MRI Safety Information

MR Conditional

MR

A patient with one product of the type *aerstent TBY* may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Parameter	Notes
Product name	aerstent TBY
Manufacturer	bess pro gmbh Gustav-Krone-Str. 7
	D—14167 Berlin
	Germany
Distributor	Leufen Medical GmbH
	Gustav-Krone-Str. 7
	D—14167 Berlin Germany
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	www.leufen-medical.eu
	contact@leufen-medical.eu
Document number and edition date	MRITBY- 1 — 2021-04
Location of MRI safety information	www.leufen-medical.eu/tby
Static magnetic field strength	1.5 T / 3 T
Type of nuclei	Hydrogen
BO Field Orientation	Horizontal
Maximum Spatial Field Gradient	19 T/m
Maximum B0*ldB0/drl product	48 T ² /m
RF Transmit Coil Type	Whole Body Coil (Integrated Transmit Coil)
RF Receive Coil Type	Whole Body Coil (Integrated Receive Coil)
RF Power Conditions	Normal Operating Mode
Maximum Whole-Body SAR	Whole body SAR ≤ 2 W/kg
	ATTENTION: Under the scan conditions defined above, the product
	<i>aerstent TBY</i> is expected to produce the following maximum tem- perature rise after 15 minutes of continuous scanning:
	 I,5 T: 4.5 ± 0.5 °C
	• 3 T: 5.4 ± 1.0 °C
	Tested REF: 512-18-050
Patient Landmarking Criteria	No restrictions
Patient Position in Scanner	No restrictions
MR Image Artifact	The presence of a product of the type <i>aerstent TBY</i> may produce an image artifact.
	Some manipulation of scan parameters may be required to compensate for the artifact.
	In vitro assessment on a comparable product (<i>aixstent OES</i>) at 1.5 ⁻ showed:
	 On spin echo sequences a maximal artifact width of 25 mm (surrounding the device)
	 On the corresponding gradient echo sequences a maximal artifact width of 15 mm (surrounding the device)

