



AMPCARE ES™ NMES



User Manual

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The AMPCARE ES™ NMES

Thank you for purchasing the AMPCARE ES NMES (Ampcare Product 50701 AMPCARE ES, model: AMPCARE ES NMES)

1. Foreword

Read this User Manual carefully before you start using your AMPCARE ES NMES. This manual has been written for the users of the AMPCARE ES NMES. It contains general safety information on the operation, precautionary practices, and care information. In order to maximize use, efficiency, and the life of the system, please read this manual thoroughly. Become familiar with the controls, as well as the accessories, before operating this system.

Before administering any treatment to a patient, the users of this equipment should read, understand, and follow the information contained in this manual for the mode of treatment available, as well as the indications, contraindications, warnings, precautions, and potential adverse events/side effects.

2. Product Description

The AMPCARE ES NMES is a portable two-channel electrotherapy unit used in treating single or multiple patients with oral-pharyngeal dysfunctions (dysphagia) and disorders of the head and neck.

Stay current with the latest clinical developments in the field of Ampcare ESP™ (Effective Swallowing Protocol) Therapy System, and observe all applicable precautionary measures for treatment.

Federal Law restricts this device to sale by or on the order of a physician or licensed practitioner.

This equipment is to be used only by a licensed practitioner certified in the use of the Ampcare ESP™ Therapy System.

3. General Safety

- Read, understand, and practice the precautionary and operating instructions. Know the limitations and hazards associated with using any electrical stimulation device. Observe the precautionary and operational decals placed on the unit.
- DO NOT operate this unit in an environment where other devices are being used that intentionally radiate electromagnetic energy in an unshielded manner. Portable and mobile RF communications equipment can affect Medical Electrical Equipment.
- DO NOT use sharp objects such as a pencil point or ballpoint pen to operate the buttons on the control panel.
- Environmental Conditions:
 - Operating Temperature: +5°C to +40°C / 41°F to 104°F
 - Operating Humidity: 10%RH to 93%RH
 - Operating Atmospheric Pressure: 700 hPa to 1060 hPa
 - Storage/Transport Temperature: -25°C to +70°C / -13°F to 158°F
 - Storage/Transport Humidity: 8% to 93% R.H
 - Storage Atmospheric Pressure: 700 hPa to 1060 hPa
- Make sure the unit output is turned off before connecting the lead wires to the unit prior to therapy or before removing electrodes from the skin after therapy.
- Place the patient in a comfortable position during AMPCARE ES NMES therapy session.
- Do not submerge or otherwise immerse in liquids as the AMPCARE ES NMES is not designed to prevent the ingress of water or liquids. Ingress of water or liquids could cause malfunction of internal components of the system and therefore create a risk of injury to the patient.
- Inspect lead wires and associated connectors for signs of damage before each use. Replace damaged lead wires immediately with new before any treatment is applied.
- Always check the stimulation controls before treating a patient. The stimulation amplitude/intensity should always be adjusted gradually.
- Keep the unit away from sources of high magnetic fields such as TVs, microwaves, and hi-fi speakers, as these may affect the LCD screen.
- Keep the device away from a fireplace or radiant heater, as the heat may affect the device.

- Keep the device away from nebulizer or steam kettle, as the moisture may affect the device.
- Keep the device away from lint and dust, as long-term exposure to lint or dust may affect the plug/sockets or connector contacts.
- Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when electrical stimulation is in use.
- Before administering the AMPCARE ES NMES waveform you should become acquainted with the operating procedures for each mode of treatment available, as well as the indications, contraindications, warnings, and precautions. Consult other resources for additional information regarding the application of electrotherapy, Electrical Stimulation, and AMPCARE ES NMES.
- Simultaneous connection of a patient to high frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
- Keep electrodes separated during treatment. Electrodes in contact with each other could result in improper stimulation or skin burns.
- Electrodes should be inspected before each use for resistance (i.e. hydration level, tack, discoloration, and impurities). Follow the manufacturing guidelines on electrode packaging.
- Patients with an implanted neurostimulation device must not be treated with AMPCARE ES NMES anywhere on their body. Energy from AMPCARE ES NMES can be transferred through the implanted neurostimulation system, can cause tissue damage, and can result in severe injury or death.
- Handle, clean, and dispose of components and accessories that have come in contact with bodily fluids according to National, Local, and Facility rules, regulations, and procedures.
- Only use the Ampcare E Series Electrodes and accessories designed specifically for use with the AMPCARE ES NMES Unit.

