OSCAR
Ultrasonic Arthroplasty Revision Instrument
User Manual
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INDICATIONS FOR USE

The Orthosonics OSCAR 3 is intended to be used for cutting and removal of bone and acrylic bone cement in orthopaedic applications.

Warnings and Cautions

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<th>Details</th>
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<tr>
<td><strong>Caution:</strong></td>
<td>Handle the acoustics (handset and probes) with care. Do not attempt to modify the acoustics. Damage or changes can affect the ability to attain resonance and reduce the effectiveness of the device. Do not use if damage is suspected.</td>
</tr>
<tr>
<td><strong>Caution:</strong></td>
<td>Sparks may be produced if the probes touch anything metal while activated. This equipment is not to be used in the presence of flammable gases or liquids.</td>
</tr>
<tr>
<td><strong>Caution:</strong></td>
<td>Use only OSCAR accessories to assure compatibility.</td>
</tr>
<tr>
<td><strong>Caution:</strong></td>
<td>This device should only be used by surgeons who are (1) trained in the types of surgical procedures that are to be carried out and (2) trained in the specific use of ultrasonic surgical instruments.</td>
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<tr>
<td><strong>Caution:</strong></td>
<td>The probes may become hot during use. Do not allow the probes to contact tissue following use.</td>
</tr>
<tr>
<td><strong>Caution:</strong></td>
<td>Do not allow the probes to contact tissue between activations, in case accidental activation should occur.</td>
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<tr>
<td><strong>Caution:</strong></td>
<td>Care should be taken when operating in the vicinity of nerves.</td>
</tr>
<tr>
<td><strong>Caution:</strong></td>
<td>To avoid the risk of electric shock, this equipment must only be connected to supply mains with protective earth.</td>
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INTRODUCTION

The task of removing PMMA bone cement during revision arthroplasty has always posed a challenge to the surgical team. Difficulty in visualisation, ambiguity in discriminating between cement and bone and unpredictable scheduling all add to unnecessary complications and in the worst cases severely compromised bone stock and the need for expensive prostheses and other reconstructive materials.

Removing these unpredictable problems requires a device that can be relied upon to restore a planned schedule and outcome. Ultrasound, when applied correctly, can make the cement removal part of the operation predictable, safe and by definition more efficient and quicker.

PMMA bone cement responds instantly to a vibrating wave-guide. The putty-like consistency of the cement is then easily removed from the endosteum through novel design of the wave-guides (probes). Cancellous bone is affected by ultrasound and will be removed when subjected to the energy levels deployed during cement removal. Cortical bone will not be affected due to the probe design and the energy levels used. It does not absorb ultrasound as readily as the cement and therefore the surgeon will have awareness of the position of the probe within the bone through both audible and tactile feedback. It is important to refer to the operating techniques discussed later in this manual, because any tool is potentially dangerous if used contrary to the controlled methods described. The design of the probes is critical to safe cement removal; by always transferring the softened cement as the probe moves heat build up is not a major issue, provided irrigation is deployed according to the techniques outlined later. As technology has advanced control of the production of ultrasound, its delivery and monitoring, is now fully under digital circuitry.

OSCAR was introduced specifically to facilitate the removal of bone cement during hip revision procedures using ultrasound to soften the cement shell holding the implant in place. Special probes are deployed in a sequence to collect and remove the softened cement from the host bone. The technique reduces manual force to a minimum and practically eliminates the risk of bone fracture and perforation. The technology has become accepted as the standard means of joint revision where cement fixation is involved.

Ultrasound and the Removal of Bone Cement

Ultrasound is the name given to high frequency vibrations (above 16 kHz) which travel through air, liquid or solid media as pressure and displacement waves. In a bounded system, standing waves may be established, which produce a much greater concentration of acoustic energy, and scope for rapid local heating at absorption sites. Attempts were made at the Endo Clinic in Hamburg in the early 1970's to remove bone cement by melting it with ultrasound. Bone cement is remarkable in that it can maintain a temperature gradient of 200° over a distance of 1 mm. This means that if molten cement can be removed rapidly, the residual cement hardly increases in temperature, thus minimising damage to adjacent bone. In the initial studies in Hamburg, however, it was found difficult to remove the molten cement.

The technology is now available to do this, using a series of specially designed handsets and probes in conjunction with a portable ultrasonic generator (“OSCAR” Orthosonics System for Cemented Arthroplasty Revision). Animal studies have demonstrated that when the tip of the probe is in contact with the endosteal bone surface for a period of 10 seconds, cell death to a depth of only 50 microns occurs. This contrasts with cell death to a depth of 500 microns, which occurs when conventional PMMA is applied to the endosteal surface.

Cement removal using this technique is extremely rapid, and can normally be accomplished in 25 minutes or less. The risk of bone perforation or fracture is negligible when OSCAR is used, as the probes are designed to emit a characteristic sound the moment they come into contact with the bone surface. The equipment is simple to operate, and both efficient and predictable in its performance. It has been designed with surgeons, scrub nurses, technicians and hospital engineers in mind and its use permits the accurate scheduling of theatre lists.
Cementless Prosthesis Revision

Over the last 15 years total joint surgery has moved, in some countries, away from cemented fixation to the use of press-fit prostheses. These are normally either porous or hydroxyapatite coated stems and acetabular shells, which encourage bony in-growth to provide fixation and stability. Inevitably, a percentage of these will require revision and the specific task of separating the implant from the bone will require osteotomes and burrs leading to a complex and potentially damaging procedure.

Precedents exist for the use of ultrasound powered osteotomes and adding this function to the OSCAR system was a natural extension of the intended use in order to cater for the changing needs in arthroplasty revision surgery. Ultrasound remains one of the most effective and safe energy forms available for powering surgical instruments. By careful design of the oscillatory system, collateral damage due to local heating can be minimized to levels significantly below that associated with high speed burrs and oscillating saws. Low force cutting coupled with precise control of energy delivery to the operating site, ensure that ultrasonically powered osteotomes will answer surgical needs in growing demand for revision arthroplasty.
BENEFITS OF OSCAR 3

Ultrasound and the Removal of Bone Cement

Multiple applications -
- Suitable for all cemented joints with specialist probes for unusual procedures
- Capability for help in removing uncemented prostheses.

Efficient -
- Cement removal - speedy and complete removal of the cement with low risk of damage to the bone
- Cementless stem extraction - low profile probes maximise conservation of bone

Feedback -
- Audible, visual and tactile warning of probe position

Status -
- Visual and audible signals indicate progress of the probes

User friendly -
- Simple connection, micro-processor tuning and power delivery
- Hand or footswitch control

Economical -
- Reusable probes for cement removal, predictable theatre scheduling

Safe -
- Preferential ultrasonic absorption of bone cement - minimal damage to bone unless using specific tools for bone cutting

Portable -
- Easily transported
THE EQUIPMENT

The OSCAR 3 system is comprised of a portable generator which has 2 output channels. Both channels 1 and 2 drive standard OSCAR cement removal handsets or OSCAR osteotome handsets. The channels can be activated via an air footswitch or via the handset switches.

