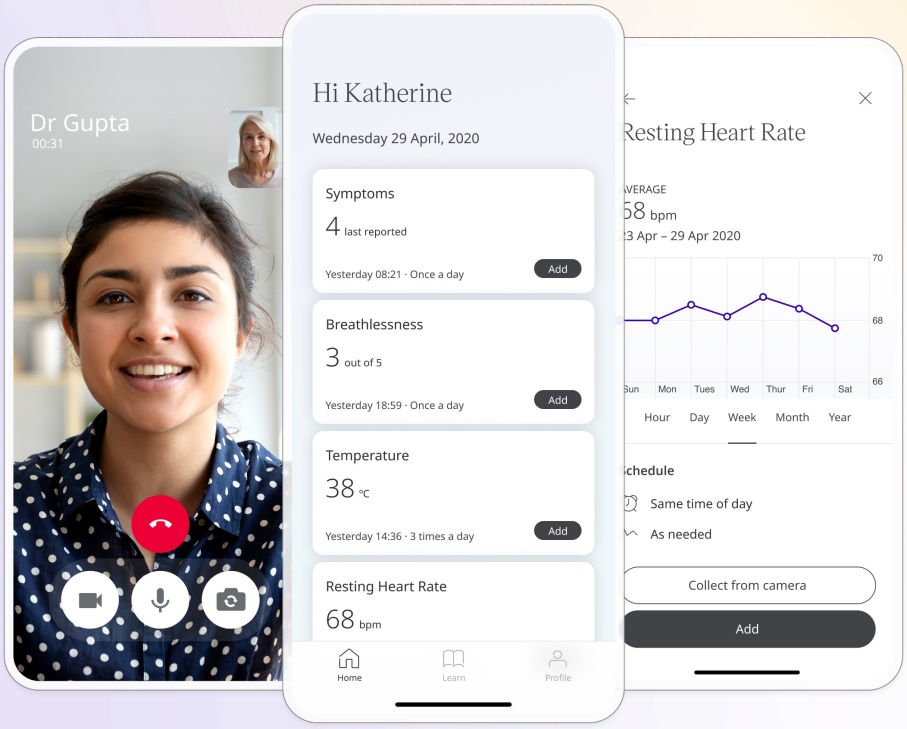
Huma remote patient monitoring / virtual care solution



Service Definition Document

HUMA

HUMA RPM - SERVICE DEFINITION DOCUMENT (G-CLOUD 14)

1. Services

The Huma Remote Patient Monitoring (RPM) / virtual care platform is an EU MDR Class IIb software-as-a-medical device which connects patients and clinical teams, facilitated by real-time visualisation of data, without recourse to face-to-face appointments. Huma's technology has two components:

1. **A smartphone facing Patient App** (available on Android and iOS) to capture health data and guide patients through the digital care plan; and
2. **A web-browser based Clinician Portal** to enable care teams to manage patients remotely and provide proactive care, advice and guidance.

Overview of technology	
Huma solution overview	Huma is the provider of a Software Solution which it makes available to Patients and End Users via a Patient App, Clinician Portal and Platform. The Software Solution facilitates the collection of personal data, including health data, from Patients and their connected devices. The Software Solution is configurable to capture Patient Data for particular medical conditions and Patient cohorts. The Software Solution will support remote patient monitoring (RPM), enabling End Users to triage Patients and manage multiple Patients at once and divert care to the most in need.
Specification	

