weheal

TS200

We Heal Smart TENS
& Body Analyzer

Version: 2019_v1.0

We Heal Biotechnology Co.

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1.Product Specifications

1.1 Device information

Trade name	WeHeal smart transcutaneous electrical nerve stimulation & body analyzer.
Model	TS200
Output waveform	Monophasic or biphasic rectangular pulse
Pulse length/ frequency	40 – 800 µs / 1 – 200 Hz
Output voltage/ current	Max. 50 V / 90 mA (500 ohm)
Power specification	DC 5V⎓0.5A Lithium-ion battery (2100 mAh)
Treatment time	Adjustable from 1 to 60 minutes
Intensity	Adjustable from 1 to 50
Bluetooth	BLE 4.0
Operating conditions	10°C – 40°C (50°F – 104°F) at a relative humidity of 30 – 85%
Storage/ Transport conditions	5°C –40°C (41 °F – 104 °F) at a relative humidity of 10% – 85 %
Use range atmospheric pressure/ altitude limit	700 – 1060 hPa / 3000 m
Galvanic skin response	Measuring the skin resistance at 100Hz
BIA (bioelectrical impedance analysis)	Operating at 50 KHz or 100 KHz
Software version	MCU v3.4/ BLE v2.9

This device complies with standards IEC 60601-2-10 , ANSI/AAMI NS4:2013 , IEC 60601-1-6 , ISO 14971 , IEC 62304 , IEC 60601-1-6 , IEC 60601-1-11 , IEC 60601-1-8 , EN 301489-1 , EN 301489-17 , EN 300328 , EN/IEC 60601-1 and EN/ IEC 60601-1-2 , and is subject to special precautionary measures with regard to electromagnetic compatibility. Please note that portable and mobile HF communication systems may interfere with this unit.
The serial number is located on the device. We reserve the right to make changes to improve and develop the product. More details can be requested from the stated Customer Services address on the device.
Note: If the device is not used according to the instructions specified, perfect functionality cannot be guaranteed!

1.Product Specifications

1.2 Intended use

TENS- transcutaneous nerve stimulation	symptomatic relief of neuro-muscular pain, chronic intractable pain, and post traumatic and post-surgical pain.
EMS- electrical muscle stimulation	Improvement and facilitation of muscle performance, relaxation of muscle spasm, increasing local blood circulation, prevention or retardation of disuse atrophy, and maintaining or increase range of motion.
Impedance plethysmograph	Use bioelectrical impedance analysis (BIA) technology to determine and estimate body composition, including body fat, body water percentage, body muscle mass, bone mass, and visceral fat rating.
Galvanic skin response	measurement of skin resistance. The device is not intended for use in any diagnosis.

1.Product Specifications

1.3 Contraindications

The device is not a substitute for medical consultation and treatment. Consult your doctor first if you are experiencing any pain or are suffering from a chronic illness such as cancer, diabetes, high blood pressure, and blood coagulation/thrombo-embolic diseases. To avoid damage to health, we strongly advise against using the We Heal Smart TENS & body analyzer in the following situations:

- **Do not use** this device if you have a cardiac pacemaker, known cardiac arrhythmias or heart disorders, the implanted defibrillator, or other implanted metallic or electronic device. Do not place the stimulation electrodes on the front ribcage near to the heart. Such use could cause electric shock, ventricular fibrillation, and induce cardiac arrest or death.
- **Do not use** this device if you have high temperature (> 38℃), seizure disorder, on the injured or irritated skin, or if you are pregnant.
- **Do not use** this device in humid environments (e.g. in the bathroom), when bathing or showering, or after consuming alcohol.
- **Do not place the electrodes** on the neck/carotid artery area, genital area, skeletal skull structure, or around the eyes, mouth, throat or larynx. The stimulation should not be applied across or through the head or the heart.
- **Do not use** by children or people with restricted physical, sensory (e.g. reduced sensitivity to pain) or mental skills or a lack of experience and/or lack of knowledge, unless they are supervised by a person who is responsible for their safety or are instructed by such a person in how to use the device. Keep the device away from children.
- **Do not use** the device if the device is damaged. **Do not** drop or disassemble the device. **Do not** attempt to open and/ or repair the device yourself. Failure to comply will result in voiding of the warranty. The manufacturer is not liable for damage resulting from improper or careless use. Contact your retailer or the customer services if the device is damaged.

