Living up to Life





Leica RUV800

User Manual and Installation Instructions

10 743 305 – Version 02

Thank you for purchasing the Leica RUV800.

In developing our systems, we have placed great emphasis on simple, self-explanatory operation. Nevertheless, we suggest studying this manual so that you know and are able to utilize all the benefits of your Leica RUV800 in an optimum way.

For valuable information about Leica Microsystems products and services and the address of your nearest Leica representative, please visit our website:

www.leica-microsystems.com

Thank you for choosing our products. We hope that you will enjoy the quality and performance of your Leica Microsystems Leica RUV800.

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1.1 BASICS

Carefully read through this user manual before assembling and starting up the instrument. Keep this user manual close to the instrument.

1.2 INTENDED USE

The Leica RUV800 is part of a microscope system. It enables fundus observation of the patient's eye using a surgical microscope. It is intended ...

- · For use in hospitals, clinics, and practices.
- · For use within the patient environment.

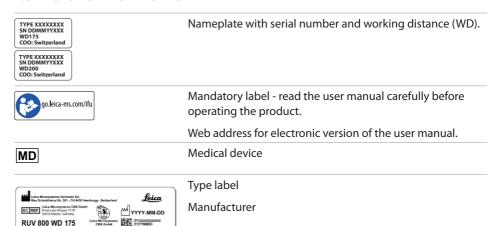
The conditions of installation and use must correspond to surgical applications:

- · Low vibration
- Careful handling
- · Clean environment
- Use with a sterile cover, sterile control elements, and a sterile ophthalmoscopy lens

The owner/operator must make sure that only trained personnel operate the instrument, and that this personnel is familiar with the special functions of the surgical microscope and the carrier unit. He or she must ensure that the instrument is cleaned, sterilized, disinfected and modified according to this user manual.

The owner/operator must ensure that the connected microscope system satisfies the requirements. In particular, this includes having the leakage current of the microscope system meet the requirements of the standard IEC/EN 60601-1, since the Leica RUV800 is suspended on the surgical microscope without insulation.

1.3 SIGNS AND LABELS





REF yyyyyyyy

SN DDMMYYXXX

(01) 07630003581034 (11) 201007 (21) 07102000004	UDI Label - GS1 Data Matrix Code (01) - Device Identifier (DI) Product identifiers (PI) (11) - Date of manufacturing (21) - Serial number
•••	Manufacturer
\sim	Date of manufacture
REF	Catalogue number
SN	Serial number
CE	CE marking

1.4 SYMBOLS IN THIS USER MANUAL



NOTE

Can cause death or severe injury.

Can cause property damage.





This user manual contains important safety notes as well as information on using the instrument (see the section "Safety Notes").

Information that is not safety-related, but is useful or important.

1.5 REQUIRED TOOLS

No tools are required for installing the Leica RUV800.

1.6 DISPOSAL



The respective applicable national laws must be observed for disposal of the products, with the involvement of corresponding disposal companies. The unit packaging is to be recycled.

1.7 PRODUCT IDENTIFICATION

The model code and serial number of your product are provided on the nameplate on the Leica RUV800 (see section 1.3). Copy this information to the line below so that it is handy in case you have questions for our representatives or service locations.

Type: Serial number:

2.1 SAFETY NOTES

- For the safety of patients, users, and third parties, the microscope system may be operated
 only if the applicable User Manuals are heeded. This includes this user manual for the
 Leica RUV800 as well as the instructions that belong to the surgical microscope.
- The microscope system is intended for use exclusively as outlined in the applicable User Manuals.
- · Keep the user manual and instructions in an accessible location at all times for later use.
- Inform your Leica representative immediately if you detect any product defects that could
 potentially cause injury or harm.
- Use only original accessories from Leica Microsystems or accessories that Leica Microsystems
 has expressly permitted. Only original parts from Leica Microsystems may be used for
 maintenance work.
- If unauthorized personnel has modified, repaired, or performed maintenance on the Leica RUV800, or if the instrument has been improperly handled or operated, Leica Microsystems disclaims all liability.
- The prism block must not be sterilized. Liquids that leak into the instrument will damage it.
- Contact the manufacturer at least once a year to ensure that any new knowledge that pertains to safety can be applied.
- Ensure that only instructed users use the Leica RUV800.