Patient Data collection modules	The smartphone Patient App includes:
	- Remote patient monitoring of patients at home
	- Care plan detailing the data items (and associated frequency) the Patients are required to provide.
	- Patient Data collection modules to include:
	  - Journal – free text information recorded by the Patient relating to their condition;
	  - Symptoms log – information recorded by the Patient relating to their symptoms;
	  - Questionnaires – bespoke or licensed questionnaires (e.g. EQ-5D-5L)
	  - Weight / BMI – either by Patient manual data entry or via connected third party device
	  - Heart rate – by Patient manual data entry, via connected third party device or smartphone
	  - Blood pressure – either by Patient manual data entry or via connected third party device;
	  - Blood glucose –either by Patient manual data entry or via connected third party device;
	  - Temperature – capture of the Patient's temperature either by Patient manual data entry or via connected third party device;
	  - Pulse oximetry – either Patient manual data entry or via connected third party device;
	  - Photos - uploaded and stored by the Patient relating to the Patient's condition;
	  - Documents – upload and share documents between Patients and Care team (End Users)
	  - Steps – capture step count from the Patient's smartphone device or wearable
	  - Learn and education – section for the inclusion of Client provided educational content and information for Patients to support, for example, self-management support
	  - Other Data collection modules as required by the Client for the Project and as available within the Software Solution (e.g. ECG, Peak Flow).

	Other Patient Data that can be captured includes: - Forename, surname, date of birth, gender, mobile telephone number, e-mail address and NHS number. The Clinician Portal includes: - Patient prioritisation based on the values of the submitted vital signs data; - Telemedicine capabilities allowing the care team (End Users) to video call the Patients; - Messaging capabilities - Care team (End User) notes and detailed Patient profile; - Data export capability in JSON and CSV formats; - Ability to onboard and offboard Patients from the Clinician Portal.
Patient Consent	Patients give consent to share their data with their care team to access the Huma Patient App. Huma has an in-built consent module which provides clear information to patients so they can make an informed decision on their data.
Clinician roles	Care teams can review and monitor patients using the web-browser clinician portal. The platform has Rules Based Access Controls to limit access to patient information in line with Trust policies / procedures.
Supported platforms and browsers	The Clinician Portal is accessible from any device via standard internet access and is compatible with the following web-browsers (most recent version and one previous version of each web-browser are supported): Chrome, Firefox, Safari, Opera, Electron and Microsoft Edge. The Patient App is available on Android and iOS smartphones (device agnostic). The Huma Patient App is compatible with iOS 13 or above, and Android minimum 6 and maximum Android 12. (6.0). The Software Solution language is English (UK).
Services	
Launch Preparations	Huma will provide preparatory services to configure the Software Solution for the Project in accordance with the Specification. In addition, Huma will provide End User training on the Software Solution on a train-the-trainer basis, and the supporting documentation to enable End Users to onboard Patients. On completion of the Launch Preparations, Huma will make the Software Solution available for access by End Users.
Deployment and Implementation Services	Huma will provide clinical / deployment specialists to help co-design pathways, develop standard operating procedures and support implementation. This team will work alongside Client clinical and operational staff throughout the Project and provide ongoing support with regular touchpoints to ensure End Users and Patients are engaged and the Project is achieving expected benefits and outcomes.
Software Services	Huma will provide the Software Solution for the Project (as configured during the Launch Preparations in accordance with the Specification) for use by Patients and End Users during the Subscription Term. We provide full maintenance of the Software Solution throughout the lifetime of the contract.

Support Services	Huma will solely provide technical Support Services for Patients and End Users via the Software Solution and via support@huma.com during normal business hours. Huma will not be responsible for any Adverse Events reporting or any clinical or medical support and assistance to Patients and End Users. Huma will actively monitor the Patient App usage and will provide the Client with updates on Patient App registrations and Patient App module usage.
Regulatory, Interoperability and Information Governance	
Accreditations	Huma has the following credentials: - EU MDR Class IIb certification - DTAC Approved - FHIR HL7 v2 integration capabilities (REST API) with SNOMED CT coding - NHS Data Security and Protection Toolkit certification (YGMA8), 22/23 Standards - Information Commissioner registration (ZA078203) - NHS approved Data Protection Impact Assessment (DPIA) collateral - CyberEssentials and CyberEssentials+ certified - ISO27001 Information Security Management System Certified - ISO13485 Certified Quality Management System