1.Product Specifications

1.4 Precautions

- **Do not** expose the device to direct sunlight or high temperatures.
- Keep the device away from sources of heat and do not use it close (approx. 1 m) to shortwave or mobile phones, as doing so can result in unpleasant current peaks.
- **Ensure that no metallic objects or high-frequency surgical devices** are in contact with the electrodes during stimulation, which could result in electrical burns.
- **Do not** use the device more than 1 hour, which could result in electrical burns.
- The treatment effect can be affected by the physical, mental and medical conditions of the user.
- **Do not** modify electrodes (e.g. by cutting or change it's shape). This may increase the current intensity, which is potentially hazardous, an effective current intensity beyond 2 mA/cm² requires increased awareness.

1.5 Device summary description

The WeHeal smart TENS & body analyzer is a combination of TENS/EMS unit, galvanic skin response unit, and impedance plethysmograph unit. It is powered by rechargeable lithium-ion battery which is permanently built into the main unit. This device can work independently or receive remote control signals through Bluetooth module. The correspondent App for Android oriOS system can remote control the functions of this device.

The TENS/EMS unit delivers nerve or muscle stimulation by applying an electrical current to electrodes, which are attached on the patient's skin. The output waveform, pulse length/frequency, treatment time, and intensity are adjustable according to the intended treatment of patient. The stimulator has 2 output channels, accessed through jacks at the top of the housing, so that it may stimulate either 2 or 4 electrodes simultaneously.

The galvanic skin response and impedance plethysmograph units measure skin resistance and estimate body composition by bioelectrical impedance analysis (BIA) technology with a low, safe, electrical current.

1.Product Specifications

1.6 Signs and symbols

	Do not use this product if you have implanted pacemaker installed
IP22	Protected against ingress of solid foreign objects greater than 12.5 mm in diameter. Protected against drops of water falling at up to 15° from vertical
SN	Serial number
	Read the instructions before use
	Electrodes as the applied part, type BF
	Manufacturer
	Class II symbol
	Disposal in accordance with the Waste Electrical and Electronic Equipment EC Directive – WEEE

1.Product Specifications

1.7 Replacement parts and accessories

1.7.1Electrodes:

Adhesive electrodes (small) Ø35mm x 2sets (4pcs); adhesive electrodes (Big) 97x47mm x 1set (4pcs).

- At distances below 5 cm, the unit primarily stimulates surface structures intensively. Greater distances (>15 cm) between electrodes mean a larger tissue volume is stimulated, but less intensively. Consequently, you must increase the impulse intensity.
- Clean the skin prior to any application; do not use skincare lotions or oils prior to treatment.
- To ensure that the adhesive electrodes remain adhesive for as long as possible, clean them carefully with a damp, lint-free cloth or clean the underside of the electrodes under lukewarm, running water and pat dry with a lint-free cloth.
- Replace the electrodes if they still do not adhere securely after cleaning the electrodes. You can obtain the replacement electrodes directly from customer services.
- Electrodes item numbers: GMP 001357

1.7.2Connection cable : The black head of the connection cable is the negative pole of the wire, and the white head is the positive pole of the wire.

1.7.3Other accessories :USB charging cord x 1; soft shell package x 1.

1.7.4Recommended adaptor :

