Quality Control Standards in Preclinical MRI

The quality of MR images is only as good as the instrument allows them to be. For high caliber images, rigorous standards must be assured throughout the lifetime of the instrument. These begin with instrument design and manufacturing, scrutinized via extensive factory acceptance protocols, continue with meticulous acceptance protocols and are maintained via regular quality assurance tests and planned preventative maintenance.

Quality Management Standards

While it is not uncommon for preclinical MRI manufacturers to be certified according to ISO 9001, the stringent medical product management standard ISO 13485 and the environmental management standard ISO 14001 verify a superior process quality level with a sustainable practice. Instrument owners can inform themselves about the ISO standards to which the production of their instrument was held when these are publicly documented, for example on the manufacturer's website.

Figure 1

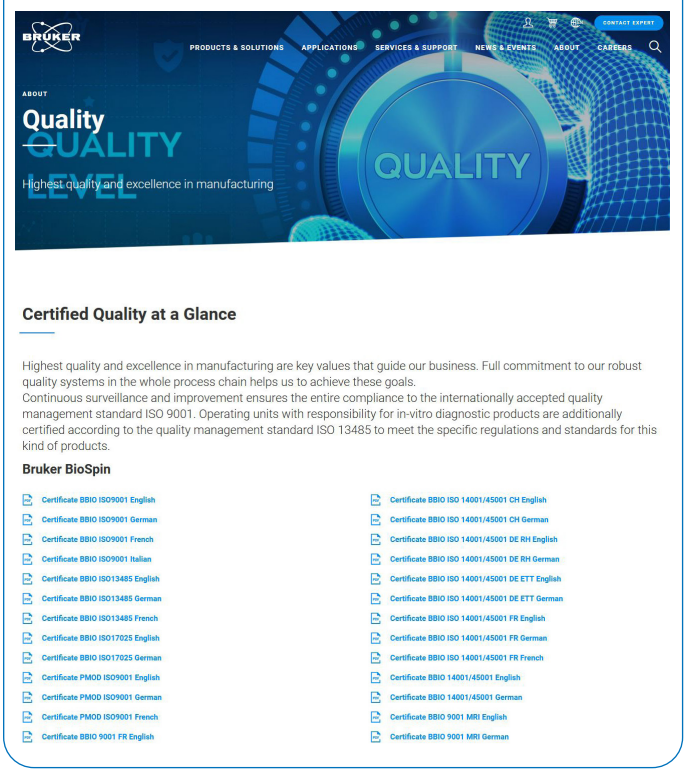


Figure 1: Example of website listing certified ISO standards. https://www.bruker.com/en/about/quality.html Factory

Factory Acceptance Test

In addition to the documented designs and regular inspections of production facilities, there are several quality assurance steps to be completed. With the Factory Acceptance Test, quality assurance of essential components is performed before delivery to the customer.
Such Factory Acceptance Tests for MRI consoles include a transmit linearization of phase and amplitude for each frequency for which the instrument is intended. Phase and amplitude stability over short and long terms must also be within range. After proper transmission has been guaranteed, the next step is calibration of the receive path from the RF coil interface to the receiver. This is to be checked for Rx only as well as for TxRx set-ups. After control of transmission and receive paths, the procedure should continue with the gradient power amplifier tuning and gradient calibration. Here ramp time, current, and voltage for all channels must be tested. Furthermore, it must be confirmed that duty cycle violations are properly handled. Finally, the shim currents for all first, second, and third order shims must be calibrated.

Installation Protocol

After transport and installation, it is essential that full functionality is once again verified at the customer's site and documented in an Installation Protocol.
Concerning the general instrument installation, a multitude of parameters must be verified, ranging from safety checks such as torque check of power lines and check of protective grounding to performance parameters such as gradient strength and slew rates. Additionally, for *in vivo* measurements, regulations for Waste Anesthesia Gas (WAG) extraction or adsorption and animal warming, for instance, must be taken into account.
Once these basics have been established, the operational qualification can take place. In addition to checks of random magnetic field fluctuations and distortions, it must be confirmed that each coil provides sufficient signal-to-noise (SNR) and homogeneity under standardized conditions. For ghosting check, an RF coil setup and protocol with very high SNR should be established and long echo times in off center slices controlled. As in all other control stages, supporting software tools that allow for automated, reproducible and user independent results are essential.

