...reducing avoidable harms

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Raising the bar for CE marking powered pressure area care support surfaces

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Introduction

In the current economic climate healthcare providers face increasing financial pressure to improve performance, while simultaneously maintaining or even reducing spend.

In line with almost all medical device tenders the decision to purchase, rent, lease and use a powered pressure area care (PAC) support surfaces is often based on a combination of cost, ease of use and claims around product performance and safety i.e. what type of patients can be placed onto the mattress and how safe the product is when in use.

When considering the performance and safety of powered PAC support surfaces it is imperative that healthcare providers are aware that; (1) these devices can be classified as either Class I or Class IIa medical devices; (2) just how low the current bar is set for initially gaining and then maintaining a CE mark for a Class I medical device, and (3) the potential benefits that classifying these products as Class IIa devices can offer.

Only by understanding these key points is it possible to make a truly informed decision when purchasing, renting, leasing and using these products.

Pressure ulcer prevention, product performance and patient safety

Pressure ulcers (PU) are a recognised 'avoidable harm' event and with the correct care bundle in place almost all PUs are preventable. Providing an appropriate support surface to each patient is a key element of the care bundle.

All support surfaces (mattresses and cushions) designed for PU prevention and management are medical devices that can be broadly categorised into:

- 'Non-powered' products, offering reactive (static) therapy i.e. foam mattresses, static air-filled products, static hybrids (see Figure 1).
- 'Powered' products, offering active (alternating pressure) therapy which requires either mains or battery operation (See Figure 2).

Since powered PAC support surfaces are typically used for higher risk patients it is essential that manufacturers' claims of clinical performance and safety are accurate and supported with relevant data.

Part of the medical device procurement process is understanding how devices perform and how safe they are when in use. Another way to look at this is to ask the questions:

What performance claims does the manufacturer make for the product? And can these claims be verified / supported?

Ultimately if PAC devices fail to meet the manufacturers stated performance and safety claims patients risk developing a pressure related tissue injury. Mattresses failing to live up to their claims will therefore have a major impact on patient outcomes and ultimately this will have significant financial implications for the healthcare provider who will have to pay for treating wounds that should have been prevented in the first place.

FIGURE 1.
FUSION™ Response mattress

FIGURE 2.
QUATTRO® Plus mattress system

FIGURE 3a.

FIGURE 3b.

FIGURE 3.
Labelling differences between Class I devices and Class IIa, IIb and III devices. Figure 3a shows a CE mark from a Class I medical device (e.g. Talley FUSION Response). There is no number after the CE mark therefore this device is NOT audited by a Notified Body. Figure 3b shows a CE mark from a Class IIa medical device (e.g. Talley QUATTRO Plus / Acute). The number after the CE mark is proof that this device is independently audited by a Notified Body.

So how can you be confident that manufacturer claims of support surface performance and safety are a true reflection of the medical device you are buying, providing and using?

Fortunately it is a legal requirement for manufacturers to ensure that any medical device they manufacturer and sell must carry a CE mark.

Unfortunately not all CE marked medical devices are subjected to independent auditing by recognised Notified Bodies. Therefore just because a device carries a CE mark it does not automatically mean that claims of device performance and safety have been independently verified and confirmed by a recognised Notified Body.

One very quick and simple way to differentiate between a Class I device and devices in Class IIa, IIb and III is to look at the CE mark on the product. If the CE mark is followed by a number, then the device is independently audited by a Notified Body. A CE mark WITHOUT a number after it is a Class I device and this is NOT audited by a Notified Body (see Figure 3).

Manufacturers' claims for more simplistic (Class I) medical devices are never questioned or confirmed by an independent Notified Body and in this regard this specific area of medical device classification and regulation is, and remains, to all intents and purposes unregulated.

Medical device classification and CE marking

Medical devices will fall into one of the following classes detailed in Table 1 [1];

As you ascend the categories from Class I to Class III the level of regulation and legislation increases accordingly to reflect the potential risk posed by the device. All Medical Devices (irrespective of classification) must be supported by a complete product Technical File, the purpose of which is two-fold:

1. To ensure all foreseeable product associated risks have been identified and mitigated for. Where these cannot be designed out of the product appropriate steps have been taken to minimise the risk posed to patients / nurses etc.
2. To ensure products are both effective and safe when in use.

