CAUTION: FEDERAL (U.S.) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

NOTE: Ototronix strongly recommends the completion of a MAXUM training course before performing these procedures.

A successful fitting of the MAXUM System requires an accurate deep-canal impression be taken. All clinicians involved in these procedures should not attempt this type of fitting unless they have completed a MAXUM training course.

ONLY THE IMPRESSION MATERIAL SUPPLIED BY OTOTRONIX SHOULD BE USED FOR DEEP PERITYMPANIC IMPRESSIONS.

ONLY THE OPTIMAX FITTING SOFTWARE AND PROGRAMMING CORDS SUPPLIED BY OTOTRONIX SHOULD BE USED FOR PROGRAMMING THE IPC WITH DIGITAL PROCESSOR.
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The MAXUM System is an electromagnetic, partially implanted, middle ear hearing device. The MAXUM System consists of a permanent ossicular implant magnet and an external digital sound processor that is worn in the external ear. The device is provided with specialized surgical instruments for the proper insertion and placement of the implant.

The MAXUM IPC System with a digital processor consists of a permanent ossicular implant magnet and an Integrated Processor and Coil (IPC). The IPC houses an electromagnetic coil and the external sound processor.

The sound processor in the IPC receives sound, amplifies it, and sends electrical signals to the coil at the tip of the device. This coil changes the sounds to electromagnetic signals, which cause the implant to vibrate. These vibrations travel through the cochlea, stimulating the hair cells and nerves that send impulses to the brain that are interpreted as speech or sounds.
Indications for Use

The MAXUM Systems are indicated for use in adults, 18 years of age or older, who have a moderate to severe sensorineural hearing loss and desire an alternative to an acoustic hearing aid.

Prior to receiving the device, it is recommended that an individual have experience with appropriately fit hearing aids.

Contraindications

The MAXUM Systems are contraindicated for subjects who have:

- Conductive hearing loss
- Retrocochlear or central auditory disorder
- Active middle ear infections
- Tympanic membrane perforations associated with recurrent middle ear infections
- Disabling tinnitus

Magnetic Resonance Imaging (MRI) examinations are contraindicated for patients implanted with the MAXUM. Patients implanted with a MAXUM System should not undergo an MRI examination, enter a room where MRI exams are performed, or get close to other strong magnetic fields.

If a patient has a medical or occupational need to be exposed to strong magnetic fields such as a need for MRI examinations or working with MRI equipment, contact Ototronix at 877-410-4327.

Nickel Sensitivity: Maxum Implant Assembly, Split Coil versions (P/N M220L and M220R) are contraindicated for patients with foreign body sensitivity to metals containing nickel. Where material sensitivity is suspected, appropriate tests should be conducted prior to implantation. (Maxum Implant Assembly, Full Coil versions (P/N M210L and M210R) do not contain nickel and this contraindication does not apply.)
MAGNETIC RESONANCE IMAGING (MRI) EXAMINATIONS

MRI is contraindicated for patients implanted with the MAXUM. Patients implanted with a MAXUM System should not undergo an MRI examination, enter a room where MRI exams are performed, or get close to other strong magnetic fields. The effects of these exams on the implant are unknown.

If an MRI is necessary, the implant should be removed and re-implanted after the exam.

ELECTROCONVULSIVE THERAPY

Electroconvulsive therapy is contraindicated for patients implanted with the MAXUM. Electroconvulsive therapy must never be used on a patient with a MAXUM System implant because it may damage the implant or the patient’s hearing.

COBALT TREATMENT, PET SCANS, TRANSCRANIAL DIAGNOSTIC ULTRASOUND, OR LINEAR ACCELERATION TECHNIQUES

The effect of cobalt treatment, PET scans, transcranial diagnostic ultrasound, and linear acceleration techniques on the implant are unknown. Before undergoing any of these procedures, MAXUM System users should consult their physicians about the potential risks.

MAGNETIC SURGICAL INSTRUMENTS

If other surgeries are to be performed in the middle ear space of the implanted ear, avoid using magnetic (ferric) instruments. Such instruments will attract the implant, and may damage the implant or the patient’s hearing.
ELECTROMAGNETIC COMPATIBILITY
The MAXUM Systems have been found to comply with the test requirements of EN60601-1-2, Electromagnetic Compatibility for Medical Devices. Compliance indicates the systems are reasonably protected from harmful interference in a typical medical installation. However, these devices may be affected by systems that produce, utilize, or radiate radio frequency energy. If your MAXUM System appears to be affected, try the following solutions to resolve the problem:

- Reorient and/or relocate the interfering device.
- Increase the separation between the MAXUM System and the interfering device.

If these solutions do not resolve the problem, please inform your hearing health care professional, your physician or contact Ototronix at 877-410-4327.

ANTITHIEFT DETECTORS AND AIRPORT SECURITY DEVICES
Anti-theft detectors found in retail stores, public libraries, etc., and airport security devices produce electromagnetic fields. Some MAXUM System users may hear distorted sounds when passing through or near one of these devices. Testing with the MAXUM has indicated that the device is not damaged by these systems.

Do not stand near or lean against anti-theft devices in doorways of department stores and libraries. Anti-theft devices in stores and libraries are safe, providing you walk through them at a normal pace. When passing through an anti-theft system, walk though the center of the gates. If only one gate is present stay as far away as possible from it.

If scanning with a hand held metal detector is necessary at airport security stations, warn the security personnel that you have an implanted medical device. Ask them not to hold the metal detector to the device any longer than absolutely necessary. You may wish to ask for an alternate form of personal search.
RADIO FREQUENCY IDENTIFICATION (RFID) SYSTEMS
RFID is a technology that uses radio waves to exchange data between a reader and an electronic tag attached to an object. RFID Systems are used currently in keyless entry systems, passports and identification, retail sales and asset management, toll roads and many others.

