MiiS Horus Scope
DSC 300
User Manual

Contents

Preparations

Before use

Prior to installation and start-up of the Horus Scope, carefully read the user manual. As with all technical devices, the proper function and safety operation of this device depend on the user complying with the safety recommendations described in these operating instructions. In addition, please make sure that it does not appear damaged or broken. If there are breaks on the outer casing or other visual defects, please contact the manufacturer or a certified service facility.

⚠ Caution: Federal law restricts this device to sale by or on the order of a physician, and other countries shall be follow.

Indication for Use

Intended for qualified healthcare professionals who are trained in its use.
The device is intended to be used in professional healthcare (e.g. hospital or clinic, etc.)
The device may be used on any human group.
The device does not provide a diagnosis or therapy.
The clinical benefit is for healthcare professionals, helping deliver state-of-the-art care to their patients.

Contraindications

⚠ This instrument must not be used for the following patients:
  • Patients who are hypersensitive to light.
  • Patients who recently underwent photodynamic therapy (PDT).
  • Patients taking medication that causes photosensitivity.
  • Patients with a history of migraines.
  • Patients with a history of photosensitive epilepsy.
  • Patients with any kind of disease which could be induced by flash or strong light.

Camera handling

Protect the camera from excessive vibration, force, or pressure.

⚠ Avoid using the camera under the following conditions, which may damage the lens, the monitor, or the control unit and may also cause the camera to malfunction or prevent recording:
  • Dropping or hitting the camera against a hard surface.
  • Exerting excessive force on the lens or the monitor.

The camera is not dust resistant, splash resistant, or waterproof. Avoid using the camera in places with excessive dust or sand, or where water can come into contact with the camera.

⚠ Avoid using the camera under the following conditions, which present the risk that sand, water, or foreign material may enter the camera through the lens or gaps around buttons. Be especially careful because these condition may damage the camera, and such damage may not be repairable:
  • Operate in extremely dusty or sandy places
  • Exposing the camera to rain or moisture

Focus calibration

A. Focus calibration of DEA 200(→ 48)

> To ensure the quality and performance of image, calibrate the working distance of your DEA 200 **every month** is recommended.

Condensation (when the lens or the monitor is fogged up)

⚠ Condensation may occur when the camera is exposed to sudden changes of temperature or humidity. Avoid these conditions because they may soil the lens or the monitor, cause mold, or damage the camera.

⚠ If condensation does occur, turn off the camera and wait for about two hours before using it. Once the camera adjusts to the surrounding temperature, the fogging will clear naturally.

Safe eye screening

⚠ While no acute optical radiation hazards have been identified with the camera, it is recommended that the intensity of light directed into the patient's eye be limited to the minimum level necessary for diagnosis. Infants, aphakes, and persons with diseased eyes are at greater risk. The risk may also be increased if the person being examined has had any exposure to the same instrument or any other ophthalmic instrument that uses a visible light source within the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography. The intended use of this device is for routine ophthalmic exams of typically less than 60 seconds per eye. While any medical procedure has its benefit versus risk factor, more complicated exams should not exceed three minutes of exam time within 24 hours. Significant use of this device beyond its intended use is not recommended as it may cause harm to the eyes.

⚠ During the operation of using the camera, please follow the below instructions.
   • Always use the camera or accessories in accordance with the directions and recommendations contained in this user manual.
   • When operating the device, please make sure that the optical lens does not touch the eyes or nose of the patient in order to avoid harm.
   • For illumination and photography with the camera, do not select an exposure higher than required. Do not shine light on the eye beyond the recommended time during examination. Otherwise, the examined eye may experience pain or be injured.

No compensation for missed shots

⚠ We cannot compensate for missed shots if technical problems with the camera or card prevent recording.

Usage cautions and notes

When in use

⚠ The camera may become warm if used for long periods of time, but this is not its fault.

⚠ Keep the camera as far away as possible from electromagnetic equipment (such as micro- wave ovens, TVs, video games, etc.).

⚠ Do not use the camera near radio transmitters or high-voltage lines.

⚠ Never leave the camera and the battery in a car or on a car hood in the summer. Doing so may cause leakage of the battery electrolyte, overheating, fire, or a battery

explosion due to the high temperature.

⚖ If the fundus lens and control unit get wet, do not attempt to dry with a heater, microwave, autoclave, or UV light.

⚖ Do not extend the supplied cables. Do not keep the power cord near any heat source.

⚖ When the camera is not in use, please disconnect the power plug and keep it in a safe place.

⚖ The performance criteria of the following description are accepted when operating the device: temporary function abnormal but can be resumed after restarting without operator intervention. Unless basic safety cannot be achieved.

⚖ In any operating conditions, the camera can be returned to the photo mode is regarded as the normal state.

Charging the battery

⚖ The time required for charging varies depending on the conditions of battery usage. Charging takes longer at high or low temperatures and when the battery has not been used for some time.

⚖ The battery will get warm during charging and for some time thereafter.

⚖ The battery will be drained completely if not used for long periods of me, even after being charged.

⚖ Only use Li-ion Battery 3.6V/Capacity 3350mAh which shall be provided by the manufacturer or distributors. The battery has designed the protection circuit. To ensure the safety of the product operation, if the battery reaches its life time, please contact the manufacturer or distributor to buy the spare battery.

NOTE

⚖ ***The battery cannot be affected by external force impact. Its appearance cannot be damaged. If the battery is broken or damaged by external force, DO NOT USE to avoid dangerous.***

Optical Radiation hazard

⚖ "CAUTION – The light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. Exposure to light from this instrument when operated at maximum intensity will exceed the safety guideline after 60 seconds."

RELATIVE SPECTRAL DISTRIBUTION OF ILLUMINATION LIGHT
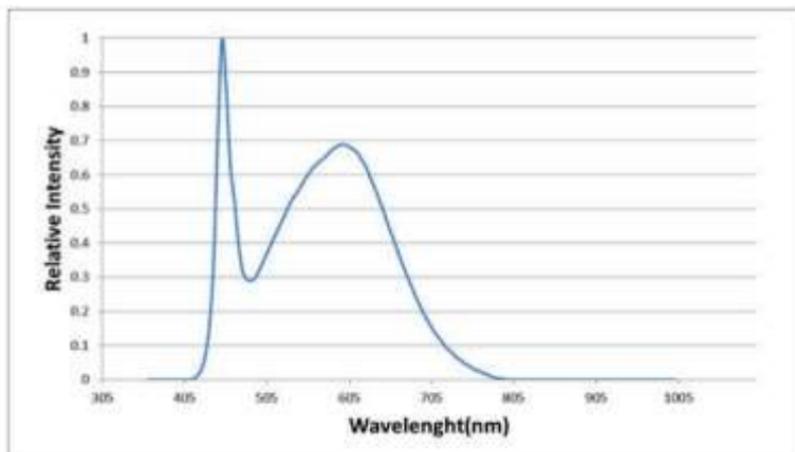
Memory cards
- If you purchase different memory capacity of memory card, must be preceded format to FAT32.
- To prevent damage to cards and data:
  - Avoid high temperatures, direct sunlight, electromagnetic fields, and static electricity.
  - Do not bend, drop, or expose to strong impacts.
  - Do not touch the terminals or allow them to become dirty or wet.
  - When operating this device, please do not remove or insert the memory card.

When disposing of/transferring memory cards:

- If using the "format" or "delete" functions on your camera or computer, this only changes the file management information and does not completely delete the data from the memory card. When disposing of or transferring your memory cards, we recommend physically destroying them or using commercially available computer data erasing so ware to completely delete the data from the card. Data on memory cards should be managed responsibly.

Accessories

About the Fundus Image Management System (L type), Model: SD 1:
- The Fundus Image Management System is a software which can analyze optic nerve images shot by DEC 200.
- It can estimate the relative amount of hemoglobin at different regions of the optic nerve, and other indexes such as Vertical Cup/Disc ratio, the Cup/Disc area ratio.
- Please refer to the user manual of SD 1 for more details.

About the slit lamp jig:
- Attach the slit lamp jig only to slit lamp equipment that has been qualified by MiiS.

Make sure the jig is completely locked by pushing it downward.
⚠ The slit lamp jig is only suitable for DEC 200.

Protection
⚠ Do not attempt to remove the cover from the product to prevent the product from malfunctioning.
⚠ No modification of this device is allowed. The performance would be subject to any modification and may cause hazardous radiation exposure.

CLASS 1 LED PRODUCT

EMC (electromagnetic compatibility)
During installation and opera on of the device, observe the following instructions:
⚠ Do not use the device simultaneously with other electronic equipment to avoid electromagnetic interference with the operation of the device.
⚠ Do not use or stack the device near, on, or under other electronic equipment to avoid electromagnetic interference with the opera on of the device.
⚠ Do not use the device in the same room as other electronic equipment, such as life-support equipment that has major effects on the life of the patient and results of treatment, or any other measurement or treatment equipment that involves small electric current.
⚠ Do not use the system with portable and mobile radio frequency communication systems because that may have an adverse effect on the operation of the device.
⚠ Do not use cables or accessories that are not specified for the device because that may increase the emission of electromagnetic waves from the device and decrease the immunity of the device to electromagnetic disturbance.
⚠ Do not touch the lens connecting pins of the control unit or the signal pad of the lenses without special precautions.
⚠ When operating the device simultaneously with other electronic equipment, please make sure the distance between two devices is no closer than 30 cm (12 inches), including cables specified by the manufacturer.

