音特电子
YINT ELECTRONICS

Improvement, innovation, saving, win-win

Exploring the EMC Technology of Semi-Automatic Thromboelastography

http://www.yint.com.cn

Table of contents

音特电子
YINT ELECTRONICS

1. International and domestic standards

1.1 International Standards

1. Semi-automatic thromboelastographs primarily adhere to the IEC 60601 series of electromagnetic compatibility standards. IEC 60601-1-2, specifically for medical device electromagnetic compatibility, specifies requirements and test methods for electromagnetic compatibility of medical electrical equipment, including limits on emissions and immunity. This standard aims to ensure that the equipment functions properly in an electromagnetic environment while not causing electromagnetic interference to other nearby devices.
2. In the EU market, medical devices must comply with CE certification requirements, and IEC 60601-1-2 is a key component of the electromagnetic compatibility component of CE certification. This requires that semi-automatic thromboelastographs exported to the EU must meet all of the standards specified in this standard, including testing requirements for radiated emissions, conducted emissions, electrostatic discharge immunity, and radio frequency electromagnetic field immunity.

1.2 Domestic standards

- Domestic electromagnetic compatibility standards for semi-automatic thrombelastography primarily refer to GB/T 18268.1 and GB/T 18268.26.
- GB/T 18268.1 specifies general electromagnetic compatibility requirements for electrical equipment for measurement, control, and laboratory use, covering electromagnetic emission limits and immunity requirements.
- GB/T 18268.26 specifies specific electromagnetic compatibility requirements for in vitro diagnostic (IVD) medical devices.

- Domestic manufacturers of semi-automatic thrombelastography devices must conduct electromagnetic compatibility design and testing based on these standards during product development and production. Prior to market release, these products must undergo electromagnetic compatibility testing conducted by relevant testing agencies based on these standards to ensure they meet domestic market access requirements.

音特电子
YINT ELECTRONICS

2. Electromagnetic compatibility (EMC) content for electronic components

The international standard IEC 60601-1-2 covers several key aspects of electromagnetic compatibility for electronic components.

2.1.1 Emission Requirements:

Electromagnetic interference generated by equipment is strictly limited, including both conducted and radiated RF emissions. For example, conducted RF emissions within a specific frequency range must not exceed certain limits to prevent interference with other nearby electronic equipment through conductive paths such as power lines. For radiated RF emissions, the intensity of electromagnetic energy radiated into the surrounding space is limited to avoid interference with nearby wireless communication devices, medical monitoring equipment, and the like.

2.1.2 Immunity:

Equipment must exhibit excellent anti-interference capabilities. For example, it must be able to withstand electrostatic discharges of a certain intensity without malfunctioning or degrading performance, ensuring that static electricity generated by medical personnel during equipment operation does not affect normal operation. Furthermore, it must be able to withstand interference from RF electromagnetic fields. When exposed to RF electromagnetic fields such as mobile phone signals and wireless LAN signals, the equipment must continue to operate stably, ensuring the accuracy of test results.

2.2 EMC content of electronic parts in domestic standards

The domestic standards GB/T18268.1 and GB/T18268.26 share similarities with international standards regarding electromagnetic compatibility for electronics, while also incorporating specific domestic requirements.

2.2.1 Emissions:

Electromagnetic emissions from devices are also strictly controlled, with specific limits and test methods established to ensure that the devices do not cause excessive interference to other equipment when usec … complex domestic electromagnetic environments.

2.2.2 Immunity Requirements:

Emphasis is placed on the need for devices to withstand common domestic electromagnetic interference sources.

For example, considering the characteristics of the domestic power grid environment, requirements are set for the device's power port immunity to ensure normal operation despite power grid interference such as voltage fluctuations and harmonics.

Regarding immunity to electrical fast transients (EFTS), the device is required to withstand bursts of certain intensity and frequency, ensuring that data loss and malfunctions are avoided when exposed to such interference, thereby ensuring the reliability of the medical testing process.

音特电子
YINT ELECTRONICS

3. Problems in practical application

3.1 Pain point: Electromagnetic interference leads to unstable test results

In the complex electromagnetic environment of hospitals, there are various electronic devices nearby, such as MRI equipment, high-frequency electrosurgical units, and wireless communication devices. The electromagnetic interference generated by these devices may affect the proper functioning of a semi-automatic thrombelastograph, leading to deviations or fluctuations in test results.

For example, when the signal strength of a nearby wireless communication device is high, it may couple into the thrombelastograph's signal transmission lines, interfering with the instrument's acquisition and processing of blood sample test signals. This can lead to inaccurate coagulation parameters such as R value, K value, α angle, and MA value, thus affecting the doctor's accurate assessment of the patient's coagulation function.

