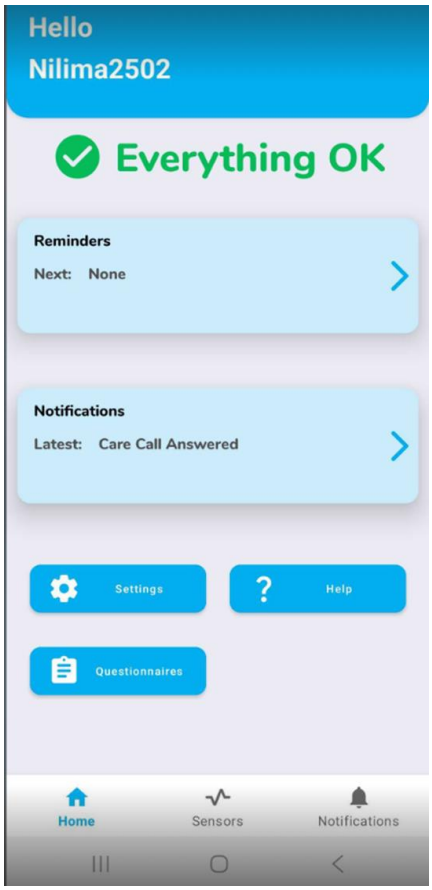
Instructions for Use

BLUEEYE CARE APP



These instructions were put together with great care. If you should still find details here, which do not agree with how the system is handled, we would appreciate it if you let us know so that we can correct the discrepancies as quickly as possible.

Should there be a serious incident or undesirable side effects during handling and use of the product which are not specified in these instructions for use, please report these to us with a detailed description of the incident or side effects. Please use the contact details below for this purpose.

The specifications and figures in this user manual are subject to change due to optical or further technical developments.

Information about the product and the manufacturer

Product Name: BlueEye Care (BlueEye Care App)

A product of

be-on-market GmbH

Lilienstrasse 33, 91244 Reichenschwand, Germany

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Service Provider Details: RedZinc

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Version of these instructions for use - Final build 26.04.0

Version 01 from 23-04-2026

Contents

1 Scope of Delivery

1.1 Standard Scope of Delivery

Part/Trade Name	Description	Part/Order Number
BlueEye Care App	Software for smartphone	BC-APP-001
BlueEye Hotdesk	Web Application	BC-HOT-001
Green Box	Packaging for other accessories	BC-BOX-001
Quick Guides	Link in application and provide print out in each Green Box	BC-QCG-001

Table 1.1: Standard Scope of Delivery

1.2 Product Variants

This device has no variants.

1.3 Accessories

Note: these are not part of the medical device and are not considered as medical device accessories per MDR definition.

Part/Trade Name	Description	Part/Order Number
Charging Cable	USB cable	BC-ACC-001
Smartphone/Mobile Device	Compactible smartphone	BC-ACC-002
Active SIM Card	Compactible in smartphone	BC-ACC-003
Power charging station	Compactible for charging	BC-ACC-004
Phone charging dock	Compactible for smartphone	BC-ACC-005
Pulse Oximeter (Viatom Checkme O_2 (records SpO_2, heart rate; BLE 4.0)	CE marked wearable sensor	BC-ACC-006
Multi-vital Patch (VivaLNK VV330 ECG patch platform (model: VV330 / vv330)	CE marked wearable sensor	BC-ACC-007
BP Monitor (iHealth Neo wireless Blood Pressure Monitor- Model BP5S)	CE marked wearable sensor	BC-ACC-008
Infrared Thermometer (iHealth Thermopro- Model NT13B)	CE marked wearable sensor	BC-ACC-009

Table 1.2: Accessories

1.4 Replacement Parts

Part/Trade Name	Description	Part/Order Number
Sensor Module	Replacement for any sensor	BC-RP-001
Green Box Cover	Replacement of packaging cover	BC-RP-002

Table 1.3: Replacement Parts

1.5 Consumable Parts

Part/Trade Name	Description	Part/Order Number
Sensor pads	Disposable adhesive pads	BC-CONS-001
Cleaning wipes	Wipes for device hygiene	BC-CONS-002

Table 1.4: Consumable Parts

2 Product Description

2.1 Intended Purpose

BlueEye Care (also referred to as BlueEye Virtual Ward or BlueEye) consists of two applications: BlueEye Care Smartphone App or BlueEye Care App, a patient-facing smartphone app that connects to CE-marked wearable sensors and securely transmits physiological data; and BlueEye Hotdesk, a web-based clinician console used by professional healthcare providers to view patient lists and dashboards. The system supports remote observation of patients enrolled in virtual-ward (hospital-at-home) programs by receiving, storing, and displaying vital-sign information and trends for clinical review and care coordination. It does not perform automated clinical interpretation, diagnosis, or therapy, nor does it provide life-critical alarms or monitoring that requires immediate intervention.

Notes:

- The software visualizes and routes data from connected CE-marked sensors and performs only non-interpretive processing (e.g., trends and range/status highlighting). It does not generate automated clinical interpretations, diagnoses, or therapy recommendations, and it does not provide life-critical alarms.
- The software is not an alarm or life-support system and is not intended for use where immediate danger monitoring is required.

2.2 Intended Patient Population

The software may be used with patients of any age, sex, ethnicity, and skin type, as selected by professional healthcare providers for participation in a virtual-ward program and who can comply with sensor wear and basic smartphone usage (with caregiver assistance where needed).

2.3 Medical Indications

BlueEye Virtual Ward is intended to support remote observation of the physiological parameters ECG, SpO2, blood pressure, heart rate, temperature and weight for patients enrolled in a virtual-ward (hospital-at-home) service across a broad range of medical conditions where home monitoring is clinically appropriate at the discretion of a healthcare professional.

Typical use includes cardiopulmonary and general medical conditions where trend visibility and remote check-ins are beneficial (e.g., post-acute follow-up, step-down from hospital to home, chronic disease management...).

