

Symani[®]

SURGICAL SYSTEM

Symani Surgical System's Safety and Performance



LAB.00497 Rev.22
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(December 2024)

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Equipment and Software Version

This User Manual provides technical information about the use and operation of the Symani Robotic Assisted System for Microsurgery MMI SW Build:1.44 and later HW: CMM-X010 (*) and CNS-Y00 (**).

(*) "X" is the identifier of the plug type (e.g., "B", "E", "G", "J", "F", "K", "I")

(**) "Y" is the identifier of the Console model (e.g., "0" for flat seat, "1" for saddle seat)

This User Manual provides technical information about the use and operation of the NanoWrist Instruments.

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1 Introduction

This document reports the Symani Surgical System's safety and performance as requested by the MDR 745/2017 / Annex I / Chapter III/ Point 23.1.

The information reported in the present document are extracted from the Instructions for Use of the Symani (CNF-00177 Rev.22).



NOTE: Symani users must follow all provided instructions for system use and the use of its components, Instruments, and accessories.

For Customer Service and Reporting of Complaints or Adverse Events

Use the following information for customer service, including ordering, reporting complaints or adverse events, and general information regarding MMI, our products and services.



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For Technical Support

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1.1 Professional Instructions for Use

Device Name: Symani

Indications for Use

The Symani System is intended for soft tissue manipulation to perform microsurgery techniques such as anastomosis, suturing and ligation on small anatomical structures such as blood vessels, nerves and lymphatic ducts, for open surgery procedures.

The Symani System's teleoperated-Instruments are indicated for use during microsurgical procedures when use of a motion scaling function is deemed appropriate by the surgeon.

The Symani System is not intended for use on the heart, central circulatory system, and central nervous system.

The System is indicated for adult and pediatric use. It is intended to be used by trained physicians in an appropriate operating environment in accordance with the Instructions for Use.

Symani is a medical device system dedicated to use in professional healthcare facility environment.



NOTE: Symani is a medical device system compatible with general High Frequency (HF) Surgical Equipment, complying with IEC 60601-2-2.



NOTE: If the Symani System has a failure or system error due to EM disturbances the system will stop, preserving the essential performance of a safe state (refer to Chapter Error! Reference source not found. for instruction to recover the proper functionality).



NOTE: In case of occurrence of unrecoverable system failure, the Symani System must be turned off and restarted. If system failure persists, MMI suggests to remove system from the operative field and continue the microsurgical procedure manually.




WARNING: The dimensions and spatial configuration of the Instruments may cause risk to the patient when accessing recessed cavities through natural orifices, such as the middle ear, throat, or nasal cavities. Use of the Symani Instruments in such cases should be carefully evaluated. In particular, to safely use the Instruments in recessed cavities, their dimensions must be large enough to allow Instrument insertion in the Center Axis position and then the movements required to perform the surgical task.




WARNING: The use of Symani Instruments presents additional risks in surgical procedures where uncontrolled, rapid or macroscopic movements of the anatomical structures being treated cannot be prevented. Use of the Symani teleoperated-instruments in such cases should be avoided. Therefore, the patient shall be either under general anesthesia or appropriately stabilized.




WARNING: Use of the Symani System in the presence of MRI, CT, diathermy, or Electromagnetic Security Systems has not been tested. The Symani System should not be used near active devices where the intensity of EM disturbances is high, like magnetic resonance imaging (MRI), Computerized Tomography (CT), diathermy, or Electromagnetic Security Systems.

 **WARNING:** The Console EM transmitter of the tracking system is ON starting from the moment the machine is turned on. Therefore, the system should not be used on patients with active implantable or wearable medical device or a device using a permanent magnet (e.g., pacemakers, implantable defibrillators, cochlear implants, nerve stimulators for pain relief or incontinence, deep brain stimulators, infusion pumps, and any implantable or body worn permanent magnet). Users with active implantable or wearable medical device or a device using a permanent magnet should not be present from the moment the System is turned on.


