INSTRUCTIONS FOR USE
SOLOASSIST IIS

Status: 2025-08

1828-190039-09

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 SOLOASSIST IIS 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 SOLOASSIST IIS 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 SOLOASSIST IIS. In conjunction with the instructions by our trained specialists, it allows you to safely handle the SOLOASSIST IIS.

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 SOLOASSIST IIS.

	Never use the SOLOASSIST IIS in the OR without having been instructed by an authorised person in its safe use.
	Make sure that the rail of the operating table is secured and locked before using the device.
	Continuously monitor the patient and the SOLOASSIST IIS while you control one of the powered movements.
	Never open the SOLOASSIST IIS or the POWER SUPPLY. Risk of an electric shock!

	Always steady the endoscope before you unlock the quick fastener between endoscope and CLAMP (Ø5 / Ø10), as well as between CLAMP (Ø5 / Ø10) and UNIVERSAL JOINT
	Do not use the disposables if you notice any damage to the packaging or the disposables themselves!
	The device is not intended for the operation in explosive areas. Ensure a sufficient distance to highly flammable gases (e.g. O2, anaesthetic gases).
	The SOLOASSIST IIS and the POWER SUPPLY are not suitable for mechanical / automated cleaning or disinfection procedures!
	Do not reach into the system's range of motion during the movement.
	The TROLLEY is intended for the storage and transport of the SOLOASSIST IIS when not in use. Never use the TROLLEY to place the SOLOASSIST IIS next to the operating table during the application.
	Devices that are connected to the analogue and digital interfaces of the SOLOASSIST IIS 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: 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 SOLOASSIST IIS, 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.
	Caution! The JOYSTICK input device and the components of the PRODUCT GROUP JOYSTICK must be cleaned, disinfected and sterilised before each use! Therefore, follow the instructions in the separetely available reprocessing instructions „Processing instructions JOYSTICK-IIS – EN 1828-240238“ without exception!
	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 SOLOASSIST IIS only when it has reached room temperature again after a previous storage at high or low temperatures.
	Avoid tripping hazards when connecting the cables.

	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.
	Positions outside the shown range of motion cannot be reached! Should one or several axes have reached their maximum joint angle, the movement of the SOLOASSIST IIS will stop! In order to prevent this, place the arm preferably in a central location in the operating field.

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

The system provides for a large range of motion that allows for an all-round view of 360 ° and this with an inclination of the endoscope of up to 90 ° to the perpendicular.

The input device used is either the sterile reprocessable JOYSTICK, the sterile covered REMOTE CONTROL or the VOICE CONTROL, which is operated by the surgeon via a wireless headset.

Sterilisation in a fractionated vacuum at 134°C places a high load on the JOYSTICK input device and the components of the PRODUCT GROUP JOYSTICK. Therefore, all components that are processed have a limited service life despite the use of selected materials. You can find more information on this in the document "Processing instructions JOYSTICK-IIS - EN 1828-240238".

The SOLOASSIST IIS is lightweight and compact despite its large range of motion and is fastened directly to the Operating table using a quick-clamping system. A repositioning and registration to the patient is not necessary even if the Operating table has been moved in the meantime. To allow the surgeon to convert to an open surgery in case of an emergency, the SOLOASSIST IIS can be completely removed in the shortest possible time.

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 JOYSTICK, REMOTE CONTROL or VOICE CONTROL. 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 SOLOASSIST IIS must be firmly connected to the operating table during its use. It is not permitted to place it on an equipment trolley, a side table or similar.

	The TROLLEY is intended for the storage and transport of the SOLOASSIST IIS when not in use. Never use the TROLLEY to place the SOLOASSIST IIS next to the operating table during the application.
	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 SOLOASSIST IIS 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 SOLOASSIST IIS can not be used for argon plasma coagulation mode.

User Group:

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

The SOLOASSIST IIS 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 SOLOASSIST IIS. The device may be operated exclusively by instructed personnel. The instruction is to be documented.

Patient Group:

All patients with a minimum weight of 5 kg.

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 SOLOASSIST IIS is a robotic computer driven system whose function is to hold and position a rigid laparoscope / endoscope.

Contraindications:

The SOLOASSIST IIS 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 SOLOASSIST IIS may not be used for fields other than the application fields named above. The SOLOASSIST IIS 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 SOLOASSIST IIS 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 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 SOLOASSIST IIS 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 SOLOASSIST IIS 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 SOLOASSIST IIS based on this instruction manual.

