INSTRUCTIONS FOR USE
DEXTER ENDOSCOPE ARM

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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.

DEXTER ENDOSCOPE ARM is the trade name of the SOLOASSIST IID, which was developed within the SOLOASSIST II product family.

The DEXTER ENDOSCOPE ARM, or SOLOASSIST IID, is a customised product variant of the SOLOASSIST II.

1 Introduction

Please read this instructions for use to learn about the correct use of the DEXTER ENDOSCOPE ARM 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 DEXTER ENDOSCOPE ARM 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 DEXTER ENDOSCOPE ARM. In conjunction with the instructions by our trained specialists, it allows you to safely handle the DEXTER ENDOSCOPE ARM.

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

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.

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 DEXTER ENDOSCOPE ARM.

	Never use the DEXTER ENDOSCOPE ARM in the OR without having been instructed by an authorised person in its safe use.
	Before use, ensure that the attachment securely grips and locks the tool rail of the operating table, or that of the ENDOSCOPE CART.
	Please note that the height-adjustable ENDOSCOPE CART must not be adjusted in height during surgery! The position of the DEXTER ENDOSCOPE ARM in relation to the patient (TROCAR POINT) must not change during surgery!
	Please note that the ENDOSCOPE CART remains firmly secured to the floor during surgery! The position of the DEXTER ENDOSCOPE ARM in relation to the patient (TROCAR POINT) must not change during surgery!

	Please note that during the operation the setting of the operating table must remain unchanged! The position of the patient (TROCAR POINT) in relation to the DEXTER ENDOSCOPE ARM must not change during the operation!
	Continuously monitor the patient and the DEXTER ENDOSCOPE ARM while you control one of the powered movements.
	Never open the DEXTER ENDOSCOPE ARM or the POWER SUPPLY. Risk of an electric shock!
	Always steady the endoscope before you unlock the quick fastener between endoscope and ENDOSCOPE CLAMP, as well as between ENDOSCOPE CLAMP and JOINT.
	The device is not intended for the operation in explosive areas. Ensure a sufficient distance to highly flammable gases (e.g. O2, anaesthetic gases).
	Do not reach into the system's range of motion during the movement.
	Devices that are connected to the analogue and digital interfaces of the DEXTER ENDOSCOPE ARM must comply with the standards for electromedical devices. All configurations must meet the requirements of the system standard EN 60601-1. The person connecting additional devices is responsible for the compliance with this standard!
	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 DEXTER ENDOSCOPE ARM, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
	All serious incidents related to the product must be reported to the manufacturer and the competent authority in the country concerned.
	Do not use a STERILE COVER if you can detect damage to the packaging or the STERILE COVER itself!
	Modifications to the device are not permitted.
	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.
	Operate the DEXTER ENDOSCOPE ARM only when it has reached room temperature again after a previous storage at high or low temperatures.
	Avoid tripping hazards when connecting the cables.

	Never place the CANTILEVER, JOINT, PROBE PIN, ENDOSCOPE CLAMP and TENSION SLEEVE in a disinfection bath together with contaminated surgical instruments.
	Do not store CANTILEVER, JOINT, PROBE PIN, ENDOSCOPE CLAMP and TENSION SLEEVE in the same container with soiled surgical instruments after use.
	All components to be used in a sterile condition - except the STERILE COVER - are delivered in a non-sterile condition. Prior to their first application, you must carry out the *complete* treatment of the sterilisable components in accordance with the "Processing instructions IID – EN 1933-210035“!
	Except for the CANTILEVER, the JOINT, the PROBE PIN, the TENSION SLEEVE and the ENDOSCOPE CLAMP - the DEXTER ENDOSCOPE ARM as well as the POWER SUPPLY are **not** suited for the mechanical/ automated cleaning or disinfection process!
	The quick clamping for the docking to the operating table is designed for a maximum Trendelenburg position of 30°. Never exceed that range.
	Should there be a power failure while using the device, check its safe operation prior to the next use!
	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.
	Should there be a power failure or should the POWER SUPPLY be accidently disconnected during use, the TROCAR POINT will be lost and must be reset.

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 DEXTER ENDOSCOPE ARM simulates an arm working in several degrees of freedom. The endoscopic camera is registered in the TROCAR POINT which serves as a pivot point. Based on this zero point, the device calculates the required individual movements of the axes in order to achieve the desired total movement.

The DEXTER ENDOSCOPE ARM is equipped with an electromechanical drive in order to perform the arm movements. An integrated activation function allows you to manually move the DEXTER ENDOSCOPE ARM at the push of a button.

The DEXTER ENDOSCOPE ARM is specially adapted to the DEXTER, which can fully control the DEXTER ENDOSCOPE ARM. For more information, refer to the document "DEXTER Instructions for use".

Despite its large range of movement, the DEXTER ENDOSCOPE ARM is light and compact and is attached either directly to the operating table by means of a quick-release clamp, or to the ENDOSCOPE CART provided for this purpose.

During the development of the DEXTER ENDOSCOPE ARM, we attached importance to a constant availability and extensive reusability. For this reason, you will need only one STERILE COVER per operation for a safe application.

