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EMC Core Technology for Comprehensive Diagnosis and Treatment Equipment for Tinnitus and Deafness

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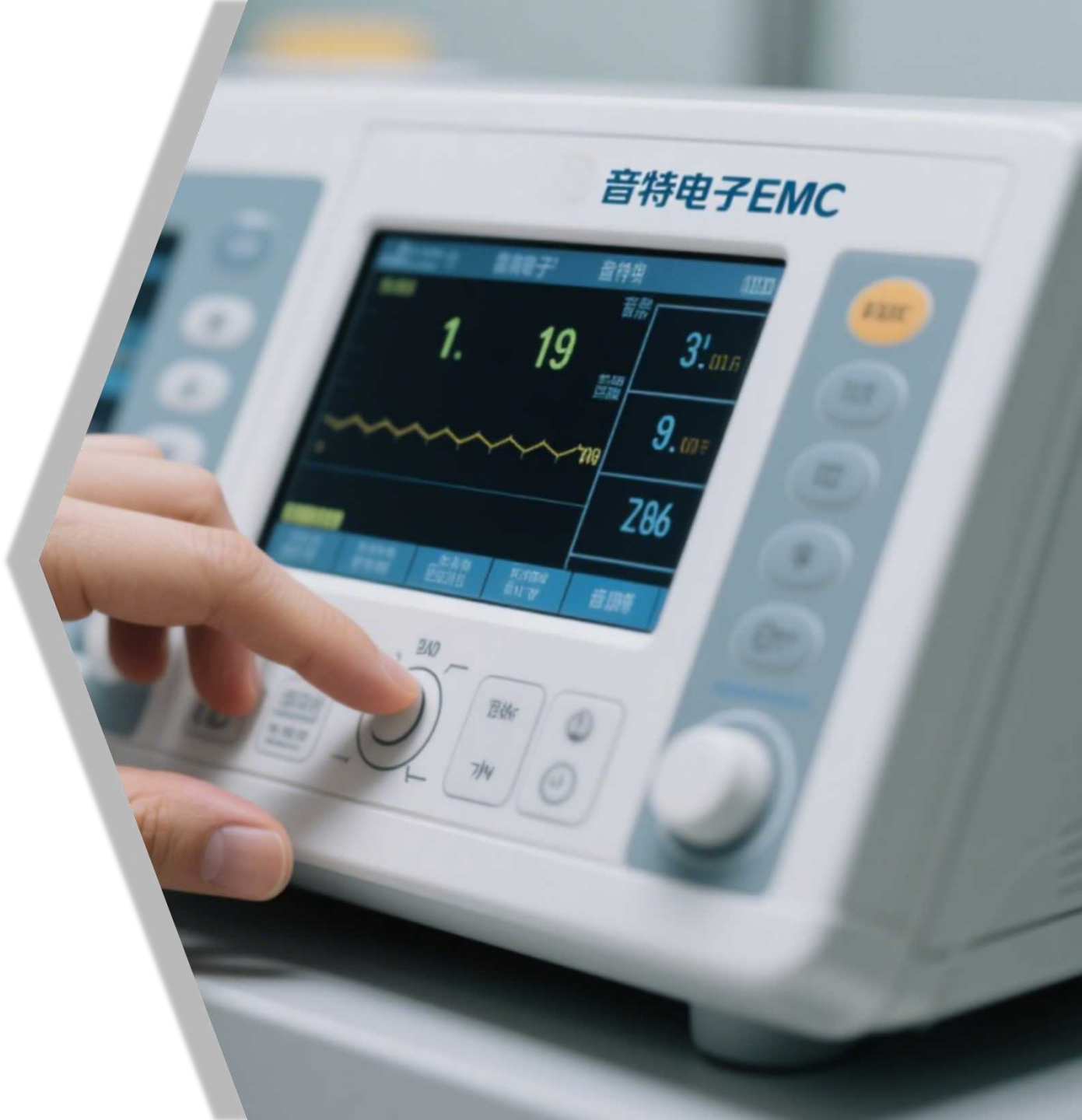
1. International and domestic standards



1.1 International and domestic basic safety and general performance standards

Standard number	Standard Name	Standard Content
IEC 60601-1:2005+AMD2:2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (including 2020 revisions))	Covering core requirements such as equipment electrical safety (such as leakage current ⩽ 0.5 mA), mechanical strength (such as 1.5-meter drop test), and environmental adaptability (temperature range 10-40°C), new risk management requirements for Software as a Medical Device (SaMD) have been added, clarifying that the equipment must pass YY/T0648
IEC 60601-1-2:2014+AMD1:2020	Medical electrical equipment - Part 1-2: Electromagnetic compatibility (EMC) (with 2020 revision)	The regulation requires devices to pass tests such as electrostatic discharge (±8 kV contact discharge) and radio frequency field immunity (10 V/m@80-2700 MHz). It also adds EMC exemptions for home medical environments (such as Bluetooth communication devices) and requires device labels to state "Keep at least 30 cm away from wireless devices."
IEC 60601-2-66:2019	Medical electrical equipment - Part 2-66: Particular safety requirements for hearing aids and assistive listening systems	The dedicated safety standard for hearing aids has been revised to include a voltage range of 1.6-4.5 V, a drop test height of 1.0 meter, new overheating protection requirements for rechargeable batteries, and a requirement that the mechanical coupling strength of bone conduction vibrators must be verified according to ISO 389-3.
ISO 13485:2016	Medical Device Quality Management Systems – Regulatory Requirements	Manufacturers are required to establish a full-process quality management system from design to after-sales service, including supplier audits (e.g., chip suppliers must comply with ISO9001), change control (e.g., software upgrades must be revalidated), and adverse event reporting (e.g., abnormal sound output from tinnitus maskers must be reported within 48 hours). Certification must be conducted through a third-party audit (iso.org).
ISO 14971:2019	Medical Device Risk Management - Application Guide	Mandatory FMEA analysis of device usage risks (e.g., nerve damage from electrical stimulation overload)

