INSTRUCTIONS FOR USE OF THE MEDICAL DEVICE

SiDLY CARE | PRO

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1. Description of the product

The SiDLY Care PRO wristband is a medical device. Its basic functionality is the ability to call for help / raise an SOS alarm in the event of a threat to the life of the person being monitored, as well as measuring pulse and saturation.

The construction of the SiDLY Care PRO device is made of medical elastomer and polypropylene. The device has the form of a wristband with an adjustable range of fastening the strap on the wrist. On the front of the shield, there is an SOS button described in Braille. There are 3 RGB LEDs under the SOS button. On the back of the housing there is a device label, a sim card cover, a sensor used to perform diagnostic measurements. The device is also equipped with a wristband removal sensor, an internal speaker and a microphone that enable two-way voice communication.

The SiDLY wristband can work with a mobile phone and the sidly-platform.com platform (or another platform dedicated by the manufacturer). Installing a SIM card enables the device to work properly, provided that it works in a place with 2G mobile phone coverage. The device is reusable as long as its functionality is maintained.
In addition to the functionalities that meet the definition of a medical device, the band has other functions useful during patient care, such as location.

The product is intended, among others, for the disabled and the elderly in order to improve their safety, it also allows sending automatic messages when the patient is outside the pre-defined area.

2. Manufacturer and Service

SiDLY Sp. z o.o.
Chmielna 2/31 Street
00-020 Warsaw, Poland
phone: + 48 667 870 126
e-mail: office@sidly.eu www.sidly.eu

Only personnel trained and authorized by the manufacturer may carry out service repairs.

3. Warnings regarding safe use

All measurements of saturation and pulse are medical measurements. Each measurement has a measurement reliability: 1-3. The reliability is shown in the mobile app, and on the platform as differently coloured graphs. The lighter the color, the less reliable the measurement is.

Reliability 1 Reliability 2 Reliability 3

Very dense hair, tattoos, user movement, low perfusion have great influence on the accuracy of the band measurements

Before starting the use, familiarize yourself with this instruction manual.

If any information provided in the manual is incomprehensible, contact the manufacturer for assistance (the company's address and contact details can be found on the following website: https://sidly.eu and on the device's label).

The manufacturer is liable only for defects and damage to the device resulting from the manufacturer's fault, a

material defect, improper processing or incorrect assembly.

Measurements near a source of intense heat/cold or intense lighting may also result in erroneous indications of the device.

The manufacturer is not responsible for: defects caused by the use of the device contrary to the principles of use, as a result of alterations, design changes made by the user or third parties, defects caused by the user's failure to conduct maintenance, cleaning and adjustment of the appliance, defects caused by external factors, in particular mechanical damage, damage caused by chemical agents, defects related to the natural wear and tear consistent with the properties or intended use of the device, damage caused by mechanical, thermal, chemical and other factors caused by the user or external forces.

4. Contents of the package

The package contains:

- SiDLY Care Pro band (color: black)
- Torx T3 screwdriver (when a wristband without a SIM card was ordered)
- SiDLY wireless charger
- Micro-USB power adapter (5V)
- micro-USB Power adapter cable, 5V
- SiDLY Care PRO instruction manual

After purchase, make sure that all listed elements are included in the package. The package can be reused or recycled.

Fig. 1 Contents of the package

5. Intended use

- Possibility of triggering an alarm by a monitored patient in the event of a noticeable deterioration in health
- In the case of pregnant women with an active lifestyle, the ability to call for help (immediately)
- Early response to abnormalities in the functioning of the body (telerehabilitation, among other in a group of people after a heart attack)
- Ability to measure saturation in a group of people with breathing difficulties
- The possibility of measuring saturation in a group of people suffering from COVID-19 and after infection, who struggle with breathing difficulties
- It supports the diagnosis of tachycardia and bradycardia.

6. Contraindications

- Children under 16 years of age
- Hypersensitivity to the medical elastomer (interview)
- Wounds or other skin lesions (e.g. atopic dermatitis)
- Presence of arteriovenous fistulas in a group of dialysis patients
- Patients with advanced peripheral artery atherosclerosis (e.g. obstruction of the subclavian artery)

Particular caution should be paid in a group of people with an implanted pacemaker or a cardioverter – defibrillator. It is recommended to insert the SiDLY Care PRO on the opposite side of the implanted device.

In women after mastectomy, it is recommended to place SiDLY Care PRO on the opposite side to place of operation.

During operation, the band can periodically exceed the temperature of 41°C. There is a risk of burns.
In the event of any skin changes, take off the band and consult a physician.

The manufacturer recommends using the band on clean, undamaged skin.

Despite the use of the highest quality raw materials and taking into account the growing number of people struggling with allergies, there is a risk of sensitization and / and skin irritation. If skin irritation is observed, discontinue use of the product and consult a physician.

7. Possible complications

- allergic reaction to the elements, from which the band is made,
- disturbances in the operation of the heart stimulating systems,
- inappropriate prescription of medications (in the case of incorrect measurements made by the device or in the absent of a reminder to take medications).

8. Precautions for use

In order to ensure the proper functioning of the device, it must fit snugly around the user's wrist.

It is recommended to place the device 2-3 cm from the left wrist in a proper manner – without causing discomfort. Do not wear the band with the strap too tight. Squeezing too tightly may result in restricted blood flow to the user's hand and, as a consequence, expose them to anemia.

Remove the device for bathing or swimming in the pool. Do not immerse the device in water. A direct, strong impact on the wristband will damage it. Puncturing the battery with a sharp object may cause a fire by releasing the energy stored in the Lithium polymer battery.

It is unacceptable to use the device with a dirty, scratched or damaged sensor's glass located on the bottom of the device.

It is unacceptable to use a wet or frosted device.