 **WARNING:** The Symani System **MUST NEVER** be used by or on a person with a pacemaker. The EM tracking system may cause interference on internal or external pacemakers. The use of the system by users or on patients with pacemakers may cause these devices to enter an asynchronous mode or may inhibit pacemaker operation entirely. A label on the back of the Console back rest reinforces this warning.




*Figure 1-1: Symani **MUST NOT** be used by or on a person with a active implantable or wearable medical device or a device using a permanent magnet.*


 **WARNING:** Only for users considered to be at particular risk from electromagnetic fields and in relation to areas of Knees and Perineum of the operator sitting on the Console.


- It is recommended to limit use of the device by pregnant healthcare professionals.
- It is recommended to seek the opinion of a competent doctor before a healthcare professional with a magnetic prosthesis in their lower limb uses the system.

 **WARNING:** Only instruments and accessories provided and approved by Medical Microinstruments, Inc. can be used with the Symani System.

 **WARNING:** If Symani is used with other Medical Electrical (ME) Equipment, leakage currents can be additive.

 **WARNING:** Symani shall not be used with laser ME Equipment.

 **WARNING:** Before each use, the compatibility of the Symani System, with any instruments and other applied parts including those of other ME Equipment, shall be checked according to any criteria for safe use defined in the instructions for use.

 **WARNING:** If the Symani System is used simultaneously with high frequency (HF) surgical equipment, in case of contact, the NanoWrist Instruments could transfer current to patient causing tissue

burning, or the Instrument tendons breakage. Avoid contact with high frequency (HF) surgical equipment during combined use.



WARNING: Do not stack other equipment on the Symani System.

Essential Performances

In fully functional conditions, the surgeon-controlled motion of the Master Controllers is scaled down and reliably translated to corresponding Instrument tip motions in a precise and reproducible manner, with a maximum acceptable deviation of tip position of 5% with respect to the user commanded translation displacement, and of 15% with respect to the user commanded angular displacement.

Degradation or total loss of the performance shall not cause a deviation of tip position greater than 6mm.

Representative Uses

Symani is intended for manipulation of soft tissue to perform microsurgical techniques such as anastomosis, suturing and ligation on small anatomical structures such as blood vessels, nerves and lymphatic ducts. Symani is intended for use on any anatomical areas that can be accessed by open surgery such as the head, neck, thorax, abdomen, and limbs.

Training

The System should be used only by surgeons who have developed adequate robotic skills to perform the tasks associated with each procedure and who have received specific training provided by MMI in the use of this device. Training provided by MMI is limited to the use of Symani and does not replace the necessary medical training and experience required to perform microsurgical procedures.

Additional Considerations for Paediatric Surgical Procedures

Performance during a paediatric surgical procedure is based on the similarity of tasks performed during an adult surgical procedure. As is appropriate with any surgical procedure, consideration must be given to patient size and workspace volume when using the system and Instruments.

1.2 General Precautions, Warnings, and Contraindications

Symani is to be used in accordance with the User Manual and should not be moved or used by any person who has not been trained by an MMI representative. Read all instructions carefully. Failure to properly follow instructions, notes, cautions, warnings and danger messages associated with this equipment may lead to serious injury or surgical complications for the patient. While these messages appear throughout the manual, this chapter provides some general precautions.

All relative and absolute contraindications to traditional surgical technique also apply to the use of Symani.

Robotic Procedure Precautions

Only physicians having adequate training and experience with microsurgical techniques should perform robotic procedures with Symani. Medical literature should be consulted regarding techniques, complications, and hazards before performing any microsurgical procedure.



WARNING: Symani is not intended for use in an oxygen-rich environment.



WARNING: In order to avoid interference with the Symani system, RF communication systems, such as smartphone or wireless amplifier, and RFID systems shall be kept at minimum distances from Symani system as specified in Table 3a, Table 3b and Table 3c. EM interference may cause system malfunctioning or system halt.