01

The semi-automatic thromboelastograph's own anti-interference design may be insufficient, and its ability to resist interference from power supply, space electromagnetic field, etc. is weak. In different usage environments, such as wards and operating rooms in different hospitals, the equipment may not operate stably due to large differences in electromagnetic environment.

02

In the operating rooms of some old hospitals, due to the aging of electrical equipment, the power quality is poor, and there are many voltage harmonics and noise. When the thromboelastogram is connected to such a power supply, it may be interfered by the power conduction, causing the internal circuit of the instrument to work abnormally, affecting the accuracy and repeatability of the test

When operating a semi-automatic thromboelastograph, medical staff's actions, such as inserting and removing test reagents and connecting external devices, may generate transient electromagnetic pulses. If these interferences are not effectively suppressed, they can affect the normal operation of the device.

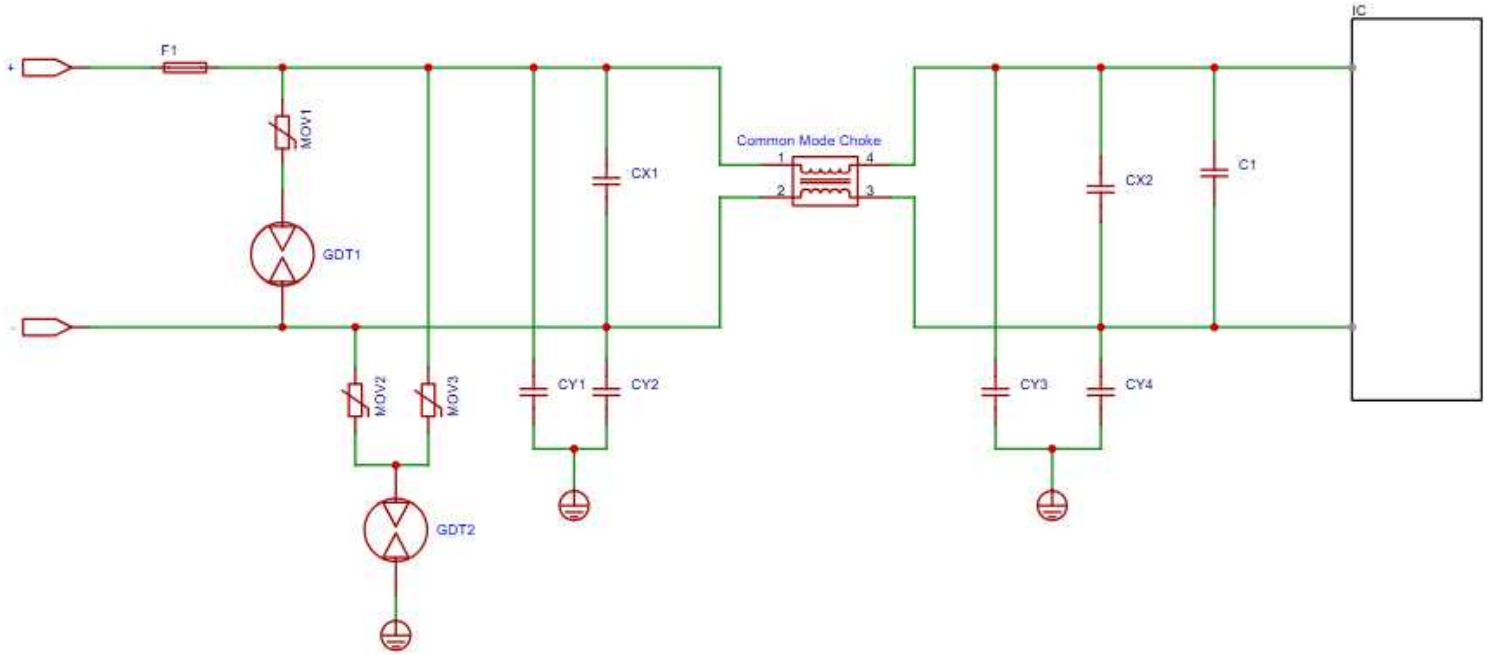
Case study: At a prefecture-level hospital, medical staff rapidly inserting and removing test reagent bottles can generate electrostatic discharge (ESD). This EMD can enter the device's internal circuitry, disrupting the instrument's microprocessor and causing issues such as device freezes and data errors, hindering the smooth progress of testing.

