MAKO®

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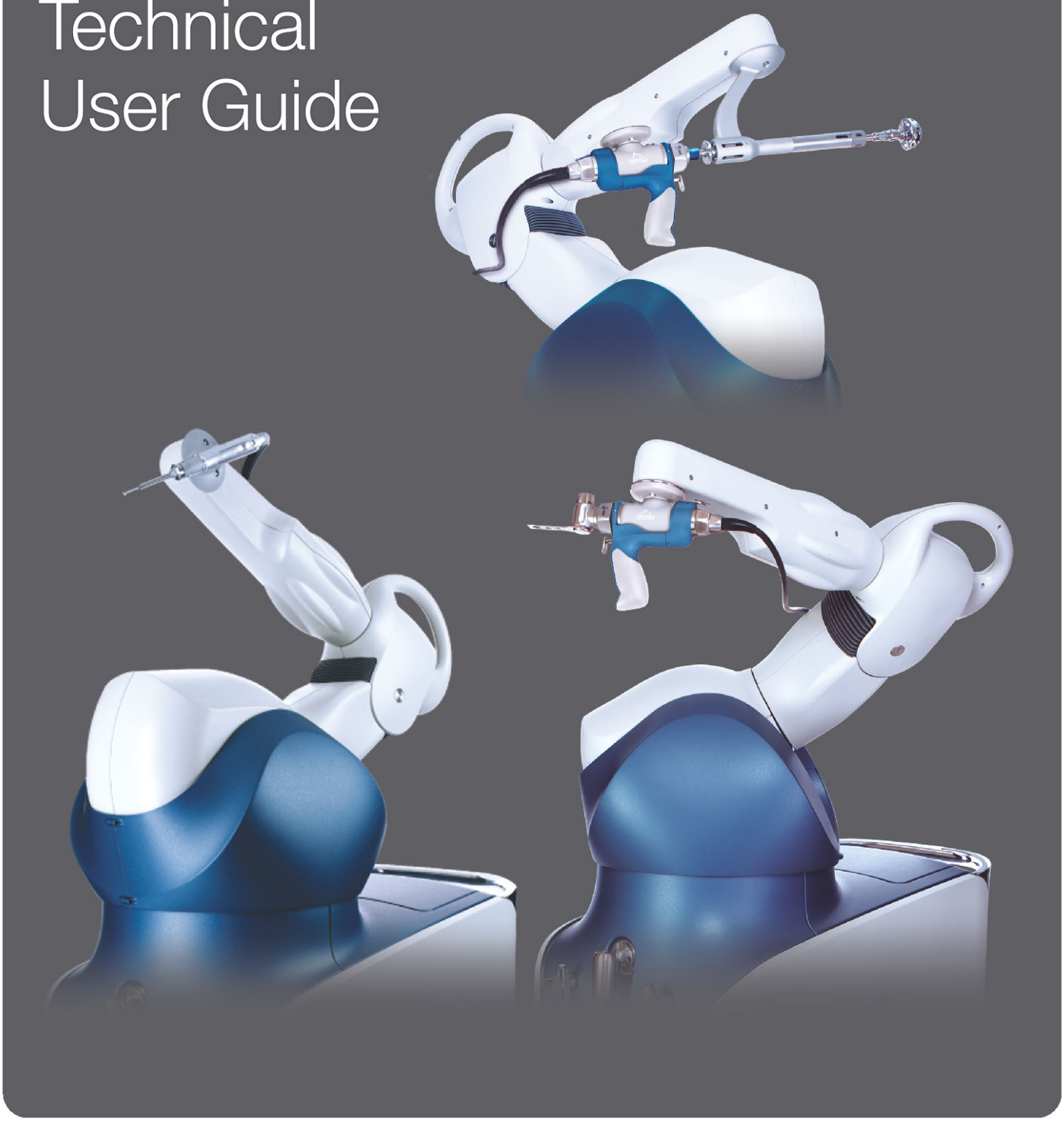
Technical User Guide



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INTRODUCTION

User Manual Terms of Use

This manual is provided by MAKO Surgical Corp. (Stryker) and should be used for informational purposes only. Terms and Conditions related to the use of the Mako System can be found in the placement agreement with the system user.

