



Welch Allyn® Green Series™ Exam Light IV

901067 EXAM/PROCEDURE LIGHT

Instructions for use ENGLISH

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Intended use

The Welch Allyn GS Exam Light IV is designed to meet the various needs of the physician's office, hospital environment, and specialist's office. It is not intended for rendering diagnosis or surgery.

Indications for use

The devices shall be used in hospitals and health care facilities by trained healthcare professionals to provide additional illumination while performing examinations and minor procedures.

Contraindications

The devices shall not be used to render diagnosis or in surgery.

Symbol descriptions

For information on the origin of these symbols, see the Welch Allyn symbols glossary: welchallyn.com/symbolsglossary

WARNING The warning statements in this manual identify conditions or practices that could lead to illness, injury, or death. Warning symbols will appear with a grey background in a black and white document.

CAUTION The caution statements in this manual identify conditions or practices that could result in damage to the equipment or other property, or loss of data.

- # Product Identifier
- REF Reorder number
- LOT Lot code
- GTIN Global Trade Item Number
- Consult instructions for use



- MD Medical device
- Rx ONLY Prescription only or "For Use by or on the order of a licensed medical professional"
- Manufacturer
- EC REP Authorized Representative in the European Community
- WARNING High intensity light
- Use indoors
- Temperature limits
- Atmospheric pressure limitation
- Humidity limitation
- Power on/off
- Alternating current (AC)
- Do not re-use, Single use device
- Mass in kilograms (kg)
- Fragile
- This way up
- Stacking limit by number
- Keep dry
- Recyclable
- Separate collection of Electrical and Electronic Equipment. Do not dispose as unsorted municipal waste.

Warnings

WARNING Read and understand the instructions before using this product. Failure to understand the operating requirements for this product might result in injury to yourself or the patient, and/or might damage the instrument.

WARNING Illumination is intense. To minimize risk of harm to the eyes from optical radiation hazards, avoid looking at bright light sources and their reflections, do not stare at the light source in operation, and protect eyes where normal pupil sizes and aversion responses are not present.

WARNING Use the examination light in its intended working range of 16 in (40 cm). Exposures at closer distances may be harmful to skin. To minimize risk of harm to the skin from optical radiation hazards, minimize illumination intensity at the tissue examination site, minimize exposure times, and take additional precautions when skin sensitivity has been altered through tissue trauma or the use of anesthesia.

WARNING This is a class A product. In a hospital/physician's office environment this product might cause radio interference in which case the user should take adequate measures.

WARNING This product complies with current required standards for electromagnetic interference and should not present problems to other equipment or be affected by other devices. As a precaution, avoid using this device in close proximity to other equipment.

WARNING Do not modify this equipment. Any modification of this equipment can lead to patient injury. Any modification of this equipment voids the product warranty.

WARNING Personal injury risk. To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

WARNING Personal injury risk. The power cord is the disconnect device to isolate this equipment from supply mains. Position the equipment so that it is not difficult to reach to disconnect the cord.

Cautions

CAUTION Only authorized Hillrom Service Centers can perform service on this product.

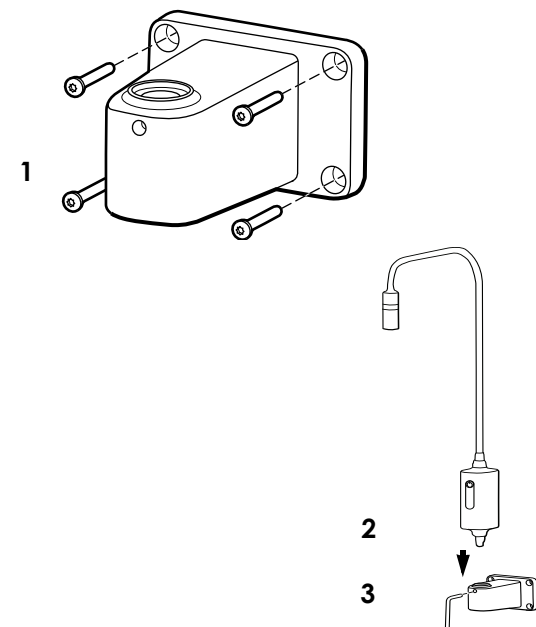
CAUTION There are no user serviceable/replaceable parts.

Residual risks

This product complies with relevant electro-magnetic interference, mechanical safety, performance, and biocompatibility standards. However, the product cannot completely eliminate potential patient or user harm from the following:

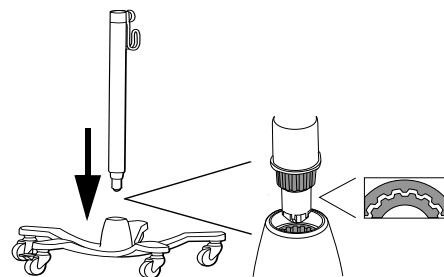
- Harm or device damage associated with electro-magnetic hazards,
- Harm from mechanical hazards,
- Harm from device, function, or parameter unavailability,
- Harm from misuse error, such as inadequate cleaning, and/or
- Harm from device exposure to biological triggers that may result in a severe systemic allergic reaction.