Cleaning and Disinfection
The device is a precision photo electronic instrument that shall be handled with specific care. Please note the following cleaning instructions:
⚠ Turn off the device before cleaning it.
⚠ Disinfect the control unit and charging station with CaviWipes and maintain 3~5mins. Wait for the cleaning liquid to dissolve before turning the power on and connecting the charging station and USB cable to the control unit.
⚠ It is recommended to clean the fundus lens with a CaviWipes that is commercial product and be manufactured by THORLABS Inc. (www.thorlabs.com).
⚠ If a replacement for the eyecup or rubber pad is needed, please contact the manufacturer or retailer.
⚠ Clean the eyecup or rubber pad before each use.
⚠ Disinfect the eyecup or rubber pad with CaviWipes.
NOTE

⚜ ***The device is not intended to be sterilized. Disinfect the control unit and charging station with CaviWipes).***

Maintenance

⚜ Please check control unit and optical lens once every 3 months.

> It is the health care provider to protect patient health information and to meet regulatory and HIPAA compliance. The images on DSC 300 may contain identifiable patient information and it is the responsibility of the health care provider to ensure that data safeguards are implemented to protect patient health information.
>
> Please note that the actual controls and components, menu items, and other information of your camera may differ from those in the illustrations provided in these instructions.

Operating Environment

- Ambient temperature: 10°C to 35°C
- Relative humidity: 30% to 90%
- Atmospheric pressure: 800hPa to 1013hPa
- Shock (without packing):   10G, duration 6ms

Environment for Storage

- Ambient temperature: -10°C to +55°C
- Relative humidity range: 10% to 95%
- Atmospheric pressure: 700hPa to 1013hPa

NOTE

⚜ ***It is recommended to remove the battery if the device is stored over two weeks.***

Environment for Transportation

- Ambient temperature: -40°C to +70°C
- Relative humidity range: 10% to 95%
- Atmospheric pressure: 500hPa to 1013hPa
- Vibration, sinusoidal: 10Hz to 500Hz: 0.5G
- Shock: 30G, duration 6ms
- Bump: 10G, duration 6ms

NOTE

⚜ ***It is recommended to remove the battery if the device is stored over two weeks.***

Regulations

⚜ Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

⚓ This device has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2: 2014. These limits are designed to provide reasonable protection against harmful interference in a standard medical installation. If this device does cause harmful interference to other devices, which can be determined by turning the system off and on, the user is encouraged to try to correct the interference through one or more of the following measures: Reorient or relocate the receiving device.

- Increase the separation between the system and other devices.
- Connect the device to an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.

⚓ The International Electrotechnical Commission sets the essential requirements for electrical and electronic equipment that may disturb or be disturbed by other equipment. The device complies with these requirements as shown in the tables in "Symbols and standards: EMC" ($\rightarrow$ 64). Follow the guidance in the tables for use of the device in an electromagnetic environment.

IT Network Security

Computers used to connect to the device should be note the following security instructions:

⚓ Make sure anti-virus software is installed in personnel computer before connecting the device to it and keep the latest version.
Recommended anti-virus software,
- ESET Endpoint Antivirus
- Bitdefender Antivirus
- kaspersky anti-virus

⚓ The device can only be updated or processed by original factory or a legally authorized distributor. Do not allow unauthorized persons or users to update or process the software with any memory card.

⚓ Users must keep patient information in a safe place.

⚓ Physically destroyed the memory card when abandoned.

Names of components

Scope of Delivery

Product Name	Model Name	Accessories
Control unit	MiiS Horus Scope DSC 300	1. Battery 2. Power adapter 3. Mini USB cable 1.8m (Shield) 4. Micro HDMI cable 2.0m (Shield) 5. Charging station 6. Memory card 7. Portable chin rest (Optional) 8. Image Management System, Model: SA 1 standalone (option) 9. Image Management System, Model: SB 1 (free download) 10. Image Management System, Model: SD 1 standalone (option)
Eye Fundus Camera	MiiS Horus⁺ Scope DEC 200	1. Eyecup 2. MiiS Horus Portable Chin Rest: CR 100 (Optional) 3. Slit lamp jig (Optional)
Eye Anterior Camera	MiiS Horus⁺ Scope DEA 200	1. Forehead
Eye Surface Camera	MiiS Horus⁺ Scope DGC 200	

Intended for use

MiiS Horus⁺ Scope DEC 200 is a digital hand-held eye fundus camera used to record digital photographs and video of fundus (including retina, macula, and optic disc) of the human eye and surrounding area.

MiiS Horus⁺ Scope DEA 200 is a digital hand-held eye anterior camera used to record digital photographs and video of anterior segment (including cornea, anterior chamber, and lens) of the human eye and surrounding area

MiiS Horus⁺ Scope DGC 200 is the eye surface optical lens used to record digital photographs and video of anterior area of human eye and surrounding area.
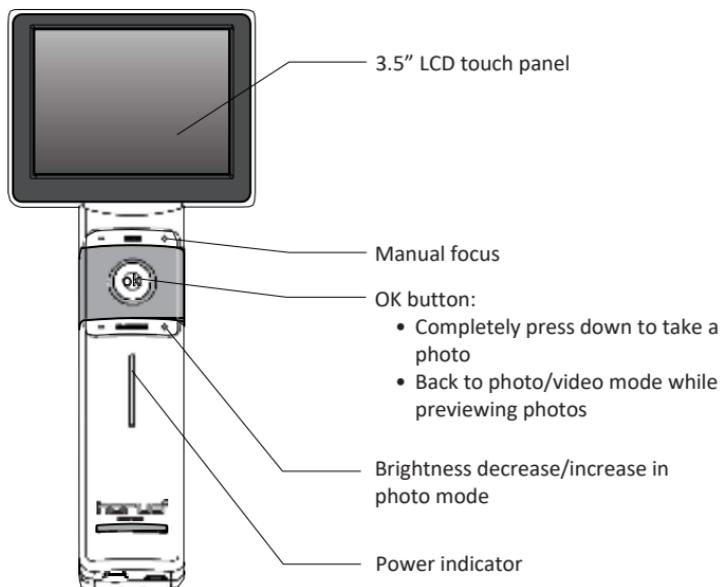
> It is the health care provider to protect patient health information and to meet regulatory and HIPAA compliance. The images on DSC 300 may contain identifiable patient information and it is the responsibility of the health care provider to ensure that data safeguards are implemented to protect patient health information.
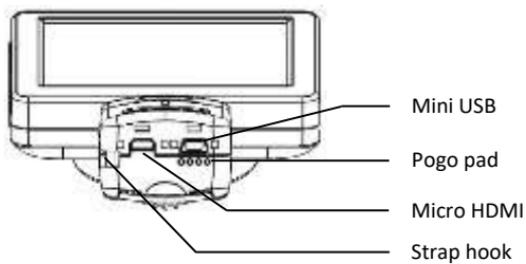
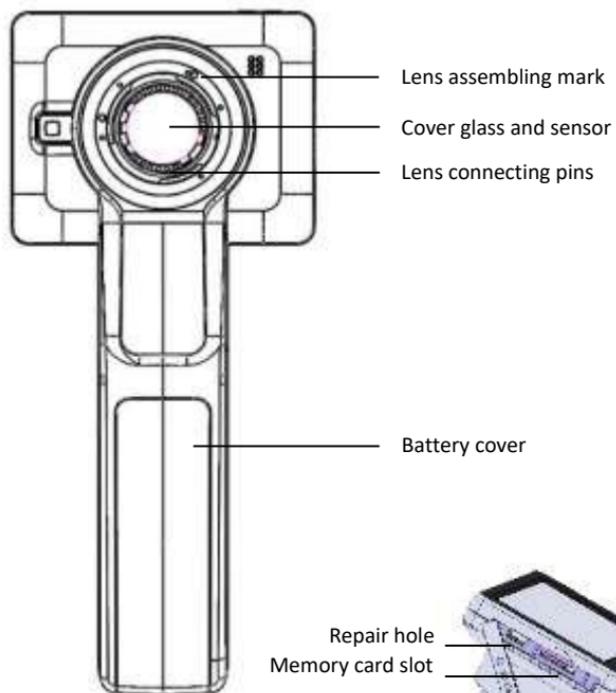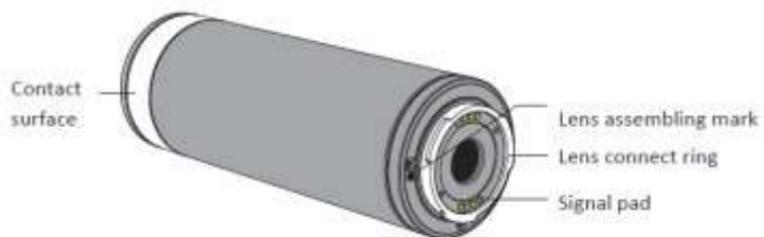## Control Unit (MiiS Horus Scope DSC 300)

Top view ››

Power button

Lens lock

Front view ››

3.5" LCD touch panel

Manual focus

OK button:
- Completely press down to take a photo
- Back to photo/video mode while previewing photos

Brightness decrease/increase in photo mode

Power indicator

Bottom view ››

Mini USB

Pogo pad

Micro HDMI

Strap hook

Rear view ››

Lens assembling mark

Cover glass and sensor

Lens connecting pins

Battery cover

Repair hole

Memory card slot

Charging Station

Mini USB connector

Optical Lens of MiiS Horus+ Scope DEC 200 (Eye Fundus Camera)

Contact surface

Lens assembling mark

Lens connect ring

Signal pad

Optical Lens of MiiS Horus+ Scope DEA 200 (Eye Anterior Camera)

Lens assembling mark

Lens connect ring

Signal pad

Zoom position

Assistant lighting switch

Filter wheel

Assistant lighting

Assistant lighting

Lighting track

Lighting assy.

