



# spot-on<sup>®</sup> cordfree

## Instructions for Use

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**orangedental**  
premium innovations

DDI Inside





## 1. DEAR CUSTOMER

### 1.1. Prologue

With **spot-on**<sup>®cordfree</sup> you have acquired a product that represents the latest state of the art and has been manufactured according to strict quality criteria. As we continue to develop our products, it is possible that the images and drawings in this document may differ slightly from the product you have acquired.

This manual contains a detailed description and instructions for use. If you have any further questions or suggestions, please do not hesitate to contact us by telephone or e-mail.

These instructions for use are part of **spot-on**<sup>®cordfree</sup>. Please keep them to hand for future reference. If you pass this product on to third parties, please also include this document as it contains important information on commissioning and handling the product.

Use this manual to familiarize yourself with the product before using it during part of any treatment.

#### 1.1.1. Responsibility of the Manufacturer

The **spot-on**<sup>®cordfree</sup> has been manufactured in accordance with the state of the art and recognised safety regulations.

orangedental GmbH & Co. KG [hereinafter 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 authorised by orangedental.
- >> the device is used in accordance with the instructions for use.

### 1.1.2. Responsibility of the Operator

The operator is among other things responsible for:

- >> compliance with accident prevention regulations and the Ordinance on the Installation, Operation and Use of Medical Devices (German regulation - MPBetreibV).
- >> the operation.
- >> maintenance.
- >> the proper and safe condition of the product and the availability of this manual at the place of use.
- >> following the safety instructions contained in this manual (cf. section 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 ..... 2
- 1.2. Contents ..... 3
- 1.3. Conventions, Symbols used ..... 4
- 2. About the Product..... 6**
- 2.1. Intended Use ..... 6
- 2.2. Scope of delivery ..... 7
- 2.3. Accessories ..... 7
- 3. Installation ..... 9**
- 4. Usage..... 11**
- 4.1. Settings ..... 13
  - 4.1.1. Adjusting the brightness ..... 13
  - 4.1.2. Automatic switch-off..... 14
- 5. Assembly of spare parts and accessories ..... 16**
- 5.1. Mounting the spot-on<sup>®blue</sup>cordfree ..... 16
- 5.2. Mounting the orange filter ..... 17
- 6. Safety, Handling and Maintenance ..... 18**
- 6.1. General ..... 18
- 6.2. Hygiene ..... 19
  - 6.2.1. Cleaning..... 20
  - 6.2.2. Disinfection..... 20
  - 6.2.3. Disinfectants for spot-on<sup>®cordfree</sup> ..... 21
- 6.3. Maintenance and servicing ..... 21
- 6.4. Disposal ..... 22
- 7. Spezifications, Conformity ..... 23**
- 7.1. Requirements for the practical environment ..... 23
- 7.2. Product labelling..... 23
- 7.3. Technical data ..... 24
  - 7.3.1. Dimensions..... 24
  - 7.3.2. Electrical characteristics ..... 24
  - 7.3.3. Optical characteristics..... 24
  - 7.3.4. Product service life ..... 25

7.3.5. EMC Classification..... 25  
 7.3.6. Compliance with standards ..... 25  
 7.3.7. Environmental conditions ..... 25  
 7.3.8. Electromagnetic compatibility ..... 26

**8. WARRANTY CONDITIONS ..... 32**

**1.3. Conventions, Symbols used**

In these instructions, the conventions stated below indicate important information:

**WARNING:** This symbol is used if deviating from the procedure described may result in physical injury or death.



**CAUTION:** This symbol is used if deviating from the procedure described may result in damage to the product or loss of data.



**IMPORTANT:** The use of the term **IMPORTANT**, formatted in bold capitals, indicates advice for the use of the device or for the application of a certain procedure.

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

Symbols used on the product, its packaging or in these instructions have the following meanings.

**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 device.



**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 device is in conformity with and fulfills all requirements of the medical device regulation (EU) 2017/745.



