What lies beneath?

BHTA guidance to assist in choosing an appropriate healthcare polyurethane foam mattress

Contents

1. Introduction

In April 2014, the National Institute for Health and Care Excellence (NICE) published a clinical guidance document (cg179)[1] on prevention and management of pressure ulcers, superseding guidance issued in 2005 (cg29). Within the guidance, there are several references to 'High Specification Foam Mattresses' – terminology used in a number of studies – alongside recommendations for their use.

Members of the BHTA Beds and Support Surfaces Section have argued that the term should not be used as there is no grounds to use the words 'High Specification'. There is also concern that the terminology unwittingly creates confusion and allows any manufacturer to lay claim to providing a 'high specification foam mattress' without a benchmark against which to make this claim. It takes the focus away from the principles of holistic clinical care and proper risk assessment, and their leading to selection of a mattress that will deliver the desired outcome for a patient.

Looking at the different clinical requirements and physical properties for foam mattresses, different properties and their values come into play depending on the needs identified. A single property that might be considered a "high" specification in relation to one patient could well be a "low" specification for the next.

Note 1. When cg179 was reviewed in 2018, NICE decided not to make any changes despite it being pointed out by the BHTA that there is no universally accepted (see Note 2) definition of High Specification Foam.

Note 2. The Cochrane Review (CD001735)[2] states "It should be emphasised, however, that there is no international definition of what constitutes a standard foam hospital mattress, and, indeed, this changes over time within countries, and even within hospitals." However, in the Pan Pacific Clinical Practice Guideline for the Prevention and Management of Pressure Injury (2012)[3], there is a table offering minimum recommendations for high specification foam mattresses. The recommendations are somewhat vague in places, and this material has not been validated elsewhere, see Table 6 Annex D.

1 https://www.nice.org.uk/Guidance/cg179

2 Mcinnes, E.; Jammali-Blasi, A; Bell-Syer, S.; Dumville, J. and Cullum, N., Support surfaces for pressure ulcer prevention. Cochrane Database of Systematic Reviews, 2011. https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD001735.pub4/full

3 https://www.nzwcs.org.nz/images/ publications/2012_AWMA_Pan_Pacific_Abridged_Guideline.pdf

1. Introduction

Different healthcare environments have differing needs from their respective mattress options – for example, a mattress used in a surgical ward with 24/7 demands will generally have contrasting materials requirements than a less frequently used day care unit. Likewise, it would be perfectly feasible to have a mattress that could be described as being made of 'high specification foam' containing, say, high density foam with a non-stretch cover, but which would still not necessarily protect against the risk of developing pressure ulcers. It is the patient who is at 'high risk', not the product.

In the absence of suitable knowledge and guidance as to what a 'high specification mattress' should be, it is tempting for organisations to purchase lower priced mattresses to try to reduce costs, but in doing so potentially sacrifice quality. This can lead to purchase of mattresses which fail prematurely, in turn leading to the cost of replacement often outweighing the original savings made.

In this document we describe the various features that contribute to the performance of a pressure re-distributing mattress and which, as such, should be considered when selecting one that is appropriate for the clinical setting in which it is to be used, in line with assessment of the care needed by the patient. It provides background information on key aspects to consider.

Foam density, hardness, cover fabric, and a number of other characteristics, all play a part, and claims about the performance of the final product should be supported by evidence from testing and clinical evaluation. No one factor should be taken in isolation, and it should be remembered that the mattress is a composite of foam and cover.

This guidance is intended to help clinical practitioners and procurement teams make an informed decision as to their choice of options available on the market.

Note 3. We have included signposting of appropriate standards where they exist. BS standards can be purchased from the British Standards Institute (BSI)[4]; ISO standards from BSI or from the International Organization for Standardization (ISO)[5]; and the DIN standard from Beuth[6].

Note 4. Where values are expressed these are for guidance and understanding only. This document must not be taken as a 'prescription' for future product.

Note 5. This document relates only to foam mattresses, and does not apply to hybrid foam and air mattresses, nor to alternating pressure mattresses.

4 https://shop.bsigroup.com/

5 https://www.iso.org/store.html

6 https://www.beuth.de/en

2. Mattress performance

The ISO 20342 'Assistive products for tissue integrity when lying down' series of standards is being developed to cover testing related to clinical needs, and to the properties of mattresses – see Annex C. The clinical aspects are covered in: Microclimate (Part 2), Shear (Part 6), Pressure Distribution (Part 8); and the physical properties in: Strength and Impact Testing (Part 3), Durability (Part 4), Cleaning and Disinfection (Part 5), Foam (Part 7). The last of these (ISO 20342-7) will contain essentially the material to be found in Annex B.

A number of these mattress standards are being based on parallel standards that have been developed over the years for cushions (in the ISO 16840 series) and in the US for mattresses (in ANSI/RESNA SS-1-2019)[7].

2.1 Clinical efficacy

When assessing and selecting a mattress, the clinician should always be clear which characteristics will be most relevant to achieve the desired outcome for the patient.

There is a number of ways to compare mattresses intended for use in a clinical setting. Assessing the needs of the patient comes first. Up to how many hours at a time will they be on the bed? In those hours, how mobile are they with respect to changing position and to leaving the bed? How vulnerable are they in relation to the health of their skin and deeper tissue – considering both intrinsic factors such as age, diabetic, smoker, etc, and extrinsic factors such as pressure, shear, friction, etc? How important is managing skeletal challenges – accommodating skeletal abnormalities, or prevention of deformities? These are all aspects for which clinical risk assessment scales are employed to help assess an individual so that the best equipment and treatment needed by that individual can be prescribed.

