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Improvement, innovation, saving, win-win

Electromagnetic compatibility solution for pulse oximeter electronic circuits

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Table of contents

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1. Interpretation of Oximeter Industry Standards (International + Domestic)

1.1 International Industry Standards

- Internationally, numerous standards exist for pulse oximeters.
- ISO 9919:1992 EN specifies requirements for medical pulse oximeters, covering performance, safety, and reliability.
- It applies to all types of medical pulse oximeters, both handheld and fixed. Performance requirements include accuracy, stability, response time, repeatability, measurement range, and resolution, ensuring the device accurately measures a patient's blood oxygen saturation.
- In terms of safety and reliability, devices must comply with relevant safety standards and obtain CE certification to ensure stable and reliable operation under various conditions. Manufacturers are also required to regularly calibrate and verify the devices and provide calibration and verification records to facilitate maintenance by users and medical institutions.
- ISO80601-2-61:2017 sets specific requirements for the basic safety and essential performance of pulse oximeters, covering multiple aspects such as electrical safety and electromagnetic compatibility. This ensures the devices can function properly in complex electromagnetic environments, ensuring patient safety. Compliance with IEC60601-1-2 is also required.

1.2 Domestic Industry Standards

- In the domestic pharmaceutical industry, YY0784-2010 is a commonly used implementation standard for pulse oximeters. This standard details the basic safety and key performance requirements for pulse oximeters intended for human use, including essential components for normal use, such as pulse oximeters, pulse oximeter probes, and probe cable extensions.

- In terms of key technical parameters for pulse oximeters, it clarifies concepts related to blood oxygen saturation, such as SaO_2 (arterial oxygen saturation), SpO_2 (pulse oximeter saturation), FO_2Hb (fractional oxygen saturation), and SO_2 (functional oxygen saturation), and provides mathematical expressions.

- It distinguishes between displayed range and claimed range to avoid confusion and provide clear guidance for the standardized production and use of products.

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2. Requirements for instrument EMC testing

2.1 EMC test item ESD static electricity

Electrostatic discharge immunity test

According to the IEC60601-1-2 standard, this test simulates the interference of human electrostatic discharge on pulse oximeters.

During the test, different levels of electrostatic discharge pulses are applied to the device's casing, interfaces, and other parts to observe whether the device functions properly and whether there are any malfunctions, data errors, or corruption.

When the device is powered on, ±8kV air discharge tests and ±4kV contact discharge tests may be performed on parts that are easily exposed to human body contact, such as buttons and display frames, to ensure that the device can continue to operate stably despite the electrostatic interference encountered in daily use.

2.2 EMC Test Items CE Test

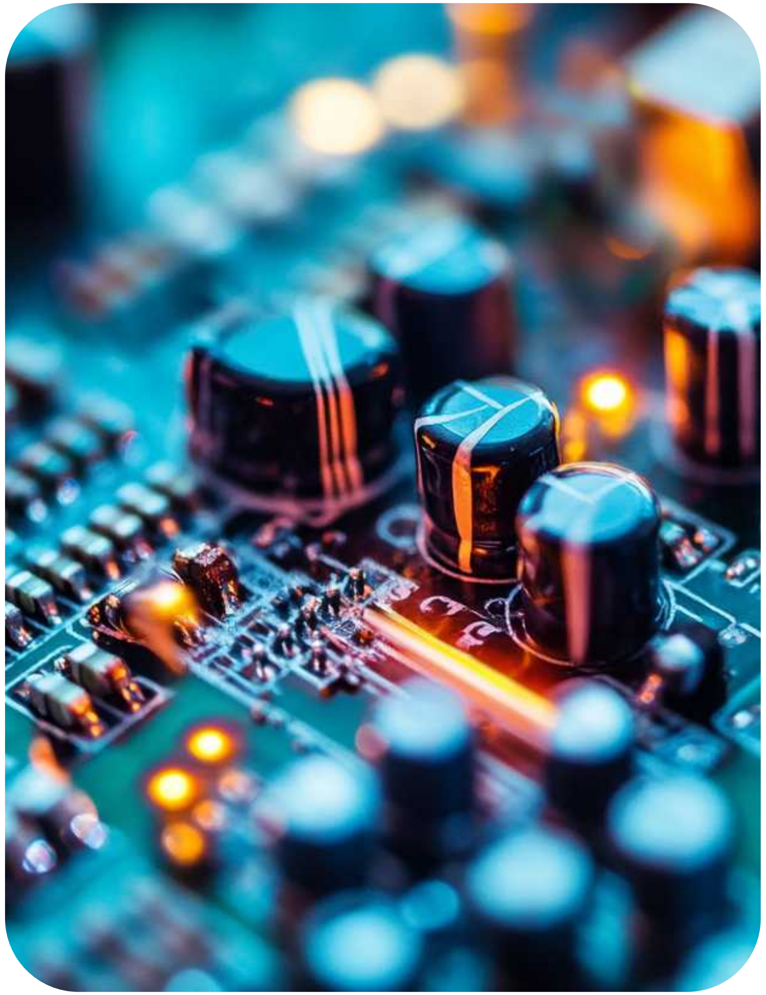
Radio frequency electromagnetic field immunity test

According to the standard, the device is exposed to a radio frequency electromagnetic field environment, typically in the 80MHz-2.7GHz frequency range.

The device's performance under varying radio frequency electromagnetic field intensities is tested by adjusting the field strength.

Under a field strength of 1V/m, the device's blood oxygen saturation measurement accuracy is checked to ensure it is within the tolerance range, pulse rate measurement is accurate, and the device exhibits no abnormalities such as freezing or restarting. This assesses the device's ability to resist radio frequency electromagnetic field interference.

Field strengths are typically 3V/m or higher.



Electrical fast transient burst immunity test

According to the standard, a burst of electrical fast transient (EFT) pulses is injected into the device's power and signal ports.

