

XO[®] ODONTOSURGE

User Guide





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1 GENERAL INFORMATION

Your new XO ODONTOSURGE is a HF Soft Tissue Handling unit designed for effective and safe HF Soft Tissue Handling with decisive importance attached to ease of use and minimum patient discomfort and apprehension.

However, safe and effective HF Soft Tissue Handling is dependent not only on equipment design but also, to a large extent, on factors under the control of the operator. It is important that the instructions in this manual be read, understood, and followed in order to enhance safety and effectiveness.

In particular, for those with little or no experience with HF Soft Tissue Handling, and also for those familiar with conventional low frequency units, we kindly ask that you take the time to carefully study this manual prior to first using XO ODONTOSURGE, in order to familiarize yourself with and be able to take full advantage of the unique qualities and attributes of XO ODONTOSURGE.

We are confident that you will find that XO ODONTOSURGE will be a major adjunct to your daily practice. We thank you for choosing XO ODONTOSURGE and welcome you to the realm of HF Soft Tissue Handling.

XO CARE A/S

2 SAFETY INFORMATION

XO ODONTOSURGE is designed to comply with the general safety requirements of EN 60601-1-2 + EN 60601-2-2 §202.6.1.1.1B.

2.1 INTENDED USE

XO ODONTOSURGE is intended to be used by the skilled dental practitioner to cut or remove the soft tissue or to control bleeding during surgery in the oral cavity.

2.2 INTERMITTENT OPERATION

XO ODONTOSURGE is designed for intermittent operation at 25% with duty time 10 sec. and cycle time 40 sec. corresponding to the dental mode of treatment.

2.3 WARRANTY

For the XO ODONTOSURGE, XO CARE A/S grants a warranty of 12 months as from the date of the invoice.

Defects proven to be caused by failure of materials, construction or manufacturing will be repaired free of charge. Any further liability is explicitly declined.

The warranty does not apply to normal wear and tear or to damage resulting from accident, abnormal use, misuse, abuse or neglect.

Responsibility as to the safety, reliability and performance of the XO ODONTOSURGE will not be accepted by XO CARE A/S:

- a. If the equipment has not been used under normal conditions for its intended purposes and in strict accordance with this manual and/or
- b. If any technical changes including repairs, adjustments/calibrations and reconstructions have been made by anyone other than XO CARE A/S or specialists approved by XO CARE A/S.

The purchaser assumes all risks and liabilities resulting from the use of the XO ODONTOSURGE, whether used separately or in combination with other products not manufactured by XO CARE A/S.

XO CARE A/S continually strives to improve its products and therefor reserves the right to improve, modify or discontinue products at any time, and to change the specifications without notice and without incurring obligations.







2.4 VIGILANCE SYSTEM

The Medical Device Vigilance System imposes on manufacturers the duty to promptly report to Competent Authorities in case a medical device made by the manufacturer has caused an incident that led to a serious deterioration of the state of health of a patient or user.

In the improbable event that your XO ODONTOSURGE should be involved in such an incident, it is therefore very important that you:

- a. Promptly inform XO CARE A/S,
- b. immediately stop using the unit, and
- c. Immediately store the unit separately and exactly in the condition it was in, i.e. without any kind of cleaning or disassembling.

2.5 SYMBOLS

	Please consult the User Guide
	Serial number
	Manufacturing date
	Warning
	Disposal
	Class 1, type CF (IEC 601-1)

2.6 MAINTENANCE AND SAFETY

Please observe the following instructions at all times:

1. The XO ODONTOSURGE must be installed and operated in accordance with this Manual.
2. The XO ODONTOSURGE and its accessories must not be taken into use, if signs of operational, electrical or mechanical defects are found.
3. The XO ODONTOSURGE must not be taken into use, if heavy sparking between instrument and tissue is observed.

XO ODONTOSURGE is a maintenance-free device. In the event, that the conditions as described in the above point 2 and 3 occurs, XO ODONTOSURGE has to be sent to your dealer or to XO CARE A/S for repair.

3 IMPORTANT NOTES AND WARNINGS



RISK OF ELECTRICAL HAZARD!

DO NOT ATTEMPT TO OPEN THE CONTROL BOX OR TO DISASSEMBLE THE HANDPIECE.

