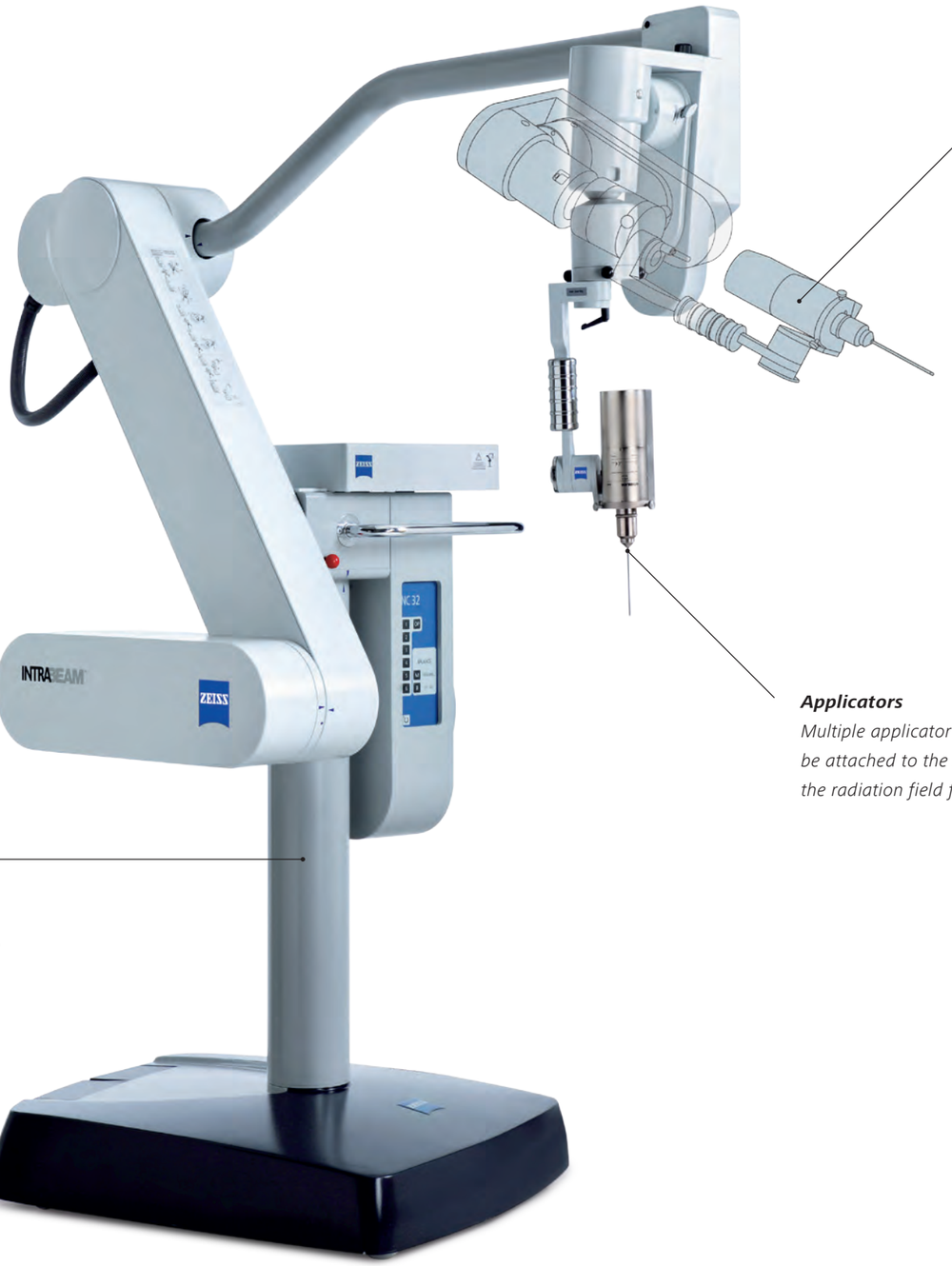
INTRABEAM

Technical Specifications

Content

1. System Description

INTRABEAM® received FDA approval in the USA in 1997 and was awarded the CE certification in Europe in 1999 for the irradiation of targeted lesions using intersitial, intraoperative, intracavity or surface irradiation techniques. Treatment can be performed in operating rooms; structural alterations for radiation protection are normally not required. The miniaturized accelerator of INTRABEAM produces low-energy x-ray photons which are emitted isotropically (equally distributed). The INTRABEAM carrier system with six degrees of freedom, weight compensation and magnetic brakes ensures easy, flexible and precise positioning of the miniaturized accelerator into the targeted area. Ideally integrated in the INTRABEAM Cart, the control unit ensures exact setting and monitoring of the desired dose. INTRABEAM is a mobile system which is therefore suitable for use in multiple operating rooms.



Miniaturized Accelerator
The miniaturized accelerator emits low-energy X-ray photons (max. 50 kV) in an isotropic distribution for uniform dose delivery.

Maneuverability
Six axes allow the miniaturized accelerator to be placed anywhere in three dimensional space required for therapy.

Applicators
Multiple applicator types (see page 6 ff), which can be attached to the miniaturized accelerator, adapt the radiation field for a variety of applications.

Floor Stand
The Floor Stand combines performance with reliability, flexibility and ease of use: electromagnetic brakes lock the miniaturized accelerator in the treatment position with millimeter accuracy. Suitable for mobile use in any OR.

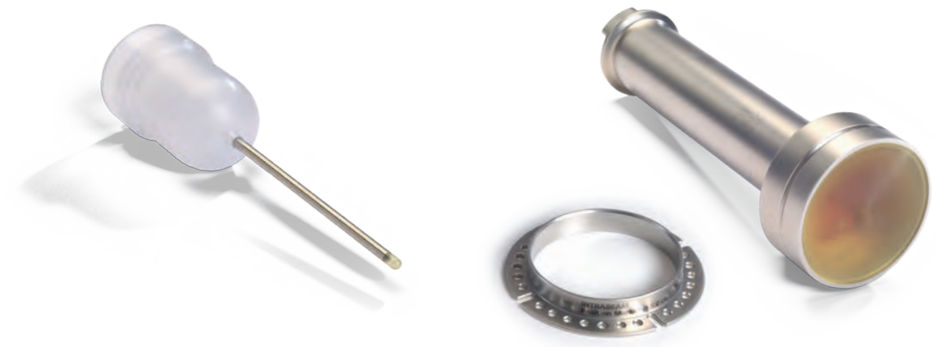
2. Applications

The physical and radiobiological characteristics of the miniaturized accelerator's low-energy photons allow for use in a range of applications. This allows use within many body sites. A range of different applicators is available to meet the various clinical requirements.

