INTRABEAM System from ZEISS
Technical Specifications
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1. System Description

The INTRABEAM® System from ZEISS 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 interstitial, intraoperative, intracavitary or surface irradiation techniques. The ZEISS INTRABEAM System consists of the ZEISS NC32 INTRABEAM Floor Stand, the ZEISS INTRABEAM Cart and the ZEISS INTRABEAM System PRS 500 with XRS 4. Treatment can be performed in operating rooms; structural alterations for radiation protection are normally not required. The X-ray Source (XRS) of the ZEISS INTRABEAM System is a miniaturized linear accelerator and produces low-energy X-ray photons which are emitted isotropically (equally distributed). The ZEISS NC32 INTRABEAM Floor Stand with six degrees of freedom, weight compensation and magnetic brakes ensures easy, flexible and precise positioning of the XRS into the targeted area. Ideally integrated in the ZEISS INTRABEAM Cart, the Control unit PRS 500 ensures exact setting and monitoring of the desired dose. The ZEISS INTRABEAM System is mobile and therefore suitable for use in multiple operating rooms.

2. Mobility of the System & Components

The ZEISS INTRABEAM System is highly mobile and all components are easily transportable. Most components, such as the 1.6 kg XRS, are stored in containers upon the ZEISS INTRABEAM Cart. The ZEISS INTRABEAM Cart and ZEISS NC32 INTRABEAM 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 PRS 500 Terminal, the Control unit PRS 500, the 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 the usage in the OR. The cart and floor stand can be moved through standard width doors and within elevators. When in use, the XRS is inserted in the arm of the ZEISS NC32 INTRABEAM Floor Stand. The ZEISS NC32 INTRABEAM Floor Stand can be moved smoothly to any position in the OR due to its integral casters located in the base. Weight compensation and six axes provide enough freedom to position the XRS within any position in three dimensional space needed for access to the treatment area. Electromagnetic brakes hold the XRS in the exact position during treatment. The operator can monitor and control the system at any time during the treatment from the PRS 500 Terminal on the ZEISS INTRABEAM Cart.
**XRS - Miniaturized Linear Accelerator**

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

**Maneuverability**

Six axes allow the XRS 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 XRS, adapt to the radiation field for a variety of applications.

**ZEISS NC32 INTRABEAM Floor Stand**

The ZEISS NC32 INTRABEAM Floor Stand combines performance with reliability, flexibility and ease of use: electromagnetic brakes lock the XRS in the treatment position with millimeter accuracy. Suitable for mobile use in any OR.
3. Applications

The physical and radiobiological characteristics of the low-energy photons of the XRS allow the use in a range of applications within many body sites to meet the various clinical requirements.

3.1 ZEISS INTRABEAM Spherical Applicator
The ZEISS 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 using purse-string suture. The probe tip is centered within the applicator and therefore the tumor cavity. The ZEISS INTRABEAM Spherical Applicators are available in the diameters 15, 20, 25, 30, 35, 40, 45 and 50 mm. The applicators are reusable and sterilizable. Please refer to the instruction for use.

3.2 ZEISS INTRABEAM Needle Applicator
The ZEISS 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 the ZEISS INTRABEAM System vertebral metastases can be irradiated intraoperatively in a targeted, localized and minimally invasive technique using the ZEISS INTRABEAM Needle Applicator. After the intraoperative radiotherapy the affected vertebra is stabilized by the insertion of bone cement by using vertebroplasty or balloon kyphoplasty. The ZEISS INTRABEAM Needle Applicator is intended for single use only and has a diameter of 4.4 mm.
3.3 ZEISS INTRABEAM Flat Applicator
The ZEISS INTRABEAM Flat Applicator is used for the treatment of tumors on surgically exposed surfaces, e.g. tumors of the gastrointestinal tract. The ZEISS 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 ZEISS INTRABEAM Flat Applicators are available in the diameters 10, 20, 30, 40, 50 and 60 mm. The applicators are reusable and sterilizable. Please refer to the instruction for use.

