Mofixx System User Manual

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CE

Mofixx System User Manual

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Mofixx System User Manual

1 GENERAL INFORMATION

Caution: Do not use the product without carefully reading this user manual.

This manual contains warnings and safety instructions which needs to be read carefully.

Symbols manual	Explanation
	Caution refers to important safety information
	Warning refers to a possible hazardous situation which could lead to harm.

In case of any questions after reading this text, please contact Mofixx B.V.

2 INTRODUCTION

2.1 Device description

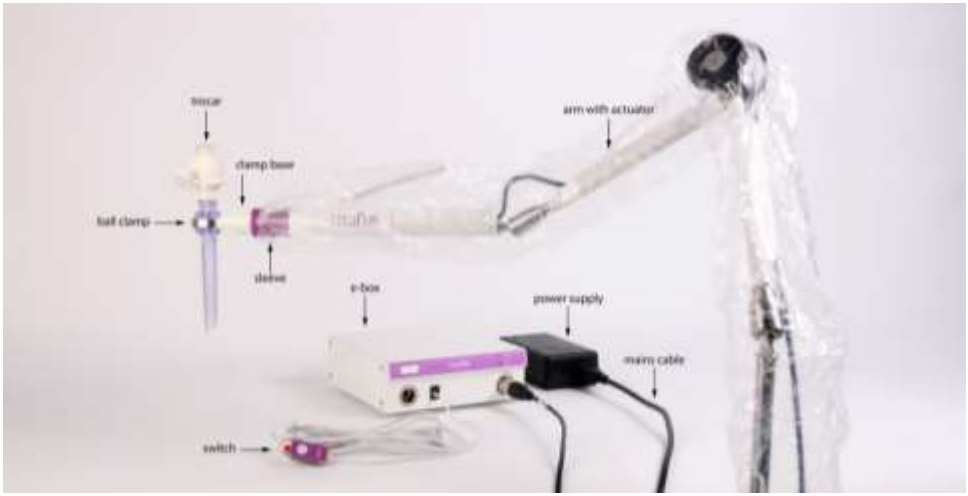

Figure 1

The Mofixx system (Catalogue number Z1101-1000) is a laparoscopic camera and instrument holder that ensures static stabilization of laparoscopes and laparoscopic instruments without the need for an assistant.

The laparoscope holds the Mofixx trocar in a fixed position. The trocar sphere can be tightened by strapping a ball clamp, securely fixating the laparoscope in the trocar in a desired position. The clamp is the most distal part of the holding arm. The surgeon can release the fixation by activating a (sterile) switch (normal position is fixated).

The benefits of using Mofixx are the improved working conditions for both surgeon and OR-assistant; stable image, no coordination between surgeon and OR-assistant holding the camera required, and the reduction of the number of people needed for a minimal invasive surgery procedure.

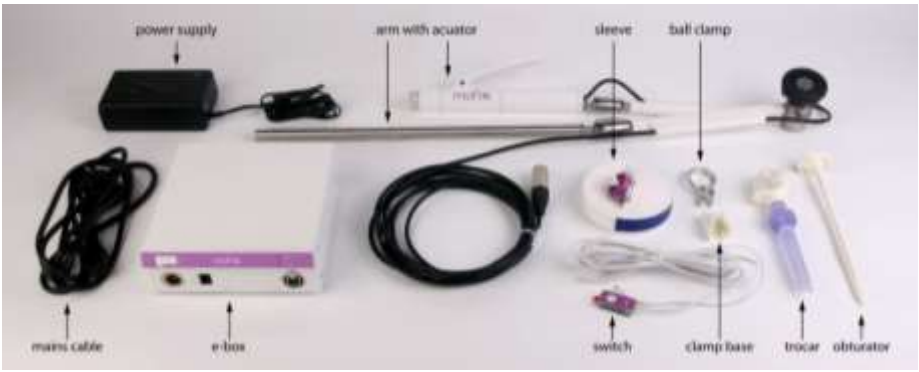

Figure 2

Key features:

- Camera and instruments can be intuitively positioned with one hand by the surgeon;
- Simply move around "drag and drop";
- Ergonomic in use, more space for surgical procedures in the operation area;
- Versatile use for laparoscopic camera and other instruments;
- More stable images on the monitor;
- Cost efficient, solo surgery is possible.

The Mofixx system is classified as a medical device according to the European Regulation for Medical Devices (EU) 2017/745.

Unique Device Identification:

- Basic UDI-DI: 8720299714 7Z1101-SYSTEMEZ
- UDI-DI for system: 08720299714700
- UDI-DI for packaging level including 3 ball clamps: 18720299714707

2.2 Intended use

The Mofixx system is intended to hold and stabilize the laparoscope or laparoscopic surgical instrument in a desired position during a laparoscopic procedure.

2.3 Indications for use

Patients undergoing abdominal, urological and/or gynaecological minimally invasive surgery procedures.

2.4 Contraindications

There are no known contraindications.

2.5 Accessories and other devices to be used with the device

Following accessories and other devices shall be used with the Mofixx system

- Mofixx trocar (single-use sterile device that can be purchased from Mofixx B.V.)
- Clamp base (provided with each Mofixx trocar); disposable part that connects the ball clamp with trocar to the sleeve on the actuator
- Mofixx sleeve (single-use sterile device that can be purchased from Mofixx B.V.)
- Mofixx switch (single-use sterile device that can be purchased from Mofixx B.V.)

- DIN clamp. The arm is compatible with most standard non-isolated DIN-rail clamps. The DIN-rail clamp is not part of the Mofixx product portfolio and can be ordered as separate accessory.

Warning: Only use the Mofixx system in combination with blunt laparoscopic instruments. Never use it in combination with e.g. knives and scissors.

Caution: Do not use the trocar without carefully reading the instructions for use of the Mofixx trocar. This is a separate manual.

