

XO[®] ODONTOGAIN

User Guide



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1 INTRODUCTION

Your new XO ODONTOGAIN is a multi-purpose dental scaler for periodontology, endodontics and prophylaxis. A high degree of freedom as to your choice of irrigation liquid has been a main objective.

Particularly interesting is the possibility of subgingival scaling with PVP-Iodine as an antimicrobial irrigation solution. However, a variety of other irrigation liquids can be used at your own choice, including sterile irrigation liquids.

The XO ODONTOGAIN even gives you the possibility of having two different irrigation liquids at hand during the treatment, and it is easy to switch between the two liquid sources just by operating a finger touch pad.

The integrated peristaltic roller pump system does not make any direct contact with the liquid to be pumped. With an appropriately sterilized irrigation line and by using appropriate sterile handling procedures, it is therefore possible to transfer liquid from a sterile liquid source to the treatment site without affecting the sterility.

In this connection the pre-sterilized disposable irrigation tubing kits of all XO ODONTOGAIN are highly effective together with the autoclavable hand piece and hand piece cord.

We kindly ask and recommend that you take the time to carefully study this manual in order to familiarize yourself with the XO ODONTOGAIN.

By following our instructions and recommendations, you and your patients will appreciate and benefit from the advanced technology and ergonomics that have been invested into the XO ODONTOGAIN based on decades of experience.

We are confident that you will find XO ODONTOGAIN a major adjunct to your daily practice. We thank you for choosing XO ODONTOGAIN.

In case of problems or questions, please feel free to contact your dealer.

XO CARE A/S

Literature on PVP-Iodine treatment (Scientific documentation)

Greenstein: Povidone-Iodine's effects and role in the management of periodontal diseases: A review, Journal of Periodontology, 1999, 70, 1397-1405.

Rosling, Hellström, Ramberg, Socranskym and Lindhe: The use of PVP-Iodine as an adjunct to non-surgical treatment of chronic periodontitis, Journal of Clinical Periodontology, 2001, 28.

Serino: Outcome of treatment in subjects with different severity of periodontal disease, Thesis, Department of Odontology, Göteborg University, Göteborg 2001.

Slots and Jorgensen: Efficient antimicrobial treatment in periodontal maintenance care, JADA, 131, 1293-1304.

2 SAFETY INFORMATION

2.1 INTENDED USE

XO ODONTOGAIN is intended for professional use by qualified and trained operators for treatment in the oral cavity.

2.2 REGULATIONS

XO ODONTOGAIN is designed to comply with the general safety requirements of EN 60601-1-2 and EN60601-1:2006.

2.3 WARRANTY

For the XO ODONTOGAIN, 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 ODONTOGAIN 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 ODONTOGAIN, 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 therefore 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 ODONTOGAIN 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





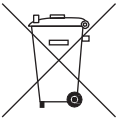

	Please consult the User Guide
	Serial number
	Manufacturing date
	Warning
	Disposal
	Class B

Figure 1 Symbols

2.6 MAINTENANCE AND SAFETY

Please observe the following instructions at all times:

- XO ODONTOGAIN must be installed and operated in accordance with this Manual.
- XO ODONTOGAIN and its accessories must not be taken into use, if signs of operational, electrical or mechanical defects are found.

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.



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

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



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

ALWAYS USE THE XO ODONTOGAIN SYSTEM FOR ITS INTENDED PURPOSE ONLY.

XO CARE A/S ACCEPTS NO LIABILITY FOR DAMAGE OR INJURY CAUSED DIRECTLY OR INDIRECTLY BY IMPROPER USE.

ALWAYS CLEAN AND STERILIZE NEW OR REPAIRED HANDPIECES AND INSTRUMENT INSERTS BEFORE FIRST USE.

ALWAYS AVOID CONTACT WITH PORCELAIN CROWNS, VENEERS AND COMPOSITE RESIN RESTORATIONS.

AVOID TOUCHING THE PATIENTS LIPS, TONGUE OR MUCOSA WITH THE UN-COOLED PART OF THE INSTRUMENT TIP.

