Instruction Manual for the Avery Breathing Pacemaker System

902A Antenna

I-110A Receiver

E377-05 Electrode

Mark IV Transmitter

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The contents of this document are identical to the printed version (6025-AB) distributed to patients, caregivers and physicians who use the Implanted Diaphragm Pacing System. In the event of any changes, printed labeling and package inserts supersede this document.

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# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>KEY:</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>● - For Patients and other users</td>
<td></td>
</tr>
<tr>
<td>● - For Medical Professionals</td>
<td></td>
</tr>
</tbody>
</table>

- GENERAL CAUTIONS REGARDING BREATHING PACEMAKERS | 2
- RECYCLING INFORMATION | 2
- LABEL SYMBOLS | 3
- INTRODUCTION AND GENERAL INFORMATION | 5
  - System Overview | 5
  - Benefits of Diaphragm Pacing | 5
  - Answers to Some Commonly Asked Questions | 6
  - Regulatory Approval/Certification | 6
  - Financial Considerations | 6
  - Indications | 6
  - Patient Selection | 6
  - Ordering Equipment | 6
  - Device Tracking Requirements | 6
- PREOPERATIVE SCREENING | 7
- MARK IV TRANSMITTER | 8
  - External Controls, Indicators and Function | 8
  - Carrying the Transmitter | 9
  - Batteries | 9
- 902A / 902AL ANTENNAS | 10
  - Connection and Removal | 10
  - Antenna Care | 10
  - Intraoperative Use of Antennas | 11
- IMPLANTED COMPONENTS | 11
- STERILIZATION PROCEDURES FOR NON CE IMPLANTS | 12
- RESTERILIZATION PROCEDURES FOR CE IMPLANTS | 13
- SURGICAL PROCEDURES | 14
  - Anesthesia | 14
  - Cervical Approach for New Implants | 14
  - Thoracic Methods for New Implants | 15
  - Surgical Approach for Receiver Replacement | 16
  - Surgical Approach for Electrode Replacement | 16
  - Implanted Medical Device Registration Form | 17
- POSTOPERATIVE CARE AND INITIATION OF PACING | 18
  - Postoperative Care | 18
  - Diaphragm Reconditioning | 19
  - Transtelephonic Monitoring - TTM | 19
- TROUBLESHOOTING | 20
- CUSTOMER SERVICE AND SHIPPING INSTRUCTIONS | 21
  - Customer Service | 21
  - Shipping Instructions | 21
- WARRANTIES AND IDENTIFICATION | 22
  - Limited Warranty | 22
  - Patient Identification Card | 23
GENERAL CAUTIONS REGARDING BREATHING PACEMAKERS

WARNINGS

! Failure of the diaphragm pacer could lead to respiratory arrest.

! Failure of the diaphragm pacing system can occur due to battery failure, broken battery connector wires, or intermittent antenna cable or connector, or component failure in the receiver, electrode wire, or external transmitter.

! Infection may occur as a result of the surgical procedure, or in the postoperative period due to wound infection or septicemia. If unresponsive to antibiotics, removal of the implants may become necessary.

! Any implant removed from one patient must not be reimplemented in another patient.

! One patient’s transmitter must not be used for another patient.

! Do not use any other diaphragm pacing, phrenic nerve stimulation or other stimulating equipment to power our diaphragm pacer implants. This voids warranty and could cause serious injury or death.

! Magnetic Resonance Imaging (MRI), shock wave lithotripsy and therapeutic diathermy are contraindicated.

! Radio Frequency (RF) may interfere with demand-type cardiac pacemakers. If a cardiac pacemaker is involved, the cardiac pacemaker leads should be bipolar and the breathing pacemaker implant(s) should be at least 10cm from the cardiac pacemaker.

! The transmitter should not be used within one meter of flammable anesthetics or in oxygen-enriched environments.

! If use of a defibrillator is necessary, the implanted receiver and the phrenic nerve could be damaged.

A permanent tracheostomy may be required to obtain adequate ventilation. Diaphragm pacing can induce or worsen upper airway obstruction. Augmentation of the force of inspiration and laryngeal and pharyngeal musculature is the probable cause.

Exposure to a powerful transmitter such as navigational, maritime or amateur communications may interfere with the operation of the pacer. According to U.S. F.C.C. and foreign tables of frequency allocation, transmissions in the 2 MHz region may include: Radio navigation (LORAN-A), mobile distress, and emergency position indicating radio beacon (EPIRB) for aircrafts.

! Exposure of the implanted components to therapeutic levels of ultrasound energy should be avoided as an implanted device may inadvertently concentrate the ultrasound field and cause harm.

! Exposure to therapeutic dosages of ionizing radiation may damage implanted components or interfere with the operation of the pacer. Any damage to the implanted components may not be immediately detectable.

! Close proximity to a cell phone may interfere with the operation of the pacer. Cell phones and WiFi-enabled devices should be kept a minimum of 10 cm from the implants.

! The transmitter emits a low level of radio frequency output at 2 MHz which may interfere with other devices in its proximity running at the same frequency.

CAUTIONS

! Federal (USA) law restricts this device to sale by or on the order of a physician.

! A device for providing artificial ventilation by mask, mouth piece or tracheal tube should be available for those patients who are continually dependent on the phrenic pacemaker as an alternative to mechanical ventilation.

! An apnea alarm should be provided to summon help should diaphragm pacer failure occur.

! The safety of diaphragm pacing in pregnancy has not been established.

! Diaphragm pacing systems should not be used aboard commercial aircraft without prior clearance with the pilot or airline.

RECYCLING INFORMATION

! Dispose of depleted batteries in accordance with the battery manufacturer instructions or local environmental recycling laws.

! In accordance with Directive 2002/96/EC of the European Union, waste electrical and electronic equipment (WEEE) should not be disposed of as unsorted municipal waste. Contact the ABD Customer Service Department for instructions on how to return transmitters that are no longer in use at no cost.
# LABEL SYMBOLS

ISO 15223-1:2012 - Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements

<table>
<thead>
<tr>
<th>Title</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>5.1.1</td>
</tr>
<tr>
<td><strong>Description:</strong> Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.</td>
<td></td>
</tr>
<tr>
<td>Authorized representative in the European Community</td>
<td>5.1.2</td>
</tr>
<tr>
<td><strong>Description:</strong> Indicates the Authorized Representative in the European Community.</td>
<td></td>
</tr>
<tr>
<td>Date of Manufacture</td>
<td>5.1.3</td>
</tr>
<tr>
<td><strong>Description:</strong> Indicates the date when the medical device was manufactured.</td>
<td></td>
</tr>
<tr>
<td>Use-by date</td>
<td>5.1.4</td>
</tr>
<tr>
<td><strong>Description:</strong> Indicates the date after which the medical device is not to be used.</td>
<td></td>
</tr>
<tr>
<td>Batch code</td>
<td>5.1.5</td>
</tr>
<tr>
<td><strong>Description:</strong> Indicates the manufacturer's batch code so that the batch or lot can be identified.</td>
<td></td>
</tr>
<tr>
<td>Catalogue number</td>
<td>5.1.6</td>
</tr>
<tr>
<td><strong>Description:</strong> Indicates the manufacturer's catalogue number so that the medical device can be identified.</td>
<td></td>
</tr>
<tr>
<td>Serial number</td>
<td>5.1.7</td>
</tr>
<tr>
<td><strong>Description:</strong> Indicates the manufacturer's serial number so that a specific medical device can be identified.</td>
<td></td>
</tr>
<tr>
<td>Sterilized using aseptic processing techniques</td>
<td>5.2.2</td>
</tr>
<tr>
<td><strong>Description:</strong> Indicates a medical device that has been manufactured using accepted aseptic techniques.</td>
<td></td>
</tr>
<tr>
<td>Sterilized using steam or dry heat</td>
<td>5.2.5</td>
</tr>
<tr>
<td><strong>Description:</strong> Indicates that a medical device that has been sterilized using steam or dry heat.</td>
<td></td>
</tr>
<tr>
<td>Non-sterile</td>
<td>5.2.7</td>
</tr>
<tr>
<td><strong>Description:</strong> Indicates a medical device that has not been subjected to a sterilization process.</td>
<td></td>
</tr>
<tr>
<td>Do not use if package is damaged</td>
<td>5.2.8</td>
</tr>
<tr>
<td><strong>Description:</strong> Indicates a medical device that should not be used if the package has been damaged or opened.</td>
<td></td>
</tr>
<tr>
<td>Do not re-use</td>
<td>5.4.2</td>
</tr>
<tr>
<td><strong>Description:</strong> Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.</td>
<td></td>
</tr>
<tr>
<td>Consult instruction for use</td>
<td>5.4.3</td>
</tr>
<tr>
<td><strong>Description:</strong> Indicates the need for the user to consult the instructions for use.</td>
<td></td>
</tr>
<tr>
<td>Caution</td>
<td>5.4.4</td>
</tr>
<tr>
<td><strong>Description:</strong> Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.</td>
<td></td>
</tr>
<tr>
<td>Not made with natural rubber latex</td>
<td>Negates 5.4.5</td>
</tr>
<tr>
<td><strong>Description:</strong> Natural rubber latex is not used as a material in this medical device, as part of its manufacturing process, its container and/or its packaging.</td>
<td></td>
</tr>
</tbody>
</table>

ISO 7010:2011 - Graphical symbols -- Safety colors and safety signs -- Registered safety signs

<table>
<thead>
<tr>
<th>Title</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Warning Sign</td>
<td>W001</td>
</tr>
<tr>
<td><strong>Description:</strong> To signify a general warning</td>
<td></td>
</tr>
<tr>
<td>Refer to instruction manual/booklet</td>
<td>M002</td>
</tr>
<tr>
<td><strong>Description:</strong> To signify that the instruction manual/booklet must be read</td>
<td></td>
</tr>
</tbody>
</table>
### LABEL SYMBOLS (Cont.)

