

Melding two worlds into one benefit.



ZEISS INTRABEAM 600



Seeing beyond



Melding two worlds into one benefit.

ZEISS INTRABEAM 600

ZEISS INTRABEAM 600 ensures local precision during tumor bed sterilization, as time matters, directly combining surgery and irradiation into one step, rounded up by proven performance with a strong evidence base in radiotherapy for truly personalized treatments.

The first model of INTRABEAM® received FDA clearance in the USA in 1997 and received CE certification in Europe in 1999 for the targeted irradiation of lesions using interstitial, intraoperative, intracavity or surface irradiation techniques. The current INTRABEAM® 600 from ZEISS consists of the ZEISS INTRABEAM Workplace with the integrated Control Console 600, the X-ray source (XRS) and the quality assurance (QA) tools.

Using the ZEISS NC32 INTRABEAM Floor Stand with six degrees of freedom, weight compensation and magnetic brakes ensure easy, flexible and precise positioning of the XRS into the targeted area for low-energy X-ray irradiation in the tumor cavity.

ZEISS INTRABEAM 600

Overview

*INTRABEAM Software
& radiance® Software*

Keyboard & Mouse

*Quality assurance tools (QA)
& X-ray source (XRS)*

*Additional XRS &
Instructions for Use*

UNIDOS E & Computer



X-ray source (XRS)

INTRABEAM Applicators



ZEISS INTRABEAM 600

In Detail

As third device generation of IORT from ZEISS, the new INTRABEAM 600 is the first fully integrated and connected treatment platform for IORT addressing multiple clinical needs in one solution.



Improving clinical workflows

Digital imaging and communications in medicine (DICOM) connectivity offers integration of the INTRABEAM 600 from ZEISS into your hospital infrastructure for pre-, intra- and post-treatment workflows (e.g. picture archiving and communication system (PACS)) while ensuring secure data exchange and on-site documentation possibilities.



Enhancing usability

The user-friendly graphical user interface (GUI) of the ZEISS INTRABEAM 600 makes it easy to deliver IORT treatments, offering holistic treatment modalities for supported oncological indications. The ergonomic design of the new ZEISS INTRABEAM 600 is tailored to improve ease of use for all quality assurance (QA) procedures, creating a modern working atmosphere.



Demonstrating a new level of precision

With radiance® the ZEISS INTRABEAM 600 integrates the first available 3D treatment planning simulation software for IORT. For pre-, intra- and post-treatment operations, radiance® offers the possibility of case selection and dose computation near critical organs with the Monte Carlo algorithm to correct tissue heterogeneity and enable easy documentation.



ZEISS INTRABEAM 600

Technical Data

ZEISS INTRABEAM Workplace

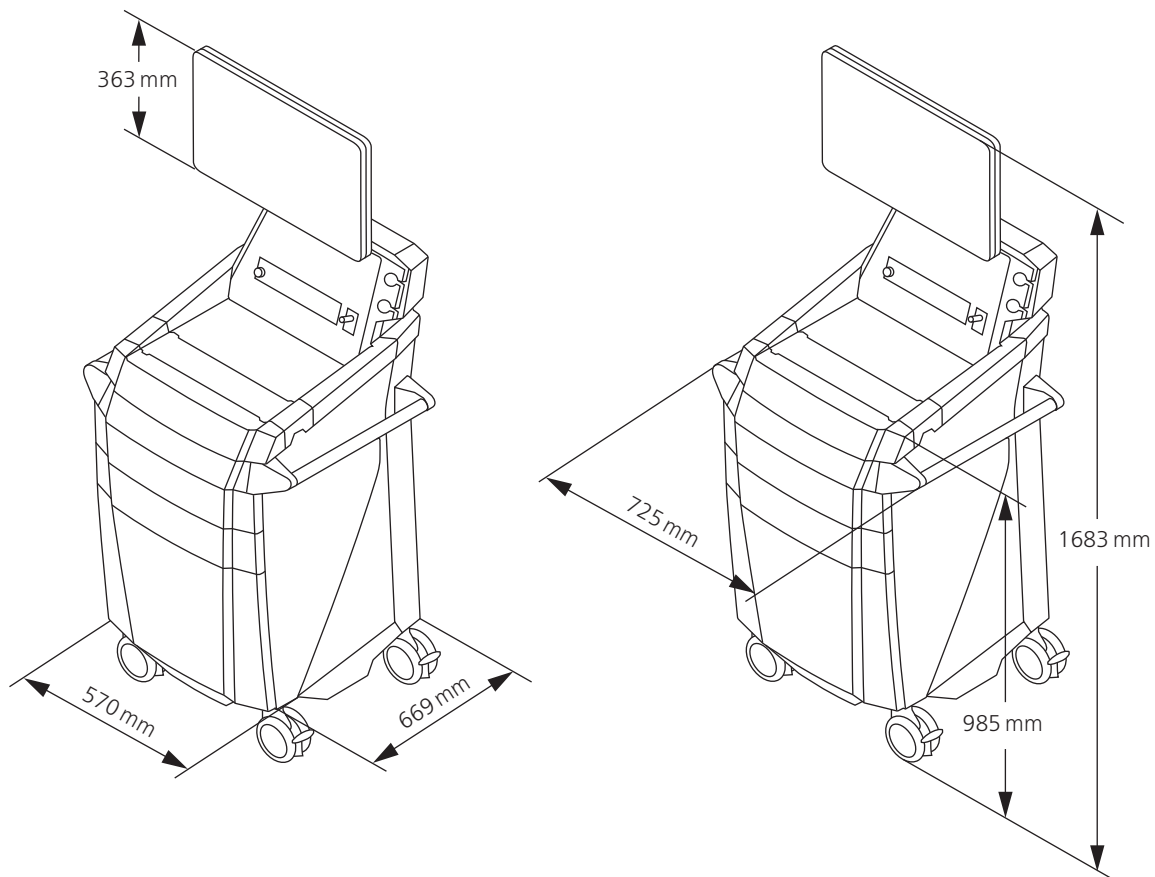
| | |
|--------------------------------------|--|
| Total weight with full configuration | max. 155 kg / 341.72 lbs. |
| Dimensions | 900 × 1690 × 600 mm / 35.43" × 66.54" × 23.62" (width × height × depth) |
| Nominal voltage ranges, switchable | (115 V) 110 V – 125 V (230 V) 220 V – 240 V |
| Rated frequency | 50 Hz – 60 Hz |
| Connected load | 300 VA |

