

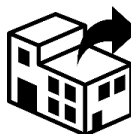


TITAN Standard Power Unit (SPU01)

Operator's Manual



Manufactured For:
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Distributed By:
Teleflex Medical, Inc.
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Overview



Please read all information carefully

Failure to properly follow instructions may lead to serious surgical consequences. This manual is designed to provide instructions for use for the TITAN Standard Power Unit (SPU01). It contains important information for the operation of the TITAN SPU01. It should be kept easily accessible during use.

Standard Conventions Used

The Use of WARNING, Caution, and Note Statements

Information relative to the completion of a task in a safe and thorough manner will be supplied in the form of a WARNING, a Caution, or a Note statement. These statements are found throughout the documentation.

These statements should be read before continuing to the next step in a procedure.

WARNING: A Warning statement indicates an operating or maintenance procedure, practice, or condition that, if not strictly observed, could result in personal injury or loss of life.

Caution: A Caution statement indicates an operating or maintenance procedure, practice, or condition that, if not strictly observed, could result in damage to or destruction of the equipment.

Note: A Note statement indicates an operating or maintenance procedure, practice, or condition that is necessary to accomplish a task efficiently

Chapter 1 – General Information

Indications

The Titan SGS® linear cutter is intended for longitudinal transection and resection of gastric tissue for sleeve gastrectomy pouch creation. The TITAN Standard Power Unit (SPU01) is intended to be used to power the TITAN Stapler.

Contraindications

There are no CONTRAINDICATIONS specific to the TITAN SPU01. WARNINGS for the TITAN SPU01 are listed below. Refer to the TITAN SGS® Instructions for Use for CONTRAINDICATIONS and WARNINGS for the TITAN SGS®.

Device Description

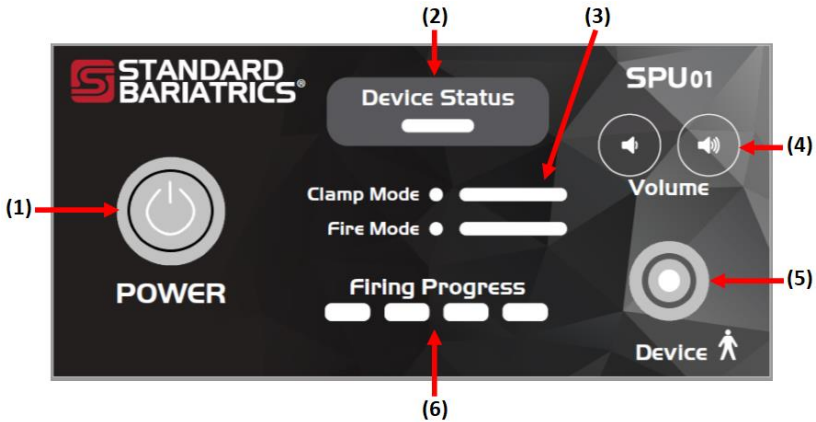
The TITAN SPU01 supplies power to the TITAN SGS®. The SPU01 uses visual and audible status indicators to provide feedback to the user during use.

How Supplied

The TITAN SPU01 is supplied in a semi-ready-to-use state. The shipping box contains the SPU01, power cord, and Operator's Manual. The TITAN Stapler is not included in this packaging and must be purchased separately.

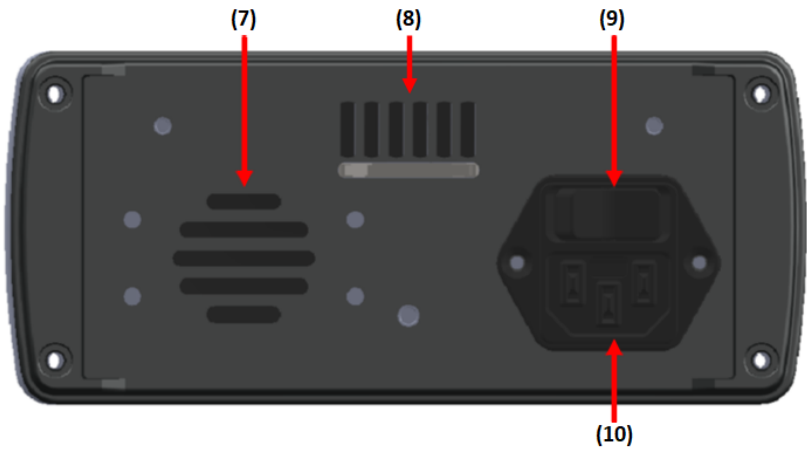
Illustration and Nomenclature

Front Panel of TITAN SPU01:



- | | | |
|-----|-----------------------------------|---|
| (1) | POWER ON/ OFF
BUTTON | Glow white when the TITAN SPU01 is powered on |
| (2) | DEVICE STATUS | Displays the status of the TITAN SGS® |
| (3) | CLAMP MODE | Displays the Status of the TITAN SGS® during
“Closure System Mode” |
| (3) | FIRE MODE | Displays the Status of the TITAN SGS® during “Fire
System Mode” |
| (4) | VOLUME | Controls the volume of the audio feedback |
| (5) | DEVICE
CONNECTOR
RECEPTACLE | Receptacle used to attach the TITAN SGS® to the
power supply |
| (6) | FIRING PROGRESS | Displays the progress of the staple firing |

Back Panel of TITAN SPU01:



- | | | |
|------|-----------------------|--|
| (7) | SPEAKER PORT | Allows sound to escape |
| (8) | FAN EXHAUST HOLES | Provide airflow to the internal components
CAUTION: Do not block |
| (9) | POWER ON/ OFF SWITCH | Allows the unit to be powered on from the front panel |
| (10) | POWER CORD RECEPTACLE | Receptacle used to attach the power cord to the power supply |

Warnings

1. Read all sections of this manual prior to use.
2. Verify the SPU01 is fully operational prior to using the TITAN Stapler (TITAN SGS®).
3. This SPU01 is for use only by qualified medical personnel trained in the proper use of staplers. Inappropriate use or use by untrained medical personnel may result in hazardous electrical output.
4. Do not use with any devices other than the TITAN Stapler (TITAN SGS®).
5. Do not use the SPU01 in the presence of flammable anesthetics; other flammable gases; near flammable fluids; or flammable objects. Observe appropriate fire precautions at all times.
6. Do not use the SPU01 in oxygen- enriched atmospheres, nitrous oxide (N₂O) atmospheres or in the presence of other oxidizing agents.
7. Non-flammable agents should be used for cleaning and disinfection wherever possible. Flammable agents used for cleaning or disinfecting, such as solvents of adhesives, should be allowed to evaporate before device use.
8. Do not operate the SPU01 in a moist environment as a shock hazard may exist. If liquids have entered the SPU01, the unit shall be returned to Standard Bariatrics® for testing prior to use.
9. Do not operate the SPU01 in close proximity to volatile solvents such as methanol or alcohol as combustion may occur.
10. Equipment that is hot from use can cause a fire. Do not place flammable materials (such as gauze or surgical drapes) near or in contact with the equipment.
11. Avoid use of the SPU01 adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, monitor the SPU01 and the other equipment to assure normal operation.
12. Portable RF communication equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the SPU01, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
13. No customer modification of the SPU01 is allowed; modification of this unit could have a negative impact on electrical safety and electromagnetic emissions.
14. The SPU01 contains no operator- serviceable parts. For servicing, contact Standard Bariatrics® (reference “Maintenance, Repair and Service” section).
15. To avoid the risk of electric shock, the SPU01 must only be connected to a supply main with protective earth.
16. Do not use extension cords.
17. To isolate the SPU01 from supply mains power, disconnect the power cord either from the back panel of the unit or from the wall. Ensure that access to these points are kept clear.



Warnings Continued



18. Ensure that the TITAN SGS® is correctly connected to the SPU01 and that no wires are exposed from the cable, connector or Stapler.
19. In case of system failure, ensure availability of the appropriate backup equipment relevant to the specific procedure.

Cautions



1. Removing screws from the front and back panels of the SPU01 or opening of this unit invalidates the warranty and could create hazardous conditions.
2. Do not sterilize the SPU01. Sterilization may damage the unit.
3. Do not restrict the openings on the bottom and back panel of the SPU01, as they provide the required airflow for cooling.
4. If electromagnetic interference with other equipment is suspected, reorient the device or remove possible sources of interference (for example, cellular phones, radios, etc.) from the room.
5. Do not use sharp objects to touch the SPU01.

Customer Service

WARRANTY

Standard Bariatrics® warrants the SPU01 to be free from defects in material and/or workmanship under normal use for a period of five (5) years.

