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Electromagnetic compatibility of medical infusion pumps

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1. International industry standards

1.1 International Standard ISO 14708

ISO 14708-4:2022 is a standard for active implantable medical devices in surgical implants. Part 4 specifically addresses implantable infusion pump systems. This standard specifies specific requirements for active implantable medical devices used to deliver drugs to specific locations within the human body, providing basic safety assurance for patients and users. For reference, please refer to the following national standards:

GB 16174.1-2015, General Requirements for Active Implantable Medical Devices

GB 9706.224-2021, Extracorporeal Infusion Pumps; some safety requirements are comparable.

1.2 International Standard ISO 14708

ISO14708-4:2022 indirectly refers to ISO 14117:2019. Implantable infusion pumps must meet the following EMC tests.

Test items	Standard basis	Key requirements
RF radiation immunity	IEC 61000-4-3	In the 80 MHz to 2.7 GHz frequency band, it must withstand a field strength of 3 V/m or 10 V/m (depending on the intended use environment)
Electrostatic Discharge (ESD)	IEC 61000-4-2	Contact discharge ±2 kV to ±8 kV Air discharge ±2 kV to ±15 kV, equipment must maintain basic performance
lectrical fast transient (EFT)	IEC 61000-4-4	Power ports ±1 kV to ±4 kV Signal ports ±0.5 kV to ±2 kV, must not cause program errors or data loss
Surge immunity	IEC 61000-4-5	Power port ±1 kV~±2 kV (line to ground), the equipment shall not be damaged or have permanent function loss
Conducted RF immunity	IEC 61000-4-6	150 kHz to 80 MHz frequency band, 3 V/m or 10 V/m, the device must not be falsely triggered or have abnormal output
Power frequency magnetic field immunity	IEC 61000-4-8	Withstands 30 A/m magnetic fields (such as near MRI environments) to avoid unexpected pump shutdowns or dosage errors

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2. Domestic industry standards

2.1 国内标准 GB 9706

ICS 11.040
C 30

中华人民共和国国家标准

GB 9706.1—2020
代替 GB 9706.1—2007，GB 9706.15—2008

医用电气设备　第 1 部分：基本安全和基本性能的通用要求

Medical electrical equipment—Part 1: General requirements for basic safety and essential performance

(IEC 60601-1:2012,MOD)

ICS 11.040.20
CCS C 31

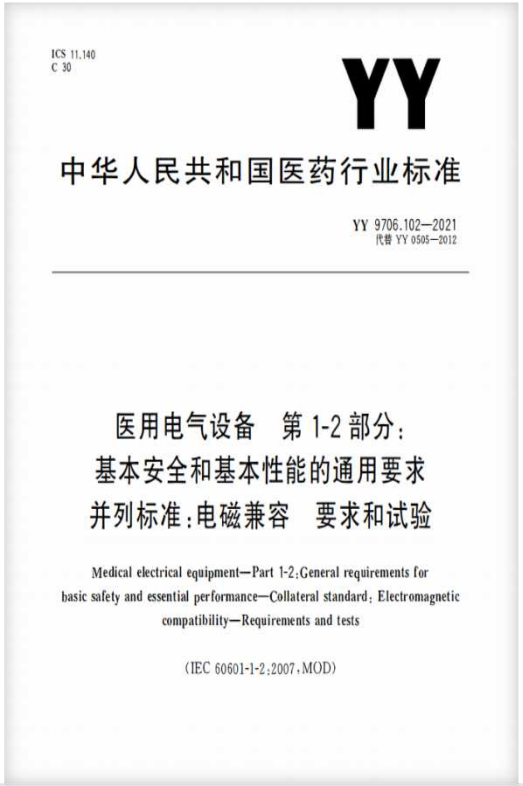
中华人民共和国国家标准

GB 9706.224—2021
代替 GB 9706.27—2005

医用电气设备　第 2-24 部分：输液泵和输液控制器的基本安全和基本性能专用要求

Medical electrical equipment—Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers

(IEC 60601-2-24:2012,MOD)



ICS 11.140
C 30

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中华人民共和国医药行业标准

YY 9706.102—2021
代替 YY 0505—2012

医用电气设备　第 1-2 部分：基本安全和基本性能的通用要求　并列标准：电磁兼容　要求和试验

Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance—Collateral standard: Electromagnetic compatibility—Requirements and tests

(IEC 60601-1-2:2007,MOD)

ICS 11.040.01
C 30

YY

中华人民共和国医药行业标准

YY 9706.108—2021
代替 YY 0709—2009

医用电气设备　第 1-8 部分：基本安全和基本性能的通用要求　并列标准：通用要求，医用电气设备和医用电气系统中报警系统的测试和指南

Medical electrical equipment—Part 1-8: General requirements for basic safety and essential performance-Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

(IEC 60601-1-8:2006+A1:2012,MOD)

2.2 Domestic Standard GB 9706.224-2021

It is part 2-24 of medical electrical equipment and specifies the basic safety and essential performance requirements for infusion pumps and infusion controllers.

project	content	Standard basis	Remark
EMC basic standards	Cited by YY 9706.102-2021 (equivalent to IEC 60601-1-2:2014)	201.2	General requirements
Immunity test level	Modify the test voltage of YY 9706.102 to adopt the contact discharge and air discharge levels in Table 202.101	202.6.2.2.1	See standard
Basic performance requirements	High priority alarms such as blockage alarms and air detection must still function properly after EMC testing.	202.6.2.1.3	Key safety features
Electrostatic discharge (ESD) testing	According to IEC 61000-4-2, use the adjusted test levels (see Table 202.101)	202.6.2.2.1	The device status after each discharge needs to be evaluated separately
Special requirements for portable infusion pumps	It is allowed to relax the characteristics of the auditory alarm signal (such as frequency, harmonics), but the volume must be ⩾ 45 dBA (1 meter) and cannot be adjusted	208.6.3.3.1	Suitable for insulin pumps, etc.
Performance requirements after testing	Voltage 1-3: The device must operate normally within the specification range Voltage 4: Temporary degradation is allowed, but it must not cause permanent damage or cause danger (such as incorrect infusion)	202.6.2.2.1	Need to avoid data loss or unrecoverable failures

2.3 Domestic Standard GB 9706.1-2020

GB 9706.1-2020, "Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance," is cited as a parallel standard and is equivalent to IEC 60601-1-2. It specifically specifies electromagnetic compatibility requirements and test methods for medical electrical equipment.

1. It specifies the electromagnetic environment characteristics of the power supply network, including the transient overvoltage category (usually Category II) and the voltage fluctuation range (90% to 110% of the nominal voltage).

2. It specifies specific requirements for power supply network transients, short interruptions, and voltage fluctuations.