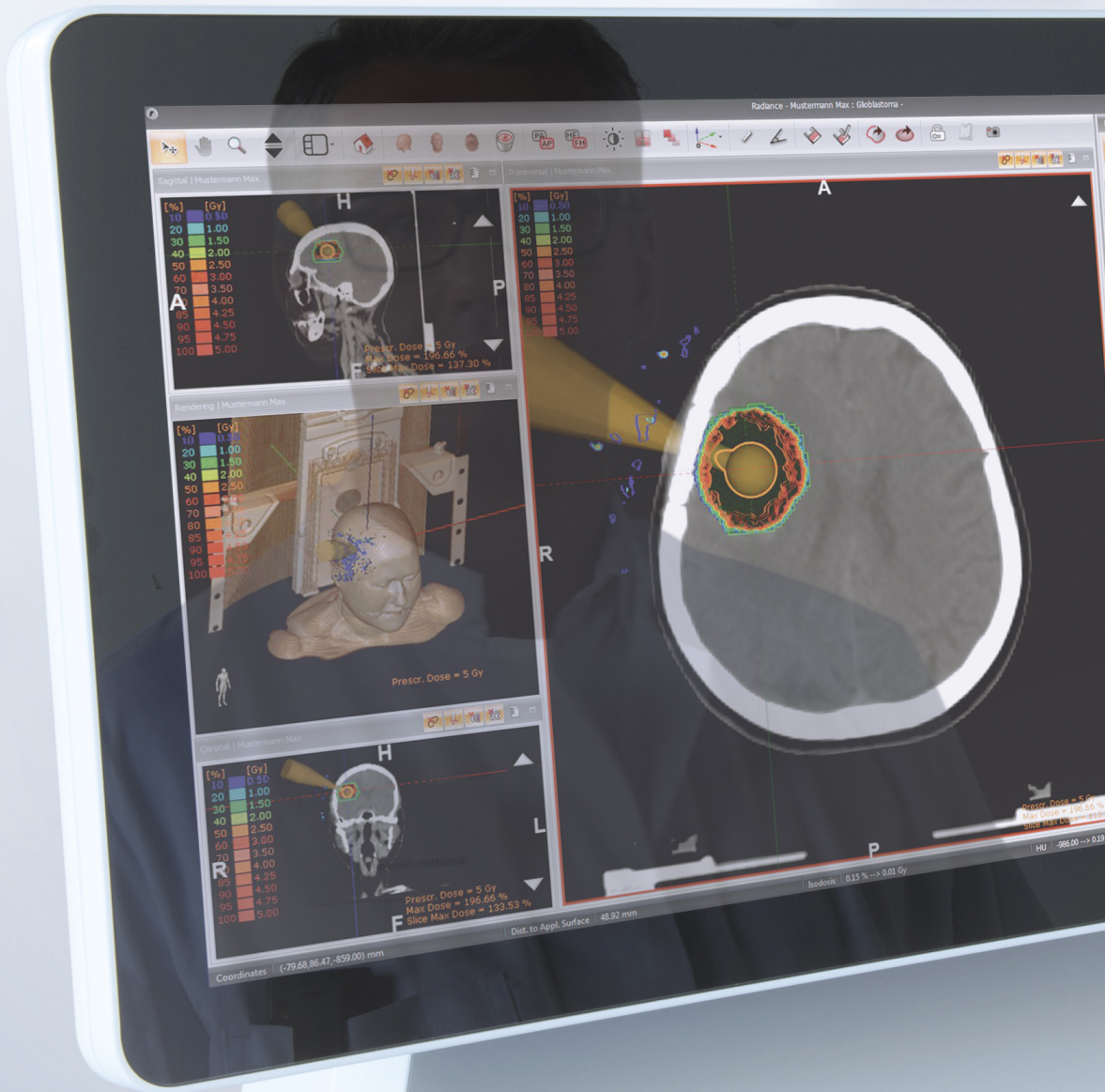
Control Console 600

| | |
|----------------------------------|---|
| Weight | 4.5 kg / 9.92 lbs. |
| Dimensions | 305 × 89 × 381 mm / 12.00" × 3.50" × 15.00" (width × height × depth) |
| Power connection | Via workplace isolating transformer |
| Input voltage | 100 V – 240 V |
| Rated frequency | 50 Hz – 60 Hz |
| Power consumption | 60 VA |
| Selectable operating parameters: | 40 kV / 40 μA 50 kV / 5, 10, 20 or 40 μA |

