TX-series
XENON ILLUMINATORS
RISK MANAGEMENT DOCUMENTS

Applications Engineering
Release Date : 10-30-18
REVISION A where marked : 01-28-19

Applicability:

TX-series Analog
TX-series Digital
ELITE 1000-series Analog
EX-series Digital

Factory Location:

6018 Bowdendale Avenue
Jacksonville, FL 32216
904-737-7611 voice
904-733-0012 fax

RISK MANAGEMENT FILE
EQUIVALENCY STATEMENT for
EX400, EX300 and ELITE 1000 to
Tx-series IEC 60601 REPORTS

The CUDA-branded EX-400-series and EX300-series are equivalent products in all aspects to the IEC 60601 tested TX-series Illuminators Tx450D and TX350D.

The CUDA-branded ELITE1000 is an equivalent product in all aspects to the IEC 60601-tested TX-series Illuminator Tx350A.

These CUDA-series product designators are branding labels ONLY.

The fact that these units are covered by the TX-series IEC 60601 reports is borne-out by the fact that the rear-placard label on these CUDA-series products carries the same MODEL NUMBER as listed in the model names within the first page of the detailed IEC 60601 reports.

12/16/15

William Broyles
Director of Engineering

Date

6018 Bowdendale Avenue, Jacksonville, FL 32216-6042 USA
877-677-2832 voice www.sunoptictech.com 904-733-0012 fax

Product configuration and variations

All products listed in the cover sheet of this report are variants of the original TX-series XENON Illuminators in both 300- and 400-watt versions.

Variations by model series do not present different safety changes which may impact the Risk Analysis of the Tx-series XENON product line, nor which require different testing, even if an updated Risk Analysis report is contained herein. All systems are factory-tested to meet the applicable clauses of the standards listed in this summary report.

Due to the length of time required to develop this product, various reports herein may reference any number of different product references; this document unifies these reports together for the Tx-series XENON Illuminators and all variations thereof.

Of note, the Tx-series were interchangeably referred to, and documented at various times, as:

- Tx350A
- Tx450D
- Tx300A
- Tx350D
- ELITE1000
- x50
- and others...

Summary declaration of conformity to applicable design standards

All Tx-series XENON Illuminators, branded variants and OEM-derived products are conformant to applicable clauses of the following standards:

- IEC 60601-1 , per the testing report contained in this document, for Basic Safety on all clauses determined to apply to the product-series;
- IEC 60601-2 , per the testing report contained in this document, for Electro-Magnetic Conformity on all clauses determined to apply to the product-series;
- BS EN 62366 Usability Engineering per the Revision of the report contained in this document compilation;
- RoHS Conformant
- MDD/93/42, with a Declaration of Conformity issued by Sunoptic Technologies

Product performance characteristics and manufacturing flow

Refer to APPENDIX M "Product Performance Characteristics" for a table of performance characteristics for each series of the Tx-series XENON Illuminator and product variants, including the flow of manufacturing for these types of products and materials list.

Descriptive Report and Test Results

\\MASTER CONTRACT: 220792
REPORT: 70052667
PROJECT: 70221052

Edition 1: March 23, 2016; Project 70052667 – Irvine
Prepared by Ayub Yancheshmeh; Reviewed by Vamsee Patta

Edition 2: May 01, 2019; Project 70221052 - Irvine
Issued by Darya Moshrefi; Reviewed by Calvin Luong

Report pages reissued

Contents:

Attachments*: *To be kept at CSA Main file only*
Attachment #1: User Manual
Attachment #2: Risk Management Files

PRODUCTS

CLASS 8780 01 - MEDICAL ELECTRICAL EQUIPMENT (Canadian adopted IEC 60601-1 3rd edition)
CLASS 8780 81 - MEDICAL ELECTRICAL EQUIPMENT (US Adopted IEC 60601-1 3rd edition)

Fiberoptic Light Source, Medical Electrical Equipment:

Medical Electrical Equipment, Model S180T (or Titan 180), S180T-IND, S180T-CMP, T-LS180130408, T-LS180130415, T-LS180130422, rated 100-120V~, 50/60Hz or 220-240V~, 50Hz, 250W max.; Model S300T (or Titan 300), S300T-IND, S300T-CMP, T-LS300130409, T-LS300130416, T-LS300130423, rated 100-120V~, 50/60Hz or 220-240V~, 50Hz, 450W max.; Model S400T (or Titan 400 or IB6620240), S400T-IND, S400T-CMP, T-LS400130410, T-LS400130417, T-LS400130424 rated 100-120V~, 50/60Hz or 220-240V~, 50Hz, 720W max, Model Titan TX350A, TX350D (**NN-7013 for OEM – Nico Corporation**), model rated 100-12 Vac, 50/60 Hz, 220-240Vac, 50Hz 500-watt is when used with the WARNER ballast and the 750-watt is for the product when build using the MHC ballast, Model Titan, **TX450D** rated 100-12 Vac, 50/60 Hz, 220-240Vac, 50Hz, 750 W. Cord connected: Appliance Coupler / Detachable Cord, Portable.

1. Medical device protection against electric shock: Class I
2. Applied Part protection against electric shock: Type BF
3. Degree of protection against ingress of water or particulate matter: IPX0
4. Method of Sterilization: None
5. Suitability for use in an Oxygen Rich Environment: Medical device not intended to be used in an Oxygen Rich Environment
6. Suitability to use Medical device in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide: Medical device not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

34 Bunsen, Irvine, CA, U.S.A. 92618
Telephone: 949.733.4300 1.800.463.6727 Fax: 949.733.4320 www.csagroup.org

7. Mode of operation: Continuous
8. Environmental Conditions: Normal: 10-40°C, 30-75% RH, 700-1060hPa

APPLICABLE REQUIREMENTS

CSA Standards:

CAN/CSA-C22.2 No. 60601-1:08	Medical Electrical Equipment - Part 1: General Requirements for basic safety and essential performance (Adopted IEC 60601-1:2005 + CORR.1)
CAN/CSA-C22.2 No. 60601-1:08 TC 2:2011 (Corrigendum 2)	Technical Corrigendum 2:2011 to CAN/CSA-C22.2 No. 60601-1:08 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005 - CORR.2)
CAN/CSA-C22.2 No. 60601-2-18:11	Medical Electrical Equipment – Part 2-18: Particular Requirements for the Basic Safety and Essential Performance of Endoscopic Equipment (Adopted IEC 60601-2-18:2009, Third Edition)

ANSI/AAMI Standards:

ANSI/AAMI ES60601-1:2005 (IEC 60601-1:2005, MOD)	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance
ANSI/AAMI ES60601-1:2005 / C1:2009 (CORRIGENDUM 1)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Corrigendum 1

Subject to the following qualifications:

(1) The main supply cord set provided with the equipment must be an approved type acceptable to the authorities in the country where the equipment is sold.
(2) Units provided with other than North American Certified power supply cord sets are certified as a component.
(3) The user replaceable mains (line) fuse must be an approved type acceptable to the authorities where the equipment is sold.
(4) Evaluated to CAN/CSA-C22.2 No. 60601-1:08 and ANSI/AAMI ES60601-1:2005 excluding (Not Evaluated) requirements for Electromagnetic compatibility (Clause 17), Usability (Clause 7.1.1 and 12.2), Biocompatibility (Clause 11.7)
(5) SAFETY HAZARDS resulting from the intended physiological function of EQUIPMENT covered by this Standard are not considered.
(6) Interconnection of this medical device with other medical devices, medical used systems or non-medical devices shall be evaluated to the requirements of Clause 16 in the end use application.
(7) Safety Risk Management: A risk management process complying with the requirements of standard ISO 14971 was inspected during the evaluation of this medical device and/or additional considerations were taken into account since the subject legacy medical device was evaluated to the previous edition of this standard. The risk management decisions affecting the testing requirements have been taken into consideration during the evaluation of this medical device. Changes/Updates in risk management documents during the lifecycle of this medical device that affect the safety of this medical device shall be communicated to the CSA Group as a condition for continued compliance.

MARKINGS

The manufacturer is required to apply the following markings:

- Products shall be marked with the markings specified by the particular product standard.
- Products certified for Canada shall have all Caution and Warning markings in both English and French.

Additional bilingual markings not covered by the product standard(s) may be required by the Authorities Having Jurisdiction. It is the responsibility of the manufacturer to provide and apply these additional markings, where applicable, in accordance with the requirements of those authorities.

The products listed are eligible to bear the CSA Mark shown with adjacent indicators 'C' and 'US' for Canada and US (indicating that products have been manufactured to the requirements of both Canadian and U.S. Standards) or with adjacent indicator 'US' for US only or without either indicator for Canada only.

The manufacturer is required to apply the following markings:

- Products shall be marked with the markings specified by the particular product standard.
- Products certified for Canada shall have all Caution and Warning markings in both English and French.

