

hilo

Hilo Band

EN – User Manual
FR – Manuel d'utilisation
DE – Bedienungsanleitung
IT – Manuale d'uso
ES – Manual de usuario



ENGLISH

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1 Introduction

The Hilo Band is the smart way to track your Blood Pressure over days and nights without any effort. The Hilo Band is designed to be discreet, with no lights or alarms bothering you during your daily life. With its accuracy and ease of use, Hilo is the perfect solution to track your blood pressure 24 / 7.

Hilo offers a new way to monitor your heart health that easily integrates into your life. Our device tracks your Blood Pressure through unnoticeable measurements performed multiple times per day. All you need to do is to wear the bracelet. You can access your data anytime by simply looking at the Hilo mobile application.



Please read this User Manual carefully to gain a complete understanding of the device's functions and safety-related information.

Support: In case you have any additional questions, or you encounter any issues, please contact Aktiia's Customer Service through our Help Center / FAQ (Frequently Asked Questions) on our website at www.aktiia.com.

Incident and Adverse Event: For any incident or event, please contact immediately Aktiia at support@aktiia.com with mention of the Incident or Adverse Event in the email content or title.

2 Intended purpose

Hilo Band is a non-invasive blood pressure (BP) monitor intended to measure optical Photoplethysmography (PPG) signals on the user's wrist and to calculate blood pressure values using a Pulse Wave Analysis (PWA) technique, following a calibration process using an oscillometric blood pressure monitor.

Hilo Band can also calculate heart rate based on the same measurement and analysis technology.

3 Indications for use

The Hilo Band is indicated for blood pressure and heart rate monitoring of adult patients for home use only.

4 Contraindications

The Hilo Band **IS NOT INTENDED** to be used:

- on patients suffering from sustained cardiac arrhythmias that can lead to weak or unstable pressure pulses including tachycardia (heart rate at rest > 120bpm) and atrial fibrillation;
- on patients suffering from pathologies that systematically reduce peripheral perfusion including Raynaud's disease, diabetes, renal dysfunctions (eGFR < 60mL/min/1.73 m²), hyper-/hypothyroidism, pheochromocytoma or arteriovenous fistula;
- on pregnant women;
- on damaged/injured skin;
- on patients below 21 y.o. and above 85 y.o.

5 Intended population

The Hilo Band is intended to be used on and by adult population, aged between 21 and 85 years old. There are no restrictions related to the user's sex and ethnicity.

6 Intended clinical benefits

The Hilo system enables long-term unbiased blood pressure and heart rate monitoring. This clinical benefit to the user stems from the acceptable accuracy, stability and automaticity of the blood pressure and heart rate estimation in compliance with the requirements of the relevant standards, ISO 81060-2 Non-invasive sphygmomanometers -- Part 2: Clinical investigation of intermittent automated measurement type and 80601-2-61 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.



Hilo Band does not provide any diagnosis of your blood pressure.

Consult your physician for an appropriate analysis of your blood pressure data for diagnosis.

7 Technological characteristics



The Hilo Band uses PPG technology (Photoplethysmography) to acquire optical data on your wrist. The PPG data are then transferred through the Hilo mobile application to a secured cloud server on which Hilo's algorithms estimate your blood pressure through advanced processing of the optical data. The Hilo Band detects if the user is moving before initiating a PPG measurement and will provide blood pressure measurement only when the user is still.

This product is licensed under patents owned by CSEM SA, Switzerland.



8 Important safety information

Please read the important safety information in this user manual before using the device. Any serious incident occurring in relation to the Hilo Band should be reported to Aktiia and the competent authority of the Member State in which the user and / or patient is established.




Warning and Caution symbols definition:

Symbol	Definition	Symbol	Definition
	The “WARNING” sign in this user manual indicates a potentially hazardous situation which, if not avoided, could result in serious injury or death.		The “CAUTION” sign in this user manual indicates a potentially hazardous situation which, if not avoided, could result in minor injury to the user or patient or damage to the equipment or other property.

Important safety information, including residual risk and side effect, about Hilo Band / Important caution information:

	A risk of swallowing and suffocation has been identified as residual risk: The pod on your Hilo Band is small enough to be swallowed by a young child. To prevent risk of suffocation, never leave your Hilo Band unattended!
	No modification of the equipment is allowed.

