Instructions for Use

English

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ClearRead CT Console for IntelliSpace Portal

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Table of contents

459801861791_A/881 * 2020-12-31

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1 Safety and Warning Precautions

Safety Operation Precautions

NOTICE

- For continued safe use of this equipment, follow the instructions contained in this Physician's Training Manual. Read this guide carefully before using the equipment, and refer to it as necessary.
- Federal law restricts this device to sale by or on the order of a physician.
- Only adult chest axial CT series are suitable for processing with ClearRead CT.

4598018661791_A/881 * 2020-12-31

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GENERAL USE WARNINGS

WARNING

- **Use of the device on any image projection other than the axial CT chest views is not supported.**
- **Only the original chest CT series is to be used for diagnostic interpretation by physicians. ClearRead CT output is designed only as an aid to the interpretation process.**
- **Conditions of image quality that diminish sensitivity and/or specificity, such as artifacts due to patient motion and/or manmade devices in the field of view during the image acquisition, e.g., pacemaker, that may lead to reconstruction artifacts and diminish the effectiveness of the device.**
- **Incorrect DICOM headers or other factors can cause ClearRead CT to reject an input CT series for processing, in which case no result will be returned for viewing. Do not delay your reading of the primary series in order to view the ClearRead CT output.**
- **ClearRead CT relies on Patient Position and Patient Orientation information from the DICOM header. If the header is incorrect, the system might fail to process the series.**
- **Users should never be dissuaded from working up a finding even if it is not seen on the ClearRead CT output. The device will not identify all areas that represent nodules.**
- **A standard CT series is expected to contain both lungs. CT series not containing both lungs might fail to be processed.**
- **ClearRead CT has an option to send CAD results as an overlay. If your site uses a PACS that can receive and display overlays, and your ClearRead CT has been configured to send overlays, you must establish controls to prevent or record user editing of the CAD results.**
- **ClearRead CT should be installed, serviced, and configured only by trained personnel.**
- **ClearRead CT is a medical device. It should be used only as described in the accompanying Riverain manuals. Other activities (such as web browsing, email, or installation of third-party software without specific authorization from Riverain) are prohibited. Software authorized by Riverain Technologies should be scanned with anti-virus software before use.**
- **If the ClearRead CT Vessel Suppress micro-nodule filter is enabled, nodules with measured diameter of less than or equal to 5mm may be retained.**

459801861791_A/881 * 2020-12-31

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2 About ClearRead CT Console

Introduction

Your institution has installed the Riverain ClearRead™ CT system for chest computed tomography volumes integrated in Philips' IntelliSpace Portal system. ClearRead CT consists of Computer-Aided Nodule Detection markers on native volumes. The nodule detection component identifies regions of interest associated with solid, sub-solid, and/or ground glass nodules. This manual provides physicians who use the ClearRead CT system with an understanding of how the system works, what to expect when using ClearRead CT, and most importantly, the indications for use.

For any questions or concerns not addressed in this manual, go to: http://www.riverain-tech.com

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Definitions

Actionable Nodule	Image locations in the CT series with suspicious nodular features, i.e., characteristics, for which radiologist(s) recommends further examination, typically through analysis of a prior exam and/or additional imaging such as follow-up CT, diagnostic CT, PET-CT, etc.
CAD	Computer-Aided Detection
CT	Computed Tomography
ROI	Region Of Interest
VDT	Volume Doubling Time
DICOM	Digital Imaging and Communications in Medicine
PACS	Picture Archiving and Communications System

4598018617 91_A/881 * 2020-12-31

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Indications for Use

ClearRead CT is comprised of computer assisted reading tools designed to aid the radiologist in the detection of pulmonary nodules during review of CT examinations of the chest on an asymptomatic population, as well as in already diagnosed patients[1]. The ClearRead CT requires both lungs be in the field of view. ClearRead CT provides adjunctive information and is not intended to be used without the original CT series.

[1] Intended population for ClearRead CT differs in different markets. Please contact your representative for more details. In the United States, ClearRead CT is cleared for the asymptomatic population only.

Contraindications

There are no contraindications for use of the device.

Adverse Effects

There are no known direct risks to the health or safety of the patient from the physical use of the ClearRead CT system. This is a post-processing application and does not require additional radiation dose to the patient.

Possible indirect risks are:

- The physician may be dissuaded from working up an earlier finding if the device fails to mark that site, thus missing a possible nodule.
- The physician may be misled into working up a benign finding that would not otherwise have been acted upon.

