Pre-Acquisition Questionnaire (PAQ Form)

The purpose of this Form is to provide information to an NHS organisation about a medical device(s) which the NHS organisation has already evaluated & selected to approve acquisition of a device(s) – whether by purchase, exchange, rental, lease, donation or other agreement. (Note: The term 'Device' as used here is as defined in the Medical Devices Regulations 2002 and includes equipment, systems and accessories. In the case of systems the requirements below apply both to the individual constituent Devices and the configured system as a whole). The form must be completed in full.

PART I – General Information

Section A - Product Identification

No.	Question	Manufacturer Response
A1.1	UDI Device Identifier *e.g. GTIN 14-digit format, leading with zero(es) for GTIN-13/GTIN-12*	05060079630411
A1.2	Device Description (GMDN Code & Term):	37001 Patient-height Measure
A1.3	Make:	MARSDEN
A1.4	Model Name:	Marsden HM-250P Portable Height Measure
A1.5	Manufacturer's Product Code:	HM-250P
A1.6	Manufacturer:	Invicta
A1.7	NHS eClass Code:	N/A
A1.8	Place of Manufacture or GLN (Global Location Number):	5060079630008
A1.9	UK Supplier / Distributor Name:	Marsden Weighing Machine Group Ltd
A1.10	UK Responsible Person (for non-UK manufacture):	P. Fletcher-Dyer

Please tick what additional information has been attached to this PAQ:

Declaration/s of Conformity (B1.1.2)	☒	Pre-use quality assurance requirement details (D3.1.2)	☐
UK Approved Body / EU Notified Body letter confirming the validity of certificates (B1.6.2)	☐	User training details (D4.1.2)	☐
MHRA's notice of 'no objection' (B2.1.3)	☐	Technical training details (D4.2.2)	☐
Notification to the MHRA (B2.2.2)	☐	Decontamination / reprocessing training details (D4.3.2)	☐
List of accessories for the device (C1.2.2)	☐	Installation requirements (E1.1.2)	☐
List of compatible accessory suppliers (C1.2.4)	☐	ICT infrastructure requirements E1.2.2)	☐
Safety notice details (C1.9.2)	☐	Acceptance testing protocol (E1.3.1)	☐
Details of hazard/s and their management (C2.1.3)	☐	Test equipment / tooling software for servicing (E3.1.2)	☐
End-of-life waste management details (C3.4)	☐	Decontamination details (E5.1.3)	☐
Device brochure / technical specification (D1.1)	☐	Decontamination equipment & materials (E5.4.2)	☐

User manual or instructions (D1.2)	☐	Special post-processing Device storage requirement details (E5.4.4)	☐
Technical manual (D1.3)	☐	Digital Technology Assessment Criteria form (F1.6)	☐

Section B - Regulatory Compliance

No.	Question		Manufacturer Response
B1- Device Regulatory Compliance			
B1.1.1	Does the Device have a valid UKCA and/or CE-marking for its intended use?		YES
B1.1.2	Attach the relevant Declaration/s of Conformity.		YES
B1.2.1	*Under which legislation has the Device been conformity assessed?*	The UK Medical Devices Regulations 2002	Choose an item.
		EU Medical Devices Regulation	Choose an item.
		EU Medical Device Directive	Choose an item.
		EU Active Implantable Medical Devices Directive	Choose an item.
		EU In-Vitro Diagnostic Medical Devices Regulation	Choose an item.
		EU In-Vitro Diagnostic Medical Devices Directive	Choose an item.
		Other	N/A
B1.2.2	If other, please specify.		N/A
B1.2.3	If a Medical Device, which EU classification?		CLASS Im. Note Classification given for guidance only
B1.2.4	If an In-Vitro Diagnostic Medical Device, which EU category?		N/A
B1.4.1	Has this included UK Approved Body assessment?		N/A
B1.4.2	If yes, provide UK Approved Body identification number and name:		N/A
B1.5.1	Has this included EU Notified Body conformity assessment?		N/A
B1.5.2	If yes, provide EU Notified Body identification number & name:		N/A
B1.6.1	What is the expiry date for the Device's certificate?		5 Years
B1.6.2	If the certificate/s have expired or has an expiry date within the next 12-month period, attach the UK Approved Body/ EU Notified Body's letter confirming the continued validity of certificates		N/A
B2- Non-Marked Devices *(If not CE or UKCA marked)*			
B2.1.1	Is this a Medical Device for 'Clinical Investigation'?		NO
B2.1.2	If YES, quote the MHRA 'no objection' reference number:		N/A
B2.1.3	If YES, attach a copy of the MHRA's notice of 'no objection'.		N/A
B2.2.1	Is this an In-Vitro Diagnostic Medical Device for 'Performance Evaluation'?		N/A
B2.2.2	If YES, attach a copy of notification to the MHRA.		N/A
B3- Custom-Made Devices			
B3.1.1	Is this a 'custom-made' Medical Device?		No
B3.1.2	If YES, name the prescribing Medical Practitioner:		N/A

