

MRI Guide

Is my patient safe in an MRI?

- ✓ Implantable valve
Polaris®
Sophy®
- ✓ ICP Catheter
Pressio®





INTRODUCTION

If you work as an imaging technician, it's possible that you might encounter patients who have Sophysa medical devices. It is important for you to be aware of the potential risks associated with MRI scans as they are related to our devices as well as of the precautions that should be considered.

This MRI-Guide reviews the risks and details how to safely perform an MRI examination for you and your patient.

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IMPLANTABLE VALVES

The basics



MR CONDITIONAL EXAMINATION CONDITIONS

POLARIS®



▶ 1.5 or 3 Tesla



▶ Spatial gradient magnetic field limited to 19 T/m



▶ Whole body averaged SAR (Specific Absorption Rate) for 15 minutes exposure limited to:

- 2 W/kg (normal operating mode)
- 4 W/kg (mode of first level controlled operation)

Maximum Width of Artifacts at 3 Tesla

Valve	Spin Echo sequences	Gradient Echo sequences
Polaris®	59 mm max.	71 mm max.

Polaris® valve

MRI Stable Adjustable valve

Products references

SPV-140	SPVA-140	SPVB	SPVA-SX	SPVB-2010
SPV	SPVA	SPV140-SX	SPVB-SX	
SPV-300	SPVA-300	SPV-SX	SPV-2010	
SPV-400	SPVA-400	SPVA-140-SX	SPVA-2010	



MR CONDITIONAL EXAMINATION CONDITIONS



▶ 1.5 or 3 Tesla



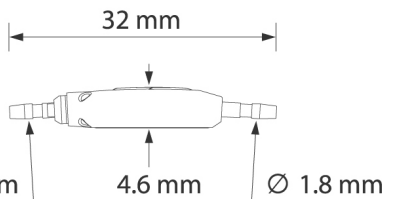
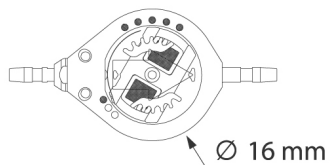
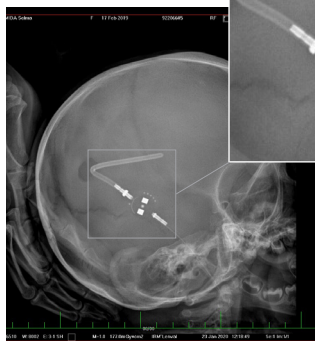
▶ Spatial gradient magnetic field limited to 19 T/m



▶ Whole body averaged SAR (Specific Absorption Rate) for 15 minutes exposure limited to:

- 2 W/kg (normal operating mode)
- 4 W/kg (mode of first level controlled operation)

X-Ray of the implanted valve



Immediate effects

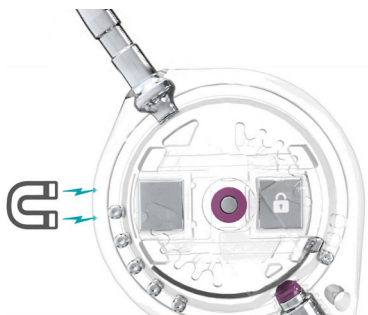


After a 15-minute exposure a 3.4 °C maximum global heating, including a 3.2 °C environmental heating and a **0.2 °C heating related to the device.**

Maximum Width of Artifacts at 3 Tesla

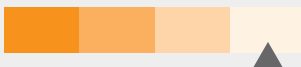
Spin Echo sequences	59mm max.
Gradient Echo sequences	71mm max.

MRI-STABILITY



- The rotor of the Polaris valve includes a patented magnetic locking system.

MRI-Stable valve



Low risk of the valve pressure being accidentally changed



It is important to inform the physician about the potential risk of inadvertent changes to the pressure.

Although the valve's self-locking system was designed to be resistant to magnetic fields, it is still recommended to confirm the pressure setting of the valve both prior to and following an MRI scan or exposure to a powerful magnetic field.

