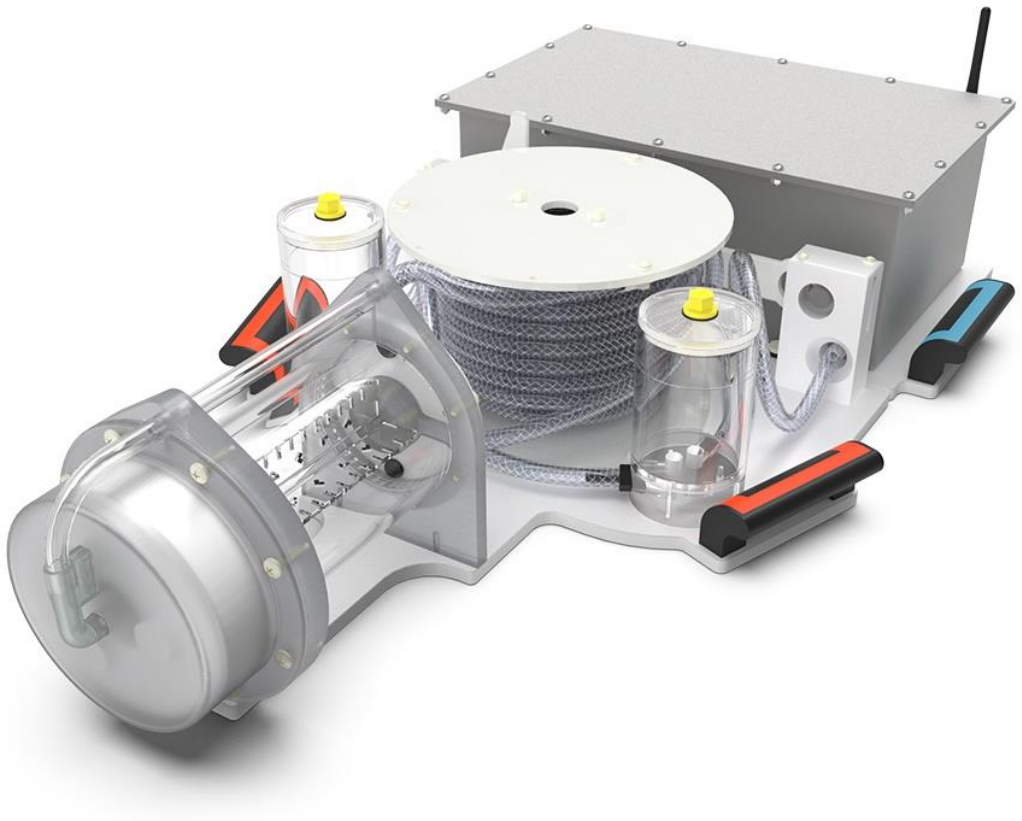
QASPER: INSTRUCTIONS FOR USE



REVISION HISTORY

REVISION	DESCRIPTION	ISSUED BY	DATE
A	First draft release	A Oliver-Taylor	25/01/2019
B	Second draft release	A Oliver-Taylor	08/07/2019

Contents

FIGURES

FORWARD

The instructions for use contain all the information necessary to operate the QASPER system in accordance with its specifications. This information includes explanations of the functions of the controls, displays and signals, the sequence of operation, and connection and disconnection of the parts and accessories you can remove.
You must regard these instructions as a part of the equipment. It is important that these instructions are read thoroughly.

DECLARATION OF CONFORMITY

CE

The QASPER System is in conformity with the essential requirements and provisions of:

- Medical Device Directive 93/42/EEC as amended 2007/47/EC, Class I.
- Machinery Directive 2006/42/EC as amended 2009/127/EC
- RoHS Directive 2011/65/EU
- Radio Equipment Directive 2014/53/EU

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DISCLAIMER

Gold Standard Phantoms considers itself responsible for the effects on safety, reliability and performance of the equipment only if:

- Assembly operations, re-adjustments, modification or repairs are carried out by persons authorised by ourselves, and
- The electrical installation of the room where the device is used meets the requirements of the standards in force, and
- The device is used in accordance with this book.

GLOSSARY AND ABBREVIATIONS

Term	Description
QASPER	Quantitative Arterial SPin labelling PErfusion Reference
MRI	Magnetic Resonance Imaging
ASL	Arterial Spin Labelling
SoC	State of Charge (battery level in percent)

PLC	Perfusion Labelling Chambers
Perfusate	The water-based liquid that circulates through the QASPER system.
USB	Universal Serial Bus
QA	Quality Assurance
pCASL	Pseudo Continuous Arterial Spin Labelling: a labelling strategy that uses a rapid pulse train to label inflowing blood at a plane.
PASL	Pulsed Arterial Spin Labelling: a labelling strategy that uses a single inversion pulse to label a bolus of blood.
EPI	Echo Planar Imaging: a rapid MRI image acquisition technique
3D-GRASE	3D GRAdient and Spin Echo: A rapid MRI image acquisition technique that combines EPI and Fast Spin Echo pulse sequences that can acquire an entire 3D volume in a single shot.
QUIPPSS/Q2TIPS	Methods of truncating the labelled bolus for PASL labelling, giving it a defined temporal duration.
TOF	Time-of-Flight Angiogram: a MRI technique for visualising the vasculature.
FOV	Field of View
TE	Echo Time
TR	Repeat Time
T1	Spin-Lattice relaxation time
T2	Spin-spin relaxation time

QUICK START GUIDE

ABOUT QASPER

QASPER is a Perfusion Phantom for use with Arterial Spin Labelling (ASL) Magnetic Resonance Imaging (MRI). It is a calibration standard for MRI based perfusion measurements using ASL. It simulates the process of delivery of arterial blood to an organ in a controlled and reproducible manner.

At the heart of the QASPER phantom is an MRI compatible pump that delivers a liquid at a calibrated flow rate to a simulated capillary bed. During operation, fluid is pushed around a closed system that is simply placed on the patient couch of an MRI scanner: it is not necessary to put tubing through waveguides, or to empty and re-fill the system at each use. The phantom continuously reports via wireless connection to a computer application its real-time operating state such as flow rate, temperature, battery drain etc, and can also be controlled by the user for example to set the flow rate set point to a specified value. The computer application provides an intuitive graphical user interface for visualisation and control of the phantom, providing complete control and assurance during image acquisition that the phantom is operating as intended. Furthermore, data acquired of each phantom session can be saved for later comparison and combined analysis with the imaging data.

So that quality assurance measurements can be made effectively, QASPER was designed to be used with clinical ASL sequences and protocols. Computational fluid dynamics and numerical tracer kinetics simulations were used to develop and design the flow path that the liquid takes, ensuring that transit times and perfusion rates are in both the healthy and abnormal physiological range.

The flow path within QASPER comprises of three compartments. The first simulates the feeding arteries and arterioles that supply arterial blood to an organ. Vessel geometry and flow velocities within this region match those found in the human body. Compartment two uses a porous polymer substrate to simulate the microvascular, incoherent flow observed at the capillary bed. The third compartment represents the remainder of the cardiovascular system; venous return from the organ to the heart where it is pumped back. A deliberately long, labyrinthine flow path ensures that none of the labelled bolus is recirculated before the label decays and ensures fully developed equilibrium magnetisation.

1 INTRODUCTION

1.1 ABOUT THIS BOOK

The purpose of this book is to promote the safe use of the QASPER system during its expected service life. It describes the use of the device as intended by the manufacturer, and you should regard it as part of the device.

This book gives instructions and information for healthcare professionals. It includes the details necessary for you to brief other operators on the known contraindications to the use of the device, and on the precautions to be taken.

Keep this book for future use. You can order replacement copies from Gold Standard Phantoms during the expected life of the device, or alternatively download from www.goldstandardphantoms.com.

1.2 IDENTIFICATION

WARNING 1. Do not make modifications to medical equipment. This creates a risk to the patient

This book is only for the models and variants of the device listed in the table, and their approved accessories.

Model	Remarks
QASPER System 1.0.0	Manufactured from April 2018

1.3 MANUFACTURER AND CONTACT INFORMATION

The manufacturer of the QASPER system is Gold Standard Phantoms Limited. If you need help in setting up, using or maintaining the QASPER system, or you wish to make a report of an unexpected operation, tell the manufacturer at the address shown below.

Address	Gold Standard Phantoms Limited Unit 103 Belgravia Workshops 159-163 Marlborough Road London N19 4NF United Kingdom
Telephone	+44 (0) 207 684 7749
Email	service@goldstandardphantoms.com

1.4 ENTRY INTO SERVICE

The QASPER system must be put into service in accordance with the instructions in this book. The device is for use within hospitals and imaging centres, especially in radiology departments.

2 INTENDED USERS

2.1 PATIENT POPULATION

The QASPER system is not designed to be used on or with patients. It is to be scanned on its own.

2.2 SPECIAL SKILLS, TRAINING AND KNOWLEDGE

The device must be used by a skilled person who has the applicable education and experience to enable them to perceive risks and to avoid hazards which operation or maintenance of the device can create.

The QASPER system must be operated by trained and competent personnel and used in accordance with approved clinical practise.

Generally, it is expected that the QASPER system is set up by personnel who have training in operating in and around the environment of an MRI scanner.

2.3 MAINTENANCE PERSONNEL

The QASPER system requires preventative inspection and battery recharge after use. This should be done by someone who has familiarised themselves with the instructions in this book, and who are confident

2.4 SERVICE PERSONNEL

The QASPER system can only be serviced by personnel authorised by Gold Standard Phantoms.

3 SCOPE OF USE

The QASPER System is intended for use in conjunction with the following MRI systems, when combined with the appropriate cable assembly:

Manufacturer	Model	Field Strength	Compatible QASPER Power Cable
Philips	All models	1.5T	GSP 1036
GE	All models	1.5T	GSP 1036
Siemens	All models	1.5T	GSP 1037
Siemens	All models	3T	GSP 1007
Philips	All models	3T	GSP 1021
GE	All models	3T	GSP 1021
Canon	All models	3T	GSP 1007
Philips	All models	7T	GSP 1034
GE	All models	7T	GSP 1034
Siemens	All models	7T	GSP 1035

If you wish to use the phantom with an MRI scanner that is not of the type listed above, please contact Gold Standard Phantoms.

4 WARNINGS, CAUTIONS AND SIDE-EFFECTS

Like other devices of this nature, the use of the QASPER system has inherent risks and side effects. Whilst every effort has been taken to prevent these risks, be careful when using this device

4.1 ABOUT WARNINGS AND CAUTIONS

A **WARNING** is given when the personal safety of the patient or a user can be affected. Disregarding this advice can cause an injury.

A **CAUTION** is given when special instructions must be followed. Disregarding this advice can cause damage to the device or other equipment.

To make sure that all users are satisfactorily informed, we have included warnings and cautions throughout this book. This section gives warnings and cautions of a general nature. Additional warnings and cautions appear with specific instructions and actions.
All users must familiarise themselves with all of the warnings and cautions contained in this book.

4.2 WARNINGS

WARNING 1. Do not make modifications to medical equipment. This creates a risk to the patient
WARNING 2. Only the *GSP 1015 Power Supply Unit Charger* should be used to charge the *GSP 1005 Power Supply*. Do not use any other battery charger or AC-DC adapter. Doing so could cause damage to the battery and may cause a fire.
WARNING 3. Before taking the transport case into the magnet room, remove the following MRI Unsafe items: GSP 1015 Power Supply Charger, QASPER-LINK Wireless Interface Charger and charging cable, GSP 1026 QASPER-LINK USB Interface, and USB Cable.
WARNING 4. Due to the size and weight of the *GSP 1006 Phantom*, only physically capable and competent individuals should attempt to lift the Phantom on their own. Adhere to local manual handling safety guidelines/rules. Gold Standard Phantoms accepts no liabilities for personal injury, or damage that occurs to the QASPER system or other equipment when one person lifts the phantom on their own.
WARNING 5. Before use, make sure all the functions of the device operate correctly. Also examine the device and its accessories for any loose or damaged parts. Do not use the device if there are loose or damaged parts.
WARNING 6. The *Power Supply* contains a li-ion battery that has a steel enclosure. DO NOT bring the *Power Supply* any closer to the magnet once the magnetic field alarm sounds. Failing to do this will pose a projectile hazard.

4.3 CAUTIONS

CAUTION 1. Only use the *GSP 1014 QASPER-LINK Wireless Interface Charger Cable* to supply power to the *QASPER-LINK Wireless Interface*
CAUTION 2. Before placing the phantom into the wheeled transport case, ensure that the antenna at the rear of the *Pump Unit* is correctly folded. Failure to do so will result in it being caught in the case, damaging the antenna and other components in the *Pump Unit*.
CAUTION 3. Do not automatically move the *Phantom* to/from isocentre. If this is done without any means to restrain the *Pump Unit*, it will be moved by the Lorentz force it experiences. If the

restraining tethers between the *Pump Unit* and *Perfusion Units* become taught this could result in the *Perfusion Unit* being moved (and thus losing alignment).

