

Prewired Neonatal ECG electrodes PD50-SFC and PD60-F4C



KEY FEATURES

- Web backing materials fully covered with hypo allergenic hydrogel
- Pre-attached carbon leadwires with safety plug (DIN plug) 1.5 mm and connector for 4mm banana plug
- Available in 3 lead sets
- Electrodes with carbon leads are x-ray translucent

PRODUCT	
<i>Recomm. Application</i>	Monitoring (Adult)
<i>Characteristics</i>	disposable, pregelled, no latex, non sterile
<i>Shelf Life</i>	36 months unopened, 7 days opened
<i>Wearing time</i>	up to 72 hours
<i>Storing Conditions (min/max)</i>	+5° C/ +30° C
<i>X-Ray Translucent</i>	yes

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

MATERIALS	
<i>Sensor</i>	ABS (Ag/AgCl coated)
<i>Lead</i>	Carbon
<i>Lead insulation</i>	PVC
<i>Connector</i>	Tinned Brass
<i>Plastic material for connector</i>	PVC
<i>Label</i>	PE-Foil
<i>Backing Material:</i>	PE-Foam
<i>Adhesive</i>	Solid adhesive gel
<i>Gel</i>	Solid adhesive gel
<i>Release Liner</i>	Siliconized PET-Foil (transparent)

STANDARD PACKAGING	
<i>Pieces / Card</i>	3
<i>Pieces / Pouch</i>	3
<i>Pieces / Box</i>	150
Lot number and expiration date on every pouch and box	

BIOCOMPATIBILITY		
<i>Test - ISO 10993-1</i>	<i>Gel</i>	<i>Leads</i>
<i>Cytotoxicity</i>	pass	pass
<i>Skin Irritation</i>	pass	pass
<i>Sensitization</i>	pass	pass

DIMENSIONS	
<i>Electrode Shape</i>	rectangular – 24 x 23 mm
<i>Electrode Size - max L/W [cm]</i>	-
<i>Total Area [cm²]</i>	appr. 5.5
<i>Gel Area [cm²]</i>	appr. 5.5
<i>Adhesive Area [cm²]</i>	appr. 5.5
<i>Lead Length</i>	50 cm

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>	29/ 19/ 14

ELECTRICAL VALUES	Units	Typical Values	AAMI Limits
<i>DC-Offset</i>	[mV]	≤ 1.5	≤ 100
<i>DC-Offset (5 sec after Capacitor Discharge)</i>	[mV]	≤ 15	≤ 100
<i>Recovery Slope</i>	[mV/sec]	≤ -0.5	± 1
<i>AC-Impedance with 10 Hertz</i>	[Ω]	≤ 500	≤ 2000
<i>Internal Noise Test</i>	[µV]	≤ 10	≤ 150
<i>Bias-Tolerance (over 24 h)</i>	[mV]	≤ 20	≤100 (over 8h)