The MAXUM Systems are reasonably protected from harmful interference from RFID Systems. Some MAXUM System users may hear distorted sounds when passing through or near one of these devices. Testing with the MAXUM has indicated that the device is not damaged by these systems.

It is recommended that you keep a separation distance of 6 inches (15 cm) between your MAXUM and items thought to contain RFID systems.

CELL PHONE COMPATIBILITY
Some hearing device users have reported buzzing sounds when they are using cell phones, indicating that the cell phone and hearing device may not be compatible. According to the ANSI C63.19 standard (ANSI C63.19-2006 American National Standard Methods of Measurement of Compatibility Between Wireless Communications Devices and Hearing Aids), the compatibility of a particular hearing device and cell phone can be predicted by adding the rating for the hearing device immunity to the rating for the cell phone emissions. For example, the sum of a hearing device rating of 2 (M2) and a telephone rating of 3 (M3) would result in a combined rating of 5. Any combined rating that equals at least 5 would provide “normal use”; a combined rating of 6 or greater would indicate “excellent performance.”

The immunity of the MAXUM has been found to be M4. While this rating system was created for acoustic hearing aids, the equipment performance measurements, categories and system classifications are based upon the best information available but cannot guarantee that all users will be satisfied.

NOTE: The performance of individual hearing aids may vary with individual cell phones. Therefore, if you are purchasing a new phone, be sure to try it with your MAXUM prior to purchase. For additional guidance, please ask your cell phone provider for the booklet entitled “Hearing Aid Compatibility with Digital Wireless Cell Phones.”
PATIENT SELECTION

Specific patient selection criteria is outlined below:

- Adults, 18 years of age or older
- Sensorineural hearing loss
- Pure tone air-conduction threshold levels shall fall at or within:


<table>
<thead>
<tr>
<th>Frequency (kHz)</th>
<th>0.25</th>
<th>0.5</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower Limit</td>
<td>0</td>
<td>0</td>
<td>10</td>
<td>35</td>
<td>50</td>
<td>50</td>
<td>40</td>
</tr>
<tr>
<td>Upper Limit</td>
<td>50</td>
<td>60</td>
<td>70</td>
<td>75</td>
<td>75</td>
<td>80</td>
<td>100</td>
</tr>
</tbody>
</table>

- Word recognition scores of 60% or better
- Normal middle ear anatomy
- Psychologically and motivationally suitable candidate with realistic expectations of the benefits and limitation of the device

The patient must be made aware of the Contraindications and Warnings associated with the MAXUM System. Ensure that the patient has reviewed and understands these Contraindications and Warnings prior to proceeding.

Ear Impression

The next step in determining patient candidacy requires taking a deep ear impression (See MAXUM DEEP EAR IMPRESSION) in order to determine if the ear canal meets the minimum requirements for manufacture of the IPC. The minimum measurements of the canal area to accommodate the IPC are:

- 3 mm canal diameter from the second bend of the canal to the medial end
- 4 mm in width at the canal aperture (canal opening)
- 20 mm length from aperture to the medial end of the canal

Upon determination of patient candidacy, the surgical procedure can be scheduled. The magnet comes in Right and Left ear configurations.
Ear selection should be based on the following criteria which are listed in order of decreasing importance:

1) Poorer ear by air conduction threshold, 5 dB or greater average difference 500-4000 Hz

2) Poorer ear by speech recognition scores, 8% or greater difference

3) Poorer ear by SRT, 5 dB or more difference

4) Symmetrical ears/ear not used for telephone chosen

5) Symmetrical ears/patient preference
MAXUM DEEP EAR IMPRESSION

Performed by Physician assisted by Clinician

Precautions

Proper fitting of this hearing device requires the taking of deep canal impressions. Clinicians should not attempt this type of fitting unless they have completed the Ototronix training course and developed the necessary skills needed to make this type of impression safely. ONLY THE IMPRESSION MATERIAL SUPPLIED BY OTOTRONIX SHOULD BE USED FOR DEEP PERITYMPANIC IMPRESSIONS. Many impression materials have a shore value too high to use safely for these very deep fittings and could damage the skin of the ear canal.

About the MAXUM Impression

It is critical to obtain an accurate and complete deep ear impression including landmarks of the Tympanic Membrane in order to manufacture the IPC. These landmarks include the surface of the TM, umbo, and malleus and are used to position the coil.

This necessitates taking a deep ear impression that contacts the tympanic membrane surface without the use of an otoblock. For this use, a specialized impression set and procedure have been developed. The physician and assistant (usually the audiologist or hearing instrument specialist) perform the deep ear impression procedure using a topical anesthetic and an otologic microscope.

The deep ear impression should be taken a minimum of 7 days prior to surgical implantation. Ototronix will release the implant after receipt and approval of the deep ear impression.

Most of the items needed for the deep ear impression are provided in the Clinician’s Set available through Ototronix.

Other materials provided by the clinic:

- Topical anesthetic
- Otologic microscope
- Nasal speculum
- Removal Tool (e.g. non-cutting cerumen curette)
Procedure

1. The physician examines the canal and tympanic membrane of the ear to be implanted and cleans the canal walls. Removal of any cerumen or epithelial debris is performed. *(A perforation in the tympanic membrane is a contraindication, preventing the procedure.)* The physician medically clears the patient for the deep ear impression.

2. The patient is placed in a prone position for examination and anesthetizing of the ear canal. Components should be assembled and the Impression Placemat reviewed. The topical anesthetic solution is removed from the ear canal. Almond oil is liberally applied into the ear canal from single-use applicator bottle. A cotton swab is dipped in the oil in the ear canal and used to lubricate the helix, concha, and tragal areas of the ear. The clinician covers the patient’s ear with a paper towel. The patient is instructed to turn his/her head in a dependent position to allow the oil to drain from the ear canal. It is important to retain a liberal amount of oil coating the canal walls and tympanic membrane. The impression gun, impression cartridge, and extended tubing should be assembled. Some impression material should be expressed prior to administering to ensure proper mixing before inserting the tubing tip into the patient’s ear.

