



FIELD MONITORING SYSTEM INSTALLATION GUIDE

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1. IMPORTANT NOTES – READ BEFORE USE

Please read these notes as well as the entire manual in order to prevent harm to users and subjects as well as damage to the MR system, the Acquisition System, and connected RF front ends such as camera heads.

The use in conjunction with high power RF pulses is only allowed with RF front ends that are explicitly denoted to operate with external high-power RF pulses, and only at the specified frequency.

This Acquisition System, its front ends and the resulting data must not be used for clinically relevant decisions.

DISCLAIMER

This is an investigational device.

This product contains software libraries under the MIT license:

LUFA Library. Copyright (C) Dean Camera, 2013.

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www.lufa-lib.org

Only trained users shall install the Acquisition System and the corresponding front end (such as a camera head), use, and handle it. The device is connected to and used with the MR system at the user's own risk and liability for the MR system, its surrounding installations, as well as people, volunteers, and patients involved.

Skope Magnetic Resonance Technologies asks the user of the system to take explicit notice of the risks involved with this system present in the MR system during high power RF pulses. The installation and usage of the Acquisition System and its front ends (such as camera heads) requires experts trained in the art of RF engineering and safety, establishing state of the art safe operation for the MR scanner, the field camera and – if involved – the subject.

Skope Magnetic Resonance Technologies does not take any responsibility or liability for damages, harm, loss of data or similar incidents that are in direct or indirect relation to the usage or presence of any of its devices.

In accordance to investigational device usage practice, clinical evaluation of this device requires:

- ▶ *An Investigational Device Exemption (IDE) approved by an institutional review board. If the study involves a device posing significant risk, the IDE must also be approved by FDA;*
- ▶ *Informed consent from all volunteers and patients;*
- ▶ *Labeling 'for investigational use only';*
- ▶ *Monitoring of the study and;*
- ▶ *Required records and reports.*

The content of this document can change without notice.

READ PRECAUTIONS THOROUGHLY BEFORE USE



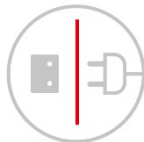
Avoid High Power RF Transmission Pulses

The unit or any of its components must not be exposed to any high power RF transmission pulses, if the RF front end is not otherwise specified.



Do not use during standard MRI Exams

The device or any parts of the device must not be used, remain close or be connected to the scanner during MRI exams on humans or living animals, if no dedicated field monitoring examination is being performed.



Disconnect when not in use

The device should not be powered and should not be connected to the MR system, while not being directly supervised by a trained expert.

Always disconnect the trigger and sync lines and power down the device when leaving the scanner area or when the measurements are paused or finished. Do not leave any connection to the scanner during investigations that do not involve field monitoring.



Avoid improper Connections

Make sure to establish all connections correctly. Wrong connections can harm the device irreversibly.



Temperature Range

The device must be stored within the temperature range of +16°C to +26°C. Transport of the device must be at temperatures in the range of +13°C to +33°C.



Handle with Care

Protect the device against strong mechanical forces, torques, shocks and vibrations. Do handle the connectors and especially the field probe cable with care, avoiding excessive mechanical forces, bending and torques being applied to any part during manipulation, measurement and storage.



ESD Protection

Protect the device from electrostatic discharges (ESD protection). Do not touch any conductive surfaces while not being grounded.



Never leave Ports open

Never leave one or several of the ports open (e.g., SMA connectors on the Clip-on Camera head). Improper termination or other sources of RF reflections will harm the power amplifier. Stop the measurement if a field probe is not operating properly or shows unusually low signal. If a field probe shows a strong RF mismatch or wrong tuning it can be temporarily replaced by a (non-magnetic) 50 Ohm termination.

Do not connect other devices such as NMR coils or similar to the outputs of the Clip-on Camera head connection box.

Do not operate the system when damaged, especially in the case of (partially) ruptured cables and loosened connectors.



Do not cover Cooling Slots

Do not block any of the venting slots, nor reduce the airflow by objects in close vicinity. Overheating of the electronics may degrade its performance and reduce its lifetime.



Keep Acquisition System away from strong Magnetic Fields

Do not expose the Acquisition System to external magnetic fields (> 5 gauss), since it contains ferrites and ferromagnetic material.