Motivation for Creating ClearRead CT

Low dose CT is the preferred method for annual lung cancer screening for at risk patients. However, interpreting a chest CT is a challenging task, owing to the large number of images commonly present in a chest CT series and number of interfering structures that compete with the detection of lung nodules. Given the clinical importance of detection of lung cancer using CT, it is clear that a technology that aids in the detection and tracking of nodules would be useful to medical professionals and patients alike.

The American Cancer Society statistics show that if lung cancer is found early enough, the 5-year survival rates more than triples. A proactive approach to early lung cancer detection is essential to turning the tide in the fight against this devastating disease. ClearRead CT is designed to provide assistance in the detection and tracking of nodules which may represent cancer.

4598018617 91_A/881 * 2020-12-31

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Summary of ClearRead CT

ClearRead CT[2] is a computer-aided detection (CAD) system intended to identify and mark regions of interest (ROIs). The ClearRead CT | Vessel Suppress and ClearRead CT | Detect modules of the system operates across all nodule types, including solid, sub-solid and ground glass ranging from 5mm and 30mm in size. The use of ClearRead CT | Detect leads to a reduction in oversight errors.

[2] ClearRead CT | Detect operates only on studies with slice thickness less than or equal to 3mm, while the ClearRead CT | Vessel Suppress can operate on studies with slice thickness less than or equal to 5mm.

Conformance to Standards

The ClearRead CT system conforms to the DICOM standards for digital communications of medical information.

4598018617 91_A/881 * 2020-12-31

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3 Working with ClearRead CT Console

How ClearRead CT Works

ClearRead CT is a software solution for automated detection of solid, sub-solid, and/or ground glass nodules in chest CT exams. ClearRead CT relies on advanced algorithms from the engineering disciplines of image analysis and machine learning. The Vessel Suppress and Detect components of the system detect and characterize the nodules in the series. The software performs a series of steps to detect regions of interest containing features associated with nodules.

The system receives, as input, a thoracic CT scan along with its associated acquisition parameters (pixel spacing, slice spacing, and slice thickness) via the DICOM header. The CT scan first goes through a process called *acquisition normalization*, that standardizes the appearance of CT to have a similar noise, contrast, lung density and slice thickness properties. This step of acquisition normalization makes ClearRead CT robust across different device manufacturers and provides repeatability among the wide range of clinical protocols. Once the CT scan has been normalized, an *anatomy segmentation* step is performed to define and segment various anatomical regions present in the series. The anatomy segmentation step includes a *body segmentation* step to find the patient body, an *airway segmentation* step to find the trachea, the main bronchi and the carina, and a *lung segmentation* step that defines the left and right lung regions separately. ClearRead CT is designed to detect nodules only within the lung-field region. Regions outside the lungs are not considered for nodule detection.

Performance Expectations

General Performance Characteristics

ClearRead CT has been designed to detect nodules between 5mm to 30mm in size. However, ClearRead CT may detect some nodules smaller than 5mm in diameter.

In a blind, third-party study, ClearRead CT detected 82.0% of known actionable nodules. Actionable nodules were comprised of solid, sub-solid and ground glass. The average false positive rate per normal patient was 0.7469 false positives per CT series. For emphasis, it is noted that ClearRead CT | Detect and the radiologist will not necessarily detect the same nodules.

Appropriate Series

ClearRead CT has been designed for processing series volumes that meet the following constraints:

- Axial oriented scans with no more than +/- 1 degree of rotation
- Maximum slice thickness of 3mm for Detect
- Maximum slice spacing of 3mm for Detect

459801861791_A/881 * 2020-12-31

- Minimum contiguous volume of 80 mm
- Maximum contiguous volume of 1067 mm
- Consistent table height and patient position throughout the scan

Series volumes that do not follow these constraints will be marked as errors within the ClearRead CT software and are not processed.

ClearRead CT can operate over a wide range of CT lung scans; however, the system has been designed to optimize detection and characterization of nodules. As such, like a radiologist would, ClearRead CT prefers scans configured to assist with that set of tasks, such as the following:

- Soft reconstruction kernels over sharp ones
- Inspiration over expiration
- Non-contrast over contrast
- Thin-slice over thick-slice

Scans not following these recommendations will still process; but, may not be as optimal as scans that do. The ideal image sequence from ClearRead CT's point of view for nodule detection would be a non-contrast, thin-slice, inspiration acquisition and soft reconstruction series.

