Instruction Manual

for the

Avery Diaphragm Pacing System
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**KEY:**
- For Patients and other users
- For Medical Professionals

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# LABEL SYMBOLS

ISO 15223-1:2016 - 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>Description: 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>Description: 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>Description: 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>Description: 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>Description: 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>Description: 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>Description: 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>Description: 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>Description: 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>Description: Indicates a medical device that has not been subjected to a sterilization process.</td>
<td></td>
</tr>
<tr>
<td>Do not re-use</td>
<td>5.2.8</td>
</tr>
<tr>
<td>Description: Indicates a medical device that should not be used if the package has been damaged or opened.</td>
<td></td>
</tr>
<tr>
<td>Temperature Limit</td>
<td>5.3.7</td>
</tr>
<tr>
<td>Description: Indicates the temperature limits to which the medical device can be safely exposed.</td>
<td></td>
</tr>
<tr>
<td>Do not re-use</td>
<td>5.4.2</td>
</tr>
<tr>
<td>Description: 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>Description: 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>Description: 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>Latex free</td>
<td>Negates 5.4.5</td>
</tr>
<tr>
<td>Description: 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>
### Rx Only

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescription only</td>
<td>Federal law restricts this device to sale by or on the order of a physician</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Warning Sign</td>
<td>To signify a general warning</td>
</tr>
<tr>
<td>Refer to instruction manual/booklet</td>
<td>To signify that the instruction manual/booklet must be read</td>
</tr>
</tbody>
</table>

### ISO 7000 / IEC 60417 - Graphical symbols for use on equipment

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product information; information point</td>
<td>To identify a place where information may be found, especially in an emergency</td>
</tr>
<tr>
<td>General symbol for recovery/recyclable</td>
<td>To indicate that the marked item or its material is part of a recovery or recycling process.</td>
</tr>
<tr>
<td>Type BF applied part</td>
<td>To identify a type BF applied part complying with IEC 60601-1</td>
</tr>
<tr>
<td>Direct Current</td>
<td>To indicate on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals</td>
</tr>
<tr>
<td>Bell, cancel temporarily</td>
<td>To identify the control for AUDIO PAUSED or to indicate that the ALARM SYSTEM is in the AUDIO PAUSED state.</td>
</tr>
</tbody>
</table>

### 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>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>MR Unsafe</td>
<td>An item that is known to pose hazards in all MR environments.</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingress Protection</td>
<td>Degrees of protection provided by enclosures of electrical equipment against intrusion, dust, accidental contact, and water</td>
</tr>
</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>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Waste Electrical and Electronic Equipment</td>
<td>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.</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conformite Europeenne</td>
<td>Conformity marking for certain products sold within the European Economic Area</td>
</tr>
</tbody>
</table>
2 ACRONYMS AND UNITS OF MEASUREMENT

<table>
<thead>
<tr>
<th>ABD</th>
<th>Avery Biomedical Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>PMA</td>
<td>Premarket Approval</td>
</tr>
<tr>
<td>EU</td>
<td>European Union / Union Européenne</td>
</tr>
<tr>
<td>CE</td>
<td>European Conformity / Conformité Européenne</td>
</tr>
<tr>
<td>RF</td>
<td>Radio Frequency</td>
</tr>
<tr>
<td>MHz</td>
<td>MegaHertz</td>
</tr>
<tr>
<td>BPM</td>
<td>Breaths per Minute</td>
</tr>
<tr>
<td>ms</td>
<td>milliseconds</td>
</tr>
<tr>
<td>µs</td>
<td>microseconds</td>
</tr>
<tr>
<td>kPa</td>
<td>KiloPascals</td>
</tr>
<tr>
<td>m</td>
<td>Meters</td>
</tr>
</tbody>
</table>

3 REGULATORY APPROVAL / CERTIFICATION

The Avery Diaphragm Pacing System 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 since 2010. The equipment is marked:

![CE Mark]

4 WARNINGS

- Failure of the Avery Diaphragm Pacing System could lead to respiratory arrest.

- Failure of the diaphragm pacing system can occur due to battery failure, 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 a patient must not be reimplanted.
One patient’s equipment 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 pacemaker 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 implanted, the cardiac pacemaker leads should be bipolar and the breathing pacemaker receiver 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 radiofrequency output at 2 MHz which may interfere with other devices in its proximity running at the same frequency.

Do not use the Avery Diaphragm Pacemaker in the presence of electromagnetic or other interference.

Use of the transmitter adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
Use of accessories, transducers and cables other than those specified or provided by Avery could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 20 cm (8 inches) to any part of the Spirit transmitter, including cables specified by Avery. Otherwise, degradation of the performance of this equipment could result.

5 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.

The safety of operating the diaphragm pacing system in all types of commercial aircraft environments has not been established.

The Avery Diaphragm Pacemaker has not been tested with other implanted or body worn medical device such as cardiac pacemaker, infusion pump, Implantable Cardioverter Defibrillators (ICDs), Functional Electrical Stimulation (FES), Vagal Nerve Stimulators (VNS) or cochlear implants. The Avery Diaphragm Pacemaker might interfere with operation of other medical devices including those implantable and body worn devices listed above.

Avoid getting closer than 30cm to EAS and metal detectors operating in the frequency ranges between 210Hz and 8.7MHz. Do not use this device around EAS and metal detectors outside of the above-indicated frequency ranges and be aware that EAS devices could be concealed and not visible.

6 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.


7 INTRODUCTION AND GENERAL INFORMATION

System Overview
The Avery 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 system consists of electrodes implanted near the phrenic nerves, radio frequency receivers implanted in subcutaneous pockets, antenna assembly and an external Spirit transmitter control unit powered by AA batteries.

The Spirit has a left and a right antenna connected to it. Each antenna sends radio frequency (RF) energy to each passive receiver. The antenna is placed on the skin over the implanted receiver. The RF waves are transmitted through the skin to the implanted receiver. The receiver converts the waves into electrical pulses that are delivered to the phrenic nerve via the electrode.

When the nerve is stimulated, the diaphragm muscle contracts, moving down. A negative pressure inside the lungs is created and air fills the lungs. This is the inhalation phase of breathing.

The Spirit then stops generating the stimulus signals, which allows the diaphragm to relax, moving back up, which forces the air inside the lungs out. This is the exhalation phase of breathing. This cycle of signals followed by no signals is repeated automatically by the Spirit, producing a more natural breathing pattern.

Components in the System
The complete system consists of:

- a) One or two Spirit transmitter control units (batteries included)
- b) Two or more antennas
- c) Two RF receivers (implanted)
- d) Two electrodes (implanted)
- e) Silicone protective case

Non-dedicated accessory:

- f) Carrying case

For bilateral stimulation (stimulation of both phrenic nerves) two antennas, two electrodes and two receivers are needed. For unilateral stimulation (stimulation of only one phrenic nerve) one antenna, one electrode and one receiver are needed. Refer to Figure 1 for entire system.

