

tediselmedical

ANTEA

USER AND CLEANING MANUAL



CE 0197

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1. Manufacturer

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2. Security information

Important notes in these operating instructions are marked with graphic symbols and signal words.

2.1. Injury risk warnings

Signal words such as DANGER, WARNING or CAUTION describe the degree of risk of injury. The triangular symbols visually emphasise the degree of danger.



WARNING

Refers to a potentially hazardous situation which, if not avoided, could result in death or serious injury.



CAUTION

Refers to a potential hazard which, if not avoided, may result in minor or slight injury.



DANGER

Refers to an immediate danger which, if not avoided, will result in death or serious injury.



Risk of finger entrapment

2.1. Warnings of risk of damage

The signal word WARNING describes the degree of risk of material damage. The triangular symbols visually emphasise the degree of danger.



Damage to surfaces: warns of damage to surfaces due to unsuitable cleaning agents and disinfectants.



NOTICE

Refers to a potential hazard which, if not avoided, may cause damage to the equipment.

2.2. Supplementary symbols used in the safety instructions



Fire hazard



Explosion hazard: warns of ignition of explosive gas mixtures.



Dangerous voltage: warns about electric shocks that can cause serious injury or death.

2.3. Additional information



A NOTE provides additional information and useful tips for the safe and efficient use of the device.

2.4. Proper use of oxygen.

2.4.1. Oxygen explosion



Oxygen becomes explosive when it comes into contact with oils, greases and lubricants.

Compressed oxygen presents an explosion hazard:

- Ensure that oxygen and gas outlets are free of oil, greasy materials and lubricants!
- Do not use cleaning agents containing oil, grease or lubricants.

2.4.2. fire hazard



Escaping oxygen is fuel:

- Naked flame, red-hot objects and open lights are not allowed when working
- Do not smoke!

3. Risks

3.1. Gas explosion



Oxygen becomes explosive when it comes into contact with oils, greases and lubricants.

When in contact with oxygen in the air, medical gases may form an explosive or easily flammable gas mixture. The equipment is not suitable for use in environments containing flammable anaesthetic mixtures with high concentrations of oxygen or nitrous oxide.

If such high concentrations of flammable anaesthetic mixtures with oxygen or nitrous oxide occur in the vicinity of the device, there is a risk of ignition under certain conditions.

3.2. Risk of device malfunction



CAUTION: If one device is connected to the equipment and trips the protection mechanism of the corresponding circuit in the health care facility, other devices connected to the equipment will also lose power.

3.3. Fire hazard



Plug-in connections for the supply of medical gases must not come into contact with oil, grease or flammable liquids.

3.4. Danger of electric shock



Signal cables (network, audio, video, etc.) must be electrically isolated from equipment and the connection points of the building's wiring to prevent contact with currents that can cause serious injury or death.

3.5. Essential Performance and Basic Safety Considerations

To ensure the BASIC SAFETY and ESSENTIAL PERFORMANCE, the following conditions shall be met during intended use:

- the electrical outlets operate properly
- the light modules operate properly

However, due to external unexpected EM disturbances, the ESSENTIAL PERFORMANCE may be degraded, resulting in:

- Risk for the user/patient

- Cessation or interruptions to the power in the electrical outlets

3.6. EM Interference



WARNING: portable RF communications equipment, including antennas, can affect the systems. These types of devices should be used no closer than 30 cm (12 inches) to any part of the system, including cables.

4. Symbols used



Applicable part B



Earth (mass)



Equipotentiality



Protective earth (ground)



Connection point for neutral conductor



Nurse call button



Direct lighting



Indirect lighting



Operating instructions



Health Product



Waste electrical equipment



CE symbol



Product code



Unique identification code



Serial number



Manufacturer



Date of manufacture



Reference to the instruction manual



Damage to surfaces



Fire hazard



Danger of explosion



Hazardous voltage



NOTICE

Notice



Risk of finger entrapment



WARNING

Warning



CAUTION

Caution



DANGER

Danger

5. Product data

This manual refers to the Antea model. This model is part of the SICA family.

5.1. Storage conditions

The individual packaging of this type of product consists of a bubble wrap on the inside and a cardboard box on the outside. Non-stackable packaging.