It is unacceptable to use the device after discovering its damage or incorrect operation before contacting the manufacturer.

The device is not intended to perform its functions in an airplane due to the inability to send any notifications to the server.

The device is sensitive to strong impacts – therefore, it is unacceptable to throw the band on purpose.

It is recommended to remove the device before an MRI scan (risk of damage to the wristband) or X-rays (risk of damage to the device).

In order to ensure that the device works properly, it must be used in places with an access to the 2G cellular network.

The device should be charged in a free space – do not cover the device with anything during charging.

The device uses light radiation for measurements. It is not recommended to look at the diodes on the bottom of the device for too long. Looking at the LEDs for too long may result in temporary discomfort/blinding of the user.

9. Charging

SiDLY Care PRO has a built-in lithium-polymer battery and a dedicated charger included in the set.
Battery charging process:
Connect SiDLY Care PRO to a power source with the use of the included power adapter and inductive charger with a micro USB port. Batteries have a limited number of charge cycles. Frequent charging will shorten the battery life.

In order to charge the SIDLY Care PRO:

- Remove the band from the user's hand,
- Put the plug of the power adapter in the micro USB port of the inductive charger,
- Put the charger on a flat surface,
- Put the wristband on the charger and make sure that the red and green LEDs are ON.

In order to complete charging of the SIDLY Care PRO :

- check whether the red diode turned off (thus signaling the completion of charging)
- Take the band off the charger,
- Disconnect the power adapter plug from the socket.

After connecting to the power supply, the induction charger must be placed on a flat surface. Do not hold the charger (connected to the power supply) with hands from underneath.

If you stop charging the device by disconnecting the charger from the power supply or removing the band from the charger, red and green diodes will turn off, and then the green diode will switch on and off (cyclically) – in the event of further correct operation.

The battery must be fully charged when it is put into operation for the first time. The user is informed that the device has been charged with a message sent to the SiDLY Care mobile app and a dedicated online platform with the following content: “Battery charged”.

The user of the band is informed about the need to charge the band by flashing red LED (if the band is not connected to the charger). In the event of a low battery condition, a message is sent to the SiDLY Care mobile app and a dedicated internet platform with the following content: “Battery low”.

The way of using the charger may contribute to cracking and breaking the cable. The charger cable may weaken or become brittle if it is repeatedly bent in the same place. Bend the cable in a gentle way without breaking.

It is recommended to frequently check the condition of the cable and connector, as well as search cavities, cracks and other damages. If the described damages occur, stop using the cable.

10. Warnings regarding elevated temperature

The SiDLY Care Pro may in rare cases exceed a temperature of 41 ° C when worn.

If 41 ° C, the band will automatically pulse orange diode everty 10 seconds to inform the user about reaching elevated temperature togheter with sending a notification „High Temperature” to the platform and the mobile app.

The user should not wear the band in the elevated temperature mode for more than 4 hours.

It is not recommended for people with skin diseases, hypersensitive skin and people with burns to wear the band in the increased temperature mode.

The band may reach elevated temperature while charging. Elevated temperature mode is disabled on the charger. It is recommended to leave the band for few minutes after charging to cool down.

11. Product use

General principles

Before each use, check the technical condition of the device. In the event of any deformations, cracks or other mechanical damages, the device should be withdrawn from use.

The SiDLY Care PRO device is designed to be placed on the wrist (it is recommended to place it on the left wrist). Place SiDLY Care PRO after putting on the clothes. Wearing clothes while the band is installed can damage the device – clothes can catch the device and damage it.

Preparation to work

In the case of transport between environments with different temperatures, the device may only be switched on after a few hours. In this case, it is necessary to wait until the condensation water, which may be produced by temperature differences, disappears.

First activation

During the first start-up procedure, place the device on the charger and format the battery by fully charging the device. Estimated charging time is about 3 hours. A full charge will be signaled by activation of the green diode (the red diode will go out) and the appropriate voice message.

Preparation to work

The device is turned on by placing the band on the charger that is connected to the mains or by pressing the button on the band. In order to start the device:

1. When the device has a charged battery:

- Press and hold the SOS button for 2 seconds
- After 2 seconds, the device will start to light with different LED colors (colors of the rainbow)
- Then you will see a steady green LED for approx. 10 seconds
- After 30 seconds, you will hear two short beeps and the device running message

2. When the device has a discharged battery:

- Insert the micro USB plug of the power adapter into the micro UBS socket of the induction charger,
- After the correct positioning of the device on the charger, you will see (in a sequence):
  a. LEDs shining in different colors (colors of the rainbow),
  b. Green LED lighting (up to 10 seconds
  c. You will hear two short beeps (up to 30 seconds from starting the device and the voice message “device activated”),
  d. Then the LEDs will turn green and red to signal the correct charging of the device,
- When fully charged, the LED will turn green.

The device is turned off when the battery installed in the device is fully discharged or by placing the device on the induction charger and holding the SOS button for about 30 seconds (if you correctly try to turn off the device, you can hear short beeps (after about 27 seconds) – every half of a second each, and the LED will turn yellow – this means that when the signals stop, the band will turn off).

Synchronization of the device

In order to synchronize the device with the app, you must register the user on the website: www. sidly-platform. com or other apps dedicated by the manufacturer. During the registration procedure, please follow the instructions provided on the appropriate platform. In the next step, download and install the “SiDLY Care” app from Google Play™ or App Store® (make sure that the device, on which the app is to be installed, has Android™ 6.0 (or later) version).

During the installation procedure, follow the instructions presented on the mobile phone or tablet (mobile device). Downloading of the application is not required for the adequate operation of the tele-care system, but it greatly facilitates the monitoring of data from the band.

After successful installation, add the user of the band via the manager account on the website: www.sidly-platform.com. In order to do this, log via the proper website (www. sidly-platform.com) or other websites dedicated by the manufacturer.