Scope statement: BlueEye Care is intended to be used only with CE-marked physiological sensors whose intended purpose (from the sensor IFU) is compatible with remote monitoring use and whose technical characteristics meet the minimum interface and data requirements below. The platform does not modify the sensor's intended purpose and does not claim sensor performance beyond the sensor manufacturer's specifications.

2.3.1 Contraindications

- Not intended for situations requiring continuous, life-critical alarm monitoring or where immediate intervention is expected (e.g., ICU-level monitoring).
- Not intended to be used as the sole basis for diagnosis or therapy decisions.
- Any sensor-specific contraindications (e.g., MRI, pregnancy limits, skin integrity) are governed by the respective sensor IFU and clinical judgement.

2.4 Intended User

Medical use (primary users). The software is intended to be used by professional healthcare providers (e.g., physicians, nurses, allied health professionals, clinical coordinators) who have received site-standard training on the virtual-ward workflow and on using the BlueEye dashboard. Users should have basic computer literacy and access to the organization's clinical network and identity management.

Patient/caregiver interactions (secondary users). Patients and/or caregivers do not perform clinical interpretation; they may interact with the companion mobile app only to wear/operate sensors, confirm prompts, and support data transmission as instructed. Users should have basic smartphone literacy and be able to operate a smartphone. If a patient is unable to operate a smartphone, alternatively a caregiver could operate it for them.

Non-medical activities. Installation, configuration, and IT maintenance are performed by trained personnel under the healthcare organization's IT/security policies.

2.5 Intended Use

Intended place of operation

The patient app is intended to be used in the patient's home (or other non-acute residential setting) with review at a clinical monitoring center. Use in outpatient for onboarding is also acceptable.

The clinician Hotdesk is intended to be used in a clinical monitoring center or the healthcare professional's workplace (e.g., hospital/clinic/GP practice), on a managed workstation or laptop.

Intended use environment.

- Reliable sensor-to-phone connectivity (e.g., Bluetooth) and phone-to-cloud internet connectivity as per site policy.
- Adequate power/charging for the patient smartphone and sensors.
- Suitable light conditions to allow proper screen visualization.
- Environmental conditions suitable for the sensors' IFU; the software itself has no special environmental constraints beyond standard IT requirements.

Intended body site of application

Not applicable to the software. Any body-site contact pertains to the sensors; those requirements are governed by the sensor IFU.

Intended duration and frequency of use.

The software may be used for transient, short-term, or long-term remote monitoring, including continuous use > 30 days, as determined by the responsible clinician and service protocol.

Clinician use - BlueEye Hotdesk

Per-use/session duration (per patient review): typically, 1–10 minutes (may range 1–30 minutes) to open the dashboard, review trends/notes, and document actions.

Shift use (aggregate): the dashboard may remain open during monitoring rounds or clinics, resulting in short-term cumulative use (≈1–4 hours per shift) depending on workload and local practice.

Frequency: configured by the service protocol. As a reference for virtual-ward workflows, clinicians review each enrolled patient ~1-3 times per day (and additionally on demand).

Patient use - BlueEye Care (smartphone app)

Background operation: runs continuously to relay sensor data while the patient is enrolled (long-term).

Interactive tasks (per use):

- Status/battery checks or app prompts: ≈1-5 minutes.
- Questionnaires or symptom checks (when scheduled): ≈5-15 minutes.
- Video consultations (when scheduled): ≈5-30 minutes.

Frequency: as scheduled by the care team (e.g., status checks as needed; questionnaires daily/weekly; video consultations per appointment).

Intended location/type/duration of contact

Not applicable to the software (non-contacting device). Contact classifications (surface/externally communicating/implant; direct/indirect; duration) apply to the sensors and are addressed in their IFU.

Invasiveness

The software is non-invasive. (Any invasive classification applies to the sensors themselves, not to this software.)

Cleaning, disinfection, sterilization

The software is a non-sterile, non-contacting medical device delivered electronically. No cleaning/sterilization applies to the software. Cleaning of hardware (smartphones, hubs, sensors) follows the sensor manufacturer's IFU and local infection-control policies.

Required equipment

- Patient-side: compatible CE-marked sensors, a smartphone running the companion app, and access to mobile/Wi-Fi connectivity.
- Clinician-side: access to the BlueEye dashboard via a supported browser and organizational identity (MFA recommended).
- Optional: video-consultation accessories as per site policy.

Service activities

Routine software maintenance (updates, security patches, certificate renewals, backups, monitoring) is performed by the healthcare organization or its designated IT service under the manufacturer's maintenance plan. Sensors follow manufacturer service/replacement guidance.

Storage and transport

Not applicable, the device is software only.

2.5.1 Precautions for Use

- Use only with supported, CE-marked sensors.
- Ensure user authentication, role-based access, and network security per site policy.
- The software does not generate life-critical alarms and must not be relied upon in situations requiring immediate clinical intervention.
- Clinical decisions should not be based solely on software display; confirm with clinical assessment and source data when needed.

2.5.2 Disclaimers

- The software does not perform diagnosis or therapy and is not an alarm or life-support system.
- Not intended for contexts requiring immediate intervention or continuous life-critical alarm monitoring (e.g., ICU).
- Clinical decisions must not rely solely on the software display; confirm with clinical assessment and source data where appropriate.

- Use only with supported CE-marked sensors and supported software versions in accordance with the sensors' IFU and site policies.
- Performance may be affected by connectivity, configuration, or user/environmental factors; ensure the operational requirements are met.

2.6 Clinical claims

Limitations (apply to all claims):

The software does not perform automated clinical interpretation, diagnosis, or therapy recommendations and does not provide life-critical alarms or monitoring that requires immediate intervention. Clinical decisions remain the responsibility of the healthcare professional.

Direct clinical performance

None

Indirect clinical performance

Remote monitoring/observation

The software enables remote observation of physiological parameters by receiving, storing, and displaying data from CE-marked sensors (for further specifications refer to chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**) for review by professional healthcare providers within a virtual-ward (hospital-at-home) service.

