NIKOTRACE

Technical Data Sheet
Disposable ECG Electrodes



6559

Recommended Application: Monitoring (X-Ray)

CATH/ NUCLEAR

PRODUCT INFORMATION		PRODUCT/REGULATORY INFORMATION	
Backing Material	Foam	PVC & Latex Free	✓
Shape, Size (mm)	Kidney, 47 x 42 x 1	DEHP Free	✓
Total Area (mm^2)	1561	RoHS Directive Compliant	✓
Adhesive Type	Enhanced, Medical Grade	Bio-Compatible (ISO 10993)	✓
Adhesive Area (mm^2)	1139	ISO 13485 Certified	✓
Gel Type, Area (mm^2)	Wet, 284	FDA Registered*	✓
Connector	Carbon (RT) Stud	Health Canada Licensed*	✓
Sensor	Ag/AgCl	CE Mark per 2017/745 EU MDR**	✓
Release Liner	Siliconized PET Film	MRI Conditional / X-Ray Radiolucency	✓
Standard Packaging	5 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)	0.15	Not More than 100
AC Impedance @ 10Hz (ACZ) (ohm)	51	Not More than 2000
Defibrillation Overload Recovery (SDR) (mV/sec)	0.0	Not More than 1.0
AC Impedance after SDR (ACZ) (ohm)	49	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)