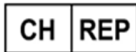
**DISPOSAL**

This symbol means that the device labelled must not be discarded 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:



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

## 2. ABOUT THE PRODUCT

The **spot-on**<sup>®cordfree</sup> is characterised by the fact that the battery is attached directly to the lighting unit and therefore no cable is required.

Another special feature of **spot-on**<sup>®cordfree</sup> is the integration of a position sensor and the associated automatic switch-off. The motion sensor determines the current orientation of the lighting unit. If this corresponds to the usual working position, the lamp is activated and the oral cavity can be illuminated. When it is nearly horizontal, the lighting unit is deactivated. This prevents, for example, your assistant from being blinded.

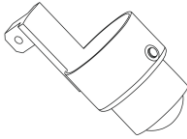
### 2.1. Intended Use

The **spot-on**<sup>®cordfree</sup> is used for illumination of the oral cavity of a patient using a binocular loupe system of the practitioner. The **spot-on**<sup>®cordfree</sup> 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-on**<sup>®blue</sup><sup>cordfree</sup> improves the visibility of composites and composite residues as well as plastic residues from orthodontic brackets by using a special spectral range. The **spot-on**<sup>®blue</sup><sup>cordfree</sup> is intended for use by orthodontists, dentists or dental professionals in dental workplaces. There are no known contraindications for the use of the **spot-on**<sup>®blue</sup><sup>cordfree</sup>. There are no restrictions regarding the intended patient group.



**2.2. Scope of delivery**



**Lighting unit**  
The magnetic adapter is already mounted on it.



**2 battery units**



**Power supply** for charging the battery unit



**Charging cable** for connection between power supply unit and charging unit



**Charging unit**



**Allen key**

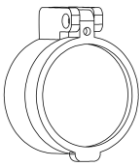
**2.3. Accessories**

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



1 battery unit

ArtNr. zublup0499500



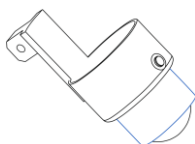
Orangefilter

ArtNr. zublup0499440



Endo bridge

ArtNr. zublup0499910



Lighting unit  
spot-on blue cordfree

ArtNr. zublup0499890

### 3. INSTALLATION

Before using the **spot-on**<sup>®cordfree</sup> for the first time, you should charge the battery unit completely. After approx. one hour the battery is 80% charged; after two hours it is fully charged.

In order to charge, connect the charging cable with the supplied power supply unit and plug it into a suitable mains socket. Now plug the Micro-USB plug of the charging cable into the socket of the charging unit. Insert either one or both battery units into the recesses provided in the charging unit. The magnets in the charging unit ensure correct positioning. As long as the battery unit is charging, the respective LED lights up orange. When it turns off completely, the corresponding battery is fully charged. Now remove the battery unit from the charging unit by pulling out the battery unit while holding the charging station with your other hand.

**CAUTION:** If one of the LEDs lights up permanently without a battery being inserted, please disconnect the charging unit from the mains plug and no longer use the charging unit. Get in touch with orangedental.

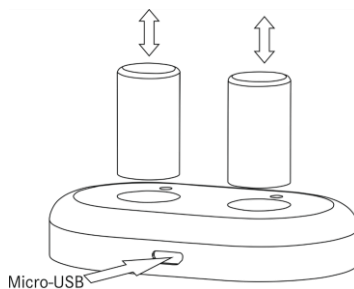


Figure 1: charging batteries

**Note:** Do not use a USB port on your PC for charging. This cannot provide the required power.

Now you can insert the battery unit into the lighting unit. The magnetic system ensures correct positioning.

