

**SPECIFICATION
FOR
UNDERPADS**

(This specification is released for procurement purposes until revised or rescinded)

SCOPE

This specification covers the requirements for underpads for managing incontinence.

I. APPLICABLE STANDARDS

The following documents of issue in effect on the date of the Invitation For Bids shall form a part of this specification:

Federal Regulation 16CFR Part 1632
Total Capacity Test - ISO Test Method 11948-1:1996 – Urine-Absorbing Aids – Whole Product Testing

The Rewet Test referenced herein Section III. A has replaced the previous Shuster Test Method TM-223C - Rewet Test for Briefs and Underpads.

International Organization for Standardization (ISO); Reference <http://www.iso.org/iso/home.htm>
Reference for ordering standards: <http://www.iso.org/iso/store.htm>

II. CLASSIFICATION

Premium and Standard Performance Categories

III. REQUIREMENTS

A. Product Performance Requirements

Each underpad shall be compliant to the Rewet, Rate of Acquisition and Total Capacity performance requirements outlined in Table 1. Rewet values indicated herein are maximum allowable and are shown in grams. The Total Capacity values indicated herein are minimum allowable and are shown in grams. Rate of Acquisition values indicated herein are maximum allowable and are shown in seconds.

Table 1

Two product categories – Premium and Standard, differentiated by lab performance.					
Performance Specification		Use standard lab measurements as detailed in Attachment A			
		Rate of Acquisition (ROA) & Rewet Tests		100 ml saline solution	
		Total Capacity		As per ISO Method	
Premium Performance Underpad			Product Performance ⁽¹⁾		
Size	Overall Dimensions (inches)	Minimum Matt Surface Area ⁽²⁾ (square inches)	ROA	Rewet	Total Capacity
			≤	≤	≥
A	17 X 24	236	100 seconds	15 grams	600 grams
B	23 x 23	321	100 seconds	15 grams	900 grams
C	23 x 36	575	100 seconds	15 grams	1,500 grams
D	30 x 30	622	100 seconds	15 grams	1,800 grams

E	30 x 36	781	100 seconds	15 grams	2,100 grams
F	36 x 36	958	100 seconds	15 grams	2,100 grams
Standard Performance Underpad			Product Performance ⁽¹⁾		
Size	Overall Dimensions	Minimum Matt Surface Area ⁽²⁾	Total Capacity		
	(inches)	(square inches)	>		
A	17 X 24	236	400 grams		
B	23 x 23	321	600 grams		
C	23 x 36	575	900 grams		
D	30 x 30	622	1,100 grams		
E	30 x 36	781	1,200 grams		
F	36 x 36	958	1,600 grams		
⁽¹⁾ Products need to comply with each of the three performance standards.					
⁽²⁾ The matt size or fill area consists of the fluff mat or absorbent core not including the outer edges of the nonabsorbent protective poly backing.					

B. Construction Requirements

1. The absorbent core shall consist of cellulose fiber and/or absorbent polymer.
2. The backsheet shall be moisture impervious.
3. The topsheet shall resist moisture return to the skin, and may be constructed of polyethylene, polypropylene or polyester, either in apertured film form or in fiber nonwoven fabric form.
4. Adhesives and glues used in constructing the pad shall be water-insoluble, and will form continuous seals at the edges of the absorbent core to minimize leakage.
5. All materials used in the pad shall be safe for skin contact and shall be harmless if ingested in small quantities.
6. The core material shall be bonded to the coversheet or backsheet to prevent movement or migration during handling or use for the premium performance underpads.
7. The underpad shall conform to the minimum requirements of SECTION III.A, Table 1.

IV. TESTS EVALUATION AND QUALITY ASSURANCE

A. Testing Requirements

Underpads are classified into the appropriate performance requirements based on results submitted by an independent laboratory for the following qualifying tests.

1. Total Absorbent Capacity: ISO Test Method 11948-1:1996. Protocol for this test may be purchased from the ISO (International Organization for Standardization) or from ANSI (American National Standards Institute).
2. Rate of Acquisition Test (ROA) and Rewet Tests: Refer to the Appendix A of this document for the test method.

