



# Ampcare Lead Wires

Transcutaneous Electrical Stimulation Lead

For Use with Ampcare ES NMES & Ampcare E Series Electrodes



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## Indications/Intended Use:

A non-sterile, insulated, electrical conducting wire intended to be used to connect Ampcare E Series Electrodes to the Ampcare ES NMES.



## Instructions for Use:

1. Inspect the Lead Wires: Before each use, inspect for any visible damage such as cracks in the insulation or exposed copper core. Replace if damaged.
2. Connect to the Ampcare ES NMES: Insert the right-angle lead wire plug into the designated output jack on the unit. Ensure a secure fit to avoid signal disruption. Refer to the Ampcare ES NMES User Manual for additional instructions.
3. Attach to Ampcare E Series Electrodes: Insert the red and black pin connector of the lead wires to the electrodes by inserting the pins into the corresponding sockets on the electrodes. Refer to the Ampcare E Series Electrodes IFU for further details.
4. Remove After Use: After the session, turn off the Ampcare ES NMES unit, and gently detach the lead wires from the unit and electrodes.

## Patient Population:

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

## Intended Users:

Trained, licensed health care professionals involved in patient care, whether they are in a hospital, skilled nursing facility, in-patient or out-patient rehabilitation center, long-term care facility, assisted living facility, private practice clinic, or at home with home health treatment.

## Precautions

- Do not put the lead wire on or wrapped around the neck.
- Do not use damaged lead wires, as this may cause electrical shorts or improper operation.
- Avoid contact with water or other liquids during use.

## Potential adverse event / side effect:

There are no known adverse events/side effects. Ensure proper electrode placement to avoid discomfort or ineffective treatment.

## Troubleshooting:

If the ES NMES unit does not function properly, check the lead wires for secure connections and inspect for damage. Check the lead wires with the lead wire conduction tester provided. Replace the lead wires if any issues persist.

## Maintenance and Care:

- Clean the wires with a dry cloth after use to remove any debris.
- Avoid pulling or bending the wires excessively to prevent damage.

## Specifications:

- 21 CFR 898 Compliant
- Wire Length: 1250 mm ± 10 mm
- Wire Type: Copper Core; PVC Insulated
- Color: Red & Black

## Storage / Handling:

Store the wires in a dry, cool place when not in use.

**Disposal:** Dispose of components in accordance with local, regional, national, or international regulations.

**Warranty:**

Ampcare agrees that if any defect in materials or workmanship appears in this product within six months after the original date of consumer purchase, it will replace the product in question free of charge. This applies only if the product has been used as directed and has not been damaged through misuse, accident, or neglect.

If a defect appears, please check that the product is being used in accordance with instructions. If so, return it with this warranty and proof of purchase to your nearest Ampcare Dealer.

**Ordering Information:**

The Ampcare Lead Wires are intended to be used with the Ampcare ES NMES and Ampcare E Series Electrodes as part of the Ampcare ESP Therapy System, a neuromuscular electrical stimulation protocol FDA-cleared for the treatment of dysphagia.

Contact Ampcare for details about ordering in your area.

Product Number	Product Description
50701	Ampcare ES NMES
50709	Ampcare E Series Electrodes
50712	Replacement Lead Wires with Tester

**Instructions for the Ampcare Lead Wire Tester**

1. Plug the right-angle lead wire plug into the output socket of either Channel 1 or Channel 2 of your Ampcare ES NMES Unit.
2. Place the red lead wire pin in the red socket and the black lead wire pin in the black socket of the conduction tester.
3. Turn up the intensity/amplitude for the channel that you are testing. The light in the middle of the conduction tester should illuminate. Turn up the intensity for the designated channel until the light illuminates.
4. The light may light up continuously or blink depending on the program settings (i.e., frequency and phase duration) when you test the device. If it blinks it should be a systematic blinking with set intervals (e.g., 5 seconds on and 25, 20 or 15 seconds off – per the duty cycle selected).
5. Gently pivot the right angle plug to ensure a good connection during the stimulation on times.
6. Gently move your fingers up the wire to the red and black shields taking care not to touch the metal pins.
7. This should ensure no interruptions in connectivity. If the light does not light up or you notice a break in connectivity the most likely reason is that there is a short in your lead wire. In that case, please test the other lead wire in the same channel to confirm this.
8. Once you have tested a good lead wire and confirmed that the previous lead wire has a fault, you should dispose of the faulty lead wire.
9. Replacement lead wires can be sourced from Ampcare, LLC.
10. If after replacing the lead wire you still encounter a problem with connectivity, contact your dealer or Ampcare, LLC.

**Explanation of Symbols:**



Authorized Representative in the European Community



European Union Mark of Conformity



Medical Device

UKRP

United Kingdom Responsible Person

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\*In case of serious injury, report to manufacturer and competent authority\*  
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## Indications/Intended Use:

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## Instructions for Use:

1. Inspect the Lead Wires: Before each use, inspect for any visible damage such as cracks in the insulation or exposed copper core. Replace if damaged.
2. Connect to the Ampcare ES NMES: Insert the right-angle lead wire plug into the designated output jack on the unit. Ensure a secure fit to avoid signal disruption. Refer to the Ampcare ES NMES User Manual for additional instructions.
3. Attach to Ampcare E Series Electrodes: Insert the red and black pin connector of the lead wires to the electrodes by inserting the pins into the corresponding sockets on the electrodes. Refer to the Ampcare E Series Electrodes IFU for further details.
4. Remove After Use: After the session, turn off the Ampcare ES NMES unit, and gently detach the lead wires from the unit and electrodes.

