USER MANUAL

Keep this leaflet: you may need to read it again. Discard previous versions

Important information - please read prior to use . See also instruction leaflets PQPRO for single use probes and PQRMD for reusable medical devices.

Oscar Pro™

System

ORTHOFIX®
ORTHOPEDICS

0. IMPORTANT INFORMATION UPON DELIVERY

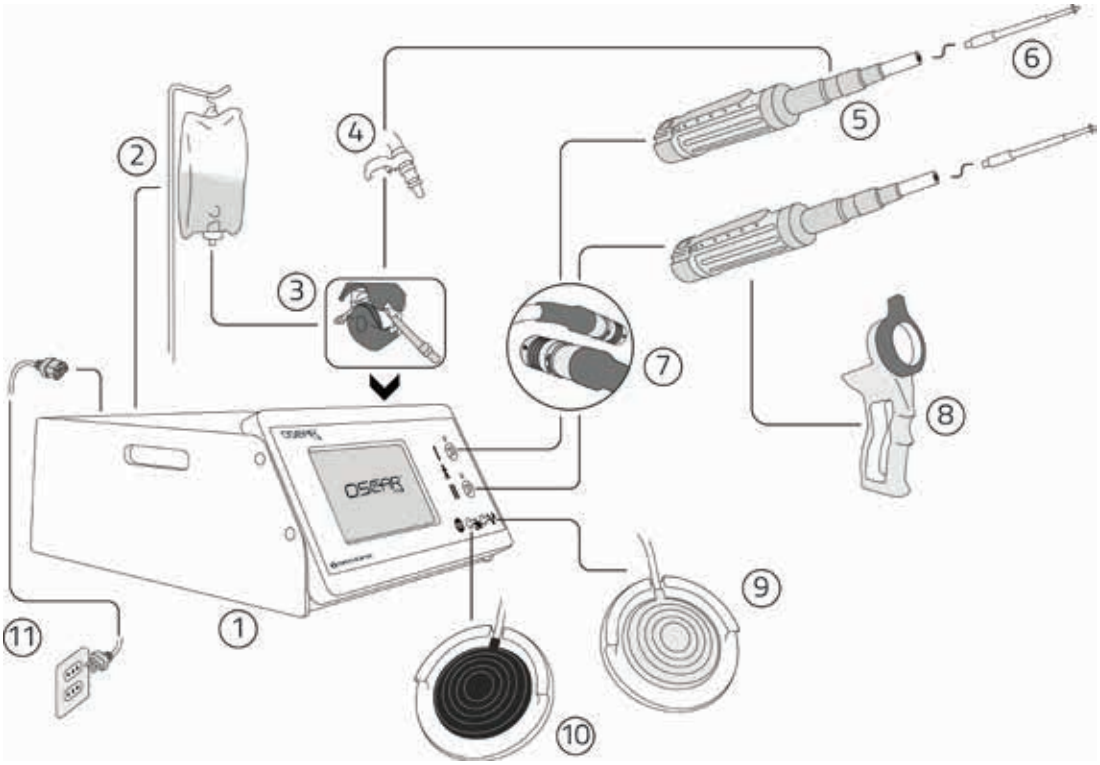
Section 0 and **Section 1** of this Manual contain important information for the identification, handling and first power on of the OSCAR PRO™.

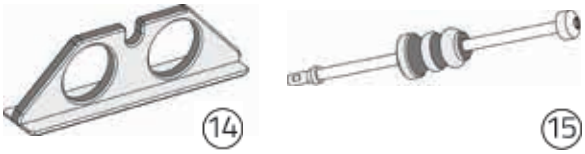
Conventions on Warnings and Precautions	
WARNING	Disclosure of residual risk after all possible mitigations applied by Orthofix.
PRECAUTION	Prescription of risk mitigation to be adopted by user to minimise exposure to hazard.
NOTE	Useful information to allow efficient use of the system.

0.1. FIRST VERIFICATION UPON DELIVERY

Conventions on Warnings and Precautions	
PRECAUTION	In case of visible damage to packaging or device upon delivery, do not use the device and contact the manufacturer for assistance or replacement.
PRECAUTION	After receiving OSCAR PRO™, transport and store the device in its dedicated transport case. Using different container may result in damage, malfunction or failure before or during use.

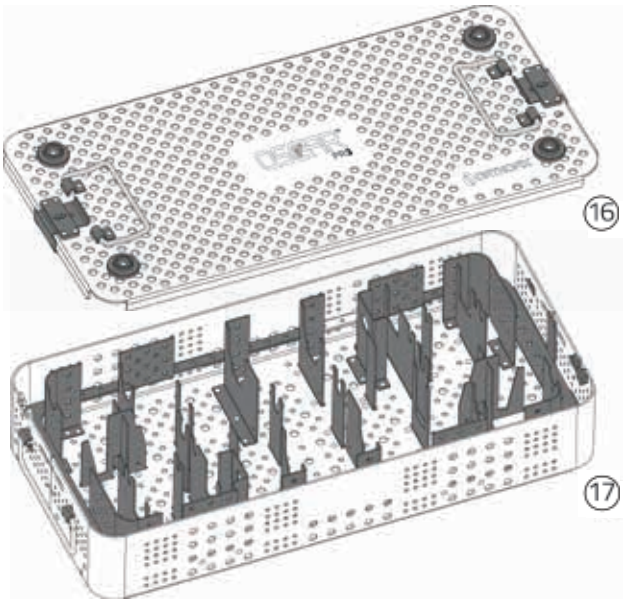
0.2. DEVICE PARTS IDENTIFICATION





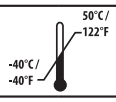
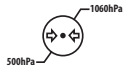
Part #	Code	Description
1	OS4000*	OSCAR PRO GENERATOR
2	04BEAM	OSCAR PRO HOLDER FOR WATER BAG L459mm
3		PERISTALTIC PUMP, embedded in the generator
4	2000972	STERILE KIT FOR PERISTALTIC PUMP (not for sale in Canada)
4	800001	STERILE KIT FOR PERISTALTIC PUMP US (not for sale in Canada)
5	04HAND*	OSCAR PRO UNIVERSAL HANDSET
6		PROBE, various models, provided separately
7	04CABLE	OSCAR PRO UNIVERSAL HANDSET CABLE
8	04UHH	OSCAR PRO UNIVERSAL HANDSET HANDLE
9	04FOOT-W*	OSCAR PRO FOOTSWITCH FOR IRRIGATION
10	04FOOT-U*	OSCAR PRO FOOTSWITCH FOR ULTRASOUND
11		OSCAR PRO MAIN LEAD, various models
12	SPAN7mm	SPANNER 7mm
13	SPAN8/9mm	SPANNER 8/9mm
14	04HOLD	OSCAR PRO HANDSET HOLDER
15	04IPL200	OSCAR PRO SLAP HAMMER
16	04TRAY-02	OSCAR PRO LID TRAY
17	04TRAY-01	OSCAR PRO BASE TRAY

* Component of the device: OSCARPRO – ULTRASOUND MEDICAL SYSTEM



0.3. SYMBOL EXPLANATION

APPENDIX 1	Markings	
Symbol	**Description**	
MD	Medical Device	
REF	Catalogue number	
LOT	Batch code	
	Follow instruction for use	
CE / CE 0123	CE marking in conformity to applicable European Medical Device Directives/Regulations	
	Date of manufacture	Manufacturer
VOLTAGE: 115-240 V 50-60 Hz	Supply AC Voltage Supply AC Frequency	
POWER: 250 VA	Input Power	
28kHz 150W	Output Power	
T5A H 250V 5x20mm	Fuse Details	
|	Supply Power ON	
○	Supply Power OFF	
	Disposal. In accordance with the WEEE 2012/19/UE Directive, the product and all its parts (cable, batteries, accessories, etc.) may not be treated as domestic waste. For further information regarding disposal, contact the appropriate department of your local council or the manufacturer service personnel.	
	Warning: counterrotating rollers. Do not operate with open cover.	
	On peristaltic pump embedded in the generator: Flow direction of irrigation liquid.	
FOR INTERMITTENT USE ON/OFF	10 | 20 s	
	Output connector	
	Type B Applied Part	
	Equipotential	
	From left to right: Ultrasound - Footswitch connections - Irrigation	
	Wi-Fi connectivity	
	USB port (for mass storage NOT connected to other devices, network or power supply)	
	Caution	

	Stand-by
Rx Only	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
	Temperature limitation
	Humidity limitation
	Atmospheric Pressure limitation
	Non-sterile
	Unique Device Identifier
	Caution : Consult instructions for use for important cautionary information
	Consult instructions for use or consult electronic instructions for use
FRAGILE	Fragile
	Ultrasound
	Irrigation
	Locking – Unlocking direction

0.4. SPECIFICATIONS

APPENDIX 2	Technical Specification	
Symbol	**Description**	
Dimensions:	Generator	377 mm(width) x 180 mm(height) x 415 mm(depth)
Weight:	Generator	9.1 Kg.
	Transport case (loaded with generator) and accessories	19.5 Kg
	Handset	0.8 Kg
	Transport case (loaded with handset, probes, accessories)	11.9Kg
Fuse Type	T5A H 250V 5x20mm	
Power Supply input	115 – 240 V	
Power Consumption	250 VA	
Output – Frequency of operation	28kHz (Channel I and II)	
Output - Accuracy of frequency display	±1%	

Output power	150 W		
Volume Adjustment	53 dbA - 88 dBa		
Mode of operation	Intermittent Use ON | OFF (Channel I & II) 10s | 20s		
Electrical Classification	Generator Class I - generator has a protective earth connection Handset probes: Type B (patient applied parts are at earth potential)		
Power Supply Switch	Mean to isolate equipment circuits electrically from the supply mains on all poles simultaneously		
Wireless: Radio-frequency specifications	Transmission and receiving frequencies [bandwidth]	Maximum output	
	2.4GHz 801.11b [2400~2483.5 MHz]	12.95mdBm	19.72 mW
	2.4GHz 801.11g [2400~2483.5 MHz]	12.89mdBm	19.45 mW
	2.4GHz 801.11n HT20 [2400~2483.5 MHz]	12.78mdBm	18.97 mW
	2.4GHz 801.11n HT40[(2400~2483.5 MHz]	10.28mdBm	10.67 mW
Handset materials	Handset enclosure: Aluminum alloy EN-AW 7075 conforming to UNI EN 573 Handset transducer: Titanium alloy + Piezoelectric ceramic + Silicone rings		
Slap Hammer material	Stainless Steel AISI304 conforming to ASTM F899 and ISO 7153-1		
Ingress protection	Generator: IPX0 Handset: autoclavable		
Environment for transport and storage	Temperature: Humidity: Atmospheric pressure:	-40°C to +50°C | -40 °F to +122 °F 10% to 90% 500hPa to 1060hPa	
Environment for use	Temperature: Humidity: Atmospheric pressure:	10°C to 30°C | +50 °F to +86 °F 30% to 75% 700hPa to 1060hPa	
Other Accessories	Transport cases for the generator (GENERATOR FLIGHT CASE) and for the instrument tray (INSTRUMENT FLIGHT CASE).		
Items to be sterilised (moist heat sterilisation)	Reference **section 9.5** for details of reprocessing. 04HAND OSCAR PRO UNIVERSAL HANDSET 04CABLE OSCAR PRO UNIVERSAL HANDSET CABLE 04UHH OSCAR PRO UNIVERSAL HANDSET HANDLE 04HOLD OSCAR PRO HANDSET HOLDER SPAN7MM SPANNER 7 MM SPAN8/9MM SPANNER 8/9MM 04IPL200 OSCAR PRO SLAP HAMMER 04TRAY OSCAR PRO INSTRUMENT TRAY		
Detachable parts	See **section 3.2** for identification. 04HAND-05 HANDSET HORN ENCLOSURE 04HAND-04 HANDSET BUTTON LEVER		
OSCAR PRO™ has been designed and built in accordance with ISO 13485 Quality Assurance standard for medical devices and Part 820 of the Title 21 of the Code of Federal Regulations of the USA.			

0.5. ELECTRICAL SAFETY STATEMENT

The equipment complies with EN 60601-1 and IEC 60601-1.

The verification of electrical safety according to EN 60601-1 and IEC 60601-1 is performed by Orthofix before delivery and is valid until the date specified in the dedicated label on the back panel of the generator.

The generator is provided with a receptacle for connection of a POTENTIAL EQUALIZATION CONDUCTOR conforming to requirements of EN 60601-1 (ref. Figure 8 and symbol in **section 0.3**).

Warning and Precaution	
WARNING	The electrical safety label is valid if all parts of the system are used, transported and stored according to the instructions of this manual. After the expiry date of electrical safety, Orthofix is not responsible for malfunctioning, damage to the device, environment or other objects, or harm to users or patient, that may be related to the loss of electrical safety.
PRECAUTION	To avoid the risk of electric shock, this equipment must be connected to a grounded power supply. Appropriate system grounding can only be ensured when an approved, hospital-grade receptacle and matching power cord are used. Install plug and receptacles as per local regulations before operating the unit. Power cord, plug and receptacle should be examined to verify that they are in good working condition before connecting the generator. Never pull on the power cord to remove it from the receptacle.

The product is covered by worldwide patents covering all international markets. Orthofix will provide circuit diagrams, component parts lists and descriptions on request. However, Orthofix does not designate any part of the equipment as user-repairable.

0.6. ELECTROMAGNETIC COMPATIBILITY (EMC) STATEMENTS

This equipment has been tested and found to comply with the limits for a medical device.
However, should interference occur, 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 be 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.

Warning	
WARNING	Careful consideration should be given to patients who have pacemakers or other active implanted devices. Interference produced can cause pacemaker or other active implantable device to malfunction, enter an unsafe mode, or cause permanent damage to the device. Consult the pacemaker or other active device manufacturer Instruction For Use for specific info.

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions		
OSCAR PRO™ is intended for use in the electromagnetic environment specified below. The customer or the user of OSCAR PRO should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The OSCAR PRO™ must emit electro-magnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	OSCAR PRO™ is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Complies	

Table 2

Guidance and manufacturer's declaration - electromagnetic immunity			
OSCAR PRO™ is intended for use in the electromagnetic environment specified below. The customer or the user of OSCAR PRO should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	8kV contact 2kV, ± 4kV, ± 8kV, ± 15kV air	8kV contact 2kV, ± 4kV, ± 8kV, ± 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for signal lines	± 2kV for power supply lines ± 1kV for signal lines	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV line to line ± 2kV line to earth	± 1kV differential mode ± 2kV common mode	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5s	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5s	Main power quality should be that of a typical commercial or hospital environment. If the user of OSCAR PRO™ requires continued operation during power main interruptions, it is recommended that OSCAR PRO™ be powered from an uninterruptible power supply.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment
NOTE UT is the a.c. main voltage prior to application of the test level			

Table 3

List of Cables		
Item	**Length**	**Type**
Handset Cable	3.0 m	Shielded 4-conductor
Power cord	3.0 m	Unshielded 3-conductor

Precaution	
PRECAUTION	The use of accessories, handsets and cables other than those provided with OSCAR PRO™ may result in increased emissions and reduced immunity of the device. Such issues may result in user and/or patient harm. Use only Orthofix branded equipment and accessories.

Table 4

Guidance and manufacturer's declaration - electromagnetic immunity			
OSCAR PRO™ is intended for use in the electromagnetic environment specified below. The customer or the user of OSCAR PRO should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3Vrms 150kHz to 80MHz 3V/m 80MHz to 2.5GHz	3Vrms 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of OSCAR PRO™, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$, 80MHz to 800MHz $d = 2.3\sqrt{P}$, 800MHz to 2.3GHz 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 80MHz and 800MHz, the higher frequency range applies NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which OSCAR PRO™ is used exceeds the applicable RF compliance level above, OSCAR PRO should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary,such as re-orienting or relocating OSCAR PRO. [b] Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.			

Table 5

Recommended separation distances between portable and mobile RF communications equipment and OSCAR			
OSCAR PRO™ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of OSCAR PRO™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and OSCAR PRO™ as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter	**Separation distance according to frequency of transmitter**		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	**80MHz to 800MHz $d = 1.2\sqrt{P}$**	**800MHz to 2.5GHz $d = 2.3\sqrt{P}$**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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 80MHz and 800MHz, 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.			

0.7. SUMMARY OF SAFETY INFORMATION

Please read this section of the manual carefully. It contains a summary of all precaution, warning and caution statements contained in the manual. However, the user is advised to read the entire manual and operate the device only in accordance with all of the instructions contained herein. Servicing of this device should only be performed by qualified technicians authorised by Orthofix. There are no service controls accessible to the user.

0.7.1. Warnings

CONTEXT	INFORMATION
Preparation	The electrical safety label is valid if all parts of the system are used, transported and stored according to the instructions of this manual. After the expiry date of electrical safety, Orthofix is not responsible for malfunctioning, damage to the device, environment or other objects, or harm to users or patient, that may be related to the loss of electrical safety.
Use	Careful consideration should be given to patients who have pacemakers or other active implanted devices. Interference produced can cause pacemaker or other active implantable device to malfunction, enter an unsafe mode, or cause permanent damage to the device. Consult the pacemaker or other active device manufacturer Instruction For Use for specific info.
Use	Portable and mobile RF communication equipment can affect medical electrical equipment. If RF equipment is necessary, monitor the OSCAR PRO™ for appropriate function during the procedure.
Use	During use, warning messages may be displayed on the screen in relation to a specific event or machine status. Refer to **section 10** of this manual for the meaning of each message.
Use	In case of excessive load, the OSCAR PRO™ warns the user with specific luminous and acoustic signals. See **section 8** and **section 10**.
Reprocessing	Single use devices MUST NOT BE REUSED, as they are not designed to perform as intended after the first usage. The used probes MUST BE discarded after the surgical procedure. Do not attempt to reuse or re-sterilise any single-use items.
Reprocessing	Personnel working with contaminated medical devices must follow safety precautions as per the healthcare facility's procedures.
Reprocessing	Take care when handling handsets with probes attached, some edges are serrated and sharp.
Reprocessing	DO NOT USE detergents and disinfectants with fluoride, chloride, bromide, iodide or hydroxyl ions. Their use will damage the devices and may cause device failure during use.
Reprocessing	Contact with saline solutions should be kept to a minimum.
Reprocessing	The use of ultrasonic washers is not permitted for cleaning the ultrasonic generator, the handsets, the main lead and the footswitches with their pneumatic tubes.
Reprocessing	The ultrasonic generator, main lead and footswitches with their pneumatic tubes must not be immersed in cleaning solution.
Reprocessing	Sterilisation of the ultrasonic generator, main lead and footswitches with their pneumatic tubes is not permitted.

