

FOCUSTM

FOCUSTM Light Systems
Instructions For Use

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FOCUS™ XTEND
Control Unit



FOCUS™ 5000 K
FOCUS™ 6500 K



FOCUS™ Nano 6500 K

FOCUS™ XTEND CONTROL UNIT

FOCUS™ XTEND is a portable control unit equipped with a rechargeable lithium-ion battery pack. It can be used with lamp units LED 5000 K, LED 6500 K and LED Nano 6500 K.

OPERATION

The FOCUS™ XTEND control unit is designed for hands-free operation and is operated by pressing the front panel with the hand or the elbow - this will help maintain a hygienic environment. A short press will activate the unit, and further clicks will cycle the unit through low, medium and high settings. A long press switches the unit off.

The control unit will not activate unless there is a lamp unit plugged in. FOCUS™ XTEND is compatible with all FOCUS™ LED lights.

RECHARGING

Connect the supplied charger to the mains and to the control unit using the DC socket on the side of the control unit.



Only use the supplied charger, as any other charger may damage the electronics in the control unit.

Charging takes about 2.5 hours. When the unit is fully charged, the charge indicator will turn off. The lowest setting gives up to 24 hours continuous use and the highest approximately 6 hours. When the battery is reaching the end of its natural life, after about 500 charges, it will need to be charged more frequently. When this starts to limit your working time, it is time to have the lithium-ion battery in the control unit replaced by RØNVIG Dental.

MAINTENANCE

Clean with a soft cloth, and ensure all jacks and connections are free of dust and dirt. Your light and control unit are not designed to be immersed in water. Clean off any splashes immediately to avoid damaging your unit.

MANUFACTURER WARRANTY

The FOCUS™ Light system (control unit including battery and lamp unit) is covered by a 3 year manufacturer warranty on materials and construction. The cable is covered by a 1 year warranty. Normal wear and tear and damages due to inadequate use or maintenance are not covered by the warranty. In the event of malfunction, please return the device to RØNVIG Dental for repair.

TECHNICAL SPECIFICATIONS

Light intensity	Variable
Approx. operating time	6-24 hours depending on chosen light intensity
Heat development	40 to 60°C depending on setting and time in use
Weight, control unit	156 gram
Battery pack	Lithium-ion, 2-cell 7,2V 1.2 AH
Charging time	Approx. 2.5 hours
Power supply	12-13 V DC, 1A Medico

SPECIFICATIONS

Charge: 12-13V DC/1A, medical
Temperature range:
Operating: 10 – 35°C
Storage: -20 – 60°C
Humidity: 10 – 95 %
Classifications: COUNCIL DIRECTIVE 93/42/EEC Class 1
Standards: EN60601-1
Disposal: Separate collection for electronic equipment

FOCUS™ LED LAMP UNITS

FOCUS™ lamp units are intended to be used with the FOCUS™ XTEND control unit.

REF 54521: FOCUS™ NANO 6500 K

REF 54535: FOCUS™ 5000 K

REF 54537: FOCUS™ 6500 K

MAINTENANCE

All parts can be wiped over with a cloth with alcohol-free disinfection products. Your LED light is not designed to be immersed in water. Clean off any splashes immediately to avoid damaging your light. Take care not to damage the lens.

Do NOT use alcohol-based products, ultrasonic cleaners, autoclave or chemical sterilization.

MANUFACTURER WARRANTY

The FOCUS™ Light system (control unit including battery and lamp unit) is covered by a 3 year manufacturer warranty on materials and construction. The cable is covered by a 1 year warranty. Normal wear and tear and damages due to inadequate use or maintenance are not covered by the warranty. In the event of malfunction, please return the device to RØNVIG Dental for repair.

SPARE PART – DETACHABLE CABLE

Replacement cables can be ordered from your RØNVIG Dental dealer.



GENERAL WARNINGS



The lamp housing itself may become warm. Avoid touching the lamp housing during extended use at high light intensity.

Do not use the FOCUS™ LED if the device is cold or moist.

The FOCUS™ LED produces a very powerful light. Do not look directly into the cone of light, and do not point it into the eyes of other people.

Use only the supplied battery charger. Use of any other battery charger may result in damage to the device.

The FOCUS™ LED is constructed from delicate components. To obtain an optimal lifetime, always handle the device, including the lamp housing and its lead, with care.

