OSSEODOC

DRILL SYSTEM

Operating Instructions

CE 1639

Rx Only

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REF 2100346-0006/2023.12

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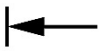
1 SYMBOLS USED

Symbol	Description	Symbol	Description
	CE Marking with number of the notified body.		UL Classification Mark for the United States and Canada.
	Protective earth (ground).		Connector for potential equalization lead.
Rx Only	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.		Type B device.
	CAUTION! Dangerous voltage.		Component sensitive to electrostatic discharge.
	CAUTION! Refer to the accompanying documents.		Danger of catching fingers Do not put your fingers in rotating parts.
	Materials to be recycled. The disposal and/or recycling of materials must be performed in accordance with the directives and the legislation in force.		Electrical or electronic materials to be recycled.
	Consult the accompanying documents.		Follow instructions for use.
	Manufacturer.		Coupling ring opening direction.
	Cleaning in machine authorized.		Sterilizable in autoclave up to the specified temperature.

2 CE/UL CONFORMITY

CE 1639

CE Marking with number of the notified body testifying that the device complies with European standards for electro-medical devices and the 93/42 EEC directives:

- General safety rules EN 60601-1
- Electromagnetic compatibility EN 60601-1-2: 2014

Classified by Underwriters Laboratories Inc. with respect to electric shock, fire and mechanical hazards only in accordance with ANSI/AAMI/IEC/EN ES60601- 1 (2012, 3.1 ed.) and CAN/CSA-C22.2 No. 60601-1 (2014).

Essential Performances according to EN IEC 60601-1:
Reliable activation/deactivation of the motor using the foot control.
Variations in the device speed and incorrect functioning do not represent unacceptable risks.

3 GENERAL

3.1 System description

Easy to use and small in size, the OSSEODOC control for bone microsurgery is practical and efficient. Touch-sensitive keys make it possible to select 4 motor speeds, the direction of rotation, two irrigation options and 4 peristaltic pump deliveries. The same functions are also available on the foot control. Pilot lamps and audible signals indicate the functions activated.

3.2 Intended use

The OSSEODOC system is intended to convert electrical energy to mechanically drive handpieces and microsaws used to cut and shape bones.

3.3 Indication for use

Product intended for professional use. The OSSEODOC system used with handpiece and microsaws has been designed for shaping bones as part of surgical operations in the areas of ENT and head and neck surgery such as otology, maxillofacial, rhinoplasty surgery.

3.4 Contraindications

None currently known.

4 PRECAUTIONS-WARNING

4.1 Warnings and precautions for use

For additional information, please contact Bien-Air Surgery SA at the address indicated on the back cover of this document.

⚠ **CAUTION**

Do not use this device in the presence of a flammable gas.

⚠ **CAUTION**

Avoid excessive pressure on the tool. The use of a tool with excessive pressure may cause an inordinate amount of heat buildup resulting in a thermal injury to tissue. See tools instruction for use for further information.

The device and its accessories should be used only by duly trained and competent medical personnel, in particular in compliance with the legal provisions in force regarding occupational safety, health and accident prevention measures, and the present user manual. According to these measures, the user has the following obligations:

- To only use devices in perfect working condition. In the event of irregular operation, excessive vibrations, abnormal overheating or other signs suggesting malfunctioning of the device, work must be suspended immediately. In this case, contact a repair center approved by Bien-Air Surgery SA.
- Make sure that the device is used only for the purpose for which it is intended, protect yourself, patients and third parties from all danger and avoid contamination from the product.

The device and its accessories are designed solely for medical treatment. Any use not in conformity with the intended use is unauthorized and may prove dangerous. This medical device complies with the European legal provisions in force.

Do not modify this equipment without authorization from the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

⚠ **CAUTION**

Never submerge the OSSEODOC control unit in disinfection solutions.

Install the control unit on an appropriate mounting to prevent risks of injury or infection for yourself, the patient or third parties. Use only Bien-Air Surgery SA original maintenance products, accessories and/or spare parts. The use of other products, accessories or parts could void the guarantee and/or endanger the patient or the operator.

⚠ **CAUTION**

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

For USA, use a power supply cord type SJT, AWG18, C13, 2m length, Nema 5 15P Hospital grade, UL classified.

Use a power supply cord that complies with regulations and norms in force in the country where the OSSEODOC unit is used.

⚠ **CAUTION**

Do not lift the pedal by the connection cable!

⚠ **CAUTION**

Handle the pedal with care, making sure not to throw it on the floor.

⚠ **CAUTION**

Danger of electrocution: Never open the device when it is connected to a mains power supply.

Use only original maintenance products, accessories and/or spare parts approved by the legal manufacturer. The use of other products, accessories or parts could void the guarantee and/or endanger the patient or the operator.

4.2 Environmental protection and indications for device disposal

This equipment must be recycled. The disposal and/or recycling of materials must be performed in accordance with the directives and the legislation in force. Electrical and electronic equipment may contain dangerous substances which constitute health and environmental hazards.

The user can return the device to the distributor or use a firm accredited for the treatment and recovery of this type of equipment (European directive 2012/19/EU).

4.3 Precautions regarding electromagnetic compatibility (EMC)

Regarding the EMC, and in order to maintain basic safety and the essential performances (refer to the Chap. 13 ACCOMPANYNG DOCUMENTS ACCORDING TO IEC 60601-1-2:2014, CHAPTER 5 for more information) for the expected service life of 10 years, the medical electrical equipment requires special precautions and must be installed and put into operation in accordance with the appropriate information provided in the service manual and in the present document. The OSSEODOC control unit complies with the EMC requirements according to IEC 60601-1-2:2014.

Radio-transmitting equipment, cellular phones, etc. should not be used in the immediate vicinity of the device as this could affect its operation. Special precautions should be taken when using strong emission sources such as high frequency surgical equipment and other similar equipment, to ensure that HF cables are not routed above or near the device. If in doubt, please contact a qualified technician or Bien-Air Surgery SA.

⚠ CAUTION

The use of the OSSEODOC control unit adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the OSSEODOC and other equipment should be observed to verify that they are operating normally.

Pins of connectors identified with the ESD warning control symbol should not be touched and connections should not be made to these connectors unless ESD precaution procedures have been followed.

