



spot-on^{nxt}

Instructions for Use

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 from 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.

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

1.1.1. Copyright(s) and Trademark

Windows is a registered trademark or a brand of Microsoft Corporation in the USA and/or other countries.

1.1.2. 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 only carried out by persons authorised by orangedental,
- >> The device is used in accordance with the instructions for use.

1.1.3. Responsibility of the Operator

Among other things, the operator is responsible for:

- >> Adherence to the accident prevention regulations as well as regulation concerning the installation, operation and use of active medical products – MPBetreibV).
- >> The operation.
- >> The maintenance.
- >> The proper and safe condition of the product, and storing the instructions manual at the location of use.
- >> Following the safety instructions contained in these instructions (cf. section 1.3 Conventions, symbols used)

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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:** Use of the term **IMPORTANT** in this formatting indicates advice on using the device or on applying a certain procedure.
- Note:** Notes are used to make you aware of important or unusual points.



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

CHECK INSTRUCTIONS

By labeling the product with this symbol, the manufacturer is pointing out that the instructions for use (i.e. this document) contain warnings and safety information which should be observed when the product is used.



ATTENTION

indicates that there are warnings or regulations concerning the product which are not specified on the label itself.



MANUFACTURER

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



DATE OF MANUFACTURER

This symbol indicates the date of manufacture.



ORDER NUMBER

This symbol indicates the order number.



SERIAL NUMBER

This symbol is used to indicate the serial number.



CE MARKING

By attaching this symbol to the device, the manufacturer declares that the product labeled complies with the EMC regulations 93/42 “Medical devices”.



DISPOSAL

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



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.

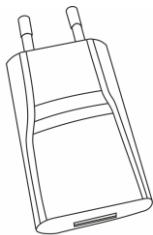
2.1.1. Delivery Scope



spot-on^{nxt} lamp
This is normally
already mounted on
the glasses
Art.no. 00.005.343



Battery unit for
attachint to arm or
belt
Art.no. 00.005.365



Power supply unit
for charging the
battery unit
Art.no. 00.005.354



Charging cable for
connecting power
supply unit and
battery unit
Art.no. 00.005.591

Innensechskantschlüssel
Art.no. 00.006.928

2.1.2. Spare Parts and Accessories

All parts displayed above can be reordered under the article number from your warehouse at orangedental.



Two arm straps of
different lengths with
snap-on coupling
long Art.no. 00.005.387
short Art.no. 00.005.398

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 comes on underneath 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 refer to the separate instructions for use regarding the mounting of the lamp. Now allow the magnetic plug on the lamp, as shown in the illustration bellow, to snap into the battery casing coupling.

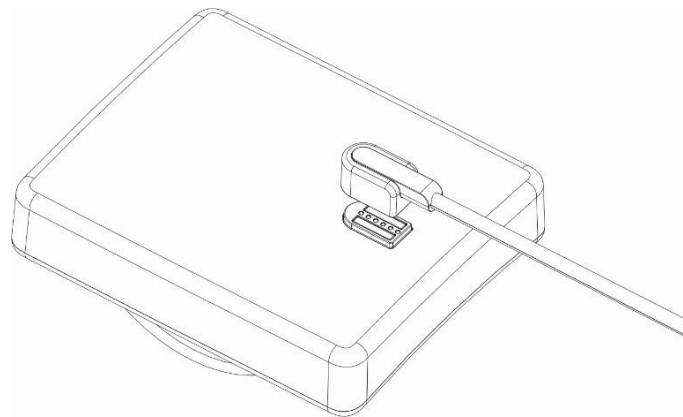


Illustration: Plug for connecting the charging or lamp cable

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 projecting lug on the lower part. Please remember that the device has a sensor key. Therefore, it should not be placed where you place your arm when sitting. The key also works through clothing, providing it is not too thick.

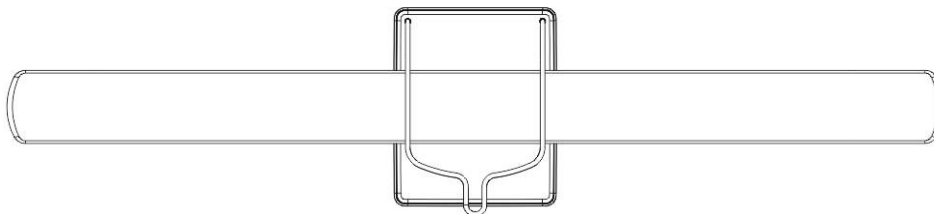


Illustration: Installing the arm strap

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 bulkier arms) to the rear side of the casing underneath both of the spring arms.