Indications
This system 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 (both pediatric and adult) who have:

- Functional lungs and diaphragm muscle;
- Viable phrenic nerves;
- Absence of infection;
- A clear and adequate upper airway (including nasopharynx, pharynx, and larynx);
- Adequate physical care giver quality and availability including nursing, family support and medical care.

The intended users of the Spirit transmitter are:

- Patient (who has the system)
Ongoing experience with diaphragm pacing disproves some of the concerns expressed by early investigators in the field. With patients pacing continuously for more than 10 years, 20 years and some for more than 30 years, 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.

Benefits of Diaphragm Pacing
Diaphragm pacing provides respiratory function far superior to that provided by mechanical ventilators because the inhaled air is drawn into the lungs, 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 circulatory return (negative, not positive pressure);
- Natural breathing and speech;
- Ease of eating and drinking;
- Increased patient mobility;
- Discrete use due to the small size of external components and totally silent operation.

Answers To Some Commonly-asked Questions
Ongoing experience with diaphragm pacing disproves some of the concerns expressed by early investigators in the field. With patients pacing continuously for more than 10 years, 20 years and some for more than 30 years, follow-up show that diaphragm pacing:

- 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.

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 Spirit transmitter control unit comes with a three year warranty and the implanted receivers and electrodes both come with a five year warranty.

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 Requirement
Medical Device Tracking regulations of the U.S. FDA 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.
THE SPIRIT TRANSMITTER CONTROL UNIT

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 factory personnel could be dangerous. Such action may damage equipment, cause serious injury or death, and voids all warranties.

If a sudden increase in amplitude setting (greater than 30% above normal setting) is required for effective pacing, notify your 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 +5°C to +37°C (41 °F to 99°F) because the transmitter may fail to function at very high or low temperatures.

If ambient temperature exceeds +37°C, then measures should be taken to ensure antennas remain at +37°C or less as they are in contact with the skin.

Do not steam sterilize.

Pets and pests should not be allowed in contact with the transmitter.

The Spirit does not work while the batteries are being changed. The side of the Spirit corresponding to the batteries being replaced does not work until new batteries are inserted.

Be sure to turn the Spirit ON when pacing and OFF when not pacing.

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### Basic Safety & Essential Performance including Technical Specifications

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value / Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulse Width</td>
<td>Default: 150 µs</td>
</tr>
<tr>
<td>Pulse Interval</td>
<td>Default: 50 ms</td>
</tr>
<tr>
<td></td>
<td>Range: 40 ms - 130 ms</td>
</tr>
<tr>
<td>Inspiratory Period</td>
<td>Default: 1.3 s</td>
</tr>
<tr>
<td></td>
<td>Range: 1.20 s - 1.45 s</td>
</tr>
<tr>
<td>Expiratory Period</td>
<td>Dependent on inspiratory period and respiratory rate</td>
</tr>
<tr>
<td>Stimulus Amplitude</td>
<td>000 - 999</td>
</tr>
<tr>
<td>Amplitude Slope</td>
<td>Default: True Zero</td>
</tr>
<tr>
<td>Respiratory Rate</td>
<td>Default: 12 BPM</td>
</tr>
<tr>
<td></td>
<td>Range: 6 BPM - 30 BPM</td>
</tr>
<tr>
<td>Energy source</td>
<td>Four AA (1.5 V) alkaline batteries, two for each side</td>
</tr>
<tr>
<td>Battery life</td>
<td>Greater than 400 hours</td>
</tr>
<tr>
<td>RF carrier Frequency</td>
<td>2.05 MHz</td>
</tr>
<tr>
<td>Mechanical dimensions</td>
<td>Transmitter with protective case: 158.0 mm (W) x 100.0 mm (L) x 37.5 mm (H)</td>
</tr>
<tr>
<td>Weight (batteries included)</td>
<td>Transmitter with protective case: 426 g</td>
</tr>
<tr>
<td>Temperature Range (unpowered)</td>
<td>-25 °C - +70 °C</td>
</tr>
<tr>
<td>Humidity Range</td>
<td>10% - 93%, non-condensing</td>
</tr>
<tr>
<td>Pressure Range</td>
<td>70 kPa - 106 kPa</td>
</tr>
<tr>
<td>Temperature Range</td>
<td>+5 °C - +37 °C</td>
</tr>
<tr>
<td>Humidity Range</td>
<td>15% - 93%, non-condensing</td>
</tr>
<tr>
<td>Pressure Range</td>
<td>70 kPa - 106 kPa</td>
</tr>
<tr>
<td>Ingress Protection (IP)</td>
<td>Spirit Transmitter – IP4X; protects against solid objects larger than 1.0mm Silicone Case - IPX2; protects against rain or dripping water at 3mm/min with case tilted at 15°. Combined Ingress Protection of Spirit and Case – IP 42</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>Alarms</td>
<td>Display icons, LED indicator and sounder</td>
</tr>
<tr>
<td>Alarm priority</td>
<td>All high</td>
</tr>
<tr>
<td>Alarm Sound pressure</td>
<td>50 dB at 1 m</td>
</tr>
<tr>
<td>Alarm mute pause</td>
<td>30 seconds</td>
</tr>
</tbody>
</table>

Table 1 - Spirit Parameter Table
The Essential Performance of Avery Diaphragm Pacing System is to provide adequate ventilation to the patient. Adequate ventilation is obtained by the stimulus/device output (i.e. Output Amplitude, Inspiratory Period, Respiratory Period, Pulse Interval and Pulse Width) generated by the system. This clinical function, if lost or degraded, could result in Hypoventilation which is an unacceptable risk.

The Spirit transmitter control unit (Spirit) generates stimulus patterns and delivers them to the phrenic nerves via the external antennas, implanted receivers and electrodes. The Spirit design has two independent output stimulus generators, each with its own battery power source, visual indicators and amplitude adjustment keys. Refer to Figures 3 and 4. Although each stimulus generator is independent from the other, they are electronically linked to begin phrenic nerve stimulation simultaneously at the desired respiratory rate that is set for each side.

Optimization adjustments require access to the internal parameters that can only be done in consultation with ABD Customer Service.

The Spirit 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 Spirit transmitter is 10 years. No calibration, preventive or scheduled maintenance are required during the lifetime of the transmitter.

Extreme impact, exposure to moisture, dirt or temperatures may damage the Spirit affecting its ability to function properly.

Each antenna is placed on the skin, centered over the receiver. The Spirit generates a stimulus pulse train which is converted into RF energy at the antennas. The antennas are held to the skin by adhesive tape or proper garment. The RF pulses are sent through the skin.