3. **Solo technique:** Using visualization, the clinician inserts the tubing attached to the impression cartridge down the ear canal without contacting the TM. The clinician squeezes the trigger of the cartridge injection tool to begin the flow of impression material, using the tube to direct the filling of the ear canal and concha, taking care to keep the tube tip immersed in the impression material.

**Two person technique:** Using microscopic visualization, the clinician utilizes a nasal speculum to hold the ear canal open for the insertion of the tubing attached to the cartridge injection tool down to the TM. The trained assistant squeezes the trigger of the cartridge injection tool to begin the flow of impression material while the clinician uses the tube to direct the filling of the ear canal and concha, taking care to keep the tube tip immersed in the impression material.

**For both options:** (If the tube is pulled above the surface of the impression material, an air bubble or void may develop.) Avoid allowing the impression material to be in contact with contaminants including vinyl or latex gloves.
The patient should be instructed to open and close mouth at least every 30 seconds during the curing. A timer should be set for 8 minutes. Setup time is at least eight minutes and the earmold impression material should no longer feel sticky (tacky) to the touch. The impression is carefully removed from the ear canal by gently separating the impression from the helix and tragal area with an impression removal tool such as non-cutting Buck cerumen curette. The helix area of the impression can be gently twisted forward as the impression is gradually and slowly lifted out of the ear canal. It helps to have the patient open and close his or her jaw during extraction.

4. Examine the impression to verify adequacy of canal size and the depth to the tympanic membrane. A cast of the tympanic membrane should be seen on the medial end of the impression and the landmarks of the handle of the malleus and umbo clearly identifiable. If the impression is not deep enough or has voided area(s) produced by air/oil bubbles, Step 3 of this impression procedure should be repeated. Either an adequate impression is obtained or it is determined the canal size is inadequate in size or shape to accommodate the IPC. The Impression Template (provided in the Clinician’s Kit) is used to measure the dimensions of the impression. The minimum measurements of the canal area to accommodate the IPC are:

- 3 mm in canal diameter from the second bend of the canal to the medial end
- 4 mm in canal aperture width (canal opening)
- 20 mm for length from aperture to the medial end of the canal

5. Following the ear impression procedure, the clinician should visually inspect the ear canal and TM to ensure the health and integrity of those structures. Impressions should be sent to Ototronix for release of the implant after receipt and approval of the deep ear impression.
After the deep ear impression has been taken, the next step for the patient is the surgical implant procedure. The surgical approach for implanting the internal portion of the MAXUM System is common otological surgery practice, and the implantation protocol has been standardized. The surgical protocol is designed to properly position and to maximize the stability of the implant.

For more information on the implant procedure, please refer to the MAXUM Surgeon’s Manual.
MAXUM FITTING

The MAXUM System IPC is custom-made based upon the deep ear impression. Following medical clearance by the physician, the MAXUM IPC is fit to the patient approximately 10 weeks post implantation.

The following sections detail device fitting and optimization. These adjustments should be made in coordination with hearing tests for optimal hearing benefit. Please contact Ototronix Clinical Support with questions about making adjustments or remaking the IPC.

Before You Begin

The MAXUM System has been found to be in conformity with IEC-60601-1 Medical Safety if the requirements detailed in the section titled SAFETY are met. Please read the SAFETY section before connecting to the system.

When the patient is connected to the system, make the patients aware of all connecting cables and ask them to minimize movements to reduce the risk of snagging or pulling cables.

Electroacoustic analysis is performed on each IPC prior to shipment with programming parameters set to default positions. Upon initializing the processor for the patient, the software customizes or “autofits” the fitting parameters derived from the audiometric information entered into the OptiMAX program.

PROGRAMMING THE IPC

Please refer to the OptiMAX Programming Guide included with the OptiMAX Software for instructions on IPC fitting/programming.
Listening Check of the MAXUM System

The MAXUM System processor may be subjectively assessed with the use of an acoustic hearing aid’s telecoil for a listening check.

To perform a listening check, use a hearing aid with a Telecoil switch to which a listening tube (hearing instrument stethoscope) is coupled. Switch the acoustic hearing aid to the “T” position and hold the MAXUM System IPC in close proximity to the acoustic hearing aid’s T Coil. Talk into the microphone of the IPC and listen through the listening tube.

NOTE: The telecoil of the acoustic hearing aid will “shape” the signal from the MAXUM System.

IPC Wearing Schedule

The patient should be counseled that insertion and wearing of the IPC may cause some initial discomfort and should resolve spontaneously over the first two-week wearing period.

Provided the device is comfortable, the patient can wear it as much as desired. If desired, the wearer should adhere to a wearing schedule limiting the use of the device and then increasing the wearing time over a two-week period. This information is included in the User Guide as well.

<table>
<thead>
<tr>
<th>Sample IPC Wearing Schedule</th>
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</thead>
<tbody>
<tr>
<td><strong>Day 1 &amp; 2</strong></td>
</tr>
<tr>
<td><strong>Day 3 &amp; 4</strong></td>
</tr>
<tr>
<td><strong>Day 5 &amp; 6</strong></td>
</tr>
<tr>
<td><strong>Day 7 &amp; 8</strong></td>
</tr>
<tr>
<td><strong>Day 9 &amp; 10</strong></td>
</tr>
</tbody>
</table>

After Day 10, the patient should be able to wear the device for the amount of time desired. If the IPC is not comfortable after two weeks of wearing it, the patient is instructed to contact his/her hearing care professional.