(Acceleration voltage /
beam current)

is the maximum current of the X-ray tube over
the entire voltage range





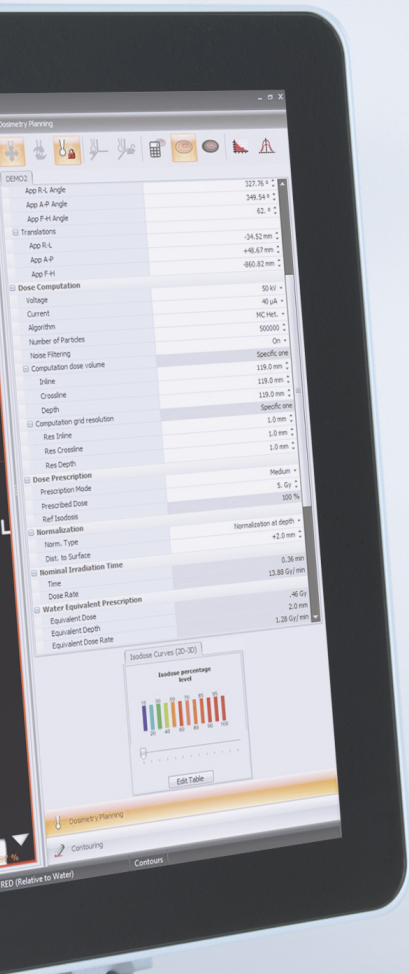
Power on

Ready

X-Ray on

Pause

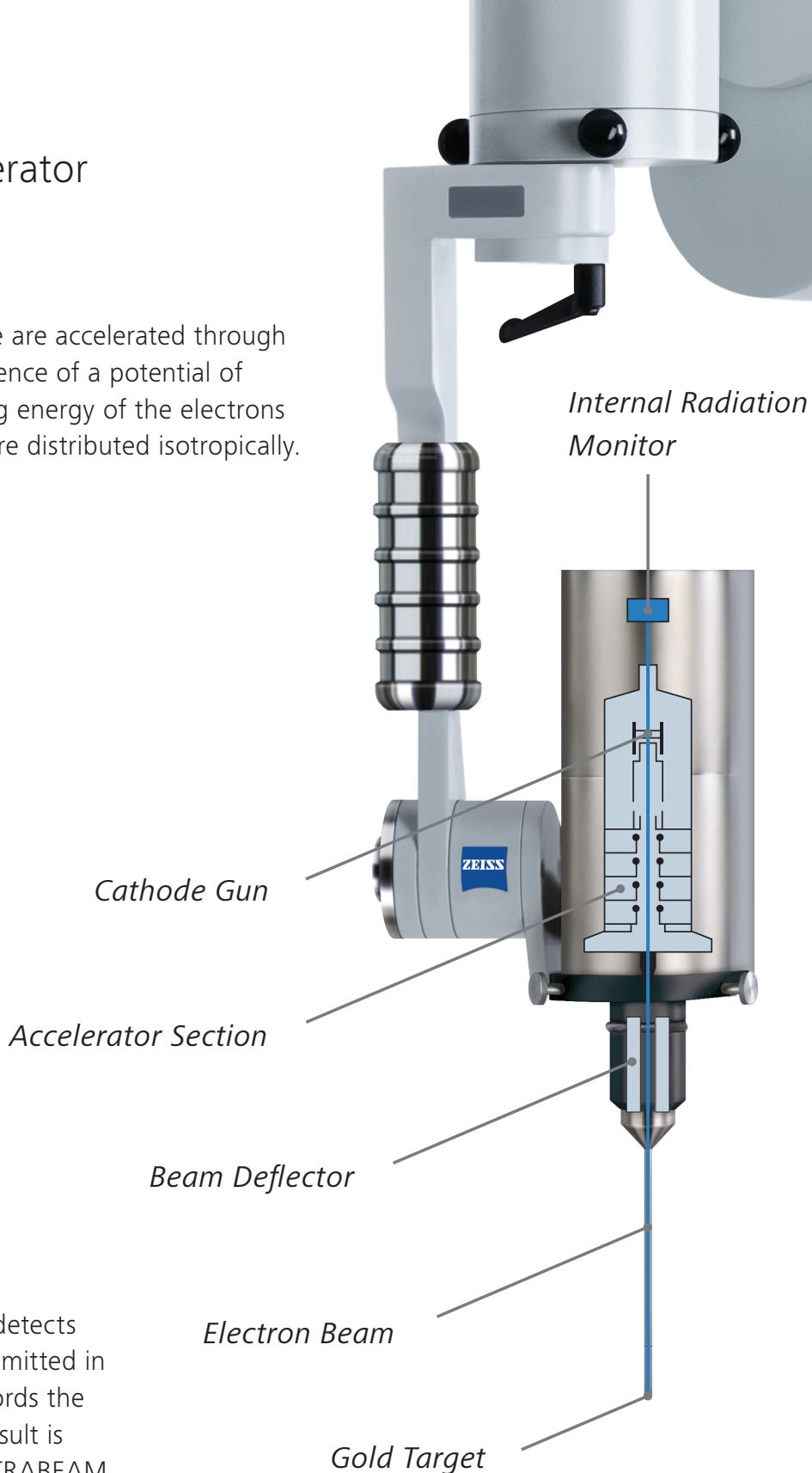
Pause



X-ray source (XRS)