Figure 2

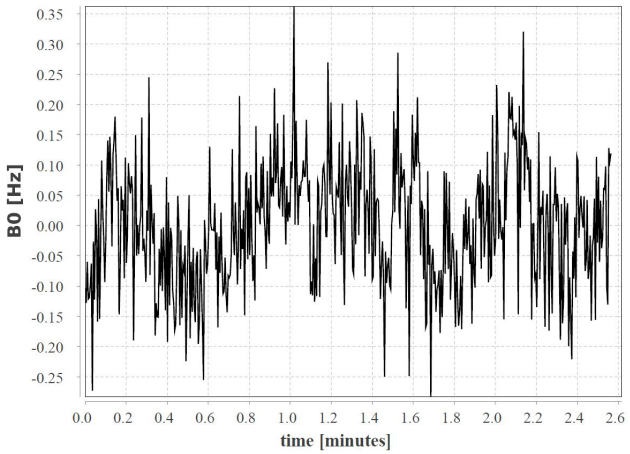


Figure 2: An initial prerequisite: Magnetic Field Stability Test.

In addition to standard controls of the most common GRE and SE sequences, as well as T1 and T2 mapping methods, it is desirable to have confirmation of proper functioning of sequences employed in fMRI and spectroscopy. As EPI is often used for functional imaging where small changes in image intensity are evaluated, not only the EPI typical N/2 ghosting needs to be small but also image intensity must be very constant in subsequent EPI images. An automatism to evaluate image intensity over time is of great help.

Figure 3

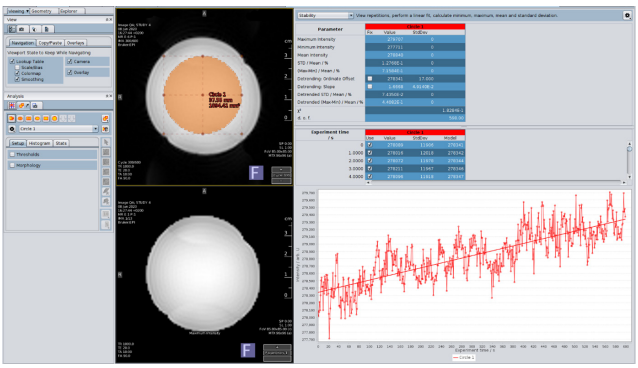


Figure 3: Example of an EPI image intensity reproducibility test demonstrating the availability of automized tools for quality controls.

In volume selective spectroscopy, it must be confirmed that the necessary gradient switching does not create any distortions to the signal. The most demanding test is with a small voxel acquired off center with a minimum echo time. A good voxel selective shimming procedure is vital to obtain a small linewidth. Likewise, water suppression must also achieve a maximum suppression factor without distortion of nearby signals.

Quality Assurance Throughout Instrument Lifetime

To confirm proper functioning throughout the lifetime of the instrument, quality assurance (QA) tests should be performed regularly. In order to perform reproducible, comparable images, firstly, a standardized imaging subject is needed. This phantom must have defined relaxation values and should be asymmetrical, allowing differentiation of axial, sagittal, and/or coronal planes. Not only is this phantom itself essential, but also the method of fixation is imperative to allow referencing of results obtained with proven standards. One example of such a phantom and phantom holder is seen in Figure 4.

Figure 4

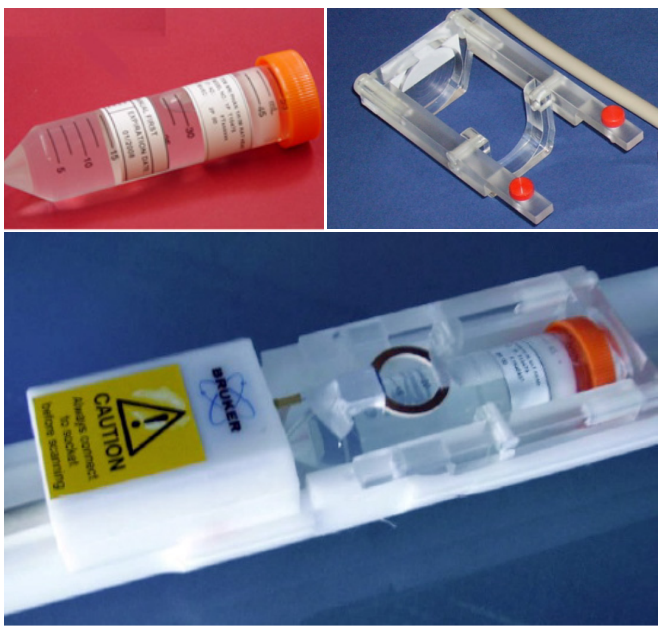


Figure 4: Top left: standardized phantom[1], top right: phantom holder, and bottom: phantom in phantom holder on cradle with coil prepared for QA test.

