hilo

EN - User Manual
FR - Manuel d’utilisation
DE - Benutzerhandbuch
IT - Manuale d'uso
ES - Manual del usuario
RO - Manual de utilizare
SV - Bruksanvisning
NL - Gebruikershandleiding
NO - Brukerhåndbok
FI - Käyttöohje
DA - Brugervejledning

User Manual - Content

1. Introduction

The Hilo system is a smart, effortless way to track blood pressure day and night. It consists of the Hilo Band, Hilo Cuff, and a Hilo App, offering discreet and accurate monitoring without disrupting daily life. By wearing Hilo Band, users receive multiple unnoticeable measurements per day, with easy access to their data via the Hilo App.

Hilo Band uses photoplethysmography (PPG) to acquire optical data on your wrist. The PPG data are then transferred through the Hilo App to a secured cloud server on which Hilo's algorithms estimate your blood pressure. 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.

Hilo Cuff uses the oscillometric measuring method to detect blood pressure. Before every measurement, the unit establishes a "zero pressure" equivalent to the atmospheric pressure. With inflation of the arm cuff, the unit detects pressure oscillations generated by the brachial artery pulsatility, which are used to determine the systolic and diastolic pressure, as well as pulse rate.

Hilo is a medical device from Aktiia company.

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

Important

Please follow Hilo App on-screen instructions and carefully read the instructions of this User Manual 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.hilo.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. Any serious incident occurring in relation to the Hilo Band or Hilo Cuff may also be reported to the competent authority of the Member State in which the user and / or patient is established.

Warranty

Do not attempt to disassemble Hilo as this will result in permanent damages and will void your warranty. Please refer to Terms and Conditions on our website at www.hilo.com

2. Hilo Package Content

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

hiloBand

Pod, strap and charger

hiloCuff

Cuff and charging cable

User manual

3. Important Information

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.

Hilo Cuff is an oscillometric blood pressure monitor intended to initialize Hilo Band which is a component of Hilo. Hilo Cuff helps with measurement of baseline blood pressure and heart rate of a user to initialize Hilo Band device.

Indications for use

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

Hilo Cuff is used to initialize Hilo Band. Hilo Cuff is indicated to be used for measuring blood pressure and heart rate in adults for home use only.

Intended population

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.

Hilo Cuff is intended to be used by adult population with arm circumference ranging from 22cm to 42cm (about 8¾˝- 16½˝). There are no restrictions related to the user's sex and ethnicity.

Intended clinical benefits

Hilo 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 Noninvasive sphygmomanometers – Part 2 and ISO 80601 Medical electrical equipment – Part 2-61. The Hilo Band has successfully completed clinical validation under ISO 81060-2, demonstrating its effectiveness in measuring systolic/diastolic blood pressure and heart rate in a study involving 85 subjects.

Authorized and compatible devices

Your Hilo Band requires initialization and periodic reinitialization. This procedure must be realized with Hilo Cuff. The Hilo App can be downloaded on compatible iOS and Android devices.
See www.hilo.com for details on the compatible devices.

4. Contraindications

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.

Hilo Cuff IS NOT INTENDED to be used:

- On patients with implanted electrical devices, such as cardiac pacemakers or defibrillators;
- On neonatal patients, children, patients with preeclampsia, premature ventricular beats, atrial fibrillation, peripheral arterial disease, and patients undergoing intravascular therapy or arterio-venous shunt, or people who have received a mastectomy;
- By any person who is pregnant or may possibly be pregnant.

Important

Please consult your doctor prior to using the device if you have one of these listed conditions.

