

# MIT-T01 Microbial invasion sealing instrument



## 1. introductions

The MIT-T01 Microbial Invasion Sealing Instrument is suitable for microbial invasion sealing tests and is widely used for sealing testing of various materials such as penicillin bottles, ampoules, infusion bags, pre filled needles, eye drops, and other sterile packaging bags.

## 2. specifications

No.	Item	Spec.
1	Vacuum degree	-94kPa to 400kPa
2	Accuracy	Grade 0.25
3	Pressure tank	20L stainless steel tank, can customize
4	operating and control	Auto control, touch screen operating
5	Vacuum degree keeping performance	Auto gas replenishment and constant pressure maintenance
6	Air source pressure	0.7-0.9Mpa(air source prepared by client)
7	Air source connecting port	φ6mm Polyurethane pipe
8	Voltage	AC 220V 50Hz / AC 120V 60Hz
9	Dimension	Host:356x506x225mm
10	Weight	Host:9kg 20L pressure tank:15kg

### 3. test principle

Microbial invasion test method, also known as microbial challenge method, is a common sealing integrity testing method, usually conducted simultaneously with simulated filling. By simulating the filling of the culture medium according to the simulation filling verification plan, followed by plugging and capping, the visual inspection is qualified. After sterilization in the validated sterilization cabinet, the sealing surface of the container is immersed in a high concentration of bacterial solution, so that the culture medium in the sample container fully contacts the inner surface of the seal. The neck of the sample and the outer surface of the seal should be completely immersed in the bacterial suspension. After soaking for a certain period of time, it is taken out and regularly cultured to check for microbial invasion and determine the integrity of the container sealing system. At the same time, a positive control test needs to be conducted to confirm the growth promoting ability of the culture medium. Vacuum or overpressure challenge conditions are usually used in testing.

### 4. test standard

GB/T 10440、GB/T 18454、GB/T 19741、GB/T 8368、YY/T0681、YY 0285、ASTM F1140

### 5. application

<b>Basic application</b>	Sealing testing of penicillin bottles and ampoules
	Sealing testing of infusion bags and pre filled needles
	Sealing test of eye drops

### 6. features

- Key components are selected from world-renowned imported brands, with a pressure accuracy of 0.25 level
- Imported high-speed and high-precision sampling chips to ensure real-time and accurate testing data
- Automatic constant pressure air supply ensures that testing can be conducted under preset pressure conditions
- Automatic blowback unloading function, making the end of the test process simple and smooth
- Automatically adjust the pressure according to the customer's set pressure to improve the accuracy of pressure regulation
- High degree of freedom pressure time combination to achieve different testing conditions for customers
- Adopting stainless steel tanks, it is convenient for users to perform high-temperature disinfection on the tank body, improving the accuracy of the test
- Adopting large capacity stainless steel tanks to improve testing efficiency
- Large size high-definition color LCD screen, convenient for users to control and display real-time data and curves
- Support quick viewing of historical data

### 7. packing list

**Standard configuration:** Host, embedded software, 20L stainless steel pressure tank, Ø 6mm polyurethane pipe

**Optional item:** Non standard pressure tank

**Note:** The air source interface of this machine is a Ø 6mm polyurethane pipe; The gas source is provided by the user.