User Manual

Stepper, Stabilizer, Template, and Accessories for Biopsies, Interstitial LDR and HDR Brachytherapy, and Cryotherapy of the Prostate

The equipment in its optional storage case.

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Warnings and Cautions

Storage and Handling Instructions: The universal articulate arm (stabilizier), stepper, template and template holder is delivered to you packed in a cardboard box:

- Avoid exposure to high temperatures above 120°F and below 50°F.
- Protect the equipment form shock, scratches and other damage.
- Do not store the equipment in direct sunlight or warm and humid places.

Federal Law restricts this Device to Sale by, or on the order of, a Physician, or Veterinarian.

Intended Use: The universal articulate arm is comprised of the articulate arm with OR-side adapter. The equipment assists in the manual positioning of objects attached to it.

The universal articulate arm (stabilizier), stepper, template and template holder (= the system) will only assist in the positioning of the objects. The true position of the objects can only be determined by observing the objects directly.

Do not attach any objects to the system other than those specified in this manual.

Only operate the system in accordance to the safety precautions given in this operation manual.

Only use the system in connection with other products that are also CE or FDA certified.

The use of the system for purposes not defined in this manual is prohibited.

Disclaimer: Users must have a working knowledge of English and be a physician familiar with the planned treatment or diagnostic process. The universal articulate arm (stabilizier), stepper, template and template holder is not to be connected directly to any electrical power source. Every reasonable precaution has been taken during the design and manufacture of these devices in order to ensure their reliability would not be compromised. Nevertheless, the following precautions should be observed:

- The system is not packaged sterile. The system must be disinfected each time before use.
- The template must be sterilized before each use.
- It is the responsibility of the user to check if the OR side rail and table supporting the universal articulate arm is sufficiently sturdy.
- Before using the equipment, check the universal articulate arm (stabilizier), stepper, template and template holder for damages and functionality before using them
- Do not use the system if any damages or functional irregularities are detected.
- Only use the system if all the joints of the articulate arm are completely rigid when the hand lever is released and the articulate arm is locked and solidly connected to the OR-side rail.
- Follow all the warnings, attentions, dangers and cautions mentioned in the chapter “Safety” of this user manual.
- It is the responsibility of the user to select the correct patient.
- Only one patient may be treated at the same time.

Contents

1. Safety 5
1.1. Description of the Symbols Used 5
1.2. General Safety Information 5
1.3. Mechanical Safety 7
1.4. Safety Precautions 7
1.5. Intended Use 10
1.6. Conformity with Standards 10
2. Introduction 11
2.1. About this User Manual 11
2.2. General Information on the Biopsy, Cryo- / Brachytherapy Equipment 11
3. Biopsy, Cryo- / Brachytherapy Equipment - Overview 12
4. Mounting and Dismounting the Stepper-Stabilizer-Template Assembly to / from the Side Rail of the Surgical Table 13
4.1. Connecting the biopsy, Cryo- / Brachytherapy Equipment to the OR-Side Rail 13
4.2. The Articulate Arm (Stabilizer) (3) 14
4.3. Assembly of the Handgrip (X) 16
4.4. Mounting / Dismounting the Stepper (2) 18
4.5. Basic Adaptation of the Probe Cradle to the Size of the Probe Handle 20
4.6. Mounting / Dismounting the Template Holder 21
5. Working with the Stepper (2) 22
5.1. Basic Adjustments before Usage 22
5.2. Inserting / Retrieving the Ultrasound Probe into / from the Stepper 23
5.3. Using the Probe Support Option on the Template holder 28
5.4. Mounting the Stepper on the Articulate Arm 29
5.5. Normal Operation of the Stepper 29
6. Working with the Arm (3) 30
7. Cleaning Disinfection and Sterilization 31
7.1. Cleaning of the Templates, Template Holder, Probe Support Stepper, and Probe Receptacle 32
7.2. High-level Disinfection or Sterilization of the Centering Tube 34
7.3. Cleaning and Disinfection of the Articulating Arm 34
7.4. Cleaning and Disinfection of the Incremental Encoders 34
8. Appendix 35
8.1. Technical Data 35
8.2. Incidence Report Form for The biopsy, Cryo- / Brachytherapy equipment 37

1. Safety

1.1. Description of the Symbols Used

The symbol „ATTENTION“ points to a safety hazard that absolutely must be observed.

The symbol „ATTENTION“ with the subscript „DANGER“ points to a direct hazard which can cause serious injuries, death, considerable damages, or fire. Measures for the elimination of this danger have to be taken immediately.

The symbol „ATTENTION“ with the subscript „WARNING“ signalizes the possibility of a hazard that can cause serious injuries, death, considerable damages, or fire. Measures for the prevention of this danger have to be taken immediately.

The symbol „ATTENTION“ with the subscript „CAUTION“ reflects situations that require special attention in order to avoid harm to patient, user, or third parties.

This symbol points to unusual conditions, special circumstances, or possible working methods that can occur during the use of this product.

EU-Conformity label

1.2. General Safety Information

For reasons of simplification the stepper, stabilizer, template, and accessories in total are called “Biopsy, cryo- / brachytherapy equipment” in the following text.

The stepper has been designed for the use with specific ultrasound probes. Make sure you have the appropriate stepper for the ultrasound probe in use.

Carefully read chapter “Safety” before you use the biopsy, cryo- / brachytherapy equipment.

Always keep this operating manual at hand.

You may only operate the biopsy, cryo- / brachytherapy equipment as defined and in accordance to the safety precautions of this operating manual. It must be operated by trained physicians.

The operator is always responsible for the observation of the regulations which apply to the installation and operation of the biopsy, cryo- / brachytherapy equipment (see medical product law or local regulations).

Only use the biopsy, cryo- / brachytherapy equipment, if there are no external or visible damages.

The safety of the equipment can only be ensured if all operations, modifications, controls, and inspections are executed by persons trained accordingly by D&K Technologies or through persons authorized by D&K Technologies.

Only use peripheral devices approved by D&K Technologies.

The biopsy, cryo- / brachytherapy equipment is not intended for direct patient contact.

Please note that the biopsy, cryo- / brachytherapy equipment must always be secured when you mount or detach an ultrasound probe. If you ignore this precaution the ultrasound probe, the biopsy, cryo- / brachytherapy equipment as well as other surrounding objects may be damaged or persons may be injured

1.3. Mechanical Safety

Excessive shocks or vibrations can damage the biopsy, cryo- / brachytherapy equipment.

Do not disassemble the products and especially, do not oil or grease the joints of the articulate arm.

Do not submerge the arm in any liquid.

Only operate the biopsy, cryo- / brachytherapy equipment in a room under the following environmental conditions: Room temperature (10°C to 50°C), no condensed water or other liquids may come in contact with the biopsy, cryo- / brachytherapy equipment (see cleaning instructions).

Do not install the biopsy, cryo- / brachytherapy equipment in the immediate vicinity of a radiator. Protect it against direct solar radiation.

1.4. Safety Precautions

The biopsy, cryo- / brachytherapy equipment is not packaged sterile. The equipment must be disinfected before use. The template must be sterilized before use.

Check the biopsy, cryo- / brachytherapy equipment for damages before using it. Do not use it if any damages are detected.

Check that the step size is set correctly at 5 or 2.5 mm as required by the application and check that the steps are truly at 5 or 2.5 mm respectively by observing the scale on the stepper. The individual steps are designated by a "click" that must be heard as well as felt, i.e., a change in pressure is felt on the knob for moving the probe holder (F) when the stepper locks into each step. Do not use the stepper if an error occurs.

Only use the articulate arm (stabilizer) if all the joints are completely rigid when the hand lever is released.

Do not use the biopsy, cryo- / brachytherapy equipment that show cracks or other damages.

Make sure that the OR-side rail adapter of the articulate arm is securely fastened to the OR-side rail.

The biopsy, cryo- / brachytherapy equipment will only assist in the positioning of the needles and seeds. The true position of the needles and seeds can only be determined by observing the ultrasound image on the ultrasound system and probe used. The template coordinates on the biopsy, cryo- / brachytherapy equipment do not necessarily coincide with the biopsy, cryo- / brachytherapy template on the ultrasound image in case of misalignment.

Make sure that the stepper's lock to the sliding-block linkage on the underside of the stepper is pushed fully onto the sliding-block linkage of the stabilizer.

If the handle has been disassembled for cleaning make sure it is correctly reassembled as described in this manual all screws are fully tightened.

Make sure that the template is securely fastened to the template holder and to the stepper.

The biopsy, cryo- / brachytherapy equipment only assists in positioning the biopsy, cryo- / brachytherapy needles. The true positions of the biopsy, cryo- / brachytherapy needles and brachytherapy seeds can only be detected by observing the ultrasound image of the ultrasound system used. The coordinates on the biopsy, cryo- / brachytherapy equipment and the template in particular do not necessarily coincide with the coordinates displayed on the ultrasound image.

Before starting to work, the alignment of the needle grid in the template and the ultrasound probe in combination with the template displayed on the ultrasound unit must be checked each time and possibly adjusted on the ultrasound unit (consult the manual of the ultrasound system if necessary). You may not set to work before this has been checked and if necessary all alignments have been corrected.

Observe the special advice concerning cleaning and disinfection.

For cleaning and disinfection remove the ultrasound probe from the biopsy, cryo- / brachytherapy equipment (see cleaning instructions).

To avoid contamination of patients and users, the biopsy, cryo- / brachytherapy equipment has to be cleaned and disinfected before and after each use (see cleaning instructions).

Before each use, the position of the template needle grid relative to the ultrasound template must be checked. Please see chapter “Basic Adjustments before Usage”.

1.5. Intended Use

The biopsy, cryo- / brachytherapy equipment assists in the manual positioning of needles in the interstitial cryo- / brachytherapy treatment of the prostate and in biopsies.

