

INSTRUCTIONS FOR USE

ARTip solo voice for ARTip solo

Status: 2025-04

2039-210047-03

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1 Introduction

Please read this instruction manual to learn about the correct use of the ARTip solo VOICE before using it for the first time.

Keep the instruction manual close to the site of operation and ensure that the user can access it at all times.

| | |
|---|--|
|  | Never use the ARTip solo VOICE 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 ARTip solo VOICE for ARTip solo. In conjunction with the instructions by our trained specialists, it allows you to safely handle the ARTip solo VOICE for ARTip solo.


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 ARTip solo VOICE for ARTip solo.

| | |
|---|--|
|  | The ARTip solo VOICE is designed exclusively for use with the ARTip solo camera guidance system. Do not use it with other devices. |
|  | Observe all safety instructions in this operating manual as well as the operating manual for the ARTip solo. |
|  | The device is not intended for the operation in explosive areas. Ensure a sufficient distance to highly flammable gases (e.g. O ₂ , anaesthetic gases). |
|  | Never open the device. Risk of an electric shock! |

| | |
|---|--|
|  | The ARTip solo VOICE is a device of protection class I. Only connect the ARTip solo VOICE to a power outlet with a protective earth conductor. |
|  | Unplug this unit from the power supply to disconnect it completely from the mains. Make sure that the mains connection is accessible at all times. The mains plug is considered to be the disconnecting device from the mains. |
|  | Devices that are connected to the analogue and digital interfaces of the ARTip solo VOICE for ARTip solo 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 ARTip solo VOICE, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. |
|  | 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. |
|  | The ARTip solo VOICE 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 ARTip solo VOICE should be monitored in order to check the proper operation with this arrangement. |
|  | Only use the original HEADSET that was delivered with the ARTip solo VOICE or that you have obtained as spare part from AKTORMed or an authorised dealer. |
|  | All serious incidents related to the product must be reported to the manufacturer and the competent authority in the country concerned. |
|  | Avoid tripping hazards when connecting the cables. |
|  | Modifications to the device are not permitted! Warranty seals are attached to the housing of the ARTip solo VOICE, which indicate unauthorised opening of the ARTip solo VOICE. If you notice a damaged warranty seal, check the functionality of the ARTip solo VOICE before using it. If you still have doubts about the proper condition, please contact the Karl Storz Service or the respective service partner. |
|  | MEDICAL ELECTRICAL DEVICES are subject to special EMC precautions. The ARTip solo VOICE may only be installed and commissioned in accordance with the EMC instructions contained in this manual. |
|  | 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 ARTip solo VOICE. |
|  | Operate the ARTip solo VOICE only when it has reached room temperature again after a previous storage at high or low temperatures. |

| | |
|---|---|
|  | If there is a power failure or if the unit is accidentally switched off during use, all stored values are lost and must be reset. |
|  | Wait a few seconds after switching off the device before restarting the ARTip solo VOICE. |
|  | Do not press the power switch again while the ARTip solo VOICE is still shutting down. |
|  | The national regulations are to be complied when the product or its components are disposed of or recycled. |

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 ARTip solo VOICE is an optional input device for the ARTip solo. It enables the surgeon to control the ARTip solo and thus the position of the endoscope with simple commands via speech. There is no need for user training or language training.

In addition, up to three endoscope positions can be stored and recalled, and the speed of movement of the ARTip solo can be set in three stages.

The ARTip solo VOICE can either be used as a stand-alone input device or in parallel to a connected joystick.

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 ARTip solo VOICE is an accessory for the ARTip solo. Do not use the ARTip solo VOICE with other devices.

Essential Performance:

Recording and processing voice commands

The system records spoken commands from the user via a HEADSET and uses them to form driving commands for the ARTip solo.

Saving positions

The system can store camera positions and allows the user to recall them.

Environment:

Operating room. Ideally, the ARTip solo VOICE for ARTip solo is placed in the endoscopy tower.