⚠ CAUTION

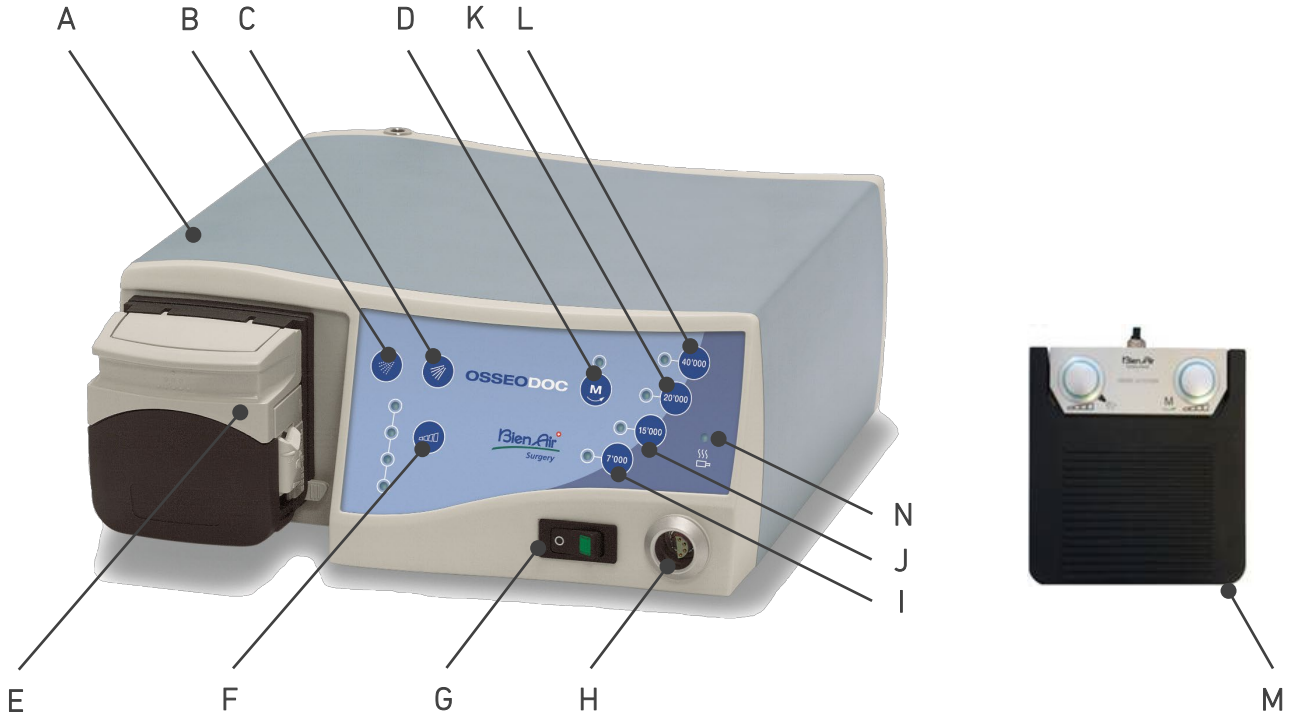
Use of accessories, transducers and cables other than those specified or provided by Bien-Air Surgery SA could result in increased electromagnetic emissions or a decreased electromagnetic immunity of the equipment and result in improper operation.

See Chap. 13 ACCOMPANYNG DOCUMENTS ACCORDING TO IEC 60601-1-2:2014, CHAPTER 5.

⚠ CAUTION

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the OSSEODOC control unit, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

5 DESCRIPTION OF THE **OSSEO**DOC DEVICE



A	**OSSEO**DOC control unit	H	Motor connector
B	Intermittent irrigation	I	Speed up to 7'000 rpm
C	Continuous irrigation	J	Speed up to 15'000 rpm
D	Clockwise / CCW rotation	K	Speed up to 20'000 rpm
E	Irrigation Pump	L	Speed up to 40'000 rpm
F	Irrigation flow setting	M	Multifunction foot pedal
G	Power switch	N	Motor overheating LED

5.1 Micromotors

BASCH: REF 1700074

BASCH-1: REF 1700502

5.2 Available sets

Set **OSSEO**DOC **BASCH** with pump	REF 1700168
1 control unit **OSSEO**DOC with pump	REF 1600331
1 micromotor **BASCH**	REF 1600076
1 cable for **BASCH** micromotor	REF 1600342
1 watertight multi-function pedal with 2 buttons	REF 1600407
1 irrigation stand	REF 1500017
1 set of 10 irrigation lines with 2 flow rate ranges	REF 1100037
1 set of 10 irrigation clips	REF 1300064

Set **OSSEO**DOC **BASCH** without pump	REF 1700169
1 control unit **OSSEO**DOC without pump	REF 1600332
1 micromotor **BASCH**	REF 1600076
1 cable for **BASCH** micromotor	REF 1600342
1 watertight multi-function pedal with 2 buttons	REF 1600407

Set **OSSEO**DOC **BASCH-1** with pump	REF 1700525
1 control unit **OSSEO**DOC with pump	REF 1600331
1 micromotor **BASCH-1**	REF 1600884
1 cable for **BASCH-1** micromotor	REF 1600342
1 watertight multi-function pedal with 2 buttons	REF 1600407
1 irrigation stand	REF 1500017
1 set of 10 irrigation lines with 2 flow rate ranges	REF 1100037
1 set of 10 irrigation clips	REF 1300064

Kit pump (for **OSSEO**DOC REF1700169)	REF 1700170
1 peristaltic pump	REF 1600333
1 irrigation stand	REF 1500017
1 set of 10 irrigation lines with 2 flow rate ranges	REF 1100037
1 set of 10 irrigation clips	REF 1300064

6 CONTROL UNIT AND FOOT PEDAL

6.1 Technical data

Subject to technical amendments and modifications of the models.

Environmental conditions:

Environmental conditions:	Operation	Transport	Storage
Temperature:	+10°C (50°F) to +30°C (86°F)	-25°C (-13°F) to +70°C (158°F)	0°C (32°F) to +40°C (104°F)
Relative humidity (including condensation)	20% to 80%	10% to 90%	10% to 90%
Atmospheric pressure:	700 hPa to 1060 hPa	600 hPa to 1060 hPa	600 hPa to 1060 hPa

Control unit OSSEODOC

Marquing:
CE 1639 as per 93/42 EEC directive.

Supply voltage:
115 - 230 Vac / 1.5A – 0.8A / 50/60 Hz.

Fuses:
2 fuses T 2,5 AH 250 Vac (for 230 VAC).
2 fuses T 3,15 AH 250 Vac (for 115 VAC).

Motor power supply:
1 push-pull type connectors / <50 Vdc.

Electrical insulation class:
Class I.

Applied parts:
Type B.

Medical class:
IIa as per 93/42 EEC directive.

Protection class:
IP 40.

Size / Weight:
(W x H x D) 261 x 110 x 300 mm (height with irrigation stand: 510 mm) / 5,0 kg with pump, 4,1 kg without pump.

Irrigation pump:
Delivery from 15 to 130 ml/min, 4 + 4 irrigation flow rate values (with two-speed Bien-Air Surgery SA irrigation line).

Irrigation stand:
Stainless steel

Multi-function pedal

Protection class:
IPX8 as per CEI 529.

