BORA 2 LED
BORA 2 LK

ENG INSTRUCTIONS FOR USE.

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CE 0123 Rx Only

REF 2100408-0001/2021.07

MEDICAL DEVICE (REF)

TU Bora 2 LED
1601152-001

TU Bora 2 LK
1601153-001

OPTIONAL ACCESSORIES (REF)

Unifix coupling
1600363-001

Lubrimed
1600037-006

1000003-001

1600243-001

1600036-006

1600064-006

Table of contents

1 Symbols

1.1 Description of symbols used

Sym	Description	Sym	Description
	Manufacturer.		Catalogue number.
	CE Marking with number of the notified body.		Serial number.
	Data Matrix code for product information including UDI (Unique Device Identification).		Medical Device.
	General symbol for recovery/recyclable.		Recyclable electrical and electronic material.
	CAUTION: hazard that could result in light or moderate injury or damage to the device if the safety instructions are not correctly followed.		WARNING: hazard that could result in serious injury or damage to the device if the safety instructions are not correctly followed.
	Operator's manual; operating instructions.	Rx Only	Caution: in accordance with federal law (USA), this device is only available for sale upon recommendation by an accredited practitioner.
EC REP	Authorized EC Representative in the European Community.		Wear rubber gloves.
	Thermo washer disinfectable.	135°C	Sterilizable in a steam sterilizer (autoclave) up to the specified temperature.
	Lamp; lighting, illumination.		

2 Identification & Intended Use

2.1 Identification

Medical device manufactured by Bien-Air Dental SA.

Type

Turbine type high-speed handpiece. Unit supplied by a hose, via a special ISO 9168 coupling. Anti-heat push-button bur changing mechanism. Ceramic ball bearings, 4 sprays. Optical glass rod, with light.

2.2 Classification

Class IIa according to European Directive 93/42/EEC relating to medical devices. Those medical devices comply with the legislation in force.

2.3 Intended use

Product intended for professional use only. It is intended for use in general dentistry. The device is not intended for use in implantology or oral surgery.

2.4 Intended patient population and medical conditions

The intended patient population includes any person visiting a dental practitioners' office to receive treatment in line with the intended medical condition. There is no restriction concerning subject age, race, or culture. The intended user is responsible to select the adequate device for the patient according to the specific clinical application.

2.5 Intended user

Devices shall be used only by dentists and dental professionals in a dental office.

2.6 Intended medical condition

General dentistry which includes restorative dentistry, dental prophylaxis, orthodontics and addresses the maintenance or reestablishment of dental health.

2.7 Patient contra-indications

No specific patient contra-indications exist for the turbine device family when the device is used as intended.

2.8 In case of accidents

The turbine must not be used until repairs have been completed by a qualified and trained technician authorized by the manufacturer. If any serious incident occurs in relation to the device, report it to a competent authority of your country, as well as the manufacturer through your regional distributor. Observe relevant national regulations for detailed procedures.

3 Warnings and precautions for use

3.1 General information

The device must be used by qualified dental professionals in compliance with the current legal provisions concerning occupational safety, health and accident prevention measures, and these instructions for use. In accordance with such requirements, the operators:

- must only use devices that are in perfect working order; in the event of irregular functioning, coolant failure, excessive vibration, abnormal heating, unusual noise or other signs that may indicate malfunction of the device, the work must be stopped immediately; in this case, contact a repair center that is approved by Bien-Air Dental SA and have the service personnel carry out repair work.
- must ensure that the device is used only for the purpose for which it is intended, must protect themselves, their patients and third parties from any danger.

3.2 Warnings

⚠ WARNING

Any use other than that for which this device is intended is prohibited and may prove dangerous.

⚠ WARNING

Medical personnel using or performing maintenance on medical devices that are contaminated or potentially contaminated must comply with universal precautions, in particular the wearing of personal protective equipment (gloves, goggles, etc.). Pointed and sharp instruments should be handled with great care.