Check Signs of Malfunction

If any signs of malfunction or damage occur, do not continue to operate the device, since serious harm or further damage might result.

This holds particularly for probe heads with deteriorating signal or signs of mechanical damage of the casing, the cabling, or the connectors.

Please follow the advice in the troubleshooting section and contact Skope for further support.

2. PREPARATIONS AND INSTALLATION

Find a site for the rack of the Acquisition System. The rack is 60 cm wide and 80 cm deep. The maximum field strength at the rack's position must be below 5 Gauss. The Acquisition System should never be exposed to a magnetic fields larger than 5 Gauss – also not when transported – in order not to damage sensitive components (ferrites, etc.).

The rack should not be placed close to strong sources of electromagnetic interference such as RF, gradient and shim amplifiers, electric motors (pumps), power supplies, and larger computer systems. Also keep away from devices that are sensitive to electromagnetic immission.

The three mains plugs (screen, digitizer, booster unit) required by the Acquisition System should be common ground and on common ground with the penetration panel of the Faraday cage. Ground currents and hums might result in corrupted data acquisition.

Make sure that the rack is mounted in a mechanically stable fashion and that the breaks on the casters are tightened.

Connect the trigger signal cable to the connector 'Ext. Trig. in' on the booster unit. Check that this and all other cables – in particular the RF cables – are well connected to the Acquisition System and the Faraday cage. When tightening the SMA connections use an appropriate torque wrench (e.g. Huber & Suhner 74_Z-0-0-77).

The routing of RF connections from the Acquisition System to the camera head (in the scanner-isocenter) should not exceed 20 m in total.

1. Never expose the Acquisition System to magnetic fields larger than 5 Gauss.

Consider electromagnetic interference.

Connect mains on common ground with the Faraday cage.

2. Prevent mechanical stress and tension on cables and connectors.
3. Check that the 'Supply' is connected correctly.
4. Connect to common ground.
5. Red LED indicate powering.

Do not apply power RF pulses when using a Dynamic Field Camera head.

3. CONNECTION TO THE FARADAY CAGE

Route the provided twenty coaxial cables (RX 1-16, Trig, TX, and 5V supply) to the penetration panel of the Faraday cage. Avoid misconnections, e.g., by labeling the panel connectors on both sides.

Make sure that the cables are routed such that they stay clear of strong sources of RF interference, are free of mechanical stress and tension, and safe from people potentially tripping on the cables. Additional cable fixation close to the rack and to the panel is recommended to prevent damage on cables and connectors.

It is recommended not to remove the cables from the booster unit of the Acquisition System. Make sure that the cables in the rack do not apply strong forces onto the connectors and that the rack-internal strain relieve is properly tightened.

4. INSTALLATION OF THE PERIPHERALS

Mount the screen to the display port of the digitizer, the mouse and the keyboard to the USB ports. Please use the provided screen, since the display of the *ScanApplication* software is scaled to that particular screen resolution (1920 x 1200 pixels). It is recommended to fix these cables with cable ties to the rack.

Do use the provided power mains from the plugbar in the rack for mains connections, since it provides a common ground.

If the system is supposed to work with network connections or other external devices, connect them accordingly.

5. CONNECTING THE FIELD CAMERA HEAD

The cables connecting the camera head to the RF penetration panel of the Faraday shield are run together in a bunch of cables enclosed by a braid. Uncoil the cable bunch, such that no twist is induced in the cables and no torque nor strain is applied to the camera head.

Wire up the connections to the RF penetration panel from the camera head side. Please take special note of the up-link connections (Supply, TX, Trig), where misconnections prevent the system to operate and can potentially induce system damage.

Position the camera head on the patient support and fasten the cable bunch to prevent strong forces or torque on the camera head; consider patient support movement when fixating the cables. Position the camera head aligned to the magnetic field (head first) and with the camera head center essentially in the isocenter.

6. CONNECTING TO THE MAINS

Make sure that the booster unit is switched off.

Connect the digitizer, the booster unit and the screen to commonly grounded mains using the plugbar provided in the rack. Do not connect any of the units individually to different mains and do not remove any of the provided ground connections.

7. INITIAL TESTS

Switch on the power of the booster unit and then turn on the digitizer. Wait for the digitizer to boot and start the *ScanApplication*. The default password is *skope*; set a new password.