1.8 Contact information

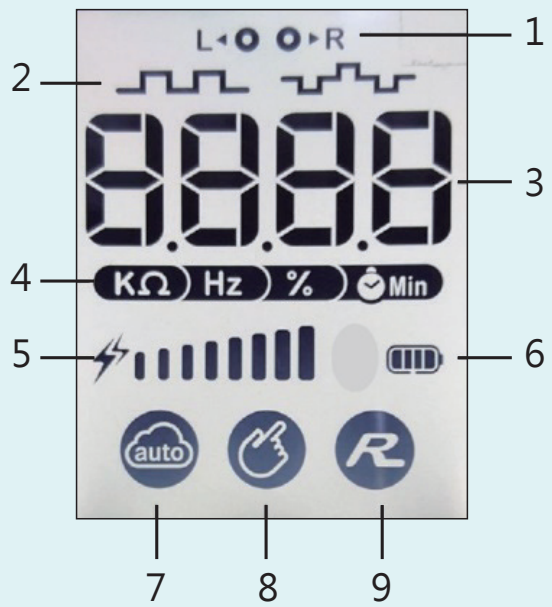
Manufacturer: We Heal Biotechnology Co.
Address: 9F., No. 205, Minsheng 2nd Rd., Chyan Jin Dist., Kaohsiung City 801, Taiwan (R.O.C.)
Phone: +88672216313
Website: www.weheal.com
Email: service@weheal.com.tw

2.General instructions

2.1 Buttons

	**ON/OFF** button：Press 1 sec to turn on and 3 secs to turn off **ENTER** button：**START/PAUSE** button
	**BACK** button **Shift** button : switch the display of treatment setting
< >	**Setting** button ：choose left or right, increasing or decreasing the frequency, impulse width, and working time

2.2 Display



1. Electrode positioning indicator
2. Impulse waveform
3. Number display
4. Display for impedance and resistance (KΩ), frequency (Hz), pulse width (%) and timer
5. Impulse intensity
6. Battery level display
7. Auto (programmed) mode
8. Manual mode
9. Body analyzer

2.General instructions

2.3 Device appearance

warning light

Dimensions: 121 x 60 x 28 mm
Weight: 134.2g
Color: Black or pink

The socket for the connection cables.

The socket for the USB charging cord.

2.4 Initial notes on use

- Connect the connection cables with the electrodes.
- Guide the connection cable plugs into the socket on the top of the device. Do not pull, twist or make sharp bends in the cables.
- If the battery level is low, charge this device with the USB charging cord and the corresponding adaptors
  (HPU15-102-P88D101, Input Voltage:100 - 240 Vac, 47–63 Hz, 0.2–0.4A; Output Voltage: 5Vdc/2.4A (max), 12W. Make sure the voltage of the power source is correct before connecting the equipment to the power outlet.
- When this device is charging, the blue light is on and this device cannot be used for any applications. When charging is finished, unplug the charging cord and adaptor to disconnect the device from Mains supply.
- Do not charge the device on the place where it is difficult to disconnect the device!

2.General instructions

2.5 Starting applications

Step 1 Pressure the ON/OFF button to switch on the device.

Step 2 Use the >/< button to navigate through the 

modes and press the **ENTER** button to confirm your selection.

2.6 Cleaning, storage and disposal

Cleaning the device

Please turn off the device while cleaning the device. Clean the device after use with a soft, slightly damp cloth. If it is very dirty, you can also moisten the cloth with a mild soapy solution. Ensure that no water enters the device. Do not use any chemical or abrasive cleaning agents.

Storage

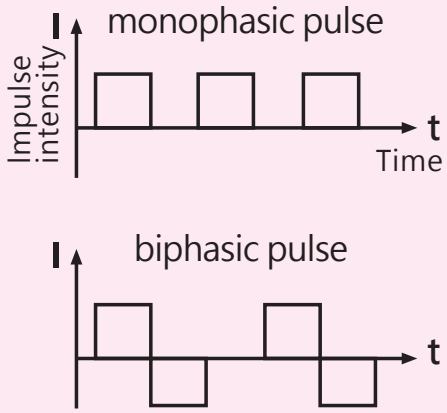
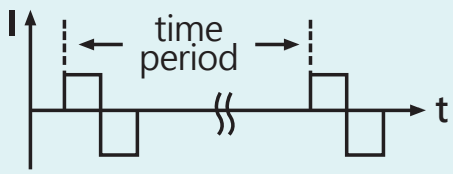
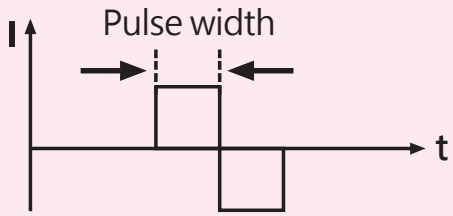
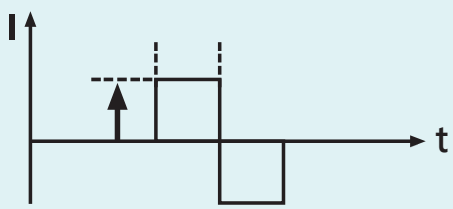
Do not make sharp bends in the connection cables and electrodes. Disconnect the connection cables from the electrodes. Reapply the electrodes to the carrier foil after use. Store the device and accessories in a cool, well-ventilated space. Never place any heavy objects on the device.

