

# Value Analysis Information Kit for ZEISS TIVATO 700



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### Why ZEISS?



#### **ZEISS Visualization Systems**

Continuing to support you in advancing surgical visualization

We understand your everyday challenges and expectations from a surgical microscope. These insights drive us in developing a surgical visualization system that supports you to push the boundaries of surgical care and bring your surgical experience to the next level.

**ZEISS Visualization Systems** elevate your complete surgical experience with:

- Legendary ZEISS optics that deliver brilliant, crystal clear resolution and bright illumination, fully integrated into a compact optical head.
- Superior ergonomics, maneuverability and workflow efficiency through its integration concepts.
- Second to none advancements in the fields of imaging technologies like intraoperative fluorescence and 3D visualization.

For the period 2017 to 2020, ZEISS' Net Promoter Score (NPS) on its microsurgical products is **81**, which is exceptional.

- 1. Significantly higher than leading medical device and equipment companies.<sup>1</sup>
- 2. On par with some of the strongest brands in the world such as Apple and Bose.<sup>2</sup>

The Net Promoter Score is an index ranging from -100 to 100 that measures the willingness of customers to recommend a company's products or services to others. It is used as a proxy for gauging the customer's overall satisfaction with a company's product or service and the customer's loyalty to the brand.

### Global leader in advancing surgical visualization

...did you know

### 10 million

surgeries performed around the world every year by Neurosurgeons using ZEISS visualization systems

### 2,000

More than 2000 ZEISS fluorescence options have been implemented in neurosurgical clinics worldwide.

### 15 million

Over 15 million cataract operations are performed with ZEISS surgical systems all over the world every year.

¹ https://customer.guru/net-promoter-score/industry/medical-products-and-equipment

<sup>&</sup>lt;sup>2</sup> https://www.pcmag.com/news/the-best-brands-for-2020

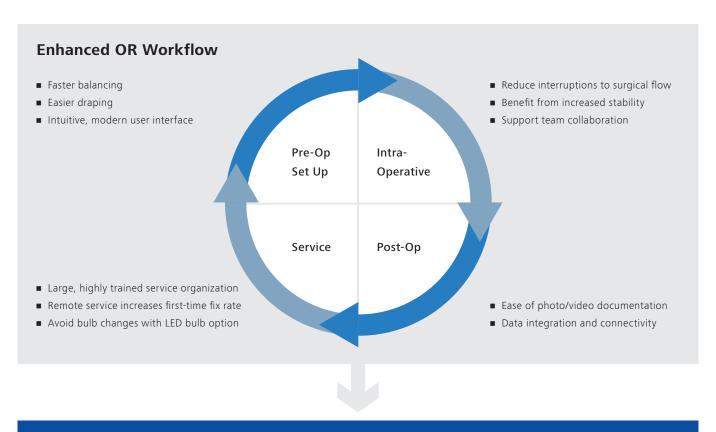
### **Executive Summary**

Hospitals and integrated health delivery systems are constantly looking for ways to improve efficiencies and outcomes in the operating room (OR), in a way that doesn't unduly burden the surgical team. To achieve these goals, surgical teams require advanced technology, capable of performing complex procedures in simple, intuitive ways. Reliable performance for all of your patients is key.

For demanding surgical applications in ENT, Spine and P&R look no further than TIVATO® 700 from ZEISS, the latest Advanced

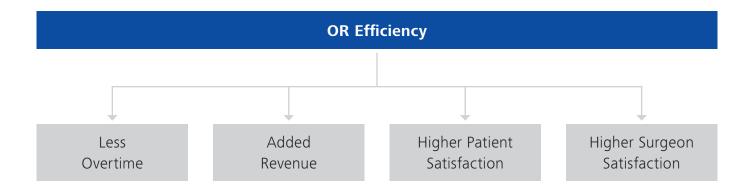
Visualization System. Understanding your daily workload, this fully integrated visualization system enhances usability and is built on the digital and robotic technologies that are defining the future of microsurgery.

This document focuses on the operational and clinical value of the ZEISS TIVATO 700. It outlines how key features of the device and supporting services help to maximize OR **Resource Utilization**, improve **Staff Satisfaction**, and protect **Patient Safety** – all of which we believe are key priorities for any OR.



