MINNOVA™

PELVIC FLOOR STIMULATION SYSTEM

INSTRUCTION MANUAL
CAUTION: Federal law (USA) restricts this device to sale by, or on the order of, a physician.
Introduction

The Minnova™ Pelvic Floor Stimulation (PFS) system uses mild electrical stimulation to help control or cure urinary incontinence. The system consists of an external, battery-powered stimulator and an electrode.

Product Description

Minnova system components and accessories include:

- Minnova pelvic floor stimulator
- ComfortPulse™ vaginal or rectal electrode
- Two AA (1.5V) alkaline batteries
- Carrying case
- Instruction manual

Indications for Use

Pelvic Floor Stimulation is indicated for acute and ongoing treatment of urinary incontinence in cases where the following results may improve urinary control:

- Improvement of urethral sphincter closure
- Strengthening of pelvic floor muscles
- Inhibition of the detrusor muscle through reflexive mechanisms
⚠️ **Contraindications**

Minnova should not be used if the patient has any of the following conditions:

- Active urinary tract infection
- Pregnancy or attempting pregnancy
- Recent history of vaginal bleeding between menstrual periods
- Infections or lesions in the area of electrode placement
- Diminished sensory perception
- Inability to understand the directions for use or operate the device correctly
- History of urinary retention or post-void residual volume greater than 200cc
- History of cardiac arrhythmia
- Demand type implanted pacemaker or defibrillator

⚠️ **Warnings**

Review the following warnings before using Minnova:

- The patient should discontinue use and immediately consult a clinician if irritation, pain or unusual bleeding occurs.
- Keep out of reach of children.
- Do not use in water (for example, while bathing). This equipment is not rated for use while immersed or under dripping water.
- Do not use simultaneously with high frequency hospital diagnostic/therapeutic equipment. Doing so may result in burns at the site of the electrodes and possible damage to the device.
- Do not use simultaneously with patient monitoring equipment such as EKG monitors without investigating the possibility of output from the device causing erroneous monitor readings.
• Do not attempt to plug the electrode lead wire into wall sockets or line cord receptacles (i.e. extension cords) under any circumstances. Doing so could result in severe shock or burns.

• Do not carry batteries in a pocket, purse, or any other place where the terminals could become short circuited, (e.g. by way of a coin or paper clip). Intense heat could be generated and injury may result.

• The long term effects of chronic electrical stimulation are unknown.

• Do not use with products other than those recommended by Empi.
⚠️ Precautions

Review the following precautions:

• **It is not recommended to use device while under the influence of alcohol or other substances**, such as sleeping pills or tranquilizers, which could affect the patient’s ability to operate the system correctly.

• **Removing or inserting the electrode while the system is on could result in discomfort.**

• **Use while operating hazardous equipment, machinery or motorized vehicles** could cause abrupt changes in stimulation which can startle the patient and create a hazard.

• **Do not use in close proximity (e.g. <1m) to transmitting cellular (wireless) telephones or two-way radios.** This equipment may produce instability in the stimulator output. Sudden unexpected changes in output could startle the patient and create a hazard.

• **Use while sleeping** is not recommended.

• The patient should discontinue use and consult a clinician if a significant change in the stimulation sensation occurs without changing the intensity settings. It is normal to feel a difference in sensation when changing positions during stimulation.

• **Do not use in close proximity such as 3 feet (1meter) to shortwave or microwave therapy equipment.** This equipment may produce instability in the stimulator output or may shut the stimulator off. Sudden unexpected changes in output could startle the patient and create a hazard.
Before Treatment

An examination of the rectal or vaginal tissue should be completed prior to initial treatment to rule out any contraindications, establish the baseline tissue condition and assess the physiology discussed below. Pelvic floor stimulation may not be successful if the urethra has excessive scarring or if there is significant denervation of the pelvic floor. The neuromuscular structures involved in urine storage must also be at least partially preserved. Patients with intact sacral reflex arcs and some innervation of the pelvic floor may benefit from pelvic floor stimulation.