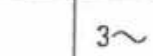
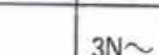
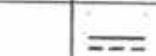
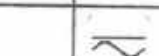
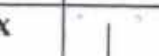
Additional bilingual markings not covered by the product standard(s) may be required by the Authorities Having Jurisdiction. It is the responsibility of the manufacturer to provide and apply these additional markings, where

Nameplate adhesive label material approval information:

On the Equipment Exterior:
Equipment is plainly marked in a permanent manner in a place where the details will be readily visible after installation with the following:

- The CSA applicable mark / / with optional reference to Standard, CAN/CSA-C22.2 No. 60601-1:08 and ANSI/AAMI ES60601-1:2005 as per adopted IEC 60601-1:2005 3rd edition
- Manufacturer's identification: Name and/or CSA file number on the same label as the CSA Mark. The name and/or trademark should appear elsewhere on the equipment if only the file number is used on this label.
- Catalogue/Model/Type designation.
- Date of manufacture: Month and year of manufacture or date code. If a serial number is used instead of date of manufacture, a record of serial numbers shall be kept traceable to date of manufacture. (Not related to date of sale).
- Marking on the unit that indicates the manufacturing location if the equipment is manufactured at more than one factory location.
- Complete electrical ratings; in volts (V), hertz (Hz), and amperes(A), Volt-amperes (VA) or Watts (W) with the IEC 60417-5032 alternating current symbol adjacent to the marked voltage and dc current symbol IEC 60417-5031 for each model.
- The IEC 60417-5333 "Type BF " symbol for degree of protection against electric shock; If there is more than one applied part with different degrees of protection, the relevant symbols shall be clearly marked on such applied parts or on or near relevant outlets.
- The Fuse rating, Volts and type adjacent to the accessible fuses or fuse-holder; (A, V, type)
- The IEC 417-5021 equipotential symbol adjacent to the equipotential earth terminal.
- Interchangeable fuses accessible only with the aid of a tool shall be identified either by type and rating next to the fuse, or by at least a reference traceable in the Technical Manual.
- The "OPERATING INSTRUCTIONS" the ISO 7000-1641 symbol on the nameplate, and the ISO 7000-0434A symbol marked near output
- On the power supply cord or on the equipment there is a tag or label indicating that "GROUNDING RELIABILITY CAN ONLY BE ACHIEVED WHEN EQUIPMENT IS CONNECTED TO AN EQUIVALENT RECEPTACLE MARKED 'HOSPITAL ONLY' OR 'HOSPITAL GRADE' " or equivalent wording.
- The IEC 417-5008 and 417-5007 symbols (I and O) adjacent to the main power switch indicating "ON and OFF" positions.

The following General Symbols (Table D.1) shall be applied as indicated

Indicate X in column if used	Symbol	Standard Reference	Title	Indicate X in column if used	Symbol	Standard Reference	Title
X		IEC 60417-5032	Alternating current			IEC 60417-5010	"ON" / "OFF" (push-push)
		IEC 60417-5032-1	Three-phase alternating current			IEC 60417-5011	"ON" / "OFF" (push button)
		IEC 60417-5032-2	Three-phase alternating current with neutral			IEC 60417-5264	"ON" for part of the EQUIPMENT
		IEC 60417-5031	Direct current			IEC 60417-5265	"OFF" for part of the EQUIPMENT
		IEC 60417-5033	Both direct and alternating current			IEC 60417-5638	Emergency stop
		IEC 60417-5019	Protective earth (ground)			IEC 60417-5840	TYPE B APPLIED PART
		IEC 60417-5017	Earth (ground)	X		IEC 60417-5333	TYPE BF APPLIED PART
X		IEC 60417-5021	Equipotentiality			IEC 60417-5335	TYPE CF APPLIED PART
		IEC 60417-5172	CLASS II equipment			IEC 60417-5841	Defibrillation-proof TYPE B APPLIED PART
X		ISO 7000-0434A	Caution risk of danger or Attention, consult ACCOMPANYING DOCUMENTS			IEC 60417-5334	Defibrillation-proof TYPE BF APPLIED PART
X		ISO 7000-1641	Operating Instructions			IEC 60417-5336	Defibrillation-proof TYPE CF APPLIED PART
X		IEC 60417-5007	"ON" (power)			IEC 60417-5036	Dangerous voltage

X		IEC 60417-5008	"OFF" (power)			ISO 7000-1051	Do not reuse
		IEC 60417-5016 *	Fuse	X		IEC 60417-5041*	Caution , hot surface

* Note: Not part of the TABLE D.1

The following Safety Signs (Table D.2) shall be applied as indicated

Indicate X in column if used	Safety Sign	Standard Reference	Title	Indicate X in column if used	Safety Sign	Standard Reference	Title
		ISO 7010-W001	General warning sign			ISO 7010-M001	General mandatory action sign
		ISO 60878/ISO 3864-B.3.6	Caution risk of electric shock or Attention Dangerous Voltage			IEC 60878 Safety 01	Follow operating instructions
		ISO 7010-xxx2	Pushing prohibited			ISO-7010-M002	Refer to instruction manual/ booklet
		ISO 7010-xxx3	Sitting prohibited			Figure 14 of IEC 60825-1*	Warning label - Hazard symbol Radiation of laser apparatus
		ISO 7010-xxx4	Stepping prohibited				

* Note: Not part of the TABLE D.2

On the Equipment Interior:

- The IEC 60417-5019 "Protective earth" symbol adjacent main protective earth terminal;

Note Jurisdictions in Canada may require these markings to be also in French. It is the responsibility of the Customer to provide bilingual marking, where applicable, in accordance with the requirements of the Provincial Regulatory Authorities. It is the responsibility of the Customer to determine this requirement and have bilingual wording added to the "Markings".

Marking Method: The above markings are made via silk screening, die stamping, moulding or on CSA certified or UL recognized adhesive nameplate material compatible with the surface used, or other equivalent permanent means that can pass the label rub test as per 7.1.3

ACCOMPANYING DOCUMENTS

ME EQUIPMENT shall be accompanied by documents containing at least the instructions for use and a technical description. The ACCOMPANYING DOCUMENTS shall be regarded as a part of the ME EQUIPMENT.

The ACCOMPANYING DOCUMENTS shall identify the ME EQUIPMENT by including, as applicable, the following:

- Name or trade-name of the MANUFACTURER and an address to which the RESPONSIBLE ORGANIZATION can refer;
- MODEL OR TYPE REFERENCE

The ACCOMPANYING DOCUMENTS shall specify any special skills, training and knowledge required of the intended OPERATOR or the RESPONSIBLE ORGANIZATION and any restrictions on locations or environments in which the ME EQUIPMENT can be used.

The ACCOMPANYING DOCUMENTS shall be written at a level consistent with the education, training and any special needs of the person(s) for whom they are intended.

SPECIAL ADVICE FOR FIELD REPRESENTATIVES

1. Markings as above shall appear on each medical device.

2. The protective earthing conductor shall be green or green/yellow.

3. The medical device shall be marked with a fixed warning notice stating that transport may be undertaken only in a certain position which is clearly described in the instructions for use or illustrated by inscription on the equipment.

4. The supply cord, if hard-wired into the unit, shall have the following colour coded wires:
Neutral - white or natural grey; supply - black, or red. Exceptionally the following colours can be accepted, Neutral - blue, supply - brown when identified in the user/installation manual.

5. The operator's manual shall contain instructions for replacement of parts subject to deterioration.

6. A correctly rated fuse link shall be fitted in each supply lead, except for PERMANENTLY INSTALLED Medical Electrical Equipment; the neutral conductor shall not be fused.

7. There shall be no indicator lights that are red in color except to indicate a warning of danger or need for urgent action.

8. Component Substitution

a) Critical components (those identified by mfr name, cat no) are not eligible for substitution without evaluation and report updating.
b) Component descriptions marked with the identifier "(CT)" are subject to annual pickup and Conformity Testing.
c) Component descriptions marked with the identifier "(INT)" are the only components that are eligible for substitution at the factory.
d) Substitution of a CSA Certified component with a component "Certified" or "Listed" by another organization may result in annual sample pickup and Conformity Testing.
e) Substitution of a "Certified" or "Listed" component with a component that is "Recognized" or "Accepted" is not permitted without evaluation and report updating.

9. The shipping package shall be marked with the prescribed transport and storage environmental conditions such as humidity range, atmospheric pressure range and temperature range. The range of environmental conditions for shipping shall be disclosed by the manufacturer and indicated in the user manual. The units shall be as per the ISO 31 or ISO 80000-1 standard (metric units) and units outside the SI unit system as indicated in TABLE 1 of the IEC 60601-1:2005 or other types of units (Imperial units) can be used as long as the metric units are included Example: Celsius and Fahrenheit, Meters and Feet.

Environmental Conditions for Shipping	Environmental Conditions for Storage
Temperature: e.g. -40 to +70°C	Temperature: e.g. -40 to +70°C

Relative Humidity: e.g 10-100% RH	Relative Humidity: e.g 10-100% RH
Altitude: e.g. 500 to 1060 hPa	Altitude: e.g. 500 to 1060 hPa

10. The accompanying documents include a glossary of symbols used on the product and in accompanying documents. The symbols or safety signs applied to the medical device shall be explained in the accompanying documents. Examples include: Alternating Current, Protective Earth, Type B, On, Off, Caution and Safety symbols and signs, Equipotentiality.

