Robocath

INTUITIVE VASCULAR ROBOTICS

R-One™

SAFETY INFORMATION

MC-000-220923-00-00

Warnings

The system should only be used by interventional cardiologists and their staff, who have received specific training for the use of the R-One™ device. The training provided by Robocath is limited to the use of the system and does not replace the expertise and medical training necessary to perform coronary angioplasty.

The movement of the guidewire and/or stent/balloon catheter with the system should not be performed without viewing them using X-rays.

The navigation speed of the guidewire and/or stent/balloon catheter should be adapted to the arterial areas traversed. The fast navigation mode should only be used when the guidewire and the stent/balloon catheter are in the guide catheter.

Precautions for use

The R-One™ system is not recommended for heavily calcified lesions, ostial lesions, and chronic total occlusions (CTOs).

The R-One™ Robotic Platform is designed to be used exclusively in combination with the Mobile Radioprotection Screen and the R-One™ Consumable Kit.

The R-One™ system is only compatible with the equipment described in Table 1.

Device/equipment
0.014'' guidewires
Rapid exchange stent/balloon catheter
Y connectors: - Super Ketch™ by Minvasys - Honor® Hemostasis Valve by Merit Medical

Table 1: Equipment compatible with the R-One™ system

Use of the system with other devices has not been evaluated.

Recommandations for use

For an optimal use of the system, it is recommended to use a 6 Fr guiding catheter minimum.

Additional warnings and cautions

a. Possibility of conversion to manual technique

The R-One™ system does not prevent, at any time, reversion to the manual method. While the R-One™ system is safe and effective, some environmental or equipment failures can render the R-One™ system unusable.

CAUTION: The interventional cardiologist must always be ready to revert to the manual method.
CAUTION: In the event of a power failure, follow the conversion procedure to manual technique to complete the procedure.

b. Automatic system safety mode

In the event that the system detects an internal malfunction, it will automatically trigger its safety mode, resulting in:

- Cutting off the power supply to the actuators that enable the drive of the guidewire and the stent/balloon catheter,
- The activation of safety mode notifications on the Robot and Command Unit.

CAUTION: In safety mode, follow the conversion procedure to manual technique to complete the procedure.

c. Emergency stop

The system is equipped with two emergency stop buttons located on the Command Unit and on the Robot (see Figure 1). Activation of one of the emergency stop buttons will automatically cut off the power supply to the actuators that enable the drive of the guidewire and the stent/balloon catheter.

WARNING: Do not block access to the emergency stop buttons.
CAUTION: When pressing an emergency stop button, conversion to manual technique is required to complete the intervention.

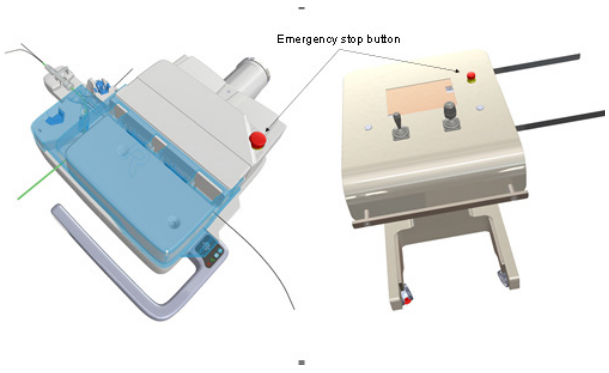

Figure 1: View of the emergency stop areas

Power supply

The R-One™ system has been designed in accordance with the standard IEC 60601-1 ed. 3.1. Its operating mode as well as the type and degree of protection against the risks of electrocution are described below:

- **Operating mode:** Continuous
- **Type of protection**: Class 1

The system power is carried by the Command Unit:

System component	Voltage	Power
Command Unit	100 – 240 Vac 50 – 60 Hz Automatic detection	96VA continuous 368VAC peak power

Table 2: Authorized power sources for using the R-One™ system

WARNING: To avoid the risk of electric shock, the system must only be connected to a power supply with protective earthing.

WARNING: Any change to the R-One™ system is prohibited.

WARNING: Risk of electric shock: Do not use the system if cables are worn.

CAUTION: When cleaning the system, be sure to unplug the unit from the mains.