The following test criteria apply to the above tests

- a. Underpads performance will be based on the average result of tests performed on five (5) samples for each size.
- b. The submittal of test reports including the Total Absorbent Capacity, Rewet, and ROA tests shall be complete and current to within 24 months of testing. Testing shall have been conducted on the current product, model designation and identical construction to the product submitted. All test reports are to be in-hand and furnished upon request.
- c. The product manufacturer shall certify by signature of an officer of the company that data and information submitted is accurate, truthful and consistent with internal test data obtained from the current production of the product submitted for evaluation.
- d. Products which are made by a manufacturer to be distributed under different brand names (“private label” products) may not need to be retested under for each brand name if an officer of the

company (the original manufacturer), lists all such products by name and product code, signs and attests that the products are identical in manufacture, construction and performance. Any differences between the original and the rebranded product shall be identified and explained. Acceptance of the original test reports or request for supplemental testing will be determined based upon a review of the products and the information supplied. Authorization shall also be provided by a signature of an officer of the company (the original manufacturer), that the company providing the rebranded product is authorized to use any data acquired on the product by the original manufacturer.

- e. Supplemental independent third party testing may be required for products upon submittal for evaluation if the product or test data submitted is determined different or inconsistent with the manufacturers published literature, or if inconsistent with results submitted to other states and agencies for the identical products and test methods.

B. Laboratory Requirements

1. Tests are to be performed on the underpads by an independent third party laboratory that routinely markets testing services for the incontinent products industry and as determined by representatives of the Division of Purchase and Contract as acceptable. For the purposes of this document, "an independent third party laboratory" means an analytical laboratory that is not a subsidiary of, affiliated with, or on retainer for, the potential contractor. The following are not considered an "independent third party laboratory" for the purposes of this specification.
 - a. Any laboratory located in a private residence.
 - b. Testing conducted in a manufacturing plant or in a physical laboratory facility owned by, operated by, or otherwise affiliated with the manufacturer of the product being tested.
 - c. Testing performed by employees of, or other personnel hired by, the contracting company.
 - d. The laboratory cannot be owned in whole or in part by the product manufacturer, distributor, provider or any of its parent or subsidiary companies.
2. The independent third party test laboratory shall provide references from a minimum of three incontinent product manufacturers that have had incontinent product testing performed by that test laboratory. Test laboratories submitting references may be requested to submit copies of invoices for previous testing of incontinent products from that independent third party laboratory over the last three years. The State reserves the right to contact companies providing laboratory references for additional details and verification.
3. The laboratory shall provide all documentation requested to verify documented procedures, practices, accuracy and responsible oversight.
4. Test documentation submitted shall include test procedures with the data that is dated and signed by the laboratory technician and a manager responsible for technical oversight.
5. Test reports shall indicate test data in the identical format and units as indicated herein.
6. The product manufacturer shall certify by signature of an officer of the company that data submitted is accurate, truthful and consistent with data obtained from the current production of the product submitted for evaluation.
7. Future laboratory requirements are intended to require an ISO-17025 quality registration or certification for a testing laboratory from an accredited quality certifier.

C. Other Requirements

1. The underpad shall conform to the requirements of Federal Regulation 16CFR Part 1632.
2. The underpad may be evaluated for acceptance by a committee composed of representatives of the using hospitals and institutions. The committee, at its discretion, may recommend rejection any product that it deems not acceptable.
3. The successful contractor shall provide a trained representative who will be available to provide in-service training and follow-up service to the using agency at no cost.

D. Quality Assurance

The State reserves the right to have the bidder submit any product to an independent third party laboratory selected by the state to provide a full test report for a product for which there is a concern that the product construction or performance are not meeting the guarantees and specifications indicated herein during the life of the contract. The sample to be tested may be sourced from the customer's inventory or sourced from

a distributor or vendor from current supply. All cost associated with the product purchase, freight and testing shall be borne by the bidder.

Products determined not in compliance with these specifications herein with may be removed from the Qualified Products List for that commodity.

V. WARRANTY

The contractor warrants to the owner that all products furnished under this specification will be new, of good materials and workmanship, and agrees to replace promptly any product which by reason of defective materials or workmanship shall fail this specification. Such replacement shall be free of any charge to the user or agency.

