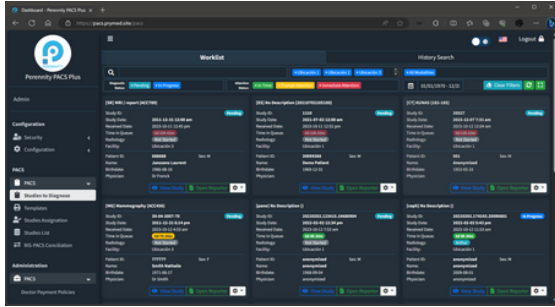




# PRODUCT TECHNICAL SPECIFICATIONS

## Perennity Enterprise PLUS



### GENERAL INFORMATION

Name:	Perennity Enterprise PLUS
Tradename:	Perennity Enterprise PLUS (Full PACS)
Country of Origin:	Belgium
Document Date:	October 12, 2023
Revision:	1.1

Perennity Enterprise PLUS (Full PACS) is a web-based digital technology solution with graphical interfaces available in English and Spanish, designed to manage the processes of radiological studies from the moment a patient schedules their appointment until their radiological images and interpretation reports are delivered to the appropriate location.

#### General Features:

- It is classified as Class Level "A" by leading forensic platforms (immuniweb.com, securityheaders.com, etc.) that monitor and diagnose security, and it complies with HIPPA requirements. This ensures that the delivered studies remain private and cannot be intercepted. The results delivery portal acts as a secure "barrier" between "external" users and the "internal" PACS.
- Databases and files generated in the system's operation are the client's property and are stored where the client requests.
- The system displays the institution's logo and the name of the branch, location, or medical care unit on screens related to login, patient scheduling, and others.
- It features a user interface with icons, graphs, and a menu of tools. It also provides a help menu explaining the system's functionality.
- The desktop theme can be changed from dark to light, depending on the user's preference.
- It allows the use of a DICOM viewer from a web browser on any computer connected to the Institution's network, without the need to install any software or certificates. In other words, the system does not rely on remote connectivity tools.
- It supports the handling and display of images in both DICOM and non-DICOM formats.

- The DICOM and non-DICOM studies viewer is compatible with various internet browsers (Internet Explorer, Mozilla Firefox, Safari, Google Chrome, etc.).
- The system supports service classes such as:
  - DICOM Query/Retrieve.
  - DICOM Service Class.
  - DICOM SR (Structured Reporting).
  - DICOM Verification Service Class.
  - DICOM Media Service Class.
  - DICOM Worklist.
  - DICOM Storage.
  - DICOM Storage Commitment.
- It allows access to studies and interpretation notes together or separately.
- The system behaves the same whether working locally or remotely.
- The system can send studies to the Institutional VNA using the DICOM standard (in native format). This means that the study can be viewed in any DICOM viewer without proprietary compression or access locks.
- The system can send studies to the Institutional VNA with the desired frequency and time, giving priority to urgent studies or those specifically requested, based on business rules and storage requirements.
- The reports generated by the system are printable in PDF format and exportable to Excel and/or CSV formats.

