STANDARD TEST METHODS FOR MEDICAL TEXTILES

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SITRA

FACE MASK

FACE MASK

A surgical face mask is an important medical device used to protect both surgical patients and operating room personnel from the transfer of microorganisms, body fluids and particulate material.

IMPORTANT TEST METHODS TO EVALUATE FACE MASK PRODUCT CHARACTERISTICS

- Air permeability
- Bacterial filtration efficiency %
- Splash resistance

Bacterial filtration efficiency %
-ASTM F 2101

This test method measures the percent efficiency at which the face mask filters bacteria passing through the mask. The maximum filtration efficiency that can be determined by this method is 99.9%

SPLASH RESISTANCE MMHG-ASTM F1862

This test method is used to evaluate the resistance of medical face masks to penetration by the impact of a small volume (2ml) of a high velocity stream of synthetic blood. Medical face mask pass/fail determinations are based on visual detection of synthetic blood penetration

SURGICAL GOWN

Surgical gowns are worn by the doctors and nurses in the operating theater to address dual function of preventing transfer of microorganism and body fluids from the operating staff to the patient and also from patient to staff

BASIC REQUIREMENTS NEEDED FOR SURGICAL GOWN

- Resist the penetration of liquids and microorganisms
- Breathable
- Flexible
- Inexpensive

DIFFERENT TEXTILE STRUCTURES USED IN SURGICAL GOWN

- Single use type, made up by non-woven techniques
- Reusable category and normally developed through weaving

Major Organizations Have Published Guideline For Healthcare Workers

- Centers for Disease Control and prevention (CDC)
- Association of pre-operative Registered Nurses (AORN)
- Occupational Safety and Health Administration (OSHA)
- Operating Room Nurses Association of Canada (ORNAC)
- Association for the Advancement of Medical Instrumentation (AAMI)

AAMI CLASSIFICATION

There are four tests that must be performed in order to evaluate the performance of surgical gown.

1. Spray Impact Penetration Test
2. Hydrostatic Head Test
3. Resistance to synthetic blood
4. Viral penetration resistance

AAMI CLASSIFICATION SYSTEM

- **There are four levels of barrier performance, level 4 being the highest protection available**

Least Protective

Most Protective

Level	Test	Result
1	AATCC 42 Water Impact (WI)	≤ 4.5 g
2	AATCC 42, WI AATCC 127 Hydro Head (HH)	≤ 1.0 g ≥ 20 cm
3	AATCC 42, WI AATCC 127, HH	≤ 1.0 g ≥ 50 cm
4	ASTM F1671, Gowns ASTM F1670, Drapes	Pass Pass

- AAMI - Association for the Advancement of Medical Instrumentation

SPRAY IMPACT PENETRATION TEST: AATCC 42

A volume of synthetic blood is allowed to spray against the taut surface of a test specimen backed by a weighed blotter. The blotter is then reweighed to determine water penetration and the specimen is classified accordingly.

WATER RESISTANCE: HYDROSTATIC PRESSURE TEST

One surface of the test specimen is subjected to a hydrostatic pressure, increasing at constant rate, until three points of leakage on its surface. The water may be applied from above or below the test specimen.

Resistance to synthetic blood-ASTM F 1670

A specimen is subjected to body fluid stimulant (synthetic blood) for a specified time and pressure. Visual observation is made to determine when penetration occurs. Any evidence of synthetic blood penetration constitutes failure. Results are reported as pass or fail

RESISTANCE TO PENETRATION BY BLOOD-BORNE PATHOGENS - ASTM F 1671

- This test method is used to measure the resistance of materials used in protective clothing to penetration by blood borne pathogens using a surrogate microbe under conditions of continuous liquid contact Protective clothing material pass/fail determinations are based on detection of viral penetration.

