INSTRUCTIONS FOR USE
ENDOFIX exo
with ENDOSCOPE CLAMP V

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1412-220214-03

Issued copies of this document are not subject to revision. We reserve the right to make modifications to the devices for the purpose of technical progress or product improvements without prior notification.

1 Introduction

Please read this instructions for use to learn about the correct use of the ENDOFIX EXO before using it for the first time.

Keep the instructions for use close to the site of operation and ensure that the user can access it at all times.

	Never use the ENDOFIX EXO in the OR without having been instructed by an authorised person in its safe use.

1.1 Purpose of the document

This document tells you how to handle the ENDOFIX EXO. In conjunction with the instructions by our trained specialists, it allows you to safely handle the ENDOFIX EXO.

This document has been created for anyone put in charge with the setup, operation and cleaning of the device.

	This document describes the correct use of the ENDOFIX EXO with the ENDOSCOPE CLAMP V for the VITOM 3D exoscope, which cannot be prepared sterilely. Information on the use of the ENDOFIX EXO with sterile reprocessable ENDOSCOPE CLAMPS and endoscopes can be found in the instructions for use provided for this purpose. Therefore, use the sterile DRAPE for the VITOM 3D exoscope to also sterilely cover the ENDOSCOPE CLAMP V, the CONTROL and the ENDOFIX EXO.

1.2 Notes on this document

Notes to avoid damage to property:

	This symbol is found in front of notes to assist the user, to facilitate the use of the device or to prevent faults.

Safety information to avoid risk of injury:

	This symbol indicates safety information. Non-compliance with the corresponding information may lead to damage or even injuries for the patients and / or the user.

Words written in CAPITAL LETTERS indicate parts or accessories of the system as well as important terms regarding their use.

The designations VITOM 3D and Karl Storz used in these operating instructions are protected designations and/or registered trademarks of Karl Storz SE & Co. KG, Dr.-Karl-Storz-Straße 34, 78532 Tuttlingen.

1.3 Important notes on the safe handling (summary)

The incorrect operation or non-compliance with precautionary measures may cause serious incidents, injuries of patients or damage to persons or material.

Therefore, use this instruction manual to fully inform yourself about the correct operation and handling of the ENDOFIX EXO.

	Make sure that the rail of the operating table is secured and locked before using the device.

	Always hold the exoscope firmly before releasing the lock on the ENDOSCOPE CLAMP V.
	Always hold the ENDOSCOPE CLAMP firmly before unlocking it by pressing the UNLOCK BUTTON.
	The device is not intended for the operation in explosive areas. Ensure a sufficient distance to highly flammable gases (e.g. O2, anaesthetic gases).
	Never open the ENDOFIX EXO or the POWER SUPPLY. Risk of an electric shock!
	The TROLLEY is intended for the storage and transport of the ENDOFIX EXO. When using the ENDOFIX EXO to hold and move an endoscope or exoscope, the ENDOFIX EXO must be firmly connected to the tool rail of the operating table. Use on the TROLLEY is not permitted!
	All serious incidents related to the product must be reported to the manufacturer and the competent authority in the country concerned.
	Do not use sterile DRAPE if you can see damage to the packaging or to the sterile DRAPE itself!
	Do not use a sterile DRAPE whose expiry date has passed!
	Observe all safety instructions in these instructions for use as well as in the instructions for use for the VITOM 3D exoscope.
	Keep the CONTROL at least 15 cm (6 inches) away from magnetically susceptible medical devices such as pacemakers, cochlear implants or neurostimulators.
	Check the configuration for any possible collision with parts of the operating table before using the device. The maximum transverse tilt depends on the respective operating table.
	The quick clamping for the docking to the operating table is designed for a maximum Trendelenburg position of 30°. Never exceed that range.
	Avoid tripping hazards when connecting the cables.
	Operate the ENDOFIX EXO only when it has reached room temperature again after a previous storage at high or low temperatures.
	Pull the power plug of the POWER SUPPLY in order to completely disconnect this device from the mains. Make sure that the POWER SUPPLY can be accessed at any time.
	Disconnect the POWER SUPPLY from the mains for at least 5 seconds to rectify a fault in the POWER SUPPLY.

	Modifications to the device are not permitted.

1.4 Modifications

Subject to technical modifications!

Both the device and the instructions for use are developed and improved on a continuous basis. Some illustrations may therefore slightly differ from the actual delivery condition.

These instructions for use have been prepared with the utmost care. We are not liable for mistakes and printing errors!

Your improvement suggestions in regard to our products or these instructions for use are always welcome. Please contact the address provided in this instructions for use or your competent sales partner.

1.5 General product description

The ENDOFIX EXO replicates an arm that can guide and position an exoscopic camera (VITOM 3D) in several degrees of freedom. The ENDOSCOPE CLAMP V, which was specially developed for this purpose, is used for secure attachment to the ENDOFIX EXO.

An integrated DEACTIVATION PUSHBUTTON permits manual movement of the ENDOFIX EXO at the push of a button.

The system presents a large scope of movement in order to provide the user with ample access to the situs.

In order to reposition a guided exoscopic camera, the ENDOFIX EXO is unlocked by a CONTROL at the push of a button.