Responsibility of Standard Bariatrics®

Standard Bariatrics® is responsible for safety, reliability and performance of the equipment only if:

1. Setup procedures in this manual are followed.
2. Persons authorized by Standard Bariatrics® carry out modifications or repairs.
3. The electrical installation of relevant room complies with local codes and regulatory requirements such as IEC.
4. The SPU01 is used in accordance with this Operator Manual.

Customer Service

Contact the Standard Bariatrics® Customer Service Department or your local representative for any customer or technical support. Customer Service may be reached at (513) 620-7751.

Chapter 2 – Instructions for Use

Setup

CAUTION: Do not restrict the vents on the back panel of the TITAN SPU01 to avoid overheating.

1. Examine the TITAN SPU01 for any signs of physical damage to. Do not use damaged product.
2. Secure the TITAN SPU01 on a flat surface of a suitable fixture in the appropriate position.
3. Connect the hospital grade power cord supplied with the TITAN SPU01 to the power cord receptacle on the back panel of the TITAN SPU01 and to a grounded electrical outlet. The power requirements for the TITAN SPU01 are listed on the label on the top panel of the generator.

NOTE: Do not use extension cords or three- prong to two-prong adaptors. The power cord should be periodically checked for damaged insulation or connectors.

CAUTION: Verify that the generator is stable before powering up.

4. Turn on the TITAN SPU01 using the On/Off switch on the back panel of the TITAN SPU01. Depress the Power button on the front panel of the TITAN SPU01. The power button will illuminate white, the TITAN SPU01 will announce “System ready. Waiting for device.” And the Device Status indicator will illuminate green.
5. Touch the speaker buttons to adjust the volume.

Staple System Use

1. Connect the TITAN SGS® instrument to the TITAN SPU01. The TITAN SPU01 will alert the user by announcing “System ready. Closure System Mode”. The Device Status indicator will remain illuminated green.
2. Reference the TITAN SGS® Instructions for Use for operation instructions.

SPU01 Operating Modes

- **SPU01 Initialization** – This mode is entered automatically after the TITAN SPU01 is successfully turned on.
- **Closure System Mode** – This mode is entered upon connecting the TITAN SGS® device following initialization.
- **Timeout** – This mode is entered once jaws are fully closed and Safety Button on TITAN SGS® is depressed once.
- **Firing System Mode** – This mode is entered following the Timeout acknowledgement by depressing the TITAN SGS® Safety Button a second time.
- **Post Firing Clamp Mode** – This mode is entered following successful completion of firing.
- **Warning Mode** – This mode is entered upon detection of any recoverable conditions during Closure System, Firing System or Post Firing Clamp Modes. The TITAN SPU01 provides audible and visual feedback corresponding to the error received.
- **Error Mode** – This mode is entered upon detection of any unrecoverable error condition during Closure System, Firing System or Post Firing Clamp Modes. This requires the TITAN SGS® to be manually bailed out. Reference the TITAN SGS® Instructions for Use for manual bail out instructions.

Shutdown

1. Turn off the TITAN SPU01 using the On/Off button on the front panel.

Chapter 3 – Troubleshooting and Audio and LED Indicator Guide

Error Messages

The TITAN SPU01 includes integrated diagnostics that monitor the operation of the TITAN SPU01 and TITAN stapler and flash either informative LEDs or announce the message.

Error message settings are not adjustable by the operator nor can priority be reassigned. Error message settings also do not adjust to operator inputs nor do they change through power loss.

LED and Audio Feedback Guide

Standard Audible Feedback and LED Indicators

The TITAN SPU01 has several audible and visual indicators providing information to the user. The following audible feedback and LED indicators are provided during use of the device:

Timing of Occurrence	Audible Feedback	SPU01 and TITAN SGS® LED Indicators
SPU01 Initialization		
Power On	“System Ready, Waiting for Device.”	Front panel power button illuminates white; Device Status LEDs illuminate green
Closure System Mode		
TITAN SGS® is plugged in	“System Ready.” “Closure System Mode”	Device Status LEDs illuminate green Clamp Mode LEDs illuminate green Safety Button LEDs blink green twice
Initiate TITAN SGS® jaw opening by pressing the Trigger Up	None	Clamp Mode LEDs blink green during opening
Fully open the TITAN SGS® jaws	“Device Open”	Clamp Mode LED illuminates solid green once open
Initiate TITAN SGS® jaw closure by pressing the Trigger Down	None	Clamp Mode LEDs blink green during closure
Fully close the TITAN SGS® jaws	"Device Closed"	Clamp Mode LED illuminates solid green once closed Safety Button LED blinks green

