

Compliance

Surgical Tables Incorporated (STI) manufactures medical devices that are compliant with the Center for Devices and Radiological Health (CDRH) Code of Federal Regulation 21 Subchapter J Part 1020 Section 30 (CFR21 Subchapter J part 1020.30), the performance standard for ionizing radiation emitting products. Additionally, STI's products are manufactured according to the Food & Drug Administrations (FDA) Current Good Manufacturing Practices (CGMP's).

FDA PRODUCT CLASSIFICATION

Device Description: Radiologic Table

Product Code: KXJ

Regulation Number: 892.1980

Device Class: 2

GMP Exempt: No

510(k) Exempt: Yes

Warranty:

Surgical Tables Incorporated provides a 2-year parts and labor warranty on all MAX Series imaging tables. The warranty is only valid to the original purchaser and is not transferable. Surgical Tables Incorporated has the right to assess if mis-use has occurred. In the case of mis-use the warranty is void.



Surgical Tables Incorporated

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MAX
series

USERS MANUAL

Intended Use:

The MAX Series is a mobile imaging table which is intended to support a 500 pound patient. Surgical Tables Incorporated MAX Series is intended to be used with mobile x-ray for minimally invasive procedures.

Cautions/Warnings:

Do not operate any of the MAX Series imaging tables without proper training or without reading and understanding this user's manual.

The MAX Series imaging tables are rated for a 500 pound patient. Do not place a load larger than 500 pounds onto the MAX Series imaging table. Do not allow a patient to board at the head end of the table.

Do not attempt to move the MAX Series imaging table with the brakes locked.

If anything happens to the MAX Series imaging table that is out of the normal conditions of operation or the MAX Series imaging table is not functioning normally, call Surgical Tables Incorporated. Do not attempt to fix your MAX Series imaging table without consulting Surgical Tables Incorporated. Surgical Tables Incorporated must have knowledge of any complaints, problems or issues with the MAX Series imaging tables.

Patient is to be restrained to the MAX Series imaging table during use.

The operator of the MAX Series imaging table is responsible for the patients safety during use. The operator must be certain the patient can not be harmed by moving the MAX Series imaging table or during operation of the MAX Series imaging table.

Make sure all 4 castors are locked before allowing a patient to board the MAX Series imaging table.

Cleaning Recommendations:

ROUTINE CARE: Wipe clean with neutral soap suds and lukewarm water. Rinse and dry.

DISINFECTION: Most phenolic or quaternary type disinfectants can be used. User must dilute disinfectants and germicides in accordance with manufacturer's instructions. It is recommended that all cleaning agents first be spot tested on an inconspicuous part to ensure that they do not do damage.

BLOOD CONTAMINATION: Contamination with blood on the patient pad can be disinfected with 1:10 dilution of household bleach (5.25% sodium hypochlorite) as recommended by the CDC (US Department of Health and Human Services, February 1989).

ODOR CONTROL: To prevent odors on long term incontinent applications, clean the patient pad daily. The use of a scented cleaner/disinfectant is recommended.

WARNING: Iodophor type disinfectants (Betadine, for example) will stain the patient pad.

WARNING: Prolonged contact with bleach solutions, improper dilution ratios for any cleaning agent, or poor rinsing of the patient pad after disinfecting and cleaning may cause damage to both the appearance and performance.

Overview

For all MAX Series imaging tables which have motorized movements, the system includes a remote control (figure 1) which allows the operator to position their patient.

Each Max Series imaging table has rotating and lockable casters (figure 2).

The Max Series imaging table has a 24" wide by 84" long patient surface (figure 3) which is designed to support up to 500 lbs.

The optional 180° rotating armboards (figure 4a) & procedural Armboards (figure 4b) are intended to support arm weight only. The armboards are not to support the patients' weight during boarding or normal use. For even more versatility.

Convenient footswitch for hands free use (figure 5).

For safety and user control the MAX Series incorporates a power switch, emergency stop and removable power cord (figure 6).

The MAX Series incorporates a modern base design (figure 7) that allows for maximum access of mobile x-ray systems.