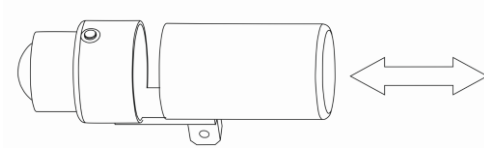


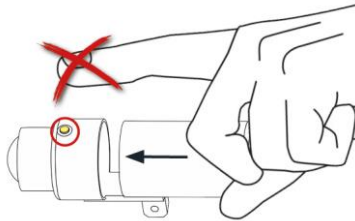
Figure 2: Inserting the battery

**Note:** If no adapter is attached to the magnifying glasses yet, please use the supplied Allen key or contact orangedental if necessary.

## 4. USAGE

### Switching on

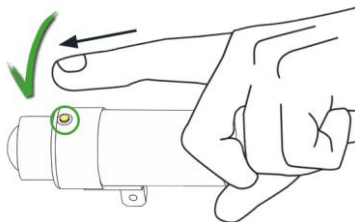
Insert a battery into the lighting unit (see 3: Installation). The LED now lights up for one second. During this time, the touch sensor is calibrated and should therefore not be touched.



The LED then turns off automatically. The spot-on<sup>®cordfree</sup> is now ready for use.

The spot-on<sup>®cordfree</sup> is operated by a touch sensor located in the centre of the lighting unit. It is possible to feel a minimal elevation of the sensor.

**Note:** If you have difficulty feeling the touch sensor, swipe your finger forward from the battery unit.



If you touch the sensor with your finger briefly (less than one second), the light switches on. This is always the case, regardless of the orientation of the spot-on<sup>®cordfree</sup>; the automatic switch-off function is still deactivated here (see 4.1.2: Automatic switch-off). It is activated once the value has fallen below the switch-off angle, unless the automatic switch-off function is turned off (see section 4.1.2).

Look through the magnifying glasses onto a flat surface. You can optimally adjust the illumination of your field of vision by pressing up or down the lamp which is mounted on the glasses.

## Switching off

With another short touch of the touch sensor, you switch off the light again.

If the light is currently deactivated due to the automatic switch-off function, a short flash acknowledges the successful switch-off.

**Note:** If the **spot-on**<sup>®cordfree</sup> is no longer needed, remove the battery to prevent it from deep discharging.

## Charging

To charge the batteries, connect the charging cable to the supplied charging unit and plug it into a suitable mains socket. Now plug the Micro-USB plug of the charging cable into the socket of the charging unit. Then insert either one or both battery units into the recesses provided in the charging unit. The magnets in the charging unit ensure correct positioning. As long as the battery unit is charging, the respective LED lights up orange. When it turns off completely, the corresponding battery is fully charged. Now remove the battery unit from the charging unit by pulling out the battery unit while holding the charging station with your other hand.

**CAUTION:** If one of the LEDs lights up permanently without a battery being inserted, please disconnect the charging unit from the mains plug and no longer use the charging unit. Contact orangedental.

**Note:** Do not use a USB port on your PC for charging. The USB port cannot provide the required power. Normally the USB interface in the computer switches off due to overload. If, contrary to expectations, it does supply power, the charging process would take three to four times as long as with the supplied USB power supply unit.

The charging process is completed when the respective orange LED goes out completely. After approx. one hour, the battery is 80% charged. The battery is fully charged after about two hours.

## Power saving mode

If the light is not moved within approx. two minutes, the energy-saving mode is automatically activated and the light switches off by itself off. If the lamp is moved again, it is automatically switched on.

## 4.1. Settings

### 4.1.1. Adjusting the brightness

The factory setting is a luminous intensity of 10,000 lux. To change the light intensity, press the touch sensor six times when it is switched on (the light is switched off and on again three times). Then each time you press the touch sensor, the light intensity of the light changes from the lowest level, through the middle level to the highest and from the highest to the lowest.

**Note:** If the touch button is not pressed for three seconds, you leave the setting mode. Pressing the touch button again switches the **spot-on**<sup>®cordfree</sup> off (see 4: Switching off).