NEVER USE THE INSTRUMENT INSERTS WITHOUT AMPLE SUPPLY OF IRRIGATION.

DO NOT ATTEMPT TO SHARPEN, BEND OR OTHERWISE RE-SHAPE THE INSTRUMENT TIPS.

IN RARE CASES THE INSTRUMENT TIP MAY FRACTURE, IN PARTICULAR IF DAMAGED OR IMPROPERLY HANDLED.

4 PART DESCRIPTION



Figure 2 XO ODONTOGAIN PARTS

- | | |
|-------------------|-------------------------------------|
| 1. Bag hanger | 6. Hand piece holder, detachable |
| 2. Spear | 7. Power cord |
| 3. Vessel support | 8. Hand piece |
| 4. Control box | 9. Instruments (depending on model) |
| 5. Handpiece cord | 10. Sterile tubing kit |

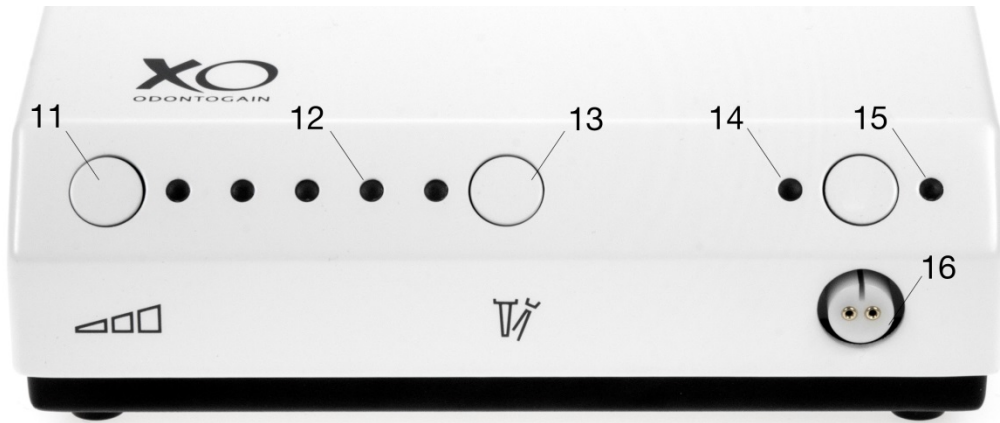


Figure 3 Front view

- | | |
|-------------------------------------|---------------------------------------|
| 11. Touch pad, power setting | 14. Indicator lamps, liquid selection |
| 12. Indicator lamps | 15. Touch pad, irrigation selection |
| 13. Touch pad, irrigation flow rate | 16. Connector, handpiece cord |

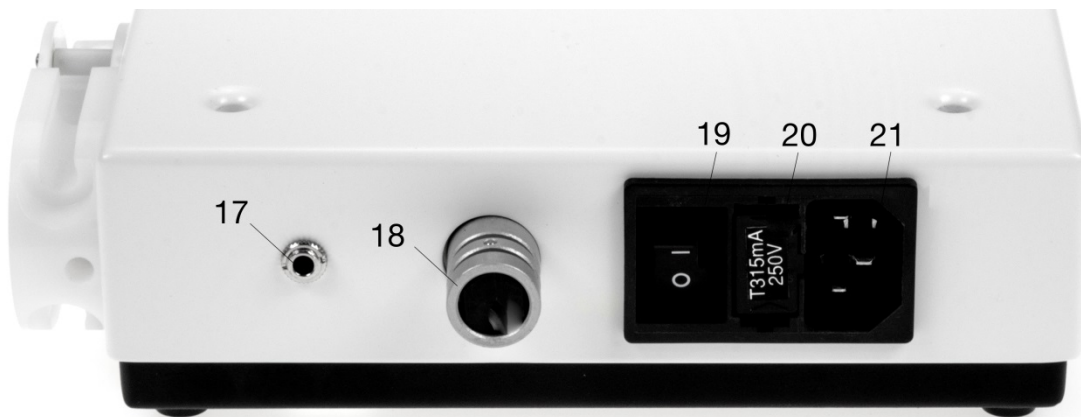


Figure 4 Rear view

- | | |
|----------------------------------------|-----------------|
| 17. Connector, foot control (optional) | 20. Fuse drawer |
| 18. Pinch valve, irrigation selection | 21. Power inlet |
| 19. Mains, ON/OFF | |

5 SETUP AND PREPARATION

5.1 CONTROL BOX

Insert the power cord (7) into the power inlet socket (21) at the rear of the control box (4), and insert the cord plug into a Mains outlet with protective grounding. XO ODONTOGAIN can be powered with any line voltage between 100 and 240 VAC without further measures.