CAUTION 4. The *Tuned Connection Cable* can only be connected in one orientation. The short end connects to the *Pump Unit*, and the long end to the *Power Supply*. Do not try to connect the other way round: this will damage the connectors and sockets.

CAUTION 5. Ensure that the *GSP 1005 Power Supply* is switched OFF when not in use. Failure to do so will result in the battery becoming over-discharged.

CAUTION 6. If the *Power Supply* battery becomes over-discharged to the point where the internal cut-off circuitry is activated, the *Power Supply Charger* will not be able to successfully charge the battery. If this occurs, please contact Gold Standard Phantoms. To avoid this from happening ensure that the *Power Supply* is recharged after each use, and if not used for a long period of time, ensure that it is checked and recharged every month.

CAUTION 7. Ensure that the base is correctly locked together before attempting to lift the *Phantom*. Failure to do so could result in the two parts becoming separated, potentially resulting the Phantom being dropped and damaged.

5 EQUIPMENT DESCRIPTION

5.1 ABOUT THE QASPER SYSTEM

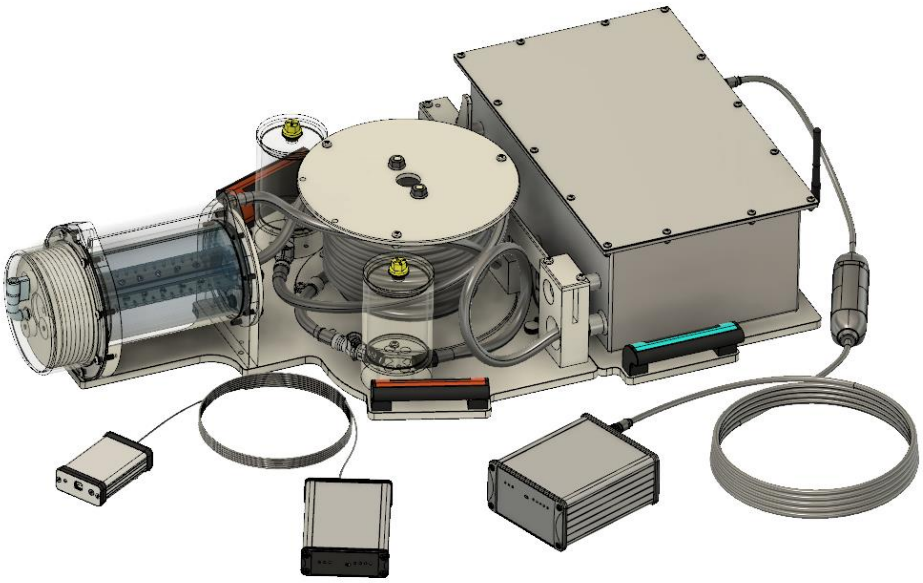

Figure 1: The QASPER System

The QASPER System consists of the following components:

ID	Name
GSP 1006	Phantom
GSP 1005	Power Supply Unit
GSP 1008	QASPER-LINK Wireless Interface
GSP 1026	QASPER-LINK USB Interface
GSP 1007	Tuned Connection Cable (Siemens/Canon 3T)
GSP 1021	Tuned Connection Cable (Philips/GE 3T)
GSP 1034	Tuned Connection Cable (Philips/GE 7T)
GSP 1035	Tuned Connection Cable (Siemens 7T)
GSP 1036	Tuned Connection Cable (Philips/GE 1.5T)
GSP 1037	Tuned Connection Cable (Siemens 1.5T)
GSP 1019	Fibre Optic Data Cable
GSP 1015	Power Supply Charger
GSP 1018	QASPER-LINK Wireless Interface Charger
GSP 1014	QASPER-LINK Wireless Interface Charging Cable

During normal operation the *Phantom* is placed on the patient couch of the MRI scanner, with the head section located within a head coil. A liquid, hereafter referred to as the perfusate is pumped in a highly controlled manner to the head section where it passes through a porous polymer substrate that simulates the capillary bed. The *Phantom* is powered by the *Power Supply*, which connects via a cable loom. The *Tuned Connection Cable* used must be matched to the type of MRI scanner being used in conjunction with the QASPER system. Additional cable looms are available as a purchasable accessory from Gold Standard Phantoms.

The *Phantom* makes a wireless connection to the *QASPER-LINK Wireless Interface*, enabling remote control of the flow rate that the perfusate is pumped at, and real-time telemetry of the *Phantom's* operating conditions. The *QASPER-LINK Wireless Interface* is located within the MRI scan room.
Data is sent in/out of the magnet room via the *Fibre Optic Cable*. The *QASPER-LINK USB Interface* is located next to the host control computer to an interface between the fibre optic and USB data.
The QASPER system will function without the presence of a host computer. Under these conditions the flow rate will be set at its default rate (350ml/min), and a LED will be lit when this flow rate is being achieved.

The constituent components will now be described in further detail.

5.1.1 GSP 1006 PHANTOM

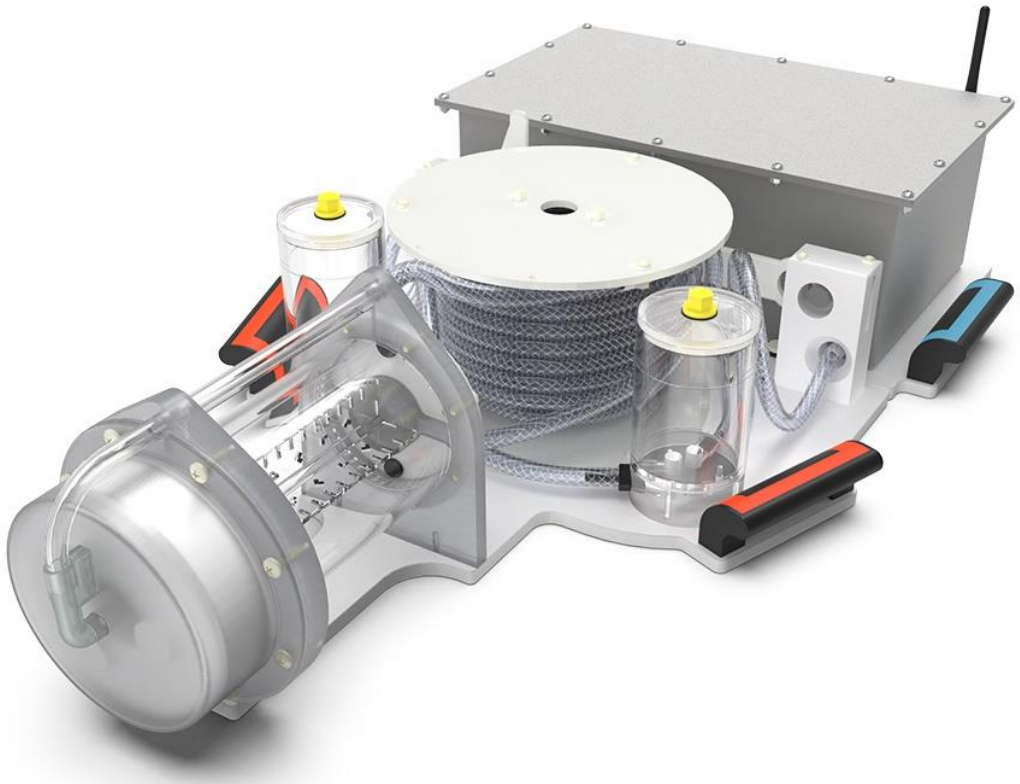

Figure 2: GSP 1006 Phantom

The *Phantom* comprises of two units, the *Perfusion Unit* and *Pump Unit*. They are fixed together using a latch mechanism. They should be locked together when lifting the *Phantom*, and during transport within the *Wheeled Transport Case*. When placed on the patient couch of the MRI scanner, the lever slides across to disengage the latch, and the *Perfusion Unit* and *Pump Unit* moved apart. This means the pump can be located outside of the gradient coil's field, mitigating the induction of gradient induced eddy-currents into the system, which can affect the flow measurement and can also cause motion artefacts in the *Perfusion Unit*.

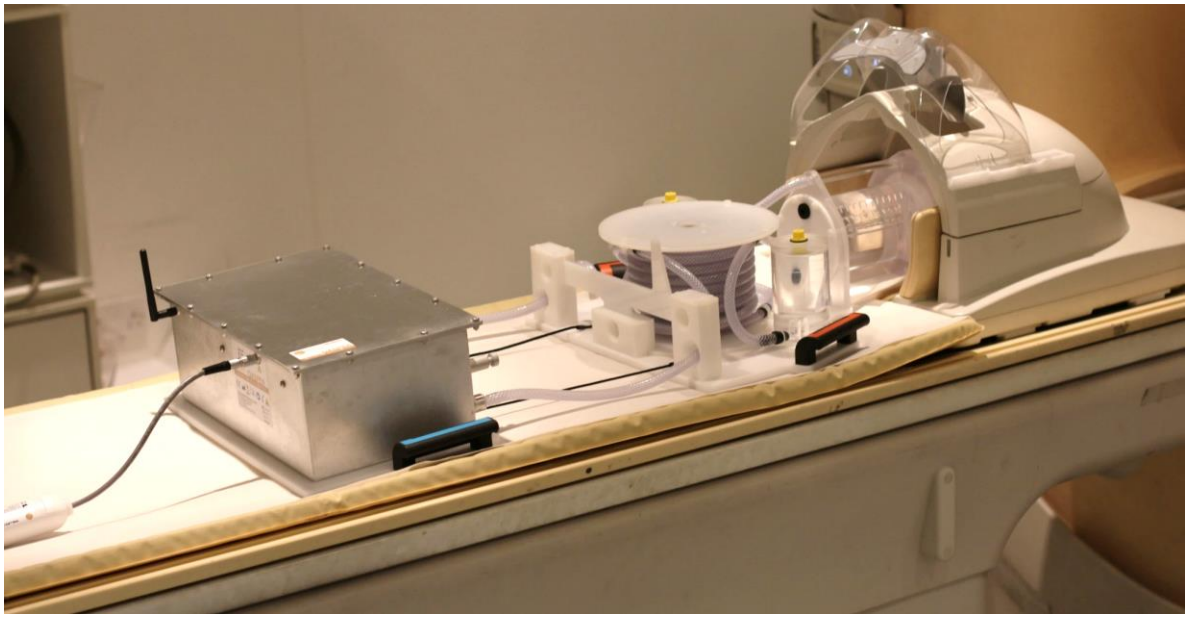

Figure 3: *Phantom* with *Perfusion Unit* and *Pump Unit* detached, ready to be scanned

5.1.1.1 PERFUSION UNIT

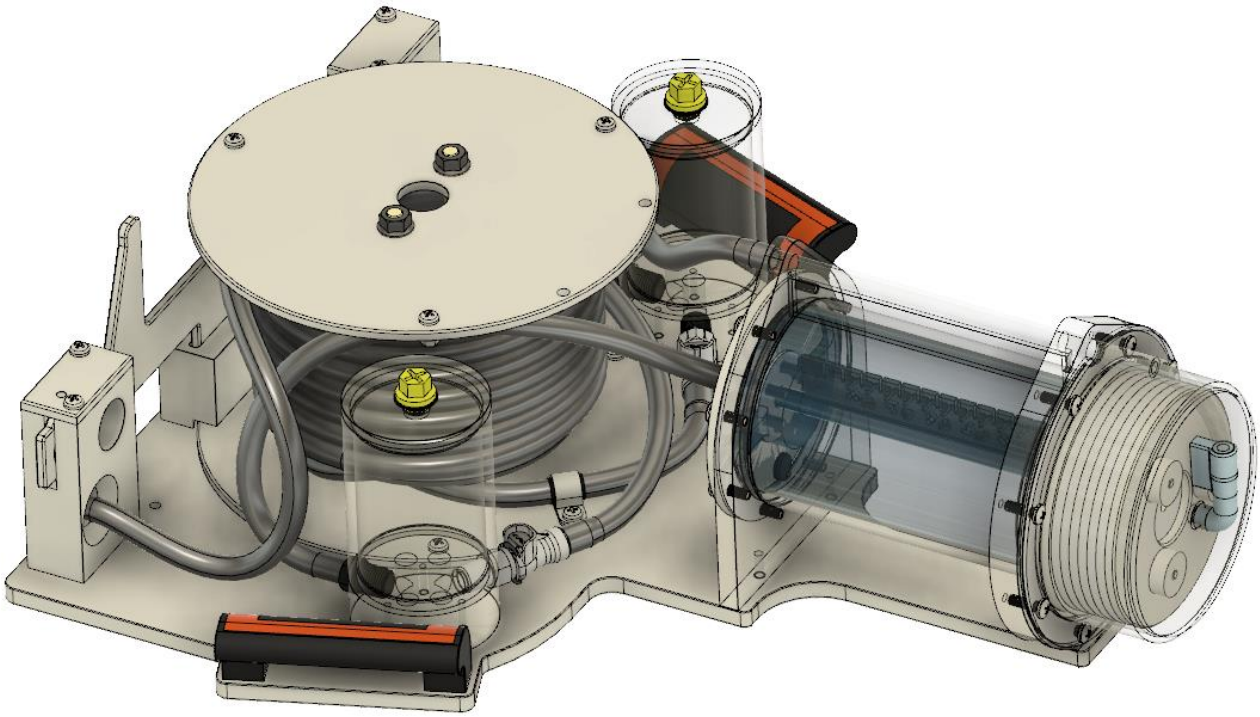

Figure 4: *Perfusion Unit*

The *Perfusion Unit* contains the Perfusion and Labelling Chambers (*PLC*) at the “head” end. This is where the ASL labelling and imaging takes place. In addition, there are two bubble traps and a coiled hose reservoir. The coiled hose reservoir slows down the transit of perfusate around the circuit so that it takes approximately two minutes, ensuring there is fully developed equilibrium magnetisation, and preventing the recirculation of any labelled perfusate.