Field of View (FOV)

A standard CT series is expected to contain both the lungs. The entire intrathoracic cavity must be included even if the patient has had prior lung surgery (e.g., lobectomy). For images that have single lung or cropped lungs, the system might fail to process the case. If the FOV is a square of a circle, it should not clip the lungs. If this occurs, the ClearRead system might fail to process the case. For cases with chest tubes, large amount of fluid, or other gross abnormalities, the ClearRead CT system might not produce optimal results.

ROI Markers

ClearRead CT | Detect uses the segmented contour on the center slice to indicate a region of interest. A numeric is also present near the segmented nodule to indicate the finding.

True Positive and False Positive Marker Types

A standard CT series is expected to contain both the lungs. The entire intrathoracic cavity must be included even if the patient has had prior lung surgery (e.g., lobectomy). For images that have single lung or cropped lungs, the system might fail to process the case. If the FOV is a square of a circle, it should not clip the lungs. If this occurs, the ClearRead system might fail to process the case. For cases with chest tubes, large amount of fluid, or other gross abnormalities, the ClearRead CT system might not produce optimal results.

A ClearRead CT false positive is a case where ClearRead CT marks a region and there is no lung nodule. The following are the predominant sources of false positives:

4598018617 91_A/881 * 2020-12-31

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Imaging Artifacts:

- Beam hardening artifacts due to metallic structures or the contrast agent
- Image noise due to low-dose acquisition
- Partial volume error

Benign Pathologies:

- Scars
- Mucous plugs
- Pleural plaques

Other Pathologies:

- Tuberculosis (TB)
- Pneumonia
- Presence of other lung diseases such as Emphysema, Pulmonary Embolism, etc.

Normal Anatomy:

- Residual vessel
- Bronchial structure
- Protrusions on the pleural surface

4598018617 91_A/881 * 2020-12-31

Using ClearRead CT

ClearRead CT Output Objects and Case Interpretation

The radiologist reviews the marked regions using the original images and determines whether any action is required. Although the ClearRead CT marker is typically centered on the region of interest, it is possible some markers will not be perfectly centered.

ClearRead CT findings are either displayed in IntelliSpace Portal's Lung Nodule Assessment application or automatically processed and exported as gray scale presentation state (GSPS) object which can be reviewed along with the original series on a selected DICOM Viewer.

ClearRead CT limits the number of findings to up to twenty-five (25) per CT series.

Detection Errors vs Interpretation Errors

There are two types of errors in cancer detection:

- In an oversight error, the radiologist fails to see a nodule.
- In an interpretation error, the radiologist sees a nodule but decides it is not actionable.

Computer-aided detection (CAD) helps decrease oversight errors. In this process, the ClearRead CT system aids the radiologist in reducing oversight errors.

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How to Respond to ClearRead CT Markers

If upon review of the ROI, a nodule or other abnormality is observed, the radiologist should proceed according to their usual protocol for the type of abnormality observed.

When ClearRead CT has marked a finding that the radiologist can see but determines it is likely benign, the criteria for ordering further evaluation should be the same as if the radiologist noticed the finding without the use of the ClearRead CT system.

If there is no clear explanation for the cause of the marked ROI, the radiologist should dismiss the region as a false positive.

Potential Effects of ClearRead CT False Negatives

A ClearRead CT false negative is a case in which the computer fails to mark a true lung nodule. As previously indicated, the device will not mark all nodules. Therefore, the clinical action should never be reversed based on the absence of a ClearRead CT marker.

Configurability: Selective Processing

ClearRead CT has the ability to filter images using Boolean logic operations on any of the fields in the DICOM header. This filter allows ClearRead CT to distinguish chest CT volumes from other incorrect modalities or anatomy. Thus, it is important that your images contain DICOM headers that are properly populated according to the DICOM standard and that accurately reflect the acquisition and anatomical properties of the image. In addition to selecting only chest CT series, the filter may be extended to control demographic or other characteristics of the images sent to ClearRead CT. For example, the filter can be used to exclude pediatric exams, or to reject images from a particular modality.

Possible Error Messages

If the ClearRead CT system is unable to process a series, the console outputs log messages indicating the processing status and processing errors.

It is important to note that incorrect DICOM headers can cause ClearRead CT to reject an input image for processing, in which case no result will be returned for viewing. Do not delay reading of the primary image in order to view the ClearRead CT results.

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