Inline PET Module

Site Planning Information

This manual was written by

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P/N: (tbd) - Version 0.3

For further technical assistance for this product, please do not hesitate to contact your nearest BRUKER dealer or contact us directly.

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1 About this Manual

This manual provides support for the system owner when planning installation and meeting the installation requirements of a PET moduleby specifying planning data.

1.1 Intended Use

This manual is to be used by the system owner and planning offices that have been entrusted by the operator to plan installation and meet the installation requirements of an PET system.

The manual does not provide specific guidelines to the layout and radioactive protection calculation of laboratories using radioactive materials. Bruker cannot provide service for such detailed planning task of radioprotection and certification. It is strongly recommended the include local third party planning services with the expertise and all certifications to plan the set-up and certification of such laboratories. Bruker can assist you in finding suitable local planning services.

This manual doesn't intend to provide instructions for installation. A PET instrument may only be installed by Bruker BioSpin or by personnel authorized by Bruker BioSpin.

1.2 Additional Documents

This manual extends the Site Planning Information of the Bruker MRI imaging instruments of the BioSpec series for the sole purpose of adding site planning requirements and information that relate to adding a PET Inline module to the MRI imaging instrument.

This manual describes the site planning requirements and contains information for the site planning of the PET Inline module. Please refer to the site planning information of the main MRI imaging instruments for any requirements on site planning and safety relevant aspects of the main MRI instrument.

1.3 Responsibilities

The responsibility for planning installation and for correctly implementing the installation requirements lies with the MR system owner, also if the system owner has outsourced planning services to external provider. Unless otherwise stipulated in the individual case by the contract of sale, Bruker can only provide information to the system owner.

The transfer of risk is established in the general business terms and /or in the "Terms and Conditions" of the respective contract of sale and must accordingly be taken into account when the MR system owner plans the installation. If there is a delay of receipt on the part of the MR system owner after readiness for shipment has been sent to Bruker BioSpin MRI, the MRI system owner may be charged for the resulting additional costs. The regulations on a delay of receipt are established in the General Business Terms and the "Terms and Conditions" of the respective contract of sale.

1.4 Validity

The current manual represents the technical status of the installation requirements at the time of publication. Technical modifications that are established in the general business conditions and in the “Terms and Conditions” of the contract of sale may require modifications in the installation requirements. Any instrument configurations shown in this manual are typical examples. However, the final configuration of the ordered instrument is solely defined by the corresponding contract.

1.5 Symbols and Conventions

Safety instructions in this manual and labels of devices are marked with symbols. The safety instructions are introduced using indicative words which express the extent of the hazard. In order to avoid accidents, personal injury or damage to property, always observe safety instructions and proceed with care.

General Hazard

Sign indicating a general hazard.

Read the manual for safety instructions or action guidelines.
Noncompliance with the information provided in the manual may result in hazards or incorrect operation.

Hazardous Electrical Voltage

Sign indicating hazardous electrical voltage.

Noncompliance with the safety instructions provided in the manual may result in serious hazards.

Radioactive Material or Ionizing Radiation

Sign indicating radioactive material or ionizing radiation.

Noncompliance with the safety instructions provided in the manual may result in serious hazards.

⚠ DANGER

DANGER indicates a hazardous situation, which, if not avoided, will result in death or serious injury.

This is the consequence of not following the warning.

1. This is the safety condition.

▶ This is the safety instruction.

⚠ WARNING

WARNING indicates a hazardous situation, which, if not avoided, could result in death or serious injury.

This is the consequence of not following the warning.

1. This is the safety condition.

▶ This is the safety instruction.

⚠ CAUTION

CAUTION indicates a hazardous situation, which, if not avoided, may result in minor or moderate injury or severe material or property damage.

This is the consequence of not following the warning.

1. This is the safety condition.

▶ This is the safety instruction.

NOTICE

NOTICE indicates a property damage message.

This is the consequence of not following the notice.

1. This is a safety condition.

▶ This is a safety instruction.

SAFETY INSTRUCTIONS

SAFETY INSTRUCTIONS are used for control flow and shutdowns in the event of an error or emergency.

This is the consequence of not following the safety instructions.

1. This is a safety condition.

▶ This is a safety instruction.

This symbol highlights useful tips and recommendations as well as information designed to ensure efficient and smooth operation.

