



Odyssey® Digital Light System

Instructions for Use and Care



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English

SurgiTel®, A Division of General Scientific Corp.

Odyssey Digital Light System

Instructions for Use and Care

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Regulatory Device Names:

Odyssey Digital Micro Light System

Odyssey Digital Mini Light System



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Regulatory Compliance

- **FDA:** Complies with 21 CFR 801 (labeling) and 21 CFR 820 (QSR).
- **EU:** Complies with MDR 2017/745, EMC Directive 2014/30/EU. Tested to EN 5501:2016/A11:2020 and IEC 60601-1-2:2020.
- **UK:** Complies with UKCA requirements for Class I medical devices.
- **ISO:** Manufactured under ISO 13485:2016.
- **Device Classification:** Class I (non-sterile, no measuring function).
- **Patents:** True color beam family optics, U.S. Patent Numbers: US 9,383,077 B2; US 9,494,299 B2.
- **Translations:** This IFU is available in English. For translations into EU languages, contact the manufacturer or authorized representative.

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1. Device Description

The SurgiTel® Odyssey Digital LED Headlight is a portable, battery-powered illumination device designed to provide high-intensity lighting for professional clinicians during medical, surgical, or dental procedures. The device attaches to loupes or glasses using an appropriate adapter and includes a rechargeable lithium-ion battery, adjustable light intensity, and a power switch. Your SurgiTel® LED headlight has been designed to meet the demanding needs of today's clinical professionals by allowing you to see, work, and feel your best.

2. Intended Purpose

The SurgiTel® Odyssey Digital LED Headlight is intended for use by trained healthcare professionals to provide focused illumination during clinical and surgical procedures requiring enhanced visualization of anatomical structures. The device is suitable for use in controlled clinical environments such as operating rooms, dental clinics, or outpatient facilities.

2.1 Package Contents

- Odyssey Digital Mini LED or Odyssey Digital Micro LED Light
- Odyssey Digital Battery Control Unit
- Cable for Digital Odyssey Light Unit
- Belt Clip
- USB Type-A Charging Block
- USB Type-A to Type-C Cable
- Accessory Kit (including hex key, O-rings, garment clips)

3. Indications for Use

- Illumination of anatomical structures during surgical, diagnostic, or dental procedures.
- Enhanced visualization for precision tasks in medical, dental, or veterinary practices.

4. Contraindications

- Not intended for use in environments with extreme electromagnetic interference that may affect device performance.
- Use in environments with flammable gases or materials due to risk of ignition.
- Not suitable for procedures requiring sterile fields unless used with appropriate sterile covers.
- Not for use with patients or operators with photosensitivity conditions that may be exacerbated by high-intensity light.
- Not for use by non-qualified personnel or for non-clinical purposes.

5. Precautions, Warnings, Safety

- **User Familiarity:** The user must be thoroughly familiar with the use and care of this product. Study this manual carefully before clinical use.
- **Inspection:** Ensure the device is inspected before each use (see Section 6.1).
- **Fire Hazard:** Do not place the LED light unit on any flammable object while operating.
- **Heat Hazard:** The LED unit may become hot during operation. Turn off before handling or adjusting.
- **Eye Safety:** Avoid direct light contact with the eyes. Do not point the light directly at the eyes of the operator, patient, or others. Patients should wear safety glasses.
- **Battery and Light Safety:** Use only the provided Odyssey Digital Battery Control Pack, Digital LED Light, Battery Charger, and AC Power Adapter. Do not use other light systems or power components in combination with the Odyssey Digital System. Do not disassemble, modify, short-circuit, expose to extreme heat (e.g., inside a car or in direct sunlight), or allow any components to get wet.
- **Light-Cured Composites:** Follow operational guidelines for light-cured composites (see Section 6.3).
- **Allergies:** Discontinue use if skin irritation occurs due to contact with device materials.
- **Environment:** Do not use the device outdoors or in wet or hot environments. Keep it dry at all times.
- **Electromagnetic Compatibility (EMC):** Avoid using near strong electromagnetic fields to prevent interference.
- **Adverse Events:** Report any serious incidents as outlined in Section 9.

6. Instructions for Use

6.1 Preparation

1. Inspect the LED system for damage (e.g., cuts or punctures on the light cord, scratches on the optical face). Do not use if damaged.
2. Ensure the battery is charged and connections are secure before use.
3. Attach the LED light to loupes or glasses using the appropriate adapter. (See Figures 1 and 2)
4. Use the included garment clips to route the cable appropriately. (Figure 3)
5. Ensure the LED extension cable connection is secure to prevent movement or detaching during use.