Timing of Occurrence	Audible Feedback	SPU01 and TITAN SGS® LED Indicators
Timeout		
Enter Firing System Timeout by depressing one of the Safety Buttons	“Timeout. Check jaws to ensure there are no tissue folds, no tissue is present in the no tissue zone and no unintended objects are clamped in the jaws. Press Safety Button to acknowledge and enter firing mode.”	Safety Button LED blinks green
Firing System Mode		
Enter Firing System Mode by depressing one of the Safety Buttons (a second time)	“Device ready to fire.”	Device Status LEDs illuminate green Fire Mode LEDs illuminate green Safety Button LEDs illuminate green
Begin ‘manual’ firing by pressing and holding the Trigger Down	None	Fire Mode LED blinks green; First (of four) Firing Progress bars blinks green
Begin ‘automatic’ firing by pressing and holding the Trigger Down while simultaneously depressing a Safety Button, then releasing both.	“Auto firing mode enabled.”	Fire Mode LED blinks green; First (of four) Firing Progress bars blinks green
Fire 25%	“Firing 25% complete”	Fire Mode LED continues to blink green; First (of four) Firing Progress bars illuminates green; second (of four) Firing Progress bars blinks green
Fire 50%	“Firing 50% complete”	Fire Mode LED continues to blink green; First and second (of four) Firing Progress bars illuminate green; third (of four) Firing Progress bars blinks green
Fire 75%	“Firing 75% complete”	Fire Mode LED continues to blink green; First, second and third (of four) Firing Progress bars illuminate green; fourth/ last (of four) Firing Progress bars blinks green
Complete firing	“Firing Complete”	Fire Mode LED is no longer illuminated; All four Firing Progress bars illuminate green

Timing of Occurrence	Audible Feedback	SPU01 and TITAN SGS® LED Indicators
Pause firing: In 'manual' mode by releasing Trigger Down button In 'automatic' mode by pressing any button (Trigger Up, Trigger Down or Safety Button)	"Firing Paused"	Fire Mode LED illuminates solid green; Firing Progress LEDs continue to operate based on the percentage complete (i.e. if 50% complete: Second (of four) Firing Progress bars illuminates solid green; third (of four) Firing Progress bars blinks green)
Post Firing Clamp Mode		
Open the TITAN SGS® jaws by pressing the Trigger Up	None	Clamp Mode LEDs blink green during opening
Fully open the TITAN SGS® jaws	"Device Open"	Clamp Mode LED illuminates solid green once open
Close the TITAN SGS® jaws by pressing the Trigger Down	None	Clamp Mode LEDs blink green during closure
Fully close the TITAN SGS® jaws	"Device Closed"	Clamp Mode LED illuminates solid green once closed Safety Button LED blinks green

Error Messages

The following error messages are provided with audible feedback and visual indicators to notify the user of an error:

Timing of Occurrence	Audible Feedback	LED Indicators	Solution
SPU01 Initialization			
Power On Initialization is not successful	"ERROR: Stapler Power Unit Failure to initialize. Restart or replace Stapler Power Unit."	Device Status LEDs blink red	Restart SPU01 or replace SPU01
TITAN SGS® is plugged in and EEPROM fails to read	"ERROR: TITAN SGS® Failure to initialize. Plug TITAN SGS® in again or replace device."	Device Status LEDs blink red	Remove TITAN SGS® connector and re-plug securely or replace TITAN SGS®
TITAN SGS® has previously been fired	"ERROR: TITAN SGS® has already been fired. Please replace device."	Device Status LEDs blink red	Replace TITAN SGS®

