



# ROSHAN RAI SEPAHAN

Sterility Assurance Products

**Roshan Rai Sepahan**

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[www.kbmed.ir](http://www.kbmed.ir)



**RRS Sterilization Test**

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## RRS Steam Sterilization Emulating Indicator - Type 6

RRS type 6 steam indicators for steam autoclaves gives an exact indication whether the sterilization process has been successful or not.

### Features:

- Appropriate for two time-temperature
  - 121°C, 15 min
  - 134°C, 3.5 min
- Evaluate multiple critical parameters of sterilization process
  - Time
  - Temperature
  - Steam



Available in four different designs (14-110, 14-11610, 14-11620, 14-11630)

- Each indicator should be put in a pack, pouch or device intended for sterilization
- Check the indicator color change after finishing sterilization process
- Easy adhesion to the documentation notebook
- Laminated surface prevents washing out the chemical substances
- Easy interpretation by observing the evident color change
- Color reference on each indicator simplifies sterility evaluation
- Cost-effective indicator
- Simple and environmentally friendly disposal
- Conforms to ISO 11140 -1

# Integrator for Steam and Plasma Sterilization

## RRS Steam and Plasma Sterilization Indicator - Type 4

- Used to monitor both time and temperature in a sterilizer
- Designed for both steam and hydrogen peroxide sterilization
- Evident color change according to the color reference

RRS Type 4 sterilization integrator is used to monitor the sterilizer's performance.

Each indicator is put in each pouch, package or device intended for sterilization.

The color change according to the reference indicates whether the sterilization process has been successful or not



### Features:

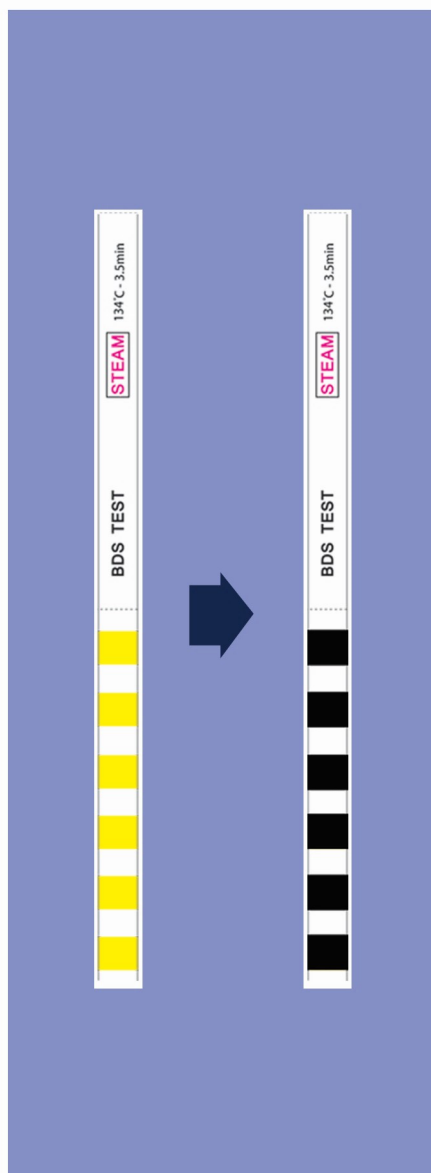
- Used to monitor both time and temperature in the sterilizer
- Designed for both steam and hydrogen peroxide sterilization
- Available in three models
- Self-adhesive labels in roll or sheet
- Laminated test strip for steam
- Laminated test strip for steam with ability to register specifications
- Test strip for plasma
- Conforms to ISO 11140-1



## Bowie & Dick Test Strips

### Steam sterilization indicator-Type2

**RRS Bowie-Dick Test** designed to check the steam sterilizer's performance. This is a daily test that detects any failure in sterilization process such as sterilizer air leaks, poor steam and inadequate vacuum, time and temperature. The test also evaluates steam penetration into the hollow and porous loads.



- Appropriate for pre-vacuum sterilizer
- Evaluate air removal and steam penetration into the hollow and porous loads.
- Easy interpretation by evident color change from yellow to black
- Test strip will be filed and documented
- Conforms to ISO 11140-1

The test set contains a stainless steel helix chamber and a 4.5 meters tube which simulate vacuum condition in a sterilizer. A type 2 test strip will be placed in the chamber. this test should be performed daily in the empty sterilizer. The yellow color of the indicator have to turn black completely to make sure of sterilizer's accurate function. The color change is permanent and the test strips can be documented.