3.4 ZEISS INTRABEAM Surface Applicator
The ZEISS INTRABEAM Surface Applicator is developed for 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 ZEISS INTRABEAM Surface Applicator is available in diameters of 10, 20, 30 and 40 mm. The applicators are reusable and sterilizable. Please refer to the instruction for use.
4. XRS – Miniaturized Linear Accelerator

The current miniaturized linear accelerator of the ZEISS INTRABEAM System is the XRS 4 and 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 PRS 500 Terminal so that the operator knows what dose is being delivered at any time throughout treatment.

* Subject to appropriate calibration.
5. Beam Characteristics

- Point-source type X-ray emission
- Spherical dose distribution around the isocenter of the 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 isocenter)

**Beam characteristics of the 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 4 μA

**Beam characteristics of the ZEISS INTRABEAM Needle Applicator**

![Depth Dose Curve](image)

**Percentage Depth Dose Curve:**
Normalized at 10 mm

![Graph](image)
Beam characteristics of the ZEISS INTRABEAM Flat Applicator, 50 mm diameter

The ZEISS 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 ZEISS INTRABEAM Surface Applicator, 40 mm diameter

The ZEISS 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
Radiation measurement during treatment delivery
To measure the radiation exposure a realistic anthropomorphic phantom with a silicone breast was created in which a 35 mm spherical applicator was inserted. The irradiation area was covered with a ZEISS 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.

Example 1:
Without the use of any means of external radiation protection other than covering the irradiation area appropriately with the ZEISS INTRABEAM Radiation Shield, Flat*, 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.

* The ZEISS INTRABEAM Radiation Shield, Flat is not produced anymore. Therefore, ZEISS recommends to use the ADDCO X-Drape® D-110.
A full set of quality assurance and dosimetry tools is provided with the ZEISS INTRABEAM System. 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 XRS 4). 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 and all later on operations, a completely shielded, manually adjustable ZEISS INTRABEAM Water Phantom can be used to verify the depth dose curve.

### Verification of the Isotropy and the Dose Output

#### 7.1 QA Check (QA Tools)

Inside the so called PDA (Photo Diode Array), five diodes positioned orthogonally to each other measure the radiation of the 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 is verified as well. The counts measured by the internal radiation monitor are compared with the reading of the ionization chamber. The XRS is not enabled for treatment planning until a coefficient has been computed.

Temperature and pressure sensors are located within the Control unit PRS 500 and the PAICH. Pressure and temperature can be calibrated to ensure exact dose calculation.
Online dose monitoring

7.2 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 PRS 500 Terminal so that the operator knows what dose is being delivered at any time throughout treatment.

* Subject to appropriate calibration.

Independent verification of the Depth Dose Curve and the Dose Distribution

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

7.4 Commissioning
(System calibration by ZEISS and with the ZEISS INTRABEAM Water Phantom)
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 the source ensures the verification of the depth dose curve. Even the total measurement of a depth dose curve is possible.
8. The ZEISS INTRABEAM Water Phantom

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 the INTRABEAM System from ZEISS.

- Dosimetric determination of the depth dose curve and the isotropy of the XRS 4 X-ray source 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 4 probe tip.
- Measurement of the bare XRS or with a mounted applicator.
- Two measuring chambers at two orthogonal planar orientations (X-Y and Z plane) for the X-ray detector and the 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 (+/- 0.1mm accuracy) of the XRS 4 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 PRS 500 Terminal. The Control unit PRS 500 controls the XRS. The ionization chamber detects the X-rays and delivers the measured values to the UNIDOS E dosimeter.
8.1 Measurement of the depth dose curve in a radiation-shielded water tank
The probe tip is positioned at discrete distances to the ionization chamber. The dose recorded at these discrete positions along the Z axis gives rise to the depth dose curve of the XRS.

