

## Schirmer Tear Test Strips with Blue Mark

### DEVICE DESCRIPTION

A disposable whatman filter paper No 41 graduated strip (5mm width x 41mm length) with a least count of 1 mm. It's having a round blunt tip and a blue colour line in between tip to 5mm mark. Blue dye (FD & C Blue No.1) wicks up the scale to improve visibility in measuring tear production. This strip is packed individually in pouches before sterilization.

### INTENDED USE / INDICATION FOR USE

Transient Use (Less than 60 Minutes). It is recommended to withdraw the product after 60 minutes from the patient. The user is accountable for any type of problem taking place in case of use after 60 minutes of the same device.

### TARGET AGE GROUP

Use All Age Groups

### DURATION OF USE

Transient Use (Less than 60 Minutes). It is recommended to withdraw the product after 60 minutes from the patient. The user is accountable for any type of problem taking place in case of use after 60 minutes of the same device.

### STORAGE CONDITIONS

- Store at specified temperature and humidity (Temperature in between 5°C to 55°C and Humidity in between 55RH to 75RH).

### CONTRAINDICATIONS

The device should not be used in patients who show hypersensitivity to any of the components of the preparation. Schirmer Tear Test Strips with blue mark contraindicated in patients with ocular surface damage, inflammation or ulcers of cornea and conjunctiva.

### NATURE OF BODY CONTACT

Eyeball

### MODE OF ACTION

To conduct a Schirmer's test, a doctor places a piece of filter paper inside the lower eyelid of both eyes and the person closes their eyes. After 5 minutes, the doctor removes the filter paper. The doctor then assesses how far the tears have travelled on the paper. In general, the smaller the amount of moisture on the paper, the fewer tears that person has produced.

### HOW SUPPLIED

Schirmer tear test strips with blue mark are supplied sterile, in individual pouches. 100 such pouches are enclosed within an outer printed box. The overall packing contains Schirmer tear test strips with blue mark and medical literature insert, in an outer enclosing box, with external identification stickers.

### MATERIALS USED

Whatman Filter Paper no. 41

### CAUTIONS

Do not use the device if the sterilized package is open or damaged.

### DEVICE LIFE

The expiration date of the product is the sterility expiration date. The product should not be used after the indicated sterility expiration date.

### RETURN OF DAMAGED PRODUCT

Return the product in its original packing identified by the batch number, purchase information, your reference and reason for return. Please contact your local distributor office regarding product return/exchange.

### EXPLANICATION OF SYMBOL:

Symbol	Meaning
	Caution
	Manufacturer
	Date of Manufacture
	Do not re-sterilize
	Consult instructions for use
	Keep away from sunlight
	Don't re-use
	Authorized Representative in European Community
	This side up
	Do not use hook

- Accuracy:** The printed scale of a Schirmer strips is a mm scale from 00 mm to 35 mm with a least count of 1 mm. The accuracy of the complete scale (0 to 35) mm is  $\pm 1$ mm which implies an accuracy of  $\pm 0.028$ mm between two graduated mm lines

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### WARNING

- Madhu Instruments Pvt. Ltd does not hold any responsibility if the device is reused. Reusing the device may cause serious problems to patients are as under: -
  - The used strip might not have printed scale and may not comply with the claim.
  - The filter paper tip gets deformed after wetting. The used strip might not be in a position to be used again due to this deformed shape.
  - Reusing the device may cause the transfer of contagious and communicable disease to the patient and other serious problems to patients due to re-use of device such as HIV, Hepatitis, contagious diseases/communicable disease/undue diseases etc.
- Only qualified medical practitioner should use the device as per the intended use.
- Sterility is guaranteed only when the packing is neither opened nor damaged. Do not re-sterilize the device by any method. Madhu Instruments Pvt Ltd assumes no liability for devices that have been re-sterilized.
- Do not reuse the device.
- Read instruction before use.
- Store at specified temperature and humidity (Temperature in between 5°C to 55°C and Humidity in between 55RH to 75RH).
- The used strip and pouch should be disposed off in compliance with the local regulatory requirements.
- Do not use the device after sterility expiry date.
- For External use only.
- Keep out of reach of children.
- Keep away from sun light.

### PRECAUTIONS

- When handling the product care should be taken to avoid damage from handling. Avoid crushing and crimping damage to the product due to application of surgical instruments such as forceps etc.

### DIRECTION FOR USE

- Do not apply any topical medication to the eye or perform any manipulation of the eye before performing this test.
- Position patient in examining chair with head against a headrest.
- Examination room lights should be dimmed.
- Carefully open strips taking care not to touch the rounded end of the strip.
- While the patient looks up, carefully insert rounded end into the lower temporal lid margin of the eye, making sure the strip fits snugly.
- Wait for 5 minutes, remove the strip and record the length of the moistened area indicated by the distance travelled by the blue indicator dye.

### REPORTING

Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as product related and that were not previously expected in nature, severity or incidence must be report to Madhu Instruments Pvt. Ltd.

### DISPOSAL OF THE USED DEVICE

The used device should be disposed off in compliance with the local regulatory requirements.

Symbol	Meaning
	Conformity of European Norm with Notified Body Number
	Batch Code
	Use by date
	Temperature Limit
	Do not use if package is damaged
	Humidity Limitation
	Sterilized using Ethylene Oxide
	Handle with care
	Maximum stacking

**EC REP**

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