Reprocessing	During washing, avoid contact between devices because movement could cause damage to devices and the washing efficacy could be reduced.
Reprocessing	Do not include additional devices or instruments in the sterilisation tray. Sterility is not guaranteed if the sterilisation tray is overloaded.
Maintenance	Use only USB mass storage devices with no connection with other devices and no connection to power supply. Failing to comply with this restriction may expose the hospital network to security violation and compromise the integrity of the device.
Maintenance	A data log copied to a USB device can be also transmitted via Wi-Fi, but not vice versa.

0.7.2. Precautions

CONTEXT	INFORMATION
Preparation	In case of visible damage to packaging or devices upon delivery, do not use the device and contact the manufacturer for assistance or replacement.
Preparation	After receiving OSCAR PRO™, transport and store the device in its dedicated transport case. Using different containers may result in damage, malfunction or failure before or during use.
Preparation	Handle handsets, probes and cables with care, as inappropriate treatment may affect the safety and performance of the unit. Before use it is recommended that the cables are inspected for damaged insulation. Damaged cables should be replaced before further use of the system.
Preparation	The OSCAR PRO™ generates high voltages within the generator itself and the connected handset. To avoid injury, the generator should ~~be~~ never be operated before ensuring that its cover is properly closed and has not been tampered with. Do not attempt to remove or disassemble the cover. There are no user-serviceable parts inside the generator. All servicing should only be performed by an authorised Orthofix representative. No modification of this equipment is required nor allowed.
Preparation	In conditions of incorrect use or insufficient maintenance, electrical medical devices may present a residual risk of unexpected shutdown, electric shock or fire. Follow use instructions and ordinary maintenance instructions to prevent occurrence of those issues. This manual shall be kept in close proximity to the system for easy referral when needed.
Preparation	Adequate air circulation is needed to cool electronic components inside of the generator. Do not block the cooling fan at the generator rear or the air vents on the generator bottom. Do not place the generator on a towel, foam or other soft surface since the material may block the air vents. Blocking these vents may cause the generator to overheat and malfunction or create a shock hazard. A clear drape can be used to protect the generator front panel but do not cover the pump housing or other generator sections.
Preparation	This device is considered medical electrical equipment. Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this operator's manual.
Preparation	OSCAR PRO™ must not be used adjacent to or stacked with other electrical equipment. If adjacent or stacked use is necessary, the generator should be observed to verify normal operation.
Preparation	Connecting the generator to a power outlet with inadequate voltage or frequency may cause the unit to malfunction or create a shock or fire hazard. In case of fuse replacement, ensure that the correct fuses are used (refer to **section 11**).
Preparation	To avoid the risk of electric shock, this equipment must be connected to a grounded power supply. Appropriate system grounding can only be ensured when an approved, hospital-grade receptacle and matching power cord are used. Install plug and receptacles as per local regulations before operating the unit. Power cord, plug and receptacle should be examined to verify that they are in good working condition before connecting the generator. Never pull on the power cord to remove it from the receptacle.
Preparation	The use of accessories, transducers and cables other than those specified may result in increased emissions and reduced immunity of the device. Such issues may result in user and/or patient harm. Use only Orthofix branded equipment and accessories.
Preparation	Allow the devices to reach room temperature before use.
Preparation	When inserting the irrigation line in the pump, make sure that the intended flow direction matches the indication arrow on the pump cover.
Use	Improper connection of the handset cable may present a shock hazard. Confirm that the handset connector is dry prior to plugging it in.
Use	Ensure that the software status bar, positioned in the right corner of the header, is continuously blinking as feedback that the Graphic User Interface is operational.
Use	When enabling the irrigation function, verify that no spillage is occurring along the entire line from the water bag to the handset.
Use	Do not lift or drag the handset by the handset cable, as this may damage both the handset and the cable. Never pull on the handset cable to remove it from the connector.
Use	The use of accessories which are not OSCAR PRO™ original components may result in decreased system performance or failure of the device. Such issues may result in user and/or patient harm. Use only Orthofix branded equipment and accessories.
Use	DO NOT use this equipment in the presence of flammable anaesthetic mixture with air or with oxygen or nitrous oxide to prevent fire ignition.
Use	OSCAR PRO™ must not be used adjacent to or stacked with other electrical equipment that may interfere with its normal functionality or decrease its immunity. Minimum distances to other electrical medical devices or electrical appliances are stated in the EMC information provided in this operator's manual.

Use	In case of high loads and prolonged use, in exceptional cases beyond the recommended 10s duty cycle, the handset may accumulate heat up to 45°C. Overheating may affect the user and might reduce the handset transducer's life. For this reason, audible and visible alarms inform the user when the system is approaching this condition. Proceed by changing the handset in use or by reducing the active time of the duty cycle in favour of the cooling time, until the temperature limit returns within the acceptable range.
Use	DO NOT operate pump with pump cover in raised position. Rollers might pinch loose clothing or fingers, resulting in personal injuries.
Use	During use, the probe for cement removal may reach a temperature up to 120°C, depending on the use. Irrigation, either manual or assisted by the OSCAR PRO™ irrigation function, must be used whenever temperature control is deemed necessary to limit overheating effects such as bone necrosis around the cemented area. See **section 5.6** of this manual and the operative technique for specific indications.
Use	During use, the probe for bone cutting may reach a temperature above 47°C. Irrigation, either manual or assisted by the OSCAR PRO™ irrigation function, must be used to limit overheating effects such as necrosis of bone or other surrounding tissues. See **section 5.6** of this manual and the operative technique for specific indications.
Use	To ensure effective cooling, the irrigation flow shall be directed on the tip of the probe by adjusting the direction of the dedicated irrigation nozzle.
Use	Follow the appropriate sequence of steps to shut down the generator: first, select the power off option from the menu function and then, once the procedure is complete, including pump cleaning if necessary, the user can proceed with the switch off by pressing the ON|OFF switch positioned in the rear panel of the generator.
Use	During bone cutting, bone necrosis may result if the probe is not moved relative to the bone. A continuous probe motion is recommended in order to minimise contact duration with the ultrasonic tip and minimise heat build-up. In this instance a more frequent intermittent use must be applied.
Use	Extra care should be taken when operating the energised probe in the vicinity of nerves.
Use	Do not operate OSCAR PRO™ Probes on the surgical site simultaneously with laser equipment or high frequency surgical equipment. The combined effect may lead to device damage and patient injury.
Reprocessing	All reusable handset parts and accessories must be properly decontaminated, cleaned and sterilised before each use as per the instructions contained in this manual. Failure to do so may lead to infections, which can result in serious harm or death.

0.7.3 Risks due to the re-use of "Single Use" Device

The "SINGLE USE" non implantable device of Orthofix is identified through symbol "  " reported on the label or indicated in the "Instructions For Use" supplied with the products. The re-use of a "SINGLE USE" non implantable device cannot guarantee the original mechanical and functional performances, compromising the effectiveness of the products and introducing health risks for the patients.

0.7.4 Sterile & Non-Sterile Products

Orthofix devices are provided as STERILE or NON-STERILE and they are labeled as such. In the case of STERILE products, product integrity, sterility and performance are assured only if the packaging is undamaged. Do not use if packaging is compromised, unintentionally opened or if a component is believed to be faulty, suspect or damaged. The products supplied NON-STERILE require cleaning, disinfection and sterilization prior to use according to procedures reported in the following instructions.

1. FIRST POWER ON

The tasks in this section allow you to:

- Configure the system with your language preference.
- Set the local date/time.
- Verify the basic integrity of the generator interface, handset cables and handsets before installation in the operating theatre.

Precautions	
PRECAUTION	Allow the devices to reach room temperature before use.
PRECAUTION	In conditions of incorrect use or insufficient maintenance, electrical medical devices may present a residual risk of unexpected shutdown, electric shock or fire. Follow use instructions and ordinary maintenance instructions to prevent occurrence of those issues. This manual shall be kept in close proximity to the system for easy referral when needed.

1. Position the OSCAR PRO™ Generator on a flat surface.

Precautions	
PRECAUTION	Adequate air circulation is needed to cool electronic components inside of the generator. Do not block the cooling fan at the generator rear or the air vents on the generator bottom. Do not place the generator on a towel, foam or other soft surface since the material may block the air vents. Blocking these vents may cause the generator to overheat and malfunction or create a shock hazard. A clear drape can be used to protect the generator front panel but do not cover the pump housing or other generator sections.

2. Connect the generator to the power supply using the power cord provided.

Precautions	
PRECAUTION	OSCAR PRO™ must not be used adjacent to or stacked with other electrical equipment. If adjacent or stacked use is necessary, the generator should be observed to verify normal operation.
PRECAUTION	Connecting the generator to a power outlet with inadequate voltage or frequency may cause the unit to malfunction or create a shock or fire hazard. In case of fuse replacement, ensure that the correct fuses are used (refer to **section 11**).
PRECAUTION	The OSCAR PRO™ generates high voltages within the generator itself and the connected handset. To avoid injury, the generator should never be operated before ensuring that its cover is properly closed and not tampered with. Do not attempt to remove or disassemble the cover. There are no user-serviceable parts inside the generator. All services should only be performed by an authorized Orthofix representative. No modification of this equipment is required nor allowed.

3. Using the main power switch located on the back of the generator, turn the system ON (position "I").

4. A loading page appears on the touchscreen showing the progress of the system start-up.

Figure 1 LOADING PAGE

5. Select your preferred language from the ones listed.

The system interface, messages, errors and help section will be presented in the selected language until any system reset. The reset procedure will return the system to the default configuration.

Reset procedure described in **section 6**.

Figure 2 FIRST POWER ON - LANGUAGE SETTING

6. Now, the user can adjust the date and time settings.

Setup local date/time using the [+] and [-] symbols.

The date/time settings will remain in use until the next system reset. The reset procedure will revert back to the system's default configuration.

Figure 3 FIRST POWER ON - DATE/TIME SETTING

7. Touch the Continue button to complete the configuration. The Surgical Functions menu appears.

CHECK1. Verify that the system's clock displays the correct time and date on the bar at the bottom of the page.
CHECK2. Verify that the dashes in the top right corner are lit up and they are changing brightness in sequence.

Figure 4 SURGICAL FUNCTION MENU

8. After touching one of the options in the Surgical Functions menu, the generator surges for Handset connection.

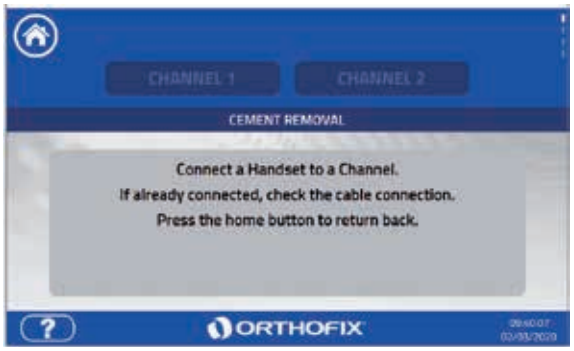


Figure 5 AWAITING HANDSET CONNECTION

9. Position the Instrument Tray on a table.

Precautions	
PRECAUTION	Handle handsets, probes and cables with care, as inappropriate treatment may affect the safety and performance of the unit. Before use it is recommended that the cables are inspected for damaged insulation. Damaged cables should be replaced before further use of the system.
PRECAUTION	Do not lift or drag the handset by the handset cable, as this may damage both the handset and the cable. Never pull on the handset cable to remove it from the connector.

10. Connect a Handset Cable to a Handset and connect the Handset Cable to the socket beside the "I" symbol on the front panel of the Generator.

CHECK3. After completing the connection, the box "CHANNEL 1" on the screen should turn from faded to light blue.

NOTE: Do not press the activation button on the handset as indicated on the screen, as no scan is possible without a probe connected to the horn. If pressed accidentally, continue to follow the sequence after the scan ends.

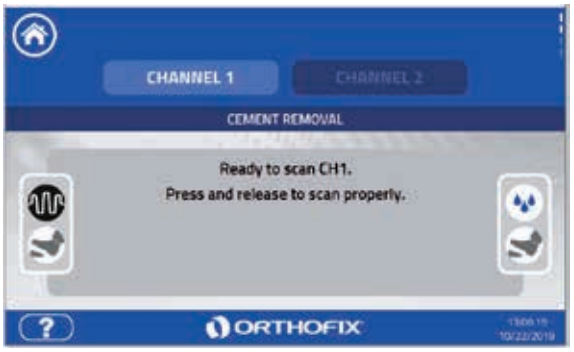


Figure 6 READY TO SCAN

11. Unplug the Handset Cable from CHANNEL 1 and repeat step 10 with a different Handset Cable and Handset on CHANNEL 2 (symbol "II" on the front panel of the Generator).

12. Unplug the Handset Cable from CHANNEL 2.
13. Touch the Home icon to return to the Surgical Functions menu.
14. Touch the On-Off icon to switch the interface off.
15. Turn the main power switch off (position "O").
16. In the event that one or more of CHECK 1, CHECK 2 or CHECK3 fail, contact an Orthofix agent for assistance.

The first power ON procedure ends with the above steps. In order to test additional functionalities and/or verify additional hardware components (probe connection and scan, footswitches connection and activation, peristaltic pump activation) in a functional setting, proceed with **section 4**. This section provides the steps for connecting and putting the complete system into operation.

Details on each OSCAR PRO™ Generator software menu are provided in **section 5**.

2. CLINICAL INFORMATION

2.1. INTENDED PURPOSE

Ultrasound system for the cutting and removal of bone and acrylic bone cement.

2.2. INDICATIONS FOR USE

The OSCAR PRO™ is indicated for orthopaedic surgery on the appendicular skeleton.
Specific indicated procedures include:
- Osteotomy (ETO and TTO procedure).
- Cemented prosthesis revision.
- Cementless prosthesis revision.

2.3. CONTRAINDICATIONS

DO NOT USE the OSCAR PRO™ if a surgical candidate exhibits or is predisposed to any of the following contraindications:
- Orthopaedic application on the axial skeleton (such as artificial disc replacements or spinal arthroplasty).
- Patients with general medical conditions not suitable for surgery.

2.4. INTENDED PATIENTS

OSCAR PRO™ is ndicated for adults and adolescent (greater than 12 years) patients.

2.5. INTENDED USERS

The product is intended for use by Healthcare Professionals (HCP) only. Such HCPs must have full awareness of the appropriate orthopaedic procedures and be familiar with the devices, instruments and surgical procedures.

2.6. DISCLAIMER

The HCP is fully responsible for the selection of the appropriate treatment and relevant device for the patient (including post-operative care).

2.7. POSSIBLE ADVERSE EVENTS

A successful result is not achieved in every surgical case. Additional complications may develop at any time due to improper use, medical reasons or device failure that require surgical re-intervention.
Preoperative and operative procedures including knowledge of surgical techniques and proper selection of the device are important considerations in the successful utilization of the device by the HCP.
Possible adverse events resulting from the usage of the OSCAR PRO™ are:
- Pain and stiffness at the surgery site.
- Necrosis of soft tissues and/or cortical bone due to overheating.
- Iatrogenic fractures.
- Breaking, loosening, bending or reduced performance of the probes.
- Prolonging of surgery and possible extra anesthesia.
- Intrinsic adverse events associated with anesthesia and surgery.
- Burns to patient or intended user due to accidental contact with probe.

2.8 MRI (Magnetic Resonance Imaging) SAFETY INFORMATION

OSCAR PRO™ System is not meant to be used in a MR environment. The use in a MR environment can lead to system malfunction.

2.9. EXPECTED CLINICAL BENEFITS AND PERFORMANCE CHARACTERISTICS OF THE DEVICE

EXPECTED CLINICAL BENEFITS
- EFFICIENT: Specific probes are utilized in sequence to soften and remove cement from the bone. The technique reduces manual force to the minimum, resulting in low risk of bone fracture and perforation.
- SAFE: All probes are designed to preserve the bone quality and soft tissue. The system is designed with specific audible and visual feedback to provide the user a safe and efficient operating environment for their patients.
- The surgeon can intuitively guide the probe and reduce the likelihood of unnecessary fracture or perforation of the patient's bone, whilst removing and clearing bone cement from the intramedullary canal.

PERFORMANCE CHARACTERISTICS OF THE DEVICE

- VERSATILE: Single use probes have been designed for providing high quality performance for every case with safety in mind. The vast range of probes are designed to provide an optimal choice for a number of different revision surgeries.
- Self-adjusted ultrasonic power
- Multi-functional Universal Handset
- Interactive user interface
- Extensive portfolio of SU probes
- Focused instrumentation
- Data Log

2.10. INFORMATION FOR THE PATIENT

The HCP shall warn the patient about the surgical and residual risks and make him/her aware of possible adverse events. A successful result is not achieved in every surgical case. Additional complications may develop at any time due to improper use, medical reasons or device failure. The HCP shall instruct the patient to report any unusual changes to the operative site to his/her physician.

2.11 NOTICE ABOUT SERIOUS INCIDENTS

Any serious incident occurred in relation to the device should be reported to Orthofix Srl and the competent authority of the Member State in which the user and/or patient is established.

3. PRODUCT DESCRIPTION

3.1. PRINCIPLE OF OPERATION

The OSCAR PRO™ is a portable electromedical generator, intended for use in operating theatre. It has two output channels. These channels are microprocessor controlled and are designed to produce ultrasonic energy at the resonant frequency of the attached handset. The channels can be activated via an air footswitch or via the handset switch.
A 7" colour touchscreen enables interaction with the generator.

