# INSTRUCTIONS FOR USE

## Surgical Electric Support Arm

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**Target Audience**
This leaflet (IFU) is intended for healthcare professionals.

**User training**
The following instructions for use are for informational purposes only. All healthcare professionals are responsible for their medical training and experience and must apply the following instructions in accordance with good clinical practice and the patient's state of health.

**Information for users**
Any serious incident in relation to the device should be notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
For any further incidents, please return the product concerned to the manufacturer and contact directly by email quality@isomedfrance.fr.

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# 1. General Description

MD Medical device

The **Surgical Electric Support Arm** is an electromechanical system comprising of a main housing unit, a fixed rail clamp, an articulated arm, a handle, instrument clamps, and a power adapter. This system is intended to provide rigid, static positioning of surgical instruments such as endoscopes, retractors, and other diagnostic and therapeutic tools. This device is provided non-sterile and must be cleaned and disinfected prior to use. As an active device not intended for direct contact with the human body, it possesses only indirect influence on clinical outcomes.

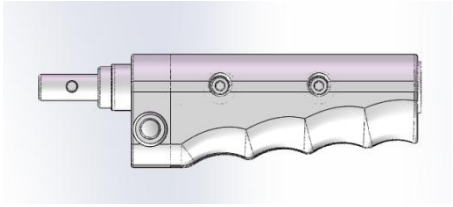
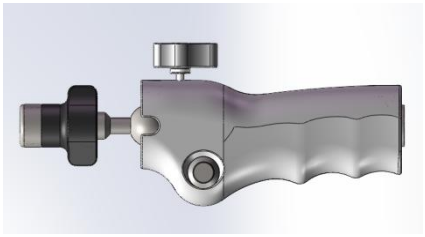
The **Surgical Electric Support Arm** is available with two types of handles: The F Series and the R Series. Handles for the F Series are fixed while handles for the R Series are rotatable. The device overview for both F Series and R Series handle types are shown as follows:


**Device Overview - F Series**


**Device Overview - R Series**

# 2. Models and Specifications

Based on differences in the handles and working lengths of the articulated arms, the **Surgical Electric Support Arm** is available in a total of fourteen models, as shown in the table below:

| Handle type | Model | Working length (mm) | Tolerance (mm) |
|---|---|---|---|
| F Series<br>(Fixed handle)<br>  | BSC600F | 600 | ±15 |
| | BSC650F | 650 | |
| | BSC700F | 700 | |
| | BSC750F | 750 | |
| | BSC800F | 800 | |
| | BSC850F | 850 | |
| | BSC900F | 900 | |
| R Series<br>(Rotatable handle)<br>  | BSC600R | 600 | ±15 |
| | BSC650R | 650 | |
| | BSC700R | 700 | |
| | BSC750R | 750 | |
| | BSC800R | 800 | |
| | BSC850R | 850 | |
| | BSC900R | 900 | |

Each series of handles shall be used with corresponding models of instrument clamps. Each instrument clamp model is designed to hold different types of instruments. Select the appropriate instrument clamp based on surgical requirements. The following table shows sample images of the two handle types, along with their corresponding instrument clamps:

| | | | | |
|---|---|---|---|---|
| F series |  <br>F-EN3D |  <br>F-EASY |  <br>F-PLAT |  <br>F-UNIV |
| R series |  <br>R-EN3D |  <br>R-EASY |  <br>R-PLAT |  <br>R-UNIV |
| Maximum Compatible Instrument OD | 45 mm | 20 mm | 18 mm | 18 mm |

# 3. Intended Purpose and Indications for Use

## 3.1 Intended Purpose

The **Surgical Electric Support Arm** is a non-invasive active device intended to provide rigid, static positioning of surgical instruments such as endoscopes, retractors, and other diagnostic and therapeutic tools.

## 3.2 Intended User

The **Surgical Electric Support Arm** is intended for use by qualified and trained healthcare professionals.

## 3.3 Intended Patient Population

The **Surgical Electric Support Arm** is intended for use in patients as determined by an attending healthcare professional.

## 3.4 Indications

Intended for use in various surgical procedures where stable instrument positioning is required.

## 3.5 Contraindications

There are no known contraindications for the use of this device.

# 4. Warnings and Precautions

## 4.1 Warnings

⚠ Use only components and accessories supplied or explicitly authorized by the manufacturer of this device. The use of unauthorized parts may compromise system safety, lead to equipment damage, or result in injury to the user or patient.