Warning: The Mofixx sterile devices (trocar, sleeve, and switch) are intended for single patient use ONLY. Never reuse a single-use device. Re-use can cause cross-infection between patients.

Warning: Never use a single-use part after the expiry date or with a damaged sterile barrier packaging.

The Mofixx system can be used to fixate laparoscope and laparoscopic instruments with maximum weight of: 0,35kg and a nominal diameter of 10 mm (when used in combination with Mofixx trocar Z1101-1300/1400) or 10,3 mm (when used in combination with Mofixx trocar Z1101-1310S/1410S).

Warning: Before use, verify the configuration to verify the suitability of the Mofixx system in combination with the laparoscopic cameras and instruments used at your health care facility.

2.6 Complications

Warning: Use of the Mofixx system should be restricted to surgeons who have had relevant and adequate training and experienced in performing abdominal, urological and gynaecological minimally invasive surgery procedures, and are familiar with the conceivable complications that may occur at any time during or after the procedure.

Complications with the use of the Mofixx system are identical to complication that occur during or after manual minimal invasive surgery procedures, which include:

- Vascular injuries
- Visceral injuries
- Post-operative Trocar site hernia (PTSH)
- Surgical site infections
- Aseptic inflammatory reactions of fat layer
- Extraperitoneal /subcutaneous emphysema
- Haemorrhage

Any serious incident (incident that directly or indirectly led, might have led or might lead to death, temporary or permanent health deterioration of a patient, user or any other person or a serious public health risk) that has occurred related to the Mofixx system, should be reported to the manufacturer and / or distributor and to the competent authority in the Member State in which the user is located.

3 EXPLANATION OF SYMBOLS

One or more of the following markings may appear on the Mofixx system, Mofixx switch, or Mofixx sleeve or its packaging.

Symbol	Explanation
	CE mark
	Medical device
	Manufacturer
	Manufacturing date
	Catalogue number
	Batch code
	Unique Device Identification
	Serial number
	Use by date
	Do not use if package is damaged and consult instructions for use
	Sterilized using ethylene oxide
	Single sterile barrier system
	Keep dry
	Keep away from sunlight
	Caution
	Consult instructions for use or consult electronic instructions for use
	Do not re-use
	Do not resterilize
	Equipotentiality Terminal (Ground)

Symbol	Explanation
IPX1	Protection against dripping water
	Waste of electrical and electronic equipment; it must be sent to separate collection facilities for recovery and recycling

4 USER INSTRUCTIONS

Warning: Do not install, use or de-install the Mofixx system without carefully reading this user manual.

4.1 Unpacking

Check if the Mofixx system box contains all parts and necessary manuals:

- Arm with actuator
- E-box
- Power supply
- Mains cable
- 3 Ball clamps
- Mofixx system user manual

Check if parts are undamaged. Contact the service department of your local sales agent in case damage is found or the packaging is seriously damaged.

Check if Mofixx system is suitable to connect to the existing mains supply.

Clean and disinfect all parts. See chapter 4.6.

4.2 Installation instructions

Installation should be executed with at least 2 persons, one sterile person identified with '**S**' (sterile) and one non-sterile person identified with and '**N**' (non-sterile). Keep sterile and non-sterile actions strictly separated to prevent contamination.

Make sure the Mofixx system is used in an environment described in chapter - - Guidance electromagnetic emissions and immunity.

Required materials (see chapter 7 for part numbers):

- arm with actuator
- e-box
- power supply
- mains cable
- ball clamp (sterile)
- Mofixx trocar with obturator and clamp base (sterile)
- Mofixx sleeve (sterile, single use)
- Mofixx switch (sterile, single use)
- non-isolating DIN-clamp

Warning: Portable and mobile RF communications equipment can affect the Mofixx system performance.

Warning: Never use the Mofixx system when one of the cables is damaged.

Caution: When using multiple Mofixx systems, keep actuator, e-box and power supply matched to make sure the stored data on product use is correct. They are identifiable by serial numbers. These numbers can be found on the backside of the e-box, on the backside of the actuator handle and on the power supply.

Caution: Check proper fixation of the actuator housing parts and fixation of actuator to the arm before each procedure.

Caution: Check if ball clamp is not bent or damaged in any other way. If so replace ball clamp and return damage ball clamp to the 'service department of your local sales agent'.

4.2.1 Install e-box

(N) Plug power supply into e-box and place e-box into the video tower or another cart/trolley available in the OR. Connect e-box with the mains supply using the mains cable and when required use the equipotentiality plug provided on the back to ground the system.

Warning: Always use the dedicated power supply delivered with the Mofixx system. Use of mains cable other than the one delivered with the Mofixx system may result in increased emissions or decreased immunity of the system

Warning: The mains socket should be easily accessible. In the event of operational error, the plug should be immediately removed from the socket.

4.2.2 Install switch

(Using sterile camera→S; using non-sterile camera→N) Peel away the protective cover at the backside accessing the adhesive layer and attach/stick the switch to the laparoscopic camera. Position in a way it is easily accessible and not hindering operation of the camera controls. Select a stable position with the switch cable going in the **same direction as the camera cable** (see **Fout! Verwijzingsbron niet gevonden.**).

(N) Connect the switch cable to the e-box.

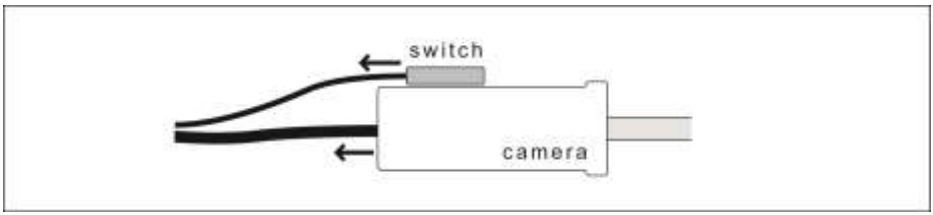

Figure 3

4.2.3 Assemble trocar and clamp:

Clean and sterilize the ball clamps before use. See chapter 4.6.1

(S) Place the sphere of the trocar into the ball clamp (see 1 **Fout! Verwijzingsbron niet gevonden.**). Attach the clamp base to the ball clamp (see 2 **Fout! Verwijzingsbron niet gevonden.**). Match pin on ball clamp with hole in clamp base for right installation (see 3 **Fout! Verwijzingsbron niet gevonden.**).