	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 SOLOASSIST IIS, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
	Operate the SOLOASSIST IIS only when it has reached room temperature again after a previous storage at high or low temperatures.

2 System Description

2.1 Overview

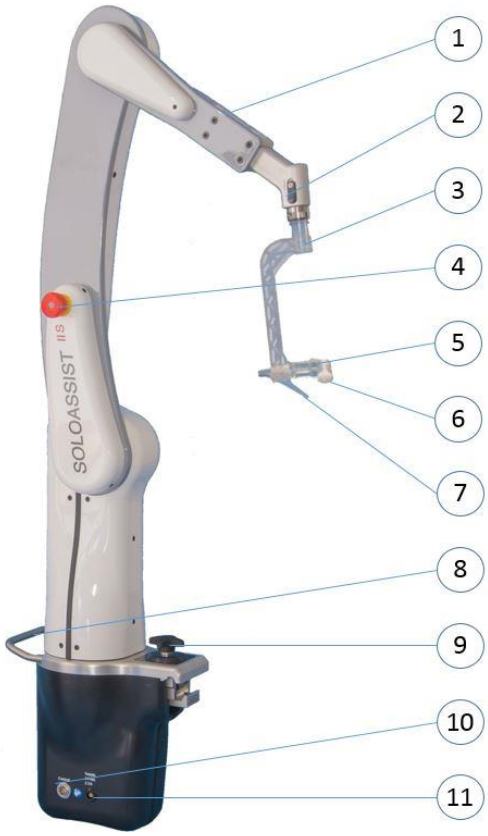


fig. 1: Overview System Description

Number	Description
1	Control panel
2	Releasing slider
3	UNIVERSAL JOINT
4	EMERGENCY STOP
5	CLAMP
6	KNURLED NUT
7	STYLUS TIP
8	Handle
9	Quick-fastener for fastening to the operating table
10	Connection Control (JOYSTICK / REMOTE CONTROL / VOICE CONTROL)
11	Supply Connection (POWER SUPPLY)

Table 1: Overview System Description

2.2 System components

Component	Picture	Description
SOLOASSIST IIS Arm (multiple patient multiple use)		The SOLOASSIST IIS arm is the executing component and is fastened via a quick-fastener to the operating table.
POWER SUPPLY (multiple patient multiple use)		The POWER SUPPLY supplies the SOLOASSIST IIS with the requiered 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 SOLOASSIST IIS and the POWER SUPPLY. The SUPPLY CABLE is 3.5m long. Use exclusively the SUPPLY CABLE supplied with the equipment.

Component	Picture	Description
UNIVERSAL JOINT (single use)		The UNIVERSAL JOINT forms a rotation connection between the SOLOASSIST IIS and the CLAMP. The UNIVERSAL JOINT is for single use only.
CLAMP Ø10 (single use)		The CLAMP Ø10 holds the endoscope and forms a rotatable connection between the UNIVERSAL JOINT and the endoscope The KNURLED NUT with the corresponding SCREW is pre-assembled on the CLAMP Ø10.
CLAMP Ø5 (single use)		The CLAMP Ø5 holds corresponding endoscopes and forms a rotatable connection between the UNIVERSAL JOINT and the endoscope.
ENDOSCOPE HOLDER (single use)		The ENDOSCOPE HOLDER consists of a UNIVERSAL JOINT, CLAMP Ø10 and CLAMP Ø5. The ENDOSCOPE HOLDER is for single use only.
STERILE COVER (single use)		For the sterile single-use covering of the SOLOASSIST IIS.
JOYSTICK (multiple patient multiple use)		The SOLOASSIST IIS can be moved using the JOYSTICK. The JOYSTICK can be autoclaved and has a service life of up to 150 cycles. As the JOYSTICK is safety-relevant for the function of the SOLOASSIST IIS, its use is electronically limited to 150 applications. A left and a right version of the JOYSTICK and various attachment options for the surgical handles are available. For more information, please refer to the instructions for use for the JOYSTICK-IIS: 1828-240237

Component	Picture	Description
REMOTE CONTROL (multiple patient multiple use)		The SOLOASSIST IIS can be moved by motor using the REMOTE CONTROL. In addition, the integrated LASER POINTER can be used to point out anatomical structures on the screen. The REMOTE CONTROL is covered sterilely during use. For more information, please refer to the instructions for use for the REMOTE CONTROL: 2038-210029
VOICE CONTROL (multiple patient multiple use)		The VOICE CONTROL evaluates the spoken commands of the user and transmits them to the SOLOASSIST IIS. Ideally, the voice control is accommodated in the endoscopy tower (equipment trolley). You can find more information on this in the instructions for use for VOICE CONTROL: 1515-170066
TROLLEY (multiple patient multiple use)		The TROLLEY is intended for the storage as well as transport of the SOLOASSIST IIS when not in use.