Timing of Occurrence	Audible Feedback	LED Indicators	Solution
Closure System Mode or Post Firing Clamp Mode			
Soft close limit of Closure System Mode reached upon closing jaws	"WARNING: High load detected. Please inspect TITAN jaws before proceeding. Open jaws to continue."	Device Status LEDs blink yellow	Inspect TITAN SGS® jaws; remove possible obstructions; press Trigger Up
Soft open limit of Closure System Mode reached upon opening jaws	"WARNING: High load detected. Please inspect TITAN jaws before proceeding. Close jaws to continue."	Device Status LEDs blink yellow	Inspect TITAN SGS® jaws; remove possible obstructions; press Trigger down
Hard limit of Closure System Mode reached	"Critical load detected. Please engage manual bailout."	Device Status LEDs blink red	Engage manual bailout and replace TITAN SGS®
Firing System Mode			
Primary Soft limit of Firing Mode reached	"WARNING: High load detected. Please inspect TITAN jaws before proceeding. Hold Trigger Down to continue firing."	Device Status LEDs blink yellow	Inspect TITAN SGS® jaws; remove possible obstructions; press Trigger Down to continue firing if no obstructions are present
Secondary Soft limit of Firing Mode reached	"High load detected. Pausing for tissue relaxation. Hold trigger down to continue firing."	Device Status LEDs blink yellow	Wait for audio prompt to complete then press Trigger Down to continue firing
Hard limit of Firing Mode reached	"Critical load detected. Please engage manual bailout."	Device Status LEDs blink red	Engage manual bailout and replace TITAN SGS®
Firing Timeout limit exceeded	"Firing time limit exceeded. Please engage manual bailout."	Device Status LEDs blink red	Engage manual bailout and replace TITAN SGS®

No Power Output

If there is no power output, attempt to correct this problem using the table below.

Possible Cause	Solution
SPU01 not turned on	Turn power on by switching back panel Power On/ Off Switch and depress power button on front panel
SPU01 is not plugged in	Confirm electrical connections and then turn power on by switching back panel Power On/ Off Switch and depress power button on front panel
TITAN SGS® is not connected	Connect and confirm TITAN SGS® connection to front panel Device Connector Receptacle
Broken TITAN SGS® Cable	Replace TITAN SGS®
Fault in TITAN SGS®	Replace TITAN SGS®
Internal SPU01 Failure	Contact Standard Bariatrics® Customer Service

If problems persist, Contact the Standard Bariatrics® Customer Service Department at (513) 620-7751 or your local representative for any customer or technical support

Electromagnetic or Other Interference

The TITAN SPU01 has been tested and found to comply with the limits for medical devices in IEC 60601-1-2: 2014. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

The TITAN SPU01 generates and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If the TITAN SPU01 does cause harmful interference to other devices, which can be determined by turning the TITAN SPU01 off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

1. Reorient or relocate the receiving device.
2. Increase the separation between the TITAN SPU01 and the other devices.
3. Connect the TITAN SPU01 into an outlet on a circuit different from that to which the other device(s) are connected.
4. Contact the Standard Bariatrics® Customer Service Department at (513) 620-7751 for help.

Chapter 4 – Cleaning, Maintenance and Repair

Electrical Safety Checks

The hospital is responsible for ensuring that the TITAN SPU01 has an electrical safety check performed by qualified service personnel at least once a year.

CAUTION: Do not remove the screws from the front and back panels of the TITAN SPU01. Removing the screws invalidates the TITAN SPU01 warranty.

Cleaning Instructions

Before cleaning, thoroughly inspect the TITAN SPU01 for any signs of damage, cracks or improper mechanical function. Do not use the TITAN SPU01 if there are signs of damage. Discard and replace the TITAN SPU01 by contacting and sending the TITAN SPU01 to Standard Bariatrics® for repair where appropriate, if damage or degradation is present.

Cleaning

Before cleaning, turn the TITAN SPU01 off at the back panel and unplug the power cord from the grounded electrical outlet. Clean the TITAN SPU01 following the hospital protocol.

Note: The following instructions are recommended for cleaning the TITAN SPU01, when cleaning is necessary. It is the user's responsibility to qualify any deviations from these processing methods. If cleaning is unnecessary and the TITAN SPU01 is not contaminated with blood or other bodily fluids, it is the responsibility of the hospital to adhere to required cleaning frequencies.

WARNING: Spilling or spraying fluids on or into the TITAN SPU01 (including into the TITAN Stapler receptacle) or immersing the TITAN SPU01 may result in damage to the device and creates a risk of shock or fire. Ensure the TITAN SPU01 is completely dry before operating the TITAN SPU01.

WARNING: Avoid caustic or abrasive cleaners.

If cleaning is necessary or the TITAN SPU01 is contaminated with blood or other bodily fluids, it shall be cleaned within two hours of contamination, before the contamination can dry.