Functions:
Direction of motor rotation selection speed control, irrigation pump start/stop and flow rate selection.

Size/Weight:
(W x H x D) 160 x 55 x 170 mm / 0.830 kg.

Cable length:
295 cm. ±5 cm.

FIG. 1

FIG. 2

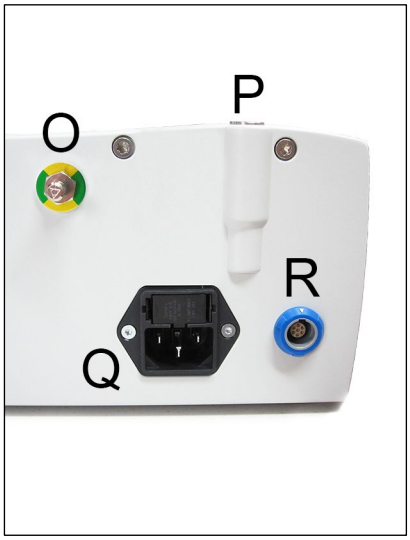


FIG. 3

6.2 Set-up

6.2.1 Unpacking and checking

⚠ **CAUTION**

Before operating the device, it should be stored for 24 hours according to operation environmental conditions.

1. When unpacking the cardboard box, check its contents against the delivery voucher. If items are missing or if the equipment is damaged, notify the sender immediately. If the shipment box is damaged, notify the carrier.
2. After unpacking, keep the shipment box and the packing materials. They could be useful for returning the device.

6.2.2 Preparation

1. Place the **OSSEO**DOC control unit in the non-sterile area, on a table, on a carriage or on any other surface, out of reach of the patient, with the main switch and power cord always accessible. The **OSSEO**DOC control unit must never be placed on the floor.
2. Check the fuse value (115 / 230 Vac) and position the voltage selector according to the voltage (FIG.1).
3. The control unit is powered by your line voltage (115 / 230 Vac). Place the main switch G (FIG.2) in position 0 and connect the power cable to the plug Q (FIG.3).
4. Connect the pedal cable to output R (FIG.3) on the back of the unit, align the plug with the connector according to the marks.
5. Connect the **BASCH** or **BASCH-1** motor cable to output H (FIG.2) on the front on the right.
6. Align and attach the bracket to the housing P (FIG.3) provided on the back of the box and suspend the bag or bottle.

⚠ **CAUTION**

Before performing any operation on the device, touch a metallic surface to eliminate any static electricity.

Depending on the country's regulations, attach the ground wire to the potential equalization connector O (FIG.3). The purpose of the potential equalization connector is to equalize potentials between different metal parts that can be touched simultaneously, or to reduce differences of potential which can occur during operation between the bodies of medical electrical devices and conductive parts of other objects.

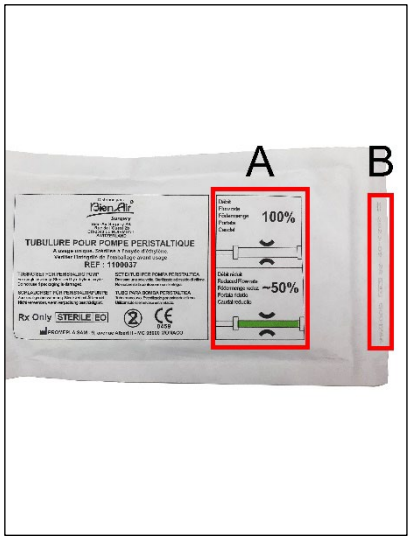


FIG. 4

FIG. 5

FIG. 6

6.2.3 Use of the irrigation line

1. Check the integrity of the irrigation line packaging and the use-by date FIG.4.B. Only Bien-Air lines ensure trouble-free operation.
2. Remove the disposable sterile irrigation line from its bag. Use a new irrigation line for each patient, reuse could lead to a cross contamination.
3. Connect the flexible hose to the spray tube of the attachment or contra-angle.
4. Install the white or green silicone segment on the irrigation pump and close the pump cover (FIG.5). Check the location of the "V" in the chuck mechanism.

⚠ CAUTION

Risk of hose perforation!

DANGER

Do not operate the pump when the cover is open. Danger of catching fingers!

⚠ CAUTION

Before connecting the irrigation line to the handpiece, the user must fully prime the tubing until air is completely purged and a small amount of liquid comes out the tip.

5. Remove the spike protection, and perforate the bottle cap.
6. Attach the irrigation line to the motor cable using the irrigation clips provided.

Irrigation line with 2 flow rates FIG.4.A

100% flow rate using the white silicone segment: From 30 to 130 ml/min.

~50% flow rate using the green silicone segment: From 15 to 65 ml/min.

Bien-Air Surgery SA attachment allows the connection of an irrigation line. For this, insert the end of the irrigation line into the spray tube (FIG.6).

FIG. 7

6.3 Use

6.3.1 Power-up

At power-up (switch G FIG.7 in position 1), a green light will turn on inside the switch.

Various keys located under a watertight membrane can be used to select the work mode and to perform the appropriate adjustments depending on the planned operation. To each selected mode corresponds a specific LED.

6.3.2 Continuous irrigation synchronized with the motor

Press the C) Continuous irrigation button to activate and deactivate the continuous irrigation. The irrigation flow is symbolized by green LED. This function is also activate / deactivate by the left foot pedal button.

6.3.3 Intermittent irrigation

Press the B) Intermittent irrigation key to activate and deactivate the intermittent irrigation function. The irrigation pump is activated only at the end of the pedal rocker's travel by applying a stronger pressure to it.

6.3.4 Adjustment of the irrigation flow

Press on the F) Irrigation flow setting key increases the irrigation flow. The flow is symbolized by the LED displayed on the left of the key F) Irrigation flow setting.

NOTE:
For instruments without peristaltic pump (without irrigation), B) Intermittent irrigation, C) Continuous irrigation and F) Irrigation flow setting keys are inactive. However, C) Continuous irrigation remains valid to activate or deactivate audible acknowledgment.

6.3.5 Configurable options

Keyboard beep on each button press on keyboard or foot pedal.

To activate or deactivate the keyboard beep, press C) Continuous irrigation for 5 seconds until beep.

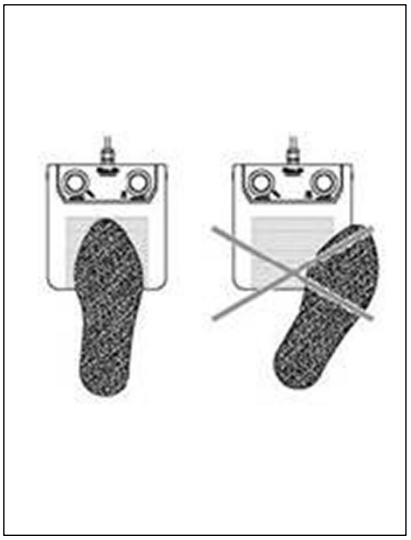


FIG.8

FIG.9

FIG.10

6.3.6 Foot Pedal

The pedal functions allow the surgeon to change settings without the assistance of another person.

