ClariCT.AI for syngo.via OpenApps

User Manual

ClariPi Inc.

ClariCT.AI for syngo.via OpenApps

User Manual

1 Read Me First
1.1 About This Guide

This guide is an introduction to using and managing the software, providing in formation on the purpose, prerequisite skills, components, features, and graphic conventions that identify the visual symbols used throughout the guide.

All operators must read the complete instructions before operating the ClariCT.AI software. This product should be used only by qualified and trained personnel.

ClariCT.AI is intended for exclusive use by the professionals. The software is intended to assist healthcare professionals in the diagnosis and cannot fully substitute their clinical judgement.

The software should only be used in combination with equipment that have the listed minimum system requirements.

Federal law restricts this device to the sale by or on the order of a physician.

Do not use the equipment if a known safety problem exists. Call your local service provider and have the system repaired.

1.2 Notices for Safe and Proper Usage

This guide uses pictures or icons to reinforce the printed message. It uses the corresponding international symbol or icon next to the warning or caution message.

This guide addresses safety and notices with these symbols for the following purposes:

⚠ Caution

Caution is used to identify conditions or actions in which a potential hazard may exist that will or can cause minor personal injury or property damage if the instructions are ignored.

ⓘ **Important**

Important indicates information where adherence to procedures is crucial or where your comprehension is necessary to apply a concept or effectively use the product.

The device uses the international symbol with the following international standards and regulations.

Symbols

⚒	Manufacturer
EC REP	Authorized representative in European Countries
SN	Serial Number
⚠	Warning, Caution
ⓘ	Important information for effective use
📖	Consult Instructions for Use

1.3 Manufacturer Information

⚒ **Manufacturer**
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2 Introduction

2.1 Overview

ClariCT.AI software is intended for the denoise processing and enhancement of CT DICOM images when higher image quality and/or lower dose acquisitions are desired.

By integrating ClariCT.AI into the workflow, its utilizing facilities are enabled to take images in low dose while maintaining image quality similar to that of images taken in standard/high dose.

Such practice has two major benefits. First, it is good for patients' health. Not only is it beneficial for most patients, but especially appealing for patients who are susceptible to dose levels such as pregnant women, children, cancer patients and patients requiring frequent examination. Second, taking images in low dose slows down the wear and tear of CT scanner components. Particularly with X-ray tubes, extending its lifespan will result in lower operating costs. ClariCT.AI is also effective for enhancing CT images using degraded quality images due to equipment obsolescence, extending its useful life thereby.

Although ClariCT.AI can handle CT images with all body parts, it is especially effective for denoising head, chest, heart, and abdomen body parts. Also, while it can handle CT images with coronal and sagittal view, it performs best on axial view images.

ClariCT.AI may also improve the image quality of low-dose non-diagnostic Filtered Back Projection images as well as Iterative Reconstruction images.
(*In the case of applying to IR images, we recommend using the device as the secondary image presentation).

This document assumes using of ClariCT.AI for syngo.via OpenApps, a distribution that is integrated with Siemens syngo.via OpenApps platform and makes use of features provided by the system such as delivering, filtering, and presenting DICOM data.

2.2 Indications For Use

ClariCT.AI is a software device intended for networking, communication, processing and enhancement of CT images in DICOM format regardless of the manufacturer of CT scanner or model.

2.3 User Characteristics

ClariCT.AI is designed for use by trained and experienced medical professionals including radiologists and technologists.

ClariCT.AI does not require a user with a deep understanding of the underlying mathematics and computer science to use.

2.4 Precautions and Important Information Before Use

⚠ Caution 1

Before using ClariCT.AI, the site physicist, in collaboration with the radiologist, should conduct image quality evaluations with varying degrees of ClariCT.AI and different scan techniques, both at routine dose and with decreased dose. This should be done using your site's preferred method and phantoms. Using this information, an appropriate starting point for ClariCT.AI level and diagnostic scanning techniques can be incorporated into your site's protocols.

⚠ Caution 2

ClariCT.AI might reject an input CT series data or fail the process if given DICOM that has incorrect headers or due to other factors. In case the delivery of the process result is remarkably delayed, proceed the diagnosis with the original images to prevent interruption of medical care.

⚠ Caution 3

ClariCT.AI can handle denoising of reformatted views (coronal and sagittal views). However, the users should always refer to

the original reformatted images if using the reformatted views for diagnosis since the algorithm was not separately trained on reformatted views.

⚠ **Caution 4**

ClariCT.AI will reject the process images with the following attributes:
- Modality that is not "CT".
- Photometric Interpretation tag has value other than "MONOCHROME1" or "MONOCHROME2".

2.5 Definitions, Acronyms, and Abbreviations

- DICOM Images
  A Digital Imaging and Communications in Medicine (DICOM) is a standard for handling, storing, printing, and transmitting information in medical imaging. It includes a file format definition and a network communications protocol.

- PACS
  A Picture Archiving and Communication System (PACS) is a medical imaging technology which provides economical storage of, and convenient access to, images from multiple modalities (source machine types).

- syngo.via
  syngo.via is the integrated imaging software provided by Siemens, which offers multi-modality and fast 3D reading and AI-powered applications.

