Monitoring Wristwatch | Disposable Patch

User Guide

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 Technologies Ltd. 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: Consult with a physician before use of the device.

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

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Disclaimer

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1. 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 Customer Support for assistance.

1.1. 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.

2. OVERVIEW OF SYSTEM

2.1. Description of Device

The BB-613WP is a non-invasive wristwatch or patch used for monitoring of vital signs in clinical and non-clinical settings.

Features and benefits:

- Easy of use.
- Ability to transmit the data to the App.
- BLE Communication.

3. CONDITIONS FOR USE

3.1. 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.

3.2. 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 with patients with localized infection, ulceration or skin lesions involving the wrist.

⚠ Do not use with 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 if there is a known allergy to metals, plastic and silicon.

4. SAFETY

4.1. 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.

4.2. 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.

4.3. Safety Instructions

Warnings:

⚠ DO NOT USE BEFORE READING THIS USER MANUAL.

⚠ Only apply the device on clean, intact wrist 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 (device straps too tight).

⚠ Regarding the frequency of sensor relocation and inspection of application site: The device must be located on the wrist to activate the device properly. Check the application site every 4 hours for skin integrity. If there is any concern, remove the device and replace with another

device on the other hand.

⚠ Do not use the device if you have known allergy to plastic, silicon and metals.

⚠ 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.

⚠ 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 **Section 12. Specifications**). Operating the device outside the declared environmental conditions can lead to incorrect measurements.

Cautions:

ⓘ The watch is for adult patients with wrist a 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 **Section 12. Specifications**), do not use the device.

ⓘ If the display on the device is not working properly, or the On/Off button is faulty, as shown in **Section 5.2. Detailed Description of Watch (Front)**, do not use the device.

- Do not disassemble any part of the system components. This system is not user-serviceable.
- Do not place the device in liquid or put it where it could fall into liquid.
- Use the device only for the purpose described in the instructions 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.
- Clean the device between uses (See **Section 8. 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**).
- The device 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 **Section 14. 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 BB app
- Do not leave phone unattended and open.
- Use security measures to lock phone when not in use.
- Do not install apps that may contain malware.

Notes:

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

5. CLEANING AND MAINTENANCE

5.1. Notes on 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 device:

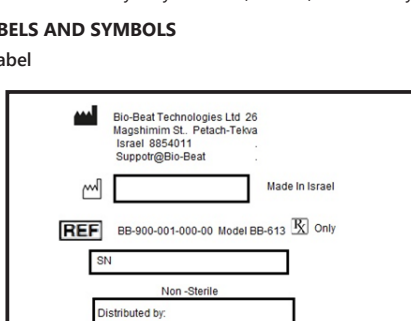
5.2. Cleaning the Biobeat device

- **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.

6. LABELS AND SYMBOLS

6.1. Label



Box label

14.1. SYMBOLS

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

Symbol	Meaning
CE 0086	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

Symbol	Meaning
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

15.SPECIFICATIONS

Performance	
Measurement Range	
SpO2	70%-100%
PR (pulse rate)	40-240 bpm
Blood pressure	SYS-60 to 250 mmHg + 5
	DIAS- 40 to 150 mmHg+5
Accuracy	
Arterial Oxygen Saturation, 70% to 80% 80% to 90% 90% to 100%	± 3%
Pulse Rate Accuracy	± 3 bpm
Resolution	
Arterial Oxygen Saturation (SpO2)	70%-100%, ±3% or ±3 digits Display: 2 characters
Pulse Rate	±3% or ±3 digits Display: 3 characters
Electrical	
Battery for wristwatch	Rechargeable lithium polymer
Capacity	3 days of continuous use
Number of spot checks on fully charged battery	Minimum 500