The sterilisation inside a fractional vacuum at 134°C puts a lot of strain on the material. That is why all components that are treated will have only a limited life despite the use of selected materials. For more information on this, please refer to “Processing instructions IID – EN 1933-210035”.

The product works with software. You can find out more in document 1515-240319 (Cybersecurity label – Soloassist), which is available on request.

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.

Enabling the repositioning of an endoscope

The system allows the user to reposition the endoscope using the SURGEON CONSOLE of DEXTER. In case of power loss or other failures this function is not available or may be degraded.

Manual repositioning of the endoscope

The system enables the user to reposition the endoscope by hand by pushing a button. In case of power loss this function is not available.

Environment:

Operating room. The DEXTER ENDOSCOPE ARM must be either firmly attached to the operating table, or firmly attached to the ENDOSCOPE CART during use. If the DEXTER ENDOSCOPE ARM is used on the ENDOSCOPE CART, the ENDOSCOPE CART must be secured in its position relative to the operating table.

	The device is not intended for the operation in explosive areas. Ensure a sufficient distance to highly flammable gases (e.g. O2, anaesthetic gases).

During HF Surgery, the DEXTER ENDOSCOPE ARM is only compatible with following HF SURGICAL EQUIPMENT:

Power Cut mode capability of 300 W, working frequencies to include at least 400 kHz ± 100 kHz;

Coagulation mode capability of 100 W, working frequencies to include at least 400 kHz ± 100 kHz;

The DEXTER ENDOSCOPE ARM can not be used for argon plasma coagulation mode.

User Group:

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

The DEXTER ENDOSCOPE ARM 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 DEXTER ENDOSCOPE ARM. The device may be operated exclusively by instructed personnel. The instruction is to be documented.

Application:

Holding and guiding the endoscopic camera for the minimally invasive intervention in abdominal surgery, thoracic surgery, urology or gynaecology.

The intended use of the DEXTER ENDOSCOPE ARM is a robotic computer driven system whose function is to hold and position a rigid laparoscope / endoscope.

Contraindications:

The DEXTER ENDOSCOPE ARM is controlled by the surgeon performing the operation. In case of intraoperative complications that can not be managed laparoscopically and the surgeon must convert to an open surgery, it has to be ensured that the required medical personnel is available.

The DEXTER ENDOSCOPE ARM may not be used for fields other than the application fields named above. The DEXTER ENDOSCOPE ARM may be used exclusively for holding and moving an endoscope.

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 DEXTER ENDOSCOPE ARM has indirect clinical benefit for the patient. The benefits of the device lie primarly with the user. The positioning or fixation of the endoscope during minimally invasive interventions using robotic systems relieves the assistant from a long-lasting static holding task while allowing for solo procedures with a stable endoscope image.

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 resulting from improper use or combination with equipment other than the DEXTER, or other accessories, cannot 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 DEXTER ENDOSCOPE ARM 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 DEXTER ENDOSCOPE ARM 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 DEXTER ENDOSCOPE ARM based on this instruction manual.

	All components to be used in a sterile condition - except the STERILE COVER - are delivered in a non-sterile condition. Prior to their first application, you must carry out the *complete* treatment of the sterilisable components in accordance with the "Processing instructions IID – EN 1933-210035“!
	Operate the DEXTER ENDOSCOPE ARM only when it has reached room temperature again after a previous storage at high or low temperatures.

2 System Description

2.1 Overview

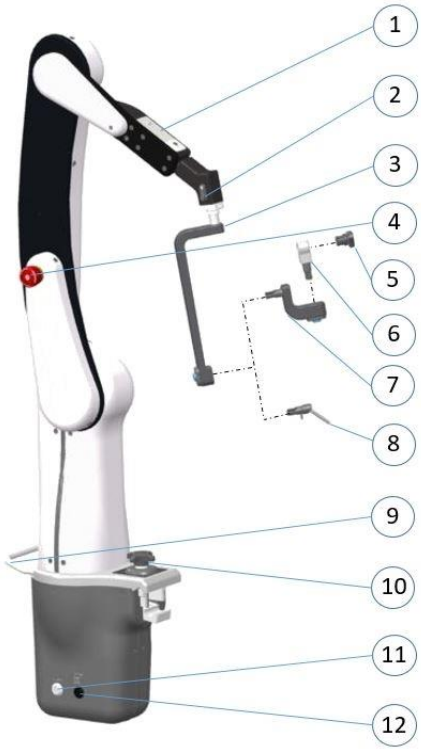


fig. 1: System overview

Number	Description
1	Control panel
2	Releasing slider
3	CANTILEVER
4	Emergency stop
5	TENSION SLEEVE
6	ENDOSCOPE CLAMP
7	JOINT
8	PROBE PIN
9	Handle
10	Quick-fastener for fastening to the operating table / ENDOSCOPE CART
11	Control connection (SURGEON CONSOLE of DEXTER)
12	Power supply connection

