



opt-on® 2.7/3.3 TTL

Instructions for Use

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SDDI inside

1. DEAR CUSTOMER

1.1. Prologue

The product that you have purchased – the **opt-on^{2.7}/opt-on^{3.3}** is state-of-the-art technology and has been produced in accordance with the strictest quality criteria. As we are constantly developing our products further, it is possible that the illustrations and drawings in this document may differ slightly from the product that you have purchased.

These instructions contain an exact description and explain how to use the **opt-on^{2.7}/opt-on^{3.3}**. If you have any additional questions or ideas, we would be pleased to help you by telephone or by email.

These instructions accompany the **opt-on^{2.7}/opt-on^{3.3}**. Please keep them to hand. If you pass this product on to a third party, please give them this document too as it contains important information on commissioning and handling the product.

Please use these instructions to familiarize yourself with the product before you use it during treatment.

1.1.1. Responsibility of the Manufacturer

The **opt-on^{2.7}/opt-on^{3.3}** is manufactured in accordance with the state-of-the-art technology and the recognized safety-related rules and regulations.

orangedental GmbH & Co. KG [hereafter referred to as orangedental] only considers itself responsible for the effects on safety, reliability and performance of the device, if:

- >> Assembly, add-ons, readjustments, alterations or repairs are only carried out by persons authorized by orangedental,
- >> the device is used in accordance with the instructions for use.

1.1.2. Responsibility of the Operator

Among other things, the operator is responsible for:

- >> adherence to the accident prevention regulations as well as the regulation concerning the installation, operation and use of active medical products (German regulation MPBetreibV).
- >> the operation.
- >> the maintenance.

- >> the proper and safe condition of the product.
- >> the storage of the instruction manual at the location of use.
- >> following the safety instructions contained in these instructions (see chapter 1.3: Conventions, Symbols Used).

1.2. Contents

- 1. Dear Customer 1**
- 1.1. Prologue 1
 - 1.1.1. Responsibility of the Manufacturer 1
 - 1.1.2. Responsibility of the Operator 1
- 1.2. Contents 3
- 1.3. Conventions, Symbols Used 4
- 2. About the Product 6**
- 2.1. Intended Use 6
- 2.2. System Components 6
- 2.3. Accessories/ Spare Parts 6
 - 2.3.1. Spare Parts Loupe Frame 6
 - 2.3.2. Accessories 7
- 3. Individual Fitting 8**
- 3.1. Fitting of Nose Pads 8
- 3.2. Inclination 8
- 3.3. Mounting of Lanyard 8
- 4. Installation of expendable Parts and Accessories 9**
- 4.1. Change the Temple 9
- 4.2. Change the Hinge 10
- 4.3. Change of Varioclips 11
- 5. Safety, Servicing and Maintenance 12**
- 5.1. Cleaning 12
- 5.2. Disinfection 12
 - 5.2.1. Disinfection Agents for opt-on^{2.7}/opt-on^{3.3} 13
- 5.3. Disposal 13
- 6. Specifications and Conformity 14**
- 6.1. Requirements regarding the Practice Environment 14
- 6.2. Technical Data 14
 - 6.2.1. Loupe Data 14
 - 6.2.2. Ambient Conditions 14
 - 6.2.3. Conformity with Standards 15

1.3. Conventions, Symbols Used

In these instructions, the conventions set out below indicate important information:

WARNING: This symbol is used if deviating from the procedure described can lead to physical injury or death.



CAUTION: This symbol is used if deviating from the procedure described can lead to damage to the product or to loss of data.



IMPORTANT: The usage of the term **IMPORTANT**, formatted in bold capitals, provides instructions about the use of the device or a process.

Note: Notes are used to highlight important or unusual points.

The meaning of the symbols, which are used on this product, its packaging or in these instructions, is listed below.

CHECK INSTRUCTIONS

This symbol indicates that this user manual contains important, mandatory instructions which must be followed to comply with the safety standards for the medical product.



ATTENTION

This symbol indicates that there are warnings or regulations concerning the product which are not specified on the label. It advises the reader to consult the accompanying documents.



MANUFACTURER

This symbol is used in order to display the name and address of the manufacturer of the medical product.



DATE OF MANUFACTURE

This symbol indicates the date of manufacture.



UDI-DI

This symbol indicates the UDI-DI number and the GTIN.



SERIAL NUMBER

This symbol is used to indicate the serial number.



MEDICAL DEVICE

This symbol is used to indicate that the product is a medical device.



CE MARKING

This symbol, attached by the manufacturer, indicates that the medical product is in conformity with and fulfills all requirements of the medical device regulation (EU) 2017/745.