⚠ 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.

⚠ Use of accessories and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.

⚠ Do not use portable RF communications equipment (including peripherals such as antenna cables and external antennas) with separation distance under 30 cm (12 inches) to any part of the **Surgical Electric Support Arm**, including cables provided by the manufacturer. Otherwise, degradation of the performance of this device could result.

## 4.2 Precautions

⚠ Do not use in environments with strong magnetic fields such as MRI scanners.

⚠ Do not disassemble, repair, or modify this device. Unauthorized modifications may lead to permanent equipment damage.

⚠ Should the instrument clamp loosen, detach, or be subjected to a severe impact or collision, cease use immediately and contact the manufacturer to arrange an inspection of the device.

⚠ Do not store together with chemical solvents.

⚠ Do not place liquids near the power switch to prevent fluid ingress causing equipment malfunction.

⚠ Do not immerse in ethanol-based organic agents when disinfecting the device.

⚠ Do not use in the surgical field prior to covering the device with a sterile drape.

# 5. Preparation

1. Verify power connection: Upon connecting the main housing unit to the power supply, press the power switch, the power indicator light should illuminate.
2. Verify system structural integrity: When the system is powered on, the articulated arm should remain in a fixed position.
3. Verify articulated arm mobility: When the system is powered on, pressing the activation button should place the articulated arm in a free-flow state.

⚠ Do not connect the device to a power supply network without protective grounding to prevent the risk of electric shock.

⚠ Do not position this device where it is difficult to access and disconnect the mains plug.

# 6. Instructions for Use and Maintenance

## 6.1 Instructions for Use

Step 1: Attach the fixed rail clamp to the surgical table side rail. Ensure they are level before tightening. Rotate the main housing unit to the desired angle and tighten the clamping handle on the main housing unit. Verify the stability of the main housing unit.
Step 2: Connect the main housing unit to the power supply with the power adapter provided.
Step 3: Turn on the power switch and verify that the articulated arm maintains a static position. Cover the device with a sterile drape to be provided by the user.
Step 4: Press and hold the activation button located on the handle to move the articulated arm. Release the button to fix the arm in place. Verify that the arm can maintain both a static and mobile state when doing so.
Step 5: Select the appropriate instrument clamp according to surgical needs and attach to the handle.
Step 6: Secure the endoscope or surgical tool into the instrument clamp. Press and hold the activation button to move the articulated arm to the desired surgical position. Release the button to lock the arm in place.
Step 7: (Applicable to R Series handles only) To adjust the orientation at a fixed position, loosen the orientation lock on the handle and rotate the orientation knob accordingly. Tighten the lock once the desired orientation is achieved.
Step 8: Following the operating procedure, move the articulated arm away from the patient. Dismount the surgical instrument, press and hold the activation button to loosen the articulated arm, then turn off the power switch. Disassemble and disinfect the instrument clamp using the recommended solvent. If necessary, disassemble the main unit.

⚠ After use, make sure the articulated arm is loosened before turning off the power switch.

## 6.2 Maintenance

| | |
|---|---|
| **Instrument clamp:** | Disinfect by first rinsing under running utility water and then submerging in a neutral detergent for 10 minutes. Do not exceed this duration.<br>To remove detergent residue, rinse thoroughly with running distilled water. Dry the component completely to prevent corrosion.<br>Before placement in the designated storage container, confirm the clamp is free of debris and operates as intended. |
| **Main housing unit, articulated arm, fixed rail clamp, power adapter:** | After powering off, manually wipe down with disinfectant alcohol or ethanol. Avoid liquid ingress into the device during cleaning, as this may cause damage. |

⚠ After disinfection, store carefully away from moisture, high temperatures, and dust to prevent bacterial growth.

⚠ Manage the disinfection environment appropriately and pay attention to the disinfection duration.

⚠ Keep away from water and direct sunlight.

⚠ Keep away from dust and air containing chlorides or sulphides.

⚠ Do not store together with chemical solvents.

# 7. Technical Specifications

| | | |
|---|---|---|
| Adapter | Input | 100-240 VAC, 50-60 Hz, 2.5-1.3 A |
| | Output | 24 VDC, 9.2 A, 221 W MAX |
| Rated Input | | 24 VDC, 80 W |
| Maximum payload of the articulated arm | | 2 kg |
| Maximum payload of the overall system | | 20 kg |
| ⚠ Use only the power adapter provided with this device. This adapter has been validated for electrical safety and EMC compatibility. Use of unauthorized power adapters may result in equipment damage or injury to the user or patient. | | |

# 8. Service-life

- 5 years.