**ISO 7000 5th edition (2014) - Graphical symbols for use on equipment -- Registered symbols**

<table>
<thead>
<tr>
<th>Title</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product information; information point</td>
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</table>

<table>
<thead>
<tr>
<th>Title</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>General symbol for recovery/recyclable</td>
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</table>

**ISO 60417:2002 (Database) Graphical symbols for use on equipment**

<table>
<thead>
<tr>
<th>Title</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type BF applied part</td>
<td>5333</td>
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</table>

<table>
<thead>
<tr>
<th>Title</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct Current</td>
<td>5031</td>
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**ASTM F2503:2013 - Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment**

<table>
<thead>
<tr>
<th>Title</th>
<th>Reference</th>
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</thead>
<tbody>
<tr>
<td>MR Unsafe</td>
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</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Title</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingress Protection</td>
<td>-</td>
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</tbody>
</table>

**EN 50419:2006 - Marking of electrical and electronic equipment in accordance with article 11(2) of Directive 2002/96/EC (WEEE)**

<table>
<thead>
<tr>
<th>Title</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Waste Electrical and Electronic Equipment</td>
<td>Figure 1</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Title</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescription Use Only</td>
<td>-</td>
</tr>
</tbody>
</table>

**Council Decision 93/465/EC - CE - Conformity Marking**

<table>
<thead>
<tr>
<th>Title</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conformite Europeenne</td>
<td>Annex B(d)</td>
</tr>
</tbody>
</table>

**Title: Ingress Protection**

**Description:** Degrees of protection provided by enclosures of electrical equipment against intrusion, dust, accidental contact, and water.

**Title: Waste Electrical and Electronic Equipment**

**Description:** Indicates adherence to the directive 2002/96/EC of the European Union that designates safe and responsible collection, recycling and recovery procedures for all types of electronic waste.

**Title: Prescription Use Only**

**Description:** Federal law restricts this device to sale by or on the order of a physician.

**Title: Conformite Europeenne**

**Description:** Conformity marking for certain products sold within the European Economic Area.
INTRODUCTION AND GENERAL INFORMATION

System Overview

The Diaphragm Pacing System is an implantable diaphragmatic/phrenic nerve stimulator that provides support for patients with chronic ventilatory insufficiency whose diaphragm, lungs and phrenic nerves have residual function.

The application of repetitive stimulus patterns to the phrenic nerves causes smooth, rhythmic contractions of the diaphragm, which result in the inhalation of air into the lungs. The pacing system consists of electrodes implanted near the phrenic nerves, radio receivers implanted in subcutaneous pockets and an external transmitter/antenna assembly that provides power to the system via 9-Volt batteries.

The external transmitter and antenna send energy and stimulus information to the passive receiver implant. The receiver translates radio waves into stimulating pulses that are delivered to the phrenic nerve by the electrode. The diaphragm muscle contracts and produces the inhalation phase of breathing. The transmitter then stops generating signals, which allows the diaphragm to relax and exhalation occurs. This cycle of signals followed by no signals is repeated automatically by the transmitter, producing a more natural breathing pattern. See Figure 1.

The transmitter contains the controls used to individually adjust the parameters of stimulation to suit each patient. Since 1968, over 2,000 phrenic nerve implants have been performed throughout the world. Patients from several months of age to over age 80 years have been successfully implanted and paced long term. Many patients have been successfully paced for more than 20 years and the longest patients have been pacing continually for over 40 years.

<table>
<thead>
<tr>
<th>Item Name</th>
<th>Quantity Provided</th>
<th>Model Number</th>
</tr>
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<tbody>
<tr>
<td>Transmitter</td>
<td>1-2</td>
<td>Mark IV</td>
</tr>
<tr>
<td>Antennas</td>
<td>6 -10</td>
<td>902A or 902AL</td>
</tr>
<tr>
<td>Receivers</td>
<td>2</td>
<td>I-110A (Monopolar)</td>
</tr>
<tr>
<td>Electrodes</td>
<td>2</td>
<td>E-377-05 (Monopolar)</td>
</tr>
<tr>
<td>Transtelephonic</td>
<td>1</td>
<td>TTM</td>
</tr>
<tr>
<td>Monitoring Transmitter</td>
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<td></td>
</tr>
<tr>
<td>Carrying Case</td>
<td>1-2</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Table 2. System Components

Benefits of Diaphragm Pacing

Diaphragm pacing provides physiological respiratory function far superior to that provided by mechanical ventilators since the inhaled air is drawn into the lungs by the musculature, rather than being forced into the chest under mechanical pressure. The benefits of diaphragmatic pacing include:

- cost effectiveness because patients can live outside of hospitals and the cost of a ventilator and its disposables is eliminated.
- lower infection rate due to reduction in suctioning, elimination of external humidifier and ventilator circuits and the possibility of tracheostomy tube removal (some patients have had their tracheostomy closed).
- improved venous return (negative, not positive pressure).
- natural breathing and speech.
- ease of eating and drinking.
- increased patient mobility.
- unobtrusive use due to the small size of external components and totally silent operation.

Figure 1. Bilateral Pacing System
INTRODUCTION AND GENERAL INFORMATION (Cont.)

Answers to Some Commonly-Asked Questions
Ongoing experience with diaphragm pacing disproves some of the concerns expressed by early investigators in the field. Years of follow-up show that diaphragm pacing:

- does not “burn out” nerves/muscles in normal operation.
- can provide safe and effective bilateral pacing twenty-four hours per day.
- can permit decannulation and discontinuation of tracheostomy tubes in selected patients.
- can provide unilateral pacing where bilateral pacing is not possible due to destruction of the other phrenic nerve.
- can provide safe operation near properly functioning microwave ovens and other equipment.

Regulatory Approval / Certification
This equipment has full US FDA PMA approval. It complies with requirements of the European Directive for active implantable medical devices (90/385/EEC). The EC Declaration of Conformity is based on an approved ISO-13485 quality system and a design examination by a Notified Body. Authorization to affix the CE Mark was obtained in 1995 by TUV Rheinland. Currently, we have been certified by BSI Management Systems (London, UK) since 2010. The equipment is marked:

Financial Considerations
Our equipment is reimbursed by Medicare and many private and government insurance plans around the world. When applying to carriers for approval (or “prior approval”), it is important to explain that diaphragm pacing may pay for itself in less than a month by permitting discharge to a less costly environment.

Unlike mechanical ventilators, pacers do not require expensive maintenance and disposable supplies, saving over $1,000 per month, every month for decades. The external Mark IV transmitter control unit comes with a three year warranty and the implanted receivers and electrodes both come with a five year warranty.

Indications
This device is indicated for persons who require chronic ventilatory support because of upper motor neuron respiratory muscle paralysis (RMP) or because of central alveolar hypoventilation (CAH) and whose remaining phrenic nerve, lung and diaphragm function is sufficient to accommodate electrical stimulation.

Candidates for diaphragm pacing include, but are not limited to, patients who have:

- central alveolar hypoventilation.
- decreased day or night ventilatory drive (i.e. sleep apnea, Ondine’s curse).
- brain stem injury or disease.
- spinal cord injury or disease.

Patient Selection
Diaphragm pacing is generally indicated for prospective candidates who have:

- functional lungs and diaphragm muscle.
- Intact or repaired phrenic nerves.
- absence of infection.
- a clear and adequate upper airway (including nasopharynx, pharynx and larynx).
- adequate physical caregiver quality and availability including nursing, family support and medical care.

Implantation of a new diaphragm pacing system can be done on an inpatient or outpatient basis, depending on the patient’s, hospital’s or surgeon’s preference and rules of the appropriate insurance carrier. The hospital or clinic should have support facilities and personnel to be able to care for the type of patient involved. For example, a patient with quadriplegia disability may need lifting, turning or mechanical ventilatory support.

The surgical procedure usually takes one to four hours depending on patient, surgical experience, anesthesia support and facility staffing.

Ordering Equipment
Once the surgeon has decided on a surgical approach, please contact us to order the appropriate equipment and arrange for one of our representatives to be present at the operation.

Equipment should be selected according to the patient’s needs, the existence of previously implanted devices and presence or absence of a cardiac pacemaker. It is mandatory to inform us of the patient’s name and address at the time of ordering to facilitate future follow-up. The equipment can be shipped overnight by courier to most North American locations, and within a few days overseas.

Device Tracking Requirements
Medical Device Tracking regulations of the U.S. Food and Drug Administration require that we be notified when a diaphragm pacing:

- system is implanted.
- receiver or electrode is explanted. Include the date, name, mailing address and telephone number of the explanting physician.
- patient dies.
- device is returned.
- device is permanently retired from use or otherwise permanently discarded.

There are no risks associated with the disposal of the device as none of the components contain hazardous and/or toxic materials. Explanted components should be disposed of in accordance with hospital policy or autoclaved and returned to us for quality assurance testing and archiving.
PREOPERATIVE SCREENING

Cautions

♦ Failure of the diaphragm to contract when transcutaneous stimulation is applied to the phrenic nerve does not necessarily mean that the nerve will not respond to direct stimulation.
♦ Definitive test of phrenic function is achieved via open dissection of the phrenic nerve.
♦ Ensure sleep apnea is central apnea, not obstructive apnea.

Patient Testing Techniques

Transcutaneous screening tests may produce “false negatives” especially if the laboratory relies solely on EMG techniques and has limited testing experience. For example, many sleep apneics who breathe spontaneously during the day have been falsely reported as “negative.” The most unequivocal test is to expose the nerve and stimulate directly using the nerve test probe.