The user is obliged to verify whether the version of the browser and the phone on which the application is to be installed is compatible with the current version of the platform / mobile application. Lack of compatibility may prevent the display of measurements

NOTE:

Individual clients with a purchased tele-care package should use the following website:
https://sidly-platform.com/start

At least one emergency phone number is required. Entering two other numbers is optional.

To successfully add the band, it is recommended to watch the instructional video on the website: www.sidly-platform.com/help.

By default, SMS messages that inform about the fall and/or pressing the SOS button are sent to the guardian's phone number (provided as the emergency number). Notifications about a correctly or incorrectly installed band, battery status and information about the measurement results are sent to the "SiDLY Care" app (you can also turn on the SMS notification option).

You should enter the band's IMEI number in a correct way. In order to change the IMEI number, remove the band from the platform and add it again.

After a maximum of 60 minutes after conducting the above-mentioned steps, the user will receive an SMS message to the determined emergency phone number with the following text:

“Congratulations! Your SiDLY Care has been set up and it is now ready for use. We wish you a pleasant use”. The above mentioned procedure only occurs during the first start of the device.

Description of the functionality of the product

After the first start-up, the following functionalities of the device are active:

- Detecting the removal of the band,
- Step counter,
- Voice messages,
- SOS function,
- Fall detector function,
- GSM/GPRS.

The figure presents information about LED colors and their reactions depending on the function conducted by the device. For example: three blinks of the red diode – occurs when the band is completely discharged and the user tries to start it by pressing SOS. Additionally, when the band is completely discharged, it cannot be turned on without being connected to the charger, and the discharge status is indicated by a red LED flashing three times. Moreover, there is an indication of the lack of a SIM card by flashing blue and red LEDs plus a buzzer sound when trying to start the band without a SIM card. Note: yellow LED blinks when the band is in a place with insufficient GSM signal level.

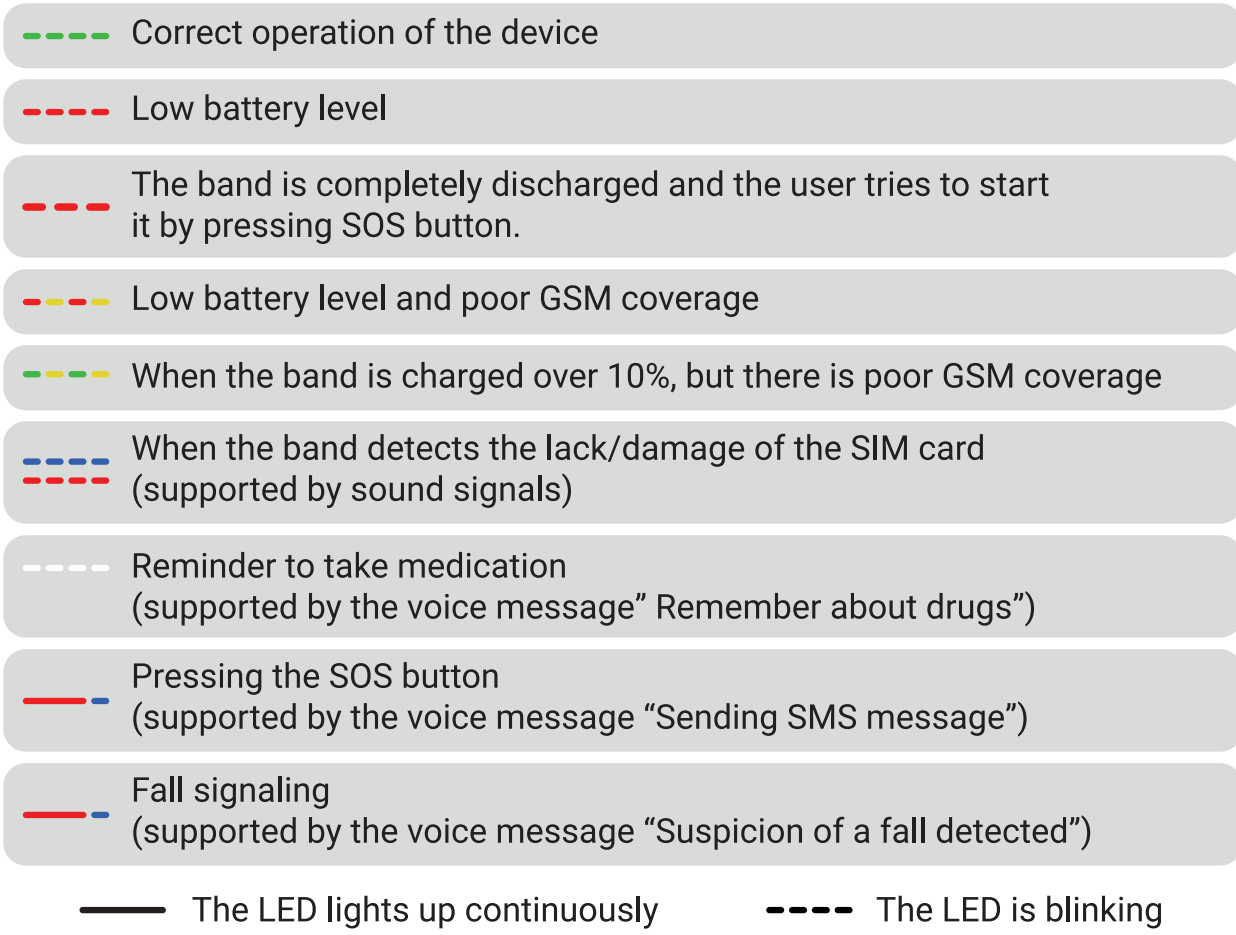


Fig. 2 Light communication of the band

When the band is completely discharged, it is not possible to turn it on without the connection to the charger, and the discharge is signaled by a red diode blinking three times. After a complete discharge, the band cannot send the SOS alarm.

