Laser Robot Arm

INSTRUCTION FOR USE

Original edition

Product Trade Name: Laser Robot Arm (LRA)
Reference: ATL-A-7D001

Manufacturer
ATLAS medical technologies GmbH
Lohrheidestraße 53
44866 Bochum
Germany
E-mail: service@atlas4d.de
Internet: www.atlas4d.de

Purpose of the instruction for use:

This instruction for use is part of the product and describes the system components, their structure, and operation. They provide important information for the safe and effective use of the Laser Robot Arm. Operating personnel must complete user training prior to operating the Laser Robot Arm (LRA). These instructions for use serve to supplement and deepen the user training.

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Glossary

C

CE · Conformité Européenne
CT · Computed tomography

D

DVT · Digital Volume Tomography

EAR · Waste electrical and electronic equipment register

EMC · Electromagnetic compatibility

F

FGI · Facet infiltration

I

IEC · International Electrotechnical Commission

L

LRA · Laser Robot Arm

P

PRT · Periradicular therapy

R

RF · Radio frequency

Explanation of symbols

Below are the pictograms that you will find on the product or on the packaging and in this document.

	Manufacturer
	Date of manufacture
REF	Reference number / Item number
SN	Serial number
MD	Medical device
	To ensure safety, follow the instructions for use
	Potential equalization (PE)
	Protective earth
	Fragile, handle with care (Symbol on transport box)
	indicates the temperature limits to which the medical device can be safely exposed
	Alternating current (AC)
	Marks an information message indicated as a note.
	General warning sign: Warning, observe the warnings and safety information in this document.
	Warning: laser beam, observe the warnings and safety information in this document.
	Warning! Crushing danger
	Warning; Radioactive material or ionizing radiation
	Separate collection for WEEE (waste of electrical and electronic equipment)
CE	Conformity marking according to the European Medical Devices Regulation 2017/745 (EU MDR).

1 General information about the product

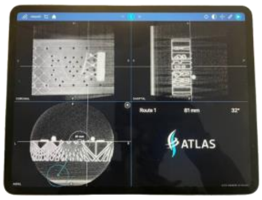
1.1 Scope of delivery

Laser Robot Arm Hardware

Robot arm with 7 degrees of freedom and integrated end effector. This consists of a camera module and laser unit. Mounted on a medical, lockable trolley that carries the computer unit and electronics.

Laser Robot Arm Cable Assembly

Network cables, voltage cables for Systems and trolleys, monitor cables and control cables. All cables required for operation are included.



Laser Robot Arm Interface (iPad)

Planning interface consisting of tablet, stylus and stand.

Laser Robot Arm Planning Software

Pre-installed software package with all components needed for operation.

WARNING: After receipt, check the delivery for completeness and integrity using the delivery note. The delivery left our house in perfect condition. If there is still reason for complaint, please contact our technical service.

1.2 Product description and intended use

Type

The Laser Robot Arm, hereinafter also referred as LRA, provides visual support for implementing a preoperatively planned position of an instrument (e.g. puncture needles). The system supports the user by transferring a previously planned procedure plan to the control unit of the Laser Robot Arm (LRA) and transmitting it to the patient with a visible laser beam. A control unit positions the LRA laser according to the planning.

The LRA indicates the needle entry point and puncture depth.

The LRA is an independent device with no physical connection to the CT or the needle/instrument to be navigated.

WARNING: Please refer to these instructions for use to operate the system correctly and safely. You will find an overview and explanation of all relevant steps to set up the system, which are necessary for a navigated operation.

Intended use

The Laser Robot Arm is an robot arm designed to provide visual guidance to physicians for the manual positioning and advancement of rigid, straight instruments such as needles, during image-guided percutaneous procedures. It is intended for use in minimally invasive procedures, including periradicular therapy, and is compatible with computed tomography (CT) imaging.

Medical indication

Medical indications include minimally invasive percutaneous procedure for chronic pain management such as:

- Periradicular therapy
- Facet infiltration
- Biopsy

Contraindication

The Laser Robot Arm (LRA) must not be used:

- for patients for whom CT-based procedures are contraindicated (e.g. pregnancy)
- patients who are unable to cooperate, such as those with psychiatric conditions, cognitive impairments, or severe anxiety.
- when the target region cannot be reached with the system (curved access path, uncertainty due to the anatomical region, puncture angle outside LRA specifications).

Patient group

In addition to indication and contraindication, the use of the Laser Robot Arm does not require any special restriction of patient groups according to age, weight, health, condition or gender.

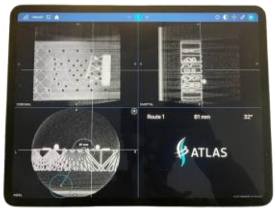
The performance of paediatric surgical procedures based on the similarity of the tasks performed in surgical procedures on adults must be carried out at the discretion of the physician and after thorough consideration of the individual risk-benefit situation.

Components

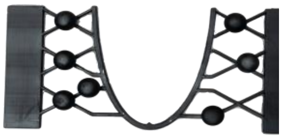
The Laser Robot Arm comes with an iPad (**A**), which serves as a workstation for tablet-based interaction with the system.

For the application, a Patient Tracker is attached to the patient's skin using Medical Adhesive Tapes. The Patient Tracker is used for the orientation of the laser and is intended to detect and compensate for further movements of the patient after imaging.

*The Patient Tracker is an accessory to the Laser Robot Arm and is not included. Medical Adhesive Tapes are referenced as (**C**), and the Patient Tracker as (**B**).*



A.



B.

C.