Testing in quadriplegics may show nerve conduction with little to no diaphragm movement observed. Lack of immediate movement may be attributable to an unconditioned muscle due to prolonged dependency on mechanical ventilation. Months of stimulation may be required before sufficient diaphragm function returns.

Screening for diaphragm function may include one or more of the following:

- fluoroscopy to observe diaphragm movement in patients with some spontaneous ventilatory drive
- transcutaneous stimulation of the phrenic nerves in the neck in combination with the following to confirm diaphragm movement:
  a) electromyogram (EMG) techniques,
  b) fluoroscopy,
  c) measurement of phrenic nerve conduction time (PNCT), and
  d) measurement of transdiaphragmatic pressure.

The simplest method of predicting nerve viability and diaphragm function is transcutaneous phrenic nerve stimulation with simultaneous fluoroscopy of the diaphragm and measurement of the phrenic nerve conduction time (PNCT).

The phrenic nerve is stimulated transcutaneously with a hand held cathode covered with saline or electrode jelly pressed against the skin overlying the anterior scalene muscle, above the clavicle and behind the lateral posterior border of the sternocleidomastoid muscle. The anode is best attached on the posterior cervical surface or between the scapulae.

The stimulator should be set to deliver a stimulus pattern composed of square wave pulses of 500 to 1,000 μseconds duration at the frequency of twenty pulses per second at a current level of 20 to 100 milliamperes. Using a spirometer and fluoroscopy, a tidal volume of more than 50 ml. and diaphragmatic movement in excess of 3.0 cm. is considered desirable in patients with no voluntary movement of the diaphragm.

When measuring PNCT, two surface electrodes are placed at the costal margin in the anterior axillary line in the eighth or ninth intercostal space and a ground electrode is placed on the xiphoid process. The conduction time from the site of phrenic nerve stimulation in the neck to the diaphragm action potential is recorded on a storage oscilloscope.

Normal PNCT is between 6 and 9 ms. (shorter in children). A prolonged PNCT of more than 11 ms. latency may suggest damage to the phrenic nerve, but the clinical significance of this is uncertain.
**MARK IV TRANSMITTER**

**Warnings**
- Do not drop.
- Do not allow to become wet or be placed under a drip bag.
- Turn the transmitter off to change the batteries.
- Do not allow unsupervised children to adjust the transmitter.
- The internal transmitter controls should only be adjusted upon the advice of the physician and by Avery personnel.
- Repairs or modifications by anyone other than Avery personnel could be dangerous. Such action may damage equipment, cause serious injury or death, and voids all warranties.
- If a sudden increase in amplitude dial setting (greater than 30% above normal setting) is required for effective pacing after new batteries have been installed, notify the patient’s physician immediately. The patient may have an infection or there may be a mechanical failure of the equipment.
- Do not exceed operating temperature range of +41°F to +99°F (+5°C to +37°C) because the pacer may fail to function at very high or low temperatures.
- If ambient temperature reaches +37°C, then measures should be taken to ensure antennas remain at +37°C or less as they are in contact with the skin.

**Cautions**
- Do not steam sterilize.
- Pets and pests should not be allowed in contact with the transmitter.
- The transmitter does not work while the batteries are being changed.
- Be sure to turn the transmitters ON when pacing and OFF when not pacing.
- For patients who are to be paced unilaterally, contact the Customer Service Department to verify which side of the patient’s transmitter controls the front panel respiratory rate knob.

The Mark IV transmitter generates stimulus patterns and delivers them to the phrenic nerves via the external antennas, implanted receivers and electrodes. The Mark IV transmitter design employs two independent output stimulus generators, each with its own battery power source, external indicators and respiratory rate control (Figures 3 & 4). Although each stimulus generator is independent from the other, they are electronically linked to begin phrenic nerve stimulation simultaneously at the desired external respiratory rate setting.

**Figure 3. Mark IV Transmitter**

The independent stimulus generators provide for asynchronous stimulation (e.g. different stimulus pulse widths, pulse intervals, etc.) that may be desirable in some patients in order to optimize their respiration. Optimization adjustments require access to the internal controls that can only be done in consultation with Avery personnel. The Mark IV transmitter is constructed of materials that minimize the possibility of accidental damage, but it is a delicate instrument and should be treated as such. The expected service life of the Mark IV transmitter is 10 years with a warranty of 3 years. There is no calibration, preventative or scheduled maintenance during the lifetime of the transmitter.

**Figure 4. Top Panel of Mark IV Transmitter**

- **ON / OFF Switch**
  - Turns the transmitter stimulus output on/off on each side. In earlier Mark IV transmitters, the left transmitter circuitry activates the external respiratory rate control knob. If the LEFT side is switched off the external respiratory control knob is inactive and the transmitter will generate respiratory stimulus patterns at the default rate (9 breaths per minute) despite the external respiratory rate control knob setting. Contact the Customer Service Department to verify which side of the patient’s transmitter controls the front panel respiratory rate knob.

- **AMPLITUDE Dial**
  - Sets the level of stimulus output of each side of the transmitter, adjusting the patient’s tidal volume. Patients may notice the need to change the amplitude setting with routine changes from the supine to the upright position. This is a normal variation and each patient’s requirements will be different.

- **RATE Knob**
  - Sets the level of bilateral breaths per minute. For patients who are to be paced unilaterally, Contact the Customer Service Department to verify which side of the patient’s transmitter controls the front panel respiratory rate knob.

- **“A” (Antenna) Indicator Light**
  - Verifies the stimulus output and antenna integrity for each side of the transmitter by lighting during each inspiratory interval.
  - Allows the physician, caregiver or patient to troubleshoot loss of stimulation by using a good, spare antenna and observing return of the indicator light.

**External Controls, Indicators and Function**
Adjustment of the external controls is performed on an individual basis by the physician, caregiver or patient as necessary. The description of the controls and indicators is as follows:

- **Battery Indicator**
- **Amplitude Dial**
- **Rate Knob**
- **Antenna Connector**
- **Antenna Indicator**

Extreme impact, exposure to moisture, dirt or temperatures beyond its capability may damage the transmitter and affect its ability to function correctly. The transmitter can be cleaned using a damp cloth, making sure liquid does not enter the transmitter.
MARK IV TRANSMITTER (Cont.)

“B” (Battery) Indicator Light
- Verifies the integrity of battery wires and power circuitry for each side of the transmitter by lighting during each inspiratory interval, as long as adequate battery voltage remains.
- Provides adequate warning of battery failure; the transmitter continues to produce stimulus patterns for 48 hours after the battery indicator extinguishes.
- Alerts the physician, caregiver or patient of required battery replacement and prevents the installation of either a dead or inadequate battery.

Carrying the Transmitter
A nylon carrying case is provided with the breathing pacemaker system. The case helps protect the antennas by supporting the strain relief area behind the connector, and protects the transmitter from water splashes and inadvertent changes to the front panel amplitude dials. The case has pockets designed to carry spare antennas, batteries and the patient identification card. The case is provided with a nylon belt and integrated belts loops allowing it to be worn at the waist, carried over the shoulder, or fastened to other items, such as a wheelchair. It is recommended that the transmitter case be used at all times. Should you choose not to use the provided carrying case, ensure that the transmitter is always attached securely to protect it from being dropped, or becoming wet.

Batteries

Warning
- The transmitter does not work while the batteries are being changed.

Cautions
- Use only alkaline batteries such as “Duracell” MN1604, for its long life characteristics.
- Keep spare batteries on hand at all times.
- Do not use any other type battery except in an emergency.
- Carbon-zinc batteries are less expensive but have a shorter life and are not recommended for diaphragm pacing.
- Rechargeable 9-Volt batteries should not be used due to short life and rapid decrease in battery voltage.
- Remove batteries if transmitter is not used for extended periods.
- Lithium ion batteries have been tested and, due to the cyclical nature of the transmitters, do not provide the long life expected of them.

Adapters that plug into wall outlets in place of batteries should never be used. Use of these adapters could result in serious injury or death.

The Mark IV transmitter requires two 9-volt batteries, one for each side of the transmitter, located in a compartment behind the rear panel. As battery voltage decreases, stimulus output decreases which then reduces tidal volume. When the battery indicator, located on the transmitter front panel no longer flashes during inspiration, the battery voltage is inadequate and the battery needs to be replaced.

Adequate warning is provided and the transmitter will continue to function, however the functioning time is variable and battery replacement should be performed as soon as possible.

When replacing batteries:

Turn transmitter off. The transmitter will not work while batteries are being changed. Failure to turn off transmitter while changing batteries will result in damage to the internal circuits.

1. Turn the transmitter over and slide the button latch on the rear panel toward the center of the transmitter.
2. Lift the cover up and off. Slide the batteries out of the case.
3. Carefully unsnap the batteries from the connector clip. Do not pull on the wires.
4. Ensure the polarity of the battery terminals line up correctly with the polarity of the terminals on the connector clip.
5. Press the connectors evenly and firmly onto the contacts of the new batteries.
6. Replace the batteries in the battery compartment ensuring that the wires are placed inside the compartment.
7. Replace the rear panel by attaching the side without the battery compartment.

Dispose of depleted batteries in accordance with the battery manufacturer instructions or local environmental recycling laws.