A variety of probes may be fitted to the end of shaft within the handset called "Horn". The probes allow the surgeon to carry out a range of procedures with maximum efficiency. Each probe works as a waveguide; its shape and overall length are 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 waveguide to the tip of the probe, which vibrates at the frequency of resonance of the system handset plus the probe. The rapid oscillatory movement produces heat when the tip of the probe is in contact with the bone cement, causing the cement to liquefy almost immediately.
OSCAR PRO™ can also be used for cutting bone for the revision of a cementless prosthesis; the implant is removed by cutting through the bone interface surrounding the stem. This is done using a variety of flat, narrow osteotomes coupled to the handset.
OSCAR PRO™ includes a peristaltic pump to maintain a steady flow of saline which is useful for cementless prosthesis revision procedures.

3.2. SYSTEM OVERVIEW

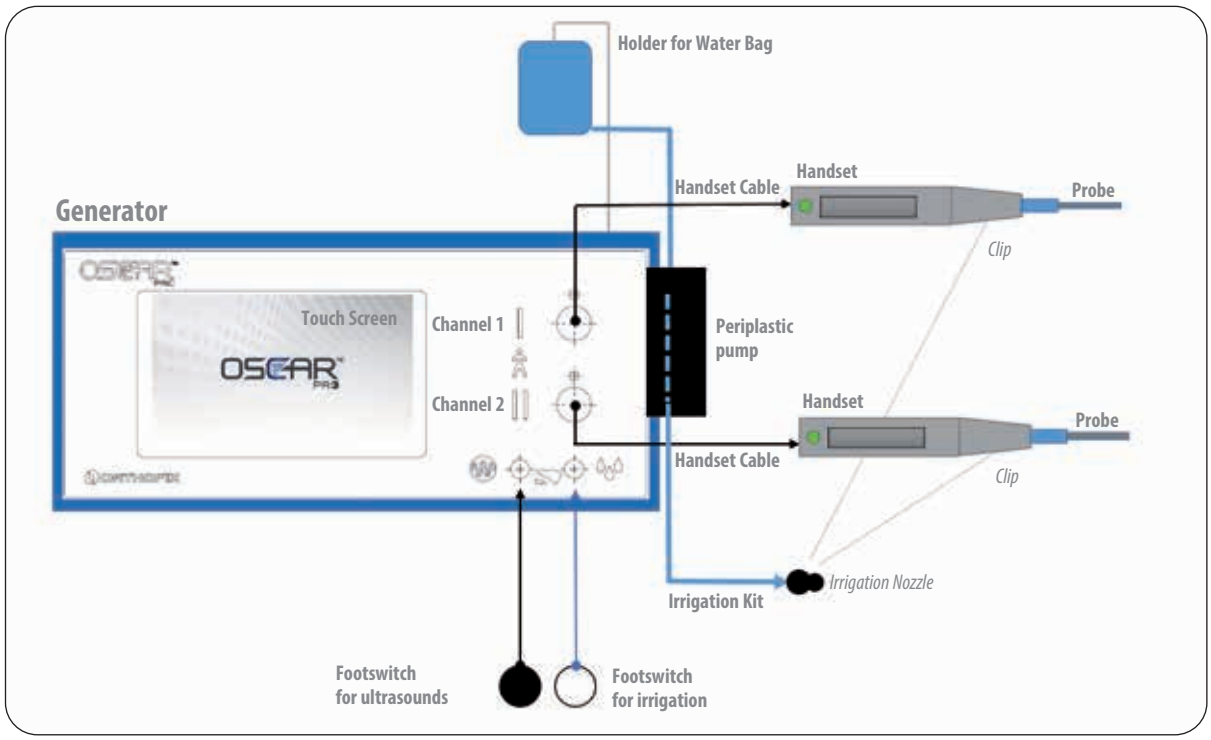


Figure 7 INTERCONNECTION DIAGRAM FRONT VIEW

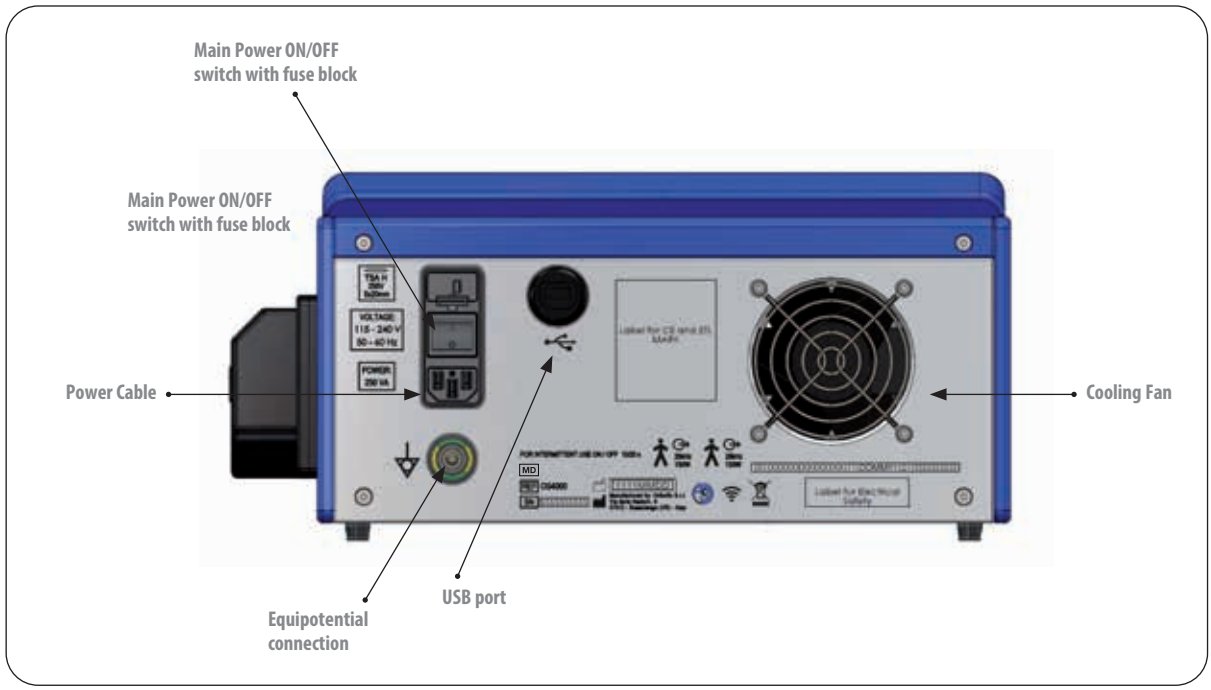


Figure 8 INTERCONNECTION DIAGRAM REAR VIEW

Fig. 7 and Fig. 8 represent in a schematic way the interconnections viewed from the front (Fig. 7) and rear (Fig. 8).
The **Generator** is a controlled electric signal generator that creates waveforms within the ultrasound's frequency range. It accommodates two channel output ports. Status information is provided by the RGB LED located on the front panel of the generator.

The integrated **software** provides controls for the system components including the GUI (Graphical User Interface), the peristaltic pump, the connected handsets and air footswitches.

It is equipped with a 7" display and touch screen for intuitive setting up of the system, on-screen help and visible feedback. Audible feedback is provided by the integrated speaker.

A peristaltic pump integrated into the generator provides the irrigation function, which can be used to deliver an active flow of sterile liquid. Its purpose is to cool the probe and clean the anatomic area. The generator provides the mechanical energy for the flow by means of a stepper motor controlling a peristaltic pump.

A single-use **irrigation tube** is provided separately in sterile condition:
- Its silicone portion must be properly installed into the peristaltic pump.
- One end is connected to the bag of saline solution (max 2 liters) hanging from the Beam for water bag, connected to the generator.
- The other hand is connected to the cover of handset's horn with a clip. Saline solution/irrigation fluid is not provided.
- The **irrigation nozzle**, an integral part of the single-use sterile irrigation kit, is included with the appropriate clips to attach the irrigation tube to the handset.

The **handset cable** provides data transmission and power. The 3-metre handset cable allows the generator to be positioned outside the sterile area.

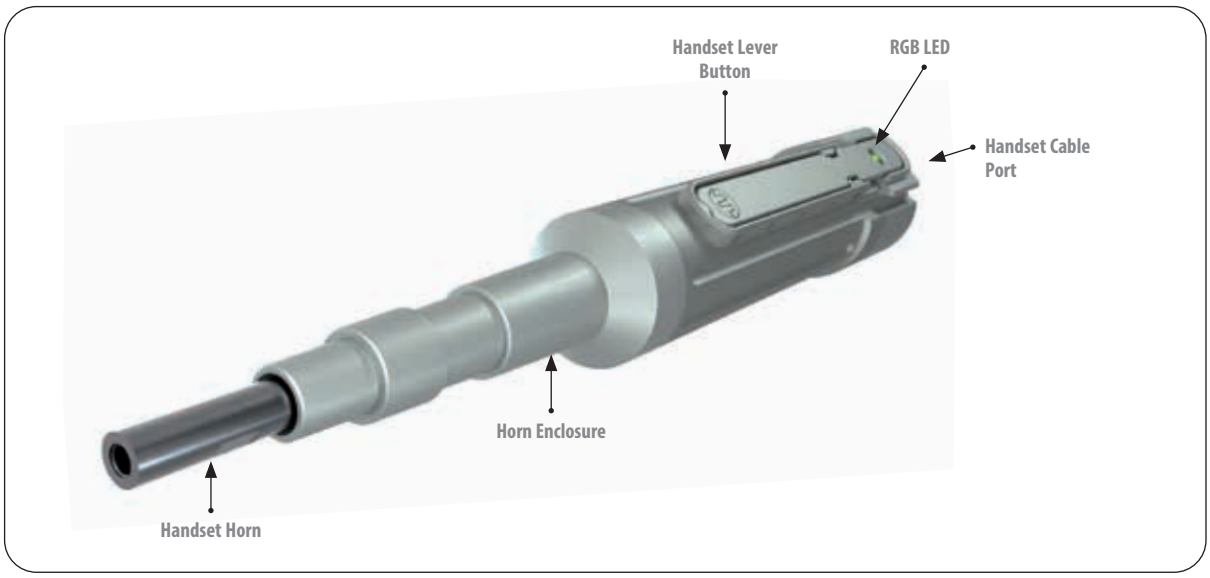


Figure 9 HANDSET MAIN PARTS

Inside the handset, a transducer converts the electrical signal transmitted by the generator via the handset cable into mechanical vibrations at ultrasonic frequency. The vibrations are conveyed through the handset horn up to the probe connected to the handset.
The **horn enclosure** provides protection to the proximal portion of the vibrating element and is designed to be disassembled for reprocessing.
The **handset lever button** triggers some operative functions of the generator. The RGB LED provides feedback about the handset status, in addition to the information on the generator screen.

The single-use **probes** are the mechanical end effector of the system. The probes can be coupled to the handset using a thread connection. They are sterile-packed and provided separately. Please refer to the Operative Technique for the selection of the appropriate probe related to the surgical function.

Two **air footswitches** can be connected by means of pneumatic tubes to the air nozzles on the front of the generator:

Footswitch for ultrasound, identifiable by the black color of the connection tube and the specific icon on the generator. Allows the user to activate the selected handset as an alternative to the handset button.

Footswitch for irrigation, identifiable by the transparent color of the connection tube and the specific icon on the generator. Allows the user to start and stop the water flow generated by the peristaltic pump.

The hospital-grade **main lead** provides the system with the required power. The model of the power cord (currently UK, EU, US) depends on the market where the product will be operated.

The ON/OFF switch positioned on the rear of the generator allows the generator to be powered once it is connected to the main power source using the power cable.

A USB port is positioned on the rear of the generator for downloading the data log to external devices(for mass storage NOT connected to other devices, network or power supply). It is also possible to copy the data log by activating the Wi-Fi connection within the dedicated software menu.

The following image is a system diagram, describing how the various system components address system functionalities and redundancy.
The red arrows show how the different components are linked in terms of feedback, while the black arrows represent the power supply line to the various items.

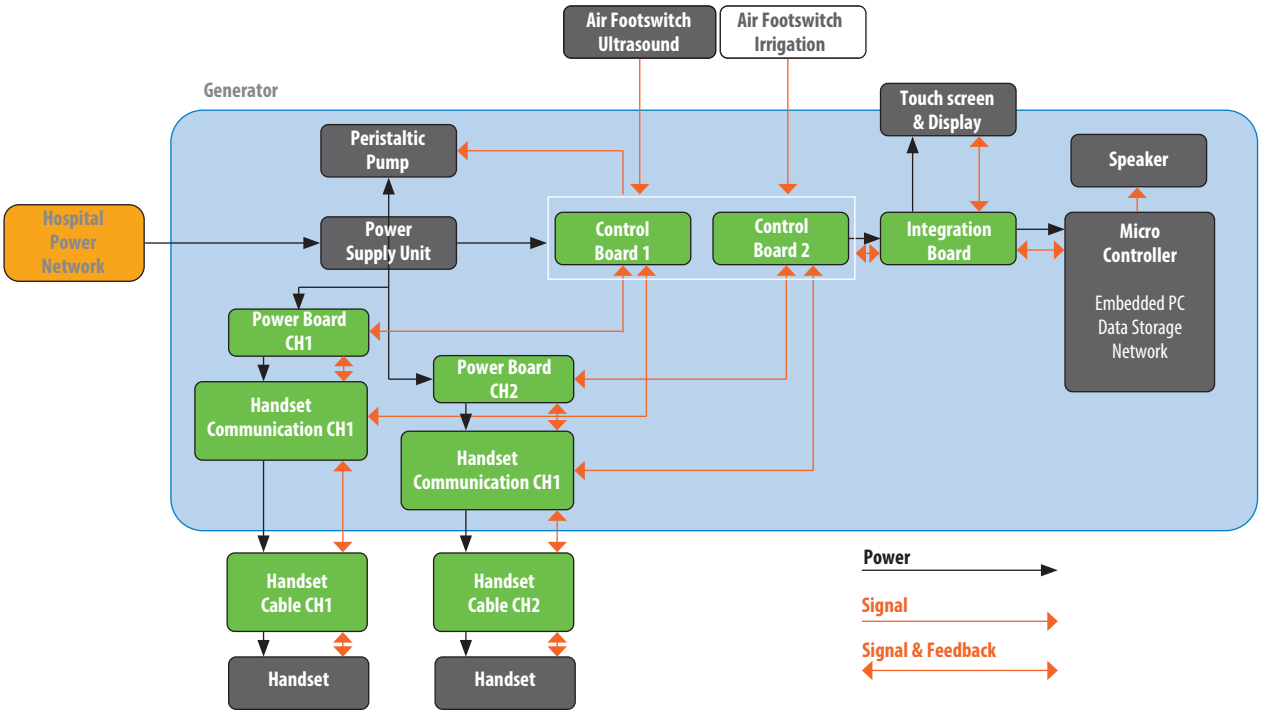


Figure 10 OSCAR PRO™ SYSTEM DIAGRAM

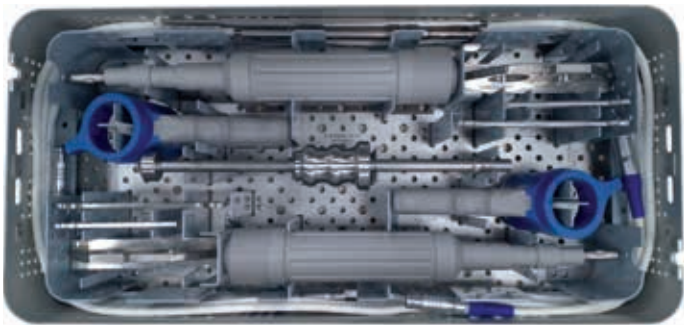
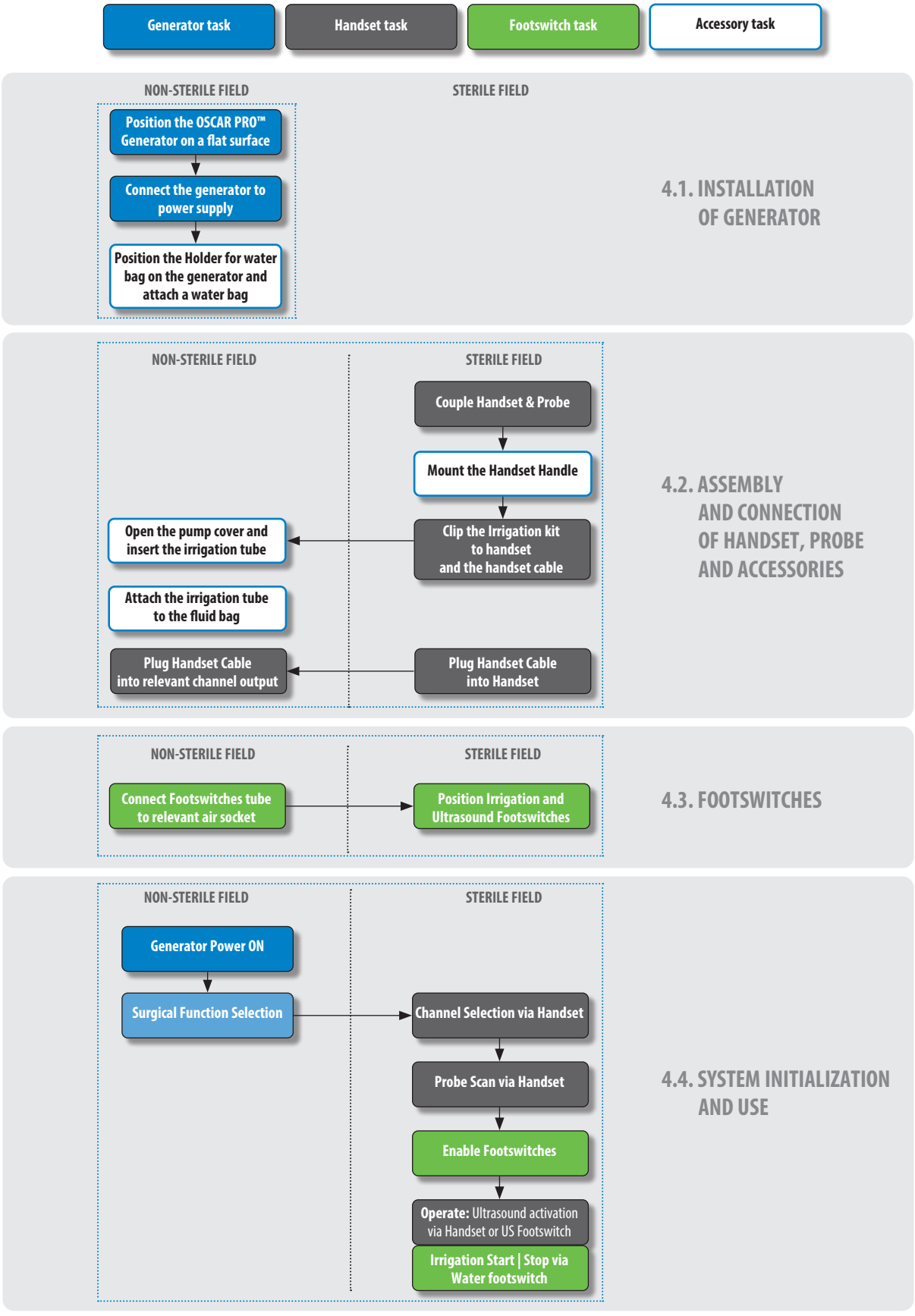


Figure 11 OSCAR PRO™ INSTRUMENT TRAY

OSCAR PRO™ Instrument Tray		Quantity
04HAND	OSCAR PRO UNIVERSAL HANDSET	2
04CABLE	OSCAR PRO UNIVERSAL HANDSET CABLE	2
04UHH	OSCAR PRO UNIVERSAL HANDSET HANDLE	2
04HOLD	OSCAR PRO HANDSET HOLDER	2
04IPL200	OSCAR PRO SLAP HAMMER	1
SPAN7MM	OPEN END WRENCH 7MM	2
SPAN8-9MM	OPEN END WRENCH 8-9MM	2
04TRAY-01	OSCAR PRO BASE TRAY	1
04TRAY-02	OSCAR PRO LID TRAY	1

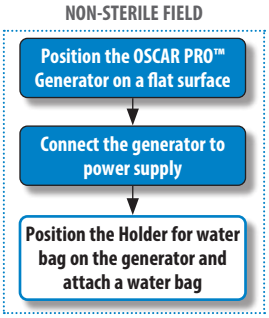
4. SYSTEM SETUP

The following flow diagrams and descriptions represent the logical sequence from set-up to start of use. The sequence separately identifies the steps that are to be performed within the sterile field vs the non-sterile field.



