

Certificate of conformity

Product name:
In-ear hearing AIDS

Product model: LT2316

Production date: See fuselage
radium engraving information

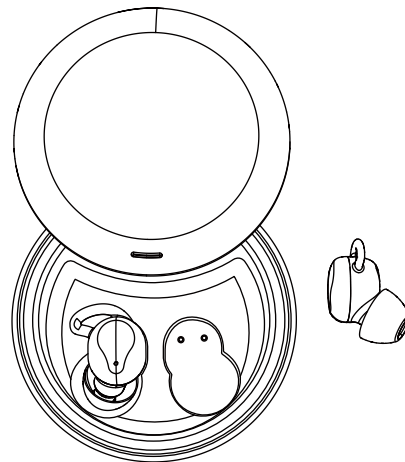
Inspector: _____

Date of inspection: _____

★ This product is allowed to leave
factory after passing inspection

In-ear hearing AIDS

LT2316



Instruction manual

- Before using this product, please read the product manual carefully or purchase and use under the guidance of medical personnel.
- Please refer to the "Instruction Manual" for details of forbidden contents or precautions. Please keep it properly after reading it for reference at any time.

Catalogue

- I 、【 Product performance, main structure 】
- II 、【 Scope of Application, object of Use 】
- III、【Contraindications, precautions, warnings and suggestive instructions】
- IV、【Interpretation of graphics, symbols, abbreviations and other contents used in medical device labels】
- V 、【Usage Method】
- VI、【Troubleshooting】
- VII、【Product maintenance】
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- IX、【Packaging Content】
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In-ear hearing AIDS

Instruction manual

⚠ Note: Read the instructions carefully before use

Introduction

1.Instructions

This manual describes the use, maintenance, repair and technical parameters of the In-ear hearing aids. In order to ensure the correct and safe use of hearing AIDS, you must carefully read and understand the contents of the instruction manual before using the hearing aid.Keep this manual properly after reading it and place it in a convenient location.

2.Copyright

The Company owns the copyright of this non-publicly published specification and has the right to treat it as confidential information. This manual is only used as a reference for the use, maintenance and repair of hearing aid products. Without the permission of the Company, no person shall use, disclose or allow others to obtain all or part of the information in this manual by any means, nor shall any part of this manual be photocopied, duplicated or translated into other languages.

3.Manufacturer's liability

The company is responsible for the safety, reliability and performance of hearing AIDS only in the following cases:

- (1) The user uses the hearing aid correctly according to the instructions;
- (2) The maintenance of hearing AIDS shall be carried out by personnel approved by the company;
- (3) The power supply used meets the requirements of the manual.

4.Warranty and after-sales service

This hearing aid can not be repaired by the user, all repair work should be carried out by the company's authorized technicians. If necessary, the company can provide them with circuit diagram, component list, drawing notes, calibration rules and other necessary maintenance technical data or consumable specifications. The warranty covers all hearing aid failures caused by the failure of material components or production processes:

- (1) Hearing AIDS disassembled by the user or by personnel not approved by the Company;
- (2) Artificial damage or irresistible natural disaster damage to the hearing aid;
- (3) Hearing AIDS damaged by improper use by the user and not operated according to this instruction manual;
- (4) Hearing AIDS out of warranty.

5. Return goods

To return goods to the Company, please follow these instructions:

(1) Contact the service department of the company, briefly explain the reason for return, and obtain the right of goods.

(2) Freight: The user shall bear the freight of the hearing aid shipped to the company.