Despite its large scope of movement, the ENDOFIX EXO is light-weight and compact and is fastened directly to the OP table by means of a quick-acting clamp. Thus, repositioning with reference to the patient is not necessary even if the OP table is moved in the meantime.

Constant availability and a large degree of re-usability were key issues during development of the ENDOFIX EXO. For this reason, only a sterile DRAPE is required for safe use.

By using ENDOFIX EXO, ENDOSCOPE CLAMP V and CONTROL within the sterile DRAPE, wipe disinfection is sufficient for these components. For more details, see chapter 4.4 in these instructions for use.

1.6 Intended use / Notes on product liability

Essential Performance:

Stable fixation of an endoscope

The system holds an endoscope in a fixed position, which was adjusted by the user. This will also be assured when power is lost.

Environment:

Operating room. The ENDOFIX EXO must be firmly attached to the operating table during use. It is not permitted to "place it on" or on an equipment cart, side table, or similar.

During HF Surgery, the ENDOFIX EXO is only compatible with following HF SURGICAL EQUIPMENT:

- Power Cut mode capability of 300 W
- Coagulation mode capability of 120 W

The ENDOFIX EXO can not be used for argon plasma coagulation mode.

	The TROLLEY is intended for the storage and transport of the ENDOFIX EXO. When using the ENDOFIX EXO to hold and move an endoscope or exoscope, the ENDOFIX EXO must be firmly connected to the tool rail of the operating table. Use on the TROLLEY is not permitted!
	The device is not intended for the operation in explosive areas. Ensure a sufficient distance to highly flammable gases (e.g. O2, anaesthetic gases).

User Group:

A mandatory requirement for using the ENDOFIX EXO is the proper assembly and maintenance of the device as well the compliance with this instruction manual.

The ENDOFIX EXO is used primarily by the surgeon performing the operation. He must have sufficient experience in the use of minimally invasive operating techniques and received instructions in the handling of the ENDOFIX EXO. The device may be operated exclusively by instructed personnel. The instruction is to be documented.

Application:

Holding and guiding the endoscopic camera for minimally invasive intervention in ENT, skull base and thoracic surgery.

In open surgery, the ENDOFIX EXO is used to hold and guide an incident light optic (exoscope).

Contraindications:

The ENDOFIX EXO must not be used outside of the fields of application detailed above. The ENDOFIX EXO may be used exclusively for holding and moving an endoscope.

The ENDOFIX EXO is not suitable for outpatient interventions where the patient is only under partial anesthesia.

The manufacturer will only consider himself liable for the safety-related characteristics, reliability and performance if

- the user has been fully instructed in the proper use of the device.
- the readjustments, modifications or repairs are performed exclusively by the manufacturer or an institution expressly authorised by the manufacturer.
- the device is used under the specified environmental conditions in rooms used for medical purposes in which the electrical installation meets the requirements of the VDE 0100-710 or IEC 60364-7-10 standard.
- the device is used entirely in accordance with this instruction manual.

Clinical Benefit:

The ENDOFIX EXO has no direct clinical benefit for the patient. The ENDOFIX EXO offers the user the following clinical benefits:

- Stable and steady image of the endoscope during the surgical procedure
- Allows the surgeon to work with both hands
- No more ergonomically unfavourable static holding of the endoscope required

Warranty:

The manufacturer issues a 12 month warranty on the performance of the product. The period of validity of this warranty is limited to claims that have been immediately asserted in writing within the named period after the invoice date - if applicable, with a reference to repairs stating the invoice number. Legal warranty claims are not restricted by this warranty.

If you did not purchase the product directly from the manufacturer, please contact your sales partner for the processing of the warranty.

This warranty covers only defects that have not been caused by normal wear, misuse, improper handling, external influences, deficient or incorrect preparations, or force majeure.

All warranty claims will be lost if the user itself or a non-authorized repair shop has carried out repairs or modifications on the product.

Liability claims arising from the improper use or from a combination with other devices or accessories can not be asserted.

⚠	All serious incidents related to the product must be reported to the manufacturer and the competent authority in the country concerned.

1.7 Receiving inspection

Please check the ENDOFIX EXO and the enclosed accessories immediately upon receipt for possible transport damage and defects.

Claims for damages can be asserted only if the seller or the freight forwarder is immediately informed. A damage report has to be prepared immediately. The damage report must be submitted directly to the manufacturer or the representative of the manufacturer so that the claims for damages can be reported to the insurance company.

When a device is returned to the manufacturer, use, if possible, the original packaging. The following accompanying documents are to be enclosed: Name and address of the owner, ID and serial number (see name plate) as well as a description of the defect.

1.8 Initial operation

The operator may operate the ENDOFIX EXO only after the manufacturer or the supplier:

- has performed a functional test of the devices at the place of operation and
- has instructed the persons responsible for the operation in the proper handling of the ENDOFIX EXO based on this instruction manual.

	Operate the ENDOFIX EXO only when it has reached room temperature again after a previous storage at high or low temperatures.