### **OR Efficiency**

### **Executive Summary**



### What The Impact Looks Like...

Less Overtime: a 2018 study of 302 hospitals found that OR staff costs alone average \$10 per minute.3

**Added Revenue**: fitting in an additional case, even a relatively simple ENT procedure, can yield \$1000-\$2000 in added net patient revenue per day.<sup>4</sup>

**Patient Satisfaction** can be negatively impacted when start times are delayed, or the case gets canceled out of concern that it would finish after the end of regularly scheduled hours.

**Surgeon Satisfaction**: studies have shown turnover time to be a major factor surgeons say would make them switch hospitals.<sup>5</sup>

<sup>&</sup>lt;sup>3</sup> Childers P, Maggard-Gibbons M. Understanding Costs of Care in the Operating Room. JAMA Surgery, 2018;153(4)

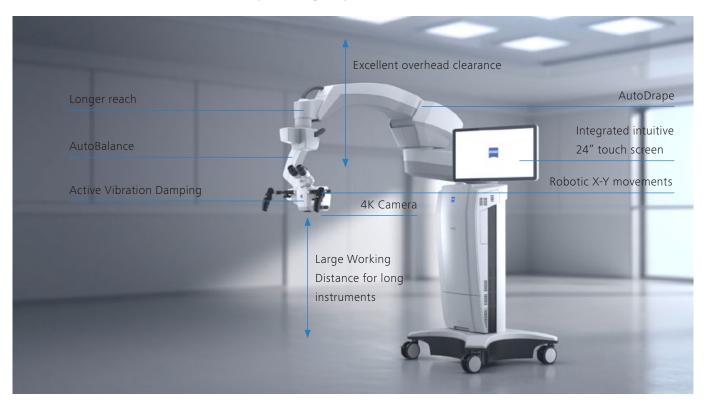
<sup>&</sup>lt;sup>4</sup> Pakdil F, Harwood T. Factors That Influence Efficiency in Performing ENT Cases: A Qualitative and Quantitative Analysis. Journal of Medical Systems, Vol. 29, No. 3, June 2005

<sup>&</sup>lt;sup>5</sup> Masursky D, Dexter F. Surgeons' and Anesthesiologists' Perceptions of Turnover Times. Anesthesia & Analgesia, 2011; 112(2)

### **Product Overview**

For demanding surgical applications in ENT, Spine and P&R look no further than TIVATO 700 from ZEISS. In addition to advanced visualization, ZEISS TIVATO 700 is designed to streamline workflow and save time throughout the perioperative process, while ensuring your OR operates smoothly.

#### Convenient features to automate OR set up and surgical procedures



# The future of service and high availability: ZEISS Smart Services

ZEISS is the first to offer care providers secure, remote customer service. This means faster reaction times to system concerns, increased system availability, and reduction of costly downtime.

# Enhance workflow and collaboration with all-digital

ZEISS TIVATO 700 comes with a **full Connectivity Package**.

Manage surgical data digitally with **ZEISS Connect App** and dedicated functionalities to integrate into your existing hospital IT infrastructure.

**ZEISS Observe App** enables streaming in real-time on a mobile device and ZEISS VR ONE Plus glasses to watch it in 3D with depth perception.



### **OR Turnover**

Process re-engineering studies have identified surgical microscope setup as a common area where turnover time (TOT) delays occur. For example, a case study at a university hospital in the US asked surgical staff to list common causes for TOT delays.<sup>6</sup> Among the causes they cited were:

 Nurses unfamiliar with scopes have to share knowledge, especially when scopes are posted simultaneously in multiple

- Moving equipment between rooms
- Replacing burnt out lightbulbs

The ZEISS TIVATO 700 is designed to make OR turnover more efficient, with an intuitive interface and automated features to improve usability and reduce common causes of delay.



<sup>6</sup> Pakdil F, Harwood T. Factors That Influence Efficiency in Performing ENT Cases: A Qualitative and Quantitative Analysis. Journal of Medical Systems, Vol. 29, No. 3, June 2005

### Replace manual set up with automation at a click of a button

#### **Automated Draping**

The unique AutoDrape® and air evacuation features quickly ensure system readiness in the operating theater with any surgical configuration – simply and effectively at the touch of a button. ZEISS SMARTDRAPE® is another feature that saves time through an improve drape folding technique.

