

# Multipurpose Camera & Scope System User Manual



## 1 RCS-100 with optics lenses and accessories

Model:	Description:	Accessories
Handset Module	Control Unit for imaging	Wifi-SD, Type-c USB cable, mains adapter
Otoscope Module (OT)	Module for eardrum imaging	specula
Dermatoscope Module (DE)	Module for skin imaging	-----
General Module (GE)	Module for mouth and throat imaging	-----

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RCS-100

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## 2 Important information read prior to start-up

You have purchased a high quality Riester RCS-100, which has been manufactured according to the Directive 93/42 EEC and is subject to the strictest quality controls at all times. Read these instructions for use carefully before putting the unit into operation and keep them in a safe place. If you should have any questions, we are available to answer queries at all times. Our address can be found in these instructions for use. The address of our sales partner will be given upon request. Please note that all instruments described in these instructions for use are only to be used by suitably trained personnel. The perfect and safe functioning of this instrument is only guaranteed when original parts and accessories from Riester are used.

## 2.1 Important Symbols

Symbol	Symbol Note
	Caution must be taken. Read user manual before use
	Type B indicates the device is classified as a device with a Type B applied part
	The operator is advised to read the instructions of user manual
	Manufacturer serial number
	Lot number
	Manufacturing date
	Manufacturer
	CE mark
	The symbol indicating li-battery recyclable
	The symbol indicating separate collection for Waste Electric and Electrical Equipment per Directive 2000/532/EC
	The symbol indicating separate collection for Waste Electric and Electrical Equipment per Directive 2002/96/EC
	Temperature for transport and storage condition
	Relative Humidity for transport and storage condition
	Non-ionizing radiation
	Attention: Do not look into the beam
	LED light Do not look in the beam Class 1 LED
	Fragile. Show transport package contents fragile, so handling should be handled with care
	Beware the package from getting wet
	Upward. It shows the correct position to transport the package
	Keep away from sunlight
	„Green dot“ (country-specific)

## 2.2 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 handset 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.

The camera is not dust or splash resistant or waterproof. Avoid using the camera in places with excessive dust, sand or where water can come into contact with the camera. Particular care should be given to the lens and gaps around buttons. In extremely dusty or sandy places, or exposing the camera to rain, or moisture, can result in damage which may not be repairable.

## 2.3 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.

### 3 Warnings and contraindications!

#### 3.1 When in use

- The camera may become warm if used for prolonged period of time.
- Keep the camera as far away as possible from electromagnetic equipment (such as microwave 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 optical 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.
- Disposal of used ear specula must be performed in accordance with current medical practices or local regulations regarding disposal of infectious, biological medical waste.
- Disposal of spent lithium battery must be performed in accordance with local regulations regarding disposal of lithium battery waste.

#### 3.2 Charging 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 stay warm for some time thereafter.
- The battery will be drained completely if not used for long periods of time, even after being charged.
- Only use Li-ion Battery 3.6 V and 2.600 mAh provided by the manufacturer. The battery has an integrated protection circuit. To ensure the safety of the product operation, if the battery reaches its lifetime, please contact the manufacturer to buy a spare battery.

#### 3.3 Protection

- Do not attempt to remove the housing 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.

### 4 Intended use

The Riester camera system (RCS-100) is a portable and multifunctional electronic imaging diagnostic system which consists of OT, DE, and GE three replaceable modules. This camera system is designed to be operated by anyone who is eighteen years and older or medical professionals to capture images and video in specified operating environment.

#### Otoscope (OT):

intended to capture images and videos of eardrum of the ear.

#### Dermatoscope (DE):

intended to capture images and videos of skin.

#### General Lens (GE):

intended to capture digital images and video of mouth / throat.