1.2 Acoustic Performance and Test Methods

Standard number	Standard Name	Standard Content
ISO 8253-1:2010	Acoustics - Audiometric methods - Part 1: Pure-tone air and bone conduction audiometry	The audiometer frequency accuracy is specified to be ±1% (e.g., 2000Hz error ⩽ 20Hz). Sound pressure level calibration requires the use of TDH-50P headphones with HA-1 artificial ears. The bone conduction vibrator must pass the mechanical coupling test of ISO389-3 standard. The masking noise must meet the equivalent continuous A sound level requirements of ANSIS 3.44-1996.
ISO 8253-3:2022	Acoustics - Audiometric methods - Part 3: Speech audiometry	New requirements for speech balance in multilingual test materials (such as Mandarin Chinese and Spanish) have been added. The test signal must pass the frequency weighting (A-weighting) of IEC61672-1. The speech recognition rate test must be conducted under a signal-to-noise ratio of +10dB. The test results must be compared with the reference database of ISO7029.
IEC 60645-1:2017	Electroacoustics - Audiometric equipment - Part 1: Pure tone and speech audiometric equipment	The original IEC 60645-1 (pure tone) and IEC60645-2 (speech) standards are integrated, requiring the device harmonic distortion to be ⩽3% (125-8000 Hz) and the frequency response range to cover 125-12000 Hz. The speech audiometry module must pass the ISO8253-3 test material verification, and a new verification process for AI algorithm-assisted audiometry has been added.
IEC 60645-5:2004	Electroacoustics - Audiometric equipment - Part 5: Instruments for measuring acoustic impedance of hearing	The probe audio frequency (226 Hz/1000 Hz) and pressure range (-400 to +200 daPa) of acoustic immittance test equipment are specified. The middle ear muscle reflex test must comply with the environmental noise limits of ISO1996-1. The equipment must pass the calibration verification of YY/T0761. New encryption requirements for wireless transmission data are added.
IEC 60118-16:2022	Electroacoustics - Hearing aids - Part 16: Definition and verification of hearing aid functionality	Regarding the noise reduction and feedback suppression functions of smart hearing aids, it is stipulated that the noise reduction effect must pass the inversion method test (SNR improvement ⩾ 1dB), the manual/automatic program switching response time must be ⩽ 200 ms, and multi-channel processing must comply with the measurement uncertainty requirements of ISO 21748, filling the gap in the standard of hearing aid function testing in China. National Standard Information Public Service Platform

1.EU CE Marking (MDR Regulation)

Classification Rules: Hearing aids and audiometers are Class IIa, while neurostimulation devices may be Class IIb or III. They must comply with the General Safety and Performance Requirements (GSPR) of MDR Annex I.

Technical Documentation: This includes a risk management report, clinical data (such as residual suppression test results), labeling and instructions (including the CE mark and UDI code).

2.US FDA Certification

510(k) Pathway: Non-implantable tinnitus devices (such as maskers) must demonstrate substantial equivalence to marketed products (such as ANSI S3.44-1996 devices) through equivalence comparisons. (accessdata.fda.gov)

De Novo Pathway: Innovative devices (such as Lenire) must submit multicenter clinical trial data demonstrating safety and efficacy (such as a THI score improvement rate ⩾ 58.6%).

3.Other Regions

Japan PSE Certification: Must comply with the electromagnetic compatibility requirements of JIS C60601-1-2 and the hearing device performance standard of JIS T0601-2-70.

Australian TGA Certification: Comply with AS/NZS 60601 series standards and registered with TGA