#### **Automated Balancing**

For the safety of both patient and surgeon, microscopes must be properly balanced prior to every procedure. On most devices this is done by manually adjusting separate nobs for each rotational axis, in a process rife with trial and error. With AutoBalance on the ZEISS TIVATO 700 can be balanced in a matter of seconds, with the click of a single button on the intuitive setup screen.

#### **Intuitive Interface**

The ZEISS TIVATO 700 features an intuitive graphical user interface, similar to that of a tablet or smartphone. Usability reduces training time and makes setup simple for everyone on your OR team. Features include saving preferred settings for each surgeon (e.g. grip position, brightness, etc.) and reloading them with the click of a button. These features and user interface are common across other ZEISS visualization systems, such as the ZEISS KINEVO 900, making it easy for surgical teams to seamlessly move between systems.

#### **Simplified Transport and Video Start Up**

Its integrated design makes moving the ZEISS TIVATO 700 easy. Unlike other surgical microscopes, which require external plug ins, ZEISS TIVATO 700's video system is fully integrated and ready to go.

#### Avoid Bulb Changes (LED Option)

ZEISS TIVATO 700 provides the unique flexibility of choosing either LED lightbulbs with high color rendering index (CRI), or Xenon light source. An LED CRI bulb lasts on average 50,000 hours, meaning it can go 20+ years without needing replacement. While Xenon bulbs provide enhanced visualization for certain procedures, LED CRI lights are clinically suitable for many of the most common ENT and spine surgeries.

50,000 lifetime hours - 100x the hours of a Xenon bulb







Intuitive UI



Simplified video set up

### **Intraoperative Workflow**

Demanding microsurgical applications in ENT, Spine and P&R require advanced technology capable of performing complex procedures in simple, intuitive ways. Advanced visualization, ease-of-use, and ergonomic design are key. The ZEISS TIVATO 700 raises the bar with all new functionalities to streamline your surgical workflows – **Workflow-Enhancing Visualization**, **Ultimate Reach and Flexibility**, **All-Digital**.



Cochlea implantation surgery\*

"Due to the screen technology and the integrated 4K camera, you can integrate the entire OR team into the procedure. ... This leads in the end to patient safety, quicker surgery, and shorter time under anesthesia."

Dr. Andreas Korge, Schoen Clinics , Munich, Germany

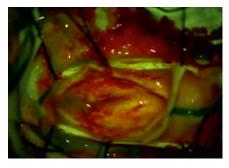
#### **Workflow-Enhancing Visualization**

#### **Enabling Collaboration**

Because OR efficiency is all about teamwork and collaboration, the ZEISS TIVATO 700 provides state-of-the-art visualization for the entire surgical team. With integrated 4K camera technology, and a large external 4K monitor, you can broadcast the procedure to the entire OR staff in brilliant detail every step of the way.

#### Fluorescence

Leveraging brilliant apochromatic optics from ZEISS, venture into new fields including the use of intraoperative fluorescence options.<sup>7</sup> Assess patency of vessels joined by anastomosis with ZEISS INFRARED 800. Go even further with ZEISS YELLOW 560 to visualize fluorescence-stained structures for additional clinical applications.



Lumbar spinal tumor with ZEISS YELLOW 560\*\*

<sup>&</sup>lt;sup>7</sup> Please use the fluorescent agent as per the approval status for the application in your country.

<sup>\*</sup> Image courtesy of Prof. Dr. Joachim Hornung, University Clinic, Erlangen, Germany

<sup>\*\*</sup> Image courtesy of Prof. Dr. Talat Kırış from LIV Hospital Cancer Center, Istanbul, Turkey

### **Intraoperative Workflow**

#### **Ultimate Reach and Flexibility**

The extra long reach of the ZEISS TIVATO 700 arm allows surgical teams to avoid disruptions mid-procedure, where otherwise they would need to reposition the entire microscope:

- during bilateral (dual) ear surgeries, when switching between the left and right side of the patient's head,
- when scanning the entire length of the spine is required,
- when a cross-over procedure is needed during lumbar decompression surgeries.

Other microscopes require repositioning in these situations, which adds to procedure time and may hinder desired outcomes. Other microscopes require repositioning in these situations, which adds to procedure time and may hinder desired outcomes.

