NIKOTRACE

Technical Data Sheet
Disposable ECG Electrodes



3014

Recommended Application: (long term) Monitoring

STRESS
HOLTER
CATH/ NUCLEAR

PRODUCT INFORMATION		PRODUCT/REGULATORY INFORMATION	
Backing Material	Clear Tape	PVC & Latex Free	✓
Shape, Size (mm)	Round, 50	DEHP Free	✓
Total Area (mm^2)	1964	RoHS Directive Compliant	✓
Adhesive Type	Enhanced, Medical Grade	MRI Conditional	×
Adhesive Area (mm^2)	1660	Bio-Compatible (ISO 10993)	✓
Gel Type, Area (mm^2)	Solid, 201	ISO 13485 Certified	✓
Connector	Stainless Steel Stud	FDA Registered*	✓
Sensor	Ag/AgCl	Health Canada Licensed*	✓
Release Liner	Siliconized PET Film	CE Mark as per 2017/745 EU MDR**	✓
Standard Packaging	3 pcs per Liner Card 60 pcs per Pouch 600 pcs per Inner Box	Product shelf life in an intact, originally sealed pack	24 Months

ELECTRICAL CHARACTERISTICS

Particulars	Typical Readings	AAMI Limits
DC Offset Voltage (DCO) (mV)	0.12	Not More than 100
AC Impedance @ 10Hz (ACZ) (ohm)	60	Not More than 2000
Defibrillation Overload Recovery (SDR) (mV/sec)	0.0	Not More than 1.0
AC Impedance after SDR (ACZ) (ohm)	46	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)

NIKOTRACE

Technical Data Sheet
Disposable ECG Electrodes



3016

Recommended Application: Monitoring

ICU/CCU
EVENT

PRODUCT INFORMATION		PRODUCT/REGULATORY INFORMATION	
Backing Material	Non-woven cloth	PVC & Latex Free	✓
Shape, Size (mm)	Round, 50	DEHP Free	✓
Total Area (mm^2)	1964	RoHS Directive Compliant	✓
Adhesive Type	Enhanced, Medical Grade	MRI Conditional	×
Adhesive Area (mm^2)	1660	Bio-Compatible (ISO 10993)	✓
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