During HF Surgery, the ARTip solo and ARTip solo VOICE is only compatible with following HF SURGICAL EQUIPMENT:

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

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

The ARTip solo and the ARTip solo VOICE cannot be used for argon plasma coagulation.



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

User Group:

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

The ARTip solo VOICE 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 ARTip solo VOICE.

Application:

Input of voice commands for controlling the ARTip solo.

Contraindications:

The restrictions on the use of the ARTip solo 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 instruction manual.

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 ARTip solo VOICE 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 ARTip solo VOICE 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 ARTip solo VOICE for ARTip solo based on this instruction manual.






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

Location of the Bluetooth Dongle:

The Bluetooth dongle for the HEADSET is located under the protective cap on the back of the ARTip solo VOICE. The protective cap ensures a secure connection and prevents the Bluetooth dongle from being unplugged and replaced with another USB device. Further information can be found in document no. 1515-240319 (Cybersecurity label – Soloassist).



fig. 1: Bluetooth dongle for the HEADSET

| | |
|---|---|
|  | <p>Modifications to the device are not permitted!</p> <p>Warranty seals are attached to the housing of the ARTip solo VOICE, which indicate unauthorised opening of the ARTip solo VOICE. If you notice a damaged warranty seal, check the functionality of the ARTip solo VOICE before using it. If you still have doubts about the proper condition, please contact the Karl Storz Service or the respective service partner.</p> |
|  | <p>The supplied dongle has already been paired with the HEADSET. Make sure not to swap the HEADSET with another ARTip solo VOICE.</p> |
|  | <p>Only use the original HEADSET that was delivered with the ARTip solo VOICE or that you have obtained as spare part from AKTORMed or an authorised dealer.</p> |

2 System Description

2.1 Overview



fig. 2: Overview

| Number | Description |
|--------|-----------------------------------|
| 1 | Connection ARTip solo |
| 2 | Display „Ready“ |
| 3 | Display „Connected“ |
| 4 | Display „HEADSET“ |
| 5 | Display „Voice input active“ |
| 6 | Display „Speed“ |
| 7 | On/off switch |
| 8 | Connection supply cable and fuses |
| 9 | Bluetooth Dongle for the HEADSET |

Table 1: Overview

2.2 System components





| Component | Picture | Description |
|--|--|--|
| ARTip solo VOICE (multiple patient multiple use) |  A rectangular, light blue device with a small screen and buttons. The brand name 'STORZ' is visible on the left, and 'ARTip solo voice' is on the right. | The ARTip solo VOICE evaluates the spoken commands of the user and transmits them to the ARTip solo. Ideally, the ARTip solo VOICE is placed in the endoscopy tower. |
| HEADSET with charging station (multiple patient multiple use) |  A black headset with a microphone, resting on a black charging station. | The HEADSET is worn by the user and records the voice commands. The HEADSET can be stored in the charging station and charged for the next use. The charging station can be set up independently from the ARTip solo VOICE. |
| CONNECTION CABLE (multiple patient multiple use) |  A coiled black cable with two connectors at each end. | The CONNECTION CABLE connects the ARTip solo with the ARTip solo VOICE. The total length is 3500 mm. |
| Y-LINE (multiple patient multiple use) |  A black cable that splits into two branches, each ending in a connector. | The Y-LINE allows simultaneous connection of the ARTip solo VOICE and a JOYSTICK to the ARTip solo. The total length is 300 mm. |

Table 2: System components

Overview accessories and spare parts:

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

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

| Article number | Article name | Description |
|----------------|------------------------------|---------------------------------|
| 202445 | ARTip solo voice | ARTip solo VOICE for ARTip solo |
| 171882 | HEADSET | HEADSET with charging station |
| 172039 | CHARGER HEADSET | CHARGER HEADSET |
| 171896 | CONNECTION CABLE | CONNECTION CABLE |
| 171895 | Y-LINE | Y-LINE |
| 2039-210047 | Manual ARTip solo voice – EN | - |
| 2039-210046 | Manual ARTip solo – EN | - |