TECHNICAL CHANGES INCLUDING REPAIRS, ADJUSTMENTS/CALIBRATIONS AND MODIFICATIONS MUST BE CONDUCTED ONLY BY XO CARE A/S OR BY SPECIALISTS APPROVED BY XO CARE A/S.



DO NOT USE IN OXYGEN RICH ENVIRONMENTS

THE RISK FOR IGNITING FLAMMABLE GASES OR OTHER MATERIALS IS INHERENT IN SOFT TISSUE SURGERY AND CANNOT BE ELIMINATED BY DEVICE DESIGN.

THE CONTROL BOX MUST NOT BE EXPOSED TO EXCESSIVELY HIGH OR LOW TEMPERATURES AND EXTREME MOISTURE.

USE OF XO ODONTOSURGE MAY INTERFERE WITH OTHER UNSHIELDED ELECTROMEDICAL EQUIPMENT.

TO AVOID THE DANGER OF ELECTRIC SHOCK, THIS DEVICE MUST ONLY BE PLUGGED IN TO A GROUNDED POWER SUPPLY.



DO NOT USE XO ODONTOSURGE ON OR NEAR PATIENTS OR PERSONNEL WITH IMPLANTED CARDIAC PACEMAKER.



PAY ATTENTION TO THE FACT THAT ERRORS IN THE INSTRUMENT CAN LEAD TO ELECTRIC SHOCK.

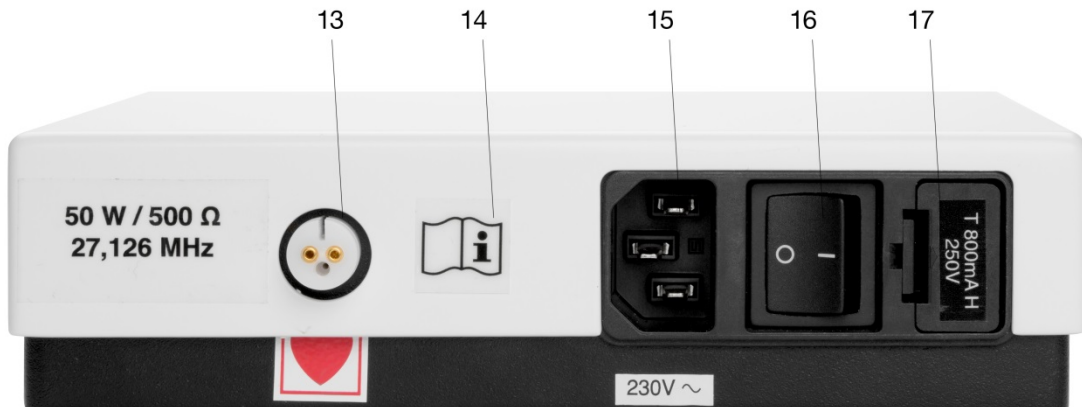
4 PARTS DESCRIPTION



- | | | | |
|----|--|----|------------------------------------|
| 1. | Handpiece holder | 6. | Detachable handpiece |
| 2. | Control box | 7. | Seven instruments in holder casing |
| 3. | Mode switch panel | 8. | Handpiece cord |
| 4. | Instrument socket | 9. | Main power cord |
| 5. | ON/OFF finger switch for instrument activation | | |



- 10. Green lamp
- 11. Blue lamp “COAG”
- 12. Yellow lamp “CUT”



- 13. Handpiece cord connector
- 14. Warning symbol - Please refer to section 2.5.
- 15. Mains power inlet
- 16. Mains ON/OFF switch drawer
- 17. Fuse

5 FEATURES

5.1 HIGH FREQUENCY

XO ODONTOSURGE operates at a frequency of 27 Megahertz (MHz) which is about ten times higher than conventional Soft Tissue Surgery units. This exceptionally high operating frequency results in multiple advantages - operationally as well as functionally.