Mounting Table/wall mount

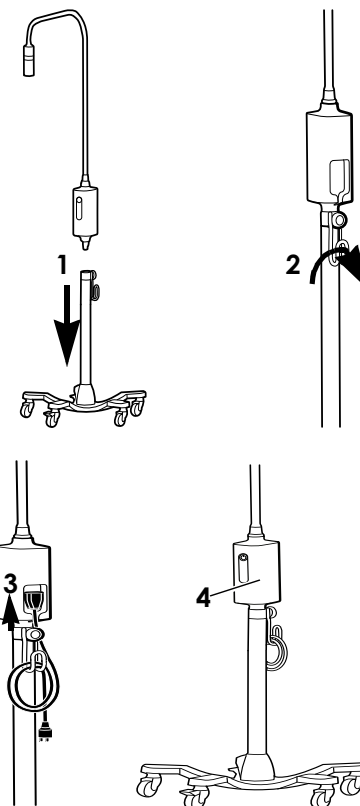


WARNING Ensure that the mounting bracket is securely anchored to the wall or table, or that the mobile stand is securely assembled, and the exam light is securely fastened to the bracket or stand as directed. Do not hang or place objects on the equipment.

Setup instructions Mobile stand assembly instructions



Setup



Cleaning

WARNING Ensure that the device is unplugged from wall socket.

Focusing sleeve

1. Clean with a cloth dampened with warm water and mild detergent.
2. Follow with a cloth dampened with warm water.
3. Dry with a clean cloth.

Control box

1. Clean with a cloth dampened with any of these approved cleaning agents:
 - warm water and mild detergent
 - 70 percent isopropyl alcohol
 - 10 percent bleach solution
2. Follow with a cloth dampened with warm water.
3. Wipe dry with a clean cloth.

After cleaning, inspect the device for wear, fraying, or other damage. Do not use if you see signs of damage, if the instrument malfunctions, appears not to be working properly, or if you notice a change in performance. Contact Hillrom Technical Support department for assistance.

Troubleshooting Green light not illuminated

Possible cause
Power supply fault. No power supplied to light.

Solution
Verify all cables are connected correctly.

Green light illuminated

Possible cause
Light is not functioning correctly.

Solution
Contact Hillrom Technical Support.

Disposal

Users must adhere to all federal, state, regional, and/or local laws and regulations as they pertain to the safe disposal of medical devices and accessories. If in doubt, the user of the device should first contact Hillrom Technical Support for guidance on safe disposal protocols.

welchallyn.com/weee

PATENT/PATENTS

hillrom.com/patents

May be covered by one or more patents. See above Internet address. The Hill-Rom companies are the proprietors of European, US, and other patents and pending patent applications.

Hillrom Technical Support

For information about any Hillrom product, contact Hillrom Technical Support at hillrom.com/en-us/about-us/locations

Notice to users and/or patients in EU

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Performance characteristics

Spot size: Adjustable from 4 to 10 inches in diameter ± 10% at 16 inch working distance

Spot type: Sharp Edge

Specifications

Electrical

Input: 100-240 V~ 50Hz-60Hz, 0.30A max

Environment

- Temperature
 - Operating: 50 °F – 95 °F (10 °C – 35 °C)
 - Transport/storage: -4 °F – 120 °F (-20 °C – 49 °C)
- Relative humidity, non-condensing
 - Operating: 15 – 90%
 - Transport/storage: 15 – 95%
- Atmospheric pressure
 - Operating: 700 – 1060 hPa
 - Transport/storage: 500 – 1060 hPa

Equipment classification

Safety Class 1, Continuous Operation

Additional technical information

welchallyn.com/gsseries

Standards and compliance

The device complies with the following standards:

- IEC 60601-1
- IEC 60601-1-2
- Country-specific standards are included in the applicable Declaration of Conformity



Lot code

YYWW (on product)
YYDDD (on package)
YY= last 2 digits of the year
WW= week of the year
DDD=consecutive day of the Julian year

Guidance and manufacturer's declaration/EMC

For information about electromagnetic compatibility (EMC), see the Welch Allyn website welchallyn.com/emc-examlight.

A printed copy of the emissions and immunity information can be ordered from Welch Allyn for delivery within 7 calendar days.

Accessories

- 48950 Mobile Stand for GS Light IV
- 48955 Table / Wall Mount for GS Exam Light IV / GS 300 / GS 600
- 44215 12" Wall Mount Extension
- 52640 Disposable Sheaths for GS Exam Light IV

Warranty

Five years.

Hill-Rom reserves the right to make changes without notice in design, specifications and models. The only warranty Hill-Rom makes is the express written warranty extended on the sale or rental of its products.