Instructions for Use

Understanding and adhering to the instructions of this manual is essential so that WIWE may show as accurate values as possible about the user's state of health!
Web: http://mywiwe.com/en/

Delivery package includes

- 1 WIWE device
- 1 USB cable
- 1 User manual

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CE 1011

1 Product description

WIWE is a cardio diagnostic device. Item number of the white WIWE: DSW0001, item number of the black WIWE: DSW0002.
The WIWE is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The WIWE also displays ECG rhythms and detects the presence of cardiac arrhythmia (e.g., atrial fibrillation, ventricular tachycardia) and normal sinus rhythm. The WIWE records additional measurements, including average heart rate and blood oxygen level. The WIWE is intended for use by healthcare professionals, patients with known or suspected heart conditions and health conscious individuals.
The device is not intended for pediatric use.

1.1 Diagnostic device

The device provides information on the average heart rate, on the possible deviation from normal ECG and on *blood-oxygen saturation (SpO_2) rate*. It displays arrhythmia, the risk for afib-related stroke and the deviation of the state of the heart muscle from normal. The device also features a *pedometer* function.

1.2 Evaluation of the result, risk levels

The accurate evaluation and detailed representation of the recorded measurements are done with the help of an application that is free to download from application stores (App Store and Google Play online stores). For the evaluation, the phone receives data from the device via Bluetooth connection. The evaluated measurements appear on the phone's screen showing its risk levels, and can be forwarded to the doctor via e-mail with one tap.

1.3 Scope of WIWE.

- WIWE is a measuring device that monitors the properties of the user's cardiac activities with the help of an application that runs on smartphones. It is a device that serves mainly for *checking the heart rhythm* – at home and on the way. **Do not use the device during driving or activities which may cause danger!**
- WIWE does not replace neither medical checks of heart activities, nor medical ECG recording, which can be achieved with a more complex, multi-channel ECG measuring configuration.
- **WIWE will not prepare diagnosis of the potential causes based on the changes in ECG. This is exclusively reserved for your doctor.**

1.4 Accumulator

The device operates with an accumulator. The built-in accumulator can be charged with the USB cable supplied with the device according to the charging of WIWE's accumulator chapter. **Do not measure during charging.**

2 Cautionary and safety information

2.1 General information

- Adhering to the directions of the manual is essential for WIWE to function as intended, to the greatest satisfaction of the user, and that is when you get the most accurate test result, and a safe and smooth operation.
- The housing which can be accessed by the customer and the sensors are made from a biocompatible material so the occurence of allergic reactions are not expected.
- The parameters of WIWEs that are already marketed cannot be altered. **Do not change the device's cover!**
- Not all cardiovascular diseases can be detected with WIWE, so if you experience any symptoms of **acute heart disease, or if you are unsure of your symptoms – regardless of the test results of WIWE – please turn to your doctor immediately!**
- WIWE is meant to measure ECG in repose, that is why it is recommended to perform measuring while being still, 15-20 minutes after heavy physical activities, when the body goes back to resting state.
- WIWE displays any deviations in the heart rhythm. Among the many reasons, there can be physiological changes, which means they can be harmless ones too, but diseases of various severity may also trigger them. **Turn to your doctor when disease is suspected!**
- Those ECGs, which are recorded with WIWE reflect the momentary heart activity, thus previous or following changes may not necessarily be detected.
- Using WIWE is advised for users of 18 years or more, since the ECG of children is different from that of adults. Using WIWE does not pose a threat to children, nor greater risk than using any other electronic device at home.
- WIWE determines the degree of oxygen saturation (SpO2) in the blood by measuring the ECG at the same time. SPO2 may be significantly affected by the user moving his finger while measuring, or the finger does not fully cover the optical sensor, or by pushing and not just touching the sensors. For accurate measurement, just touch the sensors, do not press!
- **Do not perform self-diagnosis or self-treatment based on the measurement results of WIWE** without consulting your doctor. Especially do not start a new treatment arbitrarily, and do not change the type of the existing medical treatment and the dose of prescribed medication! We suggest that you keep the resulting ECG curves, and send or show it to your doctor, if necessary. It is particularly true if the status messages of WIWE are not showing the normal (green) symbol.

2.2 Important safety information

- ATTENTION! Some parts of the WIWE device's case can reach 43 °C throughout the charging process. Because of this fact please wait 5 minutes, while the device cools down to the normal temperature. Do not use WIWE while it's charging!