I、【Product introduction】

Product name: In-ear hearing AIDS

Model specification: LT2316

Registrant/Manufacturer/after-sales service unit:

Residence/After-sales service Address:

Production address:

Production date: See label

Service life: 2 years

Manual version number: V1.0

Specification preparation/revision date: January 2025

After-sales phone/contact phone:

Product technical requirement Number:

Medical Device Registration Certificate Number:

Production license Number:

1、Technical parameters

◎Normal working conditions

Working environment	Temperature 0°C ~ +40°C, relative humidity ≤80%, atmospheric pressure 80kPa-106kPa
Storage environment	Temperature -10°C ~ +55°C, relative humidity ≤80%, atmospheric pressure 50kPa-106kPa
Operating voltage	Lithium battery 3.7V

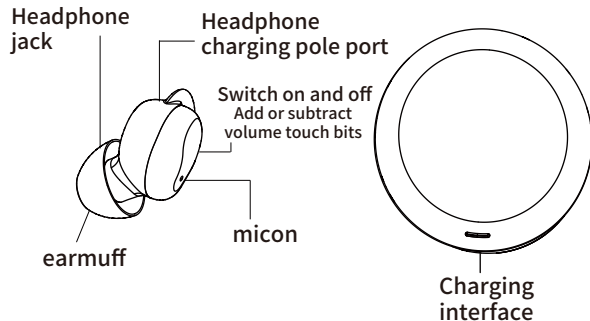
◎Electroacoustic performance of the product

Type specification	Maximum OSPL90	Output sound pressure level (HF average)	Full tone gain	Full sound gain	Rated power supply current consumption
LT2316	≤110dB±3dB	105dB±3dB	40dB±5dB	35dB±5dB	≤6mA

◎Other instructions

When the ambient temperature is 20 ° C, the time it takes for the device to go from -10 ° C after use to the time it is ready for its intended use	The time is 30 minutes
When the ambient temperature is 20 ° C, the time required for the device to be ready for its intended use from 55 ° C after use	The time is 30 minutes

2、Function schematic structure composition



(Model number: LT2316)

Note: The application part of this device is the earphone shell and silicone ear cap.

3、Classification

- (1) According to the type of anti-shock classification: internal power supply;
- (2) Classification according to the degree of shock prevention: BF type application part;
- (3) According to the degree of protection of liquid intake classification: IP22;
- (4) Input power : not applicable;
- (5) According to the safety of the flammable anesthetic gas mixed with air or the flammable anesthetic gas mixed with nitrous oxide when used Degree classification: equipment that cannot be used in either case;
- (6) Classified by operation mode: belongs to continuous operation equipment;
- (7) Rated voltage of the equipment: lithium battery d.c.3.7V;
- (8) Whether the equipment has the application part of defibrillation discharge effect protection: No;
- (9) Signal input and signal output: none;
- (10) Permanently installed equipment or non-permanently installed equipment: non-permanently installed equipment.
- (11) Electromagnetic compatibility according to GB4824-2013 "Industrial, Scientific and Medical (ISM) radio frequency equipment disturbance characteristics; limits and measurement methods" grouping: belongs to Group 1 Class B.

4、Safety standards

- (1) GB 9706.1-2020 《Medical Electrical Equipment Part I: General Safety Requirements》
- (2) GB/T 14199-2010 《General Specification for Electroacoustic hearing AIDS》。
- (3) YY 9706.111-2021 《Medical Electrical Equipment - Part 1-11: General requirements for Basic safety and basic performance and parallel standards: Requirements for medical electrical equipment and medical electrical systems for use in home care Settings》

II 、 【 Scope of application, object of use, working principle】

Scope of application: Experience matching, hearing compensation for patients with air conduction hearing loss.

Target: Suitable for children and adults with induced hearing loss;

However, children under the age of 12 should be supervised by an adult.

Working principle: Pick up the sound through the microphone, convert the sound signal into an electrical signal, and then go through the sound amplification processor, and then convert the electrical signal into a sound signal by the speaker.

III 、 【Contraindications, precautions】

1、Contraindications:

Acute external otitis, tympanitis, chronic suppurative otitis media (in the period of abscess infection), acute suppurative otitis media is not suitable for wearing air conduction hearing AIDS, patients allergic to this product material.