B4-Other		
B4	If NO to B2.1.1, and to B2.2.1 and to B3.1.1 provide justification of the Device's status *(e.g.: MHRA-approved humanitarian grounds)*	N/A
B5- Quality Management		
B5.1.1	Is the manufacturer currently certified to any management / Quality System Standards?	YES
B5.1.2	If YES, which Standard/s & certification body? (*e.g., EN-ISO-9001, 13485, 14001, etc.)*	ISO 9001:2015

Section C – Product Details

No.	Question	Manufacturer Response
C1- Product Details		
C1.1.1	Are there special storage requirements?	No
C1.1.2	If yes, specify	N/A
C1.2.1	Does the Device have accessories?	No
C1.2.2	If YES, attach details of all accessories encompassed by the PAQ return for the device	N/A
C1.2.3	If YES, does the device offer compatibility with other suppliers' or manufacturers accessories?	N/A
C1.2.4	If YES, attach a list of compatible suppliers for the accessories	N/A
C1.3	Is this Model a subcomponent of a system?	No
C1.3.1	If YES, attach system details	N/A
C1.4	Identify the mobility of the Device:	Easily moved without assistance
C1.5	What is the Device warranty period and what is covered under Warranty?	1 year
C1.6	Is this an implantable Device?	No
C1.7	When was this Model first placed upon the market?	2009
C1.8	Confirm the manufacturer / supplier has a system for notification of Device alerts / upgrades to a named hospital representative.	Confirmed
C1.9.1	List here any manufacturer Field Safety Notices, MHRA Device Safety Information, National Patient Safety Alerts or other form of safety communications that have affected the device.	None
C1.9.2	Attach details including corrective actions, plans and status for all safety communications listed.	N/A
C2- Hazards		
C2.1.1	Does the Device present particular hazards that require special safety management measures? *(e.g.: ionising / non-ionising radiation; contamination / infection; hazardous materials; hazardous mechanical / electrical energy; etc.)*	No
C2.1.2	If YES, specify the nature of the hazard/s.	N/A
C2.1.3	If YES, attach details of the hazard/s and the measures required for their management.	N/A
C3- End of Life Commitment		
C3.1.1	What is the recommended working lifetime **or** number of uses for this Device?	7 years

C3.1.2	If working lifetime is measured in number of uses, how does the Device monitor the number of cycles it has been run for?	N/A
C3.2.1	Is this model likely to be superseded in the next 3 years?	No
C3.3	To what date is manufacturer product support for this Model guaranteed?	10 years post-final unit sale – no current date
C3.3.1	To what date is availability of all parts required to maintain this Model guaranteed?	10 years post-final unit sale – no current date
C3.3.2	To what date is availability of all accessories / consumables guaranteed?	10 years post-final unit sale – no current date
C3.3.3	To what date is the availability of maintenance and repair services guaranteed?	Dependent on Service Level Agreement – contact service@marsdengroup.co.uk to organise
C3.4	Attach details for end-of-life waste management of the Device.	See Device