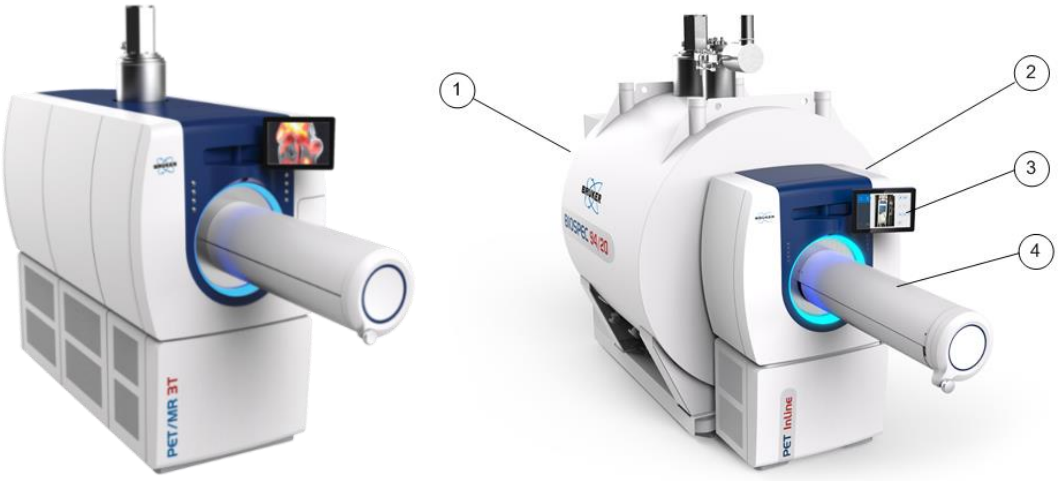
2 Overview: Inline PET Module

The PET Inline Module for MRI imaging instruments consists of the following functional components:

- **PET Detector and Electronics** , mounted in front of the main MRI imaging system
- **Animal Transport System** and **TouchScreen**
- **PET Server** for data storage and Image reconstruction
- **PET/MR Workplace** to control the PET and MR data acquisition

These components are located at different sites within the laboratory.

- **the magnet room:** PET Detector (1) and PET Electronics (2)
- **the operator area:** PET Server & Workplace



(1) MRI imaging system (here: BioSpec 94/20 USR)
(2) PET Inline Module, incl. PET Detector and PET Electronics
(3) Touch Screen (HMI)
(4) Animal Transport System (ATS)

3 Safety

The following chapter provides safety information that is relevant for the site preparation for installation and the installation of the PET module itself. It is assumed that the PET module is installed in combination with an MRI instrument and that all safety instructions for the site preparation of the MRI instruments are known to the system owner.

During the site preparation and during the actual installation of the PET module, people, buildings, and equipment can in principle be put at risk. The following safety measures must therefore be heeded by the MR system owner.

- General Safety aspects with respect to high voltages and handling of heavy loads
- Safety aspects relating to strong magnetic fields
- Safety aspects from radioactive materials

3.1 General safety aspects

Installation, initial commissioning, retrofitting, repairs, adjustments or dismantling of the device must only be carried out by Bruker Service or personnel authorized by Bruker. Damage due to servicing that is not authorized by Bruker is not covered by your warranty.

WARNING

⚠ WARNING

Danger of injury from electrical shock.

A life threatening shock may result when the service access housing is opened and work performed while connected to the line power.

Only electrically qualified personnel should open the housing and carry out work.

- ▶ Disconnect from line power.
- ▶ Prevent reconnection.
- ▶ Test for absence of harmful voltages.

⚠ CAUTION

Heavy load.

Unpacking and installation of the PET module and the Animal Transport System requires handling of loads of 150 kg and more.

- ▶ Ensure compliance with worker protection regulatory limits

▶ Potentially, hire professional staff trained in handling heavy loads.

3.2 Safety aspects relating to strong magnetic fields

The Site Planning Information of the main MRI instruments provides all safety warnings arising from working in strong magnetic fields. Please be familiar with the required safety measures and make sure that only trained and qualified personnel get access to the PET and MRI instruments.

⚠ DANGER

Danger of severe injury by magnetic field effects.

Magnetic field bear various risks that can lead to severe injury and death.

- ▶ Read carefully all safety instructions of the main MRI instrument
- ▶ Follow strictly all safety instructions given in the safety section of the main MRI instrument
- ▶ Always be aware about strong magnetic fields when entering the controlled access zone of the MRI instrument

The PET module and the PET electronics is designed to be compatible with strong magnetic fields. Do not replace any parts of the PET system by non-compliant spare parts.

⚠ DANGER

Danger of severe injury by magnetic field effects.

Non-compliant replacement of parts of the PET Module could be magnetic and therefore processes a possible risk of severe injury or death by effects of the magnetic field.

- ▶ Do replace parts only by original spare parts
- ▶ Do not modify any parts of the PET instrument
- ▶ Do not use any magnetic tools for the installation of the PET module inside the scanner room

3.3 Safety aspects relating to the use of radioactive material

By definition, the operation of the PET module requires the use of radioactive tracers. The usage of such materials is normally strictly regulated by the local occupational standards and permissions and under the responsibility of the system owner and/or the local radiation officer.

The tune-up and the acceptance tests that are performed during the installation of the PET module requires the use of radioactive tracers. It is essential that the laboratory holds the required rights for the use of radioactive tracers before the start of the installation.

Please refer to chapter 8.2 for detailed information about the need of radioactive tracers during installation and acceptance.

⚠ WARNING

Health hazard by ionizing radiation.

Radioactive sources are to be used for the operation of the PET module. Compliance with occupational safety and health regulations are in the responsibility of the System Owner (responsible body).

- ▶ Care for regulatory clearance prior to the installation of the instrument.
- ▶ Ensure compliance with regulatory
- ▶ Make sure that the correct warning signs are clearly visible at all entrances to the regulated areas.