## Storage:

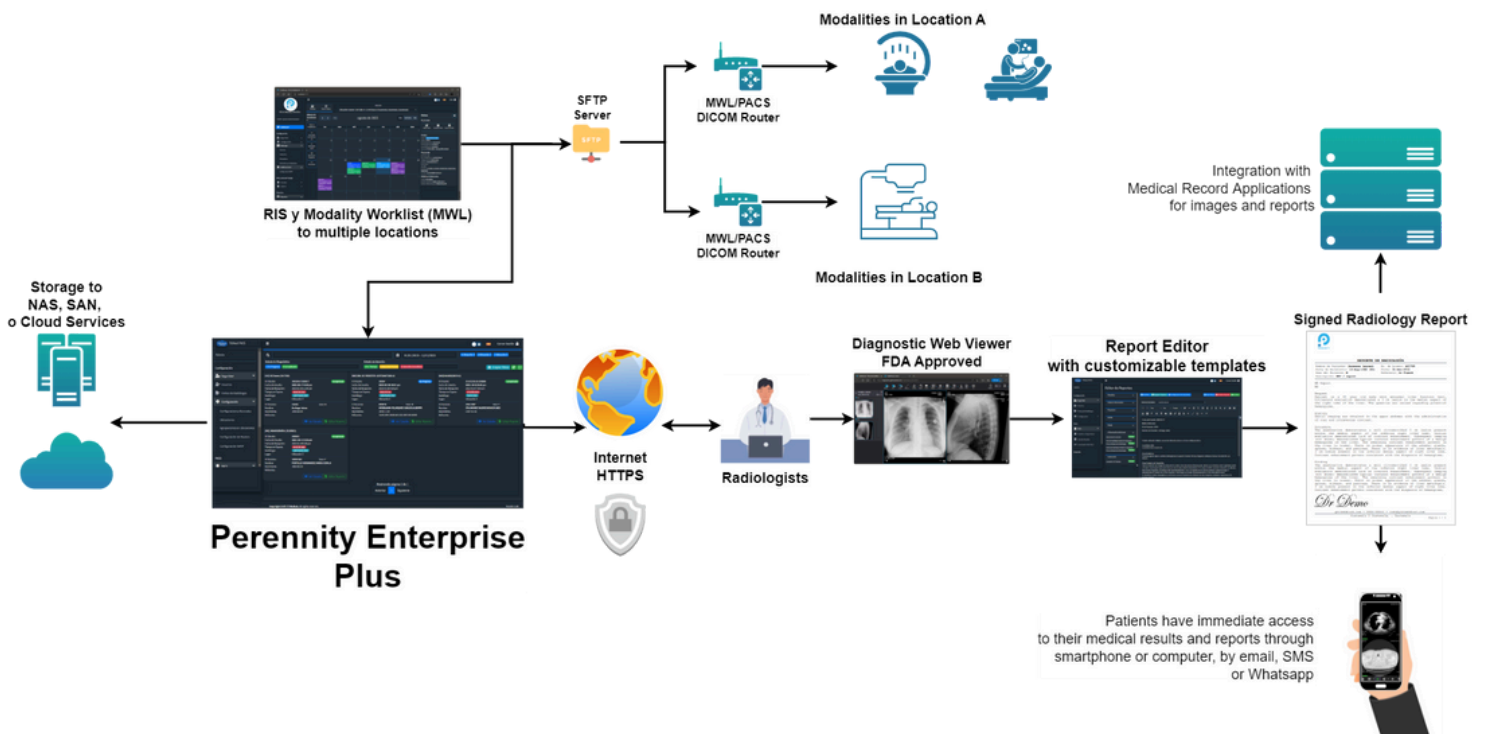
- The system stores and retrieves DICOM studies according to the modality's worklists.
- The system allows the use of service classes: DICOM STORAGE SERVICE CLASS, DICOM QUERY/RETRIEVE SERVICE CLASS, DICOM STORAGE COMMITMENT, DICOM VERIFICATION SERVICE CLASS.
- The system supports DICOM LOSSLESS compression levels.
- The system allows the import of DICOM studies from portable media.

## Quality Management:

- It complies with the requirements of an ISO 9001 quality assurance system, as Perennity is a certified company and understands the concepts of process management and continuous improvement.
  - Designed to manage processes online through improvement objectives, goals, and real-time records.
  - Provides traceability for each executed event.
  - Manages version control.
  - Generates reports and Key Performance Indicators (KPIs) to facilitate continuous improvement management.

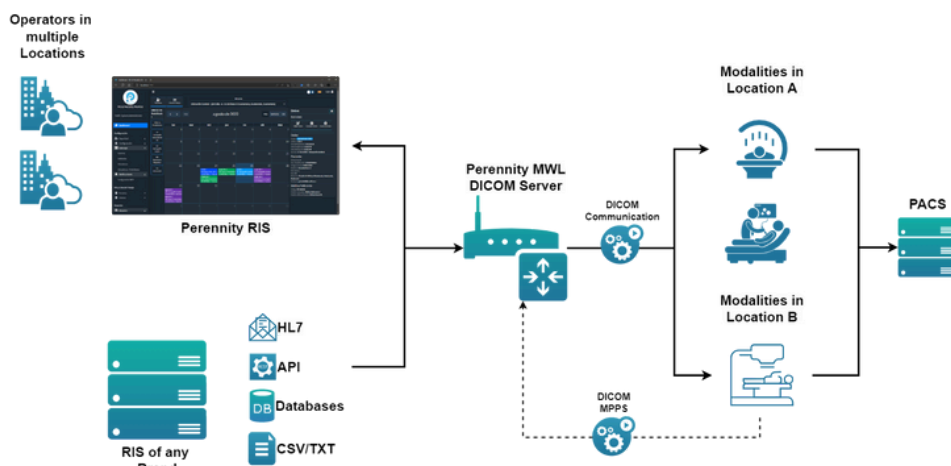
## For patient management, the system can:

- Maintain a local patient record.
- Retrieve the Electronic Record Identifier and patient demographic data from the Institution's Central Database Query Web Service to complete or update the patient's record.
- Accept patient demographic data via HL7 messaging from the Institution's Medical Systems.
- Perform local searches to view patient data.
- Allow local patient registration for cases where Institution Web Services are not available.