Check the powering of the booster unit and the camera head. If correctly powered, red LED lights show up inside both boxes.

Make sure that the body coil of the MRI scanner (or a transmit coil) does not emit any RF excitation pulses on any frequency. If possible, disconnect the unblanking of the MRI system's power amplifier to safely prevent any power RF to be sent.

Move the camera head to the magnet's isocenter. Please make sure that the cables move freely into the bore.

Make sure that the Faraday shield is closed. Acquire single FIDs with the system without any gradient action of the MRI scanner. Refer to the software manual part of the Acquisition System for the correct settings.

Check if the FIDs from the different field probes are acquired with roughly equal signal amplitude.

Check that the FIDs and their spectra are free of any modulation bands and spikes.

Unplug the Trig. line of the booster unit at the penetration panel to avoid excitation of the field probes and again acquire FIDs with the Acquisition System. The noise signals acquired in this way should be substantially free from immision (white noise signals). Reconnect the trigger line.

8. MALFUNCTION HANDLING

No FID signals appear on the screen. / There is no excitation at all.	<ul style="list-style-type: none"> ▶ Check the correct routing and connection of the cables. ▶ Check the powering of the booster unit and the camera head (or other T/R front end) by checking the working of the red LED lights. ▶ Check that the acquisition frequency of the Acquisition System corresponds to the resonance frequency for the given nucleus at the current magnetic field strength of the MRI system. ▶ Check that an RF excitation pulse (TX) is sent by the booster unit to the T/R front end on the RF port (rear side of booster unit). This is best verified using a mixed signal scope connected to said port and the Acquisition System acquiring self-triggered FIDs. The pulse should be of about 0 dBm over 50 Ω. ▶ Contact Skope if not resolvable.
Booster unit does not power up.	<ul style="list-style-type: none"> ▶ Check mains connection and power switch. ▶ Contact Skope if not resolvable.
T/R front end does not power up.	<ul style="list-style-type: none"> ▶ Using a voltmeter, check that the supply output of the booster unit provides 7-7.5 V. ▶ Contact Skope if not resolvable. Do not use alternative power supplies.
The FIDs exhibit strong modulation.	<ul style="list-style-type: none"> ▶ If the modulations are at 50 Hz and its higher harmonics, check the system for ground currents and for vibration of the cables in the magnetic field. If this is the case, the ground of the camera and the Faraday cage are not on a common potential. Please refer to the entity in charge of the site installation to clarify this issue. ▶ Check if strong electromagnetic emission is present at the location of the spectrometer. Especially signals coupling into the clocking of the ADCs (semi-rigid connections) can cause PM/FM modulations. ▶ Do check that the cables in front of the booster unit leading to the Faraday cage are closely tied together. Loops in front of the panel can pick up modulating low frequency signals. ▶ Check if all SMA connectors (hex nuts) of the front panel connectors of the booster unit are properly fastened. Low contact resistance of the panel connectors to the panel is essential for noise and modulation reduction. ▶ Contact Skope if not resolvable.

Noise floor of the monitoring system is not clean.	<ul style="list-style-type: none"> ▶ Monitoring system internal emission has been cleared carefully and tested at assembly of the unit. Therefore immission from other devices is a probable cause. ▶ Are the signals also visible if the MRI scanner acquires a noise spectrum? ▶ Check the penetration panel. ▶ Check the surroundings of the monitoring system with a pick-up loop and a spectrum analyzer to find potential noise sources. Consider shielding if necessary.
Noise floor of the MRI scanner signals is not clean.	<ul style="list-style-type: none"> ▶ Turn off the booster unit as well as the digitizer and check again. ▶ If the disturbances vanish, please verify the penetration panel or contact Skope for finding a solution. ▶ If the emissions are still present, disconnect the booster unit cables at the penetration panel and check again. ▶ If the problem is solved, the penetration into the Faraday cage appears to be the issue. ▶ If the problem persists, also remove the T/R front end. ▶ If the problem is resolved now, the penetration into the Faraday cage appears to be the issue. ▶ If the problem still exists, please check whether the MR scanner, operated on its own, acquires a clean noise floor.

For further troubleshooting, please refer to the Acquisition System manual.

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