INSTRUCTIONS FOR USE REMOTE CONTROL for SOLOASSIST

Status: 2025-04

2038-210029-04

1 Introduction

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

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 instructions for use to fully inform yourself about the correct operation and handling of the REMOTE CONTROL for SOLOASSIST.

⚠	The REMOTE CONTROL is designed exclusively for use with the SOLOASSIST camera guidance system. Do not use it with other devices.
⚠	Observe all safety instructions in this instructions for use as well as the instructions for use for the SOLOASSIST.
⚠	Never use the REMOTE CONTROL if you notice any damage. Call the sales partner responsible for you.
⚠	Only use original accessories. The use of accessories not approved by the manufacturer may endanger the patient or damage the unit.

⚠	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 REMOTE CONTROL is not suitable for machine / automated cleaning or disinfection processes!
⚠	Do not use the disposables if you notice any damage to the packaging or the disposables themselves!
⚠	All serious incidents related to the product must be reported to the manufacturer and the competent authority in the country concerned.
❗	Do not look directly into the laser beam and do not point the laser beam at other people!
❗	Avoid tripping hazards when connecting the cables.
❗	The national regulations are to be complied when the product or its components are disposed of or recycled.
❗	Make sure that contaminated disposable products are disposed separately.
❗	Operation with the REMOTE CONTROL is only available after a TROCAR POINT has been saved on the SOLOASSIST. See SOLOASSIST instructions for use.

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 REMOTE CONTROL is an optional input device for the SOLOASSIST, which is additionally equipped with a LASER POINTER. It enables an experienced surgeon to control the movement of the SOLOASSIST during an operation and at the same time to show the surgeon performing the operation anatomical structures on the screen with the aid of the LASER POINTER.

The REMOTE CONTROL can be used as the sole input device, or in parallel with the preferred input devices of the performing surgeon, such as JOYSTICK or VOICE CONTROL.

Covered with the COVER REMOTE, the REMOTE CONTROL can be used in a sterile environment.

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

The REMOTE CONTROL is an accessory for the SOLOASSIST. Use the REMOTE CONTROL only in conjunction with SOLOASSIST.

Environment:

Operating theatre. The REMOTE CONTROL for SOLOASSIST is used in the sterile environment during an operation.

⚠	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 REMOTE CONTROL is not suitable for machine / automated cleaning or disinfection processes!

User Group:

A mandatory prerequisite for the use of the REMOTE CONTROL is the proper installation and handling of the unit as well as the observance of these instructions for use. In addition, the instructions for use of SOLOASSIST must be observed.

The REMOTE CONTROL is primarily operated by the experienced surgeon who guides the performing surgeon during an operation. Both surgeons must have sufficient experience in the use of minimally invasive surgical techniques and be instructed in the use of the REMOTE CONTROL. The operation may only be carried out by instructed personnel. The instruction must be documented accordingly.

Application:

•   Entering direction commands to control the SOLOASSIST

•   Use of the integrated LASER POINTER to illustrate anatomical structures on the screen

Contraindications:

The restrictions on the use of the SOLOASSIST apply.

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 assembly, 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 instructions for use.

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

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.

1.7 Receiving inspection

Please check the REMOTE CONTROL 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 sales partner 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 REMOTE CONTROL only after the manufacturer or the sales partner:

- 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 REMOTE CONTROL for SOLOASSIST based on this instructions for use.

🛈	Operate the REMOTE CONTROL 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

Position	Description
1	LASER BUTTON
2	LASER POINTER
3	Button „Move image up"
4	Button „Move image down"
5	Button „Move image to the right"
6	Button „Move image to the left"
7	Button „Zoom in"
8	Button „Zoom out"
9	Plug for connection to the SOLOASSIST

Table 1: Overview

LASER POINTER:

The LASER POINTER has a Class 1 laser module, which means that there is no danger to the viewing eye from reflections of the laser beam, nor from looking directly into the laser beam.

Nevertheless, do not look directly into the laser beam and do not point the laser beam at other people.
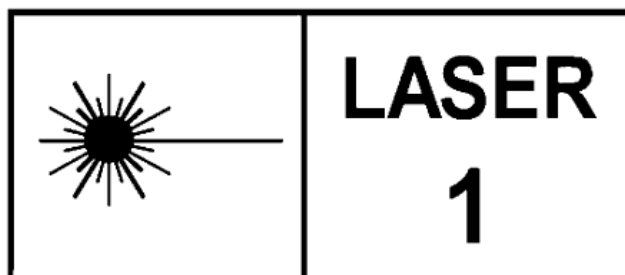

fig. 2: LASER POINTER

	Do not look directly into the laser beam and do not point the laser beam at other people!