Table 1: System overview

2.2 System components

Component	Picture	Description
DEXTER ENDOSCOPE ARM (multiple patient multiple use)		The DEXTER ENDOSCOPE ARM is the executing component and is fastened via a quick-fastener to the operating table. Alternatively, the DEXTER ENDOSCOPE ARM can also be attached to the ENDOSCOPE CART using the quick-release fastener. The ENDOSCOPE CART is then positioned next to the operating table.
POWER SUPPLY (multiple patient multiple use)		The POWER SUPPLY supplies the DEXTER ENDOSCOPE ARM with the required operating voltage and is designed for a wide input voltage range. Use only the original POWER SUPPLY with the supplied cables.
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 DEXTER ENDOSCOPE ARM and the POWER SUPPLY. The SUPPLY CABLE is 3.5m long. Use exclusively the SUPPLY CABLE supplied with the equipment.

Component	Picture	Description
CANTILEVER (multiple patient multiple use)		The CANTILEVER is a pivoting connection between the DEXTER ENDOSCOPE ARM and the JOINT. The CANTILEVER is autoclavable; the useful life is at least 500 cycles
PROBE PIN (multiple patient multiple use)		The PROBE PIN is used to register the patient by probing the TROCAR POINT. It is attached to the CANTILEVER instead of the JOINT. The PROBE PIN is autoclavable. The service life is at least 500 cycles.
JOINT (multiple patient multiple use)		The JOINT forms a rotatable connection between CANTILEVER and ENDOSCOPE CLAMP. The JOINT is autoclavable. The service life is at least 500 cycles.
TENSION SLEEVE (multiple patient multiple use)		The TENSION SLEEVE accepts the endoscope in a secure and gentle way. They are available for endoscopes with 4 mm, 5 mm and 10 mm as well as for endoscopes measuring up to 12.7 mm. The TENSION SLEEVES are marked with different colors. The TENSION SLEEVE is autoclavable; the useful life is at least 100 cycles
ENDOSCOPE CLAMP (multiple patient multiple use)		In combination with the TENSION SLEEVE, the ENDOSCOPE CLAMP is a pivoting connection between JOINT and endoscope. The ENDOSCOPE CLAMP is autoclavable; the useful life is at least 500 cycles.
STERILISATION TRAY XL (multiple patient multiple use)		The STERILISATION TRAY XL with fixture for the CANTILEVER is intended for the mechanical cleaning. It also provides space for the JOINT, the PROBE PIN, the ENDOSCOPE CLAMP and for the TENSION SLEEVE.

Component	Picture	Description
STERILE COVER IID (single use)		For the sterile single-use covering of the DEXTER ENDOSCOPE ARM and the upper part of the ENDOSCOPE CART.
ENDOSCOPE CART (multiple patient multiple use)		With the ENDOSCOPE CART, the DEXTER ENDOSCOPE ARM can be positioned next to the operating table for use. The ENDOSCOPE CART is mechanically height-adjustable. The ENDOSCOPE CART is also intended for storage and transport of the DEXTER ENDOSCOPE ARM outside the application. If you have any questions about this system component, please contact: Distalmotion SA, Route de la Corniche 3B, 1066 Epalinges, Switzerland +41 21 510 58 90 support@distalmotion.com

Table 2: Components and accessories

Overview accessories and spare parts:

When ordering the parts, please contact the manufacturer or the corresponding representative directly.

Please use only original accessories. The use of accessories not approved by the manufacturer may pose a risk to the patient and lead to damage on the device.

Article number	Model number Distalmotion	Article name	Name
212499	348	DEXTER ENDOSCOPE ARM	DEXTER ENDOSCOPE ARM with POWER SUPPLY and SUPPLY CABLE
172035	392	POWER SUPPLY	POWER SUPPLY
182205 (EU)	393	POWER CORD	POWER CORD (EU)
182205 (GB)	394	POWER CORD	POWER CORD (GB)
172054	395	SUPPLY CABLE	SUPPLY CABLE
212480	352	CANTILEVER	CANTILEVER
212482	407	JOINT	JOINT
212518	350	PROBE PIN	PROBE PIN
222590	408	ENDOSCOPE CLAMP	ENDOSCOPE CLAMP
141365	361	TENSION SLEEVE D5	TENSION SLEEVE 5 mm
141339	362	TENSION SLEEVE D10	TENSION SLEEVE 10 mm
222599	409	STERILE COVER IID PU/ 50 ea.	STERILE COVER IID for the DEXTER ENDOSCOPE ARM, PU with 50 pieces REF E6784
192282	349	STERILISATION TRAY XL	STERILISATION TRAY XL for sterilisable parts
252797	828	IFU DEXTER ENDOSCOPE ARM – EU	Manual DEXTER ENDOSCOPE ARM – EN (1933-210033) Manual DEXTER ENDOSCOPE ARM – DE (1933-210032) Manual DEXTER ENDOSCOPE ARM – FR (1933-210037) Processing instructions IID – EN (1933-210035) Processing instructions IID – DE (1933-210034) Processing instructions IID – FR (1933-210038)

Table 3: Accessories and spare parts

2.3 Mechanical data

Weight	11,5 kg
Dimensions (W x H x D)	167 x 1059 x 291 mm
Safe working load	1 kg
Connection to the operating table	Quick-fastener, suitable for European and US standard rails

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

	Devices that are connected to the analogue and digital interfaces of the DEXTER ENDOSCOPE ARM must comply with the standards for electromedical devices. All configurations must meet the requirements of the system standard EN 60601-1. The person connecting additional devices is responsible for the compliance with this standard!
	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 DEXTER ENDOSCOPE ARM, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
	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.

