



Minnesota Health Care Programs Requirements for Incontinence Products

Effective July 1, 2013, Minnesota Health Care Programs will only cover adult-sized disposable incontinence briefs and disposable underwear that appear on the 2013 MHCP Incontinence Products List. Pad and Pant systems can be considered adult small briefs if tested. Any pediatric- and youth- sized products, and any liners, guards, pads and shields can be covered by MHCP.

Manufacturers of adult disposable incontinence products who want products on the MHCP Incontinence Products List must submit a statement attesting that the MHCP requirements below are met by all of the included products and that the manufacturer agrees to submit to testing as required by MHCP. The statement must be signed by an officer of the company or other employee with authority to contract for the company and must specify the products to be included on the List, by name and product number, as well as a contact person who should be notified of testing requirements. **Results of internal or independent laboratory testing performed within 6 months of the date of submission for medium sized product must be included.**

Where a manufacturer makes products to be distributed under different brand names (“private label” products), an officer, or other employee with authority to contract for the company, of the manufacturing or the distributing company must submit the statement described above. The contact person to be notified of testing requirements may represent either the manufacturer or the distributor.

The MHCP testing requirements are based on the National Quality Performance Standards for Disposable Adult Absorbent Products for Incontinence that have been assembled by the National Association for Continence.

MHCP will publish the Incontinence Products List, including any received test results noting the source of the results (internal or independent lab), on the Minnesota Department of Human Services website no later than April 30, 2013. Additional products may be added at any time by submitting a statement as described above. Products may be removed from the List at any time by request of the manufacturer (requests to remove product do not need to be signed by an officer of the company). If there is a change to manufacturing that can reasonably be expected to affect a product on the List, the manufacturer must submit a new statement attesting that the requirements are met.

Testing Requirements

- Once per State Fiscal Year (July 1 – June 30), MHCP will select 1 – 3 products, sized medium or large, from each manufacturer on the Incontinence Products List. The testing requirement should not be expected to take place during the same time period each year, nor should it be expected that all manufacturers will be tested at the same time.
- In addition to annual testing, MHCP reserves the right to require testing on any product, at any time, based on a good faith belief that the product does not meet MHCP criteria.
- The manufacturer will be notified of the product name(s), size(s) and MHCP enrolled supplier(s) that have been selected.

State of Minnesota Requirements for Incontinence Products

- Following notification, the manufacturer will arrange for product to be shipped directly from the MHCP supplier to an independent laboratory for testing.
- For each test, five replicates should be completed, with the arithmetic average of the five replicates reported to MHCP.
- Testing for Rewet will be performed according to the methodology in Appendix A.
- Testing for Rate of Acquisition will be performed according to the methodology in Appendix B.
- Testing for Retention Capacity will be performed according to the methodology in Appendix C.
- Testing for Breathability will be performed according to the methodology in Appendix D.
- Testing for Elastic Elongation may be performed using any test methodology chosen by the manufacturer. This test is considered a proxy for the degree of “stretch” present in the product, with adequate stretch being necessary to assure better fit and fewer leaks. The result should be reported as a percentage, derived by dividing (stretched length minus unstretched length) by (unstretched length) of the elastic.
- If test results are not received by MHCP within 12 weeks of notification, all products from that manufacturer will be removed from the Incontinence Products List until test results are received.
- If test results show that MHCP requirements are not met, the tested product will be removed from the Incontinence Products List and the manufacturer will be notified of 1 – 3 additional products to be tested.
- Test results will remain on the Incontinence Products List for 36 months from the date of the required statement unless MHCP is notified by the manufacturer that there has been a change in manufacturing that could reasonably be expected to affect test results or if test results show that MHCP requirements are not met.

Laboratory Requirements

- Test results must be submitted to the Minnesota Department of Human Services, Purchasing and Service Delivery Division by an independent laboratory. Results may be sent via e-mail by the laboratory to Patrick.Lee@state.mn.us or via US Mail to Patrick Lee, Minnesota Department of Human Services, PO Box 64984, St. Paul, MN 55164-0984.
- For each test, five replicates should be completed, with the arithmetic average of the five replicates reported to MHCP.
- The laboratory must be ISO 9000 compliant.
- The laboratory cannot be owned in whole or in part by the diaper manufacturer, distributor or provider or any of its parent or subsidiary companies.
- DHS will not require use of a specific laboratory, but will maintain a list of laboratories known to perform these tests.