Section D – Resources & Training

No.	Question	Manufacturer Response
D1- Resources		
D1.1	Provide the URL to the device brochure / technical specification. *If no URL, confirm it is attached to form*	Unit does not require instruction
D1.2	Provide the URL to the User Manual or instructions. *If no URL, confirm it is attached to form*	Unit does not require instruction
D1.3	Provide the URL to the Technical Manual. *If no URL, confirm it is attached to form*	Unit does not require instruction
D1.4	What support resources are available? *(e.g., e-learning, helpdesk, literature, website resources, etc)*	Technical support technical@marsdengroup.co.uk
D2- Loan Devices		
D2.1.1	Is identical loan device normally available in the event of equipment failure or safety recall?	N/A
D2.1.2	If YES, what is the typical delivery time for loan equipment?	N/A
D2.2	Is loan equipment provided free of charge within warranty period?	N/A
D3- Pre-Use Procedures		
D3.1.1	Does the Device require periodic pre-use procedures to be undertaken by users? *(e.g., calibration, qualification, PoCT controls, etc.)*	NO
D3.1.2	If YES, attach details of quality assurance requirements	N/A
D4- Training		
D4.1.1	Is competency-based user training available from the manufacturer or an authorised provider?	Not Required
D4.1.2	If YES, attach details *(details must include amount offered, duration, location, etc. (and costs, if any))*	Not Required
D4.2.1	Is competency-based technical training (test, maintenance, repair) available from the manufacturer or an authorised provider?	Not Required
D4.2.2	If YES, attach details *(details must include amount offered, duration, location, etc. (and costs, if any))*	Not Required

D4.3.1	Is competency-based decontamination / reprocessing training available from the manufacturer or an authorised provider?	Not Required
D4.3.2	If YES, attach details *(details must include amount offered, duration, location, etc. (and costs, if any))*	Not Required
D4.4	Are qualification / competency records of training providers available upon request?	Not Required
D4.5	Is training available for the lifetime of the Device?	Not Required

Section E – Technical Support

No.	Question	Manufacturer Response
E1- Installation		
E1.1.1	Does the Device have installation requirements and / or require ancillary services or other prerequisite arrangements?	No
E1.1.2	If YES, attach detail.	N/A
E1.2.1	Does the Device have ICT/ infrastructure needs (such as Connecting to Image system and PAC/ HL7 connectivity requirements)?	No
E1.2.2	If YES, attach detail.	N/A
E1.3.1	Has a protocol for post-delivery device inspection and acceptance testing been attached?	No
E1.3.2	If NO, attach justification	Not required
E1.3.3.1	If YES, is any test equipment/ tooling required to carry out acceptance testing?	N/A
E1.3.3.2	If YES, attach detail.	N/A
E1.3.4	If YES, is acceptance testing and setup of equipment carried out by the Manufacturer or Authorised Supplier?	N/A
E2- Servicing and Maintenance		
E2.1	Is the device serviceable (as opposed to single-use disposable)?	Dependent on Service Level Agreement – contact service@marsdengroup.co.uk to organise
E2.2.1	Does the manufacturer recommend scheduled testing and/ or preventative maintenance for this device?	Yes
E2.2.2	If YES, what is the recommended test / maintenance interval?	At least Annual. Customer specifies interval
E2.2.3	If NO, attach justification	N/A
E2.3	Who is responsible for servicing / maintenance?	service@marsdengroup.co.uk
E2.4.1	Is there a service centre?	Service is either on-site or at Marsden HQ
E2.4.2	If YES, what support is available? *(e.g. return to base, send out engineer, site-based service)*	Dependent on Service Level Agreement
E2.4.3	If YES, in what country is the service centre located?	Rotherham, UK
E2.4.4	If YES, what is the estimated timescale for faulty equipment repair or replacement (in weeks)?	Dependent on Service Level Agreement

