Evaluation: Trumpf Medical TruLight 5520 Major LED Surgical Light

Updated 2/13/2019 | Published 3/9/2016

EXECUTIVE SUMMARY

Rating

★★★★☆

Findings

Our rating is based on the following findings:

Performance—Good. The Trumpf Medical TruLight 5520 offers reliable illumination at varying working distances without manual refocusing, as well as adjustable color temperature.

Safety—Good. The Trumpf Medical TruLight 5520 meets all our required safety criteria.

Workflow—Excellent. The Trumpf Medical TruLight 5520 offers infinite rotation about the light head, without stops, as well as easy-to-use controls for adjusting field size.

Patient Experience—Not evaluated

Interoperability—Not evaluated

Cybersecurity—Not evaluated

Maintenance—Good. The Trumpf Medical TruLight 5520 meets all our required maintenance criteria.

User Experience—Not evaluated

Cost of Ownership—Estimated $70,000 over 10 years for an installation including two surgical lights, a high-definition (HD) video camera, and a flat-panel arm with HD video monitor.

COMPARE RATINGS FOR ALL DEVICES

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COMPARATIVE RATINGS—ALL DEVICES

Here's how the Trumpf Medical TruLight 5520 compares with the other products we've evaluated.

Ratings: Major LED Surgical Lights

Click the device names below to view our complete findings for each model. Products are listed alphabetically by supplier.

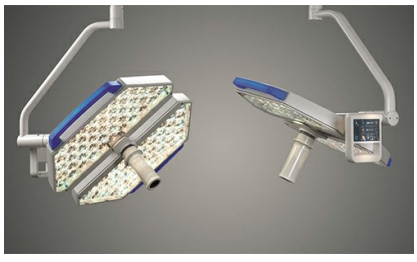
Model	Rating	Where Marketed	Performance	Safety	Workflow	Patient Experience	Interoperability	Cybersecurity	Maintenance	User Experience	Cost of Ownership (Estimated) over 10 Years
Amico iCE-30m Last updated 2/2019	★★★★☆	Worldwide	Good	Good	Excellent	Not evaluated	Not evaluated	Not evaluated	Good	Not evaluated	$66,000
Draeger Polaris 600 Last updated 2/2019	★★★☆☆	Worldwide	Fair	Good	Excellent	Not evaluated	Not evaluated	Not evaluated	Good	Not evaluated	$67,000
Getinge Maquet PowerLED II 500	★★★★☆	Worldwide	Good	Good	Excellent	Not evaluated	Not evaluated	Not evaluated	Good	Not evaluated	$73,000

Last updated 10/2019											
Getinge Maquet PowerLED II 700 Last updated 10/2019	★★★★★	Worldwide	Excellent	Good	Excellent	Not evaluated	Not evaluated	Not evaluated	Good	Not evaluated	$73,000
Maquet Volista 600 Last updated 3/2016	★★★☆☆	Worldwide	Good	Good	Good	Not evaluated	Not evaluated	Not evaluated	Good	Not evaluated	$84,000
Mindray HyLED X9 Last updated 4/2021	★★★★☆	Africa, Asia Pacific, Europe, Middle East (not sold in the U.S.)	Good	Good	Excellent	Not evaluated	Not evaluated	Not evaluated	Good	Not evaluated	$73,000 Calculation based on prices for China, a major market for the product
Rimsa Unica Last updated 9/2019	★★★☆☆	More than 90 countries, including Indonesia, Italy, Japan, and Thailand (not available in U.S.)	Fair	Good	Excellent	Not evaluated	Not evaluated	Not evaluated	Good	Not evaluated	$76,000 Calculation based on prices for Italy, a major market for the product
Skytron Aurora Four Last updated 3/2016	★★★☆☆	Worldwide	Fair	Good	Excellent	Not evaluated	Not evaluated	Not evaluated	Good	Not evaluated	$86,000
Steris HarmonyAIR M5 Last updated 2/2019	★★★☆☆	Worldwide	Good	Good	Good	Not evaluated	Not evaluated	Not evaluated	Good	Not evaluated	$121,000
Stryker Berchtold LED F628 Last updated 3/2016	★★★☆☆	Worldwide	Fair	Good	Excellent	Not evaluated	Not evaluated	Not evaluated	Good	Not evaluated	$120,000
Stryker Visum LED II Last updated 3/2016	★★★☆☆	Worldwide	Good	Good	Good	Not evaluated	Not evaluated	Not evaluated	Good	Not evaluated	$110,000
Trilux Aurinio Wave FT Last updated 9/2019	★★★★☆	Africa, Europe, Middle East, and other countries such as Brazil, Indonesia, Israel, and Thailand (not available in U.S.)	Good	Good	Excellent	Not evaluated	Not evaluated	Not evaluated	Good	Not evaluated	$99,000 Calculation based on prices for Germany
Trumpf Medical iLED 7 Last updated 2/2019	★★★★★	Worldwide	Excellent	Good	Excellent	Not evaluated	Not evaluated	Not evaluated	Good	Not evaluated	$71,000
Trumpf Medical TruLight 5520 Last updated 2/2019	★★★★☆	Worldwide	Good	Good	Excellent	Not evaluated	Not evaluated	Not evaluated	Good	Not evaluated	$70,000