2、Precautions:：

- Before fitting the hearing aid, professional examination and hearing test should be carried out, and the hearing aid fitting engineer should debug and try it on and use it under the guidance of the fitting engineer.
- Moisture-proof, shock-proof and heat-proof.
- Do not immerse the hearing aid in any liquid, and remove the hearing aid before swimming and washing your hair. After swimming or washing, wait for the ear canal to dry before putting on the hearing aid.
- After taking off the hearing aid at night, it should be placed in a box with a desiccant, avoid light, avoid high temperature, high humidity environment, and avoid falling.。
- The outer surface of the hearing aid should be kept clean, and earplugs, ear molds, earwax in the cerumen baffle should be cleaned frequently.
- The function and volume control switch should be used correctly, and the switch should be turned on and off as gently as possible to avoid excessive force and excessive force.
- Hearing AIDS should be regularly sent to the fitting center for maintenance and inspection to ensure that the hearing AIDS are in good condition.
- Do not overuse this product for a long time, so as not to damage your hearing. If you feel uncomfortable, stop using it.
- If the hearing aid is not used for a long time, the internal resistance of the battery may release the battery charge below the operating voltage. If the hearing aid does not turn on, make sure it is fully charged before attempting to do so.

- If you hear tinnitus, check that the size of the silicone ear cap (silicone sleeve) is suitable for the user's ear canal and tighten to prevent air leakage.
- Do not remove the inside of the hearing aid without permission.
- Hearing AIDS should avoid electromagnetic radiation, and do not use them in high-frequency hyperthermia or radiation therapy and in strong magnetic fields.
- Do not use it in an explosive environment or in a dangerous state.
- Hearing AIDS can not be treated as ordinary municipal garbage. Because hearing AIDS have built-in batteries, use battery handling facilities to protect the environment.
- Do not allow children to play with this product and accessories to avoid injury to children or damage to the machine.
- Please learn to adjust the volume before wearing, so as not to damage your hearing.
- Warning: This device and accessories contain small parts that are easy to be inhaled or swallowed (such as silicone ear caps, earphones), and should be placed in a place that is difficult for infants and children to access to prevent the device or accessories from being swallowed and causing choking hazards.
- Warning: Some patients may have an allergic reaction to the accessible materials on the product. If there is an allergic reaction, please stop using immediately.
- Warning: It may cause contact injury to patients (the equipment may cause cutting wounds, bruises, burns, electric shock and other risks to patients).
- Warning: If the use of accessories other than the instructions (such as silicone ear caps, charging cables, etc.) will have an adverse impact on the safety of the device, and may also cause allergic reactions in patients.
- Warning: Replacement of batteries by inadequately trained personnel can result in hazards (sources) (such as overtemperature, fire or explosion)
- Warning: When the headset is turned on, do not clean, disinfect and maintain the headset. Please turn off the phone and then maintain the earphones and silicone ear caps.
- Note: The protection level of the equipment against liquid intake is IP22. Please note that small cotton wool, dust or water and other liquids may cause damage to the equipment.

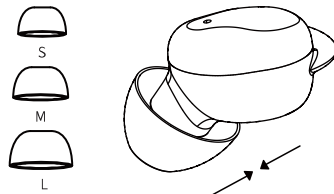
IV、【 Interpretation of graphics, symbols, abbreviations, etc. used in medical device labels】

	The degree of shock protection is BF type		Please refer to the instructions
	Dispose of discarded electrical and electronic equipment separately (please comply with local laws and regulations)		
	Improper use or listening at too high a volume for too long may damage your hearing		
	Make progress		Handle with care
	Fear of the sun		Keep from getting wet
R	Right ear	L	left ear
IP22	Prevents solid foreign objects with a diameter of not less than 12.5mm, and prevents water dripping vertically when the housing is tilted at 15°		

V、【 Usage method】

1、 Installation instructions

Choose the right size silicone ear cap (there are many different sizes of silicone ear caps in the box, you should choose the most suitable one when using to make your ears more comfortable and can better eliminate noise) Connect the silicone ear cap to the hearing aid headset.