To manage these needs and to optimise the outcomes, the physical characteristics of the materials in the mattress and its cover will play an important role in managing the patient's needs (in conjunction with clinical judgment and manual repositioning of the patient). Some aspects are subjective, and therefore will be dictated by the patient's view of what is 'comfortable'. Others can be assessed by prescribed physical characteristics and measured by established test methods (see Annexes).

7 https://www.resna.org/standards/support-surfaces/support-surfaces

2. Mattress performance

Note 1. The mattress is a composite. Therefore it is important that a mattress be tested as a complete item. The performance of the mattress in terms of clinical efficacy, functionality, and longevity is dependent on both the cover and the foam interior. If the cover is changed to a different type (e.g. from a different manufacturer), the way the foam performs, and the way the cover fits, may be affected.

2.1.1 Microclimate
We know that 'microclimate' is a critical measure, not only for skin health, but also for comfort. Microclimate covers the quality of the skin-support surface interface with respect to heat and water vapour accumulation or transfer.

The effects of heat and humidity on the skin can be summarized as follows:

- When the skin becomes moist, the friction between the skin contacting materials increases, potentially increasing the forces transmitted to the skin.
- Skin that is wetted gradually loses much of its mechanical strength and is therefore susceptible to deformation and tearing at lower force levels as compared with drier skin.
- Conversely, there are health challenges of having skin that is too dry.
- Because increased local skin temperature is one of the drivers of local perspiration, when the skin warms beyond a 'perspiration threshold', moisture production from the skin itself increases markedly.
- The metabolic demand of the skin is increased by approximately 10% for each degree Centigrade of warming.
- When blood flow within the outer layer (the integument) is limited, lack of oxygen supply (ischaemia) becomes more severe in warm skin than in cooler skin, under the same loading conditions. Warm skin, when loaded, is therefore more susceptible to ischaemic injury.

The physical attributes of a support surface to cover these elements that we can measure are:

- **2.1.1.1 Heat Transfer**. All of the mattress elements impact on human well-being and directly affect the thermoregulation process. We can gauge the ability of a mattress to help prevent heat build-up between the body and the mattress surface by measuring the temperature gradient and heat transport in Watts per square metre transmitted away from the body.
- **2.1.1.2 Moisture Vapour Transfer Rate (MVTR)**. Often referred to as 'breathability', this is the ability of a fabric to allow moisture vapour (but not liquid itself) to

pass through the coating, drawing moisture away from the user. Generally, the greater the moisture vapour permeability, the better the cover will aid micro-climate. We can gauge the ability of a mattress to help prevent moisture build up between the body and the mattress surface by measuring the rate of moisture transfer through the mattress.

Note 2. Coated support surface materials with higher MVTR values are typically less resistant to physical abrasion, disinfectants, and other aging elements.

Note 3. Traditionally, a manufacturer will quote on the results of tests of the cover material only. However, for the user the rate at which the heat and moisture can pass through the whole mattress, i.e. the top cover, the foam inside, and then the bottom cover, is of key importance. There are further test methods available which test the mattress as a composite for heat and water vapour transfer and these will be covered in ISO 20342-2.

- **2.1.1.3 Sensible moisture.** Unlike water vapour, sensible moisture is moisture we can see and feel, such as from perspiration, incontinence, etc. This testing measures the ability of a support surface to handle and dissipate any moisture build up.

2.1.2 Pressure redistribution

Pressure is force/area, and the force on a support surface comes from gravity applied to the mass of the body. The tissues most at risk from pressure injury are those over bony prominences, where the depth of tissue tends to be less, and over protruding parts of the anatomy. These areas tend to be around the occipital area of the head, ears, shoulders, sacrum, pelvis, heels, and ankles.

If the aim is to increase the area over which the body mass is spread (to reduce the pressure), this can be achieved by allowing greater immersion into the support surface so that more of the body is enveloped by the support surface.

Figure 1: Immersion does not necessarily equate to envelopment

To allow for this, the mattress and foam selected need to have the appropriate thickness, density, and hardness to support the whole body without ‘bottoming out’ (i.e. still having uncompressed foam underneath), without hammocking reducing the immersion, and providing sufficient resilience or flexibility to accommodate quickly to changes of position, such as turning. These properties need to continue day after day, and month after month – not just on the day of purchase.

Note 4. Some support surfaces are manufactured with different foams in different areas, e.g. using different foams, with lower hardness around the areas of the bony prominences to allow for greater immersion of these more vulnerable parts of the body.

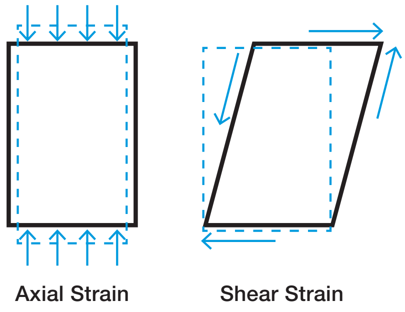
To this end, the test standards for foam provide measures of density and hardness, whereas other standards provide the means to test the ability of the foam to return to its original shape and for the effects of daily use – See below under Materials, and also Annex B.