Important safety information, including residual risk and side effect, about Hilo Band / Important warning information:

	This device may only be used for the purposes described in this User Manual. Aktiia cannot be held liable for damage or injury caused by incorrect use. Always follow the operating procedures described in this User Manual to measure your blood pressure accurately and safely.
	Hilo Band is designed as a device for personal use (single user) only. Do not share your device with others as it may result in inaccurate blood pressure readings.
	The strap of your Hilo Band contains silicone material. Avoid wearing the Band in case of known allergy to silicone. Despite selecting medical grade materials for our device, skin irritation and skin reaction may occur as side effect. In case of skin irritation or reaction, stop wearing your Hilo Band to allow your skin to recover. Please also consult the section Care and maintenance of this manual. If symptoms persist or worsen, consult your doctor before using your Hilo Band.

9 Package contents

Make sure to remove all components from the packaging and inspect for damage.

If the Hilo packaging or any other components are damaged or open upon reception, do not use and contact Aktiia's Customer Service through our Help Center / FAQ (Frequently Asked Questions) on our website at www.aktiia.com.

Your Hilo Band is supplied in a box containing the following items:

1 Hilo Band with pod and strap	
1 Charging station	
1 User Manual	Latest version of Hilo Band user manual can also be found online at: www.aktiia.com/ifu

10 Operating requirements

To use the Hilo Band you need to download the free Hilo mobile application (Hilo app) from the Apple App Store or Google Play. Creation of a user account via the Hilo app is required to make use of the Hilo Band.

Access to the Internet is required to:

- Download the Hilo app
- Create and access your Hilo user account
- Access to your personal email in order to validate creating your Hilo account
- Update the Hilo device firmware
- Visualize your new Blood Pressure data
- Receive insights on your Blood Pressure readings

11 Authorized and compatible devices

Your Hilo Band requires initialization and periodic reinitialization. This procedure must be realized with an authorized compatible device, the Hilo Cuff. The Hilo Cuff is an oscillometric blood pressure monitor provided by Aktia with your Hilo Band.

12 Set up and initialization procedures



1. Charge the Hilo Band and the Hilo Cuff before first use.

Connect the USB connector of the charging station to a power source and place the Hilo Band on the charging station, making sure to remove the plastic cover from the bottom of the Hilo Band. A red light at the bottom of the charger will start glowing. When the charge is completed, the indicator light stays a steady red color.



To charge the Hilo Cuff, please refer to the provided Hilo Cuff user manual for operating information.

2. Download the Hilo app.

Scan the QR code or go to the Apple App Store or Google Play to download and install the Hilo app.

3. Create a user account on the Hilo app.

Open the Hilo app on your mobile device and follow the instructions to register and set up your personal account. You will need access to your personal email in order to validate your new Hilo account.

4. Pair your Hilo Band with your mobile device.

Place the Hilo Band on the charging station, follow the on-screen instructions to enable the appropriate permissions, and pair it with your mobile device. Wait until pairing is confirmed by the Hilo app.

5. Pair your Hilo Cuff with your mobile device.

Unplug the Hilo Cuff from the charging cable and power **ON** using the toggle switch. When a blue light begins to blink, follow the cuff pairing instructions in the Hilo app.

6. Fit your Hilo Band on your wrist.



Follow the Hilo app on-screen instructions or carefully read the instructions in the “Correct Hilo Band positioning” section of this user manual.

7. Fit your Hilo Cuff on the opposite arm.

Follow the on-screen instructions. Note that the Hilo Cuff must be worn on the opposite arm as the Hilo Band. For example, if you wear the Hilo Band on your RIGHT wrist, place the Hilo Cuff over your LEFT arm, and vice versa.



The accuracy of blood pressure measurement done by Hilo Cuff depends on the correct Cuff positioning. Please carefully read the instructions in the section “Correct Hilo Cuff positioning” of this user manual.

8. Initialize your Hilo Band.

In the Hilo app, carefully follow the instructions to complete the initialization procedure. The Hilo cuff will start inflating.

9. Switch OFF your Hilo Cuff.



The accuracy of the initialization process depends on your body posture during the initialization. Carefully read the section “Body Posture during Initialization Procedure” of this user manual.