4. Indications for Use and Intended Uses

Indications for Use for AMPCARE ES NMES

Muscle re-education by application of external stimulation to the muscles necessary for pharyngeal contraction.

Intended Uses for AMPCARE ES NMES

The waveform is a square symmetrical biphasic waveform with the application for use on the musculature of the face.

The intended uses are for prevention or retardation of disuse atrophy, for muscle re-education, and for relaxation of muscle spasms in the treatment of swallowing musculature dysfunction in post-traumatic conditions or after neurological insult with impaired neuromuscular function. The AMPCARE ES NMES waveform is a symmetrical biphasic waveform with the application for use on the swallowing musculature in the anterior portion of the neck.

The AMPCARE ES NMES therapy treatment intended uses are: muscle re-education of the swallowing musculature in the treatment of dysphagia (swallowing problems) from any etiology except mechanical causes that would need surgical intervention (for instance, obstructing tumors). Non-mechanical causes of dysphagia include: neurological and muscle disorders; cardiovascular accidents; respiratory disorders with swallowing complications; iatrogenic conditions (conditions caused by surgery); fibrosis/stenosis arising from radiation; disuse due to stroke, intubation hypoxic encephalopathy, or birth-related anoxic injuries; and trauma to the head and neck.

This device is a prescription device intended for use by or on the order of a physician or other licensed health professional.

5. Contraindications

- This device should not be used on patients with cardiac demand pacemakers or other implanted electronic devices.

6. Warnings

- The long-term effects of electrical stimulation are unknown.
- Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
- This device should not be used when cancerous lesions or infections are present in the treatment area.
- Stimulation should not be applied over places where active range of motion is contraindicated (e.g. fractures, anastomosis).
- Stimulation should not be applied transthoracically in that the induction of electrical current into the heart may cause cardiac arrhythmias.
- Stimulation should not be applied transcerebrally.
- Care must be taken when operating this equipment adjacent to or stacked with other equipment. Potential electromagnetic or other interference could occur to this or other equipment. Try to minimize this interference by not using other equipment in conjunction with it. (i.e. cell phones, MRI, electro surgery, defibrillation, etc.)

7. Precautions

- Safety of powered muscle stimulation for use during pregnancy has not been established.
- Caution should be used for patients with suspected or diagnosed heart problems.
- Caution should be used for patients with suspected or diagnosed epilepsy.
- Caution should be used in the presence of the following:
 - When there is a tendency to hemorrhage following acute trauma or fracture.
 - When individuals cannot give clear feedback. Patients may not indicate when current becomes uncomfortable.

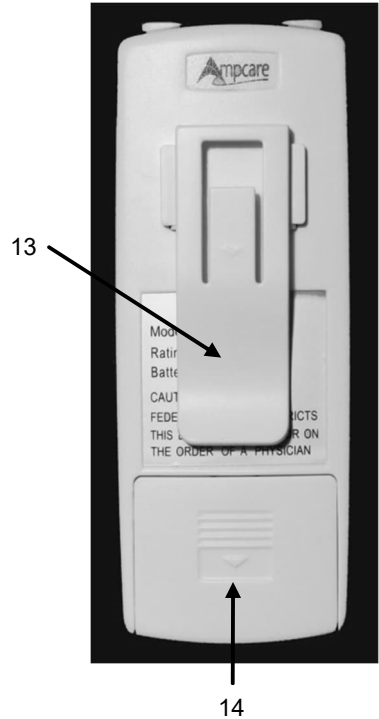
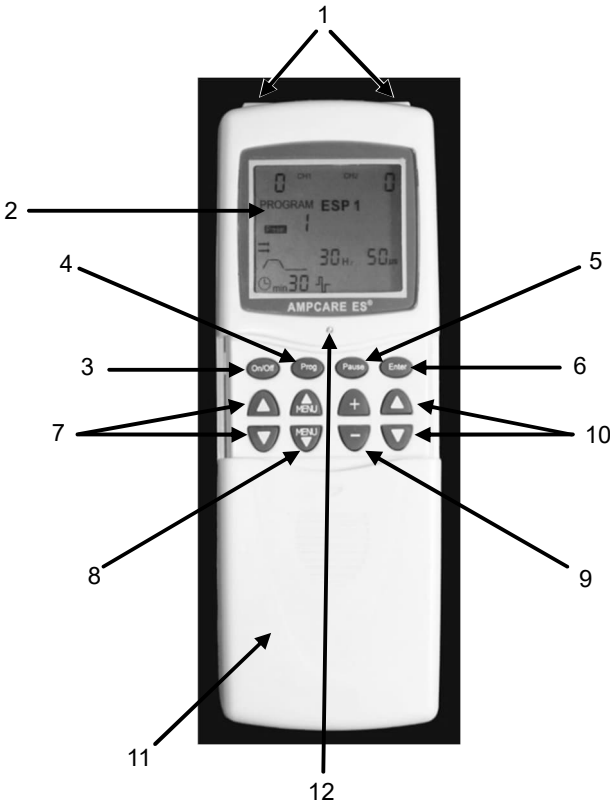
- Following recent surgical procedures when muscle contraction may disrupt the healing process.
- Over a menstruating or pregnant uterus.
- Over areas of the skin which lack normal sensation.
- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternative conductive medium or an alternative electrode placement.
- Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
- Powered muscle stimulators should be kept out of the reach of children.
- Powered muscle stimulators should be used only with the lead wires and electrodes recommended for use by the manufacturer.
- Portable powered muscle stimulators should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.