Table 3: Article numbers

2.3 Mechanical data

ARTip solo VOICE





| | |
|------------------------|-------------------|
| Weight | 2,8 kg |
| Dimensions (W x H x D) | 350 x 80 x 250 mm |
| Type of enclosure | IP20 |

HEADSET

| | |
|-----------------------|---|
| Type | Sennheiser MB Pro 1 UC ML, including BTD 800 USB ML |
| Mode of wear | Single-sided head band |
| Technology | Bluetooth® Version 4.0 supported profiles: HSP 1.2 + HFP 1.6 + A2DP 1.2 |
| Speaking time | Up to 15 h |
| Standby time | Up to 450 h |
| Charging time | 2 h 30 min |
| Charging time for 50% | 40 min |
| Reach | Up to 25 m (depending on environment) |
| Weight | 63 g |
| Type of modulation | GFSK |
| Bandwidth | 1 MHz |


2.4 Electrical data

| | |
|------------------------|----------------------|
| Input voltage | 100 - 240V~; 47-63Hz |
| Max. power consumption | 60W |
| Safety Class | I |
| Mode | continuous |
| Mains fuses | 2x T1A – 5x20 mm |

| | |
|---|---|
|  | <p>Devices that are connected to the analogue and digital interfaces of the ARTip solo VOICE for ARTip solo must comply with the standards for electromedical devices.</p> <p>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!</p> |
|  | <p>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.</p> |
|  | <p>Unplug this unit from the power supply to disconnect it completely from the mains. Make sure that the mains connection is accessible at all times. The mains plug is considered to be the disconnecting device from the mains.</p> |
|  | <p>The ARTip solo VOICE is a device of protection class I. Only connect the ARTip solo VOICE to a power outlet with a protective earth conductor.</p> |

HEADSET

| | |
|--------------------------------|--|
| Transmission frequency HEADSET | 2.402 MHz to 2.480 MHz |
| Output power HEADSET | 9 dBm / 7,90 mW |
| Output power Dongle | 8 dBm / 6,30 mW |
| Frequency range Dongle | 2.402 MHz bis 2.480 MHz |
| Microphone type | Ultra noise-cancelling |
| Frequency range | 150 Hz to 6.800 Hz |
| Loudspeaker type | Dynamic, neodymium magnet |
| Frequency range | 150 to 15.000 Hz |
| Sound pressure | Max. 118dB (SPL) limited by ActiveGuard (® Sennheiser) |

| | |
|---|--|
|  | <p>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 ARTip solo VOICE.</p> |
|---|--|

2.5 Environmental conditions

for transport and storage


| | |
|-----------------------|----------------------------|
| Temperature | -20°C to +60°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 | 20% to 85%, non-condensing |
| Air pressure | 700 hPa to 1060 hPa |

2.6 Storage and transport

The ARTip solo VOICE must always be transported in a suitable packaging. Any position is possible during transportation.

| | |
|---|--|
|  | Operate the ARTip solo VOICE only when it has reached room temperature again after a previous storage at high or low temperatures. |
|---|--|

2.7 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 |
|  | 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

2.8 Application parts

In terms of the 60601 standard, the ARTip solo VOICE has no application parts that have contact with the patient when used as intended.

2.9 Name plate

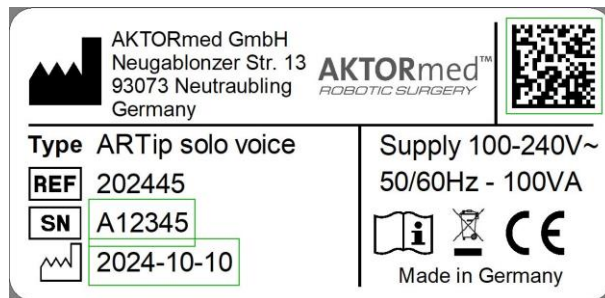


fig. 3: Name plate

2.10 Identification according to MDR (Medical Device Regulation)

The ARTip solo VOICE for ARTip solo is as an accessory of a class I medical device also a class I medical device.