Notifications / escalation (clarification)

If configured by the healthcare provider/service protocol, the software may present review prompts based on predefined thresholds/ranges or missing data states (e.g., out-of-range values or absence of expected measurements) and may support routing/escalation of the review task within the care team workflow (e.g., assignment to a responsible clinician or escalation pathway). These notifications are not life-critical alarms, are not intended to trigger immediate intervention, and do not replace clinical judgement or the sensor manufacturer's alarm functions.

Trend and context visualization

The software presents current and historical values and trends for monitored parameters to support recognition of changes over time and coordination of care. Trend views are derived from the time series of received measurements and are displayed for review within defined time windows (as implemented in the software).

Care-team workflow support

The software supports clinical workflows (e.g., onboarding of a patient to the service, monitoring lists, review notes/case documentation, routing/escalation for review, and discharge documentation) to assist with clinical review and follow-up.

Non-critical review notifications (if configured)

The software may provide configurable notifications/prompts to review data; these are not life-critical alarms and are not intended to trigger immediate clinical intervention.

Customizable pathways

The software may allow configuration of workflow elements to support different virtual-ward service pathways (e.g., step-down care after surgery or proactive disease management), such as configuring patient monitoring schedules, review prompts, and documentation templates, as defined by the healthcare organization. Configuration affects workflow presentation and does not change the underlying measurement provided by connected sensors.

Therapeutic/diagnostic claims

The software does not provide diagnosis, therapy recommendations, or automated clinical decision-making and is not intended as a life-critical alarm system requiring immediate intervention.

Patient benefit

No claims are made that use of the software reduces length of hospital stay, reduces admissions/readmissions, or improves patient wellbeing; such outcomes depend on the clinical service model, pathways, patient selection, and local implementation.

2.6.1 Non-clinical Claims

Interoperability (declared devices)

Works with specified CE-marked sensors and the companion patient app to ingest, validate, and relay data to the clinical dashboard in the declared configurations.

Data integrity & time alignment

Implements timestamping, unit handling, and basic plausibility checks to display sensor values accurately; indicates data currency/connection status.

Usability for intended users

The UI is designed and validated for professional users operating a virtual-ward dashboard; patients/caregivers are not expected to interpret clinical data.

Security controls (per guidance)

Supports user authentication, role-based access control, encrypted transmission/storage as designed, audit logging, and update/patch processes.

Connectivity & deployment options

Supports **smartphone-to-cloud data relay** and **browser-based clinician access** under site IT policies; deployment options may include cloud or on-prem as specified.

Data retention & export

Provides record retention per configuration and export/view functions for clinical documentation (e.g., CSV/PDF/API as declared).

Reminders/questionnaires/video session access (supportive features)

Includes non-diagnostic supportive functions (e.g., reminders, patient questionnaires, video-consult links) to facilitate adherence and communication.

Internationalization/accessibility

Supports multiple languages and accessibility options appropriate for professional users (e.g., keyboard navigation, readable contrast), as declared.

2.7 Functional Description

The software comprises the following functional units/modules:

1. **Patient mobile application (BlueEye Care smartphone app)**: the patient app comprises the following functional modules: sensor connection and data relay (pairing/connection with supported sensors and transmission of measurements to the service), view measurements (patient-facing display of their recorded measurements where enabled), questionnaires (completion of assigned questionnaires), reminders (display and acknowledgement of reminders), and video-consult access (access to video consultation links/sessions when configured by the service)
2. **Ingestion & data services**: secure reception, validation (format/unit/time), storage, and availability to clinician clients. *(Back-end service; no diagnostic algorithms claimed.)*

3. **Clinician web application (BlueEye Hotdesk)**: BlueEye Hotdesk comprises the following functional modules: authentication and user access (login and access to the dashboard), patient onboarding and management (enrolment/onboarding and patient list management), remote patient monitoring dashboard (review of measurements, trends, and questionnaire responses), presentation of prompts (e.g., missing values, out-of-range values, connectivity/data status prompts), notifications (non-life-critical notifications as configured), clinical documentation (notes and care coordination records where enabled), workflow support (including escalation routing and discharge documentation where configured), and video-consult access (clinician access to video consultations when configured).
4. **Support & operations features**: audit logging, update/patch processes, optional remote support to the patient smartphone per site policy.

2.7.1 Labelling

Symbol	Significance
	Identifies the brand and trademark owner of BlueEye Care
	Identifies the product name
	CE label (for Class II/III products, the quarter-digit identification number of the Notified Body involved must be indicated)
	Medical Device Symbol Indicates that the product in question is a medical device
	UDI-Symbol displays a carrier containing information about a unique product identification
	The inspection of the accompanying documents is a binding act

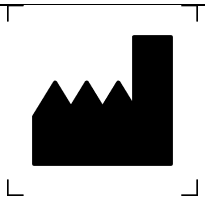
Symbol	Significance
	Warning symbol
	Manufacturer symbol: name and address are in the immediate vicinity of the symbol
	Date of manufacture (Date comes in immediate vicinity of the symbol)
	Do not dispose in trash (the sensors)

Table 2.1: Labelling

3 Safety Instructions

Read these instructions for use carefully. They are part of the device and have to be available at all times. Do only use the device for the intended purpose described in this document (see chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**).

For your own safety as well as for the safety of your patients and according to the requirements of the Medical Device Regulation, please observe the following:

CAUTION: Important safety or performance information or immediate response from operator required.

INFORMATION: Other important information with or without the need of operator response.

3.1 General remarks

	Monitoring does not replace clinical judgement and patients must seek help if symptoms worsen. In emergencies patients should contact their healthcare professional and report events to the manufacturer details mentioned in this document.
	The device is not intended to be used by clinicians as the sole basis for diagnosis or therapy decisions.