The standard for the protection of laboratory staff against radiation exposure are commonly stated “As Low as Reasonably Achievable (ALARA) . ALARA can be achieved in part by considering concepts of time (decay), distance, probability of exposure and shielding. In order to implement these principles in laboratory workflow, it is essential to include all steps of handling radioactive tracer material, starting from the delivery of radioactive materials, its transport pathways and usage up to the final disposal of radioactive waste, materials and tools as well as the probability of persons being exposed to radiation.

It is strongly recommended the include local third party planning services with the expertise and all certifications to plan the set-up and certification of laboratories using radioactive materials. Bruker can assist in identifying suitable local radiation planning partners.

3.4 Emergency plan

PET specific emergency procedures for the case of different emergency situations need to be established, documented and trained in form of an emergency plan. It is the responsibility of the system owner to establish such emergency procedures and documents. Typical emergency situation are listed below, but the list is not meant to be complete:

- Event of Fire, i.e. training of personnel and the local fire brigade
- Contamination with radioactive materials, i.e. training of medicare staff
- Spilling of radioactive fluids, i.e. safety protection for cleaning

3.5 Biological safety

In relation to the health and safety of employees and laboratory animals, we refer to compliance with national specifications and regulations. Repairs by Bruker BioSpin MRI can only be carried out after decontamination of equipment has been demonstrated in writing and any damage to the health of Bruker employees has been ruled out. Appropriate aids, access and procedures that rule out any damage to the health of service personnel must therefore be provided for maintenance, service, and repair of the PET system.

- Measures and aids for cleaning and decontaminating hardware and accessories.
- If there a hazard category exists: Planning a physical separation between various hazard areas for different parts of the MR system, e.g. technical room and its access in a non-hazardous area.

4 Standards and Certifications

4.1 Standards

The PET systems meet the standards listed below in relation to electrical safety and electromagnetic compatibility:

Safety

- EN 61010-1:2010
- IEC 61010-1: 3rd edition

EMC:

- EN 61326-1:2013
- IEC 61326-1: 2nd edition

4.2 Environmental Conditions

The following environmental conditions must be guaranteed to maintain electrical safety at the installation site.

To achieve the full performance of the PET system, the requirements for the **enhanced environmental conditions** for the operation of the PET module must be met. Please also refer to the enhanced environmental conditions that are required for the operation of the MRI imaging system.

General conditions:

- Use in indoors, only
- Altitude up to 2000 m above sea level.
- Temperature range 5°C to 40°C
- Highest relative humidity 80% for temperatures up to 31°C, declining thereafter linearly to 50% relative humidity at 40°C
- Overvoltage Category II
- Pollution degree 2

Electrical network specifications

- Double insulation
- IP classification 32
- Power supply fluctuations no greater than +/- 10%
- Transient over-voltages as they normally occur in the main power supply

5 Laboratory Infrastructure and Interactions

The following chapters describe the planning factors, which concern the operational procedure and possible interactions between the PET system and its surroundings.

5.1 Operational Procedures

In addition to the regulatory clearance of the laboratory for PET investigations, it is recommended already for the planning phase to consider the workflow and to establish operational procedures for the daily work in the lab. Important factors affecting the layout of the laboratory are:

- Avoid long routes between tracer preparation, animal preparation, and imaging instrument
- Consider cleaning and disinfection areas
- Access and procedures for service and maintenance

5.2 Interactions

Today, no interactions between the environment at the installation site and the quality of PET imaging is known. No functional specifications are required with respect to environmental conditions like floor vibration, electromagnetic or magnetic interactions, or others.

In general, the environmental factors to avoid interference between the imaging instrument and its surrounding are much more demanding for the MRI instrument.