Electromagnetic compatibility

All information mentioned in this section comes from requirements of the standard IEC60601-1-2 Ed4.
The medical device R-One™ complies with applicable medical electrical equipment standards. However, the user should ensure that electromagnetic interferences do not generate any additional risks.
This section includes necessary information to ensure the installation and commissioning of the device under the best conditions in terms of electromagnetic compatibility.
The different cords of the device must be separated from each other.
Certain types of mobile telecommunication devices such as mobile phones are likely to interfere with the medical device. The separation distances recommended in this chapter must therefore be strictly observed.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided as it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Cables length

Cables and accessories	Maximum length	Test type	In compliance with:
Cables, cords	> 3 m	RF emissions	CISPR 11, Class A
		Harmonic current emissions	IEC 61000-3-2
		Voltage fluctuations/Flicker	IEC 61000-3-3
		Electrostatic discharge immunity	IEC 61000-4-2
		Radiated, radio-frequency, electromagnetic field immunity	IEC 61000-4-3
		Fast transients in bursts immunity	IEC 61000-4-4
		Transient overvoltage immunity	IEC 61000-4-5
		Immunity to conducted disturbances, induced by radio-frequency fields	IEC 61000-4-6
		Power frequency magnetic field immunity	IEC 61000-4-8
		Voltage dips, short interruptions and voltage variations immunity	IEC 61000-4-11

Recommended separation distances:

The R-One™ system is intended for use in an electromagnetic environment in which radiated radio frequency (RF) disturbances are controlled.
The client or user of the R-One™ system can help prevent electromagnetic interference by maintaining a minimum distance, in function of the maximum power of the RF transmission equipment.

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 R-One™ system, including cables specified by the manufacturer. Otherwise, this could result in degradation of the performance of this equipment.

Electromagnetic emissions:

The R-One™ system is intended for use in the electromagnetic environment specified below. The user or installer of the R-One™ system should ensure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment - notes
Electromagnetic radiation disturbance (Radiated emissions) (CISPR 11)	Group 1	The R-One™ system uses RF energy for its internal functions.
Supply terminals disturbance voltage (Conducted emissions) (CISPR 11)	Class A	The EMISSIONS characteristics of this device allow it to be used in industrial and hospital areas (Class A defined in CISPR 11). When used in a residential environment (for which class B defined in CISPR 11 is normally required), this device may not provide adequate protection for radio frequency communications services. The user may need to take corrective measures, such as relocating or reorienting the device. Home health care environment and professional health care facility environment.
Harmonic current emissions (IEC61000-3-2)	Class A Compliant	
Voltage fluctuations/ Flicker (IEC61000-3-3)	Compliant	

Magnetic and electromagnetic immunity:

The R-One™ system is intended for use in the magnetic and electromagnetic environment specified below. The client or user of the R-One™ system should ensure that it is used in such an environment.

Immunity test	Test level according to IEC60601	Level of compliance	Electromagnetic environment - notes
Electrostatic discharge (ESD) (IEC61000-4-2)	± 8 kV on contact ± 15 kV in the air	± 8 kV on contact ± 15 kV in the air	Professional health care facility environment.
Fast transients in bursts (IEC61000-4-4)	± 2 kV for power supply lines	± 2 kV for power supply lines ± 1 kV for signal ports	Professional health care facility environment.
Transient overvoltage immunity (IEC61000-4-5)	± 1 kV in differential mode ± 2 kV in common mode	± 1 kV in differential mode ± 2 kV in common mode	Professional health care facility environment.
Magnetic field at assigned power frequency (IEC61000-4-8)	30 A/m	30 A/m	Professional health care facility environment.
Voltage dips, short interruptions and voltage variations (IEC61000-4-11)	0 % UT during 0.5 cycles A 0°, 45°, 90°, 135°, 180°, 225°, 270° et 315° 0 % UT during 1 cycle 70 % UT for 25 to 50 cycles at 50 Hz for 30 to 60 cycles at 50 Hz Single-phase at 0°	0 % UT during 0.5 cycles A 0°, 45°, 90°, 135°, 180°, 225°, 270° et 315° 0 % UT during 1 cycle 70 % UT for 25 to 50 cycles at 50 Hz for 30 to 60 cycles at 50 Hz Single-phase at 0°	Professional health care facility environment. If R-One™ use requires continued operation during mains power interruptions, it is recommended to use a separate power source (UPS, etc.).
Voltage interruptions (IEC61000-4-11)	0 % UT ; for 250 cycles at 50 Hz for 300 cycles at 60 Hz	0 % UT ; for 250 cycles at 50 Hz for 300 cycles at 60 Hz	Professional health care facility environment. If R-One™ use requires continued operation during mains power interruptions, it is recommended to use a separate power source (UPS, etc.).