Test Results

- The arithmetic average of the five replicates for EACH Parameter should be reported, not individual values.
- Testing should take place and be reported on medium size product.
- Product acceptance will be based on the following:
 - Any three of the four required tests must meet or exceed the specified target value, summarized in the table below (elastic elongation should be tested but is not considered in product acceptance):

**State of Minnesota
Requirements for Incontinence Products**

Parameter	Brief Target Value	Disposable Underwear Target Value
Side Panel Breathability	≥ 100 cfm	≥ 100 cfm
Elastic Elongation (stretch versus recovery)	<u>Should be reported but no target value</u>	<u>Should be reported but no target value</u>
Rewet	≤ 1.0 grams	≤ 0.5 grams
Rate of Absorption (Acquisition)	≤ 50 secs	≤ 35 secs
Retention Capacity	≥400 grams	≥400 grams

- No more than one of the four required tests (elastic elongation should be tested but is not considered in product acceptance) may fall more than 15% outside of the threshold target value, as illustrated in the following table:

Parameter	15% Target Value for Briefs	15% Target Value for Disposable Underwear
Side Panel Breathability	≥ 85 cfm	≥ 85 cfm
Elastic Elongation	<u>Should be reported but no target value</u>	<u>Should be reported but no target value</u>
Rewet	≤ 1.15 grams	≤ .58 grams
Rate of Absorption	≤ 58 secs	≤ 40 secs
Retention Capacity	≥340 grams	≥340 grams

**State of Minnesota
Requirements for Incontinence Products**

**Appendix A
Recommended Test Method for Rewet**

The test method requires the following steps:

- Weigh a stack of dry filter paper and record as weight W1. The stack should have a dry weight of 10.0 grams.
- Measure out a volume of test solution (0.9% NaCl solution) for each of the products being tested, centering the dosing tube over the target crotch zone of each product:
 - Briefs medium size or larger: 200 ml
 - Briefs small or youth size: 100 ml
 - All sizes of protective underwear: 100 ml
- Deliver the solution into tube by fully opening the stopcock on the funnel or starting the metering pump. After all of the fluid has passed into the product, start the timer and wait 10 minutes.
- After the 10 minute waiting period, stop the timer and place the stack of filter paper in the center of the wetted target area and place a 1.0 psi cylindrical weight on top of the dry filter paper.
- Re-start the timer and wait one minute. Remove the weight and the wetted out papers.
- Reweigh the filter paper stack and record as weight W2.
- Repeat the steps, recording each result separately.
- Rewet, measured in grams, equals $W2 - W1$.

**State of Minnesota
Requirements for Incontinence Products**

**Appendix B
Recommended Test Method for ROA**

- The test method recommended for Rate of Acquisition (ROA) requires the following steps:
- As with the rewet rate, utilize a 250-ml separatory funnel, discharging 7 ml/second or a metering pump calibrated to deliver desired fluid amount at a constant rate of 7 ml/second. The stainless steel cylindrical weight is to weigh 9.8 lbs: 9.0 cm, 1.0 psi. The dosing tub with weight has a weight of 2.2 lbs, measuring 4" X 4" X 0.5" and a tube height of 9", diameter 1". Filter paper is AFI Grade 950, 9.0 cm diameter or equivalent filter paper. (Note: A different loading will be required for smaller than medium product sizes, i.e., 200-ml funnel for small and 100 ml for youth sizes.)
 - Prepare the products so that each lies flat. Trim waist elastic and leg gathers from the brief and fold back any front and back wing flaps. Unfold the undergarment, trim waist elastic and leg gathers, if present. Tear at the side seams of protective underwear; trim waist elastic and leg gathers.
 - With a graduated cylinder, measure out a volume of test solution (0.9% NaCl) for each product as noted above for the Rewet Test. Transfer the solution to the separatory funnel.
 - Center the dosing tube over the target crotch zone. Deliver the test solution into the tube by fully opening the stopcock on the funnel or starting the metering pump.
 - Start the timer when the fluid flow starts from the funnel or pump. Stop the timer when all the solution has passed into the product. Record the time in seconds as the **Rate of Acquisition (ROA)**.