There is also a large range of cement removal probes, prosthesis removal probes, and a dedicated cleaning system.

A dedicated trolley, with probe and footswitch storage facilities is also available.

The Generator

The generator is mains powered and completely portable. It consists of an integrated power supply unit, enabling the generator to be powered from 240Vac mains, a control circuit, 2 power circuits and an LCD. The control circuit controls the 2 power circuits. A block diagram of the electrical system is shown in (Figure 1).

Generator

![Diagram of the OSCAR 3 generator](Figure 1 - OSCAR 3 Generator overview)

Handset Key

- Cement Removal Handset
- Osteotome Handset
The two channel outputs running the handsets are microprocessor controlled and are designed to produce ultrasonic energy at the resonant frequency of the attached handset. The frequency range is 27.9 to 28.5 kilohertz.

Careful control of the generator output ensures that the energy delivered to the handsets increases automatically in response to the increased load. In effect, as a probe is pushed into bone cement, (or bone for osteotomes) more energy is supplied to the handset - ranging from a few watts to a 150-watt output. In practice, the peak loads do not exceed 130 Watts when piercing solid cement or cutting bone.

Once connected to the mains supply, the generator (Figure 2) is activated by the ON/OFF switch at the back on the LCD side of the enclosure. Both of the output channels have a 4 way socket for connection of OSCAR cables, which in turn connect to cement removal or osteotome handsets. Each channel also has an air nozzle socket, positioned below each output socket. The footswitch tubing connects to these air nozzles.
The Handsets

Cement Removal Handset

Each handset contains a piezo-ceramic sandwich transducer - the ultrasonic “motor”, and a mechanical focusing device - the “horn” (B). These are enclosed in a water and pressure tight stainless steel casing which incorporates a small hand operated switch (A). This switch when depressed once and held will operate the handset; a click will be felt. The electrical connection is at the rear end of the handset (C). The shroud and end cap (D & E) are removed from the handset prior to autoclaving.

A variety of probes may be fitted to the output end of the horn via a screwed coupling, and these permit the surgeon to carry out a range of procedures with maximum efficiency. Each probe consists of a waveguide, which is an integral number of half wave lengths long, its shape and overall length being chosen to suit a particular case.

The signal from the generator induces the crystals within the handset to vibrate, producing ultrasonic energy. This energy is focused along the wave guide to the tip of the probe, which will vibrate at approximately 28.3 kHz. The rapid oscillatory movement produces heat when the tip of the probe is in contact with bone cement, causing the cement to liquefy almost immediately.
Osteotome Handset

In order to cut both cortical and cancellous bone the transducer which is used to generate axial vibration in the OSCAR handset has been redesigned so that its output impedance is compatible with bone tissue. This results in reduced displacement amplitude and the ability to sustain a higher distal load. Bone cutting handsets are identified by their gold outer sleeve case and larger size connecting thread at the output end. (see Figure 4 below).

The Probes

All the probes in the OSCAR system are detachable from the main handsets. There are a multitude of probes available. Each handset type has its own range of unique probes. Each probe is attached to the main handset via a screw threaded connection. Once connected correctly the probe acts as a waveguide, focusing and directing the ultrasound energy generated within the handset to the probe tip or blade, enabling the handset to perform the task at hand, be it removal of bone cement or bone cutting.

Cement Removal

The cement removal probes are for use with the Cement Removal Handset. (See Figure 3). The Cement Removal Handset can be run from either Channel I or II of the OSCAR 3 generator.

There are many different cement removal probe designs. All probes are made of a titanium alloy, and screw into the distal part of the horn. They are tightened using the supplied 9mm spanner unless otherwise specified. Each probe is designed to perform a different function, grooving, scraping, piercing or cutting. Those probes designed to cut through regions of compact cement have heads incorporating two or more perforations or grooves. Friction between the bone cement and the high velocity tip surface of the ultrasonic probe causes rapid heating at points of contact. A small volume of cement melts, and under the advancing impetus of the probe tip this molten cement is forced through the ports in the head, or the grooves in the body solidifying behind it when the ultrasonic energy is turned off.

Smoke is generated during the procedure. The dominant components are methylmethacrylate, benzine and styrene. All concentrations produced are well below OES/MEL values. (OES = occupational exposure standards, MEL = maximum exposure limits).
Once broken up in this way, the cement can readily be removed, either by withdrawing the probe with adhering cement or using conventional instruments.

Probes designed solely for scraping material from the endosteal surface of the bone are not equipped with perforations in the probe head. A description of individual probe designs follows:

**Consumable Probes**

Do not allow any consumable probe to come into contact with a metal surface whilst active, as this will cause damage to the probe.

Consumable probes are reusable, however they will wear and become damaged after a number of uses. The number of uses varies depending on type and duration of use.

As further probes are developed their status will be made clear as to whether they are re-usable (consumable) or single use.

**The Groover**

**OHG2020 (Consumable)**

The groover (Figure 5) has a flattened spear-shaped head with one hole on each side, and a forward cutting blade at the most lateral aspect of the device.

The groover is used primarily to cut longitudinal channels in the proximal cement mantle, in order to weaken the integral cement mass and permit segmental removal with conventional instruments. When the groover comes into contact with bone, a high pitched squeaking noise is heard, and resistance encountered. Note: this squeaking is a reaction between the probe and the bone and not generated from the module. This audible feedback cannot be relied upon if the bone is osteoporotic, dead or if some residual cement is still present to dampen the sound.

**The Axisymmetric Reverse Scraper**

**OHS2061, OHS2081, OHS2100 (Consumable)**

The scraper (Figure 6) is spear shaped, with no perforations within the head and is supplied with three tip diameters, 6mm, 8mm and 10mm. Note: the 10mm scraper has a short wave guide. The cutting edge is machined at an angle of 20 degrees to the axis of the probe, and it is used for removing well bonded proximal or distal cement and membrane from the endosteal surface by applying a reverse scraping action.
**Piercers**  
**OHP2061, OHP2081, OHP2100, OHP2101, OHP2111, OHP2131 (Consumable)**

The piercer is a round, spear shaped device with 4 perforations in the head and is used for fenestrating the distal plug of cement to provide a clear channel, which can then be enlarged using the long scraper. The piercer is supplied in various tip diameters ranging from 6mm to 13mm ([Figure 7](#)). When the piercer strikes cortical bone there is a high pitched audible squeaking noise and resistance is felt.

It should be noted that the piercer will de tune when it is in contact with bone, unless it is circumferentially compressed by bone, when de tuning will not occur but resistance will be felt and no smoke will be generated.