11. All markings, symbols and warning statements appearing on the equipment appear in each of the accompanying documents.

12. For medical device that may be serviced by the RESPONSIBLE ORGANIZATION, the technical description includes a statement that the supplier will make available on request circuit diagrams, component part lists, etc.

13. Internal wiring is CSA certified, secured and routed away from sharp edges and surfaces of pcb's.

14. Safety Risk Management / ISO14971:

    When safety risk management documents which are updated/modified that would affect the safety of the medical device, the certification report must be reviewed to remain in compliance.

ALTERATIONS

1. The units are marked as noted under "**MARKINGS**" above.

FACTORY TESTS

The equipment at the conclusion of manufacture, before shipment, shall be subjected to the following tests which may be made at room temperature.

Applicable Factory Test (indicate by X)	Type of Factory Test
X	**Ground Continuity:** **For Grounded Units:** Each machine shall be tested for ground continuity, as follows: Each appliance that has provision for grounding by fixed wiring means or has a power-supply cord having a grounding conductor shall be tested, as a routine production-line test, to determine grounding continuity is provided between the point of connection of the equipment grounding means (grounding blade of the attachment plug in the case of a portable appliance) and the accessible dead metal parts of the appliance that are likely to become energized. Only a single test need be made if the accessible metal selected is conductively connected to all other accessible metal. Any indicating device (an ohmmeter, a battery-an-buzzer combination or the like) may be used to determine compliance.
X	**Dielectric Strength:**

Applicable Factory Test (indicate by X)	Type of Factory Test
	For Grounded Units (Class I): Each medical device shall withstand for one min, without breakdown, the dielectric strength value based on operating voltage and type of means of protection (MOOP or MOPP), this voltage shall be applied between live parts and exposed metal parts. Line and Neutral to an exposed metal parts of the enclosure: 1500 Vac **Transformers Connected to Vac Supply:** Each transformer before assembly into the medical device shall be subjected to the following dielectric strength tests for a period of one minute, without breakdown: A Vac potential applied between each winding and the core and metal enclosure, with all other windings grounded to the core and metal enclosure. The test potential shall be: (a) Primary to core - 1500 Vac (1000 Vac if operating voltage is 120 Vac). (b) Primary to secondary - 4000 Vac (3000 Vac if operating voltage is 120 Vac). (c) Secondary to core - 500 Vac. Note: Although ac voltages are quoted above, coupling components within the product may require the tests be conducted using dc voltages or peak voltages. Where dc voltages are used, the test values are increased by 1.414 times the ac voltages. The test period may be shortened by using a potential 20 percent higher for one second. Transformer manufacturer's written agreement to conduct Dielectric Strength Test on 100 percent production will be acceptable, to exclude this transformer component to be re-tested. **For Double Insulated Units (Class II) Having Exposed Metal Parts:** The medical device at the conclusion of manufacture, before shipment, shall withstand for one minute, without breakdown, the application of : 3000 Vac between live parts and exposed non-current-carrying metal parts. **For Double Insulated Units (Class II) Not Having Exposed Metal Parts:** The equipment at the conclusion of manufacture, before shipment, shall withstand for one minute, without breakdown, the application of : 3000 Vac between live parts and metal foil in contact with plastic enclosure. **For 3 phase products:** The plate rating (reference voltage) of that medical device shall be tested according as per Test Voltages indicated in TABLE 6 and/or TABLE 7 of the IEC 60601-1 3rd standard. 1500 Vac between live parts and exposed non-current-carrying metal parts. Warning: The factory test(s) specified may present a hazard of injury to personnel and/or property and should only be performed by persons knowledgeable of such hazards and under conditions designed to minimize the possibility of injury.

Applicable Factory Test (indicate by X)	Type of Factory Test
X	**Leakage Current:** Measurement of the EARTH and/or ENCLOSURE leakage currents in Normal Condition and Single Fault shall be conducted at ambient temperature without a moisture preconditioning treatment. In cases where the number of settings of parameters of the equipment or of switches of the measuring supply circuit or of the application of a metal foil (Class II) or the application of the measuring device, to be performed during the test would be unacceptable and the results of certain tests would indicate the highest value(s), then the routine tests may be restricted to the setting(s) provoking these highest values. Warning: The factory test(s) specified may present a hazard of injury to personnel and/or property and should only be performed by persons knowledgeable of such hazards and under conditions designed to minimize the possibility of injury. Note: Manufacturers may also opt to conduct additional PATIENT and TOUCH leakage currents as part of their factory tests. Particular attention is made that these setups may be very complex and could be very time consuming to perform. Follow-Up services shall limit their activities to the factory process as indicated/documented by the manufacturer. When considering use of tests described in the IEC 60601-1 standard as factory tests, see Annex K of the IEC/TR 62354 or see IEC 62353 (recurrent tests) for alternative factory tests methods. Alternative factory tests methods can only be used when reviewed and accepted by CSA through a written approval.

INTRODUCTION

A representative sample of the subject product was examined and is described in the body of this report. Unless specifically stated otherwise, the following general definitions, terminology and construction details apply:

Nomenclature of Critical Components:

Object/part No	Manufacturer/ trademark	Type/model	Technical data	Standard	Mark(s) of conformity[1])
1: [N1], Object					[N2], [N3]

[N1] Code: [INT] [CT]

The term "(INT)", following the component name, denotes a certified component that can be replaced by one from another certified source (approved by OSHA/SCC accredited body for the same application) provided that it has an equivalent rating, configuration (size, orientation, mounting) and that applicable minimum creepage and clearance distances are maintained from live parts to bonded metal parts and secondary parts.

The term "(CT)", following the component name, denotes a component that is subject to periodic re-testing unless evidence of re-testing equivalent to the CSA program is available.

[N2] Code: Agency Approvals Logos/Marks

"CSA or  **"** = CSA Certified for Canada only

"CSAus or  **"** CSA Certified for USA only

"eCSAus or  **"** CSA Certified for Canada and USA

"UR or  **"** = UL Recognized for USA only, **"cUR or**  **"** = UL Recognized for Canada only,
"cURus or  **"** = UL Recognized for Canada and USA

"UL or  **"** = UL Listed for USA only, **"cUL or**  **"** = UL Listed for Canada only, **"cULus or** **"** = UL Listed for Canada and USA.

Note: Other Agency approval Logos/marks can also be used.

#: Pound Sign: The "#" the pound denotes that the used Monogram does not appear on the component. A pound behind any other test house's logo/mark denotes that their monogram does not appear on the component.

Accepted: The Accepted word means tested in end-product to applicable standard of that end-product. That component meets all the requirements of the end equipment or system.

[N3] Code: CSA Master Contract number (123456) or UL or UR Licence number (E123456).

Other Definitions

Mechanical Construction: Unless otherwise specified, all mechanical parts are provided with lock washers or other equivalent means to prevent separation of mechanical parts. Screws between metal parts, covers, etc. employ star washers or masked screw heads and prevents paint build up to insure good electrical continuity between parts. All accessible dead metal parts, including covers, screen, brackets, and fan guards are readily connected with bolts, straps, or wires to the housing or frame. Fuse holders and rotational switches are prevented from rotation by a positive means such as keying, the use of lock washers or other equivalent means.

All exposed edges, projections and corners of the enclosure, frame, guards and the like are smooth, well rounded and free from burrs. All surfaces in contact with moving internal wiring or cables are smoothed to prevent abrasion of insulation. All ferrous metal parts are painted, plated, or protected by equivalent means to prevent corrosion, except for bearing and latching surfaces.

Solder Connections: All connections are made mechanically secure prior to soldering.

Dimensions: All dimensions specified are approximations only, and shown in millimetres (mm).

Internal Wiring: All primary and grounding circuit conductors are Certified and UL Recognized, rated min 80°C, 300 V ac. All wiring is suitably routed and secured away from sharp edges and moving parts to prevent chafing of the insulation. Alternatively, additional insulation is provided where the wiring passes over sharp edges and through holes. All mains circuit wiring shall be doubly secured at all connection points.

Crimp Connectors: All crimp-type connectors used in primary and grounding circuits are  or appropriately sized for the gauge of conductors used, vinyl insulated (optional for grounding), rated min 90°C, 250 Vac.

Connectors: All connectors used in primary circuits are  or , appropriately sized for the number and gauge of conductors used, rated min 250 Vac.

Printed Circuit Boards (PC-B): All PC-B's are made of paper phenolic, paper epoxy or glass epoxy, min 1.6 mm thick  , unless circuit is limited to less than 15 W.

Bonding: All accessible metal parts liable to become energized are acceptably connected together, and to the grounding means, by straps and/or conductors, bolts, screws and star washers (to ensure surface coating penetration), in conformance to Clause 3.4 of CSA Standard C22.2 No. 0.4.

