Section 4.2.3.1 Claims
This section lays in with ‘intended use’ and essentially states the manufacturer will set out clear device claims i.e. what the APTI will do from a clinical standpoint. The standard stipulates that all claims in the product’s introduction or instruction for use are supported by evidence either with a specific test or clinical evidence demonstrating that the mattress delivers the clinical outcome the manufacturer claims.

BENEFIT TO PROVIDERS AND PATIENTS: Supporting product claims with test data or clinical evidence ensures manufacturers do not overstate product performance. This helps ensure product marketing claims can; 1) be trusted – when prescribing products to patients, and 2) be challenged as part of a tendering process.

Section 4.6 Clinical evaluation
Manufacturers are required to compile a full clinical evaluation report to MEDDEV 2.7/1 for all PAC support surfaces.7

BENEFIT TO PROVIDERS AND PATIENTS: Accurate claims of product performance and safety allow providers and clinicians to make product performance to patients’ clinical needs. Clinical Evaluation Reports (CERs) focus on PAC mattress performance and safety and ensure all product performance and safety claims are supported by relevant clinical data. CERs prevent manufacturers making spurious, far reaching claims that cannot evidence.

NOTE: Notified Bodies already audit CERs for Class Ilb PAC mattresses. However, CERs for Class I devices are never audited by a Notified Body. Healthcare providers setting up a PAC mattress tender should look specifically for evidence of, or evidence of the CERs. If PAC support surface they are considering using as it ensures manufacturers product claims are accurate, supported by data and that they are adhering to the MED/MDR and ISO 20342-1 PAC mattress standard.

Section 5 - Safety requirements

Section 5.1.3 Education and training
Manufacturers who offer education and training on the safe use of their PAC support surface must clearly describe the intentions and outcomes from this activity and outline the duration, and any cost implications associated with the training. Manufacturers must also provide all relevant test, examinations and certifications.

BENEFIT TO PROVIDERS AND PATIENTS: Patients will be far more likely to gain maximum benefit from the mattress if clinical staff set it up correctly for patients’ individual needs. Where there is a clear training process providers can tailor their approach to choosing the right surface to the patient’s unique needs.

Section 8 - Safety of electrical equipment

Section 8.1 General electrical requirements and 8.2 Electromagnetic compatibility
Manufacturers of an APTI containing electrical or electronic devices/components shall conform to IEC 60601-1-2.

BENEFIT TO PROVIDERS AND PATIENTS: Manufacturers of electrical equipment must ensure that it meets the highest IEC safety standards. Conforming to these standards ensure that any electrical safety risks posed by the equipment is minimised.

Discussion
With all healthcare providers and clinicians focussed on reducing preventable pressure ulcers and developing the most effective harm-free care it is essential that every PAC mattress (APT) attains the highest standards of device safety and claims of product performance are accurate and supported by appropriate clinical data.

Having an agreed baseline for the safety of all foam, hybrid and air mattresses and transparency around device performance claims allows providers to choose their preferred PAC products by aligning product claims with their patients’ demographics and clinical needs.

ISO 20342-1 applies to all UK PAC support surface manufacturers and distributors and is primarily focussed on setting a minimum safety requirement for these medical devices. All healthcare providers and stakeholders involved in PAC support surface procurement and provision should be aware of, and familiar with, ISO 20342-1 as it may impact on their choice of PAC mattress.

Conclusions
Understanding the content of the new ISO standard allows stakeholders involved in mattress procurement to call-out specific elements of mattress safety pertinent to them and include these in their mattress tender specification.

For example, the need to have an intended use statement and a Clinical Evaluation Report written to MEDDEV 2.7/1 could be included as part of the tender specification for all mattresses. This would ensure the products in the tender meet the healthcare provider requirements and that device performance and safety claims are not overstated as they must be supported by relevant evidence and clinical data.

When tendering for powered PAC mattresses perhaps an obvious requirement in the tender specification would be for the product to meet the current electrical safety standard.

With an increasing focus on patient safety and preventing patient harm from pressure ulcers, setting a ‘minimum bar’ for PAC support surface safety is clearly a step in the right direction and should be welcomed by policy makers, providers, clinicians, patients, manufacturers and distributors of these medical devices.

By mandating a minimum requirement in PAC support surface tenders specifications, healthcare providers can drive manufacturers and distributors to adopt and comply with this new device safety standard, which will ultimately be reflected in enhancing patient safety and reducing the risk of preventable pressure ulcers.

References