All controls of the Spirit are done via an easy-to-use display and keypad. Adjustment of the external controls is performed on an individual basis by the physician, caregiver, or patient as necessary.

**Keypad**

The Keypad is made of a sealed overlay with feedback to ensure the command is entered. The keypad contains 12 keys. Most of the keys have multiple functions. Refer to Figure 3.

![Figure 3 - Main functions of the keypad keys. Also shown is the LED alarm indicator.](image)

Keys that are enabled generate a feedback through a notifier sound to alert that the key press was acknowledged. The notifier sound is a short beep. Keys that are not enabled do not cause any action and do not generate any feedback (short notifier beep).

The sound warnings are generated by an internal sounder or speaker. The sounder also works as a notifier for keypad feedback. The visual alarms have an LED indicator on the keypad overlay below the display and icons on the display.

The following are the keys, organized in groups:

<table>
<thead>
<tr>
<th>Key</th>
<th>Keypad is unlocked</th>
<th>Keypad is locked</th>
</tr>
</thead>
<tbody>
<tr>
<td>↑</td>
<td>Key 0 increases and Key 1 decreases the left side amplitude, respectively. If amplitude is at 998, it will increment to only 999.</td>
<td>No effect</td>
</tr>
<tr>
<td>Key</td>
<td>Function</td>
<td></td>
</tr>
<tr>
<td>-------</td>
<td>--------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>🔄️</td>
<td>For Avery Technician use only.</td>
<td></td>
</tr>
<tr>
<td>🗝️</td>
<td>Locks keypad.</td>
<td></td>
</tr>
<tr>
<td>🅱️</td>
<td>Pressing and holding key for minimum of 2 seconds turns left side output on or off.</td>
<td></td>
</tr>
<tr>
<td>⬆️ 4</td>
<td>Key 4 increases and Key 5 decreases the respiratory rate, respectively.</td>
<td></td>
</tr>
<tr>
<td>⬇️ 5</td>
<td>Pressing and holding key for a minimum of 2 seconds turns right side output on or off.</td>
<td></td>
</tr>
<tr>
<td>⬆️ 9</td>
<td>Key 9 increases and Key 8 decreases the right side amplitude, respectively. If amplitude is at 998, it will increment to only 999.</td>
<td></td>
</tr>
<tr>
<td>⚡️</td>
<td>Activates the LCD backlight.</td>
<td></td>
</tr>
<tr>
<td>🆕 7</td>
<td>Key temporarily mutes the alarms.</td>
<td></td>
</tr>
</tbody>
</table>

### Table 2 - Keypad functions

<table>
<thead>
<tr>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>No effect</td>
</tr>
<tr>
<td>Pressing key for minimum of three seconds unlocks keypad</td>
</tr>
<tr>
<td>No effect</td>
</tr>
<tr>
<td>No effect</td>
</tr>
<tr>
<td>No effect</td>
</tr>
<tr>
<td>No effect</td>
</tr>
<tr>
<td>Activates the LCD backlight</td>
</tr>
<tr>
<td>Activates the LCD backlight</td>
</tr>
<tr>
<td>No effect</td>
</tr>
</tbody>
</table>

When increasing the left or right amplitude:
1. One keystroke increases the value by two.
   Example: 100, 102, 104, 106, etc.
2. Holding the key for more than 1 second, the value will jump in increments of 2 every 250 ms (or 8 per second).
3. Holding the key for more than 4 seconds, the value will jump in increments of 10 every 250 ms (or 40 every second) until reaching 200.
4. To increase the amplitude more than 200, the key has to be released and then pressed again. Repeat for each increase of 200.
5. Once the amplitude is at 998, it will not increase more than 999.

When decreasing the left or right amplitude:
1. One keystroke decreases the value by two.
   Example: 100, 98, 96, 94, etc.
2. Holding the key for more than 1 second, the value will decrease 2 every 250 ms (or 8 per second).

3. Holding the key for more than 4 seconds, the value will decrease 10 every 250 ms (or 40 every second) until reaching 200.
4. To decrease the amplitude more than 200, the key has to be released and then pressed again. Repeat for each decrease of 200.

### Display

The graphics display shows all the relevant stimulation parameters as follows:

- Respiratory Rate
- Right and left amplitudes
- Right and Left battery charge
- Right and left antenna condition
- Right and Left RF signal
- Alarm icon
- Lock icon
- Parameter mode icon
- Mute icon

### Figure 4 - Icons and numbers of the Display

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description / meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>500</td>
<td>Right or Left Amplitude</td>
</tr>
<tr>
<td>12</td>
<td>Respiratory Rate</td>
</tr>
</tbody>
</table>
When both sides (left and right) are turned off, the respiratory rate, the battery, the lock and mode icons will be displayed. Refer to Figure 5.

Operating Modes
The Spirit has two Operating Modes:
1. Default Mode
2. Programmed Mode (Avery Technician use only)

Default Mode / Mode 1
In default Mode, the Spirit generates diaphragmatic stimulation based on the default parameters, as follows:
- Pulse width – 150 µs
- Pulse interval – 50 ms
- Inspiratory Period – 1.3 s

These parameters are set in factory and cannot be changed by the patient or caregiver.

The display shows the icon below to indicate the Default Mode or Mode 1 is set:

Alarms
The Spirit transmitter indicates alarm conditions through two types of alarms: sound alarms and visual alarms. Refer to Figure 7.

The sound warnings are generated by an internal sounder or speaker. The sounder will work as a notifier
for alarms and a notifier for keypad feedback. The visual alarms have icons on the display and a bright red LED on the keypad overlay below the display.

All alarms have only one priority level. When the cause of the alarm disappears, the alarm turns off, without the need for the user to take any additional action.

![Image of Spirit alarms](image)

**Figure 7 - The Spirit alarms**

### Description of the Alarms

There are several causes for an alarm to occur. Alarms are activated in the following situations:

1. An antenna is disconnected while the corresponding side is still active (i.e. turned on).
   **Alarms:** the speaker beeps, the LED indicator flashes, the corresponding antenna icon flashes, and the fault icon turns on:

   ![Image of alarm icons](image)

   **Note:** if the side is turned off, there is no alarm when the antenna is disconnected.

2. The antenna wire is damaged or broken, creating either an open circuit or a short circuit. This condition can be intermittent.
   **Alarms:** the speaker beeps, the LED indicator flashes, the corresponding antenna icon flashes, and the fault icon turns on:

   ![Image of alarm icons](image)

   **Note:** if the side is turned off, there is no alarm when the antenna is disconnected.

3. The battery charge of one of the battery groups is below 8%.
   **Alarms:** The speaker beeps, the LED indicator flashes, the corresponding battery outline flashes, and the Fault icon turns on:

   ![Image of alarm icons](image)

   **Note:** Although the batteries may still have some remaining power, it is advisable to immediately replace them.

4. An internal error occurred.
   **Condition 1 Alarm:** The speaker beeps, the LED indicator flashes, and the Fault icon turns on:

   ![Image of alarm icons](image)

   **Condition 2 Alarm:** The speaker beeps and the LED indicator flashes:

   ![Image of alarm icons](image)

   **Note:** In this condition, the information displayed may not be accurate.

This internal error condition may be recovered. Do the following:

a) Remove all four batteries;

b) Wait 15 seconds;

c) Insert the batteries again. If they are not new, install four fresh batteries;

d) Check the display. If it matches Figure 5, the Spirit recovered from the alarm condition and the amplitudes may need to be readjusted to the previous settings. If not, please contact ABD Customer Service.

