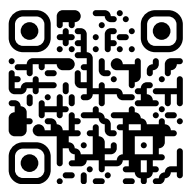




arLoupe™ Digital Loupes

Instructions for Use and Care



Quick Start

www.surgitel.com/ifu-arloupe

English

SurgiTel®, A Division of General Scientific Corp.
arLoupe™ Digital Loupes

Instructions for Use (IFU)

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Manufacturer

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Table of Contents

1. Product Overview and Models	1
2. Intended Use	1
3. Safety Information.....	1
4. Package Contents.....	3
5. Getting Started.....	3
6. Fitting and Adjustment.....	4
7. Operation	5
8. Photo, Video and HDMI Functions	6
9. Cleaning and Disinfection	7
10. Maintenance and Storage	8
11. Troubleshooting	8
12. Technical Specifications.....	10
13. Symbols, Product Information and Disposal	Inside Back Cover
14. Manufacturer and SurgiTel Support.....	Inside Back Cover

1. Product Overview and Models

The arLoupe™ Digital Loupes are wearable digital visualization systems that provide magnified visualization and illumination during professional procedures, education, training, documentation, and related visualization activities.

The system uses a digital camera and integrated Micro-OLED displays in place of traditional optical magnification. The headset provides hands-free viewing with adjustable digital magnification, illumination, image and video capture, HDMI output, removable storage, and adjustable viewing position.

Available Models

Model Number	Product Model	Working Distance	Magnification
90001-1	arLoupe G-W3509	50 cm (19.7")	3.5x, 5x, 7x, 9x
90001-2	arLoupe G-W3509	60 cm (23.6")	3.5x, 5x, 7x, 9x
90002-1	arLoupe G-W5012	50 cm (19.7")	5x, 7x, 9x, 12x
90002-2	arLoupe G-W5012	60 cm (23.6")	5x, 7x, 9x, 12x

Refer to Section 12, Technical Specifications, for additional device specifications.

2. Intended Use

arLoupe™ Digital Loupes are intended to provide magnified digital visualization and illumination for qualified professional users during dental, medical, and veterinary procedures, as well as education, training, documentation, case review, and collaboration activities.

Intended users include qualified dental professionals, dental hygienists, healthcare professionals, veterinary professionals, educators and trainers, and trained personnel involved in visualization or documentation activities.

Contraindications

No contraindications are known when arLoupe™ Digital Loupes are used according to this IFU.

3. Safety Information

General Warnings

- Read and understand all instructions before operating arLoupe™ Digital Loupes.
- Do not use the device if the device, battery, cables, or accessories are damaged.
- Do not use the device after exposure to liquid or conditions outside the specified operating environment.
- Do not modify, disassemble, or attempt internal repair of arLoupe™. Repairs and service must be performed by authorized personnel.
- Use appropriate professional judgment. The device is not intended for diagnostic use and is not a substitute for appropriate clinical methods.

User Safety and Visual Comfort

- Inspect the device and accessories before use.
- Confirm the battery is properly installed and charged.
- Confirm the headset and displays are properly adjusted before beginning use.
- Stop using the device if eye discomfort, headache, dizziness, nausea, visual fatigue, or difficulty maintaining comfortable viewing occurs.
- Maintain awareness of surrounding objects, personnel, and equipment while wearing the device. Avoid walking or performing activities where reduced environmental awareness could create a hazard.

Display Alignment

- Position the headset comfortably and center your eyes within the viewing area.
- Adjust the headset's vertical tilt and declination angle to optimize viewing alignment.
- Confirm the image appears as a single, clear stereoscopic image.
- Confirm the user can comfortably view the entire display area.
- Use the alignment markers to verify proper headset positioning.
- Improper positioning may cause double images, reduced image clarity, eye strain, or discomfort.

Illumination Safety

- Do not intentionally stare directly into the LED light source.
- Use the lowest illumination level appropriate for the application.
- Avoid directing the LED light toward another person's eyes for extended periods.