Voice communication

The device is equipped with voice messages:

a. THE DEVICE IS RUNNING – Turning the band on

b. BATTERY IS NOT CHARGED – Battery is low

c. BATTERY FULLY CHARGED – Battery is fully charged

d. SENDING SOS MESSAGE – Occurs when the SOS procedure is started by pressing SOS button

e. CONNECTION ERROR – Occurs when it was not possibly to correctly send the synchronization frame.

f. REMEMBER YOUR MEDICATION – Occurs for the time the medication alert was set up on platform.

g. WARNING POSSIBLE FALL DETECTED – Occurs when the band detected fall

The language of voice messages can be set from the platform.

SOS button/Panic Button

Triggering the SOS alarm is done by holding the SOS button on a properly installed band. The start of the emergency procedure is signaled by the red LED being turned on and when the device generates a voice message: “Sending SOS message”. First, the band sends an SMS message to all emergency numbers registered on the platform

“Note – SOS!”. Then it calls to emergency numbers. After the end of conversation or when the bend has not reached any of the emergency numbers, the bans gets the location by using the available technologies: GPS, LBS, WiFi, aGPS – depending on the technological possibilities in the selected area. After sending the SMS in a correct way, the heart rate measurement is started. Completion of the heart rate measurement and saturation during the SOS procedure is signaled by a blue LED. This means that the results and information are being sent to the platform. After the measurement, a second SMS message is sent with information about the heart rate, saturation and the location of the user.

NOTE! In order to ensure that this function works properly, the 2G telephone network coverage is required for the user’s band.

Incoming calls

The band has the function of answering incoming calls. An incoming call is signaled by a flashing white diode and a sound signal. To answer the call, press the SOS button.

NOTE! The band will receive incoming calls only from emergency numbers and numbers added to the white list on the website: www.sidly-platform.com.

Band removal sensor

The band removal sensor checks (at five-minute intervals) the current state of wearing the band. The status of wearing or removing the band is updated on the platform and in the mobile app at intervals of approx. five minutes. If within approximately one hour the band does not change the status, a message will be sent to the platform and the SiDLY Care mobile app. If the band is installed for an hour, the following message will be sent: “The band is on for an hour”. If the band is removed for an hour, the following message will be sent: “The band was removed – one hour”. This functionality can also be enabled as SMS notifications.

Measurements of pulse and saturation

The device measures the pulse and saturation. The measurement can be triggered automatically by setting the time interval at which time measurements should be made. In the event of difficulties related to the lack of cellular network coverage the band will save the measurement in it’s memory and send it when GSM will become available. The time interval of measurements is changed in the “Users” tab, then “Details” of the band, then “Configure” and “Configure band” tab. Select “Advanced settings” option.

After the measurement procedure is completed, the measurement data is sent via GPRS to sidly-platform.com or other platforms dedicated by the manufacturer and to the mobile app.

It is important to remember about the correct positioning of the band on the hand (green areas present places where the band should be installed, and red areas are places where the band should not be installed).

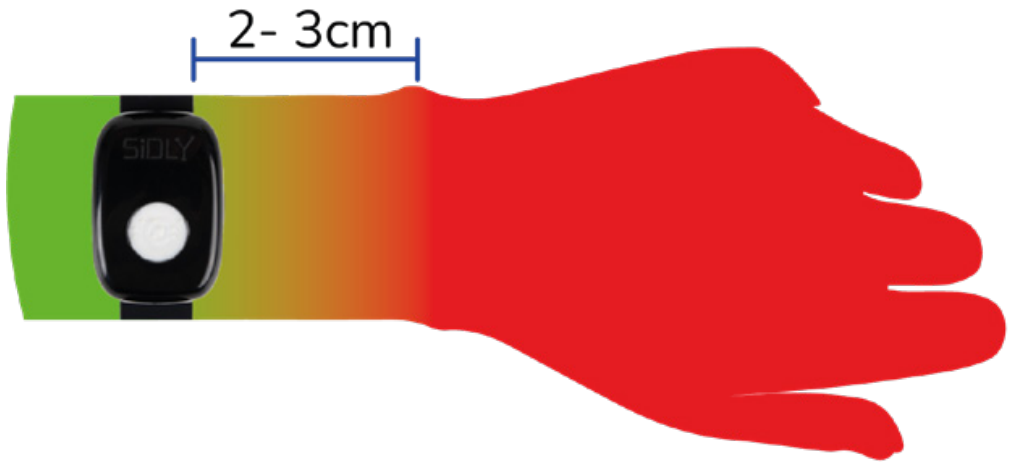


Fig. 3 Correct location of the band.