   **Note:** The alarm can be temporarily muted for 30 seconds. After unlocking the keypad and pressing the F key, the following icon will appear:

   ![Image of alarm icons](image)

   After 30 seconds, it will disappear and the alarm will sound again. Refer to Figure 8.
Figure 8 - The display when the alarm occurs and the display after the alarm is muted

What To Do in Case of an Alarm

It may take a few seconds until an alarm is acknowledged or cleared.

1. Verify the antenna connector is properly inserted into the Spirit socket. If not, insert it properly until a click is heard.

2. Check to ensure the antenna loop is centered over the receiver.

3. Check if the antenna needs to be replaced.

4. Check the capacity of the batteries on each side. If the left or the right battery icon shows just the outline (no bars), the batteries on that side are depleted. Replace both batteries with new ones of the same type.

If none of the above steps clears the alarm, please contact our ABD Customer Service Department.

Batteries

When the bars are turned off and only the outline is visible, the charge is less than 8%. The sounder sounds an alarm, the LED and the display error icon flashes warning that the battery is depleted. The batteries for that side should be replaced immediately.

The Spirit requires four AA Alkaline batteries, two for each side. See Figures 12 and 13. The time each battery pair lasts depends on the stimulation amplitudes, respiratory rate and internal parameters. The lower the amplitudes the longer the batteries will last.

Note: The batteries for both sides do not have to be replaced at the same time. However, for convenience, if the charge level is similar, it is advisable to replace all four batteries at the same time.

Battery Gauge

Adequate warning is provided and the Spirit will continue to function. The system constantly monitors the battery voltage and the icons on the display give a precise level of the battery charge of each side. The battery icon shows up to four bars depending on the charge level, as follows:

- Battery charge between 75% and 100%
- Battery charge between 50% and 74%
- Battery charge between 25% and 49%
- Battery charge between 10% and 24%
- Battery charge less than 10%

The batteries are located in a compartment on the back side of the case.
Replacing the batteries

Figure 9 - Removing the Spirit from the silicone protective case

Figure 10 - Opening the battery compartment

Figure 11 - Removing the battery compartment door

Figure 12 - The battery compartment indicating the two groups of batteries

Figure 13 - The “L” and “R” on the labels indicate each side. The “+” on battery symbols indicate the proper direction.
To replace the batteries do the following:

a) Remove the Spirit from the carrying case;
b) Turn off the side corresponding to the battery pair you want to replace; or, turn off both sides if all four batteries are going to be replaced;
c) Remove the silicone protective case. By sliding the protective case over the antenna wires, the antennas do not need to be removed. Refer to Figure 9;
d) Open the battery compartment door located in the back of the Spirit by unlatching the lock with a fingernail. Refer to Figure 10, 11.
e) Remove the batteries one side at a time. Refer to Figure 12;
f) Replace them with fresh batteries only. Observe the polarity of the batteries. Refer to Figures 12 and 13. Refer to the labels inside the battery compartment for proper direction;
g) If replacing the four batteries, repeat the procedure for the batteries on the other side;
h) Make sure the batteries are making good contact with the spring contacts;
i) Close the battery compartment;
j) Insert the Spirit into the silicone protective case;
k) Insert the Spirit into the carrying case.

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

Cleaning / Disinfecting the Spirit
The Spirit can be cleaned with a damp cloth, making sure liquid does not enter the transmitter. The Spirit is a single-patient use device, professional hygienic maintenance or disinfection is not necessary.

Carrying the Spirit
Besides the silicone soft case which protects the transmitter against water splashes, shock or vibration, a nylon carrying case is provided with the Avery Diaphragm Pacing System. The case helps protect the antennas by supporting the strain relief area behind the connector, and protects the Spirit from water splashes. 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 case be used at all times. Should you choose not to use the provided carrying case, ensure that the Spirit is protected from being dropped or becoming wet.
9 THE 902A / 902AL ANTENNAS

A spare pair of antennas should be on hand at all times.

The Diaphragm Pacing 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.

Do not put two antennas over each other (overlapping) as this could affect proper operation of the Diaphragm Pacing System.

When connecting to the Spirit, properly align the connectors and press them 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.

Antenna connectors should be free from dirt, dust and lint.

Store spare antennas in a dry place.

When disconnecting from the Spirit, pull antenna connector barrel straight out of transmitter. Do not twist.

Autoclave only for use during surgery.

The antenna is one-meter long (two meters for 902AL) wire, covered with silicone rubber, with a loop of circular wound wire at one end and a metal connector at the other end. The antennas transfer the stimulus pattern from the Spirit, through the skin to the implanted receivers and electrodes. Each system is shipped with multiple antennas: two for immediate use, the others as spares. Refer to Figure 14.

Figure 14 - Antenna

Store the spare antennas in a dry place. Antennas carry a 90-day warranty.

Proper care and gentle handling will make the antennas 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.

Operating Range

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 and cease when the separation distance is about 90mm.

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 15.
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 Connection**
1. Turn the Spirit off.
2. With the Spirit in one hand and the antenna connector in the other hand, align the half-moon shaped (semi-circle) guide inside the antenna connector with the flat surface of the half-moon shaped (semi-circle) guide inside the Spirit socket. When properly positioned, the two half-moon (semi-circle) guides form a whole circle. Refer to Figure 16.
3. Press the antenna connector directly into the Spirit socket until it “clicks” into place. Do not turn to lock antenna into place. Refer to Figure 17.

**Antenna Removal**
1. Turn the Spirit off
2. Firmly holding the Spirit, grasp the antenna connector only by the rough collar (barrel) of the metal plug. Refer to Figure 18.
3. Do not rotate the metal plug when it is in the Spirit socket.
4. Do not pull on the wire or its rubber covering.
5. Holding the connector, pull it straight out.
6. Do not twist it or force it to disconnect.

**Antenna Care**
- Each antenna wire should run in a straight line or be gently looped between the receiver site and the Spirit. 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 Spirit may not work properly if dirt accumulates in the antenna connectors or the Spirit sockets.

