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Improvement, innovation, saving, win-win

Portable Coagulation Analyzer EMC Technology Analysis

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1.International and domestic standards content

1.1 List of International Standards

International Standard Number	Standard Name	Core Content
ISO 15189:2022	Quality and capability requirements for medical laboratories	The system stipulates a quality control system including calibration traceability, performance verification (e.g. PT intra-batch precision CV≤5%), and result reporting, and requires 3Q verification (installation, operation, and performance confirmation) to ensure that the equipment meets clinical testing requirements.
CLSI H59-A	Quantitative D-dimer testing for excluding venous thromboembolism	Clarify the sample processing, threshold setting and anti-interference requirements for D-dimer detection (such as accuracy of icterus and hemolysis samples), which indirectly requires the instrument to have high specificity and anti-interference capabilities.
CLSI H57	Coagulation Analyzer Performance Verification	Validation methods such as precision (PT intra-batch CV≤3%), linear range (FIB r≥0.98), and carryover contamination rate (≤10%) are specified, covering core indicators such as PT, APTT, and FIB.
ISO 22870:2016	Point-of-care testing (POCT) quality management requirements	Bedside coagulation testing equipment requires fast response (such as ACT detection ≤ 3 minutes), portability and data transmission compatibility, and needs to pass electromagnetic compatibility (EMC) testing
Note: EU IVDR "In Vitro Diagnostic Medical Devices Regulation", ASTM F2382-24 "Potent Test Method for Blood Contact Materials", US FDA 510(k) Pre-Market Notification		

1.2 International Standard Number and Standard Name

There are 36 international standards related to coagulation meters, covering fields such as laboratory medicine, veterinary medicine, and medical devices.

For example, the German Institute for Standardization's DIN 58910-1:2016-02, titled "Hematological Enzymology—Determination of the Thromboplastin (Prothrombin) Time—Part 1: Reference Measurement Procedure for the Determination of Thromboplastin Time Using Citrated Venous Plasma," specifies a reference measurement procedure for the determination of the thromboplastin time using citrated venous plasma. This standard provides internationally standardized methodological guidance for related tests, helps ensure the accuracy and consistency of test results, and facilitates international medical communication and research.

The American Society for Testing and Materials' ASTM F3209-24A, titled "Standard Guide for Autologous Platelet-Rich Plasma, Platelet Gels, and Whole Blood Gels for Use in Tissue Engineering and Cell Therapy," is not a direct testing standard for coagulation meters, but it provides guidance on how to process and analyze samples such as autologous platelet-rich plasma in tissue engineering and cell therapy applications, enabling coagulation meters to better meet the needs of these cutting-edge medical fields.

1.3 List of International Standards

National Standard No.	Standard Name	Core Content
YY/T 0659-2017	Coagulation analyzer	- Technical performance: PT intra-batch precision CV≤3%, FIB linear range 0.7-5.0g/L (r≥0.98), carryover rate ≤10% - Safety requirements: Comply with GB 4793.1 (electrical safety), GB/T 18268.26 (electromagnetic compatibility) - Environmental adaptability: Passed high temperature (40°C), low temperature (-20°C) and humidity (80% RH) stability tests
China National Medical Products Administration Guiding Principles	Guidelines for Technical Review of Coagulation Analyzer Registration	It is mandatory to test the four basic indicators of PT, APTT, FIB, and TT (PT must report the INR value), use calibrators traceable to WHO standards and conduct regular in-house quality control.
JJF （征求意见稿）	Coagulation Analyzer Calibration Specifications	- Temperature control: Incubation part 37.0±1.0°C, reagent cooling part ≤16°C - Channel difference: The range of test results between different channels of semi-automatic instrument is ≤10% - Metrology characteristics: FIB indication error ±10%, linear correlation r≥0.98

1.4 Domestic standard number and standard name

In China's standard classification, coagulation analyzers are classified as medical laboratory equipment. Industry Standard YY/T0659-2017, titled "Coagulation Analyzers," provides detailed regulations for the technical requirements, test methods, inspection rules, labeling, packaging, transportation, and storage of coagulation analyzers. This standard serves as an important basis for the production, testing, and use of coagulation analyzers in China, ensuring the quality and performance of coagulation analyzers in the domestic market.

National Metrology Technical Specification JJF1945-2021, "Coagulation Analyzer Calibration Specification," defines the metrological characteristics, calibration conditions, calibration items, and calibration methods for coagulation analyzers. By standardizing the calibration process and requirements, it ensures the accuracy and reliability of coagulation analyzer measurement results, providing precise data support for clinical diagnosis.

