Platform User Guide

September 2021
PM-0002-02

Important

This User Manual is subject to periodic review, update and revision.

Do not use a defective product. Do not repair this product or any of its parts other than in accordance with written instructions provided by Biobeat.

The user of this product has sole responsibility for any malfunction that results from improper use, faulty maintenance, improper repair, unauthorized service, damage, or alteration by anyone other than Biobeat Technologies Ltd.

The safety, reliability, and performance of this device can only be assured under the following conditions:

- The device has been used according to the accompanying operating instructions.
- All fittings, extensions, readjustments, changes, or repairs have been carried out by Biobeat's authorized representatives.

Biobeat Technologies Ltd. reserves the right to change or improve its products and accompanying technical literature without specific notice of changes or improvements.

This product is protected by the following US patent applications:

US20180020960(A1)

PCT/IL2017/050752

and other pending US patents.

Caution: Federal law restricts this device to be sold by or on the order of a physician.

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CE 2797 CE indicates compliance of this device with the medical device directive 93/42/EEC on medical devices Annex II excluding Section 4.

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PLEASE READ THIS USER MANUAL BEFORE OPERATING THE SYSTEM

Disclaimer

Information provided by Biobeat Technologies Ltd. is believed to be accurate and reliable. However, Biobeat Technologies Ltd. assumes no responsibility for the use of such information, nor for any infringements of patents or other rights of third parties that may result from its use.

About this User Manual

This User Manual provides the information necessary to operate the Biobeat System.

PLEASE READ THIS USER MANUAL BEFORE OPERATING THE SYSTEM. If any part of this User Manual is not clear, contact Biobeat for assistance.

PLEASE RETAIN THIS USER MANUAL FOR FUTURE REFERENCE.

Types of Warnings, Cautions and Notes

Three types of special messages appear in this User Manual

⚠ **Warning:** A warning indicates precautions to avoid the possibility of personal injury or death.

⚠ **Caution:** A caution indicates a condition that may lead to damage to equipment, or a lower quality of treatment.

Note: A note provides other important information.

Table of contents

Chapter 1 System Overview

The Biobeat monitoring platform measures vital signs in real-time using wireless, non-invasive, medical-grade technology. The Biobeat wrist-monitor offers a simple solution for long-term monitoring, ideal for nursing homes and home care, while our chest-monitor offers a short-term hospital-oriented solution.

How does Biobeat's solution work?

Biobeat monitoring solution is based on our PPG sensor, designed to allow a clear reading of PPG signal wave, enabling measurement of a wide range of vitals. The Biobeat chest-monitor and wrist-monitor each collect and measure 12 parameters from the patient, additionally, the chest-monitor measures a one-lead ECG.

The device transmits the measurement data to the Biobeat gateway or cellphone app. All data is uploaded to and stored on the Biobeat Cloud (HIPAA and GDPR compliant). The healthcare provider can then access all data through the Biobeat web platform.

What are the parts of the Biobeat Monitoring Platform?

Biobeat chest-monitor — made up of the chest-monitor sensor and the adhesive unit.

Biobeat chest-monitor sensor — The BB-613P is a wireless, non-invasive, medical-grade sensor. It is designed for single patient use, enabling monitoring while eliminating risk of disease and infection transmission. The battery life lasts for up to 5 days, at the end of which the sensor is disposed of.

Biobeat adhesive unit – The adhesive unit is made up of four petals and a plastic frame in the middle to secure the sensor. Two of the petals have ECG electrodes.

Biobeat wrist-monitor – The BB-613W is a device worn on the wrist, made for long-term monitoring and management of patients. The device is made of an aluminum case with silicone straps, the battery life is sufficient for up to 3 days of continuous use and a charge takes up to two hours in a dedicated charging cradle.

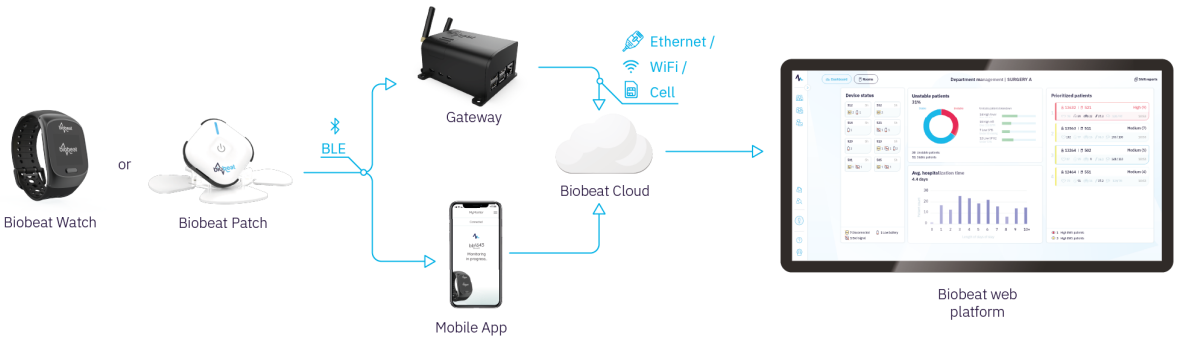
Biobeat gateway — Gateways are placed in a facility to collect data from devices via Bluetooth and upload the data to the cloud using Internet connection. The data can be accessed through the web platform.

Biobeat mobile applications — The Biobeat mobile applications enables remote monitoring of patients with the Biobeat wrist-monitor and chest-monitor. The apps transmits all measurement data to the web platform, where it can be viewed and managed.

Biobeat web monitoring management platform — The Web monitoring management platform is an Internet-based application system that allows real-time viewing and management of multiple patients. The system includes a dashboard view of an entire ward, customizable alerts for each patient and vital sign, historical trend view of all vital signs and export of adjusted reports amongst many other functions.

Vitals and parameters measured:

- Respiratory rate
- Pulse rate
- Heart rate variability
- Pulse pressure
- Systemic vascular resistance
- Cardiac output
- Skin temperature
- Blood oxygen saturation
- One lead ECG* (Chest monitor only)
- Blood pressure
- Mean arterial pressure
- Stroke volume
- Cardiac index



Chapter 2 General Considerations

2.1 Warnings, Cautions and Indications for Use

Indications

The BB-613WP is a portable physiological signal measurement device. It is indicated for use in the measurement, spot-checking monitoring, displaying, and storage of biophysical parameters as an adjunct in the assessment of cardiovascular and respiratory status of adult patients.

The specific indications for use include estimates of: Blood oxygen saturation (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), cardiac output (CO), stroke volume (SV), respiratory rate (RR), skin temperature (TEMP), one lead EKG (patch only), mean arterial pressure (MAP), pulse pressure (PP), systemic vascular resistance (SVR), cardiac index (CI), and pulse rate variability (HRV). The parameters are sent using a gateway or a mobile device to the cloud storage. We can retrieve the parameters from the cloud and send them to any medical center with appropriate permission.

The device is intended to be used in healthcare facilities by clinical professionals or under their guidance, or in patient's home under clinician's guidance. This device is NOT designed to be used in life support situations.

The BB-613W/P is indicated for the non-invasive spot checking for adult (+18) patients in hospitals, clinics, long-term care, and home use.

Skin temperature is used as an adjunct to other clinical diagnostic procedures by tracking changes in skin temperature.

The BB-613P is also intended to record, store, transfer, and display single-channel electrocardiogram (ECG) rhythms.

The BB-613P ECG is not intended for automated diagnosis.

A baseline reference measurement of blood pressure and heart rate should be entered into the Web Platform before use of the device. The baseline reference measurement is performed using a standard blood pressure cuff-based oscillometric device.

Note: *Standard blood pressure is considered to be an average of 3 consecutive measurements.*

Contraindications

- ⚠ Do not use with neonatal or pediatric patients.
- ⚠ If the BB-613WP is mechanically damaged it must not be used and must be disposed.
- ⚠ Do not use with patients with significant deformity, swelling, irritation, degenerative changes or edema of the wrist.
- ⚠ Do not use the wrist monitor on patients with localized infection, ulceration or skin lesions involving the wrist.
- ⚠ Do not use the wrist monitor on patients that have restricted blood flow e.g. tourniquet, pressure cuff or IV line.
- ⚠ Do not use with patients with tremors or convulsions.
- ⚠ Do not use with patients with peripheral vascular disease affecting the hands.
- ⚠ Do not use on an area with a tattoo.
- ⚠ Do not use the device if there is any known allergy to metals, plastic and silicon.
- ⚠ Warning: MR-unsafe!
  - DO NOT use in MRI or a CT environment.
  - Do not expose the device to a magnetic resonance (MR) environment.
  - The device may present a risk of projectile injury due to the presence of ferromagnetic materials that can be attracted by the MR magnet core.
  - Thermal injury and burns may occur due to the metal components of the device that can heat during MR scanning.
  - The device may generate artifacts in the MR image.
  - The device may not function properly due to the strong magnetic and radio frequency fields generated by the MR scanner.

SAFETY

Electrical Safety

The device complies with the requirements of AAMI/ANSI/IEC/EN 60601-1+ED-3 for safety of medical equipment:

Class II equipment type BF applied part.

Mode of operation: spot measurement.

Degree of mobility: portable.

EMC Compliance

The device complies with the requirements of IEC/EN 60601-1-2+ED-4 for EMC of medical equipment:

The device has Class BF III compliance.

Warnings

- ⚠ DO NOT USE BEFORE READING THIS USER MANUAL.
- ⚠ Only apply the device on clean, intact skin.
- ⚠ The device can only measure while the patient is at rest.
- ⚠ This device is not defibrillation proof per IEC60601-1.
- ⚠ Do not use the device in an MR environment or in an explosive atmosphere, such as in the presence of a flammable anesthetic.
- ⚠ In case of discomfort, inspect the device sensor application site to ensure correct sensor alignment and skin integrity.
- ⚠ Avoid excessive pressure to the sensor application site as this may cause damage to the skin beneath the sensor.
- ⚠ If a skin reaction appears following the use or during the use of the device, stop using the device immediately.
- ⚠ This device is intended only as an adjunct in patient assessment.
- ⚠ The system contains no user-serviceable components.
- ⚠ Do not immerse the device in water or any other liquid.
- ⚠ Diseases with peripheral circulatory disturbance may cause incorrect readings (including, but not limited to, diabetes, hyperlipemia, hypertension and atherosclerosis).
- ⚠ The pulse rate indicator is not suitable for monitoring the frequency of cardiac pacemakers.
- ⚠ The device must be able to measure the pulse properly to obtain an accurate SPO2 measurement. Verify that nothing is hindering the pulse measurement before relying on the SPO2 measurement.
- ⚠ General operation of the device may be affected by the use of an electrosurgical unit (ESU). This device should not be used adjacent to other equipment. If adjacent use is necessary, the device should be observed carefully to verify normal operation.
- ⚠ The device is intended for indoor operation.
- ⚠ The device should not be used as a substitute for a laboratory blood analyzer.
- ⚠ Excessive pressure from the device for prolonged periods can induce pressure injury.
- ⚠ Do not use the device outside the declared environmental

conditions **(see Chapter 2.4 - Specifications).** Operating the device outside the declared environmental conditions can lead to incorrect measurements.

⚠ The GATEWAY must be connected to a UPS-powered outlet.

- In the event of a power failure, there is no communication.
- During a power outage, the device stores up to 3 hours of data.
- When the electricity is renewed, the communication is automatically renewed and all the data is sent to the cloud.

Cautions:

⚠ The wrist-monitor device is for adult (+18) patients with a wrist circumference between 18-25 cm.

⚠ Disposal of this device should be performed in accordance with local regulations.

⚠ If the temperature or humidity is outside of the recommended range **(see Chapter 2.4 - Specifications)**, do not use the device.

⚠ If the display on the wrist monitor is not working properly, or the center key is faulty, as shown in **Chapter 3.1 - Wrist-monitor**, do not use the device.

⚠ Do not disassemble any part of the system components. This system is not user-serviceable.

⚠ Use the device only for the purpose described in the indications for use.

⚠ Do not use accessories which are not supplied or recommended by the manufacturer.

⚠ Do not use the device if it is not working properly or if it has suffered any damage, for example, a damaged casing, or damage caused by dropping the equipment or splashing water on it. Stop using the device and contact the manufacturer.

⚠ Keep these instructions.

⚠ Do not share an outlet with another electrical device.

⚠ Do not connect to an outlet controlled by a wall switch.

⚠ Do not use the device with an extension cable.

⚠ Do not use an adapter that was not supplied with the device.

⚠ The device is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin. Factors that may degrade pulse oximeter performance or affect the accuracy of the measurement include the following:

- Device not applied correctly
- Excessive motion
- Methemoglobin
- Intravascular dyes

⚠ Avoid too much light such as sunlight or bright indoor lighting.

⚠ The device has no audible alarms and is intended for periodic spot checking.

⚠ The wrist-monitor may not work when circulation is reduced. Warm or rub the wrist area to increase perfusion.

⚠ Clean the device between uses (See **Chapter 2.2 - Cleaning and maintenance).**

⚠ Do not sterilize, autoclave, or immerse this device in liquid. Do not pour or spray any liquids into the device.

⚠ Do not use cleaning solutions other than those recommended, as permanent damage could result (see **Chapter 2.2 - Cleaning and maintenance).**

⚠ The chest-monitor should not be used as a replacement or substitute for ECG.

⚠ Pulse rate measurement is based on the optical signal detection of a peripheral blood flow pulse and therefore may not detect certain arrhythmias.

⚠ Do not expose the device to excessive moisture such as direct exposure to rain. Excessive moisture can cause the monitor to perform inaccurately or fail.

⚠ This device is a precision electronic instrument and must be repaired by Biobeat Technologies Ltd. qualified technical professionals. Field repair of the device is not possible. Do not attempt to open the case or repair the electronics. Opening the case may damage the device and void the warranty.

⚠ The equipment complies with IEC60601-1-2 for electromagnetic compatibility for medical electrical equipment and / or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio frequency transmitting equipment and other sources of electrical noise in health care and other environments, it is possible that high levels of interference due to close proximity or strength of a source might disrupt the performance of this device. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to the EMC information specified in this manual – see **Chapter 9.1 - Manufacturer's declaration(EMC).**

⚠ Portable and mobile RF communications equipment including CT, MRI, diathermy, RFID, and electronic article security systems can affect medical electrical equipment.

⚠ Follow local, state, and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.