3. When measuring patient leakage current, it is necessary to consider external voltages on the signal input/output (such as coupled voltages caused by electromagnetic interference) to ensure that they do not exceed the permissible limit.

2.4 Domestic Standard YY/T 1653-2020

YY/T 1653-2020 is the industry standard for infusion pump tubing. It specifies in detail the materials, dimensions, physical properties, chemical properties, and biological properties of infusion pump tubing to ensure compatibility between the tubing and the infusion pump, prevent leakage, blockage, and other problems, and ensure a smooth and safe infusion process. It is an important component of the overall infusion pump system to meet safety and performance standards.

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3.EMC test related requirements

3.1 Electrostatic Discharge (ESD) Immunity Requirements

The EMC standard for medical electrical equipment stipulates that the electrostatic discharge (ESD) immunity indicators for medical equipment are: ±2kV, ±4kV, and ±6kV for air discharge. During testing, compliance with these requirements is determined based on the medical device immunity compliance criteria.

To test whether medical equipment can withstand external ESD interference, an electrostatic generator is typically used. It can generate electrostatic voltages ranging from thousands to tens of thousands of volts, simulating actual ESD on the test equipment. Simulated ESD can be divided into contact discharge and air discharge. Contact discharge involves directly contacting the discharge electrode of the electrostatic generator with the metal casing of the device. Air discharge involves bringing the discharge electrode of the electrostatic generator close to the device under test, causing a spark to discharge the device. Indirect discharge, or indirect air discharge, involves discharging the discharge electrode of the electrostatic generator through a 0.5m x 0.5m metal plate placed vertically 10cm from the device's housing.

3.2 Fast transient burst immunity requirements

Because the AC power supply used by medical electrical equipment is typically connected to the public power grid, the potential generated by the closing of switches or relays in high-power inductive loads in other electrical equipment on the grid can cause intermittent discharges. This intermittent discharge generates fast transients with considerable energy in the power lines, potentially causing interference to medical equipment on the grid. The standard stipulates that fast transients of ±0.5kV, ±1kV, and ±2kV should be applied to AC and DC power lines.

During the test, compliance with the requirements will be determined according to the medical equipment immunity compliance criteria. To verify the ability of electrical and electronic equipment to withstand fast transients on the public power grid, a fast transient generator with a specific waveform should be used to inject the transients into the power lines, other signal cables, and interconnecting cables through a coupling device.

3.3 Lightning Surge Immunity Requirements

When lightning strikes naturally, the powerful electromagnetic field can induce large voltage surges on power lines or communication lines, known as surges. Furthermore, surges similar to lightning voltages can occur when high-power loads are switched on and off, or when power system faults occur.

Surges have a low frequency and can be transmitted through power lines or communication lines to distant equipment, disrupting normal operation or even damaging it. The standard requires applying ±0.5kV, ±1kV, and ±2kV to ground on each phase of an AC power line; and ±0.5kV and ±1kV to phase on each phase.

To verify whether electrical and electronic equipment can withstand surge voltage interference from the public power grid, a surge voltage is injected into the power line through a coupling device. The test method applies to national standard GB/T17626.5.

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4. Industry pain points of medical infusion pumps

4.1 Industry Pain Points

Pain Point Ranking	Problem Area	Condensation capacity	Briefly describe the solution
1	EMC talent shortage	Medical-grade EMC rectification experience	Third-party EMC solution professionals (such as free training from Yinte Electronics)
2	The contradiction between low power consumption and high precision	Ultra-low power analog circuit design	Use new low-noise power supply ICs (such as TI's TPS series)
3	Motor drive EMI	Motor control and EMC collaborative design	Optimize PCB layering and grounding strategies, and increase EMI components
4	Interference with wireless functions	RF and digital circuit isolation design	Select medical-grade wireless modules
5	Conflict between safety regulations and EMC	Safety-EMC collaborative design capabilities	Simulation-driven design (such as ANSYS HFSS)
Typical Cases	The infusion pump motor drive circuit radiation exceeds the standard (30MHz~1GHz frequency band), requiring repeated design modifications, increasing costs.		
	Low-noise LDO power supplies and dynamic power management, but balancing accuracy and EMC performance		
	Stepper motors/DC motors generate high-frequency noise when starting and stopping, which can easily cause radiated emissions (RE) and conducted emissions (CE) to exceed the standards.		
	Wireless modules (such as Bluetooth Low Energy) introduce radio frequency interference, which may affect the reliability of the infusion pump control circuit.		
	Common mode choke + Y capacitor combination, but be careful to avoid leakage current exceeding the standard		

4.2 Regulatory Policy Risks

The medical device industry is subject to strict regulation, with increasingly stringent policies. As a critical medical device, the production, sale, and use of infusion pumps must comply with relevant laws and standards. Companies must constantly monitor regulatory changes to ensure their products meet the latest standards and regulations.

Regulatory changes may require product improvements and recertification, increasing costs and time, potentially delaying product launches and impacting market competitiveness.

If companies fail to promptly adapt to regulatory changes, they risk product recalls and fines, severely damaging their reputation and financial performance.

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5. Circuit design solutions for EMC

01

Floating Ground

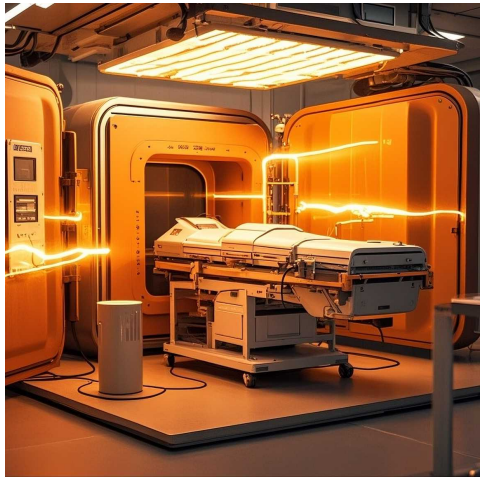
Insulate the "zero" potential of the circuit or the "zero" potential of the equipment from the public grounding system, or the public wire that may cause circulating current, that is, do not ground it, so that this "zero" potential is a floating "zero" potential relative to the zero potential of the earth. Common methods include transformer isolation and optocoupler isolation. The advantage of floating ground is strong anti-interference ability, because it cuts off the direct connection with the public grounding system, reducing the possibility of external interference entering the equipment through the grounding line. But the disadvantage is static electricity accumulation. When the charge accumulates to a certain level, the potential difference between the equipment ground and the public ground may cause violent static electricity discharge, and become a very destructive interference source. The solution is to connect a discharge resistor across the floating ground and the public ground. The resistance value should be appropriate not to affect the leakage current requirement of the equipment. The accumulated static electricity is slowly released through the discharge resistor to avoid the harm caused by static electricity discharge.