2.1 INTRABEAM Spherical Applicator
The INTRABEAM Spherical Applicators are used for the intracavitary or intraoperative delivery of radiation to the tumor bed, e.g. at the time of breast conserving surgery. The applicator fills the tumor cavity created by the tumor excision. The tumor bed tissue adheres to the applicator via surface tension. The probe tip is centered within the applicator and therefore the tumor cavity. The INTRABEAM Spherical Applicators are available in the diameters 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5 cm. The applicators are reusable and sterilizable. Please refer to the instruction manual.

2.2 INTRABEAM Needle Applicator
The INTRABEAM Needle Applicator can be used for the interstitial irradiation of tumors, e.g. in the treatment of vertebral metastases. Spinal metastases are often accompanied by severe pain and the danger of a compression fracture. In Kypho-IORT with INTRABEAM vertebral metastases can be irradiated intraoperatively in a targeted, localized and minimally invasive technique using the needle applicator. After the intraoperative radiotherapy the affected vertebra is stabilized by the insertion of bone cement in a procedure known as kyphoplasty. The single use INTRABEAM Needle Applicator has a diameter of 4.4 mm.

2.3 INTRABEAM Flat Applicator*
The INTRABEAM Flat Applicator is used for the treatment of tumors on surgically exposed surfaces, e.g. tumors of the gastrointestinal tract. The INTRABEAM Flat Applicator has an optimized flat radiation field (by means of a flattening filter) at 5 mm from the applicator surface. Using the Position Marker, a sterilizable metal ring which may be placed on the surgically exposed surface, the area to be irradiated can be isolated. The INTRABEAM Flat Applicators are available in the diameters 1, 2, 3, 4, 5 and 6 cm. The applicators are reusable and sterilizable. Please refer to the instruction manual.



** This INTRABEAM applicator has CE certification and is awaiting FDA approval. As of April 2012.*

2.4 INTRABEAM Surface Applicator*

The INTRABEAM Surface Applicator is used in the treatment of tumors on the surface of the body, for example, irradiation of non-melanoma skin cancers. It is particularly useful for patients with high surgical risk or for the purposes of cosmesis. The applicator creates an optimized flat radiation field (by means of a flattening filter) on the target surface. Using the Position Marker, a sterilizable metal ring which may be placed on the surface of the body, the area to be irradiated can be isolated. The INTRABEAM Surface Applicator is available in diameters of 1, 2, 3 and 4 cm. The applicators are reusable and sterilizable. Please refer to the instruction manual.

2.5 INTRABEAM Cylinder V Applicator*

The INTRABEAM Cylinder V Applicator is used for the irradiation of vaginal wall tumours and consists of a cylindrical applicator and a probe guard which may be inserted in the applicator. The Dwell Stepper allows the probe guard, which encases the tip of the miniaturized accelerator, to be precisely positioned in the INTRABEAM Cylinder V Applicator. This enables manual stepping of the probe tip and establishment of a homogeneous cylindrical dose distribution of a user defined length. The INTRABEAM Cylinder V Applicator is available in diameters of 2, 2.5, 3 and 3.5 cm. The applicators are reusable and sterilizable. Please refer to the instruction manual.