Battery Safety

- Use only approved arLoupe™ battery systems and charging accessories.
- Do not open, modify, puncture, or damage the battery.
- Do not expose the battery to excessive heat, moisture, or fire.
- Do not use a battery that is swollen, leaking, damaged, or overheating.
- Disconnect the charger when charging is complete.
- Cleaning and Infection Control
- Do not immerse the device in liquid.
- Do not use autoclave or steam sterilization.
- Do not apply cleaning agents directly to electronic components.
- Use cleaning and disinfecting products compatible with electronic medical equipment.

Recording and Data Management

arLoupe™ may capture images and video for documentation, education, training, and case review. Users are responsible for following applicable privacy requirements, obtaining appropriate consent before recording, protecting stored files, and managing recorded data according to facility policies.

Cybersecurity

arLoupe™ Digital Loupes do not connect directly to external networks. Users are responsible for maintaining security of recorded data stored on removable media and connected display equipment.

4. Package Contents

Component	Quantity
arLoupe™ Digital Loupe Headset	1
Rechargeable Battery System	2
Battery Charger	1
HDMI Cable	1
Remote Control	1
Protective Carrying Case	1
Accessories	As applicable
Instructions for Use	1

5. Getting Started

5.1 Before Use

1. Inspect the device, battery, cables, and accessories for visible damage.
2. Verify that the battery has sufficient charge.
3. Confirm that the selected arLoupe™ model matches the user's intended working distance.
4. Install a compatible microSD card if image capture or video recording is required.
5. Adjust the headset and displays before beginning visualization activities.



5.2 Battery Installation

1. Attach the battery to the headset or included shoulder pad using the magnetic connection.
2. Confirm the device indicator activates and the headset powers on normally.



5.3 Charging

1. Connect the supplied charger to the battery charging port and an appropriate power source.
2. Battery Status Indicator: Blue—charging; Green—fully charged; Red—low battery; Yellow—power on.
3. Disconnect the charger when charging is complete.



Rechargeable Battery (x2)



Battery Shoulder Pad



Remote Control

Battery runtime is up to 2 hours with the BP064 battery. Actual runtime may vary based on battery condition, operating mode, illumination settings, and recording activity.

5.4 Powering On

1. Attach a charged battery.
2. Press the power button on the control unit.
3. Wait approximately 5 seconds for system startup.
4. Confirm the arLoupe™ logo appears in the display.
5. Confirm LED illumination activates.

If the device does not power on, refer to Section 11, Troubleshooting.

5.5 Remote Control Pairing

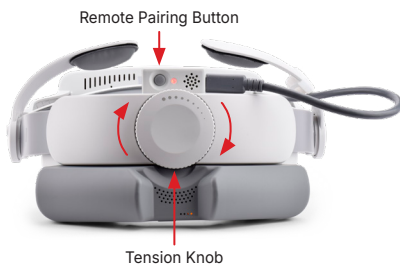
1. Install batteries in the remote control.
2. Connect a charged battery to arLoupe™.
3. Press and hold the pairing button on the headset control unit for approximately 5 seconds.
4. Confirm the indicator begins flashing.
5. Press the pairing button on the remote control.
6. Successful pairing is indicated when the headset indicator stops flashing.

The remote control enters sleep mode after approximately 30 minutes without operation. Press any remote button to reactivate it.

6. Fitting and Adjustment

6.1 Wearing the Headset

1. Place the headset securely on the user's head.
 2. Adjust the rear headband tension knob until comfortable.
 3. Position the display module in front of the eyes.
 4. Adjust the vertical position of the headset.
 5. Adjust the declination angle to achieve a comfortable viewing position.
- arLoupe™ may be worn with prescription eyewear.