Connect the handpiece cord (5) with the connector (16) on the front of the control box.

Attach the handpiece holder (6) by inserting its tongue into the slot in the side of the control box (left or right side at option).

5.2 HANDPIECE AND INSTRUMENT INSERT

Connect the handpiece (8) with the connector socket at the end of the hand piece cord (5).

Snap the instrument insert (9) into the open end of the hand piece.

5.3 ERGONOMICS

Operator compatibility and ease of use coincide with XO ODONTOGAIN'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 ODONTOGAIN.

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

Furthermore, XO ODONTOGAIN 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.

5.4 THE IRRIGATION LINE

XO ODONTOGAIN is delivered with irrigation tubing kits in pre-sterilized packages. The kits are for one time use only and cannot be re-sterilized.

NOTE! The tubing kits have been sterilized by radiation. Sterility cannot be relied upon 1) if the package has been opened or damaged, and 2) after the expiration date stamped on the package.

The tubing kit is designed for transferring irrigation liquid from liquid sources to the irrigation inlet on the handpiece cord - see illustration below.



Figure 5 Pre-sterilized tubing kit

5.5 ATTACHING TUBING KIT



Figure 6 Unpack the tubing set and place the tubing as shown



Figure 7 Tubing placed correct around the pump wheel



Figure 8 Place the 2 tubings in the pinch-valve



Figure 9 The other tubing from the pump wheel is connected to the irrigation inlet at the handpiece cord



Figure 10 Tubing kit attached

NOTE! For sterile operation it is of course necessary to observe appropriate sterile handling procedures during the attachment of the tubing kit.

Detaching after use of the tubing kit takes place in the reverse order. However to re-lease the valve part from the inner valve slot it is necessary to push the black button on the free end of the pinch valve.

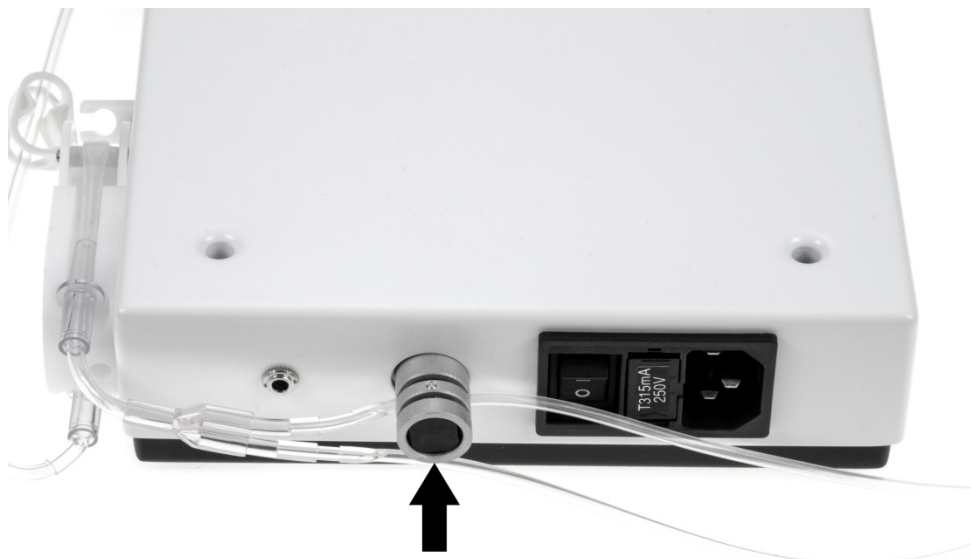


Figure 11 Push black button while detaching from inner valve slot.