#### **Long Working Distance**

When working with long instruments, the added working distance of up to 625mm allows the surgeon to maintain continuous focus.

With other systems, limited space when working under the microscope arm can lead the surgeon to temporarily move the system out of the surgical field and proceed without the benefit of magnification and illumination.

#### Stability Taken To A New Level

The ZEISS TIVATO 700's innovative **Active Vibration Damping** minimizes vibration that can disrupt the surgical workflow, for example, after repositioning the visualization system.

Using robotics, this new technology also allows the surgeon to make small, smooth and precise X-Y movements using the joystick, without opening the microscope brakes.



View the interactive demo of a dual cochlear implant with a single setup.



View the interactive demo of working under the arm using long instruments.

"The stability of the system is amazing. We look for things like – does it have dampening? Does it vibrate a lot? Can I release the brake without any movement or tremor? And it performed exceedingly well."

"The dampening and rigidity is done very well in this new system. It's much better than some older systems."

Dr. Yu Hip Cho, Union Hospital Polyclinic, Hong Kong

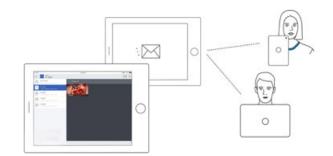
Seilesh C. Babu, Michigan Ear Institute

### **Digital Connectivity and Post-Operative Workflows**

With current technological landscapes the integration of medical devices into your existing IT systems is crucial. The ZEISS TIVATO 700 comes with a full **Connectivity Package** to streamline postoperative image and video management today, and future-proof your investment for tomorrow.

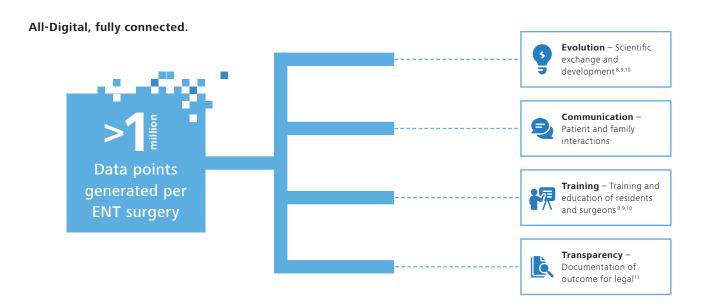
#### **Post-Op Workflows**

Managing images and videos can become a burden for surgeons performing multiple procedures per day. The **ZEISS Connect App**, an intuitive tablet app, simplifies documentation and automates the organization process. Network integration using DICOM standards, via a wireless connection, allows data transfer.



#### **Connecting With the Digital Future**

As surgery continues to evolve and increase in complexity, it has become a huge data generator. During a complex ENT procedure, for instance, millions of data points get generated. Managing this data allows for numerous potential benefits. For example, analyzing and modeling data captured in the OR could help predict workflow and optimize OR efficiency. 8.9 It could support future decision-making, drive quality improvements in surgery, and consequently improve patient outcomes. 8.9.10 To maximize these future opportunities, you need your OR equipment to be integrated within your overall hospital IT infrastructure. The ZEISS TIVATO 700 not only provides advanced visualization but is also designed to simplify the process of data capture, processing and connectivity.



<sup>&</sup>lt;sup>8</sup> Vedula SS and Hager GD. Surgical data science: The new knowledge domain. Innov Surg Sci 2017;2:109-121

<sup>&</sup>lt;sup>9</sup> Stauder R et al. Surgical data processing for smart intraoperative assistance systems. Innov Surg Sci 2017;2:145-152

<sup>&</sup>lt;sup>10</sup> Maier-Hein L et al. Surgical data science: Enabling next-generation surgery. Available at: https://arxiv.org/ftp/arxiv/papers/1701/1701.06482.pdf

<sup>11</sup> Joo S Et al. BMJ Quality and Safety 2016; 25:911-913

### **ZEISS Service Leadership**

#### The future of service and high availability: ZEISS Smart Services

ZEISS is the first to offer care providers secure, remote customer services as an additional offering to the already established ZEISS OPTIME service agreements. Remote Service benefits include faster reaction times to system concerns, increasing system availability, and reducing costly downtime.