6 Site Preparation Requirements

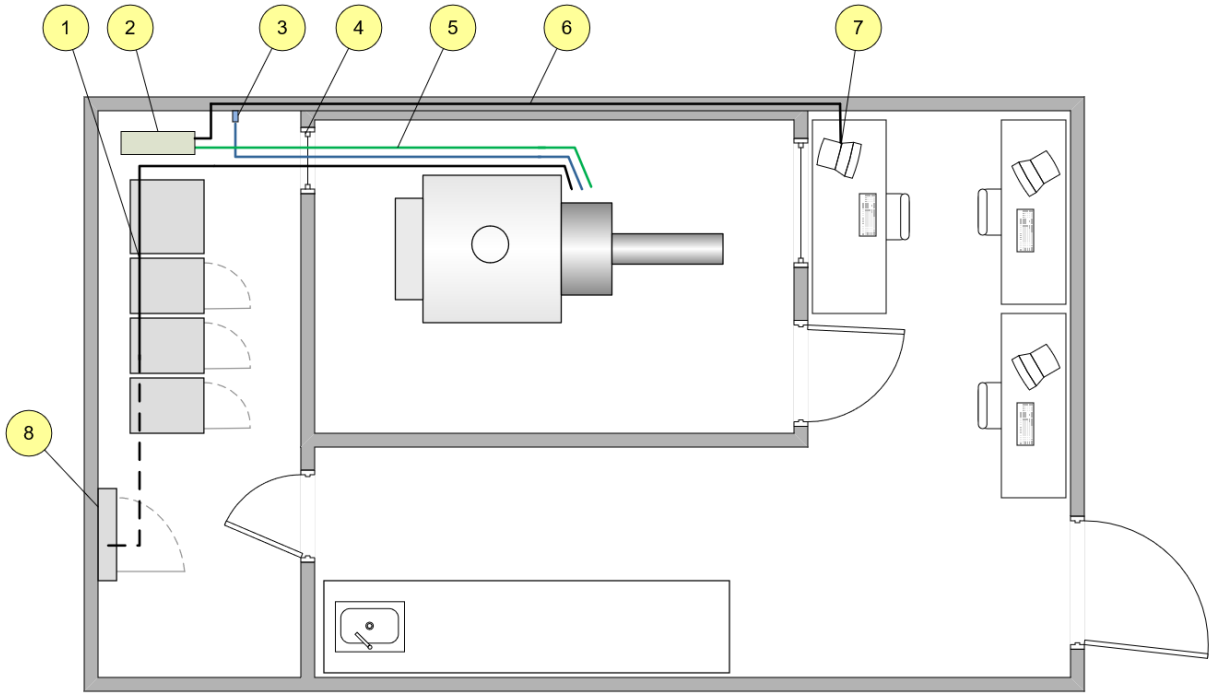
6.1 Installation Overview

Planning of the installation of the PET module comprises the following subject areas:

- Defining the general laboratory structure for optimized workflows and adequate operational procedures

- Realization of the required Infrastructure for the installation and operation of the PET module:
  - Extension of the existing MRI filter plate to host feedthroughs for the PET Module
  - Installation of ultra-fast Ethernet lines between PET Electronics and PET Reconstruction Server
  - Provision of compressed air
  - Installation of electrical power for the PET workplace
  - Realization of enhanced environmental conditions

In order to optimally prepare the site before the installation starts, the filter plate and compressed air connectors (if ordered from Bruker) can be sent upfront prior to the installation. Please contact your local Bruker office for obtaining the components upfront.



1 Power Supply from MIN MRI cabinet (MR Classic) – LPD (MR3)
2 PET reconstruction server
3 Compressed air supply
4 MRI filter plate

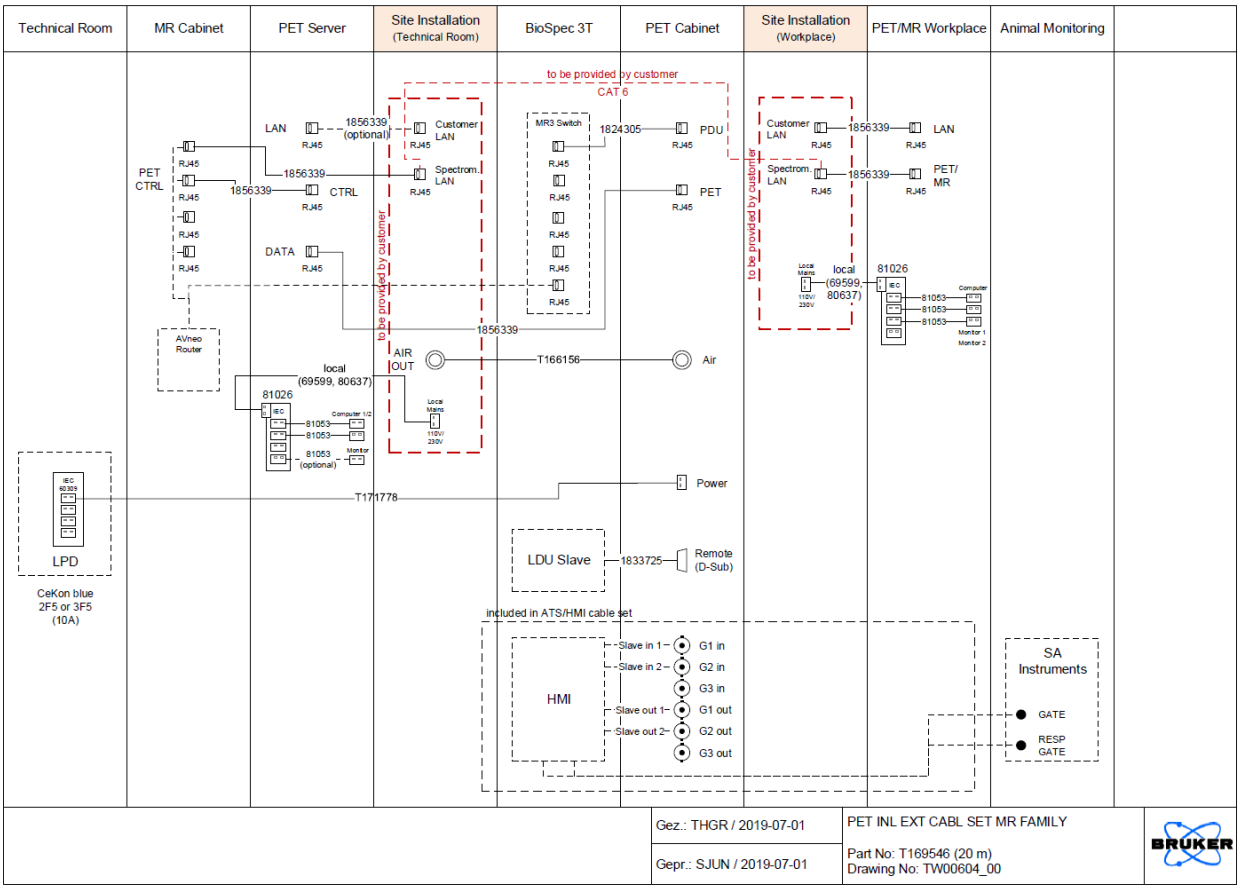
5	Ultra-fast Ethernet line to PET reconstruction server
6	LAN connection to MR workplace
5	PET/MR workplace and PET Reconstruction Server
7	MR/PET workplace
8	Line Power Distributor (LPD)