Slit wheel

Optical Lens of MiiS Horus+ Scope DGC 200 (Eye Surface Camera)

Lens assembling mark

Lens connect ring

Signal pad

Charging the battery

Always charge before first use

Prior to first use, insert the battery into the control unit and close the battery cover referred to the below section. Connect USB connector to the power adapter. Let the battery be charged for at least five hours.
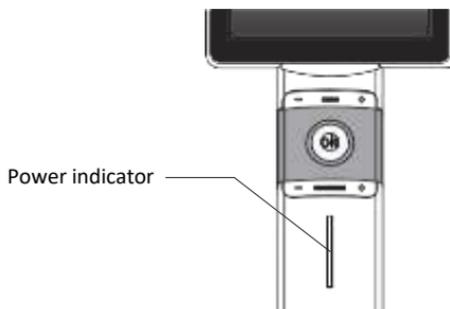
Connect to a power adapter

Extra usb powered, connect to second usb port on NB

Battery replacement

Open the battery cover by digging out the gap in the bottom of battery cover with a finger or something pointed.
- Tilt the battery cover and remove the battery cover by lifting it up.
- Remove the original battery and replace a new battery along the correct direction.
- Place the battery cover and secure it in place.
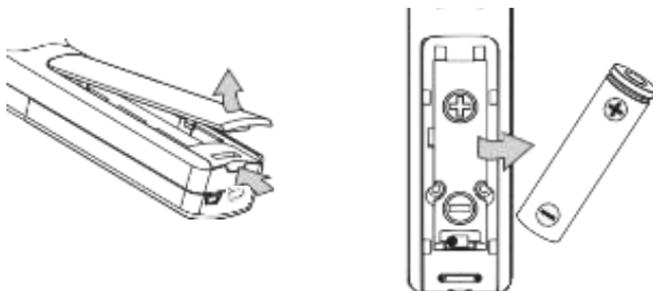
Power indicator

Power indicator

| System Status	Power off			Power on		
Light color	No Light	Blinking blue Light	Orange Light	Blue Light	Blinking blue Light	Mixed blue and orange Light
Information	System off	Power less than 25%	Charging	Normal operation	Power less than 25%	Connect to PC via USB cable or enable USB live video

Assembling

(Take Eye Fundus Camera as an example.)

Step 1. ↘

Align the marks of the optical lens and control unit.

Mark on the
optical lens

Mark
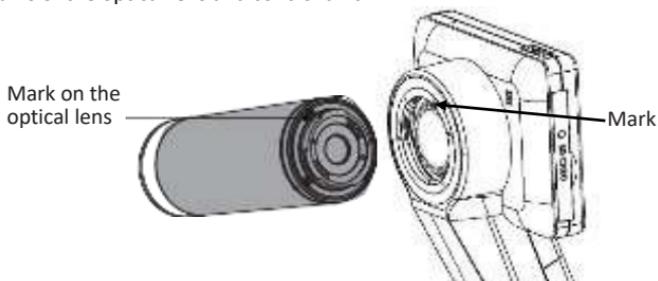
Step 2. →

Hold the optical lens and attach it to the
control unit. Rotate and fasten the optical lens
in a clockwise direction. You will hear a click
when the lens locks into the control unit.
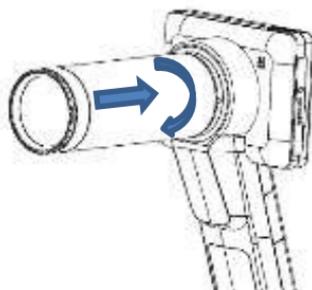
Step 3. ←

Turn on the power (→ 12). When optical lens and control unit
are assembled correctly, the information icons will appear on
the top of LCD touch panel. The screen will turn on, and then
the blue light of the power indicator (→ 17) will also turn on.

FOCUS

Step 4. →

To unlock the optical lens, press
the lens lock and then rotate the
optical lens in a counterclockwise
direction. Then the optical lens
will be unfastened.

Using the Setup mode

To turn on the system, press the power button (→ 12) to turn on the control unit. Approximately one to two seconds later, the boot screen will appear on the LCD panel.

Note:

When below conditions occur, user needs to turn off the power and reassemble the optical lens and control unit.

1. Optical lens isn't correctly assembled to the control unit.
   → When turning on the device, the device stays at boot screen and can't enter to control interface.
2. The black screen appears on the LCD panel during operation.
   → Please check the optical lens is well-assembled to the control unit.

A. DEC 200

Enter the Setup mode

Using the [Setup] menu

It is recommended that all setting items are set according to user's requirements for first-time use.

Bring up the [Setup] menu

Touch the photo icon and then touch the setup icon.

Exit the [Setup] menu

Once a setting adjustment is made, the new value affects the system immediately. Use the upper back button ⟨ or the OK button to exit the screen.

[Aiming Light/Capture Light]

The default setting of [Aiming Light/Capture Light] is [IR/White LED]. In the setting, DEC 200 employs IR illumination for alignment and focusing to assure patient comfort. With IR, the user observes fundus images monochromatically. At the moment of pressing the shutter button, the system will turn on the white LED instantly. Static images and motion pictures will be captured in full color.

If the setting is [White LED/White LED], then the user observes images in full color and capture static images and motion pictures in full color.

[IR brightness]

The IR brightness has 5 levels; the default setting is level 3. The range is from 1 to 5.

[WHT brightness]

The WHT brightness has 16 levels; the default setting is level 10. The range is from 0 to 15.

[Standby]

User can set standby mode to be on or off. Once the mode is on, the LCD panel will be turned off if the system is idle for three minutes. To touch the screen or press OK button to wake up the system.

[Date Setting]

User can change the current date setting from the screen.

[Time Setting]

User can change the current time setting from the screen.

[UVC]

While connecting DSC 300 to a computer via USB cable, the product works as a USB storage device. If UVC mode is on, pictures can be shown both on the LCD panel of the product and the screen of the computer. To display image on the computer, please install webcam application prior to enabling UVC mode. A freeware webcam application (e.g., Horus UVC view, Amcap) is a software that can receive UVC signal on the computer. User can search for relevant information over the Internet.

Free UVC viewer is available in any search engine.

[Quality check]

User can turn on or turn off the quality check function. If quality check function is on, the device will take a few seconds to analyze the quality of the image and then the quality will be shown on the screen in preview and display mode.

Preview   Display

NOTE

⚠ *The green color means the image quality is good. The orange or red color means the quality is acceptable and will come out a message to notify user to save or not.*

[DICOM]
  Export image with or without DICOM format.

[Factory Setting]
  User can recover the device to its factory settings.

[Format SD Card]
  User can format the Memory Card (SD card).

NOTE
  ⚠ *All information will be deleted after Memory Card is formatted.*

[Red Free Function]
  DEC 200 allows digital red free images to be created directly from the information of the initial color image.

After turn on red free function, it will take more than 3 seconds to do image process after shooting. And there is a red free switch icon at the left-down corner of image. By press the icon to switch image into red free mode.
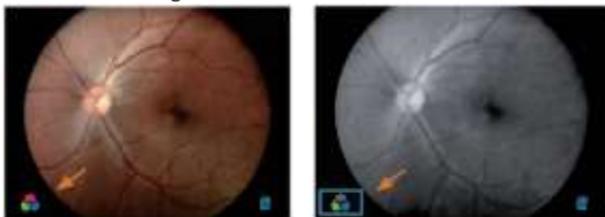
Wireless connection

[Wi-Fi]
  User can turn on/off the Wi-Fi.

[Wi-Fi setting – Direct Mode]
  User can select "Direct mode" and connect DSC 300 with PC through Wi-Fi directly.

Click "Change" icon to change the password.

[Wi-Fi setting – AP Mode]
 User can select "AP mode" to connect to internet through an AP.

[Upload to website – AP Mode]
 User can select "Upload setting" to set the URL, department and password.
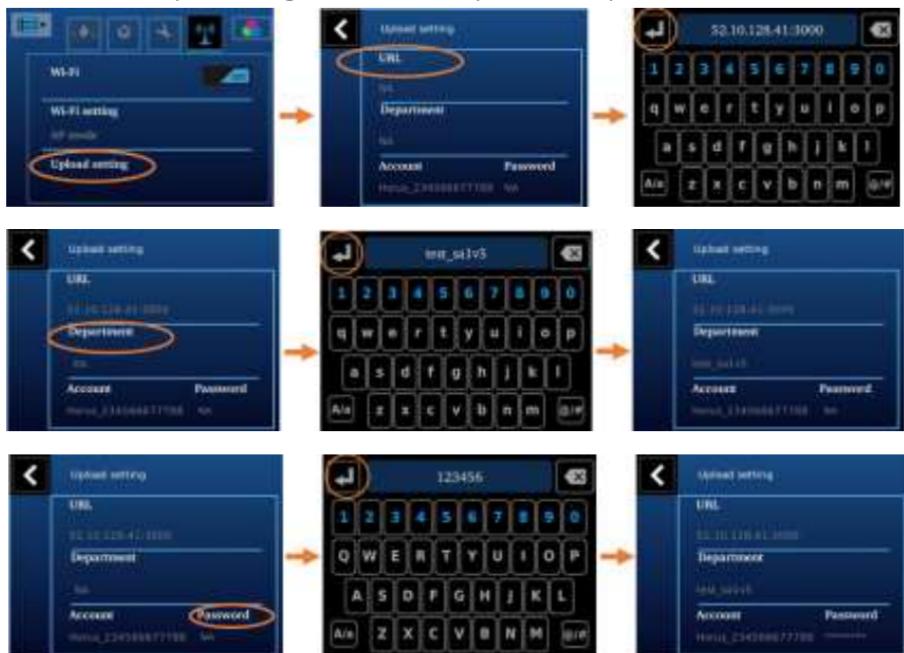
After select the images and input the patient's information, user can upload the data to website.
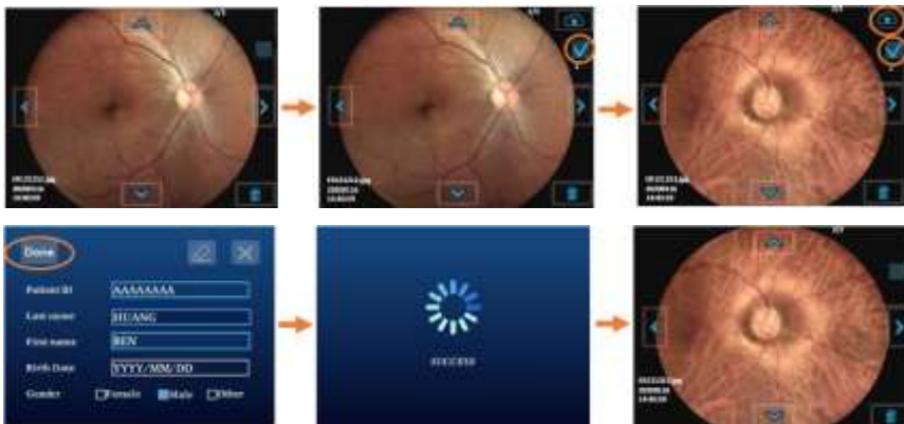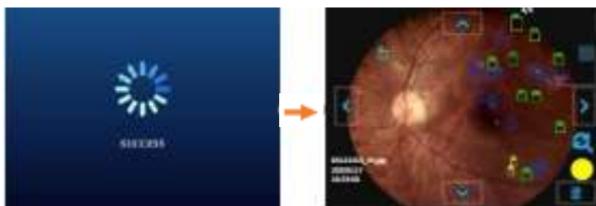

