OPERATING MANUAL

MODULITH® SLK

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Table of Contents

Introduction

This operating manual contains all the information required for operating the MODULITH® SLK manufactured by STORZ MEDICAL AG.

General Safety Information that must be complied with when using the lithotripter is summarised in Chapter **1 GENERAL SAFETY INFORMATION**. It is particularly important to read this chapter with great care before working with the lithotripter. Following this safety information enables you to safeguard against dangers to people and to the device at all times. The safety information is also provided at the points where it has to be followed as part of an operating procedure.

Chapter **2 PRINCIPLES** contains general information about the medical and physical principles of extracorporeally induced shock wave therapy as used in the MODULITH® SLK. In addition, this chapter contains important information about the topic of intended use, preconditions for operation as well as the conditions for setting up the device.

Chapter **3 SYSTEM DESCRIPTION** presents the structure of the device and its components. This chapter contains all information about the available functions and capabilities of the device.

All controls and displays are described in Chapter **4 CONTROLS AND OPERATION**.

Chapter **5 TREATMENT PREPARATION AND TREATMENT** deals with the measures that have to be taken before the start of treatment (tests to ensure the functional safety and correct condition of the device). This is followed by a description of the actual patient treatment process, which includes a detailed description of the operating procedures for positioning the patient, localising the stone, triggering the shock waves and the steps that must be followed after the end of treatment.

Chapter **6 STATUS DISPLAYS AND ERROR MESSAGES** deals with all status displays that can appear when using the device. It provides information and instructions for rectifying malfunctions.

Information about caring for the lithotripter and working procedures for establishing or maintaining perfect working order is given in Chapter **7 CARE/TECHNICAL SAFETY CHECKS**. In addition, the Technical Safety Checks that must be carried out at regular intervals are described.

Chapter **8 TRANSPORT** contains information on how to transport the device and how to prepare it for treatment following transport.

Chapter **9 TECHNICAL SPECIFICATIONS** summarises the technical specifications of the MODULITH® SLK lithotripter.

Chapter **10 OPTIONS AND ACCESSORIES** contains a description of the options and available accessories.

Chapter **11 X-RAY LOCALISATION (OPTION)**contains the description on X-ray localisation. However, it is essential to comply with the separate operating manual for the X-ray device before localisation is performed.

Chapter **12 ULTRASOUND LOCALISATION (OPTION)** describes the ultrasound localisation process. However, it is essential to comply with the separate operating manual of the ultrasound device before localisation is performed.

Preface

Before starting to work with the MODULITH® SLK, familiarise yourself with the content of the operating manual. When using the localisation systems, please also refer to the separate operating manuals for these devices. Knowledge of the content of this manual is an essential prerequisite for operating the entire system.

Text design

This operating manual contains certain types of text design intended to assist you in comprehending the significance of the text based on its appearance.

Instructions for actions

- This text instructs you in how to operate your device correctly.
  - This text subdivides an action into steps or comments on the action step.

⇨ *This text shows the result of an action.*

Lists

– This text is part of a list.

Menus and buttons

Names of MENUS and BUTTONS are greyed out and highlighted in small caps.

The operating procedure descriptions also contain references to the buttons that you have to press and what you can expect to see in the text.

Cross references to other chapters

Cross references to other chapters are highlighted in bold and in small caps.

Warning notes

This manual contains warnings, safety instructions and specific operating instructions in accordance with liability regulations.

DANGER refers to a situation of acute danger which, if not avoided, could lead to serious or fatal injury.

DANGER

The source of the danger is stated here.

These are the possible consequences!

► The instructions for avoiding the danger are given here.

WARNING refers to a situation of potential danger which, if not avoided, could lead to serious injury.

WARNING

The source of the danger is stated here.

These are possible consequences!

► The instructions for avoiding the danger are given here.

CAUTION indicates that incorrect operation could lead to minor injuries.

⚠ CAUTION

The source of the danger is stated here.

These are the possible consequences!

► The instructions for avoiding the danger are given here.

NOTICE indicates that incorrect operation could lead to damage to the device.

NOTICE

The source of the danger is stated here.

These are possible consequences!

► The instructions for avoiding the danger are given here.

Other instructions

This text indicates additional information concerning special features, etc. and/or operating instructions.

Abbreviations

The following abbreviations are used in this manual:

SW	Shock wave
SW_trigger_button	Shock wave trigger button
CC	Cranio-caudal
PE	Posterior-anterior
ESWT	Extracorporeal Shockwave Therapy
SMLI	Storz Medical Lithotripsy Index
F2	Dual Focus

The following symbols are used in this operating manual:

Symbol	Meaning
CE 0197	CE mark
	Manufacturer
EC REP	EC Representative
SN	Serialnumber of the device
	UDI (Unique Device Identification): Barcode on the type plate for machine-readable identification of the medical device.
REF	Article number of the unit
MD	Symbol: Medical Device
	General warning sign
	Electrical warning sign
	X-ray radiation warning sign
	Explosive substances warning sign
	Mandatory sign: Wear ear protection

Tab. 0-1 Safety signs and other symbols used

1 General Safety Information

1.1 Instructions for safe use

The following chapter contains all the safety information for handling the MODULITH® SLK.

DANGER

Incorrect handling of the device

Risk of injuries to the patient and the operating personnel!

- ► Read this chapter carefully before you start using the MODULITH® SLK.
- ► Read the separate operating manuals for all devices associated with the MODULITH® SLK.

1.1.1 Intended use and operational safety

This device is intended for use in extracorporeally induced shock wave therapy in order to treat the indications specified in Chapter **2.1.1 INDICATIONS**.

The user must possess the necessary technical proficiency and knowledge of the operating manual to use this device in line with its intended purpose. The device is only to be used for the applications described in Chapter **2.1.1 INDICATIONS**. Combination with other methods for treating stones is possible. Refer to the medical literature for the relevant information. However, you must ensure that the safety standard of the lithotripter is not impaired.

Furthermore, the device is only allowed to be operated by trained personnel who fulfil the preconditions for operation in Chapter **2.5 PRECONDITIONS FOR OPERATION**.

Use of the device is only permitted in medical rooms that have been designed in accordance with the relevant national requirements.

Connecting additional devices

Incorrect localisation may occur if the additional devices used are incompatible withthe MODULITH® SLK.

- Only connect devices approved by the manufacturer of the MODULITH® SLK to the MODULITH® SLK !
- Comply with the information in **3.7 COMPATIBLE ADDITIONAL DEVICES**.

Checks and inspections prior to treatment

Before using the device, the user must make sure it is functioning safely and that it isin proper condition.

- After switching on the MODULITH® SLK it is essential to perform the functional-checks before starting lithotripsy. (See **5.2.2 FUNCTIONAL CHECKS**).
- The periodic maintenance procedures prescribed by the manufacturer mustbe carried out on schedule and by suitably authorised personnel (see also **7.1 CLEANING AND DISINFECTION**).

Protection against electrical hazards

Sources of voltage can give rise to currents as a result of body resistance, which not only flow through the patient but can also impair or even endanger the physician and the nursing staff

- Therefore, have the connection of the MODULITH® SLK carried out by authorized specialists in accordance with the national guidelines.
- Devices that are not medical products in accordance with EN 60601 must be set up outside the patient environment.
- Do not touch electrical connectors while you are touching the patient.
- Only the accessories specified in chapter **3.7 COMPATIBLE ADDITIONAL DEVICES** are to be connected to the MODULITH® SLK.

DANGER

Improper connection:

There is a risk of electric shock!

► Do not connect the device to a power supply network unless it has a protective conductor.

► Never use multi-socket power strips.

The requirements for rooms used for medical purposes applicable in the particular country must always be observed. With regard to the mains connection, installation must be carried out in accordance with the applicable national regulations. For connection data, see chapter **9 TECHNICAL SPECIFICATIONS**.

Protection against high voltage

High-voltage components are identified as follows:

DANGER

Contact with high-voltage parts:

Severe or fatal injury!

► Only operate the device if the housing is intact and closed

► Work in the area of high voltage is only allowed to be performed by personnel suitably authorised by the manufacturer.

Protection against radiation

X-rays are hazardous to health.

- Exercise the greatest of care when dealing with X-ray radiation.
- Only work with the X-ray radiation application if you have the necessary technical proficiency.

- Comply with statutory regulations.
- During operation of the X-ray device, comply with all regulations relating to the X-ray radiation application.

WARNING

Sustained or repeated radiation exposure

Health risk for the patient and the person administering the treatment!

- ▶ Take protective measures.
- ▶ Keep the exposure times as short as possible.
- ▶ Restrict the exposure area.
- ▶ Maintain a sufficient distance from the radiation source.
- ▶ Use badges to monitor the radiation levels received.
- ▶ Avoid unnecessary radiation exposure of the patient.
- ▶ Remove obscuring objects from the primary beam (this includes the hands of the operator).
- ▶ Use automatic dose rate control whenever possible.

Protection against explosion

The device is not allowed to be used in potentially explosive atmospheres (according to classification AP and APG of IEC 60601-1) i.e. in the reach of anesthetic gas mixtures with air, oxygen or nitrogen oxide.

DANGER

Risk of explosion due to flammable and explosive materials

Injuries to patients, people administering the treatment and third parties!

- ▶ During operation, avoid using the substances specified in the following section.
- ▶ Switch off the device before cleaning and disconnect the mains plug.
- ▶ Comply with the information on cleaning in Chapter **7.1 CLEANING AND DISINFECTION**

The following agents are NOT to be used during operation:

– Highly inflammable and potentially explosive inhalation anaesthetics and mixtures of the same, such as
  - Ether pro narcosi (diethyl ether)
  - Cyclopropane.

– Inflammable, highly volatile skin cleaning agents and skin disinfectants which can form a potentially explosive atmosphere, such as
  - Washing ether
  - Petrol ether.

Protection against noise

The noise level during administration of shockwaves is within the safe range. Nevertheless, we recommend wearing suitable ear protection during treatment in order to minimise exposure to noise.

Temperature

Shock wave triggering is stopped automatically if the water temperature in the water circuit rises above 41°C. The device generates an error message and the coupling cushion is deactivated.

⚠ CAUTION

There is also a risk of skin coming into contact with the hot surface in the case of obese patients.

Minor burns and skin reddening may result!

► Swivel the therapy head into the park position.

1.1.2 Safety during treatment of the patient

General note:

– Organs with gas inclusions, in particular parts of the lung, are NOT to be exposed to shock waves.
– Implants in the patient are not allowed to be in the shock wave path. The function of the implant may be impaired.
– Do not administer any shock waves through the bone structure. This significantly weakens the energy of the shock waves.

Safe positioning of the patient

Correct positioning before and during treatment is the responsibility of the therapist.

- Take particular care when positioning the patient.
- Help the patient to get on and off the table to avoid the risk of falls.

Air bubbles reduce the effectiveness of shock waves. Therefore, air bubbles must always be removed from the shock wave path.

- Use your hand to smooth out any air bubbles in the coupling agent and between the patient and the coupling cushion.
- Remove body hair in the area of the shock waves. Air bubbles could collect in these areas.
- Position the patient so there are no skin folds in the shock wave path. Administering shock waves through skin folds can cause haematomas and petechiae.

Checking during treatment

The triggering of shock waves must be carried out under constant supervision of the patient.

Therefore, there must always be a line of sight to the patient, including from the installation site of the remote control panel for operating the MODULITH® SLK.

In general, there is a risk of haemorrhage or the formation of haematomas in the area around the focal point. These can be caused by impermissible focusing on tissue.

- Continuously monitor the congruence between the stone and focal position during lithotripsy.
- Always carry out X-ray or ultrasound monitoring if you are moving the patient table at the same time as triggering shock waves.

Pain or discomfort can cause the patient to make inadvertent movements.

- Therefore, check the position of the patient regularly by X-ray or ultrasound monitoring.

Heart activities can be influenced by treatment with very high energies outside the refractory phase of the heart muscle.

- Work with ECG monitoring in order to detect extrasystoles.

No lithotripsy treatment is permitted if a display on the control panel fails. No treatment is allowed if a touch screen (operating monitor) fails.

- Heed the status displays at all times.
- No cleaning and maintenance work is to be carried out while the device is being used on the patient.

1.1.3 Safety when moving the device

- Before moving parts of the device, make sure no-one is within the action radius of these components.
- The motor drive of the therapy arm is very powerful. Make sure limbs are kept out of the working area between the additional devices and drive modules.
- Always secure the MODULITH® SLK in the treatment or transport position, otherwise uncontrollable movement may occur.
- Move the therapy head with the greatest of care, because swivelling of the therapy head can result in people becoming trapped and objects being damaged.

1.1.3.1 Load compensation mechanism (rocker)

If the pressure exerted by the therapy head on the patient is too high, the MODULITH® SLK is able to change position and reduce the load thanks to its integrated load compensation mechanism (rocker). In addition, the device generates an acoustic warning signal and activates a row of red warning LEDs on the therapy head. At the same time, the control panel displays a corresponding warning message.

- Familiarise yourself with how the rocker works. Read about this in Chapter **1.1.3.1 LOAD COMPENSATION MECHANISM (ROCKER)**

The location of the operating personnel cannot be taken into account here. The user must therefore monitor the movements of the device at all times.

1.1.3.2 Emergency stop buttons

Use the emergency stop if the patient, the operator or the device is placed at risk by an inadvertent movement of the device.

- Familiarise yourself with the emergency stop function in Chapter **1.1.3.2 EMERGENCY STOP BUTTONS**.

1.1.3.3 Freeing the patient after a power failure

The therapy head cannot be moved by the motor if the electrical power supply is interrupted. To allow the patient to dismount after OT treatment, it is necessary for the therapy head to be removed and swivelled away from the patient manually.

- Familiarise yourself with the process of freeing a patient. To find out more about this process, consult Chapter **1.1.3.3 FREEING THE PATIENT AFTER A POWER FAILURE**

1.2 Warning against damage to equipment and the device

Electromagnetic compatibility

This device complies with the requirements of the applicable standard on electromagnetic compatibility (see **9.3 EMC MANUFACTURER'S DECLARATION**). Nevertheless, portable and mobile HF communications equipment (e.g. mobile phones), including antennae, can interfere with medical electrical equipment. They should not be used closer than 30 cm from the device – including the cables specified by the manufacturer.

The use of accessories or cables not authorised by the manufacturer can result in increased interference emissions or reduced resistance to interference emissions by the device:

This MODULITH® SLK is not allowed to be positioned immediately next to or jointly with other devices. If operation near or jointly with other devices is required, the device must be checked in that particular environment to ensure operation according to technical specifications. The MODULITH® SLK is allowed to be set up and operated close to the **3.7 COMPATIBLE ADDITIONAL DEVICES** accessories listed in

The separate operating manual for all devices associated with MODULITH® SLK (such as locating systems, ECG devices) are to be viewed as an integral part of the complete operating manual. Always comply with all EMC information contained in these manuals.

Due to its emission characteristics, this device is suitable for use in industrial areas and hospitals (CISPR11 Class A). If it is used in domestic environments (which normally require CISPR 11 Class B), the device may not provide adequate protection for RF communications equipment. The device may need to be moved or realigned, or other actions may need to be taken.

Setup and operation

There are ventilation slits on the rear of the device which must not be covered by other objects.

- Observe the movements of the device at all times.

Storage and transport

Incorrect storage and transport can result in damage to the device and device failure.

- Completely empty the water circuit and the therapy head before you transport the device or put it into storage.
  ⇨ *Otherwise, there is a risk of the water freezing, which will lead to damage. Please contact your responsible Service centre if this does happen.*
- Comply with the ambient conditions specified in Chapter **9 TECHNICAL SPECIFICATIONS**.
- Make sure that no cables are crushed or sheared.
- Use the supplied transport protection for transport and storage.

1.3 Manufacturer`s Responsibility

WARNING

No modifications are to be made to this device without the permission of the manufacturer.

The manufacturer of the MODULITH® SLK is only responsible for the impact of its product on safety, reliability and performance if:

– maintenance of the device is performed at the intervals specified by the manufacturer
– installation, expansions, conversions, new installations, modifications or repairs are performed by people authorised by the manufacturer
– the electrical installation in the rooms in question corresponds to the requirements of DIN/IEC
– the device is used in compliance with the operating manual

The periodic maintenance measures specified by the manufacturer must be performed on schedule by personnel suitably authorised. Original parts from the manufacturer must be used; otherwise, the manufacturer's liability shall be rendered null and void.

1.4 Owner`s Responsibility

The owner is responsible for complying with the relevant national statutory provisions governing setting up and operating technical medical equipment. (For Germany, according to the Medical Devices Act)

The periodic maintenance procedures prescribed by the manufacturer must be carried out on schedule and by personnel suitably authorised (see also Chapter **7.3 TECHNICAL SAFETY CHECKS**).

It is expressly stated that the use of unauthorised accessories and/or unauthorised equipment combinations shall render the product liability null and void.

The device is only to be used with accessories, wear parts and disposable articles that have been checked by the testing body responsible for testing the device to ensure that they can be used without risk.

2 Principles

2.1 Medical principles

Different procedures can be used for treating different lithiases. Within this range of possibilities, the application of extracorporeally generated shock waves represents a non-invasive procedure that can be used for destroying stones of different compositions in various stone presentations.

So that the information can be presented as neutrally as possible without having to refer to a particular type of application, the area that is to be treated is described below using the term 'target area'.

Thus, the target area for lithotripsy is the stone that is to be treated. Target area in the pain/cardiac treatment of the painful area or the area to be treated.

Intended use:

The device of the MODULITH® SLK is intended for use in extracorporeally induced shock wave therapy in order to treat the indications specified in Chapter **2.1.1 INDICATIONS**.

2.1.1 Indications

2.1.1.1 Urological Indications

If the urology cushion is installed, structures close to the surface are hard to reach. However, the penetration depth can still be reduced by applying sufficient ultrasound gel.

Urinary calculi

- Kidney stones
- Ureter stones
- Bladder stones
- Staghorn calculi

Gall stones

- Bile duct stones
- Gallbladder stones

Pancreatoliths / pancreatic duct stones

Salivary stones

IPP / PD

- Induratio Penis Plastica
- Peyronie's disease

2.1.1.2 Orthopedic Indications

If the orthopaedic cushion is installed, care must be taken during urological treatment to ensure there are as few folds as possible between the coupling cushion and the coupling site. When treating structures far from the surface, the reduced water pressure in the coupling cushion can form folds and hence reflective layers. This can impair the transmission of shock waves in the body.

Tendinopathy / tendinitis / tendonitis / tendinosis / tendon pain

- Insertion tendonitis in general
- Insertion tendonitis near the surface (paratendinary area)
- Painful shoulder with and without calcifications / tendinopathy of the shoulder, supraspinatus or rotator cuff (with and without calcification)
- Trochanter pain / trochanteric tendinosis / trochanteric bursitis
- Femoral tendinopathy
- Patellar tip syndrome / iliotibial band syndrome / patellar tendinopathy / jumper's knee
- Tibial edge syndrome / tendinopathy of the tibialis muscle / tibial tendonitis
- Achillodynia / Achilles tendinopathy
- Radial or ulnar humeral epicondylitis / tennis elbow / golfer's elbow / elbow tendinosis

Pseudoarthroses / non-healing / delayed-healing bone fractures

Plantar fasciitis / calcaneal spur

All applications listed here are possible with the MODULITH® SLK.

- However, please bear in mind that the ergonomics of the device do not support all types of positioning of the patient.
- Check in advance whether precise positioning is possible for the desired treatment type.

2.2 Lithotripsy

2.2.1 Contraindications

The following contraindications apply for high-energy focused shock wave treatments[1], especially for lithotripsy.

No patient treatment is allowed under the following circumstances:

- Target area cannot be definitely localised
- Malignant tumour in the shock wave path
- Thrombosis in the shock wave path
- Air-filled tissue (particularly lung tissue) in the shock wave path
- Brain or spinal column in the shock wave path
- Pregnancy
- Haemorrhagic diathesis, unless compensated for at least 24 hours before and 48 hours after treatment
- Untreated infection (e.g. urinary tract infection together with urinary tract stones)
- Aneurysm in the shock wave path
- Arterial calcium deposits in the shock wave path
- Anatomical obstruction in the distal periphery of the stone
- Pacemakers and defibrillators not authorised for ESWT / ESWL
- Ehlers-Danlos syndrome
- Acute hypertension
- Coagulopathies
- Thrombocytopenia
- Extended thromboplastin time
- Previous treatment with platelet aggregation inhibitors
- Treatment with anticoagulants
- Area of the epiphyseal plate in children
- Administration of contrast agents containing gases for ultrasound diagnostics less than 24 hours before treatment

2.2.2 Increased risk of side effects

There is an increased risk of side effects in the following cases:

- Obesity (BMI > 30)
- Very thin (BMI < 21.5)
- Single kidney
- Bilateral stones (do not treat both sides in one session)
- Diabetes mellitus
- Immunosuppression
- Heart disease
- Pre-existing arterial hypertension
- More than 4000 high-energy shock waves in one session

[1] Treatment with energy levels 10 - 90

Special precautionary measures

There are no contraindications in the following cases providing special precautionary measures are taken:

- Stones in the distal ureter in women of child-bearing age: Do not expose the patient to X-ray radiation, or only to a limited extent.
- Stones in children: Only use a low number of shock waves with low-energy intensities.
- Cysts in the shock wave path
- Cardiological risk groups: Carry out anaesthesiological monitoring during shock wave treatment.
- Pacemakers authorised for lithotripsy according to the manufacturer's information

In all the aforementioned cases, it is the responsibility of the doctor to decide whether a therapy can be undertaken in spite of any fundamental doubts, after stating the risk to the patient, obtaining a declaration of consent from the patient, and with due consideration for the medical risks. The normal precautionary measures apply to the treatment of at-risk patients.

2.2.3 Side effects

Treatment with the MODULITH® SLK may cause the following side effects and risks:

- Reddening of the skin and petechiae
- Haematuria
- Pain/colic
- Cardiac arrhythmia
- Urinary obstruction in kidneys due to steinstrasse
- Bruising of the skin at the shock wave entry point
- Haematoma
- Fever
- Injury to the kidney and neighbouring organs

2.3 Medical accompanying measures

Basically, the MODULITH® SLK permits treatment without anaesthetic. The decision as to whether anaesthetic is administered depends on the patient's sensitivity to pain and is left up to the discretion of the doctor giving treatment.

- Reassure the patient before starting treatment by conducting a detailed pre-treatment discussion.
  The patient must be observed and provided with the normal level of medical care during treatment.
- During the entire treatment, conduct interim checks on the fragmentation of the stone, observe the patient and (where applicable) monitor the anaesthetic effect
- Perform ECG monitoring if possible.

2.4 Low-energy targeted shock wave therapy

2.4.1 Contraindications

For low-energy targeted shock wave therapy [1] the following limited contraindications apply

No patient treatment permitted:

No patient treatment is allowed under the following circumstances:

- Malignant tumour in the treatment area
- Brain or spinal column in the treatment area
- Pregnancy

2.4.2 Side effects

- Swelling, reddening, haematoma
- Petechiae
- Pain

These side effects generally abate after 5 to 10 days.

[1] Treatments with energy levels 1 - 9

2.5 Preconditions for operation

2.5.1 Operating personnel

The MODULITH® SLK is intended exclusively for use by healthcare professionals and may only be used by qualified and instructed medical personnel. Such a specialist is expected to have practical knowledge of medical procedures and applications as well as of the technology and should be experienced in treating the indications stated in **2.1.1 INDICATIONS**.

The professional must have the basic physical and cognitive abilities required (e.g. vision, hearing, reading ability and good spatial awareness). Furthermore, the basic functions of the extremities must be guaranteed. The user must have adequate specialist knowledge for operating the imaging localisation systems. The device is designed for a demographic target group aged between 18 and 65 years.

2.5.2 Training of the operating personnel

Operators of the MODULITH® SLK must have been adequately trained in using this system safely and efficiently before they operate the device described in this manual. Basic training is provided by personnel authorised by STORZ MEDICAL AG using the operating manual and is documented in the device manual. The operator must be trained in the following areas:

- Operation and intended use of the device and equipment combinations, including practical exercises
- Effect and functionality of the device and equipment combinations as well as the applied energies
- Settings of all operating and control elements, including the positioning of the patient
- Training on correctly setting the ultrasound device in order to position the treatment area in the therapy focus
- Training on correctly setting the X-ray device in order to position the treatment area in the therapy focus
- Indications for use of the device
- Contraindications and side effects of shock waves
- Explanation of the warnings in all operating modes
- Information about the emergency stop function and procedure for freeing patients using the integrated compensation mechanism (rocker) in dangerous situations
- Training on how to perform the functional checks
- Localisation with ultrasound
- Localisation with X-ray, with reference to the potential risks.

Further training requirements vary from country to country. It is the operator's responsibility to ensure that the training meets the requirements of all applicable local laws and regulations. Further information about training on the operation of this system can be obtained from your STORZ MEDICAL AG dealer. You can also contact us directly at the following address:

STORZ MEDICAL AG		
Lohstampfestrasse 8	Telephone:	+41 (0) 71 677 45 45
Postfach	Fax:	+41 (0) 71 677 45 05
CH-8274 Tägerwilen		
Switzerland	URL:	www.storzmedical.com

2.6 Physical principles

A shock wave is an expanding acoustic wave which induces oscillation in the bulk of the material or even in individual atoms only. Shock waves differ from sinusoidal ultrasound waves in that they have steeply rising pressure pulses with only a small tensile wave component. This means the shock wave has a wide frequency spectrum. It undergoes significantly less attenuation in tissue compared to an ultrasound wave, which explains why the penetration depth is correspondingly greater. The shock waves are generated extracorporeally in the aqueous environment. Because water has approximately the same density as the tissues of the human body that contain liquids, there is little energy loss on transition of shock waves into the body.

The shock waves are induced in the patient's body by means of a coupling cushion with a diaphragm and a coupling agent.

2.6.1 Shock wave generation

In the therapy source of the device MODULITH® SLK, a rapid current pulse changes the diameter of a cylindrically shaped body. This gives rise to a cylindrical shock wave emanating outwards.

2.6.2 Focusing

The shock waves created in this way are focused by a paraboloidal reflector (**Fig. 2-1**). The penetration depth in the patient is 175 mm. The aperture opening is 178 mm. The spread of the focus varies slightly depending on the energy level selected. The reference values for the size of the focus are 6.3 mm x 62 mm. The size figures are given as length x diameter.

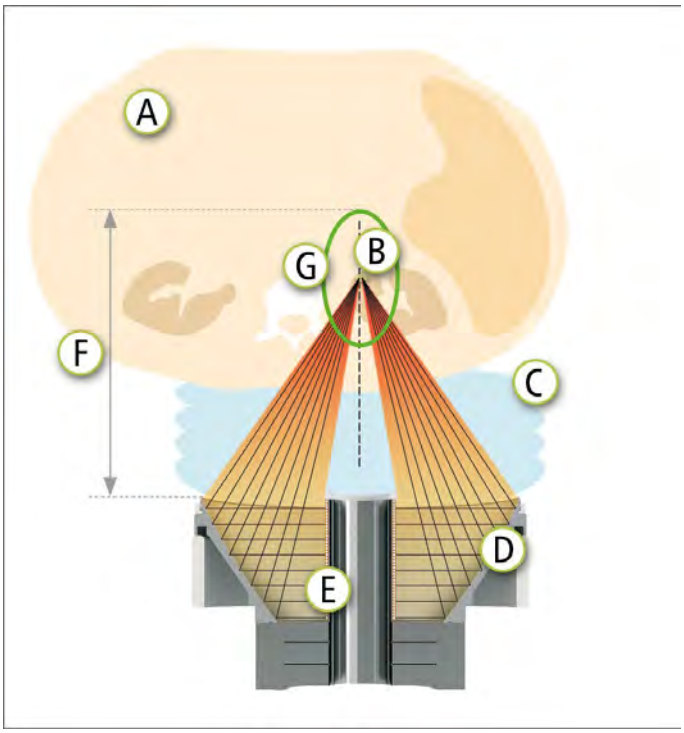


Fig. 2-1 Principle of the therapy focus

A) Patient's body
B) Focusposition
C) Coupling cushion
D) Reflector (with aperture opening of 178 mm)
E) Cylinder coil
F) Penetration depth (175 mm)
G) Focus volume

2.6.3 Propagation of the shock waves

The physical laws of acoustics apply to the propagation in media. This means shock waves are partially reflected and fragmented at boundaries between materials with different levels of acoustic impedance (sound resistance). They are conducted with almost no attenuation in tissue with similar acoustic impedance.

2.6.4 Effect of different media on shock waves

The performance of the shock waves works on the basis of the fact that compressive or tensile fluctuations arise at boundaries of media with different acoustic impedances. The greater this differential, the greater the effective energy at this point.

Therefore, care must be taken during treatment to ensure that the shock waves only pass through tissue with a similar acoustic impedance until the target area is reached. In particular, this means that no gas-filled structures (such as lung tissue) should be placed in the shock wave path. Applying shock waves through bone reduces shock wave energy and must be avoided where possible.