8. Potential Adverse Events/Side Effects

- Mild pain and superficial burns have been reported with the use of powered muscle stimulators. Skin irritation has been reported with the use of electrodes.

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.

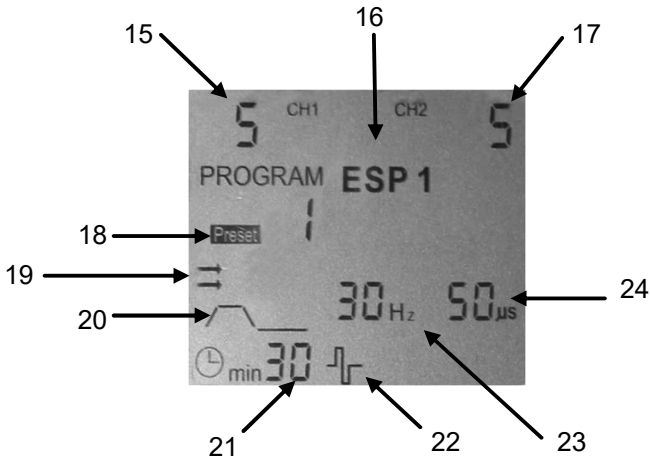
9. Nomenclature



Keypad and case

1. **Channels 1 and 2** – Lead wires connect in the respective ports.
2. **Operator LCD Panel** – see items 15-24.
3. **Power On/Off Button** – used to turn unit On or Off.
4. **Program Button** – used to select electrical stimulation program.
5. **Pause Button** – used to pause the treatment.
6. **Enter Button** – used to enter the selected parameter.
7. **Channel 1 Intensity Up and Down Controls** – used to increase or decrease Channel 1 intensity.
8. **Menu Up and Down Controls** – used to modify selected parameters.
9. **Parameter Up and Down Controls** – used to increase or decrease parameter increments.
10. **Channel 2 Intensity Up and Down Controls** – used to increase or decrease Channel 2 intensity.
11. **Control Button Cover** – used to maintain selected parameters.
12. **LED Light Indicator** – blinks when unit is administering current.
13. **Belt Clip** – attach to patient during therapy session.
14. **Battery Compartment** – push in and slide down to insert/replace batteries. Do not use rechargeable batteries.

Liquid Crystal Display (LCD)



15. **Channel 1 Intensity Indicator** – shows the intensity of Channel 1 during therapy session.
16. **Program Indicator (ESP1, ESP2, MANUAL)** – shows the program selected.
17. **Channel 2 Intensity Indicator** – shows the intensity of Channel 2 during therapy session.
18. **Preset or Manual Indicator** – shows if the frequency and phase duration are preset or manually selected.
19. **Synchronous Indicator** – shows that Channel 1 and 2 will work synchronously if both are in use.
20. **Duty Cycle Indicator** – shows the activation/cycle on time and rest/cycle off time of the duty cycle.
21. **Timer Icon and Treatment/Countdown Timer** – therapy session and rest/cycle off time timer. See “Other operating functions” section for more details.
22. **Waveform Indicator** – symmetrical biphasic waveform fixed.
23. **Pulse Rate Indicator** – shows the frequency measured in Hertz.
24. **Phase Duration Indicator** – shows the phase duration measured in microseconds.

10. Specifications

Please read the following detailed specifications carefully before using the unit.

Output Configuration – Dual channel electrically isolated with miniature safety connectors.