About This Manual

This manual provides information regarding hardware components of the Mako System for use as a reference.

This user guide supports Mako Model 3.11x.x.

Legal Manufacturer Support / Feedback

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Indications for Use

The Mako System is intended to assist the surgeon in providing software-defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures.

The Mako System is indicated for use in surgical knee and hip procedures, in which the use of stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be identified relative to a CT-based model of the anatomy.

These procedures include unicondylar knee replacement and/or patellofemoral knee replacement (PKA); Total Knee Arthroplasty (TKA); and Total Hip Arthroplasty (THA).

Patents

Reference: U.S. Patents www.stryker.com/patents.

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Governing Law

Any legal action or proceeding related to this manual or the information contained in it shall be brought exclusively in a court in Bergen County, New Jersey, and shall be governed by the laws of the State of New Jersey, without regard to conflicts of laws principles.

Responsibility

Under the terms of the service contract, maintenance and repair of the Mako is the responsibility of Stryker.

CE Mark

Refer to the product label for the CE mark status and the legal manufacturer. The CE mark is only valid if found on the product label.

General Warnings and Consideration

	*Unless qualified by Stryker, healthcare facility Biomedical Engineering departments should limit system repair/maintenance to electrical safety testing as outlined in the Preventive Maintenance section of this manual.*
	*There are no user serviceable parts in the Mako, refer to your Stryker authorized personnel for service.*
	*Accessory equipment connected to the digital interfaces must be certified according to the respective IEC standards (e.g., IEC 62368 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the systems requirements of IEC 60601-1.* *Any person who connects additional equipment to the signal input or signal output part configures a medical system, and is responsible for ensuring that the system complies with the systems requirements of IEC 60601-1. If in doubt, consult the technical service department or your local representative.*
	*When other medical equipment is attached to the Mako, leakage currents can be additive and should be checked.*
	*Before each use, the compatibility of the Mako with any independent surgical instruments and other applied parts shall be checked according to the criteria for safe use defined in this and other accompanying documents.*
	*The information contained in this technical user guide complies with 60601-1 Edition 3.1 (IEC 60601-1:2012), 60601-1 Edition 3.2 (IEC 60601-1:2020), 60601-1-2 Edition 4.0 (IEC 60601-1-2:2014), and 60601-1-2 Edition 4.1 (IEC 60601-1-2:2020).*
	*Do not attach non-medical equipment to the medical system.*
	*Do not use multiple socket outlets, power strips, or extension cords with the Mako system.*
	*Do not touch non-medical equipment in the patient vicinity and the patient at the same time.*
	*Before each use, the surface of the surgical instruments which are intended to be inserted into a patient should be checked to ensure there are no unintended rough surfaces, sharp edges, or protrusions.*
	*Accessories or other medical or non-medical equipment that are not specified by Stryker shall not be connected to any mechanical interfaces of the Mako, including but not limited to the cutting system and accessories.*
	*Images contained in this document are for illustrative purposes only and may slightly differ from your actual device. The instructions contained in this guide are applicable for all Mako Model 3.11x.x components.*

MAKO SYSTEM

The main components of the Mako System are the Mako, Guidance Module, and Camera Stand. Other instrumentation and accessories are available for use with the system, but are not discussed in this manual.

The Mako

The Mako Robotic Arm facilitates controlled bone resection by applying stereotactic boundaries to a cutting burr. The upper portion of the Robotic Arm articulates, allowing motion with six Degrees of Freedom (DOF). The lower base houses the computer and power components, cable panel, user panel, and positioning lever. A smaller fixed arm is attached to the base and supports a reference array.



Figure 1. The Mako



There are no user-serviceable parts on the Mako.

Guidance Module

The Guidance Module acts as a computer workstation, houses one of the two system computers, and coordinates input from the various system components.



Figure 2. Guidance Module

There are no user-serviceable parts on the Guidance Module.

Camera Stand

The camera or position sensor is used to track the location of passive tools. The camera is mounted on a mobile stand and can be positioned for height, angle, and rotation by adjusting the arm or the stand. The camera stand also includes a surgeon monitor display.



