Evaluations & Guidance - Product Evaluation

Evaluation: Trumpf Medical iLED 7 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—Excellent. The Trumpf Medical iLED 7 provides superior shadow dilution. It also offers reliable illumination and pattern size at varying working distances without manual adjustments, as well as adjustable color temperature.

Safety—Good. The Trumpf Medical iLED 7 meets all our required safety criteria.

Workflow—Excellent. The Trumpf Medical iLED 7 offers infinite rotation about the light head, without stops, as well as easy-to-use of controls for adjusting field size.

Patient Experience—Not evaluated

Interoperability—Not evaluated

Cybersecurity—Not evaluated

Maintenance—Good. The Trumpf Medical iLED 7 meets all our required maintenance criteria.

User Experience—Not evaluated

Cost of Ownership—Estimated $71,000 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 iLED 7 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 Last updated 10/2019	★★★★☆	Worldwide	Good	Good	Excellent	Not evaluated	Not evaluated	Not evaluated	Good	Not evaluated	$73,000
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 ILED 7

Summary of Findings

The Trumpf Medical iLED 7 is a major LED surgical light that is an excellent choice for most facilities. It has superior shadow dilution and numerous other performance- and workflow-enhancing features for providing bright and reliable illumination in the OR.

The iLED 7. (Image courtesy of Trumpf Medical.)

Device Details

- Name: iLED 7
- 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 iLED 7 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 wireless high-definition (HD) video camera may be mounted in the central light handle that provides controllable views of the surgical site that may be transmitted to video monitors around the OR; all iLED 7 light heads are camera-ready.

3. Major components and features:

   a) Seventy-two LEDs (six zones of 9 LEDs, plus a central ring of 18 LEDs), 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) Four intensity settings from 30% to 100% illuminance, plus a dim "endo" mode for procedures requiring low light.

      (2) SmartAssist technology that will detect obstructions between the light head and the surgical site, such as a surgeon's head, and redistribute power from up to two zones of LEDs to other zones of the light so as not to lose intensity.

   c) High color rendering index (CRI) value of 97.

   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 60,000 hours.

   f) Large light head diameter of 28 in (71.1 cm), with LEDs spanning approximately 23 in (58.4 cm). The iLED 7 light head is not available in other sizes.

   g) Depth of field of 76 in (193.0 cm). This is the largest depth of field claimed by any of the manufacturers.

   h) User-adjustable field size, from approximate diameters of 6.7 to 10 in (17.0 to 25.4 cm) as measured by ECRI.

   i) Standard automatic focusing to the selected pattern size based on distance from the surgical site from 0.8 to 1.3 m away.

   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 light head, or sterilizable handle accessory. All sterile handles are also interchangeable with Trumpf Medical TruLight handle options.

   l) Controls

      (1) Intensity and pattern size controls at central sterile handle.

      (2) Wireless wall-mounted touchscreen to control power, field size, color temperature, and illumination intensity on a series of individual lights. Also available as a tablet.

   m) An opening beyond the central handle in the middle of the light to increase local airflow and discourage any accumulation of surgical smoke above the surgical field.

Significant Findings

Performance—Excellent

Major Advantage

Superior shadow dilution:

1. With a mask obstructing the surgical site to simulate a clinician's head, the iLED 7 still delivers 95% of its maximum illuminance. With a mask and a tube over the light sensor to simulate the bottom of a deep patient cavity, the light head delivers 86% of its maximum illuminance.

2. With two masks obstructing the surgical site to simulate two clinicians' heads, the iLED 7 still delivers 67% of its maximum illuminance. With two masks and a tube over the light sensor to simulate the bottom of a deep patient cavity, the light head delivers 63% of its maximum illuminance.

3. The iLED 7 automatically detects an obstruction in the field and will shut off power to up to two zones of LEDs, providing a boost in illumination to the remaining zones in order to offset the effect of the obstruction. This is a standard feature on all iLED 7 light heads.

4. Providing nearly the maximum light output even when obstructed is a beneficial feature—the higher the remaining illuminance when obstructed, without requiring the surgical team to take action to increase illuminance, the better the light quality.