Pulse parameters such as rise time, pulse width, and repetition frequency are strictly regulated. For example, a rise time of 5ns, a pulse width of 50ns, and a repetition frequency of 5kHz are required. The test observes whether the device can maintain normal operation under the presence of the burst interference, preventing equipment failures caused by transient interference in the electrical environment.

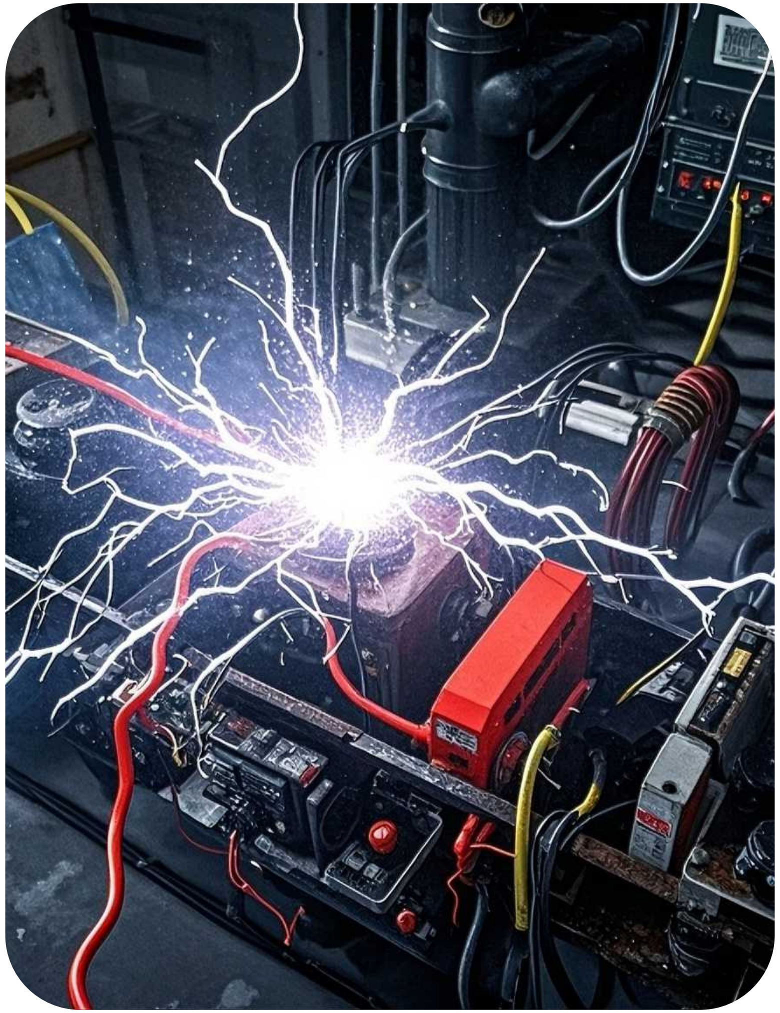
Typical levels: ±2 kV for power lines, ±1 kV for signal lines

2.4 EMC Test Item Surge

Surge immunity test

This test simulates surges caused by switching operations and lightning strikes in the power system, testing the device's power and communication ports.

Based on relevant standards, different surge voltage and current levels are set, with a 1kV surge applied between lines and a 2kV surge applied between lines and ground. This test verifies the device's ability to withstand surges and ensures reliability in harsh electrical environments.



3. Analysis of industry EMC pain points

3.1 Measurement accuracy is affected by interference

In a complex medical environment, there are a large number of electromagnetic interference sources, such as other medical equipment and wireless communication equipment. These interferences can affect the signal acquisition and processing of the pulse oximeter, resulting in inaccurate blood oxygen saturation and pulse rate data. When there is a high-frequency surgical device in operation nearby, the strong electromagnetic radiation it generates may cause deviations in the oximeter's measurement results, misleading the doctor's diagnosis and treatment.

3.2 Poor adaptability to different environments

Pulse oximeters may be used in varying environmental conditions, including temperature, humidity, and air pressure.

Some existing products have shortcomings in environmental adaptability. In high-temperature and high-humidity environments, the device's internal electronic components may be damaged by moisture or experience performance changes, affecting measurement accuracy. In low-temperature environments, battery performance degrades, potentially causing unstable operation and inability to measure properly.

Some pulse oximeters may experience performance drift over extended periods of continuous operation, causing measurement results to gradually deviate from the true value. The device's anti-interference capabilities may also degrade over time, making it ineffective in resisting electromagnetic interference. This can affect the device's stability and reliability, making it unsuitable for long-term clinical monitoring.

3.3 Top 5 EMC Pain Points

EMC test items	Common Problems	main reason	Improvement measures
RF radiation immunity (IEC61000-4-3)	Jumpy SpO_2 /pulse rate readings, signal loss (due to Wi-Fi/cell phone interference)	Insufficient sensor cable shielding and imperfect software filtering algorithm	Optimize PCB layout, increase cable shielding layer, and improve digital filtering algorithm
Electrostatic discharge (ESD) (IEC61000-4-2)	The device freezes, resets, or falsely reports "sensor detached"	The shell is poorly grounded and ESD protection devices are not used.	Strengthen grounding design and add protection components such as TVS diodes at contact points
Electrical fast transient/burst (EFT/B) (IEC61000-4-4)	Data drift, false alarms (such as a sudden spike in heart rate)	Insufficient power supply filtering and poor signal isolation circuit immunity	Add π-type filter and optimize signal line common mode filtering
Conducted Emissions (CE) (CISPR 11)	The power line noise exceeds the standard and interferes with other medical equipment	Switching power supply EMI filter design defects, no shielded cable	Optimize the power filter circuit (X/Y capacitors, differential mode inductors) and use shielded cables
Power frequency magnetic field immunity (IEC61000-4-8)	Value fluctuations (when near transformers or high-current equipment)	Sensor circuits are sensitive to magnetic fields and lack magnetic shielding	Use differential signal transmission and key components are shielded with high magnetic alloy

4. Circuit design EMC solution

4.1 Hardware Circuit Design Optimization

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01.
Filter circuit design

Design filter circuits at the power input and signal input ends respectively. For power input, use LC filter circuit to utilize the characteristics of inductance and capacitance to block high-frequency interference signals from entering the device. At the same time, smooth the DC power supply and reduce the impact of power supply fluctuations on the circuit. At the signal input end, select the appropriate RC filter circuit according to the signal frequency to filter out high-frequency noise mixed in the signal, improve the purity of the signal, and ensure accurate transmission and processing of the measurement signal.