- ATTENTION! Danger of choking! The USB cable supplied with the device could signal “danger of choking” because of its length. Make sure not to let children reach it.
- WIWE and a defibrillator are not to be used at the same time.
- Do not use the device during MRI scanning!
- The pacemaker or other electronic stimulator of the user and the WIWE can be used at the same time, they do not interfere with each other’s functioning. The doctor, however, must be aware of the presence of these devices around WIWE and has to evaluate the ECG curve knowing this.
- WIWE must be protected from radiant heat, dropping and humidity! Do not use it under water or moist environment.

3 Description of WIWE

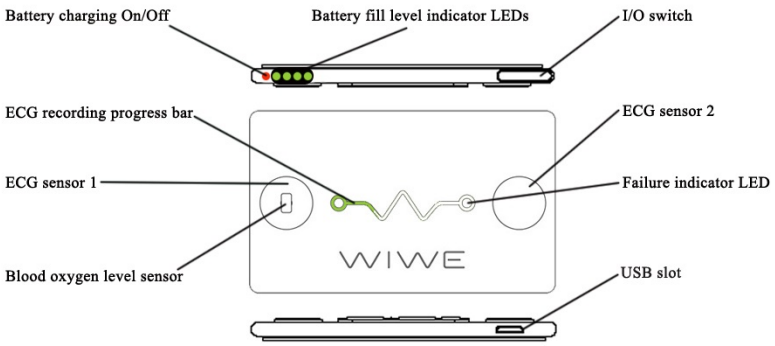
3.1 Main function

- Recording, assessment and analysis of ECG data.

3.2 Fitness functions

- Blood oxygen level (SpO_2) measurement
- Pedometer

3.3 Functional features:



- Sampling data transmitted via the two electrodes get onto the smartphone for processing through Bluetooth communication.
- A flash of lights runs through the LED line the second the search for bluetooth connection starts. Once the connection is established, the green LED light on the right starts to blink, and after initiating a measurement, the light is steady.
- WIWE needs 10 seconds preparation and 60 seconds measuring time in order to record the ECG.
- Interruption of measurement within 60 seconds is indicated with 3 flashes on the process indicator LED line.
- The progress of the measurement process is indicated by the LED line. When preparing for the measurement and during measurement (70 seconds in total) the process indicator LED lights turn on one by one, from left to right.
- After the 60 second measurement phase, the device keeps on measuring for maximum another 10 seconds, if the user does not let go of the electrodes. In the meantime, the last red LED light glows more and more brighter.
- Maximum of 50 measurements' data can be stored on WIWE. When reaching 50 measurements, the process indicator LED line blinks 3 times, which indicates the need for synchronization, and after that old measurement data records are overridden in the device. In the phone, however, unlimited amount of data can be saved.
- *Measuring blood oxygen level*: takes place the same time as the ECG recording.
- *Pedometer*: depending on the settings, WIWE counts the steps the user takes, which can be summarized daily, weekly, monthly and annually, along with the calories of energy consumption.

3.4 WIWE services

- The database management system of the WIWE application can store the personal information and records of more users at the same time and user information and measurements can be easily managed.
- The application's automatic evaluation of the recorded ECG notifies the user and helps the doctor's work.
- Old and new ECG records can be viewed and retrieved.
- Measurements can be sent to any e-mail address via the application's share function in the form of a PDF attachment, thus can be printed with any type of printer on regular paper as well.

3.5 Mobile application

- The mobile application draws up an ECG curve in real time on the smartphone's screen based on WIWE's measured data.
- The ECG curve appears in correct proportion on the smartphone's screen, that is why it can be monitored without using any paper.

WIWE works in full funcionality with its application running on a smartphone.

System requirements: The mobile application is not compatible with all types of phones, that is why we suggest you to check the compatible phone types in the annex.

Any operating system updates, changes to a newer version on the mobile phone will not cause problems using WIWE, since phone manufacturers guarantee that software made for previous versions of operating systems will run on new versions, too. The manufacturer of WIWE monitors changes and updates the application, if necessary.

How to download: The application can be downloaded free of charge from App Store and from Google Play web store. (https://itunes.apple.com/us/app/wiwe/id996406127; https://play.google.com/store/apps/details?id=hu.sanatmetal.wiwe)

How to install: During installation, the application will ask for permissions for ***Bluetooth communication***, ***Access to the list of names*** and ***Access to the E-mail application***.

How to launch: The application can be launched with the WIWE icon on the phone screen.

Initial use: At the initial use of the application, a four-step wizard helps the user with the basic settings. Providing detailed information is optional, however, it is recommended for the smooth operation of the device and the application. Each of the setting's steps can be skipped individually, in which case the default settings will take effect.

