TruWave Plus
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Zynex Medical
Contact Information

CUSTOMER SERVICE  (866) 940-7030
Supplies: To order more electrodes or other accessories
Technical Support: Questions or problems with using your device
Device Return: Order a postage paid return envelope to return your device at no charge

MAIN OFFICE  (800) 495-6670
Billing Questions: Questions regarding insurance benefits and covered benefits for durable medical equipment or questions about an Explanation of Benefits form you received in the mail

FAX NUMBER  (800) 495-6695

MAILING ADDRESS
Zynex Medical
9990 Park Meadows Drive
Lone Tree, CO 80124

EMAIL  info@zynexmed.com

WEBSITE  zynexmed.com
TruWave Plus
Waveforms

About the TruWave Plus
The Truwave Plus is one of only a few devices available on the market today with three separate modalities to treat a wide variety of symptoms. This unique device incorporates Interferential Current (IFC), Transcutaneous Electrical Nerve Stimulation (TENS), and Neuromuscular Electrical Nerve Stimulation (NMES).

Interferential Current (IFC)
Interferential Current is used for a wide range of applications, generally with the purpose of either pain relief and/or muscle stimulation. Interferential Current differs from other types of electrical stimulation by its frequency and the principle of “interference”. A substantially higher frequency (4,000 Hz) than traditional stimulation (1-150 Hz), allows the applied stimulation to penetrate the skin with less resistance. The skin impedance is approximately 100 times less using a higher frequency than using traditional TENS and NMES devices. The theory is that more of the stimulation energy reaches the nerve and muscle fibers and hence becomes more productive. With more stimulation reaching the affected area, IFC is recommended to be applied 3-4 times a day for 30-40 minutes per treatment.

Transcutaneous Electrical Nerve Stimulation (TENS)
Transcutaneous Electrical Nerve Stimulation has been used for the treatment of acute and/or chronic pain for over 40 years. TENS delivers electrical impulses through the skin in the range of 1-150 Hz. TENS treatments can range from 20 minutes to many hours and can be applied as needed for pain relief.

Neuromuscular Electrical Stimulation (NMES)
Neuromuscular Electrical Nerve Stimulation (NMES) is indicated for treatment of a variety of muscular dysfunctions. NMES is commonly used for prevention of disuse atrophy, muscle re-education, relaxation of muscle spasms, maintaining or increasing range of motion, increasing local blood circulation, and strengthening weak or injured muscles. NMES works by sending electrical impulses through electrodes placed on motor points located on the targeted muscle or group of muscles. When the stimulation is applied at the correct level, the targeted muscle will contract.

Important:
This device must be ordered or prescribed by a licensed physician.
**TruWave Plus**
**Electrodes & Leadwires Set-up**

**Step 1**
Open electrode package and remove electrodes from package. Keep electrodes on plastic backing.

**Step 2**
Insert leadwire pin connectors into electrode connectors as shown below. **RED** leadwire connectors on one side and **BLACK** leadwire connectors on the other side.

**IFC** modality requires ALL 4 electrodes (2 channels)

**TENS** and **NMES** modalities can use 2 electrodes (1 channel) or 4 electrodes (2 channels)
**TruWave Plus**

**Electrode & Leadwires Set-up (continued)**

**Step 3**
Remove each electrode from the plastic backing and place on the treatment site according to the type of modality selected.

**Electrode Arrangement**
When using the **IFC** modality, **RED** and **BLACK** leadwires must be placed in a crisscrossed pattern as shown in the diagram below.

**TENS** or **NMES do not** need to be crisscrossed and can be placed in a side by side pattern.

**Note:** Refer to pages 11-24 for detailed examples of electrode placements for different areas of the body.
TruWave Plus
Electrodes & Leadwires Set-up (continued)

**Step 4**  Plug leadwires into the top of the device. The IFC modality requires both sets of leadwires to be connected (channel 1 & 2). TENS and NMES can use 1 set (Channel 1) or 2 sets (Channel 1 & 2) of leadwires.