5. Safety information

	hiloBand	hiloCuff
Warnings	• Hilo is not intended to be a diagnostic device. Self-diagnosis of measurement results and self-treatment are potentially dangerous. You should always consult your doctor for relevant interpretation and diagnosis based on your personal blood pressure results. • No modification of the equipment is allowed.	
	• 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! • 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.	• Keep the device out of reach of young children to avoid swallowing of small parts. • This device is intended for non-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the arm or for functions other than obtaining a blood pressure measurement. • If you are taking medications, consult your physician to determine the most appropriate time to measure your blood pressure. Never change a prescribed medication without consulting your physician. • Do not apply the cuff over a wound, otherwise it can cause further injury. • Batteries shall not be exposed to excessive heat such as direct sunshine, fire, or other similar situations. The battery could explode causing injury or death. • 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.

	hiloBand	hiloCuff
Cautions	• Hilo 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 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. • Check Hilo before use, do not use it if it is damaged in any way. The use of a damaged unit may cause injury or improper results. • The accuracy of blood pressure measurement provided by Hilo depends on on your body posture during the initialization and on the correct Hilo Cuff positioning. Follow Hilo App on-screen instructions and carefully read the instructions in the “How to initialize” section of this User Manual. • Please sit down and relax for 5 minutes before starting the initialization procedure. • Do not use or clean Hilo while charging. • Please use accessories and detachable parts specified / authorised by the manufacturer. Otherwise, it may cause damage to the unit or danger to the user. • Hilo integrates built-in and not changeable batteries, do not attempt to replace them, only charge in accordance with the user instructions supplied with the device. • 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 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. • Hilo is not suitable for use in MRI (Magnetic Resonance Imaging) environment.	
	• The strap of your Hilo Band contains Medical grade Silicone material. Avoid wearing the device 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. • 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.	• The strap of your Hilo Cuff contains polyester, nylon or plastic. Avoid wearing the device in case of known allergy to those materials. • Do not inflate the Hilo Cuff on the same limb which other monitoring equipment is applied simultaneously. This could cause temporary loss of function of the monitoring equipment that is being simultaneously used. • Check that operation of Hilo Cuff does not result in prolonged impairment of the patient‘s blood circulation. Too frequent and consecutive measurements could cause disturbances in blood circulation and injuries. • On the rare occasion of a fault causing Hilo Cuff to remain fully inflated during measurement, open the cuff immediately. Prolonged high pressure (cuff pressure > 300mmHg or constant pressure < 15mmHg for more than 3 minutes) applied to the arm may lead to an ecchymosis. • Hilo Cuff measurements may be inaccurate if taken in the following circumstances: within 1 hour after eating or drinking; immediate measurement after tea, coffee, smoking; within 20 minutes after taking a bath; when talking or moving your fingers; in a very cold environment; when you want to discharge urine. • Dust may affect the performance of Hilo Cuff. Please use the soft cloth to clean the whole unit before and after use. Don’t use any abrasive or volatile cleaners.

6. How to charge the device

1. Use the cable provided

Connect the USB cable to Hilo Cuff.

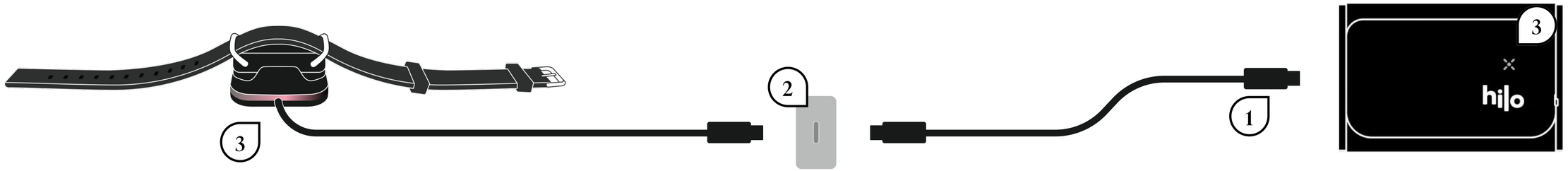
2. Plug into Power Source

Use a compatible USB charger or computer port.

3. Charging Indicator

Hilo Band - glowing red while charging / steady red when fully charged.