TRUMPF MEDICAL TRULIGHT 5520

Summary of Findings

The Trumpf Medical TruLight 5520 is a major LED surgical light that is very good choice for most facilities. It has several performance- and workflow-enhancing features for providing bright and reliable illumination in the operating room (OR) setting.



The TruLight 5520. (Image courtesy of Trumpf Medical.)

Device Details

- Name: TruLight 5520
- Date evaluated: March 2016
- Manufacturer: Trumpf Medical Systems Inc. [441254]
- Healthcare Product Comparison System (HPCS) comparison chart: Lights, Surgical
  (HPCS is available to members of Health Devices Gold and SELECTplus.)

Device Description

1. The Trumpf Medical TruLight 5520 is used to provide high-quality, consistent, and shadow-free illumination for surgical teams to see into deep cavities in a patient's body.

2. An optional high-definition (HD) video camera may be mounted in the central light handle that provides controllable views of the surgical site, which may be transmitted to video monitors around the OR; not all TruLight 5520 light heads are camera-ready.

3. Major components and features:

a) Ninety LEDs (two separate light hemispheres, separated by a gap where the central handle is attached), intended to redundantly overlap beams of light as a means of shadow dilution.

b) Maximum light illuminance intensity: approximately 160,000 lux, as measured by ECRI.

(1) Six intensity settings from 50% to 100% illuminance

(2) Plus a dim "endo" mode for procedures requiring low light.

c) High color rendering index (CRI) value of 93.

d) Four values of color temperature (3,500 kelvins [K], 4,000 K, 4,500 K, 5,000 K) for different specialties or surgeon preference.

e) Claimed LED life of 40,000 hr.

f) Large light head diameter of 27 in (68.6 cm), with LEDs spanning approximately 22 in (55.9 cm).

(1) Trumpf Medical markets other series of TruLight surgical lights, listed below, each with different performance characteristics. ECRI did not evaluate the performance of these light heads.

(2) TruLight 3000 series with maximum illuminance of 160,000 lux and light head diameter of 27 in (68.6 cm); this major surgical light does not have the additional features of the TruLight 5520.

(3) TruLight 1000 exam light series with maximum illuminance of 80,000 lux and light head diameter of 12 in (30.5 cm).

g) Depth of field of 37 in (94.0 cm).

h) Two user-adjustable field sizes: approximate diameters of 7 and 10 in (17.8 and 25.4 cm) as measured by ECRI.

i) Optional adaptive lighting control (ALC Plus) feature that automatically maintains field size based on the light head's distance from the surgical site from 0.8 to 1.2 m.

j) Mounts are available for various ceiling heights from approximately 8.5 to 11 ft (2.6 to 3.4 m) and can allow up to four arms off a central spindle that can be outfitted with devices such as surgical lights and video monitors; as of 2016, Trumpf Medical cannot add more arms to an existing installation. The mounting system is compatible with third-party end effectors such as x-ray shields and HD video cameras.

k) Configurable central sterile handle, interchangeable with an HD video camera on any camera-ready light head, or sterilizable handle accessory. All handles are also interchangeable with Trumpf Medical iLED 7 handle options.

l) Controls

(1) Power, pattern size, and illumination intensity controls on the light head.