Disposal

For environmental reasons, do not dispose of the device in the household waste at the end of its useful life. Dispose of the unit at a suitable local collection or recycling point. Dispose of the device in accordance with EC Directive – WEEE (Waste Electrical and Electronic Equipment). If you have any questions, please contact the local authorities responsible for waste disposal.

3.Functions

3.1 TENS/EMS current parameter

Impulse shape		It distinguishes between monophasic and biphasic pulse currents. In monophasic pulse currents, the current flows in one direction and in biphasic pulse currents the electrical impulse alternates its direction. The device provides both monophasic and biphasic rectangular wave.
Impulse frequency		IThe frequency indicates the number of individual impulses each second and is given in Hz (Hertz). It can be calculated by determining the cyclic value for the time period.
Impulse width		This indicates the duration of an individual impulse in microseconds. Pulse width
Impulse intensity		Intensity levels indicates the output voltage/ current of the stimulus. The setting used should be effective but should never cause an unpleasant sensation, such as pain, at the site of application. While a gentle tingling indicates sufficient stimulation energy levels, **any setting that causes pain should be avoided.** During longer applications it may be necessary to make readjustments due to the adjustment processes over time at the site of application.

3.Functions

3.2 TENS/EMS auto (programmed) mode

Step 1 The digital EMS/TENS unit features a total of 15 programs. Use the >/< setting buttons to select the program number you want and press the **ENTER** button to confirm your selection.

Step 2 You can set the impulse intensity of both channels in all programs.

Program table:

No.	Mode	Area of application, indications
1	TENS	Pain relief in shoulder, back and ankle
2	EMS	Strengthening abdomen and back muscles
3	MASSAGE	Tapping massage
No.	**Mode**	**Area of application, indications**
4	TENS	Chronic pain in low back
5	TENS	Pain in back, buttock, thigh
6	TENS	Pain relief
7	TENS	Pain relief
8	EMS	Shaping the muscle
9	EMS	Tightening the muscle
10	MASSAGE	Tapping massage
11	TENS	Pain relief
12	TENS	Pain relief
13	MASSAGE	Relaxing massage
14	TENS	Pain relief
15	TENS	Pain relief

You can apply the program on the discomfort position except the contraindicated area (section 1.4).

3.Functions

3.3 TENS/EMS manual mode

Step 1 Place the electrodes on the desired area for treatment. Choose the waveform.

Step 2 Set the impulse frequency between 1 to 200 Hz.

Step 3 Set the impulse width between 1%-20% (40-800 μs).