# Radiological Information System (RIS):

Process diagram



## Radiological Information System (RIS):

### Institutional elements of the system are configurable:

- Institution name, address, logo
- Branches, Locations, or Medical Care Units
- Modalities
- Modalities by Branch, Location, or Medical Care Unit
- Radiology services or procedures
  - Patient preparation conditions for studies

### The way RIS + MWL works is flexible depending on what the Institution has already implemented:

- Full RIS + MWL functionality
- Standalone RIS
- Standalone MWL

### It offers various integration options or connections to existing institution applications (billing, medical records, HIS):

- The system can resend messages in case of network or Institution HL7 Server unavailability.
  - Manages and logs errors returned by Institution HL7 Server.
  - Can display a monitoring screen for sending HL7 messages to Institution HL7 Server.
- Web Services
  - The system allows configuration of communication parameters for sending messages to Institution Web Services.
  - The system can handle messages based on the responses received from Institution Web Services.
- API (Incoming and/or outgoing)
- Databases
- Text files
- CSV files

### For appointment management, the system can:

- Import appointment information previously collected by the Branch, Location, or Medical Care Unit provided by the Institution if electronic records are available.
- Accept Imaging Study requests via HL7 messaging from the medical system for registration in the RIS system when required.
- Accept, via HL7 messaging, the registration, cancellation, modification, and rescheduling of appointments from the medical system for each modality's worklists.
- Send a response message for each received HL7 message.
- Send imaging study records to the Institution's systems via HL7 messaging.
- Acknowledge the receipt of Imaging Study requests to the Institution's Medical Systems via HL7 messaging.
- Manage and register Ordinary Study Requests and schedule appointments according to the availability assigned by the Branch, Location, or Medical Care Unit at the counter.
- Generate a receipt for the patient with the scheduled studies and prior instructions.
- Register Imaging Study Requests for hospitalized patients according to the availability assigned by the Medical Care Unit.
- Register Urgent Imaging Study Requests.
- Confirm the patient's arrival for Scheduled Studies.

### **Patient Registration:**

- Unique identification
  - Personal Identification Document
  - Social Security Number
  - System-generated unique identifier or Electronic Record Identifier
- Patient data is registered only once, regardless of the Branch, Location, or Medical Care Unit where it is done, as their identification is unique within the institution.
- Name and surname in accordance with institutional standards.
- Gender
- Date of Birth
- Home address
- Email address
- Phone number

### **The medical data for referring patients is registered only once when not available:**

- Active license number
- Name and surname
- Clinic or hospital name
- Email address
- Phone number

