Evaluations & Guidance - Product Evaluation

Evaluation: Trumpf Medical TruSystem 7000 Mobile Operating Room Table

Published   12/7/2018

EXECUTIVE SUMMARY

Rating

★★★★☆

Findings

The Trumpf Medical TruSystem 7000 is a mobile OR table intended for use during general surgery and bariatric procedures, and, with accessories, orthopedic procedures and imaging. Overall, the table is a very good choice for facilities looking for a mobile OR table for general surgery.

Our rating is based on the following findings:

Performance—Excellent. The specified weight capacity is 454 kg (1,000 lb) for all tabletop positions. The table includes features for programming user- and facility-specific settings. The system is capable of synchronous motion—that is, multiple sections can move simultaneously to expedite movement into complex positions, including flex and reverse flex. The table has a maximum height of 114 cm (45 in).

Safety—Good. The table includes overload protection using sensors to detect potentially unsafe positioning, and will advise the user on positioning adjustments that will resolve the situation. The table has a collision detection feature that stops movement of components if they are in danger of colliding with the floor, base, column, or other components of the table.

Workflow—Good. The table uses a hydraulically driven system to assist with directional travel and turning the table. Referred to as the running gear, the system includes four freely swiveling casters and a fifth caster located in the center of the table. The hand control includes a key to activate Running Gear Assistance, also called Wheel Assist, which automatically lowers the fifth caster to facilitate movement and turning on the spot.

Patient Experience—Not evaluated

Interoperability—Good

Cybersecurity—Not evaluated

Maintenance—Good

User Experience—Good

Cost of Ownership—Good

COMPARE RATINGS
FOR ALL DEVICES

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COMPARATIVE RATINGS—ALL DEVICES

Here's how the Trumpf Medical TruSystem 7000 compares with the other products we've evaluated.

Ratings: Operating Room Tables

Click the product names below to view our complete findings. Products are listed alphabetically by supplier.

Model	Date Last Updated	Rating	Performance	Safety	Workflow	Patient Experience	Interoperability	Cybersecurity	Maintenance	User Experience	Cost of Ownership
Getinge Maquet Meera	12/2018	★★★☆☆	Good	Good	Good	Not evaluated	Excellent	Not evaluated	Good	Good	Good
Steris 4085	1/2019	★★★☆☆	Excellent	Good	Good	Not evaluated	Good	Not evaluated	Good	Good	Good
Steris 5085	1/2019	★★★☆☆	Excellent	Good	Good	Not evaluated	Good	Not evaluated	Good	Good	Good
Stryker Operon D860	12/2018	★★★☆☆	Excellent	Good	Fair	Not evaluated	Good	Not evaluated	Good	Good	Good
Trumpf TruSystem 7000	12/2018	★★★★☆	Excellent	Good	Good	Not evaluated	Good	Not evaluated	Good	Good	Good
Trumpf TruSystem 7000 dV	12/2018	★★★★☆	Excellent	Good	Good	Not evaluated	Good	Not evaluated	Good	Good	Fair

TRUMPF MEDICAL TRUSYSTEM 7000

Summary of Findings

The TruSystem 7000 is a very good choice for a mobile OR table for surgical applications. Our findings are based on in-house lab testing, clinical literature review, and user feedback.

Figure 1. *The TruSystem 7000. (Image courtesy of Trumpf Medical Systems.)*

Device Details

- Name: TruSystem 7000 Mobile Operating Room Table
- Date evaluated: December 2018
- Manufacturer: Trumpf Medical Systems Inc. [441254]
- Healthcare Product Comparison System (HPCS) comparison chart: <u>Tables, Operating; Orthopedic</u> (HPCS is available to members of Health Devices Gold

and SELECTplus.)

- Software version evaluated: 5.2.5.2

Device Description

1. The Trumpf Medical TruSystem 7000 is a mobile OR table intended for general surgery. Key manufacturer-reported specifications are listed in the table below.

2. The TruSystem 7000 may be used for intraoperative imaging. It includes a 35.6 cm (14 in) imaging window, continuous x-ray cassette channel, and optional upper-body and lower-body carbon-fiber tabletops.

