Doccla RPM

v2.123.0

Doccla RPM
Patient App - User Manual

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Introduction

This user manual has been written for patients who must use Doccla RPM app. The user manual has been written in a way to be thorough and understandable for patients. No prior teaching or workshop participation is necessary to understand it.

Your health

⚠ Always be mindful of your own well being and health. If you experience any new symptoms or unexpected deterioration of existing symptoms you should seek medical attention outside the use of this app. You should also contact a healthcare professional if you are unsure about your symptoms, if the app does not provide expected information, or if you are unable to use the app as intended.

Do not rely solely on this app for medical decisions.

A printed copy of this user manual can be requested free of charge by contacting Doccla UK at support@doccla.com

Intended purpose

Doccla Remote Patient Monitoring (RPM) is software intended for use in the remote monitoring of clinically stable chronic or post-operative conditions where the responsible healthcare professional has determined that intermittent remote monitoring is clinically appropriate and safe, with no risk of rapid or serious deterioration in adult and paediatric patients (≥1 month old) for whom intermittent remote monitoring is considered clinically appropriate and safe by the responsible healthcare professional.

This software is intended to be used by qualified healthcare professionals in non-clinical and low-acuity clinical environments, including patient homes, community care settings, rehabilitation facilities, nursing homes, and outpatient follow-up contexts.

This medical device software is contraindicated for patients who are clinically unstable, require real-time physiological monitoring, are at risk of serious or rapid deterioration, or are unsuitable for remote monitoring due to functional, cognitive, or environmental limitations.

This medical device software uses measurements obtained from compatible third-party medical devices, manual entry or questionnaires, spanning chronic disease management, post-operative care, and specialist clinical pathways in order to produce visualisations of patient data, trend displays, and alerts triggered by deviations from healthcare-professional-defined thresholds.

These outputs are intended to support clinical review, prioritisation, and follow-up actions by qualified healthcare professionals within existing clinical workflows, and to inform assessment of patient status. The outputs do not provide diagnosis, prognosis, or therapeutic recommendations and do not replace clinical judgement.

Medical indications

Doccla RPM is indicated to support the remote monitoring in the following categories of measurement types (“Measurement types in scope” section below) and clinical areas (“Clinical areas in scope” section below), either through compatible third party medical devices, manual entry or questionnaires.

Measurement types in scope

Measurement Category	**Specific Parameters**	**Primary Clinical Area(s)**
Vital signs	Blood pressure, pulse/heart rate, SpO2, respiratory rate, temperature, consciousness (AVPU)	All clinical areas (see “Clinical areas in scope” section below)
Composite early warning scores	Calculated from vital sign components, e.g. NEWS2	All clinical areas (see “Clinical areas in scope” section below)
Respiratory function	Peak flow, SpO2, FEV1, FEV6, FEV1/FEV6 ratio, FEF25-75, respiratory rate, COPD prediction score, oxygen therapy hours	Respiratory
Cardiac monitoring	ECG, pulse, LVAD parameters (pump flow, speed, power, pulse index)	Cardiology
Glycaemic monitoring	Blood glucose (mmol/L and mg/dL), blood glucose weekly average	Diabetes
Body composition & weight	Weight (kg/lb), body cell mass, fat mass, phase angle, height, BMI (derived)	Heart failure, frailty, diabetes
Activity & rehabilitation	Daily steps, daily steps weekly average, sit-to-stand test, Borg rating, VAS pain score	Frailty, respiratory, cardiology
Urinalysis	Urine blood, leukocytes, glucose, nitrite, combination dipstick, volume	Renal, specialist
Obstetrics / maternal	FeMOM ECG, FeMOM CTG, FeMOM short-term variability, FeMOM baseline, oxygen therapy, maternity BP	Obstetrics
Renal / dialysis	Peritoneal dialysis, inflow bag colour/volume, outflow bag volume, ultrafiltration volume	Renal
Haematology / biochemistry	Haemoglobin, CRP (manual entry)	Specialist
Subjective patient-reported	Multiple choice, integer/decimal scales, yes/no, free text (PROMs/symptom questionnaires)	All clinical areas (see “Clinical areas in scope” section below)