Battery charging time	4 hours when powered off
Use- life	3 years
Shelf- life	2 years
Charger Isolation: class ll double isolation	5V AC/DC Adapter
AC Power for battery charger	100-240V, 50-60 Hz, 10VA max
Battery for Patch	
Capacity	5 days of continuous use
Shelf- life	3 years
Non-rechargeable	One-time (single) use
Environmental	
Operating temperature	4°C to 39°C (39°F to 103°F)
Operating humidity	Up to 95%, non-condensing
Pressure	700 to 1060 hPa
Operating altitude	-378 m to 3050 m (-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	465 hpa to 1060 hPa
Operating altitude	-378 m to 6098 m (-1240 feet to 20000 feet)
Physical Characteristics - Wristwatch	
Dimensions (monitor enclosure)	48 x 38 x 16 mm
Weight	2 oz. (55 g) including battery
Physical Characteristics - Patch	
Dimensions	40 x 40 x 16 mm
Weight	Weight 1 oz. (30g)
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	15 Meter

BIOBEAT TERMS OF USE

Biobeat Ltd. ("**Biobeat**", "**we**" or "**us**") produce various products, including a watch and a patch, which track various medical parameters (the "**Watch**" and the "**Patch**", respectively, and together, "**Biobeat Devices**"). Biobeat Devices, together with the Biobeat application to which Biobeat Devices transmit information tracked by the applicable Biobeat Device ("**Biobeat's Application**"), allows the User (the "**User**"), to use Biobeat Devices' functionalities as specified under the Documentation (as defined below). Biobeat Devices, the Application, the Biobeat websites: www.bio-beat.com and https://www.biobeat.cloud/ (together the "**Website**"), and any other services or devices provided by Biobeat shall be referred to herein, collectively, as the "Biobeat Services". Please read these terms of use ("**Terms**") carefully as they govern the User's use of Biobeat Services and create a binding contract between the User and Biobeat.

BY USING BIOBEAT SERVICES IN ANY MANNER, THE USER ACKNOWLEDGES THAT IT ACCEPTS THESE TERMS. THESE TERMS SHALL BE EFFECTIVE AS OF THE EARLIER OF (I) THE DATE OF SUCH FIRST USE; OR (II) THE USER'S APPROVAL OF THESE TERMS (THE "**EFFECTIVE DATE**"). IF THE USER DOE'S NOT AGREE WITH THESE TERMS, IT MAY NOT USE THE WATCH.

1. Use of Biobeat Services

Use of the Biobeat Devices is permitted only to individuals above the age of 18.

In order to make use of Biobeat Devices, the User will be required to download, install and register and create a designated account at Biobeat's Application and/or the Website. Use of Biobeat Devices without providing the required personal details (such as age, weight etc.) through Biobeat's Application and/or the Website may produce or transmit inaccurate or incorrect information. The User shall be responsible for all activity that occurs in association with its account and Biobeat shall not be liable for any Loss (as defined below) caused by the use of such account, including without limitation if pursuant to the User's failure to maintain the confidentiality of its account credentials.

Please note that in the process of downloading or installing Biobeat's Application, the User may be presented and/or be required to approve, Biobeat's Application's term of service, which shall govern the User's use of the Biobeat Services. In the event of any contradictions between the provisions of these Terms and the provisions of Biobeat's Application terms and conditions, the provisions of Biobeat's Application terms and conditions shall prevail.

Please note that we are entitled to change these Terms from time to time (including in order to comply with applicable law and/or regulation) by posting an updated version on Biobeat's Application. Any such change shall be effective within 30 days of the date in which the updated terms were posted on Biobeat's Application. By continuing to use the Biobeat Services following a change, the User is accepting such change. Unless such change is in connection with a change of applicable law and/or regulation, such changes shall only apply to the extent they do not materially affect the User's rights and obligations under these Terms.

2. Privacy

In addition to the information the User is required to provide Biobeat, as part of Biobeat's Application's and/or Website registration process, Biobeat's Services collects and transmit data to Biobeat on an ongoing basis. Any information that Biobeat collects in connection with the User's use of Biobeat's Services, shall be subject to Biobeat's Privacy Policy www.bio-beat.com. Please note that Biobeat Services allow the User to share information with third parties. Such information sharing will require active acts to be performed by the User, as set forth under the Documentation (as defined below). Such information sharing shall be solely and exclusively under the User's responsibility.