Warnings and Precautions	
WARNING	Portable and mobile RF communication equipment can affect medical electrical equipment. If RF equipment is necessary, monitor the OSCAR PRO™ for appropriate function during the procedure.
WARNING	During use, warning messages may be displayed on the screen in relation to a specific event or machine status. Refer to **section 10** of this manual for the meaning of each message.
WARNING	In case of excessive load, the OSCAR PRO™ warns the user with specific luminous and acoustic signals. See **section 8** and Troubleshooting **section 10**.
PRECAUTION	All reusable handset parts and accessories must be properly decontaminated, cleaned and sterilised before each use as per the instructions contained in this manual. Failure to do so may lead to infections, which can result in serious harm or death.
PRECAUTION	Allow the devices to reach room temperature before use.
PRECAUTION	The use of accessories which are not OSCAR PRO™ original components may result in decreased system performance or failure of the device. Such issues may result in user and/or patient harm. Use only Orthofix branded equipment and accessories.
PRECAUTION	This device should only be used by qualified surgeons who are (1) suitably trained in the arthroplasty revision surgery procedures that are to be carried out and (2) trained in the specific use of ultrasonic surgical instruments intended for use during arthroplasty revision.
PRECAUTION	DO NOT use this equipment in the presence of flammable anaesthetic mixture with air or with oxygen or nitrous oxide to prevent fire ignition.
PRECAUTION	OSCAR PRO™ must not be used adjacent to or stacked with other electrical equipment that may interfere with its normal functionality or decrease its immunity. Minimum distances to other electrical medical devices or electrical appliances are stated in the EMC information provided in this operator's manual.

4.1. INSTALLATION OF GENERATOR



NON-STERILE FIELD

Position the OSCAR PRO™ Generator on a flat surface

The OSCAR PRO™ Generator can be placed on an appropriate table or cart outside of the sterile field.

Connect the generator to the power supply

Verify the cable lengths to facilitate the power connection and the handset use in the sterile field. On the back panel, insert the supplied power cable in the power socket.
If the operative room is provided with a conductor for potential equalization, connect it to the dedicated receptacle indicated with the relevant symbol (ref. **section 0.3**) on the back panel. The main power switch is also located at the back of the unit.

Position the fluid bag stand on the generator and attach the fluid bag

Insert the holder for the fluid bag into the opening provided for this purpose on the outside of the generator.

Note and Precautions	
NOTE	Prior to attaching the fluid bag to the fluid bag stand, check that the size/weight of the bag is less than 2 l. If necessary, it is possible to connect the irrigation tube to an independent, hospital-owned, fluid bag holder. Ensure the irrigation tube is long enough to be attached to the independent fluid bag holder.
PRECAUTION	Adequate air circulation is needed to cool electronic components inside of the generator. Do not block the cooling fan at the generator rear or the air vents on the generator bottom. Do not place the generator on a towel, foam or other soft surface since the material may block the air vents. Blocking these vents may cause the generator to overheat and malfunction or create a shock hazard. A clear drape can be used to protect the generator front panel but do not cover the pump housing or other generator portions.

4.2. ASSEMBLY AND CONNECTION OF HANDSET, PROBE AND ACCESSORIES

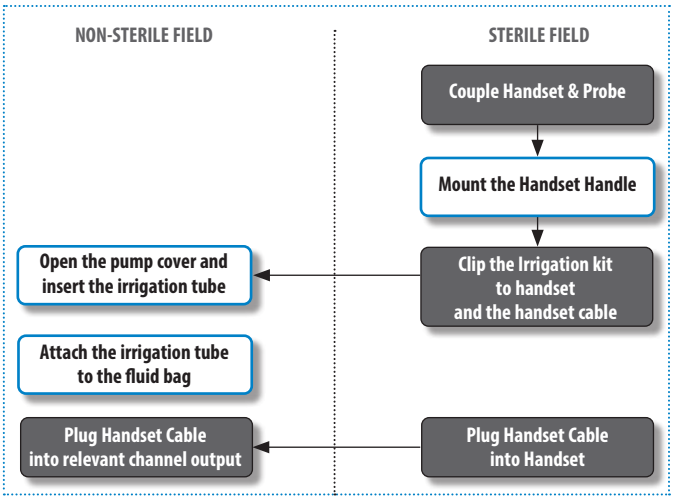


Figure 12 HANDSET HORN POSITION

STERILE FIELD

Couple the Handset & Probe

Remove the handset from the sterile tray. Position the handset horn on the handset holder.

Figure 13 HANDSET HOLDER FOR PROBE COUPLING

Each handset can be set up with a different probe tip. The selection of the appropriate probe is linked to the surgical function. Refer to the Operative Technique for details about the different probe types and design.

Attach the required probe to the handset using the suitable sterilised spanners, as shown.

Figure 14 HANDSET-PROBE COUPLING

Each probe is marked with a number so that the appropriate spanner can be easily identified.

Figure 15 HANDSET HANDLE POSITION

STERILE FIELD

[Optional] Mount the Handset Handle

In case of use of the accessory handle, ensure to position it prior to attaching the irrigation tube.

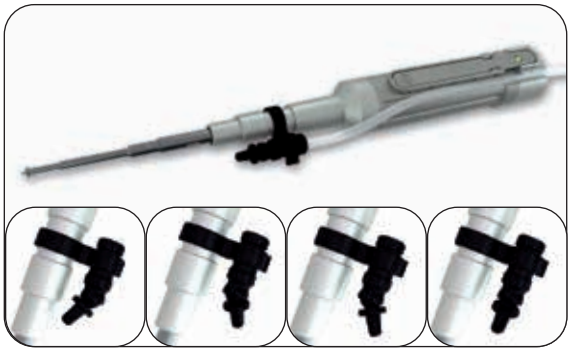


Figure 16 IRRIGATION NOZZLE ATTACHMENT

Clip the irrigation kit to the Handset

Attach the irrigation nozzle to the handset in the position shown using the black clip. The nozzle can be directed by the surgeon to target the probe tip as needed.

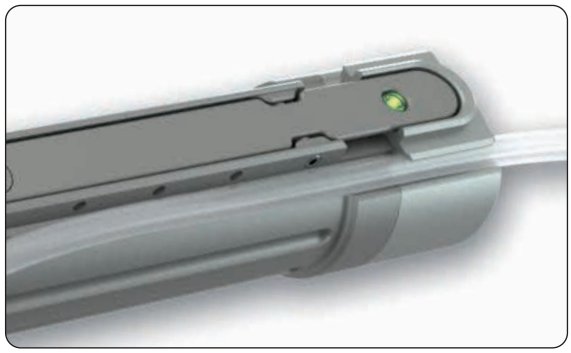


Figure 17 IRRIGATION TUBE ROUTING

Route the irrigation tubing supplied in the single-use pack along the handset, and press it into the dedicated slot in the handset housing. Additional black clips are available to connect the irrigation line to the handset cable.

NON-STERILE FIELD

Open the pump cover and insert the irrigation tube

Identify the peristaltic pump on the right side of the main unit and lift the cover to accommodate the softer silicone section of the tubing, as shown in Fig. 18. Once this is in position, secure the cover back down with a click.

The near end of the tubing can then be inserted into a sterile bag of irrigation fluid (max 2 liters) hanging appropriately from the beam for the water bag connected to the generator.

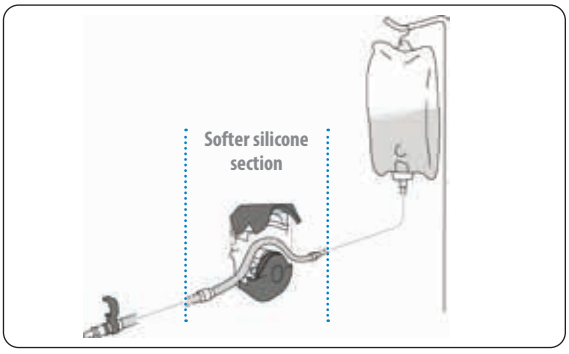


Figure 18 IRRIGATION TUBE POSITIONING

Precaution	
PRECAUTION	When inserting the irrigation line in the pump, make sure that the intended flow direction matches the indication arrow on the pump cover.

Figure 19 PLUGGING THE HANDSET CABLE INTO THE HANDSET

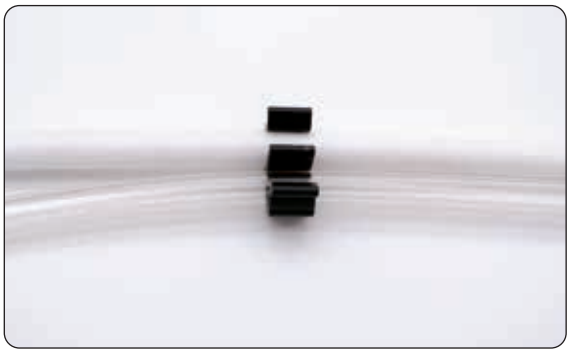


Figure 20 CLIPPING IN THE TUBE & HANDSET CABLE

STERILE FIELD

Plug handset cable into handset

The OSCAR PRO™ handset is now ready for attachment. It is recommended that both handsets are added to and set up on the main unit.

This should speed up intra-operative workflow by negating the need to switch between different probe tips.

First, connect the cable to the handset, then hand the loose cable end to the staff in the non-sterile field to connect to the generator.

For the purposes of improved cable management, the irrigation cable can be clipped to the handset power cable near the handset using the black clips.

Note and Precautions	
PRECAUTION	Do not lift or drag the handset by the handset cable, as this may damage both the handset and the cable. Never pull on the handset cable to remove it from the connector.
PRECAUTION	Improper connection of the handset cable may present a shock hazard. Confirm that the handset connector is dry prior to plugging it in.
NOTE	There is only one irrigation line, which may be mounted on the handset that is most likely to be used in conjunction with the irrigation function. However, the irrigation line can be removed from one handset and connected to the other at any moment by removing and relocating the black clips.

NON-STERILE FIELD

Plug the handset cable into the relevant channel output

Connect the handset to the channel on the front panel of the generator.

The attachment points are on the front of the unit indicated by this sign:

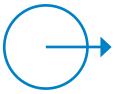


Figure 21 HANDSET CABLE PLUG

To connect the handset cable, line up the red dots on the cable connector and generator/handset and push.

The connector will click into place.

To disconnect, pull on the front grooved part of the connector.

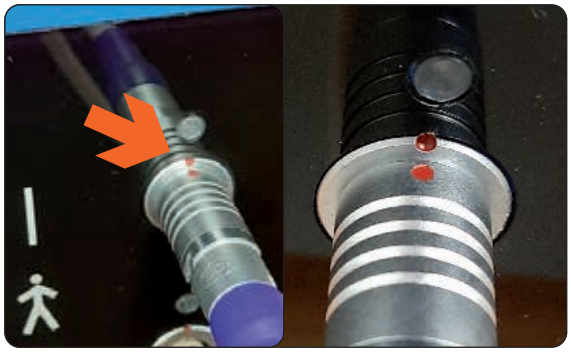
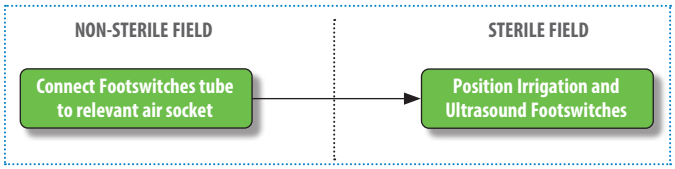


Figure 22 LINING UP THE CABLE CONNECTOR AND THE RECEPTACLE

4.3. FOOTSWITCHES



NON-STERILE FIELD

Connect the footswitch tube to the relevant air socket

Connect the air tube to the relevant air nozzle on the front panel of the generator. The icons indicate the correct connection for the ultrasound and water air footswitch.

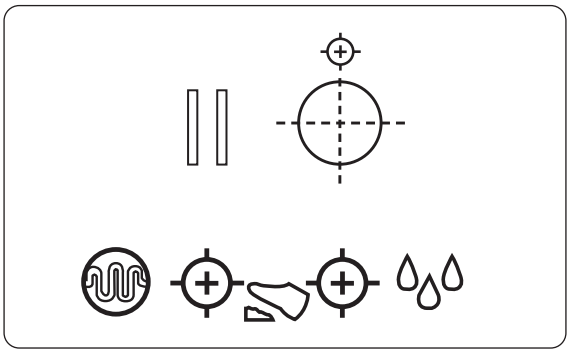


Figure 23 Footswitch connection

STERILE FIELD

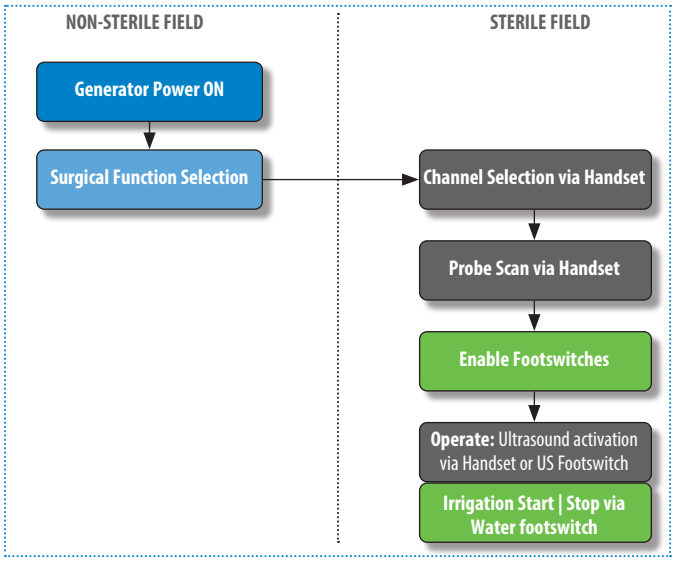
Position the irrigation and ultrasound footswitches

Position the two air footswitches on the floor of the non-sterile field, sliding them to the sterile area.

The black air footswitch activates the ultrasound as an alternative to the handset switch.

The white air footswitch activates the irrigation flow.

4.4. SYSTEM INITIALIZATION AND USE



NON-STERILE FIELD

Generator power ON

The main power switch is located at the back of the unit. Turn on the generator.

A loading page appears on the touchscreen showing the progress of the system start-up.

Figure 24 LOADING PAGE

Note	
NOTE	When the system is turned ON the light sequence on the handset LED is blue, green, blue, red, then off. This is a visibility testing sequence; no specific operation is being performed by the system during this sequence.

Take note of the message and acknowledge by touching the button Continue.

In the case of the first power ON, or a power ON after a system reset, the user is also asked to configure the date/time and choose their preferred language.

Details in **section 1** in this manual.

Figure 25 USER MANUAL REFERENCE

Surgical function selection

Precaution	
PRECAUTION	Ensure that the software status bar, positioned in the right corner of the header, is continuously blinking as feedback that the Graphic User Interface is operational.

This section lists the available surgical functions.

In order to start using the OSCAR PRO™ system, select the desired surgical function.

The selection of the desired surgical function requires appropriate selection and deployment of the hardware (handset + probes).
The system operates with one surgical function at time.

Details available in **section 5.4**.