**Step 5**  Proceed to page 10 to start treatment or page 7 to program device.
TruWave Plus
Device Programming Instructions

Programming Device

*Turn device on by pressing channel 1 or 2 Up Button once*

1. Press *Program Button* once to enter programming mode
2. Press *Up Button* until desired modality is displayed on screen
3. Press *Program Button* once to “lock in” desired modality
4. Press *Up Button* until desired mode is displayed on screen (see next page for detailed description of each mode)
5. Press *Program Button* to “lock in” mode
6. Press *Up Button* until desired treatment time is displayed on screen
7. Press *Program Button* to “lock in” treatment time
8. To view Data (Compliance Meter) press *Down Button* once
9. Press *Program Button* to return to Operating Mode and start treatment (see page 10 for Device Operating Instructions)
### TruWave Plus

#### Preprogrammed Modes

**Interferential Current (IFC)**

<table>
<thead>
<tr>
<th>Mode</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low-High</td>
<td>The IF frequency sweeps between 1 Hz and 150 Hz over a period of 15 seconds continuously.</td>
</tr>
<tr>
<td>Low</td>
<td>The IF frequency sweeps between 1 Hz and 10 Hz over a period of 15 seconds continuously.</td>
</tr>
<tr>
<td>Combo</td>
<td>Combo consists of three 2 minute cycles which repeat over the duration of the treatment. 1st cycle - IFC frequency sweeps between 1 Hz and 10 Hz over a 15 second period. 2nd cycle - IFC frequency sweeps between 80 and 150 Hz over a 15 second period. 3rd cycle - IFC frequency of 50 Hz is on for 6 seconds, followed by 6 seconds of off time.</td>
</tr>
</tbody>
</table>

**Transcutaneous Electrical Nerve Stimulation (TENS)**

<table>
<thead>
<tr>
<th>Mode</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sweep</td>
<td>TENS frequency sweeps between 1 Hz and 125 Hz over 14 seconds. Pulse Width adjusts down by 50% when frequency is sweeping up and back to original Pulse Width (150 µsec.) when frequency is sweeping down.</td>
</tr>
<tr>
<td>Constant</td>
<td>The Frequency is set at 80 Hz with a default Pulse Width set at 150 µsec.</td>
</tr>
<tr>
<td>Modulated</td>
<td>The frequency shifts between 66 and 100 Hz at an interval of 6 seconds. The Pulse Width will also shift during the 6 seconds interval. The default Pulse Width is 225µsec. and when the frequency is at it’s minimum, the Pulse Width is at it’s maximum and visa versa.</td>
</tr>
</tbody>
</table>

**Neuromuscular Electrical Stimulation (NMES)**

<table>
<thead>
<tr>
<th>Mode</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simultaneous</td>
<td>Preset 10 second ON &amp; OFF time, 35 Hz, 300µsec P-W, ramp up 3 seconds, ramp down 1 second, Simultaneous</td>
</tr>
<tr>
<td>Alternating</td>
<td>Preset 10 second ON &amp; OFF time, 35 Hz, 300µsec P-W, ramp up 3 seconds, ramp down 1 second, Alternating</td>
</tr>
<tr>
<td>Fatiguing</td>
<td>Preset 10 second ON &amp; OFF time, 80 Hz, 300µsec P-W, ramp up 3 seconds, ramp down 1 second, Simultaneous</td>
</tr>
</tbody>
</table>
TruWave Plus
Device Controls

**Program Mode:** Displays TENS, IFC, or NMES, Specific Mode, Timer, Data

**Operating Mode:** Displays mA level & remaining treatment time & alerts

---

**LCD Display**

- **Leadwire Connection**
- **Channel 1**
  - Uses electricity from wall socket instead of 9v battery
- **A/C Adapter Outlet**
  - Channel 1 increase intensity control
  - Channel 1 decrease intensity control
- **Up Button**
  - Channel 1 & 2 Intensity Lights & Low battery indicator
- **Down Button**
  - Program Button
    - Navigate between different modalities and modes
  - On button, channel 2 increase intensity control, change option in program mode
  - Off button, channel 2 decrease intensity control, change option in program mode
- **Status LEDs**
TruWave Plus
Device Operating Instructions

