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InWave

User's Manual

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InWave
Warranty Information

The InWave device is warranted to be free from defects in material, workmanship, and structural integrity when subjected to normal domestic use and service for five years after the original purchase.

During that time, Zynex Medical, Inc. will repair or replace, at its discretion, the InWave device that has been used in a standard manner. This warranty does not cover misuse or use contrary to the operating instructions supplied.

Warranty obligations are limited to replacement or repair of defective parts and components, at the option of Zynex Medical, Inc. This Warranty is only valid for the original purchaser of this product and will not be honored if product ownership is transferred or is resold.

To obtain warranty service, please contact Technical Support at the number listed on page 4 of this manual.

NexWave
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Zynex Medical
Contact Information

CUSTOMER SERVICE **1-800-495-6670**

Supplies: To order additional probes or batteries

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 **1-800-495-6670**

Billing Questions: Questions regarding insurance benefits and covered benefits for Durable Medical Equipment (DME) or questions about an Explanation of Benefits form you received in the mail

FAX NUMBER **1-800-495-6695**

MAILING ADDRESS

Zynex Medical, Inc.
9655 Maroon Circle
Englewood, CO 80112
USA

EMAIL **info@zynex.com**

WEBSITE **www.zynex.com**

Care, Maintenance, and Disposal (cont.)

Before and after each use, clean the probe thoroughly with mild soap and water. Rinse thoroughly after washing. Do not immerse it in water. Dry the probe and store it in a safe location.

Before disposing, to avoid the risk of biohazards, thoroughly disinfect probe by washing it with soap and water, rinsing it, and then drying. Dispose of properly in accordance with all local, federal and international regulations. Probes may also be returned to Zynex Medical or the distributor.

Care, Maintenance, and Disposal

Control Unit

The enclosure and display window can be cleaned using a damp cloth or antiseptic wipe. Allow the unit to dry thoroughly before using. Do not spray cleaning solutions directly onto the unit, or immerse it in water.

Before each use, the unit should be visually inspected for signs of wear or damage. Discontinue use and contact Zynex Medical if any damage is noticed.

Dispose of properly in accordance with all local, federal and international regulations. See WEEE symbol description on page 8. The unit may also be returned to Zynex Medical, Inc. or the distributor for disposal.

Battery

Use only 9 V alkaline batteries to power the InWave. The battery compartment on the back of the device opens by sliding the cover downwards.

Low battery is indicated by the battery icon in the display. Replace with a new battery. Remove the battery if the device will be inactive for greater than two weeks.

The InWave operates normally even if the 9 V battery is inserted with reverse polarity.

Dispose of properly in accordance with all local, federal and international regulations. See Chemical Risk Reduction Ordinance SR 814.81, Annex 2.15 or 40CFR273.2 for additional information. Batteries may also be returned to Zynex Medical, Inc. or the distributor for disposal.

Vaginal Probe

Note: The probe is for **single patient use only**. Follow the directions of your prescribing physician.

Before each use, the probe should be visually inspected for signs of wear or damage. Discontinue use and contact Zynex Medical if any damage is noticed.

Description

The InWave is a multiple-mode stimulator which allows users a choice of treatment options. The InWave causes muscle contractions which exercise and strengthen the pelvic floor muscles.

The InWave requires no special skills, knowledge, or training. Simply follow the instructions given in this User's Manual and by your therapist or doctor.

Stress Urinary Incontinence Treatment

The output delivers electrical impulses at a frequency of 50 Hz, which produce smooth, even muscle contractions. This type of stimulation exercises and strengthens the pelvic floor muscles, which aids in the control of stress incontinence.

Stimulation can be set to 3 or 5 second duration, with a resting period of 5 or 10 seconds between contractions. Default treatment time is 15 minutes.

Urge Urinary Incontinence Treatment

The output delivers electrical impulses at a frequency of 12.5 Hz, which produce a series of short, rapid contractions. This type of stimulation aids in the relaxation of involuntary muscle contractions which cause urge incontinence.

Stimulation can be set to 6 or 10 second duration, with a resting period of 3 or 10 seconds. Default treatment time is 20 minutes.