⚠ In compliance with the European Directive on Waste for Electrical and Electronic equipment (WEEE) 2002/96/EC, do not dispose of this product as unsorted municipal waste. This device contains WEEE materials; please contact your distributor regarding return or recycling of the device. If you are unsure how to reach your distributor, please call Biobeat Technologies Ltd. for your distributor's contact information.

Cyber warnings

⚠ Android OS level restrictions that prevent unauthorized operations.

⚠ App certificate that assures data security for Biobeat home care mobile application.

⚠ Do not leave smartphone unattended and unlocked.

⚠ Use security measures to lock smartphone when not in use.

⚠ Do not install apps that may contain malware.

Respiration Rate warnings

⚠ The device is not intended to be used as an apnea monitor.

⚠ Do not to rely on the respiration monitoring for detection of cessation of breathing and to always follow hospital guidelines and best clinical practices, including monitoring additional parameters that indicate the patient's oxygenation status.

⚠ The device is not intended for use by pediatric population.

Note: A baseline reference measurement of blood pressure and heart rate should be entered into the Web Platform before use of the device. The baseline reference measurement is performed using a standard blood pressure cuff-based oscillometric device.

Note: Standard blood pressure is considered to be an average of 3 consecutive measurements.

Note: This device is not for use by persons under the age of 18 years.

2.2 Cleaning and Maintenance

The Biobeat System does not require maintenance or cleaning on a routine basis, except as suggested in this User Manual. Service should only be provided by an authorized Biobeat Technologies Ltd. representative. Failure to do so voids the warranty.

Please observe the following cautions when cleaning the Biobeat:

⚠ **Caution**: Should the device become wet, wipe off all moisture and allow sufficient time for drying before operating.

⚠ **Caution**: Contact with solvents can cause severe deterioration of plastic parts and malfunctioning of the instrument and accessories.

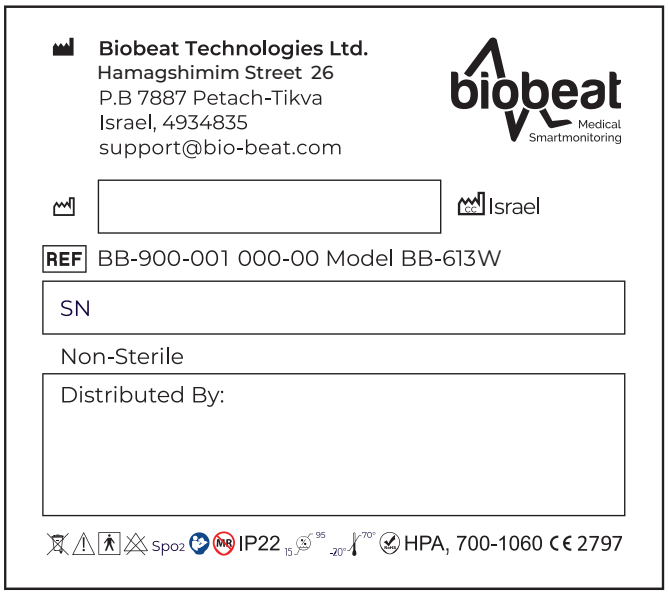
The outer surface of the device may be cleaned with a soft, lint-free cloth moistened by ethyl alcohol (70-85%) until visually clean.

When under warranty, repair and service must be performed by Biobeat Technologies Ltd. When the Biobeat warranty is not applicable, repairs may be made by Biobeat Technologies Ltd. or authorized representatives, on a parts and labor basis.

⚠ **Warning**: Do not remove the covers of the device components. Only perform maintenance procedures specifically described in this User Manual.

2.3 Labels and Symbols

A number of internationally recognized symbols are found on the Biobeat BB-613WP devices and packaging. These relate to safety requirements and standards and are described below.



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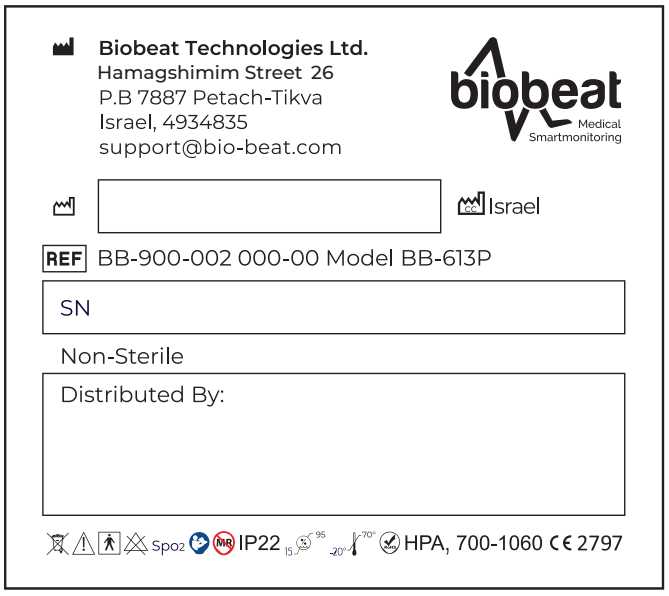

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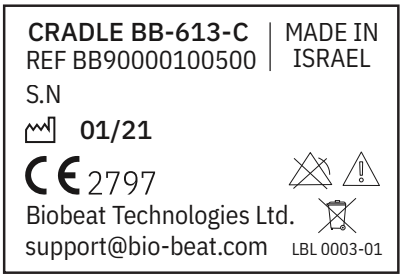


Symbol	Meaning
CE 2797	CE Mark, indicating that the device complies with the Council Directive 93/42/EEC (MDD)
	The System cannot be disposed as unsorted municipal waste. Contact your local distributor for unit disposal.
	Caution, consult accompanying documents
SN	Serial number
	Manufacturer
	Manufacturing date
	Country of manufacture
	Use-by-data
REF	Catalogue number
	Caution: law prohibits dispensing without prescription

Symbol	Meaning
	Type BF Applied Part
	No alarms
	Underwriters Laboratories
	Conforms to the European RoHS directive
IP22	Ingress Protection Marking level 22: Protected against access of fingers or similar objects, and water dripping at an angle of up to 15 degrees
	"Do not use the device in an MR environment."
	Storage temperature -20°C - +70°C
	Read Instruction Manual
LOT	Batch code
	Humidity Limitation
EC REP	Authorized representative

2.4 Specifications

Parameter	Effective Range	Accuracy	Unit
Blood Pressure	Sys: 60 to 250 Dias: 40 to 150	±5	mmHg
Mean arterial pressure	50-180	±5	mmHg
PR (pulse rate)	40-250	±3%	Beats per minute
Saturation (spo_2)	70-100 40-70	±2% or ±2 digits ±3% or ±3 digits	%
Respiratory Rate	0-40	±3	Respirations per minute
Stroke Volume	20-130	±10	ml/beat
Cardiac Output	1.5-13	±10%	L/min
Systemic Vascular Resistance	700-1600	±15%	dyn x sec/cm^{-5}
Skin temperature*	32-42	±0.5°C	°C
Heart Rate Variability	0-30	±2%	%
Pulse Pressure	10-100	±5	mmHg
Cardiac Index	1.5-6	±10%	L/min/m^2
One Lead ECG	17 Bits ENOB with 1.1µVP-P		
Electrical - Chest-monitor			
Battery type	Non-rechargeable - Lithium / Manganese dioxide		
Voltage	3.0V		
Capacity	400mah		
Estimated Battery Life	Up to 5 days		
Shelf- life	3 years		
Electrical - Wrist-monitor			
Battery type	Rechargeable lithium polymer		
Voltage	3.7V		
Capacity	160mah		
Estimated Battery Life	Up to 3 days of continuous use		
Battery charging time	2 hours when powered off		
Use- life	3 years		
Shelf- life	2 years		
Power requirements	Charger Isolation: Class ll double isolation 5V AC/DC Adapter AC Power for battery charger - 100-240V, 50-60 Hz, 10VA max		
Environmental			
Operating temperature	4°C to 42°C (39°F to 103°F)		
Operating humidity	Up to 95%, non-condensing		
Pressure	900 to 1060 hPa		
Operating altitude	-378m to 3050m (-1240 feet to 10000 feet)		

Parameter	
Storage and transportation	
Storage temperature	-20°C to 70°C (-4°F to 158° F)
Humidity	Up to 95%, non-condensing
Pressure	465 to 1080 hPa
Operating altitude	-378m to 6098m (-1240 feet to 20000 feet)
Physical Characteristics - Chest-monitor	
Adhesive unit shelf-life	2 years
Adhesive unit usage time	3 days
Dimensions	Monitor enclosure - 38 x 38 x 16 mm Adhesive unit - 85 x 85 x 13 mm
Weight - Sensor	14 g (0.5 oz.) including battery
Physical Characteristics - Wrist Monitor	
Dimensions (monitor enclosure)	56 x 39 x 16 mm
Weight	55 g (2 oz.) including battery
Compliance	
Equipment Classification	IEC 60601-1
Type of Protection (battery power)	Internally powered
Accuracy pulse oximeter equipment	ISO 80601-2-61
Degree of Protection – Sensor	Type BF-Applied Part
Mode of operation	Spot Check
Enclosure degree of ingress protection	IP 22
Bluetooth	
Operating Frequency Range	2402-2480 MHZ
Channels	40
Channel separation	2 MHZ
Modulation	GFSK
External Antenna gain	n-VARIANT: 2.14 DBI
Bluetooth 4.2	IEEE 802.15.1
Transmission range	8 Meter
Intended use environment	
Bluetooth	

- *Approximated body temperature accuracy may be greater than ±0.5°C / ±0.9°F in cases where environment temperature is lower than 10°C / 50°F, above 45°C / 113°F or when subject is physically active.*
- *Adhesive unit should be stored in a chilled environment .*

The device was tested and passed the qualification criteria defined for medical grade monitoring systems, including:

Test	Standard	Class/Severity level	Test result
Emission (IEC 60601-1-2 section 7.1 & 7.2)			
Conducted emission Freq. range:150 kHz - 30 MHz	CISPR 11 /	Group 1 Class B: 230 VAC & 120 VAC mains	Complies
Radiated emission Freq. range: 30 - 1000 MHz	CISPR 11	Group 1 Class B	Complies
Immunity (IEC 60601-1-2 section 8.9 & 8.10)	IEC 61000-3-2	AC mains	N/A
Voltage changes, Voltage fluctuations and Flicker test	IEC 61000-3-3	AC mains	Complies
Immunity (IEC 60601-1-2 section 8.9 & 8.10)			
Immunity from Electrostatic discharge (ESD)	IEC 61000-4-2	8 kV contact discharges & 15 kV air discharges	Complies
Immunity from radiated electromagnetic fields	IEC 61000-4-3	10.0 V/m; 80 MHz ÷ 2.7 GHz, 80% AM, 1 kHz	Complies
Immunity from Proximity field from wireless communications equipment	IEC 61000-4-3	List of frequencies, from 9 V/m up to 28 V/m, PM (18 Hz or 217 Hz), FM 1 kHz	Complies
Immunity from Electrical Fast transient (EFT)	IEC 61000-4-4	± 2.0 kV on AC mains; Tr/Th – 5/50 ns, 100 kHz	Complies
Immunity from Surge	IEC 61000-4-5	±1.0 kV DM on AC mains; Tr/Th – 1.2/50 (8/20) µs	Complies
Immunity from conducted disturbances induced by radio-frequency fields	IEC 61000-4-6	3.0 & 6.0 VRMS on AC mains; 0.15÷ 80 MHz, 80% AM, 1 kHz	Complies
Immunity from power frequency magnetic field	IEC 61000-4-8	30 A/m @ 50 Hz & 60 Hz	Complies
Immunity from voltage dips, short interruptions and voltage variations	IEC 61000-4-11	On 230 VAC & 120 VAC mains: 0 % - 0.5 cycle & 1 cycle; 70% - 25 cycles; 0% - 250 cycles	Complies

Chapter 3 Getting started

3.1 Biobeat Wrist-monitor

A non-invasive wearable wrist-monitor device used for monitoring of vital signs in clinical and non-clinical settings. The device transmits the data collected via BLE to a gateway or mobile app, which can then be accessed from the web platform.

Note: The Biobeat wrist-monitor is not waterproof.

Components

1. Biobeat wrist-monitor with a silicone strap
2. Charging dock
3. USB C charging cable

Wrist-monitor display

Wrist-monitor screen

Battery and Bluetooth status

- Bluetooth Status: when the wrist-monitor is connected to the app, a circle will show around the Bluetooth icon.
- Battery status: three bars in the battery icon indicate the battery is fully charged.

Getting started

Take the Biobeat wrist-monitor out of the box and fully charge it.

1. **Charging:** The wrist-monitor should be charged upon first use. It is recommended to charge it on a daily basis too. The wrist-monitor is powered by a rechargeable Lithium battery. A full charge takes between 1-2 hours.
   a. Attach the device correctly to the cradle. The Biobeat logo that is located on the base of the cradle should be parallel to the logo on the Biobeat wrist-monitor.
   b. An indication of the charging status appears on the center of the screen once the device is charging.

Wrist-monitor charging cradle

2. Turn on the Biobeat wrist-monitor by pressing the center key shortly until you see the Biobeat logo appear.
3. Viewing the vital sign measurements can be done using the Biobeat web platform (See **Chapter 4 Web Monitoring Management Platform**)
4. While using the phone application, connect the wrist-monitor to the Biobeat Home care mobile application: see **Chapter 5 Mobile Application.**
5. While using the Biobeat gateway, make sure you have an active gateway in the vicinity of the patient (up to 10 meters/30 yards). See instructions on gateway set up in **Chapter 7 Troubleshooting**.

Note: Upon first activation of the device the time will show a default value. Only after connection to the Biobeat Home care mobile app, the time will be synchronized with your local time zone.

Fastening the wrist-monitor

Fasten the wrist-monitor to either wrist, there is no difference between right or left hands. Apply the device on clean, intact wrist skin. The correct positioning for the device is when the back of it is placed lightly on top of the skin while it is touching the skin but not making pressure marks.

Wrist-monitor buttons

Biobeat's wrist-monitor only has one button – the center key. It is used to turn the wrist monitor on and off.

