FRAMEWORK AGREEMENT SPECIFICATION FOR PRESSURE AREA CARE AND PATIENT HANDLING

1. Introduction

1.1 This Framework Agreement is for the supply of Pressure Area Care and Patient Handling Products and Related Services including:

- Beds, Cots and Cribs
- Integrated Bed and Mattress Systems
- Mattresses
- Cushions
- Prevention and Support Aids
- Hoists and Stand Aids
- Patient Transfer Equipment
- Slings
- Slide Sheets
- Bathing Equipment
- Product Rental and Managed Services

1.2 The Framework Agreement will be split into the following lots:

Lot Number	Lot Title
1	Beds, Mattresses, Pressure reducing products and Manual Handling Equipment and associated products
2	Managed Service for Beds, mattresses, and associated products
3	Rental and Decontamination

Lot 1

Pressure Area Care and Patient Handling					
Lot 1 – Products associated with pressure area care and patient handling.					
1.1	1.2	1.3	1.4	1.5	1.6
Beds, Cots and Accessories	Integrated Bed and Mattress Systems	Mattresses and Accessories	Hoists, Stand Aids and Accessories	Pressure Mapping and Skin Assessment Devices	Bathing Equipment and Accessories
Community Beds	Paediatric	Static Mattresses	Mobile Hoist Electrical	Pressure Mapping Systems	Shower Trollies
Acute Beds	Adult	Dynamic Mattresses	Mobile Hoist Hydraulic	Skin/Tissue Assessment Systems & Accessories	Changing Trollies
Maternity / Birthing Bed	Plus Size	Hybrid Mattresses	Portable and Ceiling Gantry Hoists		Shower/Changing Trolley Accessories and Spare Parts
Cots and Cribs	Accessories	Overlay Mattresses	Sit to stand		
Accessories		Mattress Pumps and Accessories	Bath hoists		
			Swimming Pool Hoists		
			Manual Stand Aids		
			Electric Stand Aids		
			Assisted Lifting and transfer devices		

Lot 1

Pressure Area Care and Patient Handling				
Lot 1 – Patient Handling Products, Cushions and Pressure Reducing Aids Support				
1.7	1.8	1.9	1.10	1.11
Pressure Reducing and Positioning Aids	Cushions and Accessories	Patient Transfer Equipment	Slings and Accessories	Slide Sheets
Heel Offloading Bootees	Static Cushions	Turn Table	Loop Slings	Flat Slide Sheets
Heel Protector	Dynamic Cushion	Swivel Cushion	Clip Slings	Tubular Slide Sheets
Pressure Reducing Pads	Hybrid Cushions	Sitting Transfer Board		Insitu Slide Sheets
Patient Positioning Aids	Cushion Pumps and Accessories	Supine Transfer Board		
Falls Protection Mat		Supine Transfer Sheet		
		Transfer equipment accessories		
		Handling Belts / Transfer Belts		

Lot 2 and 3

Services associated with Pressure Area Care and Patient Handling	
Lot 2	Lot 3
Managed Service for Beds, mattresses, and associated products	Rental and Decontamination for equipment covered under lot 1

1.3 Full technical specifications of the product lines awarded to the Framework Agreement (each a "**Technical Specification**" and together the "**Technical Specifications**") must be made available to NHS Supply Chain on request during the term of the Framework Agreement.

- Applicants must notify NHS Supply Chain immediately about any proposed changes to the Technical Specifications throughout the term of the Framework Agreement.
- If changes to the Technical Specification, of any product line awarded to the Framework Agreement, mean that the product line no longer meets the minimum requirements outlined in the Specification, NHS Supply Chain reserves the right to exclude that product line from the Framework Agreement.
- NHS Supply Chain reserves the right to request evidence of compliance with the Specification throughout the term of the Framework Agreement.

1.4 The provider must ensure that any product recall or field safety notice issued by the Medicines and Healthcare products Regulatory Agency (MHRA) or any alert from the NHS Improvement, is to be actioned in accordance with relevant guidelines and reported to the participating customers Authorised Person/ Medical Device Safety Officer (MDSO) in writing.

2 **Criteria applicable across all product lines**

Standards and Legislation

2.1 This framework agreement specification refers to several standards and legislation. The list of standards and legislation is not intended to be exhaustive and any relevant standards and legislation which applies to the Framework Agreement (even if not stated) must be complied with by Applicants (together with those listed in this Framework Agreement Specification the "**Standards and Legislation**").

2.2 Product lines must comply with the Standards and Legislation (as amended, extended or re-enacted from time to time).

2.3 Evidence of compliance to the Standards and Legislation must be provided by Applicants awarded to the Framework Agreement ("**Suppliers**") to NHS Supply Chain during the tender submission and upon request during the term of the Framework Agreement; in the event that sufficient evidence is not provided by Suppliers NHS Supply Chain reserves the right to suspend product lines until such evidence is provided by Suppliers.

2.4 The following tables relate to the standards and legislation which are applicable to each of the lots within the framework agreement for the supply of Pressure Area Care and Patient Handling products, including beds and associated products, rental and decontamination.