Miniaturized linear accelerator

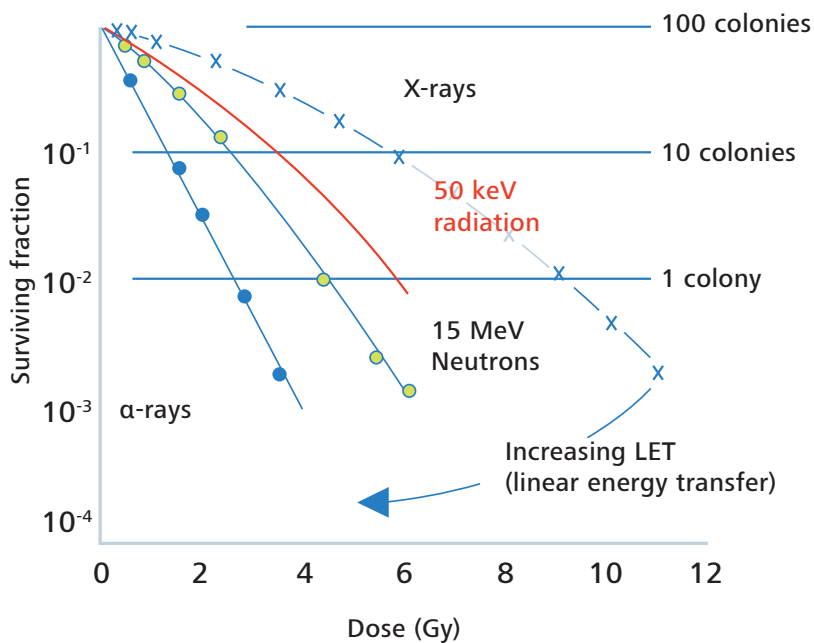
The electrons emitted by the cathode are accelerated through the drift tube with a maximum difference of a potential of 50 kV onto a gold target. The braking energy of the electrons creates low-energy photons, which are distributed isotropically.



Online dose monitoring

The internal radiation monitor (IRM) detects the part of the low-energy photons emitted in the direction of the cathode and records the dose output in real-time.* The IRM result is displayed on the GUI of the ZEISS INTRABEAM Workplace so that the user knows which dose is being delivered at any time throughout the treatment.

* Subject to appropriate calibration.



- Point-source type X-ray emission
- Spherical dose distribution around the isocenter of the X-ray source (XRS)
- Steep dose gradient (approx. 1/r³) in water (soft tissue equivalent)
- Positional accuracy of delivered dose +/- 1 mm at 40 mm treatment diameter (from isocenter)

Unlike megavolt X-rays, low-energy X-rays have an increased RBE.^{1,2}

Technical Data

| | |
|------------|---|
| Weight | 1.62 kg / 3.57 lbs. |
| Dimensions | 70 × 175 × 110 mm / 2.75" × 6.89" × 4.32" (width × height × depth) |
| Probe | Diameter 3.2 mm, length 100 mm, coated with chromium nitride (CrN) |

¹ Herskind, C. et al. (2006). Influence of different dose rates on cell recovery and RBE at different spatial positions during protracted conformal radiotherapy. *Radiation Protection Dosimetry*, 122(1-4), 498-505.

² Wenz, F. et al. (2007). Intraoperative radiotherapy (IORT) with the INTRABEAM system in breast cancer. Current status of the TARGIT study. *Der Gynäkologe*, 40(6), 464-467.

NC32 INTRABEAM Floor Stand

Combining precision and flexibility

The ZEISS NC32 INTRABEAM Floor Stand combines performance with reliability, flexibility and ease of use and is suitable for mobile use in any OR. Electromagnetic brakes position and hold the XRS and the associated applicator during the irradiation with millimeter accuracy.

Maneuverability

Six axes of mobility allow placement of the XRS anywhere in three dimensional space, no matter where it is exactly required for the treatment.