Figure 3. Camera Stand Left (knob) and Right (lever)

There are no user-serviceable parts on the Camera Stand.

USER APPLICATION SOFTWARE

The Mako (MAKOplasty) application software provides functionality to:

- Import or acquire patient CT DICOM data.
- Display the patient data using 2D and/or 3D representations.
- Register points in the patient data sets to the patient using various tracked instruments and tools.
- Display locations of tracked instrumentation with respect to other tracked instrumentation, registered patient anatomy, or the Mako.
- Communicate with the Mako and with the tool tracking system.
- Manage the application pages and the screen layout.

Mako Software

A separate software application runs on the Mako and is transparent (not accessible to the user).

Functionally, this application can be divided into 3 basic categories:

- Error/Safety monitoring.
- Mako hardware control.
- Peripheral connectivity.

Reporting Problems

Hardware

There are no internal user-serviceable parts in the Mako. Unless qualified by Stryker, do not open any system panels. Problems experienced during pre-operative, intra-operative, or post-operative use of the Mako should be reported to MAKO Surgical Corp.

Software

Software error reports are logged through the software and collected by Stryker authorized personnel during preventive maintenance.

MAKO SYSTEM TECHNICAL INFORMATION

Stryker makes available to Stryker-trained personnel circuit diagrams, component part lists, descriptions, calibration instructions, or other information which will assist the appropriate qualified technical personnel to repair parts of equipment designated by Stryker.

The information contained in this technical user guide complies with 60601-1 Edition 3.1 (IEC 60601-1:2012), 60601-1 Edition 3.2 (IEC 60601-1:2020), 60601-1-2 Edition 4.0 (IEC 60601-1-2:2014), 60601-1-2 Edition 4.1 (IEC 60601-1-2:2020), and 80601-2-77 Edition 1.0 (IEC 80601-2-77:2019).

To identify which standard to follow, review the label located on the Mako (Figure 4).

- If the model number is a 5-digit or 6-digit number (e.g., 3.1XX.X or 3.1XX.XX), then follow 60601-1 Edition 3.1 (IEC 60601-1:2012), 60601-1 Edition 3.2 (IEC 60601-1:2020), 60601-1-2 Edition 4.0 (IEC 60601-1-2:2014), 60601-1-2 Edition 4.1 (IEC 60601-1-2:2020), and/or 80601-2-77 Edition 1.0 (IEC 80601-2-77:2019) standards listed in this guide.
- If the model number is a 4-digit number (e.g., 3.1XX), then follow 60601-1-2 Edition 3 (IEC 60601-1-2:2007).