The biopsy, cryo- / brachytherapy equipment will only assist in the positioning of the needles and seeds. The true position of the needles and seeds can only be determined by observing the ultrasound image on the ultrasound system and probe used. The template coordinates on the biopsy, cryo- / brachytherapy equipment do not necessarily - in case of misalignment - coincide with the cryo- / brachytherapy template on the ultrasound image.

Only operate the biopsy, cryo- / brachytherapy equipment in accordance to the safety precautions given in this operation manual.

The use of the biopsy, cryo- / brachytherapy equipment for purposes not defined in this manual is prohibited.

1.6. Conformity with Standards

The biopsy, cryo- / brachytherapy equipment is in accordance to the FDA and EU-Regulation of the Council for the adaptation of legal regulations of the member states for medical products (93/42/EWG) (Medical Device Directive) a class 1 medical product. When combined with a medical device (ultrasound system), the manufacturer of the ultrasound system is obliged to state the conformity of the complete configuration. The biopsy, cryo- / brachytherapy equipment is developed and produced in conformance with the generally acknowledged state of the art rules of technology and carries the CE label:

CE

The biopsy, cryo- / brachytherapy equipment is FDA registered under the name “SolidLock Positioning”

Further information about the conformity with national / international norms is available from:

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D&K Technologies is an DIN EN ISO 9001, EN ISO 13485 certified company by TUEV NORD CERT.

2. Introduction

You have acquired the biopsy, cryo- / brachytherapy equipment by D&K Technologies. We congratulate you on the choice of this equipment.

We thank you for the confidence you have shown to us in purchasing this equipment.

2.1. About this User Manual

This user manual contains detailed information on the biopsy, cryo- / brachytherapy equipment by D&K Technologies. It is intended as a reference book for your daily work. This user manual informs you about installation and configuration of the biopsy, cryo- / brachytherapy equipment, technical data, and settings.

For further information concerning biopsies, cryo- / brachytherapy please consult the standard literature and inquire with your local D&K Technologies distributor.

In order to be able to use the biopsy, cryo- / brachytherapy equipment optimally, please carefully read this manual. First of all, familiarize yourself with chapter “Safety”, to avoid damages and to avert dangers.

The numbers and letters used in this manual to designate certain components are only used once and always refer to the same component.

Always keep this user manual at hand.

2.2. General Information on the Biopsy, Cryo- / Brachytherapy Equipment

The biopsy, cryo- / brachytherapy equipment has been developed in close cooperation with physicians working in cryo- / brachytherapy for many years. The biopsy, cryo- / brachytherapy equipment gives the user the easiest and thus safest approach to interstitial cryo- / brachytherapy possible.

Modern design, material, and color give your biopsy, cryo- / brachytherapy equipment a very pleasant appearance.

The optional case allows for carefree transport and storage.

The stepper has been designed for the use with specific ultrasound probes. Make sure you have the appropriate stepper for the ultrasound probe in use.

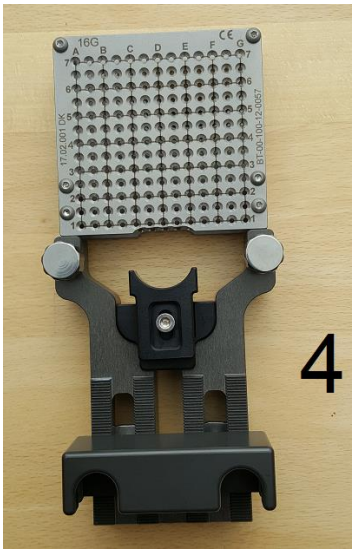
The biopsy, cryo- / brachytherapy equipment is comprised of the following components:

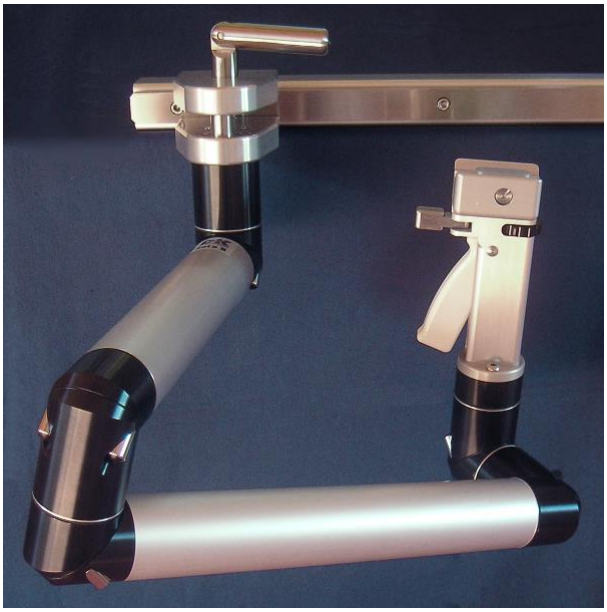
- Articulate arm (= Stabilizer) including a universal OR-side rail adapter
- Stepper
- Template

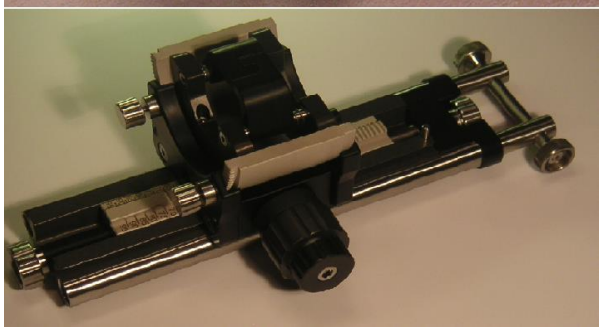
The biopsy, cryo- / brachytherapy equipment has been produced observing a high standard of quality - for your and your patient’s safety.

- ISO 9001
- CE-marked
- FDA registered

3. Biopsy, Cryo- / Brachytherapy Equipment - Overview







Components (some are optional):

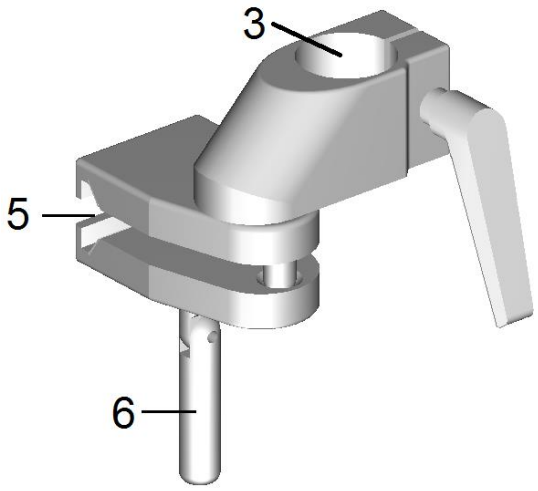
Top: Template in universal template holder (4) including optional probe support and template – Handle adapter for Probe GE ERB7 (7) – Centering tube for probe B-K-Medical 8658 MFI (6) - Probe handle centering tube for probe Hitachi EUP U533 or Aloka C41L47RP or Aloka CL4416R

Bottom left: Articulate arm (stabilizer) SoLo B with universal OR-side rail adapter

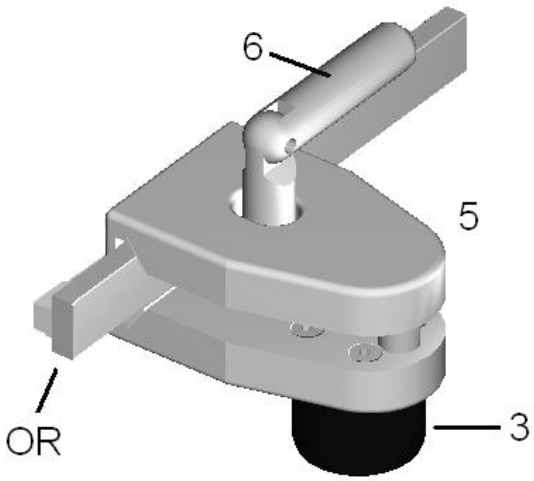
Bottom right: Stepper

4. Mounting and Dismounting the Stepper-Stabilizer-Template Assembly to / from the Side Rail of the Surgical Table

4.1. Connecting the biopsy, Cryo- / Brachytherapy Equipment to the OR-Side Rail



Setup 1 - Attaching the universal OR-side rail adapter to the OR-side rail



Setup 2 - Attaching the universal OR-side rail adapter to the OR-side rail

Components:

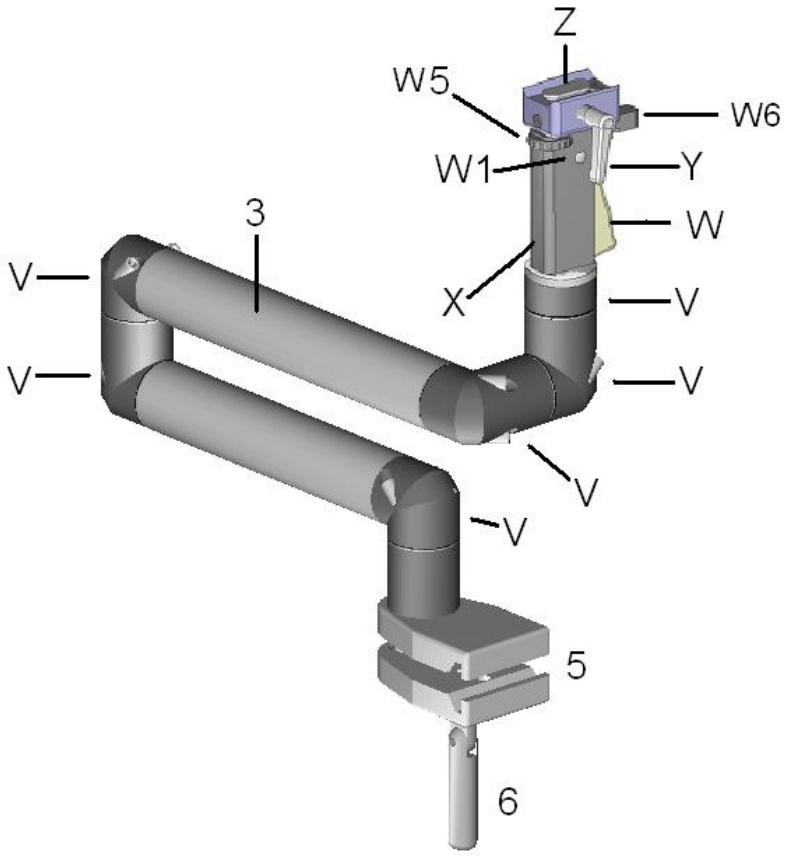
3	Articulate arm (Stabilizer)
5	Universal OR-side rail adapter
6	Lever for fixing the OR-side rail adapter together with the stepper/stabilizer at a defined position to the side rail
OR	OR-side rail

Depending on the construction of the surgical table and on the application, one of the 2 basic setups above can be selected.

