Platform User Guide

REVISION-1.3
July 2020

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.

Biobeat Technologies Ltd.
26 Hamagshimim Street
Petah-Tikva 4282300, Israel
Tel: + 972 3 9333022
Fax: + 972 77 470 1636
E-mail: info@bio-beat.com
http://www.Biobeat.com

CE 2792 Ce symbol CE indicates compliance of this device with the In Vitro Diagnostic Medical Device Directive 98/79/EC.

EC REP Obelis s.a. Tel: +(32) 2 732-59-54
Bd General Wahis 53 Fax: +(32) 2 732-60-03
1030 Brussels, Belgium mail@obelis.net

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.

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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 a wide range of vitals. The Biobeat chest-monitor and wrist-monitor each collect and measure 14 parameters from the patient, the chest-monitor also measures a one-lead ECG in addition to the other parameters.

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 7 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.

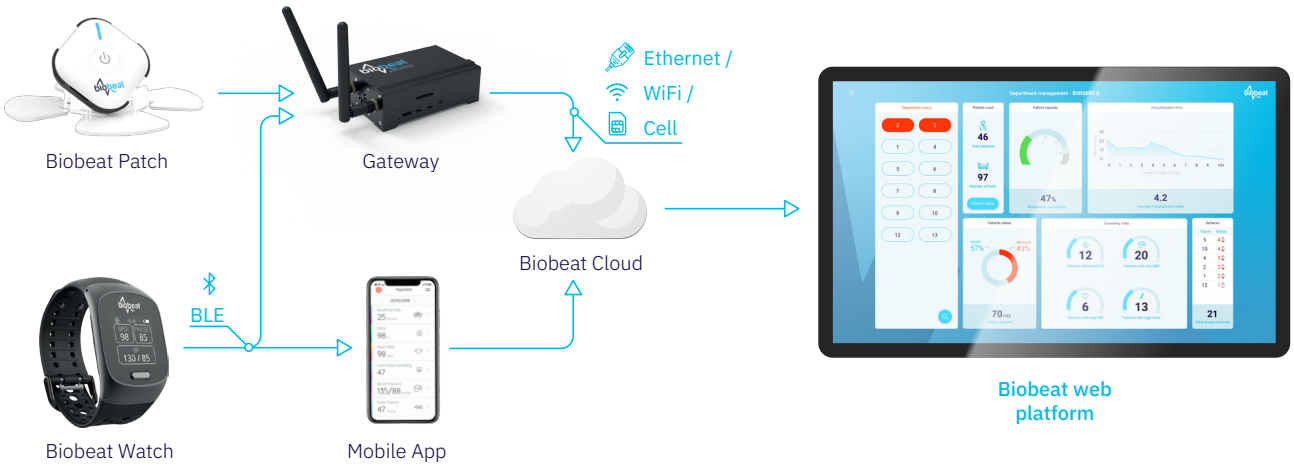
Biobeat Wrist-monitor – The BB-613W is device worn on the wrist, made for long-term monitoring and management of patients. The device is made of an aluminum case with silicone straps, the battery life is sufficient for up to 3 days of continuous use and a charge takes up to two hours in a dedicated charging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

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



Chapter 2 General Considerations

2.1 Warnings, Cautions and Indications for Use

Indications

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.

The BB-613WP is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use.

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 in MRI or a CT environment.
- ⚠ Do not use the device if there is any known allergy to metals, plastic and silicon.

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.
- ⚠ Frequency of sensor relocation and inspection of application site: check the application site every 4 hours for skin integrity. If there is any concern, remove the device and replace with another device over a different skin location.
- ⚠ 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 2.5 - Specifications).** Operating the device outside the declared environmental conditions can lead to incorrect measurements.

Cautions:

- ⚠ The wrist-monitor device is for adult 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 2.5 - 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 2.3 - 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 Section 8. Cleaning and Maintenance).

⚠ Do not use cleaning solutions other than those recommended, as permanent damage could result (see **Chapter 2.3 - Cleaning and maintenance).**

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

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

⚠ 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 8.1 - 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

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.

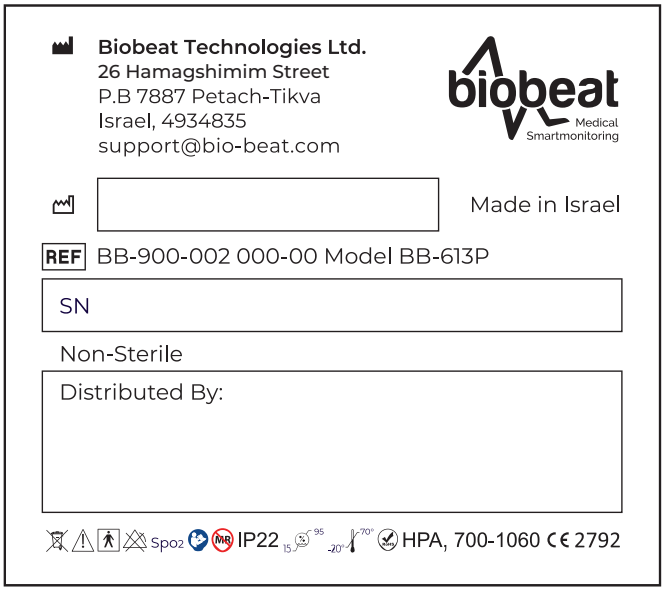
The outer surface of the device may be cleaned with a soft, lint-free cloth moistened by ethyl alcohol (70-85%) until visually clean.

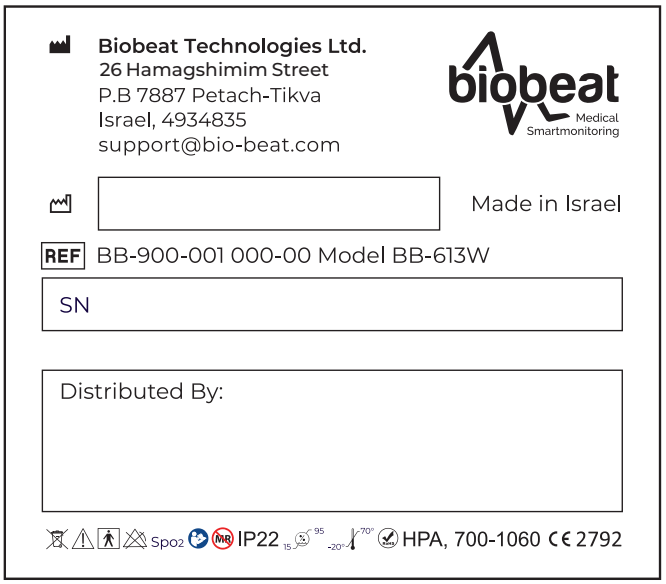
When under warranty, repair and service must be performed by Biobeat Technologies Ltd. When the Biobeat warranty is not applicable, repairs may be made by Biobeat Technologies Ltd. or authorized representatives, on a parts and labor basis.

⚠ **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.