Output Waveforms – AC Mode: Rectangular symmetrical biphasic with zero net DC.

Intensity Control – Dual intensity potentiometers:

Ch1 intensity up/down 20 steps, 0 to a maximum of 100mA* into 500Ω

Ch2 intensity up/down 20 steps, 0 to a maximum of 100mA* into 500Ω

Unit Dimensions – width x height x depth is 66 x 136 x 30.7 mm

Standard Weight – 98 grams

Power Source – Internal Power Source: Two AA LR6 Alkaline Batteries
– Do not use rechargeable batteries

Safety Recognition – Meets IEC/EN 60601-1

Waveform Specifications – is a symmetrical biphasic waveform.

| | |
|--|--------------------------------------|
| Output Mode..... | electrodes |
| Output Intensity..... | 0-100mA* |
| Channel Mode..... | Single and Co-Contraction |
| Phase Duration..... | 50-250µsec |
| Mode Selection..... | Constant Charge |
| Set Intensity..... | Individual Channel Intensity Setting |
| Cycle Time..... | 5/15, 5/20 and 5/25 |
| Frequency..... | 5-50 Hz |
| Ramp..... | 1 sec |
| Treatment Time..... | 5-30 minutes |
| Available on Channels..... | 1 & 2 |
| Software Version..... | R4_03 |
| Protection Against Electric Shock..... | Type BF |
| Applied Part..... | Ampcare E Series Electrodes |

* ***Intensity setting controls output amperage, which is limited based on phase duration. Refer to section 10 “Intensity” of this manual for more detailed information.***

Three mode features

a) Program Preset 1, ESP 1 – electrical stimulation program 1

| | |
|-----------------|--|
| Frequency | Fixed, 30 Hz |
| Phase duration | Fixed, 50 μ s |
| Waveform | Symmetrical biphasic rectangular |
| Cycle on time | Fixed 5 sec |
| Cycle off time | Adjustable 25 sec, 20 sec and 15 sec |
| Ramp up | Fixed 1 sec |
| Ramp down | Fixed 0 |
| Treatment timer | Fixed 30 min |
| Intensity | Adjustable 0 – 20*, Max. 50V across 500 Ω |

b) Program Preset 2, ESP 2 – electrical stimulation program 2

| | |
|-----------------|--|
| Frequency | Fixed, 30 Hz |
| Phase duration | Fixed, 250 μ s |
| Waveform | Symmetrical biphasic rectangular |
| Cycle on time | Fixed 5 sec |
| Cycle off time | Adjustable 25 sec, 20 sec and 15 sec |
| Ramp up | Fixed 1 sec |
| Ramp down | Fixed 0 |
| Treatment timer | Fixed 30 min |
| Intensity | Adjustable 0 – 20*, Max. 50V across 500 Ω |

c) Program Manual 3, Manual 3 – electrical stimulation program 3

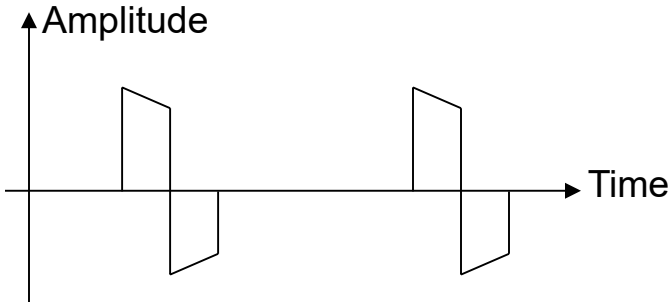
| | |
|-----------------|--|
| Frequency | Adjustable 5-50 Hz |
| Phase duration | Adjustable 50-250 μ s |
| Waveform | Symmetrical biphasic rectangular |
| Cycle on time | Fixed 5 sec |
| Cycle off time | Adjustable 25 sec, 20 sec and 15 sec |
| Ramp up | Fixed 1 sec |
| Ramp down | Fixed 0 |
| Treatment timer | Adjustable 5-30 min |
| Intensity | Adjustable 0 – 20*, Max. 50V across 500 Ω |

* ***Intensity setting controls output amperage, which is limited based on phase duration. Refer to section 10 “Intensity” of this manual for more detailed information.***

Output

a. Waveform:

Symmetrical biphasic rectangular waveform



b. Output parameters:

Detailed output parameters of the 2 preset programs and 1 manual program regarding to the frequency, phase duration, ramp up, ramp down, cycle on time, cycle off time, and program duration are as follows.