**State of Minnesota
Requirements for Incontinence Products**

**Appendix C
Recommended Test Method for Retention Capacity**

The test method for Retention Capacity requires the following steps:

A. EQUIPMENT:

- A.1. Fisher & Paykel Ecosmart Model WA37T26G washing machine or equivalent piece of equipment. Must be capable of a 7 minutes & 15 second spin cycle at 670 rpm.
- A.2. Weighing Tray – large enough for product being tested
- A.3. Lab Balance - capable of weighing to nearest gram

B. PROCEDURE:

- B.1. Upon completion of a liquid absorption capacity test (ISO Capacity Method ISO 11948-1: 1996(E)), place the wet product in the washer with the absorbent core facing the side of the tub.

Note: Multiple products may be spun at the same time providing there is no overlapping of the product's core. If testing multiple samples, identify them with indelible ink for identification.

- B.2. Push the power button on the washing machine panel to turn the washer on.
- B.3. Using the arrow button, select the Spin cycle under the Wash Progress display.
- B.4. Select Medium at the Spin Speed display, and then push the Start/ Pause button. Medium spin speed is 670rpm and the complete cycle time is 7-minutes 15-seconds.
- B.5. The machine's lid will automatically lock to prevent opening during the cycle and the spin cycle will start.
- B.6. When the spin cycle is complete, the machine will beep and the lid will automatically unlock.
- B.7. Remove the product, place in a tare weighing tray and record the spun weight.

C. CALCULATIONS:

- C.1. Calculate the retention capacity by: ***Spun Weight - Dry Weight (Recorded prior to liquid absorbent capacity test) = Retention Capacity***
- C.2. Report the amount liquid retained in grams as Retention Capacity.

**State of Minnesota
Requirements for Incontinence Products**

**Appendix E
Recommended Test Method for Breathability**

1. Scope

This test method as described below by the INDA standard test WSP 070.1.R3 (12) also includes EDANA's ERT 140.2-99 and covers the measurement of the air permeability of nonwoven materials.

This test method applies to most fabrics including woven fabrics, nonwoven fabrics, air bag fabrics, blankets, napped fabrics, knitted fabrics, layered fabrics, and pile fabrics. The fabrics may be untreated, heavily sized, coated, resin-treated, or otherwise treated.

SI values are regarded as the official standard system of measurement for this standard test method.

NOTE 1: SAFETY

This standard does not claim to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use. It is expected that the person performing this test has been fully trained in all aspects of this procedure.

2. Normative References

The following referenced documents are indispensable for the application of this document:

2.1 ISO test methods

- a) ISO 5725 -1 Accuracy (trueness and precision) of Measurement Methods and Results – Part 1: General Principles and Definitions
- b) ISO 5725 -2 Accuracy (trueness and precision) of Measurement Methods and Results – Part 2: Basic Method for the Determination of the Repeatability and Reproducibility of a Standard Measurement Method
- c) ISO 139 : Textiles — Standard atmospheres for conditioning and testing
- d) ISO 2859-1:1999 Sampling procedures for inspection by attributes
- e) ISO 3951-1:2005 Sampling procedures for inspection by variables
- f) ISO 9237 : 1995 Determination of the Permeability of Fabrics to Air

2.2 WSP test methods

- a) WSP 001.0.R3 (12) Standard Terminology Relating to the Nonwoven Industry, EDANA's and INDA's Standard Test Methods

3. Terms and Definitions

For the purpose of this document, the following term and definition apply: **Air permeability**

Air permeability is the velocity of an air flow passing perpendicularly through a test specimen under specified conditions of test area, pressure drop (ΔP) and time.

4. Principle

The rate of flow of air passing perpendicularly through a given area of fabric is measured at a given pressure difference across the fabric test area over a given time period.

Air permeability is an important factor in the performance of nonwoven products, i.e. air and gas filters made from different processes, several different types of protective clothing and vacuum cleaner bags. In protective clothing, for example, comfort as it relates to breathability is directly related to air permeability.