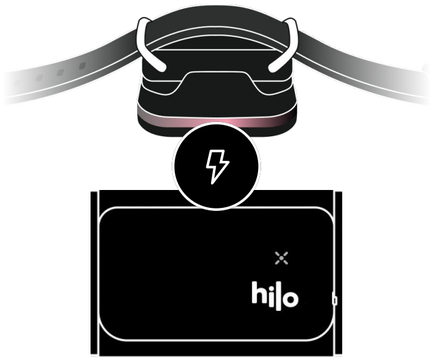
Hilo Cuff - blinking red if out of battery / blinking green while charging / steady green when fully charged.



Important

Charge the device fully before first use.

7. How to set up the device



1. Charge the Device

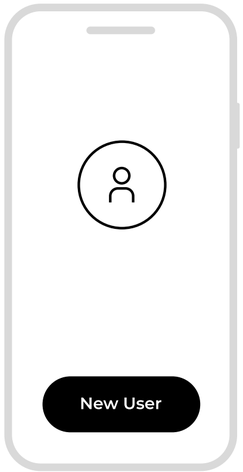
Connect the charging cable to the device's port and a power source. Wait until fully charged.

GET IT ON Google Play

Download on the App Store

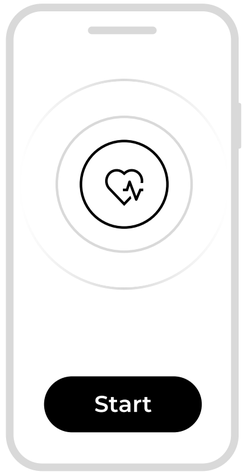
2. Download the Mobile App

Install the official Hilo app from the App Store or Google Play.



3. Create a User Profile

Enter your personal details (e.g., age, weight, height) in the app for accurate tracking.



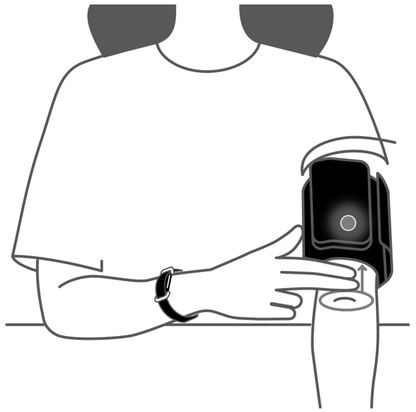
4. Follow the instructions in the app

Follow the on-screen prompts to complete the process.

8. How to initialize the device

1. Rest in a Quiet Position

- Sit down and relax for 5 minutes before starting the initialization procedure.
- Sit upright with your back straight and your feet flat on the floor. Do not cross your legs.
- Do not move or tense your arm muscles during measurement.
- Relax, and do not move or talk.

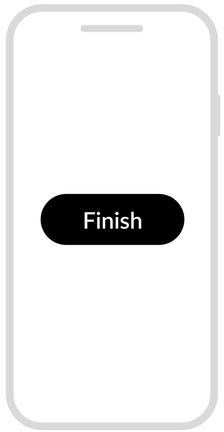


2. Ensure Hilo Cuff Proper Fit

- Remove garments from your upper arm.
- Place the hard plastic measuring body on the inner side of your arm, with the logo/LED on the bottom.
- Blue light closest to your elbow.
- Secure and tighten the cuff around your arm so that it fits closely.

3. Ensure Hilo Band Proper Fit

- When wearing an Hilo Band on your RIGHT wrist, place the Hilo Cuff over your LEFT arm, or vice versa.
- Make sure to initialize it on the same wrist you'll use throughout the month.
- Fasten your Hilo Band around your wrist making sure it is snug but not too tight.
- The clasp is on the underside of the wrist, the sensor in direct contact with the skin.



4. Follow the instructions in the app

- Follow the on-screen prompts to complete the process.

9. Classification of Blood Pressure

The European Society of Hypertension (ESH) has created the following guide for classifying blood pressure values. The table is not intended to provide a basis for any type of diagnosis or emergency assessment; the table only depict different classifications of blood pressure. Consult your physician for an interpretation and diagnosis based on your personal blood pressure results.