2.11 Contact

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

Karl Storz SE & Co. KG
Dr.-Karl-Storz-Straße 34
78532 Tuttlingen
GERMANY



Web: www.karlstorz.com eMail: info@karlstorz.com
Phone: +49 7461 708-0 Fax: +49 7461 708-105

3 Setup / Commissioning

The ARTip solo VOICE for ARTip solo is ideally located in the equipment tower.



Step 1: Establish the electrical connection

Connect the supply line to the ARTip solo VOICE and then plug the supply line into a suitable power outlet.
Connect the charging station of the HEADSET to a suitable power outlet.

| | |
|---|--|
|  | Unplug this unit from the power supply to disconnect it completely from the mains. Make sure that the mains connection is accessible at all times. The mains plug is considered to be the disconnecting device from the mains. |
|  | Avoid tripping hazards when connecting the cables. |

Step 2: Connect HEADSET and wear

The HEADSET communicates with the ARTip solo VOICE via a Bluetooth connection. For this purpose a Bluetooth dongle is plugged into the back of the ARTip solo VOICE. The connection to the HEADSET is then automatically established when the ARTip solo VOICE is started.

| | |
|---|---|
|  | Never remove the Bluetooth dongle from the ARTip solo VOICE. |
|  | Only use the original HEADSET that was delivered with the ARTip solo VOICE or that you have obtained as spare part from AKTORMed or an authorised dealer. |

The HEADSET can be worn with the speaker on the left or right ear. To do this, swivel the microphone boom in the appropriate direction. The length of the retaining strap can be adjusted as required.

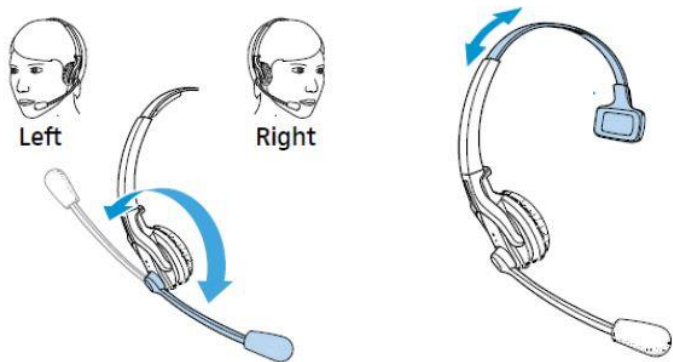


fig. 4: Customise HEADSET

Adjust the microphone boom so that the microphone is about 2-3 cm from the corner of your mouth.

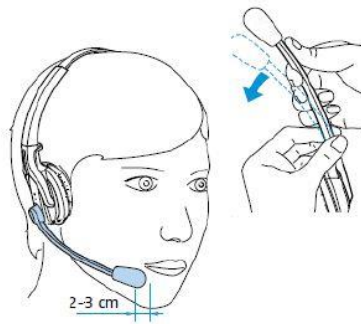


fig. 5: Adjust microphone boom

For details on how to use the HEADSET, please refer to the supplied user manual of the HEADSET.

Step 3: Charge HEADSET

Place the HEADSET in the receptacle of the charging station for safe storage and charging.