<table>
<thead>
<tr>
<th>Specification</th>
<th>Range or Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transmitter Warranty</td>
<td>3 Years</td>
</tr>
<tr>
<td>Bilateral Stimulus Redundancy</td>
<td>Yes</td>
</tr>
<tr>
<td>Left / Right Asynchronous Redundancy</td>
<td>Yes</td>
</tr>
<tr>
<td>Transmitter Energy Source</td>
<td>9-Volt Battery (disposable alkaline, 2 each)</td>
</tr>
<tr>
<td>Battery Life</td>
<td>&gt; 400 Hours</td>
</tr>
<tr>
<td>Battery / Antenna Indicators</td>
<td>Yes</td>
</tr>
<tr>
<td>Transmitter / Battery Weight</td>
<td>0.54 kg</td>
</tr>
<tr>
<td>Transmitter Dimensions</td>
<td>146 mm x 25 mm x 140 mm</td>
</tr>
<tr>
<td>Respiratory Rate</td>
<td>6 to 24 breaths per minute</td>
</tr>
<tr>
<td>Default Respiratory Rate</td>
<td>9 breaths per minute</td>
</tr>
<tr>
<td>Inspiratory Period</td>
<td>1.2 to 1.45 seconds</td>
</tr>
<tr>
<td>Pulse Interval</td>
<td>&gt; Factory Set to 12</td>
</tr>
<tr>
<td>Pulse Width</td>
<td>40 to 130 milliseconds</td>
</tr>
<tr>
<td>Minimum Slope</td>
<td>150 +/- 10 microseconds</td>
</tr>
<tr>
<td>Stimulus Amplitude</td>
<td>true zero</td>
</tr>
<tr>
<td>Carrier Frequency</td>
<td>2.05 megahertz</td>
</tr>
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<td>Carrier Frequency</td>
<td>2.05 megahertz</td>
</tr>
</tbody>
</table>

Table 5a. Mark IV Transmitter Specifications

Table 5b. Transport & Storage Conditions
The antenna is a one meter long (two meters for 902AL) wire, covered with silicone rubber, with a loop of concentrically wound wire at one end and a metal connector at the other end. The antennas transfer the stimulus pattern from the transmitter transcutaneously to the implanted receivers and electrodes. Each system is shipped with multiple antennas, two for immediate use, the others as spares. Store the spare antennas in a dry place. Antennas carry a 3-month warranty. Proper care and gentle handling will make them last longer but they will eventually wear out. ABD recommends replacement of antennas every six months (expected service life).

Defective antennas must be replaced as required. It is also recommended to always have a spare pair available. Old antennas should be discarded, as they cannot be repaired. The antennas must be properly positioned directly over the implanted receiver for maximum operating efficiency. The loop should lie flat against the skin. If the loop is not directly over the receiver, the radio signals reaching the receiver will not be full strength. Each antenna may be held in place with hypoallergenic adhesive tape. Apply tincture of benzoin first; after it dries tape the antennas to the skin. A suggested method for taping on the antenna loop is shown in Figure 6.

Alternatively, use elastic netting that fits snugly or conforms to body shape, other adhesive dressings (i.e. steri-drape), elastic bandages or a gas-permeable dressing. An additional piece of tape applied to the antenna cable just below the loop may help with stabilization. A thin layer of polypropylene or similar material may alleviate skin irritation due to perspiration when placed beneath the antenna. The amplitude dial settings on the transmitter may have to be adjusted accordingly to maintain proper ventilation.

Antenna Care
• Each antenna wire should run in a straight line or be gently looped between the receiver site and the transmitter. Do not bend or kink the wire.
• The point of greatest stress is the antenna/connector joint; keep this area free from bending or pulling.
• Wash antennas periodically with warm water and mild soap. Do not soak. Rinse and dry thoroughly.
• Do not allow the metal connectors to become wet.
• Adhesive tape buildup can be removed with an alcohol-dampened cloth.
• The stimulator may not work properly if dirt accumulates in the antenna plugs or transmitter connector sockets.

Antenna Connection
1. Turn transmitter off.
2. Align the flat surface of the “D”-shaped guide inside the antenna plug with the flat surface of the “D”-shaped guide inside the transmitter socket. When properly positioned, the two “D”-shaped or semicircular guides form a whole circle. Refer to Figure 7.
3. Press the antenna plug directly into the transmitter connector socket until it “clicks” into place. Do not turn to lock antenna into place.

Antenna Removal
1. Turn transmitter off.
2. Hold the transmitter firmly.
3. Grasp the antenna connector only by the rough collar (barrel) of the metal plug.
4. Do not pull on the wire or its rubber covering. Don’t rotate the metal plug when it is in the transmitter connector.
5. Pull straight up and out. Do not twist it or force it to disconnect.
6. With routine use the antennas should not need to be disconnected from the transmitter frequently. It is preferable to remove the antennas from the skin and leave them attached to the transmitter.

Warnings
◆ A spare pair of antennas should be on hand at all times.
◆ The breathing pacemaker system will not work unless the antennas are affixed to the patient’s skin, directly over the implanted receivers.
◆ The antenna wire must be routed away from the neck to minimize risk of strangulation and asphyxiation.

Cautions
◆ When connecting to the transmitter properly align connectors and press into place. Do not twist.
◆ Keep skin clean and dry.
◆ Place adhesive tape in a new location each day to avoid skin irritation, or put antenna next to skin by other means: netting, elastic bandages, specialized garments or gas-permeable dressing.
◆ Avoid repeated bending/strain as this may crack the insulation on the antenna.
◆ Antenna connectors should be free from dirt, dust and lint.
◆ Store spare antennas in a dry place.
◆ When disconnecting from the transmitter, pull antenna connector barrel straight out of transmitter. Do not twist.
◆ Autoclave only for use during surgery.

Figure 6. Antenna Loop Taping

Figure 7. Antenna Connection
IMPLANTED COMPONENTS

Receivers
The implanted I-110A receiver, shown in Figure 8, is a small disc-shaped device that contains electronic circuitry embedded in epoxy resin and coated with silicone rubber. Each receiver converts the stimulus energy from the antennas into distinct stimulus pulses and transfers them to the electrodes attached to the phrenic nerves.

The monopolar receiver (Model I-110A) has a single connector, uses an integrated anode (horseshoe shaped) plate and the patient’s body tissue to complete the electrical stimulus circuit.

Electrodes
The implanted electrode, shown in Figure 9, is composed of highly flexible, stainless steel fibers insulated by silicone rubber, with a platinum nerve contact on one end and a connector that mates to the receiver, on the other end. Each electrode accepts the stimulus pulses from the receiver and transfers them to the phrenic nerve, causing the diaphragm muscle to contract.

The monopolar electrode (Model E-377-05) is composed of a single wire assembly.

Antenna Sterilization
Sterilization should take place in accordance with established hospital policy. In the absence of an established policy, or at a minimum, the following procedures may be followed:

1. Remove antenna from packaging using powder-free gloves.
2. Steam autoclave only. Place in an open tray on a lint free cloth. Set autoclave to the following settings:
   - Temperature/Pressure: 270°F (132°C) / 30 PSI (206.8 kPa)
   - Use “pre-vacuum” method if available.
   - Do not exceed 275°F (135°C).
   - Exposure Time: 10 minutes
   - Drying Time: 10 minutes

Autoclave ONLY if intraoperative testing is to be performed. Autoclaving may shorten antenna life.

Warning
◆ Handle only with powder-free gloves.

Intraoperative Use of Antennas
The 902AL antennas should be used with the patient’s Mark IV transmitter for intraoperative testing. This can be achieved by:

1. Placing the loop end of the antenna into a sterile, single-use instrument drape such as those used for endoscopic instrumentation.
2. Sterilize the antenna via steam autoclave.

It is recommended that at least two antennas be prepared for use in the sterile field so that a spare would be immediately available.

Once sterile, the loop end of the antenna should be introduced into the sterile field and the connector end shall remain outside of the sterile field so that it can be mated to the Mark IV transmitter. The connector end of the antenna shall remain outside of the sterile field for the duration of the procedure.

Figure 8. I-110A (Monopolar) Receiver
Dimensions: Diameter 30mm, Thickness 9mm, Weight 7.5 gm

Figure 9. E-377-05 (Monopolar) Electrode
Wire Length: 500 mm
STERILIZATION PROCEDURES FOR NON CE IMPLANTS

**Warnings**
- Sterilization temperature should not exceed 275°F (135°C).
- Ultrasonic cleaning can damage receivers and electrodes.
- Never gas sterilize receivers or electrodes. Residual ethylene oxide or other chemicals can cause severe tissue reaction.

**Cautions**
- Steam autoclave required system components.
- Remove all packaging material from items to be sterilized.

Refer to the device labeling and package inserts for current sterilization procedures. In the event of any changes, device labeling and package inserts supersede the procedures shown in this manual.

NOTE: Any component removed from its outer bag may not be returned to us for credit. Items that are returned undamaged, in the original sealed package and received within 15 days of shipment will receive credit less 20% to cover the expense of reinspection, repackaging and restocking. We recommend that all items be left in the packaging until they are known to be needed, at which time they should be removed from the packaging, and (as appropriate) sterilized.

Prior to sterilization:
- Remove the following items from its boxes or packages using powder-free gloves:
  a) electrodes,
  b) receivers, and
  c) two (2) antennas

Do not gas sterilize receivers, electrodes, antennas or accessories. Items must be segregated if gas sterilized by mistake and returned to Avery Biomedical Devices for archiving.

Use only powder-free gloves when handling because residual powder grains can damage nerve tissue. Bare skin contact is not permitted.

Items with long lead lengths (i.e. electrodes, antennas) should be placed flat and coiled so that the leads do not lie on top of each other.

No cleaning of components is required prior to sterilization.