Symbol	Meaning
CE 2792	CE Mark, indicating that the device complies with the Council Directive 98/79/EC (IVD)
	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
	Consult instructions for use
REF	Catalogue number
	Caution: law prohibits dispensing without prescription
	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
MR	"Do not use the device in an MR environment."
	Storage temperature -20*C - +70*C

2.4 Specifications

Parameter	Effective Range	Accuracy	Unit
Blood Pressure	Sys: 60 to 250 Dias: 40 to 150	±5	mmHg
Pulse Rate	40-240	±3%	Beats per minute
Saturation	70-100	±3%	%
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 Based Temperature	20-45ºC / 68-113 ºF	±0.5ºC / ±0.9ºF	ºC / ºF
Heart Rate Variability	0-30	±2%	%
Pulse Pressure	10-100	±5	mmHg
Cardiac Index	1.5-6	±10%	L/min/m^2
ECG One Lead	7 Bits ENOB with 1.1µVP-P		
Electrical - Chest monitor			
Battery type	Non-rechargeable - Lithium / Manganese dioxide		
Capacity	Up to 6 days		
Shelf- life	3 years		
Electrical - Wrist monitor			
Battery type	Rechargeable lithium polymer		
Capacity	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 39°C (39°F to 103°F)		
Operating humidity	Up to 95%, non-condensing		
Pressure	900 to 1080 hPa		
Operating altitude	-378m to 3050m (-1240 feet to 10000 feet)		
Storage and transportation			
Storage temperature	-20°C to 70°C (-4°F to 158° F)		
Humidity	Up to 95%, non-condensing		
Pressure	900 to 1080 hPa		
Operating altitude	-378m to 6098m (-1240 feet to 20000 feet)		
Physical Characteristics - Chest monitor			
Sticker Shelf-life	2 years		
Sticker usage time	3 days		
Dimensions	Monitor enclosure - 38 x 38 x 15 mm Adhesive unit - 85 x 85 x 12 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		

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

Standard / Guidance Number	Standard or Guidance Document Title
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
MDD 93/42 EEC	European Council Directive concerning Medical Devices
EN 1041:2008	Information supplied by the Manufacturer with Medical Devices
EN ISO 15223-1:2012	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
MEDDEV 2.7.1	1.5-13
Rev. 4	Guidance for Medical Devices - Evaluation of Clinical Data
ISO 14155 (Second Edition, 2011)	Clinical investigation of medical devices for human subjects - Good clinical practice [Including: Technical Corrigendum 1 (2011)]
ISO 10993-1:2009	Biological Evaluation of Medical Devices.
ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for In Vitro Cytotoxicity
ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
EN 60601-1-2 (Third Edition 2007 tests)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-1-11 (Second Edition, 2015)	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EC 62133-2:2012	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
IEC 62304 (Edition 1.1, 2015)	Medical device software - Software life cycle processes
ISO 80601-2-61 (First Edition, 2011)	Medical electrical equipment - Part 2-61: Particular Requirements for basic safety and essential performance of pulse oximeter equipment
IEC 60068-2	Electronic Equipment and Product Standards Procedures included within this Standard
IEC 60068-2-27 (Edition 4, 2008)	Shock
IEC 60068-2-64 (Edition 2, 2008)	Vibration, broadband random
ISO 81060-2:2013	Non-invasive sphygmomanometers -- Part 2: Clinical investigation of automated measurement type

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. USBC connector
4. Power connector

Wrist-monitor display

Vital signs display

There are 4 measurement screens available:

Respiratory
(HR, TEMP, RR, SPO2)

Cardio Vascular #1
(BP, PP ,HRV)

Cardio Vascular #2
(CO, SV, SVR, CI)

Wellness
(calories, movement, sweat)

Wrist-monitor screens

SPO2 and Respiratory Rate measurements are best obtained when staying still without speaking.

Cardiovascular values will be calculated only after inputting a baseline profile into the web platform profile in the web platform- see **"Chapter 5: Web Platform- Patient Admission."**

Battery, Bluetooth and signal 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.
- Signal: this icon indicates the strength of the signal acquired from the device.
- No signal means the wrist-monitor is not on the wrist, is not positioned correctly or the patient is moving too much – causing no vitals to be displayed. A poor signal means that the wrist-monitor may not be positioned correctly on the wrist, or that the patient is moving too much, but that some vitals can still be displayed.

Note: If a reading does not appear within 60 seconds, the

No Signal *Poor Signal* *Good Signal*

wrist-monitor may be positioned too tightly or loosely. The correct positioning for the wrist-monitor is when the back of the device is placed lightly on top of the skin while it is touching the skin but not making pressure marks.

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 charger. The Biobeat logo that is located on the base of the charger 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.
2. Turn on the Biobeat wrist-monitor by pressing the center key shortly until you see the Biobeat logo appear.
3. Connect to the Biobeat Home care mobile application: **see "Chapter 6: Mobile Application"**

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 may be used to toggle between each of the 4 screens to view the different vital signs.

Turning the wrist-monitor off / End of use

1. Press and hold the center key until a menu appears.
2. Toggle between the menu options by pressing the button until Shut Down is selected.
3. Press and hold the button when the Shut Down option is selected to turn off the wrist-monitor.

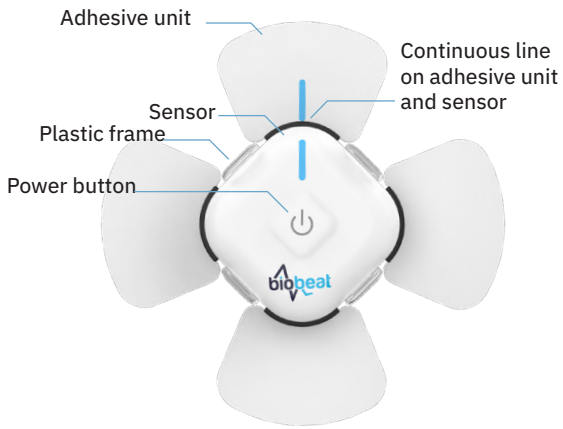
⚠ Do not take measurements while eating, drinking, smoking, taking medicine or exercising. Sit comfortably on a chair or lie down in bed to achieve a relaxed state.

⚠ Please contact Biobeat 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 7 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 5-7 days of use, until the battery runs out.

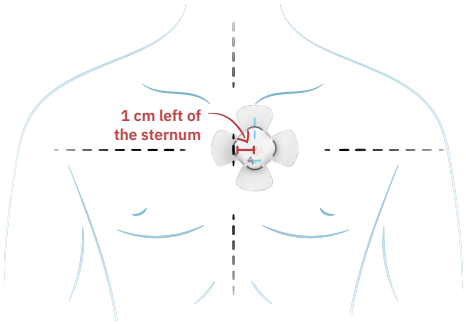
Note: The sensor is not waterproof. It must be removed before showering.

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 figure 2. 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 left the sternum, just below the clavicle as show in figure 3. 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 5 – Web Platform.**

In order to receive data from the device 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**.