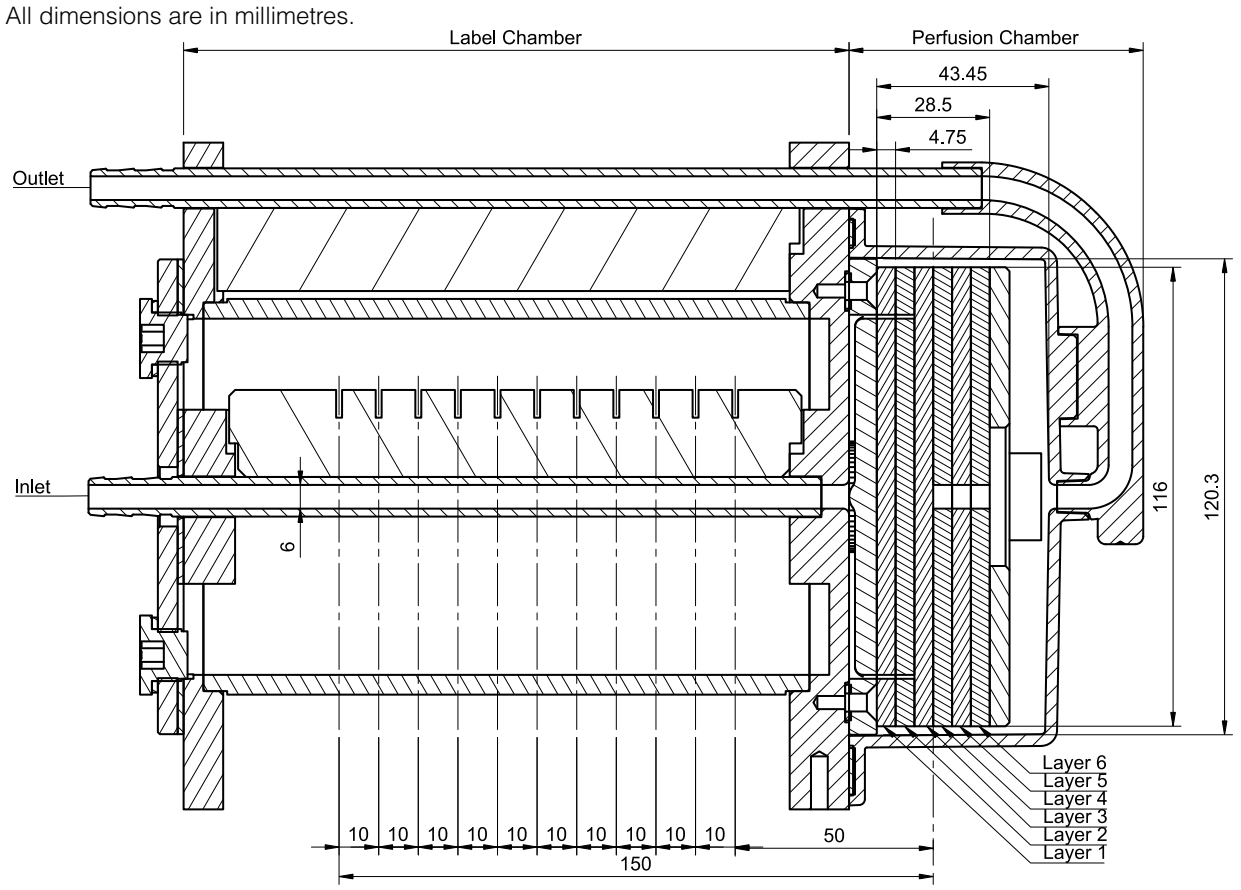

Figure 5: Cross-section through the mid-plane of the of the *PLC*.

The labelling chamber mimics a neck and contains a single 6mm diameter “artery” through which perfusate flows, surrounded by static perfusate. At a flow rate of 350ml/min the velocity of the perfusate as it travels through this tube is approximately 20/40 cm/s (mean/peak)[1].

After the labelling chamber, the perfusate flows into a branching region, where it splits into sixty 1mm wide channels that travel radially in the axial plane, before turning 90° to run axially into the perfusion chamber via 1mm diameter “arteriole” holes. The dimensions and arrangement of this branching region has been optimised to ensure that the transit time is equivalent to the transit time in adult humans (0.5-1.5s[1]).

The perfusion chamber contains six 4.75mm thick, 116mm diameter discs of porous UHMW-PE[2], which simulate the capillary bed of an organ. The 1mm arterioles extend into the first two layers of the material. Perfusate is delivered via these holes into the perfusion matrix material, where once inside it slowly (1-2mm/s, dependent on flow rate) travels through to the periphery of the perfusion chamber. Perfusate then exits via an axially located hole at the distal end of the perfusion chamber, returning to the pump.

The interface plane between layers 3 and 4 of the porous stack defines the mid-point of the perfusion chamber. When scanning, it is recommended that this location is used as the centre of the imaging field of view (FOV). Fiducial markers within the labelling chamber define fixed offsets for the label plane location. The first marker is at a distance of 50mm, and subsequent markers at

[1] At the default system flow rate of 350ml/min.
[2] Pore sizes ranging from 3-30um, with mean pore size 7um.

10mm intervals up to 150mm from the centre of the porous stack.

There are two bubble traps in the system, located before the *PLC*, and after the reservoir. Bubbles flowing within the system are caught in the bubble traps, preventing them from entering either the *PLC* or pump.

The reservoir consists of a long length of coiled tubing. Its purpose is to extend the perfusate circulation time to two minutes[1] ensuring that fully-developed equilibrium magnetisation enters the PLC, and preventing the recirculation of any labelled perfusate before the label has time to fully decay.

5.1.1.2 PUMP UNIT

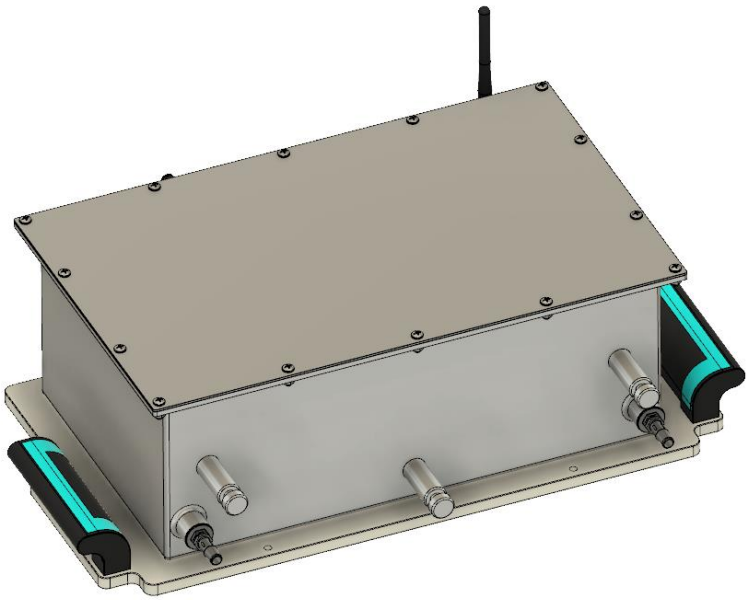

Figure 6: *Pump Unit*.

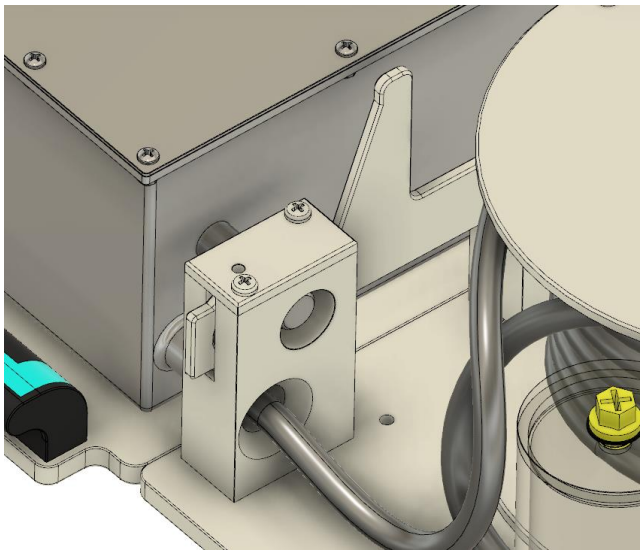

Figure 7: Base split mechanism

The *Pump Unit* delivers continuous flow at a controlled rate to the perfusion unit. It uses piezoelectrically operated diaphragm pumps, which are completely MRI compatible as they contain no ferromagnetic material and generate for electro-magnetic interference. A calibrated

flow meter and microcontroller-based system actively controls the flow rate during operation. The workings of the Pump Unit are housed in an aluminium enclosure that is electromagnetically shielded, preventing interference between the MRI scanner and the housed circuitry.

To minimise the induction of gradient eddy currents and subsequent vibrations, and prevent transmission of these to the *PLC*, the *Pump Unit* and *Perfusion Unit* are mechanically decoupled using a latch mechanism. This consists of three attachment bosses that are secured by a sliding latch that is located on the *Perfusion Unit*.

5.1.1.3 FLOW CONTROL

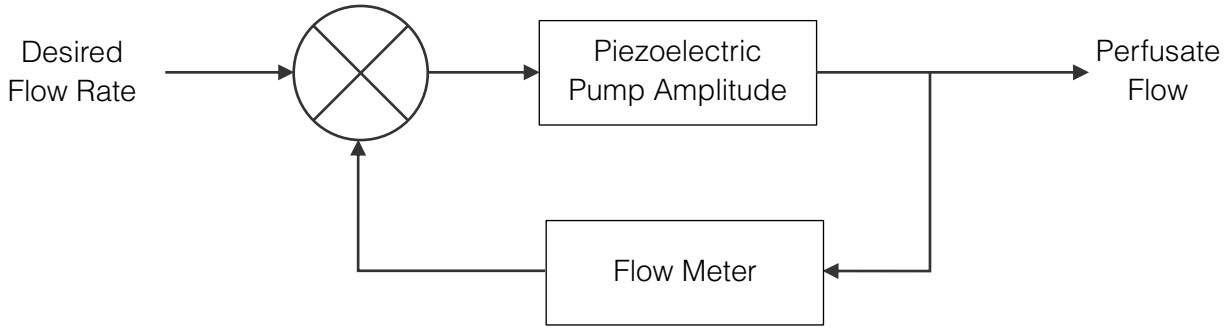

Figure 8: Auto flow control algorithm

Active, closed-loop flow control ensures that the same perfusate flow rate is achieved in the system over a wide range of operating conditions. The piezoelectric pumps are driven by high voltage sinusoidal waveforms, and the perfusate flow rate is governed by this amplitude. A calibrated optical turbine flow meter continuously measures the system flow rate, and this information is used by a 32-bit ARM microcontroller to adjust the piezoelectric pump waveform amplitude using a proportional-integral-derivative (PID) algorithm so that the desired flow rate is achieved. Due to the intrinsic noise in the flow measurement and the oscillating nature of PID based controllers, the actual flow rate will fluctuate, typically by a few percent of the desired value. Note that at high flow rates (>400-450ml/min) the increase in system pressure due to the resistance in the porous material means that pulsations from the piezoelectric pumps are less effectively dampened, and as a result the flow measurement and subsequent flow stability will have more fluctuations (as much as 10%). This is normal.

There is an upper flow rate limit, governed by the maximum amplitude that the piezoelectric pumps can be driven at. Because the achieved flow rate is highly dependent on factors such as temperature, this upper limit will vary, but usually should be 450ml/min or greater. Always check that the desired flow rate is achieved, if the piezoelectric pump amplitude is 1.0 then this is unlikely.

5.1.1.4 DATA COMMUNICATIONS

The pump unit continuously measures the perfusate flow rate and temperature. These values, as well as operating parameters are sent via a wireless and fibre optic link to a host computer running the *QASPER Pump Control Software*.

5.1.2 GSP 1005 POWER SUPPLY

Figure 9: GSP 1005 Power Supply

The *GSP 1005 Power Supply* provides low and high voltage power to the *GSP 1006 Phantom*. This is because the piezoelectrically operated diaphragm pumps located in the *Pump Unit* require a high voltage waveform to actuate them. Ferromagnetic components are used to generate the high voltages (+150V and -150V) from a low voltage battery. However, these components will not function if there is excessive ambient magnetic field, so a separate power supply is required that can be located away from the MRI scanner. The power supply has the following features:

- Contains a 11.1V, 2400mAh lithium ion battery, providing approximately 2 hours of phantom use per charge.
- Monitors the high and low voltages delivered to the phantom.
- Communicates with the phantom, reporting parameters such as the battery level.
- Magnetic field sensor and alarm function: continuously monitors the magnetic field and sounds an alarm if the ambient magnetic field exceeds approximately 32mT.
- LED indication of the battery state of charge.