1. Clean as follows:
 - a. The outer surfaces of the TITAN SPU01 shall be cleaned with cleaning wipes that contain less than 90% Isopropyl alcohol (IPA) for a minimum of two minutes. Do not allow fluid to enter the TITAN SPU01.
 - b. Pay attention to all areas where fluids or contamination may gather, such as around the On/ Off Button, around the TITAN SGS® receptacle or any tight crevices/ grooves.
 - c. Allow to air dry.

- d. Conduct a final confirmation of the cleaning process by visually inspecting the SPU01 and wipe for remaining contamination.
 - e. If contamination remains on the SPU01 or wipe, repeat steps 1a thru 1e, using a new cleaning wipe.
 2. Following cleaning, plug the TITAN SPU01 into a grounded electrical outlet and/or turn the TITAN SPU01 on to verify functionality. Power up TITAN SPU01 by pressing the ON/OFF button on the front panel. If any errors are received, contact Standard Bariatrics® to begin the return process.

Maintenance, Repair and Service

TITAN Standard Power Unit is carefully inspected before shipment. The TITAN SPU01 should be inspected upon receipt as items may become damaged in transit.

The TITAN SPU01 has been validated for five (5) years useful life. Contact Standard Bariatrics® for information upon reaching the end of useful life.

Periodic calibration is not required for the TITAN SPU01.

Contact the Standard Bariatrics® Customer Service Department at (513) 620-7751 if service or a replacement power cord is required.

Disposing of the TITAN SPU01 (Environmental Protection)

The TITAN SPU01 shall not be disposed of at the end of life with other waste. To recycle waste equipment, contact Standard Bariatrics® (513) 620-7751 to discuss local waste disposal solutions and processes.

The TITAN SPU01 poses disposal risks similar to consumer electronics such as computers. There are no radioactive substances or hazardous liquids that may leak from within the TITAN SPU01.

Chapter 5 – Conformance to Standards

The TITAN SPU01 conforms to the following standards:

5. EN (IEC) 60601-1 (with Canadian and US National Deviations) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
6. EN (IEC) 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
7. AIM 7351731 Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers



The TITAN SPU01 complies with Federal Register CFR 47, Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) The TITAN SPU01 may not cause harmful interference, and (2) the TITAN SPU01 must accept any interference received, including interference that may cause undesired operation.

Note: The TITAN SPU01 has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. The TITAN SPU01 generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of the TITAN SPU01 in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own exposure.

Appendix

System Specifications

Main Fuses	3.15A 250VAC 300VDC Slow Blow Fuse
Degree of Protection Against Electrical Shock	Type B
Class of Protection Against Electrical Shock	Class I, Earthed
Ingress Protection of Enclosure	IPx0
Main Input	100-240V, 50/60 Hz
Output	Motor Outputs: 15VDC, 0.4A (closure motor) 15VDC, 1.8A (firing motor) Safety Switch LED Outputs: 3.3VDC, 10mA
Ambient Operating Conditions	Temperature: 15°C to 27°C (59°F to 80°F) Humidity: 15% - 90% Relative Humidity (RH), non- condensing Atmospheric Pressure Range: 700 hPa – 1060 hPa
Storage Conditions	Storage Temperature Limitations: Upper Limit: 27°C (80°F) Lower Limit: 15°C (59°F) Storage Humidity Limitation: 15 - 90% Relative Humidity (RH)
Weight	1.8 kg (4.0 lbs)
Overall Dimensions	22 cm x 157 cm x 69 cm
Power Cord	Removable power cord with the following characteristics: Plug Style: NEMA 5-15 North American, Hospital Grade per UL 817 Receptacle: IEC 60320 C13 with straight non-angled cord entry Cord Length: 4 meters nominal Current Rating: 13A Voltage Rating: 125VAC Wiring Code: North American Cordage Description: SJT (UL) or SJT (CSA) Conductors: 16 AWG 3C Agency Approvals: UL and CSA

Electromagnetic Compatibility (EMC)

The Standard Power Unit requires special precautions regarding electromagnetic capability (EMC) and must be installed and used in accordance with the EMC information provided in this manual. The SPU01 is intended for use in the electromagnetic environments specified below.

CAUTION: Ensure that the SPU01 is used only in these environments.

Electromagnetic Emissions

Emissions Test	Compliance	Guidance
RF Emissions CISPR 11	Group 1	The SPU01 uses RF energy only for its internal function. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The Generator G11 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations and Flicker Emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity Guidance












For electromagnetic immunity, performance criteria are: the SPU01 must not change operating modes or fire without command.










Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge IEC 61000-4-2	±8kV Contact ±2kV, ±4kV, ±8kV, ±15kV Air	±8kV Contact ±2kV, ±4kV, ±8kV, ±15kV Air	The relative humidity should be at least 30%.
Electrical Fast Transient/ Burst IEC 61000-4-4	±2kV on Power Supply Lines ±1kV on Input/ Output Lines	±2kV on Power Supply Lines ±1kV on Input/ Output Lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV line(s)-to-line(s) ±2kV line(s) to earth	±1kV Differential Mode ±2kV Common Mode	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency Magnetic Fields IEC 61000-4-8	30 A/m (50 and 60 Hz)	30 A/m (50 and 60 Hz)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.









Electromagnetic Environment Guidance			
Immunity Test	IEC 60601 Test Level	Compliance Level	
Voltage Dips, Short Interrupts and Variation on Power Supply Lines IEN 61000-4-11	30% Reduction for 500mS at 0° phase angle ^a 100% Interruption for 10mS at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° phase angles	30% Reduction for 500mS at 0° phase angle 100% Interruption for 10mS at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° phase angles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SPU01 requires continued operation during power mains interruptions, it is recommended that the SPU01 be powered from an uninterruptible power supply or a battery.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz	3 Vrms	WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the SPU01, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the SPU01, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

^a Voltage of the SPU01 is less than 25% of the highest rated input voltage; tests were only run at a single input voltage.

Symbols

Symbol	Definition	Reference Standard/ Requirement
	Catalogue Number	ISO 15223-1, Section 5.1.6
	Serial Number	ISO 15223-1, Section 5.1.7
	Manufacturer	ISO 15223-1, Section 5.1.1
	Distributor	ISO 15223-1, Section 5.1.9
	Date of Manufacture	ISO 15223-1, Section 5.1.3
	Use- by Date	ISO 15223-1, Section 5.1.4
	Non- Sterile	ISO 15223-1, Section 5.2.7
	Medical Device	ISO 15223-1, Section 5.7.7
	Do not use if the package is damaged	ISO 15223-1, Section 5.2.8
	Keep Dry	ISO 15223-1, Section 5.3.4
	Fragile, Handle with Care	ISO 15223-1, Section 5.3.1

Symbol	Definition	Reference Standard/ Requirement
	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician	21 CFR 801, Section 109
	Refer to Instruction Manual	IEC 60601-1, Table D.2, No. 10
	Electrical and Electronic equipment. Return waste to a collection system or treatment and recycling facilities. Follow decontamination instructions before returning waste.	Article 11(2) of Directive 2002/96/EC
	Operating Temperature Limitations: Upper Limit: 27°C (80°F) Lower Limit: 15°C (59°F) Storage Temperature Limitations: Upper Limit: 27°C (80°F) Lower Limit: 15°C (59°F)	ISO 15223-1, Section 5.3.7
	Operating Humidity Limitation: 15-90% Relative Humidity (RH), Non-condensing Storage Humidity Limitation: 15-90% Relative Humidity (RH)	ISO 15223-1, Section 5.3.8
	Operating Atmospheric Pressure Limitation: 700 hPa – 1060 hPa	ISO 15223-1, Section 5.3.9
	SGS Certification Mark	Nationally Recognized Testing Laboratory (NRTL) Classification Mark
	The TITAN SPU complies with Federal Register CFR 47, Part 15 of the FCC Rules.	Federal Register CFR 47, Part 15 of the FCC Rules
	Caution	ISO 15223-1, Section 5.4.4

Symbol	Definition	Reference Standard/ Requirement
	General Warning Sign	IEC 60601-1, Table D.2, No. 2
	Warning, Electricity	IEC 60601-1, Table D.2, No. 3
	On (Power)	IEC 60601, Table D.1, No. 12
	Off (Power)	IEC 60601, Table D.1, No. 13
	Alternating Current	IEC 60601, Table D.1, No. 1
	Applied Part Type B (TITAN SGS®, Stapling End Effector and Shaft)	IEC 60601, Table D.1, No. 19
	Volume	N/A
	Non-ionizing Radiation	IEC 60601-1-2, Clause 5.1.1
IP_{N₁}N₂	IPx0 N ₁ = x No data available to specify a protection rating with regards to solid particulate protection. N ₂ = 0 No protection against contact and ingress of objects or liquids	IEC 60601, Table D.3, No. 2



SPU01



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