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 4.3 – replace device"**

Chapter 4 Web Monitoring Management Platform

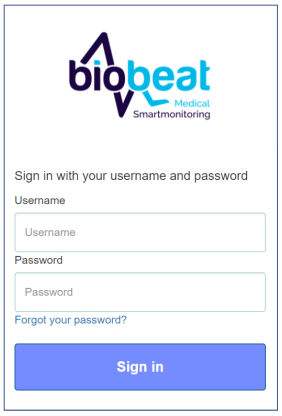
The Biobeat Web Monitoring Management Platform allows the remote monitoring and management of a large number of patients through one simple system. The platform is web-based, and can be accessed from any internet platform.

4.1 Sign-in screen

You will receive a link with a user name and temporary password in order to access the web platform. Upon first entry to the platform you will be asked to reset your password.

You will also be notified as to which email address can be used to reset the password if needed.

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 Biobeat webapp. The screen gives the user a general overview of the department status. All patient's data, rooms and system settings can be accessed from this screen.

Two different views are presented depending on the type of screen:

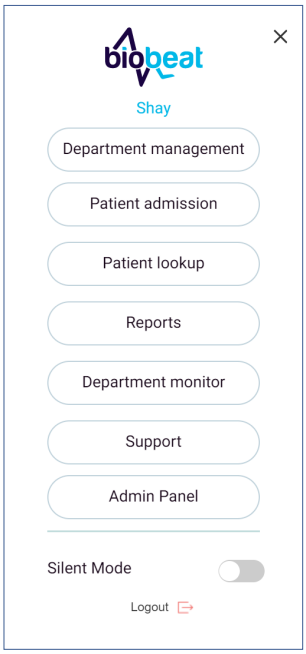
- **Wide View** – this is the default view on a desktop/laptop and displays the tiles with more details when additional information or images are available.
- **Mobile View** – this is the default view on small screens and mobile devices.

Menu Bar

A click on the Menu Symbol which is located on the upper left side of the screen will open the Biobeat Menu Bar.

The menu enables easy navigation between the following web platform screens : Patient Admission, Patient Lookup, Reports, Department monitor.

The menu bar also enables selection of on/off for silent mode and logging out from the user.



Department Rooms

Located on the left side of the screen (first tile on a mobile device).

1. **Room List**

   Select the room you would like to view from the Department Room Tile.

   Each room screen allows you to access the monitor and the portfolio for each patient assigned to it.

   - **Transparent** room number means no patient is assigned to the room.
   - **Blue** room number mean the room is occupied
   - **Red** room number means patient alert, one of the patients in this room has triggered an alert.

2. **Room Search**

   Click on the magnifying glass, type in the desired room number and select Enter when done.

Patient Capacity

Indicates the total number of patients and beds. The occupation percentage is shown at the bottom of the tile (2nd tile on a mobile device.)

Patient Lookup – on the bottom right of the tile. Enables the search of a specific patient. Once selected, a list of all patients in the department will appear. You can look up a patient by ID number or chest-monitor number.

Hospitalization Time

Presents a histogram of the length of stay (in days) and the number of patients that stayed for each amount of days. This graph is updated every day.

Patient Status

Displays the number of stable patients out of the total number of patients, in numbers and in percentage. An unstable patient is a patient that has appeared on the exceeding vitals tile, having passed the threshold for one of the following vitals: heart rate, SPO2, systolic blood pressure or temperature.

Exceeding Vitals

Displays a count of patients that have exceeded the system's defined thresholds for four vital signs. This tile is not customizable.

The vital signs that are presented are SPO2 (< 93% saturation), low systolic blood pressure (< 80 mmHg), high heart rate (> 150 BPM) and high fever (<37.5 degrees Celsius).

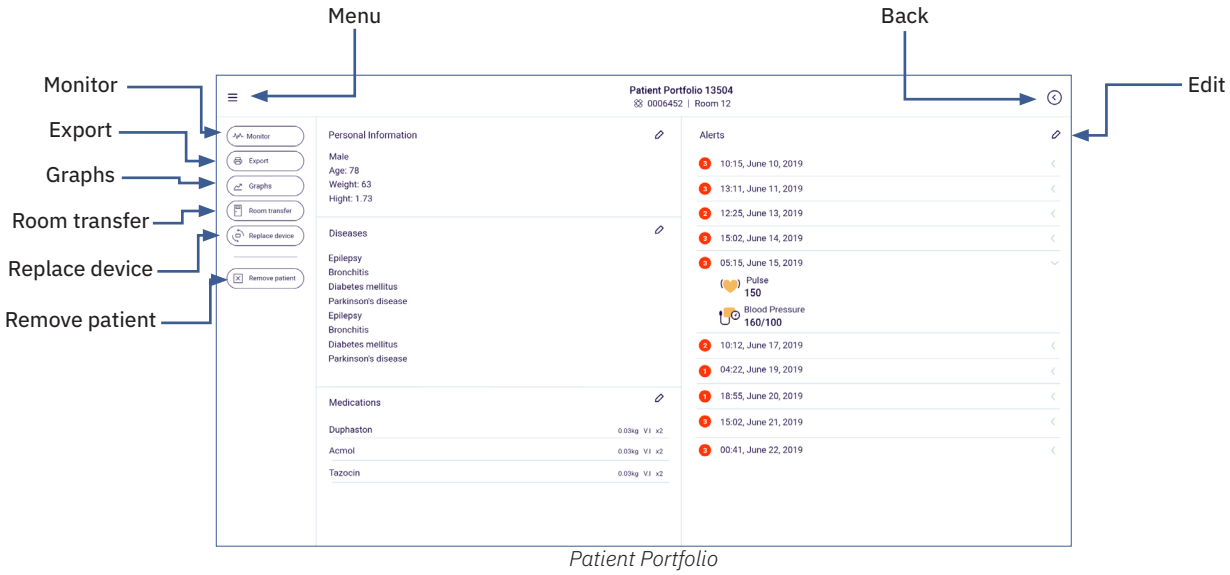
Note: Each patient alert threshold may be changed through patient portfolio

Batteries

Displays the sensors that have a low battery (under 5% left), sorted by the room they are assigned to. These sensors should be replaced in order to continue monitoring (see 4.3 patient portfolio)

A low battery will also be indicated on the department monitor screen.

4.3 Patient Portfolio



Patient Portfolio

The Patient Portfolio presents the patient's medical and personal information and allows access to the patient monitor and graphs.

The Patient Portfolio screen also enables editing the patient's personal information including medical diagnoses and medications, and basic actions such as changing room number, replacing the device and discharging the patient.

The Patient Portfolio screen can be accessed through the following screens:

- From the Department Management screen or the Menu by clicking on Patient Lookup and selecting the patient requested.
- From the Department Monitor Screen by clicking on Patient Name.
- From the Department management screen → Room Tile → selecting the patient's room → selecting required patient's portfolio

Monitor

The Monitor screen displays the patient's vital signs in real time. The Monitor screen is described separately in the following pages.