3. User's Obligations; Permitted and Prohibited Uses

Amongst the other requirements of these Terms, the User is required to comply in all respects with the instructions related

to the use of Biobeat Devices, as specified in the documentation accompanying each Biobeat Device (for instance, without limitation, any instructions document, user manual or guide) and any instructions posted on Biobeat's Application and/or Website (all collectively, the "**Documentation**"), including without limitation, requirements related to the equipment required for use of certain components of the Biobeat's Services (which may include, without limitation, a computer with adequate software, a supported mobile device and adequate internet access). The User shall be solely responsible for the consequences of its failure to comply with the instructions of the Documentation.

Subject to the full payment for Biobeat's Services, and to these Terms, Biobeat grants the User with a limited, revocable, non-exclusive, non-transferable, non-sublicensable license, to (i) access and use the applicable Biobeat Service, and (ii) access and view Biobeat Materials and Biobeat Stats (as defined below). This license is provided solely for the User's and its personnel use, and does not allow for any use that was not explicitly permitted under these Terms.

Notwithstanding anything to the contrary herein, the User may not perform, attempt to perform, or encourage or assist others in performing any of the following: (i) connecting to or accessing Biobeat Devices other than through the use of the Biobeat Application and/or Website (without limitation, use of any device that is not manufactured, distributed, or sold by or on behalf of Biobeat, including without limitation any knock off or counterfeit versions, is prohibited), (ii) use of any Biobeat Materials, and/or any Biobeat Stats for commercial purposes without Biobeat's consent, (iii) accessing or tampering with non-public areas of the Biobeat Services, (iv) testing the vulnerability of any Biobeat system, breaching any security or authentication measures, or circumventing any technological measure implemented by Biobeat or any of its providers to protect the Biobeat Services, (v) decompiling, disassembling, reverse engineering, tampering with, or attempting to derive the source code of any portion of the Biobeat Services, (vi) copying, adapting, modifying, preparing derivative works based upon the Biobeat Services, Biobeat Materials and/or Biobeat Stats, and/or (vii) distributing, licensing, selling, transferring, publicly displaying, publicly performing, transmitting, broadcasting or otherwise exploiting the Biobeat Services, Biobeat Materials, Biobeat Stats and/or any portion thereof in a manner not explicitly permitted herein.

4. Warranty

Biobeat warrants to the User (for as long as Biobeat Devices were purchased from Biobeat and/or any authorized retailers and/or distributors and/or resellers of Biobeat (collectively "**Authorized Resellers**"), that Biobeat Devices as delivered are and shall remain free from martial defects in materials or workmanship under normal use (in accordance with the Documentation), for a period of 12 months from the original date of purchase from

Biobeat or an Authorized Reseller of the applicable Biobeat Device, as applicable (the "**Warranty**", and the "**Warranty Period**", respectively). Biobeat shall have no liability under the Warranty unless the User shall notify Biobeat or its Authorized Resellers, as applicable, in writing promptly (and in no event later than 30 days) after discovery of the alleged non-compliance, such notification to include a detailed explanation of the alleged non-compliance. Determination of whether a Biobeat Device is non-compliant and the exercise of the Warranty shall be in accordance with Biobeat's instructions and applicable policies at such time.

Without derogating from any warranty disclaimers under Section 5, which shall apply to the Warranty as well, the Warranty shall not apply (a) to any Biobeat Device that has been subject to misuse, accident or neglect, or which has been used in a manner not compliant with these Terms, the Documentation, or industry practices and standards; (b) any Biobeat Device that has been operated with third party software or equipment not approved in writing for use with the applicable Biobeat Device by Biobeat; and/or (c) any Biobeat Device that has been modified, supported or repaired by any third party not authorized in writing to do so by Biobeat. Additionally, the Warranty does not extend to any battery power supply included in/with Biobeat Devices. It is further clarified that Biobeat does not provide any warranty regarding the installation, maintenance, or service of Biobeat Devices, and that the Warranty does not include any coverage of shipping, handling, or delivery of non-compliant or replacement products.