6.2 Viewing and Display Alignment

1. Position the headset comfortably and center your eyes within the viewing area.
2. Adjust the headset position and vertical tilt until the four corner alignment markers are clearly visible.
3. Confirm the image appears as a single, clear stereoscopic image.
4. If double images or distortion persist, reposition the headset and adjust the headband tension.



Four Corner Alignment Markers

6.3 Working Distance

For proper focus, position the device according to the model's working distance and maintain the recommended distance between the headset and viewing target.

7. Operation

7.1 Digital Magnification

Model	Available Magnifications
G-W3509	3.5x, 5x, 7x, 9x
G-W5012	5x, 7x, 9x, 12x

1. Press the magnification adjustment buttons on the remote control.
2. Select the desired magnification level.
3. Confirm the selected magnification displayed on the screen.



7.2 LED Illumination

The integrated LED provides adjustable illumination and includes color-temperature compensation and an integrated orange curing filter.

1. Press the LED control button.
2. Cycle through the available illumination settings.
3. Select the appropriate illumination level.

7.3 White Balance Compensation

arLoupe™ includes Auto White Balance (AWB) to compensate for variations in lighting conditions and support accurate image color reproduction. AWB is recommended for most applications. Manual settings: 3500K, 4500K, and 5500K.

1. Access the white balance settings through the device controls.
2. Select the desired color temperature compensation setting.
3. Confirm the image color reproduction is appropriate for the viewing environment.

7.4 Orange Curing Filter

The integrated orange curing filter is designed to reduce exposure to curing-light wavelengths during light-curing procedures.

1. Position the filter in front of the illumination source.
2. Verify the filter is fully engaged before beginning curing procedures.

7.5 Low Battery and Shutdown

- When battery power becomes low, the device may display a low-battery warning.
- Image quality may decrease as available power decreases.
- Replace or recharge the battery as soon as practical.
- If the battery is not replaced, the system may automatically shut down to protect the device.

7.6 Ending Use

1. Power off the headset.
2. Disconnect the battery if the device will not be used for an extended period.
3. Remove and store the microSD card if required.
4. Clean the device according to Section 9.

8. Photo, Video and HDMI Functions

8.1 Still Image Capture

Still images can be captured to a compatible microSD card.

1. Insert a compatible microSD card.
2. Position the camera toward the intended viewing area.
3. Press the photo capture button.
4. Confirm the image capture indicator appears.
5. The image is saved to the microSD card.

Image format: JPG.



8.2 Video Recording

1. Insert a compatible microSD card.
2. Position the camera toward the intended viewing area.
3. Press the video recording button.
4. Confirm the recording indicator appears.
5. Press the video button again to stop recording.

Video format: H.264; 1080p resolution; 60 frames per second.

8.3 microSD Card Requirements

- microSD card
- Class 10 recommended
- Capacity up to 512 GB

8.4 HDMI Output

HDMI output is provided for visualization, education, and documentation.

1. Connect the supplied HDMI cable to the headset HDMI output port.
 2. Connect the other end to the external display device.
 3. Select the appropriate HDMI input source on the display.
 4. Confirm the live image appears.
- External display performance depends on connected equipment.
 - HDMI output is intended for visualization and educational purposes.
 - Use appropriate privacy practices when displaying captured images or video.

9. Cleaning and Disinfection

9.1 Before Cleaning

1. Power off the device.
2. Disconnect the battery.
3. Remove external accessories.
4. Inspect the device for damage.

Use a soft, lint-free cloth and approved cleaning solutions compatible with electronic equipment.

9.2 Headset and Exterior Surfaces

1. Wipe exterior surfaces using a soft cloth lightly moistened with an appropriate cleaning solution.
2. Remove visible debris and residue.
3. Allow surfaces to dry completely before use.

Do not immerse the device, spray cleaning solutions directly onto it, allow liquid to enter openings/connectors/electronic components, or use abrasive materials.

9.3 Displays and Camera Lens

1. Use a clean microfiber or lint-free optical cloth.
2. Gently remove fingerprints, dust, or debris.
3. Avoid excessive pressure on display surfaces.