Mixed Urinary Incontinence Treatment

Mixed treatment modes consist of a 2, 5, or 10 minute stress treatment followed by a 2, 5, or 10 minute urge treatment. This combination of stimulation types aids in both stress and urge incontinence in the manner mentioned above.

Important: This device must be ordered or prescribed by a licensed physician.

Safety Information

• Equipment Classification

Per the International Electrotechnical Commission standard IEC 60601-1, and the European standard EN 60601-1, Medical Electrical Equipment, General Requirements for Basic Safety and Essential Performance, the InWave is classified as follows:

- **Type BF Equipment**
  A Type BF piece of equipment is one that provides a specific degree of protection against electric shock, particularly regarding allowable leakage current. Type BF applied part is one that is floating above ground and is isolated from all other parts of the equipment.
  .
- **Internally Powered Equipment**
  The InWave is powered by an internal, 9 VDC, MN1604, battery and is classified as Internally Powered Equipment.

- **Electromagnetic Compatibility**
  Conforms to IEC 60601-1-2.

- **Environmental Conditions for Operation**
  Temperature: 0° - 40° C (32° - 104° F)
  Humidity: 0 - 95%, non-condensing
  Atmospheric Pressure: 500 – 1060 hPa
  Altitude: -400 - 2500 m (-1312 - 8202 ft.)

- **Environmental Conditions for Transportation and Storage**
  Temperature: -20° - 70° C (-4° - 158° F)
  Humidity: 0 - 95%, non-condensing
  Atmospheric Pressure: 500 – 1060 hPa
  Atmospheric Pressure: 500 – 1060 hPa
  Altitude: -400 - 11000 m (-1312 - 36089 ft.)

- **Water Ingress**
  Ordinary equipment. This device does not have protection against ingress of water.

- **Battery Power**
  One 9 V alkaline battery is used. The battery compartment on the back of this device opens by sliding the cover downwards. Use 9 V alkaline batteries only. Any type of lithium, rechargeable, or other types of 9 V batteries may damage the device.

Specifications and Accessories

Stress UI Mode

Output Current:	0-80 mA (1 KΩ load, 20% accuracy)
Frequency:	50 Hz (20% accuracy)
Pulse Width:	200 µs (20% accuracy)
Stress Programs:	5/10, 3/10, 5/5
On Time:	3 or 5 sec. (20% accuracy)
Off Time:	5 or 10 sec. (20% accuracy)
Ramp Up Time:	1 sec. (20% accuracy)
Ramp Down Time:	1 sec. (20% accuracy)
Waveforms:	Symmetrical, rectangular, biphasic, with zero DC current

Urge UI Mode

Amplitude:	0-80 mA (1 KΩ load, 20% accuracy)
Frequency:	12.5 Hz (20% accuracy)
Pulse Width:	200 µs (20% accuracy)
Urge Modes:	10/3, 6/3, 10/10
On Time:	6 or 10 sec. (20% accuracy)
Off Time:	3 or 10 sec. (20% accuracy)
Ramp Up Time:	1 sec.(20% accuracy)
Ramp Down Time:	0.5 sec. (20% accuracy)
Waveform:	Symmetrical, rectangular, biphasic, with zero DC current

Mixed UI Mode

Amplitude:	0-80 mA (1 KΩ load, 20% accuracy)
Frequency:	12.5 and 50 Hz (20% accuracy)
Pulse Width:	200 µs (20% accuracy)
Mix Modes:	10:10, 5:5, 2:2
On-Time:	3, 5, 6, or 10 sec. (20% accuracy)
Off-Time:	3, 5, or 10 sec. (20% accuracy)
Ramp Up:	1 sec. (20% accuracy)
Ramp Down:	1 or 0.5 sec. (20% accuracy)
Waveforms:	Symmetrical, rectangular, biphasic, with zero DC current

Other Specifications

Treatment timer:	5 to 25 min., in 5 min. increments, with no timer setting (20% accuracy)
Compliance meter:	Records total usage time in minutes and number of times used
Dimensions:	2.9 x 4.6 x 1.0 in.
Weight:	5.8 oz. including battery
Warranty:	5 year manufacturer's warranty on materials and workmanship. Accessories excluded.