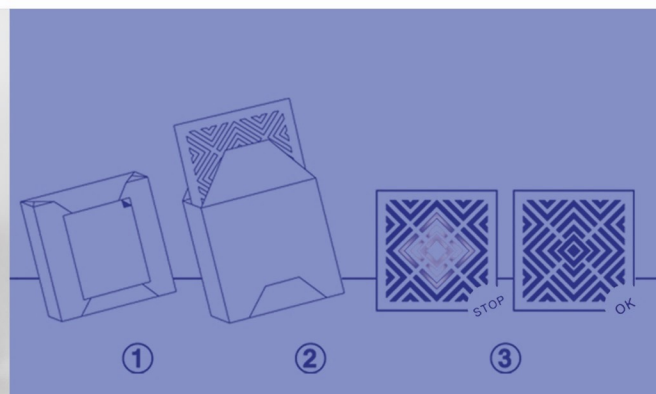
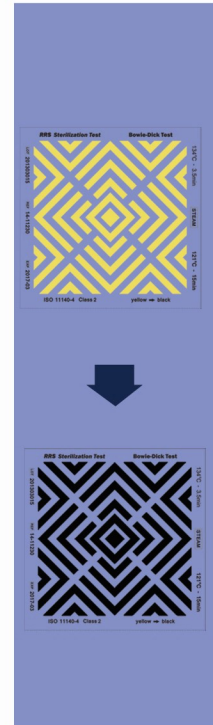


## Bowie & Dick Test Pack - Type 2

**RRS Bowie-Dick Pack** is designed to check the steam sterilizer's performance. This is a daily test that detects any failure in sterilization process such as air leaks, poor steam and inadequate vacuum, time and temperature. This test also evaluates steam penetration into the textile and porous loads.

### Features:

- Appropriate for pre-vacuum sterilizer to detect the residual air
- Easy interpretation by evident color change from yellow to black
- The pattern enhances the detection easiness of failure
- Laminated surface
- Test sheet will be filed and documented
- Environmentally friendly
  - Non toxic ink
  - Barrier are made from paper board
- Conforms to ISO 11140-4

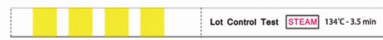


The package contains a Bowie and Dick test sheet with chemical indicator (type2) which is placed between two bundles of barrier paperboards and packed in an outer wrap. Barrier paperboards simulate 7 kg of cotton textile. The yellow color of the indicator have to turn black fully consistent to make sure of sterilizer's complete function. The color change is permanent and the Bowie and Dick test sheet can be documented.

# Process Challenging Device (PCD)

## for sterilization chemical indicators-Type 2

**RRS PCD** is the most challenging device to monitor sterilization process. This test is used to ensure the sterilization process of challenging loads such as long tubes with small diameter, internal surface of devices and porous items has been done successfully



### Features:

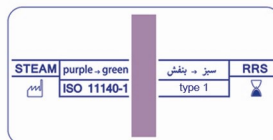
- Monitors all critical factors in the sterilization process
- Evaluates air removal and steam penetration inside the hollow and porous loads
- Easy interpretation by evident color change from yellow to black
- Test strip will be filed and documented.
- Appropriate for steam, ethylene oxide, hydrogen peroxide and formaldehyde sterilizers.
- Conforms to ISO 11140-5

The test set contains a stainless steel chamber and a helix tube (1.5 meters). The test strip is placed in the chamber. The yellow color of the indicator have to turn black fully to make sure of sterilizer's accurate function.



## Documentation Label with Chemical Indicator-Type 1

RRS double label documentation indicators used by labeler to be printed production date, expiration date and other required information about operator and autoclave number and etc. on the indicator provides assurance whether the package is exposed to sterilization cycle, not considering critical parameters parameters such as time, steam, and temperature.



### Features:

- Designed for steam, EO, plasma formaldehyde and gamma sterilization.
- Calibrated for 3.5 minutes at 134 °C, and 15 minutes at 121°C
- Evident color change for easy interpretation
- Conforms to ISO 11140-1

## Marker with Indicator Ink for Steam Sterilization Process-Type1

The marker produced by Roshan Rai Sepahan company is used to write on the following :

- Products in sterilizers
- Adhesive tapes
- Packing pouches

### Product Specifications

Used in autoclave as sterilization process indicator

Ability to write without pressure

Lack of toxic substances

Change the color from blue to red





# Self-Contained Biological Indicators (SCBIs)

## Conforms to ISO 11138

The color change of biological indicator to yellow, indicates a defect in the sterilization process after the mentioned period of time. If there is no color change in the indicator after the specified period of time, the result of the test will be negative and this indicates that sterilization performance is perfect.