02

Single-point grounding

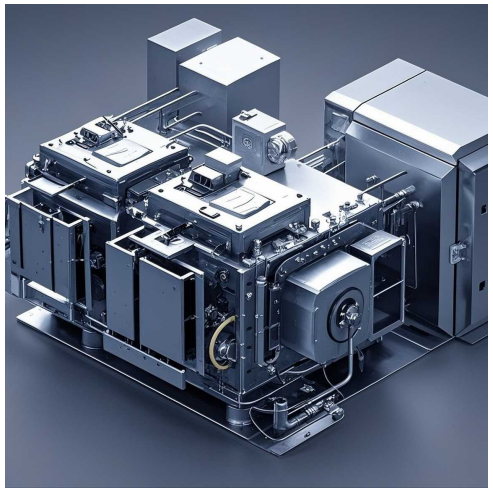
Single-point grounding is when all points in a circuit or device that require grounding are connected to a single, defined physical reference point. If single-point grounding is used in a system, each device must have its own single ground point, and each device's ground is then connected to the system's single, designated reference ground point. This grounding method effectively prevents ground loop interference at low frequencies and ensures grounding stability. However, its disadvantage is that at high operating frequencies, the system exhibits a certain reactance effect, resulting in poor grounding effectiveness. This is because the inductance of the ground line at high frequencies creates a large impedance, affecting grounding effectiveness.

5.2 Shielding Design



Electric field shielding

The mutual induction between objects with different potentials in instruments and equipment can be viewed as the voltage distribution between distributed capacitors. To reduce the interference of interference sources on the induced objects, measures such as increasing the distance between the interference source and the induced object to reduce the distributed capacitance, placing the induced object as close as possible to the ground plane to increase its capacitance to ground, and adding a metal shielding layer between the two are common. The shielding layer must be a well-conducting conductor with sufficient strength and good grounding. For example, equipment that directly contacts the human body, such as electrocardiographs, monitors, acupuncture and electrotherapy devices, or silver needles, should be kept away from the radiation zone of ultrashort wave therapy machines, high-frequency electrosurgical units, X-ray machines, CT scans, MRI machines, and any other medical equipment that radiates electromagnetic waves. This is why the high-voltage cable shielding layer of X-ray machines is so important. A good shielding layer can effectively block electric field interference and ensure the normal operation of the equipment.

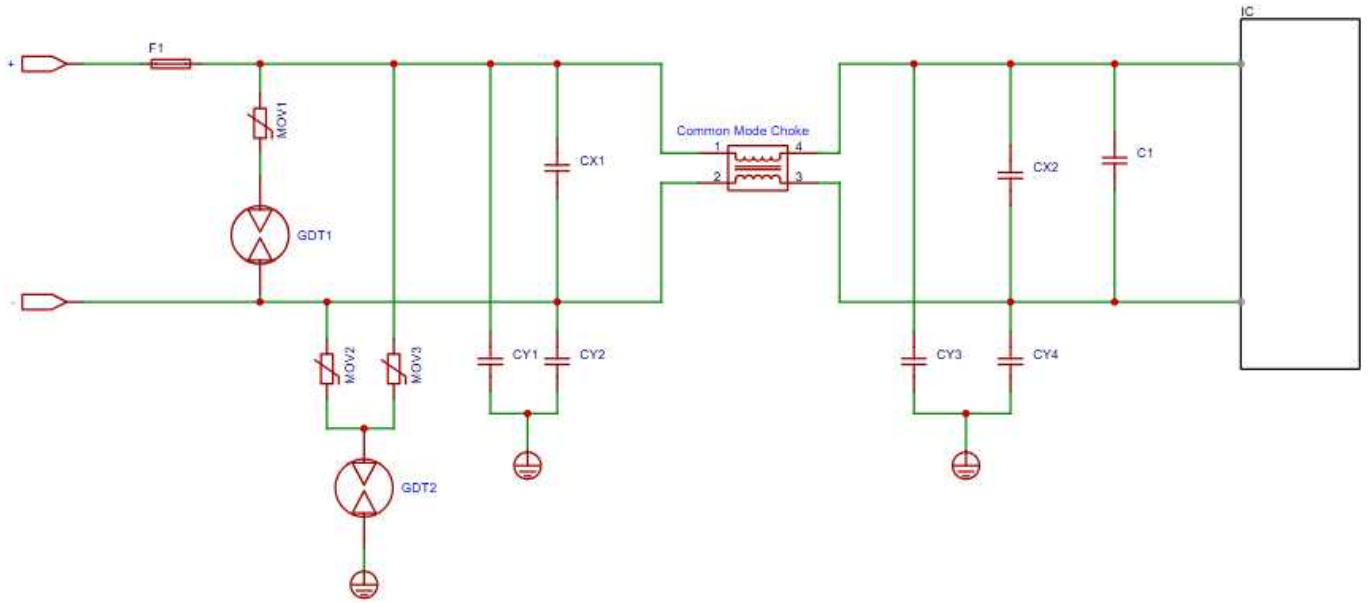


Magnetic field shielding

Magnetic field shielding refers to the shielding of DC or low-frequency magnetic fields. The shielding principle is to use the high magnetic permeability and low magnetic resistance of the shielding body to create a magnetic shunt effect on the magnetic flux, thereby weakening the magnetic field inside the shielding body. In order to reduce the magnetic resistance of the shielding body, the material used must be high magnetic permeability and have a certain thickness. The shielded object should be placed in the center of the shielding body as much as possible, and it is important that gaps and ventilation holes are distributed along the direction of the magnetic field to reduce magnetic field leakage. For example, in some medical devices that are sensitive to magnetic fields, high magnetic permeability metal materials are used to make shielding covers to wrap the equipment, which can effectively shield the interference of external magnetic fields and ensure the measurement accuracy and stability of the equipment.