To prevent any pressure change



It is important to ensure that the patient remains still while in the immediate vicinity and inside the tunnel during MRI examinations. If there is a rotational movement on the valve simultaneous with exposure to a powerful magnetic field (for example: 3-Tesla MRI) there is a possible risk of the setting being accidentally changed.

Sophy[®] SM8

Adjustable valve MRI-Unstable

Products references*

SM8-140	SM8-400	SM8A-2010	SM8-2030
SM8	SM8-400-2010	SM8B-2010	SM8-2031
SM8-2010	SM8A	SM8-2020	SM8-2040
SM8-300	SM8B	SM8-2021	

*These references are not available for sale, but you may have a special case with this type of valve.

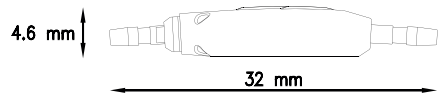
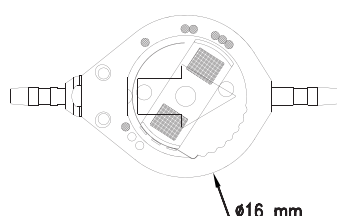
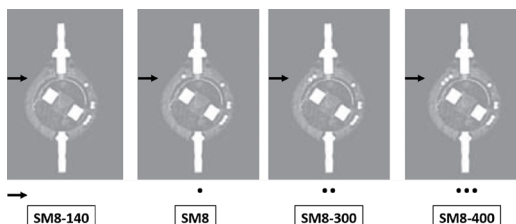
MR CONDITIONAL EXAMINATION CONDITIONS

▶ **1.5 or 3 Tesla**

▶ **Spatial gradient magnetic field limited to 19 T/m**

▶ **Whole body averaged SAR (Specific Absorption Rate) for 15 minutes exposure limited to:**

- 2 W/kg (normal operating mode)
- 4 W/kg (mode of first level controlled operation)



Immediate effects



After a 15-minutes exposure a 3.6 °C maximum global heating, including a 3.4 °C environmental heating and a **0.2 °C heating related to the device.**

Maximum Width of Artifacts at 3 Tesla	
Spin Echo sequences	59mm max.
Gradient Echo sequences	77mm max.

MRI-UNSTABLE PRESSURE VALVE



It is important to inform the physician about the potential risk of inadvertent changes to the pressure.

- The SM8 devices are not fitted with a magnetic lock, so there is a risk of the pressure being accidentally changed in the presence of a magnetic field.



High risk of the valve pressure being accidentally changed



Check the valve pressure settings before and after undergoing an MRI exam
(with the adjustment kit or the valve X-Ray).


Sophy[®] SM1 Monopressure Valve

Products references*


SM1-L	SM1A-L	SM1B-L	SM1-2010L	SM1A-2010L
SM1-M	SM1A-M	SM1B-M	SM1-2010M	SM1A-2010M
SM1-H	SM1A-H	SM1B-H	SM1-2010H	SM1A-2010H

*These references are not available for sale, but you may have a special case with this type of valve.


MR CONDITIONAL EXAMINATION CONDITIONS



▶ 1.5 or 3 Tesla

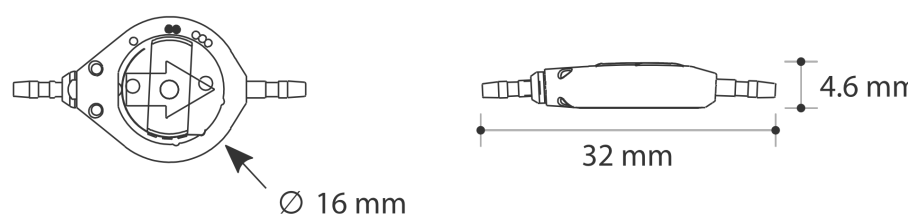


▶ Spatial gradient magnetic field limited to 19 T/m




▶ Whole body averaged SAR (Specific Absorption Rate) for 15 minutes exposure limited to:

- 2 W/kg (normal operating mode)
- 4 W/kg (mode of first level controlled operation)



SM1 valves are monopressure devices, so there is **no risk of any accidental pressure change**. There are 3 different pressures for the Sophy Mini Monopressure valve, Low (L), Medium (M) and High (H).

