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Improvement, innovation, saving, win-win

Analysis of EMC core technology of feces analyzer

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1. International and domestic standards

1.1 International Standard Number and Name

Standard number	Standard Name	Core Content
ISO 15189	Quality and capability requirements for medical laboratories	Standardize the overall process of medical laboratories, including sample processing, testing operations, and result reporting related to stool analysis, to ensure laboratory capacity and quality
ISO 22870	Performance evaluation standards for in vitro diagnostic medical devices	Used to verify the performance indicators of stool analyzers such as detection accuracy and reliability, and to clarify the methods and requirements for performance evaluation
ISO 13485	Medical device quality management system requirements	Regulations on the quality management system of stool analyzer manufacturers, covering the entire process of design, production, inspection, etc., to ensure that products meet international quality standards
CLSI GP41-A6	Guidelines for Clinical Laboratory Specimen Processing (Including Stool Analysis)	Involves operational specifications for the collection, storage, pretreatment, and microscopic examination of stool samples, guiding laboratory standardized operations
21 CFR Part 820	US Medical Device Quality Management System Regulations	Require stool analyzer manufacturers to follow quality system requirements such as design control, production records, and post-market monitoring to ensure product safety and effectiveness
EU IVDR (Regulation (EU) 2017/746)	EU In Vitro Diagnostic Medical Device Regulation	Risk classification of stool analyzers (B/C/D), clarifying that high-risk devices must be reviewed by a notified body, requiring them to be labeled with a UDI, submit clinical data, and strengthen post-market monitoring.

1.2 Domestic standard number and name

Standard number	Standard Name	Core Content
YY/T 1745-2021	Industry standard for stool analyzers	The technical indicators of stool analyzers are stipulated as follows: detection rate ⩾ 90% (quality control products/simulated samples), carryover contamination rate ⩽ 0.05%, clinical compliance rate ⩾ 80% (compared with manual microscopy), and functional requirements such as visible element identification and occult blood detection are clarified.
GB/T 18268.1-2010	Electromagnetic compatibility requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirements	Corresponding to IEC 61326-1, standardizes the electromagnetic compatibility of fecal analyzers to prevent electromagnetic interference from affecting detection accuracy
GB/T 29791.3-2013	Medical devices—Labels and instructions—Part 3: In vitro diagnostic devices	Corresponding to ISO15223-3, it specifies the content requirements of the label and instructions of the stool analyzer, including the scope of application, detection limit, interference factors, etc.
GB 9706.1- 2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	
GB 4824- 2019	Industrial, scientific and medical equipment - Radio frequency disturbance characteristics - Limits and methods of measurement	

1.3 Other national and institutional standards and requirements

Standard No. / Certification Path	Standard Name / Regulation Name	Core Content
FDA 510(k) certified (Class II)	U.S. Food and Drug Administration Premarket Notification for Class II Medical Devices	Applicable to low- to medium-risk devices such as fecal occult blood test analyzers, which need to demonstrate "substantial equivalence" to marketed devices and submit performance verification data (such as accuracy and repeatability)
FDA PMA application (Class III)	U.S. Food and Drug Administration Class III medical device premarket approval	Applicable to high-risk testing equipment (such as parasite/pathogen typing), which requires submission of complete clinical trial data to prove safety and clinical effectiveness, and has a more stringent review process.
21 CFR Part 820	US Medical Device Quality Management System Regulations	Requires fecal analyzer manufacturers to comply with full-process quality system requirements including design control, production records, corrective and preventive measures, and post-market monitoring
EU IVDR (Regulation (EU) 2017/746)	EU In Vitro Diagnostic Medical Device Regulation	Risk classification: Class B (e.g., occult blood testing) can be self-declared or reviewed by a notified body; Class C/D (e.g., parasite/cancer screening) requires review by a notified body; requires a UDI label, submission of clinical data, and enhanced post-marketing monitoring

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2. Standard electronic part electromagnetic compatibility EMC content

2.1 EMC content for electronic components in international standards

The international standard IEC 60601-1-2 sets very strict requirements for electromagnetic emissions from electronic components.

It stipulates that both conducted and radiated emissions within the radio frequency range must not exceed specified limits to prevent interference with surrounding electronic equipment, such as medical monitors and communications equipment. In terms of interference immunity, the device must be able to withstand electromagnetic interference of a certain intensity, including electrostatic discharge, radio frequency electromagnetic field radiation, and electrical fast transient bursts, to ensure that the device does not malfunction, suffer data errors, or suffer damage when exposed to these interferences.