1. At the high frequency, the entire surface of the patient's body is acting as a large passive or neutral electrode which, via the air, returns the high frequency signal.
As a result the conventional and cumbersome passive or patient electrode which also increases patient apprehension is rendered obsolete by XO ODONTOSURGE.
2. The high operating frequency is far from frequencies that are able to stimulate nerve tissues. It is however recommended that in most cases, some level of anaesthesia be used for patient comfort.
3. The high frequency plays a central role for the completely automatic and instantly responding power tuning system of XO ODONTOSURGE.
As a result the unique power tuning system is continuously controlling and precisely adapting the power output from a cutting instrument. The instrument delivers the exact amount of energy to make a perfect incision, irrespective of varying clinical conditions. If a cutting instrument nears bone or tooth structures, the tuning system immediately reduces the power to avoid thermal bone tissue necrosis.

5.2 ERGONOMICS

Operator compatibility and ease of use coincide with XO ODONTOSURGE's unique use of High Frequency and automatic power tuning.

The passive patient electrode as well as current waveform selection switches and power adjustment switches found on conventional units, are rendered obsolete by XO ODONTOSURGE.

As well, there is no need for the conventional foot switch, as the ON/OFF activation control is contained in the handpiece.

Furthermore, XO ODONTOSURGE is easily portable between clinic rooms, and its sleek and clutter-free design makes it unlikely to arouse patient apprehension as is often the case with conventional units.

6 SETUP

Your XO ODONTOSURGE comes complete with control box, handpiece and cord, casing including a selection of 7 different instruments, and a mains power cord.

6.1 HANDPIECE AND CORD

Connect the handpiece with the matching connector at the end of the handpiece cord.

Connect the opposite end of the handpiece cord with the matching connector at the rear of the control box.

Clip the handpiece in place by pressing it laterally into the handpiece holder.

6.2 HANDPIECE HOLDER

Attach the handpiece holder by inserting its tongue into the slot in the side of the control box (left or right side at option).

6.3 CONTROL BOX

Check that your unit is correctly rated for your local power line supply voltage (see rear of the control box).

Connect the power cord with the matching power inlet on the rear of the control box, and plug into a wall socket with appropriate protective ground connection.

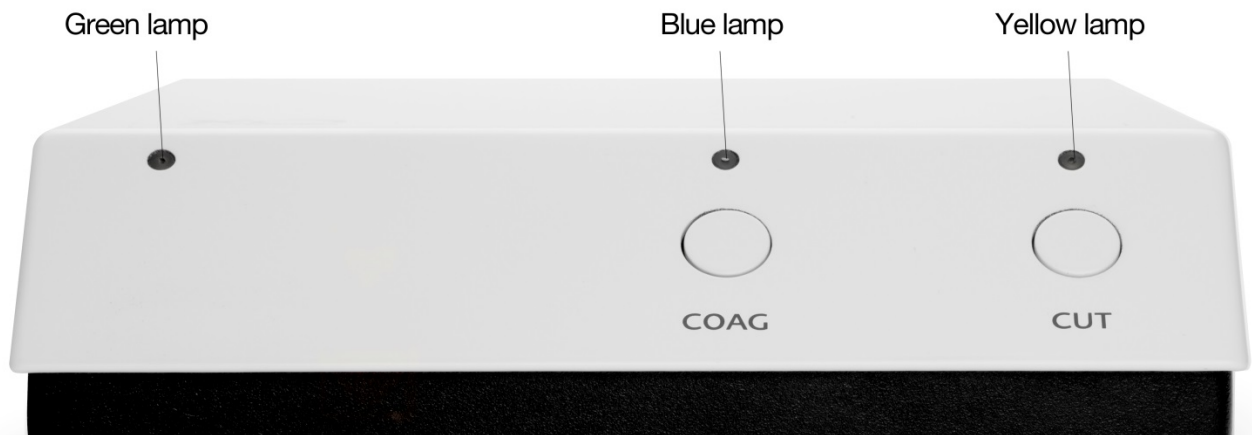
NOTE! Should your unit not be equipped with the appropriate power cord (i.e. pins different from your local standard) contact your dealer.

Your unit is now ready to be switched ON by pushing the main ON/OFF switch on the rear of the control box.

7 OPERATION CONTROLS

7.1 MODE SWITCH PANEL

The green lamp turns on as soon as the unit is switched ON by means of the main ON/ OFF switch at the rear of the control box.