02.
Shielding design

Shield the device's circuit board and surround it with a metal shield to prevent external electromagnetic interference from entering the circuit board. At the same time, prevent electromagnetic interference generated inside the circuit board from leaking out and affecting other devices. Use good grounding measures between the shield and the circuit board to ensure the shielding effect. Use shielded cables for the device's cables to prevent external interference during signal transmission.

03.
Grounding design

Establish a complete grounding system and reliably ground the metal casing of the equipment and the grounding layer of the circuit board. Use a combination of single-point grounding and multi-point grounding. For low-frequency circuits, use single-point grounding to avoid interference caused by ground loops; for high-frequency circuits, use multi-point grounding to reduce grounding resistance and improve anti-interference capabilities. Ensure that the grounding resistance meets the requirements of relevant standards. Generally, the grounding resistance is required to be less than 1Ω to effectively release static electricity and electromagnetic interference generated by the equipment.

4.2 Software Algorithm Optimization

Anti-interference algorithm design

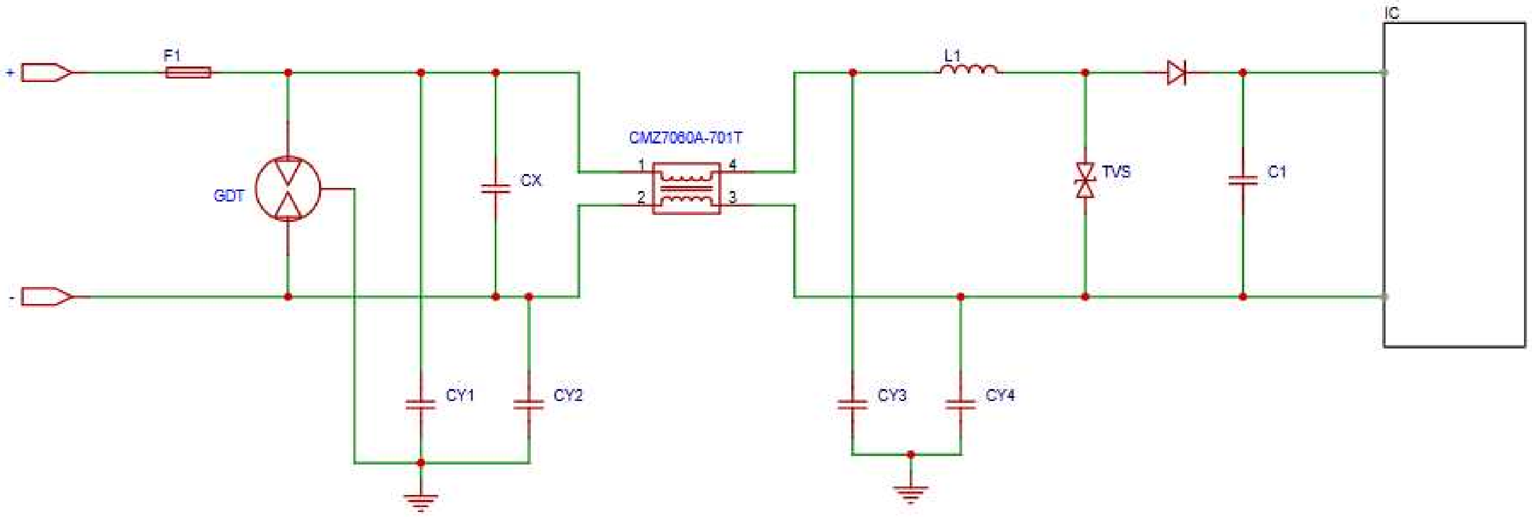
Design anti-interference algorithms in the software to process the collected signals. Use digital filtering algorithms, such as mean filtering and median filtering, to remove noise and interference from the signals. Identify and remove abnormal data points through algorithms to prevent them from affecting the measurement results. Combined with adaptive filtering algorithms, automatically adjust the filtering parameters according to changes in environmental interference to improve the accuracy and stability of signal processing.

Data verification and error

During data transmission and storage, data verification and error correction technology is used. For example, CRC (Cyclic Redundancy Check) algorithm is used to verify data. CRC is performed on the received data at the receiving end. If data errors are found, they are corrected through error correction algorithms to ensure data integrity and accuracy and prevent electromagnetic interference from causing data transmission errors that affect measurement results.

4.3 DC Power Interface EMC and Reliability Design

DC power interface: used to connect an external power adapter (such as 5V DC input). Some motherboard chips support power supply via USB.