5.3 AC power interface EMC and reliability design

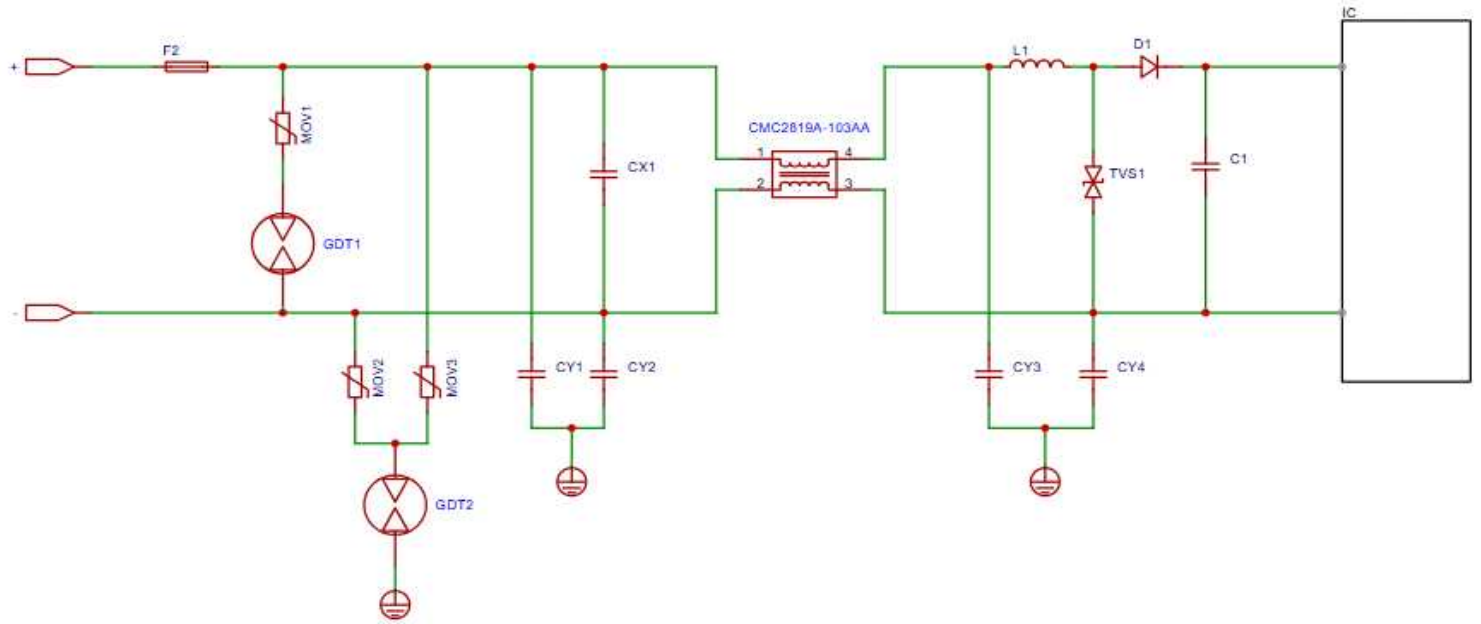
AC power interface: used to connect external 220V AC input



model	Device Type	Use Location	effect	Encapsulation
2R600L	GDT	Power interface	surge, lightning protection (outdoor products, focus on the issue of continuous current)	2RXXXL
14D561K/14D511K	MOV	Power interface	surge, lightning protection	14D
CMZ/CML	EMI common-mode suppressors	Power interface	Common-mode rejection	SMD

5.4 12V/24V Vehicle Power Supply Interface EMC and Reliability Design

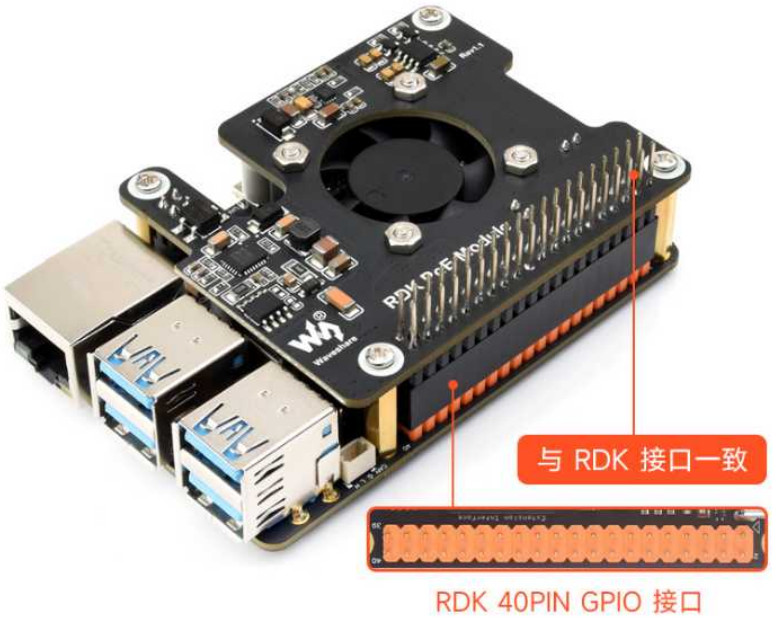
DC power interface: used to connect to an external 12V/24V vehicle power input, supporting offline use (such as when the patient is moving)

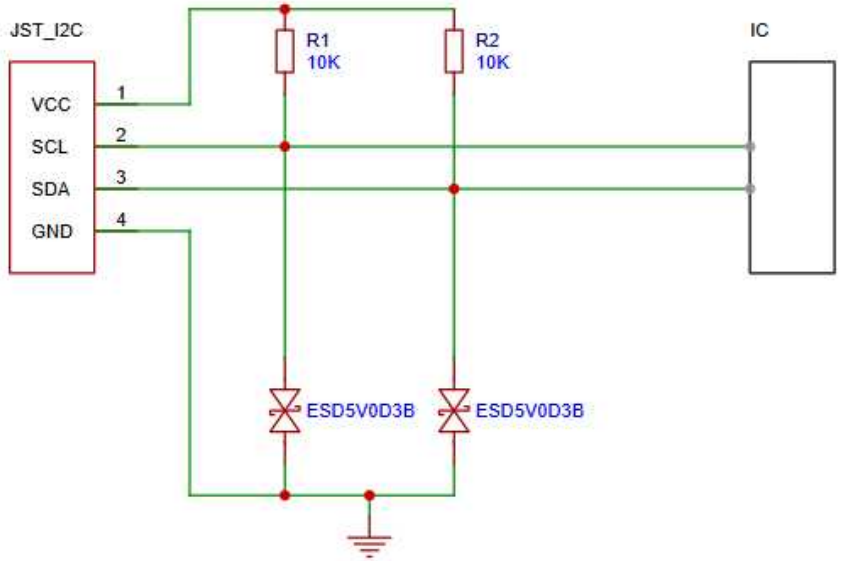


model	Device Type	Use Location	effect	Encapsulation
2R600L	GDT	Power interface	surge, lightning protection (outdoor products, pay attention to the problem of continuous current)	2RXXXL
14D561K/14D511K	MOV	Power interface	surge, lightning protection	14D
CMZ/CML	EMI common-mode suppressors	Power interface	Common-mode rejection	SMD
SMBJ24CA/SMBJ33CA	TVS	Power interface	surge, load dump	SMB

5.5 JST interface EMC and hot-swap reliability design

JST interface: a dedicated interface for connecting batteries, servos, and other devices