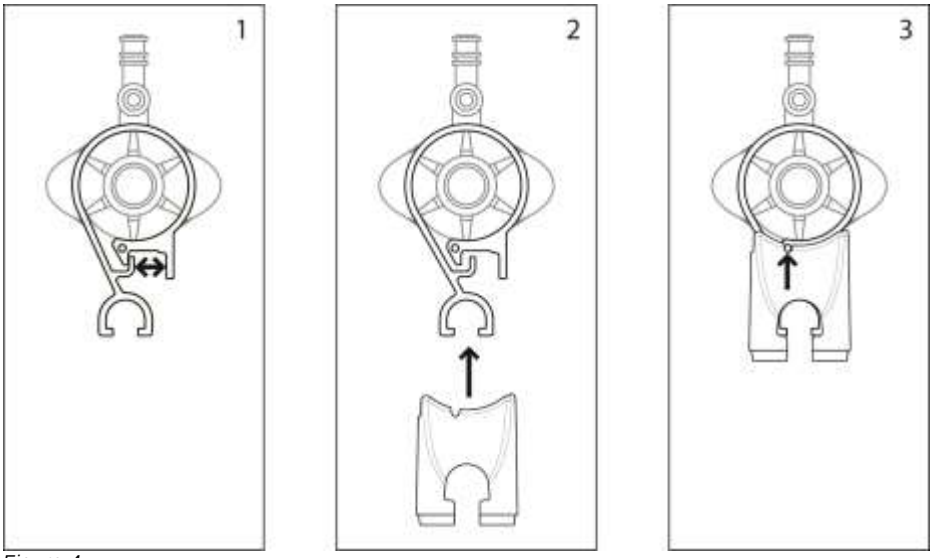

Figure 4

Warning: Only use a dedicated Mofixx trocar in combination with the Mofixx system

Caution: Never open ball clamp further than showed in picture 1 (**Fout! Verwijzingsbron niet gevonden.**) and never twist it. This will lead to permanent deformation by which proper functioning cannot be guaranteed.

4.2.4 Install arm

Caution: Install the arm before the patient is covered with sterile drapes to prevent contamination.

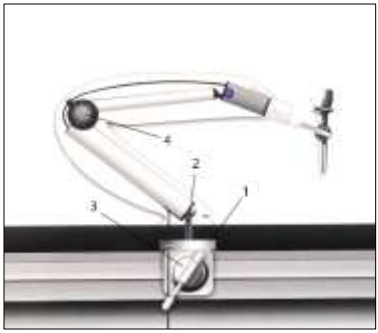

Figure 5

(N) Attach DIN-clamp to the DIN-rail of the operating table (see 1 in Figure 5), fixate arm into DIN-clamp (see 2 in Figure 5) and lock it by rotating (clockwise) the t-screw (see 3 in Figure 5)

(N) Rotate the adjustment knob (see 4 in Figure 5) counter clockwise to release three joints of the holding arm, swivel it to the desired position and lock it by rotating the adjustment knob clockwise.

Warning: Always use a non-isolating DIN rail clamp for mounting the arm to the OR-table.

Warning: Make sure that the OR table is at a safe potential equalisation level.

Warning: When releasing the central handle (turn counter clockwise); the arm-system may not be rotated above the stopper.

(S) Attach coupling part of the Mofixx sleeve to the actuator by pushing it on along the axis of the actuator. (Push the cylinder shaped housing of the sleeve, not the pin). You will hear a clack sound when attached properly. Roll out sleeve along the arm. (See Figure 6)

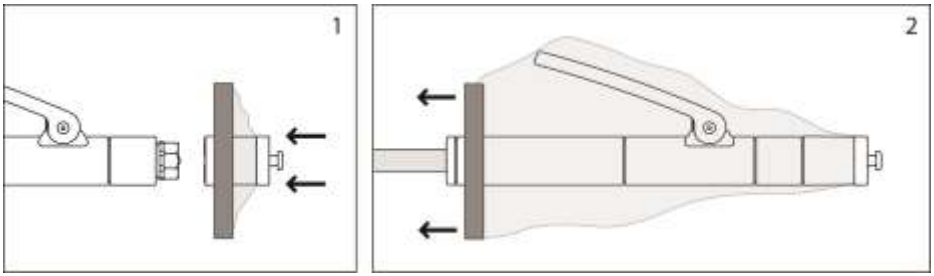

Figure 6

(N) Connect the cable to the e-box.

Warning: Always make sure the actuator and related switch are attached to the same e-box in case two or more Mofixx systems are used.

(S) Position the arm in its desired position after the patient is covered with sterile drapes. Make sure the end of the actuator is close to the spot where the trocar will be inserted in a way it does not obstruct the working area.

Warning: Make sure the rotary knob on the arm is tightened so that the arm stays sufficiently stable in position. Insufficient tightening of the holding arm / clamp socket may result in inadvertent movement. The holding arm/clamp socket may move or drop, which could result in injuries.

Caution: Position the handle of the actuator upwards for easy access.

4.2.5 Power up the e-box

(N) Use power switch on front of e-box to power up the system. The power LED will turn green.

4.2.6 Place trocar

(S) Insert the Mofixx trocar into the patient according to the instructions for use of the Mofixx trocar.

Position the arm and attach the ball clamp to it by pressing the handle on the actuator fully while placing the pin of the sleeve coupling part into the ball clamp hole (see Figure 7). Make sure the position of the ball clamp allows making all desired camera movements.

