Appendix E System Specifications

Contents

E.1 Design Life

The system has a design life of 5 years. However, even after 5 years, the standard maintenance contract provides preventive maintenance, inspection, and re-qualification by Intuitive personnel that extends the service life of the system until the next scheduled service, which occurs at least every 2 years.

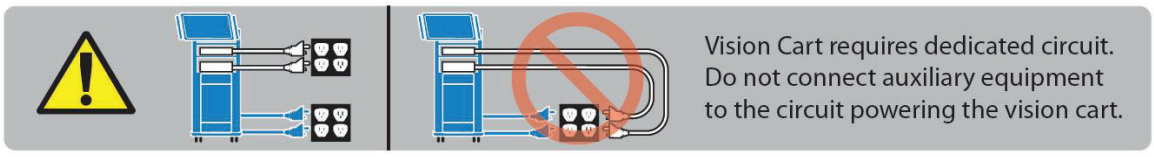
E.2 Power Requirements – Main Components

The system has three main components requiring electrical power: the Console, the Robot, and the Tower. The integrated VIO dV electrosurgical unit also requires electrical power. To ensure optimum performance, make sure each component of the system (including the VIO dV) is connected to a dedicated, noise-free, and well-grounded AC power outlet.

⚠ **CAUTION:** To avoid overloading circuits, all three components – Tower, Robot, and Console – must operate on separate, dedicated power circuits. Do not connect ancillary devices such as insufflators or energy devices on the same circuit as the system components, particularly the Tower because it has large power requirements. Ancillary devices must be connected to wall outlets on separate circuits from all system components.

A label on the rear of the Tower reinforces this caution. Its text appears below the label image.

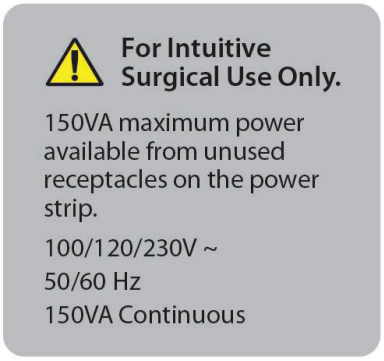
Figure E.1 Tower power caution label



"Vision Cart requires dedicated circuit. Do not connect auxiliary equipment to the circuit powering the Vision Cart."

The integrated power strip in the Tower also has the label below:

Figure E.2 Tower integrated power strip caution label



For Intuitive Use Only.

150 VA maximum power available from unused receptacles on the power strip.

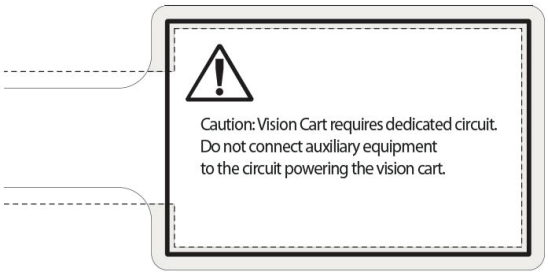
100/120/230 V~

50/60 Hz

150 VA Continuous

A label wrapped around the Tower power cord also reinforces this point:

Figure E.3 Tower power cord caution label



Caution: Vision Cart requires dedicated circuit. Do not connect auxiliary equipment to the circuit powering the Vision Cart.

The tables below provides dedicated circuit requirements for each component.

Table E.1 Dedicated circuits required for 115 VAC, 60 cycle at 15 and 20 amperes

System Component	Circuit	Voltage VAC	Ampere Service
Console 1	1	115	15
***Optional* Console 2**	2	115	15
Robot	3	115	15
Tower	4	115	20[a]
This circuit can be shared with other auxiliary devices such as an insufflator, third-party electrosurgical unit, video recorder, etc.	5	115	As needed
Notes a. Circuit breaker for the Tower needs to be suitable for motor-transformer loads. (For example, tripping characteristic "K".)			

Table E.2 Dedicated circuits required for 230 VAC, 50 cycle at 10 Y

System Component	Circuit	Voltage VAC	Ampere Service
Console 1	1	230	10
***Optional* Console 2**	2	230	10
Robot	3	230	10
Tower	4	230	10[a]
This circuit can be shared with other auxiliary devices such as an insufflator, third-party electrosurgical unit, video recorder, etc.	5	230	As needed
Notes a. Circuit breaker for the Tower needs to be suitable for motor-transformer loads. (For example, tripping characteristic "K".)			

The Console, Robot, and Tower automatically adapt to 100–230 VAC. This technique is called "Auto Sense" (see table below). Refer to the electrical rating label located on the bottom rear panel of the system components.