NOTICE: If the ear becomes sore, the patient is to discontinue the use of the device and notify the audiologist. If any draining or bleeding occurs, the patient is instructed to discontinue use and contact their physician promptly.
CLINICAL CONSIDERATIONS

Evaluation procedures should include standard audiometric measures including air and bone-conduction thresholds, immittance measures, speech recognition, and hearing aid evaluation. Additionally, qualitative (subjective) questionnaires may help to determine if a candidate’s lack of perceived benefit with an acoustic hearing aid may be addressed with an implantable middle ear hearing device. Care should be taken to ensure that the subject’s perceived lack of benefit from the hearing aid(s) is not attributable to poor fit or lack of function. The ear selected for implantation of the MAXUM System should be equal to or worse than the non-implant ear. The safety and effectiveness of bilateral implantation and implantation in pregnant women, nursing mothers, children, or those with unilateral hearing impairment has not been established.

Adverse Events—MAXUM System (BTE) Study

Summarized in Table 1 are the adverse events reported on a total of 103 subjects reported as of April 4, 2001. Four (4) subjects were reported as having serious adverse events, all of which were determined by a physician to be “definitely” unrelated to the device. The events included a cardiovascular disorder, carcinoma, and two (2) deaths.

Table 1. Adverse Events Reported (n=103 Subjects)

<table>
<thead>
<tr>
<th>Description</th>
<th>No. Reported</th>
<th>No. Resolved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abnormal Ear Sensation</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Device Noise/Electromagnetic Interference</td>
<td>15</td>
<td>12</td>
</tr>
<tr>
<td>Ear Disorder</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Ear Mold Assembly Failure</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Ear Pain</td>
<td>30</td>
<td>28</td>
</tr>
<tr>
<td>Increased Hearing Loss</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Hematoma Ear</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>Infection</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Outer Ear Irritation</td>
<td>14</td>
<td>14</td>
</tr>
<tr>
<td>Paresthesia</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Processor Failure</td>
<td>13</td>
<td>12</td>
</tr>
<tr>
<td>Skin Irritation</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Taste Perversion</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Tinnitus</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Transient Balance Involvement</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Tympanic Membrane Damage</td>
<td>6</td>
<td>5</td>
</tr>
</tbody>
</table>
1 Investigator reported abnormal ear sensation consisting of fullness; event resolved during the normal healing period after implant.

2 Engineering analysis determined these events to be associated with the Printed Circuit Board (PCB) assembly operation. The operation has been modified and validated. Low levels of EMI have been found to be dependent upon the location and strength of the electromagnetic source. Three events reported as unresolved were due to their intermittent nature and will be monitored by the Investigator at the subjects’ next visits.

3 Investigator reported middle ear effusion; event resolved during the normal healing period after implant.

4 Engineering analysis of the ECAs resulted in improved manufacturing processes and controls that have been implemented to eliminate systematic failures.

5 These events were related to the operative procedure or to the ECA fitting. In most of the cases these events resolved through longer healing periods postimplant or through ECA modifications. The Investigator is continuing to monitor the 2 subjects whose events were reported as unresolved.

6 Audiological data indicated that the hearing loss appears to be conductive. Investigator reported that he will continue to monitor the subject.

7 Each of the reported hematomas resolved through normal healing.

8 The infections also included Otitis Media (2) and Otitis Externa (2). Each of the reported events resolved through otologic management.

9 Outer ear irritation consisted of ear irritation (7), ear canal abrasion (2), ear edema (2), ear inflammation (2), and ear abrasion external (1).

10 The investigator reported this event as a transient neurological effect.

11 Processor failures were determined to be associated with the PCB assembly operation. The operation has been modified and validated. Analysis of the unresolved processor failure was in-process at the submission of this data.

12 Several observations of skin irritation were reported, including Eczema (2) and Pruritis (1). The investigators noted that each event was resolved.

13 Taste perversion can be related to the severing or irritation of the chorda tympani nerve during the implantation procedure. Resolution occurred spontaneously without treatment or surgical intervention. One case remains unresolved and will be monitored by the Investigator.

14 Subject medical records noted a past history of tinnitus. This case will be monitored by the Investigator.

15 Transient balance involvement comprised of reports of dizziness (1), nausea (1), vertigo (2), and vomiting (1). Each event resolved spontaneously.

16 Four reported events were resolved through surgical intervention and one event resolved without intervention. One event is not resolved and the Investigator is monitoring the subject. (Non-serious adverse events unrelated to the device are not included in Table 1. These events consisted of: Unconfirmed ECA/Sound Processor failures (16), broken ECAs due to user abuse, improper use, or adjustments that damaged the device (7), tooth disorder (1), and infection in the non-implant ear (1)).
Potential Adverse Events

Surgery of the middle ear requires manipulation of the ossicular bones (malleus, incus, and stapes) and exposes the inner ear to the risk of surgical trauma. Serious complications may arise either during or after surgery that may include, but are not limited to: sensorineural or conductive deafness due to trauma during surgery; granular inflammatory lesions; device displacement after surgery due to development of scar tissue; damage to the incus; non-functioning implant; and infection after surgery. Additional surgery may be required to correct these conditions, if possible. There may also be numbness, swelling or discomfort around the ear, the possibility of facial paresis, and/or the disturbance of balance or taste, but they are usually transient and resolve within a few weeks after surgery.

Implant Device Failures and Replacements

There were no implant device failures, revisions or replacements reported in the MAXUM System (BTE) study. Some failures of the external Sound Processor and Earmold Coil Assembly were noted and analyzed. Improved manufacturing processes and controls have been implemented to eliminate systematic failures.
Clinical Study Summary—MAXUM IPC System with a Digital Processor

A limited confirmatory study of the IPC with a digital processor was conducted on a subset of 10 subjects, 9 of which were from the original (BTE) study, with similar results.

Clinical Study Summary—MAXUM IPC System with an Analog Processor

A limited confirmatory study of the IPC with an analog processor was conducted on a subset of 10 subjects from the original MAXUM System (BTE) study, with similar results.

