

# Ampcare

## E Series Electrodes



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ampcarellc.com/ifu Medical Device



In the USA, Federal law restricts this device to sale by or on the order of a licensed practitioner.

### Indications for Use

Ampcare's E Series Electrodes (cutaneous electrodes) are intended to be used to apply electrical stimulation current to the patient's skin. Example electrical stimulation current applications of these electrodes are:

- 1) Electrical muscle stimulation (EMS) for neck muscle stimulation.
- 2) Functional electrical stimulation (FES).
- 3) Neuromuscular electrical stimulation (NMES), including for muscle re-education by application of external stimulation to the muscles necessary for pharyngeal contraction.

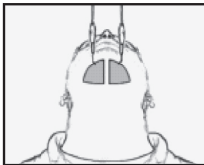
The intended patient population is adults and youth suffering from dysphagia or dysarthria.

### Contraindications

Do not use cutaneous electrodes for stimulation if the patient has a cardiac pacemaker, implanted defibrillator, or other implanted electronic device. Such use could cause electric shock, burns, electrical interference, or death.

### Instructions for Application of Electrodes

- 1) Make certain stimulation device is off prior to applying or removing electrodes. Note: Electrodes should be applied only to normal, intact, clean, healthy skin.
- 2) Clean application area with soap and water, rinse, dry.
- 3) Remove electrode from backing by grasping the edge of the electrode and peeling it off backing.
- 4) Place each electrode on exact skin location, as determined by licensed practitioner, by applying the center of the electrode first and then smoothing down to the electrode edges.
- 5) Connect lead wire pins to electrodes. Recommended lead wires are Ampcare product 50712.
- 6) Attach lead wire to the stimulation device. Licensed practitioner must select the maximum duration of use, compatible with the treatment selected from the above Indications for Use.



## For use with Ampcare ESP Therapy System

Self-Adhering Reusable Stimulating Electrodes  
with 0.08" Socket/Pin Connector

### Instructions for Removal of Electrodes

- 1) Turn off stimulation device after the selected treatment time has been concluded.
- 2) Remove electrode from skin by peeling from the electrode edge.
- 3) Place each electrode upon backing for future use. To extend electrode life, place backing and electrodes in package, then reseal.

### Warnings

Do not place stimulation electrodes across the chest because the introduction of electrical current into the chest may cause rhythm disturbances to the heart, which could be lethal.  
Do not place stimulation electrodes over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins).  
Do not place stimulation electrodes over, or in proximity to, cancerous lesions.

### Precautions

The long-term effects of cutaneous electrodes for electrical stimulation are unknown. Since the effects of stimulation of the brain are unknown, stimulation electrodes should not be placed transcranially.  
Keep electrodes out of the reach of children.  
Use caution if electrodes are applied over areas of skin that lack normal sensation.  
Replace self-adhesive electrodes if they no longer stick firmly to the skin.

### Adverse Reactions

Users may experience skin irritation and burns beneath the electrodes with the use of stimulation electrodes applied to the skin.  
Users may experience headache and other painful sensations during or following the application of electrical stimulation near the eyes, and to the head and face.  
Serious adverse events related to the use of the device should be reported to the manufacturer as well as the relevant authorized representative and competent authority.

### Advisory

The size, shape, and type of electrodes may affect the safety and effectiveness of electrical stimulation. Ampcare E Series Electrodes are designed to distribute the electrical current as uniformly as possible throughout the electrode surface area.  
The electrical performance characteristics of electrodes may affect the safety and effectiveness of electrical stimulation. To decrease impedance and maintain performance, a maximum of 5 uses is recommended.  
Using stimulation electrodes that are too small or incorrectly applied could result in discomfort or skin burns.  
Contact the manufacturer of the electrical stimulation device if you do not know if the electrode can be used with the stimulation device.

### Performance Characteristics

Electrical Resistance (Impedance) Ohms ( $\Omega$ ): <150  
Electrical Dispersion Coverage (Uniformity): 80-100%

### Handling, Storage, and Cleaning

Ampcare E Series electrodes are intended for single patient use only. Do not share electrodes among multiple persons because of the risks of adverse skin reactions and disease transmission. Electrode life varies depending on skin conditions, skin preparation, type of stimulation, storage conditions, and climate of usage.  
Place electrodes in package when not in use, and reseal package to extend electrode life.  
Do not clean electrodes. Replace self-adhesive electrodes if they become soiled.  
Store at room temperature for best results. Avoid extreme heat. Do not freeze.  
Dispose of electrodes in accordance with local regulations.



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