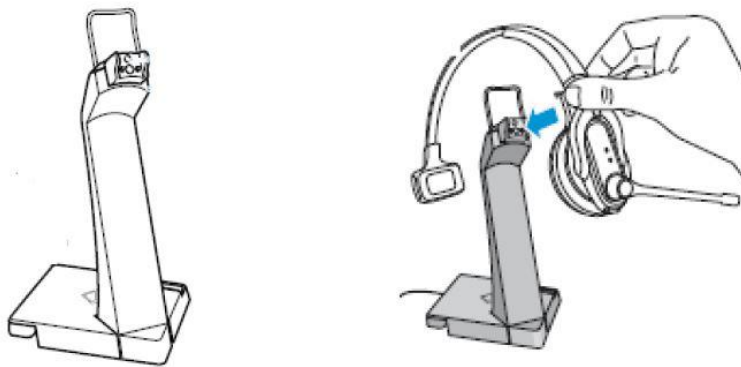


fig. 6: Charging HEADSET

Step 4: Connecting ARTip solo to ARTip solo VOICE

| Picture | Description |
|--|---|
|  | Connect the CONNECTION CABLE to the CONTROL jack on the ARTip solo.  |
|  | Connect the other end of the CONNECTION CABLE to the ARTip solo VOICE jack. |

Table 5: Connecting the ARTip solo to the ARTip solo VOICE

Step 5 (optional): Connecting an additional joystick

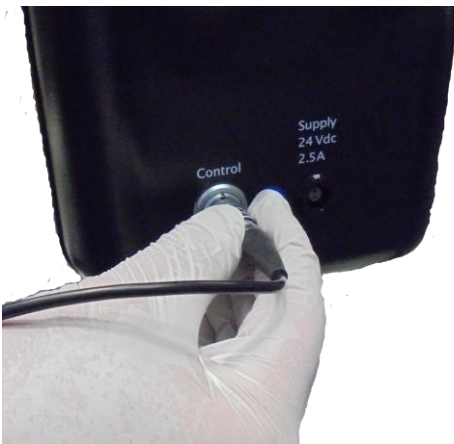


| Picture | Description |
|---|--|
|  | Instead of the CONNECTION CABLE, connect the Y-LINE to the CONTROL jack of the ARTip solo.  |

Table 6: Option additional joystick

Connect the CONNECTION CABLE to a socket on the Y-LINE.
Connect the JOYSTICK to the other Y-LINE socket.

The use of the JOYSTICK is generally described in the ARTip solo instruction manual, and in particular in the JOYSTICK-IIA instruction manual.

| | |
|---|--|
|  | If ARTip solo VOICE and JOYSTICK are used simultaneously, movement will be stopped in case of conflicting inputs (e.g. left with the JOYSTICK, right with the ARTip solo VOICE). |
|---|--|

4 Operation

ARTip solo VOICE for ARTip solo is controlled by voice input at the HEADSET. The HEADSET is wireless and is worn by the surgeon.

After the ARTip solo VOICE has been connected to the mains, it is in standby mode. The power switch is orange.



| Display | Symbol | Colour | Meaning |
|---------|---|--------|--|
| Standby |  | Orange | The ARTip solo VOICE is powered but not started. |
| ON |  | Green | The ARTip solo VOICE is switched on. |

Table 7: Switch on ARTip solo VOICE



Switch ON

Briefly press the power switch to start the ARTip solo VOICE. The power switch will light green.

The start process of the ARTip solo VOICE usually takes about one (1) minute. During this time, only the green power switch lights up. After the successful start of the ARTip solo VOICE, further operating elements light up.

Switch OFF

Briefly press the power button to turn off the ARTip solo VOICE. The power switch will remain green for a few seconds. After successful completion of the software, the ARTip solo VOICE is in standby mode again. The power switch will light orange.

| | |
|---|---|
|  | Do not press the power switch again while the ARTip solo VOICE is still shutting down. |
|  | Wait a few seconds after switching off the device before restarting the ARTip solo VOICE. |

Status displays








| Display | Symbol | Colour | Meaning |
|-------------|---|--------|--|
| Speed |  | Green | Displays the chosen speed in terms of three levels. |
| Ready |  | Green | Is lit once ARTip solo VOICE has been started successfully. |
| Connected |  | Green | Is lit once ARTip solo VOICE has been connected to a ARTip solo successfully. |
| HEADSET |  | Green | Is lit if the dongle of the HEADSET has been recognised |
| Voice input |  | Green | The voice input field lights up green when the keyword "SOLO" is recognized. The system is then ready to execute voice commands. This field flashes green during a software update. |