**The Acetabular Probe**  
**OHA2030 (Consumable)**

The Acetabular probe ([Figure 8](#)) is used to assist in the removal of the acetabular cup. It is important to remember that when using OSCAR, none of the activated instruments should be allowed to make contact with metallic components; this is particularly relevant when considering its application to the acetabular cup.
Single Use Probes

Single use probes should not be reprocessed under any circumstances.

The Single Use Piercer
OHP2080SU (Disposable)

The piercer (Figure 9) loses its cutting edge over time in the same way as the axisymmetric reverse scraper. In response to customer feedback, Orthosonics has developed a single use piercer probe. The single use probe has an SU in its batch number etched onto its' side to distinguish it from the reusable probe. In addition the wording 'single use' is etched onto the shaft. This probe also differs from the consumable piercers by being ½ wave-length, and requiring a 7mm spanner for fixation. It is extended using special extension bars, OHE2001SU and OHE2000SU, long and short respectively, and although they have the designation SU at the end of the identification, this does not signify they are single use. There is no wording 'single use' on the shaft.

The Single Use Axisymmetric Reverse Scraper
OHS2080SU (Disposable)

Over time the cutting edge of the scraper probe loses its sharpness. Many customers expressed an interest in a cheaper, disposable probe that can be discarded after a single use so as to provide optimum cutting ability at all times. In response to this request Orthosonics has developed a single use axisymmetric reverse scraper (Figure 10). Its size and mass are much reduced from the reusable probes, making them cheaper to purchase. The single use probe has an SU in its batch number etched onto its' side to distinguish it from the reusable probe. In addition the wording 'single use' is etched onto the shaft. It is designed to be used with the special extension bars, OHE2001SU and OHE2000SU, long and short respectively, and although they have the designation SU at the end of the identification, this does not signify they are single use. There is no wording 'single use' on the shaft.
The Slim Shafted Piercer (OHP2062SU) and Scraper (OHS2062SU) (Disposable)

Upper limb revision surgery involves removing cement from the thinner cortices and narrower medullae of the ulna and humerus. Two probes, one piercer and one scraper (Figure 11) each with a 6mm head, are available with 4mm shanks to allow good access. Due to the fragile nature of the slim shank these probes have been designated single use.

Their clinical use is similar to the femoral piercers and scrapers, however, in accordance with safety instructions already mentioned, increased frequency of irrigation should be used when removing cement from the humerus and ulna.

Inertial Probe Loading Instrument (Slaphammer) IPL200 (Consumable) and Extraction Probe EXP2681SU (Disposable)

This extraction probe (Figure 12) is designed to remove larger pieces of cement and the cement plug. However, the deployment of this probe is to be undertaken with care because the technique relies on the probe being embedded in cement, which is allowed to solidify. Instructions for use are located in the Surgical Technique section of this manual.
Uncemented Stem Removal

Fixation of uncemented stems is achieved by creating a porous coating on the implant or by adding hydroxyapatite to selected portions of the surface, both of which encourage bony ingrowth and generation of new cancellous bone. When revision is necessary, the implant is removed by cutting through what is a substantially cancellous bone interface surrounding the stem. This is done using a variety of flat, narrow osteotomes coupled to the specially designed osteotome handset. The essential feature of the osteotomes is a series of edge serrations forming a saw blade. The osteotomes are introduced beside the prosthesis stem to form a series of extended slots which effectively isolate the implant from the host bone. In some cases it may be necessary to cut into cortical bone when the depth of cancellous bone is limited.

Osteotome Probes

The osteotome probes are classed as SINGLE USE. They are for use with the osteotome handset (See Figure 4). Osteotome handsets can be run from Channels I & II of the OSCAR 3 generator. After use, the Osteotome probes should be disposed of as per normal operating room procedures, ideally in a suitably sized sharps container.

Curved Serrated Osteotome Probe (Disposable) Figure 16

Hoe Probe
6mm OHH2062SU (Disposable)
8mm OHH2081 (Disposable)

This probe (Figure 17) is designed to remove small pieces of cement during upper extremity revisions. Similar to the reverse scraper, the hoe probe is used in a back scraping motion to remove cement in narrow canals.

Flat Serrated Osteotome Probe (Disposable) Figure 14

Flat Non Serrated Osteotome Probe (Disposable) Figure 15
The Cables
(For Use with Cement Removal and Osteotome Handsets)

Silicone rubber cables with screened conduction wires are supplied with the equipment to connect the handsets to the generator. Each cable contains 2 separate ground leads for safety reasons. This means in effect, that the patient will be grounded when in contact with the device and this may cause hospital diathermy equipment to alarm and cease functioning, as this apparatus will not work when the patient is grounded.

(Action: turn off the diathermy machine while OSCAR is being used)

The Trolley

A dedicated trolley (Figure 19) for the OSCAR 3 generator is available. This provides storage facilities for the various probe attachments and footswitches. The trolley has fully lockable castor wheels and allows for easily moving and positioning the OSCAR 3 system within the theatre environment.

Footswitch

A double air footswitch (Figure 20) can be used on either of the output channels on the OSCAR 3 generator. Channels I & II utilise cement removal and osteotome handsets, which both have handset mounted switches, but can also be operated from the attached footswitch.
CLEANING AND STERILISING PROCEDURES

After Use

Take care when handling handsets with probes attached - some edges are serrated and sharp.
Detach all probes from handsets using two spanners as shown in (Figure 21). If the probe is single use, dispose of in a “sharps” bin.

Probe Cleaning
(Cement Removal Consumable Probes ONLY)

After surgical use it is necessary to remove all traces of PMMA from each instrument head prior to sterilisation. This avoids the risk of contamination from small traces of tissue, which might be trapped under the cement. The cleaning system (Figure 21) is designed for use in the “sluice” room and consists of a small trolley mounted enclosure containing an ultrasound generator with timing control circuit and a cleaning cell.

Ensure that all pins and sockets on ends of handsets and handset cables are dry then re-assemble the cables, shrouds and each contaminated probe to the handset.

Insert a new cleaning cell in the OSCAR cleaning equipment. Each handset with its contaminated probe is connected via the handset cable to the socket at the rear of the enclosure. As with connection to the generator, the red dot on the handset cable must be aligned with the red dot on the connection at the rear of the cleaning system. The probe is then inserted into the cleaning cell when it is automatically energised by special circuitry incorporated in the apparatus. It is held in place in this way until the cleaning cycle is complete. A short cycle, (15 seconds) and long cycle, (30 seconds) are selectable to provide optimum cleaning conditions. Should traces of cement remain after removal from the cell, the operation may be repeated until visual inspection of the cement removal head indicates that cleaning is complete.

The cleaning cells (Figure 22) are SINGLE USE ONLY and must be discarded after use due to contamination build up.