2.1.3 Shear and friction

Shear 'stress' occurs at right angles to pressure. Thus, pressure compresses tissues creating 'axial strain' (strain equates to distortion). The shear stresses at right angles to the pressure create 'shear strain', distorting the tissues of the skin below the surface.

Shear strain distorts the tissues more critically than the axial strain, in that it can lead to cell wall disruption, and thus the flow of nutrients into the cells and metabolites out of the cells. Shear strain can lead to cell death five times more quickly than the axial strain on blood vessels and on the tissues themselves.

Figure 2: Axial Strain vs Shear Strain



The shear stress arises from the frictional forces that occur between the surface of the skin and the support surface cover. Thus the cover materials are crucial as to whether they 'catch' the skin and cause it to distort, or whether they allow the skin to move with the cover material.

Note 5. It is the dynamic friction on the skin of the ankles and heels when the occupant's body is being moved across or from the bed that leads most frequently to the 'pressure injuries' observed on the feet i.e. it is not just the materials of the support surface that lead to tissue damage. It can also be derived from manual handling deficiencies.

Beneath the cover, the amount that the foam will distort in the direction of the shear stress on the skin will affect how much of the shear strain, i.e. the distortion of the deeper skin tissues, can be dissipated through the foam.

The outer materials of a support surface will have the most impact on the outer surfaces of the skin, whereas the deeper materials will have more impact on the deeper levels of the skin tissues. However, if a mattress cover is selected to protect the skin from friction and shear stress damage, this benefit may be overridden if a sheet that has inferior shear stress reduction properties, is placed over the mattress cover.

The indentation hardness, and the density to a lesser extent, of the foam will be proportional to the amount of shear strain the mattress foam will dissipate

Note 6. Support surfaces on bed frames which allow positional changes around the knees and hips give rise to increased shear stresses on the tissues around the pelvis and base of the spine in particular. The choice of appropriate materials for this application is even more critical.

2.2 Materials

2.2.1 Mattress cover and fabrics

A waterproof coating has been applied to mattress cover fabrics since the 1950s – usually a polyurethane compound poured onto a moving conveyor loaded with a nylon fabric – often known as "proofed nylon" (direct coating). This was used until the 1990s, when knitted polyester and knitted polyamide (nylon) became available with a transfer coated polyurethane that had the ability to stretch and recover with the fabric itself (transfer coating). This had a massive effect in improving distribution of pressure across the mattress surface, as the patient was now immersed 'in' the mattress and not 'on' the mattress and getting increased benefit from the foams inside.

Developments ensued to enhance the performance of the fabrics including, for example, durability, hydrolysis resistance, compliance with biocidal product regulations, flame retardancy requirements; and resistance to chlorine releasing agents, and to fungal growth.

Cover and fabric characteristics, and the standards covering these are covered in Annex A.

2.2.2 Polyurethane foam

Commercial production of flexible polyurethane foam started in the UK in 1954 and developed rapidly, replacing the more traditional types of fillings such as metal springs, animal hair, vegetable fibres, or latex rubber.

Polyurethane flexible foam can be manufactured with different structures, feel, and density, and the growth in its use has been due to the material's unique flexibility and properties, including:

- Excellent cushioning
- Resistance to fatigue
- Very good ageing resistance and flexibility between -20°C and 120°C
- Ease of contouring and shaping by mechanical means

2. Mattress performance

Whilst there is a wide range of polyurethane foams available, the most suitable types for healthcare mattresses in the UK are as follows:

- Combustion-modified ether (CME) foam: The standard format for flexible polyurethane foam in the UK.
- Combustion-modified high resilience (CMHR) foam: High Resilient foams demonstrate a more elastic behaviour and for this reason they play a more active part when body loading is redistributed such as migrating across the mattress surface.
- Combustion-modified viscoelastic (VE) foam: Often referred to as memory foam, this has additional chemicals which increase its viscosity and usually its density. It is sensitive to both pressure and temperature. For healthcare mattresses visco foams would typically be supported by another combustion-modified foam (as above).

For a mattress used in clinical settings, there are five key inter-related foam characteristics to consider, none of which should be taken in isolation:

- Density: the more dense the foam, the less air there is in the foam. Thus, higher density foams are generally considered to be more durable since there is more material to support the mass of the user.
- Indentation hardness: sometimes referred to as the comfort factor. Hardness is the ability of the foam to resist compression.
- Fatigue (resistance to constant load pounding).
- Compression set (wet and dry): the percentage compression set is a measure of the permanent deformation of a foam.

Please refer to Annex B for details of the test standards employed to cover these characteristics, and indications of the relevant values for the required outcomes, when selecting which kind of foam you will need in your mattress to achieve the desired results.

2.3 Causes and consequences of damage

The incidence of mattresses failing due to cover failure was a major issue addressed by the Medicines and Healthcare products Regulatory Agency (MHRA), with a Medical Device Alert: MDA/2010/002 published on 5 January 2010[8].

The concerns outlined, including those around ‘strikethrough’ are addressed in BHTA’s publication, “Protect, Rinse and Dry”[9] which focuses on the causes and consequences of damage and provides guidance on caring for the mattress. It is recommended that this is read for the ‘do’s and dont’s’ of effective maintenance.