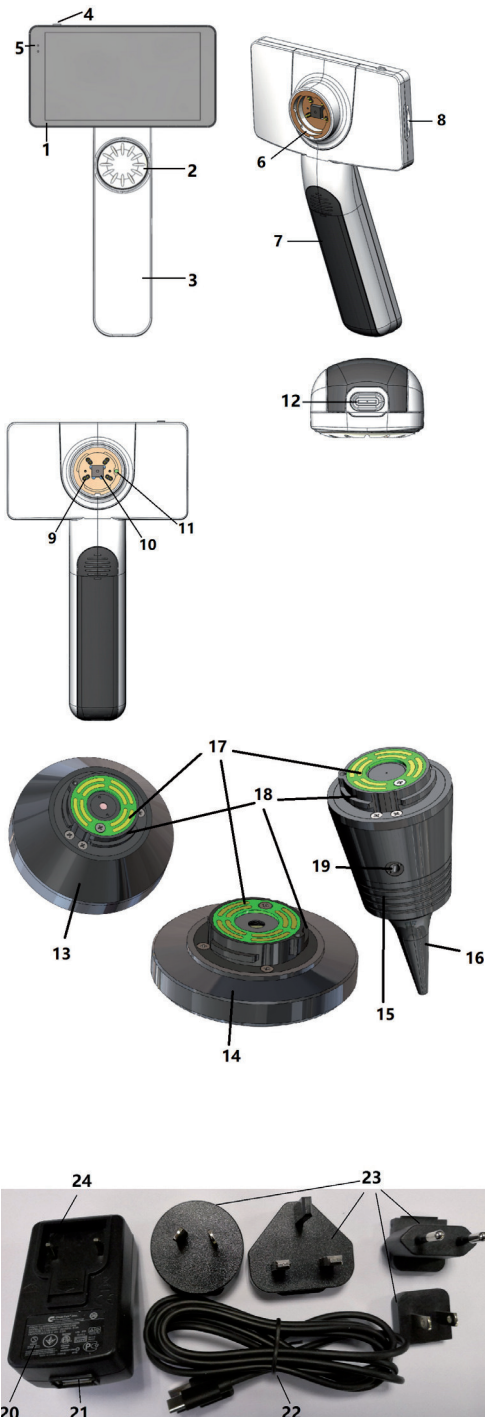
### Specified operating environment:

- Professional healthcare facility environment:  
Physician offices, Dental offices, Clinics, Limited care facilities, Freestanding surgical centers; Freestanding birthing centers; Multiple treatment facilities; Hospitals (emergency rooms, patient rooms, intensive care, surgery rooms except near HF SURGICAL EQUIPMENT, outside the RF shielded room of an ME SYSTEM for magnetic resonance imaging).

### 5 What to do before first use

- Remove the Riester Camera System from the sales package and check that all parts are undamaged
- Install the battery as instructed in point 7.3 of this manual.

## 6 Main unit



1. Touch screen
2. Wheel
3. Handle
4. Power button (on/off)
5. LED-display
6. Lens mount
7. Battery cover
8. Wifi-SD slot
9. Lens connecting pins
10. CMOS
11. Positioning fixed point
12. Type-C USB connector
13. DE module
14. GE module
15. OT module
16. Disposable specula
17. Contact PCB
18. Lens connector
19. Hole for pneumatic test
20. Charging adapt
21. USB connector
22. Type-C USB cable
23. Adapt connector
24. Adapt connector mount

## 7 Operating instruction

### 7.1 Lens exchange:



- a) Lens assembly:
  - 1) Hold the handset in the left hand and the lens to be mounted in the right hand
  - 2) Align lens marks with handset marks
  - 3) Hold and rotate the lens clockwise and install it in place
- b) Lens removal:
  - 1) Hold the handset in the left hand and the lens in the right hand
  - 2) Rotate the lens counter clockwise and remove the lens

### 7.2 Specula replacement

- a) Install specula:  
Fingers pinch the specula to be installed, align OT and gently push it in and lock the specula.



**Warning:** ⚠️  
Only use the specula provided by the manufacturer.

**Warning:** ⚠️  
Check the accessories and their packages for any sign of damage, do not use them if any damage is detected.

- b) Remove specula:
  - 1) Hold the handset in the left hand and the lens in the right hand.

- 2) Fingers pinch the specula replacement device and pull it outward until the specula fall off.

**Warning:**

The disposal of specula shall meet requirements of local laws and regulations.