[1] Bruker patent # DE-102005045679-B3, GB-2433785-B2, US-7368912-BB

Using such a phantom, an accompanying phantom holder, and a standardized supplier provided QA protocol, each coil can be tested for SNR on a regular basis. Ideally a QA Test Report is automatically created and saved in a defined directory.

Use of such standardized phantoms not only allows comparison of data from one QA test to the next, it also simplifies inter-site collaborations as it allows initial study planning coordination and standardization. Such an inter-site comparison with a standardized phantom was conducted with twelve MRI instruments across six countries and two continents in a study done by the Tristan consortium with the extremely consistent results.[1]

Figure 5

IMA 1, Slice Position Cd5.00 mm, TE = 15.0 ms

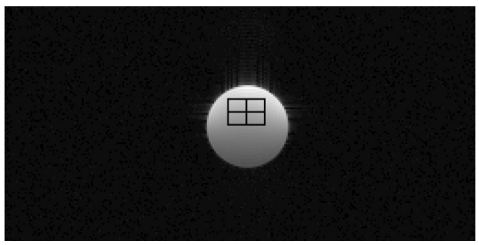


Image specific SNR values

IMA	Slice Position	Echo Time	Normalized SNR [1/mm³]
1	Cd5.00 mm	15.0 ms	8427
2	0.00 mm	15.0 ms	8221
3	Ro5.00 mm	15.0 ms	9908

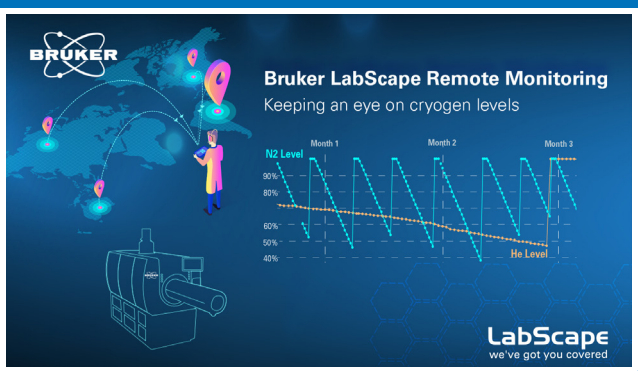
Image specific Symmetry values

IMA	Slice Position	Echo Time	L-R Symmetry
1	Cd5.00 mm	15.0 ms	3.9 %
2	0.00 mm	15.0 ms	1 %
3	Ro5.00 mm	15.0 ms	0.7 %

Figure 5: RF coil check measurements with automatic object contour finding and automatic placement of evaluation area (rectangular cross) for SNR and symmetry results.

Planned Maintenance

In addition to the quick and easy regular quality assurance tests that the customer should perform, some instrument suppliers provide regular scheduled on-site visits involving extended maintenance checks including replacement of parts with defined life expectancies. Furthermore, some suppliers can remotely monitor vital systems to verify the health of the instruments, allowing fastest intervention and failure prevention.



Conclusions

Taken together, rigorous instrument production with continuous assurance checks throughout the lifetime of the instrument ensure optimal performance and guarantee optimal and reliably reproducible results.

List of Abbreviations

EPI - Echo Planar Imaging
fMRI - functional Magnetic Resonance Imaging
GRE - Gradient Echo
ISO - International Organization for Standardization
MR - Magnetic Resonance
MRI - Magnetic Resonance Imaging
QA - Quality Assurance
RF - Radio Frequency
Rx - Recieve
SE - Spin Echo
SNR - Signal to Noise Ratio
TxRx - Transmit-Recieve
WAG - Waste Anesthesia Gas

References

1. Waterton JC, et al. Repeatability and reproducibility of longitudinal relaxation rate in 12 small animal MRI systems. Magnetic Resonance Imaging Volume 59, June 2019, Pages 121-129. https://doi.org/10.1016/j.mri.2019.03.008

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