The *Power Supply* is to be used within the MRI scan room, located towards the edges of the room, where the ambient magnetic field is less than approximately 32mT.

It is not possible to charge the *Power Supply* and power the *Phantom* at the same time. To extend the operating time of the QASPER system please purchase additional Power Supply Kits from Gold Standard Phantoms.

The power supply will supply high voltages to the phantom until the battery state of charge reaches 5%, at this point they will be turned off and fluid will no longer be pumped around the phantom system.

5.1.3 GSP 1015 POWER SUPPLY UNIT CHARGER

Figure 10: GSP 1015 Power Supply Unit Charger

The *GSP 1015 Power Supply Unit Charger* is used to charge the lithium-ion battery contained within the GSP 1005 Power Supply. Only this charger should be used to charge the battery. It comes supplied with a plug for the specific locale the QASPER system was sold to (e.g. UK, EU, USA, AUS etc).

WARNING 2. Only the *GSP 1015 Power Supply Unit Charger* should be used to charge the *GSP 1005 Power Supply*. Do not use any other battery charger or AC-DC adapter. Doing so could cause damage to the battery and may cause a fire.

5.1.4 GSP 1008 QASPER-LINK WIRELESS INTERFACE

Figure 11: *QASPER-LINK Wireless Interface*

The *GSP 1008 QASPER-LINK Wireless Interface* initiates a wireless connection to the *Phantom*, and converts data sent/received to a fibre optic data link. Each *QASPER-LINK Wireless Interface* is paired for use with a specific *GSP 1006 Phantom*, and this is indicated on a label on the underside of the *QASPER-LINK Wireless Interface*.

The *QASPER-LINK Wireless Interface* has the following features:

- Automatically initiates a wireless connection to the paired *Phantom*[3].
- LED indication of the wireless connection status.
- LED indication of the battery state of charge.
- Battery operated with a 3.7V lithium-polymer battery life. Battery life greater than 10 hours.
- Can be powered/charged directly from a USB connection, or the supplied QASPER-LINK Wireless Interface charger.

5.1.5 GSP 1018 QASPER-LINK WIRELESS INTERFACE CHARGER AND GSP 1014 QASPER-LINK WIRELESS INTERFACE CHARGER CABLE

Figure 12: *GSP 1018 QASPER-LINK Wireless Interface Charger* and *GSP 1014 QASPER-LINK Wireless Interface Charger Cable*

The *GSP 1018 QASPER-LINK Wireless Interface Charger* is an AC-DC adapter that supplies 5V over a USB port. The *GSP 1014 QASPER-LINK Wireless Interface Charger Cable* connects between the USB socket on the charger and the power-in socket on the *QASPER-LINK Wireless Interface*.

CAUTION 1. Only use the *GSP 1014 QASPER-LINK Wireless Interface Charger Cable* to supply power to the *QASPER-LINK Wireless Interface*

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[3] Multiple *QASPER-LINK Wireless Interfaces* can be paired to the same *Phantom*.

5.1.6 GSP 1026 QASPER-LINK USB INTERFACE

Figure 13: GSP 1026 QASPER-LINK USB Interface

The *GSP 1026 QASPER-LINK USB Interface* connects between a host computer and the fibre optic data link. Powered by the USB connection to the computer, it converts optical data to a virtual com port (VCP), which appears as a serial COM port on a Windows computer. A driver may be required for the host computer, this can be downloaded from https://www.ftdichip.com/Drivers/CDM/CDM21228_Setup.zip

5.1.7 TUNED CONNECTION CABLE

Figure 14: QASPER Tuned Connection Cable

The *Tuned Connection Cable* connects between the *GSP 1005 Power Supply Unit* and the *GSP 1006 Phantom*. It carries both low and high voltage power to the phantom, and low-speed communications between the two devices.

A tuned cable trap is mounted on the *QASPER Tuned Connection Cable* to prevent radio frequency interference with the MRI scanner. Its tuned frequency should match the MRI scanners'. As such there are multiple versions of the *Tuned Connection Cable*:

ID	Compatible MRI System
GSP 1007	Siemens/Canon 3T (123.2 MHz)
GSP 1021	Philips/GE 3T (127.7 MHz)
GSP 1034	Philips/GE 7T (298.0 MHz)
GSP 1035	Siemens 7T (297.2 MHz)
GSP 1036	Philips/GE 1.5T (63.9 MHz)
GSP 1037	Siemens 1.5T (63.3 MHz)

The model and compatible MRI scanners is indicated on the label on the cable trap, as shown in Figure 15.

Figure 15: Cable Trap Label

The *Tuned Connection Cable* can only be connected in one orientation. The short length of cable (~30cm) after the cable trap has a six-pin connector that mates with a socket in the *Pump Unit*. The long length of cable (>4.5m) has an eight-pin connector that mates with a socket in the *Power Supply*.

The 7T versions of the cables are approximately 10m in length, providing extra distance in the case of unshielded magnets.

5.2 GENERAL ARRANGEMENT

The general arrangement of the QASPER system is as follows:

The *Phantom* is placed on the patient couch of an MRI scanner, with the *PLC* located inside the head coil. The latch mechanism is disengaged, and the *Pump Unit* positioned at its maximum distance away from the *Perfusion Unit* so that the tethers are taught. The *Power Supply* is connected to the *Phantom* via the *Tuned Connection Table*, and then switched on. The pump will start, and after a short stabilisation period, perfusate will be pumped around the phantom at the default flow rate (350ml/min).

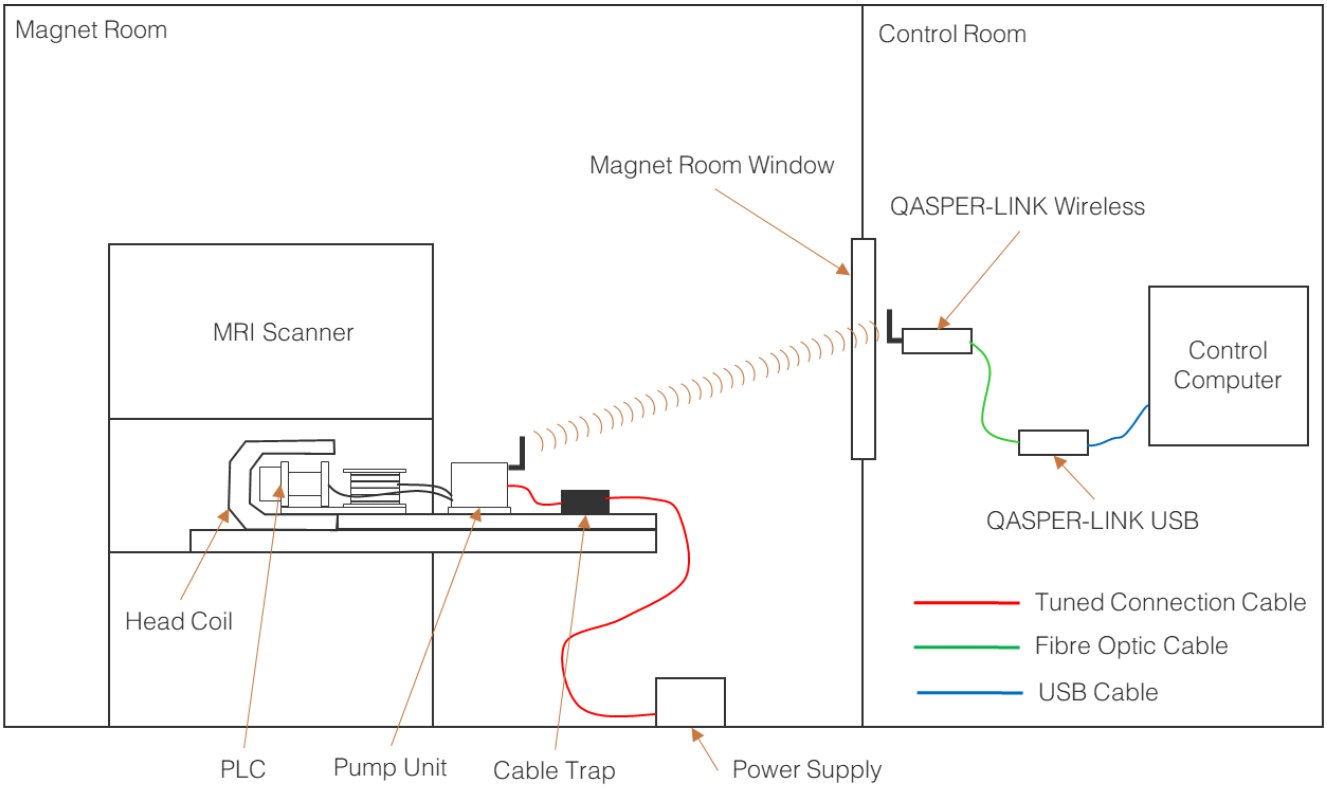
If a paired *QASPER-LINK Wireless Interface* is brought into communications range with the *Phantom* and switched on, a wireless connection will automatically be established between the *Phantom* and *QASPER-LINK Wireless Interface*. The *QASPER-LINK Wireless Interface* then connects via fibre optic cable to the *QASPER-LINK USB Interface*, which connects to a computer by USB so that the QASPER Control Software can monitor and control the *Phantom*.

There are two ways that the data communications equipment can be arranged. If there is a window into the MRI scan room, it is possible that the wireless connection between the *Phantom*

and *QASPER-LINK Wireless Interface* will operate through the window. Alternatively, the *QASPER-LINK Wireless Interface* can be left in the MRI scan room, and a fibre optic cable run through a waveguide. The two techniques are summarised in the table below:

	Communications through window	Communications through waveguide
Requirements	Window in the MRI scan room that does not shield 2.4GHz.	Accessible waveguide in the MRI scan room.
Ease of setup	Easy	Depends on how accessible the waveguide is.
Advantages	Quick to set up	Connection is not dependent on wireless performance through the window.
Disadvantages	The wireless signal may not be strong enough if the room's shielding is particularly effective, or if there is no direct line of sight between the scanner bore and the window.	The supplied fibre optic cable is only 5 metres long.

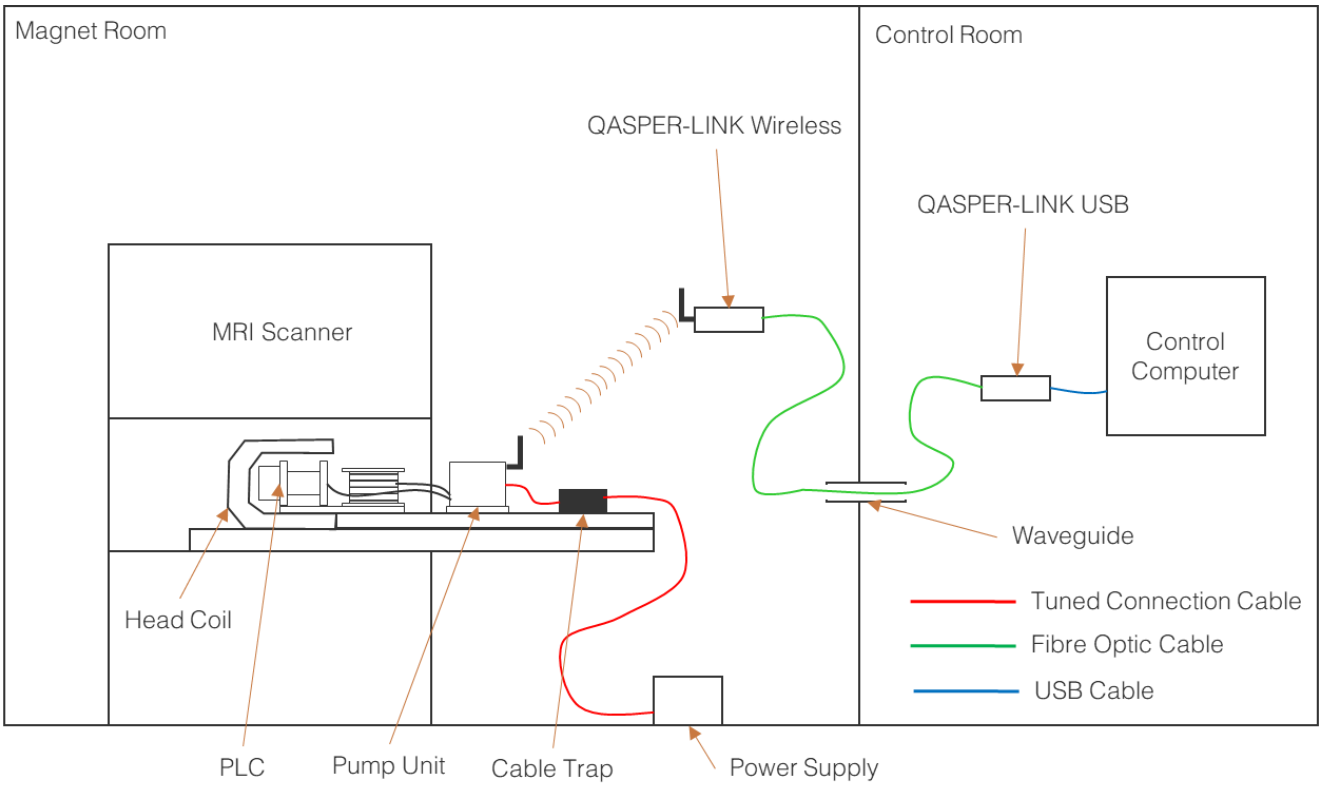
5.2.1 COMMUNICATIONS THROUGH WINDOW



The *QASPER-LINK* wireless communications operate at 2.4GHz. Because an MRI scan room only needs to have effective shielding close to the operating frequency of the MRI scanner, in many cases it is possible that this wireless connection can be established through a window. To do so the *QASPER-LINK Wireless Interface* should be positioned close to the window on the outside of the magnet room (if there is a ledge or windowsill this is ideal). The fibre optic cable then connects between the *QASPER-LINK Wireless Interface* and *QASPER-LINK USB Interface*, which connects by USB to the control computer.

