Site Planning Guide

Inveon
Multimodal CT + PET + SPECT

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Legal Notice

Site Planning Guide
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Important Information

Warnings and Cautions

Notice: This equipment is intended only for use on non-human research subjects and specimens. The equipment is not intended for clinical or diagnostic use.

Warning: To prevent damage to equipment and/or injury to subjects and personnel, installation of Inveon equipment can only be performed by Siemens authorized personnel.

Warning: To prevent damage to equipment and/or injury to subjects and personnel, only use replacement parts and supplies provided by and/or recommended by Siemens.

Warning: If this equipment is used in a manner not specified by Siemens or Siemens authorized suppliers, the protection provided by the equipment may be impaired and can cause damage to equipment and/or injury to subjects and personnel.

Warning: To prevent damage to equipment and/or injury to subjects, do not position the equipment so that it is difficult to operate the disconnecting devices. See the Room Planning Diagrams section for more information.

Dedicated PET Scanner Warnings and Labels

This device contains mechanical and electrical components that may be subject to wear or deterioration under normal system use. In order to ensure continued reliable performance and safe operation, the system must be inspected, and required maintenance performed, by qualified personnel at specified intervals. Maintenance of the systems is available from factory trained and equipped SMS service representatives. Contact SMS for further information. The various warnings and symbols of warnings to heed when using the equipment are shown below.
Laser Warning

The Inveon Dedicated PET scanner employs a Class 1 (< 0.4mW) laser for animal positioning. The laser is located on the front of the gantry to the left of the bore. Lasers should only be serviced by Siemens qualified personnel. Lasers can only be activated through the Inveon Acquisition Workplace software.

Caution: Do not stare into the laser beam. Use of laser controls or adjustments or performance or procedures other than those specified herein may result in hazardous radiation exposure.

High Voltage Warning

The Inveon Dedicated PET scanner employs line AC voltages ranging from 100 – 250 V and has a 220V internal AC power distribution network. Additionally, the detectors operate at voltages of approximately 1000 V. Internal high voltage points are identified with the label to the left.

Radiation Sources

The Inveon Dedicated PET scanner contains two sealed and collimated $^{57}$Co sources used for transmission studies. The sources are identified with the label to the left, which is affixed to the gantry. When operating the scanner, avoid unnecessary radiation exposure. Extend the source from its lead shielding only when necessary. Limit personnel in the area to those required to perform the scan or calibration procedure. Observe all radiation monitoring, safety and reporting requirements of your facility and regulating agency.
Other Product Labels

Manufacturer’s Label

The manufacturer’s label is affixed to the rear of the scanner, near the main power input. Please refer to the model number and serial number when requesting service.

Compliance Statement

Certification of compliance with FDA performance standards is declared in the label affixed to the rear of the scanner near the manufacturer’s label.

Main Power Label

The scanner power rating is specified near the main power inlet. The scanner is factory configured to accept local standard power.

CE Mark
Inveon Multimodality Scanner Warnings and Labels

This device contains mechanical and electrical components that may be subject to wear or deterioration under normal system use. In order to ensure continued reliable performance and safe operation, the system must be inspected, and required maintenance performed, by qualified personnel at specified intervals. Maintenance of the systems is available from factory trained and equipped SMS service representatives. Contact SMS for further information. The various warnings and symbols of warnings to heed when using the equipment are shown below.

Radiation Warning Labels

When configured with the microCT module, the Inveon Multimodality system is a cabinet x-ray system. In compliance with FDA directives (21 CFR 1020.40), warning labels are affixed to all controls capable of initiating x-ray production (Control Warning Labels) and to all user access ports (Access Port Warning Labels). The locations and appearance of these labels are defined below.