Clinical areas in scope

Clinical Area	Representative Pathway Types
Cardiology	Heart failure (optimisation, HFpEF, HFrEF, telehealth), LVAD, atrial fibrillation, arrhythmia, post-ablation, post-PCI, TIA/stroke, palpitation, community cardiology
Respiratory	COPD (including COPD prediction, early supported discharge, proactive monitoring), asthma, ARI, COVID-19, pneumothorax, pulmonary rehab, oxygen therapy, paediatric bronchiolitis, respiratory general
Frailty	General frailty, care home, frailty with/without observations, frailty falls, proactive frailty
Diabetes	Type 1/2 blood glucose monitoring, gestational diabetes (diet, HBGM, insulin, metformin), diabetes oncology
Obstetrics	Hypertension screening, blood pressure management, maternity BP, preeclampsia, ROCH blood pressure
General	Step-up/step-down, home monitoring, virtual wards, community matrons, MOA early supported discharge
Palliative	Palliative care, comfort tracker (long/short), IPOS, care home
Renal	UTI, urology, peritoneal dialysis
Specialist	OPAT, paediatrics (general, respiratory, oncology, haematology), orthopaedics, surgery, colorectal, hepatology, infectious diseases, MPox, gynaecology

Main functionalities

Data Collection and Integration: Acquisition of physiological and non-physiological data through compatible third party medical medical devices, manual entry, or connected systems.

Alert Configuration and Generation: Allows healthcare professionals to configure thresholds and/or validated algorithms that generate alerts when patient data deviate from predefined criteria. Where configured, this includes calculation of composite early warning scores from patient-submitted vital signs data using clinician-defined scale settings. Alerts are based solely on clinician-defined inputs and do not interpret, diagnose, or recommend treatment.

Data Visualisation and Trend Analysis: Presentation of historical and current patient data to support clinical interpretation and prioritisation.

Doccla RPM supports intermittent monitoring only and is not intended for real-time monitoring.

Benefit claims

Doccla RPM is intended to deliver clinical benefit by enabling timely clinician response to deviations from clinician-defined thresholds in clinically stable patients, and by providing a monitoring experience

that patients find acceptable and are willing to sustain. The two clinical benefits being formally claimed, and their corresponding outcome parameters, are set out below.

Benefit	Benefit Claim	Mechanism	Outcome Parameters
Benefit 1	Timely clinical review and prioritisation	Doccla RPM generates alerts when measurements from clinically stable patients breach clinician-defined thresholds, enabling timely review and documented follow-up action within existing clinical workflows	Time from threshold breach to first qualifying clinician review. Proportion of alerts with a documented clinical action within a prespecified time window. Time to first documented action.
Benefit 2	Acceptable and usable remote monitoring	Patients are willing and able to engage with remote monitoring over the duration of their care pathway, supporting the completeness and clinical utility of monitoring data	Patient-reported acceptability and usability. Patient engagement and retention. Compliance with expected measurement schedules.

Patient population

Adult and paediatric patients (≥1 month old) for whom intermittent remote monitoring is considered clinically appropriate and safe by the responsible healthcare professional.

Intended users

Doccla RPM is intended to be used by:

- Qualified healthcare professionals: For configuring monitoring parameters, reviewing patient data, and responding to alerts through the clinician portal.
- Patients and caregivers: For entering or transmitting data via the patient or carer mobile application.

All users must receive appropriate training in the safe operation of the software and any connected medical devices.

Contraindications

Doccla RPM is contraindicated for patients who are clinically unstable, require real-time physiological monitoring, are at risk of rapid or serious deterioration, or are unsuitable for remote monitoring due to functional, cognitive, or environmental limitations.

The above contraindications are further detailed below by clinical area, based on results of risk management. Suitability for remote monitoring must be assessed prior to enrolment and reviewed periodically by the responsible healthcare professional.

The contraindications below describe clinical presentations that are outside the intended purpose of Doccla RPM. Where a clinical area is named, the contraindication applies to the acute or unstable presentation of that condition. The diagnosis alone does not determine suitability - the responsible healthcare professional’s assessment of the patient’s current clinical status does.