音特电子
YINT ELECTRONICS

4. I/O interface and circuit solutions

4.1 AC power interface EMC and reliability design

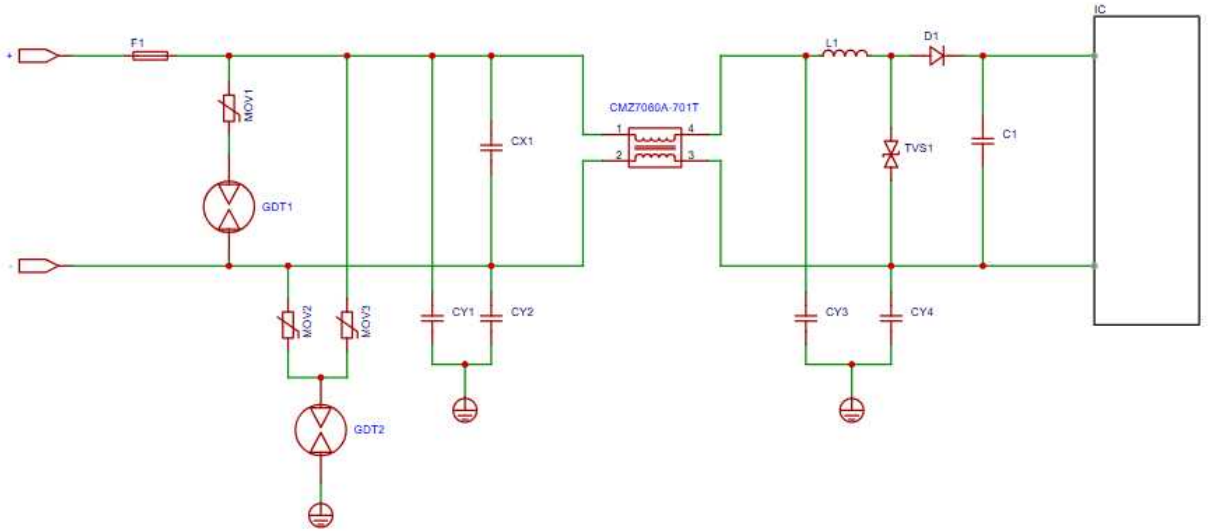
AC power interface: used to connect external 220V AC input



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

4.2 12V/24V DC power interface EMC and reliability design

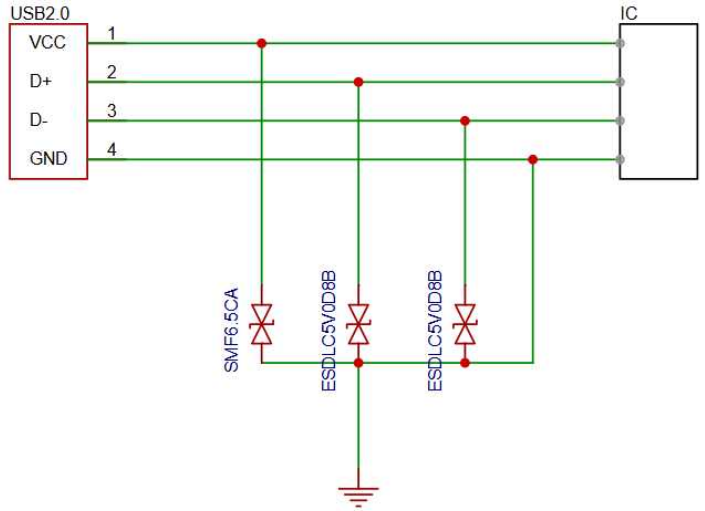
DC power interface: used to connect external 12V/24V DC power input to power internal modules (such as motors and sensors)



model	Device Type	Use Location	effect	Encapsulation
2R090L	GDT	Power interface	Surge and lightning protection (for outdoor products, pay attention to the issue of continuous current)	2RXXXL
20D820K	MOV	Power interface	Surge and lightning protection	20D
CMZ7060A-701T	EMI common-mode suppressors	Power interface	Common-mode rejection	7060
SMBJ15CA/SMBJ28CA	TVS	Power interface	Surge, load dump	SMB