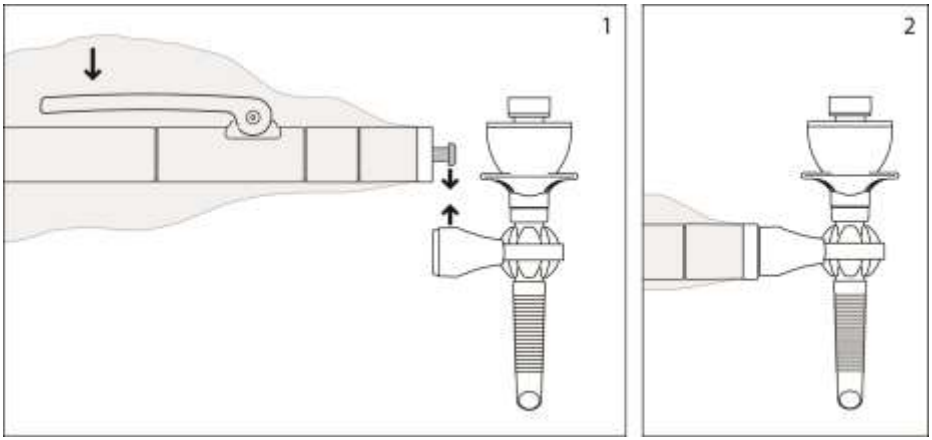

Figure 7

4.2.7 Verify proper installation

(S) Press the switch to release the ball clamp and place laparoscopic camera into the trocar. Release the switch while holding the camera and check proper fixation of the camera. When the system is responding correct it is ready to use. When it is not responding correctly, check chapter 5.

4.3 Operational instructions

4.3.1 Positioning of the holding arm

Hold the holding arm close to the actuator.

Rotate the adjustment knob located at the central joint of the arm system counter clockwise to release the three joints of the holding arm.

Swivel the holding arm and any joint extensions to the desired position.

Hold the holding arm in the desired position and lock all joints simultaneously by rotating the adjustment knob located at the central joint of the arm system clockwise. Minimal clamping force will be reached after 2 x 360 degrees, maximum after 3.5 x 360 degrees.

Warning: Do not use the Mofixx system without carefully reading the user manual.

Warning: Before use, verify the configuration to verify the suitability of the Mofixx system in combination with the laparoscopic cameras and instruments used at your health care facility.

Caution: Always hold the inserted camera when the switch is released.

4.3.2 Operation

When switch is pressed, the laparoscopic camera or instrument can be inserted, moved, or removed from trocar.

The laparoscopic camera or instrument can be repositioned in all following directions at the same time:

- Up and down along the axis of the laparoscopic camera.
- Rotation around the centre of the trocar ball (see Figure 8).

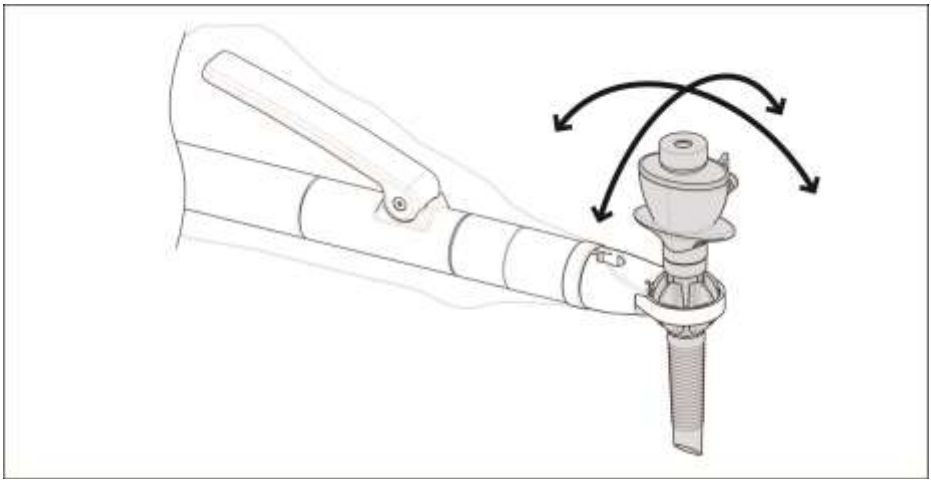

Figure 8

Range of movement: inside ring approximately 95°, locally round clamp base approximately 85°. Full 360° rotation is possible in one direction by rotating the clamp base relative to actuator. (see Figure 9)

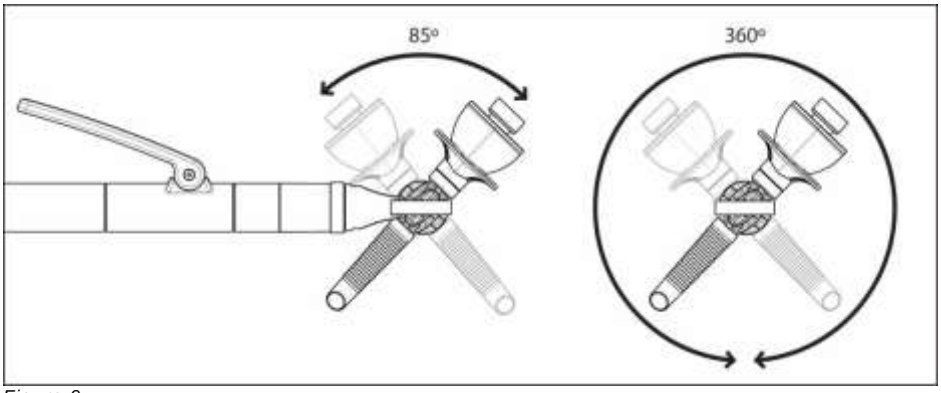

Figure 9

Caution: Besides movement from the trocar inside the ball clamp, the ball clamp (and clamp base) can also rotate relative to the actuator (see Figure 10). To achieve this rotate the trocar until it touches the ball clamp, than use a little more force to rotate the ball clamp. This way the field of operation can be enlarged without having to reposition the arm.