Sterilization of equipment should take place in accordance with established hospital policy for implants. In the absence of an established policy, or at a minimum, the following procedures may be followed:

**Receivers (Model I-110A)**
1. Remove receiver from box and packaging using powder-free gloves.
2. Steam autoclave only. Place in an open tray on a lint free cloth. Set autoclave to the following settings:
   - Temperature/Pressure: 270°F (132°C)/30 PSI (206.8 kPa)
   - Use “pre-vacuum” method if available.
   - Do not exceed 275°F (135°C).
   - Exposure Time: 10 minutes
   - Drying Time: 10 minutes

**Electrodes (Model E-377-05)**
1. Remove electrode from box and packaging using powder-free gloves.
2. Steam autoclave only. Place in an open tray on a lint free cloth. Set autoclave to the following settings:
   - Temperature/Pressure: 270°F (132°C)/30 PSI (206.8 kPa)
   - Use “pre-vacuum” method if available.
   - Do not exceed 275°F (135°C).
   - Exposure Time: 10 minutes
   - Drying Time: 10 minutes

**Antennas (Model 902A, Model 902AL)**
1. Remove antennas from box and packaging using powder-free gloves.
2. Steam autoclave only. Place in an open tray on a lint free cloth. Set autoclave to the following settings:
   - Temperature/Pressure: 270°F (132°C)/30 PSI (206.8 kPa)
   - Use “pre-vacuum” method if available.
   - Do not exceed 275°F (135°C).
   - Exposure Time: 10 minutes
   - Drying Time: 10 minutes

**Transmitters (Mark IV, TTM Data Transmitter)**

ABSOLUTELY CANNOT BE STEAM AUTOCLAVED.

Sterilization of the transmitter is not required for any surgical procedure.

Should sterilization be desirable for any other reason, ethylene oxide (ETO) gas can be used.
RESTERILIZATION PROCEDURES FOR CE IMPLANTS

(!) Warnings

- Sterilization temperature should not exceed 275°F (135°C).
- Ultrasonic cleaning can damage receivers and electrodes.
- Never gas sterilize receivers or electrodes. Residual ethylene oxide or other chemicals can cause severe tissue reaction.

(!) Cautions

- Steam autoclave required system components.
- Remove all packaging material from items to be sterilized.

Refer to the device labeling and package inserts for current sterilization procedures. In the event of any changes, device labeling and package inserts supersede the procedures shown in this manual.

NOTE: Any component removed from its outer bag may not be returned to us for credit. Items that are returned undamaged, in the original sealed package and received within 15 days of shipment will receive credit less 20% to cover the expense of reinspection, repackage and restocking. We recommend that all items be left in the packaging until they are known to be needed, at which time they should be removed from the packaging, and (as appropriate) sterilized.

The implantable I-110A receivers and E377-05 electrodes were sterilized using steam sterilization before shipment. Inspect the sterile package for seal integrity and damage to the package before opening and using the contents. If there is any uncertainty regarding the sterility of the components, they can be resterilized at the hospital.

Prior to resterilization, remove the items from its boxes and packaging using powder-free gloves

Do not gas sterilize receivers, electrodes, antennas or accessories. Items must be segregated if gas sterilized by mistake and returned to Avery Biomedical Devices for archiving.

Use only powder-free gloves when handling because residual powder grains can damage nerve tissue. Bare skin contact is not permitted.

Items with long lead lengths (i.e. electrodes, antennas) should be placed flat and coiled so that the leads do not lie on top of each other.

No cleaning of components is required prior to sterilization.

ABD cannot accept the responsibility for the resterilization of any components. If the decision is made to resterilize, such resterilization should take place in accordance with established hospital policy for implants. In the absence of an established policy, or at a minimum, the following procedures may be followed:

Receivers (Model I-110A)

1. Remove receiver from box and packaging using powder-free gloves.
2. Steam autoclave only. Place in an open tray on a lint free cloth. Set autoclave to the following settings:
   • Temperature/Pressure: 270°F (132°C) / 30 PSI (206.8 kPa).
   • Use "pre-vacuum" method if available.
   • Do not exceed 275°F (135°C).
   • Exposure Time: 10 minutes
   • Drying Time: 10 minutes

Electrodes (Model E-377-05)

1. Remove electrode from box and packaging using powder-free gloves.
2. Steam autoclave only. Place in an open tray on a lint free cloth. Set autoclave to the following settings:
   • Temperature/Pressure: 270°F (132°C) / 30 PSI (206.8 kPa)
   • Use "pre-vacuum" method if available.
   • Do not exceed 275°F (135°C).
   • Exposure Time: 10 minutes
   • Drying Time: 10 minutes

Transmitters (Mark IV, TTM Data Transmitter)

ABSOLUTELY CANNOT BE STEAM AUTOCLAVED.

Sterilization of the transmitters is not required for any surgical procedure.

References:
SURGICAL PROCEDURES

Anesthesia

**Warnings**

- Do not administer muscle relaxants (or short-acting agents) as its use may affect the ability to test the diaphragm function intraoperatively.
- Administer antibiotics intraoperatively and for an appropriate period postoperatively.
- Do not perform surgery if the patient has any sign of infection.

Anesthesia may not be required if the patient is insensate. Patients with sensation in the chest will need local anesthesia. However, depending on the age of the patient, his/her ability or willingness to cooperate or preference of the surgeon or anesthesiologist, general anesthesia may be chosen.

The usual method is to intubate the patient endotracheally for the duration of the surgery with the tracheostomy tube removed and the stoma cleaned and sealed off. Alternatively, an endotracheal tube can be placed through the stoma and the whole area sealed off with a transparent adhesive drape. This may be required in patients who have undergone C1-C2 stabilization. If necessary, anesthesia can be provided through the tracheostomy tube if the area and the tubes are sealed off using a transparent adhesive drape.

Cervical Approach for New Implants

**Warnings**

- This surgical site may not be desirable if tracheal stoma is present or lung infection suspected.
- Begin antibiotic administration 24 hours prior to surgery.
- Verify implantable components are sterile.
- Mark patient’s skin with sterile pen for appropriate receiver pocket location when patient is lying flat.
- Injury to the phrenic nerves may occur due to surgical trauma, interruption of blood supply, foreign body reaction and infection.
- Place receivers between dermal and muscle layers during implant to prevent erosion through skin.
- Place anode plate downward towards the rib cage.
- Wipe connector contacts clean with dry sponge prior to mating.
- Do not place receivers too high on chest wall as to cause electrode wire fatigue from repeated arm/shoulder movement (if applicable).
- Ensure adequate receiver separation to prevent antenna loop overlap.
- Make loops in the electrode wire near the nerve and receiver to provide adequate strain relief.
- Test receiver and electrode function after mating.
- Place a nonabsorbable suture tie around mated connectors.
- Ensure wires do not pass beneath incisions.
- Test receiver and electrode function again after closing incision.
- If difficulty is encountered in identifying the phrenic nerve or in avoiding the stimulation of other nerves in the cervical region, then it may be prudent to discontinue the cervical approach and consider using the thoracic approach.
- Infection may occur as a result of the surgical procedure, or in the postoperative period due to wound infection or septicemia. If unresponsive to antibiotics, removal of the implants may become necessary.
- Do not plicate diaphragm.

1. Prep and drape in the usual fashion.
2. Use two 5 cm. incisions 2 cm. above and parallel to the mid-portion of each clavicle.
3. Divide platysma and identify the lateral border of the sternocleidomastoid muscle.
4. Medially retract sternocleidomastoid muscle.
5. Identify preascine fat pad laterally.
6. Retract scalenus anticus (and internal jugular vein) laterally.
7. Use a nerve test probe to identify phrenic nerve.
8. Expose phrenic nerve via meticulous dissection.
9. Gently create a tunnel under the nerve, 10-12 mm. in width with a right-angled clamp.
10. Slide electrode under phrenic nerve and lay nerve in groove of electrode.
11. Suture electrode to underlying tissue. Take care that the nerve is lying straight within the electrode after retractors are removed.
12. Create a subcutaneous pocket approximately 5 cm. below the clavicle for receiver.
13. Tunnel electrode cable connector beneath skin to receiver pocket area.
14. Leave slack on the electrode wire at the site of insertion near the phrenic nerve.
15. Wipe connector clean with dry sponge.
16. Attach electrode connector to receiver. Insert receiver into pocket (anode disc side down).
17. Test receiver and electrode function after mating.
18. Place a single nonabsorbable tie around the mated connectors to prevent fluid intrusion.
19. Excess wire may be coiled anywhere in the subcutaneous pocket.
20. Close the supraclavicular incision.
21. Test receiver/electrode function again after closing skin.
22. Repeat procedure on other side for bilateral implantation.
23. Complete and submit the Implanted Medical Device Registration Form (See page 17).
**SURGICAL PROCEDURES (Cont.)**

**Thoracic Approach for New Implants**

**Warnings**
- Begin antibiotic administration 24 hours prior to surgery.
- Verify implantable components are sterile.
- Mark patient's skin with sterile pen for appropriate receiver pocket location when patient is lying flat.
- Injury to the phrenic nerves may occur due to surgical trauma, interruption of blood supply, foreign body reaction and infection.
- Place receivers between dermal and muscle layers during implant to prevent erosion through skin.
- Place anode plate downward towards the rib cage.
- Wipe connector contacts clean with dry sponge prior to mating.
- Test receiver and electrode function after mating.
- Do not place receivers too high on chest wall as to cause electrode wire fatigue from repeated arm/shoulder movement (if applicable).
- Ensure adequate receiver separation to prevent antenna loop overlap.
- Make loops in the electrode wire near the nerve and receiver to provide adequate strain relief.
- Place nonabsorbable suture tie around mated connectors.
- Ensure wires do not pass beneath incisions.
- Test receiver and electrode function again after closing incision.
- Infection may occur as a result of the surgical procedure, or in the postoperative period due to wound infection or sepsis/emia. If unresponsive to antibiotics, removal of the implants may become necessary.
- Place electrode as close to the diaphragm as possible for anastomosis patients.
- Do not plicate diaphragm.