Figure 1 - Dovetail Mounting



Figure 2 - FLM Clip Mounting

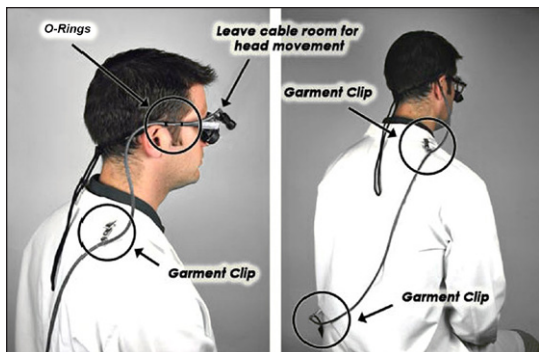


Figure 3 - Cable Routing

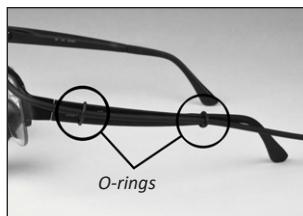


Figure 4 - O-rings

6.2 Adjustments and Cable Routing

- **Cable Routing:** Slide O-rings onto the temple arm to secure the LED cord. (Figure 4)
- **Battery Pack Placement:** Use the Odyssey Battery Control Pack belt clip correctly to avoid damage.
- **Hinge Tension Adjustment:**
 1. Remove the hinge set screw using the provided hex key. (Figure 5)
 2. Use two flat-head screwdrivers to adjust the special screw and nut for desired tension.
 3. Reassemble and tighten the set screw.

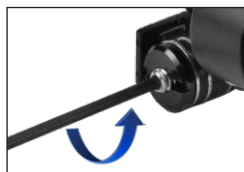


Figure 5



Scan to
watch video

6.3 Operation

1. **Power On / Off:** Press and hold power button (Figure 6) 2 seconds to turn the light on or off.
2. **Light Intensity:** Short press the power button to cycle through three brightness levels: Max, Medium, and Low. The unit will retain the last selected brightness level when powered off and back on.
3. **Battery Level:** The three-step battery level indicator lights (see Figure 7) are located on top of the unit. Three lights indicate a 100% charge, two lights indicate 70%, one light indicates 30%, and the single light will blink when the battery level falls below 15%.



Figure 6
Power Button



Figure 7
Battery Level



Figure 8
Charging Port



Figure 9
Orange Flip-Up Filter

4. **Recharging:** To recharge, connect the included USB Type-C charger to the USB Type-C port located on the bottom of the control unit (see Figure 8).
5. **Charging Indicator:** The charging indicator light, located next to the charging port on the bottom of the unit, glows red while charging and turns green when charging is complete.
6. **Light-Cured Composites:** When working with light-cured composites, set the light to a lower intensity and use an orange color filter (strongly recommended) to prevent premature hardening. (Figure 9)
7. **Maximum Continuous Operation:** Approximately over 8 hours at full load.

7. Cleaning and Maintenance

- **Cleaning:** Wipe down with a damp cloth using room-temperature water. Do not immerse in water or any liquid. Avoid using running water or disinfectant sprays near open slots on the light unit. Do not use any disinfectants containing alcohol, hydrogen peroxide, ethanol, ammonia, glutaraldehyde, iodophors, bleach, acid, phenol, or acetone that have not been approved for use by SurgiTel. Do not use an autoclave. For a full list of recommended disinfectants, visit www.surgitel.com/help.
- **Factory Cleaning:** Available for difficult cleaning situations. Contact SurgiTel Customer Support at (800) 959-0153.
- **Storage:** Store in a dry, dust-free environment, and safe place to prevent scratches or damage to the optical face.
- **Maintenance:** Regularly inspect the device during maintenance to ensure ongoing safety (see Section 6.1 for inspection details). If visible, the system is no longer safe to use and should be taken out of service immediately.



Scan for
current list of
recommended
disinfectants.

8. Troubleshooting

The following table lists common issues, their possible causes, and recommended actions to resolve them. If the issue persists, discontinue use and contact SurgiTel Customer Support.

Issue	Possible Cause	Recommended Action
Light does not turn on	Battery not charged or improperly connected	See Section 6.3 for charging instructions
Battery charge indicator shows flashing red	Charging error or defective battery	Disconnect and reconnect the AC charger. Try a different power outlet. If flashing persists, replace the battery and contact SurgiTel Customer Support.
Light intensity cannot be adjusted	Faulty intensity button or internal malfunction	Ensure the power button is being pressed down properly. If unresponsive, turn off the device and contact SurgiTel Customer Support.
Light overheats	Prolonged use or blocked ventilation	Turn off the light and allow it to cool for 10–15 minutes. Ensure ventilation slots are not obstructed.
Light flickers or dims	Low battery or loose cable connection	Check battery charge (green = charged, red = low). Recharge if necessary. Verify LED extension cable connection is secure.
Device does not charge	Faulty charger, USB cable, or USB port.	Use only the supplied charger and adapter. Low voltage charger may cause fault in unit. Test with a different power outlet. Ensure the rechargeable inlet is properly connected. If the issue persists, contact SurgiTel Customer Support.
Light misaligned with field of view	Improper adapter or hinge tension	Adjust hinge tension or reattach the adapter to loupes/glasses. Ensure secure attachment.
Short battery cycle	Aging battery	Replace battery cell.