Clinical Area	Contraindication
Cardiology	Patients in acute cardiac decompensation (e.g., acute decompensated heart failure, haemodynamically unstable arrhythmia, acute MI) requiring inpatient or emergency management.
	Patients requiring real-time cardiac monitoring or surveillance.
	Post-operative cardiac patients prior to clinical stabilisation where condition has not yet been confirmed stable by the responsible clinician.
Respiratory	Acute exacerbations of COPD or asthma requiring inpatient treatment or active titration of unstable oxygen requirements.
	Acute respiratory failure or patients requiring high-flow oxygen therapy where condition cannot be managed remotely.
Frailty	Patients with severe physical frailty who are unable to operate the patient application or connected measurement devices independently, where carer support is not available or cannot be confirmed.
	Patients with significant cognitive impairment or severe mental health conditions who are unable to engage with the monitoring process, where carer-assisted use has been assessed as insufficient.
	Patients assessed as high risk for rapid deterioration associated with falls or acute frailty episodes, where the intermittent monitoring cadence of Doccla RPM is insufficient to detect deterioration in time.
Diabetes	Patients with poorly controlled Type 1 diabetes requiring continuous or near-continuous glucose monitoring integrated with insulin delivery (e.g., closed-loop systems).
	Diabetic ketoacidosis (DKA) or hyperosmolar hyperglycaemic state (HHS) - acute conditions requiring immediate clinical intervention.

Clinical Area	Contraindication
	Patients with gestational diabetes where the rapidity of physiological change in glycaemic status and insulin sensitivity requires direct, continuous clinical assessment at the point of care.
Obstetrics	Hypertensive crisis requiring emergency assessment.
	Pre-eclampsia with severe features (e.g., severe-range blood pressures, symptoms of end-organ involvement) requiring inpatient management.
	Patients where blood pressure variability or instability is such that intermittent readings cannot provide a clinically safe picture of the patient’s status.
General	Patients requiring monitoring at a frequency or acuity level that exceeds Doccla RPM’s intermittent monitoring capability.
	Patients without access to a compatible smartphone or tablet, or without sufficient and reliable internet connectivity, where this cannot be resolved at onboarding and neither manual data entry nor carer-assisted data submission has been assessed as a clinically acceptable alternative.
	Patients who are unable or unwilling to use Doccla-supported measurement devices, and for whom manual data entry is not a clinically acceptable alternative.
	Patients who cannot meaningfully consent to remote monitoring, including understanding the non-emergency nature of the service and associated data collection.
Palliative	Patients in the terminal phase of illness where remote monitoring has not been specifically agreed with the patient, their family, and the clinical team as consistent with their goals of care.
	Patients for whom alert-based threshold monitoring is not aligned with their agreed care plan (e.g., where a do-not-escalate decision is in place but thresholds have not been adjusted accordingly).
Renal	Patients with acute kidney injury (AKI) or rapidly deteriorating renal function requiring frequent in-person clinical review.
	Patients undergoing acute or urgent-start peritoneal dialysis where fluid balance and electrolyte management requires more frequent clinical input than intermittent remote monitoring can support.
Specialist	Paediatric patients under 1 month of age (minimum age for intended use).
	Post-operative surgical or orthopaedic patients in the immediate post-operative period prior to clinical stabilisation, where wound status or acute complications require in-person assessment.

Clinical Area	Contraindication
	Patients on OPAT (outpatient parenteral antibiotic therapy) or infectious disease pathways where systemic infection may deteriorate rapidly and requires a monitoring cadence beyond Doccla RPM's intermittent model.
	Oncology and haematology patients undergoing active treatment where the treatment protocol or current clinical status creates a risk of acute life-threatening complications requiring inpatient management

Terms and Definitions

Term / Abbreviation	Definition
AKI	Acute kidney injury
ARI	Acute respiratory infection
AVPU	Alert, Voice, Pain, Unresponsive - a scale used to assess level of consciousness
BMI	Body mass index
BP	Blood pressure
COPD	Chronic obstructive pulmonary disease
CRP	C-reactive protein - a biochemical marker of inflammation
CTG	Cardiotocography - monitoring of fetal heart rate and uterine contractions
DKA	Diabetic ketoacidosis
ECG	Electrocardiogram
FEF25-75	Forced expiratory flow between 25% and 75% of forced vital capacity
FeMOM	Fetal and Maternal Outpatient Monitoring - a proprietary obstetric monitoring device
FEV1	Forced expiratory volume in one second
FEV6	Forced expiratory volume in six seconds
FEV1/FEV6	Ratio of FEV1 to FEV6, used as a surrogate for FEV1/FVC in spirometry
FVC	Forced vital capacity
HBGM	Home blood glucose monitoring
HFpEF	Heart failure with preserved ejection fraction
HFrEF	Heart failure with reduced ejection fraction
HHS	Hyperosmolar hyperglycaemic state
HCP	Healthcare professional
IPOS	Integrated Palliative care Outcome Scale