Start Treatment:

Before starting treatment electrodes must be placed on the treatment site (refer to pages 11-24 for examples) and leadwires and electrodes connected to the device. (see Electrodes & Leadwires Set-up on page 4)

1. Turn TruWave Plus ON by pressing Channel 1 Up Button once.
2. Increase intensity* by pressing Channel 1 Up Button until a strong but comfortable stimulation level is felt. Repeat for Channel 2 if both leadwires are attached and device is in TENS or NMES mode.
3. Once desired level of stimulation is set, the unit will automatically shut off at the preset treatment time shown on the display. If Treatment Timer has been set to Continuous then the device will need to be shut off manually. (Refer to Programming Instructions on page 7 to adjust Treatment Timer)
4. To turn off device manually, press and hold the Channel 2 Down Button until display turns off.

* Intensity level can be increased or decreased with either channel 1 or channel 2 Up and Down buttons when device is set to IFC Mode. If “Chan. 1 or 2 Electrode” message is displayed on the screen, see “Display Alerts” below.

During Treatment:

IMPORTANT: Button controls lock after 20 seconds of inactivity. To unlock button controls, press Down button once.

Increase Intensity:

To increase intensity after the button controls have locked, press the Down button once and then press the Up button for either channel to desired level.

Decrease Intensity:

To decrease intensity press the Down button for each channel until desired level of stimulation is felt. While in IFC mode, pressing either channel Down button will decrease the stimulation level. (pressing and holding the Down button will turn device off)

Display Alerts:

Chan. 1 or 2 Electrode: Leadwire(s) and/or electrode(s) may not be attached properly, check all connections and try again. If problem persists, call Technical Support (see page 2)

Bat: Replace Battery immediately or connect the A/C Adapter
PAIN CONTROL

INTENSITY LEVEL:
The stimulation level should be set to a strong, but comfortable strength.

DEVICE SET-UP:

<table>
<thead>
<tr>
<th>Modality</th>
<th>Mode</th>
<th>Treatment Time</th>
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<tbody>
<tr>
<td>IFC</td>
<td>Low-High, Low, Combo</td>
<td>40 minutes 4 times/day</td>
</tr>
<tr>
<td>TENS</td>
<td>Modulated, Sweep, Constant</td>
<td>As needed</td>
</tr>
<tr>
<td>NMES</td>
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</tr>
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ELECTRODE PLACEMENT

Electrodes should surround the targeted treatment site with area of pain located in the center of the electrode area.

IFC Modality

Place the electrodes with the RED and BLACK ends of the leadwires according to pattern depicted on figure to the left.

TENS / NMES Modality

Place the electrodes with the RED and BLACK ends of the leadwires according to pattern depicted on figure to the left.

Using both channels and crisscrossing the electrodes is optional when using the TENS or NMES modality.
PAIN CONTROL

INTENSITY LEVEL:
The stimulation level should be set to a strong, but comfortable strength.

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*Using both channels and crisscrossing the electrodes is optional when using the TENS or NMES modality.*
PAIN CONTROL

INTENSITY LEVEL:
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TENS / NMES Modality
Place the electrodes with the RED and BLACK ends of the leadwires according to pattern depicted on figure to the left.

Using both channels and crisscrossing the electrodes is optional when using the TENS or NMES modality.
**Back of Leg**

**PAIN CONTROL**

**INTENSITY LEVEL:**
The stimulation level should be set to a strong, but comfortable strength.

**DEVICE SET-UP:**

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*Using both channels and crisscrossing the electrodes is optional when using the TENS or NMES modality.*
**PAIN CONTROL**

**INTENSITY LEVEL:**
The stimulation level should be set to a strong, but comfortable strength.

**DEVICE SET-UP:**

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**TENS / NMES Modality**

Place the electrodes with the RED and BLACK ends of the leadwires according to pattern depicted on figure to the left.