2.2 IMPORTANT INSTRUCTIONS FOR OPERATION



Be sure to observe the following instructions for assembly and operation. Failure to observe them can result in personal injuries or death!

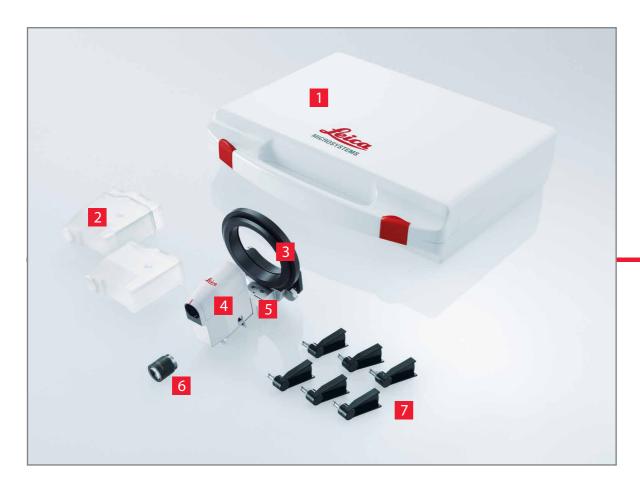
- · Avoid extreme mechanical stress on the Leica RUV800.
- Make sure that the Leica surgical microscope is balanced.
- The maximum load capacity of the carrier unit must not be exceeded.
- For the installation on the Leica surgical microscope, use only the adapter from Leica Microsystems.
- Before each use, ensure that the mechanical connections are attached securely and free of defects.
- Do not begin any operation if a technical defect is known or believed to be present.
- · Do not make any changes to this instrument.

2.3 ABOUT THIS USER MANUAL

- The contents of this user manual are protected under copyright laws.
 Translation of these contents is not permitted without written permission from Leica Microsystems (Schweiz) AG, Medical Division.
- The figures and illustrations shown could differ from the delivered instrument due to ongoing research and development.

3 STANDARD DELIVERY Leica RUV800 / Ref. 10 743 305 / Version 01

3.1 STANDARD DELIVERY



- 1 Transport case
- 2 Sterilizable covers (3×)
- 3 Adapter
- 4 Prism block
- 5 Suspension
- 6 Ophthalmoscopy lens
- 7 Focusing levers (6×)







CD with the User Manual in various languages (PDF)

4.1 IMPORTANT SAFETY NOTES



Check the following points before each operation! Failure to observe them can result in injuries to the patient!

Hazards to personnel from improper use:

- · Observe the user manual.
- · Avoid extreme mechanical stress on the Leica RUV800.
- Use the Leica RUV800 exclusively with a surgical microscope suitable for ophthalmology.

Hazards to personnel from improper installation:

- The maximum load capacity of the carrier unit must not be exceeded.
- Install the Leica RUV800 on the corresponding surgical microscope only with the appropriate, original Leica adapter.

Hazards to personnel from a defective instrument:

- Before each use, ensure that all mechanical connections are attached securely and free of defects.
- Do not begin any operation if a technical defect is known or believed to be present.

Hazards to the patient from an infection or contamination as a result of non-sterile operation:

- Sterilize the sterilizable control elements before use (see section 7.3).
- Before each operation, equip the Leica RUV800 with the corresponding sterile control elements.
- Outer surfaces of sterile control elements may be touched by sterile personnel only.

Hazards to personnel from falling parts:

 Make sure that all attachments are firmly connected to one another and/or with the surgical microscope.

Hazards to personnel from improper setup:

- Make sure that the working distance used for the objective (175 mm or 200 mm) matches the length of the suspension. To do so, check the engraving on the suspension and the objective.
- Ensure that all mechanical connections are attached securely and free of defects.
- Make sure that the surgical microscope is balanced.
- Make sure that when the Leica RUV800 is in the working position its spring suspension pulls it upwards slightly, so that if it accidentally touches the eye, it does not put pressure on the eye.
- Make sure that the Leica RUV800 is equipped with a sterile cover and sterile control elements.

4 SETUP BEFORE THE OPERATION Leica RUV800 / Ref. 10 743 305 / Version 01

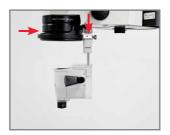
4.2 CHECKING THE SUSPENSION



Before each operation, check whether the length of the suspension matches the working distance used for the objective. Failure to observe them can result in injuries to the patient!