In case of a cryo- / brachytherapy application setup 2 will be used most often. In this case the arm will be initially pointing toward the floor.

The universal OR-side rail adapter (5) is placed over the OR-side rail (OR) in the desired position as shown above. The lever (6) is turned clockwise until the OR-side rail adapter (5) is securely fixed to the OR-side rail. The lever (6) can be flipped 90° to two sides for convenience in order to always have a secure grip on it.

4.2. The Articulate Arm (Stabilizer) (3)



Articulate arm (3) with 6 joints, handgrip, and universal OR-side rail adapter (5 + 6)

Components:

V 360° rotational joints (6 joints in most cases)

W Lever for locking and unlocking all joints at the same time (Pull to unlock and let go to lock)

W1 Pin that can be pushed out of the handle (X) to remove lever (W)

W5 Elevation selector

W6 Swivel angle selection lever

X Handle

Y Rotating lever for locking an object to the arm. The lever moves lock Z up and down. The position of the lever can be changed by pulling the lever away from the handle (X) and rotating the lever into the desired position so that it does not interfere with the device attached.

Z Lock that slides into the sliding block linkage on the underside of an object that is to be connected to the arm.

The articulate arm must be fixed to the OR-side rail or as described in chapter “Connecting the Arm to the OR-Side Rail “. Alternately another device specified by D&K Technologies may also be used.

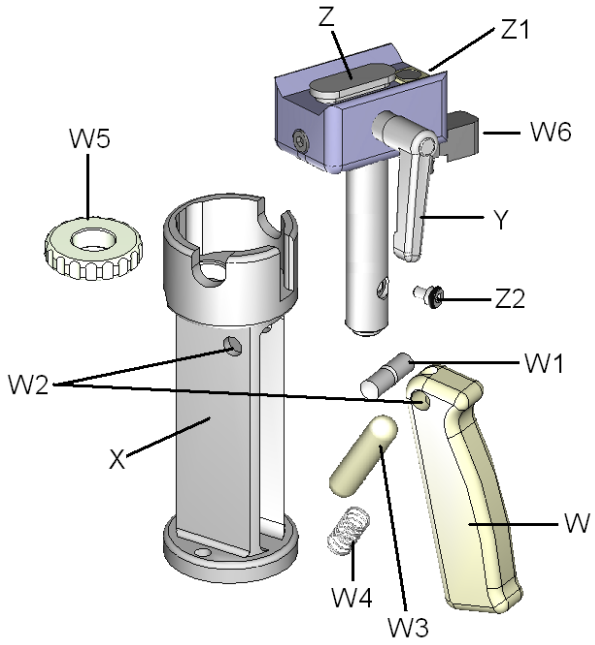
The articulate arm includes 6 (in most cases) rotating joints that are connected to one another by tubes of different length. The arm must be hand held tightly by the handle (X) when moving the arm. All joints are unlocked simultaneously by pulling (or pressing) lever (W). **Always pull lever (W) all the way to its end stop when moving the arm.** The joints are all locked in place simultaneously by releasing lever (W) completely. When lever (W) is pressed fully, the arm can be moved freely. Releasing lever (W) will lock the arm in the position it is in at the time being.

A device connected to the handgrip lock (Z) can be moved up and down up to ± 1 cm from its center position by rotating the elevation selector (W5) clockwise or counter clockwise. Please observe the change in position of the elevation device. By moving the swivel angle selection lever (W6) a device connected to the handgrip lock can be pivoted left and right by and angle of ± 15° from its center position.

Devices specified by D&K Technologies may be fixed to the articulate arm. Slide the sliding block linkage on the underside of an appropriate device over the lock (Z). It may be necessary to move lock (Z) to its top most position by rotating lever (Y). Please observe lock (Z) while rotation lever (Y). Rotate lever (Y) to locking a device to the arm. **Please check if the attached device is solidly locked to the handgrip.**

The position of lever (Y) can be changed by pulling the lever away from the handle (X) and rotating the lever into the desired position so that it does not interfere with the attached device.

4.3. Assembly of the Handgrip (X)



Handgrip assembly / disassembly

Components:

X Handle

W Lever for locking and unlocking all joints simultaneously (Pull all the way to unlock and let go to lock)

W1 Pin that can be pushed out of the handle (X) to remove lever (W) and force transfer pin (W3)

W2 Holes for pin (W1)

W3 Force transfer pin

W4 Inner handle security spring for force transfer pin

W5 Elevation selector

W6 Swivel angle selection lever

Y Rotating lever for locking a device to the arm. The lever moves lock (Z) up and down. The position of the lever can be changed by pulling the lever away from the handle (X) and rotating the lever into the desired position so that it does not interfere with the attached device.

Z Lock that slides into the sliding block linkage on the underside of an object.

Z1 Elevation slider

Z2 Elevation lock screw

The handgrip can be disassembled for cleaning. To do this, push pin (W1) out of the handgrip holes (W2) with a small rod. Lever (W) and the force transfer pin (W3) as well as the security spring (W4) will then fall out of the handle (X).

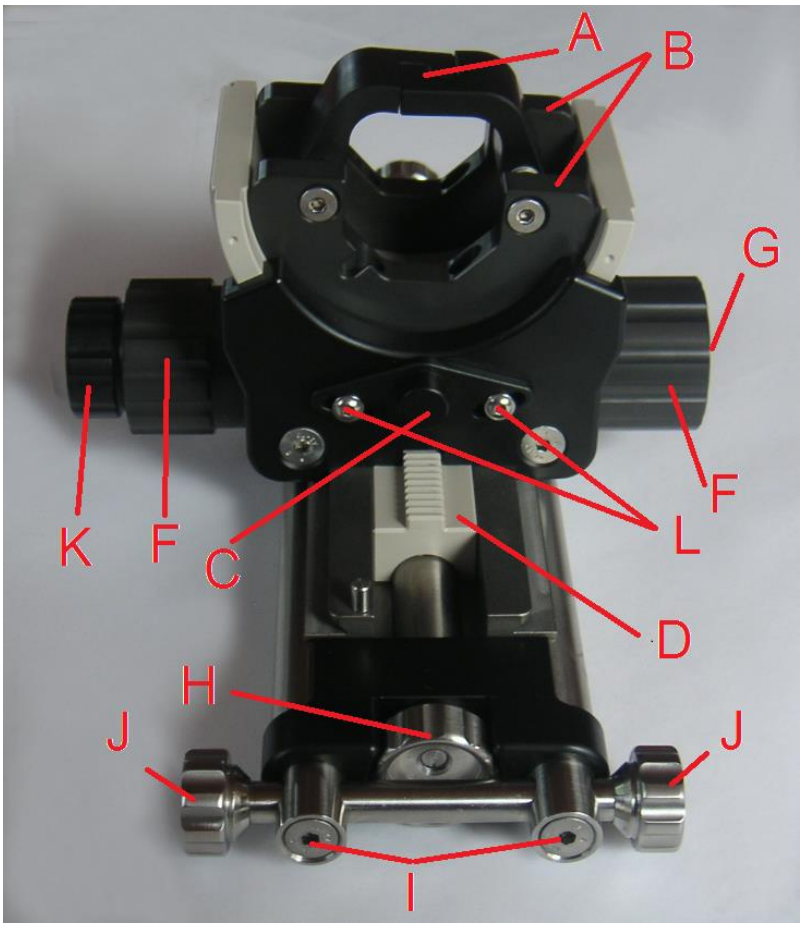
Should it be necessary to remove the elevation assembly (W5, W6, Y, Z, Z1, Z2) for cleaning, remove the parts (W1, W2, W3, X) first, as just described above. Then remove the elevation lock screw (Z2) with the supplied Alan wrench by turning it counter clockwise. Then rotate the elevation selector (W5) counter clockwise until the elevation assembly remaining (Y, Z, Z1) is pushed out of the handle (X). The Elevation selector W5 will then drop out. **The remaining elevation assembly (W6, Y, Z, Z1) cannot be disassembled any further.**

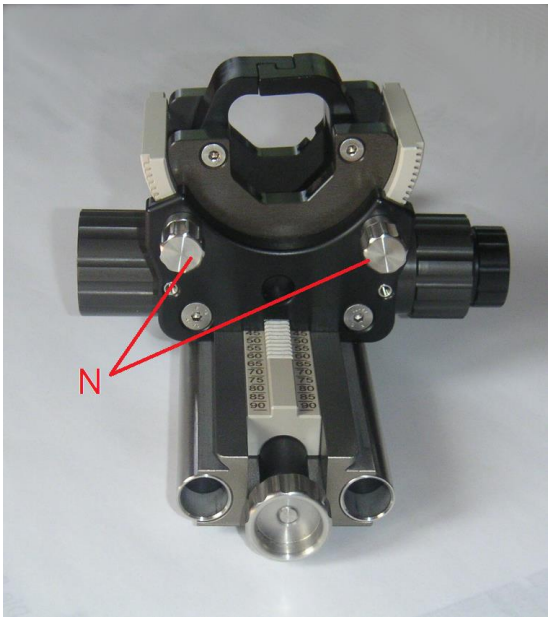
The elevation assembly is reassembled by following the above explanations in reverse order.