### 7.3 Battery replacement



- 1) Hold down and push out the battery cover with your fingers and remove the battery cover.
- 2) Remove the original battery and the battery cable.
- 3) Hold the battery cable with your thumb and forefinger and connect it to the connector in the correct direction.
- 4) Put the battery into the battery compartment and tidy up the cable. See 3.2 for type of battery.
- 5) Replace the battery cover by pushing it up in lock position.

**Warning:**

If the device is unlikely to be used for an extended time period, remove the batteries prior to shipping or storage by skilled or trained person.

### 7.4 Power-on/off

- 1) Press power button for 3 seconds to power on/off the system.
- 2) After power on the screen display the startup picture.
- 3) About 25 seconds, the system completed start-up and automatically recognizes the lens (if a lens is installed) and display the appropriate main page.

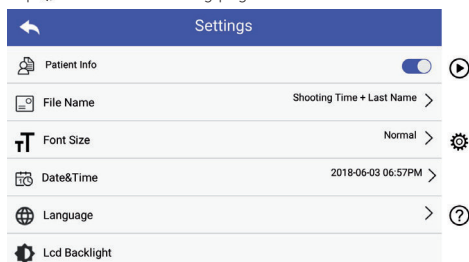
### 7.5 Indicator LED

An indicator on the top left corner of the device shifts in white and green to show device status.

- The handset works in sleep mode: green light flashing
- Low battery: white light flashing
- Battery charging: white light is on
- Full charged: green light is on

### 7.6 Settings

Tap to enter the setting page.



User can set parameter by select item in setting list and touch screen. It is recommended that all setting items are set according to user's requirements for first-time use . Tap to enter the setting page.

Patient data:

"Patient data" can be enabled/disabled.

If disable, the patient information icon will not be shown on the screen and the photos/videos record name is excluding the patient last name, file name setting will also be invisible and deactivated.

If enable, file name setting will be visible to choose.

- File name format:

User can choose shooting time or last name appears first in the record name.

Patient Info	File Name Rule	Module	File Name
enable	Last Name + Shooting Time	OT	Last name + shooting time + O + L/R
		DE	Last name + shooting time + D
		GE	Last name + shooting time + G
	Shooting Time + Last Name	OT	shooting time + Last name + O + L/R
		DE	shooting time + Last name + D
		GE	shooting time + Last name + G
disable		OT	shooting time + O + L/R
		DE	shooting time + D
		GE	shooting time + G

- Font size:

User can set the system font size to small, normal, large or extra large.

- Date & time:

User can set the current date & time.

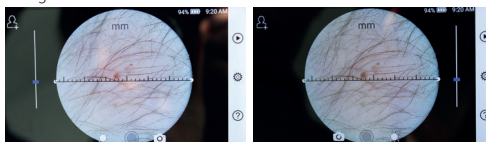
- Language:

User can set system language as "English, Chinese, German, Spanish, Russian, French, Italian, Arabic".

- LCD backlight:

User can set LCD screen backlight brightness.

- Right handed mode:



left handed

right handed

User can set left / right handed operation mode according to their operating habits.

- Preserve lens setting:

The system can be set to 'default' mode or 'record keeping' mode. When the lens is changed in 'default' mode, the system will reset to default parameters. When the lens is changed in 'record keeping' mode, the parameters of the last used lens would be preserved.

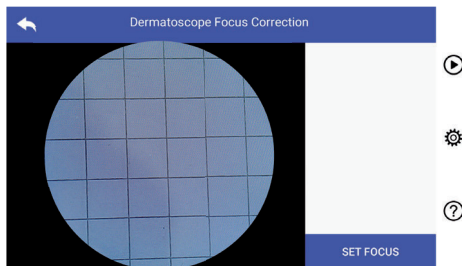
- Picture preview time:

When a photo is taken, the photo can be previewed for 2, 3, or 5 seconds. The user can set the preview time to meet their requirements.

- Dermatoscope ruler unit:

There is a software ruler in the main interface of dermatoscope, user can set the software ruler unit to mm or inch.