Overview of System Components

NOTE: The Patient Tracker component is a single-use product and is supplied together with the Medical Adhesive Tapes in a non-sterile state. For more information, see ***Chapter 5.2.1 Preparation.***

Usage

After image acquisition and transmission of the image data to the LRA-iPad, the user can transfer the planning he has made on a medical image-compliant monitor to the LRA. The LRA mechanics transfers the planning from the user to the patient by automatically aligning the laser so that the laser beam indicates the needle path according to the procedure planning. After the patient table has been moved out of the imaging system, the Laser Robot Arm orients itself to the Patient Tracker attached to the patient. The puncture point is displayed as a laser point on the patient's skin, where the Physician places the instrument (e.g. puncture needle) and pierces through the skin. More detailed information on planning and application can be found in ***Chapter 5.***

Range of applications

The Laser Robot Arm (LRA) can be used for minimally invasive percutaneous procedure for chronic pain management that can be performed with straight instruments, see the section "Indication".

- A wide range of access routes can be displayed. Please refer to the specification of the Laser Robot Arm.
- The system is preconfigured to support engagement angles within an artificial range of 45° to 135° (with 90° as vertical reference), ensuring reliable navigation while maintaining flexibility for clinical workflows.

Patient treatments are carried out on the patient table of the Imaging System.

Material

Depending on the application with an Imaging System, an associated Patient Tracker is required for each intervention. This is an accessory to the navigation System and is intended for single use only (not included).

Quality Assurance

Automatic calibration ensures that the needle entry point and angle are displayed correctly.

Intended Users/ User Profile

The Laser Robot Arm (LRA) may only be operated by qualified healthcare professionals trained to use the Laser Robot Arm (LRA). The operator (the person or entity responsible for the use and maintenance of the Laser Robot Arm) must ensure that all users of the Laser Robot Arm receive instruction from Atlas medical Technologies GmbH in the Laser Robot Arm-LRA in accordance with applicable laws and regulations. Possible users are, for example, orthopedists, interventional radiologists or operating room staff.

Technical work on the device, including installation, repairs, and maintenance, may only be performed by trained personnel certified by ATLAS Medical Technologies GmbH.

Use Environment

The Laser Robot Arm is designed for operation in a professional healthcare facility (clinics/hospitals and doctors' offices). Further specifications are listed in **Chapter 10.3**.

1.3 Conformity

CE

The navigation robot has been found to be compliant with the European Medical Devices Directive and has been certified with the CE marking.

Therefore, it is compliant with the following Directive: 2017/745 (EU MDR).

1.4 Manufacturer

The manufacturer acts in accordance with international and national standards and laws. Information about compliance can be provided upon request. Please contact your regional consultant or contact the manufacturer using the following contact details:

ATLAS medical technologies GmbH
Lohrheidestraße 53
D-44866 Bochum
Germany

E-Mail: service@atlas4D.de
Internet: www.atlas4D.de

2 Safety notes

2.1 Safety instructions in this guide

Read this manual carefully and follow the instructions before operating the Laser Robot Arm. Pay special attention to all information that is introduced with the following indications: "**WARNING!**". These instructions are particularly important for the safe use of the system. For better highlighting, these notices are marked with the warning sign pictogram.

In addition, this manual contains tips on how to use the Laser Robot Arm efficiently. These notices are also provided with the information pictogram and are introduced accordingly by "**NOTE**". Read these notes carefully.

2.2 General safety instructions

- Please note the information on the operation, maintenance and repair of medical devices in the Medical Devices Operator Ordinance (MPBetreibV) and other applicable regulations.
- To ensure the accuracy of navigation and to maintain the operational readiness of the LRA, qualified maintenance is required at intervals of 12 months.
- Only authorized after-sales service may carry out installation, repair and maintenance work.
- Unperformed or unqualified maintenance, as well as poorly performed repairs, will affect the accuracy of the LRA display.
- Failure to operate or inadequate inspection of the components can lead to injury to the patient or damage to the components!
- In the event of unsuccessful quality assurance, defects, or malfunctions, the LRA must be blocked and checked.
- The LRA is a highly precisely adjusted precision system. Treat it with appropriate care.
- Use the LRA only for its intended purpose.
- Instructions, warnings and cleaning instructions in the instructions for use must be followed.
- The interface (iPad) is not a certified diagnostic monitor. It serves to transfer the predefined planning and visualization of the needle path.
- To detect the Patient Tracker, the LRA arm moves to the calibration position. Make sure the arm can move freely. Risk of damage to the LRA.

- The LRA's computer unit needs clean air in sufficient quantities for its cooling.
- The LRA workstation (iPad) may only be used for the LRA application. Do not connect any other devices to the iPad.

- Do not stare directly into the laser beam of the LRA and make sure that your patients do not stare into the laser beam.

- Danger from moving mechanical parts. Risk of injury if the LRA arm is touched. Do not touch the LRA Systemic arm during an intervention. Pay attention to the working area of the LRA.
- Avoid any force applied to the robot arm and make sure that your patients do not touch the System. Applying force can lead to misalignment or defects.
- Lock the rollers of the LRA trolley after positioning the system. Movement during the procedure can lead to inaccuracy in the planning.
- The device is not suitable for use in the vicinity of flammable or explosive gases. Before using explosive or flammable gas, the LRA must be switched off.
- No component inside the device can be replaced by the user himself. Do not open any of the LRA enclosures.
- If the patient is defibrillated, make sure that he or she has no contact with the LRA.
- The system is connected to the protective conductor via the power plug. The operation of the LRA components is only permitted with the mains voltage specified on the nameplate and sufficient voltage stability. The plugs and cables must be routinely inspected and replaced if damaged.
- Use the systems only in rooms that comply with the applicable laws and regulations on the safety of electrical installations.
- The system is intended for operation in a professional clinic environment only. The emission characteristics of this device make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). When used in residential areas (which normally require CISPR 11 Class B), this equipment may not provide sufficient protection for radio frequency communication services. The user may then need to take corrective actions, such as relocating or reorienting the device.
- In case of burning smell or other emergencies, unplug the LRA from the socket.
- Unauthorized installation of software as well as modifications or modifications to the device are not permitted for security reasons.
- Prevent liquids such as water, detergents, and disinfectant sprays from entering the interior of the unit.
- The system must not be stacked or in direct mechanical contact with other equipment.
- Use only the cables supplied with the device for operation. Other cables can have a negative impact on electromagnetic compatibility.
- Do not use radios in the immediate vicinity (< 30 cm) of the system including its cables
- The basic function of the device is laser navigation. If this function is disturbed, no navigated interventions with the system are possible.