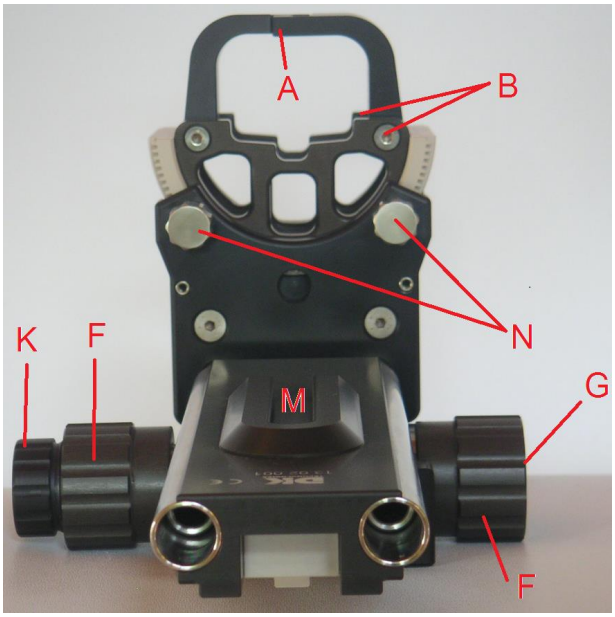
When reassembling the handgrip make sure that the security spring (W4) is first placed over the small metal rod that is visible inside the handle (X) and that the force transfer pin (W3) is placed on top of the small metal rod as well. At the same time the force transfer pin (W2) must be placed into the grove on the back of lever (W). Lever (W) is then placed into the handle (X) in such a way that pin (W1) can be pushed through holes (W2) and the holes in lever (W). A small “click” is felt when pin (W1) is in its correct center lock position in the handle (X).

If the handgrip is not assembled correctly the joints cannot be unlocked by pressing lever (W). In that case repeat the above steps carefully.

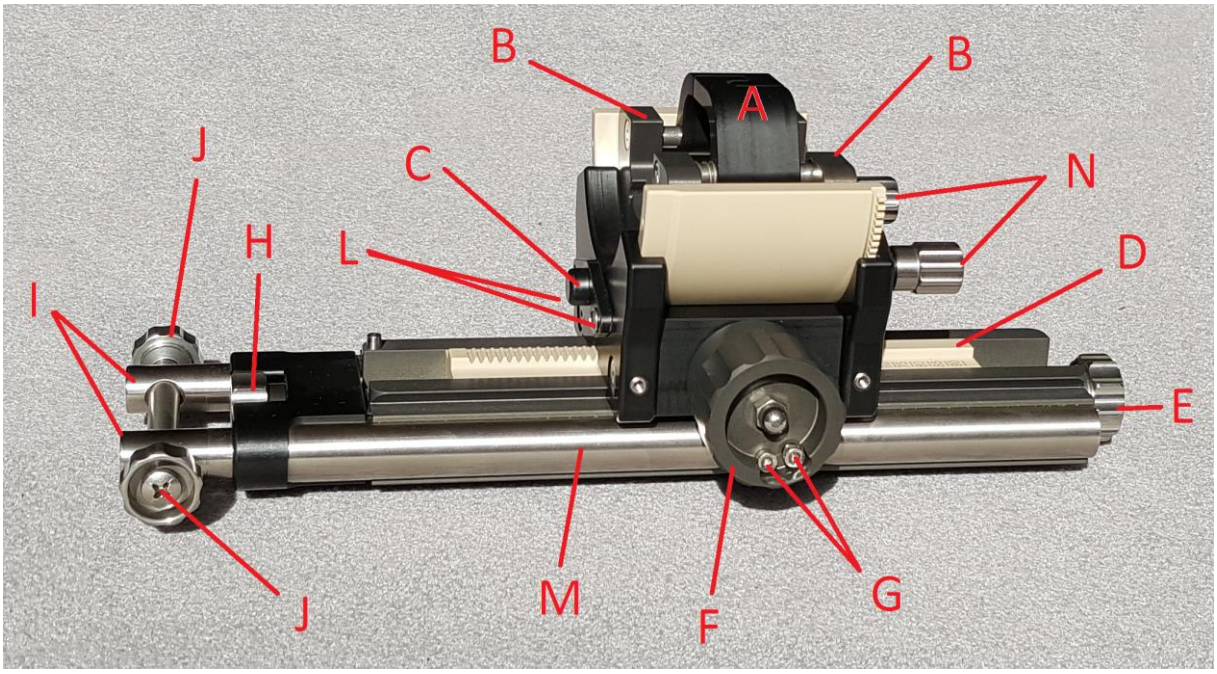
4.4. Mounting / Dismounting the Stepper (2)







Stepper, Top View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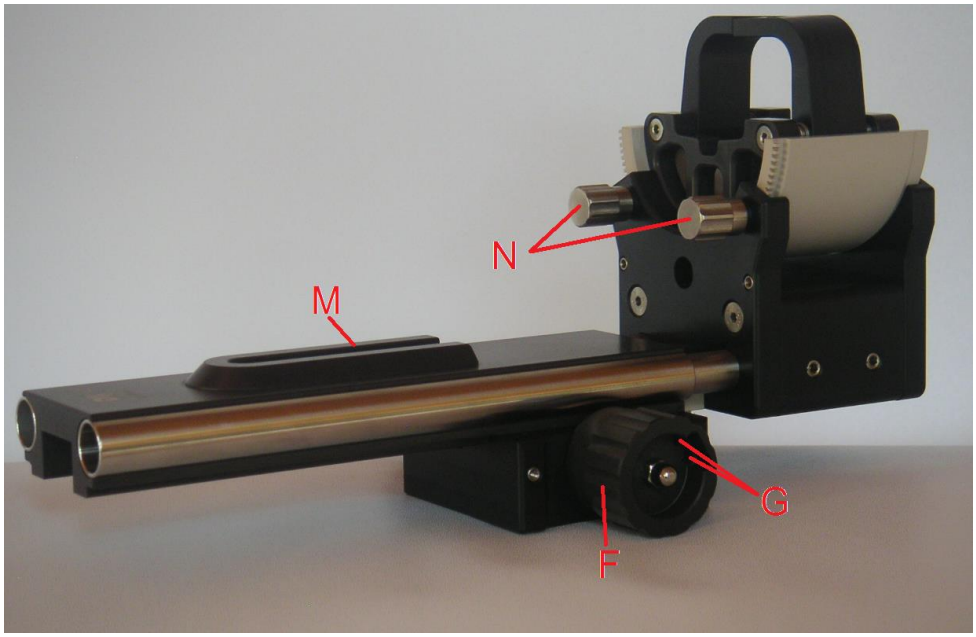
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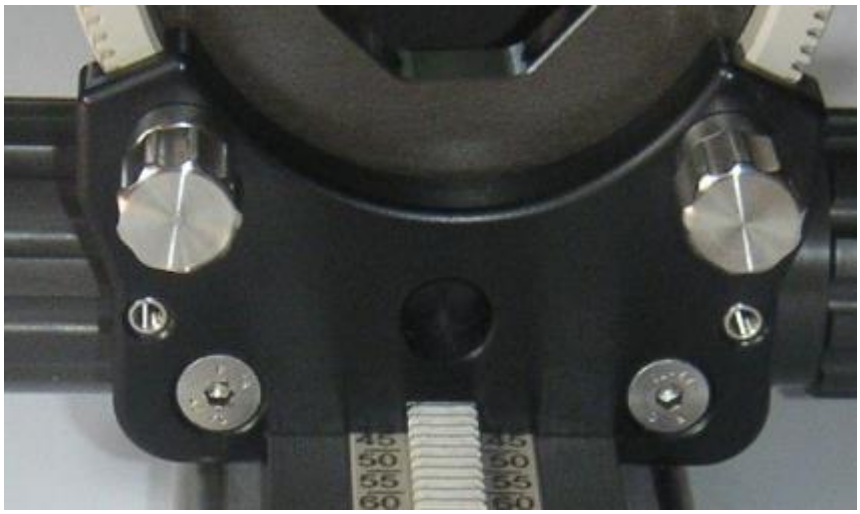


Cradle rotary position definition assembly **Attention: Do not reinsert the cradle with the tracking stepper components attached.**

Components:

Knobs F as well as the probe cradle B and clamps A comprise the ”probe holder”.

A	Probe clamp
B	Probe cradle (rotation ± 70°around central click position) (inner and outer cradle)
C	Cradle rotary click assembly
D	Analog positioning slider with scale (mm)
E	Knob for moving the analog positioning slider (D) and the complete probe holder at the same time to a user defined position
F	Knob for moving the complete probe holder to a user defined position.
G	Screws for selecting the size of the step increments of the complete probe holder: 2.5 mm, continuous, and 5 mm. **Attention when changing the setting: Please screw the screws G to their end stops. Do not move the knob during this procedure.**
H	Release knob for loosening and securing the template rail position
I	Template rails to which the template is fasted. They can be moved in and out (100 mm maximum travel)
J	Template screws for loosening and securing the template
K	Knob for securing the probe holder in a user defined position
L	Screws for defining the central click position of the probe cradle
M	Sliding-block linkage
N	Screws for locking the probe cradle rotational position

In order to mount the stepper (2) onto the handgrip (X) of the arm (3) turn lever Y on the handgrip (X) of the stabilizer (3) in such a way that brings lock Z into its top position. Then push the stepper’s (2) sliding-block linkage (M) forward over lock Z. Turn lever Y clockwise until the stepper (2) is locked in position.

To detach the stepper, just reverse the above actions.