Turning the wrist-monitor off / End of use

1. Press and hold the center key for three seconds until the wrist monitor is turned off.

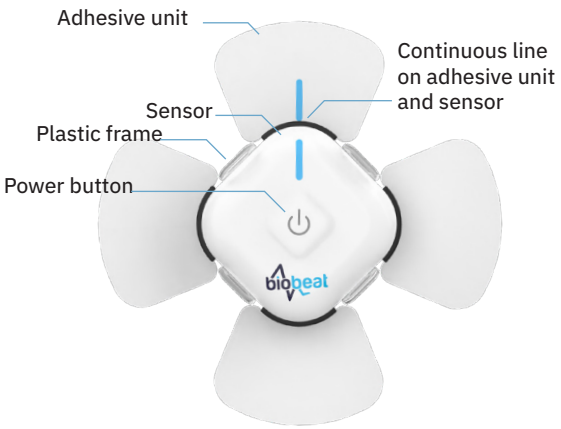
⚠ Do not take measurements while eating, drinking, smoking, taking medicine or exercising. Sit comfortably on a chair or lie down in bed to achieve a relaxed state.

⚠ Please contact Biobeat's support or your local distributor if the device does not turn on.

⚠ Do not use the device if the center key is faulty.

3.2 Biobeat Chest-monitor

The Biobeat chest-monitor is a single-patient use device for vital sign monitoring, mainly meant for use in hospital settings and short-term monitoring scenarios. Each sensor can be used for up to 5 days until the battery ends, the sensor is not rechargeable.



Biobeat chest-monitor

Components:

The chest-monitor is comprised of a sensor and an adhesive unit.

1. Adhesive unit - the adhesive unit is made up of four petals and a plastic frame in the middle to secure the sensor. Two of the petals have ECG electrodes.
   a. The Biobeat adhesive unit is disposable and is not waterproof. It must be removed before every shower, and replaced with a new one after the shower.
   b. It is made of the strongest FDA©-approved medical glue in order to ensure maximum adhesion.
2. Biobeat Sensor
   a. The chest-monitor sensor is non-rechargeable and lasts for 5-6 days of use, until the battery runs out.

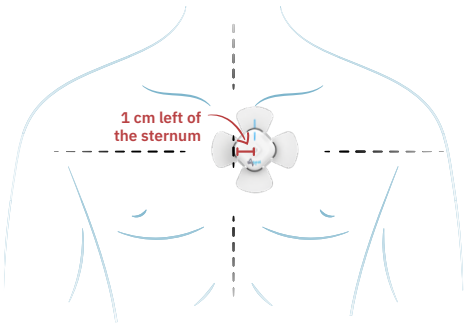
Note: The sensor is not waterproof. It must be removed before showering.

Getting started:

1. Connecting the sensor to the adhesive unit:
   a. Switch the sensor on: press the power button for 2 seconds (a blue light will turn on).
      Make sure the LEDs on the back of the sensor are switched on and are flashing continuously.
   b. Attach the sensor to the adhesive unit's plastic frame as seen in the figure below. Make sure the vertical line on the sensor is continuous with the line on the adhesive unit. Apply pressure on the four corners of the sensor until you hear the plastic clasps click and fasten around the sensor.
2. Attaching the chest-monitor to the patient's chest:
   a. Any hair on the chest should be removed before use.
   b. Clean the skin over which the chest-monitor will be placed with an alcohol swab and wait until the skin is completely dry before proceeding to the next step.
   c. Remove the white paper from the back of the adhesive unit.

Note: The following step is vital to ensure maximum utilization of the Biobeat System. Apply the Biobeat chest-monitor properly.

   d. Attach the chest-monitor to the patient's chest. The chest-monitor should be located 1 finger's width to the left of the sternum, just below the clavicle as show in the figure below. The Biobeat logo should be pointed downwards and the blue line upwards.
   e. The entire surface of the adhesive unit should be attached to the skin.
3. SPO2 and breathing rate measurements are obtained while remaining still without speaking for the duration of 40 seconds.



Placing the chest-monitor

Operation:

Instructions on viewing all vital sign measurements are detailed in **Chapter 4 Web Monitoring Management Platform.**

In order to receive data from the device:

1. While using the phone application: Connect the chest-monitor to the Biobeat Hospital at Home mobile application (**see Chapter 5 Mobile Application**).
2. While using the Biobeat gateway: make sure you have an active gateway in the vicinity of the patient (up to 10 meters/30 yards). **See instructions on gateway set up in Chapter 6 Biobeat Smart Gateway Box.**

Replacing the adhesive unit or chest-monitor sensor:

The Biobeat adhesive unit is disposable and is not waterproof.

Remove Biobeat sensor before every shower:

1. Remove the chest-monitor from the patient by pulling it off.
2. Unclasp the four plastic clips in order to remove the sensor from the adhesive unit.
3. Follow steps 1-2 in the **"Getting started"** segment in order to reattach the same sensor (or a new sensor) to the patient while using a new adhesive unit.
4. If the sensor was replaced, also see **Chapter 4.4 Patient Details View**

Chapter 4 Web Monitoring Management Platform

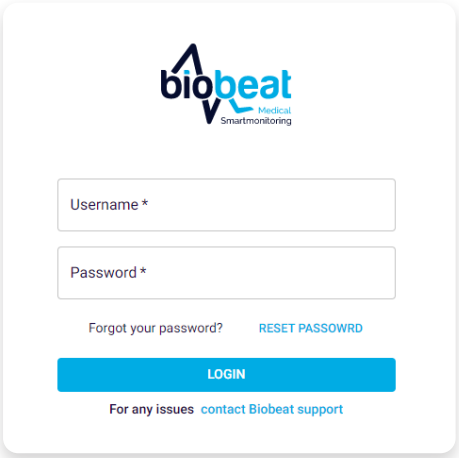
The Biobeat Web Monitoring Management Platform allows the remote monitoring and management of a large number of patients through one simple system. The platform is web-based, and can be accessed from any Internet platform.

4.1 Sign-in screen

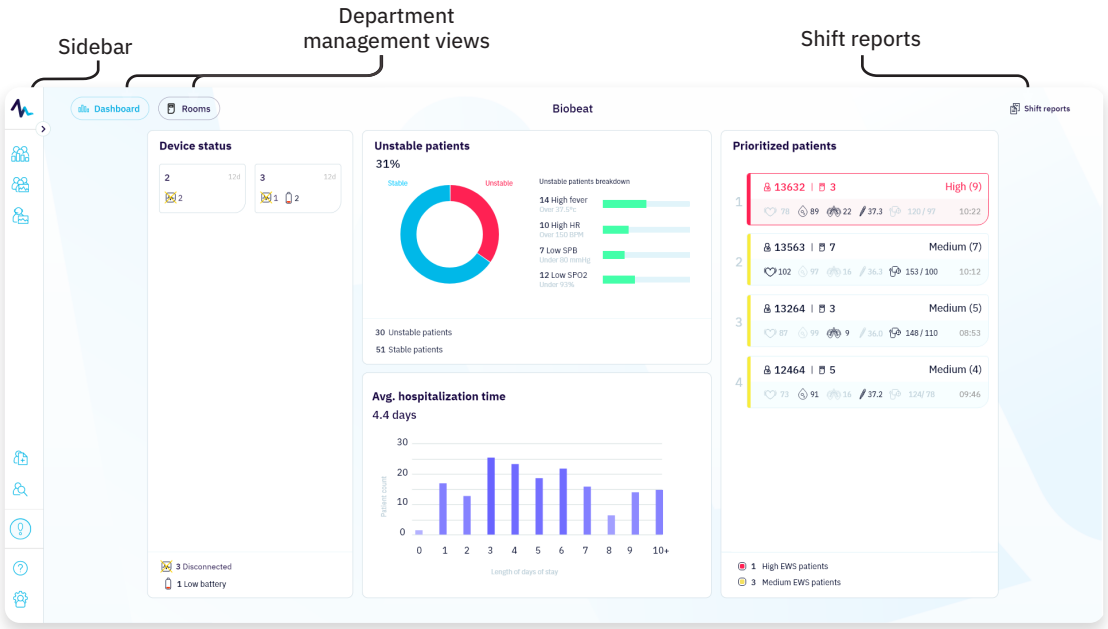
Sign-in to the web monitoring management platform using the link provided by Biobeat. A username and temporary password will be sent to new users via email. Upon first entry to the platform, you will be asked to reset your password.

In case of a missing password, use the reset password option found in the sign-in page.

Note: In order to protect patients' medical data, please make sure the password is protected and only known by mandatory personnel.



4.2 Department Management Screen



Department Management screen

The Department Management screen is the homepage of the web platform. The screen gives a general overview of the department status, its assigned patients and their biobeat devices.

The department management screen is comprised of two different views. The Dashboard view gives a visual overview of the department and highlights important patient and device information, while the Rooms view is used to quickly find and access patient's details according to the department rooms. In order to switch between Dashboard and Rooms view, click on the selected view button on the top left.

Navigation Sidebar

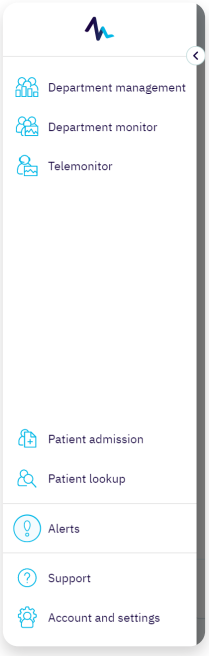
The sidebar is found on the left side of the web platform and is accessible on all system screens. Clicking on the arrow symbol, located on the upper left of the sidebar, will expand the sidebar to reveal the buttons' labels.

The sidebar enables easy navigation between the different web platform screens and tools. This includes the **Department Management, Department Monitor, Telemonitor, Patient Admission, and Patient Lookup.**

The sidebar also enables viewing of unattended alerts using the alerts center and easy access to the system support and user settings.

From the settings menu the following actions are available:

- Viewing which user is currently logged and its client's name.
- Changing the active department (in cases when multiple departments are available).
- Activation of **"Silent mode"**- when activated, notifications will not be displayed for a duration of 30 minutes.
- Logging out.

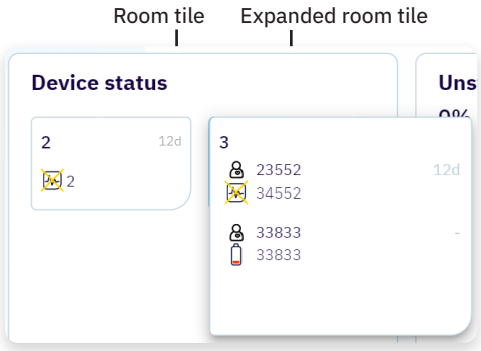


Dashboard view

The dashboard view highlights important information about the department, its admitted patients and their assigned devices using various modules.

Device status

The device status module lists devices that are either disconnected or have a low battery (under 5%) which needs to be attended in order to continue monitoring. The number of disconnected devices and low battery devices are detailed per room. Clicking on a room tile will expand the tile to a detailed list of disconnected/low battery devices with the Patient ID, device ID number and the time past since the device was last available .



Device status module

Patient status

The Patient Status module displays the number and percentage of stable patients out of the total number of admitted patients. An unstable patient is defined by having one or more of the following exceeding vitals: SPO2 (< 93% saturation), low systolic blood pressure (< 80 mmHg), high heart rate (> 150 bpm) and high fever (>37.5 degrees Celsius).

In addition, a breakdown of patients with exceeding vital signs is available. Pressing a vital sign will reveal a list of patients currently counted with the selected vital.

Hospitalization time

Displays a graph of the length of stay (in days) and the number of patients that stayed for each number of days.

Prioritized patients

Displays all patient who currently have an Early Warning Score (EWS) rank of medium or high risk. Patients are listed according to their score from high to low. For every patient at risk current vitals (HR, SPO2, RR, Temperature and BP) will be presented as well as the EWS. Vital contributing to the EWS count are highlighted.

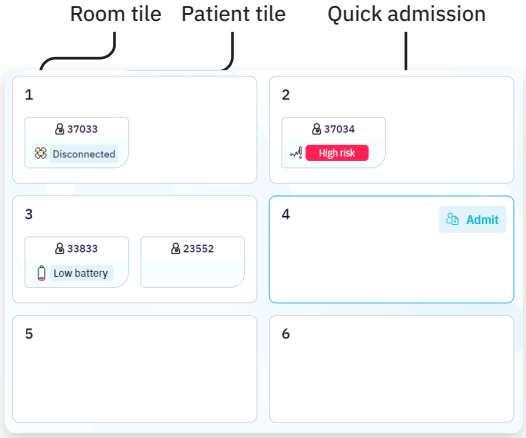
Prioritized patients module

Rooms view

The Rooms view displays all patients currently admitted to the active department in the context of their assigned rooms. For every patient, the screen will alert on the following status:

- EWS status
- Low battery status
- Disconnected status

If a patient has none of these alerts, the patient tile will be empty.



Rooms view tiles

Quick patient admission

When in rooms view, quickly admit a patient to as specific room by selecting the “Admit” button found on the top right corner of a selected room tile (see **Chapter 4.3 Patient admission).**

Shift Reports

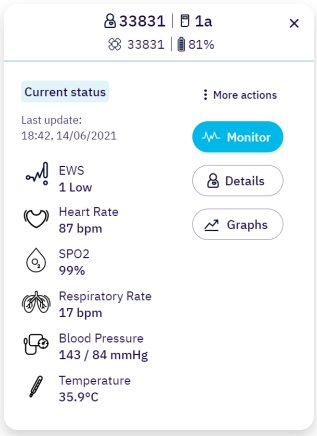
The Shift reports button is located on the top right of the department management screen. For additional information regarding production and viewing reports, see **Chapter 4.11 Shift Reports**.

Patient Quick-view

The quick-view window will be displayed when selecting a patient anywhere in the department management screen (dashboard or rooms view).

The quick-view window will show the following information:

- **Patient’s information** - ID number, room, device ID and remaining battery
- **Device status** - Disconnected / Low battery
- Last vital signs measurement - time and values, including the current EWS level
- **Quick access** to Patient’s monitor, Details and Graphs
- **More actions** - as will be described in the Patient’s details section



Patient quick view

4.3 Patient admission

In order to monitor patients' vitals, a patient admission process is required first.

Before admission

1. Have the wrist-monitor or chest-monitor ready for use.
2. Make note of the patient's personal information: weight, height, gender at birth and year of birth.
3. Take a measurement of the patient's pulse and blood pressure. Measurement should be taken using a standard cuff while the patient is sitting and at rest for at least 5 minutes. It is recommended to take 3 measurements and use the average as the baseline value.

Note: The pulse and blood pressure baseline measurement should be taken using regulatory approved medical equipment only. These measurements impact the calibration of the device, and should be as exact as possible.