- OpenApps
  A service provided by syngo.via which enables its users to browse, download and integrate clinical applications developed by Siemens Healthineers and other third-party vendors.

2.6 Hardware Requirements

- CPU: Intel i5 10500K processor or better, 64-bit
- RAM: 8GB or more
- Storage: 16GB of disk space
- GPU:

The app requires CUDA-enabled GPU to be used in clinical environment. The required GPU spec differs depending on the number of exams that need to be processed on a daily basis.

Number of Exams to be Processed Daily	GPU Requirement
less than 30	Nvidia Quadro K2200
less than 50	Nvidia Quadro P2000
less than 100	Nvidia Quadro RTX 4000
over 100	Please contact ClariPi

Graphic driver must support:

- CUDA: 11.4
- cuDNN: 8.2.2.26

3. Workflow

3.1 Overview

ClariCT.AI provides two modes: GUI mode and Background mode. When evaluating the application, it is recommended to use the GUI mode. When using GUI mode, the user can compare the original and denoised images in a side-by-side view of the windows.

When adopting the application in clinical workflow, it is recommended to use Background mode. By utilizing the OpenApps PACS ready technology, the app would run in the background automatically without the need of user interactions.

3.2 Workflow Integration

ClariCT.AI can seamlessly integrate with PACS and the existing user site infrastructure using features provided by syngo.via. The recommended setting is to automate the whole workflow from taking an exam using a CT scanner to viewing the denoised image in radiologist's reading environment. To integrate ClariCT.AI into the workflow, please configure syngo.via OpenApps settings to run ClariCT.AI automatically using OpenApps PACS ready technology such as below.

•Activate automatic processing on incoming studies

- •Activate automatic archiving
- •Configure appropriate routing rules for ClariCT.AI.
  - • (required) The modality must be "CT"
  - • (optional) The description contains "LOW DOSE"

4. User Interface
4.1 Overview

To run ClariCT.AI in GUI mode, user must select a specific series from the patient browser of syngo.via. Then, the user can open the series with ClariCT.AI using the "Open with" option.
The ClariCT.AI will open with its native UI, the MixView, to view the processed results.

When opened from study or patient level that includes multiple CT series, the app will automatically select first series from the datasets, as the app is designed to process and display single series at a time.

The app will store the result data in syngo.via when process is completed. However, the app will not store any data if the app is terminated before process completion. This is due to prevent app from storing incomplete DICOM series to syngo.via storage or PACS environment.

4.2 MixView

MixView is a special type of viewer designed to provide an easy comparison of image quality for original and denoised images side-by-side. It also provides user with convenient functionalities such as zoom in/out, window width/level adjustment, window width/level preset, pan & scroll.

4.2.1 Scrolling Over Image Slices

By default, MixView will show the first slice on screen with the original image on the left panel and the denoised image on the right panel. User can scroll over image slices by scrolling the mouse wheel located at the middle of mouse with the mouse cursor on an image panel. Scroll up/down the mouse wheel, then you will see both original and denoised images moving in synchronization.

4.2.2 Zoom

User can zoom in/out of image by mouse dragging with the **right mouse** button. Place mouse cursor on an image panel, press and hold the right mouse button and move around the mouse until the image zoom in/out is at the desired size. User can drag the mouse right/up to zoom-in the image and drag the mouse left/down to zoom-out of the image. You may make image pan & scroll by dragging the mouse wheel button. Image zoom, pan & scroll applies to the original and denoised images at the same time.

4.2.3 Adjusting Window Width/Level

User can adjust the Window Width/Level by mouse dragging with the **left mouse** button. Place mouse cursor on an image panel, press and

hold the left mouse button and move around the mouse until the image Window Width and Level fits to the desired level. Dragging the mouse to the right narrows Window Width, while dragging the mouse to the left widens Window Width. Dragging the mouse up decreases Window Level, while dragging the mouse down increases Window Level. You will see the window width/level adjustment takes effect on the original and denoised images at the same time.

4.2.4 Window Width/Level Preset

MixView provides users with the options to adjust the Window Width/Level Preset. Click the **Window Preset** button at bottom of the MixView window. A dialog will appear allowing to apply a preset value of Window Width/Level. Three user-configurable preset buttons are provided. Clicking the buttons applies a preset value to the current opened images. Users may enter Window Width/Level directly at the dialog. Clicking the Configure button opens a new dialog where you can set up the names and preset values for the three buttons.
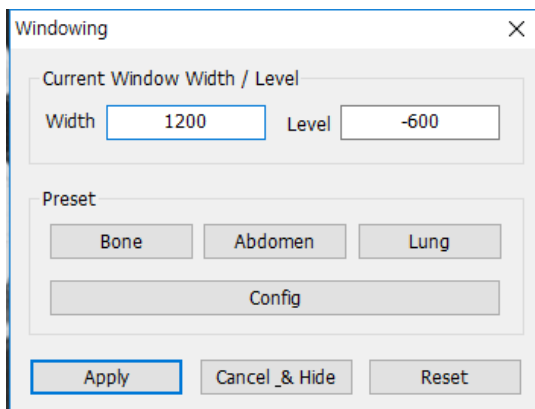
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