It is recommended to set screen saver function for over 2 minutes on the phone in order to ensure uninterrupted measurements**.**

3.5.1 How to use the mobile application:

After an account registration, pairing the WIWE with the mobile phone and establishment of Bluetooth connection the device is ready for use. The account registration cannot be skipped, however, there is a possibility to initiate measurement anonymously and without an account. For setting up the connection, it is necessary to turn on Bluetooth communication on the phone.

The mobile application and the WIWE can be matched by **pressing the ON/OFF button on the device.** When properly matched, the application will automatically recognize the WIWE, if measurement is initiated with the paired device.

When matching:

- make sure WIWE and your mobile phone are on.
- make sure Bluetooth connection is enabled on your mobile phone.
    - make sure WIWE and your mobile phone are within each other's range (Bluetooth communication distance), and they should not be removed from that range!
    - Pairing WIWE and your mobile phone can also be done later, when initiating measurement.

4 Things to do before using WIWE

After unpacking WIWE, before usage, the mobile application required for operation needs to be downloaded and started. Once this is done and the device is turned on by pressing the button on the top of the device, WIWE – within the normal operational temperature threshold and on an adequate battery level – can be utilized right away. In case of extreme storage temperature you need to wait while the temperature of the device's case reaches the normal operational threshold, which means approximately 10 minutes from -25 °C to +5 °C and approximately 5 minutes from +60 °C to +40 °C in case of an environment with normal room temperature.

4.1 Ready for operation

For the proper operation of WIWE, please check the conditions below before every usage:

- Intactness of the device. Make sure that the device is not damaged and in a usable condition!
- Cleanness of the sensors.
- Battery level. The device is fully charged when the 4 LED lights on top are lit when you turn on the device. If at least two of the LED lights are not lit, the accumulator must be charged before use. See Charging the accumulator section.

5 Measuring

Users can take a measurement with the help of the WIWE devie and the mobile application, during which the resulting measurements can be viewed on the phone screen and these can be shared with others (eg. with your doctor).

5.1 Before measuring:

Please consider the points below in order to get precise measurement results:

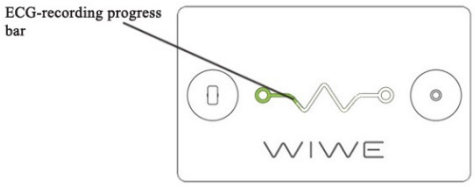
- Electrodes should be in contact with the skin of the fingertips directly.
- Fingertips should completely cover the electrodes.
- If your skin is very dry, make it moist with a wet cloth before measuring.
- If the electrodes are contaminated, remove the contamination from the surface with a soft wipe.
- When measuring, the hands should not touch any other body part. Please bear in mind that the skin of your left and right hand cannot touch during measuring, and neither the user's skin, nor the device's electrodes can touch metal devices. Otherwise measurement cannot be performed properly.
- Do not move during the measuring, because any muscle movement can cause false measurement.
- Measuring should be performed preferably in sitting or lying position, but not standing.

5.2 Account registration

- Since WIWE and the application can be used by more than one user, medical data and measurements of the individuals are suggested to be separated. For this, you have the opportunity to create accounts on your mobile phone.
- Account registration cannot be skipped, however, there is a possibility to initiate measuring anonymously, without an account.
- You can find detailed information about registering an account in the Advanced guide of your mobile application's Information section.

5.3 Measurement:

- After initiating a measurement on your smartphone, press the ON button as the appearing illustration shows you to on your phone in order to establish the radio (Bluetooth) connection.
- Measurement is done by placing the same fingers of your left and right hand on the sensors.
- Touch the electrodes and gently hold your fingers on them. For a successful measuring, a preparatory process is also required, when the user places their same two fingers of each of their hands on the WIWE sensors and becomes relaxed. During the preparatory period, the application checks whether the contact was adequate, and whether the data received from WIWE are suitable for starting a measurement. The preparatory period is 10 seconds long.



- In case of a normal measurement the mobile phone, in individual cases the process indicator on the front of the WIWE shows that the measuring process has started.
- Letting go of the sensors within 30 second will result in the interruption of measurement.
- After 60 seconds, the application indicates on the phone screen when data collection is finished. During data collection, the application displays the ECG, their pulse and blood oxygen saturation level of the user who touched the sensors.
- At the end of the measurement, evaluation may take a few seconds, then you can check the results on your mobile phone.
- In case of an unsuccessful measurement please follow the instructions appearing on your phone. Repeat the measurement.
- When the failure signaling LED blinks on the device, it means that ECG signs are unstable or weak. In this case repeat the measurement.
- The device will only start measuring, if the battery voltage level allows at least one measurement.