This is the recommended method for communications and should be attempted first. Note that a wireless connection may be established (i.e. the *QASPER-LINK Wireless Interface* connection LED is green), but data throughput too low to be able to reliably receive streamed data using the QASPER pump control software. If the data plotting stutters, or there are gaps in the received data then the connection through the window is sub-optimal, and the waveguide method should be used.

5.2.2 COMMUNICATIONS THROUGH WAVEGUIDE



The fibre optic cable can also be run through a waveguide from the magnet room to the control room. The cable can either be left permanently or removed each time. In this configuration, the *QASPER-LINK Wireless Interface* should be located within the magnet room, close to the waveguide. The supplied fibre optic cable is 5m in length, if a longer cable is required please contact Gold Standard Phantoms.

5.3 CONTROLS AND INDICATORS

5.3.1 GSP 1006 PHANTOM PUMP UNIT

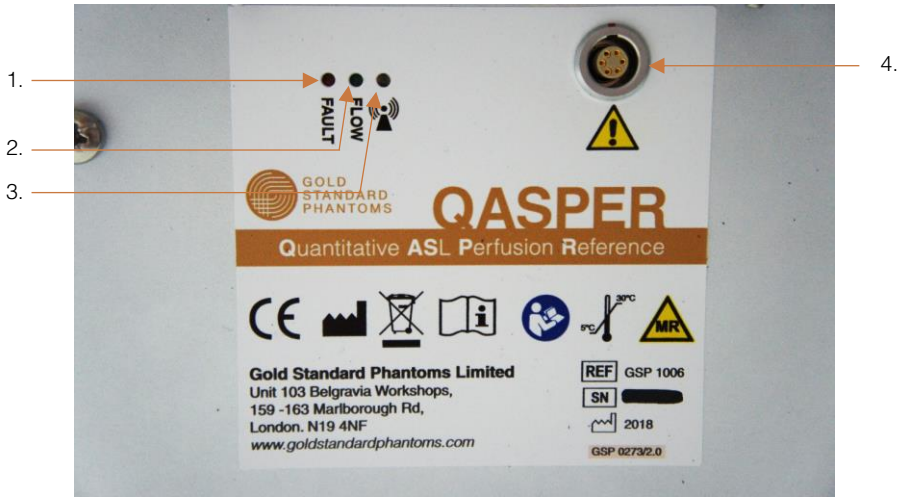


Figure 16: *GSP 1006 Phantom: Pump Unit*, rear panel

ID	Name	Type	Description
1.	Fault LED	Red LED	Lit if there is a fault
2.	Flow LED	Green LED	Indicates whether the pump is on, and the state of the auto flow control. Flow: ✓ / Flow Control: ✓ / Flow Rate Met: — / LED Code: 5Hz Flash Flow: ✓ / Flow Control: ✓ / Flow Rate Met: ✓ / LED Code: On Flow: ✓ / Flow Control: — / Flow Rate Met: — / LED Code: 1Hz Flash Flow: — / Flow Control: — / Flow Rate Met: — / LED Code: Off
3.	Connection LED	Bi-colour Red/Green LED	Indicates the status of the wireless Connection: Waiting for connection: Red and Green LEDs alternately flashing Connected: Green On Fault: Red On
4.	Power Socket	6-Pin Socket	Mates with QASPER Power Cable

5.3.2 GSP 1005 POWER SUPPLY UNIT

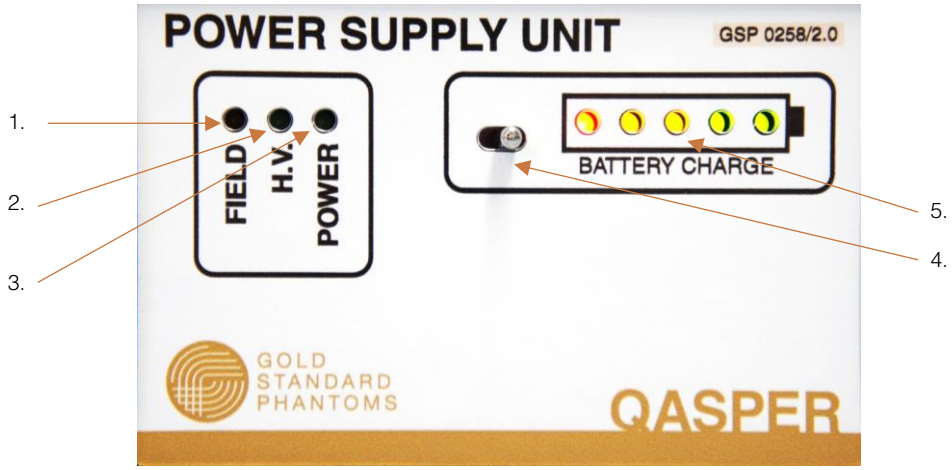


Figure 17: *GSP 1005 Power Supply*, front panel

ID	Name	Type	Description
1.	Field LED	Red LED	Flashes at a rate proportional to the measured ambient magnetic field. Solidly lit when the field exceeds 32mT
2.	HV LED	Green LED	Indicates if the high voltages are supplied to the Phantom. Mode: High Voltages On — LED Code: On Mode: High Voltages Off — LED Code: Off
3.	Power LED	Green LED	Indicates if the Power Supply Unit is on or off. Mode: Power Supply On — LED Code: On Mode: Power Supply Off — LED Code: Off
4.	Battery SoC Switch	Momentary sliding switch	Slide to the left to illuminate the Battery SoC LED Array
5.	Battery SoC Array	LED Array	Displays the battery SoC level: Red — SoC > 0% Yellow — SoC > 20% Yellow — SoC > 40% Green — SoC > 60% Green — SoC > 80%

Figure 18: GSP 1005 Power Supply Unit, rear panel

ID	Name	Type	Description
1.	On/Off Switch	Slide Switch	Turns the Power Supply On (left) and Off (right)
2.	Power Socket	8-Pin Socket	Mates with the QASPER Power Cable, or GSP 1015 Power Supply Charger

5.3.3 GSP 1008 QASPER-LINK WIRELESS INTERFACE

Figure 19: *GSP 1008 QASPER-LINK Wireless Interface*, front panel

ID	Name	Type	Description
1.	Power In LED	Red LED	Indicates whether a valid 5V power source is present at the power socket. Mode: Power input present — LED Code: On Mode: Power input not present — LED Code: Off
2.	Battery Charging LED	Red LED	Indicates if the internal battery is being charged Mode: Battery Charging — LED Code: On Mode: Battery not charging — LED Code: Off
3.	Connection LED	Bi-colour Red/Green LED	Indicates the status of the wireless connection: Mode: Waiting for connection — LED Code: Red and Green LEDs alternately flashing Mode: Connected — LED Code: Green On Mode: Fault — LED Code: Red On
4.	Battery SoC Switch	Momentary sliding switch	Slide to the left to illuminate the Battery SoC LED Array
5.	Battery SoC Array	LED Array	Displays the battery SoC level: Red — SoC > 0% Yellow — SoC > 25% Green — SoC > 50% Green — SoC > 75%

Figure 20: *GSP 1008 QASPER-LINK Wireless Interface*, rear panel

ID	Name	Type	Description
1.	Power Socket	8-Pin Socket	Mates with the *GSP 1014 QASPER-LINK Wireless Interface Charging Cable*
2.	On/Off Switch	Slide Switch	Turns the *QASPER-LINK Wireless Interface* On (right) and Off (left)

3.	Antenna Socket	Coaxial Socket	The *QASPER-LINK Wireless Interface* antenna screws on here. This is normally attached permanently.
4.	FO-Receive	Fibre Optic Receiver	Receives optical data
5.	FO-Transmit	Fibre Optic Transmitter	Transmits optical data

Note: silicone plugs are supplied for the fibre optic transmit and receive ports, these should be inserted when the unit is not in use to prevent the ingress of dust that may degrade performance.

5.3.4 GSP 1026 USB FIBRE OPTIC TRANSCEIVER

Figure 21: *GSP 1026 QASPER-LINK USB Interface*, fibre optic panel

ID	Name	Type	Description
1.	Transmit LED	Red LED	Indicates data is being transmitted. Mode: Data transmitting — LED Code: On Mode: Idle — LED Code: Off
2.	Receive LED	Red LED	Indicates data is being received Mode: Data received — LED Code: On Mode: Idle — LED Code: Off
3.	FO-Receive	Fibre Optic Receiver	Receives optical data
4.	FO-Transmit	Fibre Optic Transmitter	Transmits optical data

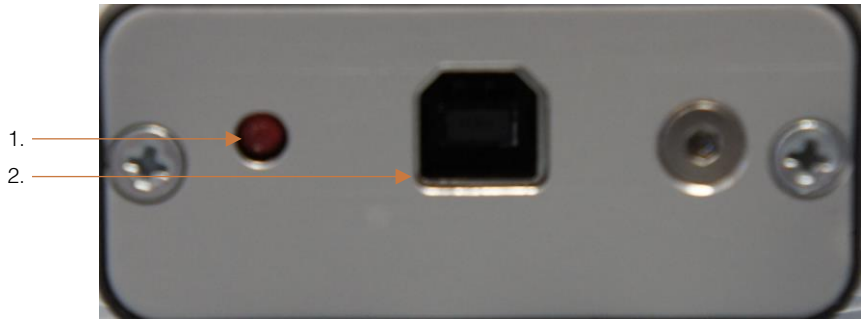


Figure 22: *GSP 1026 QASPER-LINK USB Interface*, USB panel

ID	Name	Type	Description
1.	Power LED	Red LED	Indicates the *QASPER-LINK USB Interface* is on. Mode: Power On — LED Code: On Mode: Power Off — LED Code: Off
2.	USB	USB B Socket	USB cable mates with this socket

5.3.5 GSP 1015 POWER SUPPLY CHARGER

Figure 23: *GSP 1015 Power Supply Unit Charger*, front panel

ID	Name	Type	Description
1.	Error LED	Red LED	Indicates if there is an error. Mode: LED Code Charge Error: Flash 2Hz Charge OK: Off
2.	Charge/Ready LED	Green LED	Indicates the charging status Mode: LED Code Charging: Flash 1Hz Charge Complete: On Not charging: Off

5.3.6 GSP 1018 QASPER-LINK WIRELESS INTERFACE CHARGER

Figure 24: *GSP 1018 QASPER-LINK Wireless Interface Charger*, front panel

ID	Name	Type	Description
1.	Power LED	Orange LED	Indicates if the charger is powered. Mode: LED Code Charger On: On Charger Off: Off

6 GETTING STARTED

6.1 UNPACKING THE EQUIPMENT

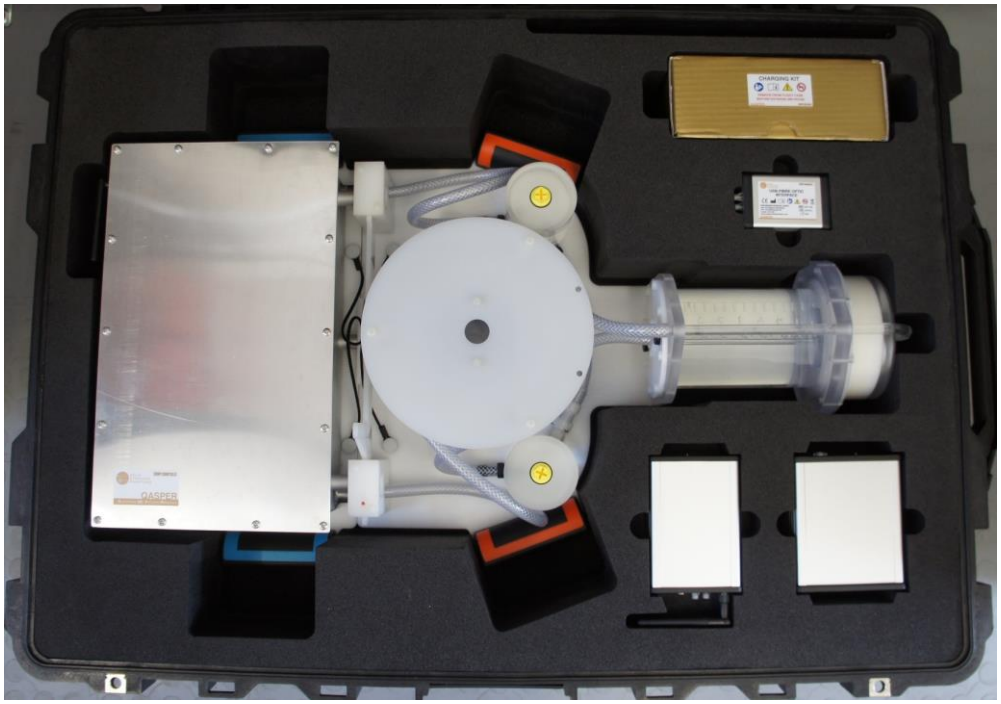


Figure 25: QASPER System in its *Wheeled Transport Case*

The QASPER system is transported and stored within a *Wheeled Transport Case*. The case itself is mostly made from plastic, however a small number of parts are stainless steel. It can be safely brought into the MRI scan room of a 3T or 1.5T magnet, so long as it is kept at the edges of the room, in the same locations that the *Power Supply* can safely operate.