6.2 Interconnection Overview

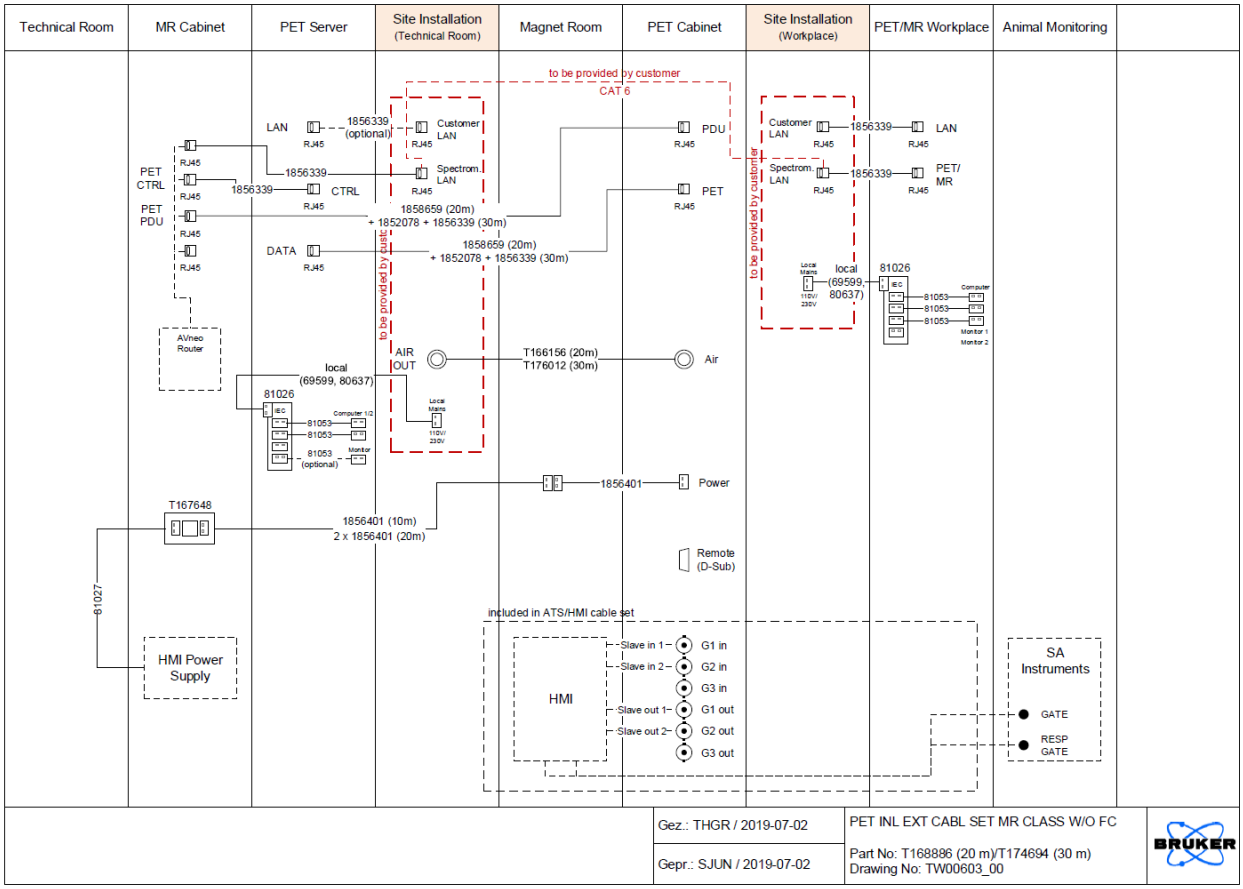
The figures provides the overview of the external wiring and interfacing with the BioSpec MRI instrument. Please note the indicated site installations that need to be installed during site preparation prior to installation: (i) a ultra-fast Ethernet line, (ii) mains in the operator room and (iii) compressed air outlet. Please refer to the specific requirements on these installations in the subsequent chapters.

Since the interconnections depend on the MRI instrument type and installation type (w/wo Faraday cage) several external wiring schemes are provided for the different combinations of the PET module with MRI instruments.