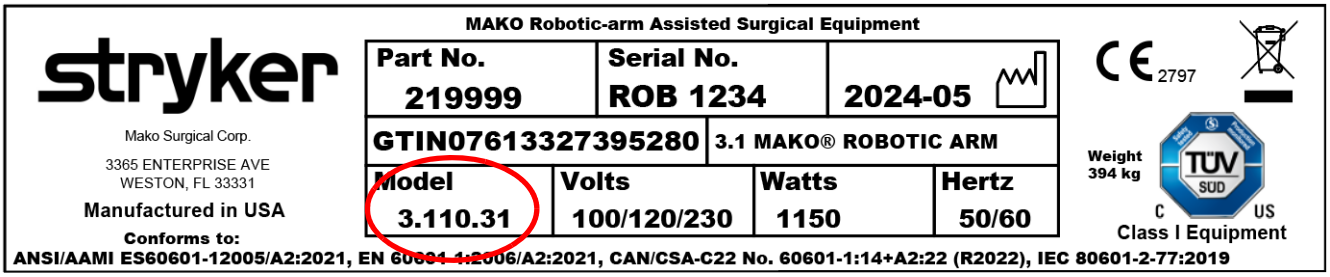

Figure 4. Mako Label

Table 1 Mako System Technical Information

	Guidance Module	Mako	Camera Stand	MICS Handpiece*
				
*For information regarding the MICS 3 Handpiece, see the MICS 3 User Guide (PN 700002834078).				
Physical				
Storage Dimensions (LxWxH)	31" x 27" x 63" 78.8 cm x 68.6 cm x 160.1 cm	24" x 35" x 56" 61 cm x 88.9 cm x 142.3 cm	Knob adjusted: 42" x 27" x 79" 106.7 cm x 68.6 cm x 200.7 cm Lever adjusted: 36” x 27” x 76” 91.4 cm x 68.6 cm x 193.1 cm	21” x 9” x 4” 53.4 cm x 22.9 cm x 10.2 cm
Operating Dimensions (LxWxH)	31" x 27" x 63" 78.8 cm x 68.6 cm x 160.1 cm	35" x 49" x 56" 88.9 cm x 124.5 cm x 142.3 cm	Knob adjusted: 56" x 27" x 79" 142.3 cm x 68.6 cm x 200.7 cm Lever adjusted: 48” x 27” x 76” 122 cm x 68.6 cm x 193.1 cm	9” x 9” x 4” 22.9 cm x 22.9 cm x 10.2 cm
Power Requirements	N/A	100 / 120 / 230 V, 1150 W, ~50/60 Hz	N/A	N/A
Weight	114 lbs (51.7 kg)	866 lbs (394 kg)	190 lbs (86.2 kg)	4.3 lbs (1.95 kg)
Footprint	27" x 31" 68.6 cm x 78.8 cm	24" x 35" 61 cm x 88.9 cm	27" x 31" 68.6 cm x 78.8 cm	N/A

Table 1 Mako System Technical Information (continued)

Environmental	
Humidity	20% to 80% (non-condensing)
Temperature	Operating: 10° to 32° Celsius/ 50° to 89.6° Fahrenheit Storage: -20° to 50° Celsius/ -4° to 122° Fahrenheit Transport: -20° to 50° Celsius/ -4° to 122° Fahrenheit
Barometric Pressure	Sea level 1060 hPa to max conditions (3000M) 700 hPa



The Environmental Technical Information listed above is for a professional healthcare environment such as an operating room or surgery center.

Table 1 Mako System Technical Information (continued)

EMC Information	
RF emissions CISPR 11	Class A
ESD Contact / Air IEC 61000-4-2	+/- 8 kV contact / +/- 15 kV air
Radiated RF IEC 61000-4-3	3 V/m
Fast Transients (EFT) IEC 61000-4-4	+/- 2 kV for power supply lines; +/- 1 kV for input/output lines
Line surge immunity IEC 61000-4-5	+/- 1 kV differential; +/- 2 kV common mode
Conducted RF IEC 61000-4-6	3 Volts
Power frequency (60 Hz) magnetic field IEC 61000-4-8	IEC 60601-1-2:2007 (3rd Edition) 3 A/m IEC 60601-1-2 (4.x Edition) 30 A/m
Voltage dip immunity IEC 61000-4-11	IEC 60601-1-2:2007 (3rd Edition) Operated on 5%, 5%, 40%, and 70% of AC main power for 250 cycles, 0.5 cycles, 5 cycles, and 25 cycles, respectively. IEC 60601-1-2 (4.x Edition) Ut=0%, 0.5 cycle (0,45,90,135,180,225,270 and 315 degree) Ut=0% 1 cycle Ut=70% 25/30 cycles (@0 degrees) Ut=0%, 250/300 cycle
Voltage interruptions IEC 61000-4-11	IEC 60601-1-2 (4.x Edition) Ut=0%, 250/300 cycle

The EMC Information listed above is for a professional healthcare environment such as an operating room or surgery center.

Regulatory Compliance	
Safety approvals	TUV SUD NRTL certification to: ANSI/AAMI ES60601-1:2005/A2:2021 EN60601-1:2006/A2:2021 CAN/CSA-C22.2 No. 60601-1:14+A2:22(R2022)
Applicable standards	IEC 60601-1:2005/AMD2:2020 EN60601-1:2006/AMD2:2021 ANSI/AAMI ES60601-1:2005/A2:2021 CAN/CSA-C22.2 No. 60601-1:14+A2:22(R2022) UL 60601-1:2003 CAN/CSA-C22.2 No 601.1-M90 IEC 80601-2-77:2019

Classifications

Per IEC 60601-1, the Mako has been classified as:

- Continuous Operation, according to mode of operation.
- Class I, according to type of protection against electric shock.
- Type B Applied Part, according to degree of protection against electric shock.
- IPX0 rating, according to degree of protection against the ingress of fluids.
- Not MR safe, do not use the Mako near an MRI.