Minnova Features

The Minnova device features are described below and shown in Figure 1.

1. **Intensity Control Knob**
   controls the intensity level. Note: The numerical scale is for reference only. It is not intended to correlate to any measurable output parameter of the device.

2. **Electrode Connector**
   connects the electrode lead wire to the device.

3. **Frequency Selection Slide Switch**
   selects the stimulation frequency of either 50Hz or 12.5Hz.

4. **Session Start Indicator Light**
   blinks rapidly for 10 seconds when Start button is pressed.

5. **START Button**
   initiates the 15 minute intermittent stimulation of 5 seconds of stimulation followed by 10 seconds of rest.

6. **Battery Compartment**
   secures two AA (1.5V) batteries. Note: A Ni-Cd rechargeable battery is not recommended because it does not provide the device with enough power, and the device may shut off after a very short time.

7. **Stimulation Indicator Light**
   illuminates when the Intensity Control Knob is turned on and during the 5 second stimulation phase.
Initial Fitting and Treatment

The initial fitting of the electrode and the initial treatment session should be done under medical supervision.

1. **Before inserting the electrode, make certain that the electrode lead wire is not connected to the device.**
2. Insert and position the electrode per the electrode instructions for use.
3. **Do not turn the device on unless the electrode is positioned properly.**
4. Verify that the device is **OFF**. To turn the device off, the intensity control knob should be turned to “0” so that you hear a “click.” The “click” indicates that the device is off.
5. Connect the electrode lead wire to the device.
6. Set the frequency selection to the appropriate frequency, 12.5Hz or 50Hz.
7. Turn the device **ON** and set the stimulation intensity level by slowly turning the Intensity Control Knob to the most comfortable level which elicits a pelvic floor contraction. If there is discomfort, turn the intensity down to a comfortable level and check that the electrode is positioned properly.
8. Once desired intensity is set, press the **START** button to initiate a 15 minute treatment session.
9. After treatment session is completed, turn the device **OFF** by turning the intensity control knob to the “0” position. Note: The “click” indicates that the device is off.
10. Disconnect the electrode from the device before removing the electrode.
11. Remove the electrode and clean by following the Electrode Cleaning Instructions.
Typical PFS Treatment Protocols

The treatment protocol prescribed will vary depending upon the type of incontinence being treated. The following treatment protocols are recommended based upon current clinical studies.¹

**Protocol for Genuine Stress Incontinence (GSI):**
- **Frequency:** 50Hz
- **Use:** Twice a day (once in morning, once in evening), daily or every other day
- **Session Length:** 15 minutes

**Protocol for Urge Incontinence:**
- **Frequency:** 12.5Hz
- **Use:** Twice a day (once in morning, once in evening), daily or every other day
- **Session Length:** 15 minutes

**Protocol for Mixed Incontinence (Combination of Stress and Urge Incontinence):**
- **Frequencies:** 50Hz and 12.5Hz
- **Use:** Use 50Hz in the morning, and 12.5Hz in the evening, daily or every other day
- **Session Length:** 15 minutes

**Treatment Duration**

For maximum benefit, the Minnova Pelvic Floor Stimulation System should be used according to prescribed protocols for approximately 20 weeks.

**Maintenance**

In order to maintain the degree of continence achieved during the first 20 weeks of treatment, the patient should continue to use the device 2 - 3 times a week or as needed for their level of dryness.

Caring For The Device

Cleaning
To clean the Minnova device, wipe it with a cloth moistened with soap and water. Never immerse the device in water or other liquids.

Maintenance
Under normal conditions, the device does not require periodic preventative maintenance or calibration; however, all information necessary to perform periodic safety checks by a qualified technician is included in the Technical Information Section.

Changing the Battery
Change the battery when indicated by a SLOWLY blinking green light next to the start button. Be sure polarity (“+” and “–”) markings on battery match with markings on device.