Clinical Study Summary—MAXUM BTE System

One hundred-three (103) subjects underwent the implant procedure with the MAXUM BTE System and were fit with the BTE style Sound Processor. The following clinical study summary is based on ninety-five (95) subjects who had completed 20-week assessments. The assessment compared preoperative results with an optimally fit acoustic hearing aid in the ear to be implanted to post operative results with the MAXUM System. “Optimally fit” as defined by the clinical study included insertion gain matching using National Acoustic Laboratories-Revised (NAL-R) prescriptive target ranges (+5 dB for 500, 1000, and 2000 Hz and +12 dB for 3000 and 4000Hz) and evidence of improvement in aided benefit.

Subjects were tested to find hearing thresholds, sound field thresholds, speech testing in quiet and noise, aided benefit, and subject perceptions.

All items showing improvements were determined to be statistically significant. For more detailed information about the MAXUM System (BTE), please refer to the section below on Clinical Study Results.

1. For most subjects, the change in residual hearing was not significant. Average decrease in air conduction thresholds at 20 weeks was 4.2 dB across the frequency range of 250 to 8000 Hz. Average bone conduction thresholds decreased by 1.1 dB. Few subjects (10/95 or 10.5%) had greater than 10 dB of change by air conduction. Few subjects (4/95 or 4%) had greater than 10 dB of change by bone conduction.

2. There was an average increase in functional gain of 7.9 dB with the MAXUM compared to their acoustic hearing aid. For the high frequencies of 2000, 3000, and 4000 Hz, there was an average increase in functional gain of 9.6 dB.
3. The Articulation Index score results showed an improvement of 11.9% with the MAXUM. The MAXUM System shows an improved audibility over acoustic hearing aids.

4. Speech recognition in quiet showed a 5.3% improvement with the MAXUM when compared with the subjects’ Acoustic hearing aids.

5. Speech testing in noise results with the Speech Perception in Noise (SPIN) test showed no difference between the MAXUM System and acoustic hearing aids.

6. The Abbreviated Profile of Hearing Aid Benefit (APHAB) scores showed an improvement of approximately 20% across three different sub-scales with the MAXUM when compared to acoustic hearing aids.

7. When subjects compared their pre-implant acoustic hearing aid with the MAXUM in the Hough Ear Institute Profile* (HEIP) test, the results showed that:
   a. Out of 94 subjects responding, 84 of those subjects (89%) preferred the MAXUM in terms of overall satisfaction.
   b. Sixty-three of 94 subjects (67%) reported feedback with their acoustic hearing aids. Eight of 94 subjects (8.5%) reported feedback with the MAXUM. Out of 94 subjects responding, 93 of them (99%) preferred the MAXUM as having the least amount of feedback.
   c. Fifty of 92 subjects (54%) reported occlusion with their acoustic hearing aids. 21 of 92 subjects (23%) reported occlusion with the MAXUM.
   d. Out of 94 subjects responding, 84 of those subjects (89%) responded that they preferred the MAXUM over their acoustic hearing aids in the areas of sound quality.
   e. Twenty-one of 41 (51%) subjects reporting tinnitus pre-implant reported that their hearing aid decreased their perception of tinnitus. Twenty of 30 (67%) subjects reporting tinnitus post-implant reported that the MAXUM System decreased their perception of tinnitus.

*HEIP is a validated but not standardized questionnaire addressing the subjects’ perception of the presence of tinnitus, feedback, and occlusion as well as sound quality judgments and device preference.
Clinical Study Results: MAXUM IPC System with a Digital Processor

A limited confirmatory study of the IPC with a digital processor was conducted on a subset of 10 subjects, 9 of which were from the original (BTE) study, with similar results.

Clinical Study Results: MAXUM IPC System with an Analog Processor

A limited confirmatory study of the IPC with an analog processor was conducted on a subset of 10 subjects from the original (BTE) study, with similar results.

Clinical Study Results: MAXUM System (BTE)

One hundred-three (103) subjects underwent the implant procedure with the MAXUM System implant and were fit with the BTE style sound processor. The following clinical study summary is based on ninety-five (95) subjects who had completed 20-week assessments. The assessment compared preoperative results with an optimally fit acoustic hearing aid in the ear to be implanted to post operative results with the MAXUM System. Optimally fit, as defined by the clinical study, included insertion gain matching using National Acoustic Laboratories-Revised (NAL-R) prescriptive target ranges (±5 dB for 500, 1000, and 2000 Hz and ± 12 dB for 3000 and 4000 Hz) and evidence of improvement in aided benefit. Subjects were tested to find hearing thresholds, sound field thresholds, speech testing in quiet and noise, aided benefit, and subject’s perceptions.

RESIDUAL HEARING

For most subjects (85 of 95 or 89.5%), residual hearing with the MAXUM System was not significantly affected. Average decrease in air conduction thresholds at 20 weeks was 4.2 dB across the frequency range of 250 to 8000Hz. Average bone conduction thresholds decreased by 1.1 dB. Few subjects (10 of 95 or 10.5%) had greater than 10 dB of change. Eight of 95 subjects (8%) experienced a change between 10 to 15 dB in hearing thresholds and 2 of 95 subjects (2%) experienced a change greater than 15 dB.
INCREASED FUNCTIONAL GAIN AND AIDED THRESHOLDS

The MAXUM System provided 7.9 dB additional functional gain when comparing the subject’s acoustic hearing aid performance to that of the MAXUM Systems at the 20 week assessment. The MAXUM demonstrated a statistically significant improvement in averaged aided sound field thresholds and functional gain from 500–4000 Hz. At 36 and 52 weeks, the additional functional gain was 7.9 dB and 7.0 dB, respectively. All three (3) time points, showed a statistically significant gain in average functional gain (each p-value < 0.05, Paired t-test).