- **Dermatoscope focus correction:**  
In dermatoscope mode, user can correct the focusing length. Place the DE lens on the desired surface, at the desired focus distance. The system will automatically focus. If the focus is poor, pick up the camera and repeat. When the image can be seen clearly tap .SET FOCUS' to save the focus data and then return to the main menu.

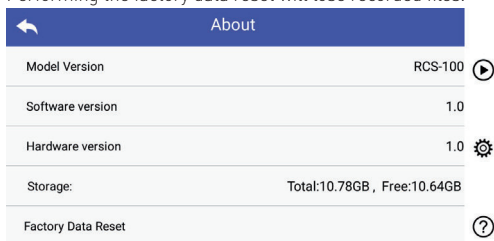


- **Hospital name:**  
When hospital name is entered, it will be displayed at the bottom right of test report.


- **About:**  
About item shows model version, software version, hardware version, storage and factory data reset.

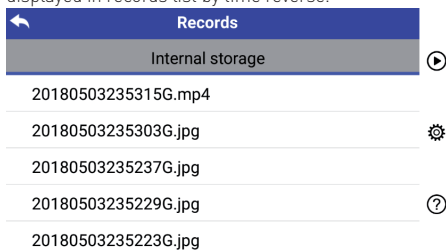
- **Factory data reset:**

**Warning:**   
Performing the factory data reset will lose recorded files.



### 7.7 Records manager




Tap  to enter the records management page. All records displayed in records list by time reverse.



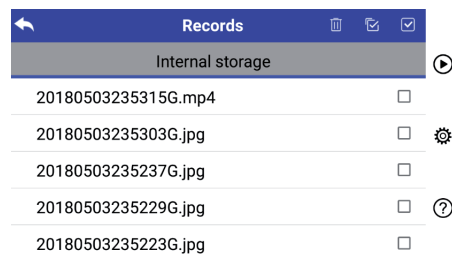
- Review a record:  
Click on the record wanted to review and enter record view page.
  - Finger slides on the touch screen left/right to review previous/next record.
  - Use two fingers to move closer (zoom in) or farther away (zoom out) to view the image on the touch screen.




When the image is zoomed in, use a finger to move the image around the screen so the entire image can be seen.



- Tap  to delete the picture.
- Tap  to enter a page that all photos are displayed in square form.
- Tap  to come back to main page.

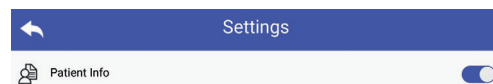
- Delete records:  
Long press a record to enter the record deletion page.












- Tap a record to select/deselect it.
- Tap  to select/deselect all records.
- Tap  to delete the selected records.
- Tap  to come back to main page.

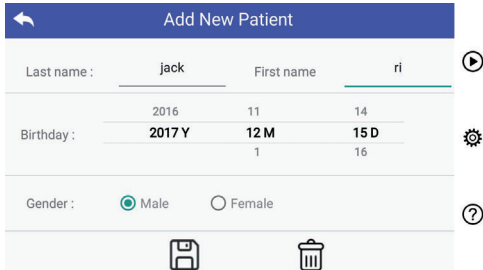
### 7.8 Patient information

- Patient information data:



"Patient Info" in parameter setting page,  patient information enable and  patient information disable.

- Patient information add/edit (patient Info ):  
If patient did not add (shown by ):
  - Tap  to enter the patient information add page.
  - Enter the correct last name, first name, birthday, gender.
  - Tap  to finish the patient information addition.
 If patient has already added (shown by ):
  - Tap  to enter the patient information edit page.
  - Enter the correct last name, first name, birthday, gender.
  - Tap  to complete the patient information editing.



### 7.9 Connect PC

#### a) USB disk mode:

Image data transfer method to a PC is similar as with a USB Stick. When connected to a PC running Microsoft Windows, the operating system displays optional mode of operation.

RCS-100

Wählen Sie eine Aktion für dieses Gerät aus.

- Fotos und Videos importieren  
Fotos
- Digitale Medienlisten mit Gerät synchronisieren  
Windows Media Player
- Gerät zum Anzeigen der Dateien öffnen  
Explorer
- Keine Aktion durchführen

It is possible to select an appropriate image viewing program, or simply open the folder to view and transfer files to the PC.