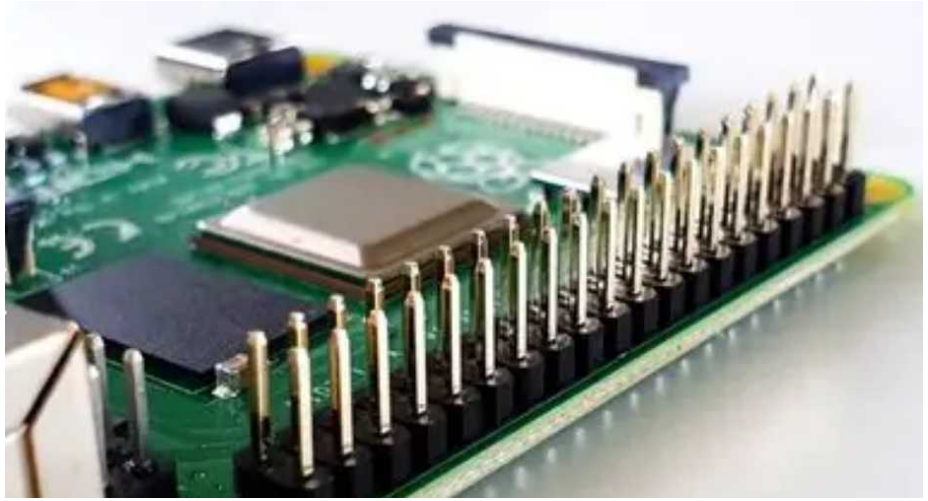


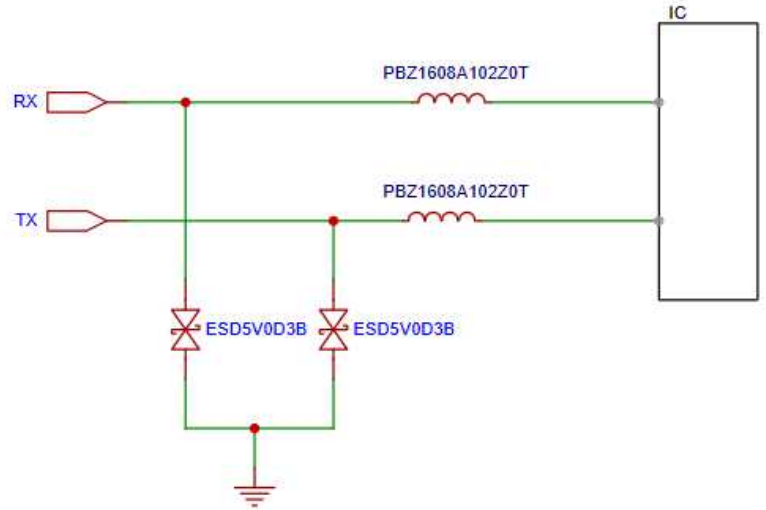


model	Device Type	Use Location	effect	Encapsulation
ESD5V0D3B	ESD	I2C interface	Surge, static electricity	SOD323

5.6 GPIO/UART/I2Cinterface EMC and Hot-Swap Reliability Design

GPIO interface (general purpose input and output): used to connect sensors, actuators and other peripherals, supporting custom programming control

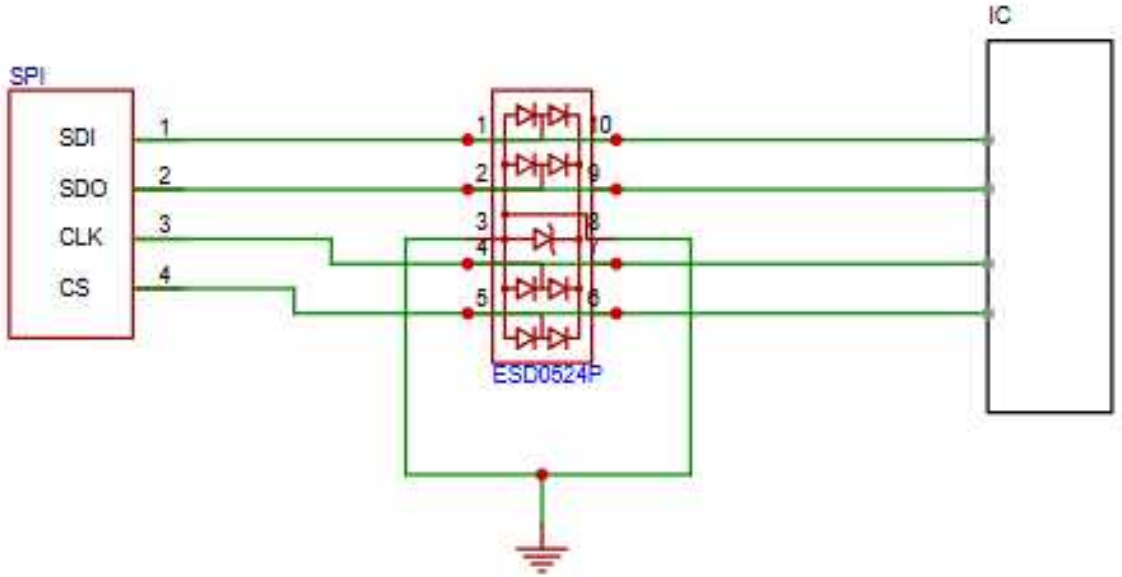


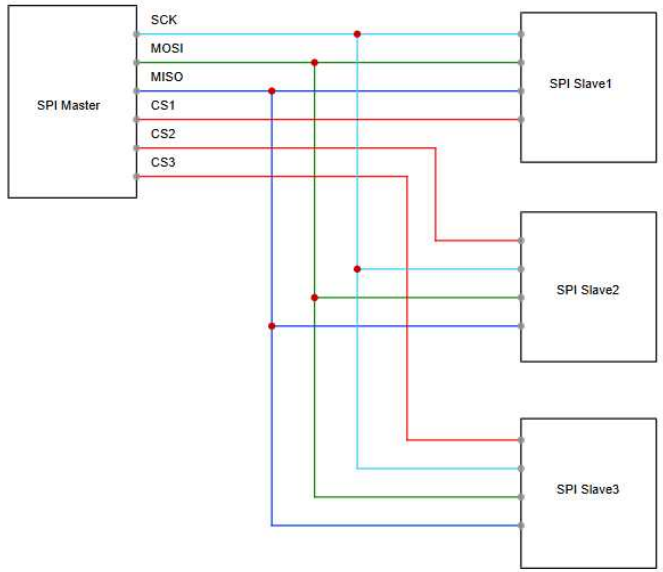


model	Device Type	Use Location	effect	Encapsulation
ESD5V0D3B	ESD	GPIO interface	Surge, static electricity	SOD323
PBZ1608A102Z0T	magnetic beads	GPIO interface	Eliminate high-frequency interference	1608