1. Insertion of the ionization chamber

2. Positioning of the XRS

3. The measurement is performed at various specified distances. The probe tip is moved discretely.

8.2 Comparison of the calibrated depth dose curve using measured values determined with the ZEISS INTRABEAM Water Phantom.

A X-ray source

B X-ray source with 40 mm ZEISS INTRABEAM Spherical Applicator

<Graphs showing dose rate vs. water depth for X-ray source and X-ray source with 40 mm ZEISS INTRABEAM Spherical Applicator, with 5% error for each parameter>
8.3 Isotropy measurement in a radiation-shielded water tank

The Isotropy measurement verifies the geometry of the distribution of the spherical radiation output of the XRS 4 probe tip. The isotropy check is performed using maximum beam current and the beam voltage selected for the relevant XRS.

![1. Insertion of the ionization chamber](image1.png)

![2. Positioning of the XRS](image2.png)

![3. The XRS is rotated in 45° increments for the measurement](image3.png)

![4. Isotropy is determined in 8 click stop settings (always in 45° increments)](image4.png)

8.4 Technical data

All nonsterile ZEISS INTRABEAM components can be easily cleaned and disinfected. The design of the ZEISS INTRABEAM Water Phantom ensures fast and easy cleaning.

<table>
<thead>
<tr>
<th>ZEISS INTRABEAM Water Phantom Features</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight</td>
<td>approx. 40 kg</td>
</tr>
<tr>
<td>Dimensions</td>
<td>approx. (400 mm x 520 mm x 580 mm)</td>
</tr>
<tr>
<td>(width x height x length)</td>
<td></td>
</tr>
<tr>
<td>Water tank capacity</td>
<td>approx. 6 liters</td>
</tr>
<tr>
<td>Shielding, lead glass</td>
<td>2 mm Pb equivalent at 50 kV X-radiation</td>
</tr>
<tr>
<td>Shielding, complete</td>
<td>Maximum radiation leakage &lt;23 mR/h (=200 µSv/h)</td>
</tr>
<tr>
<td></td>
<td>(based on DIN EN 60601-2-8: 1997; Chapter 29. 1. 102)</td>
</tr>
<tr>
<td>Positioning unit</td>
<td>Mechanical accuracy of Z positioning system: min. 0.1 mm</td>
</tr>
</tbody>
</table>

The ZEISS INTRABEAM Water Phantom is an accessory of the ZEISS INTRABEAM System and must only be used in combination with the ZEISS INTRABEAM System.
9. Safety Concept (Interlock)

A monitoring system checks the ZEISS INTRABEAM System during the treatment and quality assurance. It prevents the user from 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 an acoustic signal is triggered. To obtain the license for the utilization of the INTRABEAM System from ZEISS, it may require the creation of a safety plan and/or failure analysis, a hospital radiation protection manual and an emergency plan.* Implementation assistance can be provided by 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 XRS. Only then and only when the device protects the environment from radiation, the XRS will 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 twice to press the start button via the user interface to initiate and perform the test, avoiding unintentional execution of a verification test.
- The optical interlock enables the system to detect if the XRS has been correctly mounted on the ZEISS NC32 INTRABEAM Floor Stand. The system also detects whether the applicator has been attached correctly. The XRS will only be enabled for radiation emission if it has been correctly mounted on the ZEISS INTRABEAM NC32 Floor Stand intended for it.
- Once the XRS has been successfully connected to the ZEISS NC32 INTRABEAM Floor Stand, 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.

* Depends on the local regulations
9.2 Interlock to prevent unintended access to the controlled area

- Radiation emission is acoustically and visually indicated on the XRS 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 ZEISS INTRABEAM System 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 unit PRS 500 to the X-ray source is returned by the X-ray source and checked for completeness and correctness by the Control unit PRS 500. If the signal is not correctly returned by the XRS, 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.

9.4 Interlock to prevent incorrect dose entry

- The dose is entered by one person (usually a medical physicist), and a second person, who must be a physician (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 System from ZEISS is a closed system. Only data conforming to the specific data format of the application software can be loaded via CD/DVD. Treatment reports are transferred to the final storage location via a one way USB connection (only exportation).

