spot-on® nxt

Instructions for Use

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orangedental
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DDI inside

1. DEAR CUSTOMER

1.1. Prologue

The product that you have purchased – spot–on^{nxt} 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 form the product that you have purchased.

These instructions contain an exact description and explain how to use the spot–on^{nxt}. If you have any additional questions or ideas, we would be pleased to help you either by telephone or by email.

These instructions accompany the spot–on^{nxt}. 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 spot–on^{nxt} 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 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. Content

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 procedure.

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.

MD

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.

CE

Disposal

This symbol means that the device labelled must not be disposed of with normal household waste.

Swiss Representative

By affixing this mark, the manufacturer indicates its mandated Swiss authorized representative, the so-called CH REP. For orangedental GmbH & Co. KG this task is mandated to:

CH REP

Forstgarten International Holding GmbH
Rorschacher Straße 302
9016 St. Gallen - Switzerland

2. ABOUT THE PRODUCT

2.1. Intended Use

The spot–on^nxt is used for illumination of the oral cavity of a patient using a binocular loupe system of the practitioner. The spot–on^nxt is designed for use by dentists or qualified dental personnel within a dental workspace. There are no known contraindications for the use of the lamp. There are no restrictions regarding the intended patient group.

As an accessory to the spot-on cordfree, the spot–onblue^nxt improves the visibility of composites and composite residues as well as plastic residues from orthodontic brackets by using a special spectral range. The spot–onblue^nxt is intended for use by orthodontists, dentists or dental professionals in dental workplaces. There are no known contraindications for the use of the spot–onblue^nxt. There are no restrictions regarding the intended patient group.

2.2. Delivery scope

spot–on^nxt lamp
This is normally already mounted on the glasses

Battery unit for attachment to arm or belt

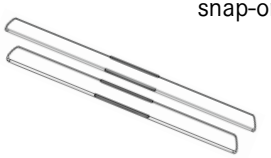
Power supply unit for charging the battery unit

Charging cable for connecting power supply unit and battery unit

Allen key

2.3. Spare Parts and Accessories

The following parts below can be reordered from orangedental GmbH & Co KG via your depot under the article number indicated.



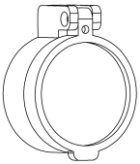
snap-on arm strap

Art.Nr. zublup0499380 (long)

Art.Nr. zublup0499390 (short)

Battery unit

ArtNr. zublup0499400



Orangefilter

ArtNr. zublup0499440

Endo bridge

ArtNr. zublup0499910

Lighting unit
spot-on blue nxt

ArtNr. zublup0499900

3. INSTALLATION

Before you use the device for the first time, you should completely charge the battery unit of the spot-on[nxt]. In order to do so, place the USB plug of the charging cable into the socket of the charger. Now allow the plug on the other side of the charging cable to snap into the socket of the battery unit. Since plug and socket are magnetic, this happens almost automatically. Make sure that the plug is not at an incline. Due to their shape and the magnetic forces, the plug and socket can only be placed together in one direction. Then plug the power supply unit into a suitable power socket. A small orange lamp lights up below the magnetic socket while the battery unit is charging. The lamp has two lighting levels: bright, during the main charging time and darker, in the precharge time and recharging time.

Note: If the lamp is not already attached to the magnifying glasses, please contact orangedental if necessary. Now allow the magnetic plug on the lamp, as shown in the illustration bellow, to snap into the battery casing coupling.

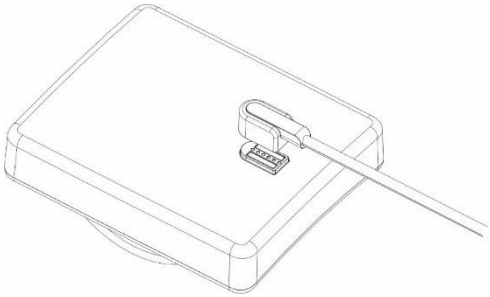


Illustration: Plug for connecting the charging or lamp cable

If you want to use the battery unit in the traditional way, attach the battery now to the clip on the rear side of your belt, your pocket or waistband. In order to insert the clip more easily, there is a small protruding lug on the lower part. Please remember that the device has a sensor key. Therefore, it should not be positioned where you place your arm when sitting. The key also works through clothing, providing that it is not too thick.

