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Dental Medical Industry and EMC Solutions

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1. Interpretation of dental medical equipment standards

1.1 Overview of International Standards

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01

The international standard IEC 60601-1-2:2015 specifically specifies the electromagnetic compatibility (EMC) requirements for the basic safety and essential performance of medical electrical equipment. Medical equipment, especially life-support equipment, has extremely stringent requirements for leakage current and anti-interference capabilities. For example, radiated emissions must be reduced by an additional 3-10dB in specific frequency bands. During testing, the equipment must simulate clinical use and must not be interrupted due to interference. A medical-grade filter must be used at the power input to meet the withstand voltage requirement of 2×Un+1000V. Low-capacitance TVS diodes must be used on signal lines to avoid signal distortion. Regarding electrostatic discharge (ESD) immunity, the equipment must not malfunction or lose data under interference, and a three-level protection system (GDT+MOV+TVS) can be used.

02

The international standard IEC 80601-2-60:2019 specifies special requirements for basic safety and basic performance of dental equipment. In terms of safety structure, the equipment must be stable and ergonomically constructed to prevent accidental injury to the user. Accessible safety switches must be easy to operate and be able to quickly cut off the power supply in an emergency. Grounding measures must be strictly implemented in accordance with the standard to ensure that the current can be safely conducted to the earth in the event of leakage. There are clear quantitative indicators for isolation voltage, insulation, electrical clearance, creepage distance, and withstand voltage to ensure the safety and reliability of the equipment's electrical performance.

1.2 Details of domestic standards

China has established a comprehensive standard system based on international standards and incorporating its own industry characteristics.

Regarding electromagnetic compatibility for medical electrical equipment, the YY 9706.102-2021 standard is adopted, equivalent to IEC 60601-1-2. It will be implemented on May 1, 2023, and covers tests for conducted emissions, radiated emissions, and harmonic currents. It requires equipment to maintain basic performance under interference, comprehensively guaranteeing the electromagnetic compatibility of motherboards.

Regarding the safety of dental equipment, the GB 9706.260-2020 standard is adopted, equivalent to IEC 80601-2-60. It requires dental equipment to use highly conductive shielding materials (such as copper and aluminum) to improve interference resistance. However, it does not specify separate EMC test limits, so it must be implemented in conjunction with YY 9706.102-2021.

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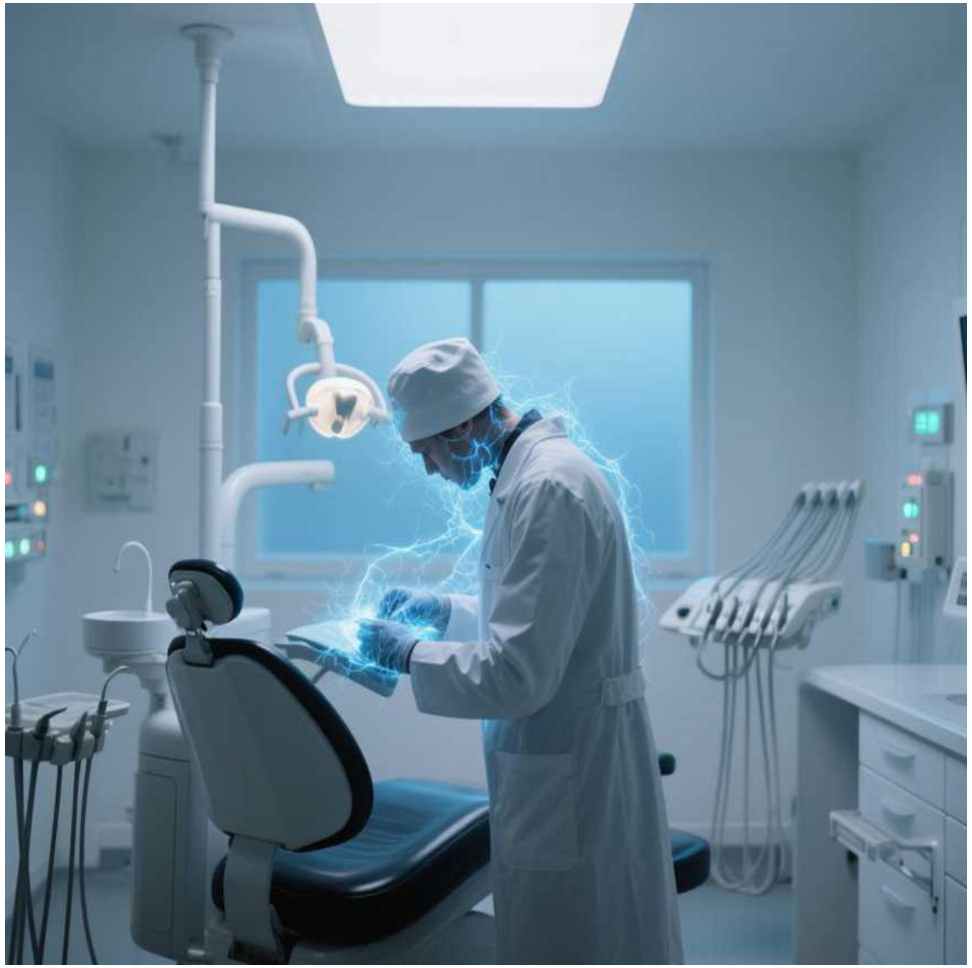
2. Analysis of EMC electromagnetic compatibility test requirements