2.7 Functional principle

The shock waves are generated by a cylinder source and are focused by a paraboloidal reflector. They are coupled with the patient's skin by the water-filled therapy source via a diaphragm and coupling agent. When a shock wave passing through biological tissue or bodily fluid encounters a stone, this gives rise to high compressive and tensile stresses at the transition point. These exceed the mechanical strength of the stone and lead to crack formation. The same effects can be observed on the reverse side of the stone, where the shock waves emerge. When shock waves are used repeatedly, their effects can range from detaching small stone particles to the complete disintegration of the stone into extremely small concretions (sanding).

2.8 Conditions for setup

Any necessary measures must be agreed with the manufacturer before setting up the MODULITH® SLK device.

The ambient conditions specified below must be maintained.

Ambient conditions	Storage and transport	Operation
Ambient temperature	0°C - 60°C, frost-free	10°C - 30°C
Relative air humidity	5% - 95%, non-condensing	10% - 90%, non-condensing
Air pressure	500 hPa - 1060 hPa	800 hPa - 1060 hPa

Tab. 2-1 Ambient conditions

2.8.1 Electrical connection and fusing

The MODULITH® SLK is connected to the mains using a plug. The requirements for rooms used for medical purposes applicable in the particular country must always be observed. With regard to the mains connection, installation must be carried out in accordance with the applicable national regulations.

The following connection and fuse protection values apply:

Device version: 1 mains adapter	
Mains voltage	100 - 240 VAC
Mains frequency	50 Hz / 60 Hz
Power consumption	<1.0 kVA
Mains input voltage	10A

Device version: 2 mains adapters	
Mains voltage	230 VAC
Mains frequency	50 Hz
Power consumption	<1.0 kVA
Mains input voltage	10A
Mains voltage	115 VAC
Mains frequency	50 Hz / 60 Hz
Power consumption	<1.0 kVA

Device version: 2 mains adapters	
Mains input voltage	10 A

2.8.2 Hygiene requirements

The hygiene requirements for the room are absolutely dependent on how else the device is used.

2.8.3 Space requirements

A room measuring at least 4 x 5 m in size is recommended to ensure safe treatment with the MODULITH® SLK.

3 System Description

3.1 Complete system

The MODULITH® SLK consists of the following main components (**FIG. 3-1**):

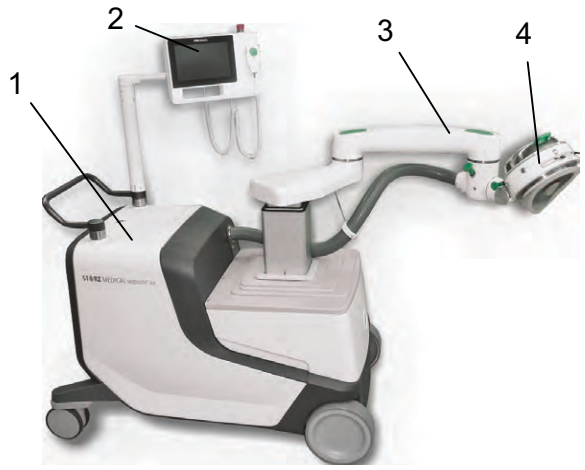


Fig. 3-1 MODULITH® SLK

1 Basic unit
2 Control panel
3 Therapy arm
4 Therapy head

An X-ray or ultrasound system can be used for localising and positioning the stone at the treatment focus.

The following section contains a description of the structure and function of the main components. For information about operating them, please refer to Chapter **4 CONTROLS AND OPERATION**.

Side definition

The sides of the device are defined as follows in this operating manual:

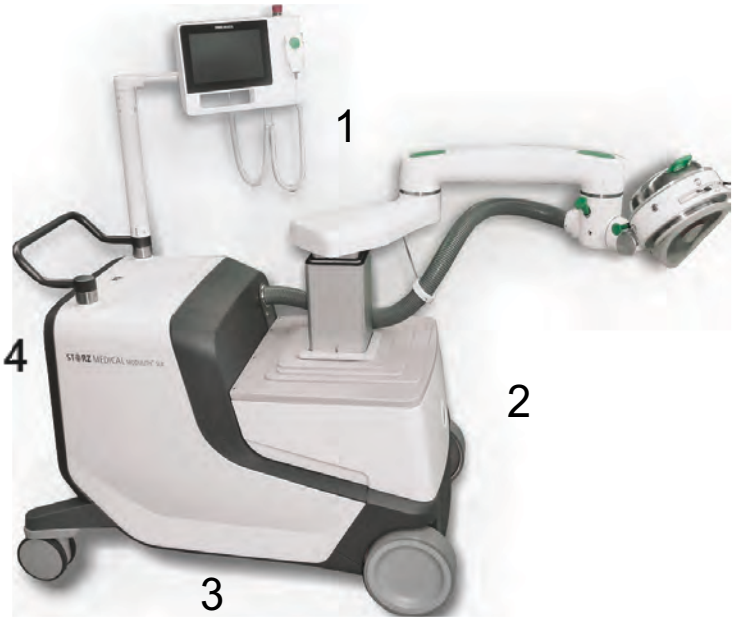


Fig. 3-2 Side definition of the device

1 Left side
2 Front
3 Right side
4 Rear

3.2 Therapy unit

3.2.1 Therapy arm and therapy head

The therapy arm connects the therapy head to the basic unit of the MODULITH® SLK. The therapy head is swivelled into the treatment position for shock wave treatment. The therapy arm makes it possible to position the therapy source precisely over the target area. Once it has been roughly positioned manually, it should be finely adjusted via the control panel touchscreen.

3.2.1.1 Rough manual positioning

The therapy arm features two unlock buttons and two unlocking pins. When these are operated, the relevant swivel joint is released and the arm segment can be moved.

Once the end position is reached, the joint re-engages of its own accord.

⚠ CAUTION

Risk of collision when the therapy head is moved.

Risk of crushing injuries to limbs!

► Always monitor movements of the therapy head visually.

Pressing both of the unlock buttons on the therapy arm allows you to adjust the angle of the relevant arm segment.

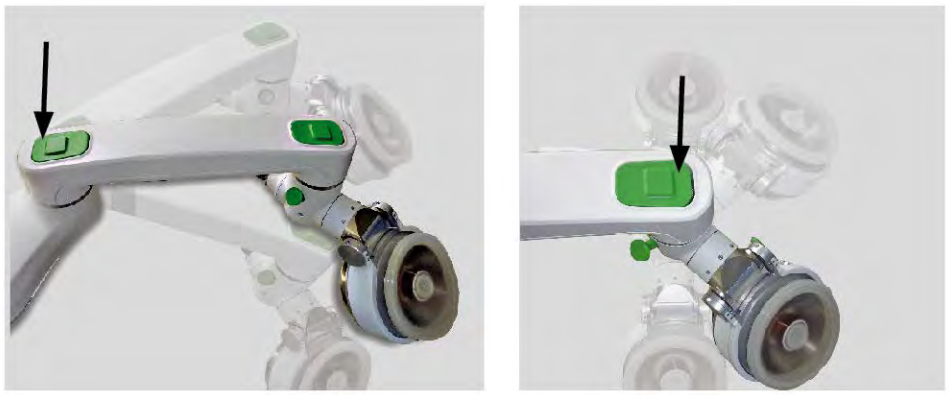


Fig. 3-3 Setting the angle of the arm segment

Pulling the rear unlocking pin (**Fig. 3-4**) frees the therapy head so that it can rotate. You can then move it into the UT or OT position.

Fig. 3-4 Unlocking the therapy head and rotating it manually

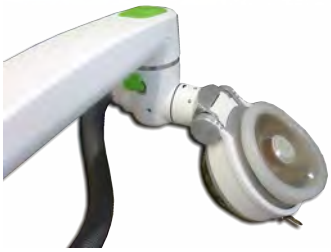
Pulling the front unlocking pin allows you to tilt the therapy head by 45°.

Fig. 3-5 Tilting the therapy head by 45°

Adjustable therapy head position

Treatment position OT 45° lateral

Treatment position UT 45° lateral



Treatment position OT 90° - AP

Service position (UT 0°)

3.2.1.2 Motorised fine positioning

The fine positioning of the therapy unit is carried out via the touch control panel.

Fig. 3-6 Touchscreen with arrow buttons for moving the therapy arm

You can use the navigation arrows to select the following direction of movement.

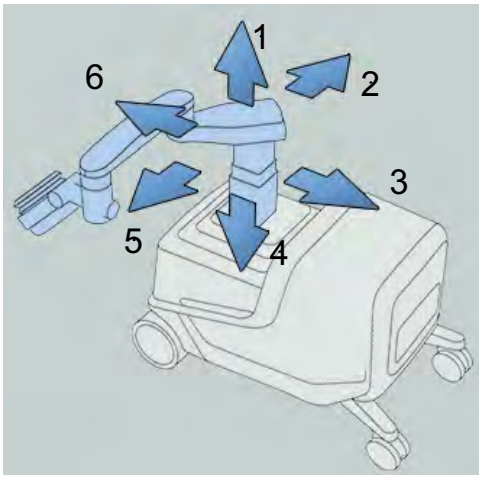


Fig. 3-7 Directions for motorised movement of the therapy arm

1 z-up
2 x-right
3 y-back
4 z-down
5 x-left
6 y-front

3.2.1.3 Possible treatment positions

If it is combined with a mobile patient table that has treatment cutouts in the side, the MODULITH® SLK can be used in both the UT and the OT positions. The therapy arm is angled and is parallel with the short edge of the device. The therapy head is positioned at a 45° angle in both cases. This allows the patient to be treated in the supine position and in the prone position.

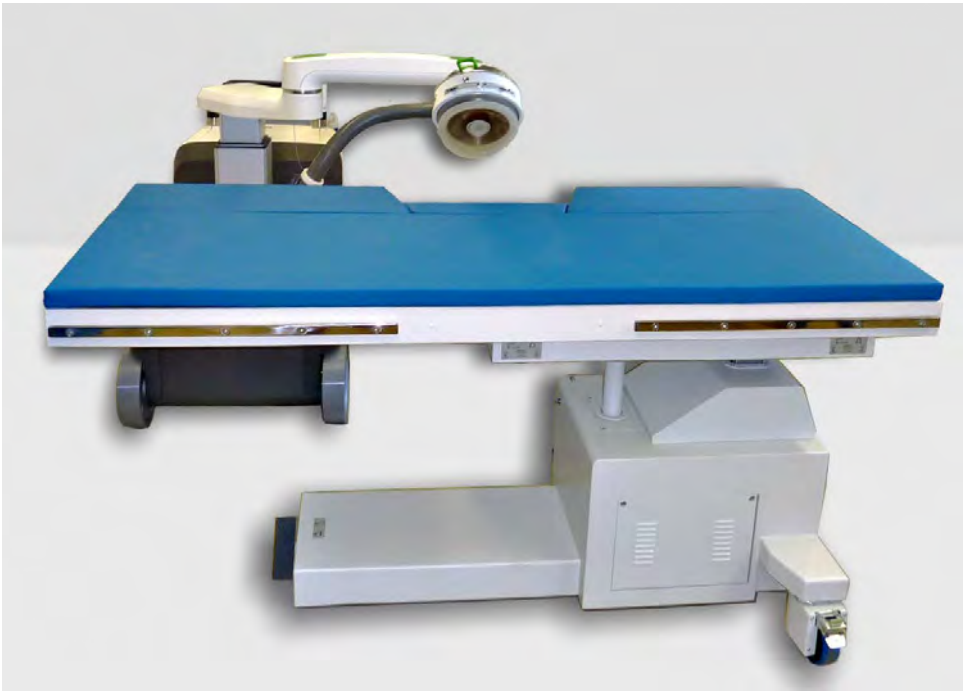


Fig. 3-8 Therapy head position: 45°- OT with table

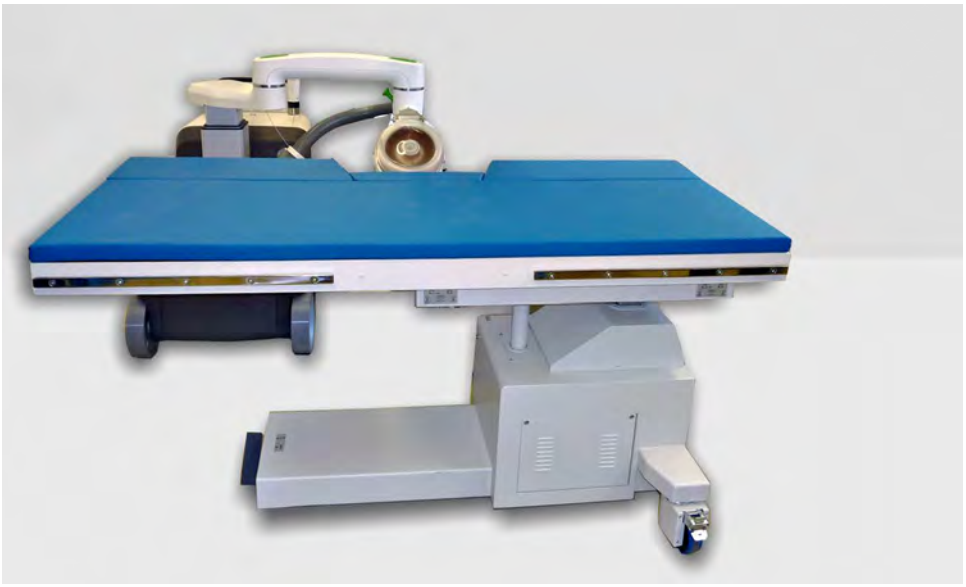


Fig. 3-9 Therapy head position: 45°- UT with table

For use with a urological X-ray workstation, the devices can be set up in relation to each other as follows:

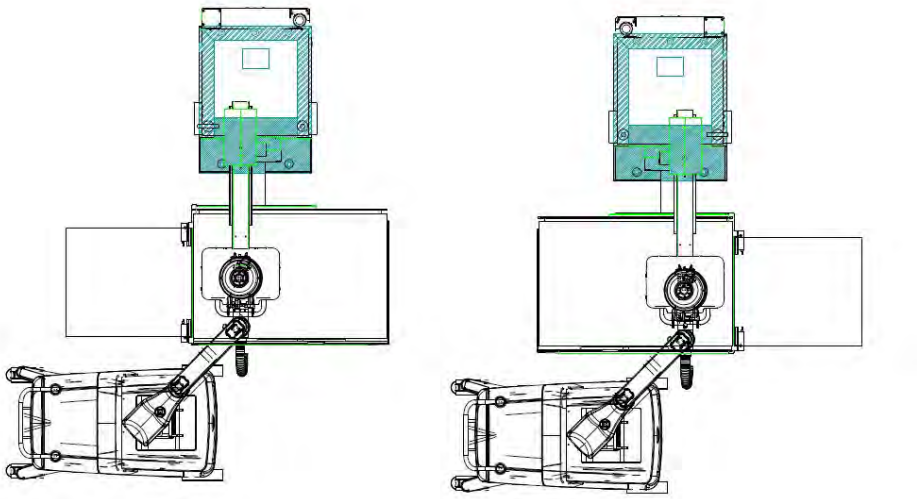


Fig. 3-10 Lithotripter and X-ray unit are each located on one side of the patient table

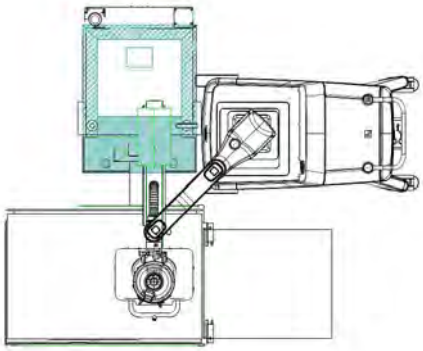


Fig. 3-11 Lithotripter and X-ray unit are on the same side

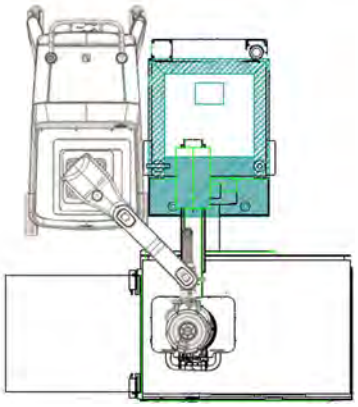


Fig. 3-12 Lithotripter and X-ray unit are next to each other at the front

For treatment in this particular environment, the therapy head must be in OT 90°. Stone therapy is performed with the patient in the prone position.

3.2.1.4 Park position

Whenever the device is not required, the therapy head should be swivelled into the park position on the right-hand side of the device. The supplied transport bracket should be fitted to support the therapy unit during storage and transport. (see Chapter **8.2 PREPARING THE DEVICE FOR TRANSPORT**).

Fig. 3-13 Park position

3.3 Control panel

The control panel of the device is composed of the following components:

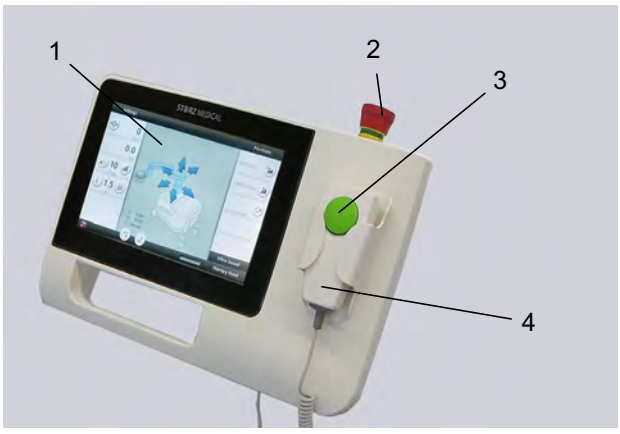


Fig. 3-14 Control panel

1 Display with touchscreen
2 Emergency stop button
3 SW trigger button
4 Hand switch

3.4 Joystick for movement control (optional)

The device can be controlled using a hand-held joystick as described in Chapter **4.1.4 JOYSTICK OPERATION (OPTIONAL)**.

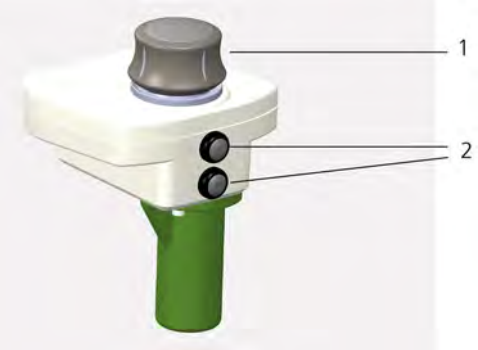


Fig. 3-15 Joystick controls, front

1 Controller (therapy arm control)
2 Ultrasound transducer controls

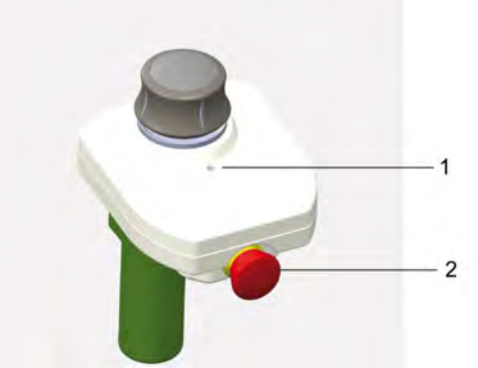


Fig. 3-16 Joystick controls, rear

1 Status LED
2 Emergency stop button

– An essential control element for the joystick is a three-axis controller for moving the therapy head.
– The joystick is attached to the connector with the remote control panel symbol ().
– The joystick can be stored in the gel bottle holder of the ultrasound device.

The joystick features a status light diode (LED). It can show four statuses:

Status LED	
Flashing green	Calibrate controller on control panel
Lit up steady green	Joystick is ready for use
Flashing red	The emergency stop button is being pressed
Lit up steady red	Internal error

3.5 Basic unit

The basic unit forms the base of the MODULITH® SLK and holds all components of the lithotripsy subsystems. The following items are installed in the basic unit:

- Electrical power supply
- Electronic control unit
- Shock wave generation and triggering system
- Water circuit
- Drive systems for moving the therapy arm
- Connectors for external devices/options

3.5.1 Water circuit and coupling cushion

The therapy source is coupled to the patient by means of the coupling cushion. The water circuit is used for generating the required coupling pressure. The circuit consists of a reservoir tank, the degassing system, pumps and control elements. The water is actively cooled. The coupling cushion on the therapy source is manually filled with water (coupled) or drained (decoupled). The device automatically controls the coupling pressure exerted on the patient and compensates for any changes in distance. If corrections to the coupling pressure are still required, these can be performed manually using the control panel. For this, please read Chapter **4.2.5 SETTING THE CUSHION PRESSURE**

If therapy is interrupted during treatment and the coupling cushion drained, the same initial position can be achieved again by repeating coupling.

3.5.2 Airbag

An airbag is installed inside the therapy head. The airbag permits in-situ X-ray localisation in the 0° position at urological workstations, whilst the patient is coupled to the therapy head. For X-ray localisation, the airbag is inflated with air in order to achieve good image quality due to the therapy source being filled with water.

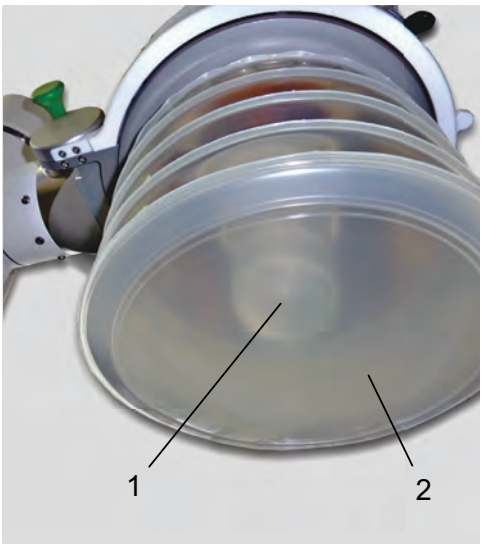


Fig. 3-17 Therapy source with airbag inflated

1 Airbag
2 Coupling cushion

The airbag can only be blown up if the therapy head is in the 0° OT treatment position and the coupling cushion is filled with water.

3.5.3 Triggering shock waves

Triggering

The shock waves are released by means of a trigger. You can choose between two trigger types:

1) Internal triggering
2) ECG triggering.

Internal triggering

Internal triggering releases shock waves at a fixed frequency of 0.5 Hz (one shock wave every two seconds) to 4 Hz (four shock waves per second). The maximum possible frequency for generating shock waves depends on the selected energy level. Increasing the energy level may reduce the shock wave frequency. The energy of the shock waves can be adjusted between levels 1 and 90 using the buttons in the 'Shock wave' area. Level 90 corresponds to the highest energy level. The range between the minimum and maximum energy values is subdivided into 26 different levels. The selected energy level is displayed on the screen. The magnitude of energy for individual treatment depends on the composition and size of the stone to be fragmented, as well as the patient's pain sensation.

ECG triggering

Shock waves can be triggered by means of ECG-controlled triggering.

- Please note that only additional devices supplied by the manufacturer are to be used for ECG triggering.

3.5.4 Shock wave parameters

Treatment with shock waves is influenced by the following parameters:

Parameters	Settings options
Shock wave energy	Can be adjusted between 1 and 90 in the 'Shock wave' function. The energy level can be changed during shock wave triggering.
Trigger type	Can be adjusted to various values in the 'Shock wave' function for internal or ECG triggering.
Number of shock waves	Not more than 4000 shocks should be administered in each treatment. The precise amount is defined by the doctor based on medical aspects.

Tab. 3-1 Shock wave parameters

3.6 External connectors

Some connectors for external devices can be found on the rear of the basic unit. These connectors can be used for optional connection of the following devices:

– ECG device
– Hand switch with trigger button
– Remote control panel
– optional: Collision detector for mobile C-arms

The connector for the collision detector is not used on this device. A dummy connector must always be used in this connector while the device is in operation (see **FIG. 3-18 EXTERNAL CONNECTOR PLATE**). If the device is operated with two remote control panels, one is always locked and must be unlocked by touching the screen.

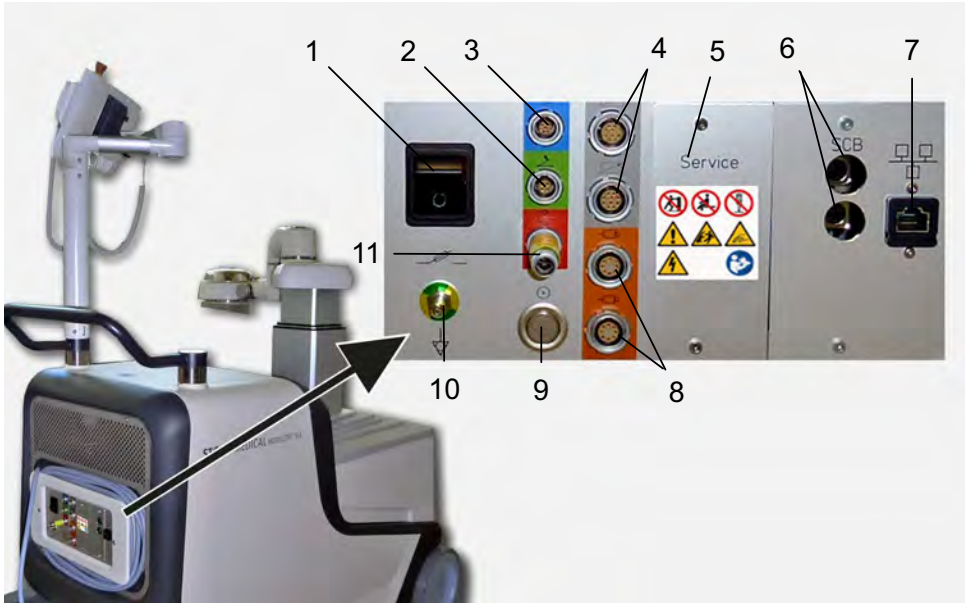


Fig. 3-18 External connector plate

1 Main switch
2 Foot switch connector (not in use)
3 ECG triggering connector
4 Control panel / remote control panel / joy stick connectors
5 For service personnel only
6 SCB connectors (optional)
7 Ethernet connector (optional)
8 Connector for additional hand switches
9 Reset button (for service personnel only)
10 Potential equalisation connector
11 Connector for collision detector with dummy connector

3.6.1 Connecting additional device

DANGER

Use of incompatible additional devices:

Risk to health due to incorrect treatment

- ► Only connect devices to the MODULITH® SLK that have been authorised by the manufacturer.
- ► Also read Chapter **3.7 COMPATIBLE ADDITIONAL DEVICES**

3.6.2 ECG devices

The ECG device for ECG-controlled triggering is an option and is not included in the standard scope of delivery.

- Check whether this option forms part of your device configuration.

The ECG device must be connected to the MODULITH® SLK in order for shock waves to be triggered via ECG.

The installation site must be carefully selected so that the operator can read the screen with ease.

- Connect the ECG cable to the female connector with the ECG signal.

⇨ *The connection for ECG-controlled triggering has been established.*

NOTICE

Risk of collision during therapy head movements.

Damage to equipment may occur.

► Pay attention to the swivelling range of the therapy arm.

3.6.3 Option: Remote control panel

With the optional remote control panel, the MODULITH® SLK can be controlled from a remote control workstation. This means the radiation exposure of the user is reduced to a minimum. The remote control panel corresponds to the normal control panel.

- Check whether this option forms part of your configuration.
- Connect the remote control panel to the female connector with the remote control panel symbol.

⇨ *The connection for the remote control panel has been established.*

3.6.4 Option: Collision detector for mobile X-ray C-arms

Option: Collision detector for mobile X-ray C-arms

- Check whether this option forms part of your device configuration.
- Connect the collision detector for mobile X-ray C-arms to the socket with the C-arm symbol .

3.6.5 In-line unit

- Connect the brown coded spiral cable of the in-line unit for in-line ultrasound localisation to the connector (**FIG. 3-19** /1) at the therapy head.

Fig. 3-19 Connector for the in-line unit

1 In-line unit connector

3.7 Compatible additional devices

3.7.1 X-ray devices

List of suitable C-arms	
Manufacturer	Type
Philips	BV Libra
	BV Endura
	BV Pulsera
	Vectra
Technix	TCA 6
Ziehm Imaging	Ziehm Solo
	Ziehm Compact
	Ziehm 8000
	Ziehm Vision R
	Ziehm Vision FD
GE Healthcare / OEC Medical Systems	7700 Series/Compact
	7900 Fluorostar
	GE OEC Brivo 850
	GE OEC Brivo 785
ATS	Arco FP
	Arco FP-S
Siemens	Cios Fit
	Cios Select
	Cios Connect
	Cios Fusion
	Cios Flow

Tab. 3-2 List of suitable devices

3.7.2 Urological workstations

The MODULITH® SLK can be used in combination with the following urological workstations.

List of suitable systems	
Manufacturer	Type
STORZ MEDICAL	Primera ST 360
SIEMENS Healthineers	Uroskop Omnia Max

Tab. 3-3 List of suitable devices

3.7.3 Ultrasound devices

The following ultrasound devices are allowed to be operated together with the MODULITH® SLK.

List of suitable ultrasound devices	
Manufacturer	Model
HITACHI ALOKA	Prosound 6
HITACHI ALOKA	Prosound 2
HITACHI ALOKA	3500 SX
FUJIFILM / HITACHI / ALOKA	F37
Samsung	HS50
Samsung	HS30

Tab. 3-4 List of suitable devices

Technical specifications, connection ratings and application conditions are detailed in the separate operating manual for the ultrasound device. The separate operating manual also provides you with information about other applications. The ultrasound device is informed of the position of the in-line transducer by means of a control cable.