**Thoracotomy Method:**
1. Use 5-7 cm transverse incision over 2nd or 3rd intercostal space.
2. Extend incision down to costal cartilage and rib surface.
3. Enter pleural space.
4. Use small pediatric retractor.
5. Pack off lung with two pads, superior & inferior.
7. Identify phrenic nerve.
8. On patient right side: implant electrode just inferior to junction of SVC and right atrium.
9. On patient left side: implant at level of main PA as it crosses out from pericardial reflection.
10. Dissect phrenic nerve bundles.
11. Lay nerve in groove of electrode.
12. Affix electrode to pericardium with ligatures to both sides.
13. Create a pocket at the lateral portion of the thoracic incision for receiver implantation on rib cage.
14. Wipe connector clean with dry sponge.
15. Attach electrode connector to receiver.
16. Insert receiver into pocket anode disc side down.
17. Test receiver and electrode function after mating.
18. Place a single nonabsorbable tie around the mated connectors to prevent fluid intrusion.
19. Excess wire may be coiled anywhere in the subcutaneous pocket.
21. Test receiver and electrode function again after closing incision.
22. Repeat procedure on other side for bilateral implantation.
23. Complete and submit the Implanted Medical Device Registration Form (See page 17).

**Thoracoscopy Method:**
1. Establish single contralateral lung ventilation.
2. Insert a 5mm trocar in the 7th intercostal space in the posterior axillary line.
3. Inflate the chest to 5mm Hg pressure at flow rate 3 to speed up lung deflation.
4. Insert a 5mm trocar in the 9th intercostal space in the posterior axillary line.
5. Insert a 5mm trocar in the 5th intercostal space in the posterior axillary line.
6. Identify the phrenic nerve at the cephalad aspect of the pericardium avoiding pulmonary hilum.
7. Make 2 parallel incisions in the mediastinal pleura.
8. Make a small subcostal incision and form a subcutaneous pocket to house the receiver.
9. Place a 4 inch length of Penrose drain over the electrode connector – tie in position with a nonabsorbable suture.
10. Prepare the electrode with one 4-0 nonabsorbable suture through one of the eyelets.
11. Feed the entire electrode into the chest through the lowermost trocar space.
12. Pass a tonsil clamp from the subcutaneous pocket under the ribs and through the anterolateral and peripheral aspects of the diaphragm into the chest cavity.
13. Grasp the free end of the Penrose drain and pull the connector and excess wire into the subcutaneous pocket.
14. Pass the phrenic nerve electrode through the incisions in the mediastinal pleura so that the phrenic nerve lies in the groove of the electrode.
15. Suture the electrode in position either side of the nerve using 4-0 non absorbable sutures.
16. Remove Penrose drain and attach electrode connector to receiver.
17. Insert receiver into pocket anode disc side down.
18. Test electrode and receiver function after mating.
19. Place a nonabsorbable tie around the mated connectors to prevent fluid intrusion.
20. Pull sufficient wire into the chest cavity to prevent traction on the phrenic nerve. Excess wire may be coiled anywhere in the subcutaneous pocket.
21. Place a chest tube of appropriate size for the patient through the most trocar space.
22. Inflating the chest to 5mm Hg pressure at flow rate 3 to speed up lung deflation.
23. Connect chest tube to suction.
24. Test receiver and electrode function again after closing incisions.
25. Repeat procedure on other side for bilateral implantation.
26. Take an intraoperative chest X-ray. If there is no pneumothorax, no air leaks or other contraindications to removing the chest tubes, remove them while the patient remains under anesthesia and place occlusive dressings.
27. Complete and submit the Implanted Medical Device Registration Form (See page 17).
Surgical Approach For Electrode Replacement

**Warnings**

- Autoclave required system components.
- Carefully dissect tissue surrounding connectors.
- Complete replacement of phrenic nerve electrode if insulation is damaged.
- Form new subcutaneous pocket for smaller receiver otherwise electrical contact may be compromised.
- Ensure adequate spacing between receivers to prevent overlap of antenna loops.
- Place anode plate downward towards the rib cage.
- Wipe connector contacts clean with dry sponge prior to mating.
- Test receiver and electrode function after mating.
- Teflon bag (if previously used) should be discarded.
- Ensure wires do not pass beneath incisions.
- Make loops in the electrode wire near the nerve and receiver to provide adequate strain relief.
- Test receiver and electrode function again after closing incision.
- Infection may occur as a result of the surgical procedure, or in the postoperative period due to wound infection or septicemia. If unresponsive to antibiotics, removal of the implants may become necessary.

Evaluation of a recent chest X-ray will facilitate electrode replacement by identifying the location of connectors and anode discs.

Receivers have an expected service life of 10 years and have a warranty of 5 years. Replacement can be done under local anesthetic on an outpatient basis unless patient logistics or hospital or insurance carrier rules prohibit. Patient preparation, ordering of equipment and anesthesia guidelines are the same as discussed above. The recommended surgical procedure is:

1. Carefully dissect down to the cuff of the old electrode.
2. Clip electrode wire of failed electrode close to cuff and leave cuff in situ under the nerve.
3. Implant new electrode distal to the original. Refer to New Implant section of this manual for electrode attachment procedure.
4. As this is a new electrode, pacing should be deferred in the immediate postoperative period.
5. Complete and submit the Implanted Medical Device Registration Form (See page 17).

Evaluation of a recent chest X-ray will facilitate electrode replacement by identifying the location of the receiver connector.

Most diaphragm pacing phrenic electrodes will serve the patient for their entire life. In rare instances electrodes have been damaged or destroyed through stretching because of growth of the individual, trauma to the electrode or wire because of invasive procedures (e.g. insertion of jugular lines using a large bore needle) or surgical trauma to the electrode at the time of receiver replacements (damage to insulation). The recommended electrode replacement surgical procedure is:

1. Carefully dissect down to the cuff of the old electrode.
2. Clip electrode wire of failed electrode close to cuff and leave cuff in situ under the nerve.
3. Implant new electrode distal to the original. Refer to New Implant section of this manual for electrode attachment procedure.
4. As this is a new electrode, pacing should be deferred in the immediate postoperative period.
5. Complete and submit the Implanted Medical Device Registration Form (See page 17).

**NOTE:** Company policy requires that all explanted components be steam sterilized prior to its return for evaluation.
**IMPLANTED MEDICAL DEVICE Registration Form**

**INSTRUCTIONS:**
Please type or print all requested information and return to the address above. Your prompt and careful attention in completing this form is extremely important. Copies should be maintained in the patient’s record and the physicians file.

This form:
- ensures identification of the implanted system with the correct patient
- facilitates device tracking, implant record upkeep, and proper patient after-care
- validates Warranty agreement
- enables us to prepare and mail the patient’s identification card

<table>
<thead>
<tr>
<th><strong>IMPLANTING PHYSICIAN / SURGEON</strong></th>
<th><strong>PATIENT INFORMATION</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: ___________________________</td>
<td>Name: __________________</td>
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<tr>
<td>Address: _________________________</td>
<td>SSN: __________________</td>
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<tr>
<td>City: ___________________________</td>
<td>DOB: __________________</td>
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<td>State: __________________________</td>
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<td>Country Code  City/Area Code  Number</td>
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<tr>
<td><strong>PHYSICIAN REGULARLY FOLLOWING PATIENT</strong></td>
<td><strong>NEXT OF KIN</strong></td>
</tr>
<tr>
<td>Name: __________________________</td>
<td>Name(s): _______________</td>
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<td>Address: _________________________</td>
<td>Relation: ______________</td>
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<td>Country Code  City/Area Code  Number</td>
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<tr>
<td><strong>MEDICAL CENTER OR HOSPITAL</strong></td>
<td><strong>EQUIPMENT IDENTIFICATION</strong></td>
</tr>
<tr>
<td>Name: __________________________</td>
<td>Surgery Date: __________</td>
</tr>
<tr>
<td>Address: _________________________</td>
<td>Electrode Model: [ ] E-377-05 [ ] Other</td>
</tr>
<tr>
<td>City: ___________________________</td>
<td>Lot Number: _____________</td>
</tr>
<tr>
<td>State: __________________________</td>
<td>Location: [ ] Cervical [ ] Thoracic [ ] Other</td>
</tr>
<tr>
<td>Country: _________________________</td>
<td>Receiver Model: [ ] I-110A [ ] Other</td>
</tr>
<tr>
<td>Phone: __________________________</td>
<td>Serial Numbers: (Left) __________ (Right) __________</td>
</tr>
<tr>
<td></td>
<td>Transmitter Model: __________</td>
</tr>
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<td></td>
<td>Serial Number: ____________</td>
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<tr>
<td></td>
<td>TTM Serial Number: __________</td>
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<td></td>
<td>Country Code  City/Area Code  Number</td>
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<tr>
<td><strong>CLINICAL DIAGNOSIS</strong></td>
<td><strong>STERILIZATION VERIFICATION</strong></td>
</tr>
<tr>
<td>________________________________</td>
<td>[ ] Check here to verify that the receiver(s) and/or electrode(s) identified above were sterilized prior to implantation.</td>
</tr>
</tbody>
</table>

White Copy -- ABD
Yellow Copy -- Patient Chart
Pink Copy -- Personal Physician
POSTOPERATIVE CARE AND INITIATION OF PACING

**Warnings**
- The breathing pacemaker system will not work unless the antennas are affixed to the patient's skin, directly over the implanted receivers.
- Infection may occur as a result of the surgical procedure, or in the postoperative period due to wound infection or sepsis. If unresponsive to antibiotics, removal of the implants may become necessary.
- Remove implants if infection or receiver erosion occurs.
- The patient's CO₂ level should be in the mid to upper 30's.