Replacement cells are supplied with sealed ends; the seals are broken as the first revision instrument is inserted.
Single Use Probes & Osteotome Probes

The probes are supplied pre-sterilised and are designed for single patient use. After use the probes should be disposed of in a suitable “sharps” bin.

Washing

After use, remove the probes, cables, shrouds and end caps from each handset (See Figure 3). Use a non-abrasive brush, pad or similar (so as to avoid scratching the metal surface) underwater to remove any soil that adheres to the handset. The items below can be placed into a washer/disinfector load basket and passed through a standard instrument cycle. Visual inspection should be used to prove that soil is removed from the load with the cycle selected.

- Handsets (with shrouds and end caps detached)
- Handset Cables
- Re-usable Probes
- Spanners
- Slaphammer

Allow them to air dry and cool for 30 minutes.

Autoclaving

Cement Removal Handsets (with shrouds and end caps detached)
Osteotome Handsets (with shrouds and end caps detached)
Handset Cables
Re-usable Probes
Spanners

To sterilise, wrap the instrument tray and use a porous load steam autoclave. The parameters for this are 134-137°C for a minimum of 3 to 3.5 minutes. These instruments have been validated for sterilisation by this method, in an autoclave conforming to EN285.

Care should be taken to ensure that the cables are not kinked during sterilisation as this can produce cracks in the cable and reduce its life.

After Autoclaving

The handsets should be allowed to cool for at least 2 hours.
It is always best to begin with the equipment at room temperature before using again.

Generator & Footswitch

The generator and footswitch may be cleaned with a cloth moistened with Isopropyl Alcohol after use.

- The handset should not be stored or transported with the probes attached.
- A valid decontamination certificate must accompany each returned handset.

N.B. ALL PARTS SHOULD BE PLACED ON ONE TRAY AND RETURNED TO THE THEATRE AS A FULL SET.
SAFETY PRECAUTIONS AND EQUIPMENT CARE

BEFORE USE

Scratches on Probes

OSCAR probes are susceptible to damage if forced into contact with metal (e.g. screw, retractor, or part of the prosthesis) when active. The consequence of scratching a probe is to raise the mechanical stress in the region of the scratch (a "stress raiser") when the probe is vibrating. If the stress is raised sufficiently there is a risk of the probe suffering metal fatigue and cracking. Fatigue failure is more likely if the stress raiser is close to one of the fixed points of maximum mechanical stress in the vibrating probe.

Replace any probe which has a scratch in the regions indicated below, if the scratch is deep enough to be detected by sliding a fingernail over it.

- **Long Probes** (eg. 6, 8, 10mm piercers, 6, 8mm scrapers)
  Scratches at the midpoints of the two thinnest straight sections of the shaft.

- **Short Probes** (eg. 10mm scraper, groover)
  Scratches at the midpoint of the thinnest straight section of the shaft.

- **Acetabular**
  Scratches near the head where the curvature is tightest.

**Note 1.** Scratched probes may be returned to the manufacturer for assessment and polishing if no other damage is evident.

**Note 2.** Single use probes, due to their smaller distal stem section are more vulnerable to fatigue failure related to surface impact damage. This is more likely in the case of prosthesis removal instruments when metal contact is unavoidable. However the flat osteotomes are designed to be used so that the flat faces rub against the prosthetic stem and distal contact is avoided. This method of application also avoids damage to the serrated edges.

Damage or Wear on Piercer and Scraper Cutting Heads

The curved flange on the cutting head of most probes will eventually become blunt. The lifetime depends on the amount of use but efficient cement cutting is generally reduced significantly after approximately 30 revisions. In addition to this part of the flange may break off if it has worn down, especially on the piercer probes that have holes in the flange.

- Replace any probe for which the rear facing cutting edge is clearly rounded.
- Replace any probe on which more than 25% of the flange circumference is missing.
- Replace any piercer probe which has “lost” one or more of the holes in the flange.

Damage or Wear on Cables

Before use it is recommended that the cables are inspected for damaged insulation.
Warnings -In Use

- Do not operate OSCAR in the presence of flammable gases or liquids.

- Single use probes should not be reprocessed under any circumstances.

- As no clinical evaluation is available, Orthosonics Ltd is unable to confirm the safety of use of the OSCAR where a patient or an operator of the unit has been fitted with a cardiac pacemaker. It is, therefore, left to the clinician's discretion as to the use of the OSCAR in this situation. However no adverse effects have been reported.

- Please take care of the handsets, probes and cables as rough treatment may affect the safety and performance of the unit.

- The use of handsets or probes not supplied as part of the OSCAR system may damage the generator and create a safety hazard for the operator and patient.

- Avoid allowing an energised probe to come into contact with any metal surface.

- Avoid touching or holding the probes when the handset is energised.

- The generator may be shutdown ( disconnected ) by use of the switch on the rear panel.

- Where possible, avoid allowing probes to become stuck in cement as this may cause the generator thermal trip to operate. However if this situation occurs refer to section Problems and Solutions: Removal of probe stuck in cement.

- Do not allow an energised probe to come into firm contact with skin or muscle, as this will cause a friction burn. Skin should be protected with a dry swab.

- Do not over tighten the probes to the handsets.

- The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by Orthosonics Ltd as replacement parts for OSCAR (see Appendix 2 for full listing), may result in increased emissions or decreased immunity.

- OSCAR should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary OSCAR should be observed to verify normal operation in the configuration in which it will be used.

- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

- Mains Isolation is achieved by use of the double pole switch located on the rear panel.

- No modification of this equipment is allowed.

- Do not use OSCAR simultaneously with laser equipment or high frequency surgical equipment.
Storage of Equipment Between Cases

Do not operate OSCAR in the presence of flammable gases. It is recommended that the handsets and cables are stored, between cases, in a large autoclave tray and again, care should be taken to ensure that the cable is not kinked close to the connector. In this situation it is much easier to coil the cable when the handset is disconnected.

Maintenance

There are no user-serviceable parts in OSCAR.

Any damage to the handsets or cables should be reported and the components returned to Orthosonics Ltd for repair or replacement at the earliest opportunity.

Fuse Replacement

To replace rear fuses, first disconnect generator from supply mains. The fuse drawer may be extracted by inserting a small flat bladed screwdriver into the slot adjacent to the On/Off switch. Ensure that the replacement fuse is of the correct type (see Appendix 1).

Disposal

All SINGLE USE probes must be disposed of following standard Theatre procedures, ideally in an appropriately sized 'sharps' bin after use.

The generator, handset and footswitch may be returned to the manufacturer for safe disposal at their end of life.