3.7.4 ECG devices

The following ECG devices are allowed to be operated together with the MODULITH® SLK.

List of suitable ECG devices	
Manufacturer	Model
STORZ MEDICAL	StorM Sync S
Mindray	iPM8, ePM10

Tab. 3-5 List of suitable ECG devices

3.7.5 Patient table

The MODULITH® SLK may only be used in conjunction with tables that satisfy the requirements of the EN 60601-2-54, EN 60601-2-43 or EN 60601-2-46 standards and that are equipped with an emergency stop button.

4 Controls and Operation

4.1 Controls

4.1.1 Main switch

The main switch for switching the lithotripter on and off is located on the back of the device.

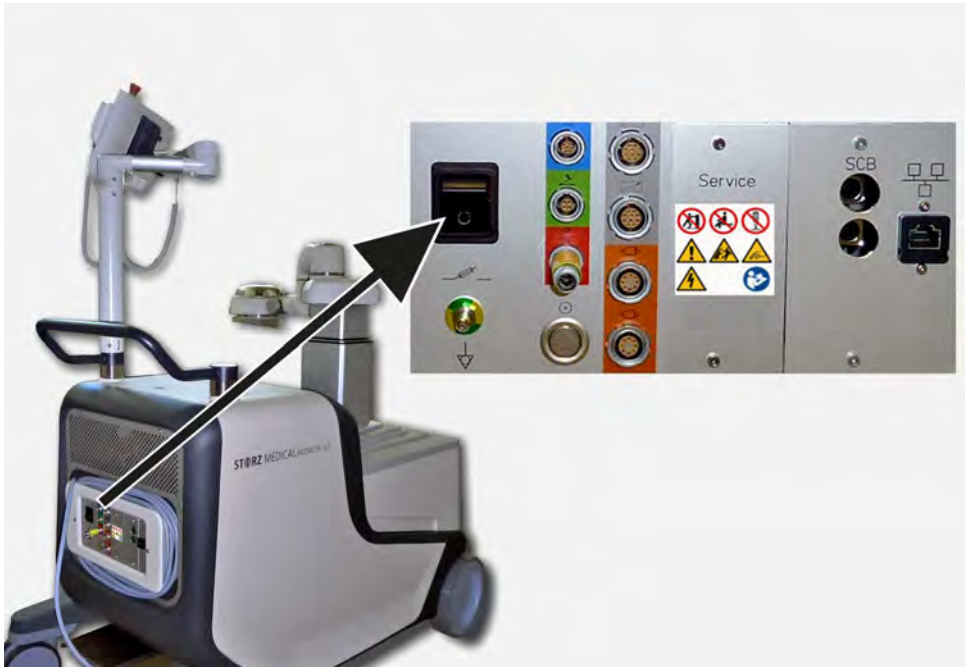


Fig. 4-1 Main switch

4.1.2 Control panel

4.1.2.1 Emergency stop buttons

The emergency stop button of the MODULITH® SLK is integrated in the control panel and is easily accessible.

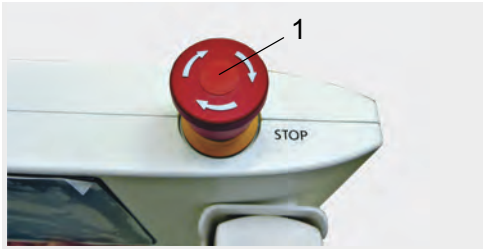


Fig. 4-2 Emergency stop button in the control panel

1 Emergency stop button in the control panel

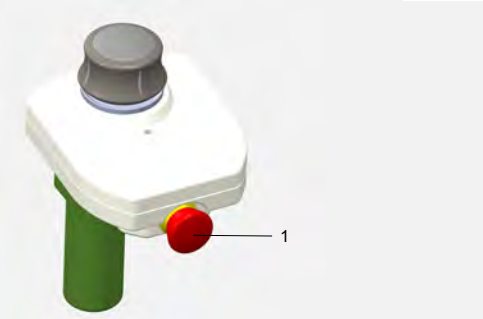


Fig. 4-3 Emergency stop button in the (optional) joystick

1 Emergency stop button in the joystick

Triggering an emergency stop

- Immediately press the red emergency stop button in case of danger.
  ⇨ *The emergency stop button remains latched after it has been activated, and is illuminated.*

⇨ *All movements of the device and shock wave triggering are stopped. The coupling cushion is deactivated.*

Cancelling an emergency stop

The emergency stop button may only be unlatched if the cause of the danger has been eliminated.

- Confirm the error message on the display by pressing the "Alarm off key".
- Turn the emergency stop button to release it
  ⇨ *Movements can be performed again.*

4.1.3 Hand switch

- The green button on the hand switch (1) triggers the shock waves.
- The release button on the rear of the switch (2) enables the therapy head to be moved while the shock waves are being administered.

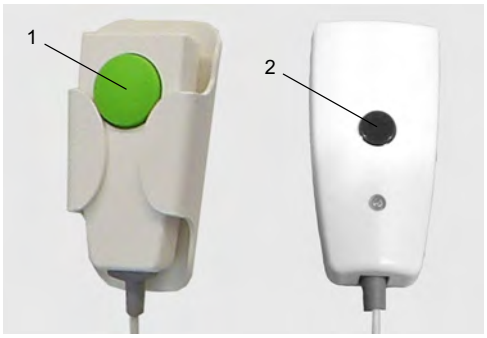


Fig. 4-4 Hand switch

1 SW trigger button
2 Release button

4.1.3.1 Triggering shock waves

- Press and hold the SW trigger button.
  ⇨ *Shock waves are triggered at the set frequency and energy level for as long as you keep the button pressed.*
- Release the SW trigger button if you want to interrupt the treatment.
  ⇨ *Shock wave triggering is stopped.*
- Press the SW trigger button again in order to continue treatment.

Triggering stops automatically after each batch of 1000 shock waves.
- Before continuing treatment, check the position of the target area.

4.1.3.2 Enabling motorised movement of the therapy head

Motorised movement during shock wave triggering is only possible if the user presses the release button on the rear of the hand switch at the same time as pressing the relevant navigator button on the control panel. This is to prevent the therapy head from being moved by mistake.

- For further information, consult Chapter **4.2.2 MOVING THE THERAPY HEAD** .

4.1.4 Joystick operation (optional)

If the optional joystick is connected, the LED in front of the controller will flash green. A status message will appear on the control panel display.

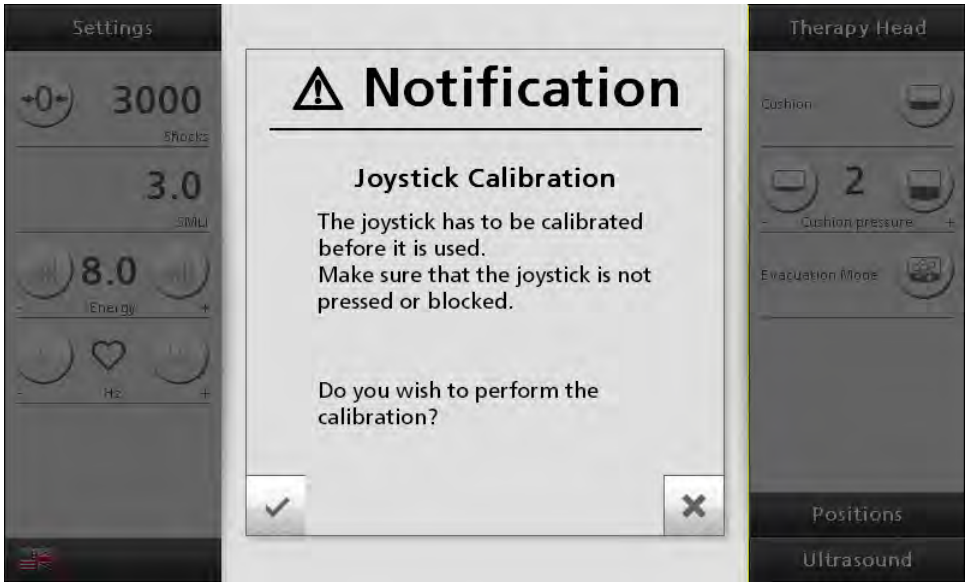


Fig. 4-5 Joystick calibration information

- Make sure that the joystick is not being operated or blocked.
- Confirm the message.

  The LED joystick lights up a steady green.
  ⇨ *It is now possible to move the therapy head and the inline transducer.*

⇨ *If you do not confirm the message, it will be displayed again the next time you move the joystick.*

4.1.4.1 Therapy head controller

- The therapy head can be moved vertically up or down (along the Z axis) by pressing the controller down or pulling it up.
- The therapy head can be moved horizontally (along the X axis) by pushing or pulling the controller in the direction of the emergency stop button or the inline transducer buttons.
- The therapy head can be moved horizontally left or right (along the Y axis) by pushing the controller to the left or the right.

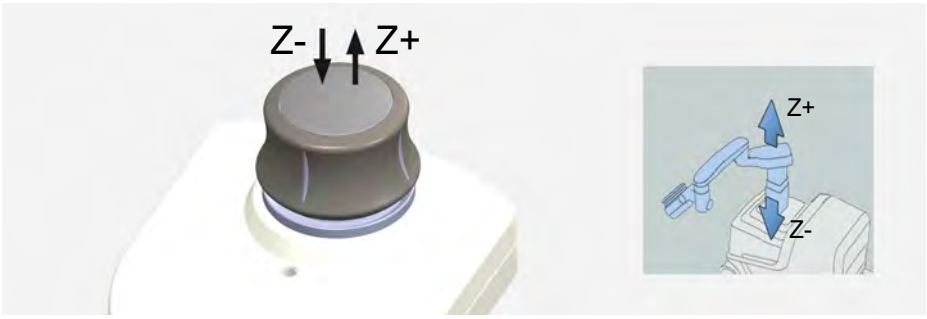


Fig. 4-6 Vertical movement in Z direction (up / down)

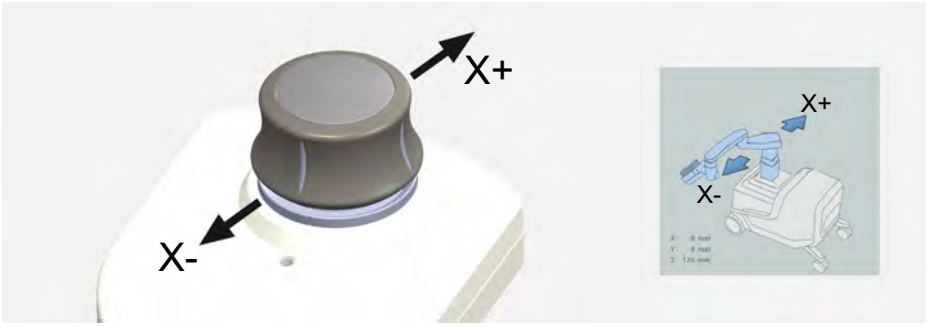


Fig. 4-7 Horizontal movement in X direction

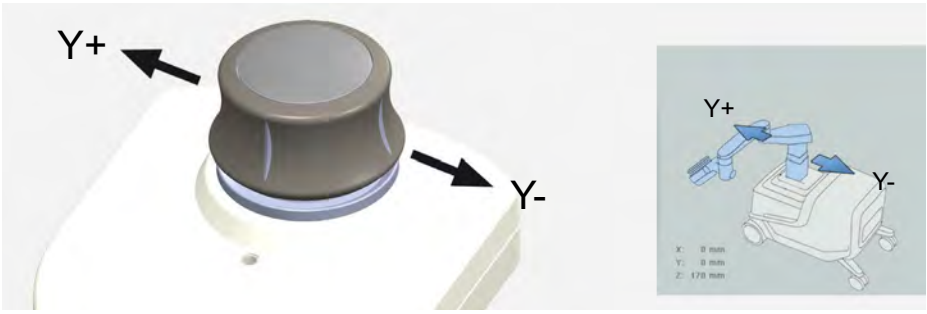
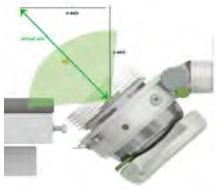


Fig. 4-8 Horizontal movement in Y direction

 *Fig. 4-9 Gradual movement by +/- 45°*	Turn the joystick: The therapy head moves +/- 45°. 

4.1.4.2 Inline transducer controls

You can use the joystick to control the ultrasound inline transducer (optional) (see Chapter **3.1 COMPLETE SYSTEM**

- Press the top button (**FIG. 4-10** / 1).
  ⇨ *As long as you keep the button pressed, the ultrasound inline transducer will be moved in (away from the patient).*
- Press the bottom button (**FIG. 4-10** / 2) and hold it down.
  ⇨ *The ultrasound inline transducer will be moved out (towards the patient).*

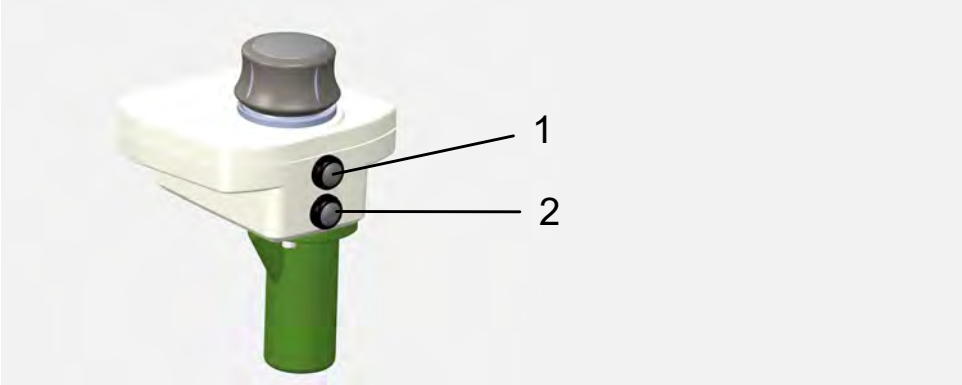


Fig. 4-10 Control of the ultrasound inline transducer

1 Transducer: away from patient
2 Transducer: towards patient

4.1.5 Load compensation mechanism (rocker)

If the therapy head exerts too much contact pressure on the patient, the MODULITH® SLK is able to change position and reduce the load thanks to its integrated load compensation mechanism (rocker). If the therapy head encounters an obstacle, the additional force on the therapy head causes the rocker to change position in the lifting column base. The therapy unit 'tips' backwards by a few degrees, thereby reducing the pressure on the patient/obstacle.

At the same time, motorised movement of the device is brought to an emergency stop and the coupling cushion is deactivated.

The device signals this using:

– An acoustic warning signal
– A row of flashing red warning LEDs on the therapy head
– A warning message on the control panel display

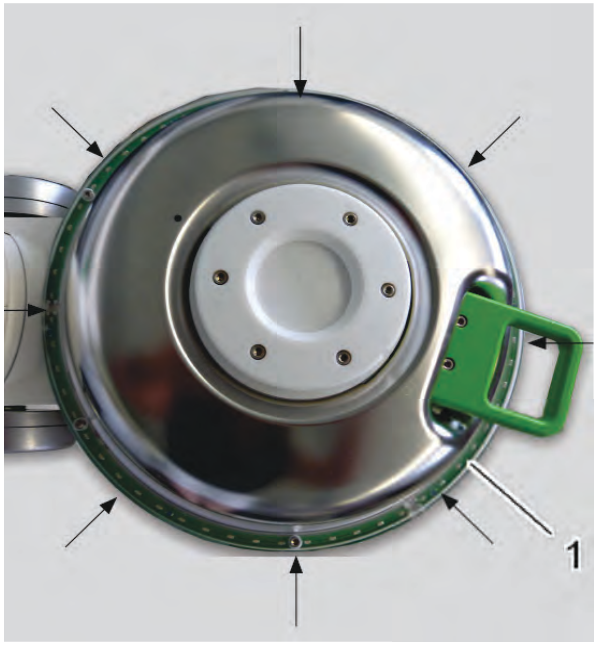


Fig. 4-11 Device signalling risk of collision

1 LEDs around the therapy head light up red if a load compensation has been triggered

Proceed as follows:

- Remove the obstacle from the travel path.
- Move the patient table out of the collision area with the patient still on it.
- If the patient table can no longer be moved, follow the instructions in Chapter **4.1.6 FREEING THE PATIENT AFTER A POWER FAILURE** .
  ⇨ *As soon as the force stops being applied to the therapy head, the therapy unit re-engages in the horizontal position.*
- Confirm the message on the control panel.

4.1.6 Freeing the patient after a power failure

The therapy head cannot be moved by the motor if the electrical power supply is interrupted. To allow the patient to dismount after OT treatment, you must separate the therapy head from the patient and swivel it away from the treatment area manually.

- Switch the device off at the main switch.
- Release the brakes on the MODULITH® SLK
- Raise the therapy arm until the therapy head separates from the patient and the therapy unit 'tips' back slightly.

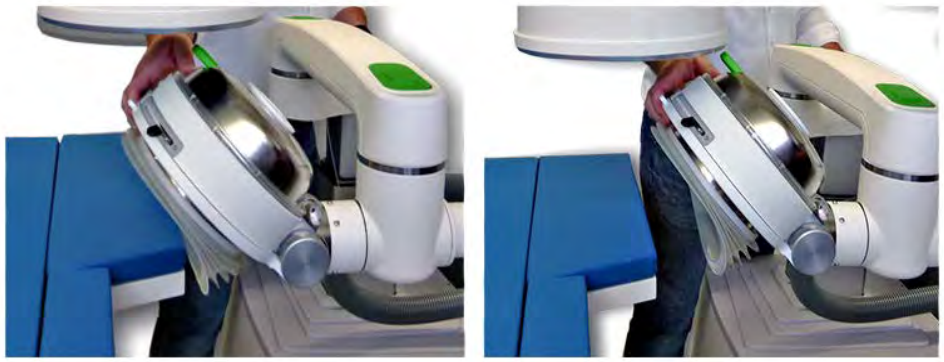
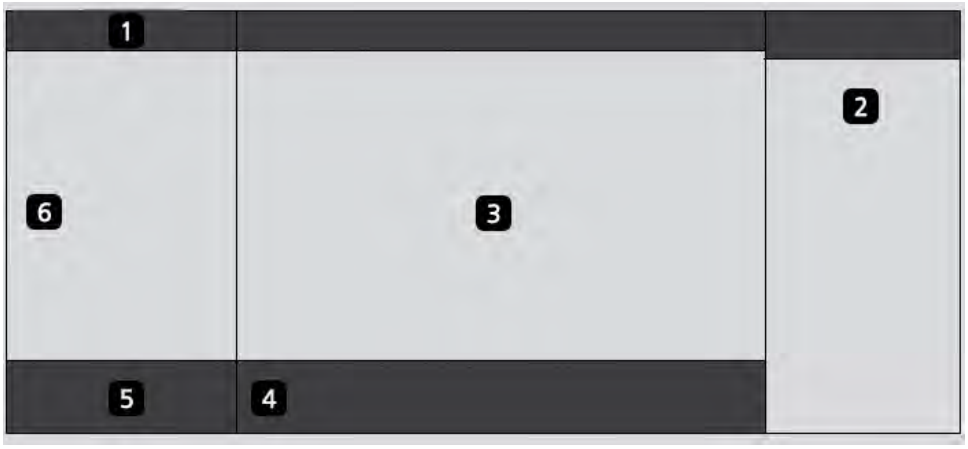


Fig. 4-12 Tipping the therapy unit to free a patient after a power failure

- Roll the MODULITH® SLK away from the patient.
- Secure the wheels again and reapply the foot brake.

4.1.7 Display

The screen consists of a colour LCD display with a resolution of 800 x 480 pixels. The display is divided into various areas in order to display different information.



1 Settings
2 Function fields: Therapy head - Table positions - Ultrasound
3 Function field for movements - Arrow keys for moving the patient table and therapy head
4 Buttons for the mounting and treatment position / Progress indicator
5 Language / Date / Time
6 Function field for shock wave parameters

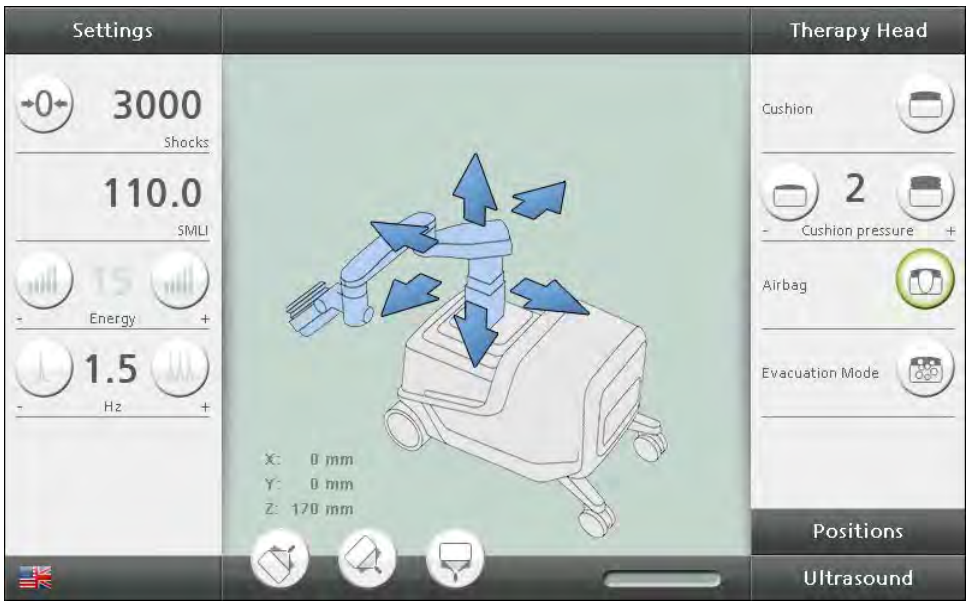


Fig. 4-13 Structure of the display

WARNING

If a control panel display or a touchscreen / operating monitor should fail, the safety of the patient can no longer be ensured

Risk of patients being placed under strain due to ineffective treatment or even impairments to their health!

- ► Abort the treatment.
- ► Inform your service centre.

4.1.8 Meaning of the individual symbols

Display of the function status

The status of the individual functions is indicated by the colour of the buttons.

 Normal display	Field is active – function can be selected
 Field has a green outline	Field is active – function is being performed
 Field is semi-transparent	Field is passive – function cannot be selected

Tab. 4-1 Display of the function status

The left function field is used for displaying and setting the shock wave parameters.

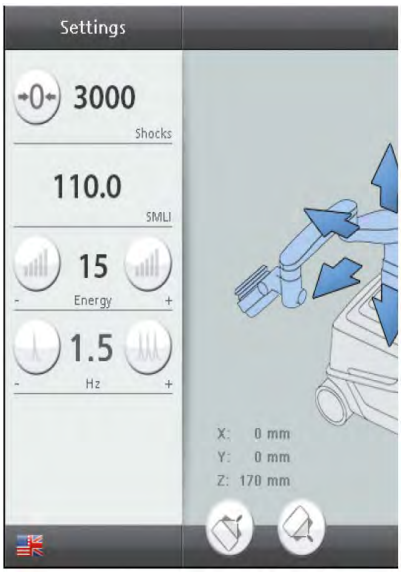
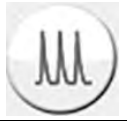


Fig. 4-14 Shock wave parameter function

Symbols	Meaning
	Reset field
	Optional: Exporting treatment data
	Reduce energy level
	Increase energy level
	Reduce frequency
	Increase frequency

Tab. 4-2 List of symbols for shock wave parameters

Function field for therapy head movements

Pressing the arrow buttons in the Movement function field triggers movements of the therapy head.

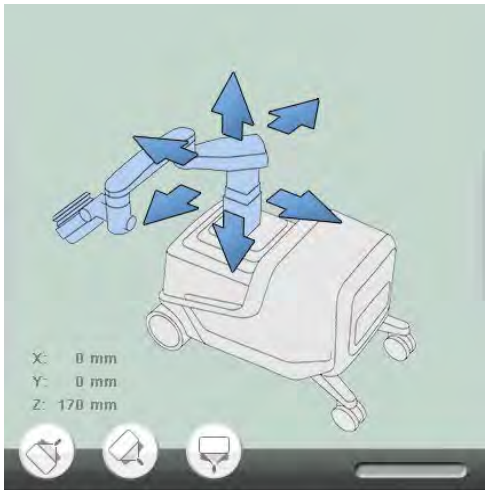


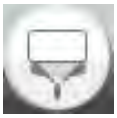
Fig. 4-15 Function field for movement

The status of movement sequences is indicated by the arrow symbols.

Therapy head movements

Symbols	Meaning
Blue arrow 	This movement direction can be selected.
Blue arrow with white outline 	Movement is being executed in the direction of the arrow.
Semi-transparent arrow 	This movement direction cannot be selected.
Semi-transparent arrow with bar 	The limit position has been reached. This movement direction can no longer be selected.
Blue arrow with yellow bar 	The required movement cannot be selected because the travel path is blocked. The required movement can only be performed after the blockage situation has been resolved.

Tab. 4-3 Arrow symbols for therapy head movements

Symbols	Meaning
	Call up most recently saved UT position
	Call up most recently saved OT position
	Call up most recently saved OT 90° position

Tab. 4-4 Buttons – calling up saved positions

Function field for therapy head

Various function fields can be activated in the side menu of the display by pressing the corresponding button. The activated function field then moves to the top line of the display, while the other function fields are arranged at the bottom.

- Press THERAPY HEAD to activate the field and see the various functions.

Fig. 4-16 Function field therapy head MODULITH® SLK

Symbols	Meaning
	Coupling cushion on/off
	Reduce cushion pressure
	Increase cushion pressure
	Airbag control on/off
	Venting the therapy head

Tab. 4-5 List of symbols for therapy head

Function field for ultrasound

Various function fields can be activated in the side menu of the display by pressing the corresponding button. The activated function field then moves to the top line of the display, while the other function fields are arranged at the bottom.

- Press ULTRASOUND to activate the field and see the various functions.

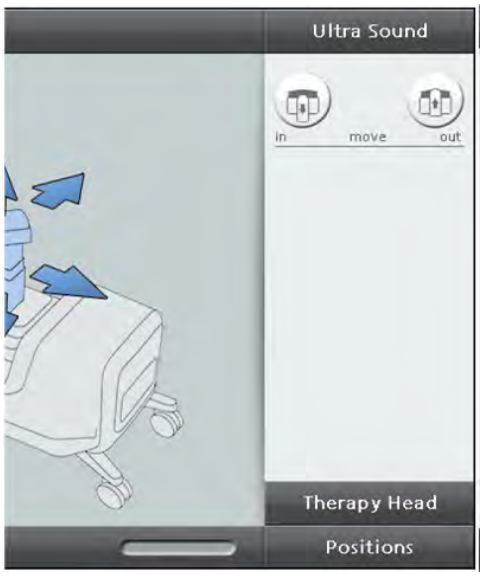


Fig. 4-17 Function field for ultrasound

Symbols	Meaning
	Move in ultrasound in-line unit
	Move out ultrasound in-line unit

Tab. 4-6 List of symbols for ultrasound

Function field for positions

Various function fields can be activated in the side menu of the display by pressing the corresponding button. The activated function field then moves to the top line of the display, while the other function fields are arranged at the bottom. Press POSITIONS to activate the field and see the various functions.

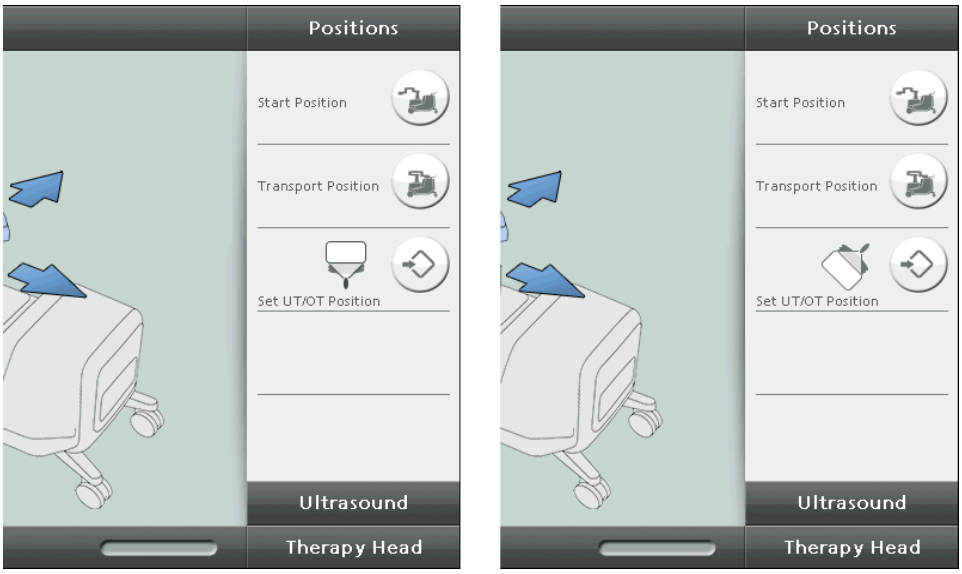
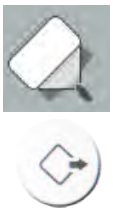
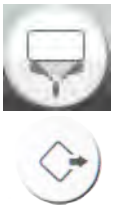


Fig. 4-18 Function field – positions

Symbols	Meaning
	Move to the starting position
	Move to the transport position
	Save OT position (only if therapy head is in OT)
	Save UT position (only if therapy head is in UT)
	Save OT 90° (only if therapy head is in OT)

Tab. 4-7 Symbols for Positions

4.2 Touch Screen: Operation

You can access all functions of the MODULITH® SLK via the control panel display. The procedures are explained below:

4.2.1 Setting shock wave parameters

4.2.1.1 Resetting parameter settings

Prior to starting a new therapy session, you should reset all parameters to their initial values.