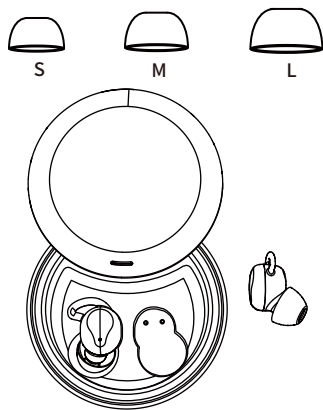


2、Power on

① Press and hold the Power button for 3S to start the device. The prompt tone is "Power on". The green light is steady for 1 second and then turns to green and blinking slowly
B. Take out the automatic boot from the charging bay, prompt tone "Power on", green light steady for 1 second, turn to green light slow blinking, and automatically enter the hearing aid mode after 10 seconds

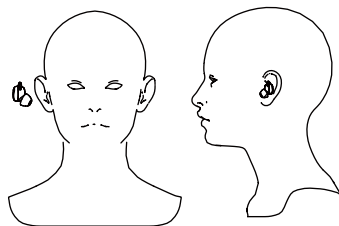
② Choose a silicone ear cap that fits you from the 3 different sizes provided, then fasten the connection port between the machine and the silicone ear cap, and insert the silicone ear cap into the inner ring.

Tip: Install the bottom of the ear cap (large circle) to the hearing aid headset, do not install in the opposite direction.



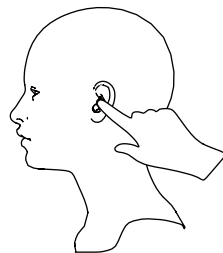
3、Wear

Slowly push the headset with the silicone ear cap into the ear hole until it is close to the ear canal and feels comfortable ("L" is left "and" R "is" right ")



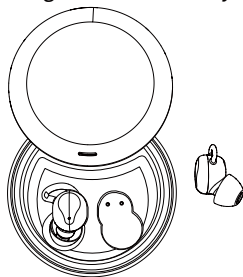
4、Turn it off

A. In the startup state, hold down the Power button for 3S to shut down, the prompt tone "Power off", the green light is on for 1 second, and then it is turned off.
B. Put it into the charging bin when it is turned on, and the headset will automatically shut down



5、Charging

Put the earphone into the charging bay. The earphone will charge automatically. The green light will blink slowly



6、Mode conversion

Double click the Power button in the hearing aid mode state to convert three modes Beep -- Noise reduction mode

Doo -- Universal mode

Beep -- Noise reduction mode

7、charging bin charging operation method

The user must choose a charger that meets the requirements of GB9706.1-2020 to charge the product, connect the big end of the charging cable to the adapter, and then connect the small end of the charging cable to the charging bin:

- ① The white light of the charging bay flashes, indicating that it is connected and charged.
- ② Four white lights are long on, indicating that the battery is fully charged.

VI、【Troubleshooting】

Please follow these steps to confirm exclusions:

1. Please make sure that you can turn on the hearing aid (long press the power button for 3S to turn on the hearing aid, the prompt tone "Power on", The blue light is on for 1 second and then goes out, indicating that it is turned on);
2. Adjust the volume repeatedly to confirm whether the hearing aid has sound;
3. The above two steps are silent, please ensure that it is fully charged before starting, and then repeat the step
4. If there is no sound in the above three steps, you can judge that the hearing aid is not working properly or is faulty. Please contact your local distributor or send it back to our company.

VII、【Product maintenance】

1. Please charge the hearing aid in time when not in use to ensure that there is enough power for use.
2. Clean the earphone cover with a clean soft cloth.
3. Please use a cleaning brush to remove the dirt on the silicone ear cap, then clean the silicone ear cap with pure water, and put it in a ventilated place until dry.

VIII、【Transportation and storage methods】

1.Transport conditions: anti-fall, handle lightly: prevent sun, rain or mechanical collision, keep dry.



Make progress



Handle with care



Keep from getting wet



Fear of the sun

2.Storage conditions: The product should be stored in a cool and dry place, and the environment should meet the following conditions:

(a) Ambient temperature: -10°C~55°C;

(b) Relative humidity: $\leq 80\%$;

(c) Atmospheric pressure: 50kPa-106kPa;

3.Operate with care to avoid collisions or strong impacts.