⚠ WARNING

The device must not be used if any open lesions or damaged soft tissue are present or if a recent extraction has taken place. The air current could propel infected material into the wounds, causing an infection and a risk of embolism.

⚠ WARNING

Any modification of the medical device is strictly forbidden.

⚠ CAUTION

Install the device on an appropriate outlet to protect against the risk of injury or infection.

⚠ CAUTION

It is essential to use dry, purified compressed air in order to ensure the long working life of the device. Maintain the quality of the air and the water by regular maintenance of the compressor and the filtration systems.

Note : *Using unfiltered hard water will speed up blockage of the hoses, couplings and spray diffusers.*

Note : *The illustrations contained in these instructions are given merely as an indication. They may not give rise to any claim. For any further information, please contact Bien-Air Dental SA at the address given on the back cover.*

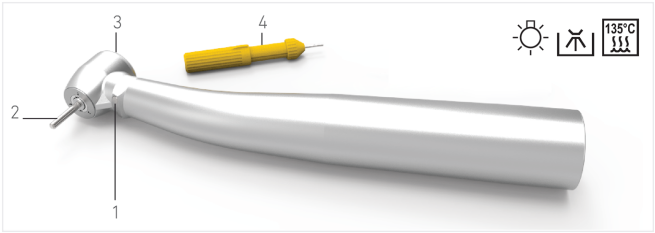

FIG. 1

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4 Description

4.1 Overview

FIG. 1

(1) Light output

(2) Bur (not supplied)

(3) Push-button

(4) Lubrimed greaser

Electric power supply

The power supply systems must be in compliance with IEC 60601-1 and IEC 60601-1-2 standards. Declaration by the manufacturer regarding electromagnetic compatibility: refer to the tables section 10 EMC.

TU Bora 2 LED

Classification of medical equipment according to IEC 60601-1: Type B applied parts

4.2 Technical data

Technical data	TU Bora 2 LED	TU Bora 2 LK
Connection	Unifix 4-way coupling	coupling LK 4HL coupling Multiflex®*
Head height (with a 19 mm bur)	21 mm	
Head diameter	12 mm	
Air consumption (drive)	45 - 55 Nl/min (at 300 kPa)	45 - 55 Nl/min (at 300 kPa)
Spray outlet	4 mixed	
Spray pressure	min 1 bar (water) 2-4 bar (air)	
Spray water flow	110 ml/min**	
Spray air flow	5-6 Nl/min**	
Drive air pressure	250-300 kPa	250-320 kPa
Lighting	Integrated LED and optical multifiber	Optical multifiber
Electric supply	3.1-3.7 VDC/VAC	N/A

MULTIflex® is a registered trademark of KaVo Dental GmbH.
***With water (air) pressure set to 2 bar, and without air (water) supply pressure, respectively.*

Compatible shanks:	
Type (ISO 1797)	Type 3 (Ø 1.59-1.6 mm)
Min. fitting length	11 mm
Bur max. length	21 mm
Bur max working diameter	2 mm

⚠ CAUTION
The minimum spray water consumption admitted is 1 bar.

4.3 Performances

Performances	TU Bora 2 LED	TU Bora 2 LK
speed of rotation (no load)	375-390 krpm	
Maximum torque	1.7 mNm	

4.4 Bur chuck

FIG. 2
Tip diameter 1.60 mm, type 3 as per ISO 1797- 1; max length for short to long types 21 mm, code 4 to 5 as per ISO 6360-1 (max. working diam. 2 mm).

⚠ WARNING
Follow the guidelines for use, according to the bur manufacturer's instructions. Never use a bur if the shaft is not compliant, as there is a risk it can become detached during the procedure and injure the practitioner, the patient or third parties.