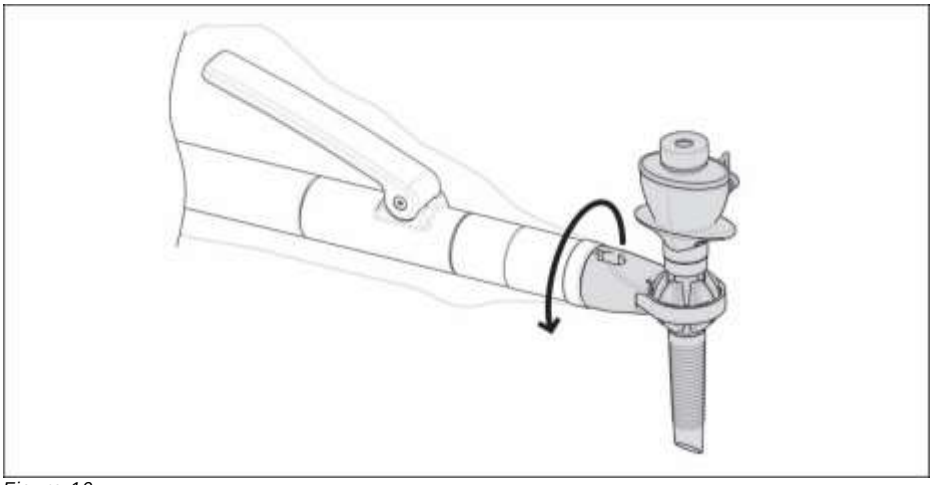

Figure 10

Caution: Never rotate further than the position shown in Figure 11. If overstretching does happen, release the switch so the system moves back in secured position. When the camera cannot move freely after pressing the switch again, gently rotate trocar cup around its axis.

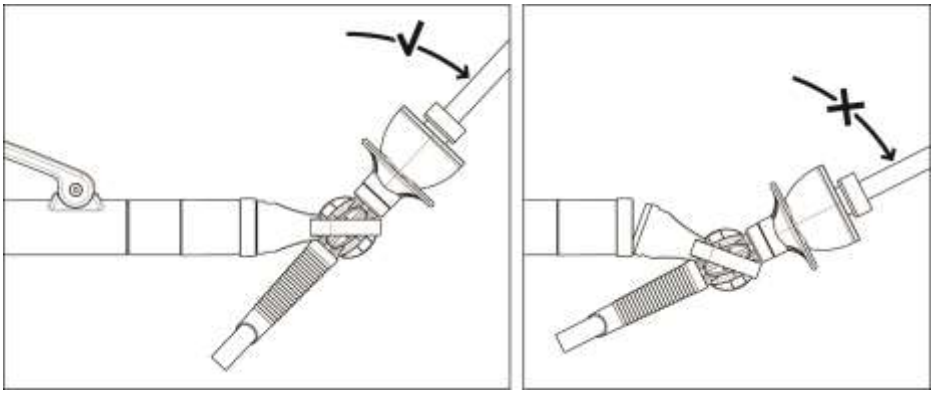

Figure 11

When switch is released:

- Inserted laparoscopic camera is fixated in current position.

Warning: Always keep a grip on the laparoscopic camera until the actuator has finished its closing action (motor sound can be heard). First check/feel if it is locked before releasing the camera.

4.3.3 Manual control

In case the product does not respond when pressing the switch, the manual control can be used to continue the procedure with the Mofixx system. Instead of pressing the switch, press the handle on the actuator.

Warning: Always hold the inserted laparoscopic camera or instrument while pressing the handle on the actuator.

Caution: Make sure proper functioning of the device is verified after the procedure.

Caution: To prevent disconnection of the clamp the handle should not be pressed completely.

Upon releasing the handle on the actuator the laparoscopic camera or instrument is fixated in its current position.

4.4 Switch to open surgery during procedure

In case the MIS procedure has to be changed to open surgery the Mofixx system can be removed quickly by following the steps below. The person that should execute the step is identified by '**S**' (sterile) and '**N**' (non-sterile).

(S) Remove the laparoscopic camera or instrument from the trocar.

(S) Disconnect clamp with attached trocar by pressing the handle while you move the sleeve pin out of the clamp hole (see Figure 12).

(S) Reposition or **(N)** remove arm to create work space.

(S) Remove the trocar with attached ball clamp.

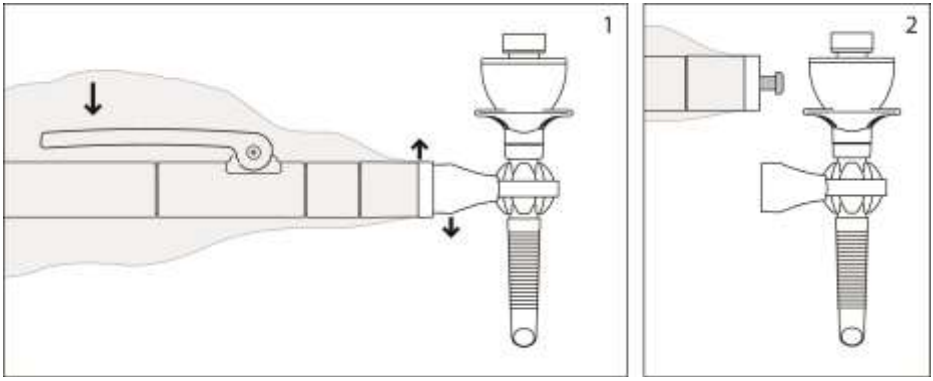

Figure 12

4.5 De-installation

The de-installation should be executed with at least 2 persons, one sterile and one non-sterile person. The person that should execute the de-installation step is identified by '**S**' (sterile) and '**N**' (non-sterile).Following the procedure, it is important to keep sterile and non-sterile actions strictly separated to prevent contamination.