2.1 Electrostatic Discharge Immunity



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Medical electrical equipment must meet specific electrostatic discharge immunity indicators, with air discharge being ±2KV, ±4KV, and ±6KV respectively. This simulates the electrostatic contact conditions that may occur in daily life, such as the static electricity generated by medical staff or patients when touching the equipment.

02

During the test, an electrostatic generator is used to simulate actual electrostatic discharge scenarios. Contact discharge is to discharge by directly contacting the discharge electrode of the electrostatic generator with the metal shell of the device; air discharge is to discharge the discharge electrode close to the device under test and discharge the device through sparks; indirect discharge is to discharge the discharge electrode through a 0.5m*0.5m metal plate placed vertically 10cm away from the shell surface of the device under test. If the device can operate normally during the test without freezing, data loss, malfunction, etc., it meets the requirements.

2.2 Fast transient burst immunity

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During the test, a fast transient pulse group generator that can generate a specific waveform is used to inject the transient pulse group into the power line or other signal cables and interconnecting cables through a coupling device. If the equipment can maintain normal functions during the test without malfunctioning or displaying errors, it meets the immunity requirements.

02

Since the AC power supply used by medical electrical equipment is connected to the public power grid, the discontinuous discharge caused by the closing of high-power inductive load switches or relay contacts of other electrical equipment will form fast transient pulse groups in the power line, which may interfere with medical equipment. The standard stipulates that the levels of ±0.5KV, ±1KV and ±2KV fast transient pulse groups should be applied to the AC and DC power lines.

2.3 Lightning Surge Immunity

01

Natural lightning or high-power load switching, power system failure will generate surges, which will interfere with the normal operation of equipment and even cause damage. The standard requires that the phase line of the AC power line should be applied with ±0.5KV, ±1KV and ±2KV to the ground; the phase line should be applied with ±0.5KV and ±1KV to the phase line.

02

During the test, the surge voltage is injected into the power line through the coupling device according to the national standard GB/T 17626.5. If there is no hardware damage or performance degradation after the test, it means that the device has passed the test.

2.4 Immunity to voltage dips, short interruptions and voltage variations

01

Power system failure or drastic load changes can cause power interruption or power supply voltage sag. Voltage sag refers to a sudden drop in voltage at a certain point in the electrical system for a short period of time, which returns to normal after a short duration of half a cycle to a few seconds. Short-term interruption refers to the disappearance of power supply voltage for a period of time, generally not exceeding 1 minute, and the voltage drops to zero, which can be considered a voltage sag of 100% amplitude. The standard has clear requirements for voltage sag, short interruption and voltage variation of the power supply.

02

During the test, voltage dips and short interruptions are tested using a voltage regulating transformer and switch according to the specified requirements. If the equipment can maintain normal function during the test, or can quickly return to normal after recovering from a short-term change, it meets the immunity requirements.

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3. Insights into Industry Pain Points and Common EMC Issues

3.1 In-depth exploration of industry pain points

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Dental equipment is increasingly demanding on precision and functionality. Cone-beam CT (CBCT)-based navigation systems can match preoperative planning with intraoperative bone tissue position in real time, dynamically adjusting the drill path. Dynamic stability control must resist interference from hand shake, tissue reaction forces, and other factors during surgery to maintain the stability of the operating trajectory. Multimodal collaborative operation equipment must support multiple operation modes, including drilling, milling, and laser cutting, and integrate with auxiliary functions such as irrigation and hemostasis to ensure operational continuity.

02

Cost pressure:
High R&D and production costs, including investment in advanced technology, procurement of high-precision components, and rigorous quality testing, result in expensive equipment and increase procurement costs for medical institutions.

03

Fierce market competition:
Many companies have entered the dental equipment market, creating intense competition. Internationally renowned brands dominate the high-end market with advanced technology and brand advantages, while domestic companies compete in the mid- and low-end markets. Companies need to improve their competitiveness in product quality, price, and service.