SPECIAL INSTRUCTIONS FOR FIELD SERVICES

1. Component descriptions marked with either the "(INT)" or "(INT*)" identifiers may be substituted with other components providing the requirements specified under the notes in the "Description" are complied with.

COMPONENT SPECIAL PICKUP

1. Component descriptions marked with the identifier "(CT)" are subject to annual pickup and Conformity Testing.

DESCRIPTION

Notes:

1. Component Substitution
   a) Critical components (those identified by mfr name, cat no), which are NOT identified with either "INT" or "INT*" are not eligible for substitution without evaluation and report updating
   b) The term "INT" means a "Certified" and/or "Listed" (or a "Recognized" and/or "Accepted") component may be replaced by one "Certified" and/or "Listed" by another certification organization accredited by the appropriate accreditation body or scheme requirements to the correct standard, for the same application; providing the applicable country identifiers are included and requirements in item "d" below are complied with.
   c) The Term "(INT*)" means a "Recognized" and/or "Accepted" component may be replaced by a component that is CSA Certified. The applicable country identifiers shall be included, the requirements in item "d" below as well as any "conditions of suitability" for the component (as recorded in this descriptive report) shall be complied with;
   d) Components which have been substituted, must be of an equivalent rating, configuration (size, orientation, mounting) and the applicable minimum creepage and clearance distances are to be maintained from live parts to bonded metal parts and secondary parts.
   e) Substitution of a "Certified" and/or "Listed" component with a component that is "Recognized" or "Accepted" is not permitted without evaluation and report updating.
   f) Substitution of a "Recognized" and/or "Accepted" component by one that is not CSA Certified is not permitted without a proper evaluation as well as a report update because the Conditions of Acceptance of the original component may be different than the Conditions of Acceptance of the substitute component.

General: The fiberoptic light source is a portable light source intended for use in operating rooms by doctors during endoscopic procedures. Equipment is a light source not intended for direct connection the patient, but rather through a non-conductive fiber-optic cable.

Models S180T, S300T, and S400T are identical in construction and layout. The differences are within the lamp and power supplies incorporated within the unit. All models have been investigated for a maximum operating ambient of 40°C and for continuous operation.

IB6620240 is identical to the Model Titan S400T with the modifications on the front panel, the air baffle/diverter at the back and higher CFM fan.

All internal wiring is reliably routed and secured away from sharp edges having a radius less than 1.5mm.
Additional insulation is provided where wiring passes over sharp edges and through holes.

Switching components are secured by the method suggested by their construction and manufacturer.

Model Similarity:

The following models are identical in construction to model S180T. The critical components, sheet metal design, and other controlled aspects would not change. The only differences would be case color and graphics:

S180T-IND, S180T-CMP, T-LS180130408, T-LS180130415, T-LS180130422

The following models are identical in construction to model S300T. The critical components, sheet metal design, and other controlled aspects would not change. The only differences would be case color and graphics:

S300T-IND, S300T-CMP, T-LS300130409, T-LS300130416, T-LS300130423

The following models are identical in construction to model S400T. The critical components, sheet metal design, and other controlled aspects would not change. The only differences would be case color and graphics:

S400T-IND, S400T-CMP, T-LS400130410, T-LS400130417, T-LS400130424

Notes:

b) The term "INT" means a "Certified" and/or "Listed" (or a "Recognized" and/or "Accepted") component may be replaced by one "Certified" and/or "Listed" by an organization (accredited by OSHA/SCC), for the same application; providing the applicable country identifiers are included and requirements in item "d" below are complied with.

c) The term "INT*" means a "Recognized" and/or "Accepted" component may be replaced by one "Recognized" and/or "Accepted" by an organization (accredited by OSHA/SCC), for the same application, providing the applicable country identifiers are included, the component is **also** CSA Certified, the requirements in item "d" below are complied with and any "conditions of suitability" for the component (as recorded in this descriptive report) are complied with.

d) Components which have been substituted, must be of an equivalent rating, configuration (size, orientation, mounting) and the applicable minimum creepage and clearance distances are to be maintained from live parts to bonded metal parts and secondary parts.

LIST OF CRITICAL COMPONENTS

Object/part No	Manufacturer/ trademark	Type/model	Technical data	Standard	Mark(s) of conformity[1])
1: External Enclosure	Sunoptic Technologies	Metal	Construction / Material: Painted metal, two-piece construction held together by screws. Dimensions: 35.7cm (L) by 31.5 cm (D) by 14.2cm (W) by 1.57 mm thick. Lamp access door on side of enclosure, approximately 13.6 cm by 10 cm.	CSA 60601-1 ANSI/AAMI ES60601-1 IEC 60601-1	Accepted, tested in overall end product.
1a: External Ventilation Openings	Sunoptic Technologies	Enclosure Ventilation Openings	Enclosure Right Side: Four columns of fifteen openings on right side of enclosure. Dimensions of each	CSA 60601-1 ANSI/AAMI ES60601-1 IEC 60601-1	Accepted, tested in overall end product.

Object/part No	Manufacturer/ trademark	Type/model	Technical data	Standard	Mark(s) of conformity[1])
			opening: 25.4 mm by 2.3 mm. Enclosure Bottom: Three columns of thirty openings and one column of twenty-seven openings on bottom side of enclosure. Dimensions of each opening: 25.4 mm by 2.3 mm. Fan Ventilation Opening: Overall Diameter: Approx. 120.0mm. Provided with a fan grille secured to chassis via 4 screws.		
2: Marking and Labelling System (INT)	Brady	THT-19-423-1	Material: Polyester Dimensions: 50 x 75 x 0.5 mm Color: White Gloss Impression type: Thermal Transfer	UL 969	
3: Detachable Power Cord Set (INT)	Interpower	86610710	Type SJT, 3 Conductor 18AWG (min), NEMA 5-15P to IEC 320-C13 Rated: 125 V min, 60° C Hospital Grade type attachment cap (green dot)	CSA 21 CSA 42 UL 817	
4: Type BF Patient Applied Part Output Connector (INT)	Sunoptic Technologies	Light Guide Adapter	Mechanical turret style mounts for various types of fiberoptic cables	CSA 60601-1 ANSI/AAMI ES60601-1 IEC 60601-1	Accepted, tested in overall end product.

Additional information:

Grounding and Bonding Details:

Grounding: One min No 18 AWG green and yellow grounding conductor is mechanically secured by a certified quick-disconnect terminal to the ground terminal at one end, the other end terminates singly in a crimp type, closed loop connector, secured to the chassis by a min No 6, plated or non-ferrous threaded stud, nut and star-washer.

The following components are for model S180T:

Object/part No	Manufacturer/ trademark	Type/model	Technical data	Standard	Mark(s) of conformity[1])
5: Lamp Switch	Carling Technologies	LRGSCK 511-CB-W-0/012V	Rated: 6-24V. Located in the secondary low voltage circuit.	CSA 60601-1 ANSI/AAMI ES60601-1 IEC 60601-1	Accepted, tested in overall end product.
6: Hour Meter (INT)	Curtis Instruments Inc.	Model: 701FR001O 1248 D2060A	Rated: 12-48Vdc, 0.8mA max.	UL 863	
7: Appliance Inlet (INT)	Schurter AG	DC11.0031.001	Rated: 250V, 12A	CSA 42 UL 498	
8: EMI Filter (INT)	Schaffner	FN2090B-6-06	Rated: 110/250Vac, 50/60Hz, 6A	CSA 8 UL 1283	
9: Circuit Breaker (2 provided) (INT)	Schurter AG	T9-611P-4A	Rated: 240Vac, 4A	CSA 235 UL 1077	
10: Power Supply	Excelitas Technologies Corp. (Perkin Elmer Optoelectronics)	PS175-12	Rated Input: 100-240Vms, 50-60Hz. Rated Output: 175W max.	CSA 601.1 UL 60601-1	
10a: Alternate, Power Supply	Warner Power Conversion LLC	P/N: 70-223201	Rated Input: 100/120/230Vac, 47-63Hz. Rated Output: 175W max.	CSA 601.1 UL 60601-1	
11: Lamp (INT)	Perkin Elmer Optoelectronics	PE175BUVM	Rated: 12.5V, 14A 175W Xenon lamp	CSA 60601-1 ANSI/AAMI ES60601-1 IEC 60601-1	Accepted, tested in overall end product.
11a: Lamp, Alternate (INT)	Perkin Elmer Optoelectronics	PE175BFM	Rated: 12.5V, 14A. 175W Xenon lamp	CSA 60601-1 ANSI/AAMI ES60601-1 IEC 60601-1	Accepted, tested in overall end product.
11b: Alternate Power Supply	MHC Technologies	MHCT400CXE	Rated Input: 100-240Vac, 50/60Hz, 7.5 A max. Rated Output: Aux: 12 Vdc, 3 A Lamp: 30 A, 475 W	CSA 60601-1 ANSI/AAMI ES60601-1	
12: Fan (INT)	NMB	Model: FBA12G12L	Rated: 12Vdc, 0.24A, 68CFM	CSA 113 UL 507	
13: Interlock Switch (INT)	Honeywell	V7-2B17D8	Rated: 250 Vac, 11A	CSA 61058-1 CSA 55 UL 61058-1	