NOTE: The foot pedal must always be connected.

For good pedal stability and operation, make sure to place your foot correctly in the center of the pedal (FIG.8)!

Left button for irrigation control (FIG.9):

Long press on the button: (approx. 2 sec): Change of direction of motor rotation.

or

Short press on the button: Flow rate increased.

Right button for motor control (FIG.9):

Long press on the button: (approx. 2 sec): Change of direction of motor rotation.

or

Short press on the button: Change in motor rotation speed.

Variable speed drive (rocker switch):

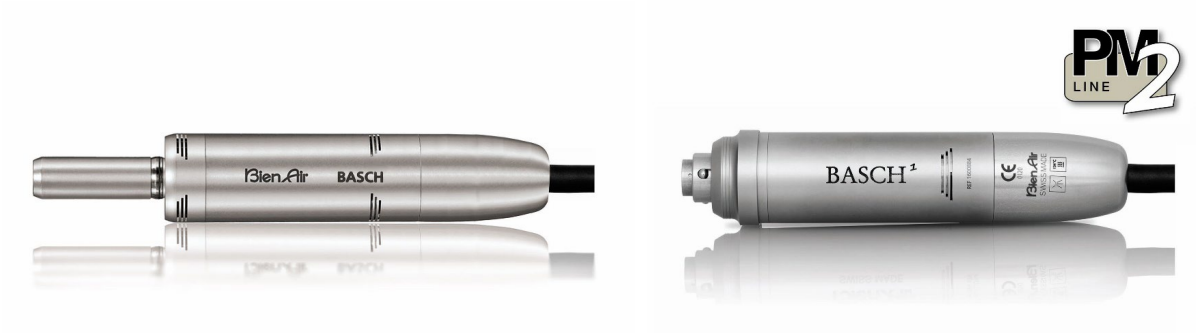
Variable motor speed control.

When intermittent irrigation is activated, the irrigation pump starts only at the end of the pedal rocker's travel (by applying a stronger pressure to it).

6.3.7 Power down

To switch off the control unit, put the switch to 0 (FIG.10 G).

7 BASCH/BASCH-1 MICROMOTOR



The **BASCH** micromotor is designed to drive various types of surgical handpieces with E type as per ISO 3964 coupling.

The **BASCH-1** micromotor is designed to drive the PM2 surgical handpieces. It's connected to the **OSSEO**DOC control unit by a specific cable.

The **BASCH**/**BASCH-1** micromotor are delivered "non sterile". Clean, lubricate and sterilize the **BASCH**/**BASCH-1** micromotor with the cable before first use.

7.1 Technical data

Subject to technical amendments and modifications of the models.

Environmental conditions:

Environmental conditions:	Operation	Transport	Storage
Temperature:	+10°C (50°F) to +30°C (86°F)	-25°C (-13°F) to +70°C (158°F)	0°C (50°F) to +40°C (86°F)
Relative humidity (including condensation)	20% to 80%	10% to 100%	10% to 90%
Atmospheric pressure:	700 hPa to 1060 hPa	600 hPa to 1060 hPa	600 hPa to 1060 hPa

Type:
Direct current, brushless, self-ventilated.

Applied parts:
All housing surfaces of micromotor are considered "applied parts" of Type B.

Power supply:
0 – <24 VDC 7 A max.

Coupling:
E Type as per ISO 3964, for the **BASCH**; PM2 Bien-Air Surgery for the **BASCH-1**.

Motor torque:
Max. 40 mNm.

Speed:
500 to 40'000 rpm, +/- 5%.

Noise level:
As per ISO 11498: < 62 dBA at 45 cm.

Period of operation:
To avoid overheating of the applied parts and the associated risk of burn injuries of patient or surgeon, the following rules must be respected:

1. Limit the maximum speed of rotation according to the bur diameter as indicated on the packaging and/or in the present operating instructions.
2. Do not exceed the maximum permitted speed of rotation for the attachment
3. Adequate irrigation is recommended.
4. Period of continuous operation: 10-15 minutes at low load. 5-7 minutes at medium load. 1-2 minutes at high load followed by a minimum interruption period of 30 seconds.

When the micromotor external surface temperature rises more than ca. 21°C (69,8°F) above the ambient temperature, an alarm is ringing (see Chap. 10.1 **OSSEO**DOC control unit for further explanation). To continue the surgery, wait for the motor to cool down or disconnect the micromotor and use another one. If you reconnect the same motor, you can continue to use it for a short period but under the surgeon's full responsibility. In this case beware of not touching the patient with the micromotor (high risk of burn injuries).

Size/Weight:
BASCH: Diameter 21 mm, length 100 mm, including coupling / 120 g, without cable and without attachment.
BASCH-1: Diameter 21 mm, length 77 mm, including coupling / 115 g, without cable and without attachment.

Motor/cable:
Push-pull type connector at **OSSEO**DOC end, length 295 cm ±5 cm.

7.2 Motor cable connection

Before connecting the specific motor cable, check the cleanliness of the rear of the micromotor and the cable plug.

1. Present the micromotor in correct alignment (align the cable reference with the reference on the motor).
2. Insert the plastic connector in position.
3. Tighten the connector nut as far as possible.
4. Before use, run the micromotor at moderate speed for a few seconds to distribute and remove excess lubricant.

7.3 Attachment insertion and removal on the BASCH-1 micromotor

1. Insert the attachment on the micromotor nose and turn it to ensure proper coupling.
2. Connect the irrigation line to the attachment to the thrust stop.
3. Insert the irrigation line into the openings of the fixing flanges previously laid on the power cable.
4. To remove the attachment, pull the micromotor coupling ring back and remove the attachment.

⚠ CAUTION

Never insert an instrument onto a rotating micromotor.

7.4 DRILL mode

The practitioner can adjust irrigation functions, the speed and direction of rotation of the bur.

Direction of rotation:

In DRILL mode, rotation is continuous. Rotation is continuous in clockwise by default.

Press the D) Clockwise / CCW rotation to activate and deactivate the counterclockwise motor rotation. An alternate beep is ringing when the key is active.

Speed adjustment:

I) Speed up to 7'000 rpm: Selection of speed range from 500 to 7'000 rpm.

J) Speed up to 15'000 rpm: Selection of speed range from 500 to 15'000 rpm.

K) Speed up to 20'000 rpm: Selection of speed range from 500 to 20'000 rpm.

L) Speed up to 40'000 rpm: Selection of speed range from 500 to 40'000 rpm.