- The entire trajectory of the robot arm must be free of any objects, equipment, or persons. The user is responsible for verifying that no obstruction is present within the defined movement path to prevent the risk of collision during operation.

WARNING: "This device has been tested for RF protection on selected frequencies only and use near transmitters with other frequencies may result in incorrect operation."

WARNING: Failure to use this device in the specified environment may result in impaired performance, interference with other devices, or interference.

2.3 Special safety instructions

If the following instructions are disregarded, there is a risk of patient injury.

- Prepare the procedure carefully, make sure that the patient is stable, observe your patient and work quickly!
- The height of the CT table must not be changed during the entire treatment.
- Before inserting the needle, make sure that the laser indicator and the depth of the needle are plausible.
- Have puncture needles of different lengths ready. Selecting a suitable needle length makes it easier to estimate the puncture depth. If necessary, use an instrument with a depth Tracker or depth stop.
- Note that the puncture needle may deviate from the planned needle path (influences of needle bending, oblique needle grinding, deflection of the needle tip by structures such as ligaments, etc.). This is especially true for thin and less stiff needles. If you are unsure, take control photos!
- Avoid any physical contact with the LRA with non-sterile gloves! There is a risk of infection through the transmission of germs from the non-sterile robot arm to the patient.
- Needles without a stylet punch out a skin cylinder when inserted, which can be used to transport germs from the surface of the skin into the depths. Avoid dangerous, deep infections by following the following procedure: Insert the needle through the skin and place the punched-out skin cylinder directly under the skin by flushing it out with liquid (e.g. with a local anaesthetic).
- For puncture instruments where there is no discernible reference point at the distal end that is in line with the instrument's puncture axis, mark a distal reference point on the instrument.
- Do not use the system if the service life has been exceeded, the maintenance interval has not been adhered to, or if there are faults.

2.4 Notes on radiation protection

Protect patients and your team from X-rays. Medical staff no longer need to be exposed to X-rays at all in most LRA interventions. Your patients also benefit significantly from the LRA. Clinical studies show that an LRA not only shortens the procedure time and improves precision, but also that the radiation exposure of patients is almost halved.

The following points should help you minimize the radiation exposure of your image-guided interventions:

- Before taking the image, make sure that the imaging System gantry is at 0.0°. Images that have a gantry tilt cannot be used for navigation. A new image recording means a considerable and avoidable radiation exposure.
- Before taking the image, make sure that the reconstruction of the CT images

is done without x/y offsets. If you have accidentally taken pictures with offset, a new reconstruction is necessary. A new CT image is not necessary.

- Position your patient in accordance with the travel paths of the imaging System table and the LRA. A repositioning with new image acquisition must be avoided.

Observe the ALARA principle and keep the radiation exposure of your patients as low as possible:

- For the planning and control of puncture procedures, the image quality of low-dose protocols is sufficient in most cases.
- Minimize radiation exposure by minimizing the number of layers for planning and controlling the procedure.

2.5 Patient data protection

Privacy Compliance: Users of the Laser Robot Arm have the option to assign a password before operating the system to prevent unauthorized access to individually identifiable health information.

WARNING: To protect sensitive health data, the manufacturer strongly recommends using a password to operate the navigation System.

2.6 Cyber and Information Security

Do not install any software on the LRA machine.

To protect against computer viruses, you must not use the Laser Robot Arm for any other purpose.
During the installation of the Laser Robot Arm in your facility by personnel trained by the manufacturer, we will inform you about the security options when connecting the system to the network (PACS communication, firewall settings and secure wireless connection).

WARNING: Do not connect storage media or third-party devices to the device, e.g. by inserting a wireless dongle (e.g. Bluetooth or WLAN) into the USB or LAN ports.

2.7 Product monitoring

Our goal is to provide you with state-of-the-art, secure systems. The product is constantly monitored, optimized and further developed. For product improvements, we need feedback from our customers.

Please inform us immediately about:

- Disruptions to security and surveillance features,
- problems with the handling of the system,
- Restrictions in usability,
- dangerous situations or accidents involving the system.

We will contact you to further improve the safety, reliability and functioning of the system.

2.8 Limitation

The manufacturer is not liable for damage caused by:

- improper use or handling,
- the use is caused for a purpose other than the intended purpose (e.g. by internet use beyond remote maintenance),
- non-compliance with these instructions for use occurs,
- unauthorized changes and modifications,
- inadequate maintenance by unauthorized persons,
- Software and hardware damage caused by overvoltage, voltage interruptions and unqualified shutdown.

2.9 User´s responsibilities

Please note the information on the operation, maintenance and repair of medical devices in the Medical Devices Operator Ordinance (MPBetreibV) and other applicable regulations. The Operator agrees that the System may only be operated by persons who:

- are familiar with its use and have been instructed accordingly,
- have read and understood these instructions for use and have read the
- meet the qualification requirements for CT/CT-guided interventions.

In addition, the operator agrees

- To comply with all legal requirements for the operation of the product,
- use the product only for its intended purpose,
- to have the device checked and adjusted at annual intervals to ensure

  its function and to detect and eliminate defects,
- comply with the applicable regulations when processing patient data.