Additional functional gain is needed to compensate for the residual hearing threshold change. Aided thresholds are improved with the MAXUM System regardless of the decrease in residual hearing. Individual results will vary.

The figure at right shows aided thresholds comparing the MAXUM to the acoustic hearing aid.

A similar analysis was performed for the high frequency average of 2000, 3000 and 4000 Hz (referred to in the protocol as the High Frequency Warble Tone Average-HFWTA of functional gain). The average improvement in the high frequency range at 20 weeks compared to performance with an acoustic hearing aid is 9.6 dB. At 36 and 52 weeks, the average improvement in HFWTA is 9.2 dB and 10.8 dB, respectively. At each of the three (3) time points, the improvement from performance with an acoustic hearing aid achieved statistical significance (each p-value < 0.05, Paired t-test).
CHANGE IN ARTICULATION INDEX

A secondary outcome measuring audibility is the Articulation Index (AI) and was assessed at pre-implant and 20 weeks. The AI was used to calculate the level of audibility based on aided hearing thresholds. The average improvement in Articulation Index scores comparing performance with the MAXUM to the acoustic hearing aid was 11.9%. The improvement was statistically significant (p-value < 0.05, Paired t-test).

SPEECH PERCEPTION RESULTS

There are two (2) additional secondary efficacy measures of performance using audiometric speech tests. These consist of the NU-6 (50-item word list) and the Speech Perception In Noise (SPIN) test. Tables 2 and 3 show the results on the aided NU-6 test and the SPIN (aided, low predictability sentences-raw scores) test. The results indicate average improvements with the MAXUM on the NU-6 performance of 5.3%, 5.0%, and 12.2% across the 20, 36, and 52-week assessments, respectively. The NU-6 improvement from the acoustic hearing aid to the MAXUM was statistically significant at the 20 and 52-week follow-ups. On average, SPIN scores were similar pre-implant and post-implant at the 20 and 36 week assessments.

The average change in SPIN aided, low predictability sentences at 20 weeks was -0.1 words. For the 36 and 52-week follow-ups, the average improvements were 0.1 words and 4.2 words. The SPIN improvement from the acoustic hearing aid to the 52-week follow-up was statistically significant (p-value = 0.0135, Paired t-test).

<table>
<thead>
<tr>
<th>Table 2 - Summary of NU-6 Aided Word Test (mean±SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NU-6 (% Correct)</td>
</tr>
<tr>
<td>Acoustic HA (N=103) Optimally Fit Hearing Aid 76.8±16.6 N/A</td>
</tr>
<tr>
<td>20 Weeks (N=95) MAXUM 82.1±11.9 N/A</td>
</tr>
<tr>
<td>Improvement 5.3±16.6 0.0026 *</td>
</tr>
<tr>
<td>36 Weeks (N=33) MAXUM 83.8±10.3 N/A</td>
</tr>
<tr>
<td>Improvement 5.0±15.4 0.0700</td>
</tr>
<tr>
<td>52 Weeks (N=12) MAXUM 86.7±9.9 N/A</td>
</tr>
<tr>
<td>Improvement 12.2±12.6 0.0066 *</td>
</tr>
</tbody>
</table>

* Statistically Significant (Paired t-test, p-value < 0.05)

Reference: Clinical Report

<table>
<thead>
<tr>
<th>Table 3 - Summary of SPIN Aided, Low Predictability Test (mean±SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPIN Aided, Low Predictability (# Correct out of 25)</td>
</tr>
<tr>
<td>Acoustic HA (N=102) Optimally Fit Hearing Aid 9.8±5.4 N/A</td>
</tr>
<tr>
<td>20 Weeks (N=95) MAXUM 10.0±5.0 N/A</td>
</tr>
<tr>
<td>Improvement -0.1±5.9 0.8743</td>
</tr>
<tr>
<td>36 Weeks (N=22) MAXUM 9.9±5.9 N/A</td>
</tr>
<tr>
<td>Improvement 0.1±8.2 0.9664</td>
</tr>
<tr>
<td>52 Weeks (N=12) MAXUM 12.2±6.2 N/A</td>
</tr>
<tr>
<td>Improvement 4.2±5.0 0.0135 *</td>
</tr>
</tbody>
</table>

* Statistically Significant

Reference: Clinical Report
IMPROVEMENTS IN PERCEIVED AIDED BENEFIT IN VARIOUS LISTENING SITUATIONS

The Abbreviated Profile of Hearing Aid Benefit (APHAB) is a questionnaire used to assess the subject’s perceived performance benefit in three areas: Ease of Communication (EC), Reverberation (RV), and Background Noise (BN). These were reported at pre-implant using the subject’s acoustic hearing aid and at 20 weeks using the MAXUM System. On average, the hearing aid condition provided a score of 34.7 points of aided benefit and the MAXUM 20 week condition provided a score of 42.2 points of aided benefit for the three subscales. While individual results varied, the average improvement across the three subscales is 7.2 ±19.9 points of improvement of aided benefit which is statistically significant.

Figure 5
Aided Benefit (APHAB)
Out of 94 subjects responding, 84 of those subjects (89%) preferred the MAXUM in terms of overall satisfaction. Satisfaction was measured by a four point scale with four being very satisfied and one being not at all satisfied. Using this scoring method, satisfaction with the MAXUM increased by an average of 30.8% (median = 16.7%) from the subject’s acoustic hearing aid (p-value < 0.0001, Paired t-test).

- Sixty-three of 94 subjects (67%) reported having feedback with their acoustic hearing aid. At 20 weeks, only 8 (9%) subjects reported feedback using the MAXUM System (p-value < 0.0001, McNemar’s Test). Out of 94 subjects responding, 93 subjects (99%) preferred the MAXUM as having the least amount of feedback.

