



OPERATOR'S MANUAL

VIEW MEDICAL SURGILIGHT™

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Device Overview

DISCLAIMER

PLEASE READ PRIOR TO USE:

This user manual must be read and understood by all involved personnel prior to operating the View Medical SurgiLight in any circumstances. The information and procedures given in this manual do not relieve involved personnel from their responsibility to perform work with their own safety in mind as well as others' safety who may also be operating the View Medical SurgiLight. Failure to follow the cautions and instructions in this manual constitutes abnormal use and can result in injury.

An electronic version of this manual is available on the BihlerMED website using this link provided below:

→ www.bihlermed.com/surgilight_manual

INTRODUCTION

The SurgiLight by View Medical is a surgical lighting system that aims to provide surgeons with a safe and practical illumination device to focus on specific target areas. It mounts to the handle attachment anchor point of various overhead surgical lights, and features a long, flexible shaft that will allow the user to direct the light onto the incision from any desired angle. The LED bulb provides a bright and localized light while the attached battery pack delivers a long functional life. The View Medical SurgiLight shall be used in conjunction with the sterile Disposable Handle Assembly. This sub-assembly consists of a plastic housing with an inserted plano-convex plastic lens and a polyethylene cover sleeve. The Disposable Handle Assembly attaches to the SurgiLight and is essential to the overall functionality of the surgical light. The dual purpose handle gives the user the ability to focus the light by rotating the handle and serves as a layer of protection for the light-emitting diode (LED) housing. The medical cover sleeve is extended over the SurgiLight to provide a sterile barrier to the flexible shaft.

DEVICE SPECIFICATIONS

Maximum Illuminance.....	125,000 Lux (Burst Mode)
Light Field Diameter (at 14").....	3.25" to 5.25"
Color Temperature.....	4000K
Battery Life (at 4 th continual setting).....	> 5 hours

DEVICE CLASSIFICATION

2816-01-0001 View Medical SurgiLight – Class II US FDA

2816-01-0002 Disposable Handle Assembly – Class I US FDA

Case Contents



List of Contents

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1	SurgiLight Operator's Manual	5	Battery Charger
2	SurgiLight IFU	6	Table Mount Adapter
3	Battery	7	Power Supply
4	SurgiLight Device	8	Power Supply Cord

Safety Information

SURGILIGHT DEVICE WARNINGS AND PRECAUTIONS



- 1) Before every procedure, inspect the View Medical SurgiLight prior to use to ensure cleanliness, proper function, and that it is properly secured to the overhead light or table mount. Do not use a device that is damaged or loose.
- 2) Follow the instructions of other manufacturer's equipment when used in conjunction with this product.
- 3) The SurgiLight must be used in conjunction with the Disposable Handle Assembly to provide a sterile barrier.
- 4) Do not immerse the electrical components in liquid when cleaning.
- 5) Do not shine the light directly into eyes as it could temporarily impair vision and/or cause harm.
- 6) Excessive force on the shaft could cause the device to malfunction. Care should be taken when handling the device and manipulating the shaft into the desired location.

DISPOSABLE HANDLE ASSEMBLY WARNINGS AND PRECAUTIONS



- 1) The Disposable Handle Assembly is sterile unless the package is opened or damaged. Inspect the package prior to use, do not use if the package is opened or damaged.
- 2) The Disposable Handle Assembly should never be reused, reprocessed, or resterilized. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and create a risk of contamination.

BATTERY WARNINGS AND PRECAUTIONS

- 1) The smart battery charger shall only be used to charge SMBUS batteries with form factors RRC2040, 2040-2, 2054, 2057 or smart batteries with a similar footprint.
- 2) The battery charger may not be located in the vicinity of a patient. In accordance with EN60601-1-1, the horizontal distance must be at least 1.5 meters.
- 3) Do not insert a fully charged battery into the charger repeatedly. Due to the high initial charge, the battery could be overcharged which could lead to damage to the battery and charger.
- 4) Use the battery charger in dry, indoor environments only. Wet or moisture covered products should not be used.
- 5) Before every procedure, check the battery charge level.
- 6) Keep battery terminals away from metal objects to avoid short circuits.
- 7) Do not subject battery to mechanical shock.
- 8) Do not open the charger or power supply case, there are no user serviceable parts inside.