Table 2: System components

Overview accessories and spare parts:

For orders, please contact the manufacturer directly or your responsible representative.

Only use original accessories. The use of accessories not approved by the manufacturer may endanger the patient or cause damage to the device.

Article number	Article name	Name
182220	SOLOASSIST IIS	SOLOASSIST IIS
172035	POWER SUPPLY	POWER SUPPLY
182205	POWER CORD	POWER CORD
172054	SUPPLY CABLE	SUPPLY CABLE
242695	JOYSTICK-LH-IIS	JOYSTICK
212510	REMOTE CONTROL	REMOTE CONTROL
171894	VOICE CONTROL	VOICE CONTROL
120874	TROLLEY	TROLLEY
192289 *	STERILE SET IIS PU/ 10 ea.	STERILE SET IIS with 10 pieces ENDOSCOPE HOLDER REF 182214 and 10 pieces STERILE COVER REF 6001-40001, individually sterile packed
242704 *	STERILE SET IIS PU/ 10 ea.	STERILE SET IIS with 10 pieces ENDOSCOPE HOLDER REF 182214 and 10 pieces STERILE COVER REF E6785, individually sterile packed
1828-190039	Manual SOLOASSIST IIS – EN	-
1828-240237	Manual JOYSTICK-IIS – EN	-
1828-240238	Processing instructions JOYSTICK-IIS – EN	-
2038-210029	Manual REMOTE CONTROL – EN	-
1515-170066	Manual VOICE CONTROL – EN	-

Table 3: Article numbers

* The two STERILE COVERS REF 6001-40001 and REF E6785 are matched to the device in terms of fit and function; due to country-specific approvals, only one STERILE COVER may be available in each case.

2.3 Mechanical data

Weight	12,5 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

Range of motion:

The positions reached by the SOLOASSIST IIS depend on the select cantilever position (see 3.1 / step 3) as well as the positioning at the operating table. The following figure illustrates the range of motion. The area that can be reached by the tip of the arm is highlighted in yellow.

The range of motion is to be measured in such a way that the endoscope can be moved at least within a 300 mm semi-sphere radius around the TROCAR POINT. There are sufficient reserves available for an application-oriented positioning of the arm at the operating table.

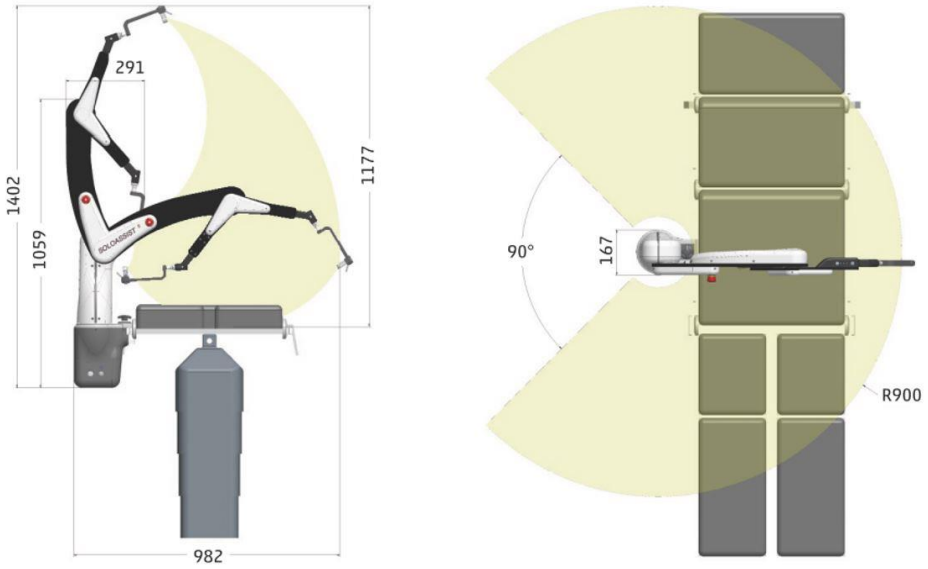


fig. 2: Range of motion

	Positions outside the shown range of motion cannot be reached! Should one or several axes have reached their maximum joint angle, the movement of the SOLOASSIST IIS will stop! In order to prevent this, place the arm preferably in a central location in the operating 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

	Devices that are connected to the analogue and digital interfaces of the SOLOASSIST IIS 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 SOLOASSIST IIS, 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 SOLOASSIST IIS:

- 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 SOLOASSIST IIS 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 SOLOASSIST IIS 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
Control	Connection for the input devices
Supply	Power Supply
Type	Construction type
	Device conforms to the regulation MDR - 2017/745 (Medical Device Regulation)
	Date of manufacture
	Manufacturer
	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 SOLOASSIST IIS 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.