OTHER TEST METHODS EVALUATE THE SURGICAL GOWN

- Water vapour transmission rate
- Tensile Strength
- Air Permeability
- Stiffness
- Flammability
- Bursting strength
- Thermal resistance

INTERNATIONAL SPECIFICATIONS FOR SURGICAL GOWN

- Specification for surgical gown-ASTM F 2407

  This specification establishes requirements for the performance, documentation, and labeling for surgical gowns used in healthcare facilities

- European EN 13795 aims to establish requirements for surgical gown, surgical drape and clean air suits used as medical devices for patients, clinical staff and equipment

SURGICAL DRAPE

TEST METHODS

- Drape
- Air permeability
- Weight per unit area
- Breaking strength and elongation of textile fabrics
- Flammability
- Anti bacterial activity assessment (Qualitative)
- Antibacterial activity assessment (Quantitative)
- Thermal resistance
- Linting test

HOSPITAL BED LINEN

TEST METHODS TO EVALUATE THE CHARACTERISICS OF BED LINEN

- Weight/square metre
- Tensile strength
- Tear strength
- Antibacterial activity assessment (Qualitative)
- Antibacterial activity assessment (Quantitative)

BABY DIAPER

- Diaper is used for wrapping the newly born or young children, who have not developed the fixed routine for making water or latrine.

- Diapers retain the liquid for about two hours

- Diapers can play an important role in contamination prevention and the reduction of infection

- Disposable diapers are more effective in urine/feces containment than cloth

- Increased contamination of surfaces in day care settings has been linked to infectious diarrhea outbreaks

DIAPER CONSTRUCTION

- Cover stock / top sheet layer (non-woven material)
- Absorbent core (Cellulose fluff pulp + Super absorbent polymer)
- Back sheet: Polyethylene film structure or a film / non-woven composite

IMPORTANT PROPERTIES REQUIRED FOR THE BABY DIAPER

- Soft
- High absorbency
- Protection against leakage
- Should not re-wet
- Comfortable

TEST METHODS TO EVALUATE THE FUNCTION OF BABY DIAPER

- Speed of Absorption
- Re-wet
- Absorbent Capacity
- Absorbent Retention
- Fit and Comfort

First three performances are very important

LIQUID – STRIKE THROUGH TIME (SIMULATED URINE)

This test method measures the strike through time (i.e.) the time taken for a known volume simulated urine applied to the surface of a test piece of non-woven cover stock, which is in contact with an underlying absorbent pad, to pass through non-woven.

DIAPER RE-WET

The purpose of the test is to examine the ability of diaper cover stock to resist the transport back onto the skin of a liquid which has already penetrated the cover stock.

INCONTINENCE PRODUCT

INCONTINENCE PRODUCT TESTING

- Volume of leaked liquid
- Absorption rate
- Wicking rate
- Wettability
- Permeability

SANITARY NAPKIN

TEST METHODS

- **Absorbency**

  The sanitary napkins shall absorb 30 ml of coloured water or oxalated Sheep or goat blood or test fluid when lowed onto the centre of the napkin (at the rate of 15 ml per minute) and it shall not stain through/leak through at the bottom sides of the sanitary napkin

TEST METHODS

- **pH Value**

  The sanitary napkin shall be free from acids and alkali and the pH of the absorbent material shall be 6 to 8.5

- **Disposability**

A disposable sanitary napkin with the covering removed, shall be immersed in 15 litres of water and stirred. The pad shall disintegrate in the water in not more than 5 minutes

GAUZE BANDAGE

Test methods to evaluate the characteristics of Gauze bandage

- Yarn count (Tex)
- Threads/10cm
- Colouring matter
- Surface active substances
- Sulphated ash
- Ether soluble substances
- Water soluble substances
- Loss on drying
- Foreign matter
- Viable micro organism prior to sterility (cfu/gram)
- pH
- Absorbency(second)

PLASTER OF PARIS BANDAGE

TEST METHODS TO EVALUATE THE CHARACTERISTICS OF PLASTER OF PARIS BANDAGE

- Threads per unit length
- Weight of the fabric (GSM)
- % Calcium sulphate
- Tensile strength, kg/cm2
- Compressive strength kg/cm2
- Setting time, minutes
- Alkalinity

CREPE BANDAGE

TEST METHODS TO EVALUATE THE CHARACTERISTICS OF CREPE BANDAGE

- Yarn count
- Warp yarn twist
- Threads/10cm
- Stretchability
- Breaking load
- pH

NON-WOVEN GAUZE BANDAGE

Non-woven gauze is of mesh structure (similar to woven cloth) made from viscose rayon, polyester blend fabric with minimum 65% viscose content.