Part 1 of the above is accounted for by the Essential Requirements laid out in the Medical Device Directive (2007/47/EC) [2] and its associated annexes. Part 2 of the above relating to device effectiveness and safety is covered by MEDDEV 2.7.1 revision 4 which details the requirements for a full Clinical Evaluation report for the device in question and ongoing assessment of the device via post market surveillance (reactive) and post-market clinical follow-up (proactive) once the product is launched into the marketplace. [3]

TABLE 1.
Medical device classification and Notified Body auditing requirements

MEDICAL DEVICE CLASSIFICATION	GENERAL DESCRIPTION	LEGAL REQUIREMENT FOR AUDIT BY NOTIFIED BODY
Class I	Non-invasive devices (i.e. a bed frame, walking aid, patient hoists, stethoscopes etc.)	No
Class IIa	Active therapeutic devices (intended to administer or exchange energy), invasive devices and dressings	Yes
Class IIb	Active therapeutic devices (intended to administer or exchange energy in a potentially hazardous way), invasive devices and dressings for extensive, complex wounds	Yes
Class III	Implantable devices / pharmaceuticals	Yes

As a legal requirement Class IIa, IIb and Class III medical devices, and the Technical Files upon which their registrations are based, are audited every 2 years by a Notified Body (The NB is a company-appointed independent auditor that confirms that the device is both effective and safe and it can continue to be sold / rented / used for its intended purpose).

Class I medical devices do not receive mandatory, independent auditing and the manufacturer is responsible for self-certifying the device to confirm it meets all necessary legal and regulatory requirements. Self-certification effectively means no compulsory independent assessment of the Clinical Evaluation report (which proves device effectiveness and safety) nor any product performance claims made in the literature, instructions for use etc.

This raises the question *"how do we know Class I medical devices meet legal requirements, are safe to use, fit for purpose, clinically effective, and perform to the level stated by the manufacturer?"* The simple answer is that for Class I devices, we don't! This lack of compulsory independent auditing and regulation (or self-regulation) with regard to Class I devices is understandable for very low risk products e.g. bed frames, walking aids, cotton wool, or sticking plasters. However, where Class I devices clearly impact on patient outcomes – for example active therapy support surfaces for PU prevention and management – this self-regulation must surely be questioned. If these devices do not perform effectively patients will develop pressure related tissue injuries.

Making the case for all powered support surfaces to be Class IIa medical devices

Current classification of active therapy support surfaces

For powered PAC mattresses the current guidelines and legislation around medical device classification is ambiguous and open to interpretation. This ambiguity has resulted in some manufacturers classifying their powered PAC mattresses as Class I devices, while others opt to classify their products as Class IIa devices.

Manufacturers registering their powered PAC support surface as a Class I medical device can therefore self-certify and CE mark their product without any compulsory external, independent auditing of the product Technical File. This is not the case for manufacturers registering their powered PAC support surfaces as Class IIa and by placing their products into this category they voluntarily accept the far greater regulation and controls that come with this classification.

Ultimately this grey area in the current regulation represents a significant potential risk for healthcare providers. Where the powered PAC support surfaces being used under patients are Class I devices, these are effectively unregulated. Therefore claims of performance and safety have not been independently verified. Where providers are using Class IIa devices they can be confident that these devices are subjected to far greater scrutiny and regulation and that all of the manufacturers claims around product performance and safety are independently verified by a recognised Notified Body.

In simple terms you can be confident that a Class IIa device will safely deliver the performance and therapy that your patients require.

Without wishing to press the 'panic button' the current ambiguity regarding powered PAC mattress classification and the lack of regulation around Class I medical devices makes it entirely possible that some powered PAC support surfaces may have no Technical File documentation and no Clinical Evaluation report. If this 'worst case' scenario is true then these products are effectively being placed under patients despite being illegal and potentially dangerous.

Raising the bar: Benefits of mandatory Class IIa classification for all powered support surfaces

At first glance classifying a powered support surface as Class I or Class IIa may seem an arbitrary, irrelevant, peripheral issue to procurement, clinicians, healthcare providers and patients.