Starting a Patient Admission Process

1. Start a patient admission process, can be done in one of the following ways:
   - On the sidebar, select **patient admission.**
   - From **Department management - Rooms view**, select "**Admit**" directly from one of the room tiles.
2. Enter the chest-monitor or wrist-monitor device ID.

The device ID can be found on a white sticker at the back of the wrist-monitor face or on the front of the chest-monitor sensor. The serial number can also be scanned using a barcode scanner.

Only unassigned devices can be used when admitting a patient.

Note: Replaced devices are considered as assigned to a patient until the patient is removed from the department and therefore cannot be assigned to a new patient (see **Chapter 4.4 Patient Details View***).*

Admission Process Steps

Room Assignment

Select a room in which the patient will be admitted. This step is automatically skipped if the admission process was initiated via the **Rooms view**.

Personal information

Enter the patient's personal details and baseline values as described below.

All fields are mandatory.

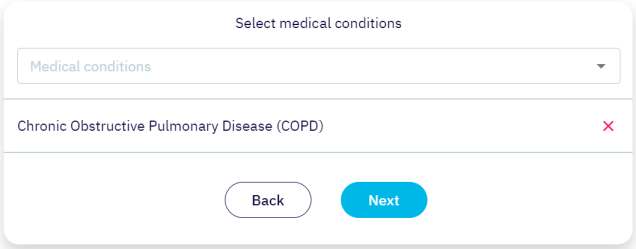
1. Enter the patient identifier. This number is used to pair between the device and the patient. This can be a hospital admission number, a patient's case number, a subject's study number or any other number or name chosen by your organization. Make sure you follow the organization's decision so that this field is uniform between patients.
2. Next, select the patient's gender and type in the year of birth, weight and height as required.
3. Enter the patient's pulse and blood pressure at rest, taken using a blood pressure cuff or arterial line. **Note that the baseline measurement can be modified at any time if required. Keep in mind that this data impacts the accuracy of measurements taken using the sensors, and therefore should be as exact as possible.**
4. Measuring Mode - select the measurement frequency of the device.
5. Select Next to advance to the next screen.

Note: The measurement frequency impacts the device battery life. The measuring mode can be changed at any stage. In urgent mode the battery life will last for 20-24 hours. In normal mode the wrist-monitor battery will last for up to 3 days and the chest-monitor battery will last for up to 5 days. In Long hospitalization mode (every 15 minutes) the chest-monitor and wrist-monitor batteries will last for up to 6 days.

Medical Conditions

Any diagnoses the patient has may be entered at this stage, solely for convenience of the healthcare team. If there is not a need to have this information listed in the Biobeat system, this stage can be skipped.

1. Click the 'Medical conditions' text field and type in information about the patient's current or previous medical conditions.
2. Options will auto populate in a drop-down list while typing.
3. Select the appropriate condition from the drop-down list.
4. Repeat steps 2+3 as necessary.
5. Click Next to advance to the next screen.

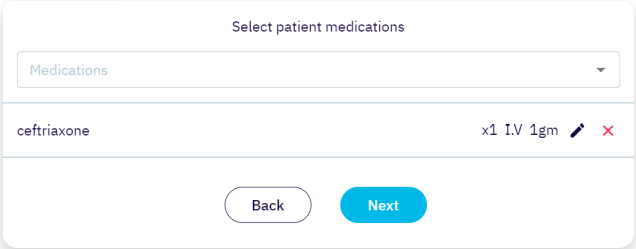


Medical conditions selection

Medications

Any medications the patient is taking may be entered at this stage, solely for convenience of the healthcare team. If there is not a need to have this information listed in the Biobeat system, this stage can be skipped.

1. Click on the 'Medications' text field.
2. Type in any medications the patient is taking.
3. Options will auto populate while typing.
4. Select the appropriate medication.
5. Several drop-down options will appear.
   - **Route** specifies the route of administration of the drug.
   - **When** specifies the time of administration 'Morning', 'Evening', or 'Night'.
   - **Select the dosage units in the 'Unit' field.**
   - Enter the dosage in the field '**Dosage**'.
6. Click Add when finished.



Medications selection

Vitals' Threshold Alerts

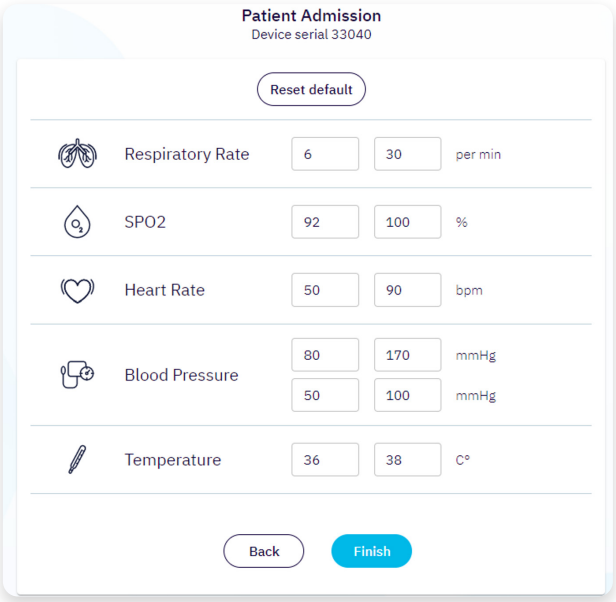
An alert will be triggered every time a vital is measured above or below a set threshold.

The default thresholds that appear are predefined by the system admin. The thresholds can be customized for each patient that is admitted and can be changed at a later stage.

An alert can be set to the following vitals: Respiratory Rate, SPO2, Heart Rate, Blood Pressure, and Temperature.

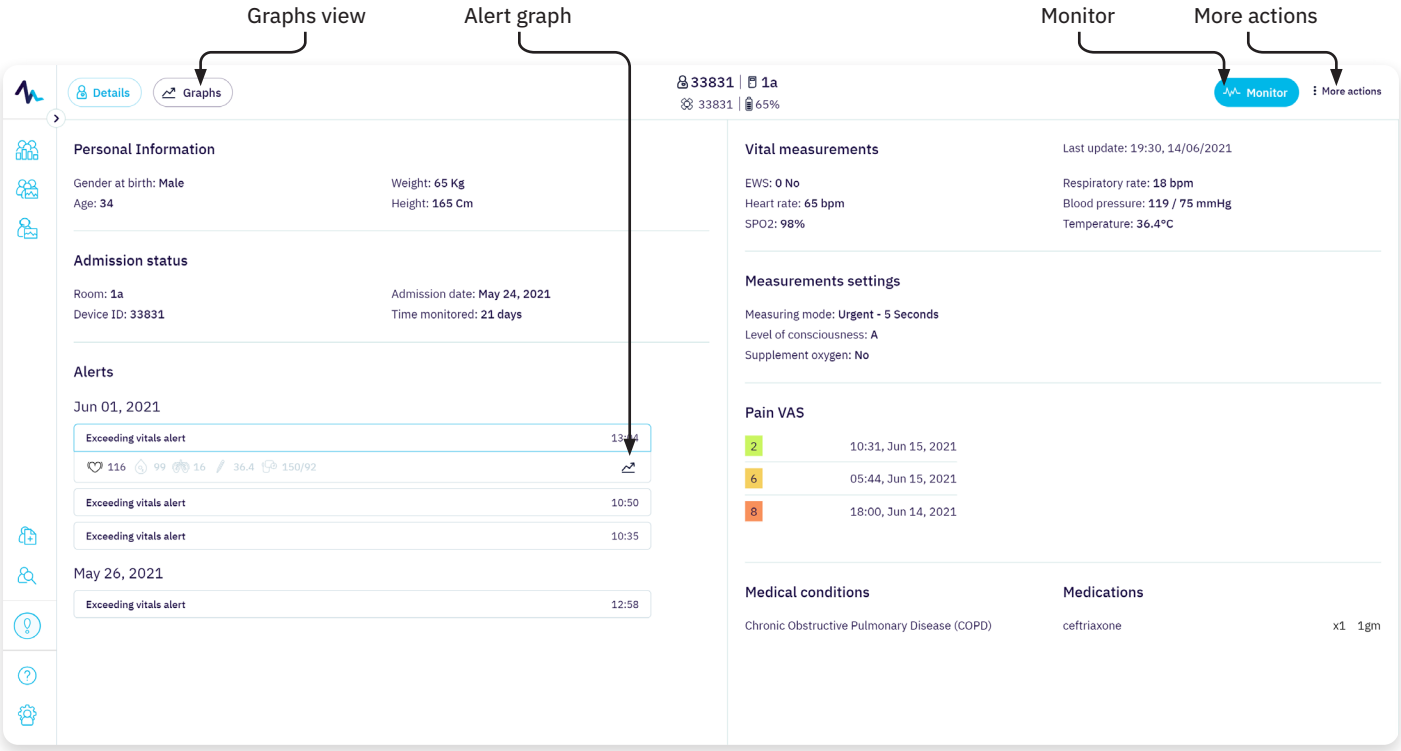
Note: The alert thresholds should only be changed by a medical professional after considering the outcomes.

1. Change the low and the high threshold values for each of the vital signs, as needed.
2. Click Reset Default at the top of the screen in order to return to the default thresholds set by the admin.
3. Press the "Finish" button to finish the patient admission process.



Vitals threshold settings

4.4 Patient Details View



Patient details view

The patient details view shows the patient's medical and personal information.

The patient details view also enables editing the patient's admission information, and perform actions such as transferring the patient between rooms, replacing the device and discharging the patient.

Graphs

The Graph button will switch the page to graphs view, displaying trends and past measurements of each of the patient's collected vital signs, in different time resolutions such as hour, day and several days (See **Chapter 4.5 Patient Graphs View**)

Monitor

The Monitor screen displays the patient's vital signs in real time and is accessible from the **Monitor** button on the top right of the screen (see **Chapter 4.6 Patient Monitor**)

Personal information

Displays the personal demographics as entered during the admission process. This information can be edited (see **"Edit admission"**).

Admission Status

Displays the patient's current room assignment, device number, first admission date and total monitoring time (number of days between the first and last measurements taken).

Room assignment can be changed at any time (see **"Patient transfer"**).

Alerts

Displays a list of the patient's past recorded alerts in chronological order (See **Chapter 4.10 Patient Alerts**).

Press the alert in order to view the patient vitals at the time when the alert was triggered. The exceeding vital/s which triggered the alert are highlighted.

To view an hourly graph at the time when the alert was triggered, press the Graph button on the right.

Vital Measurements

Displays patient's last vital signs measurements.

Measurement Settings

Displays the current measuring mode (measuring interval), and patient's status for EWS calculation (level of consciousness and supplement oxygen).

In order to change the EWS settings, select EWS settings in the **More actions** menu, then select patient's Level of consciousness and supplement oxygen status.

Pain VAS Rating

In order to add Pain VAS rating, select the Add VAS rating in the More actions menu, then select the relevant score and the time when it was taken.

Medical Conditions and Medications

Displays the personal medical conditions and medications as entered during the admission process. This information can be edited (see "**Edit admission**").

More Actions

On the top right of the screen, select more options in order to access the following settings and actions:

- Edit admission
- Replace device
- Patient transfer
- Print
- EWS settings
- Add VAS ratings
- Remove patient

Edit admission

Change patient's details, known medical conditions, medications and alert thresholds by selecting the relevant fields and updating the current admission information.

Note: Remember that the measurement mode impacts the device's battery life.

Note: When editing the pulse and blood pressure baseline, enter data taken only while using authorized medical equipment. This baseline impacts measurement accuracy, and so it should be as exact as possible.

Once the information is updated, select "Save changes".

Replace Device

This function is used when a new device is being assigned to the same patient, for example when a chest-monitor's battery runs out and the patient needs to keep being monitored. It enables the history and settings to be transferred seamlessly to the new device.

After selecting **Replace Device**, type in the new device ID and then click **Replace Device** to confirm.

If the device is a chest-monitor:

1. Remove the old sensor from the adhesive unit on the patient's chest and replace it with the new one. Make sure it is fully attached and that all 4 plastic clips are fastened around the new sensor.
2. If the old adhesive unit is removed from the patient, attach a new adhesive unit according to the steps in **Chapter 3.2 Biobeat Chest-monitor.**

Patient Transfer

If a patient is transferred to a different room or department, this function is used to simply change rooms for the patient in the system.

1. Click on **Patient transfer.**
2. Select a Department.
3. Select the new room number for the patient to be assigned to.
4. Press **Change room** to confirm the change.

Print

The print function generates a patient's health record summary, including his admission information and recent measurements taken.

Remove Patient

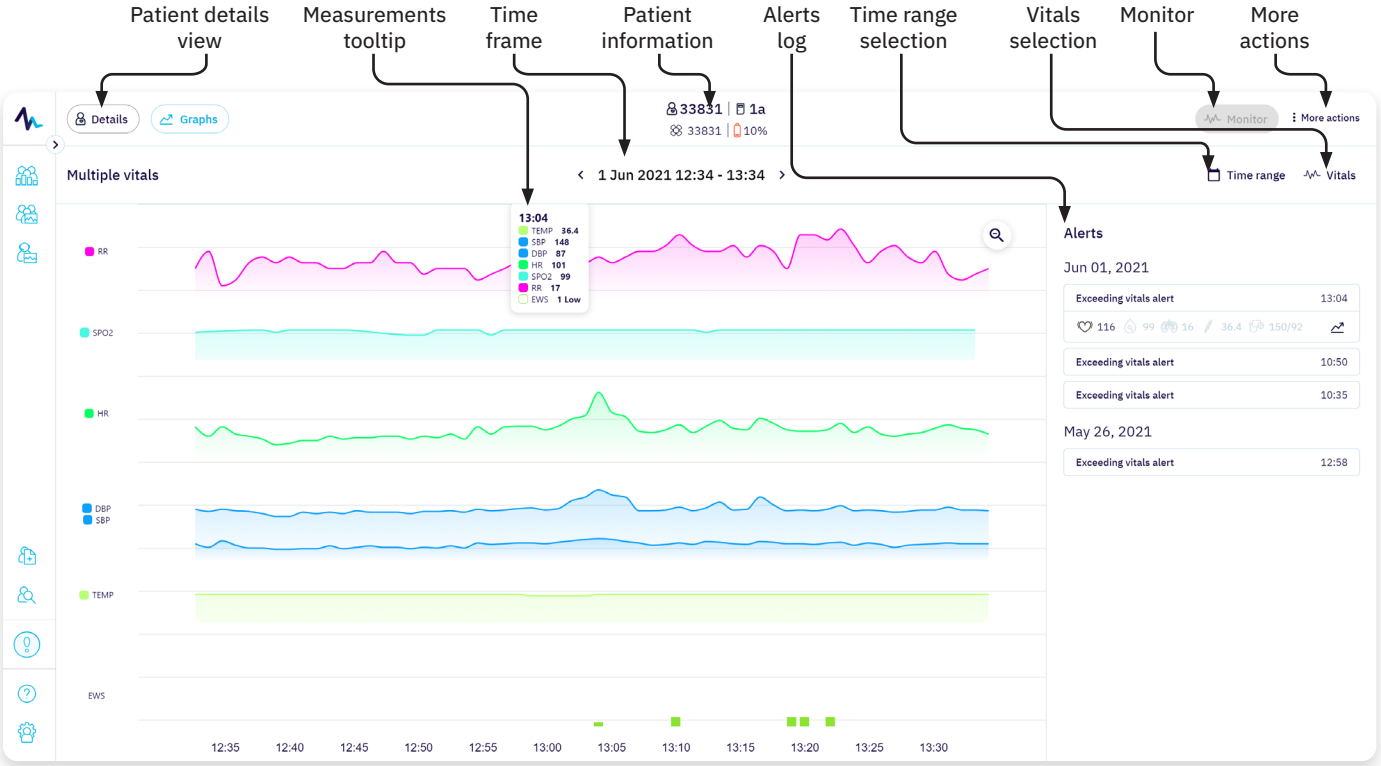
This function is used in order to delete a patient from the system, for example, when a patient is discharged.