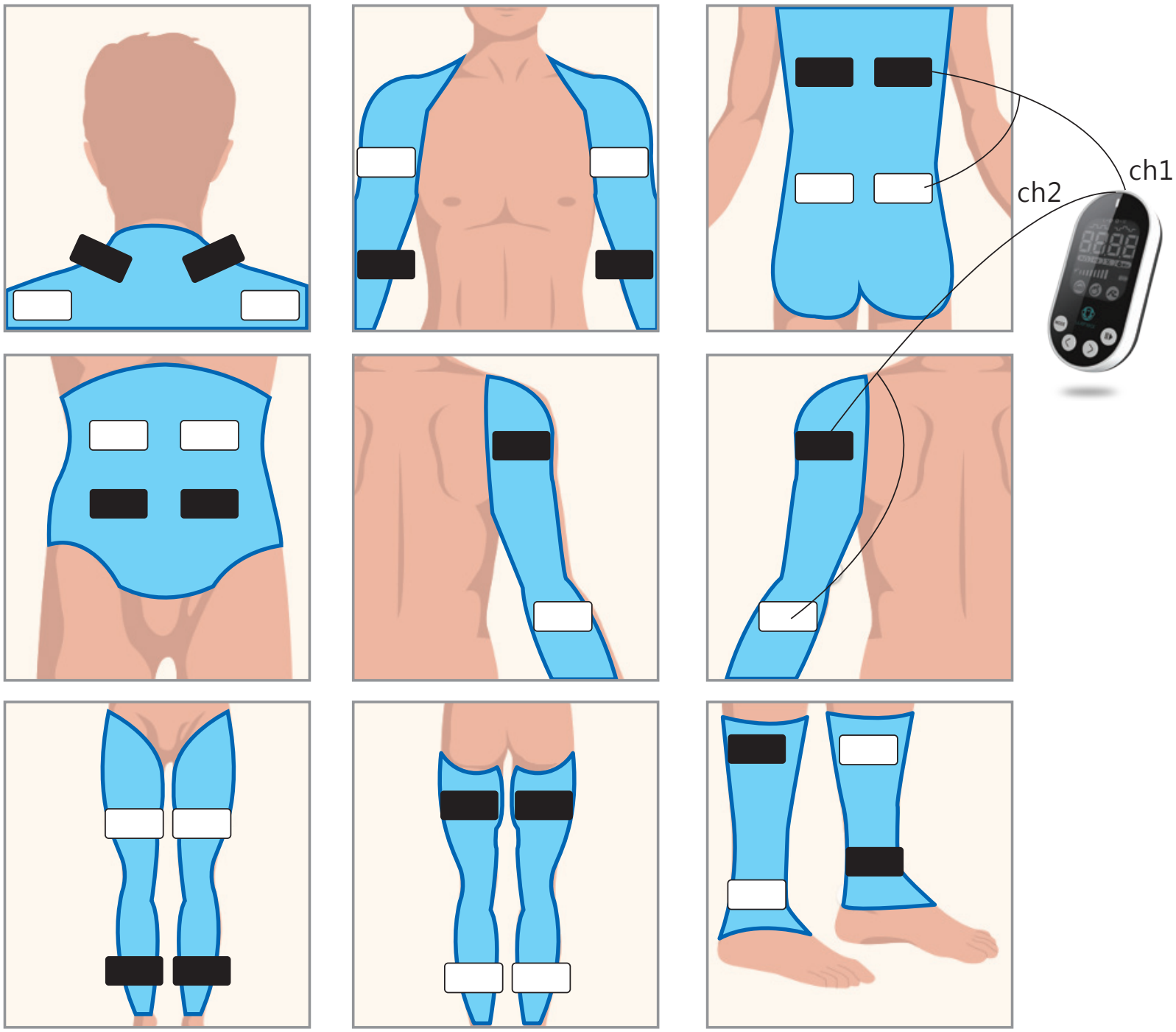
Step 4 Set the timer. Adjust the impulse intensity.

3.4 Body analyzer (galvanic skin response and BIA)

Program No.	Indications
1	Measure skin conductance (galvanic response)
2	Estimate body fat, body water percentage by bioelectrical impedance analysis
3	Estimate body muscle mass, bone mass, and visceral fat rating by bioelectrical impedance analysis

3.Functions

3.5 Positioning of electrodes



3.Functions

3.6 App instruction

Visit www.weheal.com for further additional information and instruction.

3.6.1 **Blue light** It represents that this device is charging.

3.6.2 **Orange light** It represents that at least one of the electrodes are not adhered to the body. Please adhere the electrodes to the body.

3.6.3 **Green light** It represents the device is in connection with correspondent Apps.

3.6.4 **Reset the machine** If the device is not work, **press > and ⏯ simultaneously for 5 secs,** the device will return to default status. Contact customer service if you cannot reset the machine.