- UNIVERSAL JOINT
- Base plate with connection to the operating table

2.10 Name plate

fig. 3: Nameplate

2.11 Identification according to MDR (Medical Device Regulation)

The SOLOASSIST IIS 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
LOT	Lot number
	Can be used until
STERILE EO	Sterilised with ethylene oxide
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

Symbol	Description
	Keep dry
	Protect from sunlight
	Manufacturer

Table 5: Symbols for disposable items

2.13 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 SOLOASSIST IIS

Follow the following work steps to mount the SOLOASSIST IIS 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 6: Mounting on operating table

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

	Positions outside the shown range of motion cannot be reached! Should one or several axes have reached their maximum joint angle, the movement of the SOLOASSIST IIS will stop! In order to prevent this, place the arm preferably in a central location in the operating field.
	For more information on the positioning, refer to the SETUP cards for the individual procedures (e.g. CHE, fundoplication, sigma resection...).

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 SOLOASSIST IIS.

	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 cantilever features an additional pivot joint at its distal end. This adjustment option allows you to largely avoid collisions with the surgeon's instruments.

In the standard position, the UNIVERSAL JOINT points downward. Select a joint position that seems suitable for the planned intervention.

Change the joint position as follows:

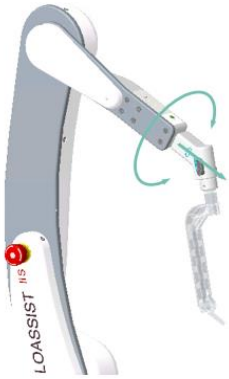
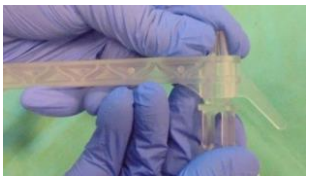
Picture	Description
	This joint allows you to change the angle position of the UNIVERSAL JOINT in 45° increments.
	1 Pull the joint head forward. 2. Turn the pivot joint into the desired position. 3. Let the joint head lock in again.

Table 7: Changing joint position

⚠	If applicable, disconnect a connected endoscope from the UNIVERSAL JOINT if you change the joint position.
❗	The joint position can be changed at any time while the SOLOASSIST IIS is in use. A new adjustment of the TROCAR POINT is not necessary.

Step 4: Prepare the STERILE COVER

⚠	Do not use the disposables if you notice any damage to the packaging or the disposables themselves!

Step	Description
	Remove the UNIVERSAL JOINT, CLAMP Ø10 and CLAMP Ø5 from the packaging and place these parts in readiness.
	Press the two legs of the CLAMP Ø10 together and pull the CLAMP Ø10 out of the UNIVERSAL JOINT.
	Remove the STERILE COVER from the packaging and place it in the ready position.
	Open the folded STERILE COVER in the middle (adhesive marking with blue arrow).
	Grasp the STERILE COVER with one hand. Insert the plug of the UNIVERSAL JOINT through the opening in the elastic part of the STERILE COVER.
	Pull the UNIVERSAL JOINT through.
	Pull the elastic front end of the STERILE COVER over the conical collar of the plug.

Step	Description
	Make sure that the elastic front end of the STERILE COVER comes to rest as shown in the picture.

Table 8: Preparation of the STERILE COVER

Step 5: Connect the UNIVERSAL JOINT and cover the arm with the STERILE COVER

	The SOLOASSIST IIS 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.

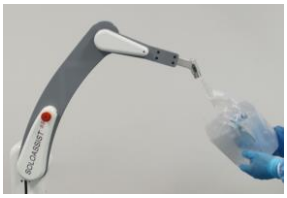
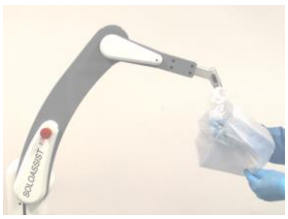
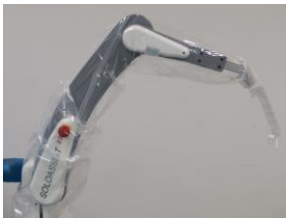
Step	Description
	Guide the UNIVERSAL JOINT with STERILE COVER from below to the arm.
	Insert the plug of the UNIVERSAL JOINT into the mounting of the arm until the UNIVERSAL JOINT audibly engages. Check the correct engagement by pulling on the UNIVERSAL JOINT.
	Slide the STERILE COVER over the arm.
	Grasp the STERILE COVER and pull it down over your arm. Retrieve any excess length of the STERILE COVER pull down.