Select Remove Patient and select confirm on the pop-up message to delete the patient from the system.

Note: Once patients are removed, their medical history and measurements will no longer be available to the user. All data will still be saved in the Biobeat Cloud.

After patient is removed from the system, an automatic health record summary report will be generated.

4.5 Patient Graphs View



Patient graphs view

The Graphs section enables viewing measurement history and trends, segmented by hourly and daily time frames.

In order to access patient graphs:

- In the **Patient Details** view or patient quick-view → click on Graphs.
- In the **Patient lookup** windows → select a patient → click on **Graphs.**

Time range selection:

1. Select the Time range button on the top right of the page.
2. Select a day from the calendar for a daily view. To view a specific hour, press the **Hour** button, choose a time and press **OK**. To quickly jump to the current time, use the **Current hour** or the **Today** shortcuts.
3. Use the left and right arrows in order to move the time frame forward or backward.

Selecting a specific point on any graph will pin the tooltip showing all vitals measured at the selected time.

Press the magnifying glass (+) button in order to switch from a daily view to an hourly view for the selected time. Pressing the magnifying glass (-) button in hourly view will switch back to a daily graph view.

Vital presentation selection

As a default, a multiple vitals view will be displayed when entering the graphs view. Multiple graphs view includes temperature, blood-pressure, heart rate, SPO2, Respiratory rate and EWS view together on the same time scale.

To change between multiple vitals view to a specific vital graph view:

1. Select the Vitals button on the top right of the graphs page.
2. Select Single graph.
3. Select a vital to view its graph.

Single graph will show only the selected Vital requested and the EWS graph. When Heart Rate is presented, and ECG graph will be shown as well.

ECG graph

An ECG graph will be presented in the heart rate graph's hourly resolution. A 10 second strip of an ECG graph is displayed when a single point on the heart rate graph is selected. Clicking and sliding left and right on the ECG graph will show next and previous segments of the ECG signal. The ECG graph contains two minutes of ECG measurements (one minute before and after the selected time point).

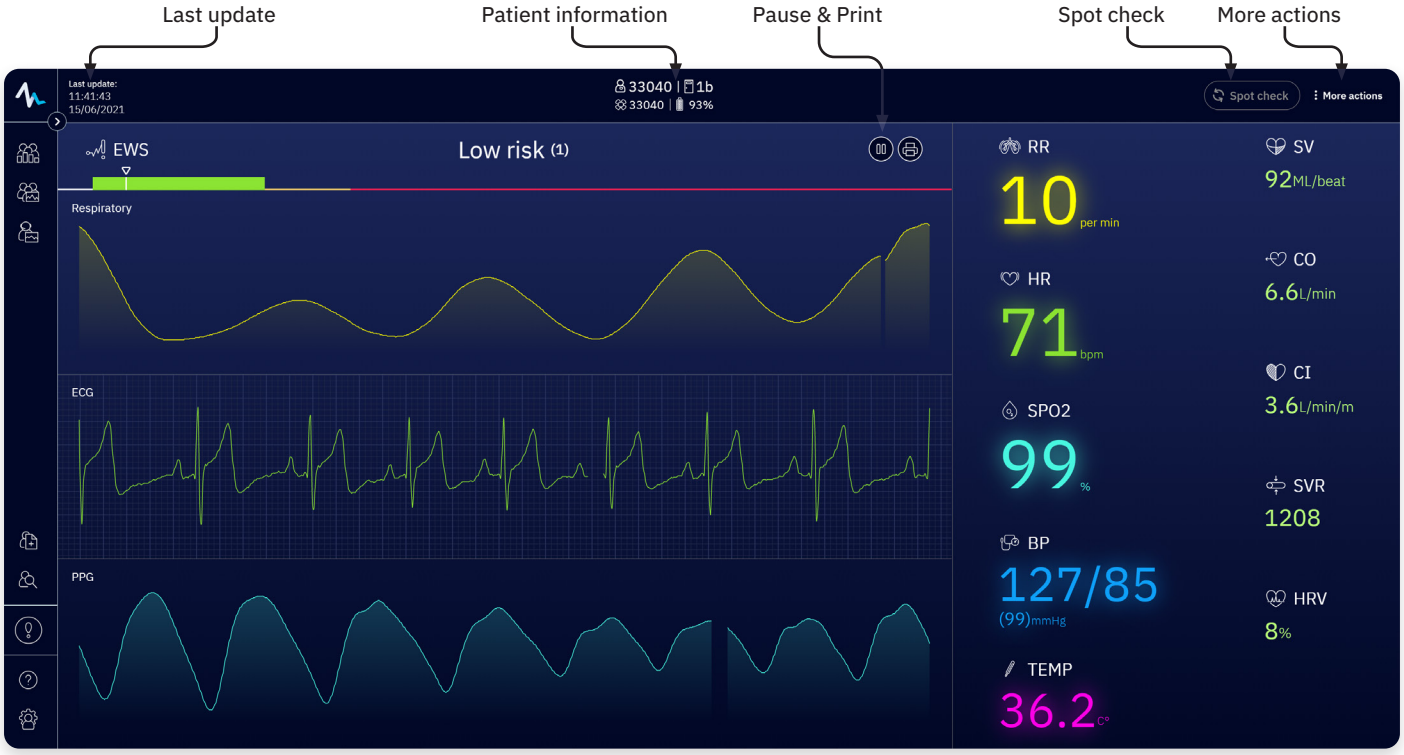
Alerts

Displays a list of the patient's past records (See **Chapter 4.10 Patient Alerts**).

Press the alert in order to view the patient vitals at the time when the alert was triggered. The exceeding vital/s which triggered the alert are highlighted.

To view an hourly graph at the time when the alert was triggered, press the Graph button found right to the alert vitals.

4.6 Patient Monitor



The **patient monitor screen** displays all vital signs measured in real time. When using a chest-monitor device, a one-lead ECG trace, a PPG, and respirations plots are displayed.

Navigate to Patient Monitor screen in several ways:

- Department management screen → Room tile → select the patient's room → select Monitor.
- Department management screen → Patient capacity tile → Patient Lookup → Patient Portfolio → select Monitor.

Vital Signs and Parameters:

The monitor screen shows 10 vital signs and parameters. The parameters presented are:

- Respiratory Rate (RR, rpm)
- Heart Rate (HR, bpm)
- Blood oxygen saturation (SPO2, %)
- Blood Pressure (BP, mmHg)
- Mean Arterial Pressure (MAP, mmHg)
- Stroke Volume (SV, mL)
- Cardiac output (CO, L/min)
- Skin Temperature (°C)
- HRV (Heart Rate Variability, %)
- Systemic Vascular resistance (SVR, dyn x sec/cm^{-5})
- Cardiac Index (CI, L/min/m2)

When the measurement is taken, the vitals will appear in color. In between measurement intervals, or while a device is disconnected the vitals will appear in gray in addition to the timestamp in which the measurements were taken.

Pressing the HR,BP, SPo2, RR and skin temperature will open an hourly graph view for the selected vital.

Early Warning Score

The Early Warning Score (EWS) is an international scoring system used for fast assessment of a patient's severity status. The EWS is found above the live graphs area of the patient monitor. For more information see **Chapter 4.9 Early Warning Score.**

ECG

In cases where the patient is using a chest-monitor device, an ECG graph is displayed above the parameters measured, on a standard ECG grid. This is a one-lead ECG that can be used to monitor heart rate and arrythmias. It does not replace a twelve-lead ECG, and should not be used for definite diagnosis of ECG abnormalities (as in any other one-lead ECG).

The ECG signal strength is indicated by color:

- A good ECG signal will be displayed with a green graph.
- A poor ECG signal will be displayed with a gray graph. If the signal continues to be poor for over one minute, the ECG will disappear.
- When a predefined heart rate threshold is exceeded, the ECG graph will be colored red.

Functions enabled:

- Select the **Pause** "⏸" button beside or under the ECG title to freeze the ECG frame. The ECG will be frozen until the play "▶" button is clicked, or spot check function is selected.
- Select **Print** "🖨" to download a PDF file of the last minute of an ECG recording on an A4 sheet with a standard grid. This page can be printed.

Patient information

The patient's information is presented on the top of the screen. This includes the device type (chest-monitor or wrist-monitor), device serial number, patient identifier, room number, and battery status.

Spot Check

The spot-check button appears on the top left of the screen. This enables a measurement on demand of all vital signs and parameters and changes the measurement frequency to Urgent (once every 5 seconds) for a period of two minutes. After two minutes the measurements interval will return to the defined measurements interval.

Note: The spot check button will only be available for devices connected to a gateway box. For mobile phone connected devices, this button will be grayed out.

More Actions

Press the more actions menu on the top right in order to edit the patient alert thresholds and change the EWS settings (consciousness level and supplement oxygen).

Monitor Alerts

When a vital threshold is exceeded, the corresponding vital sign will be colored in red. If the Heart Rate threshold is exceeded, ECG graph will be colored in red, accordingly (for vital threshold settings see **Chapter 4.3 Patient admission**).

Alert notifications

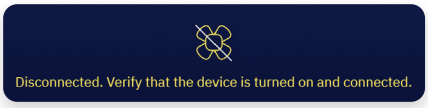
When viewing a patient's monitor, alert notifications window for the viewed patient will be silenced (will not be displayed on top of the monitor screen).

Device issues messages

When a device is unable to perform measurements, a device issue message will appear, describing the cause for the paused monitoring.

Device Disconnected: This message will be displayed when there is no connection between the cloud and the device, causing a pause in the data stream.

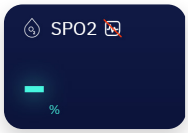
This could be due to several reasons, such as an issue with the device, the connection between the device to the gateway/ phone application, or connection between the gateway/phone application and the cloud. See **Chapter 7 Troubleshooting**)



Bad reading: This message will be displayed when a good Bluetooth connection between the gateway/app and the device is maintained, but the vitals readings are poor. This means there are no vitals being measured.

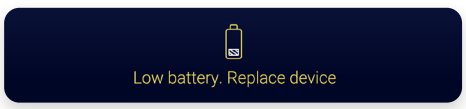
Poor reading: A poor reading can lead to having only some vital signs missing. Breathing rate and SPO2 are more sensitive vitals, and may not be displayed if the patient is speaking or moving too much, or if the device is not positioned correctly. In these cases a "" icon will be displayed next to the SPO2 or RR measurements.

This issue can be resolved by repositioning the device or changing the adhesive unit if a chest-monitor is being used. See **Chapter 7 Troubleshooting** for further instructions.



A bad reading SPO2

Low battery: The patient monitor screen will display this message if the device has been turned off and the last battery status was less than 5%. This device serial number will also be listed in the device issue module tile in the Department Management screen.



ECG not available: This message will be displayed when there is an issue with the ECG reading. This issue can be usually resolved by checking that the device is properly connected to the adhesive unit and attached properly to the patient.

4.7 Department Monitor

Department report screen

The **Department Monitor** allows users to view several patient monitors simultaneously. Each user can customize and control the patients viewed on the department monitor. The information and measurements presented are similar to those in the **patient monitor screen.**

The top row of each patient tile will display the device serial number, patient identifier, device battery level, room number, and the date/time of the last vital measurement. Pressing the patient information box will lead to the patient details page.

Using the Department Monitor

Enter the department monitor from the menu on the left side of the screen.

Adding patients:

1. Click Add Monitor on the top right of the screen to add patients to the screen.
2. A list with all patients admitted to the department will be displayed. Patients already added to the department monitor, will not appear in the list.
3. Click on the Patient row to add the patient to the Department Monitor screen.

Spot check

The spot check function on the department monitor works the same way as on the patient monitor screen. Similar to the patient monitor, the spot check button is only available for devices connected to a gateway box.

In order to initiate a spot check, press the "" button that appears on the top right of a patient monitor

ECG view

The ECG shown on the department monitor is similar to the ECG shown on the patient monitor screen. In the department monitor screen, the ECG is presented on a black background (with no grid) and the freeze/print buttons are not available.

Device issues messages

The same device issue messages presented on the patient monitor screen will also appear on the department monitor screen: device disconnected, bad reading, ECG not available and low battery. For instructions to address these notifications see **Chapter 7 Troubleshooting**.

4.8 Telemonitor

The Telemonitor screen is aimed for the use of telehealth centers and allows monitoring an entire department in a single view. This screen includes of a minimized version of a patient monitor for all patients assigned to the active department.

Each patient monitor includes the following information:

Patient info

- Patient ID
- Device ID
- Room Number
- Battery status

Live vitals

- Heart rate
- Skin temperature
- Blood pressure
- Blood oxygen saturation
- Respiratory rate
- EWS score

The viewed patients are automatically updated when a new patient is assigned to or dismissed from the department.

Note that the number of displayed patients in a single view depends on the displayed device screen resolution, window size and browser zoom level. Viewing additional patients can be done by scrolling or changing the browser zoom level.