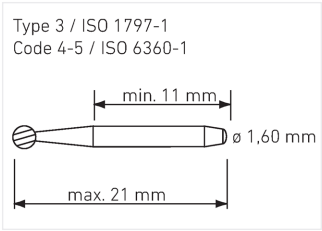

FIG. 2

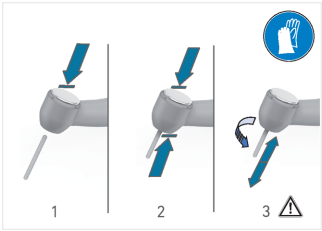

FIG. 3

5 Operation

Pictograms used

Pictograms used	
	Movement in the direction indicated.
	Movement to the stop in the direction indicated.
	After initial mechanical resistance, tighten fully in the direction indicated.
	Back and forth movement.
	4-way fitting.
	Electric powered 4-way fitting (4VLM).

5.1 Changing the bur

FIG. 3

Push-button bur locking.

1. Press the push-button and simultaneously pull out the bur.
2. Press the push-button, insert the new bur until it is locked in place and release the push-button.
3. Check that the bur rotates freely and that it is locked by gently pushing and pulling the bur.

⚠ WARNING

Never partially insert a bur to increase its active length.

⚠ WARNING

Do not operate the device until a tool has been inserted in the chuck. To prevent the push-button from overheating, which could lead to burns, it must not be activated when the instrument is rotating. Soft tissue (tongue, cheek, lips, etc.) must be protected by moving it away using a retractor or dental mirror.

⚠ CAUTION

Always ensure that the spray outlets are not obstructed.

⚠ CAUTION

If the bur cannot be easily and fully inserted into the chuck, contact your usual supplier or Bien-Air Dental SA for repair.

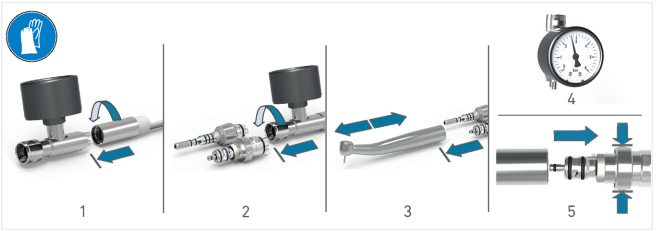

FIG. 4

5.2 Installing the turbine

The TU Bora 2 LED is connected to a Unifix rotating quick-connect coupling (4-way) and the TU Bora 2 LK to a coupling LK 4HL.

1. Connect the pressure gauge to the hose and screw it in fully.
2. Connect the coupling (Unifix or LK 4HL) to the pressure gauge and screw it in fully.
3. Insert the turbine onto the coupling. Check that the turbine is correctly connected by moving it back and forth.
4. Adjust the required air pressure using the Bien-Air Dental SA pressure gauge (between 2.5 and 3 bar for TU Bora 2 LED, between 2.5 and 3.2 bar for TU Bora 2 LK).
5. Adjust the water and air spray pressure (section 4.2) and operate without load the turbine for at least 5 seconds to check that it performs properly.
6. To disconnect the BORA 2 LED from the Unifix coupling, press the 2 side lockers (FIG. 4 step 5) and simultaneously remove the turbine from the coupling.

6 Operating conditions

TU Bora 2 LED

Operating conditions	
Temperature range:	+10°C / +35°C
Relative humidity range:	30% - 80%
Air pressure range:	700 hPa - 1060 hPa

TU Bora 2 LK

There are no particular operating conditions required.

7 Cleaning and servicing

7.1 Maintenance - General information

⚠ **WARNING**

The instrument is supplied "non sterile". Clean, lubricate and sterilize the device prior to first use.

7.1.1 Precautions for maintenance

- Within a maximum of 30 minutes after each treatment, clean, disinfect and lubricate the instrument. Observing this procedure eliminates any blood, saliva or saline solution residues and prevents the transmission system from being blocked.
- Only use original Bien-Air Dental SA maintenance products and parts or those recommended by Bien-Air Dental SA. For suitable maintenance products refer to section 7.1.2 Suitable maintenance products. Using other products or parts may cause faults during operation and/or void the warranty.