Graphs

The Graph button will open up the graphs screen, presenting trends and past measurements of each of the patient's collected vital signs, in different time resolutions such as hour, day and several days. For more information about the graphs see **chapter 5.2 Web Platform- Graphs.**

Room transfer

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

1. Click on Room Transfer to see all rooms in the facility.
2. Select the new room number the patient is assigned to.
3. Confirm your choice to transfer the patient by selecting Yes on the bottom of the screen.

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.

1. Select **Replace Device** and type in the new **device serial number**. Click **Save**.

If the device is a chest-monitor:

2. 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.
3. 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.**

Remove Patient

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

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

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

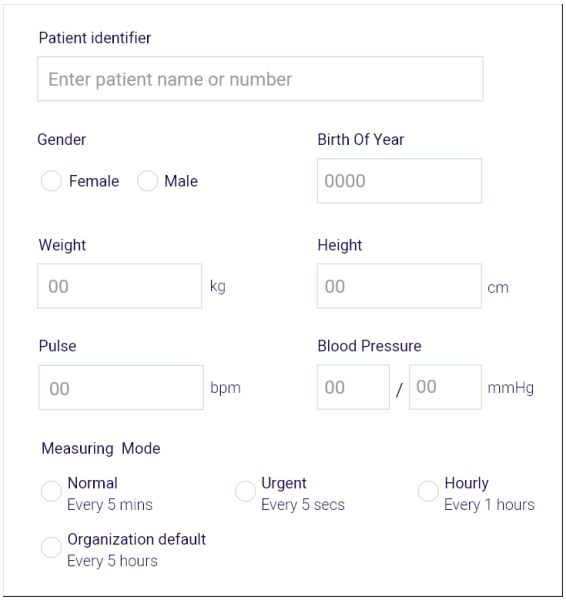
Edit Personal Information

The Personal Information is where patient demographics and baseline vitals are listed.

1. To edit the patient's Personal Information, click the pencil icon on the top right of the section in the Patient Portfolio.
2. Edit Patient Identifier, Gender, Year of Birth, Weight, Height, Pulse, Blood Pressure, and Measuring Mode.

   Note: Remember the measurement mode impacts the device's battery life.
3. Click Save to keep changes or Cancel to discard changes and return to the Patient Portfolio.

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.



Edit Diseases, Medications, and Alerts

In order to edit Diseases, Medications, or Alert Settings:

1. Click the pencil icon on the top right of the required section.
2. Make changes to the list or values.
3. Click **Save** to keep changes or **Cancel** to discard changes and return to the **Patient Portfolio.**

Note: refer to Chapter 5 - Web Platform: Operating the System for a detailed explanation of diseases, medications and alert settings.

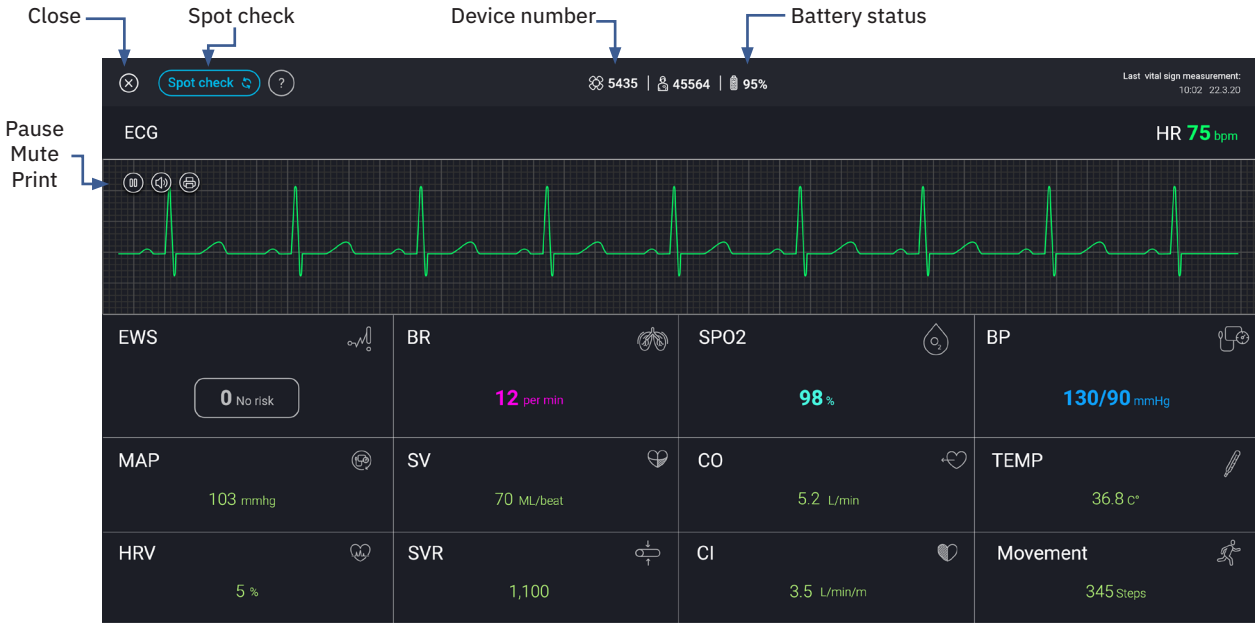
Export

Selecting the **Export** function generates a PDF report of that patient's information.

Each exported PDF file contains the patient's baseline, device serial number, entered diseases, entered medications, a list of past alerts and all vitals measured during 3 different time periods: a real-time measurement, a measurement 8 hours before the export and a measurement 16 hours before the export.

A PDF will be saved to the download destination as specified on the computer.

4.4 Patient Monitor Screen



Patient monitor screen

The **patient monitor screen** displays all vital signs measured in real time. When using a chest-monitor device, a one-lead ECG trace is displayed too.

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 14 vital signs and parameters. The parameters presented are:

- Heart Rate (HR, bpm)
- Respiratory Rate (RR, rpm)
- 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, mmHg x min/L)
- Cardiac Index (CI, L/min/m2), Movement

When the measurement is taken, the vitals will appear in color. In between measurement intervals, the vitals will appear in gray and the screen will present the time of last measurement.

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.

Functions enabled:

- Select the **Pause** "⏸" button next to ECG 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 ECG recording on an A4 sheet with a standard grid. This page can be printed.
- Select the **Speaker** button "🔊" to mute or unmute the ECG graph.

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 calculated and presented in the vital signs area of the patient monitor. For more information see **EWS section.**

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 measurement frequency will return to the defined measurement frequency.

Click the **X** at the top left of the screen to close the **patient monitor screen** and return to the patient portfolio.

Notifications:

When a device is unable to perform measurements, a notification message will appear, describing the cause for pausing activity.

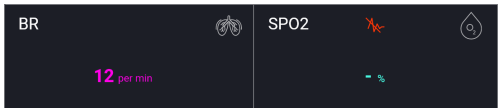
Device Disconnected: The **patient monitor screen** will display this message when there is no connection between the cloud and the device, causing a pause in the data stream.

This could be due to several reasons, such as an issue with the device, the connection to the Gateway or connection between the Gateway and the cloud. See troubleshooting for further instructions.