8 CLEANING/MAINTENANCE/STERILIZATION

8.1 General indications

⚠ **CAUTION**

Do not place the BASCH / BASCH-1 in an ultrasonic bath.

⚠ **CAUTION**

Never rinse instruments in cold water to cool them.

⚠ **CAUTION**

Never submerge the BASCH / BASCH-1 in disinfection solutions.

⚠ **CAUTION**

Do not place stainless steel instruments or motors in physiological saltwater solutions (NaCl solution) as prolonged contact may cause corrosion.

Customary precautions:

Hospital procedures must be followed.

Universal precautions must be complied with by hospital personnel working with contaminated or potentially contaminated medical instruments.

Pointed and sharp instruments should be handled with great caution.

Agents required for cleaning:
Detergents:

The cleaning has been validated using an enzimatic pH neutral detergent (Steris Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner). An alkaline detergent might reduce the lifetime of the device.Detergents should be used at the concentration, temperature and duration recommended by the detergent manufacturer.

⚠ **CAUTION**

Do not use detergents that are corrosive or contain chlorine, acetone or bleach, aldehydic products or alcohols.

Lubricant:

Only use "*Lubrifluid*" from Bien-Air Surgery SA.

Brush/cleaning gun:

The brushes should be non-aggressive to avoid damaging the device. Nylon brushes with flexible hairs or soft bristles. For further specifications, see corresponding micromotor chapter. Use the cleaning gun with the appropriate nozzles for the various ducts.

Storage:

Bien Air Surgery SA strongly advises storing only sterilized devices so as to reduce the risks of corrosion.

Ambient conditions of storage after sterilization:

- Store the equipment in a clean, dry place at ambient temperature (10–30°C (50–86°F), 20–80% humidity).
- Do not expose the equipment to direct sunlight.
- Do not expose the equipment to permanent X-ray irradiation.
- Do not store the equipment in places that could be reached by liquid splashes.
- Do not store the equipment in the following ambient conditions:
  - Dust
  - Saline or sulfurous atmosphere
- Do not store the equipment in a location where there is a risk of release of flammable gases.

Point of use cleaning precautions:

This operation is important to facilitate the subsequent cleaning stage (it prevents debris from drying and sticking to the equipment).

Cleaning precautions:

Complete cleaning can lower the initial microbial load, eliminate organic matter and prevent biofilm formation. This stage is essential and influences the quality of the disinfection procedure as a whole. Cleaning combines the physico-chemical action of the product and the mechanical action of brushing and rinsing.

For automatic cleaning:

Comply with the washer/disinfector loading instructions provided by the manufacturer.

Make sure that all the instruments have been correctly attached to the baskets.

Wind up the cable correctly and without any tension (minimum inner diameter 8 cm).

Make sure that the instruments do not touch one another, that the cable does not touch the sides of the washer/disinfector and that internal canals are properly rinsed.

Remove the instruments from the washer or disinfector immediately after the machine stops and move on quickly to lubrication and sterilization, to avoid corrosion.

Sterilization precautions:

The shelf life of stored sterilized instruments depends on the type of packaging used and the storage conditions (refer to the DIN 58953 standard, section 9, or the existing local regulations).

Since no reprocessing methods have been validated for removal of transmissible spongiform encephalopathy (TSE) agents from medical devices, this device should not be used for patients with known or suspected TSE agent disease, including CJD and vCJD. Bien-Air Surgery recommends incineration of devices that have come into direct contact with patients suspected or confirmed with TSE/CJD diagnosis.

The sterilizer manufacturer's instructions concerning operation and the load configuration should be complied with explicitly.

Do not exceed a temperature of 138°C (280°F).

Before re-using, the instrument must be allowed to cool to ambient conditions, without forced cooling.

Only legally marketed, FDA cleared sterilizers, sterilization wrap/pouches, biological indicators etc. should be used by the end-user for packaging terminally sterilized devices. For USA only: use sterilization cycles consistent with the cycle specifications in ANSI/AAMI ST79 "comprehensive guide to steam sterilization and sterility assurance in health care facilities".

Packing for sterilization:

Wrap the instrument with its cable immediately after cleaning in individual packing such as a paper/plastic pouch or sterilization wrap, for steam sterilization.

Make sure that the cable does not touch the sides of the sterilizer.

Or

Packing in stiff boxes and trays with defined, pre-configured lids and apertures and wrap the stiff boxes or tray.

Bien-Air Surgery SA can provide a sterilization tray designed for this type of item.

In the USA, FDA-approved sterilization wraps or container must be used.

BASCH / BASCH-1 micromotors are delivered "non-sterile".

Before use, please comply with the present section. The cycles described below are compatible with the BASCH / BASCH-1 micromotors and their cables:

- Clean, lubricate and sterilize the instrument and the cable before first use.
- Clean, lubricate and sterilize the instrument and the cable before each further use.
- After each use, perform cleaning maintenance and sterilization of the micromotor as quickly as possible.

As soon as you have finished using the BASCH / BASCH-1 proceed as follow:

- Disconnect the motor power cables from the OSSEODOC control unit.
- Do not disconnect the power cable on BASCH / BASCH-1 side.

NOTE: To ensure the cleanliness of the rear of the micromotor and the cable plug, the motor specific electric power cable must be disconnected after 10 to 15 sterilizations or once a month. If necessary, clean with a detergent solution and dry the two parts with non-woven towelettes. Connect the motor cable again.

- Disconnect the irrigation line from the attachment.
- Separate the instrument from the BASCH / BASCH-1 and treat it in accordance with its instructions.

For instruction per instrument, see Chap. 8.2 OSSEODOC control unit and foot pedal; 8.3 BASCH micromotor and 8.4 BASCH-1 micromotor.

FIG. 11

FIG. 12

8.2 OSSEODOC control unit and foot pedal

1. Use enzymatic detergents with a neutral pH (6.0-8.0).
2. Soak a clean cloth and carefully clean the surfaces and also under the pedal's rocker switch (see FIG.11 and FIG.12).

⚠ CAUTION

The OSSEODOC control unit and the foot pedal are not sterilizable!

8.3 BASCH micromotor

⚠ CAUTION

Never submerge the micromotors in disinfection solutions.

⚠ CAUTION

To avoid water staying between the cable and the micromotor always hold/place the micromotor with the front end down (minimum 45°) during the entire cleaning process.

8.3.1 Point of use cleaning

⚠ CAUTION

Initial cleaning should be performed at the point of use and as soon as possible after the completion of the surgical procedure.

⚠ CAUTION

Point of use cleaning should be followed by pre-cleaning.

Loosely rub the whole micromotor and its cable with non-woven towelettes (pre-soaked with water).