** This INTRABEAM applicator has CE certification and is awaiting FDA approval. As of April 2012.*

Component	INTRABEAM Spherical Applicator	INTRABEAM Needle Applicator	INTRABEAM Flat Applicator	INTRABEAM Surface Applicator	INTRABEAM Cylinder V Applicator
Available sizes	1.5 cm, 2.0 cm, 2.5 cm, 3.0 cm, 3.5 cm, 4.0 cm, 4.5 cm, 5.0 cm diameter	4.4 mm diameter	1.0 cm, 2.0 cm, 3.0 cm, 4.0 cm, 5.0 cm, 6.0 cm diameter	1.0 cm, 2.0 cm, 3.0 cm, 4.0 cm diameter	2.0 cm, 2.5 cm, 3.0 cm, 3.5 cm diameter
Components of a set	■ INTRABEAM Sperical Applicator ■ Sterilization container	■ INTRABEAM Needle Applicator ■ Guide shaft (2x)	■ INTRABEAM Flat Applicator ■ INTRABEAM Position Marker ■ INTRABEAM Lumen Plug	■ INTRABEAM Surface Applicator ■ INTRABEAM Positionsmarker ■ INTRABEAM Lumen Plug	■ INTRABEAM Cylinder V Applicator ■ INTRABEAM Cylinder V Probe Guard ■ INTRABEAM Lumen Plug ■ INTRABEAM Cylinder V Dwell Stepper ■ INTRABEAM Cylinder V Base Plate
Usage	reusable	single use	reusable	reusable	reusable
Anatomical Sites	Any part of the human body (not intended for use on the heart or in the central circulatory system)	Any part of the human body (not intended for use on the heart or in the central circulatory system)	Any part of the human body (not intended for use on the heart or in the central circulatory system)	Skin	Vagina and surrounding tissue
Geometry of dose distribution	spherical dose distribution	spherical dose distribution	Flat dose distribution, optimized for tissue radiation in 5 mm distance from the applicator surface	Flat dose distribution, optimized for tissue radiation directly in contact with the surface	Cylinder-shaped dose distribution
Fixation to the region of interest		Guide shafts can be used for deep approach routes	Fixation via INTRABEAM Position marker (can be sewed or glued to the region of interest) possible	Fixation via INTRABEAM Position marker (can be sewed or glued to the region of interest) possible	Fixation by use of INTRABEAM Cylinder V Base Plate
Length [mm]	ø 1.5 cm: 167.5 mm (6.59″) ø 2.0 cm: 170.0 mm (6.69″) ø 2.5 cm: 172.5 mm (6.79″) ø 3.0 cm: 175.0 mm (6.89″) ø 3.5 cm: 177.5 mm (6.99″) ø 4.0 cm: 180.0 mm (7.09″) ø 4.5 cm: 182.5 mm (7.19″) ø 5.0 cm: 185.0 mm (7.28″)	94 mm (Probe length)	ø 1.0 cm: 169.05 mm (6,67″) ø 2.0 cm: 174.05 mm (6,85″) ø 3.0 cm: 178.05 mm (7,01″) ø 4.0 cm: 181.55 mm (7.15″) ø 5.0 cm: 184.35 mm (7.26″) ø 6.0 cm: 185.55 mm (7.31″)	ø 1.0 cm: 169.05 mm (6.67″) ø 2.0 cm: 174.05 mm (6.85″) ø 3.0 cm: 178.05 mm (7.01″) ø 4.0 cm: 181.55 mm (7.15″)	ø 2.0 cm: 120.5 mm (47.4″) ø 2.5 cm: 120.5 mm (47.4″) ø 3.0 cm: 120.5 mm (47.4″) ø 3.5 cm: 120.5 mm (47.4″)
Inner diameter (absorption body)	N/A	N/A	ø 1 cm: 10 mm (0.39″) ø 2 cm: 20 mm (0.79″) ø 3 cm: 30 mm (1.18″) ø 4 cm: 40 mm (1.57″) ø 5 cm: 50 mm (1.97″) ø 6 cm: 60 mm (2.36″)	ø 1 cm: 10 mm (0.39″) ø 2 cm: 20 mm (0.79″) ø 3 cm: 30 mm (1.18″) ø 4 cm: 40 mm (1.57″)	N/A
Outer diameter	ø 1.5 cm: 15 mm (0.59″) ø 2.0 cm: 20 mm (0.79″) ø 2.5 cm: 25 mm (0.98″) ø 3.0 cm: 30 mm (1.18″) ø 3.5 cm: 35 mm (1.38″) ø 4.0 cm: 40 mm (1.57″) ø 4.5 cm: 45 mm (1.77″) ø 5.0 cm: 50 mm (1.97″)	ø 4.4 mm	ø 1 cm: 14 mm (0.55″) ø 2 cm: 24 mm (0.94″) ø 3 cm: 34 mm (1.34″) ø 4 cm: 44 mm (1.73″) ø 5 cm: 54 mm (2.13″) ø 6 cm: 64 mm (2.52″)	ø 1 cm: 14 mm (0.55″) ø 2 cm: 24 mm (0.94″) ø 3 cm: 34 mm (1.34″) ø 4 cm: 44 mm (1.73″)	ø 2.0 cm: 20 mm (0.79″) ø 2.5 cm: 25 mm (0.98″) ø 3.0 cm: 30 mm (1.18″) ø 3.5 cm: 35 mm (1.38″)
Materials used for applicators and components	■ Stainless steel ■ ULTEM (Polyetherimide)	■ Stainless steel ■ ULTEM (Polyetherimide) ■ Polycarbonate	■ Stainless steel ■ ULTEM (Polyetherimide) ■ EPDM	■ Stainless steel ■ ULTEM (Polyetherimide) ■ EPDM	■ Stainless steel ■ ULTEM (Polyetherimide) ■ EPDM

3. Mobility of the System & Components

The INTRABEAM system is highly mobile and all components are easily transportable. Most components, such as the 1.6 kg miniaturized accelerator, are stored in containers upon the INTRABEAM Cart. The cart and floor stand can be easily stowed away with components when not in use. The cart's spacious table top allows the system quality assurance check to be carried out in situ. The touch key terminal, control console, dosimeter and all other components required for system quality assurance and the treatment are mounted ergonomically on the cart. Large casters and guiding rollers ensure easy transportation inside and outside the operating room. The set up of the cart also ensures quick and easy cleaning before entering the OR.

The cart and Floor Stand can be moved through standard width doors and within elevators. When in use, the miniaturized accelerator is inserted in the arm of the INTRABEAM carrier. The carrier can be moved smoothly to any position in the OR due to its intergral casters located in the base. Weight compensation and six axes provide enough freedom to position the miniaturized accelerator within any position in three dimensional space needed for access to the treatment area. Electromagnetic brakes hold the miniaturized accelerator in the exact position during treatment. The operator can monitor and controls the system at any time during the treatment from the control panel on the INTRABEAM Cart.

4. System Dimensions

INTRABEAM Floor Stand

Weight:	275 kg / 606 lbs
Transport position:	740 x 1940 x 1500 mm / 29.13" x 76.38" x 59.06" (Width x height x length)

INTRABEAM Control Unit

Weight:	4.5 kg / 9.92 lbs
Dimensions:	381 x 305 x 89 mm / 15.00" x 12.01" x 3.50" (Width x height x length)
Rated voltage:	100-240 V AC
Power consumption (max.):	60 VA
Rated frequency:	50-60 Hz
Beam current at 40 kV:	40 µA
Beam current at 50 kV:	5, 10, 20 or 40 µA

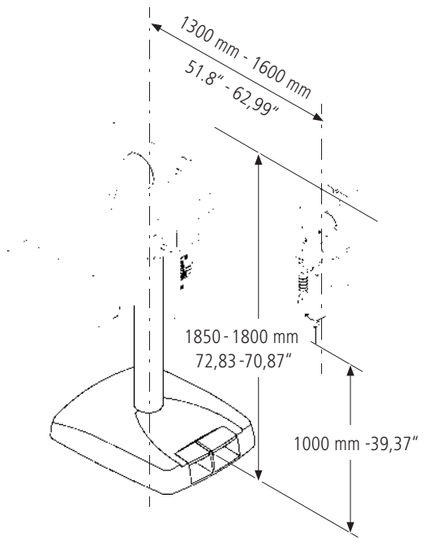
INTRABEAM Cart

Unloaden weight of cart: (incl. permanently mounted user terminal)	105 kg / 231 lbs
Payload max.:	95 kg / 209.43 lbs
Dimensions:	900 x 1690 x 600 mm / 35.43" x 66.53" x 23.62" (Width x height x length)