[Wi-Fi setting – DIB 100]
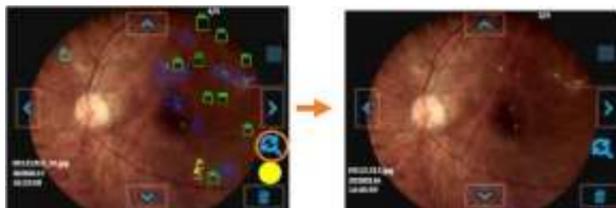User can select "DIB 100" and connect DSC 300 with DIB 100 through Wi-Fi.

[Transfer data to DIB 100]
When DSC 300 is connected with DIB 100, user can select images and transfer to DIB 100.

Click the "switch" button to switch between the original image and processed one.

B. DEA 200

Enter the Setup mode

Using the [Setup] menu

It is recommended that all setting items are set according to user's requirements for first-time use.

Bring up the [Setup] menu

Touch the photo icon and then touch the setup icon.

Exit the [Setup] menu

Once a setting adjustment is made, the new value affects the system immediately. Use the upper back button ![back] or the OK button to exit the screen.

Settings

[Background Illumination]

User can turn on/off and adjust brightness of the background illumination by icon in live view mode. The brightness levels are between 0B to 5B.

Background illumination brightness level

[Exposure time/Color]

User can adjust Exposure time/Color setting by touching the corresponding column

1. Color adjusting range from 0 to 20. (Default: R:3, B:15)

2. Exposure time from 1/30" to 1/120". (Default: 1/60")

[Standby]

User can set standby mode to be on or off. Once the mode is on, the LCD panel will be turned off if the system is idle for three minutes. To touch the screen or press OK button to wake up the system.

[Date Setting]

User can change the current date setting from the screen.

[Time Setting]

User can change the current time setting from the screen.

[UVC]

While connecting DSC 300 to a computer via USB cable, the product works as a USB storage device. If UVC mode is on, pictures can be shown both on the LCD panel of the product and the screen of the computer. To display image on the computer, please install webcam application prior to enabling UVC mode. A freeware webcam application (e.g., Horus UVC view, Amcap) is a software that can receive UVC signal on the computer. User can search for relevant information over the Internet.

Free UVC viewer is available in any search engine.

[Format SD Card]

User can format the memory card (SD card).

NOTE

⚠ ***All information will be deleted after memory card is formatted.***

[DICOM]

Export image with or without DICOM format.

[Factory Setting]
  User can recover the device to its factory settings.

Wireless connection

[Wi-Fi]
  User can turn on/off the Wi-Fi.

[Wi-Fi setting – Direct Mode]
  User can select "Direct mode" and connect DSC 300 with PC through Wi-Fi directly.
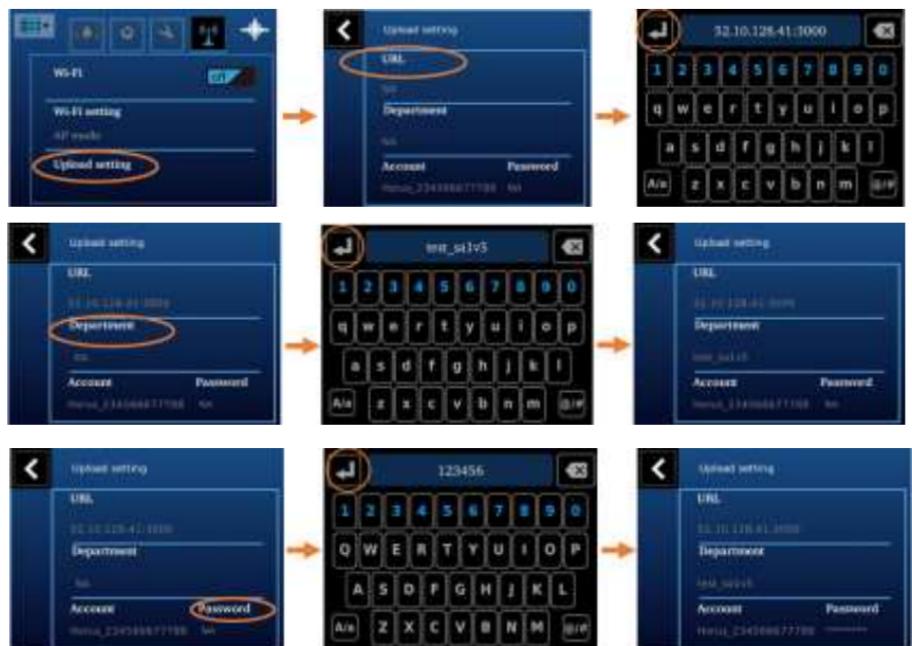

  Click "Change" icon to change the password.

[Wi-Fi setting – AP Mode]
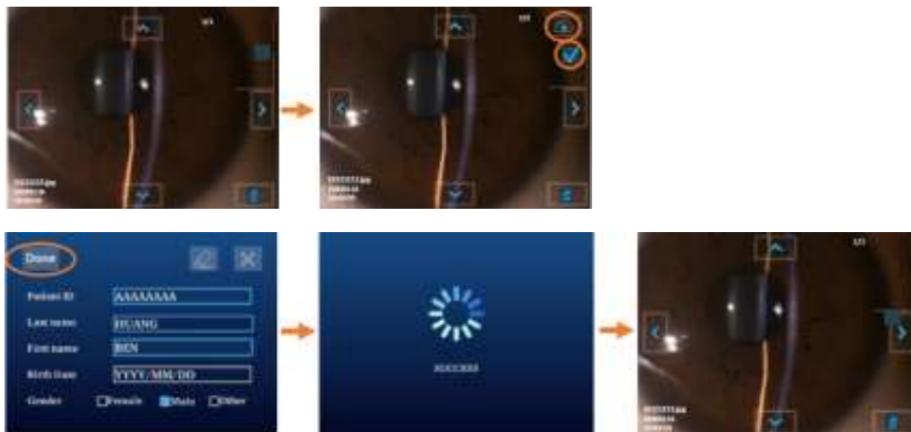 User can select "AP mode" to connect to internet through an AP.

[Upload to website – AP Mode]
 User can select "Upload setting" to set the URL, department and password.

After select the images and input the patient's information, user can upload the data to website.

C. DGC 200

Enter the Setup mode

Using the [Setup] menu
It is recommended that all setting items are set according to user's requirements for first-time use.

Bring up the [Setup] menu
Touch the photo icon and then touch the setup icon.

Exit the [Setup] menu
Once a setting adjustment is made, the new value affects the system immediately. Use the upper back button ![back] or the OK button to exit the screen.

Settings

[AF/MF Mode]
User can set Auto Focus mode to help image focus when taking pictures. Or chose Manual Focus mode and push the focus button on unit to do focus. Tap on the item to toggle the AF or MF mode.

[Standby]
User can set standby mode to be on or off. Once the mode is on, the LCD panel will be turned off if the system is idle for three minutes. To touch the screen or press OK button to wake up the system.

[Date Setting]
  User can change the current date setting from the screen.

[Time Setting]
  User can change the current time setting from the screen.

[UVC]
  While connecting DSC 300 to a computer via USB cable, the product works as a USB storage device. If UVC mode is on, pictures can be shown both on the LCD panel of the product and the screen of the computer. To display image on the computer, please install webcam application prior to enabling UVC mode. A freeware webcam application (e.g., Horus UVC view, Amcap) is a software that can receive UVC signal on the computer. User can search for relevant information over the Internet.

| Horus UVC View 🔍

Free UVC viewer is available in any search engine.

[Format SD Card]
  User can format the Memory card (SD card).

NOTE
  ⚠ ***All information will be deleted after memory card is formatted.***

[DICOM]
  Export image with or without DICOM format.

[Factory Setting]
  User can recover the device to its factory settings.

Wireless connection
[Wi-Fi]
  User can turn on/off the Wi-Fi.

[Wi-Fi setting – Direct Mode]
   User can select "Direct mode" and connect DSC 300 with PC through Wi-Fi directly.

   Click "Change" icon to change the password.