The first table relates to all standards which are applicable to all lots within the framework, with subsequent tables relating to specific sublots, as noted in the table title. If the standard or legislation is mandatory, the Supplier must provide evidence that they comply with these. For standards which have not been mandated, the expectation is that suppliers will comply with these standards. If the supplier does not hold certification for a specific standard, it is expected that an alternative standard

which is substantially equivalent, is held to confirm compliance. Evidence of compliance to the standards/legislation/directives must be made available on request at any time during the Framework Agreement; in the event that sufficient evidence is not supplied NHS Supply Chain reserves the right to suspend product until such evidence is available. The list of standards and legislation is not intended to be exhaustive as detailed in paragraph 2.1 above.

STANDARDS AND LEGISLATION	TENDER REQUIREMENTS
Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) All products must have their CE or UKCA marking evident on the product and/or packaging. Or **Medical Devices Regulation 2017/745 (as amended)** All products must have their CE or UKCA marking evident on the product and/or packaging. All products must have their CE or UKCA marking evident on the product and/or packaging.	<u>Class I</u> • Declaration of conformity to the Medical Devices Directive 93/42/EEC **to be provided with your Tender response.** <u>Class I Sterile, Class I measuring, Class IIa, Class IIb and Class III</u> • CE certificate from a notified body **to be provided with your Tender response; and** • Declaration of conformity to the Medical Devices Directive 93/42/EEC **to be provided with your Tender response.** **Where not Applicable** Provide a statement confirming why this Directive does not apply to your product(s) submitted for a product line. You will need to do this for each product line where this Directive is not applicable to your product(s).

2.5 Electrical product lines must comply with the requirements of the Directive on waste electrical and electronic equipment (WEEE Directive 2012/19/EU) and the Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive 2002/95/EC).

2.6 All product lines and packaging should be latex free where possible. If a product line or any packaging contains latex this must be clearly labelled on the product line or packaging (as applicable) to inform the user.

3 Warranty

3.1 Products in lots 1.1, 1.2, 1.3, 1.4, 1.5 and 1.6 within the Framework Agreement for Pressure Area Care and Patient Handling equipment will require a 12 month warranty against manufacturing defects.

3.2 All product lines must be supplied to the customer with a minimum 12 months shelf life.

3.3 Spares and Replacement parts should be available for the lifetime of a product to allow trusts repair and extend the life of products.

4 Product Performance

4.1 Suppliers may be asked to provide clinical evidence to support claims with regards to product performance and efficacy.

5 Product Evaluations

5.1 NHS Supply Chain reserves the right to evaluate any products included on the contract. Products must be provided free of charge to enable product evaluation.

5.2 Any product trials / evaluations agreed to take place by both the Provider and/or Trust will be at no charge. For the avoidance of doubt this includes, but is not limited to:

- Product and equipment
- Delivery charges
- Loan kit charges
- Training and clinical support

Discussions on length of trial and outcomes will be agreed with the customer prior to a trial commencing.

6 New Products/Changes in Specification

6.1 Where a current product covered under this Specification is either:

- Withdrawn from the market
- Cannot be supplied
- Superseded by a new product (or inadequate stock levels)

The Provider agrees to supply an equivalent product at a reduced price or at the price agreed for the original product under this Agreement. If no direct alternative is available a superior product must be provided, limiting the financial impact on the customer.

6.2 The Provider must inform NHS Supply Chain in writing of any new products which the Provider wishes to include on the contract for consideration/evaluation.

6.3 Products may not be added under this framework agreement until they have been checked against the specification and desktop/paper based evaluations have been completed.

6.4 The Provider must inform NHS Supply Chain and customers in writing of any proposed changes to the specification of existing products for the goods being supplied against the contract, including proposed changes to:

- Packaging quantity or format
- Product coding
- Manufacturing changes such as but not limited to new site, change of raw materials and/or product characteristics.

Notification of any such proposals shall be made at least three months prior to the proposed implementation date of any changes.

7.0 **Product / Packaging Features**

7.1 It is the responsibility of the Supplier to ensure that packaging is appropriate for the equipment being supplied in terms of handling, storage and ease of use by the customer.

7.2 Product packaging must include but is not limited to:

- Product name
- Product re-order code
- GS1-128 and/or ITF-14 codes
- UKCA/CE Mark
- Use by/Expiry date (where applicable)
- Material composition (where applicable)
- Weight (where applicable)
- Quantity (where applicable)
- Size (where applicable)

7.3 Where appropriate all materials used in products must be recyclable and identified as such through appropriate ISO symbols.

7.4 Batch codes and/or Lot numbers and/or Serial numbers are to be identifiable to aid in recording product details and applied to the product wherever possible.

7.5 Products and packaging shall be labelled aligned to CE/UKCA regulations ensuring where possible clear and easy to follow symbols / diagrams / pictures are used to minimise reliance on text, aiding the end user to accurately identify the product they need.

7.6 All medical products must be supplied with user instructions in English or pictures which negate the need for text. It is mandatory requirement that all medical devices include instructions for use and desirable to have a machine-readable code.

7.7 For re-useable products, (multiple patient use or single patient use) cleaning and/or decontamination instructions and care guidance must be supplied with the product.

7.8 When generic terms are used to define sizes, such as small, medium and large, the size must be accompanied by the exact size range. For example: a medium sized product with dimensions of 100cm x 80cm, should include this information. The sizing information must be provided either on the product, packaging or in the user guide or instructions for use.

7.9 Where applicable, any digital connectivity, software, associated apps and hardware must meet the requirements of the customer alongside provision of required training and ongoing support, this will be defined and agreed locally between the customer and supplier, and may incur extra costs.