Term / Abbreviation	Definition
LVAD	Left ventricular assist device
MDR	EU Medical Device Regulation 2017/745
MOA	Medicine for Older Adults
NEWS2	National Early Warning Score 2 - a standardised clinical scoring system for detecting patient deterioration based on vital signs
OPAT	Outpatient parenteral antibiotic therapy
PCI	Percutaneous coronary intervention
PROMs	Patient-reported outcome measures
ROCH	Remote optimisation of chronic hypertension
RPM	Remote patient monitoring
SaMD	Software as a Medical Device
SpO2	Peripheral oxygen saturation, measured by pulse oximetry
TIA	Transient ischaemic attack
UTI	Urinary tract infection
VAS	Visual analogue scale
WCAG	Web Content Accessibility Guidelines

Warnings and Precautions

Warnings ⚠

- Doccla RPM must not be used as a substitute for emergency medical services. If a patient's condition deteriorates acutely or requires immediate clinical intervention, contact emergency services without delay.
- Doccla RPM supports intermittent monitoring only. It must not be used for real-time monitoring of patient status. Alerts are threshold-based and do not guarantee detection of all clinically significant changes.
- Do not attempt to modify, reverse-engineer, or alter any component of the Doccla RPM software. Unauthorised modification may compromise the safety and performance of the device and renders any CE marking invalid.
- Doccla RPM must only be accessed using login credentials assigned to the individual user. Credentials must not be shared with or disclosed to any other person

Precautions

- Ensure that Bluetooth is enabled on the patient’s device during the monitoring period. Where Bluetooth connectivity cannot be established, manual data entry or carer-assisted data submission should be considered as alternatives. Patients and carers must be instructed on all available data submission methods at onboarding.
- All users must receive appropriate training before using Doccla RPM. Clinicians must be trained by a qualified representative or a colleague who has completed such training. Patients and carers must be onboarded by a trained member of the clinical or support team.
- Only measurement devices listed as compatible with Doccla RPM must be used for automated data capture. Use of unsupported devices may result in data not being received or being incorrectly parsed. Where automated capture is not possible, manual data entry must be assessed for clinical acceptability.
- Patients and carers must be clearly informed at onboarding that Doccla RPM is a monitoring support tool and is not an emergency service. Patients must understand that the absence of an alert does not confirm that their condition is stable or that no clinical action is required.
- Endpoint devices used to access Doccla RPM - including clinician workstations, patient smartphones, and carer devices - must be maintained with current operating system updates and up-to-date endpoint security software.

Telemedicine platform Doccla RPM

In Doccla RPM you will be using a mobile device (tablet or phone) along with an optional set of medical measurement devices: The combination of mobile device + measurement device will be referred to as an Doccla RPM kit in this user manual.

Supported measurement

The Doccla RPM app supports manual input of measurements as well as automatic input of measurements using Bluetooth enabled devices. The following set of devices are all supported by Doccla RPM:

Bluetooth integrated devices

Device type	Manufacturer	Model name	Device Image
Activity Tracker	Beurer	AS80	

Device type	Manufacturer	Model name	Device Image
Blood pressure monitor	A&D	UA-651BLE	
Blood pressure monitor	A&D	UA-656BLE	
Blood pressure monitor	TeleRPM	BB2284-AE01	
ECG	AliveCor	KardiaMobile6L	
Multi-Vital ECG Sensor	Vivalink	VV350	
Multi-Vital Bracelet	Corsano	CardioWatch 287-2B	
Oximeter	Masimo	MightySat Rx	
Oximeter	Nonin	3150BLE	

Device type	Manufacturer	Model name	Device Image
Oximeter	Nonin	Onyx 3230	
Oximeter	Kinetik	MD300CI218R	
Peak Flow Meter	Vitalograph	asma-1 BT	
Thermometer	Kinetik	ET-100EB	
Weight scale	A&D	UC-352BLE	
Weight scale	Transtek	Body Scale GBS-2012-B	

Remember to keep Bluetooth switched on

Automatic input of measurements requires that Bluetooth is enabled. Do not turn off Bluetooth. If you turn off Bluetooth measurements can no longer be collected from the devices automatically.