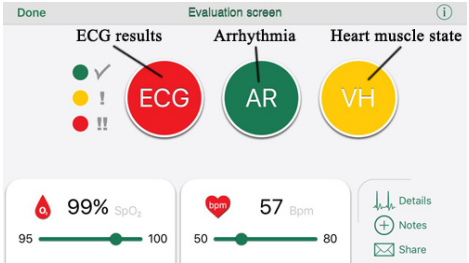
5.4 Frequent causes of inaccurate measurement

1. Inadequate contact between the electrodes and the fingers.
2. Left hand skin and right hand skin touch during measuring.

5.5 Results display screen

After the measurement and evaluation, measurement data can be viewed on your phone screen. It is recommended to show these results to a doctor as well, so that any changes in your health may be diagnosed by them.

To have a quick overview of all these data, measurement and evaluation data are summarized on the Evaluation screen.



The evaluation of the main measured data is indicated by 3 circles in a row of the same diameter on the screen. In the center of the circles, ECG (Electrocardiography), AF (Atrial fibrillation) and VH (Ventricular heterogeneity) abbreviations show which health parameter group they stand for. The filling colors of the circles can be green, yellow or red, depending on the evaluation of the measurement's results. Green color stands for „normal" condition, yellow means „minor deviation from normal condition" and red is „major deviation from normal condition".

Underneath the circles, SPO_2 button shows oxygen saturation, whereas Bpm shows the pulse value.

By tapping on each of the buttons on the screen, further information can be found on the abbreviations and the filling color with an explanation.

1. **ECG**: ECG-parameter deviations from the average (normal, minor, major deviation)
2. **AR/AF**: Arrhythmia or atrial fibrillation, detection of heart rate fluctuation deriving from the heart's irregular contractions, and in case of detected arrhythmia and lack of significant P wave, the testing of possible atrial fibrillation (normal, heart rate fluctuation, suspicion for atrial fibrillation)
3. **VH**: information on the state of the heart muscle, ventricular heterogeneity (VH) rate (normal, minor deviation, major deviation). In case the gray signal is on, this feature cannot be not evaluated from these data.
4. **SPO2**: Blood oxygen saturation (SPO_2) indicated in %. The measured value also appears on the line underneath the number of the measured result, and the color of the line stands for the acceptance level (normal, minor deviation, major deviation).
5. **Bpm**: heart rate (HR) per minute (bit per minute: Bpm). The measured value also appears on the line underneath the number of the measured result, and the color of the line stands for the acceptance levels (normal, minor deviation, major deviation).

By tapping on the **Details button** in the lower right corner, you can get more detailed information.

- *ECG parameters*: Graph of average majority cycle, it shows 4 types of associated data and reference values, too. Deviations are indicated by a red exclamation mark(s) next to each type of data (1 – minor deviation, 2 – major deviation).
- *ECG curve*: ECG curve recorded during data collection, which can be leafed in the length of the measurement and magnified max. 4 times.
- *Arrhythmia or suspicion for atrial fibrillation*: Graph of suspicion for atrial fibrillation, which assesses the measurement based on the number of clusters and the dispersion around the diagonal.
- *Ventricular heterogeneity*: Graph of ventricular repolarization heterogeneity. A special algorithm determines the values of the graphs based on two parameters of the recorded ECG curve.
- *Comments for the measurement*: Comments can be added to each measurement. Comments about the circumstances of the measurement, or information such as type of pills taken can help the doctor to evaluate the measured data and to make an accurate diagnosis.
- *Sharing the result*: You can share the evaluated measurement with others via e-mail (it is suggested to send to your general practitioner or specialist). A detailed description can be found in the Information menu point, under the Advanced guide section in your mobile application.

Previous measurements and evaluated results can be accessed, too. In **My profile** option on your mobile application, you can view your **Health journal,** where you can track changes in the recorded data of your state of health.

6 Measurement without a phone:

Sometimes a phone is not available to the user. In such cases there is also an opportunity to take a measurement. In such cases, please follow these steps:

1. Turn on the device.
2. Make sure that the failure warning signal does not blink.
3. Please follow the steps described in the "Measurement" section.
4. The process indicator on the front of the device will show the progress of the measurement.
5. Please wait until the last LED of the process indicator is green.
6. When measurement is ready, WIWE is storing the result of the measurement until the next phone synchronization. (See Synchronization section)
7. If any errors occur during measuring, the failure warning signal will blink on the device. In this case, please repeat the measurement.