(2) Wall-mounted push-button panel to control power, field size, manual or auto distancing, color temperature, and illumination intensity on an individual light. Each light has its own wall panel.

m) An opening between the light hemispheres to increase local airflow and discourage any accumulation of surgical smoke above the surgical field.

Significant Findings

Performance—Good

Minor Advantages

1. Reliable illumination at different working distances:

a) The TruLight 5520 will automatically adjust the power distribution of its LEDs when it senses a change in distance from the surgical field—this results in the light head outputting 81% of its maximum illuminance with the light head 1.2 m from the sensor. This distance may more closely mimic the working distance in a surgery, when compared to the 1 m required by International Electrotechnical Commission (IEC) standard IEC 60601-2-41:2009.

b) Note: Trumpf Medical claims that with appropriate calibration, the TruLight 5520 light head is capable of reaching 100% maximum illumination at a distance of 1.2 m from the

sensor.

c) The IEC light standard requires that surgical lights function at a working distance of 1 m, but this may not always be a practical working distance for some clinical specialties or taller surgeons. A light head that automatically adjusts output based on changing working distances without sacrificing too much intensity allows for comparable illumination without need for manual adjustment in these circumstances.

2. Adjustable color temperature:

a) The TruLight 5520 offers four different color temperatures that visibly output a warm to cool range of light, while delivering 95% to 97% of maximum illuminance.

b) Some surgeons may prefer adjustable color temperature based on experience or specialty.

(1) Experience—as an example, surgeons more used to operating with a halogen light may prefer a warmer, yellower light temperature.

(2) Specialty—as an example, orthopedic surgeons may prefer cooler, bluer light temperatures while cardiac surgeons may prefer warmer, yellower light temperatures.

The option to change color temperature while still outputting maximum illuminance offers a facility more diversity.

Safety—Good

LED surgical lights radiate very little heat compared to halogen lamps and are not likely to burn patient tissue; the risk of multiple light heads generating too much heat at the surgical site should be outlined in a light's instructions for use (IFU) where applicable. Also, currently, light head manufacturers are streamlining their light heads in order to reduce the risk of infection by maintaining laminar flow and minimizing any turbulent airflow that might deposit debris in the surgical field. However, the clinical evidence on how laminar flow relates to surgical infections is inconclusive.

Workflow—Excellent

Major Advantage

Infinite rotation about the light head:

1. The TruLight 5520 has no rotational stops about the light head.
2. A range of motion with no stops means surgical teams never have to unwind and reorient the light if it hits a rotational stop, saving procedural time as well as not risking damage to internal wires should the light head be forced beyond a stop.

Minor Advantages

1. Easy field size adjustment:

a) In our subjective testing, we found it easy to adjust the field size of the light head with small and large patterns selectable on the push-button control panel, from approximately 7 to 9.6 in (17.7 to 24.2 cm). Further, the light will automatically adjust to this field size up to 1.2 m away from the surgical site, if the standard "auto-distance" feature is engaged.

b) Smooth and intuitive controls allow for improved workflow in the OR. An adjustable focus or field size allows the surgical team more control over the illuminated area on the surgical field. Also, automatic focusing enables control over spot size without having to mechanically adjust anything at the sterile handle.

2. Sterile field light adjustments:

a) The hub of the sterile handle on the TruLight 5520 features a capacitive touch sensor that allows the operator control over light intensity from the sterile field. Note: This feature requires the use of a proprietary disposable handle cover.

b) Some clinicians may prefer to adjust the surgical light to their desired intensity without having to wait for adjustment from outside the sterile field (e.g., the circulating nurse adjusting the intensity from the wall-mounted controls).