2 System Description

2.1 Overview

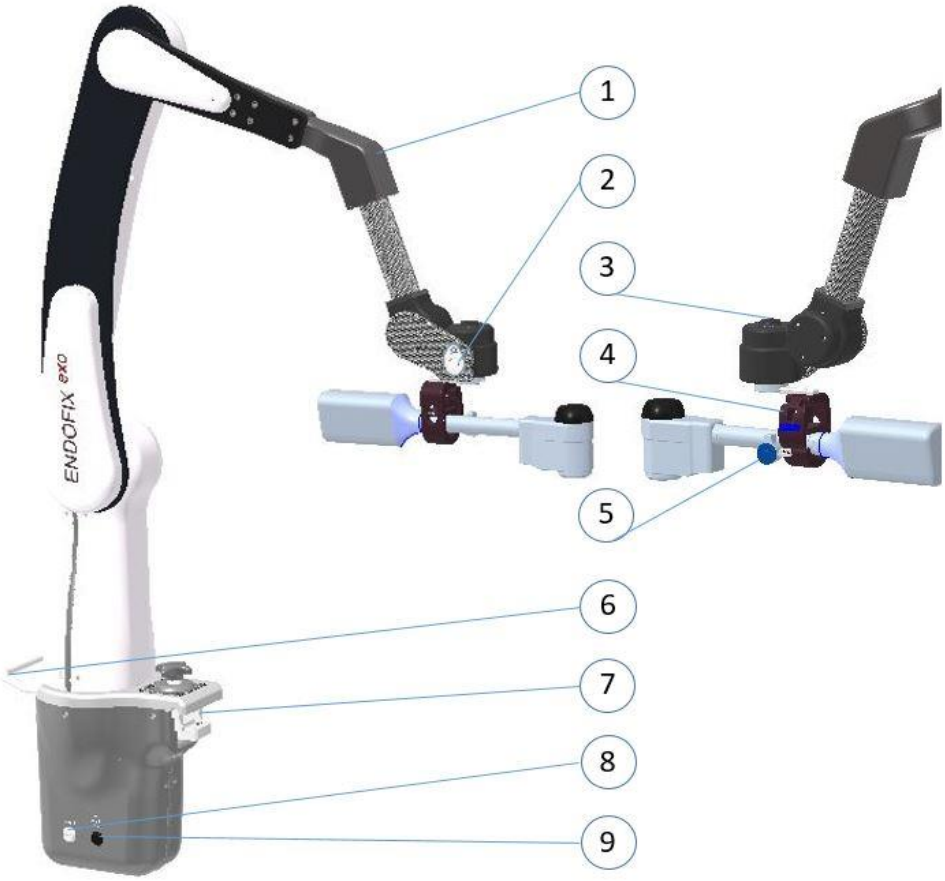


fig. 1: System overview

Number	Description
1	Arm
2	DEACTIVATION PUSHBUTTON
3	UNLOCK BUTTON for the ENDOSCOPE CLAMP
4	ENDOSCOPE CLAMP V
5	CONTROL
6	Handle
7	Quick-fastener for fastening to the operating table
8	CONTROL connection
9	Power supply connection

Table 1: System overview

2.2 System components

Component	Picture	Description
ENDOFIX EXO (multiple patient multiple use)		The ENDOFIX EXO is the support for the endoscope and is fastened to the OP table by means of a quick coupling.
POWER SUPPLY (multiple patient multiple use)		The POWER SUPPLY supplies the ENDOFIX EXO with the required operating voltage and has been designed for a wide range of input voltages. Only use the original POWER SUPPLY.
POWER CORD (multiple patient multiple use)		The POWER CORD supplies the POWER SUPPLY with AC current. Use exclusively the POWER CORD supplied with the equipment or country specific POWER CORDS.
SUPPLY CABLE (multiple patient multiple use)		The SUPPLY CABLE is used to establish the electrical connection between the ENDOFIX EXO and the POWER SUPPLY. The SUPPLY CABLE is 3.5 m long.
CONTROL (multiple patient multiple use)		The CONTROL is used to unlock the arms of the ENDOFIX EXO at the push of a button. In the application described here with the ENDOSCOPE CLAMP V, a wipe disinfection is sufficient to prepare for the next use.
ENDOSCOPE CLAMP V (multiple patient multiple use)		The ENDOSCOPE CLAMP V automatically engages in the quick-release fastener of the ENDOFIX EXO and securely holds the VITOM 3D exoscope in the designated place. The ENDOSCOPE CLAMP V is prepared for the subsequent use with a wipe disinfection.

Component	Picture	Description
WIRE BASKET (multiple patient multiple use)		The WIRE BASKET with lid is used to store CONTROL and ENDOSCOPE CLAMP V.
TROLLEY (multiple patient multiple use)		The TROLLEY is intended for storage of the ENDOFIX EXO while it is not in use, and for transporting it.

Table 2: System components

Overview accessories and spare parts:

For orders, please contact the manufacturer or your sales partner directly.

Only use original accessories. The use of accessories not approved by the manufacturer can lead to a patient hazard or damage to the device.