Table 8: Status indications

| | |
|---|--|
|  | A green "HEADSET" indicator does not automatically mean that a connection to the HEADSET exists. |
|---|--|

4.1 Voice Commands

The Voice Command Set allows precise control over the positioning of the endoscope during surgery. Each command sequence starts with the keyword "SOLO". Once this keyword has been recognized, commands are accepted within 10 seconds. During this period, the "Voice input" indicator lights green.

| Display status | Description |
|---|---|
|  | The ARTip solo VOICE waits for the keyword "SOLO" and is in standby mode. |


| | |
|---|---|
|  | <p>The keyword has been recognized, the ARTip solo VOICE is now ready to accept commands, which are then executed by the ARTip solo.</p> <p>10 seconds after the last detected command, the ARTip solo VOICE returns to standby mode.</p> |
|---|---|

Table 9: Activate ARTip solo VOICE

If no command is detected within this period, the ARTip solo VOICE will return to standby mode and wait for the keyword "SOLO" to be renamed again. If a correct command is detected, the period restarts, which means that successive commands can be given without renaming the keyword "SOLO". All command words are expected in English.

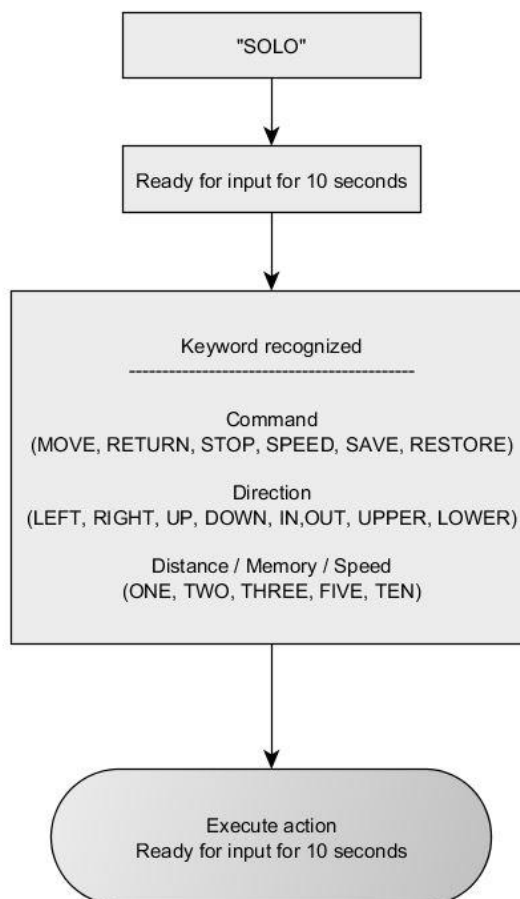


fig. 7: Flowchart voice input

4.1.1 Motion Commands

A motion command consists of direction (LEFT, RIGHT, UP, DOWN) or zoom (IN, OUT), and distance (ONE, TWO, THREE, FIVE, TEN). The direction can be modified to 45° with the command words UPPER and LOWER. The keyword MOVE repeats the last movement.

All directions refer to the monitor image. Pay attention to the anatomically correct adjustment of the image horizon.