2.5 Important performance characteristics

Important performance characteristics of the DEXTER ENDOSCOPE ARM:

- No movement in case of faults
- Constant availability without a dangerous failure of the system

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 DEXTER ENDOSCOPE ARM should always be transported in a suitable packaging. Any position is possible during transportation.

The ENDOSCOPE CART is used for storage between uses.

	Operate the DEXTER ENDOSCOPE ARM 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
	Device conforms to the regulation MDR - 2017/745 (Medical Device Regulation)
	Date of manufacture
	Manufacturer
	Distributor
	Model number
	Serial number
	Reference number
Rx only	Sale only on instruction of a physician (US federal law)
	Authorised representative in Switzerland
	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 Application parts

In accordance with the standard, the DEXTER ENDOSCOPE ARM does not feature any application parts that are in contact with the patient when used properly. However, the following parts can be touched by the patient.

- PROBE PIN
- Base plate with connection to the operating table

2.10 Name plate

fig. 2: Name plate

2.11 Identification according to MDR (Medical Device Regulation)

The DEXTER ENDOSCOPE ARM including accessories is a class I medical product. Sterile disposables are class Is medical devices.

2.12 Symbols of disposable items

Symbol	Description
REF	Reference number
QTY	Quantity
LOT	Lot number
#	Model number
	Can be used until
UDI	Unique Device Identification
MD	Medical Device
CE XXXX	Notified body of CE conformity
STERILE EO	Sterilised with ethylene oxide in a single barrier system

Symbol	Description
EC REP	Authorised representative in the European Community
CH REP	Authorised representative in Switzerland
	Do not use if packaging is damaged
	Do not re-sterilise
	Do not reuse
	Free of latex
	Manufacturer
	Distributor
	Importer

Table 5: Symbols on STERILE COVER IID

2.13 Contact

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

Manufactured for:

Distalmotion SA
Route de la Corniche 3B
1066 Epalinges
Switzerland

Phone: +41 21 510 58 90
eMail: support@distalmotion.com

Manufacturer:

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 DEXTER ENDOSCOPE ARM

The DEXTER ENDOSCOPE ARM can be mounted on the operating table, or on the ENDOSCOPE CART, with the following steps and put into operation for subsequent use. This is usually done **before** the patient is washed and covered with sterile drapes.

Step 1: Mount it to the operating table / ENDOSCOPE CART

Step	Description
	The unit is lifted and hooked onto the standard rail of the operating table or ENDOSCOPE CART.
	After the unit has been placed on the standard rail, the unit is aligned perpendicular to the operating table or ENDOSCOPE CART and the clamping screw is tightened by hand.

Step	Description
	The attachment to the ENDOSCOPE CART is identical to the attachment to the operating table. In both cases, make sure that the unit is attached to the standard rail without any wobbling.

Table 6: Mounting on OR table / ENDOSCOPE CART

⚠	Make sure that the DEXTER ENDOSCOPE ARM is firmly locked on the rail of the operating table before using the device.
⚠	Please note that the height-adjustable ENDOSCOPE CART must not be adjusted in height during surgery! The position of the DEXTER ENDOSCOPE ARM in relation to the patient (TROCAR POINT) must not change during surgery!
⚠	Please note that the ENDOSCOPE CART remains firmly secured to the floor during surgery! The position of the DEXTER ENDOSCOPE ARM in relation to the patient (TROCAR POINT) must not change during surgery!
⚠	Please note that during the operation the setting of the operating table must remain unchanged! The position of the patient (TROCAR POINT) in relation to the DEXTER ENDOSCOPE ARM must not change during the operation!

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 DEXTER ENDOSCOPE ARM.

❗	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.
❗	Use only the original POWER SUPPLY, POWER CORD and SUPPLY CABLE.
❗	Avoid tripping hazards when connecting the cables.

Step 3: Select cantilever position

The DEXTER ENDOSCOPE ARM has an additional swivel joint at its distal end. This adjustment option allows collisions with the surgeon's instruments or the instruments of the DEXTER to be largely avoided.

In the standard position, the CANTILEVER points downwards. Select a joint position that seems suitable for the planned intervention.

Change the joint position as follows:

Picture	Description
	This joint allows you to change the angle position of the CANTILEVER in 45° increments.
	1 Pull the joint head forward. 2. Turn the pivot joint into the desired position. 3. Let the joint head lock in again.

Table 7: Changing joint position

	If applicable, disconnect a connected endoscope from the CANTILEVER if you change the joint position.
	The joint position can be changed at any time while the DEXTER ENDOSCOPE ARM is in use. A new adjustment of the TROCAR POINT is not necessary.