5.7 SPI Interface EMC and Hot-Swap Reliability Design

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



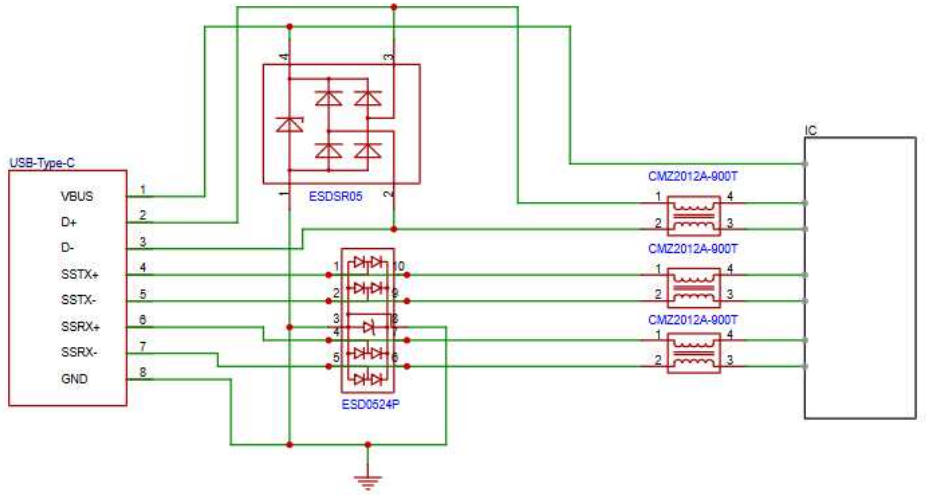


model	Device Type	Use Location	effect	Encapsulation
ESD0524P	ESD	SPI interface	Surge, static electricity	DFN2510

5.8 USB-Type-C interface EMC and hot-swap reliability design

USB interface:

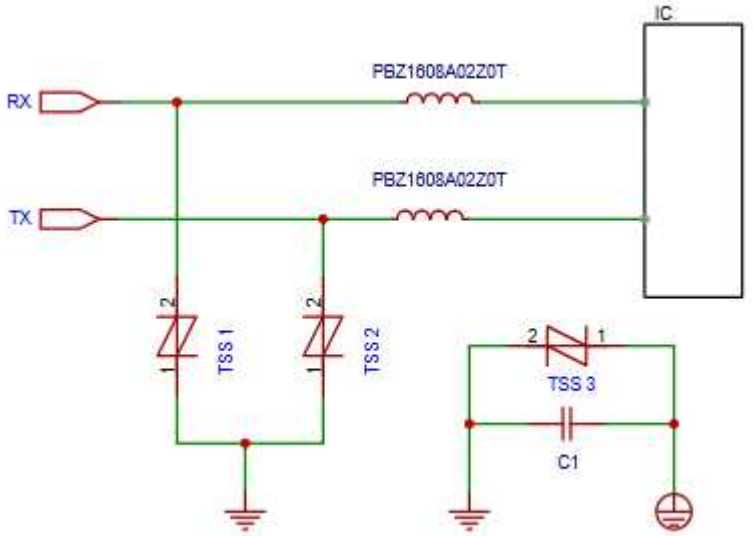
The USB interface boasts high-speed data transmission capabilities and is widely used to connect robots to external storage devices, sensors, and more. Its high-speed data transfer rate can reach 5Gbps, enabling rapid transmission of large amounts of data, such as robot vision image data. Its plug-and-play functionality allows users to easily connect and replace devices, enhancing the convenience of robot use and playing a key role in various robotic applications.



model	Device Type	Use Location	effect	Encapsulation
ESD0524P	ESD	USB interface	Surge, static electricity	DFN2510
ESDSR05	ESD	USB interface	Surge, static electricity	SOT143

5.9.1 RS-232 Interface EMC and Reliability Design

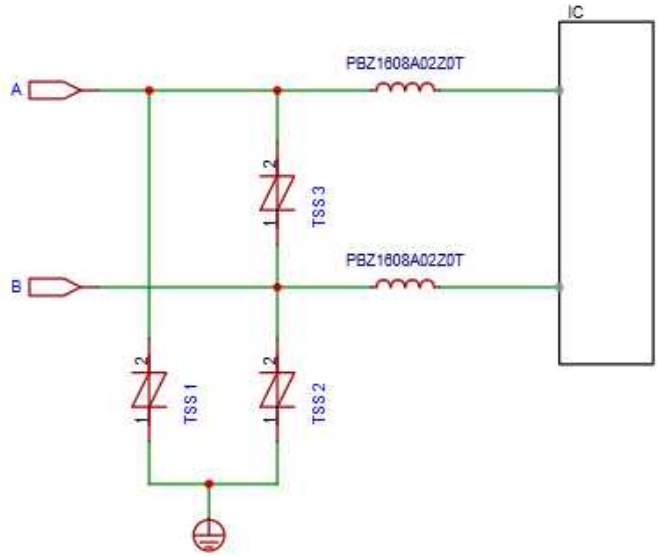
RS232 interface: It is one of the commonly used serial communication interfaces. RS232 is suitable for short-distance device interconnection (such as printers, mice, etc.), but it requires a level conversion chip (such as MAX232) to adapt to different logic levels.



model	Device Type	Use Location	effect	Encapsulation
P0220SCL	TSS	RS232 interface	Surge, static electricity	SMB
P3100SCL	TSS	RS232 interface	Lightning strike、Surge, static electricity	SMB
PBZ1608A02Z0T	magnetic beads	RS232 interface	Eliminate high-frequency interference	1608

5.9.2 RS-485 Interface EMC and 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.

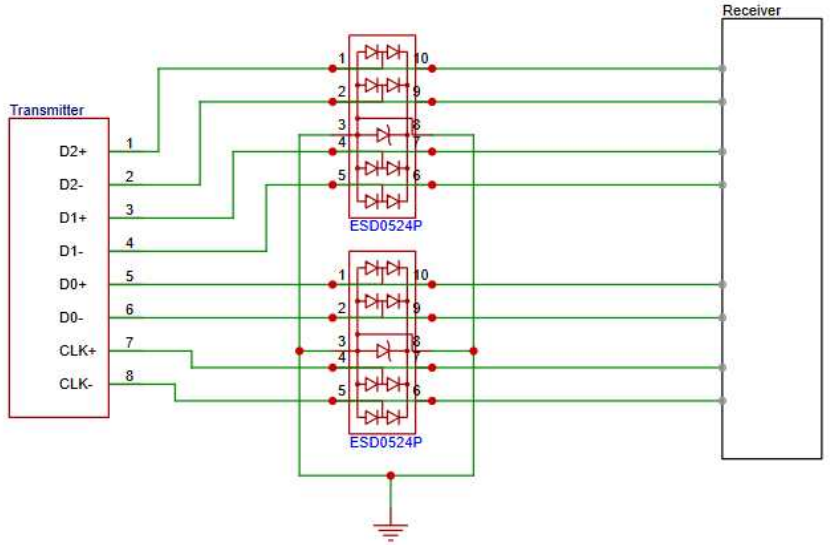


model	Device Type	Use Location	effect	Encapsulation
P0080SCL	TSS	RS485 interface	Surge, static electricity	SMB
PBZ1608A02Z0T	magnetic beads	RS485 interface	Eliminate high-frequency interference	1608

5.9.3 LVDS Interface EMC and Reliability Design

LVDS interface:

LVDS is a low-voltage differential signaling technology that uses a low swing voltage (about 350mV) to transmit data through a pair of differential lines, supporting transmission rates of up to several thousand Mbps. Its core advantages include low power consumption, low noise, and strong anti-interference capabilities. It is widely used in high-speed backplanes, cables, and PCB communication links.