What is the cost of downtime in the OR?

The revenue per minute is \$74 for an otolaryngology operating room of an academic health system.<sup>12</sup>





Encrypted error log files sent to ZEISS

Remote engineer analyzes error log files

Ensures needed spare parts are available

#### **Customer Care from ZEISS**

At ZEISS, service and support is a strength.

97%

of our customers have expressed their satisfaction with our services.

We offer proven, comprehensive and award-winning support solutions.

To deliver on our promise of partnership, the ZEISS standard is:

- A large Field Service organization with over 350 qualified service technicians worldwide
- On-site service response up to next day for busy practices
- Over 125,000 parts in inventory and locally stocked with 98 percent on-time delivery
- A fully staffed Call Center answering 98 percent of those calls in under two minutes
- Over two-thirds of service calls resolved over the phone without deploying an on-site engineer
- High 1st time fix rate
- Industry leading Service Level Agreements (SLAs):

ZEISS OPTIME GUARANTEE

<sup>&</sup>lt;sup>12</sup> Lean Management in Academic Surgery Ryan M Collar, MD, Andrew G Shuman, MD, Sandra Feiner, RN, Amy K McGonegal, RN, Natalie Heidel, BS, Mary Duck, BS, Scott A McLean, MD, John E Billi, MD, David W Healy, MD, MRCP, FRCA, Carol R Bradford, MD, FACS J Am Coll Surg 2012;214:928–936. © 2012

### **Patient Experiences**

The average cost of an SSI incident in a U.S. hospital ranges from \$11,874 - \$34,670.13

While improving intra-operative efficiency is important for a number of reasons, first among them is the impact on patient safety. Prolonged procedure duration is associated with several negative clinical outcomes, including increased risk of surgical site infection (SSI), as well as pulmonary complications.

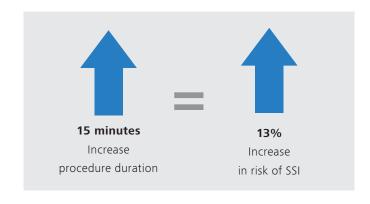
A meta-analysis of 81 studies found that the likelihood of SSI increased with increasing time increments; for example, a 13%, 17%, and 37% increased likelihood for every 15 min, 30 min, and 60 min of surgery, respectively.<sup>14</sup>

#### Other Ways ZEISS TIVATO 700 Can Help Reduce SSIs

The TIVATO 700 from ZEISS supports disinfection success even in the time-sensitive environment of the OR. Reduced cabling and intelligent design support simple, quick, and effective cleaning, and help prevent microbial contamination of your surgical visualization system – and your patients.

### Additional Ways TIVATO 700 Can Improve Patient Safety

Unlike other traditional surgical microscopes (e.g., Leica's



PROvido), surgical teams have the option to use LED surgical lights, rather than Xenon bulbs.

Xenon bulbs burn brighter and hotter than LED lights, posing particular safety risks for pediatric patients. Clinical studies have documented how the most common complication is auricular burns and scarring during otologic surgeries. Furthermore, these studies conclude 300W Xenon bulbs are responsible for these injuries. 15,16,17



**Reduced Cable Clutter** 

Integrated design and wireless connection to external monitors



More Overhead Clearance

Avoids inadvertent contact and cross-contamination



AutoBalance

Reduces touching of visualization system nobs and

<sup>13</sup> The Direct Medical Costs of HAIs in U.S. Hospitals and the Benefits of Prevention, R. Douglas Scott II, CDC, 2009. http://www.cdc.gov/HAI/pdfs/hai/Scott\_CostPaper.pdf

<sup>&</sup>lt;sup>14</sup> Cheng, Chen, et al. Prolonged Operative Duration Increases Risk of Surgical Site Infections: A Systematic Review. Surgical Infections, 2017; 18(6):722-735. https://www.ncbi.nlm.nih.gov/pubmed/28832271

<sup>15</sup> Marine Parodi, et al. Using a new otologic operating microscope: Unexpected complications. (International Journal of Pediatric Otorhinolaryngology, 2015).

<sup>16</sup> James Batesa, et al. Otological surgery in paediatric photosensitive patients. (International Journal of Pediatric Otorhinolaryngology, 2018).