Precautions During Surgical Procedure

The handset instruments are machined from a special titanium alloy and the profile of each instrument is carefully controlled to minimise the likelihood of metal fatigue and to ensure that it functions correctly throughout its expected life of six to nine months (30-50 operations). It is important to ensure that the instrument tip does not touch any metal component whilst the handset is engaged. Even a brief contact with a screw, retractor, or part of the prosthesis can result in serious damage and impair the performance of the instrument. Sparks may sometimes be seen if the probe tip comes into contact with metal.

The back scraper will lose its sharp cutting edge if it is in contact with hard cortical bone. Cracks in the piercer head will reduce its cutting efficiency, although it will still function.

If a probe becomes damaged during a procedure it is possible to replace it by unscrewing it from the distal part of the horn using a 9mm spanner. While replacing a probe in this way it is most important not to get talcum powder, blood or any form of contamination on the mating surfaces as this will cause them to become eroded and materially affect the ultrasonic conduction of the wave guide, making it less efficient. Cables should not be compressed during cement removal as this can cause fracture of the components of the cable.

Any damage to the probes or cables should be notified and the components returned to Orthosonics for repair or replacement at the earliest opportunity.

Irrigation During Cement Removal

Irrigation of the bone canal following a period of cement removal is important for two reasons. Firstly, it clears the canal of cement debris and secondly it maintains safe operating temperatures.

It is recommended that irrigation, in the form of pulsed lavage or manual irrigation, is used intermittently following use of the scrapers or groover probes and that the frequency of irrigation is more frequent when using the piercer probes.

It is recommended that irrigation is used more frequently in the following instances:

1. Cement removal in the upper extremity limbs
2. Knee revisions
3. Cases of femoral cortices which are particularly thin

Do not irrigate during ultrasonic energy application, this will compromise the speed of removal and efficacy of transmission. The design of the OSCAR probes is specifically aimed at achieving rapid heating and transference of the softened cement. Cooling during an energy cycle will delay this action and reduce the energy available.

Notes:
If possible chilled saline should be used
Refer to video material of OSCAR use
Irrigation During Cementless Revision

It is important to maintain a steady flow of saline around the prosthetic stem during insertion of the flat osteotomes, particularly when cutting cortical bone. This ensures that the metal on metal interface is kept cool and lubricated whilst the active edges of the osteotome are cutting bone.
OPERATIVE TECHNIQUE

Setting Up

Taking the required handsets (see Figure 3 & Figure 4), attach the required probes to the handset horn as shown in (Figure 22) seen opposite. Attach the required probe to the handset horn using suitable sterilised spanners. One on the handset horn and one on the probe. Do not use a single spanner to attach the probe as this may damage the handset.

Connect the handset to either channel on the front panel of the generator. To connect the handset cable, line up the red dots on the cable connector and generator/handset connector and push. The connector will click into place (to disconnect pull on the front grooved part of the connector). If footswitch activation is required then connect the air tubes (note colour coding) from the footswitch to the relevant air nozzle on the front panel to channel I or II. (See Figure 23) below.

First ensure that the device is plugged into mains voltage and that the switch on the back of the machine is in the ‘ON’ position.

When the generator is first switched on, the LCD will display **SELECT A CHANNEL**. In order to select the required channel, simply depress the required handset switch or footswitch once on cement removal or osteotome handsets. Once selected, the generator will sound a beep and the appropriate channel LED will illuminate. The LCD will display which type of handset has been selected. (See Figure 24).

Channel I Selected
To activate the selected channel, press and hold either the handset switch or footswitch. When activated the relevant channel LED will turn yellow and the sounder will activate. The handset will tune to its resonant frequency. Only one channel can be active at any one time. To change channels, connect appropriate handset and depress the hand/foot switch once.

**Channel LED illuminates yellow**
*When handset active*

Channel I Activated

The generator will now tune the handset to its resonant frequency every time the handset is operated. When the handset is activated the LED for that channel will turn yellow and the sounder will beep on / off as long as the handset is active. The frequency is displayed and the power bar graph indicates power delivery to handset. A countdown timer will commence from the moment the handset activates. (Maximum ON time is 30 seconds). When the countdown timer approaches zero, the sounder pitch will rise.

The handsets will feel silky when light pressure is applied to the attached probe. **It is most important not to squeeze the probe**, as this will cause a friction burn to the tissues. It is equally important not to allow the probe to come into firm contact with the patient’s skin or muscle during operation. The shroud allows the surgeon to hold the handset with both hands in a comfortable and controllable manner. The patient’s tissue should be protected using a dry swab.

As pressure is exerted on the handset the power output will increase and this is displayed via the power bargraph. If too much pressure is exerted, the cutting performance will decrease and an alarm will sound. This will occur when the power bargraph is on full deflection to the right. As the pressure on the handset relaxes the alarm will cease and cutting performance will improve.

**The Display**

The LCD will display the handset frequency, the time left for activation and a power bargraph, illustrating loading of the handset. (As the mechanical load on the handset / probe is increased, the power delivered to the handset increases). With no load applied, i.e., with the handset running in air, the bargraph should display one or two illuminated rectangles.
Each channel LED indicator has the following meaning:

- Blue indicator illuminates when channel is selected.
- Yellow indicator illuminates when handset is active.

**WAIT - REDUCE PRESSURE**

This means too much pressure has been exerted on the handset as the handset is switched on. The channel will automatically reset after 4 secs. If this message repeatedly occurs even when running the handset in air, it is likely that the probe has fatigued and should be replaced. If the message remains then the handset has failed.

**ERROR NO LOCK**

This means the generator could not find a handset resonance in the correct frequency range. The generator will automatically reset.

**OVERTEMP**

This means the power devices within the channel power circuit have become too hot and to avoid damage the channel has shut down. The devices may overheat through extended periods of heavy loading. Allow the channel power circuit to cool for several minutes. The generator will reset the channel.

If the 'overtemp' message continues even after 10 minutes have passed, and repeated resets do not clear the message, then the power devices may have failed on that channel output.

**ACTIVE TOO LONG**

The countdown timer has timed out...the maximum time the handset can be run continuously is 30 seconds. This is to guard against the power devices overheating.

**CEMENT RELEASE MODE**

This is most likely to occur when a piercer is being used. If the tip of the piercer is pushed too deeply into the cement and allowed to remain in situ, then the cement behind the tip is liable to solidify and trap the probe. If this happens, the load on the probe may be excessive preventing normal resonance because of the mass of cement now attached to the probe. If this occurs the generator will automatically enter a 'stuck in cement' mode and display.

Energise the handset, but do not apply any pressure on the handset for the first 2 seconds of use (this gives the channel a better chance to find a resonant feature). The generator will perform repeated scans of the handset, sounding a double beep as it does so. Whilst this occurs, gently remove the probe from the cement. When free from cement the channel mode will return to normal operation.

This procedure may lead to an **OVER-TEMPERATURE** message on the LCD. Allow the channel to cool for several minutes. When the channel resets attempt removal again. This process may take a couple of attempts, depending how deep the probe is stuck in the cement.