[Wi-Fi setting – AP Mode]
   User can select "AP mode" to connect to internet through an AP.
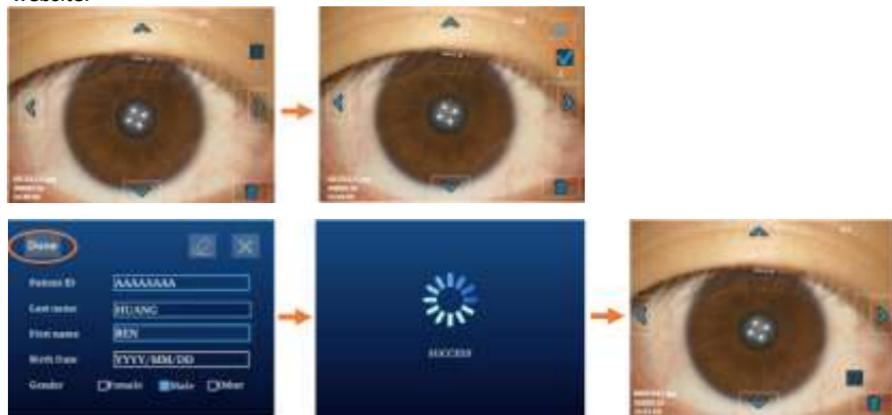
[Upload to website – AP Mode]

User can select "Upload setting" to set the URL, department and password.

After select the images and input the patient's information, user can upload the data to website.
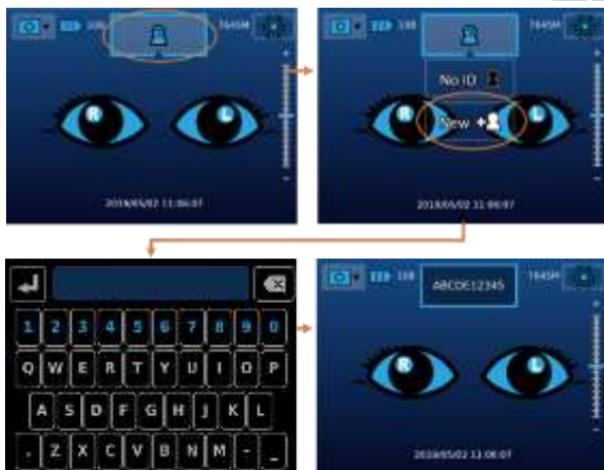
Entering the patient ID

Using patient ID as partial file name is supported in DSC 300.

<u>Create a new patient ID from scratch (DICOM off)</u>

By gently pressing the OK button, the user always goes back to a shooting mode, either photo or video mode; from the top information icons, tap [icon] to start the process.

<u>Create a new patient ID from scratch (DICOM on)</u>

By gently pressing the OK button, the user always goes back to a shooting mode, either photo or video mode; from the top information icons, tap [icon] to start the process.
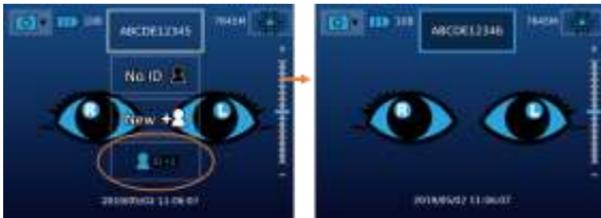*NOTE*
1. All of the information are necessary to finish this step.
2. Please note that the device could only record with 1 patient information.
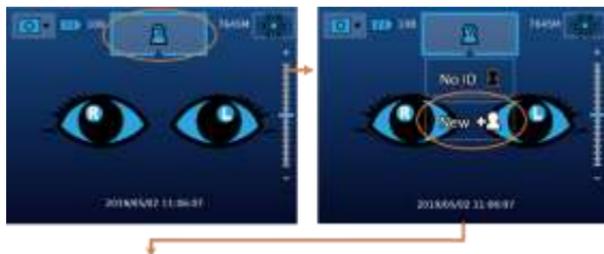
Create a new patient ID on an existing one

After a patient ID is set, the user can quickly create a new patient ID that is based on the existing ID plus 1 e.g., ABCDE12345 → ABCDE12346.


File naming rule

Product Name	Model Name	Picture Name without ID	Picture Name with ID
Eye Fundus Camera	DEC 200	ELHHMMSS.jpg ERHHMMSS.jpg	ELXXXXXXXXXXHHMMSS.jpg ERXXXXXXXXXXHHMMSS.jpg
Eye Anterior Camera	DEA 200	ALHHMMSS.jpg ARHHMMSS.jpg	ALXXXXXXXXXXHHMMSS.jpg ARXXXXXXXXXXHHMMSS.jpg
Eye Surface Camera	DGC 200	GLHHMMSS.jpg GRHHMMSS.jpg	GLXXXXXXXXXXHHMMSS.jpg GRXXXXXXXXXXHHMMSS.jpg

Meaning of each symbol:

Symbol	Refer to
EL	Left eye photo taken by the eye fundus camera
ER	Right eye photo taken by the eye fundus camera
AL	Left eye photo taken by the eye anterior camera
AR	Right eye photo taken by the eye anterior camera
GL	Left eye photo taken by the eye surface camera
GR	Right eye photo taken by the eye surface camera
HH	Hour
MM	Minute
SS	Second
XXXXX	Patient ID, up to 20 characters

Example:
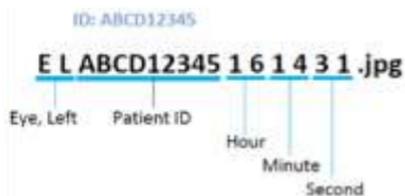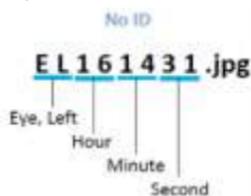
The image name is explained as follows:

EL: Left eye photo taken by the eye fundus camera; hour: 16; minute: 14; and second: 31.
If the given patient ID is ABCD12345, the image mane would be written as
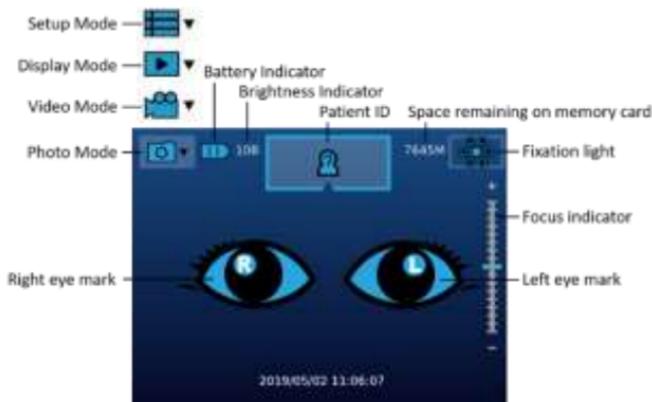ELABCD12345161431.jpg

Taking pictures

A. DEC 200
Sequence of operations

Step 1: Turn on the power

Press the power button to turn on the control unit. Approximately one to two seconds later, the boot screen will appear on the LCD panel. After about 15 seconds, the information icons will appear on the top of the LCD panel.

Step 2: Make sure memory card is inserted

Once the memory card has been inserted, the user can start to take photographs in any shooting mode, either photo or video mode.

Step 3: Choose a shooting mode

Tap the photo or the video mode icon to enter a shooting mode.

Step 4: Mark left /right eye

By doing so, the user can tell whether a photo/video is left eye or right eye of examinee record from its file name.

Step 5: Trigger Auto Shooting

There is a green frame on the screen which acts as "IR spot indicator". When users move IR spot (a bright square) into this green frame, the auto-shooting function will be triggered and a picture will be captured automatically.

Notes

⚠ *If it's difficult to activate auto-shooting, there are 2 options:*

1. Let IR spot into the frame then completely press OK button to take a photo.
2. By tapping MF icon or pressing focus-adjustment buttons of the control unit ([— ⚙ ⬦]), to switch to manual focus mode. After optimizing the focus via focus-adjustment buttons, completely press OK button to take the photo.
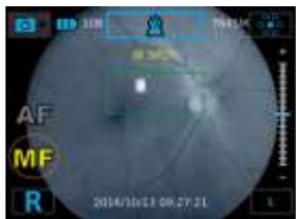
Holding position

Hold the control unit with one hand and use the other hand to hold the front side of the lens. Maintain the lens at the same height of the eye being examined. To stabilize the lens, rest the lens on the part of the hand between the thumb and index finger and put your middle and index fingers on the examinee's forehead, as showed in the following image.
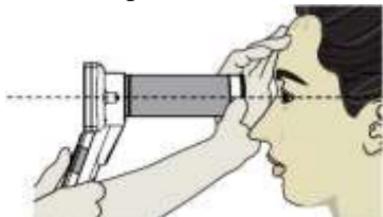
View the examined eye keeping the lens horizontal to the examined eye. Then move forward slowly until you can see the optic disk in the controller screen. (For sanitary reasons, make sure the controller lens does not touch the patient's eyes or nose.)

Fixation lamp

Choose fixation LED position and ask the examinee to look at the fixation LED. Adjust the brightness of fixation LEDs by using the brightness adjustment keys of the control unit. 5B is the maximum brightness level in fixation setting.
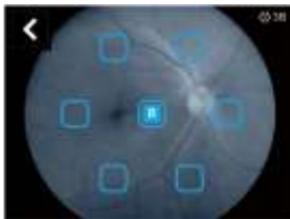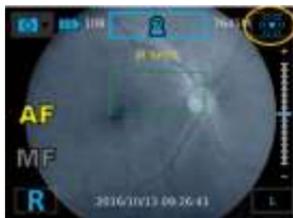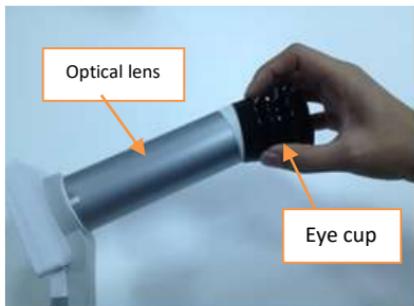
Eye Cup Installation

Step 1: Put the eye cup on the front of optical lens.

