RCS-100

Gebrauchsanweisung

Instructions for use

Mode d'emploi

Instrucciones de uso

Istruzioni per l'uso

Инструкция по эксплуатации

CE

Riester

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1. Introduction

1.1 Important information prior to use

You have purchased a high-quality Riester device, which was manufactured in compliance with Regulation (EU) 2017/745 and is subject to the strictest quality controls at all times. Read through these instructions for use carefully before using the device and keep them in a safe place. If you have any questions, we are available at any time, and our contact information is provided at the end of this IFU. Contact information for Riester sales and dsitribution partners can be provided upon request. Please note all instruments described in these instructions for use may only be used by appropriately trained personnel. The safe functioning of this device is only guaranteed if Riester original parts and accessories are used.

1.2 Safety symbols

Symbol	Note on symbol
	Caution! Read operating instructions 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
	Medical device
	Manufacturer's serial number
	Production lot number/batch
	Date of manufacture
	Manufacturer
	CE-Mark
	The symbol indicates that a recyclable lithium ion battery has been installed
	The symbol refers to the separate collection of waste electrical and electronic equipment in accordance with Directive 2000/532/EC
	The symbol refers to the separate collection of waste electrical and electronic equipment in accordance with Directive 2002/96/EC
	Temperature for transportation and storage
	Relative humidity for transportation and storage
	Non-ionizing radiation
	Attention: Do not look into the beam
	LED light Do not look into the beam Class 1 LED

1.3 Packaging symbols

Symbol	Note on symbol
	Fragile. The package should be handled with care.
	Keep the package from getting wet.
	This way up. The symbol indicates the correct positioning for transporting the package.
	Keep away from sunlight
	„Green Dot" (country-specific)

1.4 Purpose
The Riester Camera System (RCS-100) is a portable and multifunctional electronic imaging diagnostic system with three interchangeable modules (otoscope (OT), Dermatoscope (DE) and General (GE). This camera system can be operated by healthcare professionals to capture images and videos in specific working environments.

Specification of the application parts:
OT: For taking pictures and videos of the eardrum.
DE: For taking pictures and videos of the skin.
GE: For capturing digital images and videos in general, e.g. mouth/pharynx, other body parts, injuries etc.

1.4.1 Indications
The instruments serve as an aid to the trained clinician in the detection, diagnosis, monitoring, treatment or alleviation of illnesses, injuries and disabilities.

Specification of the application parts:
OT: For taking pictures and videos of the eardrum.
DE: For taking pictures and videos of the skin.
GE: For capturing digital images and videos in general, e.g. mouth/pharynx, other body parts, injuries etc.

Specification of the other accessories:
LA 4° adapter: Adapter for connecting endoscopes up to Ø 4 mm.
LA 9° adapter: Adapter for connecting endoscopes from Ø 5 mm.
Compatible with a wide range of endoscopes on the market from all leading manufacturers (e.g. Wolf, Storz, Olympus, Schölly)

In combination with endoscopes:
For taking pictures and videos of the throat, nose, ears, frontal sinus and pharyngeal area

1.4.2 Contraindications
There are no known contraindications.

1.4.3 Intended patient population
The device is intended for all patients.

1.4.4 Intended operator/user
The camera system can be used by healthcare professionals to record images and videos as described in the operating instructions and in the working environment specified therein.
Specified working environment:
- Professional environment of healthcare facilities:
  Medical offices, dental offices, clinics, limited care facilities, freestanding surgical centres; freestanding birthing centres; multiple treatment facilities; hospitals (emergency rooms, patient rooms, intensive care units, operating rooms except near RF surgical equipment, outside the RF-shielded room of an ME system for magnetic resonance imaging).

1.4.5 Required skills/operator training
The operators should have the appropriate qualifications to operate this RCS-100 Riester Camera System. All connections and links are clearly explained in the user manual.
The user must strictly adhere to the specifications in the user manual.

1.4.6 Environmental conditions
The device is intended for use in rooms with a controlled environment.
The device must not be exposed to adverse/harsh environmental conditions.

1.5 Warnings/caution
⚠ The camera may become warm if used for long periods of time.

⚠ There may be a risk of ignition of gases if the device is operated in the presence of flammable mixtures or mixtures of pharmaceuticals with air or with oxygen or nitrous oxide.

The device must not be operated in rooms in which flammable mixtures or mixtures of pharmaceuticals and air or oxygen or nitrous oxide are present, e.g. operating theatres.

⚠ 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 bonnet 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 batteries must be performed in accordance with local regulations regarding disposal of Li-battery waste.

⚠ Do not attempt to remove the product casing to prevent or correct a product malfunction.

⚠ No modification of this device is allowed. Such modifications can affect performance and cause hazardous radiation exposure

⚠ Warning: only use the speculum provided by the manufacturer.

⚠ Check the accessories and their packaging for any sign of damage. Do not use them if damage is found.

⚠ The disposal of specula must meet requirements of local laws and regulations.

⚠ If the device is unlikely to be used for an extended time period, have the rechargeable battery removed by a skilled or trained person prior to shipping or storage.

⚠ Resetting the factory data will cause recorded files to be lost.

⚠ This device only supports the TOSHIBA FlashAir Wifi-SD card (available as an option). The use of other brands of Wifi-SD/SD cards is not guaranteed.

⚠ The PC should meet the EN 60950-01 standard.

⚠ The device may not be sterilized.

⚠ 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 the camera, or hitting it against a hard surface.
- Exerting excessive force on the lens.

The camera is not protected from dust, splash resistant, or waterproof. Do not use the camera in locations with excessive dust, sand, or where water may come in contact with the camera. Particular attention should be paid to the lens and the gaps around the buttons.
In extremely dusty or sandy locations, or if the camera is exposed to rain or moisture, irreparable damage can occur.

⚠ For proper functioning and safe handling, the LA 4° and LA 9° adapters must be screwed on as far as they will go and locked.

⚠ For proper function and safe handling, the endoscopes must be inserted and locked into the LA 4° and LA 9° adapters as far as they will go.

⚠ Condensation
(when lens or monitor fog 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 mould, 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.

⚠ 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 become completely drained if not used for long periods of time, even if it has been charged.