Biobeat's exclusive obligation with respect to a breach of the Warranty shall be, at its option, to either (i) repair Biobeat Devices (by itself or by one of its representatives); (ii) replace the applicable Biobeat Device with an identical product or product having similar features as determined by Biobeat; or (iii) to refund the User or the Authorized Reseller (as applicable) the purchase price paid for the applicable Biobeat Device, all within a reasonable time, and solely to the extent it is determined by Biobeat that the applicable Biobeat Device does not conform to the Warranty. The Warranty Period for any repaired or replaced Biobeat Device shall be the remainder of the original Warranty Period for the original applicable Biobeat Device.

5. Disclaimers; Use at Own Risk

OTHER THAN TO THE EXTENT SPECIFICALLY AND EXPLICITLY SPECIFIED IN THESE TERMS OR THE DOCUMENTATION, BIOBEAT DEVICES ARE PROVIDED "AS IS," WITHOUT WARRANTY OF ANY KIND. WE EXPLICITLY DISCLAIM ANY IMPLIED WARRANTIES, STATUTORY OR OTHERWISE, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT.

ANY WARRANTY PROVIDED IN THESE TERMS OR THE DOCUMENTATION SHALL NOT APPLY TO THE EXTENT BIOBEAT

DEVICES ARE USED IN A MANNER WHICH IS NOT COMPLIANT WITH THESE TERMS, THE DOCUMENTATION, AND/OR ANY OTHER APPLICABLE TERMS.

While Biobeat aims to provide information, which is accurate and complete through the Biobeat Services, Biobeat, makes no warranty regarding the accuracy and completeness of any statistics, parameters, data or information monitored, collected and/or displayed through any of the Biobeat Services, unless with respect to a specific indication for which Biobeat holds a valid approval to be used with respect to, from the applicable regulatory authorities in the territory in which the applicable Biobeat Device is being so used by the User ("**Biobeat Stats**"). While certain components of the Biobeat Services are compliant with various international standards and regulations, the Biobeat Services, and the Biobeat Stats in particular, are not intended to diagnose, treat, monitor, cure, or prevent any disease, and are not intended to match or replace (a) any services or information produced by medical or scientific measurement devices)except with respect to a specific indication for which Biobeat holds a valid approval to be used with respect to, from the applicable regulatory authorities in the territory in which the applicable Biobeat Device is being so used by the User) (b) any monitoring by the User of consumption of medication or of any other medical treatment, and (c) any checkups, services or treatments by physicians and other medical care professionals. Additionally, Biobeat makes no warranty that Biobeat Devices and/or the Biobeat Services will meet the User's requirements and/or any medical or regulatory standards or be available on an uninterrupted, secure, or error-free basis. The User acknowledges and agrees that if it relies on any Biobeat Services, including without limitation the Watch, Biobeat Stats, the User do so solely at its own risk.

Without derogating from the aforementioned, the User acknowledges that Biobeat Devices may be impaired, or produce or transmit inaccurate or incorrect information due to any use which is not in full compliance with the Documentation, including without limitation (a) failure to provide the required personal details through Biobeat's Application or input by the User of incorrect personal details; (b) use of the Watch when it is not fully charged; (c) cellular, internet and/or Bluetooth interruptions; (d) use with respect to applicable patients belonging to certain populations (such as populations of certain age groups) with which the Biobeat Services do not optimally function (as set forth under the Documentation); (e) failure to place and initialize Biobeat Devices in accordance with the instructions set forth under the Documentation; (f) use of any Biobeat Devices for any period in excess of the period allowed under the Documentation; (g) cleaning or upkeep of Biobeat Devices, in any manner which is not fully compliant with the Documentation.