TEST METHODS

- Weight (GSM)
- Length and width
- Fluorescence
- Sterility
- Foreign matter
- Absorbency (second)

SUTURES

Tests should be carried out for sutures

- Diameter
- Tensile strength
- Bending stiffness
- Surface roughness
- Knot pull strength
- Knot security

CIRCULAR KNITTED BANDAGES

THE FOLLOWING TESTS SHALL BE CONDUCTED FOR CIRCULAR KNITTED BANDAGES

- Thickness
- Air permeability
- Weight per unit area
- Breaking strength and elongation of textile fabrics
- Skin irritation
- Anti bacterial activity assessment (Qualitative)
- Antibacterial activity assessment (Quantitative)
- Thermal resistance

COMBINED WOUND DRESSINGS

- Wound contact layer
- Middle absorbing layer
- Base material

THE FOLLOWING TESTS SHALL BE CONDUCTED FOR COMBINED WOUND DRESSINGS

- Skin irritation test
- Air permeability
- Weight per unit area
- Breaking strength and elongation of textile fabrics
- Absorbency
- Anti bacterial activity assessment (Qualitative)
- Antibacterial activity assessment (Quantitative)
- Thermal resistance

Elastic adhesive bandage

It consists of a woven fabric, elastic in warp direction and coated with the adhesive mass containing zinc oxide. The adhesive mass may be porous or permeable to air and water vapour

Test methods

- Threads per 10cm
- Weight of the fabric (GSM)
- Weight of adhesive mass
- Zinc oxide content in adhesive mass
- Adhesive strength g/2.5cm
- Moisture vapour permeability
- Regain length