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2. Contents of EMC for electronic parts

2.1 EMC content in international standards

- EMC (Electromagnetic Compatibility) refers to the requirement that electronic or electrical equipment or systems, when operating in an expected electromagnetic environment, do not experience performance degradation, loss of function, or damage due to the surrounding electromagnetic environment. Furthermore, they do not generate excessive electromagnetic energy in the surrounding environment, potentially impacting the normal operation of surrounding equipment.

- International standards focus on EMC requirements for portable coagulation analyzers in terms of electromagnetic interference (EMI) and electromagnetic immunity (EMS). Regarding EMI, the EMI generated by the device itself must not exceed certain limits to avoid adverse effects on other nearby electronic equipment. For example, in a hospital setting, a coagulation analyzer must not interfere with the normal operation of other medical equipment, such as electrocardiogram (ECG) monitors and ultrasound diagnostic equipment, ensuring electromagnetic compatibility and stable operation of the entire medical environment.

- Electromagnetic immunity (EMS) requires that the device's own EMI exposure remain within a certain range, ensuring that the portable coagulation analyzer can accurately perform coagulation tests in complex electromagnetic environments, such as those in hospitals where interference from various communication signals and electrical equipment is present, without being affected by surrounding electromagnetic interference, thus ensuring the reliability of test results.

2.2 EMC content in domestic standards

01

Domestic standards also prioritize the EMC performance of portable coagulation analyzers. Key electromagnetic interference (EMI) testing includes conducted interference (CE) testing, which examines power lines, signal lines, and control lines to determine whether the electromagnetic interference (EMI) emitted by the device exceeds standards. These lines act as "bridges," potentially transmitting EMI generated within the device to other devices or systems. Radiated interference (RE) testing also assesses whether the electromagnetic energy radiated into space by the device is within specified limits, preventing interference with other electronic devices in the surrounding area.

02

Electromagnetic immunity (EMS) test items, such as the electrostatic discharge (ESD) test, simulates the electrostatic discharge phenomenon generated when the human body or objects touch the equipment, and verifies whether the equipment can withstand this instantaneous high voltage shock without failure or performance degradation; the electrical fast transient (EFT) test examines the equipment's resistance to electrical fast transient pulse group interference. These pulse groups may be generated by nearby electrical switch operations, motor start-up and shutdown, etc., to ensure that the equipment can still operate normally in the face of various interferences in the actual use environment

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3.Problems in the practical application of portable coagulation analyzers

3.1 Accuracy Issues

Portable coagulation analyzers of different brands and models have differences in the accuracy of test results. Even for products of the same brand, the test error may gradually increase with the increase of usage time and changes in the usage environment. For example, in some primary medical institutions, due to the lack of professional calibration equipment and regular calibration mechanisms, the coagulation analyzer test results after a period of use may deviate from the standard test results of large hospital laboratories by more than the allowable range, causing doctors to misjudge the patient's coagulation status and affecting the formulation of subsequent treatment plans.

The sample collection and processing process has a significant impact on the accuracy of the test results. If the blood collection operation is not standardized, such as incomplete disinfection of the blood collection site, hemolysis during the blood collection process, or improper sample storage, the sample coagulation or deterioration before the test, etc., the test results of the coagulometer will be biased. For example, in field emergency or community medical services, due to limited conditions, it is difficult to achieve the same strict standards as in professional laboratories in the sample collection and processing process, thus affecting the accuracy of the test.

3.2 Stability Issues

01

The performance of portable coagulation analyzers may be affected under different ambient temperature and humidity conditions, resulting in unstable test results. In high temperature and high humidity environments, the electronic components inside the instrument may be damaged by moisture, or their performance parameters may drift, causing fluctuations in test results. For example, in the summer in the south, some grassroots hospitals do not have good temperature control and dehumidification equipment. When coagulation analyzers are used in such environments, the repeatability of test results is poor, which brings difficulties to clinical diagnosis.

02

The battery life of the instrument will also affect its stability. If the battery is insufficient, the instrument's operating voltage may be unstable, affecting the acquisition and processing of signals during the test, and thus affecting the test results. In some emergency rescue scenarios, if the coagulation analyzer is interrupted due to battery exhaustion during the test, not only will the test results not be obtained in time, but the instrument may also be damaged, delaying patient treatment.

