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*	00853061006302
A1.2	Device Description (GMDN Code & Term):	14745 Respiratory Gas Monitor
A1.3	Make:	Maxtec
A1.4	Model Name:	MaxO2 ME
A1.5	Manufacturer's Product Code:	R230P01-001
A1.6	Manufacturer:	Maxtec
A1.7	NHS eClass Code:	FJA
A1.8	Place of Manufacture or GLN (Global Location Number):	USA
A1.9	UK Supplier/ Distributor Name:	Viamed Ltd.
A1.10	UK Responsible Person (for non-UK manufacture):	Emergo Consulting (UK) Limited

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.		Attached
B1.2.1	Under which legislation has the Device been conformity assessed?	The UK Medical Devices Regulations 2002	Choose an item.
		EU Medical Device Directive	Yes
		EU In-Vitro Diagnostic Medical Devices Directive	Choose an item.
		EU Active Implantable Medical Devices Directive	Choose an item.
		EU Medical Devices Regulation	Yes
		EU In-Vitro Diagnostic Medical Devices Regulation	Choose an item.
		Other	Choose an item.
B1.2.2	If other, please specify.		Click or tap here to enter text.
B1.2.3	If a Medical Device, which EU classification?		Click or tap here to enter text.
B1.2.4	If an In-Vitro Diagnostic Medical Device, which EU category?		Choose an item.
B1.4.1	Has this included UK Approved Body assessment?		No
B1.4.2	If yes, provide UK Approved Body identification number and name:		Click or tap here to enter text.
B1.5.1	Has this included EU Notified Body conformity assessment?		Yes
B1.5.2	If yes, provide EU Notified Body identification number & name:		TÜV SÜD 0123
B1.6.1	What is the expiry date for the Device's certificate?		31/12/2028
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		Choose an item.

B2- Non-Marked Devices *(If not CE or UKCA marked)*

B2.1.1	Is this a Medical Device for 'Clinical Investigation'?		Choose an item.
B2.1.2	If YES, quote the MHRA 'no objection' reference number:		Click or tap here to enter text.
B2.1.3	If YES, attach a copy of the MHRA's notice of 'no objection'.		Choose an item.
B2.2.1	Is this an In-Vitro Diagnostic Medical Device for 'Performance Evaluation'?		Choose an item.
B2.2.2	If YES, attach a copy of notification to the MHRA.		Choose an item.

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:		Click or tap here to enter text.

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)*	Click or tap here to enter text.

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 13485

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	Choose an item.
C1.2.1	Does the Device have accessories?	Yes
C1.2.2	If YES, attach details of all accessories encompassed by the PAQ return for the device	Attached
C1.2.3	If YES, does the device offer compatibility with other suppliers' or manufacturers accessories?	No
C1.2.4	If YES, attach a list of compatible suppliers for the accessories	Choose an item.
C1.3	Is this Model a subcomponent of a system?	No
C1.3.1	If YES, attach system details	Choose an item.
C1.4	Identify the mobility of the Device:	Portable (i.e., it can be carried by a single person)
C1.5	What is the Device warranty period and what is covered under Warranty?	24 months, defects of material and of construction
C1.6	Is this an implantable Device?	No
C1.7	When was this Model first placed upon the market?	2016
C1.8	Confirm the manufacturer / supplier has a system for notification of Device alerts/ upgrades to a named hospital representative.	Yes
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.	No
C1.9.2	Attach details including corrective actions, plans and status for all safety communications listed.	Choose an item.

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.)*	Yes
C2.1.2	If YES, specify the nature of the hazard/s.	Oxygen Sensor
C2.1.3	If YES, attach details of the hazard/s and the measures required for their management.	Attached

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?	Click or tap here to enter text.
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?	2032
C3.3.1	To what date is availability of all parts required to maintain this Model guaranteed?	2032
C3.3.2	To what date is availability of all accessories / consumables guaranteed?	2032
C3.3.3	To what date is the availability of maintenance and repair services guaranteed?	2032
C3.4	Attach details for end-of-life waste management of the Device.	Attached

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*	Attached
D1.2	Provide the URL to the User Manual or instructions. *If no URL, confirm it is attached to form*	Attached
D1.3	Provide the URL to the Technical Manual. *If no URL, confirm it is attached to form*	Attached
D1.4	What support resources are available? *(e.g., e-learning, helpdesk, literature, website resources, etc)*	Helpdesk, user manual

D2- Loan Devices

D2.1.1	Is identical loan device normally available in the event of equipment failure or safety recall?	No
D2.1.2	If YES, what is the typical delivery time for loan equipment?	Click or tap here to enter text.
D2.2	Is loan equipment provided free of charge within warranty period?	Choose an item.

