NIKOTRACE

Technical Data Sheet
Disposable ECG Electrodes



6550

Recommended Application: Monitoring

STRESS
HOLTER
ECHO

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	MRI Conditional	×
Adhesive Area (mm^2)	1139	Bio-Compatible (ISO 10993)	✓
Gel Type, Area (mm^2)	Wet, 284	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	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)