- The dose to be administered must only be prescribed by an appropriately trained, authorized physician (this is a legal requirement in most countries; information during system training and note in the user manual).
# 10. Technical Data ZEISS INTRABEAM Applicators

<table>
<thead>
<tr>
<th>Component</th>
<th>ZEISS INTRABEAM Spherical Applicator</th>
<th>ZEISS INTRABEAM Needle Applicator</th>
<th>ZEISS INTRABEAM Flat Applicator Set</th>
<th>ZEISS INTRABEAM Surface Applicator Set</th>
</tr>
</thead>
<tbody>
<tr>
<td>Available sizes</td>
<td>15 mm, 20 mm, 25 mm, 30 mm, 35 mm, 40 mm, 45 mm, 50 mm diameter</td>
<td>4.4 mm diameter</td>
<td>10 mm, 20 mm, 30 mm, 40 mm, 50 mm, 60 mm diameter</td>
<td>10 mm, 20 mm, 30 mm, 40 mm diameter</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Components of a set</th>
<th>ZEISS INTRABEAM Spherical Applicator</th>
<th>ZEISS INTRABEAM Needle Applicator</th>
<th>ZEISS INTRABEAM Flat Applicator Set</th>
<th>ZEISS INTRABEAM Surface Applicator Set</th>
</tr>
</thead>
<tbody>
<tr>
<td>Usage</td>
<td>Reusable</td>
<td>Single use</td>
<td>Reusable</td>
<td>Reusable</td>
</tr>
<tr>
<td>Anatomical Sites (but not restricted to)</td>
<td>Any part of the human body (not intended for use on the heart or in the central circulatory system)</td>
<td>Any part of the human body (not intended for use on the heart or in the central circulatory system)</td>
<td>Any part of the human body (not intended for use on the heart or in the central circulatory system)</td>
<td>Skin</td>
</tr>
<tr>
<td>Geometry of dose distribution</td>
<td>Spherical dose distribution</td>
<td>Spherical dose distribution</td>
<td>Flat dose distribution, optimized for tissue radiation in 5 mm distance from the applicator surface</td>
<td>Flat dose distribution, optimized for tissue radiation directly in contact with the surface</td>
</tr>
<tr>
<td>Fixation to the region of interest</td>
<td>Guide shafts can be used for deep approach routes</td>
<td>Fixation via ZEISS INTRABEAM Position marker (can be sewed or glued to the region of interest) possible</td>
<td>Fixation via ZEISS INTRABEAM Position marker (can be sewed or glued to the region of interest) possible</td>
<td></td>
</tr>
<tr>
<td>Length [mm]</td>
<td>ø 15 mm: 167.5 mm (6.59&quot;) ø 20 mm: 170.0 mm (6.69&quot;) ø 25 mm: 172.5 mm (6.79&quot;) ø 30 mm: 175.0 mm (6.89&quot;) ø 35 mm: 177.5 mm (6.99&quot;) ø 40 mm: 180.0 mm (7.09&quot;) ø 45 mm: 182.5 mm (7.19&quot;) ø 50 mm: 185.0 mm (7.28&quot;)</td>
<td>94 mm (Probe length)</td>
<td>ø 10 mm: 169.05 mm (6.67&quot;) ø 20 mm: 174.05 mm (6.85&quot;) ø 30 mm: 178.05 mm (7.01&quot;) ø 40 mm: 181.55 mm (7.15&quot;) ø 50 mm: 184.35 mm (7.26&quot;) ø 60 mm: 185.55 mm (7.26&quot;)</td>
<td>ø 10 mm: 169.05 mm (6.67&quot;) ø 20 mm: 174.05 mm (6.85&quot;) ø 30 mm: 178.05 mm (7.01&quot;) ø 40 mm: 181.55 mm (7.15&quot;)</td>
</tr>
<tr>
<td>Inner diameter (absorption body)</td>
<td>N/A</td>
<td>N/A</td>
<td>ø 10 mm: 10 mm (0.39&quot;) ø 20 mm: 20 mm (0.79&quot;) ø 30 mm: 30 mm (1.18&quot;) ø 40 mm: 40 mm (1.57&quot;) ø 50 mm: 50 mm (1.97&quot;) ø 60 mm: 60 mm (2.36&quot;)</td>
<td>ø 10 mm: 10 mm (0.39&quot;) ø 20 mm: 20 mm (0.79&quot;) ø 30 mm: 30 mm (1.18&quot;) ø 40 mm: 40 mm (1.57&quot;)</td>
</tr>
<tr>
<td>Outer diameter</td>
<td>ø 15 mm: 15 mm (0.59&quot;) ø 20 mm: 20 mm (0.79&quot;) ø 25 mm: 25 mm (0.98&quot;) ø 30 mm: 30 mm (1.18&quot;) ø 35 mm: 35 mm (1.38&quot;) ø 40 mm: 40 mm (1.57&quot;) ø 45 mm: 45 mm (1.77&quot;) ø 50 mm: 50 mm (1.97&quot;)</td>
<td>ø 4.4 mm</td>
<td>ø 10 mm: 14 mm (0.55&quot;) ø 20 mm: 24 mm (0.94&quot;) ø 30 mm: 34 mm (1.34&quot;) ø 40 mm: 44 mm (1.73&quot;) ø 50 mm: 54 mm (2.13&quot;) ø 60 mm: 64 mm (2.52&quot;)</td>
<td>ø 10 mm: 14 mm (0.55&quot;) ø 20 mm: 24 mm (0.94&quot;) ø 30 mm: 34 mm (1.34&quot;) ø 40 mm: 44 mm (1.73&quot;)</td>
</tr>
<tr>
<td>Materials used for applicators and components</td>
<td>Stainless steel</td>
<td>Stainless steel</td>
<td>Stainless steel</td>
<td>Stainless steel</td>
</tr>
<tr>
<td></td>
<td>ULTEM (Polyetherimide)</td>
<td>ULTEM (Polyetherimide)</td>
<td>EPDM</td>
<td>ULTEM (Polyetherimide)</td>
</tr>
<tr>
<td></td>
<td>Polycarbonate</td>
<td></td>
<td></td>
<td>EPDM</td>
</tr>
</tbody>
</table>
11. Technical Requirements

