

Test Certificate

concerning the test of influences on MRI systems caused by non-Siemens products

1. Test certificate, product designation and manufacturer

This is to certify that the following product

Prima 451 MRI Anaesthesia System,

tested with AVS ventilator with serial number AVM0717-001, Nuffield Ventilator with serial numberPE0004, Sigma Delta Vaporizer with serial number D0312-0082, Suction Controler with serial number PE0001, A200SP Absorber with serial number PE0005, Anaesthetic Gas Scavenge System (AGSS) US with serial number PE0002, Anaesthetic Gas Scavenge System (AGSS) UK with serial number PE0003 and Gaussmeter with serial number 201

of the manufacturer:

Penlon Ltd Abingdon Science Park, Barton Lane Abingdon, OX14 3NB

does not impair the functioning of the MRI systems of Siemens Healthcare GmbH, Magnetic Resonance Systems, specified in section 2:

Potential functional restrictions of the MRI systems are indicated in section 4.

Possible adverse effects of the MRI systems on the product indicated above are expressly not subject of the test on which this certificate is based. Therefore, this certificate does not imply non-interference of the above-mentioned product through the MRI system.

2. MAGNETOM systems involved

Seq. no. MR System or option (type designation)

- 1 Sola (1.5 Tesla)
- 2 Sempra (1.5 Tesla)
- 3 Amira (1.5 Tesla)
- 4 Aera (1.5 Tesla)
- 5 Espree (1.5 Tesla)
- 6 Avanto (1.5 Tesla)
- 7 Avanto a Tim+Dot System (1.5 Tesla)

- 8 Avanto Dot Upgrade (1.5 Tesla)
- 9 Avanto fit (1.5 Tesla)
- 10 Avanto fit Upgrade (1.5 Tesla)
- 11 ESSENZA (1.5 Tesla)
- 12 ESSENZA a Tim+Dot System (1.5 Tesla)
- 13 ESSENZA Dot Upgrade (1.5 Tesla)
- 14 Symphony (1.5 Tesla)
- 15 Symphony a Tim System (1.5 Tesla)

3. Applications

The Penlon Prima 451 MRI Anaesthesia System is intended for use for the following purpose in connection with magnetic resonance application; the test certificate refers to this purpose:

• MRI Anesthetic Workplace

4. Limitations

During the use of this product the following limitations of functionality and/or applications of the MRI systems, options and accessories apply:

• n.a.

5. Warnings

The following safety precautions must be observed when using this product in connection with the MRI systems listed in section 2:

 The Prima 451 MRI Anaesthesia System includes ferromagnetic components and may therefore be operated at a minimum distance corresponding to 100 mT only. For safety reasons, a relevant warning note must be included in the operating instructions and affixed on the Prima 451 MRI Anaesthesia System.

6. Validity

This test certificate shall be valid until revoked by Siemens Healthcare GmbH.

Erlangen, 2018-06-25 Siemens Healthcare GmbH

Lochner

i.V. Ster

Steiner



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2. MAGNETOM systems involved

Seq. no. MR System or option (type designation)

- 1 Vida (3 Tesla)
- 2 Prisma (3 Tesla)
- 3 Prisma fit Upgrade (3 Tesla)
- 4 Spectra (3 Tesla)
- 5 Skyra (3 Tesla)
- 6 Skyra fit Upgrade (3 Tesla)
- 7 Verio (3 Tesla)

- 8 Verio Dot Upgrade (3 Tesla)
- 9 Verio a Tim+Dot System (3 Tesla)
- 10 Trio a Tim System (3 Tesla)
- 11 Trio (3 Tesla)
- 12 Biograph mMR (3 Tesla)

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