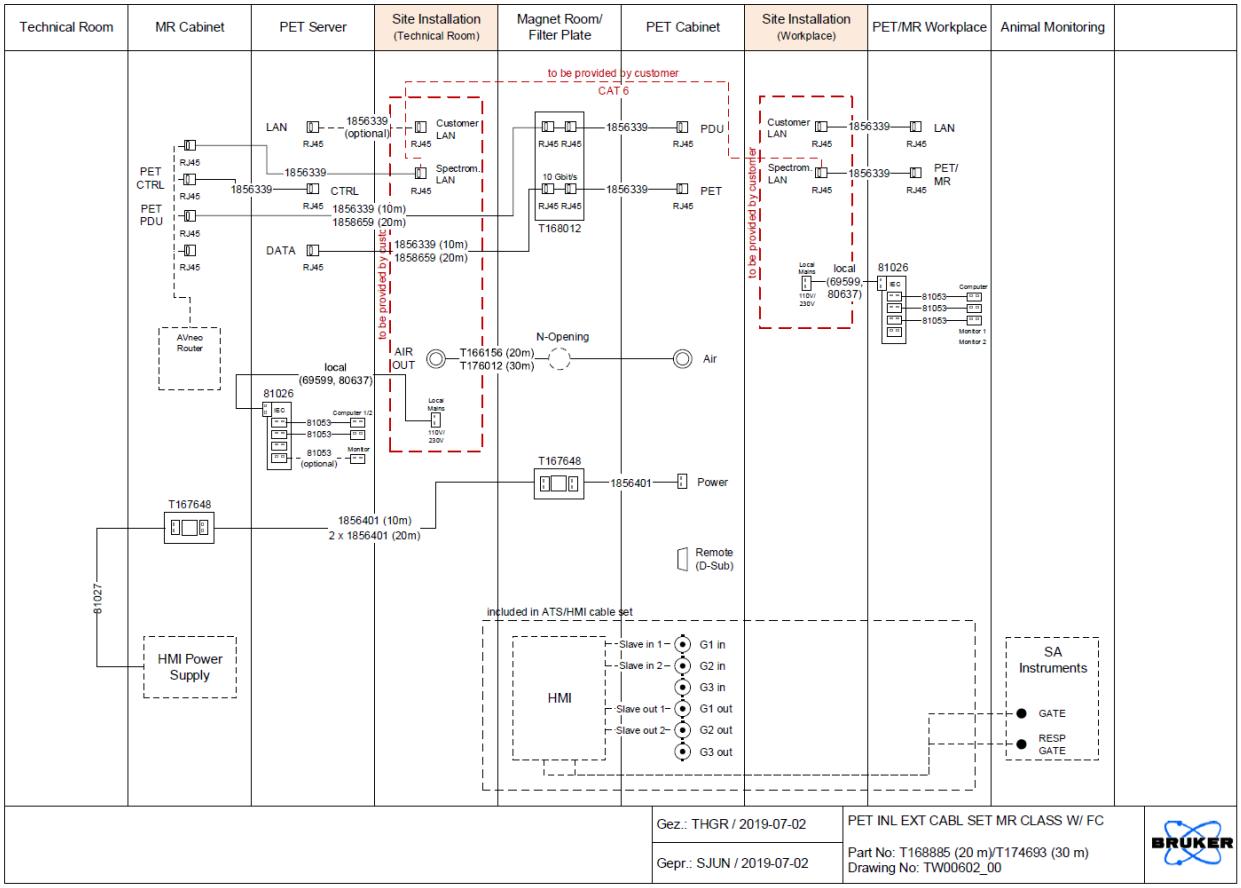
Interconnection for the PET/MR 3T



Interconnections for HF MRI without Faraday cage

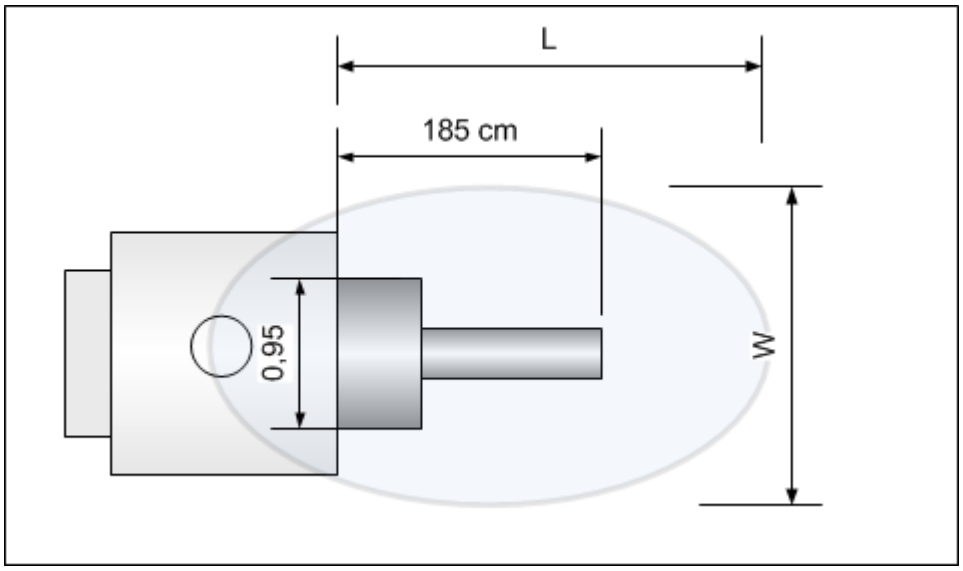


Interconnections for HF MRI with Faraday cage



6.3 Space Requirements

The installation and operation of a PET modules requires additional space in the magnet room.