	If the patient does not have access to the internet or there is missing data for prolonged periods, they should be excluded from the virtual ward and alternative monitoring methods should be used.
	BlueEye Care (App) is only compatible with the following already-provided CE marked sensors: 1. Pulse Oximeter (Viatom Checkme O_2 (records SpO_2, heart rate; BLE 4.0) 2. Multi-vital Patch (VivaLNK VV330 ECG patch platform (model: VV330 / vv330) 3. BP Monitor (iHealth Neo wireless Blood Pressure Monitor- Model BP5S) 4. Infrared Thermometer (iHealth Thermopro- Model NT13B)
	Please make use of the sensor instructions and training provided.
	Only use the medical device with compatible systems. Refer to Section 4.4 System Compatibility

Table 3.1: General remarks

3.2 Operation of the Device

	Wording used for status indicates transmission/connection state or threshold-based prompt, not diagnosis
	The system has a not life-critical alarm system; not for immediate intervention.
	Patients should make sure to continuously charge the sensors and their phone.
	Patients should answer questionnaires as truly as possible.
	Check internet connectivity and ensure a stable broadband or Wi-Fi connection. If the issue persists for a prolonged period, inform the clinician/support team immediately. The patient should not be monitored using the app until data transmission is restored.
	If the application fails to connect, data do not transmit, or displayed readings appear incorrect, first verify internet connectivity and restore a stable Wi-Fi/broadband connection before continuing monitoring. If the issue persists, the clinician/support team must be informed.

Table 3.2: Operation of the Device

3.3 Side Effects and Contraindications

	BlueEye Care is non-invasive and no side effects are known.
	BlueEye Care is contraindicated for: • Not intended for situations requiring continuous, life-critical alarm monitoring or where immediate intervention is expected (e.g., ICU-level monitoring). • Not intended to be used as the sole basis for diagnosis or therapy decisions. Any sensor-specific contraindications (e.g., MRI, pregnancy limits, skin integrity) are governed by the respective sensor IFU and clinical judgement.

Table 3.3: Side Effects and Contraindications

4 Initial Operation

4.1 Unpacking of the Device

There is no physical unpacking required for the BlueEye Care app, as it is software delivered directly to the mobile device provided.

4.2 Installation

No installation required as the BlueEye Care app is preinstalled by BlueEye team prior to device handover.

4.3 Configuration

This smartphone must have:

- Reliable internet connection.
- Bluetooth connectivity should be on.

Setup

Take out sensors and smartphone from the Green Box and ensure they are fully charged before use. Use the cables and power charging station and phone charging dock supplied in the Green Box for charging devices.

Charging the Smartphone

Figure 1 Smartphone charging dock with cable (L); smartphone kept charging on the dock (R)

To charge the smartphone:

5. Put the smartphone on the charging dock in a way that the 'Type C' charging point inserts into the smartphone charging port. See Figure 1 above.
6. Insert the loose end of the smartphone charging dock into the power adapter.

Note – Please always keep the smartphone on the charging dock when not in use to ensure enough battery for usage.

Charging the Multi-Vital Signs (MVS) Patch

Figure 2 Micro-B charging cable (L); two charging dots in MVS case (M); Green dot marked on MVS patch and charging cable (R)

To charge the MVS patch:

1. Insert the smaller end of the micro-B charging cable (marked with Green dot) into the patch charger (marked with Green dot). See Figure 2 above.
2. Insert the larger end of the micro-B charging cable to the power adapter.
3. Place the MVS patch onto the MVS case.
4. Make sure the two dots on the patch align with the two dots on the case.
5. Close the lid and charge the patch fully before each use. This may take up to 3-4 hours.
6. As shown in the image in the middle (second row), the charging case displays white light when the charging is on and the MVS patch is not fully charged. The case displays green light when the MVS patch is fully charged.

Charging the SpO2 Sensor

Figure 3 Micro-D charging cable (L); SpO2 sensor watch (M); Red dot marked on SpO2 charging cable and watch (R)

To charge the SpO2 Sensor:

1. Insert the smaller end of the micro-D charging cable (marked with Red dot) into the charging port on the SpO2 watch (marked with Red dot). See Figure 3 above.
2. Insert the larger end of the micro-D charging cable to the power adapter.

Charging the Blood Pressure (BP) Sensor

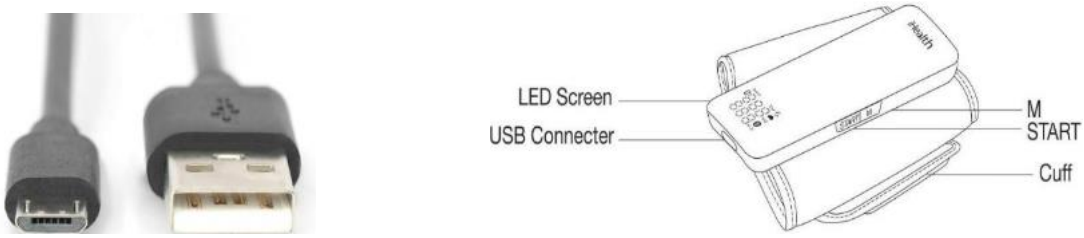


Figure 4 Micro-B charging cable (L); BP Sensor (R)

To charge the Blood Pressure (BP) sensor:

1. Insert the smaller end of the micro-B charging cable (marked with Blue dot) into the 'USB Connector' port in BP Cuff (marked with Blue dot).
2. Insert the larger end of the micro-B charging cable to the power adapter.

Battery Installation for Infrared Thermometer

When the battery power becomes low, the low battery symbol will appear on the display. The thermometer still can be used this time, but the battery should be replaced as soon as possible. If the battery runs out completely the "Lo" will be displayed along with the low battery symbol on the display.

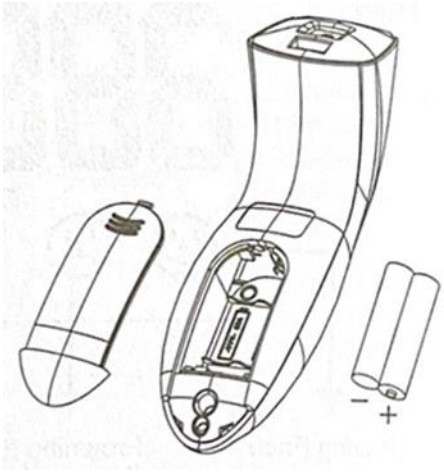


Figure 5 Battery placement for Infrared Temperature Sensor

Replacing the battery:

1. Gently slide the battery cover back. See Figure 5 above.
2. Carefully remove the old batteries and properly discard.
3. Insert new batteries (Two 1.5V alkaline AAA Size) according to the proper polarity.
4. Slide the battery cover back.