WARNING 3. Before taking the transport case into the magnet room, remove the following MRI Unsafe items: *GSP 1015 Power Supply Charger*, *QASPER-LINK Wireless Interface Charger* and charging cable, *GSP 1026 QASPER-LINK USB Interface*, and USB Cable.

The transport case is intended to last for the service life of the device.

- The weight of the case with its contents is approximately 35kg.
- The outside of the box carries information to identify the device and to show the conditions for transport and storage.

Keep the transport case, to hold the QASPER system with its accessories when the device is not in use, or stored, or returned for servicing.

6.1.1 LIFTING THE PHANTOM

The *Phantom* weighs approximately 12kg, and has four handles, two on the *Perfusion Unit* (orange) and two on the *Pump Unit* (blue). It is designed be lifted by either one or two people.

6.1.1.1 ONE PERSON LIFT

WARNING 4. Due to the size and weight of the *GSP 1006 Phantom*, only physically capable and competent individuals should attempt to lift the Phantom on their own. Adhere to local manual handling safety guidelines/rules. Gold Standard Phantoms accepts no liabilities for personal injury, or damage that occurs to the QASPER system or other equipment when one person lifts the phantom on their own.

For one person to lift the phantom, one orange and one blue handle should be used. Lift the phantom using these handles, taking care to ensure that the Phantom remains flat.

6.1.1.2 TWO PERSON LIFT

Person A should lift using the two orange handles. Person B should lift using the two blue handles. During lifting ensure that the Phantom remains flat.

6.2 BEFORE USE

WARNING 5. Before use, make sure all the functions of the device operate correctly. Also examine the device and its accessories for any loose or damaged parts. Do not use the device if there are loose or damaged parts.

Each time before use, ensure the following

1. The *Power Supply* and *QASPER-LINK Wireless Interface* have sufficient charge. Please see section 7.3 for the charging procedure.
2. Check the system for any signs of damage.
3. Clear any bubbles that are present in the perfusion chamber. Please see section 7.5 for this procedure.

6.3 STORAGE

It is recommended that the phantom is stored in the MRI scan room when not in use, ensuring that the phantom is in thermal equilibrium and preventing exposure to temperature extremes. The phantom can be stored either inside, or outside of the wheeled transport case.

CAUTION 2. Before placing the phantom into the wheeled transport case, ensure that the antenna at the rear of the *Pump Unit* is correctly folded. Failure to do so will result in it being caught in the case, damaging the antenna and other components in the *Pump Unit*.

Storage guidelines:

- Ensure that the Power Supply and QASPER-LINK Wireless Interface are switched OFF after use. Failure to do so will result in flat batteries (see section 7.3).
- On a weekly basis ensure that the Phantom's pump runs for at least 5 minutes. This ensures that the perfusate stays well mixed.
- On a weekly basis check the battery levels and recharge as necessary.
- Store at a temperature between 15°C and 30°C (ideally at 20°C).

6.4 SETTING UP

6.4.1 PHANTOM PLACEMENT

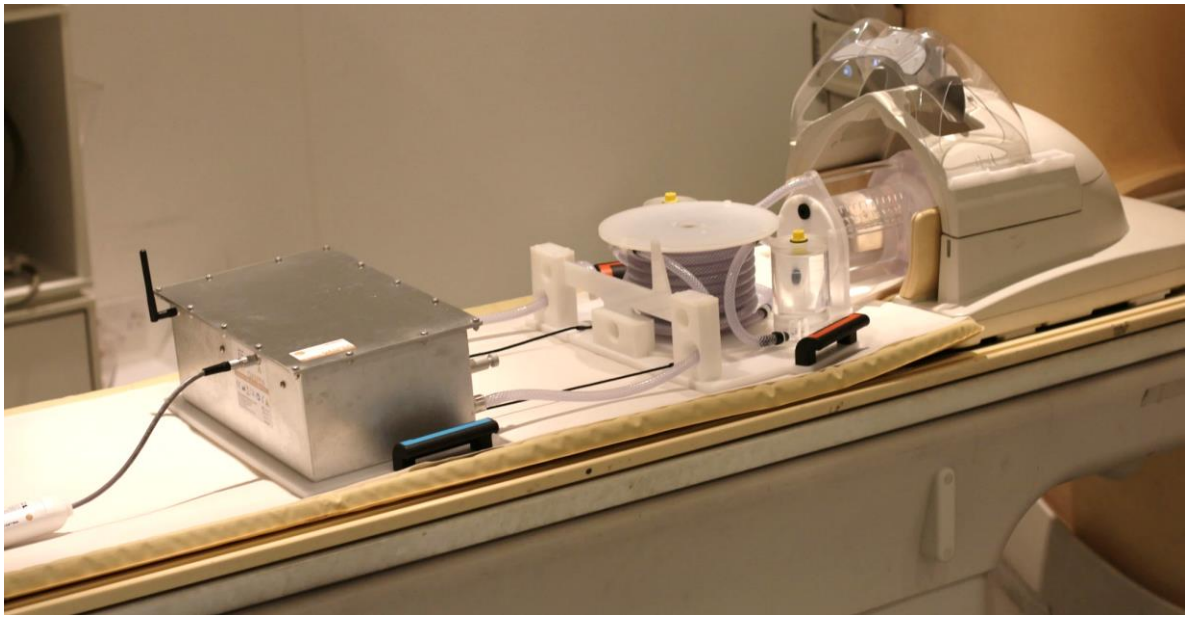


Figure 26: Phantom with *Perfusion Unit* and *Pump Unit* detached, ready to be scanned

1. The phantom should be placed on the patient couch so that the *PLC* is located in the head coil.
2. The antenna at the rear of the *Pump Unit* should be oriented either horizontally or vertically as shown in *Figure 26*.
3. The base split mechanism should be disengaged, and the *Pump Unit* moved to its full extent away from the *Perfusion Unit*.
4. If necessary, use foam padding/sandbags to raise the height of the *Perfusion Unit* so that it can be optimally placed in the head coil.
5. Use the laser market along the top of the *PLC* to align the Perfusion Unit in the L-R direction.

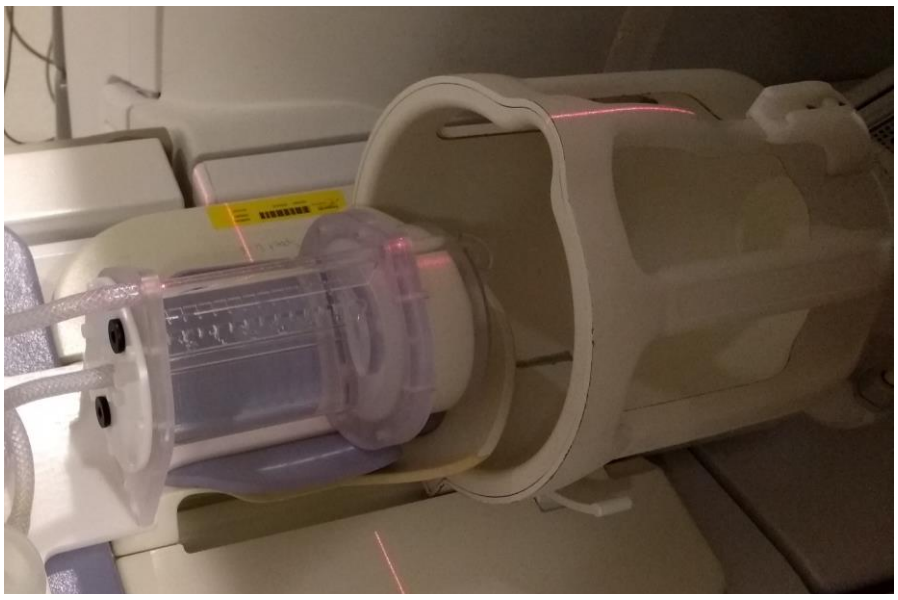


Figure 27: Using the laser marker to align in the L-R direction

6. AP/HF alignment can be done either visually, or with a small plastic spirit level (not supplied).

7. Manually move the phantom to isocentre: the aluminium pump box will experience a lorentz force that opposes motion, causing it to pull away from the Perfusion Unit. This can be avoided by firmly pressing the pump enclosure down onto the patient couch during motion.

CAUTION 3. Do not automatically move the *Phantom* to/from isocentre. If this is done without any means to restrain the *Pump Unit*, it will be moved by the Lorentz force it experiences. If the restraining tethers between the *Pump Unit* and *Perfusion Units* become taught this could result in the *Perfusion Unit* being moved (and thus losing alignment).

6.4.2 GSP 1005 POWER SUPPLY LOCATION

The *Power Supply* should be located within the magnet room, in a location where the ambient magnetic field is below 32mT. The *Power Supply* has a built-in magnetic field sensor and alarm that will sound if it exceeds this limit. Typically, locations at the edges of the magnet room, off axis, and low down on the floor will be well below this.

To establish a safe location, first turn the *Power Supply* on before entering the magnet room. A beep will sound briefly. Enter the magnet room, and locate the *Power Supply* in a suitable location, ensuring that the device does not alarm.

If the *Power Supply* does produce a beep, immediately move further away from the magnet.

WARNING 6. The *Power Supply* contains a li-ion battery that has a steel enclosure. DO NOT bring the *Power Supply* any closer to the magnet once the magnetic field alarm sounds. Failing to do this will pose a projectile hazard.

Once a suitable location has been found, connect the *Phantom* to the *Power Supply* using the *Tuned Connection Cable*.

CAUTION 4. The *Tuned Connection Cable* can only be connected in one orientation. The short end connects to the *Pump Unit*, and the long end to the *Power Supply*. Do not try to connect the other way round: this will damage the connectors and sockets.

6.4.3 GSP 1008 QASPER-LINK WIRELESS INTERFACE LOCATION

There are two options for the *QASPER-LINK Wireless Interface*, depending on the communications configuration (see section 5.2 for more information).

For communications through the window, the *QASPER-LINK Wireless Interface* is best located close to the console room window, however any location that has acceptable wireless reception is acceptable. In this configuration it is also possible to power/charge the *QASPER-LINK Wireless Interface* whilst using it, as the *QASPER-LINK Wireless Interface Charger* can be used outside of the magnet room.

For waveguide communications the *QASPER-LINK Wireless Interface* is located within the magnet room, normally close to an available waveguide. Because the *QASPER-LINK Wireless Interface* charger is MRI Unsafe it cannot be taken into the magnet room, therefore ensure that the *QASPER-LINK Wireless Interface* has sufficient charge before using.

7 OPERATING INSTRUCTIONS

7.1 SWITCHING ON AND OFF

7.1.1 PHANTOM

1. Connect the *Tuned Connection Cable* between the *Power Supply* and *Phantom*.
2. Slide the on/off switch on the *Power Supply* to the on position.
3. After a couple of seconds, the pump will start, the LEDs on the panel on the *Pump Unit* will be lit, and an audible hum will be heard indicating the fluid is being pumped.
4. The pump will always start with a default flow rate of 350ml/min. If this flow rate is being met then the flow LED at the rear of the *Pump Unit* will be lit green.

To turn off reverse these steps. Ensure that the *Power Supply* is turned off after use.

CAUTION 5. Ensure that the *GSP 1005 Power Supply* is switched OFF when not in use. Failure to do so will result in the battery becoming over-discharged.

7.1.2 DATA COMMUNICATIONS

These instructions assume that the Phantom is switched on.