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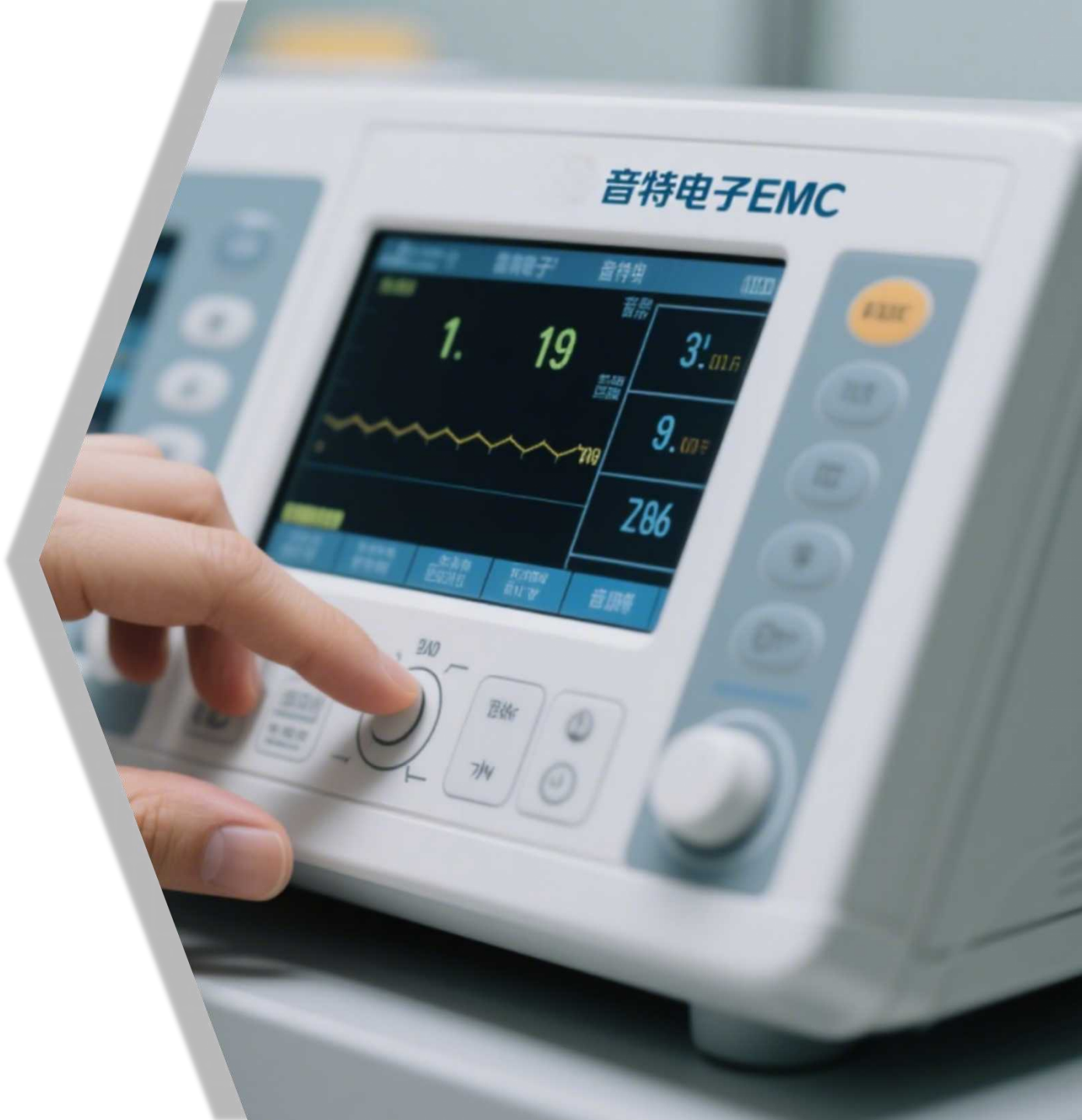
2. Standard electronic part electromagnetic compatibility EMC content



2.1 The meaning and importance of electromagnetic compatibility

Electromagnetic compatibility (EMC) refers to the state in which devices can function together and perform their respective functions in a shared electromagnetic environment.

In a hospital setting, comprehensive tinnitus and deafness diagnosis and treatment equipment must operate alongside numerous instruments, meters, power grids, and other equipment. Electromagnetic emissions from these devices must not degrade functionality or impair performance, nor disrupt the normal operation of other equipment. This is crucial for ensuring the stable operation of medical equipment and the smooth delivery of medical services.

2.2 Research fields of electromagnetic compatibility

01

The interference source studies the mechanism and characteristics of electromagnetic radiation generated by electronic equipment, such as the electromagnetic radiation that may be generated when the circuit inside the diagnostic equipment is working.

02

The anti-interference performance of sensitive equipment focuses on the equipment's resistance to electromagnetic interference. If tinnitus and deafness comprehensive diagnosis and treatment equipment is to be able to accurately detect and treat in complex electromagnetic environments, it must have good anti-interference performance.

03

The propagation characteristics of electromagnetic disturbances study the laws of electromagnetic disturbance propagation through space radiation, wire conduction, etc., so as to take targeted measures to suppress the propagation of disturbances.

04

Electromagnetic compatibility measurement methods include measurement techniques and specifications for electromagnetic emissions and immunity, and accurate measurements are used to determine whether the equipment complies with EMC standards.

05

Electromagnetic compatibility analysis within and between systems ensures electromagnetic harmony between components within the equipment and between different equipment systems

2.3 Explanation of Basic Terms

01

Emission is the process of a device releasing electromagnetic energy to the outside world. If the electromagnetic energy emitted by the tinnitus and deafness comprehensive diagnosis and treatment equipment is too large, it may interfere with other medical equipment.

02

Performance degradation means that the function or performance of the device cannot meet the expected standards due to interference, such as inaccurate device detection data and affected treatment effects.

03

Electromagnetic interference is an electromagnetic phenomenon that causes equipment performance degradation or poses a threat to life safety. For example, electromagnetic noise generated by nearby high-power equipment may interfere with diagnostic and treatment equipment.

04

Interference signals are signals that have a negative impact on useful signals and will affect the device's accurate detection and analysis of tinnitus and deafness signals.

05

Interference degree reflects the ability of the equipment to maintain normal operation in the face of electromagnetic interference. The higher the interference degree, the less the equipment is affected by the interference.

06

Sensitivity reflects the susceptibility of the device to electromagnetic interference. The higher the sensitivity, the lower the immunity and the more susceptible it is to interference.

07

The margin is the difference between the actual measured value and the standard requirement. It is usually recommended that the margin be at least 3dB to ensure that the device can meet the EMC standard in different environments.