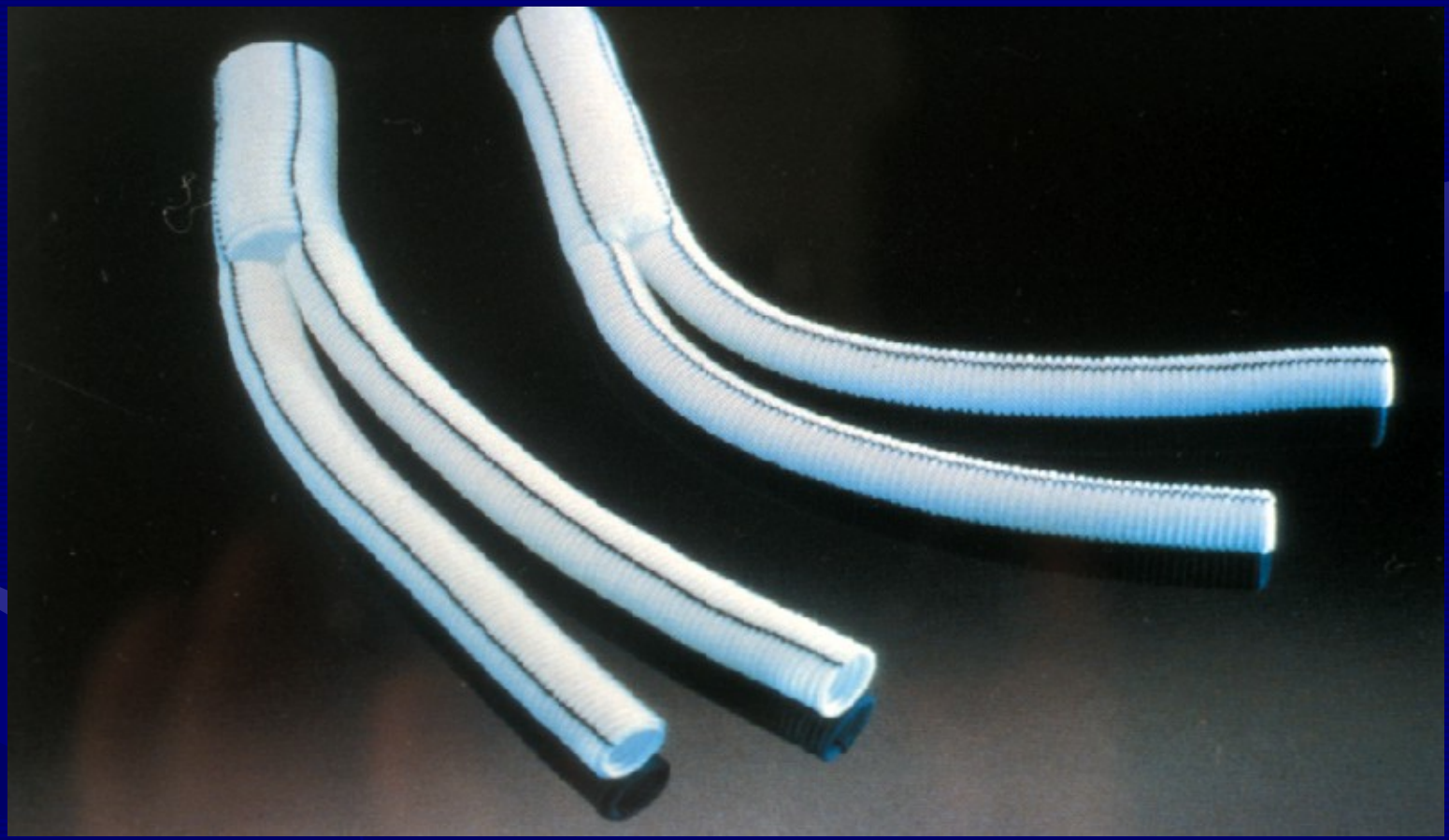
CELLULOSE WADDING

Cellulose wadding consists of compressed sheets of felted fibres, consisting almost entirely of cellulose. The fibres are bleached good white.

TEST METHODS

- Weight per unit area (GSM)
- Sulphated ash
- Loss on drying
- Absorbency(second)
- Chloroform soluble substances

VASCULAR GRAFT



Arteries are the blood vessels, which carry oxygenated blood throughout the body. These arteries sometimes get damaged and fail to do the work properly. Artificial grafts are developed to act as blood vessels and they are called as vascular grafts.

TEST METHODS TO EVALUATE VASCULAR GRAFT

- Biocompatibility
- Porosity
- Bursting strength
- Tensile strength
- Water permeability

IMPLANTABLE TEST METHODS

Most of the implantable products will be tested for the Biocompatibility test

- Biocompatibility - Reaction of textile with blood and tissue of the body

- This test & skin irritation test can be conducted at Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Trivandrum.

ROLE OF SITRA TESTING SERVICES FOR MEDITECH PRODUCT

- Preparation of proposed draft standards for different Meditech product

- Facilities for testing and evaluation of products of medical textiles

PROPOSED STANDARD TEST METHODS FOR MEDITECH PRODUCT DEVELOPED BY SITRA

- Gown
- Surgical drapes
- Face mask
- Bed linen
- Baby diaper
- Incontinence products
- X-ray detectable gauze
- Gauze bandage

- Plaster of Paris bandage
- Elastic adhesive bandage
- Cellulose wadding
- Impermeable plastic wound dressings
- Crepe bandages
- Sutures
- Absorbent cotton

- Non-woven gauze bandage
- Vapour- permeable waterproof plastic wound dressings
- Vascular craft
- Perforated film dressings
- Knitted viscose primary dressings

FEATURES OF NEW TESTING FACILITIES AVAILABLE IN SITRA MEDITECH LAB

LISTER AC & WETBACK

SITRA


Instrument for measurement
of liquid strike through time
LISTER AC

SITRA

Test piece is placed on filter papers

↓

Simulated urine is discharged on to a test piece through strike plate

↓

Electrical conductive liquid starts the timer by means of electrodes

↓

After the liquid has penetrated into the absorbent pad the electrical circuit is interrupted and the timer is automatically stopped