Finger touch-switches:

COAG-switch: Turns blue lamp on and off.

- Blue lamp ON means coagulation mode (COAG-mode) with handpiece ready to operate.
- Blue lamp OFF means standby mode (ST.BY-mode) with handpiece inoperative.

CUT-switch: Turns yellow lamp on and off.

- Yellow lamp ON means cutting mode (CUT-mode) with handpiece ready to operate.
- Yellow lamp OFF means standby mode (ST.BY-mode) with handpiece inoperative.

ON/OFF Finger switch:

ON: Press and hold the rubber ring between fingers (acoustic signals).

OFF: As soon as released.

Note! The finger switch is only operative in the active modes i.e. in the CUT mode or in the COAG mode.



8 HOW TO OPERATE

On switching XO ODONTOSURGE unit ON, the mode switch panel will automatically go to the standby mode (only green lamp on).

NOTE! The control box must not be placed so that it can be touched by patients.

8.1 CUTTING (DISSECTION)

1. The HF cable must be placed so that it touches the patient as little as possible.
2. Instruments must always be kept away from the patient.
3. As a first step, always make sure that the unit is in the standby mode (only green lamp on). If necessary, touch switches to turn blue and yellow lamps off.
4. Insert the desired cutting instrument (wire instrument) fully and firmly into the handpiece.
5. Touch the CUT-switch to turn the yellow lamp on. CUT- mode.
6. The instrument is now ready for operation. Activate the instrument by pressing and holding the ON/OFF Finger switch on the handpiece. Note the acoustic signal for cutting.

8.2 COAGULATION (HAEMOSTASIS)

1. As a first step, always make sure that the unit is in the standby mode (only green lamp on). If necessary, touch switches to turn blue and yellow lamps off.
2. Insert the desired coagulation instrument (ball or rod instrument) fully and firmly into the handpiece.
3. Touch the COAG-switch to turn the blue lamp on. COAG-mode.

- The instrument is now ready for operation. Activate the instrument by pressing and holding the ON/OFF finger switch on the handpiece. Note the acoustic signal for coagulation.

IMPORTANT! Do not start clinical work until having carefully studied Section 9 "Preparation and Familiarization".

CAUTION For the sake of operator safety, instruments should only be inserted/ removed from the handpiece when the mode setting is in standby – only green lamp on.

CAUTION Any treatment must be initiated by checking that the ON/OFF finger switch responds with an acoustic signal. Do not touch the instrument, when the acoustic signal is sounding.

CAUTION Always switch to standby-mode (only green lamp on) as soon as the treatment has been completed and also during any pause in an on-going treatment.

CAUTION Pay attention of the danger of kindling of inflammable materials such as oxygen, cotton and gauze, in connection with spark formations from regular use of HF surgery instruments.

9 PREPARATION AND FAMILIARIZATION

When taking XO ODONTOSURGE into use for the first time, it is strongly recommended that the operator gets familiar with XO ODONTOSURGE by practising before starting to work under clinical conditions.

This can be done with a piece of fresh and lean meat which, when held in the operator's hand, constitutes an acceptable clinical model.

9.1 DISSECTION EXERCISE

- Select the standby mode by touching switches to turn blue and yellow lamps off.
- Insert a straight needle wire instrument.
- Touch the CUT-switch to turn yellow lamp on, and check that the ON/OFF finger switch responds with an acoustic signal.
- Place the meat in the palm of one hand on a piece of paper towel. The meat should not be dry. If it is, moisten lightly with water.
- Hold the handpiece in a pencil-type grip and hold the instrument in position slightly above the tissue surface. Activate the instrument by pressing and holding the ON/ OFF finger switch. You will hear the acoustic signal for the CUT-mode.
- Make an incision a few millimetres deep in the meat by advancing the instrument in a single continuous stroke, while using the high speed suction for odour evacuation.

7. Practise making shallow and deep incisions - also incisions of varying depth. While making the incisions, the instrument should always be kept in motion and be moved as rapidly as the tissue resistance permits.

Next, practise tissue sculpting or "electroplaning" using the wire loop instrument, and "troughing" with a wire hook instrument. You will observe that the shape of the instrument, and the angle of the instrument to the tissue surface will determine the shape of the cut.