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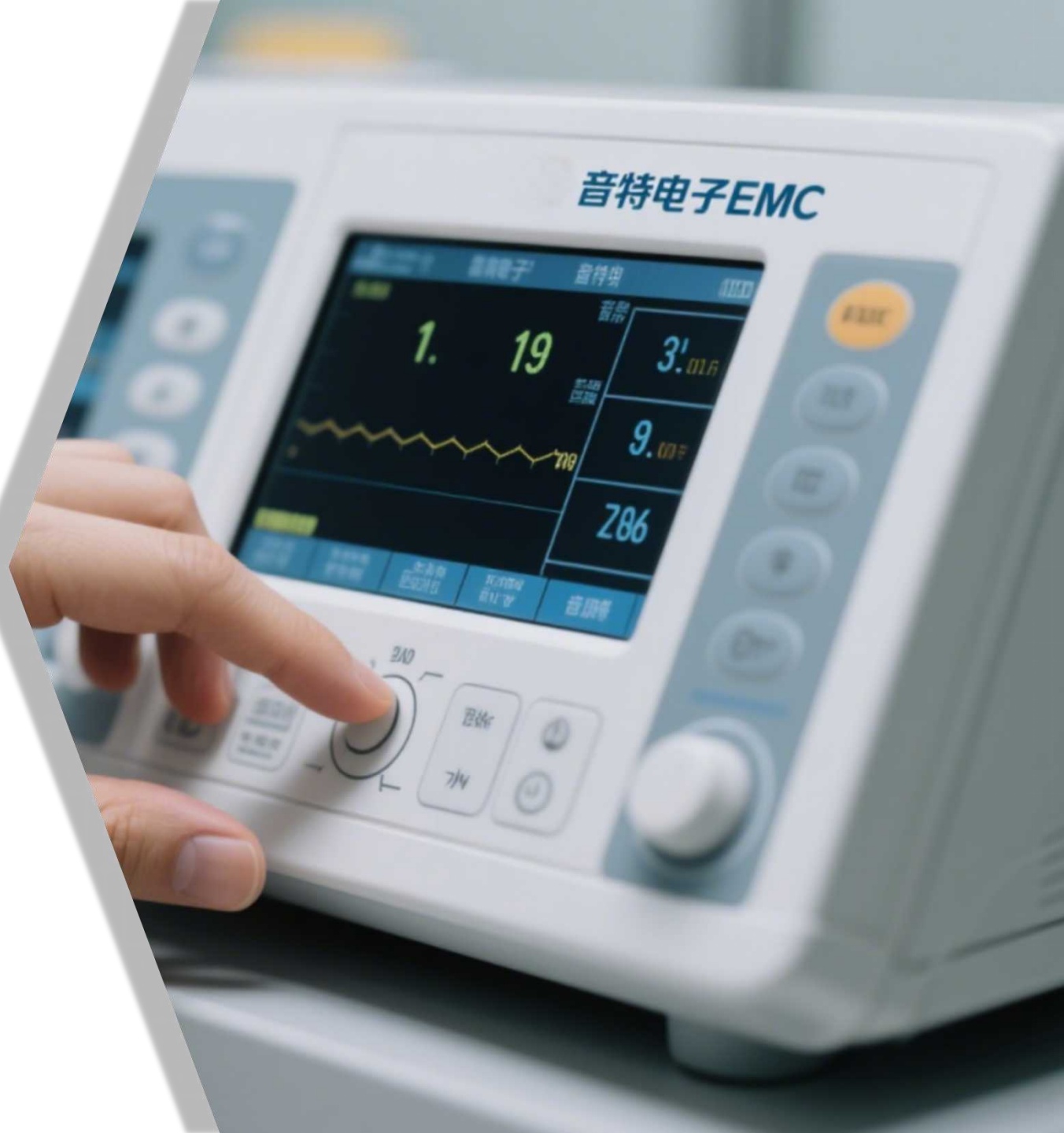
3. Application issues of comprehensive diagnosis and treatment equipment for tinnitus and deafness



3.1 Pain points in actual application process

Electromagnetic interference leads to detection errors: In the complex electromagnetic environment of the hospital, electromagnetic interference generated by other medical equipment and communication equipment around may cause errors in the detection of key data such as the degree of hearing loss and tinnitus frequency by tinnitus and deafness comprehensive diagnosis and treatment equipment, affecting the doctor's accurate judgment of the patient's condition.

Insufficient immunity affects the treatment effect: If the device's immunity is insufficient, it may be subject to external electromagnetic interference during the treatment process, which may lead to unstable treatment parameters, such as deviations in the intensity and frequency of sound stimulation, thus failing to achieve the expected treatment effect and delaying the patient's recovery process.

Equipment compatibility issues: When tinnitus and deafness comprehensive diagnosis and treatment equipment is connected to the hospital information system and other auxiliary medical equipment, compatibility issues such as communication failures and data transmission errors may occur due to poor electromagnetic compatibility, hindering the smooth progress of medical processes and the effective management of patient information.