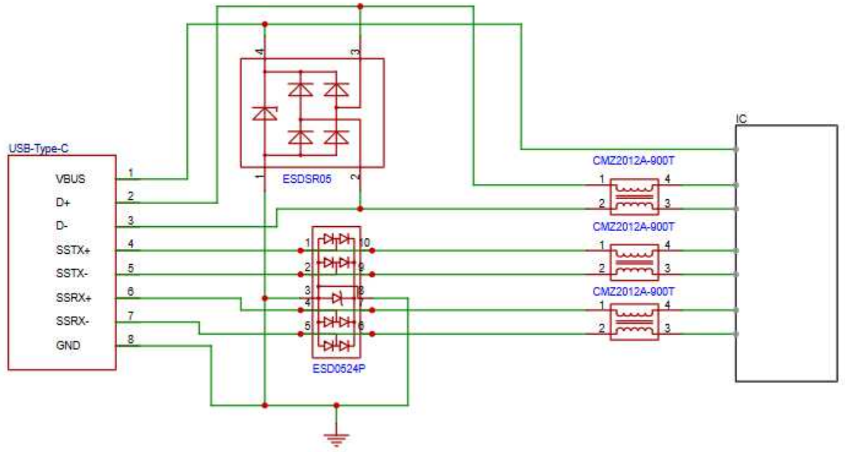


model	Device Type	Use Location	effect	Encapsulation
3R090L	GDT	Power interface	Surge, lightning protection (outdoor products, pay attention to the problem of continuous current)	3RXXXL
SMBJ6.5CA	TVS Transient Voltage Suppressor Diodes	Power interface	Surge, load dump	SMB/Do-214AA
CMZ7060A-701T	EMI common-mode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

4.4 USB-Type-C Interface EMC and Hot-Plug Reliability Design

USB-Type-C port:

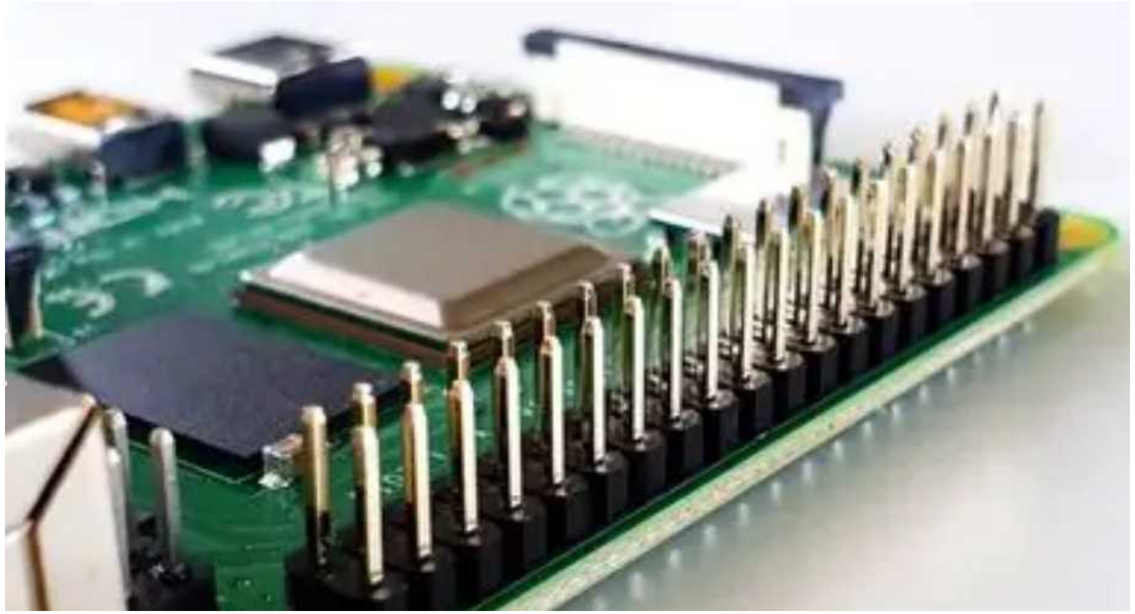
The USB-Type-C interface has high-speed data transmission capabilities and is widely used to connect machines with external storage devices, sensors, etc. Its data transmission rate in high-speed mode can reach 10Gbps, which can quickly transmit large amounts of data, such as visual image data; it has a plug-and-play feature, which makes it convenient for users to connect and replace devices at any time, improving the convenience of machine use and playing a key role in various machine application scenarios.

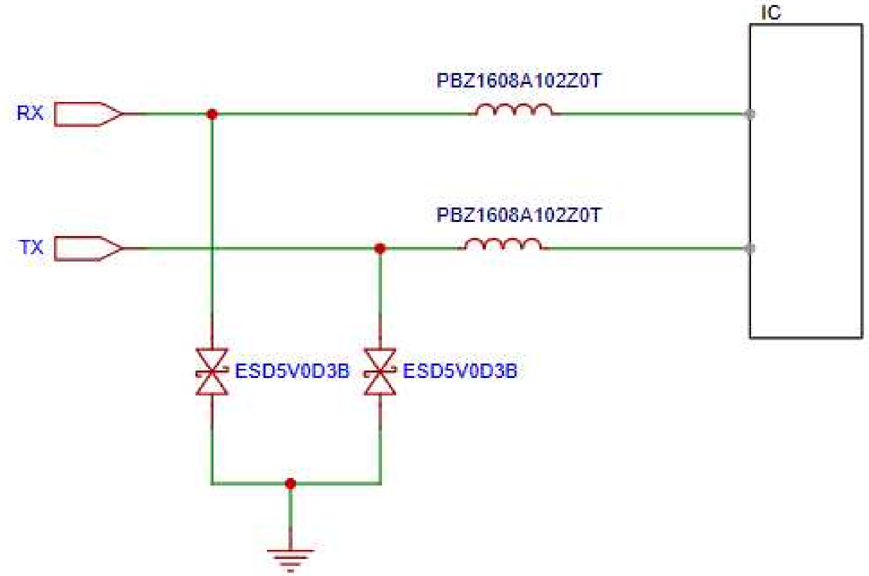


model	Device Type	Use Location	effect	Encapsulation
ESD0524P	ESD	USB interface	Surge, static electricity	DFN2510
ESDSR05	ESD	USB interface	Surge, static electricity	SOT143