Should an individual channel fail for any reason, the remaining channels will remain operational. When convenient return the system for servicing to Orthosonics Ltd.
Probe Use

CEMENT REMOVAL

The following description relates to hip surgery but is equally applicable to other forms of revision Arthroplasty. It is essential that the patient be placed on his/her side to facilitate cement removal. Following removal of the femoral component it is important to have adequate access to the cement. To this end it is worthwhile removing bone from the upper portion of the greater trochanter to allow straight access to the cement within the femoral canal.

Removal of the Proximal Cement Mantle

The proximal cement in the upper third of the shaft is usually loose, with a membrane between it and the bone. This cement can be removed simply, using the groover to cut longitudinal channels through it. When the cutting edge of the groover is placed in contact with the cement, the friction generated by the ultrasonic beam will heat up the cement, which softens and extrudes through the holes in the side flanges (Figure 27). The groover is then pushed gently down the femoral canal in contact with bone to remove a trough of cement. This trough can be extended within the femoral canal as far as the groover can go.

It is usual to make 3 longitudinal troughs within the cement at approximately 120-degree intervals. The amount of force required is similar to that needed push a knife through hard butter.

Once the 3 longitudinal grooves have been made, it is necessary to make circumferential grooves at approximately 1.5 to 2 cm intervals down the cement mantle. This can be done using either the groover or a back scraper. The fragments of bone cement can then be folded into the medulla and removed with forceps. The proximal cement is removed incrementally, using this technique, down to the level of the cement plug.

Figure 27: Removal of proximal cement mantle
Removal of Well Bonded Cement and Residual Membrane

Any residual well bonded cement which remains after removal of the proximal cement mantle, and the fibrous membrane which is usually adherent to the endosteal surface, may be removed using the axisymmetric reverse scraper (back scraper).

The back scraper cuts by focusing ultrasonic energy on to the retroverted cutting edge at the back of its spear shaped tip. The scraper can also be used to remove the proximal cement if the mantle is too thin for the groover.

The cutting edge is put into contact with the cement or the membrane and withdrawn with a moderate amount of force for removing cement, or just gentle pressure for removing the membrane. The membrane will peel off in strips leaving a raw cancellous surface which is ideal for bone grafting should this be required.

Removal of the Cement Plug

Removal of the cement plug is performed using the piercer. The piercer focuses ultrasound to the very tip of its spear shaped head causing the cement to liquefy at the point of contact. The liquid cement then flows backwards through the perforations in the head and solidifies behind it.

The piercer is gently pushed into the cement plug, and after advancing it for between 1.5 and 2 cm the switch on the handset is released and the handset is removed 1 or 2 seconds later. This short period of time allows the cement to solidify behind the flange for most efficient removal. (Figures 29 & 30). If the piercer is pushed with too much force, the energy at the tip will reduce and the system will work less efficiently.

The cement removed using the piercer can be simply wiped from the waveguide using a wet swab, after each application. Should the tip of the piercer come in contact with bone, the waveguide will de tune slightly and produce an audible high pitched squeaking noise. Resistance will be felt and the volume of smoke generated will diminish.
Removal of the Cement from the Distal Femur

Once the plug has been perforated, it is necessary to remove the cement that is in contact with the distal femur and this can be done either with the groover or, if the femur is too narrow, with a long back scraper. (Figure 31)

There is sometimes a polythene cement restrictor distal to the cement plug. The ultrasonic device will cut through polythene, but it does so at a slower rate than when cutting through bone cement.

In these circumstances it is necessary to wait for a few seconds before advancing the probe, as polyethylene absorbs more ultrasonic energy than polymethylmethacrylate.

Use of Extraction Probe

For rapid removal of the cement plug and under certain conditions, the OSCAR system incorporates an extraction probe and slap hammer. The extraction probe, like the piercer probes, is designed to penetrate the cement in a forward motion. The surgeon sinks the probe into the plug up to a reasonable depth and then rotates the probe and handset 90 degrees.

By removing the power and holding the probe insitu in the canal for 30 seconds, the cement re-hardens around the probe. The handset can then be detached and the slap hammer connected. Do not place excessive force on the slap hammer when in use.

X-rays will give good indication of when the extraction probe can be used. Ensure that there is good bone stock, delamination of the cement, an even tapered canal, and the cement lies above any isthmus. Incorrect positioning of the probe can easily lead to bone fracture, or other damage within the canal.
Removal of Cement from the Acetabular Cup

It is important to remember that when using OSCAR, none of the activated instruments should be allowed to make contact with metallic components; this is particularly relevant when considering its application to the acetabular cup.

By reference to the x-rays, identify and locate all metallic parts associated with the prosthesis. The acetabular probe can be used to remove cement posterior to the cup by making a series of curved slots extending from the exposed circular profile towards the centre of the cemented hemispherical surface (Figure 32).

Four or five slots should be sufficient to loosen the acetabular component, which may then be removed by careful use of a cement chisel.

Figure 32: Removal of cement from acetabular cup
UNCEMENTED STEM REMOVAL

Fixation of uncemented stems is achieved by creating a porous coating on the implant or by adding hydroxyapatite to selected portions of the surface, both of which encourage bony ingrowth and generation of new cancellous bone; when revision is necessary the implant is removed by cutting through what is a substantially cancellous bone interface surrounding the stem. This is done using a variety of flat, narrow osteotomes coupled to the specially designed bone cutting handset. The essential feature of the osteotomes is a series of edge serrations forming a saw blade. The osteotomes are introduced beside the prosthetic stem to form a series of extended slots which effectively isolate the implant from the host bone. In some cases it may be necessary to cut into cortical bone when the depth of cancellous bone is limited.

Irrigation During Cementless Revision

It is important to maintain a steady flow of saline around the prosthetic stem during insertion of the flat osteotomes, particularly when cutting cortical bone. This ensures that the metal on metal interface is kept cool and lubricated whilst the active edges of the osteotome are cutting bone. Ovine studies indicate that even without coolant only minimal damage is likely to occur at the cut interface providing that energised sequences are limited to 5-10 seconds. With cooling the full 20 second active sequence allowed by the generator control system is safe.

Please note: All osteotome probes for use with the gold osteotome handsets, are fitted with M6 threaded spigots so that they cannot be used in error with the standard cement removal handsets, which have M5 threads.

Acetabular Cup Removal

The curved serrated osteotome (See Figure 16) probe is used in a similar fashion as the cemented version Acetabular probe. The probe is first used to create slots around the circumference of the cup. Once the slots are created, the probe can be used in a lateral motion to cut the remaining bony ingrowth interface.

It is important to remember to activate the probe before advancing into a previously created slot and to not create manual pressure before activating the probe. Doing so may lead to the probe improperly tuning and possibly breaking during use.