Do not attempt to repair the device yourself. Should the device become damaged or not work properly, return the headlamp to RØNVIG Dental for repair.

FOCUS™ 5000 K **FOCUS™ 6500 K**

TECHNICAL SPECIFICATIONS	
Lamp weight	17 g
Control unit	XTEND
Working time	6-24 hours
Charging time	2.5 hours
Settings	Low, medium, high
LED diode	<p>FOCUS 6500 K Bright, neutral white (≤6.500 Kelvin)</p> <p>FOCUS 5000 K True colour, low-blue (≤5.000 Kelvin)</p>
Light intensity at 35 cm	<p>FOCUS 5000 K Max 15,800 lux</p> <p>FOCUS 6500 K Max 18,600 lux</p>
Light spot at 35 cm	70 mm
Connect system	Yes
Heat development	40 to 60°C Depending on setting and time in use

FOCUS™ NANO 6500 K

TECHNICAL SPECIFICATIONS	
Lamp weight	9 g
Control unit	XTEND
Working time	Up to 12 hours
Charging time	2.5 hours
Settings	Variable
LED diode	Neutral white (≤6.500 Kelvin)
Light intensity at 35 cm	Max 27,400 lux
Light spot at 35 cm	80 mm
Connect system	Available
Heat development	40 to 60°C depending on setting and time in use

Table 1: Electromagnetic emissions

The FOCUS™ XTEND LED is intended for use in the electromagnetic environment specified below. The customer or the user of the FOCUS™ XTEND LED should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CISPR11	Group 1	The device 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 CISPR11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2: Electromagnetic immunity

The FOCUS™ XTEND LED is intended for use in the electromagnetic environment specified below. The customer or the user of the FOCUS™ XTEND LED should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC61000-4-2	±6KV contact ±8KV air	±6KV contact ±8KV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 40%
Electrical fast transient/burst IEC61000-4-4	±2KV for power supply lines ±1KV for input/output lines	±2KV for power supply lines ±1KV for input/output lines	Mains power supply quality should be that of typical residential area.
Surge IEC61000-4-5	±1KV differential mode ±2KV common mode.	±1KV differential mode ±2KV common mode	Power frequency magnetic fields should be that of typical residential area.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC61000-4-11	5% UT for 0.5 cycle 40%UT for 5 cycles 70%UT for 25 cycles <5%UT for 5 seconds	5% UT for 0.5 cycle 40%UT for 5 cycles 70%UT for 25 cycles <5%UT for 5 seconds	Mains power supply quality should be that of typical residential area.
Power frequency (50- 60Hz) magnetic field. IEC61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be that of typical residential area.

Table 3: Electromagnetic immunity

The FOCUS™ XTEND LED is intended for use in the electromagnetic environment specified below. The customer or the user of the FOCUS™ XTEND LED should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic environment guidance
Conducted RF IEC61000-4-6	3Vrms 150KHz to 80 MHz	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1,17\sqrt{P}$ $d=1,17\sqrt{P}$ 80 MHz to Hz to 800 MHz
Radiated RF IEC61000-4-3	3V/can 80MHz to 2,5GHz	3V/m	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 range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1

At 80 MHz and 800 MHz, 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 assess 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

b)

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

Table 4:
Recommended separation distances between portable and mobile RF communications equipment and the FOCUS™ XTEND LED

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment

Rated maximum output Rated maximum output	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = 1,17\sqrt{P}$	$d = 1,17\sqrt{P}$	$d = 3,5\sqrt{P}$
0,01	0,12	0,12	0,35
0,1	0,37	0,37	1,11
1	1,2	1,2	3,5
10	3,7	3,7	11,1
100	12	12	35

For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (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 to 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.

EXPLANATION OF SYMBOLS USED IN THE FOCUS™ XTEND LABELLING

	CE mark.
	Interference may occur in the vicinity of equipment marked with this symbol.
	To be disposed of as electronic waste according to WEEE Directive 2012/19/EU.
	Serial number.
	Manufacturing company.
	Medical Device.



RØNVIG DENTAL Mfg.

Gl. Vejlevej 59 · DK-8721 Daugaard · Denmark

Tel.: +45 70 23 34 11 · E-mail: contact@ronvig.com · www.ronvig.com



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