2.2 EMC content of electronic parts in domestic standards

- **YY/T 1745-2021 "Stool Analyzer Industry Standard"**

Scope of Application: China's dedicated standard for stool analyzers, explicitly citing the GB/T18268 series as the EMC standard. National Medical Products Administration Medical Device Technical Review Center

- **Core EMC Content:** Compliance requirements require the instrument host to comply with both GB/T18268.1-2010 (General Requirements) and GB/T18268.26-2010 (IVD-Specific Requirements) for Group I, Class A devices. National Medical Products Administration Medical Device Technical Review Center

- **Test Method:** EMC testing is conducted in accordance with the aforementioned standards, including immunity (ESD, EFT, RF fields, etc.) and emission limits (conducted and radiated). National Medical Products Administration Medical Device Technical Review Center

- **Clinical Compliance Rate:** The device must maintain ⩾80% compliance during EMC testing. Positive detection compliance rate (compared with manual microscopy) National Medical Products Administration Medical Device Technical Review Center

- **Anti-interference capability:** The device must operate stably in typical medical electromagnetic environments (such as Wi-Fi and high-frequency electrosurgical units) without data misjudgment. National Medical Products Administration Medical Device Technical Review Center

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3. Problems in the actual application of fecal analyzers

3.1 Pain Points Electromagnetic interference causes unstable detection data

For example, when large medical equipment such as an MRI machine is operating nearby, its powerful electromagnetic field may couple into the stool analyzer's circuitry, causing fluctuations in the detection signal and biased test results, affecting the doctor's accurate assessment of the patient's condition. Baseline drift caused by power-frequency magnetic fields (e.g., nearby transformers or MRI equipment) can also occur.

Symptom:

During a "blank control" test (testing a pure saline sample), the device should display "0 interferences," but instead exhibits persistent baseline fluctuations (the value fluctuates repeatedly between 0 and 5) indicating "suspected impurities." After extended use, the calibration standard's test value may deviate by more than 10% (e.g., the standard value is 100, but the measured value is 90 or 110).

Cause:

50Hz power-frequency magnetic fields (intensity exceeding 30A/m) interfere with the optical detection system's photodiode, causing a DC offset in the output signal and affecting data calibration stability.

3.2 Pain Points: Insufficient anti-static ability

During actual operation, electrostatic discharge (ESD) may occur when operators come into contact with the equipment. Due to the limited anti-static capacity of some components in stool analyzers, ESD may interfere with the device's internal circuitry, causing it to freeze, reboot, or malfunction. This not only affects testing efficiency but may also interrupt sample testing, necessitating retesting, increasing time and sample loss.

Symptom:
When medical personnel wearing rubber gloves touch the device's operating panel (such as the touchscreen or buttons), the display may suddenly flicker, menus may display garbled characters, or the entered sample number or test mode may be automatically altered. In severe cases, this may trigger a false alarm (a "system error" message appears even when no fault is present).

Cause: Human static electricity (especially in dry environments) can couple to the device's control circuitry through contact or air discharge, interfering with the microprocessor's signal processing and causing logical errors.

3.3 Pain Points: Sensitive to Power Supply Interference

A hospital's power supply system may experience voltage fluctuations, harmonics, and other power interference issues. If a stool analyzer is sensitive to power interference, power fluctuations can cause malfunctions, such as inaccurate test parameters and unstable sensor operation. This makes it difficult for stool analyzers to provide reliable test results in environments with poor power quality.

Mechanical transmission failures caused by electrical fast transients (EFTs)

Symptom:

During the automatic sampling process, the robotic arm may suddenly freeze (stopping above the sample rack), or the sample needle (the component that draws stool suspension) may deviate from its preset trajectory and strike the outer wall of the sample tube. In some devices, the "sample mixer" may experience inconsistent speed, resulting in inadequate sample mixing and poor test uniformity.

Cause:

High-frequency pulses (5kHz) generated by motor startup and switching in the power grid are coupled to the device's motor drive circuit through the power line, interfering with the stepper motor's control signal and reducing mechanical motion accuracy.

3.4 Pain Points: Lightning Surge Damage

Device downtime or hardware damage caused by surge interference (such as lightning strikes or power grid switching)

Symptom:

During a thunderstorm or after a power line switch in a hospital's power distribution room, the device suddenly displays a black screen and becomes unresponsive (unable to boot). Alternatively, after restarting, the device displays a "Sensor communication failure" message. Upon disassembly, the optical detection module's circuit board is found to be burned (with scorch marks).

Cause:

Surge voltage (up to 4kV between line and ground) breaks down the device's power module's lightning protection circuitry, directly damaging sensitive electronic components (such as operational amplifiers and sensor interface chips).