The operator is responsible for maintenance and quality assurance. The operator must treat the LRA with care. Exterior surfaces must be kept clean according to cleaning instructions. Maintenance work by the operating personnel is not required.

WARNING! The information provided by the navigation System is intended to support the doctor. Nevertheless, the navigation System cannot replace a detailed knowledge of the anatomy. All procedures and instructions described here do not relieve the user of his responsibility regarding clinical judgement and clinical procedure.

WARNING! The operator may only use the Laser Robot Arm (LRA) if it is in perfect condition and has received appropriate training for safe and efficient use.

WARNING! Before using the device, it is essential to perform a calibration check using the provided calibration phantom. This process ensures the accuracy and reliability of the measurements taken by the device. This calibration procedure must be performed before each use of the device to ensure optimal performance and accurate results.

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WARNING! Before each use of the system, ensure that all cartwheels are properly locked using the designated locking mechanism. Confirm that the cart is stable and shows no signs of wobbling or movement. If instability or a fault in the fixation system is detected, do not use the device and contact technical support.

2.10 Obligation to report serious incidents

Any serious incidents related to the device must be reported to the manufacturer and the competent national authority where the user and/or patient is established, in accordance with country-specific requirements. Please note the relevant reporting deadlines and regulations in your country for reporting incidents.

3 Installation and commissioning

The installation in the DVT/CT room, as well as the connection to the monitors, are subject to the initial installation. To do this, contact the service department.

Exemplary setup in the CT room

NOTE: Please note the installation plan provided by Atlas medical technologies GmbH.

NOTE: an installed system must not be dismantled or relocated on its own. Please contact the service.

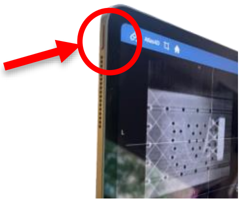
NOTE: When hiring new personnel, the customer or facility is required to request training from ATLAS Medical Technologies so that the new personnel are trained in the use of the Laser Robot Arm device.

4 Startup

Starting the system

To turn on the Laser Robot Arm (LRA), please follow these steps:

1. Turn on the main power button located at the back of the device.



2. Turn on the LRA workstation (iPad). To do this, press the button at the top left of the LRA iPad.

NOTE: Please make sure the device is turned on by checking if the status light is blue, indicating that the System is active

5 Procedure of an LRA-guided intervention

The procedure of an LRA-guided intervention with a CT device is listed in bullet points under 5.1 and described in detail in 5.2 below. The user-defined planning of the intervention is transferred to the LRA workstation (iPad).

5.1 Workflow (short description)

1. Preparations
2. Positioning the patient
3. Attach Patient Tracker
4. Acquisition of CT images
5. Send CT images to LRA workstation (iPad)
6. Moving patients out of the CT gantry until laser marking
7. Planning of laser-guided intervention
8. Send planning to the Laser Robot Arm
9. Perform LRA-guided intervention.

5.2 Workflow (detailed description)

5.2.1 Preparations

- Make sure that the Laser Robot Arm Laser Robot Arm and the LRA workstation are switched on and working properly (e.g. there is no error message, etc.).

- Remove the Patient Tracker and the two Medical Adhesive Tapes from the non-sterile packaging. Make sure that all the necessary materials are at hand, especially a Patient Tracker appropriate for the application together with the Medical Adhesive Tapes.

Patient Tracker

A. Patient Tracker **B.** Medical Adhesive Tapes

NOTE: To ensure proper and secure fixation of the Patient Tracker, only the specified medical adhesive tape (Reference: ATL-D-PA001ns) must be used. Using alternative materials may result in insufficient adhesion, which can compromise the stability and positioning of the Tracker during the procedure. Atlas cannot guarantee the correct fixation or performance of the Tracker if the specified adhesive tape is not used.

5.2.2 Positioning the patient

- Choose a patient position that is comfortable and stable and in which an LRA-guided treatment is well performed. Pay attention to the travel options from the table and the Laser Robot Arm.
- Perform the first skin disinfection.

5.2.3 Attach Patient Tracker

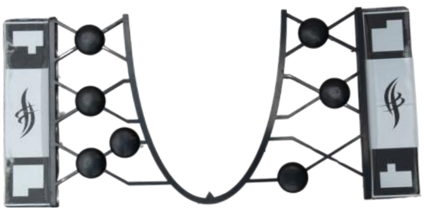
NOTE: To do this, refer to the instructions for use of the Patient Tracker.

Positioning of the Patient Tracker

Attach the Patient Tracker to the patient in the expected intervention area.

Place the Patient Tracker on the expected intervention area, inside the hole of the non-sterile drape, on the patient according to the following illustration:

Direction Gantry/Table-Headboard



Towards the foot of the

Attached Tracker using the example of the CT Tracker

The opening ("U") points upwards towards the gantry/table-head of the patient table.

WARNING: Make sure that the Patient Tracker is stuck and does not move during the entire application/intervention process.