*Using both channels and crisscrossing the electrodes is optional when using the TENS or NMES modality.*
PAIN CONTROL

INTENSITY LEVEL:
The stimulation level should be set to a strong, but comfortable strength.

DEVICE SET-UP:

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ELECTRODE PLACEMENT

Electrodes should surround the targeted treatment site with area of pain located in the center of the electrode area.

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Place the electrodes with the RED and BLACK ends of the leadwires according to pattern depicted on figure to the left.

**TENS / NMES Modality**
Place the electrodes with the RED and BLACK ends of the leadwires according to pattern depicted on figure to the left.

Using both channels and crisscrossing the electrodes is optional when using the TENS or NMES modality.
PAIN CONTROL

INTENSITY LEVEL:
The stimulation level should be set to a strong, but comfortable strength.

DEVICE SET-UP:

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ELECTRODE PLACEMENT

Electrodes should surround the targeted treatment site with area of pain located in the center of the electrode area.

**IFC Modality**
Place the electrodes with the **RED** and **BLACK** ends of the leadwires according to pattern depicted on figure below.

**TENS / NMES Modality**
Place the electrodes with the **RED** and **BLACK** ends of the leadwires according to pattern depicted on figure below.

*Criossing the electrodes is optional when using the TENS or NMES modality.*

**ACHILLES TENDON**

**ANKLE**
**PAIN CONTROL**

**INTENSITY LEVEL:**
The stimulation level should be set to a strong, but comfortable strength.

**DEVICE SET-UP:**

<table>
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**ELECTRODE PLACEMENT**

*Electrodes should surround the targeted treatment site with area of pain located in the center of the electrode area.*

**IFC Modality**

Place the electrodes with the **RED** and **BLACK** ends of the leadwires according to pattern depicted on figure to the left.

**TENS / NMES Modality**

Place the electrodes with the **RED** and **BLACK** ends of the leadwires according to pattern depicted on figure to the left.

*Using both channels and crisscrossing the electrodes is optional when using the TENS or NMES modality.*
PAIN RELIEF & EDEMA REDUCTION

Post-operative pain and swelling may be reduced by the application of electrical stimulation immediately after surgery and continuing as needed.

INTENSITY LEVEL:
The stimulation level should be set to a strong, but comfortable strength.

DEVICE SET-UP:

<table>
<thead>
<tr>
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<th>Mode</th>
<th>Treatment Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>IFC</td>
<td>Combo</td>
<td>40 minutes 3 to 4 times per day</td>
</tr>
<tr>
<td>TENS</td>
<td>Constant</td>
<td>As needed for pain and swelling</td>
</tr>
<tr>
<td>TENS</td>
<td>Modulated</td>
<td>As needed for pain and swelling</td>
</tr>
</tbody>
</table>

ELECTRODE PLACEMENT

When applying electrodes in the operating room, sterile electrodes must be used and placed away from incisions as shown below. Electrodes applied outside the operating room do not need to be sterile and should be placed around the bandaged area in the pattern shown below.

Electrodes should surround the targeted treatment site with area of pain located in the center of the electrode area.

IFC Modality

Place the electrodes with the RED and BLACK ends of the leadwires according to pattern depicted on figure to the left.

TENS Modality

Place the electrodes with the RED and BLACK ends of the leadwires according to pattern depicted on figure to the left. Crisscrossing the electrodes is optional when using TENS Waveform.

Protocol based on the following study: The Effects of Home Interferential Therapy on Post-Operative Pain, Edema, and Range of Motion of the Knee, by Gregg J. Jarit, MD, Karen J. Mohr, PT, SCS, Robert Waller, BS and Ronald E. Glousman, MD. Published in Clinical Journal of Sports Medicine, 13:16-20 © 2003 Lippincott Williams & Wilkins, Inc, Philadelphia.
SPASM REDUCTION

Muscle spasm may be reduced by intentionally fatiguing the associated muscle or muscle group.

INTENSITY LEVEL:
The stimulation level should be set to a strong, but comfortable strength.