7 Synchronization

When synchronizing, measured data are transferred from the user's default WIWE device to the phone via Bluetooth connection, if the phone and the WIWE are connected. Synchronization is only available for the owner account of the WIWE. Synchronization is necessary, because WIWE's *ECG measurement and pedometer function* works independently from the application and data are only stored on the device's memory until they are transferred onto the phone by synchronization. The application notifies you whether the synchronization was successful or not. In case of a successful synchronization, data stored on WIWE – after data are save in the phone – are deleted, and in case it was unsuccessful, synchronization has to be repeated. The synchronization progress is indicated by the process indicator LEDs running back and forth.

8 What to do in case dysfunction is noticed.

WIWE can be restarted by pressing the ON button for 8 seconds.

WIWE was designed to operate flawlessly in the long run. With any complaints regarding the operation of the device, please turn to our Customer service (info@myWIWE.com).

8.1 Impacts in a home environment

- *WIWE requires handling similar to any home electronics devices in general*.
- WIWE is protected against water and dust (IP 22 classification, it's protected against the infiltration of solid objects bigger than 1-2 mm in diameter and also against dripping water). Please protect the devices against any harmful effects occurring in a home environment which can influence the correct functioning of the WIWE. It needs to be protected from extreme sunlight, dust, domestic animals, rodents. The contaminated device and its electrodes need to be cleaned and only use the device in its intact state.
- *Please do not store it in moist environment. Heavy electromagnetic areas must be avoided, so do not put it on a speaker, microwave oven or near similar electronical devices. It does not require any special storage and treatment.*

9 USB connection

WIWE's battery can be charged through the USB plug on the bottom of the device with the USB cable shipped with the WIWE. This can be done with the use of a regular USB power supply or an electronic device.

Please read the specifications of the „Charging WIWE's accumulator" section!

Type of the applicable USB cable: the USB cable shipped with the WIWE.

10 Charging WIWE's accumulator

Connection of the AC adapter may influence the precision of the measurement, therefore **please do not perform measurement when the device's accumulator is being charged.** WIWE's battery can be charged through the USB plug on the bottom of the device with a USB cable.

Charging WIWE's accumulator from an electric power source can only be performed with the USB cable supplied with the delivery or with a regular electronic device.

Use a commercially available USB power supply appropriate to the IEC 62684-2011-01 standard to charge the WIWE.

- The leftmost LED of the LED line on the top of the device is glowing red whilst the device is charging.
- The accumulator is fully charged when the red LED light is out. The device can be unplugged.
- Any charging disturbances (eg. accumulator wears out) are indicated by the charger indicator LED blinking.

The accumulator can be charged any time; it is not necessary to wait until it goes dead.

With normal operating circumstances, the USB charger provides 5V DC voltage. The voltage range of the USB port is 4.75 – 5.25 V DC. Current consumption of the WIWE charging unit during charging max.: 100 mA.

WIWE is a low-voltage device, general safety rules that apply to electric household appliances must be adhered to when charging the accumulator.

The lifespan of the accumulators is limited. WIWE's accumulator cannot be changed. You can find how much time it takes for the accumulator to go dead at the device's technical information.

11 After usage

- The device automatically shuts down after use, but you can also turn it off with the ON/OFF button.
- After use, clean the electrodes with soft and dry cloth, if necessary.
- When WIWE is used by someone other than its owner, the sensors need to be cleaned which can be done with a wet, antiseptic cloth if anybody other than the owner uses it. After this you need to wait for the device to dry completely before you use it again.

12 Potential problems and troubleshooting.

1. It is very unlikely for WIWE to malfunction. However, if you experience any functional failures, you can find information on the possible solutions at www.myWIWE.hu, www.myWIWE.com website.
2. You may ask questions at info@myWIWE.com e-mail address, too.
3. The device does not require any special handling.

13 Storage requirements

- Do not use and do not store WIWE in a moist room, and in places where it could get in contact with water.
- Do not use and do not store WIWE where there is extreme air pressure, temperature or high humidity; rooms with poor ventilation, air that is dusty, salty or sulfuric, or where chemical substances may get into the air, and where gas leak could occur.
- Do not expose the device to radiant heat.