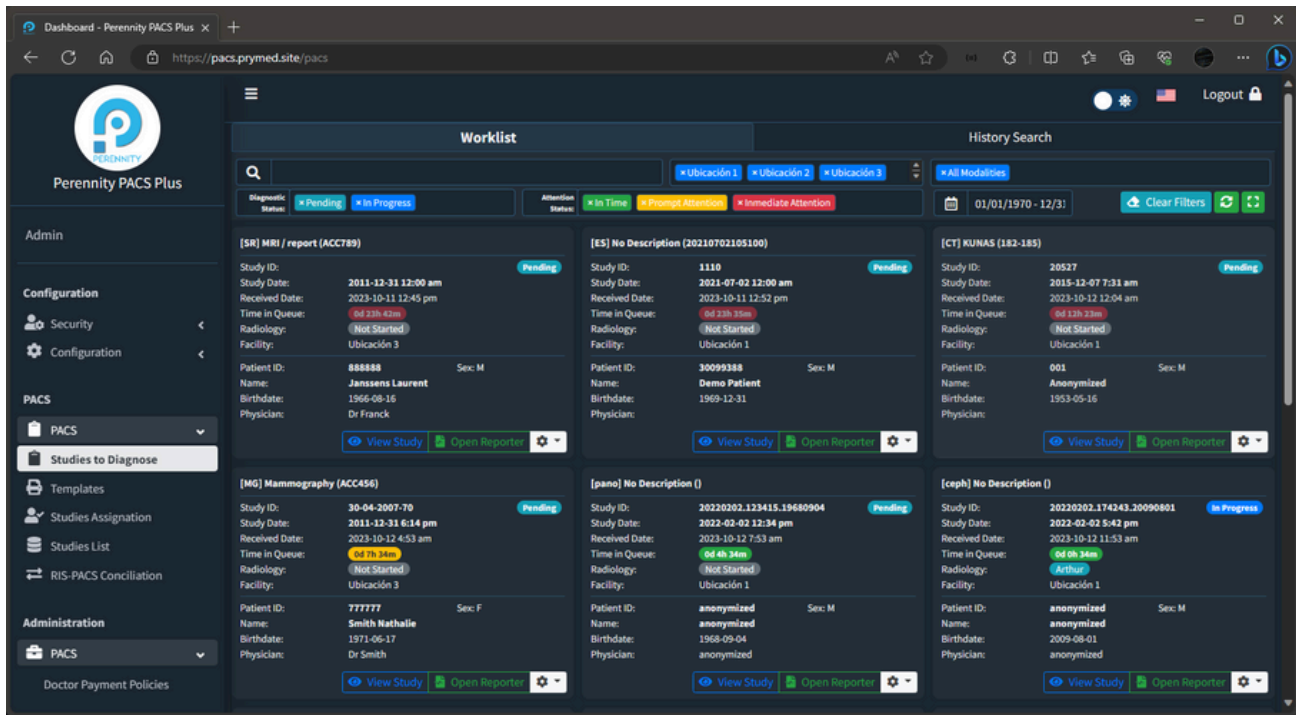
### **Patient Appointment Management:**

- By Branch, Location, or Medical Care Unit
- Appointments can be scheduled for the future.
- Selection of service type and modality according to the previously entered catalog.
- Selection of appointment date and time.
- Assignment of the appointment.
- Generation of a work order that allows:
  - Editing the order
    - Changing the date and/or time
    - Moving the appointment to another Branch, Location, or Medical Care Unit
    - Canceling the order
    - Printing the order

### **MWL (Modality Worklist):**

- A worklist is automatically generated for each modality.
- The technician for the corresponding modality uses the worklist to locate the patient.
- The patient is selected, and no data entry is required.
- The system automatically records patient data in DICOM format.
- When the work is completed, the entire study is automatically transferred to the PACS.
- Tracks patient waiting times, by technician and modality.

# PACS (Picture Archiving and Communication System)



## Overview of PACS:

- It allows levels of compression (DICOM LOSSLESS).
- DICOM Image Management.
- Enables radiologists to view study images from their workstations.
- Allows specialist physicians easy access to significant study images or series.
- Permits simultaneous visualization of images from different studies conducted on the same patient for comparison.
- Provides standard grayscale and/or color viewing based on the modality.
- Maintains the DICOM standard according to the modality and lossless compression (DICOM LOSSLESS).

## Radiologist's Workstation for Study Interpretation:

- The PACS automatically receives radiological studies from modalities and places them on the radiologist's workstation in a worklist available for diagnostic reporting.
- The desktop theme can be changed from dark to light, depending on the user's preference.
- Allows the location of the studies through different search criteria:
  - Modality
  - Location
  - Interpretation status
    - Pending
    - In Progress
      - Dictation
      - Preliminary
      - Completed
    - Finalized
  - Attention status
    - On time
    - Urgent (approaching the radiologist's time limit for generating interpretation)
    - Immediate attention (emergency)

- Study dates
- Detailed search after applying filters
  - Study description
  - Access number
  - Study ID
  - Radiologist interpreting
  - Patient data
    - ID (e.g., social security number)
    - Name and/or Surname
    - Date of Birth
    - Referring physician
    - Gender
- Allows the selection of studies from all branches, locations, or medical care units.
- Divides the workstation presentation into a worklist and a historical search.