4.9 Early Warning Score

The Early Warning Score (EWS) is an international scoring system used for fast assessment of patient's state of severity, giving the medical team an "early warning" indicating of a patient's potential for deterioration. The EWS is calculated based on vitals including: respiratory rate, SPO2, systolic blood pressure, heart rate and temperature.

The EWS also takes into account whether the patient is receiving oxygen supplement and the patient's level of consciousness. These two parameters are entered manually into the patient management app in order to calculate the EWS and the patient's risk level.

Monitor alerts

For patient with vitals exceeding the pre-selected thresholds both the monitor and the exceeding vitals will be colored in red as well as patient with medium/high EWS.

Device issue messages

Device issue messages are shown in an abridged format for the following issues:

Disconnected - monitor border will be colored yellow.

Low battery - monitor border will be colored yellow.

Bad vital readings - monitor border will be colored red.

Prioritized button

Pressing this button reorganizes the patients according to the following order:

- Patients with medium or high EWS ratings.
- Patient with exceeding vitals.
- Patients with device issues.
- Patients with no alerts.

Alerts only toggle

Enabling this toggle, hides all patients with normal status (no exceeding vitals alerts and no device issues). This view is updated automatically when a patient goes in/out of an alert status.

Calculation chart

The Early Warning Score is calculated according to the following chart:

Physiological parameters	3	2	1	0	1	2	3
Respiratory rate (BPM)	≤8		9-11	12-20		21-24	≥25
Oxygen saturation (%)	≤91	92-93	94-95	≥96			
Any supplemental oxygen		Yes		No			
Temperature (°C)	≤35		35.1-36.0	36.1-38.0	38.1-39.0	≥39.1	
Systolic blood pressure	≤90	91-100	101-110	111-219			≥220
Heart rate (BPM)	≤40		41-50	51-90	91-110	111-130	≥131
Level of consciousness				A			V, P or U

Risk level

The risk level is determined according to the calculated score:

- Low risk: 0-4
- Medium risk: 5-6 or single vital with a score of 3
- High risk: 7-20

Viewing the score

The EWS is calculated continuously while the patient's measurement are taken and can be viewed either live in the patient monitor, department monitor and telemonitor or by viewing the patient file views (patient details and graphs). In addition, patients with medium or high EWS are highlighted in the prioritized patients module found in the department dashboard view or the patient tiles in the rooms view .

Clicking on the EWS label on the patient monitor screen or on the department monitor screen will open the Early Warning Score screen.

The EWS screen enables the following:

4. Viewing a patient's current EWS and risk level.
5. Viewing the vitals used in order to calculate the EWS, marked on the chart.


EWS score index

Physiological parameters	3	2	1	0	1	2	3
Respiratory rate (BPM)	≤8		9-11	12-20		21-24	≥25
Oxygen saturation (%)	≤91	92-93	94-95	≥96			
Any supplemental oxygen		Yes		No			
Temperature (°C)	≤35		35.1-36.0	36.1-38.0	38.1-39.0	≥39.1	
Systolic blood pressure	≤90	19-100	101-110	111-219			≥220
Heart rate (BPM)	≤40		41	51-90	91-110	111-130	≥131
Level of consciousness				A			V, P or U

Low risk 0 1 2 3 4 | Medium risk 5 6 or single vital at 3 | High risk 7 8 9 ... 20

EWS chart

Changing the EWS patient settings

Changing the patient EWS settings for whether the patient is receiving oxygen supplements and the patient's level of consciousness can be done using the "More actions" menu found in the patient file screen, patient monitor or the department monitor.

- In order to change the oxygen supplement parameter, select "Yes" or "No" according to patient's status. The default value is "No".
- In order to change a patient's level of consciousness select A (alert) or V/P/U (verbal/pain/unconscious). The default value is "A".

4.10 Patient Alerts

An alert is triggered when a set of predefined conditions are met. For some alerts these conditions are set for all admitted patients in the department while other alerts can be defined individually per patient.

The following alert types are available when using the web management app:

Low battery – Triggered when a device's battery goes below 5%.

Suspected patient deterioration – Triggered when a patient EWS changes from low to medium or from medium to high.

Exceeding vitals – Triggered when a patient's vitals exceed the vital thresholds set for the patient (see **4.3 Patient admission**).

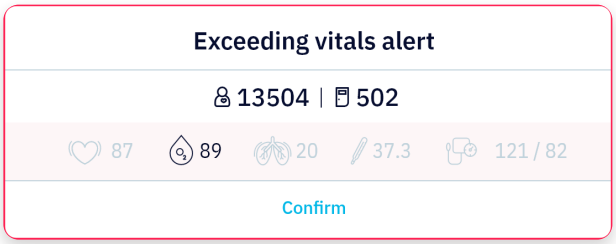
Custom alerts – A specific set of predefined conditions can be set to trigger a custom alert (e.g. HR above 100 bpm and RR above 25 bpm). These types of alerts can defined by a system admin.

When an alert is triggered, it will be presented as follows:

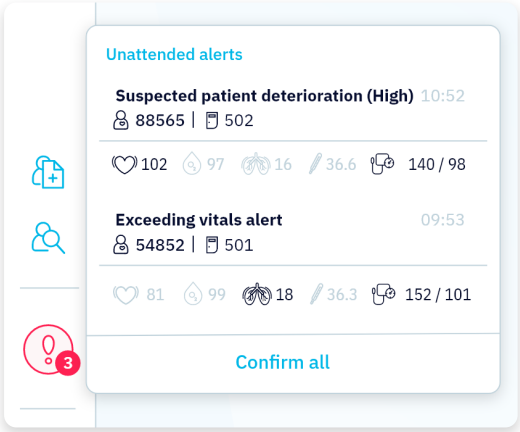
1. A notification popup will appear on the top of the screen, displaying the heart rate, respiratory rate, temperature, blood pressure and blood oxygen saturation. The vitals causing the alert trigger will be highlighted.
2. The notification popup can be confirmed by pressing the confirm button, otherwise it will be automatically hidden after 10 seconds. Unattended alerts will be aggregated and highlighted in the notification center (found in the sidebar) to be reviewed and confirmed at a later time.
3. On the patient file screen, under the alerts section, the alert will be logged including the following vitals - heart rate, respiratory rate, temperature, blood pressure and blood oxygen saturation. Vitals which caused the alert to be triggered will be highlighted. These alerts will remain in the alert log after the vital has returned to normal range.

Note: device battery alert will not be logged to a patient's file.

Note: Alerts triggered based on a patient's measurements may change the device's measuring mode to 5 seconds for a short time to validate whether the set conditions were not met only momentarily.

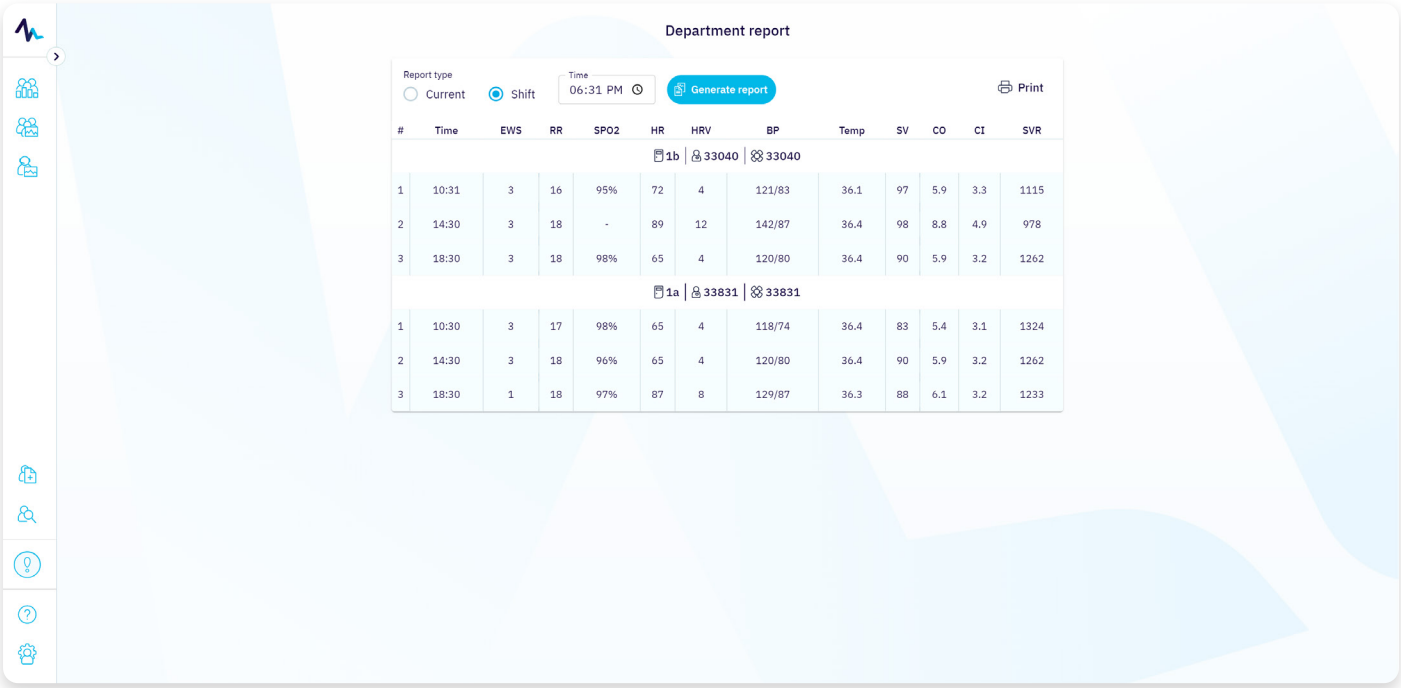


Alert notification popup



Notification center with unattended alerts

4.11 Shift Reports



Department report screen

The report system allows the user to produce, view, print and export reports including vital measurements and patient history.

Producing Shift reports

1. From department management screen, select **"Shift reports"** on the top right.
2. Select one of the two available report types:

- Department
- Medications

Department Report

The Department Report will list measurements for each patient at a specific time or during a shift.

Current report - Generating a **"current"** report will show the last good measurement for all admitted patients in an eight hour period from current time.

Shift report - Generating a **"Shift"** report will show up to three measurement throughout an eight hour period (start, middle and end of the shift).

The shift end time can be selected by changing a different time.

The report includes:

- Device serial number
- Patient identifier
- Room number
- Measurement time
- EWS score
- Respiratory rate (BR)
- Blood oxygen saturation (SPO2)
- Heart rate (HR)
- Heart rate variability (HRV)
- Blood pressure (BP)
- Temperature (Temp)
- Stroke volume (SV)
- Cardiac output (CO)
- Cardiac Index (CI)
- Systemic Vascular Resistance (SVR)

Select **"Print"** to download a PDF version of the generated report.

Medications Report

The Medications Report lists all of the medications that need to be administered during the requested shift (morning, evening or night). The Medications Report lists:

- Device serial number
- Patient identifier
- Room number
- Medication
- Method (of delivery)
- Quantity

Chapter 5 Mobile Applications

5.1 Biobeat remote monitoring application

The Biobeat mobile applications enables remote monitoring of patients with the Biobeat wrist-monitor and chest-monitor. The apps transmit all measurement data to the web platform, where it can be viewed and managed.

Download Biobeat monitoring apps

1. Enter the App Store/Google Play store on your mobile phone.
2. Download and install the Biobeat monitoring application according to the device in use (wrist- or chest- monitor).

Turn on the Biobeat monitoring device

Turn on your Biobeat wrist-monitor or chest-monitor before trying to connect to the app.

1. In case the wrist-monitor is used, make sure the device is fully charged.
2. Press and hold the center key for 2 seconds in order to turn the device on.

Pair Your Device

1. Open the Biobeat app on your mobile phone.
2. Read and approve the terms of use provided upon opening the app.
3. Make sure the phone's Bluetooth function is enabled.
4. You may be asked to enable location services for the app. This is important as the pairing process cannot be completed otherwise.
5. Tap connect to search for your device.
6. The app will find your device according to its serial number (located on the white sticker on the back of the device).
7. Select your device serial number in order to pair it with your app.
8. The pairing process will be completed.

Renaming your device

You can rename your device. Select a new name, then press save.

Using the app

Now that your device is paired to the app, you can view the monitor connectivity status at any time.

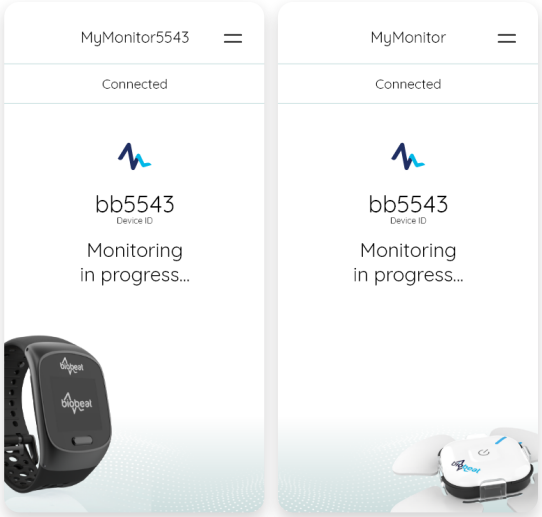


Figure 18- Mobile Apps display

Verifying your data is being synced

In order for all device data to be synced with the web platform, it is important to verify connectivity of the device with the mobile app and the app with the data cloud.

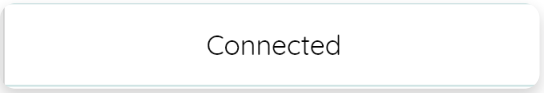
Wrist-monitor connectivity indication

When your wrist-monitor is connected to the app there will be a circle around the Bluetooth icon on the device's screen.

Every so often, you should verify connectivity to the app by noting the circle around the icon.

Device connectivity indication

On the top section in the main screen of the home care application an indicator will show the connection status between the monitoring device and the phone application.



Connected - the device is connected to the app.

Disconnected - the device is turned off or disconnected from the app. In this case, make sure the device is on and the phone's Bluetooth is enabled. If the problem persists, see troubleshooting.

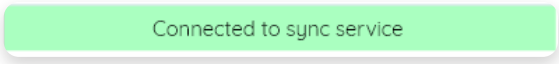
Cloud connectivity indication

Below the device connection status, an indicator will show the connection status between the phone application and the cloud.

No network connection - The phone is disconnected from the Internet..

Connecting to sync service... - The app is attempting to connect to the cloud

Connected to sync service - The app is connected to the cloud. This indication will disappear two seconds after establishing connection to the cloud.