Step 4: Prepare the STERILE COVER

⚠	Do not use a STERILE COVER if you can detect damage to the packaging or the STERILE COVER itself!

Step	Description
	Remove a STERILE COVER from the package and lay it out ready.
	Open the folded STERILE COVER in the center (sticker with green arrow).
	Reach with one hand into the STERILE COVER and insert the pin of the CANTILEVER through the opening in the elastic part of the STERILE COVER.
	Pull the CANTILEVER through.
	Pull the elastic front end of the STERILE COVER over the conical collar of the connector.

Table 8: Preparation of STERILE COVER IID

Step 5: Connect the CANTILEVER and cover the arm with the STERILE COVER IID

	The DEXTER ENDOSCOPE ARM is usually covered with the STERILE COVER after the skin disinfection has been carried out but before the patient is covered with a sterile drape.

Step	Description
	Insert the CANTILEVER with STERILE COVER, pin first, to the distal end of the DEXTER ENDOSCOPE ARM.
	Insert the pin of the CANTILEVER into the corresponding receptacle until the CANTILEVER audibly clicks into place.
	Check if it correctly locked in place by pulling at the CANTILEVER.
	Grab the STERILE COVER and pull it over the arm.
	Gather any excess length of the STERILE COVER downward.

Table 9: Sterile Cover

	Use only the original STERILE COVER which you have bought from the manufacturer or an authorised partner.

Step 6 (optional): Obtain ENDOSCOPE CART sterile

If the DEXTER ENDOSCOPE ARM is used on the ENDOSCOPE CART, the upper area of the ENDOSCOPE CART must be covered with sterile material.

To do this, pull the STERILE COVER IID over the upper part of the ENDOSCOPE CART.

fig. 3: Obtain ENDOSCOPE CART sterile

Proceed with the sterile covering of the patient at this point according to the usual procedure in your place.

3.2 Connecting the DEXTER ENDOSCOPE ARM to the SURGEON CONSOLE of the DEXTER

Connect the DEXTER ENDOSCOPE ARM as follows:

Step	Description
	Connect the ENDOSCOPE ARM DATA CABLE of DEXTER to the input socket (“Control”) on the DEXTER ENDOSCOPE ARM. Connect the ENDOSCOPE ARM DATA CABLE to the SURGEON CONSOLE of DEXTER.

Table 10: Connection of the DEXTER ENDOSCOPE ARM

3.3 Mounting the ENDOSCOPE CLAMP to the endoscope

Select the TENSION SLEEVE suitable for the endoscope. There are types available for 4, 5, 10 and 12.7 mm endoscopes. The possible clamping range in each case can be taken from the following table:

TENSION SLEEVE	Endoscope shaft diameter [mm]	Article number	Colour
D4	3.3 to 4.1	161774	Blue
D5	4.4 to 5.5	141365	Grey
D10	9.1 to 10.4	141339	Black
D12.7	11.4 to 12.7	161773	Green

Table 11: Clamping range of the TENSION SLEEVEs

Picture	Description
	Loosely screw the TENSION SLEEVE into the ENDOSCOPE CLAMP.
	Slide the ENDOSCOPE CLAMP over the endoscope and tighten the TENSION SLEEVE by hand.

Table 12: ENDOSCOPE CLAMP attachment

	Tighten the ENDOSCOPE CLAMP only enough so that you can still turn the endoscope easily.

3.4 Mounting PROBE PIN or JOINT on the CANTILEVER

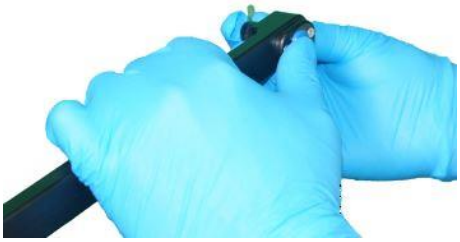
Picture	Description
	Insert the PROBE PIN into the hole of the CANTILEVER. The PROBE PIN audibly engages with a "click". The PROBE PIN is used to probe the TROCAR POINT.
	Insert the JOINT into the hole of the CANTILEVER. The JOINT engages audibly with a "click". The JOINT is used to attach the endoscope.
	Press the blue release button on the CANTILEVER to remove JOINT or PROBE PIN again.

Table 13: Mounting PROBE PIN or JOINT

4 Operation

The DEXTER ENDOSCOPE ARM is operated either by unlocking the axes and the subsequent manual positioning or via motor using the SURGEON CONSOLE as a control element.

For details, see the instruction manual „DEXTER Instructions for use“ for the DEXTER.

For the motor-driven adjustment, you must register the position of the patient to the DEXTER ENDOSCOPE ARM. This registration is the basis for the calculation of movements.

