TITAN Tx350
Model Tx350-A
Xenon Illuminator with Manual Dimming
Operation Manual

Sunoptic Technologies®
6018 Bowdendale Avenue
Jacksonville, FL 32216 USA

Customer Service: 904 737 7611
Toll Free 877 677 2832

RMS UK, Ltd.
28 Trinity Road
Nailsea, Somerset BS48 4NU
United Kingdom
TEL: 01275 858891
# TABLE OF CONTENTS

1. INTRODUCTION

2. WARNINGS

3. SPECIFICATIONS

4. OPERATING ELEMENTS, SYMBOLS AND FUNCTIONS
   4.1 FRONT PANEL
   4.2 REAR PANEL

5. INSTALLATION
   5.1 SETTING UP LIGHTSOURCE
   5.2 CONNECTING LIGHT CABLE

6. OPERATION
   6.1 POWERING UP LIGHTSOURCE
   6.2 LIGHT BRIGHTNESS CONTROL
   6.3 LAMP LIFE HOURS DISPLAY

7. CLEANING AND DISINFECTION

8. MAINTENANCE, SERVICING AND REPAIR, WARRANTY
   8.1 LAMP REPLACEMENT
   8.2 WARRANTY

9. END OF PRODUCT LIFE

10. TROUBLESHOOTING

11. CHART OF MEDICAL DEVICE SYMBOLS USED
1. INTRODUCTION

Congratulations on the purchase of your new Titan Tx350 Xenon Illuminator!

This user-friendly Xenon Illuminator is a high efficiency lightsource utilizing state-of-the-art illumination technology. It offers a variety of features such as:

- 5600º K daylight brightness for perfect color definition
- Quiet operation
- Compact and light weight
- Turret which adapts to various types of light guides
- Mechanical dimming
- Easy lamp replacement
- Hour Meter (resettable)

This Operator Instructions for Use Manual will help you to install the device and optimally integrate it with other components of your system. It will instruct you how to operate the Xenon Illuminator and how to keep it clean. It will give you maintenance and service guidelines as well as recommendations for best performance results.

INTENDED USE

The intended use of this device is to illuminate surgical sites by delivering light to headlamp luminaries and other instruments via a fiberoptic cable.
2. WARNINGS/CAUTION

⚠️ WARNING  The illuminator uses a highly concentrated lightsource (luminous power per area) and this high energy density is retained through connected lightguides and instruments. The output of a connected instrument left in close proximity or contact with tissue or flammable materials may present a risk of injury or fire depending upon application. Qualified personnel must determine a safe working distance and intensity setting for each application. The output should never be left on unattended.

⚠️ Caution  Rx only. Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

⚠️ Caution  To prevent fire or electric shock, do not open or expose the lightsource unit to rain or moisture. Refer all servicing to qualified personnel only.

⚠️ Caution  Not suitable for use in presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.

⚠️ Caution  To prevent any potential electro-magnetic interference, do not use any kind of cellular phone near the lightsource.

⚠️ Caution  This product should be used only with type BF endoscopic instruments which have been certified according to IEC 60601-1 for medical equipment and IEC 60601-2-18 for endoscopic equipment.

This symbol indicates type BF equipment.

⚠️ Caution  User must not alter this device in any fashion. Doing so voids all warranties and statements of suitability for any purpose.

⚠️ Caution  All devices connecting to the Illuminator must be classified as medical equipment. Additional information processing equipment connected to the Illuminator, a Medical System and the operator must determine that all equipment complies with the appropriate end-product standards (such as IEC 60950 or IEC 60065 and the Standard for Medical System, IEC 60601-1-1).

⚠️ Caution  Always set the intensity control to the minimum level and insert the fiberoptic cable into the unit before turning on the power. When light is not required at the surgical site the intensity control should be set to the fully dimmed position. If it becomes necessary to remove the fiberoptic cable without turning the unit off turn the intensity control to the fully dimmed position.

⚠️ Caution  The fiberoptic cable must be electrically NON-CONDUCTIVE. It should not have conductive shielding or any other conductive connection between the patient and equipment. Such connection will impair safety of the equipment. It must be rinsed free of soaking/disinfectant solution and dried before plugging into the lightsource receptacle. Ensure the optical surface is clean before connecting the cable to the lightsource.

