

# Unilect™ 4535M



## Key Benefits

- Latex free
- PVC free (in contact with skin)
- Universal size monitoring electrode
- Cost efficient

## Unilect™ 4535M

Universal size wet gel monitoring electrode made from polyethylene foam conveniently presented with 3 pieces

to a strip. The electrode has a high-tack, acrylic adhesive and is constructed without the use of latex.

# Specifications

Dimensions	
Electrode size (length x width in mm)	32 x 45
Adhesive area (in mm <sup>2</sup> )	1085
Height excluding connector (in mm)	1.6
Sensor	
Sensor material	Silver, silver chloride (Ag/AgCl)
Gel system	Chloride based, wet gel
Gel area (in mm <sup>2</sup> )	255
Sensor area (in mm <sup>2</sup> )	77
Electrical data (ANSI/AAMI) <sup>10</sup>	
AC impedance - typical	79 Ω
DC offset potential - typical	0.3 mV
Defibrillation overload recovery - typical	10.6 mV
Rate of change for polarisation potential - typical	-0.3 mV/s
Combined offset instability and internal noise	1.9 μV
Bias current tolerance	4.6 mV

Environment	
PVC-free electrode (in contact with skin)	Yes
Latex-free electrode	Yes
PVC-free packaging	Yes
X-Ray & MRI	
X-ray	No
MRI	No
Lifetime	
Opened pouch	Information available upon request
Sealed pouch*	24 months

\*from date of production

Accessories	
Skin Preps	Ref: 2121M
Related Products	
Please see data sheet no.	4500M-H

## Materials

Electrode	
Bio-compatible	Yes <sup>1-8</sup>
Sponge	Polyurethane foam (PU)
Backing material	Polyethylene foam (PE)
Backing material adhesive	Acrylic
Supporting label	Printed Polyvinyl Chloride (PVC)
Connector	Nickel plated brass, snap type
Release liner	Siliconised polyester

Packaging	
Pouch (outer/middle/inner layers)	Polyester (PET)/aluminium/polyethylene (PE)
Pouch dimensions	210 x 240 mm
Inner carton	Printed corrugated board
Inner carton dimensions (Ext)	191 x 226 x 156 mm
Shipping carton	Printed corrugated board
Shipping carton dimensions (Ext)	793 x 393 x 235 mm

Standard Packaging	
Quantity/liner	3
Quantity/pouch	60
Inner carton	300
Shipping carton	3000
Minimum sales	3000

Precaution	
Single patient use only	

## Available configurations\*

Quantity/pouch	60
4535M	Quantity per inner/outer box 300/3000

1. Conductive Gel: Tissue Culture Cytotoxicity Test using L929 Cells. SPL project number: 885/001. Test facility: Safepharm Laboratories Limited.
2. Conductive Gel: British Standard 5736 - Part 6 (Method 1) Delayed Contact Dermatitis Study in the Guinea Pig. SPL project number: 885/00. Test facility: Safepharm Laboratories Limited.
3. Conductive Gel: British Standard 5736 - Part 7 Skin Irritation Test of Extracts from Medical Devices in the Rabbit. SPL project number: 885/003.est facility: Safepharm Laboratories Limited.
4. Foam Coated with Pressure Sensitive Adhesive: BS EN ISO 10993-5/USP 24 Tissue Culture Cytotoxicity Test using L929 Cells - Indirect Contact (Agar Diffusion) method. SPL project number: 1209/004. Test facility: Safepharm Laboratories Limited.
5. Foam Coated with Pressure Sensitive Adhesive: ISO 10993-5 Tissue Culture Cytotoxicity Test using L929 Cells - Indirect Contact (Agar Diffusion) method. SPL project number: 1209/003 Test facility: Safepharm Laboratories Limited.
6. Foam Coated with Pressure Sensitive Adhesive: International Standard ISO 10993-10: 1995 Acute (Single Exposure) Skin Irritation Test in the Rabbit. SPL project number: 1209/001. Test facility: Safepharm Laboratories Limited.
7. Foam Coated with Pressure Sensitive Adhesive: International Standard ISO 10993-10: 1995 Maximisation Sensitisation test in the Guinea Pig. SPL project number: 1209/002. Test facility: Safepharm Laboratories Limited.
8. Biocompatibility Safety Assessment of Paper and PU Foam\_Version 5th February 2010. Data on File. ConvaTec.
9. Testing adhesion of 2 groups of ECG electrodes. A prospective time study. March 23, 2006, Data on file, ConvaTec.
10. American National Standard Institute /Association for the Advancement of Medical Instrumentation (ANSI/AAMI). EC12:2000 Section 4.2.2.1 to 4.2.2.5.

Manufactured by  
**Unomedical Ltd.**  
Stroudwater Business Park,  
Stonehouse, GL10 3SX  
Great Britain  
Tel. +44 (0) 1453 827696  
Fax +44 (0) 1453 827861  
www.unomedical.com

Distributed by  
**Ambu A/S**  
Baltorpbakken 13  
DK - 2750 Ballerup  
Denmark  
Tel. +45 7225 2000  
Fax +45 7225 2053  
www.ambu.com