POTENTIAL ADVERSE EFFECTS

There is the potential risk for tissue damage including necrosis due to excessive heat at a prolonged period of time from the light source. To reduce the risk of thermal damage to tissue, use the lowest light intensity settings necessary for visualization and avoid prolonged illumination of tissue.

Design Overview: Overhead Light Mount

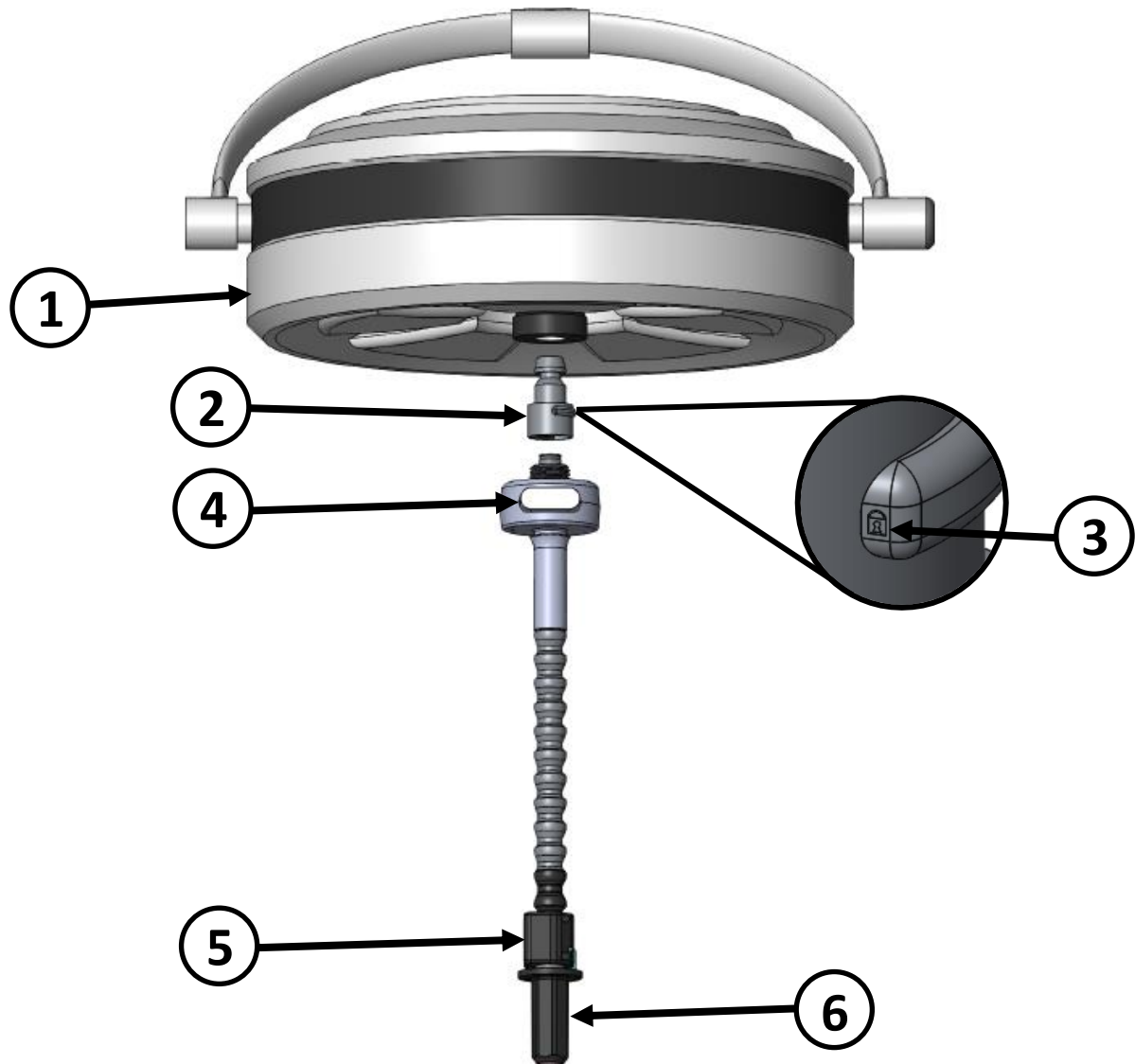


Diagram Components			
1	Overhead Light	4	Battery
2	Overhead Light Adapter	5	Control Panel
3	Locked Indicator	6	Disposable Handle Assembly

Setup/Installation

OVERHEAD LIGHT CONFIGURATION

- 1) Remove the existing handle attached to the overhead light, as shown in Figure 1, per the overhead light's Instructions for Use. Contact the manufacturer of the light if instructions for removing the handle are not included.

- 2) Find the correct adapter to attach to the SurgiLight that will mount to the overhead light.



WARNING: Contact BihlerMED if you are unsure that the provided adapter is compatible with your existing overhead light. Failure to securely connect the SurgiLight to the existing overhead light could lead to disconnection during use.