Dental equipment contains numerous electronic components, and electromagnetic interference is a common problem. High-speed rotation in dental motors can interfere with nearby electronic sensors, affecting the device's accurate acquisition of oral data. Electromagnetic interference not only affects device performance but can also lead to diagnostic and treatment errors, compromising healthcare quality.

Case:

Scenario	Software Algorithm	Motor system	Positioning technology
Minimally invasive immediate implantation	AI-based bone density analysis + automatic path planning	Micro servo motor (ϕ8mm, torque 1N・m)	Optical navigation (error ⩽ 0.3mm)
Complex bone augmentation surgery	Multimodal image fusion + stress simulation algorithm	Direct-drive stepper motor (resolution 1.8°)	Electromagnetic tracking (strong penetration)
Children's dental implants	Force control anti-overload algorithm + virtual barrier protection	Voice coil motor (response time < 10ms)	Ultrasound real-time imaging (no radiation)

01 Electromagnetic emission (EMI) exceeds the standard

Principle: High-frequency components within a device (such as motors, power supplies, and processors) radiate electromagnetic noise (such as radio frequency interference and harmonics) during operation.
Example: The brush commutation of a dental handheld motor generates high-frequency pulse noise. If not effectively filtered, this noise can couple to the display's driver circuitry, causing pixel signal distortion, flicker, or screen distortion. If EMI from power modules (such as switching power supplies) is not suppressed, it can be transmitted through the power line to the control system, interfering with the MCU's logic signals and causing display errors (such as data read errors).

02 Insufficient electromagnetic immunity (EMS)

Principle: The device lacks immunity to external electromagnetic interference (such as radio frequency signals from other equipment in the hospital and power grid fluctuations). Case in point: A nearby dental CT or laser device generates a strong electromagnetic field. If the display's driver chip lacks interference mitigation (e.g., lacks a shield or decoupling capacitor), this can cause the display controller to malfunction. Grid surges or harmonics (such as the start-up and shutdown of high-power equipment in the operating room) can intrude through the power lines, causing the display's power module to output unstable, leading to display anomalies.

03 Electromagnetic compatibility (EMC) design flaws

Principle: Improper layout of modules within the device leads to electromagnetic coupling (such as wire crosstalk and ground loops).
Example: Display cables are routed parallel to motor drive cables, creating parasitic capacitance coupling. High-speed motor pulse signals can interfere with the display signal, causing image flicker. Poor grounding system design (such as mixing digital and analog grounds) can cause high-frequency noise to flow back through the ground wires into the display circuitry, interfering with the reference voltage of the display driver chip.

3.4 Analysis of Common EMC Issues

04 Electronic Component Aging and EMC Performance Degradation

Capacitor Failure: As electrolytic capacitors age, their ESR increases, filtering capabilities decline, and power ripple increases, potentially causing unstable display power supply.

Shield Corrosion: As metal shielding covers or conductive adhesive strips age, their electromagnetic shielding effectiveness decreases, making it easier for external interference to penetrate the circuit.

Overheating Accelerates Aging: Inadequate EMI filtering can cause increased heating of inductive components (such as inductors) in the circuit, accelerating thermal aging of surrounding components (such as resistors and chips).

Electrical Stress Damage: Continuous electromagnetic interference can cause chips to operate abnormally for extended periods (such as frequent resets and logic errors), causing wear on internal transistors and shortening their lifespan.

05 Coupling effect of heat dissipation and EMC

Poor heat dissipation degrades EMC performance: Component temperature rise causes parameter drift. At high temperatures, capacitor and resistor values may deviate from their nominal values, leading to filter circuit failure (e.g., RC filter cutoff frequency shift) and reduced EMI suppression. Thermal deformation causes structural shielding failure: When plastic casings deform due to heat, the gap between shielding seams increases (e.g., exceeding λ/20, where λ is the interference wavelength), increasing electromagnetic leakage.

EMC design impacts: Heat dissipation paths: Shielding covers restrict heat dissipation. All-metal shielding can obstruct air flow. Without designing heat dissipation holes or heat conduction paths, components operate at high temperatures, creating a cycle of "poor heat dissipation → degraded EMC → increased susceptibility to failure." Common grounding and heat dissipation paths: Improper grounding design (e.g., grounding through a heat sink) can allow thermal noise to mix with the ground line, exacerbating electromagnetic interference.

4. Solutions to EMC issues in dental equipment

4.1 EMC Design Introduces "DFMEA"

1. Application Logic of DFMEA in EMC Design

Core Objectives:

Through structured analysis, identify potential failure modes, causes, and impacts in EMC designs, enabling proactive preventive measures.