#### b) UVC mode:

The camera can work on UVC mode.

- 1) Please activate the UVC-mode in the settings.
- 2) Open windows system UVC component on computer.
- 3) Camera connects to the computer by USB cable.
- 4) Power on the camera.
- 5) Windows UVC component automatically connect the camera and display the preview image of the Camera.

#### Warning:

PC should follow EN 60950-1 standard.

### 7.10 Wifi-SD

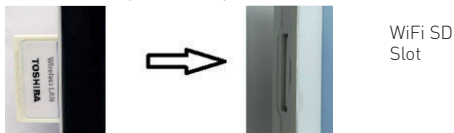
This device only supports TOSHIBA FlashAir Wifi-SD card (optional) to expand internal storage or support Wlan. You can also use the TOSHIBA FlashAir center setup guide. More information about the card can be found in TOSHIBA internet pages: <http://www.toshiba-personalstorage.cn>

#### Warning:

Does not guarantee use of other brands of Wifi-SD/SD cards.

#### a) Wifi-SD card installation:

Put Wifi-SD card into handset card slot (as shown below) and push it into place.



#### b) Use Wifi-SD on handset:

When Wifi-SD is installed, system first saves records on Wifi-SD until it is full, and then system saves records on internal storage.

#### c) PC connect Wifi-SD:

In the PC (with Wifi function) Wifi management page, select the name of „flashair\_XXXXXXXX“ connection, and enter the password (initial password 12345678).

After the connection is successful, the PC automatically displays file management page, and you can view captured records that had been saved on Wifi-SD/SD on the file management page.

### 8 Imaging using optics module otoscope (OT)

The RCS-100 camera with otoscope lens is intended to capture digital images and videos of the eardrum.

#### It consists of:

- Camera handset.
- Attachable otoscope module.
- Disposable specula (default Ø 4).

The otoscope supports adjust brightness, manual/auto focus, left/right ear mode.

The picture brightness can be automatically adjusted by the system according to the illumination intensity of the subject in real time, and it can be adjusted manually.

The brightness level can be adjusted manually in 6 steps. Illumination will turn off when the brightness level is at the lowest level, and it will turn on when the brightness level is more than the lowest level.



#### 8.1 Steps for eardrum imaging:

- 1) Connect the inflation system (when a pneumatic test is required).
- 2) Install disposable specula.
- 3) Tap / to select the left or right ear to be examined.
- 4) Tap L/M/H to select the specula, low (L), medium (M), high (H)
- 5) The examiner pulls the auricle using one hand to straighten the ear canal as much as possible, and using the other hand gently put the lens into the external auditory canal until the front end of OT reaches the cartilage site.
- 6) Tap to enter adjust brightness function and turn wheel or slide the process bar to adjust brightness of the picture.
- 7) Tap / / to select manual/auto focus.

When is selected, click on the position in the preview area where you want to focus, the system will automatically focus according to the selected position.

When is selected, turn the wheel or drag the focus progress bar on the touch screen to complete manual focus.

- 8) Tap / to select a capture mode.

#### a) When photo mode is selected:

#### To take photos

Tap to enter picture taking photo mode .

- Tap again or turn the wheel to capture photo.
- When the photo has captured, will change to , and

- the image will be saved in Wifi-SD (if used) or in internal memory.

#### To record video

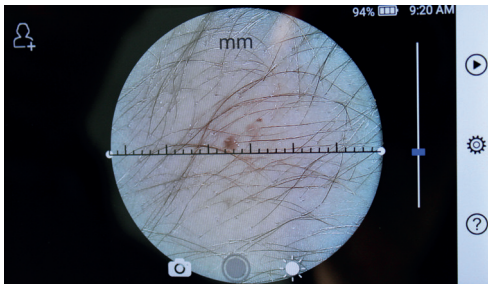
- When video mode is selected:
  - Tap to enter video capture mode.
  - Tap or turn the wheel to start the video and will change to.
  - Tap or turn the wheel to stop the video with showing the saving reminder information. And the video will be saved in Wifi-SD (if used) or in internal memory.
- Tap to review the results of the photo or start the next photo.