- 3) Place the correct adapter on the protruding stem of the SurgiLight and begin threading the adapter clockwise, as shown in Figure 2. Resistance will be felt as the push button release of the adapter is drawn inwards. Keep threading the adapter clockwise until the bottom of the adapter meets the base of the SurgiLight.

- 4) The push button release will slide back out to its original position and the locked indicator etched on the side of the button will be fully visible when the overhead light adapter is connected properly.



WARNING: Check connection if locked indicator is not visible.

- 5) Insert the adapter into the now-empty cavity of the overhead light per the overhead light's Instructions for Use, as shown in Figure 3, until the adapter is mounted effectively to the overhead light and is secure.
- 6) After use, remove the SurgiLight from the overhead light after using the same method as used prior to the procedure with the existing overhead light handle.
- 7) To detach the overhead light adapter from the SurgiLight, simultaneously depress the push button release and rotate the adapter counter-clockwise until the adapter is free to move off the stem of the SurgiLight.

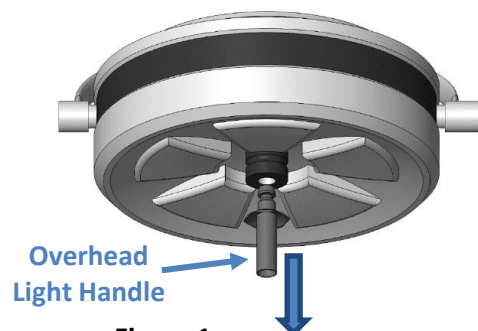


Figure 1.

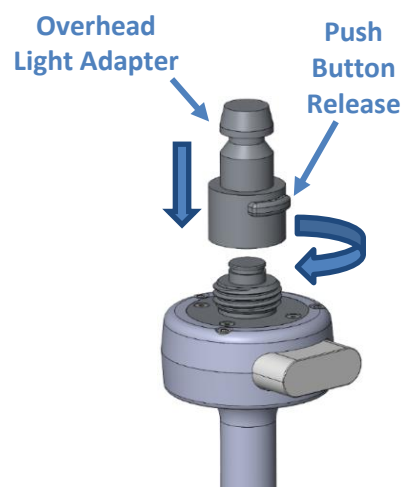


Figure 2.

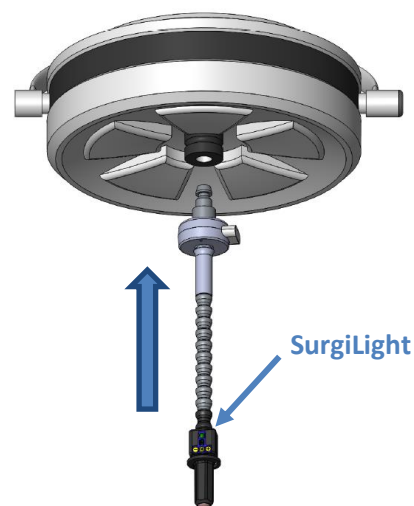


Figure 3.