14 Safety requirements

14.1 Ensuring electromagnetic compatibility

- Electronic appliances such as mobile telecommunication device radiation may disturb the operation of WIWE, therefore always consider the signals indicating electromagnetic compatibility (EMC, electromagnetic compatibility) of devices around WIWE and use them accordingly.
- WIWE conforms to IEC 60601-1-2 international standard of medical electrical equipment and systems electromagnetic tolerance, however, if the electromagnetic environment exceeds the limits set by IEC60601-1-2, it could disturb the operation of WIWE to the extent that partial or complete loss of function may occur. That is why the source of disturbance nearby needs to be found and eliminated (within 1m range) before the loss of function or malfunction occur, before continuing to use WIWE.

14.2 Countermeasures to be applied in case sources of disturbance frequently occur:

- Heavy electromagnetic disturbance caused by a nearby source of disturbance (eg. radio, other electronic appliance). If the source cannot be eliminated, use WIWE in another room. In all other cases, you have to make sure that source of disturbance eg. household electric appliances, is not used near WIWE. Keep at least 30cm distance between the source of disturbance and WIWE!
- Impact of direct or indirect electrostatic discharge:
  Before use, make sure that the user and the immediate vicinity of the user are free of electrostatic energy. Proper air humidity and antistatic flooring may decrease the risk for electrostatic discharge.

15 Maintenance and checks

- WIWE had been calibrated by the manufacturer, there is no need for further calibration. With proper use, the system does not need any kind of maintenance.
- Before use, please check the integrity of the device. Do not use a damaged device and do not charge its accumulator.
- WIWE must not be changed in any way.
- In case of malfunction or incorrect functioning, the distributor must be informed.
- Any repairs can only be performed by the manufacturer or the person or company appointed by the manufacturer.

16 Waste management and liquidation

According to the ordinance of hazardous electronic wastes, broken WIWE devices must be placed in special containers suitable for wastes like this and maintained for this purpose!

It cannot be placed amongst household waste!

If the device suffers a malfunction or damage that cannot be recovered, or the user decides to destroy the device for any other reason, it must be handled as hazardous waste, and therefore can only be handed over to appropriate collection sites.

17 Important legal information

Descriptions, suggestions and any other information about WIWE, illustrations and any other references had been provided with great care, based on practical and experimental results and experiences. Nevertheless, Sanatmetal Ltd. will not be liable in any way for damages deriving from the application of descriptions, suggestions or illustration. The manufacturer is unable to supervise whether

the user proceeds according to the instructions for use when using the device, neither appropriate measurement circumstances, nor methods during the functioning, use and maintenance of WIWE. That is why the manufacturer will not be liable in any way and will not take responsibility for damages, financial loss or personal injuries that resulted in inaccurate measurement results, unprofessional operating, improper use, and maintenance, or that are associated to the above mentioned in any way.
Information in the WIWE instructions for use is solely for information purposes. Due to the constant development programs related to WIWE, the manufacturer reserves the right to do changes without prior notice.
The product cannot be declared to be faulty the fact that later on a safer, more accurate product will be distributed. Sanatmetal Ltd. will not take responsibility for damages, costs or expenses associated to the use of WIWE, regardless if they are direct or indirect, if they have consequences, or unique."

Compatible phone types:

iOS:
The application minimally runs on phones with iOS 8.1, which have Bluetooth 4.0 and Bluetooth Low Energy protocol and standard.
List of compatible devices:
iPhone 4S; iPhone 5; iPhone 5C; iPhone 5S; iPhone 6; iPhone 6 Plus
Android: The application minimally runs on phones with Android 5.0, which have Bluetooth 4.0 and Bluetooth Low Energy protocol and standard.
List of compatible devices:
Samsung Galaxy Note 3, Samsung Galaxy A3, Samsung Galaxy S4; Samsung Galaxy S5; Samsung Galaxy S6 edge, Samsung Galaxy S7,
SONY Xperia™ Z, SONY Xperia™ Z3 Compact; Sony Xperia Z5,
HTC One M7, LG G4, HTC One A9,
Huawei P8

Notes:

- If you cannot find your own phone type in the list does not necessarily mean that it cannot be used with WIWE. Please see more information on our website (http://mywiwe.com/hu/) for an updated list of compatible mobile phones!
- WIWE can be matched with Ipads and tablets, too. Please find more information on our website (http://mywiwe.com/hu/) about tested types!
- The smartphone must conform to the relevant general requirements and EN 60950 standard.

Symbols:


Caution! Read the instructions for use before use!


The WIWE shall be powered only with direct current


Name and address of the manufacturer


Type BF Applied Part.


Keep it dry!