4.1 Controls and status displays

The DEXTER ENDOSCOPE ARM features two illuminated controls (1/5) as well as three more status displays (2-4).

fig. 4: Control Panel

Controls

Button	Symbol	Function
1		Sets the TROCAR POINT
5		Unlocks the DEXTER ENDOSCOPE ARM for the manual positioning

Table 14: Control elements

Status displays

Display	Symbol	Colour	Meaning
1		White	OFF: No DEXTER connected PULSATING*: Device is ready, no TROCAR POINT is set ON: Device is ready, TROCAR POINT is set
2		Yellow	ON: The connected SURGEON CONSOLE is defective
3		Yellow	ON: One or more axes of the DEXTER ENDOSCOPE ARM has/have reached the maximum angle. A further movement in this direction is no longer possible.
4		Yellow	ON: Service, an internal error has been detected.
5		Green	OFF: No power supply ON: Operational BLINKING**, if the button 1 (set TP) is pressed: The TROCAR POINT has been successfully set. BLINKING**, if no button is pressed: The pivot joint at the distal end of the cantilever arm has not correctly locked into place.

Table 15: Status displays

* PULSATING: The corresponding display slowly becomes brighter and darker again.

** BLINKING: approx. 1 s on and then 1 s off.

	Should the yellow display 4 "Service“ light up, an error has occurred in the DEXTER ENDOSCOPE ARM. In this case, the device must be immediately checked. However, the device can still be operated.

The DEXTER ENDOSCOPE ARM features an EMERGENCY STOP button. Once pressed, the EMERGENCY STOP button will light red and be locked.

Picture	Description
	Press this button if you do not think you have given a command to move the endoscope.
	In order to release the EMERGENCY STOP again, turn the switch clockwise.

Table 16: Emergency Stop

4.2 Manual positioning

The DEXTER ENDOSCOPE ARM features unlockable brakes that allow you to manually move the arm quickly and accurately at any time. The weight of the endoscope will be largely compensated in the process.

Picture	Description
	In order to reposition the arm, hold the arm at the pivot joint and press the button (5) "Unlock“. The arm can now move freely. As soon as you have reached the desired position, release the button (5). The arm is immediately locked again and the image detail is stable.

Table 17: Manual positioning

4.3 Motor-driven adjustment

If the DEXTER ENDOSCOPE ARM is adjusted via a motor, the **tip of the endoscope** moves along the surface of an imagined sphere in space. The image detail can therefore be intuitively changed during the operation. The motor-driven adjustment takes place via the SURGEON CONSOLE of the DEXTER.

	The motor-driven adjustment is available only after a TROCAR POINT (see 4.4.1) has been saved.

Please follow the instructions in the document "DEXTER Instructions for use" to control the DEXTER ENDOSCOPE ARM with the SURGEON CONSOLE.

All movement directions are based on the monitor image. Ensure the anatomically correct setting of the image horizon.

Corresponding movements of the endoscope within the trocar

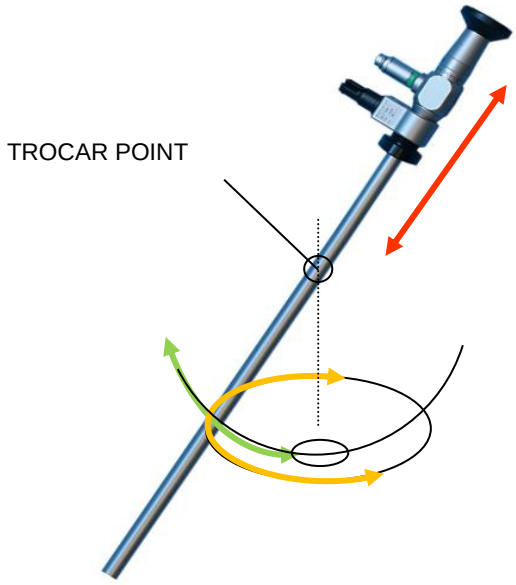


fig. 5: Endoscope movement

4.4 Operating procedure

In the following, it is assumed that point 3 (assembly and commissioning) has been completed and the DEXTER ENDOSCOPE ARM is ready for use.