Implementation Process:

Define Functional Requirements: Clarify equipment EMC performance indicators (e.g., emission limits, immunity levels).

Identify Potential Failure Modes: Analyze design weaknesses that could lead to EMC non-compliance.

Assess Risk Priorities: Calculate RPN values based on Severity (S), Occurrence (O), and Detection (D).

Develop Preventive/Detection Measures: Optimize the design for high-risk areas.

Tracking and Verification: Confirm improvement effectiveness through testing.

2. Typical DFMEA Analysis Items in EMC Design

System/Component	Potential failure modes	Failure impact	Possible causes	Preventive measures	Verification measures
Power Module	Conducted emission exceeds the standard	Interference with the power grid or other equipment	Inadequate filter circuit design and common mode choke saturation	Increase the order of EMI filters and select high saturation current cores	Line Impedance Stabilization Network (LISN) Testing
Motor drive	High-frequency radiation interference	Affecting the display or sensor signal	Motor brush sparks, improper PWM modulation frequency selection	Add RC snubber circuit and use sine wave drive technology	Near-field probe scans radiation hotspots
Display	Electrostatic discharge (ESD) causes screen distortion	Affecting doctors' operational judgment	The screen is not grounded and lacks ESD protection devices.	Add TVS diode array and metal frame grounding	IEC 61000-4-2 ESD
Sensor interface	Radio frequency interference causes signal distortion	Inaccurate measurement data	The distance between differential signal lines is too large and no common mode filtering is added	Reduce the spacing between differential pairs and increase common-mode inductance	Radio frequency electromagnetic field immunity (RS) test
PCB Design	Signal crosstalk causes false triggering	Device malfunction	High-speed signal lines are routed parallel to sensitive lines	Increase ground plane isolation and key signal ground processing	Time Domain Reflectometry (TDR) to detect impedance discontinuities
Shell structure	Electromagnetic leakage at joints	Radiation emission exceeds the standard	The metal shell seams are not conductively connected and the sealing ring is aging.		

3. Risk Assessment and Prioritization of EMC-DFMEA

Risk Priority Number (RPN) Calculation:

RPN = Severity (S) × Occurrence (O) × Detection (D)

Severity (S): 1 (negligible) to 10 (life-threatening)

Occurrence (O): 1 (extremely unlikely) to 10 (almost certain)

Detection (D): 1 (definitely detectable) to 10 (undetectable)

Decision Rules:

RPN ⩾ 100: Immediate action is required.

S ⩾ 8: Prioritize regardless of RPN value.

RPN 50 ⩽ < 100: Include in improvement plan.

RPN < 50: Acceptable risk.

4.4 EMC Design Introduces "DFMEA"

4. Key Tools for Implementing EMC-DFMEA

- **Simulation Tools:**

ANSYS HFSS: PCB-level electromagnetic field simulation, prediction of radiation ho

CST Studio: Whole-system EMC performance simulation, optimization of enclosure shielding design

- **Test Equipment:**

Spectrum analyzer + receiving antenna: Radiated emissions testing

EMC test receiver: Conducted emissions testing

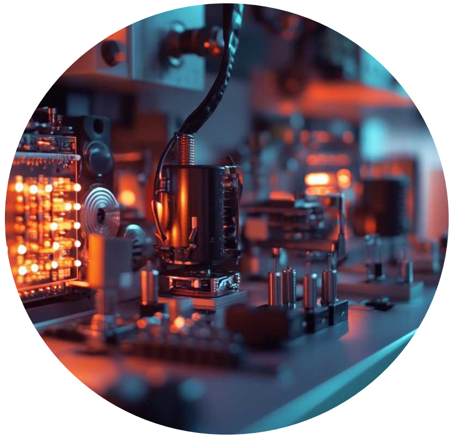
Oscilloscope + probe: Signal integrity analysis

- **Standardized Template:**

Adopts the AIAG-VDA DFMEA form, adding EMC-specific fields (e.g., "EMC Standard Clauses" and "Test Methods")

4.5 EMC Design Introduces "DFMEA"

5. Core Elements of EMC-DFMEA Implementation for Dental Equipment



Cross-departmental collaboration

Hardware engineers, EMC engineers, and reliability engineers jointly participate in analysis

Standards integration

References are made to medical device EMC standards such as IEC 60601-1-2 and YY 9706.102

Full lifecycle management

Design phase: Predict risks through simulation

Prototype phase: Verify effectiveness of measures through EMC testing

Mass production phase: Regular spot checks to monitor EMC stability

Continuous improvement

Establish a failure case library, identify common issues, and optimize design guidelines

6. Typical Case: EMC-DFMEA Improvement of Oral Implant Equipment

Problem Description:

During testing of a well-known company's oral implant navigation device, it was discovered that high-frequency noise generated by the motor drive module interfered with the optical positioning system, resulting in reduced positioning accuracy.