Accessories

Probe:	400024, 1.0" dia. X 5.8" long, (Manufacturer P/N PR-03J)
Battery:	130010, battery, 9 V, alkaline, MN1604

Troubleshooting	
Problem	**Solution**
Unit stays on even after treatment ends.	Press and release the On/Standby button to turn the InWave off. Otherwise the unit will shut off automatically after five minutes of no stimulation. Alternatively you can start a new treatment session after the last one ends.
Cannot increase stimulation level from its current setting.	Press and release Unlock button to unlock this safety feature. Then increase stimulation to the desired level/ intensity. Intensity level locked after twenty seconds of keypress inactivity.
Display shows “Check Connections”.	The probe is not properly connected to the device. Check to see that the probe connector is properly and completely inserted into the device. Turn the device off and disconnect and reconnect the probe if necessary to establish a better electrical contact. If the “Check Connections” indicator persists the probe may be faulty. Contact Zynex technical support (Page 4) for further assistance.

- **Flammable Anesthetics**
  This device is not suitable for use in the presence of a flammable anesthetic mixture with air, or in the presence of a flammable anesthetic mixture with oxygen or nitrous oxide.

- **Mode of Operation**
  This device is suitable for continuous operation.

- # Symbols

Safety symbols shown on the device above are defined below.

On/Standby. This symbol indicates that the labeled switch electronically cycles the DC power on and off for part of the equipment.

General Warning Sign. Follow warnings stated in the instruction manual to prevent potential hazards.

Refer to Instruction Manual/Booklet. The operator must read, understand, and follow all instructions in the accompanying document including all warnings, cautions, and precautions before using this medical device.

Type BF Equipment. This symbol indicates that the patient applied parts (electrodes) are Type BF (floating from ground) offering the user a specific level of safety.

Waste Electrical and Electronic Equipment (WEEE). This product may contain substances known to be hazardous to the environment or to human health. It should be disposed of properly (for example, at your local waste collection agency or recycling plant) and in accordance with local ordinances. See page 28 for disposal instructions.

• Service and Calibration

- Do not remove the cover. There are no user serviceable parts. Refer all service to authorized personnel. No modification of the equipment is allowed.

- No preventative inspections are required. Factory testing and calibration ensure equipment accuracy and response. Contact Zynex Medical for factory re-calibration if necessary.

Precautions
Mixed UI Mode

Precautions (Cont.)

- Stimulation from the vaginal probe should not be applied transthoracically, placed on the chest and upper back, or from the vaginal probe crossing over the heart as this may cause cardiac arrhythmias.
- Stimulation from the vaginal probe should not be applied directly on the eyes, covering the mouth, or on the front of the neck (particularly the carotid sinus).
- Do not use this device while under the influence of drugs or alcohol.
- Do not insert or remove the vaginal probe while the device is on.
- Do not use this device while in the close proximity of wireless devices.
- Use this device only as directed.
- Do not immerse the unit in water or any other liquid.
- The vaginal probe should not remain inserted into the vagina when the unit is not in use.
- This device should not be used while sleeping or when anything else has been inserted into the vagina such as a diaphragm or tampon.

Adverse Reactions

- Vaginal irritation is a potential adverse reaction. Discontinue use at any sign of vaginal irritation.

Safety References

Zynex Medical, Inc. is responsible for the safety, reliability, and function of the device only when repairs and adjustments have been made by persons authorized by Zynex Medical, Inc., and the device has been used in accordance with the user's manual. Repairs and technical safety tests shall only be performed by authorized personnel.

SEE PAGE 7 FOR SYMBOL DEFINITIONS

Warnings
Mixed UI Mode

Warnings (Cont.)

- Maximum RMS voltage (500 Ω load) = 4 V
- Maximum RMS current (500 Ω load) = 8 mA
- Maximum output power (500 Ω load) = 32 mW
- Maximum RMS voltage (1 KΩ load) = 8 V
- Maximum RMS current (1 KΩ load) = 8 mA
- Maximum output power (1 KΩ load) = 64 mW
- Maximum RMS voltage (2 KΩ load) = 10 V
- Maximum RMS current (2 KΩ load) = 5 mA
- Maximum output power (2 KΩ load) = 50 mW

- A yellow LED indicator is provided next to the lead wire connector to show that the unit is delivering energy for any non-zero value of stimulation output (1 to 80 mA).
- The long-term effects of chronic electrical stimulation are unknown.
- Safety has not been established for the use of the InWave during pregnancy.
- Discontinue use of this device in the event of pain or bleeding.
- Do not use this device in water.
- Warning labels are legible from a distance of 30 cm or less, at a 90° angle or less, and at 500 lux or greater luminous intensity.