8 https://www.gov.uk/drug-device-alerts/medical-device-alert-all-types-of-bed-mattresses-contamination-through-damaged-mattresses-or-covers

9 http://bhta.com/wp-content/uploads/2019/05/BHTA-PRD-A4-16pp.pdf

2.4 Legal requirements

2.4.1 CE marking

Healthcare mattresses are medical devices and to be placed on the market in the UK they must currently meet the requirements of the European Union Medical Devices Directive 93/42/EEC[10], or the new European Union Medical Devices Regulation 2017/745[11] (the Regulation fully replaces the Directive in May 2020). Compliance with the requirements is indicated by the CE mark.

Depending on design intent, mode of function, and clinical claims, medical mattresses can be Class I, Class IIa, or even Class IIb. (The classification rules are set out in Annex VIII of the MDR.) Where a manufacturer makes claims that their mattress is intended for use with patients with injured skin, including, but not exclusively, management of microclimate, it is a Class IIa device (rule 4).

Where a mattress is Class IIa or IIb a Notified Body must certify compliance and the Notified Body number must appear alongside the CE mark.

2.4.2 Fire resistance

The challenges of flammability testing have different approaches from around the world, but in most cases hang off furnishing standards. For wheelchairs and cushions, there exists a flame standard (ISO 7176-16:2012) for upholstered parts, and a surrogate cigarette standard for cushions and back supports (ISO 16840-10:2014 +A1:2018). These standards have been developed to overcome the challenges that furnishing standards present, from applying a heat source at the junction between the seat and the back support (a junction that does not exist for an isolated cushion or mattress).

Further, the risk element should be taken into consideration – FDA and MHRA records indicate that where injuries have occurred or lives lost due to fire, these have usually been derived from electrical faults in a wheelchair, and the risk in this area is covered by ISO 7176-14:2008. For this population of users, the risk of harm from tissue injury is greater than from fire, and thus these standards recognise that the provision of appropriate tissue protection should rank ahead of, not be design-restricted by, the flammability resistance requirements.

> Note 7. The surrogate cigarette was developed to provide a uniform standardised heat source, as compared with commercial cigarettes where the heat output varies considerably from one cigarette to the next. In addition, the surrogate heat source does not carry the health risks of tobacco-based products.

There has been increasing concern in recent years that flame retardant chemicals can create their own health risks in their own right, and at the same time can impair the clinical efficacy of the materials from which support surfaces are constructed. As a result

10 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31993L0042

11 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0745

Table 1: Fire resistance tests

BS 7177:2008 +A1:2011 Specification for resistance to ignition of mattresses, mattress pads, divans and bed bases

Hazard Category	Ignition Source	Typical Examples
Low Hazard (Domestic Use)	Smouldering Cigarette BS EN 597-1:2015 Match flame equivalent BS EN 597-2:2015	Domestic dwellings (including non motorised caravans)
Medium Hazard	Smouldering Cigarette BS EN 597-1:2015 Match flame equivalent BS EN 597-2:2015 Ignition Source 5 (Crib 5) BS 6807:2006	Hospitals Hostels Hotels Old peoples' homes Residential schools Holiday camp chalets
High Hazard	Smouldering Cigarette EN 597-1:2015 Match flame equivalent BS EN 597-2:2015 Ignition Source 5 (Crib 5) BS 6807:2006	Certain hospital wards Offshore installations Hostels Hotels

organohalogens as a fire retardant have been banned in various parts of the world.

Having said this, many health institutions in the UK stipulate that all of the materials used within the manufacture of mattresses for hospitals meet the minimum furnishing standards requirement of ignition source 5, often referred to as Crib 5, a heat source which burns for some minutes (see Table 1, Medium Hazard).

For full compliance the mattress must be tested as a composite, and as well as for Crib 5, must be tested with ignition sources 1 and 2, Cigarette and Match respectively. It is important to note that the Crib 5 test should be undertaken both on top and below the mattress surface.

Note 8. Table 1 lists various British and European flammability tests: an anomaly within this is that at the higher hazard levels, a manufacturer has to test to smouldering cigarette, match flame, and Crib 5 levels. If it passes Crib 5, it will pass ignition sources 1 and 2 as well.

Note 9. If, by design, the top of the mattress differs from the bottom, then the flammability tests should be carried out in the primary intended orientation and then repeated with the mattress turned upside down.

Note 10. Upon request, the manufacturer should provide certification from a UKAS accredited test house demonstrating compliance with all of the aforementioned tests.

2.5 Other considerations

2.5.1 Occupant weight limits

Most manufacturers provide a maximum occupant weight guide for each mattress design, which will be lower than the safe working load.

2.5.2 Weight of the mattress

The manufacturer should identify the weight of their product for manual handling purposes.

2.5.3 Bed frame and accessories

When selecting an appropriate mattress, consideration should also be given to the bed frame and use of accessories such as side rails, to ensure that unsafe gaps are not introduced which may become a hazard for the occupant.

Note 11. External factors, such as good care and maintenance, and use of bed frames and accessories must never be overlooked.

Please see the MHRA advice on "Safe Use of Bed Rails"[12] for further information on this subject.

12 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0745

3. Conclusion

There are a great many ways to compare mattresses intended for use in a clinical setting. The manufacturer should always be able to explain and, where possible, validate their claims when proposing which features are most important and why.

To achieve desired outcomes there will often need to be a degree of compromise between different factors and these will vary depending on healthcare environments and on the bed occupant's state of health, etc. When assessing and selecting a mattress, the clinician should always be clear which characteristics are the most relevant to achieve the desired outcome for the patient.