	Specification
Minimum Distance in front of the magnet	L ≥ 250 cm
Minimum Distance for user access	W ≥ 180 cm

6.4 Enhanced Environmental Requirements

The PET module is safe for the operator under the environmental conditions as given in chapter 4.1. In order to achieve the full performance specifications of the PET module, the following enhanced environmental conditions need to be fulfilled and provided by a suitable air conditioning system.

To achieve the full performance of the PET system, the requirements for the **enhanced environmental conditions** for the operation of the PET module must be met.

	Specification
Room Temperature Range	22 +/- 3°C

Max. Room Temperature drift	< 2°C / hour
Humidity	40 - 80 %

6.5 Faraday Cage Requirements

The following additional filter elements and feedthroughs for the PET module need to be installed on existing openings (covered by blind plates) of the existing BioSpec MRI filter plate:

- Ethernet filter, to be installed instead of a 80 x 40 mm blind plate
- Power filter, to be installed instead of a 80 x 40 mm blind plate
- Trigger feedthroughs, to be installed instead of a 100 x 100 mm blind plate
- Compressed air will be feed through an existing opening of an unused N connector

During the site planning and site preparation, the availability of such non-used blide plates need to be verified. Please contact your local Bruker office in case that no such blind plates and openings are available.

6.6 Compressed Air Requirements

A connection point for compressed air needs to be provided in close proximity to the filter plate. The air quality must fulfill category II of ISO 8573-1 [1:4:2].

	Specification
Air quality	dry air, dew point max. 6°C [4]
Oil filter	< 0.1 mg/m^3 [2]
Particle filter	< 20000 particle/m^3 with 0.1 - 0.5 µm diameter [1]
Flow and Pressure	250 l/min @ 4 bar
Connection	Pipe thread G1/2” according to ISO 228-1
Tube to filter plate	Bruker provides a 6 m tube with min. 20c m bending radius

Connector for compressed air
Type: FESTO KD4-1/2-A (2145) - Bruker SAP PN: 1813228

NOTICE
Risk of deteriorate performance or possibly wrong measurement results. A failure of the compressed air system during operation of the PET Module will deteriorate the performance and might lead to wrong results. It does not but do not bear the risk of a damage of the PET Module ▶ consider to install a compressed air supervising unit.

6.7 Data Line Requirement

At least one Ethernet line needs to be installed between the technical and operator room. Optional an LAN connection to the www of the reconstruction server is recommended for service purposes.

	Specification
Ethernet Category (LAN)	CAT6 S/FTP TIA/EIA-568-A (ISO 11801)
Ethernet Category (PET CTRL)	CAT6 S/FTP TIA/EIA-568-A (ISO 11801)
Receptacle	RJ-45 CAT 6
Max distance to filter plate	10 m
Max distance to PET server	10 m (optional 20m)

6.8 PET Workplace Requirements

The PET workplace comprises the PET/MR workplace computer and a dedicated PET reconstruction server. The PET reconstruction are installed in the technical room and require:

- A minimum of two line power sockets using local power connectors plugs
- 2x CAT 6 Ethernet connection to the www and the PET/MR workplace

IEC Socket	Specification	Ethernet Connection
PET/MR workplace computer	1x 110/230V 50/60Hz 1~PN	YES
PET Reconstruction Server	2x 110/230V 50/60Hz 1~PN	YES
Monitor	2x 110/230V 50/60Hz 1~PN	NO
Spare Socket	1x 110/230V 50/60Hz 1~PN	NO

6.9 Electrical Power Backup and UPS

The risk of loss of data during power outages can be minimized by the use of uninterruptible power supply systems (UPS). Bruker does not provide such UPS systems upon delivery. If required, Bruker can assist you in identifying suitable UPS systems to cover the electrical power of the PET Reconstruction Server and the PET/MR workplace during power outages.

Suitable devices are double conversion units with a rating of 1.6 kVA.

7 Technical Data

Physical Specifications

	Length	Height	Width	Weight
PET Module	40 cm	115 cm	95 cm	190 kg

Electrical Power Consumption PET Module

	Specifications
Voltage	110V/230V, 50/60 Hz 1~PN
Protection	6 Ampere /B
Power Consumption	450 Watt

Heat Dissipation

	Specifications
Into Air (Magnet Room)	~ 500 Watt
Into Air (Operator Console)	~ 250 - 800 Watt

Electrical Power Consumption PET Reconstruction Server – technical room

	Specifications
Voltage	110V/230V, 50/60 Hz 1~PN
Protection	10 Ampere /B
Peak power consumption	800 Watt
Idle power consumption	250 Watt

8 Delivery and Installation Requirements

8.1 Delivery and Storage

The PET Module is shipped in a single crate (Bruker SAP PN 182 8683, 1450 x 1450x 1390 mm) weighing approximately 100 kg. The crate includes the PET electronics, the PET module, the PET reconstruction server and all accessories. In certain configurations, additional components may be shipped in a smaller second crate.
Upon arrival, all packages of the PET Module need to be

- Checked visually for obvious damages that need to be immediately reported to Bruker
- stored in a locked and safe room that fulfils the environmental conditions mentioned in chapter 4.2

Do not unpack the instrument. Uncrating of the system without the permission or supervision of Bruker personnel will void the warranty

Keep the original crates and packing materials, at least as long as the warranty is valid. When the packaging material is no longer needed, dispose of in accordance with the relevant local guidelines and regulations.