⚠ Only use the Li-ion rechargeable batteries 3.6V and 2,600 mAh provided by the manufacturer. The battery has an integrated protection circuit. To ensure the safety of operation of the product, if the battery has reached the end of its lifespan, please contact the manufacturer.

⚠ This device is a precision photoelectronic instrument that must be handled with special care.

Please note the following cleaning instructions:

- Turn off the device before cleaning it.
- Disinfect the control unit and charging adapter with a soft cloth with 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.
- Cleaning the optical lens with a cleaning cloth or lens cleaning tissue, such as e.g. THORLABS Inc.(www.thorlabs.com) is recommended. Before each use, clean the areas of the dermatoscope lens where it came into contact with patients:
- Disinfect dermatoscope lens head with a soft cloth with alcohol (70% ethyl alcohol). Wait for the cleaning liquid to evaporate before connecting the handset.
  Replace the speculum before each use. If a replacement for the speculum is needed, please contact the manufacturer or retailer.

⚠ Never place the camera, the modules or the adapter in liquids! This will lead to irreparable damage!

⚠ The item is not approved for machine reprocessing and sterilization. This will lead to irreparable damage!

⚠

- Do not attempt to remove the product casing to prevent or correct a product malfunction.
- No modification of this device is allowed. Such modifications can affect performance and cause hazardous radiation exposure

⚠ It is recommended to remove the battery if the device is stored for more than 2 weeks.

⚠ All serious incidents related to the product must be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is resident.

2. First use
2.1 Scope of delivery

Item no.:
1970-H
Camera, with plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

1970-HDGO
Camera, with dermatoscope, general, and otoscope lens with plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

1970-HDGX
Camera, with dermatoscope and general, lens with plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

1970-HDXO
Camera, with dermatoscope and otoscope lens with plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

1970-HDXX
Camera, with dermatoscope lens with plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

1970-HXGO
Camera, with dermatoscope, general, and otoscope lens with plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

1970-HXGX Camera, with general lens and plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

1970-HXXO
Camera, with otoscope lens and plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

1970-HDGOAAX
Camera, with dermatoscope, general, and otoscope lens, LA 4° adapter, LA 9° adapter with plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

1970-HDGXAAX
Camera, with dermatoscope and general lens, LA 4° adapter, LA 9° adapter with plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

1970-HDXOAAX
Camera, with dermatoscope and otoscope lens, LA 4° adapter, LA 9° adapter with plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

1970-HDXXAAX
Camera, with dermatoscope lens, LA 4° adapter, LA 9° adapter with plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

1970-HXGOAAX
Camera, with general and otoscope lens, LA 4° adapter, LA 9° adapter with plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

1970-HXGXAAX
Camera, with general lens, LA 4° adapter, LA 9° adapter with plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

1970-HXXOAAX
Camera, with otoscope lens, LA 4° adapter, LA 9° adapter with plug-in power supply, cable, 4 country-specific power plugs, 1 user manual
1970-HXXXAAX Camera, with LA 4° adapter, LA 9° adapter with plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

1970-HDGOAXX
Camera, with dermatoscope, general and otoscope lens, LA 4° adapter, with plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

1970-HDGXAXX
Camera, with dermatoscope and general lens, LA 4° adapter, with plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

1970-HDXOAXX
Camera, with dermatoscope and otoscope lens, LA 4° adapter with plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

1970-HDXXAXX
Camera, with dermatoscope lens, LA 4° adapter with plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

1970-HXGOAXX
Camera, with general and otoscope lens, LA 4° adapter, with plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

1970-HXGXAXX
Camera, with general lens, LA 4° adapter with plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

1970-HXXOAXX
Camera, with otoscope lens, LA 4° adapter with plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

1970-HXXXAXX
Camera, with LA 4° adapter with plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

1970-HDGOXAX
Camera, with dermatoscope, general and otoscope lens, LA 9° adapter with plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

1970-HDGXXAX
Camera, with dermatoscope and general lens, LA 9° adapter with plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

1970-HDXOXAX
Camera, with dermatoscope and otoscope lens, LA 9° adapter with plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

1970-HDXXXAX
Camera, with dermatoscope, LA 9° adapter with plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

1970-HXGOXAX
Camera, with general and otoscope lens, LA 9° adapter with plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

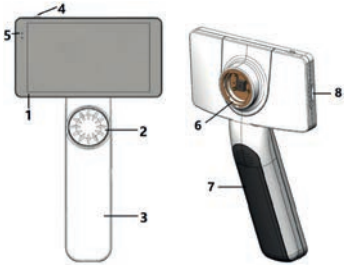
1970-HXGXXAX
Camera, with general lens, LA 9°adapter with plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

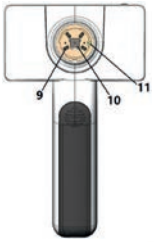
1970-HXXOXAX
Camera, with otoscope lens, LA 9° adapter with plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

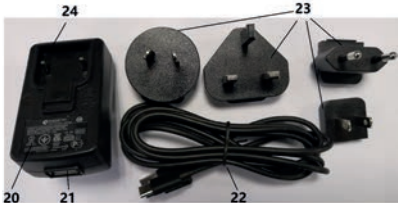
1970-HXXXXAX
Camera, with LA 9° adapter with plug-in power supply, cable, 4 country-specific power plugs, 1 user manual

⚠ Remove the Riester camera system from the packaging and check all parts for damage.

2.2 Device function
1. Touchscreen
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. PCB contact
18. Lens connector
19. Opening for pneumatic test
20. Charging adapter
21. USB port
22. Type C USB cable
23. Plug adapter
24. Plug-in connection for adapter
25. Endoscope (third-party product - not included)
26. Adapter for connecting endoscopes
27. Locking mechanism for lens connection
28. Locking mechanism for endoscopes
29. Lens connector







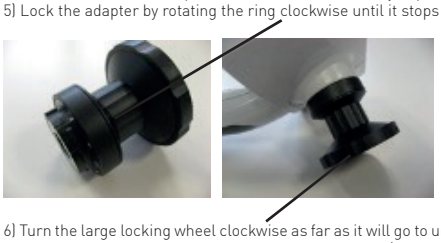
3. Operation and function
3.1 Symbol identification
-
3.2 Startup
3.2.1 Exchange lens/module
⚠

a) Assembly of the lens/module:
1) Hold the handset in the left hand and the lens/module to be attached in the right hand.
2) Align lens markings with handset markings.
3) Hold and rotate the lens clockwise until it is firmly in place.

b) Removal of lens/module:
1) Hold the handset in the left hand and the lens/module in the right hand.
2) Rotate the lens/module counter-clockwise until able to remove it.