- Press -0- SHOCK WAVE PARAMETERS in the function field.
  - ⇨ *The display in the shock waves (SW) line is reset to 0.*
    The energy level and frequency are reset to their respective start values
    The coupling cushion is deactivated and the degassing process commences.

⇨ *You can start a new treatment.*

4.2.1.2 Exporting SMLI / treatment parameters (option)

The SMLI (Storz Medical Lithotripsy Index) reflects the cumulative shock wave energy value administered in the course of a treatment. Using the SMLI, it is possible to compare the total energy applied in shock wave treatments conducted with different energy levels and involving different numbers of shock waves. You can save the SMLI at the end of each treatment after resetting the shock wave display.

- Press ◇ in the SHOCK WAVES function field.
  - ⇨ *The SMLI value is provided at the interface to an external software application (e.g. StorM-Base).*

4.2.1.3 Selecting the energy level

The energy level of the shock waves can be changed in the range from level 1 to level 90.

90 corresponds to the highest energy level. To set the required energy level

- Press the ENERGY line to increase the energy level or
- Press in the ENERGY line, to reduce the energy level.
  - ⇨ *The selected energy level appears in the ENERGY line.*

⇨ *Shock wave triggering now takes place with the set energy level.*

The energy level is increased or decreased in the range from 1 to 10 in increments of 1 and in the range from 10 to 90 in steps of 5.

4.2.1.4 Selecting the trigger frequency

The device triggers shock waves at a fixed frequency of 0,5 Hz (one shock wave every two seconds) to 4 Hz (four shock waves per second).

- Press in the FREQUENCY line to increase the frequency, or
- Press in the FREQUENCY line to reduce the frequency level.
  - ⇨ *The selected shock wave frequency appears in the FREQUENCY line.*

⇨ *Shock wave triggering now takes place at the set frequency.*

The maximum possible frequency for generating shock waves depends on the selected energy level. When increasing the energy level, the shock wave frequency is reduced if necessary (see Chapter **5.4 TREATMENT – LITHOTRIPSY**).

4.2.2 Moving the therapy head

⚠ CAUTION

Risk of collision when the therapy head is moved.

Risk of crushing injuries to limbs!

► Always monitor movements of the therapy head visually.

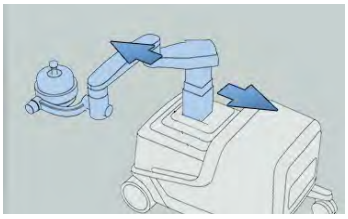
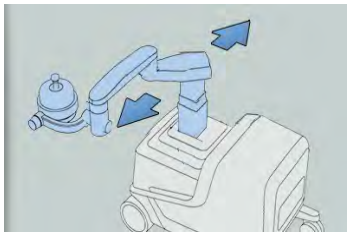
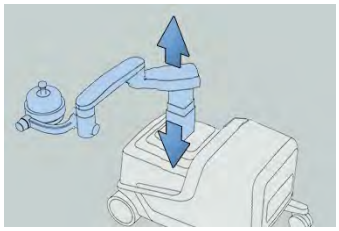
⚠ CAUTION

Risk of collision when the therapy head is moved.

Risk of crushing injuries to limbs!

► When setting up the ECG device, make sure it is outside of the swivel range of the therapy arm.

- Therapy head movements are performed using the following arrow buttons:

Arrow symbol	Movement
	Horizontal movement in Y direction (in combination with C-arm: lateral)
	Horizontal movement in X direction (in combination with C-arm: caudal/cranial)
	Vertical movement in Z direction (up/down)

Tab. 4-8 Movement directions of the therapy head

Motorised movement is only possible if the user presses the black release button on the rear of the hand switch at the same time as pressing the relevant arrow button. This is to prevent the therapy head from being moved by mistake.

- Manually pre-position the therapy head in one of the therapy positions.

The therapy head can be moved while shock waves are being administered if the black release button and the green button on the hand switch are pressed simultaneously.

- Press the black release button on the back of the hand switch and hold it down.
- Also press the arrow button that corresponds to the required direction of movement on the touchscreen.

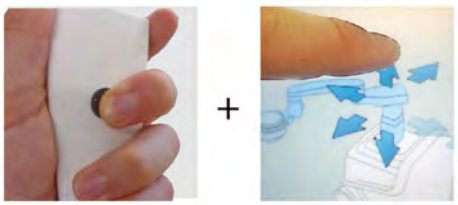


Fig. 4-19 Moving the therapy head

⇨ *The arrow button is given a white outline.* 
The therapy head moves in the direction of the arrow.

- Keep the arrow and the release button pressed until the required position is reached.
  ⇨ *The therapy head remains stable in the selected position once you release the buttons.*

The design of the particular patient or X-ray table determines whether it is preferable for the therapy head to be used in the 0° position (OT) or in the 45° position (UT/OT).

4.2.2.1 Store the therapy head position

To save a therapy head position for treatment in UT 45° or OT 45°:

- Under POSITIONS press the save button and hold down for approx. 3 seconds.

⇨ *The position has been successfully saved when:*
- the relevant position button in the lower area of the display has a green outline.
- a therapy head symbol with a tick is shown on the display.

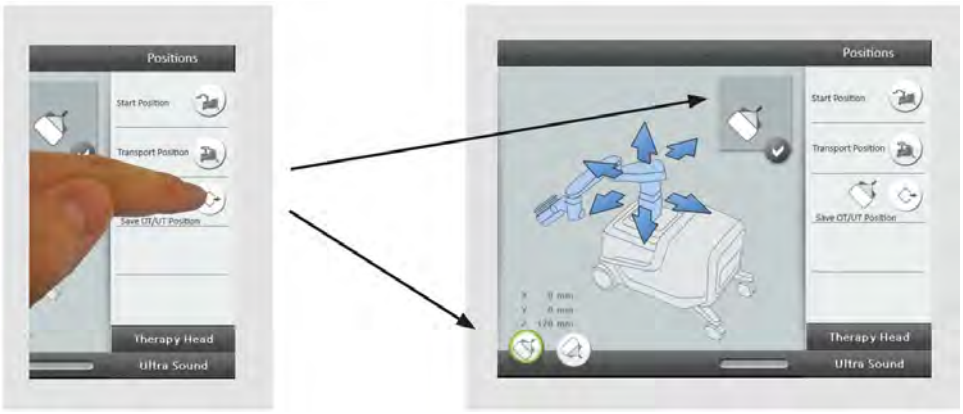


Fig. 4-20 The therapy head position in 45° UT was saved successfully

4.2.2.2 Calling up stored therapy head positions

To call up a saved therapy head position:

- Press the black release button on the back of the hand switch and hold it down.
- Also press the required position button in the area at the bottom-left of the display until a signal tone is heard.

Fig. 4-21 Calling up stored therapy head positions

- Once the signal tone is heard, you can release the position button. Keep the release button pressed down.
  ⇨ *The device will now automatically move to the saved position.*

⇨ *The saved position has been reached when:*
- the relevant position button in the lower area of the display has a green outline.
- a therapy head symbol with a tick is shown on the display.

If the therapy head symbol with a tick is not shown, the therapy head is not correctly positioned.
A screen then appears prompting you to rotate the therapy head in OT or UT.

Manually rotate or tilt the therapy head into the correct position and ensure that it is locked.

4.2.3 Move to the starting position

To move the therapy head to the start position (X = 0, Y = 0, Z = 99):

- Press the black release button on the back of the hand switch and hold it down.
- Press the button under POSITIONS until a signal tone sounds.

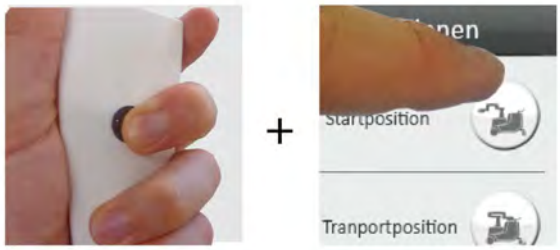


Fig. 4-22 Move to the starting position

- Once the signal tone is heard, you can - release the button. Keep the release button pressed down.
  ⇨ *The device will now automatically move to the start position.*

⇨ *The start position has been reached when:*
- the symbol for the start position with a tick is shown on the display.

4.2.4 Move to the transport position

To move the therapy head to the transport position (X = 0mm, Y = -70mm, Z = 160mm):

- Press the black release button on the back of the hand switch and hold it down.
- Press the button under POSITIONS until a signal tone sounds.

Fig. 4-23 Move to the starting position

- Once the signal tone is heard, you can - release the button. Keep the release button pressed down.
  ⇨ *The device will now automatically move to the transport position.*
- The transport position has been reached when:
  - the symbol for the transport position with a tick is shown on the display.

Further information on transport can be found in Chapter **8.2 PREPARING THE DEVICE FOR TRANSPORT**

4.2.5 Setting the cushion pressure

For coupling, the device automatically generates a predefined coupling pressure as soon as the therapy head is in the treatment position. It is also possible to undertake minimal corrections to the coupling pressure.

- Press THERAPY HEAD.
  ⇨ *The various functions of the menu become available.*
- Press to gradually drain the coupling cushion, or
- Press to gradually fill the coupling cushion.

4.2.6 Selecting or deselecting coupling cushion

To select or deselect the coupling cushion manually, proceed as follows:

- Press THERAPY HEAD.
  ⇨ *The various functions of the menu become available.*
- Press to deselect the cushion.
  ⇨ *The green outline of the button goes out.*

⇨ *The coupling cushion is deactivated.*

- To re-select the cushion, press .
  ⇨ *A green outline around the button indicates that the function has been activated.*

⇨ *The coupling cushion has been selected.*

System degassing is only possible when the cushion is deselected. The only time a degassing cycle is performed automatically is after device start-up or after a reset.

The coupling cushion can only be deselected or deactivated if the inline transducer is moved in.

4.2.7 Selecting or deselecting airbag

If the therapy head is in the 0° OT treatment position and the coupling cushion is activated, the airbag in the coupling cushion is automatically inflated if no ultrasound inline unit is mounted. The airbag can also be selected or deselected manually in order to switch from X-ray localisation to ultrasound localisation, for example.

- Press THERAPY HEAD.
  ⇨ *The various functions of the menu become available.*

Activating the airbag

- Press to activate the airbag.
  ⇨ *A green outline around the button indicates that the function has been activated.*

⇨ *The airbag has been inflated. X-ray localisation can be performed.*

Deactivating the airbag

- Press again to deactivate the airbag.
  ⇨ *The green outline of the button goes out.*

⇨ *The airbag has been deactivated. Ultrasound localisation can be performed, or the in-line unit used.*

After 20–30 shock waves, the airbag is automatically deactivated. Use the black button on the rear of the hand switch to reactivate it (and stop it again).

4.2.8 Venting the therapy head

If there are air bubbles in the coupling cushion, they can be automatically sucked out by the device using the VENT function. Note that venting can only be performed in the UT 0° position (service position) or OT 90° position. The position of the therapy head is described in chapter **3.2.1.1 ROUGH MANUAL POSITIONING**.

- Press THERAPY HEAD.
  ⇨ *The various functions of the menu become available.*
- Press  .
  ⇨ *A green outline around the button indicates that the function has been activated.*
  Venting is in progress.
- Allow the device to vent until no more air bubbles are visible in the coupling cushion.
- Press again  to switch off the function.
  ⇨ *The green outline of the button goes out.*

⇨ *Venting has been switched off.*

The venting process also ends automatically after a venting cycle.

4.2.9 Controlling the ultrasound in-line unit

- The in-line unit can be inserted into the therapy head for ultrasound in-line localisation. The following functions are available for controlling the in-line unit in the therapy head.
- Press ULTRASOUND.
  ⇨ *The various functions of the menu become available.*

Moving the ultrasound in-line unit in and out

- Press  .
  ⇨ *The in-line unit moves closer to the patient or*
- Press  .

⇨ *The in-line unit moves away from the patient.*

Optionally, you can also control the in-line unit with the joystick (Chapter **4.1.4.2 IN-LINE TRANSDUCER CONTROLS**).

4.2.10 Displaying device-specific information

The SETTINGS menu contains the following functions.

Sub-menu	Function
Save start values	Save start values: This function saves the current treatment parameters (energy level, frequency, cushion pressure) as start values.
System information	For displaying the counter reading, temperature, etc.
Configuration information	For displaying details of the installed hardware along with the software and hardware indices
Service trace	For activating and deactivating the service trace function
Water level indicator (only with therapy head in service position = 0° UT)	For dynamic indication of the therapy head water level
Service	Password-protected area for authorised service technicians.

Tab. 4-9 Device-specific information

4.2.10.1 Save start values

This function saves the current treatment parameters (energy level, frequency, cushion pressure) as start values.

To save the most recently used parameters as start values, proceed as follows

- Press SETTINGS.
  ⇨ *The list of sub-menus is opened.*
- Press SAVE START VALUES.

⇨ *The current treatment parameters have now been saved. They will be loaded automatically the next time the device is switched on or the next time the shock counter is reset.*

4.2.10.2 Displaying counter readings

- Press SETTINGS.
  ⇨ *The list of sub-menus is opened.*
- Press SYSTEM INFORMATION.
  ⇨ *The system information is displayed together with the counter readings, water temperature and error lists.*

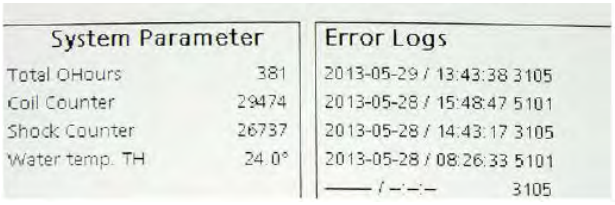


Fig. 4-24 System information

4.2.10.3 Displaying the hardware and software versions

- Press SETTINGS.
  ⇨ *The list of sub-menus is opened.*
- Press CONFIGURATION.
  ⇨ *The software and hardware versions are displayed, including the serial numbers.*

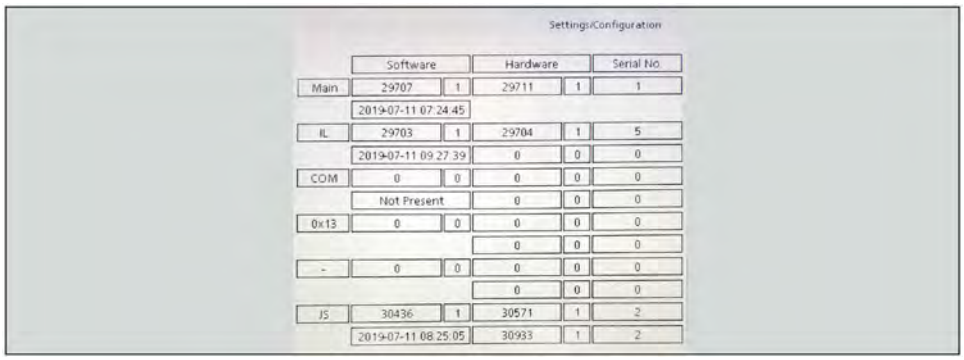


Fig. 4-25 Configuration menu

4.2.10.4 Activating and deactivating the service trace function

This function provides information on the status of individual software processes. If necessary, this information can be communicated to your responsible service centre.

- Press SETTINGS.
  ⇨ *The list of sub-menus is opened.*
- Press SERVICE TRACE ON.
  ⇨ *A yellow field containing status information appears in the top part of the display.*

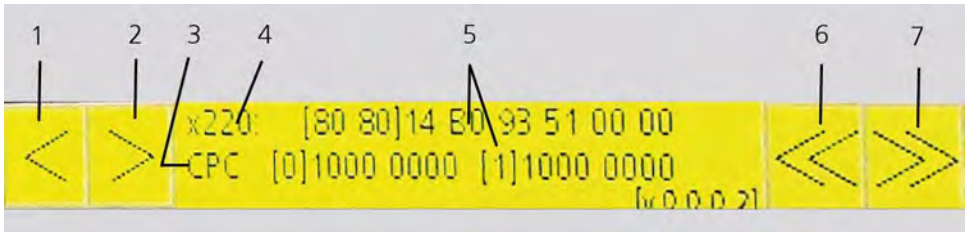


Fig. 4-26 Service trace

1 Select previous process
2 Select next process
3 Process name
4 Process number
5 Status message
6 Previous status message
7 Next status message

If the service trace function is activated, the window will remain visible at all times regardless of which action is currently being performed.

4.2.10.5 Water level indicator

Move the therapy head into the service position (0° UT).

Fig. 4-27 Service position

- Press SETTINGS to view the water level indicator.
  ⇨ *The water level is represented using two different scales.*

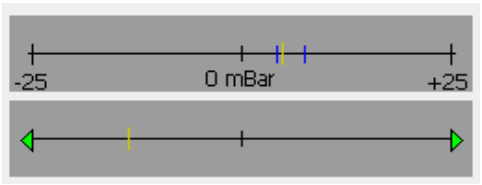


Fig. 4-28 Water level indicator

- For details of how to check the water level, please consult Chapter **7.2 CHECKING THE WATER LEVEL IN THE THERAPY HEAD**.

5 Treatment Preparation and Treatment

5.1 General information about treatment

Safety information

Before using the device, the user must make sure it is functioning safely and in proper condition. For this, please also read Chapter **5.2.2 FUNCTIONAL CHECKS**.

DANGER

Use of incompatible additional devices:

Risk to health due to incorrect treatment

► Only connect devices to the MODULITH® SLK that have been authorised by the manufacturer.

► Also read Chapter **3.7 COMPATIBLE ADDITIONAL DEVICES**

WARNING

Contact voltage

Injury caused by electric shock!

► Do not touch electrical connectors while you are touching the patient.

- Before moving parts of the device, such as the therapy head, make sure that no-one is within the action radius of these components.

The patient must be observed and treated with the normal level of medical care during treatment with shock waves. This includes checking the fragmentation process, monitoring the vital signs and, if necessary, monitoring the anaesthetic. The precise alignment of the target area/object in the treatment focus must be constantly monitored and corrected if required.

5.2 Preparing the device

Before you start treatment, you must ensure that the device is in the correct condition. This chapter explains which measures are required to ensure that this is the case.

CAUTION

In the event that the device or its components malfunction.

Various injuries are possible!

► Before starting treatment, it is essential to perform the **5.2.2 FUNCTIONAL CHECKS**.

5.2.1 Switching on

- Switch on the MODULITH® SLK at the main switch on the back of the device.
  ⇨ *The device starts with a beep sound and the LEDs around the therapy head light up.*

- Switch on the localisation system (X-ray or ultrasound device).
- Carry out the functional checks as described in Chapter **5.2.2 FUNCTIONAL CHECKS**.

5.2.2 Functional checks

Before each treatment, make sure the device is functioning safely and that it is in proper condition. The following tests must be performed every day before starting treatments:

– Inspection of the emergency stop button
– High-voltage test (HV test)
– Focus check
– Inspecting the load compensation mechanisms
– Inspection of the additional devices

5.2.2.1 Inspection of the emergency stop button

- Perform any motorised movement of the device.
- Press the emergency stop button during movement.
  ⇨ *The movement must stop immediately.*
  No further movements are possible.

⇨ *Inspection of the emergency stop button was successful.*
Turn the emergency stop button to authorise the movements again.

Do not use the device if the emergency stop button is defective.
- Immediately inform your responsible Service centre.

- Repeat the test, if necessary, with additional emergency stop buttons.

5.2.2.2 High voltage test

A high-voltage test (HV test) must be performed each time after the MODULITH® SLK is switched on. The system uses this test to ensure that the energy generated matches what is required. The high-voltage test requires the shock wave trigger button to be pressed manually. After the control panel is started, the prompt to operate the trigger button is displayed for several seconds. The triggering of shock waves is blocked until the test has been completed.
To complete the high-voltage test:

- Press the SW trigger button.
  ⇨ *After the trigger button is pressed, the system reports whether the high-voltage test was successful.*

⇨ *The high-voltage test has been performed successfully. The display of energy levels in the* SHOCK WAVE PARAMETERS *function field is now active. You can now select the shock wave parameters for treatment.*

A corresponding error message appears on the display if the system detects a malfunction during the test. The device is blocked to prevent further treatments.

- Immediately inform your responsible Service centre.

5.2.2.3 Focus check

Instructions for checking the focus of the localisation system used can be found in Chapter **11 X-RAY LOCALISATION (OPTION)** and Chapter **12 ULTRASOUND LOCALISATION (OPTION)**. Please also refer to the separate operating manuals for the particular localisation system and the additional devices.

5.2.2.4 Load compensation mechanism (rocker)

- Move the therapy head into the OT treatment position.
- Push against the therapy head until the therapy unit tilts backwards slightly.

Fig. 5-1 Inspecting the load compensation mechanism

⇨ *The device should now:*
- emit an acoustic warning signal
- activate the red warning LEDs on the therapy head
- show a corresponding error message on the display.

- Return the therapy unit to the normal position.
  ⇨ *The device should now:*
  - set the acoustic warning signal.
  - deactivate the warning LEDs.
  - The error message remains on the display until it is reset manually.
  - Press the 'Alarm off - button' to acknowledge the error:

⇨ *The rocker has been checked successfully.*

5.2.2.5 Inspection of the additional devices

- For more information, consult the operating manual for the additional devices used.

5.3 Treatment preparation

Preparatory measures include safe patient mounting and positioning of the patient. Before you start positioning the patient and administering treatment, the device must be prepared as follows:

- Make sure that all necessary device tests have been performed after switching on the lithotripter. For further information, see Chapter **5.2 PREPARING THE DEVICE**.

5.3.1 Patient mounting and positioning of the patient

⚠ WARNING

Danger of falling when getting onto the table without assistance.

Risk of concussion and fall-related injuries!

► Help the patient to climb onto the table.

⚠ CAUTION

Skin folds in the shock wave path can cause

cause minor haematomas and petechiae.

► Position the patient so there are no skin folds in the shock wave path.

- Put the patient into the position envisaged for treatment.
- Connect the ECG if necessary.
- Move the patient table into the treatment position.
- Correct the position of the patient so that the stone or the target area is located approximately above the focal point.
- Fix the position of the patient by pushing the cushions under the patient's head and knees.
- Perform an X-ray or ultrasound localisation. For this, please read Chapter **11 X-RAY LOCALISATION (OPTION)** and 12 **12 ULTRASOUND LOCALISATION (OPTION)**.

5.3.2 Stone localisation and positioning

The stones to be treated are moved into the treatment focus using the localisation system. An X-ray and/or a supplied ultrasound system can be used for this purpose. For a detailed description of stone localisation and positioning of the stone in the treatment focus, refer to Chapter **11 X-RAY LOCALISATION (OPTION)** and **12 ULTRASOUND LOCALISATION (OPTION)**.

⚠ CAUTION

Stone cannot be localised.

Risk to health due to ineffective treatment!

- ► Change from X-ray to ultrasound localisation or vice versa.
- ► Do not perform further treatment if the stone cannot be localised.

5.3.3 Coupling

⚠ CAUTION

Material damage to the coupling cushion reduces permeability to shock waves.

Risk to health due to ineffective treatment!

- ► Check the coupling cushion for material damage.

By default, the MODULITH® SLK automatically presses the coupling cushion against the patient's body with a predefined pressure as soon as the coupling cushion is activated. In addition, with the Modulith SLK models the airbag is inflated if no ultrasound in-line unit is mounted and the therapy head is in the 0° position.

⚠ CAUTION

Air bubbles in the coupling cushion reduce the effectiveness of shock waves.

Risk to health due to ineffective treatment.

- ► Do not trigger any shock waves if air bubbles are visible.
- ► Vent the therapy head (**4.2.8 VENTING THE THERAPY HEAD**).

The coupling cushion can be activated in any position.

Water temperature during coupling

The water temperature in the coupling cushion must always be in a range that is comfortable for the patient. The water may be too cold for coupling immediately after transport or storage in cold temperatures.

⚠ CAUTION

Cold water in the coupling cushion.

Possibility of hypothermia of the patient!

- ► Leave the device idling after switching on, until an adequate water temperature has been reached.

The device generates an error message if the water temperature in the coupling cushion is too high. The coupling cushion is then automatically deactivated and detaches from the patient.

⚠ CAUTION

There is also a risk of skin coming into contact with the hot surface in the case of obese patients.

Minor burns and skin reddening may result!

► Swivel the therapy head into the park position.

5.3.3.1 Therapy head coupling in UT position

Proceed as follows to couple the UT therapy source to the patient:

⚠ CAUTION

Reduced shock wave efficiency due to air bubbles between the coupling cushion and skin.

Risk to health due to ineffective treatment!

► Carefully smooth the air bubbles towards the outside using your hand.

Proceed as follows to couple the therapy source in the UT position to the patient:

- Move the therapy head into the treatment position.
- Turn the therapy head to the UT position.
- To avoid air bubbles in the coupling medium, apply a large, compact amount of ultrasound gel to the coupling cushion.

Fig. 5-2 Ultrasound gel applied to the treatment region

Only use ultrasound gel as the coupling medium.

- Do NOT spread the gel by hand. Instead, do this by activating the coupling cushion. When the coupling cushion is inflated, the air bubbles are pushed to the side.

In spite of automatic cushion pressure control, the coupling pressure of the coupling cushion may no longer be at the optimum value after the table has been moved in the Z-axis direction.

- Make sure that the patient is always correctly coupled.

A minimal correction to the coupling pressure can be performed manually as follows:

- Increase or decrease the coupling pressure according to the patient's physique.
  ⇨ *The coupling pressure is in the optimum range if the coupling cushion is making contact with the patient's body over a wide area.*

Shock wave triggering is blocked automatically if the cushion pressure is too high. The device generates an error message.

➔Read about this in Chapter **6 STATUS DISPLAYS AND ERROR MESSAGES**.

⚠ CAUTION

The coupling cushion may alter the position of the patient slightly, causing the stone to move outside of the treatment focus.

Risk to health due to ineffective treatment!

► If necessary, check the position of the stone by taking an exposure.

5.3.3.2 Therapy head coupling in OT position

⚠ WARNING

If an electrical power failure occurs during OT treatment, it will not be possible to decouple the patient from the therapy head by lowering the table with the motor.

Strain on the patient due to being in a constrained position!

► Switch off the device at the main switch.

► Separate the therapy head from the patient manually. See Chapter **4.1.6 FREEING THE PATIENT AFTER A POWER FAILURE**

Proceed as follows to couple the OT therapy source to the patient:

- Swivel the therapy arm into the treatment position.
- Turn the therapy head to the OT position manually.
- To avoid air bubbles in the coupling medium, apply a large, compact amount of ultrasound gel to the patient's body in the treatment region.

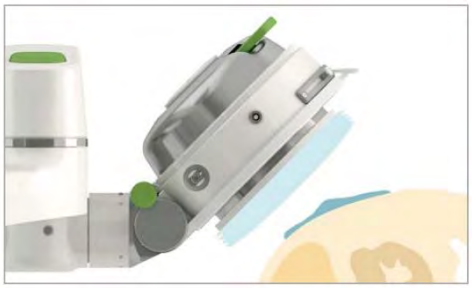


Fig. 5-3 Ultrasound gel applied to the treatment region

Only use ultrasound gel as the coupling medium.

- Do NOT spread the gel by hand. Instead, do this by activating the coupling cushion. When the coupling cushion is inflated, the air bubbles are pushed to the side.

Fig. 5-4 Coupling

- Check the quality of the coupling visually.

In spite of automatic cushion pressure control, the coupling pressure of the coupling cushion may no longer be at the optimum value after the table has been moved in the Z-axis direction.

- Make sure that the patient is always correctly coupled.

A minimal correction to the coupling pressure can be performed manually as follows:

- Increase or decrease the coupling pressure according to the patient's build and stature.
  ⇨ *The coupling pressure is in the optimum range if the coupling cushion is making contact with the patient's body over a wide area.*

5.4 Treatment – lithotripsy

ECG monitoring of the patient is recommended during treatment. Furthermore, the patient's blood pressure and general condition should be checked at regular intervals. The noise level during administration of shock waves is within the safe range. Nevertheless, we recommend wearing suitable ear protection during treatment in order to minimise exposure to noise.

5.4.1 Setting the trigger type

The choice between fixed shock wave triggering and ECG-controlled shock wave triggering must be based on the medical opinion of the doctor administering treatment. ECG triggering is recommended for treating at-risk patients in order to avoid cardiac arrhythmia in the patient during treatment. The fixed-frequency trigger settings are used for patients with normal indications.

⚠ CAUTION

Incorrect additional device connected.

Possibility of device damage.

► Only use the additional device supplied by STORZ MEDICAL AG for ECG-based triggering.