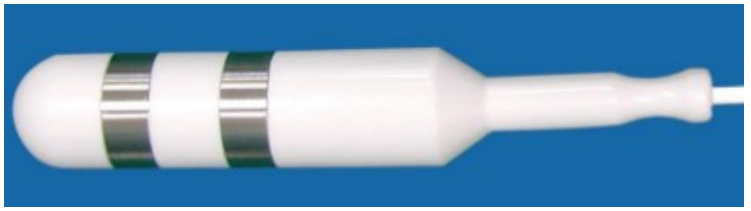
Precautions

- Stimulation settings should be based on the guidance of the prescribing practitioner.
- This device should be kept out of the reach of children.
- This device should only be used with the leads and vaginal probe recommended for use by the manufacturer.
- This device should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at risk of injury.
- Patients with implanted electronic devices, e.g., a cardiac pacemaker, should not use this device unless advised by a physician.
- Simultaneous connection of a patient to high frequency surgical equipment may result in burns at the site of the vaginal probe and possible damage to the stimulator.
- Operations within close proximity (within one meter) of shortwave or microwave therapy equipment may produce instability in the stimulation output.

Probe Setup

Step 1 Remove the probe from its package

Note: Only Zynex Medical probes are approved for use with the InWave. P/N 400024 is provided standard.



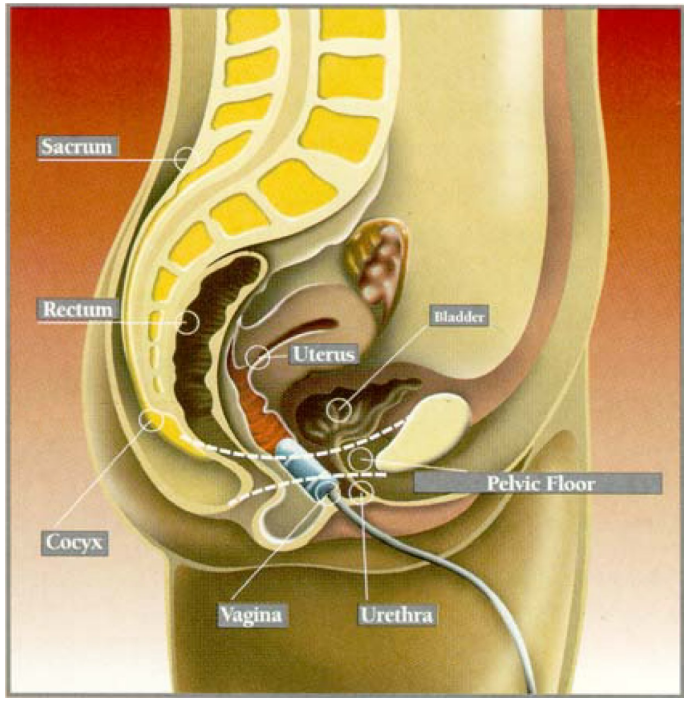
Probe Setup (cont.)

Step 2 Insert vaginal probe as shown below. If needed, a small amount of water-based lubricant can be applied to the tip of the probe to aid in insertion. Initial placement of the vaginal probe and selection of the treatment program should be performed under the guidance of a physician. **Note:** Overuse of a lubricant can cause lack of stimulation, and lead to ineffective treatment.

CAUTION: Do not insert or remove the probe when the device is on. The device must be turned off prior to insertion or removal of the probe.

See the directions included with the probe for further information.

Note: Vaginal probes are for **single patient use only**.



Indications for Use
Mixed UI Mode

Indications

- The InWave is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge, and mixed urinary incontinence in adult females.

Contraindications

- The InWave should not be used in the presence of the following:
  - Following recent surgical procedures when muscle contraction may disrupt the healing process.
  - During menstrual cycle or pregnancy.
  - Irregular menstrual cycles.
  - Urinary or vaginal infection.
  - History or current symptoms of urinary retention.