11.1 Electrical requirements
Two electrical outlets are necessary in order to operate the ZEISS INTRABEAM System during treatment – one for the ZEISS NC32 INTRABEAM Floor Stand and one for all components on the ZEISS INTRABEAM Cart which are connected together with a medical insulating transformer.

<table>
<thead>
<tr>
<th>ZEISS NC32 INTRABEAM Floor Stand</th>
<th>ZEISS INTRABEAM Cart (Medical Insulating Transformer)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rated voltage</td>
<td>100 V / 115 V / 230 V</td>
</tr>
<tr>
<td>Rated frequency</td>
<td>50 - 60 Hz</td>
</tr>
<tr>
<td>Power consumption</td>
<td>max. 400 VA</td>
</tr>
<tr>
<td>Electrical standard</td>
<td>IEC 60601-1; CAN/CSA-C22.2 No. 601.1-M90</td>
</tr>
<tr>
<td></td>
<td>IEC 60601-1 / UL 60601-1; CAN/CSA-C22.2 No. 601.1-M90</td>
</tr>
<tr>
<td>Product classification</td>
<td>Type B</td>
</tr>
<tr>
<td>Case protection</td>
<td>IP20</td>
</tr>
<tr>
<td>Protection class</td>
<td>Protection class I</td>
</tr>
</tbody>
</table>

11.2 Ambient requirements*

Operation:

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

Transportation and Storage:

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

* Valid for the core system, requirements could differ for accessories. Please see separate the instruction for use.
### 12. Processing (Cleaning, Disinfection, Sterilization)

All non-sterile components of the INTRABEAM System from ZEISS can be easily cleaned and disinfected. Large casters and nearly no tight cleavings ensure simple and quick cleaning of the ZEISS INTRABEAM Cart. The ZEISS NC32 INTRABEAM Floor Stand can also be cleaned in a very short time.