Article number	Article name	Description
171943	ENDOFIX EXO	ENDOFIX EXO
172035	POWER SUPPLY	POWER SUPPLY
182205	POWER CORD	POWER CORD
172054	SUPPLY CABLE	SUPPLY CABLE
171906	CONTROL	CONTROL
222595	ENDOSCOPE CLAMP V	ENDOSCOPE CLAMP V for the VITOM 3D
222630	WIRE BASKET	WIRE BASKET
120874	TROLLEY	TROLLEY
1412-220214	Manual ENDOFIX EXO V – EN	-

Table 3: Article numbers

2.3 Mechanical data

Weight	12 kg
Dimensions (W x H x D)	165 x 1059 x 313 mm
Safe working load	1 kg

Connection to the operating table Quick-fastener, suitable for European and US standard rails

Range of motion:

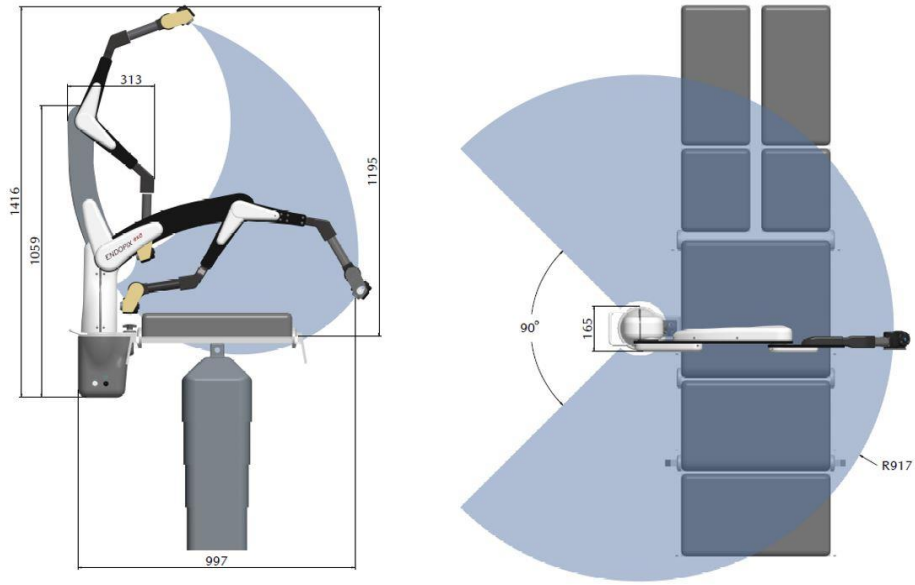


fig. 2: Range of motion

	Positions outside of the illustrated range of movement cannot be reached. To avoid this, position the arm as centrally as possible within the OP field.

2.4 Electrical data

POWER SUPPLY	Type BET-0624M, Bicker Elektronik GmbH
Input voltage	100 - 240V~; 50-60Hz
Max. power input	60W
Output voltage	24 V DC
Protection class	II
Operating mode	continuous
Mains fuses	none

	Pull the power plug of the POWER SUPPLY in order to completely disconnect this device from the mains. Make sure that the POWER SUPPLY can be accessed at any time.
	Disconnect the POWER SUPPLY from the mains for at least 5 seconds to rectify a fault in the POWER SUPPLY.

2.5 Important performance characteristics

Essential performance features of the ENDOFIX EXO are:

- The system hold an endoscope in a fixed position, which was adjusted by the user. This must also be assured when power is lost.
- The system allows the user to reposition the endoscope at the push of a button. In case of power failure or other failures, this function may not be available.

2.6 Environmental conditions

for transport and storage

Temperature	-20°C to +70°C
Relative air humidity	10% to 90%, non-condensing
Air pressure	700 hPa to 1060 hPa

for the operation

Temperature	+15°C to +37°C
Relative air humidity	10% to 85%, non-condensing
Air pressure	700 hPa to 1060 hPa

2.7 Storage and transport

The ENDOFIX EXO should always be transported in suitable packaging. Any position is possible during transportation.

For storage between the applications, we recommend the optional TROLLEY.

	Operate the ENDOFIX EXO only when it has reached room temperature again after a previous storage at high or low temperatures.

2.8 Symbols used on the name plates / labels

Symbol	Description
	Observe the instructions for use
	Follow the instructions for use
CE	Device conforms to the regulation MDR - 2017/745 (Medical Device Regulation)
	Date of manufacture
	Manufacturer
SN	Serial number
REF	Reference number
Rx only	Sale only on instruction of a physician (US federal law)
CH REP	Authorised representative in Switzerland
MD	Medical Device
	Dispose products marked with this symbol separately with electric and electronic devices. The disposal is carried out by the manufacturer within the EU for free.

Table 4: Symbols on nameplate and label

2.9 Name plate

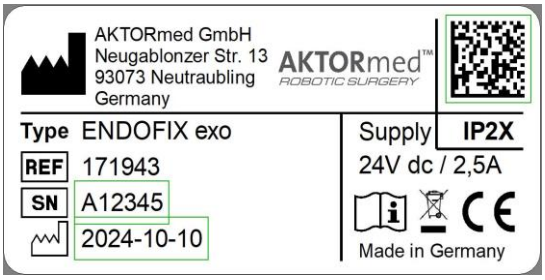


fig. 3: Name plate

2.10 Identification according to MDR (Medical Device Regulation)

The ENDOFIX EXO including accessories is a class I medical product. Sterile disposables are class Is medical devices.