Table 9: Obtain sterile

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

	Only use the original STERILE COVER - REF 6001-40001, or REF E6785 - , as well as the original ENDOSCOPE HOLDER - REF 182214 - , which you have purchased from the manufacturer or an authorised partner.

3.2 Mounting the JOYSTICK to the surgical instrument

The JOYSTICK is designed so that it is preferably connected to the left hand while used with the surgical instrument. A JOYSTICK version for the right hand as well as different instrument adapters are available. Please refer to the JOYSTICK instructions for use for details (Manual JOYSTICK-IIS – EN 1828-240237).

fig. 4: JOYSTICK on the instrument

Please refer to the document “Manual REMOTE CONTROL – EN 2038-210029” for details on the setup, commissioning and connection of the REMOTE CONTROL.

Please refer to the document “Manual Voice Control – EN 1515-170066” for details on the setup, commissioning and connection of the VOICE CONTROL.

3.3 Mounting the CLAMP on the Endoscope

Select the CLAMP suitable for the endoscope. The ENDOSCOPE HOLDER contains one CLAMP each for Ø10 mm and Ø5 mm.

The **CLAMP Ø10** can safely accommodate all endoscopes with an outer diameter of **8 to 11 mm**.

The **CLAMP Ø5** can safely accommodate all endoscopes with an outer diameter of **4 to 6 mm**.

Contact us if you use an endoscope with a different outer diameter.

Step	Description
	Slide the CLAMP Ø10 onto the endoscope and tighten the KNURLED NUT by hand. Only tighten the KNURLED NUT so that you can still rotate the endoscope.
	If you use the CLAMP Ø5, the screw must be removed from the CLAMP Ø10 and inserted into the CLAMP Ø5 mm.

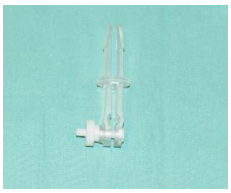
Step	Description
	Turn the KNURLED NUT loosely onto the screw. You can now attach a Ø5 mm endoscope to the CLAMP Ø5. Only tighten the KNURLED NUT so that you can still rotate the endoscope.

Table 10: Mounting CLAMP on the Endoscope

4 Operation

The SOLOASSIST IIS is operated either by unlocking the axes and subsequent manual positioning or by motorised operation using the JOYSTICK / REMOTE CONTROL / VOICE CONTROL.

To use the motor adjustment, the patient's position must be registered with the SOLOASSIST IIS. This registration is the basis for the calculation of the movements.

4.1 Controls and status displays

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

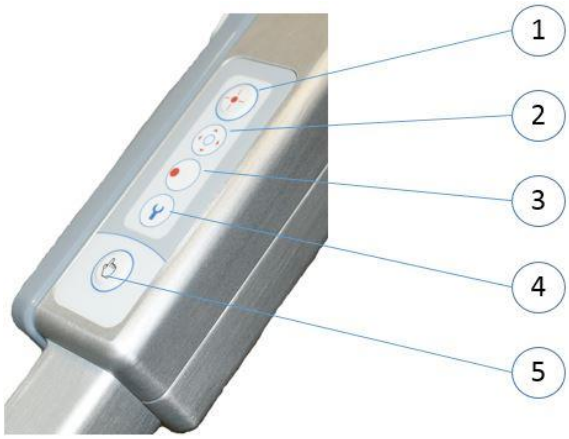


fig. 5: Control panel

Controls

Button	Symbol	Function
1		Sets the TROCAR POINT
5		Unlocks the SOLOASSIST IIS for the manual positioning

Table 11: Control elements

Status displays

Button	Symbol	Colour	Function
1		White	OFF: No JOYSTICK / REMOTE CONTROL / VOICE CONTROL connected PULSATING*: Device is ready, no TROCAR Point is set ON: Device is ready, TROCAR POINT is set
2		Yellow	ON: The connected JOYSTICK is defective FLASHING**: Life warning first stage, the JOYSTICK had more than 140 applications BLINKING***: Life warning second stage. The connected JOYSTICK had more than 145 applications. We recommend an immediate replacement.
3		Yellow	ON: One or more axes of the SOLOASSIST IIS 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 12: Status display

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

** FLASHING: approx. 0.3 s on and then 3 s off

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

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

	Should the yellow display 2 "Joystick“ flash, then the useful life of the JOYSTICK has almost been reached. Replace the JOYSTICK immediately. Once the display has started to blink, you can use the JOYSTICK no more than 5 x!