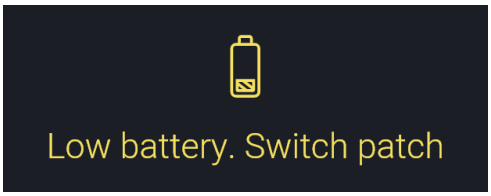
Bad Signal: The **patient monitor screen** will display this message when a good Bluetooth connection between the Gateway/app and the device is maintained, but the PPG signal (signal measured by the device) is not good. This means there are no vitals being measured.

A bad signal can lead to trouble reading all vital signs, or only some vital signs. **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.** This issue can be resolved by repositioning the device or changing the adhesive unit if a chest-monitor is being used. See **Troubleshooting** for further instructions.

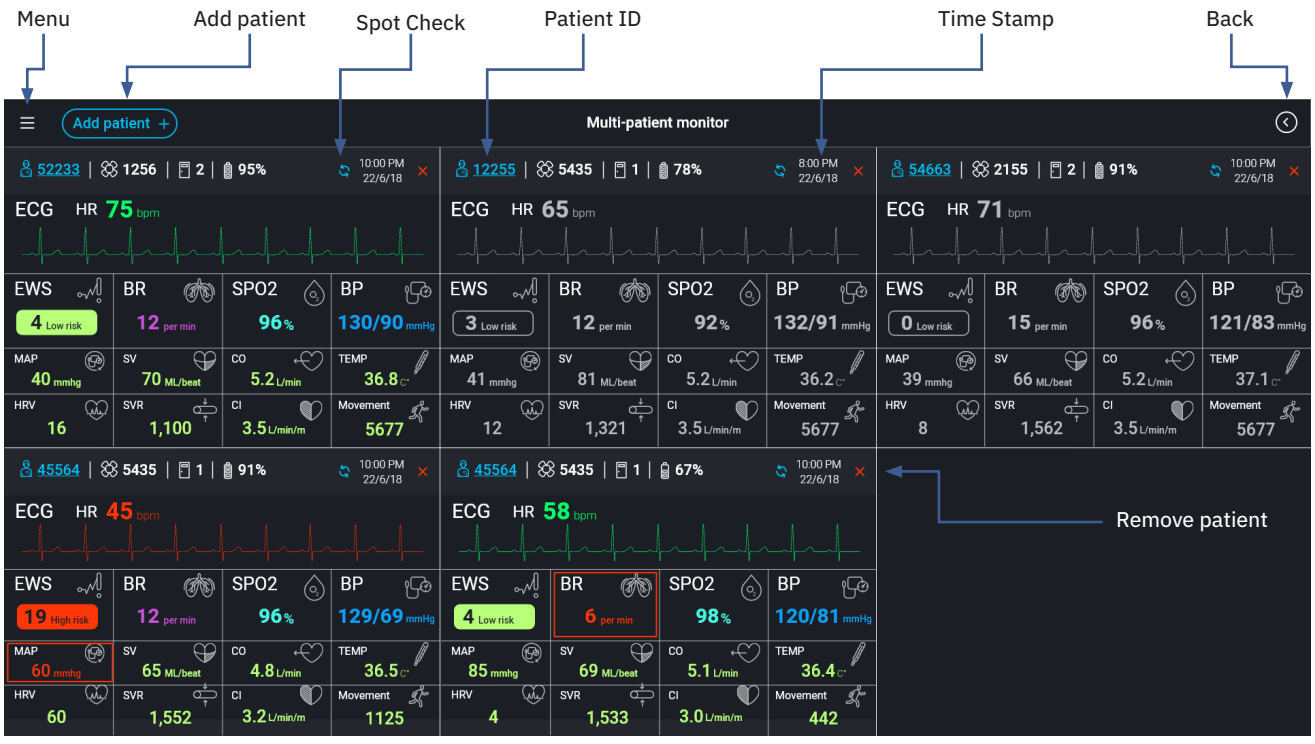
The image below demonstrates what some vitals (SPO2) not being displayed looks like:



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 **Batteries** tile in the Department **Management screen.**



4.5 Department Monitor Screen



Department Monitor

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.

Using the Department Monitor

Entering the Department Monitor:

1. Click the **menu** icon on the upper left side of your screen (3 lines) and select **Department Monitor.**
2. When first accessing the Department Monitor, a blank screen will show.

Adding patients:

1. Click **Add Patient** on the top left of the screen to begin adding patients to the screen.
2. A list with all patients admitted to the system will pop up.
3. Once patients are added to the department monitor, the list will show only patients who have not yet been added.
4. Click on the Patient Identifier to add the patient to the Department Monitor screen.
5. Click X when done.

Spot check

The spot check function in the department monitor works in the same way as in the patient monitor screen. In order to initiate a spot check, press the " " button that appears next to the time of last measurement in each patient tile.

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.

Notifications

The same notifications presented on the patient monitor screen also appear on the department monitor screen: device disconnected, bad signal and low battery. For instructions to address these notifications see **troubleshooting.**

4.6 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 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 supplements and the patient's level of consciousness. These two parameters are entered manually into the Biobeat web platform in order to calculate the EWS and the patient's risk level.

Calculation chart

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

Physiological Parameters	3	2	1	0	1	2	3
Respiration Rate (BPM)	≤8		9-11	12-20		21-24	≥25
Oxygen Saturations (%)	≤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 (mmHg)	≤90	19-100	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 score calculated:

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

Presenting the score

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

The EWS screen enables the following:

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

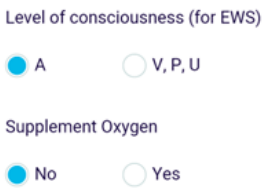
EWS score index

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

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



Chapter 5 Web Platform- Patient Admission & Management

5.1 Patient admission

Before admission:

1. Have the chest-monitor sensor and adhesive unit ready for use.
2. Make note of the patient's personal information: weight, height, sex and year of birth.
3. Take a measurement of the patient's pulse and blood pressure. Take the measurement with 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.

Patient admission process:

Starting the process and pairing a device:

1. Click the menu button on the upper left side of the screen.
2. Select **Patient Admission.**
3. The first screen is device serial number. Manually enter the wrist-monitor or chest-monitor serial number (located on a white sticker on 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.
4. Click **Next** and wait while **Connecting**.

Personal information

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

All fields are mandatory.

Patient admission

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, using a blood pressure cuff to take this measurement and enter it into the system. Note that if you do not have the exact details when admitting the patient, you can later modify these fields in the system. This data impacts the system, and so it should be as exact as possible.
4. Measuring Mode - select the measurement frequency of the device.

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 organization default mode (every 15 minutes or every hour) the chest-monitor battery will last for up to 6 days.