2.11 Contact

If you have any further questions in connection with the product, please contact:

AKTORmed GmbH
Neugablonzer Str. 13
93073 Neutraubling
GERMANY

Web: www.aktormed.com
eMail: info@aktormed.com
Phone: +49 9401 93 20 110

3 Setup / Commissioning

3.1 ENDOFIX EXO, ENDOSCOPE CLAMP V and VITOM 3D

Follow the following work steps to mount the ENDOFIX EXO to the operating table and to put it into operation for the following application. This is usually done **before** the patient is washed and covered with sterile drapes.

Step 1: Mount it to the operating table

Step	Description
	The device is lifted to the standard rail and mounted.
	Once the device is placed on the standard rail of the operating table, align it perpendicular to the operating table and tighten the clamp screw by hand.

Table 5: Mounting on operating table

	To make the best possible use of the ENDOFIX EXO's range of motion, we recommend checking the accessibility of the operating field after installation. The position on the operating table can now still be corrected.

⚠	Make sure that the ENDOFIX EXO is firmly locked on the rail of the operating table before using the device.

Step 2: Establish the electrical connection

Connect the POWER CORD to the POWER SUPPLY and then plug the POWER CORD into a suitable wall outlet. Connect the SUPPLY CABLE to the POWER SUPPLY and then connect the SUPPLY CABLE to the input jack of the ENDOFIX EXO.

❗	Pull the power plug of the POWER SUPPLY in order to completely disconnect this device from the mains. Make sure that the POWER SUPPLY can be accessed at any time.
❗	Disconnect the POWER SUPPLY from the mains for at least 5 seconds to rectify a fault in the POWER SUPPLY.
❗	Use only the original POWER SUPPLY, POWER CORD and SUPPLY CABLE.
❗	Avoid tripping hazards when connecting the cables.

The ENDOFIX EXO is ready to operate once the green LED on the DEACTIVATION PUSHBUTTON is lit. You can now move the arms by pressing the DEACTIVATION PUSHBUTTON to a position where the ENDOSCOPE CLAMP V and the VITOM 3D can be mounted comfortably.

fig. 4: Operational readiness

Step 3: Mount ENDOSCOPE CLAMP V and the VITOM 3D

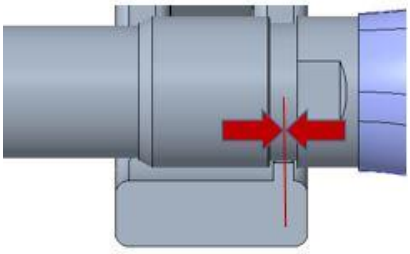
Step	Description
	Insert the plug of the ENDOSCOPE CLAMP V into the quick-release fastener of the extension arm until the ENDOSCOPE CLAMP V audibly engages. The ENDOSCOPE CLAMP V can also be mounted on the ENDOFIX EXO rotated by 180°; however, mount it as shown so that the VITOM 3D can be mounted as shown in the following procedure. Check the correct engagement by pulling the ENDOSCOPE CLAMP V.
 	Open the knee lever on the ENDOSCOPE CLAMP V and insert the VITOM 3D. The groove on the VITOM 3D must come to rest against the retaining protrusion on the ENDOSCOPE CLAMP V.
	Close the knee lever and check that the VITOM 3D is firmly seated in the ENDOSCOPE CLAMP V.
	Lay the camera cable and the light guide in generous loops along the support arm. Fix both to the support arm and connect the camera cable and light guide to the corresponding devices.

Table 6: Mount ENDOSCOPE CLAMP V and the VITOM 3D

3.2 Mounting the CONTROL to the ENDOSCOPE CLAMP

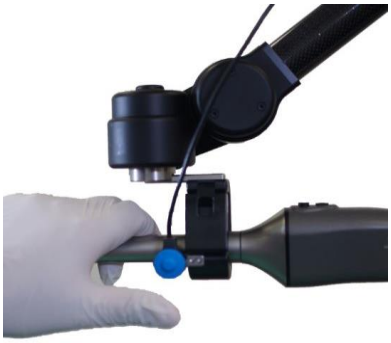
Step	Description
	Slip the CONTROL over the bracket of the ENDOSCOPE CLAMP V. Lay the cable of the CONTROL along the support arm in generous loops and fix it to the support arm.
	Connect the CONTROL to the connector „CONTROL“ on the ENDOFIX EXO.
	The status LED next to the DEACTIVATION PUSHBUTTON indicates that the CONTROL is ready to operate.
	You can now position the VITOM 3D freely in the room by pressing the CONTROL. When the CONTROL is released, all joints of the ENDOFIX EXO are locked again.

Table 7: Mounting the CONTROL to the ENDOSCOPE CLAMP V

⚠	Keep the CONTROL at least 15 cm (6 inches) away from magnetically susceptible medical devices such as pacemakers, cochlear implants or neurostimulators.