Under no circumstances should the product be stored with open or damaged packaging. If the product is inspected on receipt and installation is not carried out within 1 day, the product packaging must be resealed.



NOTICE: Failure to follow these instructions may result in damage to the equipment.

Recommended temperature range: -20 °C to 60 °C

Recommended humidity range: 10 % to 75 %.

Atmospheric pressure: 500 hPa to 1,060 hPa

5.2. Operating conditions



NOTICE: Failure to follow these instructions may result in damage to the equipment.

Recommended temperature range: -10 °C to 40 °C

Recommended humidity range: 30 % to 75 %.

Atmospheric pressure: 700 hPa to 1,060 hPa

5.3. Service life

The useful life of the SICA family of products is determined by the useful life of the medical gas inlets it incorporates, which is 8 years.

5.4. Product description

These systems have three main differentiated functions within the hospital and according to the area for which they are intended:

- Medical gas services
- Electrical, voice and data services
- Nurse call

The ANTEA model consists of a chassis made from aluminium profiles that allows the integration of electrical equipment, lighting, call, voice and data systems, and the installation and channelling of medical gas outlets.

Cables and accessories may be provided by the facility.



WARNING: The use of external cables or accessories not provided by Tedisel may negatively affect EMC performance.

5.4.1. General characteristics

Chassis made from a tubular structure of aluminium profile and sheet metal with 2 cavities, the first one designed to house medical gas inlets and the other to house electrical and voice and data elements.