Customers may use the NHS Digital Technology Assessment Criteria for health and social care (DTAC) for assessment of the devices and it is recommended that suppliers familiarise themselves with these criteria to meet clinical safety, data protection, technical security, interoperability and usability and accessibility standards. Systems or products which hold or transmit patient records must be compliant with the latest General Data Protection Regulation (GDPR).

8.0 **Training and Clinical Support**

8.1 Suppliers must provide initial product training and clinical support, free of charge to the customer. The frequency of training will be determined by the trust when the product is purchased. Any subsequent training can be agreed with the trust and supplier.

8.2 The supplier must work with the customer to identify training requirements and to create a training plan, where required. Training and clinical support must be delivered in line with the timeline agreed with the customer.

8.3 The training and clinical support should be provided by a company representative with extensive product knowledge or a trainer who holds a clinical or professional qualification in relation to the products available within the Pressure Area Care and Patient Handling portfolio.

8.4 Provision of training certification to support clinical revalidation is essential, CPD accreditation is desirable.

8.5 Training should be available in multiple formats such as but not limited to face-to-face sessions, online videos and webinars.

8.6 It would be desirable for companies (manufacturers and suppliers) to join the Life Science Industry National Credentialing Register at the appropriate level for all staff entering hospitals, to be confirmed directly with organisations. Further guidance can be found on the Life Science Industry website at https://lifescienceindustry.co.uk/

8.7 **Enhanced Education and Training -** Suppliers awarded may offer a service where an equipment audit is conducted and subsequent training or education (aside of standard product training) may be provided to supplement existing trust education programs e.g. additional manual handling training or condition awareness training such as pressure ulcer prevention training. These would be determined with the trust through mutual agreement and may incur additional costs.

9.0 **Customer Service**

9.1 It is expected that the supplier provides customer service to deal with customer queries via email and telephone. The customer service support must be available Monday – Friday from 9am to 5pm.

9.2 Suppliers providing products must provide telephone and email Technical support alongside the customer service support to respond to any Technical support queries. Technical support must be available Monday – Friday from 9 am – 5pm. The supplier must provide and emergency contact for out of hours cover.

Specific Product Area Requirements

Products are grouped and divided into 4 lots based on evaluation weighting. There are sublots which contain categories according to product function and type.

Following award suppliers will be required to fill in feature capture forms/equivalency matrices for their products for technical information such as but not limited to safe working load, maximum user weight, minimum and maximum height adjustability, dimensions etc.

Definitions –

- **Single patient use** – the product can be used multiple times with the same patient.
- **Reusable** – The product can be used multiple times, by different individuals. The product must be decontaminated in line with manufacturer's instructions before it is used by another individual.

Lot 1.1 Beds, cots and accessories

The scope of this sublot includes, Beds, Cots and Accessories, used in acute hospitals, mental health and community settings. The table below provides greater detail of the products included

Community Beds	Adult community bed	Standard Profile	An electric profiling bed designed for Adult use in a Nursing, Care Home and Community environment, typically folding or breaking down for transportation. Low Profile mattress platform must go lower than 320mm from the floor at its lowest position.
		Low Profile	
	Plus size community bed	Standard Profile	An electric profiling bed designed for Adult of plus size (height, width and/or weight) for use in a Nursing, Care Home and Community environment, typically folding or breaking down for transportation. Low Profile mattress platform must go lower than 320mm from the floor at its lowest position.
		Low Profile	
	Paediatric community bed	Standard Profile	An electric profiling bed designed for Paediatric use in a Nursing, Care Home and Community environment, typically folding for transportation or breaking down. Low Profile mattress platform must go lower than 320mm from the floor at its lowest position.
		Low Profile	

Acute Beds	Adult Acute Bed	Standard Profile	An electric profiling bed designed for Adult use in an acute hospital environment. Low Profile mattress platform must go lower than 320mm from the floor at its lowest position.
		Low Profile	
	Plus size acute bed only	Standard Profile	An electric profiling bed designed for Adult of plus size (height, width and/or weight) for use in an acute hospital environment. Low Profile mattress platform must go lower than 320mm from the floor at its lowest position.
		Low Profile	
	Paediatric acute bed only	Standard Profile	An electric profiling bed designed for Paediatric use in an acute hospital setting. Low Profile mattress platform must go lower than 320mm from the floor at its lowest position.
		Low Profile	
	Maternity / Birthing Beds		An electric bed designed for use during maternity care and child birth.
Cots and Cribs	Community cot	Fixed Height	A small bed with sides suitable for babies or infants to be cared for at home or hospital setting.
		Adjustable Height	
	Acute cot	Fixed Height	
		Adjustable Height	
	Baby Crib	Fixed Height	
		Adjustable Height	
Bed and Cot Accessories and Spares	IV Pole		Accessories which can be added to the bed or replacement parts to prolong the life of the bed, examples are (but not limited to) side rails, head end, bottom end, IV pole, cylinder attachment, spare wheels

All products will have the minimum specification of:

- Height adjustable (Not cots or cribs),
- Profiling (Not maternity beds, cots or cribs),
- Electronics IPX 4
- Protective mechanism to prevent damage to the wall socket without removing the plug e.g. quick release plug/curly cable (desirable feature for community beds)
- Compatible with static, hybrid and dynamic mattresses,
- Full technical specification including cleaning guidelines,