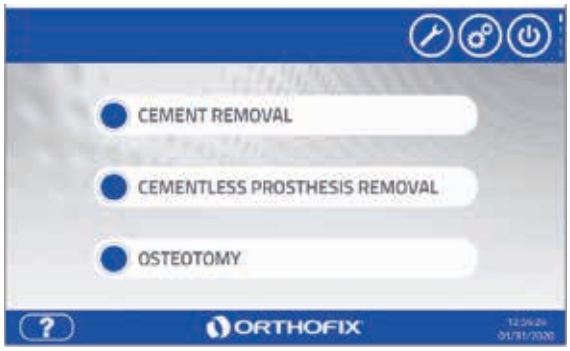


Figure 26 SURGICAL FUNCTION MENU

STERILE FIELD

Note	
NOTE	The following steps are intended to be executed from the sterile field using the connected hardware (handset/footswitches).

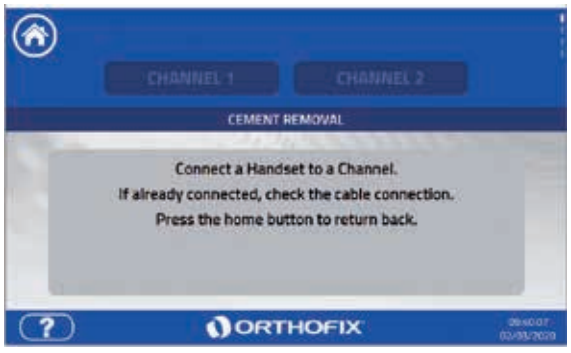


Figure 27 SELECT CHANNEL

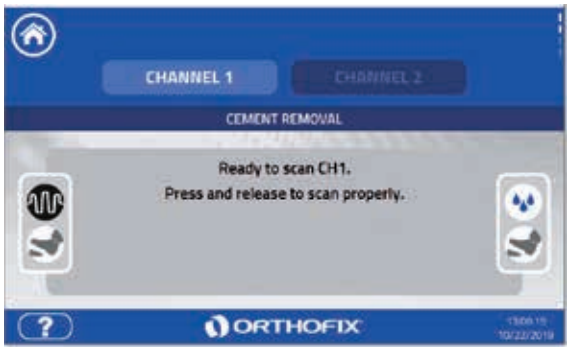


Figure 28 PROBE SCAN

Channel selection via handset

Press and hold the button on the selected handset for 3 seconds:
→ the handset LED will turn from green to blue.

This selects and activates the corresponding channel and therefore the handset to be used. This step can also be done by tapping the Channel button on the touchscreen.

Details available in **section 5.5**.

Probe scan via handset

Proceed with a probe scan by pressing the handset button. This step allows the system to recognise the coupled probe as appropriate for the selected surgical function.

Details available in **section 5.5**.

Note	
NOTE	If the probe is not recognised, first check the hardware: ensure correct connection of probe and avoid any contact of probe and handset horn with any object. Repeat scan. Alternatively, manual selection of the probe is available as an option. Select the probe currently attached to the handset by checking the product code marked on the proximal side. Ensure that the probe is appropriate for the surgical function selected. Confirm the selection.

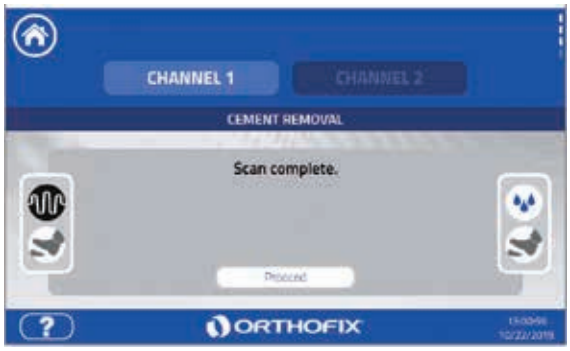


Figure 29 ENABLING THE FOOTSWITCH

Enable the footswitches

Press and release each footswitch to enable the corresponding function.
When enabled, the footswitch icon border appears in blue on the touchscreen.

The black footswitch can activate the ultrasound as an alternative to the handset switch.

The white footswitch can activate the irrigation.
The first press of the irrigation footswitch will preload the pump.

Note	
NOTE	The black footswitch can activate the ultrasound as an alternative to the handset switch. The white footswitch can activate the irrigation as a control of the irrigation. The first press of the irrigation footswitch will preload the pump. The irrigation is then activated/deactivated with a single press of the footswitch.

The user can now start to operate by pressing the handset button.

Activate the ultrasound by pressing and holding the handset button or the relevant footswitch. This will initiate the cycle countdown.

Ultrasound stops when the handset button and/or footswitch is released, or if the countdown cycle ends.

The countdown for maximum continuous emission starts when pressing the handset button or the ultrasound footswitch.

The countdown stops when releasing the handset button or ultrasound footswitch.

Details available in the **section 5.6**.

Figure 30 OPERATE

Note	
NOTE	The emission of ultrasound may be limited to a few seconds. Proceeding in short applications allows better control of the surgical effect on the anatomical site and allows the probe to better withstand mechanical and thermal stress. See operative technique for details on surgical approach.

Figure 31 IRRIGATION

Irrigation start/stop

Irrigation can be started and stopped by pressing the relevant footswitch.

The irrigation flow rate can be adjusted via the touchscreen by tapping the flow level icon. Verify that the irrigation fluid bag is properly connected and the fluid bag is not empty.

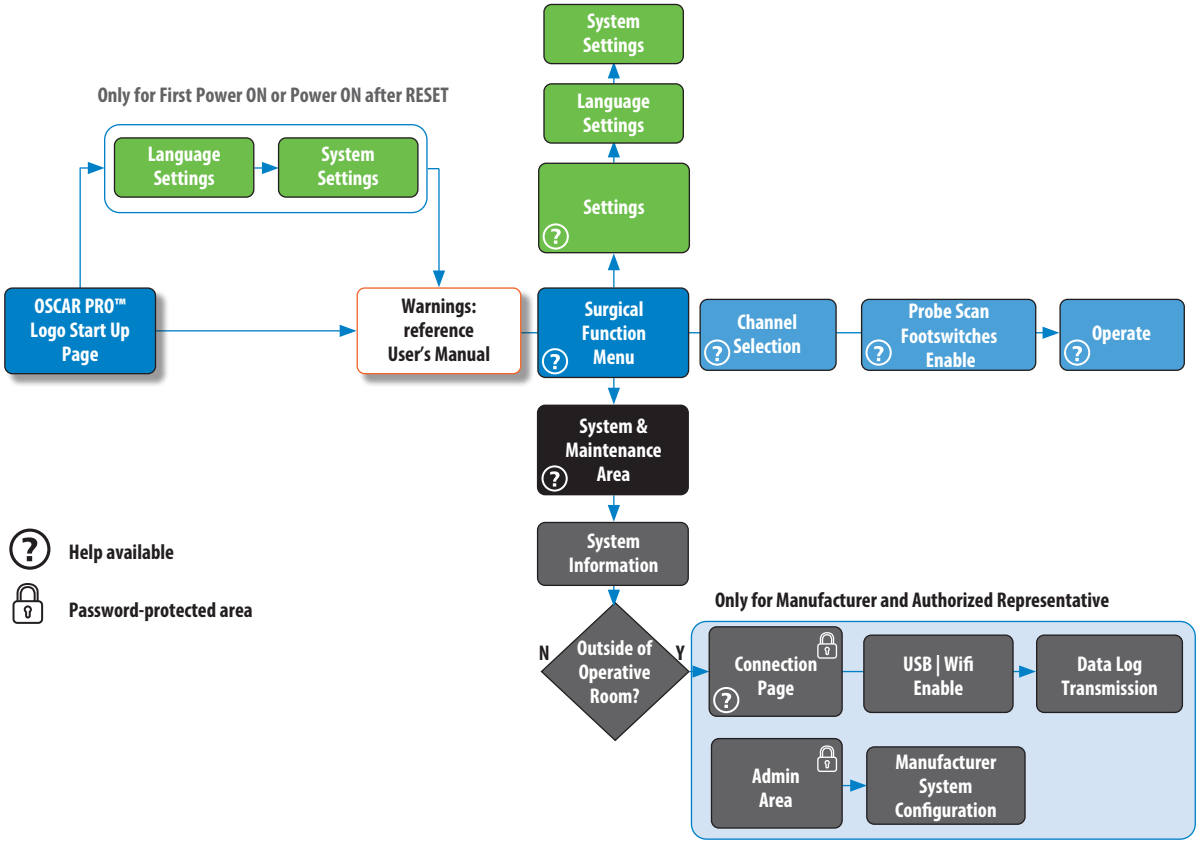
Irrigation is mandatory for specific surgical functions

Precaution	
PRECAUTION	DO NOT activate the pump with pump cover in raised position. Rollers might pinch loose clothing or fingers, resulting in personal injuries.

5. OSCAR PRO™ GENERATOR MENU FUNCTIONS MAP

The OSCAR PRO™ generator provides controls for the system components, including the GUI (Graphical User Interface), the peristaltic pump and the connected handsets and air footswitches. The user can interact with the software through a touchscreen display.

The following software menu map provides a visual representation of how the software is organised and is designed to facilitate navigation and access of information. The map also provides the sequence of screen information and indicates where help sections are available or if the area is password-protected. Detailed information about each menu option is provided in the following sections of the manual.



5.1. STATUS BAR

A status bar is positioned on the screen. This status bar flashes continuously as feedback that the GUI (Graphical User Interface) is responsive. If it is not flashing, it means that the GUI may not respond to user interaction. To address this scenario, refer to **section 10:** Troubleshooting in this manual.

Figure 32 STATUS BAR

5.2. ON SCREEN HELP

Help content is available where indicated with the ? icon in the footer of the screen.

Figure 32 STATUS BAR

The help pop-up will provide information that is specific to that section.

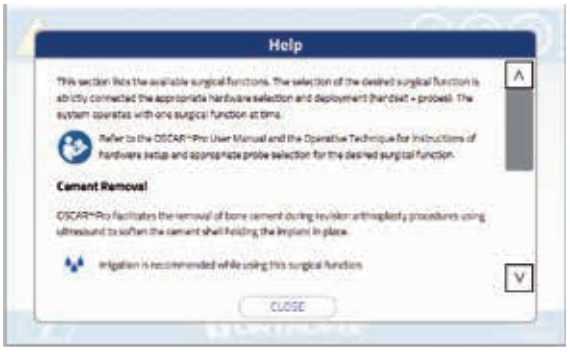


Figure 33 ON SCREEN HELP EXAMPLE

5.3. SETTINGS

This section allows the language settings to be selected and changed and the basic system settings, such as volume level and date/time, to be managed.

5.3.1. Language settings

The OSCAR PRO™ system supports a select number of languages. This allows the user to switch from the currently used language to another available from the list of system languages. The user can select their preferred language either during the first power on procedure or at any time within this section.

Once the language selection is confirmed, the system interface, messages, errors and help section will be presented in that language until any system reset. The reset procedure will revert the system to the default configuration.

Figure 34 SETTINGS - LANGUAGE PAGE

5.3.2. System settings

Figure 35 SETTINGS PAGE

5.3.2.1. Date/Time

Within this tab, the user can adjust date and time settings. The user can setup the local date/time settings during the first power on procedure or at any time within this section.

Using the [+] and [-] icons, the user can adjust the date and the time.

Once saved, this timestamp will be used as the reference for the system's clock and it will appear on the status bar. The date/time settings will remain in use until the next system reset. The reset procedure will revert back to the system's default configuration.

5.3.2.2. Audio Volume

The system includes a speaker to provide audio feedback, such as operation cycle end and other warnings.
In this section, the user can adjust the volume level by using the and icons to turn the volume level up or down according to preference or environmental conditions. The volume can also be adjusted while the system is in use. The volume cannot be set to zero.

The volume adjustment will remain set until any changes are made while in use or until a system reset. The reset procedure will revert back to the system's default configuration.

5.4. SURGICAL FUNCTIONS

This section lists the available surgical functions. The selection of the desired surgical function requires appropriate selection and deployment of the hardware (handset + probes).
The system operates with one surgical function at time.

- Verify that at least one channel is active with the adequate hardware connected prior to selecting the surgical function.
- Verify that the footswitches are connected and irrigation is ready. Some surgical functions require irrigation while operating.

Refer to the relevant section of this OSCAR PRO™ User Manual and the Operative Technique for instructions about hardware set-up and appropriate probe selection for the desired surgical function.

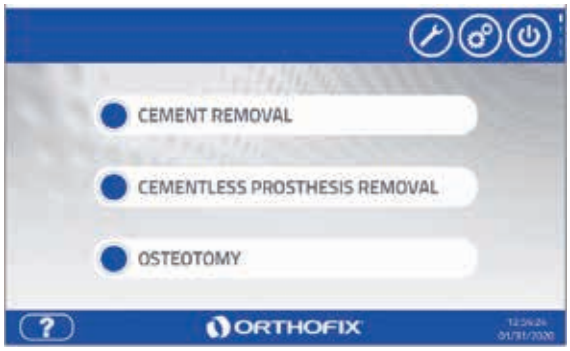


Figure 36 SURGICAL FUNCTION MENU PAGE

5.4.1. Cement Removal

OSCAR PRO™ facilitates the removal of bone cement during revision arthroplasty procedures using ultrasound to soften the cement shell holding the implant in place. Specific probes are deployed in sequence to collect and remove the softened cement from the host bone. The technique reduces the need to use manual force to a minimum and minimises the risk of bone fracture and perforation.

Irrigation is ***recommended*** while using this surgical function.

5.4.2. Cementless Prosthesis Removal

Ultrasound remains a safe and efficient energy form used for cementless prosthesis revision. When revision of a cementless prosthesis is necessary, the implant is removed by cutting the bone near the interface between the bone and the implant.

Irrigation is ***mandatory*** while using this surgical function.

5.4.3. Osteotomy

The bone cutting probe portfolio expands the possibilities of the OSCAR PRO™ system to enable certain osteotomies. These are performed using a variety of flat, narrow osteotomes connected to the handset. Osteotome blades vary in their geometry and length in order to meet different clinical and user needs, allowing precise and controlled bone cutting

Irrigation is ***mandatory*** while using this surgical function.

5.5 SELECT CHANNEL & PROBE SCAN

This section summarises how to

- Enable and activate a channel.
- Prompt OSCAR PRO™ to recognise the probe as appropriate for the selected Surgical Function.
- Enable the footswitches: one for managing ultrasound activation as an alternative option to the handset button and the other for managing the irrigation.

Before proceeding, verify that:

- At least one handset is properly connected to the generator via the handset cable and
- the appropriate probe is already coupled to the connected and selected handset,
- the irrigation kit is correctly connected to the handset and the saline solution bag via the peristaltic pump, prior to enabling the water footswitch and
- the footswitches are attached to the correct generator ports.

On-screen instructions support the user through the activation sequence.

Refer to the relevant section of the OSCAR PRO™ User Manual and the Operative Technique for instructions about hardware setup and appropriate probe selection for the desired surgical function.
The main steps are:

- Select channel: select the channel linked to the handset to be used.
- Probe scan: check the coupled probe is appropriate for the selected surgical function.
- Enable footswitch: enable the ultrasound footswitch and irrigation footswitch.

5.5.1. Selecting a channel

The OSCAR PRO™ generator is provided with two channels. When you attach a handset via the handset cable, the related channel icon will automatically turn from shaded to bright.

To select and activate a channel, and therefore the handset to be used:

- Tap on the respective [Channel 1] or [Channel 2] button on the touchscreen or
- press and hold the button on the handset for 3 seconds: the handset LED will turn from green to blue.

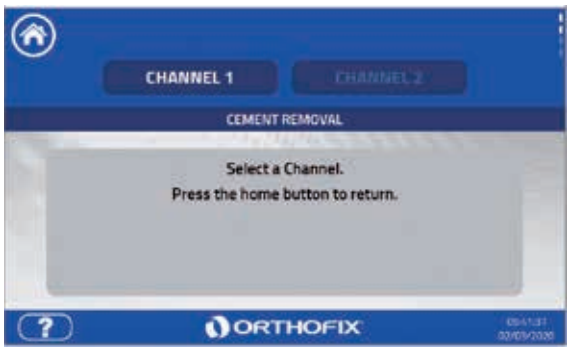


Figure 37 SELECT CHANNEL PAGE

Note	
NOTE	It is possible to connect both handsets to the generator at any time, but only one channel can be active at a time.

5.5.2. Probe Scan

Once the desired channel is activated, proceed with the probe scan by pressing the handset button. This step allows the system to recognise the coupled probe as appropriate for the selected surgical function.

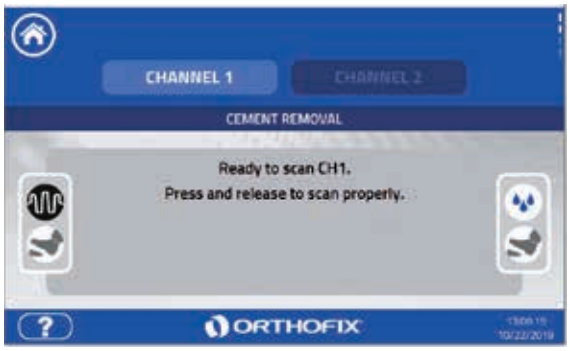


Figure 38 PROBE SCAN PAGE

Note	
NOTE	If the probe is not recognised, first check the hardware: ensure correct connection of the probe and avoid any contact of the probe and handset horn with any object. Repeat scan. Alternatively, manual selection of the probe is available as an option. Select the probe currently attached to the handset by checking the product code marked on the proximal side. Ensure that the probe is appropriate for the surgical function selected. Confirm the selection.

5.5.3. Enabling the footswitch

Press and release the footswitch to enable the corresponding function.
The black footswitch is for ultrasound activation as an alternative to the handset switch. The white footswitch is for activating the irrigation. The first press of the irrigation footswitch will preload the pump.

5.5.4. Switching channel

It is possible to switch between channels by tapping on the other channel on the touchscreen or by pressing the button of the handset not currently in use for a few seconds.
The generator and handset LED provides feedback related to the active channel and the handset in use.

5.6. OPERATE

This section provides an overview of the main operating screen of the OSCAR PRO™ system.

Refer to the OSCAR PRO™ User Manual and the Operative Technique for additional information and for any troubleshooting support.

While in use, the screen reports real-time information about

- Delivered power.
- Frequency.
- Cycle countdown timer.