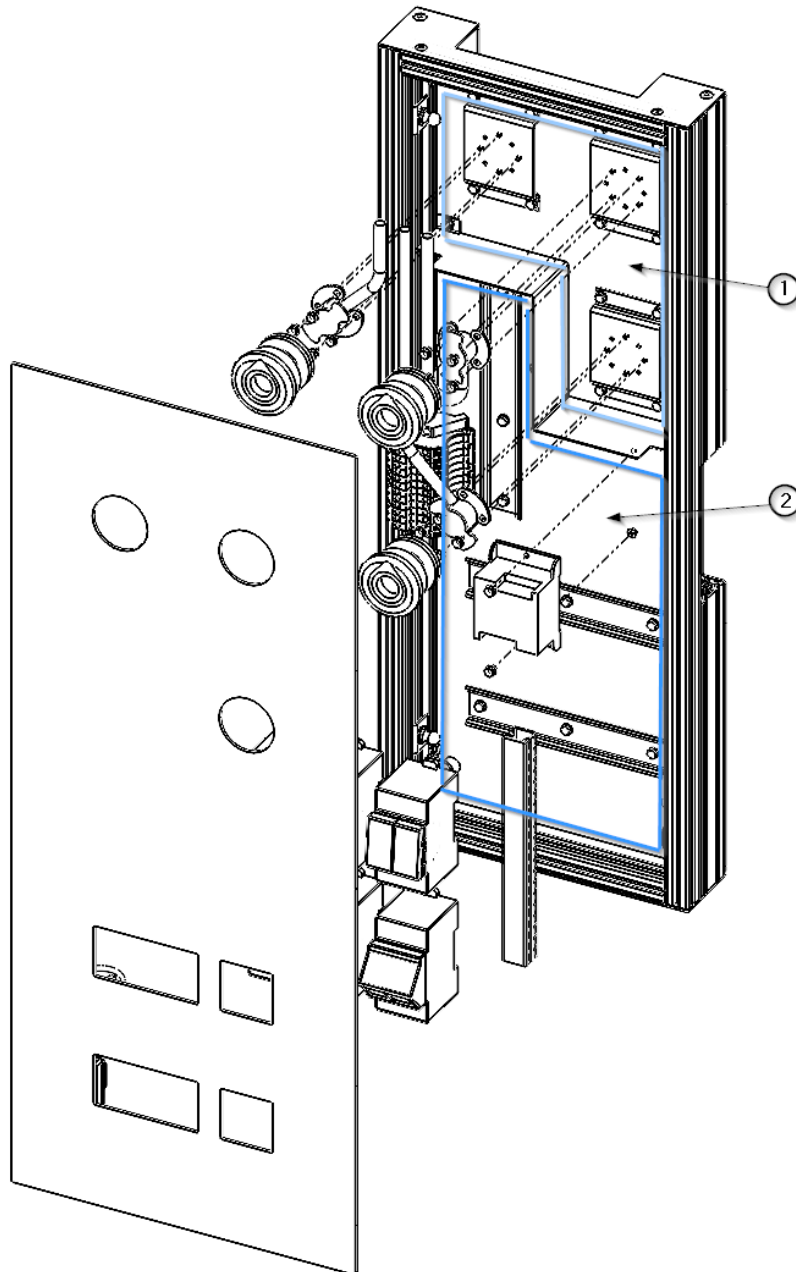
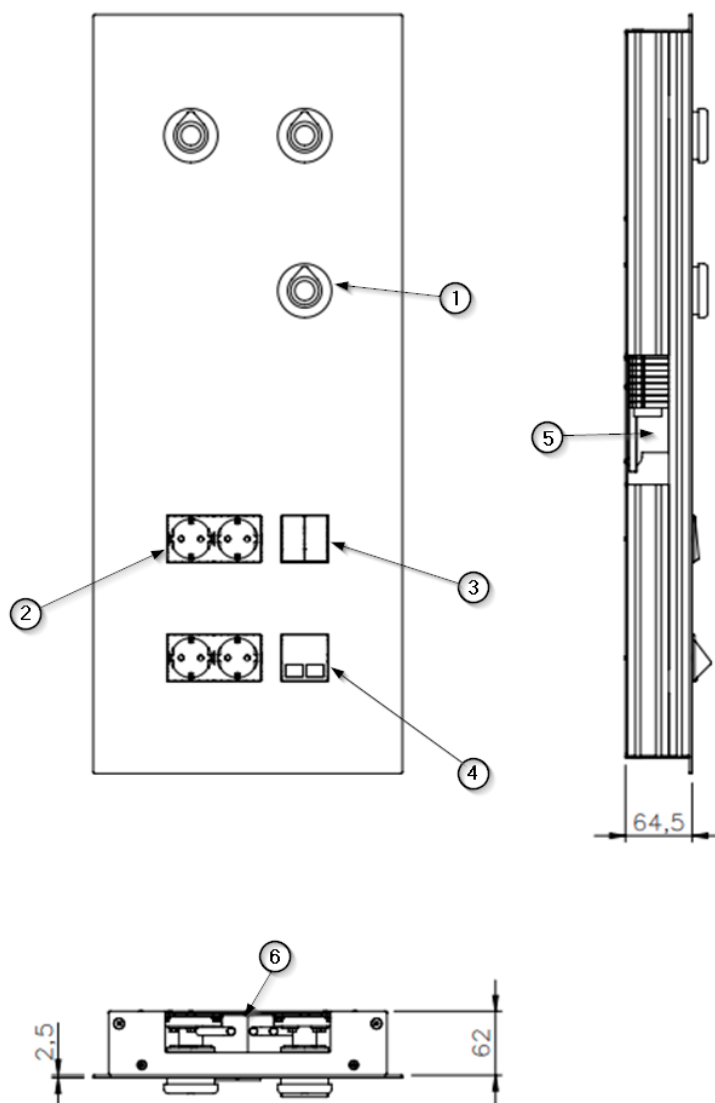


Fig. 1 Main chassis section of ANTEA

A typical ANTEA configuration with standard electrical and gas equipment is shown below:



*Medidas adaptables según proyecto

Fig. 2 Model configuration for ANTEA

1. Gas inlets
2. Electrical outlets for power supply of equipment
3. Double switch for lighting operation
4. 45° double RJ45 socket
5. Side entry for electrical connections to the installation and weak signals
6. upper entry for connection of gas pipes to the system

5.4.2. Other features and configurations

Below is a summary of the different features and configurations that the ANTEA model allows:

1. Assembly

The supply head can only be flush-mounted.

2. Chassis dimension and orientation

The dimensions of the chassis are variable according to each project. The maximum dimension of the equipment may vary according to the requirements of the project or the installation.

The chassis orientation can be horizontal (the most common) or vertical.

3. Treatment and finishing

Aluminium profiles can be supplied untreated and subsequently polished or anodised.

The finishes can be epoxy paint or anti-bacterial paint. The standard colour used is matt white, but any other colour is possible according to project specifications.