5.4.1.1 Setting ECG triggering

- Press ↓ in the FREQUENCY line and reduce the trigger value until the heart symbol appears.
  ⇨ *Shock wave triggering is now ECG-triggered.*

5.4.1.2 Setting internal triggering

If ECG triggering is switched off, you must specify the shock wave frequency:

- Set the triggering in the SHOCK WAVE PARAMETERS function field using the buttons and .

Energy level	Max. shock wave frequency
1	4 Hz
2	4 Hz
3	4 Hz
4	4 Hz
5	4 Hz
6	4 Hz
7	4 Hz
8	3 Hz
9	3 Hz
10	3 Hz
15	3 Hz
20	3 Hz
25	3 Hz
30	3 Hz
35	3 Hz
40	3 Hz
45	3 Hz
50	2 Hz
55	2 Hz
60	2 Hz
65	2 Hz
70	2 Hz
75	2 Hz
80	2 Hz
85	2 Hz
90	2 Hz

Tab. 5-1

The maximum possible frequency for generating shock waves depends on the selected energy level. Increasing the energy level may reduce the shock wave frequency.

The shock wave energy should be increased gradually during treatment. The low levels are used less for lithotripsy and more for familiarising the patient. Better disintegration results are obtained at the higher energy levels. The selection of energy levels is based on the medical opinion of the doctor administering treatment.

5.4.2 Energy selection

Treatment should always start at a low energy level. This also applies when resuming treatment after an interruption.

- Select a low energy level (see Chapter **4.2.1 SETTING SHOCK WAVE PARAMETERS**).

5.4.3 Triggering shock waves

Once all necessary preparations have been taken, it is possible to start lithotripsy treatment.

- Make sure that the shock wave counter is at zero and a low energy level has been set.
- Remove the SW trigger button from the holder on the control panel and press it.
  ⇨ *Shock waves are triggered at the set trigger frequency for as long as you keep the button pressed.*
- Observe and treat the patient with the usual medical care during shock wave therapy.

  This includes
  - Checking the progress of fragmentation
  - Monitoring the vital signs
  - Monitoring the anaesthetic effect
  - Maintaining the exact position of the stone in the treatment focus
  - Making corrections if necessary

⚠ CAUTION

Moving the patient at the same time as triggering shock waves can result in the stone moving out of focus.

Risk to health due to ineffective treatment!

► Only move the patient while simultaneously monitoring the situation with X-rays or ultrasound.

Triggering stops automatically after each batch of 1000 shock waves. The SW trigger button must be pressed again in order to continue treatment.

- Use the interruption in shock wave triggering after 1000 shocks to check the position and disintegration.

5.5 End of treatment

- Press  to set the shock wave counter to zero.
- Press  (optional) to export the treatment parameters to an external software application.

5.5.1 Patient dismounting

- If you have performed the treatment with ECG triggering, remove the cables and electrodes from the patient.
- Remove the coupling agent from the patient's body using paper towels.

WARNING

Danger of falling when getting onto the table without assistance.

Risk of concussion and fall-related injuries!

► Help the patient to climb onto the table.

- Allow the patient to dismount.

5.5.2 Cleaning and disinfection after treatment

Clean and disinfect the device after every treatment (Chapter **7.1 CLEANING AND DISINFECTION**).

- Wipe the coupling agent off the coupling cushion.
- Spray the coupling cushion and the table cushion with disinfectant solution.
- Clean and disinfect the coupling cushion after each treatment.
- Clean the remaining parts of the device as required using soap or disinfectant solution.

5.6 Switching the device off and disconnecting it from the mains

Completely retract the ultrasound inline transducer of the therapy head.

To disconnect the device from the mains, switch the main switch on the back of the device to the 'Off' position.

6 Status displays and error messages

6.1 Status displays

The appearance of the graphic symbols changes to indicate the particular status of the procedure you wish to perform.

Symbols	Meaning
 Blue	The required procedure can be selected.
 Blue with white aura	The required procedure is being performed.
 semi-transparent	The required procedure cannot be selected. The end of the movement/travel path has been reached.
Yellow bar in front of the arrowhead	The required procedure cannot be selected. The movement/ travel path is blocked. The required position can only be reached after the blockage situation has been resolved.

Tab. 6-1 Arrow colour coding

Symbols	Meaning
 black/white	The required procedure can be selected.
 black/white with green outline	The required procedure is being performed.
 semi-transparent	The required procedure cannot be selected.

Tab. 6-2 Field colour coding

The following displays appear in the lower display area:

Symbols	Meaning
	Progress display
	Flag symbol: displays the currently set menu language

Tab. 6-3 Displays

The following pictograms indicate the device status:

Pictogram	Meaning
	Conduct HV test
	Rotate therapy head into 45° OT position!
	Rotate therapy head into 45° UT position!
	Therapy head in 45° OT
	Therapy head in 45 ° UT
	Device is in starting position
	Device is in transport position

Tab. 6-4 Pictograms

6.2 Warning notes/error messages

Warnings and error messages are shown on the display. All the messages listed below are shown on the control panel. They are displayed against a yellow background. To acknowledge these messages, the »Alarm off« button must be pressed. If several errors have to be acknowledged, you can scroll through the error messages using the arrow keys.

Fig. 6-1 Error message on display

Message code	Message text
Error 1001	Fault in movement control • Press the 'Alarm off' button to acknowledge. • Please call the Service Department if the fault persists!
Important 1003	Memory fault movement line. The stored values have been replaced by default settings. Current settings might have been changed. • Please call the Service Department.
Error 1004	Activated safety circuit The 'Emergency stop' button has been pressed. All movements of the device are blocked. • Unlock the 'Emergency stop' button.
Error 1006	Load compensation mechanism was triggered. The forces exerted by an obstacle trigged the rocker mechanism. • Remove the obstacle
Error 1203	Therapy head decoupled. Therapy head position is undefined. All movements and shock wave generation are blocked. • Couple the therapy head manually • Please call the Service Department if the fault persists!
Error 1601	Internal in-line controller fault Error on the in-line controller: Press 'Alarm off' to acknowledge the fault. • Please call the Service Department if the fault persists!
Error 2101	Water level too low There is not enough water in the system. Water circuit and shock wave generation are blocked. • Check for water leaks. • Please call the Service Department!
Error 2103	Water level too high The water circuit is overfilled. The therapy head swivel has been blocked. • Check and correct the water level. • Call the Service Department if the fault persists!
Error 2104	Excess pressure in coupling cushion The water pump has a malfunction. The water circuit is blocked. • Please call the Service Department!

Message code	Message text
Error 2108	Water/air system fault There is a malfunction in the water/air system. Coupling cushion and shock wave generation are blocked. • Please call the Service Department!
Error 2202	Degassing vacuum insufficient: Faulty degassing pump or leakage in degassing unit. Complete the treatment in the normal way. • Please call the Service Department!
Error 2203	Water poorly degassed: Poorly degassed water can dissipate the shock wave energy. Coupling cushion and shock wave generation are blocked. • Please call the Service Department!
Error 2204	Degassing deactivated Continuing use can result in lower treatment power or damage to the coil! • Weigh up the pros and cons before you continue with the treatment. • Please call the Service Department!
Error 2301	Water temperature elevated: The water temperature has exceeded 38°C. Check the room temperature and air circulation. • Continue treatment.
Error 2303	Water temperature too high: Water temperature is higher than 40°C. Coupling cushion and shock wave generation are blocked. Wait for cool-down. • Please call the Service Department if the fault persists!
Error 2304	Water temperature too high: Water temperature is higher than 41°C. The safety switch is activated. Coupling cushion and shock wave generation are blocked. • Please call the Service Department!
Error 2305	Water/air system fault • Please call the Service Department!
Error 2306	Low water temperature Water temperature below 15°C. System has to idle for warm-up. • Coupling cushion is deactivated.
Error 2307	Water temperature too low System temperature below 3°C. Water system might be frozen. All pumps are disabled. System may be damaged. • Please call the Service Department!

Message code	Message text
Error 2401	Defective airbag: Leaking airbag. There is air in the coupling cushion. Coupling cushion and shock wave generation are blocked. • Please call the Service Department!
Error 2402	Water/air system fault Airbags are functioning with restrictions. • Complete the treatment in the normal way. • Please call the Service Department!
Important 3001	Treatment limit exceeded The recommended maximum number of shock waves per patient/treatment has been exceeded. • Consider the risks and side effects before continuing treatment.
Error 3003	Buffer battery empty Some internal data may not be accessible. Continue treatment. • Please call the Service Department!
Error 3103	High-voltage generation fault: High-voltage value incorrect. Shock wave generation blocked. • Please call the Service Department!
Error 3105	High-voltage generation fault: Shock wave generation is blocked. Press ALARM OFF button to acknowledge the error. • Please call the Service Department!
Error 3107	High-voltage generation fault: Shock wave generation is blocked. • Please call the Service Department!
Error 3109	High-voltage generation fault: High Voltage checkback value incorrect. Shock wave generation blocked. Please call the Service Department!
Error 3131	High-voltage generation fault: • The system has failed the high voltage test. Cushion functions and shock wave has been deactivated. • Please call the Service Department!
Error 3201	'Trigger button' fault • Please check whether the 'Trigger button' is pressed. • Press the 'Alarm off' button to repeat the test. • Please call the Service Department if the fault persists!
Error 3202	• Release 'Hand switch' button

Message code	Message text
Important 3401	Coil replacement is due: • Continue the treatment or replace the coil at the next possible moment. • Please call the Service Department!
Error 3402	Expected service life of coil exceeded: Further use can lead to damage to the device • Please call the Service Department!
Error 3403	Coil service life exceeded Shock wave generation is blocked in order to prevent interruptions in treatment or damage to the device. • Please call the Service Department!
Error 3411	No coil counter card A valid coil counter card could not be detected by the system. Shock wave generation is blocked. • Check whether the card is present. • Please call the Service Department!
Error 3415	Coil counter card fault Incompatible coil counter card Shock wave generation is blocked. • Please call the Service Department!
Error 3416	Coil counter card fault Invalid coil counter card Shock wave generation is blocked. • Please call the Service Department!
Error 5101	Activated safety circuit: All system movements are blocked by the C-arm. • Check function of C-arm collision detector. • Please call the Service Department if the fault persists!
Error 7001	Internal fault in main control unit Error message from main control unit • Press 'Alarm off' button to acknowledge the fault. • Please call the Service Department if the fault persists!
Error 7002	Internal fault in main control unit Error message from main control unit. The entire system is blocked. • Please call the Service Department!
Important 7003	Main control unit memory fault: The stored values have been replaced by default settings. Current settings might have been changed. • Please call the Service Department!

Message code	Message text
Error 7101	Invalid LithoPos values The system has received invalid values for automatic table positioning. LithoPos has been blocked. • Please call the Service Department!
Error 8001	Internal fault on control panel: • Press the ALARM OFF button to acknowledge the fault and restart the control panel. • Please call the Service Department if the fault persists!
Error 8002	No system communication: No communication between control panel and system. Control panel is blocked. The displayed values are invalid. • Please call the Service Department!
Error 8003	Control panel incorrectly configured: No communication between control panel and system. Control panel is blocked. The displayed values are invalid. • Please call the Service Department!
Error 8004	Interrupted communication between control panel and system: • Pressing the ALARM OFF button restarts communication. • Please call the Service Department if the fault persists!
Error 8005	Communication protocol infringed Invalid communication between control panel and system: • Pressing the 'Alarm off' button restarts communication. • Please call the Service Department if the fault persists!
Error 8006	Communication protocol infringed Invalid communication between control panel and system. • Touch the OK button to restart communication. • Please call the Service Department if the fault persists!
Error 8007	Internal fault on control panel There is an internal fault on this control panel. Control panel blocked. The displayed values are invalid. • Please call the Service Department!

Message code	Message text
Error 8008	Internal fault on control panel There is an internal fault on this control panel. Control panel blocked. The displayed values are invalid. • Please call the Service Department!
Error 8009	Internal fault on control panel There is an internal fault on this control panel. Control panel blocked. The displayed values are invalid. • Please call the Service Department!

Tab. 6-5 Fault messages

7 Care/Technical Safety Checks

7.1 Cleaning and disinfection

The following chapter contains information about cleaning the individual parts of the device.

DANGER

Risk of explosion due to the use of flammable and explosive cleaning agents and disinfectants during operation

Injuries to patients, people administering the treatment and third parties!

- ► Make sure that treatments and cleaning work are carried out only by qualified and instructed healthcare professionals.
- ► Avoid using highly volatile cleaning agents and disinfectants, which can form a potentially explosive atmosphere.
- ► Switch the system off before cleaning and disinfection.

CAUTION

Risk of injury !

Injuries to patients and people administering the treatment

- ► No cleaning and maintenance work is to be carried out while the device is being used on the patient.

7.1.1 Hygiene regulations

The hygiene regulations for rooms in which the MODULITH® SLK is installed depend on how else the device is used. If the system is also used for positioning the patient during endoscopy, the applicable hygiene regulations for endoscopic procedures must also be adhered to.

The same applies to other diagnostic or therapeutic measures.

7.1.2 Cleaning the parts of the device

Overall external cleaning depends on how frequently the device is used and on whether it is used for other medical diagnostic or therapeutic procedures. All parts that come into contact with the patient must be cleaned before each treatment.

We also recommend cleaning after the final treatment of the day and before a longer period of inactivity.

- Check that the system has the correct operating status for cleaning and switch the system off before cleaning if necessary. See **TAB. 7-1**

Device parts	Interval	Operating status
Patient table	For each treatment	Switched on
Table padding	For each treatment	Switched on
Patient foil	For each treatment	Switched on
Coupling cushion	For each treatment	Switched on
Therapy head	Every day	Switched off
Control panels, monitors and touch screen	Every day	Switched off
Basic unit, X-ray column, C-arm and monitor arm	Every day	Switched off
Multifunctional foot switch	Every day	Switched off
X-ray foot switch	Every day	Switched off

Tab. 7-1 Operating status when cleaning

7.1.3 Disinfection

For disinfecting surfaces, we recommend using liquid solutions of commercially available surface disinfectants with an aldehyde and/or amphoteric surfactant base.

- Please comply with the information in the operating manual for the disinfectant.

7.2 Checking the water level in the therapy head

The water level in the therapy head can be checked as follows:

- Turn the therapy head to the 0° UT position.
- Press SETTINGS to view the water level indicator.

The water level is represented using two different scales. The two blue lines on the lower scale indicate the absolute min. and max. range for the water level inside the coupling cushion. The two green lines show the currently calibrated water level +/-2%. The upper scale shows a magnified view of this area again. This scale is the one that should be used subsequently for filling up the water level in the coupling cushion.

Fig. 7-1 Scales indicating the water level inside the coupling cushion

- Check the water level using the upper scale:

Yellow indicator is in the centre of the scale	Optimal water level
Yellow indicator is left of centre	Water level too low • Follow the instructions in Chapter **7.2.1 FILLING WITH WATER**
Yellow indicator is right of centre	Water level too high • Follow the instructions in Chapter **7.2.2 DRAINING WATER**
Yellow indicator is not visible on upper scale	The water level is outside the calibrated range. Check the lower scale to see if the water level is too high or too low, and drain/fill the water circuit accordingly.

Tab. 7-2 Checking the water level

7.2.1 Filling with water

- Turn the therapy head to the 0° UT position.
- Press SETTINGS to view the water level indicator.
- Connect the filled water bag to the water connector on the therapy head and position the water bag above the connector. The hose of the water bag must be completely free of air.
- Fill the water circuit and check the water level using the scale.
- Detach the water hose from the connector as soon as the yellow indicator is in the centre of the scale.

7.2.2 Draining water

- Turn the therapy head to the 0° UT position.
- Press SETTINGS to view the water level indicator.
- Connect the empty water bag to the water connector on the therapy head and position the water bag below the connector. The hose of the water bag must be completely free of water.
- Drain some water out of the water circuit and check the water level using the scale.
- Detach the water hose from the connector as soon as the yellow indicator is in the centre of the scale.

7.3 Technical safety checks

During the annual maintenance procedures, the service technician performs the following safety checks and inspections based on the relevant national regulations. These checks must be performed with the additional devices connected. They include:

- Visual check for legibility and completeness of all warning notices attached to the device
- Function test of the display
- External visual check for damage to the components of the device
- Visual check for leaks in the water circuit at maximum pressure
- Visual check of all cable connections
- Check to ensure the energy levels are being displayed correctly
- Check to rule out the possibility of accidental shock wave triggering
- Inspection of localisation using the focus phantom
- Inspection of the water temperature control at 28 °C
- Inspection of the temperature cut-off switch at 41 °C
- Inspection of all limit and position switches as well as cut-out switches and trigger buttons
- Inspection of interlocks
- Check the collision detector (only SLK in-line).
- Inspection of sequential mobility
- Functional test of the disconnection points to externally connected devices such as ECG, ultrasound, X-ray.
- Inspection of internal triggering and ECG triggering as well as internal monitoring.
- Inspection of emergency stop precautions: Emergency stop button and load compensation mechanism
- Inspection of high-voltage monitoring
- Inspection of water degassing
- Inspection of electrical safety in accordance with EN 60601-1 or the relevant national regulations for the MODULITH® SLK.
- Inspection of electrical safety in accordance with EN 60601-1 or the relevant national regulations for the additional devices used for X-ray, ultrasound and ECG (if present). It is essential to comply with the information provided by the manufacturer(s) in the operating manuals for the additional devices.
- Inspection of the braking system

7.4 Service life

The average expected service life of the MODULITH® SLK is approx. 10 years.

If the service life is exceeded, device failures are likely.

7.5 Disposal

Never dispose of the device together with municipal household waste. At the end of the service life, the device must be returned to the manufacturer or distributing company so that it can be recycled and/or disposed of in an environmentally friendly manner.

- Please contact the manufacturer or distributing company in relation to this.
- When disposing of wear parts, you must comply with the relevant national disposal regulations.
- Comply with the relevant information in the operating manuals for the additional devices.

8 Transport

8.1 General information about transport

Measures relating to transport, checking before start-up, and start-up of the device must only be undertaken by personnel who have received training from the manufacturer. An individual should be physically able to move the device on a level surface. Two people are required if the MODULITH® SLK is moved up or down a slope.

- Always secure the MODULITH® SLK using the foot-operated holding brake and the caster locks when it is not being moved.

In the transport position, it is possible to move the device through doorways that are > 710 mm wide.

Fig. 8-1 Dimensions in transport position

Before transporting the device to a new treatment room for the first time, check the entire transport pathway with regard to possible obstacles and inaccessible points. These include constrictions at doorways, fixed items of furniture in corridors, tight corners in corridors, bumps and other unevenness in the floor, as well as lifts.

- Observe the dimensions of the MODULITH® SLK .

8.2 Preparing the device for transport

The following steps are required in order to prepare the MODULITH® SLK for transport:

- Unfasten all cable connections between the MODULITH® SLK and the additional devices, apart from the collision detector.
- Remove all removable parts:
  such as the ultrasound in-line unit
- Move the therapy head into the service position.

Swivelling the therapy head to the transport position

- Press to approach the transport position.
  ⇨ *The therapy head is pre-positioned for the transport position and approaches the following coordinates:*
  - X = 0mm
  - Y = -70mm
  - Z = 160mm
- Once the signal tone is heard, you can - release the button. The therapy head will automatically move to the transport position.
  ⇨ *The transport position has been reached if:*
  - a signal tone sounds briefly.
  - the symbol for the transport position with a tick is shown on the display.
- Switch off the device and disconnect the mains cable from the mains socket.
- Wind the mains cable onto the cable holder on the rear of the device.

Fig. 8-2 Rear of device with cable holder

- Place the transport cushion for the therapy arm in the space between the column and the transport handle.

Fig. 8-3 Transport cushion

- Turn the therapy head to the 0° UT position.

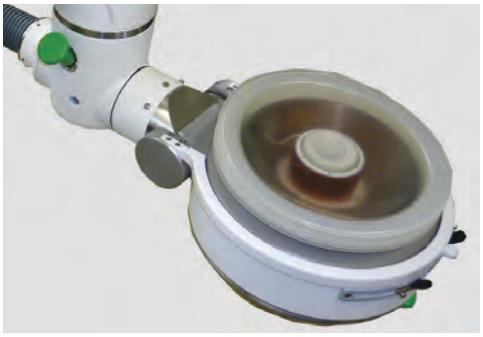


Fig. 8-4 Therapy head in = 0° UT position

- Unlock the therapy arm: To do so, press the unlocking button on top of the first swivel joint (**Fig. 8-5**).

Fig. 8-5 Unlocking the therapy arm

- Swivel the therapy arm into the transport position so that the therapy head and the swivel joint are positioned directly above the recesses in the transport cushion.

Fig. 8-6 The therapy unit has been placed in the transport position

The shifted weight will cause the column to tilt backwards slightly so that the therapy head rests on the transport cushion.

- To secure the transport cushion with the therapy unit, attach the supplied tensioning straps as shown in **FIG. 8-7** .

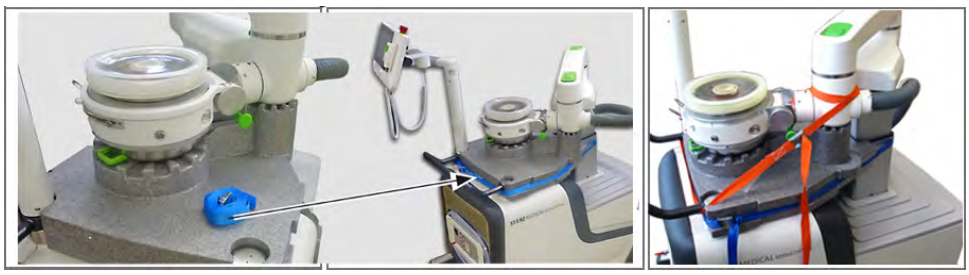


Fig. 8-7 Transport position secured with transport straps

8.3 Transporting the device

It is essential to comply with the warnings below in order to transport the device safely.

WARNING

Collision during transport.

Risk of injury to the operator and third parties.

- ► Move the MODULITH® SLK carefully and slowly.
- ► Make sure that the transport pathways are free and accessible.
- ► Avoid collisions with people and objects.
- ► Do not drive over ramps.

CAUTION

There is a risk of damage to the cables during transport.

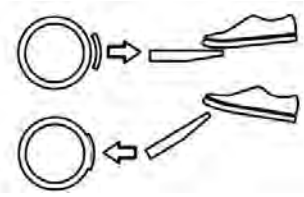
The device is not functioning!

- ► Reel in the mains cable prior to transport.
- ► Remove all other cables prior to transport.

8.3.1 Transport within the building

- Before transporting the device to a new treatment room for the first time, check the entire transport pathway inside the hospital for possible obstacles and inaccessible points.
- In particular, look out for constrictions at doorways, fixed items of furniture in corridors, tight corners in corridors, bumps and other unevenness in the floor as well as lifts.
- When selecting the transport pathway, bear in mind the limited ground clearance of the device as well as the width of the corridors.
- If necessary, use appropriate ramps.
- Be aware that older style lifts may drop down slightly when a load is moved inside them.
- Release the foot-operated holding brake.

  To operate the brake, the foot pedal must be pressed.



If the pedal is in the upper position, the brake is on. The device can no longer be moved (**FIG. 8-8**).

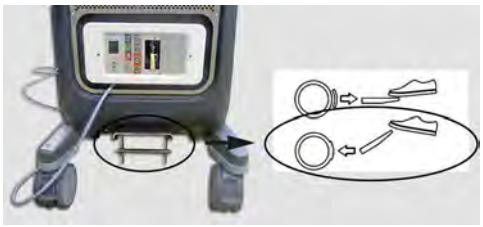


Fig. 8-8 Pedal up: Brake is securedpress pedal to release

If the pedal is in the lower position, the brake is off. The device can be moved (**FIG. 8-9**).

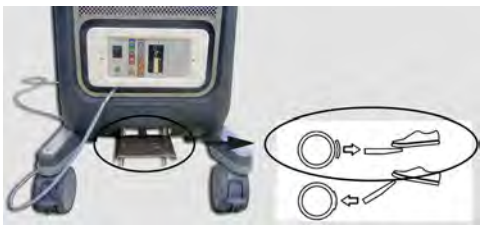


Fig. 8-9 Pedal down: Brake is releasedpress pedal to secure

- Open the wheel locks on the rear transport rollers.

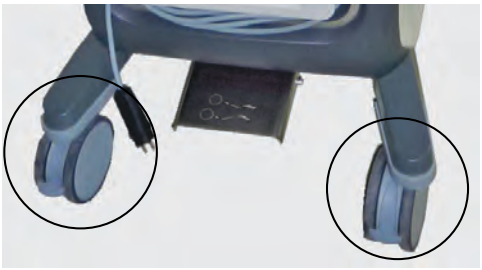


Fig. 8-10 Manual rear brake function

- Grip the device at the transport handle.
- Move the device slowly and carefully.

8.3.2 Transport outside the building

All measures for transport outside the building and start-up of the MODULITH® SLK may only be carried out by personnel trained by the manufacturer.

- To prepare the MODULITH® SLK for transport, follow the instructions in Chapter **8.2 PREPARING THE DEVICE FOR TRANSPORT** and Chapter **8.3.1 TRANSPORT WITHIN THE BUILDING**.

8.3.2.1 Transport vehicles

Only transport vehicles which guarantee sufficient protection of the items being transported are allowed to be used. This includes, in particular:

– Protection against the weather such as rain, snow, buffeting; e.g. by having an enclosed transport bay.
– Protection against temperatures below +5°C and above 45°C as well as against relative air humidity in excess of 65%; e.g. by means of air-conditioning systems with temperature monitoring.
– Soft suspension to protect the device against damage caused by vibrations. Air suspension is preferred.
– Adequate permitted payload. This depends on several factors such as the X-ray C-arm used.

⚠ WARNING

Base plate not attached correctly.

Risk of injury/accidents due to uncontrolled movement of the device!

► Make sure that the base plate has been attached correctly in the transport vehicle.

8.3.2.2 Loading and unloading the device

The loading and unloading procedure of the MODULITH® SLK must be performed with the greatest of care. Before loading, check that all measures have been taken as described in Chapter **8.2 PREPARING THE DEVICE FOR TRANSPORT**.

NOTICE

The device is heavy.

Material damage possible during transport!

- ► Move the device carefully and slowly.
- ► Avoid collisions with people and objects.
- ► Do not drive over ramps.
- ► Do not drive over cables, since these could be damaged.

- Only select transport paths where there are no slopes greater than 10% and where safe transport is guaranteed without any of the aforementioned obstacles.

  Loading and unloading should be performed on a smooth and level roofed area with direct access to the building.
- If possible, the lithotripter should not be transported across open ground.
- The supplied covering sheet only protects the device against light rain and snow. There is no protection against splash water from below caused by heavy precipitation, so this must be avoided at all costs. Never leave the device outdoors for long periods.

Two variants are available for loading and unloading the truck, depending on the type of vehicle:

– Ramps
– Lifting platform.

Both variants must guarantee absolute safety during the loading and unloading procedure.

For the lifting platform, this means:

– Adequate safe working load for the weight of the transportable MODULITH® SLK, the transport device as well as additional devices, e.g. mobile C-arm, etc.
– Sufficient size to accommodate the MODULITH® SLK and the transport device.

The ramps also have to provide an adequate minimum loading capacity. Furthermore, they have to be secured against slipping during loading and unloading. They must be sufficiently long so that the gradient to the ground when installed does not exceed 10°.

- In general, loading and unloading must be performed with the greatest of care. Apply the truck parking brake to prevent it from rolling away.
- Operate the lifting platform carefully and correctly. Precise knowledge of the operating manual for the lifting platform is a precondition for safe loading and unloading.

A transport plate ensures that the device is securely fixed in the truck during transport

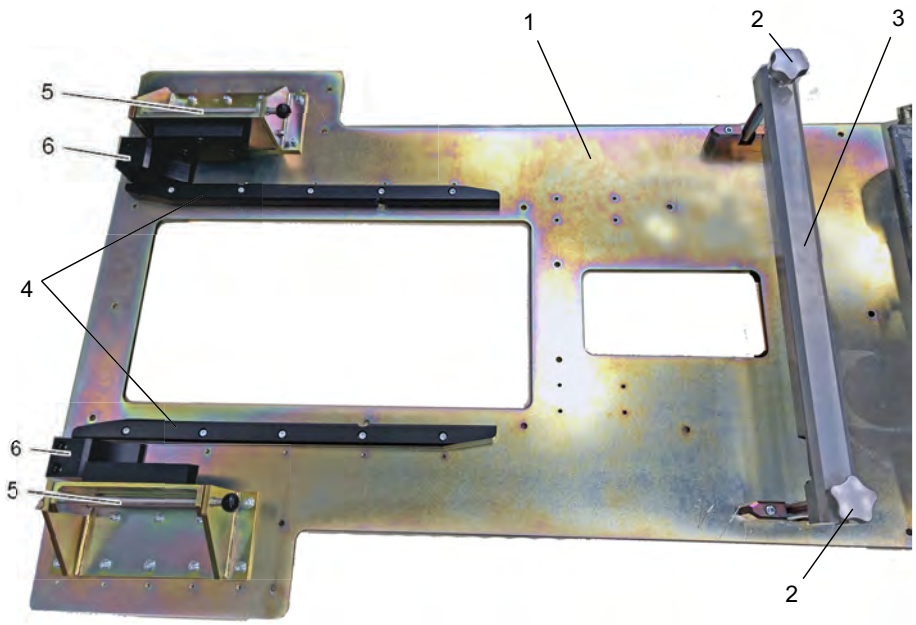


Fig. 8-11 Transport plate for fixing the device in the truck

1 Base plate
2 Clamping screws for the crossbar
3 Crossbar
4 Guide rails
5 Wheel clamps with pin and splint to secure the large wheels
6 Wheel stops

- Push the MODULITH® SLK onto the plate with the large wheels in front until both front wheels touch the wheel stops (**Fig. 8-11** /6).
  ⇨ *The big wheels should now be exactly level with the wheel clamps.*

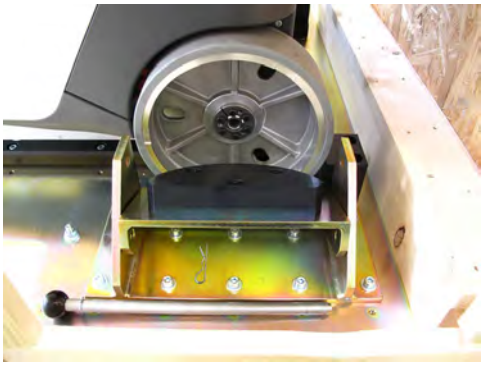


Fig. 8-12 Large wheels positioned correctly at the height of the wheel clamps

- Close the wheel clamps, lock them with the pin (**Fig. 8-11** /1) and secure the pin with the splint (**Fig. 8-13** /2).