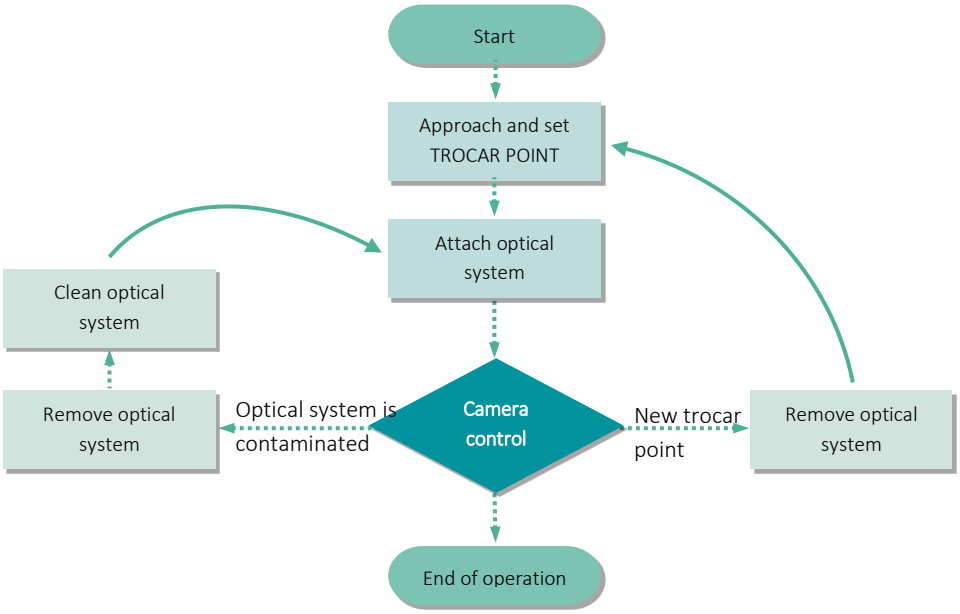


fig. 6: Workflow

⚠	Continuously monitor the patient and the DEXTER ENDOSCOPE ARM while you control one of the powered movements.

4.4.1 Approaching and saving the TROCAR POINT (patient registration)

In order to establish a relation between patient and DEXTER ENDOSCOPE ARM, it is necessary to know the position of the patient on the operating table. This is done by the following procedure, which is also called registration.

After switching on, the DEXTER ENDOSCOPE ARM can immediately be moved manually by pressing the "Unlock" key (5).

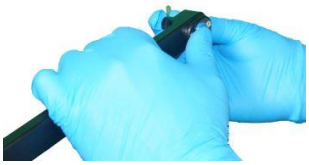
Step	Description
	Attach the PROBE PIN to the CANTILEVER.
	Press the button (5) "Unlock“ and move the PROBE PIN of the CANTILEVER to the entrance point of the trocar into the abdominal wall.
	Press the button (1) "TP“ on the control panel of the DEXTER ENDOSCOPE ARM. You will receive a visual feedback when pressing the button. The "Ready“ display (5) begins to blink green.
	Move the PROBE PIN away again by pressing the button (5) "Unlock" and remove the PROBE PIN from the CANTILEVER.

Table 18: Saving trocar point

	Should there be a power failure or should the device be accidentally turned off during its use, the TROCAR POINT will be lost and must be newly fixed.

4.4.2 Mounting the endoscope

Step	Description
	Attach the JOINT to the CANTILEVER. The JOINT engages with a "click".
	Move the DEXTER ENDOSCOPE ARM so that the JOINT comes close to the endoscope (optic) already inserted and roughly positioned in the trocar.
	Attach the endoscope (optic) to the CANTILEVER by hooking in the ENDOSCOPE CLAMP. The ENDOSCOPE CLAMP engages with a "click".

Table 19: Endoscope attachement

4.4.3 Camera control

The endoscope position can be changed at any time either manually (see 4.2) or via motor (see 4.3).

The motor driven adjustment of the DEXTER ENDOSCOPE ARM makes the right/left, up/down movement in relation to the monitor image intuitive and it can be accurately zoomed.

Please follow the instructions in the document "DEXTER Instructions for use" to control the DEXTER ENDOSCOPE ARM with the SURGEON CONSOLE.

4.4.4 Cleaning the endoscope (optical system)

Step	Description
	Press the blue release button on the JOINT and pull out the ENDOSCOPE CLAMP with the optic.
	After cleaning, you can reattach the endoscope (optic). The ENDOSCOPE CLAMP locks into place automatically. The release button does not have to be pressed to hook in. The viewing angle set before cleaning is available again after hanging.

Table 20: Cleaning optics

4.4.5 Setting a new TROCAR POINT

If applicable, uncouple a connected endoscope.

Replace the JOINT on the CANTILEVER with the PROBE PIN.

Approach the new TROCAR POINT as described under 4.4.1.

Press "TP“ the button (1). The display on the "Ready“ button (5) will begin to blink.

4.4.6 Ending the application

Step	Description
	Remove the endoscope (optical system) by pressing the unlocking button on the JOINT.
	Remove the JOINT by pressing the blue release button on the CANTILEVER.
	Remove the CANTILEVER from the boom joint by pushing the side release slides towards the CANTILEVER.
	Dispose the used STERILE COVER of the DEXTER ENDOSCOPE ARM. Bring the DEXTER ENDOSCOPE ARM into an upright position for the subsequent storage on the ENDOSCOPE CART.
	Disconnect all cable connections and unplug the POWER SUPPLY.

Step	Description
	Loosen the TENSION SLEEVE and detach the ENDOSCOPE CLAMP from the endoscope.
	Place the CANTILEVER, the JOINT, the PROBE PIN, the ENDOSCOPE CLAMP and the TENSION SLEEVE into the STERILISATION TRAY XL.
	The DEXTER ENDOSCOPE ARM can now be taken from the operating table and placed on the ENDOSCOPE CART.

Table 21: End of operation

4.5 Wipe disinfection

The DEXTER ENDOSCOPE ARM 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 22: Disinfecting agents

4.6 Reprocessing

The STERILISABLE ARM COMPONENTS must be cleaned, disinfected and sterilised prior to each use; this also applies in particular for the first time use after the delivery as all STERILISABLE ARM COMPONENTS are not delivered in a sterilised condition (clean and disinfect the components after the removal of the protective transport packaging; sterilise the components according to the corresponding packaging).