8.3.2 Pre-cleaning

1. Rinse the micromotor including the first 10cm of the cable under running tap water (cold, max 20°C / 68°F) and brush with nylon soft bristles brush for no less than 30 seconds on the outside surfaces. Make sure water goes through all the ventilation openings. Continue brushing until soil is no longer visible.
2. Rinse the entire cable under running tap water (cold, max 20°C / 68°F) and wipe with a wet non-woven towelette as long as soil is still visible.
3. Perform manual or automated cleaning.

8.3.3 Cleaning

Manual cleaning:

Thoroughly wash the micromotor and its cable with detergent solution as follows:

1. Loosely rub the entire cable with detergent impregnated non-woven wipes, moving back and forth.
2. Wash the micromotor by pouring detergent solution. Then, with a nylon soft bristles brush, brush the outside surfaces including the first 10cm of the cable with a soaked brush (especially in the corner, edges and openings) for no less than 30 seconds. Continue brushing until soil is no longer visible.

Thoroughly rinse the micromotor and its cable under running tap water as follows:

1. Rinse the whole cable for no less than 30 seconds.
2. Rinse the micromotor for no less than 30 seconds. Make sure water goes through all the ventilation openings.
3. Dry the micromotor and the power cable by wiping with a clean and dry non-woven towelette.

Automatic cleaning:

Place the micromotor with its cable in the appropriate washer/disinfector basket and treat via a standard instrument washer/disinfector cycle (place the micromotor with the tip downward minimum angle 45°).

Use exclusively a validated washer / disinfector.

This product has been validated with an automated cycle consisting of the following stages:

Pre-wash:

Cold tap water (<45°C / 113°F) for minimum 2 minutes.

Washing:

Hot tap water, 50°C to 60°C (122°F to 140°F) with enzimatic pH neutral detergent (like Steris Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner), minimum 5 minutes.

Neutralization:

Cold tap water (<45°C / 113°F) for minimum 2 minutes.

Rinsing:

Cold critical water acc to AAMI TIR34 (<45°C / 113°F) for minimum 2 minutes.

Thermal disinfection by rinsing:

Hot critical water acc to AAMI TIR34 (90°C / 194°F) for minimum 5 minutes.

Operator is responsible for the implemented value A0 according A0 concept described in EN ISO 15883 (for example, A0 600 90°C (194°F) / 1 min.)

Ventilated dynamic drying:

70°C (158°F), for minimum 22 minutes.

8.3.4 Inspection, lubrication and testing

Carefully inspect each part to make sure that all visible contamination has been eliminated. Where there is contamination, repeat the cleaning process.

After each cleaning operation and before each sterilization, lubricate the BASCH with "*Lubrifluid*" from Bien-Air Surgery SA as follows:

Insert the tapered end of the "*Lubrifluid*" spray in the tip of the BASCH micromotor and squirt for approx. 0.5 seconds.

Then leave the BASCH micromotor to rest upright with the tip downwards for at least 5 minutes.

NOTE: The motor ball bearings have lifetime grease and should not have additional lubrication.

8.3.5 Sterilization

Sterilization by steam/moist heat is the recommended method for the BASCH micromotor and its cable. The following table of sterilization parameters, using a B type cycle with Pre-Vac, is recommended by Bien-Air Surgery SA to provide a sterility assurance level (SAL) of 10^{-6}:

Parameters				
Temperature	132°C (270°F)	134 °C [3] (273°F)	134 °C [3] (273°F)	135 °C (275°F)
Time	4 min.	3 min. [1]	18 min. [2]	3 min. [1]
Minimum drying time	40 min. [4]			

[1] The cable must be separated from the BASCH micromotor by unscrewing the cable cap.

[2] Parameters recommended by the World Health Organization for treating instruments in the event of contamination by Non-Conventional Transmissible Agents (NCTA).

[3] Not for users in US healthcare facilities.

[4] Refer to sterilizer manufacturer recommendations for drying times per load configuration.

8.4 BASCH-1 micromotor

⚠ **CAUTION**

Never submerge the micromotors in disinfection solutions.

⚠ **CAUTION**

To avoid water staying between the cable and the micromotor always hold/place the micromotor with the front end down (minimum 45°) during the entire cleaning process.

8.4.1 Point of use cleaning

⚠ **CAUTION**

Initial cleaning should be performed at the point of use and as soon as possible after the completion of the surgical procedure.

⚠ **CAUTION**

Point of use cleaning should be followed by pre-cleaning.

Loosely rub the whole micromotor and its cable with non-woven towelettes (pre-soaked with water).

8.4.2 Pre-cleaning

1. Rinse the micromotor including the first 10cm cable under running tap water (cold, max 20°C / 68°F) and brush with nylon soft bristles brush for no less than 30 seconds on the outside surface. Make sure water goes through all the ventilation openings. Continue brushing until soil is no longer visible.
2. Rinse the coupling mechanism of the BASCH-1 under running tap water (cold, max 20°C / 68°F) for no less than 10 seconds while pulling back and rotating the locking ring of the coupling mechanism at least 3 times.
3. Rinse the entire cable under running tap water (cold, max 20°C / 68°F) and wipe with a wet non-woven towelette as long as soil still visible.
4. Perform manual or automated cleaning.

8.4.3 Cleaning

Manual cleaning:

Thoroughly wash the micromotor and its cable with detergent solution as follows:

1. Loosely rub the entire cable with detergent impregnated non-woven wipes, moving back and forth.
2. Wash the micromotor by pouring detergent solution. Pull and rotate the locking ring of the BASCH-1 at least 3 times. Then, with a nylon soft bristles brush, brush the outside surfaces including the first 10cm of the cable with a soaked brush (especially in the corner, edges and openings) for no less than 30 seconds. Continue brushing until soil is no longer visible.
3. Wash the coupling mechanism of the BASCH-1, then pull and hold it while brushing with nylon soft bristles brush around the whole circumference twice.

Thoroughly rinse the micromotor and its cable under running tap water as follows:

1. Rinse the whole cable for no less than 30 seconds.
2. Rinse the micromotor for no less than 30 seconds. Make sure water goes through all the ventilation openings.
3. Rinse the coupling mechanism of the BASCH-1 including the locking ring for no less than 30 seconds while pulling back and rotating the locking ring at least 3 times.
4. Dry the micromotor and the power cable by wiping with a clean and dry non-woven towelette.

Automatic cleaning:

Pull the coupling ring of the BASCH-1 back and release it under running tap water at least 2 times. Then, with a nylon soft bristles brush, brush the coupling mechanism for no less than 15 seconds. Continue brushing until soil is no longer visible on the outside surfaces.

Place the micromotor with its cable into the appropriate washer/disinfector basket and process via a standard washer/disinfector cycle (place the micromotor BASCH-1 with the coupling at the bottom at a minimum angle of 45°).

Use exclusively a validated washer / disinfector.