3. Major hardware components include the following:

a) Tabletop: The 200.1 × 54 cm (79 × 21.25 in) modular tabletop includes a head section, back section, center section, and leg section. Additional sections are available as options.

b) Column: A stainless steel, height-adjustable column connects the tabletop to the base. It includes a column-mounted backup control panel, which has keys for adjusting height, slide, Trendelenburg, tilt, leg up/down, back up/down, level, and patient orientation. Mobility controls include wheel lock, wheel unlock, and Wheel Assist—a feature used for table relocation. The panel also includes indicator lights for AC power, battery power, and pendant malfunction. At the head end of the running gear is a button for mechanical release of the floor locks in the case of an emergency.

c) Base: A stainless steel base with 360° rotatable casters and floor locking capabilities. Floor locks are self-compensating (i.e., they level the table when locked). The base also houses an electromechanical system to drive all motion of the table, and an internal rechargeable battery with a specified operating time of 16 hours.

d) Running gear: A hydraulically driven system located in the base of the table consisting of four freely swiveling casters and a fifth caster located in the center of the table for use during Wheel Assist to support movement and turning on the spot.

e) Pads: Double-layer viscoelastic pads with Velcro fasteners to attach to each section of the tabletop.

f) Rails: Attached to the tabletop to secure the patient and for accessory attachment.

g) Hand control: A handheld remote control to operate the table, including the following:

(1) Tabletop adjustments, including height, longitudinal slide, Trendelenburg/reverse Trendelenburg, tilt, back-section angulation, leg-section angulation, flex and reverse flex positioning, and return-to-level

(2) System controls, including floor locks, Wheel Assist, and power control.

(3) A touchscreen to view and adjust table positions and system settings, execute programmable table adjustments, and view guidance and warning messages for safe operation.

Figure 2. *The hand control and backup control. (Images courtesy of Trumpf Medical Systems.)*

4. Typical location where the device is used: OR

5. Optional device components and software features:

a) Carbon-fiber tabletops for upper- and lower-body imaging

b) Modules for specialized positioning, including: double-jointed head section; widening segments for the center, back, and leg sections; two-part and four-part leg sections; pelvic extension; neurologic headrest; and orthopedic extensions

Key Specifications: Trumpf Medical TruSystem 7000	
Actuator system	Electromechanical
Weight capacity, level	454 kg (1,000 lb)
Weight capacity, fully articulated	454 kg (1,000 lb) in both normal and reverse orientations
Height	58.4 to 114.3 cm (23 to 45 in)
Trendelenburg/reverse Trendelenburg	45°/45°
Longitudinal shift (slide)	45.7 cm (18 in)
Lateral tilt	30° left/30° right
Tabletop rotation	Feature is not available
Back section	90° up/-45° down
Leg section	90° up/-105° down
Head section	45° up/90° down
Flex	Level to 15° back up and 15° leg up
Reverse flex	Level to -30° back down and -18° leg down
Kidney elevator height	Feature is not available

Significant Findings

We performed a variety of tests on this product, including physical testing, a review of product literature/specifications, and asking users about their experience with the device. For more details, see the ECRI Institute's Testing section of our Evaluation Background on this technology.

Performance—Excellent

Major Advantages

1. Weight capacity:

a) The specified weight capacity is 454 kg (1,000 lb) for all tabletop positions.

b) Sufficient weight capacity is required for correct functioning of controls and to prevent tipping or other instability issues.

2. Automated functions:

a) The table includes features for programming facility- and user-specific settings. Facility configuration settings include the option to activate a pause when the table passes through level on the way to a different position; the option to activate intermittent pauses during adjustments in tilt, Trendelenburg, and slide; and setting of the signal tone volume. User-programmable capabilities include the option to create up to 30 customized positions, which can then be saved into preset categories (e.g., Main, General/Visceral, Ortho, Trauma, Gyn/Uro, Neuro).

b) Automated features can facilitate configuring the table into the optimum position for surgery.

3. Synchronous movement:

a) The system is capable of moving more than one section at a time. While users cannot activate two motions at the same time, the table will move multiple sections simultaneously during return-to-level and when moving into preprogrammed positions, including flex, reverse flex, and beach chair.

b) Synchronous movement can expedite table positioning.

4. Maximum height:

a) The table can reach a maximum height of 114 cm (45 in).

b) Height adjustment improves comfort for the surgeon and surgical staff during procedures.

Minor Advantages

1. Trendelenburg range of adjustment:

    a) The table can be positioned at 45° Trendelenburg and -45° reverse Trendelenburg.

    b) Extreme Trendelenburg positioning may be advantageous for certain procedures.