Step 2: If you want to change the direction of mask wing, one hand holds the lens, the other hand rotates mask to the direction you wanted. The idea is using the mask wing

Step.1   **Step.2**

Examination conditions

After the optical lens is attached to the control unit and setup is complete, the user can start taking images. Approaches for taking the image of human eye fundus are as follows:

- Have the examinee stay in <5 lux dark room; in such an environment, a newspaper is nearly impossible to see. Remove the patient's glasses or contact lenses. Make sure that the eye's pupil has a diameter larger than 4 mm, or be sure to sufficiently dilate in advance.

Q&A troubleshooting of DEC 200

A good image should have two characteristics:

1. Positions
   The macula and the optic disc are horizontally aligned in the middle.
2. High contrast
   The macula, optic disc, and vessels are all clear.
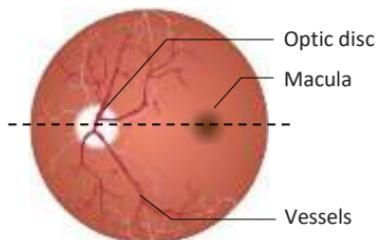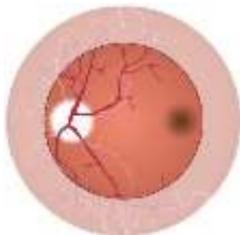

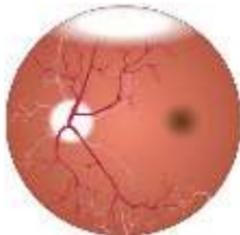If the above characteristics can't be found in the shot, possible failures might be the following:

1. Small fundus image	2. White hot spot on the top of the image	3. Dark shadow on the top of the image

| The lens is too far away from the examinee's eye. | The lens is too close to the examinee's eye. | The lens is much lower than the visual axis. |
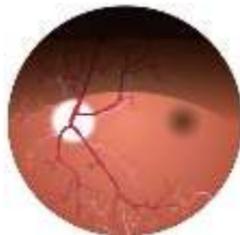
4. Dark shadow on the bottom of the image	5. Line or spot within the view	6. Blue or white shadow on the bottom of image
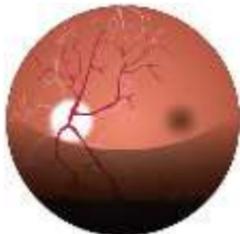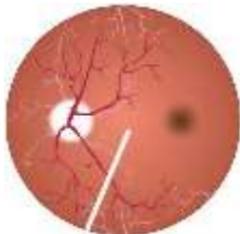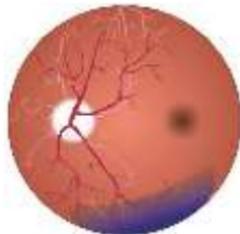
| The lens is much higher than the visual axis. | The lens is much higher than the visual axis. | Cornea reflection |

B. DEA 200

Sequence of operations

Step 1: Turn on the power

Press the power button to turn on the control unit. Approximately one to two seconds later, the boot screen will appear on the LCD panel. After about 15 seconds, the information icons

Setup Mode — Battery Indicator
Display Mode — Brightness Indicator
Video Mode — Patient ID — Space remaining on memory card
Photo Mode — 38 — 7645M — Background Illumination — 5
Right Eye Mark — R — 2018/11/11 10:09:54 — Left Eye Mark

will appear on the top of the LCD panel.

Step 2: Make sure memory card is inserted

Once the memory card has been inserted, the user can start to take photographs in any shooting mode, either photo or video mode.

Step 3: Choose a shooting mode

Tap the photo or the video mode icon to enter a shooting mode.

Step 4: Mark left/right eye

By doing so, the user can tell whether a photo/video is left eye or right eye of examinee record from its file name.

Step 5: Select slit shape and color filters

Select slit shape and color filters by rotating wheels on slit module.

Step 6: Aim and preview

Position the camera correctly and adjust to appropriate settings to get a clear preview. The image brightness can only be changed in photo mode.

Step 7: Press the OK button to shoot

Holding position

Hold the control unit with one hand and use the other hand to hold the lighting track. Maintain the lens at the same height of the eye being examined. To stabilize the lens, rest the track on the part of the hand between the thumb and index finger and put your middle and index fingers on the examinee's forehead, as showed in the left image. Besides, using the accessory of forehead holder can replace the support on the examinee's forehead, as the below right image.
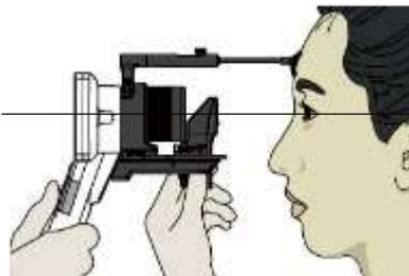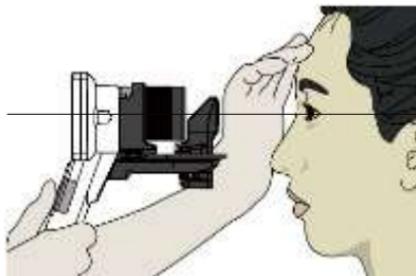
View the examined eye keeping the lens horizontal to the examined eye. Then move forward slowly until you can see the full exterior of eye in the controller screen. (For sanitary reasons, make sure the controller lens does not touch the patient's eyes or nose.)

Focus calibration - Assembling of Correction Rod

Step 1: Remove **screw A** in counter-clockwise direction.
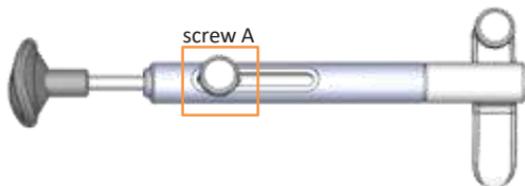
Step 2: Rolling the **inner axis** and the **shaft** to find out **correction rod hole**, then align the **shaft circle hole** with **correction rod hole**.
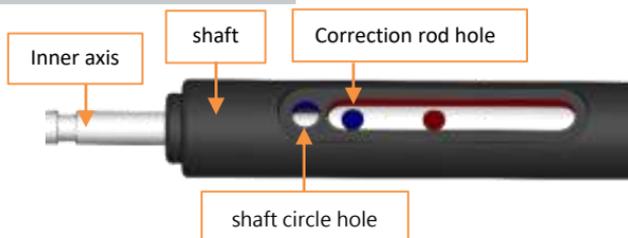
Step 3: Tighten **screw A** in clockwise direction to **correction rod hole** (under **shaft circle hole**).
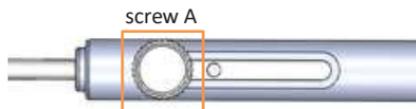
Step 4: Remove **rubber pad** of forehead stopper.

Step 5: Assemble **correction plate** to the front end of **inner axis**.
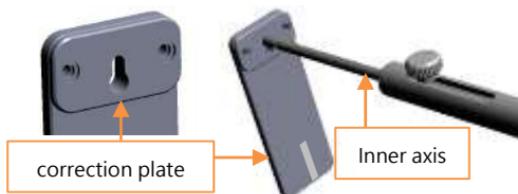
correction plate ← | Inner axis

Step 6: Tighten **screw B** in clockwise direction to fix **correction rod** on DEA 200**.**

screw B
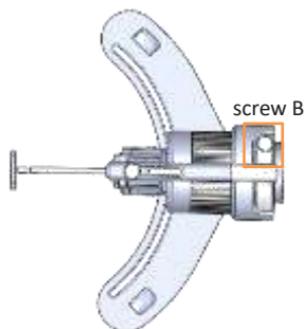
Focus calibration

Step 1: Move **Slit Module** far away from **Zoom lens** (more than 30 degrees), then rotate position of Zoom lens to Tele (16x) end.

Zoom lens

Tele

Wide

Slit Module

Step 2: Enter to **Auto-calibration mode** by screen.

Step 3: **Half press OK button** to active auto focus function.
Check the image of correction rod on the screen is clear or not.
If the image is not clear, please half-press the OK button again.

Image of correction Plate

Step 5: Long press the date and time till it changes to "*Save Motor Position*" to finish calibration.

Step 6: Remove the **Correction Rod** and start to use the device with the best image quality.

Assembling of Forehead Stopper

Step 1: Remove **screw A** in counter-clockwise direction

Screw A

Step 2: Rolling the **inner axis** and the **shaft** to find out **forehead stopper hole.**

Inner axis

shaft

Correction rod hole

shaft circle hole
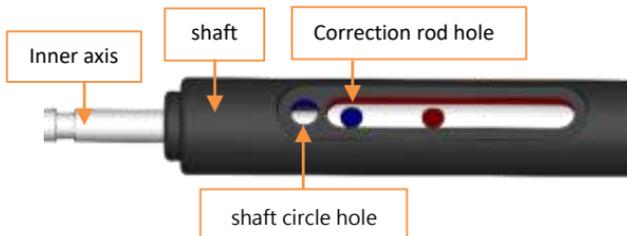
Step 3: Tighten **screw A** in clockwise direction to **forehead stopper hole**.
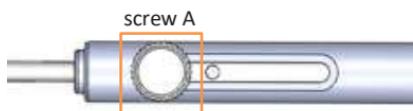
screw A

Step 4: Remove **correction plate** from the front end of inner axis.

correction plate

Step 5: Assemble **rubber pad** to the front end of **inner axis.**

rubber pad

Step 6: Tighten **screw B** in clockwise direction to fix correction rod on DEA 200**.**

screw B

C. DGC 200

Step 1: Turn on the power

Press the power button to turn on the control unit. Approximately one to two seconds later, the boot screen will appear on the LCD panel. After about 15 seconds, the information icons will appear on the top of the LCD panel.

Step 2: Make sure memory card is inserted

Once the memory card has been inserted, the user can start to take photographs in any shooting mode, either photo or video mode.

Step 3: Choose a shooting mode

Tap the photo or the video mode icon to enter a shooting mode.

Step 4: Mark left/right eye

By doing so, the user can tell whether a photo/video is left eye or right eye of examinee record from its file name.