EMERGENCY STOP

The SOLOASSIST IIS features an EMERGENCY STOP button. Once pressed, the EMERGENCY STOP button will light red and be locked.

Picture	Description
	Press this button if you think that the device is performing a movement but you have not given a command to do so to JOYSTICK / REMOTE CONTROL / VOICE CONTROL.
	To cancel the EMERGENCY STOP, turn the switch clockwise.

Table 13: Emergency Stop

4.2 Manual positioning

The SOLOASSIST IIS 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
	To reposition the arm, hold the arm by the boom and press button (5) "Unlock". The arm will move freely. Once you have reached the desired setting, release the button (5). The arm is immediately locked again and the image section is stable.

Table 14: Manual positioning

4.3 Motor-driven adjustment

If the SOLOASSIST IIS is adjusted by motor, **the tip of the endoscope moves** on the surface of an imaginary sphere in space. Thus, **the image section can be changed intuitively during the operation**. The motorised adjustment is carried out with the aid of JOYSTICK / REMOTE CONTROL / VOICE CONTROL. The following is an example of motorised adjustment with the JOYSTICK. For details on motorised adjustment for your preferred input device, please refer to the relevant instructions for use.

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

Assignment of the control buttons on the JOYSTICK

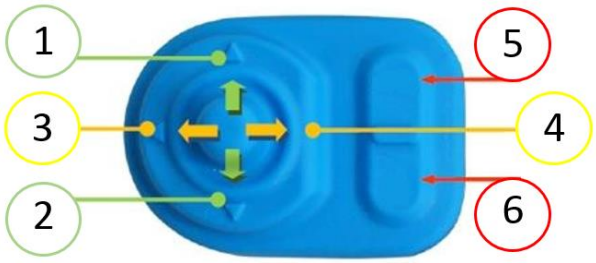


fig. 6: Buttons on the Joystick

Button	Description
1	Move image up
2	Move image down
3	Move image to the right
4	Move image to the left
5	Zoom out
6	Zoom in