8.2 Use of Radioactive Tracers for the Installation

It is the responsibility of the system owner (responsible body) to register the PET with their state, local or country specific Radiation Safety Agency. This should be coordinated with the Radiation Safety Officer (RSO) at your facility. Clearance is prerequisite for the PET installation.

For the tune up of the PET module during installation, sealed radioactive sources (so called “phantoms”) are required. These phantoms are ordered by Bruker and need to be delivered directly to the customer site. Prerequisite for the process is that the customer provides all locally required permission to handle sealed and open radioactive sources in a hot laboratory environment. The clearance document needs to be sent to Bruker and to the local supplier of the sealed radioactive phantoms at least 2 months prior to delivery of the PET Module.

The provision of the release documents is under the responsibility of the customer.
Without having the documents provided in time to Bruker and E&Z, the installation cannot include any on-site test tune-up and verification tests.
In this case, the PET Module will be installed without any such verification tests and the customer needs to accept the installation under these conditions.

Bruker uses the company Ecker and Ziegler and its worldwide offices to purchase the required phantoms.

Bruker PN	E&Z PN	Description
1827065	RFQ1379-068-2	Ge-68 normalization phantom, Activity 7.4 MBq
1849304	MMS09-022-10U	Na-22 NEMA NU 4 Point Source, Activity 370 kBq

Please see www.ezag.com for the contact information of your nearby E&Z office.

The phantom ordering process must be started shortly after the time of the PET purchase. Although the radioactive sources are standard items, the lead time is typically 8 weeks. Depending on the country, customs, importation, and coordination with local agencies can add additional lead time to the delivery. **An import license is required. Consult your Radiation Safety Officer (RSO) or equivalent consultant for assistance**.

For the execution of the verification tests of the acceptance procedure of the PET module, daily access to FDG is required at various activities and quantities. It is assumed that the customer can provide FDG in time and in the required quantities.

A local supplier of the FDG must be defined and delivery of the required quantities and activities needs to be confirmed by the customer.

The following quantities are required in a typical installation, but might differ in certain cases depending on the individual progress of the installation and acceptance.

Date	Time	FDG Activity and Volume
Day 1	9:00 am	No FDG required, all tests using the point sources
Day 1	5:00 pm	50 MBq, / 1ml
Day 2	9:00 am	3.7 MBq, / 1ml
Day 2	1:00 pm	3.7 MBq, / 1ml
Day 3	9:00 am	3.7 MBq / 1 ml
Day 3	1:00 pm	3.7 MBq / 1 ml

8.3 Required Mounting Tools

For the assembly of the PET Module and the ATS during installation, the following tools need to be provided by the customer during the installation phase.

- fork lift for in-house transport of the crates
- small crane or pneumatic fork-lift for mounting the ATS

8.4 Required Laboratory Equipment

For the calibration process and for performing the verification tests of the acceptance procedure, Bruker requires a functional PET tracer laboratory with the following minimum set of equipment:

- Calibrated Dose Calibrator in close proximity of the PET Module installation site
- Hazardous disposal containers and general disposal containers
- Laboratory Safety Equipment for Bruker Staff
    - Nitrile gloves
    - Lab coats
    - Safety glasses
- Syringes
- 15 ml Falcon tubes
- Cleaning wipes

9 Contact

Manufacturer:

Bruker BioSpin MRI GmbH
Rudolf-Plank-Strasse 23
D-76275 Ettlingen, Germany
phone: ++49 (0)721-5161-6531

Service Hotline:

phone: ++49 (0)721-5161-6521
email: mri-hardware-support@bruker.com

For all other questions: visit the homepage www.bruker.com or at

10 Appendix 1: Pre-Installation Checklist

The time between purchase and delivery of the instrument must be used to fulfill the requirements for the installation. A close cooperation between the responsible person at the site and Bruker is mandatory. The pre-installation checklist below needs to be completed prior to scheduling the installation.

Please e-mail a scanned copy to mri-hardware-support@bruker.com

Customer Information	
Institution	
System Owner Name	
Responsible Person for Site Planning	
Phone	
Email	
Delivery Address	
Installation Requirements	**Completed**
License to handle radioactive material provided to Bruker	
License to handle radioactive material provided to E&Z	
Local Provider for FDG nominated	
Compressed Air installed and available	
High-speed Ethernet line between scanner room and PET workplace installed	
Power socket for the PET Workplace	
Ethernet connections for the PET workplace	
Access route to installation room free	
Sufficient space to unpack the PET module	
Laboratory Equipment	**Available**
Calibrated Dose Calibrator	

Availability of FDG during verification tests	
Safety and Protection clothes for personal	
Facility access at extended working hours for Bruker personnel	

As the person named responsible for the installation planning by the customer, I hereby confirm the details given beforehand:

Place / Date _____

Name (in block letters) _____

Signature _____