Step 5: Aim and preview

User can select white light or blue light to take image by tapping the white light/blue light switch icon on screen. The default setting is white light.

Position the camera correctly and adjust to appropriate settings to get a clear preview. The image brightness can only be changed in photo mode. The user can rely on the auto focus of DSC 300 to improve clarity or adjust focus manually.

Step 6: Press the OK button to shoot

Photo mode

The device's default setting is "photo mode." User can take a picture or video in "photo mode" or "video mode," respectively.

Photo mode:
For DEC 200, the default setting of "Aiming Light/Capture Light" is "IR/White LED". Therefore, the image before pressing the OK button is monochrome color. When a picture is just taken, the screen shows the result image in full color in auto review mode. To leave auto review, gently press the OK button.

For DEA 200, press down the OK button halfway to do auto-focus or press focus button to do manual focus; press it all the way to take a still picture. The screen will show the image you just take, user can zoom in/out for detail check and also delete it, until press OK button to go back live view mode.

To adjust the brightness of the image, user can press the brightness adjustment keys of the control unit. The higher value you set, the brighter image you get. Image brightness adjustment range:

Reference brightness of capture light for DSC 300 series:

Product Name	Model name	Default Value		Min. Value	Max. Value
Eye Fundus Camera	DEC 200	White light：	10	0	15
		IR：	3	1	5
Eye Anterior Camera	DEA 200	Slit：	5	0	5
		Background：	5	0	5
Eye Surface Camera	DGC 200		3	0	5

Reference brightness table for DEC 200:

Classification	Aiming light (IR)	Capturing light
Light Skin Blond	1	3-5B
Light Skin Brunette	3	8-10B
Dark Skin	5	12-14B

NOTE
⚠ **When taking pictures, please do not remove or insert the memory card and delete pictures, otherwise the system will be abnormal.**

Video mode

Video mode: Completely press the OK button to start recording. Press again to end recording. For DEC 200, the default setting of "Aiming Light/Capture Light" is "IR/White LED." During the video shooting, user can press "the brightness adjustment key +" to enhance the white LED for two seconds. It helps capture brighter motion pictures within a video.
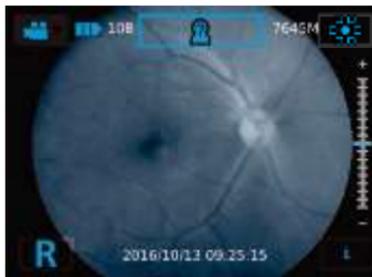
NOTE
⚓ *When recording videos, please do not remove or insert the memory card and delete pictures, otherwise the system will be abnormal.*

Playback

Display mode

Touch the photo icon and then the display icon to see the photos that have been taken.

▶▾ Display mode:
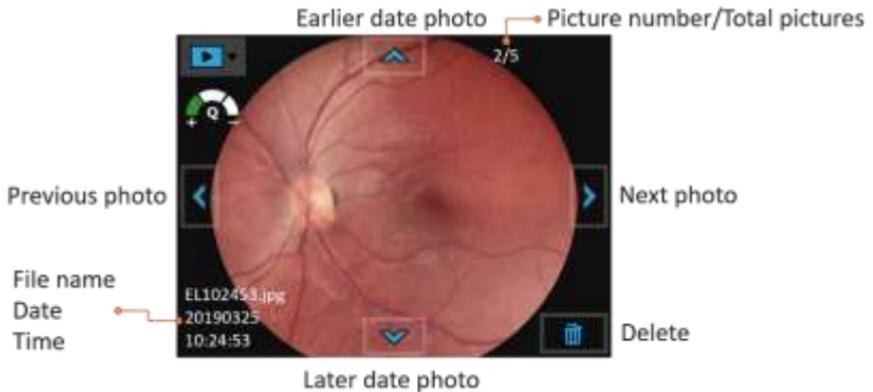
Click the left or right arrow symbols to go to the previous or next photo, respectively. Click the up or down arrow symbol to backward in days or forward in days. Zoom in and out on the photo while in display photo. The user can delete photos by touching the delete icon.

The device does not support the video file display on the control unit. Please download the video file (.avi) to the computer to watch.

Enlarged viewing

Using two fingers to zoom in and out with pinching. Pressing OK button to return to Photo/Video mode.
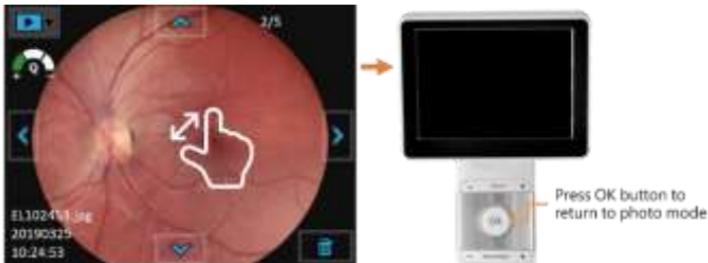
Deleting pictures

Tap the delete icon 🗑 to delete the image. By using the delete functions on your camera, this only changes the file management information and does not completely delete the data from the memory card. When disposing of or transferring your memory cards, we recommend physically destroying them or using commercially available computer data erasing software to completely delete the data from the card.
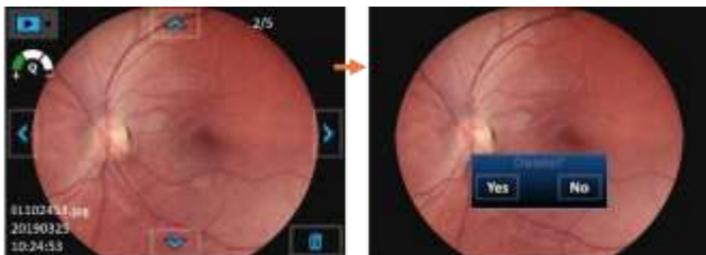
Chin Rest

Scope Set up

Device
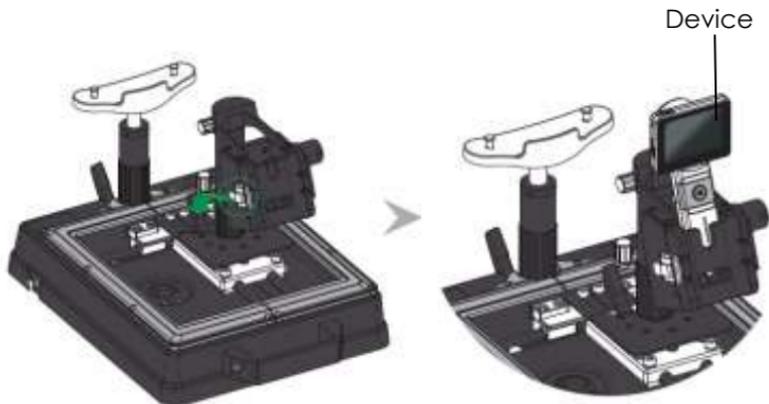
The Height Adjustment of Chin Rest and Scope

⚠ *Use chin rest paper for each new patient.*
Ensure that the examinee has not placed his/her hand or fingers under the chin rest. Otherwise, hand or fingers may be hurt.

Miscellaneous

File transferring
Transfer images to an electronic device (e.g., personal computer, laptop, or mobile phone) via the USB cable or memory card.

> It is the health care provider to protect patient health information and to meet regulatory and HIPAA compliance. The images on DSC 300 may contain identifiable patient information and it is the responsibility of the health care provider to ensure that data safeguards are implemented to protect patient health information.

Viewing on a computer/laptop screen
Turn on UVC mode to simultaneously view images both on LCD panel and the computer/lap- top screen.

Viewing on a TV screen
Connect the camera and a TV through an HDMI cable, you can simultaneously view images on both sides.

UVC and HDMI

Photo mode:
When UVC was on and connected with the USB cable, HDMI will be turned off.

Video mode:
UVC and HDMI always be off.

Preview and playback mode:
When UVC was on and connected with the USB cable, HDMI will be turned off.

Technical description

MiiS Horus Scope DSC 300, control unit：

Focus	Auto & manual focus
Picture Resolution	2560 x 1920 pixels
Video Resolution	2560 x 1920 pixels
LCD Monitor	3.5" TFT LCD
Image Format	JPEG (Photograph) and H.264 (Video)
Interface	Mini USB 2.0, Micro HDMI (1.4), Wi-Fi (2,4G)
File Transfer	Mini USB Port to PC with USB cable 1.5±0.3m (Shield)
Dynamic Video Output	HDMI output with A-D HDMI cable 2.0m (Shield) USB live video enable from USB port with USB cable 1.5±0.3m
File Storage	Memory card, Supports 2GB to 32GB by FAT32 Format.
Dimension	(L)202.5±5% x (W)89 ±5% x (H)88 ±5% mm
Weight	295±5% grams
Power Source	Rechargeable Lithium Battery 3.6V / Capacity 3350mAh
External Power	Source: 100~240 VAC, 50/60 Hz
Power Adapter Spec.	Input Spec.: 100-240Vac, 0.4-0.2A, 50-60Hz; Output Spec.: 5-6V DC, 2.4-2.0A
Charging station Input Spec.	5-6V DC, 2.4-2.0A
Operating Time	Standby mode: 6 hours Operating mode: 1.5~4.5 hours (Depend on optical lens used)
Charging Time	6 hours by DSC 300
Expected service life (defined by manufacturer)	5 years from the date of initial operation *Proper maintenance is necessary.