DEVICE SET-UP:

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<tr>
<td>IFC</td>
<td>Combo</td>
<td>40 minutes 3 to 4 times per day</td>
</tr>
<tr>
<td>NMES</td>
<td>S Fatig</td>
<td>40 minutes 3 to 4 times per day</td>
</tr>
</tbody>
</table>

ELECTRODE PLACEMENT

Electrodes should surround the targeted treatment site with area of pain located in the center of the electrode area.

IFC Modality
Place the electrodes with the RED and BLACK ends of the leadwires according to pattern depicted on figure to the left.

NMES Modality
Place the electrodes with the RED and BLACK ends of the leadwires according to pattern depicted on figure to the left.
TruWave Plus
Indications for Use

Safety References

Zynex Medical (Zynex) is only responsible for the safety, reliability and function of the device when repairs, adjustments and changes have been carried out by persons authorized by Zynex for such work and the device is used according to the user manual. Repairs and technical safety tests shall only be carried out by trained personnel.

Indications

This stimulator should only be used under supervision for adjunctive therapy for the treatment of medical diseases and conditions.

Interferential Current (IFC)

- Symptomatic relief of chronic intractable pain, post-traumatic and post-surgical pain.
- Increasing local blood circulation
- Reduce Edema (swelling)

Neuromuscular Electrical Stimulation (NMES)

- Prevention of retardation of disuse atrophy
- Muscle re-education
- Maintaining or increasing range of motion
- Relaxation of muscle spasms
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis

Transcutaneous Electrical Nerve Stimulation (TENS)

- Symptomatic relief of chronic intractable pain, post-traumatic and post-surgical pain.
TruWave Plus
Contraindications & Warnings

Contraindications

- This stimulator should not be used on patients with a cardiac demand pacemaker.
- Electrodes should not be placed so that current will be applied to the carotid sinus (neck) region or transcerebrally (through the head).
- This stimulator should not be used whenever pain syndromes are undiagnosed, until etiology is established.

Warnings

- The safety of TENS devices for use during pregnancy or birth has not been established.
- This device is not effective for pain of central origin. (This includes headache)
- This device should only be used under the continued supervision of a physician.
- This device does not have curative value.
- This device offers symptomatic treatment such as suppressing the sensation of pain which would otherwise serve as a protective mechanism.
- The user must keep the device out of the reach of children.
- Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when this device is in use.
- The long-term effects of chronic electrical stimulation are unknown.
- Stimulation should not be applied over the carotid sinus nerves, particularly in patients with known sensitivity to the carotid sinus reflex.
- Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
- Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
- Stimulation should not be applied transcerebrally.
- Stimulation should not be applied over swollen, infected, or inflamed areas of skin eruptions, e.g. phlebitis, thrombophlebitis, varicose veins, etc.
- Stimulation should not be applied over, or in proximity to, cancerous lesions.
TruWave Plus
Precautions

- Isolated cases of skin irritation may occur at the site of the electrode placement following long-term application.
- Effectiveness is highly dependent upon patient selection by a person qualified in management of pain patients.
- Safety of powered muscle stimulators 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:
  1. When there is a tendency to hemorrhage following acute trauma or fracture;
  2. Following recent surgical procedures when muscle contraction may disrupt the healing process;
  3. Over the menstruating or pregnant uterus; and
  4. Over the 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 alternate conductive medium, or alternate electrode placement.
- Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
- This device should be kept out of reach of children.
- This device should be used only with the leads and electrodes recommended for use by the manufacturer.
- This device should not be used while driving, operating machinery, or during any activity in which voluntary muscle contractions may put the user at undue risk of injury.