Contains radio frequency emitters


Must not be placed among household waste!

WIWE measuring device Technical information

Dimensions of WIWE	87,50 × 54,7 mm x 5,9 mm
Weight:	40 g
accumulator:	Ultra thin chargeable Li-Po accumulator, 180 - 200mAh, 3.7V
dimensions of the accumulator	1x61x44mm,
Lead number	**2**
Estimated operating time of the device with the accumulator charged once	with ECG+SPO2 measurement and step counting circa 5 days (3 ECG+SPO2 measurements and sending to phone via Bluetooth every day, 12-hour step counting per day)
Maximum recording capacity	circa 50 (number of measurements with fully charged accumulator)
Memory	storing data of 50 measurements on the device's own memory
Operation:	Intermittent
Display	Mobile phone screen
Full featured alphanumeric keyboard	only when a smartphone is connected
Communication	Connection to a smartphone: **Bluetooth** 4.0 ;
Controls:	"ON" button; 2 electrodes, everything else from WIWE software via phone.
Accessories:	Standard micro-USB cable
Heart rate measurement range:	30 - 240 bpm ± 2 bpm
Sampling frequency:	500 Hz
Operating temperature range:	between 5C°and +40C°
Storage temperature range	-25C°- +60C°
Allowed operational and storage relative humidity:	15% - 90% (without condensation)
Operational and storage air pressure range:	750 – 1060 hPa
Estimated operating time:	6 years
Warranty	2 years
Declaration of conformity	The product conforms to 93/42/EEC Medical device directive
Safety class of device	BF
IP mark	IP22
Defibrillator protection	Not to be used with defibrillator!
User protection:	floating earth EN 60601-1 BF type, Disconnection: DC/DC converter isolation IC with reinforced lining (LTM2882IY-5)
Assessment	only when smartphone is connected
Power:	accumulator
CMRR (common mode rejection ratio):	> 120 dB
Input resistance:	> 5 Mohm

18 Electromagnetic compatibility

The product complies with the EMC-standard according to IEC60601-1-2, but the mobile communication devices' emissions can disturb the product's functioning. For the proper functioning of the device please follow the instructions of the user manual.

Electromagnetic disturbance emission		
THE WIWE MOBILE AND HEART DIAGNOSTIC DEVICE WAS MADE TO BE USED IN AN ELECTROMAGNETIC ENVIRONMENT WITH THE CONDITIONS BELOW. THE USER NEEDS TO ENSURE, THAT THE DEVICE IS FUNCTIONING WITH THESE CONDITIONS.		
Disutrbance emission examination	**Compliance**	**Electromagnetic environment – guideline**
RF emissions, MSZ EN 60601-1-2:2008, MSZ EN 55011:2010	**Class B** Approved: 30-1000MHz,	• The WIWE device's consumption is lower, than 75 W. Its disturbance emission is negligible. so it won't cause any disturbances in the functioning of the device. • WIWE mobile diagnostic deivce is suitable to use in any kind of establishment, including houses and establishments directly connected to the low voltage network supplying the houses. • The WIWE mobile heart diagnostic device is not suitable to be connected with other devices.
RF emissions, supply gateway MSZ EN 60601-1-2:2008, MSZ EN 55011:2010	**Class B** Approved: 0,15-30MHz	
Overtone emissions MSZ EN 60601-1-2:2008, MSZ EN 61000-3-2 : 100Hz-2kHz	[**non applicable]**	
Changes in voltage /flicker emissions MSZ EN 60601-1-2:2008, MSZ EN 61000-3-3:2013	[**non applicable]**	

Electromagnetic disturbance allowance			
THE WIWE MOBILE AND HEART DIAGNOSTIC DEVICE WAS MADE TO BE USED IN AN ELECTROMAGNETIC ENVIRONMENT WITH THE CONDITIONS BELOW. THE USER NEEDS TO ENSURE, THAT THE DEVICE IS FUNCTIONING WITH THESE CONDITIONS.			
Disturbance allowance examination	**IEC 60601 examination level**	**Compliance**	**Electromagnetic environment - guideline**
Electrostatic discharge (ESD) MSZ EN 60601-1-2:2008	± 6 kV on contact ± 8 kV on strikeover	approved	Wood, concrete or ceramic floor case needed. If the floor is covered with plastic, then the relative humidity should be at least 30 %.
Quick electrical transients/burst MSZ EN 60601-1-2:2008	±2kV L, N–reference between earth	approved	The energetic quality of the network needs to be equal with the usual used in commercial or hospital environment.
Shockwave (Surge) MSZ EN 60601-1-2:2008	1kV L-N	approved	The energetic quality of the network needs to be equal with the usual used in commercial or hospital environment.
Voltage breaking, short time voltage outages fluctuations on the input supply wires MSZ EN 60601-1-2:2008	100%, 60%, 30% 1, 5, 25 periods	approved	The energetic quality of the network needs to be equal with the usual used in commercial or hospital environment. WIWE was made to use in battery mode. At least 50 measurements can be done with it.
Magnetic field with network frequency (50/60 Hz) MSZ EN 60601-1-2:2008	3 A/m	non applicable	There is no part in the WIWE which is sensitive for the network's electromagnetic field.