Setting Up the Smartphone and Connecting to Wi-Fi

To get started, take the smartphone out of the Green Box and follow the steps below to set it up for use.

Figure 6 Smartphone supplied in Green Box

5. Turn on smartphone by pressing the side key (shown in Figure 6) for a few seconds. Check the battery percentage, charge it if it is not fully charged. You can also restart and power off phone by long pressing the side key.
1. To connect the smartphone to the Wi-Fi available at the patient's home, swipe down the smartphone screen to access quick settings.
2. In quick settings, long press the Wi-Fi button.
3. In the following page, turn on Wi-Fi (if not already turned on) by checking the toggle button shown in the image on the right.
4. The page displays a list of available networks. Identify the patient's Wi-Fi with its name and press on it.
5. In the following page, enter the Wi-Fi password if needed, check auto-reconnect button, and press 'Connect' button at the bottom of the page to connect to the Wi-Fi at the patient's home (Checking auto-reconnect will ensure that smartphone is automatically connected to the same Wi-Fi next time it is restarted/disconnected).

App Update:

To ensure the BlueEye Care App is updated to the latest approved version for safe and effective use we follow the below steps

6. A new, validated version of the BlueEye Care App is released by the BlueEye team.
7. The clinic is notified in advance regarding the scheduled software update.
8. A visit from BlueEye team is arranged with the clinic to perform the update.
9. The authorized person from BlueEye team installs the latest version of the application on designated devices.
10. After installation, functional checks are performed to verify proper operation of the application.
11. Confirmation of successful update is communicated to the clinic staff.

4.4 System Compatibility

Requirements:

- Stable internet connectivity is required for data synchronization and real-time monitoring.

Version Information:

- The application version is displayed within the BlueEye Care app. (On the app homepage click on Settings button, then at the bottom the version number is mentioned)

- Users should ensure they are using the latest released version for optimal performance and security as BlueEye team notify the users about the software update schedules along with the latest version to be released. Refer to Section 'App Update' under 4.3 Configuration

Note:

- It is recommended to use the stable internet connection (Wi-Fi or 4G or 5G)

4.5 Verification Before Usage

1. Clinicians should ensure the BlueEye Care app is pre-installed and opens without errors, and the SIM card is active.
2. Clinicians should ensure that all devices, including the smartphone and sensors, are fully charged before handover to patients.
3. Clinicians should perform a quick functional test to ensure the app shows accurate readings and system alerts. Refer to Section 7. Functional Check.
4. Patients should have stable internet connection for real-time data transfer.
5. The sensors transmit vital signs data to the BlueEye Care app via Bluetooth. Patients should keep the smartphone nearby to maintain continuous data connection. The smartphone and sensors rely on Bluetooth connectivity, which works best within a range of approximately 30 feet or 10 meters.
6. Patients should ensure proper placement of sensors for accurate readings.
7. For video consultations with the clinical team, patient should ensure that they are in a private, quiet environment to avoid interruptions.

4.6 Security Control

- The application shall require unique 7 digit code for patient onboarding authentication. Refer Section 5.1.1.
- All patient data shall be encrypted in transit and at the rest to protect patient information.
- The system shall maintain the patient's activity for traceability like replying to the questionnaire, taking a new reading from the sensors etc.
- The application shall be maintained with regular updates, patches and back up mechanism.
- Access to patient data shall be restricted to authorized clinical team only and confidentiality shall be maintained.

5 Operation

5.1 Making the Product Ready for Operation

1. Patients should ensure the smartphone has a stable internet connection.
2. Patients should ensure the smartphone and all sensors are charged fully.
3. Clinicians should verify that the app screen shows correct connectivity and patient information before starting monitoring.
4. Patients should verify the app screen shows the correct patient information.

5.1.1 Patient Onboarding (Performed by clinicians with the patients):

Patient onboarding is the process of admitting patient to the respective ward and is the first step. For onboarding, the clinician needs to be either in person with the patient or on a phone call with them.

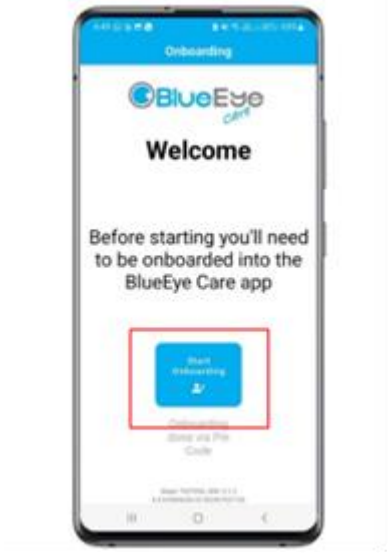
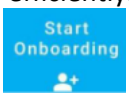


Figure 7 BlueEye Care App onboarding screen

1. Open the BlueEye Care app on the smartphone. The BlueEye Care app is pre-installed.
2. When opening the BlueEye Care app for the first time on your smartphone, the app will request overlay and storage permissions. It is important to grant these permissions to ensure that the BlueEye Care app functions properly and efficiently.
3. For onboarding, press 'Start Onboarding' 

button (see Figure 7 above) on the app's home screen.
4. Follow further instructions from the clinician on their Hotdesk for onboarding. You will be given a 7-digit code to type in and click the 'Register' button.
5. After you press on the 'Register' button, you will be shown a 3-digit code on screen. Give this 3-digit code to the Hotdesk user, which they will enter in BlueEye Hotdesk.
6. After the clinician enters the 3-digit code, you will see an 'Onboarding Successful' message in the BlueEye Care app. See the Figure 8 below.