Intraoperative Use of Antennas
Intraoperative testing with the patient’s Spirit is necessary. Two 902A or 902AL (long) antennas should be sterilized before introducing it into the sterile field. Refer to STERILIZATION PROCEDURES on page 23.

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 Spirit. The connector end of the antenna shall remain outside of the sterile field for the duration of the procedure.

10 IMPLANTED COMPONENTS

Handle implanted components with powder-free gloves only.

Receivers
The implanted I-110A receiver is a small disc-shaped device that contains electronic circuitry embedded in epoxy resin and coated with silicone rubber. Refer to Figure 19.

Each receiver converts the stimulus energy from the antennas into distinct stimulus pulses and transfers it to the electrodes.

The receiver 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 is comprised of highly flexible, stainless steel strands 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 it to the phrenic nerve, causing the diaphragm muscle to contract.

The electrode (Model E-377-05) is composed of a single wire assembly. Refer to Figure 20.

Figure 19 - Receiver front (top); Receiver back (bottom) showing anode plate; Receiver dimensions: diameter 30 mm, thickness 9 mm, weight 7.5 g, lead length 50 mm

Figure 20 - Electrode E-377-05
Wire length 500 mm
11 PREOPERATIVE SCREENING

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 µs to 1,000 µs of duration at the frequency of 20 Hz (50 ms of pulse interval) at a current level of 20 mA to 100 mA.

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.
**12 STERILIZATION PROCEDURES**

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.

Sterilization temperature should not exceed 275 °F (135°C).

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

Never gas sterilize receivers, electrodes, antennas or accessories. Residual ethylene oxide or other chemicals can cause severe tissue reaction. If gas sterilized by mistake, items must be segregated and returned to ABD for archiving.

Ultrasonic cleaning can damage receivers and electrodes.

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.

Steam autoclave required system components.

Remove all packaging material from items to be sterilized.

No cleaning of components is required prior to sterilization.

**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) 902A or 902AL antennas

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 receivers 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 electrodes 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 / 902AL)**
1. Remove the two antennas from the 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.
Spirit Transmitter Control Unit (Spirit)

Absolutely cannot be steam autoclaved.

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

Should sterilization be desirable for any other reason, ethylene Oxide (ETO) gas can be used.

13 RESTERILIZATION PROCEDURES FOR CE IMPLANTS

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.

Sterilization temperature should not exceed 275 °F (135 °C).

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

Never gas sterilize receivers, electrodes, antennas or accessories. Residual ethylene oxide or other chemicals can cause severe tissue reaction. If gas sterilized by mistake, items must be segregated and returned to ABD for archiving.

Ultrasonic cleaning can damage receivers and electrodes.

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.

Steam autoclave required system components.

Remove all packaging material from items to be sterilized.

No cleaning of components is required prior to sterilization.

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.

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 their boxes and packaging using powder-free gloves.

ABD cannot accept the responsibility for the resterilization of any components. If the decision is made to resterilized, 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 receivers 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 electrodes 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
Spirit Transmitter Control Unit (Spirit)

Absolutely cannot be steam autoclaved.

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

14 SURGICAL PROCEDURES

Anesthesia

*Do not administer muscle relaxants (or short-acting agents) as its use may affect the ability to test the diaphragm function intraoperatively.*

*Do not perform surgery if the patient has any sign of infection.*

*Administer antibiotics intraoperatively and for an appropriate period postoperatively.*

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

*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 non absorbable 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 midportion of each clavicle.
3. Divide platysma and identify the lateral border of the sternocleidomastoid muscle.
4. Medially retract sternocleidomastoid muscle.
5. Identify prescaline 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 in place to underlying tissue using non absorbable suture. Take care that the nerve is lying straight within the electrode after retractor s 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 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 using Spirit and sterile antenna.
18. Increase amplitude to twice the threshold and ensure there is no arm movement due to stimulation of other nerves. If arm movement is observed, then reposition electrode and retest.
19. Once function is verified by diaphragmatic excursion or tidal volume measurement, place single-nonabsorbable tie around the mated connector to prevent fluid intrusion.
20. Excess wire may be coiled anywhere in the subcutaneous pocket.
21. Close the supraclavicular incision.
22. Test receiver/electrode function again after closing incision using Spirit and sterile antenna.
23. Repeat procedure on other side for bilateral implantation.
24. Complete and submit the Implanted Medical Device Registration Form (See page 30).

Thoracic Approach for New Implants

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 side 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 non absorbable 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 septicemia. 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 superior vena cava and right atrium.
9. On patient left side: implant at level of main pulmonary artery as it crosses out from pericardial reflection.
10. Dissect phrenic nerve bundles.
11. Lay nerve in groove of electrode.
12. Suture electrode to pericardium using 3-0 or 4-0 non absorbable sutures on 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 using Spirit and sterile antenna.
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 using Spirit and sterile antenna.
22. Repeat procedure on other side for bilateral implantation.
23. Complete and submit the Implanted Medical Device Registration Form (See Page 30).

**Thoracoscopic/VATS 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 suture.
10. Prepare the electrode with one 3-0 or 4-0 non absorbable suture through one of the eyelets.
11. Feed the entire electrode into the chest through the lower-most trocar space.
12. Pass a tonsil clamp from the subcutaneous pocket under the ribs and through the anterolateral and
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 on either side of the nerve using 3-0 or 4-0 non absorbable sutures.

16. Remove Penrose drain and attach electrode connector to receiver.

17. Insert receiver into pocket anode side down.

18. Test electrode and receiver function after mating using Spirit and sterile antenna.

19. Place a nonabsorbable tie around the mated connector 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 caudal-most incision in a position that will not interfere with the electrode wire.

22. Inflate lung under vision, close all incisions.

23. Connect chest tube to suction.

24. Test receiver and electrode function again after closing incisions using Spirit and sterile antenna.

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 30).

Surgical Approach For Receiver Replacement

- Autoclave required system components
- Carefully dissect tissue surrounding connectors.

Complete replacement of phrenic nerve electrode is required if insulation is damaged.

Form new subcutaneous pocket for new receiver otherwise electrical contact may be compromised.

Place anode side downward towards the rib cage.

Ensure adequate spacing between receivers to prevent overlap of antenna loops.

Wipe connector contact 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 receiver replacement by identifying the location of the connectors and anode discs.