T. Edward Imbery, MD, et al. Thermal Variations of Operative Microscopes in Otology. (American Academy of Otolaryngology, 2017).

### **Bulb Cost Savings**

Surgical lighting is one of the most important elements in the operating room. The surgical team must be able to see accurately – with clear visibility, adequate brightness, minimal shadows, and no glare.

Depending on the application care providers may prefer Xenon or high CRI rated LED bulbs. The ZEISS TIVATO 700 provides you the option to use both types of bulbs, whereas other microscopes (e.g., Leica PROvido) only come equipped with

Xenon lights. While Xenon lights provide higher brightness and color rendering index (CRI), they burn hotter, are noisier than LED lights, and must be replaced far more frequently (100x more often as LED bulbs).

#### LED

- CRI rating of 95
- Emit very little heat
- Long life, LED lights can last 50,000 hrs

VS.

■ CRI rating of 100

Xenon

- Emit lots of heat and noise
- Must be replaced, Xenon lights last approximately 500 hrs

While an LED bulb can last 25 years, Xenon lights must be typically replaced 4X per year. Below we present a summary of the annual out-of-pocket costs of using microscopes that only come equipped with Xenon bulbs.

Typical Hospital OR	
Work weeks	50
Hours per week	40
Hours per year	2000

		LED	Xenon
Lifetime Hours		50,000	500
Replacement Costs	Bulbs	_	\$416.30
	Shipping	_	\$15
Total cost per microscope per year		_	\$1,725.20
Replacement costs over life of scope (10 years)		_	\$17,252.00

### **Time Savings Worksheet**

Calculate the potential time savings per day from advanced features of the ZEISS TIVATO 700. Time savings will vary by OR and by day, depending on the number and type of cases scheduled. The top section applies to OR days with a high number of shorter procedures. The bottom section applies in particular to procedures where long microscope reach saves intraoperative time.

#### 1. Reducing Setup Time (Turnover Time)

Use the calculation below to quantify time saved when a high number of shorter procedures (e.g. 6-8) are scheduled for the same day. Setup time savings will be the dominant factor on such days.

Turnover & Set Up Time		Minutes
A. Minutes/case saved in draping (via AutoDrape)		
B. Minutes/case saved balancing microscope (via AutoBalance)	+	
C. Total setup time saved per case (A+B)	=	
Procedure Time		
D. Minutes/case saved due to reduced vibration (via Active Damping)	+	
Total Time Savings		
E. Total mins saved per case (C+D)	=	
F. Number of procedures per day	х	
G. Total setup time saved per day (E X F)	=	

#### 2. Avoiding Scope Repositioning

Use the calculation below to quantify time saved due to the longer reach of the ZEISS TIVATO 700. This is most beneficial during procedures where the surgical team would otherwise need to reposition the scope part way through. Examples include bilateral cochlea implants.

Procedure Time	Minutes	
H. Minutes/case saved by avoiding scope repositioning (via longer reach)		
I. Minutes/case saved due to reduced vibration (via Active Vibration Damping)	+	
Total Time Savings		
J. Setup time savings per case (row C above)	+	
K. Total minutes saved per case (H+I+J)	=	
L. Number of procedures per day	х	
M. Total setup time saved per day (K X L)	=	

### **Competitive Comparison**

Below are the key factors evaluating different options. We invite you to compare the ZEISS TIVATO 700 point-for-point with traditional microscopes (e.g. Leica PROvido).

Requirements for Consideration	ZEISS TIVATO 700	Traditional Microscope e.g. Leica PROvido	Benefit
Automated draping with AutoDrape® and SMARTDRAPE ZEISS	Yes	No, only manual draping	Faster set up and TOT
Fully integrated video 4K video package	Yes	No, only HD camera available	Faster set up and TOT
Automated balancing with AutoBalance	Yes	No, manual AB/AC balancing	Faster set up and TOT
Active Vibration Damping	Yes	No, only mechanical damping	OR time savings
Long working distance	Yes	No, reach is only 600mm	OR time savings
Long working distance and overhead clearance	Yes	Limited scope potentially must be repositioned	OR time savings
Robotic X-Y movements for small and precise movements	Yes	Yes, but with potentially vibrations due to missing active vibration demping	OR time savings
Full digital connectivity	Yes	Limited connectivity	Post-op time savings
Option of high-CRI LED light	Yes	No, Leica only offers Xenon light	Cost savings
Availability and reliability	Yes, via ZEISS Smart Services	Conventional support	Cost savings and improved up time

### **Awards and Testimonials**

ZEISS visualization systems have won multiple awards in recognition of the quality and innovative nature of their design.