Working distance WD200: The WD designation of the objective must agree with the laser inscription on the suspension.



Working distance WD175: The WD designation of the objective must agree with the laser inscription on the suspension.

Possible uses on Leica surgical microscopes		
Leica M844 / Leica M820 / Leica M822 Standard set		
Leica M620	with an additional adapter	

4.3 INSTALLATION



Fasten the adapter to the front threads using the two screws.



Stick the suspension onto both lugs.



Tighten the screw on the suspension.



Push the prism block into the holder on the suspension so that it clicks into place.



Pull the sterilizable cover over the Leica RUV800.



Carefully press the magnifier's bayonet lock from below onto the Leica RUV800 and fasten this with a short counterclockwise turn.



After it engages, the lasered line on the magnifier and the printed (red) line on the prism block are collinear.



Press the focusing lever into the opening on the side so that it audibly clicks into place. Focusing levers can be attached on the left, right, or both sides of the prism block.

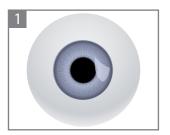


Fold the Leica RUV800 upwards.

! WARNING

Check that the magnifier and focusing lever are securely in place. Serious injury could result if one of these parts becomes loose during the operation!

5.1 SWINGING IN AND FOCUSING THE LEICA RUV800



Focus on the patient's iris using low magnification.

! WARNING

Always keep a firm hold on the prism block while swinging in and lowering the instrument. Make sure that it cannot touch the patient's eye.



Swing the prism block forwards.



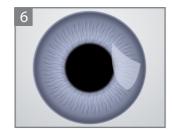
Firmly hold the prism block while carefully lowering the Leica RUV800.



Look through the eyepieces and switch to maximum magnification. Use the focusing lever on the prism block for fine focus.



Rotate the Leica RUV800 into the desired position.



Set the desired magnification on the surgical microscope.

5.2 SWINGING OUT THE LEICA RUV800



Always keep a firm hold on the prism block while lifting and swinging out the instrument. Make sure that it cannot touch the patient's eye.



Hold the prism block in your hand and press it upwards as far as it will go.



Swing the prism block backwards as far as it will go.

6.1 TAKE-DOWN AND STORAGE

! WARNING

Never remove the Leica RUV800 while the patient is below the surgical microscope. Falling parts can cause serious injuries.



Press the clip on the suspension downwards and pull the Leica RUV800 out of the holder.



Remove the Leica RUV800 in reverse order of how it was installed (see section 4).



Store the prism block in the provided protective case to protect it from dust and dirt.

6.2 TRANSPORT



The Leica RUV800 may be transported only in the case provided.

7.1 CLEANING AND DISINFECTING PARTS THAT CANNOT BE STERILIZED



The processing person is responsible for reprocessing with the equipment, materials and personnel and for achieving the desired results in the reprocessing installation. Generally, this requires validation and routine monitoring of the process. The processing person should also examine every deviation from the supplied instructions carefully to determine effectiveness and possible detrimental consequences.



Parts made of anodized aluminum are damaged by alkaline cleaning agents. To clean the non-sterilizable elements, use only pH-neutral cleaners and disinfectants that are suitable for glass, aluminum, plastic, and painted surfaces.



Always make sure that no liquids get into the prism block. They will damage the instrument. Use special caution when cleaning the glass surfaces to avoid damage. Do not use any abrasives or scouring agents.

Cleaning and disinfecting the	Cleaning and disinfecting the prism block		
Scope of application	Cleaning and disinfecting the outer surface of the prism block		
Manual cleaning by wiping	Use a pH-neutral, medical cleaning agent that has been checked according to national guidelines and regulations concerning hygiene.		
Disinfection by wiping	Use a formaldehyde-free, medical disinfectant based on propanol and ethanol that has been checked according to national guidelines and regulations concerning hygiene.		
Maintenance, monitoring, and checking	Before and after each processing, check all articles for mechanical damage. Replace damaged articles.		
	After the work, make sure that the instrument is ready to operate and the front lens and eyepieces are clean.		

7 STERILIZING AND CLEANING Leica RUV800 / Ref. 10 743 305 / Version 01

7.2 INSTRUCTIONS FOR REPROCESSING STERILIZABLE PARTS



For reprocessing sterilizable parts, all preparatory measures listed in Section 7.1 apply.