4.3 USB-2.0 interface EMC and hot-swap reliability design

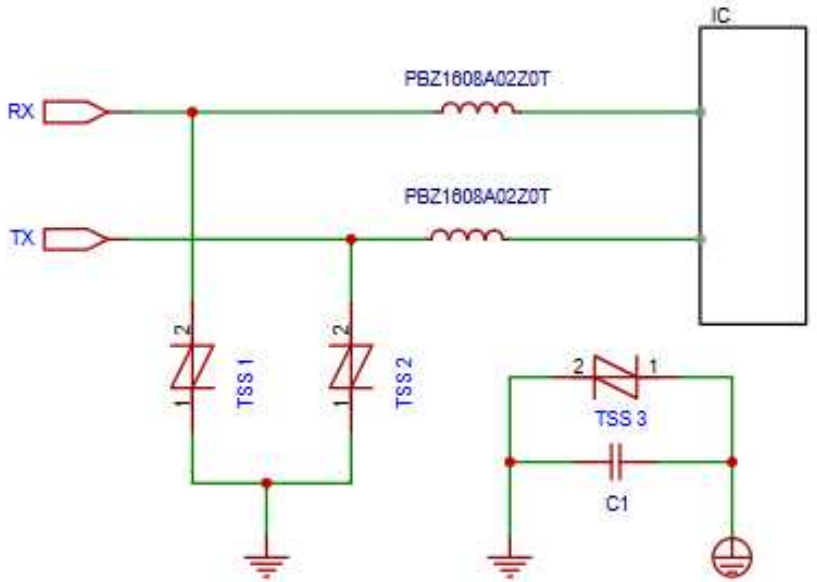
USB-2.0 interface: USB 2.0 is designed to provide faster data transfer speeds and better device compatibility; it also achieves a leap in interface speed, increasing it from the original maximum of 12 Mbps to 480 Mbps; this allows the USB interface to meet the needs of more high-bandwidth devices, such 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 RS-232 interface EMC and hot-swap reliability design

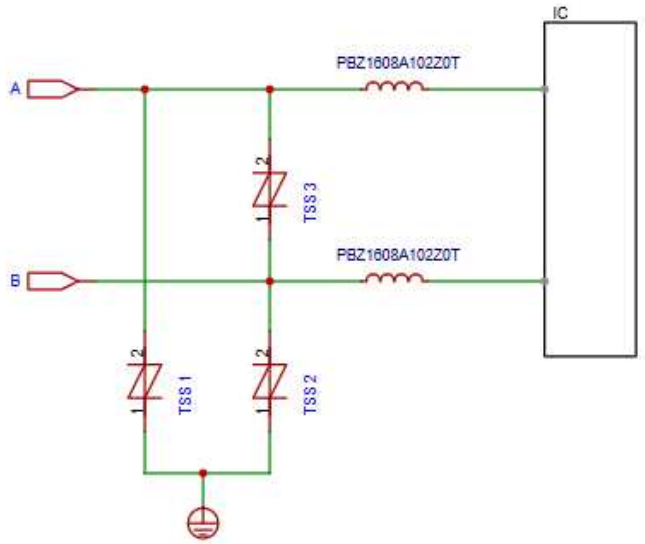
RS232 interface: It is one of the commonly used serial communication interfaces. RS232 is suitable for short-distance device interconnection (such as printers, mice, etc.), but it needs to adapt to different logic levels through a level conversion chip (such as MAX232)



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

4.5 RS-485 interface EMC and hot-swap reliability design

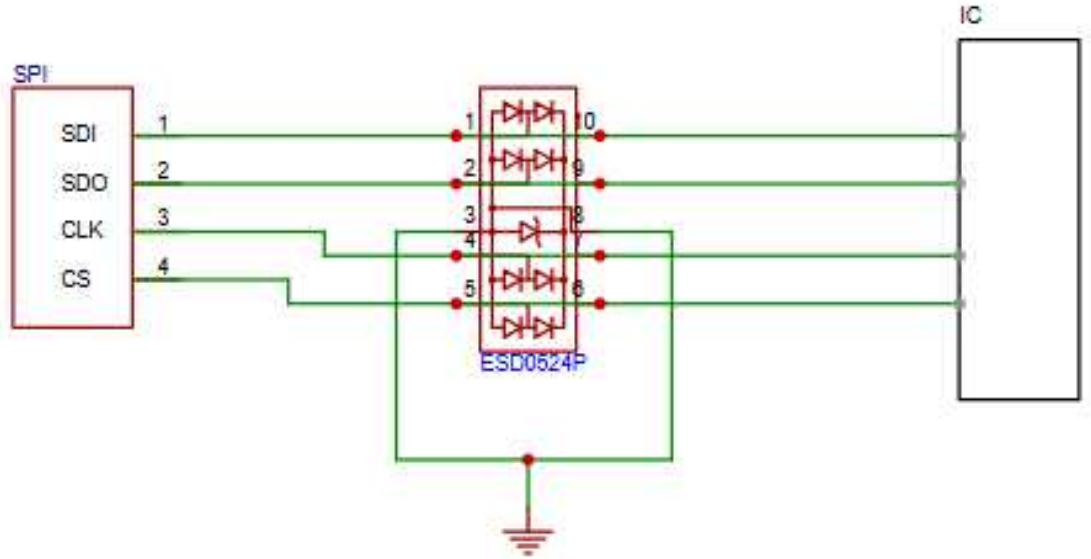
RS485 interface: RS-485 is a serial communication standard that can support multiple devices to communicate through the same serial bus; it is suitable for medium and long distance communication and has good anti-interference ability and data transmission stability.