Warnings

- Output waveform/power information:
  When delivering stimulation energy, the InWave in Mixed UI mode is a constant current output device. Therefore its output voltage, current, and power are dependent upon the load as well as the pulse width and frequency of the output waveform. The maximum peak voltage that the InWave can produce is 100 V (2 KΩ load). The maximum peak current that the InWave can produce is 80 mA (1 KΩ load). The maximum output power that the InWave can produce is 64 mW (1 KΩ load).
  - Maximum peak output voltage (500 Ω load) = 40 V
  - Maximum peak output current (500 Ω load) = 80 mA
  - Maximum peak output voltage (1 KΩ load) = 80 V
  - Maximum peak output current (1 KΩ load) = 80 mA
  - Maximum peak output voltage (2 KΩ load) = 100 V
  - Maximum peak output current (2 KΩ load) = 50 mA
  - Pulse width: 200 µs
  - Frequency: 50 or 12.5 Hz

Precautions
Urge UI Mode

Precautions (Cont.)

- Stimulation from the vaginal probe should not be applied transthoracically, placed on the chest and upper back, or from the vaginal probe crossing over the heart as this may cause cardiac arrhythmias.
- Stimulation from the vaginal probe should not be applied directly on the eyes, covering the mouth, or on the front of the neck (particularly the carotid sinus).
- Do not use this device while under the influence of drugs or alcohol.
- Do not insert or remove the vaginal probe while the device is on.
- Do not use this device while in the close proximity of wireless devices.
- Use this device only as directed.
- Do not immerse the unit in water or any other liquid.
- The vaginal probe should not remain inserted into the vagina when the unit is not in use.
- This device should not be used while sleeping or when anything else has been inserted into the vagina such as a diaphragm or tampon.

Adverse Reactions

- Skin irritation and electrode burns are potential adverse reactions. Discontinue use at any sign of vaginal irritation.

Safety References

Zynex Medical, Inc. is responsible for the safety, reliability, and function of the device only when repairs and adjustments have been made by persons authorized by Zynex Medical, Inc., and the device has been used in accordance with the user's manual. Repairs and technical safety tests shall only be performed by authorized personnel.

SEE PAGE 7 FOR SYMBOL DEFINITIONS

Probe Setup (cont.)

Step 3 Verify that the battery has been inserted into the InWave, then plug the probe connector into the top of the device (see picture below). If necessary, insert battery according to the instructions on page 28.

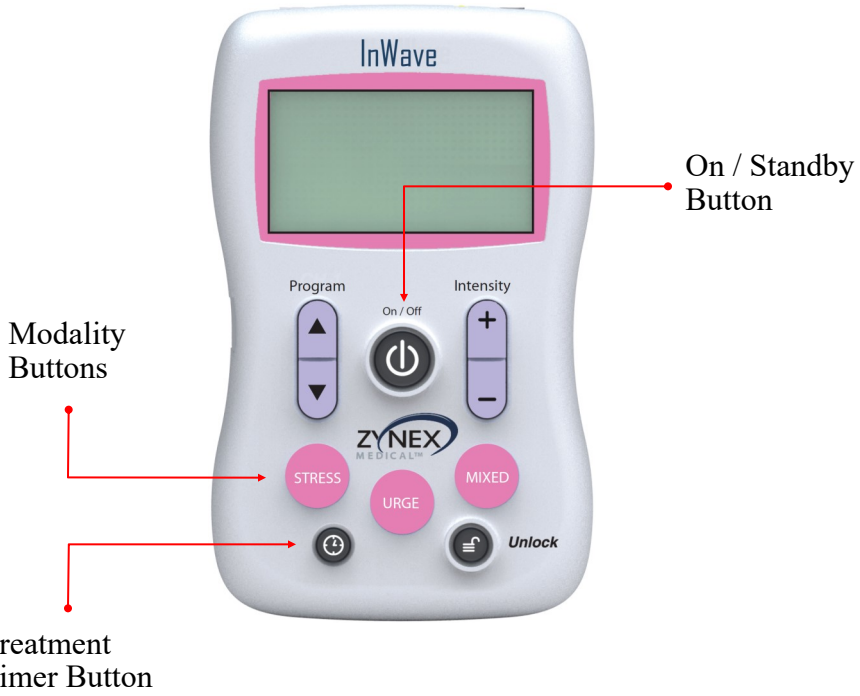
Step 4 Proceed to page 15 to start treatment, or page 12 to program device.