4.Warranty and service

In case of a claim under the warranty please contact your local dealer or the local representation. In case of returning the unit please add a copy of your receipt and a short report of the defect.
The following warranty terms shall apply:

- The warranty period for this product is 3 years warranty period from date of purchase. In case of a warranty claim, the date of purchase has to be proven by means of the sales receipt or invoice.
- This product does not need regular verification. Repairs (complete unit or parts of the unit) do not extend the warranty period.
- The warranty shall not be valid for damages because of the following reasons:
  (1) improper use, e.g. not follow the user instructions
  (2) repairs or tampering by the customer or unauthorized third parties
  (3) transport from the manufacturer to the consumer or during transport to the service center.
  (4) The warranty shall not be valid for accessories which are subject to normal wear and tear
  (5) Liability for direct or indirect consequential losses caused by the unit are excluded even if the damage to the unit is accepted as a warranty claim.

Local dealer/ retailer

Purchase Date: _____/_____/_____

5.Electromagnetic compatibility information

Table 1. Guidance and manufacturer’ s declaration – electromagnetic emissions

The TS200 is intended for use in the electromagnetic environment specified below. The customer or the user of the TS200 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The TS200 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 CISPR 11	Class B	The TS200 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	Not applicable	

5.Electromagnetic compatibility information

Table 2. Guidance and manufacturer’ s declaration – electromagnetic immunity

The TS200 is intended for use in the electromagnetic environment specified below. The customer or the user of the TS200 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	Contact:±8 kV Air:±2 kV,±4 kV,±8 kV, ±15 kV	Contact:±8 kV Air:±2 kV,±4 kV, ±8 kV,±15 kV	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	+ 2kV for power supply lines + 1kV for input/output lines		Mains power quality should be that of a typical home healthcare environment.
Surge IEC 61000-4-5	+ 0.5kV, +1kV line(s) to line(s)		Mains power quality should be that of a typical home healthcare environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % UT; 0,5 cycle 0 % UT; 1 cycle 70 % UT; 25/30 cycles Voltage interruptions: 0 % UT; 250/300 cycle	Voltage dips: Not applicable Not applicable Not applicable Voltage interruptions: Not applicable	Mains power quality should be that of a typical home healthcare environment. If the user of the TS200 requires continued operation during power mains interruptions, it is recommended that the TS200 be powered from an uninterruptible power supply or a battery.
Power frequency (50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	The TS200 power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare environment.

NOTE *UT* is the a.c. mains voltage prior to application of the test level.

5.Electromagnetic compatibility information

Table 3. Guidance and manufacturer' s declaration – electromagnetic immunity

The TS200 is intended for use in the electromagnetic environment specified below. The customer or the user of the TS200 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	IEC 60601 test level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the TS200, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 800 MHz to 2,7 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 metres (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:
Radiated RF IEC 61000-4-3			

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 TS200 is used exceeds the applicable RF compliance level above, the TS200 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the TS200.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

5.Electromagnetic compatibility information

Table 4. Recommended separation distances between portable and mobile RF communications equipment and the TS200

The TS200 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the TS200 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TS200 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		
	50 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	N/A	0,12	0,23
0,1	N/A	0,38	0,73
1	N/A	1,2	2,3
10	N/A	3,8	7,3
100	N/A	12	23

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.

5.Electromagnetic compatibility information

Manufacturer’ s declaration-electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment
The TS200 is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the TS200 should assure that it is used in such an environment.

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance LEVEL (V/m) (for home healthcare)
385	380 –390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1 kHz sine	2	0,3	28	28
710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9	9
810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28	28
1 720 1 845 1 970	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	28
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	28
5 240 5 500 5 785	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9

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.

6.Federal Communications Commission (FCC) Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- **Reorient or relocate the receiving antenna.**
- **Increase the separation between the equipment and receiver.**
- **Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.**
- **Consult the dealer or an experienced radio/TV technician for help.**

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1) **this device may not cause harmful interference, and**
2) **this device must accept any interference received, including interference that may cause undesired operation of the device.**

- **RF Exposure Warning!**

This device contains transmitters and receivers which emit Radio Frequency (RF) energy. The device is designed to comply with the limits for exposure to RF energy set by the Federal Communications Commission (FCC) of the United States, Industry Canada (IC) of Canada, and the regulating entities of other countries.

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