Finally, the most important conclusion is that the term 'high specification foam' is not an appropriate term. The characteristics of the materials inside the mattress selected for the desired clinical outcome will dictate the selection of the foam performance characteristics; alongside this, the characteristics of the cover materials and their performance are critical to the health and integrity of the bed occupant's skin.

Annex A
Mattress covers and fabrics

A1. Cover characteristics
Different fabrics may be used for the top, side and base because, for example, some mattresses are non-turn and others are flip and rotate, so require different characteristics. The cover should be:

- Fully removable, with zips protected from, and seams resistant to, fluid ingress
- Latex free, and REACH and RoHS compliant
- Easy to check for strikethrough (i.e. light in colour inside)
- Labelled (manufacturer details, care instructions, CE mark, flammability standard)
- Machine washable (in accordance with manufacturer's instructions)
- Resistant to cleaning agents
- Resistant to damage (abrasion, cuts, snags, tears, or scratches)
  (See notes 1 and 2.)

A2. Fabric characteristics
Listed in Table 2 are some of the tests that may be undertaken to support a manufacturer's claims (the figures are indicative). As the ISO standards listed in Annex C are published many of these tests will be superseded.

Table 2: Fabric characteristics: applicable standards

Published standard	Purpose
BS EN ISO 3801:1977 Textiles - Woven fabrics - Determination of mass per unit length and mass per unit area	Ascertaining the weight of both the coating and the substrate: measured in grams per square metre. The overall weight of the fabric material is made up of the coating and the substrate itself. Fabrics can be coated on one side or on both sides. Typically, the weight range can vary between 130gsm – 310gsm. For a healthcare mattress you would normally expect to see a top fabric weight of between 190gsm and 260gsm.
BS EN ISO 13934-1:2013 Textiles - Tensile properties of fabrics - Part 1: Determination of maximum force and elongation at maximum force using the strip method	Calculating the maximum stretch of the fabric, and tensile strength. Expressed as a % this shows how far a fabric will stretch before it breaks. Expressed in Newtons per 5cms (N/5cms) this determines the force required to break the fabric. Results typically vary depending on the direction of test, e.g. higher elongation results across the width of a fabric (weft) compared with the length (warp), will often be seen.

Annex A

Published standard	Purpose
BS EN ISO 4674-1:2016 Rubber- or plastics-coated fabrics – Determination of tear resistance – Part 1: Constant rate of tear methods	Expressed in Newtons, this determines the force required to continue to tear a coated fabric once it has been cut. Separate values are given for warp (along) and weft (across) directions.
BS EN ISO 811:2018 Textile fabrics – Determination of resistance to water penetration – Hydrostatic pressure test	This test demonstrates that there are no small holes or areas of weakness in the covering fabric which would allow liquids to penetrate through and contaminate the foam core (ingress). The fabric is clamped onto the head of the device and water is pumped at a steady rate allowing the pressure to increase. The pressure is typically recorded as 'Kilopascals' (kPa) or millimetres mercury (100mm Hg = 1 kPa). Generally, manufacturers express a minimum value e.g. 3500mm Hg or 35 kPa. They are often much higher than this.
BS EN ISO 2411:2017 Rubber- or plastics-coated fabrics. Determination of coating adhesion	Determining the strength with which the coating adheres to the substrate. Expressed in Newtons, this is a measure of how well-bonded the coating is to the substrate. Low coating adhesion can result in delamination, which would make the polyurethane more susceptible to physical damage. Typical minimum values are 35N/50mm or 20N/22mm.
BS 3424-12:1996, ISO 1419:1995 Testing coated fabrics. Accelerated ageing tests	This test exposes the coated fabric to high levels of heat and humidity which accelerates the ageing process of the coating polymers. Often referred to as 'the jungle test', it is a way of assessing longer term performance over a shorter period. The level of hydrolysis resistance can vary significantly between different types of polyurethane coating. Typically a coated mattress fabric should still be waterproof after 8 weeks of accelerated ageing. Anything less may limit the product lifetime.
BS 3424-34:1992 Testing coated fabrics. Method 37. Method for determination of water vapour permeability index (WVPI) DIN 53122-1:2001: Testing of plastics and elastomer films, paper, board and other sheet materials – Determination of water vapour transmission	Often referred to as 'breathability' these tests measure the ability of a fabric to allow moisture vapour (but not liquid itself) to pass through the coating. This can be expressed either as a % (BS 3424) or as g/m²/24hrs (DIN 53122). Generally, the greater the moisture vapour permeability, the better the cover will aid micro-climate. It should be noted, however, that coatings with higher WVPI values are typically less resistant to physical abrasion, disinfectants, and artificial ageing.

Published standard	Purpose
BS EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity, skin irritation and skin sensitisation	Test that the cover materials are not harmful to the bed occupant. The coated side of the fabric, which is in contact with the patient, is tested for cytotoxicity, skin irritation, and skin sensitivity. Recognised optimal values are Grade 2 or lower for cytotoxicity and 0 for skin irritation and sensitivity.
BS 7175:1989 Methods of test for the ignitability of bed covers and pillows by smouldering and flaming ignition sources	These tests determine the ability of the coated fabric to resist the spread of fire. A predetermined amount of fuel, consisting of wood and newspaper is made into a small cube-like structure known as a Crib; these are numbered according to size. Fabric may be tested by wrapping it around a combustion modified (flame retardant) foam. Typically a Crib 5 is placed above the fabric and set alight, the test might be repeated with the Crib 5 placed underneath the construct. Flame retardants added to the coating help the fabric to self extinguish rather than becoming additional fuel for the fire which would encourage it to spread. It should be noted however that this does not automatically imply that the final mattress will be flame resistant. The mattress as a whole should be tested.