2. ABOUT THE PRODUCT

2.1. Intended Use

The loupe **opt-on^{2.7}/opt-on^{3.3}** is solely used to support the visual inspection / to survey findings/ to aid in treatment by dental professionals using optical magnification in a dental treatment room. There are no known contraindications for the use of the magnifying glasses. There are no restrictions regarding the intended patient group.

2.2. System Components

Loupe Incl. one pair of Varioclips for the needed working distance	lup0499000 (2.7) resp. lup0499100 (3.3)
lanyard	00.001.934
micro fiber tissue	zub0498210
Box	zublup0499290
manual	00.000.527



2.3. Accessories/ Spare Parts

All parts can be ordered at your dealer or [orangedental](http://orangedental.com).

2.3.1. Spare Parts Loupe Frame

Frame	No. frame	No. right temple	No. left temple	No. frame front
frame A (164) <i>size: L; color: white</i> (6554)	00.002.013	00.002.283	00.002.327	00.002.248
frame A (165) <i>size: S; color: white</i> (6554)	00.002.024	00.002.294	00.002.338	00.002.226
frame A (164) <i>size: L; color: glossy black</i> (6550)	00.002.035	00.002.261	00.002.305	00.002.250
frame A (165) <i>size: S; color: glossy black</i> (6550)	00.002.046	00.002.272	00.002.316	00.002.237
frame A (170) <i>size: L; color: clear</i> (6053)	00.004.263	00.005.051	00.007.367	00.006.063
frame A (171) <i>size: S; color: clear</i> (6053)	00.004.195	00.005.062	00.004.948	00.006.074

Frame	No. frame	No. right temple	No. left temple	No. frame front
frame A (164) <i>size: L; color: brown (former copper matt) (6051)</i>	00.004.296	00.005.073	00.004.950	00.006.085
frame A (165) <i>size: S; color: brown (former copper matt) (6051)</i>	00.004.230	00.005.084	00.004.961	00.005.872
frame A (164) <i>size: L; color: red (6064)</i>	00.004.285	00.005.095	00.004.972	00.006.096
frame A (165) <i>size: S; color: red (6064)</i>	00.004.228	00.005.106	00.004.983	00.006.107
frame A (164) <i>size: L; color: black matt (6071)</i>	00.004.274	00.005.117	00.004.994	00.004.871
frame A (165) <i>size: S; color: black matt (6071)</i>	00.004.217	00.005.128	00.005.005	00.004.882

Description	No.
hinge right	00.002.340
hinge left	00.002.351
Pads Euro (1pair)	00.002.362
Pads Asia (1 pair)	00.006.120
1 pair protection lenses with ocular	individual
1 pair Varioclips	working distance 250 mm=10 inch
1 pair Varioclips	working distance 300 mm=12 inch
1 pair Varioclips	working distance 350 mm=14 inch
1 pair Varioclips	working distance 400 mm=16 inch
1 pair Varioclips	working distance 450 mm=18 inch
1 pair Varioclips	working distance 500 mm=20 inch

2.3.2. Accessories

Description	No.
lanyard	00.001.934
box	zublup0499290
micro fiber tissue	zub0498210
clip in prescription adapter	zublup0499100
clip in prescription adapter for long eye lashes	zublup0499101
individual prescription lenses for clip in prescription adapter	zublup0499250
Protect-on face shield complete system incl. 10 face shields	lup0499300EN

3. INDIVIDUAL FITTING

Your **opt-on**^{2.7}/**opt-on**^{3.3} has been produced individually for your interpupillary and working distance. You can take the following additional fittings:

3.1. Fitting of Nose Pads

There are two different nose pad positions:

>> click in: loupe position high



>> click out: loupe position low



3.2. Inclination

There are three inclination positions. You can change the inclination of your loupe or compensate different height of ears.



3.3. Mounting of Lanyard

You can use your loupe with or without lanyard. The lanyard can be slid over the earpiece. By tightening the lanyard you achieve weight relief for your nose.



4. INSTALLATION OF EXPENDABLE PARTS AND ACCESSORIES

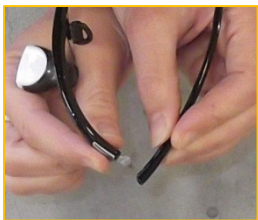
If your loupe needs to be repaired, you can send the loupe to your dealer or orangedental. Often it is possible just to order the spare parts and mount the parts on your own, to save time and money. You can also change the Varioclips to change the working distance.

4.1. Change the Temple

Retract the temple and hold it as shown at the picture.



Push the temple.



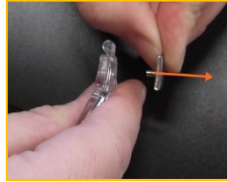
To mount the new temple, just press it to the hinge.

