

Wireless Specifications:

The Ocelot TDS 1000 uses Bluetooth Wireless Technology to communicate data to the tablet. The Tablet cannot send data to the Ocelot TDS 1000.

Bluetooth wireless characteristics:

During treatment, the Ocelot TDS 1000 communicates wirelessly via Bluetooth radios. Bluetooth uses a radio technology called frequency-hopping spread spectrum, which chops up the data being sent and transmits parts of it on up to 40 frequency bands of 2 MHz each in the range 2,402-2,483.5 GHz (allowing for guard bands). The Bluetooth module is BLE with a maximum transmit power of 3 dBm. The Bluetooth set up and configuration is fully automatic and does not require any user set up. If the patient goes out of range (typically greater than 100 feet / 30 meters) there will be a visual alert.

The RDU and tablet shall have a Bluetooth connection to the tablet, dictated by BLE 4.2 protocol.

The Bluetooth characteristics of the Ocelot TDS 1000 are as follows:	
FFC ID	WAP2001
Radio Technology	Bluetooth: Frequency-hopping spread spectrum
Bluetooth specification	RDU V 4.2 Tablet V4.2
Bluetooth Class / Power	Power range -18 dbm to +3 dbm
Rx Sensitivity	LE 2M PHY: ≤-70 dBm LE 1M PHY: ≤-70 dBm LE Coded PHY (S=2): ≤-75 dBm LE Coded PHY (S=8): ≤-82 dBm
RF frequencies	40 channels (2 MHz each; centered from 2.402 to 2.480 GHz) in the range 2,400-2,483.5 GHz
Communication Topologies	Point-to-Point (including piconet) Broadcast Mesh
Positioning Features	Presence (Advertising) Proximity (RSSI) Direction (AoA/AoD) Distance (Coming)
Data rate	LE 2M PHY: 2 Mb/s LE 1M PHY: 1 Mb/s LE Coded PHY (S=2): 500 Kb/s LE Coded PHY (S=8): 125 Kb/s
Distance	Up to 100 feet / 30 meters line of sight
Alert	LED on Ocelot TDS 1000
Pairing process	Connect via App
Security	Proprietary communication protocol between Tablet and Ocelot TDS 1000. Bluetooth Low Energy LE Legacy connections V4.0 & 4.1 - 2 phase TK/STK or V4.2 LE Secure Connections Just Works


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Ocelot TDS 1000 / Mobile Device Security:

- The Ocelot TDS 1000 communicates with the Tablet over Bluetooth® The Standard with Bluetooth® protocol prohibiting the Ocelot TDS 1000 from communicating to more than one Tablet at a time.

The Ocelot TDS 1000 only collects and transfers data while it is in operation during a procedure while paired with a Tablet. No Personal Health Information is stored.


Bluetooth Environment Warnings:

 **CAUTION:** Be sure to use in a location where visibility between the Ocelot TDS 1000 and connected Mobile Device is clear. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. If the distance between the device and mobile device are farther than 30 meters apart or are separated by an obstruction, they might not communicate, or the communication distance may be shorter. To assess the electromagnetic environment, an electromagnetic site survey should be considered.

 **CAUTION:** TendoNova Corporation cannot accept liability for any damages incurred due to impaired operation or data loss, etc. that occur through the improper use of this product.

Electromagnetic Interference

This device has been tested and found to comply with the limits for medical devices in ANSI/AAMI/IEC 60601-1-2:2014. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.








 **Caution:** The presence of radio frequency transmitting equipment, including mobile and portable equipment such as cell phones, and other sources of electrical noise may disrupt the performance of this device. The Ocelot TDS 1000 System can radiate radio frequency energy and, if not used in accordance with these instructions, may

cause harmful interference with other devices in the vicinity. Evidence of such interference may be in the form of erratic readings, incorrect functionality, or loss of operation. Should this occur, a site survey should be conducted to determine the source of disruption and action taken to eliminate the source.

The following recommended procedures may be used to correct the interference:

- Turn equipment in the area “off” and “on” to identify the offending equipment
- Increase the separation between this device and any interfering equipment
- Reorient or relocate the offending device
- If additional assistance is required, contact manufacturer

Electromagnetic Environment Warnings:

-  **CAUTION:** Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.
-  **CAUTION:** Portable and mobile RF communications equipment can affect Medical Electrical Equipment.
-  **CAUTION:** Device must not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.
-  **CAUTION:** The Device may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.
-  **CAUTION:** Use of accessories and cables other than those specified, with exception of parts sold by TendoNova Corporation as replacements for internal components, may result in increased emissions or decreased immunity of the device.
-  **CAUTION:** The Device incorporates an RF transmitter and RF receiver that operate within a frequency band of 2.400-2.483.5 GHz.
-  **WARNING:** No modification of this equipment is allowed.

Coexistence:

- Bluetooth® low-energy technology uses Frequency-Hopping Spread Spectrum (FHSS) technology to achieve a robust and reliable transmission in 'noisy' RF environments found in industrial and medical applications. FHSS also minimizes interference from Bluetooth® technology to other wireless ISM band radio technologies.
- Multiple Ocelot systems may be used simultaneously while adjacent to one another.

FCC Compliance:


- Intentional emitter
- US/ FCC part 15, Subpart C
- FCC ID: WAP2001
- Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- This device complies with Part 15 of the FCC rules. Operation is subject to the following conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interferences received, including interference that may cause undesired operation.