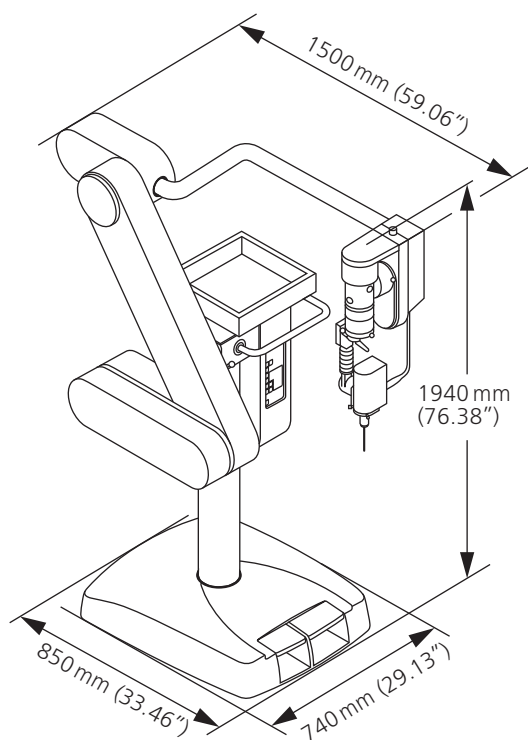


NC32 INTRABEAM Floor Stand

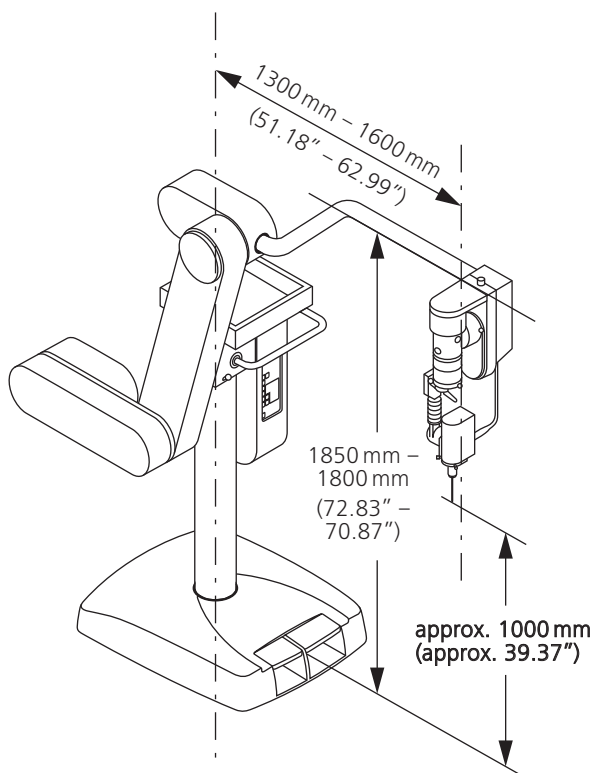
Technical Data

In order to operate the ZEISS INTRABEAM 600 during treatment two electrical outlets are necessary – one for the ZEISS NC32 INTRABEAM Floor Stand and one for the ZEISS INTRABEAM Workplace.

| | |
|------------------------|---|
| Rated voltage | 100 V / 115 V / 230 V |
| Rated frequency | 50 – 60 Hz |
| Power consumption | max. 400 VA |
| Electrical standard | IEC 60601-1; CAN/CSA-C22.2 No. 601.1-M90 |
| Product classification | Type B |
| Case protection | IPX0 |
| Protection class | Protection class I |



ZEISS NC32 INTRABEAM Floor Stand
transport position



ZEISS NC32 INTRABEAM Floor Stand
working position

INTRABEAM Applicators

Enabling full treatment versatility

ZEISS INTRABEAM Spherical Applicators

are used for the intracavity or intraoperative radiation delivery to the tumor bed. 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.



ZEISS INTRABEAM Needle Applicator

can be used for the interstitial irradiation of tumors, e.g. in the treatment of vertebral metastases or brain tumors. The applicator creates a spherical dose distribution emitted from the center to the probe tip and sterilizes the tumor directly in place or fills the tumor cavity created by the tumor excision respectively.



ZEISS INTRABEAM Flat Applicators

are used for the treatment of the tumor bed on surgically exposed surfaces. They have an optimized flat radiation field (by means of a flattening filter) at 5 mm from the applicator surface (measurement in water).



ZEISS INTRABEAM Surface Applicators

are used for the treatment of the tumor bed on surgically exposed surfaces and have an optimized flat radiation field (by means of a flattening filter) on the target surface.



INTRABEAM Applicators

Technical Data



| Components | ZEISS INTRABEAM Spherical Applicator | ZEISS INTRABEAM Needle Applicator | ZEISS INTRABEAM Flat Applicator Set | ZEISS INTRABEAM Surface Applicator Set |
|--|--|---|--|---|
| Available Sizes (ø in mm) | 15, 20, 25, 30, 35, 40, 45, 50 | 4.4 | 10, 20, 30, 40, 50, 60 | 10, 20, 30, 40 |
| Components | ZEISS INTRABEAM Spherical Applicator | ZEISS INTRABEAM Needle Applicator + Guide Shafts (6x) | ZEISS INTRABEAM Flat Applicator + Position Marker + Lumen Plug | ZEISS INTRABEAM Surface Applicator + Position Marker + Lumen Plug |
| Usage | Reusable | Single use | Reusable | Reusable |
| Anatomical Sites (but not restricted to) | 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) | Any part of the human body (not intended for use on the heart or in the central circulatory system) |
| 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 (measurement in water) | Flat dose distribution, optimized for tissue radiation directly in contact with the applicator surface |
| Fixation to the region of interest | – | Guide shafts can be used for deep approach routes | Fixation via ZEISS INTRABEAM Position Marker (can be sewed or glued to the region of interest) possible | Fixation via ZEISS INTRABEAM Position Marker (can be sewed or glued to the region of interest) possible |
| Length [mm] | Ø 15 mm: 167.5 mm Ø 20 mm: 170.0 mm Ø 25 mm: 172.5 mm Ø 30 mm: 175.0 mm Ø 35 mm: 177.5 mm Ø 40 mm: 180.0 mm Ø 45 mm: 182.5 mm Ø 50 mm: 185.0 mm | 94 mm (Probe length) | Ø 10 mm: 169.05 mm Ø 20 mm: 174.05 mm Ø 30 mm: 178.05 mm Ø 40 mm: 181.55 mm Ø 50 mm: 184.35 mm Ø 60 mm: 185.55 mm | Ø 10 mm: 169.05 mm Ø 20 mm: 174.05 mm Ø 30 mm: 178.05 mm Ø 40 mm: 181.55 mm |
| Inner diameter (absorption body) | N/A | N/A | Ø 10 mm: 10 mm Ø 20 mm: 20 mm Ø 30 mm: 30 mm Ø 40 mm: 40 mm Ø 50 mm: 50 mm Ø 60 mm: 60 mm | Ø 10 mm: 10 mm Ø 20 mm: 20 mm Ø 30 mm: 30 mm Ø 40 mm: 40 mm |
| Outer diameter | Ø 15 mm: 15 mm Ø 20 mm: 20 mm Ø 25 mm: 25 mm Ø 30 mm: 30 mm Ø 35 mm: 35 mm Ø 40 mm: 40 mm Ø 45 mm: 45 mm Ø 50 mm: 50 mm | Ø 4.4 mm | Ø 10 mm: 14 mm Ø 20 mm: 24 mm Ø 30 mm: 34 mm Ø 40 mm: 44 mm Ø 50 mm: 54 mm Ø 60 mm: 64 mm | Ø 10 mm: 14 mm Ø 20 mm: 24 mm Ø 30 mm: 34 mm Ø 40 mm: 44 mm |
| Materials used for applicators & components | Stainless steel ULTEM® (Polyetherimide) | Stainless steel ULTEM® (Polyetherimide) Polycarbonate | Stainless steel ULTEM® (Polyetherimide) EPDM (Ethylene Propylene Diene Monomer) Rubber | Stainless steel ULTEM® (Polyetherimide) EPDM (Ethylene Propylene Diene Monomer) Rubber |