Positive control should have a color changes from violet to yellow for the steam plasma and formaldehyde indicators, and green to yellow for ethylene oxide and dry heat indicators and orange to yellow for gamma indicator that indicates validation of the incubation process.

### Warning :

Avoid reuse of biological indicators.

Do not break the indicator immediately after leaving and do not force a lot to move it , because it can cause outpour of the fluid from the SCBIs.

### Maintenance of biological indicator :

Keep in a dark place at temperature of 10-30 ° C and a relative humidity of 80% -90%.

Do not put in a freezer.

Do not put these indicators near disinfectants and other chemical products.

### Disposal instruction

Dispose the biological indicators after use, in accordance with your country's health and safety laws. You can put the positive biological indicators in an autoclave at 121°C for at least 20 minutes or put at steam sterilizer under vacuum at 134°C for 10 minutes.



## RRS Biological Indicators for Dry Heat

RRS Biological indicators are known by most experts as sterilization process monitoring indicators and they evaluate the sterilization process directly by using the most resistant microorganisms.

### Types of biological indicators

#### Vial of self contained biological indicator

Is formatted from a plastic tube with a glass capsule containing special culture medium for growth and a filter strip inoculated with specific spores.

#### Ampoule of self contained biological indicator spores

A glass ampoul containing of special spore in the culture that is in the form of liquid for steam sterilizer and powder for dry heat sterilizer

#### Spore stripe

Contains a spore stripe which is packed with special coating and is incubated after use with special culture medium



### Composition of biological indicators:

Each tube contains a glass of culture medium for growth and a paper impregnated with a population of the spores

- *G. stearothermophilus* (ATCC 7953) for steam, plasma and formaldehyde
- *B. atrophaeus* (ATCC 9372) for ethylene oxide and dry heat indicators
- *B. pumilus* (ATCC 27142) for gamma indicators



## Dry-Bath Incubator For Biological Indicators (Steam & EO)

RRS Dual Incubator designed for both STEAM and EO  
Self Contained Biological Indicators SCBIs

14-3210



### Features:

- Two modes
  - C (48 Hours) for Ethylene Oxide biological indicators  $37 \pm 2^\circ$
  - C (24 Hours) for steam biological indicator  $56 \pm 2^\circ$
- Easy time/temperature selection
- Working power: 24 volts
- Reduces electrical hazards
- Equipped with a timer and alarm
- benefiting a backup battery to save time and temperature
- The ability to turn off and disconnect while keeping the setting and Passed Time (24 or 48 Hours)
- notification beep on cycle termination
- Digital LCD screen displays time and temperature



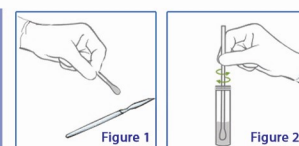
## Protein Test

A protein assay kit for detecting protein residue on the surfaces after washing

Protein residue test is a rapid test for detecting the residual proteins on the endoscopes, surgical instrument, and also surfaces of washing or disinfectant machines and ultrasonic cleaners



**Figure 3.** Negative result:  
Lack of protein residue  
on the surface of the  
instrument



**Figure 4.** Positive result:  
Presence of protein residue  
on the surface of the  
instrument

### Instructions for Use

- 1- Gloves must be used while using protein kit to avoid protein contamination by skin.
- 2- Rub the swab firmly over the desired surface if the surface is wet; and if the surface is dry, first moisturize the swab by sterile or distilled water and then rub it firmly over the desired surface (Figure 1).

**Note:** It should be mentioned that protein mostly remains in the pipes and gaps of the instruments.

- 3- Unscrew the reagent tube and swirl the swab for 30 seconds in the brown reagent (Figure 2).
- 4- Remove the swab and screw the cap.
- 5- Check the colour of the reagent, visually. If the color has changed to blue it shows that the sample contains protein on the desired surface. Darker blue shows presence of more proteins on the surface. If the reagent remains brown, protein is not detected (Figure 3 and 4).

**Maintenance:** Keep in the fridge or in the 2-25 °C, away from sunlight, high temperature, disinfectants, and chemical agents.