	Systolic (mmHg)		Diastolic (mmHg)
Optimal	< 120	and	< 80
Normal	120 - 129	and/or	80 - 84
Elevated	130 - 139	and/or	85 - 89
High blood pressure - Stage 1	140 - 159	and/or	90 - 99
High blood pressure - Stage 2	160 - 179	and/or	100 - 109
High blood pressure - Stage 3	> 179	and/or	> 109

Important

- To view and sync your data in the Hilo app, an active internet connection is required.
- To sync your data, Bluetooth must be enabled on your phone. Some Android versions may also require Location Services.
- Data syncs automatically when you open the Hilo App. If it doesn't, swipe down to sync manually.

10. Care, maintenance and disposal

hiloBand

- Hilo comprises sensitive components and must be treated with caution. Observe the storage and operating conditions described in this User Manual.
- Hilo Band does not contain any part or component that requires maintenance operation by the user.
- Please ensure that 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.
- To prevent the accelerated aging of materials and compromise water resistance, please clean Hilo Band with a damp cloth after exposure to saltwater, sweating, products such as soap, soapy water, shampoos, conditioners, perfume, cosmetics, detergents, mosquito repellent, or hand sanitizing gel. We also recommend drying Hilo Band with a soft cloth.
- Avoid exposing your device to extreme atmospheres (e.g. saunas or steam rooms) and/or immersion under pressurized water or high velocity water.

hiloCuff

- Hilo comprises sensitive components and must be treated with caution. Observe the storage and operating conditions described in this User Manual.
- Store in a dry place and avoid sunshine.
- Avoid intense shaking or collisions.
- Use a slightly damp cloth to remove any dirt or dust.
- Avoid immersing in the water. Clean with a dry cloth if wet.
- Avoid dusty environments or fluctuating temperatures.
- Avoid washing the device other than with a damp cloth (per above).

Hilo is 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.

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.

11. Troubleshooting

I don’t see a red light when charging my Hilo Band.

1. Remove the blue protection sticker from the bottom.
2. Verify that the charging station is well connected to a power supply.

Hilo Band was not found.

1. Place your Hilo Band on the charging station and connect it to the power supply.
2. Verify that Smartphone Bluetooth is on and permissions are granted.

Hilo Cuff was not found.

1. Switch the Hilo Cuff ON.
2. Charge Hilo Cuff by connecting it to a power supply with the USB cable.

Status LED of Hilo Cuff is flashing red.

1. Battery is low. Charge Hilo Cuff by connecting it to a power supply with the USB cable. Wait until status LED is steady green.

There is no reliable measurement data for this period.

1. Hilo Band only measures your blood pressure while you are at rest. You might not get any measurements during periods of high activity.
2. Adjust your Hilo Band, it can be either too tight or too loose.

User Manual

FAQs

12. Specifications

	hiloBand	hiloCuff
Measurement method	Photoplethysmography	Oscillometric testing mode
Measurement range	40-250 mmHg for blood pressure 40-180 beats/min for heart rate	Rated cuff pressure: 0mmHg~299mmHg (0kPa ~ 39.9kPa) Measurement pressure: SYS: 60mmHg~230mmHg (8.0kPa~30.7kPa) DIA: 40mmHg~130mmHg (5.3kPa~17.3kPa) Pulse value: (40-199)beat/minute
Measurement accuracy	± 5 mmHg for blood pressure | ± 5 pulse/min for heart rate	± 2 mmHg for blood pressure | ± 5 pulse/min for heart rate
Storage conditions	-20°C to +60°C | 700hPa to 1060hPa | 10% to 95% RH	-5 °C to +50 °C | A relative humidity range of ≤ 93%, non-condensing, at a water vapour pressure up to 50hPa
Operating conditions	+5 °C to +40 °C | 700 hPa to 1060 hPa | 15% to 90% RH	+5 °C to +40 °C | 700 hPa to 1060 hPa | 15% to 90% RH
Maximum temperature of the applied parts	Up to 43°C	—
Power source	Li-Ion rechargeable battery 3.7 Vdc 55mAh	Li-Ion rechargeable battery 3.7 Vdc 1000mAh
Protection	IP68	IP22
Circumference size	14 cm to 21 cm / 5 ½ to 8 ¼ inches	22cm to 42cm / 8 ¾ to 16 ½ inches
Communication	BLE 5.0	BLE 4.2
Service life	Can maintain the performance characteristics for a maximum of 500 charge cycles (expected service life > 3 years).	May vary by the frequency of measurement and cleaning and storage state. The typical service life is 10,000 measurements.