WETBACK

WETBACK

After test piece has been tested with liquid strike through test 15 ml of simulated urine has to be added

↓

The dead weight is lowered and put on to the test piece

↓

Filter papers are weighed & placed it onto the sample

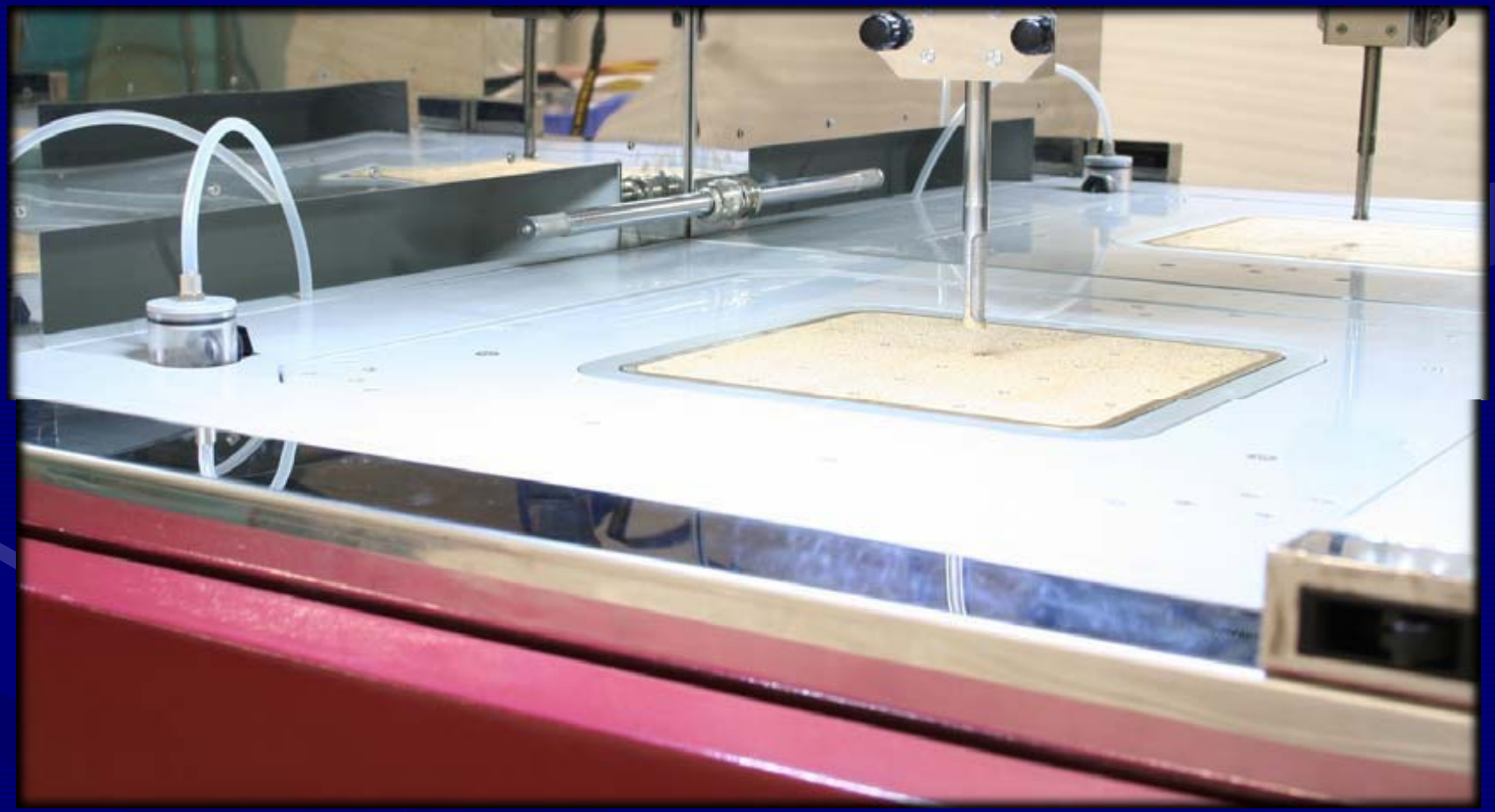
↓

The weight once again lowered and put onto the sample

↓

Filter paper reweighed

SWEATING GUARDED HOT PLATE



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- **THERMAL RESISTANCE, RCT**

  Temperature difference between the two faces of a material divided by the resultant heat flux per unit area in the direction of the gradient.