3.3 Obtain VITOM 3D and ENDOFIX EXO sterile

⚠	Do not use sterile DRAPE if you can see damage to the packaging or to the sterile DRAPE itself!
⚠	Do not use a sterile DRAPE whose expiry date has passed!

Step	Description
	Remove the sterile DRAPE from the packaging.
 	The plastic frame of the sterile DRAPE only fits the lens of the VITOM 3D in the orientation shown. Place the plastic frame of the sterile DRAPE over the lens of the VITOM 3D. Check the correct fit of the plastic frame on the lens.
	Pull the sterile DRAPE completely over the VITOM 3D and the ENDOFIX EXO.

Step	Description
	Gather up excess foil of the sterile DRAPE and fix the foil with the adhesive strips. Make sure that the VITOM 3D and the joints of the ENDOFIX EXO have sufficient freedom of movement. At this point, continue with the patient's sterile drape according to the usual procedure in your hospital.

Table 8: Obtain VITOM 3D and ENDOFIX EXO sterile

4 Operation

The ENDOFIX EXO is operated by unlocking all 6 axes and subsequent manual positioning using the CONTROL.

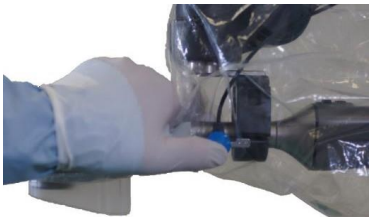
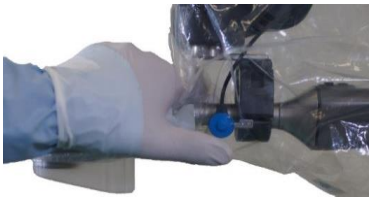
Step	Description
	Press the button on the CONTROL with the thumb of your left hand to unlock the ENDOFIX EXO and set a new position for the exoscope.
	As soon as the button on the CONTROL is released, all 6 axes are locked again. You can now release the exoscope.

Table 9: Operating the ENDOFIX EXO with the CONTROL

4.1 DEACTIVATION PUSHBUTTON and status displays

The ENDOFIX EXO features a lit DEACTIVATION PUSHBUTTON which can be used to vary the position before and after surgery even without the CONTROL.

Picture	Description
	DEACTIVATION PUSHBUTTON to move the arms. The flush green LED is lit when the ENDOFIX EXO is supplied with electrical power.
	Status display for the CONTROL. The LED (also green) displays the CONTROL's readiness for operation. The CONTROL is operative if it is connected to the ENDOFIX EXO and has been secured to the bracket of the ENDOSCOPE CLAMP.

Table 10: DEACTIVATION PUSHBUTTON and status displays

4.2 Weight compensation

The ENDOFIX EXO is equipped with a weight balance to compensate for the weight of the endoscope and camera head. Due to the different levers with the extension arms fully retracted and fully extended, the weight balance is still largely in place. A complete weight balance is only achieved in a middle boom position.

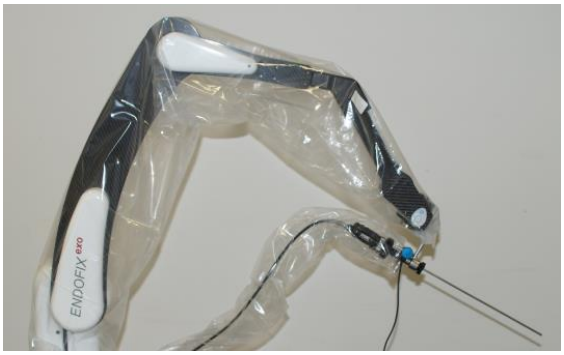


fig. 5: Perfect counterbalance

If the extension arms are positioned very close to the body of the device, there is a certain overcompensation of the weight of the endoscope and camera head.

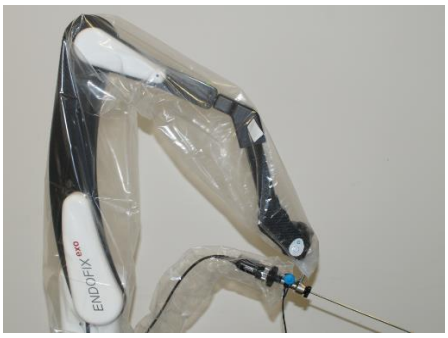


fig. 6: Weight balance overcompensated

If, on the other hand, the extension arms are extended quite far, the weight balance is no longer quite adequate for the weight of the endoscope and camera head. You will then feel some weight in your hand when operating the CONTROL.