Figure 33 - Acetabular cup removal
Tibial & Femoral Component Extraction

The steps in removing the knee components with the OSCAR bone cutting probes are similar to the stem extraction steps in hip revisions. The 6mm flat osteotome probe is used to penetrate the interface and create slots under the prosthesis. The 6mm flat serrated probe can then be used laterally to break the remaining bond between bone and prosthesis. Again, the high-pitched noise will be created by the active probe being in contact with the prosthesis. It is important to not use heavy manual force when this noise is present and to continually use irrigation while the probe is active. The OSCAR osteotome probes can greatly assist in the conservation of bone. By being a space creating tool, no wedging or forcing is needed; leading to less stress to the surrounding bone. With OSCAR, no levering motion is needed or should be used, as levering can lead to more bone loss than desired.

Stem Extraction from the Femur

The steps in removing the knee components with the OSCAR osteotome probes are similar to the stem extraction steps in hip revisions. The 6mm flat osteotome probe is used to penetrate the interface and create slots under the prosthesis. The 6mm flat serrated probe can then be used laterally to break the remaining bond between bone and prosthesis. Again, the high-pitched noise will be created by the active probe being in contact with the prosthesis. It is important to not use heavy manual force when this noise is present and to continually use irrigation while the probe is active. The OSCAR bone cutting probes can greatly assist in the conservation of bone. By being a space creating tool, no wedging or forcing is needed; leading to less stress to the surrounding bone. With OSCAR, no levering motion is needed or should be used, as levering can lead to more bone loss than desired.
PROBLEM & SOLUTIONS

Probe Stuck in Cement

This is most likely to occur when a piercer is being used. If the tip of the piercer is pushed too deeply into the cement and allowed to remain in situ, then the cement behind the tip is liable to solidify and trap the probe. If this happens, the load on the probe may be excessive preventing normal resonance because of the mass of cement now attached to the probe. If this occurs the generator will automatically enter a ‘stuck in cement’ mode and display CEMENT RELEASE MODE. Energise the handset, but do not apply any pressure on the handset for the first 2 seconds of use (this gives the channel a better chance to find a resonant feature). The generator will perform repeated scans of the handset, sounding a double beep as it does so. Whilst this occurs, gently remove the probe from the cement. When free from cement the channel mode will return to normal operation. If the display shows WAIT - REDUCE PRESSURE just wait for 4 seconds and the module will reset automatically. Again, energise handset but apply little pressure on the handset for the first two seconds of use, then slowly remove probe.

This procedure may lead to an OVER-TEMPERATURE message on the LCD. Allow the channel to cool for several minutes. When the channel resets attempt removal again. This process may take a couple of attempts, depending how deep the probe is stuck in the cement.

Metal Fatigue

This can occur if the probe comes into contact with metal and becomes scratched, causing a stress riser to appear. When this happens, fragments of the probe are at risk of coming off during operation.

Solution: Change the probe and replace at the earliest opportunity.
Intermittent Power During Operation

If the handset/probe suffers from intermittent power and a clicking noise, caused by the tripping of relays, coming from the generator, then the cable connecting the handset to the generator will have fractured.

Solution: Change the cable associated with the defective system.

Low Power During Operation

i. The probe will appear to be working inefficiently if it is pressed too hard into the cement. The generator will alert the surgeon by sounding an alarm.

Solution: Ease of pressure to enable the probe to work at maximum efficiency always press the tip gently into the cement and use gentle force:- allow the ultrasound to do the work.
Avoid excessive force at all times.

ii. Lack of power during cutting can be due to the interface between the probe and the handset being slack.

Solution: Tighten the connection using the 9mm spanner provided. The power level can also be diminished if this interface is not clean and has been damaged due to the presence of particles. Should this occur, it is necessary to re surface the interface, which can be done by Orthosonics Ltd.
Should the stud attached to the probe become loose, it must be returned to Orthosonics Ltd for repair.

iii. Loss of power when cutting cement can also be due to the crystals in the handset overheating. The crystals will heat up naturally during normal use, but if excessive force is used for prolonged periods of time this heating will affect performance. As the handset warms up its resonant frequency will drop. If the handset becomes too warm the frequency will drop out of the handsets’ working range and the channel will shut down. The LCD will display ERROR NO LOCK.

Solution: Use another handset and allow the hot handset to cool down. The channel will reset automatically when the handset is cool.
## APPENDICES
### Appendix 1 - Markings on the OSCAR 3 Front and Back Panels

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<th>Markings</th>
<th>Description</th>
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## Appendix 2 - OSCAR Parts List

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<tr>
<td>Piercer 8mm (Single Use)</td>
<td>1</td>
<td>Figure 9</td>
<td>OHP2080SU</td>
</tr>
<tr>
<td>Piercer 6mm Slim Shafted (Single Use)</td>
<td>1</td>
<td>Figure 11</td>
<td>OHP2062SU</td>
</tr>
<tr>
<td>Acetabular Probe</td>
<td>1*</td>
<td>Figure 8</td>
<td>OHA2030</td>
</tr>
<tr>
<td>Extension Bar</td>
<td>1*</td>
<td></td>
<td>OHE2000</td>
</tr>
<tr>
<td>Slaphammer</td>
<td>1</td>
<td>Figure 13</td>
<td>IPL200</td>
</tr>
<tr>
<td>Extraction Probe (Single Use)</td>
<td>1</td>
<td>Figure 12</td>
<td>EXP2681SU</td>
</tr>
<tr>
<td>Flat Serrated Osteotome</td>
<td>OPTION</td>
<td>Figure 14</td>
<td>OHSO2060SU</td>
</tr>
<tr>
<td>Flat Non Serrated Osteotome</td>
<td>OPTION</td>
<td>Figure 15</td>
<td>OHFO2060SU</td>
</tr>
<tr>
<td>Curved Serrated Osteotome</td>
<td>OPTION</td>
<td>Figure 16</td>
<td>OHC252060SU</td>
</tr>
<tr>
<td>Instrument Cleaner</td>
<td>1</td>
<td></td>
<td>OC200</td>
</tr>
<tr>
<td>Cleaning Cell</td>
<td>10</td>
<td></td>
<td>OC201</td>
</tr>
<tr>
<td>Spanner</td>
<td>1*</td>
<td></td>
<td>OSSP8</td>
</tr>
<tr>
<td>Spanner</td>
<td>2*</td>
<td></td>
<td>OSSP9</td>
</tr>
<tr>
<td>Generator Carry Case</td>
<td>1*</td>
<td></td>
<td>OSC300</td>
</tr>
<tr>
<td>Handset Carry Case</td>
<td>1*</td>
<td></td>
<td>OHC301</td>
</tr>
<tr>
<td>Extension Bar Long (For Single Use Probes)</td>
<td>OPTION</td>
<td></td>
<td>OHRE2001</td>
</tr>
<tr>
<td>Piercer Probe 10mm (Single Use)</td>
<td>1</td>
<td></td>
<td>OHP2100SU</td>
</tr>
<tr>
<td>Scraper Probe 10mm (Single Use)</td>
<td>1</td>
<td></td>
<td>OHS2100SU</td>
</tr>
<tr>
<td>Hoe Probe 6mm (Single Use)</td>
<td>OPTION</td>
<td>Fig 17</td>
<td>OHH2062SU</td>
</tr>
<tr>
<td>Hoe Probe 8mm (Single Use)</td>
<td>OPTION</td>
<td>Fig 17</td>
<td>OHH2081SU</td>
</tr>
<tr>
<td>Acetabular (Single Use)</td>
<td>OPTION</td>
<td></td>
<td>OHA2030SU</td>
</tr>
</tbody>
</table>

