

Q&A on the appropriate use of NWSP 354.0:

Absorption before Leakage Using an Adult Mannequin

This Q&A aims to answer questions users of the method may face in terms of the scope and reliability of the test method.

Q1: Why has this method been introduced, back in 2009?

In the eighties the so-called Rothwell method (ISO 11948-1) was introduced as a lab performance test for adult incontinence products. This test measures the absorption capacity of a product using the dunk and drip principle. Although widely used, the full absorption capacity this method delivers, is not very consumer relevant, instead users are, among other consumer relevant parameters, more interested in the absorption before leakage. This is defined as the absorption capacity right before the product starts leaking.

Such method measuring the absorption before Leakage, will take into account product features apart from the absorption capacity of the core, like body fit, leg gathers, waistband, etc. This explains how the new method resulted in a so-called mannequin test method.

Q2: What is the scope of the test method?

To answer this question, please see below quote (*italic*) from the <u>EDANA website</u>. This method has been developed for testing adult incontinence products for moderate and severe incontinence, that are to be used by bedridden patients. The method is designed for 'all in ones' (AiO's) also called briefs, with sizes XS, S, M, L and XL, and pads (held in place by elastic mesh briefs or other close-fitting underwear) with Absorption Before Leakage (ABL) values between 300 and 1100 g.

It's important to be aware of the following 2 notes copied from the method on the scope: NOTE 1: This test has been designed for the evaluation of the performance of incontinence products for non-ambulatory adults in residential settings and nursing homes.

NOTE 2: This test is not applicable to incontinence products for light and moderate incontinence and other situations, than described above.

Q3: Why can't the method be used for a wider range of products?

This is a very important question; the short reply is that products need to have a 'real life like fit' with the mannequin to make the method deliver a realistic test result.

This limits the scope twofold. As the developers targeted on having only one mannequin in order not to make the method too expensive, this limits the size range. With the M size mannequin, XS and XL size products challenge the closing system, respectively may create excessive folding. Secondly, as the mannequin is static and simulating a bed-ridden user in lying position, the method can only realistically be used for products that are used by immobile people.

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Q4: What's the relation between NWSP 354.0 and the national standards?

The standards introduced in Russia, Germany and Spain are all directly based on NWSP 354.0, but they are not identical. National Standardisation Bodies used the NWSP 354.0 as a starting point for devising their national standards. The differences in terms of principles are very limited but the scope of products is deviating. These national standards have been created to meet the needs of national bodies that are responsible for reimbursement schemes. They needed a method that was endorsed by all (national) stakeholders; hence a national standard is more appropriate than an international industry standard.

Q5: And how does NWSP 354.0 relate to the work on the international standard ISO 19331?

As the reply on Q4 already suggested, it appeared to be a good idea to create one global standard that all parties could refer to. This work was started in 2014 by ISO TC173/SC3/WG2 but aborted in 2019 after experts couldn't reach consensus about the scope in relation to the requested accuracy of the method based on the draft method at hand. It was concluded that a more rigorous change of the approach for assessing the user relevant product performance was needed.

Q6: Does this affect the validity of NWSP 354.0.R1 (15)?

That method is still valid and applicable, provided the scope is respected, and the users of the method understand the accuracy of the method. This accuracy can be found in Appendix A of the method where the results of the Round Robin tests that concluded the development are reported per product type.

However, one outcome of the ISO work on this method (see Q5) is that users of the method would like to see a better accuracy than what NWSP 354.0.R1 (15) can deliver. Therefore, EDANA is considering a revision of NWSP 354.0.

Q7: Is there a date foreseen for the publication of the revised NWSP 354.0?

No, however, EDANA will work on improvements in this method and possibly also on a new method. Once a workplan is established and the timeline gets clearer, more details will be included in this Q&A.

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