2.2 System components

Component	Picture	Description
REMOTE CONTROL (multiple patient multiple use)		The SOLOASSIST can be moved by motor via the REMOTE CONTROL. In addition, the integrated LASER POINTER can be used to point out anatomical structures on the screen.
COVER REMOTE (single use)		For the sterile disposable cover of the REMOTE CONTROL.
Y-LINE (multiple patient multiple use)		The Y-LINE allows the simultaneous connection of the REMOTE CONTROL and a JOYSTICK, or a VOICE CONTROL to the SOLOASSIST.

Table 2: System components

Overview accessories and spare parts:

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

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

Article number	Article name	Name
212510	REMOTE CONTROL	REMOTE CONTROL
242687	COVER REMOTE PU/ 10 ea.	COVER REMOTE PU with 10 pieces REF E6783
171895	Y-LINE	Y-LINE
2038-210029	Manual REMOTE CONTROL – EN	-
1206-140108	Manual SOLOASSIST II – EN	-
1828-190039	Manual SOLOASSIST IIS – EN	-

Table 3: Article numbers

⚠	Only use original accessories. The use of accessories not approved by the manufacturer may endanger the patient or damage the unit.

2.3 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

2.4 Storage and transport

The REMOTE CONTROL must always be transported in a suitable packaging. Any position is possible during transportation.

| ❗	Operate the REMOTE CONTROL only when it has reached room temperature again after a previous storage at high or low temperatures.

2.5 Symbols used on the name plates / labels

Symbol	Description
📖ℹ	Observe the instructions for use
(icon)	Follow the instructions for use
LASER 1	Laser class 1 according to DIN EN 60825-1:2022-07
IP4X	Protection class IP4X according to DIN EN 60529
CE	Device conforms to the regulation MDR - 2017/745 (Medical Device Regulation)
(icon)	Date of manufacture
(icon)	Manufacturer
SN	Serial number
REF	Article number
Rx only	Sale only on instruction of a physician (US federal law)
CH|REP	Authorised representative in Switzerland
MD	Medical Device
(icon)	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.

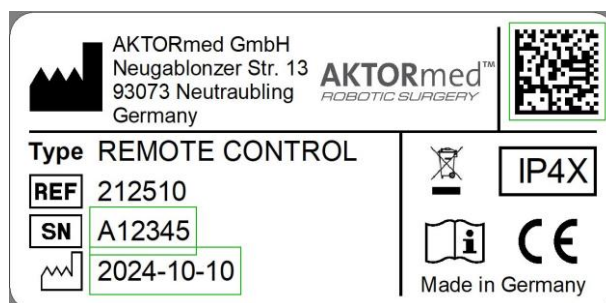*Table 4: Symbols on nameplate and label*

2.6 Name plate

fig. 3: Nameplate

2.7 Symbols on COVER REMOTE

Symbol	Description
REF	Reference number
LOT	Lot number
(hourglass symbol)	Can be used until
STERILE EO	Sterilised with ethylene oxide
EC REP	Authorised representative in the European Community
CH REP	Authorised representative in Switzerland
(importer symbol)	Importer
(damaged packaging symbol)	Do not use if packaging is damaged
(do not re-sterilise symbol)	Do not re-sterilise
(do not reuse symbol)	Do not reuse
(latex free symbol)	Free of latex
(manufacturer symbol)	Manufacturer

Table 5: Symbols on COVER REMOTE

2.8 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

⚠	Do not use the disposables if you notice any damage to the packaging or the disposables themselves!
⚠	Do not use a COVER REMOTE whose expiry date has passed!

Step 1: Obtain sterile

Step	Description
	Remove the COVER REMOTE from the packaging.
	Open the folded COVER REMOTE in the centre (adhesive marking with arrow).
	Have the REMOTE CONTROL inserted into the COVER REMOTE prepared in this way.
	Hold the REMOTE CONTROL in the COVER REMOTE and pull the excess telescopic fold over the cable.
	Fix the provided adhesive tape of the COVER REMOTE to the cable outlet of the REMOTE CONTROL so that the foil is tightly attached to the LASER POINTER.

Table 6: Obtain REMOTE CONTROL sterile

Step 2: Establish the electrical connection

Step	Description
	If the REMOTE CONTROL has been designated as the sole input device, connect the plug of the REMOTE CONTROL directly to the "Control" socket of the SOLOASSIST.
	If another input device such as JOYSTICK or VOICE CONTROL is to be used, first plug the Y-LINE into the "Control" socket and then connect the two input devices to the Y-LINE.
	Please remember that each input device can only work if the TROCAR POINT has been saved for that intervention. See SOLOASSIST instructions for use.