⚠️ Caution  When using high intensity lightsources at full output, the recommended distance from the headlight module to the patient is not less than 12 inches (30.5 cm). If using less than 12 inches from the patient, the light intensity must be reduced.
3. SPECIFICATIONS

<table>
<thead>
<tr>
<th>Item</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lamp type</td>
<td>Ceramic type 300 watt Xenon</td>
</tr>
<tr>
<td>Power</td>
<td>300 Watt</td>
</tr>
<tr>
<td>Color temperature</td>
<td>5600° K</td>
</tr>
<tr>
<td>Lamp life</td>
<td>1000 hours (typical)</td>
</tr>
<tr>
<td>Lamp replacement</td>
<td>Cartridge replacement from the side of the unit</td>
</tr>
<tr>
<td>Light guide adapter</td>
<td>Turret type to accommodate standard Storz, ACMI, Wolf, Olympus cable endtips</td>
</tr>
<tr>
<td>Brightness control</td>
<td>Mechanical progressive shutter control from the front panel</td>
</tr>
<tr>
<td>Input voltage</td>
<td>100-120 V AC, 50/60 Hz</td>
</tr>
<tr>
<td></td>
<td>220-240 V AC, 50 Hz</td>
</tr>
<tr>
<td>Power consumption</td>
<td>450 watt max</td>
</tr>
<tr>
<td>Regulatory Approvals</td>
<td>UL60601, EN 60601-1, EN 60601-1-2, CAN/CSA, C22.2, No 601.1-M90</td>
</tr>
<tr>
<td>Equipment Class</td>
<td>BF-type</td>
</tr>
<tr>
<td>Mode of Operation</td>
<td>Continuous operation</td>
</tr>
<tr>
<td>Water Resistant</td>
<td>Not Protected Equipment, IPX0</td>
</tr>
<tr>
<td>Operating Environment Temperature</td>
<td>+20° to +40° C (68° to 104° F)</td>
</tr>
<tr>
<td>Relative Humidity</td>
<td>30 to 85%</td>
</tr>
<tr>
<td>Air Pressure</td>
<td>700 to 1060 hPa</td>
</tr>
<tr>
<td>Storage Environment Temperature</td>
<td>-20° to +60° C (-4° to 140° F)</td>
</tr>
<tr>
<td>Relative Humidity</td>
<td>0 to 95%</td>
</tr>
<tr>
<td>Air Pressure</td>
<td>700 to 1060 hPa</td>
</tr>
<tr>
<td>Dimensions, mm (inch)</td>
<td>338 (13.3)Width x 155 (6.1)Height x 457 (18)Depth front-to-back</td>
</tr>
<tr>
<td>Weight, kg (lb)</td>
<td>10kg (22lb)</td>
</tr>
</tbody>
</table>
4. OPERATING ELEMENTS, SYMBOLS AND FUNCTIONS

4.1 FRONT PANEL

![Figure 1. Lightsource Front Panel](image)

<table>
<thead>
<tr>
<th>No.</th>
<th>Name</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Lamp switch</td>
<td>Turns the lightsource on and off; illuminates blue when turned on.</td>
</tr>
<tr>
<td>2</td>
<td>Intensity Control</td>
<td>Mechanically controls the light output</td>
</tr>
<tr>
<td>3</td>
<td>Turret</td>
<td>Accepts lightsource endtip of fiberoptic cable</td>
</tr>
</tbody>
</table>
### 4.2 REAR PANEL

Figure 2. Lightsource Rear Panel

<table>
<thead>
<tr>
<th>No.</th>
<th>Name</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Fan</td>
<td>Fan 12V DC, airflow for cooling of unit</td>
</tr>
<tr>
<td>2</td>
<td>Circuit breaker</td>
<td>Over current protection.</td>
</tr>
<tr>
<td>3</td>
<td>AC mains power switch and input module</td>
<td>Accepts AC Power cord and switches on AC power</td>
</tr>
<tr>
<td>4</td>
<td>Hour Meter</td>
<td>Allows tracking of total running time on unit and provides a control on individual lamp hours</td>
</tr>
<tr>
<td>5</td>
<td>Grounding Connector</td>
<td>For electric potential equalization</td>
</tr>
</tbody>
</table>
5. INSTALLATION

5.1 SETTING UP THE LIGHTSOURCE

Place the lights source on a stable surface (cart, counter, stand, etc.).