Design Overview: Table Mount

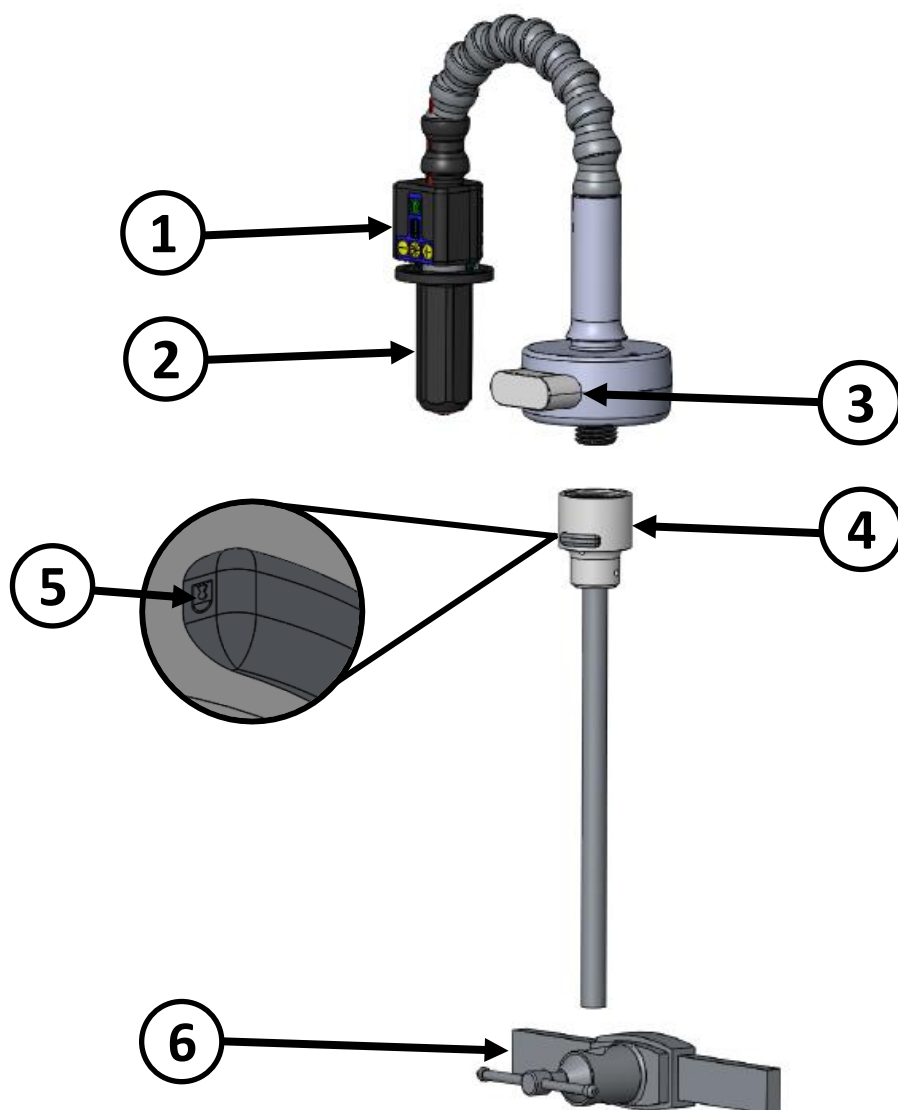


Diagram Components			
1	Control Panel	4	Table Mount Adapter
2	Disposable Handle Assembly	5	Locked Indicator
3	Battery	6	Table Side Rail Clamp

Setup/Installation

TABLE MOUNT CONFIGURATION

- 1) Remove the Overhead Light Adapter, as shown in Figure 4, prior to attaching the Table Mount Adapter. Place a Table Mount Adapter on the protruding stem of the SurgiLight and begin threading the adapter clockwise, as shown in Figure 5.
- 2) Resistance will be felt as the push button release of the adapter is drawn inwards. Keep threading the adapter clockwise until the bottom of the adapter meets the base of the SurgiLight.
- 3) The push button will slide back out to its original position and the locked indicator etched on the side of the button will be fully visible when the table mount adapter is connected properly.