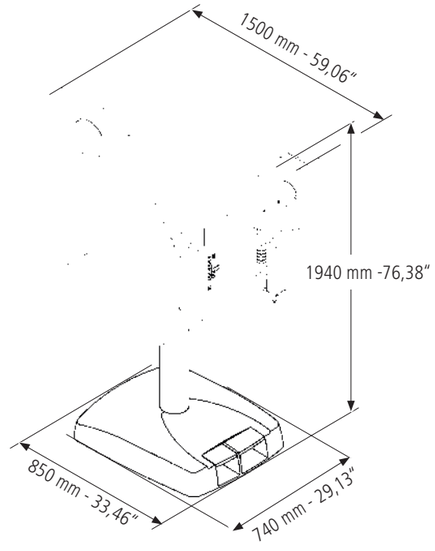
Miniaturized Accelerator: INTRABEAM X-ray Source XRS 4

Weight:	1.6 kg / 3.57 lbs
Dimensions:	70 x 175 x 110 mm / 2.75" x 6.89" x 4.32" (Width x height x length)

1 Working position



2 Transport position

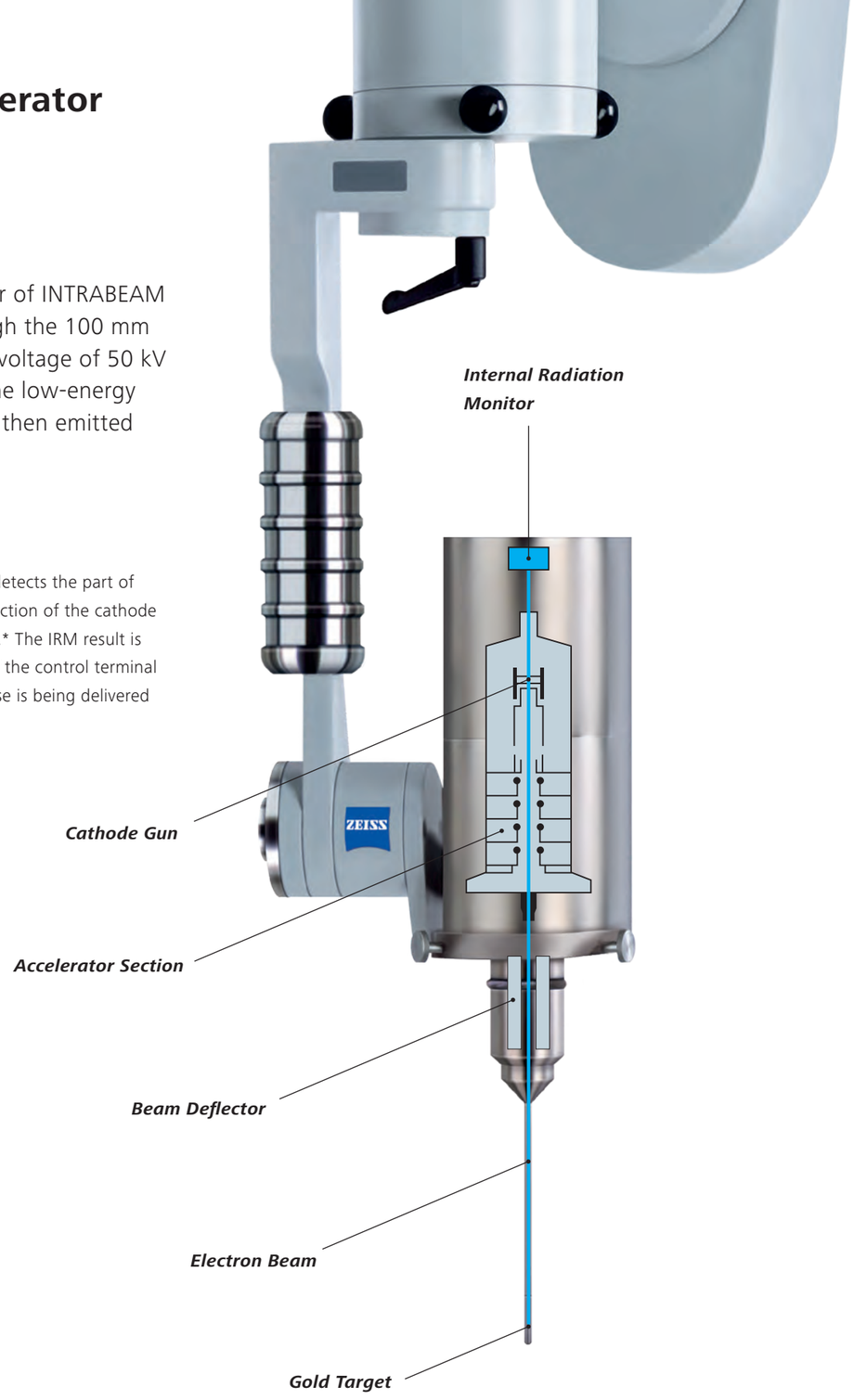


5. Miniaturized Accelerator

The miniaturized accelerator of INTRABEAM accelerates electrons through the 100 mm drift tube with a maximum voltage of 50 kV onto a gold target where the low-energy photons are generated and then emitted isotropically.

Online dose monitoring
An internal radiation monitor (IRM) detects the part of the x-ray photons emitted in the direction of the cathode and records dose output in real-time.* The IRM result is displayed on the treatment screen of the control terminal so that the operator knows what dose is being delivered at any time throughout treatment.

** Subject to appropriate calibration.*

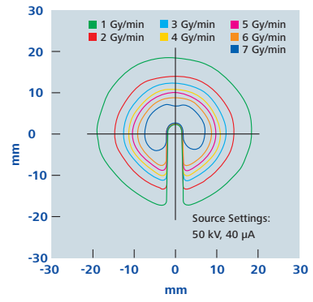


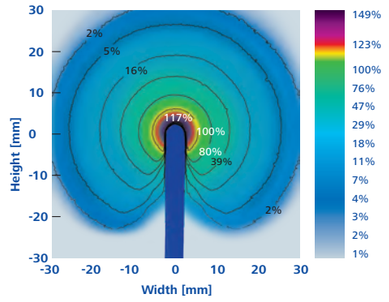
6. Beam Characteristics

- Point-source type x-ray emission
- Spherical dose distribution around the isocentre of the miniaturized accelerator (XRS 4)
- Steep dose gradient (approx. $1/r^3$) in water (soft tissue equivalent)
- Positional accuracy of delivered dose +/- 1 mm at 40 mm treatment diameter (from isocentre)