Additional standards required by products awarded to this sublot (where applicable)	
BS EN 60601-1-11:2015+A1:2021	Medical electrical equipment — General requirements for basic safety and essential performance. Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
BS EN 60601-2-52:2010+A1:2015	Medical electrical equipment. Requirements for basic safety and essential performance of medical beds.
BS EN 60529: 1992+A2:2013	Degrees of protection provided by enclosures (IP Code).
BS ISO 22882:2016	Castors and wheels. Requirements for castors for hospital beds.
BS 1694:1990	Specification for hospital ward cots for children.
EN 716-2:2017	Furniture — Children's cots and folding cots for domestic use —Part 2: Test methods
BS EN 50637:2017	Medical electrical equipment. Requirements for the basic safety and essential performance of medical beds for children (and others of small stature).
The Non-Automatic Weighing Instruments (NAWI) Regulations 2016.	Demonstrating compliance with the regulation for all products which contain a weighing instrument.

Lot 1.2 Integrated Bed and Mattress Systems

The scope of this sublot includes bed frames which have integrated mattress as standard.
The table below provides high level detail of the products included:

Integrated Bed and Mattress Systems	Cot	Bed Frames which come with an integrated mattress as standard
	Paediatric	
	Adult	
	Plus Size	
	Maternity/Birthing	
Integrated Bed and Mattress System Accessories	IV Pole	Accessories which can be added to the bed or replacement parts to prolong the life of the bed, examples are (but not limited to) side rails, head end, bottom end, IV pole, cylinder attachment, spare wheels
	Oxygen Cylinder Holder	
	Power Cord/Adaptor	
	Replacement Controller	
	Side Rail Pads	
	Spare Wheels/Casters	
	Leg supports/stirrups	
	Other	

All products will have the minimum specification of:

- Height adjustable
- Profiling
- Electronics IPX 4
- Protective mechanism to prevent damage to the wall socket without removing the plug e.g. quick release plug/curly cable),
- Full technical specification including cleaning guidelines

Mattresses should meet the specification set out in 1.3

Additional standards required by products awarded to this sublot (where applicable)	
BS EN 60601-1-11:2015+A1:2021	Medical electrical equipment — General requirements for basic safety and essential performance. Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
BS EN 60601-2-52:2010+A1:2015	Medical electrical equipment. Requirements for basic safety and essential performance of medical beds.

Additional standards required by products awarded to this sublot (where applicable)	
BS EN 60529: 1992+A2:2013	Degrees of protection provided by enclosures (IP Code).
BS ISO 22882:2016	Castors and wheels. Requirements for castors for hospital beds.
BS 7068:1989	Specification for alternating pressure air mattresses or equivalent
BS ISO 20342-1:2022	Assistive products for tissue integrity when lying down — General requirements) or equivalent
BS EN 50637:2017	Medical electrical equipment. Requirements for the basic safety and essential performance of medical beds for children (and others of small stature).
The Non-Automatic Weighing Instruments (NAWI) Regulations 2016.	Demonstrating compliance with the regulation for all products which contain a weighing instrument.

Lot 1.3 Mattresses and Accessories

The scope of this sublot includes Mattresses and Accessories, suitable for beds and cots in the acute and community setting, including adults, plus size and paediatric patient requirements.

The table below provides high level detail of the products included:

Static Mattresses	Cot and Crib Bed	Foam	A mattress designed and tested to reduce pressure with a cover which allows for decontamination. It has no electricity supply. Can be made of foam, memory foam, air cells, gel or a combination of these materials. Must be a minimum of Crib 5, unless the product is for use in the Mental Health Setting, then the minimum requirement must be Crib 7.
		Memory Foam	
		Gel	
		Air cells	
		Combination	
	Paediatric Bed	Foam	
		Memory Foam	
		Gel	
		Air cells	
		Combination	
	Adult Bed	Foam	
		Memory Foam	
		Gel	
		Air cells	
		Combination	
	Plus Size Bed	Foam	
		Memory Foam	
		Gel	
		Air cells	
		Combination	
Dynamic Mattresses	Mattress only	Cot and Crib Bed	Mattress designed to relieve and redistribute pressure and made of cells which can be adjusted using a compatible pump.
		Paediatric Bed	
		Adult Bed	
		Plus Size Bed	
	Mattress and Pump	Cot and Crib Bed	Mattress and compatible pump package. Designed to relieve and redistribute pressure and made of cells which can be adjusted using the compatible pump.
		Paediatric Bed	
		Adult Bed	
		Plus Size Bed	
Hybrid Mattresses	Powered Hybrid Mattress only	Cot and Crib Bed	A mattress designed to relieve and redistribute

		Paediatric Bed	pressure and made of a combination of air cells and foam which can be used in static mode or active mode when used with a compatible pump.
		Adult Bed	
		Plus Size Bed	
	Powered Hybrid Mattress and Pump	Cot and Crib Bed	A mattress designed to relieve and redistribute pressure and made of a combination of air cells and foam which can be used in static mode or active mode when used with a compatible pump.
		Paediatric Bed	
		Adult Bed	
		Plus Size Bed	
Automated Turning Systems	Including Pump		Automated turning system to be placed on top or underneath a mattress.
	Excluding Pump		
Overlays	Mattress	Static	A Pressure reducing surface which sits over an existing mattress or trolley to provide enhanced pressure reducing care
		Dynamic	
	Trolley	Static	
		Dynamic	
Mattress Accessories	Pump		Accessories used to ex tend the life of mattresses such as but not limited to new covers or inserts or to support the care of patients such as lateral turning devices
	Cover		
	Infills		
	Replacement Cells		