2. Unobstructed access at maximum slide:

    a) When adjusted to maximum forward slide, the table provides 80 cm (31.5 in) of unobstructed access at the patient's head. When adjusted to maximum reverse slide, the table provides 59.1 cm (23.25 in) of unobstructed access at the patient's foot.

    b) Ample clearance from the tabletop to the floor facilitates positioning the patient for intraoperative imaging.

3. Lateral tilt:

    a) The table is capable of a lateral tilt of 30° to the patient's right, and 30° to the patient's left.

    b) Lateral tilt may improve the surgeon's ability to optimize patient position for certain procedures.

4. Flex and reverse flex positioning:

    a) The table can be positioned into both flex and reverse flex positions.

    b) Flex and reverse flex positions may be advantageous for certain procedures.

5. Advanced positioning capabilities:

    a) The table includes Temporary Slow Traverse, a feature that, when activated, reduces the adjustment speed of all positioning to 25%, 50%, or 75% of the normal speed.

    b) This feature is helpful for precise positioning.

Minor Disadvantage

1. No kidney elevator:

    a) The table does not include a kidney elevator.

    b) Kidney elevators help position the patient for certain procedures, such as a nephrectomy.

Safety—Good

Major Advantages

1. Overload protection:

    a) There are four force sensors, one on each corner of the table, to detect potentially unsafe patient positioning. If an incorrect or unsafe configuration is detected, an audible tone sounds, and the key on the hand control for the recommended correction will blink.

    b) Incorrect loading of the table can cause it to tip over, potentially injuring patients and staff.

2. Anti-collision feature:

    a) The table includes a collision detection feature that will stop the movement of table components if they are in danger of colliding with the floor, running gear, or column. Collision detection is based on the known geometry of the table and any manufacturer-approved accessories when moved into various positions; the system cannot detect objects placed on the base or other accessories that may alter the geometry. Therefore, only manufacturer-approved accessories should be used, to ensure that the system is operating to its full potential. If a potential collision is detected, the system will emit a warning tone to indicate that the maximum adjustment range will soon be reached. If movement continues, the system will automatically stop any unsafe movements before a collision occurs.

    b) Anti-collision features protect patients and users from injury that may result from adjusting the table into an unsafe configuration.

Minor Advantage

1. Safety alerts:

    a) Visual indicators on the back-up control panel alert users to malfunctions in the system.

    b) Proactively warning users of predictable failures may prevent injuries to patients and staff.

Minor Disadvantage

1. Manual repositioning of the tabletop:

    a) Table positioning is accomplished electronically; there are no manual controls.

    b) The ability to manually reposition the tabletop may be necessary if a facility loses power for an extended period of time.

Workflow—Good

Major Advantage

1. Mobility:

    a) The table uses a hydraulically driven system to assist with steering and turning of the table. Referred to as the running gear, the system includes four freely swiveling casters and a fifth caster located in the center of the table. The hand control includes a key to activate Running Gear Assistance, also called Wheel Assist, which automatically lowers the fifth caster to facilitate movement and turning on the spot.

    b) Features to assist users with moving an OR table significantly enhance workflow and may reduce the incidence of back strains and other injuries to staff when moving the table.

Minor Advantage

1. Display of table position:

    a) The hand control includes a keypad and touchscreen display. Numeric values are provided for Trendelenburg/reverse Trendelenburg, tilt left/right, height, slide, back up/down, leg up/down, and flex up/down. The display is backlit and illuminates the available position adjustments.

    b) A comprehensive display of table position and operating status facilitates accurate and reproducible positioning.

Patient Experience—Not Evaluated

Patient experience is not a selection factor; patients are anesthetized.

Interoperability—Good

The technology has been evaluated against ECRI Institute's criteria for interoperability and found to meet all required criteria.

Cybersecurity—Not Evaluated

OR tables are not networked devices.

Maintenance—Good

Minor Advantage

1. Preventive maintenance interval:

    a) The first preventive maintenance is due in year two after purchase of the system. The second maintenance is due in year four. After year five, annual maintenance is required.

    b) A longer maintenance interval reduces workload for biomedical engineering staff.

User Experience—Good

The technology has been evaluated against ECRI Institute's criteria for user experience and found to meet all required criteria. As part of our testing, we asked clinicians who were new to the system to rate ease of use. The platform scored similarly to competing devices. We have included comments from these users below.