**Durability:** 18 months after production

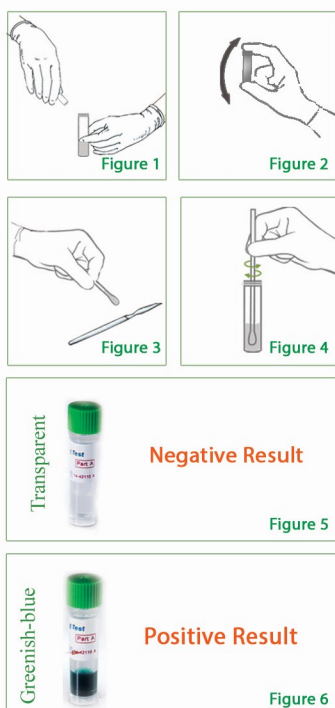
## Hemo-Test

RRS hemo-test is a rapid and accurate test for detection of blood residues on the surfaces of, endoscopes surgical instruments, washing or disinfectant machines and ultrasonic cleaner.

### Product features:

- Ready-to-use
- The colour change from colorless to greenish-blue within one minute indicates that there are blood residues on the surfaces.
- Detection of blood residue from 0.1 µg
- Insensitive to fingerprints (No false positives)

14-42110



### Instruction for use:

Figure 5 : Lack of the blood residue on the surface of the instrument (colorless or transparent)

Figure 6 : Presence of the blood residue on the surface of the instrument (greenish-blue)

### Instructions for Use:

- 1- First, pour part B that contains a clear solution into part A (Figure1)
- 2- Shake immediately part A tube after adding the solution of part B until the solid content of A tube is completely dissolved (Figure 2)
- 3-If the surface is wet rub the swab firmly over the desired surface, is otherwise first, moisturize the swab by sterile or distilled water and then rub it firmly over the desired surface (Figure3)
- 4-Unscrew the part A tube, insert and swirl the swab in the clear reagent (Figure 4)
- 5-The colour change from colorless to greenish-blue within one minute indicates that there are blood residues on the surfaces and if the intended surface is blood residues the colour of the indicator solution would remain colorless (Figure 5 & 6).



## Automatic Rotary Sealer (R900)

**RRS rotary sealer device (R900)** is designed and made with beautiful design and high quality for sealing medical packages that performs this sealer functions automatically with high speed .

By passing the paper from the defined location, the machine starts automatically and seals the medical packages.



### Advantages of R900 sealer device

- Touch Screen
- Sewing distance adjustment mechanism from the edge
- Adjustable temperature for sealing according to the type - of wrapping
- Easy recording and entrying of information on the touch screen of device
- Energy saving with auto power off in stand-by mode
- Equipped with a USB port for connecting to a printer for printing the label containing the name of the center, name and code of operator sterilization date and expiration, sterilizer number, batch number and the product name



## Testing of Sealer Device

Performance of the sewing and packaging device should be evaluated. Roshan Rai Sepahan Company has designed and made two test methods to evaluate the sealer device.

### 1- Sealer Ink Test

RRS Ink test is a standard and ideal method for leak detection in medical sterile packages that by using of penetration of ink into porous surfaces provide the possibility of detecting the leakage points



#### Instruction :

14-81210

- 1- Turn on the sealer device and allow it to reach to its appropriate operating temperature.
- 2- Cut about 10 cm from the roll of one package and seal one side.
- 3- Using of dropper, up take about 2 ml of the ink and pour it from opening side of the packaging.
- 4- Then rub it with your hand to expose the entire of package with the ink.
- 5- After 20 seconds, check the gaps of package to make sure it is sealed.
- 6- The ink leakage in the gaps will be visible easily.

**Conclusion:** If the ink does not penetrate into the sealed area, it indicates the sewing is healthy.

### 2- Paper test

#### Instruction

- 1- Turn on the sealer device and allow it to reach to its appropriate operating temperature
  - 2- separate about 10 cm from the roll of one package
  - 3- Place a sheet of sealer test between it and pass through the sewing device
- Conclusion:** The part passed through the device must have a continuous and darker line than the other parts, and no bubbles are visible.

#### Notification

- 1- The quality of the seal steps should be verified by using the test paper and ink, and then archived.
- 2- Having a regular and intermittent monitoring program makes it fast to detect any changes or problems in the packaging process.



14-81110

## Film Roll Dispenser with Cutting Blade Device for Sterile Packaging

**RRS dispense** for sterile packaging rolls is a particular device for prepartition of pouches with different lengths for a variety of application.

The dispenser of packaging rolls are designed and built in Roshan Rai of Sepahan Company in order to provide possibility to put more rolls for the users. It should be noted that the cutter blade and the ruler mounted on the machine allow the user to cut the rolls in different lengths easily.

### Advantages :

- High quality and durability
- Beautiful design
- With two floors
- With cutting blade
- With ruler