Warning: Always disconnect the trocar from the actuator before de-sufflation.

4.5.1 Disconnect the trocar:

(S) Hold the camera and disconnect the clamp with attached trocar by pressing the handle while you move the sleeve pin out of the clamp hole. (see Figure 13)

Warning: Make sure the laparoscopic camera or instrument is held when you start disconnecting the trocar.

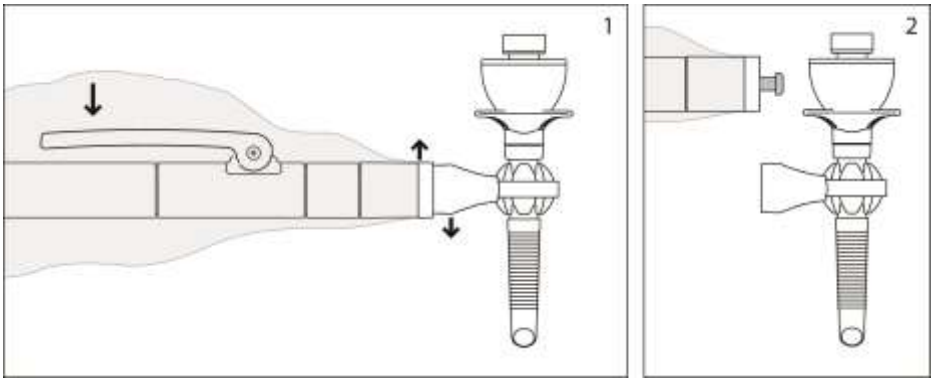

Figure 13

4.5.2 Switch off the system:

(N) Use power switch on front of e-box to turn off the system.

4.5.3 Remove the trocar

(S) The trocar with the attached ball clamp can now be removed from the body. Leave the laparoscopic camera in place during de-sufflation and removal of the trocar. Exteriorization of the cavity contents can occur if the laparoscopic camera is first pulled from the trocar.

4.5.4 Remove arm:

(N) Disconnect arm from DIN-clamp and remove DIN-clamp from operating table.

Patient can be transported.

Warning: When releasing the holding arm, grasp it securely with one hand prior to loosening the adjustment knob on the central joint with the other hand in order to avoid sudden abrupt downward movement.

4.5.5 Remove sleeve from arm:

(N) Remove the sleeve from the actuator by pulling the coupling part off while pressing the handle on the actuator fully. (see Figure 14)

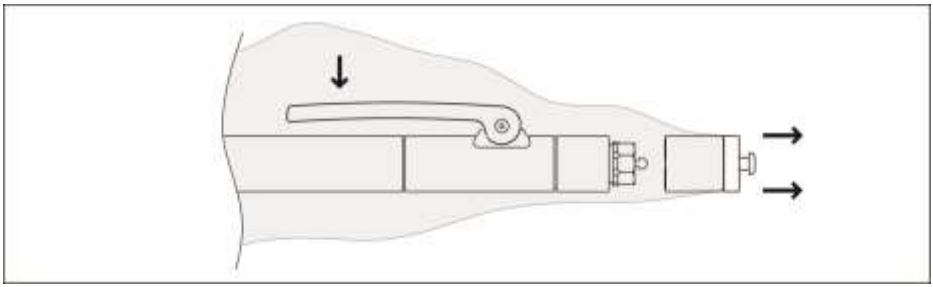

Figure 14

4.5.6 De-assemble ball clamp and trocar

(N) First pull off clamp base (see Figure 15) and then remove the trocar from the ball clamp.

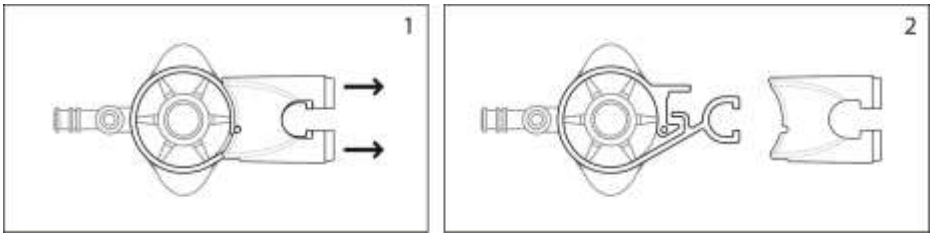

Figure 15

Do not throw away the reusable metal ball clamp.

4.5.7 Disposal single-use parts

(N) Remove switch from laparoscopic camera and throw away all single-use parts (trocar, obturator, clamp base, switch and sleeve).See also chapter 4.7.

4.5.8 Store reusable parts

(N) The reusable parts (arm with actuator, e-box, power supply, mains cable and ball clamp) can now be stored. Store at ambient non-condensing temperature and humidity conditions. Instructions for cleaning can be found in chapter 4.6.

4.6 Cleaning

Warning: Always follow cleaning instructions as described in this manual.

4.6.1 Cleaning, disinfection and sterilization of ball clamp

Sterilize the ball clamp before each use.

Before sterilization, check the ball clamp for cracks, scratches, deformation, wear, and other damages. Replace and dispose of any ball clamps that demonstrate damages or that did not perform according specification during normal use.

Clean the ball clamp immediately after use by removing all visible contamination in order to prevent caking of dirt. Remove (blood) residues with a soft brush and a detergent (neutral or alkaline detergent). Make sure to clean the corners properly. Mechanical cleaning is preferred over manual cleaning (WIP). Use a neutral or alkaline detergent. Check after automated cleaning for visible contamination. If necessary, repeat the cycle or clean manually.

Thermal disinfection (eg. 10 minutes at 93°C) is permitted.

Steam Sterilize at 134°C, minimal 3 minutes.