Repair
There are no user serviceable parts inside the device. If the device becomes damaged or needs repair, please contact the Clear Lake Service Center at 1-800-862-2343 for instructions. In the case of repairs or returns outside of North America, contact your Authorized Empi Distributor, or contact Empi directly.

Storage
To properly store the device for an extended period of time, i.e. 90 days or more, remove the battery from the device and store the device in a dry location.

Disposal
To properly dispose of the device, ship the device, postage prepaid, to Clear Lake Service Center. Please enclose a note indicating that the item is being returned for disposal or recycling.
Technical Information

**Standard Conditions** (Unless otherwise indicated.)
2 x 1.5V battery voltage, 500Ω resistive load, 23°C

**Output Specifications** (Tolerances ± 15% unless noted)
- Output type: Amplitude regulated current source over the range of 100Ω to 500Ω.
- Waveform: Alternating (balanced symmetrical biphasic with no dc component, See figure A)
- Amplitude Range: 0 to 100mA
- Pulse width at 50% amplitude: 300µs
- Pulse frequency: 12.5Hz or 50Hz
- Maximum rms current: 20mA
- Maximum charge per pulse: 60µC
- Duty cycle: ON time: 5 seconds, OFF time: 10 seconds
- Session duration: 15 minutes

**Battery Information**
- Expected typical battery life at 40mA intensity: >30h
- Recommended battery: Two AA 1.5V DC alkaline, IEC R6, such as Eveready No. 91. Do not use a Ni-Cd rechargeable battery or device may shut down after a short period of time.
- Required Electrodes: Empi electrodes with custom touchproof connector.
**IEC 601 Classification**

- Type BF applied part. Class II device. Internally powered only. Ordinary protection against ingress of liquids. Continuous operation. Not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

**Physical Dimensions**

- **Approximate Size (H x W x D)**: 110mm x 70mm x 30mm
  
  (4.3 in x 2.8 in x 1.2 in)

- **Approximate weight (without battery)**: 100 grams (4 oz)

**Environmental Conditions**

- **Operation**: 10°C to 50°C (+50°F to +122°F); Up to 75% relative humidity (non-condensing); Air pressure 50kPa to 106kPa.

- **Transportation & storage**: -40°C to +70°C (-40°F to +158°F); 10% to 100% relative humidity condensing; Air pressure 50kPa to 106kPa.

- Store in a cool dry place

**Waveform Shown is Typical**

Balanced symmetrical biphasic waveform. Output current into 500Ω, 750Ω and 1kΩ resistive load at maximum intensity setting.

![Simulated Minnova output waveform in the time domain](image)

**Figure A.**
Electromagnetic Compatibility (EMC) Tables

<table>
<thead>
<tr>
<th>Emission tests</th>
<th>Compliance</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions</td>
<td>Group 1</td>
<td>The Minnova uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RF emissions</td>
<td>Class B</td>
<td>The Minnova is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Harmonic emissions</td>
<td>Not Applicable- Battery Operated Device</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/ flicker emissions</td>
<td>Not Applicable- Battery Operated Device</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The Minnova is intended for use in the electromagnetic environment specified below. The customer or the user of the Minnova should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>±6kV contact</td>
<td>±6kV contact</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>IEC 61000-4-2</td>
<td>±8kV air</td>
<td>±8kV air</td>
<td></td>
</tr>
<tr>
<td>Electrical fast transient/burst</td>
<td>±2kV for power supply lines</td>
<td>Not Applicable-Battery Operated Device</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-4</td>
<td>±1kV for input/output lines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surge</td>
<td>±1kV differential mode</td>
<td>Not Applicable-Battery Operated Device</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-5</td>
<td>±2kV common mode</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines</td>
<td>&lt;5% $U_T$ (&gt;95% dip in $U_T$) for 0.5 cycle</td>
<td>Not Applicable-Battery Operated Device</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-11</td>
<td>40% $U_T$ (60% dip in $U_T$) for 5 cycles</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>70% $U_T$ (30% dip in $U_T$) for 25 cycles</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt;5% $U_T$ (&gt;95% dip in $U_T$) for 5 sec</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Power frequency (50/60Hz) magnetic field</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NOTE $U_T$ is the a.c mains voltage prior to application of the test level.
**Electromagnetic Compatibility (EMC) Tables**