Receivers have 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. Remove residual teflon bag (if used during previous implant) and discard.
2. Cut suture tie, if previously used to secure mated connector.
3. Disconnect connector by rolling while pulling apart.
4. Examine the plating material on the connector for the phrenic nerve electrodes. Scrape lightly with scalpel if there is evidence of discoloration or oxidation. Wipe clean with dry sponge.
5. Form a new subcutaneous pocket by blunt dissection.
6. Attach electrode to receiver, insert receiver into the pocket anode side down towards the rib cage.
7. Test receiver and electrode function using Spirit and sterile antenna.
8. Once function is verified by diaphragmatic excursion or tidal volume measurement, place single-nonabsorbable tie around the mated connector to prevent fluid intrusion.
10. Test receiver and electrode function again after closing incision using Spirit and sterile antenna.
11. Patient may be paced immediately after surgery.
12. Provide a prudent course of antibiotics postoperatively.
13. Complete and submit the Implanted Medical Device Registration Form (See page 30).

Surgical Approach For Electrode Replacement

- Begin antibiotic administration 24 hours prior to surgery.
- Autoclave required system components.
- Wipe connector contact 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 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 replacement (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 on pages 25 – 28 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 30).

Note: Company policy requires that all explanted components be steam sterilized prior to its return for evaluation.
Pursuant to Regulation (EU) 2016/679, General Data Protection Regulation, Avery Biomedical Devices notifies that the purpose of collecting the patient’s personal information is to enable routine administration and to monitor and maintain a record of patient’s details related to the utilization of Avery Diaphragm Pacing System. The regulation also specifies that the patient has the right to have his or her data erased (right to be forgotten) when te personal information is no longer necessary in relation to the purposes for which it is collected.

<table>
<thead>
<tr>
<th>IMPLANTING PHYSICIAN / SURGEON</th>
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<td>__________________</td>
<td>[ ] Check here to verify that the receiver(s) and/or electrode(s) identified above were sterilized prior to implantation.</td>
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15 POSTOPERATIVE CARE AND INITIATION OF PACING

The Avery Diaphragm Pacing System will not work unless the antennas are affixed to the patient’s skin, directly over the implanted receivers.

Remove implants if infection or receiver erosion occurs.

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.

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 placement of internal jugular lines in patients who have cervical implants to avoid damage to the implanted electrode or electrode wire.

Do not take tranquilizers or other drugs that may affect breathing or depress the cell bodies of the anterior horn of the spinal cord. Do not use non-prescription medications without consulting your physician.

Wait at least 10 to 14 days before initiating pacing to allow for complete perineural healing and resolution of edema in receiver pocket.

Each hemidiaphragm is subject to fatigue.

Do not remove implants that do not work initially.

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 Baclofen) may diminish the performance of the pacer or prevent it from working.

Avoid twiddling with the implanted receivers as this may result in damage to the implanted receiver and/or electrode wire.

Changes in atmospheric pressure (for example, a change in altitude above sea level) may diminish the performance of the pacer or prevent it from working.

Postoperative Care

Immediate postoperative care should include:

- maintenance of usual, chronic ventilatory support and/or pacing on the 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 CO\textsubscript{2} level should be in the mid to upper 30’s prior to pacing. If necessary, this
level should be gradually adjusted during the 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 to 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.

Threshold Adjustment

Regardless of patient diagnosis, determination of each hemidiaphragm threshold is required prior to the start of effective bilateral diaphragm pacing.

Threshold is the lowest amplitude setting that starts muscular contraction. The procedure to determine threshold amplitudes is as follows:

1. Using Figure 3 as a guide, turn off both sides of the Spirit by pressing the power ON/OFF buttons on the keypad.
2. Insert new batteries into the Spirit.
3. Ensure that the antennas are properly positioned over each receiver site, firmly affixed with adhesive tape or other snug dressing.
4. Connect the left antenna carefully into the socket marked PATIENT LEFT.
5. Turn on the left side by pressing the left power ON/OFF key.
6. Adjust the amplitude on the left side to 300 by pressing the UP arrow key.
7. If required, preoxygenate patient briefly then discontinue alternate means of ventilation.
8. To determine the threshold, slowly increase the amplitude by pressing the left up arrow key until the smallest diaphragm contraction is achieved while the three-wave icon on the display is visible.

**Note:** Threshold is the lowest stimulus amplitude to produce the smallest contraction of the diaphragm. It can be observed in one or more of the following ways:

- a) patient reports appropriate sensation
- b) manual palpation
- c) visual observation at the costal margin
- d) respirometer (10 cc excursion)
- e) fluoroscopy

Patient reporting and manual palpation are the simplest methods.

**Note:** Stimulation occurs when the three-wave icon over the antenna icon appears (inspiratory period). When the three-wave icon disappears (expiratory period), there is no stimulation.

9. If needed, place a small AM radio, set at 1600 kHz near the transmitter. You will hear a burst of static-like clicks with each stimulation when the transmitter is ON.
10. Once the threshold has been determined for left side, thoroughly ventilate the patient (as needed).
11. Repeat the above procedure to determine threshold for the right side.

Amplitude Adjustment

1. After determining the threshold (the lowest amplitude setting), the maximum amplitude needs to be determined.

**Note:** In general, the higher the amplitude the larger the diaphragm contraction.

2. Gradually increase the amplitude by pressing the left up arrow key until no further increase in diaphragm contraction or tidal volume is seen.
3. Repeat for the right side.

**Note:** Tidal volumes on the right are often larger than the volumes on the left because of size difference between the two lungs.

4. Turn on both sides and adjust each side to achieve optimal tidal volume and patient comfort.
Breathing Rate Adjustment

The breathing rate is set to provide the minute volume required by the patient:

\[ \text{Minute Volume} = \text{Breathing Rate} \times \text{Tidal Volume} \]

The breathing rate is factory set at 12 bpm and should be adjusted to provide adequate ventilation dependent upon the Tidal Volume obtained and the Minute Volume requirement of the patient.

Initiation of Pacing

Patients’ amplitude requirements should be carefully monitored, and medical care sought if more than a 30% increase in amplitude is required (with new batteries 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 Spirit amplitude settings.

1. Proceed with pacing until diaphragm fatigue appears. In newly-implanted patients this may vary — 5 minutes to 5 hours are both “normal.”

   **Note:** Readjustment of each amplitude may be required for appropriate tidal volume and patient comfort. Do not decrease the amplitude settings below the determined threshold point. Patients may notice the need to change the amplitude setting slightly with routine changes from the supine to the upright position. This is a normal variation and each patient’s requirements will be different.

2. Check blood gases periodically. Non-invasive pulse oximetry and either capnography or transcutaneous CO₂ monitoring is suggested.

3. Each day, resume pacing until fatigue occurs or until 24 hour pacing is achieved.

Diaphragm Reconditioning

For patients who obtain little or no tidal volume when stimulation is first initiated, diaphragm reconditioning must be performed. Effective retraining of the diaphragm can only take place if the Spirit can stimulate at the same time with the patient’s ventilator so that the hemi-diaphragms can be exercised by contracting under pressure.