Immediate effects



After a 15-minutes exposure a 3.2 °C maximum global heating, including a 2.9 °C environmental heating and a **0.2 °C heating related to the device**.

Maximum Width of Artifacts at 3 Tesla

Spin Echo sequences	9mm max.
Gradient Echo sequences	12mm max.

Reservoirs and catheters

Products references

RE-2010	RE-1021	RE-1030	RE-1031	RE-1141
RE-2011	RE-2021	RE-2023	RE-2031	RE-1241

And all ventricular, pectoral, atrial and peritoneal catheters references.

MR MR SAFE



Adjustment Kits

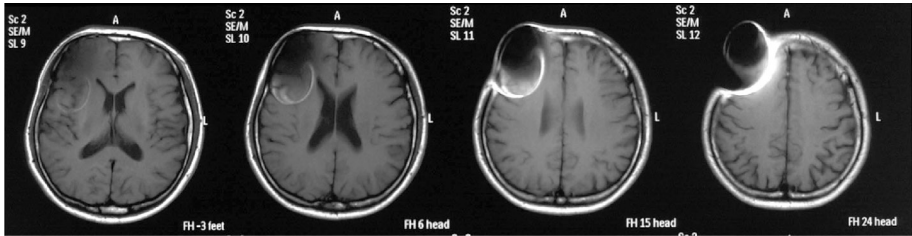
PAK2	SAK
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MR UNSAFE



Do not place the Magnet close to a powerful magnetic field (e.g. MRI).
It could become a dangerous projectile or its performance could be affected.

How to handle artifacts?



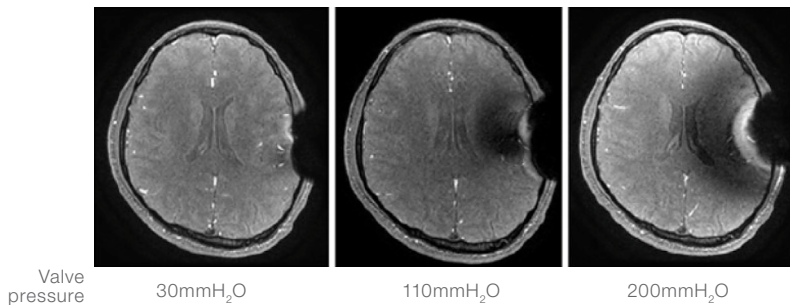
How to choose the correct MRI sequences?

The selection of MRI sequences is typically tailored to the specific diagnosis, although certain principles can be applied:

- Prefer Spin Echo Imaging with the lowest possible number of echoes per train (TSE-factor)
- Use a refocusing angle of 180°
- Use a low T_e
- Exclude Gradient Echo and EPI type images

Valve Adjustment

Consider the option of temporarily changing* the valve setting if MRI artifact is problematic.



*Setting Pressure can change the size and shape of MRI artifacts caused by adjustable shunt valves : a study of the 4 newest models - Uchida, Amano, Nakatogawa, Masui, Ando, Nayakama, Sata Sameshima and Tanaka - J Neurosurg May 18, 2018

ICP/T Catheters

The basics



MR CONDITIONAL EXAMINATION CONDITIONS



▶ 1.5 or 3 Tesla



▶ Maximum spatial field gradient of 19 T/m (extrapolated).



▶ Whole body averaged SAR (Specific Absorption Rate) limited to 2 W/kg (Normal Operating Mode) for 15 minutes exposure at 1.5 or 3 Tesla.



▶ Do not scan a patient with a high body temperature.



▶ Do not use an emission/reception head coil (RF emission coil for the head) or a simple RF emission head coil. Only use an RF emission/reception whole body coil or an RF emission whole body coil with a simple RF reception head coil.

