

ECG Electrode 2015

Solid gel, Stress-Foam Backing Material



PRODUCT	
<i>Recomm. Application</i>	Monitoring
<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>	-

CLASSIFICATION AND STANDARDS	
<i>Classification (MDR Annex VIII)</i>	Class I
<i>Classification (CFR 21 870.2360.)</i>	Class II

MATERIALS	
<i>Stud</i>	Stainless Steel
<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>	-
<i>Gel</i>	Solid Adhesive Gel
<i>Release Liner</i>	Siliconized PET-Foil (transparent)

STANDARD PACKAGING	
<i>Pieces / Card</i>	5
<i>Pieces / Pouch</i>	30
<i>Pieces / Box</i>	300
Lot number and expiration date on every pouch and box	

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]	≤ 15	≤ 100
<i>Recovery Slope</i>	[mV/sec]	≤ -0,3	± 1
<i>AC-Impedance with 10 Hertz</i>	[Ω]	≤ 150	≤ 2000
<i>Internal Noise Test</i>	[μV]	≤ 10	≤ 150
<i>Bias-Tolerance (over 24 h)</i>	[mV]	≤ 10	≤100 (over 8h)

DIMENSIONS	
<i>Electrode Shape</i>	-
<i>Electrode Size - max L/W [cm]</i>	4.5 / 3.4
<i>Total Area [cm²]</i>	appr. 12.9
<i>Gel Area [cm²]</i>	appr. 2.0
<i>Adhesive Area [cm²]</i>	appr. 12.3

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

DIMENSIONS PACKAGING	
<i>Box (L/W/H) [cm]</i>	22/ 18/ 15