5.6 IRRIGATION LIQUID SOURCES

The XO ODONTOGAIN is designed for operation with two liquid sources at hand for use at your choice.

Switching between the two liquid sources takes place by operating the finger touch pad (15). The indicator lamp to the left of the touch pad (15) indicates that the tubing valve part in the inner valve slot is open for operation.

Insert the stem of the vessel support (3) into one of the socket holes in the top of the control box (4). Place a bottle and use the spear (2).

The bag hanger (1) can be inserted into either of the two socket holes for suspension of a sealed bag or bottle. In case of a glass bottle, the green vent flap on the cannula should be opened to allow admission of filtered air into the bottle during its emptying.

6 OPERATION

The control box is turned on and off by operating the I/O main switch (19) at the rear. When turned on (Switch position I) at least one of the indicator lamps (12) at the front of the control box will be illuminated.

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

With the control box turned on, the tip vibrations and liquid spray of an instrument insert in the handpiece can be started and stopped by operating the switch ring at the front end of the handpiece (Vibration off - push switch ring forward).

As an alternative, the start/stop operation can be made by a foot control (to be ordered separately) connected to the connector socket (17) at the rear of the control box.

6.1 POWER SETTING

The amplitude or output power of the tip vibration can be adjusted by operating the circular finger touch pad (11) on the front of the control box. The lamps (12) at the front indicate (orange light) the actual setting.

6.2 SPRAY INTENSITY

The intensity or quantity of liquid sprayed from an operating instrument tip can be adjusted by operating the touch pad (13).

1. Touch the pad (13) until the lamps (12) change to green light.
2. Adjust the liquid spray by operating the pad (13). The lamps (12) (green light) indicates the actual setting.
3. The lamps (12) automatically go back to orange light, if untouched for a period of a few seconds.

6.3 EXCHANGE OF INSTRUMENT INSERTS

The handpiece is designed to accept quick-change interchangeable instrument inserts.

1. Pull the instrument collar to snap out an instrument insert.
2. Shake the handpiece to empty off liquid, if any.
3. Snap in another instrument insert with a clockwise turning motion. Make certain that it is fully seated in the handpiece.

7 MAINTENANCE, CLEANING AND STERILIZATION

7.1 INSTRUMENT INSERTS

The shape of the instrument tip is vital to the efficiency of the rotating tip and the ultrasonic effect.

NOTE! Do not attempt to sharpen, bend or otherwise re-shape the instrument tips!

It is important that the instrument is always firmly seated in the handpiece and the ferrite rod is properly tightened to the tip.

Regularly - and especially in the case of instrument malfunction - check and tighten the ferrite rod to the tip. (Use the clamp wrench and steel pin provided to change and tighten ferrite rods).

The instrument tip will be worn during use. At the end of the lifetime of the tip the lamps (12) will start flashing, thereby indicating that it is time for instrument replacement.

The instrument tip and ferrite rod can be sterilized by steam autoclaving at a maximum temperature of 135° C/275° F.

7.2 FERRITE ROD

You can easily exchange the ferrite rod yourself - if broken or otherwise damaged. Use the special service kit (part no. 207114) - see illustration below:



Figure 12 Exchange of ferrite rod

NOTE! When you mount a new ferrite rod, it is important that it is firmly and correctly tightened to the tip part. Otherwise the high frequency vibrations generated in the rod will not be properly transferred to the instrument tip. This would cause poor tip

vibrations and reduced lifetime for the instrument insert.

7.3 HANDPIECE AND HANDPIECE CORD

Do not soak in liquid. Clean only by wiping with alcohol based or soap water based disinfectant solutions.

Do not use any disinfecting or cleaning products containing aggressive chemicals. Do not soak in ultrasonic cleaners with ultrasonic cleaning solutions, nor place the handpiece in soaking basins with liquid chemicals.

The handpiece and the cord can be sterilized by steam autoclaving at a maximum temperature of 135° C/275° F.

7.4 CONTROL BOX

Clean by wiping with alcohol based or soap water based disinfectant solutions.