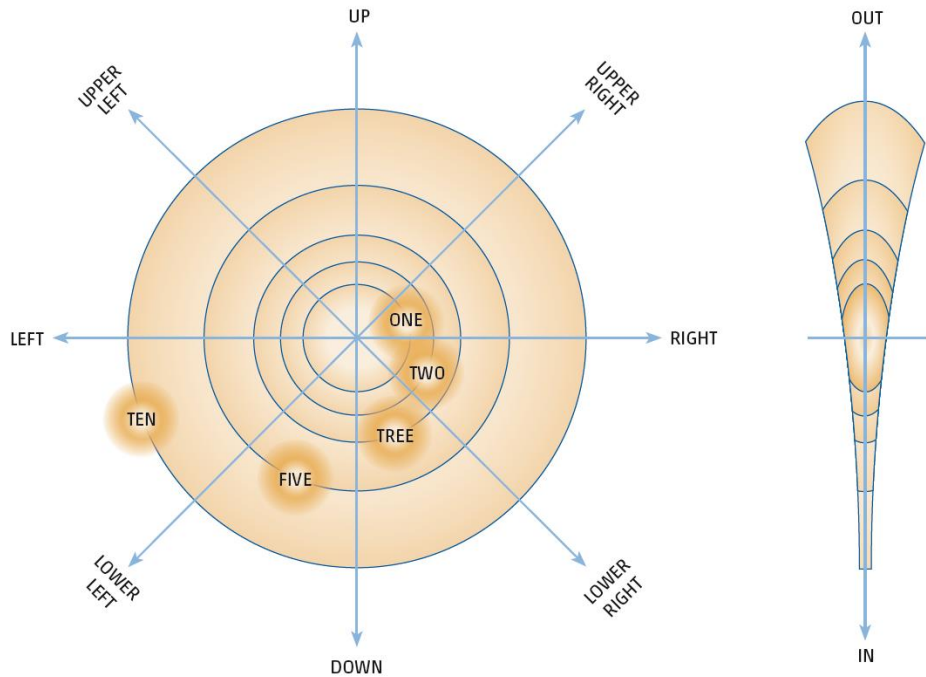


fig. 8: Motion Commands

| Desired image change | Requered command |
|----------------------------------|------------------|
| Image to the right | ONE RIGHT |
| Image to the left | ONE LEFT |
| Image up | ONE UP |
| Image down | ONE DOWN |
| Image 45° upwards to the right | ONE UPPER RIGHT |
| Image 45° upwards to the left | ONE UPPER LEFT |
| Image 45° downwards to the right | ONE LOWER RIGHT |
| Image 45° downwards to the left | ONE LOWER LEFT |
| Overview | ONE OUT |
| Detail view | ONE IN |
| Repeat movement | MOVE |

Table 10: Motion commands



The keyword ONE in the table above is an example of the distance. This executes the minimum movement step. The procedure for the further movement steps (TWO, THREE, FIVE, TEN) must be used in the same way.

Corresponding movements of the endoscope within the trocar

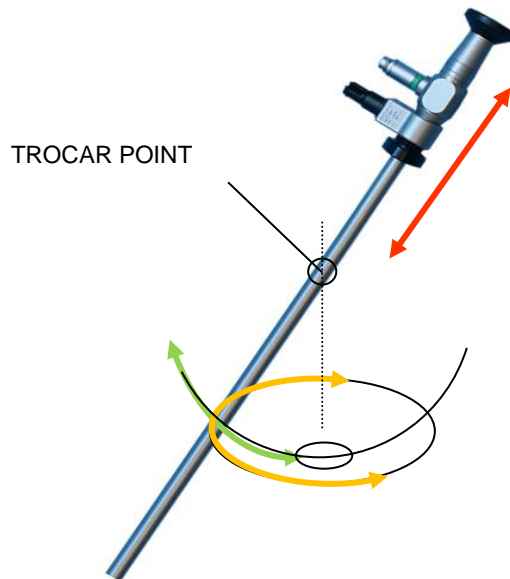


fig. 9: Endoscope movement

4.1.2 Store and recall positions

The key words SAVE and RESTORE, followed by ONE, TWO or THREE can be used to save and to restore, if required, up to three positions. The key word RETURN is used to undo the last movement.

4.1.3 Set speed

The key word SPEED, followed by ONE, TWO or THREE can be used to adjust the speed of movements of ARTip solo to three preset speed levels.

4.1.4 Cancel movement

Via voice input

A movement can be stopped at any time by entering the key word "STOP", even if voice input is not active (display box "Voice input" is not lit). As long as voice input is active, a movement can be interrupted by entering any key word.

Via manual movement

A movement is interrupted once the unlock button of ARTip solo (see ARTip solo manual) is actuated.