4.5 GPIO/UART Interface 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

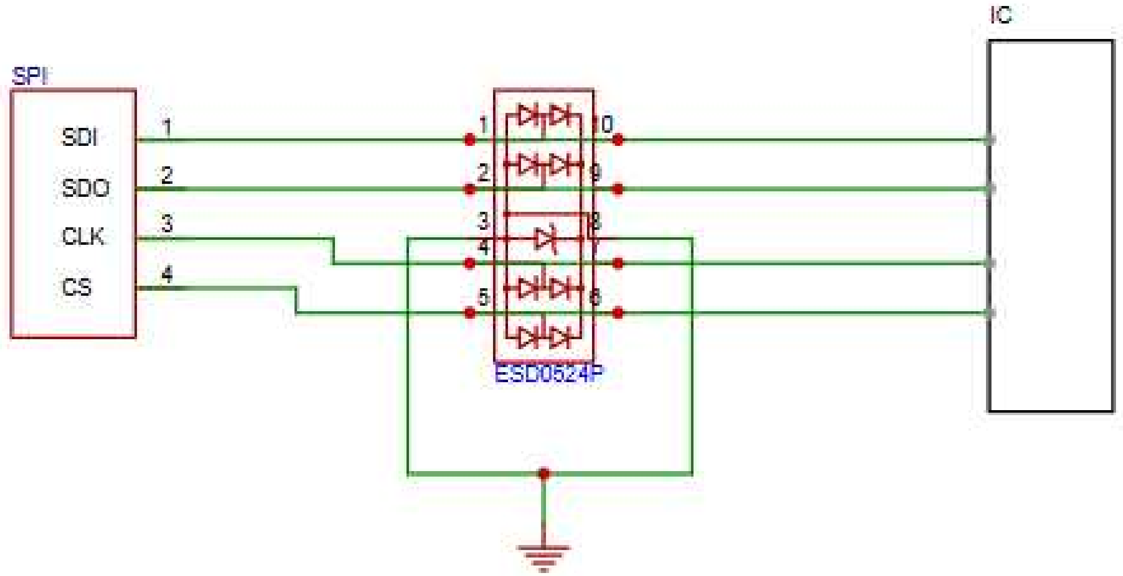


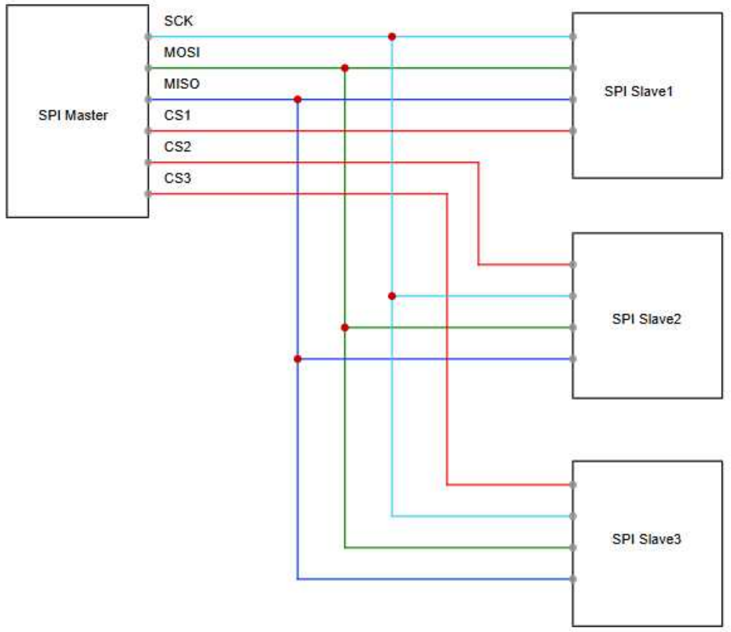


model	Device Type	Use Location	effect	Encapsulation
ESD5V0D3B	ESD	GPIO interface	Surge, static electricity	SOD323
PBZ1608A102Z0T	magnetic beads	GPIO interface	Eliminate high-frequency interference	1608

4.6 SPI interface EMC and hot-swap reliability design

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



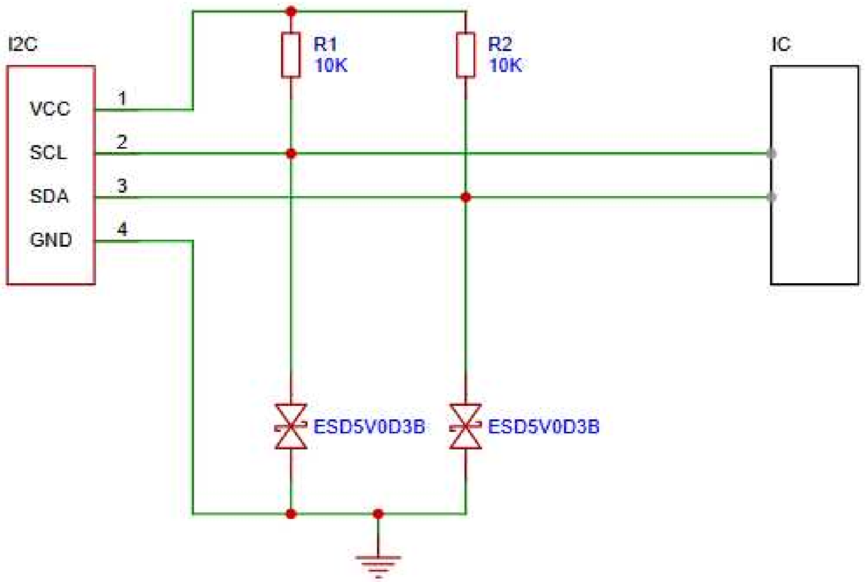


model	Device Type	Use Location	effect	Encapsulation
ESD0524P	ESD	SPIinterface	Surge, static electricity	DFN2510