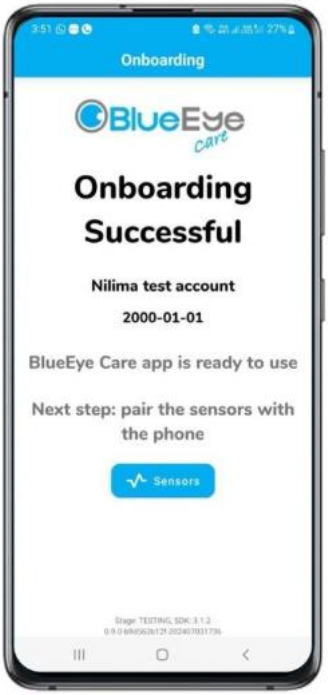


Figure 8 'Onboarding successful' screen in BlueEye Care app

5.2 Application to the Patient (Performed by the patient)

1. Ensure the correct patient profile is shown in the BlueEye Care app.
2. For the external sensors or accessories used, attach them. Refer to the below sections for sensor placement.
3. Confirm that all connected sensors are recognized by the app and transmitting data correctly to the BlueEye Care app. Match the data with the data displayed on the sensor.
4. Start monitoring only after verifying that the app and Hotdesk display real-time data.

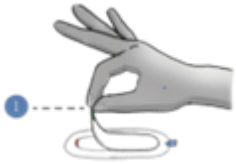
5.2.1 Sensor Placement

Set-up Multi-Vital Signs (MVS) Patch

After a successful onboarding and smartphone set-up, the patient with help from the clinician (on their first time) needs to set-up sensors. The Multi-Vital Signs (MVS) patch provides information on ECG, skin temperature, respiration, and heart rate. To set-up MVS patch, follow the steps below:

a. Prepare the skin

- Prepare the left middle chest area for MVS patch placement. If body hair is present in the area of patch placement, shave it.
- Thoroughly clean the area with an alcohol wipe.
- Allow area to dry completely.



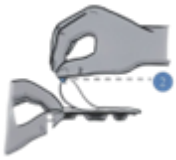
b. Peel the cover from the adhesive.

- Place the patch on the adhesive.
- Before applying a new adhesive, gently wipe both sides of the patch with a 70% isopropyl alcohol wipe.

- Align the 3 electrode dots of the patch with the 3 hydrogel windows on the adhesive.
- Be sure to press the patch firmly onto the adhesive.

c. Peel the cover from the adhesive

- The cover will be on the bottom side of the patch.



d. For optimal adhesion, stretch chest forward.

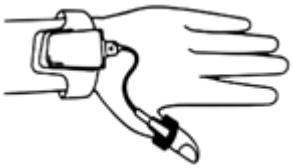
- Moving shoulders back with a full inhalation to ensure the skin is at maximum stretch.

e. Place the patch on the middle upper left chest, at an angle

- Make sure the heart symbol on the patch is upright.
- Press the patch firmly on chest and around the margin of the adhesive.

Set-up SpO2 Sensor

SpO2 sensor provides information on pulse rate, and SpO2. Set-up the SpO2 monitor by following the steps below:



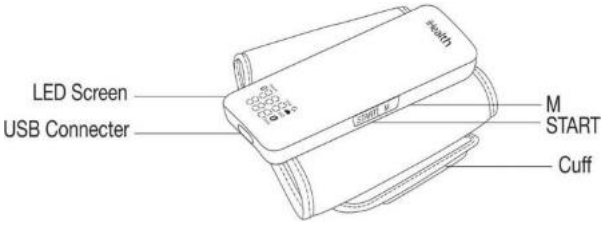
a. Start monitoring.

- Wear the watch on the left wrist and wear the sensor on the thumb
- Connect the sensor cable to the watch.
- Turn on the watch by pressing the On/Off button. After a few seconds, the sensor will begin to monitor. You will feel a strong vibration in your hand when the SpO2 sensor is turned on.

b. Stop monitoring.

- Removing the sensor from the finger will start a 10-second countdown. Recorder turns off automatically minutes after the sensor is removed from finger. It can be turned off manually by pressing the On/Off button for about 2 seconds.
- During the countdown, if the sensor is put back on to the finger, the data recording will resume.

Set-up Blood Pressure Cuff

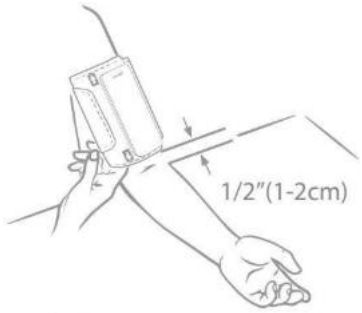


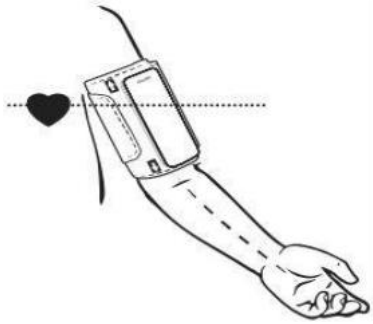
Blood Pressure (BP) Cuff provides information on systolic and diastolic blood pressure in the range of 60 to 260 mmHg and 40 to 199 mmHg, respectively. Set-up the BP Cuff by following the steps below:

a. Turn on the BP Cuff.

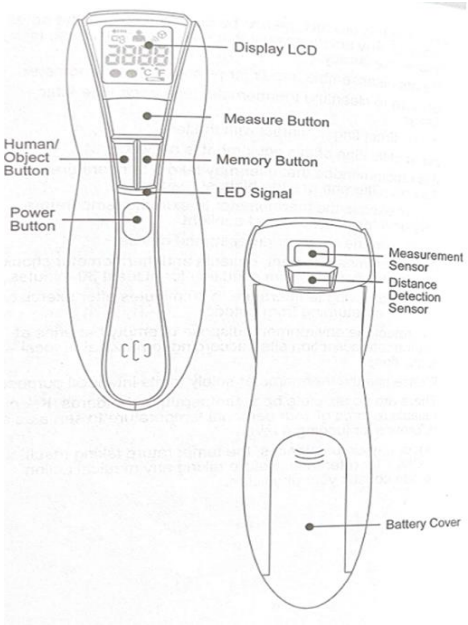
- Press the START button for at least 3 seconds until the LED screen displays all characters to power on the monitor on first use.

b. Apply the BP Cuff.