NOTE Avoid places where the lights source may be splashed with liquid. Absolutely DO NOT use in any environment with explosive or flammable gases.

This lights source pulls cooling air into its cabinet through a filtered grille in the bottom panel underneath the front portion and exhausts warm air from the fan in the rear.

DO NOT block the space in front or below the front of the lights source or impede exhaust air flow behind or above the cabinet.

A clear space minimum of 5”/12.7cm behind and above the cabinet is required.

The lights source should not be placed where its exhaust will influence other devices, nor where the heated air from other devices will influence the lights source.

Make sure the rear power switch is in OFF position.

Connect AC power cord to the power inlet located on the rear panel of the lights source.

Make sure power cord is completely seated into the power inlet.

CAUTION Use only cords provided with the lights source.

Plug the AC power cord into a wall outlet using the three (3) prong plug supplied with the unit.

CAUTION To prevent electric shock, connect power cords of peripheral equipment through medical isolation transformers.

NOTE When using medical isolation transformer, be sure to check the transformer power ratings.

Make sure that the power cord is connected to the main power with three prong plug (USA use UL2601-1 rated isolation transformers and/or power strips only).

CAUTION Nearby radio or TV units may subject this equipment to radio interference. To avoid adverse electromagnetic effects, DO NOT operate this equipment near RF energy equipment.
5.2 CONNECTING THE LIGHT CABLE

Connect the fiberoptic cable to endoscope or other instrument and then plug the cable lightsource endtip into the appropriate port of the turret on the front panel.

6. OPERATION

6.1 POWERING UP THE LIGHTSOURCE

To operate the lightsource: Attach the lightsource to the instrument or headlamp. Turn on the rear power switch. Turn on the lamp switch The fan will start. The indicator on lamp switch will light.

6.2 LIGHT BRIGHTNESS DISPLAY AND CONTROL

The light brightness adjustment enables the user to obtain a brighter or dimmer illumination of the object of observation. Adjust the light intensity by sliding the intensity control knob from left (off) to right (brightest.)

**NOTE**  The brightness control operates a progressive mechanical shutter. The lamp is running at full power if the power switch is on no matter where the brightness control is set.

6.3 LAMP LIFE HOURS DISPLAY

The hour meter shows the total elapsed running time of the unit.

7. CLEANING and DISINFECTION

**NOTE**  *Always disconnect the power cord before cleaning the system and while unit is drying if wet-wiped.*

Disinfection agents should be commercially available cleansers commonly used for disinfection of electronic equipment cabinets in hospitals, such as ethyl or isopropyl alcohols, disinfecting sprays containing quaternary ammonium compounds or hydrogen peroxide.

Do not use strongly caustic or acidic cleansers such as “Clorox” hypochlorite bleach, ammonia, muriatic acid or similar products. Do not use acetone, methyl ethyl ketone or halogenated / chlorinated hydrocarbon solvents or cleaners containing any of these restricted compounds.

Apply cleaning agents by light spray or dampened towels. Do not pour liquids over the cabinet.

Do not allow frank liquids to enter the cabinet seams or ventilation openings.
8. MAINTENANCE, SERVICING AND REPAIR, WARRANTY

Performance of preventive maintenance is not essential. Regular maintenance can, however, contribute to identifying potential problems before they become serious; thus, enhancing the instrument’s reliability and extending its useful operating life. Maintenance services can be obtained from your local representative or from the manufacturer.

Defective items or equipment are to be serviced and repaired exclusively by persons authorized by the manufacturer. All repair work shall employ original manufacturer’s parts only.

8.1 LAMP REPLACEMENT

**WARNING**
CERAMIC lamps are at high internal pressure when cold and at operating temperature; therefore, CERAMIC lamps may unexpectedly rupture resulting in discharge of hot fragments of quartz and/or glass and metal.