Note: Do not attempt to repair the device yourself, as this may void the warranty or cause further damage. For persistent issues or suspected malfunctions, follow the adverse event reporting procedure (Section 9).

9. Adverse Events

In case of adverse events (e.g., skin irritation, burns, or device malfunction), discontinue use and report to:









- USA: SurgiTel Customer Service (800) 959-0153 or support@surgitel.com
- EU: AF Pharma Service Europe SL
- Report to competent authorities (e.g., FDA via MedWatch or EU national authorities) as required.






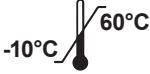

10. Technical Data

- **LED Light:** Available with either a Micro wide-beam optic or a Mini high-intensity optic. Both optics produce an achromatic beam.
- **LED Life:** Up to 10,000 hours (estimated based on intensity used)
- **AC Charger:** Input: 100–240 V AC, 50–60 Hz, 0.4 A / Output : +5 V DC, 2.5 A
- **Charging Voltage:** 5 V at 2.5 A (12.5 W)
- **Charge Time:** Approximately 3 to 4 hours
- **Maximum Continuous Operation:** Approximately over 8 hours at full load.
- **Battery:** Odyssey Digital Battery Control Pack, rechargeable
- **Battery Cell:** Rechargeable Lithium-Ion 7.2 V, 3,350 mAh, 24 Wh, replaceable
- **Battery Life:** Expected to last for approximately 500 full charge cycles before significant degradation. Actual lifespan may vary based on usage and charging habits.
- **Intensity, Light Output:** Mini Optic: 85,000 lux, Micro Optic: 55,000 lux
- **Protection:** Against electronic shock; Class II including AC/DC adapter
- **Color Temp:** Neutral (4,000 K) / Cool (5,700 K)
- **LED Body Weight:** 5 g
- **LED Cable Weight:** 18 g
- **Battery Control Unit Weight:** 151 g
- **Sterilization status:** Non-sterile device. Sterilization not required.
- **Operating Conditions:**
 - Temperature: 0 to 40 °C
 - Humidity: 10 to 75%
 - Pressure: 101.3 kPa (1 atm)
- **Transport Conditions:**
 - Temperature: -10 to 60 °C
 - Humidity: 30 to 60%
 - Pressure: 11.6 to 101.3 kPa
- **Storage Conditions:**
 - Temperature: -10 to 45 °C
 - Humidity: 30 to 60%
 - Pressure: 101.3 kPa (1 atm)

11. Classification

- **Protection Against Electric Shock:** Class II including AC/DC Adapter.
- **Applied Parts:** No applied parts.
- **Protection Against Harmful Ingress of Water:** Ordinary IPX0.

Symbol Glossary		
Symbol	Symbol Title	Explanatory Text
	European Conformity	European conformity (CE) mark for Class I medical devices.
	UK Conformity	UK Conformity (UKCA) mark for Class I medical devices (non-sterile, no measuring function, and not reusable surgical instrument).
	Authorized Representative in the European Community	Indicates the authorized representative in the European Community.
	Authorized Representative in the United Kingdom	Indicates the authorized representative based in United Kingdom.
	Manufacturer	Indicates the medical device manufacturer.
	Waste Stream Disposal Warning	Do not dispose of electronic products with general waste.
	Direct Current	Indicates the device uses direct current.
	Alternating Current	Indicates the device uses alternating current.

Symbol Glossary		
	Class II Equipment	Indicates double insulation for protection against electric shock.
	Attention	Consult accompanying documents.
	Unique Device Identifier	Indicates the UDI for traceability.
	Importer	Indicates importer.
	Keep Dry	Indicates to protect from moisture.
	Temperature Limit	Indicates minimum and maximum temperature.
	Batch Code/ Lot Number	Indicates the manufacturer's batch/ lot code.

12. Disposal and Recycling

Dispose of the LED light, battery, and charger in accordance with applicable local, regional, and national regulations governing medical devices and electronic waste.



Do not dispose of these components in general household waste.

For proper disposal or recycling options, contact SurgiTel or your local authorized distributor.

These components may contain materials that require special handling at the end of their life cycle to avoid environmental harm and comply with the EU Waste Electrical and Electronic Equipment (WEEE) Directive and relevant FDA regulations.

SurgiTel[®]

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