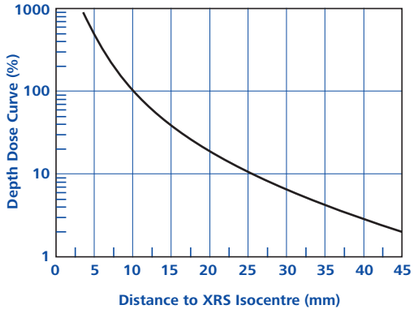
Beam characteristics of the miniaturized accelerator (XRS 4)
Spherical dose distribution of the emitted x-rays.
The steep dose gradient (due to rapid low kV x-ray attenuation) ensures a localized dose distribution.
40 kV / 40 µA
50 kV / 5, 10, 20 or 40 µA

Beam characteristics of the INTRABEAM Needle Applicator



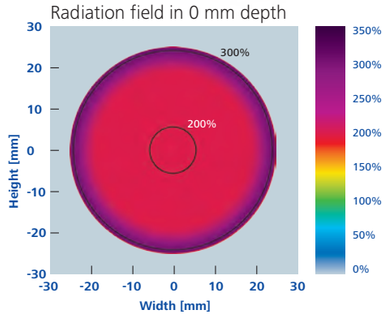


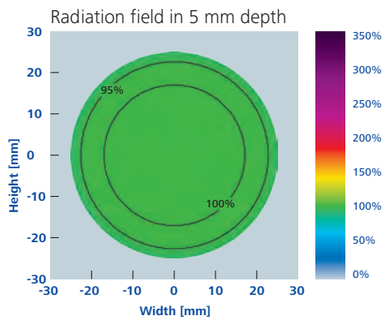
Percentage Depth Dose Curve:
Normalized at 10 mm

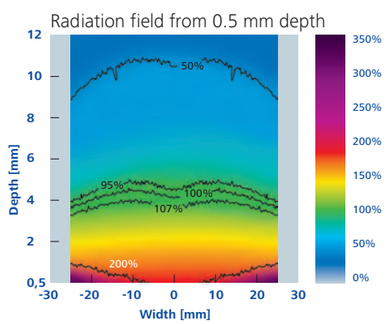


Beam characteristics of the INTRABEAM Flat Applicator, 5 cm diameter

The INTRABEAM Flat Applicator has an optimized flat radiation field (by means of a flattening filter) at 5 mm from the applicator surface.
50 kV / 5, 10, 20 or 40 µA

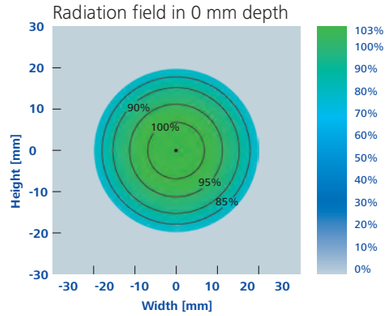


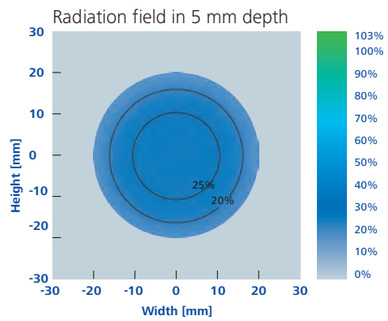


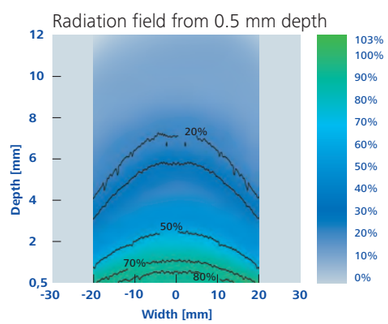


Beam characteristics of the INTRABEAM Surface Applicator, 4 cm diameter

The INTRABEAM Surface Applicator creates an optimized flat radiation field (by means of a flattening filter) upon the target surface.
50 kV / 5, 10, 20 or 40 µA



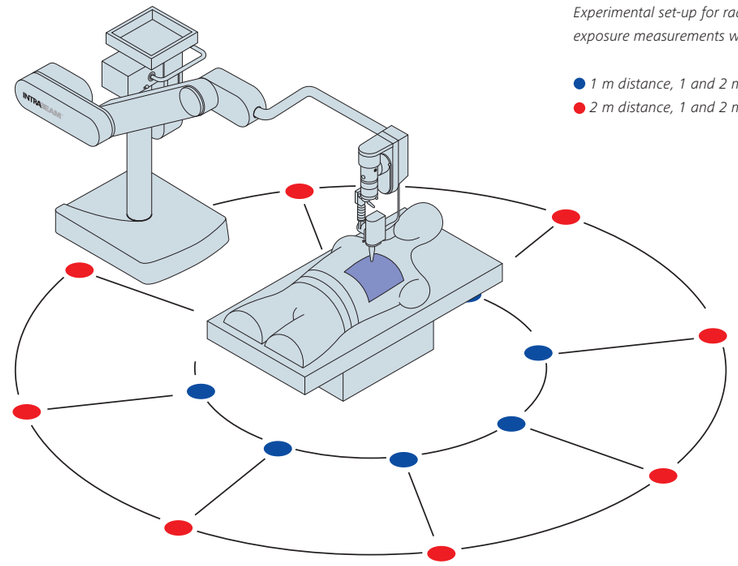




7. Radiation Safety

Radiation measurement during treatment delivery

To measure the radiation exposure a realistic anthropomorphic phantom with a silicone breast was created in which a 3.5 cm spherical applicator was inserted. The irradiation area was covered with the INTRABEAM Radiation Shield, Flat as in a standard clinical procedure. Measurements were taken at eight different angles relative to the isocenter of the source at a radial distance of 1 and 2 m. The measurements were then repeated at 1 and 2 m above floor level.



Experimental set-up for radiation exposure measurements with the phantom

- *1 m distance, 1 and 2 m height*
- *2 m distance, 1 and 2 m height*

Examples to illustrate the exposure level with INTRABEAM

Example 1:

Without the use of any means of external radiation protection other than covering the irradiation area appropriately with the flat INTRABEAM radiation shield, 10 patients can be treated a year until an exposure dose of 1 mSv is reached at a distance of 2 m from the x-ray source at a height of 1 meter.