However, there are significant benefits to raising the bar for CE marking all powered support surfaces and making it mandatory for all of these products to be classified as Class IIa medical devices. Notable benefits include;

- **Safeguarding patients.** Healthcare providers and clinicians have a duty of care to provide patients with the very best care that they can deliver. Under current legislation for Class I medical devices none of the product claims around performance or safety have to be independently verified. For a product that can impact significantly on patient outcomes surely this cannot be right?

  Forcing powered support surfaces into Class IIa would guarantee that all claims of product performance and safety have been confirmed BEFORE a CE mark is awarded for the product and these claims would be reviewed regularly throughout the product lifecycle. This would safeguard patients by guaranteeing that providers and clinical staff could confidently provide a safe and effective product to their patients.

- **Optimising budgets.** It is often attractive for senior management, procurement and tissue viability to look towards less expensive PAC support surfaces in order to cover more beds with an equivalent or even reduced spend. This is only a cost-effective solution if there is no increase in PU incidence i.e. if product performance and safety remain at an appropriate level.

  Mandatory classification for all powered support surfaces into Class IIa will ensure healthcare providers can optimise their budgets by balancing product costs vs. product performance and safety as these product characteristics will have been independently verified by a Notified Body.

- Creating a level playing field for manufacturers. Companies incur significant costs meeting legal requirements and compiling Technical File documentation. In addition, manufacturers of Class IIa devices also pay their Notified Body to perform regular compliance checks and audits throughout the lifecycle of the product. This spend must be recouped during the product lifecycle.

  Uplifting all powered support surfaces to Class IIa would force all manufacturers to create similarly detailed documentation and to have this checked and reviewed throughout the product lifecycle. This would effectively level the playing field for manufacturers as every manufacturer would incur similar costs. From a procurement perspective this would enable a more realistic comparison between products.

How can we push for tighter regulation? What questions should we ask?

The MHRA are currently reluctant to make it mandatory for all powered PAC support surfaces to be Class IIa medical devices and they advise "all manufactures of Active Air Mattresses systems" to adopt the recommendations set out in current legislation. The concern for providers and clinicians must be that some manufacturers will ignore this advice and continue to self-certify products.

Keeping the patient as the central focus it would surely be safer to classify all of these devices as Class IIa. This would then force manufacturers to provide appropriately detailed documentation around product performance and safety.

Perhaps healthcare providers, front line clinicians and the various UK societies that represent tissue viability should now lobby the MHRA to ensure the products placed under patients are the highest possible standard.

A good potential starting point for providers, procurement and clinicians is to begin by requesting companies to;

- Provide documented evidence that the mattresses they are purchasing/using adhere to the highest performance and safety standards (i.e. a clinical evaluation report to MEDDEV 2.7/1 rev. 4)
- Provide certificated, independent evidence of compliance with these standards (i.e. CE certifiction from a Notified Body)
- Adopt the more stringent Class IIa classification for powered support surfaces.

An obvious way to force this issue back onto manufacturers is to include this in all powered support surface tenders. This would ensure that (1) the relevant documentation is seen prior to making any decision on purchasing (2) the product is Class IIa with the assurance that the relevant safety standards are being met, (3) the company is audited by an independent Notified Body and not just accepting the word of the company representative.

NHS Trusts and other healthcare providers have the potential to drive this issue from the 'bottom-up' by insisting that only powered support surfaces with Class IIa device classification are considered for use. Companies with nothing to hide should be more than happy to talk through the documentation that stands behind their products and supports their claims and their Class IIa classification.

At least by doing this it would ensure that any powered support surfaces used by the provider were legal, safe and effective. This is the minimum that our patients deserve.

Conclusion

Classification of powered PAC support surfaces is a grey area and devices can be classified as Class I or Class IIa depending upon interpretation of the current guidelines.

Class IIa medical devices are subjected to far greater regulation and mandatory Class IIa classification for all powered PAC support surface would 'raise the bar' significantly for these devices. This would have far reaching consequences for manufacturers and providers thereby enhancing patient safety and increasing transparency within the industry, ultimately protecting both patients and providers.

References

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