This is not a prescriptive list, nor exhaustive. Where a fabric manufacturer uses an antimicrobial ingredient, this must meet the requirements of the Biocidal Products Regulation (EU 528/2012)[13].

Note 1. Seams can be either stitched, or welded using high frequency, ultrasonic, or heat techniques, each of which provides differing levels of protection against fluid ingress. Seams which are not welded will not give protection from fluid ingress. Consideration should be given to the environment in which the cover is intended to be used.

Note 2. Thorough rinsing and drying of covers between and after cleaning or disinfection is essential, as explained in BHTA's publication, "Protect, Rinse and Dry"[14], which also sets out the potential causes and consequences of damage.

13 https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:167:0001:0123:EN:PDF

14 (http://bhta.com/wp-content/uploads/2019/05/BHTA-PRD-A4-16pp.pdf)

Annex B
Polyurethane foam

For a mattress used in clinical settings, there are four key inter-related foam characteristics to consider, none of which should be taken in isolation:

- Density
- Indentation hardness
- Fatigue (resistance to constant load pounding)
- Compression set (wet and dry)

Key applicable standards for testing these characteristics are listed in Table 3. As the ISO standards listed in Annex C are published, some of the standards listed in Table 3 will be superseded.

B1. Density

Density gives a total weight per unit volume for the foam and is normally expressed as kilos per cubic metre: the higher the number, the greater the density. Foam densities can vary from as low as 14kg/m³ up to 65kg/m³ or even beyond.

Table 3: Polyurethane foam: key applicable standards

Characteristic	Standard(s) applicable
Density	BS EN ISO 845:2009 Cellular plastics and rubbers. Determination of apparent density.
Indentation hardness	BS EN ISO 2439:2008 method B Flexible cellular polymeric materials. Determination of hardness (indentation technique).
Fatigue (Resistance to constant load pounding)	BS EN ISO 3385:2014 Flexible cellular polymeric materials. Determination of fatigue by constant load pounding. BS 3379:2005+A1:2011 Combustion modified flexible polyurethane cellular materials for loadbearing applications. Specification. BS EN ISO 5999:2013 Flexible cellular polymeric materials. Polyurethane foam for load-bearing applications excluding carpet underlay. Specification.
Compression set (wet and dry)	BS EN ISO 1856:2018 Flexible cellular polymeric materials. Determination of compression set. BS EN ISO 13362:2000 Flexible cellular polymeric materials. Determination of compression set under humid conditions.

A healthcare mattress can have several foams within its design – for example, it could have:

- A firm base with a minimum density of 39kg/m³ to help prevent 'bottoming out'.
- A similar density for firm sides/mattress edges to aid support and movement.
- A density of 35kg/m³ for the main body of the mattress, including top layers. (Densities of up to 55kg/m are common or even higher with some grades, particularly viscoelastic foams.)
- A lower grade, e.g. a minimum density of 30kg/m³, for reduced load bearing head and heel zones. In these zones such grades can be used in combination with higher density base/supportive foams.

Higher densities (and greater hardnesses) would be recommended for bariatric care.

B2. Indentation hardness

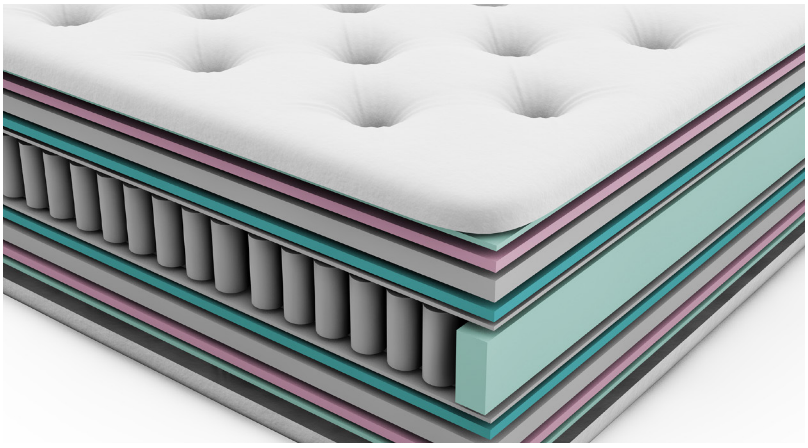
Hardness indicates how firm the foam is. The lower the number, the softer the foam. Hardness in foams is described as the force required to achieve a given degree of compression. A foam grade of a specific density can have a variety of hardnesses depending on the chemistry. Hardness is usually defined as the force necessary to compress the foam to 40% of its original thickness and is usually expressed as a force in Newtons (N).

The British standard BS 5223-2:1999 Specification for Hospital Bedding specifies a hardness range of 110N to 140N, but it is important to note that this is for a single grade foam block, whereas modern mattresses are more usually multi-layered.

Using foam grades of varying densities and hardnesses in combination allows for load bearing areas, patient comfort, and pressure redistribution. This can be achieved by layering increasingly softer foams onto others, or by 'profiling' or 'castellating' the upper surface to reduce the surface tension of the foam. (Durability may be affected if profiling removes too much foam.)