- Radiologist Worklist:
  - Worklist (displays pending or in-progress studies), indicating those requiring attention, those with urgency, and those in progress.
  - Indicates the attention status with a traffic light system: green for on-time, yellow for those requiring prompt attention, and red for those needing immediate attention.
  - The worklist presents patient study data in a card or list format.
  - Study type or service performed, Study ID, study date, reception date and time, waiting time, radiologist working on it, branch, location, or medical care unit, patient ID, gender, patient name, date of birth, and referring physician.
  - Below the card, there are action buttons:
    - View Study opens the diagnostic viewer certified by the FDA and CEE, with a dynamic set of tools depending on the images and the type of study to be interpreted.
      - Zoom and pan.
      - Rotate and flip.
      - Video playback with adjustable speed.
      - Contour or pattern enhancement.
      - Magnifying glass.
      - Marking of key images.
      - Spinal column labeling.
      - Comments (according to DICOM GSPS standard).
      - Notes.
      - Annotations and arrows on the images.
      - Hounsfield units (tissue density).
      - Distances.
      - Angles.
      - ROI.
      - Multiplanar reconstruction (MPR).
        - Line cut manipulation.
        - Thickness and number of cuts control.
      - Window-level adjustments (brightness and contrast).
      - Measurement of real-size distances in the study and calibration tool available at the workstation.
      - "Multiframe" display (e.g., cardiology studies, ultrasound, nuclear medicine).
      - Integrated report display.
  - Edit Report: Allows the radiologist to choose a report template based on the modality and study type they are working on, and write their diagnostic report, which can be digitally signed and sealed once completed.
    - The radiologist can edit and correct the report as many times as needed, as long as it has not been sent to its destination.
    - If the report has already been sent and an amendment is required, an addendum can be created, which can be signed by the same radiologist or a different one.
    - If the radiologist finds the study images unclear or insufficient for diagnosis, they can return them to the modality technician, and a trace of this is recorded.
    - If the radiologist encounters something urgent while generating their interpretation, the system channels the communication.
    - All actions performed by the radiologist are digitally logged, allowing the generation of an audit trail containing the study's traceability.
    - It can preserve each radiologist's preferences from any workstation where they start a session.
    - It allows users to mark specific studies as "Teaching Studies."
    - It allows anonymizing patient data in studies for research and educational purposes.
- Historical Search:
  - Allows viewing the patient's study history and locating any study that has already been interpreted.

#### Different ways to assign studies to radiologists:

- Unassigned (all radiologists can view the list and select any study).
- Assignment by radiologist specialty (by modality).
- Assignment by branch, location, or medical care unit.
- Manual assignment.

#### Configuration and Customization:

- User role registration
  - Administrator
  - Chief Radiologists
  - Radiologists
  - Operators
  - Transcribers
- Radiologist signature registration.
- Server configuration
  - PACS Configuration
  - DICOM Configuration
  - DICOM Rules
    - Forwarding rules
    - HL7 for report delivery
    - PACS storage drives
    - PACS storage rules
- Branch, Location, or Medical Care Unit and unification of modalities in a branch, location, or medical care unit.
-

- Router Configuration (each router has a DICOM Server)
  - DICOM Server
  - HL7 Server
  - Query/Retrieve and filters
  - Transfers
- SMTP Server Configuration for Email Communication.

#### **Studies List:**

- An optional tool for the PACS administrator.
- Displays studies within a specified time frame.
- Includes various search filters.
- Allows the following actions:
  - Download the study.
  - Send the study in DICOM format to another location.
  - Delete a study.
  - Edit the study.
    - Modify study metadata.
    - Remove images or image series.
  - Maintains a traceability log that shows the changes made to a study.

#### **RIS-PACS Reconciliation:**

- Verifies the consistency of the process and ensures everything is in order.