⚠ **CAUTION**

- Carry out cleaning- disinfection-sterilization processes without a bur in the chuck mechanism.
- Use detergents that are pH 8-11, are neither corrosive nor contain chlorine, acetone and/or aldehydes.
- Do not submerge in physiological liquid (NaCl) nor use saline solution to keep the device moist until it can be cleaned.
- Clean using manual cleaning or automated washer/disinfector only (do not use an ultrasonic cleaner)
- As with all instruments, following each sterilization cycle, including drying, remove the device to avoid excess exposure to heat which can result in corrosion.
- Use only dynamic sterilizers: do not use a steam sterilizer with a gravity displacement system.

7.1.2 Suitable maintenance products

Preliminary cleaning

- Use tap water if the local tap water has pH within the range 6.5 - 8.5 and chloride content below 100 mg/l. If the local tap water does not meet these requirements, use demineralized (deionized) water instead.

Manual cleaning:

- Spraynet.

Manual disinfection:

- Alkaline detergent or detergent-disinfectant (pH 8- 11) recommended for cleaning-disinfection of dental or surgical instruments. Disinfectant products composed either of didecyldimethylammonium chloride, quaternary ammonium carbonate or neutral enzymatic product. (e.g. Neodisher® mediclean) are also allowable.

Automatic cleaning-disinfection:

- Use an alkaline product recommended for cleaning in a washer-disinfector for dental or surgical instruments (pH 8-11).

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7.2 Cleaning

Preparation

1. Disconnect the device from the coupling.
2. Remove the bur (FIG. 3 step 1).

Remove dirt / deposits

1. Clean the exterior and interior of the device under tap water at 15°C-38°C (59°F-100°F) provided that the local tap water has a pH within the range of 6.5 - 8.5 and a chloride content below 100 mg/l. If the local tap water does not meet these requirements, use demineralized (deionized) water instead

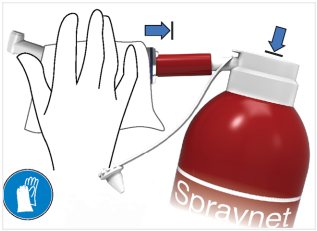

FIG. 5

7.3 Disinfection

7.3.1 Manual cleaning/disinfection

1. Dip the device in a bath containing a disinfectant product (e.g. didecyldimethylammonium chloride, quaternary ammonium carbonate or neutral enzymatic product which are allowable chemical agents). Follow the concentration and duration recommended by the fabricant of the disinfection product.
2. Brush the device with a smooth, flexible brush (e.g. soft- bristled toothbrush). DO NOT USE a wire brush.
3. **Optional:** perform additional cleaning and disinfection of the external surfaces with non- woven wipes impregnated with a disinfection product (e.g. didecyldimethylammonium chloride).
4. Rinse the device twice with running tap water (15°C-38°C) (59°F-100°F) provided that the local tap water has a pH within the range of 6.5 - 8.5 and a chloride content below 100 mg/l. If the local tap water does not meet these requirements, use demineralized (deionized) water instead.
5. After selecting the appropriate nozzle, spray inside the device with Spraynet (**FIG. 5**).
6. Dry the external surfaces with sterile non-woven compresses (low linting textiles).

7.3.2 Automatic disinfection (optional)

Note : *The automatic cleaning- disinfection can replace the previous steps 4 to 6 but is not necessary for obtaining a proper cleaning and disinfection of the device, if steps 1-3 are properly and timely realized.*

Washer-disinfector

Carry out automatic cleaning- disinfection using an approved washer-disinfector which complies with ISO standard 15883-1.

Detergent and washing cycle

Use an alkaline or enzymatic detergent recommended for cleaning in a washer-disinfector for dental or surgical instruments (pH 8-11).

Recommended specifications for the thermo-disinfection cycle.

Phase	Parameters
Pre-cleaning	<45°C (113°F); ≥ 2 minutes
Cleaning	55°C-65°C (131°F-149°F); ≥ 5 minutes
Neutralization	≥ 2 minutes
Rinsing	Tap water, ≤30°C (86°F), ≥ 2 minutes cold water
Thermal Disinfection	90°C-95°C (194°F-203°F), 5-10 minutes
Drying	18-22 minutes

⚠ **CAUTION**

Never cool devices by rinsing them.