1. Connect the QASPER-LINK USB Interface to a host computer using the USB A-B cable.
2. Connect the QASPER-LINK USB Interface to the QASPER-LINK Wireless Interface using the fibre optic cable.
3. Slide the on/off switch on the QASPER-LINK Wireless Interface to the on position.
4. Wait for the QASPER-LINK Wireless Interface and Phantom to initiate a wireless connection (both connection LEDs will be lit solid green once the connection is established).
5. Start the QASPER Pump Control software on the host computer and connect to the phantom. Follow the instructions in the QASPER Pump Control software manual for further details.

To turn of reverse these steps. Ensure that the QASPER-LINK Wireless Interface is turned off after use.

7.2 BUILT-IN TEST FACILITIES

Both *the GSP 1005 Power Supply* and *GSP 1008 QASPER-LINK Wireless Interface* contain built-in test facilities to check the battery state of charge. This is achieved by sliding the Battery SoC switches on either device, resulting in the Battery SoC LED arrays being lit. Operation is identical on both devices, however:

- *Power Supply*: This feature can be operated regardless of whether unit is powered or not.
- *QASPER-LINK Wireless Interface*: This feature can only be operated when the unit is powered.

7.3 BATTERY RECHARGING

The *Power Supply* and *QASPER-LINK Wireless Interface* both contain batteries. These must be recharged between use.

7.3.1 POWER SUPPLY

The *Power Supply* is charged using the *GSP 1015 Power Supply Charger*. To charge:

1. Ensure that the *Power Supply* is off.

2. Plug the *Power Supply Unit Charger* into a power outlet socket.
3. Plug the charge cable into the Power Socket on the *Power Supply*.

The full charge will take approximately 5-6 hours. During charging the Charge/Ready LED on the Power Supply Charger will flash green and will be lit solidly when charging is complete.

To prevent over-discharge of the battery, the Power Supply Unit will not allow the pump to run if the battery is less than 5%. When this happens please stop using the QASPER system and charge the power supply as soon as possible. This will prevent the risk of over-discharge.

CAUTION 6. If the *Power Supply* battery becomes over-discharged to the point where the internal cut-off circuitry is activated, the *Power Supply Charger* will not be able to successfully charge the battery. If this occurs, please contact Gold Standard Phantoms. To avoid this from happening ensure that the *Power Supply* is recharged after each use, and if not used for a long period of time, ensure that it is checked and recharged every month.

7.3.2 QASPER-LINK WIRELESS INTERFACE

The *QASPER-LINK Wireless Interface* is charged using the *QASPER-LINK Wireless Interface Charger*. To charge:

1. Plug the *QASPER-LINK Wireless Interface Charger* into a power outlet socket.
2. Plug the *QASPER-LINK Wireless Interface Charger Cable* USB connector into the socket in the *QASPER-LINK Wireless Interface Charger*.
3. Plug the other end into the Power Socket on the *QASPER-LINK Wireless Interface*.

When power is supplied to the *QASPER-LINK Wireless Interface*, the 'Power In LED will be lit. If the battery is being charged, the Battery Charging LED will also be lit. Unlike the *Power Supply*, the *QASPER-LINK Wireless Interface* can be switched on and used whilst being charged.

7.4 SEPARATING THE PUMP AND PERFUSION UNIT

The *Pump Unit*'s aluminium enclosure ensures the necessary shielding from the high-power radiofrequency transmissions generated by the MRI scanner, and ensures that no interference is generated by the pump's circuitry that would otherwise result in image artefacts. However, because of its construction it is susceptible to coupling to the induction of eddy currents by the MRI gradients, resulting in significant vibrations that can:

- Affect the flow measurement, resulting in over/underestimation of the flow rate.
- Cause motion/vibrations in the *PLC*, degrading image quality.

To prevent these problems, during MRI scanning the *Pump Unit* and *Perfusion Unit* should be separated, and the *Pump Unit* moved to its full extent away from the *Perfusion Unit*. This is achieved using the *Base Split Mechanism*, illustrated in *Figure 28*.

To separate the *Pump Unit* and *Perfusion Unit*:

1. Slide the lever towards the opposite side of the *Phantom*. The marker is red when the latch is engaged, and white when the latch is disengaged (*Figure 28*.a)
2. Slide apart the *Pump Unit* and *Perfusion Unit* (*Figure 28*.b).
3. Manually feed the hoses through from the *Perfusion Unit* whilst separating the *Pump Unit* and *Perfusion Unit* until the tethers are pulled taught (*Figure 28*.c).

To join the *Pump Unit* and *Perfusion Unit*, the process is reversed:

1. Bring the *Pump Unit* and *Perfusion Unit* together whilst manually feeding the hoses back to the *Perfusion Unit*.
2. Ensure that the base plates of the two parts are touching, and that the tethers are not trapped in between.
3. Slide the lever back to its original position. This requires the latch to correctly engage with the slots on the attachment bosses. Once locked the marker will be red.

It is recommended that this process is practised several times by each user of the QASPER system.

CAUTION 7. Ensure that the base is correctly locked together before attempting to lift the *Phantom*. Failure to do so could result in the two parts becoming separated, potentially resulting the Phantom being dropped and damaged.

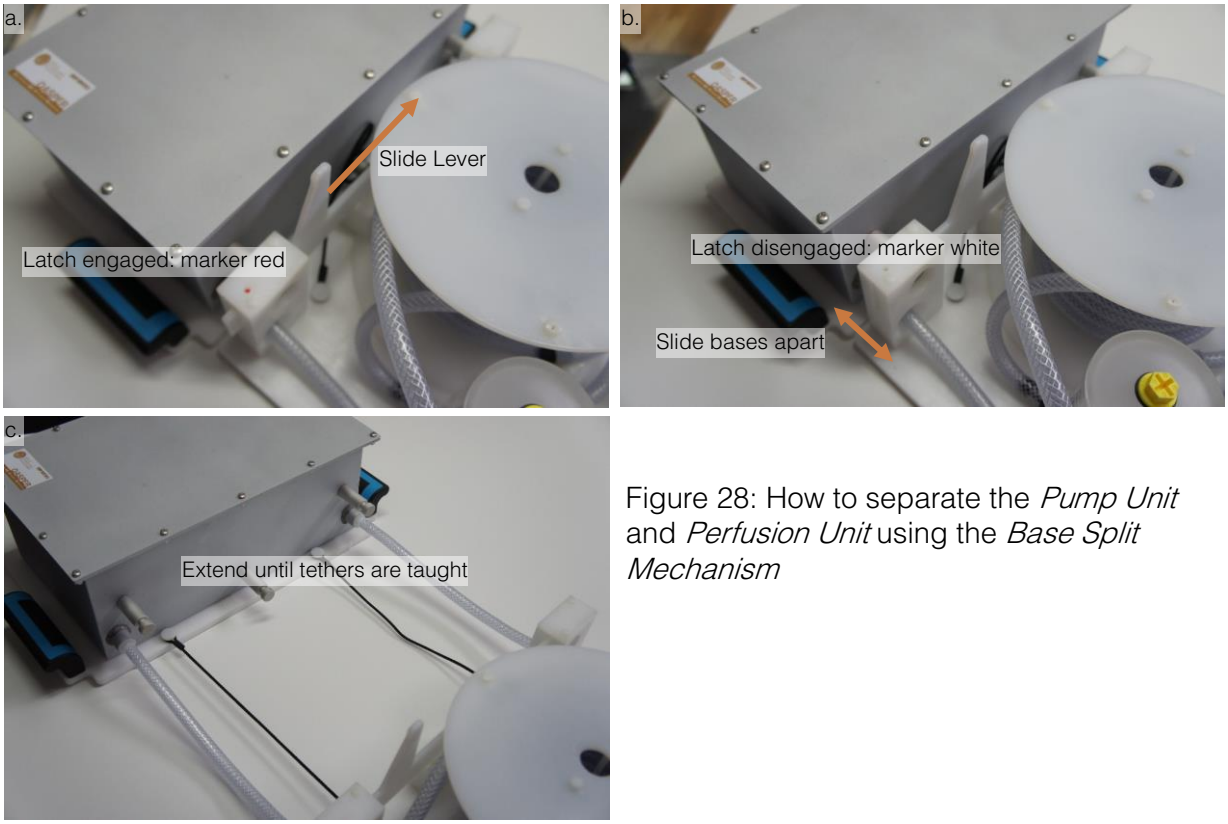


Figure 28: How to separate the *Pump Unit* and *Perfusion Unit* using the *Base Split Mechanism*

7.5 AIR CLEARANCE

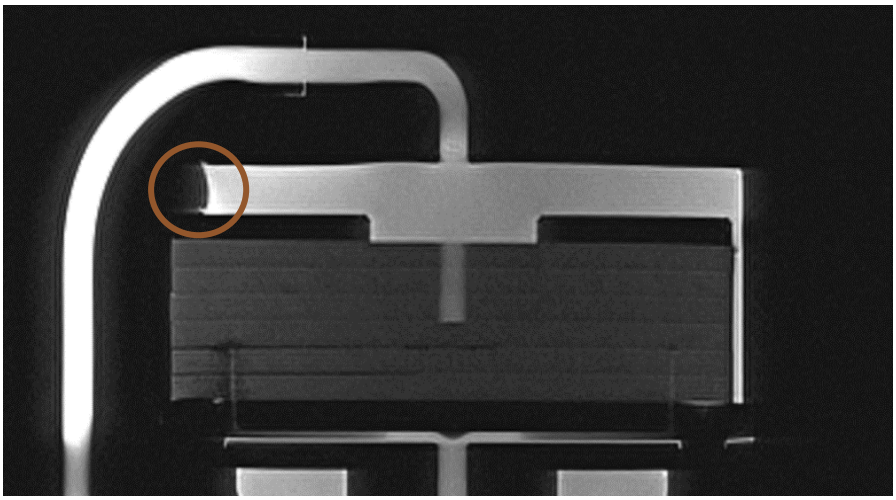


Figure 29: Presence of air in the perfusion chamber

From time-to-time, bubbles may form in the perfusion chamber, as shown by the circled region in the MRI image in *Figure 29*. This is quite normal and is a consequence of the porous material become increasingly saturated with perfusate over time. It is advised to remove these from the perfusion chamber, as they will lead to image artefacts. To do so, perform the following procedure.

1. Separate the *Perfusion Unit* and *Pump Unit* (see section 7.4) so that the tethers are fully taught.
2. Turn the pump on.
3. Tilt the *Perfusion Unit* so that the *PLC* is oriented vertically.
4. The bubbles will now be able to flow out of the perfusion chamber. Manually adjust the inclination angle to help move the bubbles to the exit of the perfusion chamber.

The perfusion chamber should be checked visually for the presence of air/bubbles before each scan session as they may affect the perfusion measurement.

7.6 QASPER PUMP CONTROL SOFTWARE

The latest version of the QASPER Pump Control Software can be downloaded from www.goldstandardphantoms.com/downloads. A user guide is included with the software, please refer to this.

8 USING THE QASPER SYSTEM FOR ASL QUALITY ASSURANCE MEASUREMENTS

Quality Assurance (QA) tests in MRI typically involves routine imaging of a test object (i.e. phantom) with a consistent protocol. By keeping the test conditions as similar as possible each time, differences due to changes in the imaging hardware can be detected.

Making QA measurements with the QASPER system follows this principle, and to perform the most effective QA protocol it is useful to understand the sources of variability in the operation of the QASPER system that attribute to variance in the ASL perfusion measurement.

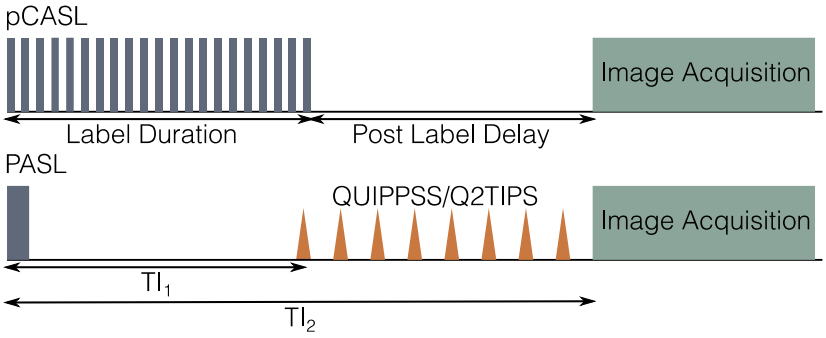


Figure 30: pCASL and PASL Labelling Strategies

The two main labelling strategies for ASL are detailed in Figure 30: pseudo-continuous ASL (pCASL) and pulsed ASL (PASL). Both share similarities in that the inflow is labelled, creating a bolus of defined temporal length (Label Duration for pCASL and TI1 for PASL with QUIPPSS/Q2TIPS), and after a prescribed period of time an image is acquired, usually with a fast acquisition technique such as EPI or 3D-GRASE. This is performed for both a label condition, and a control (where no labelling takes place but all other parameters are the same), and then these images are subtracted to obtain a perfusion weighted image, also known as ΔM. Because the actual perfusion signal is of low SNR, multiple control/label pairs are acquired and then averaged together.

The ΔM image has arbitrary units. For quantification, this must be divided by an image of the equilibrium magnetisation, M_0, that is obtained from the same acquisition, resulting in the normalised ΔM:

$$\Delta M_{Normalised} = \frac{\Delta M}{M_0}$$

The normalised ΔM can then be fitted to a model for quantification of the perfusion rate. For more information on the acquisition, processing and quantification of ASL, please see the 2015 ASL White Paper: https://doi.org/10.1002/mrm.25197.