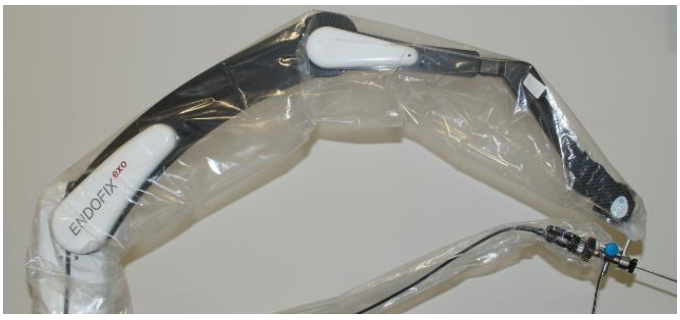
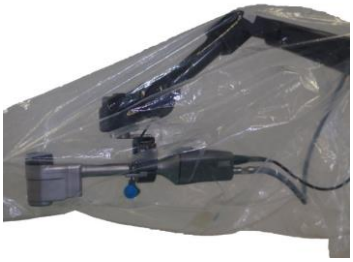
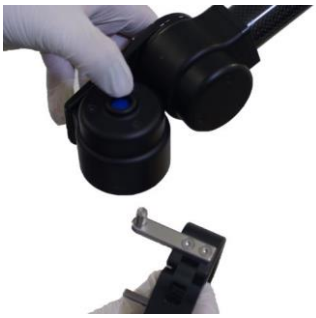


fig. 7: Weight balance undercompensated

4.3 Ending the application

Step	Description
	Switch off the camera unit and the light source of the VITOM 3D. Loosen the plastic frame on the lens of the VITOM 3D and pull off the used DRAPE.
	Remove the CONTROL from the bracket of the ENDOSCOPE CLAMP V.
	Hold the VITOM 3D firmly and open the knee lever on the ENDOSCOPE CLAMP V. Remove the VITOM 3D and store it in a suitable place. Make sure that the VITOM 3D has cooled down sufficiently, as hot surfaces may still be present.
	Press the blue UNLOCK BUTTON of the quick coupling in order to remove the ENDOSCOPE CLAMP V.
	For subsequent storage, put the ENDOFIX EXO onto the TROLLEY in upright position.

Step	Description
	Disconnect all cable connections and remove the POWER SUPPLY from the mains.
	The ENDOFIX EXO can be removed from the OP table and stored on the TROLLEY. Carry out the wipe disinfection for the ENDOFIX EXO, the ENDOSCOPE CLAMP V and the CONTROL. Then store ENDOSCOPE CLAMP V and CONTROL in the WIRE BASKET.

Table 11: After use

4.4 Wipe disinfection

The ENDOFIX EXO, the ENDOSCOPE CLAMP V and the CONTROL has been successfully tested with the following disinfectants for wipe disinfection with regard to the material compatibility of the surfaces.

You can perform wipe disinfection with the disinfectants mentioned here and similar disinfectants with regard to the active substances contained.

Use a soft cloth to apply the disinfectant and follow the manufacturer's instructions regarding the exposure time of the disinfectant used.

disinfectant	agent	mass concentration in 100 g solution:
Microbac (cloths)	Benzyl-C12-18-Alkyldimethylammoniumchlorid	0,4 g
	Didecyldimethylammoniumchlorid	0,4 g
Meliseptol HBV (cloths)	1-Propanol	50 g
	Didecyldimethylammoniumchlorid	0,075 g
Incidin Liquid	2-Propanol	35 g
	1-Propanol	25 g
Isopropanol	2-Propanol	63,1 g

Table 12: Disinfecting agents

5 Troubleshooting

In case the ENDOFIX EXO does not behave as expected, the following hints should enable you to solve simple problems yourself.

⚠	Never open the ENDOFIX EXO or the POWER SUPPLY. Risk of an electric shock!
❗	Always contact the manufacturer's service or a representative expressly authorised by the manufacturer: • if you are not able to solve the problem with the help of the following information or • if safe work is no longer ensured.

Symptom	Solutions
LED on DEACTIVATION PUSHBUTTON is not lit 	Check the power supply: • Tight fit of the SUPPLY CABLE on the ENDOFIX EXO • Tight fit of the SUPPLY CABLE on the POWER SUPPLY • Connection to the socket • Use another socket • Disconnect the POWER SUPPLY from the mains for at least 5 seconds to rectify a fault in the POWER SUPPLY
The status display CONTROL is lit in orange and the CONTROL does not work 	• The CONTROL has not been mounted onto the bracket of the ENDOSCOPE CLAMP • The CONTROL is only ready to operate if it is connected to the ENDOFIX EXO and is placed on the ferromagnetic bracket of the ENDOSCOPE CLAMP
The ENDOFIX EXO cannot be unlocked via the CONTROL although it is inserted and placed on the bracket of the ENDOSCOPE CLAMP.	The CONTROL is faulty. Replace the CONTROL by a new one.

Table 13: Troubleshooting

6 Service

The ENDOFIX EXO is basically maintenance-free. However, regular inspections and safety tests are imperative in order to ensure a reliable operation over its lifetime.

6.1 Handover certificate

The manufacturer or a representative expressly authorized by the manufacturer will commission the device upon delivery.

6.2 Regular inspections

Perform the following checks before each use of the device:

– Check POWER CORD for damage.

– ENDOFIX EXO and accessories for external damage.

	Never use the ENDOFIX EXO if you detected any damage. Contact the corresponding service.

6.3 Annual safety-related inspection

A regular maintenance is not required. However, the manufacturer requires a specialist or a hospital technician to carry out a precautionary safety inspection on a regular basis in order to ensure a reliable operation over its lifetime. This inspection must be carried out at least once a year.