Follow national and international applicable laws and regulations for sterilisation of medical devices.

4.6.2 Cleaning and disinfection of arm with attached actuator

The arm with attached actuator can be manually cleaned. Only use a damp cloth with 'domestic' soapy water.

Make sure that cleaning agents and disinfectants do not contain acids (≤ pH 5) / Oxidizing acids, bases (≥pH 10 [pH 8,5-9]), organic solvents, alcoholic disinfection agents, benzene, phenol or ammonia, halogens, halogenated hydrocarbons, sodium chloride (in higher concentration) or oxidants / peroxides / hypochlorite. Never use metallic brushes or steel wool to clean instruments.

Warning: Release all joints prior to cleaning procedures to ensure adequate cleaning of joints. However, never disassemble the actuator from the arm or take apart the actuator itself.

Caution: Do not put the arm with attached actuator into a bucket of water and do not clean it by using an autoclave or cleaning bath.

Caution: In case more thorough cleaning is needed contact the 'service department of your local sales agent'.

4.6.3 Cleaning and disinfection of e-box

The **e-box** can be cleaned using a damp cloth with 'domestic' soapy water. Subsequently disinfect with a damp cloth with 70% alcohol.

Warning: Always disconnect power supplier before cleaning.

4.7 Disposal

Dispose of any used single-use parts that have been in contact with the human body according to local applied regulations for bio-hazardous waste.

The E-box classifies as Electrical and Electronic Equipment according to EU WEEE Directive (2012/19/EU) and has been manufactured with high quality parts and materials which can be reused and are suitable for recycling. Do not dispose of the waste product with normal domestic and commercial waste at the end of its service life. Take it to the collection centre for the recycling of electrical and electronic equipment. Please consult your local authorities to learn about these collection centres.

5 FAILURE ANALYSIS

Problem	Solution
Ball clamp cannot be attached to the actuator	1) Make sure handle on actuator is pressed fully. 2) Check if sleeve is properly connected to the actuator. Reconnect to make sure. 3) Check if trocar, ball clamp and ball clamp base are properly connected.
E-box is switched on but power LED is not lit.	Check if e-box is properly connected to the mains supply.
System does not respond when switch is pressed.	1) Check status LED: - LED is not lit: check if e-box is connected with the mains supply and switch is turned on. - LED is blinking: check proper connection switch to e-box. - LED is lit: check proper connection actuator to e-box. 2) When using two or more Mofixx systems: check if switch and related actuator are connected to the same e-box. 3) Apply new switch.
Fixating and releasing the laparoscopic camera is not functioning properly.	1) Check if the sleeve and clamp are properly connected. Reconnect to make sure. 2) Check if camera or instrument diameter is suitable to use with Mofixx trocar. 3) Turn off system and turn on again.
System is not stable	1) Check if housing parts of the actuator are properly fixated to each other. If not: rotate loose parts to fixate. Warning: Make sure actuator goes to 'service department of your local sales agent' after the procedure. 2) Check proper fixation actuator to arm. If not: rotate end part of arm with a tool to fixate. 3) Check proper fixation arm using rotary knob. All 3 (three) joints of the arm must lock correctly. 4) Check proper fixation arm to DIN-clamp 5) Check proper fixation DIN-clamp to DIN-rail
Handle on actuator cannot be pressed	Check if movement is obstructed by the sleeve or something else on the outside of the actuator. Caution: Instructions to remove system without using the handle on the actuator: 1) When possible take out the camera. 2) Release arm knob. 3) Move actuator so the trocar is pulled out of the body.

Problem	Solution
Joints of the arm are not functioning properly	1) Check if the 3 joints are released, by turning the rotary knob counterclockwise. 2) If the joints are released (and do not move), lubricate the joints with a small amount of oil.

Please contact 'service department of your local sales agent' when problem is not fixed.

6 SERVICE AND MAINTENANCE

Proper fixation of the actuator to the arm should be checked before each procedure by the user. Do not try to repair or disassemble the Mofixx system in the event of a malfunction. This can damage the appliance and will invalidate the guarantee.

It is recommended to service the product with a periodic interval of 1 year by the service department of your local sales agent. Contact information can be found on the Mofixx website: www.Mofixx.com.

Have the serial number of the Mofixx system ready when you contact the service department of your local sales agent for technical support. The serial number can be found on the back of the e-box.

Warning: Always contact the 'service department of your local sales agent' for a service check in case the actuator or e-box has been dropped.

7 TECHNICAL SPECIFICATIONS

7.1 General

7.2 Mofixx system

The Mofixx system is composed of the following parts.

- Arm with actuator,
- E-box,
- Power supply, and
- Mains supply cable
- Ball clamp.

Specifications:

- Catalogue number: Z1101-1000
- Product life: 5 years,
- Service interval: 1 year
- EMC tested according to EN 60601-1-2
- Use, storage and transport conditions: non-condensing humidity conditions

7.3 Arm with actuator

The arm with actuator is used to position and fixate the position of the ball clamp. The arm has to be mounted to a standard non-isolated DIN-rail clamp on the DIN-rail of the patient table. A sterile sleeve is used to cover this part. The actuator is connected to the e-box and is used to tighten the ball clamp that fixates the Mofixx trocar. By using the handle on the actuator or single-use switch the ball clamp is released and the Mofixx trocar can rotate around its centre.

Specifications:

- Catalogue number: Z1101-9200
- Length arm+actuator: 1170 mm
- Diameter actuator: 28.5 mm
- Weight: 2.25 kg
- Cable length: 490 cm (cable permanently connected)
- Handle force: 85N (≈8,7kg)
- Arm: Geomed, Assisto 2x 250 mm + 400 mm vertical (CE approved)
- Arm material: stainless steel
- Round knob on arm: Ø56 mm, polyamid
- Arm can be mounted on DIN-rail using DIN-clamp suitable to fixate a Ø16 mm rod. DIN-clamp is not part of the Mofixx system.
- Mofixx can be used to fixate laparoscopic cameras and instruments with a maximum weight of: 0,35kg.