IX、【Package content】

Part name	quantity	Expected service life	Part name	quantity	Expected service life
Headphones	A set	Two years	Charging cable	A piece of	Two years
User manual	A copy	/	Silicone ear cap	One pair each big, medium and small	Two years

X、【Electromagnetic compatibility】

The electromagnetic compatibility of the In-ear hearing AIDS LT2316 complies with GB/T25102.13-2010 Electroacoustic hearing AIDS Part 13: Electromagnetic Compatibility (EMC).

In-ear hearing AIDS LT2316 complies with the field strength of the RF test signal when hearing aid immunity is specified in GB/T 25102.13					
Neighbor compatibility When $IRIL \leq 55\text{dB}$ at the following field intensities The field intensities are expressed in V/m					
Frequency range GHz	0.08~0.8	0.8~0.96	0.96~1.4	1.4~2.0	2.0~3.0
Microphone mode	/	3	/	2	/

⚠ Look out:

- In-ear hearing AIDS LT2316 meets the electromagnetic compatibility requirements of YY 9706.102-2021 standard.
- The user shall install and use according to the electromagnetic compatibility information provided by the random file.
- Portable and mobile RF communication devices may affect the performance of the In-ear hearing AIDS LT2316, avoid strong electromagnetic interference when used, such as close to mobile phones, microwave ovens, etc.
- Guidelines and manufacturer's statement can be found in the annex.

⚠ Caution:

- In-ear hearing AIDS LT2316 should not be used near or stacked with other devices, and if it must be used near or stacked, it should be observed to verify that it operates properly in the configuration it is used in.

● With the exception of cables sold by manufacturers of the in-ear hearing aid LT2316 as spare parts for internal components, the use of accessories and cables other than those specified may result in increased emission or reduced immunity of the in-ear hearing aid LT2316.

Serial number	name	Cable length (m)	Mask or not	remark
1	Charging cable	0.5	yes	/

Attachment:

Guidelines and Manufacturer's Statement — Electromagnetic Emission		
In-ear hearing AIDS LT2316 is intended to be used in the following electromagnetic environments, and the purchaser or user shall ensure that it is used in such electromagnetic environments:		
Launch test	conformance	Electromagnetic environment- A guide
Radio-frequency emission GB 4824	A set	In-ear hearing AIDS LT2316 uses RF energy only for its internal functions. Therefore, its radio frequency emission is low, and the possibility of interference with nearby electronic devices is small
Radio-frequency emission GB 4824	Group B	In-ear hearing AIDS LT2316 is suitable for use in all facilities, including domestic facilities and direct connection to the domestic public low voltage power grid
Harmonic emission GB 17625.1	inapplicability	
Voltage fluctuation/ flicker emission GB/T 17625.2	inapplicability	

Guidelines and Manufacturer's Statement - Electromagnetic immunity

In-ear hearing AIDS LT2316 is intended for use in the following electromagnetic environments, and the purchaser or user shall ensure that it is used in such electromagnetic environments:

Immunity test	IEC 60601 test level	Coincidence level	Electromagnetic environment - Guide
Electrostatic discharge GB/T 17626.2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	The floor should be wood, concrete or tile, and if the floor is covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient pulse group GB/T 17626.4	±2kV power cord ±1kV for input/output lines	inapplicability	The network power supply should be of the quality typical for use in a commercial or hospital environment
Surge GB/T 17626.5	±1 kV wire to wire ±2 kV wire to ground	inapplicability	The network power supply should be of the quality typical for use in a commercial or hospital environment
Voltage dips, short interruptions and voltage changes on the power input line GB/T 17626.11	<5 % U_T , lasting 0.5 cycles (On U_T , >95% dip) 40 % U_T , lasting 5 cycles (On U_T , 60% dip) 70 % U_T , lasting 25 cycles (On U_T , 30% dip) <5 % U_T , for 5s (On U_T , >95% dip)	inapplicability	The network power supply should be of the quality typical for use in a commercial or hospital environment. If the user of the LT2316 requires continuous operation during a power outage, it is recommended that the LT2316 be powered by an uninterruptible power supply or battery.
Power frequency magnetic field (50/60Hz) GB/T 17626.8	3A/m	3A/m, 50/60Hz	The power frequency magnetic field should have the level characteristics of the power frequency magnetic field in a typical place in a typical commercial or hospital environment

Note: U_T refers to the AC network voltage before the test voltage is applied.