Programming Instructions

Turn the device on by pressing the black On/Standby button.

1. Select the desired Modality by pressing the “STRESS”, “URGE”, or “MIX” button as instructed by your physician or healthcare practitioner.
2. Press the Up or Down Program button until the arrow on the display is next to the desired program.
3. Press the Treatment Timer button until the desired treatment time is set on the display.

The device is now ready to use.



Warnings
Urge UI Mode

Warnings (Cont.)

- Maximum RMS voltage (500 Ω load) = 2 V
- Maximum RMS current (500 Ω load) = 4 mA
- Maximum output power (500 Ω load) = 8 mW
- Maximum RMS voltage (1 KΩ load) = 4 V
- Maximum RMS current (1 KΩ load) = 4 mA
- Maximum output power (1 KΩ load) = 16 mW
- Maximum RMS voltage (2 KΩ load) = 5 V
- Maximum RMS current (2 KΩ load) = 2.5 mA
- Maximum output power (2 KΩ load) = 12.5 mW

- A yellow LED indicator is provided next to the lead wire connector to show that the unit is delivering energy for any non-zero value of stimulation output (1 to 80 mA).
- The long-term effects of chronic electrical stimulation are unknown.
- Safety has not been established for the use of the InWave during pregnancy.
- Discontinue use of this device in the event of pain or bleeding.
- Do not use this device in water.
- Warning labels are legible from a distance of 30 cm or less, at a 90° angle or less, and at 500 lux or greater luminous intensity.

Precautions

- Stimulation settings should be based on the guidance of the prescribing practitioner.
- This device should be kept out of the reach of children.
- This device should only be used with the leads and vaginal probe recommended for use by the manufacturer.
- This device should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at risk of injury.
- Patients with implanted electronic devices, e.g., a cardiac pacemaker, should not use this device unless advised by a physician.
- Simultaneous connection of a patient to high frequency surgical equipment may result in burns at the site of the vaginal probe and possible damage to the stimulator.
- Operations within close proximity (within one meter) of shortwave or microwave therapy equipment may produce instability in the stimulation output.

Indications for Use
Urge UI Mode

Indications

- The InWave is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge, and mixed urinary incontinence in adult females.

Contraindications

- The InWave should not be used in the presence of the following:

    - Following recent surgical procedures when muscle contraction may disrupt the healing process.
    - During menstrual cycle or pregnancy.
    - Irregular menstrual cycles.
    - Urinary or vaginal infection.
    - History or current symptoms of urinary retention.

Warnings

- Output waveform/power information:
  When delivering stimulation energy, the InWave in Urge UI mode is a constant current output device. Therefore its output voltage, current, and power are dependent upon the load as well as the pulse width and frequency of the output waveform. The maximum peak voltage that the InWave can produce is 100 V (2 KΩ load). The maximum peak current that the InWave can produce is 80 mA (1 KΩ load). The maximum output power that the InWave can produce is 16 mW (1 KΩ load).

    - Maximum peak output voltage (500 Ω load) = 40 V
    - Maximum peak output current (500 Ω load) = 80 mA
    - Maximum peak output voltage (1 KΩ load) = 80 V
    - Maximum peak output current (1 KΩ load) = 80 mA
    - Maximum peak output voltage (2 KΩ load) = 100 V
    - Maximum peak output current (2 KΩ load) = 50 mA
    - Pulse width: 200 µs
    - Frequency: 12.5 Hz

Preprogrammed Modes

Stress Urinary Incontinence (UI) Mode

Program	Description
5/10	The pulse width is 200 µs, and the frequency is 50 Hz. The output signal ramps up to the stimulation level set by the user in one second. The output stays on for five seconds, then ramps down to a zero level in one second. The output stays off for ten seconds. The cycle repeats for the duration of the treatment time. The default treatment time is 15 minutes.
3/10	Similar to 5/10 program except the on time is three seconds.
5/5	Similar to 5/10 program except the off time is five seconds.