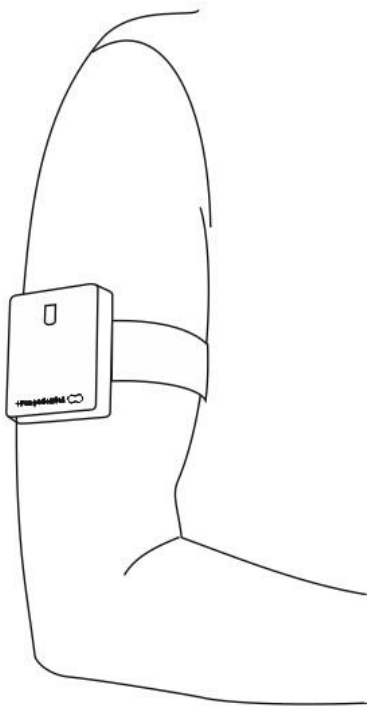
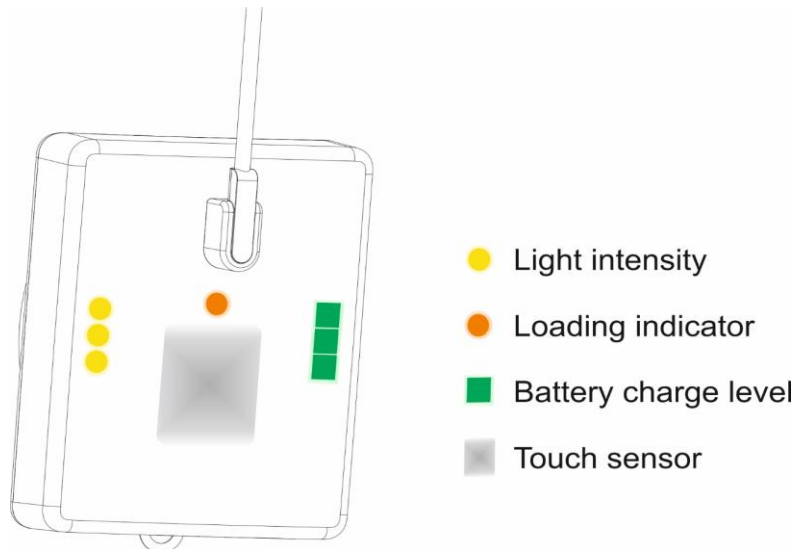


Illustration: Attaching the strap

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. USE

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 light intensity set 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 Lux¹
 2 lamps increased light capacity, approx. 30,000 Lux¹
 1 lamp normal light intensity, approx. 20,000 Lux¹

¹ measured at 25 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 once again pressing the sensor area briefly with your finger, you can switch the lamp off again. 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 on and off.

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 - 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. 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, 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.

5. SAFETY, HANDLING AND MAINTENANCE

5.1. General

Remember that the **spot-on^{next}** 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 lamp on the **spot-on^{next}** belongs to risk group 2 as per DIN EN 62471-1. Danger of dazzling! Do not look directly into the ray of light.



The ray of light must not be directed towards the eye. The **spot-on^{next}** is not to be used for eye examinations (examination of pupils).

Increased danger of dazzling. Remember that the responsiveness of the eyes diminishes when someone is under the influence of drugs, medication or alcohol.

Risk of injury to the retina.

The product emits blue light (400-780 nm). Do not look directly into the ray of light.

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



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

5.2. 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^{next}** is sealed appropriately in order to protect it when it is cleaned / disinfected with damp media / cloths.

The **spot-on^{next}** should be cleaned immediately after use in order to prevent any residual blood or protein from solidifying.

5.2.1. 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.

5.2.2. Disinfection

The **spot-on^{next}** 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 soak long enough in as per its instructions.

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

Now dry the **spot-on^{next}** 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.

5.2.3. Disinfection agents for the spot-on^{next}

The following agents have been tested for cleaning and disinfecting the **spot-on^{next}**:

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

5.3. 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.




5.4. Disposal

The **spot-on^{next}** 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.



6. SPECIFICATIONS AND CONFORMITY

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



6.1. Requirements regarding the practice environment

IMPORTANT: The **spot-on^{nxt}** should only be operated by skilled and trained persons.

Position the device so that is not exposed to direct sunshine.

6.2. Product labeling



6.3. Technical Data

6.3.1. Dimensions

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

6.3.2. Electrical characteristics

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

6.3.3. Optical characteristics

	data	unit
light intensity normal/strong/maximum approx. Measured at 25 cm working distance	20 / 30 / 45	x1000 Lux

6.3.4. Working life

	data	unit
life utility (except battery)	5	years

6.3.5. Electromagnetic compatability

	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.	

6.3.6. Conformity with standards

	Data
Protection class	IP20
Classification according to 93/42/EEC	I
Electrical safety	EN 60601-1

6.3.7. Ambient conditions

Operation conditions

Use only in a normal climate

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

Transport conditions

temperature: -40°C to +60°C
 rel. humidity: 10 - 90%
 air pressure: 500 hPa to 1060 hPa


Storage conditions

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

6.3.8. Electromagnetic compatibility

Guidance and manufacturer's declaration – electromagnetic emissions		
<p>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.</p>		
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	compliance 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 relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	Not applicable	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 applicable	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 applicable	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 typical commercial or hospital environment.
NOTE U _T ist he 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
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 V_{eff} 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 V_{eff}</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the spot-on^{nxt} including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance $d = 1.17 \sqrt{P}$ $d = 1.17 \sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ for 800 MHz to 2.5 GHz</p> <p>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).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol.</p> 
<p>NOTE 1 at 80 MHz and 800 MHz the separation distance for the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^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}.</p> <p>^b Over the frequency range 150 kHz to 80 MHz so field strengths should be less than 3 V/m.a</p>			

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.			