9.2 COAGULATION EXERCISE

The COAG mode is used with the ball instrument provided to control isolated areas of bleeding.

1. Select the standby -mode by touching switches to turn blue and yellow lamps off.
2. Insert the ball instrument fully into the handpiece and touch the COAG switch to turn blue lamp on. Check that the ON/OFF Finger switch responds with an acoustic signal.
3. Hold the instrument in position slightly above the meat tissue surface and activate the instrument by pressing and holding the ON/OFF finger switch. The acoustic signal for the COAG mode will now be heard.
4. Make repeated taps with the activated instrument on the tissue. This will result in small "target" areas of coagulation which will effectively stop spot bleeding in a clinical situation.

9.3 GENERAL ADVICE

Always activate the instrument (acoustic signal) prior to making contact with the tissue.

- Always keep the instrument clean and free of tissue remnants.
- Always keep a cutting instrument in motion in a steady, continuous stroke.
- Always keep a coagulating ball instrument in motion in a tapping movement.
- Always keep the tissue moistened. Spray with sterile water, when necessary

10 CLINICAL APPLICATIONS

XO ODONTOSURGE is intended to be used by qualified dental practitioner to cut or remove soft tissue or to control bleeding during surgical procedures, in the oral cavity.

With the correct use in the proper clinical situation, HF Soft Tissue Handling with XO ODONTOSURGE will become an invaluable tool in all phases of Dentistry. All disciplines, including prosthodontics, periodontics, endodontics, pedodontics, orthodontics, oral surgery, and of course, routine restorative dentistry will greatly benefit from your use of XO ODONTOSURGE.

Special instructions are available upon request.

10.1 CONTRAINDICATIONS TO HF SOFT TISSUE HANDLING

1. HF Soft Tissue Handling is contraindicated in patients with cardiac pacemakers.
2. HF Soft Tissue Handling should not be used in proximity to flammable anaesthetic gases and oxygen.
3. Medical consultation should always be considered prior to using HF Soft Tissue Handling in those patients who may be systemically medically compromised, especially those with abnormal healing processes such as diabetes, blood dyscrasias, collagen disturbances, and patients undergoing irradiation treatment.

11 CLEANING AND STERILIZATION

11.1 INSTRUMENTS

A prerequisite of clean and well-defined incisions is clean instruments. Fair-sized tissue remnants can be removed by wiping - REMEMBER to switch back to standby mode (only green lamp on) before touching the instrument.

Otherwise clean by immersion into a 3% hydrogen peroxide solution and subsequent wiping.

IMPORTANT! Always handle the instrument wires with care in order to avoid deformation and breakage.

The instruments are supplied non-sterile. The recommended infection control procedure is to autoclave the instruments between patients. The instruments can be sterilized by steam autoclaving (maximum temperature 135°C/271° F), conveniently when placed in the holder casing with opened or removed cover.

11.2 HANDPIECE AND CORD

The handpiece and cord should be cleaned by wiping with alcohol based or soap water based disinfectant solutions. The recommended infection control procedure is to autoclave the handpiece between patients. The handpiece, handpiece cord and handpiece holder can be sterilized by steam autoclaving (maximum temperature 135° C/250° F).

Handpiece holder/clip for handpiece can be sterilized by steam autoclaving (maximum temperature 135° C/250° F).

After sterilization it is recommended to grease the o-ring at the handpiece.

11.3 CONTROL BOX

Clean and disinfect only by wiping with an alcohol sponge or with non-aggressive surface disinfectants. The control box cannot be autoclaved.

12 ACCESSORIES & SPAREPARTS

<u>Part no.:</u>	<u>Description:</u>
225129	Handpiece
225127	Handpiece cord with connectors
220097	Holder casing with seven instruments


Instruments:

	<u>Type</u>	<u>Shank</u>	<u>Tip part</u>
220501	Needle	Straight	Straight wire, thin
220502	Needle	Angled	Straight wire, thin
220504	Loop	Straight	Circular wire, diam. 5 mm
220510	Ball	Straight	Ball, diam. 3 mm
220513	Needle	Angled	Angled wire, heavy
220514	Needle	Angled	Angled wire, thin
220521	Loop	Angled	Circular wire, diam. 5 mm

Additional, more special instruments are available. Please request separate information.