**State of Minnesota
Requirements for Incontinence Products**

5. Apparatus

5.1 Air permeability testing apparatus

5.1.1 Test head

Circular specimen holder, with an orifice allowing the test to be carried out on a area of 20 cm², 38cm² or 50 cm². The tolerance on the test heads or test areas shall not exceed more than $\pm 0.5\%$

NOTE 2: Other test areas may be used on this machine and can be purchased from the equipment manufacturer, sizes such as 5 cm², 25 cm² and 100 cm². The 100 cm² head is for measuring extremely dense specimens.

5.1.2 Clamping system to secure test specimens

Secure the specimen by means of the clamping system provided without distortion of the specimen

NOTE 3: If air leakage accrues around the gasket, check the condition of the gasket and the seal. If the leak still persists call the equipment manufacturer.

5.1.3 Powerful vacuum pump

Used for drawing a steady flow of air perpendicularly through the test area and for adjusting the airflow rate to provide the pressure differentials of between the two surfaces of the fabric being tested. The most common pressure differentials used are 100 to 200 Pa (0.4 to 0.8 inches of water). Use the desired pressure differential that meets your testing criteria. The pressure differential used shall be recorded in the final testing report.

5.1.4 Pressure gage or manometer

Connected to the test head to indicate a pressure drop across the test specimen area, with an accuracy of $\pm 2\%$.

5.1.5 Flowmeter, volumeter, counter or measure aperture

Indicating the rate of air flow through the test area with an accuracy of $\pm 2\%$.

5.1.6 Calibration Plate

With a known air permeability at the prescribed test pressure differential to verify the apparatus.

5.1.7 Means of calculating

And displaying the required results.

5.2 Some means of cutting the specimens

If your machine cannot accommodate large sheet samples (cutting dies or templates).

6. Conditioning

Bring samples to moisture equilibrium in the standard atmosphere for testing nonwovens as directed in ISO 139. Equilibrium is considered to have been reached when the increase in mass of the specimen in successive weighings made at intervals of not less than 2 hours does not exceed 0.25 % of the mass of the specimen.

NOTE 4: While conditioning for a fixed time cannot be accepted in cases of dispute, it may be sufficient in routine testing to expose the material to the standard atmosphere for testing textiles for a reasonable period of time before the specimens are tested, i.e. 4 hours.

7. Sampling

7.1 Lot Size

A lot should be established based on a logical break in the process or a prescribed by a regulation or traceability requirements.

7.2 Sampling

If provided in the customer specification, take random sample as directed. If no requirements are provided, ISO 2859-1:1999 (*Sampling procedures for inspection by attributes*) or ISO 3951-1:2005 (*Sampling procedures for inspection by variables*) can be used. In and of themselves, these are not valid sampling plans by default.

**State of Minnesota
Requirements for Incontinence Products**

An agreement between the purchaser and supplier requires taking into account process stability, producer's risk, consumer's risk, acceptable quality level, limiting quality level and cost need to be established, In general, if the test characteristic can be considered normally distributed, the sampling procedures for inspection by variables will require fewer samples. However, small samples may not reflect that normal distribution and the estimated percent defective can therefore be over or under estimated. In this case, as well as for attribute data, the sampling procedures for inspection by attributes should be used. In the absence of any sampling size requirement, the following tables can be used. Switching rules are required to maintain the AQL protection.

Attributes (1.0 AQL, General Inspection Level II)

Number of units in the lot inclusive	Number of units that comprise the lot sample
1 to 150	13
151 to 280	32
281 to 500	50
501 to 1200	80

Variables ("s" method, General Inspection Level II)

Number of units in the lot inclusive	Number of units that comprise the lot sample
1 to 15	3
16 to 25	4
26 to 50	6
51 to 90	9
91 to 150	13
151 to 280	18
281 to 500	25
151 to 1200	35

NOTE 5: An adequate specification or other agreement between the purchaser and supplier requires taking into account the variability between rolls of nonwoven fabric and between specimens from a swatch from a roll of material to provide a sampling plan with meaningful producer's risk, consumer's risk, acceptable quality level, and limiting quality level.

8. Preparation of Test Apparatus and Calibration

8.1 Set-up procedures for testing equipment

These machines could come from different manufacturers and may vary greatly. Prepare and verify calibration of the air permeability tester as directed in the manufacturer's instructions.

8.2 When using microprocessor automatic data gathering systems

Set the appropriate parameters as specified in the manufacturer's instructions.