This product has been validated with an automated cycle consisting of the following stages:

Pre-wash:

Cold tap water (<45°C / 113°F) for minimum 2 minutes.

Washing:

Hot tap water, 50°C to 60°C (122°F to 140°F) with enzimatic pH neutral detergent (like Steris Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner), minimum 5 minutes.

Neutralization:

Cold tap water (<45°C / 113°F) for minimum 2 minutes.

Rinsing:

Cold critical water acc to AAMI TIR34 (<45°C / 113°F) for minimum 2 minutes.

Thermal disinfection by rinsing:

Hot critical water acc to AAMI TIR34 (90°C / 194°F) for minimum 5 minutes.
Operator is responsible for the implemented value A0 according A0 concept described in EN ISO 15883 (for example, A0 600 90°C (194°F) / 1 min.)

Ventilated dynamic drying:

70°C (158°F), for minimum 22 minutes.

8.4.4 Inspection, lubrication and testing

Carefully inspect each part to make sure that all visible contamination has been eliminated. Where there is contamination, repeat the cleaning process.

After each cleaning operation and before each sterilization, lubricate the BASCH-1 with "*Lubrifluid*" from Bien-Air Surgery SA:

Pull the micromotor BASCH-1 coupling and spray the micromotor nose with "Lubrifluid" spray for approx. 0.1 seconds. Check the freedom of movement of the coupling ring. To do this, push it several times to full stop and release. It must always return to the starting position.

NOTE: The motor ball bearings have lifetime grease and should not have additional lubrication.

8.4.5 Sterilization

Sterilization by steam/moist heat is the recommended method for the BASCH-1 micromotor and its cable. The following table of sterilization parameters, using a B-type cycle with Pre-Vac, is recommended by Bien-Air Surgery SA to provide a sterility assurance level (SAL) of 10^{-6}:

Parameters				
Temperature	132°C (270°F)	134 °C [3] (273°F)	134 °C [3] (273°F)	135 °C (275°F)
Time	4 min.	3 min. [1]	18 min. [2]	3 min. [1]
Minimum drying time	40 min.[4]			

[1] The cable must be separated from the BASCH-1 by unscrewing the cable cap.

[2] Parameters recommended by the World Health Organization for treating instruments in the event of contamination by Non-Conventional Transmissible Agents (NCTA).

[3] Not for users in US healthcare facilities

[4] Refer to sterilizer manufacturer recommendations for drying times per load configuration.

FIG. 13

9 MAINTENANCE

OSSEODOC control unit:

Bien-Air Surgery SA recommends users have the OSSEODOC system (control unit and foot pedal) checked at least once a year.

Changing the fuse:

In case of power supply problems, check the fuses.

To change the fuse:

1. Open the box (FIG.13 S) located on the back of the unit.
2. Extract the fuse by pulling it.
3. Insert a new fuse.
4. Close the box (FIG.13 S).

NOTE: If a fuse fails a second time, have the device checked by an accredited Bien-Air Surgery SA representative.

NOTE: Block diagram is available from Bien-Air Surgery SA or its approved after sales dealer department upon request.

BASCH / BASCH-1 micromotor:

No component of the BASCH / BASCH-1 micromotor should be changed by the user.

⚠ **CAUTION**

Never disassemble the BASCH / BASCH-1 micromotor or its cable.

For all servicing and repairs, we recommend that you contact your dealer or Bien-Air Surgery SA directly.

The 2200012-service manual for repair is used by our approved after-sales dealer department for all servicing and repairs.

Bien-Air Surgery SA recommends users have their dynamic instruments checked or serviced once or twice a year depending on the usage frequency.

Maintenance and repair have to be performed exclusively by repair center approved by Bien-Air Surgery SA.

Hygiene

For the safety of the repair center's personnel, the instrument should be cleaned and sterilized completely before being returned for repair.

If that proves impossible, for example because a disinfection or sterilization would make the instrument completely unusable, clean the instrument as carefully as possible and mark it accordingly to indicate that it has not been decontaminated.

10 MALFUNCTIONS AND ERRORS

Use the table below to solve any problem encountered. If the problem cannot be resolved, stop using the product and contact a repair center approved by Bien-Air Surgery SA.

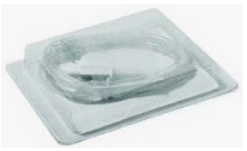
10.1 OSSEODOC control unit

Message	Description	Recommended action
An acoustic signal is emitted when control unit is powered-up.	This indicates that the pedal cable is not connected to the control unit or that the connection is defective.	Connect the pedal cable to the outlet provided at the rear of the unit; check that the plug is connected correctly.
When rocker pedal is depressed, an acoustic signal is emitted.	The motor is not connected or The device has identified a motor cable defect.	Connect motor cable or Use a new motor cable
The N LED is turned on and an acoustic signal is emitted.	The micromotor **BASCH** or **BASCH-1** is too hot to continue to work.	Wait for a moment to allow the motor to cool; the LED will turn off. or Change motor; the LED will turn off.

10.2 BASCH / BASCH-1 micromotor

Problem	Solution
The **BASCH** / **BASCH-1** micromotor is not working.	1. Make sure that the cable is properly connected to the **BASCH** / **BASCH-1** micromotor and the **OSSEO**DOC control unit. 2. Make sure that the **OSSEO**DOC control unit is turned on. 3. Check the condition of the motor power cable and the **BASCH** / **BASCH-1** micromotor (broken contact or severed cable).
The **BASCH** / **BASCH-1** micromotor cuts out completely.	Check the state of connections and cable. A part may be broken, return the micromotor to the after-sales service.
Abnormal heating of the **BASCH** / **BASCH-1** micromotor.	Check attachment function. If the operating and maintenance instructions of the motor have been observed, return the motor to after sales-service because the bearings are probably worn.
The instrument does not stay fixed on the **BASCH** / **BASCH-1** micromotor.	1. Check that the attachment ring of the **BASCH** micromotor is correctly in position and is not damaged. 2. Check that the balls and that the coupling rings of the **BASCH-1** are well placed and that they are not damaged.

11 OPTIONS / ACCESSORIES

Ref			
 Lubrifluid REF 1600064 (6 pieces per box)	 Irrigation Stand Complete REF 1500017	 Irrigation clip REF 1300064 (10 pieces per box)	 Irrigation line REF 1100037 (10 pieces per box)
	 E-Type Sterilization Tray REF 1600477	 PM2 Sterilization Tray ENT REF 1600948	

12 GENERAL TERMS OF GUARANTEE

12.1 General Information

Bien-Air Surgery SA endeavors to provide its customers with products and devices of impeccable quality which are guaranteed, within the limits of the present general terms and any specific agreements signed, against any operating fault, material or manufacturing defect.

The guarantee period is 12 months from the date of invoice.