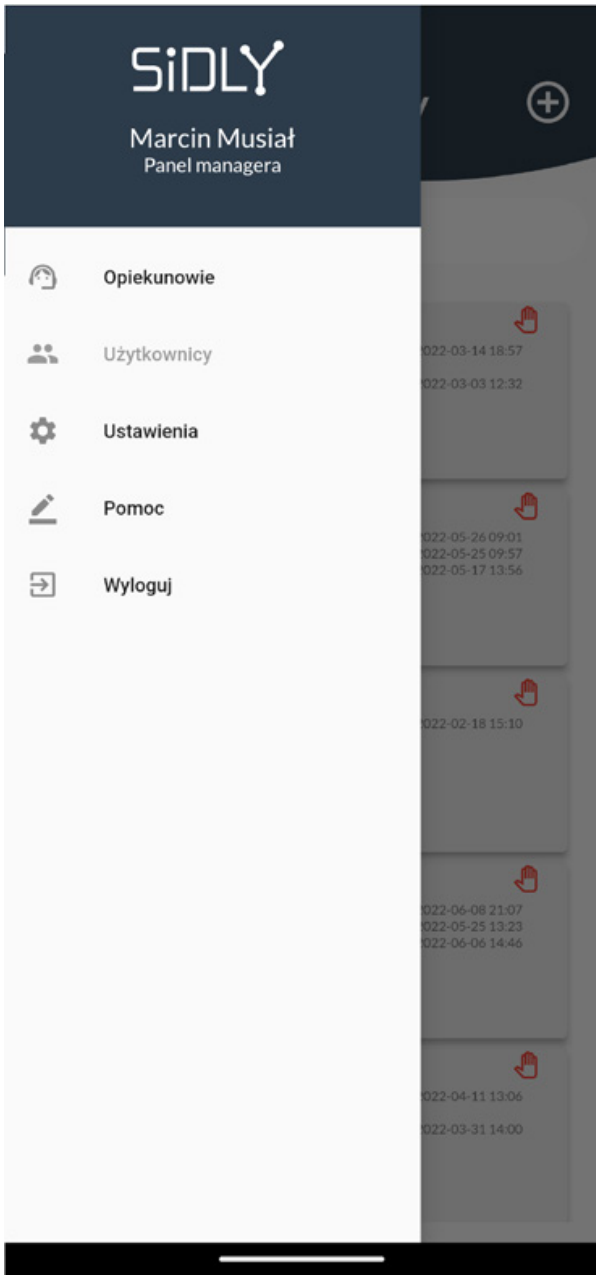


Fig. 4 Mobile app.

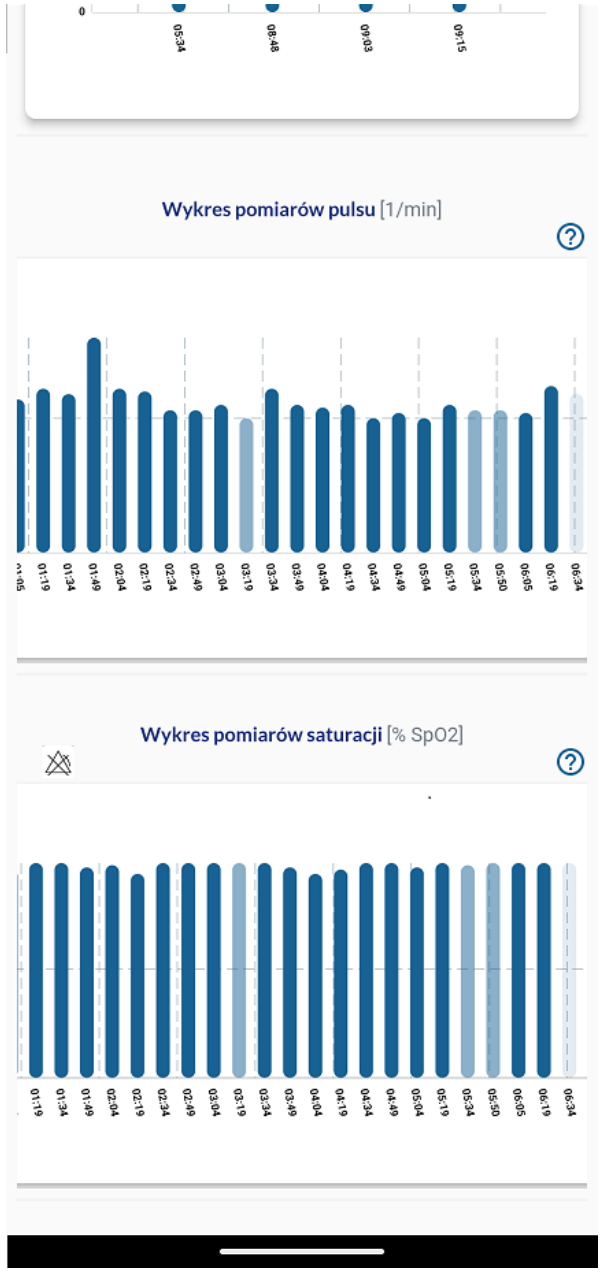


Fig. 5 Mobile app.

- Measurement results are saved in the mobile app and on the website www.sidly-platform.com (or other apps dedicated by the manufacturer), where the user is logged in. The time and date of measurement displayed on the platform is the time of measurement by the band.
- Using www.sidly-platform.com or another platform dedicated by the manufacturer, the user is able to change the frequency of the measurements. The frequency of measurements can be set

within the range of 15 minutes to 4 hours. A change is possible every 5 minutes. Less frequent measurements result in longer operating time of the device.

- The measurements performed by the SiDLY Care Pro device are displayed with a delay of at least 60 seconds from the start of the measurements. Each measurement has the date at which measurement was made . If the device has no GSM signal, the measurement is saved along with its date and time in the device memory. The measurement is sent on the next synchronization. SiDLY Care PRO stores a maximum of 12 measurements in its memory.
- Measurements must be made in the maximum stillness of the user and with a correctly fitted band. Movements may lead to erroneous measurements or to a situation, where the measurement is not carried out.
- Measurements are presented in the form of graphs and numerical data. It is recommended to press the wristband against the wrist during the measurement. If the band becomes loose during the measurement or the user makes sudden movements during the measurement, the device can make an erroneous measurement.
- Using the internet platform www.sidly-platform.com or another one dedicated by the manufacturer, you can set the informational threshold values for heart rate (min:30 [1/min] - 190 [1/min]) and Sp02% (min:70%SpO2 - max 100%SpO2) measurements. Exceeding the given informational thresholds results in the appearance of notifications on the platform and in the application.
- Failure to follow the manufacturer’s recommendations may result in erroneous measurements.
- SiDLY Care PRO does not have physiological alarms.
- When measurements exceed the declared threshhold, messages are sent to the SiDLY Care mobile app and the online platform.
- Strong electromagnetic interferences generated by, for

example, microwave ovens or antennas – may cause erroneous indications of the device.