3.2.2 Swapping the lens/module for the LA 4° adapter or the LA 9° adapter
⚠

a) Attaching the adapter:
1) Make sure that the rotating ring is turned counter-clockwise to the stop.
2) Hold the handset in the left hand and the adapter to be attached in the right hand.
3) Align adapter markings with handset markings.
4) Hold and rotate the adapter clockwise until it is firmly in place.
5) Lock the adapter by rotating the ring clockwise until it stops



6) Turn the large locking wheel clockwise as far as it will go to unlock the endoscope holder. You can now attach the endoscope (third-party product - not included in the scope of delivery). Then turn the large locking wheel counter-clockwise as far as it will go. The endoscope with adapter is now secured to the camera.

Removal of adapter:
You have the option of removing the complete unit (adapter with endoscope) from the camera, or first removing the endoscope and only then removing the adapter.
To do this, proceed as follows:
1) Turn the rotating ring counter-clockwise as far as it will go. You can now remove the complete unit from the camera by turning it counter-clockwise.
2) Or you can turn the large locking wheel counter-clockwise until it stops. You can now remove the endoscope.
3) By turning the rotary knob counter-clockwise, you can now unlock the adapter to remove it from the camera.

3.2.3 Notes on electromagnetic compatibility

⚠ There are currently no indications that electromagnetic interactions with other devices can occur when the devices are used as intended. Nevertheless, under the increased influence of unfavourable field strength, e.g. when operating radio telephones and radiological instruments, interference cannot be completely ruled out.

3.3 Inserting and removing batteries and rechargeable batteries
3.3.1 Rechargeable battery replacement

⚠

1) Press and slide out the cover of the battery compartment until able to remove it.
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) Insert the battery into the battery compartment and carefully fold the cable into the compartment.
5) Replace the compartment cover by pushing it up into the locked position.

3.3.2 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 stay warm for some time thereafter.
- The battery will become completely drained if not used for long periods of time, even if it has been charged.
- Only use the Li-ion rechargeable batteries 3.6 V and 2,600 mAh provided by the manufacturer. The battery has an integrated protection circuit. To ensure the safety of operation of the product, if the battery has reached the end of its lifespan, please contact the manufacturer.

⚠ If the device is unlikely to be used for an extended time period, have the rechargeable battery removed by a skilled or trained person prior to shipping or storage.

3.4 Replacing specula
3.4.1 Speculum mounting on/off function

a) Take the speculum to be installed with your fingers, align the OT lens and gently push the speculum in until able to lock it.

b) Speculum removal:
1) Hold the handset in the left hand and the lens in the right hand.
2) Push the speculum holder outward with your fingers until it falls off.

⚠ Warning: only use the speculum provided by the manufacturer.

⚠ Check the accessories and their packaging for any sign of damage. Do not use them if damage is found.

⚠ The disposal of specula must meet requirements of local laws and regulations.

3.4.2 On/off function

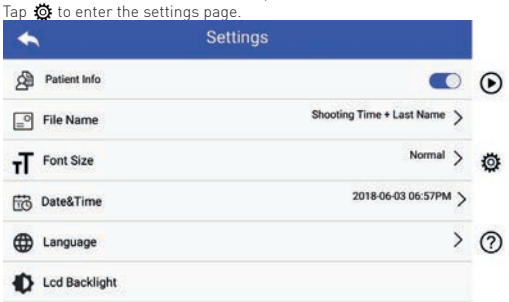
1) Press the power button for 3 seconds to turn the system on or off.
2) After powering on the screen displays the startup picture.
3) After about 25 seconds, the system completes the startup process and automatically detects the lens (if a lens is installed) and displays the corresponding main page.

3.4.3 LED display

An indicator in the upper left corner of the device is displayed in red / orange and green and shows the device status.
The handset is operating in sleep mode: green light flashes.
Low battery: red / orange light flashes.
Battery charging: red / orange light is on.
Full charged: green light is on.

3.4.4 Settings

The user can set parameters by calling up the corresponding settings lists via the touchscreen. It is recommended that all setting items are set in accordance with the user's re¬quirements for first-time use.
Tap ⚙ to enter the settings page.



- Patient data:
„Patient data" can be enabled/disabled. When disabled, the patient data icon will no longer be displayed on the screen, the patient name will be hidden when taking photos/videos, and the file name settings will also be disabled and hidden.
When enabled, the file name settings will be visible.

- Filename format:
The user can choose whether the recording time or the last name should be at the beginning of the file name.

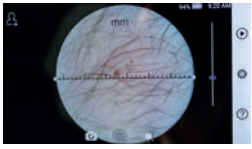
Patientendaten	Regel für Dateinamen	Modul	Dateiname
aktiviert	Nachname + Aufnahmezeit	OT	Nachname + Aufnahmezeit + O + L / R
		DE	Nachname + Aufnahmezeit + D
		GE	Nachname + Aufnahmezeit + G
	Aufnahmezeit + Nachname	OT	Aufnahmezeit + Nachname + O + L / R
		DE	Aufnahmezeit + Nachname + D
		GE	Aufnahmezeit + Nachname + G
deaktiviert		OT	Aufnahmezeit + O + L / R
		DE	Aufnahmezeit + D
		GE	Aufnahmezeit + G

• Font size:
The user can set the system font size to small, normal, large or extra-large.
• Date and time:
The user can set the current date and time.
• Language:
The user can set the system language as „English, Chinese, German, Spanish, Russian, French, Italian, or Arabic".
• LCD backlight:
The user can set the LCD screen backlight brightness.
• Sleep mode
The user can set the time interval for sleep mode.
The sleep mode serves to optimize battery life and is automatically activated if the RCS-100 is not in operation.
The options are 2, 5, 10, 30 minutes or never.
• White balance
The white balance is used to adjust the camera to the appropriate color temperature for the light to suit the working environment of the RCS-100.