**Cautions**
- Avoid excessive palpation over new receiver site to decrease the amount of local tissue trauma.
- Avoid placement of internal jugular lines in patients who have cervical implants to avoid damage to the implanted electrode or electrode wire.
- Do not do these things that may affect breathing or dehypotrochosis of the cell bodies of the anterior horn of the spinal cord.
- Do not use non-prescription medications without consulting your physician.
- Avoid excessive palpation over new receiver site to decrease the amount of local tissue trauma.
- If a patient has undergone receiver replacement and is pacing in the postoperative period, avoid excessive patient movement so that good electrical contact between receiver and adjacent tissues will be maintained until edema has resolved in the new subcutaneous pocket.
- Avoid excessive palpation over new receiver site to decrease the amount of local tissue trauma.

**Postoperative Care**
Immediate postoperative care should include:
- Maintenance of usual, chronic ventilatory support and/or pacing on an unaffected side.
- Continuation of intraoperative antibiotics for a reasonable period.
- Use of a short postoperative course of steroids to diminish the incidence of perineural edema.
- Meticulous wound care to decrease infection.
- The patient's CO₂ level should be in the mid to upper 30's prior to pacing. If necessary this level should be gradually adjusted during the 10-14 day waiting period.

In cases of receiver replacement, with undisturbed electrodes, pacing can begin immediately. With newly implanted electrodes, diaphragmatic pacing should be deferred in the immediate postoperative period. Surgical trauma causes local perineural edema and edema of the subcutaneous tissues. Healing, with fibrosis and accommodation gradually occur and pacing can safely begin at about 10-14 days postoperatively. However, some physicians may choose to wait longer depending upon patient status.

Depending on patient status, discharge from the hospital following recovery from surgery is suggested. The patient may then be brought back to the hospital or clinic for initiation of pacing or may initiate pacing at home. Regardless of patient diagnosis, determination of each hemidiaphragm threshold is required prior to the start of effective bilateral diaphragm pacing. Threshold is the lowest transmitter amplitude setting that starts muscular contraction. The procedure to determine threshold amplitudes is as follows:

1. Turn power switches “off.”
2. Insert new battery or batteries into the transmitter.
3. Ensure that the antennas are properly positioned over each receiver site, firmly affixed with adhesive tape.
4. Turn both amplitude dials fully counterclockwise to “zero.”
5. Connect each antenna carefully to the appropriately-labeled (PATIENT RIGHT/LEFT) side of the Mark IV transmitter.
6. Preoxygenate patient briefly then discontinue alternate means of ventilation (if required).
7. Turn LEFT side ON. Smoothly and slowly increase the amplitude until threshold is reached. Threshold is the lowest stimulus amplitude to produce diaphragm contraction which may be observed in one or more of the following ways:
   - Patient reports appropriate sensation
   - Manual palpation
   - Visual observation at the costal margin
   - Respirometer (10 cc. excursion)
   - Fluoroscopy
8. If available, place a small AM radio, set at 1600 kilohertz near the transmitter. You will hear a burst of static-like clicks with each stimulation when the transmitter is ON.
9. Operation can also be verified by the “B” indicator lights flashing red with each stimulation.
10. Synchronous patient reporting, palpation of movement and audible stimulus trains are the simplest approach.
11. After determining the “ascending threshold” go higher, then decrease amplitude to determine the “descending threshold” (e.g. the point where diaphragm movement disappears using any or all of the above criteria).
12. True threshold is a value between the ascending and descending thresholds.
13. Once the threshold has been determined for one side, thoroughly ventilate the patient (as needed).

**Caution**
- Avoid excessive palpation over new receiver site to decrease the amount of local tissue trauma.
- If a patient has undergone receiver replacement and is pacing in the postoperative period, avoid excessive patient movement so that good electrical contact between receiver and adjacent tissues will be maintained until edema has resolved in the new subcutaneous pocket.
- Avoid excessive palpation over new receiver site to decrease the amount of local tissue trauma.
- Each hemidiaphragm is subject to fatigue. Do not do these things that may affect breathing or dehypotrochosis of the cell bodies of the anterior horn of the spinal cord.
- Patients may experience temporary fluctuations of pacing thresholds. The patient's physician and Avery should be notified if large or continuous amplitude adjustments are required.
- Amplitude adjustment may be required with changes in patient position (e.g. sitting, supine) which may be indicated by lower measured tidal volumes, decreased blood gas levels or patient complaints of discomfort.
- When patients use the pacer while eating or drinking, they must learn to swallow between inspirations to avoid aspiration of food or liquid.
- Respiratory or other infection can alter a patient's response to diaphragm pacing and may necessitate the temporary use of alternative ventilation methods.
- Patients should be instructed in the technique of glossopharyngeal (“frog”) breathing to provide emergency respiration.
- Obtaining and wearing a Medic-Alert bracelet or other identification tag is recommended.
- Use of antispasmodic drugs (including, but not limited to Bacclofen) may diminish the performance of the breathing pacemaker or prevent it from working.
- Changes in atmospheric pressure (for example, a change in altitude above sea level) may diminish the performance of the pacemaker or prevent it from working.

**Postoperative Care**
Immediate postoperative care should include:
- Maintenance of usual, chronic ventilatory support and/or pacing on an unaffected side.
- Continuation of intraoperative antibiotics for a reasonable period.
- Use of a short postoperative course of steroids to diminish the incidence of perineural edema.
- Meticulous wound care to decrease infection.
- The patient's CO₂ level should be in the mid to upper 30's prior to pacing. If necessary this level should be gradually adjusted during the 10-14 day waiting period.

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12. True threshold is a value between the ascending and descending thresholds.
13. Once the threshold has been determined for one side, thoroughly ventilate the patient (as needed).
POSTOPERATIVE CARE AND INITIATION OF PACING (Cont.)

14. Repeat the above procedure to determine thresholds for the second side.
15. Using one or more of the above criteria (respirometer is best), determine the maximum amplitude that produces no incremental increase in diaphragm excursion or tidal volume. This should be done with ascending as well as descending amplitudes. This is called "maximum amplitude" or "maximum volume." The difference between "threshold" and "maximum amplitude" is called the "dynamic range."
16. Repeat for the second side. Tidal volumes on the right are often larger than the volumes on the left because of size difference between the two lungs.
17. Adjust each side for optimal volume and patient comfort. Readjust when pacing bilaterally. Try to achieve bilateral smooth pacing by listening to the burst of static-like clicks with each stimulation using the AM radio, or observing the "B" lights flashing on if a radio is not available, and palpating or observing the movements of the two hemidiaphragms.
18. Send a TTM as soon as pacing is started. The recording equipment in New York is in service 24 hours per day. Refer to the Transtelephonic Monitoring - TTM instruction manual.
19. If thresholds cannot be obtained, or pacing cannot otherwise be initiated, please turn to the section on "troubleshooting."
20. Proceed with pacing until diaphragm fatigue appears. In newly-implanted patients this may vary — 5 minutes to 5 hours are both "normal."
21. Check blood gases periodically. Non-invasive pulse oximetry and either capnography or transcutaneous CO₂ monitoring is suggested.
22. Each day, resume pacing until fatigue occurs or until 24 hour pacing is achieved.
23. Thresholds may vary +/- 20% from day to day and tidal volumes may vary +/- 20% from breath to breath. If greater variations are observed the patient's caregiver should:
   a) suspect subclinical or incipient infection
   b) contact patient's physician
   c) contact our Customer Service Department
24. Patients' amplitude requirements should be carefully monitored, and medical care sought if more than a 30% increase in amplitude is required (with a new battery in place) since this may indicate an upper respiratory infection (URI) or other infection.

Patients with a mild infection, who are being treated by a physician, can usually continue to use the diaphragm pacing system effectively at higher amplitude settings. A need for increased amplitude is temporary, but may persist after all clinical evidence of the infection is gone. A need for higher or lower amplitudes can change with weight loss or gain, and can readily be compensated for by adjusting the transmitter amplitude setting.

Diaphragm Reconditioning

For patients who obtain little or no tidal volume when stimulation is first initiated, such as a patient with intercostal to phrenic anastomoses, diaphragm reconditioning must be performed. Effective retraining of the diaphragm can only take place if the pacers are allowed to stimulate asynchronously with the patient's ventilator so that the diaphragms can be exercised by contracting under load. For these patients, diaphragm reconditioning should be performed as follows:

1. Contact our Customer Service Department to reset or modify the patient's external transmitter as necessary.
2. Set amplitude controls on the transmitter to 500 bilaterally.
3. Set the patient's ventilator to the slowest respiratory rate (approximately 9-12 B.P.M.) which allows for adequate ventilation.
4. The transmitter should be set to the same respiratory rate as the ventilator. Turn on transmitter at the midpoint of the ventilator cycle so that the transmitter is completely asynchronous with the ventilator.
5. Since the ventilator and external transmitter will not be set to exactly the same respiratory rate, a "phase shift" will occur, causing the pacer to eventually overlap with the ventilator cycle. Adjust the ventilator as necessary so that as pacing time increases, the transmitter remains asynchronous with the ventilator.
6. Monitor the patient at least weekly, assessing the patient's ability to obtain a usable tidal volume from the pacer alone.
7. Pace the patient for 30 minutes each day, until the tidal volume on the pacers alone is sufficient to sustain the patient for five minutes. Diaphragm reconditioning should then be continued in the recommended manner.

This retraining protocol should not be used with a ventilator using a "demand" or "pressure" type cycle. This retraining protocol should only be used with a ventilator that can operate on a pure "volume" basis. This will allow the diaphragm to be exercised while under load.