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Quality Assurance

Three elements ensuring your treatment

A full set of quality assurance and dosimetry tools is provided with the ZEISS INTRABEAM 600. The factory-calibrated system is delivered with the specific depth dose curves and a reference measurement with the ion chamber integral to the system (valid for the current XRS of the ZEISS INTRABEAM 600). Prior to every treatment, a two-step quality control check ensures that all parameters such as isotropy, internal radiation monitor and dose output do not exceed the tolerances defined during calibration. A completely shielded, manually adjustable ZEISS INTRABEAM Water Phantom can be used to verify the depth dose curve.

Inside the PDA (Photo Diode Array), five diodes positioned orthogonally to each other measure the radiation of the XRS. 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 XRS. In this test,

the internal radiation monitor (IRM) is verified as well. The counts measured by the IRM are compared with the reading of the ionization chamber. The XRS is not enabled for treatment planning until a coefficient has been computed.

Temperature sensors are located inside the PAICH and pressure sensors are located inside the Control Console 600. The pressure and temperature displays can both be calibrated to ensure accurate dose calculation.



Verification of the Isotropy and the Dose Output

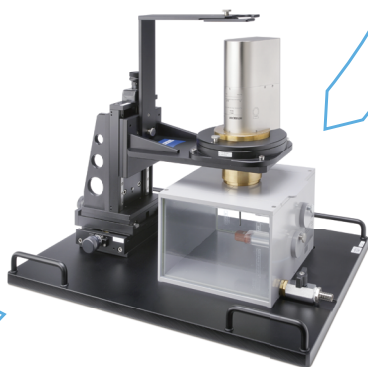


On-site dose monitoring

The IRM detects the part of the X-ray photons emitted in the direction of the cathode and records dose output in real-time (subject to appropriate calibration).

The IRM result is displayed on the monitor of the ZEISS INTRABEAM 600 so that the user knows what dose is being delivered at any time throughout the treatment.

The three elements of quality assurance with the ZEISS INTRABEAM 600



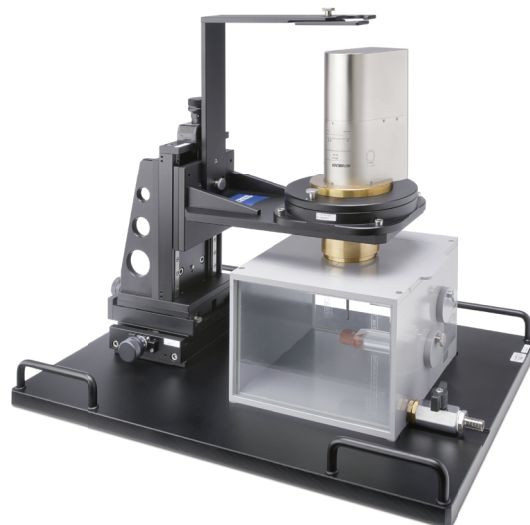
Independent verification of the Depth Dose Curve and the Dose Distribution

The ZEISS INTRABEAM Water Phantom is completely shielded and does not require any additional radiation protection. The high precision movement technique of the ZEISS INTRABEAM Water Phantom enables the physicist to position the tip of the XRS exactly above or beside the ion chambers inside the water. Accurate positioning and shifting of the source ensure the verification of the depth dose curve. Even the total measurement of a depth dose curve is possible.