3.3 Operational convenience

01

The operating interface of some portable coagulation analyzers is complex, making them difficult for non-professional medical staff or patients to operate. For example, some instruments have numerous menu options and unintuitive function settings. When performing a test, multiple steps are required to complete the operation, which is prone to misoperation. In the scenario of home self-testing, patients may not be able to obtain accurate test results due to improper operation, or they may resist the instrument, which affects their self-monitoring and management of the disease.

02

The storage and use requirements of the test reagents that come with the instrument are high, which also brings inconvenience to the operation. Some reagents need to be stored at low temperatures and have a strict expiration date after opening. In actual use, if the storage conditions of the reagents are not met or they are used beyond the expiration date, the accuracy of the test results will be affected. For example, in some medical institutions in remote areas, due to the lack of complete cold chain storage equipment, the storage conditions of the reagents are difficult to guarantee, which brings difficulties to clinical testing.

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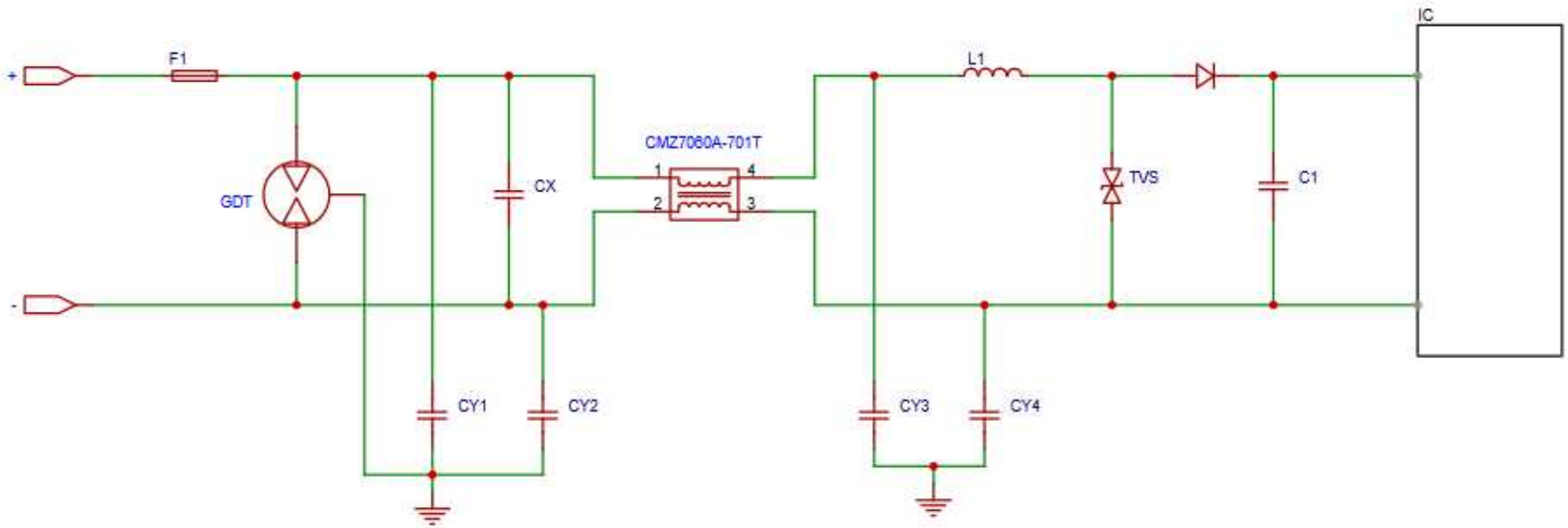
4.I/O interface and EMC solutions