7.5 IRRIGATION LINE

Note: Do not re-sterilize the tubing kit.

After use always carefully flush the entire device to eliminate all PVP-Iodine if used. Iodine may cause severe corrosion of the XO ODONTOGAIN instrument when left inside during several hours. Just place the cannula or spear in a container with clean water and let the unit operate for one or two minutes.

8 SERVICE AND REPAIR

Do not attempt to open the control box or to disassemble the handpiece.

Service and repair may only be made by approved specialists. Return the equipment to the distributor in the original packing.

Responsibility as to the safety, reliability and performance of the equipment will not be accepted by the Manufacturer or Distributor if:

- a) the equipment has not been used in strict accordance with this manual and/or
- b) any technical changes including repairs, adjustments/calibrations and/or reconstructions have been made by anyone other than the Manufacturer or specialists approved by the Manufacturer.

9 SPAREPARTS AND ACCESSORIES

<u>Part no.:</u>	<u>Description:</u>
208141	Handpiece, black M2000
200986	Handpiece holder
208050	Set of replacement O-rings for handpiece and cord
200564	Handpiece cord, black with connectors
209193	Bag hanger
209190	Spear
209351	Foot control with cord and connector for XO ODONTOGAIN
207114	Service kit, Odontogain (includes 2 ferrite rods, clamp wrench and 5 steel pins)
209102	Ferrite rods, 5pcs.
209302	Steel pin for exchange of ferrite rod, 5pcs.
309300	Clamp wrench for exchange of ferrite rod
209308	Teflon instrument holder for 3 instruments (sterilizable)
209310	Lip protector, grey (sterilizable)

Instrument inserts

Please refer to our website for an overview of different instrument inserts:

<http://www.xo-care.com/en/products/xo-instruments/xo-odontoson/instrument-tips>

NOTE! Use only original XO spare parts and accessories for XO ODONTOGAIN.

10 TECHNICAL SPECIFICATIONS

Product name:	XO ODONTOGAIN
Mains connection:	1-phase with protective earth
Mains voltage:	100 to 240V, 50/60 Hz
Primary fuses:	T315mAH, 250 VAC
Replacement of fuses:	Fuse carrier clips should be disengaged and the fuse carrier is pulled out. Replace the fuses.
Classification:	Class 1, type B (IEC 601-1) Class IIa (Directive 93/42/EEC)
Max. power consumption:	45 VA
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

11 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.

12 TROUBLE SHOOTING GUIDE

NO LAMPS ARE ILLUMINATED 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
- Main switch defective

THE DEVICE DOES NOT REACT WHEN THE HANDPIECE IS ACTIVATED:

- Handpiece is defective (can happen if it has been dropped on the floor: very typical mistake)
- Handpiece cord is defective (is disconnected due to wear)
- Connector pins in the handpiece cord may be broken
- Handpiece cord is not fully inserted in the socket of the device
- Instrument insert is defect, worn or not mounted correct, please check:
That the instrument is always firmly seated in the handpiece and the ferrite rod is properly tightened to the tip.

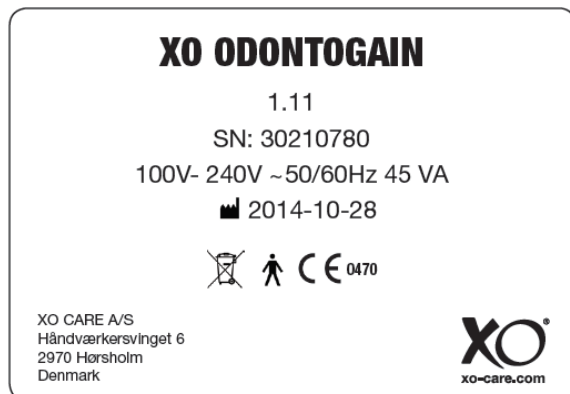
Regularly - and especially in the case of instrument malfunction - check and tighten the ferrite rod to the tip.

The instrument tip will be worn during use. At the end of the lifetime of the tip the lamps (12) will start flashing, thereby indicating that it is time for instrument replacement.

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

13 TYPE PLATE

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



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alter specifications without further notice.

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