NIKOTABS

Technical Data Sheet
Disposable ECG Electrodes



0515

Recommended Application: Diagnostic Resting ECG

PRODUCT INFORMATION	
Backing Material	PET/Paper (Carbon Coated)
Size (mm)	34 x 23
Sensor Area (mm^2)	730
Adhesive Type	Solid Adhesive Gel
Adhesive Area (mm^2)	557
Gel Area (mm^2)	557
Gel	Solid Adhesive Gel
Sensor	Ag/AgCl coating
Release Liner	Siliconized PET Film
Standard Packaging	10 pcs per Liner Card 100 pcs per Pouch 500 per Box / 5000 per Case

PRODUCT/REGULATORY INFORMATION	
PVC, Latex, and DEHP Free	✓
RoHS Directive Compliant	✓
Bio-Compatible (ISO 10993)	✓
Repositionable	✘
ISO 13485 Certified	✓
FDA Registered*	✓
Health Canada Licensed*	✓
CE Mark per 2017/745 EU MDR**	✓
MRI Conditional / X-Ray Radiolucency	✓
Product shelf life in an intact, originally sealed pack	24 Months

ELECTRICAL CHARACTERISTICS

Particulars	Typical Readings	AAMI Limits
DC Offset Voltage (DCO) (mV)	<= 30	Not More than 100
AC Impedance @ 10Hz (ACZ) (ohm)	< 1250	Not More than 2000
Defibrillation Overload Recovery (SDR) (mV/sec)	< 1.0	Not More than 1.0
AC Impedance after SDR (ACZ) (ohm)	< 1200	Not More than 2000

*Class II (CFR 21 870.2360 and SOR/98-282, Schedule 1, Rule 7, Subrule 2(b))
**Class I (MDR Annex VIII)

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Recommended Application: Diagnostic Resting ECG

PRODUCT INFORMATION		PRODUCT/REGULATORY INFORMATION	
Backing Material	PET/Paper (Carbon Coated)	PVC, Latex, and DEHP Free	✓
Size (mm)	34 x 26	RoHS Directive Compliant	✓
Sensor Area (mm^2)	778	Bio-Compatible (ISO 10993)	✓
Adhesive Type	Solid Adhesive Gel	Repositionable	✘
Adhesive Area (mm^2)	621	ISO 13485 Certified	✓
Gel Area (mm^2)	621	FDA Registered*	✓
Gel	Solid Adhesive Gel	Health Canada Licensed*	✓
Sensor	Ag/AgCl coating	CE Mark per 2017/745 EU MDR**	✓
Release Liner	Siliconized PET Film	MRI Conditional / X-Ray Radiolucency	✓
Standard Packaging	10 pcs per Liner Card 100 pcs per Pouch 500 per Box / 5000 per Case	Product shelf life in an intact, originally sealed pack	24 Months

ELECTRICAL CHARACTERISTICS

Particulars	Typical Readings	AAMI Limits
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0815

Recommended Application: Diagnostic Resting ECG

PRODUCT INFORMATION		PRODUCT/REGULATORY INFORMATION	
Backing Material	PET/Paper (Carbon Coated)	PVC, Latex, and DEHP Free	✓
Size (mm)	34 x 13	RoHS Directive Compliant	✓
Sensor Area (mm^2)	388	Bio-Compatible (ISO 10993)	✓
Adhesive Type	Solid Adhesive Gel	Repositionable	✘
Adhesive Area (mm^2)	320	ISO 13485 Certified	✓
Gel Area (mm^2)	320	FDA Registered*	✓
Gel	Solid Adhesive Gel	Health Canada Licensed*	✓
Sensor	Ag/AgCl coating	CE Mark per 2017/745 EU MDR**	✓
Release Liner	Siliconized PET Film	MRI Conditional / X-Ray Radiolucency	✓
Standard Packaging	10 pcs per Liner Card 100 pcs per Pouch 500 per Box / 5000 per Case	Product shelf life in an intact, originally sealed pack	24 Months

ELECTRICAL CHARACTERISTICS

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