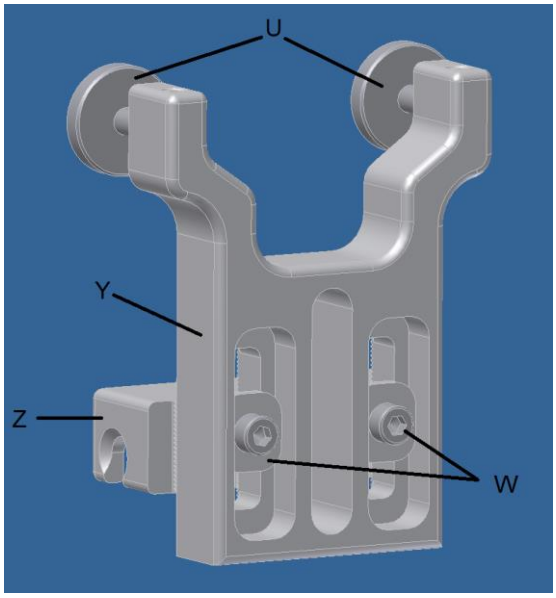
4.5. Basic Adaptation of the Probe Cradle to the Size of the Probe Handle

The probe handle of most ultrasound probes of any type differ somewhat in size. For that reason the probe cradle must be adapted to the probe handle size. The 2 probe clamps A have been pushed on to 2 metal pins. An Allen screw is situated at both ends of both pins. These screws can be loosened with an Allen key (size 2.5 mm). After they have been loosened the pins can be turned in the probe cradle.

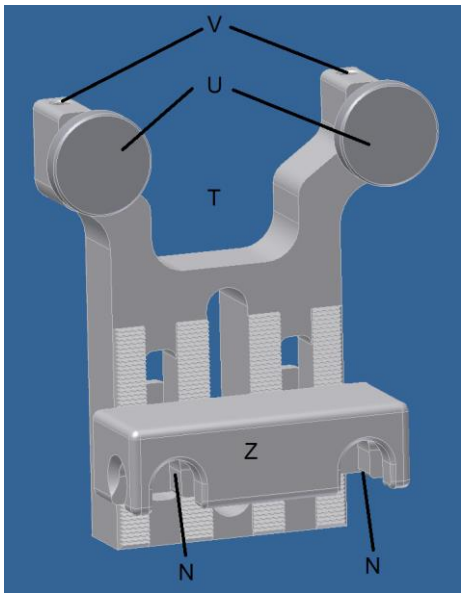
By turning the pins by hand the size of the probe cradle changes a little. The best thing to do is to put the ultrasound probe handle used into the probe cradle and lock the 2 clamps A. Press the clamps down tightly and then tighten the 4 Allen screws on the probe clamp pins at the same time. In this way the pressure exerted to the probe handle by the probe clamps can be set so that the probe will not easily be pushed out of the probe cradle.

This setting has to be done only once for any specific probe.

4.6. Mounting / Dismounting the Template Holder



Template, Rear View



Template, Front View

The template includes the actual template (not displayed) and the template holder (Y).

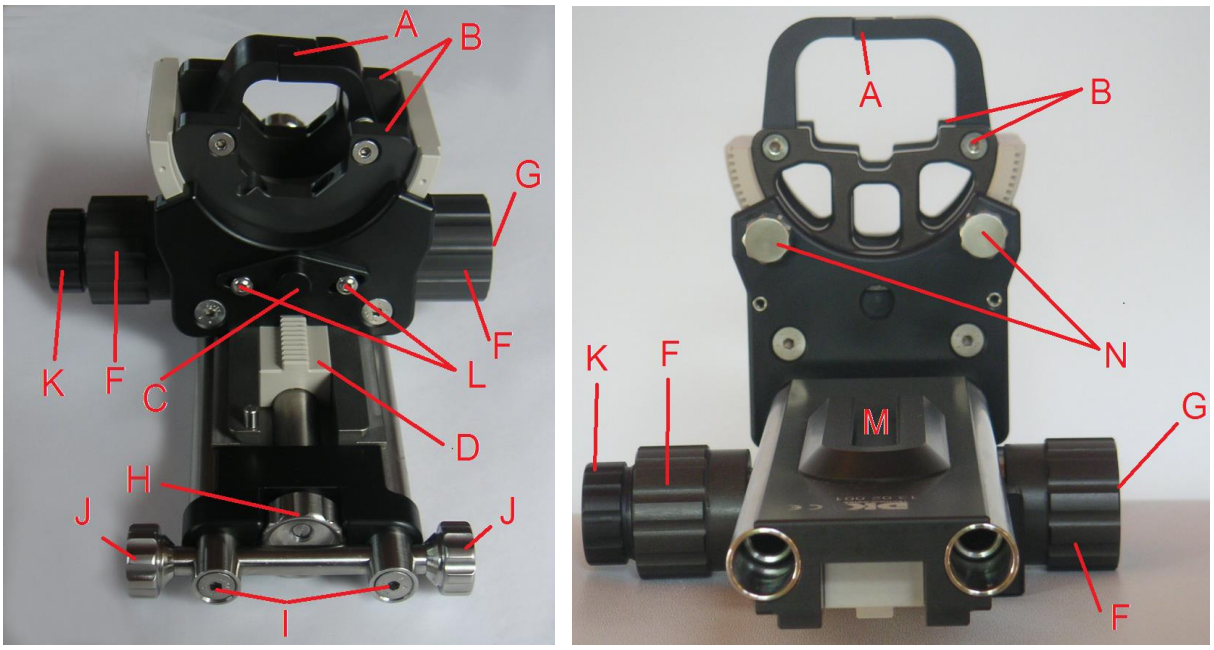
The template usually includes a grid of 13 x 13 needle guide tracks spaced 5 mm apart in horizontal and vertical directions. The ultrasound probe is positioned in the area T. The template pins are pushed onto the template holder holes (V) . The two screws (U) are screwed tight by turning them clockwise. The template holder (Y) is connected to the stepper (2) by first loosening the template screws (J) on the stepper by turning them counterclockwise and then softly pushing the template holder feet (N) over the template screws (J). After the template has been firmly pushed onto the bar connecting the screws (J) and also over the template rails (I), the screws are tightened by turning them clockwise.

Calibration

After the template holder including the template has been positioned onto the stepper (2) the Allen screws (W) may be loosened by turning them counterclockwise. The template may then be moved horizontally and vertically to coincide with the template displayed on the ultrasound imaging system used. The screws (W) are tightened by turning them clockwise. **Make sure that the template is firmly connected to the template holder.** See also chapter 5.1 “Basic Adjustments before Usage”

To detach the template, just reverse the above actions.

5. Working with the Stepper (2)



Stepper, Top View

(Designation of components see chapter “Mounting / Dismounting the Stepper (2)” above)

5.1. Basic Adjustments before Usage

Each time before starting to work, the alignment of the needle grid in the template and the ultrasound probe in combination with the template displayed on the ultrasound unit must be checked and possibly adjusted on the ultrasound unit (consult the manual of the ultrasound system if necessary). You may not set to work before this has been checked and if necessary all alignments have been corrected.

1) Insert the ultrasound probe used for biopsies, cryo- / brachytherapy into the stepper as described below in chapter “Inserting / Retrieving the Ultrasound Probe into / from the Stepper”.
2) Fix the template to the stepper as described below in chapter “Mounting / Dismounting the Template Holder”.
3) Turn on the ultrasound unit and select the appropriate ultrasound probe (consult the manual of the ultrasound system if necessary).
4) Insert the transducer part of the ultrasound probe into a physiological saline solution at room temperature.
5) Insert a needle through a selected template guide hole (D3, for example) and check if the needle appears on the ultrasound system’s monitor at the point in the ultrasound template having the same name.
6) If the needle does not show up at the correct position:
   - Please check if the template and ultrasound probe have been correctly attached to the stepper. If not, then please adjust appropriately.
   - If the probe and template have been installed correctly, then check if the probe has been correctly centered in the stepper, i.e. the cradle rotary click assembly is in its center position. Please see the drawings above. To center the probe:
     - Push the needle through a template hole in the middle row of the template. The needle should be visible in the middle of the ultrasound image at the point in the ultrasound template having the same name. If this is not the case and the needle is

displayed to the left or the right of the intended point in the image (not above or below that point):

- Loosen both screws L on the stepper by turning them counterclockwise. **Do not unscrew them completely!**
- Turn the cradle (B) clockwise or counterclockwise together with the probe manually until the needle is displayed in the appropriate position. Move the cradle rotary click assembly accordingly.
- Fasten both screws L on the stepper by turning them clockwise while holding the cradle and the probe in position.
- **Additionally**: After the template including the template holder has been mounted onto the stepper (2) and after loosening the Allen screws (W), the template may be moved horizontally and vertically so that the needle is displayed at the appropriate position and thus coincides with the template displayed on the ultrasound imaging system used. The Allen screws (W) are tightened by turning them clockwise and thus fixing the template in the desired position. **Make sure that the template is firmly connected to the template holder.**

- If the probe and template have been installed correctly, and the probe has been correctly centered then change the position of the template in the ultrasound image according to the specifications of the producer of the ultrasound system if necessary (consult the manual of the ultrasound system if needed).

5.2. Inserting / Retrieving the Ultrasound Probe into / from the Stepper

The ultrasound probe used for biopsies, cryo- / brachytherapy must be selected. Push the 2 clamps A on the stepper apart and then rotate them to the left and right respectively so that the probe cradle B is accessible.

If you are using a Philips sono DIAGNOST 360 or a ROI Unison 400 with the probe ERS 75360:

1) Push the probe handle into the cradle B. One of the 2 grooves on the probe handle must slide into the front U-shaped metal plate of the cradle B (front is toward the template).
2) Lock clamps A over the probe handle.
3) Turn the probe manually into its central click position

If you are using a Terason ultrasound system with a bi-plane endorectal probe 8BP4:

a) Top view

b) Side view

1) Push probe handle centering tube over the handle of the probe coming from the piezo-array. The screws must be on the bottom of the probe, i.e. not visible when inserted with the probe into probe cradle B. Fasten the supplied probe handle adapter to the ultrasound probe handle and pull the screws tight (2 mm Allen screws).

