Table Top Assessments – Do they truly represent the product your assessing?

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INTRODUCTION

'Table-top' assessments are a popular method of assessing the performance characteristics of wound care dressings; the 'table-top' assessment consists of clinical experts (TVNs, clinicians, surgeons) reviewing a product or various products against a 'gold standard' product, or a desired product requirement.

When medical device manufacturers design advanced wound care dressings they are designed according to user needs; these user needs are translated into design inputs e.g. must absorb exudate over 7 days, and design outputs are generated e.g. dressing has absorbency levels of Xg/100cm^2. The manufacturer performs an activity called Design Verification; during this phase of product development, the manufacturer is ensuring that the design outputs meet the design inputs. The tests are usually performed *in-vitro* against ISO standards. ISO standards determine exactly how the test should be performed, to best simulate clinical use in a laboratory environment, this includes but is not limited to: pre-conditioning requirements; incubation period; incubation conditions; appropriate test solutions.

Testing has been performed at Advanced Medical Solutions' laboratory to highlight the differences in the achieved result of performance when testing advanced wound care products against a controlled protocol and a 'table-top' assessment.

ISO13726-1:2002 Section 3.3 - TOTAL FLUID HANDLING

CLINICAL RELEVANCE

Total Fluid Handling (TFH) including Moisture Vapour Transmission Rate (MVTR) and Fluid absorbed are tested *in-vitro* as per ISO13726-1:2002 Section 3.3. This is a critical test to assess waterproof wound dressings that are indicated for ≥24hr wear time when absorption of exudate and management of the micro-environment are important.

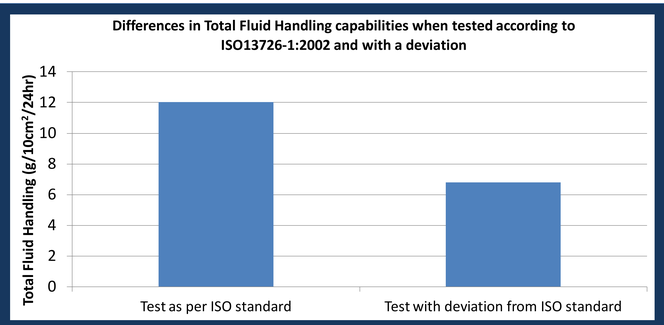
Parameter	ISO Standard	Table Top
Test solution	Solution A	Tap water
Test volume	20ml / 45ml*	Uncontrolled
Incubation time	24hours ± 30 minutes	Uncontrolled
Incubation conditions	37±1°C, humidity ≤20%RH	Room temperature - uncontrolled

METHOD

Testing was performed on Activheal silicone foam border dressings. The test volume for both Solution A and tap water was 45ml (*test volume for absorbent dressings such as foam is 45ml whereas test volume for dressings indicated for low-moderate exuding wounds is 20ml). The samples being tested as per the ISO standard were incubated at 37±1°C, humidity ≤20%RH and the samples that deviated from the ISO standard were stored at room temperature.

RESULTS

When tested as per the ISO standard the TFH capabilities were significantly higher than the table top assessment.



ISO13726-1:2002 Section 3.2 - FREE SWELL ABSORBENCY & RETENTION

CLINICAL RELEVANCE

Dressings are tested against ISO 13726-1:2002 Section 3.2 to assess their ability to absorb fluid freely and their ability to retain the fluid: this is important in wound healing as microorganisms may be released back into the wound which may cause infection and delay healing time if a dressing has poor retention. Retention of exudate in dressings is also critical as this assists in maintaining a moist, not wet, wound environment whilst reducing the risk of maceration.

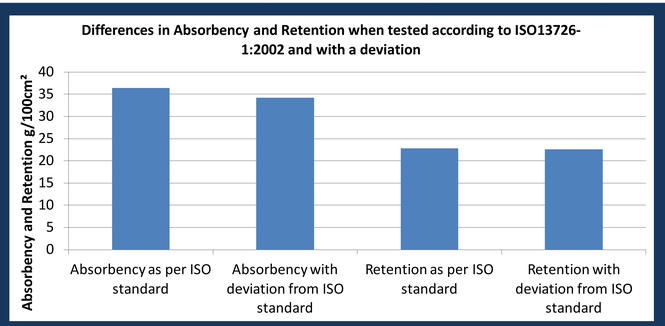
Parameter	ISO Standard	Table Top
Sample size	5x5cm	Uncontrolled
Solution conditions	Solution A warmed to 37°C	Tap water uncontrolled temperature
Test volume	40 x the weight of the sample	Uncontrolled
Incubation time	30±1 minutes	Uncontrolled
Incubation conditions	37±1°C	Room temperature – uncontrolled
Retention weight	40mmHg	Uncontrolled
Retention time	30 seconds	Uncontrolled

METHOD

Testing was performed on Activheal Aquafiber Extra dressings. The test volume of Solution A and tap water, the incubation time and retention weight and time were as per the ISO standard, therefore the only difference was the test solution.

RESULTS

When tested as per the ISO standard the absorbency capabilities were higher than the table top assessment



INDUSTRY STANDARD

THE IMPORTANCE OF SOLUTION A

Solution A is an industry standard solution which is made according to a pharmacopeia method. Solution A is deionised water with 2.5mmol calcium chloride salts and 142mmol sodium chloride salts; these salts are common in wound exudate. Tap water does not contain these salts in controlled measures; dressings are designed and testing during innovation and development including design verification using Solution A because it is a clinically relevant solution and it is referenced to be used in ISO standards including total fluid handling, free-swell absorbency and retention. Certain products, e.g. fibre dressings, may not gel when in contact with tap water, but they will in contact with Solution A; this is due to the calcium/cmc fibres within the dressing react with the test solution which is most like the wound, therefore testing with tap water does not represent the performance of the dressing in clinical use.

SUMMARY

The aim of this study was to highlight the requirements that testing laboratories need to above to when performing testing as per an ISO standard.

This study has proven that the results obtained through testing against an ISO standard using controlled parameters are different to the results obtained by using tap water in an uncontrolled environment.

Table-top assessments are quick, look-see assessment that do not fully reflect the true performance of the dressing. *In-vitro* laboratory testing is controlled and provides more reliable results. Activheal website contains *in-vitro* data on a range of products.

Data on file: LD030-16; LD088-18