All products will have the minimum specification of:

- Products should give clinical teams guidance on the type of patient the product is suitable for.
- Evidence of pressure testing/mapping must be provided on request.
- No sharp edges or areas.
- Covered zips.
- Where not universal, the head and foot end clearly indicated on the product.
- Moisture vapour permeable cover.
- Where a product is not fully welded, zip access on multiple sides to allow for full decontamination.
- The inner lining of the mattress cover must be lighter in colour than the outer cover to show fluid ingress (where products are not fully welded).
- Essential parts available for the stated lifetime of the product.
- All mattresses must be provided with cleaning/decontamination instructions – desirable to adhere to the new BS EN ISO 20342-5:2024

Additional standards required by products awarded to this sublot (where applicable)	
BS EN 60601-1-11:2015+A1:2021	Medical electrical equipment — General requirements for basic safety and essential performance. Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
BS EN 60529: 1992+A2:2013	Degrees of protection provided by enclosures (IP Code).
BS 7068:1989	Specification for alternating pressure air mattresses or equivalent
BS7177: 2008+A1	Crib Source 5 (or alternative equivalent flammability testing)
ISO 20342-1:2022	Assistive products for tissue integrity when lying down — General requirements) or equivalent

Lot 1.4 Hoists, Stand Aids and Accessories

The scope of this sublot includes hoists, stand aids and accessories which are used for lifting and moving a person or facilitate them to a standing position.

The table below provides high level detail of the products included within this sublot:

Mobile Hoists	Electric		A hoist on wheels, designed to move a patient from one surface to another. Can be powered by battery or mains power.
	Manual		A non-powered hoist on wheels, designed to move a patient from one surface to another.
Portable Gantry Hoists	Full System (Hoist and Frame)		A removable frame and electric powered hoist to assist carers in moving patients.
	Hoist Only		
	Frame Only		
Fixed Gantry Hoists	Full System (Hoist and Frame)		An electric powered hoist with a track fixed to the ceiling used to assist carers in the movement of patients.
	Hoist Only		
	Ceiling Track		
Bath hoists			A hoist which has a floor fixation outside of a bath, to lift a person in and out of a bath - Can be manual or battery operated.
Swimming Pool Hoists			A hoist to lift a person to in or out of a swimming pool - may be manual or battery operated.
Standing Aids	Electric		A powered aid to facilitate a user from a seated position to a standing position and back down again.
	Manual		A non-powered aid to facilitate a user from a seated position to a standing position and back down again.
Assisted lifting/ transfer devices and Accessories	Assisted lifting/transfer device		A mobile device which is designed to lift a person who has fallen to the floor or move a person from one surface to another (e.g. lateral transfers) and associated accessories
	Assisted lifting device Accessories	Bag/Carry Case	
		Battery	
		Charger	
		Other	

Air Assisted lifting/ transfer devices and Accessories	Air Assisted lifting cushion/chair	Single Patient Use	A mobile lifting device which when pumped with air lifts a person from the surface they are laid on, to allow safe transfer to a bed or chair and associated accessories
		Reusable	
	Air Assisted transfer mattress/device	Single Patient Use	
		Reusable	
		Cart/Trolley	
	Air Assisted lifting device accessories	Pump	
		Pump Accessory	
		Bag	
		Other	
Hoist Accessories	Stand Aid Sling Reusable		Accessories used with or to repair and prolong the life of the product
	Stand Aid Sling Single Patient Use		
	Standing Aid Walking Sling		
	Spare Battery		
	Replacement Controller/Handset		
	Other		

All products will have the minimum specification of:

- Supplied with instructions for use and/ or user manuals.
- All products used for lifting must clearly display a SWL on the product.
- Where assembly is required have the ability to be assembled without tools or tools supplied with the product to assemble.
- Where scales are included in the product, they must be digital and supplied with details for the frequency of and process for calibration.
- The scales must be compliant with The Non-Automatic Weighing Instruments (NAWI) Regulations 2016
- IPX 4 tested
- The products must be provided with clear instructions for routine cleaning.
- The product must include detailed instructions for routine and preventive maintenance instructions, for the purposes of internal Electro-Biomedical Engineers or external engineers.
- Must have essential parts available for the lifetime of the product.

Additional standards required by products awarded to this sublot (where applicable)	
BS EN 60601-1-11:2015+A1:2021	Medical electrical equipment — General requirements for basic safety and essential performance. Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Additional standards required by products awarded to this sublot (where applicable)	
BS EN 60601-1:2006+A12:2014	Medical electrical equipment. General requirements for basic safety and essential performance
BS EN ISO 10535:2021	Hoists for the transfer of disabled persons. Requirements and test methods.
BS 2099:1989	Specification for castors for hospital equipment
BS EN 60529: 1992+A2:2013	Degrees of protection provided by enclosures (IP Code).

Lot 1.5 Pressure Mapping and Skin Assessment

The scope of this sublot is products and systems which are used for measuring and assessing pressure on a product or skin changes to a patients skin/tissues.