Adverse Reactions:
Skin irritation and burns beneath the electrodes are potential adverse reactions.
### TruWave Plus
#### Trouble-shooting

<table>
<thead>
<tr>
<th>Problem</th>
<th>Perform the Following</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unit stays on – even after treatment ends.</td>
<td>Hold Off button down for 2 seconds to shut unit off – else unit will shut off automatically after 5 minutes of no stimulation. Alternatively you can start a new treatment session now, without having to start from scratch.</td>
</tr>
<tr>
<td>Can not increase level from its current setting.</td>
<td>Turn level down 1 mA to unlock this safety feature – then turn it up to the desired level/intensity. Intensity level is always locked after 20 seconds of no change of settings.</td>
</tr>
<tr>
<td>Do not feel the traditional I/F beat in the center of the four electrodes.</td>
<td>Check that the lead wires are connected correctly to the electrodes (red opposite to each other, black opposite to each other)</td>
</tr>
<tr>
<td>Display shows electrode alarm.</td>
<td>Check your electrodes. They must be fresh and stick well. Then check your electrodes again, possibly change to new electrodes. Then check that all four electrodes are connected to lead wires and that both lead wires are connected to the unit. Eventually put all four metal pins together to short-circuit the Outputs. That should stop the electrode alarm proving that the problem is the electrode quality. Replace electrodes.</td>
</tr>
</tbody>
</table>
## TruWave Plus
### Technical Specifications

#### Interferential Current (IFC)
- **Amplitude**: 0-50 mA
- **Carrier frequency**: 4000 Hz nominal
- **Modulation frequency**: Continuous 4001-4150 Hz, Freq. Shift modes 4001-4150 Hz
- **I/F Modes**: Low-High, Combo, Low
- **Muscle Mode**: 50 Hz, 6 sec. On, 6 sec. Off, Up-ramp is 1.0 sec. and down-ramp is 0.5 sec.

#### Neuromuscular Electrical Stimulation (NMES)
- **Amplitude**: 0-100 mA
- **Frequency**: 35-80 Hz
- **Pulse width**: 300 µsec.
- **NMES Modes**: S Strength, A Strength, S Fatigue
- **On-Time**: 10 seconds
- **Off-Time**: 10 seconds
- **Ramp Up**: 3 seconds
- **Ramp Down**: 1 second
- **Waveforms**: Symmetrical Biphasic

#### Transcutaneous Electrical Nerve Stimulation (TENS)
- **Amplitude**: 0-100 mA
- **Frequency**: 1-125 Hz
- **Pulse width**: 150 µsec.
- **TENS Modes**: Sweep, Modulated, Constant
- **Waveform**: Symmetrical biphasic

#### Other Specifications
- **Treatment timer**: Continuous, 10-90 minutes, 10 minutes steps.
- **Compliance meter**: Records total usage time in minutes and number of times used. Can be reset.
- **Dimensions**: 4.5 x 2.5 x 0.9 in.
- **Weight**: 5 oz. Incl. Battery
- **Warranty**: 3 Years manufacturers warranty on materials and workmanship. Accessories excluded.
TruWave Plus
Maintaining Device & Electrodes

Electrodes and Skincare
Proper skincare will help make the use of this device more comfortable and trouble-free. Prior to treatment, wash the areas where the electrodes will be placed with mild soap and water, rinse and dry the skin thoroughly. If necessary, remove excess body hair.

The TruWave Plus is intended to be used with re-usable, self-adhesive electrodes. Extended number of uses can be obtained by adding water to the adhesive surface immediately after each use and placing them on the plastic pad. They will regain their conductivity and adhesiveness as compared to leaving them dry.

Sterile electrodes may be required for some post-op applications.

Battery Power
One 9 volt Alkaline battery is used. The battery compartment on the back of the device opens by sliding the cover downwards. Rechargeable batteries are not recommended as they only have a short usage time and are not charged while in the device.

Battery replacement is indicated by either “Bat” in the display or a red flashing LED. Replace with a new 9 volt Alkaline battery.

*The TruWave Plus accommodates a 9 volt battery even if it is inserted with reverse polarity and the circuitry will ensure full functionality with reverse polarity.*

Please ensure to dispose the used batteries properly.

AC Power Adapter
The Truwave Plus comes with an AC Adapter that is plugged into the left side of the device and then into a 110v electrical outlet. While plugged in, the device uses the electrical current from the outlet and not the 9 volt battery. The battery does not have to be removed while utilizing the AC Adapter.