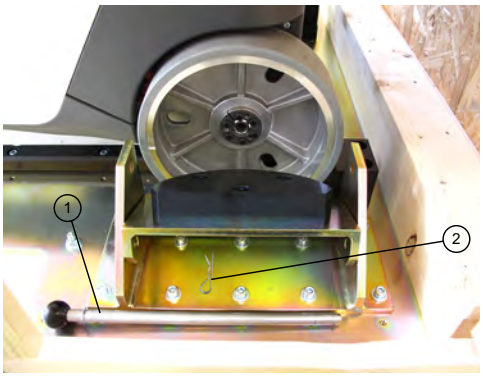


Fig. 8-13 Wheel clamp with pin and splint

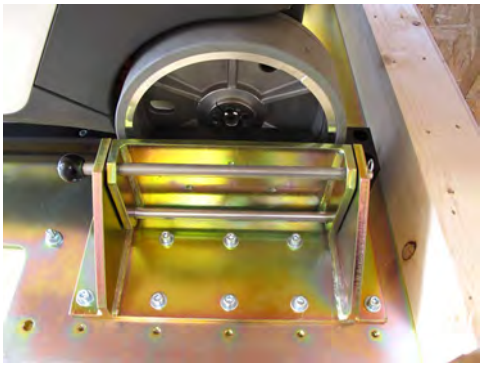


Fig. 8-14 Wheel clamp locked and secured

- Activate the holding brake.
- Mount the crossbar. This will prevent the device from lifting off the back of the base plate during a braking manoeuvre.
  - To do this, set up the two support feet of the clamping screws and fix the crossbar using the two clamping screws.

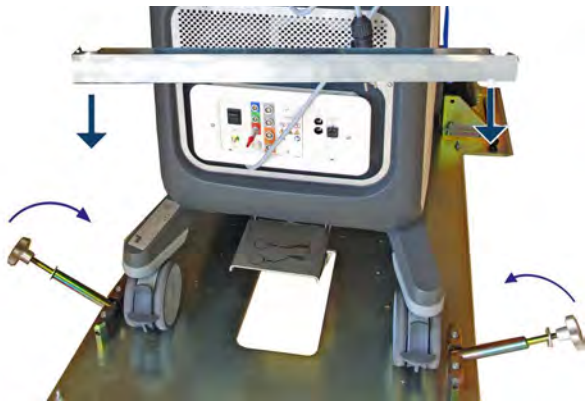


Fig. 8-15 Mount crossbar

Fig. 8-16 Crossbar mounted

⇨ *The device is now ready for transport.*

8.3.2.3 Transport

Avoid abrupt braking and acceleration manoeuvres when transporting the device in the transport vehicle. Also, windy roads should be negotiated with the appropriate degree of care. Avoid uneven roads or other obstacles if at all possible.

Ideally, each new transport route should be checked with regard to the aforementioned aspects, and a route selected which imposes the least possible strain during transport.

Regulations for road safety and the instructions of the vehicle manufacturer must be followed. The device is sensitive and requires a driving style that takes account of this fact.

- Avoid powerful vibrations.

NOTICE

The MODULITH® SLK must be secured for each transport

to avoid damage to property.

► Only secure the device at the attachment points.

► Never use the column or any other parts of the device as attachment points.

NOTICE

Storage or transport below 0° Celsius leads to

damage to the device if the water circuit freezes!

► Protect the device against frost.

► If necessary, have the water circuit drained and flush through with antifreeze.

8.3.2.4 Discharging

- Loosen the clamping screws on the crossbar and remove it.
- Open the wheel clamps on the big wheels.
- Release the foot-operated holding brake.
- Unload the MODULITH® SLK from the transport vehicle and transport it to the required location.
- Follow the instructions for selecting the transport path in Chapter **8.3.1 TRANSPORT WITHIN THE BUILDING**.

8.4 Setting up the device after transport

- Position the MODULITH® SLK at the required treatment location.
- To park it, apply the locks on the rear transport wheels and press the foot-operated holding brake below the connection panel.

⚠ CAUTION

Uncontrolled movements of the device.

Risk of injury to patient, operator and third parties.

► Secure the device using the foot-operated holding brake.

⚠ WARNING

Malfunction after transport damage.

Health risks due to device malfunction!

► First check the MODULITH® SLK for any transport damage

► If you notice any damage, immediately have the device checked by your service centre or the manufacturer.

⚠ CAUTION

Transport damage: crushed mains cable

Mains cable overload!

► Check the cable for damage after each transport.

- Unlock the therapy arm
- Turn the therapy arm to the treatment position, making sure it engages.
- Connect the device to the mains.
- Switch on the device.
  ⇨ *The therapy arm can now be moved electronically.*
- Before using it for treatment, make sure that the device has not sustained any damage during transport:
  - Check the housing for damage
  - Check the cables for damage
  - Carry out all functional checks (see Chapter **5.2.2 FUNCTIONAL CHECKS**).
  - Check the surface temperature.
- Carry out a focus check for each imaging system. See Chapter **5.2.2 FUNCTIONAL CHECKS**.

9 Technical specifications

9.1 Technical specifications

Treatment room	
Space requirements	4 m x 5 m

Water supply	Integrated water circuit with automatic processing. No water inflow and outflow required.

Classification	Therapy head
(according to EN 60601-1)	
Index of protection	I
Applied part	Type B
Operating mode	Continuous operation

SLK dimensions	
Length	1320 mm
Width	1700 mm
Height (with control panel)	1550 mm
Weight (without C-arm)	250 kg

Device version: 1 mains adapter

Electrical connections	
Mains voltage	100 - 240 VAC
Mains frequency	50 Hz / 60 Hz
Power consumption	<1.0 kVA

Device version: 2 mains adapters

Electrical connections	
Mains voltage	230 VAC
Mains frequency	50 Hz
Power consumption	<1.0 KVA
Mains voltage	115 VAC
Mains frequency	50 Hz / 60 Hz
Power consumption	<1.0 kVA

Electrical fusing	
Device input fuse	10 A

Ambient conditions	Treatment

Ambient temperature	+10°C - +30°C
Relative air humidity	10% - 90%, non-condensing
Atmospheric pressure	800 - 1060 hPA

Ambient conditions	Storage and transport
Ambient temperature	0°C - 60°C frost-free (water circuit drained)
Relative air humidity	5% - 95%, non-condensing
Atmospheric pressure	500 - 1060 hPA

Therapy head	
Opening diameter	178 mm
Focal distance	150 mm
Opening angle	61.4°

Shock wave source	**measured with a laser probe hydrophone**			
Method of generation		Electromagnetic		
Focusing method		Parabolic reflector		
		Energy levels		
		10	60	90
Distance between focal point and target point	Δz	0	0	0
Positive peak sound pressure	MPa	17	44	92
Negative peak sound pressure	MPa	9	16	20
Energy flux density*	mJ/ mm^2	0.3	1	2
Lateral size (-6 dB focal zone) (= fx and fy)	mm	10	6	4
Axial size (-6 dB focal zone)(= fz)	mm	88	62	54
Focus volume	cm^3	4.6	1.2	0.5
Pulse energy*(radius = 2.5 mm)	mJ	5	16	30

*) The absolute temporal integration limits include the positive and negative parts of the shock wave

Definitions according to EN 60601-2-36: 2015 / IEC 60601-2-36:2014 Annex BB

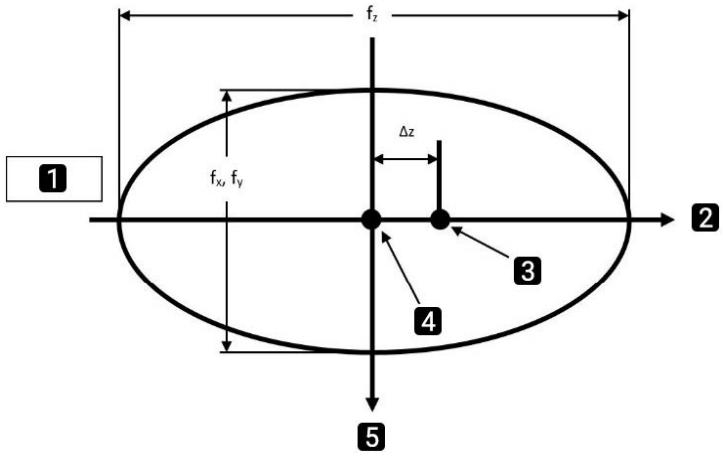


Fig. 9-1 Geometry of the shock wave focal zone

1 Source
2 Z axis (towards patient)
3 Target point
4 Focus
5 X, Y axis

Software version
The version number of the device software can be accessed via the touch panel. The current software and hardware versions (including the associated serial numbers) are displayed in the SETUP / CONFIGURATION INFO menu.

In the event of the medical product being transferred to third parties, the following must be observed:

- The complete device documentation must be delivered together with the medical product.
- The medical product may only be exported to a foreign country if the medical product and the corresponding indications are allowed there.

9.2 Essential performance

Equipment safety ("essential performance") according to IEC/EN 60601-1, 3rd edition:

– The device shall be free from incorrect display of energy levels
– The device shall be free from unintended shock wave release

are fulfilled.

Essential performance for basic safety cannot be impaired by electromagnetic interference.

9.3 EMC manufacturer's declaration

Guidelines and manufacturer's declaration – Emitted electromagnetic interference		
The MODULITH® SLK is intended to be used in the electromagnetic environment specified below. The customer or the user of the MODULITH® SLK should ensure that it is used in such an environment.		
Interference emission measurements	**Compliance**	**Electromagnetic environment – guidelines**
RF emissions acc. to CISPR 11	Group 1	The MODULITH® SLK uses RF energy only for its internal functioning. Therefore, its HF emissions are very low, and electronic devices in the immediate vicinity are unlikely to be disrupted. As per EN IEC 60601-2-36:2015 Section 202, this does not apply when triggering and generating the pressure pulse.
RF emissions acc. to CISPR 11	Class A	The MODULITH® SLK is intended for use in professional healthcare facilities.
Emission of harmonic oscillations according to IEC 61000-3-2	Class A	
Emissions of voltage fluctuations/flicker acc. to IEC 61000-3-3	Complies Pst < 1.0Plt < 0.65	
Conducted RF emissions	Class A	
Radiated RF emissions	Class A	

Guidelines and manufacturer's declaration – Resistance to emitted electromagnetic interference			
The MODULITH® SLK model is intended to be used in the following electromagnetic environment. The customer or the user should only use the device there.			
Resistance tests	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidelines**
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	±8kV contact discharge ±15kV air discharge	±8kV contact discharge ±15kV air discharge	Floors should be made of wood, concrete or ceramic tiles. If the floor is covered with a synthetic material, the relative air humidity has be at least 30%.
			When in operation, mobile radios should maintain the **safety distance** to the MODULITH® SLK including its cables. This is calculated depending on the transmission frequency:
Radiated RF interference according to IEC 61000-4-3	10 V/m (80 MHz up to 3 GHz)	10 V/m (80 MHz up to 3 GHz)	d = 1.2 √P for 80 MHz up to 800 MHz d = 2.3 √P for 800 MHz up to 6 GHz
Electrical fast transient disturbances / bursts according to IEC 61000-4-4	± 2kV/100 kHz for mains lines ± 1kV/100 kHz for input/output lines	± 2kV/100V for mains lines ± 1kV/100 kHz for input/output lines	Mains power quality should be that of a professional health care facility.
Surge voltages according to IEC 61000-4-5	± 1kV differential mode voltage (sym.) ± 2kV common mode voltage (asym.)	± 1kV differential mode voltage (sym.) ± 2kV common mode voltage (asym.)	Mains power quality should be that of a professional health care facility.
Conducted RF interference according to IEC 61000-4-6	< 3 Veff:150 kHz to 80MHz < 6 Veff: 80mHz to 230 MHz	< 3 Veff:150 kHz to 80MHz < 6 Veff: 80mHz to 230 MHz	d = 1.2 √P
NOTE 1 P = rated power of the transmitter in watts (W) according to the transmitter manufacturer's specifications d = recommended safety distance in metres (m). a) The field strength of stationary radio transmitters should be less than the compliance level at all frequencies according to an on-site survey b) Interference is possible in the vicinity of devices with the following sign.			

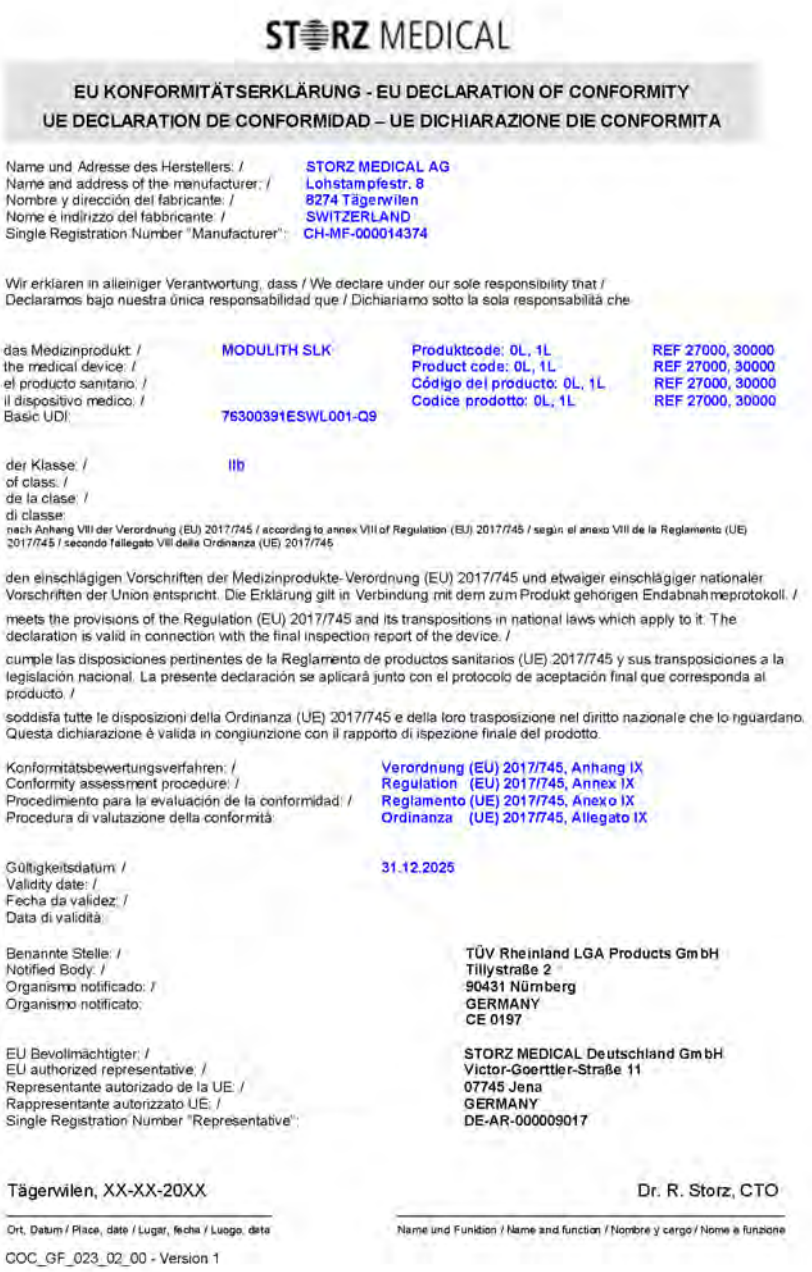
Guidelines and manufacturer's declaration – Resistance to emitted electromagnetic interference
a) The field strength of stationary transmitters, e.g. base stations of mobile phones and mobile radio communications equipment, amateur radio stations, AM and FM radio and TV transmitters cannot, in theory, be predicted exactly in advance. A study of the location should be considered in order to ascertain the electromagnetic environment with regard to the stationary transmitters. If the measured field strength at the location where the MODULITH® SLK is to be used exceeds the aforementioned compliance level, the device should be observed in order to demonstrate it is functioning in accordance with the intended use. In the event that unusual performance characteristics are observed, it may be necessary to take measures such as altering the alignment or a different location of the MODULITH® SLK.
NOTE 2: At 80 MHz and 800 MHz, the higher frequency range applies

Guidelines and manufacturer's declaration – Resistance to emitted electromagnetic interference			
Immunity tests	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidelines**
Power frequency (50/60 Hz) magnetic field acc. to IEC 61000-4-8	30 A/m	30 A/m	The values of the mains frequency magnetic fields should be those typically found in a professional health care facility.
Voltage dips, brief interruptions and fluctuations in the supply voltage according to IEC 61000-4-11	0% UT(100% dip in UT) for a ½ period 0% UT (100% dip in UT) for 1 period 70% UT (30% dip in UT) for 25 periods 0% UT (100% dip in UT) for 5 s	0% UT(100% dip in UT) for a ½ period 0% UT (100% dip in UT) for 1 period 70% UT (30% dip in UT) for 25 periods 0% UT (100% dip in UT) for 5 s	The quality of the mains power should be that of a professional health care facility. If the user of the MODULITH® SLK requires continued operation during mains power interruptions, it is recommended that the MODULITH® SLK be powered from an uninterruptible power supply. UT = mains alternating voltage prior to application of the test level
The MODULITH® SLK is intended for operation in an electromagnetic environment in which radiated RF disturbances are controlled. The operator or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MODULITH® SLK as recommended below, according to the maximum output power of the communications equipment.			
Rated power of transmitter [W]	Safety distance according to transmission frequency [m]		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 6 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Guidelines and manufacturer's declaration – Resistance to emitted electromagnetic interference
NOTE 3: In the case of transmitters that do not have their rated power specified in the table, the distance can be calculated using the equation for the column in question, where P is the rated power of the transmitter in watts [W] according to the information of the transmitter manufacturer.
NOTE 4: An additional factor of 10/3 was used when calculating the safety distance of transmitters in the frequency range from 80 MHz to 3 GHz. The purpose of this was to reduce the likelihood of a malfunction occurring in the event of a mobile communications device being inadvertently brought into the patient area.
NOTE 5: These guidelines may not apply in all situations. The propagation of electromagnetic fields is influenced by absorption and reflection from objects/people.

Subject to modifications

9.4 Certificates



STORZ MEDICAL

EU KONFORMITÄTSERKLÄRUNG - EU DECLARATION OF CONFORMITY
UE DECLARATION DE CONFORMIDAD – UE DICHIARAZIONE DIE CONFORMITA

Name und Adresse des Herstellers: / Name and address of the manufacturer: / Nombre y dirección del fabricante: / Nome e indirizzo del fabbricante: / Single Registration Number "Manufacturer":	STORZ MEDICAL AG Lohstampfestr. 8 8274 Tägerwilen SWITZERLAND CH-MF-000014374

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that / Declaramos bajo nuestra única responsabilidad que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / the medical device: / el producto sanitario: / il dispositivo medico: / Basic UDI:	MODULITH SLK 76300391ESWL001-Q9	Produktcode: 0L, 1L Product code: 0L, 1L Código del producto: 0L, 1L Codice prodotto: 0L, 1L	REF 27000, 30000 REF 27000, 30000 REF 27000, 30000 REF 27000, 30000

der Klasse: / of class: / de la clase: / di classe: IIb

nach Anhang VIII der Verordnung (EU) 2017/745 / according to annex VIII of Regulation (EU) 2017/745 / según el anexo VIII de la Reglamento (UE) 2017/745 / secondo l'allegato VIII della Ordinanza (UE) 2017/745

den einschlägigen Vorschriften der Medizinprodukte-Verordnung (EU) 2017/745 und etwaiger einschlägiger nationaler Vorschriften der Union entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen Endabnahmeprotokoll. /

meets the provisions of the Regulation (EU) 2017/745 and its transpositions in national laws which apply to it. The declaration is valid in connection with the final inspection report of the device. /

cumple las disposiciones pertinentes de la Reglamento de productos sanitarios (UE) 2017/745 y sus transposiciones a la legislación nacional. La presente declaración se aplicará junto con el protocolo de aceptación final que corresponda al producto. /

soddisfa tutte le disposizioni della Ordinanza (UE) 2017/745 e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il rapporto di ispezione finale del prodotto.

Konformitätsbewertungsverfahren: / Conformity assessment procedure: / Procedimiento para la evaluación de la conformidad: / Procedura di valutazione della conformità:	Verordnung (EU) 2017/745, Anhang IX Regulation (EU) 2017/745, Annex IX Reglamento (UE) 2017/745, Anexo IX Ordinanza (UE) 2017/745, Allegato IX
Gültigkeitsdatum: / Validity date: / Fecha da validez: / Data di validità:	31.12.2025
Benannte Stelle: / Notified Body: / Organismo notificado: / Organismo notificato:	TÜV Rheinland LGA Products GmbH Tillystraße 2 90431 Nürnberg GERMANY CE 0197
EU Bevollmächtigter: / EU authorized representative: / Representante autorizado de la UE: / Rappresentante autorizzato UE: / Single Registration Number "Representative":	STORZ MEDICAL Deutschland GmbH Victor-Goerttler-Straße 11 07745 Jena GERMANY DE-AR-000009017

Tägerwilen, XX-XX-20XX — Dr. R. Storz, CTO

Ort, Datum / Place, date / Lugar, fecha / Luogo, data — Name und Funktion / Name and function / Nombre y cargo / Nome e funzione

COC_GF_023_02_00 - Version 1

Fig. 9-2 Declaration of conformity

9.5 Cybersecurity measures

Like all computer-based systems, the system can be exposed to cybersecurity threats.

Safety-critical core functions of the device, such as shock wave triggering, are decoupled from the software and can only be activated via hardware switches.

To minimise the possibility of cyber attacks, it is the user's responsibility to observe the following protective measures:

1) The product may only be installed, commissioned, maintained, updated and operated by personnel suitably authorised. These people are employees of the STORZ MEDICAL AG or other authorised third parties. The same applies to service work such as the performance of software updates and software installations.
2) Software updates distributed by STORZ MEDICAL AG (functional or safety-relevant) must be installed via the enclosed Technical Service Information (TSI). Subsequent feedback to the STORZ MEDICAL AG or its service partner is required.
3) Software that is not distributed by STORZ MEDICAL AG or one of its service partners may not be used with the product.
4) A virus scan of the USB sticks used must be carried out to check whether they are free of viruses, malware or dangerous software.
5) All service and maintenance areas are password protected. Such access can only be granted by the STORZ MEDICAL AG.

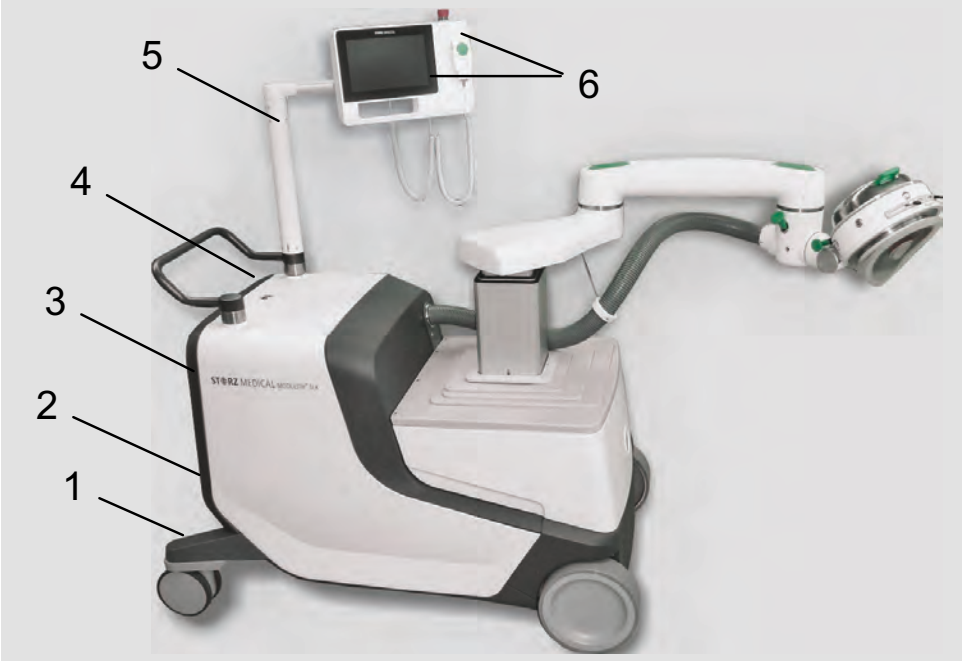
Contact the STORZ MEDICAL AG or the authorised customer service in the following cases:

– If the product shows an unknown or not logical behaviour, such as a slow reaction of the software or if the password is not accepted, access to the databases is not possible or it changes to an incorrect user interface dialogue.
– In case you are experiencing problems with the IT security of the product.
– If you have lost your password, login details or user access.

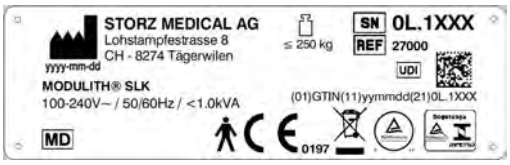
9.6 Symbols and labels

The symbols and labels displayed in this chapter are permanently attached to the following modules.

1. Affixing location

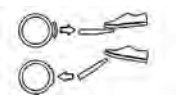


1 Basic unit – front right wheel arm

Label/symbol	Meaning
	Type plate: MODULITH® SLK with a mains adaptor
	Manufacturer
	Weight
	Application unit of type B
	Device serial number
	UDI mark

Tab. 9-1 Basic unit labelling – shock absorber

2 – Basic unit – foot-operated holding brake

Label/symbol	Meaning
	Symbol: Actuate brake

3 – Basic unit – external connection panel

Symbols	Meaning
	Coded blue: ECG connector for ECG triggering
	Coded green: Foot switch connector (not in use)
	Coded grey: Control panel / remote control panel / joystick connector
	Coded red: Collision detector connector for mobile X-ray C-arms (optional)
	Potential equalisation connector
	Coded orange: Connector for additional hand switches
	SCB connector
	Ethernet connector
	Safety switch
	Temperature mains fuse switch
	Prohibitory sign: Do not push!
	Prohibitory sign: Do not sit on the device!
	Prohibitory sign: Do not try to open the device!

Symbols	Meaning
	Danger sign: Caution!
	Danger sign: Risk of explosion! Do not operate the device in flammable environments!
	Danger sign: Take care not to get your fingers caught!
	Danger sign: Warning against high voltage!
	Mandatory sign: Please comply with the operating manual!

Tab. 9-2 Basic unit labelling – external connection panel

4 – Basic unit – top of housing

Label	Meaning
	Transport position

Tab. 9-3 Basic unit labelling – top of housing

5 – Control panel holder

Label	Meaning
	CE mark for control panel on support arm

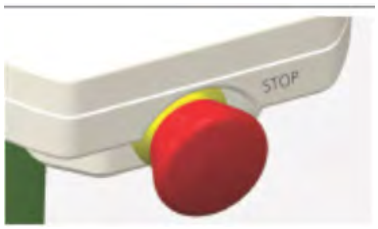
Tab. 9-4 Labelling of control panel holder

6 – Control panel

Label/symbol	Meaning
	Emergency stop
	Identification of control panel (serial number and part number)

Tab. 9-5 Labelling of control panel

7 - Joystick

Label/symbol	Description
	Emergency stop
	Identification of control panel (serial number and part number)

Tab. 9-6 Labelling joystick

10 Options and Accessories

10.1 General information

Only accessories listed in the following table are allowed to be used in conjunction with the MODULITH® SLK.

Name	Part no.
Joystick	30922
Fine adjuster for the URO table	32519
Transportation kit	31451
Urological coupling cushion (standard)	27570
Orthopaedic coupling cushion	27570.0002

DANGER

Use of incompatible additional devices:

Risk to health due to incorrect treatment

- ► Only connect devices to the MODULITH® SLK that have been authorised by the manufacturer.
- ► Also read Chapter **3.7 COMPATIBLE ADDITIONAL DEVICES**

11 X-ray Localisation (option)

11.1 General information

Safety information

The Chapter **11 X-RAY LOCALISATION (OPTION)** is an integral part of the complete operating manual for the MODULITH® SLK. All instructions, warnings and information in this complete operating manual also apply to the MODULITH® SLK with X-ray localisation.