"STERILISABLE ARM COMPONENTS“ include the CANTILEVER, the JOINT, the PROBE PIN, the ENDOSCOPE CLAMP and the TENSION SLEEVE(s). An effective cleaning and disinfection is absolutely necessary for an effective sterilisation.

As part of your responsibility, please observe the sterility of the application. For details on the reprocessing of STERILISABLE ARM COMPONENTS, please refer to the separately available reprocessing instructions “Processing instructions IID – EN 1933-210035”.

5 Emergency procedures

There are basically two emergency scenarios:

5.1 Intraoperative complications

In case of intraoperative complications not due to the use of the DEXTER ENDOSCOPE ARM, it may still be in order to remove the device as fast as possible from the OR surroundings in order to have better access to the patient.

Proceed as follows:

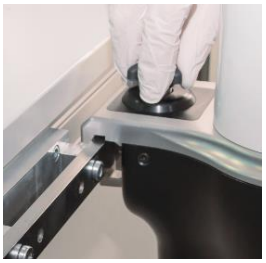
Step	Description
	Detach the endoscope (optical system) by pressing the unlocking button on the JOINT.
	Bring the DEXTER ENDOSCOPE ARM into an upright position and turn it away to the side.
 	If you still have not sufficient access to the surgery site, remove the entire arm from the operating table. Open the mount and detach the device from the operating table rail. If the DEXTER ENDOSCOPE ARM is used on the ENDOSCOPE CART, unlock the ENDOSCOPE CART and remove both from the operating environment.

Table 23: Emergency procedure

5.2 Technical problems

The technical device may still malfunction despite all the diligence during the development, testing and production.

The pressing of the emergency button will interrupt the power supply of the drives and a movement can no longer be performed.

Remove the DEXTER ENDOSCOPE ARM from the surgery surroundings as described under 5.1 and call, if necessary, an assistant for the camera movement in order to end the intervention.

⚠	A critical situation can arise if an unintended movement is carried out. Unintentional means that no movement command is given by the SURGEON CONSOLE of DEXTER, but the unit moves anyway. In this case **IMMEDIATELY** press the red EMERGENCY STOP button. 
⚠	Do not use the device for further interventions even if you think that the error no longer exists!
⚠	All serious incidents related to the product must be reported to the manufacturer and the competent authority in the country concerned.
❗	Contact the manufacturer's service or another authorised person immediately. Do not change any of the device configurations.

6 Troubleshooting

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

	Never open the DEXTER ENDOSCOPE ARM 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
Status display "Ready“ does not light	Check the POWER SUPPLY: • Tight fit of the SUPPLY CABLE on the arm • Connection to the outlet • Switch to a different outlet
Status display "Ready“ constantly blinks	The pivot joint at the distal end of the cantilever arm has not correctly locked into place. ➔ Check the pivot joint.
Status display light "Control“ is on	The SURGEON CONSOLE is defective. ➔ Call the service.
"Emergency stop“ button lights red	Check whether the emergency stop button on the DEXTER ENDOSCOPE ARM is pressed and unlock it, if applicable, by turning it clockwise.
Status display light "Service“ is on	An internal error has occurred. ➔ Call the service.
Movement does not follow the expected path. Image does not move in the expected direction.	The TROCAR POINT is possibly not set correctly. ➔ Reset the TROCAR POINT. (See chapter 4.4.1)

Table 24: Trouble shooting

7 Service

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

7.1 Handover certificate

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

7.2 Regular inspections

Perform the following checks before each use of the device:

– Check POWER CORD for damage.

– DEXTER ENDOSCOPE ARM and accessories for external damage.

	Never use the DEXTER ENDOSCOPE ARM if you detected any damage. Contact the corresponding service.

7.3 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 Distalmotion 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.

7.4 Disposal / Recycling

The manufacturer confirms that the product

DEXTER ENDOSCOPE ARM

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. 1206-140095 (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.
	In accordance with the European REACH Regulation and other environmental regulatory requirements, Dimethoxyethane (CAS Number: 110-71-4) is present in a concentration above 0.1% weight by weight (w/w) in some components of the DEXTER ENDOSCOPE ARM. This declaration is made in good faith and is based upon supplier data.

8 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 DEXTER ENDOSCOPE ARM.
	MEDICAL ELECTRICAL DEVICES are subject to special precautionary measures in regard to EMC. The DEXTER ENDOSCOPE ARM may be installed and operated only in accordance with the EMC information contained in this manual.
	The DEXTER ENDOSCOPE ARM 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 DEXTER ENDOSCOPE ARM 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 25: 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:** d = 1.2√P for 80 MHz to 800 MHz d = 2.3√P for 800 MHz to 2,7 GHz

Test	Limit	Electromagnetic environment - guidance
		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.

Table 26: 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 DEXTER ENDOSCOPE ARM, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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