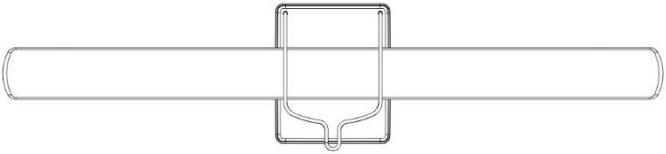


Illustration: Installing the arm strap

In order to attach the device to the arm, you should first of all put the suitable arm strap (shorter arm strap for delicate arms and longer one for larger arms) to the rear side of the casing underneath both spring arms.

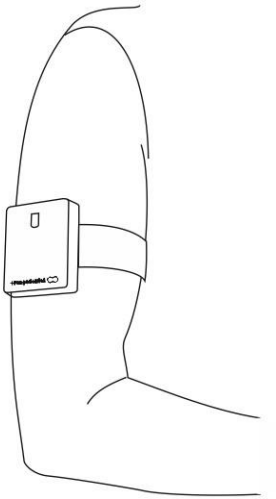
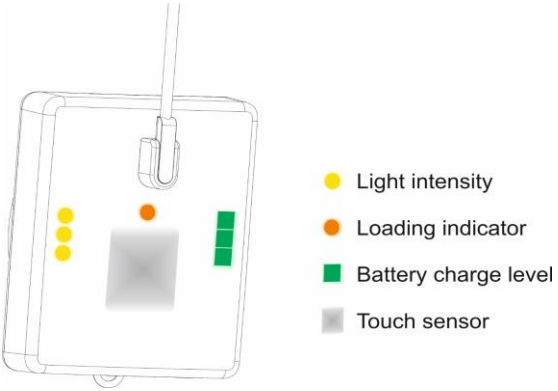


Illustration: Attaching the strap

Now press the casing with the magnetic coupling upwards on your upper arm. The straps snap automatically around your arm. If not, apply light pressure to the protruding strap. It is best to hold the strap when both ends overlap on the underside of the arm.

4. USAGE

The spot–on[nxt] is operated by means of a sensor surface situated in the middle of the battery casing and has some display elements which are not visible in normal operation.



Switching on: When you touch the sensor surface with your finger (for less than a second), the lamp switches on. During the contact time, the current battery charge level and the set light intensity are displayed.

Battery charge level (green):	3 lamps 66-100%, 2 lamps 33-66%, 1 lamp 1-33% of a fully charged battery.
Light intensity (yellow):	3 lamps maximum light capacity, approx. 45,000 Lux[1] 2 lamps increased light capacity, approx. 30,000 Lux[1] 1 lamp normal light intensity, approx. 20,000 Lux[1] [1] measured at 25 cm working distance
spot–on blue[nxt] irradiance (yellow):	3 lamps maximum light capacity, approx. 87 W/m^2 [2] 2 lamps increased light capacity, approx. 58 W/m^2 [2] 1 lamp normal light intensity, approx. 39 W/m^2 [2] [2] measured at 20 cm working distance

Look at an even surface through the magnifying glasses. By pressing the lamp on the glasses up or down, you can adjust the way your field of vision is illuminated.

Switching off: By briefly pressing the sensor surface with your finger again, you can switch the lamp off. When the lamp is switched off, only the charge level of the battery is displayed.

Adjusting the brightness: In order to alter the light intensity, touch the sensor area of the battery casing for more than one second. After this period, the light begins to become brighter and dimmer at three levels. For control purposes the three yellow lights also display the current light intensity. Let go of the sensor area again when the desired level has been reached.

This value is stored and becomes active again the next time the device is switched on. One exception is the maximum contrast level which can only be activated for 5 minutes. In order to prevent the lamp from becoming unpleasantly warm, the highest illumination level is switched down to the middle level after 5 minutes. It is likewise switched down to the middle illumination level after the device is switched off and on.

Charging: When the sensory area is touched, one to three small green lamps light up. These show the battery's state of charge. If only one lamp is lit, this means that the battery has only one third of its capacity remaining and should be charged before the lamp is used again.