# 9. Storage and Transportation

## 9.1 Operating Conditions

- Ambient temperature range: +5 to +40 °C;
- Relative humidity range: ≤ 80%;
- Atmospheric pressure range: 700 hPa to 1060 hPa.

## 9.2 Transportation and Storage Conditions

- Ambient temperature range: -20 to +50 °C;
- Relative humidity range: ≤ 90%;
- Atmospheric pressure range: 500 hPa to 1060 hPa.

# 10. Explanation of Electromagnetic Compatibility (EMC)

**Guidelines and Manufacturer's Declaration—Electromagnetic Immunity**

Information on EMC compliance (IEC 60601-1-2) (The following provisions apply to all models and specifications of the Surgical Electric Support Arm manufactured by ISOMED)

**WARNING：**

1. The Surgical Electric Support Arm may interfere with medical electrical equipment. Purchasers or users shall install and use the device in accordance with the EMC compliance (IEC 60601-1-2) information provided within this Instructions for Use.
2. Use of accessories and power adapters other than those specified may result in increased emissions or decreased immunity of the Surgical Electric Support Arm, except for power adapters sold by the manufacturer as spare internal components.
3. The Surgical Electric Support Arm shall not be used adjacent to or stacked with other equipment.
4. Stay away from areas near active high-frequency electrosurgical units (ESUs) or RF-shielded rooms of magnetic resonance imaging (MRI) systems in hospitals.
5. Guidelines and the manufacturer's declaration are detailed in Table 1 to Table 4:

**Table 1 Guidelines and Manufacturer's Declaration—Electromagnetic Emissions**

The Surgical Electric Support Arm is intended for use in the electromagnetic environment specified below. Purchasers and users shall ensure that the device is used in such an environment.

| Electromagnetic Emissions | Compliance | Electromagnetic Environment – Guidelines |
|---|---|---|
| Radio frequency emissions CISPR11 | Group 1 | The Surgical Electric Support Arm uses radio frequency energy solely for its internal functions. Therefore, its radio frequency emissions are very low, and the likelihood of interfering with other electronic equipment is minimal. |
| Radio frequency emissions CISPR11 | Class A | The Surgical Electric Support Arm is suitable for use in all facilities that are not domestic and not directly connected to a low-voltage public power supply network for residential use. |
| Harmonic emissions IEC 61000-3-2 | Not applicable | |
| Voltage fluctuations/flicker emissions IEC 61000-3-3 | Not applicable | |

**Table 2 Guidelines and Manufacturer's Declaration—Electromagnetic Immunity**

The Surgical Electric Support Arm is intended for use in the electromagnetic environment specified below. Purchasers and users shall ensure that the device is used in such an environment.

| **Electromagnetic Immunity** | **Test Level per IEC 60601** | **Compliance Level** | **Electromagnetic Environment – Guidelines** |
|---|---|---|---|
| Electrostatic discharge (ESD)<br>IEC 61000-4-2 | ±8 kV contact discharge<br>±2, ±4, ±8, ±15 kV air discharge | ±8 kV contact discharge<br>The device is fully metallic; air gap discharge cannot be tested. | The floor should be wood, concrete or ceramic tile. If the floor is covered with synthetic materials, the relative humidity shall be at least 30%. |
| Electrical fast transient/burst (EFT/B)<br>IEC 61000-4-4 | ±2 kV for power supply lines | ±2 kV for power supply lines | The quality of the mains power supply shall be typical of a commercial or hospital environment. |
| Surge<br>IEC 61000-4-5 | ±0.5, ±1 kV line-to-line<br>±0.5, ±1, ±2 kV line-to-earth | ±0.5, ±1 kV line-to-line<br>±0.5, ±1, ±2 kV line-to-earth | The quality of the mains power supply shall be typical of a commercial or hospital environment. |
| Power frequency magnetic field (50/60 Hz)<br>IEC 61000-4-8 | 30 A/m | 30 A/m | The power frequency magnetic field level shall be typical of that found in specific locations in a commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11 | Voltage dips:<br>100% Ut[#1], 0.5 cycles<br>100% Ut, 1 cycle<br>30% Ut, 25 cycles<br>Short interruptions:<br>100% Ut, 250 cycles | Compliant | If the user requires continuous operation during mains power interruptions, it is recommended that the device be powered by an uninterruptible power supply (UPS) or battery. |

[#1] Note: Ut is the AC mains voltage prior to the application of the test voltage.