WARNING: Check connection if locked indicator is not visible.

- 4) Use the protruding rod from the adapter to mount the SurgiLight to the table side rail accessory, per the manufacturer's Instructions for Use. The adjustability of the angle and length of the table mount adapter's rod can be seen in Figure 6.
- 5) To detach the table mount adapter, simultaneously depress the push button release and rotate the adapter counter-clockwise until the adapter is free to move off the stem of the SurgiLight.

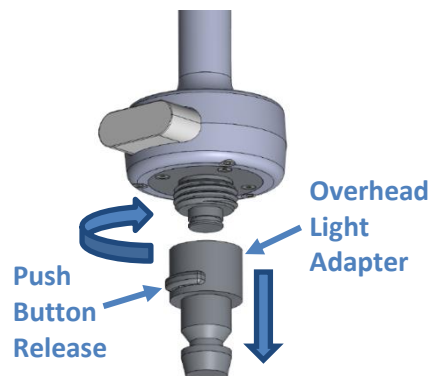


Figure 4.

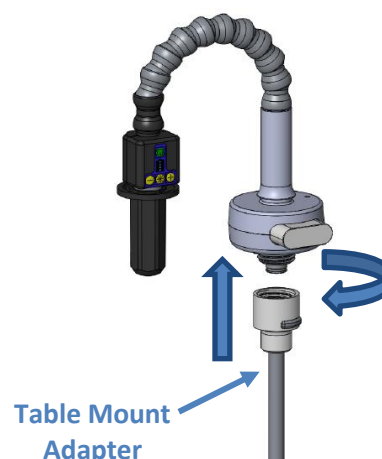


Figure 5.



Figure 6.

Operating Procedure

DIRECTIONS FOR USE

- 1) Insert a fully charged battery, with the pin connections facing up as shown in Figure 7, into the View Medical SurgiLight after the device is successfully installed. The battery level indicator on the control panel, shown in Figure 8, will light up green in sequential order after the battery has made proper connection with the terminals of the SurgiLight.

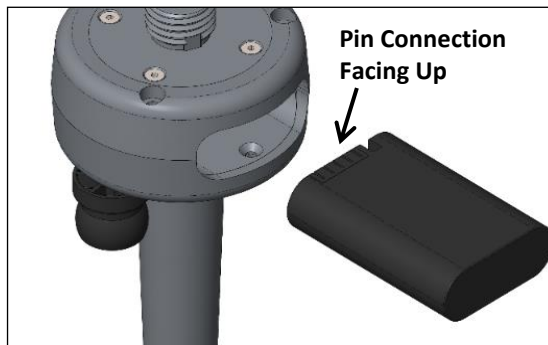


Figure 7.

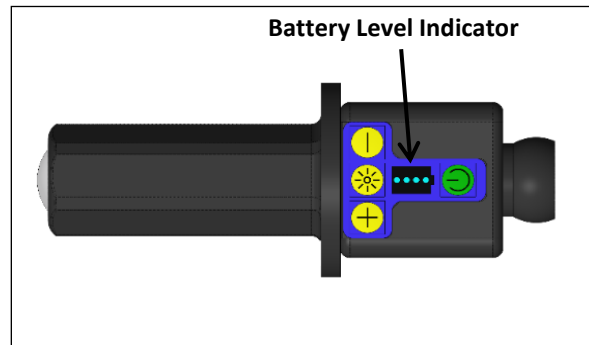


Figure 8.

- 2) Prior to each surgical procedure, open the Disposable Handle Assembly package and unravel the Medical Cover Sleeve.
- 3) Expand the elastic end of the sleeve and stretch it over the control panel box.



WARNING: To prevent cross-contamination, avoid touching any part of the SurgiLight prior to covering the unsterile components with the sleeve.