Electromagnetic immunity, radiofrequency:

The R-One™ system is intended for use in the magnetic and electromagnetic environment specified below. The client or user of the R-One™ system should ensure that it is used in such an environment.

Immunity test	Test level	Level of compliance	Electromagnetic environment - notes
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 R-One™ system, including cables specified by the manufacturer. Otherwise, it could result in degradation of the performance of this equipment.			
Radiated, radio-frequency, electromagnetic field (IEC61000-4-3)	3 V/m 80 MHz to 2.7 GHz 80 % MA to 1 kHz 10 V/m 80 MHz to 2.7 GHz 80 % MA to 1 kHz	3 V/m 80 MHz to 2.7 GHz 80 % MA to 1 kHz 10 V/m 80 MHz to 2.7 GHz 80 % MA to 1 kHz	Professional health care facility environment.
Proximity fields emitted by RF wireless communications devices (IEC 61000-4-3 provisional method)	9 V/m 710 MHz, 745 MHz, 780 MHZ, 5240 MHz, 5550 MHz, 5785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	9 V/m 710 MHz, 745 MHz, 780 MHZ, 5240 MHz, 5550 MHz, 5785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	Professional health care facility environment.
Conducted disturbances, induced by RF fields (IEC 61000-4-6)	3 V 150KHz to 80MHz 6V in ISM band and band between 0.15MHZ and 80MHZ, including amateur radio communications 80% MA to 1 KHz	3 V 150KHz to 80MHz 80% MA to 1 KHz 6V in ISM band and band between 0.15MHZ and 80MHZ, including amateur radio communications 80% MA to 1 KHz	Professional health care facility environment.

WARNING: If the device is used in inappropriate magnetic and electromagnetic environment, the product will not perform properly.

Risk of explosion

WARNING: The system should not be used in an oxygen rich environment.

Airborne noise emissions

The airborne noise emissions level, at the workstation (Command unit), does not exceed 70 dB.

Sterile and disposable components

The R-One™ Consumable Kit is sterilized by gamma irradiation.

WARNING: This product is for single use only/disposable: reuse exposes the patient or user to contamination.
WARNING: This product must not be re-sterilized.
WARNING: Check the integrity of the packaging before use. If the packaging is opened and/or damaged, do not use the product.

Table compatibility

This section contains the information needed to install the R-One™ on an intervention table.
Reminder of the weights of the R-One™ components:

- Articulated support arm = 40kg
- Robot = 12kg
- Total = 52kg

CAUTION: Ensure that the maximum accessories weight on the table is at least 52kg. Any additional medical equipment attached to the table that is not a part of the R-One™ System must be accounted for when evaluating the total weight on the table. Refer to the documentation supplied by the table manufacturer for weight load information.
CAUTION: Do not tilt or lateral tilt (cradle) the table while the R-One™ is mounted on the table.
CAUTION: The robot should be maintained over the table. Store the R-One™ System in the recommended stroring position. Damage to table or injury to user may result if the robot is located beyond the table rail.

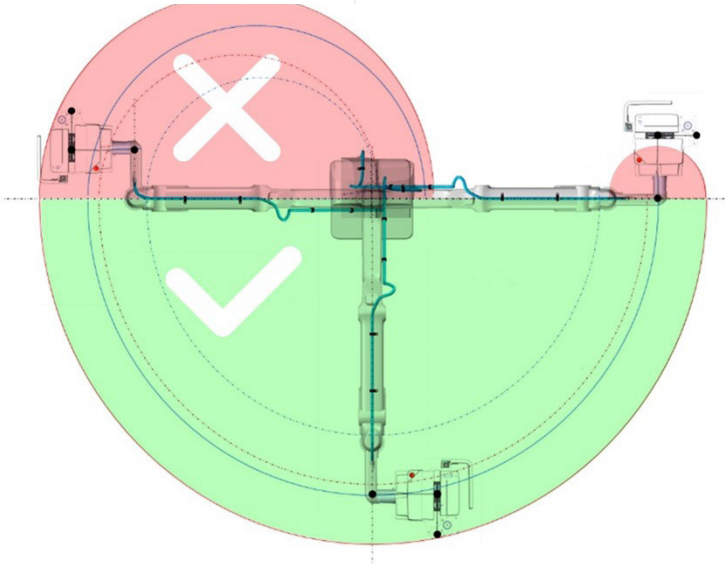

Figure 2: Correct Robot position area

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BSI, CE n°690387
The R-One robotic platform is a Class IIb medical device.
The R-One consumable kit is a Class Is medical device.

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