4.1 Power Interface EMC and Reliability Design

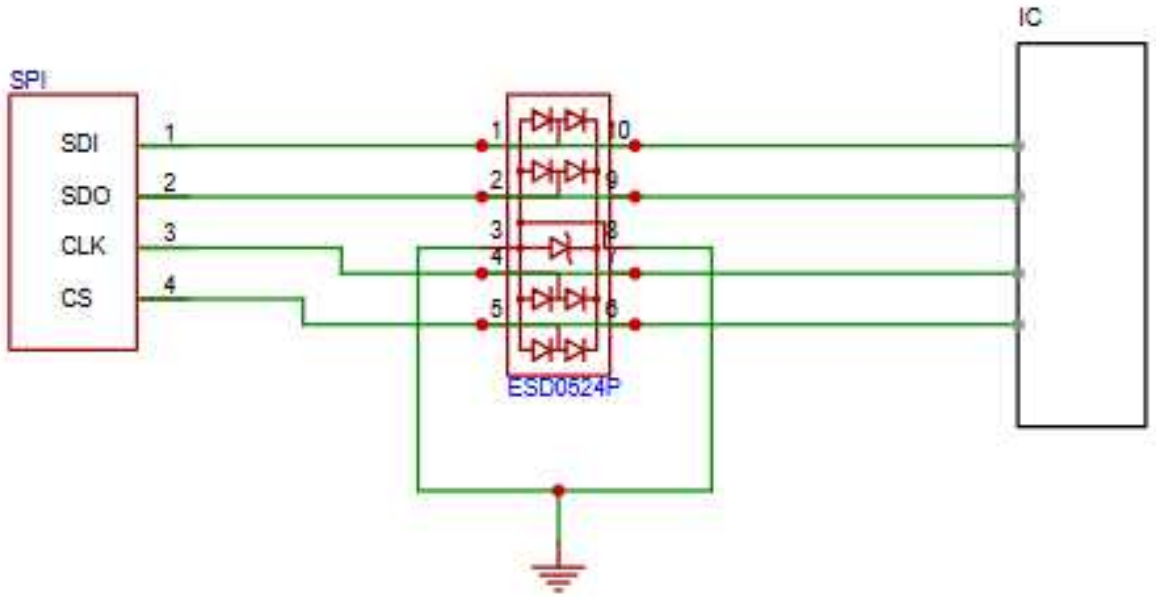
DC power interface: used to connect an external 5V DC input power adapter

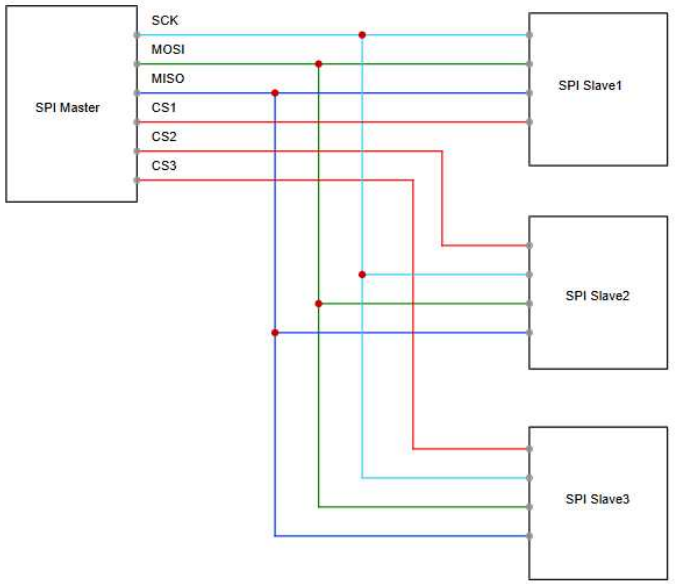


model	Device Type	Use Location	effect	Encapsulation
3R090L	GDT	Power interface	Surge, lightning protection (outdoor products, pay attention to the problem of continuous current)	3RXXXL
SMBJ6.5CA	TVS Transient Voltage Suppressor Diodes	Power interface	Surge, load dump	SMB/Do-214AA
CMZ7060A-701T	EMI common-mode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

4.2 SPI Interface EMC and Hot-Swap Reliability Design

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

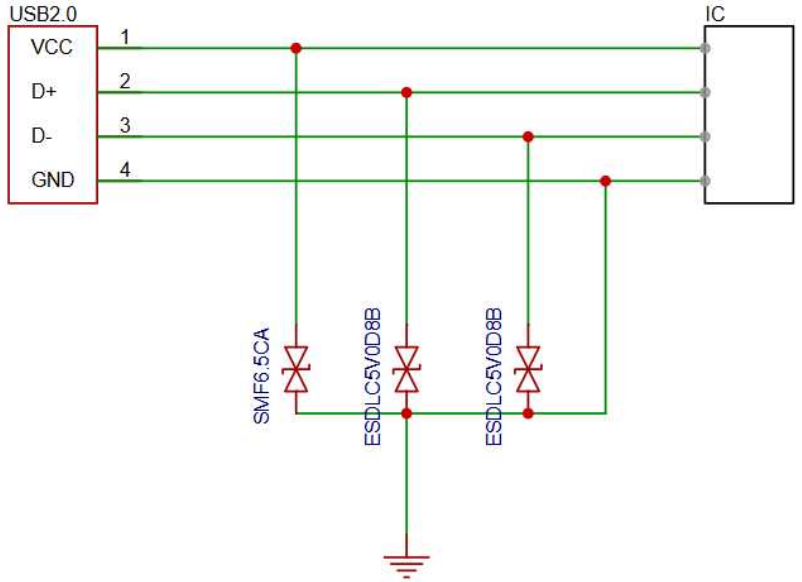




model	Device Type	Use Location	effect	Encapsulation
ESD0524P	ESD	SPIinterface	Surge, static electricity	DFN2510