-  Sit on a chair with your feet flat without crossing your legs.
- 

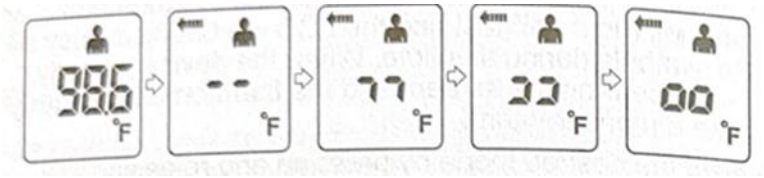
Left arm measurement Place a bare arm through the cuff and position the cuff ½" (1-2 cm) above the elbow joint. Tighten the cuff by pulling it towards your body, securing it closed with the Velcro fastener. You should be able to insert one finger between your arm and the cuff.
-  Place your hand, palm-side up, in front of you on a flat surface such as a desk or a table. The middle of the cuff should be at the level of the right atrium of your heart.
- Take an average of 3 blood pressure readings for accuracy.

Taking a Measurement with Infrared Temperature Sensor



- Press the Power Button on the thermometer. The unit will run a self-test and LCD will briefly display all of its symbols during this time. When device is ready, '00' will appear on the screen.
- Select the desired mode by pressing and releasing the Human/Object button.
- Position the thermometer under 3cm (around 1 inches) from the center of the patient's forehead with the sensor aimed between the eyebrows.

- Press and release the Measure button
- Slowly move the device toward or farther from the forehead until you have reached the correct distance. If the distance is beyond the correct distance, the dash-icon on the display flashes with beep sound in this sequence until the correct distance is achieved.



5.2.2 Pair Sensor(s) with BlueEye Care app (Performed by the patient)

After applying sensors to the body and turning them on, you need to pair them with BlueEye Care app. To do so, follow the steps below:

1. Press 'Sensors' button in BlueEye Care app to start pairing the phone with the patient sensors.

2. On the following screen, press ‘Add MVS Patch’ button to pair MVS patch or press ‘Add SpO2 Sensor’ button to pair SpO2 sensor or press ‘Add BP Sensor’ button to pair BP cuff, depending on whichever sensor you want to pair. See Figure 8 below. Please note, you are shown an option to connect for the sensors provided in your Green Box.
3. For sensor pairing, Bluetooth needs to be enabled. If it is off, BlueEye Care app will prompt you with an on-screen message to activate it. Simply follow the on-screen instructions to proceed.
4. The BlueEye Care app automatically scans the available sensors. If you do not see your sensors, press on the ‘Scan’ button. Please ensure sensors are turned on for pairing.
5. Identify and select the correct sensor by matching its name (e.g., SpO2, ECG, BP5S) with the sensor ID. The ID can be found on the back of the MVS patch and charging case, on the back of the SpO2 watch, and on the sides of the BP sensor and so on. See Figure 9 below. Once matched, press the sensor name on your device to initiate pairing.

Figure 9 Location of Sensor ID in MVS patch (L), SpO2 sensor (M), BP sensor (R)

At this stage, the sensors are paired with BlueEye Care app and are transmitting vital signs data to BlueEye Care app and BlueEye Hotdesk. You can see your vital signs data by pressing ‘Sensors’ button in the BlueEye Care app.

Please keep your smartphone nearby when transmitting sensor data to ensure efficient data transmission. The smartphone and sensor rely on Bluetooth connectivity, which works best within a range of approximately 30 feet or 10 meters.

Take readings with the BP Sensor

MVS patch and SpO2 sensor take vital signs readings automatically, but to take readings via the BP Sensor, you need to follow the steps below:

1. Press ‘Sensors’ button at the bottom of the home page in the BlueEye Care app.
2. Press ‘Start’ button in the BP block. You will feel the cuff tightening around your arm. This is expected behavior for blood pressure cuffs to measure your blood pressure.

This is when your blood pressure values are transmitted to the clinical team, who can access them via BlueEye Hotdesk.

5.3 Displays and Signals

Useful BlueEye Care App Features

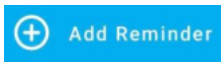
After the sensors are paired with BlueEye Care app, you have access to the following functions for your health management.

5.3.1 Reminders and Notifications

The BlueEye Care app home page provides information on reminders and notifications. See the image above.

Click ‘Reminders’ block on the home page to see a list of reminders. The following screen contains a list of upcoming reminders and gives an option to set your own reminder.

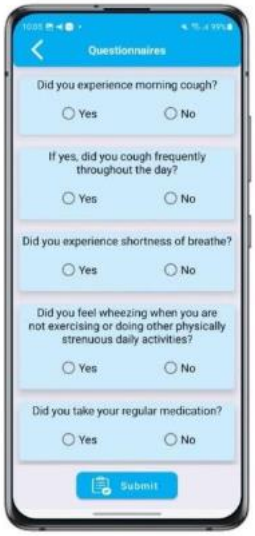
To set your own reminder:

1. Press the ‘Add Reminder’ 

button.
2. On the following screen, add your reminder title, date, and time.
3. Select a suitable repeat option.
4. Press the ‘Add Reminder’ button at the bottom of the screen. You can see this newly set reminder in the list of reminders screen.
5. To see a list of all your notifications, click on the ‘Notifications’ block on the home page of the app or the ‘Notifications’ 

button at the bottom of the home page.

5.3.2 Questionnaires



As a patient using BlueEye Care, you'll have access to personalized questionnaires that help track your health and progress. These questionnaires are designed by the clinician to gather important information about your condition and ensure that your care is tailored to your needs. Completing these questionnaires regularly allows your healthcare providers to monitor your well-being closely, make informed decisions about your treatment, and provide you with the best possible care. Follow the steps below to access the questionnaires assigned to you:

1. Press the ‘Questionnaires’ 

button on the BlueEye Care home page.
2. The following page contains a list of questionnaires assigned to you by your clinician.
3. Press on the relevant questionnaire title.
4. In the following page, answer questions by selecting the suitable options.
5. After answering all the questions, press ‘Submit’ button at the bottom of the page.