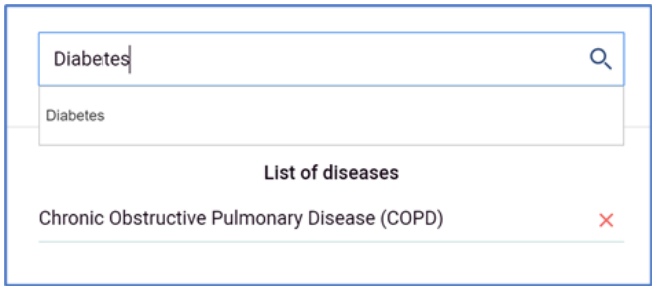
5. Once all fields are filled out, the Next button will appear on the bottom of the screen. Select it to move on to the next stage.

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 **'Enter Diagnosis'** and type in information about the patient's current or previous medical conditions.
2. Options will auto populate in a drop-down list after 4 characters are typed into the box.
3. Select the appropriate condition from the drop-down list.
4. Repeat steps 2+3 as necessary.
5. The list entered will be presented in the patient's portfolio under **List of Diseases.**

The figure demonstrates a patient with COPD and Diabetes.



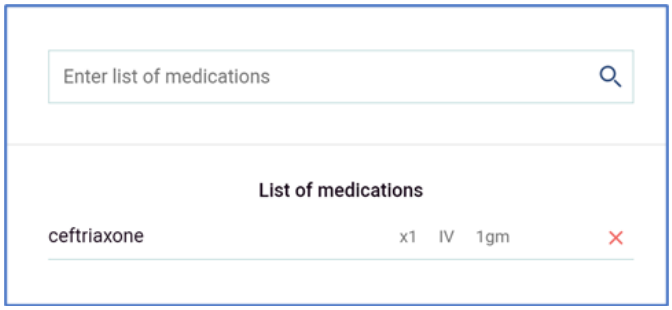
Medical condition.

6. Click Next to advance to the next screen.

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 'Enter List of Medications'
2. Type in any medications the patient is taking.
3. Options will auto populate in a drop-down list after 4 characters are typed into the box.
4. Select the appropriate medication.
5. Several drop-down options will appear.
   - **Route** specifies the **route of administration** of the medicine.
   - **When** specifies the time of administration **'Morning', 'Noon',** or **'Evening'.**
   - MCG enables selection of the dosage units.
   - Enter the dosage in the field '**Dosage**'.
6. Click **Add** when finished.



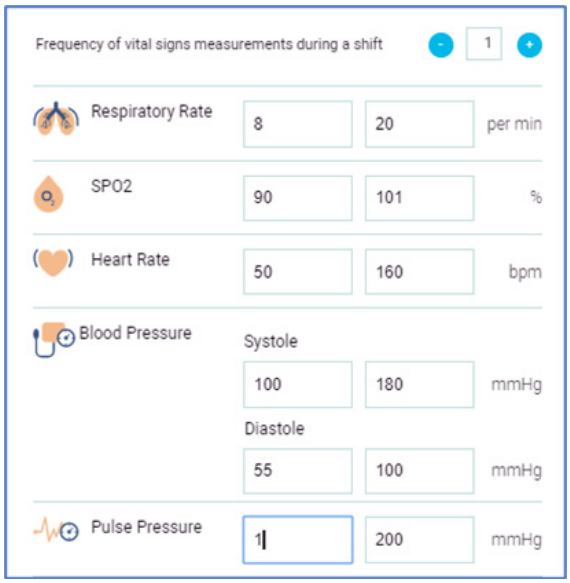
Medication list

7. Repeat steps 4-6 as needed.
8. Click **Next** to advance to the next screen.

Managing Alerts

An alert will be triggered every time a vital is measured above or below the set threshold. The default thresholds that appear are pre-defined by the admin. The thresholds can be customized for each patient that is admitted. Changes can also be made at a later stage.

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



Alerts

1. The **Frequency of vital sign measurements during a shift** field sets the number of times a measurement is taken in order to generate the personal report. This can be a maximum of 3 times per shift. The shift duration is defined for each department by the admin.
2. Change the low and the high threshold values for each of the vital signs, as needed.
3. Click **Reset Default** at the top of the screen in order to return to the default thresholds set by the admin.
4. Click **Next** to advance to the next screen.

Room Assignment

A screen with all room numbers in the department appears. Select the room the patient will be assigned to.

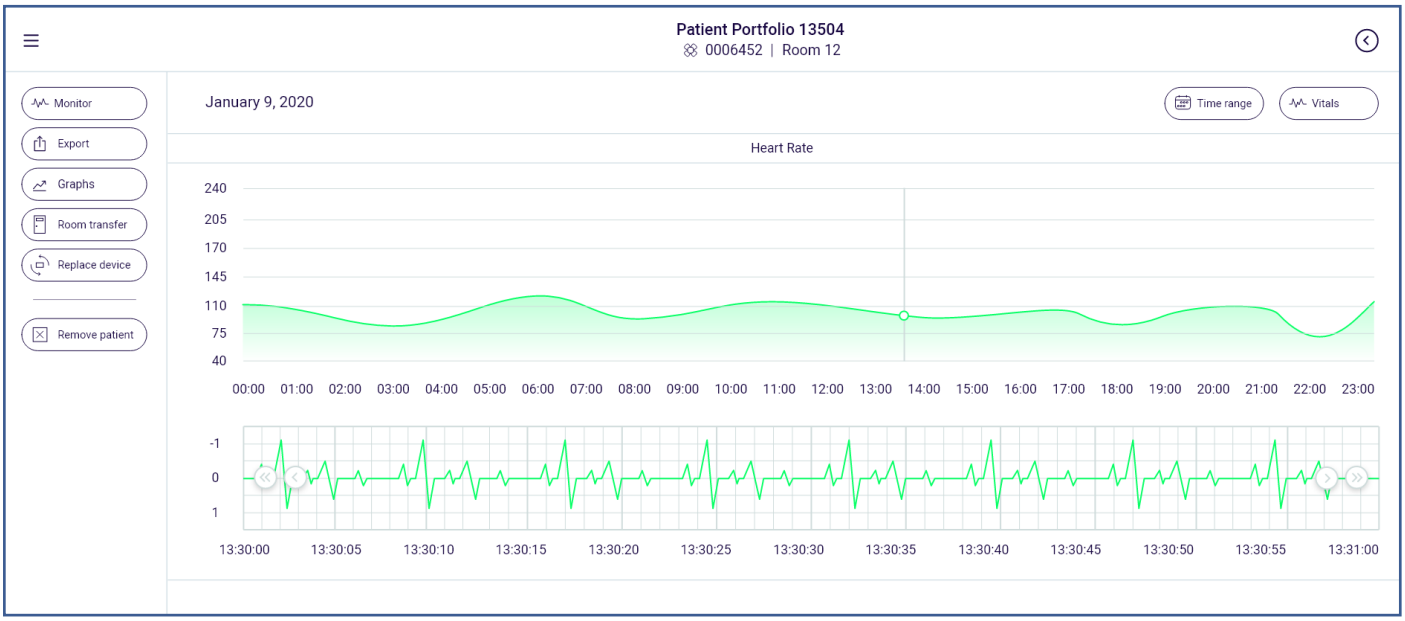
1. Click on the designated room number.
2. A confirmation message will pop up at the bottom of the screen.
3. Click '**Yes**' to confirm or '**Cancel**' to reselect room number.