⚠ **CAUTION**

If an automatic washer is used at the place of the washer/thermo-disinfector, respect the previous program for the Pre-cleaning, Cleaning, Neutralization and Rinsing phases. If the local tap water has a pH outside the range of 6.5-8.5 or if it contains more than 100 mg/l chloride (Cl-ion), do not dry the device inside the automatic washer but dry it manually with low linting textiles.

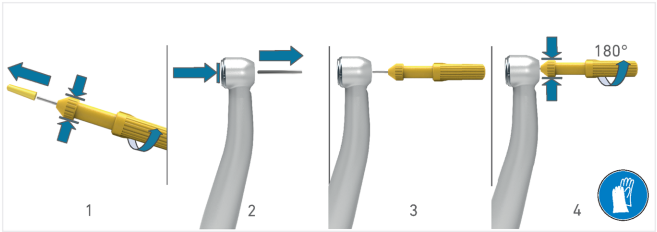

FIG. 6

7.4 Lubrication

7.4.1 Verifying cleanliness

Before lubrification,visually inspect the device to ensure it is clean. Repeat the cleaning and disinfection procedure if necessary.

Before each sterilisation lubricate with Lubrimed medical grease, or with Lubrifluid lubricant. If the local directives impose sterilization never lubricate after the sterilization.

7.4.2 Lubrication with Lubrimed

FIG. 6

1. Remove the cap from the yellow greaser and screw the knurled rear section whilst holding the front of the greaser until grease appears in the middle of the lubrication tip.
2. Insert the tip of the greaser as far as it goes.
3. Screw the knurled rear section whilst holding the front of the greaser to inject the grease (the required amount corresponds to a ½ turn of the knurled rear section; use the markers).
4. Put the cap back on after use.

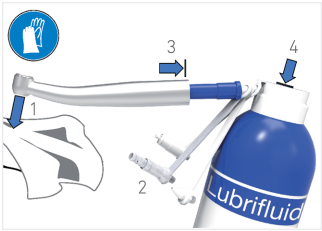

FIG. 7

FIG. 8

7.4.3 Lubrication with Lubrifluid

FIG. 7

1. Place the device in a sterile, non-woven cloth to collect the excess of lubricant.
2. Select the appropriate nozzle.
3. Insert the nozzle of the Lubrifluid can in the rear of the device's handle and activate the spray for 1 second.
4. Clean the excess oil on the exterior with a sterile, non-woven compress.

7.5 Sterilization

⚠ WARNING

The quality of the sterilization is highly dependent on how clean the instrument is. Only perfectly clean instruments may be sterilized. To improve the effectiveness of the sterilization, make sure the device is completely dry before and after the sterilization.

⚠ CAUTION

LK 4HL and Unifix couplings cannot be sterilized.

⚠ CAUTION

Do not use a sterilization procedure other than the one described below.

7.5.1 Procedure

1. Pack the device in a packaging approved for steam sterilization.
2. Sterilize using steam, following dynamic air removal cycle (ANSI/AAMI ST79, Section 2.19), i.e. air removal via forced evacuation (ISO 17665-1, ISO/TS 17665-2) at 135°C (275°F), for 3 minutes. In jurisdictions where sterilization for prions is required, sterilize at 135°C (275°F) for 18 minutes.

The recommended parameters for the sterilization cycle are:

- The maximum temperature in the autoclave chamber does not exceed 137°C (278.6°F), i.e. the nominal temperature of the autoclave is set at 134°C (273.2°F), 135°C (275°F) or 135.5°C (275°F) taking into account the uncertainty of the sterilizer with regard to temperature.
- The maximum duration of the interval at the maximum temperature of 137°C (278.6 °F) is in accordance with national requirements for moist heat sterilization and does not exceed 30 minutes.
- The absolute pressure in the chamber of the sterilizer is comprised in the interval 0.07 bar to 3.17 bar (1 psia to 46 psia).
- The rate of change of temperature does not exceed 15°C/min (59°F/min) for increasing temperature and -35°C/min (- 31°F/min) for decreasing temperature.
- The rate of change of pressure does not exceed 0.45 bar/min (6.6 psia/min) for increasing pressure and -1.7 bar/min (-25 psia/min) for decreasing pressure.
- No chemical or physical reagents are added to the water steam.