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

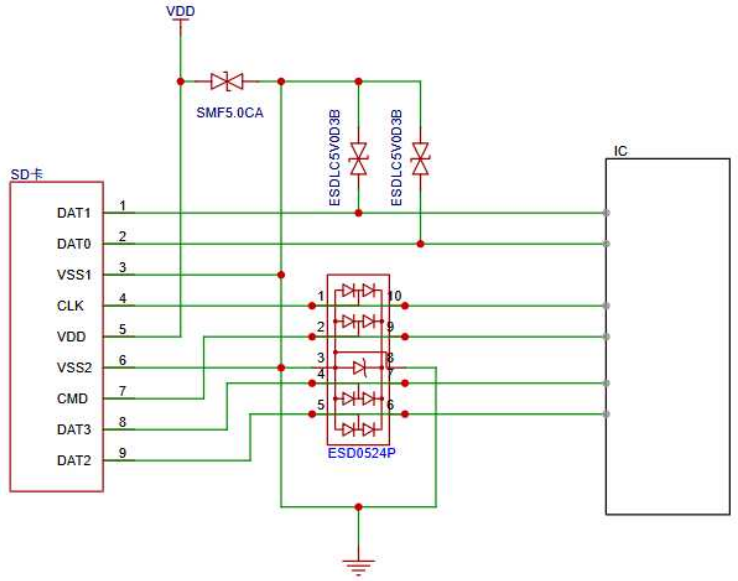
USB-2.0 interface: USB 2.0 is designed to provide faster data transfer speeds and better device compatibility; it also achieves a leap in interface speed, increasing it from the original maximum of 12 Mbps to 480 Mbps; this allows the USB interface to meet the needs of more high-bandwidth devices, such 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 Storage Interface EMC and Hot-Swap Reliability Design

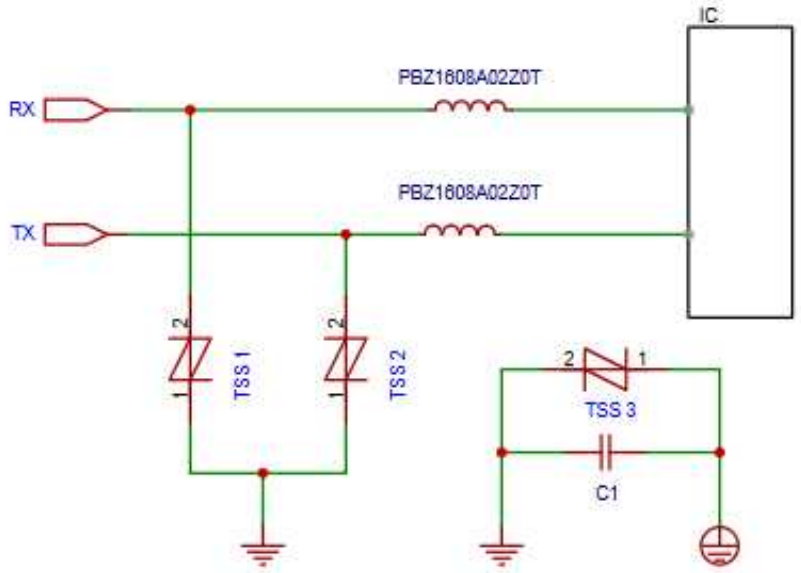
SD card slot: Used to expand storage capacity and store system files or data.
TF card slot: Some small development boards use TF cards as storage media.