The table below provides high level detail of the products:

Pressure Mapping Systems		Hardware and associated software used to map pressure distribution on products
Skin/Tissue Assessment Systems & Accessories	Skin/Tissue Assessment Device	Hardware, associated software and consumables used in the assessment of a persons skin and tissue integrity
	Skin/Tissue Assessment Accessories	

All products will have the minimum specification of:

- IFU and Full technical specification must be available with all products,
- Be supplied with instructions for use / user guide/manuals.
- Where applicable provide product pressure mapping data, if available, on the customer's request. Including pressure mapping data, which has been produced as a result of assessment conducted by an institution, independent of the supplier or manufacturer.

Additional standards required by products awarded to this sublot (where applicable)	
BS EN 60601-1-11:2015+A1:2021	Medical electrical equipment — General requirements for basic safety and essential performance. Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
BS EN 60529: 1992+A2:2013	Degrees of protection provided by enclosures (IP Code).
ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories
MEDDEV 2.1/5	Medical devices with a measuring function

Lot 1.6 Bathing Equipment and Accessories

Bathing equipment are devices which enable healthcare professionals to assist people to bathe and shower safely and easily.

The table below provides high level detail of the products included:

Shower Trollies	Adult	A height adjustable product that can be used in a shower to wash a person whilst they are in a supine or prone position.
	Plus Size/Bariatric	
	Paediatric	
Changing Trollies	Adult	A height adjustable product that can be used dry and change a person whilst they are in a supine or prone position.
	Plus Size/Bariatric	
	Paediatric	
Bathing Accessories		Products used with or replacement parts to prolong the life of the product.

All products will have the minimum specification of:

- Adjustable height
- Side rails or equivalent to prevent a patient falling
- Minimum IPX 4 rated
- Full technical specification including cleaning guidelines

Additional standards required by products awarded to this sublot (where applicable)	
ISO 20342-1:2022	Assistive products for tissue integrity when lying down — General requirements) or equivalent
BS EN 60601-1-11:2015+A1:2021	Medical electrical equipment — General requirements for basic safety and essential performance. Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
BS EN 60601-1:2006+A12:2014	Medical electrical equipment. General requirements for basic safety and essential performance
BS EN 60529: 1992+A2:2013	Degrees of protection provided by enclosures (IP Code).
BS EN 12182:2012	Assistive products for persons with disability. General requirements & test methods

Lot 1.7 Pressure Reducing and Positioning Aids

The scope of this sublot is for products designed to reduce pressure, offloading areas at risk of pressure damage and support healing to take place as well as aids to position patients and reduce the impact of falls.

The table below provides high level detail of the products included within this sublot:

Heel Offloading Bootees	Reusable Single Patient Use	A Pressure reducing products which offload the heel. Not suitable for weight bearing and cover the foot and lower leg.
Heel Protector	Reusable Single Patient Use	A Pressure reducing products which cup a persons heel, used in a non-weight bearing setting.
Pressure Reducing Pads		Products which can redistribute and reduce pressure, can be used on carious areas of the body such as, but not limited to head, elbows and hands
Falls Protection Mat		Pressure reducing mat, designed to reduce the impact of a patients fall, reducing the likelihood of injury.
Patient Positioning aids		Shaped cushions which can support the positioning of a patient e.g. in proning or side lying.

All products will have the minimum specification of:

- IFU and Full technical specification must be available with all products,
- Be supplied with instructions for use / user guide/manuals.

Where applicable, provide product pressure mapping or pressure index information, if available, on the customer's request. Including pressure mapping data, which has been produced as a result of assessment conducted by an institution, independent of the supplier or manufacturer.

Additional standards required by products awarded to this sublot (where applicable)	
BS7177: 2008+A1	Crib Source 5 (or alternative equivalent flammability testing)
ISO 20342-1:2022	Assistive products for tissue integrity when lying down — General requirements) or equivalent

Lot 1.8 Cushions and Accessories

The scope of this sublot includes cushions for chairs which are used to reduce or redistribute pressure. It excludes cushions specifically designed for wheelchair users or pads for other areas of the body.

The table below provides high level detail of the products included within this sublot:

Static Cushions		Cushions with no active features, designed to reduce pressure when a person is sat down chair.
Hybrid Cushions		Cushions with typically made with foam and air filled cells designed to reduce pressure during sitting, used in conjunction with a pump.
Dynamic Cushions		Cushions with typically made with air filled cells designed to reduce pressure during sitting and used in conjunction with a pump.
Cushion Accessories	Pump	Replacement pump for dynamic and hybrid cushions
	Cover	Replacement cushion covers to prolong the life of the product.

All products will have the minimum specification of:

- Products should give clinical teams guidance on the level of pressure damage risk the surface is suitable for.
- Evidence of pressure testing/mapping must be provided on request.
- No sharp edges or areas.
- Covered zips.
- Moisture vapour permeable cover.
- Where a product is not fully welded, zip access on multiple sides to allow for full decontamination.
- The inner lining of the cushion cover must be lighter in colour than the outer cover to show fluid ingress (where products are not welded).
- Essential parts available for the stated lifetime of the product.
- All cushions must be provided with cleaning/decontamination instructions.