Congratulations! Your Hilo Band is now initialized and ready to track your blood pressure!



You need to complete an initialization procedure at least once per month, or when prompted by the mobile application. Data obtained outside the initialization period may be inaccurate.

13 13 Correct Hilo Band positioning

Fasten your Hilo Band around your wrist with the sensor facing toward the skin on top of the wrist. The clasp is on the underside of the wrist. The sensor on the pod should be placed in direct contact with the skin. Tighten the bracelet to be snug but comfortable to ensure that the bracelet does not move around while using your hands.



14 Correct Hilo Cuff positioning

When wearing an Hilo Band on your RIGHT wrist, place the Hilo Cuff over your LEFT arm, and vice versa. The cuff must be placed on the arm opposite the bracelet wearer.

1. Remove garments from your upper arm. If you roll up your sleeve, please ensure that the garment is not too tight.
2. With the blue light closest to your elbow, put the cuff 2-3 cm (1") above your elbow joint by inserting your bare arm through it.
3. Secure and tighten the cuff around your arm so that it fits closely but you can still insert two fingers between your arm and the cuff. Please note that if the cuff is too loose, the measurement will not be accurate.
4. While seated, place your hand, palm side-up in front of you so that it is supported by a flat surface and the Hilo Cuff is at the same height as your heart. Your Hilo Cuff is positioned on the inner side of your arm, over the artery.



Please check the Hilo Cuff user manual for instructions for use.

15 Body posture during the initialization procedure



Please sit down and relax for 5 minutes before starting the initialization procedure.

Note: Blood Pressure measurements can be affected by the position of the cuff and your physiological and emotional condition.

1. With your feet flat on the ground and your back straight, sit up straight. Avoid crossing your legs.
2. Lay your hand down in front of you, palm down, on a table, desk, or other level surface.
3. Placing the Hilo Cuff's midpoint at the same level as your heart is recommended.
4. Do not move or tense your arm muscles during measurement.
5. Relax, and do not move or talk.
6. Perform initialization requesting it through the Hilo application and follow instructions of the Hilo application during the 3 cycles of measurement.

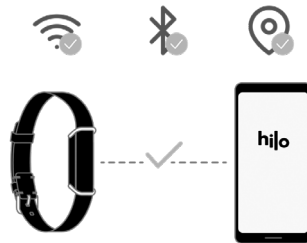


16 Accessing your data

Your Hilo Band automatically monitors your blood pressure. Measurements are triggered every hour, during the day and at night. Your personal information is stored on a secure cloud server, not on your phone or Hilo Band. Consequently, for the Hilo app to display your data and synchronize with the Aktiia safe cloud server, you must have a functional internet connection.

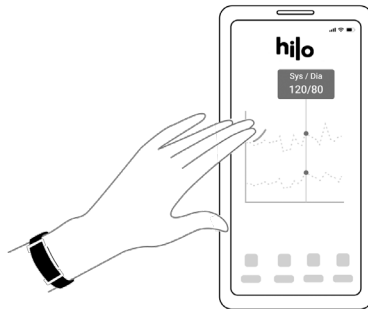
To sync your data

- Enable the Bluetooth and Internet connection on your mobile device. Depending on your Android device version, the location service should be enabled as well.
- Open the Hilo app to synchronize data from your Hilo Band. The data synchronizes automatically, with a sync indicator showing the status. Depending on how often you open the app and synchronize your data, this might take a few seconds to several minutes.
- In case you do not see a sync view when opening the app, swipe down to manually activate the synchronization.
- Make sure you open the app regularly so that the synchronization is fast, and you avoid losing data. For this reason, synching once a day is recommended.



Visualizing your Blood Pressure data

- Use the Hilo app to see your blood pressure data, every vertical line represents the average measurements taken during the displayed period.
- The top endpoint of the line is the systolic (SYS) value, and the bottom endpoint of the line is the diastolic (DIA) value.
- Tap on the line to read the numeric values, hold, and move your finger on the screen to navigate through the values.



17 How to evaluate your Blood Pressure



The Hilo app and devices are not intended to be diagnostic devices. Self-diagnosis of measurement results and self-treatment are potentially dangerous. You should always consult your doctor for relevant interpretation of blood pressure results.