Foams used in mattresses are generally softer than foams used in seating applications as the mass of the person is distributed more evenly. Seating grades tend to be much firmer as they need to provide support for the body over a much smaller area.

Annex B



With modern foam mattresses there is no minimum or preferred hardness requirement. This will vary according to mattress design and the needs of the specified environment.

- Base layers – In multi-layer constructions the base layer will be typically firmer than the upper layer(s) to help prevent 'bottoming out'.

- Side Walls – Where included, side walls can be important for supporting the patient when getting in and out of bed and therefore needs to be a firmer grade

- Body, including top layer(s) – The most important support area of the mattress which can be part of a layered construction or profiled on the upper surface.

- Head and Heel zones – If a heel zone is incorporated into the design of the mattress, it will generally consist of softer foam grades and could also be layered or profiled.

B3. Fatigue (Resistance to constant load pounding)

The fatigue rating indicates the ability of the foam to retain its performance characteristics (thickness and hardness) under repeated loading and unloading.

Fatigue is tested by controlled pounding, with the loss of hardness after pounding being indicated by a hardness and thickness loss percentage. To determine the ability of the foam to retain its thickness and hardness under repeated loading, it is subjected to a controlled pounding test (80,000 cycles at 70 cycles per minute with a loading of 750N).

The lower the figure, the higher its resistance, with percentages varying from around 40% for items like scatter cushions at one end of the scale to around 12% for items like heavy duty public transport seats at the other. The results are divided into five categories, and hospital mattresses will normally be in either S or V.

B4. Compression set (wet and dry)

The percentage compression set is a measure of the permanent deformation of a foam after it has been compressed between two metal plates for a controlled time, and temperature condition. The standard conditions are 22 hours at 70°C. The foam is compressed to a thickness given as a percentage of its original thickness, usually 50%. Compression set is expressed as the percentage loss of the original thickness that remains.

Table 4: Fatigue rating classification

Hardness loss %	Class	Typical applications
39-45	L (Light)	Padding, scatter cushions, pillows
31-39	A (Average)	Domestic furniture arms and backs, component layers for domestic mattresses (excluding cores)
22-31	S (Severe)	Domestic furniture seats, public transport backs and armrests, cinema and theatre backs and armrests, contract furniture backs and armrests, domestic foam mattress cores, healthcare mattresses
12-22	V (Very Severe)	Public transport seats, cinema and theatre seats, contract furniture seats, healthcare mattresses
12 Max	X (Extremely Severe)	Heavy duty public transport seats, heavy duty contract seats

However, simulating end use performance in hospital mattresses, humid compression set measurements are probably more significant. Some foams can be abnormally affected by humidity so an additional test is undertaken by subjecting the test apparatus to a climatic condition of 40°C/95-100% relative humidity, which is realistically close to a human body contact situation. The maximum compression set (humid aged) allowable under this standard is 12% (wet).

Annex C
ISO Mattress standards

The international standards group ISO TC 173 WG 11 Assistive products for tissue integrity is currently working on a suite of work items including appropriate test methodologies.

Table 5: ISO 20342 standards work programme

Standard	Purpose
ISO FDIS 20342-1:2018 General Requirements	This standard covers the general design and safety requirements for mattresses, covers, and slide sheets.
ISO PWI 20342-2 Impact of Microclimate on Tissue Integrity	Climate can best be described as an interaction between heat, humidity, and pressure. The climate around a human body has an impact on human well-being and directly affects the thermoregulation process aiming to keep the body core temperature around 37°C. The easier this process can be managed, the less physical burden on the tissues can be expected. The aim of this standard is to demonstrate how different materials impact on microclimate. In doing so, the group will have reviewed established tests, e.g. ISO/TS 16840-11:2014 Wheelchair seating – Part 11: Determination of perspiration dissipation characteristics of seat cushions intended to manage tissue integrity, and the latest research.
ISO PWI 20342-3 Strength and Impact	The aim of this standard is to provide criteria for ease of manufacturing and distribution of qualified products to both manufacturers and users. It will describe the test methods of mattress and positioning devices including device specific general requirements. The following test methods are involved: a. Strength of mattress and cushion type positioning device b. Tensile strength of sheet type of positioning device c. Strength of handles of sheet type positioning device d. Impact of mattress and positioning device e. Slipperiness of sheet type positioning device

Standard	Purpose
ISO PWI 20342-4 Durability	There is a distinction between the warranty and the expected life of a mattress, and different materials/components provide different expectations. The aim of this standard is to demonstrate the ability of a product to perform its required function over time, under normal conditions of use, without the need for excessive expenditure on maintenance or repair.
ISO PWI 20342-5 Cleaning and Disinfection	Different products are used in different environments such as hospitals, home care and institutions. Depending on the application, they may come into contact with different soiling products, e.g. ointment/salve, antiseptic solutions, or body fluids e.g. blood, urine, faeces, wound exudate. The products are therefore subjected to repeated cleaning and disinfection. Some of these methods and/or products can irreversibly damage the surface or reduce performance. The aim of this standard is to describe test methods that evaluate and/or compare the resistance of the mattress surface towards cleaning and disinfection products/protocols.
ISO PWI 20342-6 Shear	Different materials and construction will impact shear on tissue in different ways. These will be characterised by the magnitude of lateral force, the elasticity of the support surface, the elasticity of the patient's skin, and the coefficient of friction at all surface interfaces. This standard describes tests that compare the impact of shear, most notably sliding resistance, horizontal stiffness, and rolling shear.
ISO PWI 20342-7 Guidance for selection of foam products	There is also scheduled to be a Part 7 in the ISO 20342 series, to cover foam characteristics of a mattress. The content of Part 7 will cover much of what is in this What Lies Beneath document.
ISO PWI 20342-8 Pressure Distribution	This standard applies to the ability of a support surface to redistribute the load of the full body during extended periods of lying. Pressure redistribution is recognised as a critical factor in the prevention and treatment of pressure injuries. The aim of this standard is to cover a range of support surfaces intended to be used in the lying down position. It also considers the combination of a full body support surface and an adjustable mattress support platform.