Guidelines and Manufacturer's Statement - Electromagnetic immunity			
In-ear hearing AIDS LT2316 is intended for use in the following electromagnetic environments, and the purchaser or user shall ensure that it is used in such electromagnetic environments:			
Immunity test	IEC60601 test level	Coincidence level	Electromagnetic environment - Guide
Rf conduction GB/T 17626.6	3V (RMS) 150 kHz~80 MHz	inapplicability	Portable and mobile RF communication devices should not be used closer to any part of the In-ear hearing AIDS LT2316, including the cable, than the recommended isolation distance calculated by a formula corresponding to the transmitter frequency. Recommended isolation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz~800 MHz $d = 2.3\sqrt{P}$ 800 MHz~2.5 GHz In the formula: P—Based on the maximum rated output power of the transmitter provided by the transmitter manufacturer, in watts (W); d—Recommended isolation distance, in meters (m). The field strength of a fixed RF transmitter is determined by surveying the electromagnetic site A to determine that it should be lower than the coincidence level in each frequency range b. Interference may occur near devices marked with the following symbols. 
Rf radiation GB/T 17626.3	3V/m 80 MHz~2.5 GHz	3V/m	
Note 1: At 80MHz and 800MHz frequencies, the formula for higher frequency bands is used. Note 2: These guidelines may not be suitable for all situations,electromagnetic propagation is affected by the absorption and reflection of buildings, objects and the human body.			
a, The field strength of stationary transmitters, such as wireless (cellular/cordless) telephone and ground mobile radio base stations, amateur radio, AM and FM radio broadcasts, and television broadcasts, cannot be accurately predicted in theory. In order to assess the electromagnetic environment of a fixed RF transmitter, the electromagnetic site survey should be considered. If the in-ear hearing aid LT2316 is measured at a field strength higher than the applicable RF coincidence level above, the in-ear hearing aid LT2316 should be observed to verify normal operation. If abnormal performance is observed, supplementary measures may be necessary, such as re-adjusting the orientation or position of the in-ear hearing aid LT2316. b, in the whole frequency range of 150kHz ~ 80MHz, the field strength should be less than 3V/m.			

Recommended isolation distance between portable and mobile RF communication equipment and In-ear hearing AIDS LT2316			
In-ear hearing AIDS LT2316 is intended for use in electromagnetic environments where radio frequency radiation disturbance is controlled. Depending on the maximum rated output power of the communication equipment, the purchaser or user can protect against electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communication equipment (transmitter) and In-ear hearing AIDS LT2316 as recommended below.			
The rated maximum output power of the transmitter W	The isolation distance /m corresponding to different frequencies of the transmitter		
	150 kHz ~ 80 MHz $d = 1.2\sqrt{P}$	80 MHz ~ 800 MHz $d = 1.2\sqrt{P}$	800 MHz ~ 2.5 GHz $d = 2.3\sqrt{P}$
0.01	inapplicability	0.12	0.23
0.1	inapplicability	0.38	0.73
1	inapplicability	1.2	2.3
10	inapplicability	3.8	7.3
100	inapplicability	12	23
For the maximum rated output power of the transmitter not listed in the table above, the recommended isolation distance d, in meters (m), can be determined by the formula in the corresponding transmitter frequency column, where P is the maximum rated output power of the transmitter provided by the transmitter manufacturer, in watts (W). Note 1: At the 80MHz and 800MHz frequency points, the formula for the higher frequency band is used. Note 2: These guidelines may not be appropriate for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects and the human body.			

XI、【Disposal of waste and residues】

This product has a battery inside, and the host has electronic components. Disposal shall comply with relevant national laws and regulations.。

FCC Warning Statement

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.

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE: 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.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction

Warranty card

Product name		Stamp service
Product model		
Date of purchase		
Customer name		
Customer call		
Customer address		
Fault description		
Maintenance result		