WARNING: 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 Symani System's CMM, including cables. Otherwise, degradation of the performance of this equipment could result.



WARNING: RF communications equipment (including peripherals such as antenna, cables and external antennas) should be used no closer than 110 cm (43 inches) to any part of the Symani System's Console, including cables. Otherwise, degradation of the performance of this equipment could result.



WARNING: RFID systems should be used no closer than 15 cm (5.9 inches) to any part of the Symani System, including cables. Otherwise, degradation of the performance of this equipment could result.



WARNING: Life sustaining medical devices (e.g. ECG or respiration monitor) should be kept at a distance of at least 30 cm (1 ft) from the Console.



WARNING: For the correct functioning of Symani, make sure that there is no potential electromagnetic disturbance or other types of disturbance. In particular, use of the Symani System in the presence of MRI, CT, diathermy, or Electromagnetic Security Systems has not been tested. The Symani System should not be used in the vicinity of these devices due to the EMI hazards posed by these devices. EM interference may cause system malfunctioning or system halt.



WARNING: Cables next to the Console, including Console cables, could cause interference resulting in unwanted system interferences or exit teleoperation. Please, keep other cables away from the Console of the Symani Surgical System.



WARNING: Symani should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is unavoidable, equipment or system should be observed to verify normal operation in configuration in which it will be used.



WARNING: To preserve the correct functioning of the Symani System, it is forbidden to place any objects, in particular liquids, on top of the CMM.



Figure 1-2: Label on the CMM top panel: Liquid forbidden on top of the CMM.

1.3 Electromagnetic Compatibility

Symani is a medical device system dedicated to use in professional healthcare facility environment. Symani has been tested and found to be in compliance with IEC 60601-1-2 Edition 4.1 2020-09, International standard for Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests. It is intended to be used in an appropriate operating environment or appropriate outpatient environment, depending on the procedure, and operation of Symani is unaffected when used in the electromagnetic environment as specified in Tables 2 below in this section [Electromagnetic Compatibility](#). Special precautions and installation information for Symani for electromagnetic compatibility (EMC) are provided in this section. The safety of the Symani System is unaffected when exposed to full range of electromagnetic environments as described in the IEC 60601-1-2 Edition 4.1 2020-09 standard. Only use cables and accessories provided by MMI. Performance of cables or accessories, other than those specified by MMI, as replacement parts for internal components cannot be guaranteed. Any resulting damage to the System will not be covered under warranty. Equipment in the appropriate operating environment, depending on the procedure, can cause Electromagnetic Interference (EMI), which may affect the function of these devices. Such effects are prevented by use of equipment with Electromagnetic emission characteristics proven to be below recognized limits, as identified in the tables below. In the event of suspected interference caused by other equipment, which prevents the proper functioning of Symani, contact MMI and/or discontinue use of the System until the problem can be resolved.

EMC Tables

The following tables contain the Manufacturer’s declaration and additional information required by IEC 60601-1-2 Edition 4.1 2020-09.

Table 1: Guidance and manufacturer’s declaration – electromagnetic emissions		
The Symani Surgical System is intended for use in the electromagnetic environment specified below. The customer or the user of the Symani Surgical System should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Symani Surgical System uses RF energy only for its internal function. Its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Symani Surgical System is suitable for use in all establishments other than domestic.
Emission of harmonic oscillations according to IEC 61000-3-2	N/A	N/A
Voltage fluctuations / flicker emissions according to IEC 61000-3-3	N/A	N/A



NOTE: 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 re-orienting the equipment.