Annex D

Australian minimum recommendations for high specification foam mattresses

Table 6: Minimum recommendations for high specification foam mattresses[15]

Characteristics	Explanation	High specification mattress
Classification	Classification according to the Australian Standards (AS2281-1993).	Type H/HR H - conventional resilience, heavy duty HR - high resilience LR - Low resilience
Multi-layering	Multi-layering of various grades / types of foam alters design features. Different density-hardness layers produce a harder base that increases upper weight limit. Slow recovery foam increases the surface area contact, redistributes pressure, reduces peak pressures and allows immersion of bony prominences. Has potential to increase skin surface temperature.	Common feature
Density – hardness in single layer mattresses	Density is the weight of the foam in kilograms per cubic metre kg/m3. Hardness is the ability of foam to 'push back' and carry weight. Hardness is defined as the amount of force (in Newtons) required to indent a sample of the foam by a specific percentage of the original thickness. This is known as the indentation force deflection (IFD). In Australia and Europe hardness is measured at 40% IFD. Density/hardness defines the grade of foam and is stated with density followed by hardness.	35-130 kg/m^3 (minimum for single layer foam mattress) Variance in the hardness exists in top and middle layers of multilayer designs.
Support factor	An indicator of foam comfort that is calculated as a ratio: IFD at 65%. IFD at 25% = support factor. A higher value usually indicates a softer feel and good base support.	IFD: 1.6 to 2.6
Depth	Consider depth of the mattress alongside density/ hardness. Different foam grades require different depth to manage upper body weight and prevent bottoming out	150mm Mattress depth needs to be increased to support bariatric load.

Characteristics	Explanation	High specification mattress
Mattress cover	Vapour permeability: the relevant measurement is moisture vapour transmission rate (MVTR). Increasing the MVTR potentially allows the trans-epidermal water loss (TEWL) of intact skin to transpire through the cover. Decreasing the MVTR of the cover protects the foam from moisture degradation. Changing the MVTR becomes a compromise between managing local climatic conditions and the patient's TEWL. Allows for partial immersion in foam. Wrinkling: may add additional pressure at skin surface. Shear resistance: can be reduced with a low friction fabric. Infection control: • water proofing – prevents contamination of foam • welded seams prevent ingress of fluids • waterfall flap cover over zips • cleaning according to facility protocol and manufacturers guidelines Fire retardant properties: material must meet local standards	MVTR: minimum 300g/m^2/24hrs (equivalent to normal patient TEWL) Often 2 way stretch
Other considerations	Castellated foam: partial thickness cuts made in a regular block pattern on the top section of the foam increases surface contact area potentially reducing friction and shear. Side walls: a border or stiffener along the edge increases firmness and assists mobility and transfers Safety sides (concave shape): may reduce risk of falls but may also reduce bed mobility, need to consider facility restraint policy Hinging system: wedges removed on the inner border to allow for folding or bending of mattress to accommodate back rest and upper and lower leg sections to conform to profiling beds	Common features

15 2012 (see pages 24 and 25) – Pan Pacific Practice Guideline for the Prevention and Management of Pressure injury – https://www.nzwcs.org.nz/images/publications/2012_AWMA_Pan_Pacific_Abridged_Guideline.pdf

Glossary

Bottoming out
Occurs when the surface is no longer effectively redistributing pressure because the bed occupant has immersed excessively into the surface and is no longer being supported by it, actually resting on the underlying bed frame or support structure.

Composite
Made up of several parts or elements.

Cytotoxicity
Human cell viability when exposed to a potentially toxic substance.

Hydrolysis
The chemical breakdown of a compound due to reaction with water.

Hydrostatic pressure
The pressure that any fluid in a confined space exerts.

REACH
The acronym for Registration, Evaluation, Authorisation and Restriction of Chemicals, a European Union regulation restricting the use of harmful chemicals.

ROHS
The acronym for Restriction of Hazardous Substances, a European Union directive restricting the use of hazardous materials found in electrical and electronic products.

Strikethrough
Damage allowing fluid and bacteria to penetrate through a fabric.

Substrate
An underlying substance or layer.

Tensile strength
The ability of a material or object to be stretched or pulled without breaking.

About BHTA

The British Healthcare Trades Association (BHTA) is one of the UK`s oldest and largest healthcare associations (founded in 1917). At the heart of the Association is the Code of Practice, which sets out the standards that all members must meet to demonstrate best practice in their business dealings.

The Code of Practice is the first for consumers in the healthcare industry and has achieved approval under the Chartered Trading Standards Institute's "Consumer Codes Approval Scheme".

This guidance was produced collaboratively by the members of the BHTA Beds and Support Surfaces Section, including those involved directly with the manufacture of polyurethane foam and textiles.

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