In order to charge the device, connect the charging cable - instead of the lamp's cable - to the battery unit and connect the USB plug of the charging cable to the charging device. Now plug the charging device into a suitable mains socket.

Note: Only use the supplied charger for charging.

Note: Do not use the USB connection of your PC to charge the device. The PC cannot provide the required energy. Normally, the PC will switch off the USB interface due to overload. If it, contrary to expectation, supplies a current, the charging procedure would take 3-4 times longer than with the charging device.

The charging procedure is completed when the orange LED beneath the magnetic plug completely goes out. It takes 2 – 3.5 hours.

Note: To avoid a deep discharge of the battery, please charge the battery every three months - even when not in use.

5. ASSEMBLY OF SPARE PARTS AND ACCESSORIES

5.1. Mounting the spot-on blue^nxt

1. Disconnect the cable connection from the **spot–on^nxt** battery.
2. Remove the **spot–on^nxt** from your magnifying glasses.
3. Attach the **spot–on blue^nxt** to your magnifying glasses using the adapter.

Note: It is recommended to use a magnetic adapter when using **spot–on^nxt** and **spot–on blue^nxt** alternately.

4. Connect the cable of the **spot–on blue^nxt** light unit to the battery unit.

5.2. Mounting the orange filter

1. Make sure that the pre-assembled grub screw does not protrude into the inside of the orange filter.

2. Place the orange filter on the spot–on^nxt and screw in the grub screw using the Allen key.

3. If you do not need the orange filter, flip it all the way up.

6. SAFETY, HANDLING AND MAINTENANCE

6.1. General

Remember that the spot-on^nxt illuminates very brightly when in operation. When using it, make sure that you do not shine the device into the eyes of patients or staff. Although the light capacity is low enough for the blinking reflex of the eye to prevent damage to the retina, the dazzling effect of the lamp is very strong as soon as the light shines towards eyes.

WARNING: The spot-on^nxt (including spot-on blue^nxt) lighting unit corresponds to risk group 2 according to DIN EN 62471-1. The products emit blue light. Danger of glare! Risk of injury to the retina. Do not look directly into the light beam.

The light beam must not be directed towards the eyes. Do not use the spot-on^®cordfree for eye examinations (examination of pupils).

Increased risk of glare. Note that the reaction of the eyes decreases under the influence of drugs, medications or alcohol.

spot-on^nxt / spot-on blue^nxt:
The limit value <1 W/m² is undercut at the following distance:
≥ 1250 / 1530 / 1875 mm (normal / increased / maximum intensity)

CAUTION: Danger of heat build-up, e.g. if the lamp is covered when in operation.

If spot-on^nxt is used several times with highest light intensity, please note the heat generation of the light.

After prolonged storage it may be necessary to charge and discharge the battery several times to achieve full performance.

6.2. Hygiene

CAUTION: The lamp and the battery unit are **not** autoclavable. The resulting temperatures would destroy the plastics and electronics used.

Note: The spot-on^nxt is sealed appropriately in order to protect it when it is cleaned / disinfected with damp media / cloths.

The spot–on^nxt should be cleaned immediately after use in order to prevent any residual blood or protein from solidifying.

6.2.1. Cleaning

Take the lamp off the battery unit and pull the arm strap out of the holder. First of all, remove any residue by wiping with a mild cleaning agent.

Remove any residual detergent with a damp, lint-free disposable cloth.

6.2.2. Disinfection

The spot–on^nxt is disinfected by way of wipe disinfection.

A cloth moistened (not soaked) with disinfecting agent should be used for this purpose.

Note: The products listed in the following section have been tested positively with regard to their compatibility with the plastics used. We cannot guarantee that other agents will not affect the surfaces of the battery unit.

Wipe the battery casing, the arm strap, the cable and the lamp several times with the disinfecting cloth.

Allow the disinfecting agent to take effect long enough as per its instructions.

Now remove any residual disinfecting agent with damp, lint-free disposable cloths.

Now dry the spot–on^nxt with a sterile, lint-free disposable cloth and then allow it to dry properly. Make sure that the glass lens on the lamp is clean. Dirt on the lens can affect the light intensity.