- Taking measurements when the user is close to a source of intense heat/cold or intense lighting may also cause erroneous indications of the device.
- This product is not a substitute for advice from a physician or other healthcare professional. Always contact your doctor if you suspect any health problems. You should not change prescribed drugs without prior consultation with your doctor or other healthcare professional.
- As standard, the measurement status is signaled by an animation – a pulsating red LED diode for the duration of the measurement. If the device detects movement of the user during the measurement, it stops the measurement and tries to repeat it after a few seconds. If the device is unable to take the measurement in a correct way, it will try to repeat it when it detects the lack of user's movement.

Determination of the user's geolocation position

The user's geolocation position is determined once a day or when the SOS button is pressed or when a fall is detected. The SiDLY Care Pro band uses three independent technologies to determine the location: GPS (accuracy – approx. 10 meters), in the case of poor GPS coverage, the WiFi method is used (accuracy – approx. 15 meters). When both technologies presented above are unavailable, a-GPS technology is used. In the case of GPRS connection, the band searches the nearest BTS stations and on their basis (using the triangulation method) determines the position of the band (in extreme cases, possible error is 1.5 km). The user's location is communicated via a link to the Google map (in the case of poor coverage of openstreetmap.org) sent in SMS message to the declared emergency number. It is presented in the mobile app and on the online platform www.sidly-platform.com or other platforms dedicated by the manufacturer.

The manufacturer is not responsible for exceeding the location discrepancy. The location discrepancy may be caused by an insufficient level of infrastructure of the mobile network operator. If the band is not connected to the GPRS network, the location may not be determined.

Fall detector (it only works when the wristband is installed)

The device has a built-in fall detector, the sensitivity levels of which can be set from the platform on the manager's account. The detector detects the adequate nature of overloads and then the standstill. In the case of detecting immobility, the band starts the alarm procedure, the message "Suspicion of a fall was detected" is presented. At this point, the user can cancel the "fall" alarm by pressing the SOS button. The fall detector has 5 sensitivity levels. For the value 0, the detector is turned off, while for the value 5 – the detector will be very sensitive. Setting the value 5 can cause false positive fall alarms. However, it should be remembered that the user, if he or she can only press the SOS button, should always do it first (without waiting for the device to detect the fall). On the other hand, if the user does not cancel the detected fall, the SMS will be sent (text: "Note – Suspected fall!"). The device has a built-in fall detector, the sensitivity levels of which can be set from the platform on the manager's account. The detector detects the adequate nature of overloads and then the standstill. In the case of detecting immobility, the band starts the alarm procedure, the message "Suspicion of a fall was detected" is presented. At this point, the user can cancel the "fall" alarm by pressing the SOS button. The fall detector has 5 sensitivity levels. For the value 0, the detector is turned off, while for the value 5 – the detector will be very sensitive. Setting the value 5 can cause false positive fall alarms. However, it should be remembered that the user, if he or she can only press the SOS button, should always do it first (without waiting for the device to detect the fall). On the other hand, if the user does not cancel the detected fall, the SMS will be

sent (text: “Note – Suspected fall!”). Moreover, a voice connection with the first of the declared emergency phone numbers is initiated. If the user of the first emergency number does not answer the call, the device will automatically make a call to the second declared emergency number, and if the situation repeats, the third number will be called. If none of the three numbers answer the call, the system will display a message that the connection cannot be carried out. Then, the measurement data (heart rate) along with the location of the fall in the form of a link to the Google map or OpenStreetMap will be sent to the SiDLY Care mobile app and the online platform. Furthermore, a fall message will be sent to the app. After sending a message, the heart rate measurement procedure is triggered.

The device detects falls, in which the user becomes unconscious – characterized by the immobilization of the user. Any movement after detecting the fall may cancel the alarm.

NOTE! In order to ensure the proper functioning of this function, the 2G telephone network coverage is required.

Step counter (pedometer)

The device measures the number of steps taken on a given day. The measurement procedure is carried out in an automatic way after the user wears the band. The results of measurements are saved in the application and on the website www.sidly-platform.com (or other websites dedicated by the manufacturer), where the user is logged in – in the form of the number of steps taken and as a percentage of the determined target. The target is declared by the user on the website sidly-platform.com or other websites dedicated by the manufacturer. The goal is the number of steps that the user should take.

Barometer

The SiDLY Care PRO device measures the atmospheric pressure. The measurement procedure is carried out in an automatic way when measuring vital signs. The results of measurements are saved in

the app and on the website www.sidly-platform.com or other websites dedicated by the manufacturer, where the user is logged in. The results are presented in the form of a bar graph that includes the barometric pressure.

12. Damages / Repair / Maintenance

- In the event of a disturbance in the device's operation, its damage or suspicion of damage, it is recommended to stop its operation immediately.
- Never use a damaged device. All repairs and maintenance operations should be conducted only by the manufacturer or an authorized service center.
- In the case of independent repairs, the manufacturer is not liable for any damage.

13. Cleaning and disinfection

- If the SiDLY Care PRO product is dirty (e.g. with dust, mud, ink, cosmetics), the device should be immediately cleaned.
- In order to clean the SiDLY Care PRO product, turn off the device (put the band on the charger in order to enter the charging mode, then hold the SOS button for approx. 30 seconds).
- For cleaning, use a soft, lint-free cloth or a cleaning and disinfecting wipe.
- Moisture should not penetrate the device.
- Do not use cleaning agents (detergents) or compressed air.

There is a sensor glass on the back of the device. It should be cleaned carefully with a soft, dry cloth. Cleaning agents and abrasives will contribute to the abrasion of the sensor coating

and may impair the proper functioning of the appliance. The device does not require any special maintenance.