A screen will pop up to notify the patient admission process has been completed successfully after the system finishes creating the patient profile.

Congratulations, the patient has now been admitted to the Biobeat system.

To edit any of the patient's information and settings see: **Chapter 4.3 – Patient Portfolio.**

5.2 Web Platform- Graphs



Graphs

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

In order to access patient graphs:

- In the **Patient Portfolio** screen → click on **Graphs**, located in the list on the left-hand side.

OR

- From any patient monitor screen click on a specific vital sign to view its graph.

Time range selection:

1. Select the Time range button on the top right of the graphs page (accessed from the Patient Portfolio).
2. Select between: day (selecting a day from the calendar), week, or one of the default time values- current hour, today, current week. WW
3. Use the left and right arrows in order to toggle within the time frame.
4. Selecting a specific point on any graph will change the resolution of the graph. A weekly view will change to a daily view and a daily view will change to an hourly view.

Vital presentation selection

1. Select the Vitals button on the top right of the graphs page (accessed from the Patient Portfolio).
2. Select a vital measurement to view its graph.

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).

5.3 Reports

Personal report

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

Producing a report

1. Click the **menu** icon on the upper left side of the screen (3 lines).
2. Select the **Reports** button.
3. Select one of the three available report types:
    - Department
    - Personal
    - Medications

Department Report

The Department Report will list a single measurement for each patient at a specific time during a shift.

The report will list the best measurement (measurement with the most vitals per patients) in a 1-hour range (30 minutes before and after a selected time).

The time of measurement can be changed by your admin.

Department report

Each Department Report will show:

- Device serial number
- Patient identifier
- Measurement time
- Room number
- Heart rate (HR)
- Blood pressure (BP)
- Respiratory rate (BR)
- Blood oxygen saturation (SPO2)
- Temperature (Temp)
- Stroke volume (SV)
- Early Warning Score

View the patient selection, filter and export functions below.

Medications Report

The Medications Report lists all of the medications that need to be administered during the current shift. The Medications Report lists:

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

The report is produced according to the time of the day, and contains all medication requirements for the specific shift.

Personal Report

The **Personal Report** will list a patient's vital sign measurements in intervals as defined in the frequency of vital measurements during a shift. This is set during the Patient Admission process, and can be changed in the alerts section of the **patient portfolio**. The optional frequencies are between 1 and 3 measurements per shift. The shift length is defined by your admin. The Personal Report will list the same vitals listed in the Department Report.

View the patient selection, filter and export functions below.

Patient selection, filter, and export

1. Patient selection: click **Barcode Scan** on the top left of the screen, then manually enter the patient identifier or scan the patient's barcode if they have one. Click **Search**.
2. Filter by room: click the Filter By Room button and choose a room in order to show all patients in that room.
3. Export: click the Export button on the top right of the screen in order to export a PDF of the report.

Chapter 6 Mobile Application

6.1 Biobeat Home care mobile application

The Biobeat Home care mobile application enables remote monitoring of patients with the Biobeat wrist-monitor. The app will transmit all vital measurements data to the web platform, where it can be viewed and managed.

Download the Biobeat Home care app

1. Enter the App Store/Google Play store on your mobile phone
2. Download and install the Biobeat Home care application.

Figure 16- Home care app

Turn on the Biobeat Wrist-monitor

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

1. 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 Home care app on your mobile phone.
2. Read and approve the terms of use provided upon opening the app.
3. You will be asked to enable location services for the app. This is important as the pairing process cannot be completed otherwise.
4. Tap connect to search for your device.
5. The app will find your wrist-monitor according to its serial number (located on the white sticker on the back of the device)
6. Select your device serial number in order to pair your wrist-monitor with your app
7. The pairing process will be completed.

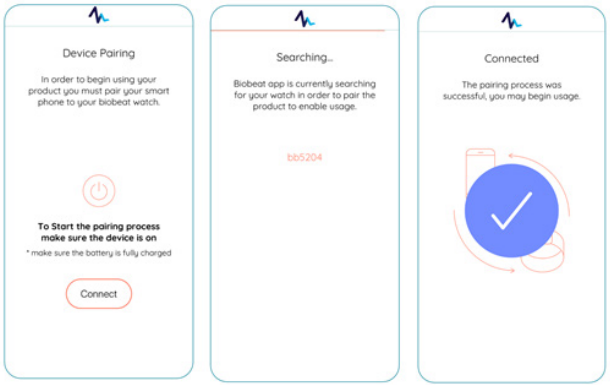


Figure 17- pairing process

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 your vitals from the app at any time.

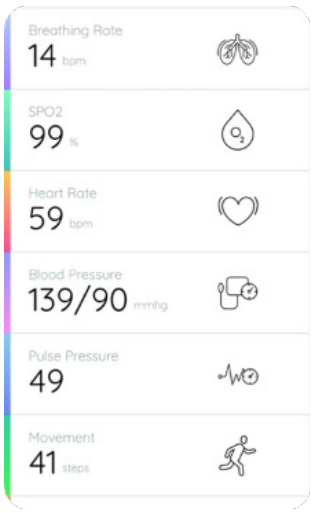


Figure 18- Mobile App display

Uploading data from your wrist-monitor

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.

Make sure to keep your phone charged and in proximity while wearing the wrist-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 the wrist-monitor or your phone, make sure the app is still connected.

Chapter 7 Biobeat Gateway

7.1 Description

1. The Gateway is a hardware device that connects to Biobeat chest-monitor or wrist-monitor via Bluetooth Low Energy (BLE), receives collected data, 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. There are currently two different types of Biobeat Gateways: Gateway A and Gateway B. Both function the same and are used for the same purpose, but have a different external design.

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.

Gateway A

Ports

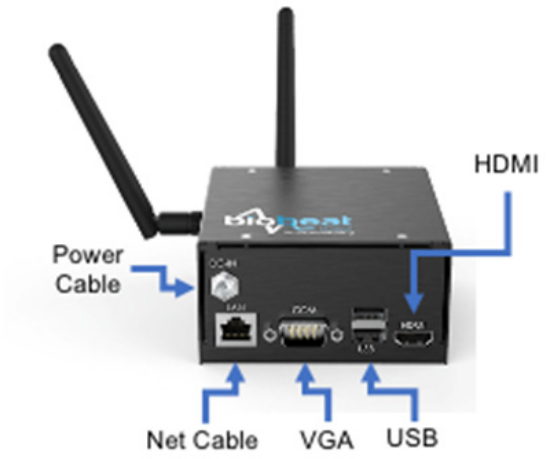


Figure 19- Gateway A

Gateway A has the following ports:

5. Power cable- connects to DC inlet.
6. Net cable- port for connecting LAN internet cable.
7. USB*2: ports for keyboard and mouse.
8. VGA and HDMI: ports for connecting a screen

7.2 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 full the 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):
   a. Connect the Bluetooth antenna to the WWAN port.
   b. Connect the WiFi antenna to the WLAN 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:
   a. Purchase a micro SIM card with data, 1GB of data per month is sufficient. Ensure the SIM card is activated before use.
   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!).**
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.