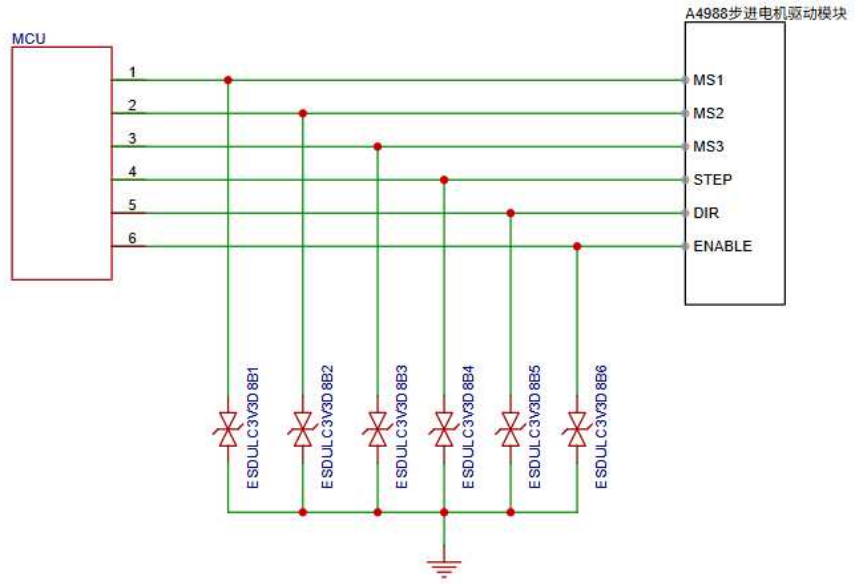


model	Device Type	Use Location	effect	Encapsulation	Features
ESD0524P	ESD	LVDS interface	Surge, static electricity	DFN2510	Large dosage, high value ratio

5.9.4 Stepper Motor Driver Module Interface EMC and Reliability Design

MCU interface:

The A4988 receives control signals from the MCU through multiple pins and controls the stepper motor simultaneously. STEP receives pulse signals from the MCU to control the number of steps of the stepper motor. DIRECTION controls the direction of the motor through high and low voltage levels. ENABLE is active at a low level, starting the drive and high at a high level stopping it. MS1-MS3 set the subdivision mode (full step, half step, quarter step, etc.) by combining high and low voltage levels.

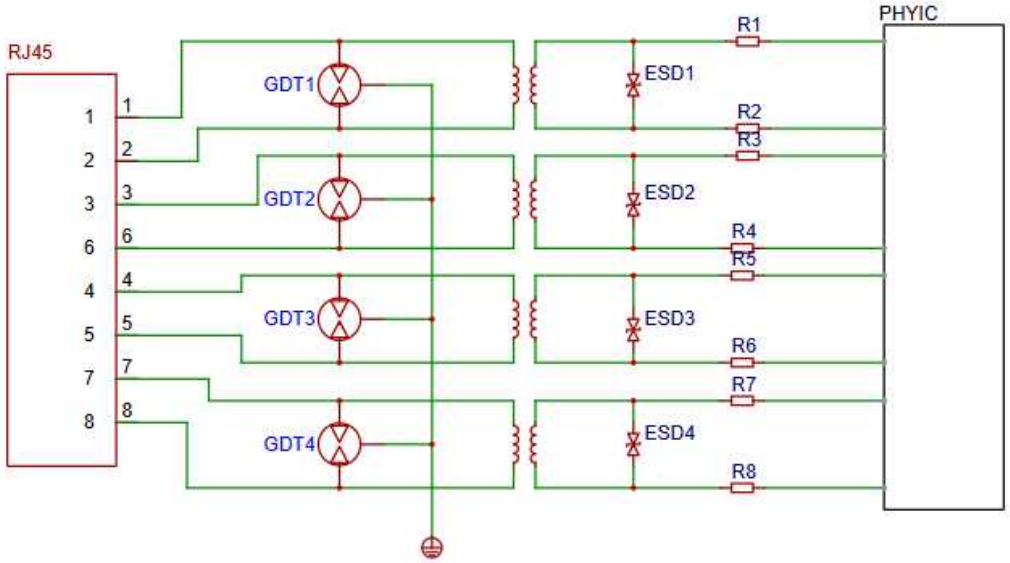


model	Device Type	Use Location	effect	Encapsulation
ESDULC3V3D8B	ESD	MCU interface	Surge, static electricity	SOD882

5.9.5 Ethernet Interface EMC and Reliability Design

Ethernet interface:

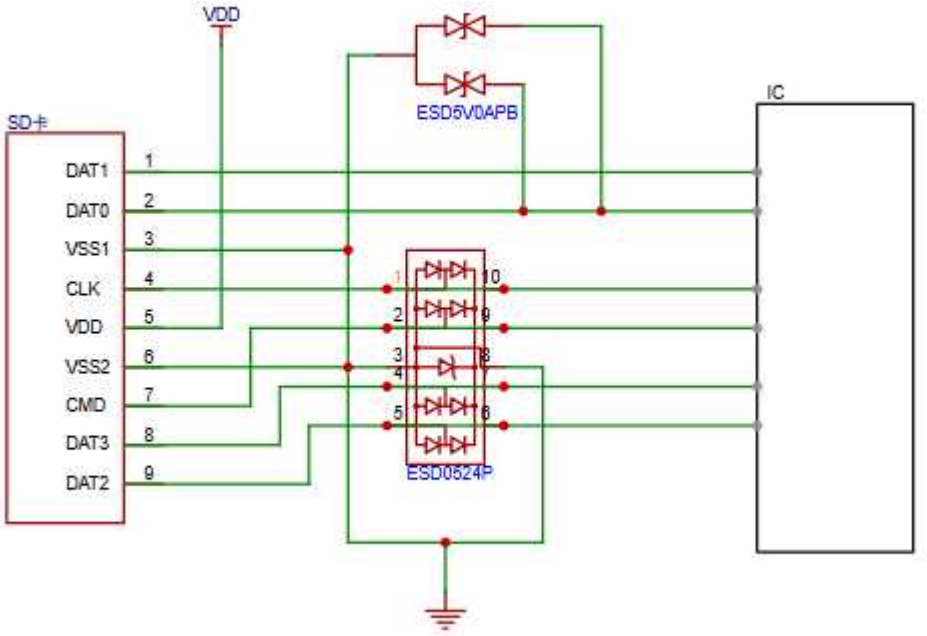
Supports wired network connections (common on intelligent robot motherboards).
The Ethernet interface provides a stable network connection for the robot, enabling remote control and data exchange. Through Ethernet, the robot can upload real-time working data to the cloud, receive remote commands, and achieve intelligent remote operation.
With transmission rates reaching 1000Mbps or higher, it meets the high-speed, stable data transmission requirements of robots in industrial automation, intelligent logistics, and other fields.