Diaphragm reconditioning should be performed as follows:

1. If necessary, contact our Customer Service Department to reset or modify the patient’s Spirit parameters.
2. Adjust the amplitude on both sides as instructed.
3. Set the patient’s ventilator to the slowest respiratory rate (approximately 9-12 B.P.M.) which allows for adequate ventilation.
4. The Spirit should be set to the same respiratory rate as the ventilator. Turn on the Spirit at the midpoint of the ventilator cycle so that the Spirit is not in sync with the ventilator.
5. The ventilator and the Spirit may not have exactly the same respiratory rate causing the pacer to eventually overlap with the ventilator cycle. Adjust the ventilator as necessary so that the Spirit does not remain in sync with the ventilator.
6. Monitor the patient at least weekly, assessing the patient’s ability to obtain a usable tidal volume from Spirit 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. Initiation of pacing should then be continued in the recommended manner.

   **Note:** 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 pressure.
16 TROUBLESHOOTING

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

The internal parameters should only be adjusted upon the advice of the physician and with the help of ABD Customer Service.

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. Check if both sides are on. Refer to Display section on pages 13 to 14 for more information.
2. Check if the right and left three-wave icons on the display are on during inspiratory periods. See Display section on page 13 to 14 for more information.
3. If the display alarm icon and sound and LED alarms are active, some problem has occurred. The batteries may be low or the antennas may be defective. See Alarms section on pages 15 to 16.
4. Check the battery icons on the display to determine if battery replacement is required. Refer to Battery Gauge section on page 16 for more information.
5. Replace the antenna with a new antenna. If the alarm condition disappears, the antenna was defective. Discard the defective antenna.

If the batteries and antennas check out as fully functional and there are no alarms but pacing is not possible:

1. 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 Spirit amplitude settings ineffective (too weak to pace). Effective pacing can be restored in a patient experiencing a temporary increase in threshold. However, a further increase in tidal volume will not be possible if the patient is experiencing diaphragm fatigue. If the patient had been pacing effectively prior to the loss of or significant reduction in tidal volume, place the patient on mechanical ventilation for 72 hours before restarting the pacing program. Call your physician and ABD Customer Service if large amplitude adjustments fail to restore effective diaphragm pacing.

2. 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 amplitude settings may be effective during treatment for infection, otherwise the patient may require mechanical ventilation.

3. 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 ABD Customer Service.

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 if the cause cannot be determined.

If the patient has not previously paced effectively, parameter changes may be required.
17  CUSTOMER SERVICE

The ABD Customer Service Department:

- Evaluates and repairs equipment
- Provides technical assistance
- Provides loaner/rental equipment

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 Standard Time) weekdays. At other times, please leave a message.

Customer Service can provide a backup unit to use while a patient’s permanent unit is returned for repair. These backup units 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 unit and a backup unit may be evident. When using a backup unit, amplitude settings may need to be adjusted upward or downward slightly. If necessary, redetermine thresholds using the procedure shown on page 32.

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

18  SHIPPING INSTRUCTIONS

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.

When returning the Spirit for evaluation or repair, please return the antennas and batteries that were in use when the problem occurred. This will permit complete system evaluation and ensure proper repair.
WARRANTIES

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

<table>
<thead>
<tr>
<th>Device</th>
<th>Warranty Period</th>
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<tbody>
<tr>
<td>Spirit 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>
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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 unit carefully for protection. This Limited Warranty shall be void unless the patient 1) returns the warranty registration card completed with all requested information 90 days from the 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 reuse.

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 Avery Diaphragm Pacing 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 system or that failures or malfunctions of the ABD 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 diaphragm pacing 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.

(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 11725-5725 USA
Telephone: (631) 864-1600 Fax: (631) 864-1610
www.averybiomedical.com

6017K 09-2019
20 IDENTIFICATION CARD

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

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 Spirit.

If any information contained on this card changes, please contact ABD so that the patient’s file is updated and a replacement card issued.
### Relevant Standards

The Spirit Control Unit is compliant to the following EMC related standards:

<table>
<thead>
<tr>
<th>Standard</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CISPR 11</td>
<td>Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement</td>
</tr>
<tr>
<td>IEC 60601-1</td>
<td>Medical electrical equipment – Part 1: General requirements for basic safety and essential performance</td>
</tr>
<tr>
<td>IEC 60601-1-8</td>
<td>Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems</td>
</tr>
<tr>
<td>IEC 60601-1-11</td>
<td>Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment</td>
</tr>
<tr>
<td>AIM 7351731</td>
<td>Medical electrical equipment and system electromagnetic immunity test for exposure to radio frequency identification readers</td>
</tr>
<tr>
<td>CFR 47, Part 18</td>
<td>Industrial, scientific, and medical equipment</td>
</tr>
</tbody>
</table>

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

The Spirit transmitter is intended for use in the electromagnetic environment specified below. The user of the Spirit transmitter should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions</td>
<td>Group 2</td>
<td>The Spirit transmitter must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RF emissions</td>
<td>Class B</td>
<td>The Spirit transmitter control unit 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>
</tbody>
</table>

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

The Spirit transmitter is intended for use in the electromagnetic environment specified below. The user of the Spirit transmitter should ensure 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) IEC 61000-4-2</td>
<td>± 8 kV contact ± 15 kV air</td>
<td>± 8 kV contact ± 15 kV air</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>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</td>
<td>30 A/m</td>
<td>30 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical domestic establishment, commercial or hospital environment.</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Conducted RF IEC 61000-4-6</td>
<td>3 Vrms 0,15 MHz-80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz</td>
<td>3 Vrms 0,15 MHz-80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the Spirit transmitter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>Recommended separation distance:</td>
<td>( d = \frac{3.5}{10} \sqrt{P} ) 80 MHz to 800 MHz ( d = \frac{7}{10} \sqrt{P} ) 800 MHz to 2.7 GHz</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiated RF IEC 61000-4-3</td>
<td>10 V/m 80 MHz to 2.7 GHz</td>
<td>10 V/m 80 MHz to 2.7 GHz</td>
<td>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</td>
</tr>
<tr>
<td>Interference may occur in the vicinity of equipment marked with the following symbol:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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.

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 Spirit transmitter control unit is used exceeds the applicable RF compliance level above, the Spirit transmitter control unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Spirit transmitter control unit.
The Spirit transmitter is intended for use in the electromagnetic environment specified below. The user of the Spirit transmitter should ensure that it is used in such an environment.

