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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.
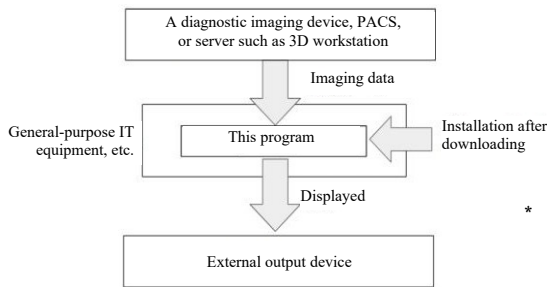
Additional functions

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 General-purpose IT equipment (recommended environment)
CPU: Intel Core i5-7500 or higher
Memory: 8 GB or more
GPU: NVidia GTX 1060 or higher
HDD: 128 GB or more
OS: Windows 10 or higher
Safety: Compliant with IEC 60950-1 (JIS C 6950-1) and IEC 62368-1 (JIS C 62368-1)
EMC: Compliant with CISPR32 (or CISPR22) / CISPR24 (or VCCI)

② Microsoft HoloLens
CPU: Intel 32-bit architecture
HPU: Custom-built Microsoft Holographic Processing Unit (HPU 1.0)
RAM: 2.0 GB
Storage: 64 GB Flash
Display: 2 HD 16:9 light engine
OS: Windows 10 or higher
Safety: Compliant with IEC 60950-1 (JIS C 6950-1)
EMC: Compliant with CISPR32, FCC/CISPR35 and CISPR24

③ 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

④ Magic Leap One
CPU: Parker SOC CPU (NVIDIA ®) CPU: Denver 2.0
RAM: 8.0 GB
Storage: 128 GB
OS: Lumin OS 0.98
Safety: Compliant with IEC 62368-1 (JIS C 62368-1)
EMC: Compliant with CISPR32/CISPR24

⑤ Meta Quest
**SoC: Qualcomm ® Snapdragon 835
Graphic: Adreno 540
RAM: 4.0 GB
Storage: 64/128 GB
Display: PenTile OLED 1440 × 1600 per eye @ 72 Hz
OS: Android 7 or higher
Safety: Compliant with IEC 62368-1 (JIS C 62368-1)
EMC: Compliant with CISPR32/CISPR35 and CISPR24

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

⑦ 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 10 or higher
Safety: Compliant with IEC 62368-1 (JIS C 62368-1)

Be sure to check the instruction manual.

EMC: Compliant with CISPR32/CISPR35 and CISPR24

**⑧ `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 10 or higher
Safety: Compliant with IEC 62368-1 (JIS C 62368-1)
EMC: Compliant with CISPR32/CISPR35

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

※ 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.

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. 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.
**20. To prevent unauthorized use, use the account management
    functions provided with the operating system of general-
    purpose IT equipment, etc., whenever possible.
**21. When using this program, please use it in a secure network
    environment such as in a hospital where security is
    ensured.
**22. 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**
Holoeyes Inc.
Mourin Building 303, 2-17-3 Minami-Aoyama, Minato-ku,
Tokyo
Tel.: 050-1744-9255
**※ If you encounter a problem that is related to cyber
security, please contact us through the contact page on the
Holoeyes MD service website.

Be sure to check the instruction manual.