Only handle lamps with protective covers in place. Do not handle lamps without their protective covers unless government approved safety glasses, facemasks (with neck protector, chest protector and gauntlets) are worn.

![WARNING]

Always disconnect power cord and turn main switch off before lamp replacement.

![CAUTION]

Take utmost care not to hit gas-seal edge of lamp; it may cause gas lamp failure.

![CAUTION]

Do not touch the lamp and patient simultaneously when changing the lamp.

Use only p/n SSX0350 lamp module for replacement. In order for this lightsource to perform as designed only p/n SSX0350 lamp module must be used. Failure to use this lamp could void the warranty.

Open the lamp compartment door.

Move the lamp positioning lever (found to the right of the lamp) clockwise, from horizontal to vertical, and pull the lamp cartridge out.

Replace lamp cartridge with new unit, pushing firmly to assure full engagement and move the lamp positioning lever counterclockwise from vertical to horizontal. Log the serial number and hours on the hour meter. Close the lamp compartment door. Re-connect the power cord and turn the lightsource on according to 6.1. Reset hour meter to zero by depressing hour meter reset button on rear panel.
NOTE If the tamper seal on the lightsourse is broken, the WARRANTY WILL BE VOIED. There are no other user serviceable parts in the unit.

8.2 LIMITED WARRANTY

Your light source carries a 3-year warranty from the date of shipment on workmanship and all defects of material. Should your product prove to have such defects within three years from the date of shipment from Sunoptic Technologies®, we will repair or replace the product or component part without charge. Should your light source need servicing under this warranty, please contact Sunoptic Technologies® for return authorization documentation. You should carefully pack the unit in a sturdy carton and ship it to the factory. Please include a note describing the defects, your name, telephone number and a return address. Warranty does not cover equipment subject to misuse, accidental damage, normal wear and tear or if transferred to a new owner without authorization from Sunoptic Technologies®. This warranty gives you specific legal rights and you may also have other rights that vary from state to state.

POST WARRANTY REPAIRS: You may return your product(s) for repair, shipping prepaid to the factory. Your product will be inspected and an estimate of repair charges will be submitted to you for approval. Payment must be received before repairs are completed.

- Telephone: toll free 877-677-2832
- FAX number: 904 733-4832
- Customer Service: 904 737 7611

10. END OF PRODUCT LIFE

In accordance with the European Waste from Electrical and Electronic Equipment (WEEE) directive, we encourage our customers to recycle this product whenever possible. Disposal of this unit must be performed in accordance with the applicable local environmental regulations.

In the US a list of recyclers in your area can be found at: http://www.eiae.org/.

Please contact customer service to issue a return authorization to return product to manufacturer at the end of product life.
## 11. CHART OF MEDICAL DEVICE SYMBOLS USED

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Manufacturer" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td><img src="image2" alt="Date of manufacture" /></td>
<td>Date of manufacture (YYYYMM or YYYY)</td>
</tr>
<tr>
<td><img src="image3" alt="Authorized Representative" /></td>
<td>“Authorized Representative” in the European Community</td>
</tr>
<tr>
<td><img src="image4" alt="Caution" /></td>
<td>Caution, consult accompanying documents</td>
</tr>
<tr>
<td><img src="image5" alt="Rx only" /></td>
<td>Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner</td>
</tr>
<tr>
<td><img src="image6" alt="Consult Instructions for Use" /></td>
<td>Consult Instructions for Use</td>
</tr>
<tr>
<td><img src="image7" alt="CE mark" /></td>
<td>CE mark</td>
</tr>
<tr>
<td><img src="image8" alt="Type BF Applied Part" /></td>
<td>Type BF Applied Part</td>
</tr>
<tr>
<td><img src="image9" alt="Not dispose in general waste" /></td>
<td>Not dispose in general waste,</td>
</tr>
<tr>
<td><img src="image10" alt="Caution: Hot Surface" /></td>
<td>Caution: Hot Surface</td>
</tr>
<tr>
<td><img src="image11" alt="Caution: Dangerous Voltage" /></td>
<td>Caution: Dangerous Voltage</td>
</tr>
<tr>
<td><img src="image12" alt="Product Safety Mark" /></td>
<td>Product Safety Mark</td>
</tr>
</tbody>
</table>