Object/part No	Manufacturer/ trademark	Type/model	Technical data	Standard	Mark(s) of conformity[1])
				UL 1054	
14: Mains Wiring (INT)	Southwire Co.	TFFN	Rated: Min. 600Vac, 105°C, 16AWG	UL 66	
15: DC Lamp Wiring (INT)	Harbor Industries (Canada) LTD	Style 3239	Rated: 14AWG, 40KvDC, VW-1	UL 758	
The following components are for model S300T:					
16: Lamp Switch	Carling Technologies	LRGSCK 511-CB-W-0/012V	Rated: 6-24V Located in the secondary low voltage circuit.	CSA 60601-1 ANSI/AAMI ES60601-1 IEC 60601-1	Accepted, tested in overall end product.
17: Hour Meter (INT)	Curtis Instruments Inc.	Model: 701FR001O 1248 D2060A	Rated: 12-48Vdc, 0.8mA max.	UL 863	
18: Appliance Inlet (INT)	Schurter AG	DC11.0031.001	Rated: 250V, 12A	CSA 42 UL 498	
19: EMI Filter (INT)	Schaffner	FN2090B-6-06	Rated: 110/250Vac, 50/60Hz, 6A	CSA 8 UL 1283	
20: Circuit Breaker (2 provided) (INT)	Schurter AG	T9-611P-5A	Rated: 240Vac, 5A	CSA 235 UL 1077	
21: Power Supply	Warner Power Conversion LLC	P/N: 70-223221	Rated Input: 100/120/230Vac, 4.3/3.6/1.8, 47-63Hz Rated Output: 300W max.	CSA 601.1 UL 60601-1	
21a: Alternate Power Supply	MHC Technologies	MHCT400CXE	Rated Input: 100-240Vac, 50/60Hz, 7.5 A max. Rated Output: Aux: 12 Vdc, 3 A Lamp: 30 A, 475 W	CSA 60601-1 ANSI/AAMI ES60601-1	
22: Lamp (INT)	Vaconics Lighting	VAC300-FM-CMB	Rated: 14V, 22A 300W Xenon lamp	CSA 60601-1 ANSI/AAMI ES60601-1 IEC 60601-1	Accepted, tested in overall end product.
22a: Alternate, Lamp (INT)	Sunoptic Technologies	P/N: SSX0035 Model: V300-Y15	Rated: 14V, 22A 300W Xenon lamp	CSA 60601-1 ANSI/AAMI ES60601-1	Accepted, tested in overall end product.

Object/part No	Manufacturer/ trademark	Type/model	Technical data	Standard	Mark(s) of conformity[1])
				IEC 60601-1	
23: Fan (INT)	NMB	Model: FBA12G12M	Rated: 12Vdc, 0.45A, 86CFM	CSA 113 UL 507	
24: Interlock Switch (INT)	Honeywell	V7-2B17D8	Rated: 250 Vac, 11A	CSA 61058-1 CSA 55 UL 61058-1 UL 1054	
25: Mains Wiring (INT)	Southwire Co.	TFFN	Rated: Min. 600Vac, 105°C, 16AWG	UL 66	
26: DC Lamp Wiring (INT)	Harbor Industries (Canada) LTD	Style 3239	Rated: 10AWG, 40KvDC, VW-1	UL 758	
The following components are for model S400T:					
27: Lamp Switch	Carling Technologies	LRGSCK 511-CB-W-0/012V	Rated: 6-24V Located in the secondary low voltage circuit.	CSA 60601-1 ANSI/AAMI ES60601-1 IEC 60601-1	Accepted, tested in overall end product.
28: Hour Meter (INT)	Curtis Instruments Inc.	Model: 701FR001O 1248 D2060A	Rated: 12-48Vdc, 0.8mA max.	UL 863	
29: Solid State Timer (INT)	SSAC / ABB	P/N: K5DB115MP	Rated: 12Vdc, 1A, time delay: 5mins, Inrush 10A	UL 508	
29a: Timer, Alternate	Sunoptic Technologies	I4009426	Rated: 12 Vdc, 1 A	CSA 60601-1 ANSI/AAMI ES60601-1 IEC 60601-1	Accepted, tested in overall end product.
30: Appliance Inlet (INT)	Schurter AG	DC11.0031.001	Rated: 250V, 12A	CSA 42 UL 498	
31: EMI Filter (INT)	Schaffner	FN2090B-6-06	Rated: 110/250Vac, 50/60Hz, 6A.	CSA 8 UL 1283	
32: Circuit Breaker (2 provided)	Schurter AG	T9-611P-6A	Rated: 240Vac, 6A.	CSA 235 UL 1077	
33: Power Supply	Warner Power Conversion LLC	P/N: 70-400000 Rev 4B	Rated Input: 120/230Vac, 4.5/2.3A, 47-63Hz	CSA 601.1 UL 60601-1	Tested with system

Object/part No	Manufacturer/ trademark	Type/model	Technical data	Standard	Mark(s) of conformity[1])
		Igniter PCB P/N: 20-216400-2	Rated Output: 400W max.	IEC 60601-1	(Refer to Ills 1 & 2)
33a: Alternate Power Supply	MHC Technologies	MHCT400CXE	Rated Input: 100-240Vac, 50/60Hz, 7.5 A max. Rated Output: Aux: 12 Vdc, 3 A Lamp: 30 A, 475 W	CSA 60601-1 ANSI/AAMI ES60601-1	
34: Lamp (INT)	Vaconics Lighting	V400Y1 or V400Y2	Rated: 14.5V, 27.5A	CSA 60601-1 ANSI/AAMI ES60601-1 IEC 60601-1	Accepted, tested in overall end product.
34a: Alternate, Lamp (INT)	Sunoptic Technologies	P/N: SSX0040 Model: V400-Y5	Rated: 14.5V, 27.5A 400W Xenon lamp	CSA 60601-1 ANSI/AAMI ES60601-1 IEC 60601-1	Accepted, tested in overall end product.
35: Fan (INT)	NMB	Model: FBA12G12M	Rated: 12Vdc, 0.45A, 86CFM	CSA 113 UL 507	
35a: Alternate, Fan (INT)	NMB-MAT	Model: FBA12G12H	Rated: 12Vdc, 1A, 103CFM	CSA 113 UL 507	
35b: Alternate, Fan (INT)	Sunon	Model: MEC0381V1-000-A99	Rated: 12Vdc, 0.845A, 138CFM	CSA 113 UL 507	
36: Interlock Switch (INT)	Honeywell	V7-2B17D8	Rated: 250 Vac, 11A	CSA 61058-1 CSA 55 UL 61058-1 UL 1054	
37: Mains Wiring (INT)	Southwire Co.	TFFN	Rated: Min. 600Vac, 105°C, 16AWG	UL 66	
38: DC Lamp Wiring (INT)	Harbor Industries (Canada) LTD	Style 3239	Rated: 10 AWG, 40KvDC, VW-1	UL 758	
Titan Tx350A, Tx350D and Tx450D components					
External Enclosure	Sunoptic Technologies	Metal	Construction / Material: Painted metal, Four-piece construction held together by screws. Dimensions: 33cm (L) by 40.5 cm (D) by 15.4cm (W) by 2.36 mm	CSA 60601-1 ANSI/AAMI ES60601-1 IEC 60601-1	Accepted, tested in overall end product.

Object/part No	Manufacturer/ trademark	Type/model	Technical data	Standard	Mark(s) of conformity[1])
			thick. Lamp access door on side of enclosure, approximately 16.1 cm by 10.4 cm.		
External Ventilation Openings	Sunoptic Technologies	Enclosure Ventilation Openings	Enclosure Bottom: Three patterns of 6.35 square holes Pattern 1 (Light output) 11 columns x 10 rows Pattern 2 11 columns x 10 rows Pattern 3 8 columns x 10 rows Fan Ventilation Opening: Overall Diameter: Approx. 120.0mm. Provided with a fan grille secured to chassis via 4 screws.	CSA 60601-1 ANSI/AAMI ES60601-1 IEC 60601-1	Accepted, tested in overall end product.
Marking and Labelling System (INT)	Brady	THT-19-423-1	Material: Polyester Dimensions: 50 x 75 x 0.13 mm Color: White Gloss Impression type: Thermal Transfer	UL 969	
Detachable Power Cord Set (INT)	Interpower	86610710	Type SJT, 3 Conductor 18AWG (min), NEMA 5-15P to IEC 320-C13 Rated: 125 V min, 60° C Hospital Grade type attachment cap (green dot)	CSA 21 CSA 42 UL 817	
Type BF Patient Applied Part Output Connector (INT)	Sunoptic Technologies	Light Guide Adapter	Mechanical turret style mounts for various types of fiberoptic cables	CSA 60601-1 ANSI/AAMI ES60601-1 IEC 60601-1	Accepted, tested in overall end product.