The clinician can see your responses to the questionnaires on the BlueEye Hotdesk.

5.3.3 View Sensor Data

The ‘Sensors’ button in BlueEye Care app allows you to view your vital signs data on your smartphone.

Press the ‘Sensors’ Sensors button at the bottom of the home page. The subsequent page shows the vital signs data for the sensors that you have put on. MVS patch collects and shows information on heart rate, respiration rate, temperature, and ECG. Whereas, SpO2 sensor collects and shows information on SpO2, and pulse rate. As you can see in the figure above, sensor data also shows you the sensor battery percentage. Please charge your sensor before any further use if the battery percentage goes below 20%.

5.3.4 Settings

The ‘Settings’ button in BlueEye Care app allows to manage app permissions, check device information, and unpair sensors.

6. Press the Settings button on the BlueEye Care app home screen.
7. Settings page shows the sensor details which are paired to the device.
1. The following page, as shown in the image above provides options to manage permissions, check device information, and unpair sensors (this option appears only if a sensor is paired with the BlueEye Care app).

- Press ‘Permissions’ to turn on/turn off overlay, storage, Bluetooth, camera, microphone, notifications permissions for BlueEye Care app.
- Press ‘Device Information’ to check your smartphone information such as model name and number, android version, phone number, BlueEye Care app version etc.
- Press ‘About’ to view the medical device label and eIFU button to view it.
- Press ‘Unpair’ for a sensor name if you wish to unpair that sensor from the BlueEye Care app.

5.3.5 Remote Support (Patient)

If you come across any issue with the BlueEye Care app and require support please contact your clinician. If any device or sensor related support will be required, then the patient can reach out to BlueEye via support@blueeye.video

5.3.6 Help

Press the ‘Help’ button in the BlueEye Care app home page, it will show you to access Green Box quick guide and BlueEye Care App IFU. If you, as a patient, have any queries and they are not resolved within the provided documentation, please contact your clinician. If any device or sensor related support will be required, then the patient/clinician can reach out to BlueEye via support@blueeye.video

6 Cleaning and Disinfection

6.1 Cleaning and Disinfection of the Device Surface

BlueEye Care is a software application and does not require cleaning or disinfection.

As the application is used with external hardware (e.g. smartphone, sensors), users should follow the manufacturer's instructions for cleaning those devices.

6.2 Cleaning and Disinfection of the Cables

BlueEye Care is a software application and does not require cleaning or disinfection.

As the application is used with external hardware (e.g. charging cables), users should follow the manufacturer's instructions for cleaning those devices.

6.3 Single Use Components

BlueEye Care is a software-based system and does not contain any components intended for single use.

As it is used with external CE marked medical sensors (e.g. ECG patch, SpO2), if these are single used components and must be disposed of after one patient use, do it according to hospital or local biomedical waste guidelines as described in their respective documentation.

7 Functional Check

Before each use, perform a basic functional check to ensure BlueEye Care App is operating correctly.

1. Verify that the BlueEye Care app opens without error.
2. Verify that all the sensors and the smartphone are charged before use.
3. Check Connectivity: Ensure the software connects successfully to the assigned patient profile and any paired sensors.
4. Confirm Data Transmission: Verify that vital data (e.g., heart rate, SpO_2, temperature etc.) is displayed and transmitted correctly to the app from the sensors.
5. Review Alerts and Notifications: Check that system alerts like reminders, notifications function as expected

8 Malfunctions and their Removal

Malfunction	Cause of the malfunction	Removal of the malfunction
Sensors not connecting	Bluetooth or location turned off	Enable Bluetooth and location, then retry sensor connection
Permissions denied	Required permissions not granted	Go to phone settings → Apps → BlueEye Care App → Permissions and enable all required permissions
App freezes or becomes unresponsive	Background apps consuming resources	Close other apps, restart the phone, and reopen the BlueEye Care App.
Notifications not received	Phone notification settings disabled	Enable notifications for the BlueEye Care App in phone settings

Malfunction	Cause of the malfunction	Removal of the malfunction
Data not coming to app	No broadband / no Wi-Fi for a prolonged period	Check internet connectivity and ensure a stable broadband or Wi-fi connection. If the issue persists for a prolonged period, inform the clinician/support team immediately. The patient should not be monitored using the app until data transmission is restored.

In case of failures which cannot be eliminated directly, have the device repaired by the manufacturer or your specialist distributor. Do not continue to operate the device in order to avoid major damage.

Patients can reach out to their clinicians for any support. The clinicians can reach out to BlueEye by logging in to their BlueEye Hotdesk account, click on Support menu and submit a support request or directly send email via support@blueeye.video

9 Maintenance/Disposal/Replacement Parts

9.1 Maintenance (Clinician/Patient)

Software Updates: Make sure the app is updated.

Device Integrity: Ensure devices and accessories are in good condition.

Functional Checks: Verify operation before use.

9.2 Putting out of Operation (Clinician/Patient)

For Patients:

- Patients can not directly delete their account or associated data.
- To stop using the application, patients should contact their healthcare provider.
- The healthcare provider may discharge the patient from monitoring, which will stop further data collection and access to active monitoring features and BlueEye Care app.

For Clinicians:

- Clinicians can discharge a patient via BlueEye Hotdesk in accordance with internal procedures.
- Discharging the patient will terminate active monitoring and prevent further data collection from the patient's devices. Patient discharge is irreversible action.

Data handling:

- Patient data is not deleted upon discharge.
- All collected data is retained in accordance with applicable regulatory, legal and institutional data retention requirements.

9.3 Disposal

BlueEye Care is software-only and does not require physical disposal.

As it is used with external CE marked medical sensors, if these or their components must be disposed of after one patient use, do it according to hospital or local biomedical waste guidelines as described in their respective documentation.