Program table:

| Program | ESP1 | ESP2 | Manual 3 |
|-----------------------------|---------------------------------------|-------------|--|
| Frequency (Hz) | 30 (fixed) | | 5-50 adjustable in 1 Hz increments |
| Phase Duration (μ sec) | 50 (fixed) | 250 (fixed) | 50-250 adjustable in 50 μ sec increments |
| Ramp Up (sec) | 1 (fixed) | | |
| Ramp Down (sec) | 0 (fixed) | | |
| Cycle ON Time (sec) | 5 (fixed) | | |
| Cycle OFF Time (sec) | Selectable values of 25, 20, or 15 | | |
| Program Duration (min) | 30 (fixed) | | 5 – 30 adjustable in 5 min increments |
| Intensity | 0 – 20 adjustable in increments of 1* | | |

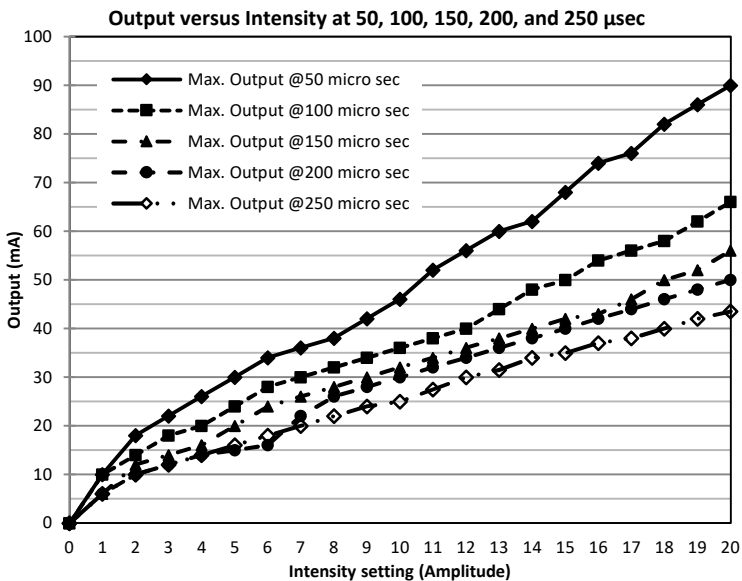
* **Intensity setting controls output amperage, which is limited based on phase duration. Refer to section 10 “Intensity” of this manual for more detailed information.**

c. Intensity:

The intensity can be increased/decreased by adjusting the intensity setting from 0 to 20. The intensity setting controls the output amperage and is dependent on the phase duration. The maximum amperage output is achieved at 50µsec phase duration with intensity at 20. The minimum amperage output is achieved at 250µsec phase duration with intensity at 1 (excluding 0 for which no amperage is output.) The table below shows numerical values obtained during bench testing for four specific intensity settings at each of the five available phase durations. Also shown is a graphical representation of the same data showing the values obtained during bench testing at each intensity value for all five phase durations.

Intensity Table: (bench-testing data: 30Hz, 500 ohms)

| Intensity | 50 µsec | 100 µsec | 150 µsec | 200 µsec | 250 µsec |
|-----------|---------|----------|----------|----------|----------|
| 5 | 30 mA | 24 mA | 20 mA | 15 mA | 16 mA |
| 10 | 46 mA | 36 mA | 32 mA | 30 mA | 25 mA |
| 15 | 68 mA | 50 mA | 42 mA | 40 mA | 35 mA |
| 20 | 90 mA | 66 mA | 56 mA | 50 mA | 44 mA |

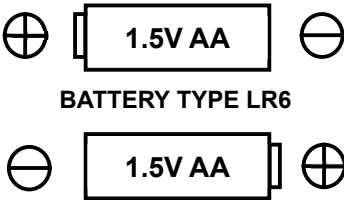
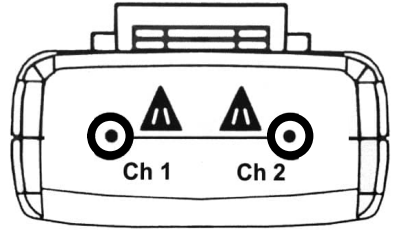


11. Markings and Labels

- Ch 1 and Ch 2 output jacks (Ch1) & (Ch2) are both marked on the top of the unit with respect to the output channels.



After inserting the lead wire plugs into both Ch 1 and Ch 2 jacks, please do not remove the plugs when the unit is working. Ensure that the unit is switched OFF before removing the plugs.



