

MRI Safety Information

Parameter	Notes															
Product name	aixstent OEC															
Manufacturer	bess pro gmbh Gustav-Krone-Str. 7 D—14167 Berlin Germany															
Distributor	Leufen Medical GmbH Gustav-Krone-Str. 7 D—14167 Berlin Germany Tel.: +49 30 816 90 93 00 Fax: +49 30 816 90 93 93 www.leufen-medical.eu contact@leufen-medical.eu															
Document number and edition date	MRIOEC- 2 — 2023-01															
Location of MRI safety information	www.leufen-medical.eu/oec															
Static magnetic field strength	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 or extremities transmit RF coils (trunk and head local transmit coils are excluded)															
RF Receive Coil Type	Any receive RF coil can be used.															
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>aixstent OEC</i> is expected to produce the following maximum temperature rise after 15 minutes of continuous scanning:															
	<table border="1"> <thead> <tr> <th>REF</th> <th>1.5 T</th> <th>3 T</th> </tr> </thead> <tbody> <tr> <td>122-24-100</td> <td></td> <td>3.4 ± 0.5 °C</td> </tr> <tr> <td>122-24-120</td> <td>7.5 ± 0.8 °C</td> <td>3.3 ± 0.4 °C</td> </tr> <tr> <td>123-24-100</td> <td>8.1 ± 1.0 °C</td> <td>3.1 ± 0.4 °C</td> </tr> <tr> <td>123-24-120</td> <td>8.3 ± 0.9 °C</td> <td></td> </tr> </tbody> </table>	REF	1.5 T	3 T	122-24-100		3.4 ± 0.5 °C	122-24-120	7.5 ± 0.8 °C	3.3 ± 0.4 °C	123-24-100	8.1 ± 1.0 °C	3.1 ± 0.4 °C	123-24-120	8.3 ± 0.9 °C	
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Patient Landmarking Criteria	No restrictions															
Patient Position in Scanner	No restrictions															
MR Image Artifact	<p>The presence of a product of the type <i>aixstent OEC</i> may produce an image artifact.</p> <p>Some manipulation of scan parameters may be required to compensate for the artifact.</p> <p>In vitro assessment on a comparable product (<i>aixstent OES</i>) at 1.5T showed:</p> <ul style="list-style-type: none"> • 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) 															