The following options are available
1. Auto white balance
2. Incandescent bulb 2800 Kelvin
3. Daylight 5600 Kelvin
4. Neon light 4500 Kelvin
5. Cloudy 7500 Kelvin
6. Twilight 10000 Kelvin
7. Shade 9000 Kelvin
8. Warm 6500 Kelvin

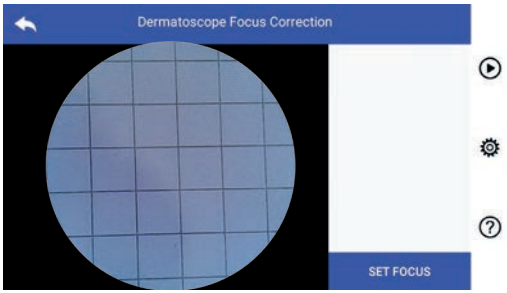
• Righthanded mode:

Lefthanded



Righthanded

User can set left/right handed operation mode according to preference.
• Retaining lens settings:
The system can be operated in standard mode or documentation mode. In standard mode, the system is reset to the default parameters each time the lens is changed. Otherwise, the same parameters are used as when the respective lens was last used.
• Picture preview time:
The user can set the review time, the time for which the image is displayed after it is captured. The review time can be set to 2, 3, 5 seconds, and freeze.
If set to freeze, the image will be displayed until the next command is given (via the control wheel or touching the display).
• Dermatoscope ruler unit:
There is a software ruler in the surface of the dermatoscope. The user can set the software ruler units to mm or inches.
• Dermatoscope focus correction
Place the DE lens on the desired surface and at the desired focus distance. The system focuses automatically. If the focus is poor, pick up the camera and repeat the process. When the image is clearly visible, tap ‚SET FOCUS' to save the focus data and then return to the main menu.



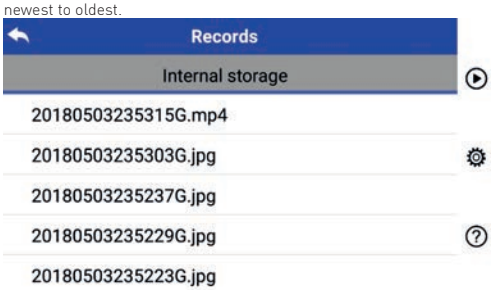
• Hospital name:
When the hospital name is entered, it will be displayed at the bottom right of the test report.
• About:
The ‚About' item displays the model version, the software version, the hardware version, memory, and factory data reset.

3.4.5 Reset to factory settings

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

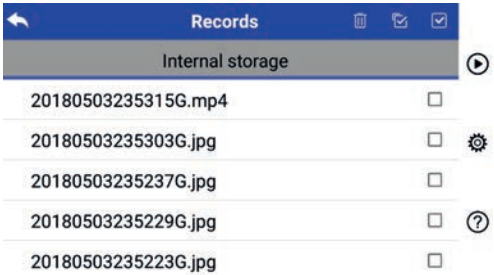
3.4.6 Record manager

Tap to open the „Records" page: All records are displayed in the list from newest to oldest.



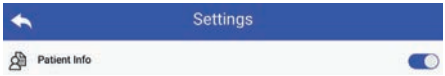
a) Reviewing a record:
Click on the file you want to display to bring up the view page.
1) Swiping your finger on the touchscreen to the left or right shows the previous or next record.
2) Move two fingers closer together or further apart on the touchscreen in order to zoom out or zoom in, so shrinking or enlarging the picture being viewed. When the image is zoomed in, you can tap in one spot with your finger to make it even larger.

3) To delete a record, tap
4) Tap to go to a page where all photos are displayed in grid fashion.
5) Tap to return to the main page.
b) Deleting records:
Long press on a file to enter the file selection.



1) Tap a file in order to select or deselect it.
2) Tap to select/deselect all files.
3) Tap to delete the selected files.
4) Tap to return to the main page.

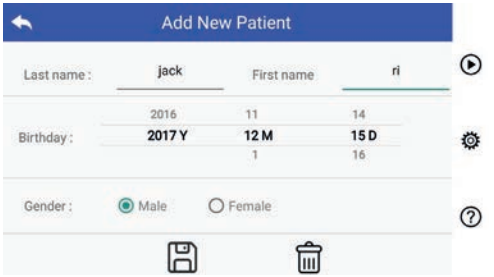
3.4.7 Patient data
a) Enabling/disabling patient data:



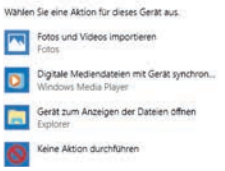
You can activate or deactivate the patient data under „patient data" in the parameter settings.

b) Adding/editing patient data (patient data active):
If the patient has not yet been added (display):
1) Tap to access the patient data entry page.
2) Enter the correct last name, first name, birth date, and gender.
3. Tap to finish the patient data addition.

If the patient has already been added (Display):
1) Tap to enter the patient data edit page.
2) Enter the correct last name, first name, birth date, and gender.
3) Tap to complete the patient data editing.



3.4.8 PC connection
1) USB hard drive mode:
The image data transfer method is similar for transfer to a PC or to a USB drive.
When connected to a PC running Microsoft Windows, the operating system displays additional modes of operation.



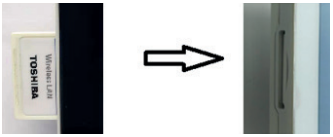
It is possible to select an appropriate image viewing program or simply open the folder to view and transfer files to the PC.
2) UVC mode:
The camera can work in UVC mode.
3) Please activate the UVC mode in the settings.
4) Open the UVC component of the Windows system on the computer.
5) Connect the camera to the computer by USB cable.
6) Power on the camera.
7) The Windows UVC component automatically connects the camera and displays the preview image of the camera.

The PC should meet the EN 60950-01 standard.

3.4.9 Wifi-SD
This device only supports TOSHIBA FlashAir Wifi-SD card (optional) to expand its internal memory or support WLAN. You can also use the TOSHIBA FlashAir Center setup guide. More information about this card can be found on the TOSHIBA internet pages: http://www.toshiba-personalstorage.cn

This device only supports the TOSHIBA FlashAir Wifi-SD card (available as an option). The use of other brands of Wifi-SD/SD cards is not guaranteed.