6. Limitation of Liability

TO THE EXTENT PERMITTED UNDER APPLICABLE LAW, NEITHER

BIOBEAT, NOR ITS AFFILIATES AND EITHER OF THEIR OFFICERS AND EMPLOYEES SHALL BE LIABLE FOR (A) ANY INCIDENTAL, SPECIAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES, COSTS, LOSSES OR EXPENSES INCLUDING WITHOUT LIMITATION LOSS OF PROFITS, DATA AND/OR GOODWILL ARISING OUT OF, OR IN CONNECTION WITH, THE BIOBEAT SERVICES AND/OR THE USER'S OR ANY THIRD PARTY'S RELIANCE UPON BIOBEAT SERVICES; AND (B) DAMAGES, LOSSES AND/OR EXPENSES ("**LOSSES**") ARISING OUT OF, OR IN CONNECTION WITH, THE BIOBEAT SERVICES AND/OR THE USER'S OR ANY THIRD PARTY'S RELIANCE UPON BIOBEAT SERVICES, IN AN AMOUNT EXCEEDING, FOR ALL CLAIMS IN THE AGGREGATE, THE TOTAL AMOUNT THE USER HAS PAID FOR THE WATCH. THE AFOREMENTIONED SHALL APPLY REGARDLESS OF WHETHER CLAIMS ARE BASED UPON CONTRACT, TORT (INCLUDING WITHOUT LIMITATION NEGLIGENCE, TO THE EXTENT PERMISSIBLE UNDER APPLICABLE LAW) OR ANY OTHER LEGAL THEORY, AND WHETHER OR NOT BIOBEAT HAS BEEN INFORMED OF THE POSSIBILITY OF SUCH DAMAGE, EVEN IF A LIMITED REMEDY SET FORTH HEREIN IS FOUND TO HAVE FAILED OF ITS ESSENTIAL PURPOSE. THE EXCLUSIONS AND LIMITATIONS OF DAMAGES SET FORTH ABOVE ARE FUNDAMENTAL ELEMENTS OF THE BASIS OF THE BARGAIN BETWEEN BIOBEAT AND THE USER.

WITHOUT DEROGATING FROM THE ABOVE, BIOBEAT SHALL HAVE NO LIABILITY WHATSOEVER FOR ANY INACCURACY, PERFORMANCE FAILURES, UNAVAILABILITY AND/OR LOSSES ARISING OUT OF ANY USE OF BIOBEAT DEVICES AND/OR BIOBEAT'S SERVICES NOT IN ACCORDANCE WITH THESE TERMS AND/OR THE DOCUMENTATION, OR IN CONNECTION WITH, ANY EXTERNAL THIRD PARTY SERVICES UPON WHICH THE BIOBEAT SERVICES RELY (INCLUDING WITHOUT LIMITATION FALURES RELATED TO CELLULAR, INTERNET OR BLUETOOTH CONNECTION OF THIRD PARTY DEVICES OR PROVIDERS) AND/OR GENERALLY FROM CAUSES BEYOND BIOBEAT'S REASONABLE CONTROL, INCLUDING, BUT NOT LIMITED TO, INTERNET FAILURE, NETWORK OR COMPUTER EQUIPMENT FAILURES, ELECTRICAL POWER FAILURES, OR ACTS OF PROVIDERS OF THIRD PARTY SERVICES.

7. Indemnity

The User will indemnify and hold harmless Biobeat, its affiliates and their respective officers and/or employees, from and against any Losses (for clarification, the term Losses shall include without limitation reasonable attorney fees) incurred due to any third party suit, claim or procedure arising out of or connected with (i) the User breach of these Terms, or (ii) the reliance by any third party upon the Biobeat Stats, in a manner not explicitly allowed under these Terms (an "**Indemnifiable Claim**"). Biobeat shall have the right to assume control of the defense and/or settlement of any Indemnifiable Claim, in which event the User will cooperate with Biobeat in asserting any available defenses.