BATTERY TYPE LR6

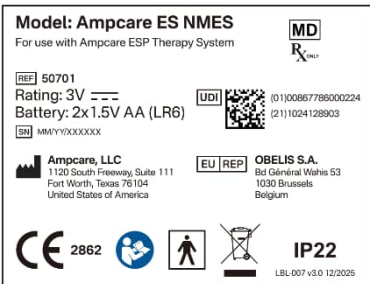
2. Battery

These symbols, as marked in the battery compartment, indicate to use only the specified batteries: 2x1.5 Volt AA Alkaline (LR6).

Do not use rechargeable batteries.

⊕ and ⊖ stand for Anode and Cathode respectively.

3. Label

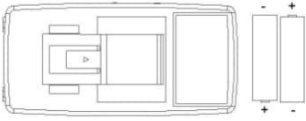


Please dispose of the device in accordance with the laws in your area. Your local council will be able to tell you where your nearest facility is. The collection facilities may send items for treatment, recovery, and recycling, so by using them you will help to save resources and minimize effects on the environment.

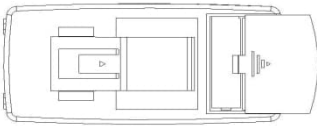
12. Set Up

How to assemble your AMPCARE ES NMES

STEP 1 BATTERY INSTALLATION:



Remove the battery cover and insert two batteries on top of fabric strap, as shown on the diagram inside the battery compartment. Replace the battery cover.

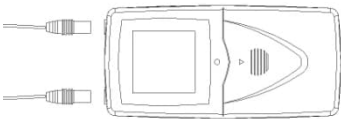


Note: Your unit will not function if the batteries are inserted incorrectly. To check, press the **On/Off** button once and the LCD display will start up. After you have made this check, press the **On/Off** button again and hold for 3 seconds to switch the unit off.



CAUTION: Replace with AA Alkaline 1.5 volt batteries (LR6). Do not use rechargeable batteries.

STEP 2 LEAD WIRE INSTALLATION:




Decide whether you wish to use the unit with one lead or two. Unravel one or both leads and insert the plug(s) into either of the jacks at the top of the unit. If only using one lead, insert into the Ch1 jack as marked on the unit.

Note: Red & Black connectors on lead wires

At the end of the recommended lead wires (Ampcare product 50712), there are red and black pin connectors. These are the anode and cathode, respectively. The following general points are made for your information:

1. More sensation and stimulation tend to come from the black pin (cathode).
2. Where applicable, place the black pin over the weakest muscle belly; e. g. if using a submandibular placement on an individual with right hemiplegia, consider placing the black pin on the right side.

Note: Refer to the Ampcare E Series Electrode Instruction Card contained within the electrode package for electrode preparation and lead wire attachment to the electrodes.

After the electrodes are placed on the patient per the Ampcare ESP Therapy System Certification Training Materials, turn the unit on by pressing the  button once.

13. Operating Directions for Use

The Keypad



Key Functions

The **On/Off** button allows the switching on or off of the unit when needed. Press it once to switch the unit ON. When the unit is ON, the unit can be switched OFF by pressing and holding the button for 3 seconds.

If you wish to switch OFF the unit while it is supplying stimulation, you need to press and hold the **On/Off** button for 3 seconds.

The **Prog** button allows the selecting of a program from the Preset 1, Preset 2 or Manual 3 options. To change the program press and hold the **Prog** button for 3 seconds. Whenever the **Prog** button is activated, the intensity level of both channels automatically resets to 0.

When the unit is ON but the intensity level of at least one channel is above 0, you can PAUSE the unit by pressing the **Pause** button once. When PAUSED the output level of both channels will be zeroed and the symbol **▶||** will be shown between Ch1 and Ch2 on the display.

To restart the unit, press the **Pause** button once and the intensity level of both channels will be progressively restored within 6 seconds.




Channel 1 & 2 have separate intensity buttons to increase and decrease the stimulation level by pressing the “UP” arrow to increase and the “DOWN” arrow to decrease (left arrows for channel 1 and right arrows for channel 2).



The Menu buttons select the adjustable parameters in the program causing them to blink.

Pressing the “+” or “-“ button adjusts the individual parameter either higher or lower.

Pressing the  button locks the adjusted parameter into the program.