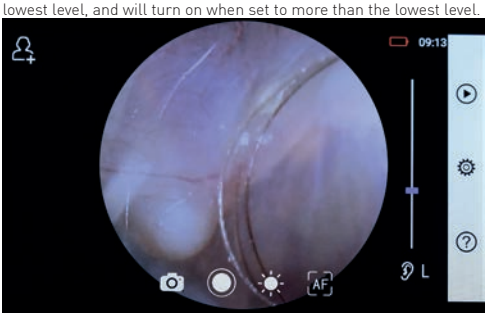
a) Wifi-SD card installation:
Insert Wifi-SD card into handset card slot (as shown below) and push it into place.



b) Using Wifi-SD on the handset:
When Wifi-SD is installed, the system first saves the records on the Wifi-SD card until this is full, and then on its internal memory.
c) PC Connect Wifi-SD:
Open the WLAN management page on the PC (with WLAN function), select the flashair_XXXXXXXXX connection and enter the password (default setting for password is 12345678).
After the connection is established, the PC will automatically display the file management page and you can view captured recordings saved to Wifi-SD on the file management page.

3.4.10 Imaging with the otoscope module (OT)
The RCS-100 otoscope lens is used to capture digital images and videos of the eardrum (tympanic membrane).
It consists of:
- Camera handset
- Attachable OT module
- Disposable specula (standard Ø 4)

The RCS-100 otoscope is intended for imaging of the eardrum. The otoscope supports brightness adjustment, manual/automatic focus, speculum sizes (Ø 2/3/4/5), left/right ear modes.
The picture brightness can be automatically adjusted by the system according to the illumination intensity of the subject in real time, or it can be adjusted manually.
The brightness level can be adjusted manually from 0 to 6 (the default is 2). The illumination will turn off when the brightness level is set at the lowest level, and will turn on when set to more than the lowest level.



3.4.11 Steps for eardrum imaging:

1) Connect the insufflator bulb (optional accessory) when pneumatic testing is required.
2) Attach the disposable speculum.
3) Tap L / R to examine the left or right ear.
4) The examiner pulls the auricle with one hand so as to straighten the ear canal as much as possible, and using the other hand gently puts the lens into the external auditory canal until the front end of the OT reaches the cartilage site.
5) Tap to adjust the brightnes and turn the wheel or drag the focus bar to adjust the brightness of the picture.
6) Tap MF, MF, AF to select manual/auto focus.
If you have selected AF click the position in the preview area where you want to focus. The system will automatically focus depending on the position selected. If MF is selected, turn the wheel or drag the focus bar on the touchscreen to adjust the focus manually.
7) Tap to select a capture mode.

Creating a photo

a) If photo mode is selected:

- Tap to switch to photo mode .
- Tap again or rotate the wheel to take a photo.
- Once the photo is taken, will change to and the image will be saved via Wifi-SD (if available) or to internal memory if „Save" is selected in the pop-up window. If „Don't save" is selected, the image will be discarded.

Creating video

b) If video mode is selected:

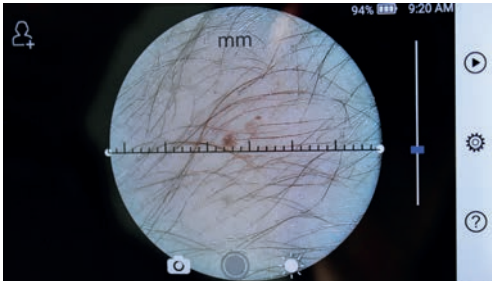
- Tap to enter the video recording mode.
- Tap again or turn the wheel to start the video. will change to
- Tap or turn the wheel to stop video recording and view the save information. The video is saved via Wifi-SD (if used) or in internal memory.

8) Tap to review the results of the recording or to start the next photo/video.

3.4.12 Imaging with the dermatoscope module (DE)

The RCS-100 DE lens is intended to capture digital images and videos of the human skin. The focus position of the DE is set at the factory; the user can reset this in the Settings page, under „Dermatoscope focus correction" (see details at section 8.6). The dermatoscope has a ruler that can be used to measure the length of the area to be photographed. The picture brightness can be automatically adjusted by the system according to the illumination intensity of the subject in real time, or it can be adjusted manually.
The brightness level can be adjusted manually from 0 to 6 (the default is 2). The illumination will turn off when the brightness level is set at the lowest level, and will turn on when set to more than the lowest level.
The device set for skin imaging consists of:

- Camera handset
- Attachable DE lens



9.1 Steps for skin imaging:

1) Clean the lens and the part of the skin area to be photographed.
2) Hold the handset with the lens against the skin area of the patient to be tested.
3) Tap to adjust the brightnes and turn the wheel or drag the focus bar to adjust the brightness of the image.
4) To adjust the ruler to the appropriate measurement angle and position, click and drag one end of the ruler or hold the centre of the ruler and move it in parallel.
5) Tap to select a capture mode.

Creating a photo

a) If photo mode is selected:

- Tap to switch to photo mode .
- Tap again or rotate the wheel to take a photo.
- Once the photo is taken, will change to and the image will be saved via Wifi-SD (if available) or to internal memory if „Save" is selected in the pop-up window. If „Don't save" is selected, the image will be discarded.

Creating video

b) If video mode is selected:

- Tap to enter the video recording mode.
- Tap again or turn the wheel to start the video. will change to
- Tap or turn the wheel to stop video recording and view the save information. The video is saved via Wifi-SD (if used) or in internal memory.

6) Tap to review the results of the recording or to start the next photo/video.
7) After the photo is taken, clean the part of the lens that came into contact with the patient.

3.4.13 Imaging with the General module (GE)

The general lens of the RCS-100 has an object area of 30 mm to 4 m and is used to capture digital images and videos in general, e.g. mouth/pharynx, other body parts, injuries etc. The picture brightness can be automatically adjusted by the system according to the illumination intensity of the subject in real time, or it can be adjusted manually. The brightness level can be adjusted manually from 0 to 6 (the default is 2). The illumination will turn off when the brightness level is set at the lowest level, and will turn on when set to more than the lowest level.
The device set for general imaging consists of:

- Camera handset
- Attachable GE lens

3.4.14 Steps for general imaging:

1) Hold the handle and move yourself into the desired position. The lens should be about 35 mm away from the desired image.
2) Tap to adjust the brightnes and turn the wheel or drag the focus bar to adjust the brightness of the image.
3) Tap MF, MF, AF to select manual/auto focus.
If you have selected AF click the position in the preview area where you want to focus.
The system will automatically focus depending on the position selected. If MF is selected, turn the wheel or drag the focus bar on the touchscreen to adjust the focus manually.
4) Tap to select a capture mode.