Electromagnetic disturbance allowance			
THE WIWE MOBILE AND HEART DIAGNOSTIC DEVICE WAS MADE TO BE USED IN AN ELECTROMAGNETIC ENVIRONMENT WITH THE CONDITIONS BELOW. THE USER NEEDS TO ENSURE, THAT THE DEVICE IS FUNCTIONING WITH THESE CONDITIONS.			
Disturbance allowance examiation	**IEC 60601 1-2 examination level**	**Compliance**	**Electromagnetic environment - directive**
Conducted RF MSZ EN 60601-1-2:2008	3Veff 0,15–80MHz modulation: 2Hz, 80% AM	[3Veff] V approved	The portable and mobile RF transmission deivces can only be used within a distance derived from a formula based on the transmitter's frequency. Suggested distance for clearance d=[3,5/V1]√P d=[3,5/E1]√P 80 MHz – 800 MHz d=[7/E1]√P 800 MHz – 2,5 GHz where P is the highest capacity of the transmission output in Watts (W) and d is the suggested distance for clearance in meters (m). The field strength determined by local measurement, coming from the deplyoed RF transmitters a. should be smaller than the compliance level in case of each frequency interval b. Disturbance can occur in the environment of devices with this symbol here:
Broadcasted RF MSZ EN 60601-1-2:2008	3 V/m 3V/m (0,08-2,5GHz) modulation: 2Hz, 80% AM	[3] V/m approved	
NOTES: 1. IN CASE OF 80 MHZ AND 800 MHZ THE HIGHER FREQUENCY INTERVAL (UPPER) NEEDS TO BE USED. 2. THESE ARE ONLY GUIDELINES. IT IS POSSIBLE, THAT ELECTROMAGNETIC SPREADING CAN'T BE USED IN EVERY SITUATION, IT IS DEPENDENT ON THE OBJECTS IN THE ENVIRONMENT, THE SPATIAL LOCATION OF THE PEOPLE AND THEIR ABSORBING AND REFLECTIVE CAPABILITES TOO.			

Suggested clearance distances between the portable and mobile RF telecommunication devices and the WIWE mobile heart diagnostic device			
THE WIWE MOBILE HEART DIAGNOSTIC DEVICE WAS MADE TO USE IN SUCH ELECTROMAGNETIC ENVIRONMENT, WHERE THE RF DISTURBANCES ARE UNDER CONTROL. THE BUYER OR USER OF THE WIWE MOBILE HEART DIAGNOSTIC DEVICE CAN HELP TO PREVENT THE ELECTROMAGNETIC DISTURBANCES BY DETERMINING THE SMALLEST CLEARANCE DISTANCE BETWEEN THE TELECOMMUNCATION DEVICES (TRANSMITTERS) AND THE WIWE, DEPENDENT ON THE TELECOMMUNACTION DEVICE'S HIGHEST OUTPUT CAPACITY.			
The transmitter's highest given output capacity W	**Clearance distance based on the transmitter's frequency (m)**		
	150 kHz – 80 MHz $d=[3,5/V_1]\sqrt{P}$	**80 MHz – 800 MHz** $d=[3,5/E_1]\sqrt{P}$	**800 MHz – 2,5 GHz** $d=[7/E_1]\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,69	3,69	7,38
100	11,67	11,67	23,33
In case of the transmitter with the highest output capacity that are not in this table the suggested clearance distance in meters (m) can be determined with the use of the equation dependent on the transmitter's frequency, where P is the highest ouput transmitting capacity given buy the manufacturer in Watts (W). 1. NOTE: In case of 80 MHz and 800 MHz the higher frequency interval (upper) needs to be used 2. NOTE: These are only guidelines. It is possible, that electromagnetic spreading can't be used in every situation, it is dependent on the objects in the environment, the spatial location of the people and their absorbing and reflective capabilites too.			