Explanation of Labels

For an explanation of all labels attached to the Mako, reference the *Mako System User Guide (PN 213957)*.

Mako Cabling

Table 2 Mako Cabling

Part Name	Length of Cable
Guidance Module (external cable to Mako)	25 ft (7.62 m)
Camera stand (external cable to Guidance Module)	25 ft (7.62 m)
MICS Handpiece	12 ft (3.66 m)
Mako Power Cord	20 ft (6.1 m)
Mako Foot Switch	14 ft (4.27 m)

Table 3 Mako Power Cord Part Numbers

Part Name	Part Number
Mako Power Cord US	207010
Mako Power Cord Japan	204427
Mako Power Cord Taiwan	211477
Mako Power Cord Italy	204426
Mako Power Cord Brazil	211562
Mako Power Cord EU	204425
Mako Power Cord Australia	210637
Mako Power Cord China	208587



Only use Stryker supplied cables with the Mako. Use of any other cables and/or accessories may negatively affect EMC performance.

Before plugging the Mako into a wall outlet outside the United States. Stryker service personnel, or their authorized representative, must configure the robot for the mains voltage of the country of installation. Failure to do so can result in serious damage to the equipment, including fire.

Electromagnetic Interference

This device is tested to the requirements of IEC 60601-1-2:2007 (3rd Edition) and IEC 60601-1-2:2020 (4.1 Edition) as shown in Table 4 for electromagnetic compliance for Class A, Group 1 medical devices. It has been shown not to emit RF energy at a level that may interfere or affect surrounding equipment. It is also shown to not be susceptible to RF or Electrostatic discharge (ESD) to a level that interferes or affects its own operation. This is predicated on the fact that the installation and operation is done in accordance with all service and operator instructions.

The Mako has special precautions regarding EMC and must be installed and put into service according to the EMC information provided in this Technical User Manual and the accompanying appendices. Portable and mobile RF communications equipment can affect the Mako.

Electromagnetic Emissions

This equipment has been tested and found to comply with the limits for a CISPR 11 class A digital device. These limits are designed to provide reasonable protection against harmful interference. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- *Reorient or relocate the receiving antenna.*
- *Increase the separation between the equipment and receiver.*
- *Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.*
- *Consult the dealer or an experienced technician for help.*

The user should not modify or change this device without written approval from MAKO Surgical Corp. Modification could void authority to use this equipment. Only use Stryker supplied cables with the Mako.

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio frequency communication services. The user might need to take mitigation measures, such as relocating or reorientating the equipment.

The Mako is not to be used in a residential environment, it is only certified for use in a professional healthcare environment such as an operating room or surgery center.

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 Mako, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Table 4 Electromagnetic Emissions

The Mako is intended for use in the electromagnetic environment specified below. The customer or the user of the Mako should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11 (RE-E)	Group 1, Class A	The Mako uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11 (RE-E)	Group 1, Class A	The Mako 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.

The Mako should not be used adjacent to or stacked with other equipment, but if adjacent or stacked use is necessary, the Mako should be observed to verify normal operation in the configuration in which it will be used.

The EMC Information listed above is for a professional healthcare environment such as an operating room or surgery center.

Table 5 Electromagnetic Immunity

The Mako is intended for use in the electromagnetic environment specified below. The customer or the user of the Mako should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level[b]	Electromagnetic Environment Guidance
Electrostatic discharge IEC 61000-4-2	IEC 60601-1-2:2007 (3rd Edition) +/- 6 kV contact +/- 8 kV air IEC 60601-1-2:2020 (4.1 Edition) +/- 8 kV contact +/- 15 kV air	IEC 60601-1-2:2007 (3rd Edition) +/- 6 kV contact +/- 8 kV air IEC 60601-1-2:2020 (4.1 Edition) +/- 8 kV contact +/- 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Table 5 Electromagnetic Immunity (continued)