Creating a photo

a) If photo mode is selected:

- Tap to switch to photo mode .
- Tap again or rotate the wheel to take a photo.
- Once the photo is taken, will change to and the image will be saved via Wifi-SD (if available) or to internal memory if „Save" is selected in the pop-up window. If „Don't save" is selected, the image will be discarded.

Creating video

b) If video mode is selected:

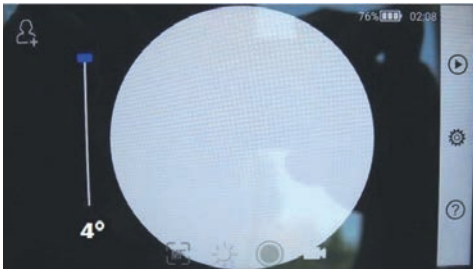
- Tap to enter the video recording mode.

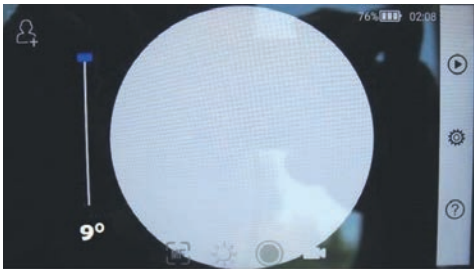
• Tap again or turn the wheel to start the video. will change to .
• Tap or turn the wheel to stop video recording and view the save information. The video is saved via Wifi-SD (if used) or in internal memory.
5) Tap to review the results of the recording or to start the next photo/video.

3.4.15 Imaging with the LA 4° adapter and LA 9° adapter in combination with endoscopes

The RCS-100 camera with adapter for endoscopes is used in combination with the endoscopes to record digital images and videos of e.g. throat, noses, ears, frontal sinuses and the pharyngeal area, etc.
It consists of:
• Camera handset
Attachable adapters in the following versions:
- LA 4° adapter
- LA 9° adapter

The RCS-100 adapter is designed to accommodate endoscopes. The LA 4° adapter is intended for endoscopes up to Ø 4 mm. The LA 9° adapter is intended for endoscopes from Ø 5 mm.
The picture brightness can be automatically adjusted by the system according to the illumination intensity of the subject in real time, or it can be adjusted manually.
The brightness level can be adjusted manually from 0 to 6 (the default is 2). The illumination will turn off when the brightness level is set at the lowest level, and will turn on when set to more than the lowest level.
Compatible with a wide range of endoscopes from all leading manufacturers (e.g. Wolf, Storz, Olympus, Scholly)





Steps for general imaging:
1) Hold the camera with the adapter and endoscope and move yourself into the desired position. The endoscope should be in the correct position away from the desired image.
2) Tap to adjust the brightnes and turn the wheel or drag the focus bar to adjust the brightness of the image.
3) Tap , , to select manual/auto focus.
If you have selected click the position in the preview area where you want to focus.
The system will automatically focus depending on the position selected.
If is selected, turn the wheel or drag the focus bar on the touchscreen to adjust the focus manually.
4) Tap to select a capture mode.

Creating a photo

a) If photo mode is selected:
• Tap to switch to photo mode .
• Tap again or rotate the wheel to take a photo.
• Once the photo is taken, will change to and the image will be saved via Wifi-SD (if available) or to internal memory if „Save" is selected in the pop-up window. If „Don't save" is selected, the image will be discarded.

Creating video

b) If video mode is selected:
• Tap to enter the video recording mode.
• Tap again or turn the wheel to start the video. will change to .
• Tap or turn the wheel to stop video recording and view the save information. The video is saved via Wifi-SD (if used) or in internal memory.
5) Tap to review the results of the recording or to start the next photo/video.

4. Care instructions

4.1 General information

The cleaning and disinfecting of medical devices serves to protect the patient, the user and third parties and to maintain the value of the medical devices.
Due to the product design and the materials used, a defined limit for the maximum possible number of reprocessing cycles cannot be determined. The service life of medical devices is determined by their function and appropriate handling.
Before return for repair, defective products must have undergone the prescribed reprocessing procedure.

⚠ We recommend that before cleaning or disinfection the device is removed from the power supply. Also remove the batteries before cleaning, disinfecting.

⚠ If a reusable device shows signs of material deterioration, it should no longer be used and should be disposed of/claimed according to the procedures described in the disposal/warranty sections.

4.2 Cleaning and disinfection

In order to avoid possible cross-contamination, the devices must be cleaned and disinfected regularly.
This device is a precision photoelectronic instrument that must be handled with special care.
Please note the following cleaning instructions:
• Turn off the device before cleaning it.
• Disinfect the control unit and charging adapter with a soft cloth with alcohol (70% ethyl alcohol). Use disinfectant (e.g. disinfectant Bacillol AF from Bode Chemie GmbH / time 30s) only according to the manufacturer's instructions. Only disinfectants with proven effectiveness according to national directives should be used. After disinfecting, wipe the instruments with a damp cloth to remove any disinfectant residue.
Please make sure that the cloth is moistened but NOT wet, so that no moisture penetrates the openings of the devices.
Wait for the cleaning liquid to evaporate before turning the power on and connecting the charging adapter and USB cable to the control unit.
• Cleaning the optical lens with a cleaning cloth or lens cleaning tissue, from e.g. THORLABS Inc. (www.thorlabs.com) is recommended.
Before each use, clean the areas of the dermatoscope lens where it came into contact with patients:
• Disinfect dermatoscope lens head with a soft cloth with alcohol (e.g. disinfectant Bacillol AF
by the company Bode Chemie GmbH / time 30s). Wait for the cleaning liquid to evaporate before connecting the handset.
Replace the speculum before each use. If a replacement for the speculum is needed, please contact the manufacturer or retailer.