DFMEA Analysis and Improvements:

Failure Mode: The motor PWM drive signal interfered with the optical sensor through spatial radiation.

Risk Assessment: S = 8 (impacting surgical accuracy), O = 7 (design lacked isolation considerations), D = 4 (discoverable during testing) → RPN = 224

Improvement Measures:

Orient the motor drive PCB and sensor PCB in an orthogonal layout to reduce electric field coupling.

Add a common-mode choke to the motor drive circuit to reduce common-mode radiation.

Add a metal shield to the optical sensor module and reliably ground it.

Verification Results: Radiated emissions were reduced by 12dBμV/m, and positioning accuracy was restored to design specifications.

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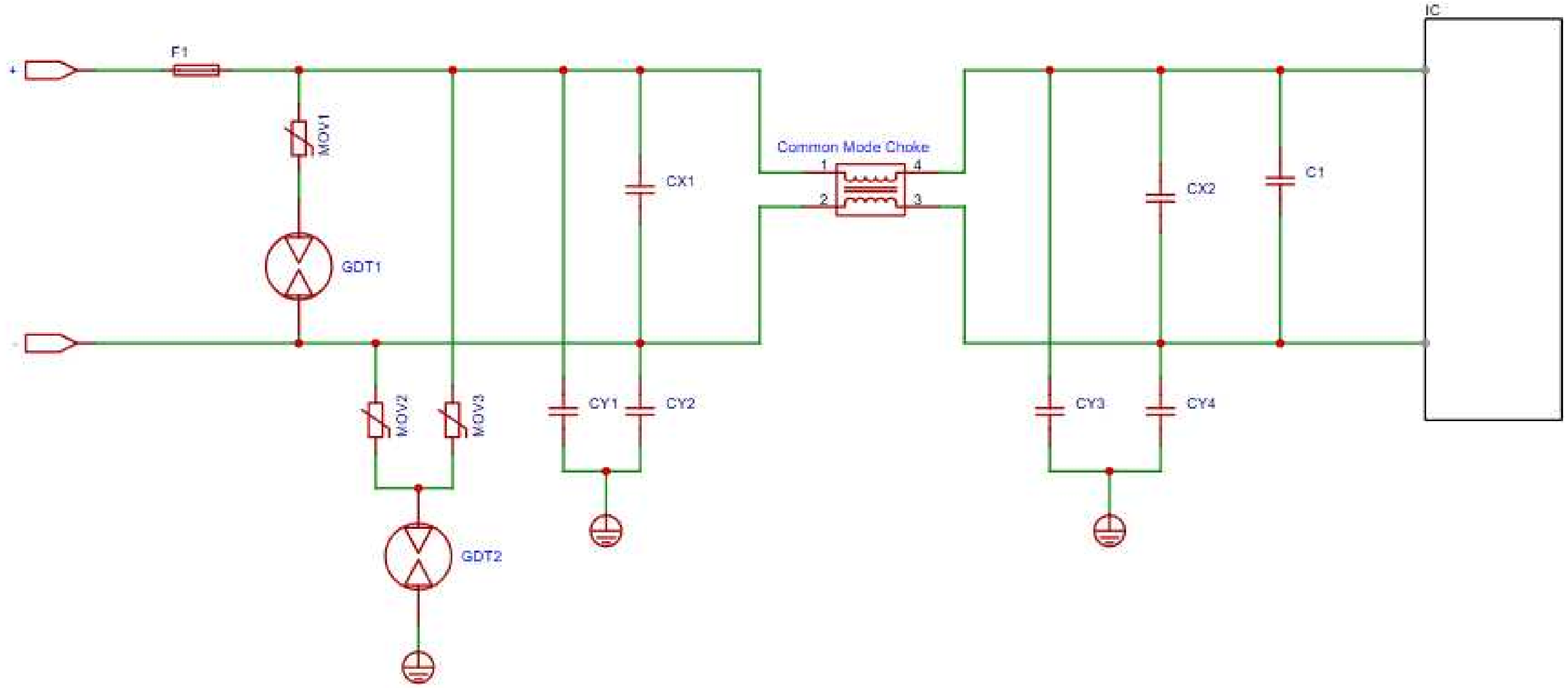
5. Analysis of commonly used interfaces and EMC design circuits