The Mako is intended for use in the electromagnetic environment specified below. The customer or the user of the Mako should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level[b]**	**Electromagnetic Environment Guidance**
Electrical fast transient/burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/ output lines	+/- 2 kV for power supply lines +/- 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	+/- 1 kV differential mode +/- 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines[a] IEC 61000-4-11	IEC 60601-1-2:2007 (3rd Edition) • <5% U_T (>95% dip in U_T) for 0.5 cycle • 40% U_T (60% dip in U_T) for 5 cycles • 70% U_T (30% dip in U_T) for 25 cycles • <5% U_T (>95% dip in U_T) for 5 sec IEC 60601-1-2:2020 (4.1 Edition) • Ut =0%, 0.5 cycle • (0,45,90,135,180,225, 270 and 315 degree) • Ut=0% 1 cycle Ut=70% 25/30 cycles (@0 degrees) • Ut=0%, 250/300 cycle	IEC 60601-1-2:2007 (3rd Edition) • <5% U_T (>95% dip in U_T) for 0.5 cycle • 40% U_T (60% dip in U_T) for 5 cycles • 70% U_T (30% dip in U_T) for 25 cycles • <5% U_T (>95% dip in U_T) for 250 cycle IEC 60601-1-2:2020 (4.1 Edition) • Ut =0%, 0.5 cycle • (0,45,90,135,180,225, 270 and 315 degree) • Ut=0% 1 cycle Ut=70% 25/30 cycles (@0 degrees) • Ut=0%, 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Mako requires continued operation during power mains interruptions, it is recommended that the Mako be powered from an uninterruptible power source.
Power frequency (60 Hz) magnetic field IEC 61000-4-8	IEC 60601-1-2:2007 (3rd Edition) 3 A/m IEC 60601-1-2:2020 (4.1 Edition) 30 A/m	IEC 60601-1-2:2007 (3rd Edition) 3 A/m IEC 60601-1-2:2020 (4.1 Edition) 30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

	*(a) UT is the AC mains voltage prior to application of the test level.* *(b) The pass-fail criteria during this testing was as follows:* *Fail criteria:* • *Loss of control of the arm - observed uncontrolled arm movement* • *Loss of hardware (permanent damage)* *Pass criteria:* • *Software protective stop (system halts, but can be restarted)* • *Transitory aberrations in the video display that self-recover*

Table 6 Guidance and Declaration – Electromagnetic immunity

The Mako is intended for use in the electromagnetic environment specified below. The customer or the user of the Mako should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level[b]**	**Electromagnetic Environment Guidance**
• Conducted RF IEC 61000-4-6 • Radiated RF IEC 61000-4-3[c]	IEC 60601-1-2:2007 (3rd Edition) • 3 V_{RMS} 150 kHz to 80 Hz • 3 V/m 80 MHz to 2.5 GHz IEC 60601-1-2: 2020 (4.1 Edition) • 6 V/m (ISM Bands - conducted only)	IEC 60601-1-2:2007 (3rd Edition) • 3 V_{RMS} • 3 V/m IEC 60601-1-2: 2020 (4.1 Edition) • 6 V/m (ISM Bands - conducted only)	Portable and mobile RF communications equipment should be used no closer to any part of the Mako, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz d = recommended separation distance in meters (m). p = maximum output power rating of transmitter in watts (W) according to transmitter manufacturer. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than compliance level in each frequency range. Interference may occur in vicinity of equipment marked with following symbol: 
• Proximity magnetic fields IEC 61000-4-39:2017	See Table 8 (Test Specifications for Enclosure Port Immunity to Proximity Magnetic Fields)		RFID fields were applied near the end effector attachment area of the robotic arm.

a.) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Mako is used exceeds the applicable RF compliance level above, the Mako should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Mako.

b.) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

c) Spot frequency tests per Table 9 of IEC 60601-1-2 were conducted. See Table 7 (Test Specifications for Enclosure Port Immunity to RF Wireless Communications Equipment).