5.2.4 Acquisition of CT images

Take CT images for procedure planning in accordance with the instructions and instructions listed below:

- CT images must fully show the puncture target, skin surface and Fiducial Tracker (choose FOV large enough)
- Observe information on radiation protection (**Chapter 2.4**)

5.2.5 Sending CT Images to LRA Workstation

After the CT scan has been completed, send the

- CT images automatically sent to the LRA workstation

  or

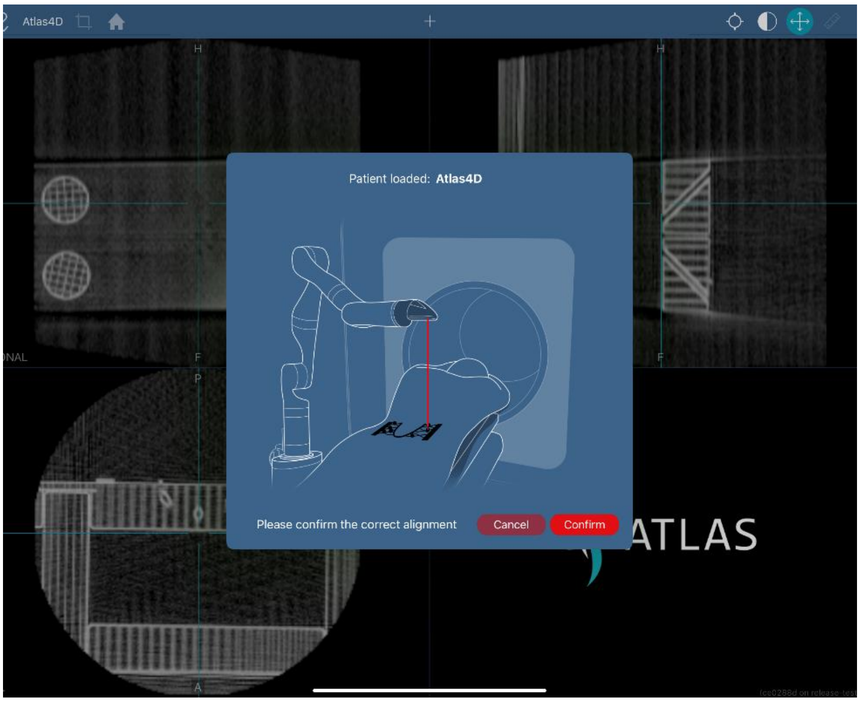
- CT images manually to the LRA workstation.

NOTE: More information on CT transmission-/DVT Images to the LRA workstation can be found in the instruction for use of your CT system or obtained from your PACS / IT administrator.

WARNING: Before starting the procedure, check the correctness of the patient's data. The patient's name must be visible in the top left corner of the interface.

5.2.6 Driving patients out of the CT gantry

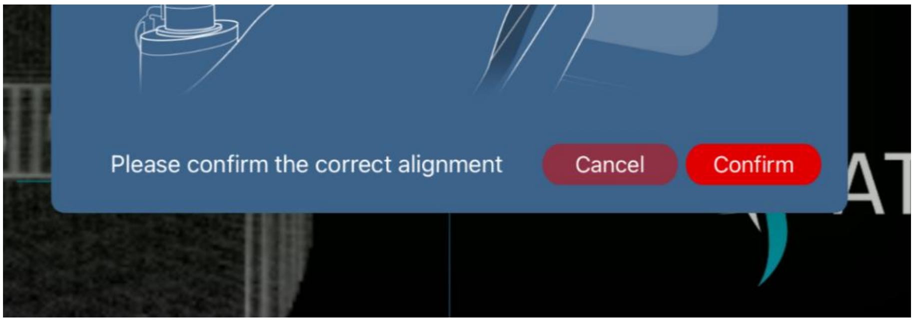
As soon as the LRA workstation receives the CT images, the following display appears on the LRA workstation:



Now move the patient out of the Imaging System gantry until the Patient Tracker is in the System's working area (see figure below).

Positioning of the Patient Tracker for CT-assisted procedures (right), relative to the laser point (red)

Then press Confirm.



The Patient Tracker detected in the camera data is registered to the Patient Tracker in the image data. As soon as the Patient Tracker has been detected in the image, the following display appears in the upper left corner of the LRA workstation.

To manually check whether the Patient Tracker is visible in the scan, you can move to the marking points via the following button:

Pressing it again indicates the next marking point. If all points in the scan volume are visible, the planning can be transferred, and the intervention can begin.

Button to check the marking points (right) and correctly recognized marking (left)

WARNING: Do not start the transfer of intervention planning before the registration has been confirmed

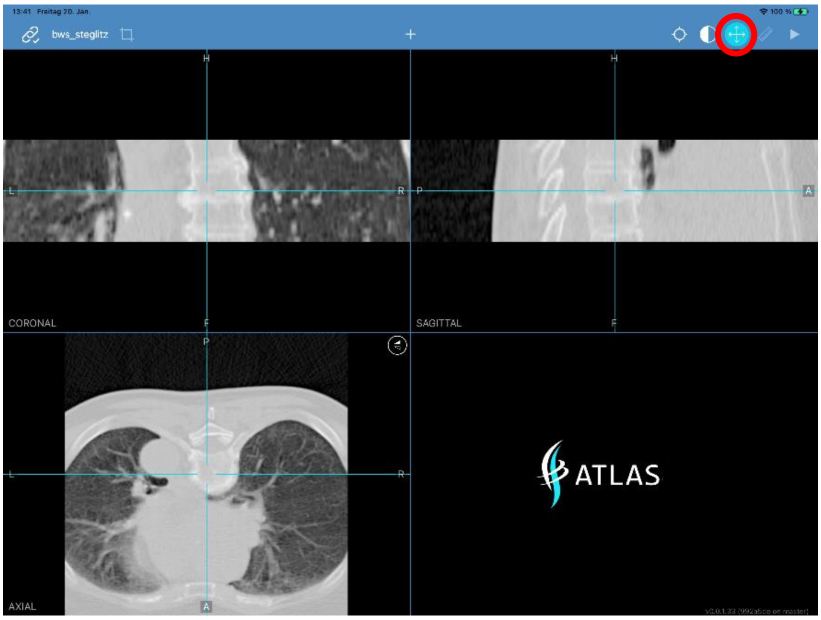
5.2.7 Transfer of planning for laser-guided intervention

The CT image data is automatically displayed on the workstation once it has been sent in full to the LRA workstation (see point 6.2.5).