Table E.3 Auto sense

System Component	Voltage	Rating
Console	100–230 V~ 50/60 Hz Auto Sense	1000 VA Continuous
Robot	100–230 V~ 50/60 Hz Auto Sense	1200 VA Continuous
Tower –includes Core, Endoscope Controller and AP5000	100–230 V~ 50/60 Hz Auto Sense	1500 VA Continuous
Core[a, b]	100–230 V~ 50/60 Hz Auto Sense	650 VA Continuous
Endoscope Controller[a]	100–230 V~ 50/60 Hz Auto Sense	450 VA Continuous

(continues on next page)

Table E.3 Auto sense (continued)

System Component	Voltage	Rating
AP5000[a]	100–230 V~ 50/60 Hz Auto Sense	175 VA Continuous

Notes

a. Core, Endoscope Controller power requirements are included in the Tower. These are provided separately for reference only.

b. If any of the carts in the system are to be run on voltage higher than 120 VAC in the U.S., it must be powered from a center-tapped, single phase circuit.

E.3 Power Specifications – Main Components

Table E.4 Power specifications for main components

	Console	Robot	Tower (includes Core, AP5000, and Endoscope Controller)
Voltage	100–230 VAC 50/60 Hz Auto Sense	100–230 VAC 50/60 Hz Auto Sense	100–230 VAC 50/60 Hz Auto Sense
Rating and Typical Current	1000 VA Continuous 8.4 A at 115 V~ 4.2 A at 230 V~	1200 VA Continuous 7.5 A at 115 V~ 3.8 A at 230 V~	1500 VA Continuous 12 A at 115 V~ 6 A at 230 V~
Typical current in sleep mode	0.7 A at 115 V~ 0.35 A at 230 V~	1.0 A at 115 V~ 1.0 A at 230 V~	2.0 A at 115 V~ 1.2 A at 230 V~
Typical current in sleep mode (battery charging)	NA	8.5 A at 115 V~ 4.6 A at 230 V~	NA
Max inrush current at 230 VAC	24.1 A	56.0 A	63.6 A
Backup Power	NA	5 min.	NA
Surge Protected	Yes	Yes	No

E.4 Power Specifications – Tower Components

Table E.5 Power specifications for Tower components

	Core [a, b]	Endoscope Controller	AP5000
Voltage	100–230 VAC 50/60 Hz Auto Sense	100–230 VAC 50/60 Hz Auto Sense	100–230 VAC 50/60 Hz Auto Sense
Power	650 VA Continuous	450 VA Continuous	175 VA Continuous
Backup Power	NA	NA	NA
Surge Protected	No	No	No

Notes

a. Core power requirements are included in the Tower. These are provided separately for reference only.

b. If the Core is powered separately from the Tower, it must be powered from a center-tapped, 240 V, single phase circuit. This requirement applies to the U.S. only.

E.5 Power Specifications – Integrated Equipment

Table E.6 Power specifications for integrated equipment

	Insufflator	Generator
Voltage	VAC 50/60 Hz T8A / T4A	VAC 50/60 Hz T8A / T4A
Power	VA max	VA max
Backup Power	NA	NA

E.6 Laser Specifications – Robot

Table E.7 Laser classification

CLASS 1 LASER PRODUCT
Complies with 21 CFR 1040.10 and 1040.11
Except for deviations pursuant to laser notice No. 50
Dated June 24, 2007

Feature/Light Source	Laser Class	Specification
Horizontal Laser	Class 1	as per IEC 60825-1
Positioning Laser	Class 1	as per IEC 60825-1

Table E.8 Laser radiation and source characteristics

Feature/Light Source	Wavelength	Specification
Horizontal Laser	532 nm	as per IEC 60825-1
Positioning Laser	532 nm	as per IEC 60825-1

E.7 Physical Dimensions

Table E.9 Physical dimensions

	Console	Robot	Tower
Height (min.)	57 in. (145 cm)	71.5 in. (182 cm)	76 in. (193 cm) with touchscreen stowed
Height (max.)	71 in. (180 cm)	98.5 in. (250.2 cm)	87.5 in. (223 cm) with touchscreen extended
Width	38 in. (96.5 cm)	41 in. (104 cm)	27 in. (68.6 cm)
Depth	34 in. (86 cm)	60 in. (150 cm)	36.5 in. (92.7 cm)
Weight	620 lbs. (280 kg)	1900 lbs. (861 kg)	818 lbs. (371 kg)
Ground Clearance	1.9 in. (48 mm)	1.9 in. (48 mm)	4 in. (10.2 cm)

E.8 Environmental Specifications

Table E.10 Environmental conditions: operating

Environmental Conditions: operating	
Temperature	10 to 30 °C (50 to 86 °F)
Humidity	10 to 85% non-condensing
Atmospheric Pressure	The system shall function properly in atmospheric pressures ranging from 523 mm HG (10,000 ft.) to 774 mm HG (-500 ft.). For every 1000 feet above sea level, the 30 °C operational temperature limit specified above will be reduced by 1 °C. (For example, the maximum operating temperature at 5000 feet will be 25 °C, and the maximum operating temperature at 10,000 feet will be 20 °C.)

Table E.11 Environmental conditions: storage and transport

Environmental Conditions: Storage and Transport	
Temperature	-20 to 60 °C (-4 to 140 °F)
Humidity	5 to 90% non-condensing

Note: Storage and transport of the system are not affected by atmospheric pressure.