NOTE: Use only original XO spare parts and accessories for XO ODONTOSURGE.

13 TECHNICAL SPECIFICATIONS

Product name:	XO ODONTOSURGE
Mains connection:	1-phase with protective earth
Mains voltage:	100/115/230V, 50/60 Hz (see rating label)
Classification:	 Class 1, type CF (IEC 601-1) Class IIb equipment (M.D.D. 93/42/EEC)
Primary fuses:	Mains 100 and 115 VAC: T2AL/250VAC Mains 230 VAC: T800mAL/250VAC
Replacement of fuses:	Fuse carrier clips should be disengaged and the fuse carrier is pulled out. Replace the fuses.
Generator frequency:	27,126 MHz
Max. output power:	50 W at non-inductive load impedance of 500 ohms
Max. output voltage:	159 VAC
Max. power consumption:	190 VA (voltamps)
Environment:	Operation: +10 °C to +35 °C. Storage: -40 °C til +70 °C. Relative humidity: 30-85% RHM, 50-106 kPa.
Manufacturer:	XO CARE A/S Usserød Mølle Håndværkersvinget 6 DK-2970 Hørsholm Danmark Tel: +45 70 20 55 11 info@xo-care.com www.xo-care.com CE 2460

14 DISPOSAL

The instruments packaging is re-usable, please retain the packaging for future use. Do not dispose the Instrument with general household waste!



DISPOSAL AS REQUIRED BY LOCAL ORDINANCES OR REGULATIONS.

DISPOSAL OF DEFECTIVE INSTRUMENTS IN ACCORDANCE WITH THE APPLICABLE RULES FOR ELECTRONIC SCRAPPING MUST OCCUR ONLY AFTER DISINFECTION.

Directive 2002/96/EC on waste of electrical and electronic equipment (WEEE).

Product disposal information

For countries in the European Union

This product (including the cables, plugs and accessory) must not be disposed of with the other household waste. Instead, it is your responsibility to dispose of your waste equipment by handing it over to a designated collection point for the recycling of waste electrical and electronic equipment. The separate collection and recycling of your waste equipment at the time of disposal will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment. For more information about where you can drop off your waste equipment for recycling, please contact your local city office, or your supplier's office.

For countries outside the European Union

Disposal of electrical products in countries outside the European Union should be done in line with local regulations.

15 TROUBLE SHOOTING GUIDE

NO LAMPS ARE ON AT THE FRONT OF THE DEVICE:

- Main switch in the mains connector is in position OFF
- Mains plug is not fully inserted in the mains connector
- The two fuses sitting in the mains connector are defective
- The HF print inside the device is defective
- Main switch is defective

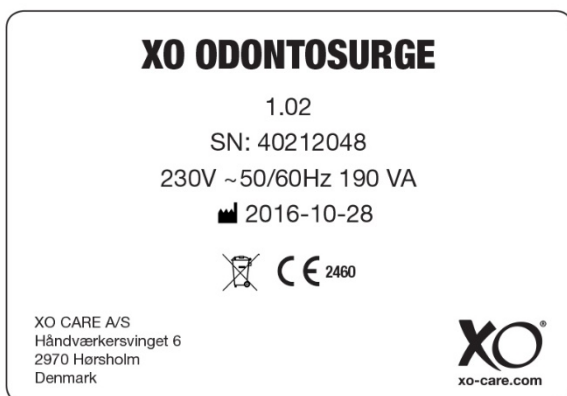
THE DEVICE DOES NOT REACT WHEN THE HANDPIECE IS ACTIVATED:

- CUT or COAG button is not activated
- Front print inside the device is defective
- Hand piece is defective (can happen if it has been dropped on the floor: very typical mistake)
- Hand piece cable is defective (is disconnected due to wear)
- Gold pins in the plugs on the hand piece cable may be broken
- Hand piece cable is not fully inserted in the socket of the device

Please contact your dealer if the instrument is still not working.

16 TYPE PLATE

The type plate is located on the bottom of the control box and contains the following information:



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and XO CARE A/S reserves the right at any time to
alter specifications without further notice.

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