ChestLink™
User Manual

Software version: 1.0
Manual date: 2023-03-09
Language: English

IMPORTANT

Refer to this guide for proper use, warnings, and cautions associated with the use of ChestLink™ medical device software. Please contact your sales representative for any questions associated with ChestLink™ software. The help and readme files included with the ChestLink™ software are provided for reference only. Please read this entire guide before using the ChestLink™ software.

INTENDED USE

ChestLink™ automatically and autonomously (without the involvement of a radiologist) evaluates a chest X-ray study. The software is indicated to automatically detect actionable radiological findings on chest radiographs. After this analysis, one of two actions is performed:
(1) If ChestLink™ is confident that a study has no actionable radiological findings, a report is automatically generated. The study is not reported on by a trained radiologist.
(2) If ChestLink™ cannot confidently rule out the presence of actionable radiological findings, the study is directed to be reported on by a radiologist.

Intended User Population: The reports generated by ChestLink™ are intended to be relied upon by a professional with the authority to request a report on a chest X-ray study. No particular training is required. ChestLink™ is intended to replace a trained radiologist's review of the study. The report generated by ChestLink™ may be used as the primary interpretation.
Note 1: Since the user population is restricted to professionals with authority to request a report on a chest X-ray study, these are not "lay users". In particular, the users are not patients. Instead, these professionals have undergone training unrelated to ChestLink™ which allows them to read and act upon radiological reports on chest X-rays. Examples of users are non-radiologist medical doctors, nurses, healthcare officers responsible for disease screening, radiographers/radiology technicians etc.
Note 2: no particular training to use the product is required, as the user already has authority to request chest X-ray reports, and is already relying on chest X-ray reports written by radiologists in their work. Reports generated by ChestLink™ are tailored to be as close to human radiologist reports as possible.
Intended Patient Population: The target population of the device is adults (patients age 18 and older) who are able to stand (such that an erect posteroanterior radiograph can be acquired).
Indications: Adults (patients age 18 and older) who are able to stand (such that an erect posteroanterior radiograph can be acquired); body area – chest.
Contraindications: Children (patients age under 18); patients unable to stand; and other situations that are not covered by "Indications".
Classification: ChestLink™ is classified as class IIb per Rule 11 according to Medical Device Regulation (EU) 2017/745.
Target markets: Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden.

Table 1. Symbol descriptions in the software label.

Symbol	Description
	**Manufacturer** Indicates the medical device manufacturer
	**Date of manufacture** Indicates the date when the medical device was manufactured
	**General warning sign** To signify a general warning
	**Consult instructions for use** Indicates the need for the user to consult instructions for use
CE 0197	**CE Marking** CE marking of conformity
MD	**Medical Device** Indicates the item is a medical device
UDI	**Unique Device Identifier** Device identification code in the GS1 system

TABLE OF CONTENTS

Chapter 1: Introduction

1.1. Overview

ChestLink™ automatically and autonomously (without the involvement of a radiologist) evaluates a chest X-ray study. The software is indicated to automatically detect actionable radiological findings on chest radiographs. After the analysis, one of two actions is performed:

- If ChestLink™ is confident that a study has no actionable radiological findings, a report is automatically generated. The study is not reported on by a trained radiologist.
- If ChestLink™ cannot confidently rule out the presence of actionable radiological findings, the study is directed to be reported by a radiologist.

Based on the type of medical institution, ChestLink™ is able to automate reporting of up to 40% of normal chest X-rays with a high level of sensitivity.

Figure 1. ChestLink™ is able to make a confident decision if chest X-ray is normal or not.

Information used by the device:

- Chest X-ray study images (either single PA image or PA+lateral images).
- Clinical inquiry and other information provided when ordering the study.

ChestLink™ is integrated with the systems storing clinical inquiries and radiological reports (e.g. RIS, HIS) as well as chest X-ray images (e.g. PACS), therefore presenting no user interface of its own to the end user. Inquiries, clinical information, and chest X-ray images reach ChestLink™ automatically via the institution's systems with no additional effort from the user. Reports generated by ChestLink™ are sent to the appropriate system automatically as well, and thus are presented to the end user (clinician) through that system.

1.2. List of abbreviations

- DICOM® – Digital Imaging and Communications in Medicine.
- HL7® – Health Level 7.
- PACS – Picture Archival and Communication System.
- RIS – Research Information System.
- HIS – Hospital Information System.
- VPN – Virtual Private Network.
- VM – Virtual Machine.
- PA – Posteroanterior.
- AP – Anteroposterior.

1.3. General Warnings

The software is intended for a limited population. Only adult PA chest X-ray images are analyzed. AP images or images of a child are not analyzed.

The software may produce a false negative report. In a rare event the software may produce a report although radiological actionable findings may be present and observed by a radiologist. However, errors occur at a much lower rate compared to the radiologist interpretations.

