nissha
MEDICAL TECHNOLOGIES

Swaromed

4019-SWARO-V50-400-4800

Reference: **4019**

Solid Gel

50 Electrodes / Pouch
4800 Electrodes / Case

APPLICATION

For: 48 Hours

Stress Test, Holter and Emergency

PRODUCT INFORMATION

Shape	Circular
Size (excl. grip)	2 in / 50 mm
Sensor (Eyelet) Diameter	0.3 in / 8 mm
Substrate Thickness (adapter excluded)	0.04 in / 1 mm
Total Product Surface Area	3.04 in^2 / 1964 mm^2
Gel Area	0.18 in^2 / 113 mm^2
Adhesive Area	2.87 in^2 / 1851 mm^2
Integrated Lead Wire (length / color)	N/A

MATERIALS

Substrate Material	Polyethylene Foam
Adhesive	Medical grade pressure sensitive adhesive
Gel Type	Solid Gel
Foam (Sponge) Material	N/A
Release Liner	PETP Film
Sensor Polymer	Glass-filled ABS - Ag/AgCl Coated
Adaptor / Connector (Stud)	Stainless Steel
Integrated Lead Wire Jacketing	N/A
Integrated Lead Wire Cord	N/A

ELECTRICAL PERFORMANCE (ANSI/AAMI EC 12)

ACZ impedance (before defib simulation) **@10 Hz**	< 300 Ohm
DC Offset Voltage (before defib simulation)	< 1 mV
SDR Slope (remaining potential after defib) **@ 30 Sec int.**	< 0.2 mV/sec
ACZ impedance repeat (after defib simulation)	< 150 Ohm
COIIN (combined offset instability and inner noise)	22 µV
Bias Current Tolerance (DC offset voltage after DC loading)	< 1.7 mV

FEATURES

MR Conditional	No
X-ray Translucence	No
Integrated Abrader	No
Repositionability	No

PACKAGING

Product Packaging Material	Foil/PET/AL/PE
Resealable Pouch	No
Product Packaging Size (L x W)	11 x 7.9 in 28 x 20 cm
Department Packaging - Box (L x W)	10.4 x 8.1 x 5.1 in 26.5 x 20.5 x 13 cm
Transport Packaging - Carton (L x W)	21.5 x 16.7 x 16.3 in 54.5 x 42.5 x 41.5 cm

BIOCOMPATIBILITY

ISO 10993	Yes
Latex Free	Yes

ENVIRONMENTAL

Halogenated Hydrocarbon Content (e.g. PVC)	None
Phthalate Derivatives Content (e.g. DEHP)	None
RoHS Compliant	Yes
REACH Compliant	Yes

SHELF LIFE

Product Shelf Life (in accordance with storage guidelines)	36 Months

REGULATORY STATUS

CE marked according to EU MDR 2017/745

Reorder Part Number: 6000616C

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