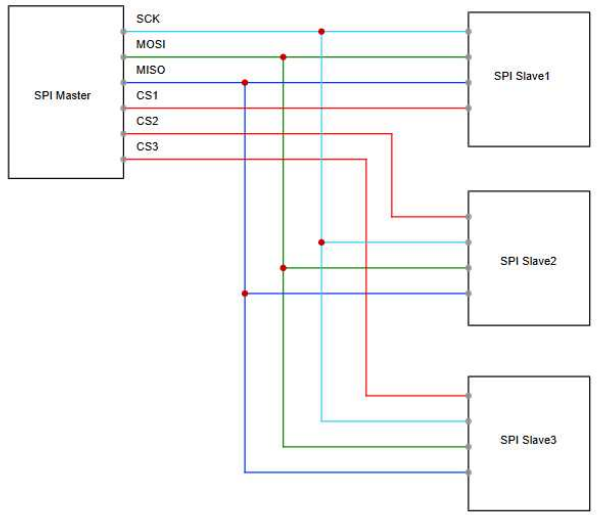


model	Device Type	Use Location	effect	Encapsulation
P0080SCL	TSS	RS485 interface	Surge, static electricity	SMB
PBZ1608A102Z0T	magnetic beads	RS485 interface	Eliminate high-frequency interference	1608

4.6 SPI interface EMC and hot-swap reliability design

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



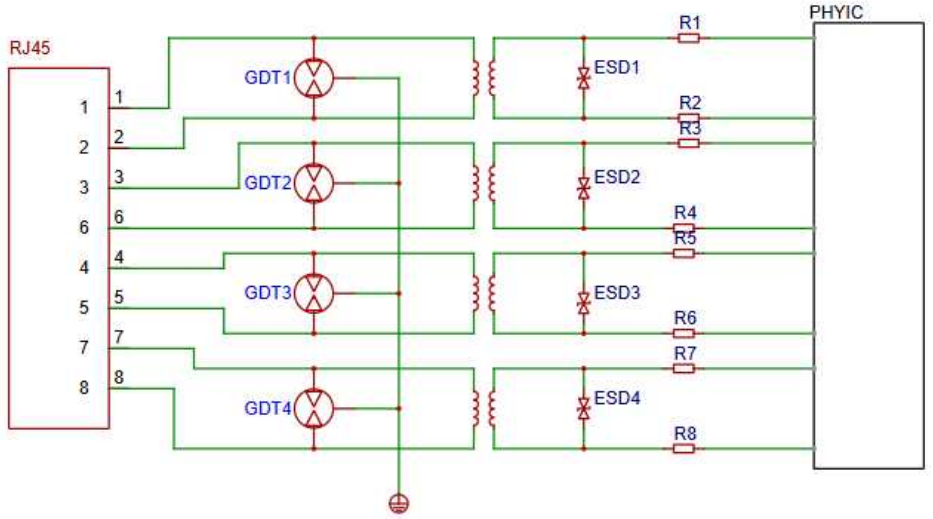


model	Device Type	Use Location	effect	Encapsulation
ESD0524P	ESD	SPI interface	Surge, static electricity	DFN2510

4.7 Ethernet Interface EMC and Hot-Swap Reliability Design

Ethernet interface：

Supports wired network connection; the Ethernet interface provides a stable network connection for the machine, supporting remote control and data interaction. Through Ethernet, the machine can upload working data to the cloud in real time, receive remote commands, and realize intelligent remote operation; its transmission rate can reach 1000Mbps or even higher, meeting the machine's demand for high-speed and stable data transmission in automation, intelligence and other fields.



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

音特电子
YINT ELECTRONICS

Improvement, innovation, saving, win-win

Foor 4,No.9 Building,Tus-Caohejing(Zhongshan)Science Park No.199,East Guangfulin Road,Songjiang District,Shanghai,China

Tel：+86-21-22817269　　Fax：+86-21-67689607　　Email：sales@yint.com.cn

http://www.yint.com.cn

Supporting organizations: Shimai Digital Pharmaceutical Industry (Hangzhou) Co., Ltd.

Shimai Pharmaceutical Consulting (Shanghai) Co., Ltd.

WeChat official account