Three different light intensities are possible:

normal light intensity approx. 10.000 Lux<sup>1</sup>

increased light intensity approx. 15.000 Lux<sup>1</sup>

maximum light intensity approx. 20.000 Lux<sup>1</sup>

<sup>1</sup> measured at a working distance of 25 cm

Irradiance **spot-on**<sup>®blue</sup><sup>cordfree</sup>:

normal light intensity approx. 19 W/m<sup>2</sup> <sup>2</sup>

increased light intensity approx. 29 W/m<sup>2</sup> <sup>2</sup>

maximum light intensity approx. 39 W/m<sup>2</sup> <sup>2</sup>

<sup>2</sup> measured at a working distance of 20 cm

The selected value is saved and is active again after the next switch-on.

**Note:** If the touch button is pressed more than 20 times, pressing the button again also exits the setting mode and switches off the **spot-on**<sup>®cordfree</sup>.

#### 4.1.2. Automatic switch-off

The **spot-on**<sup>®cordfree</sup> has a function that ensures that the lighting unit is automatically switched on or off depending on its orientation. This allows you to illuminate your working area in your working position with your head slightly bent forward, while for an angle greater than  $\alpha$  the lighting unit is automatically deactivated and therefore, for example, your assistant is not dazzled. Another positive side effect is the extension of the battery life.

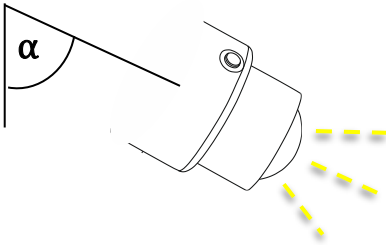


Figure 3: Switch-off angle undercut  
→ the **spot-on**<sup>®cordfree</sup> lights up

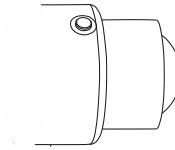


Figure 4: Switch-off angle exceeded  
→ the **spot-on**<sup>®cordfree</sup> is not lit


In order to satisfy an individual working posture, one can choose between three different angles  $\alpha$  (small, medium and large).

It is also possible to deactivate the automatic switch-off function. The selected setting is saved and is active again after the next switch-on.

**Note:** The automatic switch-off triggers with a short time delay.



## Changing the switch-off angle or deactivating the automatic switch-off function

If you want to change the switch-off angle, put on the @cordfree and switch it on. Within the next 15 seconds, tap twice from the side on one of the temples with your index finger and middle finger ("double tap"). A successful double-tap is acknowledged with a short blink.

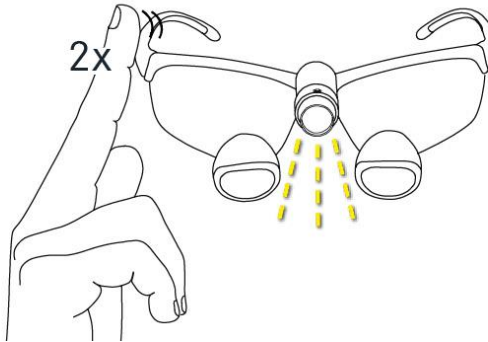



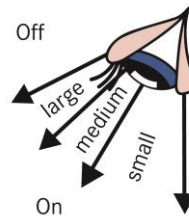
Figure 5: Double tap on temples

Immediately afterwards, press the touch sensor six times (the light is switched off and on again three times). Now you are in the mode to change the angle. Each time the touch button is pressed again, the angle is increased and indicated by a short flashing signal from the lamp. After the angle setting "large", the setting "automatic switch-off deactivated" follows.

**Note:** If the touch button is not pressed within six seconds, you leave the setting mode. Pressing the touch button again switches the @cordfree off.

### Settings

Angle small	1x blinking
Angle medium	2x blinking
Angle large	3x blinking
Deactivated	10x short-blinking



The selected setting is saved and is active again after the next switch-on.