- **WATER-VAPOR RESISTANCE, RET**

  Water-vapor pressure difference between the two faces of a material divided by the resultant evaporative heat flux per unit area in the direction of the gradient

BACTRIAL FILTERATION EFFICIENCY TESTER

SITRA

- This instrument measures the percent efficiency at which the face mask filters bacteria passing through the mask.

- The maximum filtration efficiency (99.9%) can be determined.

Bacteria aerosol is passed into the 6 agar plates without specimen

↓

The control samples collected & placed in incubator

↓

↓

Bacteria aerosol is passed with specimen

↓

Total the counts from each of the six agar plate

Bacterial filtration efficiency is calculated

Hydro head tester

SITRA

Specimen is clamped in testing head

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Hydrostatic pressure is applied on bottom layer of the specimen

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Observe the top layer of the specimen

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Stop the test when observe 3 drop

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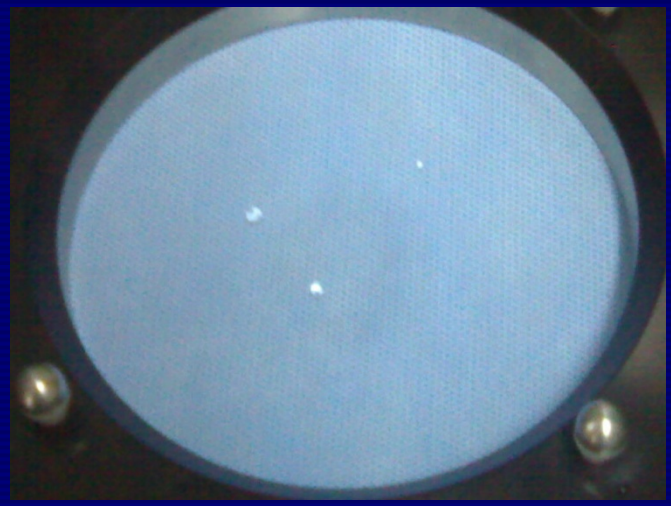
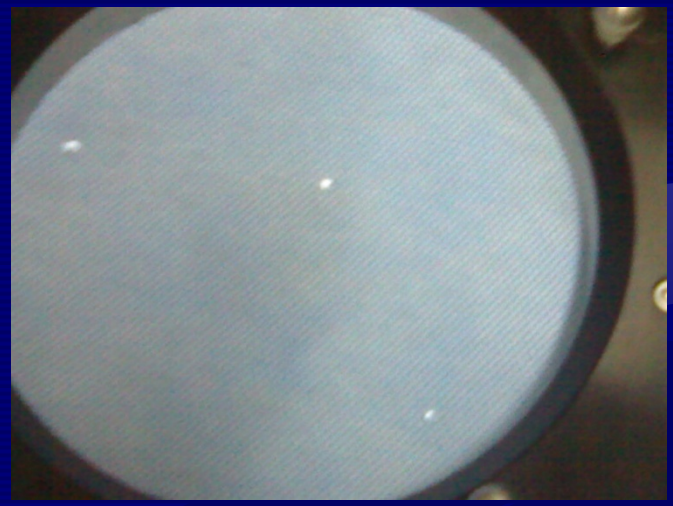
Record the average hydrostatic pressure

3 DROP IMAGE





INSTRON 6021

- Tensile strength and elongation
- Peel strength
- Stress relaxation
- Creep
- Cohesive force
- Knot strength

Centre of Excellence

- SITRA has been identified as Centre of Excellence for Medical and Hygiene Textiles by The Ministry of Textiles, Government of India.

- For more detail please visit our websites:

  www.sitra.org.in

  www.sitrameditech.org.in