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

4.5 RS-232 Interface EMC and Hot-Swap Reliability Design

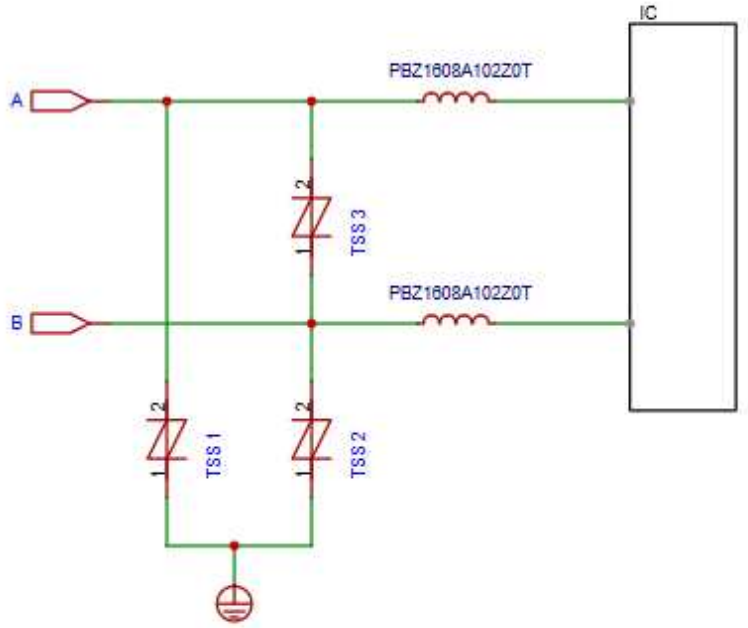
RS232 interface: It is one of the commonly used serial communication interfaces. RS232 is suitable for short-distance device interconnection (such as printers, mice, etc.), but it requires a level conversion chip (such as MAX232) to adapt to different logic levels.



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

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

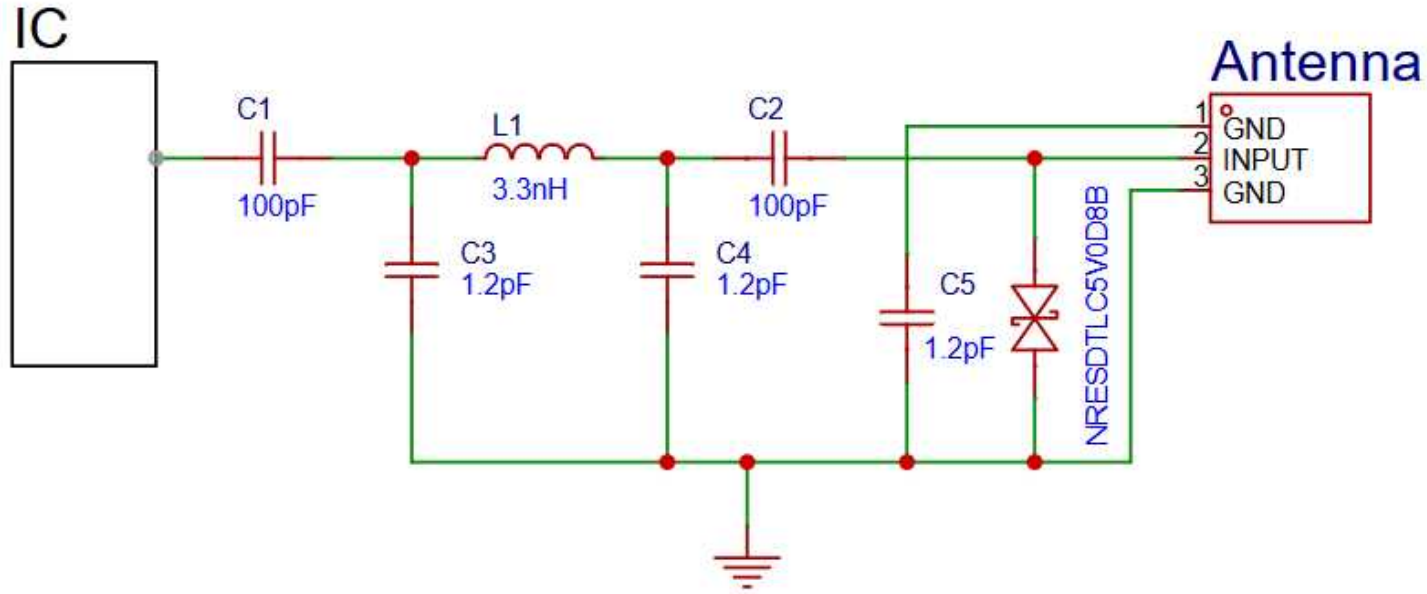
RS485 interface: RS-485 is a serial communication standard that can support multiple devices to communicate through the same serial bus; it is suitable for medium and long distance communication and has good anti-interference ability and data transmission stability.



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

4.7 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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