The following classifications are based on measurements taken on a seated person after a few minutes of rest.

It is important to note that Blood Pressure readings in everyday life conditions might be higher.

The table is not intended to provide a basis for any type of diagnosis or emergency assessment; the table only depicts different classifications of blood pressure.

Consult your physician for an interpretation and diagnosis based on your personal blood pressure results.

Europe

The European Society of Hypertension (ESH) has created the following guide for classifying blood pressure values.

BLOOD PRESSURE CATEGORY	SYSTOLIC BP mmHg		DIASTOLIC BP mmHg	COLOR INDICATOR
OPTIMAL	LESS THAN 120	AND	LESS THAN 80	Dark green
NORMAL	120-129	AND/OR	80-84	Light green
ELEVATED	130-139	AND/OR	85-89	Yellow
HIGH BLOOD PRESSURE STAGE I	140-159	AND/OR	90-99	Orange
HIGH BLOOD PRESSURE STAGE 2	160-179	AND/OR	100-109	Light red
HIGH BLOOD PRESSURE STAGE 3	HIGHER THAN 179	AND/OR	HIGHER THAN 109	Dark red

Note: Various factors such as age, obesity and medical condition should be considered for a correct evaluation.

Consult with your physicians for an accurate assessment and diagnosis of your health condition.



18 Battery handling and power supply

The battery of the Hilo Band is a built-in rechargeable li-polymer battery. Access the current charge of your bracelet via the Hilo app. If the battery is lower than 10%, please charge your device:

1. Connect the USB connector of the charging station to a power source.
2. Place the Hilo Band on the charging station as shown below. The red light on the bottom part of the charger will start glowing.
3. A steady red light indicates that the device is fully charged.

It is recommended that you charge the battery when the battery is less than 10%.

The Hilo Band charger is designed to work when connected to a constant 5V DC source.

	The battery in this device is a fixed battery and can only be changed by an authorized Aktiia Service agent.
	Should your battery be defective, please contact Aktiia Customer Service for a replacement. Lithium battery replacement by inadequately trained personnel could result in a hazard such as a fire or explosion.

Note: The battery life and charge cycles vary by use and settings.



19 Unpair your device

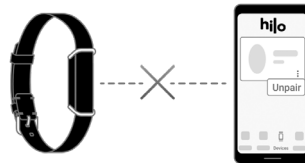
Hilo Band is designed for personal use (single user) only. The in-app pairing process links your device to your account. Suppose you wish to allow another person to use the Hilo Band. In that case, you must unpair the devices from your Hilo account.

To complete the unpairing procedure you should:

1. Login to your account.
2. Tap on the device tab.
3. Tap on the button with the three dots.
4. Press unpair.

Note: Unpairing is needed if the Hilo Band and/or the Hilo Cuff are to be linked with a new user account.

Note: Unpairing is not needed if a new mobile device is used to download the same user account's Aktiia data.



20 Troubleshooting

The Hilo Band is designed to be discreet, with no lights or alarms bothering you during your daily life.

To know if your Hilo Band is **ON**:

1. Take off your Hilo Band.
2. Examine the sensor located on the Hilo Band's underside.
3. Double tap the side of the pod (either side is fine), and a green light should blink within 5 seconds.

If the green light does not blink, your Hilo Band may be out of power.

Please charge your device with the provided charging station.



Problem	Solution
I don't see a red light when charging my Hilo Band	Verify that the charging station is well connected to a power supply through the USB cable provided.