Table 15: Movements

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

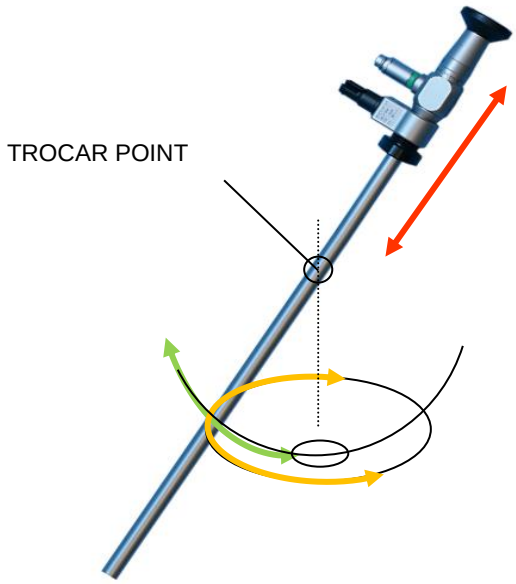


fig. 7: Endoscope movement

4.4 Operating procedure

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

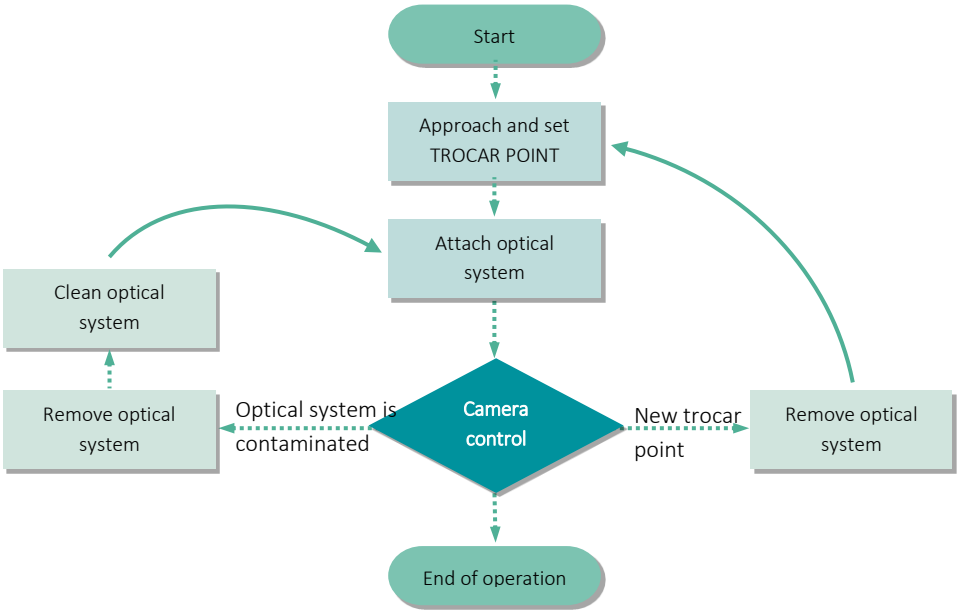


fig. 8: Workflow

⚠	Continuously monitor the patient and the SOLOASSIST IIS 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 SOLOASSIST IIS, 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 SOLOASSIST IIS can immediately be moved manually by pressing the "Unlock" key (5).

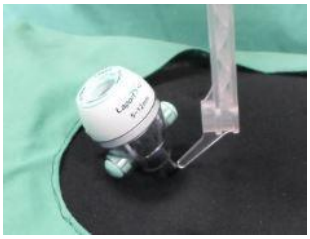
Step	Description
	Press the button (5) "Unlock" and move the STYLUS TIP of the UNIVERSAL JOINT to the entry point of the trocar into the abdominal wall.
	Press button (1) "TP" on the control panel of the SOLOASSIST IIS. You will receive visual feedback when you press the button. The "Ready" display (5) starts to blink green, the TROCAR POINT is then saved.

Table 16: Set TROCAR POINT

⚠	PLEASE NOTE! The endoscope may not be connected to the UNIVERSAL JOINT during the probing of the 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

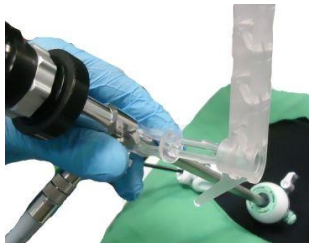
Step	Description
	Move the SOLOASSIST IIS in such a way that the UNIVERSAL JOINT comes close to the endoscope (optics) that has already been inserted into the trocar and roughly positioned.
	Attach the endoscope (optics) to the UNIVERSAL JOINT by attaching the CLAMP. The CLAMP engages with a "click".

Table 17: Attach endoscope

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 SOLOASSIST IIS makes the right/left, up/down movement in relation to the monitor image intuitive and it can be accurately zoomed.

Desired image change	Required action
Image to the right	Push JOYSTICK to the right
Image to the left	Push JOYSTICK to the left
Image up	Push JOYSTICK up
Image down	Push JOYSTICK down
Overview	Press "Zoom out“ button on the JOYSTICK
Detailed view	Press "Zoom in“ button on the JOYSTICK

Table 18: Image adjustment

	It is also possible to move the image diagonally, for example, to the top right. Press the JOYSTICK also diagonally into the desired direction.

4.4.4 Cleaning the endoscope (optical system)

Press the two legs of the CLAMP together and pull the CLAMP out of the UNIVERSAL JOINT.

After cleaning, you can attach the endoscope (optics) again. The CLAMP automatically locks into the UNIVERSAL JOINT.

The viewing angle set before cleaning is available again after hanging in.

fig. 9: Endoscope cleaning

4.4.5 Setting a new TROCAR POINT

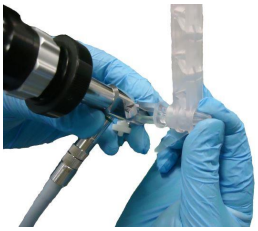
If applicable, uncouple a connected endoscope.

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.

⚠	PLEASE NOTE! The endoscope may not be connected to the UNIVERSAL JOINT during the probing of the TROCAR POINT.

4.4.6 Ending the application

Step	Description
	Remove the endoscope (optics) from the UNIVERSAL JOINT by pressing the two legs on the CLAMP.
	Loosen the KNURLED NUT and remove the CLAMP from the endoscope. Dispose of the used CLAMPS (Ø10, Ø5)
	Remove the UNIVERSAL JOINT from the arm by pulling down the side release sliders. Dispose of the used UNIVERSAL JOINT.
	Dispose of the used STERILE COVER of the SOLOASSIST IIS. Move the SOLOASSIST IIS to an upright position for subsequent storage on the TROLLEY.
	Disconnect all cable connections and unplug the POWER SUPPLY.