No special requirements or precautions have to be considered for a precautionary inspection. During the inspection, the following tests have to be performed in accordance with section 5 of the DIN EN 62353:

- 5.2 Inspection

- 5.3.2 Measurement of the protective conductor resistance, where applicable

- 5.3.3 Measurement of the leakage currents

- 5.3.4 Measurement of the insulation resistance

The test results are to be fully documented in a test report according to section 6 of the DIN EN 62353. The test report can be taken from section F of the standard.

In case of a malfunction, please contact the AKTORmed Service or the respective service partner. In addition to an accurate description of the error, please also always indicate the product identification number and serial number as shown on the name plate of the device.

6.4 Disposal / Recycling

The manufacturer confirms that the product

ENDOFIX EXO

meets the following guidelines:

- Waste electrical and electronic equipment (WEEE) 2012/19/EC,
- Electrical and Electronic Equipment Act - ElektroG,
- as well as the legal requirements of the member states of the ECC

Further information can be found in document no. 1412-170030 (Recycling pass).

	Due to the risk of an infection through contaminated products, they have to be treated prior to the disposal.
	Make sure that contaminated disposable products are disposed separately.
	The national regulations are to be complied when the product or its components are disposed of or recycled.

7 EMC

	Portable and mobile HF communication devices such as cell phones can interfere with MEDICAL ELECTRICAL DEVICES. Do not operate such devices in the direct vicinity of the ENDOFIX EXO.
	MEDICAL ELECTRICAL DEVICES are subject to special precautionary measures in regard to EMC. The ENDOFIX EXO may be installed and operated only in accordance with the EMC information contained in this manual.
	Disconnect the POWER SUPPLY from the mains for at least 5 seconds to rectify a fault in the POWER SUPPLY.
	The ENDOFIX EXO or the associated POWER SUPPLY may not be placed directly adjacent to other equipment or stacked with other equipment. If it is necessary to operate the device close to other equipment and stacked with other equipment, the ENDOFIX EXO should be monitored in order to check the proper operation with this arrangement.

Guidelines and manufacturer's declaration - Electromagnetic emissions

Emission

Test	Limit	Electromagnetic environment - guidance
Conducted emission	CISPR 11, Group 1, Class B	Device 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.
Radiated emission	CISPR 11, Group 1, Class B	
Voltage fluctuations and flicker	IEC 61000-3-3	Device is directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. Only for Home healthcare environment.

Table 14: Emission

Immunity test levels

Test	Limit	Electromagnetic environment - guidance
Electrostatic Discharge (IEC 61000-4-2)	Contact Discharge: ±8 kV Air Discharge: ±2 kV, ±4 kV, ±8 kV, ±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF EM field (IEC 61000-4-3)	80-2700 MHz; 1kHz AM 80 %; 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**

Test	Limit	Electromagnetic environment - guidance
		d = 1.2√P for 80 MHz to 800 MHz d = 2.3√P for 800 MHz to 2,7 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 meters (m).
Proximity fields form RF wireless communications equipment (IEC 61000-4-3)	385 MHz; Pulse Modulation: 18 Hz; 27 V/m 450 MHz, Pulse Modulation: 18 Hz: 1 kHz sine; 28 V/m 710, 745, 780 MHz; Pulse Modulation: 217 Hz; 9 V/m 810, 870, 930 MHz; Pulse Modulation: 18 Hz; 28 V/m 1720, 1845, 1970 MHz; Pulse Modulation: 217 Hz; 28 V/m 2450 MHz; Pulse Modulation: 217 Hz; 28 V/m; 5240, 5500, 5785 MHz; Pulse Modulation: 217 Hz; 9 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance 30 cm.
Electrical fast transients / bursts (IEC 61000-4-4)	Power lines: 2 kV; 100 kHz repetition frequency Signal lines: 1 kV; 100 kHz repetition frequency	Mains power quality should be that of a typical environment.
Surges (IEC 61000-4-5)	L-N: 1kV at 0°, 90°, 180°, 270°	Mains power quality should be that of a typical environment.
Conducted disturbances inducted by RF fields (IEC 61000-4-6)	0.15-80 MHz; 1kHz AM 80 %; 3 Vrms , 6 Vrms in ISM band	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** d = 1.2√P for 150 kHz to 80MHz 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 meters (m).
Rated power frequency magnetic fields (IEC 61000-4-8)	30 A/m, 50 Hz and 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips / Voltage interruptions (IEC 61000-4-11)	0 % UT for 0.5 cycle at 8 phase angles 0 % UT for 1 cycle at 0° 70 % UT for 25/30 cycles at 0° 0 % UT for 250/300 cycles 0°	Mains power quality should be that of a typical environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device is powered from an uninterruptible power supply or battery.

Test	Limit	Electromagnetic environment - guidance
Immunity to proximity magnetic fields (IEC 61000-4-39)	134.2 kHz; Pulse Modulation: 2.1 kHz; 65 A/m 13.56 MHz; Pulse Modulation: 50 kHz; 7.5 A/m	-
Immunity to HF Surgical equipment emissions (IEC 60601-2-2, Annex BB)	HF Mode: Cut – 300 W and Coagulation – 120 W	-

Table 15: Immunity test level

⚠	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.
⚠	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 ENDOFIX EXO, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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