Transtelephonic Monitoring - TTM

Please refer to the TTM instruction manual.
Troubleshooting

Warning

◆ Repairs or modifications by anyone other than Avery personnel could be dangerous. Such action may damage equipment, cause serious injury or death, and voids all warranties.

Caution

◆ The internal transmitter controls should only be adjusted by Avery personnel upon approval of the patient's physician.

Use the following troubleshooting procedure if either the patient cannot start diaphragm pacing or had previously paced effectively and is experiencing a loss of or significant reduction in tidal volume:

1. Use the battery indicator lights on the transmitter front panel to determine if battery replacement is required. The battery indicators should flash during inspiratory periods.

2. If the battery indicator fails to flash after the installation of a battery you know is good, a problem may exist in the battery connector or transmitter power circuit. Should this happen, please contact the Customer Service Department.

3. Use the antenna indicator lights on the transmitter front panel to determine if the antenna is good and if sufficient transmitter output is present. Use a spare, working antenna to troubleshoot between an antenna you suspect is defective or transmitter output.

NOTE: The antenna indicator lights may not flash at very low stimulus amplitudes even though the transmitter and antenna may be functioning properly.

4. If the antenna indicator fails to flash after the installation of a working antenna, ensure that the antenna is not affixed to the patient and turn amplitude dial setting fully clockwise to 999. If the “A” indicator flashes, the transmitter and antenna are good. If the “A” indicator fails to flash, call Customer Service as a problem may exist in the transmitter.

If the transmitter and antennas check out as fully functional, but pacing is not possible:

• See if effective pacing can be restored at a slightly increased amplitude setting. The patient may be experiencing a temporary fluctuation (increase) in pacing threshold, thereby making the current transmitter amplitude settings ineffective (too weak to pace). Effective pacing can be restored in patients experiencing a temporary increase in threshold; however, a further increase in tidal volume will not be possible if patient is experiencing diaphragm fatigue.

If the patient had been pacing effectively prior to the loss of or significant reduction in tidal volume, allow the patient to rest for 72 hours on mechanical ventilation before restarting the pacing program. Call the patient’s physician and Avery if large amplitude adjustments fail to restore effective diaphragm pacing.

• Check for infection. (e.g. fever, pain, redness, swelling anywhere in the body). Experience has shown that diaphragm pacing may become ineffective when the patient has any type of infection in any location. Infections may not always be evidenced by fever, but an abnormal white blood cell count may be noted. Treat any infection immediately. Pacing at slightly increased transmitter amplitude settings may be effective during treatment for infection, otherwise the patient may require mechanical ventilation.

• Be sure that the patient has not suffered an injury or accident that may have caused mechanical damage to implanted system components.

If none of these circumstances apply, contact Customer Service and send a TTM transmission to us.

The TTM will provide quantitative data of the implanted equipment and the patient’s physiological responses for evaluation. Failure to pace may be caused by medical problems, including phrenic nerve infection or edema, progression of congestive or obstructive pulmonary disease, pressure on the phrenic nerve by the electrode or the presence of neuromuscular blocking agents or drugs. Surgical intervention may be required for unequivocal discrimination between patient and equipment problems.

If the patient has not previously paced effectively, appropriate adjustments of internal transmitter settings may be required.
CUSTOMER SERVICE AND SHIPPING INSTRUCTIONS

Customer Service
• Evaluates and repairs equipment
• Provides technical assistance
• Provides loaner/rental equipment
• Analyzes TTM transmissions

The Customer Service Department can assist with system/patient troubleshooting and provide technical information regarding diaphragm pacing. Our hours are 8:00 am to 4:00 pm (Eastern USA Time) weekdays. At other times, please leave a message.

Customer Service can provide a backup transmitter to use while a patient’s permanent transmitter is returned for repair. These backup transmitters are provided on loan during the warranty period and can be rented after warranty expiration.

Due to production variances, differences in amplitude settings between the permanent transmitter and a backup transmitter may be evident. When using a backup transmitter, amplitude settings may need to be adjusted upward or downward slightly. If necessary, redetermine thresholds using the procedure shown on pages 18-19.

Depending on the nature of the repair, a patient’s permanent transmitter may also require a small adjustment in amplitude settings following a repair.

Shipping Instructions for Equipment
When returning equipment for evaluation or repair:
• Include the patient’s name and current address.
• Include a brief description of the problem.
• Secure loss insurance with the carrier for the item’s replacement cost. Check your homeowner’s or renter’s policy regarding insurance coverage of your equipment. Carrier loss insurance may be prohibitively expensive and redundant if your policy already covers your equipment.
• Use adequate packing material to prevent damage to the item during shipment.
• If shipping from outside of the United States, contact us prior to shipment in order to prevent difficulties regarding import duties.

NOTE: If the transmitter is returned for evaluation or repair, please return the antennas and batteries that were in use when the equipment problem occurred. This will permit complete system evaluation and ensure proper repair.
WARRANTIES AND IDENTIFICATION

LIMITED WARRANTY

Avery Biomedical Devices Inc. (ABD) warrants each diaphragmatic/phrenic nerve stimulator (also known as a neurostimulator, diaphragm pacer or breathing pacemaker system) against defects in materials or workmanship, as follows:

<table>
<thead>
<tr>
<th>Component</th>
<th>Warranty Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mark IV Transmitter</td>
<td>3 years from date of surgery or purchase</td>
</tr>
<tr>
<td>902A/902AL Antenna</td>
<td>90 days from date of surgery or purchase</td>
</tr>
<tr>
<td>I-110A Receivers</td>
<td>5 years from date of surgery</td>
</tr>
<tr>
<td>E377-05 Electrodes</td>
<td>5 years from date of surgery</td>
</tr>
<tr>
<td>Transtelephonic Monitoring (TTM) Transmitter</td>
<td>1 year from date of surgery or purchase</td>
</tr>
</tbody>
</table>

ABD agrees to replace the item or repair any such defects without charge, within the specified warranty period, when the warranted component is returned postpaid at the address indicated below. Be sure to wrap the component carefully for protection. This Limited Warranty shall be void unless the patient 1) returns the warranty registration card completed with all requested information within 90 days from date of surgery or 2) is registered, when applicable, by ABD personnel at the time of surgery.

The implanted devices are designed for single-patient use only and is not intended or designed for re-use. This warranty shall not apply to any products that has been repaired or altered (outside of ABD’s factory), subjected to abuse or accident, or to products that have been improperly stored or implanted, or not operated or maintained in accordance with the labeling and instructions. No warranty whatsoever is given if the breathing pacemaker system is not used as an integrated system with ABD components. No representation or warranty either expressed or implied, is made that the body of the patient will not react in any adverse way to the implantation of the ABD neurostimulator or that failures or malfunctions of the breathing pacemaker system will never occur.

Because ABD has no control over the use of its products after sale and has no control over the selection of patients, this Limited Warranty is limited to its express terms. In particular:

(1) Except as expressly provided by this Limited Warranty, ABD IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, FAILURE OR MALFUNCTION OF THE PRODUCT, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT OR OTHERWISE.

(2) This Limited Warranty is made only to the patient in whom the breathing pacemaker system was used. AS TO ALL OTHERS, ABD MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOM OR OTHERWISE. NO EXPRESS OR IMPLIED WARRANTY TO THE PATIENT SHALL EXTEND BEYOND THE PERIODS SPECIFIED ABOVE. THIS LIMITED WARRANTY SHALL BE THE EXCLUSIVE REMEDY AVAILABLE TO ANY PERSON.

(3) The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Limited Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of the Limited Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Limited Warranty did not contain the particular part or term held to be invalid. This Limited Warranty gives the patient specific legal rights.
WARRANTIES AND IDENTIFICATION (Cont.)

(4) No person has any authority to bind ABD to any representation, condition or warranty except this Limited Warranty.

(5) TO THE EXTENT THAT ANY CLAIM MADE UNDER THIS LIMITED WARRANTY IS NOT PRE-EMPTED BY FEDERAL LAW, THIS AGREEMENT SHALL BE INTERPRETED UNDER NEW YORK STATE LAW. IRRESPECTIVE OF WHETHER A CLAIM IS MADE UNDER FEDERAL OR STATE LAW, OR IN FEDERAL OR STATE COURT, ANY CLAIM OR LITIGATION RELATED TO THE DEVICE OR THIS LIMITED WARRANTY SHALL BE BROUGHT IN THE COURTS WITHIN THE STATE OF NEW YORK, AND SPECIFICALLY SUFFOLK COUNTY. This Limited Warranty is provided by:

Avery Biomedical Devices, Inc.
61 Mall Drive Commack, New York 11725-5703 USA
Telephone: (631) 864-1600 Fax: (631) 864-1610
www.averybiomedical.com

PATIENT IDENTIFICATION CARD

Upon receipt of a completed Implanted Medical Device Registration Form, ABD will issue the patient an identification card similar to the illustration below:

IN CASE OF EMERGENCY notify the physician below:

Name: _______________________________ Phone: _______________________________

Address: _______________________________

This device consists of an external transmitter and antenna and an internal receiver/electrode surgically implanted within the patient's body. The device is manufactured by:

AVERY BIOMEDICAL DEVICES, INC.
61 Mall Drive Commack, New York 11725-5703, USA
(631) 864-1600

The patient should have this identification card in their possession at all times. There is a slot for storing this identification card located on the carrying case provided with the Mark IV transmitter.

If any information contained on this card changes, please contact ABD so that the patient's file may be updated and a replacement card issued.
This is a digital copy

The contents of this document are identical to the printed version (6025-AB) distributed to patients, caregivers and physicians who use the Implanted Diaphragm Pacing System. In the event of any changes, printed labeling and package inserts supersede this document.

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For additional copies and/or questions about this document, please contact Avery Biomedical Devices, Inc.

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