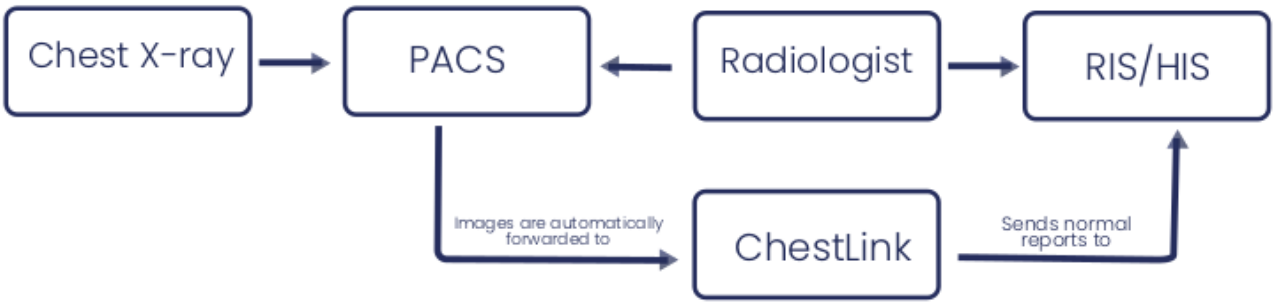
Chapter 2: Implementation

2.1. Overview

ChestLink™ is integrated with the medical institution's PACS/RIS/HIS. It runs in the background independently from PACS/RIS/HIS configuration and running processes. However, each system has to be configured to work with each other:

- PACS must be able to forward incoming chest X-rays to ChestLink™. The data is typically transmitted via DICOM® or DICOMweb™ protocol.
- ChestLink™ must be able to generate results and send them to PACS/RIS/HIS. The data is typically transmitted via DICOM®, DICOMweb™ or HL7® protocol.
- PACS/RIS/HIS must be able to analyze ChestLink™ generated results and display them to end users (clinicians).

Figure 2. ChestLink™ reporting workflow. The whole process takes around 10 seconds.



Apart from connectivity with PACS/RIS/HIS, ChestLink™ has no user interface. PACS/RIS/HIS software may have a function to display if chest X-ray study was processed by ChestLink™, and if ChestLink™ report was generated for the study. The end user (clinician) is provided with the information that the radiology report was provided by the software.

2.2. Deployment

ChestLink™ can be set up in the cloud environment (outside of the institution's IT network) or deployed locally in the institution's network in their provided VM. In both scenarios, patient data anonymization procedures are set up by enabling the anonymization options in PACS. This ensures that no sensitive personal data is processed by ChestLink™. Anonymization procedure has no effect on software's performance, as the software does not use any metadata in the chest X-ray images.

In case of local deployment, a medical institution has to provide a VM based on hardware and software specifications (see 2.3.). This also includes providing access to the local network via VPN or other means, and enabling several ports in the local network for the data transmission and monitoring purposes.

Both in cloud and local settings, ChestLink™ has to be configured to connect with PACS/RIS/HIS, which includes configuring IP addresses, ports and AET information between each other. The required information is shared among IT administrators which is a part of a standard deployment process. Upon configuration a test study case is performed to evaluate if all the connections are configured correctly.

2.3. System requirements

Recommended settings for VM:

- 64-bit CPU with 8 logical cores with AVX support.
- 16 GB of RAM.
- 1 TB disk space.
- UbuntuOS (latest LTS).
- SSH access.

2.4. Monitoring

ChestLink™ VM may collect general information about software and hardware utilization. ChestLink™ may send logs to logging service providers (Mezmo and InfluxDB) which collect information about processed chest X-ray studies:

- Operating System (OS) information.
- Unique identifiers of a processed DICOM® file metadata (SOPInstanceUID, StudyInstanceUID, etc.).
- Image processing events (DICOM® C-STORE information, duration of ChestLink™ predictions, etc.).
- Error messages.

Information collected is encrypted using TLS, as it is sent over HTTPS. All connections are initiated on the side of the ChestLink™ VM, except for maintenance access through tools such as SSH. All the processing is done inside the VM and no imaging and patient information is transferred outside the organization's network.

Chapter 3: Modes of operation

Before autonomous use ChestLink™ is thoroughly tested until both the medical institution and ChestLink™ support team are certain that the device is ready and safe to use in a clinical setting. An initial step (shadow mode) is initiated as the first step towards autonomous reporting.

3.1. Shadow mode

Shadow mode is a validation period when the software is operational but the radiology reporting process is not yet adopted for ChestLink™ use. During the shadow mode:

- The connection between ChestLink™, PACS/RIS/HIS is configured and tested.
- ChestLink™ is tested on all institution's X-ray devices to identify potential anomalies and confirm that the software is working as intended.
- Retrospective and/or prospective information is collected about software's performance.
- Software performance metrics are reported to the institution (i.e. number of studies which can be automated, the rate of automation, etc.).
- Optionally, customization of the software is performed (i.e. limitation to work with specific X-ray devices, patient groups, etc.).

During the shadow mode the radiology reporting is unchanged and uninterrupted. In the meantime all the prospective chest X-ray studies are processed and analyzed by the software, however no results are sent to the clinicians. Both the medical institution and ChestLink™ support team would monitor the software operations and would work together to minimize all the risks associated with moving to autonomous mode.

3.2. Autonomous mode

The software may only start working autonomously only after both the medical institution and the ChestLink™ support team has made sure that the software is safe to use and all the necessary configurations have been made. During the autonomous mode clinicians and patients are informed about the fact that radiological interpretation was made using the ChestLink™ medical device. The process may involve adjusting patient consent forms to clearly inform the patients of the involvement of AI systems during diagnostic procedures.

When autonomous mode is enabled, the information of ChestLink™ operation is clearly visible in PACS as a standalone DICOM® Structured Report with clear metadata indications of ChestLink™ output. RIS/HIS has clear indication that the radiology report is generated by ChestLink™ and clinicians are informed that radiological reading did not involve radiologist interpretation.

3.3. Supervision

To assert the reporting quality of ChestLink™, a sample of studies reported by ChestLink™ is provided for evaluation to radiologists in order to make sure that the software is still operating correctly - that is, there are no false negatives. This may be done periodically.

Chapter 4: Troubleshooting

Please contact your sales representative or via info@oxipit.ai for any questions associated with ChestLink™ software.