ZEISS INTRABEAM Water Phantom

Overview & Technical Data

The ZEISS INTRABEAM Water Phantom offers simplistic dosimetric determination of the depth dose curve and verification of the isotropy of the XRS and provides in-depth quality assurance for IORT from ZEISS:



- Dosimetric determination of the depth dose curve and the isotropy of the XRS and verification of measured vs. quoted data (in-house calibration).
- The depth dose curve depicts the characteristic dose rate [Gy/min] relative to the penetration depth [mm] in water for the relevant X-ray source at 40 kV and 50 kV.
- Isotropy measurement to check the geometrical distribution of the spherical radiation emitted by the XRS probe tip.
- Measurement of the bare XRS probe or with a mounted applicator.
- Two measuring chambers fixed in a perpendicular assembly (X-Y plane and X(Y)-Z plane), each for insertion of an ionization chamber. Each measuring chamber contains an adapter element for the ionization chamber insertion.
- Radiation-shielded water tank with two plastic, waterproof holders for the ionization chambers.
- Micrometer screws allow for precise positioning (+/- 0.1 mm accuracy) of the XRS probe tip in the three axial directions (X, Y, Z).
- Rotation of the XRS around the Z axis in eight click stop positions of 45° each for isotropy measurement.
- Measurements can also be controlled via the monitor. The ionization chamber detects the X-rays and delivers the measured values to the UNIDOS E dosimeter.

| | |
|------------------------------|--|
| Weight | approx. 40 kg |
| Dimensions | approx. (400 mm × 520 mm × 580 mm) (width × height × length) |
| Water tank capacity | approx. 6 liters |
| Shielding, lead glass | 2 mm Pb equivalent at 50 kV X-ray radiation |
| Shielding, complete | Maximum radiation leakage < 23 mR/h (= 200 µSv/h) (based on DIN EN 60601-2-8: 1997; Chapter 29. 1. 102) |
| Positioning unit | Mechanical accuracy of Z positioning system: min. 0.1 mm |

Quality Assurance Tools

PAICH & PDA

PAICH (Probe Adjuster Ion Chamber Holder)

The PAICH is mainly used to check the radiation output. For this test an ion chamber is affixed to the PAICH and the internal radiation monitor is verified during the same test. Temperature sensors are located inside the PAICH and pressure sensors are located inside the Control Console 600. The pressure and temperature displays can both be calibrated to ensure accurate dose calculation.



PAICH used during the "Probe adjustment" quality assurance procedure.

PDA (Photo Diode Array)

Inside the PDA, five diodes positioned orthogonally to each other measure the radiation of the XRS. The objective of this test is to assure the isotropy (i.e. spherical pattern) of the emitted soft X-Ray photon beam.



PDA used during the "Beam centering" quality assurance procedure.

Safety Concept (Interlock)

Optical & External

Optical Interlock

The XRS features an integrated optical interlock system for detecting the type of radiation shield used in the device in which the X-ray source is installed. When the XRS is inserted in its support and a ZEISS applicator is connected, the optical interlock system closes, thus enabling the generation of X-rays. When X-ray radiation is generated, an audible acoustic

signal is emitted from the loudspeaker of the control unit and the external warning lamp lights up. The status of the interlock system is always displayed in the screen masks of the application software, see the "Interlock Status" display field. The four possible interlock statuses are listed in the following table.

| Interlock status | X-ray beam generation | Device |
|------------------|-----------------------|---|
| None | Deactivated | None |
| Not shielded | Deactivated | PAICH |
| Shielded | Permissible | PAICH WITH INSTALLED IONIZATION CHAMBER (IC) PDA |
| Treatment | Permissible | THE XRS AND THE APPLICATOR ARE PROPERLY MOUNTED ON THE FLOOR STAND. |

External Interlock

Located on the back of the workplace is an external interlock connector which permits both remote control of the interlock and remote controlled display of the X-ray beam generation. This external interlock connector "EXT INTERLOCK" has the following two functions:

- Option of connecting a separate switch to stop, prevent or release the generation of X-ray radiation.
- Option of connecting an additional external display (warning lamp) to indicate that X-ray radiation is being generated.

If the customer would like to use a separate switch, for example a door switch, it must be connected to the "EXT INTERLOCK" connector with a separate plug. This connection must be performed by the customer. A plug appropriate for the external interlock connector will be delivered with the control unit. Appropriate plugs for the external interlock connector can be ordered from the ZEISS Service as spare parts as well.

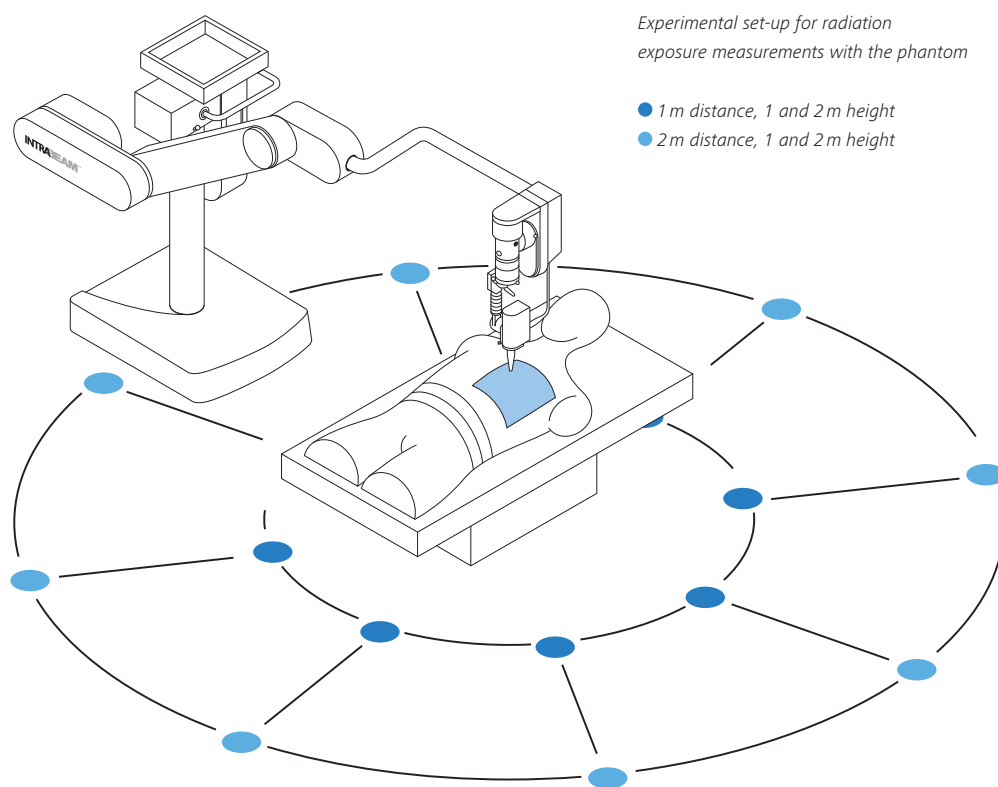
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Radiation Protection