4.7 I2C General 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
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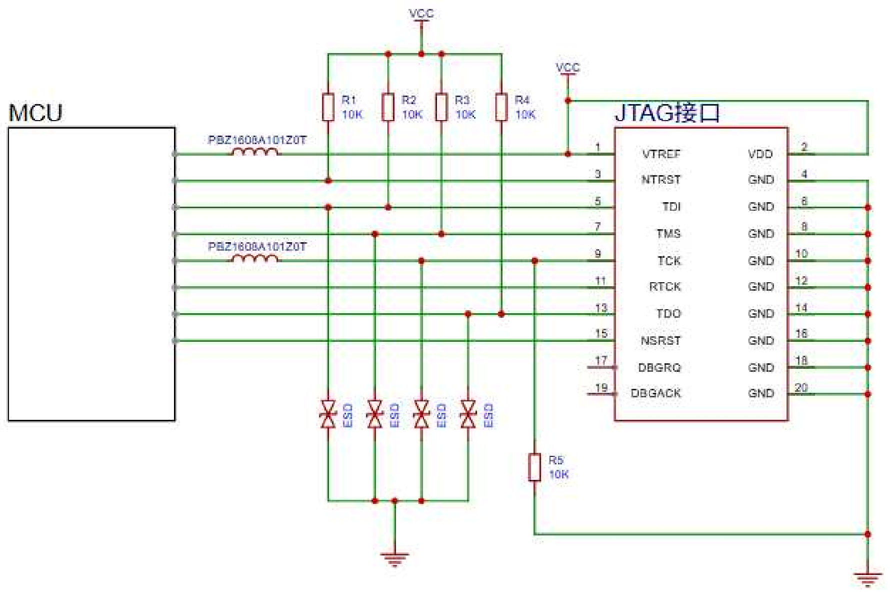
4.8 JTAG interface EMC and reliability design

JTAG interface:

JTAG (Joint Test Action Group) is an international standard test protocol with a maximum transmission rate of 48MHz. It is mainly used for internal chip testing and system simulation and debugging. JTAG technology is an embedded debugging technology that encapsulates a special test circuit TAP (Test Access Port) inside the chip and tests internal nodes through a dedicated JTAG test tool.



model	Device Type	Use Location	effect	Encapsulation
ESD3V3D8B	ESD	JTAGinterface	Surge, static electricity	DFN1006
PBZ1608A101Z0T	magnetic beads	JTAGinterface	Eliminate high-frequency interference	1608

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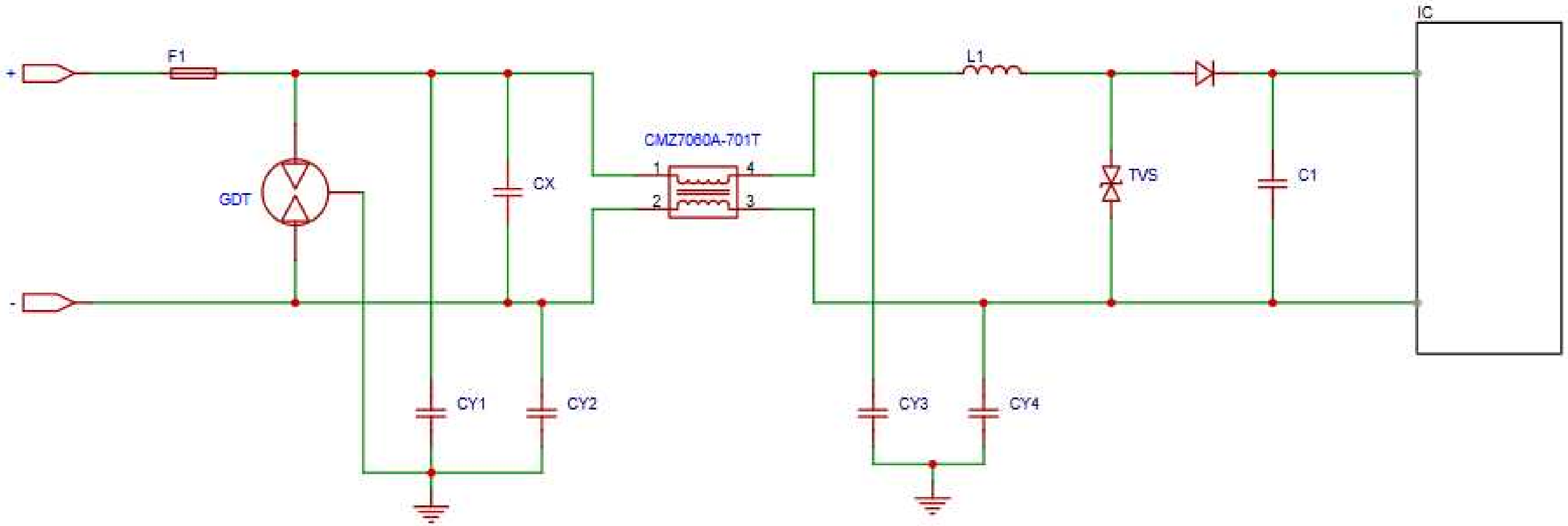

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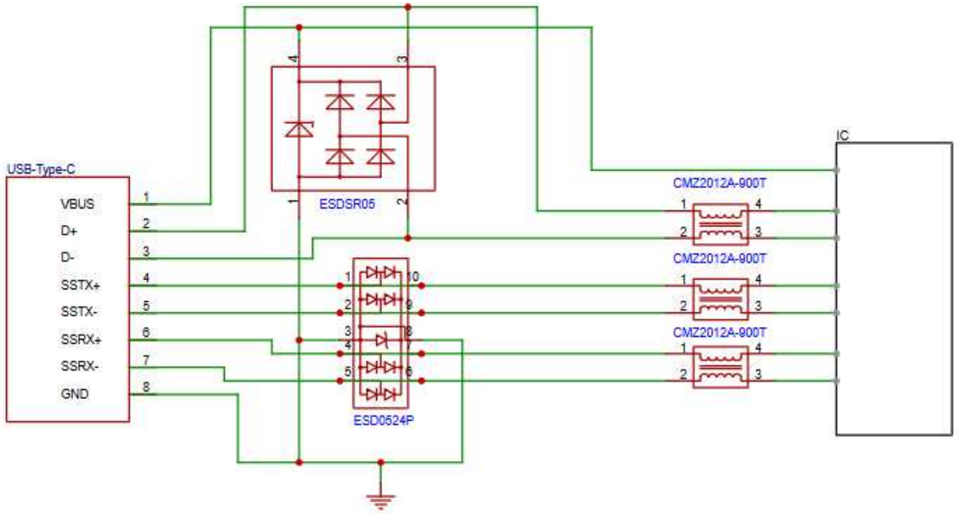