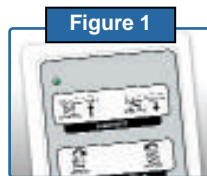


Figure 1

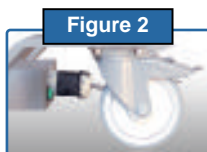


Figure 2

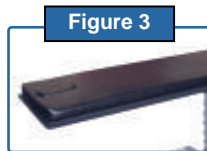


Figure 3

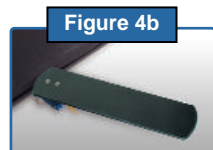


Figure 4a

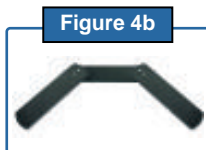


Figure 4b

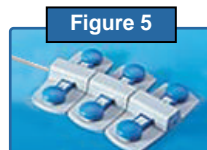


Figure 5

System Requirements:

All MAX Series imaging tables with motorized movements require 120 VAC power to operate.

Allowable humidity: 30-80% relative humidity, non-condensing

Storing Temperature: -10°F - 130°F

Operating Temperature: 40°F - 100°F



Figure 6

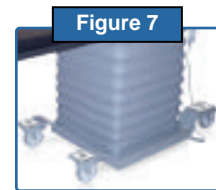


Figure 7

Optional Equipment:

Modular Siderail System (Figure 8)

Patient Transfer Bar (Figure 9)

Armboards (Figure 4)

Uninterruptible Power Supply (figure 10)

Wireless Remote Control (figure 11)

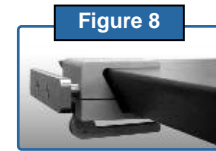


Figure 8

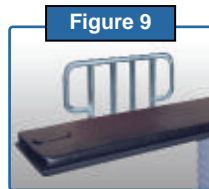


Figure 9



Figure 10



Figure 11

Table Operation & Remote Control Function:

The Max Series Surgical Table includes a remote control (figure 1) on MAX Series imaging tables with motorized movements. The remote control allows the operator to position their patient. The following describes each MAX Series imaging tables motorized movements (see MAX 5 remote control sticker located to the right for directional information):

Height

The Height buttons raise or lower the table top.

Lateral Tilt

The Lateral Tilt buttons control the lateral angle of inclination.

Trendelenberg

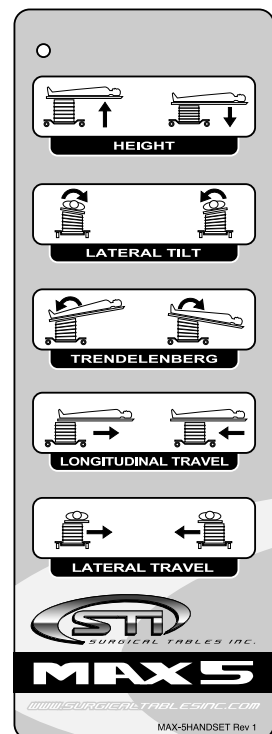
The Trendelenberg buttons control the angle of inclination of the head end.

Longitudinal Travel

The Longitudinal Travel buttons will move the table top in the longitudinal direction.

Lateral Travel

The Lateral Travel buttons will move the table top in the lateral direction.



Maintenance

Preventative maintenance is not required.

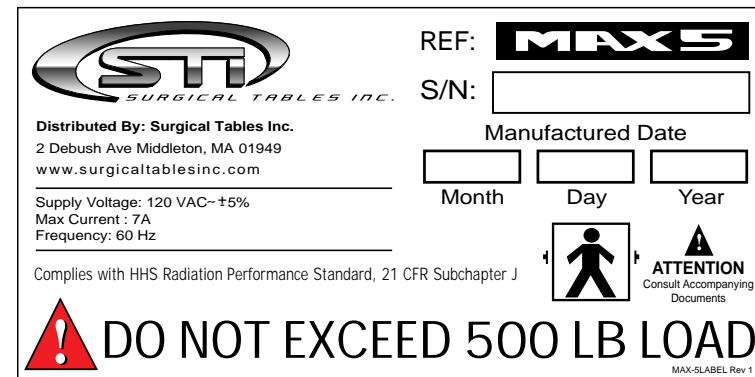
Servicing:

Do not service your MAX Series imaging table unless you have consulted Surgical Tables Incorporated.