Example 2:

If 100 procedures per year are to be performed, a distance of 2 m would need to be maintained from the public area (e.g. the corridor) to ensure that the corresponding wall and/or window shields the radiation by a factor of at least 10. This corresponds to a material with a lead equivalent of 0.05 mm at a peak energy of 50 kV such as 10 mm of concrete or 26 mm of gypsum.

Calculated based on values taken from US National Council on Radiation Protection and Measurements (NCRP), Structual Shielding Design for Medical X-Ray Imaging Facilities, Rep. 147, Bethesda, MD (2004)

Detailed information are available in our brochure "Information on Radiation Safety"

8. Quality Assurance and Dosimetry

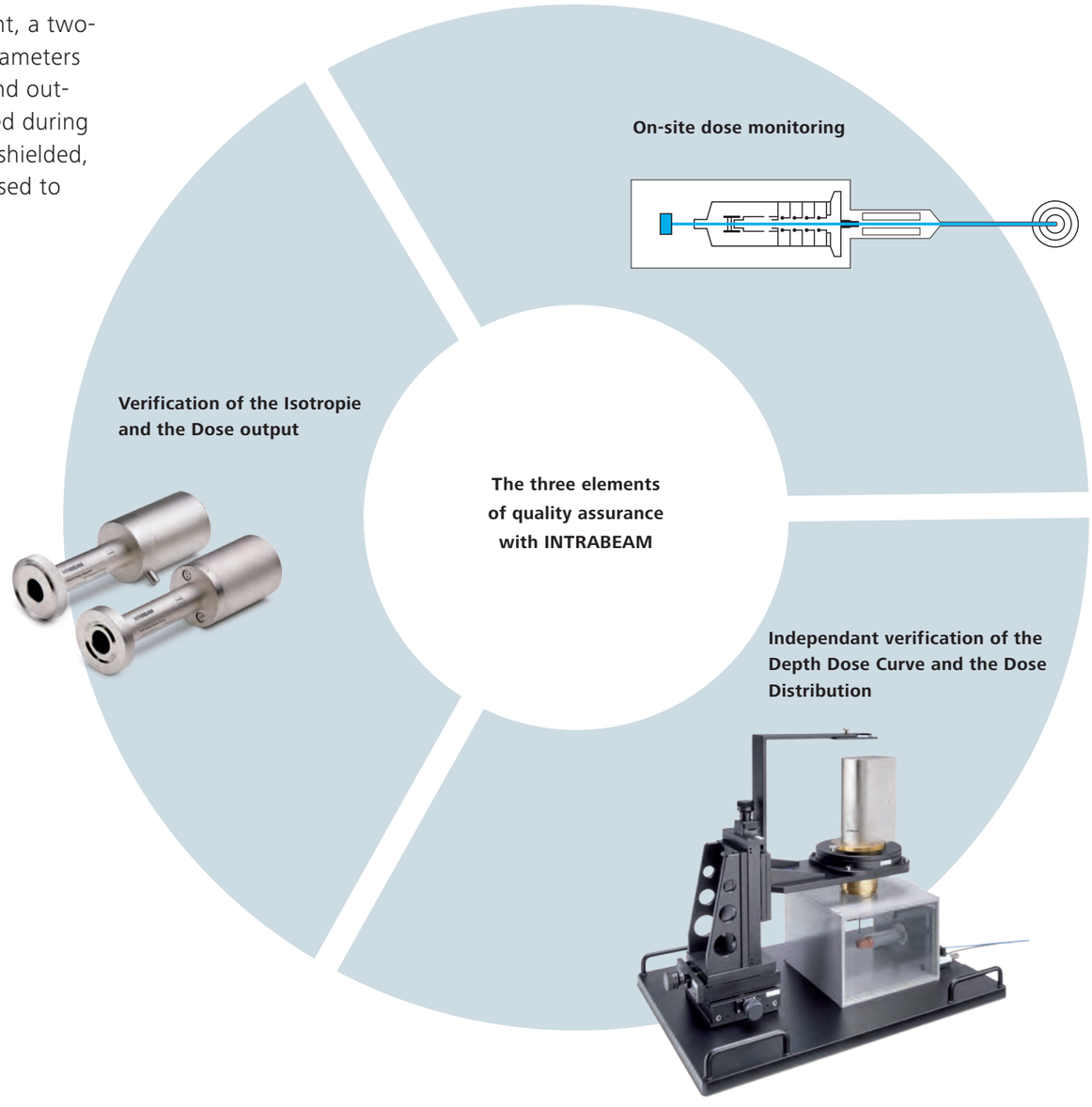
A full set of quality assurance and dosimetry tools is provided with the INTRABEAM. The factory-calibrated system is delivered with the specific depth dose curves and a reference measurement with the ion chamber integral to the system. Prior to every treatment, a two-step quality control check ensures that all parameters such as isotropy, internal radiation monitor and output work do not exceed the tolerances defined during calibration. For commissioning, a completely shielded, manually adjustable water phantom can be used to verify the depth dose curve.

Verification of the Isotropie and the Dose output

8.1 QA Check (QA Tools)
Inside the so called PDA (Photo Diode Array), five diodes positioned orthogonally to each other measure the radiation of the miniaturized accelerator. The objective of this test is to assure the isotropy (i.e. spherical pattern) of the emitted beam.

With the PAICH (Probe Adjuster Ion Chamber Holder) the output can be checked. An ion chamber is mounted onto the probe adjuster in such a way that the ion chamber window sits right above the tip of the miniaturized accelerator. In this test, the internal radiation monitor is verified as well. The counts measured by the internal radiation monitor are compared with the reading of the ionization chamber. The miniaturized accelerator is not enabled for treatment planning until a coefficient has been computed.

Temperature and pressure sensors are located within the control unit and the PAICH. Pressure and temperature can be calibrated to ensure exact dose calculation.



Online dose monitoring

8.2 Online control through IRM
An internal radiation monitor (IRM) detects the part of the x-ray photons emitted in the direction of the cathode and records dose output in real-time.*
The IRM result is displayed on the treatment screen of the control terminal so that the operator knows what dose is being delivered at any time throughout treatment.

** Subject to appropriate calibration.*

Independant verification of the Depth Dose Curve and the Dose distribution

8.3 Radiation protection during dosimetry
Every tool provided with the INTRABEAM for quality assurance is completely self shielded and does not require any additional radiation protection.