Electromagnetic Interferences

The Ocelot TDS 1000 has been designed to minimize the impact of electromagnetic interference from other electrical equipment and to minimize the interference caused to other electrical equipment. The Ocelot TDS 1000 has been tested and found to comply with the Medical Electrical Equipment - General Requirements for Safety-Collateral Standard: Electromagnetic Compatibility, IEC 60601-1-2 2014, and FCC Part 15. Due to the growth of equipment transmitting RF and other sources of electrical noise in the health-care

environment, it is possible that due to proximity or strength of the source of the interference, degradation to the performance of the Ocelot TDS 1000 may result.


Source and Response associated with Electro Magnetic Interferences:	
Source	Response
RF interference interrupting the Bluetooth transmission between the Ocelot TDS 1000 components	The Bluetooth communication interruptions will create gaps on Data display on the Ocelot Application


 **WARNING:** The Ocelot TDS 1000 may be interfered with Radiofrequency identification (RFID) systems. If an RFID system is operating near the Ocelot TDS 1000 and you experience poor data transmission, remove the RFID system, and check again the data quality. If the presence of the RFID correlates with the poor performance of the Ocelot TDS 1000, please report the issue to TendoNova customer service.


 **WARNING:** For Electromagnetic Compatibility, the Ocelot TDS 1000 has been tested to IEC 60601-1-2.

Electrostatic Discharge (ESD) precautions

ESD present on the Ocelot TDS 1000 could create artifacts. During the immunity testing below the device may experience momentary disruption that will recover within 30 seconds.

 **Warning:** precautionary measures should be taken to minimize the risk of damage to the Ocelot TDS 1000.

 **Warning:** The Ocelot TDS 1000 cannot be used or placed in a MR Environment. This could result in serious injuries and death of patients and other individuals.

 **Warning:** This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the

operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Ocelot TDS 1000 or shielding the location.

⚠ Warning: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

⚠ Warning: 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 Ocelot TDS 1000, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.”

⚠ Warning: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ Warning: 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.

Guidance and manufacturer’s declaration – electromagnetic emissions		
The Ocelot TDS 1000 is intended for use in the electromagnetic environment specified below. The customer or the user of the Ocelot TDS 1000 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Ocelot TDS 1000 uses RF energy to communicate data between the Transmitter and the Base Unit. Its RF emissions are low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	The Ocelot TDS 1000 is suitable for use in standard hospital, office, and clinical settings. Relevant

Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	<p>exclusions include areas near active HF SURGICAL EQUIPMENT, and the RF shielded room for magnetic resonance imaging, or where the intensity of EM DISTURBANCES is likely to be high such as near Electrosurgical devices, Electrocautery devices, Diathermy, X-ray, and Electromagnetic security systems (i.e., Metal detectors and Electronic Article Surveillance system (EAS or anti-theft).</p> <p>Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Ocelot TDS 1000 or shielding the location.</p>
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Guidance and manufacturer's declaration – electromagnetic immunity

The Ocelot TDS 1000 is intended for use in the electromagnetic environment specified below. The customer or the user of the Ocelot TDS 1000 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	± 8 kV contact ± 15 kV air	± 8 kV contact ± 2, 4, 8, 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	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode	± 0.5, 1 kV differential mode	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	<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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Ocelot TDS 1000 requires continued operation during power mains interruptions, it is recommended that the Ocelot TDS 1000 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 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 or U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

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>$3 V_{rms}$ $6 V_{rms}$ (ISM bands)</p> <p>$3 V/m$ 80 MHz to 2.5 GHz</p>	<p>$3 V_{rms}$ $6 V_{rms}$ (ISM bands)</p> <p>$3 V/m$ 80 MHz to 2.5 GHz</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Ocelot TDS 1000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance</p> <p> $d = 1.2 \sqrt{P}$ 150 kHz to 80 MHz $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 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 range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

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 Ocelot TDS 1000 is used exceeds the applicable RF compliance level above, the Ocelot TDS 1000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Ocelot TDS 1000.

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

Recommended separation distances between portable and mobile RF communications equipment and the Ocelot TDS 1000

The Ocelot TDS 1000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Ocelot TDS 1000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Ocelot TDS 1000 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	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 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.

Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 – 390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	2	0.3	28
870						
930						
1,720	1,700 – 1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217 Hz	2	0.3	28
1,845						
1,970						
2,450	2,400 – 2,570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0.3	28
5,240	5,100 – 5,800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9
5,500						
5,785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Ocelot TDS 1000 was tested as below for radiated immunity.

Immunity Test	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 6 V rms in ISM and amateur radio bands 3 V/m	Ocelot TDS 1000 is suitable for the electromagnetic environment of typical commercial or hospital settings.

Ocelot TDS 1000 was also tested for radiated immunity to RF wireless communication equipment at the test levels below.

Frequency (MHz)	Polarity	Pulse Modulation 50% DC	Test Level (V/m)
385	V/H	18Hz	27
450	V/H	18Hz	28
710	V/H	217Hz	9
745	V/H	217Hz	9
780	V/H	217Hz	9
810	V/H	18Hz	28
870	V/H	18Hz	28
930	V/H	18Hz	28
1720	V/H	217Hz	28
1845	V/H	217Hz	28
1970	V/H	217Hz	28
2450	V/H	217Hz	28
5240	V/H	217Hz	9
5500	V/H	217Hz	9
5785	V/H	217Hz	9