

MRI Guide

Is my patient safe in an MRI?

- ✓ Polaris®
- ✓ Sophy® Mini SM8
- ✓ Sophy® Mini SM1





INTRODUCTION

As an imaging professional, you regularly receive patients equipped with Sophysa medical devices and you wonder about the risks related to MRI and the precautions to take?

This guide is for you!

It reviews the main risks and details the safety rules to be applied. It gives you the keys to a safe examination for you and your patient.

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THE BASICS



MR CONDITIONAL EXAMINATION CONDITIONS

POLARIS®, SOPHY® SM8, SOPHY® SM1



▶ 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)

ARTIFACTS WIDTH MAXIMUM at 3 Teslas

Valve	Spin Echo sequences	Gradient Echo sequences
Polaris®	59 mm max.	71 mm max.
Sophy® SM8	59 mm max.	77 mm max.
Sophy® SM1	9 mm max.	12 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 ou 3 Teslas



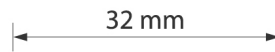
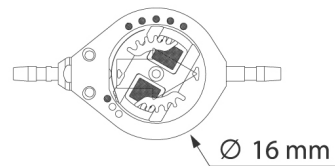
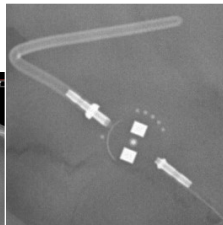
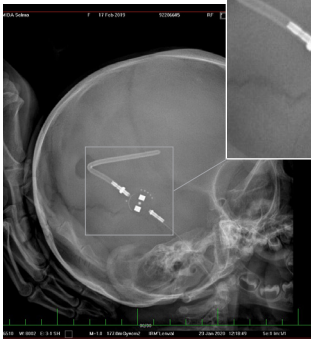
▶ Spatial gradient magnetic field limited to 19 T/m



▶ 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



4.6 mm

Ø 1.8 mm

Immediate effects

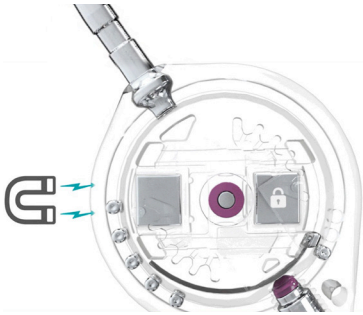


After a 15-minutes exposure a 3.4 °C maximum global heating, including a 3.2 °C environmental heating and a **0.2 °C heating related to the device.**

ARTIFACTS WIDTH MAX. at 3 Teslas

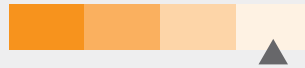
Spin Echo sequences	59mm max.
Gradient Echo sequences	71mm max.

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



Warn the physician about the possible risk of the pressure being accidentally changed.

Even though the self-locking system of the valve was designed not to be sensitive to magnetic fields, it is recommended that the pressure setting of the valve is checked before and after the MRI examination or following exposure to a powerful magnetic field.

To prevent any pressure change



During MRI examinations, make sure the patient remains immobile in the immediate proximity to the tunnel and inside it. 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 pressure 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	



MR CONDITIONAL EXAMINATION CONDITIONS



▶ 1.5 ou 3 Teslas

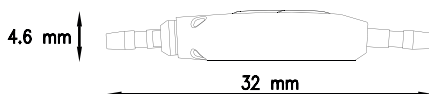
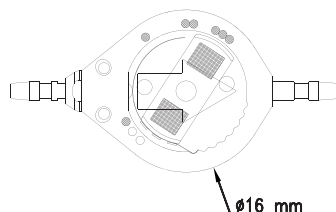
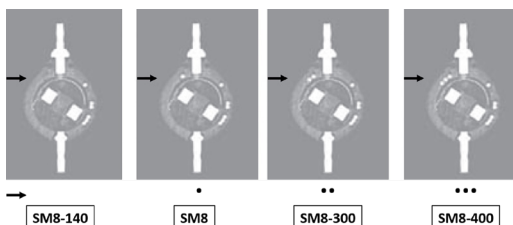


▶ Spatial gradient magnetic field limited to 19 T/m



▶ 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.**

ARTIFACTS WIDTH MAX. at 3 Teslas

Spin Echo sequences	59mm max.
Gradient Echo sequences	77mm max.

MRI-UNSTABLE PRESSURE VALVE



Warn the physician about the possible risk of the pressure being accidentally changed.

- 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 Monopression 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



MR CONDITIONAL EXAMINATION CONDITIONS



▶ 1.5 ou 3 Teslas

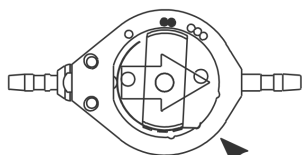


▶ Spatial gradient magnetic field limited to 19 T/m

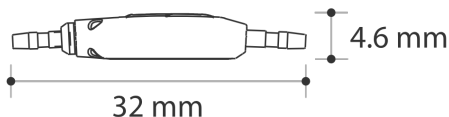


▶ Whole body averaged SAR (Specific Absorption Rate) for 15 minutes exposure limited to:

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



Ø 16 mm



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**.

ARTIFACTS WIDTH MAX. at 3 Teslas

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
All ventricular, pectoral, atrial and peritoneal catheters				

MR

MR SAFE



Adjustment Kits

PAK2

SAK



MR UNSAFE



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

Notes

A series of horizontal dotted lines for writing notes.



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