Additional information:

Grounding and Bonding Details:

Grounding: One min No 18 AWG green and yellow grounding conductor is mechanically secured by a certified quick-disconnect terminal to the ground terminal at one end, the other end terminates singly in a crimp type, closed loop connector, secured to the chassis by a min No 6, plated or non-ferrous threaded stud, nut and star-washer.

Object/part No	Manufacturer/ trademark	Type/model	Technical data	Standard	Mark(s) of conformity[1])
The following components are for model Tx350A:					
Front Panel Switch	E-Switch	Black: PV4F2G011-344 Stainless Steel: PV4F2G0SS-344	2A, 24VDC Located in the secondary low voltage circuit.	UL94 V-2 RoHS IP65	Accepted, tested in overall end product.
Hour Meter (INT)	Curtis Instruments Inc.	Model: 701FR001O 1248 D2060A	Rated: 12-48Vdc, 0.8mA max.	UL 863	
Appliance Inlet (INT)	Schurter AG	DC11.0031.001	Rated: 250V, 10A	CSA 42 UL 498	
EMI Filter (INT)	Schaffner	FN2090B-6-06	Rated: 110/250Vac, 50/60Hz, 6A	CSA 8 UL 1283	
Circuit Breaker (2 provided) (INT)	Schurter AG	T9-711C-7A	240VAC, 7A	CSA 235 UL 1077	
Power Supply Option 1	Warner Power Conversion LLC	P/N: 70-223221	Rated Input: 100/120/230Vac, 4.3/3.6/1.8, 47-63Hz Rated Output: 300W max.	CSA 601.1 UL 60601-1	
Power Supply Option 2	MHC Technologies	MHCT400CXE	Rated Input: 100-240Vac, 50/60Hz, 7.5 A max. Rated Output: Aux: 12 Vdc, 3 A Lamp: 30 A, 475 W	CSA 60601-1 ANSI/AAMI ES60601-1	
Lamp (INT)	Luxtel	1857	Rated: 14V, 22A 300W Xenon lamp	CSA 60601-1 ANSI/AAMI ES60601-1 IEC 60601-1	Accepted, tested in overall end product.

Object/part No	Manufacturer/ trademark	Type/model	Technical data	Standard	Mark(s) of conformity[1])
Lamp Fan (INT)	Delta Electronics	AUB1212H-CK15	13.2VDC, 0.39A, 88.6CFM		
Ballast Fan (INT)	Delta Electronics	Model: BFB0712L-AF00	Rated: 13.8VDC, 0.10A, 9.26CFM	CSA 60601-1 ANSI/AAMI ES60601-1 IEC 60601-1	Accepted, tested in overall end product.
Door Interlock Switch (INT)	Honeywell	V7-2B17D8	Rated: 250 VAC, 11A	CSA 61058-1 CSA 55 UL 61058-1 UL 1054	
Lamp Engagement Switch (INT)	OMRON ELECTRONICS INC	SS-5GL-3T	SW STRAIGHT LVR SPST-NO 5A 125V		
Mains Wiring (INT)	Southwire Co.	TFFN	Rated: Min. 600VAC, 105°C, 16AWG	UL 66	
DC Lamp Wiring (INT)	Harbor Industries (Canada) LTD	Style 3239	Rated: 10 AWG, 40KVDC, VW-1	UL 758	
K Type Thermocouple (INT)	Precision Measurements	CALIBRATION-20-CFCFIB-1-4-24	K type	CSA 60601-1 ANSI/AAMI ES60601-1 IEC 60601-1	Accepted, tested in overall end product.
K Type Thermocouple (INT)	TC Direct	201-500	K type	CSA 60601-1 ANSI/AAMI ES60601-1 IEC 60601-1	Accepted, tested in overall end product.
Sunoptic Control Board	Sunoptic Technologies	034-030-12	N/A	CSA 60601-1 ANSI/AAMI ES60601-1 IEC 60601-1	Accepted, tested in overall end product.
The following components are for model: T x350D and Tx450D:					
Front Panel Switch	E-Switch	PV4F2B0SS-341 Or PV4F2H0SS-341	2A, 24VDC Located in the secondary low voltage circuit.	UL94 V-2 RoHS IP65	Accepted, tested in overall end product.

Object/part No	Manufacturer/ trademark	Type/model	Technical data	Standard	Mark(s) of conformity[1])
Appliance Inlet (INT)	Schurter AG	DC11.0031.001	Rated: 250V, 10A	CSA 42 UL 498	
EMI Filter (INT)	Schaffner	FN2090B-6-06	Rated: 110/250Vac, 50/60Hz, 6A.	CSA 8 UL 1283	
Circuit Breaker (2 provided) (INT)	Schurter AG	T9-711C-7A	Rated: 240VAC, 7A	CSA 235 UL 1077	
Power Supply	Warner Power Conversion LLC	P/N: 70-400000 Rev 4B Igniter PCB P/N: 20-216400-2	Rated Input: 120/230Vac, 4.5/2.3A, 47-63Hz Rated Output: 400W max.	CSA 601.1 UL 60601-1 IEC 60601-1	Tested with system (Refer to Ills 1 & 2)
Power Supply	MHC Technologies	MHCT400CXE	Rated Input: 100-240Vac, 50/60Hz, 7.5 A max. Rated Output: Aux: 12 Vdc, 3 A Lamp: 30 A, 475 W	CSA 60601-1 ANSI/AAMI ES60601-1	
Lamp (INT)	Luxtel	400W: 1844 300W: 1857	Rated: 14.5V, 27.5A	CSA 60601-1 ANSI/AAMI ES60601-1 IEC 60601-1	Accepted, tested in overall end product.
Lamp Fan 400W (INT)	Delta Electronics	AFB1212V HE-T50F	13.2VDC, 0.9A, 119.72CFM		
Ballast Fan 400W (INT)	Delta Electronics	BFB0712HH	13.8VDC, 0.34A, 15.33CFM	CSA 60601-1 ANSI/AAMI ES60601-1 IEC 60601-1	Accepted, tested in overall end product.
Lamp Fan 300W (INT)	Delta Electronics	AFB1212V HE-T50F	13.2VDC, 0.9A, 119.72CFM	CSA 60601-1 ANSI/AAMI ES60601-1 IEC 60601-1	Accepted, tested in overall end product.
Ballast Fan 300W (INT)	Delta Electronics	BFB0712L	13.8VDC, 0.1A, 9.26CFM	CSA 60601-1 ANSI/AAMI ES60601-1 IEC 60601-1	Accepted, tested in overall end product.
Interlock Switch	Honeywell	V7-2B17D8	Rated: 250 VAC, 11A	CSA 61058-1 CSA 55	

Object/part No	Manufacturer/ trademark	Type/model	Technical data	Standard	Mark(s) of conformity[1])
(INT)				UL 61058-1 UL 1054	
Mains Wiring (INT)	Southwire Co.	TFFN	Rated: Min. 600VAC, 105°C, 16AWG	UL 66	
DC Lamp Wiring (INT)	Harbor Industries (Canada) LTD	Style 3239	Rated: 10AWG, 40KVDC, VW-1	UL 758	
K Type Thermocouple (INT)	Precision Measurements	CALIBRATION-20-CFCFIB-1-4-24	K type	CSA 60601-1 ANSI/AAMI ES60601-1 IEC 60601-1	Accepted, tested in overall end product.
K Type Thermocouple (INT)	TC Direct	201-500	K type	CSA 60601-1 ANSI/AAMI ES60601-1 IEC 60601-1	Accepted, tested in overall end product.
Sunoptic Control Board	Sunoptic Technologies	034-030-01	N/A	CSA 60601-1 ANSI/AAMI ES60601-1 IEC 60601-1	Accepted, tested in overall end product.

PATIENT CONTACT ACCESSORIES

None provided.

TEST HISTORY/TEST HISTORY

Edition 1: Project (70052667)

This project is a report update to project 2530902 to add new models Titan Tx350A, Tx350D and Tx450D, and make correction to the CoFC to remove additional non-related projects. Project 2530902 includes 3 edition which are described below. The following test conducted with passing results to add Titan series Tx350A, Tx350D and Tx450D to the report.

1. Power Input, Clause 4.11;
2. Connection to a power source by a plug, Clause 8.4.3;
3. Ground bond test, Clause 8.6.4;
4. Leakage Current, Clause 8.7;
5. Dielectric strength, Clause 8.8.3;
6. Excessive temperature, 11.1.1;
7. Single fault condition, Clause 13.2;

Project history:

Project (2530902)

The following tests were performed on a sample of the Fiberoptic Light Source(s), Model S180T (or Titan 180), rated 100-120V~, 50/60Hz or 220-240V~, 50Hz, 250W max.; Model S300T (or Titan 300), rated 100-120V~, 50/60Hz or 220-240V~, 50Hz, 450W max.; Model S400T (or Titan 400 or IB6620240), configured for the worst case conditions. Tests were performed according to the test requirements of, CAN/CSA-C22.2 No. 60601-1-08 /AAMI ES60601-1:2005 as per adopted IEC 60601-1 3rd Edition whose tests are as shown, however details are kept in the IEC 60601-1G Test Report TRF located in a CSA Office under this project number.