Prolonged and efficient use of the device depends on the skillful operation and the correct cleaning of the dirty device. Daily operation of the appliance consists in cleaning the device with a recommended cleaning and disinfecting wipe soaked in isopropyl alcohol (concentration: <70%).

14. Working, storage and transport conditions

The product cannot be:

- Used in rooms with flammable gases or vapors of flammable substances.
- Exposed to the action of weather conditions.
- Exposed to the action of moisture and liquid substances.
- Exposed to fire.
- Used immediately after transport between environments with extremely different temperatures (in this case, it might be necessary to wait until the condensed water is completely dry).

While using or charging the battery, the SiDLY Care PRO device may get hot – this is a normal phenomenon. Start using the device when the temperature of the device decreases. Do not leave the device for a long time in a hot or cooled place (e.g. in a car or under a direct sunlight).

15. Technical data

Parameter	Unit	SiDLY Care PRO
Weight	g	50,5
Dimensions width height depth adjustment range (on the wrist)	 mm mm mm mm	 max 36 max 250 max 15 1760 - 245
Minimum GSM signal strength required for communication	dBm	-108
Signal strength range for proper operation	dBm	-95
Operating frequencies of the wristband	MHz	850 900 1800 1900
Battery charging time	h	3
Device life	years	3
Water resistance	IP	67
Charging voltage	V	5
Maximum charging current	mA	1550
Battery capacity	mAh	560

Table 1. SiDLY Care PRO – parameters of the device

Parameter	Unit	Charger for SiDLY Care PRO
Charger	type	WL-1
Supply voltage	V	5
Power consumption	A	1.55
Charging frequency	kHz	120
Device protection class	-	III

Table 2. Parameters of the charges

Parameter	Unit	Plug-in power adapter for SiDLY Care PRO
Output voltage	V	5
Supply voltage	V	110-240
Power consumption	A	1.55
Device protection class	-	II

Table 3. Parameters of the plug-in power adapter

Parameters of measurements

Parameter		Value
Measurement range	Heart rate measurement	35 [1/min] - 240 [1/min]
	Saturation measurement	70%SpO2 - 100%SpO2
Measurement resolution	Heart rate measurement	1 [1/min]
	Saturation measurement	1%SpO2
Measurement accuracy	Heart rate measurement	+/- 3 [1/min]
	Saturation measurement	+/- 3%SpO2 (for the value: 70%SpO2 - 100%SpO2) undefined (for the value: 0%SpO2 - 69%SpO2)
Sp02 measurement method		Red light – wavelength: 660 nm; infrared – wavelength: 940 nm
Pulse measurement method		Green light - wavelength: - 536 nm
Maximum optical output power		Red light - 38 mW Infrared light - 15,6 mW Green light - 46 mW

Information:

Saturation is calculated on the basis of the reflectance of red and infrared signals sent by the vascularized tissues of the user's wrist. Measurements together with

adaptation take 60 seconds. During the measurement, partial pulse and saturation data is collected. After completing the measurement procedure the partial data with the highest reliability of the measurements is averaged. The measurements presented to the user via the platform and the mobile application are older than 30 seconds from the start of the measurement.
When the signal reaching the LEDs of the wristband is too weak, the band will not measure the saturation and/or pulse. The result will not appear on the platform, and the band
will start another measurement attempt within 30 seconds after the last attempt. Movement during the measurement may cancel the measurement or reduce its accuracy. 2/3 of measurements (measured by the device) will be within the measurement ranges. The wristband does not have a defined measurement accuracy during the movement. The band does not have a declared measurement accuracy under low perfusion conditions.
According to the ISO 80601-1-61: 2017 standard, functional testers or electronic pulse oximetry calibrators (POC) cannot be used to determine this relationship and assess the accuracy of SpO2 accuracy. For this purpose, it is necessary to perform desaturation tests (201.7.9.3.1.101). A functional tester is used to measure how accurately the oximeter is reproducing a specified calibration curve and pulse accuracy. The model of the functional tester used for the tests is the WhaleTEQ AECG 100.
Dell Inspiron 3593 laptop and the Xiaomi Redmi Note 8 phone were used for software validation. The product was validated on on a population with a limited pigmentation spectrum - European skin tone.

16. Electromagnetic compatibility

Tips and declaration of production – electromagnetic resistance: Resistance test: The device is intended for use in the electromagnetic environment specified below.

Emission tests: RF emission CISPR 11 Compliance: Group 1

Electromagnetic environment: tips: The device uses RF energy only for its internal function and periodically to send data to the GSM/GPRS transmission frequency system. Therefore, its RF emissions are very low and they should not cause any disturbance to nearby electronic devices.

Emission tests: RF emission CISPR 11 Compliance: Class B

Electromagnetic environment: tips: The device is suitable for use in all institutions, including homes. It can be directly connected to the public low-voltage power supply network that supplies residential buildings.

The device has been tested for resistance to radio frequency radiation at selected frequencies. Its use in close proximity to transmitters at other frequencies may result in malfunction.

The device should only be used with elements of the set provided by the manufacturer, and in particular with the wall charger.

The use of other accessories may cause the improper operation of the product.

17. Disposal

Disposal must be carried out in accordance with applicable law.

18. Product lifetime

The product's lifetime is 36 months (see the warranty conditions). However, this does not mean that the device will stop working after 36 months. With careful handling, the appliance may operate for longer time than 36 months. If the band does not work or the device is damaged, it should be withdrawn from use and recycled.

19. Incidents

Each serious medical incident related to the device should be reported to the manufacturer and to the competent authority of the Member State, in which the user or patient resides.