⚠ Never place the device in liquids!

⚠ When using 70% isopropyl alcohol, ensure the room is well ventilated!
Do not use in the vicinity of fire-triggering devices or fire.

4.3 Sterilisation

⚠ The item is not approved for machine reprocessing and sterilization. This can lead to irreparable damage!

4.4 Troubleshooting

- Failed lens recognition: If the main interface on the screen does not match the connected lens, remove the lens again to confirm whether the lens connection pins and surfaces are compromised or not. Correct any impairments and reattach the lens.
- The illumination does not work: Please test the other lenses and

check if the illumination can be controlled.
- The handset cannot be turned on: Confirm that the battery is charged.
- The battery operating time is too short: Check the battery is in good condition.

4.5 Information about the device
The RCS-100 is a portable and multifunctional electronic imaging diagnostic system. It consists of a handset (5.0 inches, 720 p, multi-touch display, 3.6 V 2,600 mAh rechargeable battery, storage capacity for 1,000 photos) and four interchangeable lenses (otoscopes, dermatoscope, general lens, adapter for connecting endoscopes).

5. Technical specifications
Handset:

Medical device:	Medical device for image reproduction and power supply for modules
Protection class/ electrical protection:	Protection class II Class II isolation equipment
Model:	RCS-100 Riester Camera System
Plug-in power supply/power supply	Input: 100 V-240 VAC / 50-60 Hz / 0.3 A Output: 5 VDC / 2 A
Classification:	Application part type B
Size and weight:	Size: 225 mm × 135 mm × 45 mm Weight: 292.0 g
LCD screen:	5.0 inch touch display (110.7 mm × 62.3 mm), 1280 × 720 p
Focus:	Automatic/manual
Photo/video format :	Photo: JPEG, video: MP4
Battery:	33.6 V, 3.7 V 2,600 mAH 18650 Li rechargeable battery
Video:	3.5 hours (fully charged battery with 25°C ambient temperature)
Charging adapter:	Input 100-240 V, 50-60 Hz, 0.3 A Output DC 5 V / 2 A
CMOS pixel density	8 M
USB	OTG and type C USB
RAM	2G LPDDR3
ROM	16G
Memory extension (OPT)	16G Wifi-SD card

Otoscope:

Size and weight:	Size: 73.5 mm × 40.0 mm × 40.0 mm Weight: 96 g
F/	2.9
Max. object distance:	15 mm, at maximum object distance FOV-
Diameter:	15 mm
Object height:	10 mm (Ø 4 speculum)
Depth of field:	10 mm
Illumination source:	LED with natural light
LED colour temperature:	4000K
Magnification on the display:	6 x

Dermatoscope:

Size and weight:	Size: 62.1 mm × 62.1 mm × 36.0 mm Weight: 108.5 g
F/	2.2
Polarisation:	Dermis/epidermis
Object distance:	0 mm
Field of view:	30 mm Ø
Optical magnification:	2.5x (from the optics)
Digital enlargement:	4x (additional)
Screen magnification:	2 x - 8 x
Illumination source:	LED with natural light
LED colour temperature:	4000K

General lens

Size and weight:	Size: 60.5 mm × 60.5 mm × 19.0 mm Weight: 66.4 g
F/	2.0
Optical magnification:	2x
Digital enlargement:	4x
Field angle:	78°
Object distance:	30 mm to 4 m
Illumination source:	LED with natural light
LED colour temperature:	5500K
Operating conditions:	For indoor use only
Ambient temperature:	10°C / 50°F to 40°C / 104°F with a relative humidity of 15% to 90% (non-condensing)
Storage conditions:	0°C / 32°F to 45°C / 113°F with a relative humidity of 15% to 95% (non-condensing)
Air pressure:	700 – 1060 hPa LA 4° adapter
Size and weight	Size: length = 51.5 mm, diameter = 54 mm Weight: 114 g
Field angle:	4°
Object distance:	2.6 mm - 2.9 mm
Illumination source:	None
Operating conditions:	For indoor use only
Ambient temperature:	10°C / 50°F to 40°C / 104°F with a relative humidity of 15% to 90% (non-condensing)
Storage conditions:	0°C / 32°F to 45°C / 113°F with a relative humidity of 15% to 95% (non-condensing)
Air pressure:	700 – 1060 hPa

LA 9° adapter

Size and weight:	Size: length = 51.5 mm, diameter = 54 mm Weight: 114 g
Field angle:	9°
Object distance:	2.6 mm - 2.9 mm
Illumination source	None
Operating conditions:	For indoor use only
Ambient temperature:	10°C / 50°F to 40°C / 104°F with a relative humidity of 15% to 90% (non-condensing)
Storage conditions:	0°C / 32°F to 45°C / 113°F with a relative humidity of 15% to 95% (non-condensing)
Air pressure:	700 – 1060 hPa

6. Spare parts and accessories

Item no.:	
13270	Dermatoscope attachment for RCS-100 camera
13271	General lens for RCS-100 camera
13272	Otoscope attachment for RCS-100 camera
13277	LA 4° adapter for RCS-100 camera
13278	LA 9° adapter for RCS-100 camera
13274	Black case for RCS-100 complete with inserts

7. Maintenance/accuracy check/calibration/applied standards
The instruments and their accessories require no special maintenance. If an instrument needs to be tested for any reason, please send it to us or an authorized Riester dealer in your area, the details of which we will provide you with upon request.

7.1 Applied standards
IEC 60601-1
IEC 60601-1-2

8. Disposal
⚠ Caution!
The used medical device must be disposed of in accordance with current medical practices or local regulations on the disposal of infectious biological medical waste.

⚠ Batteries and electrical/electronic devices may not be treated as domestic waste and must be disposed of in accordance with local regulations.

⚠ If you have any questions about the disposal of products, please contact the manufacturer or their representative.

9. Electromagnetic compatibility
The instrument satisfies the requirements for electromagnetic compatibility. Please note that under the influence of unfavourable field strengths, e.g. when operating cell phones or radiological instruments, malfunctions cannot be ruled out.

In accordance with the requirements of IEC60601-1-2:2014, the electromagnetic compatibility of this device has been verified in a test.