### Guidance and manufacturer’s declaration – electromagnetic immunity

The Minnova is intended for use in the electromagnetic environment specified below. The customer or the user of the Minnova should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Portable and mobile RF communications equipment</td>
<td>IEC 61000-4-6</td>
<td>3 Vrms 150 kHz to 80 MHz</td>
<td>3V</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>IEC 61000-4-3</td>
<td>3 V/m 80 MHz to 2.5 GHz</td>
<td>3V/m</td>
</tr>
</tbody>
</table>

**Recommended separation distance**

\[ d = \left[ \frac{3.5}{V} \right] \sqrt{\frac{P}{E}} \]

where \( P \) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and \( d \) is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey\(^a\), should be less than the compliance level in each frequency range\(^b\).

Interference may occur in the vicinity of equipment marked with the following symbol:

\[ (\text{\texttrademark}) \]

**NOTE 1** At 80 MHz and 800 MHz, the higher frequency range applies.

**NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

\(^a\) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Minnova is used exceeds the applicable RF compliance level above, the Minnova should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Minnova.

\(^b\) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
The Minnova is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Minnova can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Minnova as recommended below.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter W</th>
<th>Separation distance according to frequency of transmitter m</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 kHz to 80 MHz</td>
<td></td>
</tr>
<tr>
<td>( d = \left[\frac{3.5}{V^1}\right] \sqrt{P} )</td>
<td></td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
<tr>
<td>80 MHz to 800 MHz</td>
<td></td>
</tr>
<tr>
<td>( d = \left[\frac{3.5}{E^1}\right] \sqrt{P} )</td>
<td></td>
</tr>
<tr>
<td>800 MHz to 2.5 GHz</td>
<td></td>
</tr>
<tr>
<td>( d = \left[\frac{7}{E^1}\right] \sqrt{P} )</td>
<td></td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance \( d \) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where \( P \) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
Description of Device Markings

The markings on your Minnova device are your assurance of its conformity to the highest applicable standards of medical equipment safety and electromagnetic compatibility. One or more of the following markings may appear on your device.


Classified by Underwriters Laboratories, Inc® with respect to electric shock, fire and mechanical hazards only in accordance with UL 2601-1, CAN/CSA C22.2 No. 601.1-M90 Medical Electrical Equipment.
Limited Warranty and Disclaimer

I. Warning
While, in the opinion of Empi, Inc. (“Empi”), the use of the Minnova Pelvic Floor Stimulator (the “Product”) has met with some success in the treatment of incontinence, Empi makes no warranties to the purchaser as to the effectiveness of the product.

II. Warranty
A. Empi warrants to the initial Purchaser (“Purchaser”) (and to no other person) that the Product and the components thereof, distributed or manufactured by Empi, shall be free from defects in workmanship and materials for one year after the date of purchase (the “Warranty Period”).
B. Accessories including, but not limited to the electrode, electrode cleanser and batteries are excluded from the Warranty and are sold “As Is” because their structure is such that they may be easily damaged before or during use.