## Patient Population:

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

## Intended Users:

Trained, licensed health care professionals involved in patient care, whether they are in a hospital, skilled nursing facility, in-patient or out-patient rehabilitation center, long-term care facility, assisted living facility, private practice clinic, or at home with home health treatment.

## Precautions

- Do not put the lead wire on or wrapped around the neck.
- Do not use damaged lead wires, as this may cause electrical shorts or improper operation.
- Avoid contact with water or other liquids during use.

## Potential adverse event / side effect:

There are no known adverse events/side effects. Ensure proper electrode placement to avoid discomfort or ineffective treatment.

## Troubleshooting:

If the ES NMES unit does not function properly, check the lead wires for secure connections and inspect for damage. Check the lead wires with the lead wire conduction tester provided. Replace the lead wires if any issues persist.

## Maintenance and Care:

- Clean the wires with a dry cloth after use to remove any debris.
- Avoid pulling or bending the wires excessively to prevent damage.

## Specifications:

- 21 CFR 898 Compliant
- Wire Length: 1250 mm ± 10 mm
- Wire Type: Copper Core; PVC Insulated
- Color: Red & Black

## Storage / Handling:

Store the wires in a dry, cool place when not in use.

**Disposal:** Dispose of components in accordance with local, regional, national, or international regulations.

**Warranty:**

Ampcare agrees that if any defect in materials or workmanship appears in this product within six months after the original date of consumer purchase, it will replace the product in question free of charge. This applies only if the product has been used as directed and has not been damaged through misuse, accident, or neglect.

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**Ordering Information:**

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Product Number	Product Description
50701	Ampcare ES NMES
50709	Ampcare E Series Electrodes
50712	Replacement Lead Wires with Tester

**Instructions for the Ampcare Lead Wire Tester**

1. Plug the right-angle lead wire plug into the output socket of either Channel 1 or Channel 2 of your Ampcare ES NMES Unit.
2. Place the red lead wire pin in the red socket and the black lead wire pin in the black socket of the conduction tester.
3. Turn up the intensity/amplitude for the channel that you are testing. The light in the middle of the conduction tester should illuminate. Turn up the intensity for the designated channel until the light illuminates.
4. The light may light up continuously or blink depending on the program settings (i.e., frequency and phase duration) when you test the device. If it blinks it should be a systematic blinking with set intervals (e.g., 5 seconds on and 25, 20 or 15 seconds off – per the duty cycle selected).
5. Gently pivot the right angle plug to ensure a good connection during the stimulation on times.
6. Gently move your fingers up the wire to the red and black shields taking care not to touch the metal pins.
7. This should ensure no interruptions in connectivity. If the light does not light up or you notice a break in connectivity the most likely reason is that there is a short in your lead wire. In that case, please test the other lead wire in the same channel to confirm this.
8. Once you have tested a good lead wire and confirmed that the previous lead wire has a fault, you should dispose of the faulty lead wire.
9. Replacement lead wires can be sourced from Ampcare, LLC.
10. If after replacing the lead wire you still encounter a problem with connectivity, contact your dealer or Ampcare, LLC.

**Explanation of Symbols:**



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A non-sterile, insulated, electrical conducting wire intended to be used to connect Ampcare E Series Electrodes to the Ampcare ES NMES.



## Instructions for Use:

1. Inspect the Lead Wires: Before each use, inspect for any visible damage such as cracks in the insulation or exposed copper core. Replace if damaged.
2. Connect to the Ampcare ES NMES: Insert the right-angle lead wire plug into the designated output jack on the unit. Ensure a secure fit to avoid signal disruption. Refer to the Ampcare ES NMES User Manual for additional instructions.
3. Attach to Ampcare E Series Electrodes: Insert the red and black pin connector of the lead wires to the electrodes by inserting the pins into the corresponding sockets on the electrodes. Refer to the Ampcare E Series Electrodes IFU for further details.
4. Remove After Use: After the session, turn off the Ampcare ES NMES unit, and gently detach the lead wires from the unit and electrodes.

## Patient Population:

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

## Intended Users:

Trained, licensed health care professionals involved in patient care, whether they are in a hospital, skilled nursing facility, in-patient or out-patient rehabilitation center, long-term care facility, assisted living facility, private practice clinic, or at home with home health treatment.

## Precautions

- Do not put the lead wire on or wrapped around the neck.
- Do not use damaged lead wires, as this may cause electrical shorts or improper operation.
- Avoid contact with water or other liquids during use.

## Potential adverse event / side effect:

There are no known adverse events/side effects. Ensure proper electrode placement to avoid discomfort or ineffective treatment.

## Troubleshooting:

If the ES NMES unit does not function properly, check the lead wires for secure connections and inspect for damage. Check the lead wires with the lead wire conduction tester provided. Replace the lead wires if any issues persist.

## Maintenance and Care:

- Clean the wires with a dry cloth after use to remove any debris.
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## Specifications:

- 21 CFR 898 Compliant
- Wire Length: 1250 mm ± 10 mm
- Wire Type: Copper Core; PVC Insulated
- Color: Red & Black

## Storage / Handling:

Store the wires in a dry, cool place when not in use.

**Disposal:** Dispose of components in accordance with local, regional, national, or international regulations.

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2. Place the red lead wire pin in the red socket and the black lead wire pin in the black socket of the conduction tester.
3. Turn up the intensity/amplitude for the channel that you are testing. The light in the middle of the conduction tester should illuminate. Turn up the intensity for the designated channel until the light illuminates.
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### Potential adverse event / side effect:

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### Troubleshooting:

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