CAUTION: When cleaning, please pay attention that the disinfecting agent and liquid detergents used do not gain access to the plug or the area behind the lens.

Only use soft cloths for cleaning and disinfecting and no sharp or abrasive objects.

6.2.3. Disinfection Agents for the spot-on^nxt

The following agents have been tested for cleaning and disinfecting the spot-on^nxt:

Innocid DW-i Desinfektionstücher

PRISMAN Pharma International AG; Am Stalden 16; CH-4622 Egerkingen

Omnizid spray and wipe disinfection

OMNIDENT Dental-Handelsgesellschaft mbH; Gutenbergring 7-9; D-63110 Rodgau

6.3. Servicing and Maintenance

The device may only be repaired by a service point authorized by orangedental.

WARNING: Take the device out of operation if there are visible signs of damage or any malfunctioning. Contact your orangedental service point in such cases.

6.4. Disposal

The spot-on^nxt and the accessories contain a lithium polymer accumulator as well as components which are not suitable for disposal with normal household refuse. Please contact your dental stockist or enretec GmbH (www.enretec.de). Enquiries relating to disposal can be sent to orangedental.

7. SPECIFICATIONS, CONFORMITY

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

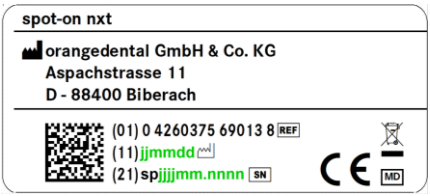
CE

7.1. Requirements for the Environment of Use

IMPORTANT: The spot–on nxt should only be operated by skilled and trained persons.

Place the device so that is not exposed to direct sunlight.

7.2. Product labeling



7.3. Technical Data

7.3.1. Dimensions

	data	unit
casing battery unit	75 x 63 x 25	mm
lamp	29 x 15 ⌀	mm
length of cable lamp	1100	mm
weight battery unit	85	g
weight lamp	7	g

7.3.2. Electrical Characteristics

	data	unit
supply voltage battery unit	5	V DC
max. power input	1500	mA
battery LiPo	9.6	Wh

7.3.3. Optical Characteristics

	data	unit
Light intensity spot-on[nxt] normal/amplified/maximum approx. measured at a working distance of 25 cm	20 / 30 / 45	x1000 Lux
Irradiance spot-on blue[nxt] normal/amplified/maximum approx. measured at a working distance of 20 cm	39 / 58 / 87	W/m²

7.3.4. Product service life

	data	unit
Product service life (except battery)	5	years

7.3.5. Conformity with Standards

	Data
Protection class	IP20
Classification according to regulation (EU) 2017/745	I
Electrical safety	EN 60601-1
Photobiological safety of lamps and lamp systems	DIN EN 62471

7.3.6. Ambient Conditions

Operation conditions

Use only in a normal climate

temperature:	+10°C to +40°C
rel. humidity:	25 to 75%
air pressure:	800 hPa to 1060 hPa

Transport conditions

temperature:	-20°C to +60°C
rel. humidity:	10 to 90%
air pressure:	500 hPa to 1060 hPa

Storage conditions

temperature:	+5°C to +50°C
rel. humidity:	10 to 75%
air pressure:	700 hPa to 1060 hPa

7.3.7. EMC-Classification

	data
EN 60601-1-2 group 1	HF energy used exclusively for its internal function.
EN 60601-1-2 class B	Is suitable for use in all buildings including domestic buildings and such that are connected directly to a public supply network which also supplies buildings which are used for domestic purposes.