Do not by any means sterilize the prism block, since it will be damaged by ingressing liquid!



The magnifier must stand upright in the autoclave, with the bayonet lock facing downwards. Otherwise, the magnifier can be damaged!



Adhere to the sequence of the preparatory measures.



Make sure that a temperature between 134°C and 137°C is used during processing.

Article No.	Article No. Designation	
10448581	RUV800 sterilizable cover	√ 1
10743296	RUV800 adapter for M844/M820/M822	✓1
10448560	RUV800 adapter for M620	√ 1
10743298	10743298 Prism block RUV800	
10743295	RUV800 suspension WD175	√ 1
10743297	RUV800 suspension WD200	√ 1
10448578	RUV800 90D ophthalmoscopy lens	√ 1
10448579	RUV800 XLView ophthalmoscopy lens	√ 1
10448580	10448580 RUV800 focusing lever	

- 1 Automatic cleaning and disinfection, pH-neutral (ISO 15883-1 Annex 2 A0 concept), steam sterilization with fractionated pre-vacuum at 134 °C for at least 5 minutes.
- 2 Cleaning the prism block: see section 7.1

7.3 REPROCESSING STERILIZABLE PARTS

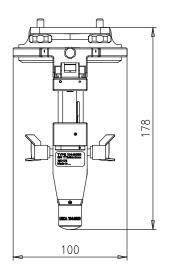
Reprocessing sterilizable co	ontrol elements		
Scope of application	See table on page 15		
Limitation on reprocessing	Frequent processing normally has only minor effects on the articles. The service life depends on the method and care used during the processing.		
	Before and after each reprocessing, inspect the articles for damage.		
	Replace damaged articles.		
Preparation for manual decontamination	Have suitable tools on hand for cleaning cavities, recesses, etc.		
Preparation for automatic	Fasten the optics to prevent damage.		
decontamination	Position the article so that liquid can freely drain from recesses.		
Suitable cleaning agents for manual cleaning	Use a pH-neutral, medical cleaning agent that has been checked according to national guidelines and regulations concerning hygiene. Follow the user manual of the respective manufacturer.		
Application with manual	Cleaning can be done in an immersion bath.		
cleaning	Clean the articles thoroughly, particularly in difficult-to-access areas.		
	Then rinse the articles for 3 minutes under running water.		
	Optics		
	Use soft cloths for cleaning; by no means use abrasive materials such as brushes.		
	Make sure that optical surfaces are not damaged.		
	Dry the optics so that no residue from water or anything else remains.		
Suitable instruments and cleaning agents for	Leica Microsystems (Schweiz) AG, Medical Division, recommends washer-disinfectors to ISO 15883-1. Follow the user manual of the respective manufacturer.		
automatic cleaning:	Use a pH-neutral, medical cleaning agent that has been checked according to national guidelines and regulations concerning hygiene.		
	Use fully desalinated water.		

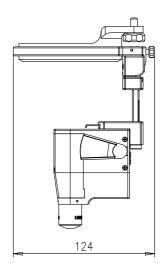
7.3 REPROCESSING STERILIZABLE PARTS (CONT'D)

Reprocessing sterilizable co	ontrol elements
Program selection	Pre-cleaning at <20 °C
	• Cleaning at 40 °C to 45 °C for 10 minutes
	Rinsing/thermal disinfection at 93 °C for 10 minutes
	No sudden temperature fluctuations
Suitable disinfectants for manual cleaning	Use a medical disinfectant with 2.2 % to 2.7 % glutaraldehyde that has been checked according to national guidelines and regulations concerning hygiene.
Application with manual	Use the disinfectant as an immersion bath in accordance with the manufacturer's specifications.
cleaning	Rinse the articles under running water.
	• Dry the articles.
• The cleaning program includes thermal disinfection at 93 °C for 10 minutes.	
Maintenance, monitoring,	Before and after each processing, check all articles for mechanical damage. Replace damaged articles.
and checking	Make sure the optics articles are clean.
	Make sure that all substances have been completely removed from the articles.
Packaging • Place the articles in sterile containers or pack the articles in two sterile drapes.	
Sterilization	• Use steam sterilization (autoclaving) with a fractionated pre-vacuum between 134°C and 137°C for at least 3.5 minutes.
After sterilization	If salt or other chemicals/minerals are used in the water supply for dishwashers and autoclaves, observe the following:
	After concluding the autoclave process and within a 60-minute time frame, wipe off the ophthalmoscopy lens in a sterile environment using 70% isopropyl alcohol (IPA) or 70% industrial methylated spirits (IMS) using a sterilized cotton swab or cloth.
	The longer you wait to wipe off the opthalmoscopy lens after autoclaving (steam sterilization), the more chemicals / minerals (e.g. salt) can crystallize on the surface of the lens. The faster you wipe off the lens with IPA or IMS, the better. If no cloths are available for wiping off the lenses, you can also immerse them in a 70% solution of IPA or IMS in a sterile location.
Storage	Store the articles as sterile instruments are commonly stored in hospitals.