**Table 3 Guidelines and Manufacturer's Declaration – Electromagnetic Immunity**

The Surgical Electric Support Arm is intended for use in the electromagnetic environment specified below. Purchasers and users shall ensure that the device is used in such an environment.

| **Electromagnetic Immunity** | **Test Level per IEC 60601** | **Compliance Level** | **Electromagnetic Environment – Guidelines** |
|---|---|---|---|
| Conducted immunity<br>IEC 61000-4-6 | 3 Vrms (150 kHz–80 MHz)<br>6 Vrms (ISM frequency band) | 3 V (6 V) | When using portable radio frequency (RF) communication equipment, the distance from the device and its cables shall not be less than the recommended separation distance. |
| Radiated immunity<br>IEC 61000-4-3 | 3 V/m<br>80 MHz-2.7 GHz | 3 V/m | Recommended separation distance #1:<br>d=1.2√p (80 MHz~800 MHz) #2<br>d=2.3√p (800 MHz~2.7 GHz)<br>Where:<br>P — maximum rated output power of the transmitter in watts (W), provided by the transmitter manufacturer;<br>d — recommended separation distance in meters (m）。<br>The field strength from fixed RF transmitters shall be determined by electromagnetic field surveying, and shall be below the compliance level in each frequency range. Interference may occur near devices marked with the relevant symbol.<br>  |

#1 Note: These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects and the human body.

#2 Note: At frequencies of 80 MHz and 800 MHz, the formula for the higher frequency band shall be applied.

Fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile cordless telephones, amateur radio, AM and FM radio broadcast and television broadcast, etc., the field strength of which cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, electromagnetic field surveying shall be considered. If the measured field strength in the location in which the Surgical Electric Support Arm is used exceeds the above RF compliance level, the Surgical Electric Support Arm shall be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Surgical Electric Support Arm.

The field strength shall be below 3 V/m over the entire frequency range of 150 kHz ~ 80 MHz.

**Table 4 Recommended Separation Distances between Portable/Mobile RF Communication Equipment and the Surgical Electric Support Arm**

The Surgical Electric Support Arm is intended for use in an electromagnetic environment where RF radiated disturbances are controlled. Purchasers and users can prevent electromagnetic interference by maintaining a minimum distance between portable/mobile radio frequency (RF) communication equipment (transmitters) and the Surgical Electric Support Arm, in accordance with the maximum output power of the communication equipment.

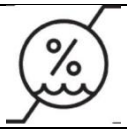
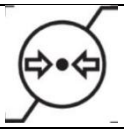
| **Maximum Rated Output Power of Transmitter (W)** | **Recommended Separation Distance d / m for Different RF Frequencies of Transmitter [#1]** | | |
|---|---|---|---|
| | **150 KHz ~ 80 MHz**<br>**$d = 1.2\sqrt{P}$** | **80 MHz ~ 800 MHz [#2]**<br>**$d = 1.2\sqrt{P}$** | **800 MHz ~ 2.5 GHz[#2]**<br>**$d = 2.3\sqrt{p}$** |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitter maximum rated output powers not listed in the table above, the recommended separation distance d (in meters) can be determined using the formula in the relevant transmitter frequency column. Where P is the maximum rated output power of the transmitter in watts (W), provided by the transmitter manufacturer.

*[#1] Note: These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects and the human body.*

*[#2] Note 1: At frequencies of 80 MHz ~ 800 MHz, the formula for the higher frequency range shall be applied.*

# 11. Symbols Guide

| Symbol | Description | Symbol | Description | Symbol | Description |
|---|---|---|---|---|---|
|  | CE marking |  | Batch number |  | Date of manufacture |
|  | Catalogue number |  | Serial number |  | Warning |
|  | Caution |  | Manufacturer trademark |  | Refer to the instruction manual/booklet |
|  | Stacking limit by 5 | IPX0 | Non-protected of water |  | Non-sterile |
|  | Waste bin |  | Keep away from sunlight |  | Keep away from rain |
|  | Temperature limit |  | Unique Device Identifier |  | Medical device |
|  | Manufacturer |  | Humidity limitation |  | Atmospheric pressure limitation |
|  | Unlock |  | Lock | | |

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