Make sure to keep your phone charged and in proximity while wearing the wrist-monitor or chest-monitor. The app will run in the background on your phone, so that the data is continuously transmitted through the app to the cloud.

When restarting a device or your phone, make sure the app is still connected.

Chapter 6 Biobeat Smart Gateway Box

6.1 Description

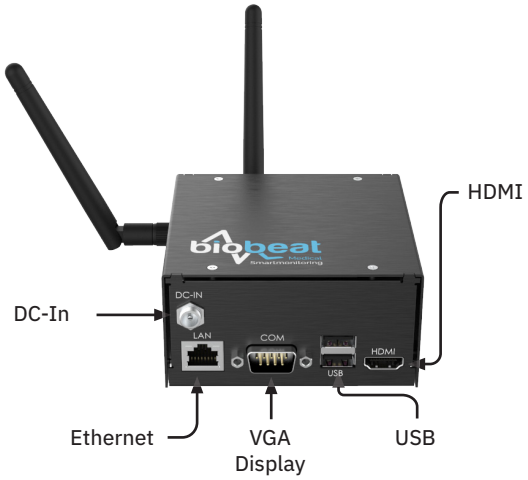
1. The Gateway is a hardware device that connects to The Biobeat chest-monitor or wrist-monitor via Bluetooth Low Energy (BLE), receives collected data, and then uploads the data to the Biobeat cloud.
2. Each Gateway can connect to up to 5 devices at once. The maximum range for connection is 10-12 meters/30 feet (a standard BLE range).
3. When on, the Gateways automatically recognize and connect to Biobeat devices that have been switched on. The devices connect to the Gateway with the strongest connection. If a patient is moving through the facility with a Biobeat device, the device will continuously disconnect and reconnect to the Gateway with the strongest connection. There is no relation between room numbers as defined in the web platform and between Gateways that are assigned to certain rooms; the devices will connect to any gateway, regardless of its room and the device's room assignment in the web platform.
4. The gateway must be connected to a UPS-powered outlet.

- In the event of a power failure, there is no communication
- During a power outage, the device stores up to 3 hours of data.
- When the electricity is renewed, the communication is automatically renewed and all the data is sent to the cloud.

Note: If a device is not connected to any Gateway, it will store the data collected internally for a period of time and will push it all to the cloud through a Gateway once the connection is regained. This can only happen if a device has previously been connected to a Gateway.

Biobeat uses two types of Gateways, both with similar function and operation. The Gateways differ from one another in appearance, port connections and Sim card insertion.

Ports



Smart Gateway Box Gen 1

Gateway Gen 1 has the following ports:

1. Power cable- connects to DC inlet.
2. Net cable- port for connecting LAN internet cable.
3. USB*2: ports for keyboard and mouse.
4. VGA and HDMI: ports for connecting a screen.

Smart Gateway Box Gen 2

Gateway Gen 2 has the following ports:

- Power cable- connects to DC inlet.
- Net cable- port for connecting LAN internet cable.
- USB*4: ports for keyboard and mouse.
- Mini-HDMI*2: ports for connecting a screen.

6.2 Set Up

Setting up the Gateway is required in order to use the Biobeat chest-monitor solution. Set up means connecting the Gateway to Internet and power.

Note: The next steps will take you through the full set up and use of the Gateway. If you are using a Gateway that has been supplied to you with an Internet connection already (such as an internal SIM card), all that is required is connecting the Gateway to an electricity port.

Setting up the Gateway:

1. Screw each of the antennas into place (each will only connect to its correct port):
2. Connect the Gateway to the electricity through the DC-In port.

Connecting to the Internet:

The Gateway requires a fast and stable Internet connection. The Internet connection can be established through a SIM card, Wi-Fi connection or Ethernet cable.

1. SIM card- Gateway Gen 1.
   a. Purchase a micro SIM card with data, 1GB of data per month is sufficient. Ensure the SIM card is activated before use.

Note: In the United States, activating the sim card requires the Gateway's IMEI number. The IMEI number is printed on the side of the Gateway (see "Identify IMEI number").

   b. Unscrew the Gateway's screw (marked in the photo below) in order to open the Gateway's SIM cell (Make sure the Gateway is disconnected from the electricity at this point!).

   c. Open the SIM tray cover by sliding it in the "open" direction (to the right if the Gateway is positioned as

in the photo below).

d. Insert the sim card facing down in the appropriate location and slide the SIM tray cover closed.

e. Screw back the Gateway's screw in order to close the Gateway's SIM cell (Make sure the Gateway is disconnected from the electricity at this point!).

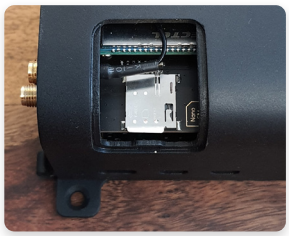
SIM card- Gateway Gen 2:

a. Purchase a micro SIM card with data, 1GB of data per month is sufficient. Ensure the SIM card is activated before use.

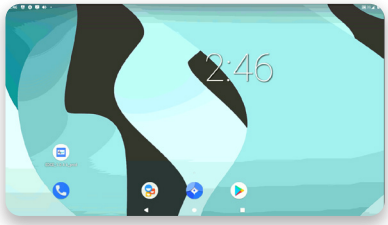
Note: In the United States, activating the sim card requires the Gateway's IMEI number (see "Identify IMEI number").

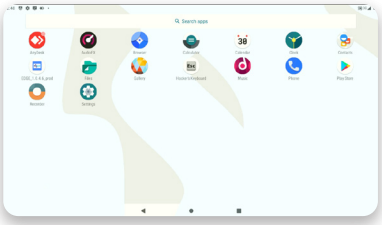
b. Open the SIM tray cover by sliding it in the "open" direction (to the right if the Gateway is positioned as in the photo below).

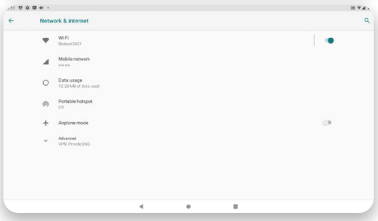
c. Insert the sim card facing down in the appropriate location and slide the SIM tray cover closed.



2. Ethernet cable:
   a. Connect a network (Ethernet) cable to the Gateway's LAN port and to a local internet outlet. Make sure the internet FireWall ports in the facility are open for the use of the app.
3. Wi-Fi:
   a. The Gateway has an Android operating system.
   b. Connect the Gateway to a monitor using an HDMI/ VGA cable.
   c. Connect a mouse to the Gateway through a USB port.
   d. Access the **Settings** panel and navigate to the Wi-Fi: Menu → Settings → Wi-Fi options → Turn Wi-Fi on → connect to the required network (connect a keyboard to the other USB port to type in a password if needed).





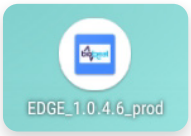


Set date and time (only during the first setup)

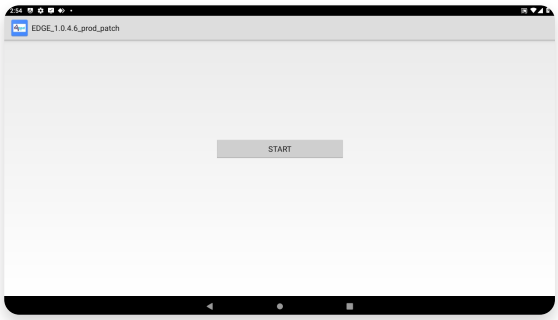
1. Open the system's Settings (see instructions above).
2. Select System. Enter Date & Time.
3. Select the appropriate time zone.

Operate the Biobeat Edge App (only during the first setup)

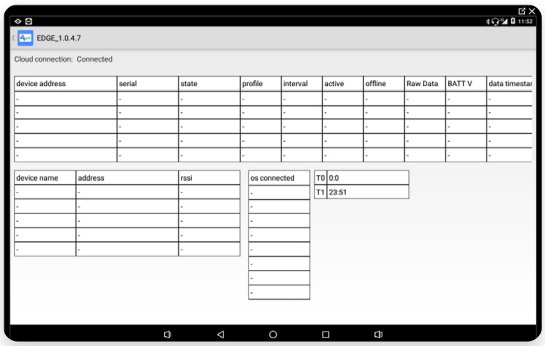
1. Open the **Menu** → **Edge**



2. Press Start.



3. Make sure the Edge application is running. The following screen will appear:



4. Disconnect the monitor and the mouse from the Gateway.

Identifying the IMEI number

The IMEI number is needed for activation of the SIM card. There are two methods in which you can identify the IMEI number:

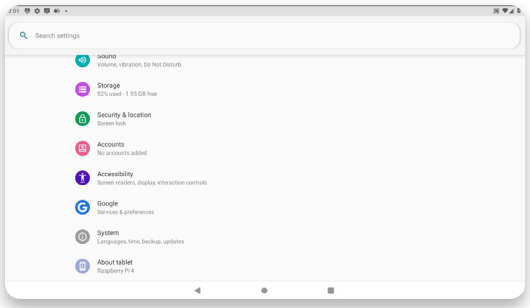
- Physically opening the Gateway (only on Gateway Gen 1).
- Through the software system.

1. Identify the IMEI by physically opening the Gateway (Gen 1):
   a. Make sure the Gateway is disconnected from the electricity.
   b. Unscrew the Gateway's screw (marked in the photo below) in order to open the Gateway's SIM cell.

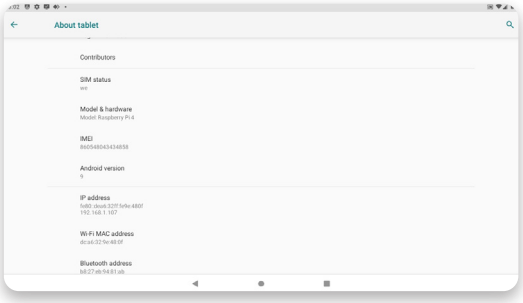
   c. You will see the IMEI number imprinted on the Gateway's modem.

2. Identify the IMEI number through the software system:
   a. Connect the Gateway to the electricity.
   b. Connect the Gateway to a monitor using an HDMI/ VGA cable.
   c. Connect a mouse to the Gateway through a USB port.
   d. Access the Settings panel: Application menu → Settings

   e. In settings, select "About tablet".



   f. Make note of the IMEI number for future use.



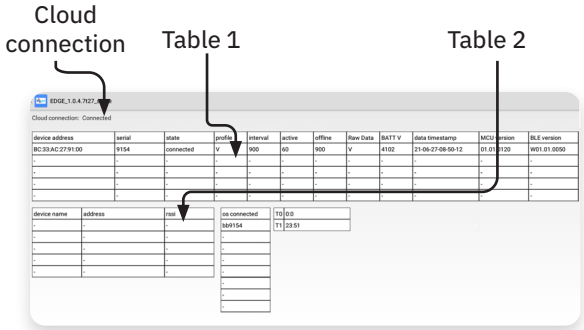
The Gateway automatically connects to Biobeat devices and transmits the data to the cloud, such that there is no need for any specific actions. Make sure the Gateway is connected to the internet, connected to the electricity and located within 10-12 meters/30 feet of the patient.

Note: Connecting a screen display and operating the Edge app is used for advanced troubleshooting only.

6.3 Operation

Operating the Biobeat Edge App:

1. Connect the Gateway to a monitor using an HDMI/VGA cable.
2. Connect a mouse to the Gateway through a USB port.
3. Open the Edge App by accessing the system's **Menu** → **Edge**.
4. The following screen will appear upon opening the Edge App.



5. The screen is divided into three sections:
   a. "Cloud Connection" – Internet connection status (Connected, Disconnected, or Connecting).
   b. Table 1: Active devices. This table will display all active devices that are connected to the Gateway.
      - Serial – Device serial number.
      - State – Connected/Disconnected.
      - Profile - A profile with a baseline is assigned to the device.
      - Interval – Measurement interval in seconds.
      - Active - The measurement duration of each interval in seconds.
      - Raw data - Data transfer type from the device.
      - Offline - Measurement interval when the device is disconnected in seconds.
      - BATT V – Battery status (<2700 = low battery).
      - Data Timestamp – Last measurement uploaded from the Device.
   c. Table 2: Connecting devices. This table displays a device that is visible to the Gateway but is not connected yet.
      - Device Name – Device serial number.
      - RSSI – Device's distance froma gateway (above 90 = the distance is too far, and Bluetooth connection may be affected)

Chapter 7 Troubleshooting

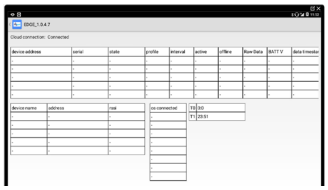
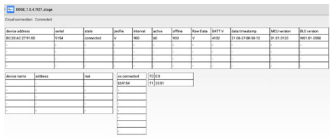
7.1 Wrist-monitor troubleshooting

The wrist-monitor does not charge	1. Make sure the wrist-monitor is attached correctly to the charger- the Biobeat logo on base of the charger should be in parallel to the logo on the Biobeat wrist-monitor. 2. Make sure the cable is connected both to the charger and to the power outlet. 3. Make sure the 8 gold pegs on the back of the wrist-monitor are clean.
The wrist-monitor constantly shows a Bad reading message in the patient monitor screen	1. Make sure the wrist-monitor is properly placed on the wrist and wait 1 minute while resting. 2. Make sure your hand is clean and dry. 3. Reset the wrist-monitor.
The wrist-monitor does not connect to the app	1. Make sure the phone's Bluetooth is on. 2. Make sure the phone's location permissions are enabled. 3. Reset the wrist-monitor.
The wrist-monitor's battery runs out in less than 24 hours	1. The wrist-monitor may be triggering many alerts, and automatically switching to 5 second measuring mode every time an alert is triggered. 2. Contact your supplier in order to verify correct alert thresholds for your user.
The app does not recognize the wrist-monitor	1. Enter the phone Bluetooth menu. 2. Select "forget device" for the Biobeat wrist-monitor. 3. Start the pairing process again (as described in **Chapter 5 - Mobile Applications**).
The wrist-monitor does not measure temperature	Contact Biobeat or your supplier for further instructions.
The strap is broken	
Wrist-monitor heats up drastically	
Wrist-monitor causes skin irritation	Remove the device and consult with a physician.