4. Vinyls and phenolics

Possibility of gluing vinyl on the front covers. Possibility of gluing phenolic panels from 0.5 to 1 mm thick. The designs or motifs of the vinyls and phenolic panels are subject to the specifications of each project. Possibility of digital printing on the front panels.

5. Controls

Lighting control and operation can be achieved via various control devices: switches, push buttons, nurse calls, potentiometers or dimmers, and selector switches.

Option to install pushbuttons or switches to control blinds.

Option to install emergency mushroom pushbuttons.

6. Electrical outlets

Option to install electrical sockets type A and B (Normal and Hospital Grade), type C, D, E, F, G, H, H, I, J, K, L, M, N, O, and multi standard sockets.

Possibility of colour variation of the electrical socket in accordance with the regulations of the region and the needs of the project.

7. Voice & data sockets and weak signals

Option to install RJ45 Cat. 5/6/6A/7/7A sockets, RJ12 sockets and RJ11 sockets.

Option to install hospital-compatible call systems, either from own supply, or provision and adaptation of modules supplied by third parties.

Option to install relays, remote switches and 24V control system for switching and manipulation of the lighting via the call system.

8. Protection mechanisms and earthing

Earthing and equipotential bonding busbars can be installed.

9. Video & audio & data sockets

HDMI, S-VIDEO, 3G BNC, 4K SDI, VGA and DisplayPort sockets can be installed.

Option to install USB 2.0/3.0/3.1 sockets. Option to install USB chargers for charging mobile devices and tablets.

10. Future provisions and/or extensions

Option to install blank covers to provide for future elements or extensions.

11. Wakefulness pilots

Option to install a 1W LED signalling lamp.

12. Gas inlets

Option to install and supply gas inlets with ISO/EN and NFPA/CGA standards. ISO/EN standards include the following types: DIN 13260-2, AFNOR NF S 90-116 / FD S 90-119, SS 875 24 30, BS 5682:2015, CM, CSN 85 2762, ENV 737-6, EN 15908, UNI 9507, SDEGA EN ISO 9170-2.

Within the NFPA/CGA regulations are the following standards: ALLIED/CHEMETRON, DISS, OHIO/OHMEDA, PURITAN/BENNETT and OXEQUIP/MEDSTAR.

Option to install various gas inlets: O₂, Medical Air, Vacuum, N₂O, CO₂, Air 800, N₂, Motive Air, Heliox and EGA inlets (Passive or with Venturi system).

6. Intended use

ANTEA belongs to the SICA family, systems designed to be fixed to the wall above the bed in hospital rooms, emergency boxes, ICU boxes, URPA boxes, etc. for the supply of medical gases, electric current and communication access points, direct and indirect nurse call device, lights and support bar for hanging other medical devices.

6.1. Incorrect use

The maximum load capacity of the technical rails, as specified in section 5.4 maximum load of the technical rail on the BHU, must not be exceeded.



See section 5.4 of this manual.

6.2. Contraindications

The SICA system is Class IIb medical devices under Rule 12 of MDD 93/42/EEC. They serve as wall-mounted supply units providing mechanical support and distribution of medical gases, power, and data connections to other medical equipment.

These devices do not have any physiological effect, nor are they used directly in contact with patients. Therefore, there are no clinical contraindications related to patient conditions or medical procedures.

The only applicable contraindications are technical in nature.

- Their installation is not recommended in areas where patients with a high risk of electromagnetic interference are cared for, if electrical outlets have been integrated without adequate protection systems.
- Do not use these devices in environments where the continuity of the electrical and/or medical gas supply cannot be guaranteed, especially if life support or intensive care equipment is connected to them.

Do not use these devices as a gas or electricity connection point for devices that are not compatible or not clinically validated, as this could jeopardise the effectiveness of the patient's treatment.

7. Use of equipment

The specifications of each of the functional elements of the equipment must be taken into account when using the equipment.

- Electrical, voice and data circuits.
- Nurse call
- Gas inlets



See product and installation drawing supplied with the equipment.



NOTICE: Details of the elements and their characteristics can be found in the product definition drawing.