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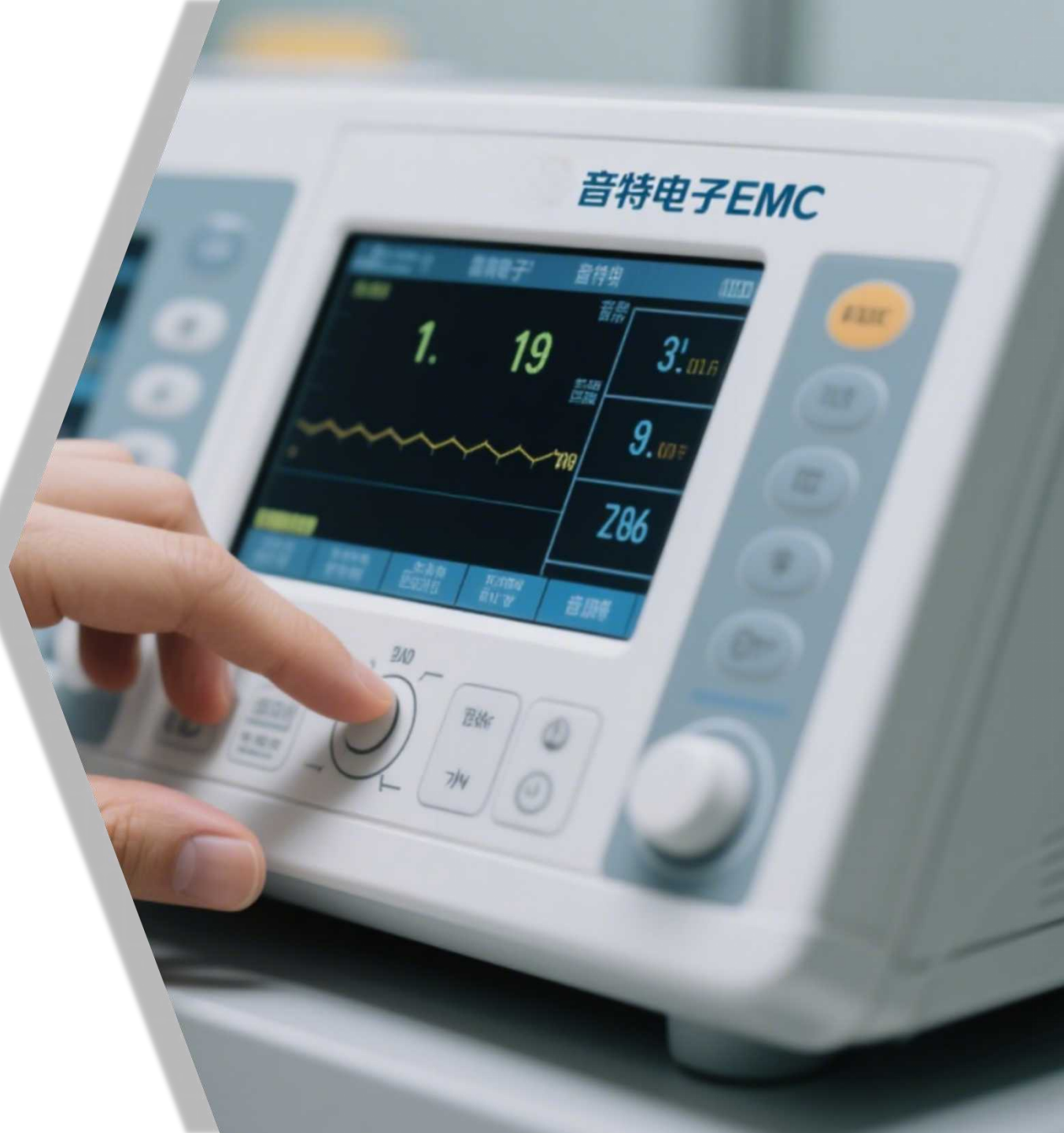
4. Equipment I/O interface and EMC solutions



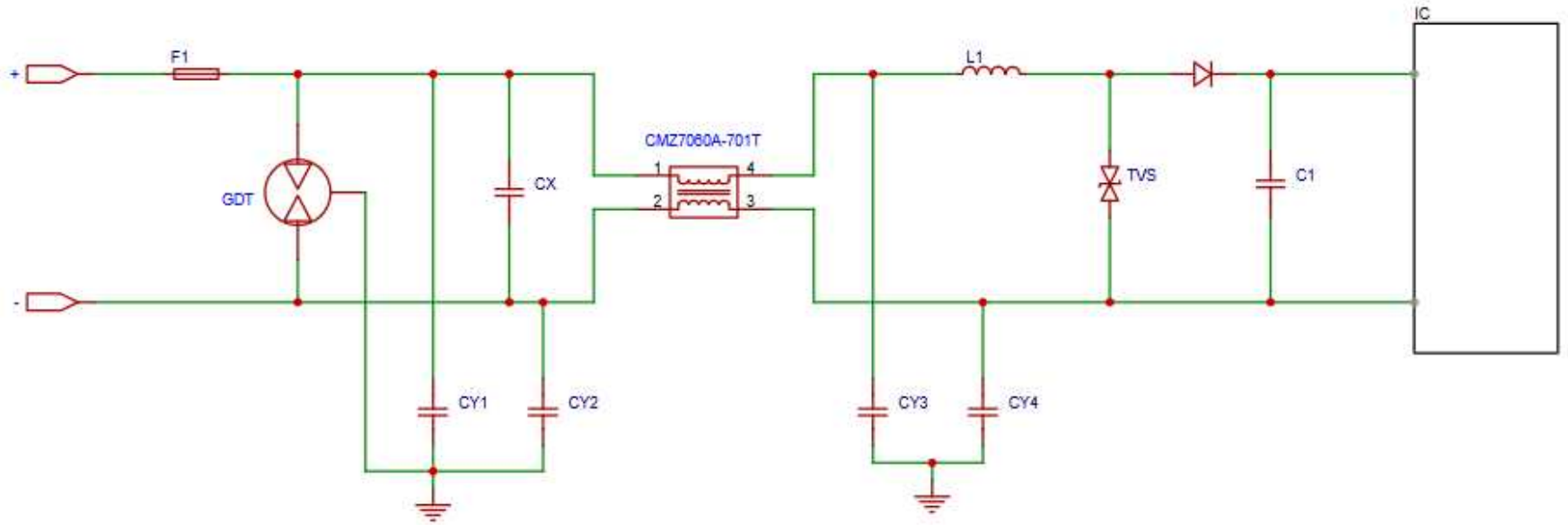
4.1 Main external I/O interfaces

Data interface: used for data transmission with external devices. For example, it can be connected to a computer to upload the patient's hearing test data, tinnitus treatment plan and other information for storage and analysis. It can also download and update the device's software program and treatment algorithm from the computer to ensure the advanced function of the device and the convenience of data management.