Maximum Width of Artifacts at 3 Tesla

Pressio® catheters

Gradient Echo sequences






59 mm max.

Pressio® Catheters (ICP/T)

Products references

PSO-PT	PSO-PB	PSO-VT
PSO-PTT	PSO-PBT	PSO-VTT

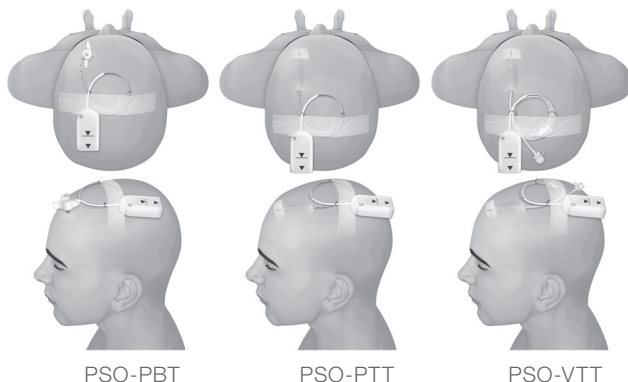
MR CONDITIONAL EXAMINATION CONDITIONS

-  **1.5 ou 3 Tesla**
-  Whole body averaged SAR (Specific Absorption Rate) limited to 2 W/kg (Normal Operating Mode) for 15 minutes exposure at 1.5 or 3 Tesla.
-  Maximum spatial field gradient of 19 T/m (extrapolated).
-  Do not scan a patient with a high body temperature.
-  Do not use an emission/reception head coil (RF emission coil for the head) or a simple RF emission head coil. Only use an RF emission/reception whole body coil or an RF emission whole body coil with a simple RF reception head coil.

Before : Preparation MRI examination - 2 solutions

MANUAL COILING

Coil the non-inserted portion of the catheter on top of the patient's head, creating loops of approximately 5 cm in size (up to 4 or 5 loops), positioned perpendicular to the primary magnetic field.



MRI SUPPORT DEVICE

PSO-MRI



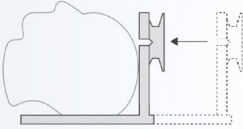
Pressio[®] Catheters (ICP/T)



MR CONDITIONAL EXAMINATION CONDITIONS

« MR Conditional » status requires an appropriate **positioning of Pressio[®] Catheter on MRI Support** as shown on the following pictures:

1



MR Support positioning

Place the support as close as possible to the patient's head.

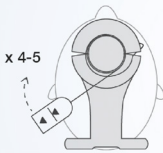
2



MR Support centering

Place MRI Support in the center of the table. Ensure that the MRI Support is aligned with the patient's head.

3



Pressio[®] Catheter coiling

Depending on length, the Pressio[®] Catheter may be coiled 4 or 5 times around the support.

4



Connector fixation

Affix Pressio[®] Catheter connector into rim of MRI Support spool.

Immediate effects



Maximum temperature rise of less than **2.2 °C** after **15 minutes of continuous scanning.**

Maximum Width of Artifacts at 3 Tesla

Gradient Echo sequences	55mm max.
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Pressio[®]2 ICP Monitor System

Products references

PSO-4000	PSO-MC01	PSO-MC04	PSO-MCT-A	PSO-MCT-D
PSO-EC30	PSO-MC02	PSO-MC05	PSO-MCT-B	PSO-MCT-E
	PSO-MC03	PSO-MC08	PSO-MCT-C	PSO-MCT-F



MR UNSAFE

The Monitor and the catheter extension cable are not suitable for use in an MRI environment or during an MRI examination.



Always disconnect the Pressio 2 ICP/T Catheter (PSO-PTT, PBT or VTT) from the Catheter Extension Cable (PSO-EC30) before any MRI examination.



Notes

A series of horizontal dotted lines provided for taking notes.

Notes

A series of horizontal dotted lines for writing notes.

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