Labeling:

All labels are adhesively applied and completely waterproof & stain resistant.

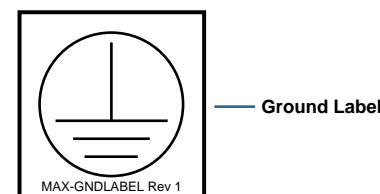
If any product labeling is damaged or missing contact Surgical Tables Incorporated to obtain new labels.



Serial Number / Warning Label



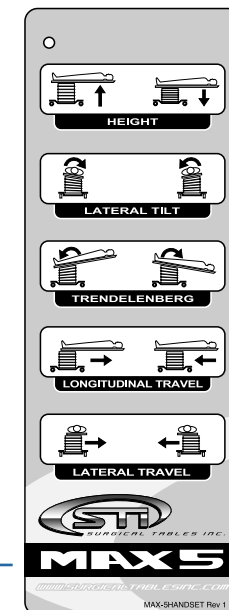
STI Brand Dome Label



Ground Label

Labels shown are not to exact Scale.

Handset Label



Technical Specifications:

MAX 5

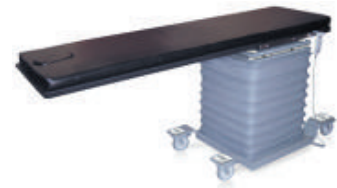
Max Series 5 Move Surgical Table

Supply Voltage: 120 VAC - ± 5%

Max Current : 7A

Frequency: 60 Hz

1. HEIGHT 32" TO 42"
2. LATERAL TILT (+/-) 17°
3. TRENDELENBERG (+/-) 20°
4. LONGITUDINAL TRAVEL .. 10" (+/- 5 ")
5. LATERAL TRAVEL..... 10" (+/- 5 ")



MAX 4

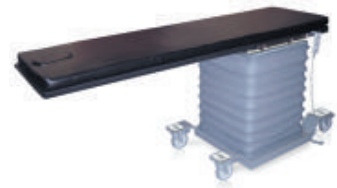
Max Series 4 Move Surgical Table

Supply Voltage: 120 VAC - ± 5%

Max Current : 3.5A

Frequency: 60 Hz

1. HEIGHT 30" TO 40"
2. LATERAL TILT (+/-) 17°
3. TRENDELENBERG (+/-) 20°
4. LONGITUDINAL TRAVEL .. 10" (+/- 5 ")



MAX 3

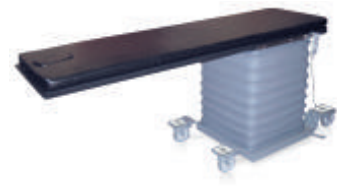
Max Series 3 Move Surgical Table

Supply Voltage: 120 VAC - ± 5%

Max Current : 3.5A

Frequency: 60 Hz

1. HEIGHT 29" TO 41"
2. LATERAL TILT (+/-) 17°
3. TRENDELENBERG (+/-) 20°



MAX 2

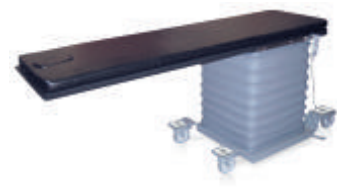
Max Series 2 Move Surgical Table

Supply Voltage: 120 VAC - ± 5%

Max Current : 3.5A

Frequency: 60 Hz

1. HEIGHT 28" TO 40"
2. LATERAL TILT (+/-) 17°



MAX 1

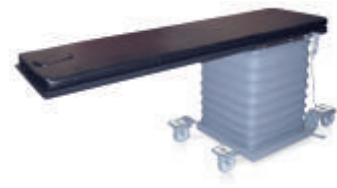
Max Series 1 Move Surgical Table

Supply Voltage: 120 VAC - ± 5%

Max Current : 3.5A

Frequency: 60 Hz

1. HEIGHT 28" TO 40"



MAX 0

Max Series Surgical Table

1. FIXED HEIGHT 36"