Urge UI Mode

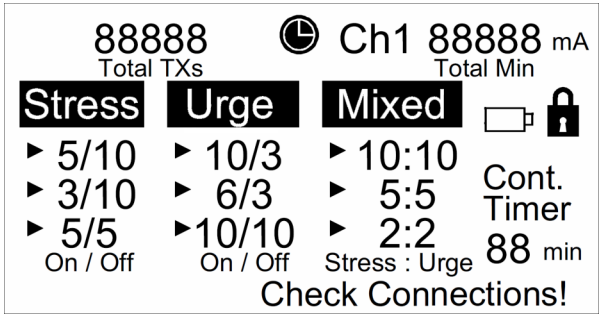
Program	Description
10/3	The pulse width is 200 µs, and the frequency is 12.5 Hz. The output signal ramps up to the stimulation level set by the user in one second. The output stays on for ten seconds, then ramps down to a zero level in 0.5 second. The output stays off for three seconds. The cycle repeats for the duration of the treatment time. The default treatment time is 20 minutes.
6/3	Similar to 10/3 program except the on time is only six seconds.
10/10	Similar to 10/3 mode except the off time is ten seconds.

Mixed UI Mode

Program	Description
10:10	A 5/10 Stress program runs for ten minutes, followed by a ten minute 10/3 Urge program. This cycle repeats for the duration of the treatment time. The default treatment time is 20 minutes.
5:5	Similar to 10/10 program except the 5/10 Stress program only runs for five minutes and the 10/3 Urge program only runs for five minutes.
2:2	Similar to 10/10 program except the 5/10 Stress program only runs for two minutes and the 10/3 Urge program only runs for two minutes.

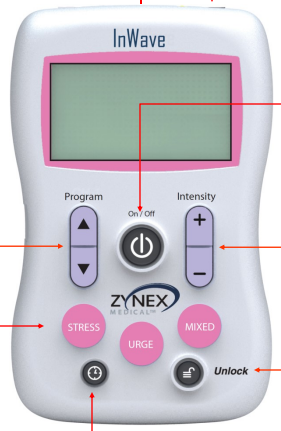
The InWave should be used daily for 15 to 20 minutes per session, for 1 to 3 months, or as directed by a physician.

Controls



Display

Lead Wire Connection
Channel 1



Turns Unit On/Off
On/Standby Button

Program Select
Up and Down Button

Channel 1 Intensity Control
Up and Down Button

Unlock Button Control
Unlock Button

Stress, Urge, Mixed
Modality Buttons

Treatment Timer
Treatment Timer Button

Precautions
Stress UI Mode

Precautions (Cont.)

- Stimulation from the vaginal probe should not be applied transthoracically, placed on the chest and upper back, or from the vaginal probe crossing over the heart as this may cause cardiac arrhythmias.
- Stimulation from the vaginal probe should not be applied directly on the eyes, covering the mouth, or on the front of the neck (particularly the carotid sinus).
- Do not use this device while under the influence of drugs or alcohol.
- Do not insert or remove the vaginal probe while the device is on.
- Do not use this device while in the close proximity of wireless devices.
- Use this device only as directed.
- Do not immerse the unit in water or any other liquid.
- The vaginal probe should not remain inserted into the vagina when the unit is not in use.
- This device should not be used while sleeping or when anything else has been inserted into the vagina such as a diaphragm or tampon.

Adverse Reactions

- Vaginal irritation is a potential adverse reaction. Discontinue use at any sign of vaginal irritation.

Safety References

Zynex Medical, Inc. is responsible for the safety, reliability, and function of the device only when repairs and adjustments have been made by persons authorized by Zynex Medical, Inc., and the device has been used in accordance with the user's manual. Repairs and technical safety tests shall only be performed by authorized personnel.

SEE PAGE 7 FOR SYMBOL DEFINITIONS

Warnings
Stress UI Mode

Warnings (Cont.)