#### 9 Imaging using optics module dermatoscope (DE)

The RCS-100 camera with dermatoscope lens is intended to capture digital images and videos of the skin. The focus position of the DE is preset at the factory, and in the "Dermatoscope Focus Correction" in the Setting page, user can reset the focus position (see the detail at section 8.6). The dermatoscope has a ruler that can measure the length of the part to be photographed. The picture brightness can be automatically adjusted by the system according to the illumination intensity of the subject in real time, and it can be adjusted manually. The brightness level can be adjusted manually from 0 to 6 (the default is 2). Illumination will turn off when the brightness level is at the lowest level, and it will turn on when the brightness level is more than the lowest level.

The device set for skin imaging consists of:

- Camera handset
- Attachable DE



#### 9.1 Steps for skin imaging:

- Clean the lens and the part of the skin area to be photographed.
- Hold the handset and hold the lens against the skin area of the patient to be tested.
- Tap to enter adjust brightness function and turn wheel or drag the process bar to adjust brightness of the picture.
- Click and drag one end of the ruler or hold the middle of the ruler and move it in parallel to adjust the ruler to the appropriate measurement angle and position.
- Tap to select a capture mode.

#### To take photos

- When photo mode is selected:
  - Tap to enter picture taking photo mode.
  - Tap again or turn the wheel to capture photo.
  - When the photo has captured, will change to and the image will be saved in Wifi-SD (if used) or in internal memory.

#### To record video

- When video mode is selected:
  - Tap to enter video capture mode.

- Tap again or turn the wheel to start the video, and will change to.
  - Tap or turn the wheel to stop the video with showing the saving reminder information. And the video will be saved in Wifi-SD (if used) or in internal memory.
- Tap to review the results of the photo or start the next photo.
  - After the photo is taken, clean the part of the lens that camera contact with the patient.

#### 10 Imaging using optics module general lens (GE)

The RCS-100 camera with general lens has an object range of 30 mm ~ 4 m, is intended to capture digital images and video of mouth and throat.

The picture brightness can be automatically adjusted by the system according to the illumination intensity of the subject in real time, and it can be adjusted manually.

The brightness level can be adjusted manually from 0 to 6 (the default is 2). Illumination will turn off when the brightness level is at the lowest level, and it will turn on when the brightness level is more than the lowest level.

The device set for general imaging consists of:

- Camera handset
- Attachable GE



#### 10.1 Steps for general imaging:

- Hold the handle and move towards desired position. The lens should be about 35 mm from the required image.
- Tap to adjust brightness. Turn wheel or drag the process bar to adjust the brightness of the picture.
- Tap to select manual/auto focus.

When **AF** is selected, click on the position in the preview area where you want to focus, the system will automatically focus according to the selected position.

When **MF** is selected, turn the wheel or drag the focus progress bar on the touch screen to complete manual focus.

- Tap to select a capture mode.
  - When photo mode is selected:
    - Tap to enter picture taking photo mode.
    - Tap again or turn the wheel to capture photo.
    - When the photo has captured, will change to and the image will be saved in Wifi-SD (if used) or in internal memory.
  - When video mode is selected:
    - Tap to enter video capture mode.
    - Tap again or turn the wheel to start the video, and will change to.
    - Tap or turn the wheel to stop the video with showing the saving reminder information. And the video will be saved in Wifi-SD (if used) or in internal memory.
- Tap to review the results of the photo or start the next photo.



## 11 Cleaning and disinfection

The device is a precision photoelectronic instrument that should be handled with care.

Please note the following cleaning instructions:

- Turn off the device before cleaning it.
- Disinfect the control unit and charging adapter with the soft cloth with little alcohol (70% ethyl alcohol). Wait for the cleaning liquid to evaporate before turning the power on and connecting the charging adapter and USB cable to the control unit.
- It is recommended to clean the optical lens with a cleaning cloth or lens cleaning tissue, such as THORLABS Inc. ([www.thorlabs.com](http://www.thorlabs.com)) lens cleaning tissue.