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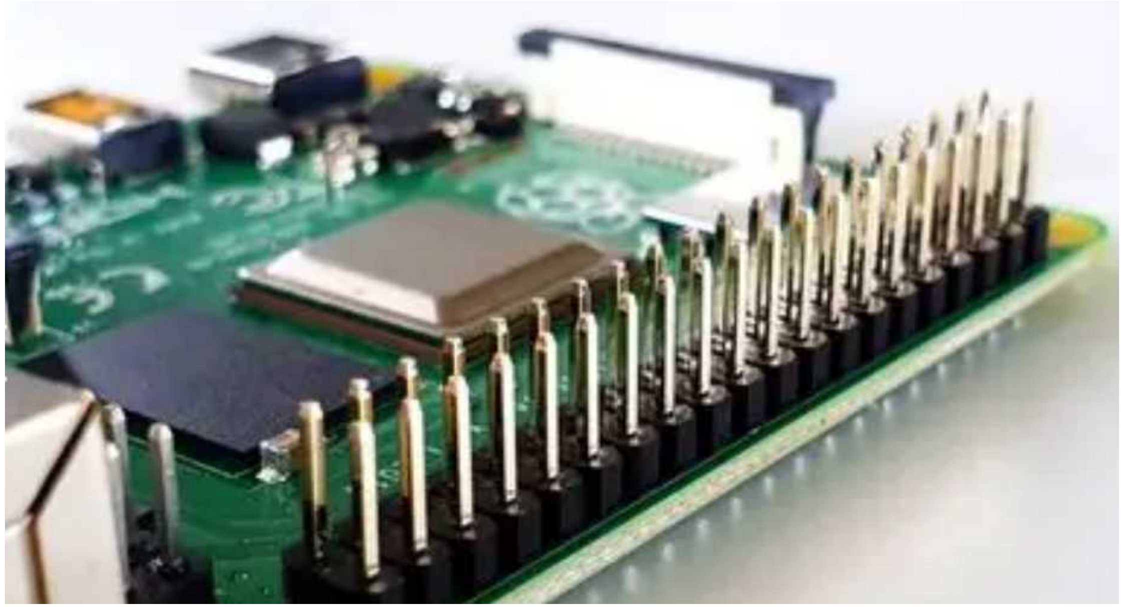
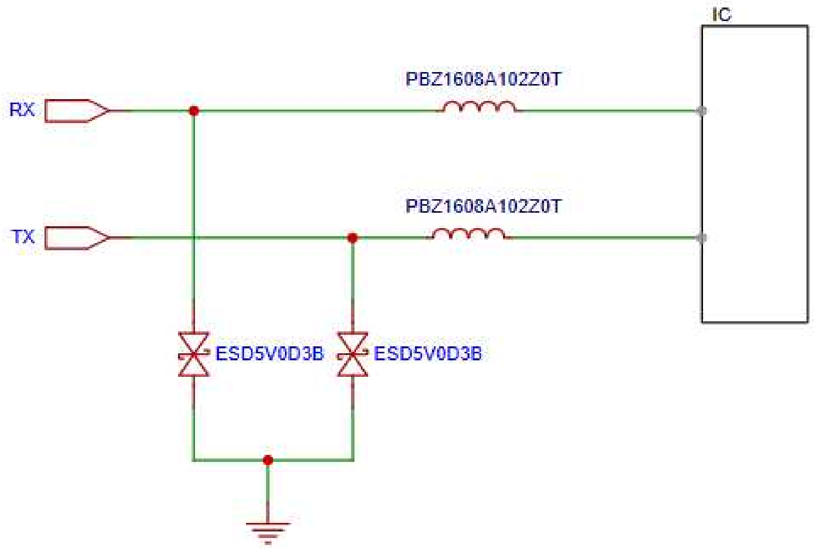
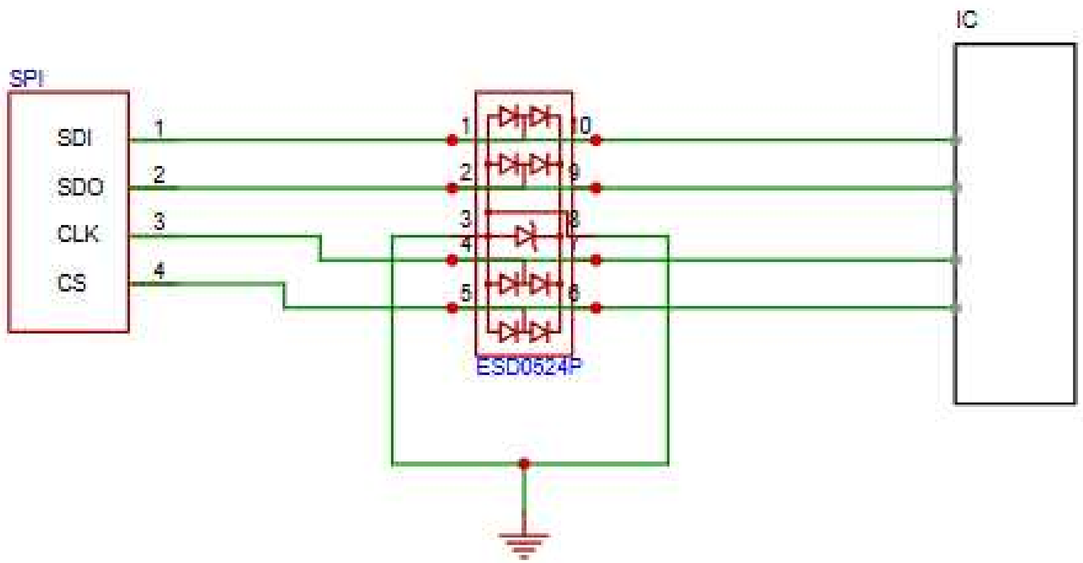