Test Location: CSA International, 2805 Barranca Parkway, Irvine, CA 92606 USA

Witness Test Location (Report 1870769, Previous CSA 601.1 and UL 60601-1 C/US Certification - Projects 1870769 and 2107429): Global Advantage 180 Brodie Dr., Unit 2, Richmond Hill, ON, L4B 3K8, Canada

SUMMARY OF TESTS and RISK MANAGEMENT

CSA / ANSI/AAMI / IEC CLAUSE	CLAUSE INFORMATION	VERDICT (P, F, N/A or N/E)	
		Risk Management	Testing
4	General requirements	---	---
4.2	Risk Management Process for ME Equipment or ME System	P	---
4.3	Essential performance	P	---
4.4	Equivalent means of safety for ME Equipment or ME System	P	---
4.6	ME Equipment or ME System parts that contact the patient	N/A	---
4.7	Single-Fault Conditions for ME Equipment	P	---
4.8	Components of ME Equipment	N/A	---
4.9	Use of components with high-integrity characteristics in ME Equipment	N/A	---
4.11	Power Input	---	P
5	General requirements for testing MEE	---	---
5.7	Humidity preconditioning treatment	N/A	P
5.9.2.1	Determination of ACCESSIBLE parts	---	P
7	ME EQUIPMENT identification, marking, and documents	---	---
7.1.2	Legibility of markings	---	P
7.1.3	Durability of marking test	---	P
8	Protection against electrical HAZARDS from ME EQUIPMENT	---	---
8.4.2 c)	Accessible parts including applied parts	N/A	P

CSA / ANSI/AAMI / IEC CLAUSE	CLAUSE INFORMATION	VERDICT (P, F, N/A or N/E)	
		Risk Management	Testing
8.4.3	ME EQUIPMENT intended to be connected to a power source by a plug-measurement of voltage or calculation of stored charge 1 s after disconnection of plug from mains supply	---	P
8.4.4	Internal capacitive circuits – measurement of residual voltage or calculation of the stored charge in capacitive circuits (i.e., accessible capacitors or circuit parts) after de-energizing ME EQUIPMENT	---	N/A
8.5.2.2	Type B applied parts	N/A	N/A
8.5.2.3	PATIENT Leads - cannot be connected to earth or hazardous voltage while the PATIENT CONNECTIONS are in contact with PATIENT	N/A	N/A
8.5.5.1a	Defibrillation-proof applied parts – measurement of hazardous electrical energies	---	N/A
8.5.5.1b	Defibrillation-proof applied parts – verification of recovery time	---	N/A
8.5.5.2	DEFIBRILLATION-PROOF APPLIED PARTS or PATIENT CONNECTIONS of DEFIBRILLATION-PROOF APPLIED PARTS - Energy reduction test –measurement of Energy delivered to a 100 Ω load	---	N/A
8.6.4	Impedance and current-carrying capability of PROTECTIVE EARTH CONNECTIONS	---	P
8.7.3b	PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL & SINGLE FAULT CONDITIONS – TYPE BF APPLIED PARTS (mA r.m.s) – measurements made with a non-frequency-weighted device (uA)	---	N/A
	PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL & SINGLE FAULT CONDITIONS – TYPE CF APPLIED PARTS (mA r.m.s) – measurements made with a non-frequency-weighted device (uA)	---	N/A
	PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL & SINGLE FAULT CONDITIONS – TYPE B APPLIED PARTS (mA r.m.s) – measurements made with a non-frequency-weighted device (uA)	---	N/A
8.7.3 c	TOUCH CURRENT under NORMAL & SINGLE FAULT CONDITIONS	---	P
8.7.3 d	EARTH LEAKAGE CURRENT under NORMAL & SINGLE FAULT CONDITIONS	---	P
8.8.3 A	Dielectric strength test of solid insulating materials with safety function – MEANS OF OPERATOR PROTECTION (MOOP) - 1 min duration	---	P

CSA / ANSI/AAMI / IEC CLAUSE	CLAUSE INFORMATION	VERDICT (P, F, N/A or N/E)	
		Risk Management	Testing
8.8.3 B	Dielectric strength test of solid insulating materials with safety function – MEANS OF PATIENT PROTECTION (MOPP) - 1 min duration	---	N/A
8.8.4.1	Mechanical strength and resistance to heat of insulations	N/A	P
8.9.2	Short circuiting of each single one of the CREEPAGE DISTANCES and AIR CLEARANCES for insulation in the MAINS PART between parts of opposite polarity in lieu of complying with the required measurements in 8.9.4	---	P
8.9.3.2	Thermal cycling tests on one sample of insulating compound forming solid insulation between conductive parts	---	N/A
8.9.3.4	Thermal cycling tests on one sample of cemented joint (see 8.9.3.3)	---	N/A
8.10.3	Connections between different parts of ME EQUIPMENT	---	P
8.11.3.5	Cord anchorage	---	N/A
8.11.3.6	Cord guards	---	N/A
9	Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	---	---
9.2.2.2	Measurement of gap "a" according to Table 20 (ISO 13852: 1996)	---	N/A
9.4.2.1	Instability in transport position	---	P
9.4.2.2	Instability excluding transport	---	P
9.4.2.3	Instability from horizontal and vertical forces	---	N/A
9.4.2.4.2	Force for propulsion	---	N/A
9.4.2.4.3	Movement over a threshold	N/A	N/A
9.4.3.1	Instability from unwanted lateral movement (including sliding)	---	N/A
9.4.3.2	Instability excluding transport	---	N/A
9.4.4	Grips and other handling devices	---	N/A
9.6.1	Acoustic energy – Human exposure	N/A	N/A
9.6.2.1	Audible acoustic energy	---	P
9.6.3	Hand-transmitted vibration	---	N/A
9.7.5	Pressure vessels	---	N/A
9.8.3.2 a & b	Static forces due to loading from persons	N/A	N/A
9.8.3.3	Dynamic forces due to loading from persons	---	N/A

CSA / ANSI/AAMI / IEC CLAUSE	CLAUSE INFORMATION	VERDICT (P, F, N/A or N/E)	
		Risk Management	Testing
10	Protection against unwanted and excessive radiation HAZARDS	---	---
10.1.1	Measurement of X–radiation - MEE not producing therapeutic/diagnostic X-radiation but producing ionizing radiation	---	N/A
11	Protection against excessive temperatures and other HAZARDS	---	---
11.1	Excessive temperatures in ME EQUIPMENT	---	P
11.1.1	Maximum temperature during NORMAL USE for parts other than APPLIED PARTS and parts likely to be touched TABLE 22 or 23	N/A	P
11.1.2.1	Temperatures, hot or cold surfaces, during NORMAL USE for APPLIED PARTS intended to supply heat to a PATIENT	N/A	N/A
11.1.2.2	Maximum temperature during NORMAL USE for APPLIED PARTS not intended to supply heat to a PATIENT TABLE 24	N/A	N/A
11.1.3d	Temperature of windings by change-of-resistance method	---	N/A
11.1.3 e	Measurements - Thermal Cut-outs are not de-activated	N/A	N/A
11.2.2.1	Risk of fire in an oxygen rich environment - alternative method to 11.2.2.1 a) 5) to determine existence of an ignition source	N/A	N/A
11.3	Constructional requirements for fire enclosures of ME equipment	N/A	P
11.5	ME equipment & ME systems intended for use in conjunction with flammable agents	N/A	---
11.6.2	Overflow in MEE	N/A	N/A
11.6.3	Spillage on ME equipment and ME system	N/A	N/A
11.6.5	Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS	N/A	N/A
11.6.6	Cleaning and disinfection of ME equipment and ME systems	P	P
11.6.7	Sterilization of ME equipment and ME systems	N/A	N/A
12	Accuracy of controls and instruments and protection against hazardous outputs	---	---
13	HAZARDOUS SITUATIONS and fault conditions	---	---
13.1.2	Measurement of power or energy dissipation in parts & components to waive SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances	---	P