Clean the position of dermatoscope lens which have been in contact with patient before each use:

- Disinfect dermatoscope lens head with the soft cloth with alcohol (70 % ethyl alcohol). Wait for the cleaning liquid to evaporate before attaching with handset.

Replace the specula before each use. If a replacement for the specula is needed, please contact the manufacturer or retailer.

### Note:

The device is not intended to be sterilized.

## 12 Troubleshooting

- Failed lens recognition: When the main interface on the screen does not match the connected lens, disconnect the lens to confirm whether the lens connection pins and surfaces is abnormal or not. After confirming, connect the lens again.
- Illumination does not work: Please test the other lenses and confirm whether the illumination can be controlled.
- The handset can not turn on: Confirm that the battery is charged.
- Battery operating time is too short: Check the battery is in good condition.

## 13 Information about the device

RCS-100 is a portable and multifunctional electronic imaging diagnostic system. Which consists of a handset [5.0 inch, 720 p, multi-touch display, 3.6 V 2.600 mAh rechargeable battery, 1000 photo storage capacity], three kinds of replaceable lenses (Otoscope, Dermatoscope, General).

## 14 Technical data

Size & weight	Size:225mm*135mm*45mm Weight:292.0 g
LCD	5.0 inch touch [110.7 mm* 62.3 mm] , [1280x720]
Focus	automatic/manual
Image/video format	picture: JPEG, video: MP4
Battery	3.7V 2600mAh [18650] li-battery Video 3.5 hours (fully charged battery at 25°C ambient temperature)
Adapt	input 100-240V 50-60Hz 0.3A output DC 5V/2A
CMOS pixels	8M
USB	OTG and type-C USB
RAM	2G LPDDR3
Rom	16G
Extend Memory(OPT)	16G wifi SD card
<b>Otoscope:</b>	
Size & weight	Size:73.5mm*40.0mm*40.0mm Weight:96g
F/#	2.9
Max object distance	15mm, At max object distance FOV diameter: 15mm
Object height	10mm [Ø4 specula]
Depth of field scope	10mm
Lighting source	natural light LED

<b>Dermatoscope:</b>	
Size & weight	Size:62.1mm*62.1mm*36.0mm Weight:108.5g
F/#	2.2
Object distance	0mm
Field of view:	30 mm Ø
Magnification	2.5x
Photography source	natural light LED
LED color temperature:	4000K
<b>General:</b>	
Size & weight	Size:60.5mm*60.5mm*19.0mm Weight:66.4g
F/#	2.0
Field angle	78°
Object distance	30mm ~ 4m
Lighting source	natural light LED

Operation condition:

- For indoor use only
- Ambient temperature: 10°C to +40°C
- Relative humidity: 15 % to 95 %, rel. non-condensing
- Atmospheric pressure: 700 hPa ~ 1060 hPa
- Storage condition:
- Ambient temperature: 0°C to +45°C
- Relative humidity: 15 % to 95 %, rel. non-condensing

### Note:

It is recommended to remove the battery if the device is stored over 2 weeks.

## 15 Environment

- 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, be sure to follow the local governing ordinances.
- 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 specula, or contact plate, follow the disposal procedures for medical waste such as needles, infusion tubes, metal instruments for surgery as specified by your medical facility to avoid infection outside the facility and environmental pollution.

## 16 Standards

Electrical safety IEC 60601-1 2005 (EN 60601-1 2006)  
EMC and regulatory compliance IEC60601-1-2:2014

ELECTROMAGNETIC COMPATIBILITY  
ACCOMPANYING DOCUMENTS ACCORDING TO  
IEC 60601-1-2, 2014, Ed. 4.0

The instrument satisfies the requirements for electromagnetic compatibility. Please note that under the influence of unfavorable field strengths, e.g. during the operation of wireless telephones or radiological instruments, adverse effects on function cannot be excluded.


The electromagnetic compatibility of this device has been verified by test according to the IEC60601-1-2:2014 requirements.