Minimal radiation exposure at all times

During a simulated breast procedure in an unshielded operating room measurements were performed using TL dosimeters LiF (Mg, Cu, P). The XRS was operated at maximum power 50 kV and 40 μ A. During the simulated treatment, a dose of 200 Gy (at the applicator surface) was delivered. This is approximately 10 times the typical

dose prescribed for a patient being treated by targeted intraoperative radiotherapy with the INTRABEAM from ZEISS. This extremely high dose was chosen in order to reach the minimum detectable dose of the TL dosimeters of 30 μ Sv. Dosimeters were processed on Rados RE200A.



Example 1

Without the use of any external radiation protection other than covering the irradiation area appropriately with the ZEISS INTRABEAM Radiation Shield, Flat, 10 patients a year can be treated 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 m.

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.

1 Sartor, G., Avanzo, M., Roncadin, M., De Paoli, A., & Capra, E. (2010). Radiation protection survey for IORT machine in unshielded surgical room. 6th International Conference of the International Society of Intraoperative Radiation Therapy (ISIRT), Arizona.

2 Avanzo, M., Sartor, G., Roncadin, M., Gontijo, C., & Capra, E. (2010). Feasibility of IORT of the breast for women of fertile age. 6th International Conference of the International Society of Intraoperative Radiation Therapy (ISIRT), Arizona

Cleaning & Disinfection

Keep your device safe and reliable

All non-sterile components of the INTRABEAM from ZEISS can be easily cleaned and disinfected. The ZEISS NC32 INTRABEAM Floor Stand can also be cleaned in a very short time. a = 4-7% hypochlorite, b = Meliseptol®, c = wipe moist, d = ethyl alcohol, distilled water (1:1) plus a dash of household dish-washing liquid also mentioned in the detailed Instructions for Use (IfU).

| Components | Cleaning | Disinfection | Single Use / Sterilization |
|--------------------------------------|----------|--------------|----------------------------|
| ZEISS NC32 INTRABEAM Floor Stand | c | b | – |
| ZEISS INTRABEAM Workplace | See IfU | See IfU | – |
| Keyboard & Mouse | See IfU | See IfU | – |
| X-ray Source (XRS) | c | a | – |
| Quality Tools (PDA/PAICH) | c | a | – |
| Cables (XRS/PAICH/PDA) | c | a | – |
| ZEISS INTRABEAM Water Phantom | d | – | – |
| ZEISS INTRABEAM Spherical Applicator | See IfU | x | Sterilizable with steam |
| ZEISS INTRABEAM Needle Applicator | – | – | Single use - sterile |
| ZEISS INTRABEAM Flat Applicator | See IfU | x | Sterilizable with steam |
| ZEISS INTRABEAM Surface Applicator | See IfU | x | Sterilizable with steam |
| ADDCO X-Drape® D-110 | – | – | Single use - sterile |
| ZEISS INTRABEAM Drapes | – | – | Single use - sterile |

Steam sterilization

Please take the following factors into account:

- The steam sterilization method is validated as per DIN EN ISO 17665-1
- The maximum sterilization temperature is 138°C (280°F; plus tolerance as per DIN EN ISO 17665-1)

Please see the instructions for use for detailed information on cleaning, disinfection and sterilization of the applicators.

Cleaning, disinfection and sterilization of applicators

The processing of the applicators was validated by ZEISS. In order to better maintain effectiveness and reproducibility we recommend to clean and disinfect the applicators by a mechanized process, if possible, as stated in the Instructions for Use. Expose the applicators and sterile containers only to temperatures not higher than 141°C (286°F).

Use the following materials for cleaning/disinfection:

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

For flat and surface applicators:

- Use the provided Lumen Plug

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, benzene)
- Oxidants (e.g. hydrogen peroxide)
- Halogens (chlorine, iodine, bromine)
- Aromatic/halogenated hydrocarbons

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 low endotoxin (maximum 0.25 endotoxin units/ml) water (e.g. purified water/ highly purified water).

Only use the steam sterilization method (fractioned vacuum method) described in the Instructions for Use for sterilization of the cleaned and disinfected applicators. Other procedures are not validated.



NC32 INTRABEAM Floor Stand



0297

INTRABEAM 600
INTRABEAM Drapes
INTRABEAM Water Phantom



0297

INTRABEAM Spherical Applicator
INTRABEAM Needle Applicator
INTRABEAM Surface Applicator Set
INTRABEAM Flat Applicator Set



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