3. Availability of ambient light:

a) The lowest intensity setting on the TruLight 5520 offers approximately 17% of maximum illuminance, providing low light to the OR. Soft ambient light is thought to lessen the glare off screens in the room for other clinicians, while still providing enough light to work.

b) Some clinicians may prefer a surgical light system that provides ambient light for procedures requiring low light, such as laparoscopic procedures. This adds more versatility to the applications and performance of the light head.

Patient Experience—Not Evaluated

LED surgical lights do not directly impact the patient experience.

Interoperability—Not Evaluated

Aside from often being mounted off the same structure as other devices in the OR, LED surgical lights do not typically interact with other technologies.

Cybersecurity—Not Evaluated

LED surgical lights are not networked devices and do not impact patient or hospital security.

Maintenance—Good

The Trumpf Medical TruLight 5520 meets all our required maintenance criteria.

User Experience—Not Evaluated

Cost of Ownership—Estimated $70,000 over 10 years

See the table for details.

Estimating Cost of Ownership for the Trumpf Medical TruLight 5520* Pricing quotes provided by Trumpf Medical unless indicated otherwise.		
Factor	**Typical Cost**	**Assumptions**
Purchase Costs		
Capital cost	$33,000 (with ALC Plus)	Average sell price (ASP) of 2 TruLight light heads—one camera-ready—plus camera preparation and a flat-panel arm. ASP without ALC Plus is $28,000.
Typical accessories	$20,000	ASP: Camera system: $13,500 Wall control: $1,700 HD monitor (from ECRI's SELECTplus database): $5,000
Warranty	$0	Typical warranty is included in capital cost and covers 1 year on parts and labor, 5 years on LEDs.
Clinical staff training	$0	Free user training before or during product opening.
Biomedical staff training	$2,000	Training available if biomeds would like to do in-servicing themselves. Cost is per person.
Infrastructure modifications	$2,300	ASP: Mounting kit, triple arm installation.
Total purchase cost	$57,000	—
Annual Operational Costs		
Consumables	$800/yr	Consumables for surgical lights are minimal—2 disposable surgical handle covers are required per surgery at approximately $0.53 each (from ECRI's PricePaid database). Cost assumes 750 procedures per OR per year. A variety of third-party disposable handle covers are available through Aspen Surgical.
Expected part replacement—averaged throughout life of device	$0	Parts are expected to last the lifetime of the light.
Service	$500/yr	Pricing dependent on configuration. Service costs were unavailable for Trumpf Medical light heads, so we estimated service cost based on average annual service values for surgical lights.
Annual license fee	$0	No associated software fees.
Average annual operational cost	$1,300	—
Estimated Cost of Ownership (for an estimated life of at least 10 years)**	**$70,000**	Total purchase cost + (annual operational cost × estimated life)

* Surgical lights are rarely purchased on their own—they are typically purchased in a configuration with multiple surgical lights and other devices mounted in an OR, such as video monitors. In an attempt to standardize the total cost of ownership, ECRI requested that each manufacturer provide a quote for two camera-ready surgical lights, one camera, and one flat-panel arm to hold an HD video monitor, plus any associated service, training, and installation costs. Since the cost of HD video monitors varied so greatly among the manufacturers, and all flat-panel arms may mount third-party monitors, an average monitor cost was calculated from the SELECTplus database and included as a standard monitor cost. Thus, rather than providing a precise representation of total cost of ownership of surgical lights, this table may be more useful as a means of comparing the offerings of the evaluated manufacturers and lights.

** Trumpf Medical estimates that a surgical light should last 10 years. Further, the LEDs are intended to last the life cycle of the device without replacement.