2) Push the probe handle into the cradle B. The probe handle centering tube fits in between the 2 U-shaped metal plates of cradle B.
3) Lock clamps A over the probe handle.
4) Turn the probe manually into its central click position

If you are using a Hitachi or Aloka ultrasound system with a bi-plane endorectal probes EUP U533 or Aloka C41L47RP or Aloka CL4416R:

a) Top view

b) Side view

Probe centering tube for probe Hitachi EUP U533 or Aloka C41L47RP or Aloka CL4416R only.

1) Push probe centering tube over the handle of the probe coming from the piezo-array. The screws must be on the top pf the probe, i.e. visible when inserted with the probe into probe cradle B. Fasten the supplied probe centering tube onto the ultrasound probe handle and pull the screws tight (2 mm Allen screws).
2) Push the probe handle into the cradle B. The probe centering tube fits in between the 2 U-shaped metal plates of cradle B.
3) Lock clamps A over the probe handle.
4) Turn the probe manually into its central click position.

If you are using a B-K Medical ultrasound system with the probe 8658S/8658T, 8658 MFI, 8558S, or 8848:

Probe centering tube for a B-K Medical ultrasound system with the probe 8658S/8658T, 8658 MFI, 8558S, or 8848 only.

1) Push the supplied centering tube over the ultrasound probe coming from the rear end of the probe (probe cable), so that the notch in the centering tube fits over the metal pin protruding from the side of the probe near the front of the probe handle.
2) The probe handle is now placed into the cradle B with the small pin-shaped protrusion on the open-ring-adapter being pushed into the notch on the front part of the cradle B (“front” is toward the template).
3) Lock clamps A over the probe handle. If the clamps do not close over the handle tightly enough or are too tight then loosen (do not unscrew completely) the Allen screws at the end of the rods connecting the U-shaped metal plates of cradle B and holding clamps A. If the optional cradle handle is used the Allen screws at the end must be removed together with the “crossbar” at the end of the handle. The metal rods can be loosened with an Allen key.

   The rods can then be turned with a pair of strong tweezers. By turning the rods the position of each clamp is changed slightly, thus they can be fitted tighter around the probe handle or alternatively may be loosed. Pull the Allen screws – or the metal rods of lever - tight when the clamps are in the appropriate position. Remount the “crossbar” if the optional cradle handle is used.
4) Turn the probe manually into its central click position.

If you are using a Siemens ultrasound system with an Endo-PII probe:

1) Push the probe centering tube over the handle of the probe coming from the cable side oft the probe. The screws must be positioned on the probe at 12 “o’clock”, i.e. visible when inserted with the probe into probe cradle B. The small grove in the centering tube near the screws (visible on the inside of the ring after closing it) must fit over the ridge running the along the length of the handle of the probe. Fasten the supplied probe centering tube to the ultrasound probe handle and pull the screw tight (2 mm Allen screw). The centering tube should be just outside of the probe cradle and will thus not allow the probe to be pushed forward towards the patient.
2) Push the probe handle into the cradle B. The grove in the probe handle at 6 “o’clock” must be pushed over the small cylinder in the middle of the rear U-shaped metal plate of cradle B (front is toward the template).
3) Lock clamps A over the probe handle. If the clamps do not close over the handle tightly enough or are too tight then loosen (do not unscrew completely) the Allen screws at the end of the rods connecting the U-shaped metal plates of cradle B and holding clamps A. The rods can then be turned with a pair of strong tweezers. By turning the rods the position of each clamp is changed slightly, thus they can be fitted tighter around the probe handle or alternatively may be loosed. Pull the Allen screws tight when the clamps are in the appropriate position.
4) Turn the probe manually into its central click position.

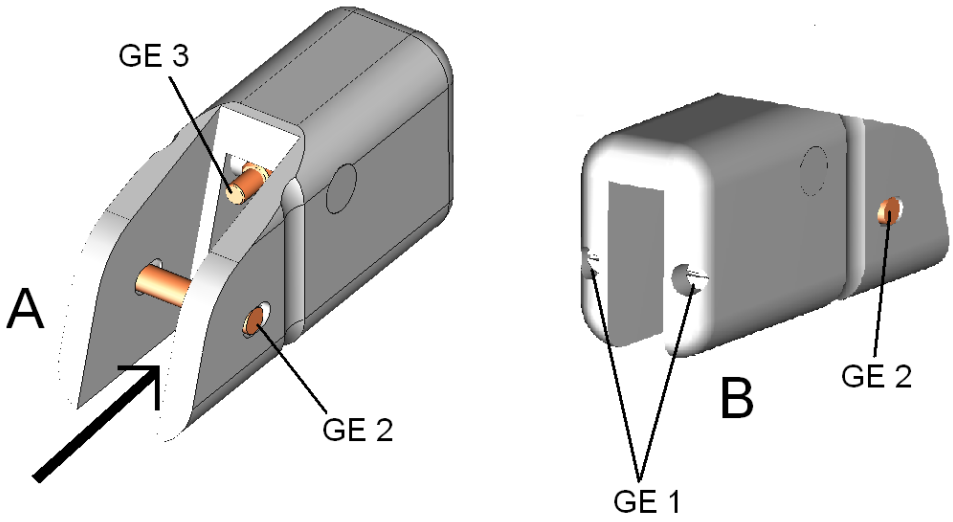
If you are using a Siemens ultrasound system with a BE 9 - 4 probe:

1) Push the probe handle into the cradle B. The piezo array for the transverse image must point upward, away from the probe receptacle. Place the probe into the receptacle in such a way that the two black caps near the probe cable fit into the U-shaped "holes" at the end of the probe receptacles.
2) Lock clamps A over the probe handle. If the clamps do not close over the handle tightly enough or are too tight then loosen (do not unscrew completely) the Allen screws at the end of the rods connecting the U-shaped metal plates of cradle B and holding clamps A. The rods can then be turned with a pair of strong tweezers. By turning the rods the position of each clamp is changed slightly, thus they can be fitted tighter around the probe handle or alternatively may be loosed. Pull the Allen screws tight when the clamps are in the appropriate position.

3) Turn the probe manually into its central click position.

If you are using a General Electric ultrasound system with an ERB7 probe:

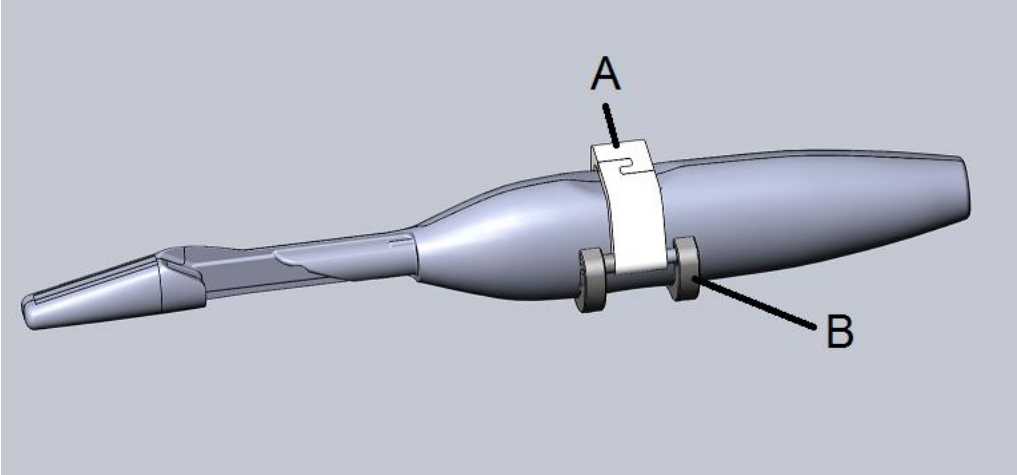
1) First detach the additional probe handle supplied by GE that can be screwed to the ERB7 probe (see GE user manual of the ERB7 probe).
2) Unscrew the screws – GE 1 – with an appropriate screw driver and remove pin - GE 2 (see drawing below).
3) Hold the probe horizontally with the transducer (piezo) elements pointing upward. Hold the probe handle adapter horizontally with the open slit pointing downward. Slide the probe handle adapter over the probe cable and push the probe handle in “arrow direction” into the probe handle adapter. The front part – A – will fit to the handle curvature. Replace pin - GE 2 – and thus push it through the probe handle adapter and the hole in the probe handle itself. Replace screws – GE 1 – and screw them into pin – GE 2 (turn pin - GE 2 - accordingly). Before tightening the screws make sure that pin – GE 3 – touches the handle of the ERB7 probe.
4) The probe cables will now be partly covered by the probe handle adapter and come out of the probe handle adapter in “B direction”.



Probe Handle Adapter for Probe GE ERB7 only

5) The probe with the probe handle adapter attached is now placed into the cradle B of the stepper. The groove on the probe handle adapter must slide into the front U-shaped metal plate of the cradle B (front is toward the template).
6) Lock clamps A over the probe handle.
7) Turn the probe manually into its central click position.

To remove the probe from the stepper, just reverse the above actions.