**EMC (electromagnetic compatibility)**

- During installation and operation 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 operation 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 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 pins connecting the control unit to the lenses or the signal pad on the lenses without special precautions.

**Attention:** 

Medical electrical equipment [ME] is subject to special precautions regarding electromagnetic compatibility (EMC). Portable and mobile radio frequency communication devices can affect medical electrical equipment. The ME device is for operation in an electromagnetic environment of home health care and intended for professional facilities such as industrial areas and hospitals. The user of the device should ensure that it is operated within such an environment.

**Warning:** 

The ME device may not be stacked, arranged or used directly next to or with other devices. When operation is required to be close to or stacked with other devices, the ME device and the other ME devices must be observed in order to verify proper operation within this arrangement. This ME device is only intended for use by medical professionals. This device may cause harmful interference or interfere with the operation of nearby devices. It may become necessary to take appropriate measures, such as redirecting or re arranging the ME device or shield.

The ME device assessed does not exhibit any essential performance features in the sense of EN60601-1, which would present an unacceptable risk to patients, operators or third parties in the event that it should present an outage or the power supply should disconnect.

**Warning:** 

Portable RF communications equipment (radios) including accessories, such as antenna cables and external antennas, should not be used in closer proximity to modules than specified by the RCS-100 parts and lines manufacturer 30 cm (12 inch). Failure to comply may result in a reduction in the device's performance features.

Table 1

Guidance and manufacturer's declaration – electromagnetic emissions		
The RCS-100 is compliance for each EMISSIONS test specified by the standard, e.g. EMISSIONS class and group.		
Emissions	Compliance	Electromagnetic environment-- guidance
RF emissions CISPR 11	Group 1	The RCS-100 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.
RF emissions CISPR 11	Class B	The RCS-100 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity		
The RCS-100 is compliance for each IMMUNITY test specified by the standard, e.g. IMMUNITY test level.		
Immunity test	IEC 60601-1-2 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air

Radiated RF EM fields IEC 61000-4-3	10V/m 80 MHz - 2.7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz - 2.7 GHz 80 % AM at 1 kHz
Electrical fast transient/burst IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	± 2 kV 100 kHz repetition frequency
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV line-to-line; ± 0.5 kV, ± 1 kV and ± 2 kV line-to-ground;	± 0.5 kV, ± 1 kV line-to-line; ± 0.5 kV, ± 1 kV, and ± 2 kV line-to-ground;
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0.15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U <sub>T</sub> : 0.5 cycle <sup>a)</sup> At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°.	0 % U <sub>T</sub> : 0.5 cycle <sup>a)</sup> At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°.
	0 % U <sub>T</sub> : 1 cycle 70 % U <sub>T</sub> : 25/30 cycles <sup>b)</sup> Single phase: at 0°	0 % U <sub>T</sub> : 1 cycle 70 % U <sub>T</sub> : 25/30 cycles <sup>b)</sup> Single phase: at 0°
	0 % U <sub>T</sub> : 250/300 cycles <sup>b)</sup>	0 % U <sub>T</sub> : 250/300 cycles <sup>b)</sup>
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz
NOTE a) U <sub>T</sub> is the a.c. mains voltage prior to application of the test level; b) e.g. 25/30 means 25 periods at 50 Hz or 30 periods at 60 Hz.		

Table 3 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test Frequency (MHz)	Band (MHz)	Service <sup>a)</sup>	Modulation <sup>b)</sup>	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance level
385	380-390	TETRA 400	Pulse Modulation 18 Hz	1.8	0.3	27	27
450	430-470	GMRS 460 FRS 460	FM <sup>c)</sup> ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
710 745 780	704-787	LTE-Band 13, 17	Pulse Modulation 217 Hz	0.2	0.3	9	9
810 870 930	800-960	GSM 800/900, TETRA 800, I den 820, CDMA 850, LTE Band 5	Pulse Modulation 18 Hz	2	0.3	28	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation 217 Hz	2	0.3	28	28
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217 Hz	2	0.3	28	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	0.2	0.3	9	9
NOTE: a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50 % duty cycle square wave signal. c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.							