8. Biobeat's Rights

Biobeat retains all right, title and interest, including without limitation design rights, patents, copyrights, trade secrets, trademarks, and any other intellectual property rights (whether or not registerable) in and to Biobeat Devices, any other parts of the Biobeat Services, the Biobeat Materials and Biobeat Stats and the technology, know how, and any other intellectual property (including without limitation any software) underlying the Biobeat Services and/or Biobeat Materials and/or, including without limitation any improvements, updates, upgrades, error-corrections or other modifications thereto, and any derivative work based thereon, regardless of their creator. It is clarified that no source code or license to use source code is provided hereunder. Except for the rights expressly granted to the User hereunder, these Terms do not grant the User any rights or licenses by implication or otherwise with respect to any of Biobeat's intellectual property.

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Without derogating from the above, as between the User and Biobeat, Biobeat shall be the sole and exclusive owner of all rights to any and all information which was absorbed, collected and accumulated by Biobeat Devices or provided to Biobeat, and any ideas, inventions and/or improvements (whether protectable by any intellectual property protection or not) conceived or derived or resulting from feedback provided by the User with respect to the Biobeat Services and/or Biobeat Materials or embodied therein ("Feedback"). The User hereby irrevocably assigns to Biobeat any rights that it may have in such Feedback, and to the extent such rights may not be assigned, the User hereby provides Biobeat a royalty free, perpetual, worldwide, exclusive, irrevocable license to use such Feedback for any purpose, including commercial purposes.

9. Updates and Changes to Services

The User agrees that Biobeat may, without providing additional notice to the Institution, automatically install updates to the Application or Biobeat Devices. In addition, if so required by applicable law or regulation, Biobeat may discontinue, temporarily or permanently, any feature or component of the Biobeat Services at any time, with or without notice, without incurring any liability aside from as explicitly specified herein. Without Derogating from the above, Biobeat may discontinue, temporarily or permanently, any feature or component of the Biobeat Services at, from any reason following a 6 months prior notice, without incurring any liability aside from as explicitly specified herein.

10. Payment

The use of Biobeat's Application may be subject to payment of certain fees or payments which are not covered by the payment made by the User for Biobeat Devices, in amounts, or covering periods of usage, as may be determined by Biobeat and made known to the User upon download and/or registration of Biobeat's Application.

11. Communication

Should the User have any questions regarding these Terms, or wish to report a violation of these Terms or abuse of the Biobeat Service, to receive help or for any other matter, the User may contact us at: info@bio-beat.com

12. Alerts and Notifications

As part of the User use of the Biobeat Services, the User may receive notifications, text messages, alerts, or e-mails. The User hereby agrees to the receipt of such communications. The User can control receipt of related communications from its account settings. The User alone shall be responsible for any messaging or data fees it may be charged by its wireless carrier.

13. Governing Law and Venue

Any disputes or claims arising out of or in connection with these Terms and/or any of the Biobeat Services, will be governed by, and construed in accordance with, the laws of the State of Israel. The User hereby irrevocably agree that the competent courts of the Tel Aviv-Jaffa District of Israel shall have exclusive jurisdiction to settle any disputes or claims arising out of or in connection with these Terms and/or the Biobeat Services (including any non-contractual disputes or claims).

14. General Terms

The headings used in these Terms are for convenience of reference only and shall not affect the interpretation or meaning of the terms and provisions of these Terms.

No modification to these Terms will be effective unless agreed to in writing by Biobeat. A failure by Biobeat to partially or fully exercise any rights or the waiver of any default of any provision of these Terms by the User shall not prevent a subsequent exercise of such right by us or be deemed a waiver by us of any subsequent breach by the User of the same or any other term of these Terms. Unless expressly provided otherwise herein, all remedies hereunder are cumulative and do not exclude any other remedies available by law.

If any provision of these Terms is found by any court or administrative body of competent jurisdiction to be invalid, unenforceable or illegal, the other provisions shall remain in full force and effect.

Biobeat Technologies Ltd.

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Email: **Info@bio-beat.com**
Website: **http://www.bio-beat.com/**