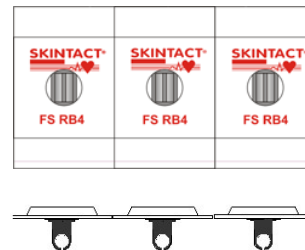


## SKINTACT ECG Electrode FSRB4

Aqua-Wet, Stress-foam backing material

### KEY FEATURES

- foam backing materials protect sensor and gel from surgical and cleaning fluids
- the liquid gel is designed for fast pick up of the ECG signal even if inadequate skin prep is carried out
- all sensors have an high quality Ag/AgCl layer with 4 mm banana adapter



PRODUCT	
<i>Recomm. Application</i>	diagnostic resting ECG
<i>Characteristics</i>	disposable, pregelled, no latex, no PVC, non sterile
<i>Shelf life</i>	24 months unopened
<i>Storing conditions (min/max)</i>	+5° C/ +30° C
<i>X-ray translucent</i>	-

DIMENSIONS	
<i>Electrode shape</i>	rectangular
<i>Electrode size - max L/W [mm]</i>	44 / 28
<i>Height [mm]</i>	11
<i>Total area [mm<sup>2</sup>]</i>	1.232
<i>Gel area [mm<sup>2</sup>]</i>	201
<i>Adhesive area [mm<sup>2</sup>]</i>	947

CLASSIFICATION AND STANDARDS	
<i>Classification (MDD Art. 9)</i>	Class I
<i>Classification (CFR 21 870.2360.)</i>	Class II

MATERIALS	
<i>Stud</i>	stainless steel, carbon adapter 4mm
<i>Label</i>	PET-foil
<i>Backing material:</i>	PE-stress-foam
<i>Adhesive</i>	medical-grade acrylate
<i>Sensor</i>	silver/silverchloride (Ag/AgCl)
<i>Sponge</i>	PET-foam
<i>Gel</i>	Aqua-Wet (liquid gel)
<i>Release liner</i>	siliconized PET-foil (transparent)

MATERIALS PACKAGING	
<i>Pouches, inner layer</i>	Polyethylene (PE)
<i>Pouches, centre layer</i>	Aluminium (Al)
<i>Pouches, outer layer</i>	Paper
<i>Boxes</i>	Cardboard

STANDARD PACKAGING		Item Number: 58036
<i>Pieces / card</i>		3
<i>Pieces / pouch</i>		30
<i>Pieces / box</i>		750
Lot number and expiration date on every pouch and box		

DIMENSIONS PACKAGING	
<i>Box (L/W/H) [cm]</i>	39/ 29/ 22

BIOCOMPATIBILITY		
<i>Test - ISO 10993-1</i>	<i>Backing material (adhesive)</i>	<i>Gel</i>
<i>Cytotoxicity</i>	pass	pass
<i>Skin Irritation</i>	pass	pass
<i>Sensitization</i>	pass	pass

ELECTRICAL VALUES	Units	Typical Values	AAMI limits
<i>DC-Offset</i>	[mV]	≤ 0,5	≤ 100
<i>DC Offset (5 sec after capacitor discharge)</i>	[mV]	≤ 10	≤ 100
<i>Recovery Slope</i>	[mV/sec]	± -0,2	± 1
<i>AC-Impedance with 10 Hertz</i>	[Ω]	≤ 300	≤ 2000
<i>Internal Noise Test</i>	[μV]	≤ 10	≤ 150
<i>Bias-Tolerance (over 24 h)</i>	[mV]	≤10	≤100