Step	Description
	The SOLOASSIST IIS can be removed from the operating table and stored on the TROLLEY.

Table 19: Ending the application

4.5 Wipe disinfection

The SOLOASSIST IIS 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 20: Disinfecting agents

	You can also disinfect the input devices REMOTE CONTROL and VOICE CONTROL with the disinfectants mentioned above.
	Caution! The JOYSTICK input device and the components of the PRODUCT GROUP JOYSTICK must be cleaned, disinfected and sterilised before each use! Therefore, follow the instructions in the separetely available reprocessing instructions „Processing instructions JOYSTICK-IIS – EN 1828-240238“ without exception!

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 SOLOASSIST IIS, 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:

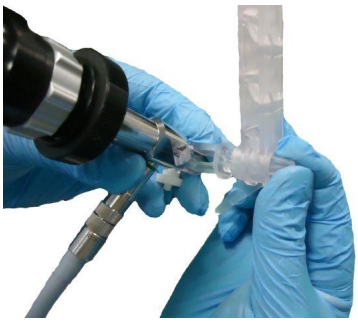
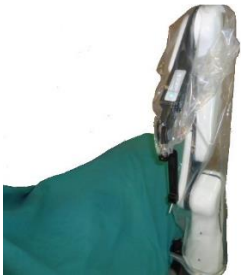
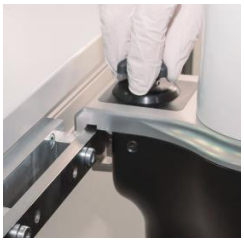
Step	Description
	Remove the endoscope (optics) from the UNIVERSAL JOINT by pressing the two legs on the CLAMP.
	Move the SOLOASSIST IIS to an upright position and turn it to the side.
 	If you do not yet have sufficient access to the surgical site, remove the arm completely from the operating table. To do this, open the operating table attachment and remove the device from the operating table rail.

Table 21: Intraoperative complications

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 SOLOASSIST IIS 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 may arise if an unintentional movement is performed. Unintentional means that no command was given by JOYSTICK / REMOTE CONTROL / VOICE CONTROL and the appliance moves anyway. In this case, press the red EMERGENCY STOP switch immediately. 
⚠	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 SOLOASSIST IIS does not behave as expected, the following hints should enable you to solve simple problems yourself.

	Never open the SOLOASSIST IIS 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 indicator "JOYSTICK" on SOLOASSIST IIS lights up	The JOYSTICK is defective. ➔ Replace the JOYSTICK with a new one.
Status display "JOYSTICK“ flashes	The JOYSTICK has been used more than 140x and is near the end of its useful life. The Joystick can be used no more than 150x and will then automatically be deactivated. ➔ Replace the JOYSTICK.
Status display "JOYSTICK“ blinks	The JOYSTICK has been used more than 145x and is near the end of its useful life. The Joystick can be used no more than 150x and will then automatically be deactivated. ➔ Replace the JOYSTICK.
Emergency stop button on SOLOASSIST IIS lights up red	Check whether the emergency stop switch on the SOLOASSIST IIS is pressed and unlock it by turning it to the right (clockwise) if necessary.
The "Service" status indicator on the SOLOASSIST IIS lights up.	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 may not be set correctly. ➔ Reset the TROCAR POINT. (see chapter 4.4.1)

Table 22: Troubleshooting

7 Service

The SOLOASSIST IIS 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.

– SOLOASSIST IIS and accessories for external damage.

	Never use the SOLOASSIST IIS 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 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.

7.4 Disposal / Recycling

The manufacturer confirms that the product

SOLOASSIST IIS

complies with the following guidelines:

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

Further information can be found in document no. 1828-190051 (Recycling pass SOLOASSIST IIS).

	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.

8 EMC

	Portable and mobile HF communication devices, such as mobile phones, can affect MEDICAL ELECTRICAL DEVICES. Do not operate such devices in the immediate vicinity of the SOLOASSIST IIS.
	MEDICAL ELECTRICAL DEVICES are subject to special EMC precautions. The SOLOASSIST IIS may only be installed and commissioned in accordance with the EMC instructions contained in this manual.
	The SOLOASSIST IIS 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 SOLOASSIST IIS 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 23: 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 where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter

Test	Limit	Electromagnetic environment - guidance
		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 24: 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 SOLOASSIST IIS, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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