Additional standards required by products awarded to this sublot (where applicable)	
BS EN 60601-1-11:2015+A1:2021	Medical electrical equipment — General requirements for basic safety and essential performance. Collateral Standard: Requirements for medical electrical

Additional standards required by products awarded to this sublot (where applicable)	
	equipment and medical electrical systems used in the home healthcare environment
BS EN 60529: 1992+A2:2013	Degrees of protection provided by enclosures (IP Code).
BS 7068:1989	Specification for alternating pressure air mattresses or equivalent
BS7177: 2008+A1	Crib Source 5 (or alternative equivalent flammability testing)

Lot 1.9 Patient Transfer Equipment

The scope of this sublot includes Aids and accessories used to assist people to move or be moved from one area/surface to another. The products are assistive technologies designed to support people who have difficulty transferring between sitting and standing positions and between seated and sustaining a standing position.

The table below provides high level detail of the products included within this sublot:

Turn Table			An aid to assist the carer to transfer a patient from surface to another using a rotating base and has handles tor the patient to hold on to.
Swivel Cushion			An cushion or pad designed to assist a patient to rotate 90 degrees in a sitting position typically to get out or in of a car.
Sitting Transfer Board			A hard transfer board which is used to bridge a gap and allows the user to sit on and slide across from one surface to another.
Supine Transfer Board	Rigid		A rigid board which is used to transfer a patient laterally in a supine position from one surface to another.
	Folding		
Supine Transfer Sheet	Single Patient Use	With Handles	A sheet which is used to transfer a user laterally in a supine position from one surface to another.
		Without Handles	
	Reusable	With Handles	
		Without Handles	
Transfer equipment accessories			Accessories used with transfer aids such as, but not limited to carry bags and replacement parts.
Handling Belts/ Transfer belts	Reusable/ Washable	Small	Belts used with patients to support carers to help move all or part of patient. Colour coded indicating the size of the product.
		Medium	
		Large	
		Extra Large	
	Single Patient Use	Small	
		Medium	
		Large	
		Extra Large	
		Multi-pack	

All products will have the minimum specification of:

- Supplied with instructions for use and/ or user manuals.
- All products used for lifting must clearly display a SWL on the product.
- All products, which are suitable for cleaning, must be provided with cleaning instructions, which should be provided either on the packaging or instructions for use.
- Must have essential parts available for the lifetime of the product.

Additional standards required by products awarded to this sublot (where applicable)	
BS EN ISO 21856:2022	Assistive products. General requirements and test methods

Lot 1.10 Slings and Accessories

The scope of this sublot is slings and accessories for transferring by lifting and moving a person, used in conjunction with a hoist.

The table below provides high level detail of the products included within this sublot:

High Back Sling	Loop Slings	Single Patient Use	Seated Sling with head support
		Reusable	
	Clip Slings	Single Patient Use	
		Reusable	
Standard Back Sling	Loop Slings	Single Patient Use	Seated Sling without head support
		Reusable	
	Clip Slings	Single Patient Use	
		Reusable	
Hygiene Sling	Loop Slings	Single Patient Use	Seated sling to allow a patient to use the toilet or shower
		Reusable	
	Clip Slings	Single Patient Use	
		Reusable	
Amputee Sling	Loop Slings	Single Patient Use	Seated sling designed specifically to lift a patient who has a single or double leg amputation
		Reusable	
	Clip Slings	Single Patient Use	
		Reusable	
Insitu Sling	Loop Slings	Single Patient Use	Seated sling designed to stay in place when a user is not being lifted.
		Reusable	
	Clip Slings	Single Patient Use	
		Reusable	
Lateral Transfer Sling	Loop Slings	Single Patient Use	A sling designed to move a user in a supine or prone position
		Reusable	
	Clip Slings	Single Patient Use	
		Reusable	

All products will have the minimum specification of:

- All products must be UKCA marked.
- The slings must be supplied with instructions for use including measurement/fitting guidance.
- The sling must have a clear label which states if it is Single Patient Use or Reusable.
- For single patient use products there must be a method for indicating which patient the product belongs to.
- Reusable products to meet the standard hospital laundry guidelines and infection control guidelines HSG(95)18
- Single patient use products should have an indicator to identify if they have been laundered.

Desirable Attributes

- Slings should adhere to the following colour coding for sizes set out in the BS EN ISO 10535:2021 – As part of our engagement there has been feedback from clinical teams and suppliers alike, that having standardised colour coding and similar sizes between suppliers would improve patient safety and be clearer for staff and patients particularly when crossing different healthcare settings. It is anticipated this will become a mandatory feature in subsequent tenders and there will be ongoing engagement throughout the life of the framework.

D.2 Recommendations for colour coding

The colour coding in Table D.1 should be used to indicate the size of a body-support unit.

Table D.1 Size ranges with colour coding applied

Size	Recommendation		
	Colour	CMYK	RGB
XX Small	Violet	30,95,0,0	153,0,153
Extra Small	White	0,0,0,0	255,255,255
Extra Small	Light grey	15,10,10,0	200,200,203
Small	Red	0,75,90,0	255,75,0
Medium	Yellow	0,0,100,0	255,241,0
Large	Green	75,0,65,0	3,175,122
Extra Large	Sky blue	55,0,0,0	77,196,255
XX Large	Orange	0,45,100,0	246,170,0

NOTE 1 Extra small can be white or grey, depending on visibility

NOTE 2 Values given in CMYK is a graphical and digital colour identification made of the colour C: Cyan M: Magenta Y: Yellow K: Keyblack.