**Note:** If the double tap has not been registered by the motion sensor, the **spot-on**<sup>®cordfree</sup> may switch to the setting mode "brightness". Set the desired brightness and then follow the instructions again as described in Section 4.1.2: Changing the switch-off angle.

## 5. ASSEMBLY OF SPARE PARTS AND ACCESSORIES

### 5.1. Mounting the **spot-on**<sup>®blue</sup><sup>cordfree</sup>

1. Remove the battery unit from the **spot-on**<sup>®cordfree</sup>.
2. Remove the **spot-on**<sup>®cordfree</sup> from your magnifying glasses.
3. Attach the **spot-on**<sup>®blue</sup><sup>cordfree</sup> to your magnifying glasses using the adapter.

**Note:** It is recommended to use a magnetic adapter when using **spot-on**<sup>®cordfree</sup> and **spot-on**<sup>®blue</sup><sup>cordfree</sup> alternately.

4. Insert a battery into the light 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**<sup>®cordfree</sup> and screw in the grub screw using the Allen wrench.



3. If you do not need the orange filter, lift it all the way to the top.



## 6. SAFETY, HANDLING AND MAINTENANCE

### 6.1. General

Keep in mind that the **spot-on**<sup>®cordfree</sup> shines very brightly and warms up during operation. When using the **spot-on**<sup>®cordfree</sup>, make sure that you do not shine into the eyes of the patient or your staff. Although the light output is so low that the eyelid closure reaction prevents damage to the retina, the glare effect of the lamp is very strong as soon as you enter the light field with your eyes.

**WARNING:** The **spot-on**<sup>®cordfree</sup> (including **spot-on**<sup>®blue</sup><sup>cordfree</sup>) 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**<sup>®cordfree</sup> 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**<sup>®cordfree</sup> / **spot-on**<sup>®blue</sup><sup>cordfree</sup>:

The limit value  $<1 \text{ W/m}^2$  is undercut at the following distance:

$\geq 880 / 1080 / 1250 \text{ mm}$  (normal / increased / maximum intensity)

**CAUTION:** Danger of heat accumulation, please do not cover during operation.



**WARNING:** The battery unit is a lithium-ion battery. Please observe the following application instructions to avoid hazards:



- Do not use a defective or damaged battery.
- Do not short-circuit it.  
The lithium-ion batteries can easily be short-circuited if they are placed on a conductive surface. Also be careful when storing (do not store in a drawer or similar with other metallic objects).
- Avoid subjecting the batteries to heat and mechanical stress. Do not store them in direct sunlight.

- Do not open the batteries.
- Only use the supplied battery units and charging unit to charge the batteries.
- Keep small cells and batteries that could be swallowed out of the reach of children.

Ingestion may result in burns, perforation of soft tissue and death. Severe burns may occur within two hours of swallowing.

If a cell or battery is swallowed, seek immediate medical attention.

- Store batteries clean and dry. If connections are dirty, clean with a dry, clean cloth.
- Do not charge batteries for long periods of time when they are not needed.
- After prolonged storage it may be necessary to charge and discharge the cells or batteries several times to achieve full performance.
- As far as possible, batteries should be removed from the device when they are not in use

## 6.2. Hygiene

**CAUTION:** The light, battery and charging unit are not autoclavable. The resulting temperatures would destroy the electronics.

**Note:** The **spot-on**<sup>®cordfree</sup> is appropriately sealed for cleaning / disinfection with moist media / wipes.



Cleaning should be done immediately after using **spot-on**<sup>®cordfree</sup> to prevent blood or protein residues from solidifying.

### 6.2.1. Cleaning

Remove the **spot-on**<sup>®cordfree</sup> from the magnifying glasses.

**IMPORTANT:** Carry out the cleaning on the assembled **spot-on**<sup>®cordfree</sup>. No cleaning agent must enter the interior of the light or battery unit.

First, remove any residue by wiping with a mild detergent.

Now remove any residues of the cleaning agent with moist, lint-free disposable cloths.