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.)*	Yes
D3.1.2	If YES, attach details of quality assurance requirements	Attached

D4- Training

D4.1.1	Is competency-based user training available from the manufacturer or an authorised provider?	No
D4.1.2	If YES, attach details *(details must include amount offered, duration, location, etc. (and costs, if any))*	Choose an item.
D4.2.1	Is competency-based technical training (test, maintenance, repair) available from the manufacturer or an authorised provider?	No
D4.2.2	If YES, attach details *(details must include amount offered, duration, location, etc. (and costs, if any))*	Choose an item.
D4.3.1	Is competency-based decontamination / reprocessing training available from the manufacturer or an authorised provider?	No
D4.3.2	If YES, attach details *(details must include amount offered, duration, location, etc. (and costs, if any))*	Choose an item.
D4.4	Are qualification / competency records of training providers available upon request?	Yes
D4.5	Is training available for the lifetime of the Device?	No

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.	Choose an item.
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.	Choose an item.
E1.3.1	Has a protocol for post-delivery device inspection and acceptance testing been attached?	Yes
E1.3.2	If NO, attach justification	Choose an item.
E1.3.3.1	If YES, is any test equipment/ tooling required to carry out acceptance testing?	No
E1.3.3.2	If YES, attach detail.	Choose an item.
E1.3.4	If YES, is acceptance testing and setup of equipment carried out by the Manufacturer or Authorised Supplier?	No

E2- Servicing and Maintenance

E2.1	Is the device serviceable (as opposed to single-use disposable)?	Yes
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?	Annually
E2.2.3	If NO, attach justification	Choose an item.
E2.3	Who is responsible for servicing/ maintenance?	Device Owner
E2.4.1	Is there a service centre?	Yes

E2.4.2	If YES, what support is available? *(e.g. return to base, send out engineer, site-based service)*	Return to supplier if required or basic PPM maintenance can be carried out in-house
E2.4.3	If YES, in what country is the service centre located?	United Kingdom
E2.4.4	If YES, what is the estimated timescale for faulty equipment repair or replacement (in weeks)?	< 2 weeks

E3- In-House Servicing

E3.1.1	Does the manufacturer support in-house servicing by providing necessary tools, software and documentation?	Yes
E3.1.2	If YES, attach details of test equipment / tooling / software required for equipment servicing.	Attached
E3.1.3	If YES, provide technical training details in D4.2.2	Not attached
E3.1.4	If YES, can repair instructions be provided (in electronic format)?	Yes

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)?	1 week

E5 – Decontamination

E5.1.1	What level of Device decontamination is required?	Disinfection
E5.1.2	For multi-component systems identify all applicable levels	Click or tap here to enter text.
E5.1.3	Provide URL to decontamination details (or attach to form)	Attached
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*	Choose an item.
E5.3	Provide guidance on suitable (and non-suitable) cleaning products available in UK?	Clinell Wipes or similar equipment wipes. Surface cleaning only.
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.	Choose an item.
E5.4.3	If YES, are there any special post-processing Device storage requirements?	Choose an item.
E5.4.4	If YES, attach detail	Choose an item.
E5.5.1	Is there a limit to the number of Device reprocessing cycles?	No
E5.5.2	If YES, what is the limit?	Click or tap here to enter text.

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.	No
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?	No
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.	No

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.

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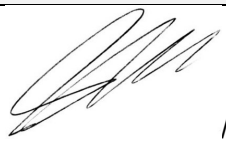
Email	info@viamed.co.uk	**Telephone:**	01535 634542
Website:	www.viamed.co.uk	**Ownership Detail:**	Supplier
Signature: *Electronic signature acceptable*	 / Click or tap here to enter text.		
Date:	01/04/2025		

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	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)*	Choose an item.
F1.2.2	If YES, has a NHS Supply Chain (NHSSC) MIA Call-Off Agreement Form been attached?	Choose an item.
F1.2.3	If YES, confirm NHSSC MIA registration number:	
F1.2.4	If NO, attach an Indemnity Insurance Certificate (for local indemnity agreement with the customer).	Choose an item.
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?	Choose an item.
F1.4.1	Is the particular item to be supplied a pre-used product?	Choose an item.
F1.4.2	If YES, attach the usage and full service history.	Choose an item.
F1.5.1	Are there any outstanding Field Safety Corrective Actions / Field Safety Notices relating to this product?	Choose an item.
F1.5.2	If YES, attach the issued Notices / Alerts.	Choose an item.

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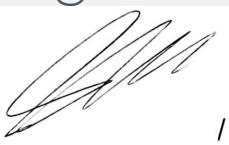
Signature: *Electronic signature acceptable*	 / Click or tap here to enter text.		
Date:	01/04/2025		