4.2. Change the Hinge

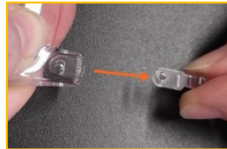
Remove the temple (see section 4.1: Change the Temple)
Push a solid, pointed tool (e.g. little screw driver) against the small silver round area.



Push the part outside



Remove the broken hinge.



To mount the new hinge, do the same procedure in reverse order.

Important: The hinge for the right side is marked with R, the hinge for the left side is marked with L.
The right temple is placed at the right ear!
The letters R and L need to face inside the loupe.



4.3. Change of Varioclips

If changing the working distance of your loupe is necessary, please contact your dealer to order Varioclips for the needed working distance. Mounting of the new Varioclips is easy. Just follow the written steps:

Remove the Varioclips. Just slide your fingernail or the added enclosed tool between the white and grey/black part.



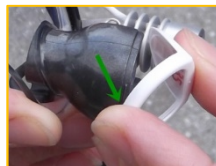
Slide until you hear CLICK and the Varioclip removes.



Take the Varioclip away.



Pose the new one at the bottom of the ocular.



Slightly push the orangedental logo on the upper side of the clip until you hear CLICK.



5. SAFETY, SERVICING AND MAINTENANCE

IMPORTANT: Please read safety instruction **opt-on^{2.7}/opt-on^{3.3}**

IMPORTANT: Please read manual attentively.

ATTENTION: When wearing the loupes do not look directly at the sun or any other bright light source to avoid injuries of your eyes.



ATTENTION: Do not leave the loupe where it is exposed to direct sunlight as this could lead to a fire.



ATTENTION: Do not use that loupe when working with laser light.



IMPORTANT: Do not use the loupe when the working area needs to be sterile.

IMPORTANT: Check that the loupe strap is fastened carefully before use.

IMPORTANT: Please note that your field of vision is restricted, while wearing the loupe and walking around.

5.1. Cleaning

Clean the loupes and eyepieces carefully using a micro fiber cloth. For coarse dirt, moisten the cloth with alcohol or water, and scrub the dirt off gently.

Note: Please clean the **opt-on^{2.7}/opt-on^{3.3}** immediately after use to prevent that blood or protein residues coagulate.

CAUTION: Only clean the loupe if the Varioclips are installed. Do not expose the plastic lens to any liquid as it could scratch the lens when drying it.



CAUTION: Only use soft cloths for cleaning. Do not use sharp or scratching objects.



5.2. Disinfection

CAUTION: Do not submerge the loupe **opt-on^{2.7}/opt-on^{3.3}** in water, sterilization, or other cleaning liquids. The loupe **opt-on^{2.7}/opt-on^{3.3}** is not waterproof.



CAUTION: Do not use aggressive solvents.



CAUTION: Any sterilization (autoclave/chemical clave procedures, iodinated agents or other proceedings) is not possible.



5.2.1. Disinfection Agents for **opt-on^{2.7}**/**opt-on^{3.3}**

The best way to disinfect your **opt-on^{2.7}**/**opt-on^{3.3}** is using a medically approved disinfection wipes, offering a broad spectrum of activity against bacteria, fungi and viruses e.g. disinfection wipes:

- Schülke kodan wipes [100g agent solution contain 30g Propan-2-ol and 30g Propan-1-ol]
- Schülke mikrozyd AF wipes [100g agent solution contain 25g Ethanol and 35g Propan-1-ol]

5.3. Disposal

Die **opt-on^{2.7}**/**opt-on^{3.3}** can be disposed with the normal waste.

6. SPECIFICATIONS AND CONFORMITY



orangedental GmbH & Co. KG
 Aspachstrasse 11 | 88400 Biberach / Riss



6.1. Requirements regarding the Practice Environment

Important: The loupe **opt-on**^{2.7}/**opt-on**^{3.3} is solely used to support the visual inspection / to survey findings / to aid in treatment by dental professionals using optical magnification in a dental treatment room.

6.2. Technical Data

6.2.1. Loupe Data

magnification	2,7x / 3,3x					
Working distance	25 cm	30 cm	35 cm	40 cm	45 cm	50 cm
	10 inch	12 inch	14 inch	16 inch	18 inch	20 inch
	The working distance of your loupe is written on your loupe ID card					
Ocular distance	The distance between the oculars has been calculated for your pupil and working distance					
weight	32 gram					

6.2.2. Ambient Conditions

Operation and Storage:

Temperature: +10°C to +40°C
 Rel. humidity: 25 to 75%
 Air pressure: 700 hPa to 1060 hPa

Transport

Temperature:	-40°C to +60°C
Rel. humidity:	10 to 90%
Air pressure:	500 hPa to 1060 hPa

6.2.3. Conformity with Standards

Classification according to Regulation (EU)2017/745 I