7.2 Chest-monitor troubleshooting

During 'patient admission' – chest-monitor serial number does not exist	1. Check that the chest-monitor serial number is correct and entered properly. 2. Check that the chest-monitor was not already admitted to the system. 3. When receiving a "device is not activated" message, contact system administrator.
Constant **"bad reading"** message in a patient monitor screen	1. Remove excessive chest hair and be sure the skin is dry by wiping body fluids. 2. Make sure the patient did not shower with or get the chest-monitor wet. 3. Make sure the patient is in seated/supine position and wait for 2 minutes. 4. Make sure the sensor is properly attached to the adhesive unit and correctly positioned. 5. Turn off the device by pressing and holding the button for 4 seconds, then turn the device back on by pressing the power button shortly. 6. Replace adhesive unit. *See **Chapter 3.2 - Biobeat Chest-Monitor** for chest-monitor placement instructions.
"Device Disconnected" alert	1. Make sure the chest-monitor is turned on by checking for the illuminated lights on the back of the device. 2. Check if the patient is within range of the gateway (10 meters/30 feet). 3. Make sure the gateway is activated and connected to the internet. If not, follow gateway troubleshooting. 4. Turn off the device by pressing and holding the button for 4 seconds, then turn the device back on by pressing the power button shortly. When connected using the Biobeat mobile application: 1. Make sure the app is turned on and connected to the device. 2. Make sure the phone's Blutooth is turned on. 3. Make sure the phone's location permissions are enabled. 4. Make sure the phone is connected to the Internet (preferably not through Wi-Fi).
Chest-monitor battery is running out quickly	1. Enter the Patient file. 2. Make sure the sampling rate is not set to Urgent measuring mode (5 seconds). *Sampling interval affects battery life. *Note: When the device is out of the range of the gateway for extended periods of time, it will shorten the battery life of the device.
Chest-monitor is causing skin irritation	Remove the device and consult with a physician.

7.3 Gateway troubleshooting

Gateway does not turn on	1. Make sure DC-in cable is properly connected. 2. Make sure the screen is on and properly connected. 3. Disconnect the gateway from DC-In. Wait 1 minute and reconnect. *If this problem continues, contact Biobeat for further instructions.
Gateway does not connect to the internet when using local operator sim card	1. Make sure the SIM card is activated with the network operator. 2. Open the gateway's SIM cell. Makes sure the sim card is properly inserted. (See **Chapter 6 Biobeat Smart Gateway Box** for SIM card placement instructions.) 3. Disconnect the gateway from DC-In. Wait 1 minute and reconnect. *If the problem continues, contact Biobeat Tech Support for further instructions.
Gateway does not connect to the internet when using Wi-Fi	1. Open the **gateway settings → network → Wi-Fi.** 2. Check the network and password settings. 3. Connect the gateway to the internet using a LAN cable. 4. *If the problem continues, contact Biobeat for further instructions.
Edge App does not appear on the menu screen	1. Click on **Search** from the menu screen. 2. Search for "Edge" app. *If the problem continues, contact Biobeat for further instructions.
Gateway power was cutoff due to power cutoff or power surge	1. Wait until power is restored to its normal state. 2. Wait 1 minute for connected monitors to reconnect.
Chest-monitor is Disconnected	1. See Troubleshooting "Chest-monitor Troubleshooting, Disconnected". After steps 1-3, continue to **Gateway Troubleshooting**, as instructed. 2. Troubleshoot the gateway for a Disconnected Chest-monitor. 3. Disconnect the gateway from DC-In. Wait 1 minute and reconnect. 4. Check Internet Connection (see above). 5. Connect a monitor with an HDMI cable, then connect a mouse to the gateway for advanced troubleshooting. a. Open Android App b. Open the **Menu** c. Connect to the Edge App d. The following screen will appear on the Edge App:  e. If the screen is empty (as shown), the gateway has no connection to the Chest-monitor. i. Check if the chest-monitor is within range of the Bluetooth signal. ii. Be sure the chest-monitor is on. iii. Be sure Bluetooth is enabled on the gateway settings. f. If the chest-monitor number is presented on the screen (as shown below), there is a good connection between the chest-monitor and the gateway. The issue is likely the Internet connection. (**Chapter 6 Biobeat Smart Gateway Box**). 

7.4 Web platform troubleshooting

Forgot username or password	1. Reset password for the Web Platform. 2. If the problem continues, contact the system administrator. 3. If you have forgotten your username, contact the system administrator.

7.5 Vitals troubleshooting

No new vitals data on the monitor	1. Check the time of last measurement on the monitor display. 2. If the last measurement was taken within less than the defined interval time, wait for the next measurement or click on **Spot Check.** 3. If the last measurement was taken a longer time than the defined measurement interval, follow the 'bad signal' troubleshooting in **Chapter 3: Chest-monitor.** 4. If continuous measurement is needed, enter the **Patient Portfolio,** select the pencil icon to edit **Personal Information,** and choose desired sampling interval.
Too many alerts for a patient	1. Enter the **Patient Portfolio,** select the pencil icon to edit Alerts, and choose desired alert thresholds.
No SPO2 displayed	1. Make sure the patient is in a seated or supine position and at rest for 2 minutes. 2. Make sure the sensor is properly attached to the adhesive unit and properly positioned on the patient. 3. Enter the **Patient Portfolio,** select **Graphs**, and view the SPO2 Graph to obtain the last measurement. *The SPO2 is highly sensitive to the location of the device on the patient and to any movement from the patient.
ECG lead does not display properly or displays in grey color	1. Make sure the patient is in a seated or supine position and allow rest without talking for 1 minute. 2. Make sure the sensor is properly attached to the adhesive unit and properly positioned on the patient.
Respiratory rate is not accurate or not measured	1. The respiratory rate measurement displays a running average of 6-8 measurements, therefore this number may update at a slower pace than the rest of the vitals. 2. Make sure the patient is in a seated or supine position and allow rest without talking for 1 minute.

Chapter 8 Legal and warranty

8.1 Manufacturer's Declaration (EMC)

Declaration of Conformity with FCC and Canadian Ministry of Health Rules for Electromagnetic Compatibility

Biobeat declares under its sole responsibility that Model BB-613WP, to which this declaration relates, complies with part 15 of the FCC Rules.

Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Federal Communication Commission (FCC) Notice

This equipment has been tested and found to comply with the limits for a class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy. If not installed and used in accordance with the instructions, it may cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on. The user is encouraged to try to correct the interference by one or more of the following measures:

Reorient or relocate the receiving antenna.

Increase the distance between the equipment and the receiver.

Consult the dealer or an experienced radio/TV technician for assistance.

RF Exposure: For body worn operation, to maintain compliance with FCC RF exposure guidelines, use only accessories that contain no metallic components and provide a separation distance of 15 mm (0.6 inches) to the body. Use of other accessories may violate FCC RF exposure guidelines and should be avoided.

The FCC requires the user to be notified that any changes or modifications to this device that are not expressly approved by Biobeat Technologies Ltd. may void the user's authority to operate the equipment.

Electromagnetic Emission and Electromagnetic Immunity Table:

EMC requirements

IEC 60601-1-2 Edition 4.0 (2014).
Environment of intended uses:
Professional Healthcare and Home Healthcare Facility Environment

Summary of Test Results

Test	Standard	Class/ Severity level	Test result
Emission (IEC 60601-1-2 section 7.1 & 7.2)			
Conducted emission Freq. range:150 kHz - 30 MHz	CISPR 11 /	Group 1 Class B: 230 VAC & 120 VAC mains	Complies
Radiated emission Freq. range: 30 - 1000 MHz	CISPR 11	Group 1 Class B	Complies
Harmonic current emission test	IEC 61000-3-2	AC mains	N/A
Voltage changes, Voltage fluctuations and Flicker test	IEC 61000-3-3	AC mains	Complies
Immunity (IEC 60601-1-2 section 8.9 & 8.10)			
Immunity from Electrostatic discharge (ESD)	IEC 61000-4-2	8 kV contact discharges & 15 kV air discharges	Complies
Immunity from radiated electromagnetic fields	IEC 61000-4-3	10.0 V/m; 80 MHz ÷ 2.7 GHz, 80% AM, 1 kHz	Complies
Immunity from Proximity field from wireless communications equipment	IEC 61000-4-3	List of frequencies, from 9 V/m up to 28 V/m, PM (18 Hz or 217 Hz), FM 1 kHz	Complies
Immunity from Electrical Fast transient (EFT)	IEC 61000-4-4	± 2.0 kV on AC mains; Tr/Th – 5/50 ns, 100 kHz	Complies
Immunity from Surge	IEC 61000-4-5	±1.0 kV DM on AC mains; Tr/Th – 1.2/50 (8/20) μs	Complies
Immunity from conducted disturbances induced by radio-frequency fields	IEC 61000-4-6	3.0 & 6.0 Vrms on AC mains; 0.15÷ 80 MHz, 80% AM, 1 kHz	Complies
Immunity from power frequency magnetic field	IEC 61000-4-8	30 A/m @ 50 Hz & 60 Hz	Complies
Immunity from voltage dips, short interruptions and voltage variations	IEC 61000-4-11	On 230 VAC & 120 VAC mains: 0 % - 0.5 cycle & 1 cycle; 70% - 25 cycles; 0% - 250 cycles	Complies

Footnotes to the above table:

Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radiobroadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

Over the frequency range of 150 kHz to 80MHz, field strength should be less than 3V/m.

Note: At 80 MHz and 800 MHz, the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The following table details the recommended separation distances between portable and mobile RF communications equipment and this device.

Recommended Separation Distance Table:

Separation Distance According to Frequency of Transmitter

Rated Maximum Output Power of Transmitter W	150 kHz to 80 MHz d= 1.17 √P	80 MHz to 800 MHz d= 1.17 √P	800 MHz to 2.5 GHz d=2.33√P
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

This device is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. Users of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80 MHz and 800 MHz, the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Note: There is no Bluetooth transmission during the measurement process. The Bluetooth transmission takes place between the measurements (5 seconds measurement time and 3.5 milliseconds Bluetooth transmission).

8.2 Repair Policy

When under warranty, repair and service must be performed by Biobeat Technologies Ltd. When the Biobeat warranty is not applicable, repairs may be made by Biobeat Technologies Ltd. or authorized representatives, on a parts and labor basis.

⚠ **Warning**: Do not remove the covers of the device components. Only perform maintenance procedures specifically described in this User Manual.

8.3 Warranty

Limited warranty for products

Biobeat warrants to users of a Biobeat-branded device (the "product"), whether such product is new or refurbished, that such product shall be free from defects in materials and workmanship under normal use for a period of sixty (60) days from a user's first use, except that if the user reside in the european economic area (eea), his/her product shall be covered for a period of two (2) years from the date of first use (the " warranty period").

If a defect or malfunction arises with respect to a product during the applicable warrant period, and Biobeat receives notice of such defect/malfunction, Biobeat will, at its option and to the extent permitted by law, either (1) repair the product at no charge, using new or refurbished replacement parts, or (2) replace the product with a new product or a refurbished product. In the event of such a defect, to the extent permitted by law, these are your sole and exclusive remedies. These limited product warranties are valid only in the jurisdictions where the products are distributed by Biobeat itself or through its authorized distributors, and is valid to the extent permitted by the applicable laws of such jurisdictions. Any replacement product will be warranted for the remainder of the original product warranty period or thirty (30) days, whichever is longer, or for any additional period of time that may be required by applicable law.

To obtain warranty service, please send an email to support@biobeat.com prior to the expiration of the warranty period, and follow the instructions given to you by Biobeat. You must deliver the product, in either its original packaging or packaging providing an equal degree of protection, to the address specified by Biobeat.

Biobeat-branded products include complex integrated components for which repair, such as cracked screens or faulty batteries, may not be possible outside of Biobeat factory conditions, and repair facilities or spare parts may not be available for your product or in your region. Therefore, goods presented for repair may be replaced by refurbished goods of equivalent type rather than being repaired. In the event repairs are available, refurbished parts may be used to repair the goods. Repair or replacement of goods which are capable of retaining user-generated data may result in loss of that data.

Biobeat does not warrant that the operation of the product will be uninterrupted or error-free. These limited product warranties do not cover software embedded in any product and related services provided by Biobeat.

These limited product warranties apply only to authorized users of products that were obtained by Biobeat or by an authorized distributor. Without limiting the foregoing, these limited product warranties do not apply to any (a) Biobeat products and services other than the products, (b) non-Biobeat products, even if included or sold with a product, including, without limitation, any counterfeit products, (c) products that are, or Biobeat reasonably believes to be, stolen, (d) consumables (such as batteries), or (e) software, even if packaged or sold with the product or embedded in the product. These limited product warranties do not apply to third-party products or accessories, including but not limited to products with the "made for Biobeat" or "works with Biobeat" logos. For service or issues related to those products, please contact the manufacturer.

These limited product warranties do not apply to a product or part of a product that has been serviced, altered, refurbished, or modified by anyone who is not authorized by Biobeat, nor does it apply to any cosmetic damage such as scratches and dents. In addition, the terms herein do not apply to damage or defects caused by (a) use with non-Biobeat products; (b) accident, abuse, misuse, mishandling, flood, fire, earthquake or other external causes; (c) normal wear and tear or aging of the product such as discoloration or stretching; or (d) operating the product (i) outside the permitted or intended uses described by Biobeat, (ii) not in accordance with instructions provided by Biobeat, or (iii) with improper voltage or power supply.

No Biobeat reseller, distributor, agent or employee is authorized to make any modification, extension, or addition to these limited product warranties. If any term contained herein is held to be illegal or unenforceable, the legality or enforceability of the remaining terms shall not be affected or impaired.

Implied warranties

Except to the extent prohibited by applicable law, all implied warranties (including, without limitation, warranties of merchantability and fitness for a particular purpose) shall either be disclaimed or if required by applicable law, limited in duration to the duration of the applicable warranty period. Some jurisdictions do not allow limitations on the duration of an implied warranty, so the above limitation may not apply to you.

Limitation of damages

Except to the extent prohibited by applicable law, Biobeat shall not be liable for any incidental, indirect, special, or consequential damages, including, without limitation, loss of profits, revenue or data, resulting from any breach of express or implied warranty or condition or under any other legal theory, even if Biobeat has been advised of the possibility of such damages. Some jurisdictions do not allow the exclusion or limitation of special, indirect, incidental or consequential damages, so the above limitation or exclusion may not apply to you.

Governing law

These limited product warranties shall be governed by the laws of the state of israel, without giving effect to any conflict of laws principles that may provide the application of the law of another jurisdiction.

National statutory rights

Consumers in some jurisdictions may have legal rights under applicable national legislation governing the sale of consumer goods, including, without limitation, national laws implementing ec directive 99/44. These rights are not affected by the warranties stated above.