5.1 Power Interface EMC and Reliability Design

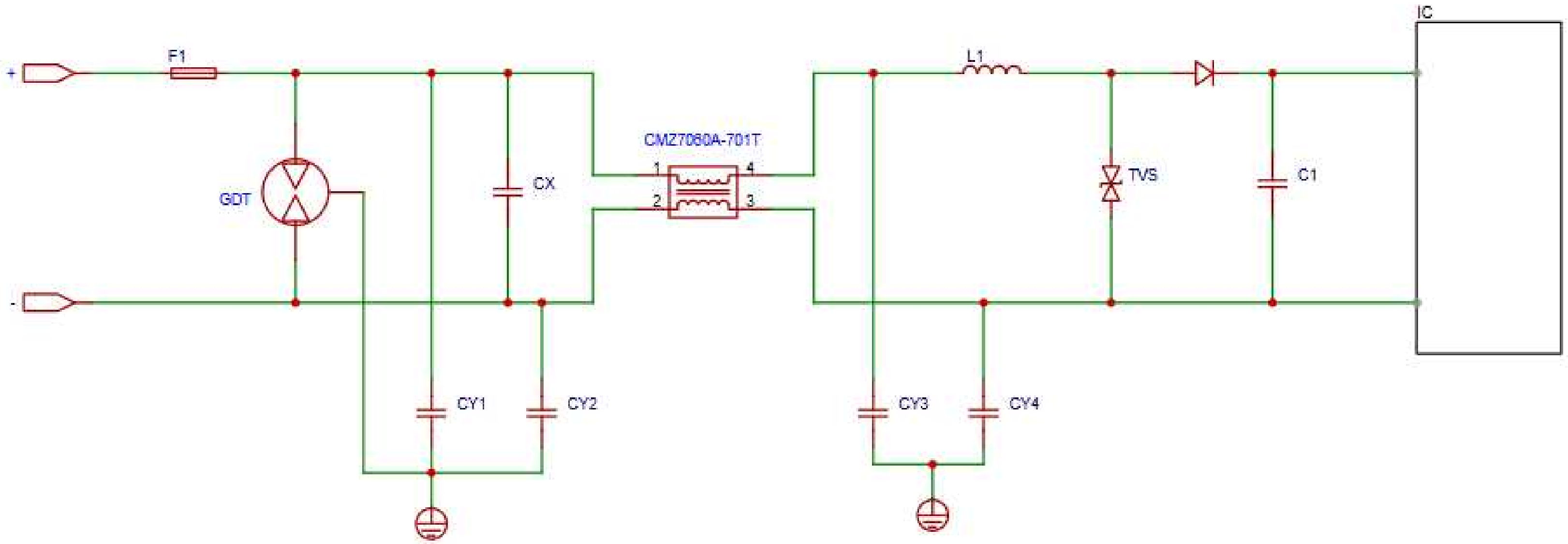
AC power interface: used to connect external 220V AC input



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

5.2 Power Interface EMC and Reliability Design

DC power interface: used to connect an external power adapter (such as 5V/12V DC input). Some motherboard chips support power supply via USB.

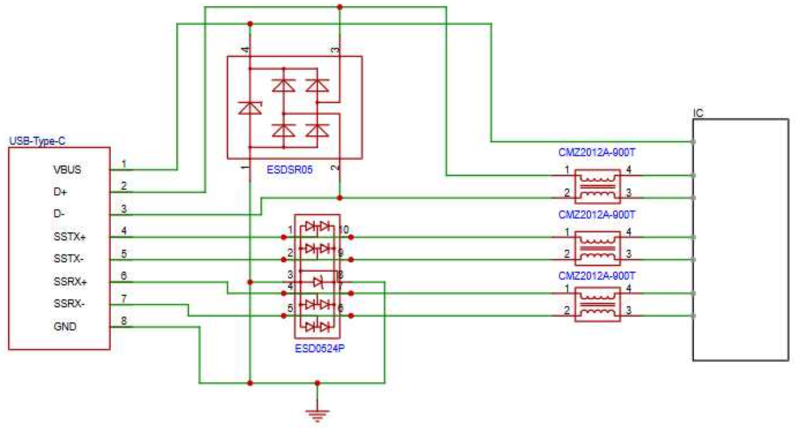


model	Device Type	Use Location	effect	Encapsulation
3R090L	GDT	Power interface	surge, lightning protection (outdoor products, focus on the issue of continuous current)	3RXXXL
SMBJ6.5CA	TVS Transient Voltage Suppressor Diodes	Power interface	surge, load dump	SMB/Do-214AA
SMCJ15CA	TVS Transient Voltage Suppressor Diodes	Power interface	surge, load dump	SMC/Do-214AB
CMZ7060A-701T	EMI common-mode suppressors	Power interface	CE conduction, common-mode rejection, smaller current, consider small encapsulation	7060