⚠ **CAUTION**

Only use dynamic air removal cycles: pre-vacuum or steam flush pressure pulse (SFPP) cycles.

After cleaning, disinfecting and sterilizing the device, and before using it, start it up at moderate speed with a bur in the locking mechanism for 10 to 15 seconds to distribute and remove the excess lubricant.

7.6 Packing and storage

The device must be stored inside the sterilization pouch in a dry and dust-free environment. The temperature must not exceed 55°C (131°F). If the device will not be used for 7 days or more after the sterilization, extract the device from the sterilization pouch and store it in the original package. If the device is not stored in a sterilization pouch or if the pouch is no longer sterile, clean, lubricate and sterilize the device before using it.

TU Bora 2 LED

Storage conditions	
Temperature limitation:	0°C / +40°C
Relative humidity limitation:	10% - 80%
Air pressure limitation:	650 hPa - 1060 hPa

TU Bora 2 LK

There are no particular storage conditions required.

⚠ **CAUTION**

If the medical device has been stored refrigerated, allow it to warm up to room temperature prior to use.

⚠ **CAUTION**

Comply with the expiration date of the sterilization pouch which depends on the storage conditions and the type of packaging.

7.7 Servicing

Bien-Air Dental SA recommends a regular service for the turbine after 4,000 processing cycles or five years.

8 Transport & disposal

8.1 Transport

TU Bora 2 LED

Transport conditions	
Temperature limitation:	-20°C / +50°C
Relative humidity limitation:	5% - 80%
Air pressure limitation:	650 hPa - 1060 hPa

TU Bora 2 LK

There are no particular transport conditions required.

8.2 Disposal

The disposal and/or recycling of materials must be performed in accordance with the legislation in force.

The device must be recycled. Electrical and electronic equipment may contain dangerous substances which constitute health and environmental hazards. In order to avoid any risk of contamination, the user must return the device sterilized to their distributors or directly contact an approved body responsible for processing and recovering this type of equipment (European directive 2012/19/EU).

9 General information

9.1 Terms of guarantee

Bien-Air Dental SA grants the user a warranty covering any operating fault, or material or manufacturing defect.

The warranty period for this medical device is 24 months from the date of invoicing.

In the event of a justified claim, Bien-Air Dental SA or its authorised representative will repair or replace the product free of charge.

All other claims of any kind whatsoever, particularly claims for damages, are excluded.

Bien-Air Dental SA cannot be held liable for damage or injury and the consequences thereof, resulting from:

- Excessive wear and tear
- Infrequent or improper use
- Failure to observe the servicing, assembly or maintenance instructions
- Damage caused by unusual chemical, electrical or electrolytic influences
- Faulty air, water or electrical connections

⚠ CAUTION

The warranty becomes null and void if damage and its consequences result from incorrect servicing or modification by third parties not authorised by Bien-Air Dental SA.
Warranty requests will only be taken into consideration if the product is accompanied by a copy of the invoice or delivery note. The following information must be clearly indicated: purchase date, product reference and serial number.

9.2 References

9.2.1 Medical devices (see cover)

REF	Legend
1601152-001	TU Bora 2 LED
1601153-001	TU Bora 2 LK

9.2.2 Optional accessories (see cover)

REF	Legend
1600363-001	Unifix coupling
1600866-001	Coupling LK 4HL Water ADJ
1600902-001	Coupling LK 4HL
1600037-006	Lubrimed medical grease, box of 6 cartridges
1000003-001	Lubrimed greasers
1600243-001	Pressure gauge 4H
1600036-006	Spraynet 500 ml cleaning spray, box of 6
1600064-006	Lubrifluid 500 ml spray lubricant oil, box of 6

10 EMC

Electromagnetic Compatibility (technical description) of turbines connectable to Unifix 4-way coupling*.