Knowledge of the content of the separate X-ray system operating manual is essential for use of the overall system.

Only instructed personnel are allowed to operate the MODULITH® SLK with X-ray system. Technical and specialist knowledge of using X-ray systems is a precondition for operating the X-ray device. This chapter does not communicate this knowledge. The actual procedures for taking X-ray images and selecting the individual X-ray parameters are described in the separate operating manual for the X-ray device.

It is essential to follow all safety information given in Chapter **1 GENERAL SAFETY INFORMATION** and in Chapter **11 X-RAY LOCALISATION (OPTION)**.

All regulations applicable to X-ray use must be observed by the user during operation of the X-ray system.

- Avoid any unnecessary radiation exposure of the patient.
- Take protective measures.
- Use lead aprons.
- Restrict the exposure times.
- Make sure that you are at a sufficient distance from the radiation source in order to reduce the radiation exposure.

11.2 Use of mobile X-ray C-arms

11.2.1 Requirements of mobile X-ray C-arms

Conventional mobile X-ray C-arms can be used providing they meet certain geometrical requirements. When determining whether a C-arm can be used with the MODULITH® SLK, the decisive factors are whether it provides complete patient protection and protection against mechanical collisions.

⚠ CAUTION

Inaccurate localisation due to incompatible C-arms.

Risk to health due to incorrect treatment.

► Only C-arms contained in the list below are to be used.

► If you wish to use other C-arms, contact STORZ MEDICAL AG first. The STORZ MEDICAL AG will then check the geometrical parameters based on the simulation programme, and reach a decision as to whether the C-arm is suitable

List of suitable C-arms	
Manufacturer	Type
Philips	BV Libra
	BV Endura
	BV Pulsera
	Vectra
Technix	TCA 6
Ziehm Imaging	Ziehm Solo
	Ziehm Compact
	Ziehm 8000
	Ziehm Vision R
	Ziehm Vision FD
GE Healthcare / OEC Medical Systems	7700 Series/Compact
	7900 Fluorostar
	GE OEC Brivo 850
	GE OEC Brivo 785
ATS	Arco FP
	Arco FP-S
Siemens	Cios Fit
	Cios Select
	Cios Connect
	Cios Fusion
	Cios Flow

Tab. 11-1 List of suitable devices

11.2.2 Setting up the system

⚠ CAUTION

When aligning the X-ray C-arm with the shock wave generator, the patient is not adequately protected against collisions.

Risk of injury due to collisions as well as unnecessary exposure to X-rays.

► Only perform the alignment of the C-arm without the patient present.

Two X-ray images are taken during X-ray localisation in order to localise the stone precisely. The first image is taken with the X-ray C-arm in the p.a. position (0°) and the second is taken after swivelling it 30°. Please be aware of any possible obstacles in the swivel path. If necessary, change the swivel direction. Geometrically, the two centre

lines of the radiation fields intersect at one point. Adjust the X-ray C-arm so that the intersection point corresponds to the focal point of the therapy head. Use the focus gauge to do this.

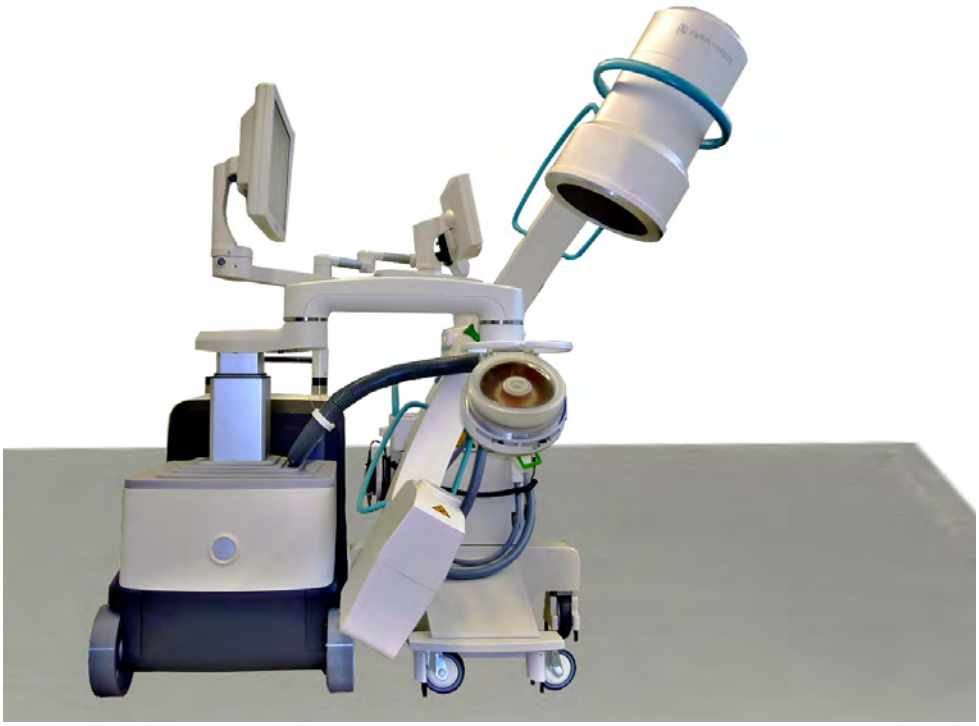


Fig. 11-1 Set-up with mobile C-arm in the PA position

The C-arm must have a targeting device, e.g. a crosshair, which is displayed on the monitor.

- Check whether this targeting device is activated.

To set up and calibrate the X-ray C-arm, proceed as follows:

- Move the X-ray C-arm into the PA position (0°).
- Secure the brakes of the C-arm.
- Position the MODULITH® SLK so that it is parallel with the X-ray C-arm.
- Roughly set the height of the therapy arm according to whether you want to use the therapy head in the UT or the OT treatment position.
- Tilt the therapy head upwards into the OT position or downwards into the UT position and allow it to lock into place.
- Manually swivel the therapy arm towards the X-ray C-arm.
- Using the motor, centre the therapy head as best you can below the image receiver.
- If the coupling cushion is filled, press to drain it before flipping the focus gauge open.
- Flip open the focus gauge. To do this, use the unlocking lever.

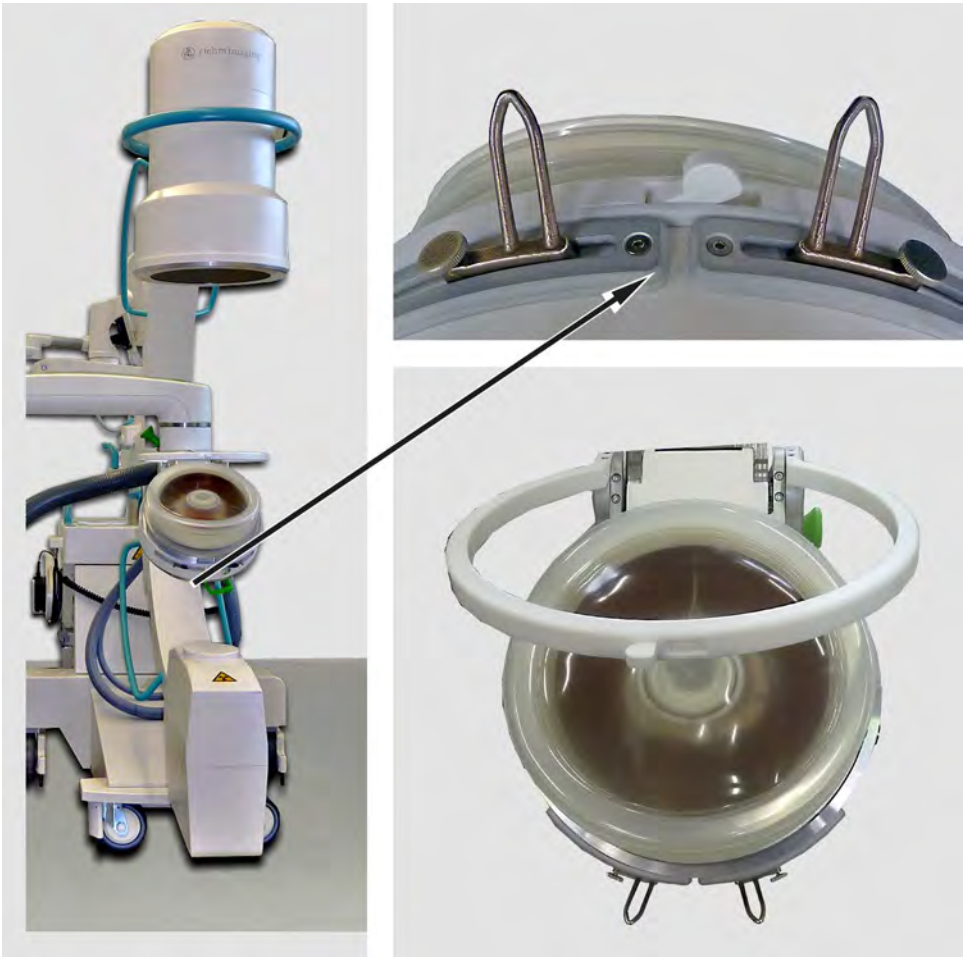


Fig. 11-2 Opening the focus gauge

- Take an X-ray image and use the arrow keys to move the therapy head in the X and Y directions until the pin of the focus gauge appears in the centre of the cross-hairs (**FIG. 11-3**).

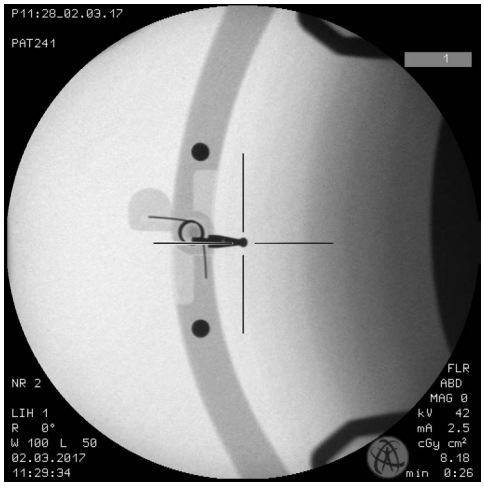


Fig. 11-3 Image in 0° UT

- Swivel the C-arm by 30° in the CC direction.

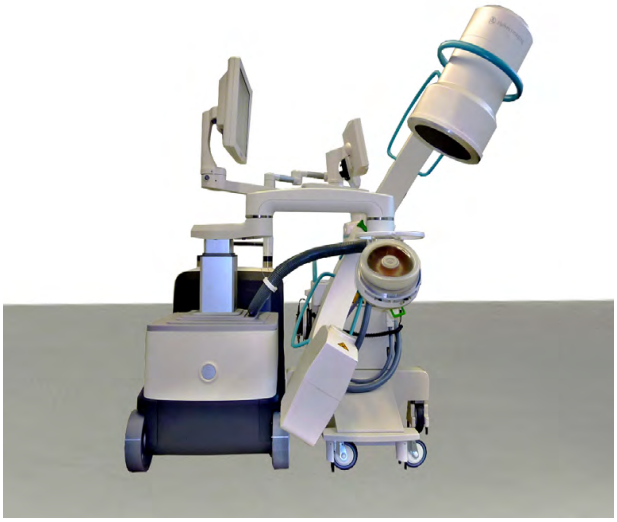


Fig. 11-4 X-ray C-arm in 30° position

- Take an X-ray image and use the arrow buttons to move the therapy head in the Z direction until the pin of the focus gauge appears in the centre of the crosshairs.

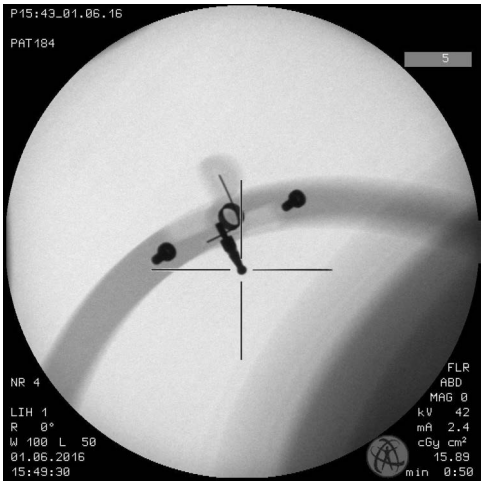


Fig. 11-5 Image in 30° UT

NOTICE

Moving the device with the focus gauge folded out

can result in damage to the table and the therapy head.

► Fold the focus gauge back down after the focus check.

- Swivel the C-arm back to the 0° position.

- Take an X-ray image.
  ⇨ *The therapy head is equipped with two calibration markers. These markers must be positioned so that both are visible at the edges of the X-ray image during AP projection in 0° in full format.*

To use the calibration markers, the X-ray image must be created in full format. Otherwise, the markers may not be visible.

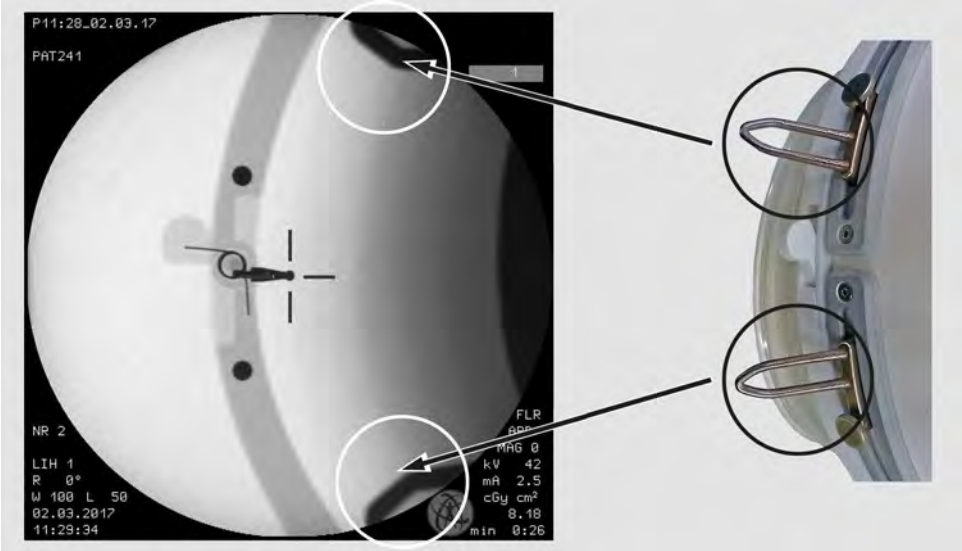


Fig. 11-6 Calibration markers visible in X-ray image

For X-ray devices with large flat panel systems, it is necessary to select zoom 1 as the reference.

- If necessary, adjust the position of the calibration markers in full format.
- To do so, loosen the two fixing screws, slide the markers to the required position and then retighten the screws.

Fig. 11-7 Adjusting the calibration markers

- Take an X-ray image to check the positioning.

⚠ CAUTION

The radiation dose of the person administering the treatment will be increased if they place their hands in the primary beam path.

X-ray-related health risks.

► Do not use radioscopy when adjusting the calibration markers.

- You can now save the current therapy head position and use it again as required. Read about this in Chapter **4.2.2.1 STORE THE THERAPY HEAD POSITION**.

11.2.3 Function tests

⚠ WARNING

Device malfunctions.

Various risks of injury!

► In addition to the functional checks described in Chapter **5** , perform a focus check every day before starting treatment. See **12.4 FOCUS CHECK**

Focus checks must also always be carried out in the following situations,

– If the C-arm or lithotripter has been knocked or moved.
– If the calibration markers are not displayed correctly in the X-ray image.

11.2.3.1 Focus check

Using the focus gauge, you should check that the centre of the crosshairs coincides with the focal point of the therapy source on the X-ray monitor.

Proceed as follows:

- If the coupling cushion is filled, press to drain it before flipping the focus gauge open.
- Flip open the focus gauge. To do this, use the unlocking lever.

Fig. 11-8 Flipping open the focus gauge

- Take an X-ray image

- Make sure that the reflection mark is in the centre of the crosshairs.

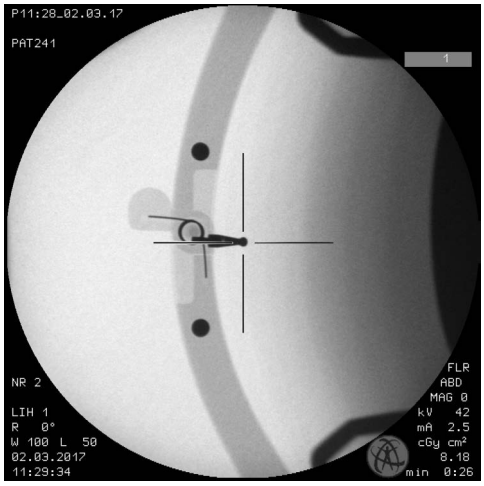


Fig. 11-9 Focus check in the 0° position

Permitted tolerance: +/- half the diameter of the reflection mark (**FIG. 11-10**).

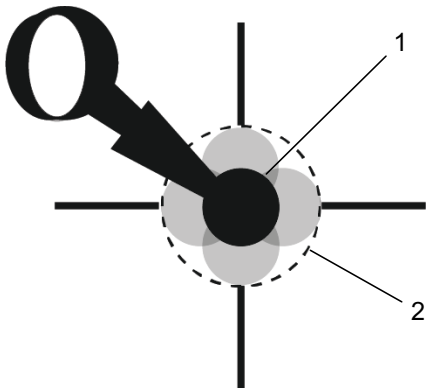


Fig. 11-10 Tolerance range in the X/Y direction

1 Reflection mark
2 Permitted tolerance

- Make sure that the therapy head has been locked in the X and Y directions.
- Swivel the C-arm by 30° in the CC direction.
- Take an X-ray image.
- Make sure that the reflection mark is in the centre of the crosshairs.

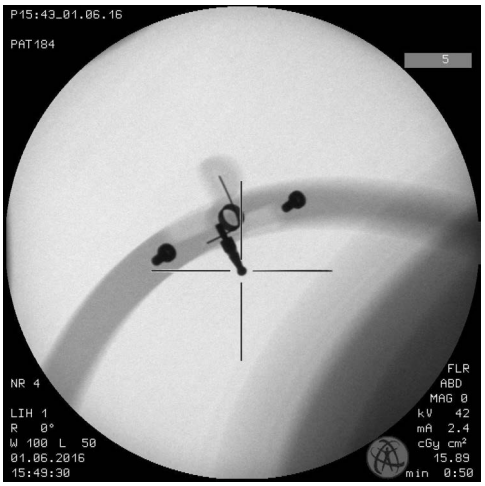


Fig. 11-11 Focus check in the 30° position

Permitted tolerance: +/- full diameter of the reflection mark (**FIG. 11-12**).

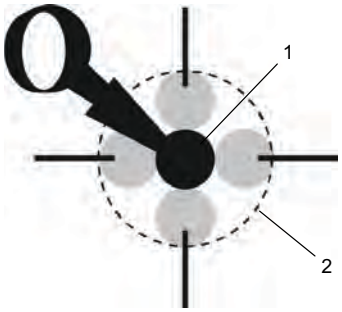


Fig. 11-12 Tolerance range in the Z direction

⚠ CAUTION

Reflection mark is not located within the specified tolerances.

Risk to health due to incorrect localisation.

► Do not perform treatment.

► Inform your Service centre.

NOTICE

Moving the device with the focus gauge folded out

can result in damage to the table and the therapy head.

► Fold the focus gauge back down after the focus check.

- Swivel the C-arm back to the 0° position.
- Take an X-ray image in full format and check the position of the calibration markers.

For X-ray devices with large flat panel systems, it is necessary to select zoom 1 as the reference.

11.2.4 Stone localisation

Positioning with the X-ray device involves two steps:

- Determining the stone position in the XY-plane with a 0° exposure
- Determining the stone position on the Z-axis (height) with a 30° exposure

⚠ CAUTION

Risk to health due to incorrect localisation.

► Precisely follow the sequence of the following steps.

- Position the lithotripter and the X-ray C-arm as described in Chapter **11.2.2 SETTING UP THE SYSTEM**.
- Make sure that the crosshairs displayed on the X-ray monitor coincide with the focal point of the therapy source (Chapter **11.2.3.1 FOCUS CHECK**)
- Set up the patient table.
- Swivel the X-ray C-arm to the 0° position.
- Allow the patient to climb onto the table.
- Position the stone that is to be treated by moving the table horizontally in the X and Y directions while taking an exposure, so that the stone is in the crosshairs of the X-ray image.
- Swivel the X-ray C-arm to the 30° position.
- Position the stone that is to be treated by moving the patient table in the Z direction (height) **only** while taking an exposure, so that the stone is in the crosshairs of the X-ray image.

⚠ CAUTION

Movement of the table after stone positioning will result in

inaccurate localisation.

► As soon as the C-arm is in the 30° position, the patient must no longer be moved in a horizontal (X and Y) direction.

- You should also avoid changing the position of the patient table or the patient in the vertical direction.

  Localisation of the stone in these two projection directions clearly determines its position in three-dimensional space. The stone will be located precisely in the treatment focus.
- Couple the therapy head to the patient. For further information, see Chapter **5.3.3 COUPLING**.

Checking the calibration

- To ensure that the stone remains precisely in focus following coupling, take an X-ray image in 0° AP projection in full format to check the accuracy of the calibration:
  ⇨ *If both calibration markers are visible at the edges of the X-ray image (***FIG. 11-13** *), the system is correctly adjusted.*

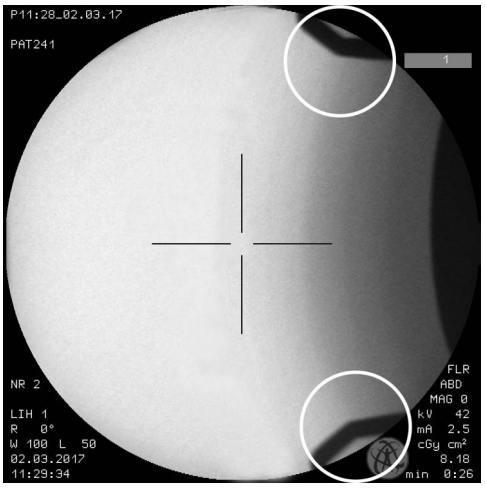


Fig. 11-13 Correct calibration

Correct calibration:
Both calibration markers are visible in the X-ray image at 0° projection in full format.
If neither marker is visible at the edges of the image or if only one marker is visible, the system is incorrectly calibrated.

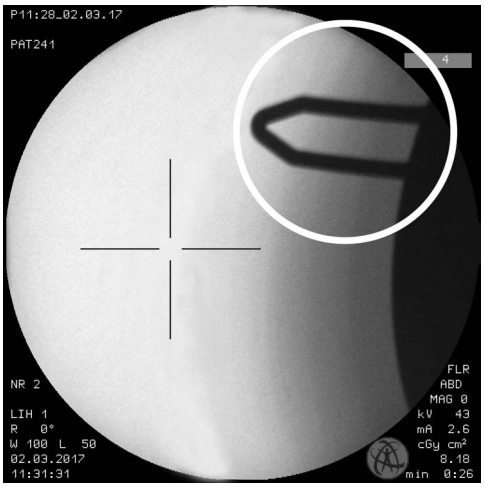


Fig. 11-14 System is incorrectly calibrated

Incorrect calibration:
Both calibration markers are not visible at 0° projection in the X-ray image. No treatment may be performed in such cases.

- Reposition the lithotripter and the X-ray arm as described in Chapter **11.2.2 SETTING UP THE SYSTEM**.

⚠ CAUTION

The stone is outside the treatment focus.

Risk to health due to unnecessary administration of shock waves!

► It is essential to ensure that the patient no longer moves after positioning to prevent the stone moving out of the treatment focus.

- During the lithotripsy procedure, carry out regular checks to determine the position of the stone by taking an exposure.
- Perform repositioning if necessary.

⚠ CAUTION

Risk of collision when the therapy head is moved.

Risk of crushing injuries to limbs.

► Always monitor movements of the therapy head visually.

► Avoid collisions.

After changing the therapy head from the lower table to the upper table position, the calibration markers must be set again in full format. Such a change is not recommended during treatment.

For X-ray devices with large flat panel systems, it is necessary to select zoom 1 as the reference.

- After coupling, check the position of the calibration markers again in full format.
  ⇨ *Collimator settings can then be selected for treatment.*
- Check the position of the calibration markers in full format every 500 - 800 shocks - or if you suspect that the system is out of adjustment.

11.3 Use of the MODULITH SLK with a urological X-ray workstation

⚠ CAUTION

Risk to health due to incorrect localisation.

► Precisely follow the sequence of the following steps.

11.3.1 Setting up the system

- Turn the therapy head of the MODULITH® SLK to the OT 0° position.
- Set up the MODULITH® SLK to the patient table as described in Chapter **3.2.1.3 POSSIBLE TREATMENT POSITIONS** described.

11.4 Setting up the system and checking the focus

11.4.1 Rough adjustment

- Move the patient table to the mounting position.
- Swivel the therapy head in and position it centrally below the collimator.
- Flip open the focus gauge.
- Switch on the light field indicator and/or activate the laser function of the collimator.
- Use the arrow buttons to move the therapy head until the therapy head crosshairs are congruent with the crosshairs displayed by the light field indicator.
- If available, use the red marking of the collimation laser as an additional point of reference.

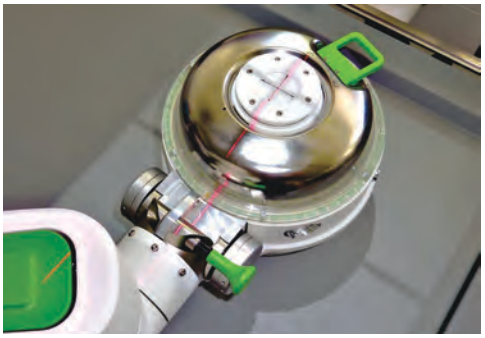


Fig. 11-15 Therapy head correctly aligned

11.4.2 Fine adjustment

- Take an X-ray image.
  ⇨ *As a rule, the monitor will show*

  1. the reflection mark of the focus phantom.

  2. two crosshairs offset in relation to one another: the crosshairs of the lithotripter and the crosshairs of the X-ray unit.

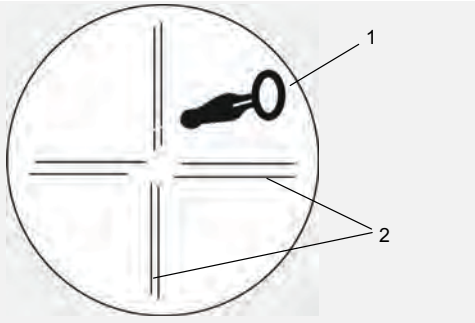


Fig. 11-16 Before the fine adjustment

- First align the horizontal lines of the crosshairs by tilting the table slightly (approx. +/- 1°).

- Align the two vertical lines of the crosshairs by tilting the therapy head of the MODULITH® SLK slightly.
  Using the dial on the optional fine adjuster (**FIG. 11-17** /1) you can position the therapy head easily and precisely.

When the dial is mounted, the positions UT 45° and OT 45° are no longer available.

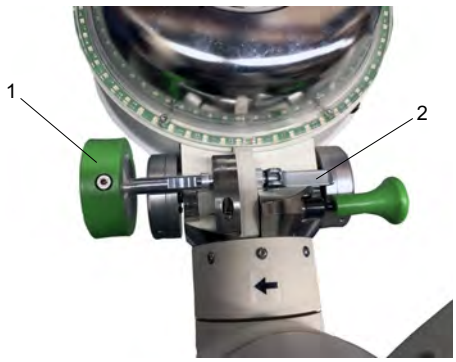


Fig. 11-17 Fine adjuster on the therapy head (optional)

- If alignment of the crosshairs is successful, lock the position of the therapy head using the tension lever on the side (**FIG. 11-17** /2).

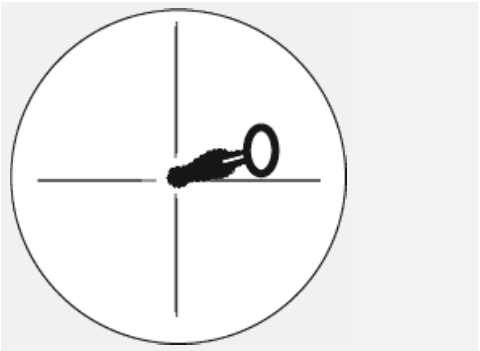


Fig. 11-18 After successful fine adjustment

- Align the crosshairs of the lithotripter with those of the X-ray system by moving the therapy head.
  ⇨ *Fine adjustment is successful when both crosshairs are on top of each other and the pin is in the centre of the crosshairs.*
  Fold the focus gauge back in.
- Swivel the therapy head out of the treatment area with the first joint of the therapy arm.

Fig. 11-19 Unlock button on the first joint

11.4.3 Function tests

WARNING

Device malfunctions.

Various risks of injury!

► In addition to the functional checks described in Chapter **5** , perform a focus check every day before starting treatment. See **5.2.2.3 FOCUS CHECK**

- To check the focus, follow the instructions in Chapter **11.4 SETTING UP THE SYSTEM AND CHECKING THE FOCUS**.