Minor Advantages

1. Reliable illumination at different working distances without manual adjustments:

    a) The iLED 7 will automatically adjust the position of the LED zones when it senses a change in distance from the surgical field. This results in the light head outputting 100% of its maximum illuminance with the light head 0.8 to 1.3 m from the sensor. (Note that ECRI only tested distances of 1.0 to 1.3 m.) These distances 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) The iLED 7 can provide this output at all three pattern sizes: small, medium, and large; note that ECRI only tested small and large pattern sizes.

    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 intensity allows for comparable illumination without need for manual adjustment in these circumstances.

2. Adjustable color temperature:

    a) The iLED 7 offers four different color temperatures that visibly output a warm to cool range of light, while delivering 95% to 100% 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 iLED 7 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, medium, and large patterns selectable on the wall panel, from approximately 6.7 to 10.4 in (17.0 to 26.3 cm). Further, the light will automatically focus to this pattern size up to 1.3 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 iLED 7 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).

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 iLED 7 meets all our required maintenance criteria.

User Experience—Not Evaluated

Cost of Ownership—Estimated $71,000 over 10 years

See the table for details.

Estimating Cost of Ownership for the Trumpf Medical iLED 7* Pricing quotes provided by Trumpf Medical unless indicated otherwise.		
Factor	**Typical Cost**	**Assumptions**
Purchase Costs		
Capital cost	$31,000	Average sell price (ASP) for 2 iLED 7 light heads plus camera preparation and a flat-panel arm.
Typical accessories	$23,000	ASP: Wireless camera system including wall receiver: $15,200. Wireless wall control: $2,700. 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	$58,000	—
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)**	**$71,000**	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**
SmartAssist: Light without hard shadows.	Performance	**ECRI agrees, and the benefit is significant.**

Even when working directly under the surgical lights, the iLED 7 Surgical Light's sensor-controlled system ensures a consistent illuminated field via the LED module's intelligent control. This allows surgeons to concentrate on their work, while the light focuses on the surgical site.		Our results indicate that the iLED 7 can offer superior shadow dilution when obstructed and will shift power from up to two zones of LEDs to unobstructed areas.
SmartPattern: A consistent light field. Trumpf Medical's SmartPattern function ensures a consistent light field size for all three field size options at standard working distances of 0.8 to 1.3 m (32 to 51 in).	Workflow	**Unknown.** During our testing, there was not a noticeable change in field size at different working distances, but we did not actually measure the field size at multiple working distances.
SmartControl: Intuitive use. Key functions can be controlled directly on the light head or using Sterile Light Control (SLC). The mobile tablet or wall control panel, both with an intuitive user interface, offer a full scope of operation.	Workflow	**ECRI agrees, and the benefit is significant.** Both the sterile handle controls and wall/tablet controls are intuitive to use; control over all features is available with the wall/tablet controls.
SmartIllumination: Consistent light intensity. The light quality and brightness of the iLED 7 Surgical Light remain the same at different working distances, color temperatures, and light field sizes without the need to be readjusted.	Performance and Workflow	**ECRI agrees, and the benefit is significant.** Our results indicate that the iLED 7 can offer maximum illuminance at small and large light field sizes from a distance of 1.0 to 1.3 m from the sensor. We did not test a distance less than 1 m.
SmartModularity: Flexibility for the future. Each light is prepped for use with the TruVidia Wireless Camera technology and can be equipped with sterile disposable and nondisposable handles, making it easier to retrofit later on.	Maintenance and Cost of Ownership	**ECRI agrees, and the benefit is significant.** All iLED 7 light heads are camera-ready and can be upgraded by switching the central handle; the TruVidia camera module is wireless. 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.
SmartDesign: Simple and aerodynamic. The opening in the middle of the light, as well as its flexible shapes, smooth surfaces, and compact size contribute to improved airflow over the surgical site.	Workflow and Maintenance	**Unknown.** Smooth surfaces would logically make for easier cleaning, with limited crevices on the warm top surface of the light providing less space for bacteria. Further, the light opening may allow for surgical smoke to disperse from the field more readily than with a solid light.

Recalls and Hazards

No recalls or hazard reports are listed in ECRI's *Health Devices Alerts* database for the Trumpf Medical iLED 7. This is expected, as Trumpf Medical did not begin marketing this light in the United States until early 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: Mindray HyLED X9 Major LED Surgical Light

Evaluation: Maquet Volista 600 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 TruLight 5520 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 iLED 7 major LED surgical light. *Health Devices* 2016 Mar 9.