In addition

- The flow rate provided for managing irrigation fluid.

Figure 39 OPERATE PAGE

Figure 40 OPERATE PAGE - DETAILS

5.6.1. Activating ultrasound

Activate the ultrasound by pressing and holding the handset button or the relevant footswitch. This will initiate the maximum operation period countdown. Ultrasound stops when handset button and/or footswitch is released, or if the countdown reaches zero.

CEMENT REMOVAL:
To minimize the risk of thermal damage to bones and soft tissues in close proximity of the cement, within the 30 seconds maximum operation period, intermittent energised sequences limited to 10 seconds are strongly recommended. In case of an exceptional clinical need to exceed this timing recommendation, the probe contact point must be changed frequently.

Irrigation is ***recommended while*** using this surgical function.

CEMENTLESS PROSTHESIS REMOVAL:

To minimise the risk of thermal damage to the cut interface between the bone and the implant, within the 30 seconds maximum operation period, intermittent energised sequences limited to 5 seconds are strongly recommended. In case of an exceptional clinical need to exceed this timing recommendation, the probe contact point must be changed frequently.

Irrigation is ***mandatory*** while using this surgical function.

OSTEOTOMY:

To reduce the risk of thermal damage to the bone undergoing the osteotomy, within the 30 seconds maximum operation period, intermittent energized sequences limited to 5 seconds are strongly recommended. In case of an exceptional clinical need to exceed this timing recommendation, the probe contact point must be changed frequently.

Irrigation is ***mandatory while*** using this surgical function.

Precautions and Notes	
PRECAUTION	During bone cutting, bone necrosis may result if the probe is not moved relative to the bone. A continuous probe motion is recommended in order to minimise contact duration with the ultrasonic tip and minimise heat build-up. When motion is slow, proceed to cut the bone in more instances between pauses.
PRECAUTION	Extra care should be taken when operating the energised probe in the vicinity of nerves.
PRECAUTION	Do not operate OSCAR PRO™ Probes on the surgical site simultaneously with laser equipment or high frequency surgical equipment. The combined effect may lead to device damage and patient injury.
PRECAUTION	In case of high loads and prolonged use in exceptional cases beyond the recommended 10s duty cycle, the handset may accumulate heat up to 45°C. Overheating may affect the user and might reduce the handset transducer's life. For this reason, audible and visible alarms inform the user when the system is approaching this condition. Proceed by changing the handset in use or by reducing the active time of the duty cycle in favour of the cooling time, until the temperature limit returns within the acceptable range.
NOTE	The emission of ultrasound may be limited to a few seconds, up to a maximum of 30 seconds. Proceeding in short applications would allow better control of the surgical effect on the anatomical site and allow the probe to better withstand mechanical and thermal stress.
NOTE	The piezoelectric components inside the handset generate heat in normal working conditions. In conditions of prolonged use or handset aging, heat may accumulate and cause a rise in temperature. The system has a continuous temperature control system that intervenes in case the temperature shifts significantly from normal operative temperature. In the event this condition occurs, audible (beep) and visible feedback (flashing red light on handset) inform the user that the handset is reaching the operative limit. If the temperature limit is reached, the system automatically stops the emission of ultrasound. In this case, it is possible to use the other handset to continue operating while the first handset is cooling down.

5.6.2. Starting/Stopping irrigation

Precautions	
PRECAUTION	When enabling the irrigation function, verify that no spillage is occurring along the entire line from the water bag to the handset.
PRECAUTION	To ensure effective cooling, the irrigation flow shall be directed on the tip of the probe by adjusting the direction of the dedicated irrigation nozzle.
PRECAUTION	During use, the probe for cement removal may reach a temperature up to 120°C, depending on the use. Irrigation, either manual or assisted by the OSCAR PRO™ irrigation function, must be used whenever temperature control is deemed necessary to limit overheating effects such as bone necrosis around the cemented area. See **section 5.6** of this manual and the operative technique for specific indications.
PRECAUTION	During use, the probe for bone cutting may reach a temperature above 47°C. Irrigation, either manual or assisted by the OSCAR PRO™ irrigation function, must be used to limit overheating effects such as necrosis of bone or other surrounding tissues. See **section 5.6** of this manual and the operative technique for specific indications.

Irrigation can be started and stopped by pressing the relative footswitch.
The irrigation flow rate can be adjusted from the touchscreen by tapping the flow rate icon. Check that irrigation fluid bag is properly connected and the fluid bag is not empty. Irrigation is mandatory for specific surgical functions.

5.6.3. Switching handset/channel

If two handsets have been prepared and connected to the generator with the desired probes, it is possible to switch from the active handset to the non-active one by simply activating the other handset with its button. This will activate the other channel and the user can proceed with the probe scan and continue with the surgery. Better time-efficiency can be achieved by having two interchangeable handsets.

5.6.4. Probe changes during surgery

As per setup condition described in Section 4.2, two handsets are connected to the generator. If a probe needs to be replaced proceed as follows:

1. Attach the new probe to the idle handset on the channel not in use as per the instructions in section 4.
2. When ready to operate with the idle handset, perform the channel activation and probe scan via the handset button as per instructions in section 4. This will switch the channel and activate the idle handset.

5.7. END OF USE

Precaution	
PRECAUTION	Follow the appropriate sequence of steps to shut down the generator: first, select the power off option from the menu function and then, once the procedure is complete, including pump cleaning if necessary, the user can proceed with switching it off by pressing the ON|OFF switch positioned in the rear panel of the generator.

5.7.1. Switching off the generator user interface

As soon as the OSCAR PRO™ is not needed to continue the surgery, exit the Operate page by touching the Home icon. Switch off the generator user interface by touching the switch icon. This step does not isolate the equipment circuits from the power supply mains.

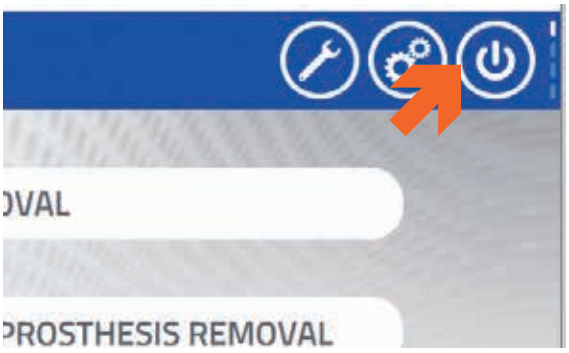


Figure 41 POWER OFF ICON

5.7.2. Purging the irrigation tube

In the event that irrigation functionality was used, before switching the generator off, the system reminds the user to empty the irrigation tube. Confirm the task and dispose of the remaining water in a bucket for waste liquids.

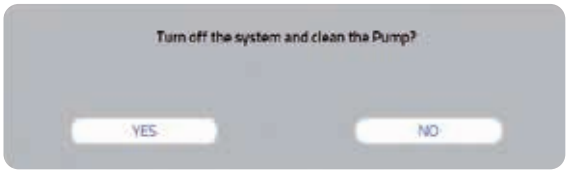


Figure 42 CONFIRM IRRIGATION LINE PURGE

5.7.3. Turn off the generator

The main power supply switch is located on the back of the unit. When steps 5.7.1 and 5.7.2, above, have been completed, the unit can be turned off to isolate equipment circuits electrically from the power supply mains on all poles simultaneously.

Figure 43 MAIN SWITCH OFF

6. SYSTEM & MAINTENANCE AREA

Touch the tool icon to access the System & Maintenance area:

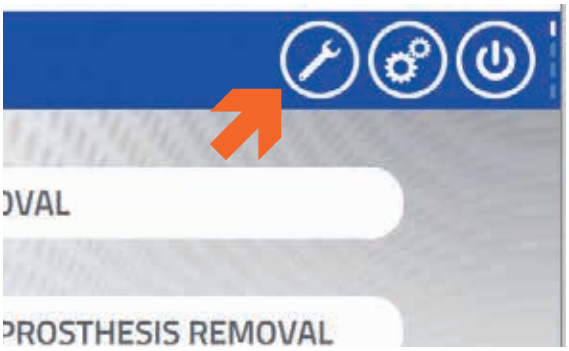


Figure 44 SYSTEM & MAINTENANCE AREA ICON

The System Area section displays the main system information:

- Serial Number of the generator.
- Software version in use on the system.
- Wi-Fi MAC address.
- Contact information.

Figure 45 MAINTENANCE AREA PAGE

6.1. RESET

Note	
NOTE	The reset procedure will not override any blocking or non-blocking errors that may be present.

When the Reset button is tapped, the system asks for confirmation.

The system will reset the system settings at the next power-on of the generator and the user will be asked to perform the Setting tasks in **sections 5.3.1** and **5.3.2.** From this section, it is possible for the appropriate personnel to access the area devoted to maintenance by tapping the [Maintenance] button.

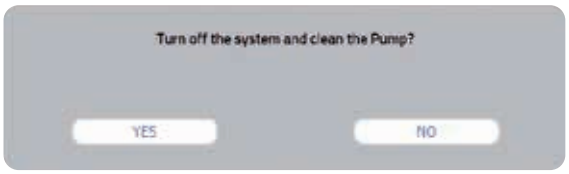


Figure 46 CONFIRMING RESET

7. CONNECTION AREA

Note	
NOTE	This section is password-protected and access is permitted to authorised Orthofix representatives only and **strictly outside the operating theatre**.

The following functionalities can be selected using the generator as a stand-alone device. No additional hardware (handsets/footswitches) is required.

From the System & Maintenance Area touch the button ***Maintenance***.

Within this area, it is possible:

- To copy or send the generator ***log*** files via USB port or WIFI connection (authorized Orthofix representatives only).
- To access the [Admin] area (Orthofix personnel only).

Figure 47 ACCESS TO MAINTENANCE AREA

7.1. COPYING OR SENDING THE DATA LOG

As the generator software collects data, errors, events or triggers that have occurred during use, it will be possible to copy this information periodically onto a USB device or to send the data log files via Wi-Fi.

Note	
NOTE	If a USB device is not connected, the Wi-Fi connectivity is the default option.

7.1.1. Copy Data Log onto USB

Warning	
WARNING	Use only USB mass storage devices with no connection with other devices and no connection to power supply. Failing to comply with this restriction may expose the hospital network to a security violation and compromise the integrity of the device.

- Insert a USB device into the dedicated port on the rear of the generator. This will enable the USB functionality.
- Select the USB tab. The page shows the name and total memory space on the connected USB device.
- Tapping the SEND button copies the log files to the USB device.
- Once this is complete, tap the CLOSE AND DISCONNECT button on the message window to disable the USB port. The USB device can be unplugged from the generator.

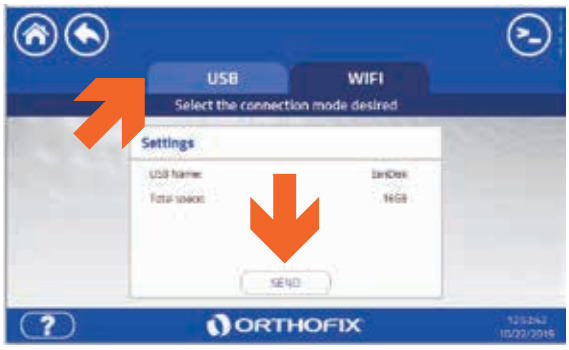


Figure 48 CONNECTION PAGE AREA

Figure 49 DATA TRANSFER SUCCESSFUL

7.1.2. Sending the data log via Wi-Fi

Warning	
WARNING	A data log copied to a USB device can be also transmitted via Wi-Fi, but not vice versa.

- Select the Wi-Fi tab. This will enable the Wi-Fi connectivity of the generator. Being outside the operating theatre is a mandatory requirement for this step.
- A list of available Wi-Fi networks will be shown.
- Select the preferred Wi-Fi network, type the password and touch the CONNECT button.
- Once successfully connected to the selected Wi-Fi network, it is possible to send the data log files by tapping the SEND button. Data log files are automatically sent to the Orthofix OSCAR PRO™ Portal.

Figure 50 WIFI CONNECTIVITY PAGE

Figure 51 DATA TRANSFER SUCCESSFUL

7.2. ADMIN AREA

The icon on the top right corner is dedicated to access to the Administrator's area. An additional dedicated password is required. No user functions are available.

Figure 52 ACCESS TO ADMINISTRATOR AREA

8. AUDIBLE AND VISIBLE FEEDBACK SUMMARY

ID	Event/Status trigger description	LIGHT FEEDBACK on handset & related channel outlet	AUDIBLE FEEDBACK	Description
FB1	System turning ON	LED colour sequence to Off	None	When system is turned ON. The light sequence is blue, green, blue, red, then off. This is a visibility testing sequence, no specific operation is being performed by the system during this sequence.
FB2	Handset cable plugged into channel outlet	LED colour sequence to Off	None	When the handset cable, with handset attached, is plugged into the respective channel outlet. The light sequence is blue, green, blue, red, then off.
FB3	Channel off	Off	None	When the channel is not selected, the LED is off.
FB4	Channel selected	Blue	None	When the channel is selected, the LED is blue.
FB5	Scan in progress	Flashing blue	None	During the scan procedure, the LED flashes blue.
FB6	Operate - ultrasound inactive	Green	None	On the Operate page, when ultrasound is inactive, the LED is green.
FB7	Operate - ultrasound active - time within 80% time range	Flashing green	Slow intermittent beep	On the Operate page, when ultrasound is active, the LED flashes green and the system emits a slow intermittent beep.
FB8	Operate - ultrasound active - 80% time range < time < maximum range	Flashing green	Fast intermittent beep	On the Operate page, when the ultrasound is active and the cycle countdown exceeds 80% of the max. operation time, the LED flashes green and the system emits a fast intermittent beep.
FB9	Ultrasound active > maximum range - cooling operation	Red	Single beep	On the Operate page, when the cycle countdown exceeds the max. operation time, the system stops the ultrasound and starts the cooling operation. The system emits a single beep at the end of the cycle countdown. The system sets a red LED if the handset button is released during the cooling time, and sets a green LED at the end of the cooling operation.
FB10	System blocking error	None	Single beep	When a system blocking error occurs, the system displays a pop-up with an error message and emits a single beep. After a few seconds, the system turns off automatically.
FB11	Handset blocking error	Red	Single beep	When a channel blocking error occurs, the system displays a pop-up with error message and emits a single beep. The system disables the channel and sets a red LED when the handset button is released until the error disappears.
FB12	Ultrasound warning	Flashing Red	Beep burst	When a warning error occurs during ultrasound activation, the system displays a pop-up with warning message and emits a single beep. The system sets flashing a red LED and emits a beep burst until the ultrasound is inactivated by the user or the warning disappears.
FB13	Temperature warning	Flashing Yellow	Beep burst	When the handset button is released and a warning error occurs, the system displays a pop-up with warning message, emits beep bursts and sets flashing yellow LED. The system sets green LED when the warning situation ends, or flashing green LED if the ultrasound is activated.
FB14	Ultrasound button issue	White	None	When an issue occurs on the ultrasound activation button on the handset, the handsets LED turns white until issue is resolved or handset channel is deactivated.

9. INSTRUCTIONS FOR PROCESSING AND REPROCESSING

DISCLAIMER

The instructions provided in this section have been written in accordance with ISO17664 and have been validated by Orthofix in compliance with international standards. The instructions are a true description of the preparation of a device for first clinical use or for re-use of multiple use devices. It remains the responsibility of the reprocessing officer to ensure that the reprocessing, as actually performed using equipment, materials and personnel in the reprocessing facility, achieves the desired result. This normally requires validation and routine monitoring of the process. The cleaning, disinfection and sterilisation processes must be adequately recorded. Likewise any deviation by the reprocessing officer from the instructions provided must be properly evaluated for effectiveness and potential adverse consequences and must also be appropriately recorded.

9.1. WARNINGS

Warnings	
WARNING	Single use devices MUST NOT BE REUSED, as they are not designed to perform as intended after the first usage. The used probes MUST BE discarded after the surgical procedure. Do not attempt to reuse or re-sterilise any single-use items.
WARNING	Personnel working with contaminated medical devices must follow safety precautions as per the healthcare facility's procedures.

9.2. LIMITATIONS ON REPROCESSING

- Repeated reprocessing has minimal effect on reusable instruments.
- End of life is normally determined by wear and damage due to use.
- Products labelled for single use only MUST NOT be reused regardless of any reprocessing.
- Damaged instruments MUST NOT be used in order to prevent potential patient injury.

9.3. POINT OF USE

It is recommended that the reusable medical devices are reprocessed as soon as is reasonably practicable. DO NOT use a fixating detergent or hot water because this can cause the fixation of residue, which may influence the result of the reprocessing process.

9.4. CONTAINMENT AND TRANSPORTATION

It is recommended that contaminated instruments are covered during transportation in order to minimise the risk of cross-contamination. All used surgical instruments must be regarded as contaminated. Follow the hospital protocols for handling contaminated and bio-hazardous materials. The handling, collection and transportation of used instruments must be strictly controlled to minimise any possible risks to the patient, personnel and any area of the healthcare facility.

9.5. CLEANING AND STERILISATION

The OSCAR PRO™ components must be cleaned and sterilised according to different instructions as summarised in the table below.