*SUPPLIED AS STANDARD
## Appendix 3 - Technical Specification

### Dimensions:
- **Caseframe:** 457mm (width) x 140mm (height) x 355mm (depth)

### Weight:
- **Caseframe:** 7.5kg
- **Transport case:** 15 kg
  - (loaded with caseframe)
- **Handsets:**
  - Cement removal / Osteotome: 0.8 kg
  - Transport case: 13.6 kg
  - (loaded with handsets, probes, accessories)

### Fuse Type:
- 2 x T5A 250V ac, 20mm

### Power supply input:
- 230V ac

### Power consumption:
- 175W

### Output - Frequency of operation:
- 28kHz (Channel I & II)

### Output - Accuracy of frequency display:
- ±1%

### Output power:
- 150W

### Mode of operation:
- Intermittent use 10s ON / 20s OFF (Channel I & II)

### Electrical classifications:
- **Generator:** Class 1 (generator has a protective earth connection)
- **Handsets:** Type B (patient applied parts are at earth potential)

### Handset:
- Titanium, stainless steel enclosure, silicone and viton components, with sealed switch and cable connector suitable for autoclave sterilisation. Connecting cable provided with earthed screen.

### Ingress protection
- **Generator:** IPX0
- **Handsets:** Autoclavable

### Environment for transport & storage
- **Temperature:** -40°C to +50°C
- **Humidity:** 10% to 100%
- **Atmospheric pressure:** 500hPa to 1060hPa

### Environment for use
- **Temperature:** 0°C to +30°C
- **Humidity:** 30% to 75%
- **Atmospheric pressure:** 700hPa to 1060hPa

OSCAR 3 has been designed and built in accordance with ISO 13485:2003 Quality Assurance standard for medical devices and Part 820 of the Title 21 of the Code of Federal Regulations of the USA. The equipment complies with BSEN60601-1. The product is covered by worldwide patents covering all international markets.

Orthosonics Ltd will provide on request, circuit diagrams, component parts lists and descriptions. However, Orthosonics Ltd do not designate any part of the equipment as user repairable.
Appendix 4: Electromagnetic Interference

This equipment has been tested and found to comply with the limits for a medical device. However should interference occur, the user can try the following measures:

1. Turn equipment off and on to confirm the source of the interference
2. Increase separation between this equipment and other devices.
3. Connect this equipment to a power socket different from that to which the other devices are connected.
4. Consult medical physics department.

Medical Electrical Equipment needs special precautions regarding EMC and needs to installed and put into service according to the EMC information provided in this manual.

Portable and mobile RF communications equipment can affect medical electrical equipment.

Table 1

<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 1</td>
<td>OSCAR uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RF emissions</td>
<td>Class A</td>
<td>OSCAR is suitable for use in all establishments other than power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Harmonic emissions</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations</td>
<td>Complies</td>
<td></td>
</tr>
<tr>
<td>/flicker emissions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Table 2**

*Guidance and manufacturer’s declaration - electromagnetic immunity*

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

<table>
<thead>
<tr>
<th>IMMUNITY test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>±6 kV contact</td>
<td>±6 kV contact</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>IEC 61000-4-2</td>
<td>±8 kV air</td>
<td>±8 kV air</td>
<td></td>
</tr>
<tr>
<td>Electrical fast transient/burst</td>
<td>±2 kV for power supply lines</td>
<td>±2 kV for power supply lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC61000-4-4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surge</td>
<td>±1 kV differential mode</td>
<td>±1 kV differential mode</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-5</td>
<td>± 2 kV common mode</td>
<td>± 2 kV common mode</td>
<td></td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines</td>
<td>&lt;5 % UT (&gt;95 % dip in UT) For 0.5 cycle</td>
<td>&lt;5 % UT (&gt;95 % dip in UT) For 0.5 cycle</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of OSCAR requires continued operation during power mains interruptions, it is recommended that OSCAR be powered from an uninterruptible power supply.</td>
</tr>
<tr>
<td>IEC 61000-4-11</td>
<td>&lt;40 % UT (&gt;60 % dip in UT) For 5 cycles</td>
<td>&lt;40 % UT (&gt;60 % dip in UT) For 5 cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt;70 % UT (&gt;30 % dip in UT) For 25 cycles</td>
<td>&lt;70 % UT (&gt;30 % dip in UT) For 25 cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt;5 % UT (&gt;95 % dip in UT) For 5 s</td>
<td>&lt;5 % UT (&gt;95 % dip in UT) For 5 s</td>
<td></td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC61000-4-8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NOTE UT is the a.c. mains voltage prior to application of the test level
**Table 3**

**Guidance and manufacturer’s declaration - electromagnetic immunity**

OSCAR is intended for use in the electromagnetic environment specified below. The customer or the user of OSCAR 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>3V rms 150kHz to 80 MHz Outside ISM bands</td>
<td>3V rms</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of OSCAR, 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 80MHz to 2.5GHz</td>
<td>3 V/m</td>
<td>Recommended separation distance</td>
</tr>
</tbody>
</table>

\[
d = \left\{ \begin{array}{ll}
\frac{P}{10000} & \text{at 80 MHz and 800 MHz} \\
\frac{P}{1000} & \text{at 800MHz to 2.3GHz}
\end{array} \right.
\]

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

- **a** Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the in the location in which OSCAR is used exceed the applicable RF compliance level above, OSCAR should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating OSCAR.
- **b** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m
Appendix 5: Contact

The product is covered by worldwide patents covering all international markets
If the unit requires repair please contact:

Orthosonics Ltd.
Burney Court
Cordwallis Park
Maidenhead
Berkshire
UK
SL6 7BZ

www.orthosonics.com

Tel: +44 (0)1628 594500
Fax: +44 (0)1628 789400
OSCAR has been designed and built in accordance with ISO 13485:2003 Quality Assurance standard for medical devices and Part 820 of the Title 21 of the Code of Federal Regulations of the USA. CE conformance has been certified and the equipment complies with BSEN60601-1.