MiiS Horus+ Scope DEC 200, Eye Fundus Camera, DSC 300 Control Unit:
- View Angle：45 degrees (Typical)
- Diopter：-20 ~ +20D (Typical)
- Dimension：20.1 x 9 x 20.3cm (Typical)
- Weight：450Grams (Typical, DEC 200 + DSC 300). DEC 200 155 Grams.
- Search Fundus Lighting：Two modes: natural white light-emitting diode (LED)or infrared LED. Green LED for fixation.
- Camera/video flash light: Natural white LED

MiiS Horus+ Scope DEA 200, Eye Anterior Camera, DSC 300 Control Unit:
- View Area：Wide End (H) 23.88*(V) 17.71mm (typ.±5%)

  Tele End (H) 11.88*(V) 8.91mm (typ.±5%)
- Working Distance：80mm (Typical)

Miscellaneous

- Illumination Angle：±45 degrees (typ.±5%)
- Slit Length：10mm (typ.±10%)
- Slit Width：0.2~10mm
- Slit Width Selection：≤0.2, 0.2, 0.5, 2.0, 5.0, Φ10 mm
- Filter：Transparent, cobalt blue, red-free (Green)
- Light：Conform to group II of ISO 15004-2:2007
- Weight：580grams (Typical, DEA 200 + DSC 300). DEA 200 285 Grams.

MiiS Horus⁺ Scope DGC 200, Eye Surface Camera, DSC 300 Control Unit:
- View Angle：21 degrees
- Dimension：10.7 x 9 x 20.3cm (Typical)
- Weight：345grams (Typical, DGC 200 + DSC 300). DGC 200 50 Grams.
- Camera/video light：Natural white LED or Blue LED

Liability

Manufacturer considers itself responsible for the effects on safety, reliability, and performance of the device only if
- The device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the general safety and performance requirements.
- Assembly operations, extensions, readjustments, modifications or repairs are carried out by persons authorized.
- The electrical installation of the relevant room complies with the requirements.
- The equipment is used in accordance with these instructions for use.

Disposition

- Follow the local governing ordinances and recycling plans regarding disposal or recycling of device components, especially when disposing of the lithium ion battery, circuit board, plastic parts that contain brominated flame retardant, LCD, or power cord.
- Follow the local governing ordinances and recycling plans when disposing of the circuit board with the lithium battery. Inappropriate disposal may contaminate the environment.
- When disposing of packing materials, sort them by material and follow local ordinances and recycling regulations.
- Inappropriate disposal may contaminate the environment.
- When disposing of eyecup and the rubber pad of forehead stopper, follow the disposal procedures for medical waste such as needles, infusion tubes, and metal instruments for surgery as specified by your medical facility to avoid infection outside the facility and environmental pollution.

Symbols and standards

Symbols

⚠	CAUTION The caution statements in this manual identify conditions or practices that could result in damage to the equipment or other property, or loss of data.
👤	Type BF – Indicates this is a product with Type BF applied parts. The device is complying with IEC 60601-1:2005.
📖	Operating Instructions for Use.
▰	Manufacturer
〰	Date of Manufacture
CE	CE-mark
((•))	Non-ionizing electromagnetic radiation
FC	The identification number assigned by the Federal Communication Commission 2AFB3M-DSC300
(((	Certification for Taiwan NCC ID: CCAJ19LP7010T1
HDMI	"**The terms HDMI**, HDMI High-Definition Multimedia Interface, and the HDMI Logo are trademarks or registered trademarks of HDMI Licensing Administrator, Inc." Confirmation Number: ST-19-039
EC REP	European Authorized Representative
REF	Catalogue Number
GTIN	Global Trade Item Number
LOT	Lot number
SN	Serial Number

	GS1 Data Matrix
MD	Medical Device
R$_x$ ONLY	Medical Prescription only
	Direct current
	Power button
Li-Ion	Recycling lithium-ion batteries
	Specific Battery Recycling
	Disposal of non-contaminated electrical and electronic equipment
	This product had an internal rechargeable battery with a Class II power supply.
	Keep away from sunlight
	Hand with care
	Fragile
	This side up
	Fragile, handle carefully
	Lithium-ion battery
	Flammable material

Standards

Electrical safety	IEC 60601-1:2005+A1:2012 (EN 60601-1:2006+A1:2013)
EMC and regulatory compliance	IEC 60601-1-2:2014 (EN 60601-1-2:2015)
Ophthalmic instruments-Fundamental requirements and test methods Part 2: Light hazard protection	ISO 15004-2:2007
Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments	ISO 15004-1:2006
General radio compliance	Federal Communications Commission (FCC) Innovation, Science and Economic Development Canada's (ISED) National Communications Commission (NCC)

- Equipment connected to the analog or digital interfaces must be certified according to the representative appropriate national standards (such as EN 60601-1 and IEC 60601-1). Furthermore, all configurations shall comply with the system standard IEC 60601-1. Anyone who connects additional equipment to the signal input part or signal output-part configures a medical system and is therefore responsible for the system complying with the requirements of the system standard IEC 60601-1. If in doubt, consult the technical service department of your local representative.

IC
Innovation, Science and Economic Development Canada
This device complies with Industry Canada licence-exempt RSS standard(s).
Operation is subject to the following two conditions:
(1) this device may not cause interference, and
(2) this device must accept any interference, including interference that may cause undesired operation of the device.

Innovation, Sciences et Développement économique Canada
Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:
(1) l'appareil ne doit pas produire de brouillage, et
(2) l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

NCC
第十二條
經型式認證合格之低功率射頻電機，非經許可，公司、商號或使用者均不得擅自變更頻率、加大功率或變更原設計之特性及功能。

第十四條
低功率射頻電機之使用不得影響飛航安全及干擾合法通信；經發現有干擾現象時，應立即停用，

並改善至無干擾時方得繼續使用。

前項合法通信，指依電信法規定作業之無線電通信。

低功率射頻電機須忍受合法通信或工業、科學及醫療用電波輻射性電機設備之干擾。

SAR

The device is designed and tested to meet the applicable limits for radio frequency (RF) exposure established by the Federal Communications Commission (U.S.A.) Specific Absorption Rate; (SAR) refers to the rate at which the body absorbs RF energy.
The minimum allowable SAR distance is 5 mm, and the maximum allowable SAR limit is 4.0 W/kg, averaged over 10 gram of tissue for the device. The following SAR values were measured during product certification, 1.060 W/kg with a (0mm gap) a value well below the maximum allowable limit of 4.0 W/kg.

L'appareil est conçu et testé pour respecter les limites applicables aux fréquences radio (RF) exposition établie par la Federal Communications Commission (États-Unis).
Taux d'absorption; (SAR) fait référence à la vitesse à laquelle le corps absorbe de l'énergie RF.
La distance DAS minimale autorisée est de 5 mm et la limite DAS maximale admissible est de 4,0 W / kg, avec une moyenne de 10 grammes de tissu pour le périphérique. Les valeurs de DAS suivantes ont été mesurées lors de la certification du produit, à 1,060 W / kg avec un (écart de 0 mm), une valeur bien inférieure à la limite maximale autorisée de 4,0 W / kg.

EMC (Electromagnetic Compatibility)

The device complies with the International Electrotechnical Commission standards (IEC 60601- 1-2: 2014) for electromagnetic compatibility as listed in the tables below. Follow the guidance in the tables for use of the device in a Professional Healthcare Environment.

EMC (IEC 60601-1-2: 2014)

Guidance and manufacturer's declaration - electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1 Class B	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The device is intended to be connected (e.g. in hospitals or doctor's offices) to dedicated supply systems (normally fed by separated transformers).
Harmonic emissions IEC 61000-3-2	Class A *1	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	*2	

*1 For the regions where the rated voltage is 220 V or greater, this device complies with class A. For the regions where the rated voltage is 127 V or less, this standard is not applicable.

*2 For the regions where the rated voltage is 220 V or greater, this device complies with this standard. For the regions where the rated voltage is 127 V or less, this standard is not applicable.

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, 4, 8, 15 kV air	±8 kV contact ±2, 4, 8, 15 kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5, 1 kV line(s) to line(s); ±0.5, 1, 2 kV Line to ground	±0.5, 1 kV line(s) to line(s); ±0.5, 1, 2 kV Line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage, dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T for 0.5 cycle (1 phase) 0% U_T for 1 cycles 70% U_T for 25/30 cycles (50/60 Hz) 0% U_T for 250/300 cycles (50/60Hz)	0% U_T for 0.5 cycle (1 phase) 0% U_T for 1 cycles 70% U_T for 25/30 cycles (50/60 Hz) 0% U_T for 250/300 cycles (50/60Hz)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50 or 60 Hz) magnetic field IEC 61000-4-8	30 A/m (50 or 60 Hz)	30 A/m at 50 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms at 0.15 – 80 MHz & 6V at ISM Frequency	3 Vrms (V1=3) at 0.15 – 80 MHz & 6V at ISM Frequency	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $E = \frac{6}{d}\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	3 V/m (E1=3) 80 MHz to 2.7 GHz 80% AM at 1kHz	Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above 3V/m., the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Test specifications for enclosure port immunity to RF wireless communications equipment						
Test frequency (MHz)	Band[a] MHz	Service[a]	Modulation[b]	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA400	Pulse modulation[b] 18 Hz	1.8	0.3	27
450	430-470	GMRS460, FRS460	FM[c]±5kHz deviation 1 kHz sine	2	0.3	28
710	704 -787	LTE band 13,17	Pulse modulation[b] 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA800, i DEN 820, CDMA 850, LTE Band 5	Pulse modulation[b] 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3,4,25; UMTS	Pulse modulation[b] 217 Hz	2	0.3	28
1845						
970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[b] 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/ n	Pulse modulation[b] 217 Hz	0.2	0.3	9
5500						
5785						

[a] For some services, only the uplink frequencies are included.
[b] The carrier shall be modulated using a 50 percent duty cycle square wave signal.
[c] As an alternative to FM modulation, 50 percent pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

⚠ **WARNING** Portable RF communicating equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer; otherwise, it could result in degradation of the performance of the equipment.

The minimum separation distance for higher immunity test levels shall be calculated using the following equation: $E = \frac{6}{d}\sqrt{P}$, where P is the maximum power in watts (W),d is the minimum separation distance in

meters [m], and Fis the immunity test level in V/m.