The Exact Imaging probe EV29L

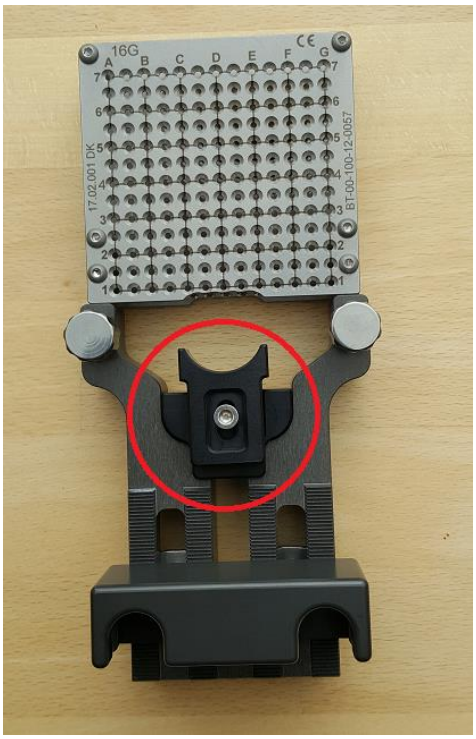
If you are using an Exact Imaging ultrasound system with an EV29L probe:

1) Open the clamps A on the probe receptacle (B).
2) Insert the probe so that the top indentation on the probe will fit beneath the clamps when locked. The indentation must be centered under the clamps.
3) Lock clamps A over the probe handle. If the clamps do not close over the handle tightly enough or are too tight then loosen (do not unscrew completely) the Allen screws at the end of the rods connecting the U-shaped metal plates of cradle B and holding clamps A. The rods can then be turned with a pair of strong tweezers or needle nosed pliers. By turning the rods the position of each clamp is changed slightly, thus they can be fitted tighter around the probe handle or alternatively may be loosed. Pull the Allen screws tight when the clamps are in the appropriate position.

To remove the probe from the stepper, just reverse the above actions.

If you are using another ultrasound system please inquire.

5.3. Using the Probe Support Option on the Template holder



Probe Support (in red circle) on Template Holder

The probe support is placed inside the “arms” of the template holder. It supports the ultrasound probe that is placed in between the template and the probe support. In that way the ultrasound probe cannot be bent and the matching of the needle positions in the template is greatly improved. The probe support is autoclavable.

Setting up the Probe Support

Push the probe support down in between the arms of the template holder as far as possible, i.e. until it is positioned as see in the image above. Then connect the template holder to the stepper and insert the ultrasound probe used into the stepper. Then loosen the screw on the probe support and push the loose part (lever) of the support upward until it just touches the ultrasound probe. Then tighten the screw again so that lever stays in the respective position.

The complete support can be pulled off the template holder for cleaning. Afterwards just push the probe support back on to the template holder. Do not loosen the screw on the support again. Make sure the screw is facing the user and not the patient.

5.4. Mounting the Stepper on the Articulate Arm

1) Rotate lever Y on the stabilizer (3) until lock Z on the stabilizer is in its top position.
2) Slide the sliding-block linkage M over lock Z of the stabilizer to roughly the center position.
3) Rotate lever Y on the stabilizer until the stepper is firmly fixed. Only little force is required!

5.5. Normal Operation of the Stepper

The template is fixed to and the ultrasound probe is inserted into the stepper. Clamp A on the stepper is locked. The probe should be in its rotational center position.

The position of the screws G on the stepper determines the type of probe movement that will result when turning knob ~~G~~ F on the stepper.

Position feedback every 5 mm: Screw one of the Allen screws G into the knob F results in a tactile feedback every 5 mm. The individual “steps” can be felt and heard during the movement. **Attention: Please screw the screws G to their end stops and then rotate back 1/2 turn. Do not move the knob during this procedure.**

Position feedback every 2.5 mm: Screw both Allen screws G into the knob F results in a tactile feedback every 2.5 mm. The individual “steps” can be felt and heard during the movement. **Attention: Please screw the screws G to their end stops and then rotate back 1/2 turn. Do not move the knob during this procedure.**

Position “ – ” Smooth analog movements without a tactile feedback are performed when none of the Allen screws G have been screwed into knob F on the stepper

Lock Position Movements are damped when knob K is tightened when rotated clockwise. This can be done at any time.

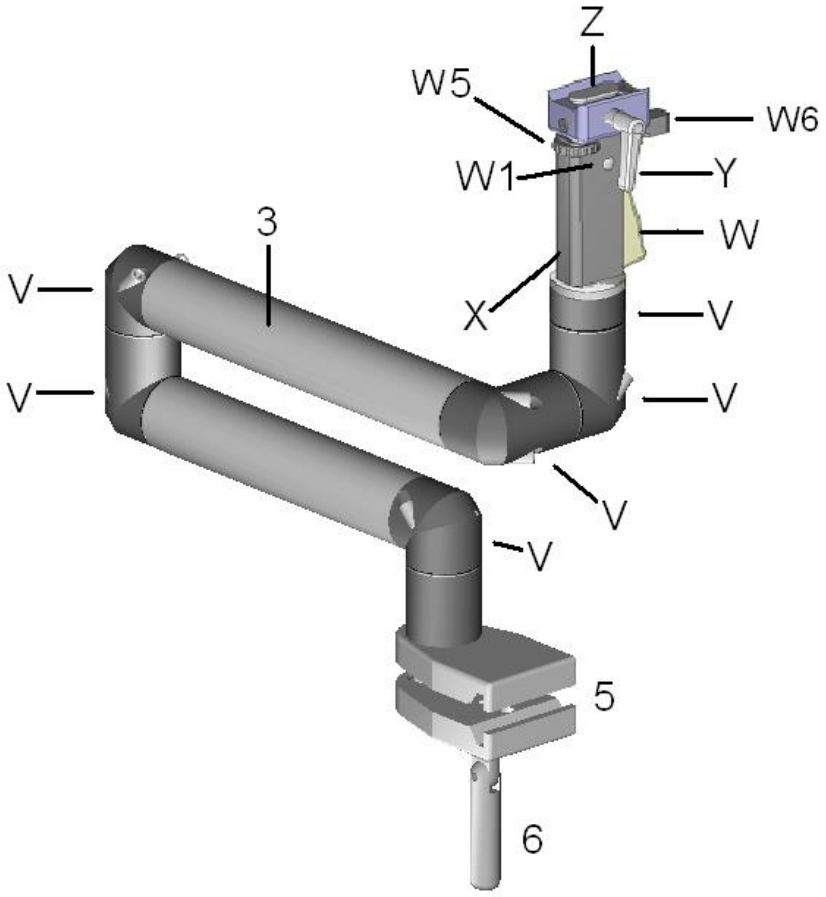
The probe can be moved forward and backward, i.e., in and out of the rectum. Rotating knob F clockwise will retract the probe. Rotating knob F counterclockwise will move the probe forward.

A specific position cannot always be reached at 2.5 mm or 5.0 mm intervals. If interstitial positions are required, then move the scale D together with the probe holder with high accuracy back and forth by turning knob E counterclockwise or clockwise respectively

In some cases – with the appropriate ultrasound probe in use - the physician might want to observe the needle in longitudinal direction. Usually the needle will not be in the central image plane. Switch the ultrasound probe to the appropriate setting on the ultrasound system. Then turn the cradle with the probe to the desired position. The probe may be rotated back to the central position at any time A light bump is felt when the cradle passes the center position.

The probe cradle can be removed for cleaning from the stepper. **Attention: Do not reinsert the cradle with the tracking stepper components attached - Remove them first.**

6. Working with the Arm (3)



Articulate arm (3) with 6 joints, handgrip, and universal OR-side rail adapter (5 + 6)

The articulate arm must be fixed to the OR-side rail as described in chapter “Connecting The biopsy, cryo- / brachytherapy equipment to the OR-Side Rail “.

The arm must be hand held tightly by the handgrip (X) when moving the arm. All joints are unlocked simultaneously by pulling (or pressing) lever (W). **Always pull lever (W) all the way to its end stop or the arm may be damaged.** The joints are all locked in place simultaneously by releasing lever (W). When lever (W) is pressed fully the arm can be moved freely. Releasing lever (W) will lock the arm in the position it is in at the time being.

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7. Cleaning Disinfection and Sterilization

The instructions provided below are meant as a guide. Infection control policies (including reprocessing, packing and storage) set for your hospital, clinic or institution must always be followed in order to prevent cross-contamination.

All equipment must be pre-cleaned immediately after each use in order to prevent soiled materials from drying on the surface. Dried or baked materials can reduce the efficacy of cleaning, disinfection and sterilization processes, and subsequently cause a risk of patient cross-contamination.

Equipment must be checked for completeness, damage, and wear after each cleaning, disinfection, and sterilization cycle.

Equipment must not be used if any signs of damage are found. A D&K Technologies distributor must be contacted immediately.

D&K Technologies will not accept any responsibility for damages that stem from the improper use of equipment. It is within the responsibility of the user to check the equipment for damages and that they are in conformance with their specifications.

All manufacturers' instructions must be followed regarding the cleaning, disinfection and sterilization of materials and equipment used. The materials listed below are suitable for the devices as long as the instructions stated by the manufacturer are followed.

The user is responsible for the proper assembly of all equipment following thorough cleaning, disinfection, and sterilization processes.

7.1. Cleaning of the Templates, Template Holder, Probe Support Stepper, and Probe Receptacle

Reprocessing Instructions According to DIN EN ISO 17664

	• The device is not packaged sterile. The device must be sterilized before each use. • To avoid contamination of patients and users. The devices must be cleaned, disinfected and sterilized before and after each use. • It is strickly prohibited to clean the device in an ultrasound cleaning device. The products may not be placed into a STERRAD or other device using H_2O_2.
Limitations on Reprocessing:	• It is recommended that the used devices are reprocessed not later than 2 hours after usage.

Risk assessment and classification of medical devices before preparation:

The nature and extent of the reprocessing depend on the application of the medical device. Therefore, the operator is responsible for the correct classification of the device and thus for determining the nature and extent of the reprocessing (see KRINKO/BfArM recommendation, clause 1.2.1 Risk assessment and classification of medical devices before preparation). Based on this user-dependent classification the operator can specify which reprocessing steps out of the following reprocessing steps in these reprocessing instructions must be carried out.

