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- * October 2024 (13th edition)

Program 1: Program for Disease Diagnosis
 Controlled medical device: Program for general-purpose diagnostic imaging device workstation (70030012)

Medical imaging software Holoeyes MD

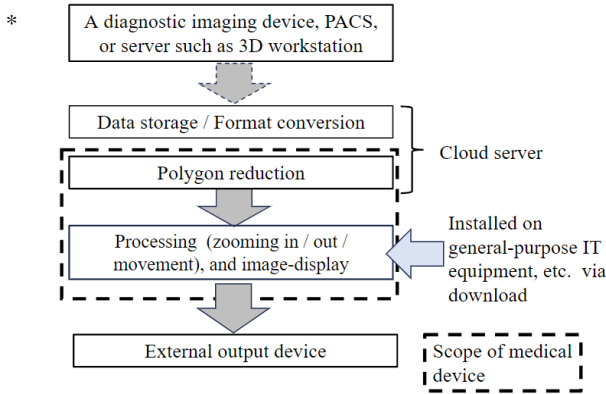
Configuration, structure, principle, etc.

<Configuration and structure>

This program processes imaging information obtained from diagnostic imaging devices and makes it available for healthcare applications. Automatic diagnosis is not performed. In addition to the standard function of image display, it has the optional function of three-dimensional (3D) image processing. The basic functions include an image- and information-processing function (zooming in and out, and movement), and an image-display function. The program is used after installation on general-purpose IT equipment, etc. It is provided as a download.

<Operation Principles>

The program receives images from a diagnostic imaging device or a server storing such imaging information, and displays them for healthcare purposes.



<Additional functions>

| Item | Function |
|------------------------------------|-------------------------------------------------------------------------------------------------------------------|
| 3D image-processing function | A function that processes a sequence of imaging data as a 3D image for display. Including virtual endoscopy, etc. |
| General image measurement function | A basic distance measurement function that uses the pixel values and position information of imaging data. |

<Not applicable to medical devices>

| Item | Function |
|-----------------------------|-----------------------------------------------------|
| Program for educational use | Remote conferencing function that shares 3D images. |

Purpose or effects of use

The program processes human body imaging information from diagnostic imaging devices for healthcare applications. This program does not have an automatic diagnosis function.

Methods of use, etc.

<Methods of use>

1. Operating environment and preliminary preparation
 This program is installed on general-purpose IT equipment, etc., that meets the below specifications. Installation is by the method specified by the marketing authorization holder.

*① Microsoft HoloLens 2

SoC: Qualcomm Snapdragon 850 computing platform
 HPU: Second-generation custom-made holographic mounting device

RAM: 4.0 GB
 Storage: 64 GB, UFS 2.1
 Display: 2k 3:2 light engine
 OS: Windows Holographic Operating System
 Safety: Compliant with IEC 62368-1 (JIS C 62368-1)
 EMC: Compliant with CISPR32, FCC/CISPR35 and CISPR24

* ② Meta Quest 2

SoC: Qualcomm® Snapdragon XR2 Platform
 Graphic: Adreno 650
 RAM: 6.0 GB
 Storage: 64/128/256 GB
 Display: Single high-speed switch LCD 1832 × 1920 per eye @ 72 Hz

* OS: Android 12 or higher

Safety: Compliant with IEC 62368-1 (JIS C 62368-1)
 EMC: Compliant with CISPR32/CISPR35 and CISPR24

* ③ Meta Quest Pro

SoC: Qualcomm® Snapdragon XR2+ Platform
 Graphic: Adreno 650
 RAM: 12 GB
 Storage: 256 GB
 Display: LCD 1800 × 1920 per eye @ 90 Hz

* OS: Android 12 or higher

Safety: Compliant with IEC 62368-1 (JIS C 62368-1)
 EMC: Compliant with CISPR32/CISPR35 and CISPR24

* ④ Meta Quest 3

SoC: Qualcomm® Snapdragon XR2 Gen2
 RAM: 8 GB
 Storage: 128 / 512 GB
 Display: Single high speed switch LCD 2064 × 2208 per eye @ 120 Hz