My Hilo Band does not connect to my mobile device	<p>Check that your mobile device Bluetooth is activated and that you enabled permissions for Bluetooth connection and location.</p> <p>If your mobile device Bluetooth is activated but your Hilo Band still does not connect, place your Hilo Band on the charging station to force a reset (you will not lose your personal data or account information). If the problem persists, contact Aktiia Customer Service.</p>
I cannot sync my Hilo Band with the Hilo app	<p>Check that your Hilo Band is connected in the Devices section. On the Home screen pull down to activate on demand syncing.</p>
I cannot pair my Hilo Band with the Hilo app	<p>Verify that your Hilo Band is correctly placed on the charger and that a red light is visible at the bottom of the charging station.</p>
The initialization recording failed	<p>Verify that Bluetooth and Location services are enabled, and the devices are connected. Verify that you have a stable internet connection.</p> <p>Verify that the Hilo Band and Hilo Cuff are positioned correctly.</p> <p>Take 5 deep breaths before starting the initialization procedure again, and make sure not to move during recording.</p>
The Hilo Band was not found	<p>Place your Hilo Band on the charging station and connect it to the power supply. Verify that Bluetooth is on and permissions are granted and try again.</p>
There is no reliable measurement data for this period	<p>The Hilo Band only measures your blood pressure while you are at rest. You might not get any measurements during periods of high activity. Please get in touch with our customer support if you don't get any measurements for more than 24 hours and other troubleshooting steps do not resolve this.</p>

21 Care and maintenance

The Hilo Band does not contain any part or component that requires maintenance operation by the user.



Do not attempt to disassemble Hilo Band as this will result in permanent damages and will void your warranty.

To mitigate the risk of skin irritation, it is advisable to maintain regular cleanliness of your Hilo Band. Simply use a damp cloth to gently clean your Hilo Band, followed by drying with a soft cloth.

Additionally, we recommend drying your Hilo Band in instances where moisture accumulates between the bracelet and your skin.

Please carefully read the additional cautions below:



Please ensure that your Hilo Band and the charger are completely dry before connecting your Hilo Band to the charger. Moisture can interfere with the charging process and may cause damage.



If exposure to water, please dry your Hilo Band off using a soft cloth.



If the device is exposed to products such as soap, soapy water, shampoos, conditioners, perfume, cosmetics, detergents, mosquito repellent, or hand sanitizing gel, it may accelerate the aging of the material of your device and compromise water resistance. Therefore, please remember to dry and clean the device with a damp cloth after exposure to these liquids. We also recommend drying it with a soft cloth.





If the device is exposed to saltwater or excessive sweating, please ensure to clean the device with a damp cloth. We also recommend drying it with another soft cloth.

22 Information about water resistance levels

The Hilo Band can be worn when dishwashing, splashing, showering or swimming. However, it cannot be used for diving or snorkeling.

Please carefully read the cautionary statements below before wearing the Hilo Band:

	<ul style="list-style-type: none">• Avoid long exposure to salt water. Make sure you rinse your Hilo Band with clear water after spending time swimming in salted water. Avoid exposing your device to immersion under pressurized water or high velocity water.• Avoid exposure to any chemical products such as solvents, detergents, perfumes or cosmetics. They may damage the strap or the casing of Hilo Band.• Avoid extreme atmospheres (e.g. saunas or steam rooms).
	<p>After exposure to water, we recommend to dry your Hilo Band using a soft cloth.</p>

The water resistance and the dust resistance are not permanent and may decrease over time with normal use due to the aging of the material.

23 Specifications

Product description	Blood pressure monitor
Model	Hilo Band
Measurement method	Photoplethysmography (PPG)
Sensor to measure PPG	Green light (wave-length 526nm); silicon receiver diode
Measurement accuracy (Blood Pressure)	± 5mmHg
Measurement accuracy (Heart Rate)	± 5 pulse/min

Measurement range	40-250 mmHg for blood pressure, 40-180 beats/min for heart rate
Classifications	Internally powered Applied parts: Pod (type BF). IP68 (Dust-tight; Protected against immersion with a maximum depth of 20 meters (~65 feet) up to 30 minutes)
Power source	Li-Ion rechargeable battery 3.7 Vdc 55mAh
Communication module	BLE 5.0 Frequency range 2.4 to 2.4835 GHz Modulation GFSK Effective radiated power <10 dBm
Operating conditions	+5°C to 40°C 700hPa to 1060hPa 15% to 90% RH
Maximum temperature of the applied parts	Up to 43°C
Storage and transportation conditions	-20°C to +60°C 700hPa to 1060hPa 10% to 95% RH
Hilo Band size	14 cm to 21 cm / 5 ½ to 8 ¼ inches (circumference)
Hilo Band weight	approximately 18g (0.6 ounces).
Mobile operating systems	iOS, Android

The Hilo Band battery can maintain the performance characteristics for a maximum of 300 charge cycles, which corresponds to an expected service life of 3 years.