Instructions:	
Point of use:	All devices should be cleaned of visible soil at the point of use, to prevent drying of soil and contaminants in and on the device. Equipment: Tap water (At least drinking water quality) • Flush all devices under running cold tap water to remove any blood or other substances from bore holes, gaps, joining surfaces and other hard to reach areas of the devices.
Containment and Transport:	It is recommended to transport contaminated devices in a closed clean box/container.
Preparation for decontamination:	Personal protective equipment (gloves, water repellent protective skirt, face protection mask or protective glasses, see also instructions of the manufacturer for the detergent and the disinfectant). • Where applicable, disassemble devices prior to Cleaning Disinfection and Sterilization without the use of tools.
Cleaning and disinfection: Automated	Equipment: Washer disinfector in accordance with DIN EN ISO 15883-1+-2 with thermal program (temperature 90-93 °C), mildly alkaline cleaner detergent (e.g. Sekumatic® MultiClean 200 ml), air gun connected to compressed air of medical grade (in accordance with local laws). 1) Bring all parts of the devices in a suitable tray on a load carrier module in the washer disinfector so that all internal and external surfaces are cleaned and disinfected. 2) After closing the door start the thermal program, the program parameters are shown in the table below. 3) At the end of the program remove the device. 4) Check if the device is completely dry, if necessary dry with single use, fluff free wipe or towel or dry by an air gun with compressed air. (Public authorities may adopt other implementing provisions (parameters for disinfection performance) within their field of responsibility.)

Automated Cleaning and Disinfection procedure:

Program Step	Water	Dosage	Time	Temperature
Pre-Rinse	Cold		5 min	
Dosage cleaner		According to manufacturer's instructions		According to manufacturer's instructions
Cleaning	Deionized water		10 min	55 °C
Rinse	Deionized water		2 min	
Disinfection	Deionized water		A_0 value >3000[1] (e.g. 5 min, 90 °C) [1] (Public authorities may adopt other implementing provisions (parameters for disinfection performance) within their field of responsibility.)	
Drying			15 min	Up to 120 °C

Maintenance, Inspection and Testing:	• Inspect all components of the devices under normal lightning for the removal of soil. Repeat manual cleaning (as described under Point of use) and automated cleaning and disinfection if components are not visible clean. • Check the device for completeness, damage, and wear after each cleaning, disinfection, and sterilization cycle. • Before using the device check for damages and functionality. • Do not use the device if any damages or functional irregularities are detected.
Packaging:	• Packaging in sterile barrier system in accordance with DIN EN ISO 11607 or DIN 58953.
Sterilization:	• Sterilizer according to DIN EN 13060 and/or DIN EN 285. • Sterilization of the device in the disassembled status as far as possible without using tools. 1) Place the packaged device in the sterilizer chamber. 2) Start the program (sterilisation for 5 min. at 134°C). 3) At the end of the program remove the device and let it cool down. 4) Check that the seal of the package is closed and the package is dry.
Storage:	Storage and shelf life as established by the processor.
Additional information:	Only validated processes may be used for the processing of medical devices.

The above instructions have been validated by the manufacturer of the medical device as a suitable method for reprocessing of the medical device for reuse. It remains in the user's responsibility to ensure that the currently performed reprocessing in the operator's unit for the device with the use of equipment, materials and personnel reached the desired and necessary result. This requires validation and routine monitoring of the processes. Likewise any variation of the user from the provided reprocessing instructions must be assessed and evaluated accurately with regard to effectiveness and potentially adverse consequences.

For cleaning and disinfection use:

Cleaning:
Neodisher Medizym®
Neodisher MediClean®
Gigasept FF new 5%iSolution, Schülke & Mayr
Bodedex forte, Bode

	Instru Zym, Laboratorium Dr. Deppe Instru Plus, Laboratorium Dr. Deppe
Disinfection:	Sekusept® Plus von Ecolab Cidex® OPA von ASP OPAL, Whiteley Medical Meliseptol, Braun-Melsungen Gigasept, Schülke & Mayr Instru Plus, Laboratorium Dr. Deppe Kohrsolin, Bode Sekusept Forte, Henkel Sekusept Extra, Henkel

NOTE: It is not possible to list all applicable products within the approved cleaning and disinfectant list. **Any product used to clean and/or high level disinfect an ultrasound transducer or flexible endoscope within your institution can be used to clean and/or high level disinfect the DK equipment.** If in doubt please contact D&K Technologies or a local D&K Technologies distributor.

7.2. High-level Disinfection or Sterilization of the Centering Tube

The Centering Tube must be reprocessed based on device classification and according to your local infection control policies. If these policies dictate high-level then apply the same high-level disinfection processes as you would for your Ultrasound Transducer. Follow all the manufacturer's instructions. The centering tubes may not be autoclaved.

7.3. Cleaning and Disinfection of the Articulating Arm

NOTE: ***The equipment must not be cleaned in an Ultrasonic Cleaning Device.***

Wipe the Articulating Arm clean with a soft cloth wetted with cold water containing a mild detergent/enzymatic solution or approved wipes, according to local infection control policy including the removal of all visible debris, blood, or fluids. Repeat the aforementioned process until all visible soiling is removed. Finally dry the Articulating Arm with a clean, soft cloth (or similar). ***Do not immerse the Articulating Arm in any fluid or hold the Articulating Arm under running water. It is strickly prohibited to clean the device in an ultrasound cleaning device***.

The Articulating Arm material is compatible with 70% alcoholic solution.

7.4. Cleaning and Disinfection of the Incremental Encoders

NOTE: ***The equipment must not be cleaned in an Ultrasonic Cleaning Device.***

Firstly, dismount the Incremental Encoders from the Stepper as per the instructions in the 'Mounting and Dismounting the Incremental Encoders' chapter. Wipe the Incremental Encoders and cables clean with a soft cloth wetted with cold water containing a mild detergent / enzymatic solution or approved wipes, according to local infection control policy, including the removal of all visible debris, blood, or fluids. Repeat the aforementioned process until all visible soiling is removed. Finally dry the Incremental Encoders with a clean, soft cloth (or similar). **Do not immerse the Incremental Encoders and cables in any fluid or hold them under running water. They may also not be heated for sterilization.**

The Incremental Encoders' material is compatible with 70% alcoholic solution.

8. Appendix

8.1. Technical Data

Prerequisite: A B/W ultrasound imaging system with an endo-rectal ultrasound probe. The rectal probe must be able to image in transverse section at least. It is advantageous to use a multi-plane probe to visualize any longitudinal plane in order to see the needle path. The frequency of the probe should range between 5 and 8 MHz in order to achieve the necessary spatial resolution as well as the necessary penetration depth.

Stepper: The precision stepper enables the user to advance, retract, and rotate an endo-rectal ultrasound probe in the rectum to image the prostate.

- The endo-rectal probe is inserted into and fixed to the stepper and positioned by moving the stepper/probe combination.
- Any endo-rectal probe from any producer can be fit to the stepper as far as the respective probe cradle is available.
- Probe can be rotated around the probe´s long axis (± 70°). The probe locks into the adjustable center position.
- Movable length of the probe with the stepper: 100 mm.
- Scale for position recognition.
- Step width: 2.5 mm or 5 mm selectable as well as free analog movement in and out of the rectum.
- Additional free analog movement of the probe to define the exact stating point for stepwise movement: 50 mm.
- Template is movable (100 mm) in the direction parallel to the ER probe's long axis and can be fixed in any position.
- Sterilizable: at least 200 times with steam at 115°C - 140°C (pressure 2 to 3 bar).

Articulate Arm (= Stabilizer): Device that can carry objects for simple manual positioning.

- Free manual positioning in all directions
- Can be fixed to the OR-side rail on any OR table via the universal OR-side rail adapter if supplied.
- Can be locked in space in any position.
- The articulate arm includes 6 (in most cases) 360° rotating joints that are connected to one another by tubes of different length. All joints are unlocked or locked simultaneously by pulling (or pressing) a single lever (W) and then releasing it.
- A universal OR-side rail adapter is fastened to one end of the arm.
- A pistol-type handgrip is connected to the other end of the arm. All joints are unlocked or locked simultaneously by pulling (or pressing) a single lever (W) and then releasing it.
- The pistol-type handgrip includes an elevation slider that allows an object attached to the handgrip to be moved up to ± 10 mm from a central position.
- The pistol-type handgrip includes a swivel device that allows an object attached to the handgrip to be rotated left and right up to ± 15° mm from its central position.
- A lock that slides into the sliding block linkage on the underside of the stepper is positioned at the top of the handgrip.

- **The articulate arm is not waterproof!**
- **The maximum torque that may be applied to any individual joint - on an arm with a tube diameter of 50 mm - may not exceed 6.5 Nm. That is equivalent to a work load of about 10.0 kg when the arm is fully extended horizontally to a length of about 65 cm.**

Template: Needle guide grid system for the biopsy, cryo- / brachytherapy needles: Matrix of 13 x 13 individual channels (all channels - depending on the template used - for 13 G, 15 G, 17 G or 18 G Gauge needles - standard). This template is mounted on a specially developed template holder.

- The annotation of the needle channel rows depends on the template selected.

  Row spacing: 5 mm in both cases

- The annotation of the needle channel columns depends on the template selected.

  Column spacing: 5 mm in both cases.

- The template is made of stainless steel.
- Sterilizable: at least 200 times with steam at 115°C - 140°C (pressure 2 to 3 bar), can be heated in air up to 200°C for an indefinite time span.
- Template size: approx. 85 x 85 x 20 mm (H x W x D).

8.2. Incidence Report Form for The biopsy, Cryo- / Brachytherapy equipment

Dear user,

Please immediately notify us by telephone of all incidences, which have resulted in a health impedance of a patient or user in connection with our product (notifiable incidences as defined by the guide line 93/42 EWG).

You may also fax this sheet.

Please contact the D&K Technologies safety officer for medical products.

Telephone: ++49 - 4133 – 51 01 85
Telefax: ++49 - 4133 – 51 90 11

Sent by:

Hospital / Office: _____

_____

Contact person: _____

_____

Telephone: _____

Fax: _____

Description of the incidence:

_____

_____

_____

_____

_____

_____

_____

_____

_____

Any person injured? yes ☐ no ☐

Incidence Report Form, 01.04.02, Dr. Klews