III. Limitations of Liabilities and Disclaimer of Warranties
A. Empi’s sole obligation in the case of any breach of the Limited Warranty set forth in Paragraph II(A) above, shall be, at Empi's option, to repair or replace the Product or parts of the Product without charge to Purchaser or to refund the purchase price of the Product. In order to recover under the Limited Warranty, Purchaser must send Empi written notice of the defect (setting forth the problem in reasonable detail) prior to expiration of the applicable Warranty Period, and within 30 days of discovery of the defect. Upon Empi’s written request and authorization, Purchaser shall return the Product to Empi, freight and insurance prepaid, for inspection. Notice and return shipment shall be sent to Empi, Inc., 47492 SD Hwy 22, Clear Lake, SD, 57226 USA or to an Empi Authorized Service Center. To locate the appropriate Service Center outside of North America, or to request shipment approval, contact Empi directly. Empi will not be responsible for damage due to improper packaging or shipment. If Empi determines in its sole reasonable discretion that the Product contains defective workmanship or materials, Empi will refund to the Purchaser the purchase price for the defective product, or return the repaired Product or a replacement thereof to Purchaser, freight and insurance prepaid, as soon as reasonably possible following receipt of the Product by Empi. If Empi determines in its sole reasonable discretion that the Product does not contain defective workmanship or materials, Empi will return the Product to the Purchaser, freight and insurance billed to the Purchaser.
B. This Limited Warranty is voided immediately as to any Product which has been repaired or modified by any person other than authorized employees or agents of Empi or which has been subjected to misuse, abuse, neglect, damage in transit, accident or negligence.
C. EXCEPT AS PROVIDED IN PARAGRAPH II(A), THE PRODUCT IS BEING SOLD ON AN “AS IS” BASIS, ALL ACCESSORIES ARE SOLD “AS IS”, AND THE ENTIRE RISK AS TO THE QUALITY AND PERFORMANCE OF THE PRODUCT IS WITH PURCHASER. THE LIMITED WARRANTY PROVIDED IN PARAGRAPH II(A) IS INTENDED SOLELY FOR THE BENEFIT OF THE INITIAL PURCHASER AND EMPI DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED,
INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. PROVIDED, HOWEVER, THAT NOTWITHSTANDING THE FOREGOING SENTENCE, IN THE EVENT AN IMPLIED WARRANTY IS DETERMINED TO EXIST, THE PERIOD FOR PERFORMANCE BY EMPI THEREUNDER SHALL BE LIMITED TO THE LIFETIME OF THE INITIAL PURCHASER. NO EMPLOYEE, REPRESENTATIVE OR AGENT OF EMPI HAS ANY AUTHORITY TO BIND EMPI TO ANY AFFIRMATION, REPRESENTATION OR WARRANTY EXCEPT AS STATED IN THIS WRITTEN LIMITED WARRANTY.

(This warranty gives Purchaser specific legal rights and Purchaser may also have other rights which vary from state to state. Some states do not allow limitations of how long an implied warranty lasts, so the above limitation may not apply to the Purchaser.)

D. EMPI SHALL NOT BE LIABLE TO ANY PERSON FOR ANY DIRECT, INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, LOST PROFITS OR MEDICAL EXPENSES CAUSED BY ANY DEFECT, FAILURE, MALFUNCTION OR OTHERWISE OF THE PRODUCT, REGARDLESS OF THE FORM IN WHICH ANY LEGAL OR EQUITABLE ACTION MAY BE BROUGHT AGAINST EMPI (SUCH AS CONTRACT, NEGLIGENCE OR OTHERWISE) THE REMEDY PROVIDED IN PARAGRAPH III(A) ABOVE SHALL CONSTITUTE PURCHASER’S SOLE REMEDY. IN NO EVENT SHALL EMPI’S LIABILITY UNDER ANY CAUSE OF ACTION RELATING TO THE PRODUCT EXCEED THE PURCHASE PRICE OF THE PRODUCT.

(This warranty gives Purchaser specific legal rights and Purchaser may also have other rights which vary from state to state. Some states do not allow limitations of how long an implied warranty lasts, so the above limitation may not apply to the Purchaser.)
Your authorized representative:

(MDSS) Medical Device Safety Service GmbH
Schiffgraben 41, 30175 Hannover, Germany
Tel: 49-511-62 62 86 30