5.3 USB interface EMC and hot-swap reliability design

USB-Type-C interface:

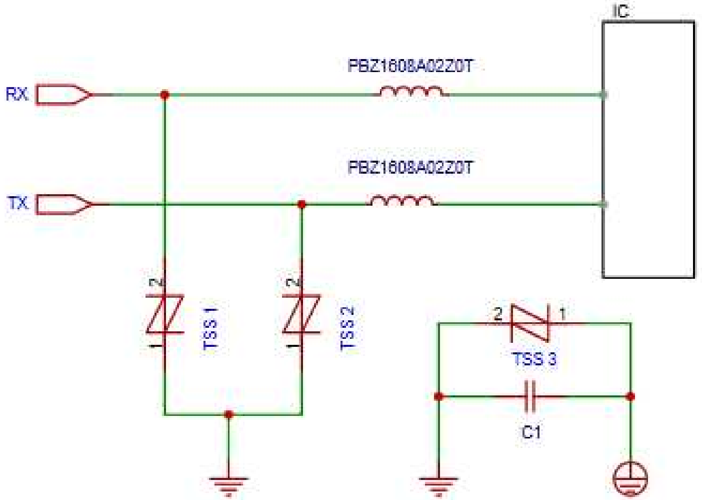
The USB interface boasts high-speed data transmission capabilities and is widely used to connect robots to external storage devices, sensors, and more. Its high-speed data transfer rate can reach 5Gbps, enabling rapid transmission of large amounts of data, such as robot vision image data. Its plug-and-play 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
CMZ2012A-900T	EMI common-mode suppressors	USB interface	Common-mode rejection	2012

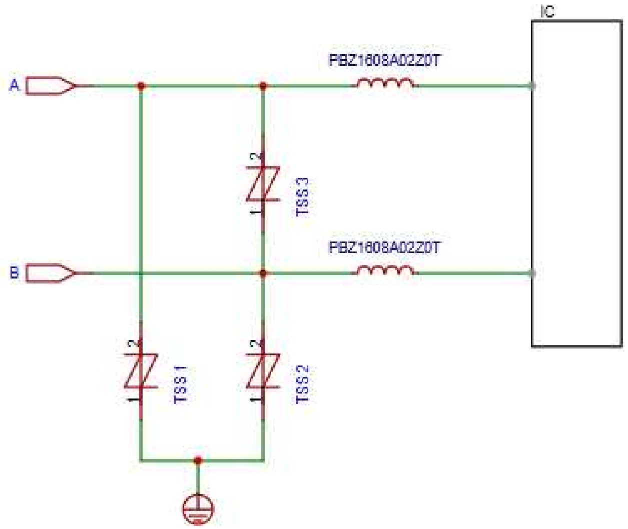
5.4 RS232 interface EMC and hot-swap reliability design

RS232 interface: RS232 is one of the commonly used serial communication interfaces. It is suitable for short-distance device interconnection (such as printers, mice, etc.) and 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

RS485 interface: RS-485 is a serial communication standard that supports 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

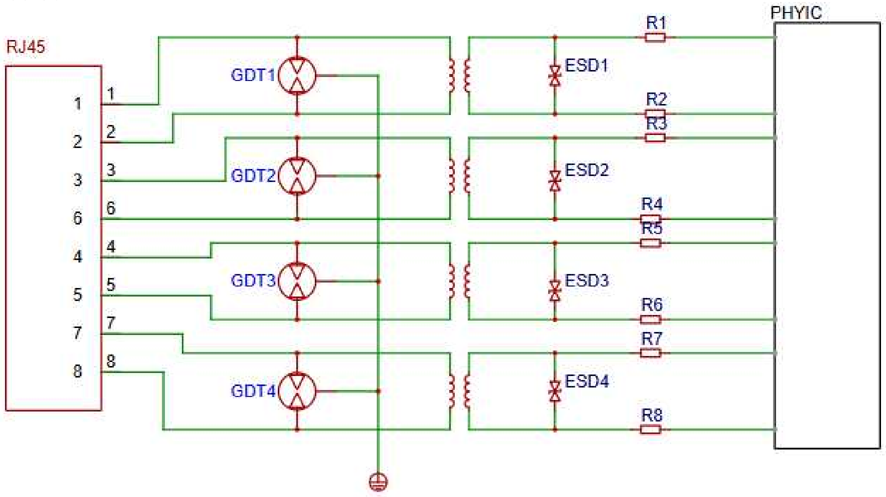
5.6 Ethernet Interface EMC and Hot-Swap Reliability Design

Ethernet interface:

Supports wired network connections (common on intelligent robot motherboards).