Emergency stop

Pressing the emergency stop button on the ARTip solo interrupts the power supply to the motors. Thus, all movements are stopped. However, the ARTip solo can continue to be moved by hand at any time.



If a JOYSTICK is simultaneously connected to the ARTip solo, the movement also stops if a button on the JOYSTICK is pressed during a movement.

4.2 Cleaning / wipe disinfection

The ARTip solo VOICE can be cleaned by wiping with a soft damp, non-wet cloth.

The ARTip solo VOICE 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 11: 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 Troubleshooting

In case ARTip solo VOICE for ARTip solo does not behave as expected, the following information is intended to help you resolve straightforward problems yourself.

| | |
|---|--|
|  | Never open the device. Risk of an electric shock! |
|  | <p>Always contact the manufacturer's service or a representative expressly authorised by the manufacturer:</p> <ul style="list-style-type: none">• 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 |
|--|---|
| The power button of the ARTip solo VOICE lights up green, otherwise no display and no function | <p>The ARTip solo VOICE was not started successfully. Press and hold the Power button for at least five (5) seconds to turn off the ARTip solo VOICE.</p> <p>Wait at least ten (10) seconds and restart the ARTip solo VOICE.</p> |
| The "HEADSET" indicator lights up, but no commands are detected | <p>Check the state of charge of the HEADSET.</p> <p>Restart the ARTip solo VOICE. Make sure that the dongle of the HEADSET is connected.</p> |
| The "Connected" indicator does not light | Check the cable connection to the ARTip solo. |
| The "Voice input" display flashes | A software update is performed. When the update is complete, remove any USB stick that may be connected. |

Table 12: Troubleshooting

6 Service

ARTip solo VOICE for ARTip solo does not require any maintenance on principle. To ensure safe operation over the duration of its service life, however, regular checks and safety inspections are essential.

6.1 Handover certificate

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

6.2 Regular inspections

Perform the following checks before each use of the device:

- Check power cord for damage
- Check ARTip solo VOICE and accessories for signs of external damage



Never use the ARTip solo VOICE for ARTip solo if you can see any damage. Call the service responsible for you.

6.3 Annual safety-related inspection

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

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

- 5.2 Inspection
- 5.3.2 Measurement of the protective conductor resistance, where applicable
- 5.3.3 Measurement of the leakage currents
- 5.3.4 Measurement of the insulation resistance

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

In case of a malfunction, please contact the Karl Storz 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.



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

6.4 Disposal / Recycling


The manufacturers confirm that the product

ARTip solo VOICE for ARTip solo




complies with the following Directives:

- Waste electrical and elctronic equipment (WEEE) 2012/19/EC,
- Electrical and Electronic Equipment Act - ElektroG in Germany,
- and the legal requirements of the EEA member states.

Further information can be found in document no. 1515-190114 (Recycling pass Voice Control).

| | |
|---|---|
|  | The national regulations are to be complied when the product or its components are disposed of or recycled. |
|---|---|

7 EMC

| | |
|---|---|
|  | MEDICAL ELECTRICAL DEVICES are subject to special EMC precautions. The ARTip solo VOICE may only be installed and commissioned in accordance with the EMC instructions contained in this manual. |
|  | 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 ARTip solo VOICE. |
|  | The ARTip solo VOICE 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 ARTip solo VOICE 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 13: 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: $d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 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 from 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° L-PE & N-PE: 2kV | Mains power quality should be that of a typical environment. |
| Conducted disturbances induced 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: $d = 1.2\sqrt{P}$ 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 14: Immunity test level

| | |
|---|--|
|  | <p>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.</p> |
|  | <p>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 ARTip solo VOICE, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.</p> |

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Manufactured by:
AKTORMed GmbH
Neugablonzer Str. 13
D-93073 Neutraubling

Distributed by:
Karl Storz SE & Co. KG
Dr.-Karl-Storz-Straße 34
78532 Tuttlingen