Based on the latest research from authoritative organizations such as NASA and the World Meteorological Organization, the top three countries and regions with the most frequent lightning activity are as follows:

First: Lake Maracaibo Region, Venezuela, Lightning Density: Annual average of 232.52 flashes/km^2 (highest globally)

Second: Kabare District, Democratic Republic of the Congo, Lightning Density: Annual average of 205.31 flashes/km^2 (highest in Africa)

Third: Kampene, Democratic Republic of the Congo, Lightning Density: Annual average of 176.71 times/km^2 (high frequency area in the equatorial region)

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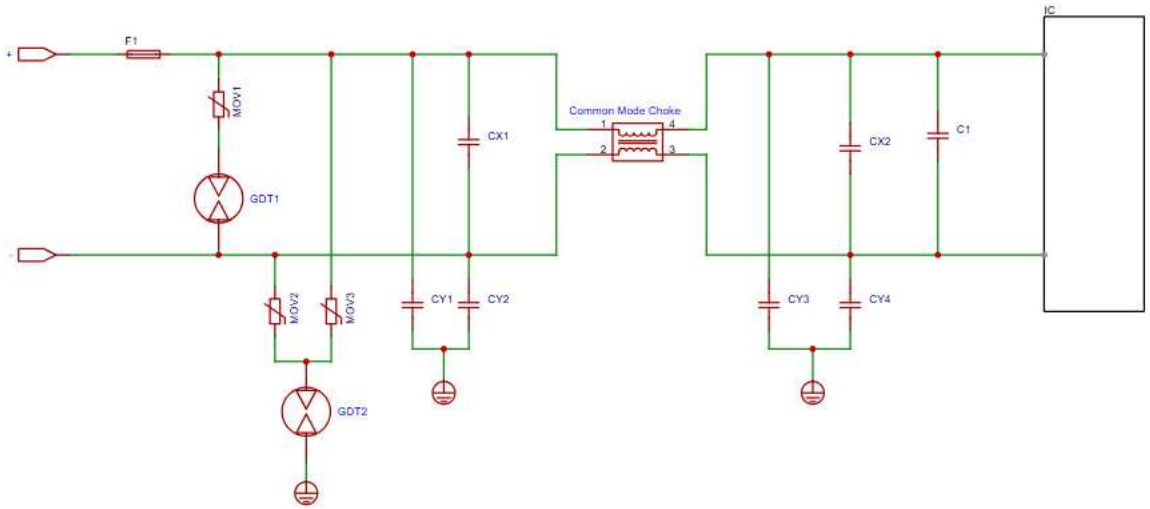
4. External I/O interface and display solutions

4.1 AC power interface EMC and reliability design

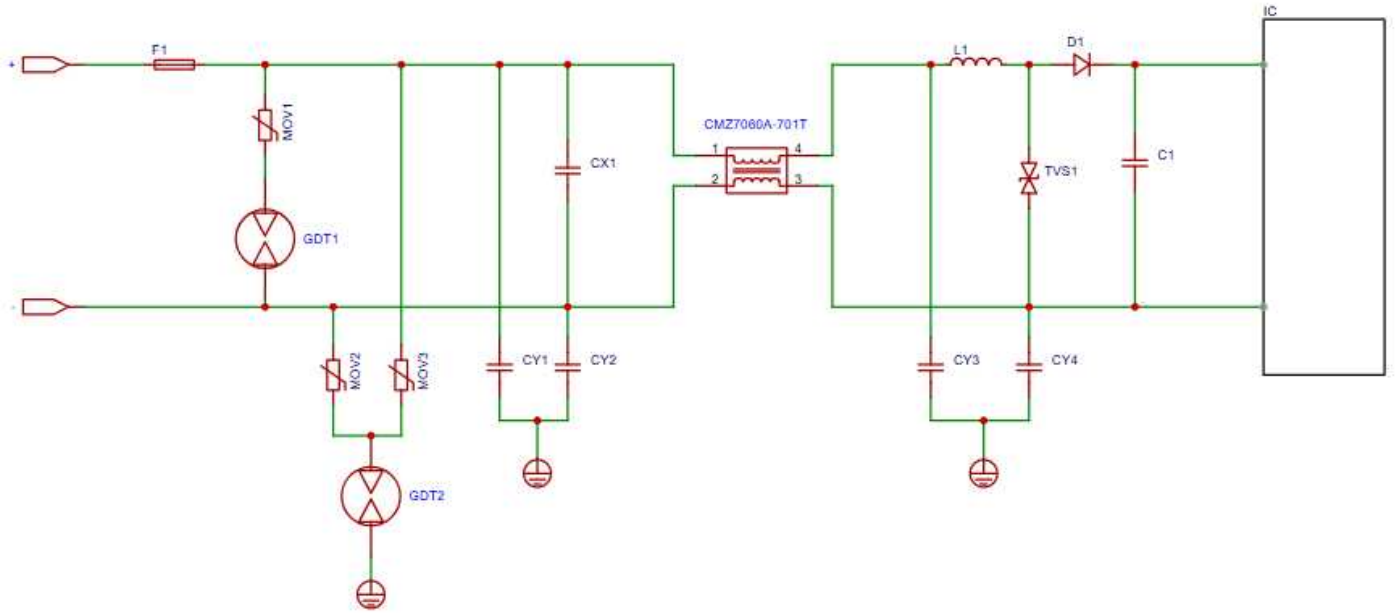
AC power interface: used to connect external 220V AC input