* OS: Android 12 or higher

Safety: Compliant with IEC 62368-1 (JIS C 62368-1)
 EMC: Compliant with CISPR32/CISPR35

** ⑤ Meta Quest 3S

SoC: Qualcomm® Snapdragon XR2 Gen2
 RAM: 8 GB
 Storage: 128 / 256 GB
 Display: LCD 1832×1920 per eye @ 90 Hz/ 120Hz
 OS: Android 12 or higher
 Safety: Compliant with IEC 62368-1 (JIS C 62368-1)
 EMC: Compliant with CISPR32/CISPR35

Specifications of external output device
 Minimum 1280 × 720 pixel resolution
 32-bit or higher color display

* Recommended service site operation environment

OS: Windows 10, macOS 12.7.5 or later
 Browser: Google Chrome latest version

※ When general-purpose IT equipment, etc., with this program downloaded and installed, is used in an environment with patients present, use the internal power supply for the general-purpose IT equipment, etc., in order to ensure safety (JIS T 0601-1, 16.6 Leakage current). Do not use the equipment when connected to an external power supply.

2. Preparation for use

- (1) Turn on the power of the device where the program will be installed.
- (2) Start the program.

3. Operation

- (1) Obtain imaging data.
- (2) Select a function.
- (3) Display images, etc.

Be sure to check the instruction manual.

4. Termination
 - (1) Terminate the program by clicking the termination icon on the screen or selecting the termination option from the menu.
 - (2) Turn off the power if necessary.

Cautions with use

Important cautions

1. Confirm that the 3D model is the appropriate one for the relevant patient before downloading it.
2. Confirm in advance that the images and data are those intended for the relevant patient.
3. Confirm that the display on the external output device screen is not distorted or missing.
4. If your PC freezes for some reason when the 3D model is being displayed, download the 3D model again after verifying that your PC has normal operation.
5. Confirm that the 3D model is not displayed with mirror reversal.
6. Confirm that the 3D model is not displayed smaller or larger than the real thing.
7. If you are too close to a magnified 3D model, the display may not function properly.
8. The educational-use program function is a non-medical function. Do not use it for healthcare.
9. The user is responsible for correcting the images and data.
10. This program should be used by healthcare professionals who are familiar with the collection and processing of imaging information, and display of such images, by each diagnostic imaging device.
11. Obtaining accurate and optimal imaging and data requires proper implementation of all procedures from image acquisition to display, including correct position information, and patient identification. It is the user's responsibility to determine whether the images and data generated are suitable for the intended use.
12. The results displayed are calculated from the images, data, and supplementary information. These may differ from the actual results due to various factors, such as inappropriate use.
13. The results of measurement by this program are calculated from the images and supplementary information. Therefore, do not make a definitive diagnosis solely on the basis of the measurements obtained with this product, but use them for reference.
14. Do not use this program for primary diagnosis.
15. Do not use this program other than for the purposes of use.
16. Do not use it in a high-concentration oxygen atmosphere, in an explosive atmosphere such as one containing flammable anesthetic gas, or in the presence of inflammable substances.
17. Before using the product, be sure to read the instruction manual for the general-purpose IT equipment, etc.
18. This program should be downloaded to the general-purpose IT equipment, etc., specified in "Methods of use". When used in combination with other devices, confirm that the device is functioning properly before use in healthcare.
- * 19. Do not use Passthrough function of the Meta Quest series devices for any purpose other than displaying the 3D model.
20. General-purpose IT equipment on which this program is installed should be stored in a physically controlled location with a key or other means to prevent unauthorized use.
21. To prevent unauthorized use, use the account management functions provided with the operating system of general-purpose IT equipment, etc., whenever possible.
22. When using this program, please use it in a secure network environment such as in a hospital where security is ensured.
23. When connecting to a USB port of a general-purpose IT equipment or other device, make sure that the security of the device to which it is connected is secured before use.

Contact Information for the Marketing Authorization Holder and Manufacturer

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*※ If you encounter a problem that is related to cyber security, please contact us through the contact page on the Holoeyes MD service website.