Other operating functions:

1. When the unit is turned on and a program is not running, if any of the keys are not pressed within 5 minutes, the unit will automatically shut off.
2. When the unit is turned on, it will automatically enter the program that the unit had worked in before the unit was turned off.
3. When the batteries are low, the battery symbol flashes in the lower right corner of the LCD indicating that the batteries should be replaced.
4. Upon replacing the batteries, the unit will need to be reprogrammed to the appropriate parameters.
5. During the therapy session, there are periods of stimulation on time and periods of rest/cycle off time. During the stimulation on time, the total therapy session remaining time is shown next to the timer icon. During the rest/cycle off time, the remaining rest/cycle off time is shown to visually prepare users for the next stimulation.

14. Programming Directions for Use

When you select one of the three programs (Preset 1, Preset 2 and Manual 3) on the AMPCARE ES NMES, all the parameters will be pre-defined per the program table below. However, it is always possible to modify the rest/cycle off time on Preset 1 and Preset 2 programs and the rest/cycle off time, treatment time, frequency, and phase duration on Manual 3 program. Having the ability to modify parameters can make the current more comfortable for different patients and body areas.

Program table:






| Program | ESP1 | ESP2 | Manual 3 |
|-----------------------------|---------------------------------------|---------------------------------------|--|
| Frequency (Hz) | 30 (fixed) | | 5-50 adjustable in 1 Hz increments |
| Phase Duration (μ sec) | 50 (fixed) | 250 (fixed) | 50-250 adjustable in 50 μ sec increments |
| Ramp Up (sec) | 1 (fixed) | | |
| Ramp Down (sec) | 0 (fixed) | | |
| Cycle ON Time (sec) | 5 (fixed) | | |
| Cycle OFF Time (sec) | Selectable values of 25, 20, or 15 | | |
| Program Duration (min) | 30 (fixed) | 5 – 30 adjustable in 5 min increments | |
| Intensity | 0 – 20 adjustable in increments of 1* | | |

- * ***Intensity setting controls output amperage, which is limited based on phase duration. Refer to Section 10 “Intensity” of this manual for more detailed information.***


Programming Preset 1 (ESP1) or Preset 2 (ESP2):

If you are using a Preset program you will only be able to modify the rest/cycle off time.

To program a treatment session:

-  1. Press the On/Off button to turn on the power to the unit.
-  2. Hold the program button down for 3 seconds until either Preset 1 or Preset 2 is shown on the screen.
3. If you do not want to modify this program you may proceed to step 7.
-  4. To modify press the “Menu up” or “Menu down” button once to program the rest/cycle off time. The pre-defined parameter will begin blinking to allow it to be modified.
-  5. Press the minus “-” or plus “+” button until the desired rest/cycle off time is selected. This can be changed from 25 to 20 or 15 seconds to lessen the amount of rest time between stimulations.
-  6. Once the parameter has been selected press the enter button to accept it.

To start a treatment session:

-  7. Use the up and down arrows until the prescribed intensity is visible in the LCD (left arrows for channel 1 and right arrows for channel 2).
8. The timer will begin counting down automatically once the intensity is increased and the LED Light Indicator will blink green when the unit is administering current.
9. Once the treatment time has reached zero the unit will automatically power off.
10. Once Preset 1 or 2 has been programmed, this will be the default until it is reprogrammed.

Programming Manual 3

If you are using the Manual 3 program you will be able to modify the frequency, phase duration, treatment time, and cycle off time.

To program a treatment session:



1. Press the On/Off button to turn on the power to the unit.
2. Hold the program button down for 3 seconds to progress to the next program; continue until Manual 3 is shown on the screen.
3. If you do not want to modify this program you may proceed to step 7.



4. To modify press the “Menu up” button to program the frequency, phase duration, and treatment time on the LCD in a clockwise direction or the “Menu down” button to program the treatment time, phase duration and frequency on the LCD in a counter clockwise direction. The pre-defined parameter will begin blinking to allow it to be modified.



5. Press the minus “-” or plus “+” button until the desired parameter is selected.



6. Once the parameters have been selected press the enter button to accept them. Once you press the enter button to select the parameters, the rest/cycle off time will automatically begin blinking and can be modified next.

To start a treatment session:



7. Use the up and down arrows until the prescribed intensity is visible in the LCD (left arrows for channel 1 and right arrows for channel 2).
8. The timer will begin counting down automatically once the intensity is increased and the LED Light Indicator will blink green when the unit is administering current.
9. Once the treatment time has reached zero the unit will automatically power off.
10. Once Manual 3 has been programmed, it will default back to the same program setting when used next.