20. Warranty conditions

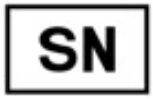
- The warranty does not exclude, limit or suspend the rights of the buyer resulting from the provisions concerning the warranty for defects in the sold products;
- The warranty covers defects and damages to the device resulting from the manufacturer's fault, material defect, improper processing or assembly. By granting a warranty, the manufacturer undertakes to replace the device with a defect-free device;
- The guarantor declares that the subject of the warranty covered by this warranty card has been handed over free from defects and made in accordance with applicable standards;
- The complaint is submitted by the user to the seller, from whom the device was purchased or to the manufacturer (address in the warranty card) along with the proof of purchase;
- The manufacturer will consider the complaint as soon as possible – no later than within 14 calendar days, counting from the day the consumer delivers the defective product to the guarantor;
- The user should file a complaint within 14 days from the date of the damage;
- The warranty is extended by the period, in which the complaint was examined – counting from the date of filling the complaint to the date of delivering a new, defect-free device to the user;
- The manufacturer will not accept a claim under the warranty if technical changes have been made to the device – without the

consent of the manufacturer or if the device has been improperly stored, used or maintained. This also applies to identified previous attempts to repair the device.

The warranty does not cover:

- Defects resulting from the use of the device in a manner inconsistent with the principles of use, modifications or design changes made by the user or third parties;
- Device flooding and the splash, water and dust resistance are not permanent conditions and resistance to normal wear and tear might decrease. A wet device should not be charged;
- The warranty does not cover damages caused by liquids;
- Defects caused by the user's failure to perform maintenance, cleaning and adjustment of the device or malfunction due to the lack of cellular network coverage;
- Defects resulting from the action of external factors, in particular mechanical damages, damages caused by the action of chemicals;
- Natural wear and tear consistent with the properties or intended use of the device;
- Damages caused by mechanical, thermal, chemical and other factors (triggered by the action of the user or external forces);
- Damages that occurred during transport of the device and during loading by any carrier;
- The manufacturer is not obliged to bear costs of compensation for losses or any other damages caused by damage, hidden defects or device's failure – apart from replacing the device with a new one;
- This warranty does not limit rights and obligations under national law;
- The warranty expires in the event of modifications, adaptations or changes to the design of the device by persons other than its manufacturer or persons indicated by the manufacturer.

21. Explanation of symbols used by the manufacturer

Symbol	Explanation
	The symbol identifies the manufacturer of the medical device
	This symbol indicates the date of production (medical device)
	It indicates that the instruction manual must be read
	It indicates the manufacturer's serial number enabling the identification of a specific medical device
	The product meets the essential requirements consistent with the Regulation of the European Parliament and the Council (EU) No. 2017/745 of 5 April 2017 for medical devices
xxxx	Number of the notified body supervising the medical device [name and address of the unit]
	Do not throw in the trash. The product is disposed of in accordance with the applicable environmental protection regulations
	The information is important for the user's safety
	Application part (BF type)

Symbol	Explanations
IP 67	The symbol that specifies the tightness class 6 – protection against access to hazardous parts by wire and dustproof protection 7 – protection against effects of short-term immersion in water (30 minutes to a depth of 0.15 m above the top of the housing or 1 meter above the bottom for housings lower than 0.85 m)
	The symbol that denotes a medical device
	Sp02 alarm not present

22. Troubleshooting

1. Lack of SIM card
Make sure that the version of the band with a SIM card has been ordered – if so, contact customer service.

2. Poor GSM coverage
Poor GSM coverage is manifested by alternating green and yellow diodes on the band. If the coverage is poor at home, measurements may not be immediately updated on the platform. The operating time of the battery may be shortened. Please contact the customer service to verify coverage.

3. The device does not start
In the event of discharge, after pressing the SOS button, the red diode flashes three times. Make sure your device is charged. If, despite long charging, the device still does not start up, hold down the SOS button for about 10-15 seconds. If the band still does not start, contact the customer service.

4. Lack of measurements on the platform

Check whether the band shows a band status other than “Inactive” on the platform. If the status of the band is presented as “Inactive”, make sure that the correct IMEI of the band is entered on the platform. If the IMEI is correct, please contact the customer service.
If the band shows “Removed” status, make sure that the wristband is correctly installed (2-3 cm from the left wrist) and wait for the measurement. Movement during the measurement may cause failure to complete the measurement procedure or significant affect the measurement result displayed on the platform.

5. The band is slowly charging/ not charging at all

Check whether the band is correctly positioned on the charger. If the band is placed in a correct way, green and red diodes should flash, and the diode on the bottom of the charger should flash green. If the band does not run on automatically on the charger, check whether the diode on the charger is flashing green.

If the diode on the charger does not flash green, check whether the charger is properly connected to the adapter attached to the wristband by the manufacturer.

If the diode on the charger flashes green, try to turn on the band with a short press of the SOS button. If pressing the SOS button does not turn on the band, check the “The device does not start” section.

If the band, despite showing green and red diodes, is charging for a long time, check whether the band stops flashing after a while. If so, try to correct the positioning of the band. If re-positioning the band does not improve charging procedure, please contact the customer service.

Use only the adapter that was attached to the band. The use of an adapter other than the adapter delivered with the band may result in failure of the charger.

6. While charging, the band makes the sound “correct the

position of the band”

If the correction of the band’s position on the charger does not work and the band / charger seems to be very hot – contact the customer service.

7. Pressing the SOS button does not trigger the emergency call

Make sure that emergency numbers are assigned to your account. In order to make a call, you need the GSM network coverage. Check whether yellow and green diodes flash (alternatively). In the event of a problem with coverage during the SOS procedure, the band should give a “connection error” message. If the band does not trigger emergency calls despite many attempts – contact the customer service.

8. The band does not show the location

The band gets the current location every 24 hours of operation – during the SOS procedure, in the interval set when downloading the alarm zone. If the band does not download the location data, please contact the customer service.

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