model	Device Type	Use Location	effect	Encapsulation
3R090L	GDT	Ethernet interface	surge	3RXXXL
ESDLC3V3D3B	ESD	Ethernet interface	Surge, static electricity	SOD323

5.9.6 Memory Card Interface EMC and Reliability Design

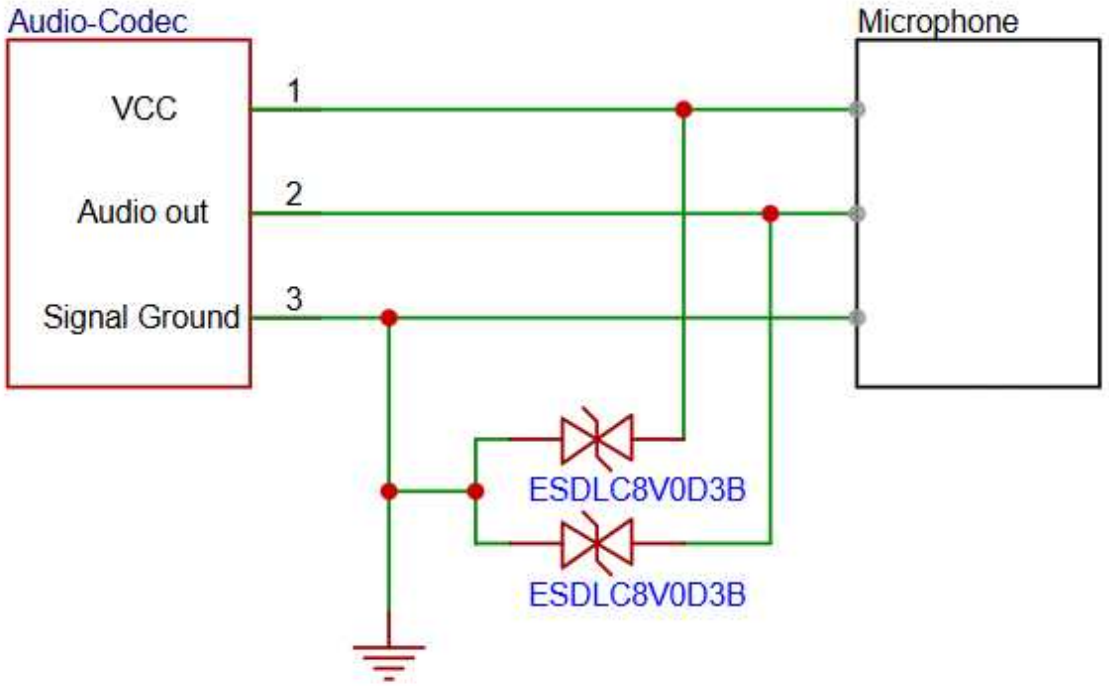
SD card slot: used to expand storage capacity and store system files or data **TF card slot:** some small development boards use TF cards as storage media



model	Device Type	Use Location	effect	Encapsulation
ESD0524P	ESD	SD card interface	Surge, static electricity	DFN2510
ESD5V0APB	ESD	SD card interface	Surge, static electricity	SOT23

5.9.7 Mic I/O Interface EMC and Reliability Design

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

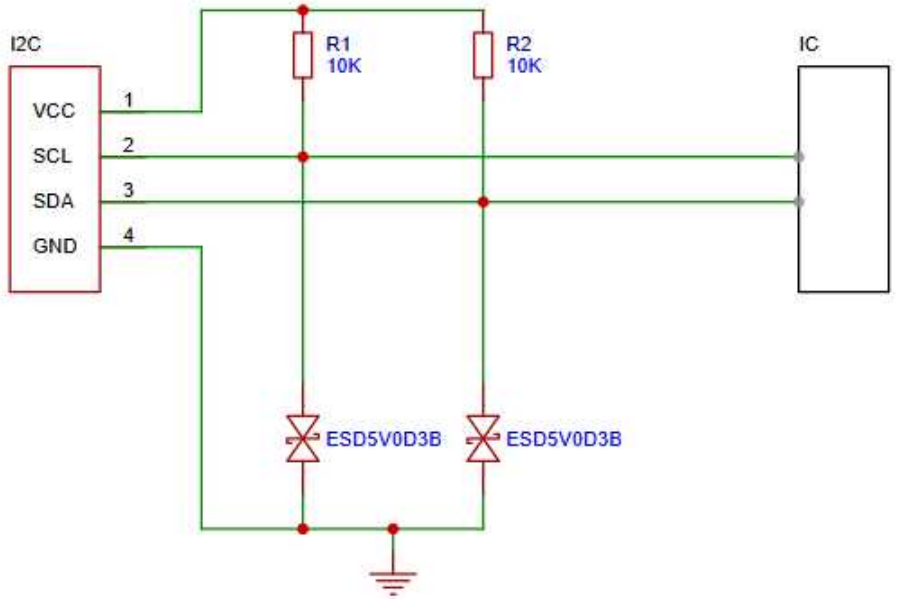


model	Device Type	Use Location	effect	Encapsulation	Features
ESDLC8V0D3B	ESD	Audio interface	Surge, static electricity	SOD323	Convenient manual welding
ESDLC5V0D8B	ESD	Audio interface	Surge, static electricity	SOD882	Suitable for machine patch

5.9.8 I2C Universal I/O Interface EMC and Reliability Design

I²C interface:

I2C (Inter-Integrated Circuit) interface is a common serial communication protocol widely used to connect low- to medium-speed sensors, memory chips, and other peripheral devices. I2C interface consists of two main signal lines: serial data line (SDA) and serial clock line (SCL).



model	Device Type	Use Location	effect	Encapsulation
ESD5V0D3B	ESD	I2C interface	Surge, static electricity	SOD323

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