Warning: The arm and actuator are pre-assembled. Never disassemble the actuator from the arm of the Mofixx system. When housing parts are not firmly attached anymore: do not use product and contact the 'service department of your local sales agent' for a service check.

7.4 E-box

The e-box connects the switch, actuator and power supply. By using the button on the e-box, the Mofixx system can be turned on. The system can be grounded using the Equipotentiality plug provided on the back of the e-box. There are two LED-lights present on the e-box. Explanation on the LED-lights can be found in table below.

LED	Status	Explanation
Upper Power LED (green)	On	Connected to the mains supply
	Off	Not connected to the mains supply
Lower Status LED (yellow)	Blinking	Switch not connected
	Off	Switch connected and not pressed
	On	Switch connected and pressed

The e-box has an USB connection for read-out basic service history logging, and software update.

Specifications:

- Catalogue number: Z1101-9300
- Dimensions: 180x180x70 mm
- Weight: 2.25 kg

7.5 Power supply:

A power supply is used to connect the e-box to the mains supply using the mains cable.

User manual – Mascot power supply can be found in packaging of the Mofixx system.

Caution: Do not use the Mofixx system without carefully reading the user manual – Mascot power supply which can be found in packaging of the Mofixx system as a separate manual.

Warning: Always use the dedicated power supply that comes with the Mofixx system.

Specifications
- Catalogue number: Z1101-9100
- Dimensions:140x80x45 mm
- Weight: 0.45 kg
- Input: 100- 240VAC; 50-60HZ max 1.6A
- Output: 24VDC / 2.5A
- CE medical approved
- Use, storage and transport conditions: non-condensing humidity conditions

7.6 Mains cable

The mains cable is used to connect the power supply to the mains supply.

Specifications
- Catalogue number: Z1101-9400

Warning: Use of mains cable other than delivered with the Mofixx system may result in increased electromagnetic emissions or decreased immunity of the system.

7.7 Ball clamp

To attach the trocar to the actuator, the stainless-steel ball clamp has to be used. Before it can be connected to the sleeve coupling part on the actuator the ball clamp should be preassembled with the trocar and clamp base. The ball clamp is a sterile reusable part and should be autoclaved before each procedure. The Mofixx system contains three ball clamps. It is possible to purchase additional ball clamps, for more information see chapter 7.

Specifications:
- Catalogue number: Z1101-9500
- Material: stainless steel 316
- Reusable part; for cleaning see chapter 4.6.
- Ball clamp covers an area with a diameter of 34.5 mm around the incision.

7.8 Mofixx sleeve

The Mofixx sleeve shall be purchased as dedicated accessory to the Mofixx system. The sterile Mofixx sleeve is used to cover the arm with actuator. The actuator movement is transmitted by the coupling part of the sleeve to the clamp.

Warning: The Mofixx system can only be used with a dedicated Mofixx sleeve.

Warning: The single use sterile Mofixx sleeve is intended to be used on an individual patient during a single procedure. Re-use of the sleeve can cause cross-infection between patients.

Specifications
- Catalogue number: Z1101-1200
- Diameter sleeve: 85 mm
- Length: 2.4 meter
- Standard CE approved camera sleeve with ring is used
- Sterilisation method: Ethylene Oxide
- Storage and transport conditions: keep dry

7.9 Mofixx switch

The Mofixx switch shall be purchased as dedicated accessory to the Mofixx system. The sterile disposable switch controls the movement of the actuator which enables the trocar to be moved. It should be pasted onto the laparoscopic camera that is used with the Mofixx system using the adhesive tape on backside and plugged into the e-box.

Warning: The Mofixx system can only be used with a dedicated Mofixx switch.

Warning: The single use sterile Mofixx switch is intended to be used on an individual patient during a single procedure even when used inside a camera sleeve. Re-use of the switch can cause cross-infection between patients.

Caution: When using a non-sterile laparoscopic camera, the switch should always be placed directly onto the laparoscopic camera inside the camera sleeve.

Specifications

- Catalogue number: Z1101-4000
- Dimensions switch: 22.5 x 9 x 38.5 mm
- Cable length: 4.2 m
- Foil switch
- Connector: Ethernet
- Sterilisation method: Ethylene Oxide
- Use, storage and transport conditions: non-condensing humidity conditions

8 GUIDANCE ELECTROMAGNETIC EMISSIONS AND IMMUNITY

8.1 Guidance and manufacturer's declaration – electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Mofixx system 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	Class B	The Mofixx system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

8.2 Guidance and manufacturer's declaration – electromagnetic immunity

The Mofixx system is intended for use in the electromagnetic environment specified below. The customer or the user of the Mofixx system 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	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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 %.
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 line(s) toline(s) ± 2 kV line(s) to earth	± 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 IEC 61000-4-11	<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 s	<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 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Mofixx system requires continued operation during power mains interruptions, it is recommended that the Mofixx system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3,0 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

8.3 Guidance and manufacturer's declaration – electromagnetic immunity

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

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Mofixx, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance - d = 1,2 $\sqrt{P}$ - *d* = 1,2 $\sqrt{P}$ 80 MHz to 800 MHz - *d* = 2,3 $\sqrt{P}$ 800 MHz to 2,5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[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 Mofixx system is used exceeds the applicable RF compliance level above, the Mofixx system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Mofixx system.

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

8.4 Recommended separation distances between portable and mobile RF communications equipment and the Mofixx system

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

Rated maximum output power of transmitter [W]	**Separation distance according to frequency of transmitter [m]**		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1,2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2,3\sqrt{P}$
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 transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (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.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

9 WARRANTY

The e-box, actuator and arm have a 2 year warranty period.

In case of failure contact the hospital technical department or your local sales agent.