Select the CT image that provides the best access to the puncture target. Select the desired view in the image viewer by moving the respective crosshairs within a viewport. For this, the scroll mode must be activated

NOTE: Click the crosshair icon in the status bar at the top right to enable scroll mode.

Move the individual layers by pressing the center of the crosshair in the respective image with your finger/mouse and then moving the crosshair.

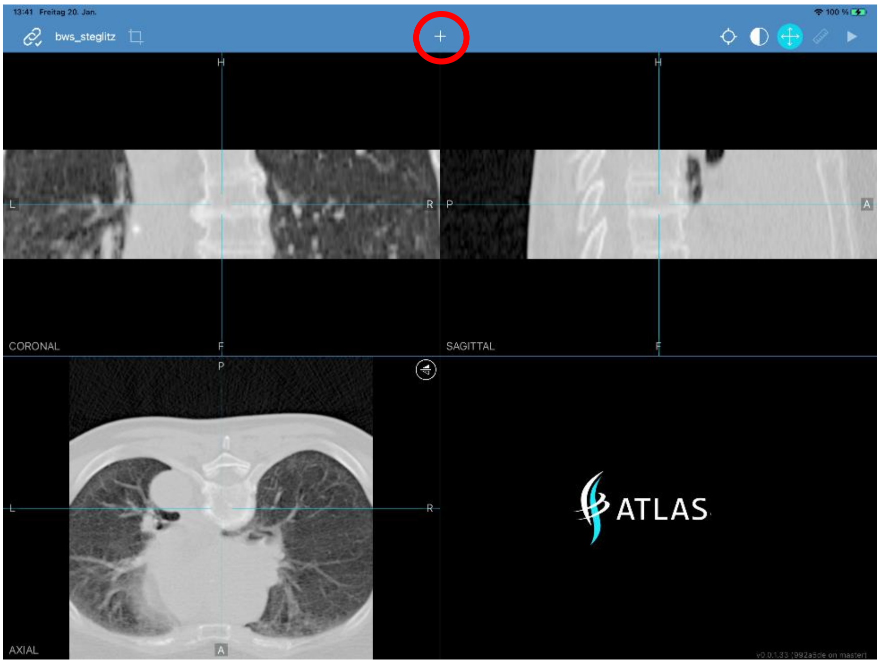


You can adjust the contrast and brightness of the image in contrast/brightness mode. For this, the contrast/brightness mode must be activated.

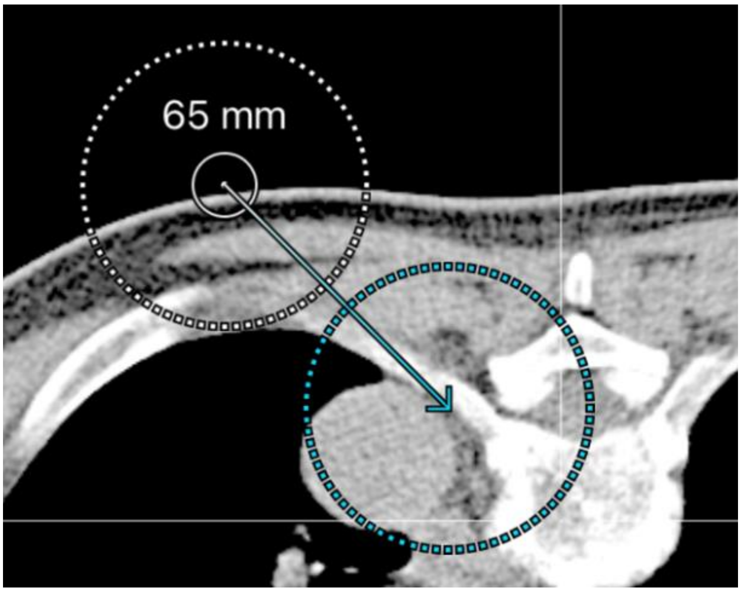
NOTE: Click on the Contrast/Brightness icon in the status bar at the top right to activate the Contrast/Brightness mode.

Change the contrast and brightness by pressing the icon (left) with your finger/mouse to the right/left or up/down on one of the images (see image below). To reset the setting, press the reset button in the lower right window.

To define the planning path, click on the "+" symbol (see the following image in the red circle). The "+" symbol is the tool for needle path planning.

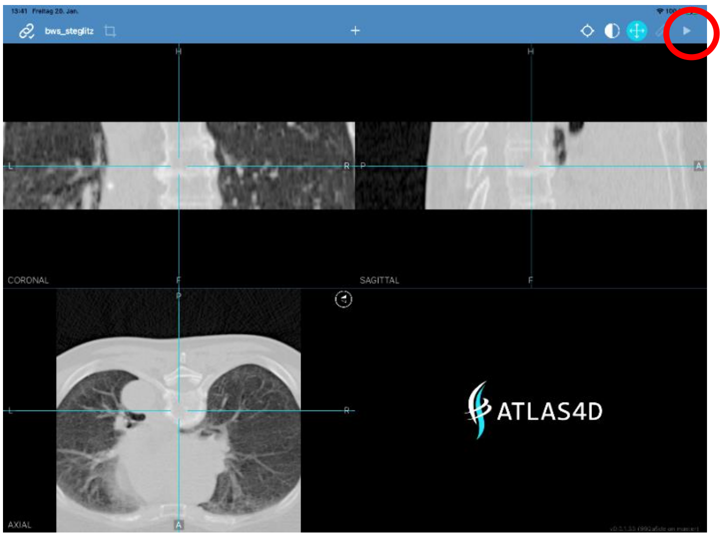


After clicking the "+" symbol, plan the puncture by using your mouse/finger to drag the ends of the inserted needle path line on the skin entry point (white) and the puncture target (blue).