In general, the guarantee does not exempt the customer from the obligation to obtain information from Bien-Air Surgery SA in case of doubt and in particular when the product is used in conditions not explicitly provided for originally.

The buyer is obliged to check the goods received within 8 days following their receipt. If the goods are not checked within the aforementioned period, the customer shall be deemed to have accepted the goods, barring hidden defects. The defect notice must be received in writing by Bien-Air Surgery SA within the aforementioned period and must contain the customer's name, the date of purchase, the product reference and serial number.

In the event of claims, Bien-Air Surgery SA or its authorized representative shall perform product repair or replacement free of charge, after analyzing the justification for the claim.

All other claims of whatsoever kind, and in particular claims for damages, are excluded.

Bien-Air Surgery SA shall not be held responsible for damage or injury and the consequences thereof, resulting in particular from:

- excessive wear,
- inappropriate use,
- failure to comply with operating instructions, assembly instructions or maintenance instructions,
- exceptional environmental, chemical, electrical or electrolytic influences,
- faulty air or water seals or electrical connections.

In any case the guarantee becomes null and void in the event of inappropriate servicing, use of non-recommended parts, accessories or consumables, or modifications to the product carried out by third parties not authorized by Bien-Air Surgery SA.

In case of dispute as to whether or not the defect exists, it shall be incumbent on the customer to prove the existence of the defect.

Guarantee claims shall be taken into consideration only upon presentation, with the product, of a copy of the invoice or delivery slip on which should appear clearly the date of purchase and the product reference and serial number.

12.2 Governing law

Swiss domestic law (Code of obligations) shall apply in addition to the general terms and conditions and particular agreements between the customer and Bien-Air Surgery SA.

12.3 Jurisdiction

2340 Le Noirmont, Switzerland.

13 ACCOMPANYNG DOCUMENTS ACCORDING TO IEC 60601-1-2:2014, CHAPTER 5

Guidance and manufacturer's declaration – electromagnetic emissions

The **OSSEO**DOC is intended for use in the electromagnetic environment specified below.

The customer or the user of the **OSSEO**DOC should ensure that it is used in such an environment.

Emissions test	Compliance	Professional healthcare facility environment – guidance
RF emissions CISPR 11	Group 1	The **OSSEO**DOC uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The **OSSEO**DOC is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity

The OSSEODOC is intended for use in the electromagnetic environment specified below.

The customer or the user of the OSSEODOC should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Professional healthcare facility environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact	±8 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	±15 kV air	±15 kV air	
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines, 100 kHz repetition frequency	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
	±1 kV for input/output lines, 100 kHz repetition frequency	Not applicable (Cable shorter than 3 meters)	
Surge IEC 61000-4-5	±1 kV line(s) to line(s)	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
	±2 kV line(s) to ground	±2 kV common mode	
Voltage dips IEC 61000-4-11	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the OSSEODOC requires continued operation during mains power interruptions, it is recommended that the OSSEODOC be powered from an uninterruptible power supply or a battery.
	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase at 0°	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase at 0°	
Voltage interruptions IEC 61000-4-11	0% UT; 250/300 cycles	0 % UT; 250/300 cycles	
Rated power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz or 60Hz	30 A/m 50Hz or 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Professional healthcare facility environment – guidance
			When using portable and mobile RF communications equipment, be sure to respect the recommended separation distance from all parts of the OSSEODOC, including cables. (Separation distance is calculated using the equation applicable to the frequency of the transmitter).
Conducted RF IEC 61000-4-6	3V 0.15MHz to 80MHz 6V in ISM bands between 0.15MHz and 80MHz 80% AM at 1kHz	3 V	**Recommended separation distance** $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.7 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	3 V/m	where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be theoretically predicted with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the OSSEODOC is used exceeds the applicable RF compliance level above, the OSSEODOC should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the OSSEODOC.

[b] Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the OSSEODOC.

The OSSEODOC is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.

The customer or the user of the OSSEODOC can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the OSSEODOC as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter (meter)		
	150 kHz to 80 MHz d = 1.2 √P	80 kHz to 800 MHz d = 1.2 √P	800 MHz to 2.5 GHz d = 2,3 √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 meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE: 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Compliance criteria

General requirements:	Requirements according to the EUT:
The following deteriorations associated with essential performance* and safety shall not be allowed: • Component failure; • Changes in programmable parameters; • Reset to factory defaults; • Change of operating mode; • False alarms; • Cessation or interruption of any intended operation, even if accompanied by an alarm; • Initiation of any unintended operation, including unintended or uncontrolled motion, even if accompanied by an alarm; • Error of a displayed numerical value sufficiently large to affect diagnosis or treatment; • Noise on a waveform in which the noise would interfere with diagnosis, treatment or monitoring; • Artefact or distortion in an image in which the artefact would interfere with diagnosis, treatment or monitoring; • Failure of automatic diagnosis or treatment, even if accompanied by an alarm; The equipment or system may exhibit deterioration of performance that does not affect basic safety or essential performance.	Essential performance*: • Motor shall remain inactive when the foot control is released. • Motor shall remain active when the foot control is engaged. • Variations in speed and incorrect functioning do not represent unacceptable risks • No unintentional start of motor • In case of ±15kV ESD air discharge, irreversible damage of EUT without unintentional start of motor does not represent an unacceptable risk

*Essential performance = performance necessary to achieve freedom from unacceptable risk.

The manufacturer shall identify which functions are essential performances. Equipment that does not perform properly could result in an unacceptable risk for patients, operators, or others. All features or functions that must perform properly to prevent harm to the patient, operator or others are important. When a failure to perform would result in an unacceptable risk for the patient, operator or others, then those features or functions are seen as essential performance.

ESD Information

The accessible pins of connectors should not be touched by staff with their fingers or with a hand tool, unless proper precautionary procedures have been followed. These connectors are identified by the ESD warning symbol.

The below information is non-exhaustive list of preventive measures to be taken to prevent the build-up of electrostatic charges:

- Use: air conditioning, humidification, conductive floor coverings, non-synthetic clothing.
- Allow static charges from your body to flow to the metal frame of the OSSEODOC or to earth or a large metal object;
- Bond your body to the OSSEODOC or to earth by means of a wrist strap.
- Before connecting or disconnecting the connector, touch a metallic surface of the OSSEODOC to eliminate any static electricity.

It is recommended that OSSEODOC users undergo basic training in the procedures relating to ESD precautions.

The basic training should include:

A) An introduction to the physics of electrostatic charges, the voltage levels that can occur in normal practice and the damage that can be done to electronic components.

B) An explanation of the methods to be used to prevent the build-up of electrostatic charges.

C) An explanation of how and why charges from your body should be discharged to earth or to the frame of the EQUIPMENT or SYSTEM.