Discussion of Key Manufacturer Claims		
Trumpf Medical Claim	**Category**	**ECRI Perspective**
Adaptive Light Control Plus (ALC Plus) ensures optimum lighting	Performance	**ECRI agrees, and the benefit is significant.**

of the surgical site. If the TruLight is moved during surgery, the integrated motion detector automatically measures the distance to the wound area and accurately adjusts the lighting so the surgeon can concentrate completely on the patient.		Our results indicate that the TruLight 5520 can offer approximately 80% of maximum illuminance at small light field sizes from a distance of 1 to 1.2 m from the sensor. We did not test a distance less than 1 m. Note that Trumpf Medical data specifications indicate that the TruLight 5520 is capable of outputting 100% maximum illuminance at 1.2 m from the light sensor.
Sterile Light Control (SLC) concept for adjusting light intensity. The integration of capacitive sensors on the sterile handle of the light head means that the surgeon can quickly and intuitively control the lighting during surgery.	Workflow	**ECRI agrees, and the benefit is significant.** Both the sterile handle controls and wall controls are intuitive to use and would not likely interrupt OR workflow.
Ease of use and simplified positioning: TruLight has nonsterile outer handles with integrated LEDs for improved visibility in endo mode. In addition, there is a control panel integrated into the outside of the light head to provide nonsterile control at the light head. Its efficient equipment and compact design make TruLight a lightweight surgical lighting system; it is easy to position and readily adapts to the requirements of the surgery being performed.	Workflow	**ECRI agrees, and the benefit is significant.** ECRI confirmed that the nonsterile grips on the perimeter of the light will glow blue in endo mode. The light head itself is easily adjusted with one hand via the central sterile handle, or from the nonsterile grips. Providing nonsterile controls may allow more versatility and access in the OR, if a wall panel is not used.
Sophisticated communication: The TruLight surgical lighting portfolio offers the integration of high-quality camera solutions with digital SD to True HD and HD-quality communication via LAN networks and the Internet. With a choice of integration in the light head or on a separate arm, the cameras can be quickly and easily installed and/or removed, depending on the application. This design is an ideal platform for research, teaching, and documentation purposes.	Maintenance and Cost of Ownership	**ECRI agrees, and the benefit is significant.** The TruLight 5520 light head is camera-ready and can be upgraded by switching the central handle. Further, TruLight 5520 sterile handles (including camera module) are interchangeable with iLED 7 handles for improved workflow between ORs, should a facility house more than one surgical light product line from the same vendor.
Extremely flat design for superior hygiene: The sophisticated heat management system ensures efficient and even heat dissipation within the light head. It prevents hot spots and makes a significant contribution to the longevity and efficiency of the LEDs by reducing heat levels. In addition, thanks to the low levels of heat generation, the airflow-optimized housing is ideal for clean room ceilings (laminar airflow). The open and compact design reduces the flow surface beneath the air-handling ceiling. At the same time, the cool light head minimizes uplift effects and turbulence.	Workflow and Maintenance	**Unknown.** ECRI did not evaluate heat generation and efficiency, as LEDs are inherently much more efficient than halogen lights. The opening between the light hemispheres may allow for surgical smoke to disperse from the field more readily than with a solid light.

Recalls and Hazards

The following data is based on *Health Devices Alerts* records from 2010 through 2016.

Link to HDA Record	Priority	Date of Last Update	Category
A24720 01: TRUMPF—Various Medical Lighting, Camera, and Monitor Systems: Welds Require Biannual Inspection	High	March 1, 2016	Installation
A25607: TRUMPF—iLED and TruLight Ceiling Mounted Surgical Light Systems: Spring Arm and Light Head May Fall if Improperly Installed or Serviced*	High	February 5, 2016	Installation
H0207: Rubber Central Axis Cable Cover on Trumpf Ceiling-Mounted System with Monitor Bracket May Fall into the Sterile Field	Normal	May 30, 2013	Installation
A17215: Trumpf—iLED and TruLight Surgical	High	June 20, 2012	Installation

Lighting Systems: ALC + Automatic Focusing Function Handle May Fall Off			

* Note that alert A25607 is an urgent recall that was active as of the date we published this Evaluation (3/9/2016).