Audio interface: responsible for outputting and inputting audio signals, outputting therapeutic sound signals to the transducer (speaker) to provide sound stimulation therapy for patients; at the same time, it can receive sound signals from external audio equipment for functions such as hearing testing, ensuring stable transmission and accurate processing of audio signals

4.2 Power Interface EMC and Reliability Design

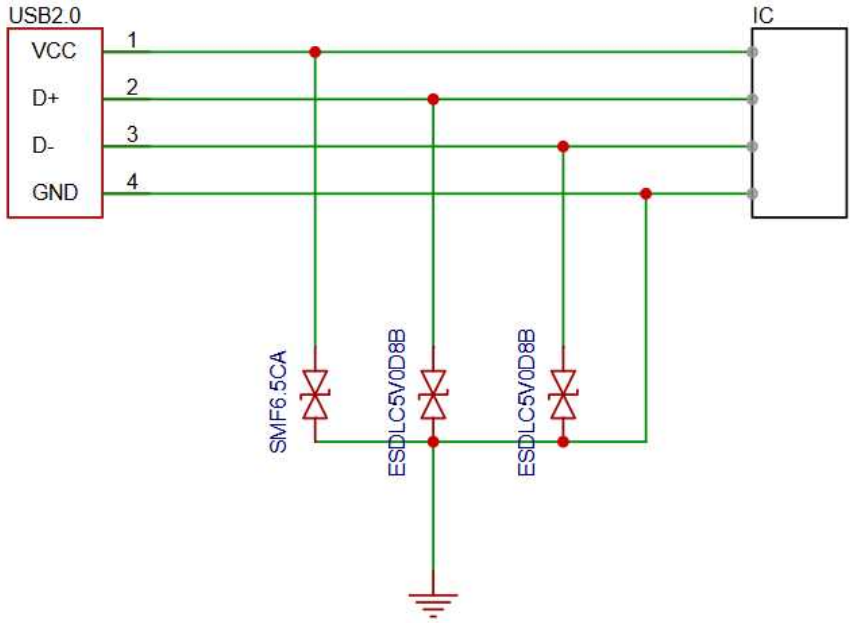
DC power interface: used to connect an external 5V DC input power adapter



model	Device Type	Use Location	effect	Encapsulation
3R090L	GDT	Power interface	Surge and lightning protection (for outdoor products, pay attention to the issue of continuous current)	3RXXXL
SMBJ6.5CA	TVS Transient Voltage Suppressor Diodes	Power interface	Surge, load dump	SMB/Do-214AA
CMZ7060A-701T	EMI common-mode suppressors	Power interface	CE conduction, common mode suppression, smaller current, consider small package	7060

4.3 USB-2.0 Interface EMC and Hot-Swap Reliability Design

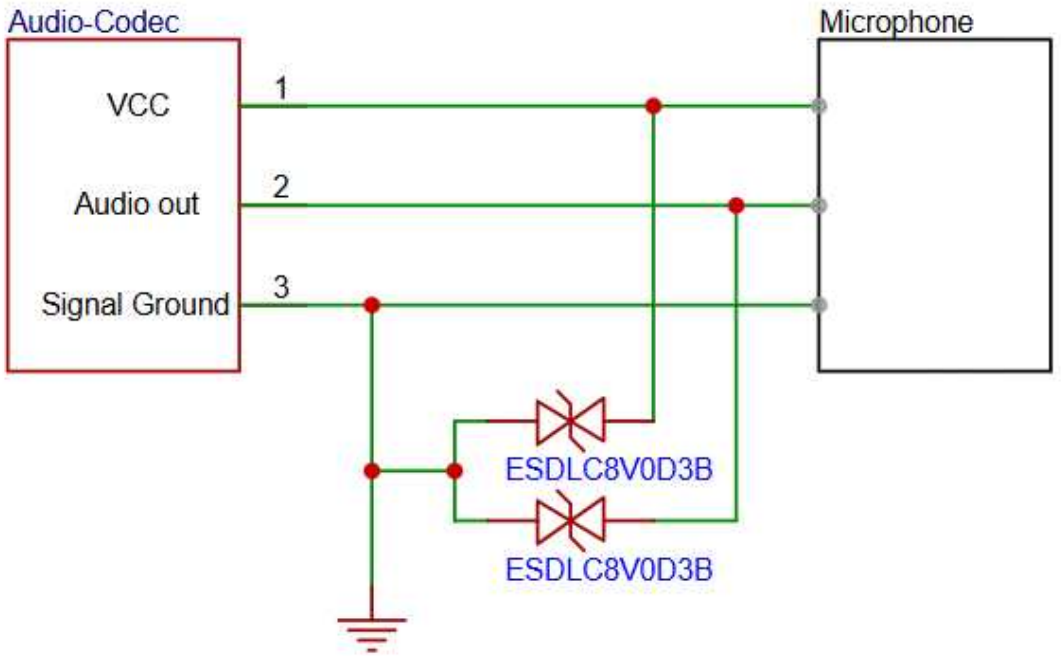
USB-2.0 interface: USB 2.0 is designed to provide faster data transfer speeds and better device compatibility; it also achieves a leap in interface speed, increasing it from the original maximum of 12 Mbps to 480 Mbps; this allows the USB interface to meet the needs of more high-bandwidth devices, such as high-speed printers, scanners, external storage devices, and multimedia devices.