### 6.2.2. Disinfection

The subsequent disinfection of the **spot-on**<sup>®cordfree</sup> is carried out as wipe disinfection on the assembled **spot-on**<sup>®cordfree</sup>.

**IMPORTANT:** No disinfectant must enter the inside of the light or battery unit.

Use a cloth moistened (not wet) with the disinfectant for this purpose.

**Note:** The products listed in section 6.2.3 below have been tested positive for compatibility with **spot-on**<sup>®cordfree</sup>. It cannot be guaranteed that other agents will not attack the surfaces.

Wipe the **spot-on**<sup>®cordfree</sup> several times with the disinfectant wipe.

Allow the disinfectant to work long enough according to its instructions.

Now remove any residues of the disinfectant with sterile, moist, lint-free disposable wipes.

Now rub the **spot-on**<sup>®cordfree</sup> dry with a sterile, lint-free disposable cloth and allow to dry thoroughly. Make sure that the glass lens of the lamp is clean. Dirt on the lens affects the light intensity.

**CAUTION:** When cleaning, please ensure that the disinfection or cleaning fluids used do not run into the interior of the light, battery or charging unit or behind the lens of the light unit.



Use only soft cloths for cleaning and disinfection and do not use sharp or scratching objects.

### 6.2.3. Disinfectants for **spot-on**<sup>@cordfree</sup>

The following products have been tested for disinfection of **spot-on**<sup>@cordfree</sup>:

Innocid DW-i disinfecting tissues

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

Bacillol<sup>®</sup> Tissues

BODE Chemie GmbH; Melanchthonstraße 27; D-22525 Hamburg

## 6.3. Maintenance and servicing

Repairs to the device should only be carried out by a service centre authorised by orangedental.

**WARNING:** Take the device out of operation immediately if it shows visible damage or malfunctions. In this case, please contact your orangedental GmbH & Co. KG service centre.



## 6.4. Disposal


The **spot-on**<sup>@cordfree</sup> and accessories contain a lithium-ion battery and other components that are not suitable for disposal in normal household waste.

Please contact your dental dealer or enrettec GmbH ([www.enrettec.de](http://www.enrettec.de)) to arrange a return of the device. Please contact orangedental GmbH & Co. KG if you have any questions in this regard.





## 7. SPEZIFICATIONS, CONFORMITY

 orangedental GmbH & Co. KG  
Aspachstraße 11 | 88400 Biberach / Riß



### 7.1. Requirements for the practical environment

**IMPORTANT:** The **spot-on**<sup>@cordfree</sup> may only be operated by qualified and trained persons.

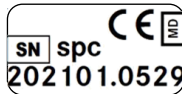
Place the device so that it is not exposed to direct sunlight.

**WARNING:** The charging station must not be within reach of the patient.

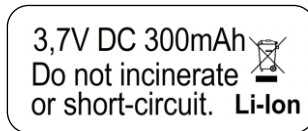


### 7.2. Product labelling

Lighting unit



Battery unit



Charging unit



## 7.3. Technical data

### 7.3.1. Dimensions

	data	unit
Housing battery unit	27 x 16 ø	mm
Housing lighting unit	32 x 17 ø	mm
Housing charging unit	80 x 46 x 15	mm
Weight battery unit	11	g
Weight lighting unit	7	g
Weight charging unit	90	g

### 7.3.2. Electrical characteristics

	data	unit
Supply voltage Battery unit	3,7	V DC
max. current consumption	300	mA
battery Li-Ion	1,2	Wh

### 7.3.3. Optical characteristics

	data	unit
Light intensity <b>spot-on</b> <sup>®cordfree</sup> normal/amplified/maximum approx. measured at a working distance of 25 cm	10 / 15 / 20	x1000 Lux
Irradiance <b>spot-on</b> <sup>®blue</sup> <sup>cordfree</sup> normal/amplified/maximum approx. measured at a working distance of 20 cm	19 / 29 / 39	W/m <sup>2</sup>

**7.3.4. Product service life**

	data	unit
Product service life (battery excluded)	3	years

**7.3.5. EMC Classification**

	Data
EN 60601-1-2 Group 1	uses HF energy exclusively for its internal function
EN 60601-1-2 Class B	is suitable for use in all establishments, including residential areas and those directly connected to a public supply network which also supplies buildings used for residential purposes.