Table 2: Manufacturer's Declaration – Electromagnetic Immunity			
Symani is intended for use in the electromagnetic environment specified below. The customer or the user of Symani should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	The relative humidity should be at least 5%. Touch a large metal object that is away from the patient before approaching and touching the Console Master Controllers.
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 100KHz repetition frequency ±1 kV for input/ output lines	Mains power quality should be that of a hospital environment with highly reliable service. Keep other cables away from the cables of the Symani Surgical System.
Surge IEC 61000-4-5	±0.5-±1 kV line-to line ±0.5, ±1, ±2 kV line-to-ground	0.5, ±1 kV line-to-line 0.5, ±1, ±2 kV line-to-ground	Mains power quality should be that of a hospital environment with highly reliable service
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0%, 0.5cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0%;1 cycle and 70%; 25/30cycles at 0° Voltage interruption 0%; 250/300cycles	0%, 0.5cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0%;1 cycle and 70%; 25/30cycles at 0° Voltage interruption 0%; 250/300cycles	Mains power quality should be that of a hospital environment with highly reliable service. If the user of the Symani requires continued operation during power mains interruptions, it is recommended that Symani be powered from an uninterruptedly power supply or a battery.
RATED Power Frequency Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital environment.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1KHz	3 V/m 80 MHz to 2.7 GHz 80% AM at 1KHz	Radiated RF fields should be at levels characteristics of a typical location in a typical hospital environment.
Conducted Disturbances induced by RF fields IEC 61000-4-6	3V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Conducted disturbances induced by RF fields should be at levels characteristics of a typical location in a typical hospital environment.
Proximity RF fields IEC 61000-4-3	See Table 3a, Table 3b and Table 3c	See Table 3a, Table 3b and Table 3c	RF communication equipment (including peripherals such as antenna, cables and external antennas) should be used no closer, including cables, than 30 cm (12 inches) to Symani system's CMM, and 110 cm (43 inches) to Symani system's Console.

Table 3a: RF communication system and recommended separation distance from the CMM-X010				
Test frequency (MHz)	Band (MHz)	Service	Compliance level	Minimum Separation Distance (m-inches)
385	380 - 390	TETRA 400	27 V/m	0.3m - 12"
450	430 - 470	GMRS 460, FRS 460	28 V/m	0.3m - 12"
710	704 - 787	LTE Band 13, 17	9 V/m	0.3m - 12"
745				
780				
810	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	28 V/m	0.3m - 12"
870				
930				
1,720	1,700 - 1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	28 V/m	0.3m - 12"
1,845				
1,970				
2,450	2,400 - 2,570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	28 V/m	0.3m - 12"
5,240	5,100 - 5,800	WLAN 802.11 a/n	9 V/m	0.3m - 12"

Table 3b: RF communication system and recommended separation distance from the Console CNS-Y00				
Test frequency (MHz)	Band (MHz)	Service	Compliance level	Minimum Separation Distance (m-inches)
385	380 - 390	TETRA 400	7.4 V/m	1.1m - 43"
450	430 - 470	GMRS 460, FRS 460	8.5 V/m	1m - 40"
710	704 - 787	LTE Band 13, 17	9 V/m	0.3m - 12"
745				
780				
810	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	7.5 V/m	1.1m - 43"
870				
930				
1,720	1,700 - 1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	28 V/m	0.3m - 12"
1,845				
1,970				
2,450	2,400 - 2,570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	28 V/m	0.3m - 12"
5,240	5,100 - 5,800	WLAN 802.11 a/n	9 V/m	0.3m - 12"

Table 3c: RFID systems and recommended separation distance from the Symani System		
Test frequency	Compliance level	Minimum Separation Distance (m-inches)
30KHz	8 A/m	0.15m - 5.9"
134.2KHz	65 A/m	
13.56MHz	7.5 A/m	

Intentional Electromagnetic Emissions of the Console

The Symani Console generates a quasi-static magnetic field with a frequency of 80 Hz, originated from the frontal part of the Console. The magnetic field RMS (Root Mean Square) strength and spatial distribution is reported in Table 4.

Table 4: Magnetic field RMS in proximity of the Console for other equipment		
Distance from Emitter	Magnetic field (RMS)	
	μT	A/m
30cm	18.3	14.56
60cm	2.91	2.31
100cm	0.77	0.62