Table 7: Connecting REMOTE CONTROL electrically

4 Operation

4.1 LASER POINTER

The LASER POINTER is activated by pressing the LASER BUTTON on the REMOTE CONTROL. You can use the green dot on the screen to draw attention to special features and details.

❗	Do not look directly into the laser beam and do not point the laser beam at other people!

Position	Description
1	LASER BUTTON to activate the laser
2	LASER POINTER (visible laser beam)

fig. 4: LASER BUTTON and LASER POINTER of the REMOTE CONTROL

fig. 5: Application LASER POINTER

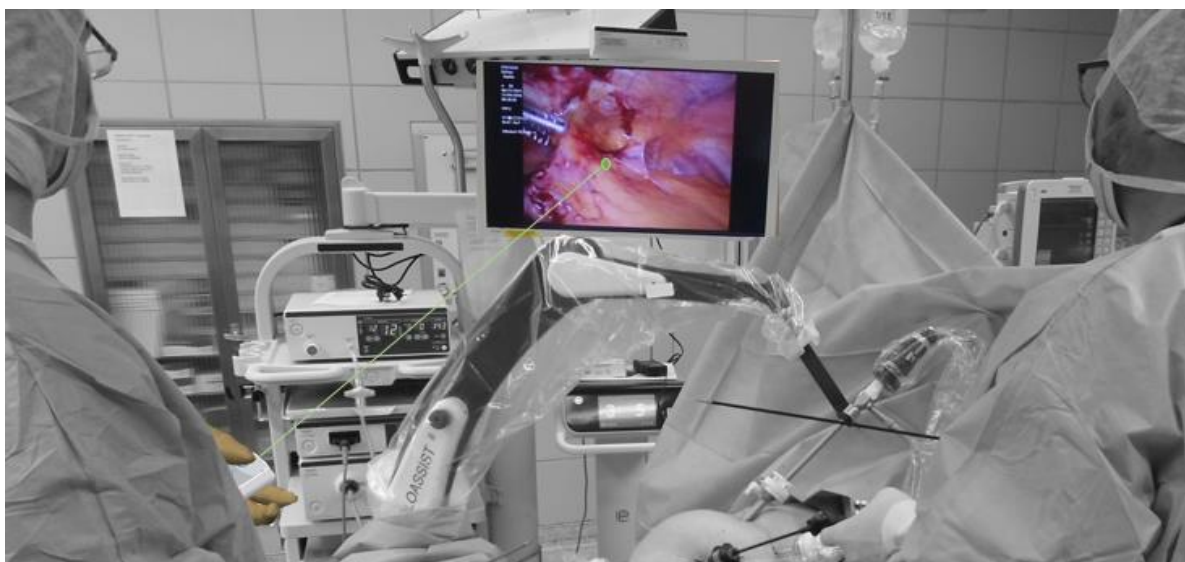|	
❗	The laser beam may be impaired if the foil is loose. Therefore, make sure that the foil of the COVER REMOTE is tightly attached to the LASER POINTER.
❗	The foil of the COVER REMOTE has been carefully selected with regard to light transmission and matched to the class 1 laser module. Therefore, only use the original COVER REMOTE for the REMOTE CONTROL.

4.2 Motor-driven adjustment

When the SOLOASSIST is adjusted by motor using the REMOTE CONTROL, **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.

Assignment of the control buttons on the REMOTE CONTROL

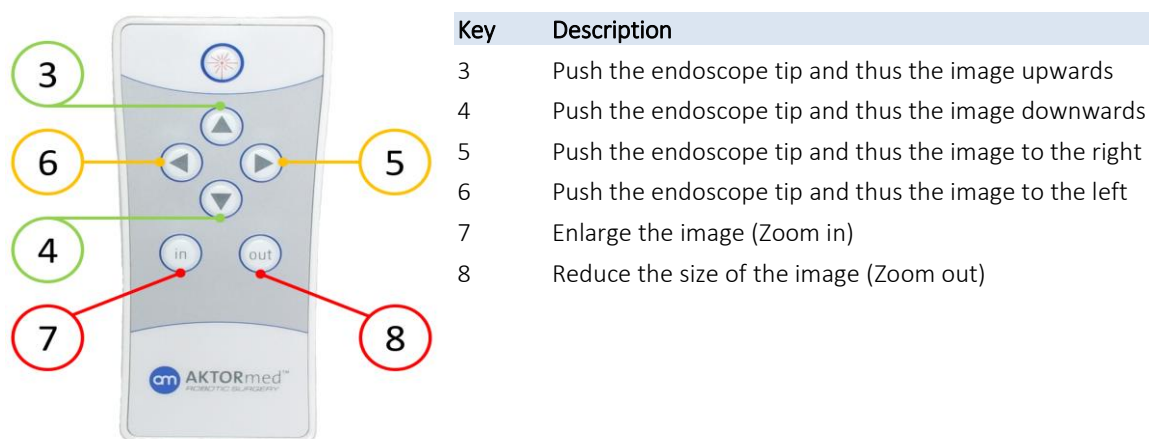| Key	Description
3	Push the endoscope tip and thus the image upwards
4	Push the endoscope tip and thus the image downwards
5	Push the endoscope tip and thus the image to the right
6	Push the endoscope tip and thus the image to the left
7	Enlarge the image (Zoom in)
8	Reduce the size of the image (Zoom out)