7.3.8. Electromagnetic Compatibility

Guidance and manufacturer's declaration – electromagnetic emissions		
The spot–on^nxt is intended for use in an environment as described below. The customer or the user of the spot–on^nxt should assure that it is used in such an environment.		
Interference emission measurements	Compliance	Electromagnetic environment – guidance
RF-emissions as per CISPR 11	Group 1	The spot–on^nxt uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions as per CISPR 11	Class B	The spot–on^nxt is suitable for use in all establishments including domestic premises and those directly connected to the public power supply network that supplies buildings used for domestic purposes.
Harmonic emissions as per IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The spot–on^nxt is intended for use in the electromagnetic environment specified below. The customer or the user of spot–on^nxt should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compli-ance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input	Not appli-cable	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to line(s)	Not appli-cable	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (>95 % dip in U_T) for 5 s	Not appli-cable	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a
NOTE U_T is the a.c. mains voltage prior to application of the test.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The spot–on^nxt is intended for use in an environment as described below. The customer or the user of the spot–on^nxt should assure that it is used in such an environment.			
Immunity test	IEC 60601-test level	compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V_{eff} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V_{eff} 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the spot–on^nxt including cables, then the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1.17 √P d= 1.17 √P for 80 MHz to 800 MHz d = 2.3 √P for 800 MHz to 2.5 GHz 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[b] Interference may occur in the vicinity of equipment marked with the following symbol.

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.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access 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 spot–on^nxt is used exceeds the applicable RF compliance level above, the spot–on^nxt should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the spot–on^nxt.

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

Recommended separation distances between portable and mobile RF communications equipment and the spot–on^nxt			
Die spot–on^nxt is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the spot–on^nxt can help prevent the electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the spot–on^nxt – as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter in Watt	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz in the ISM bands $d = 1.17 \sqrt{P}$	80 MHz to 800 MHz $d= 1.17 \sqrt{P}$	800 MHz to 2.5 GHz $d= 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in 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 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.			

8. WARRANTY CONDITIONS

1. RELATIONSHIP TO OTHER WARRANTY RIGHTS AND TO NATIONAL LAW

This guarantee does not affect the buyer's rights against the seller arising from the concluded purchase contract. The above warranty conditions apply insofar as they do not conflict with the respective national law with regard to warranty provisions.

2. WARRANTY COVERAGE

Standard warranty: orangedental GmbH & Co. KG grants a warranty of one year for mechanical and electrical components of the spot-on^nxt (including the battery unit), in accordance with the conditions described here, calculated from the date of purchase of the device by the purchaser. If defects occur within this warranty period that are not due to one of the causes listed in section 4, orangedental will either replace or repair the device at its own discretion.

Warranty services other than those mentioned above are not granted.

3. UTILISATION OF THE GUARANTEE

The warranty can only be utilised if the device has been properly set up at the purchaser's premises. In order to be able to check the justification of a warranty service in advance, the warranty service requires that the purchaser or his dealer inform orangedental by telephone about the defect that has occurred. The purchaser will receive a confirmation.

4. WARRANTY CONDITIONS

orangedental only guarantees the proper functioning of the mechanical and electrical components of the devices and does not grant the purchaser any right to free inspection or maintenance of the same or to repair of the device, in particular if the defects are due to improper use.

Defects in wearing parts that are attributable to normal wear and tear are also not covered by the warranty claim.

Furthermore, the warranty does not cover damage to the device caused by:

- improper use or misuse of the device for a purpose other than its normal purpose in non-compliance with the orangedental operating and maintenance instructions.
- connection or use of the device in a manner that does not comply with the applicable technical or safety requirements in the country in which the device is used.
- damage caused by force majeure or other causes for which orangedental is not responsible.

The warranty expires if the device has been repaired or opened by an unauthorised workshop or by the customer himself.

Should it be determined during the inspection of the device by orangedental that the existing damage does not justify the utilisation of warranty claims, the costs of the inspection service shall be paid by the customer.

Furthermore, orangedental promises the purchaser the availability or procurement of spare parts of the aforementioned type for the period of the normal service life of the device, provided that orangedental is actually and legally able to procure such parts with reasonable effort.

The warranty is provided exclusively for the original purchaser of the dealer who purchased the devices from orangedental and is not transferable. Apart from orangedental, no third party (dealer) is authorised to make warranty promises with effect for and against orangedental.

5. LIABILITY

Except in the case of intent or gross negligence, the purchaser shall not be entitled to any claims for damages due to poor performance of the guarantee, in particular not for consequential damages. The liability of orangedental is limited in all cases to the value of the goods of the device.

6. APPLICABLE LAW

German law shall apply to claims arising from the warranty.

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