7.1. Product preparation

Before COMMISSIONING, during MAINTENANCE, INSPECTION, SERVICE and after REPAIR, a functional test must be carried out at the installation site. This functional test must be carried out by the operator or a person authorised by the operator, and persons authorised by the operator must be properly instructed.

This requirement is considered fulfilled when:

1. The functional reliability of the system is assured.
2. The correct functioning of the device has been approved by the operator during the first commissioning and documented by signing a test report according to Appendix G EN 62353.



See point 3 of this manual.



WARNING: To prevent unintentional actuation of the control elements, ensure that all cables and hoses are sufficiently far away from the control elements.

7.2. Environment. Environmental conditions

Ensure that the ambient conditions are within the prescribed range for proper operation of the equipment.



See section 5.2 of this manual.

7.3. Training

The personnel performing the installation must be properly trained and qualified by the customer. The equipment must only be USED by authorised personnel. Persons who:

1. have undergone medical training and are duly registered (at those levels where legal provisions make such registration necessary).
2. have been instructed in the use of this device in accordance with this instruction manual.
3. are able to assess the tasks they perform on the basis of their own professional experience and training in relevant safety standards and can recognise the potential hazards involved in the work.

8. Cleaning

Perform this operation with slightly moist cleaning instruments to ensure that no liquid enters the equipment. Since no part or component of the system is invasive, sterilisation is not necessary.



Do not use abrasive or very hard cleaning agents that may cause damage to the exterior coatings, such as disinfectants containing sodium hypochlorite, which is highly corrosive to aluminium.



WARNING: Damage to equipment may occur.

Formaldehyde-free disinfectants such as Saint Nebul Ald from Proder Pharma are recommended.

Method of application:

3. Dilute 4 pulses of the valve supplied by the manufacturer per 5 litres of water.

4. Spray the compound on the product and let it react for 15 minutes.
5. Remove with water or soap solution using a wrung-out cloth.



Switch off the power supply

Contact with live parts can cause an electric shock.

- Always disconnect the device from the main power supply before cleaning and disinfecting it.
- Do not insert objects into the openings of the device.

9. Waste management

Applies WEE2012/19 and RoHS directive 2011/65/EU, amendment 2015/863/EU. The equipment has electrical and electronic components, so it cannot be disposed of as organic waste, but as electrical/electronic waste.

10. User information on warnings

Warning – Electric shock hazard: During maintenance or installations activities, it is necessary to verify that the system is electrically disconnected and to take the necessary measures to ensure that the system cannot be reconnected.

Explosion hazard:

- During installation activity, it is necessary to verify that the medical gas shut-off valves are properly closed and to ensure that the system cannot be reopened, or it is perfectly identified that it must not be opened.
- Do not use in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide.

Caution – Guarantee: TEDISEL only guarantees the operational safety of the pendant systems only under the condition of:

- No changes to the design of the device are made. Unauthorised changes or modifications to the device are not permitted for safety reasons.

Only original spare parts and spare parts or accessories defined and approved by TEDISEL are used. Using other parts may lead to unknown risks and must therefore be avoided.

11. Incident warning information

Any serious incident related to the product must be reported to Tedisel Ibérica and to the competent authority of the member state where the user and/or the patient are established.



See point 1 of this manual.

12. Regulations

12.1. Team ranking

According to the new MDD 93/42/EEC regulation on medical devices, this product group is classified as:

- Class IIb, according to Annex II, with the exception of section 4, rule 11.

-IP20 protection class according to IEC 60529.

Equipment designed for continuous operation.

12.2. Reference standards

The device complies with the safety requirements of the following standards and directives:

ISO11,197 Medical supply units

IEC 60601-1: Medical electrical equipment. General requirements for basic safety and essential performance.

IEC 60601-1-2: Medical electrical equipment. Part 1-2. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic disturbances.

12.3. Electromagnetic compatibility

According to EN 60601-1-2:2015 this equipment is intended for use in the electromagnetic environment specified below. The user of this equipment must satisfy himself that it is being used in such an environment.