13. 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 Hilo App 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 accounts on your behalf.

Terms and Conditions

Privacy Policy

14. EMC and RF Statements

hiloBand	hiloCuff
Hilo needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the following section.	
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.	Hilo Cuff is suitable for home healthcare environments.
Hilo 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	
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.	–
Portable and mobile RF communication equipment (e.g. cell phones) can affect the Hilo Band.	–

hiloBand

Guidance and manufacturer’s declaration - electromagnetic emissions

Hilo Band is intended for use in the electromagnetic environment specified below. The user of Hilo Band should ensure that it is used in such an environment. 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.

Emission test	Compliance	Electromagnetic environment - guidance
Conducted emissions CISPR11	Groupe 1	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

Hilo Band is intended for use in the electromagnetic environment specified below. The user of Hilo Band should ensure that it is used in such an environment. 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	±8kV contact, ±2kV; ±4kV; ±8kV; ±15kV in air	±8kV contact, ±2kV; ±4kV; ±8kV; ±15kV in air
Radiated RF electromagnetic field IEC 61000-4-3	10V/m, 80MHz at 2.7GHz, 80% MA at 1kHz	10V/m, 80MHz at 2.7GHz, 80% MA at 1kHz
Proximity fields from RF wireless communications equipment IEC 61000-4-3 (interim method)	9V/m at 710MHz; 745MHz; 780MHz; 5240MHz; 5550MHz; 5785MHz 27V/m at 385MHz 28V/m at 450MHz; 810MHz; 870MHz; 930MHz; 1720MHz; 1845MHz; 1970MHz; 2450MHz	9V/m at 710MHz; 745MHz; 780MHz; 5240MHz; 5550MHz; 5785MHz 27V/m at 385MHz 28V/m at 450MHz; 810MHz; 870MHz; 930MHz; 1720MHz; 1845MHz; 1970MHz; 2450MHz
Immunity to conducted disturbances, induced by radio-frequency IEC 61000-4-6	3V 0.15 MHZ - 80 MHz 6V in ISM and radio-amateur band between 0.15MHz and 80MHz 80% AM at 1kHz	3V 0.15 MHZ - 80 MHz 6V in ISM and radio-amateur band between 0.15MHz and 80MHz 80% AM at 1kHz
Radiated fields in close proximity IEC 61000-4-39	134.2kHz; pulse modulation 2.1kHz; 65A/m 13.56MHz; pulse modulation 50kHz; 7.5A/m 30KHz; CW; 8A/m	134.2kHz; pulse modulation 2.1kHz; 65A/m 13.56MHz; pulse modulation 50kHz; 7.5A/m 30KHz; CW; 8A/m
Power frequency magnetic field IEC 61000-4-8	30A/m, 50Hz	30A/m, 50Hz

Hilo Cuff - Guidance and manufacturer's declaration - electromagnetic emission

hiloCuff

Hilo Cuff is intended for use in the electromagnetic environment specified below. The user of Hilo Cuff should ensure that it is used in such an environment. Hilo Cuff 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.