11.4.4 Stone localisation

Stone localisation with the MODULITH® SLK at a urological X-ray workstation involves two steps:

1) Determining the stone position in the XY-plane with a 0° X-ray
2) Determining the stone position on the Z-axis (height) with ultrasound localisation.

a) Determination of the stone position in the XY-plane

CAUTION

Risk to health due to incorrect localisation.

► Precisely follow the sequence of the following steps.

- Allow the patient to climb onto the table.
- Take an X-ray image without the therapy head. Position the stone in the crosshairs of the X-ray device by moving the table horizontally in the X and Y directions.
- Swivel the source back into position and couple the therapy head to the patient. Read about this in Chapter **5.3.3.2 THERAPY HEAD COUPLING IN OT POSITION**.
- Take an X-ray image. Position the stone in the centre of the crosshairs.

Determination of the stone position in the Z-plane with in-line ultrasound localisation

- Remove the cover from the central airbag (X-ray targeting pot) on top of the therapy head.
- Connect the in-line unit. For this, please read the Chapter **12.5.1 INSERTING THE ULTRASOUND IN-LINE UNIT** and **12.5.2 CONNECTING THE ULTRASOUND DEVICE**.
- Insert the ultrasound in-line unit into the therapy head.

Fig. 11-20 MODULITH® SLK with ultrasound in-line unit

- Adjust the height (Z direction) of the therapy head of the MODULITH® SLK so that the crosshairs of the ultrasound image are on the stone.
- If necessary, use the X-ray table to carry out horizontal repositioning in the X and Y directions. For this, remove the in-line unit and place the targeting pot back in its position.
- If movements are observed during the treatment, you can bring the stone back into focus in the X-ray by moving the table.

You can now follow the further course of the treatment either by X-ray or in-line ultrasound.

- To use in-line ultrasound, insert the in-line unit into the therapy head.
- To use X-ray, remove the in-line unit from the therapy head and mount the X-ray targeting pot.

b) Determination of the stone position in the Z-plane with offline ultrasound localisation

If an ultrasonic in-line unit is not available, you can also adjust the height using a conventional ultrasound transducer.

Proceed as follows:

- Measure the skin-to-stone distance using the measurement function of the ultrasound device.

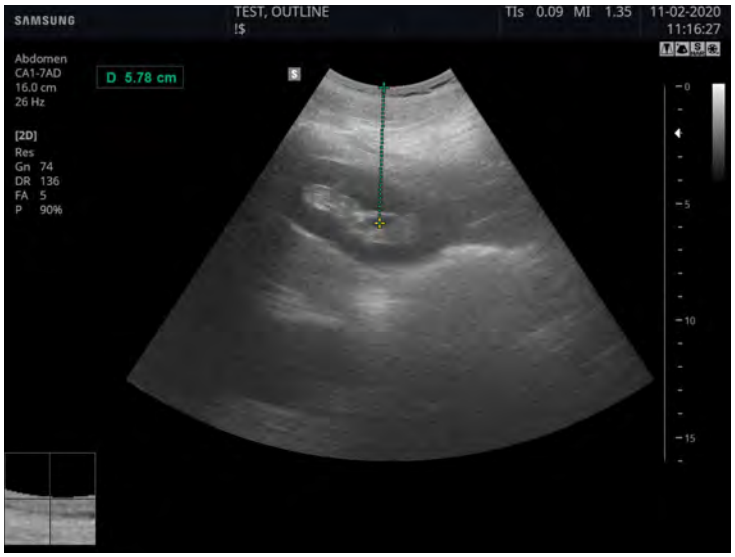


Fig. 11-21 Example: measured skin-to-stone distance = 58 mm

- Swivel the therapy head of the MODULITH® SLK into the treatment position.
- Move the focus gauge downwards.
- With the focus gauge unfolded, move the therapy head down until the white lever of the focus gauge touches the patient.
- Now note the value of the Z position on the display of the MODULITH® SLK.

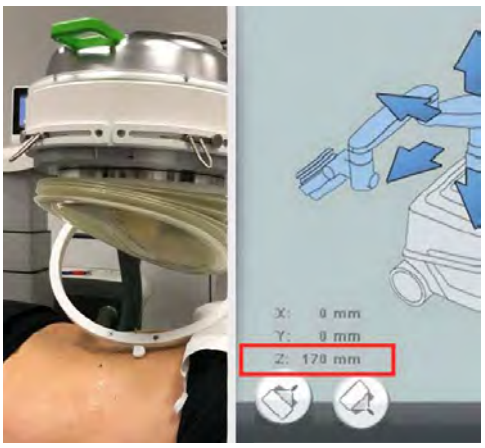


Fig. 11-22 Example: for patient contact, the value of the Z position = 170 mm

- Add 35 mm to the measured skin-to-stone distance (example: 58 mm + 35 mm = 93 mm).
- Now subtract the value obtained from the Z position of the MODULITH® SLK: Example: 170 mm - 78 mm = 92 mm. The result corresponds to the target coordinates of the MODULITH® SLK in height (Z).
- Move the MODULITH® SLK to the calculated position. You can now begin with the treatment.
- Couple the therapy head to the patient.

- Check the position of the stone using radioscopy and, if necessary, carry out a horizontal repositioning (X and Y direction) using the X-ray table.
- You can now follow the course of treatment using X-rays and offline ultrasound.

12 Ultrasound localisation (option)

12.1 General information

This chapter contains all the information required for operating the MODULITH® SLK lithotripter manufactured by STORZ MEDICAL AG with ultrasound localisation.

Only ultrasound devices authorised by the manufacturer of the MODULITH® SLK lithotripter are to be used. (See Chapter **3.7 COMPATIBLE ADDITIONAL DEVICES**).

The chapter on ultrasound localisation is part of the overall operating instructions MODULITH® SLK. All instructions, warnings and information in this complete operating manual also apply to the MODULITH® SLK with ultrasound system.

Knowledge of the contents of this chapter for the ultrasound device is an indispensable prerequisite for operating the entire system.

Only trained personnel are allowed to operate the lithotripter with ultrasound system. Detailed knowledge of working with ultrasound devices and knowledge of ultrasound diagnostics are a precondition for operating the ultrasound device. This chapter does not communicate this knowledge. The actual procedure for performing ultrasound localisations is described in the separate operating manual by the manufacturer of the ultrasound device.

Shock waves must never be triggered without coupling agent; otherwise, there is a risk of damaging the ultrasound transducer due to the reflection of shock waves.

12.2 Description of the ultrasound system

The ultrasound system integrated into the MODULITH® SLK consists of the following components:

- Ultrasound in-line unit with transducer
- Ultrasound device
- Hand-held transducer (optional)

12.2.1 Ultrasound in-line unit with transducer

The ultrasound in-line unit is pushed into the therapy head of the MODULITH® SLK (**Fig. 12-1**). The unit contains the ultrasound transducer and the motor for upward and downward movements. The in-line unit can be hooked into a holder on the ultrasound device if localisation is performed without ultrasound.

Fig. 12-1 Ultrasound in-line unit with therapy head

Precision localisation of the stone or the target region is performed using the transducer. The stone or the target region is positioned precisely in the crosshairs on the ultrasound monitor. During this process, the transducer can be rotated axially by hand by 360° to set the optimum acoustic therapy window in the patient. The shock wave path is displayed in the ultrasound image so that the best coupling direction can be assessed. The entire axial travel distance of the transducer is 90 mm.

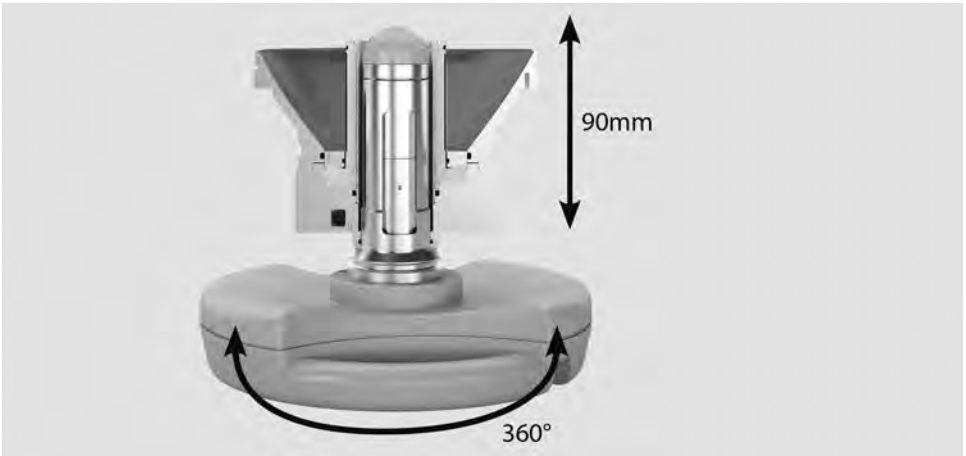


Fig. 12-2 Transducer movements

12.2.2 Ultrasound image and ultrasound monitor

The treatment process and position of the target zone in the crosshairs can be checked on the monitor during treatment. The ultrasound image required for this is provided by the in-line transducer. The ultrasound image displays the shock wave path (dashed line) with focus for assessing the best coupling direction (**FIG. 12-3**).

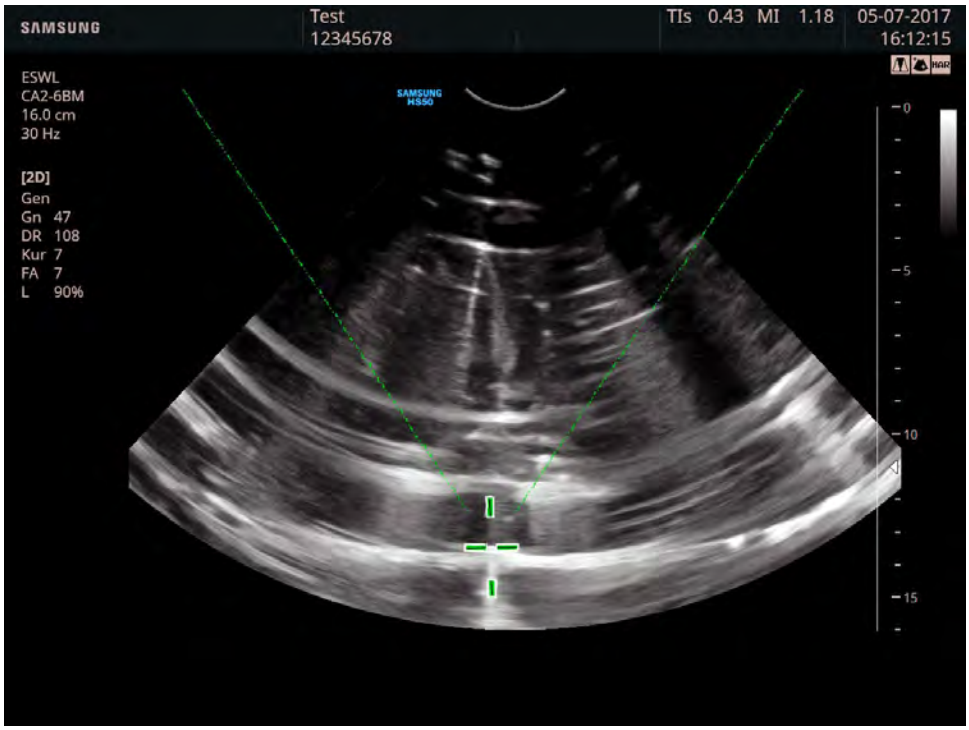


Fig. 12-3 Display on the ultrasound monitor

12.2.3 Ultrasound device

⚠ CAUTION

- ► Only personnel suitably authorised by the manufacturer of the MODULITH® SLK are allowed to install the ultrasound device.
- ► Only ultrasound devices and associated components (e.g. cables, etc.) approved by the manufacturer of the MODULITH® SLK are to be connected.

List of suitable ultrasound devices	
Manufacturer	Model
HITACHI ALOKA	Prosound 6
HITACHI ALOKA	Prosound 2
HITACHI ALOKA	3500 SX
FUJIFILM / HITACHI / ALOKA	F37
Samsung	HS50
Samsung	HS30

Tab. 12-1 List of suitable devices

Technical specifications, connection ratings and application conditions are detailed in the separate operating manual for the ultrasound device. The separate operating manual also provides you with information about other applications. The ultrasound device is informed of the position of the in-line transducer by means of a control cable.

12.3 Handling of the in-line unit

As soon as the in-line unit is inserted into the therapy head and connected to it, the following functions become available:

- Press ULTRASOUND.
  ⇨ *The various functions of the menu are now available.*

Moving the ultrasound in-line unit

- Press .
- The in-line unit is moved towards the patient.

  or

- Press .

⇨ *The in-line unit is moved away from the patient.*

12.4 Focus check

As part of the functional checks specified in Chapter **5.2.2.3 FOCUS CHECK**, it is necessary to perform the focus check daily before the start of treatment. The position of the crosshairs on the ultrasound monitor is checked using the integrated focus gauge. The focus gauge contains a reflection mark that precisely represents the focal point. The reflection mark shows up on the ultrasound monitor as a solid white (light grey) shadow.

The speed of sound in water is different from the speed of sound in soft tissue.
The special software of the ultrasound control unit takes account of this difference, and places the crosshairs based on the speed of sound to be expected in a patient (soft tissue).

Proceed as follows to perform the check:

- Switch on the MODULITH® SLK and move the therapy head to the 45° UT or 0° OT position
- Remove the cover from the central airbag on the bottom of the therapy head (see Chapter **12.5.1 INSERTING THE ULTRASOUND IN-LINE UNIT**).
- Insert the ultrasound in-line unit into the therapy head.
- Flip open the integrated focus gauge, making sure it engages.

Fig. 12-4 Flipping open the focus gauge

- Adding a few drops of silicone oil, place the focus check water pillow onto the coupling cushion.
- Activate the coupling cushion and adjust the height of the cushion so that the reflection mark touches the focus check water pillow.

Fig. 12-5 Contact between the reflection mark and focus check water pillow

1 Data cable (marked in yellow)

- Connect the in-line unit via a data cable (marked in yellow, **Fig. 12-5** /1) to the ultrasound device
- Switch on the ultrasound device and select one of the settings provided for ESWL.
- Press and move the ultrasound transducer to the lowest position (the default position once the in-line unit has been inserted) and rotate it manually about its axis until the reflection mark is clearly visible in the ultrasound image (**Fig. 12-6**).

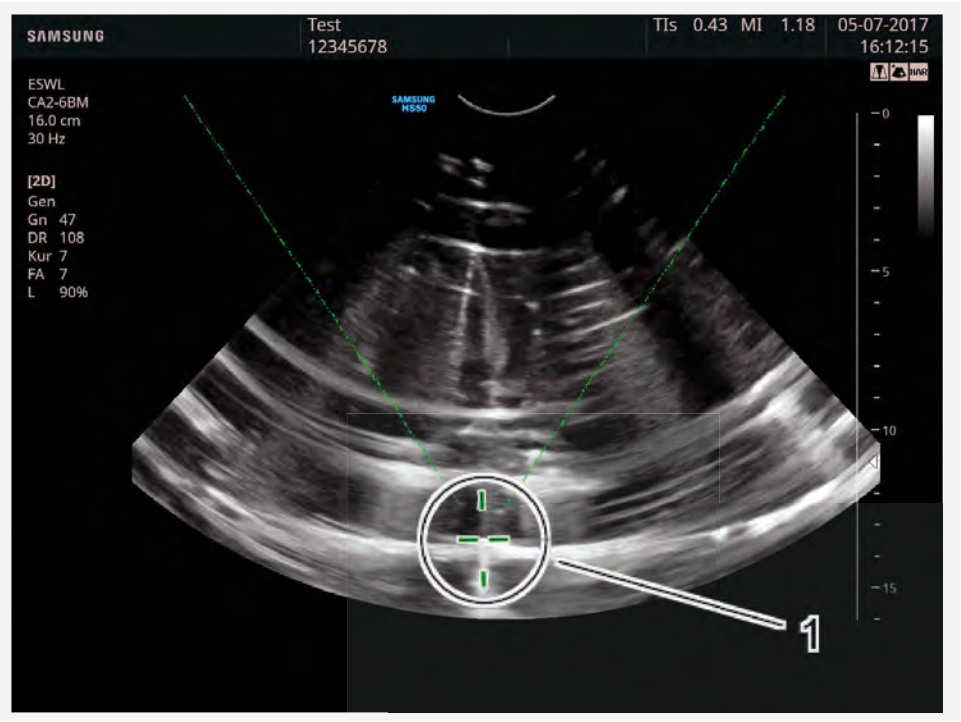


Fig. 12-6 Transducer at lowest position

Measure the distance between the centre of the crosshairs and the reflection mark.

The horizontal tolerance is H = ±1.5 mm.

The vertical tolerance is ±2 mm.

Please use the distance measurement function of the ultrasound device to take the measurements.

- Press and move the transducer to the highest position.
  ⇨ *During this process, the crosshairs must follow the reflection mark so that the vertical offset between the crosshairs and reflection mark gets smaller.*

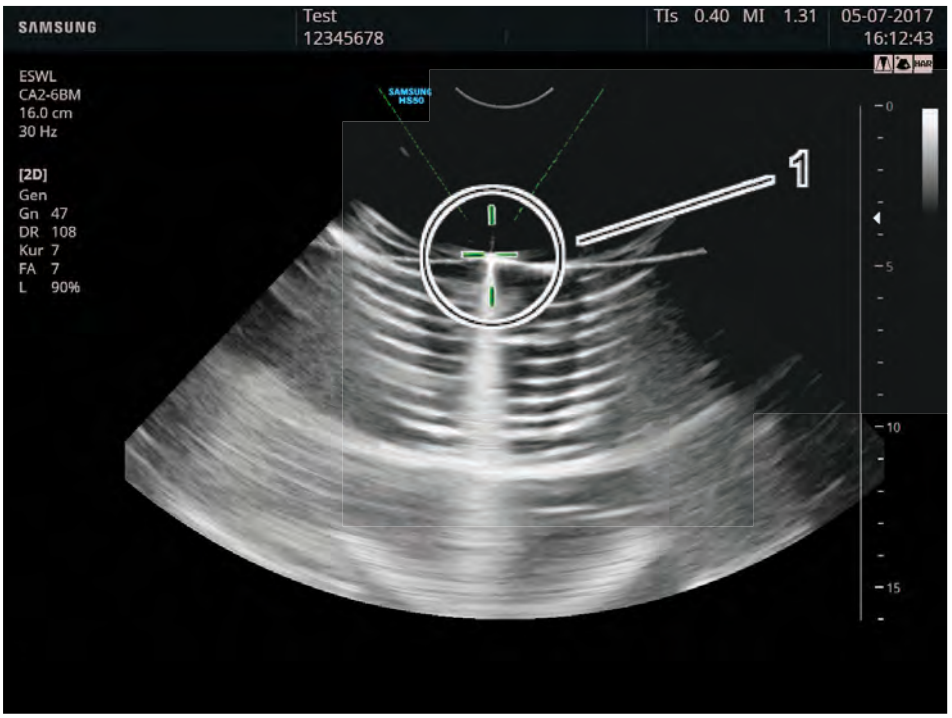


Fig. 12-7 Transducer at highest position

- Measure the distance between the centre of the crosshairs and the reflection mark.

  The horizontal tolerance is H = ±1.5 mm.
  The vertical tolerance is ±2 mm.

Please use the distance measurement function of the ultrasound device to take the measurements.

⚠ CAUTION

Reflection mark is not located within the specified tolerances.

Risk to health due to incorrect localisation.

► Do not perform treatment.

► Inform your Service centre.

12.5 Treatment preparation

12.5.1 Inserting the ultrasound in-line unit

Before the ultrasound in-line unit can be inserted, you must remove the targeting pot for the airbag from the rear of the therapy source:

- Switch on the MODULITH® SLK and move the therapy head to the 45° UT position.
- With one hand, firmly hold the cover of the central airbag (targeting pot) on the bottom of the therapy head while using your other hand to pull the unlocking lever outwards.
- Remove the cover.
- Insert the ultrasound in-line unit all the way into the therapy head until it engages.
  - While inserting the in-line unit, take care not to tilt/twist or damage the transducer.
- Connect the spiral cable with the angled plug to the female connector on the side of the therapy head (**FIG. 12-8** /4), and connect the other end of the cable with the straight plug to the brown connector on the housing of the in-line unit (**FIG. 12-8** /2).

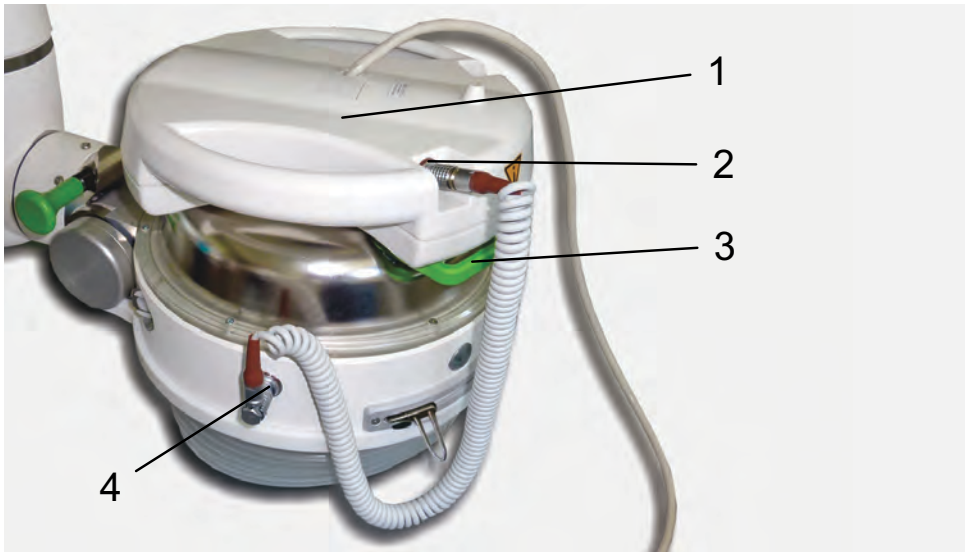


Fig. 12-8 In-line unit connected to therapy head in 0° OT

1 Inserted in-line unit
2 Connection of spiral cable to in-line unit
3 Unlocking lever
4 Connection of spiral cable to therapy head

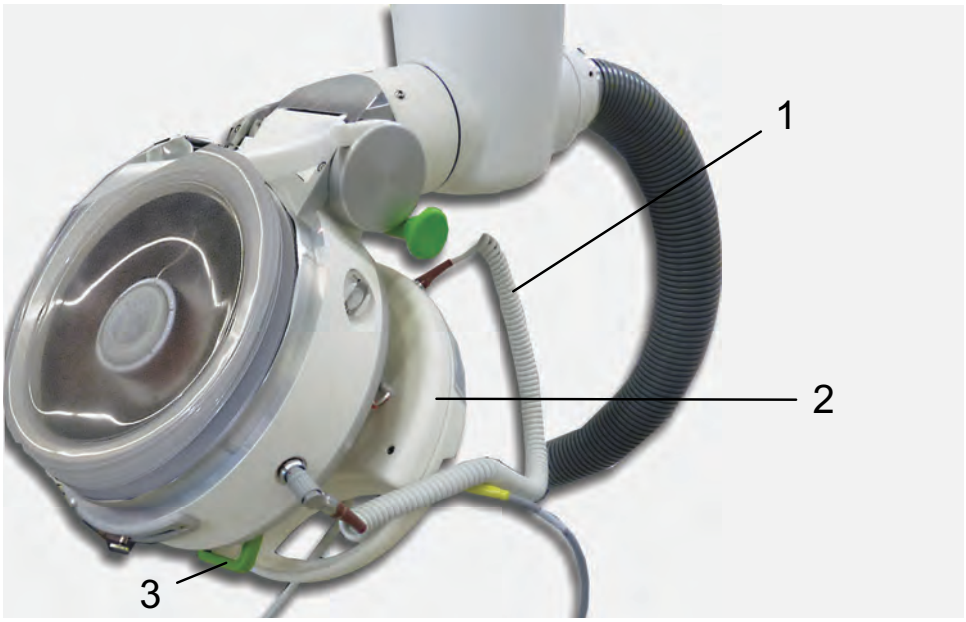


Fig. 12-9 In-line unit connected to therapy head in 45° UT

1 Connected spiral cable
2 Inserted in-line unit
3 Unlocking lever

⚠ CAUTION

► Hold the cover/ultrasound in-line unit firmly with one hand before you operate the unlocking lever. Otherwise, there is a risk that parts could drop onto the floor.

NOTICE

The airbag cannot be pumped up if the targeting pot is not in the opening.

12.5.2 Connecting the ultrasound device

- Please refer to the separate operating manual of the ultrasound device for information about connecting it to the electrical power supply.
- Connect the data cable (StorM-Link) for the ultrasound device to the yellow connector of the in-line unit.
- Connect the other end of the data cable with the D-SUB plug to the adapter or the LWL connector on the ultrasound device.

Variant 1: Connector on the FUJIFILM/Hitachi/Aloka ultrasound device

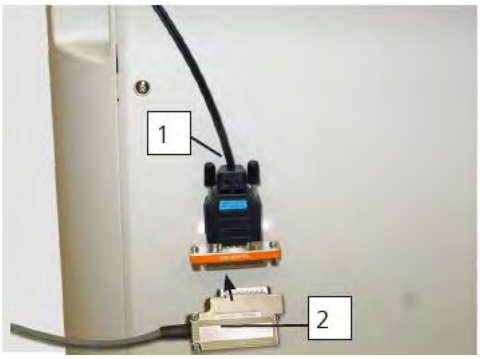


Fig. 12-10 StorM-Link data cable connector on the ultrasound device

1 LWL cable
2 Storm Link data cable

Variant 2: Connector on the Samsung ultrasound devices

Fig. 12-11 StorM-Link data cable connector on the ultrasound device

If the ultrasound device is to be used independently of the lithotripter, it is first necessary to disconnect the control cable from the ultrasound device and then the cable from the in-line unit on the therapy head. Otherwise, a warning message will be permanently shown on the ultrasound device.

12.6 Stone localisation/positioning

NOTICE

This chapter does not deal with precise operation of the ultrasound device. Experience in ultrasound diagnostics and knowledge of the separate operating manual for the ultrasound system are therefore essential prerequisites.

Localisation and positioning of stones in the treatment focus can be performed using ultrasound, ultrasound and X-ray, or only with X-ray. If the stone is difficult to detect in the ultrasound image, you can first perform X-ray localisation (option) with the therapy head in the park position. This chapter describes localisation with ultrasound. For a description of X-ray localisation, please see Chapter **11 X-RAY LOCALISATION (OPTION)**. Proceed as follows for ultrasound localisation:

- Install the in-line unit, and switch on the lithotripter and the ultrasound device (see Chapter **12.5 TREATMENT PREPARATION**).
- Position the patient so that the intended treatment region is located as close as possible to the focal point of the therapy head.
  Fine positioning will be carried out later.
- If you are using a hand-held ultrasound transducer, use it to perform rough localisation. While doing so, please bear the intended direction of treatment in mind: over-table (OT) or under-table (UT).
- Move the therapy head into the over-table (OT) or under-table (UT) position.
- Use the patient table to move the patient so the transducer is aiming at the point you previously found using the hand-held transducer. The stone to be treated should be about 15 cm in front of the therapy source.
- Couple the coupling cushion to the patient.
- Carefully move the transducer towards the patient. Check coupling as you do so. Sound shadows on the ultrasound image indicate air bubbles.
- Use your hand to stroke away any air bubbles located between the coupling cushion and patient.
- If necessary, try rotating the ultrasound in-line unit to adjust the scanning plane for optimum localisation of the stone.
- Correct the alignment by moving the patient table if necessary.

⚠ WARNING

If tissue structures that should not be within the pressure wave path are now visible in the ultrasound image, you must reposition the patient.

► After repositioning the patient, the localisation procedure must always be repeated.

- As soon as the stone is located precisely in the treatment focus following ultrasound localisation and positioning, you can continue as described in Chapter **5 TREATMENT PREPARATION AND TREATMENT**.

⚠ CAUTION

► It is essential to ensure that the patient no longer moves after positioning to prevent the target area moving out of the treatment focus.

► Do not proceed to shock wave treatment if you cannot localise the target area.

Once 20 shock waves have been triggered, the ultrasound transducer returns automatically.
If the ultrasound transducer is extended, this casts a shadow on the shock waves and reduces their effectiveness significantly.

Once 20 shock waves have been triggered, the ultrasound transducer returns automatically.

12.7 Cleaning and disinfection

After the ultrasound in-line unit has been removed from the therapy source, the unit should be cleaned and disinfected. Refer to the table in Chapter **12.7 CLEANING AND DISINFECTION** for details of cleaning agents and disinfectants.

DANGER

Risk of explosion due to the use of flammable and explosive cleaning agents and disinfectants during operation.

Injuries to patients, people administering the treatment and third parties!

- ► Ensure that treatments and cleaning procedures are only carried out by qualified and instructed medical professionals.
- ► Avoid using highly volatile cleaning agents and disinfectants which can form a potentially explosive atmosphere.
- ► Switch off the device before cleaning and disinfection and disconnect the power plug.

12.7.1 Technical safety checks

The information in Chapter **12.7.1 TECHNICAL SAFETY CHECKS** applies.