24 Warranty

Your Hilo Band is warrantied to be free from defects in materials and workmanship within two years from the date of purchase when used in accordance with the provided instructions. Issues related by strap's wearing are not covered by the warranty.

The warranty extends only to the end user. We will, at our option, repair or replace without charge the Hilo Band covered by the warranty. Repair or replacement is our only responsibility and your only remedy under the warranty.


Liquid damage is not covered under warranty. The water resistance and the dust resistance are not permanent and may decrease over time with normal use.

25 EMC and RF statements

The Hilo Band needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the following section.





The Hilo Band is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.

The Hilo Band uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

The Hilo Band is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Interference may occur in the vicinity of equipment marked with the following symbol .

Portable and mobile RF communication equipment (e.g. cell phones) can affect the Hilo Band.

CAUTIONS:

	Hilo Band should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, it should be observed to verify normal operation in the configuration in which it will be used.
	Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of Hilo Band, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
	Hilo Band and Hilo Cuff are not suitable for use in MRI (Magnetic Resonance Imaging) environment.

26 Electromagnetic compatibility information

Guidance and manufacture's declaration - electromagnetic emissions		
<p>The Hilo Band is intended for use in the electromagnetic environment specified below. The user of the Hilo Band should ensure that it is used in such an environment.</p> <p>The Hilo Band is suitable for use in "Home Healthcare Environment", i.e. all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</p>		
Emission test	Compliance	Electromagnetic environment - guidance
Conducted emissions CISPR11	Groupe 1	The Hilo Band uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radiated emissions CISPR11	Class B	
Harmonic emissions IEC 61000-3-2	Not Applicable	—
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and manufacturer's declaration - electromagnetic immunity

The Hilo Band is intended for use in the electromagnetic environment specified below. The user of the Hilo Band should ensure that it is used in such an environment. The Hilo Band is suitable for use in "Home Healthcare Environment", i.e. all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Immunity test	60601-1-2 test levels	Compliance
Electrostatic discharge IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV in air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV in air
Radiated RF electromagnetic field IEC 61000-4-3	10 V/ m 80 MHz à 2.7 GHz 80% MA à 1 kHz	10 V/ m 80 MHz à 2.7 GHz 80% MA à 1 kHz
Proximity fields from RF wireless communications equipment IEC 61000-4-3 (interim method)	9 V/ m 710 MHz, 745 MHz, 780 MHz, 5240 MHz, 5550 MHz, 5785 MHz 27 V/ m 385 MHz 28 V/ m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	9 V/ m 710 MHz, 745 MHz, 780 MHz, 5240 MHz, 5550 MHz, 5785 MHz 27 V/ m 385 MHz 28 V/ m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz

Guidance and manufacturer's declaration - electromagnetic immunity		
Immunity test	60601-1-2 test levels	Compliance
Immunity to conducted disturbances, induced by radio-frequency IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and radio-amateur band between 0,15 MHz and 80 MHz 80 % AM à 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM and radio-amateur band between 0,15 MHz and 80 MHz 80 % AM à 1 kHz
Radiated fields in close proximity IEC 61000-4-39	134,2 kHz / Pulse modulation 2,1 kHz / 65A/m 13,56 MHz / Pulse modulation 50 kHz / 7,5A/m 30 kHz / CW / 8A/m	1134,2 kHz / Pulse modulation 2,1 kHz / 65A/m 13,56 MHz / Pulse modulation 50 kHz / 7,5A/m 30 kHz / CW / 8A/m
Power frequency magnetic field IEC 61000-4-8	30 A/ m 50 Hz	30 A/ m 50 Hz

27 Compliance

This device complies with the following regulations and normative documents/standards:

2017 / 745 (EU) Regulation of the European Parliament and of the Council of 5 April 2017 on medical devices, repealing Council Directives 93 / 42 / EEC

2014 / 53 (EU) Directive of the European Parliament and of the Council of 16 April 2014

EN ISO 10993-5: 2009: Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity

EN ISO 10993-10: 2010: Biological evaluation of medical devices. Tests for irritation and skin sensitization

IEC 60601-1:2005 / A1:2012/A2:2020: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2014/A1:2020: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral

Standard: Electromagnetic disturbances – Requirements and tests

IEC 60601-1-6:2010 / A1:2013/A2:2020: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability

IEC 60601-1-11:2015/A1:2020: 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 EN IEC 62471:2008:

Photobiological safety of lamps and lamp systems

ETSI EN 301489-1 v2.2.3: ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements

ETSI EN 301489-17 V3.2.4: ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems

EN ETSI 300 328, V2.2.2: Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques

EN 62479 (2010): Assessment of the compliance of low-power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)

This device contains license-exempt transmitter(s)/receiver(s) that comply with Innovation, Science, and Economic Development Canada's license-exempt RSS(s). Operation is subject to the following two conditions:

- (1) This device may not cause interference.
- (2) This device must accept any interference, including interference that may cause undesired operation of the device.

In accordance with the IEC 60601-1 standard, this medical device does not have essential performance. Its operation is guaranteed under normal usage conditions as described in this manual, without impacting the safety of users and patients.

28 Disposal



Actuation of European directives 2002 / 95 / EC, 2002 / 96 / EC and 2003 / 108 / EC, for reduction in use of dangerous substances in the electric and electronic device and for garbage disposal. The symbol applied on the device or its packaging means that at the end of its useful life the product must not be disposed of with domestic waste.

At the end of the device's useful life, the user must deliver it to the able collecting centers for electric and electronic garbage or give back to the retailer when purchasing a new device. Disposing of the product separately prevents possible negative consequences for the environment and for health, deriving from inadequate disposal. It also allows the recovery of materials of which it's made up in order to obtain an important saving of energy and resources and to avoid negative effects to the environment and health. In case of abusive disposal of device by the user, will be applied administrative endorsements in compliance with current standard. The device and its parts are made with regard to disposal, as appropriate, in accordance with national or regional regulations. This product complies with RoHS Directive 2011/65/EU and Amendment (EU) 2015/863.

29 Network security recommendations

The following recommendations detail security measures that Hilo users should follow to ensure appropriate protection of their personal data. Failure to comply with these recommendations may lead to user personal data leakage or destruction.





















Only use mobile application authorized by Aktiia. Aktiia only makes its mobile application and subsequent updates available on official app stores.

Use unique credentials (username and password) for login to your Hilo account. Safely store your password so that no other person can access it. It is recommended to regularly update your password, at least once every 3 months.

Do not let other people login to your Hilo account on your behalf.

30 Safety symbols definitions

The signs below might be in the user manual, labeling or other component with your Hilo Band.

Symbol	Definition	Symbol	Definition
	The "WARNING" sign throughout this user manual indicates a potentially hazardous situation which, if not avoided, could result in serious injury or death.		The "CAUTION" sign throughout this user manual indicates a potentially hazardous situation which, if not avoided, could result in minor injury to the user or patient or damage to the equipment or other property.
	Symbol for "IFU are available on www.Aktiia.com/ifu "		Symbol for "THE INSTRUCTION FOR USE MUST BE READ"
	Symbol for "COMPLIES WITH MDR EU2017/745 REQUIREMENTS"		Symbol for "ENVIRONMENT PROTECTION - Electrical waste products should not be disposed with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice"
	Symbol for "MANUFACTURER"		Symbol for "SINGLE PATIENT - MULTIPLE USE"
	Symbol for "THIS EQUIPMENT IS A MEDICAL DEVICE"		Symbol for "TYPE BF APPLIED PART"
	Symbol for "UNIQUE DEVICE IDENTIFIER"		Symbol for "STORAGE AND TRANSPORTATION ENVIRONMENT – HUMIDITY LIMITS"
	Symbol for "SERIAL NUMBER"		Symbol for "STORAGE AND TRANSPORTATION ENVIRONMENT – PRESSURE LIMITS"
	Symbol for "European authorized representative"		Symbol for "STORAGE AND TRANSPORTATION ENVIRONMENT – TEMPERATURE LIMITS"
	Symbol for "Australian representative/ sponsor"		Symbol for "Radio Frequency Radiation (RF)"
	Symbol for "Importer"		Symbol for "BATCH / LOT NUMBER"

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Blood pressure monitor
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