

ECG Electrode 2016

Solid gel, Soft-Cloth Backing Material



PRODUCT	
Recomm. Application	Monitoring
Characteristics	disposable, pregelled, no latex, no PVC, non sterile
Shelf Life	36 months unopened
Storing Conditions (min/max)	+5° C/ +30° C
X-Ray Translucent	-

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

MATERIALS	
Stud	Stainless Steel
Label	PET-Foil
Backing Material:	Nonwoven Soft-Cloth
Adhesive	Medical-Grade Acrylate
Sensor	Silver/Silverchloride (Ag/AgCl)
Sponge	-
Gel	Solid Adhesive Gel
Release Liner	Siliconized PET-Foil (transparent)

STANDARD PACKAGING	
Pieces / Card	1
Pieces / Pouch	30
Pieces / Box	300
Lot number and expiration date on every pouch and box	

BIOCOMPATIBILITY		
Test - ISO 10993-1	Backing Material (Adhesive)	Gel
Cytotoxicity	pass	pass
Skin Irritation	pass	pass
Sensitization	pass	pass

DIMENSIONS	
Electrode Shape	teardrop
Electrode Size - max L/W [cm]	5.5 / 5.0
Total Area [cm ²]	appr. 20.4
Gel Area [cm ²]	appr. 2.0
Adhesive Area [cm ²]	appr. 19.8

MATERIALS PACKAGING	
Pouches, Inner Layer	Polyethylene (PE)
Pouches, Centre Layer	Aluminium (Al)
Pouches, Outer Layer	Paper
Boxes	Cardboard

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

ELECTRICAL VALUES	Units	Typical Values	AAMI Limits
DC-Offset	[mV]	≤ 0,5	≤ 100
DC-Offset (5 sec after Capacitor Discharge)	[mV]	≤ 15	≤ 100
Recovery Slope	[mV/sec]	≤ -0,3	± 1
AC-Impedance with 10 Hertz	[Ω]	≤ 150	≤ 2000
Internal Noise Test	[μV]	≤ 10	≤ 150
Bias-Tolerance (over 24 h)	[mV]	≤ 10	≤100 (over 8 h)