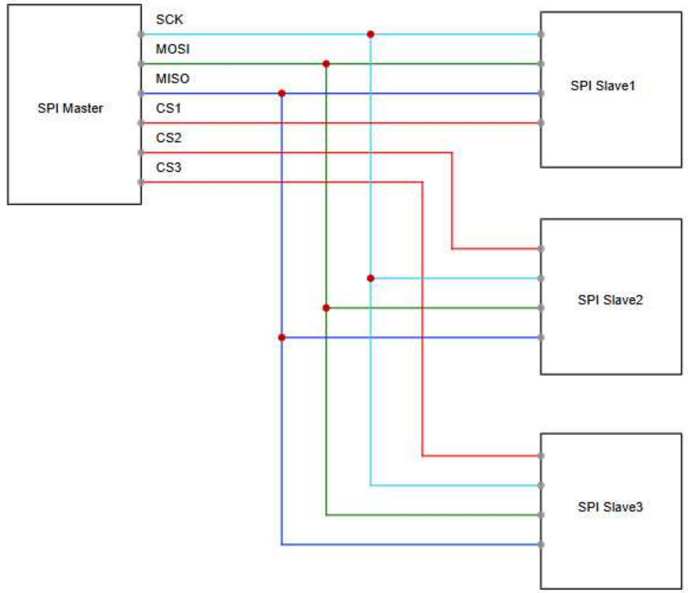


model	Device Type	Use Location	effect	Encapsulation
ESD5V0D3B	ESD	GPI Ointerface	Surge, static electricity	SOD323
PBZ1608A102Z0T	magnetic beads	GPI Ointerface	Eliminate high-frequency interference	1608

4.9.3 SPI Interface EMC and Hot-Swap Reliability Design

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





model	Device Type	Use Location	effect	Encapsulation
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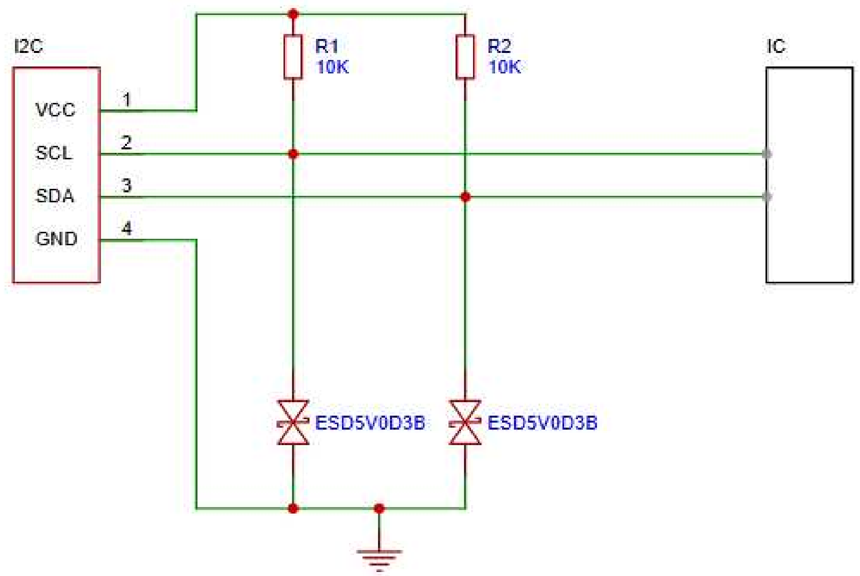

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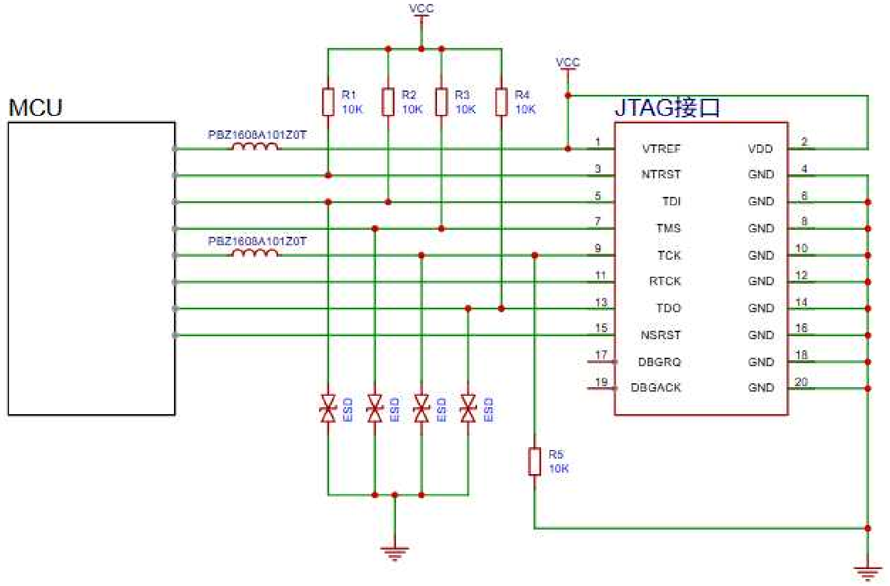

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