8.4 Commisioning
(System calibration by Carl Zeiss and with the water phantom)
A water phantom with a high precision movement technique enables the physicist to position the tip of the miniaturized accelerator exactly above or beside the ion chambers inside the water. Accurate positioning and stepping of the source ensures the verification of the depth dose curve. Even the measurement of a depth dose curve is possible.

9. Safety Concept (Interlock)

A monitoring system checks the INTRABEAM during the treatment and quality assurance. It prevents the user against unintended radiation emissions and optional unintended access to the controlled area and incorrect radiation data transmission (see 9.1 – 9.3). This safety concept is also responsible for ensuring the proper control during treatment and In case of an interference a sound alert is triggered. To obtain the license for the utilization of the INTRABEAM, it may require creation of a safety plan and/or failure analysis, a hospital radiation protection manual and an emergency plan. Suggestions on how to establish this can be provided by Carl Zeiss.

9.1 Interlock to prevent unintended radiation emission

Unintended radiation emissions are prevented by an optical interlock system and a multilayered inquiry in the software:

- The optical interlock detects whether the appropriate verification device has been correctly attached to the miniaturized accelerator. Only then and only when the device protects the environment from radiation, will the miniaturized accelerator be enabled for radiation emission. If the device is removed during the test, radiation emission is immediately deactivated by the interlock.
- The user is requested via the user interface to press the start button at least twice to confirm that he really wants to perform the test. The unintended execution of a verification test is not possible.
- The optical interlock enables the system to detect if the miniaturized accelerator has been correctly mounted on the INTRABEAM Floor Stand. The system also detects whether the applicator has been attached correctly. The miniaturized accelerator will only be enabled for radiation emission if it has been correctly mounted on the carrier system intended for it.
- Once the miniaturized accelerator has been successfully connected to the carrier system, the user must follow the menu prompts on the user interface to actively set the system status to ready for radiation emission. Radiation will only be emitted if the user presses the Start button again.
- As soon as the system is ready for radiation emission, this ready status is indicated by an acoustic signal. This warns the user that radiation will be emitted when the Start button is pressed again.
- Radiation emission can only be started by trained and authorized staff after the necessary verification steps have been completed, the dose has been verified by a password and the system has been set to the treatment mode.

9.2 Interlock to prevent unintended access to the controlled area

- Radiation emission is acoustically and visually indicated on the miniaturized accelerator and the user interface. Persons entering the controlled area are able to obtain information on the radiation status of the system.
- In addition, further safety systems such as an external warning lamp or a door contact switch can be connected with the INTRABEAM via an external interlock switch. If, for example, the external interlock is activated by opening of the door during a treatment session, radiation emission is instantly interrupted automatically and can only be resumed after the interlock has been closed and continued radiation emission has been confirmed.

9.3 Interlock to prevent incorrect radiation data transmission

- Every signal transmitted by the control console to the x-ray source is returned by the x-ray source and checked for completeness and correctness by the control console. If the signal is not correctly returned by the miniaturized accelerator, radiation emission is stopped or not started.
- The count rate is constantly monitored during treatment by the internal radiation monitor. If the count rate deviates from the planned rate by more than 10%, radiation emission is stopped.
- The ratio between the planned treatment time and the count rate is constantly monitored. In the event of any deviations, radiation emission is stopped.

9.4 Interlock to prevent incorrect dose entry

- The dose to be administered must only be prescribed by an appropriately trained, authorized doctor (this is a legal requirement in most countries; information during system training and note in the user manual).
- The dose is entered by one person (usually a physicist), and a second person, who must be a doctor (this is checked via the profile of the user name), must verify the dose planning and confirm it by entering a password.

9.5 Interlock to prevent interference with the application software

- The INTRABEAM is a closed system. Only data conforming to the specific data format of the application software can be loaded via CD/DVD.

10. Technical Requirements

10.1 Electrical requirements

Two electrical outlets are necessary in order to operate the INTRABEAM during treatment – one for the Floor Stand and one for all components on the cart which are connected together with a medical insulating transformer.

	INTRABEAM Floor Stand	INTRABEAM Cart Medical Insulating Transformer
Rated voltage	100 V / 115 V / 230 V	115 V / 230 V
Rated frequenzy	50 - 60 Hz	50 / 60 Hz
Power consumption	max. 400 VA	600 VA
Electrical standard	IEC 60601-1; CAN/CSA-C22.2 No. 601.1-M90	IEC 60601-1 / UL 60601-1; CAN/CSA-C22.2 No. 601.1-M90
Product classification	Type B	Type B
Case protection	IP20	IP20
Protection class	Protection class I	Protection class I

10.2 Ambient requirements*

Operation:

Temperature:	+15 °C … +40 °C / 59 °F ... 104 °F
Relative humdity:	30% … 75%
Air pressure:	800hPa … 1060 hPa

Transportation and Storage:

Temperature:	-20 °C … +70 °C / -4 °F ... 158 °F
Relative humdity:	10% … 90% (without condensation)
Air pressure:	500 hPa … 1060 hPa

** Requirements could differ for accessories. Please see separate user manuals.*

11. Processing (Cleaning, Disinfection, Sterilization)

All non-sterile components of the INTRABEAM can be easily cleaned and disinfected. Large casters and nearly no tight cleavings ensure simple and quick cleaning of the cart. The Floor Stand can also be cleaned in a very short time.

Component	Cleaning	Disinfection	Single Use/ Sterilizable
Floor Stand	c	b	–
Cart	c	b	–
Control Console PRS 500	c	a	–
User Terminal	c	b	–
Keyboard	c	a	–
Miniaturized Accelerator XRS 4	c	a	–
Quality Tools (PDA/PAICH)	c	a	–
Cables (XRS/QA)	c	a	–
V-/X- Block	c	a	–
INTRABEAM Water Phantom	d	–	–
Transportation Trays (XRS 4 / QA)	c	a	–
INTRABEAM Spherical Applicator	See user manual	X	Sterilizable with steam
INTRABEAM Needle Applicator	–	–	single use - sterile
INTRABEAM Flat Applicator	See user manual	X	Sterilizable with steam
INTRABEAM Surface Applicator	See user manual	X	Sterilizable with steam
INTRABEAM Cylinder V Applicator	See user manual	X	Sterilizable with steam
INTRABEAM Flat Shields	–	–	single use - sterile
INTRABEAM Drapes	–	–	single use - sterile

a = 4-7 % Hypochlorid, b = Meliseltol, c = wipe moist, d = ethyl alcohol, distilled water (1:1) plus a dash of household dish-washing liquid also mentioned in the detailled user manuals

Cleaning, Disinfection and Sterilization of Applicators

The processing of the applicators was validated by Carl Zeiss using the following procedure and can therefore be processed in a sterile manner:

If possible, clean and disinfect the applicators by machine. Expose the applicators and sterile containers only to temperatures no higher than 141°C (286 °F).