model	Device Type	Use Location	effect	Encapsulation
ESDLC5V0D8B	ESD	USB interface	Surge, static electricity	DFN1006
SMF6.5CA	TVS	USB interface	Surge, load dump	SOD123FL

4.4 Audio Interface (3.5mm) EMC and Hot-Swap Reliability Design

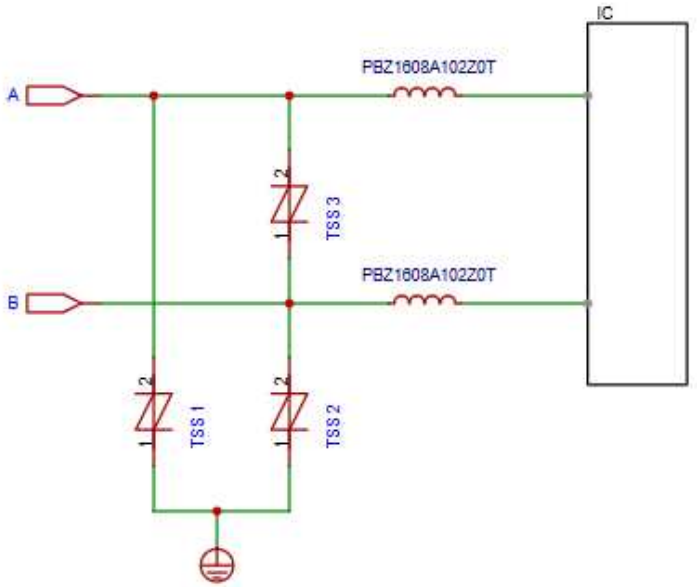
Audio interface (3.5mm): supports microphone input or speaker output



model	Device Type	Use Location	effect	Encapsulation	Features
ESDLC8V0D3B	ESD	Audio Interface	Surge, static electricity	SOD323	Convenient manual welding
ESDLC5V0D8B	ESD	Audio Interface	Surge, static electricity	SOD882	Suitable for machine patch

4.5 RS-485 Interface EMC and Hot-Swap Reliability Design

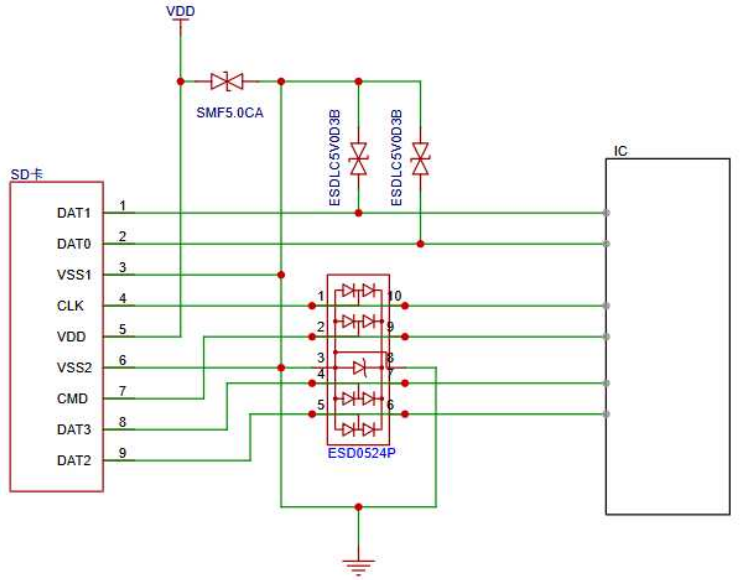
RS485 interface: RS-485 is a serial communication standard that can support multiple devices to communicate through the same serial bus; it is suitable for medium and long distance communication and has good anti-interference ability and data transmission stability.



model	Device Type	Use Location	effect	Encapsulation
P0080SCL	TSS	RS485 interface	Surge, static electricity	SMB
PBZ1608A102Z0T	magnetic beads	RS485 interface	Eliminate high-frequency interference	1608

4.6 Storage Interface EMC and Hot-Swap Reliability Design

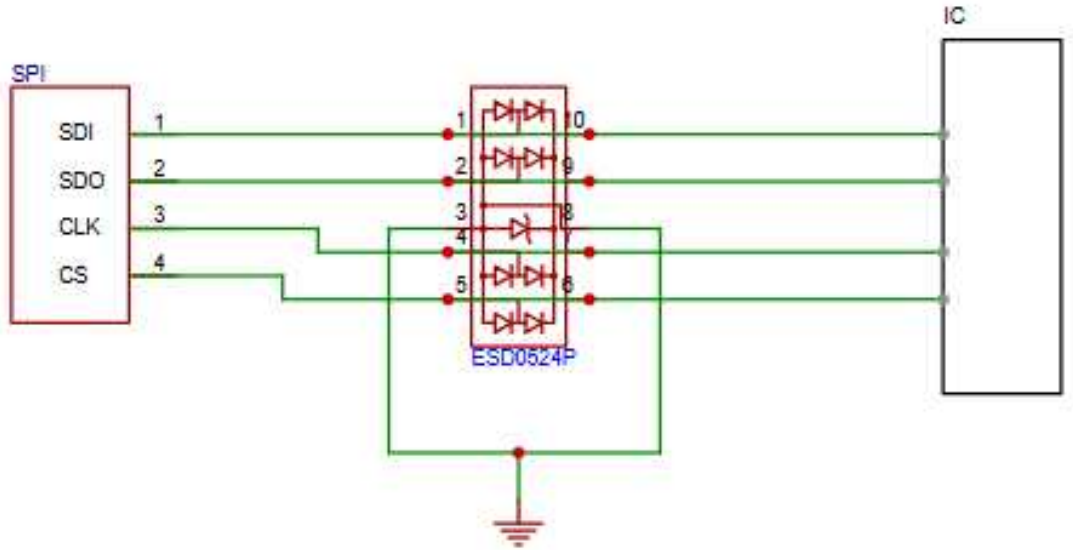
SD card slot: used to expand storage capacity and store system files or data **TF card slot:** some small development boards use TF cards as storage media