fig. 6: Direction keys on the REMOTE CONTROL

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
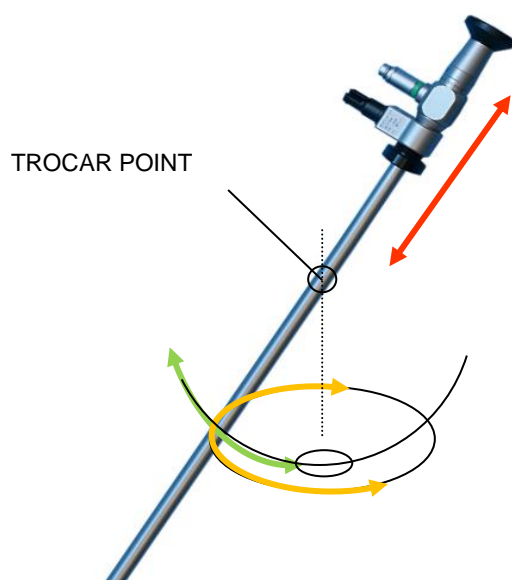
TROCAR POINT

fig. 7: Endoscope movement

❗	Operation with the REMOTE CONTROL is only available after a TROCAR POINT has been saved on the SOLOASSIST. See SOLOASSIST instructions for use.

The endoscope position can be changed at any time by manual operation on the SOLOASSIST. To do this, press the green backlit button on the control panel of the SOLOASSIST.

If the REMOTE CONTROL is used in parallel with other input devices such as JOYSTICK or VOICE CONTROL, only the command of the currently actively controlling input device is executed. A control command from another input device received during movement stops the endoscope movement immediately.

5 Ending the application

5.1 Disconnect and remove the COVER REMOTE

Step	Description
	Disconnect the plug of the REMOTE CONTROL from the SOLOASSIST.
	Detach / remove the adhesive tape from the COVER REMOTE.
	Remove the COVER REMOTE from the REMOTE CONTROL and dispose the COVER REMOTE.

Table 8: Disconnect REMOTE CONTROL and remove the COVER REMOTE

5.2   Wipe disinfection

The REMOTE CONTROL can be cleaned by wiping with a soft damp, non-wet cloth.

The REMOTE CONTROL has been successfully proved due to surface resistance against disinfecting agents:

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 9: Disinfecting agents

You can proceed the wipe disinfection by using the named disinfectants or using disinfectants with similar disinfecting agents.

Apply the disinfectants by using a soft cloth and consider the instructions of the manufacturer of the disinfectant concerning the application time.

5.3   Storage of REMOTE CONTROL

Step	Description
	To store the REMOTE CONTROL safely, place it in the pocket provided (included in the delivery) on the TROLLEY.

Table 10: Storing the REMOTE CONTROL

6   Service

The REMOTE CONTROL is basically maintenance-free. However, regular checks are essential to ensure safe operation over the lifetime of the unit.

Perform the following checks before each use of the REMOTE CONTROL:

–   Check the REMOTE CONTROL cable for damage.

–   Check REMOTE CONTROL for external damage.

⚠	Never use the REMOTE CONTROL if you notice any damage. Call the sales partner responsible for you.

7   Disposal / Recycling

The manufacturer confirms that the product

REMOTE CONTROL

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 requirements of the member states of the EEA

For more information, see document no. 2038-210036 (Recycling Pass REMOTE CONTROL).

❗	The national regulations are to be complied when the product or its components are disposed of or recycled.
❗	Make sure that contaminated disposable products are disposed separately.

8   EMC

Observe the warnings and notes on the electromagnetic compatibility (EMC) of the SOLOASSIST. You will find this information in the last chapter of the corresponding instructions for use.

C E

AKTORmed GmbH
Neugablonzer Str. 13
D-93073 Neutraubling

Internet: www.aktormed.com

AKTORmed and SOLOASSIST are registered trademarks of AKTORmed GmbH