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

<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>IMMUNITY to proximity fields from RF wireless communications equipment</td>
<td>MHz – Modulation – Field Strength</td>
<td>MHz – Modulation – Field Strength</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the Spirit transmitter control unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>385 - 18 Hz - 27 V/m</td>
<td>385 - 18 Hz - 27 V/m</td>
<td>1720 - 217 Hz - 28 V/m</td>
<td></td>
</tr>
<tr>
<td>450 - 18 Hz - 28 V/m</td>
<td>450 - 18 Hz - 28 V/m</td>
<td>1845 - 217 Hz - 28 V/m</td>
<td></td>
</tr>
<tr>
<td>710 - 217 Hz - 9 V/m</td>
<td>710 - 217 Hz - 9 V/m</td>
<td>1970 - 217 Hz - 28 V/m</td>
<td></td>
</tr>
<tr>
<td>745 - 217 Hz - 9 V/m</td>
<td>745 - 217 Hz - 9 V/m</td>
<td>2450 - 217 Hz - 28 V/m</td>
<td></td>
</tr>
<tr>
<td>780 - 217 Hz - 9 V/m</td>
<td>780 - 217 Hz - 9 V/m</td>
<td>5240 - 217 Hz - 9 V/m</td>
<td></td>
</tr>
<tr>
<td>810 - 18 Hz - 28 V/m</td>
<td>810 - 18 Hz - 28 V/m</td>
<td>5500 - 217 Hz - 9 V/m</td>
<td></td>
</tr>
<tr>
<td>870 - 18 Hz - 28 V/m</td>
<td>870 - 18 Hz - 28 V/m</td>
<td>5785 - 217 Hz - 9 V/m</td>
<td></td>
</tr>
<tr>
<td>930 - 18 Hz - 28 V/m</td>
<td>930 - 18 Hz - 28 V/m</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1720 - 217 Hz - 28 V/m</td>
<td>1720 - 217 Hz - 28 V/m</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1845 - 217 Hz - 28 V/m</td>
<td>1845 - 217 Hz - 28 V/m</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1970 - 217 Hz - 28 V/m</td>
<td>1970 - 217 Hz - 28 V/m</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2450 - 217 Hz - 28 V/m</td>
<td>2450 - 217 Hz - 28 V/m</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5240 - 217 Hz - 9 V/m</td>
<td>5240 - 217 Hz - 9 V/m</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5500 - 217 Hz - 9 V/m</td>
<td>5500 - 217 Hz - 9 V/m</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5785 - 217 Hz - 9 V/m</td>
<td>5785 - 217 Hz - 9 V/m</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IMMUNITY to known sources of EMI</td>
<td>7.7 – 8.7 MHz – 40 V/m</td>
<td>7.7 – 8.7 MHz – 40 V/m</td>
<td></td>
</tr>
<tr>
<td>a. EAS</td>
<td>1.7 – 2.3 MHz – 50 V/m</td>
<td>1.7 – 2.3 MHz – 50 V/m</td>
<td></td>
</tr>
<tr>
<td>b. Diathermy</td>
<td>30 kHz – 10 V/m</td>
<td>30 kHz – 10 V/m</td>
<td></td>
</tr>
<tr>
<td>c. X-ray</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
The Spirit transmitter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Spirit transmitter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Spirit transmitter as recommended below, according to the maximum output power of the communications equipment.

<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>80 to 800 MHz</td>
<td>( d = \frac{3.5}{10} \sqrt{P} )</td>
</tr>
<tr>
<td>800 MHz to 2.7 GHz</td>
<td>( d = \frac{7}{10} \sqrt{P} )</td>
</tr>
<tr>
<td>710, 745, 780, 5240, 5500, 5785</td>
<td>( d = \frac{6}{9} \sqrt{P} )</td>
</tr>
<tr>
<td>385, 450, 810, 870, 930, 1720, 1845, 1970, 2450</td>
<td>( d = \frac{6}{28} \sqrt{P} )</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>0.01</th>
<th>0.10</th>
<th>1.00</th>
<th>100.00</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.01</td>
<td>0.035</td>
<td>0.070</td>
<td>0.067</td>
<td>0.021</td>
</tr>
<tr>
<td>0.1</td>
<td>0.110</td>
<td>0.221</td>
<td>0.211</td>
<td>0.070</td>
</tr>
<tr>
<td>1</td>
<td>0.350</td>
<td>0.700</td>
<td>0.667</td>
<td>0.214</td>
</tr>
<tr>
<td>10</td>
<td>1.107</td>
<td>2.213</td>
<td>2.108</td>
<td>0.700</td>
</tr>
<tr>
<td>100</td>
<td>3.500</td>
<td>7.000</td>
<td>6.670</td>
<td>2.143</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 separation distance for 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.

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**Transfer Power Measurement and Operation Distance**

The Spirit transmitter was only measurable when an Isotropic Field Probe was placed 20cm, 10cm or 1 cm from any side. At 1cm away from the left antenna on the rear side, the transfer power was the highest at 3.82 V/m. At 10cm distance from the left antenna on the rear side, the transfer power was 2.05 V/m. At 20cm from either antenna and on any side, the transfer power was less than 1 V/m. The recommended separation distance to keep other electronic devices away from the Spirit transmitter would be 20cm or more due to the low power and short range of the transmitters.

**Transfer Power Measurements at 1 cm**

<table>
<thead>
<tr>
<th></th>
<th>Left Antenna (V/m)</th>
<th>Right Antenna (V/m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Front</td>
<td>2.29</td>
<td>1.38</td>
</tr>
<tr>
<td>Rear</td>
<td>3.82</td>
<td>2.20</td>
</tr>
<tr>
<td>Left Side</td>
<td>1.46</td>
<td>1.32</td>
</tr>
<tr>
<td>Right Side</td>
<td>2.39</td>
<td>1.73</td>
</tr>
</tbody>
</table>

**Transfer Power Measurements at 10 cm**

<table>
<thead>
<tr>
<th></th>
<th>Left Antenna (V/m)</th>
<th>Right Antenna (V/m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Front</td>
<td>0.92</td>
<td>0.90</td>
</tr>
<tr>
<td>Rear</td>
<td>2.05</td>
<td>1.42</td>
</tr>
<tr>
<td>Left Side</td>
<td>0.98</td>
<td>0.95</td>
</tr>
<tr>
<td>Right Side</td>
<td>0.77</td>
<td>0.79</td>
</tr>
</tbody>
</table>

**Transfer Power Measurements at 20 cm**

<table>
<thead>
<tr>
<th></th>
<th>Left Antenna (V/m)</th>
<th>Right Antenna (V/m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Front</td>
<td>0.43</td>
<td>0.61</td>
</tr>
<tr>
<td>Rear</td>
<td>0.72</td>
<td>0.83</td>
</tr>
<tr>
<td>Left Side</td>
<td>0.44</td>
<td>0.64</td>
</tr>
<tr>
<td>Right Side</td>
<td>0.51</td>
<td>0.58</td>
</tr>
</tbody>
</table>