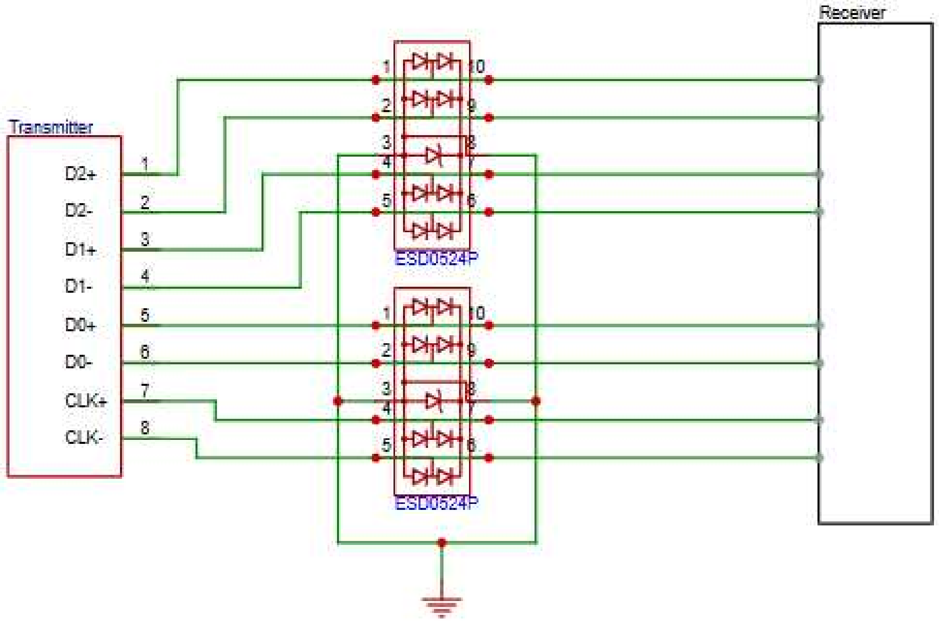
The Ethernet interface provides a stable network connection for robots, enabling remote control and data exchange. Through Ethernet, robots can upload real-time working data to the cloud, receive remote commands, and achieve intelligent remote operation.

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

HDMI interface: Used to connect to the display to output video signals (supported by some development boards)



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

5.8 CAN interface EMC and hot-swap reliability design

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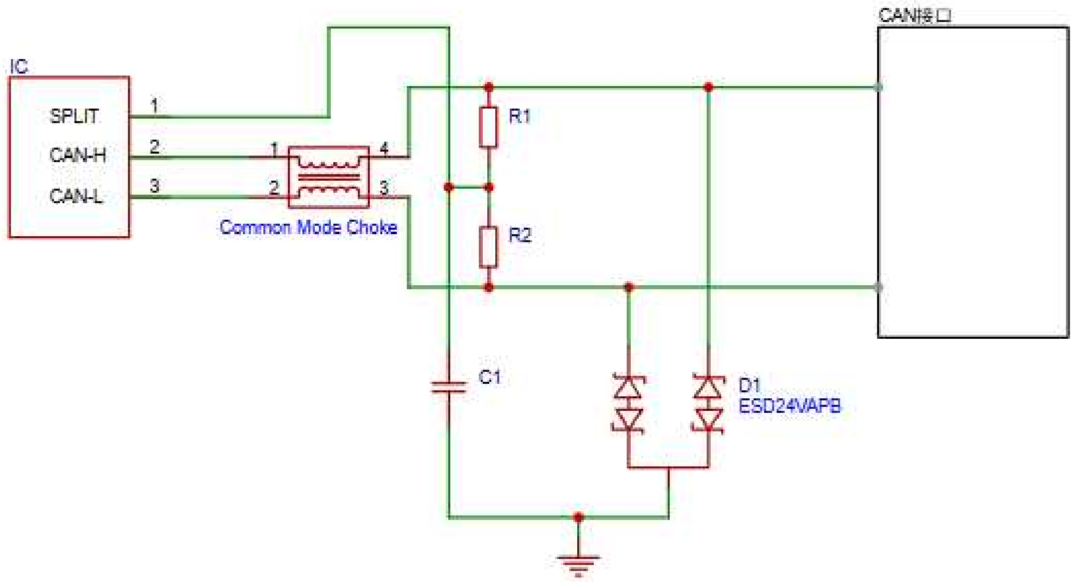
CAN interface: CAN interface Supports multi-host parallel communication, has strong anti-interference ability and real-time performance



model	Device Type	Use Location	effect	Encapsulation
ESD24VAPB	ESD	CAN interface	Surge, static electricity	SOT23
CML4532A/ CML3225A	EMI	CAN interface	Common-mode rejection	SMD

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