#### **Reports and Statistics as per Institution's Needs:**

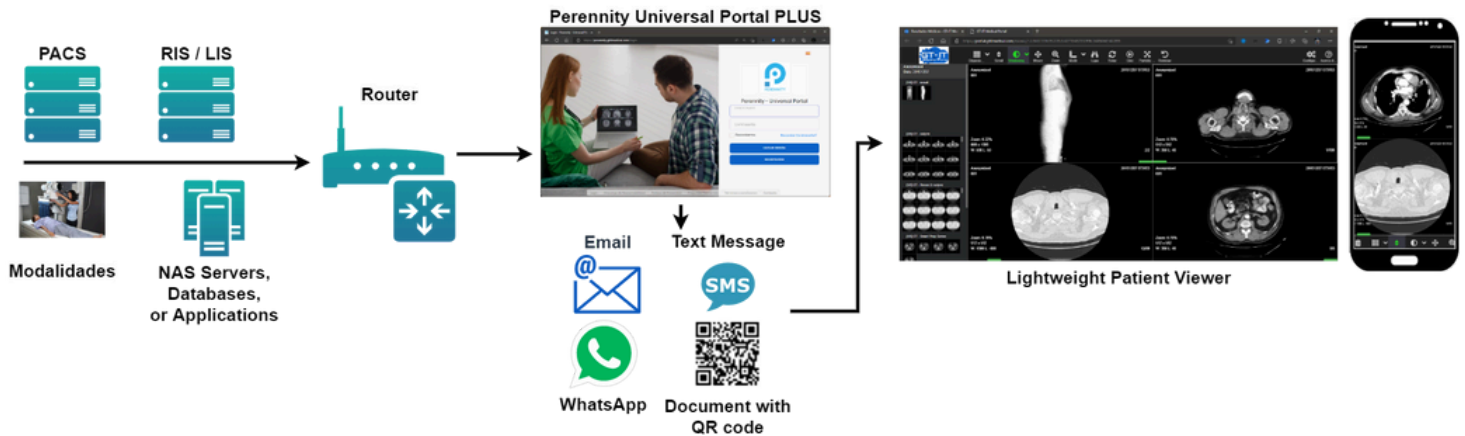
- Filters and options.
- Generated for a specified time frame.
- For all locations or a specific one.
- Detailed
  - Grouped by modality and service.
- Summarized by modality.
- Summarized by service.
- Types of reports:
  - Studies/Patients referred by physicians.
  - Radiologists' production.
  - Attention times by modality and service.
  - Radiologist attention times.
  - Studies by modality operator.
  - Demographic data.
  - Diagnoses (ICD-10).
  - Studies performed by modality.
  - BI-RADS.

#### **Integration of Studies from Another PACS (optional tool):**

- Via Perennity Auto Backup & Disaster Recovery PLUS.
- Used when a client changes their system and integrates it into Perennity Enterprise PLUS (Full PACS).
- Allows to recover previous studies from another PACS (regardless of the manufacturer's brand -VNA-) or recover them from DICOM files to integrate them into the new PACS

# Results Delivery Portal (Universal Portal)

## Process diagram



## Ways of Delivering Results:

- Results can be delivered to Patients, Referring Physicians, and the clinical record, depending on the Institution's needs.
- The portal automatically receives image studies and interpretation reports from the PACS and allows for customization of the delivery time.
  - Immediately upon the completion of the diagnostic report.
  - Later as per the institution's policy (specify the timeframe).
- Delivery can occur automatically or by operator through the following channels:
  - Email
  - QR Code
  - WhatsApp Business
  - SMS
  - Directly to the HIS or clinical record.
- Printed sheet for the patient to access the portal and check their results, which may contain:
  - QR code
  - Access identification and password
  - Institution information
  - Institutional advertising

## Options for Patients:

- Patients can access their studies from their PC, tablet, or smartphone and view their study history.
- Open studies with a proprietary Lite Viewer.
- Share their studies through:
  - Email
  - WhatsApp
- Download their studies to their PC, CD/DVD, or USB drive in various formats:
  - DICOM
  - DICOM with Viewer
  - JPEG

## Options for Referring Physicians:

- Referring physicians can access their patients' studies from a PC, tablet, or smartphone.
- By using their assigned ID and password (previously provided by the institution), they can access their patients' studies.
- Upon logging in, they will see a list of their patients ordered from the most recent to the oldest.
- Using search criteria (name, surname, etc.), they can select a patient and view the study along with the interpretation report and the study history.
- Through a Lite Viewer with measurement tools, they can view the images.
- They can share a patient's studies through:
  - Email
  - WhatsApp
- Download a patient's studies to their PC, CD/DVD, or USB drive in various formats.
  - DICOM
  - DICOM with Viewer
  - JPEG

## User Roles

- Administrator
- Operator
- Doctor
- Patient

## Everything is configured and customized according to the institution's requirements.

- Data, logo, and clinic, hospital, or diagnostic center image
- Documents and letters for patients with QR codes
- Disclaimer
- Privacy Policy
- Frequently Asked Questions
- Terms and Conditions
- Contact Information

## Company Contact Information

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