Radiation Warning Label Location (Sides)
(both sides of gantry, adjacent to control panel).
Radiation Warning Label Location (Front)
(gantry front)

Control Warning Label

Radiation Warning Label Location (Rear)
(gantry rear)

Access Port Warning Label

In addition, a control warning label is affixed to the workstation keyboard or monitor.
Laser (Class I) Warning Labels

The Inveon Multimodality system employs two Class 1 lasers for animal positioning. The lasers are located on the front of the gantry at the top and right of the bore. Lasers should only be serviced by Siemens qualified personnel. Lasers can only be activated through the Inveon Acquisition Workplace software.

Caution: Do not stare into the laser beam. Use of laser controls or adjustments or performance or procedures other than those specified herein may result in hazardous radiation exposure.

High Voltage Warning

The Inveon Multimodality system employs line AC voltages ranging from 100 – 250 V and has a 220V internal AC power distribution network. Additionally, the CT module x-ray source operates at voltages of up to 130 kV. Internal high voltage points are identified with the label to the left.

Other Product Labels

Manufacturer’s Label

A manufacturer’s label for the gantry (overall system) and for each modality module is affixed to the rear of the gantry near the main power inlet.

The gantry, or system, manufacturer’s label is identified with the words “System IVK”. Please refer to the model number and serial number when requesting service.
Compliance Statement

Each modality module is also identified with a manufacturer’s label. The label to the left indicates the scanner is configured with the Inveon microCT Module. Please refer to this model number and serial number when requesting service for a specific module.

Certification of compliance with FDA performance standards is declared in the label affixed to the rear of the scanner near the manufacturer’s label.

Main Power Label

The scanner power rating is specified near the main power inlet. The scanner is factory configured to accept local standard power.
Introduction

This guide is intended to provide a summary of the physical, electrical, and environmental requirements for the Inveon Preclinical PET, CT, and SPECT scanning system. Included is a suggested site layout to help in the early stages of planning a facility. This document should be used as a guide only as the physical layout for a system installation will vary from site to site due to limitations imposed by existing structures.

The site, its construction and preparation, and the items of which the site is constructed are not included with the system delivery. Any required structural studies must be made by the customer's architects and engineers.
Overview - Standard Components

The Inveon Multimodality and Dedicated PET gantries are shown below:

### Inveon Multimodality Module Components

- Touch Screen Control Panel
- X-ray ON lamp
- Gantry
- Door for animal placement
- Emergency Power Switch (ESTOP) (both sides of Bed Cover Shield)
- System Electronics

### Dedicated PET Module Components

- Touch Screen Control Panel
- ESTOP switch
- Gantry
- Detector Ring
- Bed Position Control (both sides of gantry)
- Animal Bed
- Main System Power Switch
- Gating Inputs
- System Electronics
### Inveon Dedicated PET

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unit weight</td>
<td>275 kg (605 lbs)</td>
</tr>
<tr>
<td>Unit height</td>
<td>150 cm (58.8 in.)</td>
</tr>
<tr>
<td>Unit width</td>
<td>82 cm (32 in.)</td>
</tr>
<tr>
<td>Unit depth</td>
<td>139 cm (54.5 in.)</td>
</tr>
<tr>
<td>Operating room temperature</td>
<td>45–80° F (7–27° C)</td>
</tr>
<tr>
<td>Operating humidity</td>
<td>30–70% non-condensing</td>
</tr>
<tr>
<td>Maximum heat generation</td>
<td>3500 Btu/hr</td>
</tr>
</tbody>
</table>
| Power requirements        | 9.5 A @ 110 VAC (USA) nominal  
|                           | [20A @ 110VAC (USA) dedicated circuit recommended] |
|                           | 5 A @ 220 VAC (USA) nominal  
|                           | [10A @ 220 VAC (outside USA) dedicated circuit recommended] |