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

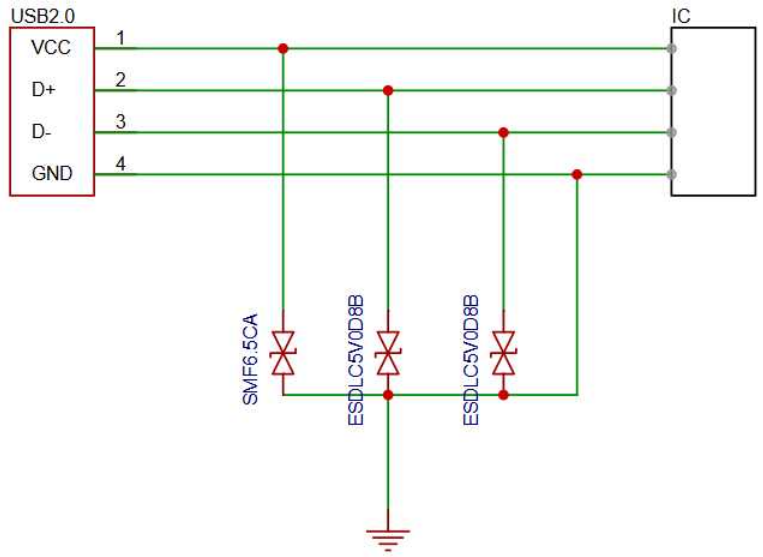
DC power interface: used to connect external 12V/24V DC power input to power internal modules (such as motors, sensors, etc.)



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.

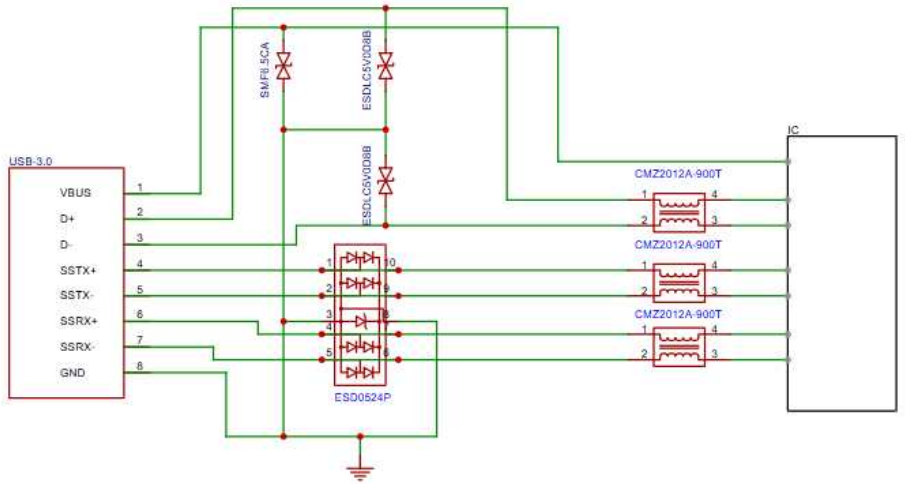


model	Device Type	Use Location	effect	Encapsulation
ESDLC5V0D8B	ESD	USB interface	Surge, static electricity	DFN1006
SMF6.5CA	TVS	USB interface	Surge, load dump	SOD123FL

4.4 USB 3.0 Interface EMC and Hot-Swap Reliability Design

USB 3.0 interface:

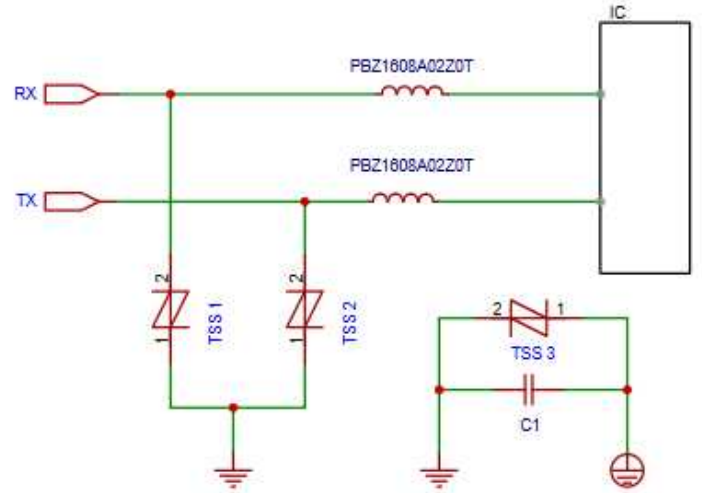
The USB 3.0 interface has high-speed data transmission capabilities and is widely used to connect machines to external storage devices, sensors, etc. Its data transmission rate in high-speed mode can reach 5Gbps, which can quickly transmit large amounts of data, such as machine vision image data. It has plug-and-play features, making 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
ESDLC5V0D8B	ESD	USB interface	Surge, static electricity	DFN1006
SMF6.5CA	TVS	USB interface	Surge, load dump	SOD123FL
CMZ2012A-900T	EMI common-mode suppressors	USB interface	Common-mode rejection	2012

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

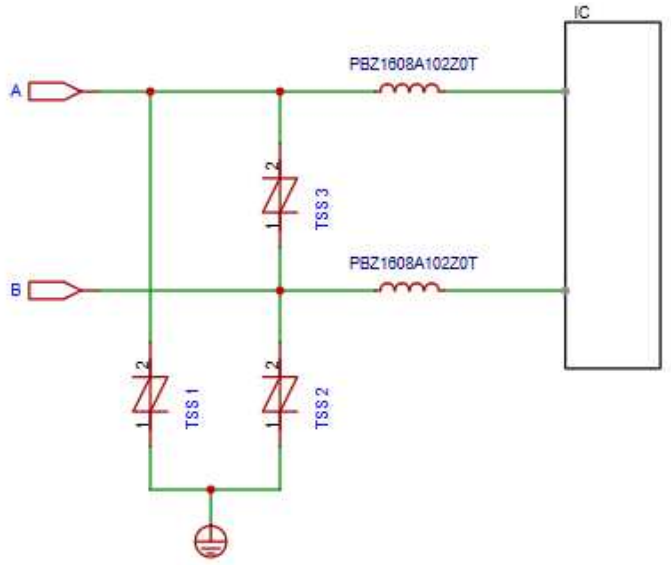
RS232 interface: It is one of the commonly used serial communication interfaces. RS232 is suitable for short-distance device interconnection (such as printers, mice, etc.), but it needs to adapt to different logic levels through a level conversion chip (such as MAX232)



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

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

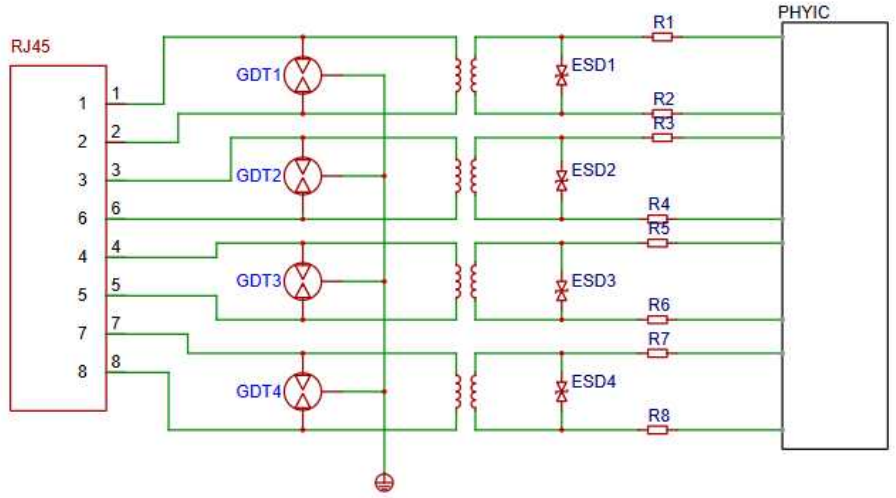
RS485 interface: RS-485 is a serial communication standard that can support multiple devices to communicate through the same serial bus; it is suitable for medium and long distance communication and has good anti-interference ability and data transmission stability.



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

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

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