- 4) Cover the entire shaft of the light by sliding the sleeve up from the base of the control panel to the top groove of the SurgiLight shaft, as shown in Figure 9.

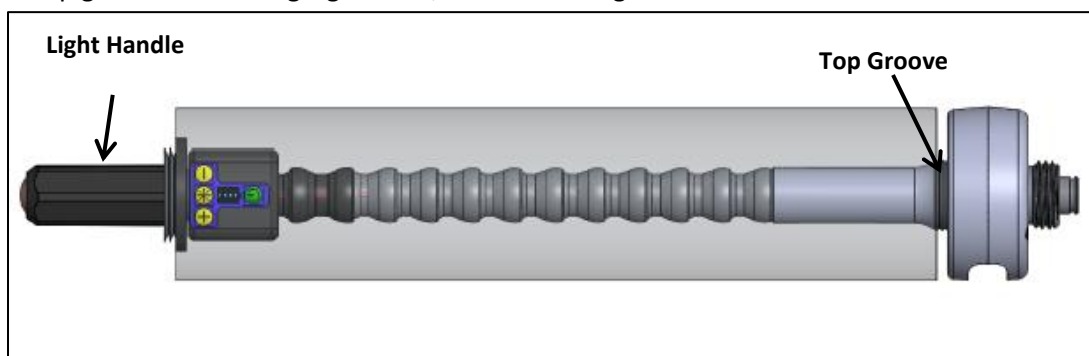


Figure 9.

- 5) Align the wide end of the groove in the light handle with the latch, as shown in Figure 10, and slide the Light Handle onto the end of the SurgiLight until the latch clicks. The light handle shall now be secured by the latch, as shown in Figure 11. Ensure the elastic ends of the sleeve are secure at the top groove at the base of the battery handle and at the base of the light handle.

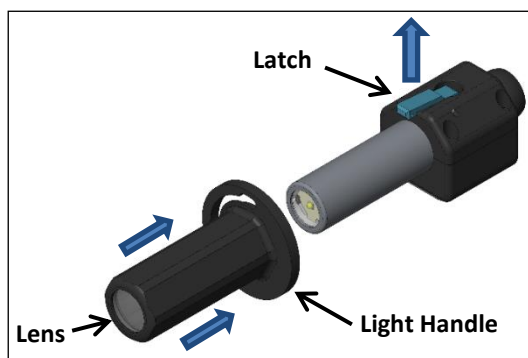


Figure 10.

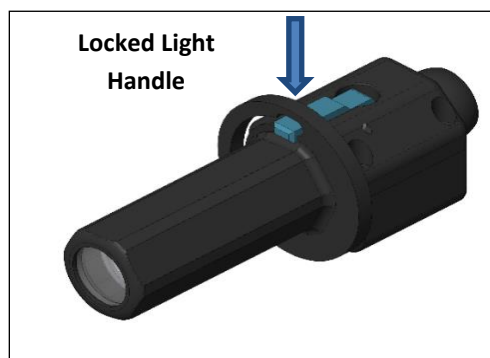


Figure 11.

- 6) Adjust the light to the desired position.



WARNING: Do not use excessive force when manipulating the position of the flexible shaft of the SurgiLight. Over-manipulation may cause the components of the shaft to separate and expose the internal components, resulting in the device not functioning properly.

- 7) Power on the light by depressing the power button on the control panel.
- 8) Use the +/- buttons to cycle through the four intensity settings in a progressive manner to adjust brightness. Use the Burst Mode button, shown in Figure 12, to activate the highest light intensity setting.

Note: The Burst Mode will automatically shut off after ten minutes of run time and return to a lower intensity setting.

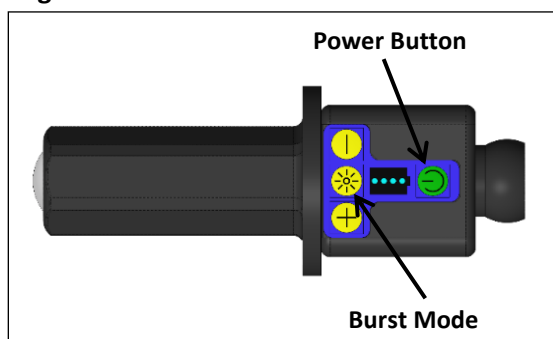


Figure 12.

