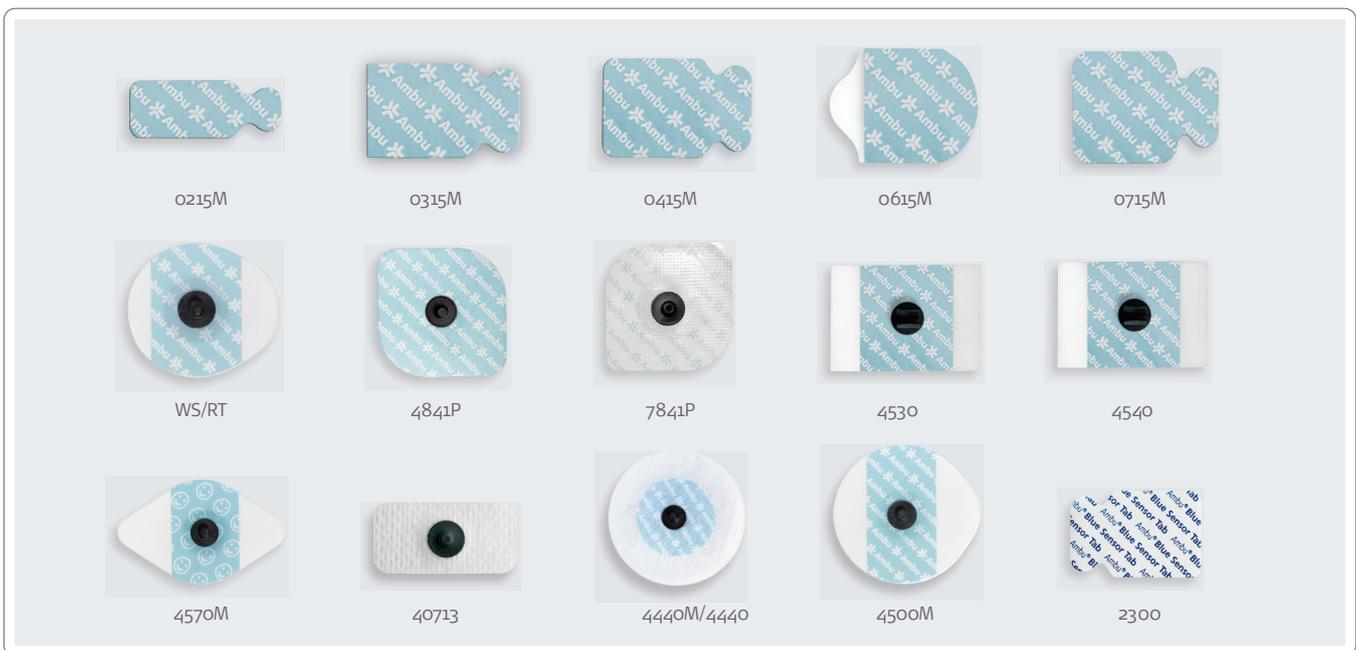


MRI – MR Conditional.

Statement of compliance for Ambu WhiteSensor and BlueSensor ECG electrodes.

The Ambu ECG electrodes WhiteSensor: 0215M, 0315M, 0415M, 0615M, 0715M, WS/RT, 4841P, 7841P, 4530, 4540, 4570M, 40713, 4440M/4440, 4500M and BlueSensor 2300 have been demonstrated to be MR Conditional.



The following marking information is based on ASTM F2503, US FDA Guidance for Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment, August 21, 2008.

A theoretical estimated WBA SAR limit of 2 W/kg "normal operating mode" limit has been used for extrapolating the

temperature increases based on in vitro test results. Measurement inaccuracies and additional safety margins should be taken into account.

It is important to note that this Statement of Compliance applies only to the electrodes and not to any monitors, cables or leadwires which may be attached to the electrode.

MRI Information

Non-clinical testing has demonstrated the above Ambu WhiteSensor and BlueSensor electrodes are MR Conditional.



MR Conditional

Static Magnetic Field

The above devices can be scanned safely in a MR environment under the following conditions:

- static magnetic field of 1.5 Tesla and 3 Tesla only, with
- spatial gradient field of 253 T/m (25,300 gauss/cm) and less
- spatial gradient field product of 684 T²/m and less

- theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR) of < 2 W/kg at 64 MHz Laboratory Test System (equivalent to 1.5 Tesla), (related to 1.3°C temperature increase)
- < 2 W/kg at 3 Tesla, (related to 2.3°C temperature increase) for 15 minutes of continuous MR scanning.

MRI related HF heating

In non-clinical testing the above ECG Electrodes produced a temperature rise of less than 1.5°C (with a background temperature increase of ≈ 1.5°C) at a maximum whole body averaged specific absorption rate (SAR) of ≈ 2.3 W/kg assessed by calorimetry for 15 min. of continuous MR scanning with whole body coil in a 64 MHz (1.5 Tesla equivalent) Medical Implant Test System, Zurich Medtech AG (Software: MITS-DUALBAND 1.2.5.2).

In non-clinical testing the above ECG Electrodes produced a temperature rise of less than 2.6°C (with a background temperature increase of ≈ 2.2°C) at a maximum whole body averaged specific absorption rate (SAR) of ≈ 2.3 W/kg assessed by calorimetry for 15 min. of continuous MR scanning with whole body coil in a 3 Tesla Signa HdxT General Electric Medical Systems (Software: 15.0_M4.0910.a) MR Scanner.

Artifact Information

ECG Electrodes, Ambu White Sensor 0215M, 0315M, 0415M, 0615M, 0715M and BlueSensor 2300

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of these devices.

MR image artifacts can affect the device surrounding on each side from the device surface as follows:

Worst-case artifacts of	Spin Echo	Gradient Echo
Test object length	1.08 mm	1.18 mm
Test object diameter	0.54 mm	1.06 mm

The MR image artifacts affect the object surrounding according to above magnitudes.

ECG Electrodes, Ambu White Sensor WS/RT, 4841P, 7841P, 4530, 4540, 4570M, 40713, 4440M /4440, 4500M

MR image quality is compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of these devices.

MR image artifacts can affect the device surrounding on each side from the device surface as follows:

Worst-case artifacts of	Spin Echo	Gradient Echo
Test object length	3.05 mm	2.82 mm
Test object diameter	1.80 mm	1.97 mm

The MR image artifacts affect the object surrounding according to above magnitudes.

Ambu A/S

Baltorpbakken 13
DK - 2750 Ballerup
Denmark
Tel. +45 7225 2000
Fax +45 7225 2053
www.ambu.com