**State of Minnesota
Requirements for Incontinence Products**

8.3 Level the test instrument

8.4 Verify the calibration

For the range and required water pressure differential that will be used

NOTE 6: When measuring some bulky materials the lateral air-flow through the clamping area may represent a significant amount of the total air-flow and may distort the test results. When testing very bulky materials the specimen should be measured twice in the same spot. The first test is done in the normal manner. However, before performing the second test cover the material with the rubber plate which is supplied with the instrument. The true air permeability of the test specimen is calculated from the difference of these two test results.

9. Procedure

9.1 Place each test specimen

Onto the test head of the test instrument, and perform the test as specified in the manufacturer's operating instructions.

NOTE 7: Place coated test specimens with the coated side down (towards low pressure side) to minimize edge leakage.

9.2 Perform tests at the water pressure differential

Specified by a material specification or contract order. In the absence of either, use the water pressure differential required by your organization, i.e. from 100 to 200 Pa (0.4 to 0.8 in. of water).

9.3 Read and record

There are numerous equations that can be used to record this data, use the proper equation for your organization. The following are some of the equations used:

- a) $\text{cm}^3/\text{s}/\text{cm}^2$
- b) $\text{l}/\text{s}/\text{cm}^2$
- c) mm/s
- d) m/s
- e) $\text{l}/\text{dm}^2/\text{min}$
- f) $\text{m}^3/\text{s}/\text{m}^2$
- g) dm^3
- h) cfm
- i) $\text{cm}^3/\text{s}/\text{cm}^2$
- j) $\text{m}^3/\text{h}/\text{m}^2$
- k) $\text{ft}^3/\text{min}/\text{ft}^2$

The individual test results shall be reported using one of the equations listed either in SI units or in inch-pound units and shall be rounded to three significant digits.

NOTE 8: Never record the finished results as; " ___Frazier units". Legally that term is too ambiguous.

9.4 Remove the tested specimen

And continue as directed in 9.1 – 9.4 until all specimens have been tested for each laboratory sampling unit.

**State of Minnesota
Requirements for Incontinence Products**

9.5 When a 95 % confidence level for results

Has been agreed upon in a material specification or contract order, fewer test specimens may be sufficient.

NOTE 9: For fabrics so open or so dense that the recommended pressure differential (200 Pa) cannot be obtained on the apparatus, another pressure differential may be used. This must be specifically stated in the report.

NOTE 10: Which side of the fabric was tested, or whether the fabric has been tested on both sides, must be mentioned.

NOTE 11: If minimum condition set for ΔP cannot be obtained, then various plies (layers) of the product should be tested. The number of plies tested should be mentioned.

10. Calculation

10.1 Air permeability, individual specimens

Calculate the air permeability of individual specimens using values read directly from the test instrument in SI units as $\text{cm}^3/\text{s}/\text{cm}^2$ or in inch-pound units as $\text{ft}^3/\text{min}/\text{ft}^2$ or use any other unit that is appropriate for your test results and round-off the results to three significant digits. When calculating air permeability results, follow the manufacturer's instructions as applicable.

NOTE 12: Remember there are some types of air permeability test equipment that require using a correction factor to attain the final results, if the testing was done at or above 600 m (2000 ft) above sea level.

10.2 Air permeability average

Calculate the average air permeability for each laboratory sampling (5 to 10 specimens) unit and for the lot.

11. Report

In addition to the precise test results, the report shall include the following information:

- a) Reference the test method used
- b) Complete identification of all materials tested and method of sampling
- c) Name and address of testing institution
- d) Make and model of testing equipment
- e) Laboratory testing conditions
- f) Number of specimens tested and note CD and/or MD if significant
- g) For computer processed data, identify the software used and the version
- h) Deviation from the standard test procedure, if any
- i) When calculated, the standard deviation or the coefficient of variation
- j) Whether or not samples were conditioned prior to testing and, if so, for how long
- k) Anything unusual noted during the testing
- l) Where ever options were given, the option used shall be reported
 - The size of the test head used
 - The air pressure differential used
 - The number of specimens for each sample
 - The reporting units, i.e. $\text{m}^3/\text{s}/\text{m}^2$

12. Precision

The precision for this method is yet to be determined.