- Maximum RMS voltage (500 Ω load) = 4 V
- Maximum RMS current (500 Ω load) = 8 mA
- Maximum output power (500 Ω load) = 32 mW
- Maximum RMS voltage (1 KΩ load) = 8 V
- Maximum RMS current (1 KΩ load) = 8 mA
- Maximum output power (1 KΩ load) = 64 mW
- Maximum RMS voltage (2 KΩ load) = 10 V
- Maximum RMS current (2 KΩ load) = 5 mA
- Maximum output power (2 KΩ load) = 50 mW

- A yellow LED indicator is provided next to the lead wire connector to show that the unit is delivering energy for any non-zero value of stimulation output (1 to 80 mA).
- The long-term effects of chronic electrical stimulation are unknown.
- Safety has not been established for the use of the InWave during pregnancy.
- Discontinue use of this device in the event of pain or bleeding.
- Do not use this device in water.
- Warning labels are legible from a distance of 30 cm or less, at a 90° angle or less and at 500 lux or greater luminous intensity.

Precautions

- Stimulation settings should be based on the guidance of the prescribing practitioner.
- This device should be kept out of the reach of children.
- This device should only be used with the leads and vaginal probe recommended for use by the manufacturer.
- This device should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at risk of injury.
- Patients with implanted electronic devices, e.g., a cardiac pacemaker, should not use this device unless advised by a physician.
- 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.
- Operations within close proximity (within one meter) of shortwave or microwave therapy equipment may produce instability in the stimulation output.

Operating Instructions

Start Treatment:

Before starting treatment, the probe must be inserted in the vagina and the probe connector must be plugged into the Lead Wire Connection on the top of the device. See pages 9-11 for instructions.

1. Turn InWave on by pressing the On/Standby button.

2. Set the desired program using the Modality and Program buttons.

3. Increase the stimulation level by pressing the Intensity Up button until a strong but comfortable stimulation level is felt.

4. Once the desired level of stimulation is set, the unit will automatically shut off at the preset treatment time shown on the display. If the Treatment Timer has been set to No Timer then the device will need to be shut off manually. *Refer to Programming Instructions on page 12 to adjust the Treatment Timer.*

4. To turn off the device manually press the On/Standby button.

Note: If "Check Connections!" message is displayed on the screen, see "Display Alerts", Page 16 and "Troubleshooting", page 26.

During Treatment:

Note: The user should assume a seated, prone, or standing relaxed position, depending upon preference and/or level of comfort.

IMPORTANT: *Button controls lock out after 20 seconds of inactivity. To unlock button controls, press the Unlock button.*

Increase Intensity:

To increase intensity press the *Up Intensity button* until the desired level of stimulation is felt.

Decrease Intensity:

To decrease intensity press the *Down Intensity* button until desired level of stimulation is felt.

Display Alerts:

Check Connections: The probe may not be connected properly. Check all connections and try again (see page 26). If the problem persists, call Zynex Technical Support (see page 4).

Low Battery: Replace the battery immediately.

Locked: The stimulation level and mode cannot be changed until the Unlock button is pressed.

Indications for Use
Stress UI Mode

Indications

- The InWave is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge, and mixed urinary incontinence in adult females.

Contraindications

- The InWave should not be used in the presence of the following:
    - Following recent surgical procedures when muscle contraction may disrupt the healing process.
    - During menstrual cycle or pregnancy.
    - Irregular menstrual cycles.
    - Urinary or vaginal infection.
    - History or current symptoms of urinary retention.

Warnings

- Output waveform/power information:
  When delivering stimulation energy, the InWave in Stress UI mode is a constant current output device. Therefore its output voltage, current, and power are dependent upon the load as well as the pulse width and frequency of the output waveform. The maximum peak voltage that the InWave can produce is 100 V (2 KΩ load). The maximum peak current that the InWave can produce is 80 mA (1 KΩ load). The maximum output power that the InWave can produce is 64 mW (1 KΩ load).

    - Maximum peak output voltage (500 Ω load) = 40 V
    - Maximum peak output current (500 Ω load) = 80 mA
    - Maximum peak output voltage (1 KΩ load) = 80 V
    - Maximum peak output current (1 KΩ load) = 80 mA
    - Maximum peak output voltage (2 KΩ load) = 100 V
    - Maximum peak output current (2 KΩ load) = 50 mA
    - Pulse width: 200 µs
    - Frequency: 50 Hz