Do not use abrasive cleaners, solvents that may damage optical surfaces, or paper products that may scratch surfaces.

9.4 Disinfection

Clean and disinfect arLoupe™ according to the user's facility infection-control procedures. Follow disinfectant manufacturer instructions and confirm compatibility with electronic equipment. Avoid liquid accumulation around electrical connections.

The device is not designed for immersion sterilization. Do not use steam sterilization, autoclave processing, or high-temperature sterilization methods.



10. Maintenance and Storage

10.1 Routine Maintenance

arLoupe™ does not contain user-serviceable internal components. Perform routine inspection before each use.

- Headset housing
- Display modules
- Camera module
- Battery connections
- Charging cable
- HDMI cable
- Remote control

Do not attempt internal repair. For service requirements, contact SurgiTel.

10.2 Storage

- Store the device in the supplied protective carrying case.
- Keep the device in a dry environment.
- Protect the device from excessive heat, cold, moisture, and impact.
- Store batteries separately when the device will not be used for an extended period.

10.3 Environmental Conditions

Condition	Range
Operating temperature	10–40°C (50–104°F)
Storage temperature	0–60°C (32–140°F)

10.4 Battery Maintenance

- Charge batteries using the supplied charger.
- Avoid completely discharging batteries for extended periods.
- Store batteries in a cool, dry location.
- Inspect batteries before use.
- Do not use batteries that are swollen, damaged, leaking, or showing signs of overheating.

11. Troubleshooting

If a problem cannot be resolved using this guide, contact SurgiTel customer service or an authorized service provider.

Problem	Possible Cause	Corrective Action
Device will not power on	Battery not connected	Confirm battery is properly attached.
Device will not power on	Battery discharged	Charge battery or replace with a charged battery.

Device shuts down unexpectedly	Low battery condition	Recharge or replace battery.
Reduced operating time	Battery aging or operating conditions	Recharge battery or replace if performance continues to decrease.
No image appears	Device not powered on	Confirm battery connection and power on device.
Only one display activates	Startup synchronization delay	Wait several seconds after powering on.
One display remains inactive	Battery insufficient or device issue	Recharge battery and restart device.
Image appears unclear	Incorrect alignment	Adjust headset position and display alignment.
Double image appears	Improper eye alignment	Adjust PD and display position.
Image appears blurry	Incorrect working distance	Confirm the correct working-distance model is being used.
Image cannot be focused	Viewing distance incorrect	Move closer to or farther from target according to model specification.
Magnification appears unclear	Display alignment incorrect	Adjust headset position.
External monitor shows no image	Incorrect HDMI input selected	Select the correct HDMI input source.
External monitor shows no image	HDMI cable disconnected	Confirm cable connections.
Intermittent HDMI signal	Cable or connection issue	Verify cable condition and connection.
HDMI output unavailable	Device not fully powered	Restart arLoupe™.
Photo cannot be captured	No microSD card installed	Insert a compatible microSD card.
Video cannot be recorded	Storage unavailable	Confirm card is installed and has available space.
microSD card not recognized	Card incompatibility	Use a compatible microSD card up to 512 GB.
Recording stops unexpectedly	Storage full	Replace card or delete files to create available storage.
Remote does not operate	Remote not paired	Perform remote pairing procedure.
Remote does not respond	Remote in sleep mode	Press any button to wake the remote.

Remote operates intermittently	Low remote battery	Replace remote batteries.
LED does not illuminate	LED turned off	Activate LED illumination.
LED brightness insufficient	Brightness setting too low	Adjust illumination level.
Color temperature adjustment unavailable	Incorrect control operation	Review operating instructions.

