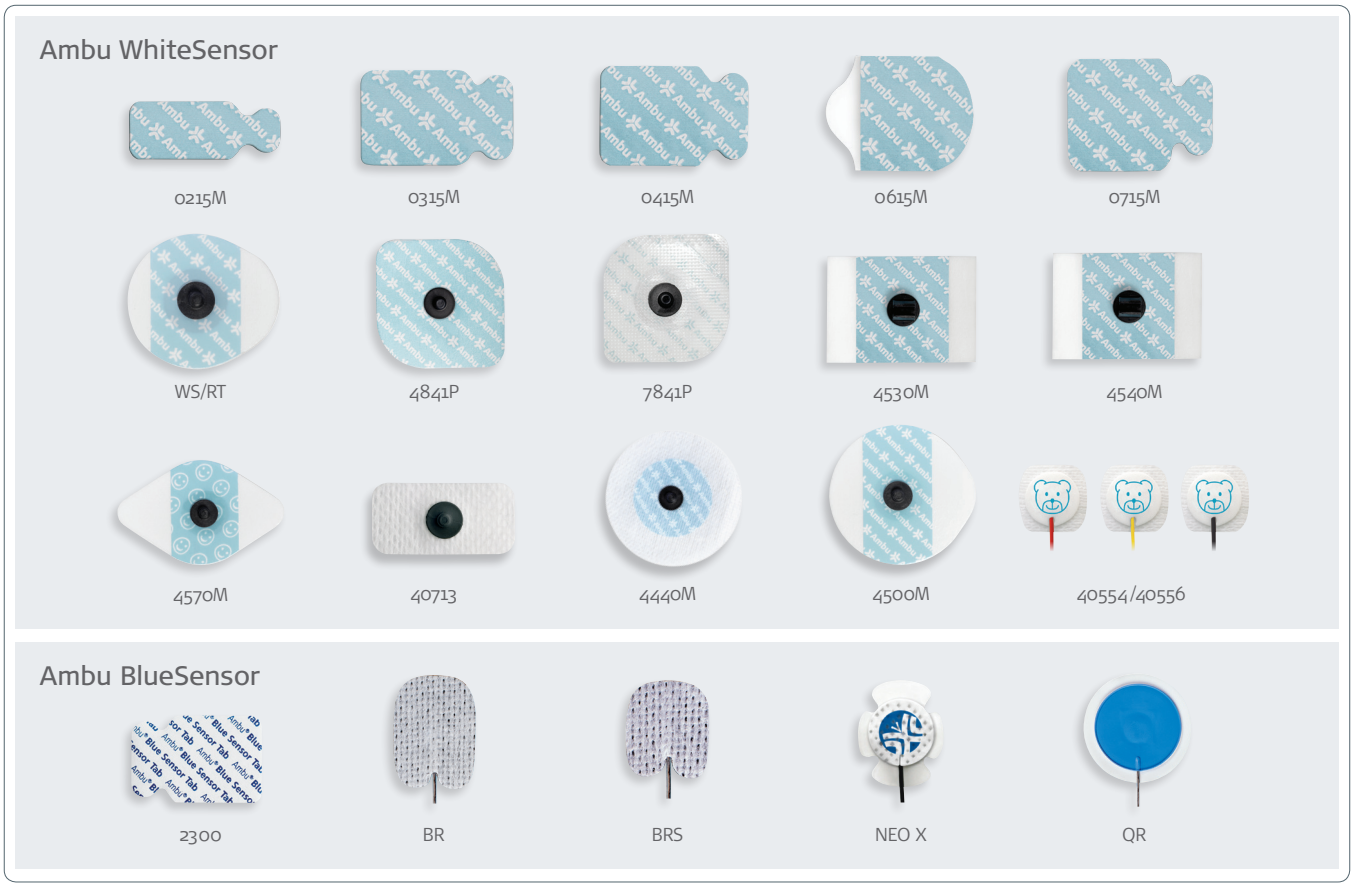
X-ray – Radiolucency. Statement of compliance for Ambu WhiteSensor and BlueSensor ECG electrodes.

The Ambu WhiteSensor ECG electrodes: 0215M, 0315M, 0415M, 0615M, 0715M, WS/RT, 4841P, 7841P, 4530M, 4540M, 4570M, 40713, 4440M, 4500M, 40554, 40556 and Ambu BlueSensor 2300, BR, BRS, NEOX, QR have been demonstrated to be Radiolucent.

X-ray



The above electrodes are tested according to ASTM F-640-12 "Standard Test Methods for Determining Radiopacity for Medical Use". Note that the standard F640-12 does not provide a minimum level of radiopacity for a tested material.

As a comparison standard the electrodes have been tested against a 99,5% aluminum sheet of 2mm thickness, which is equivalent to approx. 2 mm of cortical bone and to approx. 5 mm of soft tissue (muscle, water, brain, breast, lung).

By testing of radiopacity the ECG electrodes showed different shielding against X-rays.

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The radiopacity (x-ray shielding) relation between the electrode and the comparison standard (2 mm thick aluminum) is shown in table TAB. 1.

Test object	Max. intensity difference between test object/standard and background		Relation of test object to comparison standard
	test object	comp. std.	
81kV			
Ambu WhiteSensor ECG electrodes			
0215M	56.0	784.6	0.07
0315M	47.5	817.4	0.06
0415M	62.2	797.3	0.08
0615M	43.1	813.8	0.05
0715M	49.9	785.2	0.06
WS/RT	238.7	803.3	0.30
4841P	222.9	793.2	0.28
7841P	254.7	783.4	0.33
4530M	278.4	825.9	0.34
4540M	310.1	800.2	0.39
4570M	173.7	816.8	0.21
40713	182.1	803.9	0.23
4440M	307.7	733.9	0.42
4500M	164.0	757.8	0.22
40554	190.6	893.5	0.21
40556	191.5	812.2	0.24
Ambu BlueSensor ECG electrodes			
2300	62.2	797.3	0.08
BR	0.8	851.2	0.00
BRS	38.9	832.5	0.05
NEOX	107.7	863.0	0.12
QR	116.9	855.8	0.14

TAB. 1

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