**7.3.6. Compliance with standards**

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

**7.3.7. Environmental conditions**

**Operating conditions**

*Use only in normal climates*

temperature:	+10°C to +40°C
rel. humidity:	35 % to 85 %
air pressure:	800 hPa to 1060 hPa

**Transport conditions**

temperature: -20°C to +60°C  
 rel. humidity: 10% to 90%  
 air pressure: 700 hPa to 1060 hPa

**Storage conditions**

temperature: 0 °C to +40 °C  
 rel. humidity: 35 % to 85 %  
 air pressure: 700 hPa to 1060 hPa


**7.3.8. Electromagnetic compatibility**

Guidance and manufacturer’s declaration – electromagnetic emissions		
The <b>spot-on</b> <sup>@cordfree</sup> is intended for use in an environment as described below. The customer or the user of the <b>spot-on</b> <sup>@cordfree</sup> 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 <b>spot-on</b> <sup>@cordfree</sup> 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 <b>spot-on</b> <sup>@cordfree</sup> 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 <b>spot-on</b> <sup>®cordfree</sup> is intended for use in the electromagnetic environment specified below. The customer or the user of <b>spot-on</b> <sup>®cordfree</sup> should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance	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) ± 2kV line(s) to line(s)	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.

<p>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</p>	<p>&lt; 5 % UT (&gt;95 % dip in <math>U_T</math>) for ½ cycle</p> <p>40 % UT (60 % dip in <math>U_T</math>) for 5 cycles</p> <p>70 % UT (30 % dip in <math>U_T</math>) for 25 cycles</p> <p>&lt; 5 % UT (&gt;95 % dip in <math>U_T</math>) for 5 s</p>	<p>Not applicable</p>	<p>Mains power quality should be that of a typical commercial or hospital environment.</p>
<p>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</p>	<p>3 A/m</p>	<p>3 A/m</p>	<p>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</p>
<p>ANMERKUNG <math>U_T</math> is the a.c. mains voltage prior to application of the test.</p>			

Guidance and manufacturer’s declaration – electromagnetic immunity			
<p>The <b>spot-on</b><sup>®cordfree</sup> is intended for use in an environment as described below. The customer or the user of the <b>spot-on</b><sup>®cordfree</sup> should assure that it is used in such an environment.</p>			
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<sub>eff</sub> 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2,5 GHz</p>	<p>3 V<sub>eff</sub></p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the <b>spot-on</b><sup>®cordfree</sup> including cables, then the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance <math>d = 1.17 \sqrt{P}</math>  <math>d = 1.17 \sqrt{P}</math> for 80 MHz to 800 MHz  <math>d = 2.3 \sqrt{P}</math> 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).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey<sup>a</sup> should be less than the compliance level in each frequency<sup>b</sup></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.                  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><sup>a</sup> 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 <b>spot-on</b><sup>®cordfree</sup> is used exceeds the applicable RF compliance level above, the <b>spot-on</b><sup>®cordfree</sup> should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the <b>spot-on</b><sup>®cordfree</sup>.</p> <p><sup>b</sup> Over the frequency range 150 kHz to 80 MHz so field strengths should be less than 3 V/m.</p>			



Recommended separation distances between portable and mobile RF communications equipment and the **spot-on**<sup>®cordfree</sup>

The **spot-on**<sup>®cordfree</sup> is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **spot-on**<sup>®cordfree</sup> can help prevent the electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **spot-on**<sup>®cordfree</sup> – 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**<sup>@cordfree</sup> (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.**