Inveon Dedicated PET Module Dimensions
Inveon Multimodality System

**CT and/or CT + SPECT Scanners**

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unit weight</td>
<td>909 kg (2,004 lbs)</td>
</tr>
<tr>
<td>Unit height</td>
<td>191 cm (74.8 in.)</td>
</tr>
<tr>
<td>Unit width</td>
<td>173 cm (68 in.)</td>
</tr>
<tr>
<td>Unit depth</td>
<td>163 cm (64.3 in.)</td>
</tr>
<tr>
<td>Operating room temperature</td>
<td>45–75° F (7–24° C)</td>
</tr>
<tr>
<td>Operating humidity</td>
<td>30–70% non-condensing</td>
</tr>
<tr>
<td>Maximum heat generation</td>
<td>6500 Btu/hr</td>
</tr>
<tr>
<td>Power requirements</td>
<td>18 A @ 110 VAC (USA) dedicated circuit</td>
</tr>
<tr>
<td></td>
<td>9 A @ 220 V (outside USA) dedicated circuit</td>
</tr>
</tbody>
</table>

**Inveon Multimodality CT and/or CT + SPECT System Dimensions**

Note: Bed and bed housing are removed during installation. System will pass through a standard office door.
CT + PET + SPECT Scanners

Note: Bed and bed housing are removed during installation. System will pass through a standard office door.

Inveon Multimodality CT + SPECT + PET Dimensions

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unit weight</td>
<td>1018 kg (2,244 lbs)</td>
</tr>
<tr>
<td>Unit height</td>
<td>191 cm (74.8 in.)</td>
</tr>
<tr>
<td>Unit width</td>
<td>173 cm (68 in.)</td>
</tr>
<tr>
<td>Unit depth</td>
<td>186 cm (73 in.)</td>
</tr>
<tr>
<td>Operating room temperature</td>
<td>45–75°F (7–24°C)</td>
</tr>
<tr>
<td>Operating humidity</td>
<td>30–70% non-condensing</td>
</tr>
<tr>
<td>Maximum heat generation</td>
<td>6500 Btu/hr</td>
</tr>
<tr>
<td>Power requirements</td>
<td>18 A @ 110 VAC (USA) dedicated circuit</td>
</tr>
<tr>
<td></td>
<td>9 A @ 220 V (outside USA) dedicated circuit</td>
</tr>
</tbody>
</table>
Inveon Docked System

Inveon Docked System Dimensions
Room Planning Diagrams

Example Dedicated PET System Floor Plan
Example Multimodality System (without PET module) Floor Plan
Example Multimodality System (with PET module) Floor Plan
Example Docked System Floor Plan

Caution: The floor must be level to enable docking of the PET and Multimodality scanners.
Radiation Safety Information

Specifications for Radiation Producing Components in Inveon CT

The Inveon CT is a fully shielded cabinet x-ray system as defined by FDA Standard 21, CFR 1020.40.

Standard X-ray Source

Maximum Potential: 80 kVp
Maximum Current: 1.0 mA
Anode Material: tungsten
Focal Spot Size: <50 microns
Beam Filtration: 0.75 – 2 mm Aluminum
Duty Cycle Rating: 100%

Variable Focus X-ray Source

Maximum Potential: 130 kVp (software limited to 80 kVp)*
Maximum Current: 0.5 mA
Anode Material: Tungsten
Focal Spot Size: <10 microns
Beam Filtration: 0.25 – 2 mm Aluminum
Duty Cycle Rating: 100%

*Cabinet shielding is rated for 80 kVp. The maximum x-ray source voltage may be increased to 135 kVp subject to local regulatory approval.

Radioactive Sources in the Inveon Dedicated PET System

The Inveon PET scanner is equipped with two $^{57}$Co point sources used for attenuation correction. The point source covers the entire field of view and allows for determining the attenuation of each line-of-response for quantitative attenuation correction. During a transmission scan, the subject is positioned as for an emissions scan. The point sources are extended and rotate around the animal as data is acquired while the sources are outside of their shielded enclosures, the gantry control panels display the symbol seen in the figure below.

Symbol Displayed on Panels when Source Outside of Shielding
The source mechanism is designed to be failsafe. In the case of a loss of power, the system will automatically fully retract the sources to a safe position.

Radioactive Material (RAM) licenses must be received prior to shipment of sources. Sources must be received prior to installation. Customer can contact Sources Group in Knoxville to obtain a copy of the license amendment guideline.