11.1 Double Image / Viewing Alignment

1. Confirm the headset is positioned correctly and comfortably.
2. Center your eyes within the display eye-box.
3. Adjust the vertical tilt and headband tension to optimize viewing alignment.
4. Confirm all four digital "L" alignment markers are crisp and visible in the corners of the display.
5. Reposition the headset until the two views merge into a single, clear stereoscopic image.

If double imaging remains after proper positioning, contact SurgiTel for assistance.

11.2 Device Overheating

1. Stop using the device.
2. Disconnect the battery.
3. Allow the device to cool.
4. Inspect for damage before reuse.

If overheating continues, discontinue use and contact SurgiTel.

12. Technical Specifications

12.1 General Specifications

Specification	Value
Product Name	arLoupe™ Digital Loupes
Device Type	Wearable digital visualization system
Models	G-W3509 / G-W5012
Operating Temperature	10–40°C (50–104°F)
Storage Temperature	0–60°C (32–140°F)

12.2 Optical and Display Specifications

Specification	Value
Display System	Dual Micro-OLED displays at ~3,240 ppi
Image Sensor	Sony CMOS sensor
Photo Resolution	3840 × 2160 pixels
Video Resolution	Full HD 1080p (1920 × 1080)

Video Format	H.264
Frame Rate	60 fps
Magnification Adjustment	Digital
Pupillary Distance	Adjustable
Focus Type	Fixed focal length

12.3 Model Specifications

Model Number	Magnifications	Working Distance
G-W3509	3.5x, 5x, 7x, 9x	50 cm (19.7") or 60 cm (23.6")
G-W5012	5x, 7x, 9x, 12x	50 cm (19.7") or 60 cm (23.6")

12.4 Illumination

Specification	Value
Light Source	Integrated LED
Color Temperature	5000K
White Balance Compensation	Auto White Balance (AWB) and manual settings: 3500K, 4500K, 5500K
Curing Filter	Integrated orange filter
Brightness	15,000 lux at 20 cm (7.9")

12.5 Battery

Specification	Value
Battery Type	Rechargeable Lithium-ion
Operating Time	Up to 2 hours with BP064 battery
Charge Time	Approximately 2 hours with BP064 battery
Battery Weight	BP064 battery: 154 g • BP192 battery: 374.5 g
Battery Quantity Included	2 BP064 batteries
Charging Method	Supplied charger

12.6 Storage and Output

Specification	Value
Storage Media	microSD card
Maximum Capacity	Up to 512 GB
Photo Format	JPG
Video Format	H.264
External Output	HDMI

13. Symbols, Product Information and Disposal

Symbol	Symbol Title	Explanatory Text
	FCC Mark	Indicates compliance with applicable requirements of the U.S. Federal Communications Commission.
	European Conformity	European conformity (CE) mark for Class I medical devices.
	Unique Device Identifier	Indicates the presence of a Unique Device Identifier for the medical device.
	Distributor	Indicates the entity distributing the medical device.
	Waste Electrical and Electronic Equipment	WEEE — Do not dispose of with household waste.
	Serial Number	Indicates the manufacturer's serial number for the device.
	Address of Manufacturer	Indicates the medical device manufacturer.

Disposal and Recycling

 At the end of the product service life, dispose of arLoupe™ according to local requirements for electronic equipment. Do not dispose of the device with general household waste.

Rechargeable batteries must be disposed of according to applicable local requirements. Do not incinerate batteries, dispose of batteries in household waste, or disassemble damaged batteries. Contact local recycling authorities for proper battery disposal instructions.

Before disposal, remove the battery and removable storage media. Delete or securely manage stored image/video data according to applicable privacy requirements.

14. Manufacturer and SurgiTel Support

Manufacturer

 BEWELLTECH INC.
www.bewelltechs.com

U.S. Distributor

 SurgiTel, a Division of General Scientific Corp.
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Customer Service

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Service and Repair

Do not attempt to repair or modify arLoupe™. When contacting SurgiTel, provide the device model number and serial number, a description of the issue, and any troubleshooting steps already attempted.



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