E3- In-House Servicing		
E3.1.1	Does the manufacturer support in-house servicing by providing necessary tools, software and documentation?	No
E3.1.2	If YES, attach details of test equipment / tooling / software required for equipment servicing.	N/A
E3.1.3	If YES, provide technical training details in D4.2.2	N/A
E3.1.4	If YES, can repair instructions be provided (in electronic format)?	N/A
E4- Spare Parts		
E4.1	Are parts, consumable and accessories stocked in the UK?	Yes
E4.2.1	Are spare parts for this device available for purchase?	Yes
E4.2.2	If YES, what are the average lead times for delivery (in weeks)?	4 weeks
E5 – Decontamination		
E5.1.1	What level of Device decontamination is required?	Basic Cleaning
E5.1.2	For multi-component systems identify all applicable levels	N/A
E5.1.3	Provide URL to decontamination details (or attach to form)	Cleaning Instructions
E5.2	For sterilisable Devices, do these instructions meet the requirements of EN-ISO-17664? *NOTE: Decontamination instructions must meet the process parameters for the country they are being supplied for use in*	N/A – not a sterile product
E5.3	Provide guidance on suitable (and non-suitable) cleaning products available in UK?	Cleaning Instructions
E5.4.1	Does the Device require processing / reprocessing before / between uses?	No
E5.4.2	If YES, attach decontamination process requirements for special equipment, tools and materials.	N/A
E5.4.3	If YES, are there any special post-processing Device storage requirements?	N/A
E5.4.4	If YES, attach detail	N/A
E5.5.1	Is there a limit to the number of Device reprocessing cycles?	N/A
E5.5.2	If YES, what is the limit?	N/A

Section F - Data Security

No.	Question	Manufacturer Response
F1- Data Security		
F1.1	Does the Device store or transmit patient information that will require information governance measures?	No
F1.2	Does the Device interface, by wired or wireless connection, with Information technology (IT) equipment or network systems?	No
F1.3	Are patches available to be supplied or applied to meet compliance as per DSPT protocols.	N/A
F1.4	Is the device intended to be used in a patient home connecting to WiFi, mobile data or mobile phone to record and transmit patient information?	No

F1.5	Does the device have the capability for remote support or software updates using a network connection?	N/A
F1.6	All Devices that contain digital technology must be assessed using the Digital Technology Assessment Criteria form in addition to completing this form, even if you are piloting or trialling it. If a developer has multiple products, each one would need to be assessed against the DTAC. You can locate the DTAC form at: https://transform.england.nhs.uk/key-tools-and-info/digital-technology-assessment-criteria-dtac/ Confirm you have attached this form where applicable.	N/A

DECLARATION:
We agree that the NHS organisation will be entitled to rely upon the contents of this Form and its attachments, and that subsequent non-compliance with the statements contained herein will entitle the NHS organisation to seek redress.

Name:	Paul Fletcher-Dyer		
Position:	Group Head of QARA		
Company:	Marsden Weighing Machine Group Ltd.		
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E-mail	sales@marsdengroup.co.uk	**Telephone:**	01709 364296
Website:	www.marsdenweighing.co.uk	**Ownership Detail:**	QARA Owner
Signature: *(Electronic signature acceptable)*			
Date:	08/01/2026		

PART II – Transaction Details

Previous sections in PART I provided general information; this PART II addendum provides details specific to particular transaction/s for the supply of the product and should be completed by the device supplier (e.g. Manufacturer, Authorised Representative or other)

No.	Question	Manufacturer Response
G1.1	On what basis will the product be supplied, (including Devices for clinical investigation / research)?	PURCHASE
For supply by loan or donation, other than Devices for clinical investigation / research		
1.2.1	Is the Supplier on the NHS Supply Chain Master Indemnity Agreement (MIA) Register? *(Note: unregistered Suppliers are advised to register for the MIA Overarching Agreement with the NHSSC)*	YES
F1.2.2	If YES, has a NHS Supply Chain (NHSSC) MIA Call-Off Agreement Form been attached?	NO
F1.2.3	If YES, confirm NHSSC MIA registration number:	NHSE MIA-0003-22
F1.2.4	If NO, attach an Indemnity Insurance Certificate (for local indemnity agreement with the customer).	N/A
F1.3	For supply by loan or donation of Devices for clinical investigation / research, has confirmation of Health Research Authority (HRA) approval, including indemnity arrangements, been attached?	N/A
F1.4.1	Is the particular item to be supplied a pre-used product?	N/A
F1.4.2	If YES, attach the usage and full service history.	N/A
F1.5.1	Are there any outstanding Field Safety Corrective Actions / Field Safety Notices relating to this product?	NO
F1.5.2	If YES, attach the issued Notices / Alerts.	N/A

Name:	Sharon Angell		
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Signature: *(Electronic signature acceptable)*	*SLAngell*		
Date:	08/01/2025		