<table>
<thead>
<tr>
<th>Component</th>
<th>Cleaning</th>
<th>Disinfection</th>
<th>Single Use/ Sterilizable</th>
</tr>
</thead>
<tbody>
<tr>
<td>ZEISS NC32 INTRABEAM Floor Stand</td>
<td>c</td>
<td>b</td>
<td></td>
</tr>
<tr>
<td>ZEISS INTRABEAM Cart</td>
<td>c</td>
<td>b</td>
<td></td>
</tr>
<tr>
<td>Control unit PRS 500</td>
<td>c</td>
<td>a</td>
<td></td>
</tr>
<tr>
<td>PRS 500 Terminal</td>
<td>c</td>
<td>b</td>
<td></td>
</tr>
<tr>
<td>Keyboard</td>
<td>c</td>
<td>a</td>
<td></td>
</tr>
<tr>
<td>X-ray Source (XRS 4)</td>
<td>c</td>
<td>a</td>
<td></td>
</tr>
<tr>
<td>Quality Tools (PDA/PAICH)</td>
<td>c</td>
<td>a</td>
<td></td>
</tr>
<tr>
<td>Cables (XRS/QA)</td>
<td>c</td>
<td>a</td>
<td></td>
</tr>
<tr>
<td>V-/X- Block</td>
<td>c</td>
<td>a</td>
<td></td>
</tr>
<tr>
<td>ZEISS INTRABEAM Water Phantom</td>
<td>d</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transportation Trays (XRS 4 / QA)</td>
<td>c</td>
<td>a</td>
<td></td>
</tr>
<tr>
<td>ZEISS INTRABEAM Spherical Applicator</td>
<td>See user manual</td>
<td>X</td>
<td>Sterilizable with steam</td>
</tr>
<tr>
<td>ZEISS INTRABEAM Needle Applicator</td>
<td>–</td>
<td>–</td>
<td>Single use - sterile</td>
</tr>
<tr>
<td>ZEISS INTRABEAM Flat Applicator</td>
<td>See user manual</td>
<td>X</td>
<td>Sterilizable with steam</td>
</tr>
<tr>
<td>ZEISS INTRABEAM Surface Applicator</td>
<td>See user manual</td>
<td>X</td>
<td>Sterilizable with steam</td>
</tr>
<tr>
<td>ADDCO X-Drape® D-110</td>
<td>–</td>
<td>–</td>
<td>Single use - sterile</td>
</tr>
<tr>
<td>ZEISS INTRABEAM Drapes</td>
<td>–</td>
<td>–</td>
<td>Single use - sterile</td>
</tr>
</tbody>
</table>

- 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 detailed instruction for use.
Cleaning, Disinfection and Sterilization of Applicators

The processing of the applicators was validated by 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 Flat and Surface Applicator:
- Use the provided Lumen Plug

Cleaning / Disinfecting agent:
- The disinfecting agent must be usable 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)

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 the user 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 ZEISS INTRABEAM Spherical Applicator 18 min (prion inactivation)

Please see the instruction for use for detailed information on cleaning, disinfection and sterilization of the applicators.
13. System Dimensions

**ZEISS NC32 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)

**Control unit PRS 500**

- **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

**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)
- **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

**ZEISS INTRABEAM Cart**

- **Unload weight of cart:** 105 kg / 231 lbs
  (incl. permanently mounted user terminal)
- **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)

**X-ray Source (XRS 4) with the ZEISS NC32 INTRABEAM Floor Stand**

1. Working position

2. Transport position