- During installation and operation of the device, observe the following instructions:
- To avoid electromagnetic interference with the device's operation, do not use it simultaneously with other electronic equipment.
- Do not use or stack the device near, on or under other electronic equipment to avoid electromagnetic interference when operating the device.
- Do not use the device in the same room as other electronic devices, such as e.g. life-saving equipment that can have a major impact on a patient's life and treatment outcomes, or any other measuring or treatment device that uses weak electrical currents.
- 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 interference.
- Do not touch the pins connecting the control unit to the lenses or the signal pad on the lenses without special precautions.

⚠ Medical electrical equipment is subject to special precautions in terms of electromagnetic compatibility (EMC).
Portable and mobile radio frequency communication devices can affect medical electrical equipment. The ME device is intended for operation in a home health care electromagnetic environment and 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 use close to or stacked with other devices is required, the ME device and the other ME devices must be monitored to ensure intended operation within this configuration. This ME device is intended for use by medical professionals only. This device may cause radio frequency interference or interfere with the operation of nearby devices. It may become necessary to take appropriate corrective measures, such as redirecting or rearranging the ME device or shield.

The ME device assessed does not exhibit any essential performance characteristics in the sense of EN60601-1, which would present an unacceptable risk to patients, operators or third parties should the power supply fail or malfunction.

Warning:

⚠ Portable RF communications equipment (radios) including accessories, such as antenna cables and external antennas, should not be used in closer proximity than 30 cm (12 inches) to parts and cables of the ri-scope L instrument head specified by the manufacturer. Failure to comply may result in a reduction of the device's performance characteristics.

Guidance and manufacturer's declaration – electromagnetic		
The RCS100 complies with every EMISSIONS test specified by the standard, e.g. EMISSIONS class and group.		
Emission test	**Compliance**	**Electromagnetic environment guidelines**
RF emissions CISPR 11	Group 1	The RCS-100 uses RF energy only for its internal functions. 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.

Manufacturer's guidance and declaration on electromagnetic emissions		
The RCS100 complies with every RF-IMMUNITY test specified by the standard, e.g. RF-IMMUNITY test level.		
RF immunity test	**IEC 60601-1-2 test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contakt ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contakt ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Radiated RF EM fields IEC 61000- 4-3	10 V / m 80 MHz to 2,7 GHz 80 % AM at 1 kHz	10 V / m 80 MHz to 2,7 GHz 80 % AM at 1 kHz
Fast transient electrical disturbances/bursts 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-earth;	±0,5 kV, ±1 kV line-to-line;; ±0,5 kV, ±1 kV and ±2 kV line-to-earth;
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0,15 MHz to 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 bis 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 fluctuations of power supply lines IEC 61000-4-11	0% U_T: 0,5 cycle [a] At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0% U_T: 0,5 cycle [a] At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
	0% U_T: 1 cycle 70% U_T: 25/30 cycles [b] Single phase: at 0°	0% U_T: 1 cycle 70% U_T: 25/30 cycles [b] Single phase: at 0°
	0% U_T: 250/300 cycles [b]	0% U_T: 250/300 cycles [b]
Mains 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_T is the AC mains voltage before applying the test level;
b) 25/30 (e.g.) means: 25 periods at 50 Hz or 30 periods at 60 Hz

Test specifications for ENCLOSURE PORT IMMUNITY for RF wireless communications equipment							
Test frequency (MHz)	**Band (MHz)**	**Service [a]**	**Modulation [b]**	**Maximum power (W)**	**Distance (m)**	**IMMUNITY TEST LEVEL (V/m)**	**Level of compliance**
385	380-390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27	27
450	430-470	GMRS 460 FRS 460	FM [c] ±5 kHz deviation 1 kHz sine	2	0,3	28	28
710	704-787	LTE-Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9	9
745							
780							
810	800-960	GSM 800/900, TETRA 800, Iden 820, CDMA 850, LTE-Band 5	Pulse modulation 18 Hz	2	0,3	28	28
870							
930							
1720	1700-199o	GSM 1800;; CDMA 1900;; GSM 1900;; DECT;; LTE-Band 1, 3, 4, 25;; UMTS	Pulse modulation 217 Hz	2	0,3	28	28
1845							
1970							
2450	2400-2570	Bluetooth, WLAN, 802.11 b / g / n RFID 2450, LTE-Band 7	Puls modulation 217 Hz	2	0,3	28	28
5240	5100-5800	WLAN 802.11 a / n	Puls modulation 217 Hz	0,2	o,3	9	9
5500							
5785							

NOTE:
[a] For some services, only the uplink frequencies are included.
[b] The carrier must be modulated with a square wave signal with a 50% duty cycle.
[c] As an alternative to FM modulation, a 50% pulse modulation at 18 Hz can be used. While this does not constitute an actual modulation, it is the worst case.

10. Warranty

This product has been manufactured under the strictest quality standards and has undergone a thorough final quality check before leaving our factory.

We are therefore pleased to be able to provide a warranty of **2 years from the date of purchase** on all defects, which can verifiably be shown to be due to material or manufacturing faults. A warranty claim does not apply in the case of improper handling.

All defective parts of the product will be replaced or repaired free of charge within the warranty period. This does not apply to wearing parts. For r1 shock-proof, we grant an additional warranty of 5 years for the calibration, which is required by CE-certification.

A warranty claim can only be granted if this Warranty Card has been completed and stamped by the dealer and is enclosed with the product.

Please remember that all warranty claims have to be made during the warranty period. We will, of course, be pleased to carry out checks or repairs after expiry of the warranty period at a charge. You are also welcome to request a provisional cost estimate from us free of charge.

In case of a warranty claim or repair, please return the Riester product with the completed Warranty Card to the following address:

Rudolf Riester GmbH
Dept. Repairs RR
Bruckstr. 31
72417 Jungingen
Germany

Serial number or batch number, date, stamp and signature of the specialist dealer

99365 Rev. E 2021-11 · Änderungen vorbehalten · Subject to alterations · Sous réserve de modifications · Sujeto a modificaciones · Con riserva di apportare modifiche · возможны изменения

Rudolf Riester GmbH
P.O. Box 35 | Bruckstrasse 31 | 72417Jungingen | Germany
Tel.: (+49) 7477-9270-0 | Fax.: (+49) 7477-9270-70
E-Mail: info@riester.de | www.riester.de