Emission test	Compliance	Electromagnetic environment - guidance
Conducted emissions CISPR11	Groupe 1	Hilo Cuff 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	Class A	–
Voltage fluctuations Flicker emissions IEC 61000-3-3	Compliant	

Guidance and manufacturer’s declaration - electromagnetic immunity

Hilo Cuff is intended for use in the electromagnetic environment specified below. The user of Hilo Cuff should ensure that it is used in such an environment. Hilo Cuff 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 (ESD) IEC 61000-4-2	±8kV contact, ±2kV; ±4kV; ±8kV; ±15kV in air	±8kV contact, ±2kV; ±4kV; ±8kV; ±15kV in air
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV signal input/output 100kHz repetition frequency	±2kV for power supply lines ±1kV signal input/ output 100kHz repetition frequency
Surge IEC 61000-4-5	±0.5kV; ±1kV differential mode ±0.5kV; ±1kV; ±2kV common mode	±0.5kV; ±1kV differential mode ±0.5kV; ±1kV; ±2kV common mode
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles; single phase: at 0°.0% UT; 250/ 300 cycle	0 % UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles; single phase: at 0°.0% UT; 250/300 cycle
Power frequency magnetic field IEC 61000-4-8	30A/m, 50Hz/60Hz	30A/m, 50Hz/60Hz
Conduced RF IEC61000-4-6	3V 0.15MHz – 80MHz 6 V in ISM and amateur radio bands between 0.15MHz and 80MHz 80% AM at 1kHz	3V 0.15MHz – 80MHz 6V in ISM and amateur radio bands between 0.15 MHz and 80MHz 80% AM at 1kHz

Note: UT is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer’s declaration – electronic immunity

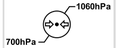
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)

Tests Frequency (Mhz)	Band (Mhz)	Service	Modulation	Modulation (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse modulation b) 18Hz	1.8	0.3	27
450	430-470	GMRS 460; FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13,17	Pulse modulation b) 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1,3,4,25 UMTS	Pulse modulation b) 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAM, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation21 7Hz	0.2	0.3	9
5500						
5785						

15. Compliance

Hilo Band	Hilo Cuff
EU RED STATEMENT: Hereby, Aktiia SA, declares that the device is compliance with the essential requirements and other relevant provisions of RE Directive 2014/53/EU.	
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	
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	
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)	
IEC 80601-2-30:2018: Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers	
IEC 62304:2006/AC: 2008 / IEC 62304: 2006+A1:2015 Medical device software - Software life-cycle processes	
ISO 81060-2 Noninvasive sphygmomanometers – Part 2: Clinical investigation of intermittent automated measurement type	
80601-2-61 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment	
IEC 62366-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices	
EN IEC 62471:2008: Photobiological safety of lamps and lamp systems	ISO 81060-1:2007: Non-invasive sphygmomanometers — Part 1: Requirements and test methods for non-automated measurement type
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.	EN 1060-3:1997+A2:2009 Non-invasive sphygmomanometers – Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems

16. Safety symbols definitions

Symbol	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.		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 "European authorized representative"
	Symbol for "STORAGE AND TRANSPORTATION ENVIRONMENT - TEMPERATURE LIMITS"		Symbol for "STORAGE AND TRANSPORTATION ENVIRONMENT - PRESSURE LIMITS"		Symbol for "STORAGE AND TRANSPORTATION ENVIRONMENT - HUMIDITY LIMITS"
	Symbol for "SERIAL NUMBER"		Symbol for "Australian representative/sponsor"		Symbol for "Radio Frequency Radiation (RF)"
	Symbol for "Importer"		Symbol for "BATCH / LOT NUMBER"		Symbol for “Radio frequency logo for Australia”
R-NZ	Symbol for “Radio Frequency for New Zealand”				

Medical Device

Hilo Blood Pressure Monitor

Manufacturer

Aktiia SA, Bassin 8a, 2000 Neuchâtel, Switzerland

Authorized representative

Veranex Germany GmbH

Landsberger Str. 302, D-80687 Munich, Germany

Emergo Australia

201 Sussex Street, Level 20, Tower II Darling Park, Sydney, NSW 2000, Australia

IFU version

8.0 - 2025.03.28

CE 0123