The intended EM environment (per IEC 60601-1-2 ed. 4.0) is *Professional healthcare facility environment.*

⚠ CAUTION

The turbine complies with the EMC requirements according to IEC 60601-1-2. Radio transmitting equipment, cellular phones, etc., should not be used in the immediate vicinity of the device, since this could affect its operation. The device is not suitable for being used close to high-frequency surgical equipment, magnetic resonance imaging (MRI) and other similar devices where the intensity of electromagnetic disturbances is high. In any case, ensure that no high frequency cables are routed above or near the device. If in doubt, contact a qualified technician or Bien-Air Dental SA.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the turbine, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ CAUTION

The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by Bien-Air Dental SA as spare parts for internal components, may result in increased emissions or decreased immunity.

⚠ CAUTION

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

The turbine is intended for use in the electromagnetic environment specified below. The customer or the user of the turbine must ensure that it is actually used in such an environment.

**Turbines connectable to coupling LK 4HL and Multiflex® do not contain electric circuitry.*

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR11	Group 1	The turbine uses RF energy for its internal operation only. 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 turbine is suitable for use in any building, including residential buildings and those directly connected to the public low-voltage power supply network that supplies buildings used for residential purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltagefluctuations/flicker emissions IEC 61000-3-3	N/A	

The turbine is intended for use in the electromagnetic environment specified below. The customer or the user of the Turbine must ensure that it is actually used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV air ±4 kV air ±8 kV air ±15 kV air	±8 kV contact ±2 kV air ±4 kV air ±8 kV air ±15 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 other lnes	N/A N/A	Mains power quality should be that of a commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV line to line ±1 kV line to line ±0.5 kV line to earth ±1 kV line to earth ±2 kV line to earth	N/A N/A N/A N/A N/A	Mains power quality should be that of a commercial or hospital environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T for 0.5 cycle, at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T for 1 cycle and 70 % U_T for 25/30 cycles at 0°	N/A N/A	Mains power quality should be that of a commercial or hospital environment. If the user of the turbine requires continued operation during mains power interruptions, it is recommended that the turbine be powered from an uninterruptible power supply or a battery.
Magnetic field due to mains frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields generated by the mains frequency should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted disturbances induced by RF fields IEC 61000-4-6	3 VRMS 0,15 MHz – 80 MHz 6 VRMS in ISM bands 0,15 MHz – 80 MHz 80 % AM at 1 kHz	3 VRMS 0,15 MHz – 80 MHz 6 VRMS in ISM and amateur bands 0,15 MHz – 80 MHz 80% AM at 1 kHz	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[1] should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF EM fields IEC 61000-4-3	3 V/m 80 MHz - 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz - 2,7 GHz 80 % AM at 1 kHz	

1. *Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and mobile field radios, amateur radios, AM and FM radio broadcasts and TV broadcasts 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 turbine is used exceeds the RF compliance level mentioned above, the turbine should be observed to verify that it is operating normally. If abnormal operation is observed, additional measures may be necessary, such as reorienting or relocating the turbine.*

Immunity test	Test freq. [MHz]	Max power [W]	Immunity test level [V/m]	Electromagnetic environment - guidance
Proximity fields from RF wireless communications equipment IEC 61000-4-3	385	1.8	27	Distance: 0.3 m
	450	2	28	
	710, 745, 780	0.2	9	
	810, 870, 930	2	28	
	1720, 1845, 1970	2	28	
	2450	2	28	
	5240, 5500, 5785	0.2	9	
Note : *U_T is the AC mains voltage prior to application of the test level.* *Essential performance per IEC 60601-1: The essential performance is to maintain the visual luminous intensity of the LED.*				

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 to the transmitter manufacturer.

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