App parts

The following section describes different parts of the Doccla RPM app.

Log on to app

When you open the Doccla RPM app you will be presented with the login screen. Enter your username and password to log in. If you check the “Remember me” checkbox, the app will remember your password and you will not need to enter your username and password again unless you explicitly logout from the app.

Please keep in mind that personally sensitive data is visible through the app. Do not share your username and password with anyone. If using the “Remember me” function, it is important that access to your device is protected by some other means (pin-code, fingerprint reader etc.).

Main menu

From the main menu you can navigate to one of the following submenus by pressing their corresponding button:

- **Start visit:** All questionnaires that can or need to be completed.
- **Messages:** Messages between you and the healthcare professionals.
- **Reviewed:** Acknowledgements of your recent measurements by healthcare professionals.
- **My results:** Tables and graphs of measurement results previously submitted by you.
- **My replies:** Tables of questionnaire replies previously submitted by you.
- **Information:** Links to further relevant material for your condition on the web.
- **Calendar:** Upcoming video conferences between you and a healthcare professional.

Depending on your condition you may not necessarily see all these menu items when logging into the Doccla RPM app.

Press the **logout** button button in the upper right corner to log out of the app.

Menu items that have a highlighted background and a number next to the title indicate that there are questionnaires to be answered or new messages from the clinicians.

Profile menu

Depending on your condition you may not necessarily see the profile menu. You can enter the profile menu by pressing the in the header. This will fold out the profile menu. From the profile menu you can navigate to one of the following sub menus by pressing their corresponding button:

- **Product information** View product information and instructions for use.

- **Change password** Change your own password .
- **Download data** Download a report containing your data.
- **Product information** ⓘ View product information and instructions for use.
- **Change password** Change your own password .
- **Download data** Download a report containing your data.

To close or unfold the profile menu, press ✖.

Change Password

This menu allows you to change your password by entering your current password followed by a new password twice and pressing change.

You can always press the **back** button ← to return to the previous menu.

Download data

This menu allows you to download a PDF report containing information about you such as: profile, messages and questionnaire answers. Press the ‘Download data’ button to download this pdf.

You can always press the **back** button ← to return to the previous menu.

My Results

This menu allows you to see previous submitted results and measurements as tables and graphs (on tablet). Press one of the measurement types in the list to see more details.

You can always press the **back** button ← return to the previous menu.

My Results – Specific measurement

After choosing a measurement type to view in the previous My results menu, you can see a graph (on tablet) and a table of results (both tablet and mobile). You can filter the amount of results shown by pressing on one of the time filters at the top of the menu.

You can always press the **back** button ← to return to the previous menu or the **home** button ⌂ to return to the main menu.

My Replies

This menu allows you to see previous submitted questionnaire replies displayed as tables. Press one of the questionnaire replies in the list to see more details. You can navigate to newer or older questionnaire replies using the **Newer** and **Older** buttons at the bottom of the screen.

You can always press the **back** button ← to return to the previous menu.

My Replies – Specific questionnaire

After choosing a questionnaire in the previous My replies menu, you can see a table with a column for the **Questions** asked and the **Replies** given.

You can always press the **back** button ← to return to the previous menu or the **home** button ⌂ to return to the main menu.

Reviewed

This menu shows you when a healthcare professional has reviewed your most recent results. A list is displayed, an entry for each of your recent results sent in to the healthcare professionals including the date and time at which it has been reviewed.

If there are no results reviewed yet, you will get the message “There are currently no reviewed results to show”.

You can always press the **back** button ←

Messages

This menu shows the messages sent between you and the healthcare professionals. The newest message will be at the bottom of the screen.

At the bottom of the screen in the white input field, you can enter a message for the healthcare professionals.

After writing the message press the paper airplane Send button to send it to the healthcare professionals.

You can always press the **back** button ← to return to the previous menu.

To attach an image to a message, click the button next to the send button. Depending on the mobile device, you can choose to take an image with the device’s camera, or upload an existing one.