NOTE 3 Values given in RGB us composed by the colour R: Red, G: Green, B; Blue.

Additional standards required by products awarded to this sublot (where applicable)	
BS EN ISO 10535:2021	Hoists for the transfer of disabled persons. Requirements and test methods.

Lot 1.11 Slide Sheets

Slide sheets are friction reducing devices that enable the moving and repositioning of patients up and down the bed as well as between surfaces.

The table below provides high level detail of the products included within this sublot:

Flat Slide Sheets Single Sheet	Reusable	<100x100	Handles
			No Handles
		200x100	Handles
			No Handles
		200x140	Handles
			No Handles
	Single Patient Use	<100x100	Handles
			No Handles
		200x100	Handles
			No Handles
		200x140	Handles
			No Handles
	On a Roll	100cm Wide	
		140cm Wide	
Flat Slide Sheets Two Pack	Reusable	<100x100	Handles
			No Handles
		200x100	Handles
			No Handles
		200x140	Handles
			No Handles
	Single Patient Use	<100x100	Handles
			No Handles
		200x100	Handles
			No Handles
		200x140	Handles
			No Handles
Tubular Slide Sheets	Reusable	<100x100	Handles
			No Handles
		200x100	Handles
			No Handles
		200x140	Handles
			No Handles
	Single Patient Use	<100x100	Handles
			No Handles
		200x100	Handles
			No Handles

		200x140	Handles
			No Handles
Insitu Slide Sheets	Reusable	Base Sheet only	Single bed
			Double Bed
		Draw Sheet	Single bed
			Double Bed
		Base and Draw Sheet	Single bed
			Double Bed
	Single Patient Use	Base Sheet only	Single bed
			Double Bed
		Draw Sheet	Single bed
			Double Bed
		Base and Draw Sheet	Single bed
			Double Bed

The definitions for the subcategories of the of slide sheets above are as follows:

- **Single patient use** – the product can be used multiple times with the same patient. The product cannot be laundered.
- **Reusable** – these products can be laundered and wiped clean. The product can be used multiple times, by different individuals. The product must be decontaminated in line with manufacturer's instructions before it is used by another individual.

All products will have the minimum specification of:

- All products must be UKCA marked.
- The slide sheet must have a clear label which states if it is single patient use or reusable.
- For single patient use products there must be a method for indicating which patient the product belongs to.
- Reusable products to meet the standard hospital laundry guidelines and infection control guidelines HSG(95)18
- The cleaning information must include the:
    - The method of cleaning i.e. Machine wash
    - Temperature of wash
    - Temperature of drying
- The product must be latex free.
- Slides Sheets coming in bags should have anti ligature and suffocation prevention features and be made of recycled material.

All slide sheets in section must be provided in the following sizes (width x length in cm) allowing for manufacturing tolerance up to a maximum of 5mm.

- ≤100cm x ≤100cm
- 100cm x 200cm
- 140cm x 200cm
- 100cm x 220cm
- 140cm x 220cm

Desirable Attributes

- Single patient use products should have an indicator to identify if they have been laundered.

Additional standards required by products awarded to this sublot (where applicable)	
ISO 20342-1:2022	Assistive products for tissue integrity when lying down — General requirements) or equivalent

Lot 2 – Managed Services for Beds, mattresses, and associated products

A service offered by a supplier where a contracting authority will have a long-term loan agreement for multiple beds, cots and/or mattresses in a hospital ward or other unit. Products will remain the sole property of the supplier who will provide bed replacement, maintenance and decontamination throughout the life of the agreement.

This is limited to products which are available through this framework agreement.

It is the expectation that participating authorities will establish their own specific service requirements and agree these and service standards with suppliers on an individual needs-based approach.

Services provided will need to adhere to and be consistent with all approved care pathways and models of care relevant to each participating authority.

Services may include, but not limited to:

- Delivery/collection
- Cleaning/decontamination
- Electrical safety testing
- Repair/maintenance
- Clinical/technical support
- Interoperable digital systems (including software and hardware)
- Staffing
- Audit and KPI reporting
- Service log

It is mandatory that the supplier complies with and supplies products in line with MDD or MDR regulations and the specification listed in the above document. A valid certificate must be in place for the duration of the framework agreement.

Lot 3 - Rental and Decontamination

Lot 3 provides for participating authorities to use the framework to facilitate the provision of a Rental service for Products covered under this framework agreement.

Trusts may choose to rent single products or multiple products to meet an unmet need with their existing equipment. Typically, but not limited to treatment of outlying or uncommon clinical cases, or in cases of increased product pressure or where trusts existing products do not support a patients needs. Examples are, admission of a bariatric patient whose weight and size are not covered by a trusts standard bed/mattress, in specialist burns cases or in case of winter pressure surge capacity.

Customers will be able to rent equipment for the period of time required, agreements will be made between the customer and the supplier.

All equipment covered by a rental agreement will remain the property of the Supplier throughout the duration of the rental period.

The Supplier is responsible for any breakdowns, repair, servicing and replacement of the equipment.

Services may include, but not limited to:

- Delivery/collection
- Cleaning/decontamination
- Electrical safety testing
- Repair/maintenance
- Clinical/technical support
- Service log

Products must meet the specification set out in the document above and be managed throughout their lifetime following **MHRA guidance: Managing Medical Devices - Guidance for healthcare and social services organisations**