The UX Design Awards is a global competition with a specific focus on user experience.



The Red Dot Award is an international design competition for product design, communication design and design concepts.



Awarded by the editors of Mechanical Engineering magazine in recognition of ascending technologies that are poised to transform their fields.



"Talking about safety and comfort, definitely the ZEISS TIVATO 700 offers a high standard. A quite brilliant compromise between being compact and techno-logically high-end. It will allow us to perform surgeries with sufficient speed, while operating on the safe side."

Luca Papavero, MD PhD, Schoen Clinics

To hear more about what surgeons have to say, click here:

www.zeiss.com/tivato

### **Technical Data**

### TIVATO 700 from ZEISS

		Packages**	Essential	Standard	Spine Comfort	ENT Comfort	Premium
System	TIVATO 700 Essential system		•	_	-	_	-
	TIVATO 700 Basic system		-	•	•	•	•
Main Tubes	Straight binocular tube		0	0	□*	□*	□*
	180° tiltable tube		0	0	-	0	-
	Foldable Tube f170/f260		-	_	•	0	•
Eyepieces	10x wide-field eyepieces		0	0	0	0	0
	12,5x wide-field eyepieces		0	0	0	0	0
Focus	SpeedFokus		-		•		•
Working Distance	200-500 mm		•	_	-	_	-
	200-625 mm		-	•	•	•	•
Illumination	Xenon – Fully integrated Xenon light source with automatic lamp exchange		-	0	0	0	•
	TriLED – Fully integrated LED light source		•	0	0	0	_
Co-Observation	Face-to-face with StereoBridge				•		
	Left/right with stereo co-observer					•	
Balance	GuidedBalance		•	-	-	-	-
	AutoBalance		-	•	•	•	•
XY-Movement	Angular movement with joystick or foot pedal		-			•	•
Video System	Standard HD Video Package – Fully integrated 1-chip HD camera, 1080p		•	0	-	_	-
	Premium HD Video Package – Fully integrated 3-chip HD camera, 1080p		□1	0	0	0	-
	4K Video Package – Fully integrated 3-chip 4K camera, 2160p		-	_	0	0	•
Video Options	Video recording						•
	HD Video-In		-			•	•
Fluorescence***	YELLOW 560		-	-		0	•
	YELLOW 560 LED						-
	INFRARED 800		-	-		0	•
Visualization	Additional Depth of Field					•	•
Networking & Storage	Integrated 1TB harddrive						•
	Wireless Network Package – Enables WLAN and WiFi Hot Spot functionality		•	•	•	•	•
	LAN Interface <sup>2</sup>		-	-			
	Shared Network Package – Storage on shared network directories						•
	DICOM Package – Patient data exchange with PACS system via DICOM						•
	ZEISS Smart Services Package – Connectivity for ZEISS Smart Services		•	•	•	•	•
Navigation	Navigation Package		_	_			

<sup>\*</sup> available as an additional tube

<sup>●</sup> Basic O Configurable □ Option

<sup>\*\*</sup> Please check with your local ZEISS representative on the timing of availability of these packages.

<sup>\*\*\*</sup> separate module necessary for activation

<sup>&</sup>lt;sup>1</sup> only available with YELLOW 560 LED

<sup>&</sup>lt;sup>2</sup> only available with Navigation Package

### **Appendix**

### Research Citations

- 1. https://customer.guru/net-promoter-score/industry/medical-products-and-equipment
- 2. https://www.pcmag.com/news/the-best-brands-for-2020
- 3. Childers P, Maggard-Gibbons M. Understanding Costs of Care in the Operating Room. JAMA Surgery, 2018;153(4)
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For US Market: ZEISS TIVATO 700 device is exempt from the pre-market notification procedures.

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Goeschwitzer Strasse 51–52 07745 Jena Germany www.zeiss.com/tivato www.zeiss.com/med/contacts