Use the following materials for cleaning/ disinfection:

- Filtered air for the drying process
- Soft brush
- Soft cloth

For the Cylinder V Applicator:

- Brush the inside of the Cylinder V Applicators and if necessary of the probe guard
- Disposable syringe (min. 10 ml) with attached long canulae

For Flat, Surface, Cylinder V Applicator:

- Use the provided Lumen Plug

Cleaning disinfecting agent:

- The disinfecting agent must be compatible with the cleaning agent used.
- The disinfecting agent must be suitable for the cleaning and disinfection of instruments made of metal and plastics.
- Rinsing with sterile or low-germ (maximum 10 microbes/ml) and lowendotoxin (maximum 0.25 endotoxin units/ml) water (e.g. purified water/ highly purified water)

The disinfecting agent must not contain the following:

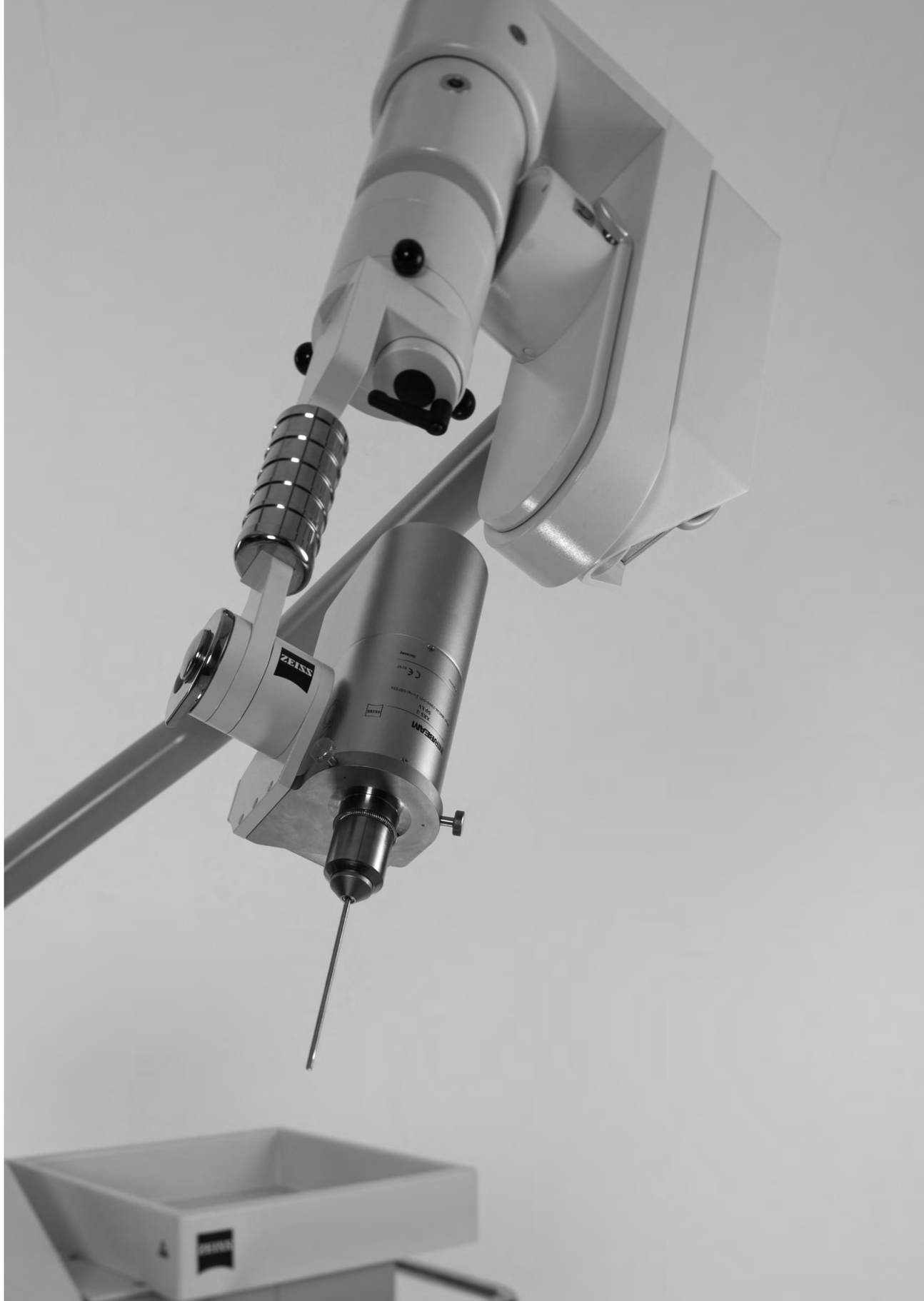
- Organic, mineral and oxidizing acids (minimum permissible pH value: 5.5)
- Strong bases (maximum permissible pH value: 8.5, recommended: neutral, enzymatic cleaning agent)
- Organic solvents (e.g. alcohol, ether, ketone, benzine)
- Oxidants (e.g. hydrogen peroxide)
- Halogens (chlorine, iodine, bromine)
- Aromatic/halogenated hydrocarbons

Only use the steam sterilization method (fractioned vacuum method) described in this manual for sterilization of the cleaned and disinfected applicators. Other procedures are not approved.

For steam sterilization, please take the following factors into account:

- The steam sterilization method is validated according to DIN EN ISO 17665-1
- The maximum sterilization temperature is 138 °C (280 °F; plus tolerance according to DIN EN ISO 17665-1
- With the fractioned vacuum method, the sterilization time (exposure time at sterilization temperature) is at least 5 min at 132°C (270 °F)/ 134 °C (273 °F) or for the INTRABEAM Spherical Applicator 18 min (prion inactivation)

Please see the user manual for detailed information on cleaning, disinfection and sterilization of the applicators.



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