E.9 Crate Dimensions

Table E.12 Crate dimensions

	L x W x H	Weight
Console	? x ? x ?" (? x ? x ?m)	? lbs (? kg)
Robot	70 x 50 x 87.5" (1.78 x 1.27 x 2.22 m)	2292 lbs (1039.6 kg)
Tower	? x ? x ?" (? x ? x ?m)	? lbs (? kg)

E.10 Electromagnetic Compatibility

The system has been tested and found to be in compliance with **IEC 60601-1-2:2007 or IEC 60601-1-2:2014, depending on the date of manufacture. For more information on IEC compliance, contact Intuitive Customer Service**.

It is intended to be used in an operating room environment and operation of the system is unaffected when used in the electromagnetic environment as specified in Tables 2 – 4 in the EMC

Tables section. Special precautions and installation information for the system for electromagnetic compatibility (EMC) are provided in this section.

The performance of the system is unaffected when exposed to full range of electromagnetic environment as described in the IEC 60601-1-2 standard. There is no degradation of performance and therefore no risks to the patient or other devices due to Electromagnetic Interference (EMI) when used in the electromagnetic environment as specified in Tables 2 – 4 below in the EMC Tables section.

Use only Intuitive-branded interconnection cables and accessories. Performance of cables or accessories other than those specified by Intuitive as replacement parts for internal components cannot be guaranteed. Any resulting damage to the system will not be covered under warranty.

Note: Use of cables or accessories other than those specified by Intuitive may result in increased electromagnetic emissions or decreased immunity of the system.

Equipment in the operating room, including the system and other portable or mobile communications equipment, can produce Electromagnetic Interference (EMI), which may affect the function of these devices. Such effects are prevented by use of equipment with EMI characteristics proven below recognized limits, as identified in the below tables.

WARNING: Symptoms of interference could include repeated faults, unintentional movement of arms, instruments or endoscope, loss or frozen video, loss of wireless connectivity. In the event of suspected interference from other equipment, which prevents the proper functioning of the system, contact Intuitive and/or discontinue use of the system until the problem can be remedied.

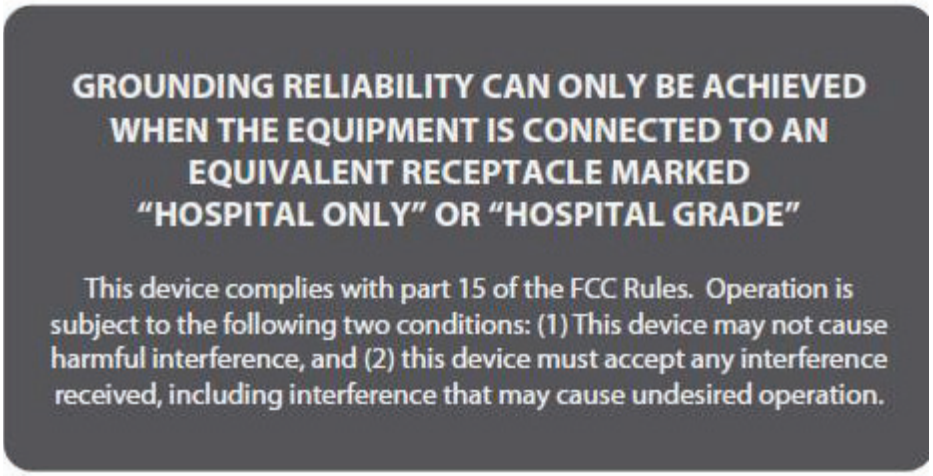
Note: The system should not be used adjacent to or stacked with other equipment. However, if adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it is used.

Note: This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

FCC Compliance

Note: This equipment 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. This equipment 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 this equipment 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 expense.

In regard to grounding reliability and electromagnetic interference, see the label below, which appears on the Console and Robot. Its text is repeated below the label image:



GROUNDING RELIABILITY CAN ONLY BE ACHIEVED WHEN THE EQUIPMENT IS CONNECTED TO AN EQUIVALENT RECEPTACLE MARKED "HOSPITAL ONLY" OR "HOSPITAL GRADE"

This device complies with part 15 of the FCC Rules. operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Essential Performance

Note: The essential performance for system during EMC testing was defined as follows during any of the required tests:

The system shall display a real-time image of the surgical site with acceptable clinical performance. If the displayed image is not live, such as when displaying a recorded image or in the event of system malfunction, it shall be obvious to the user that the displayed image is not a live image. There shall be no uncontrolled or unexpected motions of the endoscope or instrument tips.

During immunity testing, the following conditions are not allowed to meet the basic safety and essential performance criteria:

- Faults that cause system restart while in READY MODE – HEAD IN state unless allowed by the Medical standard
- Unintentional movement of the arms
- Loss or frozen image where transient flicker is acceptable

Persistent loss of connectivity for the Wireless Connectivity Option where loss of connectivity is acceptable if the connection can be re-established after the test.

EMC Tables

IEC 60601–1–2:2007

The system has been tested and found to be in compliance with IEC 60601-1-2:2007 International standard for Medical electrical equipment — Part 1-2: General requirements for basic safety and