- Subject Perceived Quality of Speech was rated by a 7-point scale. The mean percentage increase relative to the subject’s optimally fit hearing aid equaled 27.8% (median =19.2%) for the MAXUM (p-value< 0.0001, Paired t-test).

- Out of 94 subjects responding, 84 of those subjects (89%) responded that they preferred the MAXUM over their acoustic hearing aids in the area of sound quality.

- Fifty of 92 subjects (54%) reported occlusion with their acoustic hearing aids. 21 of 92 subjects (23%) reported occlusion with the MAXUM using the MAXUM System (p-value < 0.0001, McNemar’s Test). (Two of 94 subjects did not respond to the question concerning occlusion).

- Twenty-one of 41 (51%) subjects reporting tinnitus pre-implant reported that their hearing aid decreased their perception of tinnitus. Twenty of 30 (67%) subjects reporting tinnitus post-implant reported that the MAXUM System decreased their perception of tinnitus.
STORAGE, HANDLING AND STERILIZATION

See TECHNICAL SPECIFICATIONS section for information about storage conditions.

An expiration date is printed on the Impression Material Cartridge. An expiration date is also printed on the Single Pack for the impression oil. Do not use expired product. All other external components and accessories are not subject to aging.

Handle the MAXUM System components with care.

The Single Pack in the Impression Set is intended for single patient use only. Do not reuse.

For storage, handling and sterilization information for implants and surgical instruments, see Surgeon’s Manual.

INFORMATION FOR USE AND RECOMMENDED TRAINING

Surgeons should be experienced in middle ear surgery including stapedectomy. It is recommended that surgeons receive specific training regarding the deep ear impression procedure and implantation technique of the MAXUM Systems. It is strongly recommended that a surgeon work closely with a clinician when selecting candidates to be implanted and during the post operative management of patients. Surgeons should refer to the Ototronix MAXUM System Surgeon’s Manual for specific instruction for use.
SERVICE AND MAINTENANCE

Equipment Failure, Service and Repair

**WARNING:** Do not use a defective device or cabling. If you suspect that the correct function or operation safety of a MAXUM System or OptiMAX Programming System may be faulty for any reason, do not connect the suspect device or cables and ensure that it will not be used by others.

**WARNING:** Under no circumstances disassemble a MAXUM IPC. Contact Ototronix for parts or service. Parts inside the MAXUM System must only be checked or serviced by Ototronix.

For all service and repair, contact Ototronix directly.

Maintenance

No regularly scheduled maintenance is required. Occasional collection of earwax and/or debris may affect performance or comfort. The following may be performed:

- Use a brush or soft cloth to clean the canal tip or vent openings. A UV light (contained in some dehumidifiers) can be used to sanitize the IPC. Liquid sanitizing solutions may be used on the tip of the IPC if applied to a soft cloth first. **Do not soak the IPC in cleaning solution or any other liquids because that may harm the device.**

- Open the battery door and ensure that the battery contacts are clean. Ensure that the battery can be properly inserted and the door stays closed.

For any further cleaning or maintenance, contact Ototronix directly.
This manual contains information and warnings, which must be followed to ensure safe performance of the MAXUM System and OptiMAX Programming System. Local government rules and regulations, if applicable, should also be followed at all times.

**Glossary of Symbols**

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>SN</td>
<td>Serial number</td>
</tr>
<tr>
<td>REF</td>
<td>Reference number (Model)</td>
</tr>
<tr>
<td>!</td>
<td>Do Not Throw Away</td>
</tr>
<tr>
<td>📚</td>
<td>Consult Instructions for Use</td>
</tr>
<tr>
<td>☑️</td>
<td>Do Not Resterilize</td>
</tr>
<tr>
<td>! Sterilize</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>LOT</td>
<td>Lot number</td>
</tr>
<tr>
<td>☕️</td>
<td>Type BF, EN 60601-1</td>
</tr>
<tr>
<td>☭️</td>
<td>Do Not Use if Package is Damaged</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>📡</td>
<td>Non-ionizing radiation</td>
</tr>
<tr>
<td>🔄</td>
<td>Store at temperatures between -10°C and +55°C (14°F and 131°F)</td>
</tr>
<tr>
<td>🌴</td>
<td>Caution: Federal Law restricts this device to sale by or on the order of a physician</td>
</tr>
<tr>
<td>🍷</td>
<td>Single Use Only</td>
</tr>
<tr>
<td>🏴 SterileEO</td>
<td>Sterilized using Ethylene Oxide</td>
</tr>
<tr>
<td>🕒</td>
<td>Date of Manufacture</td>
</tr>
<tr>
<td>🕒</td>
<td>Use By (Expiration Date)</td>
</tr>
<tr>
<td>☔️</td>
<td>Keep Dry</td>
</tr>
<tr>
<td>☔️ 95% RH</td>
<td>Store at Relative Air Humidity of 95% or Less</td>
</tr>
</tbody>
</table>
Warning Notes

When connecting a MAXUM device to the OptiMAX Programming System, the following must be considered:

- Only connect the MAXUM device to a GN Otometrics HiPro USB according to its User Guide.
- The computer used to power the HiPro USB and run the software must be in compliance with IEC-60950.
- Only use the Ototronix provided cables to connect the HiPro USB and device.
- Only use OptiMAX software to program a MAXUM device.

**Note 1:** The MAXUM System and OptiMAX Programming System is an electromedical system. When assembling an electromedical system, the person carrying out the assembly must take into account that connecting other equipment that does not comply with the same safety requirements as the MAXUM Systems may lead to a reduction in the overall safety. If non-system equipment is connected, it is the operator’s responsibility to ensure that the assembled system complies with IEC 60601-1-1.

**Note 2:** The OptiMAX Programming System is designed to ensure compliance with requirements in EN 60601-1-1 when the PC, printer, etc., are placed out of reach of the patient, i.e. not closer than 1.8m (6ft). Only the MAXUM device, HiPro USB and the cables used to connect these are suitable for use within the patient environment.