- 9) Focus the light by rotating the light handle, as shown in Figure 13. Rotating away from the initial position shrinks the diameter of the light output, while rotating back to the initial position enlarges the diameter of the light output.

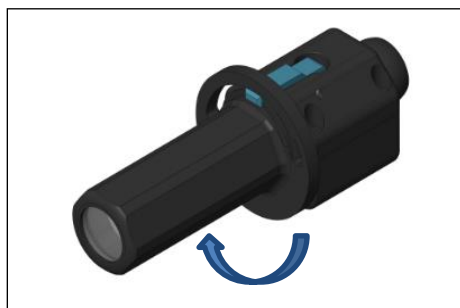


Figure 13.

General Maintenance

DEVICE HANDLING AND STORAGE

Care should be taken when handling the View Medical SurgiLight and manipulating the position of the light into the desired locations to prevent potential damage. Store the View Medical SurgiLight in its case and remove the battery when not in use. The recommended storage temperature for the battery is -20 °C to 20 °C (-4 °F to 68 °F). The battery manufacturer also recommends storing the battery with a state of charge between 40-60%.

DEVICE CLEANING

The SurgiLight shall be routinely cleaned before and after each use; do not sterilize the device. Use the following instructions to clean the device appropriately:

Cleaning Instructions:



- 1) Remove the battery and discard the Disposable Handle Assembly prior to cleaning.

WARNING: Do not immerse any portion of the SurgiLight in cleaning solution.

- 2) Articulate device within its operating range to form a “U” shape, maximizing surface area of ball joints to be cleaned.
- 3) Spray outer surfaces of the View Medical SurgiLight with 70% isopropyl alcohol. Ensure that the device is not saturated to the point of run-off as excess solution entering the housing could damage the light.



WARNING: Do not use any agent besides 70% isopropyl alcohol, as it may result in premature failure of the product.

- 4) Wipe the surfaces of the View Medical SurgiLight with a clean cloth. A soft bristle brush can be used to loosen surface debris as required.
- 5) Articulate device within its operating range to form a reverse “U” shape, exposing additional surface area of ball joints to be cleaned. Repeat steps 3 and 4.



- 6) Thoroughly air dry the View Medical SurgiLight prior to use.

WARNING: The SurgiLight should not be used until the device is completely dry.

ADAPTER CLEANING

Any adapters used in conjunction with the SurgiLight device shall be routinely cleaned before and after each use using a standard cleaner according to hospital protocol. The adapter must be removed from the SurgiLight prior to immersing or wiping the adapter with a cleaner. If required, a soft bristle brush can be used to loosen surface debris. The SurgiLight shall not be used until the device and all adapters are completely dry. Do not sterilize any component of the SurgiLight.

DEVICE DISPOSAL

Please adhere the following disposal recommendations while in accordance with the applicable local regulations:



- Dispose of the entire Disposable Handle Assembly after each use
- Do not dispose of the SurgiLight in ordinary municipal waste, recycle when possible
- Recycle the Lithium-ion battery

Battery Use and Maintenance

BATTERY CHARGING

Follow these steps to charge the battery:

- 1) Connect the cable from the main adapter to the battery charger.
- 2) Connect the power cable to the main adapter and plug it into any standard AC power outlet.
- 3) A red LED control lamp will appear indicating the battery charger's self-test. If this red LED remains on and no battery is in the charger, the battery charger is defective. If the red LED disappears after the self-test, the battery charger is ready for use.
- 4) Place a discharged battery in the battery charger bay. The battery charger will automatically begin charging the battery after recognition.
- 5) Do not remove the battery from the battery charger bay until the LED control lamp displays a constant green light.
- 6) The battery is fully charged and ready for use with the SurgiLight.