VI. DELIVERY AND PAYMENT

Delivery and payment for commodities under this specification shall be in accordance with the terms and conditions of the Invitation For Bids. The contractor shall be responsible for any packing, packaging, or protection required to insure delivery in undamaged condition.

VII. ORDERING DATA (For Purchase and Contract Use Only)

Purchasers should exercise any desired option offered herein and should specify the following in the requisition and Invitation For Bids:

1. Title, number, and date of this specification
2. Classification of underpads by performance category. (See Section II).
3. Underpad size
4. Packaging requirements

APPENDIX A

Acquisition Rate and Rewet Test Protocol

SCOPE AND PURPOSE:

1. To measure the ability of incontinence underpad to accept and retain synthetic urine (saline solution) under simulated in-use conditions of load and pressure.
2. To determine amount of time required for an absorbent article to absorb a fixed quantity of a test solution.

DEFINITIONS:

Rewet: Amount of wetness returned to the surface of an incontinent product onto an absorbent filter paper.

Rate of Acquisition (ROA): Number of seconds required to fully absorb test fluid into an incontinent product.

SAFETY AND HANDLING PRECAUTIONS:

Refer to the Material Safety Data Sheet (MSDS) of each reagent for specific information.

REAGENTS:

0.9 -% Sodium Chloride (NaCl) Solution

FLUID DOSAGE:

Single dose of 100 ml for all underpad sizes.

EQUIPMENT:

1. 250-ml separatory funnel, discharging 7ml/sec
2. NIST Traceable Timer

3. Stainless steel cylindrical weight 9.8 lbs.: 9.0 cm, 1.0 psi
4. Dosing tube with weight (weight 2.2 lbs, 4" x 4" x 0.5": tube height 9", diameter 1")
5. Filter Paper: AFI Grade 950, 9.0 cm diameter or equivalent filter paper
6. 100-ml volume graduated cylinder
7. Analytical Balance able to weigh to nearest 0.01 grams
8. Product samples

PROCEDURE:

1. Select 5 products for testing and record the production code or date for each sample
2. Precondition the samples at 65 to 70° F for a minimum of 24 hours prior to testing.
3. Prepare the product so it lies flat.
4. Measure out a volume of test solution for the product being tested (100ml or 200-ml depending on the product) with a graduated cylinder and transfer the solution to the separatory funnel.
Note: Make sure the timer is ready, as timing for the rewet test will be initiated at moment of delivery of test solution to sample..
5. Center the dosing tube over the target zone. The target zone is at the center of the underpad.
6. Deliver the test solution into the tube by fully opening the stopcock on the funnel or starting the metering pump.
7. Start the timer when fluid starts to flow from the funnel or pump.
8. Stop the timer when all solution has passed through the topsheet and record the time in seconds as the Rate of Acquisition (ROA).
Note if the fluid leaks around the flat base of the test ring. This is an indication that the absorbent core is not uniform. Highlight this in the test results.
9. Restart the timer and wait twelve (12) minutes.
10. Weigh a stack of dry filter paper and record as weight W1 – the stack should have a dry weight of about 10.0 grams
11. After the 12 minute waiting period, place the stack of preweighed filter paper on the center of the wetted target area.
12. Place a 1.0-psi cylindrical weight on the top of the dry filter paper, making sure the stack is level, not tipping to one side or the other. Start the timer.
Note: The weight should be gently lowered onto the filter paper stack.
13. After one (1) minute, remove the cylindrical weight and the wetted out papers.
14. Reweigh the filter paper stack and record the wet filter paper weight as W2.
Note: If the entire stack of filter paper is wetted, the test is invalid and must be re-evaluated with a new sample using a heavier (5.0-g additional) stack of dry filter paper.
15. Repeat the above steps for all 5 product samples; record each result separately.

CALCULATIONS:

REWET (g) = W2 (Wet filter paper weight) - W1 (Dry filter paper weight)

REFERENCES:

Above test methods were adapted from the following standards.

ERT 150.4-99 Nonwoven Coverstock Liquid Strike-Through Time (Simulated Urine)

ERT 151.2-99 Nonwoven Coverstock Wetback

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