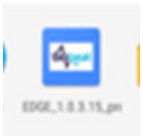
3. Wi-Fi
   a. The Gateway has an Android operating system.
   b. i. Connect the Gateway to a monitor using an HDMI/VGA cable.
   c. Connect a mouse to the Gateway through a USB port.
   d. Access the **Settings** panel and navigate to the Wi-Fi: Menu → Settings → WIFI options → Turn WIFI on → connect 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.

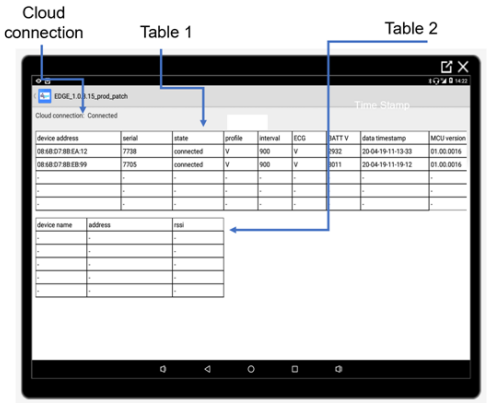
7.3 Operation

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.

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
      - Interval – Measurement interval 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 from Gateway (above 90 = the distance is too far, and Bluetooth connection may be affected)

Chapter 8 Troubleshooting

8.1 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 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 does not get a good signal reading	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. 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 wrist-monitor does not display a blood pressure measurement	1. A baseline has not been defined for the wrist-monitor. 2. Contact your supplier in order to define your baseline through the Biobeat web platform if you do not have access to it.
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 pairing process again (as described in **Chapter 6 - Mobile Application**)
The wrist-monitor was connected to the app, but doesn't reconnect after switching the phone's Bluetooth off and back on.	1. Go into the menu in the app → device management. 2. Select delete device. 3. Reconnect the wrist-monitor to the app, as (described in **Chapter 6 - Mobile Application**)
There is no new data on the monitor	1. Verify that the wrist-monitor is connected to the app (that the device has a circle sign around the Bluetooth icon). If there is no connection, see "The wrist-monitor does not connect to the app" above. 2. Reset the device. 3. Reset the app.
The wrist-monitor does not measure temperature	Contact Biobeat or your supplier for further instructions.
The wrist-monitor has caused a skin irritation	
The strap is broken	
Wrist-monitor heats up drastically	
Wrist-monitor causes skin irritation	Remove the device and consult with a physician.

8.2 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 signal"** alert	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 and holding the button for 4 seconds, then turn the device back on by pressing the power button shortly.
Chest-monitor battery is running out quickly	1. Enter the Patient Portfolio. 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 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.

8.3 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 problem continues, contact Biobeat for further instructions.
Gateway does not connect to the internet when using local operator sim card	1. Make sure 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 7 - Gateway** for SIM card placement instructions.) 3. Disconnect the Gateway from DC-In. Wait 1 minute and reconnect. *If 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 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 problem continues, contact Biobeat for further instructions.
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 connected 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. (See Chapter 7: Gateway Set Up for internet connection) 

8.4 Web platform troubleshooting

Cannot find patient in the system	1. Open application menu. 2. Choose Patient Lookup. 3. Select the patient from the list. 4. If patient does not appear on the list, restart the patient admission process. ***Chapter 4 - Web Platform** for further instructions.
Cannot see patient on Department Monitor screen	1. Open the web platform menu. 2. Enter the Department Monitor screen. 3. Click **Add Patient** 4. Select the patient from the list. 5. If the patient does not appear on the list, make sure the patient is added to the department by selecting Patient Lookup on the Department Monitor screen. 6. Refresh the internet page. 7. Check that the patient's device is turned on. The patient needs at least one measurement in order to appear on Department Monitor screen.
Patient listed with wrong room number	1. Enter the Patient Portfolio. 2. Click on Room Transfer. 3. Select the desired room number. *See Chapter 4: Web Platform: Room Transfer for further instructions.
Need to change patient name	4. Enter the Patient Portfolio. 5. Click the pencil icon to edit Personal Information. 6. Change the name. 7. *See **Chapter 4 - Web Platform for further instructions.**
Chest-monitor battery has run out – need to continue patient monitoring without deleting patient monitoring history	1. Enter the Patient Portfolio. 2. Click on Replace Device. 3. Enter new device serial number. *See **Chapter 4 - Web Platform for further instructions.**
Forgot username or password	1. Reset password for the Web Platform. 2. If the problem continues, contact system administrator. 3. If you have forgotten your username, contact system administrator.

8.5 Vitals troubleshooting

No new vitals data on the monitor	1. Check time of last measurement on monitor display. 2. If 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 ago 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 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 allow them to 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 **Graph**, and view the SPO2 Graph to obtain the last measurement. *The SPO2 vital is highly sensitive to the location of the device on the patient and 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 them to 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 taken, 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 them to rest without talking for 1 minute.

Chapter 9 Legal and warranty

9.1 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 Ltd. may void the user's authority to operate the equipment.

Electromagnetic Emission and Electromagnetic Immunity Table:

Test	Standard	Class/ Severity level	Test result
Documentation (IEC 60601-1-2 sections 4 and 5)			
General requirements for EMC	section 4.1.1.	--	Complies
External labels	section 5.1	--	Complies
Conformity of Users' Manual	section 5.2.1	--	Complies
Accuracy of Technical Description	section 5.2.2	--	Complies
Emission (IEC 60601-1-2 section 7)			
Conducted emission Freq. range:150 kHz - 30 MHz	CISPR 11	Group 1 Class B 230 / 120 VAC mains	Complies
Radiated emission Freq. range: 30 - 1000 MHz		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)			
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	*230 VAC mains:* ± 2.0 kV Tr/Th – 5/50 ns, 100 kHz	Complies
Immunity from Surge	IEC 61000-4-5	*230 VAC mains* ±1.0 kV DM Tr/Th – 1.2/50 (8/20) µs	Complies
Immunity from conducted disturbances induced by radio-frequency fields	IEC 61000-4-6	*230 VAC mains:* 6.0 Vrms, 0.15~ 80 MHz, 80% AM 1kHz	Complies
Immunity from voltage dips, interruptions and variations	IEC 61000-4-11	*230 VAC & 120 VAC mains* 0 % - 0.5 cycle & 1 cycle; 70% - 25 cycles; 0% - 250 cycles	Complies

Electronics and Telematics Laboratory
5 August 2018

Footnotes to 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 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*

9.2 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.

9.3 Warranty

Repairs of the Biobeat System under warranty must be made by authorized repair centers. If the device needs repair, contact the Biobeat Technologies Ltd. service department or your local distributor.

If you need to ship the device, pack the device and its accessories carefully to prevent shipping damage.

Duration

Biobeat Technologies Ltd. will repair or replace, at its sole discretion, the product or any defective part, provided it is returned to Biobeat within 30 days.