BATTERY INDICATORS

The battery's capacity is displayed on the battery indicator within the control panel, shown in Figure 14, as long as the SurgiLight is powered on. It may also be determined using the battery indicator located on the battery itself, shown in Figure 15. The battery indicator displays the capacity with LED indicator lights via the push button. Each LED light represents 25% of the battery's full charge. For example, four green LED lights will be illuminated when the battery percentage is between 76% and 100%. The LED light will blink when the battery percentage is less than 10%.

Battery Indicator on Control Panel



Figure 14.

Battery Indicator on Battery



Figure 15.

**Push
Button**

The LED control lamp indication on the charger provides the following information:

Indication Color	Indication Pattern	Indication Status
Red/Orange/Green	Flash Once	The charger is ready for use
Red/Green	Blinking	Battery recognition and initialization
Orange	Constant	The battery is currently charging
Green	Constant	The battery is fully charged and can be removed from the charger
Red	Blinking	The battery is too hot or too cool to be charged without damage
Red	Constant	The battery is damaged or not a rechargeable battery

Troubleshooting

BihlerMED continually strives to develop and manufacture dependable medical devices. However, problems occasionally arise during normal usage. Please use the following table if issues arise during the operation of the View Medical SurgiLight. If your issue is not listed or the solution does not fix the issue then contact BihlerMED for further assistance.

Trouble Area	Possible Cause	Corrective Action
No Light Output	Power button not activated, depleted battery, or battery not connected properly	First, try depressing the power button on the control panel with more force as the initial startup requires more force than the subsequent startups. Ensure the battery is connected properly; refer to the "Operating Procedure" section for instructions on connecting the battery. If the battery is connected properly, recharge or replace the current battery.
Low Light Output	Low charge on battery	Fully recharge battery and try again. If you are still experiencing low light output, replace the current battery.
Light will not connect to overhead light	Incorrect adapter used	Contact BihlerMED for specifications on the correct adapter for your application. Please have the make and model of the overhead light available at time of call.

Compliance Information

The emissions and immunity characteristics of the View Medical SurgiLight have been tested to the following test levels from Table 4 and Table 9 of the IEC 60601-1-2 International Standard:

Immunity Test Levels

Test	Test Standard	Test Level	Power Input Voltage/Frequency
Radiated Emissions	CISPR 11	Class A Group 1 30 – 1000 MHz	11.25 Vdc 2950 mAh Battery Power Only
Electrostatic Discharge	IEC61000-4-2	8 kV Contact Discharge VCP, HCP ±2 kV, ±4 kV, ±8 kV, ±15 kV Air Discharge	
Proximity fields from RF wireless communications equipment	IEC61000-4-3	3 V/m, 80-2700 MHz 80% AM at 1 kHz	
Rated power frequency magnetic fields	IEC61000-4-8	30 A/m @ 50 Hz or 60 Hz 3 orthogonal orientations	

RF Immunity Test Levels

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM ±5 kHz deviation 1 kHz sine	2.0	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2.0	0.3	28
870						
930						
1,720	1,700 – 1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2.0	0.3	28
1,845						
1,970						
2,450	2,400 – 2,570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2.0	0.3	28
5,240	5,100 – 5,800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5,500						
5,785						

Reference Information

Any Health Care Professional who has any complaints or who has experienced dissatisfaction in the product quality, identity, durability, safety, effectiveness, and/or performance should notify the manufacturer. If replacement parts or any further information is needed, please contact BihlerMED using the contact information listed below:

CONTACT INFORMATION



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SYMBOLS DESCRIPTION

The medical symbols used throughout this device documentation are defined as follows:

Symbol	Description	Symbol	Description
	Caution		Do not re-sterilize
	Manufacturer		Date of Manufacture
	Sterilized using ethylene oxide		Do not dispose of in ordinary municipal waste, Recycle.
	Do not re-use		Do not use if packaging is damaged.
	Batch Code		Use-by date
	Catalogue Number		Consult Instructions for Use
	Serial Number		Not made with natural rubber latex