15. Recommended Accessories, Compatible Devices

- **50701: AMPCARE ES NMES**
Ampcare ES NMES unit, 2 AA batteries, carry case, user manual
- **50709: AMPCARE E SERIES ELECTRODES**
50709LT Large/Adult or 50709ST Small/Youth
- **50707: AMPCARE RESTORATIVE POSTURE DEVICE (RPD)**
- **50708: RPD REPLACEMENT PAD SET**
- **50712: AMPCARE LEAD WIRES (2)**

16. Ordering Supplies

In the USA:

Equipment and replacement accessories can be obtained from:

Ampcare, LLC

1120 South Freeway, Suite 111

Fort Worth, Texas 76104

Phone: (682) 561-2444 Fax: (817) 348-8830

Online orders can be submitted at

www.ampcarellc.com/orders. An Ampcare certification number is required. Please contact Ampcare for product details and an order form.

International orders are processed through verified distributors.

Email info@ampcarellc.com for details.

Statement:

This unit is CE Marked, according to MDR (EU) 2017/745 and is classified as a Medical Device class IIa.



17. Training Program

The Ampcare ESP™ Therapy System certification program is recommended for healthcare providers prior to administering the technique. The training program educates the healthcare professional on the indications, contraindications, and the proper electrode placement of this treatment technique. It is recommended that only the Ampcare E Series Electrodes and Ampcare lead wires be used with the Ampcare ESP™ Therapy System.

18. Maintenance

Clean the unit with a clean, lint free cloth moistened with water and mild antibacterial soap. If a more sterile cleaning is needed, use a cloth moistened with an antimicrobial cleaner. Do not submerge the unit in water.

Long Term Storage

If the unit is to be stored or not used for 30 days or longer, remove the batteries.

19. Warranty

In addition to your statutory rights, the distributor agrees that if any defect in materials or workmanship appears in this product within two years after the original date of consumer purchase, it will repair or, at its option, replace the product in question free of charge. This applies only if the product has been used for domestic purposes and has not been damaged through misuse, accident, or neglect and has not been modified or repaired by anyone other than an authorized AMPCARE ES NMES distributor or one of its authorized agents. If a defect appears, please check that the article is being used in accordance with instructions. If so, return it with this warranty and proof of purchase to your nearest AMPCARE ES NMES dealer. Note: only our authorized service agents should carry out repairs of the AMPCARE ES NMES.

Life expectancy

Based on common usage and not being damaged through misuse, accident or neglect the AMPCARE ES NMES life expectancy is 3 years. Careful handling, storage, and not dropping or spilling liquid onto the AMPCARE ES NMES may increase the life expectancy.

Servicing

When the AMPCARE ES NMES requires servicing, contact the selling dealer or Ampcare, LLC directly.

The AMPCARE ES NMES Unit is FDA cleared, CE Marked, and battery operated, not requiring calibration. Please check with your medical facility to see if they require an annual safety check; Ampcare does not perform this service.

Warranty Repair/Replacement

All units returned to for servicing must include the following:

1. Written statement containing the following information:
 - Unit Serial Number
 - Contact Person with phone and fax numbers
 - Billing Address
 - Shipping Address (Where to Ship Unit after Repair)
 - Detailed Description of Problem or Symptoms
2. Copy of original invoice issued at purchase of unit.
3. Contact Ampcare, LLC at 1-682-561-2444 or info@ampcarellc.com for shipping information.

20. Explanation of Symbols



Type BF equipment



Refer to instruction manual/ booklet



Compliance with WEEE



CE marking with identification number of notified body



Authorized representative in the European community



Catalogue number



Medical device

Rx Only

Prescription device



Manufacturer

IP22

The first number 2: Protected against access to hazardous parts with a finger, and the jointed test finger of 12mm, 80mm length, shall have adequate clearance from hazardous parts, and protected against solid foreign objects of 12.5mm and greater.

The second number 2: Protected against vertically falling waterdrops when enclosure is tilted up to 15°.

Vertically falling drops shall have no harmful effects when the enclosure is tilted at any angle up to 15° on either side of the vertical.

Disposal of Waste Electrical and Electronic Products (WEEE)

A new law in force from July 2007 will mean that you will need to dispose of anything electrical or electronic at a collection facility, instead of in your domestic waste. New products are now being marked with the symbol to remind you. Your local council or retailer will be able to tell you where your nearest facility is. The collection facilities will send items for treatment, recovery, and recycling, so by using them you will help to save resources and minimize the effects on the environment.



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