Service and Maintenance

The following information is provided largely verbatim from the manufacturer.

Warranty

Standard warranty terms: 1 year parts and labor, 5 years on LED elements.

Inspection and Preventive Maintenance (IPM)

1. IPM frequency: Annual visual inspection with preventive maintenance every 2 years.
2. Downtime for IPM: 2 hours

In-House/Third-Party Service

1. Manufacturer supports user repair: Yes, if trained by Trumpf Medical.
2. Training required and cost: User training conducted by Trumpf Medical Sales Consultants prior to opening and/or during opening is free. Detailed product training can be conducted at factory only (Charleston, SC) with pricing starting at $2,000 per person.
3. Availability of service manual: Yes.
4. Dedicated test equipment and/or software required: Yes.
5. Availability of manufacturer assistance: Yes.

OEM Maintenance

1. Standard OEM service options
    a) Name of the option:
        (1) SmartCare Prevention Service
        (2) SmartCare Response Service
        (3) SmartCare Complete and Complete+ Service
    b) Description of coverage:
        (1) Prevention Service: Preventive maintenance program providing compliance documentation for all regulatory agencies.
        (2) Response Service: Repair-only program; inclusive of parts and labor.
        (3) Complete and Complete+ Service: Full service programs, inclusive of preventive maintenance, repairs, parts and labor. With Complete+, the offering is enhanced to include 24/7 service and on-site arrival within 4 hours.
    c) Hours of coverage: 24 hours
    d) Response time: 4 hours
    e) Uptime guarantee and standard penalty: N/A
2. Remote monitoring: N/A, no remote monitoring service for lights.
3. Software upgrade and update policy
    a) Update:
        (1) Software updates which maintain existing capabilities and enable the product(s) to perform in accordance with the specifications
        (2) Any software necessary to standardize Product(s) for service maintenance
    b) Upgrade: Trumpf Medical will make available for purchase any software upgrades which allow the Product to exceed performance specifications.

Other Purchase Options

Buy, lease, or rent are available options depending on the situation. Consumables are available through Aspen Surgical.

RELATED RESOURCES

LED Surgical Lights: The Essentials

Evaluation Background: Major LED Surgical Lights

Evaluation: Amico iCE-30m Major LED Surgical Light

Evaluation: Draeger Polaris 600 Major LED Surgical Light

Evaluation: Getinge Maquet PowerLED II 500 Major Surgical Light

Evaluation: Getinge Maquet PowerLED II 700 Major Surgical Light

Evaluation: Maquet Volista 600 Major LED Surgical Light

Evaluation: Mindray HyLED X9 Major LED Surgical Light

Evaluation: Rimsa Unica 860 Major LED Surgical Light

Evaluation: Skytron Aurora Four Major LED Surgical Light

Evaluation: Steris HarmonyAIR M5 Major LED Surgical Light

Evaluation: Stryker Berchtold LED F628 Major LED Surgical Light

Evaluation: Stryker Visum LED II Major LED Surgical Light

Evaluation: Trilux Aurinio Wave FT Major LED Surgical Light

Evaluation: Trumpf Medical iLED 7 Major LED Surgical Light

TOPICS AND METADATA

Topics

Biomedical Engineering
Equipment and Facility Planning
Technology Selection

Caresetting

Ambulatory Surgery Center
Hospital Inpatient
Hospital Outpatient

Clinical Specialty

Cardiovascular Medicine
Cardiothoracic Surgery
Maternal and Fetal Medicine
Nursing
Orthopedics
Surgery

Roles

Allied Health Personnel
Biomedical/Clinical Engineer
Clinical Practitioner
Materials Manager/Procurement Manager
Nurse

Information Type

Product Evaluation

UMDNS

Lights, Surgical [12-282]

CITATION

ECRI. Evaluation: Trumpf Medical TruLight 5520 major LED surgical light. *Health Devices* 2016 Mar 9.