Notable Findings

Positive user feedback included the following:

1. Ease of operation:

    a) Users commented positively on the handheld remote control with touchscreen display. Overall, users reported that the comprehensive display is

helpful, and that the controls are easy to use.

b) Comprehensive positioning information can be helpful to precisely position patients. User controls that are straightforward facilitate user operation and avoid unnecessary treatment delays.

2. Programmable positioning:

a) Users found the ability to store a large number of custom positions helpful for creating both procedure-specific and surgeon-specific positioning.

b) Automated positioning can expedite patient setup.

3. Table pads:

a) Users commented that they perceived the table pads to be superior to those of comparable OR tables.

b) Table pads are important to protect patients from pressure injury.

Reported issues included the following:

1. Speed of adjustment:

a) Users commented that the table moves noticeably slower than comparable OR tables.

b) Slow table positioning may cause minor delays during a procedure.

Cost of Ownership—Good

Estimating Typical Cost of Ownership for the Trumpf Medical TruSystem 7000

The costs reported in this table represent typical quotation and purchase costs reported to ECRI Institute's SELECTplus and PriceGuide databases, respectively. These figures are provided as a guide only and may vary significantly.

Factor	Typical Cost	Assumptions
Purchase Costs		
Capital cost	$50,000	Based on average quoted price in ECRI Institute's SELECTplus database. Includes head section, leg section, arm board, foot support, side rail, transfer board, and table pads.
Typical accessories	$0	None.
Warranty	$0	One-year warranty included in price.
Clinical staff training	$0	Additional clinical training price varies, depending on customer requirements and time requested.
Biomedical staff training	$0	Optional certification program for hospital engineers and maintenance staff, focused on preventive maintenance and troubleshooting techniques: $4,000. Trumpf was not able to provide estimated replacement part costs and intervals; therefore, we have included full-service contract costs in our calculations (see Service, below).
Infrastructure modifications	$0	None.
Total purchase cost	**$50,000**	—
Annual Operational Costs		

Consumables	$0	None.
Expected part replacement—averaged throughout life of device	$0	Included in SmartCare Protection+ extended warranty. Trumpf was not able to provide estimated replacement part costs and intervals; therefore, we have included full-service contract costs in our calculations (see Service, below).
Service	$3,100/yr (years two to four), then $3,875/yr (years five to 15)	SmartCare Protection+ Package extended warranty includes 24-hour phone support, preventive maintenance, repairs, and parts. Yearly fee with three-year commitment begins in year two and covers years two to four. SmartCare Complete Service package includes repair, parts, and preventive maintenance. Yearly fee with three-year commitment begins in year five. We assume continuation of service for the life of the table.
Annual license fee	$0	None.
Average annual operational cost outside warranty	$3,100/yr (years two to four), then $3,900/yr (years five to 15)	—
Estimated Total Cost of Ownership (for an estimated life of 15 years)	$100,000	Total purchase cost + (annual operational cost × estimated life, excluding warranty period)

Discussion of Key Manufacturer Claims		
Trumpf Claim	Category	ECRI Institute Perspective
The synchronized leveling system safely and anatomically returns all articulated components to a single level for optimal patient comfort.	Performance	**ECRI Institute agrees; we consider this a significant benefit.** The table will move multiple sections simultaneously during return-to-level and preprogrammed positions, including flex, reverse flex, and beach chair. For more information, see the Performance section under Significant Findings, above.
Integrated collision avoidance with the floor and OR table for increased patient safety during surgery.	Safety	**ECRI Institute agrees; we consider this a significant benefit.** The table includes a collision detection feature that will stop the movement of table components if they are in danger of colliding with the floor, running gear, or column. For more information, see the Safety section under Significant Findings, above.
Intelligent sensor technology alerts the user when the table or patient is in a compromising position, reducing the risk of tipping or falling in extreme positions–ideal for bariatric patients weighing up to 1,000 lbs / 450 kg.	Safety	**ECRI Institute agrees; we consider this a significant benefit.** If an incorrect or unsafe configuration is detected, an audible tone sounds, and the key for the recommended correction will blink. For more information, see the Safety section under Significant Findings, above.

Table articulation feedback upon every adjustment for improved communication in the OR.	Workflow	**ECRI Institute agrees.** The system includes a comprehensive display of table position and operating status. For more information, see the Workflow section under Significant Findings, above.