8.1 DIMENSIONS OF LEICA RUV800 WD175

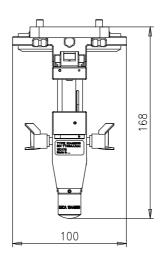
Leica RUV800 WD175 for Leica M844/M822/M820

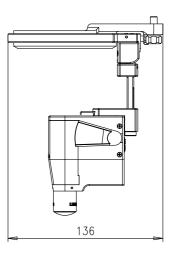




(Dimensions in mm)

Leica RUV800 WD175 for Leica M620

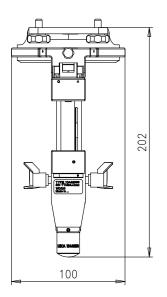


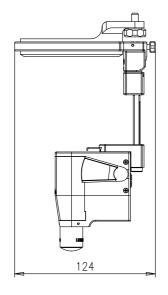


(Dimensions in mm)

8.2 DIMENSIONS OF LEICA RUV800 WD200

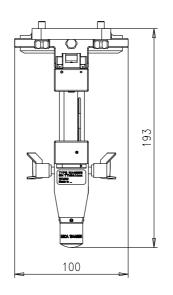
Leica RUV800 WD200 for Leica M844/M822/M820

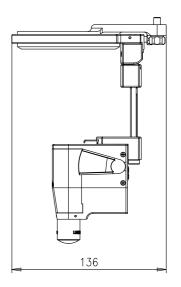




(Dimensions in mm)

Leica RUV800 WD200 for Leica M620





(Dimensions in mm)

8.3 SPECIFICATIONS

Ambient conditions	Leica RUV800 WD = 175	Leica RUV800 WD = 200
Operating temperature	+10°C – +40°C	
Storage and transport temperature	−20 °C to +70 °C	
Relative humidity	10% to 90%	
Air pressure	600 hPa to 1060 hPa	

Working distance and weight		
Required working distance of the objective	175 mm	200 mm
Weight	0.53 kg	0.55 kg

Optical specifications	Leica RUV800 90D ophthalmoscopy lens	Leica RUV800 XLView ophthalmoscopy lens
Optical power	90 dpt	132 dpt
Enabled angle	90°	124°
Distance to the cornea	7 mm	4 mm

8.4 STANDARDS FULFILLED

 The Medical Division, within Leica Microsystems (Schweiz) AG, holds the management system certificates for the international standards ISO 13485 relating to quality management and quality assurance. 9 CARE AND MAINTENANCE Leica RUV800 / Ref. 10 743 305 / Version 01

9.1 CORRECTING MALFUNCTIONS



Do not begin any operation if a technical defect is known or believed to be present. If the malfunction is not corrected by the outlined measures, contact your consultant at Leica Microsystems.

Problem	Ambient conditions		
Blurred image	Cloudy ophthalmoscopy lens	Clean the ophthalmoscopy lens using a soft cloth.Replace the ophthalmoscopy lens.	
	Contamination on the optical element	Clean the optical element using a soft cloth.	

9.2 MAINTENANCE



Even if no regular maintenance is prescribed, we recommend having a preventive safety inspection performed annually.

In order to ensure the operational safety of the system, however, we recommend having our specialists carry out regular maintenance as soon as the warranty period has ended, but at least once every three years. Please contact your local Leica service or local Leica representative for maintenance agreements.

Only original Leica Microsystems spare parts may be used for the maintenance.



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