CSA / ANSI/AAMI / IEC CLAUSE	CLAUSE INFORMATION	VERDICT (P, F, N/A or N/E)	
		Risk Management	Testing
13.2.1	General application of Single Fault Condition listed in 13.2.2 to 13.2.13as per Normal condition 8.1 a)	---	P
13.2.2	Electrical SINGLE FAULT CONDITIONS according to 8.1	---	P
13.2.3	Overheating of transformers according to 15.5	---	N/A
13.2.4	Failure of THERMOSTATS according to 13.2.13 & 15.4.2, overloading - THERMOSTATS short circuited or interrupted, the less favorable of the two	---	N/A
13.2.5	Failure of temperature limiting devices according to 13.2.13 & 15.4.2, overloading, THERMOSTATS short circuited or interrupted, the less favorable of the two:	---	N/A
13.2.6	Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate test conditions (sealed rechargeable batteries exempted)	N/A	N/A
13.2.7	Impairment of cooling that could result in a HAZARD using test method of 11.1:	---	P
	Single ventilation fans locked consecutively	---	P
	Ventilation openings on top and sides impaired by covering openings on top of ENCLOSURE or positioning of ME EQUIPMENT against walls	---	P
	Simulated blocking of filters	---	N/A
	Flow of a cooling agent interrupted	---	N/A
13.2.8	Locking of moving parts – Only one part locked at a time – Also see 13.2.10 below	---	N/A
13.2.9	Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited [1] – Also see 13.10	---	N/A
13.2.10	Additional test criteria for motor operated ME EQUIPMENT in 13.2.8 &13.2.9:	---	N/A
	For every test in SINGLE FAULT CONDITION of 13.2.8 and 13.2.9, motor-operated EQUIPMENT stared from COLD CONDITION at RATED voltage or at the upper limit of RATED voltage range for specified time:	---	N/A
	Temperatures of windings determined at the end of specified test periods or at the instant of operation of fuses, THERMAL CUT-OUTS, motor protective devices	---	N/A
	Temperatures measured as specified in 11.1.3 d)	---	N/A
	Temperatures did not exceed limits of Table 26	---	N/A
13.2.11	Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS:	---	N/A

CSA / ANSI/AAMI / IEC CLAUSE	CLAUSE INFORMATION	VERDICT (P, F, N/A or N/E)	
		Risk Management	Testing
13.2.12	Failure of parts that might result in a MECHANICAL HAZARD (See Clauses 9 & 15.3):	---	N/A
14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS	---	---
15	Construction of ME EQUIPMENT	---	---
15.1	Construction of ME equipment - Arrangements of controls and indicators of ME equipment	N/A	---
15.3.2	Push test	N/A	P
15.3.3	Impact test	N/A	P
15.3.4.1	Drop test - HAND-HELD ME EQUIPMENT	---	N/A
15.3.4.2	Portable ME equipment	N/A	N/A
15.3.5	Rough handling test	N/A	N/A
15.3.6	Mould stress relief test	---	N/A
15.4.6	Actuating parts of controls of ME EQUIPMENT – torque & axial pull tests Limitation of movement Limitation of movement	---	N/A
15.4.7.1 b)	Mechanical strength - Foot-operated control device supported an actuating force of 1350 N for 1 min	---	N/A
15.4.7.2	Accidental operation of ME EQUIPMENT - Control device of HAND-HELD and Foot-Operated	---	N/A
15.4.7.3 b	Entry of liquids – (Foot operated at least IPX1)	N/A	N/A
15.5.1.1	Overheating - Transformers	---	N/A
15.5.1.2	Transformer short circuit test short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION	---	N/A
15.5.1.3	Transformer overload test – conducted only when protective device under short-circuit test operated	---	N/A
15.5.2	Transformer dielectric strength after humidity preconditioning as per clause 5.7	---	N/A
16	ME SYSTEM	---	---
16.6.1	LEAKAGE CURRENTS in ME SYSTEM TOUCH CURRENT MEASUREMENTS	---	N/A
16.7	Protection against MECHANICAL HAZARDS	---	N/A
17	Electromagnetic compatibility		
17	Electromagnetic compatibility of ME equipment and ME systems (IEC 60601-1-2)	N/A	N/A

Project (2624096)

Report was updated to add alternate model numbers. No testing was deemed necessary.

Project (2716578)

Report was updated to add alternate power supply from MHC Technologies, model MHCT400CXE. Additional testing was required.

Test Location: CSA Group, 2805 Barranca Parkway, Irvine, CA 92606 USA

SUMMARY OF TESTS and RISK MANAGEMENT

CSA / ANSI/AAMI / IEC CLAUSE	CLAUSE INFORMATION	VERDICT (P, F, N/A or N/E)	
		Risk Management	Testing
4.11	Power Input	---	P
5.7	Humidity preconditioning treatment	N/A	P
8.4.3	ME EQUIPMENT intended to be connected to a power source by a plug-measurement of voltage or calculation of stored charge 1 s after disconnection of plug from mains supply	---	P
8.6.4	Impedance and current-carrying capability of PROTECTIVE EARTH CONNECTIONS	---	P
8.7.3 c	touch current under normal & single fault conditions	---	P
8.7.3 d	earth leakage current under normal & single fault conditions	---	P
8.8.3 A	Dielectric strength test of solid insulating materials with safety function – Means of operator protection (moop) - 1 min duration	---	P
11.1	Excessive temperatures in ME EQUIPMENT	---	P
13.2.7	Impairment of cooling that could result in a HAZARD using test method of 11.1:	---	P
	Single ventilation fans locked consecutively	---	P

Edition 2: Project (70221052)

This project adds a label for an OEM model that is identical to existing model TX350D. The model designated as NN-7013 for OEM – Nico Corporation. No additional testing or evaluation is needed. The durability and legibility tests are waved due to similar printing material and font size on the label. A sample of the label is added to this report – Markings 12.

Photo 22 – Front view – Titan Tx450D

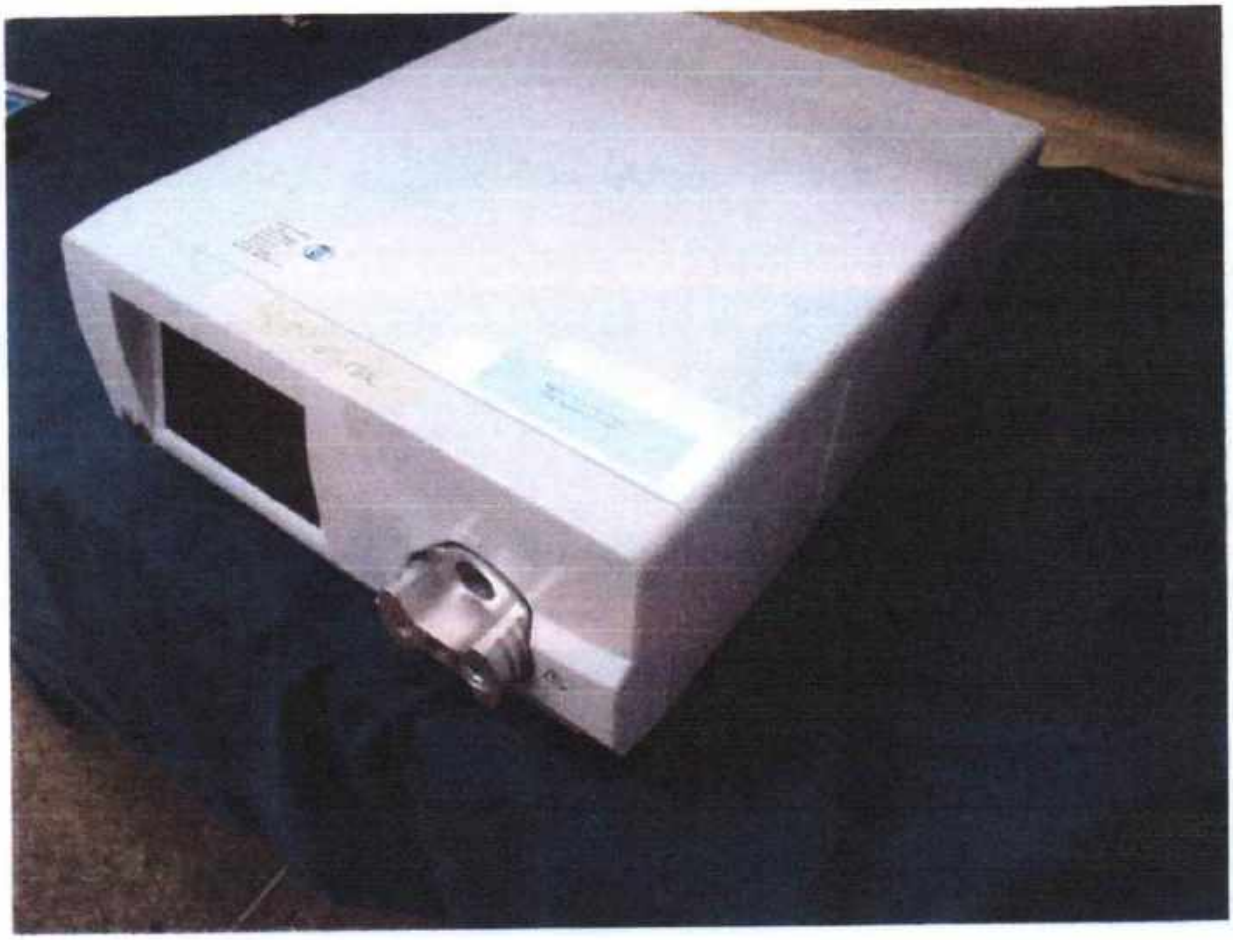


Photo 23 – Front/side view – Titan Tx450D

Photo 24 – Rear view – Titan Tx450D

Photo 25 – Internal view – Titan Tx450D

Photo 26 - Lamp

ILLUSTRATION 1