**Note 3:** While working with or touching equipment outside of the patient environment, the operator should not come into contact with the patient.

**Note 4:** Do not use more than one extension cord, power strip, multiple socket extension or combination of these to power the system. Do not connect non-system equipment to power strip or multiple socket extension if used.

**Note 5:** Do not connect items to the system which are not specified as part of the system (see TECHNICAL SPECIFICATIONS for component list).

**Note 6:** Do not use the device in the presence of flammable anesthetics (gases) or oxygen rich environments.

**Note 7:** The system is not intended to be defibrillation-proof. If possible, remove the IPC from the patient environment before defibrillation.
Component Lists

**MAXUM IPC:**
- MAXUM IPC (M3100)
- User’s Guide (403-1001-001)

**OptiMAX™ Programming System (M6100):**
*Recommended for use with GN Otometrics HI PRO USB and an EN/IEC certified Computer.*
- OptiMAX Software
- CS63 Mini Din Cable Assembly
- CS64 Flex Cable Assembly
- OptiMAX Programming Guide (403-1013-001)

**MAXUM Clinician’s Set (M5100):**
- Impression Gun
- Impression Template
- Clinician’s Guide (403-1002-001)

**MAXUM Impression Set (M5200):**
- Impression Cartridges
- Impression Single Packs
- Impression Packets

Connections

The MAXUM IPC has one CS64 4-Pin flex communication port for programming. This port should only be accessed by the Clinician. See *OptiMAX Programming Guide* for proper usage.

Power Supply

The MAXUM IPC is internally powered by a size 312, zinc air battery.

**Nominal Voltage:** 1.4V  
**Maximum Current Consumption:** < 10mA

Operating Environment

**Temperature:** -10°C to +55°C (14°F to 131°F)  
**Rel. Humidity:** <95%, non-condensing  
**Air Pressure:** 500 hPa to 1060 hPa

Storing and Handling

**Temperature:** -10°C to +55°C (14°F to 131°F)  
**Rel. Humidity:** <95%, non-condensing  
**Air Pressure:** 500 hPa to 1060 hPa
Disposal of Device

All parts of the MAXUM System and OptiMAX Programming Software must be disposed in accordance with federal, state, and local regulations.

- MAXUM external and unopened implant devices should be returned to Ototronix. Please package the device as to prevent further damage to the device.
- To return an implant that has been in contact with a patient, contact Ototronix for packaging materials.
- Any broken cabling or used batteries should be recycled or disposed.

Standards

**Safety:** EN 60601-1, Type BF  
**Electromagnetic compatibility:** EN 60601-1-2

**Systems:** EN 60601-1-1  
**Cellular telephone compatibility:** EN 60118-13

Electromagnetic Compatibility (EMC)

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>The MAXUM System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class B</td>
<td>The MAXUM System 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>Harmonic emissions IEC 61000-3-2</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/ flicker emissions IEC 61000-3-3</td>
<td>Not applicable</td>
<td></td>
</tr>
</tbody>
</table>
The MAXUM System is intended for use in the electromagnetic environment specified below. The customer or the user of the MAXUM System should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic Discharge (ESD) IEC 6100-4-2</td>
<td>±8 kV Air ±6 kV Air</td>
<td>±8kV Air ±6kV Air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic materials, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Electrical fast transient/burst IEC 61000-4-4</td>
<td>±2 kV for power supply lines</td>
<td>N/A (Device is battery powered)</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td>±1 kV for input/output lines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>±1 kV differential mode ±2 kV common mode</td>
<td>N/A (Device is battery powered)</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</td>
<td>&lt;5 % $U_T$ (&gt;95 % dip in $U_T$) For 0.5 cycle 40 % $U_T$ (60 % dip in $U_T$) For 5 cycles 40 % $U_T$ (60 % dip in $U_T$) For 5 cycles</td>
<td>N/A (Device is battery powered)</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of the MAXUM System requires continued operation during power mains interruptions, it is recommended that the MAXUM System be powered from an uninterruptible power supply or a battery.</td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

NOTE $U_T$ is the a.c. mains voltage prior to application of the test level.
Guidance and Manufacturer’s Declaration – Electromagnetic Immunity

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

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>3 Vrms 150 kHz to 80 MHz</td>
<td>3 V</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the MAXUM System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>3 V/m 80 MHz to 2.5 GHz</td>
<td>3 V/m</td>
<td>Recommended separation distance: ( d = 1.17\sqrt{P} ) 80 MHz to 800 MHz ( d = 2.33\sqrt{P} ) 800 MHz to 2.5 GHz</td>
</tr>
</tbody>
</table>

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

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

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

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 MAXUM System is used exceeds the applicable RF compliance level above, the MAXUM System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the MAXUM System.

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
### Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the MAXUM System

The MAXUM System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MAXUM System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MAXUM System as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output of transmitter W</th>
<th>Separation distance according to frequency of transmitter m</th>
<th>150 kHz to 80 MHz</th>
<th>80 MHz to 800 MHz</th>
<th>800 MHz to 2.5 GHz</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>d = \sqrt{P}</td>
<td>0.12</td>
<td>0.12</td>
<td>0.23</td>
</tr>
<tr>
<td>0.01</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.1</td>
<td></td>
<td>0.37</td>
<td>0.37</td>
<td>0.74</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>1.2</td>
<td>1.2</td>
<td>2.3</td>
</tr>
<tr>
<td>10</td>
<td></td>
<td>3.7</td>
<td>3.7</td>
<td>7.4</td>
</tr>
<tr>
<td>100</td>
<td></td>
<td>11.7</td>
<td>11.7</td>
<td>23.3</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.
Clinical Support:
(877) 410-4327 or (281) 203-0250
support@ototronix.com

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Houston, Texas 77386 USA
www.ototronix.com

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