The arrow corresponds to the needle path. For corrections, move the endpoints. Tap and hold your finger/mouse in the circles at the beginning and/or end of the planning line and move the end of the line to the desired location. The "mm" indication in the white circle indicates the depth of the puncture. If further length measurements are desired, they can be carried out by pressing the ruler icon (left).

Feature Workspace Planning



5.2.8 Send planning to Laser Robot Arm

Once you have finished planning, send the planning from the workstation to the Laser Robot Arm by pressing the "PLAY" button in the status bar at the top right.

Once the planning has been fully transmitted to the Laser Robot Arm, the laser moves into position and the "Play" indicator changes to a red "STOP" button (see left).

5.2.9 Conduct LRA-Guided Intervention

After the Laser Robot Arm has oriented itself to the Patient Tracker attached to the patient, the LRA laser displays the puncture point on the patient's skin. The instrument is placed at the laser point and pierced through the skin. As a result, the needle tip is already fixed (see picture on the left).

The instrument is then aligned so that the end (e.g. the syringe connection) is illuminated by the laser beam in the middle. When advancing the instrument to the target point, the laser point must always shine on the center of the distal end of the instrument (see picture on the left).

The instrument is advanced to the puncture depth indicated by the LRA workstation.

5.2.10 After the procedure

After the procedure is complete, press the red "STOP" button in the status display of the LRA workstation (top right) to return the laser to the initial position.

Remove the Patient Tracker along with the tape after the patient has been driven out of the CT gantry. Carefully remove the adhesive tape from the skin and dispose of both professionally in accordance with the country-specific requirements. The Patient Tracker and tape are not to be reused, as the possibility of infection and the adhesion of the tape cannot be ruled out.

5.2.11 Turning off the system

Turning off the system

In case of emergency, please turn off the appliance by unplugging the power cord of the appliance from the socket.

6 Cleaning

Cleaning the surface of the device

Manual cleaning is recommended. Keep the Laser Robot Arm (LRA) clean by rubbing the outer surfaces of the Laser Robot Arm (LRA) system components with the system switched off, preferably with a lint-free cloth if necessary. The cloth can be easily moistened with a mild, non-corrosive soapy water.

Avoid the ingress of liquids into the housing. Use an aldehyde-free rapid disinfectant to disinfect the surfaces, which allows for wipe disinfection. Apply the solution to a soft cloth and wipe the entire surface of the case and wait for the solution to dry.

WARNING: Cleaning agents and disinfectants may contain harmful or aggressive substances. They can damage LRA surfaces. Medical wipes and disinfectants that do not contain chlorine and acids can be used if it is ensured that you do not attack the surfaces of the device. Test on an inconspicuous area required!

WARNING: Penetrating liquids and aggressive cleaning and disinfecting agents can damage the LRA! Therefore, never spray or pour detergent directly onto the surface, as there is a risk that the detergent will come into direct contact with components in the device and cause irreparable damage to the electrical components.

Inspection Instruction

After cleaning, visually inspect the system for remaining dirt under suitable lighting conditions. Repeat the cleaning procedures if necessary.

7 Call for Remote Service

Your Laser Robot Arm is set up for remote service. This means that an ATLAS service technician can operate your LRA from their office in Germany. Remote Service can be used for software maintenance (such as updates or configurations) and for teaching. Remote service is carried out via the "TEAMVIEWER" software.

For more information, please refer to the TEAMVIEWER documentation.

NOTE: An internet connection is required for remote service. If the LRA computer's internet connection is normally blocked, ask your hospital's IT administrator to unblock the Laser Robot Arm's internet connection for a few hours.

NOTE: Remote Service must be activated by you. Without your help, the service technician will not be able to access your LRA computer.

Please give your phone number to the service technician as they may need your help again (e.g. for a restart of the LRA). The technician will call you after they finish their work.

8 Maintenance and Service Notes

Contact Technical Service

Your service partner ATLAS medical technologies GmbH is responsible for questions about the product, user training, remote maintenance, repairs and annual maintenance.

E-Mail Service : service@atlas4d.de

Annual maintenance (in 12 months cycle)

Maintenance

Annual maintenance is recommended to meet specifications and to maintain operational readiness and safety.

The following work is carried out during annual maintenance:

- Testing of all mechanical and electromechanical parts/units
- Checking electrical and mechanical connections
- Checking and adjusting the accuracy of LRA navigation
- Electrical safety check
- Internal cleaning work
- Checking computer hardware, software and data maintenance
- Calibration of the system

Service Assignment

Maintenance is carried out by from Atlas medical technologies certified personnel.

- Instruct the ATLAS service to carry out the "annual maintenance" at least 4 weeks before the due date.
- You can find the next appointment for the annual maintenance on the sticker located at the System's stand.

Shelf Life

The expected lifespan of the Laser Robot Arm is seven years when the preventive maintenance cycles are carried out.

Repairs

In the event of operational disruptions, please contact ATLAS Service by email or telephone, stating as precise a description of the fault as possible, including the article number and serial number.

Important information when reporting errors to the service

- Description of the problem
- Text and error number (e.g. STA85) of the error message
- Photos of the problem are very helpful

The Laser Robot Arm (LRA) can only be transported, installed, maintained and repaired by the manufacturer ATLAS medical technologies GmbH or by authorized companies or persons.

The manufacturer accepts no liability for damage caused by inadequate or unqualified maintenance and unauthorized repairs.

WARNING: The Laser Robot Arm must not be operated if maintenance activities and tests required by applicable laws or other national guidelines are not carried out (e.g. regular electrical safety inspection).

NOTE: The manufacturer recommends keeping a medical device book for the repair and preventive maintenance work carried out. Write down relevant information about the type of work, the company that performed the work, and other important information.