Table 1. Map of processes for each component

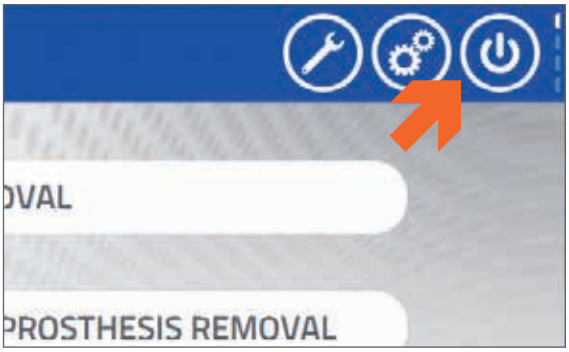
CODE	DESCRIPTION	APPLICABLE PARAGRAPH MARKED WITH "o"					
		9.5.1	9.5.2		9.5.3	9.5.4	9.5.5
			9.5.2.1	9.5.2.2			
OS4000*	GENERATOR	o	o	-	o	-	-
O4BEAM	HOLDER FOR WATER BAG	o	o	-	o	-	-
O4FOOT-W*	FOOTSWITCH FOR IRRIGATION	o	o	-	o	-	-
O4FOOT-U*	FOOTSWITCH FOR ULTRASOUND	o	o	-	o	-	-
O4POW . . . [local model]	MAIN LEAD	o	o	-	o	-	-
O4HAND*	UNIVERSAL HANDSET	o	-	o	o	o	o
	HORN ENCLOSURE			o	o		
	LEVER BUTTON			o	o		
O4CABLE*	UNIVERSAL HANDSET CABLE	o	-	o	o	o	o
O4UHH	UNIVERSAL HANDSET HANDLE	o	-	o	o	o	o
SPAN7MM	OPEN END WRENCH 7MM	-	-	o	o	o	o
SPAN8-9MM	OPEN END WRENCH 8-9MM	-	-	o	o	o	o
O4HOLD	HANDSET HOLDER	-	-	o	o	o	o
O4IPL200	SLAP HAMMER	-	-	o	o	o	o
O4TRAY-01	BASE TRAY	-	-	o	o	o	o
O4TRAY-02	LID TRAY	-	-	o	o	o	o

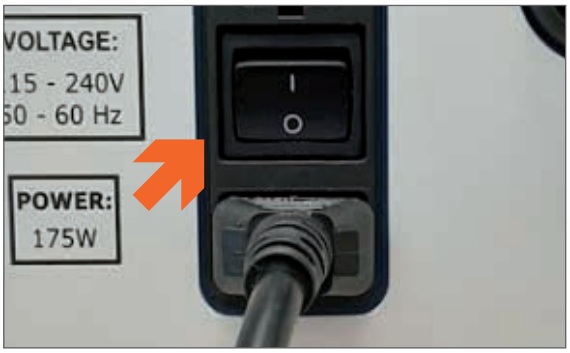
* Component of the device: OSCARPRO™ – ULTRASOUND MEDICAL SYSTEM

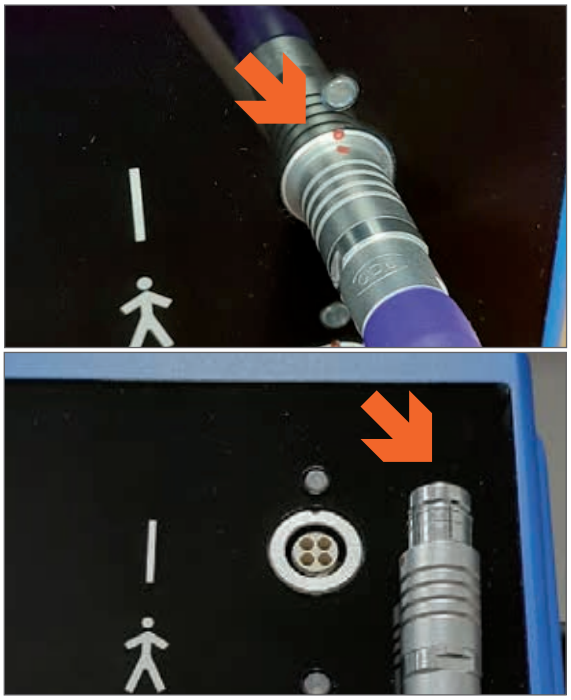
9.5.1. Disconnection and Disassembly

Follow the steps below in order to prepare the devices for the reprocessing phase.

Table 2. Disconnection of components

STEP	DESCRIPTION
Switching off the generator user interface.	• From the Surgical Function menu touch the Power button.  *Figure 53 POWER OFF* • This initiates the system shut-down, including pump purge and eventual error listing.  *Figure 54 MESSAGES AT POWER OFF*

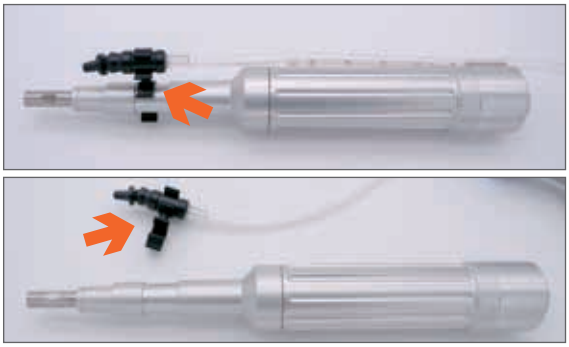
STEP	DESCRIPTION
Turn off the generator.	• Once the system shuts down, set Main Power switch on generator rear to OFF.  *Figure 55 MAIN SWITCH OFF*
Disconnect the Power Cable.	• Once the system shut down procedure is completed, remove the Power cable from the socket and disconnect it from the OSCAR PRO™ Generator.  *Figure 56 POWER CABLE DISCONNECTION*
Disconnect the equipotential cable (not provided by Orthofix).	• Once the system shut down procedure is completed, disconnect the equipotential bonding from the OSCAR PRO™ Generator.  *Figure 57 EQUIPOTENTIAL CABLE DISCONNECTION*

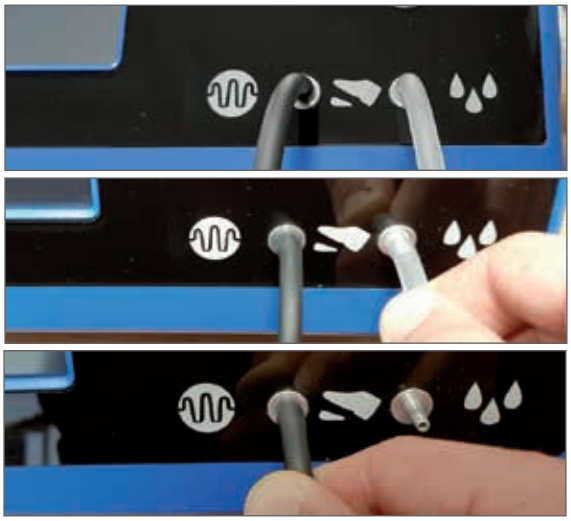
STEP	DESCRIPTION
Disconnect the handset cable from the generator.	• Pull the cable connector from receptacle on the front panel of the generator.  *Figure 58 HANDSET CABLE DISCONNECTION FROM GENERATOR* • Repeat the operation if a second handset was used.

Warning

WARNING Take care when handling handsets with probes attached, some edges are serrated and sharp.

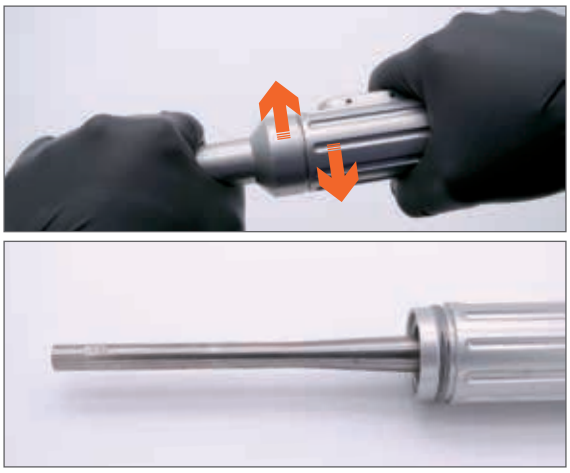
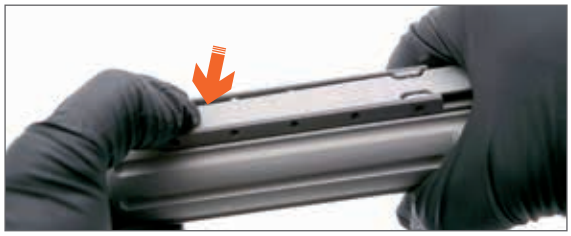
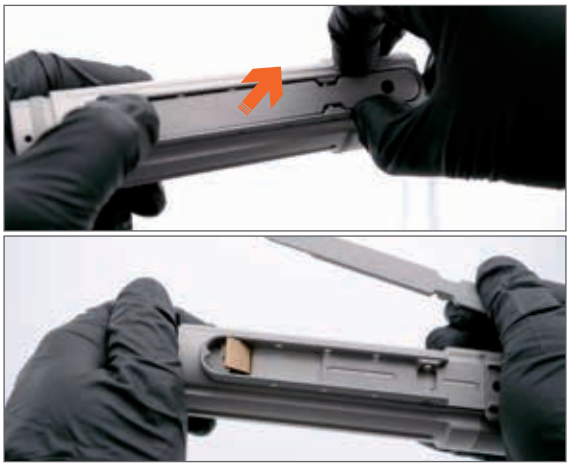
Disconnect the handset cable from the handset.	• Pull the handset cable plug from the handset.  • Repeat the operation if a second handset was used.  *Figure 59 HANDSET CABLE DISCONNECTION FROM HANDSET* • Prepare the handset cable(s) for the reprocessing phase.

STEP	DESCRIPTION
Disconnect the irrigation tube from the handset.	• Remove the black clip and the irrigation tube from the handset.  *Figure 60 WATER IRRIGATION DISCONNECTION* • Remove the clips from the handset cable.
Remove the handset handle.	• Rotate the handle lever in order to remove the handset from the secure position.  • Pull the handle from the handset.  *Figure 61 HANDSET HANDLE DISCONNECTION* • Prepare the handle for the reprocessing phase.

STEP	DESCRIPTION
Remove the probe.	• Position the handset horn on the handset holder. Detach the probe from the handsets using the spanner. The size is marked on the probe.  *Figure 62 PROBE DISASSEMBLY* • The probe is single use; dispose of item in accordance with standard hospital procedures for disposal of bio-contaminated waste.
Remove the irrigation tube from the peristaltic pump.	• Open pump cover. Remove tubing from pump compartment.  *Figure 63 REMOVAL OF IRRIGATION TUBE FROM PUMP* • Remove the tubing from the irrigant container. • The Irrigation set is single use; dispose of the item in accordance with standard hospital procedures for bio-contaminated waste.
Remove Footswitch connection.	• Pull the tubing of the footswitch from the receptacle on the front panel of the generator.  *Figure 64 DISCONNECTION OF IRRIGATION TUBE FROM GENERATOR*

STEP	DESCRIPTION
Remove the beam for water bag.	• Remove the irrigant container. • Remove the beam for the water bag from the OSCAR PRO™ Generator. • Prepare the beam for the reprocessing phase.

Table 3. Handset disassembly

STEP	DESCRIPTION
Remove the horn enclosure.	• Unscrew the horn enclosure and pull it from the handset.  *Figure 65 DISASSEMBLY OF HANDSET HORN ENCLOSURE* • Prepare the horn enclosure for the reprocessing phase.
Remove the lever button.	• Push the lever button in order to remove it from its proper position.  • Pull the lever near the hinge to disconnect it from the handset.  *Figure 66 DISASSEMBLY OF HANDSET BUTTON LEVER* • Prepare the lever button and the disassembled handset for the reprocessing phase.

9.5.2. Cleaning

Warnings	
WARNING	DO NOT USE detergents and disinfectants with fluoride, chloride, bromide, iodide or hydroxyl ions. Their use will damage the devices and may cause device failure during use.
WARNING	Contact with saline solutions should be kept to a minimum.
WARNING	The use of ultrasonic washers is not permitted for cleaning the ultrasonic generator, the handsets, the main lead and the footswitches with their pneumatic tubes.
WARNING	The ultrasonic generator, main lead and footswitches with their pneumatic tubes must not be immersed in cleaning solution.
WARNING	Sterilisation of the ultrasonic generator, main lead and footswitches with their pneumatic tubes is not permitted.

9.5.2.1. Generator, Beam for water bag, Footswitches, Main Lead, Equipotential Cable

9.5.2.1.1. General considerations

Staff shall use protective equipment following the safety precautions in accordance with the procedure of the healthcare facility. In particular, staff should take note of the instructions provided by the cleaning agent manufacturer for correct handling and use of the product.

9.5.2.1.2. Manual cleaning

The OSCAR PRO™ generator, the footswitch and the main lead must be cleaned using the following procedure:

1. Wipe the footswitch and generator, including the irrigation pump and the main lead using absorbent paper or non-shedding cloth soaked with sufficient disinfectant solution. Orthofix recommends the use of isopropyl alcohol.
2. Wipe all the surfaces of the devices carefully.
3. Carefully hand-dry using absorbent, non-shedding cloth.
4. Dispose of the cloth or paper with contaminated waste.

No other reprocessing steps are necessary for these components.

9.5.2.2. Handsets, handset cables and instruments

9.5.2.2.1. General considerations

Staff shall use protective equipment following safety precautions in line with the policy of the healthcare facility. In particular, staff should take note of the instructions provided by the cleaning agent manufacturer for correct handling and use of the product.

The quality of the water used for diluting cleaning agents and for rinsing medical devices should be carefully considered. The use of purified sterile water is recommended.

9.5.2.2.2. Automatic cleaning and disinfection using washer-disinfector

The OSCAR PRO™ handsets, cables and instruments must be cleaned using the following instructions:

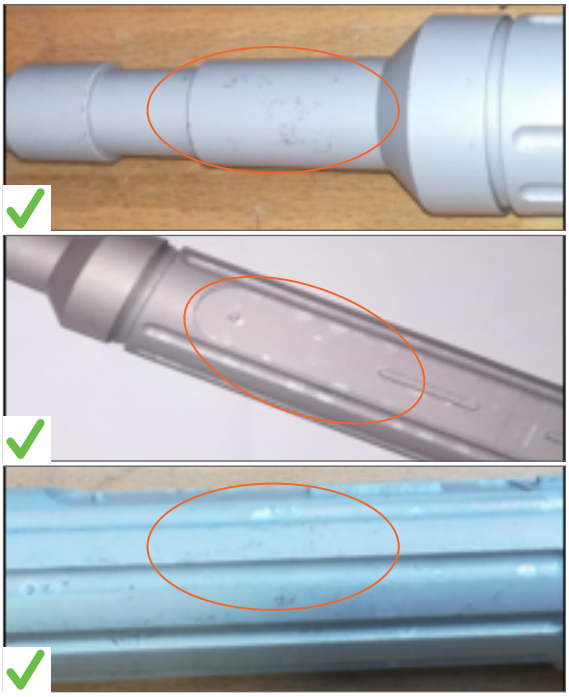
1. Use a washer-disinfector in compliance with EN ISO 15883 that is properly installed, qualified and regularly subjected to maintenance and testing.
2. Ensure that the cleaning receptacle is clean and dry, no visible foreign material may be present.
3. Ensure that the washer-disinfector and all services are operational.
4. Load the medical devices into the washer-disinfector. Place heavier devices in the bottom of the baskets. Wherever possible, all parts of disassembled devices should be kept together in one container.
5. Use the approved thermal disinfection program. When using alkaline solutions, a neutraliser must be added. Orthofix recommends that cycle steps are at least as follows:
    a. Pre-cleaning for 4 min.
    b. Cleaning with a slightly alkaline enzymatic cleaning solution 0.5% for 10 min. at 55 °C.
    c. Neutralization with basic neutralizing agent solution 0.1% for 6 min.
    d. Final rinsing with deionised water for 3 min.
    e. Thermal disinfection at least 90°C or 194° F (max 95 °C or 203° F) for 5 minutes.
6. Select and start a cycle according to the recommendations of the washer manufacturer.
7. On completion of the cycle, ensure that all stages and parameters have been achieved.
8. Wearing protective equipment, unload the washer-disinfector when it has completed the cycle.
9. If necessary, drain off excessive water and dry by using clean, disposable, absorbent, non-shedding cloth or a mechanical drying facility. Do not exceed a drying temperature of 140 °C (284 °F).
10. Visually inspect each device for remaining soiling and dryness. If soiling remains, repeat the cleaning process as described above.

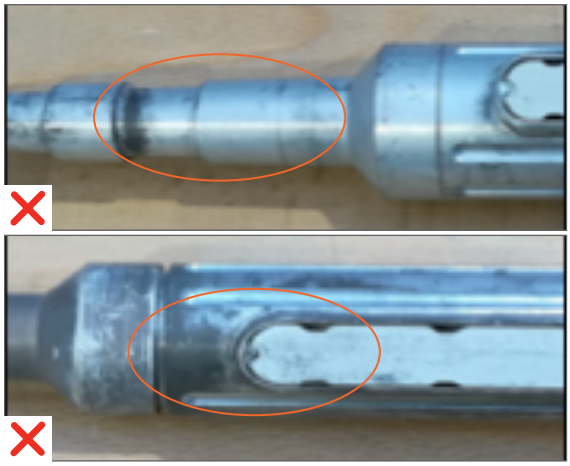
Warning and Note	
WARNING	Avoid contact between devices because movement during washing could cause damages on devices and the washing efficacy could be reduced.
NOTE	The suitability of other solutions, concentration, time and temperature shall be checked and validated by the user following the manufacturer technical datasheet of the detergent.

9.5.3. Maintenance, inspection and function testing

The following guidelines shall be applied to all Orthofix instruments that are labelled for multiple use.
All functional checks and inspections described below also cover the interfaces with other instruments or components.
The failure modes below may be caused by end of life of the product, improper use or improper maintenance.
Orthofix does not typically specify the maximum number of uses for re-useable medical devices. The useful life of these devices depends on many factors including the method and duration of each use, and the handling between uses. Careful inspection and functional testing of the device before use is the best method of determining the end of the serviceable life for the medical device.
Moreover, it is important to follow the cleaning procedure suggested by Orthofix in order to avoid damages related to incorrect handling.
The following general instructions apply to all Orthofix products:

- If visual inspection indicates that the device was not properly cleaned, repeat the cleaning and disinfection steps or discard the device.
- Instruments and product components must be visually inspected for any signs of deterioration that may cause failure during use.
  - Accessory instruments shall be inspected for signs of wear such as cracks or damage to surfaces
  - Handsets may present blemishes, discolored areas and drop marks. This is a characteristic of the light material used and does not compromise the safety and functionality of the device. Reference pictures below for guidance.