Interference emission measurements	Compliance	Comment
HF emissions according to CISPR 11	Group 1	The supply unit uses HF energy exclusively for its internal OPERATION. Therefore, its HF emissions are minimal and interference with devices in its vicinity is unlikely.
HF emissions according to CISPR 11	Class A	The ceiling supply unit is suitable for use in non-domestic installations and in installations that are directly connected to the PUBLIC SUPPLY NETWORK, which also supplies residential buildings.
Harmonic emissions according to	Class A	

IEC 61000-3-2		<div style="border: 1px solid black; padding: 2px; display: inline-block;">NOTA</div> 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.
Emissions of voltage fluctuations/transients according to IEC 61000-3-3	In accordance with	

Interference resistance	Test level according to IEC 60601	Level of compliance	Environment/Guidelines
Electrostatic Discharge (ESD) according to IEC 61000-4-2	±8 kV contact discharge 15 kV aerial discharge	±8 kV contact discharge 15 kV aerial discharge	Floors should be made of wood, concrete or ceramics. If the floor is covered with synthetic material, the relative air humidity should be at least 30%.
Fast transient electrical interference amplitudes / bursts according to the norm IEC 61000-4-4	±2 kV for power supply cables ±1kV for input and output cables	±2 kV for power supply cables ±1 kV for incoming and outgoing cables	The quality of the supply voltage should be typical for a commercial or hospital environment.
Overvoltage (waves) according to IEC 61000-4-5	±1 kV phase-to-phase voltage ±2 kV phase-to-earth voltage	±1 kV phase-to-phase voltage ±2 kV phase-to-earth voltage	The quality of the supply voltage should be typical of a commercial or hospital environment.

Voltage dips and fluctuations of the supply voltage according to IEC 61000-4-11	100% of UN drop for 0.5 period 100% of UN drop for 1 period 30% of UN drop for 25 periods Comment: UN is the AC mains voltage before applying the test level.	100% UN drop for 0.5 period 100% of UN drop for 1 period 30% of UN drop for 25 periods	The quality of the supply voltage should be typical for a commercial or hospital environment. If the user of the ceiling supply unit requires continuous operation even in case of power supply interruptions, it is recommended to supply the ceiling supply unit from a device with an uninterruptible power supply or a battery.
Short interruptions of the supply voltage according to IEC 61000-4-11	100% for 5 s Comment: UN is the AC mains voltage before applying the test level.		The quality of the supply voltage should be typical for a commercial or hospital environment. If the user of the ceiling supply unit requires continuous operation even in case of power supply interruptions, it is recommended to supply the ceiling supply unit from a device with an uninterruptible power supply or a battery.
Magnetic field for power supply frequencies (50/60 Hz) according to IEC 61000-4-8	30 A/m	30 A/m	The magnetic fields created by the mains frequency should be those of a commercial or hospital environment.

Interference resistance	Level of verification according to IEC 60601	Level of compliance	Environment/Guidelines
HF interference induced by	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM band	3 Vrms 6 Vrms	AM 1KHz modulation Depth 80% Depth 80%

IEC 61000-4-6			Depth 80% Depth		
HF interference induced by IEC 61000-4-3	RANGE	FREQUENCY	MODULATION	STEP	LEVEL
	A	80-1000MHz	AM 1 kHz Prof: 80%	LOG 1%	10 V/m
	B	1000-2000MHz	AM 1 kHz Prof: 80%	LOG 1%	10 V/m
	C	2000-2700MHz	AM 1 kHz Prof: 80%	LOG 1%	10 V/m
	D	385MHz	PM 18 Hz Cycle: 50%	-	27 V/m
	E	450MHz	FM 1 kHz Desv: ± 5 kHz	-	28 V/m
	F	810-930MHz	PM 18 Hz Cycle: 50%	-	28 V/m
	G	1720-1970MHz	PM 217 Hz Cycle: 50%	-	28 V/m
	H	2450MHz	PM 217 Hz Cycle: 50%	-	28 V/m
	I	5240-5785MHz	PM 217 Hz Cycle: 50%	-	9 V/m

Transmitter power rating	Safety distance as a function of the emission frequency		
	Environment/Guidelines (m)		
	150 kHz to 80 MHz $D = 1.2 P$	80 MHz up to 800 MHz $D = 1.2 P$	800 MHz up to 2.5 GHz $D = 2.3 P$
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



WARNING: stacking the device or installing the device close to other equipment may affect the performance of other systems due to EMI disturbances.