9 Disposal

If you have any questions about disposal, please contact the manufacturer. The manufacturer will take back the system at the end of its useful life and dispose of it free of charge and in an environmentally friendly manner. The customer must bear the costs of uninstallation and transport to the manufacturer's premises.
If you dispose of the system yourself, take into account environmental safety, health risks, disposal guidelines and national regulations (especially the Electrical and Electronic Equipment Act).
In the case of local disposal, sort the device components according to the material classes defined by your regional disposal company (e.g. metal, plastics, composite materials, electrotechnical components, etc.) and hand in the separated materials to your disposal company.

NOTE: ATLAS GmbH is registered as a manufacturer with the Stiftung Elektro-Altgeräte Register (EAR) under the number **DE68119103** registered.

10 Product

10.1 Specifications

LRA Hardware

Parameter	Values
Dimensions	Height: 182.9 cm, maximum in notch position of the arm Footprint: 66,0 cm × 61,0 cm
Weight	Approx. 45 kg
Line voltage	100– 240 V AC, 50/60 Hz
Maximum power consumption	400 VA (per plug)

Classification

Electrical protection class	Protection Class I (no applied part)
Software security classification according to IEC 62304 Edition 1.1 2015-06	Class A
Medical Device Class Directive 2017/745 (EU MDR)	Class I
Protection class according to IEC 60529:1989 + A1:1999 + A2:2013);	IP20
LRA-Laser	Class II laser; Output power: 0.95 mW; Wavelength: 532 nm; Operating voltage: 4.8 V DC
Explosion protection	None (device not suitable for use in potentially explosive environments
Type of electrical power supply	Mains power supply via IEC socket (plug-in device)

Key features

Deviation between planned and indicated needle entry point	≤ 1mm

WARNING: Maintenance is required to maintain specified accuracies.

10.2 EMC-Declaration

The Laser Robot Arm was tested for electromagnetic compatibility (EMC) according to IEC 60601-1-2:2014 + A1:2020, for use in professional healthcare environments. Testing covered emissions and immunity based on standards including CISPR 11 and relevant IEC 61000-4-x series. Additionally, testing was performed in accordance with FCC Part 15, Subpart B (ICES-003) for unintentional radiators.

Electro-magnetic emissions

Emission test	**Applied standard**	**Test Level Compliance**
Connection Voltages	CISPR 11:2015 +A1:2016 +A2:2019	Group 1, Class B
Interference from radiation	CISPR 11:2015 +A1:2016 +A2:2019	Group 1, Class B
AC Network Harmonics	IEC 61000-3-2:2005 +A1:2008+A2:2009	Class A
AC mains voltage fluctuations and flickering	IEC 61000-3-3:2013	Fulfilled

Electro-magnetic immunity

Immunity test	**Applied standard**	**Test Level Compliance**
Electrostatic discharge	IEC 61000-4-2:2008	±8 kilovolts (contact discharge), ±8 kilovolts (air discharge), ±15 kilovolts (air discharge)
Radio frequency electromagnetic field	IEC 61000-4-3:2006+A1:2007+A2:2010	3 volts per meter (V/m), 20 megahertz (MHz) up to 6 gigahertz (GHz)
Fast electrical surges	IEC 61000-4-4:2012	±2 kilovolts (kV) on power lines, ±1 kilovolt (kV) on input/output (I/O) lines

Surges	IEC 61000-4-5:2014 + A1:2017	±1 kilovolt (kV) differential mode (dm), ±2 kilovolts (kV) common mode (cm)
Conducted interference induced by radio-frequency fields	IEC 61000-4-6:2013	3 volts (V) from 0.15 megahertz (MHz) to 80 MHz; 6 volts (V) in ISM frequency bands between 0.15 MHz and 80 MHz; 80% amplitude modulation (AM) at 1 kilohertz (kHz)
Voltage dips, short interruptions, and voltage fluctuations on input lines of the power supply	IEC 61000-4-11:2004 + A1:2017	Reduction to: 0% of nominal voltage (UT) for 0.5 cycles, 0% UT for 1 cycle, 70% UT for 25 cycles (50 Hz), 70% UT for 30 cycles (60 Hz), 0% UT for 250 cycles (50 Hz), 0% UT for 300 cycles (60 Hz)
Immunity to near-field interference from wireless radio-frequency communication devices	IEC 60601-1-2:2014, Table 9	27 volts per meter (V/m) at 380–390 MHz; 28 V/m at 430–470 MHz, 800–960 MHz, 1700–1990 MHz, and 2400–2570 MHz; 9 V/m at 704–787 MHz and 5100–5800 MHz
Immunity to near magnetic fields	IEC 61000-4-39:2017	8 amperes per meter (A/m) at 30 kilohertz (kHz), continuous wave; 65 A/m at 134.2 kHz with pulse modulation (2.1 kHz); 7.5 A/m at 13.56 MHz with pulse modulation (50 kHz)
Power frequency magnetic fields	IEC 61000-4-8:2009	30 amperes per meter (A/m)

Transport and storage

Operating conditions

10.3 Environmental Conditions

Temperature	-10 to 35° C
Humidity	10% to 90% relative humidity, non-condensing

Temperature	10° to 30° C
Humidity	30% to 75% relative humidity, non-condensing
Statics	Ground must be flat, straight and stable.
Environment	The device is not suitable for use in the vicinity of flammable or explosive gases.

11 Appendix – Compatible Devices

Imaging Systems

The navigation software can import image data in DICOM data format. This standard is supported by all devices from the manufacturers relevant to the market. The software is compatible with the DICOM standard.

Before the first use of the Laser Robot Arm (LRA) in clinical routine, compatibility with the imaging System must be confirmed. If you have any problems with the loading process of image datasets, please contact your service representative.