8.1 RECOMMENDED QASPER QA PROTOCOL

QA requirements vary from site to site and study to study, however as a starting point we recommend a protocol that is based around some ASL acquisitions at a few different QASPER flow rates, and a few other scans that give some additional information about whether the QASPER phantom is functioning correctly.

Scan	Purpose	QASPER State
ASL	Assess perfusion measurements	At each flow rate tested
M0 (if not part of the ASL acquisition)	Acquire the equilibrium magnetisation normalisation image	At each flow rate tested
Phase Contrast Velocimetry in the label chamber/tube.	Assess the velocity and actual flow rate in the phantom system.	At each flow rate tested
TOF	Assess the integrity of the flow path	Flowing, at maximum flow rate tested for maximum SNR.
T1 Map (optional)	Assess the T1 of the perfusate	Static
T2 Map (optional)	Assess the filling of the porous material	Static

Flow rates in the range of 200ml/min to 350ml/min provide a range of transit times and perfusion rates. To determine a suitable ASL protocol we recommend starting with a protocol that is used on patients/subjects and then adapting the field of view for the QASPER phantom (as it is somewhat smaller than a head). QASPER was designed to have a similar transit time to that found in humans, so labelling parameters do not need to be modified. If you require any assistance in setting up a QA protocol please contact Gold Standard Phantoms directly – info@goldstandardphantoms.com.

8.2 QASPER QA ON GSP CLOUD

QASPER comes with a subscription to GSP Cloud for cloud-based analysis of QASPER data for quality assurance. An account for your organisation should have been set up when the phantom was purchased. To use GSP Cloud, the DICOM files are uploaded as a zip archive, after which automated processing takes place to calculate key QA metrics that can be tracked longitudinally.

GSP Cloud has an additional requirement for a QA protocol: one of the scans needs to be 'synchronised' with the QASPER Pump Control software. This is simply done by clicking the 'synchronise' button in the software when the scan starts. After uploaded data to GSP Cloud, the user needs to indicate which of the acquisitions was synchronised. We recommend doing this for either the scout/localiser, or the first ASL scan, however in practise it can be any scan. For more information please view the QASPER Pump Control Software user manual.

8.3 SOURCES OF VARIABILITY

The table below lists the most common sources of variation when using the QASPER phantom for ASL QA. Note however that this is not an exhaustive list. It also assumes a single MRI scanner, and that acquisition parameters (FOV, image matrix, TE, TR, etc) are kept consistent.

Source Name	Source Type		Effect
Flow Rate	Phantom operation	↑	Shorter transit time, increased perfusion rate
		↓	Longer transit time, decreased perfusion rate. Signal may remain in feeding tubes.
Temperature	Phantom operation	↑	Decreased viscosity of the perfusate, minimal effect on flow in range 15-25C
		↓	Increased viscosity of the perfusate, minimal effect on flow in the range 15-25C. Below 15C the viscosity may be too great to achieve the desired flow rate.

Label Plane Distance from centre of FOV	Label parameter	↑	Label plane further away from centre of FOV, transit time to porous material increased, less signal dispersion for given labelling parameters
		↓	Label plane closer to centre of FOV, transit time to porous material decreased, increased signal dispersion for given labelling parameters.
Label Duration (pCASL/CASL only)	Label parameter	↑	More labelled perfusate delivered to the perfusion chamber, increased perfusion signal, increased signal dispersion for given Post Label Delay.
		↓	Less labelled perfusate delivered to the perfusion chamber, decreased perfusion signal, decreased signal dispersion for given Post Label Delay.
Post Label Delay (pCASL/CASL only)	Label parameter	↑	More labelled perfusate delivered to the perfusion chamber, increased signal dispersion. < Transit time: Labelled perfusate remains in the feeding tubes. > Transit time: All labelled perfusate delivered, wash in of unlabelled perfusate.
		↓	Less labelled perfusate delivered to the perfusion chamber, decreased signal dispersion. < Transit time: labelled perfusate remains in the feeding tubes
Inversion Time/TI2 (PASL only)	Label parameter	↑	More labelled perfusate delivered to the perfusion chamber, increased signal dispersion.
		↓	Less labelled perfusate delivered to the perfusion chamber, increased signal dispersion.
Bolus Duration/TI1 (PASL with QUIPPSS/Q2TIPS only)	Label parameter	↑	More labelled perfusate delivered to the perfusion chamber, increased signal dispersion for given TI2.
		↓	Less labelled perfusate delivered to the perfusion chamber, decreased signal dispersion for given TI2.
Note that for PASL, the labelled bolus of perfusate will only be completely delivered to the perfusion chamber if TI2 – TI1 > Transit Time.			
FOV Location and alignment.	Acquisition parameter		Partial volume effects in the porous material will be inconsistent if this varies greatly.

8.4 EQUIPMENT SETUP

For quality assurance measurements please set up the system as described in section 6.4. Care should be taken to ensure that the phantom is positioned and aligned in a repeatable manner.

As each MRI scanner is different, in particular the relative heights of foam pads, RF coils etc on the patient couch, it is recommended that some time is taken to establish the correct combination of foam pads gives best results, and then this is documented with photographs as local standard

operating procedure. (SOP). Best results can be achieved by:

- Use large foam pads placed underneath the *Pump Unit* and *Perfusion Unit* so that the *Phantom* is raised high enough to be able to go flat into the head coil.
- Support the 'head' end of the *Phantom* in the head coil with foam padding so that it remains level. A small plastic spirit level can help here, but checking by eye is usually sufficient.
- Use the laser crosshair marker to ensure that the *PLC* is square with the MRI scanner (see Figure 31)

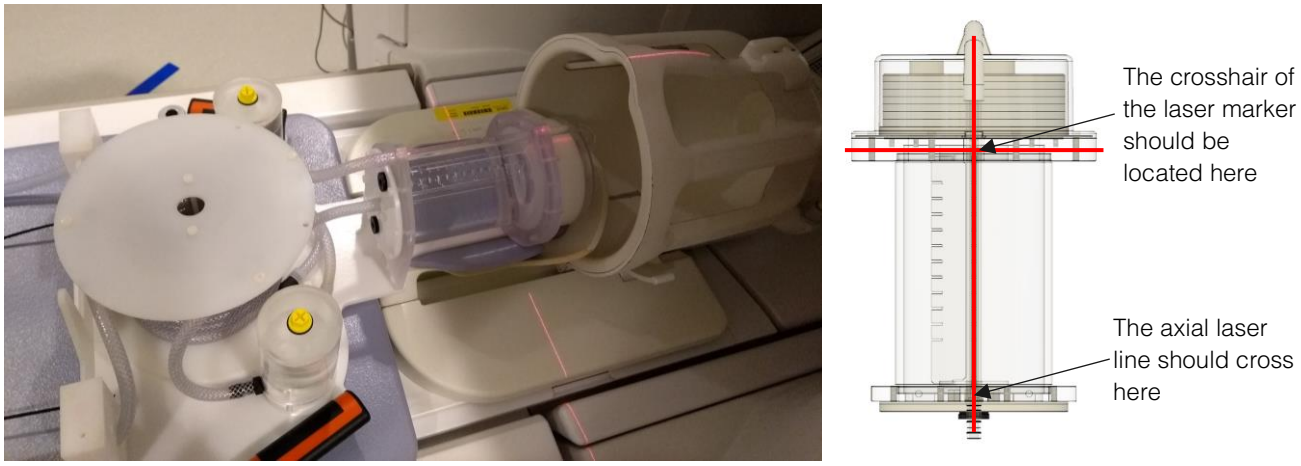


Figure 31: Standardised alignment of the QASPER phantom in a MRI scanner

8.5 MRI SCAN PLANNING

For robust and repeatable planning of ASL scans, the following should be adhered to:

Parameter	Requirements
FOV Location	Locate centre of FOV at the centre of the porous stack (see Figure 32), between the third and fourth porous layers.
FOV Orientation	Transverse slices, obliquely aligned with the porous stack if necessary.
FOV Size	Ensure the FOV covers the entire perfusion chamber in the slice direction. This is so that certain landmarks can be utilised for image registration.
Label Plane Location (pCASL only)	Locate at a fixed offset from the centre of the FOV. There are fiducial markers in the label chamber at 50mm, 60mm, 70mm, etc. to assist.

Other parameters should be standardised and kept the same for each QA measurement that is to be compared longitudinally (i.e. so that apples can be compared with apples).

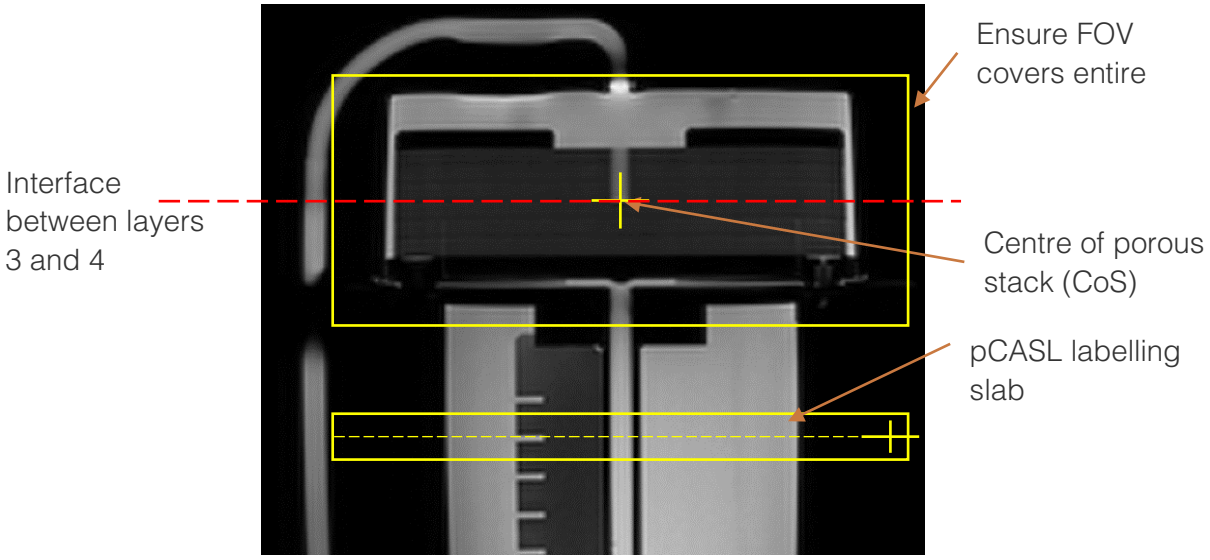


Figure 32: FOV Placement.

9 MR CONDITIONAL STATEMENTS

The following components of the QASPER system are defined as MR Conditional. In all cases testing was performed on Siemens Trio/Verio/Skyra/Prisma 3T, Philips Ingenia/Achieva 3T, GE Discovery MR750/Signa/PETMR 3T.

All other components should be considered MR unsafe and MUST NOT BE BROUGHT INTO THE MR ENVIRONMENT.

9.1 GSP 1006 PHANTOM

The *GSP 1006 Phantom* can be safely scanned under the following conditions:

- The pump should be disengaged and positioned so that the tethers are fully extended
- Static magnetic field of up to 7 Tesla.
- Spatial gradient field of up to 80mT/m
- Maximum whole body averaged SAR of 2 W/kg for 15 minutes of scanning.
- Using the correct cable trap for the MRI scanner.

9.2 GSP 1005 POWER SUPPLY

The *GSP 1005 Power Supply* can be safely used in the MR environment under the following conditions:

- The magnetic field alarm is silent. This alarm will sound when a static magnetic field is 32mT or greater.
- The power supply should be located well away from the magnet, on the ground and off-axis from the magnet.
- The *Power Supply* contains a steel-cased battery and so poses a projectile hazard.
- DO NOT BRING THE POWER SUPPLY CLOSER TO THE MAGNET THAN THE POINT AT WHICH THE ALARM SOUNDS.

9.3 TUNED CONNECTION CABLE

During MRI scanning, the QASPER system must only be used with the correct cable trap for that MRI scanner. The cable trap end of the cable connects to the phantom, and the long end of the cable connects to the power supply; each end uses a different connector so the cable can only be connected in one orientation.

9.4 GSP 1008 QASPER-LINK WIRELESS INTERFACE

The *GSP 1008 QASPER-LINK Wireless Interface* can be safely used in the MR environment under the following conditions:

- It should be placed around the edge of the scan room, close to a waveguide, and in direct sight of the patient end of the bore of the MRI scanner.
- It can be brought as close to the magnet as the *Power Supply*, there is no alarm to indicate the ambient magnetic field, however this device does not pose a projectile hazard.

9.5 GSP 1019 FIBRE OPTIC CABLE

This fibre optic cable should be passed through a waveguide and connects to the Bluetooth Transceiver. The fibre optic connectors have stainless steel crimp rings, which are weakly magnetic and so the cable should be kept at the edge of the scan room.