Recalls and Hazards

No recalls or hazards are listed in ECRI Institute's _Health Devices Alerts_ database for the Trumpf TruSystem 7000 as of October 2018.

User Survey Results

Separately from our Evaluation testing, we surveyed users of OR tables to obtain their opinions on ease of use, performance, and reliability, along with the average number of annual repairs required and the inspection intervals they use. See our survey results: User Survey Results: Operating Room Tables.

Service and Maintenance

The following information is provided largely verbatim from the manufacturer.

Warranty

Standard warranty terms: One-year warranty

Inspection and Preventive Maintenance (IPM)

1. IPM frequency: Year 2, year 4, then annually

2. Downtime for IPM: Typical time frame is 90-120 minutes once table is accessible.

In-House/Third-Party Service

1. Manufacturer supports user repair: Yes, if the in-house or 3rd party repair service technician has received Trumpf Medical/Hill-Rom training.

2. Training required and typical cost: Technical Training Programs from Hill-Rom are product certification programs specifically designed for hospital engineers, biomedical and maintenance staff. These programs focus primarily on the performance of a preventive maintenance schedule and major troubleshooting techniques. For the TruSystem 7000 Surgical Table, Trumpf Medical/Hill-Rom offers a 1-day instructor-led course covering product functionality, theory of operation, hands-on, overview of service software and troubleshooting ($4,000).

3. Availability of service manual: Service manuals are available free of charge and provided to all Trumpf Medical/Hill-Rom service trainees.

4. Dedicated test equipment and/or software required: Some in-depth diagnostic tools are available for all Trumpf Medical/Hill-Rom service trainees. Software upgrades are to be performed by Trumpf Medical/Hill-Rom service technicians with dedicated software.

5. Availability of manufacturer assistance: Service assistance for in-house and/or 3rd party service teams is available 24 hours a day, 7 days a week, 365 days a year.

OEM Maintenance

1. Standard OEM service options

a) Name of the option: SmartCare Protection Service, SmartCare Protection+ Service, SmartCare Prevention Service, SmartCare Response Service, SmartCare Complete Service.

b) Description of coverage: Protection and Protection+ are only available at the point of sale. Protection covers repairs and parts. Protection+ includes repairs, parts, and preventive maintenance. Prevention, Response, and Complete are options available after the point of sale. Prevention is preventive maintenance only. Response is repairs and parts. Complete includes repairs/parts/preventive maintenance.

c) Hours of coverage: Phone call service is available 24/7/365 regardless of coverage type. On-site service hours vary depending on urgency and contractual obligations.

d) Response time: Guarantees vary depending on contractual obligations.

e) Uptime guarantee and standard penalty: Guarantees vary depending on contractual obligations, however the standard uptime is 48 hours. If this cannot be achieved, loaner options are explored.

2. Remote monitoring: None

3. Software upgrade and update policy: All software upgrade without discrimination of level criticality, are made by the Trumpf Medical/Hill-Rom service technicians, at no charge and throughout warranty and service coverage.

Other Purchase Options

Loaners and rental programs are available for the TruSystem 7000 Surgical Table.

RELATED RESOURCES

Operating Room Tables: The Essentials

Evaluation Background: Operating Room Tables

Evaluation: Getinge Maquet Meera Mobile Operating Room Table

Evaluation: Steris 4085 Mobile Operating Room Table

Evaluation: Steris 5085 Mobile Operating Room Table

Evaluation: Stryker Operon D860 Mobile Operating Room Table

Evaluation: Trumpf Medical TruSystem 7000dV Mobile Operating Room Table

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TOPICS AND METADATA

Topics

Bariatric Medicine
Equipment and Facility Planning
Biomedical Engineering
Robotics
Service and Maintenance
Technology Management
Technology Selection

Caresetting

Ambulatory Surgery Center
Emergency Department
Endoscopy Facility
Hospital Inpatient
Hospital Outpatient
Imaging Center
Trauma Center

Clinical Specialty

Anesthesiology
Bariatrics
Emergency Medicine
Cardiothoracic Surgery
Nursing
Orthopedics
Surgery
Transplantation

Roles

Biomedical/Clinical Engineer
Clinical Practitioner
Materials Manager/Procurement Manager
Nurse
Patient Safety Officer
Risk Manager

Information Type

Product Evaluation

UMDNS

Tables, Operating [13-961]

CITATION

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