After choosing an image, a preview will be shown next to the message.

When a sent message contains an image, a thumbnail will be shown in the conversation. Click to enlarge.

When the picture is enlarged, a **Delete** button appears. Clicking it twice will delete the image permanently. You can only delete your own image.

Once deleted, a gray placeholder will be shown instead of the original image.

Start visit

This menu shows all the questionnaires currently available for you to answer. Press one of the questionnaires in order to start completing it.

You can always press the **back** button ← to

The questionnaires with a highlighted background indicate that these should be answered before the deadline displayed underneath the questionnaire title. If a questionnaire has a visible deadline but has not been marked with a highlighted background yet, that means you should not complete the questionnaire just yet but wait until you get closer to the deadline.

Answer a questionnaire

When answering a questionnaire, you are led through a series of different questions, each either showing a text, a simple input field, a measurement input field or a multiple choice question.

For each question, you navigate to the next by clicking on one of the buttons at the bottom of the screen.

The number of buttons may vary between the different screens, i.e. a **Next** button, a **No** and **Yes** button or a **Skip** and **Next** button.

At the end of a questionnaire you must choose to either send the questionnaire results to the healthcare professionals or omit the results.

When asked to perform a measurement please find the appropriate measurement device and take a measurement.

The medical devices should already have been paired with the tablet via Bluetooth allowing for automatic measurements.

If you are using devices that are not using Bluetooth, you enter the result into the questionnaire answer box.

You can always press the **back** button ← to go back to the previous question to choose a different answer or the **home** button ⌂ to return to the main menu.

Enter the value in the input field and press **Next**. (Consult the help text if needed, shown when clicking on the **?** in the top right corner)

To send the completed questionnaire results to the healthcare professionals, press **Yes**.

An acknowledgment is shown when the completed questionnaire is successfully received.

Information and guidance

This menu shows a list of links to pages, videos or document containing further information that might help you in your treatment.

When clicking such a link a popup is shown ensuring that you are aware that you are leaving the Doccla RPM app and opening the link in the web browser on your mobile device.

Calendar

The menu allows you to view upcoming video conference with a healthcare professional.

Video conference

Your clinician can choose to start a video conference with you. They will call you up on your mobile device, after which you have to accept the call by pressing the **OK** button.

Use the app as a guardian

A patient can have one or more guardians assigned to act on the patients behalf. All guardians have their own username and password, which can be used to log in to the app.

When logged in the guardian user is presented with a menu where the guardian can choose to act on behalf of the patient being assigned to the guardian. Also it is possible for the guardian to change the current password or log out of the app again.

When selecting to act on behalf of the patient, the guardian is redirected to the normal patient main menu, and can perform the same actions as if it was the patient being logged in.

Addendum

Reporting patient incident

Any serious incident that occurred in connection with the use of Doccla RPM must be reported to Doccla UK via support@doccla.com and the competent authority of the Member State where the user and/or patient is established.

Precautions

The information in this document are subject to change without notice.

Legal Notices

Doccla UK declares that the Doccla RPM software application is a medical device and is CE-marked in conformity with Regulation (EU) 2017/745 (MDR). The device complies with the applicable General Safety and Performance Requirements of the MDR. Conformity assessment was carried out by Kiwa Assurance B.V, NB no. 1912.

Manufacturer

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Hammersmith
London W6 7NL
United Kingdom

EC REP

MedEnvoy Global BV
Prinses Margrietplantsoen 33, suite 123
The Hague
2595 AM
Netherlands

Date: 2026-07
End of life: 2028-07

Manufacturer responsibility

The manufacturer is only responsible for the software of Doccla RPM itself and does therefore not take responsibility for the functionality of the measurement devices used, the tablet or other devices that

the Doccla RPM app can communicate with. The manufacturer ensures compliance with the listed Bluetooth devices in this document. No parts of this document may be reproduced or translated without the prior written permission of the manufacturer.

End of life (EOL)

The product’s End of life (EOL) is 2 years after release. After EOL there is no product support. The date for EOL can be found on the product label.

The device (Doccla RPM software) works as an assisting tool and is not a replacement of treatments. It is recommended to avoid performing a measurement with moist or wet hands. A pen or other hardware tool can be used in case of touch screen challenges.