Table 7 Test Specifications for Enclosure Port Immunity to RF Wireless Communications Equipment

Test frequency (MHz)	Band (MHz)[a]	Service[a]	Modulation	Immunity test level (V/m)
385	380 to 390	TETRA 400	Pulse modulation[b] 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM[c] +/- 5 KHz deviation 1 KHz sine	28
710	704 to 787	LTE Band 13, 17	Pulse modulation[b] 217 Hz	9
745				
780				
810	800 to 960	GMS 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[b] 18 Hz	28
870				
930				
1720	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation[b] 217 Hz	28
1845				
1970				
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[b] 217 Hz	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation[b] 217 Hz	9
5500				
5785				
If necessary to achieve the Immunity Test Level, the distance between the transmitting antenna and the ME Equipment or ME System may be reduced to 1 m. The 1 m distance is permitted by IEC 61000-4-3.				

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50% duty cycle square wave signal.

c) As an alternative to FM modulation, the carrier may be pulse modulated using a 50% duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case.

Table 8 Test Specifications for Enclosure Port Immunity to Proximity Magnetic Fields

Test Frequency	Modulation	Immunity Test Level (A/m)
134.2 kHz	Pulse modulation 2.1kHz (modulated using a 50% duty cycle square wave)	65 r.m.s., before modulation is applied
13.56 MHz	Pulse modulation 50kHz (modulated using a 50% duty cycle square wave)	7.5 r.m.s., before modulation is applied

Table 9 High Frequency Surgical Equipment Emissions

Immunity Test	IEC 80601-2-77	Compliance Level	Electromagnetic Environment Guidance
HF surgical equipment emissions	IEC 80601-2-77:2019 Ed. 1.0	No uncontrolled motion under test	Annex EE

The Mako is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Mako can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Mako as recommended below, according to the maximum output power of the communications equipment.

Table 10 Recommended separation distances between portable and mobile RF communications equipment and the Mako

Rated Maximum Output Power of Transmitter (W)	Separation Distance Based on Transmitter Frequency (m)			
	150 kHz to 80 MHz Outside ISM Bands $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	150 kHz to 80 MHz In ISM Bands $d = \left[\frac{12}{V_2}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{12}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{23}{E_1}\right]\sqrt{P}$
0.01	0.04	0.12	0.12	0.23
0.1	0.11	0.38	0.38	0.73
1	0.35	1.2	1.2	2.3
10	1.11	3.8	3.8	7.3
100	3.5	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.				



At 80 MHz and 800 MHz, the higher frequency range applies.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

PREVENTIVE MAINTENANCE

The Mako requires preventive maintenance (PM) performed by authorized service personnel to make reliable and consistent measurements of essential operational parameters. The PM session also provides the standard maintenance activities necessary to keep the system at its optimum level of performance.



Preventive Maintenance is to be performed by Stryker-qualified service personnel only.

Preventive Maintenance will be initiated by Stryker and may include the following activities:

- Inspecting the system cables and connectors.
- Inspecting and cleaning the Mako System.
- Inspecting all LED functions.
- Testing Mako homing, brakes and robotic arm calibration.
- Inspecting the UPS system on the Mako.
- Inspecting the mechanical cables in the arm.
- Inspecting motor assemblies (encoders, motor phasing, etc.).

Cleaning, disinfection and electrical safety testing are to be considered preventive maintenance activities that are performed by the healthcare facility biomedical engineering department.

SYSTEM DISPOSAL



Contact MAKO Surgical Corp. before disposing of any Mako equipment.

To dispose of Mako equipment, it is recommended that the following procedure be followed. This procedure helps ensure the safe disposal of the system. In addition, disposal must be consistent with any contractual obligations with Stryker regarding the Mako.

Procedure

1. Power down the equipment.
2. Inspect the equipment for signs of biohazard contamination.
3. De-contaminate the equipment.
4. Contact Customer Service for additional information required for removal of the system application software (as specified in the software license agreement) and disposal of any potentially hazardous materials.
5. Disassemble the equipment and dispose of it with a qualified salvage and disposal specialist.



Mako Surgical Corporation (Stryker) instruments are to be disposed of in accordance with applicable laws, rules and regulations. Follow all guidelines for disposal of electrical equipment as well as applicable federal, national, state and local regulations. If a device is being returned for evaluation, please contact your local Mako Surgical Representative for shipping and handling information.

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