation coverage for all user-facing text, verified through language-specific user interface testing.
- The system shall include a feedback module that allows doctors to report incorrect or useful AI-generated suggestions, with all feedback entries stored in the database within 2 seconds of submission and retrievable for review.
- The system shall implement a content moderation layer for LLM outputs, filtering inappropriate, misleading, or confusing content with a detection accuracy of at least 95%, validated through test cases and manual review.
- The system shall log all feedback submissions and content moderation actions for a minimum duration of 6 months to support traceability and continuous system improvement.
- The system shall ensure that moderated or blocked content is replaced with safe, contextually appropriate alternatives or a user-friendly message within 1 second of detection

3. References

IEEE. (2018). IEEE Std 830-1998 (Reaffirmed 2018): IEEE Recommended Practice for Software Requirements Specifications. IEEE Standards Association.

ISO/IEC. (2011). ISO/IEC 25010: Systems and software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE).

European Parliament. (2016). General Data Protection Regulation (GDPR). Regulation (EU) 2016/679.

T.C. Resmî Gazete. (2016). Kişisel Verilerin Korunması Kanunu (KVKK), Kanun No: 6698.

U.S. Department of Health & Human Services. (1996). Health Insurance Portability and Accountability Act (HIPAA).

World Health Organization. (2021). Ethics and governance of artificial intelligence for health.