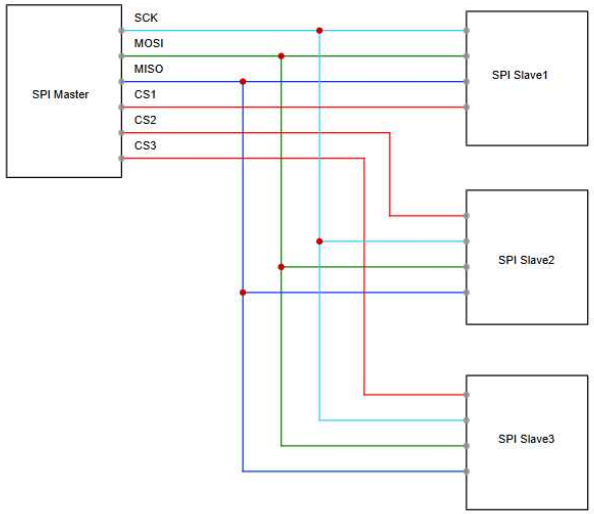


model	Device Type	Use Location	effect	Encapsulation
ESD0524P	ESD	SD card interface	Surge, static electricity	DFN2510
ESDLC5V0D3B	ESD	SD card interface	Surge, static electricity	SOD323
SMF5.0CA	TVS	SD card interface	Surge, load dump	SOD123FL

4.7 SPI Interface EMC and Hot-Swap Reliability Design

SPI interface: high-speed serial communication interface, used to connect memory chips, display screens, etc.

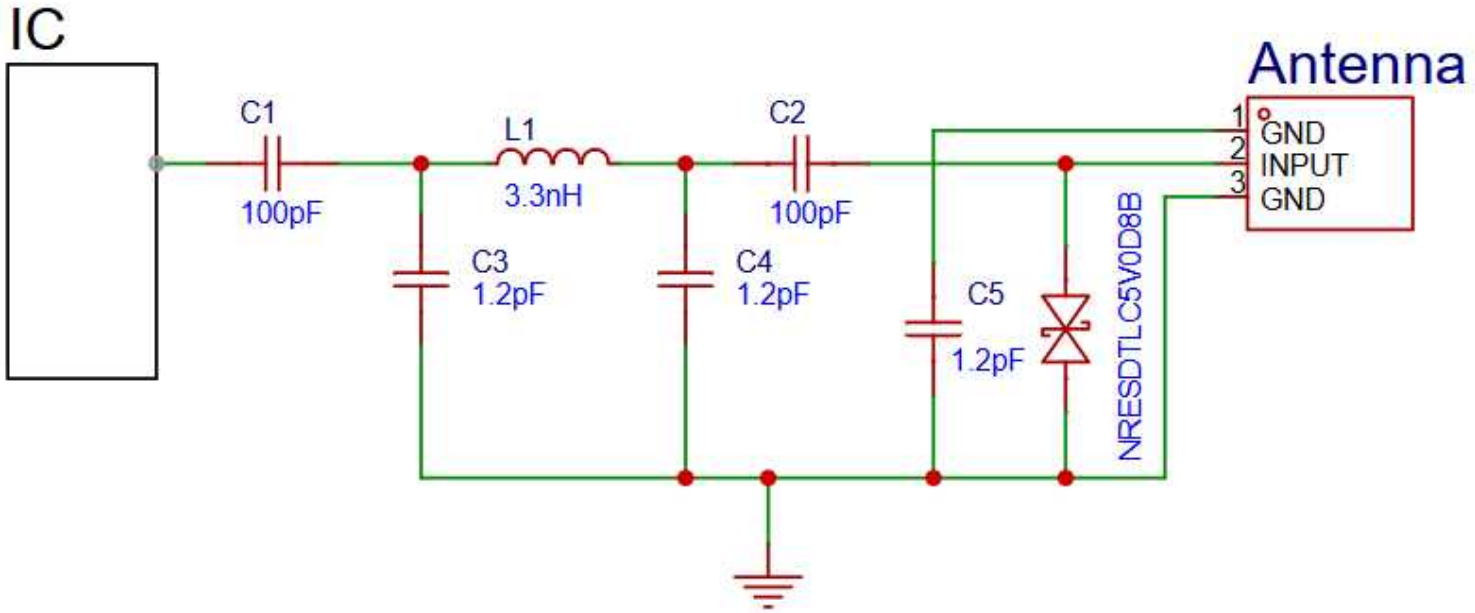




model	Device Type	Use Location	effect	Encapsulation
ESD0524P	ESD	SPI interface	Surge, static electricity	DFN2510

4.8 WIFI Antenna EMC and Reliability Design

WIFI antenna: WIFI antenna is a device used to transmit and receive electromagnetic waves. It realizes wireless communication by transmitting and receiving electromagnetic waves. At the same time, the antenna selectively receives or transmits electromagnetic waves of a specific frequency through a specific shape and size, realizing the mutual conversion between electrical signals and electromagnetic waves.



model	Device Type	Use Location	effect	Encapsulation
NRESDTLC5V0D8B	ESD	Power interface	Surge, static electricity	DFN1006

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