Note	
NOTE	The handsets are tested to withstand a minimum of 60 reprocessing cycles. Orthofix advises to perform a maintenance service on these handsets either at reaching the 60 reprocessing cycles or once a year as a standard maintenance service. Please contact your local authorized representative for further information on servicing.

All OSCAR PRO™ components need to examined regularly, prior to each use, and in case of failure, the devices must be replaced and must not be used.

- If a component or instrument is believed to be faulty, damaged or suspect, it must NOT BE USED.
- Products that show excessive fading of marked product code , UDI and lot, thus preventing clear identification and traceability, must NOT BE USED.
- When instruments form part of an assembly, check assembly with matching components.
- Inspect cables for wear and damage, ensuring that no cracks, tears or other damage is found.
- Place the devices in the dedicated sterilisation tray, looking at the placeholder markings on the bottom.

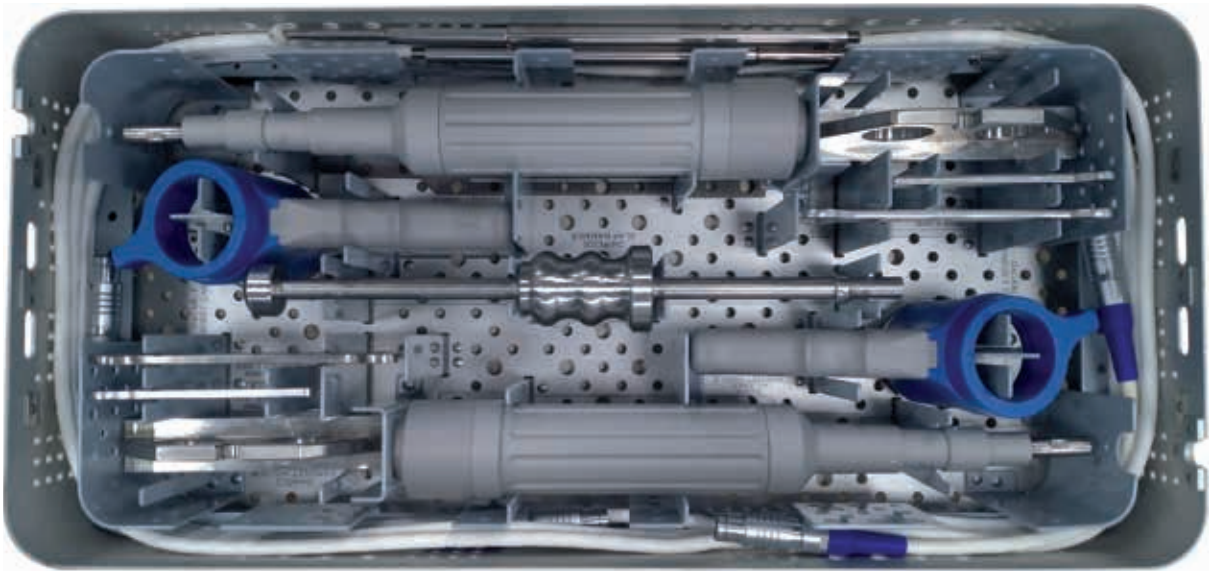


Figure 67 INSTRUMENT TRAY COMPOSITION

Instructions for service and repair are described in **section 11**.

9.5.4. Packaging

In order to prevent contamination after sterilisation Orthofix recommends using one of the following packaging systems:

a. Wrap in compliance with EN ISO 11607, suitable for steam sterilisation, and appropriate to protect the instruments or trays contained against mechanical damage. The wrap shall be resistant enough to contain devices up to 10kg. In the USA, an FDA cleared sterilisation wrap must be used and compliance with ANSI/AAMI ST79 must be granted. In Europe, a sterilisation wrap in compliance with EN 868-2 may be used.
b. Rigid sterilisation containers (such as Aesculap JK series rigid sterilisation containers). In Europe, a container in compliance with EN 868-8 may be used. Do not include additional systems or instruments in the same sterilisation container.

Warning and Note	
WARNING	Do not include additional devices or instruments in the sterilisation tray. Sterility is not guaranteed if the sterilisation tray is overloaded.
NOTE	The total weight of a wrapped instrument tray does not exceed 10kg.

9.5.5. Sterilisation

Steam sterilisation according to EN ISO 17665 and ANSI/AMMI ST79 is recommended.
Steriliser must allow a load of at least 10kg of metallic devices.
Gas plasma, dry heat and EtO sterilisation MUST BE AVOIDED as they were not validated for Orthofix products.
Orthofix recommends always using a pre-vacuum cycle for steam sterilisation. The Gravity cycle was validated but is suggested only when no other options are available.

- Use a validated, properly maintained and calibrated steam steriliser.
- The steam quality must be appropriate for the process to be effective.
- Do not exceed 140°C (284°F).
- Do not stack trays during sterilisation.

Sterilise by steam autoclaving, utilising a fractioned pre-vacuum cycle or gravity cycle according to the table below:

Steam steriliser type	Gravity	Pre-vacuum	Pre-vacuum	Pre-vacuum
Notes	Not for use in EU	-	Not for use in US	For countries following WHO guidelines
Minimum exposure Temperature	132° C (270° F)	132° C (270° F)	134° C (273° F)	134° C (273° F)
Minimum exposure Time	15 minutes	4 minutes	3 minutes	18 minutes
Drying Time	30 minutes	30 minutes	30 minutes	30 minutes
Number of pulses	N/A	4	4	4

9.5.6. Deviations from Cleaning and Sterilisation Instructions

The manufacturer has validated all cleaning, disinfection and sterilisation cycles given in this manual. It is highly recommended that the procedures given in this manual for cleaning and sterilizing the OSCAR PRO™ System and related accessories be followed. It is the responsibility of the user of this device or any accessories used with it to validate procedures for cleaning and/or sterilisation if they differ from the procedures as outlined in this manual.

9.6. STORAGE

Store the sterilised instrument in the sterilisation packaging in a dry and clean environment at room temperature.

10. TROUBLESHOOTING

10.1. EVENTS

While in use, blocking and non-blocking events may occur depending on how the device is being used. On-screen notifications are shown in addition to audible and visual feedback.

When an event occurs, a pop-up window appears with information about it, while a warning symbol appears in the screen header. A unique code is assigned to each event in order to let the user review the detailed troubleshooting below.

To review the list of messages touch the yellow icon to review the event list.

Figure 68 EVENT ICON EXAMPLE

10.1.1. Non-blocking events

A non-blocking event is a WARNING that notifies the user but allows the standard operation mode to continue following simple instructions. The screen presents a yellow popup with a message identified by a tag WAR[XXX].

Figure 69 WARNING ICON EXAMPLE

10.1.2. Blocking events

A blocking event is an ERROR that causes the system to stop.

- It could be a temporary stop, meaning that after the appropriate troubleshooting is executed the system can be used again.

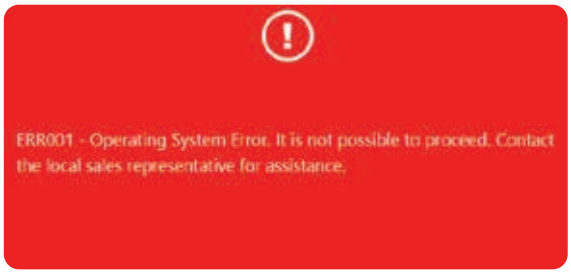


Figure 70 ERROR ICON EXAMPLE

- Alternatively, it could be a permanent blocking error, which means that the system will shut down and device assistance will have to be requested.

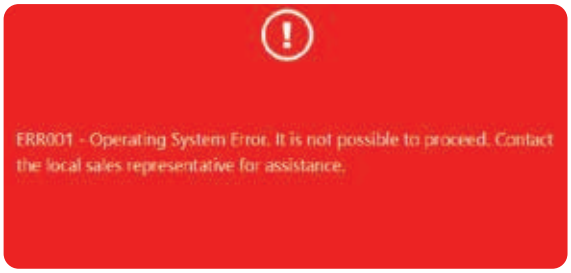


Figure 71 ERROR ICON EXAMPLE

CODE	Troubleshooting
WAR001	Low storage space available. System is fully operational. At the earliest possible opportunity, please contact your local sales representative.
WAR004	Cooling in progress. Wait until the ultrasound countdown will be available again.
WAR005	Working Frequency out-of-range. Release Handset button or Ultrasound footswitch. Please check if probe is stuck in cement. In case it is, please refer to the Operative Technique troubleshooting.
WAR006	Working Frequency out-of-range. Release Handset button or Ultrasound footswitch. Please check if probe is stuck in cement. In case it is, please refer to the Operative Technique troubleshooting.
WAR007	High temperature detected in the handset in use. Change the handset or switch to other channel to continue while the cooling completes.
WAR008	High temperature detected in the handset in use. Change the handset or switch to other channel to continue while the cooling completes.
WAR009	System clock error detected. System is operational. At the earliest possible opportunity, please contact your local sales representative.
WAR010	High temperature detected. Switch channel.
WAR011	High temperature detected. Switch channel.
WAR012	Peristaltic pump out-of-service. Please proceed using a manual and/or external irrigation system.
ERR001	Operating System Error. It is not possible to proceed. Contact local sales representative for assistance.
ERR002	Operating System Error. It is not possible to proceed. Contact local sales representative for assistance.
ERR003	Operating System Error. It is not possible to proceed. Contact local sales representative for assistance.
ERR004	Operating System Error. It is not possible to proceed. Contact local sales representative for assistance.
ERR005	Operating System Error. It is not possible to proceed. Contact local sales representative for assistance.
ERR006	Operating System Error. It is not possible to proceed. Contact local sales representative for assistance.
ERR007	Channel 1 out-of-service. Switch to Channel 2 to proceed. If the error persists, please contact local sales representative for assistance.
ERR008	Channel 2 out-of-service. Switch to Channel 1 to proceed. If the error persists, please contact local sales representative for assistance.
ERR009	Channel 1 temperature is over limit and it has been disconnected. Switch to Channel 2 to proceed.
ERR010	Channel 2 temperature is over limit and it has been disconnected. Switch to Channel 1 to proceed.
ERR011	Handset has reached maximum temperature limit. Change the handset or switch to other channel to continue while the cooling completes.
ERR012	Handset has reached maximum temperature limit. Change the handset or switch to other channel to continue while the cooling completes.
ERR013	Channel 1 out-of-service. Switch to Channel 2 to proceed. If the error persists, please contact the local sales representative.
ERR014	Channel 2 out-of-service. Switch to Channel 1 to proceed. If the error persists, please contact the local sales representative.
ERR015	Working frequency out-of-range for channel. Switch to other channel to proceed. If both channels are experiencing the same error, restart the generator. If the error persists, please contact the local sales representative.
ERR016	Working frequency out-of-range for channel. Switch to other channel to proceed. If both channels are experiencing the same error, restart the generator. If the error persists, please contact the local sales representative.
ERR017	Working frequency out-of-range for channel. Switch to other channel to proceed. If both channels are experiencing the same error, restart the generator. If the error persists, please contact the local sales representative.
ERR018	Working frequency out-of-range for channel. Switch to other channel to proceed. If both channels are experiencing the same error, restart the generator. If the error persists, please contact the local sales representative.
ERR019	Working frequency out-of-range for channel. Switch to other channel to proceed. If both channels are experiencing the same error, restart the generator. If the error persists, please contact the local sales representative.
ERR020	Working frequency out-of-range for channel. Switch to other channel to proceed. If both channels are experiencing the same error, restart the generator. If the error persists, please contact the local sales representative.
ERR021	Operating System Error. It is not possible to proceed. Contact the local sales representative.

10.2.1. Touchscreen frozen

If the touchscreen is frozen (status bar located in the right corner of the header is not flashing), this means that the GUI (Graphic User Interface) is not responding. This requires a hard shutdown of the generator through the ON | OFF switch positioned on the rear panel.

If the frozen status persists, shut down the system and contact the local sales representative.

11. SERVICE & REPAIR

Proper system earthing can only be ensured when an approved, hospital-grade power outlet and matching power cable are used. Connect the plug and outlet as per local regulations before operating the unit. The power cable, plug and outlet should be examined to verify that they are in good working condition before connecting the console. Never pull on the power cable to remove it from the power outlet.

11.1. CHANGING FUSES

To change rear fuses, first disconnect the generator from the main supply. The fuse compartment may be extracted by pressing the slot adjacent to the On/Off switch. Ensure that the replacement fuse is of the correct type (see table Appendix 2 in section 0.4).

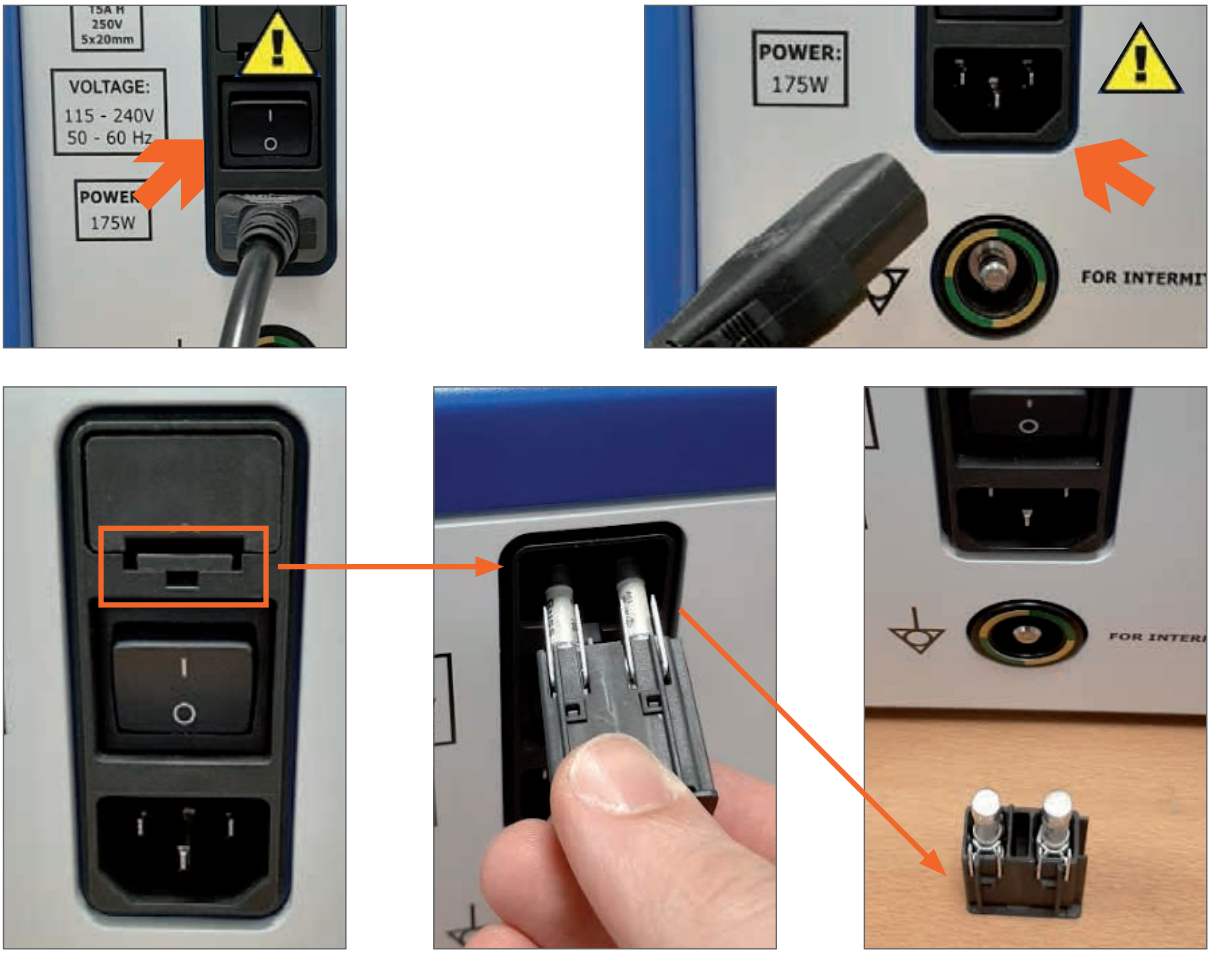


Figure 72 REPLACEMENT OF MAIN FUSES

11.2. SERVICE & REPAIR ACTIVITIES

Orthofix does not designate any part of the equipment as user repairable. If you have any questions, require assistance or wish to discuss specific troubleshooting actions, contact your local sales representative or Orthofix using the contact details provided in this User Manual.

12. DISPOSAL

- Probes are single use and must be disposed of in a dedicated bin for biohazardous sharps.
- Irrigation kit is single use and must be disposed of in a dedicated bin for biohazardous waste.
- Generator, handsets and cables are multiple use and shall be disposed properly at the end of their life. They contain materials that may be recycled if disassembled by a specialised company. Please observe local regulations regarding the disposal of packing materials and old equipment.
- All other accessories are multiple-use and shall be disposed of properly at the end of their life, determined after inspection as per **section 9.5.3** of this manual.

Important Environmental Information for Users with in the European Economic Area
The European Council Directive 2002/96/EC on Waste Electrical and Electronic Equipment (EEE), usually referred to as WEEE Directive, places responsibilities on the supplier and you, the purchaser/user to dispose of electrical and electronic equipment properly. One of the actions required for a supplier is to inform users of their obligations. The WEEE Directive requires that the EEE be disposed of at the end of its useful life in an environmentally responsible manner. The WEEE Directive requires that if replacing the EEE with a new equivalent product, the supplier shall collect the old item without cost to the user. In a similar fashion, Directive 2006/66/EC on Batteries requires that batteries be disposed of at the end of their useful life in an environmentally responsible manner. The Directive on Batteries requires that when replacing batteries with new or equivalent batteries, the supplier shall collect the old batteries without cost to the user.
If you wish to dispose of the EEE and/or the batteries without having the supplier replace them then they must not be mixed with unsorted municipal waste. You must ensure that the EEE and/or the batteries are disposed of at an authorized treatment facility. Details for special disposal procedures for EEE and/or batteries can be obtained from your local council. 

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